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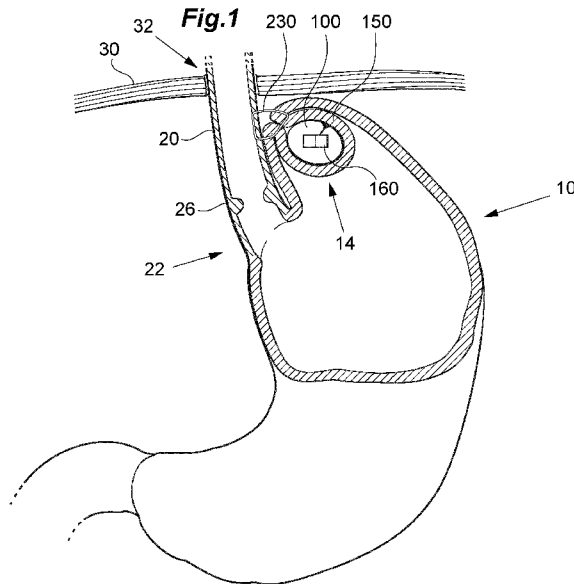
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(54) Title: TREATMENT OF GERD



(57) Abstract: An apparatus (100) for treating reflux disease in a human patient, comprising an electrode arrangement (150) for electrically stimulating the patient's muscle tissue to exercise the muscle tissue to improve the conditions for long term implantation of the apparatus, further comprising: an implantable energy source (160) configured to provide the electrode arrangement with electrical power; and a controller (170) operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue. The apparatus can be used for exercising muscle tissue of a human patient to improve the conditions for term implantation of an apparatus for treating reflux disease in a human patient, by electrically stimulating the muscle against which the apparatus is arranged to rest when implanted.

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TREATMENT OF GERD

TECHNICAL FIELD

The present inventive concept generally relates to medial implants. More specifically the inventive concept relates to medical implants for treating
5 gastroesophageal reflux disease (GERD).

BACKGROUND

Gastroesophageal reflux disease (GERD), or reflux disease, is a condition resulting in mucosal damage in the esophagus caused by recurring
10 occurrence of acid reflux in the esophagus. GERD can be treated in a number of different ways, including both medical and surgical treatments. An example of a surgical treatment is Nissen fundoplication surgery, in which the upper curve of the stomach (the fundus) is wrapped around the lower esophageal sphincter (LES) to strengthen the sphincter, prevent acid reflux, and repair a
15 hiatal hernia. This method however risks causing a constriction of the food passageway, making it more difficult for the patient to swallow.

Another example is the Anglechik prosthesis, in which a device formed like a horseshoe is placed around the esophagus above the cardia. The intended effect is to prevent the cardia from slipping up into the thorax cavity.
20 However, this device is associated with a number of complications, including migrating through and damaging the esophagus. Further, the body tends to react to a medical implant, partly because the implant is a foreign object, and partly because the implant interacts mechanically with tissue of the body. Exposing tissue to long-term engagement with, or pressure from, an implant
25 may deprive the cells of oxygen and nutrients, which may lead to deterioration of the tissue, atrophy and eventually necrosis.

It would therefore be advantageous to provide more efficient and/or less damaging techniques for treating GERD.

SUMMARY

It is an object of the present inventive concept to overcome, or at least alleviate, at least some of the drawbacks associated with the above-mentioned treatments of GERD. Further and/or alternative objectives may be
5 understood from the following.

According to an aspect, an apparatus for treating reflux disease of a human patient is provided, comprising an implantable movement restriction device and an electrode arrangement. The implantable movement restriction device has a shape and size that allows it to be arranged to rest against a
10 fundus wall portion of the patient's stomach and to be at least partly invaginated by the fundus wall portion, such that the movement restriction device is implanted at a position between the patient's diaphragm and a lower portion of the fundus wall, and such that movement of the cardia of the patient's stomach towards the diaphragm is restricted to hinder the cardia
15 from sliding through the diaphragm opening into the patient's thorax. The electrode arrangement is configured to be arranged between the movement restriction device and the fundus wall portion and to engage and electrically stimulate muscle tissue of the fundus wall portion to exercise the muscle tissue to improve the conditions for long term implantation of the movement
20 restriction device.

According to an aspect, an apparatus for treating reflux disease of a human patient is provided, comprising an at least partly ring-shaped implantable movement restriction device and an electrode arrangement. The implantable movement restriction device comprises a first portion configured
25 to be at least partly invaginated by a first wall portion of the patient's stomach and arranged such that at least a part of the first portion is arranged above the cardiac notch of the patient's stomach, and such that movement of the cardia towards the diaphragm is restricted to prevent the cardia from sliding through the diaphragm opening into the patient's thorax. The electrode
30 arrangement is configured to be arranged between the movement restriction device and the first wall portion and to electrically stimulate muscle tissue of

the first wall portion to exercise the muscle tissue to improve the conditions for long term implantation of the movement restriction device.

According to an aspect, an apparatus for treating reflux disease of a human patient is provided, comprising an elongated core and a tubular cover.

5 The elongated core has a length allowing the core to at least partly encircle the esophagus of the patient, wherein the length is variable to allow the core to be arranged in a constricting state for hindering fluid from passing from the stomach into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the patient swallowing. The tubular
10 cover is configured to encloses at least a part of the core and comprises a plurality of portions adapted to bend relative to each other to allow the core to change between the constricting state and the expanded state, when the cover is at least partly covered by fibrotic tissue, without being substantially hindered or impeded by the presence of said fibrotic tissue.

15 According to an aspect, an apparatus for treating reflux disease of a human patient is provided, comprising an elongated core having a length allowing the core to at least partly encircle the esophagus of the patient, wherein the length is variable to allow the core to be arranged in a constricting state for hindering fluid from passing from the stomach into the
20 esophagus and in an expanded state for allowing food to pass into the stomach in response to the patient swallowing. The apparatus further comprises an electrode arrangement comprising an electrode element supported by the core and configured to be arranged between the apparatus and the esophagus and to electrically stimulate muscle tissue of the
25 esophagus.

According to an aspect, an apparatus for treating reflux disease of a human patient, is provided comprising a tubular device having a length allowing the tubular device to at least partly encircle the esophagus of the patient, wherein the length is variable to allow the tubular cover to be
30 arranged in a constricting state for hindering fluid from passing from the stomach into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the patient swallowing. The outer

surface of the tubular device may comprise a plurality of portions adapted to bend relative to each other to allow the tubular device to change between the constricting state and the expanded state, when the outer surface is at least partly covered by fibrotic tissue, without being substantially hindered or
5 impeded by the presence of said fibrotic tissue.

According to an aspect, an apparatus for treating reflux disease of a human patient is provided, comprising an elongated core having a length allowing the core to at least partly encircle the esophagus of the patient. The length may be variable to allow the core to be arranged in a constricting state
10 for hindering fluid from passing from the stomach into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the patient swallowing. Further, the elongated core has a size allowing at least a portion of the elongated core to protrude above the cardiac sphincter of the patient, when implanted, such that movement of the cardia towards the
15 diaphragm is restricted to hinder the cardia from sliding through the diaphragm opening into the patient's thorax.

According to an aspect, an apparatus for treating reflux disease of a human patient is provided, which is adapted to at least partly encircle the esophagus (20) of the patient. The apparatus comprises a first implantable
20 portion and a second implantable portion, wherein the first implantable portion has a shape and size allowing it to be arranged to rest against a fundus wall portion of the patient's stomach and to be at least partly invaginated by the fundus wall portion, such that the first implantable portion is implanted at a position between the patient's diaphragm and a lower portion of the fundus
25 wall, and such that movement of the cardia of the patient's stomach towards the diaphragm is restricted to hinder the cardia from sliding through the diaphragm opening into the patient's thorax. The second implantable portion is elongated to at least partly encircle the esophagus and has a variable length for allowing the apparatus be arranged in a constricting state for
30 hindering fluid from passing from the stomach into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the patient swallowing.

According to an aspect, an apparatus for treating reflux disease of a human patient is provided, which is adapted to at least partly encircle the esophagus of the patient. The apparatus comprises a movement restriction device, an elongated support device and an electrode arrangement. The movement restriction device has a shape and size allowing it to be arranged to rest against a fundus wall portion of the patient's stomach and to be at least partly invaginated by the fundus wall portion, such that the first implantable portion is implanted at a position between the patient's diaphragm and a lower portion of the fundus wall, and such that movement of the cardia of the patient's stomach towards the diaphragm is restricted to hinder the cardia from sliding through the diaphragm opening into the patient's thorax. The elongated support device is connected to the movement restriction device and configured to at least partly encircle the esophagus. The electrode arrangement comprises an electrode element supported by the support device and configured to electrically stimulate muscle tissue of the esophagus. Further, the support device comprises a rigidity that allows the position of the electrode element relative to the esophagus to be determined mainly by the position and orientation of the movement restriction device.

According to an aspect, a method for treating reflux disease of a human patient is provided. The method involves implanting a movement restriction device such that the movement restriction device is arranged to restrict movement of the cardia of the patient's stomach towards the diaphragm to hinder the cardia from sliding through the diaphragm opening into the patient's thorax. The method comprises placing the movement restriction device such that a lower portion of the movement restriction device rests against the serosa at the angle of His, and such that an upper portion of the movement restriction device defines a gap between the movement restriction device and the patient's esophagus, when the lower portion rests against the angle of His. The method further comprises arranging a portion of the fundus of the stomach in the gap and attaching the fundus to the patient's esophagus to at least partly enclose the movement restriction device by the portion of the fundus.

According to an aspect, an apparatus for treating reflux disease of a human patient is provided, comprising an implantable movement restriction device and an elongated attacher configured to be attached to the movement restriction device and to be at least partly invaginated by a wall portion of the patient's stomach. The attacher comprises a shape and size allowing it to be invaginated by the wall portion to hinder rotation of the movement restriction device. The attacher is further configured to be invaginated by the wall portion such that the movement restriction device is arranged at a position between the patient's diaphragm and the wall portion, distant from the patient's esophagus, to restrict movement of the cardia of the patient's stomach towards the diaphragm to hinder the cardia from sliding through the diaphragm opening into the patient's thorax.

According to an aspect, an apparatus for treating reflux disease of a human patient, comprising an at least partly ring-shaped implantable movement restriction device configured to be arranged such that at a first, lower portion of the movement restriction device is arranged at the cardia of the patient's stomach and such that a second, upper portion of the movement restriction device is arranged to abut the diaphragm of the patient, such that movement of the cardia towards the diaphragm is restricted to prevent the cardia from sliding through the diaphragm opening into the patient's thorax. The apparatus is further configured to be arranged to define a gap or spacing between the second, upper portion of the movement restriction device and the outside of the esophagus when the apparatus is implanted. The apparatus may be formed of the movement restriction device as disclosed herein, or at least comprise such a movement restriction device.

According to an aspect, a method of treating reflux disease in a human patient is provided, involving implanting an apparatus comprising a movement restriction device and an elongated support device, such that the support device at least partly encircles the esophagus of the patient and such that the movement restriction device is arranged on the fundus side of the esophagus to restrict the movement of the cardia in relation to the diaphragm to hinder the cardia from sliding through the diaphragm opening into the

patient's thorax. The method comprises the steps of introducing the apparatus into the abdominal cavity, placing the apparatus such that the movement restriction device rests against the outside of the stomach's fundus, wrapping a portion of the fundus around at least a part of the movement restriction device, affixing the fundus to the esophagus such that the movement restriction device is arranged at a position between the diaphragm and the cardiac sphincter, and such that a part of the fundus is arranged between the movement restriction device and the esophagus and arranging the support device to at least partly encircle the esophagus. The movement restriction device and the second portion form a ring-shaped body extending through the pouch to at least partly encircle the esophagus.

According to an aspect, a method for affixing a fundus portion of the stomach of a human patient to the patient's esophagus is provided, wherein the fundus portion extends from the angle of His and in a direction away from the esophagus. The method comprises folding the fundus portion towards the esophagus such that the fundus portion rests against the esophagus, from the angle of His and upwards along the esophagus, and affixing the fundus portion to the esophagus by means of fasteners arranged along a first line and a second line. The first line and the second line extend along the esophagus and are arranged such that a distance between the first line and the second line increases with an increasing distance from the angle of His.

According to an aspect, an apparatus for treating reflux disease in a human patient according to any of the above aspects is provided. The apparatus comprises an electrode arrangement for electrically stimulating the patient's muscle tissue to exercise the muscle tissue to improve the conditions for long term implantation of the apparatus, as outlined above. The apparatus further comprises an implantable energy source configured to provide the electrode arrangement with electrical power, a controller operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.

According to an aspect, an apparatus for treating reflux disease of a human patient according to any one of the above aspects is provided. The

apparatus comprises an electrode arrangement, an implantable energy source configured to provide the apparatus with electrical power, an external energy source configured to be arranged outside of the patient's body and configured to provide energy to the implantable energy source, and an
5 implantable charger configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by the external energy source.

According to an embodiment, an apparatus for treating reflux disease of a human patient according to any one of the above aspects is provided.

10 The apparatus when comprises an electrode arrangement, and a controller configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue. The controller comprises an implantable communicator for transmitting and/or receiving a signal to/from the outside of the patient's body.

15 According to an embodiment of the above aspects, the electrode arrangement may be arranged on an outer surface of the movement restriction device.

According to some embodiments of the above aspects, the electrode arrangement may comprise a plurality of electrode elements, wherein each of
20 the electrode elements is configured to engage and electrically stimulate the muscle tissue. The electrode arrangement may further comprise a coiled wire for increasing a contact surface between the electrode arrangement and the muscle tissue and for allowing the electrode arrangement to follow contraction and relaxation of the muscle tissue.

25 According to some embodiments of the above aspects, the electrode arrangement may comprise a bare electrode portion configured to form a metal-tissue interface with the muscle tissue so as to allow faradaic charge transfer to be the predominant charge transfer mechanism over the interface. Alternatively, or additionally the electrode arrangement may comprise an
30 electrode portion that is at least partly covered by a dielectric material configured to form a dielectric-tissue interface with the muscle tissue so as to

allowing a faradaic portion of the charge transfer mechanism over the interface to be reduced.

According to some embodiments, the electrode arrangement may be configured to be arranged to electrically stimulate the cardiac sphincter to
5 cause the cardiac sphincter to contract. The electrode arrangement may comprise at least two electrode elements configured to be arranged on opposing sides of the cardiac sphincter. Further, the apparatus may comprise a holder configured to support the at least two electrode elements at the opposing sides of the cardiac sphincter.

10 Exemplary embodiments of a movement restriction device according to at least some of the above aspects will now be discussed.

According to an embodiment, a volume of the movement restriction device may be non-adjustable after implantation. According to another embodiment, the volume of the movement restriction device may be
15 adjustable after implantation. The volume may be adjustable invasively or non-invasively. In an example, the movement restriction device comprises an injection port for allowing a fluid to be injected or extracted from the inside of the movement restriction device so as to vary the volume of the movement restriction device after implantation.

20 According to an embodiment, the movement restriction device may comprise a biocompatible outer surface configured to rest against the fundus wall portion.

According to an embodiment, the movement restriction device may be substantially spherical or egg-shaped. In an example, the movement
25 restriction device may have a portion configured to be arranged to point away from the esophagus when implanted. In a further example, a lower portion of the movement restriction device may be wider than an upper portion.

According to an embodiment, the movement restriction device may be configured to be invaginated when placed on the outside of the fundus wall
30 portion. In another embodiment, the movement restriction device may be configured to be invaginated when placed on the inside of the fundus wall portion.

According to an embodiment, the movement restriction device may be configured to be introduced in the patient's body by means of a gastroscope or an intraluminal instrument. The movement restriction device may for example be configured to change its shape to allow it to pass through a trocar
5 during insertion into the patient's body.

According to an embodiment, the movement restriction device may be formed of at least two distinct and separable pieces configured to be assembled into the movement restriction device after insertion in the patient's body.

10 According to an embodiment, a minimum width of the movement restriction device, as measured from side to side, may be 20 mm or larger, such as 30 mm or larger, such as 40 mm or larger, such as 50 mm or larger.

According to some embodiments, the movement restriction device may comprise a first and a second portion, wherein the first and second portions
15 are configured to be arranged on opposite sides of the cardia. In an example, the movement restriction device may be configured to be arranged such that a gap is formed between the second portion of the movement restriction device and the esophagus. In an example, the second portion of the movement restriction device may be configured to be at least partly
20 invaginated by a second wall portion of the stomach.

According to an embodiment, the movement restriction device may be configured to be arranged such that a portion of the first wall portion is arranged between the first portion of the movement restriction device and the esophagus.

25 According to an embodiment, the movement restriction device may be configured to be at least partly invaginated by the first wall portion along at least half of the toroidal length of the movement restriction device.

According to an embodiment, the movement restriction device may be configured to be invaginated when placed on the outside of the stomach wall.

30 According to an embodiment, the movement restriction device may comprise two end portions configured to be coupled to each other to form a

closed ring. The end portions may be configured to be releasably attached to each other.

According to an embodiment, a poloidal circumference of the movement restriction device may be larger for the first portion and for the second portion. In an example, a minimum width of the first portion of the movement restriction device, as measured from side to side, is 20 mm or larger, such as 30 mm or larger, such as 40 mm or larger, such as 50 mm or larger. Alternatively, the width may be defined as a height measured along a normal to the plane in which the circumference extends.

According to an embodiment, the movement restriction device may have a shape conforming to a torus.

According to an embodiment, the movement restriction device may have C-shaped cross section.

According to an embodiment, an upper portion of the movement restriction device may comprise a recess defined in the outer surface of the movement restriction device.

According to an embodiment, a lower portion of the movement restriction device may comprise a curved outer surface, which may be arranged to face the esophagus. The curved outer surface may comprise a radius of curvature corresponding to or exceeding the radius of curvature of the esophagus.

According to an embodiment, an elongated support, protruding from the movement restriction device, may be at least partly invaginated in the fundus before the fundus is attached to the esophagus. The support may be oriented along the esophagus.

Exemplary embodiments of a core and a cover according to at least some of the above aspects will now be discussed.

According to some embodiments, the core may be configured to allow a transition from the constricting state into the expanded state caused by the food passing through esophagus. The core may be configured to exert an encircling pressure on the esophagus in the constricting state.

According to an embodiment, the apparatus may further comprise an attractor for resiliently attracting adjacent portions of the core to one another to generate the encircling pressure. The attractor may comprise an elastic element, and/or at least two mutually attracting magnets. Further, the
5 apparatus may comprise a link connecting a first and a second one of said at least two magnets to each other. The link may be configured to extend into at least one of said magnets in response to said magnets moving towards each other.

According to some embodiments, the core may comprise two end
10 portions configured to be coupled to each other to form a closed ring around the esophagus. The end portions may be configured to be releasably attached to each other and may comprise a respective interlockable attacher.

According to an embodiment, the core may comprise a plurality of core elements configured to be arranged in an annular array around the
15 esophagus. The core may further comprise a plurality of links, wherein each link may extend between a respective pair of core elements arranged adjacent to each other. The links may be configured to allow the respective core elements to move towards and away from each other, and may be configured to extend into at least one of the core elements of the respective
20 pair of core elements as the core elements move towards each other.

According to an embodiment, the cover may comprise an array of tubular segments.

According to some embodiments, the cover may comprise a biocompatible outer surface for long-term implantation. The cover may for
25 example be configured to rest against an outer surface of the esophagus and may further comprise a surface for promoting tissue growth. The cover may for example be formed of a polymer material, such as silicone. In further examples, the cover may be formed of or comprise a carbon-based material, such as carbon fiber material.

30 According to some embodiments, the cover may be formed of a material having a thickness of 0.1-10 mm, such as 1-5 mm. The cover may comprise at least one predefined fold along which the cover is allowed to fold

in response to the core varying its length. The cover may in some examples comprise lowered and elevated portions allowing the cover to vary its length while maintaining its surface area. Thus, the cover may be configured to be compressible and expandable in its length direction, wherein the length is
5 varied mainly due to the folding of the cover rather than elastic properties of the material. Thus, the cover may be considered to be formed of an inelastic material. In some examples, a length of the cover enclosing the at least a part of the core may exceed a length of the at least a part of the core when the at least a part of the core is arranged in the constricting state.

10 Exemplary embodiments of the attacher, which comprises a shape and size that allows it to be invaginated by the wall portion to hinder rotation of the movement restriction device as set out above in connection with some of the aspects, will now be described in the following.

According to some embodiments, a first end portion of the attacher
15 may be configured to be invaginated by the wall portion and a second end portion to be attached to the movement restriction device. The first portion and the second portion may extend in different directions relative to each other, wherein the first portion may be configured to be invaginated by the wall portion to hinder rotation of the movement restriction device around a first
20 axis, and wherein the second portion may be configured to be invaginated by the wall portion to hinder rotation of the movement restriction device around a second axis, different from the first axis. The first and second portions of the attacher may be curved to follow a curvature of the wall portion. The first portion and the second portion may be arranged at an angle to each other,
25 the angle being in the interval of 60-120 degrees, such as 90 degrees.

According to some embodiments, the attacher may be configured to be releasably attached to the movement restriction device. The attacher may be configured to allow a position of the movement restriction device to be adjusted after invagination of the attachment means. In some examples, the
30 apparatus may be configured to allow a distance between the movement restriction device and the attacher to be varied to allow the position of the movement restriction device relative to the diaphragm to be adjusted. Further,

the apparatus may be configured to allow an orientation of the movement restriction device relative to the attachments means to be varied to allow the position of the movement restriction device relative to the diaphragm to be adjusted.

5 In an embodiment, the attacher may comprise a third portion, configured to be arranged to protrude from the wall portion when implanted, and to define a distance between the wall portion and the movement restriction device. The third portion may comprise a curvature allowing the third portion to be arranged to point away from the esophagus when
10 implanted.

According to an embodiment, the movement restriction device and the attacher may be integrally formed into a single piece.

According to an embodiment, each of the movement restriction device and the attachments means may comprise a biocompatible outer surface.

15 The attacher may comprises an outer surface configured to promote tissue growth. In some examples, the attacher may be formed of a metal. In further examples, the movement restriction device may be formed of a polymer.

According to an embodiment, an outer surface of the movement restriction device may comprise a material for hindering growth of fibrotic
20 tissue.

Exemplary embodiments of the method of treating reflux disease in a human patient by implanting an apparatus comprising a movement restriction device and an elongated support device, as set out in some of the above aspects, will now be discussed in the following.

25 According to an embodiment, the apparatus may be placed such that the movement restriction device rests against the outside of the fundus at a position between the cardiac sphincter and the portion of the fundus that is to be affixed to the esophagus.

According to an embodiment, the apparatus may be placed such that
30 the portion of the fundus that is affixed to the esophagus is arranged between the cardiac sphincter and the movement restriction device.

According to an embodiment, the pouch may be formed to be open in a least two positions to form a tunnel through which the apparatus extends.

According to an embodiment, the portion of the fundus may be affixed to the patient's diaphragm.

5 According to an embodiment, affixing the portion of the fundus to the esophagus may include suturing or stapling.

According to an embodiment, the support device may comprise a first and a second end portion between which the esophagus can be introduced. The first and second end portions can be coupled to each other so as to fixate
10 the support device to the esophagus in an encircling manner.

According to an embodiment, the method may further comprise inserting a needle or a tube-like instrument into the patient's abdomen, using the needle or tube-like instrument to fill the abdomen with a gas, placing at least two laparoscopic trocars in the abdomen, inserting a camera through
15 one of the laparoscopic trocars into the abdomen, inserting at least one dissecting tool through one the laparoscopic trocars, dissecting a portion of the stomach, and at least partly closing the pouch by means of sutures, such as barbed sutures, or staples.

In the following, exemplary embodiments of the method for affixing a
20 fundus portion of the stomach of a human patient to the patient's esophagus according to the above aspect will now be described.

According to an embodiment, the abdominal part of the esophagus and the fundus can be divided by a plane into a ventral and a dorsal side. The method may comprise providing the first line on the dorsal side of the plane
25 and the second line on the ventral side of the plane. The first line may begin less than 1 cm above the angle of His and the second line began less than 3 cm above the angle of His. The second line may in some examples begin at a distance less than 2 cm from the first line.

According to an embodiment, a separating angle between the first line
30 and the second line may be in the range of 90-150 degrees.

According to some embodiments, the method may comprise providing an additional fastener between the first line and the second line, at the top of the fundus portion.

In some examples, the fasteners may comprise staples. In some
5 examples, the fasteners may comprise sutures, such as for example barbed sutures. The first line of fasteners may for example comprise a first continuous suture, and the second line of fasteners a second continuous suture.

According to some embodiments, the method may further comprises
10 placing a movement restriction device on the fundus, forming a pouch in the fundus, arranging the movement restriction device at least partly in the pouch, and invaginating the movement restriction device by the fundus by at least partly closing the pouch by fasteners. The movement restriction device may be arranged at a position between the diaphragm and the cardiac sphincter to
15 hinder the cardia from sliding through the diaphragm opening into the patient's thorax. The movement restriction device may be invaginated after affixing the fundus portion to the esophagus. Further, the pouch may be formed to be open in a least two positions to form a tunnel through which the movement restriction device may extend. In an example, the fundus may be
20 affixed to the diaphragm.

According to some embodiments an energy source may be provided. The energy source may be configured to be implanted in the body of the patient. The energy source may be configured to provide energy consuming components of the implant with electrical power. Examples of energy
25 consuming components include controllers, sensors, electrodes, and the like, as outlined above in connection with the previous embodiments and examples. Thus, in some embodiments the energy source may be configured to provide the electrode arrangement, or electrode, as outlined above with electrical power.

30 The implantable energy source may be configured to be arranged inside, or integrated with, the implanted device, such as the movement restriction device, support device, attachment means, core, or cover

according to any of the embodiments and examples described above. In some examples the energy source, or a part of the energy source, may be configured to be implanted outside the apparatus or implanted device, such as for example subcutaneously.

- 5 The energy source may comprise a primary cell, or galvanic cell, designed to be discarded after use, and not recharged like a secondary cell. Alternatively, or additionally the energy source may comprise a secondary cell, or rechargeable battery, designed to be recharged repeatedly.

- According to some embodiments, the implantable energy source may
10 be configured to be charged by an external energy source, i.e., an energy source arranged outside the patient's body. This may for example be achieved by means of an implantable charger, which may be configured to be electrically connected to the implantable energy source and to enable charging of the implantable energy source by the external energy source.
15 Thus, the charger may be configured to transmit the electrical power from the outside of the patient's body to the implanted energy source. The transmission may for example be performed wirelessly from the external source, and the charger may in some examples comprise an electromagnetic coil for facilitating the transfer.

- 20 According to some embodiments, the charger may be configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the implantable charger, and/or by controlling a transmission of electrical power from the external energy source to the implantable charger.

- 25 According to some embodiments, the charging of the implantable energy source may be controlled based on a functional status of the implanted energy source. This may for example be realized by controlling the electrical power delivered or emitted by an external energy source, or by controlling the electrical power received by a charger as outlined above.
30 Further, the charging may in some examples be controlled by controlling the electrical power delivered by the charger to the implantable energy source, either by controlling the power output from the charger or by controlling the

power received or absorbed by the implantable energy source. Thus, it will be appreciated that the charging of the implantable energy source may be controlled by varying or controlling the electrical power, supplied by the external energy source, at any point along the way to the implantable energy source. As exemplified above, the electrical power that is supplied to the
5 implantable energy source may hence be controlled at the external energy source, at the charger or at the implantable energy source itself.

The functional status of the implanted energy source may for example include a charge level or a temperature. The temperature may for example be
10 related to the energy source, the muscle tissue, or a part of the implant such as the electrode arrangement. Thus, the charging may be reduced or even stopped in case the charge level (or accumulated energy) reaches an upper limit, or in case the temperature exceeds a predetermined interval.

According to some embodiments, there may be provided a controller
15 (or processor or control circuitry) for controlling various parts or functions of the implanted device or apparatus according to any of the embodiments described above. The controller may for example be configured to include the functional status of the implanted energy source in a signal that is transmitted to the outside of the body.

20 The controller may be configured to be operable connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue. The stimulation may for example be controlled such that the muscle tissue is stimulated by a series of electrical pulses. The electrical pulses may be characterized by their voltage and/or current. In some examples, a pulse
25 of a first polarity may be followed by a pulse of a second, reversed polarity. The first polarity may for example be a positive current and the second polarity a negative current relative a current flow direction. Alternatively, or additionally the first polarity may be characterized by a positive voltage relative to a reference such as ground, and the second polarity by a negative
30 voltage.

The controller may be configured to generate a pulsed electrical stimulation signal comprising a pulse frequency of 0.01-150 Hz. The pulse

duration may be 0.01-100 ms, and the pulse amplitude in the interval 1-15 mA. Specific examples of electrical stimulation signals may be characterized by a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.

5 The controller may further be configured to generate a pulsed electrical stimulation signal having a varying composition, including different periods including build-up periods in which the amplitude is gradually increasing, stimulation periods in which the stimulation is ongoing, and pause periods wherein the stimulation is paused. Thus, in an example, the electrical
10 stimulation signal may comprise a build-up period of 0.01-2 s, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s. During the build-up period and the stimulation period the signal may comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms. These periods may be varied and combined depending on the desired stimulation of the muscle tissue and
15 may further be varied based on a response which fort example may be monitored by means of a sensor connected to the controller. The sensor may for example be configured to measure a motoric response in the muscle tissue, which may be measured as a mechanical movement or an electrical response.

20 According to some embodiments, there may be provided an implantable sensor for sensing action potentials generated by pacemaker cells of the muscle tissue. The sensor may be communicatively coupled to the controller, which may be configured to control the electrical stimulation based at least partly on the sensed action potentials. This may be particularly
25 advantageous when stimulating smooth muscle tissue, which may exhibit period contractions that are paced by the pacemaker cells. The present embodiments thus allow for the electrical stimulation signal to be tailored to amplify the sensed action potentials.

Remote controlling

30 According to some embodiments, the controller may comprise an external controller configured to be arranged outside the patient's body, and an internal controller, or implantable controller, configured to be arranged

inside the patient's body. The wireless remote control may comprise an external signal transmitter configured to communicate with the internal controller. The internal controller may thus be configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus or medical implant based on the signal. The signal may in some examples be selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

The various apparatuses and methods according to the above aspects can be combined with any of the features, examples and effects described in the present application.

BRIEF DESCRIPTION OF THE DRAWINGS

The above, as well as additional object, features and advantages of the present inventive concept will be better understood through the following illustrative and non-limiting detailed description, with reference to the appended drawings.

Figures 1-11 are schematic views of various examples of apparatuses for treating reflux disease, wherein the apparatuses are implanted in the body of the patient.

Figures 12-18B are schematic views of further examples of apparatuses for treating reflux disease.

Figures 19A and 19B are schematic views of an example of an apparatus for treating reflux disease, wherein the apparatus is implanted in the body of the patient. Figure 19A shows the apparatus in an expanded state and figure 19B shows the apparatus in a constricting state.

Figures 20A-21 are schematic views of various examples of apparatuses for treating reflux disease.

Figures 22-23C are schematic views of various examples of methods for treating reflux disease and/or implanting an apparatus for treating reflux disease.

Figures 24-27 are schematic views of various examples of apparatuses for at least partly encircling the esophagus to treat reflux disease.

Figure 28 schematically illustrates how an apparatus for treating reflux disease can be implanted in the patient.

5 Figures 29-38B are schematic views of various examples of apparatuses for treating reflux disease.

Figure 39 is a schematic cross section illustrating the anatomy of the stomach of a human patient.

10 Figures 40A-D show various examples of electrode arrangements for electrically stimulating muscle tissue of the patient.

Figures 41-42 illustrate a pulsed signal for electrically stimulating muscle tissue.

Figures 43-45 are schematic illustrations of systems for treating reflux disease.

15 Figure 46 shows a human patient in cross section when a system for treating reflux disease has been implanted.

Figures 47A-B show a cross-sectional view of an implantable remote unit for powering an implantable medical device.

20 Figure 48 shows an exploded cross-sectional view of an implantable remote unit for powering an implantable medical device.

Figures 49A-C show a detailed cross-sectional view of a first unit of an implantable remote unit for powering an implantable medical device

Figures 50A-B show alternative embodiments of connecting portions for an implantable remote unit.

25 Figures 51A-B show, schematically, a kit of components forming an implantable remote unit.

Figure 52A-B show a detailed cross-sectional view of an embodiment of an implantable remote unit for powering an implantable medical device.

30 Figure 53 shows a perspective elevated view from the right of an embodiment of an implantable remote unit for powering an implantable medical device.

Figure 54 shows a perspective elevated view from the right of a portion of an embodiment of an implantable remote unit for powering an implantable medical device.

Figure 55 shows a perspective elevated view from the right of a portion
5 of an embodiment of an implantable remote unit for powering an implantable medical device.

Figures 56-57 show cross-sectional plain side views of implantable remote units for powering an implantable medical device.

Figures 58A-D show cross-sectional plain side views of embodiments
10 of an implantable remote unit for powering an implantable medical device.

Figures 59A-D show embodiment of an implantable remote unit for powering an implantable medical device.

Figure 60 shows a perspective elevated view from the right of an embodiment of an implantable remote unit for powering an implantable
15 medical device.

Figure 61 shows a plain top view of an embodiment of an implantable remote unit for powering an implantable medical device.

Figures 62A-B show, schematically, plain top views of two embodiments of implantable remote units for powering implantable medical
20 devices.

Figures 63A-C illustrate three stages of insertion and fixation of an embodiment of an implantable remote unit for powering an implantable medical device.

Figure 64 shows a detailed cross-sectional view of an embodiment of
25 an implantable remote unit for powering an implantable medical device.

Figures 65A-E and 66A-H illustrate communication systems according to some embodiments.

DETAILED DESCRIPTION

30 In the following a detailed description of embodiments of the invention will be given with reference to the accompanying drawings. It will be appreciated that the drawings are for illustration only and are not in any way restricting the

scope of the invention. Thus, any references to directions, such as “up” or “down”, are only referring to the directions shown in the figures. It should be noted that the features having the same reference numerals have the same function, a feature in one embodiment could thus be exchanged for a feature
5 from another embodiment having the same reference numeral unless clearly contradictory. The descriptions of the features having the same reference numerals should thus be seen as complementing each other in describing the fundamental idea of the feature and thereby showing the features versatility.

Figure 1 is a schematic illustration of an apparatus 100 according to
10 some embodiments of the present disclosure. The apparatus 100 may be used for treatment of a human patient suffering from gastroesophageal reflux disease (GERD), also referred to as reflux disease. As illustrated in the present figure, the apparatus 100 may comprise a movement restriction
15 device 110 configured to be implanted in the stomach 10 for hindering the cardia 22 from sliding through the diaphragm opening 32, and an electrode arrangement 150 for stimulating and exercising muscle tissue of the stomach 10 to improve the conditions for long-term implantation.

The movement restriction device 110 may be arranged to rest against a fundus wall portion 14 of the stomach 10. In the present example, the
20 movement restriction device 110 is arranged to rest against the outside of the stomach wall. However, the movement restriction device 110 may in alternative examples and implementations be arranged to rest against the inside of the stomach wall.

The movement restriction device 110 may have a shape and size that
25 allows it to be fully or at least partly invaginated by the fundus wall portion 14. This may be achieved by forming a pouch or recess in the fundus wall portion 14 and at least partly closing the opening of the pouch or recess so as to hinder the movement restriction device 110 to be removed from the fundus wall portion 14. The invagination by the fundus wall portion 14 allows for the
30 movement restriction device 110 to be implanted at a position between the patient's diaphragm 30 and a lower portion of the fundus wall 12, such that movement of the cardia 22 towards the diaphragm 30 is restricted. By

restricting this movement, the cardia 22 may be hindered from sliding up towards, and possibly through, the diaphragm opening 32 into the patient's thorax, and the supporting pressure against the cardiac sphincter 26 exerted from the abdomen can therefore be maintained.

5 As illustrated in the example in figure 1, the movement restriction device 110 may be coupled, or affixed to the esophagus 20 at a position above the cardiac sphincter 26. The affixation of the movement restriction device 110 may preferably be of an indirect nature, achieved by affixing a part of the fundus 14 to the esophagus 20 such that the invagination can act as a
10 mechanical stop against the diaphragm 30 when the esophagus is moving upwards through the diaphragm opening 32. Further, in order to protect the tissue of the esophagus 20 from being damaged by the movement restriction device 110, the movement restriction device 110 may be implanted such that a part of the fundus is arranged between the movement restriction device 110
15 and the outside of the esophagus 20.

 The shape and size of the movement restriction device 110 is an important factor for allowing the invagination to act as a mechanical stop against the diaphragm 30. Preferably, the movement restriction device 110 may have a size and shape that allows for the invagination to be sufficiently
20 large to hinder the fundus wall portion 14 to slide through the diaphragm opening 32 together with the cardia. Further, the movement restriction device 100 may have a size and shape that allows it to be invaginated by the fundus 12 of the stomach without causing an unjustified reduction of the total volume of the stomach cavity. In addition to this, the movement restriction device 100
25 may at the same time be sufficiently small to allow it to generate a mechanical stop against the diaphragm muscle while leaving the food passageway substantially intact and unaffected. Thus, the movement restriction device 100 disclosed herein advantageously allows for the symptoms of reflux disease to be addressed while reducing the risk for compressing the food passageway.

30 To facilitate invagination and reduce the risk for damaging the tissue of the fundus wall portion 14 the movement restriction device 110 may have a substantially smooth outer surface. Any corners, edges, joints, or seams may

be rounded so as not to damage or irritate the tissue against which the movement restriction device 110 may rest when implanted. In some examples the movement restriction device 110 may have a rounded shape, for example conforming to a sphere, a spheroid, or an egg.

5 The minimum width of the movement restriction device 110, as measured from side to side, may in some examples be 30 mm or larger, such as 40 mm or larger. Additionally, or alternatively a minimum outer circumference of the movement restriction device 110 may be 150 mm or less, such as 130 mm or less, such as 110 mm or less. In further examples, 10 the minimum outer circumference may be 90 mm or less, such as 70 mm or less, such as 50 mm or less, and such that 30 mm or less. It will however be appreciated that the dimensions of the movement restriction device may vary according to the anatomy of the actual individual into which the movement restriction device 110 is to be implanted. The size and shape of the 15 movement restriction device 110 may be adapted to the individual patient to allow for the invagination to act as a mechanical stop as outlined above and thereby have an effect on reflux disease.

 The movement restriction device 110 may be formed of a biocompatible material that is suitable for long-term implantation in the human 20 body. Alternatively, or additionally, the outer surface of the movement restriction device 110 may be provided with a layer or coating of such a material. Examples of biocompatible materials include titanium or a medical grade metal alloy, such as medical grade stainless steel. In an alternative, movement restriction device 110 may be made from or comprise a ceramic 25 material such as zirconium carbide, or a stiff medical grade polymer material such as Ultra-high-molecular-weight polyethylene (UHMWPE) or Polytetrafluoroethylene (PTFE) or a thermoplastic polyester such as polylactide (PLA). Movement restriction device 110 could also comprise at least one composite material, such as any combination of metallic/ceramic 30 and polymer materials or a polymer material reinforced with organic or inorganic fibers, such as carbon or mineral fibers. Further, the movement restriction device may comprise an enclosure made from one of or a

combination of: a carbon based material (such as graphite, silicon carbide, or a carbon fiber material), a boron material, a polymer material (such as silicone, Peek®, polyurethane, UHWPE or PTFE,), a metallic material (such as titanium, stainless steel, tantalum, platinum, niobium or aluminum), a
5 ceramic material (such as zirconium dioxide, aluminum oxide or tungsten carbide) or glass.

Further, the movement restriction device 110 may according to some examples be configured to be introduced into the patient's body by means of a gastroscope or an intraluminal instrument, thereby allowing the apparatus
10 100 to be implanted by means of natural orifice transluminal endoscopic surgery (NOTES). Hence, the movement restriction device 110 may have a shape and size allowing it to be introduced and pass through a tubular instrument. In some examples, the movement restriction device 110 may be configured to change its shape, preferably resiliently, to temporarily assume a
15 smallest width that allows for the movement restriction device 110 to pass through such an instrument.

The apparatus 100 may further comprise an electrode arrangement
150 configured to be arranged between the movement restriction device 110 and the stomach wall portion 14 when the apparatus 100 is implanted. The
20 electrode arrangement 150 may be configured to electrically stimulate muscle tissue of the stomach wall portion 14 so as to exercise the muscle tissue and thereby improve the conditions for long term implantation of the movement restriction device 110. The electrode arrangement 14 may comprise at least
25 one electrode element 152, which may be configured to abut the tissue against which the movement restriction device 110 is arranged to rest when implanted and to transmit electrical impulses to the muscle tissue. It is appreciated that the electrode element 152 may be arranged in direct contact with the muscle tissue, or in indirect contact via intermediate tissue such as
30 for example connective tissue or fibrous tissue. Thus, the electrode arrangement 150 may be configured to rest against, abut or engage the tissue at least partly surrounding the implanted movement restriction device

100. The interaction between the electrode arrangement 150 and the muscle tissue will be described in greater detail in connection with figures 38-41.

The electrode element 152 may be attached directly to an outer surface of the movement restriction device 110, as shown in figure 1. In some examples, however, the electrode element 152 may be arranged on a support, such as a flexible patch, which may be configured to be attached to the medical implant. In further examples the electrode arrangement 150 may be provided as a separate item, physically distinct from the movement restriction device 110.

10 The apparatus 100 may further comprise an implantable energy source 160, which may be configured to supply the electrode arrangement 150 with electrical power for the electrical stimulation of the muscle tissue. The energy source 160 may be integrated in the in the movement restriction device 110 as shown in the present figure, wherein the energy source 160 is placed inside the movement restriction device 110 and electrically connected to the electrode element 152 arranged between the outer surface of the movement restriction device 110 and the fundus wall portion 12. The energy source 160 may in some examples be arranged outside the movement restriction device 110 as well, forming as a separate structural entity that can be implanted in the abdomen or elsewhere, such as subcutaneously.

According to some examples the energy source 160 may comprise a primary cell, i.e., a battery designed to not be recharged. In further examples, the energy source 160 may comprise a secondary cell designed to be recharged, preferably by means of an external energy source located outside the patient's body. Various examples of charging of the energy source 160 and powering of the electrode arrangement 150 is described in connection with figures 42-44, together with examples of how to control and operate the electrode arrangement 150.

Figure 2 is a schematic illustration of an apparatus 100 according to some embodiments, which may be similarly configured as the embodiments discussed with reference to figure 1. Hence, the apparatus 100 is shown when implanted in a patient to treat reflux disease, and may comprise a

movement restriction device 110 and an electrode arrangement 150 for generating an electric signal causing the muscle cells of the fundus wall portion 14 to contract and relax repeatedly. This action, or exercising of the cells by means of the electrode arrangement as shown in figures 1 and 2 has
5 been found to have a positive impact in terms of preventing deterioration and damage of the tissue and help increasing tolerance of the tissue for pressure and mechanical forces generated by the medical implant.

The present example differs from the one of figure 1 in that the movement restriction device is coupled to a user interface allowing the patient
10 or persons, such as medical staff, to interact with the apparatus 100. More specifically, the user interface may allow for communication with the implant and/or control of the operation of the implant. It may also comprise means for supplying power to the implant. The user interface may for example comprise a peripheral device 174, such as a regulator or a push-button, that is
15 connected to the movement restriction device 110 via a communication channel 172 such as a wiring or electrical lead. The peripheral device 174 may for example be implanted subcutaneously so as to facilitate access from outside the body. A user, such as the patient himself or a medical staff may interact with the peripheral device 174 to regulate or control the electrical
20 stimulation of the muscle tissue. The peripheral device 174 may for example be used to initiate or end the stimulation, or to adjust the electrical signal used for the stimulation, as described in connection with figures 38-41. The regulation and control of the electrical stimulation may be provided by a controller (not shown), which may be arranged within the movement
25 restriction device 110, integrated in the peripheral device 174, or implanted elsewhere in the body or arranged external to the body. In case of the controller being arranged outside the body, control signals may be sent to the implanted apparatus via the peripheral device 174. Such a controller may for example comprise an energy source, an electric switch, or an injection port
30 for varying a volume of the movement restriction device, depending on actual circumstances and application of the implant.

The electrode arrangement 150 may comprise a plurality of electrode elements 152 distributed over the outer surface of the movement restriction device 110 so as to allow for the tissue abutting the movement restriction device to be electrically stimulated and exercised. Each of the electrode elements 152 may comprise a contact pad, or contact surface, configured to form a junction with the surrounding tissue and which is electrically connected to a circuitry inside the movement restriction device 110. The circuitry may be configured to generate an electrical signal, for example comprising a pattern of electrical pulses, that is transmitted to the muscle tissue via the electrode elements 152.

Figure 3 illustrates an apparatus 100 for treating reflux disease of a human patient, when implanted in the patient. The apparatus 100 may be similarly configured as the apparatuses disclosed in connection with figures 1-3, with the difference of an elongated support device 120 which may be configured to at least partly encircle the esophagus 20. Hence, the apparatus 100 of figure 3 may comprise a movement restriction device 110 configured to be implanted to hinder the cardia from sliding through the diaphragm opening as discussed above, and an elongated support device 120 that may be connected to the movement restriction device 110 in a manner that allows the elongated support device 120 to be held in place around the esophagus 20 by the movement restriction device 110. The elongated support device 120 may comprise a mechanical stability, or rigidity that allows for its position relative to the esophagus 20 to be determined mainly by the position and orientation of the movement restriction device 110. Thus, the elongated support device 120 may be implanted and kept in position without having to be secured to the tissue of the esophagus 20.

The elongated support device 120 may be formed as a bracket or brace having a shape that allows it to follow at least a part of the outside of the esophagus 20. In some examples, the elongated support device 120 may have a shape conforming to a "C". The elongated support device 120 may be formed of the same material as the movement restriction device 110, or by a different material. Examples of materials include metals and polymers.

Further, the elongated support device 120 may comprise a surface layer or coating configured to hinder or reduce growth of fibrotic tissue.

The elongated support device 120 may be integrally formed with the movement restriction device 110, such that the movement restriction device 110 and the elongated support device 120 form a single piece. The elongated support device 120 may hence be referred to as a protrusion of the movement restriction device 110, having a length and orientation relative to the body of the movement restriction device 110 that allows for the protrusion to be arranged at least partly around the esophagus 20. In alternative examples the elongated support device 120 and the movement restriction device 110 may be formed as separate pieces that can be joined or attached to each other when implanted.

Similar to the movement restriction device 110, the elongated support device 120 may be formed of a biocompatible material that is suitable for long-term implantation in the human body. Alternatively, or additionally, the outer surface of the elongated support device 120 may be provided with a layer or coating of such a material. Examples of biocompatible materials include titanium or a medical grade metal alloy, such as medical grade stainless steel. In an alternative, support device 120 may be made from or comprise a ceramic material such as zirconium carbide, or a stiff medical grade polymer material such as Ultra-high-molecular-weight polyethylene (UHMWPE) or Polytetrafluoroethylene (PTFE) or a thermoplastic polyester such as polylactide (PLA). The support device 120 could also comprise at least one composite material, such as any combination of metallic/ceramic and polymer materials or a polymer material reinforced with organic or inorganic fibers, such as carbon or mineral fibers. Further, the support device 120 may comprise an enclosure made from one of or a combination of: a carbon based material (such as graphite, silicon carbide, or a carbon fiber material), a boron material, a polymer material (such as silicone, Peek®, polyurethane, UHMWPE or PTFE,), a metallic material (such as titanium, stainless steel, tantalum, platinum, niobium or aluminum), a ceramic material (such as zirconium dioxide, aluminum oxide or tungsten carbide) or glass.

The apparatus 100 may further comprise an electrode arrangement 150 comprising an electrode element 154 that is supported by the elongated support device 120, or holder 120 and configured to electrically stimulate muscle tissue of the esophagus 20. The electrode element 154 may hence be
5 arranged between the holder 120 and the outside of the esophagus 20 and configured to transmit an electrical stimulation signal to the tissue of the esophagus 20.

The electrical stimulation of the tissue may be similar as the stimulation described above for the movement restriction device 110, i.e., for exercising
10 the muscle tissue to improve the conditions for long term implantation. However, in additional or alternative examples the electrical stimulation may be configured to cause the cardiac sphincter 26 to contract. In the present example in figure 3 the apparatus 100 may be provided with an electrode arrangement 150 for electrical stimulation of the muscle tissue close to the
15 implanted movement restriction device 110 and for electrical stimulation of the cardiac sphincter muscle 26. However, it is appreciated that the electrode arrangement 150 may comprise an electrode element 154 for the stimulation of the cardiac sphincter 26 only. In other words, the electrode arrangement 150 at the movement restriction device 110 may be optional.

20 The electrode arrangement 150 may comprise at least two electrode elements 154 that are supported by the elongated support device 120 at two different positions of the cardia 22, preferably at opposing sides, so as to allow for the cardiac sphincter 26 to be electrically stimulated. The electrode arrangement 150 may be controlled to alternate between at least two modes,
25 i.e., an operation mode in which the cardiac sphincter 26 is stimulated with electrical energy and a resting mode, in which the cardiac sphincter 26 is not stimulated to allow the muscle tissue to recover.

The apparatus 100 may further comprise a user interface, comprising a peripheral device 174 and a communication channel 172 which may be
30 similarly configured to the example described above in connection with figure 2. The user interface may allow for the patient, or medical staff, to choose when the electrode arrangement 150 should be in the operation mode and

when it should be in the resting mode. For example, for some patients it may be sufficient to keep the stimulation temporarily “on” when the patient experiences reflux symptoms, such as at night the patient is lying down, whereas other patients may need the cardiac sphincter 26 to be stimulated
5 continuously, with the exception of when eating.

The user interface may further allow for the power of the electrical signal to be adjusted over time. For example, the power used for the stimulation may be increased to compensate for an increased resistance at the junction between the electrode element 154 and the tissue caused by
10 formation of fibrotic tissue.

As indicated in the present figure, the apparatus 100 may comprise an energy source 160 for supplying the electrode arrangement 150 with electrical power. The energy source 160 may be implantable, for example at a location outside the movement restriction device 110, such as subcutaneously as
15 illustrated in figure 3. The communication channel 172 may hence be configured to convey the electrical power, i.e., the electrical signal, from the energy source 160 to electrode arrangement 150. The communication channel 172 may for example comprise an electrical conductor for electrically connecting the electrode arrangement 150 of the elongated support device
20 120 (and, optionally, the movement restriction device 110) with the energy source 160.

It will be appreciated that the movement restriction device 110 may be implanted in the fundus wall portion 14 in a number of different ways, and that figures 1-3 are merely illustrative examples. In figures 1-3 the movement
25 restriction device 110 is invaginated in the fundus wall portion 14 from outside the stomach. A plurality of stomach-to-stomach sutures or staples may be applied to maintain the invagination intact and the movement restriction device 110 in the desired position relative to the cardia 22 and the diaphragm 30 of a standing patient. This allows for a growth of fibrotic tissue for keeping
30 the invagination intact over time.

Additionally, or alternatively, an affixation may be provided between the fundus wall portion 14 and the diaphragm 30, and/or the fundus wall portion

14 and the esophagus 20 as illustrated in figure 4. The movement restriction device 110 depicted in figure 4 may be similarly configured as the embodiments discussed in connection with figures 1-3, and figure 4 hence discloses a movement restriction device 110 implanted in the fundus 12 and arranged at a position above the cardia 22 so as to provide a mechanical stop reducing the symptoms of reflux disease. The movement restriction device 110 may also comprise an electrode arrangement 150 for electrically stimulating and exercising the muscle tissue affected by the implanted device 110, as described above.

10 However, in the example shown in figure 4, the movement restriction device 110 is invaginated from the inside of the stomach 10, instead of from the outside of the stomach 10. The movement restriction device 110 is hence adapted to rest against a portion of the inside wall of the fundus wall portion 14 in a position between the diaphragm 30 and at least a portion of the lower part of the invaginated stomach fundus wall 12. After invagination, a number of stomach-to-stomach sutures or staples may be applied from the inside of the stomach 10 to keep the invagination intact and to allow growth of tissue to keep the invagination over time. Additional affixations may be provided between the outside of the fundus wall portion 14 and the esophagus 20 and/or the diaphragm muscle 30 to hold the movement restriction device 110 in the desired position.

 The movement restriction device 110 disclosed in figures 1-4 may have several different configurations and may not necessarily be limited to the schematic versions outlined therein. Other configurations and designs are conceivable within the inventive concept, as defined by the appended claims. An example of such a variant is illustrated in figure 5, showing a movement restriction device 110 similar to the ones in figures 1-4 but formed of a plurality of segments 111 that are configured to be attached to be assembled into a complete movement restriction device 110. The segments 111 may for example be secured to each other by means of mutually engaging structures 114 such as protruding slits and receiving grooves, snap-fit connectors, or the like. In the present example, the movement restriction device 110 may be

formed of five segments 111: four outer parts 112 and an inner, core part 113 around which the outer parts 112 may be arranged to form a rounded and substantially smooth body suitable for invagination. The segments 111 may be configured to be securely attached to each other, or to be loosely fitted
5 and kept in their right position when invaginated by the surrounding fundus wall 12. In some examples, the segments 111 may be secured to each other by means of a wire. The wire may be biodegradable and eventually dissolved. The segments 111 may be configured to be introduced in the body of the patient separately, one by one, and assembled into the movement restriction
10 device 110 in connection with being implanted.

As shown in the present figure, a plurality of electrode elements 152 may be arranged on an outer surface of the segments 111, i.e., the surface of the outer parts 112 that is to be arranged to rest against the fundus wall portion 14 when the assembled movement restriction device 110 is implanted.
15 The segments 111 may be electrically connected to each other to allow for an electrical stimulation signal to be transmitted to the electrode elements 152 on the outer surface of the movement restriction device 110.

The movement restriction device 110 according to any of the above-mentioned examples may have a volume that is adjustable or non-adjustable
20 after implantation. In case of a non-adjustable volume, the movement restriction device 110 may be formed of a body (or several segments) being solid, i.e., which is not hollow and/or comprises substantially the same material throughout. This may allow for the shape to be varied, for example during insertion into the body, such as through a tubular instrument, while the
25 volume may be substantially the same. In case the movement restriction device 110 is adjustable in terms of volume, the device may be formed of a body (or several segments) comprising one or several cavities or voids capable of accumulating and releasing a fluid for causing a corresponding expansion and reduction of the movement restriction device 110. The fluid
30 may for example be a gas or a liquid, such as a gel, which may be introduced and extracted from the movement restriction device 110 prior to implantation, during the implantation procedure, or after it has been implanted.

Figures 6a and 6b illustrate an example of a movement restriction device 110, similar to the ones discussed with reference to figures 1-5, comprising a fluid communication port 115, or injection port, that can be used to add or remove a fluid to/from the inside of the movement restriction device 110 to thereby vary its volume. It may be desired to adjust the volume of the movement restriction device 110 post-operatively in order to fine tune or adjust the movement restriction device's 110 capability of acting as a mechanical stop against the diaphragm. It may for example be determined after the implantation, in a subsequent evaluation of the results of the operation, that an implant of another size would have been more optimal for the specific patient. This may be solved by adjusting the volume of the implant post-operatively.

As shown in the present figures, the port 115 may be positioned such that it is accessible from outside the invagination, i.e., such that the port 115 can be accessed by an instrument or connection without having to penetrate the fundus wall portion 14. In figure 6a the port protrudes to the outside of the invagination, passing between sutures or staples used for at least partly closing the pouch in which the movement restriction device 110 is arranged. The port 115 may thus be available for connection to a tube or a syringe from the abdominal region of the patient. In figure 6b the port 115 is positioned inside the invagination and accessed by a tube 116 that is connected to the port 115 and extends into the abdominal region of the patient.

The volume of the movement restriction device 110 may according to some examples be adjustable non-invasively after implantation. A non-invasive adjustment may be allowed by means of the tube 116, that may be connected to the port 115 and led to the outside of the patient's body or to an implanted volume regulator, such as a pump or a reservoir, for non-invasive regulation of the volume of the movement restriction device 110. According to other examples, the volume of the movement restriction device 110 may be adjustable invasively, e.g. by means of an instrument that is inserted into the patient's body and connected directly to the port 115 or the tube 116 for adding or removing fluid from the movement restriction device 110.

Alternatively, or additionally, an instrument such as a syringe may be inserted directly into the inside of the movement restriction device 110, penetrating and passing through the surrounding fundus wall portion 14 on the way to the movement restriction device 110.

5 It will be appreciated that the adjustable and non-adjustable characteristics of the volume of the movement restriction device 110 generally refer to a permanent state of the movement restriction device 110. In other words, an adjustment of the volume may, in the above context, result in a new volume that is substantially constant over time until the amount of fluid in the
10 movement restriction device 110 is varied again. This may be contrasted with temporary changes of the volume, which for example may be caused by a temporary or resilient compression of the material forming the movement restriction device 110. Such a temporary change in volume may for example occur during introduction of the movement restriction device 110 into the
15 body, e.g. via a tubular instrument. In other words, the movement restriction device 110 according to the examples outlined above with reference figures 1-6 may be flexible or elastic, allowing the device 110 to at least temporarily assume different shapes and, in some examples, volumes, in response to being exposed to external mechanical forces.

20 An apparatus for treating reflux disease, as outlined above, will now be described with reference to figures 7-13. The figures schematically illustrate an apparatus 100 comprising an at least partly ring-shaped implantable movement restriction device comprising a first portion 110 configured to be at least partly invaginated by a first wall portion of the patient's stomach 10 and
25 arranged such that at least a part of the first portion of the apparatus 100 is arranged above the cardia 22 of the patient's stomach 10, and such that movement of the cardia towards the diaphragm is restricted to prevent the cardia 22 from sliding through the diaphragm opening 32 into the patient's thorax. The configuration and function of the first portion 110 of the apparatus
30 100 may hence be similar to the movement restriction devices 110 previously described with reference to figures 1-6. Further, the apparatus 100 may comprise an electrode arrangement 150 which may be similar to the electrode

arrangement 150 described in connection with the examples of figures 1-6, and may hence be configured to be arranged between the first portion 110 of the apparatus 100 and the first wall portion 14 to electrically stimulate muscle tissue of the first wall portion 14 to exercise the muscle tissue and thereby
5 improve the conditions for long term implantation of the apparatus 100.

The apparatus 100 may further comprise a second portion 120, which may be configured to be arranged on an opposite side of the cardia 22, as seen from the first portion 110. The first portion 110 and the second portion 120 may together form the at least partly ring-shaped movement restriction
10 device 110, 120, which as indicated in the present figures may be configured to be arranged to at least partly encircle the esophagus 20 of the patient. The first portion 110 may for example be configured to be arranged on the fundus side of the esophagus 20, whereas the second portion 120 may be configured to be arranged on the side of the esophagus 20, i.e., the side opposing the
15 fundus 12. The movement restriction device 110 may in some examples be formed of a substantially smooth, ring-shaped body configured to encircle the esophagus 20. The movement restriction device 110 may for example have a shape conforming to a torus, with the first portion 110 forming the part arranged at the fundus side of the esophagus and the second portion 120
20 forming the part arranged at the opposite side of the esophagus 20.

The ring-shaped body of the movement restriction device 110 may comprise an opening, or be possible to open, so as to allow the body to be arranged around the esophagus. After the movement restriction device 110 has been placed around the esophagus 20, the movement restriction device
25 110 may be affixed in a desired position, preferably at least partly above the cardia 22, by for example invaginating at least one of the first portion 110 and the second portion 120 by the outer wall of the stomach 10, or by wrapping a part of the stomach wall around at least a part of the ring-shaped body. Preferably, the movement restriction device 110 is implanted such that a part
30 of the stomach wall is arranged between the movement restriction device 110 and the outside of the esophagus 20 to as to protect the tissue of the esophagus from being damaged by the movement restriction device 110, 120

abutting the tissue of the esophagus 20. As illustrated in the examples of figures 7-9 a part of the fundus 12 may be arranged between the first portion 110 and the esophagus 20 and at the same time provide an affixation of the device to the stomach 10. Further, the movement restriction device may be provided with a shape and size allowing for a gap to be defined and maintained between the second portion 120 and the side of the esophagus opposite to the fundus side. Due to the affixation of the first portion 110 to the fundus 12, the separating gap between the second portion 120 and the tissue of the esophagus 20 may be maintained after implantation.

Figure 10 shows an alternative example, in which the second portion 120 of the movement restriction device 110, 120 is arranged with a part of the stomach wall between the second portion 120 and the esophagus 20, on the side of the esophagus 20 opposing the fundus 12. On the fundus side, however, the first portion 110 may be arranged to define a distance or gap to the esophagus 20, similar to what is described figures 7-9.

Figure 11 shows a further example, wherein the first portion 110 may be placed at the angle of His and the second portion 120 invaginated by a pouch protruding into the stomach wall on the opposite side of the esophagus 20. The pouch may be arranged further down, compared to the example in figure 10. As a result, the first portion 110 and the second portion 120 may in figure 10 be implanted at substantially the same height relative to the cardia, whereas in figure 11 only the first portion 110 is implanted at least partly above the cardia 12.

Figures 12 and 13 show various examples of at least partly ring-shaped movement restriction devices 110, 120, wherein the first portion 110 and the second portion 120 may be integrally formed into a single piece as shown in figure 12, or be formed of a plurality of core elements 213 arranged in a cover 220 as shown in figure 13. The movement restriction devices 110, 120 may for example conform to a torus, which may be closed or at least partly closed when implanted. Similar to the apparatuses illustrated in figure 7-11, the apparatus may be implanted in a position wherein it at least partly encircles the esophagus 20 and may function as a movement restriction

device. The apparatuses may further comprise an electrode arrangement 150.

The electrode arrangement 150 of the examples shown in figures 7-13 may comprise one or several electrode elements 152, 154, which may be
5 arranged between at least one of the first portion 110 and the second portion 120 and the tissue against which the respective portion 110, 120 rests and operate according to principles similar to the ones discussed with reference to figures 1-6. Thus, the electrode arrangement 150 may be configured to electrically stimulate and exercise muscle tissue of the fundus wall 12 or the
10 esophagus 20 to improve conditions for long term implantation, and in some examples to electrically stimulate the cardiac sphincter muscle 26 so as to cause the sphincter to contract. In the latter case, the second portion 120 may be configured to act as an elongated support device for the electrode elements 154 for the cardiac sphincter stimulation, similar to the examples
15 disclosed in connection with the previous figures.

The apparatus 100 may be configured to be at least partly invaginated, or covered, by the stomach wall along at least half of the toroidal length (i.e., the length as seen in the direction of the circumference encircling the esophagus). An example is illustrated in figure 8, wherein a toroidally shaped
20 apparatus is at least partly covered by the fundus 14 along at least half the toroidal length. A similar arrangement is illustrated in figures 7, 9, 10 and 11, wherein at least 25%, such as for example 50%, of the circumferential length of the apparatus may be at least partly invaginated or covered by stomach wall tissue.

25 As shown in the perspective views of figures 8, 12 and 13 the apparatus 100 may be substantially ring-shaped and may comprises two end portions configured to be coupled to each other to form a closed ring. The end portions are configured to be releasably attached to each other, for example by means of a locking mechanism 216 or a fastener 216.

30 In case of the apparatus being at least partly ring-shaped, or conforming to a torus, the size of the apparatus may be characterized by its poloidal circumference and its toroidal circumference. The poloidal direction

may be understood as a direction following a small circular ring around the surface, while the toroidal direction follows a large circular ring around the torus or ring, encircling the central void in which the esophagus may be arranged. In some examples, the poloidal circumference of the apparatus
5 may be larger for the first portion 110 than for the second portion 120, as shown in figures 12 and 13. Preferably, the first portion 110, forming the movement restriction device 110, may have a larger poloidal circumference so as to provide a mechanical stop hindering movement of the cardia towards and/or through the opening in the diaphragm.

10 In some examples, the first portion 110 may have a minimal width or cross section, as measured orthogonal to the toroidal direction, being 30 mm or larger, such as 40 mm or larger.

In some examples, a minimum poloidal circumference of the first portion 110 of the movement restriction device may be 150 mm or less, such
15 as 130 mm or less, such as 110 mm or less, such as 90 mm or less, such as 70 mm or less, such as 50 mm or less, such as 30 mm or less.

In some examples, a maximum width of a cross section taken across a length direction (i.e. across toroidal direction) of the first portion 110, or movement restriction device 110, may be larger than a maximum width of a
20 cross section taken across a length direction of the second portion 120, or support device 120.

The apparatus 100 may be affixed to the stomach wall in several different ways, all of which may include to at least partly wrap the stomach wall 10 around at least a portion of the apparatus 100 and affixing the
25 stomach wall 10 to itself and/or to the esophagus 20. Some non-limiting examples of placing and affixing the apparatus 100 at the stomach wall 10 will now be discussed with reference to the ring-shaped movement restriction device 110, 120 disclosed in figures 7-13.

In figure 7, the movement restriction device has been placed around
30 the esophagus 20, such that the first portion 110 is arranged at the fundus side and the second portion 120 at the opposing side of the esophagus. A part of the fundus wall 12 has then been wrapped around the first portion 110

of the movement restriction device, from the outside of the device and into the center hole of the ring-shaped body, such that the part of the fundus wall 12 is arranged between the inner periphery of the ring-shaped body and the esophagus 20. The part of the fundus wall 12 that is wrapped around the first
5 portion 110 may be considered as a “flap” formed of the fundus wall, which may be formed outside the ring-shape and pushed into the hole defined by the ring-shape and affixed to the esophagus 20.

Figure 8 shows a perspective view of an apparatus 100 which may be similar to the one in figure 7, illustrating the affixation of the first portion 110 of
10 the movement restriction device 110, 120 to the fundus 12. The part of the fundus that is wrapped around the first portion 110 and affixed to the esophagus may form a tunnel through which the ring-shaped body may extend on its way around the esophagus.

Figure 9 shows an another example, in which the fundus portion
15 closest to the angle of His has been folded to rest against the esophagus, from the angle of His and upwards along the esophagus, and affixed to the esophagus with one or several lines of fasteners, such as staples or sutures, extending along the esophagus. The first portion 110 of the movement restriction device may then be invaginated by another portion of the fundus,
20 arranged further away from the angle of His, such that the movement restriction device is kept in place by the affixation to the esophagus and encircling the esophagus such that the second portion 120 is arranged on the opposite side of the esophagus 20.

Put differently, the method according to figures 7 and 8 may result in
25 the first portion 110 being arranged between the esophagus 20 and the portion of the fundus that is affixed to the esophagus 20, whereas the method according to figure 9 may result in the portion of the fundus 12 that is affixed to the esophagus 20 being arranged between the esophagus 20 and the first portion 110 of the movement restriction device. In the former example a part
30 of the fundus may be pushed into the hole of the ring-shaped body from below, whereas in the latter example a part of the fundus may be pushed into the hole from above.

Figure 10 shows a similar method as in figure 7, with the difference that it is the stomach wall on the side opposite to the fundus, i.e., the non-fundus side of the stomach wall, that is wrapped around the second portion 120 and introduced into the hole defined by the ring-shaped body and affixed to the esophagus. The portion of the stomach wall 10 closest to the esophagus 20 may further be folded to rest against the esophagus 20 and affixed to the esophagus 20 similar to the example of figure 9 so as to allow the second portion 120 of the movement restriction device to be arranged higher up, and preferably above the cardiac sphincter 26. The portion of the stomach wall closest to the esophagus 20 may be attached to the esophagus 20 before the stomach wall is wrapped around the second portion 120 and introduced into the hole defined by the ring-shaped body.

An apparatus for treating reflux disease of a human patient according to some examples will now be described with reference to figures 14-21. Figures 14-21 illustrate an apparatus 100 comprising an elongated core 210 having a length that allows the core 210 to be arranged to at least partly encircle the esophagus 20 of an adult human the patient. The length is variable to allow the core 210 to be arranged in a constricting state for hindering fluid from passing from the stomach 10 into the esophagus 20, and in an expanded state for allowing food to pass into the stomach 10 in response to the patient swallowing. The apparatus may hence be used for treating reflux disease by assisting contraction of the cardiac sphincter 26 and hindering stomach contents to rise up into the esophagus 20. The transition from the constricting state into the expanded state may be caused by the food passing through esophagus 20, wherein the core 210 may be configured to exert an encircling pressure on the esophagus 20 in at least the constricting state. The encircling pressure may for example be generated by an attractor 212 configured to resiliently attracting adjacent portions 213 of the core to one another. Further, the apparatus 100 may according to some example comprise an electrode arrangement 150 comprising an electrode element 154 configured to be arranged between the apparatus 100 and the esophagus 20 and to electrically stimulate muscle tissue of the esophagus 20. The electrical

stimulation may for example employed to stimulate the muscle tissue of the outer wall of the esophagus 20 so as to exercise the muscle tissue to improve the conditions for long term implantation of the apparatus 100, and/or to stimulate the cardiac sphincter 26 of the patient to cause the cardiac

5 sphincter 26 to contract.

Figure 14 shows a core 210 comprising an array of adjacent portions 213, wherein neighboring portions 213 of the array are interconnected by an attractor 212. The portions 213 of the array may for example be ball-shaped, having a substantially smooth outer surface suitable for resting against the
10 tissue of the outer wall of the esophagus 20. The portions 213 may for example be formed of a metal or a polymer and may preferably comprise a biocompatible outer surface suitable for long-term implantation in the body. The attractors 212, connecting neighboring portions 213 to each other, may comprise an elastic element, such as an elastic band or string, allowing for
15 the portions 213 to be resiliently pushed away from each other when entering the expanded state (e.g. in response to the patient swallowing a bolus of food), and pulling the neighboring portions 213 towards each other again to assume the constricting state for hinder stomach contents for pass into the esophagus 20. The core 210 may comprise a plurality of attractors 212,
20 wherein each of the attractors 212 may have a first end connected to a first one of the portions 213 and a second end to a second one of the portions 213. Thus, each attractor 212 may be arranged to extend from a first one of a pair of neighboring portions 213 to the other one of the pair of neighboring portions 213. Alternatively, a single attractor 212 may be arranged to
25 interconnect more than two portions 213 of the core 210. As indicated in figure 14, the attractor 212 may be formed of a string or band extending through each of the portions 213 of the core 210.

The core 210 may further comprise an attacher 216, or locking means, arranged at the end portions of the array of neighboring portions 213. The
30 attacher 216 may for example comprise a first part, arranged at a first end portion, which can be inserted in, or attached to, a second part arranged at

the other end portion of the core 210. Examples of attachers 216 include interlocking components, snap fasteners, and a screw assemblies.

Alternatively, or additionally, resiliency of the core 210, which allows it to assume the expanded state and the constricting state and to exert an encircling pressure on the esophagus 20, may be achieved at least part by means of attractive forces between permanent magnets. In this case, the portions of the array may comprise permanent magnets 213, which may be arranged such that there is a mutual attraction between neighboring magnets 213 of the array. The magnets 213 may be attached to each other by a connector or link, such as a band or string 212 as outlined above, which may or may not be elastic so as to further contribute to the resiliency of the core and its ability to exert an encircling pressure on the esophagus 20. The magnets 213 may in some examples be referred to as attractors.

Figure 15 shows an example wherein the core 210 comprises a plurality of magnetic portions 213, or permanent magnets 213 arranged in an array extending along the length direction of the elongated core 210. The example in figure 15 may thus be similarly configured as the apparatus 100 shown in figure 14, with the difference that the present apparatus 100 comprises a tubular cover 220 enclosing at least a part of the core 210. The cover 220 may comprise a plurality of portions 222 adapted to bend relative to each other to allow the core 210 to change between the constricting state and the expanded state, when the cover 220 is at least partly covered by fibrotic tissue, without being substantially hindered or impeded by the presence of the fibrotic tissue.

The implantation of a foreign body into the human body tends to cause an inflammatory response. The response generally persists until the foreign body has been encapsulated in a relatively dense layer of fibrotic connective tissue, which protects the human body from the foreign body. The process may start with the implant immediately and spontaneously acquiring a layer of host proteins. The blood protein-modified surface enables cells to attach to the surface, enabling monocytes and macrophages to interact on the surface of the implant. The macrophages secrete proteins that modulate fibrosis and

in turn develop the fibrosis capsule around the foreign body, i.e., the implant. In practice, a fibrosis capsule may be formed of a dense layer of excess fibrous connective tissue. The inelastic properties of the fibrotic capsule may lead to hardening, tightness, deformity, and distortion of the implant, which in
5 severe cases may result in revision surgery. On a medical device implanted in the abdomen, in the region of the stomach, the fibrotic capsule has been observed to typically grow a thickness of about 0.5-2 mm.

The presence of such a capsule of fibrotic tissue risks to hinder movement of the elongated core 210 of the apparatus 100 as described in
10 connection with the examples of figures 14-21. In particular, the presence of a relatively thick and inelastic layer of fibrotic tissue may hinder the core's 210 ability to change between the expanded state and the constricting state. To address this issue, the elongated core 210 may be arranged in, or at least partly covered by, the cover 220, which allows the core 210 to change its
15 length without being substantially hindered by fibrotic tissue surrounding the cover 220. This is allowed by the cover 220 being capable of changing its length without stretching the material of which the cover 220 is formed. While the fibrotic tissue may be inelastic and thereby withstanding stretching, it may be easier to bend or fold. Thus, the cover 220 can be considered to make use
20 of the fact that the fibrotic tissue may be more flexible than elastic in its nature, which allows for the apparatus to change its length (or circumference, as it is arranged around the esophagus 20) by folding or bending a plurality of portions of the core relative to each other. Put differently, the cover 220 may be configured to maintain a substantially constant surface as the core
25 changes between the expanded state and the constricting state, thereby allowing for the length of the elongated core 210 to vary without stretching the surrounding fibrotic tissue to a corresponding degree. The cover 220 may thus have a length that exceeds a length of the core 210 when the core 210 is arranged in the constricting state.

30 Figure 15 shows an example of a cover 220 which is tubular and arranged to accommodate an array of permanent magnets 213. The permanent magnets 213 may be attached to each other, for example by

means of an attractor 212 as discussed above in connection with figure 14, or be freely arranged in the cover 220, without any interconnections. In some examples, the permanent magnets 213 may be affixed to the cover 220, such that each permanent magnet 213 may be maintained at a predetermined
5 position relative to the cover 220. When going from the expanded state to the constricting state, neighboring magnets 213 may be pulled towards each other such that the distance between the magnets 213 in the array is reduced. The cover 220 may follow this movement by allowing the portions of the cover 220 arranged between the magnets 213 to fold or bend relative the
10 portions of the cover 220 arranged at the respective magnets 213, such that the cover 220 is configured to be compressible and expandable in its length direction.

The cover 220 may comprises a biocompatible outer surface suitable for long-term implantation in the human body, and preferably for long-term
15 implantation in a position where it rests against an outer surface of the esophagus 20. In some examples, the cover comprises a surface promoting tissue growth. The cover 220 may for example be formed of or at least comprise a polymer material (such as silicone, Peek®, polyurethane, UHWPE or PTFE,). Further, the cover may have a wall thickness of 0.1-5 mm. In some
20 examples the cover 220 may be provided with a coating, such as Parylene, polytetrafluoroethylene (PTFE), or polyurethane, or a combination of such coatings, for improving the resistance to wear.

Further, the cover may comprise an electrode arrangement 150, similar to the one discussed above in connection with the examples of figure 14. The
25 electrode arrangement 150 may hence comprise at least one electrode element 154 configured to be arranged between the cover 220 and the esophagus 20 for electrically stimulating muscle tissue of the esophagus 20. The electrode element 154 may for example be configured to stimulate muscle tissue at the outer surface of the esophagus so as to improve the
30 conditions for long-term implantation, and/or the cardiac sphincter 26 so as to cause it to contract.

Figure 16 shows an example of an apparatus 100 that may be similarly configured as the apparatuses discussed in connection with figures 14 and 15. However, as indicated in the present figure, the cover 220 may comprise at least one predefined fold 224 along which the cover is allowed to fold in response to the core 210 varying its length. In some examples, the cover 220 may comprise a bellows-shaped structure of a plurality of lowered portions 225 and elevated portions 226 that allow the cover 220 to vary its length while maintaining its surface area substantially constant. A distance between two elevated portions 226 may be long enough to prevent growth of fibrotic tissue directly connecting to adjacent elevated portions 226. Thus, fibrotic tissue may grow on the surfaces of the lowered portions 225 and the elevated portions 226, but due to the distance between adjacent elevated portion 226 fibrotic tissue may be hindered from growing directly from one elevated portion 226 to another elevated portion 226 without first passing over the intermediate lowered portion 225. The cover 220 may hence comprise a ridges and grooves, or elevated 226 and lowered 225 portions dimensioned such that the connective tissue follows the surface of the elevated 226 and lowered 225 portions and leaves a separating gap between neighboring elevated portions 226, or ridges. In case the fibrotic tissue has a thickness of about 0.5-1.5 mm, as an example, the distance between adjacent elevated portions 226 may be greater than twice the maximum thickness of the fibrotic tissue, i.e., greater than about 3 mm.

Figure 17 shows an apparatus 100 which may be similarly configured to the examples of figures 14-16. However, figure 17 further discloses an implantable energy source 160 for supplying the electrode arrangement 150 with electrical power for the electrical stimulation of the muscle tissue. The energy source 160 may be integrated in the in the elongated core 210, such as in one or several of the portions 213, as shown in the present figure. However, the energy source 160 may in some examples be arranged outside the apparatus 100 as well, forming as a separate structural entity that can be implanted in the abdomen or elsewhere, such as subcutaneously. The energy source 160 may comprise a primary cell, i.e., a battery designed to not be

recharged. In further examples, the energy source 160 may comprise a secondary cell designed to be recharged, preferably by means of an external energy source located outside the patient's body. Various examples of charging of the energy source 160 and powering of the electrode

5 arrangement 150 is described in connection with figures 42-44, together with examples of how to control and operate the electrode arrangement 150.

Figures 18a and 18b show an apparatus 100 which may be similarly configured as the examples shown in figures 14-17. The apparatus 100 may comprise an elongated core 210 having a variable length which allows the

10 apparatus to be arranged to at least partially encircle the esophagus 20 in a constricting state for hindering stomach contents from passing into the esophagus 20, and an expanded state for allowing a food bolus to pass into the stomach 10 in response to the patient swallowing. The encircling pressure exerted on the esophagus 20 may be generated by a plurality of attractors

15 212, which in the present example may comprise permanent magnets arranged in mutually attracting pairs. In figures 18a and 18b the elongated core 210 is formed of an array of links 214, such as rods or levers, extending along the length direction of the elongated core 210 and having a permanent magnet 213 attached to its respective end portion. By arranging the magnets

20 213 of the end portions of the links 214 such that magnets 213 of neighboring links attract each other, the attracting forces between the magnets 213 can be utilized to cause the elongated core to transition from an expanded state shown in figure 18a to a constricting state shown in figure 18b. In the constricting state indicated in figure 18b, adjacent magnets 213 are arranged

25 closer to each other than in the expanded state in figure 18a. If allowed to move freely, adjacent magnets 213 may abut each other. When the patient swallows food or liquids, the passing matter may cause the esophagus 20 to expand radially. This expansion may generate an expanding force acting on the apparatus 100, which may eventually overcome the attracting forces

30 between the magnets 213 and thereby cause the core 210 to expand its circumference and assume the expanded state. Once the food or liquid has passed the apparatus 100, the attracting (or constricting) forces within the

apparatus 100 may once again overcome the expanding forces of the esophagus 20, and the core 210 may hence reduce its circumference and the apparatus 100 return to the constricting state.

The apparatus 100 may further comprise a cover 220 enclosing at least a part of the elongated core 210. The cover 220 may be similar to the cover 220 discussed in connection with figures 15-17 and may be configured to hinder fibrotic tissue from growing directly on the elongated core 210. Further, the cover 220 may be configured to provide mechanical support to the elements of the elongated core 210, such as the links 214 provided with the magnets 213. The cover 220 may be tubular, comprising a wall at least partially surrounding or encasing the elongated core 210 and having an at least partly hollow interior capable of accommodating the elements of the core 210. According to the example of the present figure, the cover 220 may comprise an array of tubular segments 222 distributed along the length of the elongated core 210. In the present example, a segment 222 may be configured to accommodate at least two mutually attracting magnets 213, wherein a first one of the magnets 213 may be attached to an end portion of a first link 214 and a second of the magnets 213 may be attached to an end portion of a second, neighboring link 214 of the elongated core 213. The variation of the length of the core 210, as the apparatus 100 transitions between the expanded state and the constricting state, may thus be achieved by said magnets moving towards and away from each other in the length direction of the core 210 and within the segment 222 in which they are accommodated.

The cover 220 may be configured to follow / allow the variation of length of the core 210 by means of a first portion and a second portion of the cover 220 bending relative to each other so as to compensate for the varying length without stretching the material of the cover 220. The first portion and the second portions may be separated by a fold 224 as indicated in the figure and may further be considered as a lowered portion 225 and an elevated portion 226, respectively. Put differently, the segment 222 of the cover 220 may be configured to act as a bellows compressing and expanding in

response to the elongated core 210 contracting and expanding. The cover 220 may comprise one or several further segment 223 arranged between neighboring segments 222 comprising the magnets 213 as outlined above and accommodating a portion of the link 214 interconnecting the magnets
5 213.

The dimensions and configuration of the cover 220 may be adapted to allow fibrotic tissue to at least partly encapsule the outside of the cover 220, preferably in a layer following the outer contour of the segments such that the different portions of the cover 220 may bend and fold relative to each other
10 while bending, rather than stretching, the fibrotic tissue.

The cover 220 may further comprise an electrode arrangement 150, similar to the cover 220 disclosed in figures 15 and 16, for electrically stimulating muscle tissue of the esophagus 20. Preferably, the electrical stimulation may be adjusted to compensate for the presence of fibrotic tissue,
15 which may prevent the electrode element from directly abutting or engaging the muscle tissue. Thus, the presence of fibrotic tissue in the interface or junction between the electrical element and the muscle tissue may be compensated for by adjusting the electrical stimulation signal accordingly, as will be discussed in more detail in connection with figures 38-41.

20 Figures 18C-J shows examples of an apparatus 100 which may be similarly configured as the embodiments discussed in connection with figures 7-17 and 18A-B. However, as illustrated in figures 18C-E the apparatus 100 may be configured to, when implanted, have a limited or none touching contact with tissue at the outside of the esophagus 32 at positions between
25 the cardiac sphincter 26 and the diaphragm 30. While the outermost layer of the stomach wall 10, the tissue also being referred to as serosa, may be relatively robust and insensitive to mechanical contact with implants, the tissue forming the outermost layer of the esophagus 32 has been observed to be more sensitive to contact with implants, eventually leading to tissue
30 damages and migration. Please refer to the description of figure 39 for more details regarding the serosa and the tissue of the esophagus 32. The serosa may extend also to the cardia and may cover a lower portion of the

esophagus 32. The serosa has been observed to cover the lower portion of the esophagus 32 extending to the cardiac sphincter 26, above which there may be no serosa layer on the outside of the esophagus. The exemplifying embodiments shown in figures 18C-J are provided to illustrate a beneficial arrangement in which the apparatus has a reduced impact on the non-serosa covered part of the esophagus 32. The apparatus 100, which may be configured to be arranged to at least partly encircle the esophagus 32, may for instance be formed as a gastric band similar to the ones disclosed above. Preferably, the apparatus 100 band is arranged to not abut or touch the outside of the esophagus 32, at least on upper regions not covered by the more robust serosa layer that also covers the outside of the stomach 10. This may be achieved by providing, or arranging, a apparatus 100 having an increasing inner width d_1 , d_2 or diameter in a direction away from the stomach/cardiac notch. The width d_1 may hence be smaller closer to the cardiac sphincter 26 to allow the apparatus 100 to exert a supporting or constricting pressure on the cardiac sphincter 26, and increase to a larger width d_2 in the direction towards the diaphragm 30 so as to reduce the risk of the apparatus 100 touching or exerting a substantial pressure on the outside of the esophagus 32. As illustrated in the figures, the apparatus 100 may extend along a height h when implanted, allowing the apparatus to abut the diaphragm 30 and thereby act as a stop hindering the cardia from sliding towards and possibly past the diaphragm opening. The increasing inner width d_1 , d_2 of the apparatus may also be expressed as the inner surface of the apparatus inclining in relation to the outer wall of the esophagus 32, or pointing away from the same. The increasing width is in figure 18C illustrated by the angle α , indicating the difference between the inner surface of the apparatus 100 and the outer surface of the esophagus 32 in a direction towards the diaphragm opening.

In other examples, the portions of the apparatus 100 may be provided with a convex part with radius R arranged at the cardia, or cardiac sphincter 26, and configured to abut, or rest against, the serosa layer of the cardia. It may further be provided with a concave part with radius R' , arranged to face

the esophagus 32 and such that a spacing or gap is formed between the concave surface of the apparatus 100 and the esophagus 32. Similar to figure 18C, the apparatus 100 may have a height h , when correctly implanted in the patient, allowing the apparatus 100 to touch or abut the diaphragm 30.

5 In yet an example, the apparatus 100 may conform to cylinder having a substantially constant width d_1 , d_2 that is larger than the outer width of the esophagus 32. With this arrangement, the apparatus can be arranged around, or at least partly enclose, the esophagus 32 to provide a mechanical stop against the diaphragm (due to its height h) to prevent the cardiac
10 sphincter 26 from moving towards and possibly past the diaphragm 30, in a similar way as described above, while still leaving a spacing or gap to the tissue of the outside of the esophagus 32. Beneficially, this reduces the risk of the apparatus 100 touching the more sensitive tissue of the esophagus 32 not covered by serosa and hence the risk of damaging the esophagus 32 during
15 long term implantation.

The apparatuses 100 described in the above figures, such as figures 18C-E, may be formed as a substantially cylindrical band or sleeve that can be arranged around the esophagus 32. A few examples are illustrated in figures 18F-J, having a lower width d_1 (adapted to be arranged at the cardia)
20 and an upper width d_2 (adapted to be arranged at, or closer to, the diaphragm 30). The cylindrical shape may have a substantially uniform cross section as illustrated in figures 18E and 18G, or a conical shape with a widening cross section as illustrated in figures 18C and 18F.

The apparatuses 100 described in the above figures may in some
25 examples comprise a plurality of bodies 102 enclosed or at least partly secured in a holding means 104, 105 such as an elastic or flexible member, configured to keep the bodies 102 in an intended position in the apparatus. As illustrated in figures 18H-J, the bodies 102 may be elongated, such as ellipsoids or rod shaped, or ball shaped. The bodies 102 may be attached to,
30 or held in place by, a holding means 104, 105 being a flexible or elastic sheet of a biocompatible fabric or polymer material, such as silicone, or one or several strings or wires 105. The holding means 104, 105 may in some

examples form a sleeve configured to be arranged around the lower part of the esophagus 32, and to be flexible to allow at least the lower portion of the apparatus to vary its width as the patient swallows and a bolus passes through the esophagus 32. The bodies may be provided with a shape
5 allowing them to point away from the esophagus at the upper portion of the implanted apparatus. This may be achieved by providing the bodies with a surface, facing the esophagus, which bends or tapers away from the esophagus when moving upwards from the bottom portion of the implanted apparatus. Further, the bodies 102 may be magnetic, as previously
10 discussed. The magnetic attracting forces between neighboring bodies 102 may be employed to maintain a pressure on the lower part of the esophagus, such as the cardia or cardiac sphincter 26.

Figures 19a and 19b illustrate an apparatus 100 according to any of the examples shown in figures 14-18 when implanted around the esophagus
15 20 of a human patient. Preferably, the apparatus 100 may be placed at the same height as the cardiac sphincter 26 so as to help the sphincter to contract. The apparatus 100 may be affixed to the esophagus 20 so as to maintain its desired position, for example by means of sutures or staples. The affixation by means of attachers such as staples or sutures may be of a
20 temporary nature, and the apparatus 100 may be more permanently affixed by fibrotic tissue eventually encapsulating the apparatus 100. In further examples, the apparatus 100 may be arranged at the junction between the esophagus 20 and the stomach 10.

The apparatus 100 may be configured to exert an encircling pressure
25 on the esophagus 26 so as to constrict the esophagus 26 and thereby reduce the risk for stomach content from entering the esophagus 26. The resilient forces within the apparatus 100, causing the elongated core 210 to contract, may be generated by an elastic means, such as an elastic band or a spring, or by magnetic attraction as outlined above, and may be balanced so as to
30 allow food and liquids to pass through the esophagus 20 in response to the patient swallowing, and to allow stomach contents to pass through the esophagus 20 in response to the patient belching or vomiting.

The apparatus 100 may further comprise an electrode arrangement 150 as outlined above, for electrically stimulating and constricting the cardiac sphincter 26 and/or exercising the muscle tissue of the esophagus 20 so as to improve the conditions for long-term implantation.

5 Figures 20a and 20b show an apparatus 100 according to an example, which may be similarly configured as the apparatuses 100 discussed above with reference to figures 14-19. The apparatus 100 comprises an elongated core 210 comprising an array of adjacent portions, or core elements 213, which can be moved towards each other and away from each other in the
10 array so as to vary the length of the elongated core 210. Further, the end portions 216 of the core 210 may be attached to each other so as to form an annular or ring-shaped array, having a variable circumference and being possible to arrange to at least partly encircle the esophagus 20 of the patient. At least two of the core elements 213, or bodies 213, in the array may be
15 provided with a respective permanent magnet adapted to attract each other and thereby generate a contracting force within the core 210.

 The core 210 may further comprise a plurality of links 214 connecting the bodies 213 of the array to each other. The links 214 may be relatively rigid so as to provide mechanical support and guide the bodies 213 of the array in
20 their movement towards and away from each other. Thus, the links 214 may be configured to maintain substantially the same shape during the operation of the apparatus, i.e., as the elongated core 210 changes between the expanded state and the constricting state. The links 214 may be configured to extend into at least one of the bodies 213 it interconnects in response to the
25 bodies 213 moving towards each other. As indicated in the present figures, the body 213 may comprise a channel or passage 215 extending into the interior of the body 213. The channel 215 may be configured to allow an end portion of the link 214 to slide back and forth along the channel 215 in response to the core 210 varying its length. The end portion of the link 214
30 may further comprise a stop or abutment hindering the link 214 from leaving the channel 215 and thereby disconnect the bodies 213 of the array from each other.

Figure 20a show the elongated core 210 in the constricting state. In the particular example illustrated in the figure, the elongated core 210 has assumed a minimum length (or circumference) defined by the bodies 213 of the array abutting each other. It will however be appreciated that the

5 constricting state may be assumed also without the bodies 213 of the array touching each other. It may suffice if the bodies 213 of the array are arranged closer to each other than in the expanded state.

The constricting state may be maintained by the attractive forces between adjacent bodies 213 in the array. The forces may be overcome by

10 expanding forces from within the esophagus 20, pushing the bodies 213 of the array apart so that the elongated core 210 assumed the expanded state instead. The expanding forces may for example be caused by the patient swallowing food, belching, or vomiting. Preferably, the attractive forces are strong enough to hinder or at least reduce passage of stomach contents into

15 the esophagus in other cases than when the patient belches or vomits.

Figure 20b shows the apparatus 100 in figure 20a in the expanded state, and in the particular example in a maximally expanded state defined by the stop 217 at the ends of the links 214.

Similar to the previous examples of the apparatus 100, an electrode

20 arrangement 150 may be provided between the bodies 213 of the array and the surrounding tissue when implanted. The electrode arrangement 150 may for example comprise one or several electrode elements 154 arranged on the outer surface of one of several of the bodies 213 of the array. Similar to the examples discussed with reference to figures 1-19, the electrode element(s)

25 154 may be configured to operate as a cathode during the stimulation, using the tissue of the human body as the anode. Alternatively, or additionally, a first one of the electrode elements 154 may be configured to operate as a cathode and a second one of the electrode elements 154 as an anode, allowing an electric signal to pass between the electrode elements 154, using

30 the tissue of the human body as an electrical conductor. In some examples, the electrode arrangement 150 may be configured to provide at least two

electrode elements 154 on opposing sides of the cardiac sphincter 26 so as to facilitate contraction of the sphincter 26.

The apparatus 100 in figures 20a and 20b may further comprise a cover 220, which may be similarly configured as the examples described in connection with e.g. figures 15-19. An example of such an apparatus 100 is shown in figure 21, in which the elongated core 210 of figures 20a and 20b is at least partly enclosed in a cover 220 allowing the core 210 to change between the constricting state and the expanded state without being substantially hindered or impeded by the presence of fibrotic tissue on the outer surface of the cover 220. Similar to the previous examples, an electrode arrangement 150 may be arranged between the cover 220 and the tissue against which the cover 220 rests when implanted. The electrode arrangement 150 may for example be arranged on the outer surface of the cover 220.

A method for implanting the apparatus 100 according in the body of a patient will now be discussed with reference to the examples illustrated in figures 22a, 22b and 23. The present method may be used for affixing the apparatus 100 in the desired position by invaginating or wrapping at least a part of the device in the fundus 12 of the stomach 10, may hence be considered as an alternative to the placement shown in the for example figures 19a and 19b, wherein the apparatus 100 instead is arranged to encircle the esophagus without being invaginated or wrapped in a portion of the fundus 12. Preferably, the following method may be used when implanting a movement restriction device for reinforcing the fundus 12 to interact with the diaphragm and hindering movement of the cardia 22 up into the thorax.

Preferably, the apparatus 100 may be placed relatively high-up, above the upper edge of the lower esophageal sphincter (LES) so as to improve the effect on the reflux disease symptoms and allow the angle of His to assume its original, anatomically correct position and the LES to remain the abdomen. The present method can be divided into two separate parts: a first part in which a part of the stomach wall 14 is attached to the esophagus 20 so as to provide a "platform" positioning the apparatus 100 at the desired high, and a

second part in which the apparatus 100 is placed in a pouch formed in the outside of the fundus, or wrapped in a portion of the fundus wall.

The first part of the method is illustrated in figures 22a, 22b and 23, wherein a fundus portion 14, extending from the angle of His 28 and in a direction away from the esophagus, is affixed to the esophagus 20 after the esophagus 20 has been dissected in mediastinum. According to the method, the fundus portion 14 may be folded towards the esophagus 20 such that the fundus portion 14 rests against the esophagus 20, from the angle of His 28 and upwards along the esophagus 20. The fundus portion 14 may then be affixed to the esophagus 20 by means of fasteners 230 arranged along a first line 231 and a second line 232. The first line 231 and the second line 232 may extend along the esophagus 20 and may be arranged such that a distance between the first line 231 and the second line 232 increases with an increasing distance from the angle of His 28. The positions of the first line 231 and the second line 232 are indicated by the dashed lines in figures 22a and 22b, before the fundus portion 14 has been folded against and affixed to the esophagus 20. The fasteners 230 may for example comprise staples or sutures and may preferably be of a non-resorbable type). In case of the fasteners 230 comprising sutures, the first line 231 and the second line 232 may comprise a respective continuous suture.

The abdominal part of the esophagus 20 and the fundus 12 may be divided by a plane into a ventral and a dorsal side. In this case, the first line 231 may be considered to be arranged on the dorsal side of the plane, whereas the second line 232 may be arranged on the ventral side of the plane. The first line 231 and the second line 232 may in some example be placed at an angle of 45-75 degrees relative to the plane, such as for example 60 degrees. Put differently, a separating angle between the first line 231 and the second line 232 may be in the range of 90-150 degrees, such as for example 120 degrees. In some examples, the maximum separation between the two lines 231, 232, at the top of the lines 231, 232, may be about 2-3 cm, such as about 2.5 cm. The orientation of the lines of fasteners can be considered to describe a "V" or "Y", with the lines being separated at the top

and gradually tapering towards each other towards the angle of His 28. Optionally, an additional fastener, such as a staple or suture, may be provided at the top of the "V" or "Y" shapes. Alternatively, a third line of sutures 233 may be provided between the first and second lines 231, 232.

5 In some examples, the method may comprise beginning the first line 231 less than 1 cm, such as about 0.5 cm, above the angle of His and beginning the second line 232 less than 3 cm, such as about 2 cm above the angle of His. Preferably, the second line 232 may be started less than 2 cm, such as about 1 cm, more ventral than the first line 231.

10 Figure 23a shows the stomach 10 in figures 22a and 22b after the fundus wall portion 14 has been affixed to the esophagus 20 according to the method outlined above. The method may now be followed by the implantation of the apparatus 100, such as for example the movement restriction device as shown in figures 1-11. The apparatus 100 may be placed relatively high-up on
15 the outside of the stomach fundus wall 12 and invaginated or covered by stomach tissue. This may be achieved by forming a pouch or recess 240 in the fundus 12, placing at least a part of the apparatus 100 in the pouch or recess 240, and at least partly closing the pouch or recess by fasteners 242 as illustrated in figures 23b and 23c. Preferably, the apparatus 100 is placed
20 such that the top of the apparatus 100 is positioned at a distance from the LES that exceeds the total height of the apparatus 100 so as to reduce the risk of the LES sliding through the diaphragm opening 32. Alternatively, the top of the apparatus may be arranged further down, such at a distance from the LES exceeding half of the total height of the apparatus 100. Arranging the
25 apparatus even further down may lead to an increased risk for the LES sliding into the thorax and thereby a malfunction of apparatus 100.

 Preferably, the apparatus 100 is placed relatively close to the esophagus 20, such that the distance between the apparatus 100 and the esophagus 20 primarily is determined by the thickness of the doubled
30 stomach wall 14 placed between the apparatus 100 and the esophagus 20. This distance may for example be less than 2 cm, such as less than 1.5 cm, depending on the thickness of the stomach wall 14.

A few examples of apparatuses for treating reflux disease of a human patient will now be described with reference to figures 24-27. The apparatuses 100 may be configured to operate by combining a restriction of movement of the cardia towards the diaphragm, as discussed in connection with for example figures 1-11, with electrical stimulation for contracting the cardiac sphincter 26, as disclosed in connection with for example figures 3 and 14-20, and/or an encircling pressure on the esophagus 20, as discussed with reference to the examples of figured 14-20, for hindering stomach contents from rising through the esophagus 20. Hence, the apparatuses 100 of figures 24-27 may be configured to at least partly encircle the esophagus 20, and may comprise a first implantable portion 110 (also referred to as a movement restriction device) having a shape and size allowing it to be arranged to rest against a fundus wall portion 14 of the patient's stomach 10 and to be at least partly invaginated or covered by the fundus wall portion 14, such that the first implantable portion 110 is implanted at a position between the patient's diaphragm 30 and a lower portion of the fundus wall 14, and such that movement of the cardia 22 of the patient's stomach 10 towards the diaphragm 30 is restricted to hinder the cardia 22 from sliding through the diaphragm opening 32 into the patient's thorax. The apparatus may further comprise a second implantable portion 120 (also referred to as an elongated support device), which may be configured to at least partly encircle the esophagus 20. In some examples, the second implantable portion 120 may have a variable length for allowing the apparatus 100 to be arranged in a constricting state for hindering fluid from passing from the stomach 10 and upwards through the esophagus 20, and in an expanded state for allowing food to pass into the stomach 10 in response to the patient swallowing. In some examples, the second implantable portion 120 is formed as an elongated support device 120 connected to the first implantable portion 110 (or movement restriction device) and configured to support an electrode arrangement 150 such that it is positioned at the esophagus 20. The support device 120 may comprise a rigidity that allows the position of the electrode

arrangement 150 relative to the esophagus 20 to be determined mainly by the position and orientation of the movement restriction device 110.

More specifically, figure 24 shows an apparatus 100 comprising a plurality of core elements 213 arranged in an array and connected to each other by means of a plurality of links 214. At least one of the core elements 213 may be larger than the other core elements 213 of the array, and may be configured to form the first implantable portion 110 to be affixed to the fundus 14, for example by invagination or by at least partly covering the at least one larger core element 213 by stomach tissue. The at least one larger core element 213 may thus form a movement restriction device as discussed above in connection with figures 1-6. The smaller ones of the core elements 213 may form the second implantable portion 120 and may be arranged to encircle at least a part of the esophagus 20. The second implantable portion 120 may have a variable length so as to allow the apparatus 100 to change between the expanded state and the constricting state as outlined above in the previous examples. A maximum width of a cross section taken across a length direction of the first implantable portion 110 may preferably be larger than a maximum width of a cross section taken across a length direction of the second implantable portion 120.

The first implantable portion 110 may be configured to have a substantially fixed size and shape during operation of the apparatus, whereas the second implantable portion 120 may be configured to vary its length, and hence the constriction of the esophagus 20, in response to the patient swallowing and, preferably, belching or vomiting. The second portion 120 may thus be arrangeable in an expanded state in which a food bolus may pass through the cardiac sphincter 26, and in a constricting state in which the second portion 120 exerts an encircling pressure on the esophagus 20 so as to help the cardiac sphincter 26 to close or at least constrict the passageway of the esophagus 20.

An electrode arrangement 150, similarly configured as the electrode arrangement 150 discussed above in connection with for example figure 1 and 14, may be arranged between the first portion 110 and the fundus wall

portion 14, and/or between the second portion 120 and the esophagus 20. The electrode arrangement 150 may comprise one or several electrode elements 152, 154 for electrically stimulating and thereby exercising muscle tissue affected by the implanted apparatus 100, and/or for electrically stimulating and thereby contracting the cardiac sphincter 26.

The combined apparatus 100 shown in figure 24 advantageously employs several different mechanisms for addressing reflux symptoms. Firstly, the first portion 110, acting as a mechanical stop against the diaphragm muscle 30, makes use of the technique to hinder the cardia 22 from sliding through the diaphragm opening 32 into the thorax. Secondly, the second portion 120, acting as a constricting device, utilizes the technique to assist the cardiac sphincter 26 in its closing movement so as to further improve the closing or constrictive function of the sphincter 26. Thirdly, the electrode arrangement 150 may be employed to electrically stimulate the cardiac sphincter muscle 26 so as to further stimulate constricting.

Figure 25 shows an apparatus 100, which may be similarly configured as the embodiment discussed above with reference to figure 24. However, the present apparatus 100 may differ in that the second portion comprises an elongated support device 120 similar to the one disclosed in for example figure 3. Thus, while the first portion 110 may be invaginated or at least partly covered by the fundus tissue and arranged to act as a movement restriction device, the second portion 120 may, instead of the array of core elements shown in figure 24, comprise an elongated support device 120 that is attached to the first portion 110 and configured to at least partly encircle the esophagus 20. Preferably, the support device 110 is configured to support the electrode element 154 at a position where it can electrically stimulate muscle tissue of the esophagus 20. In some examples the support device 120 may be formed as a band 120 configured to be arranged around at least a part of the esophagus 20, and wherein a first and a second end portion of the band is coupled to the first implantable portion 110. Alternatively, or additionally, the support device 120 may comprise a rigidity that allows the position of the electrode element relative to the esophagus to be determined mainly by the

position and orientation of the movement restriction device. This allows for the elongated support device 120, and thus the electrode element 154, to be arranged and maintained in a desired position at the esophagus 20 without being affixed, such as sutures or staples, directly to the tissue of the esophagus 20. Instead, the location and orientation of the first portion 110, which may be affixed to the fundus 14, may be adjusted until the electrode element 154 is arranged at the desired position.

Figure 26 shows an apparatus 100 which may be similarly configured as the embodiment of figure 25. The present apparatus 100 may however differ in that the first portion 110, which may be configured to function as a movement restriction device 110, may be formed as a segment of a ring-shape, such as a segment of a torus as indicated in the embodiments of for example figures 7-11. The function and configuration may be similar to the ones of the embodiment of figure 26, allowing for the electrode element 154 to be positioned at the esophagus 20 without having to be affixed directly to the esophagus 20 by means of for example sutures or staples. The first portion 110 may have a curvature that conforms to a curvature of the esophagus 20, allowing for an inner curvature of the segment to be arranged to phase an outer surface of the esophagus 20, on the fundus side of the esophagus 20. The first portion 110 may for example be configured to be arranged to rest directly against the esophagus 20, such as at the angle of His 28, or be affixed to the fundus 12 in a way that allows for fundus tissue to be positioned between the first portion 110 and the esophagus 20. The at least partly ring-shaped first portion 110 may advantageously improve the stability of the apparatus 100 when implanted, allowing for the first portion 110 to be more securely affixed to the fundus 12 with a reduced risk for rotations to occur over time.

Figure 27 shows an apparatus 100 which may be similarly configured as the embodiment of figure 26. The present apparatus 100 may however differ in that the second portion 120 may comprise a plurality of core elements 213 arranged in an array and connected to each other by means of a plurality of links 214, similar to what is described in connection with the embodiment of

figure 24. The core elements 213 of the second implantable portion 120 may hence be arranged to encircle at least a part of the esophagus 20, and the second implantable portion 120 may have a variable length so as to allow the apparatus 100 to change between the expanded state and the constricting state as outlined above in the previous examples. The first portion 110, or the restriction device 110, may be similar to the corresponding portion of the embodiment of figure 26.

The apparatus 100 according to the embodiments described above in connection to figures 1-13 and 24-27 may be implanted in the body and affixed by the fundus in several different ways. As previously described, the implantation method may involve placing the first portion 110 (or movement restriction device 110) in a pouch formed in the inside or outside wall of the fundus 12, or at least partly covering the first portion 110 by fundus tissue, and affixing the first portion 110 by stomach-to-stomach sutures, before the fundus 12 is affixed to the esophagus 20 and/or diaphragm 30 so as to arrange the apparatus 100 in a predetermined or desired position in the body. Further exemplary methods will now be described with reference to figure 28.

The apparatus 100 according to any of the embodiments described above in connection to figures 1-13 and 24-27 may be affixed to the fundus such that the first portion 110, also referred to as a movement restriction device 110, is at arranged on the fundus side of the esophagus to restrict the movement of the stomach notch in relation to the diaphragm to hinder the cardia to from sliding through the diaphragm opening into the patient's thorax. This may be achieved by a method which may be referred to as "tunneling", i.e., at least partly wrapping or covering a part of the apparatus 100 in fundus tissue forming a pouch or cavity that is open in two ends so that the apparatus can extend through the pouch or cavity. Thus, the method may comprise placing the apparatus 100 such that the movement restriction device 110 rests against the outside of the stomach's fundus 12, wrapping a portion of the fundus 12 around at least a part of the movement restriction device 110, and affixing the fundus 12 to the esophagus 20 such that the movement restriction device 110 is arranged at a position between the

diaphragm 30 and the cardiac sphincter 26, and such that a part of the fundus 12 is arranged between the movement restriction device 110 and the esophagus 20.

Figure 28 shows an apparatus 100, wherein the first portion 110 has
5 been placed to rest at the outside of the fundus 12 at a position between the esophagus 20 and a portion of the fundus 12 that is wrapped over at least a part of the first portion 110 and introduced between the first portion 110 and the esophagus 20. In the present example, the apparatus 100 is ring-shaped so as to at least partly encircle the esophagus 20. The ring-shaped body
10 formed by the first and second portions 110, 120 may thus define an inner hole, through which the esophagus 20 may extend and into which a portion of the fundus 12 may be introduced and affixed to the esophagus 20. The resulting structure, by which the apparatus 100 is affixed in the body of the patient, may thus be understood as a “tunnel” having a first opening a second
15 opening through which the apparatus 100 may extend.

Alternatively, or additionally the apparatus 100 may be implanted by first affixing a portion of the fundus 12 arranged between the first portion 110 of the apparatus 100 and the esophagus 20 to the outside of the esophagus 20, in a similar manner as discussed above in connection with figures 22 and
20 23. A portion of the fundus extending from the angle of His may thus be folded upwards, along the esophagus 20 and affixed to the esophagus 20, for example by means of fixators extending along a first and a second line arranged such that a distance between the lines increases with an increasing distance from the angle of His. The first portion 110 of the apparatus 100 may
25 then be invaginated, or at least partly covered by, a portion of the fundus which is not affixed to the esophagus 20. The resulting structure may thus be understood as a “tunnel”. The apparatus 100 may be affixed and secured in a position relative the esophagus 20 by means of stomach-to-esophagus fixators (such as sutures or staples) shown in figure 28, or invaginated and
30 secured by means of stomach-to-stomach fixators. Additional fixators may in some examples be provided to also affix the fundus 12 to the diaphragm 30 (not shown in figure 28).

While the exemplary apparatus 100 shown in figure 28 is a ring-shaped apparatus formed of a first portion 110 and a second portion 120, it will be appreciated that other configurations of the apparatus 100 is possible as well. The apparatus may for example comprise only a first portion 110, i.e., not
5 have a second portion 120, thereby being a movement restriction device 110 similar to the one disclosed in for example figures 1-6. Alternatively, the apparatus may be formed as an encircling torus as indicated in figures 7-13, or comprise a core and, optionally, a cover as illustrated in figures 14-21. In further examples, the apparatus 100 may be similarly configured as the
10 examples illustrated with reference to any of figures 24-27.

Generally, the apparatus 100 may be implanted in the body of the patient by means of laparoscopic surgery. In an example, the method may comprise the steps of inserting a needle or a tube-like instrument into the patient's abdomen and using the needle or tube-like instrument to fill the
15 abdomen with a gas. Then, at least two laparoscopic trocars may be placed in the abdomen, and a camera be inserted through one of the laparoscopic trocars into the abdomen. At least one dissecting tool may be inserted through one the laparoscopic trocars and be used for dissecting an area around esophagus in mediastinum. The apparatus may be introduced into the
20 abdominal cavity, for example via one of the trocars, and placed as illustrated above. The fundus may be affixed to itself (forming the invagination) and/or to the esophagus using sutures or staples such that the apparatus 100 is secured in a desired position relative to the cardia 22 the diaphragm 30.

The apparatus 100 according to the embodiments described above in
25 connection to figures 1-13 and 24-27 may be placed at, or in the vicinity of, the junction between the esophagus 20 and the stomach 10. The position of the apparatus 100 may be secured by wrapping or folding a portion of the fundus 12 over the apparatus 100 and affixing the fundus portion to the esophagus 20, as indicated in figures 29-31 and 33. The position where the
30 esophagus 20 meets the stomach 10 may be referred to as the angle of His 28, or cardiac notch. With this placement, the apparatus 100 may be supported by the junction, abutting a portion of the outside wall of the fundus

12 extending from the angle of His and, preferably, also a lower portion of the outside wall of the esophagus 20. The outermost layer of the stomach wall may generally be formed of a serous membrane, also referred to as serosa, which is a smooth tissue membrane wall protecting the stomach wall. Due to the protective nature of the serosa, it may be desirable to place the apparatus 100 to rest against the serosa when implanted. The serosa has been observed to cover also a part of the outside wall of the esophagus 20, close to the stomach 10, and it may therefore be advisable to allow the apparatus 100 to rest also against a lower part of the esophagus 20, covered by serosa, while avoiding placing the apparatus 100 against other parts of the esophagus 20 which are not covered by serosa. This may be achieved either by folding the fundus 12 such that fundus tissue is arranged between the apparatus 100 and the esophagus 20, as shown in for example figures 1-3, 7-10 and 28. Alternatively, or additionally, this may be achieved by means of an apparatus 100, such as a movement restriction device 110 similar to the previous embodiments of figures 1-3, 7-10 and 28, having a shape that allows for the device 100 to be placed such that an upper portion points or tapers away from the esophagus 20. Referring to figures 29-33, the disclosed examples of movement restriction devices 110 may have a side phasing the esophagus 20, wherein a curvature of that side allows the movement restriction device 110 to be arranged such that a gap is defined between the movement restriction device 110 and the esophagus 20 along at least a portion of the esophagus 20. As indicated in the examples of the present figures, the gap may increase with an increasing distance from the junction between the esophagus 20 and the stomach 10. Put differently, the apparatus 100 may comprise an outer shape that allows it to be positioned to rest against a lower portion of the esophagus 20, comprising serosa, and to fall away, or point away, from the esophagus 20 as seen in an upward direction along the esophagus 20, towards regions of the esophagus 20 that generally are not covered by serosa. Preferably, the movement restriction device 110 has a rounded, substantially smooth outer surface so as to make it suitable for implantation.

These characteristics of the shape allows for the movement restriction device 110 to be placed to rest against, and supported by, the lowest portion of the esophagus 20 and extend upwards, towards the diaphragm 30, while avoiding contacting or abutting portions of the esophagus 20 which are

5 arranged further up and generally not covered by a protecting layer of serosa. Preferably, the movement restriction device 110, when arranged in such a position, may comprise an upper portion having an extension that is large enough to allow the movement restriction device 110 to function as a mechanical stop against the diaphragm 30, hindering the cardia 22 from

10 sliding upwards through the diaphragm opening 32 and thereby reducing the risk for reflux symptoms. Preferably, the movement restriction device 110 may be configured to abut the serosa of the part of the esophagus 20 extending below the cardiac sphincter 26, and leave a gap to the outer surface of part of the esophagus 20 above the cardiac sphincter 26. By allowing an upper

15 portion of the movement restriction device 110 to extend above the cardiac sphincter 26 and towards the diaphragm 30, the top portion of the movement restriction device 110 may be positioned sufficiently high to hinder the cardiac sphincter 26 from sliding through the diaphragm opening into the patient's thorax.

20 Figure 30 shows a movement restriction device 110 having a lower portion with a curvature that allows for the movement restriction device 110 to at least partly follow the circumferential curvature of the esophagus 20. Thus, the movement restriction device 110 may be configured to be arranged at the junction between the esophagus 20 and the stomach 10, and such that it at

25 least partly encircles the lower portion of the esophagus 20, which generally is covered with serosa. The movement restriction device 110 may thus be provided with C-shaped cross section along the surface adapted to be arranged to follow the circumference of the esophagus 20. Similar to what is described above, the movement restriction device 110 may point slightly

30 away from the esophagus 20 further up along the esophagus 20, to define a separating gap between the outer surface of the esophagus 20 (which generally does not comprise any serosa further away from the angle of His)

and the outer surface of the movement restriction device 110. The movement restriction device 110 may hence comprise at least two different curvatures – a first one along the circumferential curvature of the esophagus 20, and a second one allowing the upper portion of the movement restriction device 110 to fall away from the esophagus 20. The first curvature, adapted to phase the circumferential curvature of the esophagus, may comprise a radius of curvature that corresponds to or exceeds the radius of curvature of the esophagus 20.

Figures 31A-F illustrate various examples of movement restriction devices 110, which may be similarly configured as the ones discussed with reference to the embodiments shown in figures 29 and 30. It should be noted that the illustrations are schematic and not necessarily to scale. The actual shape and size of the movement restriction device 110 may vary depending on the physiology of the individual patient and may advantageously be adapted accordingly. A few characteristics may however be common to all examples illustrated in figures 31A-F. The movement restriction device 110 may have a size and outer curvature that allows it to be arranged to rest against, and supported by, the lowest portion of the esophagus 20 and/or the portion of the fundus 12 arranged close to the esophagus 20, and extend upwards, towards the diaphragm 30, while avoiding contacting or abutting portions of the esophagus 20 which are arranged further up and generally not covered by a protecting layer of serosa.

Figure 31A illustrates an example wherein the lower portion of the movement restriction device 110 is wider than the upper portion, such that the lower portion can rest against the angle of His while the upper portion may be arranged in a position defining a gap between the movement restriction device 110 and the esophagus, similar to what is described with reference to figure 29.

Figure 31B illustrates a movement restriction device 110 having a curvature that can be arranged to follow the circumference of the esophagus 20 at the angle of His, and thereby at least partly encircle the esophagus 20, and a further curvature allowing the movement restriction device 20 to taper

off from the esophagus, as seen along a length direction of the esophagus. The embodiment may be similarly configured as the one described with reference to figure 30.

Figure 31C shows the movement restriction device 110 in figure 31A
5 with an elongated support 117 as shown in figure 32. The elongated support 117 may be attached to any of the examples of the movement restriction devices 110 discussed in the context of the present application for further improving the attachment of the movement restriction device 110 to the stomach 10 and reducing the risk for the movement restriction device 110
10 moving or changing its location and/or orientation relative to the esophagus 20. The support 117 may be configured to be affixed to the esophagus or fundus as discussed below with reference to figure 32.

Figure 31D shows a further example of the movement restriction device 110, being substantially ball-shaped or spherical. For some patients it
15 may be possible to arrange such a movement restriction device 110 at the angle of His and such that the upper part of the movement restriction device 110 do not abut the part of the esophagus 20 not covered by serosa. This depends on the anatomy and physiology of the actual patient, and further on the size and curvature of the movement restriction device 110. In some, non-
20 limiting example the movement restriction device may have a shape conforming to a sphere having a diameter of 3 cm or more, such as 4 cm or more, such as 5 cm or more.

Figures 31E and F illustrate a movement restriction device 110 which may have a similar shaped and size as the embodiment shown in figure 31D,
25 with the difference that the movement restriction device 110 may be formed of a plurality of segments 111 similar to the embodiment shown in figure 5. The embodiments of figures 29-31 may further be combined with an electrode arrangement 150 for electrically stimulate and exercise the muscle tissue of the tissue against which the movement restriction device 110 rests when
30 implanted, as discussed above in connection with for example figures 1-5.

Figure 32 shows an apparatus 100 which may be similarly configured as the embodiments discussed in connection with figures 29-31, with the

difference that the present example comprises an elongated support 117, or fastener, protruding from the movement restriction device 110. The elongated support 117, which may be shaped as a lever, may be configured to be oriented to extend along the esophagus 20 and affixed to the fundus 12 so as to provide additional mechanical support of the movement restriction device 110. The support 117 may be invaginated, or at least partly covered, by the fundus 12 tissue that may be wrapped around the movement restriction device 110 and affixed to the esophagus at least partly above the movement restriction device 110. The support 117 may protrude from the movement restriction device 110 with an angle that allows for the movement restriction device 110 to be arranged (and preferably secured over time) at a position reducing or avoiding direct contact between the movement restriction device 110 and regions of the esophagus 20 not comprising any serosa. The support 117 may be folded into, or at least partly invaginated by the fundus tissue in such a way that fundus tissue is arranged between the support 117 and the tissue of the esophagus 20.

Figures 33 and 34 illustrate an example wherein the apparatus 100 according to the embodiments of figures 29-32 is used in combination with a bariatric procedure, such as for example sleeve gastrectomy. Sleeve gastrectomy, or gastric sleeve, is a surgical weight-loss procedure in the stomach is reduced in size by surgical (often laparoscopic) removal of a relatively large portion of the stomach along the greater curvature. In figure 34a the dashed line delimits the part that is to be removed, with the result shown in figure 34b. According to the present example, the implantation of the movement restriction device 100 and the sleeve gastrectomy may be performed during the same procedure, wherein the movement restriction device 100 may be positioned to rest against the angle of His and secured in this position by a portion of the fundus being affixed to the esophagus at a position above the movement restriction device 110 before the stomach is reduced along the greater curvature. It is advisable to implant the movement restriction device 110 before the sleeve gastrectomy is performed, so as to ensure that there is a sufficiently large portion of the fundus 12 available for

the fixation of the movement restriction device 110. Figure 34b shows the result, wherein the movement restriction device 110 may be encapsulated by the fundus 12 that is affixed to the esophagus 20 to form an enclosure accommodating the movement restriction device 110. The encapsulated movement restriction device 110 may thus form a mechanical stop hindering the cardia from sliding up through the diaphragm opening 32, while the overall volume of the stomach cavity has been reduced by the sleeve gastrectomy.

In case the stomach wall, such as the fundus, is not sufficiently large for allowing an apparatus according any of the embodiments of figures 1-13 and 24-34, and in particular the movement restriction device 110 as discussed in connection with any of the previous embodiments, to be at least partly invaginated or covered by the stomach wall so that the apparatus may function as a movement restriction device of the cardia, an alternative apparatus shown in figures 35-37 may be employed. The present apparatus may comprise an implantable movement restriction device 110 and an elongated attacher 117 configured to be attached to the movement restriction device and to be at least partly invaginated by a wall portion of the patient's stomach 10. As indicated in the present figures, the attacher 117 may comprise a shape and size allowing it to be invaginated by the wall portion to hinder rotation of the movement restriction device 110 when implanted. The attacher 117 may be configured to be invaginated by the outside of the wall portion such that the movement restriction device 110 is arranged at a position between the patient's diaphragm 30 and the wall portion of the stomach 10, distant from the patient's esophagus 20, to restrict movement of the cardia 22 of the patient's stomach towards the diaphragm 30 to hinder the cardia from sliding through the diaphragm opening 32 into the patient's thorax. The attacher 117 may also be referred to as a fixator, attaching means, support, and the like.

Thus, a first end portion of the attacher 117 may be configured to be affixed to the wall portion of the stomach 10 and a second end portion to be attached to the movement restriction device 110. The first end portion of the attacher 117 may be at least partly invaginated or covered by tissue of the

stomach wall, which hence may be achieved using a relatively small portion of the outer wall of the stomach 10 compared to invaginating the entire movement restriction device 110 as discussed above in connection with the previous embodiments. The present embodiment hence allows for the movement restriction device 110 to be positioned so as to function as a mechanical stop of movement towards the diaphragm 30 also in cases when there is a relatively limited amount of stomach wall available. This may for example be the case after a gastric sleeve operation.

The attacher 117 may be releasably attached to the movement restriction device 110 to allow the surgeon to insert the attacher 117 and the movement restriction device 110 as separate items. Once inserted in the body of the patient, the movement restriction device 110 and the attacher 117 may be assembled into a single unit and then affixed to the outside of the stomach 110. The attacher 117 and the movement restriction device 110 may for example be secured to each other by means of interlocking attachment means, such as a snap fitting or a form fitting. The attacher 117 may also be attached to the movement restriction device 110 by means of a fastener means such as a threading, allowing the movement restriction device 110 to be screwed onto the attacher 117. In alternative examples, however, the movement restriction device 110 and the attacher 117 may integrally formed into a single piece.

Figures 35 and 36 show an attacher 117 comprising a first portion 118 and a second portion 119 extending in different directions relative to each other, wherein the first portion 118 is configured to be invaginated by the wall portion to hinder rotation of the movement restriction device 110 around a first axis, and wherein the second portion 119 is configured to be invaginated by the wall portion to hinder rotation of the movement restriction device 110 around a second axis, different from the first axis. The first and second portions 118, 119 of the attacher 119 may further be curved to follow a curvature of the stomach. In some examples, the first portion 118 and the second portion 119 may be arranged at an angle to each other, wherein the angle for example may be in the interval of 60-120 degrees, such as about 90

degrees, so as to allow for the movement restriction device 110 to be mechanically supported by the stomach wall and movement of the restriction device 110 hindered in at least two different planes relative to the stomach portion. The attacher 117 may further comprise a third portion, being an
5 extension of the second portion 119, which may be configured to be arranged to protrude from the wall portion when implanted to define a distance between the wall portion and the movement restriction device 110. In some examples, the third portion may comprises a curvature, which preferably may be adjustable, allowing the third portion to be arranged to point away from the
10 esophagus 20 when implanted so as to reduce the risk for the movement restriction device 110 interfering with and constricting the esophagus 20.

The attacher 117 may be affixed to the stomach 10 in a procedure wherein the attacher 117 is placed onto the outer surface of the stomach 10, in a recess or fold which may be at least partly closed by means of stomach-
15 to-stomach sutures or staples. Thus, the attached 117 may be at least partly covered and mechanically supported by tissue of the stomach wall. Eventually, the suture closing the recess or fold along the attacher 117 may be covered or encapsulated by fibrous tissue, further improving the affixation, and allowing for long-term implantation of the apparatus 100.

20 Preferably, the attacher 117 is formed or, or at least comprises an outer surface of a biocompatible material suitable for long-term implantation in the body. Examples of biocompatible materials include titanium or a medical grade metal alloy, such as medical grade stainless steel. Further examples include ceramic materials such as zirconium carbide, or a stiff medical grade
25 polymer material such as Ultra-high-molecular-weight polyethylene (UHMWPE) or Polytetrafluoroethylene (PTFE) or a thermoplastic polyester such as polylactide (PLA). Further, the attacher 117 could comprise at least one composite material, such as any combination of metallic/ceramic and polymer materials or a polymer material reinforced with organic or inorganic
30 fibers, such as carbon or mineral fibers.

The attacher 117 may also comprise an electrode arrangement 150 for electrical stimulation and exercise of the muscle tissue against which the

attacher 117 rests when implanted. The electrode arrangement 150 may be configured and operate as any of the previous electrode arrangements 150 described with reference to figures 1-34.

As illustrated in figures 35-37, the movement restriction device 110
5 may have a rounded shape, for example conforming to a sphere, so as to reduce the risk for causing potential damage to surrounding tissue. The movement restriction device 117 may be formed of a polymer, or at least comprise an outer surface of such a material. The outer surface may further be provided with a material for hindering growth of fibrotic tissue. The outer
10 surface may for example comprise a permanent or degradable polymer, containing an active pharmaceutical agent, coated on the movement restriction device 117. The coating may preferably allow for a gradual release of an antifibrotic drug. The eluted drug may thus be deposited at the contact point between the movement restriction device 110 and the tissue against
15 which it abuts, such as the diaphragm 30, thereby providing targeted drug therapy. Examples of polymers include a blend of polyethylene-co-vinyl acetate (PEVA) and polybutyl methacrylate (PBMA) and poly(styrene-*b*-isobutylene-*b*-styrene), respectively. Further examples may include phosphorylcholine and poly(vinylidene fluoride-co-hexafluoropropylene)
20 polymeric coatings, respectively.

Figure 37B shows the attacher 118 when secured to the stomach wall
10 at the sutures, or row of staples, used during the gastric sleeve surgery. Thus, the seam forming the sleeve may be provided with the additional purpose of securing the attacher 118, thereby reducing the need for additional
25 surgery and interaction with the tissue of the stomach wall. Beneficially, to further improve the attachment to the stomach wall 10, a support device 130 may be arranged at the seam, as shown in figure 37C. In the present figures, a support device 130 in the form of a bar or flat rod, is disclosed. The bar may be formed or a sheet-like body with a rounded shape, such as a U-profile as
30 indicated in the present figure, configured to follow an outer curvature of the stomach wall. The bar may be provided with a plurality of apertures 131 of through-holes through which the sutures may be threaded during the gastric

sleeve surgery. The bar may hence be attached to the stomach wall by means of the same sutures or staples used for creating the gastric sleeve. The bar may further be configured to allow the attacher 118 to be securely attached thereto. In an example, the attacher 118 may be inserted between
5 the bar 130 and the stomach 10 and held in place by the sutures or staples attaching the bar to the stomach wall. As illustrated in the example shown in the present figures, the attacher 118 may have a substantially rod-shaped portion configured to run at least partly along the bar 130 and then turning slightly away from stomach wall and the esophagus to reduce the risk of the
10 movement restriction device 110, attached at the end portion of the attacher 118, touching or resting against the outside of the esophagus 32.

Further, the movement restriction device 110 may comprise an electrode arrangement 150 for electrical stimulation and exercise of the muscle tissue against which the movement restriction device 110 rests when
15 implanted. The electrode arrangement 150 may be configured and operate as any of the previous electrode arrangements 150 described with reference to figures 1-34

The movement restriction device 110 may have a shape and size that allows it to function as a mechanical stop abutting against the diaphragm 30,
20 being sufficiently large to hinder the movement restriction device 110 from passing through the diaphragm 30 and sufficiently small so as to not push against the esophagus 20 and cause constriction of the food passageway. In some examples, a minimum width of the movement restriction device 110, as measured from side to side, may be 30 mm or larger, such as 40 mm or
25 larger.

When implanted, the movement restriction device 110 may be supported by the attacher 117, which is affixed to the stomach 10, such that the movement restriction device 110 functions as a mechanical stop against the diaphragm 30 and thereby hinders the cardia 22 from sliding upwards
30 towards the diaphragm opening 32. Preferably, the movement restriction device 110 may be arranged relatively close to the diaphragm opening 32, such as less than 2 cm away from the part of the esophagus 20 passing

through diaphragm opening 32, without constricting the food passageway defined by the esophagus 20.

The position of the movement restriction device 110 relative to the diaphragm 30 and/or cardia may be adjusted after affixation of the attacher 117 to the stomach 10. The adjustment may for example be achieved by the attacher 117 being adjustable in terms of length and/or angle, wherein the attacher 117 for example may be extendible/retractable along the length directions, and/or bendable. This allows for the attacher to be affixed to a region on the outside of the stomach 10 which is suitable or even optimal for affixing the attacher 117, and for the movement restriction device 110 to be correctly aligned/positioned afterwards, without having to rearrange the affixation of the attacher 117 to the stomach 10.

In the following a detailed description of a method and system for electrically stimulating the muscle tissue against the apparatuses according to any of the embodiments discussed with reference to figures 1-37 may rest when implanted. The electrical stimulation may be performed for exercising the muscle tissue and thereby improve the conditions for long term implantation. The electrical electrode arrangement described and the electrical electrodes comprised in the arrangement may be implemented in any of the embodiments of the apparatus described herein for the purpose of exercising the muscle tissue which is in contact with the apparatus, or mechanically affected by the apparatus.

The body tends to react to a medical implant, partly because the implant is a foreign object, and partly because the implant interacts mechanically with tissue of the body. Exposing tissue to long-term engagement with, or pressure from, an implant may deprive the cells of oxygen and nutrients, which may lead to deterioration of the tissue, atrophy and eventually necrosis. The interaction between the implant and the tissue may also result in fibrosis, in which the implant becomes at least partially encapsulated in fibrous tissue. It is therefore desirable to stimulate or exercise the cells to stimulate blood flow and increase tolerance of the tissue for pressure from the implanted apparatus.

Muscle tissue is generally formed of muscle cells that are joined together in tissue that can be either striated or smooth, depending on the presence or absence, respectively, of organized, regularly repeated arrangements of myofibrillar contractile proteins called myofilaments. Striated
5 muscle tissue is further classified as either skeletal or cardiac muscle tissue. Skeletal muscle tissue is typically subject to conscious control and anchored by tendons to bone. Cardiac muscle tissue is typically found in the heart and not subject to voluntary control. A third type of muscle tissue is the so-called smooth muscle tissue, which is typically neither striated in structure nor under
10 voluntary control. Smooth muscle tissue can be found within the walls of organs and in for example the wall of the stomach 10 and the esophagus 20.

The contraction of the muscle tissue may be activated both through the interaction of the nervous system as well as by hormones. The different muscle tissue types may vary in their response to neurotransmitters and
15 endocrine substances depending on muscle type and the exact location of the muscle.

A nerve is an enclosed bundle of nerve fibers called axons, which are extensions of individual nerve cells or neurons. The axons are electrically excitable, due to maintenance of voltage gradients across their membranes,
20 and provide a common pathway for the electrochemical nerve impulses called action potentials. An action potential is an all-or-nothing electrochemical pulse generated by the axon if the voltage across the membrane changes by a large enough amount over a short interval. The action potentials travel from one neuron to another by crossing a synapse, where the message is
25 converted from electrical to chemical and then back to electrical.

The distal terminations of an axon are called axon terminals and comprise synaptic vesicles storing neurotransmitters. The axonal terminals are specialized to release the neurotransmitters into an interface or junction between the axon and the muscle cell. The released neurotransmitter binds to
30 a receptor on the cell membrane of the muscle cell for a short period of time before it is dissociated and hydrolyzed by an enzyme located in the synapse.

This enzyme quickly reduces the stimulus to the muscle, which allows the degree and timing of muscular contraction to be regulated delicately.

The action potential in a normal skeletal muscle cell is similar to the action potential in neurons and is typically about -90 mV. Upon activation, the
5 intrinsic sodium/potassium channel of the cell membrane is opened, causing sodium to rush in and potassium to trickle out. As a result, the cell membrane reverses polarity and its voltage quickly jumps from the resting membrane potential of -90 mV to as high as +75 mV as sodium enters. The muscle action potential lasts roughly 2-4 ms, the absolute refractory period is roughly
10 1-3 ms, and the conduction velocity along the muscle is roughly 5 m/s. This change in polarity causes in turn the muscle cell to contract.

The contractile activity of smooth muscle cells is typically influenced by multiple inputs such as spontaneous electrical activity, neural and hormonal inputs, local changes in chemical composition, and stretch. This in contrast to
15 the contractile activity of skeletal and cardiac muscle cells, which may rely on a single neural input. Some types of smooth muscle cells are able to generate their own action potentials spontaneously, which usually occur following a pacemaker potential or a slow wave potential. However, the rate and strength of the contractions can be modulated by external input from the autonomic
20 nervous system. Autonomic neurons may comprise a series of axon-like swellings, called varicosities, forming motor units through the smooth muscle tissue. The varicosities comprise vesicles with neurotransmitters for transmitting the signal to the muscle cell.

The muscle cells described above, i.e., the cardiac, skeletal, and
25 smooth muscle cells are known to react to external stimuli, such as electrical stimuli applied by electrodes. A distinction can be made between stimulation transmitted by a nerve and direct electrical stimulation of the muscle tissue. In case of stimulation via a nerve, an electrical signal may be provided to the nerve at a location distant from the actual muscle tissue, or at the muscle
30 tissue, depending on the accessibility and extension of the nerve in the body. In case of direct stimulation of the muscle tissue, the electrical signal may be provided to the muscle cells by an electrode arranged in direct or close

contact with the cells. However, other tissue such as fibrous tissue and nerves may of course be present at the interface between the electrode and the muscle tissue, which may result in the other tissue being subject to the electrical stimulation as well.

5 In the context of the present application, the electrical stimulation discussed in connection with the various aspects and embodiments may be provided to the tissue in direct or indirect contact with the implantable apparatus, such as for example the movement restriction device. Preferably, the electrical stimulation is provided by one or several electrode elements
10 arranged at the interface or contact surface between the apparatus and the tissue. Thus, the electrical stimulation may, in terms of the present disclosure, be considered as a direct stimulation of the tissue. Particularly when contrasted to stimulation transmitted over a distance by a nerve, which may be referred to as an indirect stimulation or nerve stimulation.

15 Hence, an electrode arrangement comprising one or several electrode elements may be arranged in, partly in, on, or in close vicinity of the tissue that is to be exercised by means of an electrical signal, similar to what is described above in connection with the embodiments of figures 1-37. Preferably, the electrode may be arranged to transmit the electrical signal to
20 the portions of the tissue that is affected, or risks to be affected, by mechanical forces exerted by the medical implant. Thus, the electrode element may be considered to be arranged between the implanted apparatus and the tissue against which the apparatus is arranged to rest when implanted.

25 During operation of the implantable apparatus, or the electrode arrangement, the electric signal may cause the muscle cells to contract and relax repeatedly. This action of the cells may be referred to as exercise and may have a positive impact in terms of preventing deterioration and damage of the tissue. Further, the exercise may help increasing tolerance of the tissue
30 for pressure and mechanical forces generated by the apparatus

 The interaction between the implanted electrode element and the tissue against which it rests is to a large extent determined by the properties

at the junction between the tissue and the electrode element. The active electrically conducting surface of the electrode element (in the following referred to as “metal”, even though other materials is equally conceivable) can either be uncoated resulting in a metal–tissue interface, or insulated with some type of dielectric material. The uncoated metal surface of the electrode element may also be referred to as a bare electrode. The interface between the electrode element and the tissue may influence the behavior of the electrode element since the electrical interaction with the tissue is transmitted via this interface. In the biological medium surrounding the electrode element, such as the actual tissue and any electrolyte that may be present in the junction, the current is carried by charged ions, while in the material of the electrode element the current is carried by electrons. Thus, in order for a continuous current to flow, there needs to be some type of mechanism to transfer charge between these two carriers.

In some examples, the electrode element may be a bare electrode wherein the metal may be exposed to the surrounding biological medium when implanted in, or at the muscle tissue that is to be stimulated. In this case there may be a charge transfer at a metal–electrolyte interface between the electrode element and the tissue. Due to the natural strive for thermodynamic equilibrium between the metal and the electrolyte, a voltage may be established across the interface which in turn may cause an attraction and ordering of ions from the electrolyte. This layer of charged ions at the metal surface may be referred to as a “double layer” and may physically account for some of the electrode capacitance.

Hence, both capacitive faradaic processes may take place at the electrode element. In a faradaic process, a transfer of charged particles across the metal–electrolyte interface may be considered as the predominant current transfer mechanism. Thus, in a faradaic process, after applying a constant current, the electrode charge, voltage, and composition tend to go to constant values. Instead, in a capacitive (non-faradaic) process charge is progressively stored at the metal surface and the current transfer is generally limited to the amount which can be passed by charging the interface.

In some examples, the electrode element may comprise a bare electrode portion, i.e., an electrode having an uncoated surface portion facing the tissue such that a conductor–tissue interface is provided between the electrode element and the tissue when the electrode element is implanted.

5 This allows for the electric signal to be transmitted to the tissue by means of a predominantly faradaic charge transfer process. A bare electrode may be advantageous from a power consumption perspective since a faradaic process tends to be more efficient than a capacitive charge transfer process. Hence, a bare electrode may be used to increase the current transferred to
10 the tissue for a given power consumption.

In some examples, the electrode element may comprise a portion that is at least partly covered by a dielectric material so as to form a dielectric-tissue interface with the muscle tissue when the electrode is implanted. This type of electrode element allows for a predominantly capacitive, or non-
15 faradaic, transfer of the electric signal to the muscle tissue. This may be advantageous over the predominantly faradaic process associated with bare electrodes since faradaic charge transfer may be associated with several problems. Example of problems associated with faradaic charge transfer include undesirable chemical reactions such as metal oxidation, electrolysis
20 of water, oxidation of saline, and oxidation of organics. Electrolysis of water may be damaging since it produces gases. Oxidation of saline can produce many different compounds, some of which are toxic. Oxidation of the metal may release metal ions and salts into the tissue which may be dangerous. Finally, oxidation of organics in a situation with an electrode element directly
25 stimulating tissue may generate chemical products that are toxic.

These problems may be alleviated if the charge transfer by faradaic mechanisms is reduced, which may be achieved by using an electrode at least partly covered by a dielectric material. Preferably, the dielectric material is chosen to have as high capacitance as possible, restricting the currents
30 flowing through the interface to a predominantly capacitive nature.

Several types of electrode elements can be combined with the present disclosure. The electrode element can for example be a plate electrode,

comprising a plate-shaped active part forming the interface with the tissue. In other examples, the electrode may be a wire electrode, formed of a conducting wire that can be brought in electrical contact with the tissue. Further examples may include needle- or pin-shaped electrodes, having a point at the end which can be attached to or inserted in the muscle tissue. The electrodes may for example be encased in epoxy for electrical isolation and protection and comprise gold wires or contact pads for contacting the muscle tissue. Some of these examples of electrodes, methods of stimulating using electrodes, and how the electrode arrangements can be arranged in connection with implantable apparatuses such as described in connection with the embodiments of figures 1-37 will be discussed below with reference to figures 38-45.

Figures 38a and 38 b show embodiments of the apparatus 100, which may be similarly configured as the embodiments discussed with reference to any of the preceding figures 1-37. Thus, figure 38a illustrates an apparatus 100 having a movement restriction device 110 configured to be affixed by the fundus 12 so as to hinder the cardia 22 from sliding upwards through the diaphragm opening, whereas figure 38b illustrates an apparatus 100 comprising a portion, such as an elongated core or support device 120, configured to at least partly encircle the esophagus 20. The encircling portion 120 may be configured to assist the cardiac sphincter in its closing of the esophagus, for example by applying an encircling pressure and/or by electrically stimulate the sphincter muscle so as to cause it to contract. The embodiments are illustrated in cross-sectional views when implanted and invaginated by the fundus 12 (movement restriction device in figure 38a) or placed around the esophagus (constricting/stimulating device in figure 38b).

The apparatus 100 in figures 38a and 38b further comprises an electrode arrangement comprising a plurality of electrode elements 152, 154 for electrically stimulating the tissue of the fundus 12 and/or esophagus 20 for exercising the muscle tissue to improve the conditions for long term implantation of the apparatus 100, as discussed above. In the embodiment of figure 38a the electrode arrangement is arranged on an outer surface of the

movement restriction device 110 and thus placed in abutment and in electrical contact with the tissue of the stomach fundus 12, to which the movement restriction device 110 may be affixed by means of invagination or at least partly covering the movement restriction device 110 by fundus wall tissue. In the embodiment of figure 38b, the electrode arrangement is arranged on an outer surface of a core element 213 and thus placed in abutment and in electrical contact with the tissue of the esophagus 20, around which the apparatus 100 may be arranged. As illustrated in figure 38b, the electrode arrangement may comprise at least two electrode elements 154 which may be placed on opposing sides of the esophagus 20 so as to cause the cardiac sphincter 26 to contract.

Each of the electrode elements 152, 154 of the electrode arrangement may be connected to a controller, such as a stimulation controller 170 by means of electrical conduits 172. The controller 170 may be configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the tissue. In the embodiment shown in figure 38a, the controller 170 may be configured to control the electrical stimulation such that the muscle tissue of the fundus 12 is stimulated by a series of electrical pulses. In the embodiment shown in figure 38a, the pulses may comprise a pulse of a first polarity followed by a pulse of a second, reversed polarity, and the pulsed electrical stimulation signal generated may comprise a pulse frequency of 0.01-150 Hz. In the embodiment shown in figure 38a, the electrical stimulation signal may comprise a pulse duration of 0.01-100 ms and a pulse amplitude of 1-15 mA. More specifically, in the embodiment of figure 38a, the electrical stimulation signal may comprise a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA. Further, in the embodiment of figure 38a, the electrical stimulation signal may comprise a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

The controller 170 of fig. 38a may be integrated in an implantable controller, and the stimulation controller may be configured to receive input from a wireless remote control, directly or via a receiver of the implantable controller, for controlling the stimulation or for programming a stimulation routine for exercising the muscle tissue to improve the conditions for long term implantation of the implantable movement restriction device 110. The programming of a stimulation routine could for example be the programming of the frequency of the stimulation, or the current and/or voltage of the stimulation.

Figure 38b shows an embodiment of the implantable apparatus 110 wherein the electrode elements 154 are connected to a stimulation controller 170 similarly configured as the one discussed with reference to figure 38a. The controller 170 may hence be configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the tissue of the esophagus 20. The stimulation of the tissue could for example be performed with electrical pulses, such as described with reference to fig. 38a, or may in the alternative be controlled as a continuous low-energy current providing a continuous stimulation of the cardiac sphincter 26.

In the embodiments shown in figures 38a and 38b, and preferably the movement restriction device 110, the implantable apparatus 110 may further comprise an implantable sensor 180 configured to sense actions potentials generated by pacemaker cells of the tissue of the stomach wall. The implantable sensor 180 may also be connected to the controller 170 by means of a sensor lead 173. The controller 170 may be configured to control the electrical stimulation based at least partly on the sensed action potentials and may be configured to generate electrical pulses amplifying the sensed action potentials. The implantable sensor 180 may be implemented in any of the embodiments of implantable apparatuses 100 for treating reflux disease as disclosed in the present application.

As described above in connection with the embodiments illustrated in figures 1-38, the apparatus may be implanted in the body so as to interact with different parts of the stomach and/or the esophagus. A first portion 110 of

the apparatus may for example be affixed to the fundus 12 so as to function as a movement restriction device, and whereas a second portion 120 of the apparatus 100 may be arranged to at least partly encircle the esophagus in order to assist in preventing stomach content to rise through the esophagus

5 20.

Figure 39 is a schematic cross section illustrating the general structure of a stomach of a healthy adult. The stomach is located in the patient's abdomen, below the diaphragm 30. Entering occurs through the esophagus 20, which may be an approximately 25 cm long fibromuscular tube passing

10 from the thorax into the abdomen through an opening 32 in the diaphragm 30. The lower part of the esophagus 20 thus be referred to as the abdominal portion of the esophagus 20. The esophagus 20 may connect to the stomach via a shorter segment, typically less than 1 cm, called the cardia 22. The cardia 22 may hence be considered to form the junction or interface between

15 the esophagus 20 and the stomach 10 and may be formed both of a portion of the esophagus 20 and a portion of the stomach. The cardia 22 may join the greater curvature of the stomach (to the right in the figure) in a cardiac notch 24, which creates an acute angle between the esophagus 20 and an upper stomach wall portion. The cardiac notch 24 may also be referred to as the

20 angle of His. Typically, the angle may be around 75 degrees in a healthy adult. Figure 39 further illustrates the cardiac sphincter 26, which may be located in the wall of the cardia 22. Functionally, the sphincter opens to allow food to pass into the stomach and then quickly closes to prevent stomach contents from flowing back into the esophagus 20. The fundus 12 is formed in

25 the upper curved part of the stomach and may be located above the cardiac notch 24. It normally does not store food, but gas produced during digestion. The volume of an empty stomach of a healthy adult human may be around 50 ml, and the fundus 12 generally makes up a relatively small part of that volume. The outermost layer of the stomach wall is called serosa 14. The

30 thickness off the serosa layer 14 may be around 1-2 mm, compared to the total stomach wall thicknesses which ranges from 3 to 4 mm. The serosa may extend also to the cardia 22 and may cover a lower portion of the esophagus

20. The serosa has been observed to cover the lower portion of the esophagus 20 extending to the cardiac sphincter 26, above which there may be no serosa layer on the outside of the esophagus.

Figure 40a is an example of a bipolar electrode arrangement 150,
5 comprising a first and a second electrode element 152, 154 which may be similarly configured as the electrode elements discussed with reference to any of the previous embodiments. In the following figures, the first and second electrode elements will be distinguished by reference numerals E1 and E2, respectively. The first and second electrode elements E1, E2 may be
10 connected to different electrical potentials. Thus, the first electrode element E1 can be operated as an anode and the second electrode element E2 can be operated as a cathode. In alternative embodiments, however, both electrode elements E1, E2 may be operated as cathodes, while using the tissue of the body as anode. The electrode elements E1, E2 may be attached
15 directly to an outer surface of the implantable device, such as disclosed with reference to figures 38a and 38b. In some examples the electrode elements E1, E2 may be arranged on a support, such as a flexible patch, which may be configured to be attached to the implantable constriction device. The electrode arrangement 150 can be arranged between the implantable
20 constriction device and the tissue (such as disclosed with reference to figures 38a and 38b) and may in some examples be provided as a separate, physically distinct item and in other examples be integrated in the apparatus 100. The electrode arrangement 150 may comprise one or several contact pads for increasing the contact surface between the electrode and the tissue
25 when implanted. During operation, the electrical signal may be delivered to the muscle tissue by means of the first and second electrode elements E1, E2 so as to stimulate contraction of the muscle cells.

Fig. 40b is another example of an electrode arrangement 150, which in the present example may be a unipolar electrode element 152, 154. The
30 electrode element E1 may for example be operated as a cathode when implanted. The electrode element 152 may be formed of a flat, coiled wire for increasing the contact surface between the electrode element 152 and the

tissue. Further, the coiled configuration allows for a certain mechanical flexibility of the electrode element 152 such that it can follow the muscle tissue during contraction and relaxation.

Figure 40c illustrates the end portion of a needle- or pin-shaped electrode arrangement 150, wherein the active portion of the electrode element 152 is provided as a bare electrode surface 155 at the end of the electrode element 152, protruding from an insulation 156 covering the rest of the electrode element 152. Thus, when implanted at or in the muscle tissue, the active, bare electrode surface 155 of the electrode element 152 may form a metal-tissue interface with the muscle tissue, wherein the interface may surround the end portion of the electrode element 152 so as to provide a relatively large contact surface. The present example is advantageous in that it can be inserted into the tissue, thereby allowing for a selective stimulation at a certain depth of the tissue.

Figure 40d shows a similar electrode element 152 as the one in figure 40c, with the difference that the present electrode element 152 comprises an active portion that is covered by a dielectric material 157 so as to protect the electrode material from deterioration and to facilitate capacitive current transfer. The dielectric material 157 may for example be electrochemically deposited tantalum oxide, which allows the electrical charge to pass through the interface but reduces the risk for electrode corrosion, gas formation and metabolite reactions.

It will be appreciated that both faradaic and capacitive mechanisms may be present at the same time, irrespectively of the type of electrode used. Thus, capacitive charge transfer may be present also for a bare electrode forming a metal–tissue interface, and faradaic charge transfer may be present also for a coated electrode forming a dielectric–tissue interface. It has been found that the faradaic portion of the current delivered to the muscle tissue can be reduced or even eliminated by reducing the duration of the pulses of the electric signal. Reducing the pulse duration has turned out to be an efficient way of increasing the portion of the signal which can be passed through the interface as a capacitive current, rather than by a faradaic

current. As a result, shorter pulses may produce less electrode and tissue damage.

The capacitive portion of the current may further be increased, relative to the faradaic portion, by reducing the amplitude of the current pulses of the electrical signal. Reducing the amplitude may reduce or suppress the chemical reactions at the interface between the electrode and the tissue, thereby reducing potential damage that may be caused by compounds and ions generated by such reactions.

In one example, the electrical stimulation may be controlled in such a manner that a positive pulse of the electrical signal is followed by a negative pulse (or, put differently, a pulse of a first polarity being followed by a pulse of a second, reversed polarity), preferably of the same amplitude and/or duration. Advantageously, the subsequent negative (or reversed) pulse may be used to reverse or at least moderate chemical reactions or changes taking place in the interface in response to the first, positive pulse. By generating a reversed pulse, the risk of deterioration of the electrode and/or the tissue at the interface between the electrode and the muscle tissue may be reduced.

Fig. 41 shows an example of a pulsed electrical signal to be applied to an electrode for electrically stimulating muscle tissue via an electrode-tissue interface as discussed above. The electrical signal may be generated by a stimulation controller arranged outside the body or implanted in the body (as described with reference to figures 38a and 38b). The stimulation controller 170 may be operatively connected to the electrode element 152, 154 by means of a lead 172, and the electrical signal shown in the present figure may either reflect the signal as generated at the stimulation controller 170, or the signal as delivered to the electrode element 152, 154 at the electrode-tissue interface. The characteristics of the electrical signal may be selected and varied determined on the electrical and properties at the electrode-tissue interface and on the actual response of the tissue. The electrical stimulation delivered to the muscle cells may depend on several factors, such as the configuration and placement of the electrode element 152, 154 at the tissue, the presence of fibrous material at the interface, the composition of the

electrolyte in the interface, accumulation of non-conducting material on the electrode surfaces, etcetera. It is therefore suggested that the characteristics of the electric signal, as shown in the present figure, be selected, and varied based on an observed or estimated response from the stimulated tissue.

5 In the present example, the electrical signal is a pulsed signal comprising square waves PL1, PL2, PL3, PL4. However, other shapes of the pulses may be employed as well. The pulse signal may be periodic, as shown, or may be intermittent (i.e., multiple series of pulses separated by periods of no pulses). The pulses may have an amplitude **A**, which may be
10 measured in volts, ampere, or the like. Each of the pulses of the signal may have a pulse width **D**. Likewise, if the signal is periodic, the pulse signal may have a period **F** that corresponds to a frequency of the signal. Further, the pulses may be either positive or negative in relation to a reference.

 The pulse frequency may for example lie within the range of 0.01-150
15 hertz. More specifically, the pulse frequency may lie within at least one of the ranges of 0.1-1 Hz, 1-10 Hz, 10-50 Hz and 50-150 Hz. It has been observed that relatively low pulse frequencies may be employed to imitate or enhance the slow wave potential associated with pacemaker cells of the smooth muscle tissue. Thus, it may be advantageous to use relatively low pulse
20 frequencies, such as 0.01-0.1 Hz or frequencies below 1 Hz or a few Hz for such applications.

 The pulse duration may for example lie within the range of 0.01-100 milliseconds, such as 0.1-20 milliseconds (ms), and preferably such as 1-5 ms. The natural muscle action potential has in some studies been observed
25 to last about 2-4 ms, so it may be advantageous to use a pulse duration imitating that range.

 The amplitude may for example lie within the range of 1-15 milliamperes (mA), such as 0.5-5 mA in which range a particularly good muscle contraction response has been observed in some studies.

30 In a preferred, specific example the electrical stimulation may hence be performed using a pulsed signal having a pulse frequency of 10 Hz, a pulse duration of 3 ms and an amplitude of 3 mA.

Fig. 42 shows an example of a pulsed signal, comprising build-up period X1, in which the amplitude is gradually increasing, a stimulation period X2 during which the muscle tissue is exposed to a contracting stimulation signal, a ramp down period X3 in which the amplitude is gradually decreasing, and a stimulation pause X4 before a new build-up period is initiated. The build-up period may for example be 0.01-2 seconds, the stimulation period 1-60 seconds, the ramp-down period 0.01-2 seconds, and the stimulation pause 0.01-60 seconds. The pulse frequency may for example be 1-50 Hz, the pulse duration 0.1-10 milliseconds and the amplitude during the stimulation period be 1-15 milliamperes. The stimulation of skeletal muscle tissue may for example be performed using a frequency of 50 Hz and pulses having a duration of 100 μ s. The current amplitude may be 1, 2.5, 7.5 or 10 mA. In particular, a desired muscle contraction response has been experimentally observed within a range of 0.5 to 5.0 mA. In the present example, a coiled electrode may be used as a cathode. Another example design is a multi-stranded wire arranged in a helical design. They can be imbricated in the muscular wall of the fundus (or esophagus) and can be stimulated in any desired pattern. The stimulus parameters may for example be biphasic pulses, 10 to 40 Hz, lasting 0.1 to 5 ms, with a current density of 3 to 5 mA/cm².

Figure 43 is a schematic outline of a system for electrically stimulating or exercising muscle cells to increase tolerance of the tissue for pressure from the apparatus 100. The system may be used in combination with the implantable apparatus 100 and may in some examples be comprised in such an apparatus 100. The system may comprise an electrode arrangement 150 which may be similarly configured as the electrodes arrangements/electrode elements discussed above in connection with the previous examples, an energy source 160 for providing the electrical energy required for generating the electrical signal, and a stimulation controller 170 controlling the generation of the electrical signal.

The electrode arrangement 150, which may comprise one or several electrode elements 152, 154, such as a bare electrode or an electrode at

least partly covered by a dielectric material 157 shown in figure 39d, may be configured to be implanted in the muscle tissue to be stimulated, or to engage the muscle, so as to form an electrode–tissue interface through which the stimulating signal may be transferred. Alternatively, or additionally, the
5 electrode element 152, 154 may be arranged in close vicinity to the muscle tissue such that an electrical coupling between the electrode element and the muscle tissue may be established. This may for example be the case when other tissue, such as connective tissue, is present between the implanted device and the muscle tissue.

10 The electrode may be electrically connected to the energy source 160, for example by means of a wiring or a lead 172, such that the electrical signal may be transferred to the electrode–tissue interface. In some examples, the electrode 152, 154 may be integrated with or attached to the apparatus, such as the movement restriction device 110, so that the electrode 152, 154 when
15 implanted in the patient is arranged at the interface between the apparatus 100 and the muscle tissue. The electrode 152, 154 can thereby be used for exercising the muscle tissue that is mechanically affected by the implant.

The energy source 160 may for example be of a non-rechargeable type, such as a primary cell, or of a rechargeable type, such as a secondary
20 cell. The energy source 160 may be rechargeable by energy transmitted from outside the body, from an external energy source, or be replaced by surgery. Further, the electrode arrangement 150 may be operably connected to a stimulation controller 170, which may comprise an electrical pulse generator, for generating the electrical pulse. The stimulation controller 170 may be
25 integrated with the energy source 160 or provided as a separate, physically distinct unit which may be configured to be implanted in the body or operate from the outside of the body. In case of the latter, it may be advantageous to allow the external control unit to communicate wirelessly with the stimulation controller 150.

30 The system may according to some examples comprise a sensor S1 that is configured to sense a physical parameter of the body and/or the apparatus 100. The sensor S1 may for example be employed to sense or

detect a bodily response to the electrical stimulation, such as for example a contraction of the stimulated muscle tissue. In an example, the sensor S1 may be configured to sense action potentials that are being sent to the muscle tissue. The action potentials may for example be generated by
5 pacemaker cells of the muscle tissue, which may be registered by the sensor S1 and transmitted to the stimulation controller 170. The stimulation controller 170 may use the received signal when controlling the energy source 160, such that the generated electrical signal amplifies the sensed action potentials.

10 The energy source 160 may preferably be an implantable energy source 160 configured to be placed on the inside of the patient's body. Preferably, the implantable energy source 160 may comprise a secondary cell, which can be charged from the outside of the body so as to reduce the need for surgical battery replacement procedures. As indicated in the present
15 figure, the implantable energy source 160 may be configured to be supplied with electrical energy from an external energy source 165 arranged outside the body. In such an example, the system may further comprise an implantable charger 190 configured to be electrically connected to the implantable energy source 160 and to enable charging of the implantable
20 energy source 160 by the external energy source 165. The implantable charger 190 may for example be configured to be electrically connected to the implantable energy source 160 by means of a wiring or a lead 172, such that the electrical energy may be transferred from the implantable charger 190 to the implantable energy source 160. The implantable charger 190 may further
25 be coupled to the external energy source 165 by a wireless coupling or by a wired coupling, using a wiring or lead 172 which may be similar to the one between the charger 190 and the implantable energy source 160. In case of the latter, the wiring or lead 172 may terminate in a terminal which may be access via the skin of the patient, either as a contact port surfacing the skin or
30 being arranged under the skin. Electrical energy may then be transmitted to the charger 190 by connecting the external energy source 165 to the port, for

example by incising the skin to expose the port and making it possible for the external energy source 165 to be plugged in.

Alternatively, the implantable charger 190 may be configured to receive energy from the external energy source 165 wirelessly, such as for example inductively. In this case, the charger 190 may comprise an electromagnetic coil configured to receive the electrical power wirelessly from the external energy source 165. The charger 190 may for example be arranged subcutaneously so as to facilitate inductive transfer of the energy via the skin of the patient.

10 The charging of the implantable energy source 160 may be controlled according to several different schemes. In an example, the charging of the implantable energy source 160 may be controlled by controlling the receipt of electrical power, from the external energy source, at the implantable charger 190. Put differently, the charger 190 may be configured to vary or control its
15 capability of receiving electrical energy from the external energy source 165. Hence, the amount of electrical power delivered to the implantable energy source 160 may be regulated at the implantable charger 190 rather than at the external energy source 165, which hence may be allowed to transmit a substantially constant power. By varying the receipt at the charger 190, rather
20 than the transmission at the external power source 165, the charging of the implantable energy source 160 may be performed without sending control signals to the external energy source 165. Instead, the intelligence required for regulating and controlling the charging of the implanted energy source 160 may be accommodated within the body of the patient, without the need of
25 communication with the outside of the body.

In an alternative embodiment, the charging of the implantable energy source 160 may be controlled by controlling the transmission of electrical power at the external energy source 165. Thus, the charger 190 (or any other component of the apparatus/system arranged in the body) may send
30 transmission instructions, for example via a control signal, to the external energy source 165 which may regulate its transmitting power accordingly.

The charging of the implantable energy source 160 may be controlled by the controller 170, which hence may be configured to issue control instructions to the implantable charger 190 and/or the external energy source 165, as discussed above. In some examples, the controller 170 may be

5 configured to indicate a functional status of the implantable energy source 160, such as for example charge level, charging capacity, voltage and/or temperature of the implantable energy source 160. The functional status may for example be used for controlling the charging of the implantable energy source 160 as described above, and for indicating the status of the

10 implantable energy source 160 to the patient or another, external entity such as medical staff. The functional status may for example be transmitted to the outside of the body, where it can be interpreted and used for diagnosis of the status/condition of the implanted apparatus. Further, the functional status may be transmitted to the outside of the body to provide a warning signal, for

15 example indicating low battery or overheating. The transmission of a signal to/from the controller 170 is described in further detail in connection with the following figures 44-48.

The functional status may for example be based on a signal from a sensor, such as a temperature sensor configured to sense a temperature of

20 the implanted energy source 160, or a current or voltage meter configured to measure an electrical condition of the implanted energy source 160. The sensor output may be transmitted to the controller 170, for example by means of a wiring or electrical conductor 172, where it can be processed and acted upon in the form of an issued signal comprising control instructions for the

25 charger 190/external energy source 165 and/or functional status information.

The functional status may in some examples be transmitted via a carrier signal to the outside of the body by means of a transmitter, which for example may be arranged subcutaneously. In some example the transmitter may be integrated in the charger 190.

30 Figure 44 shows a similar embodiment as the system described above with reference to figure 43. However, as indicated in the present figure, the system may further comprise an external signal transmitter 175, such as a

wireless remote 175, which may be configured to be operably connected to the controller 170. The external signal transmitter 175 may be arranged to allow for the patient or another external entity, such as a service technician or medical staff, to interact with the controller 170. The external signal
5 transmitter 175 may for example be used to control, or adjust, the operation of the implanted controller 170 in order to affect or adjust the electrical stimulation signal delivered to the tissue by the electrode arrangement 150. The external control of the controller 170 may for example serve the purpose of increasing or reducing an amplitude or frequency of the electrical
10 stimulation signal, or for activating/deactivating the electrical stimulation. In an example, the external signal transmitter 175 may be used for increasing the electrical stimulation of the cardiac sphincter in response to experienced reflux symptoms. In this way, the patient may be allowed to increase the contraction of the cardiac sphincter so as to further hinder stomach contents
15 from rising in the esophagus.

The signal, by which the external signal transmitter 175 is communicating with the implanted controller 170, may be selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a
20 laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

While illustrated as separate components/entities in the figure, it is appreciated that the implanted, or internal, controller 170 may be integrated in the implantable charger 190 and/or in the implantable energy source 160.
25 Further, the external signal transmitter 175 may be integrated in the wireless remote.

Figure 45 is a schematic diagram of a system, or an apparatus, which may be similarly configured as the system described with reference to figures 43 and 44. Hence, a system is disclosed, comprising an electrode
30 arrangement 150 for exercising muscle tissue affected by an implanted apparatus according to any of the embodiments discussed above in connection with figures 1-37, and a controller 170 configured to be operably

connected to the electrode arrangement 150 for controlling the electrical stimulation of the muscle tissue. The controller 170 may be coupled to an implantable energy source 160 for providing the electrode arrangement with electrical power according to a stimulation signal or pattern generated by the
5 controller 170.

Figure 45 further illustrates an implantable communicator 171, which may be configured to transmitting a signal between the controller 170 and the outside of the patient's body, similar to what is described above in connection with figure 44. The communicator 171 may be comprised in the control unit
10 170 or provided as a separate unit. The communicator 171 may hence be used for transmitting the signal comprising the functional status of the implantable energy source 160, and for communicating with an external controller 176 used for controlling or adjusting the operation of the implantable controller 170. The external controller 176 may for example be
15 comprised in a remote controller 175 as shown in figure 44.

The implantable controller 170, which also may be referred to as an internal controller or a stimulation controller 170, may be understood as any implantable unit capable of controlling the electrical stimulation of the tissue. A controller could include an electrical signal generator, a modulator or other
20 electrical circuitry capable of delivering the electrical stimulation signal to the electrode arrangement. Further, the controller may be capable of processing control signals and generate the electrical stimulation signal in response thereto, and further to generate control signals for the control of other components of the system or apparatus, such as for example the implanted
25 energy source 160 and/or the implantable charger 190. A control signal may thus be understood as any signal capable of carrying information and/or electric power such that a component of the system/apparatus can be directly or indirectly controlled.

The controller may comprise a processing unit, such as a CPU, for
30 handling the control of the electrode arrangement 150 and other components of the system. The processing unit could be a single central processing unit or could comprise two or more processing units. The processing unit could

comprise a general-purpose microprocessor and/or an instruction set processor and/or related chips sets and/or special purpose microprocessors such as ASICs (Application Specific Integrated Circuit). The processing unit may also comprise memory for storing instruction and/or data. The controller
5 170 could be adapted to keep track of different stimulation patterns and periods used for the stimulation of the muscle tissue, and in some examples also the action potentials sensed by the sensor S1. The controller 170 may further comprise a communicator, or communication unit 171 as outlined above, which may be configured for receiving and/or transmitting wireless or
10 wired signals to/from outside the body. The communication unit 171 can enable programming the controller 170 from outside of body of the patient such that the operation of the electrode arrangement 150 can be programmed to function optimally.

The controller 170, as well as other implanted components such as the
15 energy source 160, the charger 190, and the first or second portion 110, 120 of the apparatus 100, may be enclosed by an enclosure so as to protect the components from bodily fluids. The enclosures may be an enclosure made from one of or a combination of: a carbon based material (such as graphite, silicon carbide, or a carbon fiber material), a boron material, a polymer
20 material (such as silicone, Peek®, polyurethane, UHWPE or PTFE,), a metallic material (such as titanium, stainless steel, tantalum, platinum, niobium or aluminum), a ceramic material (such as zirconium dioxide, aluminum oxide or tungsten carbide) or glass. In any instance the enclosure should be made from a material with low permeability, such that migration of
25 fluid through the walls of the enclosure is hindered.

Fig. 46 shows the stomach **S** of a patient (also referred to as stomach
10 in the above figures) when an apparatus 100 according to the embodiments described with reference to the previous figures has been arranged at least partly around the esophagus E (also referred to as
30 esophagus 32 in the above figures). The apparatus 100 may be operated by means of electric leads 135 traveling inside of protective covers 136a, 136b, which combine to a single protective cover for guiding the electric leads 135

to a remote unit 140, or control unit 140, for remote operation of the apparatus 100. The operation may for instance relate to electrical stimulation and exercise of muscle tissue against which the apparatus 100 rests, as previously discussed.

- 5 In the embodiment of fig. 46, the control unit comprises a first and second portion 141', 141'' placed on different sides of a portion of muscle tissue **MT** of the patient, and connected by means of a connecting portion placed through a hole in the muscle tissue **MT**. The second portion 141' is placed on the inside of the muscle tissue **MT** and the first portion is placed on
- 10 the outside of the muscle tissue **MT** in the subcutaneous tissue **ST**. In the embodiment shown in fig. 46, the controller 300 is placed in the second portion 141'', and the implantable energy storage unit 40 is placed in the first portion 141'. The controller 300 and the implantable energy storage unit 40 are electrically connected by means of a lead running in the connecting
- 15 portion, such that electrical energy and communication can be transferred from the second 141'' to the first portion 141', and vice versa. In the embodiment of fig. 46, the first portion 141' further comprises a wireless energy receiver 305 for receiving wireless energy for charging the implantable energy storage unit 40 and/or for powering the medical device, and a
- 20 transceiver 308 for receiving and/or transmitting wireless signals to/from the outside the body. The implantable energy storage unit 40 may be any type of energy storage unit suitable for an implant, such as a re-chargeable battery or a solid-state battery, such as a thionyl-chloride battery. The energy storage unit may be equipped with an energy storage unit indicator configured to indicate
- 25 a functional status of the implantable energy storage unit. The functional status may indicate at least one of charge level and temperature of the implantable energy storage unit 40. For enabling indication of the temperature of the energy storage unit 40, the energy storage unit 40 or medical device 10 may comprising a temperature sensor.
- 30 The controller 300 may comprise at least one sensor, or be configured to receive sensor input from the at least one sensor. The sensor could be a

sensor configured to sense a physical parameter of the medical device system, such as at least one of:

- 5 A temperature of the medical device system, to avoid excessive heating of tissue connected to the medical device during operation of the medical device or charging of the energy storage unit 40. Excessive heating may also damage the medical device and/or the energy storage unit 40. Excessive heating may also be an indicator that something is wrong with the medical device 10 and may be used for triggering an alarm function for alerting the patient or physician.
- 10 A parameter related to the power consumption of the medical device system, to avoid excessive power consumption which may drain and/or damage the energy storage unit 40. Excessive power consumption may also be an indicator that something is wrong with the medical device 10 and may be used for triggering an alarm function for alerting the patient or physician.
- 15 A parameter related to strain in the medical device, such as the strain exerted on the esophagus in connection with the apparatus constricting the esophagus. Strain can be measured to avoid excessive strain which may damage medical device or the tissue of the patient. Excessive strain may also be an indicator that something is wrong with the medical device 10 and may
- 20 be used for triggering an alarm function for alerting the patient or physician.
- A parameter related to the wireless transfer of energy from a source external to the body of the patient. Excessive transfer of wireless energy may damage an implanted wireless energy received or the energy storage unit. It may also create excessive heating which may damage the tissue of the
- 25 patient.
- The controller 300 may comprise a sensor or be configured to receive sensor input from a sensor configured to sense a physiological parameter of the patient. The physiological parameter of the patient may be:
- A parameter related to the patient swallowing, such that the medical
- 30 device can be controlled on the basis of the patient eating or drinking. A sensor configured to sense a parameter related to the patient swallowing could comprises a motility sensor, which could be a piezo electric or piezo

resistive motility sensor, or an accelerometer. In the alternative, a acoustic sensor, such as a microphone, may be used to sense the patient swallowing by picking up the sound generated by the patient swallowing. In the alternative, an optical sensor may be used for sensing the opacity alteration
5 over the esophagus as food passes. A strain sensor could also be used for sensing the expansion of the esophagus as food passes.

A local temperature, to avoid local excessive heating which may damage tissue of the patient.

A systemic temperature, to avoid systemic excessive heating which
10 may cause fever and affect the overall wellbeing of the patient.

Blood saturation/oxygenation, or a parameter related to an ischemia marker such as lactate, to control and/or avoid that the flow of blood to some tissue portion is hampered by the implantation or operation of the medical device 10. Hampered blood flow may lead to tissue damage and in the worst
15 cases to tissue necrosis.

Blood pressure, which may be an indication that the strain created by the medical device is in some way damaging to the overall wellbeing of the patient. Increased blood pressure may be used for triggering an alarm function for alerting the patient or physician.

20 pH, for determining the acidity of the stomach, which could be an indicator of the function of the digestive system and/or of the frequency of ingestion. The pH may be used for controlling the medical device 10 on the basis of the patient eating or drinking.

The controller 300 may further comprise a receiver for receiving
25 patient generated control signals from a unit located external to the body of the patient. The receiver could be a wireless receiver configured to communicate with a transmitter located external to the body of the patient. The controller 300 may be configured to control the operation device 100 on the basis of the received patient generated control signal. The control signal
30 could for example being that the patient indicates to the medical device 10 that the patient has finished a portion of food which causes the medical device 10 to operate to constrict the esophagus and/or the cardia. In the

alternative, the controller 300 may be configured to control the operation device 100 on the basis of a signal related to a lapsed time or a time of day such that a constriction can be provided with certain intervals or during specific periods of the day. The controller 300 could further be configured to
5 receive a signal from a sensor external to the body of the patient and use such signal for controlling the operation of the medical device 10. The sensor external to the body of the patient could be a sensor could be a sensor measuring a parameter related to the patient eating to create input for the control of the medical device 10. Such a parameter could be related to body
10 temperature, blood pressure or the glucose level of the blood. In the alternative, the sensor could be a sensor sensing a parameter related to the external environment, such as the atmospheric pressure, which could affect the pressures in the medical device 10.

Fig. 46 shows a frontal view of a part of the abdomen of the patient
15 when the medical device 10 (previously referred to as apparatus 100 in the figures) has been implanted. This is however only an example of an embodiment and it is clear that any of the embodiments of the medical device disclosed herein can be implanted and connected in the manner described with reference to fig. 46. The apparatus, or medical device 10 is in the
20 embodiment shown in fig. 46 operated by a remote unit 140. This is however only an example of a remote unit for operation of the medical device 10 and it is clear that any of the embodiments of remote units disclosed herein can be implanted and connected in the manner described with reference to fig. 46. The remote unit 140 comprises a first portion 141', a second portion 141'',
25 and a connecting portion 142, mechanically connecting the first and second portions 141', 141''. The second portion 141'' is in the embodiment shown in fig. 46 placed on the inside of muscular tissue **MT** of the abdominal wall **AW** of the patient, whereas the first portion 141' is placed on the outside of the muscular tissue **MT** of the abdominal wall **AW**, in the subcutaneous tissue
30 **ST**. As such, the connecting portion 142 travels through a created hole in, or natural orifice between, the muscles of the muscular tissue **MT**. A cross-sectional area of the connecting portion 142, in a plane in the extension of the

muscular tissue **MT** is smaller than a cross-sectional area of the first and second portions 141', 141'', parallel to the cross-sectional area of the connecting portion 142. The cross-sectional areas of the first and second portions 141', 141'' are also larger than the created hole or natural orifice though which the connecting portion 142 is placed. As such, the first and second portions 141', 141'' are unable to pass through the created hole or natural orifice and is as such fixated to the muscular tissue **MT** of the abdominal wall. This enables the remote unit 140 to be suspended and fixated to the muscle tissue **MT** of the abdominal wall **AW**. The connecting portion 142 may be a connecting portion 142 having a circular cross-section and an axial direction **AD** extending from the first portion 141' to the second portion 141''. The plane in the extension of the muscular tissue **MT**, is in the embodiment of fig. 46 perpendicular to the axial direction **AD** of the connecting portion 142 extending from the first portion 141' to the second portion 141''.

The controller may be placed in the second portion 141'', and the implantable energy storage unit is placed in the first portion 141'. The controller and the implantable energy storage unit are electrically connected to each other by means of a lead running in the connecting portion 142, such that electrical energy and communication can be transferred from the second 141'' to the first portion 141', and vice versa. In the embodiment of fig. 46, the first portion 141' further comprises a wireless energy receiver for receiving wireless energy for charging the implantable energy storage unit and/or for powering the medical device 10, and a transceiver for receiving and/or transmitting wireless signals to/from the outside the body. Further features and functions of the controller and the implantable energy storage unit are further described with reference to figs. 65a – e and 66a-h.

The abdominal wall **AW** is in most locations generally formed by a set of layers of skin, fat/fascia, muscles and the peritoneum. The deepest layer in the abdominal wall **AW** is the peritoneum **PT**, which covers many of the abdominal organs, for example the large and small intestines. The peritoneum **PT** is a serous membrane composed of a layer of mesothelium

supported by a thin layer of connective tissue and serves as a conduit for abdominal organ's blood vessels, lymphatic vessels, and nerves. The area of the abdomen enclosed by the peritoneum **PT** is called the intraperitoneal space. The tissue and organs within the intraperitoneal space are called "intraperitoneal" (e.g., the stomach and intestines). The tissue and organs in the abdominal cavity that are located behind the intraperitoneal space are called "retroperitoneal" (e.g., the kidneys), and tissue and organs located below the intraperitoneal space are called "subperitoneal" or "infraperitoneal" (e.g., the bladder).

10 The peritoneum **PT** is connected to a layer of extraperitoneal fat **EF** which is connected to a layer of transversalis fascia **TF**. Connected to the transversalis fascia **TF**, at the area of the abdominal wall **AW** at which the section is extracted, is muscle tissue **MT** separated by layers of deep fascia **DF**. The deep fascia **DF** between the layers of muscle is thinner than the transversalis fascia **TF** and the Scarpa's fascia **SF** placed on the outside of the muscle tissue **MT**. Both the transversalis fascia **TF** and the Scarpa's fascia **SF** are relatively firm membranous sheets. At the area of the abdominal wall **AW** at which the section is extracted, the muscle tissue **MT** is composed of the transverse abdominal muscle **TM** (transversus abdominis), the internal oblique muscle **IM** (obliquus internus) and the external oblique muscle **EM** (obliquus externus). In other areas of the abdominal wall **AW**, the muscle tissue could also be composed of the rectus abdominis and the pyramidalis muscle.

25 The layer outside of the muscle tissue **MT**, beneath the skin **SK** of the patient is called subcutaneous tissue **ST**, also called the hypodermis, hypoderm, subcutis or superficial fascia. The main portion of the subcutaneous tissue **ST** is made up of Camper's fascia which consists primarily of loose connective tissue and fat. Generally, the subcutaneous tissue **ST** contains larger blood vessels and nerves than those found in the skin.

30 Placing the remote unit 140 at an area of the abdomen is advantageous as the intestines are easily displaced for making sufficient

room for the remote unit 140, without the remote unit 140 affecting the patient too much in a sensational or visual way. Also, the placement of the remote unit 140 in the area of the abdomen makes it possible to fixate the remote unit 140 to the muscle tissue **MT** of the abdomen for creating an attachment

5 keeping the remote unit 140 firmly in place. In the embodiment shown in fig. 46, the first portion 141' of the remote unit 140 is placed on the left side of the patient in between the peritoneum **PT** and the muscle tissue **MT**. The first portion 141' is placed in the subcutaneous tissue **ST** between the muscle tissue **MT** and the skin **SK** of the patient. Placing the first portion 141'

10 subcutaneously enables easy access to the first portion 141' for e.g. wireless communication using a wireless transceiver placed in the first portion 141', wireless charging of an implantable storage unit using a wireless energy receiver placed in the first portion 141', manual manipulation of for example a push button placed in the first portion 141', or maintenance or replacement of

15 the first portion 141' via a small incision in the skin **SK** at the first portion 141'.

In the embodiment shown in fig. 46, the electric leads 135 running inside of protective a cover 136 transports electric signals from the remote unit 140 to the main portion **M** of the medical device 10. The leads 135 run between the peritoneum **PT** and the muscle tissue **MT** vertically until the

20 leads 135 reach the height of the main portion **M** of the medical device 10. At this height, the leads 135 enters the peritoneum **PT** and travels substantially horizontally to the main portion **M** of the medical device 10. As such, the leads 135 are placed inside of the intraperitoneal space for as short distance as possible which reduces the risk that implanted, foreign body, elements

25 disturbs the intraperitoneal organs, reducing the risk of damage to organs, and reducing the risk that foreign body elements cause ileus.

In the embodiment shown in fig. 46, the connecting portion 142 connects the first and second portions 141', 141'' though three layers of muscle tissue **MT**, namely tissue of the transverse abdominal muscle **TM**, the

30 internal oblique muscle **IM** and the external oblique muscle **EM**. In alternative embodiments, it is however conceivable that the second portion 141'' is placed in between layers of muscle, such as between tissue of the transverse

abdominal muscle **TM**, the internal oblique muscle **IM**, or between the internal oblique muscle **IM** and the external oblique muscle **EM**. As such, it is conceivable that in alternative embodiments, the connecting portion 142 connects the first and second portions 141', 141'' through two layers of muscle tissue **MT**, or through one layer of muscle tissue **MT**.

In alternative embodiments, it is furthermore conceivable that the first portion 141' is placed in between layers of muscle, such as between tissue of external oblique muscle **EM** and the internal oblique muscle **IM**, or between the internal oblique muscle **IM** and the transverse abdominal muscle **TM**.

10 Figs. 47a, 47b and 48 show an embodiment of a remote unit 140. The remote unit 140 is configured to be held in position by a tissue portion 610 of a patient. The remote unit 140 comprises a first portion 141' configured to be placed on a first side 612 of the tissue portion 610, the first portion 141' having a first cross-sectional area A1 in a first plane P1 and comprising a first surface 614 configured to face a first tissue surface 616 of the first side 612 of the tissue portion 610. The remote unit 140 further comprises a second portion 141'' configured to be placed on a second side 618 of the tissue portion 610, the second side 618 opposing the first side 612, the second portion 141'' having a second cross-sectional area A2 in a second plane P2 and comprising a second surface 620 configured to engage a second tissue surface 622 of the second side 618 of the tissue portion 610. The remote unit 140 further comprises a connecting portion 142 configured to be placed through a hole in the tissue portion 610 extending between the first and second sides 612, 618 of the tissue portion 610. The connecting portion 142 here has a third cross-sectional area A3 in a third plane P3 and a fourth cross-sectional area A4 in a fourth plane P4 and a third surface 624 configured to engage the first tissue surface 616 of the first side 612 of the tissue portion 610. The connecting portion 142 is configured to connect the first portion 141' to the second portion 141''.

30 The connecting portion 142 thus has a portion being sized and shaped to fit through the hole in the tissue portion 610, such portion having the third cross-sectional area A3. Furthermore, the connecting portion 142 may have

another portion being sized and shaped to not fit through the hole in the tissue portion 610, such portion having the fourth cross-sectional area A4. Likewise, the second portion 141'' may have a portion being sized and shaped to not fit through the hole in the tissue portion 610, such portion
5 having the second cross-sectional area A2. Thus, the connecting portion 142 may cooperate with the second portion 141'' to keep the device in place in the hole of the tissue portion 610.

In the embodiment illustrated in Fig. 47a, the first portion 141' is configured to detachably connect, i.e. reversibly connect to the connecting
10 portion 142 by a mechanical and/or magnetic mechanism. In the illustrated embodiment, a mechanic mechanism is used, wherein one or several spring-loaded spherical elements 601 lock in place in a groove 603 of the connecting portion 142 when the first portion 141' is inserted into the connecting portion 142. Other locking mechanisms are envisioned, including corresponding
15 threads and grooves, self-locking elements, and twist and lock fittings.

The remote unit 140 is configured such that, when implanted, the first portion 141' will be placed closer to an outside of the patient than the second portion 141''. Furthermore, in some implantation procedures the remote unit 140 may be implanted such that space will be available beyond the second
20 portion, i.e. beyond the second side 618 of the tissue portion 610, whereas there may be as much space on the first side 612 of the tissue portion. Furthermore, tissue and/or skin may exert a force on the first portion 141'' towards the tissue portion 610, and provide for that the second portion 141'' does not travel through the hole in the tissue portion towards the first side 612
25 of the tissue portion. Thus, it is preferably if the remote unit 140 is primarily configured to prevent the first portion 141'' from travelling through the hole in the tissue portion 612 towards the second side 618 of the tissue portion 610.

The first portion 141' may further comprise one or several connections 605 for transferring energy and/or communication signals to the second
30 portion 141'' via the connecting portion 142. The connections 605 in the illustrated embodiment are symmetrically arranged around a circumference of a protrusion 607 of the first portion 141' and are arranged to engage with a

corresponding connection 609 arranged at an inner surface of the connecting portion 142. The protrusion 607 may extend in a central extension C1 of the central portion 142. The second portion 141'' may also comprise one or several connections 611, which may be similarly arranged and configured as the connections 605 of the first portion 141'. For example, the one or several connections 611 may engage with the connection 609 of the connecting portion 142 to receive energy and/or communication signals from the first portion 141'. Although the protrusion 607 is illustrated separately in Figs. 47a and 47b, it is to be understood that the protrusion 607 may be formed as one integral unit with the first portion 141'.

Other arrangements of connections are envisioned, such as asymmetrically arranged connections around the circumference of the protrusion 607. It is also envisioned that one or several connections may be arranged on the first surface 614 of the first portion 141', wherein the connections are arranged to engage with corresponding connections arranged on the opposing surface 613 of the connecting portion. Such connections on the opposing surface 613 may cover a relatively large area as compared to the connection 609, thus allowing a larger area of contact and a higher rate and/or signal strength of energy and/or communication signal transfer. Furthermore, it is envisioned that a physical connection between the first portion 141', connecting portion 142 and second portion 141'' may be replaced or accompanied by a wireless arrangement, as described further in other parts of the present disclosure.

Any of the first surface 614 of the first portion 141', the second surface 620 of the second portion 141', the third surface 624 of the connecting portion 142, and an opposing surface 613 of the connecting portion 142, may be provided with at least one of ribs, barbs, hooks, a friction enhancing surface treatment, and a friction enhancing material, to facilitate the remote unit 140 being held in position by the tissue portion, and/or to facilitate that the different parts of the device are held in mutual position.

The opposing surface 613 of the connecting portion 142 and the first surface 614 of the first portion 141' may provide, fully or partly, a connection

mechanism to detachably connect the first portion 141' to the connecting portion 142. Such connection mechanisms have been described previously in the presented disclosure, and can be arranged on one or both of the opposing surface 613 and the first surface 614, and will not be further
5 described here.

The opposing surface 613 may be provided with a recess configured to house at least part of the first portion 141'. In particular, such recess may be configured to receive at least a portion of the first portion 141', including the first surface 614. Similarly, the first surface 614 may be provided with a
10 recess configured to house at least part of the connecting portion 142. In particular, such recess may be configured to receive at least a portion of the connecting portion 142, and in some embodiments such recess may be configured to receive at least one protruding element to at least partially enclose at least one protruding element or flange.

15 In the illustrated embodiment, the first portion 141' comprises a first energy storage unit 304a and a controller 300a comprising one or several processing units connected to the first energy storage unit 304a. The first energy storage unit 304a may be rechargeable by wireless transfer of energy. In some embodiments, the first energy storage unit 304a may be non-
20 rechargeable. Upon reaching the life-time end of such first energy storage, a replacement first portion comprising a new first energy storage unit may simply be swapped in place for the first portion having the depleted first energy storage unit. The second portion 141'' may further comprise a controller 300b comprising one or several processing units.

25 As will be described in other parts of the present disclosure, the first portion 141' and the second portion 141'' may comprise one or several functional parts, such as receivers, transmitters, transceivers, control units, processing units, sensors, energy storage units, sensors, etc.

The remote unite 140 may be non-inflatable.

30 The first portion 141' may be detachably connected to at least one of the connecting portion 142 and the second portion 141''.

As can be seen in Fig. 48, the first, second, third and fourth planes P1, P2, P3 and P4, are parallel to each other. Furthermore, in the illustrated embodiment, the third cross-sectional area A3 is smaller than the first, second and fourth cross-sectional areas A1, A2 and A4, such that the first portion 141', second portion 141'' and connecting portion 142 are prevented from travelling through the hole in the tissue portion 610 in a direction perpendicular to the first, second and third planes P1, P2 and P3. Hereby, the second portion 141'' and the connecting portion 142 can be held in position by the tissue portion 610 of the patient also when the first portion 141' is disconnected from the connecting portion 142.

It is to be understood that the illustrated planes P1, P2, P3 and P4 are merely an example of how such planes may intersect the remote unit 140. Other arrangements of planes are possible, as long as the conditions above are fulfilled, i.e. that the portions have cross-sectional areas, wherein the third cross-sectional area in the third plane P3 is smaller than the first, second and fourth cross-sectional areas, and that the planes P1, P2, P3 and P4 are parallel to each other.

The connecting portion 142 illustrated in Fig. 47a may be defined as a connecting portion 142 comprising a flange 626. The flange 626 thus comprises the fourth cross-sectional area A4 such that the flange 626 is prevented from travelling through the hole in the tissue portion 610 in a direction perpendicular to the first, second and third planes P1, P2 and P3. The flange 626 may protrude in a direction parallel to the first, second, third and fourth planes P1, P2, P3 and P4. This direction is perpendicular to a central extension C1 of the connecting portion 142.

The connecting portion 142 is not restricted to flanges, however. Other protruding elements may additionally or alternatively be incorporated into the connecting portion 142. As such, the connecting portion 142 may comprise at least one protruding element comprising the fourth cross-sectional area A4, such that the at least one protruding element is prevented from travelling through the hole in the tissue portion 610, such that the second portion 141'' and the connecting portion 142 can be held in position by the tissue portion

610 of the patient also when the first portion 141' is disconnected from the connecting portion 142. The at least one protruding element may protrude in a direction parallel to the first, second, third and fourth planes P1, P2, P3 and P4. This direction is perpendicular to a central extension C1 of the connecting
5 portion 142. As such, the at least one protruding element will also comprise the third surface configured to engage the first tissue surface 616 of the first side 612 of the tissue portion 610.

The connecting portion 142 may comprise a hollow portion 628. The hollow portion 628 may provide a passage between the first and second
10 portions 141', 141''. In particular, the hollow portion 628 may house a conduit for transferring fluid from the first portion 141' to the second portion 141''. The hollow portion 628 may also comprise or house one or several connections or electrical leads for transferring energy and/or communication signals between the first portion 141' and the second portion 141''.

15 Some relative dimensions of the remote unit 140 will now be described with reference to Figs. 48 and 49A – 49C, however it is to be understood that these dimensions may also apply to other embodiments of the remote unit 140. The at least one protruding element 626 may have a height HF in a direction perpendicular to the fourth plane being less than a height H1 of the
20 first portion 141' in said direction. The height HF may alternatively be less than half of said height H1 of the first portion 141' in said direction, less than a quarter of said height H1 of the first portion 141' in said direction, or less than a tenth of said height H1 of the first portion 141' in said direction.

The height H1 of the first portion 141' in a direction perpendicular to the
25 first plane may be less than a height H2 of the second portion 141'' in said direction, such as less than half of said height H2 of the second portion 141'' in said direction, less than a quarter of said height H2 of the second portion 141'' in said direction, or less than a tenth of said height H2 of the second portion 141'' in said direction.

30 The at least one protruding element 626 may have a diameter DF in the fourth plane being one of less than a diameter D1 of the first portion 141' in the first plane, equal to a diameter D1 of the first portion 141' in the first

plane, and larger than a diameter $D1$ of the first portion 141' in the first plane. Similarly, the cross-sectional area of the at least one protruding element 626 in the fourth plane may be less, equal to, or larger than a cross-sectional area of the first portion in the first plane.

5 The at least one protruding element 626 may have a height H_F in a direction perpendicular to the fourth plane being less than a height H_C of the connecting portion 142 in said direction. Here, the height H_C of the connecting portion 142 is defined as the height excluding the at least one protruding element, which forms part of the connecting portion 142. The
10 height H_F may alternatively be less than half of said height H_C of the connecting portion 142 in said direction, less than a quarter of said height H_C of the connecting portion 142 in said direction, or less than a tenth of said height H_C of connecting portion 142 in said direction.

 As shown in Figs. 50A – 50B, the at least one protruding element 626
15 may have an annular shape, such as a disk shape. However, elliptical, elongated and/or other polyhedral or irregular shapes are also possible. In the illustrated embodiment, the at least one protruding element 626 extends a full revolution around the center axis of the connecting portion 142. However, other arrangements are possible, wherein the at least one protruding element
20 626 constitute a partial circle sector. In the case of a plurality of protruding elements, such plurality of protruding elements may constitute several partial circle sectors.

 As shown in Figs. 51A – 51B, 52A – 52B, the connecting portion 142 may comprise at least two protruding elements 626, 627. For example, the
25 connecting portion 142 may comprise at least three, four, five, six, seven, eight, nine, ten protruding elements, and so on. In such embodiments, the at least two protruding elements 626, 627 may together comprise the fourth cross-sectional area, thus providing a necessary cross-sectional area to prevent the first portion and second portion from travelling through the hole in
30 the tissue portion.

 The at least two protruding elements 626, 627 may be symmetrically arranged about the central axis of the connecting portion, as shown in Figs.

51a – 51b, or asymmetrically arranged about the central axis of the connecting portion, as shown in Figs. 52a – 52b. In particular, the at least two protruding elements 626, 627 may be asymmetrically arranged so as to be located towards one side of the connecting portion 142, as shown in Figs. 52a – 52b. The arrangement of protruding element(s) may allow the remote unit 140, and in particular the connecting portion 142, to be placed in areas of the patient where space is limited in one or more directions.

The first portion 141' may comprise a first energy storage unit for supplying the remote unit 140 with energy.

10 Although one type or embodiment of the implantable remote unit 140, may fit most patients, it may be necessary to provide a selection of implantable remote units 140 or portions to be assembled into implantable remote units 140. For example, some patients may require different lengths, shapes, sizes, widths or heights depending on individual anatomy.

15 Furthermore, some parts or portions of the implantable remote units 140 may be common among several different types or embodiments of remote units, while other parts or portions may be replaceable or interchangeable. Such parts or portions may include energy storage devices, communication devices, fluid connections, mechanical connections, electrical connections,

20 and so on.

To provide flexibility and increase user friendliness, a kit of parts may be provided. The kit preferably comprises a group of one or more first portions, a group of one or more second portions, and a group of one or more connecting portions, the first portions, second portions and connecting

25 portions being embodied as described throughout the present disclosure. At least one of the groups comprises at least two different types of said respective portions. By the term “type”, it is hereby meant a variety, class or embodiment of said respective portion.

In some embodiments of the kit, the group of one or more first portions,

30 the group of one or more second portions, and the group of one or more connecting portions, comprise separate parts which may be assembled into a complete remote unit. The remote unit may thus be said to be modular, in that

the first portion, the second portion, and/or the connecting portion may be interchanged for another type of the respective portion.

In some embodiments, the connecting portion form part of the first portion or the second portion.

5 With reference to Fig. 53, the kit for assembling the remote unit comprises a group 650 of one or more first portions 141', in the illustrated example a group of one first portion 141', a group 652 of one or more connecting portions 142, in the illustrated example a group of three connecting portions 142, and a group 654 of one or more second portions
10 141'', in the illustrated example a group of two second portions 141''. For simplicity, all types and combinations of first portions, second portions and connecting portions will not be illustrated or described in detail.

Accordingly, the group 652 of one or more connecting portions 142
15 comprise three different types of connecting portions 142. Here, the different types of connecting portions 142 comprise connecting portions 142a, 142b, 142c having different heights. Furthermore, the group 654 of one or more second portions 141'' comprise two different types of second portions 141''.

Here, the different types of second portions 141'' comprise a second
20 portion 141''a being configured to eccentrically connect to a connecting portion, having a first end and a second end as described in other parts of the present disclosure, wherein the second end of the second portion 141''a comprises or is configured for at least one connection for connecting to an implant being located in a caudal direction from a location of the remote unit in the patient, when the device is assembled. In the illustrated figure, the at
25 least one connection is visualized as a lead or wire. However, other embodiments are possible, including the second end comprising a port, connector or other type of connective element for transmission of power, fluid, and/or signals.

Furthermore, the different types of second portions 141'' comprise a
30 second portion 141''b being configured to eccentrically connect to a connecting portion, having a first end and a second end as described in other parts of the present disclosure, wherein the first end of the second portion

141''b comprises or is configured for at least one connection for connecting to an implantable medical device for treating reflux disease of the patient, being located in a cranial direction from a location of the remote unit in the patient, when the device is assembled. In the illustrated figure, the at least one
5 connection is visualized as a lead or wire. However, other embodiments are possible, including the first end comprising a port, connector or other type of connective element for transmission of power, fluid, and/or signals.

Thus, the remote unit may be modular, and different types of devices can be achieved by selecting and combining a first portion 141', a connecting
10 portion 142, and a second portion 141'', from each of the groups 652, 654, 656.

In the illustrated example, a first remote unit 140a is achieved by a selection of the first portion 141', the connecting portion 142a, and the second portion 141''a. Such remote unit 140a may be particularly advantageous in
15 that the connecting portion 142a may be able to extend through a thick layer of tissue to connect the first portion 141' and the second portion 141''a. Another remote unit 140b is achieved by a selection of the first portion 141', the connecting portion 142c, and the second portion 141''b. Such device may be particularly advantageous in that the connecting portion 142c has a
20 smaller footprint than the connecting portion 142a, i.e. occupying less space in the patient. Owing to the modular property of the remote units 140a and 140b, a practitioner or surgeon may select a suitable connecting portion as needed upon having assessed the anatomy of a patient. Furthermore, since remote units 140a and 140b share a common type of first portions 141', it will
25 not be necessary for a practitioner or surgeon to maintain a stock of different first portions (or a stock of complete, assembled devices) merely for the sake of achieving a device having different connections located in the first end or second end of the second portion respectively, as in the case of second portions 141''a, 141''b.

30 The example illustrated in Fig. 53 is merely exemplifying to display the idea of a modular implantable remote unit 140. The group 650 of one or more first portions 141' may comprise a variety of different features, such as first

portions with or without a first energy storage unit, with or without a first wireless energy receiver unit for receiving energy transmitted wirelessly by an external wireless energy transmitter, with or without an internal wireless energy transmitter, and/or other features as described throughout the present disclosure. Other features include different height, width, or length of the first portion. It is to be understood that first portions having one or more such features may be combined with a particular shape or dimensions to achieve a variety of first portions. The same applies to connecting portions and second portions.

10 With reference to Fig. 54, an embodiment of an implantable remote unit 140, will be described. The remote unit 140 is configured to be held in position by a tissue portion 610 of a patient. The remote unit 140 comprises a first portion 141' configured to be placed on a first side of the tissue portion 610, the first portion 141' having a first cross-sectional area in a first plane and comprising a first surface configured to face and/or engage a first tissue surface of the first side of the tissue portion 610. The device 140 further comprises a second portion 141'' configured to be placed on a second side of the tissue portion 610, the second side opposing the first side, the second portion 141'' having a second cross-sectional area in a second plane and comprising a second surface configured to engage a second tissue surface of the second side of the tissue portion 610. The remote unit 140 further comprises a connecting portion 142 configured to be placed through a hole in the tissue portion 610 extending between the first and second sides of the tissue portion 610. The connecting portion 142 here has a third cross-sectional area in a third plane. The connecting portion 142 is configured to connect the first portion 141' to the second portion 141''. Here, the first portion 141' comprises a first wireless energy receiver 308a for receiving energy transmitted wirelessly by an external wireless energy transmitter, and an internal wireless energy transmitter 308a configured to transmit energy wirelessly to the second portion. Furthermore, the second portion here comprises a second wireless energy receiver 308b configured to receive energy transmitted wirelessly by the internal wireless energy transmitter 308a.

Although receivers and transmitters may be discussed and illustrated separately in the present disclosure, it is to be understood that the receivers and/or transmitters may be comprised in a transceiver. Furthermore, the receivers and/or transmitters in the first portion 141' and second portion 141'' respectively may form part of a single receiving or transmitting unit configured for receiving or transmitting energy and/or communication signals, including data. Furthermore, the internal wireless energy transmitter and/or a first wireless communication receiver/transmitter may be a separate unit 308c located in a lower portion of the first portion 141', referred to as a proximal end of the first portion 141' in other parts of the present disclosure, close to the connecting portion 142 and the second portion 141''. Such placement may provide for that energy and/or communication signals transmitted by the unit 308c will not be attenuated by internal components of the first portion 141' when being transmitted to the second portion 141''. Such internal components may include a first energy storage unit 304a.

The first portion 141' here comprises a first energy storage unit 304a connected to the first wireless energy receiver 308a. The second portion comprises a second energy storage unit 304b connected to the second wireless energy receiver 308b. Such an energy storage unit may be a solid-state battery, such as a thionyl-chloride battery.

In some embodiments, the first wireless energy receiver 308a is configured to receive energy transmitted wirelessly by the external wireless energy transmitter and store the received energy in the first energy storage unit 304a. Furthermore, the internal wireless energy transmitter 308a is configured to wirelessly transmit energy stored in the first energy storage unit 304a to the second wireless energy receiver 308b, and the second wireless energy receiver 308b is configured to receive energy transmitted wirelessly by the internal wireless energy transmitter 308a and store the received energy in the second energy storage unit 305b.

The first energy storage unit 304a may be configured to store less energy than the second energy storage unit 304b, and/or configured to be charged faster than the second energy storage unit 304b. Hereby, charging of

the first energy storage unit 304a may be relatively quick, whereas transfer of energy from the first energy storage unit 304a to the second energy storage unit 304b may be relatively slow. Thus, a user can quickly charge the first energy storage unit 304a, and will not during such charging be restricted for a long period of time by being connected to an external wireless energy transmitter, e.g. at a particular location. After having charged the first energy storage unit 304a, the user may move freely while energy slowly transfers from the first energy storage unit 304a to the second energy storage unit 304b, via the first wireless energy transmitter 308a,c and the second wireless energy receiver 308b.

The first portion may comprise a first controller comprising at least one processing unit 306a. The second portion may comprise a second controller comprising at least one processing unit 306b. At least one of the first and second processing unit 306a, 306b may be connected to a wireless transceiver 308a,b,c for communicating wirelessly with an external device.

The first controller may be connected to a first wireless communication receiver 308a,c in the first portion 141' for receiving wireless communication from an external device and/or from a wireless communication transmitter 308b in the second portion 141''. Furthermore, the first controller may be connected to a first wireless communication transmitter 308a,c in the first portion 141' for transmitting wireless communication to a second wireless communication receiver 308b in the second portion 141''. The second controller may be connected to the second wireless communication receiver 308b for receiving wireless communication from the first portion 141'. The second controller may further be connected to a second wireless communication transmitter 308b for transmitting wireless communication to the first portion 141'.

In some embodiments, the first wireless energy receiver 308a comprises a first coil, and the wireless energy transmitter 308a,c comprises a second coil, as shown in Fig. 64.

The device may further comprise at least one sensor (not shown) for providing input to at least one of the first and second controller. Such sensor

data may be transmitted to an external device via the first wireless communication transmitter 308a and/or the second wireless communication transmitter 308b. The sensor may be or comprise a sensor configured to sense a physical parameter of the device 140. The sensor may also be or
5 comprise a sensor configured to sense at least one of a temperature of the remote unit 140, a temperature of an implantable device for stretching the stomach wall (which may be located in the main portion), a parameter related to the power consumption of the device, a parameter related to the power consumption of an stimulation device for stimulating muscle tissue touched by
10 the implantable device, a parameter related to a status of at least one of the first and second energy storage unit 304a, 304b, and a parameter related to the wireless transfer of energy from a source external to the body of the patient. The sensor may also be or comprise a sensor configured to sense a physiological parameter of the patient, such as at least one of a parameter
15 related to the patient swallowing, a local temperature, a systemic temperature, a blood saturation, a blood oxygenation, a blood pressure, a parameter related to an ischemia marker, or pH. The sensor configured to sense a parameter related to the patient swallowing may comprise at least one of a motility sensor, a acoustic sensor, an optical sensor, and a strain
20 sensor. The sensor configured to sense pH may be configured to sense the acidity in the stomach.

The sensor may be configured to sense a temperature of the device 140, to avoid excessive heating of tissue connected to the device during operation of the device, or during operation of an external implant using the
25 device, or charging of an energy storage unit in the device 140. Excessive heating may also damage the device and/or the energy storage unit. Excessive heating may also be an indicator that something is wrong with the device and may be used for triggering an alarm function for alerting the patient or physician. The sensor may also be configured to sense a
30 parameter related to the power consumption of the device 140 or the power consumption of an external implant being powered by the device 140, to avoid excessive power consumption which may drain and/or damage the

energy storage unit of the device 140. Excessive power consumption may also be an indicator that something is wrong with the device 140 and may be used for triggering an alarm function for alerting the patient or physician.

With reference to Figs. 55, 58A and 58B, an embodiment of an implantable remote unit 140 will be described. The remote unit 140 is configured to be held in position by a tissue portion 610 of a patient. The remote unit 140 comprises a first portion 141' configured to be placed on a first side 612 of the tissue portion 610, the first portion 141' having a first cross-sectional area A1 in a first plane P1 and comprising a first surface 614 configured to face and/or engage a first tissue surface 616 of the first side 612 of the tissue portion 610. The remote unit 140 further comprises a second portion 141'' configured to be placed on a second side 618 of the tissue portion 610, the second side 618 opposing the first side 612, the second portion 141'' having a second cross-sectional area A2 in a second plane P2 and comprising a second surface 620 configured to engage a second tissue surface 622 of the second side 618 of the tissue portion 610. The remote unit 140 further comprises a connecting portion 142 configured to be placed through a hole in the tissue portion 610 extending between the first and second sides 612, 618 of the tissue portion 610. The connecting portion 142 here has a third cross-sectional area A3 in a third plane P3. The connecting portion 142 is configured to connect the first portion 141' to the second portion 141''. In the illustrated embodiment, a connecting interface 630 between the connecting portion 142 and the second portion 141'' is eccentric with respect to the second portion 141''.

The first portion 141' has an elongated shape in the illustrated embodiment of Fig. 55. Similarly, the second portion 141'' has an elongated shape. However, the first portion 141' and/or second portion 141'' may assume other shapes, such as a flat disk e.g. having a width and length being larger than the height, a sphere, an ellipsoid, or any other polyhedral or irregular shape, some of these being exemplified in Figs. 55 – 57.

As illustrated in figs. 58A and 58B, the connecting interface 630 between the connecting portion 142 and the second portion 141'' may be

eccentric, with respect to the second portion 141'' in a first direction 631, but not in a second direction 633 being perpendicular to the first direction. The first direction 631 is here parallel to the line A-A, to the second plane P2, and to a length of the second portion 141''. The second direction 633 is here
5 parallel to the line B-B, to the second plane P2, and to a width of the second portion 141''. It is also possible that the connecting interface between the connecting portion 142 and the second portion 141'' is eccentric, with respect to the second portion 141'', in the first direction 631 as well as in the second direction 633 being perpendicular to the first direction 631.

10 Similarly, a connecting interface between the connecting portion 142 and the first portion 141' may be eccentric with respect to the first portion 141' in the first direction 631, and/or in the second direction 633.

The first portion 141', connecting portion 142 and second portion 141'' may structurally form one integral unit. It is however also possible that the first
15 portion 141' and the connecting portion 142 structurally form one integral unit, while the second portion 141'' form a separate unit, or, that the second portion 141'' and the connecting portion 142 structurally form one integral unit, while the first portion 141' form a separate unit.

Additionally, or alternatively, the second portion 141'' may comprise a
20 removable and/or interchangeable portion 639. In some embodiments, the removable portion 639 may form part of a distal region which will be further described in other parts of the present disclosure. A removable portion may also form part of a proximal region. Thus, the second portion 141'' may comprise at least two removable portions, each being arranged at a
25 respective end of the second portion 141''. The removable portion 639 may house, hold or comprise one or several functional parts of the remote unit 140, such as gears, motors, connections, reservoirs, and the like as described in other parts of the present disclosure. An embodiment having such removable portion 639 will be able to be modified as necessary to
30 circumstances of a particular patient.

In the case of the first portion 141', connecting portion 142 and second portion 141'' structurally forming one integral unit, the eccentric connecting

interface between the connecting portion 142 and the second portion 141'', with respect to the second portion 141'', will provide for that the remote unit 140 will be able to be inserted into the hole in the tissue portion. The remote unit 140 may for example be inserted into the hole at an angle, similar to how
5 a foot is inserted into a shoe, to allow most or all of the second portion 141'' to pass through the hole, before it is angled, rotated, and/or pivoted to allow any remaining portion of the second portion 141'' to pass through the hole and allow the remote unit 140 to assume its intended position.

As illustrated in figs. 55 – 57, the first portion 141' may assume a
10 variety of shapes, such as an oblong shape, a flat disk shape, a spherical shape, or any other polyhedral or irregular shape. Similarly, the second portion 141'' may assume a variety of shapes, such as an oblong shape, a flat disk shape, a spherical shape, or any other polyhedral or irregular shape. The proposed shapes of the first and second portions 141', 141'' may be mixed
15 and combined to form embodiments not exemplified in the illustrated embodiments. For example, one or both of the first and second portions 141', 141'' may have a flat oblong shape. In this context, the term "flat" is related to the height of the first or second portion 141', 141'', i.e. in a direction parallel to a central extension C1 of the connecting portion 142. The term "oblong" is
20 related to a length of the first or second portion 141', 141''. A definition of such length is further discussed in other parts of the present disclosure.

With reference to Figs. 58A – 58B, the second portion 141'' has a first end 632 and a second end 634 opposing the first end 632. The length of the second portion 141'' is defined as the length between the first end 632 and
25 the second end 634. The length of the second portion 141'' is furthermore extending in a direction being different to the central extension C1 of the connecting portion 142. The first end 632 and second end 634 are separated in a direction parallel to the second plane P2. Similarly, the first portion 141' has a length between a first and a second end, the length extending in a
30 direction being different to the central extension C1 of the connecting portion 142.

The second portion 141'' may be curved along its length. For example, one or both ends of the second portion 141'' may point in a direction being substantially different from the second plane P2, i.e. curving away from or towards the tissue portion when implanted. In some embodiments, the
5 second portion 141'' curves within the second plane P2, exclusively or in combination with curving in other planes. The second portion 141'' may also be curved in more than one direction, i.e. along its length and along its width, the width extending in a direction perpendicular to the length.

The first and second ends 632, 634 of the second portion 141'' may
10 comprise an elliptical point respectively. For example, the first and second ends 632, 634 may comprise a hemispherical end cap respectively. It is to be understood that also the first and second ends of the first portion 141' may have such features.

The second portion 141'' may have at least one circular cross-section
15 along the length between the first end 632 and second end 634, as illustrated in fig. 55. It is however possible for the second portion 141'' to have at least one oval cross-section or at least one elliptical cross-section along the length between the first end 632 and the second end 634. Such cross-sectional shapes may also exist between ends in a width direction of the second
20 portion 141''. Similarly, such cross-sectional shapes may also exist between ends in a length and/or width direction in the first portion 141'.

In the following paragraphs, some features and properties of the second portion 141'' will be described. It is however to be understood that these features and properties may also apply to the first portion 141'.

25 The second portion 141'' has a proximal region 636, an intermediate region 638, and a distal region 640. The proximal region 636 extends from the first end 632 to an interface between the connecting portion 142 and the second portion 141'', the intermediate region 638 is defined by the connecting interface 630 between the connecting portion 142 and the second portion
30 141'', and the distal region 640 extends from the connecting interface 630 between the connecting portion 142 and the second portion 141'' to the second end 634. The proximal region 636 is shorter than the distal region 640

with respect to the length of the second portion, i.e. with respect to the length direction 631. Thus, a heel (the proximal region) and a toe (the distal region) is present in the second portion 141''.

The second surface 620, configured to engage with the second tissue surface 622 of the second side 618 of the tissue portion 610, is part of the proximal region 636 and the distal region 640. If a length of the second portion 141'' is defined as x , and the width of the second portion 141'' is defined as y along respective length and width directions 631, 633 being perpendicular to each other and substantially parallel to the second plane P2, the connecting interface between the connecting portion 142 and the second portion 141'' is contained within a region extending from $x > 0$ to $x < x/2$ and/or $y > 0$ to $y < y/2$, x and y and 0 being respective end points of the second portion 141'' along said length and width directions. In other words, the connecting interface between the connecting portion 142 and the second portion 141'' is eccentric in at least one direction with respect to the second portion 141'', such that a heel and a toe is formed in the second portion 141''.

The first surface 614 configured to face and/or engage the first tissue surface 616 of the first side 612 of the tissue portion 610 may be substantially flat. In other words, the first portion 141' may comprise a substantially flat side facing towards the tissue portion 610. Furthermore, an opposing surface of the first portion 141', facing away from the tissue portion 610, may be substantially flat. Similarly, the second surface 620 configured to engage the second tissue surface 622 of the second side 618 of the tissue portion 610 may be substantially flat. In other words, the second portion 141'' may comprise a substantially flat side facing towards the tissue portion 610. Furthermore, an opposing surface of the second portion 141'', facing away from the tissue portion 610, may be substantially flat.

The second portion 141'' may be tapered from the first end 632 to the second end 634, thus giving the second portion 141'' different heights and/or widths along the length of the second portion 141''. The second portion may also be tapered from each of the first end 632 and second end 634 towards the intermediate region 638 of the second portion 141''.

Some dimensions of the first portion 141', the second portion 141'' and the connecting portion 142 will now be disclosed. Any of the following disclosures of numerical intervals may include or exclude the end points of said intervals.

5 The first portion 141' may have a maximum dimension being in the range of 10 to 60 mm, such as in the range of 10 to 40 mm such as in the range of 10 to 30 mm, such as in the range of 10 to 25 mm, such as in the range of 15 to 40 mm, such as in the range of 15 to 35 mm, such as in the range of 15 to 30 mm, such as in the range of 15 to 25 mm. By the term
10 "maximum dimension" it is hereby meant the largest dimension in any direction.

 The first portion 141' may have a diameter being in the range of 10 to 60 mm, such as in the range of 10 to 40 mm such as in the range of 10 to 30 mm, such as in the range of 10 to 25 mm, such as in the range of 15 to 40
15 mm, such as in the range of 15 to 35 mm, such as in the range of 15 to 30 mm, such as in the range of 15 to 25 mm.

 The connecting portion 142 may have a maximum dimension in the third plane P3 in the range of 2 to 20 mm, such as in the range of 2 to 15 mm, such as in the range of 2 to 10 mm, such as in the range of 5 to 10 mm, such
20 as in the range of 8 to 20 mm, such as in the range of 8 to 15 mm, such as in the range of 8 to 10 mm.

 The second portion 141'' may have a maximum dimension being in the range of 30 to 90 mm, such as in the range of 30 to 70 mm, such as in the range of 30 to 60 mm, such as in the range of 30 to 40 mm, such as in the
25 range of 35 to 90 mm, such as in the range of 35 to 70 mm, such as in the range of 35 to 60 mm, such as in the range of 35 to 40 mm.

 The first portion has a first height H1, and the second portion has a second height H2, both heights being in a direction perpendicular to the first and second planes P1, P2. The first height may be smaller than the second
30 height. However, in the embodiments illustrated in Figs. 58A-58B, the first height H1 is substantially equal to the second height H2. Other height ratios are possible, for example the first height H1 may be less than 2/3 of the

second height H2, such as less than 1/2 of the second height H2, such as less than 1/3 of the second height H2, such as less than 1/4 of the second height H2, such as less than 1/5 of the second height H2, such as less than 1/10 of the second height H2.

5 As illustrated in Figs. 58A-58B, the proximal region 636 has a length 642 being shorter than a length 646 of the distal region 640. The intermediate region 638 has a length 644, and a width 648. In some embodiments, the length 644 of the intermediate region 638 is longer than the width 648. In other words, the connecting interface between the connecting portion 142 and
10 the second portion 141'' may be elongated, having a longer dimension (in the exemplified case, the length) and a shorter dimension (in the exemplified case, the width). It is also possible that the length 644 of the intermediate region 638 is shorter than the width 648 of the intermediate region 638.

 The length 646 of the distal region 640 is preferably longer than the
15 length 644 of the intermediate region 638, however, an equally long distal region 640 and intermediate region 638, or a shorter distal region 640 than the intermediate region 638, is also possible. The length 642 of the proximal region 636 may be shorter than, equal to, or longer than the length 644 of the intermediate region 638.

20 The length 644 of the intermediate region 638 is preferably less than half of the length of the second portion 141'', i.e. less than half of the combined length of the proximal region 636, the intermediate region 638, and the distal region 630. In some embodiments, the length 644 of the intermediate region 638 is less than a third of the length of the second portion
25 141'', such as less than a fourth, less than a fifth, or less than a tenth of the length of the second portion 141''.

 The connecting portion may have one of an oval cross-section, an elongated cross-section, and a circular cross-section, in a plane parallel to the third plane P3. In particular, the connecting portion may have several different
30 cross-sectional shapes along its length in the central extension C1.

 Figs. 45C – 45D illustrate an embodiment similar to the one described in conjunction with Figs. 58a – 58b. However, the embodiment of Figs. 58c-

58d lacks a proximal portion, i.e. the second portion 141'' does not comprise a "heel". Furthermore, such embodiment may have a connecting portion 142 having a length and width, in directions 631 and 633 respectively, being equal to a height of the second portion in a direction parallel to the central extension C1, as illustrated. Thus, the connecting portion 142 and the second portion 141'' may be constituted by a substantially uniformly wide body.

In some embodiments the distal region 640 is configured to be directed downwards in a standing patient, i.e. in a caudal direction when the remote unit 140 is implanted. As illustrated in Figs. 59A – 59D, different orientations of the second portion 141'' relative the first portion 141' are possible. In some embodiments, a connection between either the first portion 141' and the connecting portion 142, or between the second portion 141'' and the connecting portion 142, may allow for a plurality of different connecting orientations. For example, a connection mechanism between the first portion 141' and the connecting portion 142 (or between the second portion 141'' and the connecting portion 142) may possess a 90 degree rotational symmetry to allow the second portion 141' to be set in four different positions with respect to the first portion 141, each differing from the other by 90 degrees. Other degrees of rotational symmetry are of course possible, such as 30 degrees, 45 degrees, 60 degrees, 120 degrees, 180 degrees and so on. In other embodiments there are no connective mechanism between any of the first portion 141', the connecting portion 142, and the second portion 141'' (i.e. the portions are made as one integral unit), and in such cases different variants of the device 140 can be achieved during manufacturing. In other embodiments, the connective mechanism between the first portion 141' and the connecting portion 142 (or between the second portion 141'' and the connecting portion 142) is non-reversible, i.e. the first portion 141' and the second portion 141'' may initially be handled as separate parts, but the orientation of the second portion 141'' relative the first portion 141' cannot be changed once it has been selected and the parts have been connected via the connecting portion 142.

The different orientations of the second portion 141'' relative the first portion 141' may be defined as the length direction of the second portion 141''

having a relation or angle with respect to a length direction of the first portion 141'. Such angle may be 15 degrees, 30, 45, 60, 75 90, 105, 120, 135, 150, 165, 180, 195, 210, 225, 240, 255, 270, 285, 300, 315, 330, 345 or 360 degrees. In particular, the angle between the first portion 141' and the second portion 141'' may be defined as an angle in the planes P1 and P2, or as an angle in a plane parallel to the tissue portion 610, when the remote unit 140 is implanted. In the embodiment illustrated in Figs. 58A – 58D, the length direction of the second portion 141'' is angled by 0, 90, 180, and 270 degrees with respect to the length direction of the first portion 141'.

10 The second end 634 of the second portion 141'' may comprise one or several connections for connecting to an implant being located in a caudal direction from a location of the remote unit in the patient. Hereby, when the remote unit 140 is implanted in a patient, preferably with the distal region 640 and second end 634 pointing downwards in a standing patient, the
15 connections will be closer to the implant as the second end 634 will be pointing in the caudal direction whereas the first end 632 will be pointing in the cranial direction. It is also possible that the second end 634 of the second portion 141'' is configured for connecting to an implant, i.e. the second end 634 may comprise a port, connector or other type of connective element for
20 transmission of power, and/or signals.

 Likewise, the first end 632 of the second portion 141'' may comprise one or several connections for connecting to an implant being located in a cranial direction from a location of the remote unit in the patient. Hereby, when the remote unit 140 is implanted in a patient, preferably with the distal
25 region 640 and second end 634 pointing downwards in a standing patient, the connections will be closer to the implant as the first end 632 will be pointing in the cranial direction whereas the second end 634 will be pointing in the caudal direction. It is also possible that the first end 632 of the second portion 141'' is configured for connecting to an implant, i.e. the first end 632 may
30 comprise a port, connector or other type of connective element for transmission of power, and/or signals.

With reference to figs. 60 and 61, an embodiment of an implantable remote unit 140 will be described. The remote unit 140 is configured to be held in position by a tissue portion 610 of a patient. The remote unit 140 comprises a first portion 141' configured to be placed on a first side 612 of the tissue portion 610, the first portion 141' having a first cross-sectional area in a first plane and comprising a first surface 614 configured to face and/or engage a first tissue surface 616 of the first side 612 of the tissue portion 610. The remote unit 140 further comprises a second portion 141'' configured to be placed on a second side 618 of the tissue portion 610, the second side 618 opposing the first side 612, the second portion 141'' having a second cross-sectional area in a second plane and comprising a second surface 620 configured to engage a second tissue surface 622 of the second side 618 of the tissue portion 610. The remote unit 140 further comprises a connecting portion 142 configured to be placed through a hole in the tissue portion 610 extending between the first and second sides 612, 618 of the tissue portion 610. The connecting portion 142 here has a third cross-sectional area in a third plane. The connecting portion 142 is configured to connect the first portion 141' to the second portion 141''.

With reference to Fig. 62a, the first cross-sectional area has a first cross-sectional distance CD1a and a second cross-sectional distance CD2a, the first and second cross-sectional distances CD1a, CD2a being perpendicular to each other and the first cross-sectional distance CD1a being longer than the second cross-sectional distance CD2a. Furthermore, the second cross-sectional area has a first cross-sectional distance CD1b and a second cross-sectional distance CD2b, the first and second cross-sectional distances CD2a, CD2b being perpendicular to each other and the first cross-sectional distance CD1b being longer than the second cross-sectional distance CD2b. The first cross-sectional distance CD1a of the first cross-sectional area and the first cross-sectional distance CD1b of the second cross-sectional area are rotationally displaced in relation to each other with an angle exceeding 45° to facilitate insertion of the second portion 141'' through

the hole in the tissue portion. In the embodiment illustrated in Fig. 62a, the rotational displacement is 90°.

The rotational displacement of the first portion 141' and the second portion 141'' forms a cross-like structure, being particularly advantageous in that insertion through the hole in the tissue portion 610 may be facilitated, and once positioned in the hole in the tissue portion 610 a secure position may be achieved. In particular, if the remote unit 140 is positioned such that the second portion 141'' has its first cross-sectional distance CD1b extending along a length extension of the hole 611 in the tissue portion 610, insertion of the second portion 141'' through the hole 611 may be facilitated. Furthermore, if the first portion 141' is then displaced in relation to the second portion 141'' such that the first cross-sectional distance CD1a of the first portion 141' is displaced in relation to a length extension of the hole 611, the first portion 141' may be prevented from travelling through the hole 611 in the tissue portion. In these cases, it is particularly advantageous if the hole 611 in the tissue portion is oblong, ellipsoidal, or at least has one dimension in one direction being longer than a dimension in another direction. Such oblong holes in a tissue portion may be formed for example in tissue having a fiber direction, where the longest dimension of the hole may be aligned with the fiber direction.

In the embodiment illustrated in Fig. 60, the first surface 614 of the first portion 141' is flat, thus providing a larger contact surface to the first tissue surface 616 and consequently less pressure on the tissue portion. A more stable position may also be achieved by the flat surface. Also the second surface 620 of the second portion 141'' may be flat. However, other shapes, such as those described in other parts of the present disclosure, are possible.

As shown in Fig. 62a, the connecting portion 142 may have an elongated cross-section in the third plane. It may be particularly advantageous if the connecting portion 142 has a longer length 644 than width 648, said length 644 extending in the same direction as a length direction of the second portion 141'', i.e. in the same direction as an elongation of the second portion 141''. Hereby, the elongation of the

connecting portion 142 may run in the same direction as an elongation of the hole in the tissue portion.

With reference to Fig. 62b, the rotational displacement of first cross-sectional distance of the first cross-sectional area and the first cross-sectional distance of the second cross-sectional area is shown, here at an angle about 45°. Accordingly, there is a rotational displacement, in the first, second and third planes, between a length direction 633 of the first portion 141' and a length direction 631 of the second portion 141''. Other angles of rotational displacement are possible, such as 60°, 75°, 90°, 105°, 120°, 135°, etc.

One and the same remote unit 140 may be capable of assuming several different arrangements with regards to rotational displacement of the first portion 141' and the second portion 141''. In particular, this is possible when the first portion 141' and/or the second portion 141'' is configured to detachably connect to the interconnecting portion 142. For example, a connection mechanism between the first portion 141' and the connecting portion 142, or between the second portion 141'' and the connecting portion 142, may possess a rotational symmetry to allow the first portion 141' to be set in different positions in relation to the connecting portion 142 and in extension also in relation to the second portion 141''. Likewise, such rotational symmetry may allow the second portion 141'' to be set in different positions in relation to the connecting portion 142 and in extension also in relation to the first portion 141'.

With reference to Figs. 63a – 63c, a procedure of insertion of the remote unit 140 in a tissue portion 610 will be described. The remote unit 140 may be oriented such that a length direction 631 of the second portion 141'' points downwards into the hole 611. Preferably, the second portion 141'' is positioned such that it is inserted close to an edge of the hole 611. The second portion 141'' may then be inserted partially through the hole 611, until the point where the first portion 141' abuts the first tissue surface 616. Here, a 90° rotational displacement between the first portion 141' and the second portion 141'', as described above, will allow a relatively large portion of the second portion 141'' to be inserted before the first portion 141' abuts the first

tissue surface 616. Subsequently, the remote unit 140 may be pivoted to slide or insert the remaining portion of the second portion 141'' through the hole 611. While inserting the remaining portion of the second portion 141'', the tissue may naturally flex and move to give way for the second portion 141''.

- 5 Upon having fully inserted the second portion 141'' through the hole 611, such that the second portion 141'' is completely located on the other side of the tissue portion 610, the tissue may naturally flex back.

With reference to fig. 64, an embodiment of an implantable remote unit 140, which may be referred to as a remote unit in other parts of the present disclosure, will be described. The remote unit 140 is configured to be held in position by a tissue portion 610 of a patient. The remote unit 140 comprises a first portion 141' configured to be placed on a first side 612 of the tissue portion 610, the first portion 141' having a first cross-sectional area in a first plane and comprising a first surface 614 configured to face and/or engage a first tissue surface of the first side 612 of the tissue portion 610. The remote unit 140 further comprises a second portion 141'' configured to be placed on a second side 618 of the tissue portion 610, the second side 618 opposing the first side 612, the second portion 141'' having a second cross-sectional area in a second plane and comprising a second surface 620 configured to engage a second tissue surface of the second side 618 of the tissue portion 610. The remote unit 140 further comprises a connecting portion 142 configured to be placed through a hole in the tissue portion 610 extending between the first and second sides 612, 618 of the tissue portion 610. The connecting portion 142 here has a third cross-sectional area in a third plane. The connecting portion 142 is configured to connect the first portion 141' to the second portion 141''.

At least one of the first portion and the second portion comprises at least one coil embedded in a ceramic material, the at least one coil being configured for at least one of: receiving energy transmitted wirelessly, transmitting energy wirelessly, receiving wireless communication, and transmitting wireless communication. In the illustrated embodiment, the first portion 141' comprises a first coil 658 and a second coil 660, and the second

portion 141'' comprises a third coil 662. The coils are embedded in a ceramic material 664

As discussed in other part of the present disclosure, the first portion 141' may comprise a first wireless energy receiver configured to receive
5 energy transmitted wirelessly from an external wireless energy transmitter, and further the first portion 141' may comprise a first wireless communication receiver. The first wireless energy receiver and the first wireless communication receiver may comprise the first coil. Accordingly, the first coil may be configured to receive energy wirelessly, and/or to receive
10 communication wirelessly.

By the expression "the receiver/transmitter comprising the coil" it is to be understood that said coil may form part of the receiver/transmitter.

The first portion 141' comprises a distal end 665 and a proximal end 666, here defined with respect to the connecting portion 142. In particular, the
15 proximal end 665 is arranged closer to the connecting portion 142 and closer to the second portion 141'' when the remote unit 140 is assembled. In the illustrated embodiment, the first coil 658 is arranged at the distal end 665.

The first portion 141' may comprise an internal wireless energy transmitter, and further a first wireless communication transmitter. In some
20 embodiments, the internal wireless energy transmitter and/or the first wireless communication transmitter comprises the first coil 658. However, in some embodiments the internal wireless energy transmitter and/or the first wireless communication transmitter comprises the second coil 660. The second coil 660 is here arranged at the proximal end 665 of the first portion 141'. Such
25 placement of the second coil 660 may provide for that energy and/or communication signals transmitted by the second coil 660 will not be attenuated by internal components of the first portion 141' when being transmitted to the second portion 141''.

In some embodiments, the first wireless energy receiver and the
30 internal wireless energy transmitter comprises a single coil embedded in a ceramic material. Accordingly, a single coil may be configured for receiving energy wirelessly and for transmitting energy wirelessly. Similarly, the first

wireless communication receiver and the first wireless communication transmitter may comprise a single coil embedded in a ceramic material. Even further, in some embodiments a single coil may be configured for receiving and transmitting energy wirelessly, and for receiving and transmitting
5 communication signals wirelessly.

The coils discussed herein are preferably arranged in a plane extending substantially parallel to the tissue portion 610.

The second portion 141'' may comprise a second wireless energy receiver, and/or a second wireless communication receiver. In some
10 embodiments, the third coil 662 in the second portion 141'' comprises the second wireless energy receiver and/or the second wireless communication receiver.

The second portion 141'' comprises a distal end 668 and a proximal end 670, here defined with respect to the connecting portion 142. In
15 particular, the proximal end 668 is arranged closer to the connecting portion 142 and closer to the first portion 141' when the remote unit 140 is assembled. In the illustrated embodiment, the third coil 662 is arranged at the proximal end 668 of the second portion 141''. Such placement of the third coil 662 may provide for that energy and/or communication signals received by
20 the third coil 662 will not be attenuated by internal components of the second portion 141'' when being received from the first portion 141'.

The first portion 141' may comprise a first controller 300a connected to the first coil 658, second coil 660, and/or third coil 662. The second portion 141'' may comprise a second controller 300b connected to the first coil, 658,
25 second coil 660, and/or third coil 662.

In the illustrated embodiment, the first portion 141' comprises a first energy storage unit 304a connected to the first wireless energy receiver 308a, i.e. the first coil 658. The second portion comprises a second energy storage unit 304b connected to the second wireless energy receiver 308b, i.e. the
30 third coil 662. Such an energy storage unit may be a solid-state battery, such as a thionyl-chloride battery.

In some embodiments, the first coil 658 is configured to receive energy transmitted wirelessly by the external wireless energy transmitter and store the received energy in the first energy storage unit 304a. Furthermore, the first coil 658 and/or the second coil 660 may be configured to wirelessly
5 transmit energy stored in the first energy storage unit 304a to the third coil 662, and the third coil 662 may be configured to receive energy transmitted wirelessly by the first coil 658 and/or the second coil 660 and store the received energy in the second energy storage unit 305b.

The first energy storage unit 304a may be configured to store less
10 energy than the second energy storage unit 304b, and/or configured to be charged faster than the second energy storage unit 304b. Hereby, charging of the first energy storage unit 304a may be relatively quick, whereas transfer of energy from the first energy storage unit 304a to the second energy storage unit 304b may be relatively slow. Thus, a user can quickly charge the first
15 energy storage unit 304a, and will not during such charging be restricted for a long period of time by being connected to an external wireless energy transmitter, e.g. at a particular location. After having charged the first energy storage unit 304a, the user may move freely while energy slowly transfers from the first energy storage unit 304a to the second energy storage unit
20 304b, via the first and/or second coil and the third coil.

As is readily understood by a person skilled in the art the system and embodiments disclosed in connection with figures 40-45 may be integrated in any of the embodiments discussed with reference to figures 1-38, as well as figures 46-64, thus forming part of the disclosed embodiments, and/or be
25 used in connection with such apparatuses 100 in order to address symptoms of a patient suffering from reflux disease.

The function and features of a controller for controlling the apparatuses according to any of the above aspects and embodiments will now be described with reference to figs 65A-E and 66A-H. The features of the controller
30 described with reference to figs. 65A-E and 66A-H may be implemented and combined with any of the embodiments of implantable medical devices disclosed herein, such as for example figures 1-38 and 40-64. The features

may for example be implemented in the controllers shown and/or described with reference to figs. 1, 38A-B, 40, and 43-45. Any controller may reference to figures 65A-E and 66A-H. The controller disclosed in this description, and any combination of features thereof, may comprise an internal computing unit, also called a processor or controller, for controlling a function of the implant, such as the electrical stimulation of muscle tissue and/or charging of the internal energy source, and it may comprise a communication unit and implement methods for communication, including verification, authentication and encryption of data, as described in the following.

10 In the following, the term "medical implant" should be understood as referring to any of the apparatuses, or part of the apparatuses, according to the above aspects. Thus, the medical implant may refer to the implantable movement restriction device, the electrode arrangement, the elongated core, the tubular cover, the implantable first and second portions, and/or the
15 elongated support device.

The controller may comprise a collection of communication related sub-units such as a wired transceiver, a wireless transceiver, energy storage, an energy receiver, a computing unit, a memory, or a feedback unit. The sub-units of the controller may cooperate with each other or operate
20 independently with different purposes. The sub-units of the controller may inherit the prefix "internal". This is to distinguish these sub-units from the sub-units of the external devices as similar sub-units may be present for both the implanted controller and the external devices. The sub-units of the external devices may similarly inherit the prefix "external".

25 A wireless transceiver may comprise both a wireless transmitter and a wireless receiver. The wireless transceiver may also comprise a first wireless transceiver and a second wireless transceiver. In this case, the wireless transceiver may be part of a first communication system (using the first wireless transceiver) and a second communication system (using the second
30 wireless transceiver).

In some embodiments, two communication systems may be implemented using a single wireless transceiver in e.g. the medical implant

and a single wireless transceiver in e.g. an external device (i.e. one antenna at the medical implant and one antenna at the external device), but where for example the network protocol used for data transmission from the external device to the medical implant is different from the network protocol used for data transmission from the medical implant to the external device, thus achieving two separate communication systems.

Alternatively, the wireless transceiver may be referred to as either a wireless transmitter or a wireless receiver as not all embodiments of secure wireless communication discussed herein require two-way communication capability of the wireless transceiver. The wireless transceiver may transmit or receive wireless communication via wireless connections. The wireless transceiver may connect to both the medical implant and to external devices, i.e. devices not implanted in the patient.

The wireless connections may be based on radio frequency identification (RFID), near field charge (NFC), Bluetooth, Bluetooth low energy (BLE), or wireless local area network (WLAN). The wireless connections may further be based on mobile telecommunication regimes such as 1G, 2G, 3G, 4G, or 5G. The wireless connections may further be based on modulation techniques such as amplitude modulation (AM), frequency modulation (FM), phase modulation (PM), or quadrature amplitude modulation (QAM). The wireless connection may further feature technologies such as time-division multiple access (TDMA), frequency-division multiple access (FDMA), or code-division multiple access (CDMA). The wireless connection may also be based on infra-red (IR) communication. The wireless connection may feature radio frequencies in the high frequency band (HF), very-high frequency band (VHF), and the ultra-high frequency band (UHF) as well as essentially any other applicable band for electromagnetic wave communication. The wireless connection may also be based on ultrasound communication to name at least one example that does not rely on electromagnetic waves.

A wired transceiver may comprise both a wired transmitter and a wired receiver. The wording wired transceiver aims to distinguish between it and the

wireless transceiver. It may generally be considered a conductive transceiver. The wired transceiver may transmit or receive conductive communication via conductive connections. Conductive connections may alternatively be referred to as electrical connections or as wired connections. The wording
5 wired however, does not imply there needs to be a physical wire for conducting the communication. The body tissue of the patient may be considered as the wire. Conductive connection may use the body of the patient as a conductor. Conductive connections may still use ohmic conductors such as metals to at least some extent, and more specifically at
10 the interface between the wired transceiver and the chosen conductor.

Communication, conductive or wireless may be understood as digital or analogue. In analogue communication, the message signal is in analogue form i.e., a continuous time signal. In digital communication, usually digital data i.e., discrete time signals containing information is transmitted.

15 The controller may comprise a sensation generator. A sensation generator is a device or unit that generates a sensation. The generated sensation may be configured to be experienceable by the patient such that the patient may take actions to authenticate a device, connection, or communication. The sensation generator may be configured to generate a
20 single sensation or a plurality of sensation components. The sensation or sensation components may comprise a vibration (e.g. a fixed frequency mechanical vibration), a sound (e.g. a superposition of fixed frequency mechanical vibrations), a photonic signal (e.g. a non-visible light pulse such as an infra-red pulse), a light signal (e.g. a visual light pulse), an electric
25 signal (e.g. an electrical current pulse) or a heat signal (e.g. a thermal pulse). The sensation generator may be implanted, configured to be worn in contact with the skin of the patient or capable of creating sensation without being in physical contact with the patient, such as a beeping alarm.

The sensations generated by the sensation generator may be
30 configured to be experienceable by a sensory function or a sense of the patient from the list of tactile, pressure, pain, heat, cold, taste, smell, sight, and hearing. Sensations may be generated of varying power or force as to

adapt to sensory variations in the patient. Power or force may be increased gradually until the patient is able to experience the sensation. Variations in power or force may be controlled via feedback. Sensation strength or force may be configured to stay within safety margins. The sensation generator
5 may be connected to the medical implant. The sensation generator may be comprised within the medical implant or be a separate unit.

A motor, e.g. of the active device or unit of the medical implant, for controlling a physical function in the body of the patient may provide a secondary function as a sensation generator, generating a vibration or sound.
10 Generation of vibrations or sounds of the motor may be achieved by operating the motor at specific frequencies. When functioning as to generate a sensation the motor may operate outside of its normal ranges for frequency controlling a physical function in the body. The power or force of the motor when operating to generate a sensation may also vary from its normal ranges
15 for controlling a physical function in the body.

An external device is a device which is external to the patient in which the medical implant is implanted in. The external device may be also be enumerated (first, second, third, etc.) to separate different external devices from each other. Two or more external devices may be connected by means
20 of a wired or wireless communication as described above, for example through IP (internet protocol), or a local area network (LAN). The wired or wireless communication may take place using a standard network protocol such as any suitable IP protocol (IPv4, IPv6) or Wireless Local Area Network (IEEE 802.11), Bluetooth, NFC, RFID etc. The wired or wireless
25 communication may take place using a proprietary network protocol. Any external device may also be in communication with the medical implant using wired or wireless communication according to the above. Communication with implanted devices may be thus accomplished with a wired connection or with wireless radiofrequency (RF) telemetry. Other methods of wireless
30 communication may be used to communicate with implants, including optical and ultrasound. Alternatively, the concept of intrabody communication may be used for wireless communication, which uses the conductive properties of the

body to transmit signals, i.e. conductive (capacitive or galvanic) communication with the medical implant. Means for conductive communication between an external device and an implant may also be called “electrical connection” between an external device and an implant. The

5 conductive communication may be achieved by placing a conductive member of the external device in contact with the skin of the patient. By doing this, the external device and/or the implant may assure that it is in direct electrical connection with the other device. The concept relies on using the inherent conductive or electrical properties of a human body. Signals may preferably

10 be configured to affect the body or body functions minimally. For conductive communication this may mean using low currents. A current may flow from an external device to an implant or vice versa. Also, for conductive communication, each device may have a transceiver portion for transmitting or receiving the current. These may comprise amplifiers for amplifying at least

15 the received current. The current may contain or carry a signal which may carry e.g. an authentication input, implant operation instructions, or information pertaining to the operation of the implant.

Alternatively, conductive communication may be referred to as electrical or ohmic or resistive communication.

20 The conductive member may be an integrated part of the external device (e.g. in the surface of a smartwatch that is intended to be in contact with the wrist of the person wearing it), or it may be a separate device which can be connected to the external device using a conductive interface such as the charging port or the headphone port of a smartphone.

25 A conductive member may be considered any device or structure set up for data communication with the implant via electric conductive body tissue. The data communication to the implant may be achieved by e.g. current pulses transmitted from the conductive member through the body of the patient to be received by a receiver at the implant. Any suitable coding

30 scheme known in the art may be employed. The conductive member may comprise an energy source such as a battery or receive energy from e.g. a connected external device.

The term conductive interface is representing any suitable interface configured for data exchange between the conductive member and the external device. The conductive member may in an alternative configuration receive and transmit data to the external device through a radio interface,
5 NFC, and the like.

An external device may act as a relay for communication between an implant and a remote device, such as e.g. second, third, or other external devices. Generally, the methods of relaying communication via an external device may be preferable for a large number of reasons. The transmission
10 capabilities of the implant may be reduced, reducing its technical complexity, physical dimensions, and medical effects on the patient in which the implant is implanted. Communication may also be more efficient as direct communication, i.e. without a relaying device, with an implant from a remote device may require higher energy transmissions to account for different
15 mediums and different rates of attenuation for different communication means. Remote communication with lower transmission energy may also increase the security of the communication as the spatial area or volume where the communication may be at all noticeable may be made smaller. Utilizing such a relay system further enables the use of different
20 communication means for communication with the implant and communication with remote devices that are more optimized for their respective mediums.

An external device may be any device having processing power or a processor to perform the methods and functions needed to provide safe
25 operation of the implant and provide the patient or other stakeholders (caregiver, spouse, employer etc.) with information and feedback from the implant. Feedback parameters could include battery status, energy level at the controller, the electrical characteristics of the stimulation signal, number of stimulation cycles the electrode arrangement has delivered, properties,
30 version number etc. relating to functionality of the apparatus. The external device may for example be a handset such as a smartphone, smartwatch, tablet etc. handled by the patient or other stakeholders. The external device

may be a server or personal computer handled by the patient or other stakeholders. The external device may be cloud based or a virtual machine. In the drawings, the external device handled by the patient is often shown as a smart watch, or a device adapted to be worn by the patient at the wrist of the patient. This is merely by way of example and any other type of external device, depending on the context, is equally applicable.

Several external devices may exist such as a second external device, a third external device, or another external device. The above listed external devices may e.g. be available to and controllable by a patient, in which an implant is implanted, a caregiver of the patient, a healthcare professional of the patient, a trusted relative of the patient, an employer or professional superior of the patient, a supplier or producer of the implant or its related features. By controlling the external devices may provide options for e.g. controlling or safeguarding a function of the implant, monitoring the function of the implant, monitoring parameters of the patient, updating or amending software of the implant etc.

An external device under control by a supplier or producer of the implant may be connected to a database comprising data pertaining to control program updates and/or instructions. Such database may be regularly updated to provide new or improved functionality of the implant, or to mitigate for previously undetected flaws of the implant. When an update of a control program of an implant is scheduled, the updated control program may be transmitted from the database in a push mode and optionally routed via one or more further external devices before received by the implanted controller. In another embodiment, the update is received from the database by request from e.g. an external device under control by the patient having the implant implanted in his/her body, a pull mode.

The external device may require authentication to be operated in communication with other external devices or the implant. Passwords, multi-factor authentication, biometric identification (fingerprint, iris scanner, facial recognition, etc.) or any other way of authentication may be employed.

The external device may have a user interface (UI) for receiving input and displaying information/feedback from/to a user. The UI may be a graphical UI (GUI), a voice command interface, speaker, vibrators, lamps, etc.

The communication between external devices, or between an external
5 device and the implant may be encrypted. Any suitable type of encryption may be employed such as symmetric or asymmetric encryption. The encryption may be a single key encryption or a multi-key encryption. In multi-key encryption, several keys are required to decrypt encrypted data. The several keys may be called first key, second key, third key, etc. or first part of
10 a key, second part of the key, third part of the key, etc. The several keys are then combined in any suitable way (depending on the encryption method and use case) to derive a combined key which may be used for decryption. In some cases, deriving a combined key is intended to mean that each key is used one by one to decrypt data, and that the decrypted data is achieved
15 when using the final key.

In other cases, the combination of the several key result in one “master key” which will decrypt the data. In other words, it is a form of secret sharing, where a secret is divided into parts, giving each participant (external device(s), internal device) its own unique part. To reconstruct the original
20 message (decrypt), a minimum number of parts (keys) is required. In a threshold scheme this number is less than the total number of parts (e.g. the key at the implant and the key from one of the two external device are needed to decrypt the data). In other embodiments, all keys are needed to reconstruct the original secret, to achieve the combined key which may decrypt the data.

25 In should be noted that it is not necessary that the generator of a key for decryption is the unit that in the end sends the key to another unit to be used at that unit. In some cases, the generator of a key is merely a facilitator of encryption/decryption, and the working in behalf of another device/user.

A verification unit may comprise any suitable means for verifying or
30 authenticating the use (i.e. user authentication) of a unit comprising or connected to the verification unit, e.g. the external device. For example, a verification unit may comprise or be connected to an interface (UI, GUI) for

receiving authentication input from a user. The verification unit may comprise a communication interface for receiving authentication data from a device (separate from the external device) connected to the device comprising the verification unit. Authentication input/data may comprise a code, a key,
5 biometric data based on any suitable techniques such as fingerprint, a palm vein structure, image recognition, face recognition, iris recognition, a retinal scan, a hand geometry, and genome comparison, etc. The verification/authentication may be provided using third party applications, installed at or in connection with the verification unit.

10 The verification unit may be used as one part of a two-part authentication procedure. The other part may e.g. comprise conductive communication authentication, sensation authentication, or parameter authentication.

 The verification unit may comprise a card reader for reading a smart
15 card. A smart card is a secure microcontroller that is typically used for generating, storing, and operating on cryptographic keys. Smart card authentication provides users with smart card devices for the purpose of authentication. Users connect their smart card to the verification unit. Software on the verification unit interacts with the keys material and other
20 secrets stored on the smart card to authenticate the user. In order for the smart card to operate, a user may need to unlock it with a user-PIN. Smart cards are considered a very strong form of authentication because cryptographic keys and other secrets stored on the card are very well protected both physically and logically and are therefore hard to steal.

25 The verification unit may comprise a personal e-ID that is comparable to, for example, passport and driving license. The e-ID system comprises is a security software installed at the verification unit, and a e-ID which is downloaded from a web site of a trusted provided or provided via a smart card from the trusted provider.

30 The verification unit may comprise software for SMS-based two-factor authentication. Any other two-factor authentication systems may be used. Two-factor authentication requires two things to get authorized: something

you know (your password, code, etc.) and something you have (an additional security code from your mobile device (e.g. a SMS, or a e-ID) or a physical token such as a smart card).

Other types of verification/user authentication may be employed. For example, a verification unit which communicate with an external device using visible light instead of wired communication or wireless communication using radio. A light source of the verification unit may transmit (e.g. by flashing in different patterns) secret keys or similar to the external device which uses the received data to verify the user, decrypt data or by any other means perform authentication. Light is easier to block and hide from an eavesdropping adversary than radio waves, which thus provides an advantage in this context. In similar embodiments, electromagnetic radiation is used instead of visible light for transmitting verification data to the external device.

Parameters relating to functionality of the implant may comprise for example a status indicator of the implant such as battery level, version of control program, properties of the implant, status of a motor of the implant, etc.

Data comprising operating instructions sent to the implant may comprise a new or updated control program, parameters relating to specific configurations of the implant, etc. Such data may for example comprise instructions how to operate the electrode arrangement for simulating and exercising the muscle tissue in a multi functionality implant, instructions to collect patient data at the implant, instructions to transmit feedback from the implant to an external device, etc.

The expressions “confirming the electrical connection between an implant and an external device” or “authenticating a connection between an implant and an external device”, or similar expressions, are intended to encompass methods and processes for ensuring or be reasonably sure that the connection has not been compromised. Due to weaknesses in the wireless communication protocols, it is a simple task for a device to “listen” to the data and grab sensitive information, e.g. personal data regarding the patient sent from the implant, or even to try to compromise (hack) the implant

by sending malicious commands or data to the implant. Encryption may not always be enough as a security measure (encryption schemes may be predictable), and other means of confirming or authenticating the external device being connected to the implant may be needed.

5 The expression “network protocol” is intended to encompass communication protocols used in computer networks. A communication protocol is a system of rules that allow two or more entities of a communications system to transmit information via any kind of variation of a physical quantity. The protocol defines the rules, syntax, semantics and
10 synchronization of communication and possible error recovery methods. Protocols may be implemented by hardware, software, or a combination of both. Communication protocols have to be agreed upon by the parties involved. In this field, the term “standard” and “proprietary” is well defined. A communication protocol may be developed into a protocol standard by getting
15 the approval of a standards organization. To get the approval the paper draft needs to enter and successfully complete the standardization process. When this is done, the network protocol can be referred to a “standard network protocol” or a “standard communication protocol”. Standard protocols are agreed and accepted by whole industry. Standard protocols are not vendor
20 specific. Standard protocols are often, as mentioned above, developed by collaborative effort of experts from different organizations.

 Proprietary network protocols, on the other hand, are usually developed by a single company for the devices (or Operating System) which they manufacture. A proprietary network protocol is a communications
25 protocol owned by a single organization or individual. Specifications for proprietary protocols may or may not be published, and implementations are not freely distributed. Consequently, any device may not communicate with another device using a proprietary network protocol, without having the license to use the proprietary network protocol, and knowledge of the
30 specifications for proprietary protocol. Ownership by a single organization thus gives the owner the ability to place restrictions on the use of the protocol and to change the protocol unilaterally.

A control program is intended to define any software used for controlling the implant. Such software may comprise an operating system of the implant, of parts of an operating system or an application running on the implant such as software controlling a specific functionality of the implant (e.g. the active unit of the implant, feedback functionality of the implant, a transceiver of the implant, encoding/decoding functionality of the implant, etc.). The control program may thus control the medical function of the implant, for example the electrical stimulation of the muscle tissue, etc. Alternatively, or additionally, the control program may control internal hardware functionality of the implant such as energy usage, transceiver functionality, etc.

The controller may alternatively be called an internal control unit and may include any software or hardware for controlling the implant or the communication unit. The internal control unit may comprise an internal communication unit and a storage unit and a processor for running any control program or software. The term "internal control unit" may be used to encompass any part of the implant not being the active unit or body engaging unit.

The systems and methods disclosed hereinabove may be implemented as software, firmware, hardware, or a combination thereof. In a hardware implementation, the division of tasks between functional units referred to in the above description does not necessarily correspond to the division into physical units; to the contrary, one physical component may have multiple functionalities, and one task may be carried out by several physical components in cooperation. Certain components or all components may be implemented as software executed by a digital signal processor or microprocessor or be implemented as hardware or as an application-specific integrated circuit. Such software may be distributed on computer readable media, which may comprise computer storage media (or non-transitory media) and communication media (or transitory media). As is well known to a person skilled in the art, the term computer storage media includes both volatile and non-volatile, removable and non-removable media implemented

in any method or technology for storage of information such as computer readable instructions, data structures, program modules or other data.

Computer storage media includes, but is not limited to, RAM, ROM,

EEPROM, flash memory or other memory technology, CD-ROM, digital

5 versatile disks (DVD) or other optical disk storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information, and which can be accessed by a computer. Further, it is well known to the skilled person that communication media typically embodies computer readable
10 instructions, data structures, program modules or other data in a modulated data signal such as a carrier wave or other transport mechanism and includes any information delivery media.

[0001] An embodiment of the system will now be described with reference to figures 65A-E. Figure 65A shows a patient with an implant 100. The implant

15 100 is in figure 65A placed in the abdominal area of the patient but could equally be placed in other parts of the body. The medical device 10 comprises an active unit 302, which is the part of the medical device which comprises the one or more members and operation device for operating the members etc.. The active unit is directly or indirectly connected to the
20 stomach wall of the patient for stretching the stomach wall for creating a sensation of satiety. The active unit 302 is connected to the controller 300 via an electrical connection C2. The controller 300 (further described with reference to figure 65b) is configured to communicate with an external device 320 (further described with reference to figure 65c). The controller 300 can
25 communicate wirelessly with the external device 320 through a wireless connection WL1, and/or through an electrical connection C1.

Referring now to figure 65b, one embodiment of the controller 300 will be describe in more detail. The controller 300 comprises an internal computing unit 306 configured to control the function performed by the
30 implantable medical device 10. The computing unit 306 comprises an internal memory 307 configured to store programs thereon. In the embodiment described in fig. 65b, the internal memory 307 comprises a first control

program 310 which can control the function of the medical device 10. The first control program 310 may be seen as a program with minimum functionality to be run at the medical device only during updating of the second control program 312. When the medical device is running with the first control

5 program 310, the medical device may be seen as running in safe mode, with reduced functionality. For example, the first control program 310 may result in that no sensor data is stored in the medical device while being run, or that no feedback is transmitted from the medical device while the first control program 310 is running. By having a low complexity first control program,

10 memory at the medical device is saved, and the risk of failure of the medical device during updating of the second control program 312 is reduced.

The second control program 312 is the program controlling the medical device in normal circumstances, providing the medical device with full functionality and features.

15 The memory 307 can further comprise a second, updatable, control program 312. The term updatable is to be interpreted as the program being configured to receive incremental or iterative updates to its code, or be replaced by a new version of the code. Updates may provide new and/or improved functionality to the implant as well as fixing previous deficiencies in

20 the code. The computing unit 306 can receive updates to the second control program 312 via the controller 300. The updates can be received wirelessly WL1 or via the electrical connection C1. As shown in figure 65b, the internal memory 307 of the controller 300 can possibly store a third program 314. The third program 314 can control the function of the implantable medical device

25 10 and the computing unit 306 may be configured to update the second program 312 to the third program 314. The third program 314 can be utilized when rebooting an original state of the second program 312. The third program 314 may thus be seen as providing a factory reset of the controller 300, e.g. restore it back to factory settings. The third program 314 may thus

30 be included in the implant 300 in a secure part of the memory 307 to be used for resetting the software (second control program 312) found in the controller 300 to original manufacturer settings.

The controller 300 may comprise a reset function 316 connected to or part of the internal computing unit 306 or transmitted to said internal computing unit 306. The reset function 316 is configured to make the internal computing unit 306 switch from running the second control program 312 to the first control program 310. The reset function 316 could be configured to make the internal computing unit 306 delete the second control program 312 from the memory 307. The reset function 316 can be operated by palpating or pushing/put pressure on the skin of the patient. This could be performed by having a button on the implant. Alternatively, the reset function 316 can be invoked via a timer or a reset module. Temperature sensors and/ or pressure sensors can be utilized for sensing the palpating. The reset function 316 could also be operated by penetrating the skin of the patient. It is further plausible that the reset function 316 can be operated by magnetic means. This could be performed by utilizing a magnetic sensor and applying a magnetic force from outside the body. The reset function 316 could be configured such that it only responds to magnetic forces applied for a duration of time exceeding a limit, such as 2 seconds. The time limit could equally plausible be 5 or 10 seconds, or longer. In these cases, the implant could comprise a timer. The reset function 316 may thus include or be connected to a sensor for sensing such magnetic force.

In addition to or as an alternative to the reset function described above, the implant may comprise an internal computing unit 306 (comprising an internal processor) comprising the second control program 312 for controlling a function of the implantable medical device, and a reset function 318. The reset function 318 may be configured to restart or reset said second control program 312 in response to: i. a timer of the reset function 318 has not been reset, or ii. a malfunction in the first control program 310.

The reset function 318 may comprise a first reset function, such as, for example, comprise a computer operating properly, COP, function connected to the internal computing unit 306. The first reset function may be configured to restart or reset the first or the second control program 312 using a second

reset function. The first reset function comprises a timer, and the first or the second control program is configured to periodically reset the timer.

The reset function 318 may further comprise a third reset function connected to the internal computing unit and to the second reset function.

5 The third reset function may in an example be configured to trigger a corrective function for correcting the first 310 or second control program 312, and the second reset function is configured to restart the first 310 or second control program 312 sometime after the corrective function has been triggered. The corrective function may be a soft reset or a hard reset.

10 The second or third reset function may, for example, configured to invoke a hardware reset by triggering a hardware reset by activating an internal or external pulse generator which is configured to create a reset pulse. Alternatively, the second or third reset function may be implemented by software.

15 The controller 300 may further comprise an internal wireless transceiver 308. The transceiver 308 communicates wirelessly with the external device 320 through the wireless connection W1. The transceiver may further communicate with an external device 320, 300 via wireless connection WL2 or WL4. The transceiver may both transmit and receive data via either of
20 the connections C1, WL1, WL2 and WL4. Optionally, the external devices 320 and 300, when present, may communicate with each other, for example via a wireless connection WL3.

The controller 300 can further be electrically connected C1 to the external device 320 and communicate by using the patient's body as a
25 conductor. The controller 300 may thus comprise a wired transceiver 303 or an internal transceiver 303 for the electrical connection C1.

The confirmation/authentication of the electrical connection can be performed as described herein in the section for confirmation and/or authentication. In these cases, the implanted medical device and/or external
30 device(s) 320 comprises the necessary features and functionality (described in the respective sections of this document) for performing such confirmation/authentication. By authenticating according to these aspects,

security of the authentication may be increased as it may require a malicious third party to know or gain access to either the transient physiological parameter of the patient or detect randomized sensations generated at or within the patient.

5 In figures 65a – 65c the patient is a human, but other mammals are equally plausible. It is also plausible that the communication is performed by inductive means. It is also plausible that the communication is direct.

 The controller 300 of the implantable medical device 10 according to figure 65b further comprises a feedback unit 349. The feedback unit 349
10 provides feedback related to the switching from the second control program 312 to the first control program 310. The feedback could for example represent the information on when the update of the software, i.e. the second control program 312, has started, and when the update has finished. This feedback can be visually communicated to the patient, via for example a
15 display on the external device 320. This display could be located on a watch, or a phone, or any other external device 320 coupled to the controller 300. Preferably, the feedback unit 349 provides this feedback signal wirelessly WL1 to the external device 320. Potentially, the words “Update started”, or “Update finished”, could be displayed to the patient, or similar terms with the
20 same meaning. Another option could be to display different colors, where green for example could mean that the update has finished, and red or yellow that the update is ongoing. Obviously, any color is equally plausible, and the user could choose these depending on personal preference. Another possibility would be to flash a light on the external device 320. In this case the
25 external device 320 comprises the light emitting device(s) needed. Such light could for example be a LED. Different colors could, again, represent the status of the program update. One way of representing that the update is ongoing and not yet finished could be to flash the light, i.e. turning the light on and off. Once the light stops flashing, the patient would be aware of that the
30 update is finished. The feedback could also be audible, and provided by the implantable medical device 300 directly, or by the external device 320. In such cases, the implantable medical device 10 and external device 320

comprises means for providing audio. The feedback could also be tactile, for example in the form of a vibration that the user can sense. In such case, either the implantable medical device 10 or external device 320 comprises means for providing a tactile sensation, such as a vibration and/or a vibrator.

5 As seen in figure 65b, the controller 300 can further comprise a first energy storage unit 40A. The first energy storage unit 40A runs the first control program 310. The controller 300 further comprises a second energy storage unit 40B which runs the second control program 312. This may further increase security during update, since the first control program 310
10 has its own separate energy storage unit 40A. The energy storage unit 40A can comprise a first energy storage 304a and/or a first energy receiver 305a. The second energy storage unit 40B can comprise a second energy storage 304b and/or a second energy receiver 305b. The energy can be received wirelessly by inductive or conductive means. An external energy storage unit
15 can for example transfer an amount of wireless energy to the energy receiver 305a, 305b inside the patient's body by utilizing an external coil which induces a voltage in an internal coil (not shown in figures). It is plausible that the first energy receiver 305a receives energy via a RFID pulse. The feedback unit 349 can provide feedback pertaining to the amount of energy
20 received via the RFID pulse. The amount of RFID pulse energy that is being received can be adjusted based on the feedback, such that the pulse frequency is successively raised until a satisfying level is reached.

 The controller 300 of the medical device 10 according to figure 65b further comprises a feedback unit an electrical switch 309. The electrical
25 switch 309 could be mechanically connected to a member of the medical device configured to deliver an electric stimulation signal to improve long term implantation characteristics and reduce detrimental effects on muscle tissue against which the implant rests. The switch 309 could for example be bonded to a stimulation device controlling the stimulation signal delivered to the
30 muscle tissue by the electrode arrangement to provide stimulation thereof, in any of the embodiments herein. Such a switch could for example be a switch 309 configured to switch if exposed to a temperature exceeding a threshold

value, such as a bimetal switch which is switched by the heat created by the flow of current charging or discharging the battery. In the alternative, the switch 309 configured to switch if exposed to a temperature exceeding a threshold value could be placed at a different location on the medical device

5 10 to switch in case of exceeding temperatures, thereby hindering the medical device from overheating which may cause tissue damage.

The switch 309 could either be configured to cut the power to the operation device or to generate a control signal to the processor 306 of the implantable controller 300, such that the controller 300 can take appropriate

10 action, such as reducing power or turning off the operation device.

The external device 320 is represented in figure 65c. The external device 320 can be placed anywhere on the patient's body, preferably on a convenient and comfortable place. The external device 320 could be a wristband, and/or have the shape of a watch. It is also plausible that the

15 external device is a mobile phone or other device not attached directly to the patient. The external device as shown in figure 65c comprises a wired transceiver 323, and an energy storage 324. It also comprises a wireless transceiver 328 and an energy transmitter 325. It further comprises a computing unit 326 and a memory 327. The feedback unit 322 in the external

20 device 320 is configured to provide feedback related to the computing unit 326. The feedback provided by the feedback unit 322 could be visual. The external device 320 could have a display showing such visual feedback to the patient. It is equally plausible that the feedback is audible, and that the external device 320 comprises means for providing audio. The feedback

25 given by the feedback unit 322 could also be tactile, such as vibrating. The feedback could also be provided in the form of a wireless signal WL1, WL2, WL3, WL4.

The second, third or fourth communication methods WL2, WL3, WL4 may be a wireless form of communication. The second, third or fourth

30 communication method WL2, WL3, WL4 may preferably be a form of electromagnetic or radio-based communication. The second, third and fourth communication method WL2, WL3, WL4 may be based on telecommunication

methods. The second, third or fourth communication method WL2, WL3, WL4 may comprise or be related to the items of the following list: Wireless Local Area Network (WLAN), Bluetooth, Bluetooth 5, BLE, GSM or 2G (2nd generation cellular technology), 3G, 4G or 5G.

5 The external device 320 may be adapted to be in electrical connection C1 with the medical device 10, using the body as a conductor. The electrical connection C1 is in this case used for conductive communication between the external device 320 and the medical device 10.

10 In one embodiment, the communication between controller 300 and the external device 320 over either of the communication methods WL2, WL3, WL4, C1 may be encrypted and/or decrypted with public and/or private keys, now described with reference to Figs. 65a – 65c. For example, the controller 300 may comprise a private key and a corresponding public key, and the external device 320 may comprise a private and a corresponding public key.

15 The controller 320 and the external device 320 may exchange public keys and the communication may thus be performed using public key encryption. The person skilled in the art may utilize any known method for exchanging the keys.

20 The controller may encrypt data to be sent to the external device 320 using a public key corresponding to the external device 320. The encrypted data may be transmitted over a wired, wireless or electrical communication channel C1, WL1, WL2, WL3 to the external device. The external device 320 may receive the encrypted data and decode it using the private key comprised in the external device 320, the private key corresponding to the public key with which the data has been encrypted. The external device 320 may transmit encrypted data to the controller 300. The external device 320 may encrypt the data to be sent using a public key corresponding to the private key of the controller 300. The external device 320 may transmit the encrypted data over a wired, wireless or electrical connection C1, WL1, WL2, 30 WL3, WL4, directly or indirectly, to the controller of the implant. The controller may receive the data and decode it using the private key comprised in the controller 300.

In an alternative to the public key encryption, described with reference to figs. 65a – 65c, the data to be sent between the controller 300 of the implantable medical device 10 and an external device 320, 330 or between an external device 320, 330 and the controller 300 may be signed. In a
5 method for sending data from the controller 300 to the external device 320, 330, the data to be sent from the controller 300 may be signed using the private key of the controller 300. The data may be transmitted over a communication channel or connection C1, WL1, WL2, WL3, WL4. The external device 320, 330 may receive the message and verify the authenticity
10 of the data using the public key corresponding to the private key of the controller 300. In this way, the external device 320, 330 may determine that the sender of the data was sent from the controller 300 and not from another device or source.

A method for communication between external devices and the
15 controller 300 of the implantable medical device 10 using a combined key is now described with reference to figs. 65a – 65c. A first step of the method comprises receiving, at the implant, by a wireless transmission WL1, WL2, WL3, WL4 or otherwise, a first key from an external device 320, 330. The method further comprises receiving, at the implant, by a wireless transmission
20 WL1, WL2, WL3, a second key. The second key may be generated by a second external device, separate from the external device 320, 330 or by another external device being a generator of the second key on behalf of the second external device 320, 330. The second key may be received at the medical device from anyone of, the external device 320, the second external
25 device 330, and the generator of the second key. The second external device may be controlled by a caretaker, or any other stakeholder. Said another external device may be controlled by a manufacturer of the implant, or medical staff, caretaker, etc.

In case the controller 300 is receiving the second key from the external
30 device 320, this means that the second key is routed through the external device from the second external device 330 or from another external device (generator). In these cases, the implanted medical device and/or external

device(s) comprises the necessary features and functionality (described in the respective sections of this document) for performing such routing. Using the external device 320 as a relay, with or without verification from the patient, may provide an extra layer of security as the external device 320 may not
5 need to store or otherwise handle decrypted information. As such, the external device 320 may be lost without losing decrypted information. The controller 300 a computing unit 306 configured for deriving a combined key by combining the first key and the second key with a third key held by the controller 300, for example in memory 307 of the controller 300. The third key
10 could for example be a license number of the implant or a chip number of the implantable medical device. The combined key may be used for decrypting, by the computing unit 306, encrypted data transmitted by a wireless transmission WL1 from the external device 320 to the controller 300. Optionally, the decrypted data may be used for altering, by the computing unit
15 306 an operation of the implantable medical device. The altering an operation of the implantable medical device may comprise controlling or switching an active unit 302 of the implantable medical device. In some embodiments, the method further comprises at least one of the steps of, based on the decrypted data, updating a control program running in the controller 300, and operating
20 the implantable medical device 10 using operation instructions in the decrypted data.

Methods for encrypted communication between an external device 320 and the controller 300 are provided. These methods comprise:

receiving, at the external device 320, by a wireless transceiver 328, a
25 first key, the first key being generated by a second external device 330, separate from the external device 320 or by another external device being a generator of the second key on behalf of the second external device 330, the first key being received from anyone of the second external device 330 and the generator of the second key,
30 receiving, at the external device 320 by the wireless transceiver 328, a second key from the controller 300,

deriving a combined key, by a computing unit 326 of the external device 320, by combining the first key and the second key with a third key held by the external device 320 (e.g. in memory 307),

transmitting encrypted data from the implant to the external device and
5 receiving the encrypted data at the external device by the wireless transceiver 328, and

decrypting, by the computing unit 326, the encrypted data, in the external device 320, using the combined key.

As described above, further keys may be necessary to decrypt the
10 data. Consequently, the wireless transceiver 328 is configured for:

receiving a fourth key from a third external device,

wherein the computing unit 326 is configured for:

deriving a combined key by combining the first, second and fourth key with the third key held by the external device, and

15 decrypting the encrypted data using the combined key.

These embodiments further increase the security in the communication. The computing unit 326 may be configured to confirm the communication between the implantable medical device and the external device, wherein the confirmation comprises:

20 measuring a parameter of the patient, by the external device 320,
receiving a measured parameter of the patient, from the implantable medical device 10,

comparing the parameter measured by the implantable medical device 10 to the parameter measured by the external device 320,

25 performing confirmation of the connection based on the comparison,
and

as a result of the confirmation, decrypting the encrypted data, in the external device, using the combined key.

The keys described in this section may in some embodiments be
30 generated based on data sensed by sensors described herein under the twelfth or thirteenth aspect, e.g. using the sensed data as seed for the generated keys. A seed is an initial value that is fed into a pseudo random

number generator to start the process of random number generation. The seed may thus be made hard to predict without access or knowledge of the physiological parameters of the patient which it is based on, providing an extra level of security to the generated keys.

5 Further, increased security for communication between an external device(s) and the implantable medical device is provided.

A method of communication between an external device 320 and an implantable medical device 10 is now described with reference to Figs. 65a – 65c, when the implantable medical device 10 is implanted in a patient and the external device 320 is positioned external to the body of the patient. The external device 320 is adapted to be in electrical connection C1 with the controller 300, using the body as a conductor. The electrical connection C1 is used for conductive communication between the external device 320 and the implantable medical device 10. The implantable medical device 10 comprises the controller 300. Both the controller 300 and the external device 320 comprises a wireless transceiver 308, 208 for wireless communication C1 between the controller 300 and the external device 320. The wireless transceiver 308 (included in the controller 300) may in some embodiments comprise sub-transceivers for receiving data from the external device 320 and other external devices, e.g. using different frequency bands, modulation schemes etc.

In a first step of the method, the electrical connection C1 between the controller 300 and the external device 320 is confirmed and thus authenticated. The confirmation and authentication of the electrical connection may be performed as described herein under the fifth, thirteenth and fifteenth aspect. In these cases, the implant and/or external device(s) comprises the necessary features and functionality (described in the respective sections of this document) for performing such authentication. By authenticating according to these aspects, security of the authentication may be increased as it may require a malicious third party to know or gain access to either the transient physiological parameter of the patient or detect randomized sensations generated at or within the patient.

The implant may comprise a first transceiver 303 configured to be in electrical connection C1 with the external device, using the body as a conductor. The implantable medical device may comprise a first external transmitter 203 configured to be in electrical connection C1 with the implantable medical device, using the body as a conductor, and the wireless transmitter 208 configured to transmit wireless communication W1 to the controller 300. The first transmitter 323 of the external device 320 may be wired or wireless. The first transmitter 323 and the wireless transmitter 208 may be the same or separate transmitters. The first transceiver 303 of the controller 300 may be wired or wireless. The first transceiver 303 and the wireless transceiver 102 may be the same or separate transceivers.

The controller 300 may comprise a computing unit 306 configured to confirm the electrical connection between the external device 320 and the internal transceiver 303 and accept wireless communication WL1 (of the data) from the external device 320 on the basis of the confirmation.

Data is transmitted from the external device 320 to the controller 300 wirelessly, e.g. using the respective wireless transceiver 308, 208 of the controller 300 and the external device 320. Data may alternatively be transmitted through the electrical connection C1. As a result of the confirmation, the received data may be used for instructing the implantable medical device 10. For example, a control program 310 running in the controller 300 may be updated, the controller 300 may be operated using operation instructions in the received data. This may be handled by the computing unit 306.

The method may comprise transmitting data from the external device 320 to the controller 300 wirelessly comprises transmitting encrypted data wirelessly. To decrypt the encrypted data (for example using the computing unit 306), several methods may be used.

In one embodiment, a key is transmitted using the confirmed conductive communication channel C1 (i.e. the electrical connection) from the external device 320 to the controller 300. The key is received at the controller

(by the first internal transceiver 303). The key is then used for decrypting the encrypted data.

In some embodiments the key is enough to decrypt the encrypted data. In other embodiments, further keys are necessary to decrypt the data. In one
5 embodiment, a key is transmitted using the confirmed conductive communication channel C1 (i.e. the electrical connection) from the external device 320 to the controller 300. The key is received at the controller 300 (by the first internal transceiver 303). A second key is transmitted (by the wireless transceiver 208) from the external device 320 using the wireless
10 communication WL1 and received at the controller 300 by the wireless transceiver 308. The computing unit 306 is then deriving a combined key from the key and second key and uses this for decrypting the encrypted data.

In yet other embodiments, a key is transmitted using the confirmed conductive communication channel C1 (i.e. the electrical connection) from the
15 external device 320 to the controller 300. The key is received at the controller (by the first internal transceiver 303). A third key is transmitted from a second external device 330, separate from the external device 320, to the implant wirelessly WL2. The third key may be received by a second wireless receiver (part of the wireless transceiver 308) of the controller 300 configured for
20 receiving wireless communication WL2 from second external device 330.

The first and third key may be used to derive a combined key by the computing unit 306, which then decrypts the encrypted data. The decrypted data is then used for instructing the implantable medical device 10 as described above.

25 The second external device 330 may be controlled by for example a caregiver, to further increase security and validity of data sent and decrypted by the controller 300.

It should be noted that in some embodiments, the external device is further configured to receive WL2 secondary wireless communication from
30 the second external device 330, and transmit data received from the secondary wireless communication WL2 to the implantable medical device. This routing of data may be achieved using the wireless transceivers 308, 208

(i.e. the wireless connection WL1, or by using a further wireless connection WL4 between the controller 300 and the external device 320. In these cases, the medical device and/or external device(s) comprises the necessary features and functionality for performing such routing. Consequently, in some
5 embodiments, the third key is generated by the second external device 330 and transmitted WL2 to the external device 320 which routes the third key to the controller 300 to be used for decryption of the encrypted data. In other words, the step of transmitting a third key from a second external device, separate from the external device, to the implant wirelessly, comprises routing
10 the third key through the external device 320. Using the external device 320 as a relay, with or without verification from the patient, may provide an extra layer of security as the external device 320 may not need to store or otherwise handle decrypted information. As such, the external device 320 may be lost without losing decrypted information.

15 In yet other embodiments, a key is transmitted using the confirmed conductive communication channel C1 (i.e. the electrical connection) from the external device 320 to the controller 300. The key is received at the implant (by the first internal transceiver 303). A second key is transmitted from the external device 320 to the controller 300 wirelessly WL1, received at the
20 the controller 300. A third key is transmitted from the second external device, separate from the external device 320, to the controller 300 wirelessly WL4. Encrypted data transmitted from the external device 320 to the controller 300 is then decrypted using a derived combined key from the key, the second key and the third key. The external device may be a wearable external device.

25 The external device 320 may be a handset. The second external device 330 may be a handset. The second external device 330 may be a server. The second external device 330 may be cloud based.

In some embodiments, the electrical connection C1 between the external device 320 and the controller 300 is achieved by placing a
30 conductive member 201, configured to be in connection with the external device 200, in electrical connection with a skin of the patient for conductive communication C1 with the medical device. In these cases, the medical

device and/or external device(s) comprises the necessary features and functionality (described in the respective sections of this document) for performing such conductive communication. The communication may thus be provided with an extra layer of security in addition to the encryption by being

5 electrically confined to the conducting path e.g. external device 320, conductive member 201, conductive connection C1, controller 300, meaning the communication will be excessively difficult to be intercepted by a third party not in physical contact with, or at least proximal to, the patient.

The keys described in this section may in some embodiments be

10 generated based on data sensed by sensors described herein, e.g. using the sensed data as seed for the generated keys. A seed is an initial value that is fed into a pseudo random number generator to start the process of random number generation. The seed may thus be made hard to predict without access or knowledge of the physiological parameters of the patient which it is

15 based on, providing an extra level of security to the generated keys.

Increased security for communication between an external device(s) and an implanted medical device is provided, now described with reference to figs. 65a – 65c.

In these embodiments, a method for communication between an

20 external device 320 and the implantable controller 300 is provided. The wireless transceiver 308 (included in the controller 300) may in some embodiments comprise sub-transceivers for receiving data from the external device 320 and other external devices 330, e.g. using different frequency bands, modulation schemes etc.

25 A first step of the method comprises receiving, at the implanted medical device, by a wireless transmission WL1 or otherwise, a first key from an external device 320. The method further comprises receiving, at the implanted medical device, by a wireless transmission WL1, WL2, WL3, a second key. The second key may be generated by a second external device

30 330, separate from the external device 320 or by another external device being a generator of the second key on behalf of the second external device 330. The second key may be received at the implanted medical device from

anyone of, the external device 320, the second external device 330, and a generator of the second key. The second external device 330 may be controlled by a caretaker, or any other stakeholder. Said another external device may be controlled by a manufacturer of the medical device, or medical
5 staff, caretaker, etc.

In case the medical device is receiving the second key from the external device 320, this means that the second key is routed through the external device from the second external device 330 or from the another external device (generator). In these cases, the medical device and/or
10 external device(s) comprises the necessary features and functionality (described in the respective sections of this document) for performing such routing. Using the external device 320 as a relay, with or without verification from the patient, may provide an extra layer of security as the external device 320 may not need to store or otherwise handle decrypted information. As
15 such, the external device 320 may be lost without losing decrypted information.

The controller 300 comprises a computing unit 306 configured for deriving a combined key by combining the first key and the second key with a third key held by the controller 300, for example in memory 307 of the
20 controller. The combined key may be used for decrypting, by the computing unit 306, encrypted data transmitted by a wireless transmission WL1 from the external device 320 to the controller 300. Optionally, the decrypted data may be used for altering, by the computing unit 306 an operation of the implantable medical device 10. The altering an operation of the implantable
25 medical device may comprise controlling or switching an active unit 302 of the medical device. In some embodiments, the method further comprises at least one of the steps of, based on the decrypted data, updating a control program running in the implant, and operating the implantable medical device 10 using operation instructions in the decrypted data.

30 In some embodiments, further keys are necessary to derive a combined key for decrypting the encrypted data received at the controller 300. In these embodiments, the first and second key are received as

described above. Further, the method comprises receiving, at the implanted medical device, a fourth key from a third external device, the third external device being separate from the external device, deriving a combined key by combining the first, second and fourth key with the third key held by the controller 300, and decrypting the encrypted data, in the controller 300, using the combined key. Optionally, the decrypted data may be used for altering, by the computing unit 306, an operation of the implanted medical device as described above. In some embodiments, the fourth key is routed through the external device from the third external device.

10 In some embodiments, further security measures are needed before using the decrypted data for altering, by the computing unit 306, an operation of the implantable medical device. For example, an electrical connection C1 between the implantable medical device and the external device 320, using the body as a conductor, may be used for further verification of validity of the decrypted data. The electrical connection C1 may be achieved by placing a conductive member 201, configured to be in connection with the external device, in electrical connection with a skin of the patient for conductive communication C1 with the implantable medical device. The communication may thus be provided with an extra layer of security in addition to the encryption by being electrically confined to the conducting path e.g. external device 320, conductive member 201, conductive connection C1, controller 300, meaning the communication will be excessively difficult to be intercepted by a third party not in physical contact with, or at least proximal to, the patient.

Accordingly, in some embodiments, the method comprising confirming the electrical connection between the controller 300 and the external device 320, and as a result of the confirmation, altering an operation of the implantable medical device based on the decrypted data. The confirmation and authentication of the electrical connection may be performed as described herein under the general features section. In these cases, the implantable medical device and/or external device(s) 320 comprises the necessary features and functionality (described in the respective sections of this document) for performing such authentication. By authenticating

according to these aspects, security of the authentication may be increased as it may require a malicious third party to know or gain access to either the transient physiological parameter of the patient or detect randomized sensations generated at or within the patient.

- 5 In some embodiments, the confirmation of the electrical connection comprises: measuring a parameter of the patient, by e.g. a sensor of the implantable medical device 10, measuring the parameter of the patient, by the external device 320, comparing the parameter measured by the implantable medical device to the parameter measured by the external device 320, and
10 authenticating the connection based on the comparison. As mentioned above, as a result of the confirmation, an operation of the implantable medical device may be altered based on the decrypted data.

Further methods for encrypted communication between an external device 320 and an implantable medical device 10 are provided. These
15 methods comprise:

 receiving, at the external device 320 by a wireless transceiver 328, a first key, the first key being generated by a second external device 330, separate from the external device 320 or by another external device being a generator of the second key on behalf of the second external device 320, the
20 first key being received from anyone of the second external device 330 and the generator of the second key,

 receiving, at the external device 320 by the wireless transceiver 328, a second key from the controller 300,

 deriving a combined key, by a computing unit 326 of the external
25 device 320, by combining the first key and the second key with a third key held by the external device 320 (e.g. in memory 327),

 transmitting encrypted data from the implant to the external device and receiving the encrypted data at the external device by the wireless transceiver 328, and

30 decrypting, by the computing unit 326, the encrypted data, in the external device 320, using the combined key.

As described above, further keys may be necessary to decrypt the data. Consequently, the wireless transceiver 328 is configured for:

receiving a fourth key from a third external device,
wherein the computing unit 326 is configured for:

- 5 deriving a combined key by combining the first, second and fourth key
with the third key held by the external device, and
decrypting the encrypted data using the combined key.

In some embodiments, the communication between the controller 300 and the external device 320 needs to be confirmed (authenticated) before
10 decrypting the data. In these cases, the implantable medical device and/or
external device(s) comprises the necessary features and functionality
(described in the respective sections of this document) for performing such
authentication.

These embodiments further increase the security in the
15 communication. In these embodiments the computing unit 326 is configured
to confirm the communication between the implantable medical device and
the external device, wherein the confirmation comprises:

- measuring a parameter of the patient, by the external device 320,
receiving a measured parameter of the patient, from the implantable
20 medical device 10,
comparing the parameter measured by the implantable medical device
320 to the parameter measured by the external device 320,
performing confirmation of the connection based on the comparison,
and
25 as a result of the confirmation, decrypting the encrypted data, in the
external device, using the combined key.

One or more of the first, second and third key may comprise a
biometric key.

The keys described in this section may in some embodiments be
30 generated based on data sensed by sensors, e.g. using the sensed data as
seed for the generated keys. A seed is an initial value that is fed into a
pseudo random number generator to start the process of random number

generation. The seed may thus be made hard to predict without access or knowledge of the physiological parameters of the patient which it is based on, providing an extra level of security to the generated keys.

Further, increased security for communication between an external
5 device(s) 320, 330 and an implantable medical device is provided, described with reference to Figs. 65a – 65c. The system being configured for enabling communication between an external device 320 and the controller 300 implanted in a patient. The system comprises a conductive member 321 configured to be in connection (electrical/conductive or wireless or otherwise)
10 with the external device, the conductive member 321 being configured to be placed in electrical connection with a skin of the patient for conductive communication C1 with the implantable medical device 10. By using a conductive member 321 as defined herein, an increased security for communication between the external device and the implantable medical
15 device may be achieved. For example, when a sensitive update of a control program of the controller 300 is to be made, or if sensitive data regarding physical parameters of the patient is to be sent to the external device 320 (or otherwise), the conductive member 321 may ensure that the patient is aware of such communication and actively participate in validating that the
20 communication may take place. The conductive member may, by being placed in connection with the skin of the patient, open the conductive communication channel C1 between the external device and the controller to be used for data transmission.

Electrical or conductive communication, such as this or as described
25 under the other embodiments, may be very hard to detect remotely, or at least relatively so, in relation to wireless communications such as radio transmissions. Direct electrical communication may further safeguard the connection between the implantable medical device 10 and the external device 320 from electromagnetic jamming i.e. high-power transmissions other
30 a broad range of radio frequencies aimed at drowning other communications within the frequency range. Electrical or conductive communication will be excessively difficult to be intercepted by a third party not in physical contact

with, or at least proximal to, the patient, providing an extra level of security to the communication.

In some embodiments, the conductive member comprises a conductive interface for connecting the conductive member to the external device.

5 In some embodiments, the conductive member 201 is a device which is plugged into the external device 200, and easily visible and identifiable for simplified usage by the patient. In other embodiments, the conductive member 321 is to a higher degree integrated with the external device 320, for example in the form of a case of the external device 320 comprising a
10 capacitive area configured to be in electrical connection with a skin of the patient. In one example, the case is a mobile phone case (smartphone case) for a mobile phone, but the case may in other embodiments be a case for a personal computer, or a body worn camera or any other suitable type of external device as described herein. The case may for example be connected
15 to the phone using a wire from the case and connected to the headphone port or charging port of the mobile phone.

The conductive communication C1 may be used both for communication between the controller 300 and the external device 320 in any or both directions. Consequently, according to some embodiments, the
20 external device 320 is configured to transmit a conductive communication (conductive data) to the controller 300 via the conductive member 321.

According to some embodiments, the controller 300 is configured to transmit a conductive communication to the external device 320. These embodiments start by placing the conductive member 321, configured to be in
25 connection with the external device 320, in electrical connection with a skin of the patient for conductive communication C1 with the controller 300. The conductive communication between the external device 320 and the controller 300 may follow an electrically/conductively confined path comprising e.g. the external device 320, conductive member 321, conductive connection C1,
30 controller 300.

For the embodiments when the external device 320 transmits data to the controller, the communication may comprise transmitting a conductive communication to the controller 300 by the external device 320.

The transmitted data may comprise instructions for operating the
5 implantable medical device 10. Consequently, some embodiments comprise operating the implantable medical device 10 using operation instructions, by an internal computing unit 306 of the controller 300, wherein the conductive communication C1 comprises instructions for operating the implantable medical device 10. The operation instruction may for example involve
10 adjusting or setting up (e.g. properties or functionality of) the active unit 302 of the implantable medical device 10.

The transmitted data may comprise instructions for updating a control program 310 stored in memory 307 of the controller 300. Consequently, some
15 embodiments comprise updating the control program 310 running in the controller 300, by the internal computing unit 306 of the implantable medical device, wherein the conductive communication comprises instructions for updating the control program 310.

For the embodiments when the controller 300 transmits data to the external device 320, the communication may comprise transmitting
20 conductive communication C1 to the external device 320 by the controller 300. The conductive communication may comprise feedback parameters. Feedback parameters could include battery status, energy level at the controller, the fluid level of the hydraulic restriction device, number of operations that the restriction device has performed, properties, version
25 number etc. relating to functionality of the implantable medical device 10. In other embodiments, the conductive communication C1 comprises data pertaining to least one physiological parameter of the patient, such as blood pressure etc. The physiological parameter(s) may be stored in memory 307 of the controller 300 or sensed in prior (in real time or with delay) to transmitting
30 the conductive communication C1. Consequently, in some embodiments, the implantable medical device 10 comprises a sensor 150 for sensing at least one physiological parameter of the patient, wherein the conductive

communication comprises said at least one physiological parameter of the patient.

To further increase security of the communication between the controller 300 and the external device 320, different types of authentication, verification and/or encryption may be employed. In some embodiments, the external device 320 comprises a verification unit 340. The verification unit 340 may be any type of unit suitable for verification of a user, i.e. configured to receive authentication input from a user, for authenticating the conductive communication between the implantable medical device and the external device. In some embodiments, the verification unit and the external device comprises means for collecting authentication input from the user (which may or may not be the patient). Such means may comprise a fingerprint reader, a retina scanner, a camera, a GUI for inputting a code, a microphone, device configured to draw blood, etc. The authentication input may thus comprise a code or any be based on a biometric technique selected from the list of: a fingerprint, a palm vein structure, image recognition, face recognition, iris recognition, a retinal scan, a hand geometry, and genome comparison. The means for collecting the authentication input may alternatively be part of the conductive member which comprise any of the above examples of functionality, such as a fingerprint reader or other type of biometric reader.

In some embodiments, the security may thus be increased by receiving an authentication input from a user by the verification unit 340 of the external device 320, and authenticating the conductive communication between the controller 300 and the external device using the authentication input. Upon a positive authentication, the conductive communication channel C1 may be employed for comprising transmitting a conductive communication to the controller 300 by external device 320 and/or transmitting a conductive communication to the external device 320 by the controller 300. In other embodiments, a positive authentication is needed prior to operating the implantable medical device 10 based on received conductive communication, and/or updating a control program running in the controller 300 as described above.

Figs. 65a – 65c further shows an implantable medical device 10 implanted in a patient and being connected to a sensation generator 381.

The sensation generator 381 may be configured to generate a sensation. The sensation generator 381 may be contained within the
5 implantable medical device 10 or be a separate unit. The sensation generator 381 may be implanted. The sensation generator 381 may also be located so that it is not implanted as such but still is in connection with a patient so that only the patient may experience sensations generated. The controller 300 is configured for storing authentication data, related to the sensation generated
10 by the sensation generator 381.

The controller 300 is further configured for receiving input authentication data from the external device 320. Authentication data related to the sensation generated may be stored by a memory 307 of the controller 300. The authentication data may include information about the generated
15 sensation such that it may be analyzed, e.g. compared, to input authentication data to authenticate the connection, communication or device. Input authentication data relates to information generated by a patient input to the external device 320. The input authentication data may be the actual patient input or an encoded version of the patient input, encoded by the
20 external device 320. Authentication data and input authentication data may comprise a number of sensations or sensation components.

The authentication data may comprise a timestamp. The input authentication data may comprise a timestamp of the input from the patient. The timestamps may be a time of the event such as the generation of a
25 sensation by the sensation generator 381 or the creation of input authentication data by the patient. The timestamps may be encoded. The timestamps may feature arbitrary time units, i.e. not the actual time. Timestamps may be provided by an internal clock 360 of the controller 300 and an external clock 362 of the external device 320. The clocks 360, 362
30 may be synchronized with each other. The clocks 360, 362 may be synchronized by using a conductive connection C1 or a wireless connection WL1 for communicating synchronization data from the external device 320,

and its respective clock 362, to the controller 300, and its respective clock 360, and vice versa. Synchronization of the clocks 360, 362 may be performed continuously and may not be reliant on secure communication.

Authentication of the connection may comprise calculating a time
5 difference between the timestamp of the sensation and the timestamp of the input from the patient, and upon determining that the time difference is less than a threshold, authenticating the connection. An example of a threshold may be 1s. The analysis may also comprise a low threshold as to filter away input from the patient that is faster than normal human response times. The
10 low threshold may e.g. be 50ms.

Authentication data may comprise a number of times that the sensation is generated by the sensation generator, and wherein the input authentication data comprises an input from the patient relating to a number of times the patient detected the sensation. Authenticating the connection may then
15 comprise: upon determining that the number of times that the authentication data and the input authentication data are equal, authenticating the connection.

A method of authenticating the connection between an implantable medical device 10 implanted in a patient, and an external device 320
20 according includes the following steps.

Generating, by a sensation generator 381, a sensation detectable by a sense of the patient. The sensation may comprise a plurality of sensation components. The sensation or sensation components may comprise a vibration (e.g. a fixed frequency mechanical vibration), a sound (e.g. a
25 superposition of fixed frequency mechanical vibrations), a photonic signal (e.g. a non-visible light pulse such as an infra-red pulse), a light signal (e.g. a visual light pulse), an electric signal (e.g. an electrical current pulse) or a heat signal (e.g. a thermal pulse). The sensation generator may be implanted, configured to be worn in contact with the skin of the patient or capable of
30 creating sensation without being in physical contact with the patient, such as a beeping alarm.

Sensations may be configured to be consistently felt by a sense of the patient while not risking harm to or affecting internal biological processes of the patient.

The sensation generator 381, may be contained within the controller
5 300 or be a separate entity connected to the controller 300. The sensation may be generated by a motor (denoted as M in several embodiments shown herein) of the implantable medical device 10, wherein the motor being the sensation generator 381. The sensation may be a vibration, or a sound created by running the motor. The sensation generator 381 may be located
10 close to a skin of the patient and thus also the sensory receptors of the skin. Thereby the strength of some signal types may be reduced.

Storing, by the controller 300, authentication data, related to the generated sensation.

Providing, by the patient input to the external device, resulting in input
15 authentication data. Providing the input may e.g. comprise an engaging an electrical switch, using a biometric input sensor or entry into digital interface running on the external device 320 to name just a few examples.

Transmitting the input authentication data from the external device to the controller 300. If the step was performed, the analysis may be performed
20 by the controller 300.

Transmitting the authentication data from the implantable medical device 10 to the external device 320. If the step was performed, the analysis may be performed by the external device 320. The wireless connection WL1 or the conductive connection C1 may be used to transmit the authentication
25 data or the input authentication data.

Authenticating the connection based on an analysis of the input authentication data and the authentication data e.g. by comparing a number of sensations generated and experienced or comparing timestamps of the authentication data and the input authentication data. If step was performed,
30 the analysis may be performed by the implantable medical device 10.

Communicating further data between the controller 300 and the external device 320 following positive authentication. The wireless connection

WL1 or the conductive connection C1 may be used to communicate the further data. The further data may comprise data for updating a control program 310 running in the controller 300 or operation instructions for operating the implantable medical device 10. The further data may also
5 comprise data sensed by a sensor 150 connected to the controller 300. The controller may comprise at least one unit having a sleep mode and an active mode, and the unit consumes less energy in the sleep mode than in the active mode. The unit is configured to switch from the sleep mode to the active mode on the basis of at least one signal from the sensor. The unit
10 could for example be a DSP (Digital Signal Processor), another type of processor or a wake-up circuit of the controller, which in turn activates the functions of the controller. The unit may be configured to switch from the sleep mode to the active mode on the basis of a signal from the sensor related to the patient swallowing a number of times and/or on the basis of a
15 signal from the sensor related to the patient swallowing a number of times during a time period. The number of times the patient swallows and the time could be counted/measured and compared with a pre-set or moving threshold value. The controller could further comprise at least one filtering unit configured to filter signals related to at least one of: speech, the swallowing of
20 saliva and chewing. The filter could be a digital filter implemented as hardware or software in the controller and could have the filter characteristics of a high, low or bandpass filter.

If the analysis was performed by the controller 300, the external device 320 may continuously request or receive, information of an authentication
25 status of the connection between the controller 300 and the external device 320, and upon determining, at the external device 320, that the connection is authenticated, transmitting further data from the external device 320 to the controller 300.

If the analysis was performed by the external device 320, the controller
30 300 may continuously request or receive, information of an authentication status of the connection between the controller 300 and the external device 320, and upon determining, at the controller 300, that the connection is

authenticated, transmitting further data from the controller 300 to the external device 320.

A main advantage of authenticating a connection according to this method is that only the patient may be able to experience the sensation.

- 5 Thus, only the patient may be able to authenticate the connection by providing authentication input corresponding to the sensation generation.

The sensation generator 381, sensation, sensation components, authentication data, input authentication data, and further data may be further described herein. In these cases, the implantable medical device 10 and/or
10 external device(s) comprises the necessary features and functionality (described in the respective sections of this document). Further information and definitions can be found in this document in conjunction with the other aspects.

The method may further comprise transmitting further data between
15 the controller 300 and the external device, wherein the further data is used or acted upon, only after authentication of the connection is performed.

The analysis or step of analyzing may be understood as a comparison or a step of comparing.

In one method, increased security for communication between an
20 external device(s) and an implanted controller is provided. Figs. 65a – 65c show an implantable medical device 10 comprising a controller 300 and an external device 320 which may form a system.

The controller 300 comprises a transceiver 308, 303 configured to establish a connection with an external device 320, i.e. with a corresponding
25 transceiver 328, 323. The connection may be an electrical connection C1 using the transceivers 303, 323, or a wireless connection WL1 using the transceivers 308, 328. The controller 300 further comprises a computing unit 306 configured to verify the authenticity of instructions received at the transceiver 308, 303 from the external device 320. In this aspect, the concept
30 of using previously transmitted instructions for verifying a currently transmitted instructions are employed. Consequently, the transmitting node (in this case the external device) need to be aware of previously instructions transmitted to

the implantable medical device, which reduces the risk of a malicious device instructing the implant without having the authority to do so.

In an embodiment, the computing unit 306 is configured to verify the authenticity of instructions received at the transceiver 308, 303 by extracting a
5 previously transmitted set of instructions from a first combined set of instructions received by the transceiver. The external device 320 may thus comprise an external device comprising a computing unit 326 configured for: combining a first set of instructions with a previously transmitted set of instructions, forming a combined set of instructions, and transmitting the
10 combined set of instructions to the implantable medical device. The previously transmitted set of instructions, or a representation thereof, may be stored in memory 327 of the external device 320.

The combined set of instructions may have a data format which facilitates such extraction, for example including metadata identifying data
15 relating to the previously transmitted set of instructions in the combined set of instructions. In some embodiments, the combined set of instructions comprises the first set of instructions and a cryptographic hash of the previously transmitted set of instructions. Consequently, the method comprises combining, at the external device, a first set of instructions with a
20 previously transmitted set of instructions, forming a first combined set of instructions. A cryptographic hash function is a special class of hash function that has certain properties which make it suitable for use in cryptography. It is a mathematical algorithm that maps data of arbitrary size to a bit string of a fixed size (a hash) and is designed to be a one-way function, that is, a
25 function which is infeasible to invert. Examples include MD5, SHA1, SHA 256, etc. Increased security is thus achieved.

The first combined set of instructions is then transmitted to the implanted controller 300, where it is received by e.g. the transceiver 303, 308. The first combined set of instructions may be transmitted to the implantable
30 medical device using a proprietary network protocol. The first combined set of instructions may be transmitted to the controller 300 using a standard network protocol. In these cases, the controller 300 and/or external device(s)

comprises the necessary features and functionality (described in the respective sections of this document) for performing transmission of data. By using different communication protocols, at the external device 320, for communication with the controller 300 and with a second external device 330, an extra layer of security is added as the communication between controller 300 and the external device 320 may be made less directly accessible to remote third parties.

At the controller 300, the computing unit 306 verifies the authenticity of the received first combined set of instructions, by: extracting the previously transmitted set of instructions from the first combined set of instructions, and comparing the extracted previously transmitted set of instructions with previously received instructions stored in the implantable medical device.

Upon determining that the extracted previously transmitted set of instructions equals the previously received instructions stored in the controller 300, the authenticity of the received first combined set of instructions may be determined as valid, and consequently, the first set of instructions may be safely run at the controller 300, and the first combined set of instructions may be stored in memory 307 of the controller 300, to be used for verifying a subsequent received set of instructions.

In some embodiments, upon determining by the internal computing unit 306 that the extracted previously transmitted set of instructions differs from the previously received instructions stored in the controller 300, feedback related to an unauthorized attempt to instruct the implantable medical device 10 may be provided. For example, the transceiver 308, 303 may send out a distress signal to e.g. the external device 320 or to any other connected devices. The controller 300 may otherwise inform the patient that something is wrong by e.g. vibration or audio. The implantable medical device 10 may be run in safe mode, using a preconfigured control program which is stored in memory 307 of the controller 300 and specifically set up for these situations, e.g. by requiring specific encoding to instruct the implantable medical device 10, or only allow a predetermined device (e.g. provided by the manufacturer) to instruct the implantable medical device 10. In some embodiments, when

receiving such feedback at the external device 320, the external device 320 retransmits the first combined set of instructions again, since the unauthorized attempt may in reality be an error in transmission (where bits of the combined set of instructions are lost in transmission), and where the attempt to instruct the implantable medical device 10 is indeed authorized.

The step of comparing the extracted previously transmitted set of instructions with previously received instructions stored in the controller 300 may be done in different ways. For example, the step of comparing the extracted previously transmitted set of instructions with previously received instructions stored in the controller 300 comprises calculating a difference between the extracted previously transmitted set of instructions with previously received instructions stored in the controller 300, and comparing the difference with a threshold value, wherein the extracted previously transmitted set of instructions is determined to equal the previously received instructions stored in the controller 300 in the case of the difference value not exceeding the threshold value. This embodiment may be used when received instructions is stored in clear text, or a representation thereof, in the controller 300, and where the combined set of instructions, transmitted from the external device also includes such a representation of the previously transmitted instructions. This embodiment may be robust against error in transmission where bits of information are lost or otherwise scrambled.

In other embodiments, the combined set of instructions comprises the first set of instructions and a cryptographic hash of the previously transmitted set of instructions, wherein the method further comprises, at the controller 300, calculating a cryptographic hash of the previously received instructions stored in the controller 300 and comparing the calculated cryptographic hash to the cryptographic hash included in the first combined set of instructions. This embodiment provides increased security since the cryptographic hash is difficult to decode or forge.

The above way of verifying the authenticity of received instructions at the controller 300 may be iteratively employed for further sets of instructions.

To further increase security, the transmission of a first set of instructions, to be stored at the controller 300 for verifying subsequent sets of combined instructions, where each set of received combined instructions will comprise data which in some form will represent, or be based on, the first set of instruction, may be performed.

In one example, the external device 320 may be adapted to communicate with the controller 300 using two separate communication methods. A communication range of a first communication method WL1 may be less than a communication range of a second communication method WL2. A method may comprise the steps of: sending a first part of a key from the external device 320 to the controller 300, using the first communication method WL1 and sending a second part of the key from the external device 320 to the controller 300, using the second communication method WL2. The method may further comprise deriving, in the controller 300, a combined key from the first part of the key and the second part of the key and decrypting the encrypted data, in the controller 300, using the combined key. The encrypted data may also be sent from the external device 320 to the controller 300 using the second communication method WL2. The method may then further comprise confirming an electrical connection C1 between the controller 300 and the external device 320 and as a result of the confirmation, decrypting the encrypted data in the controller 300 and using the decrypted data for instructing the controller 300.

The method may also comprise placing a conductive member 321, configured to be in connection with the external device 320, in electrical connection with a skin of the patient for conductive communication with the controller 300. By means of the electrical connection an extra layer of security is added as a potential hacker would have to be in contact with the patient to access or affect the operation of the implantable medical device 10.

Using a plurality of communication methods, may increase the security of the authentication and the communication with the implantable medical device 10 as more than one channel for communication may need to be

hacked or hijacked by an unauthorized entity to gain access to the implantable medical device 10 or the communication.

The electrical connection C1 the conductive member 321 and conductive communication may be further described herein in the general definitions section. In these cases, the controller 300 and/or external device 320 comprise the necessary features and functionality (described in the respective sections of this document).

It should also be noted that any one of the first and second communication methods WL1, WL2 may be needed to be confirmed in order to decrypt the encrypted data in the controller 300 and using the decrypted data for instructing the implantable medical device 10.

The method may further comprise the step of wirelessly receiving, at the controller 300, a third part of the key from the second external device 330. In this case, the combined key may be derived from the first part of the key, the second part of the key and the third part of the key.

The first communication method WL1 may be a wireless form of communication. The first communication method WL1 may preferably be a form of electromagnetic or radio-based communication however, other forms of communication are not excluded. The first communication method WL1 may comprise or be related to the items of the following list: Radio-frequency identification (RFID), Bluetooth, Bluetooth 5, Bluetooth Low Energy (BLE), Near Field Communication (NFC), NFC-V, Infrared (IR) based communication, Ultrasound based communication.

RFID communication may enable the use of a passive receiver circuit such as those in a RFID access/key or payment card. IR based communication may comprise fiber optical communication and IR diodes. IR diodes may alternatively be used directly, without a fiber, such as in television remote control devices. Ultrasound based communication may be based on the non-invasive, ultrasound imaging found in use for medical purposes such as monitoring the development of mammal fetuses.

The first communication method WL1 may use a specific frequency band. The frequency band of the first communication method WL1 may have

a center frequency of 13.56 MHz or 27.12 MHz. These bands may be referred to as industrial, scientific and medical (ISM) radio bands. Other ISM bands not mentioned here may also be utilized for the communication methods WL1, WL2. A bandwidth of the 13.56 MHz centered band may be 14 kHz and
5 a bandwidth of the 27.12 MHz centered band may be 326 kHz.

The communication range of the first communication method WL1 may be less than 10 meters, preferably less than 2 meters, more preferably less than 1 meter and most preferably less than 20 centimeters. The communication range of the first communication method WL1 may be limited
10 by adjusting a frequency and/or a phase of the communication. Different frequencies may have different rates of attenuation. By implementing a short communication range of the first communication method, security may be increased since it may be ensured or made probable that the external device is under control of the patient (holding the external device close to the
15 implant)

The communication range of the first communication method WL1 should be evaluated by assuming that a patient's body, tissue, and bones present the propagation medium. Such a propagation medium may present different attenuation rates as compared to a free space of an air-filled
20 atmosphere or a vacuum.

By restricting the communication range, it may be established that the external device communicating with the implanted controller 300 is in fact on, or at least proximal to, the patient. This may add extra security to the communication.

25 The second communication method WL2 may be a wireless form of communication. The second communication method WL2 may preferably be a form of electromagnetic or radio-based communication. The second communication method WL2 may be based on telecommunication methods. The second communication method WL2 may comprise or be related to the
30 items of the following list: Wireless Local Area Network (WLAN), Bluetooth, Bluetooth 5, BLE, GSM or 2G (2nd generation cellular technology), 3G, 4G, 5G.

The second communication method WL2 may utilize the ISM bands as mentioned in the above for the first communication method WL1.

A communication range of the second communication method WL2 may be longer than the communication range of the first communication method WL1. The communication range of the second communication method WL2 may preferably be longer than 10 meters, more preferably longer than 50 meters, and most preferably longer than 100 meters.

Encrypted data may comprise instructions for updating a control program 310 running in the implantable medical device 10. Encrypted data may further comprise instructions for operating the implantable medical device 10.

In one embodiment, the implantable medical device 10 may transmit data to an external device 320 which may add an additional layer of encryption and transmit the data to a second external device 330, described with reference to figs. 65a – 65c. By having the external device add an additional layer of encryption, less computing resources may be needed in the implanted controller 300, as the controller 300 may transmit unencrypted data or data encrypted using a less secure or less computing resource requiring encryption. In this way, data can still be relatively securely transmitted to a third device. The transmission of data can be performed using any of the method described herein in addition to the method or in the system described below.

Thus, in an embodiment, a system is provided. The system comprises an implantable medical device 10 comprising a controller 300 configured to transmit data from the body of the patient to an external device 320, and an encryption unit 382 for encrypting the data to be transmitted. The system further comprises an external device 320 configured to receive the data transmitted by the controller 300, encrypt the received data using a first key and transmit the encrypted received data to a third external device 330. The encryption can be performed using any of the keys described above or below. In some embodiments, the external device 320 is configured to decrypt the data received from the controller 300 before encrypting and transmitting the

data. Alternatively, the external device 320 may encrypt and transmit the data received from the controller 300 without decrypting it first.

In one example, the encryption unit 382 is configured to encrypt the data to be transmitted using a second key. The first key or the second key
5 may, for example, information specific to the implantable medical device 10, a secret key associated with the external device 320, an identifier of the implantable medical device 10 or an identifier of the controller 300. The second key could be a key transmitted by the external device 320 to the controller 300. In some examples, the second key is a combined key
10 comprising a third key received by the controller 300 from the external device 320.

The first key may be a combined key comprising a fourth key, wherein the fourth key is received by the external device 320 from a fourth device. The fourth device may be a verification unit, either comprised in the external
15 device, or external to the external device and connected to it. The verification unit may have a sensor 350 for verification, such as a fingerprint sensor. More details in regard to this will be described below. Alternatively, the verification unit may be a generator, as described above.

The system may be configured to perform a method for transmitting
20 data using a sensed parameter. The method may comprise transmitting a parameter measured by the external device 320 from the external device 320 to the controller 300. In this case, the comparison of the parameter of the patient measured by the external device 320 and the parameter of the patient measured by the controller 300 may be performed by the controller 300. The
25 implantable medical device 10 may comprise a first sensor 150 for measuring the parameter of the patient at the implantable medical device 10. The external device 320 may comprise an external sensor 350 for measuring the parameter of the patient at the external device 320.

Authentication of the connection between the controller 300 and the
30 external device 320 may be performed automatically without input, authentication, or verification from a user or patient. This is because the comparison of parameters measured internally and externally, by the internal

and external sensors 351, 350 respectively may be enough to authenticate the connection. This may typically be the case when the parameter of the patient is related to an automatically occurring physiological function of the patient such as e.g. a pulse of the patient. Certain types of authentication may
5 however require actions from the patient, e.g. having the patient perform specific movements.

In the embodiments described herein, the controller 300 may comprise or be connected to a sensation generator 381 as described above. In response to an event in the implantable medical device, such as a reset, a
10 restart, receipt of new instructions, receipt of a new configuration or update, installation or activation of new instructions or configuration or update, the controller 300 may be configured to cause the sensation generator 381 to generate a sensation detectable by the patient in which the implantable medical device 10 is implanted. In some examples, the user may after the
15 sensation verify an action, for example via a user interface of an external device 320.

The implantable medical device 10 may further implement a method for improving the security of the data transmitted from the controller 300. The method, for encrypted communication between a controller 300, when
20 implanted in a patient's body, and an external device 320, comprises encoding or encrypting, by the controller 300 or a processor 306 comprised in or connected to the controller 300, data relating to the implantable medical device 10 or the operation thereof; transmitting, by the controller 300, the data; receiving, by a second communication unit comprised the external
25 device 320, the data; encrypting, by the external device 320, the data using an encryption key to obtain encrypted data; and transmitting the encrypted data to a third external device 330. In this way, the external device 320 may add or exchange the encryption, or add an extra layer of encryption, to the data transmitted by the controller 300. When the controller 300 encodes the
30 data to be transmitted it may be configured to not encrypt the data before transmitting, or only using a light-weight encryption, thus not needing as much

processing power as if the controller were to fully encrypt the data before the transmission.

The encrypting, by the controller 300, may comprise encrypting the data using a second key. The encryption using the second key may be a
5 more light-weight encryption than the encryption performed by the external device using the second key, i.e. an encryption that does not require as much computing resources as the encryption performed by the external device 320.

The first or the second key may comprise a private key exchanged as described above with reference to encryption and authentication, or the first
10 or the second key may comprise an information specific to the implantable medical device 10, a secret key associated with the external device, an identifier of the implantable medical device 10 or an identifier of the controller 300. They may be combined keys as described in this description, and the content of the keys, any combination of keys, and the exchange of a key or
15 keys is described in the encryption and/or authentication section.

In an embodiment, the implantable medical device 10 comprises at least one sensor for sensing at least one physiological parameter of the patient or a functional parameter of the implantable medical device 10, now described with reference to figs. 65a – 65c. The sensor 351 may, for
20 example, be a pressure sensor, an electrical sensor, a clock, a temperature sensor, a motion sensor, an optical sensor, an acoustic sensor, an ultrasonic sensor. The sensor 351 is configured to periodically sense the parameter and the controller 300 is configured to, in response to the sensed parameter being above a predetermined threshold, wirelessly broadcast information relating to
25 the sensed parameter. The controller 300 may be configured to broadcast the information using a short to mid-range transmitting protocol, such as a Radio Frequency type protocol, a RFID type protocol, a WLAN type protocol, a Bluetooth type protocol, a BLE type protocol, a NFC type protocol, a 3G/4G/5G type protocol, or a GSM type protocol.

30 The controller of the implant may be connected to the sensor 351 and be configured to anonymize the information before it is transmitted. The transmission of data may also be called broadcasting of data.

In addition to or as an alternative to transmitting the data when the sensed parameter is above a predetermined threshold, the controller 300 may be configured to broadcast the information periodically. The controller 300 may be configured to broadcast the information in response to a second
5 parameter being above a predetermined threshold. The second parameter may, for example, be related to the controller 300 itself, such as a free memory or free storage space parameter, or a battery status parameter. When the implantable medical device 10 comprises an implantable energy storage unit and an energy storage unit indicator, the energy storage unit
10 indicator is configured to indicate a functional status of the implantable energy storage unit and the indication may be comprised in the transmitted data. The functional status may indicate at least one of charge level and temperature of the implantable energy storage unit.

In some embodiments the external device 320 is configured to receive
15 the broadcasted information, encrypt the received information using an encryption key and transmit the encrypted received information. In this way, the external device 320 may add an additional layer of encryption or exchange the encryption performed by the controller 300.

In an embodiment, the controller 300 is configured to transmit the data
20 using the body of the patient as a conductor C1, and the external device 320 is configured to receive the data via the body. Alternatively, or in combination, the controller 300 of the implant is configured to transmit the data wirelessly to the external device WL2.

Thus, the controller 300 may implement a method for transmitting data
25 from the controller 300 comprising a processor 306, comprising: obtaining sensor measurement data via a sensor 150 connected to or comprised in the controller 300, the sensor measurement relating to at least one physiological parameter of the patient or a functional parameter of the implantable medical device 10, and transmitting by the controller 300 the sensor measurement
30 data in response to the sensor measurement being above a predetermined threshold, wherein the sensor 150 is configured to periodically sense the parameter. The method may further comprise broadcasting the sensor

measurement data, to be received by an external device 320. The transmitting or broadcasting may comprise using at least one of a Radio Frequency type protocol, RFID type protocol, WLAN type protocol, Bluetooth type protocol, BLE type protocol, NFC type protocol, 3G/4G/5G type protocol, or a GSM type protocol.

The method may further comprise, at the processor 306, anonymizing, by the processor, the sensor measurement data before it is transmitted, or encrypting the sensor measurement data, using an encryptor 382 comprised in the processing unit 306, before it is transmitted. The transmitting of the data may further comprise to encode the data before the transmitting. The type of encoding may be dependent on the communication channel or the protocol used for the transmission.

The transmitting may be performed periodically, or in response to a signal received by the processor, for example, by an internal part of the implantable medical device 10 such as a sensor 150, or by an external device 320.

The parameter may, for example, be at least one of a functional parameter of the implantable medical device 10 (such as a battery parameter, a free memory parameter, a temperature, a pressure, an error count, a status of any of the control programs, or any other functional parameter mentioned in this description) or a parameter relating to the patient (such as a temperature, a blood pressure, or any other parameter mentioned in this description). In one example, the implantable medical device 10 comprises an implantable energy storage unit 40 and an energy storage unit indicator 304c, and the energy storage unit indicator 304c is configured to indicate a functional status of the implantable energy storage unit 40, and the sensor measurement comprises data related to the energy storage unit indicator.

In one example, the transmitting comprises transmitting the sensor measurement to an internal processor 306 configured to cause a sensation generator 381 to cause a sensation detectable by the patient in which the implantable medical device 100 is implanted.

The method may be implemented in a system comprising the implantable medical device 100 and an external device 320, and further comprise receiving the sensor measurement data at the external device 320, and, at the external device 320, encrypting the sensor measurement data
5 using a key to obtain encrypted data, and, transmitting the encrypted data. The transmitting may, for example, be performed wirelessly WL3 or conductively C1.

In the examples or embodiments transmitting data from or to the implantable medical device 10, the following method may be implanted in
10 order to verify the integrity of the data, described with reference to figs. 65a – 65b. By verifying the integrity of the data, an external device 320 or a processor 306 comprised in the controller 300 may verify that the data has not been corrupted or tampered with during the transmission. In some examples, data integrity for data communicated between a controller 300 and
15 an external device 320 or between an external device 320 and the controller 300 may be performed using a cyclic redundancy check.

Thus, in a first example, a method for evaluating a parameter of a controller 300 implanted in a patient is described. The controller 300 comprises a processor 306 and a sensor 150 for measuring the parameter.
20 The method comprises measuring, using the sensor 150, the functional parameter to obtain measurement data; establishing a connection between the internal controller 300 and an external device 320 configured to receive data from the implant; determining, by the processor 306, a cryptographic hash or a metadata relating to the measurement data and adapted to be used
25 by the external device 320 to verify the integrity of the received data; transmitting the cryptographic hash or metadata; and transmitting, from the controller 300, the measurement data.

The parameter may, for example, be a parameter of the controller 300, such as a temperature, a pressure, a battery status indicator, a time period
30 length, a pressure at a restriction device, a pressure at a sphincter, or a physiological parameter of the patient, such as a pulse, a blood pressure, or a temperature. In some examples, multiple parameters may be used.

The method may further comprise evaluating the measurement data relating to the functional parameter. By evaluating it may be meant to determine if the parameter is exceeding or less than a predetermined value, to extract another parameter from the measurement data, compare the
5 another parameter to a predetermined value, or displaying the another parameter to a user. For example, the method may further comprise, at the external device 320, to determining, based on the evaluating, that the implantable medical device 10 is functioning correctly, or determining based on the evaluating that the implantable medical device 10 is not functioning
10 correctly.

If it is determined that the implantable medical device 10 is not functioning correctly, the method may further comprise sending, from the external device 320, a corrective command to the controller 300, receiving the corrective command at the controller 300, and by running the corrective
15 command correcting the functioning of the implantable medical device 10 according to the corrective command.

The method may further comprise, at the external device 320, receiving the transmitted cryptographic hash or metadata, receiving the measurement data, and verifying the integrity of the measurement data using
20 the cryptographic hash or metadata. The cryptographic hash algorithm be any type of hash algorithm, i.e. an algorithm comprising a one-way function configured to have an input data of any length as input and produce a fixed-length hash value. For example, the cryptographic hash algorithm may be MD5, SHA1, SHA 256, etc.

25 In some examples, the cryptographic hash is a signature obtained by using a private key of the controller 300, and wherein the verifying, by the external device 320, comprises verifying the signature using a public key corresponding to the private key.

When using a cryptographic hash, the method may further comprise
30 calculating a second cryptographic hash for the received measurement data using a same cryptographic hash algorithm as the processor, and determining that the measurement data has been correctly received based on that the

cryptographic hash and the second cryptographic hash are equal (i.e. have the same value).

When using a metadata the verifying the integrity of the data may comprises obtaining a second metadata for the received measurement data relating to the functional parameter, and determining that the data has been correctly received based on that metadata and the second metadata are equal. The metadata may, for example, be a length of the data or a timestamp. In some examples the measurement data is transmitted in a plurality of data packets. In those examples, the cryptographic hash or metadata comprises a plurality of cryptographic hashes or metadata each corresponding to a respective data packet, and the transmitting of each the cryptographic hashes or metadata is performed for each of the corresponding data packets.

A similar method may be utilized for communicating instructions from an external device 320 to a controller 300 implanted in a patient. The method comprises establishing a first connection between the external device 320 and the controller 300, establishing a second connection between a second external device 330 and the controller 300, transmitting, from the external device 320, a first set of instructions to the controller 300 over the first connection, transmitting, from the second external device 330, a first cryptographic hash or metadata corresponding to the first set of instructions to the controller 300, and, at the controller 300, verifying the integrity of the first set of instructions and the first cryptographic hash or metadata, based on the first cryptographic hash or metadata. The external device 320 may be separate from the second external device 330.

The first connections may be established between the controller 300 and a transceiver of the external communication unit 323. In some examples, the communication using the second connection is performed using a different protocol than a protocol used for communication using the first communication channel. In some examples, the first connection is a wireless connection and the second connection is an electrical connection. The second connection may, for example, be an electrical connection using the

patient's body as a conductor (using 321). The protocols and ways of communicating may be any communication protocols described in this description with reference to C1, and WL1-WL4. The establishing of the first and second connections are performed according to the communication
5 protocol used for each of the first and the second connections.

When using a cryptographic hash, the verifying the integrity of the first set of instructions may comprise calculating a second cryptographic hash for the received first set of instructions using a same cryptographic hash algorithm as the processor 306, and determining that the first set of
10 instructions has been correctly received based on that the cryptographic hash and the second cryptographic hash are equal. The cryptographic hash may, for example, be a signature obtained by using a private key of the implantable medical device 10, and wherein the verifying comprises verifying the signature using a public key corresponding to the private key. In some
15 examples, the cryptographic hash is a signature obtained by using a private key of the implantable medical device 10, and wherein the verifying comprises verifying the signature using a public key corresponding to the private key. The private keys and public keys, as well as the exchange or transmittal of keys have been described in this description. Alternatively, other
20 well-known methods can be used for transmitting or exchanging a key or keys between the external device 320 and the controller 300.

When using a metadata, and wherein the verifying the integrity of the data may comprise obtaining a second metadata for the received first set of instructions, and determining that the first set of instructions has been
25 correctly received based on that metadata and the second metadata are equal. The metadata may, for example, be any type of data relating to the data to be transmitted, in this example the first set of instructions. For example, the metadata may be a length of the data to be transmitted, a timestamp on which the data was transmitted or retrieved or obtained, a size,
30 a number of packets, or a packet identifier.

In some examples, the controller 300 may transmit data to an external device 320 relating to the data information in order to verify that the received

data is correct. The method may thus further comprise, transmitting, by the controller 300, information relating to the received first set of instructions, receiving, by the external device 320, the information, and verifying, by the external device 320, that the information corresponds to the first set of instructions sent by the external device 320. The information may, for example, comprise a length of the first set of instructions.

The method may further comprise, at the controller 300, verifying the authenticity of the first set of instructions by i. calculating a second cryptographic hash for the first set of instructions, ii. comparing the second cryptographic hash with the first cryptographic hash, iii. determining that the first set of instructions are authentic based on that the second cryptographic hash is equal to the first cryptographic hash, and upon verification of the authenticity of the first set of instructions, storing them at the controller 300.

In some examples, the first set of instructions comprises a cryptographic hash corresponding to a previous set of instruction, as described in other parts of this description.

In some examples, the first set of instructions may comprise a measurement relating to the patient of the body for authentication, as described in other parts of this description.

A system and a method for communication of instructions or control signals between an external device 320 and an implantable medical device 10 will now be described with reference to Figs. 65a – 65c.

The system shown in Figs. 65a – 65c comprises an implantable medical device 10, a first external device 320, and a second external device 330. The implantable medical device a controller 300. The controller 300 is adapted to receive an instruction from an external device 320 over the communication channel WL1, C1 and run the instruction to control a function of the medical device 10. The communication channel WL1, C1 may be any type of communication channel, such as a wireless connection WL1 or a conductive connection C1 described herein. For example, the wireless connection may comprise at least one of the following protocols: Radio Frequency type protocol, RFID type protocol, WLAN type protocol, Bluetooth

type protocol, a BLE type protocol, a NFC type protocol, a 3G/4G/5G/6G type protocol, a GSM type protocol, and/or Bluetooth 5.

The first external device 320 is adapted to receive, such as through a user interface, or determine an instruction to be transmitted to the implantable medical device 10. The determination of the instruction may, for example, be based on received data from the implantable medical device 10, such as measurement data or data relating to a state of the implantable medical device 10, such as a battery status or a free memory status. The first external device 320 may be any type of device capable of transmitting information to the implantable medical device and capable of determining or receiving an instruction to be transmitted to the implantable medical device 10. In a preferred embodiment, the first external device 320 is a hand-held device, such as a smartphone, smartwatch, tablet etc. handled by the patient, having a user interface for receiving an instruction from a user, such as the patient or a caregiver.

The first external device 320 is further adapted to transmit the instruction to a second external device 330 via communication channel WL3. The second external device 320 is adapted to receive the instruction, encrypt the instruction using an encryption key, and then transmit the encrypted instruction to the implantable medical device 10. The implantable medical device 10 is configured to receive the instruction at the controller 300. The controller 300 thus comprises a wired transceiver or a wireless transceiver for receiving the instruction. The implantable medical device 10 is configured to decrypt the received instruction. The decryption may be performed using a decryption key corresponding to the encryption key. The encryption key, the decryption key and methods for encryption/decryption and exchange of keys may be performed as described in the "general definition of features" or as described with reference to Figs. 65a – 65c. Further, there are many known methods for encrypting data which the skilled person would understand to be usable in this example.

The second external device 330 may be any computing device capable of receiving, encrypting and transmitting data as described above. For

example, the second external device 320 may be a network device, such as a network server, or it may be an encryption device communicatively coupled to the first external device.

The instruction may be a single instruction for running a specific function or method in the implantable medical device 10, a value for a parameter of the implantable medical device 10, or a set of sub-steps to be performed by the controller 300 comprised in the implantable medical device 10.

In this way, the instruction for controlling a function of the implantable medical device 10 may be received at the first external device 320 and transmitted to the implantable medical device 10 via the second external device 330. By having a second external device 330 encrypting the instruction before transmitting it to the implantable medical device 10, the instruction may be verified by the second external device 330 and the first external device 320 may function so as to relay the instruction. In some alternatives, the second external device 330 may transmit the instruction directly to the implantable medical device 10. This may provide an increased security as the instruction sent to the implantable medical device 10 may be verified by the second external device 330, which, for example, may be a proprietary device managed by the medical professional responsible for the implantable medical device 10. Further, by having the second external device 330 verifying and encrypting the instruction, the responsibility authenticity and/or correctness of the instruction may lie with the second external device 330, which may be beneficial for regulatory purposes, as the first external device 320 may not be considered as the instructor of the implantable medical device 10.

Further, the second external device 330 may verify that the instruction is correct before encrypting or signing and transmitting it to the implantable medical device 10. The second external device 330 may, for example, verify that the instruction is correct by comparing the instruction with a predetermined set of instructions, and if the instruction is comprised in the predetermined set of instructions determine that the instruction is correct. If the instruction comprises a plurality of sub-steps, the second external device

330 may determine that the instruction is correct if all the sub-steps are comprised in the predetermined set of instructions. If the instruction comprises a value for a parameter of the implantable medical device 10, the second external device 330 may verify that the value is within a
5 predetermined range for the parameter. The second external device 320 may thus comprise a predetermined set of instructions, or a predetermined interval or threshold value for a value of a parameter, stored at an internal or external memory.

The second external device 330 may be configured to reject the
10 instruction, i.e. to not encrypt and transmit the instruction to the implantable medical device 10, if the verification of the instruction would fail. For example, the second external device 330 determines that the instruction or any sub-step of the instruction is not comprised in the predetermined set of instructions, or if a value for a parameter is not within a predetermined
15 interval, the second external device 330 may determine that the verification has failed.

In some embodiments, the implantable medical device 10 may be configured to verify the instruction. The verification of the instruction may be performed in the same way as described with reference to Figs. 65a – 65c. If
20 the verification is performed by comparing the instruction or any sub-steps of the instruction with a predetermined set of instructions, the controller 300 may comprise a predetermined set of instructions. The predetermined set of instructions may, for example, be stored in an internal memory of the controller 300. Similarly, the controller 300 may store predetermined
25 reference intervals for any parameter that can be set, and the controller 300 may be configured to compare a received value for a parameter to such a predetermined reference interval. If the verification of the instruction would fail, the controller 300 may be configured to reject the instruction, i.e. not run the instruction.

30 In an alternative to encrypting and decrypting the instruction, the instruction may be signed by the second external device 330 using a

cryptographic hash, and the controller 300 may be configured to verify that the signature is correct before running the instruction.

A corresponding method for transmitting an instruction will now be described with reference to Figs. 65a – 65c. The instruction may relate to a function of the implantable medical device, such as an instruction to run a function or method of the implantable medical device, or to set a value of a parameter of the implantable medical device. The method comprises: transmitting an instruction for the implantable medical device from the first external device 300 to a second external device 320, the instruction relating to a function of the implantable medical device 10, encrypting, at the second external device 330 using a first encryption key, the instruction into an encrypted instruction, and transmitting the encrypted instruction from the second external device 330 to the implantable medical device 10, decrypting, at the implantable medical device, the instructions using a second encryption key corresponding to the first encryption key. The steps performed by or at the implantable medical device may be executed by the controller 300.

The instruction may be any type of instruction for controlling a function of the implantable medical device. For example, the instruction may be an instruction to run a function or method of the implantable medical device 10 or controller 300, an instruction comprising a plurality of sub-steps to be run at the controller 300, or a value for a parameter at the controller 300. The first external device 320 may, for example, receive the instruction from a user via a user interface displayed at or connected to the first external device 320. In another example, the first external device 320 may determine the instruction in response to data received from the implantable medical device 10, such as measurement data, or from another external device. Thus, in some examples, the method may further comprise receiving, at the first external device 320, an instruction to be transmitted to the implantable medical device 10. The method may further comprise displaying a user interface for receiving the instruction. In another example, the method comprises determining, at the first external device 320, an instruction to be transmitted to the implantable medical device 10.

In some embodiments, the transmitting of the encrypted instruction from the second external device 330 to the implantable medical device 10 comprises transmitting the encrypted instruction from the second external device 330 to the first external device 320, and transmitting the encrypted instruction from the first external device 320 to the controller 300 of the implantable medical device 10. In other words, the first external device 320 may relay the encrypted instruction from the second external device 330 to the controller 300, preferably without decrypting the instruction before transmitting it.

10 The method may further comprise to, at the controller 300, running the instruction or performing the instruction. The running of the instruction may be performed by an internal computing unit or a processor 306 comprised in the controller 300, and may, for example, cause the internal computing unit or processor 306 to instruct the implantable medical device 302 to perform an
15 action.

The method may further comprise verifying, at the second external device 330, that the instructions are correct. The verifying may be performed as described above with reference to the corresponding system.

20 The method may further comprise verifying, at the controller 300, that the instructions are correct. The verifying may be performed as described above with reference to the corresponding system.

25 The method may further comprise authenticating the connection between the first external device 320 and the controller 300 over which the encrypted instruction is to be transmitted. The authentication may be performed as described herein.

30 As described above, a control program of the controller 300 may be updatable, configurable or replaceable. A system and a method for updating or configuring a control program of the controller 300 is now described with reference to figs. 65a – 65c. The controller may comprise an internal computing unit 306 configured to control a function of the implantable medical device 10, the internal computing unit 306 comprises an internal memory 307 configured to store: i. a first control program 310 for controlling the internal

computing unit, and ii. a second, configurable or updatable, with predefined program steps, control program 312 for controlling said function of the implantable medical device 10, and iii. a set of predefined program steps for updating the second control program 312. The controller 300 is configured to
5 communicate with an external device 320. The internal computing unit 306 is configured to receive an update to the second control program 312 via the controller 300, and a verification function of, connected to, or transmitted to the controller 300. The verification function is configured to verify that the received update to the second control program 312 comprises program steps
10 comprised in the set of predefined program steps. In this way, the updating or programming of the second control program may be performed using predefined program steps, which may decrease the risk that the new or updated control program is incorrect or comprises malicious software, such as a virus, spyware or a malware.

15 The predefined program steps may comprise setting a variable related to a pressure, a time, a minimum or maximum temperature, a current, a voltage, an intensity, a frequency, an amplitude of electrical stimulation, a feedback mode (sensorics or other), a post-operative mode or a normal mode, a catheter mode, a fibrotic tissue mode (for example semi-open), an
20 time open after urination, a time open after urination before bed-time.

The verification function may be configured to reject the update in response to the update comprising program steps not comprised in the set of predefined program steps and/or be configured to allow the update in response to the update only comprising program steps comprised in the set of
25 predefined program steps.

The internal computing unit 306 may be configured to install the update in response to a positive verification, for example by a user using an external device, by a button or similarly pressed by a user, or by another external signal.

30 The authentication or verification of communications between the implant and an external device has been described above.

When updating a control program of the controller 300, it may be beneficial to transmit a confirmation to a user or to an external device or system. Such a method is now described with reference to figs. 65a – 65b.

The method for updating a control program of a controller 300
5 comprised in the implantable medical device 10 according to any of the embodiments herein. The controller 300 is adapted for communication with a first external device 320 and a second external device 330, which may comprise receiving, by the internal computing unit, an update or configuration to the control program from the first external device, wherein the update is
10 received using a first communication channel; installing, by the internal computing unit 306, the update; and transmitting, by the internal computing unit, logging data relating to the receipt of the update or configuration and/or logging data relating to an installation of the update to the second external device 330 using the second communication channel; wherein the first and
15 the second communication channels are different communication channels. By using a first and a second communication channels, in comparison to only using one, the security of the updating may be improved as any attempts to update the control program will be logged via the second communication channel, and thus, increasing the chances of finding incorrect or malicious
20 update attempts.

The update or configuration comprises a set of instructions for the control program, and may, for examples comprise a set of predefined program steps as described above. The configuration or update may comprise a value for a predetermined parameter.

25 In some examples, the method further comprises confirming, by a user or by an external control unit, that the update or configuration is correct based on the received logging data.

The logging data may be related to the receipt of the update or configuration, and the controller 300 is configured to install the update or
30 configuration in response to receipt of a confirmation that the logging data relates to a correct set of instructions. In this way, the controller 300 may

receive data, transmit a logging entry relating to the receipt, and then install the data in response to a positive verification that the data should be installed.

In another example, or in combination with the one described above, the logging data is related to the installation or the update or configuration. In this example the logging data may be for information purposes only and not affect the installation, or the method may further comprise activating the installation in response to the confirmation that the update or configuration is correct.

If the update or configuration is transmitted to the controller 300 in one or more steps, the verification as described above may be performed for each of the steps.

The method may further comprise, after transmitting the logging data to the second external device, verifying the update via a confirmation from the second external device 330 via the second communication channel.

With reference to Fig. 65a – 65c there may further be provided an implantable controller 300. The controller 300 is connected to a sensor 351 wherein the sensor 351 is at least one microphone sensor 351 configured to record acoustic signals. For instance, the controller 300 may be configured to register a sound related to at least one of a bodily function of the patient and a function of the implantable medical device 10. The controller 300 comprises a computing unit 306 configured to derive at least one of a pulse of the patient from the registered sound related to a bodily function, such as information related to the patient swallowing, from the registered sound related to a bodily function. In the alternative, the controller 300 could be configured to derive information related to a functional status of the implantable medical device 10 from the registered sound, such as RPM of the motor. To this end the computing unit 306 may be configured to perform signal processing on the registered sound (e.g. on a digital or analog signal representing the registered sound) so as to derive any of the above mentioned information related to a bodily function of the patient or a function of the implantable medical device 10. The signal processing may comprise filtering the registered sound signals of the microphone sensor 351.

The implantable controller is placed in an implantable housing for sealing against fluid, and the microphone sensor 351 is placed inside of the housing. Accordingly, the controller and the microphone sensor 351 do not come into contact with bodily fluids when implanted which ensures proper
5 operation of the controller and the microphone sensor 351.

In some implementations, the computing unit 306 is configured to derive information related to the functional status of an active unit 302 of the implantable medical device 10, from the registered sound related to a function of the implantable medical device 10. Accordingly, the computing unit 306
10 may be configured to derive information related to the functional status of at least one of: a motor, a pump and a transmission of the active unit 302 of the implantable medical device 10, from the registered sound related to a function of the implantable medical device 10.

The controller may comprise a transceiver 303,308 configured to
15 transmit a parameter derived from the sound registered by the at least one microphone sensor 351 using the transceiver 303,308. For example, the transceiver 303,308 is a transceiver configured to transmit the parameter conductively (303) to an external device 320 or wirelessly (308) to an external device 320.

20 A method of authenticating the implantable medical device 10, the external device 320 or a communication signal or data stream between the external device 320 and the implantable medical device 10 is also described with reference to figs. 65a – 65c. The method comprises the steps of registering a sound related to at least one of a bodily function and a function
25 of the implantable medical device 10, using the at least one microphone sensor 351, connected to the controller 300. The method could in a first authentication embodiment comprise transmitting a signal derived from the registered sound, using the transceiver 303,308, receiving the signal in the external device 320, using the receiver 323,328 and comparing, in the
30 external device 320, a parameter derived from the received signal with a reference parameter, using the computing unit 306. The method could in a second authentication embodiment comprise receiving a signal in the

controller 300, from the external device 320, using the transceiver 323, 328 and deriving a reference parameter from the received signal, using the computing unit 306 of the controller 300, and comparing, in the controller 300, a parameter derived from the received signal with the derived reference
5 parameter, using the computing unit 306 of the controller 300. The methods further comprise the steps of the implantable controller 300 authenticating the external device 320, or the external device 320 authenticating the implantable controller 300, on the basis of the comparison. The registered sound could for example be related to the patient eating.

10 Embodiments relating to an implantable medical device 10 having a controller 300 having a processor 306 with a sleep mode and an active mode will now be described with reference to Fig. 65d. The implant, the internal communication unit and the external device(s) may have the features described above with reference to figs. 65a – 65c.

15 In an embodiment in which the controller 300 comprises a processor 306 having a sleep mode and an active mode, the controller 300 comprises or is connected to a sensor 150 and a processing unit 306 having a sleep mode and an active mode. The sensor 150 is configured to periodically measure a physical parameter of the patient, and the controller 300 is further configured
20 to, in response to a sensor measurement preceding a predetermined value, setting the processing unit 306 in an active mode. That is, the controller 300 may “wake up” or be set in an active mode in response to a measurement from, for example, the body. A physical parameter of the patient could for example be a local or systemic temperature, saturation/oxygenation, blood
25 pressure or a parameter related to an ischemia marker such as lactate.

By sleeping mode it is meant a mode with less battery consumption and/or processing power used in the processing unit 306, and by “active mode” it may be meant that the processing unit 306 is not restricted in its processing.

30 The sensor 150 may, for example, be a pressure sensor. The pressure sensor may be adapted to measure a pressure in an organ of a patient, a reservoir of the implant or a pressure exerted by at least one member. The

sensor 150 may be an analog sensor or a digital sensor, i.e. a sensor 150 implemented in part in software. In some examples, the sensor is adapted to measure one or more of a battery or energy storage status of the implantable medical device 10 and a temperature of the implantable medical device 10. In this way, the sensor 150 may periodically sense a pressure of the implantable medical device 10 or of the patient, and set the processing unit 306 in an active mode if the measured pressure is above a predetermined value. Thus, less power, i.e. less of for example a battery or energy storage comprised in the implant, may be used, thereby prolonging the lifetime of the implantable medical device 10 or increasing the time between charging occasions of the implantable medical device 10.

In some examples, the processor 306, when in set in the active mode, may cause a sensation generator 381 connected to the implant, comprised in the implantable medical device 10 or comprised in an external device 320, 330, to generate a sensation detectable by a sense of the patient. For example, the processor may cause the sensation generator to generate a sensation in response to a measure battery status, for example that the battery is above or below a predetermined level, that a measured pressure is above or below a predetermined level, or that another measured parameter has an abnormal value, i.e. less than or exceeding a predetermined interval or level. The sensation generator has been described in further detail earlier in this description.

The processing unit 306 may be configured to perform a corrective action in response to a measurement being below or above a predetermined level. Such a corrective action may, for example, be increasing or decreasing a pressure, increasing or decreasing electrical stimulation, increasing or decreasing power.

The controller 300 may comprise a signal transmitter 320 connected to the processing unit, and wherein the processing unit is configured to transmit data relating to the measurement via the transceiver 308 of the controller 300 or an additional internal signal transmitter 392. The transmitted data may be received by an external device 320.

The external device may have an external communication unit 390. The external device 320 may comprise a signal provider 380 for providing a wake signal to the controller 300. In some examples, the signal provider comprises a coil or magnet 371 for providing a magnetic wake signal.

5 The controller 300 may implement a corresponding method for controlling an implantable medical device 10 when implanted in a patient. The method comprises measuring, with a sensor of the controller 300 connected to or comprised in the controller 300, a physiological parameter of the patient or a parameter of the implantable medical device 10, and, in response to a
10 sensor measurement having an abnormal value, setting, by the controller 300, a processor 306 of the controller 300 from a sleep mode to an active mode. The measuring may be carried out periodically. By “abnormal value” it may be meant a measured value exceeding or being less than a
15 predetermined value, or a measured value being outside a predetermined interval. The method may further comprise generating, with a sensation generator 381 as described above, a sensation detectable by the patient. In some examples, the generating comprises requesting, by the processor, the sensation generator 381 to generate the sensation.

 The method may further comprise to perform a medical intervention in
20 response to a sensor measurement having an abnormal value, preferably after the processing unit has been set in the active mode.

 A system comprising an implantable medical device 10 having a controller 300 having a sleep mode and an active mode will now be described with reference to Fig. 65d. In one embodiment, the controller 300 comprises a
25 sensor 150 adapted to detect a magnetic field and a processing unit 306 having a sleep mode and an active mode, now described with reference to figs. 65a – 65c. The external control unit 320 comprises a signal provider 380 adapted to provide a magnetic field detectable by the internal sensor 150. The controller 300 is further configured to, in response to a detected magnetic
30 field exceeding a predetermined value, setting the processing unit 306 in an active mode. In this way, the external device 320 may cause a sleeping controller 300 or processor 306 to “wake up”.

The sensor 150 may, for example, be a hall effect sensor, a fluxgate sensor, an ultra-sensitive magnetic field sensor, a magneto-resistive sensor, an AMR or GMR sensor, or the sensor may comprise a third coil having an iron core.

5 The magnetic field provider 380 may have an off state, wherein it does not provide any magnetic field, and an on state, wherein it provides a magnetic field. For example, the magnetic field provider 380 may comprise a magnet 371, a coil 371, a coil having a core 371, or a permanent magnet 371. In some embodiments, the magnetic field provider 380 may comprise a
10 shielding means for preventing a magnet 371 or permanent magnet 371 from providing a magnetic field in the off state. In order to provide a substantially even magnetic field, the magnetic field provider may comprise a first and a second coil arranged perpendicular to each other.

 After the processing unit 306 has been set in an active mode, i.e. when
15 the processing unit 306 has been woken, the implant may determine a frequency for further communication between the controller 300 and the external device 320. The controller 300 may thus comprise a frequency detector 391 for detecting a frequency for communication between the controller 300 and the second communication unit 390. The frequency
20 detector 391 is, for example, an antenna. The external device 320 may comprise a frequency indicator 372, for transmitting a signal indicative of a frequency. The frequency indicator 372, may, for example, be a magnetic field provider capable of transmitting a magnetic field with a specific frequency. In some examples the frequency indicator is comprised in or the
25 same as the magnetic field provider 371. In this way, the frequency signal is detected using means separate from the sensor, and can, for example, be detected using a pin on a chip.

 Alternatively, the controller 300 and the external device 320 may communicate using a predetermined frequency or a frequency detected by
30 means defined by a predetermined method according to a predetermined protocol to be used for the communication between the controller 300 and the external device 320.

In some embodiments, the sensor 150 may be used for the communication. The communication may in these embodiments be performed with such that a frequency of the magnetic field generated by the coil is 9-315 kHz, or the magnetic field generated by the coil is less than or equal to
5 125kHz, preferably less than 58kHz. The frequency may be less than 50Hz, preferably less than 20Hz, more preferably less than 10Hz, in order to be transmittable through a titanium box.

In some embodiments, the controller 300 comprises a receiver unit 392, and the internal control unit and the external control unit are configured
10 to transmit and/or receive data via the receiver unit 392 via magnetic induction. The receiver unit 392 may comprise a high-sensitivity magnetic field detector, or the receiver unit may comprise a fourth coil for receiving the magnetic induction.

The system may implement a method for controlling a medical implant
15 implanted in a patient. The method comprises monitoring for signals by a sensor 150 comprised in the controller 300 communicatively coupled to the active unit 302, providing, from a signal provider 380 comprised in an external device 320, a wake signal, the external device 320 being adapted to be arranged outside of the patient's body, and setting, by the controller 300 and
20 in response to a detected wake signal WS, a mode of a processing unit 306 comprised in the internal control unit from a sleep mode to an active mode.

The method may also comprise detecting, using a frequency detector 391, a frequency for data communication between the controller 300 and a second communication unit 390 being associated with the external device
25 320. The frequency detector 391 is communicatively coupled to the controller 300 or the external device 320. The detection may be performed using a detection sequence for detecting the frequency. This detection sequence may, for example, be a detection sequence defined in the protocol to be used for communication between the controller 300 and the second communication
30 unit 390. Potential protocols that may be used for communication between the controller 300 and the external device 320 has been described earlier in this description. Thus, the method may comprise determining, using the frequency

detector 391, the frequency for data communication, and initiating data communication between the controller 300 and the second communication unit 390. The data communication can, for example, comprise one or more control instructions for controlling the implantable medical device 10 transmitted from the external device 320, or, for example, comprise data related to the operation of the implantable medical device 10 and be transmitted from the controller 300.

In some examples, the implantable medical device may comprise or be connected to a power supply for powering the implantable medical device 10. This will now be described with reference to fig. 65e. The medical device, the internal control unit, and the external device(s) may comprise all elements described above with reference to figs. 65a – 65c and fig. 65d. The power supply may comprise an implantable energy storage unit 40 for providing energy to the medical device, an energy provider 397 connected to the implantable energy storage unit 40 and connected to an energy consuming part of the implantable medical device 10, the energy provider 397 being configured to store energy to provide a burst of energy to the energy consuming part, wherein the energy provider 397 is configured to be charged by the implantable energy storage unit 40 and to provide the energy consuming part with electrical power during startup of the energy consuming part. The energy may for example be consumed when delivering the electrical stimulation signal, via the electrode arrangement, to the muscle tissue against which the implanted apparatus (such as the above-described movement restriction apparatuses) rests.

Alternatively, the implantable medical device 10 may comprise a first implantable energy storage unit 40 for providing energy to an energy consuming part of the implantable medical device 10, a second implantable energy storage unit 397 connected to the implantable energy storage unit 40 and connected to the energy consuming part, wherein the second implantable energy storage unit 397 is configured to be charged by the implantable energy storage unit 40 and to provide the energy consuming part with electrical power during startup of the energy consuming part. The second

implantable energy storage unit 397 has a higher energy density than the first implantable energy storage unit 40. By having a “higher energy density” it may be meant that the second implantable energy storage unit 397 has a higher maximum energy output per time unit than the first implantable energy storage unit 40. The second energy storage 397 may be an energy provider as discussed below.

The energy consuming part may be any part of the implantable medical device 10, such as a processing or computing unit, a communication unit, a device for providing electrical stimulation to a tissue portion of the body of the patient, a CPU for encrypting information, a transmitting and/or receiving unit for communication with an external unit (not shown as part of the energy consuming part in the drawings, that is, the communication unit may be connected to the energy storage unit 40 and to the energy provider 397), a measurement unit or a sensor, a data collection unit, a solenoid, a piezo-electrical element, a memory metal unit, a vibrator, a part configured to operate a valve comprised in the medical device, or a feedback unit.

In this way, an energy consuming part requiring a quick start or an energy consuming part which requires a high level or burst of energy for a start may be provided with sufficient energy. This may be beneficial as instead of having an idle component using energy, the component may be completely turned off and quickly turned on when needed. Further, this may allow the use of energy consuming parts needing a burst of energy for a startup while having a lower energy consumption when already in use. In this way, a battery or an energy storage unit having a slower discharging (or where a slower discharging is beneficial for the lifetime or health of the battery) may be used for the implant, as the extra energy needed for the startup is provided by the energy provider.

Energy losses may occur in a battery or energy storage unit of an implant if the battery or energy storage unit is discharged too fast. These energy losses may for example be in the form of heat, which may damage the battery or energy storage unit. By the apparatus described in these examples, energy may be provided from the battery or energy storage unit in a way that

does not damage the battery or energy storage unit, which may improve the lifetime of the battery or energy storage unit and thereby the lifetime of the medical device.

In some examples, the discharging from the implantable energy storage unit 40 during startup of the energy consuming part is slower than the energy needed for startup of the energy consuming part, i.e. the implantable energy storage unit 40 is configured to have a slower discharging than the energy needed for startup of the energy consuming part. That is, there is a difference between the energy needed by the energy consuming part and the energy the implantable energy storage unit 40 is capable of providing without damaging the implantable energy storage unit 40. In other words, a maximum energy consumption of the energy consuming part may be higher than the maximum energy capable of being delivered by the implantable energy storage unit 40 without causing damage to the implantable energy storage unit, and the energy provider 397 may be adapted to deliver an energy burst corresponding to difference between the required energy consumption and the maximum energy capable of being delivered by the implantable energy storage unit 40. The implantable energy storage unit 40 may be configured to store a substantially larger amount of energy than the energy burst provider 397, but may be slower to charge.

The implantable energy storage unit 40 may be any type of energy storage unit suitable for an implant, such as a re-chargeable battery or a solid-state battery, such as a tional-chlorid battery. The implantable energy storage unit 40 may be connected to the energy consuming part and configured to power the energy consuming part after it has been started using the energy provider 397.

The energy provider 397 may be any type of part configured to provide a burst of energy for the energy consuming part. In some examples, the energy provider 397 is a capacitor, such as a start capacitor, a run capacitor, a dual run capacitor or a supercapacitor. The energy provider 397 may be connected to the implantable energy storage unit 40 and be adapted to be charged using the implantable energy storage unit 40. In some examples, the

energy provider may be a second energy provider 397 configured to be charged by the implantable energy storage unit 40 and to provide the energy consuming part with electrical energy. The implantable medical device 10 may further comprising a temperature sensor for sensing a temperature of the capacitor and the temperature sensor may be integrated or connected to the controller 300 such that the sensed temperature can be used as input for controlling the implantable medical device 10 or as feedback to be sent to an external device 320.

A corresponding method for powering a medical device may also be contemplated. The method comprises the steps of initiating an energy consuming part 302 of the implant, the energy consuming part being connected to an implantable energy storage unit 40, providing an initial burst of energy to the energy consuming part using an energy provider 397 connected to the implantable energy storage unit 40 and to the energy consuming part 302, the energy provider 397 being adapted to provide a burst of energy to the energy consuming part, and subsequently powering the energy consuming part 302 using the implantable energy storage unit 40.

In some examples, a maximum energy consumption of the energy consuming part is higher than the maximum energy capable of being delivered by the implantable energy storage unit 40 without causing damage to the implantable energy storage unit 40, and the energy provider 397 is adapted to deliver an energy burst corresponding to difference between the required energy consumption and the maximum energy capable of being delivered by the implantable energy storage unit 40.

The method may further comprise the step of charging the energy provider 397 using the implantable energy storage unit 40.

Initiating an energy consuming part 302 may comprise transitioning a control unit of the medical device from a sleep mode to an operational or active mode.

The implantable energy storage unit 40 may be adapted to be wirelessly charged and the implantable energy storage unit may be connected to an internal charger 395 for receiving wireless energy from an

external device 320 via an external charger 396, and the method may comprise wirelessly charging the implantable energy storage unit 40. In some examples, the method comprises controlling a receipt of electrical power from an external energy storage unit at the internal charger 395. The internal
5 energy storage unit 40 may be charged via the receipt of a transmission of electrical power from an external energy storage unit 396 by the internal charger 395.

The embodiments described herein may advantageously be combined. For example, all the embodiments relating to the communication and
10 controlling of the medical device may be combined with the embodiments relating to the programming of the implant, the methods and systems for improving energy consumption or the power supply. The embodiments relating to the programming of the medical device may be combined with any
15 of the embodiments relating to improving the energy consumption or the power supply. The embodiments relating to the power supply maybe combined with the methods and systems for improving the energy consumption.

A computer program product of, or adapted to be run on, an internal computing unit or an external device is also provided, which comprises a
20 computer-readable storage medium with instructions adapted to make the internal computing unit and/or the external device perform the actions as described in any embodiment or example above.

Fig. 66a shows one embodiment of a system for charging, programming and communicating with the controller 300 of the implanted
25 medical device 100. Fig. 66a further describes the communication and interaction between different external devices which may be devices held and operated by the patient, by the health care provider (HCP) or by the Dedicated Data Infrastructure (DDI), which is an infrastructure supplier for example by the manufacturer of the implanted medical device 100 or the
30 external devices 320', 320'', 320'''. The system of the embodiment of fig. 66A comprises three external devices 320', 320'', 320''' capable of communicating with the controller 300.

The basic idea is to ensure the security of the communication with, and the operation of, the medical device 100 by having three external devices 320', 320'', 320''' with different levels of authority. The lowest level of authority is given to the patient operated remote control 320''. The remote control, also referred to as external device 320'' is authorized to operate functions of the implanted medical device 100 via the implanted controller 300, on the basis of patient input. The remote control 320'' is further authorized to fetch some necessary data from the controller 300. The remote control 320'' is only capable of operating the controller 300 by communicating with the software currently running on the controller 300, with the currently settings of the software. The next level of authority is given to the Patient External Interrogation Device (P-EID) 320''', which is a charging and communication unit which is held by the patient but may be partially remotely operated by the Health Care Provider (HCP) (Usually a medical doctor with the clinic providing the treatment with help of the implanted medical device 100). The P-EID 320''' is authorized to make setting changes by selecting pre-programmed steps of the software or hardware running on the controller 300 of the implanted medical device 100. The P-EID is remotely operated by the HCP, and receives input from the HCP, via the DDI.

The highest level of authority is given to the HCP-EID 320' and its controller, referred to as the HCP Dedicated Display Device (DDD). The HCP-EID 320' is a charging and communication unit which may be located physically at the clinic of the HCP. The HCP-EID 320' may be authorized to freely alter or replace the software running on the controller 300, when the patient is physically in the clinic of the HCP. The HCP-EID 320' is controlled by the HCP DDD, which either may act on a "webview" portal from the HCP-EID or be a device closed down to any activities (which may include the absence of an internet connection) other than controlling and communicating with the HCP-EID. The webview portal does not necessarily mean internet based or HTML-protocol and the webview portal may be communicated over other communicating protocols such as Bluetooth or any other type of standard or proprietary protocol. The HCP DDD may also communicate with

the HCP-EID over a local network or via Bluetooth or other standard or proprietary protocols.

Starting from the lowest level of authority, the patient remote control external device 320'' beneficially may comprise a wireless transceiver 328 for communicating with the implanted medical device 100. The remote control 320'' is capable of controlling the operation of the implanted medical device 100 via the controller 300, by controlling pre-set functions of the implantable medical device 100, e.g. for operating an active portion of the implanted medical device 100 for performing the intended function of the implanted medical device 100. The remote control 320'' is able to communicate with the implanted medical device 100 using any standard or proprietary protocol designed for the purpose. In the embodiment shown in fig. 66A, the wireless transceiver 328 comprises a Bluetooth (BT) transceiver, and the remote control 320'' is configured to communicate with implanted medical device 100 using BT. In an alternative configurations, the remote control 320'' communicates with the implanted medical device 100 using a combination of Ultra-Wide Band (UWB) wireless communication and BT. The use of UWB technology enables positioning of the remote control 320'' which can be used by the implanted medical device 100 as a way to establish that the remote control 320'' is at a position in which the implanted medical device 100 and/or the patient can acknowledge as being correct, e.g. in the direct proximity to the medical device 100 and/or the patient, such as within reach of the patient and/or within 1 or 2 meters of the implanted medical device 100.

UWB communication may be performed by the generation of radio energy at specific time intervals and occupying a large bandwidth, thus enabling pulse-position or time modulation. The information can also be modulated on UWB signals (pulses) by encoding the polarity of the pulses, their amplitude and/or by using orthogonal pulses. A UWB radio system can be used to determine the "time of flight" of the transmission at various frequencies. This helps overcome multipath propagation, since some of the frequencies have a line-of-sight trajectory, while other indirect paths have longer delay. With a cooperative symmetric two-way metering technique,

distances can be measured at high resolution and accuracy. UWB is useful for real-time location systems, and its precision capabilities and low power make it well-suited for radio-frequency-sensitive environments, such as health care environments.

5 In embodiments in which a combination of BT and UWB technology is used, the UWB technology may be used for location-based authentication of the remote control 320'', whereas the communication and/or data transfer could take place using BT or any other way of communicating different from the UWB. The UWB signal could in some embodiments also be used as a
10 wake-up signal for the controller 300, or for the BT transceiver, such that the BT transceiver in the implanted medical device 100 can be turned off when not in use, which eliminates the risk that the BT is intercepted, or that the controller 300 of the implanted medical device 100 is hacked by means of BT communication. In embodiments in which a BT (or alternatives) / UWB
15 combination is used, the UWB connection may be used also for the transmission of data. In the alternative, the UWB connection could be used for the transmission of some portions of the data, such as sensitive portions of the data, or for the transmission of keys for the unlocking of encrypted communication sent over BT.

20 The remote control 320'' comprises a computing unit 326 configured to run a software application for communicating with the implanted medical device 100. The computing unit 326 can receive input directly from control buttons 335 arranged on the remote control 320'' or may receive input from a control interface 334i displayed on a patient display device 334 operated by
25 the patient. In the embodiments in which the remote control 320'' receives input from a control interface 334i displayed on the patient display device 334 operated by the patient, the remote control 320'' may transmit the control interface 334i in the form of a web-view portal, i.e. a remote interface running in a sandbox environment on the patient's display device 334. A sandbox
30 environment is understood as running on the display device 334 but only displaying what is presented from the remote control, and only using a tightly controlled set of commands and resources, such as storage and memory

space as well as network access. The ability to inspect the host system and read or write from other input devices connected to the display device 334 may therefore be extremely limited. Any action or command generated by the patient display device may be similar to controlling a webpage. All acting
5 software may be located on the remote control that only displays its control interface onto the patient display unit.

The computing unit 326 may further be configured to encrypt the control interface before transmission to the patient display device 334, and encrypt the control commands before transmission to the implanted medical
10 device 100. The computing unit 326 is further configured to transform the received user input into control commands for wireless transmission to the implantable medical device 100.

The patient's display device 334 could for example be a mobile phone, a tablet or a smart watch. In the embodiment shown in fig. 66A, the patient's
15 display device 334 communicates with the remote control 320'' by means of BT. The control interface 334i in the form of a web-view portal is transmitted from the remote control 320'' to the patient's display device 334 over BT. Control commands in the form of inputs from the patient to the control interface 334i may be transmitted from the patient's display device 334 to the
20 remote control 320'', providing input to the remote control 320'' equivalent to the input that may be provided using the control buttons 335. The control commands created in the patient's display device 334 may be encrypted in the patient's display device 334 and transmitted to the remote control 320' using BT or any other communication protocol.

25 The remote control may normally not be connected to the DDI or the Internet, thereby increasing security. In addition, the remote control 320'' may in one embodiment have its own private key. In a specific embodiment, the remote control 320'' may be activated by the patient's private key for a certain time period. This may activate the function of the patient's display device and
30 the remote web-view display portal supplied by the remote control to the patient's display device.

The patient's private key may be supplied in a patient private key device comprising a smartcard that may be inserted or provided close to the remote control 320'' to activate a permission to communicate with the implant 100 for a certain time period.

- 5 The patient's display device 334 may (in the case of the display device 334 being a mobile phone or tablet) comprise auxiliary radio transmitters for providing an auxiliary radio connection, such as a Wi-Fi or mobile connectivity (e.g. according to the 3G, 4G or 5G standards). The auxiliary radio connection(s) may have to be disconnected to enable communication with the
- 10 remote control 320''. Disconnecting the auxiliary radio connections reduces the risk that the integrity of the control interface 334i displayed on the patient's display device 334 is compromised, or that the control interface 334i displayed on the patient's display device 334 is remotely controlled by an unauthorized device or entity.
- 15 In alternative embodiments, control commands are generated and encrypted by the patient's display device and transmitted to the DDI 330. The DDI 330 could either alter the created control commands to commands readable by the remote control 320'' before further encrypting the control commands for transmission to the remote control 320'', or could simply add
- 20 an extra layer of encryption before transmitting the control commands to the remote control 320'', or could simply act as a router for relaying the control commands from the patients' display device 334 to the remote control 320''. It is also conceivable that the DDI 330 adds a layer of end-to-end encryption directed at the implanted medical device 100, such that only the implanted
- 25 medical device 100 can decrypt the control commands to perform the commands intended by the patient. In the embodiments above, when the patient remote display device 334 is communicating with the DDI, the patient's display device 334 may be configured to only display and interact with a web-view portal provided by a section of the DDI. It is conceivable that
- 30 the web-view portal is a view of a back-end provided on the DDI 330, and that in such embodiments the patient interacting with the control interface on the

patient's display device 334 is equivalent to the patient interacting with an area of the DDI 330.

The patient's display device 334 could have a first and second application related to the implanted medical device 100. The first application is the control application displaying the control interface 334i for control of the implanted medical device 100, whereas the second application is a general application for providing the patient with general information of the status of the implanted medical device 100 or information from the DDI 330 or HCP, or for providing an interface for the patient to provide general input to the DDI 330 or HCP related to the general wellbeing of the patient, the lifestyle of the patient or related to general input from the patient concerning the function of the implanted medical device 100. The second application, which do not provide input to the remote control 320'' and/or the implanted medical device 100 thus handles data which is less sensitive. As such, the general application could be configured to function also when all auxiliary radio connections are activated, whereas switching to the control application which handles the more sensitive control commands and communication with the implanted medical device 100 could require that the auxiliary radio connections are temporarily de-activated. It is also conceivable that the control application is a sub-application running within the general application, in which case the activation of the control application as a sub-application in the general application could require the temporary de-activation of auxiliary radio connections. In the embodiment shown in fig. 66A, access to the control application requires the use of the optical and/or NFC means of the hardware key 333' in combination with biometric input to the patient's display device, whereas accessing the general application only requires biometric input to the patient's display device and/or a pin code. In an example, a two-factor authentication solution, such as a digital key in combination with a pin code could be used for accessing the general application and/or the control application.

In general, a hardware key may be needed to activate the patient display device 334 for certain time period to control the web-view portal of the

remote control 320'', displaying the control interface 334i for control of the implanted medical device 100.

In the embodiments in which the patients display device 334 is configured to only display and interact with a web-view provided by another unit in the system, it is conceivable that the web-view portal is a view of a back-end provided on the DDI 330, and in such embodiments, the patient interacting with the control interface on the patient's display device is equivalent to the patient interacting with an area of the DDI 330.

Moving now to the P-EID 320'''. The P-EID 320''' is an external device used by the patient, patient external device, configured to communicate with, and charge, the implanted medical device 100. The P-EID 320''' can be remotely controlled by the HCP to read information from the implanted medical device 100. The P-EID 320''' is adapted to control the operation of the implanted medical device 100, control the charging of the medical device 100, and adjust the settings on the controller 300 of the implanted medical device 100 by changing pre-defined pre-programmed steps and/or by the selection of pre-defined parameters within a defined range.

Similar to the remote control 320'', the P-EID 320''' may be configured to communicate with the implanted medical device 100 using BT or UWB communication or any other proprietary or standard communication method. Since the device may be used for charging the implant, the charging signal and communication could be combined. Similar to the remote control 320'', it is also possible to use a combination of UWB wireless communication and BT for enabling positioning of the P-EID 320'' as a way to establish that the P-EID 320'' is at a position which the implanted medical device 100 and/or patient and/or HCP can acknowledge as being correct, e.g. in the direct proximity to the correct patient and/or the correct medical device 100. Just as for the remote control 320'', in embodiments in which a combination of BT and UWB technology is used, the UWB technology may be used for location-based authentication of the P-EID 320'', whereas the communication and/or data transfer could take place using BT. The P-EID 320'' comprises a wireless transmitter/transceiver 328 for communication and also comprises a

wireless transmitter 325 configured for transferring energy wirelessly, which may be in the form of a magnetic field or any other signal such as electromagnetic, radio, light, sound or any other type of signal to transfer energy wirelessly to a wireless receiver 395 of the implanted medical device

5 100. The wireless receiver 395 of the implanted medical device 100 is configured to receive the energy in the form of the magnetic field and transform the energy into electric energy for storage in an implanted energy storage unit 40, and/or for consumption in an energy consuming part of the implanted medical device 100 (such as the operation device, controller 300

10 etc.). The magnetic field generated in the P-EID 320''' and received in the implanted medical device 100 is denoted charging signal. In addition to enabling the wireless transfer of energy from the P-EID 320''' to the implanted medical implant 10, the charging signal may also function as a means of communication. E.g., variations in the frequency of the transmission, and/or

15 the amplitude of the signal may be used as signaling means for enabling communication in one direction, from the P-EID 320''' to the implanted medical device 100, or in both directions between the P-EID 320''' and the implanted medical device 100. The charging signal in the embodiment shown in fig. 66A is a signal in the range 10 – 65kHz or 115 – 140 kHz and the

20 communication follows a proprietary communication signaling protocol, i.e., it is not based on an open standard. In alternative embodiments, BT could be combined with communication using the charging signal, or communication using the charging signal could be combined with an UWB signal. The energy signal could also be used as a carrying signal for the communication signal.

25 Just as for the remote control 320'', the UWB signal could in some embodiments also be used as a wake-up signal for the controller 300, or for the BT transceiver, such that the BT transceiver in the implanted medical device 100 can be turned off when not in use, which eliminates the risk that the BT is intercepted, or that the controller 300 of the implanted medical

30 device 100 is hacked by means of BT communication. In some examples, the charging signal could be used as a wakeup signal for the BT, as the charging signal does not necessarily travel very far. Also, as a means of location-based

authentication, the effect of the charging signal or the RSSI could be assessed by the controller 300 in the implanted medical device 100 to establish that the transmitter is within a defined range. In the BT/UWB combination, the UWB may be used also for transmission of data. In some
5 embodiments, the UWB and/or the charging signal could be used for the transmission of some portions of the data, such as sensitive portions of the data, or for the transmission keys for unlocking encrypted communication sent by BT. Wake-up could be performed with any other signal.

UWB could also be used for waking up the charging signal
10 transmission, to start the wireless transfer of energy or for initiating communication using the charging signal. As the signal for transferring energy has a very high effect in relation to normal radio communication signals, the signal for transferring energy cannot be active all the time, as this signal may be hazardous e.g., by generating heat.

15 The P-EID 320''' may communicate with the HCP over the Internet by means of a secure communication, such as over a VPN. The communication between the HCP and the P-EID 320''' is preferably encrypted. Preferably, the communication is sent via the DDI, which may only be relaying the information. The communication from the HCP to the implanted medical
20 device 100 may be performed using an end-to-end encryption, in which case the communication cannot be decrypted by the P-EID 320'''. In such embodiments, the P-EID 320''' acts as a router, only passing on encrypted communication from the HCP to the controller 300 of the implanted medical device 100 (without full decryption). This solution further increases security as
25 the keys for decrypting the information rests only with the HCP and with the implanted medical device 100, which reduces the risk that an unencrypted signal is intercepted by an unauthorized device. The P-EID 320''' may add own encryption or information, specifically for security reasons. The P-EID 320''' may hold its own private key and may be allowed to communicate with
30 the implant 100 based on confirmation from the patient's private key, which may be provided as a smartcard to be inserted in a slot of the P-EID 320''' or hold in close proximity thereto to be read by the P-EID 320'''. These two keys

will add a high level of security to the performed communication between the Implant 100 and the P-EID 320''' since the patient's hardware key in this example on the smartcard may activate and thereby allow the communication and action taken in relation to the implant. The P-EID 320''' may as previously
5 described change the treatment setting of the implant by selecting pre-programmed steps of the treatment possibilities. Such pre-programmed treatment options may include for example to change:

at least one of the position, frequency and level of compression of an implanted heart compression device,

10 the flow of an apparatus assisting the pump function of a heart of the patient,

the flow of an apparatus assisting the pump function comprising a turbine pump placed within a patient's blood vessel for assisting the pump function of the heart,

15 the function of an operable artificial heart valve,

at least one of the function of, the valve opening pressure and time for closure of an operable artificial heart valve for increasing the blood flow to the coronary arteries.

20 at least one of the functions of, the amount and/or concentration of a drug from an implantable drug delivery device,

at least one of the injection site and frequency as well as amount of drug delivered by an implantable drug delivery device for injecting directly into a blood vessel and change the position of the injection site, all from within the patient's body,

25 at least one of the injection site and frequency as well as amount of drug delivered by an implantable drug delivery device for injecting potency enhancing drugs into an erectile tissue of the patient,

at least one of the level of constriction, pressure or position of a hydraulic, mechanic, and/or electric constriction implant,

30 the volume of an operable volume filling device,

the constriction of an operable gastric band,

at least one of the level and time of stretching and when such stretching occur in relation to food intake of a patient for an operable implant for stretching the stomach wall of the patient for creating satiety,

when an action should be taken relating to an implant configured to
5 sense the amount of food intake based on number of times a patient swallows solid food,

at least one of the size and shape of an operable cosmetic implant,

at least one of the shape and size in the breast region of a patient of an operable cosmetic implant for adjustment,

10 at least one of pressure, volume, sensor input or time of an implant controlling medical device for the emptying of a urinary bladder,

at least one of the closing pressure, the time to close after urinating, how much extra pressure would be allowed at exercise of an implant hindering urinary leakage,

15 at least one of the closing pressure, the time to close after revealing, how much extra pressure would be allowed at exercise of an implant hindering anal incontinence,

parameters of an implant controlling the emptying of fecal matter, such as pressure, volume, pump or motor position etc.,

20 parameters of an implant monitoring an aneurysm, such as pressure, aneurysm expansion, volume, reservoir volume, etc.,

parameters of an implant for hindering the expansion of an aneurysm, such as pressure, aneurysm expansion, volume, reservoir volume, etc.,

parameters of an implant lubricating a joint, such as volume, reservoir
25 volume, etc.,

parameters of an implant for affecting the blood flow to an erectile tissue of the patient, such as the level of constriction, pressure or position of a hydraulic, mechanic, and/or electric constriction implant,

parameters of an implant for simulating the engorgement of an erectile
30 tissue, such as the level of stimulation, frequency, or amplitude of an electrical stimulation,

parameters of an implant with a reservoir for holding bodily fluids, such as volume, reservoir volume, etc.,

parameters of an implant storing and/or emptying a bodily reservoir or a surgically created reservoir, such as stimulation parameters in a peristaltic
5 wave, stretch or bending sensors, reservoir volume, etc.,

parameters of an implant communicating with a database outside the body, such as key handshake, new key pairing, signal amplitude etc.,

parameters of an implant able to be programmed from outside the body,

10 parameters of an implant able to be programmed from outside the body with a wireless signal,

parameters of an implant treating impotence, such as pressure, amount of drug delivered, time for erection period etc.,

parameters of an implant controlling the flow of eggs in the uterine
15 tube, such as the level of constriction, time period, position of a hydraulic, mechanic, and/or electric constriction implant,

parameters of an implant controlling the flow of sperms in the uterine tube, such as the level of stimulation, frequency, or amplitude of an electrical stimulation,

20 parameters of an implant controlling the flow of sperms in the vas deferens, such as the level of constriction, time period, position of a hydraulic, mechanic, and/or electric constriction implant,

parameters of an implant for hindering the transportation of the sperm in the vas deferens, such as the level of constriction, time period, position of a
25 hydraulic, mechanic, and/or electric constriction implant,

parameters of an implant treating osteoarthritis,

parameters of an implant performing a test of parameters inside the body,

parameters of an implant controlling specific treatment parameters
30 from inside the body,

parameters of an implant controlling bodily parameters from inside the body,

- parameters of an implant controlling the blood pressure,
parameters of an implant controlling the blood pressure by affecting the
dilatation of the renal artery, such as heat and time period in relation to blood
pressure,
- 5 parameters of an implant controlling a drug treatment parameter,
parameters of an implant controlling a parameter in the blood,
parameters of an implant for adjusting or replacing any bone part of a
body of the patient,
parameters of an implant replacing an organ of the patient or part of an
10 organ of the patient or the function thereof,
parameters of a vascular treatment device, such as bending,
expanding sensor,
parameters of an implant adapted to move fluid inside the body of the
patient, such as volume, pumping parameters,
- 15 parameters of an implant configured to sense a parameter related to
the patient swallowing,
parameters of an implant configured to exercise a muscle with
electrical or mechanical stimulation, such as stimulation parameters,
amplitude frequency time period etc.,
- 20 parameters of an implant configured for emptying an intestine portion
on command, such as electrical stimulation parameters, peristaltic wave
adjustment etc.,
parameters of an operable implant configured to be invaginated in the
stomach of the patient to reduce the volume of the stomach substantially
25 more than the volume of the device, such as volume,
parameters of an implant configured for emptying the urinary bladder
from within the patient's body by compressing the bladder, such as pressure,
volume and time
parameters of an implant configured for draining fluid from within the
30 patient's body,

parameters of an implant configured for the active lubrication of a joint with an added lubrication fluid, such as frequency and/or volume of the drug supplied,

parameters of an implant configured for removing clots and particles
5 from the patient's blood stream,

parameters of an implant configured for elongating or straightening a bone in the patient, to reduce scoliosis, force, length etc.,

parameters of a device to stimulate the brain for a several position to a focused point,

10 parameters of an artificial stomach replacing the function of the natural stomach,

parameters of an implant configured for adjusting the position of a female's urinary tract or bladder neck,

parameters of an implant configured for stimulating the ampulla vas
15 deference and creating temporary constriction.

When the implanted medical device 100 is to be controlled and/or updated remotely by the HCP, via the P-EID 320'', a HCP Dedicated Device (DD) 332 displays an interface in which predefined program steps or setting
20 values are presented to the HCP. The HCP provides input to the HCP DD 332 by selecting program steps, altering settings and/or values or by altering the order in which pre-defined program steps is to be executed. The instructions/parameters inputted into the HCP DD 332 for remote operation is in the embodiment shown in fig. 65f routed to the P-EID 320'' via the DDI
25 330, which may or may not be able to decrypt/read the instructions. The DDI 330 may store the instructions for a time period to later transfer the instructions in a package of created instructions to the P-EID 320''. It is also conceivable that an additional layer of encryption is provided to the package by the DDI 330. The additional layer of encryption may be a layer of
30 encryption to be decrypted by the P-EID 330, or a layer of encryption which may only be decrypted by the controller 300 of the implanted medical device 100, which reduces the risk that unencrypted instructions or packages are

intercepted by unauthorized devices. The instructions/parameters are then provided to the P-EID 320'', which then loads the instructions/parameters into the during the next charging/energy transfer to the implanted medical device 100 using any of the signal transferring means (wireless or conductive)

5 disclosed herein.

The Health Care Provider EID (HCP EID) 320' have the same features as the P- EID 320'' and can communicate with the implanted medical device 100 in the same alternative ways (and combinations of alternative ways) as the P-EID 320'''. However, in addition, the HCP EID 320' also enables the
10 HCP to freely reprogram the controller 300 of the implanted medical device 100, including replacing the entire program code running in the controller 300. The idea is that the HCP EID 320' always remain with the HCP and as such, all updates to the program code or retrieval of data from the implanted medical device 100 using the HCP EID 320' is performed with the HCP and
15 patient present (i.e. not remote). The physical presence of the HCP is an additional layer of security for these updates which may be critical to the function of the implanted medical device 100.

In the embodiment shown in fig. 66A, the HCP communicates with the HCP EID 320' using a HCP Dedicated Display Device 332 (HCP DDD), which
20 is a HCP display device comprising a control interface for controlling and communicating with the HCP EID 320'. As the HCP EID 320' always stays physically at the HCP's clinic, communication between the HCP EID 320' and HCP DDD 332 does not have to be sent over the Internet. Instead, the HCP DDD 332 and the HCP EID 320' can communicate using one or more of BT, a
25 proprietary wireless communication channel, or a wired connection. The alteration to the programming is then sent to the implanted medical device 100 directly via the HCP EID 320'. Inputting into the HCP DDD 332 for direct operation by means of the HCP EID 320' is the same as inputting directly into the HCP EID 320', which then directly transfers the instructions into the
30 implanted medical device 100.

In the embodiment shown in fig. 66A, both the patient and the HCP has a combined hardware key 333', 333''. The combined keys 333', 333''

comprises a hardware component comprising a unique circuitry (providing the highest level of security), a wireless NFC-transmitter 339 for transmitting a specific code (providing mid-level security), and a printed QR-code 344 for optical recognition of the card (providing the lowest level of security). The

5 HCP private key is supplied by a HCP private key device 333'' adapted to be provided to the HCP EID external device via at least one of; a reading slot or comparable for the HCP private key device 333'', an RFID communication or other close distance wireless activation communication to both the HCP EID 320' and the HCP DDD 332 if used. The HCP DDD 332 will be activated by

10 such HCP private key device 333'', which for example may comprise at least one of, a smartcard, a key-ring device, a watch an arm or wrist band a neckless or any shape device.

The HCP EID external device may comprise at least one of;

15 a reading slot or comparable for the HCP private key device, an RFID communication and other close distance wireless activation communication means

The HCP external device 320' may further comprise at least one wireless transceiver 328 configured for communication with a data infrastructure server, DDI, through a first network protocol.

20 A dedicated data infrastructure server, DDI, is in one embodiment adapted to receive commands from said HCP external device 320' and may be adapted to rely the received commands without opening said commands directed to the patient external device 320'', the DDI 330 comprising one wireless transceiver configured for communication with said patient external

25 device 320''.

The patient EID external device 320'' is in one embodiment adapted to receive the commands relayed by the DDI, and further adapted to send these commands to the implanted medical device 100, which is adapted to receive commands from the HCP, Health Care Provider, via the DDI 330 to change

30 the pre-programmed treatment steps of the implanted medical device 100. The patient EID is adapted to be activated and authenticated and allowed to perform the commands by the patient providing a patient private key device

333'. The patient's private key device is in one embodiment adapted to be provided to the patient external device by the patient via at least one of; a reading slot or comparable for the patient private key device 333', an RFID communication or other close distance wireless activation communication.

5 The patient EID external device, in one or more embodiments, comprises at least one of;

 a reading slot or comparable for the HCP private key device,
 an RFID communication, or
 other close distance wireless activation communication

10 The patient EID external device may in one or more embodiments comprise at least one wireless transceiver configured for communication with the implanted medical device through a second network protocol.

 The patient's key 333' is in the embodiment shown in fig. 66A in the form of a key card having an interface for communicating with the P-EID
15 320'', such that the key card could be inserted into a key card slot in the P-EID 320''. The NFC-transmitter 339 and/or the printed QR-code 344 can be used as means for accessing the control interface 334i of the display device 334. In addition, the display device 334 may require a pin-code and/or a biometric input, such as face recognition or fingerprint recognition.

20 The HCP's key 333'', in the embodiment shown in fig. 66A is in the form of a key card having an interface for communicating with the HCP-EID 320', such that in one embodiment the key card could be inserted into a key card slot in the HCP-EID 320'. The NFC-transmitter 339 and/or the printed QR-code 344 can be used as means for accessing the control interface of the
25 HCP DDD 332. In addition, the HCP DDD 332 may require a pin-code and/or a biometric input, such as face recognition or fingerprint recognition.

 In alternative embodiments, it is however conceivable that the hardware key solution is replaced by a two-factor authentication solution, such as a digital key in combination with a PIN code or a biometric input
30 (such as face recognition and/or fingerprint recognition). The key could also be a software key, holding similar advance key features, such as the Swedish Bank ID being a good example thereof.

In the embodiment shown in fig. 66A, communication over the Internet takes place over a Dedicated Data Infrastructure (DDI) 330, running on a cloud service. The DDI 330 in this case handles communication between the HCP DDD 332 and the P-EID 320''. however, the more likely scenario is that
5 the HCP DDD 332 is closed down, such that only the necessary functions of the control application can function on the HCP DDD 332. In the closed down embodiment, the HCP DDD 332 is only able to give the necessary commands to HCP EID 320' to further update the pre-programmed treatment steps of the Implant 100 via the P-EID 320''' in direct contact, or more likely indirect
10 contact via the DDI 332. If the patient is present locally, the HCP EID may communicate and act directly on the patient's implant. However, before anything is accepted by the implant, a patient private key device 333' has to be presented to the P EID 320''' or HCP EID 320' for maximum security.

The DDI 330 is logging information of the contact between the HCP
15 and the remote control 320'' via implant feedback data supplied from the implant to P-EID 320''. Data generated between the HCP and the patient's display device 334, as well as between the HCP and auxiliary devices 336 (such as tools for following up the patient's treatments e.g. a scale in obesity treatment example or a blood pressure monitor in a blood pressure treatment
20 example) are logged by the DDI 330. In some embodiments, although less likely, the HCP DDD 332 may also handle the communication between the patient's display device 334 and the remote control 320''. In fig. 66A, auxiliary devices 336 are connected to the P-EID as well and can thus provide input from the auxiliary devices 336 to the P-EID which can be used by the P-EID
25 for altering the treatment or for follow up.

In all examples, the communication from the HCP to: the P-EID 320'', the remote control 320'', the patient's display device 334 and the auxiliary devices 336 may be performed using an end-to-end encryption. In
embodiments with end-to-end encryption, the communication cannot be
30 decrypted by the DDI 330. In such embodiments, the DDI 330 acts as a router, only passing on encrypted communication from the HCP to various devices. This solution further increases security as the keys for decrypting the

information rests only with the HCP and with the device sending or receiving the communication, which reduces the risk that an unencrypted signal is intercepted by an unauthorized device. The P-EID 320''' may also only pass on encrypted information.

5 In addition to acting as an intermediary or router for communication, the DDI 330 collects data on the implanted medical device 100, relating to the treatment and to the patient. The data may be collected in an encrypted form, in an anonymized form or in an open form. The form of the collected data may
10 collected. In the embodiment shown in fig. 66A, the DDI 330 sends a questionnaire to the patient's display device 334. The questionnaire could comprise questions to the patient related to the general health of the patient, related to the way of life of the patient, or related specifically to the treatment provided by the implanted medical device 100 (such as for example a visual
15 analogue scale for measuring pain). The DDI 330 could compile and/or combine input from several sources and communicate the input to the HCP which could use the provided information to create instructions to the various devices to be sent back over the DDI 330. The data collection performed by the DDI 330 could also be in the form a log to make sure that all
20 communication between the units in the system can be back traced. Logging the communication ensures that all alterations to software or the settings of the software, as well as the frequency and operation of the implanted medical device 100 can be followed. Following the communication enables the DDI 330 or the HCP to follow the treatment and react it something in the
25 communication indicates that the treatment does not provide the intended results or if something appears to be wrong with any of the components in the system. If patient feedback from the patient display device 334 indicates that a new treatment step of the implant is needed, such information must be confirmed by direct contact between HCP and patient.

30 In the specific embodiment disclosed in fig. 66A, the wireless connections between the different units are as follows. The wireless connection 411 between the auxiliary device 336 and the DDI 330 is based

on WiFi or a mobile telecommunication regime or may be sent to the DDI 330 via the P-EID 320''' and the wireless connection 411 between the auxiliary device 336 and the patient's display device 334 is based on BT or any other communication pathway disclosed herein. The wireless connection 412
5 between the patient's display device 334 and the DDI 330 is based on WiFi or a mobile telecommunication regime. The wireless connection 413 between the patient's display device 334 and the remote control 320'' is based on BT or any other communication pathway disclosed herein. The wireless connection 414 between the patient remote control 320'' and the implanted
10 medical device 100 is based on BT and UWB or any other communication pathway disclosed herein. The wireless connection 415 between the remote control 320'' and the DDI 330 is likely to not be used, and if present be based on WiFi or a mobile telecommunication regime. The wireless connection 416 between the P-EID 320''' and the implanted medical device 100 is based on
15 BT, UWB and the charging signal or any other communication or energizing pathway disclosed herein. The wireless connection 417 between the P-EID 320''' and the DDI 330 is based on WiFi or a mobile telecommunication regime. The wireless connection 418 between the HCP-EID 320' and the implanted medical device 100 is based on at least one of the BT, UWB and
20 the charging signal. The wireless connection 419 between the P-EID 320''' and the HCP DD 332 is based on BT or any other communication path disclosed herein. The wireless connection 420 between the HPC-EID 320' and the DDI 330 is based on WiFi or a mobile telecommunication regime. The wireless connection 421 between the HPC DD 332 and the DDI 330 is
25 normally closed and not used and if so based on WiFi or a mobile telecommunication regime. The wireless connection 422 between the HCP-EID 320' and the HCP DD 332 is based on at least one of BT, UWB, local network or any other communication path disclosed herein.

The wireless connections specifically described in the embodiment
30 shown in fig. 66A may however be replaced or assisted by wireless connections based on radio frequency identification (RFID), near field communication (NFC), Bluetooth, Bluetooth low energy (BLE), or wireless

local area network (WLAN). The mobile telecommunication regimes may for example be 1G, 2G, 3G, 4G, or 5G. The wireless connections may further be based on modulation techniques such as amplitude modulation (AM), frequency modulation (FM), phase modulation (PM), or quadrature amplitude modulation (QAM). The wireless connection may further feature technologies such as time-division multiple access (TDMA), frequency-division multiple access (FDMA), or code-division multiple access (CDMA). The wireless connection may also be based on infra-red (IR) communication. The wireless connection may feature radio frequencies in the high frequency band (HF), very-high frequency band (VHF), and the ultra-high frequency band (UHF) as well as essentially any other applicable band for electromagnetic wave communication. The wireless connection may also be based on ultrasound communication to name at least one example that does not rely on electromagnetic waves.

Fig. 66A also discloses a master private key 333''' device that allow issuance of new private key device wherein the HCP or HCP admin have such master private key 333''' device adapted to be able to replace and pair a new patient private key 333' device or HCP private key device 333'' into the system, through the HCP EID external device 320'.

A system configured for changing pre-programmed treatment settings of an implantable medical device, when implanted in a patient, from a distant remote location in relation to the patient, will be discussed in the following.

Fig. 66A discloses a scenario in which at least one health care provider, HCP, external device 320' is adapted to receive a command from the HCP to change said pre-programmed treatment settings of an implanted medical device 100, further adapted to be activated and authenticated and allowed to perform said command by the HCP providing a HCP private key device 333''. The HCP EID external device 320' further comprising at least one wireless transceiver 328 configured for communication with a patient EID external device 320''', through a first network protocol. The system comprises the patient EID external device 320''', the patient EID external 320''' device being adapted to receive command from said HCP external device 320', and

to relay the received command without modifying said command to the implanted medical device 100. The patient EID external device 320''' comprises a wireless transceiver 328. The patient EID 320''' is adapted to send the command to the implanted medical device 100, to receive a
5 command from the HCP to change said pre-programmed treatment settings of the implanted medical device 100, and further to be activated and authenticated and allowed to perform said command by the patient providing a patient private key 333' device comprising a patient private key.

Although wireless transfer is primarily described in the embodiment
10 disclosed with reference to figs. 66A the wireless communication between any of the external device may be substituted for wired communication. Also, some or all of the wireless communication between an external device and the implanted medical device 100 may be substituted for conductive communication using a portion of the human body as conductor.

15 Fig. 66B shows a portion of fig. 66A, in which some of the components have been omitted to outline a specific scenario. In the scenario outlined in fig. 66B, the system is configured for changing pre-programmed treatment settings of an implantable medical device 100, when implanted in a patient, from a distant remote location in relation to the patient. The system of fig. 66B
20 comprises at least one HCP EID 320' external device adapted to receive commands from the HCP to change said pre-programmed treatment settings of an implanted medical device 100. The HCP EID 320' external device is further adapted to be activated and authenticated and allowed to perform said command by the HCP providing a HCP private key device 333'' adapted to be
25 provided to the HCP EID external device 320'. The private key device 333'' is adapted to be provided to the HCP EID external device 320' via at least one of: a reading slot or comparable for the HCP private key device 333'', and an RFID communication or other close distance wireless activation communication.

30 The HCP EID external device 320' comprises at least one of: a reading slot or comparable for the HCP private key device 333'', an RFID communication, and other close distance wireless activation communication

or electrical direct contact. The HCP EID external device 320' further comprises at least one wireless transceiver 328 configured for communication with a dedicated data infrastructure server (DDI) 330, through a first network protocol. The system further comprises a dedicated data infrastructure server (DDI) 330, adapted to receive command from said HCP EID external device 320', adapted to relay the received commands without modifying said command to a patient EID external device 320''. The dedicated data infrastructure server (DDI) 330 further comprises a wireless transceiver 328 configured for communication with said patient external device. The system further comprises a patient EID external device 320'' adapted to receive the command relayed by the dedicated data infrastructure server (DDI) 330 and further adapted to send commands to the implanted medical device 100 and further adapted to receive commands from the HCP EID external device 320' via the dedicated data infrastructure server (DDI) 330 to change said pre-programmed treatment settings of the implanted medical device 100. The patient EID external device 320'' may further be adapted to be activated and authenticated and allowed to perform said command by the patient providing a patient private key device 333', which may be adapted to be provided to the patient EID external device 320'' by the patient via at least one of: a reading slot or comparable for the patient private key device 333', an RFID communication or other close distance wireless activation communication or electrical direct contact. The patient EID external device 320'' further comprises at least one of: a reading slot or comparable for the HCP private key device, an RFID communication and other close distance wireless activation communication or electrical direct contact. The patient EID external device 320'' further comprises at least one wireless transceiver 328 configured for communication with the implanted medical device 100 through a second network protocol. The implanted medical device 100 is in turn configured to treat the patient or perform a bodily function.

The scenario described with reference to fig. 66B may in alternative embodiments be complemented with additional units or communication

connections, or combined with any of the scenarios described with reference to figures 66C – 66E.

Fig. 66C shows a portion of fig. 65f, in which some of the components have been omitted to outline a specific scenario. In the scenario outlined in
5 fig. 66C, a system configured for changing pre-programmed treatment settings of an implantable medical device 100 is disclosed. The changing of the pre-programmed treatment settings is performed by a health care provider (HCP) in the physical presence of the patient. The system comprises at least one HCP EID external device 320' adapted to receive commands from the
10 HCP, directly or indirectly, to change said pre-programmed treatment settings in steps of an implantable medical device 100, when implanted. The HCP EID external device 320' is further adapted to be activated, authenticated, and allowed to perform said command by the HCP providing a HCP private key device 333'' comprising a HCP private key. The HCP private key device in the
15 embodiment of fig. 119c comprises at least one of: a smart card, a keyring device, a watch, a arm or wrist band, a necklace, and any shaped device. The HCP EID external device 320' is adapted to be involved in at least one of: receiving information from the implant 100, receiving information from a patient remote external device 336, actuating the implanted medical device
20 100, changing pre-programmed settings, and updating software of the implantable medical device 100, when implanted. The HCP EID external device 320' is adapted to be activated, authenticated, and allowed to perform said command also by the patient, the system comprises a patient private key device 333' comprising a patient private key. The patient private key device
25 333' may comprise at least one of: a smart card, a keyring device, a watch, a arm or wrist band, a necklace, and any shaped device. The HCP private key 333'' and the patient's private key may be required for performing said actions by the HCP EID external device 320' to at least one of: receive information from the implant 100, to receive information from a patient remote external
30 device 336, to actuate the implanted medical device 100, to change pre-programmed settings, and to update software of the implantable medical device 100, when the implantable medical device is implanted.

Fig. 64fc also outlines a scenario in which the system is configured for changing pre-programmed treatment settings in steps of an implantable medical device, when implanted in a patient, by a health care provider, HCP, wherein the patient may be located at a remote location, or on a distance.

5 The system may comprise: at least one HCP EID external device 320' adapted to receive a command from the HCP, directly or indirectly, to change said pre-programmed treatment settings in steps of an implanted medical device. The HCP EID external device 320' is further adapted to be activated, authenticated, and allowed to perform said command by the HCP. The action
10 by the HCP EID external device 320' to change pre-programmed settings in the implant 100 and to update software of the implantable medical device 100, when the implantable medical device 100 is implanted, is adapted to be authenticated by a HCP private key device 333'' and a patient private key device 333'.

15 The scenario described with reference to fig. 66C may in alternative embodiments be complemented with additional units or communication connections, or combined with any of the scenarios described with reference to figures 66B, or 66D – 66E.

Fig. 66D shows a portion of fig. 65f, in which some of the components
20 have been omitted to outline a specific scenario. In the scenario outlined in fig. 66D, a system configured to change pre-programmed and pre-selected treatment actions of an implantable medical device 100 by a command from the patient is described. The system comprises an implantable medical device 100, a patient remote external device 320'', and a wireless transceiver
25 328 configured for communication with the implantable medical device 100, when the medical device is implanted, through a second network protocol. The system further comprises a remote display portal interface 334i configured to receive content delivered from the patient remote external device 320'' to expose buttons to express the will to actuate the functions of
30 the implanted medical device 100 by the patient through the patient remote external device 320''. The remote external device 320'' is further configured to present the display portal remotely on a patient display device 334 allowing

the patient to actuate the functions of the implanted medical device 100 through the display portal of the patient remote external device 320'' visualised on the patient display device 334. In fig. 66D, a further wireless connection 423 between the patient remote external device 320'' and the
5 patient EID external device 320''' is provided. This further wireless connection 423 could be a wireless connection according to any one of the wireless signaling methods and protocols described herein, and the communication can be encrypted.

The scenario described with reference to fig. 66D may in alternative
10 embodiments be complemented with additional units or communication connections, or combined with any of the scenarios described with reference to figures 66B, 66C, or 66E.

Fig. 66E shows a portion of fig. 66A, in which some of the components have been omitted to outline a specific scenario. In the scenario outlined in
15 fig. 66E, a system configured for providing information from an implantable medical device 100, when implanted in a patient, from a distant remote location in relation to the patient is described. The system comprises at least one patient EID external device 320''' adapted to receive information from the implant 100, and to send such information further on to a server or dedicated
20 data infrastructure, DDI, 330. The patient EID external device 320''' is further adapted to be activated and authenticated and allowed to receive said information from the implanted medical device 100 by the patient providing a private key. The patient private key device comprises the private key adapted to be provided to the patient EID external device 320''' via at least one of: a
25 reading slot or comparable for the patient private key device, an RFID communication or other close distance wireless activation communication or direct electrical connection, The patient EID external device 320''' comprises at least one of: a reading slot or comparable for the patient private key device, an RFID communication and other close distance wireless activation
30 communication or direct electrical contact. The patient EID external device 320''' further comprises at least one wireless transceiver 328 configured for communication with the DDI 330, through a first network protocol.

The scenario described with reference to fig. 66E may in alternative embodiments be complemented with additional units or communication connections, or combined with any of the scenarios described with reference to figures 66B – 66D.

5 Fig. 66F shows a portion of fig. 66A, in which some of the components have been omitted to outline a specific scenario. In the scenario outlined in fig. 66F a system configured for changing pre-programmed treatment settings in steps of an implantable medical device 100, when implanted in a patient, by a health care provider, HCP, either in the physical presence of the patient
10 or remotely with the patient on distance is described. The system comprises at least one HCP EID external device 320' adapted to receive a command directly or indirectly from the HCP to change said pre-programmed treatment settings in steps of the implantable medical device 100, when implanted, wherein the HCP EID external device 320' is further adapted to be activated,
15 authenticated, and allowed to perform said command by the HCP providing a HCP private key device comprising a HCP private key. The HCP private key comprises at least one of: a smart card, a keyring device, a watch, an arm or wrist band, a necklace, and any shaped device. The system further comprises a patient private key device comprising a patient private key comprising at
20 least one of: a smart card, a keyring device, a watch, an arm or wrist band, a necklace, and any shaped device. Both the HCP and patient private key is required for performing said action by the HCP EID external device 320' to change the pre-programmed settings in the implant 100 and to update software of the implantable medical device 100, when the implantable
25 medical device 100 is implanted. The patient private key is adapted to activate, be authenticated, and allowed to perform said command provided by the HCP, either via the HCP EID external device or when the action is performed remotely via a patient EID external device 320'. In the embodiment shown in fig. 66F, the communication is routed over the DDI server 330.

30 The scenario described with reference to fig. 66F may in alternative embodiments be complemented with additional units or communication

connections, or combined with any of the scenarios described with reference to figures 66B – 66E.

Fig. 66G shows an overview of an embodiment of the system, similar to the one described with reference to fig. 66A, the difference being that the HCP EID and the HCP DDD are combined into a single device.

Fig. 66H shows an overview of an embodiment of the system, similar to that described with reference to fig. 66A, the difference being that the HCP EID 320''' and the HCP DDD 332 are combined into a single device and the P EID 320''' and the patient remote control external device 320'' are combined into a single device.

One probable scenario / design of the communication system is for the purpose of changing pre-programmed treatment settings of an implantable medical device, when implanted in a patient, from a distant remote location in relation to the patient. The system comprises at least one health care provider, HCP, external device 320' adapted to receive a command from the HCP to change said pre-programmed treatment settings of an implanted medical device. The HCP external device 320' is further adapted to be activated and authenticated and allowed to perform said command by the HCP providing a HCP private key device 333'', which may be adapted to be provided to an HCP EID external device via at least one of: a reading slot or comparable for the HCP private key device, a RFID communication or other close distance wireless activation communication. The HCP EID external device comprises at least one of: a reading slot or comparable for the HCP private key device, a RFID communication, and other close distance wireless activation communication or electrical direct contact. The HCP EID external device further comprises at least one wireless transceiver configured for communication with a patient EID external device, through a first network protocol, wherein the system comprises the patient EID external device, the patient EID external device being adapted to receive command from said HCP external device, and to relay the received command without modifying said command to the implanted medical device. The patient EID external device comprising one wireless transceiver configured for communication with

said patient external device. The patient EID is adapted to send the command to the implanted medical device, to receive a command from the HCP to change said pre-programmed treatment settings of the implanted medical device, and further to be activated and authenticated and allowed to perform
5 said command by the patient providing a patient private key device comprising a patient private key.

Although the different scenarios outlined in figures 66B – 66H are described with specific units and method of signaling, these scenarios may very well be combined with each other or complemented with additional units
10 or communication connections.

The embodiments described herein may advantageously be combined. A computer program product of, or adapted to be run on, an internal computing unit or an external device is also provided, which comprises a computer-readable storage medium with instructions adapted to make the
15 internal computing unit and/or the external device perform the actions as described in any embodiment or example above.

The different aspects or any part of an aspect or different embodiments or any part of an embodiment may all be combined in any possible way. For example, all the embodiments relating to the communication and controlling
20 of the implant may be combined with the embodiments relating to the programming of the implant, the methods, and systems for improving energy consumption or the power supply. The embodiments relating to the programming of the implant may be combined with any of the embodiments relating to improving the energy consumption or the power supply. The
25 embodiments relating to the power supply maybe combined with the methods and systems for improving the energy consumption. Any method or any step of method may be seen also as an apparatus description, as well as, any apparatus embodiment, aspect or part of aspect or part of embodiment may be seen as a method description and all may be combined in any possible
30 way down to the smallest detail. Any detailed description should be interpreted in its broadest outline as a general summary description, and please note that any embodiment or part of embodiment as well as any

method or part of method could be combined in any way within the scope of the inventive concept, as defined by the appended claims. All examples herein should be seen as part of the general description and therefore possible to combine in any way in general terms.

- 5 In the following, numbered aspect groups 260SE – 275SE of the present invention are provided. The different aspects are numbered individually within the groups and the references to other aspects relate to aspects within the same group. The scope of protection is however defined by the appended claims.

Aspect group 260SE: Reflux_Stop_Exercise_General

1. An apparatus (100) for treating reflux disease of a human patient, comprising:
 - 5 an implantable movement restriction device (110) having a shape and size allowing it to be arranged to rest against a fundus wall portion (14) of the patient's stomach (10) and to be at least partly invaginated by the fundus wall portion, such that the movement restriction device is implanted at a position between the patient's diaphragm (30) and a lower portion of the fundus wall,
10 and such that movement of the cardia (22) of the patient's stomach towards the diaphragm is restricted to hinder the cardia from sliding through the diaphragm opening (32) into the patient's thorax; and
an electrode arrangement (150) configured to engage and electrically stimulate muscle tissue of the fundus wall portion to exercise the muscle
15 tissue to improve the conditions for long term implantation of the movement restriction device.
2. The apparatus according to aspect 1, wherein the electrode
20 arrangement is arranged on an outer surface of the movement restriction device.
3. The apparatus according to aspect 1 or 2, wherein the electrode
arrangement comprises a plurality of electrode elements (152), each of which
being configured to engage and electrically stimulate the muscle tissue.
25
4. The apparatus according to any of the preceding aspects, wherein the
electrode arrangement comprises a coiled wire for increasing a contact
surface between the electrode arrangement and the muscle tissue and for
allowing the electrode arrangement to follow contraction and relaxation of the
30 muscle tissue.

5. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
6. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
7. The apparatus according to any of the preceding aspects, wherein the electrode arrangement is further configured to be arranged to electrically stimulate the cardiac sphincter to cause the cardiac sphincter (26) to contract.
8. The apparatus according to aspect 7, wherein the electrode arrangement comprises at least two electrode elements (154) configured to be arranged on opposing sides of the cardiac sphincter.
9. The apparatus according to aspect 8, further comprising a holder configured to support the at least two electrode elements at the opposing sides of the cardiac sphincter.
10. The apparatus according to any of the preceding aspects, further comprising an implantable energy source (160) configured to provide the electrode with electrical power.
11. The apparatus according to aspect 10, wherein the implantable energy source is arranged inside the movement restriction device.

12. The apparatus according to aspect 10, wherein the implantable energy source is configured to be arranged outside the movement restriction device.
13. The apparatus according to aspect 12, wherein the implantable energy source is configured to be implanted subcutaneously.
14. The apparatus according to any of aspects 10-13, wherein the implantable energy source comprises a primary cell.
15. The apparatus according to any of aspects 10-14, wherein the implantable energy source comprises a secondary cell.
16. The apparatus according to aspect 14 or 15, further comprising a controller (170) configured to indicate a functional status of the implantable energy source.
17. The apparatus according to aspect 16, wherein the functional status indicates a charge level of the implantable energy source.
18. The apparatus according to aspect 16 or 17, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue and the electrode arrangement.
19. The apparatus according to any of aspects 16-18, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.
20. The apparatus according to aspect 19, further comprising an implantable charger (190) configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by the external energy source.

21. The apparatus according to aspect 20, wherein the charger comprises an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

5

22. The apparatus according to aspect 19 or 20, wherein the charger is configured to control the charging of the implantable energy source based on the functional status.

10 23. The apparatus according to any of aspects 20-22, wherein the charger is configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the implantable charger.

15 24. The apparatus according to any of aspects 20-22, wherein the charger is configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source to the implantable charger.

20 25. The apparatus according to any of aspects 1-15, further comprising a controller (170) configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.

25 26. The apparatus according to aspect 25, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

27. The apparatus according to aspect 26, wherein the controller is configured to control the electrical stimulation such that a pulse of a first
30 polarity is followed by a pulse of a second, reversed polarity.

28. The apparatus according to any of aspects 25-27, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.
- 5 29. The apparatus according to aspect 28, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
30. The apparatus according to aspect 28 or 29, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.
- 10 31. The apparatus according to any of aspects 28-30, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
- 15 32. The apparatus according to any of aspects 28-31, wherein the electrical stimulation signal comprises a build-up period (X1) of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period (X2) of 1-60 s, and a stimulation pause (X4) of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.
- 20 33. The apparatus according to any of aspects 25-32, wherein the controller comprises a wireless remote control (175).
34. The apparatus according to aspect 33, wherein the wireless remote control comprises an external signal transmitter, and wherein the controller comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.
- 25 35. The apparatus according to aspect 35, wherein the signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet
- 30

light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

36. The apparatus according to any of aspects 25-35, further comprising
5 an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.
- 10 37. The apparatus according to aspect 36, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.
38. The apparatus according to any of the preceding aspects, wherein a
15 volume of the movement restriction device is non-adjustable after implantation.
39. The apparatus according to any of aspects 1-37, wherein a volume of the movement restriction device is adjustable after implantation.
- 20 40. The apparatus according to aspect 39, wherein the volume of the movement restriction device is adjustable invasively or non-invasively.
41. The apparatus according to aspect 39 or 40, wherein the movement
25 restriction device comprises an injection port (115) for allowing a fluid to be injected or extracted from the inside of the movement restriction device so as to vary a volume of the movement restriction device after implantation.
42. The apparatus according to any of the preceding aspects, wherein the
30 movement restriction device comprises a biocompatible outer surface configured to rest against the fundus wall portion.

43. The apparatus according to any of the preceding aspects, wherein the movement restriction device is substantially spherical or egg-shaped.
44. The apparatus according to any of aspects 1-42, wherein the
5 movement restriction device has a portion configured to be arranged to point away from the esophagus when implanted.
45. The apparatus according to any of the preceding aspects, wherein the
10 movement restriction device is configured to be invaginated when placed on the outside of the fundus wall portion.
46. The apparatus according to any of aspects 1-44, wherein the
movement restriction device is configured to be invaginated when placed on the inside of the fundus wall portion.
15
47. The apparatus according to any of the preceding aspects, wherein the movement restriction device is configured to be introduced in the patient's body by means of a gastroscope or an intraluminal instrument.
- 20 48. The apparatus according to aspect 47, wherein the movement restriction device is configured to change its shape to allow it to pass through a trocar during insertion into the patient's body.
49. The apparatus according to any of the preceding aspects, wherein the
25 movement restriction device is formed of at least two distinct and separable pieces (111, 112, 113) configured to be assembled into the movement restriction device after insertion in the patient's body.
50. The apparatus according to any of the preceding aspects, wherein a
30 minimum width of the movement restriction device, as measured from side to side, is 30 mm or larger, such as 40 mm or larger.

51. The apparatus according to any of the preceding aspects, wherein a minimum outer circumference of the movement restriction device is 150 mm or less, such as 130 mm or less, such as 110 mm or less, such as 90 mm or less, such as 70 mm or less, such as 50 mm or less, such as 30 mm or less.

Aspect group 261SE: Reflux_Stop_Exercise_Torus

1. An apparatus (100) for treating reflux disease of a human patient, comprising:
 - 5 an at least partly ring-shaped implantable movement restriction device comprising a first portion (110) configured to be at least partly invaginated by a first wall portion of the patient's stomach (10) and arranged such that at least a part of the first portion is arranged above the cardiac notch (24) of the patient's stomach, and such that movement of the cardia (22) towards the
 - 10 diaphragm (30) is restricted to prevent the cardia from sliding through the diaphragm opening (32) into the patient's thorax; and
an electrode arrangement (150) configured to electrically stimulate muscle tissue of the first wall portion to exercise the muscle tissue to improve the conditions for long term implantation of the movement restriction device.
 - 15
2. The apparatus according to aspect 1, wherein the electrode arrangement is arranged on an outer surface of the movement restriction device.
- 20 3. The apparatus according to aspect 1 or 2, wherein the electrode arrangement comprises a plurality of electrode elements (152), each of which being configured to engage and electrically stimulate the muscle tissue.
4. The apparatus according to any of the preceding aspects, wherein the
- 25 electrode arrangement comprises a coiled wire for increasing a contact surface between the electrode arrangement and the muscle tissue and for allowing the electrode arrangement to follow contraction and relaxation of the muscle tissue.
- 30 5. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic

charge transfer to the be predominant charge transfer mechanism over said interface.

6. The apparatus according to any of the preceding aspects, wherein the
5 electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
- 10 7. The apparatus according to any of the preceding aspects, wherein the electrode arrangement is further configured to be arranged to electrically stimulate the cardiac sphincter (26) of the patient to cause the cardiac sphincter to contract.
- 15 8. The apparatus according to aspect 7, wherein the electrode arrangement comprises at least two electrode elements (154) configured to be arranged on opposing sides of the cardiac sphincter.
9. The apparatus according to aspect 8, further comprising a holder (120)
20 configured to support the at least two electrode elements at the opposing sides of the cardiac sphincter.
10. The apparatus according to any of the preceding aspects, further comprising an implantable energy source (160) configured to provide the
25 electrode with electrical power.
11. The apparatus according to aspect 10, wherein the implantable energy source is arranged inside the movement restriction device.
- 30 12. The apparatus according to aspect 10, wherein the implantable energy source is configured to be arranged outside the movement restriction device.

13. The apparatus according to aspect 12, wherein the implantable energy source is configured to be implanted subcutaneously.
14. The apparatus according to any of aspects 10-13, wherein the
5 implantable energy source comprises a primary cell.
15. The apparatus according to any of aspects 10-14, wherein the implantable energy source comprises a secondary cell.
- 10 16. The apparatus according to aspect 14 or 15, further comprising a controller (170) configured to indicate a functional status of the implantable energy source.
17. The apparatus according to aspect 16, wherein the functional status
15 indicates a charge level of the implantable energy source.
18. The apparatus according to aspect 16 or 17, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.
20
19. The apparatus according to any of aspects 16-18, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.
- 25 20. The apparatus according to aspect 19, further comprising an implantable charger (190) configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by the external energy source.
- 30 21. The apparatus according to aspect 20, wherein the charger comprises an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

22. The apparatus according to aspect 20 or 21, wherein the charger is configured to control the charging of the implantable energy source based on the functional status.

5

23. The apparatus according to any of aspects 20-22, wherein the charger is configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the implantable charger.

10

24. The apparatus according to any of aspects 20-22, wherein the charger is configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source to the implantable charger.

15

25. The apparatus according to aspect 1, further comprising controller (170) configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.

20 26. The apparatus according to aspect 25, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

27. The apparatus according to aspect 26, wherein the controller is
25 configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.

28. The apparatus according to any of aspects 25-27, wherein the
controller is configured to generate a pulsed electrical stimulation signal
30 comprising a pulse frequency (F) of 0.01-150 Hz.

29. The apparatus according to aspect 28, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
30. The apparatus according to aspect 28 or 29, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.
31. The apparatus according to any of aspects 28-30, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
32. The apparatus according to any of aspects 28-31, wherein the electrical stimulation signal comprises a build-up period (X1) of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period (X2) of 1-60 s, and a stimulation pause (X4) of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.
33. The apparatus according to any of aspects 25-32, wherein the controller comprises a wireless remote control (175).
34. The apparatus according to aspect 33, wherein the wireless remote control comprises an external signal transmitter, and wherein the apparatus further comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.
35. The apparatus according to aspect 35, wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

36. The apparatus according to any of aspects 25-35, further comprising an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the
5 sensed action potentials.

37. The apparatus according to aspect 36, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

10

38. The apparatus according to any of the preceding aspects, wherein a volume of the movement restriction device is non-adjustable after implantation.

15 39. The apparatus according to any of aspects 1-37, wherein a volume of the movement restriction device is adjustable after implantation.

40. The apparatus according to aspect 39, wherein the volume of the movement restriction device is adjustable invasively or non-invasively.

20

41. The apparatus according to aspect 39 or 40, wherein the movement restriction device comprises an injection port (115) for allowing a fluid to be injected or extracted from the inside of the movement restriction device so as to vary a volume of the movement restriction device after implantation.

25

42. The apparatus according to any of the preceding aspects, wherein the movement restriction device comprises a biocompatible outer surface configured to rest against the first wall portion.

30 43. The apparatus according to any of the preceding aspects, wherein the first wall portion is a fundus wall portion (14).

44. The apparatus according to aspect any of the preceding aspects, wherein the movement restriction device further comprises a second portion (120), and wherein the first and second portions of the movement restriction device are configured to be arranged on opposite sides of the cardia (26).

5

45. The apparatus according to aspect 44, wherein the movement restriction device is configured to be arranged such that a gap is formed between the second portion of the movement restriction device and the esophagus.

10

46. The apparatus according to aspect 44, wherein the second portion of the movement restriction device is configured to be at least partly invaginated by a second wall portion of the stomach.

15 47. The apparatus according to any of the preceding aspects, wherein the movement restriction device is configured to be arranged such that a portion of the first wall portion is arranged between the first portion of the movement restriction device and the esophagus.

20 48. The apparatus according to any of the preceding aspects, wherein the movement restriction device is configured to be at least partly invaginated by the first wall portion along at least half of the toroidal length of the movement restriction device.

25 49. The apparatus according to any of the preceding aspects, wherein the movement restriction device is configured to be invaginated when placed on the outside of the stomach wall.

50. The apparatus according to any of the preceding aspects, wherein the
30 movement restriction device comprises two end portions configured to be coupled to each other to form a closed ring.

51. The apparatus according to aspect 50, wherein the end portions are configured to be releasably attached to each other.

52. The apparatus according to aspect 44, wherein a poloidal
5 circumference of the movement restriction device is larger for the first portion and for the second portion.

53. The apparatus according to aspect 52, wherein a minimum width of the first portion of the movement restriction device, as measured from side to
10 side, is 30 mm or larger, such as 40 mm or larger.

54. The apparatus according to aspect 52, wherein a minimum poloidal circumference of the first portion of the movement restriction device is 150 mm or less, such as 130 mm or less, such as 110 mm or less, such as 90 mm
15 or less, such as 70 mm or less, such as 50 mm or less, such as 30 mm or less.

55. The apparatus according to any of the preceding aspects, wherein the movement restriction device has a shape conforming to a torus.

Aspect group 262SE: Reflux_Constricting-Band_Cover

1. An apparatus (100) for treating reflux disease of a human patient, comprising:
 - 5 an elongated core (210) having a length allowing the core to at least partly encircle the esophagus (20) of the patient, wherein the length is variable to allow the core to be arranged in a constricting state for hindering fluid from passing from the stomach (10) into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the
 - 10 patient swallowing; and
a tubular cover (220) enclosing at least a part of the core and comprising a plurality of portions (224, 225, 226) adapted to bend relative to each other to allow the core to change between the constricting state and the expanded state, when the cover is at least partly covered by fibrotic tissue,
 - 15 without being substantially hindered or impeded by the presence of said fibrotic tissue.
2. The apparatus according to aspect 1, wherein the core is configured to allow a transition from the constricting state into the expanded state caused
- 20 by the food passing through esophagus.
3. The apparatus according to aspect 1 or 2, wherein the core is configured to exert an encircling pressure on the esophagus in the constricting state.
- 25 4. The apparatus according to aspect 3, further comprising an attractor (212, 213) for resiliently attracting adjacent portions of the core to one another to generate the encircling pressure.
- 30 5. The apparatus according to aspect 4, wherein the attractor comprises an elastic element (212).

6. The apparatus according to aspect 4 or 5, wherein the attractor comprises at least two mutually attracting magnets (213).
7. The apparatus according to aspect 6, further comprising a link (214)
5 connecting a first and a second one of said at least two magnets to each other.
8. The apparatus according to aspect 7, wherein the link is configured to extend into at least one of said magnets in response to said magnets moving
10 towards each other.
9. The apparatus according to any of the preceding aspects, wherein the cover comprises an array of tubular segments (222).
- 15 10. The apparatus according to any of the preceding aspects, wherein the cover comprises a biocompatible outer surface for long-term implantation.
11. The apparatus according to any of the preceding aspects, wherein the cover is configured to rest against an outer surface of the esophagus.
20
12. The apparatus according to any of the preceding aspects, wherein the cover comprises a surface promoting tissue growth.
13. The apparatus according to any of the preceding aspects, wherein the
25 cover is formed of a polymer material, such as silicone.
14. The apparatus according to any of the preceding aspects, wherein the cover is formed of a material having a thickness of 0.1 to 10 mm, such as 1-5 mm.
30

15. The apparatus according to any of the preceding aspects, wherein the cover comprises at least one predefined fold (224) along which the cover is allowed to fold in response to the core varying its length.
- 5 16. The apparatus according to any of the preceding aspects, wherein the cover comprises lowered and elevated portions (225, 226) allowing the cover to vary its length while maintaining its surface area.
17. The apparatus according to any of the preceding aspects, wherein the
10 cover is configured to be compressible and expandable in its length direction.
18. The apparatus according to any of the preceding aspects, wherein a length of the cover enclosing said at least a part of the core exceeds a length of said at least a part of the core when said at least a part of the core is
15 arranged in the constricting state.
19. The apparatus according to any of the preceding aspects, wherein the core comprises two end portions (216) configured to be coupled to each other to form a closed ring around the esophagus.
20
20. The apparatus according to aspect 21, wherein the end portions are configured to be releasably attached to each other.
21. The apparatus according to aspect 20 or 21, wherein the end portions
25 comprise a respective interlockable attacher.
22. The apparatus according to aspect 1, wherein the core comprises a plurality of core elements configured to be arranged in an annular array around the esophagus.

23. The apparatus according to aspect 22, wherein the core further comprises a plurality of links, each of which extending between a respective pair of core elements arranged adjacent to each other.
- 5 24. The apparatus according to aspect 23, wherein each of the links is configured to allow the respective core elements to move towards and away from each other.
25. The apparatus according to aspect 24, wherein each of the links is
10 configured to extend into at least one of the core elements of the respective pair of core elements as said core elements move towards each other.
26. The apparatus according to aspects 22-25, further comprising an
15 attractor for resiliently attracting adjacent core elements of the annular array to each other.
27. The apparatus according to aspect 26, wherein the attractor comprises at least one of a magnet, an elastic member, and a spring.
- 20 28. The apparatus according to any of the preceding aspects, further comprising an electrode arrangement (150) configured to be arranged between the apparatus and the esophagus and to electrically stimulate muscle tissue of the outer wall of the esophagus to exercise the muscle tissue to improve the conditions for long term implantation of the movement
25 restriction device.
29. The apparatus according to aspect 28, wherein the electrode arrangement is arranged on an outer surface of the cover.
- 30 30. The apparatus according to aspect 28 or 29, wherein the electrode arrangement comprises a plurality of electrode elements (154), each of which being configured to electrically stimulate the muscle tissue.

31. The apparatus according to any of aspects 28-30, wherein the electrode arrangement comprises a coiled wire for increasing a contact surface between the electrode arrangement and the muscle tissue and for
5 allowing the electrode arrangement to follow contraction and relaxation of the muscle tissue.
32. The apparatus according to any of aspects 28-31, wherein the electrode arrangement comprises a bare electrode portion (155) configured to
10 form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
33. The apparatus according to any of aspects 28-31, wherein the
15 electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
- 20 34. The apparatus according to any of aspects 28-33, wherein the electrode arrangement is configured to be to electrically stimulate the cardiac sphincter (26) of the patient to cause the cardiac sphincter to contract.
35. The apparatus according to aspect 34, wherein the electrode
25 arrangement comprises at least two electrode elements (154) configured to be arranged on opposing sides of the cardiac sphincter.
36. The apparatus according to any of aspects 28-35, further comprising an implantable energy source (160) configured to provide the electrode
30 arrangement with electrical power.

37. The apparatus according to aspect 36, wherein the implantable energy source is arranged inside the cover.

38. The apparatus according to aspect 36, wherein the implantable energy
5 source is configured to be arranged outside the cover.

39. The apparatus according to aspect 38, wherein the implantable energy source is configured to be implanted subcutaneously.

10 40. The apparatus according to any of aspects 36-39, wherein the implantable energy source comprises a primary cell.

41. The apparatus according to any of aspects 36-40, wherein the implantable energy source comprises a secondary cell.

15

42. The apparatus according to aspect 36-41, further comprising a controller (170) configured to indicate a functional status of the implantable energy source.

20 43. The apparatus according to aspect 42, wherein the functional status indicates a charge level of the implantable energy source.

44. The apparatus according to aspect 42 or 43, wherein the functional status indicates a temperature of at least one of the implantable energy
25 source, the muscle tissue, and the electrode arrangement.

45. The apparatus according to any of aspects 36-44, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.

30

46. The apparatus according to aspect 45, further comprising an implantable charger (190) configured to be electrically connected to the

implantable energy source and enable charging of the implantable energy source by the external energy source.

47. The apparatus according to aspect 46, wherein the charger comprises
5 an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

48. The apparatus according to aspect 46 or 47, wherein the charger is
configured to control the charging of the implantable energy source based on
10 the functional status.

49. The apparatus according to any of aspects 46-48, wherein the charger
is configured to control the charging of the implantable energy source by
controlling a receipt of electrical power from the external energy source at the
15 implantable charger.

50. The apparatus according to any of aspects 46-48, wherein the charger
is configured to control the charging of the implantable energy source by
controlling a transmission of electrical power from the external energy source
20 to the implantable charger.

51. The apparatus according to aspect 28, further comprising controller
(170) configured to be operably connected to the electrode arrangement for
controlling the electrical stimulation of the muscle tissue.
25

52. The apparatus according to aspect 51, wherein the controller is
configured to control the electrical stimulation such that the muscle tissue is
stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

30 53. The apparatus according to aspect 52, wherein the controller is
configured to control the electrical stimulation such that a pulse of a first
polarity is followed by a pulse of a second, reversed polarity.

54. The apparatus according to any of aspects 51-53, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.

5

55. The apparatus according to aspect 54, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.

56. The apparatus according to aspect 54 or 55, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

57. The apparatus according to any of aspects 54-56, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.

15

58. The apparatus according to any of aspects 54-57, wherein the electrical stimulation signal comprises a build-up period (X1) of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period (X2) of 1-60 s, and a stimulation pause (X4) of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

59. The apparatus according to any of aspects 51-58, wherein the controller comprises a wireless remote control (175).

60. The apparatus according to aspect 59, wherein the wireless remote control comprises an external signal transmitter, and wherein the apparatus further comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

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61. The apparatus according to aspect 60, wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an

electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

- 5 62. The apparatus according to any of aspects 51-61, further comprising an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.

10

63. The apparatus according to aspect 62, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

Aspect group 263SE: Reflux_Constricting-Band_Stimulation

1. An apparatus (100) for treating reflux disease of a human patient, comprising:
 - 5 an elongated core (210) having a length allowing the core to at least partly encircle the esophagus (20) of the patient, wherein the length is variable to allow the core to be arranged in a constricting state for hindering fluid from passing from the stomach (10) into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the
 - 10 patient swallowing; and
an electrode arrangement (150) comprising an electrode element (154) supported by the core and configured to electrically stimulate muscle tissue of the esophagus.
- 15 2. The apparatus according to aspect 1, wherein the core is configured to allow a transition from the constricting state into the expanded state caused by the food passing through esophagus.
3. The apparatus according to aspect 1 or 2, wherein the core is
- 20 configured to exert an encircling pressure on the esophagus in the constricting state.
4. The apparatus according to aspect 3, further comprising an attractor (212) for resiliently attracting adjacent portions (213) of the core to one
- 25 another to generate the encircling pressure.
5. The apparatus according to aspect 4, wherein the attractor comprises an elastic element.
- 30 6. The apparatus according to aspect 4 or 5, wherein the attractor comprises at least two mutually attracting magnets.

7. The apparatus according to aspect 6, further comprising a link (214) connecting a first and a second one of said at least two magnets to each other.
- 5 8. The apparatus according to aspect 7, wherein the link is configured to extend into at least one of said magnets in response to said magnets moving towards each other.
9. The apparatus according to any of the preceding aspects, wherein the
10 core comprises a biocompatible outer surface for long-term implantation.
10. The apparatus according to any of the preceding aspects, wherein the core comprises two end portions (216) configured to be coupled to each other to form a closed ring around the esophagus.
- 15 11. The apparatus according to aspect 10, wherein the end portions are configured to be releasably attached to each other.
12. The apparatus according to aspect 10 or 11, wherein the end portions
20 comprise a respective interlockable attacher.
13. The apparatus according to aspect 1, wherein the core comprises a plurality of core elements configured to be arranged in an annular array around the esophagus.
- 25 14. The apparatus according to aspect 13, wherein the core further comprises a plurality of links, each of which extending between a respective pair of core elements arranged adjacent to each other.
- 30 15. The apparatus according to aspect 14, wherein each of the links is configured to allow the respective core elements to move towards and away from each other.

16. The apparatus according to aspect 15, wherein each of the links is configured to extend into at least one of the core elements of the respective pair of core elements as said core elements move towards each other.

5

17. The apparatus according to aspects 13-16, further comprising an attractor for resiliently attracting adjacent core elements of the annular array to each other.

10 18. The apparatus according to aspect 17, wherein the attractor comprises at least one of a magnet, an elastic member, and a spring.

19. The apparatus according to any of the preceding aspects, wherein the electrode arrangement is configured to electrically stimulate the muscle tissue
15 so as to exercise the muscle tissue to improve the conditions for long term implantation of the core.

20. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises a plurality of electrode elements (154),
20 each of which being configured to electrically stimulate the muscle tissue.

21. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises a coiled wire for allowing the electrode arrangement to follow a variation of the length of the core.

25

22. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said
30 interface.

23. The apparatus according to any of aspects 1-21, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
24. The apparatus according to any of the preceding aspects, wherein the electrode arrangement is configured to be to electrically stimulate the cardiac sphincter of the patient to cause the cardiac sphincter to contract.
25. The apparatus according to aspect 24, wherein the electrode arrangement comprises at least two electrode elements configured to be arranged on opposing sides of the cardiac sphincter.
26. The apparatus according to any of the preceding aspects, further comprising an implantable energy source (160) configured to provide the electrode arrangement with electrical power.
27. The apparatus according to aspect 26, wherein the implantable energy source is arranged inside the core.
28. The apparatus according to aspect 26, wherein the implantable energy source is configured to be arranged outside the core.
29. The apparatus according to aspect 28, wherein the implantable energy source is configured to be implanted subcutaneously.
30. The apparatus according to any of aspects 26-29, wherein the implantable energy source comprises a primary cell.
31. The apparatus according to any of aspects 26-30, wherein the implantable energy source comprises a secondary cell.

32. The apparatus according to aspect 26-31, further comprising a controller (170) configured to indicate a functional status of the implantable energy source.

5

33. The apparatus according to aspect 32, wherein the functional status indicates a charge level of the implantable energy source.

34. The apparatus according to aspect 32 or 33, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.

35. The apparatus according to any of aspects 26-34, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.

36. The apparatus according to aspect 35, further comprising an implantable charger (190) configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by the external energy source.

37. The apparatus according to aspect 36, wherein the charger comprises an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

25

38. The apparatus according to aspect 36 or 37, wherein the charger is configured to control the charging of the implantable energy source based on the functional status.

39. The apparatus according to any of aspects 36-38, wherein the charger is configured to control the charging of the implantable energy source by

30

controlling a receipt of electrical power from the external energy source at the implantable charger.

40. The apparatus according to any of aspects 36-38, wherein the charger
5 is configured to control the charging of the implantable energy source by
controlling a transmission of electrical power from the external energy source
to the implantable charger.

41. The apparatus according to any of the preceding aspects, further
10 comprising a controller (170) configured to be operably connected to the
electrode arrangement for controlling the electrical stimulation of the muscle
tissue.

42. The apparatus according to aspect 41, wherein the controller is
15 configured to control the electrical stimulation such that the muscle tissue is
stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

43. The apparatus according to aspect 42, wherein the controller is
configured to control the electrical stimulation such that a pulse of a first
20 polarity is followed by a pulse of a second, reversed polarity.

44. The apparatus according to any of aspects 41-43, wherein the
controller is configured to generate a pulsed electrical stimulation signal
comprising a pulse frequency (F) of 0.01-150 Hz.

25

45. The apparatus according to aspect 44, wherein the electrical
stimulation signal comprises a pulse duration (D) of 0.01-100 ms.

46. The apparatus according to aspect 44 or 45, wherein the electrical
30 stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

47. The apparatus according to any of aspects 44-46, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.

5 48. The apparatus according to any of aspects 44-47, wherein the electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

10

49. The apparatus according to any of aspects 41-48, wherein the controller comprises a wireless remote control (175).

15 50. The apparatus according to aspect 49, wherein the wireless remote control comprises an external signal transmitter, and wherein the apparatus further comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

20 51. The apparatus according to aspect 50, wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

25

52. The apparatus according to any of aspects 41-51, further comprising an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the
30 sensed action potentials.

53. The apparatus according to aspect 52, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

Aspect group 264SE: Reflux_Constricting-Band_No_Core

1. An apparatus (100) for treating reflux disease of a human patient, comprising:
 - 5 a tubular device (220) having a length allowing the tubular device to at least partly encircle the esophagus (20) of the patient, wherein the length is variable to allow the tubular cover to be arranged in a constricting state for hindering fluid from passing from the stomach (10) into the esophagus and in an expanded state for allowing food to pass into the stomach in response to
10 the patient swallowing;
wherein the outer surface of the tubular device comprises a plurality of portions (224, 225, 226) adapted to bend relative to each other to allow the tubular device to change between the constricting state and the expanded state, when the outer surface is at least partly covered by fibrotic tissue,
15 without being substantially hindered or impeded by the presence of said fibrotic tissue.
 2. The apparatus according to aspect 1, wherein the tubular device is configured to allow a transition from the constricting state into the expanded
20 state caused by the food passing through esophagus.
 3. The apparatus according to aspect 1 or 2, wherein the tubular device is configured to exert an encircling pressure on the esophagus in the
25 constricting state.
 4. The apparatus according to aspect 3, further comprising an attractor (212, 213) for resiliently attracting adjacent portions of the tubular device to one another to generate the encircling pressure.
 - 30 5. The apparatus according to aspect 4, wherein the attractor comprises an elastic element (212).

6. The apparatus according to aspect 4 or 5, wherein the attractor comprises at least two mutually attracting magnets (213).
7. The apparatus according to aspect 6, further comprising a link (214)
5 connecting a first and a second one of said at least two magnets to each other.
8. The apparatus according to aspect 7, wherein the link is configured to extend into at least one of said magnets in response to said magnets moving
10 towards each other.
9. The apparatus according to any of the preceding aspects, wherein the tubular device comprises an array of tubular segments (222).
- 15 10. The apparatus according to any of the preceding aspects, wherein the tubular device comprises a biocompatible outer surface for long-term implantation.
11. The apparatus according to any of the preceding aspects, wherein the
20 tubular device is configured to rest against an outer surface of the esophagus.
12. The apparatus according to any of the preceding aspects, wherein the tubular device comprises a surface promoting tissue growth.
- 25 13. The apparatus according to any of the preceding aspects, wherein the tubular device is formed of a polymer material, such as silicone.
14. The apparatus according to any of the preceding aspects, wherein the tubular device is formed of a material having a thickness of 0.1 to 10 mm,
30 such as 1 to 5 mm.

15. The apparatus according to any of the preceding aspects, wherein the tubular device comprises at least one predefined fold (224) along which the tubular device is allowed to fold in response to the tubular device varying its length.

5

16. The apparatus according to any of the preceding aspects, wherein the tubular device comprises lowered and elevated portions (225, 226) allowing the tubular device to vary its length while maintaining its surface area.

10 17. The apparatus according to any of the preceding aspects, wherein the tubular device is configured to be compressible and expandable in its length direction.

15 18. The apparatus according to any of the preceding aspects, wherein the tubular device comprises two end portions (216) configured to be coupled to each other to form a closed ring around the esophagus.

19. The apparatus according to aspect 18, wherein the end portions are configured to be releasably attached to each other.

20

20. The apparatus according to aspect 18 or 19, wherein the end portions comprise a respective interlockable attacher.

21. The apparatus according to any of the preceding aspects, further
25 comprising an elongated core (210) configured to be enclosed by the tubular device, and to vary its length in accordance with the varying length of the tubular device.

22. The apparatus according to aspect 21, wherein the core comprises a
30 plurality of core elements configured to be arranged in an annular array around the esophagus.

23. The apparatus according to aspect 22, wherein the core further comprises a plurality of links, each of which extending between a respective pair of core elements arranged adjacent to each other.
- 5 24. The apparatus according to aspect 23, wherein each of the links is configured to allow the respective core elements to move towards and away from each other.
25. The apparatus according to aspect 24, wherein each of the links is
10 configured to extend into at least one of the core elements of the respective pair of core elements as said core elements move towards each other.
26. The apparatus according to aspects 22-25, further comprising an
15 attractor for resiliently attracting adjacent core elements of the annular array to each other.
27. The apparatus according to aspect 26, wherein the attractor comprises at least one of a magnet, an elastic member, and a spring.
- 20 28. The apparatus according to any of the preceding aspects, further comprising an electrode arrangement (150) configured to be arranged between the apparatus and the esophagus and to electrically stimulate muscle tissue of the outer wall of the esophagus to exercise the muscle tissue to improve the conditions for long term implantation of the movement
25 restriction device.
29. The apparatus according to aspect 28, wherein the electrode arrangement is arranged on the outer surface of the tubular device.
- 30 30. The apparatus according to aspect 28 or 29, wherein the electrode arrangement comprises a plurality of electrode elements (154), each of which being configured to electrically stimulate the muscle tissue.

31. The apparatus according to any of aspects 28-30, wherein the electrode arrangement comprises a coiled wire for increasing a contact surface between the electrode arrangement and the muscle tissue and for
5 allowing the electrode arrangement to follow contraction and relaxation of the muscle tissue.
32. The apparatus according to any of aspects 28-31, wherein the electrode arrangement comprises a bare electrode portion (155) configured to
10 form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
33. The apparatus according to any of aspects 28-31, wherein the
15 electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
- 20 34. The apparatus according to any of aspects 28-33, wherein the electrode arrangement is configured to be to electrically stimulate the cardiac sphincter (26) of the patient to cause the cardiac sphincter to contract.
35. The apparatus according to aspect 34, wherein the electrode
25 arrangement comprises at least two electrode elements (154) configured to be arranged on opposing sides of the cardiac sphincter.
36. The apparatus according to any of aspects 28-35, further comprising an implantable energy source (160) configured to provide the electrode
30 arrangement with electrical power.

37. The apparatus according to aspect 36, wherein the implantable energy source is arranged inside the cover.

38. The apparatus according to aspect 36, wherein the implantable energy
5 source is configured to be arranged outside the cover.

39. The apparatus according to aspect 38, wherein the implantable energy source is configured to be implanted subcutaneously.

10 40. The apparatus according to any of aspects 36-39, wherein the implantable energy source comprises a primary cell.

41. The apparatus according to any of aspects 36-40, wherein the implantable energy source comprises a secondary cell.

15

42. The apparatus according to aspect 36-41, further comprising a controller (170) configured to indicate a functional status of the implantable energy source.

20 43. The apparatus according to aspect 42, wherein the functional status indicates a charge level of the implantable energy source.

44. The apparatus according to aspect 42 or 43, wherein the functional status indicates a temperature of at least one of the implantable energy
25 source, the muscle tissue, and the electrode arrangement.

45. The apparatus according to any of aspects 36-44, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.

30

46. The apparatus according to aspect 45, further comprising an implantable charger (190) configured to be electrically connected to the

implantable energy source and enable charging of the implantable energy source by the external energy source.

47. The apparatus according to aspect 46, wherein the charger comprises
5 an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

48. The apparatus according to aspect 46 or 47, wherein the charger is configured to control the charging of the implantable energy source based on
10 the functional status.

49. The apparatus according to any of aspects 46-48, wherein the charger is configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the
15 implantable charger.

50. The apparatus according to any of aspects 46-48, wherein the charger is configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source
20 to the implantable charger.

51. The apparatus according to aspect 28, further comprising controller (170) configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.
25

52. The apparatus according to aspect 51, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

30 53. The apparatus according to aspect 52, wherein the controller is configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.

54. The apparatus according to any of aspects 51-53, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.

5

55. The apparatus according to aspect 54, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.

56. The apparatus according to aspect 54 or 55, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

57. The apparatus according to any of aspects 54-56, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.

15

58. The apparatus according to any of aspects 54-57, wherein the electrical stimulation signal comprises a build-up period (X1) of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period (X2) of 1-60 s, and a stimulation pause (X4) of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

59. The apparatus according to any of aspects 51-58, wherein the controller comprises a wireless remote control (175).

60. The apparatus according to aspect 59, wherein the wireless remote control comprises an external signal transmitter, and wherein the apparatus further comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

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61. The apparatus according to aspect 60, wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an

electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

- 5 62. The apparatus according to any of aspects 51-61, further comprising an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.

10

63. The apparatus according to aspect 62, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

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Aspect group 265SE: Reflux_Constricting-Band_Stop

1. An apparatus (100) for treating reflux disease of a human patient, comprising an elongated core (210) having a length allowing the core to at
5 least partly encircle the esophagus (20) of the patient;
wherein the length is variable to allow the core to be arranged in a constricting state for hindering fluid from passing from the stomach (10) into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the patient swallowing; and
10 wherein the elongated core has a size allowing at least a portion of the elongated core to protrude above the cardiac sphincter of the patient, when implanted, such that movement of the cardia towards the diaphragm is restricted to hinder the cardia from sliding through the diaphragm opening (32) into the patient's thorax.
15
2. The apparatus according to aspect 1, wherein the elongated core has a maximum height exceeding 2 cm, as measured in a normal direction to the plane in which the elongated core extends when encircling the esophagus.
- 20 3. The apparatus according to aspect 2, wherein the maximum height is 3 cm or more, such as 4 cm or more, such as 5 cm or more.
4. The apparatus according to aspect 2 of 3, wherein the elongated core is configured to be implanted such that a portion of the elongated core having
25 the maximum height is arranged at the fundus side of the esophagus.
5. The apparatus according to any of the preceding aspects, wherein the elongated core comprises a plurality of portions that are movable relative to each other.
30

6. The apparatus according to aspect 5, wherein the elongated core is configured to exert an encircling pressure on the esophagus in the constricting state.
- 5 7. The apparatus according to aspect 6, further comprising an attractor (212) for resiliently attracting adjacent portions (213) of the elongated core to one another to generate the encircling pressure.
8. The apparatus according to aspect 7, wherein the attractor comprises
10 an elastic element.
9. The apparatus according to aspect 7, wherein the attractor comprises at least two mutually attracting magnets.
- 15 10. The apparatus according to aspect 9, further comprising a link (214) connecting a first and a second one of said at least two magnets to each other.
11. The apparatus according to any of the preceding aspects, further
20 comprising a tubular cover (220) enclosing at least a part of the elongated core and comprising a plurality of cover portions (224, 225, 226) adapted to bend relative to each other to allow the elongated core to change between the constricting state and the expanded state, when the cover is at least partly covered by fibrotic tissue, without being substantially hindered or impeded by
25 the presence of said fibrotic tissue.
12. The apparatus according to aspect 11, wherein the elongated core comprises an array of tubular segments (222).
- 30 13. The apparatus according to aspect 11 or 12, wherein the cover is formed of an inelastic material.

14. The apparatus according to any of aspects 11-13, wherein the cover comprises a biocompatible outer surface for long-term implantation.
15. The apparatus according to any of aspects 11-14, wherein the cover is
5 configured to rest against an outer surface of the esophagus.
16. The apparatus according to any of aspects 11-15, wherein the cover comprises a surface promoting tissue growth.
- 10 17. The apparatus according to any of aspects 11-16, wherein the cover is formed of a polymer material, such as silicone.
18. The apparatus according to any of aspects 11-17, wherein the cover is formed of a material having a thickness of 0.1 to 10 mm, such as 1 to 5 mm.
15
19. The apparatus according to any of aspects 11-18, wherein the cover comprises at least one predefined fold (224) along which the cover is allowed to fold in response to the elongated core varying its length.
- 20 20. The apparatus according to any of aspects 11-19, wherein the cover comprises lowered and elevated portions (224, 225) allowing the cover to vary its length while maintaining its surface area.
21. The apparatus according to any of aspects 11-20, wherein the cover is
25 configured to be compressible and expandable in its length direction.
22. The apparatus according to any of aspects 11-21, wherein a length of the cover enclosing said at least a part of elongated core exceeds a length of said at least a part of the elongated core when said at least a part of the
30 second implantable portion is arranged in the constricting state.

23. The apparatus according to any of the preceding aspects, comprising two end portions (216) configured to be coupled to each other to form a closed ring around the esophagus.
- 5 24. The apparatus according to aspect 23, wherein the end portions are configured to be releasably attached to each other.
25. The apparatus according to aspect 23 or 24, wherein the end portions comprise a respective interlockable attacher.
- 10 26. The apparatus according to aspect 1, wherein the elongated core comprises a plurality of bodies (213) configured to be arranged in an annular array around the esophagus.
- 15 27. The apparatus according to aspect 26, wherein the elongated core further comprises a plurality of links (214), each of which extending between a respective pair of bodies arranged adjacent to each other.
28. The apparatus according to aspect 27, wherein the elongated core
20 comprises at least some of the plurality bodies and at least some of the plurality of links, and wherein each of said links is configured to allow the respective ones of said bodies to move towards and away from each other.
29. The apparatus according to aspect 28, wherein each of said links is
25 configured to extend into at least one of the respective ones of said bodies as said bodies move towards each other.
30. The apparatus according to aspects 26, wherein the elongated core
comprises at least some of the plurality of bodies and at least some of the
30 plurality of links, and wherein the apparatus further comprises an attractor for resiliently attracting adjacent ones of said bodies to each other.

31. The apparatus according to aspect 30, wherein the attractor comprises at least one of a magnet, an elastic member, and a spring.

32. The apparatus according to any of the preceding aspects, wherein the
5 elongated core comprises a biocompatible outer surface configured to rest against the fundus wall portion.

33. The apparatus according to any of the preceding aspects, further
10 comprising an electrode arrangement (150) configured to be arranged between the apparatus and the esophagus and to electrically stimulate muscle tissue of the outer wall of the esophagus to exercise the muscle tissue to improve the conditions for long term implantation of the movement restriction device.

15

34. The apparatus according to aspect 33, wherein the electrode arrangement is arranged on an outer surface of the elongated core.

35. The apparatus according to aspect 33 or 34, wherein the electrode
20 arrangement comprises a plurality of electrode elements (152, 154), each of which being configured to electrically stimulate the muscle tissue.

36. The apparatus according to any of aspects 33-35, wherein the
25 electrode arrangement comprises a coiled wire for increasing a contact surface between the electrode arrangement and the muscle tissue and for allowing the electrode arrangement to follow contraction and relaxation of the muscle tissue.

37. The apparatus according to any of aspects 33-36, wherein the
30 electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic

charge transfer to the be predominant charge transfer mechanism over said interface.

38. The apparatus according to any of aspects 33-36, wherein the
5 electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
- 10 39. The apparatus according to any of aspects 33-38, wherein the electrode arrangement is configured be arranged to electrically stimulate the cardiac sphincter (26) of the patient to cause the cardiac sphincter to contract.
40. The apparatus according to aspect 39, wherein the electrode
15 arrangement comprises at least two electrode elements (154) configured to be arranged on opposing sides of the cardiac sphincter.
41. The apparatus according to any of aspects 33-40, further comprising an implantable energy source (160) configured to provide the electrode
20 arrangement with electrical power.
42. The apparatus according to aspect 41, wherein the implantable energy source comprises a primary cell and/or a secondary cell.
- 25 43. The apparatus according to aspect 41-42, further comprising a controller (170) configured to indicate a functional status of the implantable energy source.
44. The apparatus according to aspect 43, wherein the functional status
30 indicates a charge level of the implantable energy source.

45. The apparatus according to aspect 43 or 44, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.
- 5 46. The apparatus according to any of aspects 37-45, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.
47. The apparatus according to aspect 46, further comprising an
10 implantable charger (190) configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by the external energy source.
48. The apparatus according to aspect 47, wherein the charger comprises
15 an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.
49. The apparatus according to aspect 47 or 48, wherein the charger is configured to receive the functional status from the energy source indicator
20 and control the charging of the implantable energy source based on the functional status.
50. The apparatus according to any of aspects 47-49, wherein the charger is configured to control the charging of the implantable energy source by
25 controlling a receipt of electrical power from the external energy source at the implantable charger.
51. The apparatus according to any of aspects 47-49, wherein the charger is configured to control the charging of the implantable energy source by
30 controlling a transmission of electrical power from the external energy source to the implantable charger.

52. The apparatus according to any of aspects 29-51, further comprising controller (170) configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.
- 5 53. The apparatus according to aspect 52, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).
54. The apparatus according to aspect 53, wherein the controller is
10 configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.
55. The apparatus according to any of aspects 52-54, wherein the controller is configured to generate a pulsed electrical stimulation signal
15 comprising a pulse frequency (F) of 0.01-150 Hz.
56. The apparatus according to aspect 55, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
- 20 57. The apparatus according to aspect 55 or 56, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.
58. The apparatus according to any of aspects 55-57, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a
25 pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
59. The apparatus according to any of aspects 55-58, wherein the electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a
30 stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

60. The apparatus according to any of aspects 52-59, wherein the controller comprises a wireless remote control (175).

61. The apparatus according to aspect 60, wherein the wireless remote
5 control comprises an external signal transmitter, and wherein the apparatus further comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

10 62. The apparatus according to aspect 61, wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

15

63. The apparatus according to any of aspects 52-62, further comprising an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the
20 sensed action potentials.

64. The apparatus according to aspect 63, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

25

Aspect group 266SE: Reflux_Constricting-Band_Stop_Invaginated

1. An apparatus (100) for treating reflux disease of a human patient,
adapted to at least partly encircle the esophagus (20) of the patient,
5 comprising:
a first implantable portion (110) having a shape and size allowing it to
be arranged to rest against a fundus wall portion (14) of the patient's stomach
(10) and to be at least partly invaginated by the fundus wall portion, such that
the first implantable portion is implanted at a position between the patient's
10 diaphragm (30) and a lower portion of the fundus wall, and such that
movement of the cardia (22) of the patient's stomach towards the diaphragm
is restricted to hinder the cardia from sliding through the diaphragm opening
into the patient's thorax;
a second implantable portion (120) being elongated to at least partly
15 encircle the esophagus and having a variable length for allowing the
apparatus be arranged in a constricting state for hindering fluid from passing
from the stomach into the esophagus and in an expanded state for allowing
food to pass into the stomach in response to the patient swallowing.
- 20 2. The apparatus according to aspect 1, wherein the first portion has a
substantially fixed shape during operation of the apparatus.
3. The apparatus according to aspect 1 or 2, wherein a maximum width of
a cross section taken across a length direction of the first implantable portion
25 is larger than a maximum width of a cross section taken across a length
direction of the second implantable portion.
4. The apparatus according to any of the preceding aspects, wherein the
second implantable portion is configured to allow a transition from the
30 constricting state into the expanded state caused by the food passing through
esophagus.

5. The apparatus according to any of the preceding aspects, wherein the second implantable portion is configured to exert an encircling pressure on the esophagus in the constricting state.
- 5 6. The apparatus according to aspect 5, further comprising an attractor (212) for resiliently attracting adjacent portions (213) of the second implantable portion to one another to generate the encircling pressure.
7. The apparatus according to aspect 6, wherein the attractor comprises
10 an elastic element.
8. The apparatus according to aspect 6, wherein the attractor comprises at least two mutually attracting magnets.
- 15 9. The apparatus according to aspect 8, further comprising a link (214) connecting a first and a second one of said at least two magnets to each other.
10. The apparatus according to aspect 9, wherein the link is configured to
20 extend into at least one of said magnets in response to said magnets moving towards each other.
11. The apparatus according to any of the preceding aspects, further comprising a tubular cover (220) enclosing at least a part of the second
25 implantable portion and comprising a plurality of cover portions (224, 225, 226) adapted to bend relative to each other to allow the second implantable portion to change between the constricting state and the expanded state, when the cover is at least partly covered by fibrotic tissue, without being substantially hindered or impeded by the presence of said fibrotic tissue.
- 30 12. The apparatus according to aspect 11, wherein the second implantable portion comprises an array of tubular segments (222).

13. The apparatus according to aspect 11 or 12, wherein the cover is formed of an inelastic material.
- 5 14. The apparatus according to any of aspects 11-13, wherein the cover comprises a biocompatible outer surface for long-term implantation.
15. The apparatus according to any of aspects 11-14, wherein the cover is configured to rest against an outer surface of the esophagus.
- 10 16. The apparatus according to any of aspects 11-15, wherein the cover comprises a surface promoting tissue growth.
17. The apparatus according to any of aspects 11-16, wherein the cover is
- 15 formed of a polymer material, such as silicone.
18. The apparatus according to any of aspects 11-17, wherein the cover is formed of a material having a thickness of 0.1 to 10 mm, such as 1 to 5 mm.
- 20 19. The apparatus according to any of aspects 11-18, wherein the cover comprises at least one predefined fold (224) along which the cover is allowed to fold in response to the second implantable portion varying its length.
20. The apparatus according to any of aspects 11-19, wherein the cover
- 25 comprises lowered and elevated portions (224, 225) allowing the cover to vary its length while maintaining its surface area.
21. The apparatus according to any of aspects 11-20, wherein the cover is configured to be compressible and expandable in its length direction.
- 30 22. The apparatus according to any of aspects 11-21, wherein a length of the cover enclosing said at least a part of the second implantable portion

exceeds a length of said at least a part of the second implantable portion when said at least a part of the second implantable portion is arranged in the constricting state.

5 23. The apparatus according to any of the preceding aspects, comprising two end portions (216) configured to be coupled to each other to form a closed ring around the esophagus.

24. The apparatus according to aspect 23, wherein the end portions are
10 configured to be releasably attached to each other.

25. The apparatus according to aspect 23 or 24, wherein the end portions comprise a respective interlockable attacher.

15 26. The apparatus according to aspect 1, wherein at least one of the first and the second implantable portion comprises a plurality of bodies (213) configured to be arranged in an annular array around the esophagus.

27. The apparatus according to aspect 26, wherein at least one of the first
20 and the second implantable portion further comprises a plurality of links (214), each of which extending between a respective pair of bodies arranged adjacent to each other.

28. The apparatus according to aspect 27, wherein the second implantable
25 portion comprises at least some of the plurality bodies and at least some of the plurality of links, and wherein each of said links is configured to allow the respective ones of said bodies to move towards and away from each other.

29. The apparatus according to aspect 28, wherein each of said links is
30 configured to extend into at least one of the respective ones of said bodies as said bodies move towards each other.

30. The apparatus according to aspects 26, wherein the second implantable portion comprises at least some of the plurality of bodies and at least some of the plurality of links, and wherein the apparatus further comprises an attractor for resiliently attracting adjacent ones of said bodies to
5 each other.
31. The apparatus according to aspect 30, wherein the attractor comprises at least one of a magnet, an elastic member, and a spring.
- 10 32. The apparatus according to aspect 1, wherein the first implantable portion is formed of a single body and the second implantable portion is formed of an array of bodies, wherein the array of bodies is movable towards and away from each other.
- 15 33. The apparatus according to any of the preceding aspects, wherein a volume of the first implantable portion is non-adjustable.
34. The apparatus according to any of aspects 1-32, wherein a volume of the first implantable portion is adjustable after implantation.
20
35. The apparatus according to any of the preceding aspects, wherein the first implantable portion comprises a biocompatible outer surface configured to rest against the fundus wall portion.
- 25 36. The apparatus according to any of the preceding aspects, wherein the first implantable portion is configured to be arranged such that a part of the fundus wall portion is arranged between the first implantable portion of the apparatus and the esophagus.
- 30 37. The apparatus according to any of the preceding aspects, wherein the first implantable portion is configured to be at least partly invaginated by the fundus wall portion along at least half of a length of the apparatus.

29. The apparatus according to any of aspects 11-22, further comprising an electrode arrangement (150) configured to be arranged between the apparatus and the esophagus and to electrically stimulate muscle tissue of
5 the outer wall of the esophagus to exercise the muscle tissue to improve the conditions for long term implantation of the movement restriction device.

30. The apparatus according to aspect 29, wherein the electrode arrangement is arranged on an outer surface of the cover.

10

31. The apparatus according to aspect 29 or 30, wherein the electrode arrangement comprises a plurality of electrode elements (152, 154), each of which being configured to electrically stimulate the muscle tissue.

15 32. The apparatus according to any of aspects 29-31, wherein the electrode arrangement comprises a coiled wire for increasing a contact surface between the electrode arrangement and the muscle tissue and for allowing the electrode arrangement to follow contraction and relaxation of the muscle tissue.

20

33. The apparatus according to any of aspects 29-32, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said
25 interface.

34. The apparatus according to any of aspects 29-33, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface
30 with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.

35. The apparatus according to any of aspects 29-34, wherein the electrode arrangement is configured be arranged to electrically stimulate the cardiac sphincter (26) of the patient to cause the cardiac sphincter to contract.
- 5 36. The apparatus according to aspect 35, wherein the electrode arrangement comprises at least two electrode elements (154) configured to be arranged on opposing sides of the cardiac sphincter.
37. The apparatus according to any of aspects 29-36, further comprising
10 an implantable energy source (160) configured to provide the electrode arrangement with electrical power.
38. The apparatus according to aspect 37, wherein the implantable energy source is arranged inside the cover.
15
39. The apparatus according to aspect 37, wherein the implantable energy source is configured to be arranged outside the cover.
40. The apparatus according to aspect 39, wherein the implantable energy
20 source is configured to be implanted subcutaneously.
41. The apparatus according to any of aspects 37-40, wherein the implantable energy source comprises a primary cell.
- 25 42. The apparatus according to any of aspects 37-41, wherein the implantable energy source comprises a secondary cell.
43. The apparatus according to aspect 37-42, further comprising a controller (170) configured to indicate a functional status of the implantable
30 energy source.

44. The apparatus according to aspect 43, wherein the functional status indicates a charge level of the implantable energy source.

45. The apparatus according to aspect 43 or 44, wherein the functional
5 status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.

46. The apparatus according to any of aspects 37-45, wherein the
10 implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.

47. The apparatus according to aspect 46, further comprising an
implantable charger (190) configured to be electrically connected to the
implantable energy source and enable charging of the implantable energy
15 source by the external energy source.

48. The apparatus according to aspect 47, wherein the charger comprises
an electromagnetic coil configured to receive electrical power wirelessly from
the external energy source.
20

49. The apparatus according to aspect 47 or 48, wherein the charger is
configured to receive the functional status from the energy source indicator
and control the charging of the implantable energy source based on the
functional status.
25

50. The apparatus according to any of aspects 47-49, wherein the charger
is configured to control the charging of the implantable energy source by
controlling a receipt of electrical power from the external energy source at the
implantable charger.
30

51. The apparatus according to any of aspects 47-49, wherein the charger
is configured to control the charging of the implantable energy source by

controlling a transmission of electrical power from the external energy source to the implantable charger.

52. The apparatus according to any of aspects 29-51, further comprising
5 controller (170) configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.

53. The apparatus according to aspect 52, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is
10 stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

54. The apparatus according to aspect 53, wherein the controller is configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.

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55. The apparatus according to any of aspects 52-54, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.

20 56. The apparatus according to aspect 55, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.

57. The apparatus according to aspect 55 or 56, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

25

58. The apparatus according to any of aspects 55-57, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.

30 59. The apparatus according to any of aspects 55-58, wherein the electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a

stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

60. The apparatus according to any of aspects 52-59, wherein the
5 controller comprises a wireless remote control (175).

61. The apparatus according to aspect 60, wherein the wireless remote control comprises an external signal transmitter, and wherein the apparatus further comprises an implantable controller configured to receive a signal
10 transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

62. The apparatus according to aspect 61, wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an
15 electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

63. The apparatus according to any of aspects 52-62, further comprising
20 an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.

25 64. The apparatus according to aspect 63, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

Aspect group 267SE: Reflux_Stimulating-Band_Stop_Invaginated

1. An apparatus (100) for treating reflux disease of a human patient,
adapted to at least partly encircle the esophagus (20) of the patient,
5 comprising:
a movement restriction device (110) having a shape and size allowing
it to be arranged to rest against a fundus wall portion (14) of the patient's
stomach (10) and to be at least partly invaginated by the fundus wall portion,
such that the first implantable portion is implanted at a position between the
10 patient's diaphragm (30) and a lower portion of the fundus wall, and such that
movement of the cardia (22) of the patient's stomach towards the diaphragm
is restricted to hinder the cardia from sliding through the diaphragm opening
(32) into the patient's thorax; and
an elongated support device (120) connected to the movement
15 restriction device and configured to at least partly encircle the esophagus;
wherein the apparatus further comprises an electrode arrangement
(150) comprising an electrode element (154) supported by the support device
and configured to electrically stimulate muscle tissue of the esophagus; and
wherein the support device comprises a rigidity that allows the position
20 of the electrode element relative to the esophagus to be determined mainly by
the position and orientation of the movement restriction device.
2. The apparatus according to aspect 1, wherein electrode arrangement
comprises a plurality of electrode elements.
- 25 3. The apparatus according to aspect 1 or 2, wherein the electrode
arrangement is configured to electrically stimulate the cardiac sphincter (26)
of the patient to cause the cardiac sphincter to contract.
- 30 4. The apparatus according to aspect 3, wherein the electrode
arrangement is configured to stimulate opposing sides of the cardiac
sphincter.

5. The apparatus according to any of the preceding aspects, wherein the electrode arrangement is configured to exercise muscle tissue in contact with the apparatus to improve the conditions for long term implantation of the
5 apparatus.
6. The apparatus according to aspect 2, wherein an electrode element of the plurality of electrode elements is configured to be arranged between the movement restriction device and the fundus wall portion to electrically
10 stimulate muscle tissue of the fundus wall portion.
7. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises a coiled wire for increasing a contact surface between the electrode arrangement and the muscle tissue.
15
8. The apparatus according to any of the preceding aspects, wherein a maximum width of a cross section taken across a length direction of the movement restriction device is larger than a maximum width of a cross section taken across a length direction of the support device.
20
9. The apparatus according to any of the preceding aspects, wherein the support device is formed as a band configured to be arranged around at least a part of the esophagus, and wherein a first and a second end portion of the band is coupled to the first implantable portion.
25
10. The apparatus according to any of the preceding aspects, wherein the apparatus comprises a biocompatible outer surface for long-term implantation.
- 30 11. The apparatus according to any of the preceding aspects, wherein the apparatus is formed of a polymer material, such as silicone.

12. The apparatus according to any of the preceding aspects, wherein the movement restriction device is configured to be arranged such that a part of the fundus wall portion is arranged between the movement restriction device and the esophagus.

5

13. The apparatus according to any of the preceding aspects, wherein the movement restriction device is configured to be fully invaginated by the fundus wall portion.

10 14. The apparatus according to any of the preceding aspects, wherein the apparatus is ring-shaped and configured to be at least partly invaginated by the fundus wall portion along at least half of a circumference of the apparatus.

15 15. The apparatus according to any of the preceding aspects, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.

20 16. The apparatus according to any of aspects 1-14, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.

25

17. The apparatus according to any of the preceding aspects, further comprising an implantable energy source (160) configured to provide the electrode arrangement with electrical power.

30 18. The apparatus according to aspect 17, wherein the implantable energy source is arranged within the movement restriction device or the support device.

19. The apparatus according to aspect 17, wherein the implantable energy source is configured to be arranged outside movement restriction device and the support device.
- 5
20. The apparatus according to aspect 19, wherein the implantable energy source is configured to be implanted subcutaneously.
21. The apparatus according to any of aspects 17-20, wherein the
- 10 implantable energy source comprises a primary cell.
22. The apparatus according to any of aspects 17-31, wherein the implantable energy source comprises a secondary cell.
- 15 23. The apparatus according to aspect 17-22, further comprising a controller (170) configured to indicate a functional status of the implantable energy source.
24. The apparatus according to aspect 23, wherein the functional status
- 20 indicates a charge level of the implantable energy source.
25. The apparatus according to aspect 23 or 24, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.
- 25
26. The apparatus according to any of aspects 17-25, wherein the implantable energy source is configured to be charged by an external energy source arranged outside the patient's body.
- 30 27. The apparatus according to aspect 26, further comprising an implantable charger (190) configured to be electrically connected to the

implantable energy source and enable charging of the implantable energy source by the external energy source.

28. The apparatus according to aspect 27, wherein the charger comprises
5 an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

29. The apparatus according to aspect 27 or 28, wherein the charger is configured to receive the functional status from the energy source indicator
10 and control the charging of the implantable energy source based on the functional status.

30. The apparatus according to any of aspects 27-29, wherein the charger is configured to control the charging of the implantable energy source by
15 controlling a receipt of electrical power from the external energy source at the implantable charger.

31. The apparatus according to any of aspects 27-29, wherein the charger is configured to control the charging of the implantable energy source by
20 controlling a transmission of electrical power from the external energy source to the implantable charger.

32. The apparatus according to any of the preceding aspects, further comprising controller (170) configured to be operably connected to the
25 electrode arrangement for controlling the electrical stimulation of the muscle tissue.

33. The apparatus according to aspect 32, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is
30 stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

34. The apparatus according to aspect 33, wherein the controller is configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.
- 5 35. The apparatus according to any of aspects 32-34, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.
36. The apparatus according to aspect 35, wherein the electrical
10 stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
37. The apparatus according to aspect 35 or 36, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.
- 15 38. The apparatus according to any of aspects 35-37, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
39. The apparatus according to any of aspects 35-38, wherein the
20 electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.
- 25 40. The apparatus according to any of aspects 32-39, wherein the controller comprises a wireless remote control (175).
41. The apparatus according to aspect 40, wherein the wireless remote control comprises an external signal transmitter, and wherein the apparatus
30 further comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

42. The apparatus according to aspect 41, wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet
5 light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

43. The apparatus according to any of aspects 32-42, further comprising an implantable sensor (S1) configured to sense actions potentials generated
10 by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.

44. The apparatus according to aspect 43, wherein the controller is
15 configured to generate electrical pulses amplifying the sensed action potentials.

Aspect group 268SE: Reflux_Stop_His_Method

1. A method for treating reflux disease of a human patient by implanting a movement restriction device (100) such that the movement restriction device
5 is arranged to restrict movement of the cardia (22) of the patient's stomach (10) towards the diaphragm (30) to hinder the cardia from sliding through the diaphragm opening (32) into the patient's thorax, wherein the method comprises:
placing the movement restriction device such that a lower portion of the
10 movement restriction device rests against the serosa at the angle of His (24), and such that an upper portion of the movement restriction device defines a gap between the movement restriction device and the patient's esophagus (20), when the lower portion rests against the angle of His;
arranging a portion of the fundus (12) of the stomach in the gap; and
15 attaching the fundus to the patient's esophagus to at least partly enclose the movement restriction device by the portion of the fundus.
2. The method according to aspect 1, wherein the movement restriction device has a rounded shape.
20
3. The method according to aspect 1 or 2, comprising arranging the upper portion to point away from the esophagus.
4. The method according to any of the preceding aspects, wherein the
25 lower portion is wider than the upper portion.
5. The method according to any of the preceding aspects, wherein the movement restriction device has a C-shaped cross section.
- 30 6. The method according to any of the preceding aspects, wherein the upper portion comprises a recess defined in the outer surface of the movement restriction device.

7. The method according to any of the preceding aspects, wherein the lower portion comprises a curved outer surface, wherein the method further comprises arranging the curved outer surface to face the esophagus, and
5 wherein the curved outer surface comprises a radius of curvature corresponding to or exceeding the radius of curvature of the esophagus.
8. The method according to any of the preceding aspects, further comprising at least partly invaginating an elongated support (117), protruding
10 from the movement restriction device, in the portion of the fundus before attaching the fundus to the esophagus.
9. The method according to aspect 8, wherein the support is shaped as a lever, wherein the method further comprises orienting the support along the
15 esophagus.
10. The method according to any of the preceding aspects, further comprising arranging an electrode arrangement (150) between the movement restriction device and the portion of the fundus and/or the serosa, wherein the
20 electrode arrangement is configured to electrically stimulate muscle tissue of the portion of the fundus and/or the serosa to improve the conditions for long term implantation of the movement restriction device.
11. The method according to aspect 10, wherein the electrode
25 arrangement comprises a plurality of electrode elements (152), each of which being configured to engage and electrically stimulate the muscle tissue.
12. The method according to aspect 10 or 11, wherein the electrode arrangement comprises a coiled wire for increasing a contact surface
30 between the electrode arrangement and the muscle tissue and for allowing the electrode arrangement to follow contraction and relaxation of the muscle tissue.

13. The method according to any of aspects 10-12, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
14. The method according to any aspects 10-12, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
15. The method according to any of aspects 10-14, wherein the electrode arrangement is further configured to be arranged to electrically stimulate the cardiac sphincter (26) to cause the cardiac sphincter to contract.
16. The method according to aspect 15, wherein the electrode arrangement comprises at least two electrode elements (154), wherein the method further comprises arranging said electrode elements on opposing sides of the cardiac sphincter.
17. The method according to aspect 16, wherein the movement restriction device further comprises a holder (120) configured to support the at least two electrode elements at the opposing sides of the cardiac sphincter.
18. The method according to any of aspects 10-17, further comprising implanting an implantable energy source (160) configured to provide the electrode with electrical power.
19. The method according to aspect 18, wherein the implantable energy source is arranged inside the movement restriction device.

20. The method according to aspect 18, wherein the implantable energy source is configured to be arranged outside the movement restriction device, and wherein the method further comprises implanting the implantable energy source in the patient's body.
21. The method according to aspect 20, further comprising implanting the implantable energy source subcutaneously.
22. The method according to any of aspects 18-21, wherein the implantable energy source comprises a primary cell.
23. The method according to any of aspects 18-22, wherein the implantable energy source comprises a secondary cell.
24. The method according to aspect 18-23, further comprising implanting a controller (170) configured to indicate a functional status of the implantable energy source.
25. The method according to aspect 24, wherein the functional status indicates a charge level of the implantable energy source.
26. The method according to aspect 24 or 25, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.
27. The method according to any of aspects 24-26, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.
28. The method according to aspect 27, further comprising implanting an implantable charger (190) configured to be electrically connected to the

implantable energy source and enable charging of the implantable energy source by the external energy source.

29. The method according to aspect 28, wherein the charger comprises an
5 electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

30. The method according to aspect 28 or 29, wherein the charger is
configured to control the charging of the implantable energy source based on
10 the functional status.

31. The method according to any of aspects 28-30, wherein the charger is
configured to control the charging of the implantable energy source by
controlling a receipt of electrical power from the external energy source at the
15 implantable charger.

32. The method according to any of aspects 28-31, wherein the charger is
configured to control the charging of the implantable energy source by
controlling a transmission of electrical power from the external energy source
20 to the implantable charger.

33. The method according to any of aspects 10-23, further comprising
implanting a controller (170) configured to be operably connected to the
electrode arrangement for controlling the electrical stimulation of the muscle
25 tissue.

34. The method according to aspect 33, wherein the controller is
configured to control the electrical stimulation such that the muscle tissue is
stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

35. The method according to aspect 34, wherein the controller is configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.

5 36. The method according to aspect 34 or 35, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.

37. The method according to aspect 36, wherein the electrical stimulation
10 signal comprises a pulse duration (D) of 0.01-100 ms.

38. The method according to aspect 36 or 37, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

15 39. The method according to any of aspects 36-38, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.

40. The method according to any of aspects 36-39, wherein the electrical
20 stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

25 41. The method according to any of aspects 33-43, further comprising implanting an implantable sensor (S1) configured to sense action potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical stimulation based at least partly on the sensed action potentials.

42. The method according to aspect 44, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

Aspect group 269SE: Reflux_Stop_Gastric-Sleeve

1. An apparatus (100) for treating reflux disease of a human patient, comprising:
 - 5 an implantable movement restriction device (110); and
an elongated attacher (117) configured to be attached to the movement restriction device and to be at least partly invaginated by a wall portion of the patient's stomach (10);
wherein the attacher comprises a shape and size allowing it to be
10 invaginated by the wall portion to hinder rotation of the movement restriction device; and
wherein the attacher is configured to be invaginated by the wall portion such that the movement restriction device is arranged at a position between the patient's diaphragm (30) and the wall portion, distant from the patient's
15 esophagus (20), to restrict movement of the cardia (22) of the patient's stomach towards the diaphragm to hinder the cardia from sliding through the diaphragm opening (32) into the patient's thorax.
2. The apparatus according to aspect 1, wherein a first end portion of the
20 attacher is configured to be invaginated by the wall portion and a second end portion is configured to be attached to the movement restriction device.
3. The apparatus according to aspect 1 or 2, wherein the attacher comprises a first portion (118) and a second portion (119) extending in
25 different directions relative to each other, wherein the first portion is configured to be invaginated by the wall portion to hinder rotation of the movement restriction device around a first axis, and wherein the second portion is configured to be invaginated by the wall portion to hinder rotation of the movement restriction device around a second axis, different from the first
30 axis.

4. The apparatus according to aspect 3, wherein the first and second portions of the attacher are curved to follow a curvature of the wall portion.
5. The apparatus according to aspect 3 or 4, wherein the first portion and
5 second portion are arranged at an angle to each other, the angle being in the interval of 60-120 degrees.
6. The apparatus according to any of the preceding aspects, wherein the
10 attacher is configured to be releasably attached to the movement restriction device.
7. The apparatus according to any of the preceding aspects, wherein the movement restriction device has a rounded shape.
- 15 8. The apparatus according to any of the preceding aspects, wherein the movement restriction device has a shape conforming to a sphere.
9. The apparatus according to any of the preceding aspects, wherein the
20 attacher is configured to allow a position of the movement restriction device to be adjusted after invagination of the attachment means.
10. The apparatus according to any of the preceding aspects, configured to allow a distance between the movement restriction device and the attacher to be varied to allow the position of the movement restriction device relative to
25 the diaphragm to be adjusted.
11. The apparatus according to any of the preceding aspects, configured to allow an orientation of the movement restriction device relative to the attachments means to be varied to allow the position of the movement
30 restriction device relative to the diaphragm to be adjusted.

12. The apparatus according to aspect 3, wherein the attacher comprises a third portion, configured to be arranged to protrude from the wall portion when implanted, and to define a distance between the wall portion and the movement restriction device.
- 5
13. The apparatus according to aspect 12, wherein the third portion comprises a curvature allowing the third portion to be arranged to point away from the esophagus when implanted.
- 10 14. The apparatus according to aspect 1, wherein the movement restriction device and the attacher are integrally formed into a single piece.
- 15 15. The apparatus according to any of the preceding aspects, wherein each of the movement restriction device and the attachments means comprises a biocompatible outer surface.
16. The apparatus according to any of the preceding aspects, wherein the attacher comprises an outer surface configured to promote tissue growth.
- 20 17. The apparatus according to any of the preceding aspects, wherein the attacher is formed of a metal.
18. The apparatus according to any of aspects 1-16, wherein the movement restriction device is formed of a polymer.
- 25
19. The apparatus according to any of the preceding aspects, wherein a minimum width of the movement restriction device, as measured from side to side, is 30 mm or larger, such as 40 mm or larger.
- 30 20. The apparatus according to any of the preceding aspects, wherein an outer surface of the movement restriction device comprises a material for hindering growth of fibrotic tissue.

22. The apparatus according to any of the preceding aspects, further comprising an electrode arrangement (150) configured to be arranged between the apparatus and muscle tissue of at least one of the diaphragm and the wall portion, and to electrically stimulate muscle tissue to exercise the muscle tissue to improve the conditions for long term implantation of the apparatus.
23. The apparatus according to aspect 22, wherein the electrode arrangement comprises a plurality of electrode elements (152), each of which being configured to engage and electrically stimulate the muscle tissue.
24. The apparatus according to any of aspects 22 or 23, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
25. The apparatus according to any aspects 22 or 23, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
26. The apparatus according to any of aspects 22-25, further comprising an implantable energy source (160) configured to provide the electrode arrangement with electrical power.
27. The apparatus according to aspect 26, wherein the implantable energy source is arranged inside the movement restriction device or the attachment means.

28. The apparatus according to aspect 26, wherein the implantable energy source is configured to be arranged outside the movement restriction device and the attachment means.
- 5 29. The apparatus according to aspect 28, wherein the implantable energy source is configured to be implanted subcutaneously.
30. The apparatus according to any of aspects 26-29, wherein the implantable energy source comprises a primary cell.
- 10 31. The apparatus according to any of aspects 26-30, wherein the implantable energy source comprises a secondary cell.
32. The apparatus according to aspect 26-31, further comprising a
15 controller (170) configured to indicate a functional status of the implantable energy source.
33. The apparatus according to aspect 32, wherein the functional status indicates a charge level of the implantable energy source.
- 20 34. The apparatus according to aspect 32 or 33, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.
- 25 35. The apparatus according to any of aspects 32-34, wherein the implantable energy source is configured to be charged by an external energy source (165) arranged outside the patient's body.
36. The apparatus according to aspect 35, further comprising an
30 implantable charger (190) configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by the external energy source.

37. The apparatus according to aspect 33, wherein the charger comprises an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

5

38. The apparatus according to aspect 36 or 37, wherein the charger is configured to control the charging of the implantable energy source based on the functional status.

10 39. The apparatus according to any of aspects 33-38, wherein the charger is configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the implantable charger.

15 40. The apparatus according to any of aspects 36-39, wherein the charger is configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source to the implantable charger.

20 41. The apparatus according to any of aspects 22-40, further comprising controller (170) configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.

25 42. The apparatus according to aspect 41, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

43. The apparatus according to aspect 42, wherein the controller is configured to control the electrical stimulation such that a pulse of a first
30 polarity is followed by a pulse of a second, reversed polarity.

44. The apparatus according to aspect 42 or 43, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.
- 5 45. The apparatus according to aspect 44, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
46. The apparatus according to aspect 44 or 45, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.
- 10 47. The apparatus according to any of aspects 44-46, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
- 15 48. The apparatus according to any of aspects 44-47, wherein the electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.
- 20 49. The apparatus according to any of aspects 41-48, wherein the controller comprises a wireless remote control (175).
50. The apparatus according to aspect 49, wherein the wireless remote control comprises an external signal transmitter, and wherein the controller comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.
- 25 51. The apparatus according to aspect 50, wherein the signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet
- 30

light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

52. The apparatus according to any of aspects 41-51, further comprising
5 an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.
- 10 53. The apparatus according to any of the preceding aspects, further comprising a support device (130) arranged to be attached to the outside of the stomach wall and further to support the elongated attacher (118).
54. The apparatus according to aspect 53, wherein the support device
15 (130) is configured to be attached to a gastric sleeve seam formed during a gastric sleeve surgery.
55. The apparatus according to aspect 54, wherein the support device comprises a plurality of through-holes for receiving the fastening means, such
20 as sutures or staples, used in the gastric sleeve seam.
56. The apparatus according to any of aspects 53-55, wherein the support device (130) is formed as a bar or flat rod having a U-shaped cross section profile adapted to follow an outer curvature of the stomach wall.

Aspect group 270SE: Reflux_Band_Stop_Method

1. A method of treating reflux disease in a human patient by implanting an apparatus (100) comprising a movement restriction device (110) and an elongated support device (120), such that the support device at least partly encircles the esophagus (10) of the patient and such that the movement restriction device is arranged on the fundus side of the esophagus to restrict the movement of the cardia (22) in relation to the diaphragm (30) to hinder the cardia to from sliding through the diaphragm opening (32) into the patient's thorax, the method comprising the steps of:
- introducing the apparatus into the abdominal cavity;
 - placing the apparatus such that the movement restriction device rests against the outside of the stomach's fundus (12);
 - wrapping a portion of the fundus around at least a part of the movement restriction device;
 - affixing the fundus to the esophagus such that the movement restriction device is arranged at a position between the diaphragm and the cardiac sphincter, and such that a part of the fundus is arranged between the movement restriction device and the esophagus; and
 - arranging the support device to at least partly encircle the esophagus;
 - wherein the movement restriction device and the second portion form a ring-shaped body extending through the pouch to at least partly encircle the esophagus.
2. The method according to aspect 1, comprising placing the apparatus such that the movement restriction device rests against the outside of the fundus at a position between the cardiac sphincter and the portion of the fundus that is to be affixed to the esophagus.
3. The method according to aspect 1, comprising placing the apparatus such that the portion of the fundus that is affixed to the esophagus is

arranged between the cardiac sphincter (26) and the movement restriction device.

4. The method according to any of the preceding aspects, wherein the
5 pouch is formed to be open in a least two positions to form a tunnel through which the apparatus extends.

5. The method according to any of the preceding aspects, further
comprising affixing the portion of the fundus to the patient's diaphragm.
10

6. The method according to any of the preceding aspects, wherein
affixing the portion of the fundus to the esophagus includes suturing or
stapling.

15 7. The method according to any of the preceding aspects, wherein the support device comprises a first and a second end portion between which the esophagus can be introduced, and wherein the first and second end portions can be coupled to each other so as to fixate the support device to the esophagus in an encircling manner.

20

8. The method according to any of the preceding aspects, further
comprising:

inserting a needle or a tube-like instrument into the patient's abdomen;
using the needle or tube-like instrument to fill the abdomen with a gas;
25 placing at least two laparoscopic trocars in the abdomen;
inserting a camera through one of the laparoscopic trocars into the abdomen;

inserting at least one dissecting tool through one the laparoscopic
trocars;

30 dissecting a portion of the stomach; and

at least partly closing the pouch by means of sutures, such as barbed
sutures, or staples.

9. The method according to any of the preceding aspects, wherein the support device comprises a variable length for allowing the apparatus be arranged in a constricting state for hindering fluid from passing from the stomach into the esophagus and in an expanded state for allowing food to pass into the stomach in response to the patient swallowing.
10. The method according to aspect 9, wherein the movement restriction device has a substantially fixed shape during operation of the apparatus.
11. The method according to aspect 9 or 10, wherein the support device is configured to allow a transition from the constricting state into the expanded state caused by the food passing through esophagus.
12. The method according to any of aspects 9-11, wherein the support device is configured to exert an encircling pressure on the esophagus in the constricting state.
13. The method according to aspect 12, further comprising an attractor (212) for resiliently attracting adjacent portions (213) of the support device to one another to generate the encircling pressure.
14. The method according to aspect 13, wherein the attractor comprises an elastic element.
15. The method according to aspect 13, wherein the attractor comprises at least two mutually attracting magnets.
16. The method according to aspect 15, further comprising a link (214) connecting a first and a second one of said at least two magnets to each other.

17. The method according to aspect 16, wherein the link is configured to extend into at least one of said magnets in response to said magnets moving towards each other.

5 18. The method according to any of aspects 9-17, further comprising a tubular cover (220) enclosing at least a part of the support device and comprising a plurality of cover portions (224, 225, 226) adapted to bend relative to each other to allow the second support device to change between the constricting state and the expanded state, when the cover is at least partly
10 covered by fibrotic tissue, without being substantially hindered or impeded by the presence of said fibrotic tissue.

19. The method according to aspect 18, wherein the cover comprises at least one predefined fold (224) along which the cover is allowed to fold in
15 response to the support device varying its length.

20. The apparatus according to any of aspects 18-20, wherein the cover comprises lowered and elevated portions (225, 226) allowing the cover to vary its length while maintaining its surface area.

20

21. The method according to any of aspects 1-8, wherein the apparatus further comprises an electrode arrangement (150) comprising an electrode element (154) supported by the support device and configured to electrically stimulate muscle tissue of the esophagus.

25

22. The method according to aspect 21, wherein the electrode arrangement is configured to electrically stimulate the cardiac sphincter of the patient to cause the cardiac sphincter to contract.

30 23. The method according to aspect 22, wherein the electrode arrangement is configured to stimulate opposing sides of the cardiac sphincter.

24. The method according to any aspects 1-8, further comprising an electrode arrangement (150) configured to be arranged between the movement restriction device and the portion of the fundus to electrically stimulate muscle tissue of the portion of the fundus to exercise the muscle tissue to improve the conditions for long term implantation of the movement restriction device.
25. The method according to any of aspects 21-24, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
26. The method according to any of aspects 21-24, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
27. The method according to any of aspects 21-26, further comprising implanting an implantable energy source (160) in the patient's body, wherein the implantable energy source is configured to provide the electrode arrangement with electrical power.
28. The method according to aspect 27, wherein the implantable energy source is arranged inside the movement restriction device.
29. The method according to 27, comprising placing the implantable energy source outside the movement restriction device and the support device.

30. The method according to aspect 27, comprising implanting the implantable energy source subcutaneously.

31. The method according to any of aspects 27-30, further comprising
5 implanting a controller (170) in the patient's body, wherein the controller is configured to indicate a functional status of the implantable energy source.

32. The method according to 31, wherein the functional status indicates a charge level of the implantable energy source.

10

33. The method according to aspect 32, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.

15 34. The method according to any of aspects 31-33, further comprising implanting an implantable charger (190) in the patient's body, wherein the implantable charger is configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by an external energy source (165) arranged outside the body.

20

35. The method according to aspect 34, wherein the charger is configured to control the charging of the implantable energy source based on the functional status.

25 36. The method according to aspect 34 or 35, wherein the charger is configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the implantable charger.

30 37. The method according to aspect 34 or 35, wherein the charger is configured to control the charging of the implantable energy source by

controlling a transmission of electrical power from the external energy source to the implantable charger.

38. The method according to any of aspects 21-37, further comprising
5 implanting a controller (170) in the patient's body, wherein the controller is configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.

39. The method according to aspect 38, wherein the controller is
10 configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

40. The method according to aspect 39, wherein the controller is
15 configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.

41. The method according to any of aspects 38-40, wherein the controller
is configured to generate a pulsed electrical stimulation signal comprising a
pulse frequency (F) of 0.01-150 Hz.

20

42. The method according to aspect 41, wherein the electrical stimulation
signal comprises a pulse duration (D) of 0.01-100 ms.

43. The method according to aspect 41 or 42, wherein the electrical
25 stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

44. The method according to any of aspects 41-43, wherein the electrical
stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse
duration of 20-30 ms and a pulse amplitude of 3-10 mA.

30

45. The method according to any of aspects 41-44, wherein the electrical
stimulation signal comprises a build-up period of 0.01-2 s in which the

amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

Aspect group 271SE: Reflux_Modum-Forsell_Method

1. A method for affixing a fundus portion (14) of the stomach (10) of a human patient to the patient's esophagus (20), wherein the fundus portion
5 extends from the angle of His (28) and in a direction away from the esophagus, the method comprising:
folding the fundus portion towards the esophagus such that the fundus portion rests against the esophagus, from the angle of His and upwards along the esophagus; and
10 affixing the fundus portion to the esophagus by means of fasteners (230) arranged along a first line (231) and a second line (232);
wherein the first line and the second line extend along the esophagus and are arranged such that a distance between the first line and the second line increases with an increasing distance from the angle of His.
15
2. The method according to aspect 1, wherein the abdominal part of the esophagus and the fundus are divided by a plane into a ventral and a dorsal side, and wherein the method comprises providing the first line on the dorsal side of the plane and the second line on the ventral side of the plane.
20
3. The method according to aspect 1 or 2, comprising beginning the first line less than 1 cm above the angle of His and beginning the second line less than 3 cm above the angle of His.
- 25 4. The method according to any of the preceding aspects, comprising beginning the second line at a distance less than 2 cm from the first line.
5. The method according to any of the preceding aspects, wherein a separating angle between the first line and the second line is in the range of
30 90-150 degrees.

6. The method according to any of the preceding aspects, further comprising providing an additional fastener (233) between the first line and the second line, at the top of the fundus portion.
- 5 7. The method according to any of the preceding aspects, wherein the fasteners comprise staples.
8. The method according to any of aspects 1-6, wherein the fasteners comprise sutures, such as barbed sutures.
- 10 9. The method according to aspect 8, wherein the first line of fasteners comprises a first continuous suture, and wherein the second line of fasteners comprises a second continuous suture.
- 15 10. The method according to any of the preceding aspects, further comprising:
placing a movement restriction device (110) on the fundus;
forming a pouch in the fundus;
arranging the movement restriction device at least partly in the pouch;
20 invaginating the movement restriction device by the fundus by at least partly closing the pouch by fasteners;
wherein the movement restriction device is arranged at a position between the diaphragm (30) and the cardiac sphincter (26) to hinder the cardia (22) from sliding through the diaphragm opening (32) into the patient's
25 thorax.
11. The method according to aspect 10, wherein the movement restriction device is invaginated after affixing the fundus portion to the esophagus.
- 30 12. The method according to aspect 10 or 11, wherein the pouch is formed to be open in a least two positions to form a tunnel through which the movement restriction device extends.

13. The method according to any of aspects 10-12, further comprising affixing the fundus to the diaphragm.

5 14. The method according to any of aspects 10-13, further comprising arranging an elongated support device (120) to at least partly encircle the esophagus, wherein the elongated support device and the movement restriction device form a respective portion of an implantable apparatus for treating reflux disease.

10

15. The method according to aspect 14, wherein the support device comprises a variable length for allowing the apparatus to be arranged in a constricting state for hindering fluid from passing from the stomach into the esophagus and in an expanded state for allowing food to pass into the

15 stomach in response to the patient swallowing.

16. The method according to aspect 15, wherein the support device is configured to allow a transition from the constricting state into the expanded state caused by the food passing through the esophagus.

20

17. The method according to aspect 16, further comprising an attractor (212) for resiliently attracting adjacent portions (213) of the support device to one another to generate an encircling pressure on the esophagus.

25 18. The method according to aspect 17, wherein the attractor comprises an elastic element.

19. The method according to aspect 17, wherein the attractor comprises at least two mutually attracting magnets.

30

20. The method according to any of aspects 15-19, further comprising a tubular cover (220) enclosing at least a part of the support device and

comprising a plurality of cover portions (224, 225, 226) adapted to bend relative to each other to allow the second support device to change between the constricting state and the expanded state, when the cover is at least partly covered by fibrotic tissue, without being substantially hindered or impeded by
5 the presence of said fibrotic tissue.

21. The method according to aspect 20, wherein the cover comprises at least one predefined fold (224) along which the cover is allowed to fold in response to the support device varying its length.

10

22. The method according to any of aspects 15-21, wherein the apparatus further comprises an electrode arrangement (150) comprising an electrode element (154) supported by the support device and configured to electrically stimulate muscle tissue of the esophagus.

15

23. The method according to aspect 22, wherein the electrode arrangement is configured to electrically stimulate the cardiac sphincter of the patient to cause the cardiac sphincter to contract.

20 24. The method according to any aspects 10-14, further comprising an electrode arrangement (150) configured to be arranged between the movement restriction device and the fundus portion to electrically stimulate muscle tissue of the fundus portion to exercise the muscle tissue to improve the conditions for long term implantation of the movement restriction device.

25

25. The method according to any of aspects 10-24, wherein the electrode arrangement comprises a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said
30 interface.

26. The method according to any of aspects 10-24, wherein the electrode arrangement comprises an electrode portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
27. The method according to any of aspects 24-26, further comprising implanting an implantable energy source (160) in the patient's body, wherein the implantable energy source is configured to provide the electrode arrangement with electrical power.
28. The method according to aspect 27, wherein the implantable energy source is arranged inside the movement restriction device.
29. The method according to 27, comprising placing the implantable energy source outside the movement restriction device and the support device.
30. The method according to aspect 27, comprising implanting the implantable energy source subcutaneously.
31. The method according to any of aspects 27-30, further comprising implanting a controller (170) in the patient's body, wherein the controller is configured to indicate a functional status of the implantable energy source.
32. The method according to 31, wherein the functional status indicates a charge level of the implantable energy source.
33. The method according to aspect 32, wherein the functional status indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.

34. The method according to any of aspects 31-33, further comprising implanting an implantable charger (190) in the patient's body, wherein the implantable charger is configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by an external energy source (165) arranged outside the body.

35. The method according to aspect 34, wherein the charger is configured to control the charging of the implantable energy source based on the functional status.

10

36. The method according to aspect 34 or 35, wherein the charger is configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the implantable charger.

15

37. The method according to aspect 34 or 35, wherein the charger is configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source to the implantable charger.

20

38. The method according to any of aspects 24-37, further comprising implanting a controller (170) in the patient's body, wherein the controller is configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.

25

39. The method according to aspect 38, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

30 40. The method according to aspect 39, wherein the controller is configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.

41. The method according to any of aspects 38-40, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.

5

42. The method according to aspect 41, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.

43. The method according to aspect 41 or 42, wherein the electrical
10 stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

44. The method according to any of aspects 41-43, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.

15

45. The method according to any of aspects 41-44, wherein the electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a
20 pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

Aspect group 272SE: Reflux_Muscle_Stimulation_Kit

1. An apparatus (100) for treating reflux disease in a human patient, comprising an electrode arrangement (150) for electrically stimulating the patient's muscle tissue to exercise the muscle tissue to improve the conditions for long term implantation of the apparatus, further comprising:
an implantable energy source (160) configured to provide the electrode arrangement with electrical power; and
a controller (170) operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.
2. The apparatus according to aspect 1, wherein the electrode arrangement is configured to be arranged between the apparatus and the tissue onto which the apparatus is arranged to rest when implanted.
3. The apparatus according to aspect 1 or 2, wherein the electrode arrangement comprises an electrode element (152, 154, E1, E2) having a bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
4. The apparatus according to aspect 1 or 2, wherein the electrode arrangement comprises an electrode element having a portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
5. The apparatus according to any of the preceding aspects, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

6. The apparatus according to aspect 5, wherein the controller is configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.
- 5
7. The apparatus according to aspect 5 or 6, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.
- 10
8. The apparatus according to aspect 7, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
9. The apparatus according to aspect 7 or 8, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.
- 15
10. The apparatus according to any of aspects 7-9, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
- 20
11. The apparatus according to any of aspects 7-10, wherein the electrical stimulation signal comprises a build-up period (X1) of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period (X2) of 1-60 s, and a stimulation pause (X4) of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.
- 25
- 30
12. The apparatus according to any of the preceding aspects, wherein the at least one electrode is configured to engage smooth muscle tissue.

13. The apparatus according to aspect 12, further comprising a sensor (S1) configured to sense action potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical stimulation based at least partly on the sensed action potentials.

5

14. The apparatus according to aspect 13, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

10 15. The apparatus according to any preceding aspect, wherein the implantable energy source is configured to provide the electrode arrangement and/or the controller with electrical power.

15 16. The apparatus according to any of the preceding aspects, wherein the controller is further configured to indicate a functional status of the implantable energy source.

17. The apparatus according to aspect 16, wherein the functional status indicates at least one of charge level and temperature of the implantable
20 energy source.

18. The apparatus according to aspect 16 or 17, wherein the controller is further configured to include the functional status in a signal transmitted to the outside of the body.

25

19. The apparatus according to any of the preceding aspects, further comprising a charger (190) configured to control a charging of the implantable energy source by controlling a receipt of electrical power from an external energy source at the implantable charger.

30

20. The apparatus according to aspect 19, wherein the charger comprises an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

5 21. The apparatus according to aspect 19 or 20, wherein the charger is configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source to the implantable charger.

10 22. The apparatus according to any of the preceding aspects, wherein the controller comprises a wireless remote control.

23. The apparatus according to aspect 22, wherein the wireless remote control comprises an external signal transmitter, and wherein the controller
15 comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

24. The apparatus according to aspect 19 wherein signal is selected from
20 the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

25

25. A method for exercising muscle tissue of a human patient to improve the conditions for long-term implantation of an apparatus for treating reflux disease of a human patient, the method comprises electrically stimulating the muscle against which the apparatus is arranged to rest when implanted.

30

26. The method according to aspect 25, comprising electrically stimulating the muscle tissue by means of an electrode arrangement arranged between the muscle tissue and the apparatus.
- 5 27. The method according to aspect 25 or 26, comprising electrically stimulating the muscle tissue with a pulsed signal (PL1, PL2, PL3, PL4).
28. The method according to aspect 27, wherein the pulsed signal comprises a pulse frequency (F) of 0.01-150 Hz, such as 0.1-150 Hz, such as
10 1-130 Hz, such as 10-100 Hz, such as 25-75 Hz.
29. The method according to aspect 27 or 28, wherein the pulsed signal comprises a pulse duration (D) of 0.01-100 ms, such as 0.1-50 ms, such as 1-
15 10 ms.
30. The method according to any one of aspects 27-29, wherein the signal comprises a pulse amplitude (A) of 1-15 mA or less, such as 2-10 mA, such as 3-7 mA.
- 20 31. The method according to any one of aspects 27-30, wherein the signal comprises a pulse frequency of 0.2 Hz, a pulse duration of 0.3 ms and a pulse amplitude of 5 mA.
32. The method according to any one of aspects 27 to 31, wherein the
25 signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
33. The method according to any of aspects 27-32, wherein the pulsed signal comprises a build-up period of 0.01-2 seconds, in which the amplitude
30 is gradually increasing, a stimulation period of 1 to 60 seconds, a stimulation pause of 0.01 to 60 seconds, a pulse frequency of 1 to 50 Hz and a pulse duration of 0.1 to 10 ms.

34. The method according to any one of aspects 27-33, wherein the pulsed signal is applied by using the electrode arrangement as a cathode.

Aspect group 273SE: Reflux_Charging_Wireless_Kit

1. An apparatus (100) for treating reflux disease of a human patient, comprising an electrode arrangement (150), the apparatus comprising:
5 an implantable energy source (160) configured to provide the apparatus with electrical power,
an external energy source (165) configured be arranged outside of the patient's body and configured to provide energy to the implantable energy source, and
10 an implantable charger (190) configured to be electrically connected to the implantable energy source and enable charging of the implantable energy source by the external energy source.
2. The apparatus according to aspect 1, wherein the charger is
15 configured to control the charging of the implantable energy source by controlling a receipt of electrical power from the external energy source at the implantable charger.
3. The apparatus according to aspect 1, wherein the charger is
20 configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source to the implantable charger.
4. The apparatus according to any preceding aspect, wherein the
25 implantable energy source is configured to provide the electrode arrangement and/or the controller with electrical power.
5. The apparatus according to any of the preceding aspects, wherein the
30 controller is further configured to indicate a functional status of the implantable energy source.

6. The apparatus according to aspect 5, wherein the functional status indicates at least one of charge level and temperature of the implantable energy source.
- 5 7. The apparatus according to aspect 5 or 6, wherein the controller is further configured to include the functional status in a signal transmitted to the outside of the body.
8. The apparatus according to aspect 1, wherein the charger comprises
10 an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.
9. The apparatus according to aspect 5-7, wherein the charger is configured to receive the functional status from the energy source indicator
15 and control the charging of the implantable energy source based on the functional status.
10. The apparatus according to any of the preceding aspects, further comprising a controller (170) configured to be operably connected to the
20 electrode arrangement for controlling the electrical stimulation of the muscle tissue.
11. The apparatus according to aspect 10, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is
25 stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).
12. The apparatus according to aspect 11, wherein the controller is configured to control the electrical stimulation such that a positive pulse is followed by a negative pulse.

13. The apparatus according to any of aspects 10-12, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.
- 5 14. The apparatus according to aspect 13, wherein the electrical stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
15. The apparatus according to aspect 13 or 14, wherein the electrical stimulation signal comprises a pulse amplitude (A) of 1-15 mA.
- 10 16. The apparatus according to any of aspects 13-15, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
- 15 17. The apparatus according to any of aspects 13-16, wherein the electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.
- 20 18. The apparatus according to any of aspects 10-17, wherein the controller comprises a wireless remote control (175).
19. The apparatus according to aspect 18, wherein the wireless remote
25 control comprises an external signal transmitter (176), and wherein the controller comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.
- 30 20. The apparatus according to aspect 19 wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet

light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

21. The apparatus according to any of aspects 10-20, further comprising
5 an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.
- 10 22. The apparatus according to aspect 21, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

Aspect group 274SE: Reflux_Communication_Kit

1. An apparatus (100) for treating reflux disease of a human patient, comprising an electrode arrangement (150), the apparatus further comprising:
5 a controller (170) configured to be operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue, and wherein the controller comprises an implantable communicator (171) for transmitting and/or receiving a signal to/from the outside of the patient's body.
10
2. The apparatus according to aspect 1, wherein the signal comprises a functional status of an implantable energy source (160), wherein the implantable energy source is configured to provide the electrode arrangement and the controller with electrical power.
15
3. The apparatus according to aspect 2, wherein the functional status indicates a charge level of the implantable energy source.
4. The apparatus according to aspect 2 or 3, wherein the functional status
20 indicates a temperature of at least one of the implantable energy source, the muscle tissue, and the electrode arrangement.
5. The apparatus according to any preceding aspect, wherein the controller further comprises an external controller configured to receive the
25 signal.
6. The apparatus according to any preceding aspect, wherein the controller is configured to control the electrical stimulation such that the muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3,
30 PL4).

7. The apparatus according to aspect 6, wherein the controller is configured to control the electrical stimulation such that a positive pulse is followed by a negative pulse.
- 5 8. The apparatus according to any preceding aspect, wherein the controller is configured to generate a pulsed electrical stimulation signal comprising a pulse frequency (F) of 0.01-150 Hz.
9. The apparatus according to any of aspects 6-8, wherein the electrical
10 stimulation signal comprises a pulse duration (D) of 0.01-100 ms.
10. The apparatus according to any of aspects 6-9, wherein the electrical stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse duration of 20-30 ms and a pulse amplitude of 3-10 mA.
- 15 11. The apparatus according to any of aspects 6-10, wherein the electrical stimulation signal comprises a build-up period of 0.01-2 s in which the amplitude is gradually increasing, a stimulation period of 1-60 s, and a stimulation pause of 0.01-60 s, wherein the electrical signal comprises a
20 pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.
12. The apparatus according to any of the preceding aspects, wherein the controller comprises a wireless remote control (175).
- 25 13. The apparatus according to aspect 12, the apparatus further comprising an internal controller and an internal signal receiver connected to the internal controller, and wherein the wireless remote control comprises an external signal transmitter (176), and wherein the internal signal receiver implantable in the patient is configured to receive a signal transmitted by the
30 external signal transmitter.

14. The apparatus according to aspect 13 wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

15. The apparatus according to any of the preceding aspects, further comprising an implantable sensor (S1) configured to sense actions potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical simulation based at least partly on the sensed action potentials.

16. The apparatus according to aspect 15, wherein the controller is configured to generate electrical pulses amplifying the sensed action potentials.

17. The apparatus according to any of the preceding aspects, further comprising an implantable energy source (160) configured to provide the electrode arrangement and the controller with electrical power.

18. The apparatus according to aspect 17, further comprising an implantable charger (190) configured to be electrically connected to the implantable energy source and enable recharging of the implantable energy source by an external energy source (165), wherein the charger is configured to control the charging of the implantable energy source by controlling the receipt of electrical power from the external energy source.

19. The apparatus according to aspect 18, wherein the charger comprises an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

20. The apparatus according to aspect 18-19, wherein the charger is configured to receive the functional status from the energy source indicator and control the charging of the implantable energy source based on the functional status.

Aspect group 275SE: Reduced abutment

1. An apparatus (100) for treating reflux disease of a human patient, comprising:
 - 5 an at least partly ring-shaped implantable movement restriction device configured to be arranged such that at a first, lower portion of the movement restriction device is arranged at the cardia of the patient's stomach and such that a second, upper portion of the movement restriction device is arranged to abut the diaphragm (30) of the patient, such that movement of the cardia (22)
10 towards the diaphragm (30) is restricted to prevent the cardia from sliding through the diaphragm opening into the patient's thorax;
wherein the apparatus is configured to be arranged to define a gap or spacing between the second, upper portion of the movement restriction device and the outside of the esophagus (32) when the apparatus is
15 implanted.
2. The apparatus according to aspect 1, wherein the movement restriction device has a shape conforming to a band or sleeve adapted to at least partly encircle the esophagus.
20
3. The apparatus according to aspect 1 or 2, wherein a width of the movement restriction device is increasing towards the diaphragm of the patient, such that a first width (d1) of the first, lower portion of the movement restriction device is smaller than a second width (d2) of the second, upper
25 portion of the movement restriction device.
4. The apparatus according to aspect 1 or 2, wherein a width of the movement restriction device is substantially constant along the esophagus at which it is configured to be implanted.
30
5. The apparatus according to any of the preceding aspects, wherein an inner surface of the movement restriction device is configured to be arranged

at and angle (α) relative an outer surface of the esophagus (32), thereby defining the gap or spacing between the movement restriction device and the esophagus.

5 6. The apparatus according to any of the preceding aspects, wherein the lower portion of the movement restriction device comprises a convex surface having a first curvature radius (R) and being configured to rest against the cardia, and wherein the upper portion of the movement restriction device
10 comprises a concave surface having a second curvature radius (R') and being configured to define the gap between the movement restriction device and the esophagus (32).

7. The apparatus according to any of the preceding aspects, comprising a plurality of bodies (102) secured to each other by means of a holding device
15 (104).

8. The apparatus according to aspect 7, wherein the plurality of bodies (102) are configured to be arranged in a sequence at least partly surrounding the esophagus (32), and wherein the holding device (104) comprises a sleeve
20 or a string-shaped attachment means.

9. The apparatus according to aspect 7 or 8, wherein the plurality of bodies are elastically movable in relation to each other so as to allow the width of the movement restriction device to be varied.
25

10. The apparatus according to any of aspects 7-9, wherein the plurality of bodies are magnetic and configured to exert a constricting force on the cardia by means of an attractive magnetic force.

30 11. The apparatus according to any of aspects 7-10, wherein the bodies are elongated and configured to be arranged along the main direction of extension of the esophagus.

12. The apparatus according to any of aspects 7-11, wherein the bodies have a shape conforming to ellipsoids or rods.

CLAIMS

- 5 1. An apparatus (100) for treating reflux disease in a human patient, comprising an electrode arrangement (150) for electrically stimulating the patient's muscle tissue to exercise the muscle tissue to improve the conditions for long term implantation of the apparatus, further comprising:
an implantable energy source (160) configured to provide the electrode
10 arrangement with electrical power; and
a controller (170) operably connected to the electrode arrangement for controlling the electrical stimulation of the muscle tissue.
2. The apparatus according to claim 1, wherein the electrode
15 arrangement is configured to be arranged between the apparatus and the tissue onto which the apparatus is arranged to rest when implanted.
3. The apparatus according to claim 1 or 2, wherein the electrode arrangement comprises an electrode element (152, 154, E1, E2) having a
20 bare electrode portion (155) configured to form a metal-tissue interface with the muscle tissue, thereby allowing faradaic charge transfer to be the predominant charge transfer mechanism over said interface.
4. The apparatus according to claim 1 or 2, wherein the electrode
25 arrangement comprises an electrode element having a portion at least partly covered by a dielectric material (157) configured to form a dielectric-tissue interface with the muscle tissue, thereby allowing for a faradaic portion of the charge transfer mechanism over said interface to be reduced.
- 30 5. The apparatus according to any of the preceding claims, wherein the controller is configured to control the electrical stimulation such that the

muscle tissue is stimulated by a series of electrical pulses (PL1, PL2, PL3, PL4).

6. The apparatus according to claim 5, wherein the controller is
5 configured to control the electrical stimulation such that a pulse of a first polarity is followed by a pulse of a second, reversed polarity.

7. The apparatus according to claim 5 or 6, wherein the controller is
configured to generate a pulsed electrical stimulation signal comprising a
10 pulse frequency (F) of 0.01-150 Hz.

8. The apparatus according to claim 7, wherein the electrical stimulation
signal comprises a pulse duration (D) of 0.01-100 ms.

15 9. The apparatus according to claim 7 or 8, wherein the electrical
stimulation signal comprises a pulse amplitude (A) of 1-15 mA.

10. The apparatus according to any of claims 7-9, wherein the electrical
stimulation signal comprises a pulse frequency of 0.15-0.25 Hz, a pulse
20 duration of 20-30 ms and a pulse amplitude of 3-10 mA.

11. The apparatus according to any of claims 7-10, wherein the electrical
stimulation signal comprises a build-up period (X1) of 0.01-2 s in which the
amplitude is gradually increasing, a stimulation period (X2) of 1-60 s, and a
25 stimulation pause (X4) of 0.01-60 s, wherein the electrical signal comprises a
pulse frequency of 1-50 Hz and a pulse duration of 0.1-10 ms.

12. The apparatus according to any of the preceding claims, wherein the at least one electrode is configured to engage smooth muscle tissue.
13. The apparatus according to claim 12, further comprising a sensor (S1)
5 configured to sense action potentials generated by pacemaker cells of the muscle tissue, and wherein the controller is configured to control the electrical stimulation based at least partly on the sensed action potentials.
14. The apparatus according to claim 13, wherein the controller is
10 configured to generate electrical pulses amplifying the sensed action potentials.
15. The apparatus according to any preceding claim, wherein the implantable energy source is configured to provide the electrode arrangement
15 and/or the controller with electrical power.
16. The apparatus according to any of the preceding claims, wherein the controller is further configured to indicate a functional status of the
20 implantable energy source.
17. The apparatus according to claim 16, wherein the functional status indicates at least one of charge level and temperature of the implantable energy source.
18. The apparatus according to claim 16 or 17, wherein the controller is
25 further configured to include the functional status in a signal transmitted to the outside of the body.
19. The apparatus according to any of the preceding claims, further
30 comprising a charger (190) configured to control a charging of the implantable energy source by controlling a receipt of electrical power from an external energy source at the implantable charger.

20. The apparatus according to claim 19, wherein the charger comprises an electromagnetic coil configured to receive electrical power wirelessly from the external energy source.

5

21. The apparatus according to claim 19 or 20, wherein the charger is configured to control the charging of the implantable energy source by controlling a transmission of electrical power from the external energy source to the implantable charger.

10

22. The apparatus according to any of the preceding claims, wherein the controller comprises a wireless remote control.

23. The apparatus according to claim 22, wherein the wireless remote
15 control comprises an external signal transmitter, and wherein the controller comprises an implantable controller configured to receive a signal transmitted by the external signal transmitter and to control an operation of the apparatus based on said signal.

20 24. The apparatus according to claim 19 wherein signal is selected from the group consisting of: a sound signal, an ultrasound signal, an electromagnetic signal, and infrared signal, a visible light signal, an ultra violet light signal, a laser signal, a microwave signal, a radio wave signal, an X-ray radiation signal and a gamma radiation signal.

25

25. A method for exercising muscle tissue of a human patient to improve the conditions for term implantation of an apparatus for treating reflux disease in a human patient, wherein the method comprises electrically stimulating the muscle against which the apparatus is arranged to rest when implanted.

30

26. The method according to claim 25, comprising electrically stimulating the muscle tissue by means of an electrode arrangement arranged between the muscle tissue and the apparatus.
- 5 27. The method according to claim 25 or 26, comprising electrically stimulating the muscle tissue with a pulsed signal (PL1, PL2, PL3, PL4).
28. The method according to claim 27, wherein the pulsed signal is applied by using the electrode arrangement as a cathode.

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Fig.1

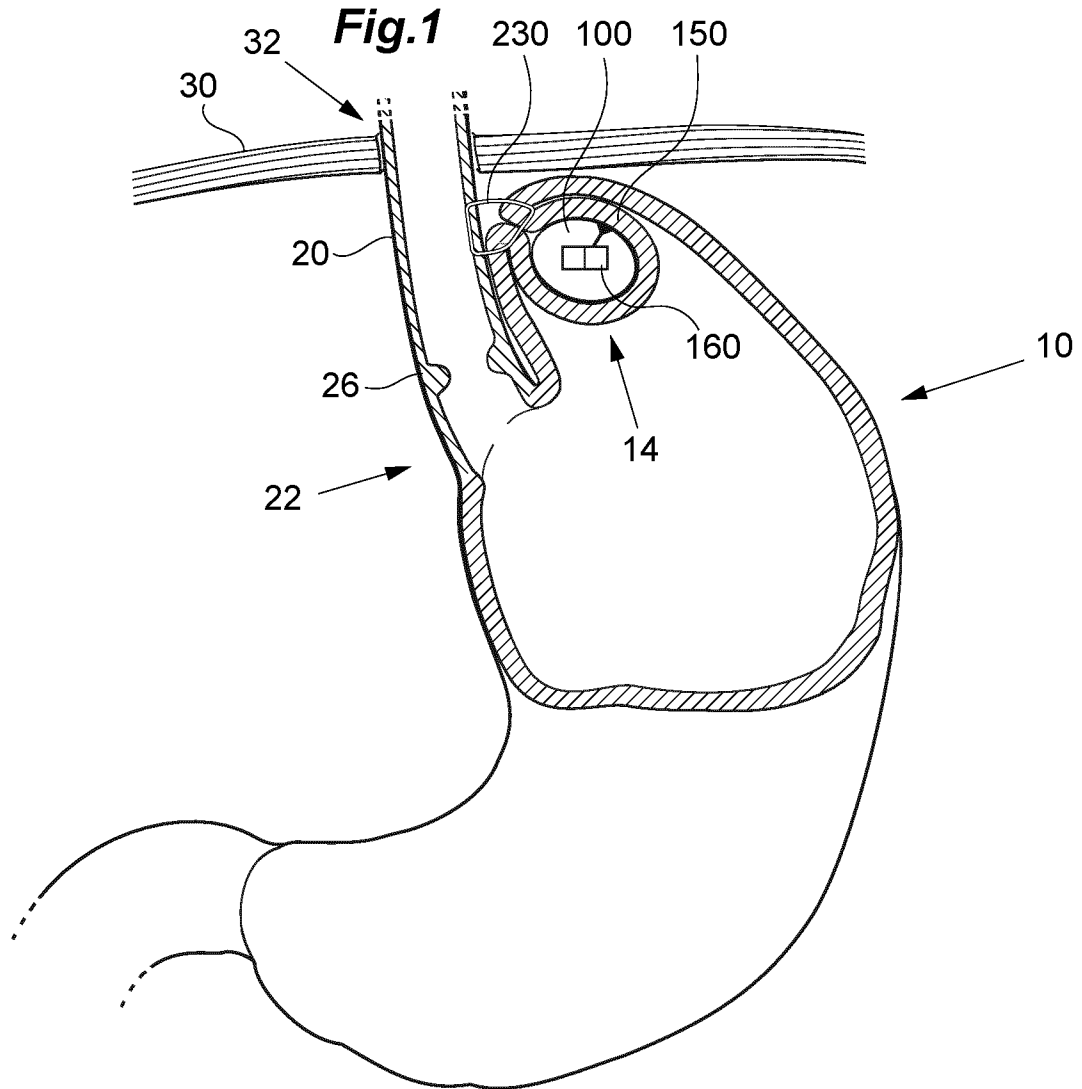


Fig.2

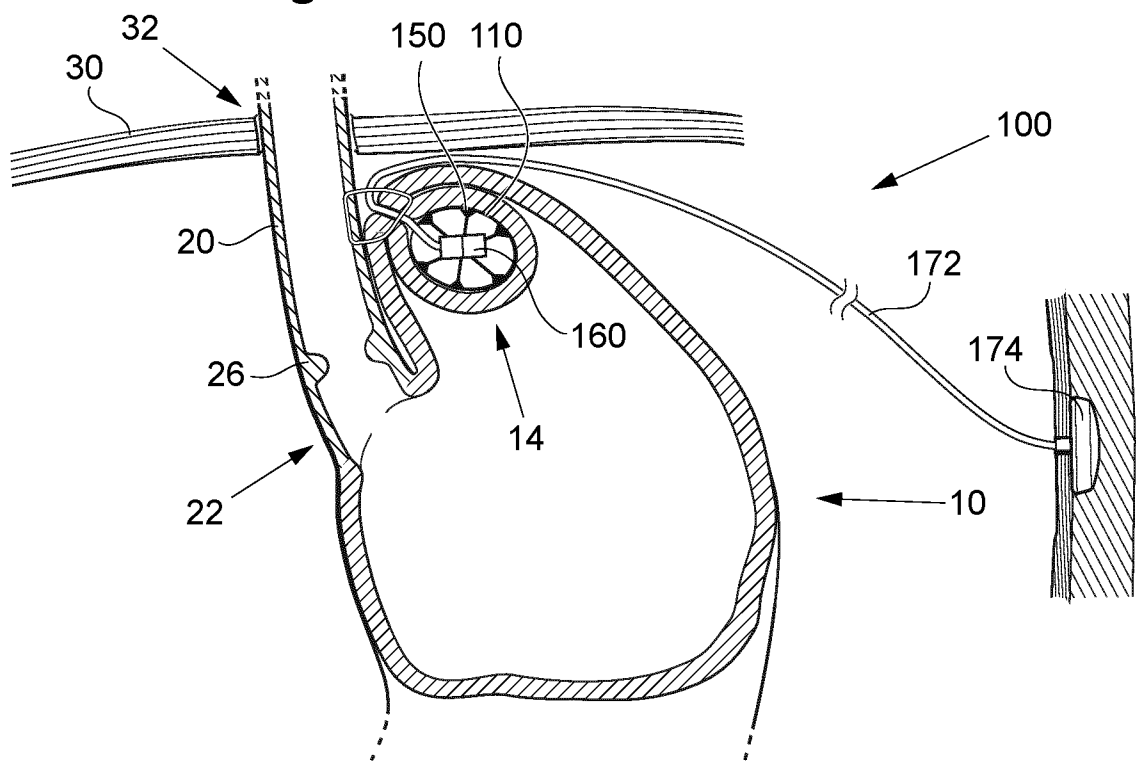
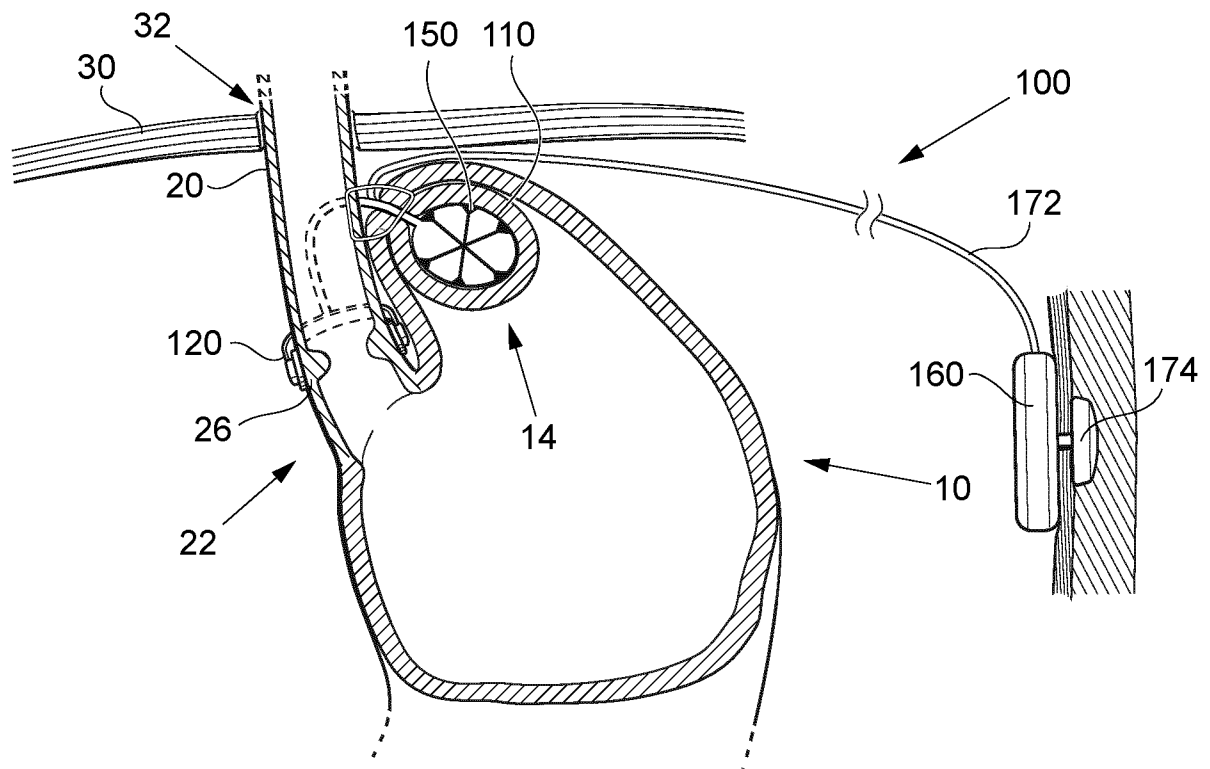
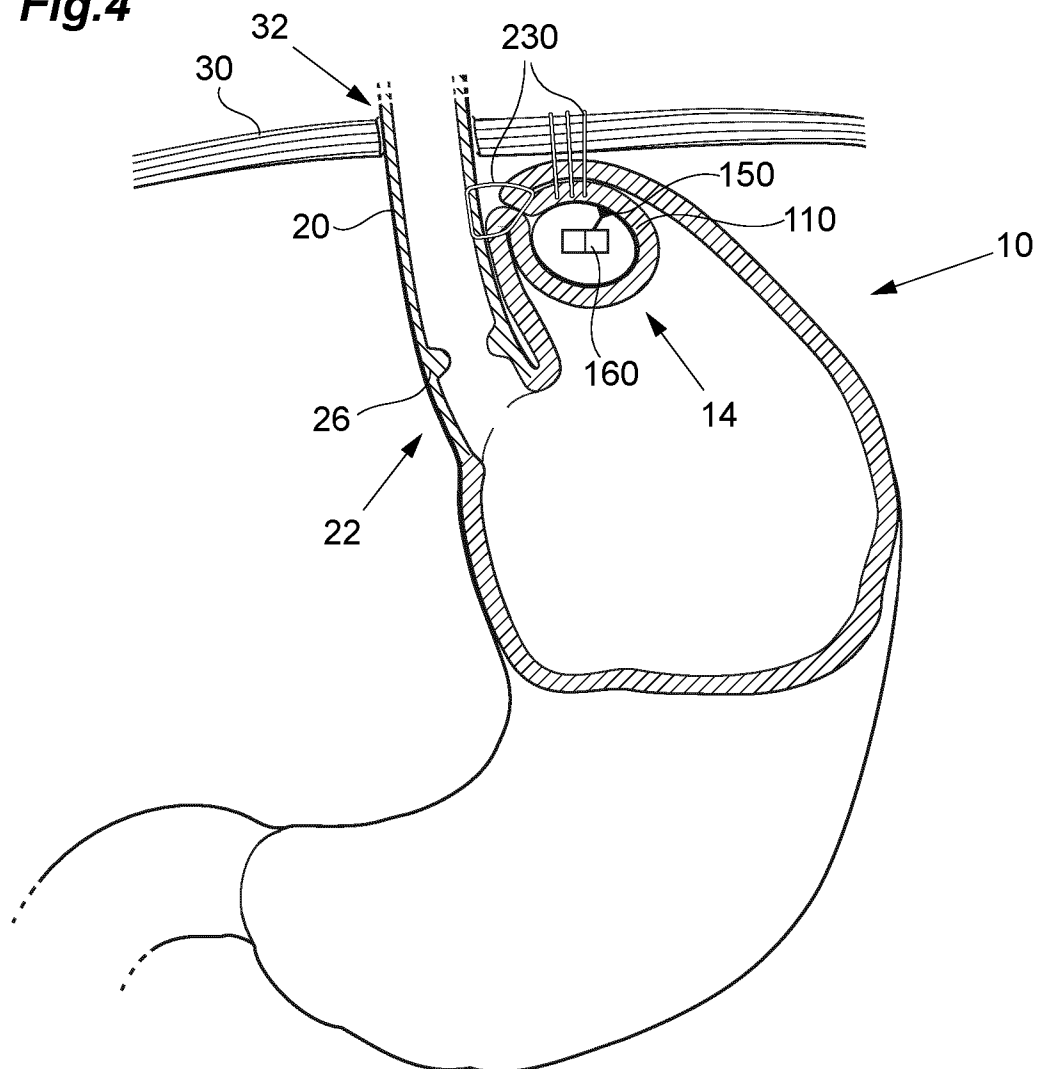
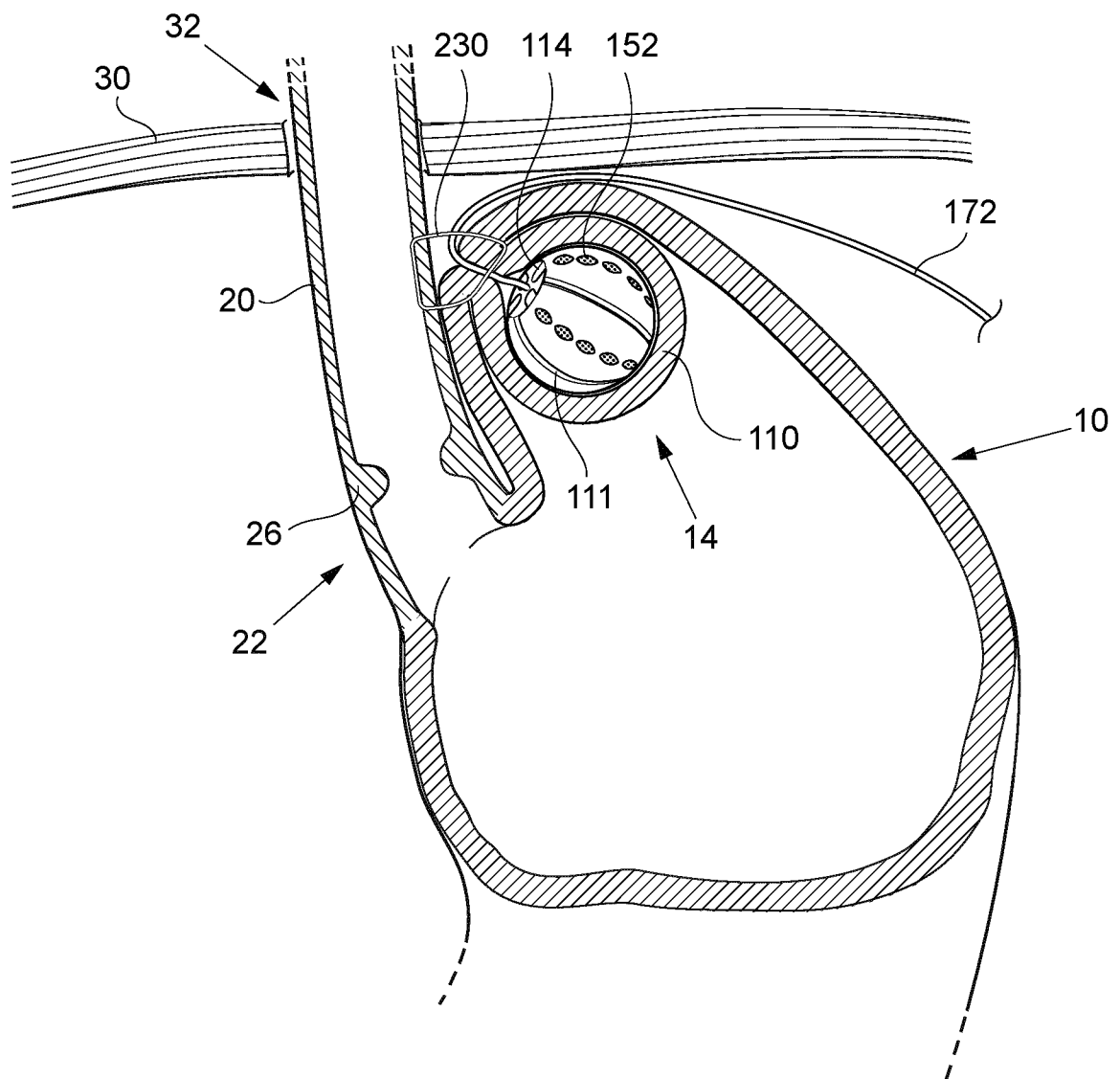
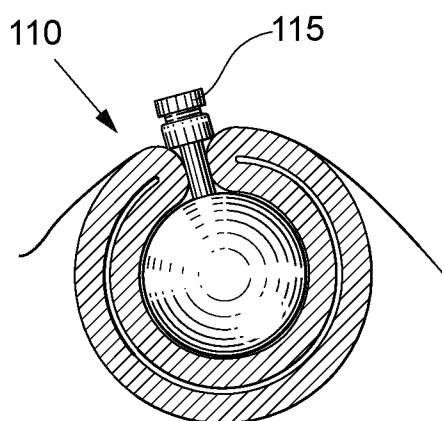
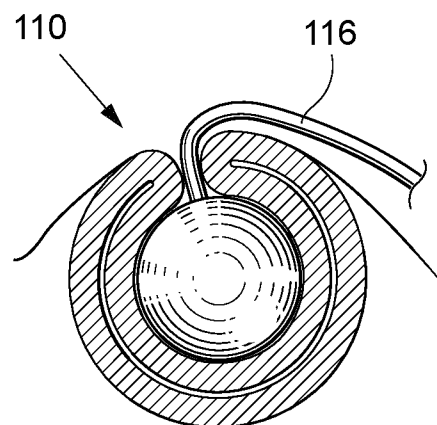


Fig.3 2/57**Fig.4**

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Fig.5**Fig.6 A****Fig.6 B**

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Fig.7

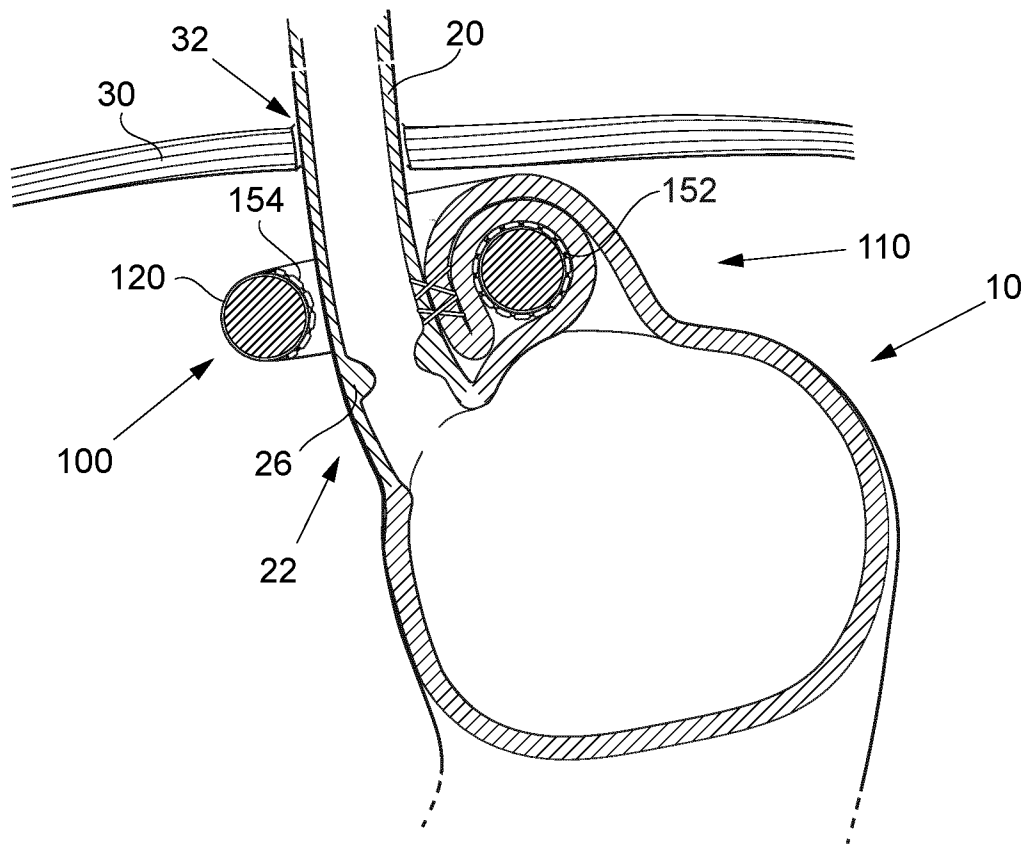


Fig.8

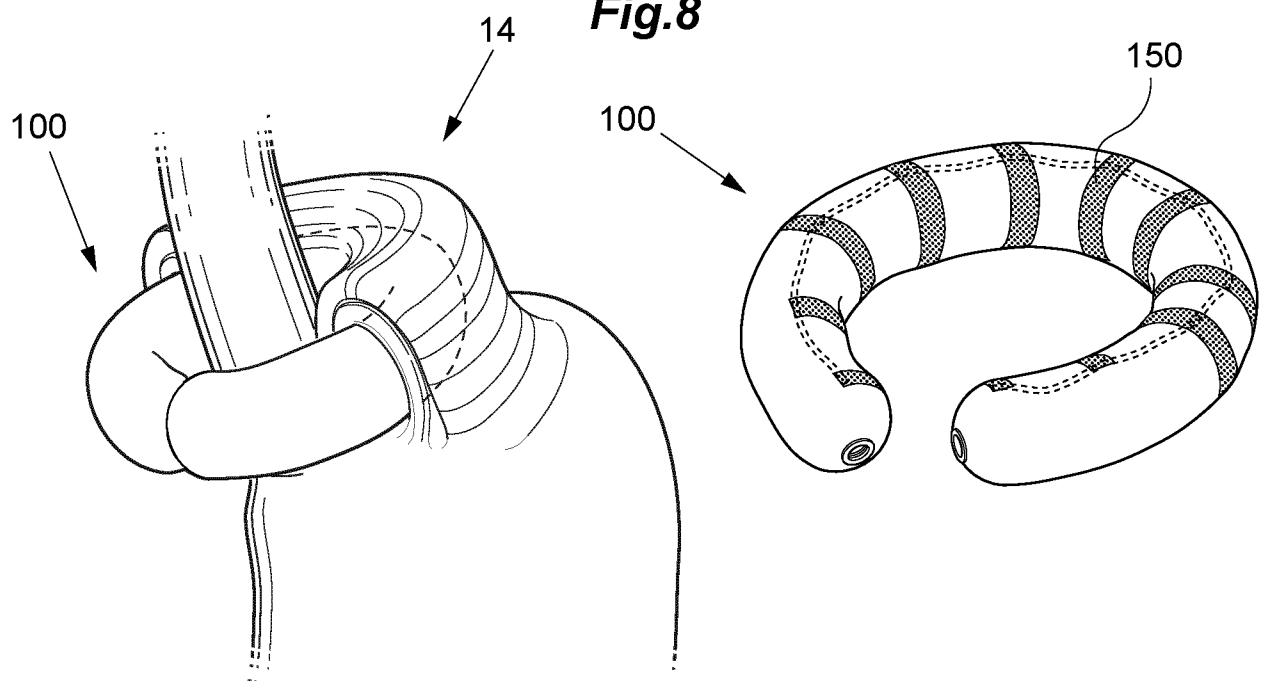
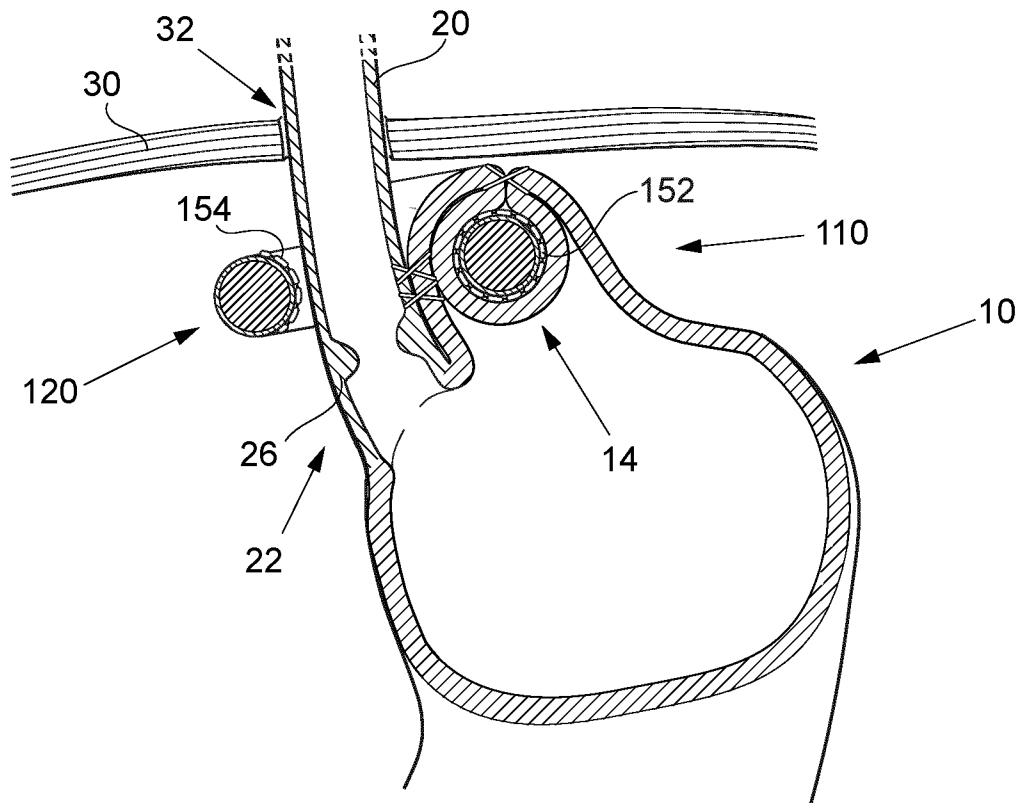


Fig.9

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Fig.10

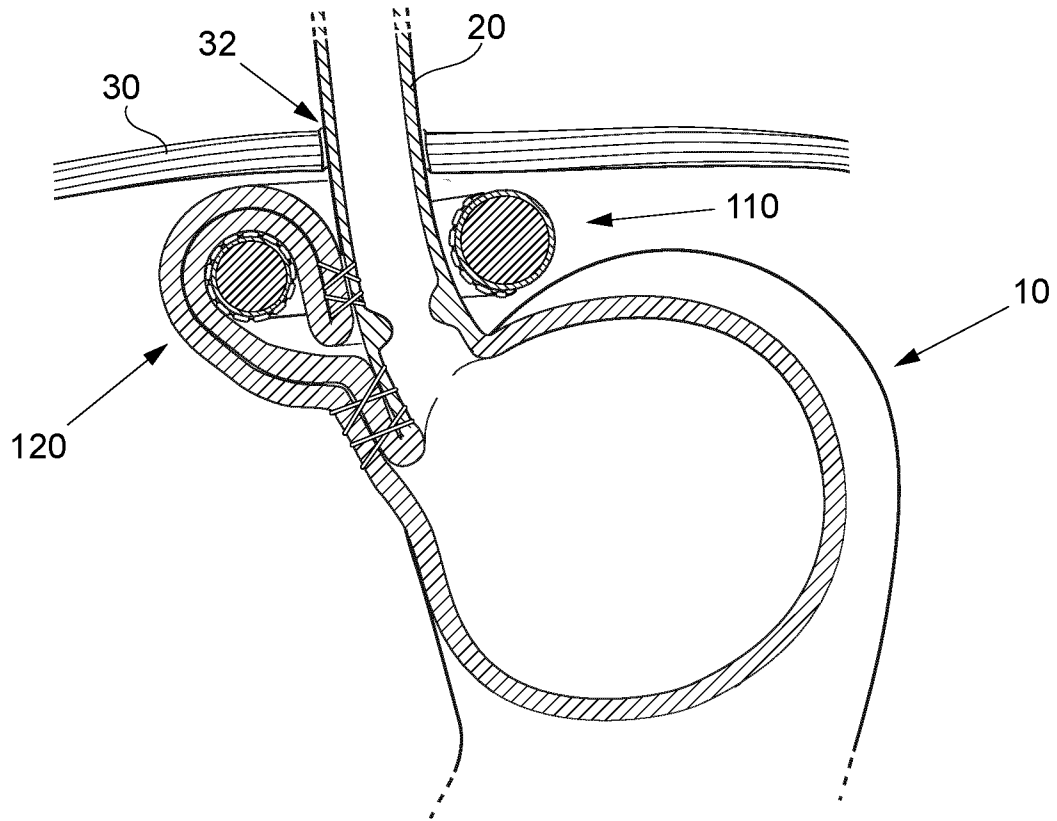
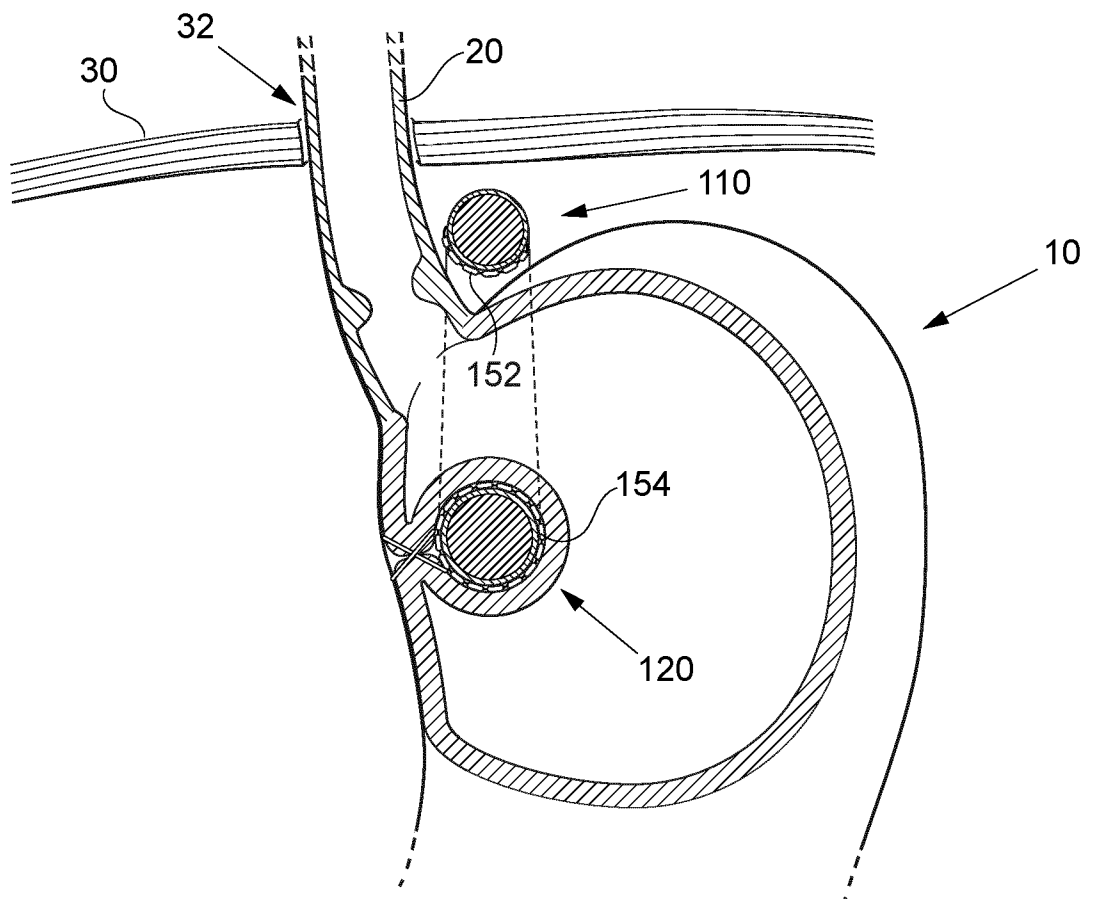
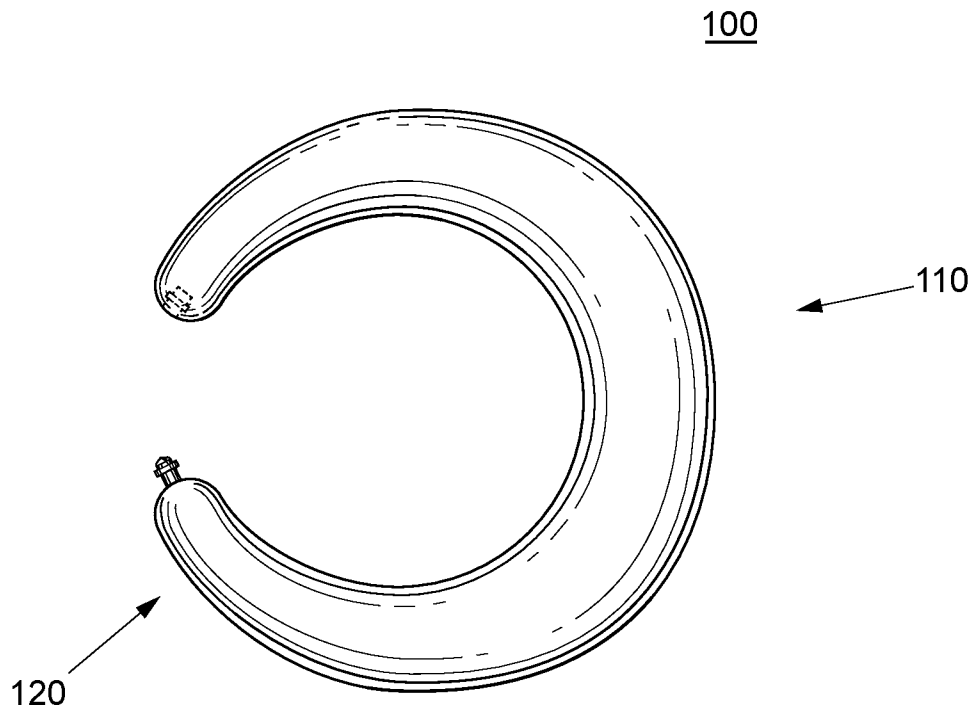


Fig.11



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Fig.12



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Fig.13

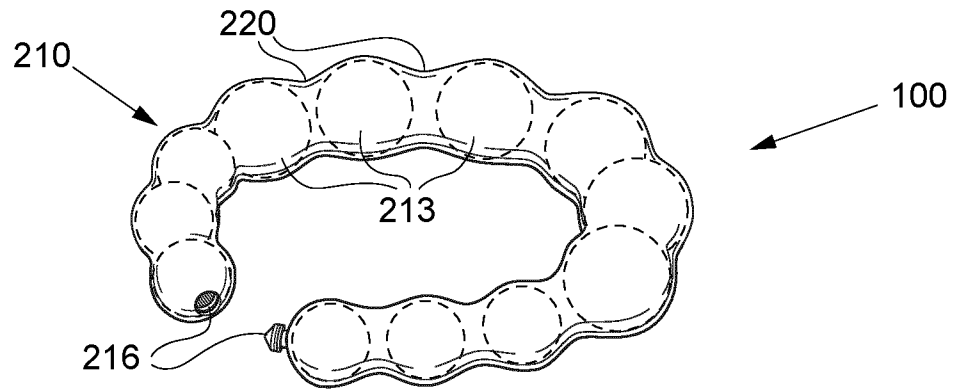


Fig.14

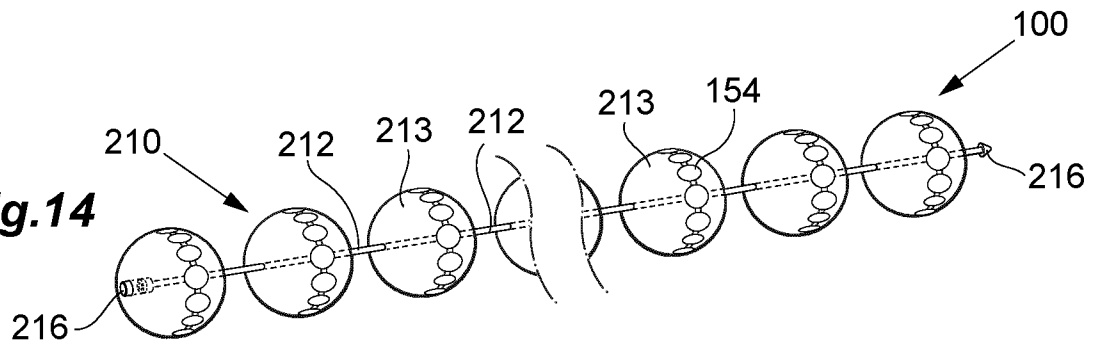


Fig.15

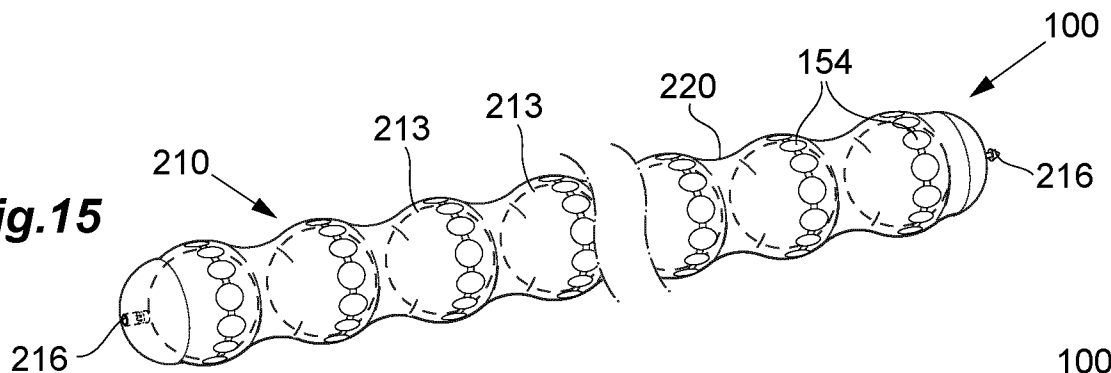


Fig.16

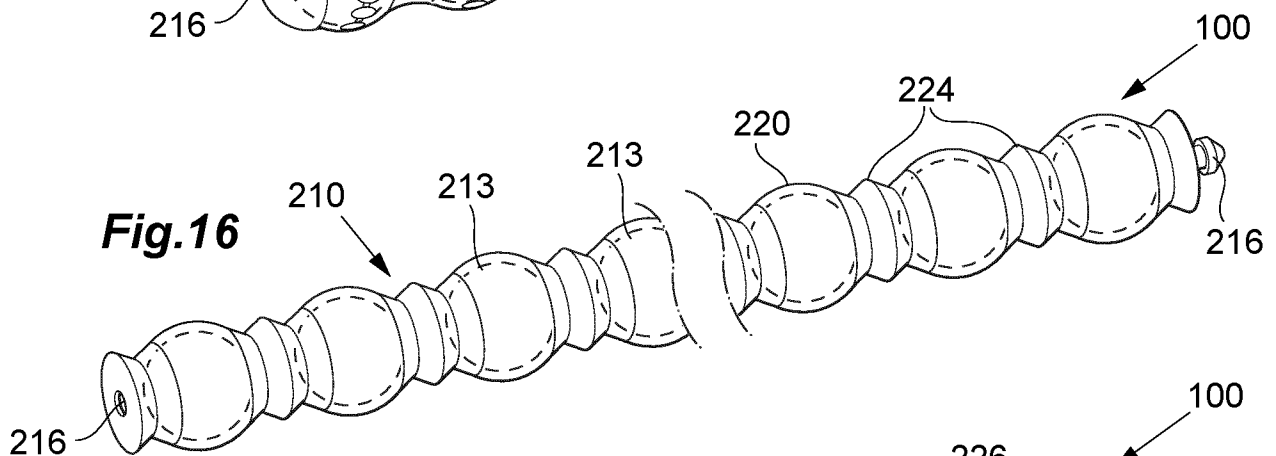
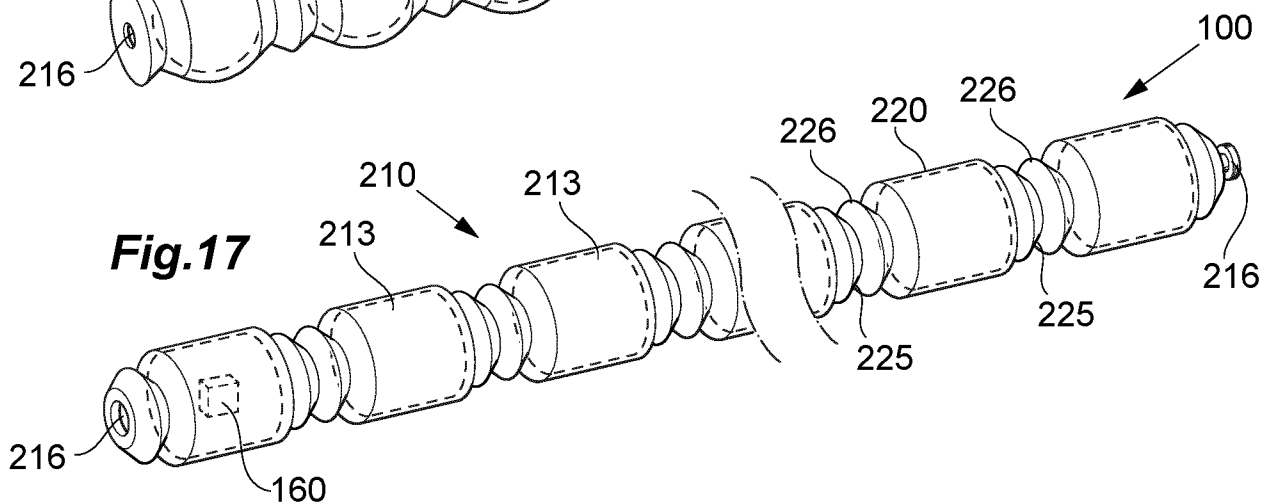
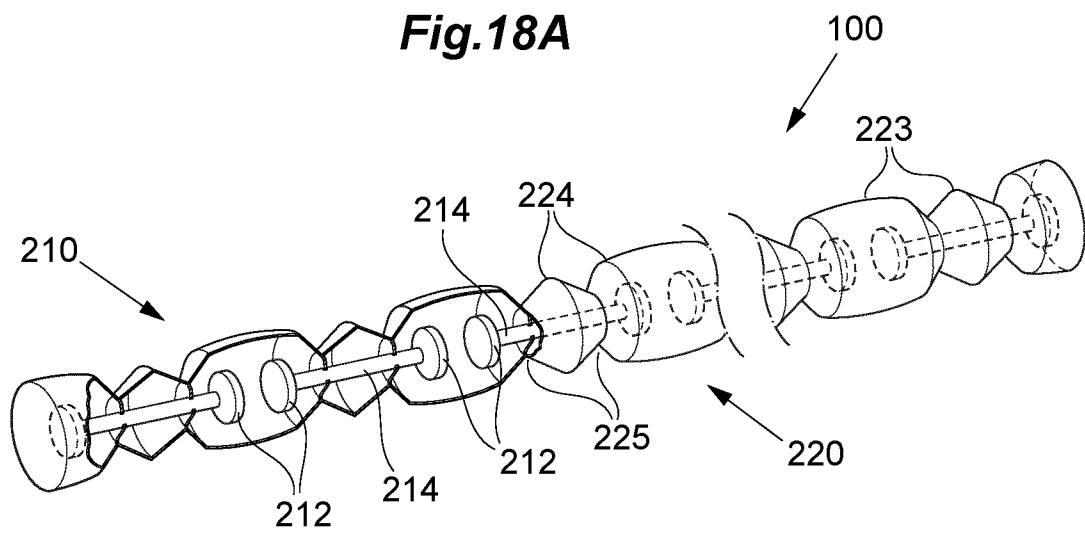
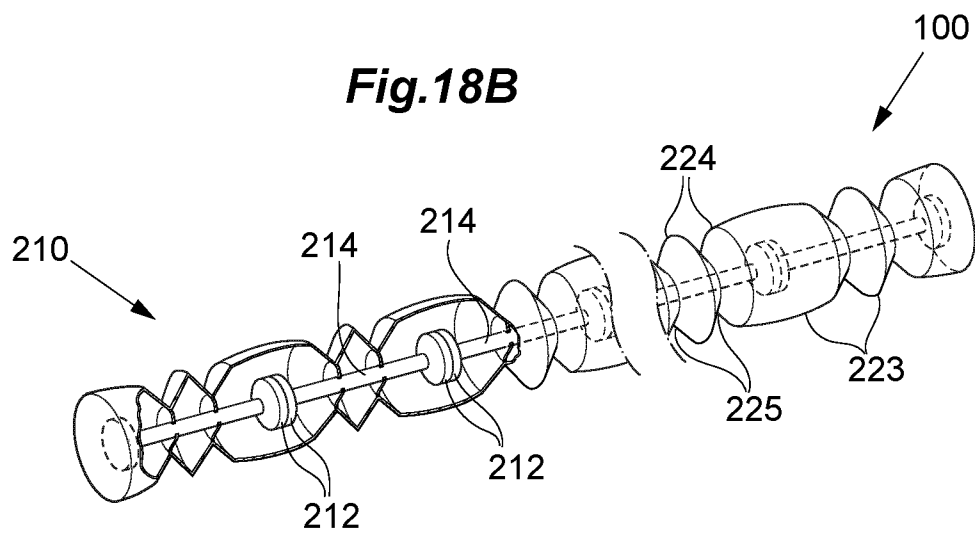


Fig.17



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Fig.18A**Fig.18B**

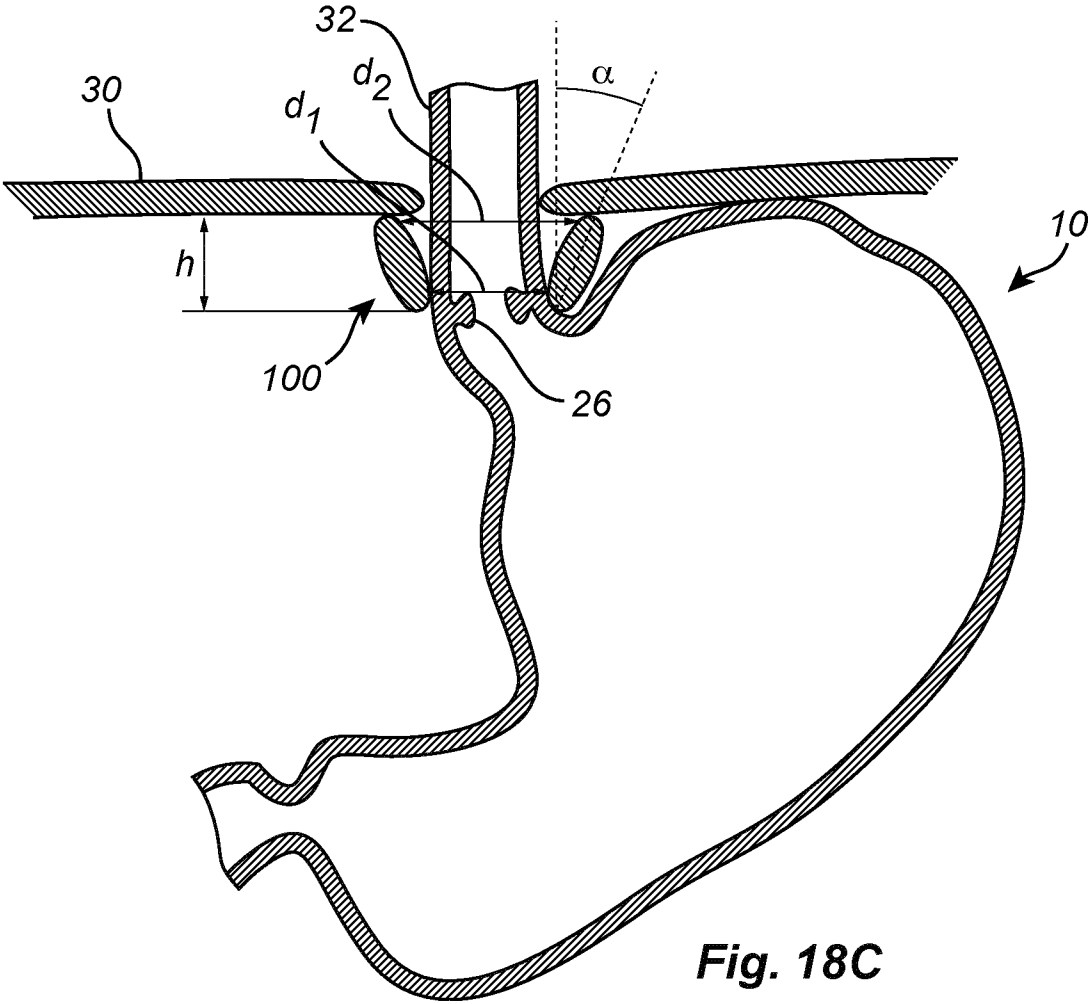
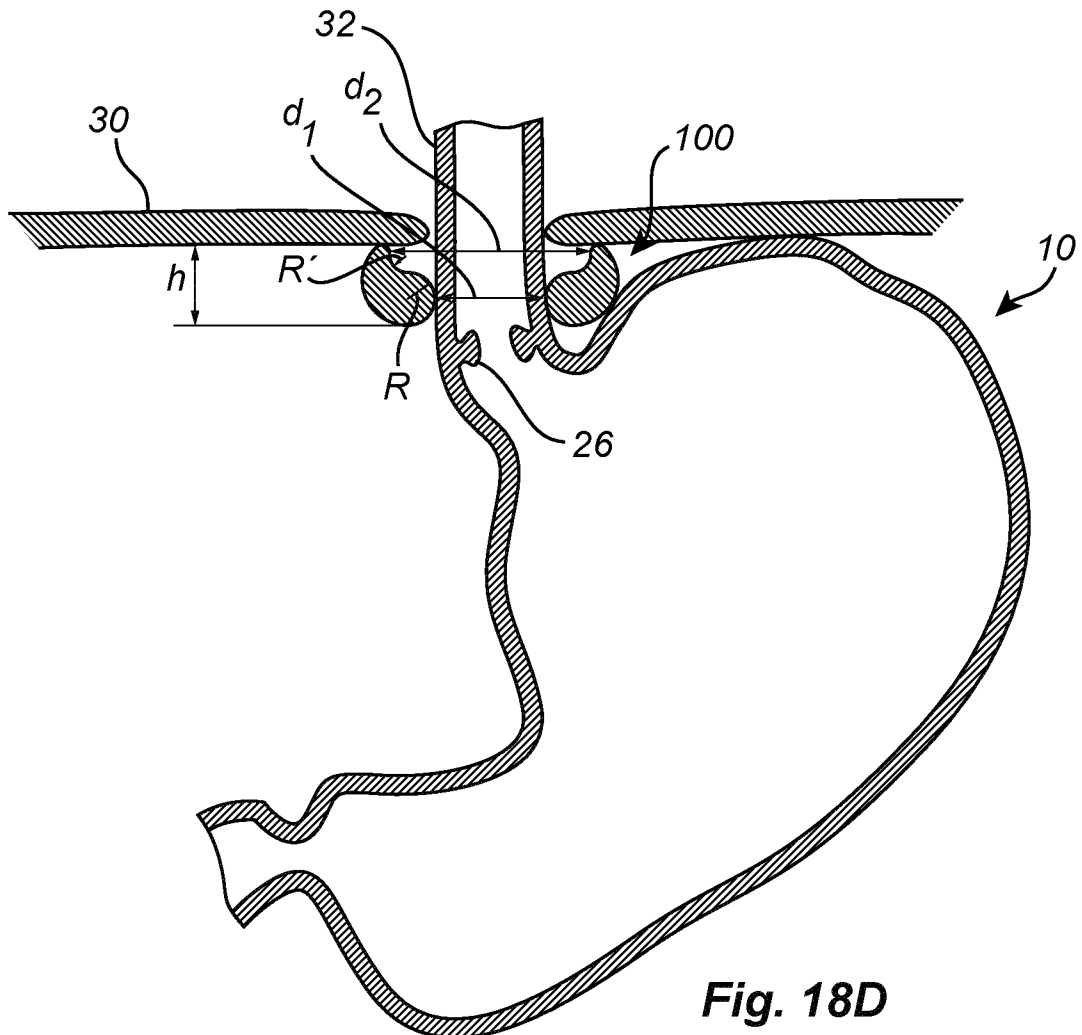
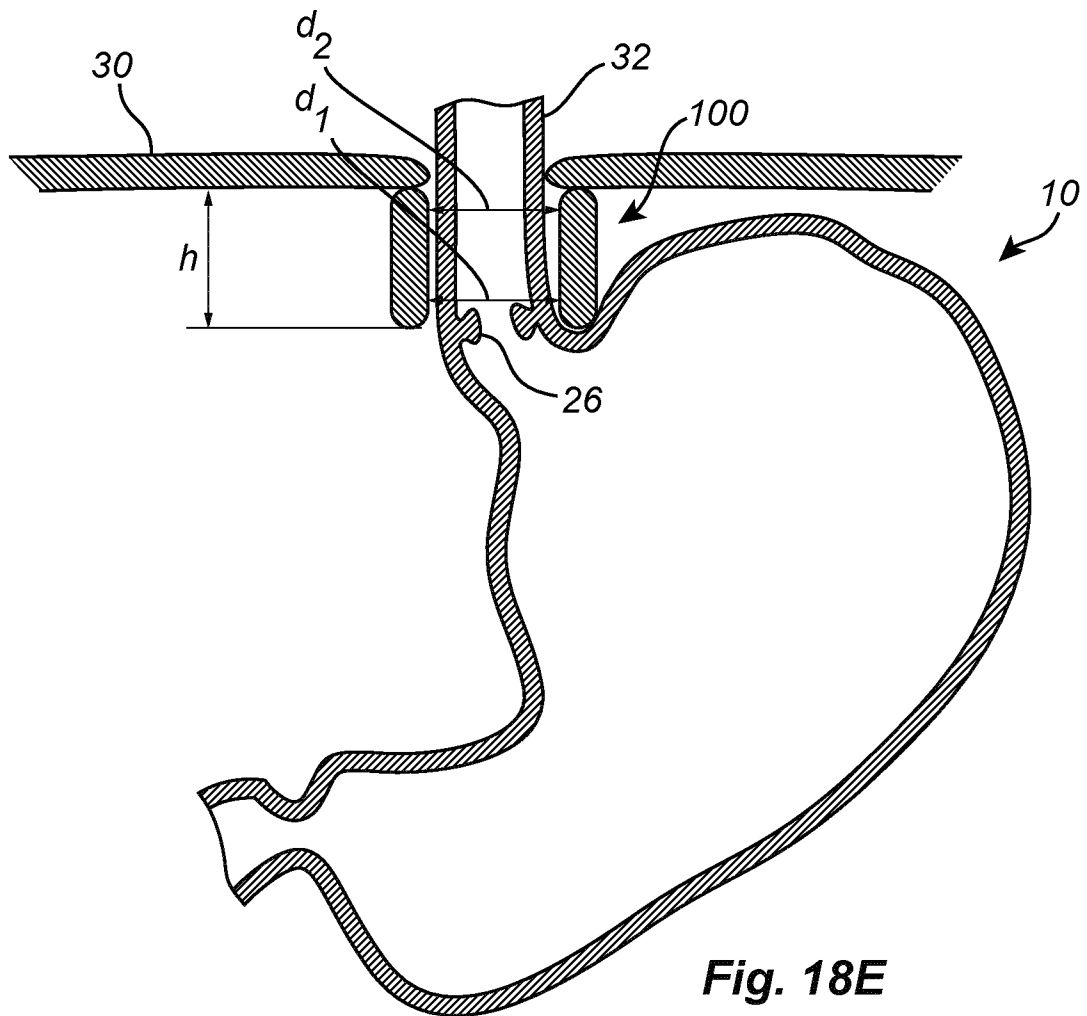


Fig. 18C





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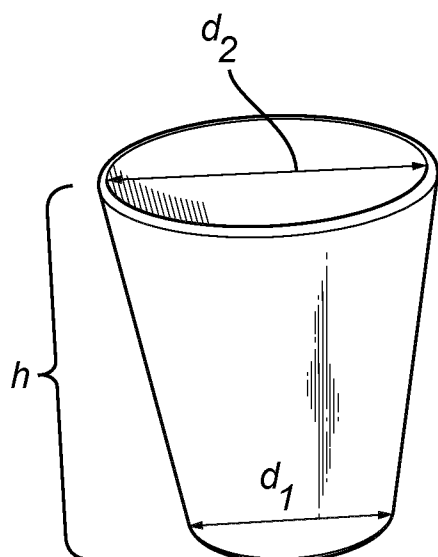


Fig. 18F

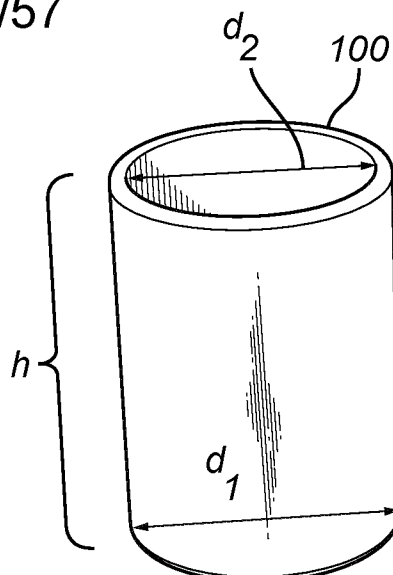


Fig. 18G

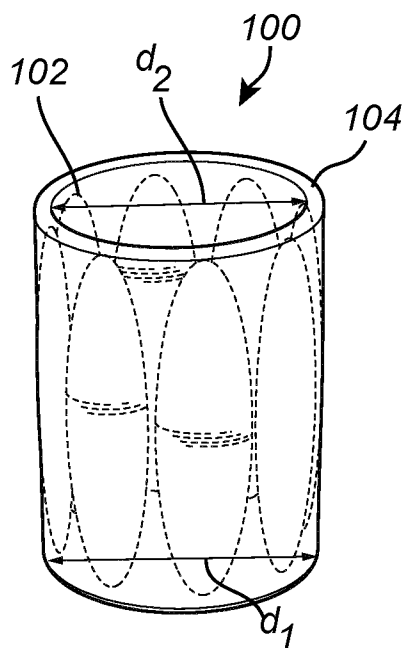


Fig. 18H

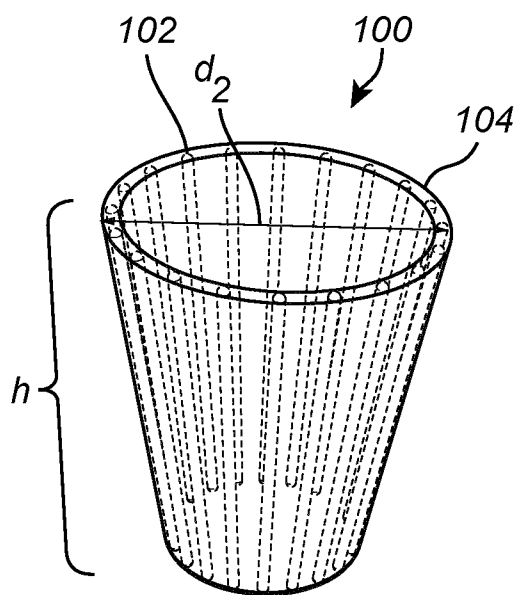


Fig. 18I

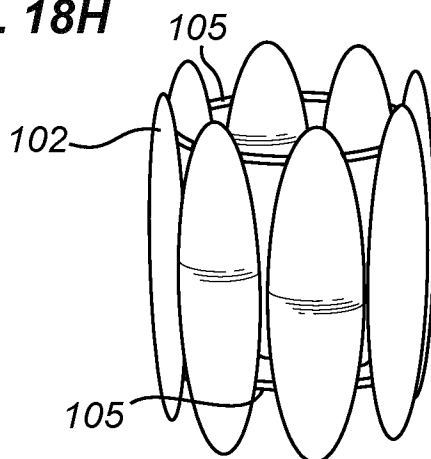
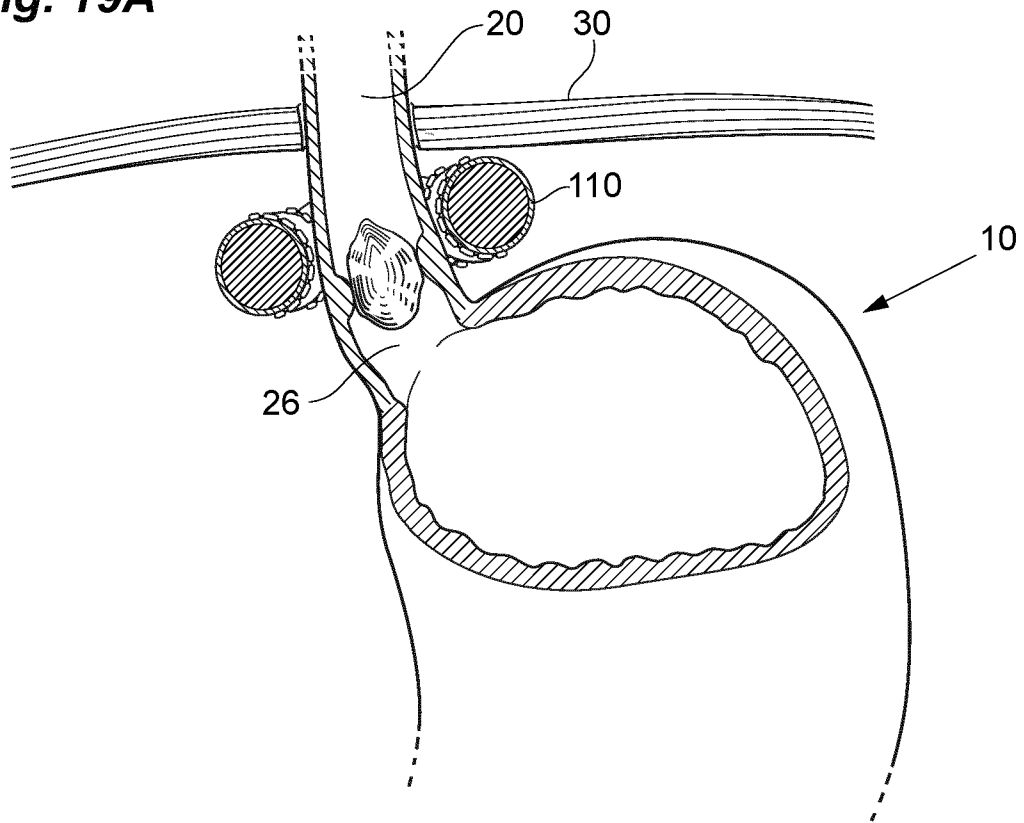
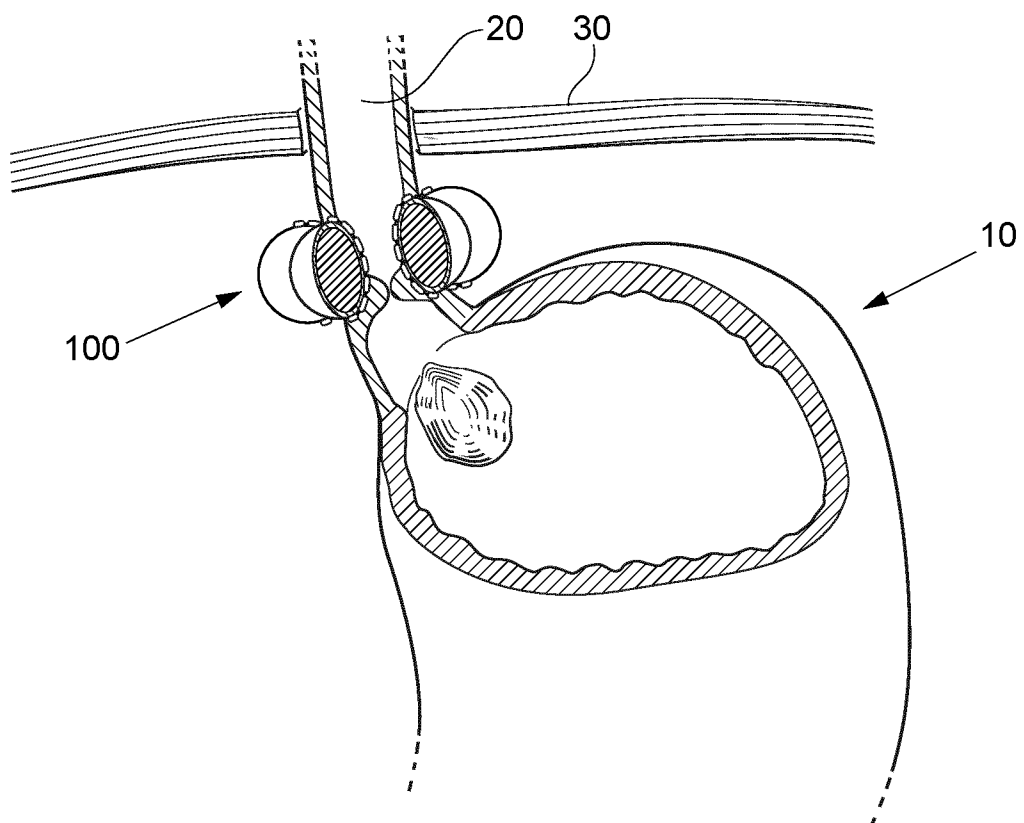


Fig. 18J

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Fig. 19A**Fig. 19B**

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Fig. 20A

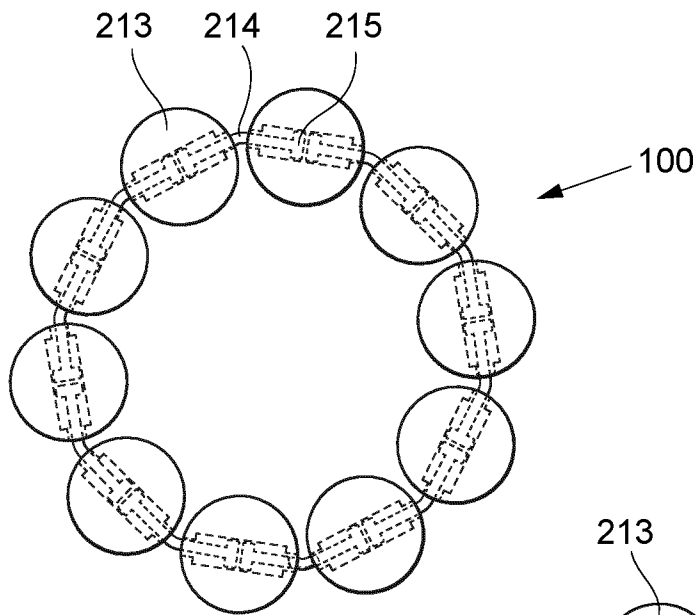


Fig. 20B

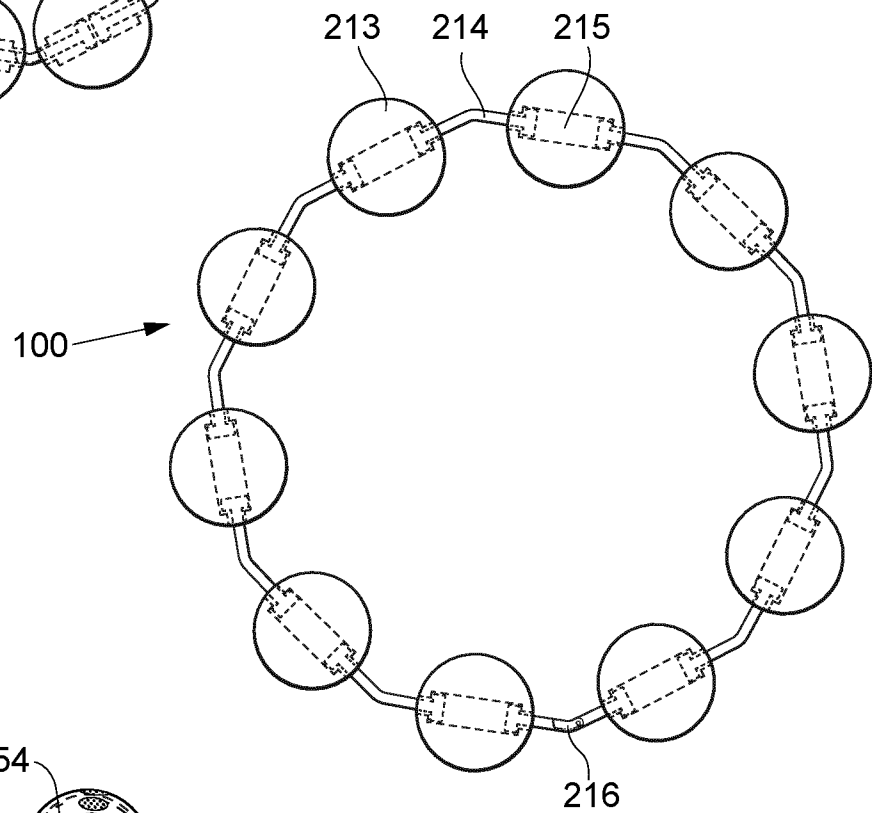
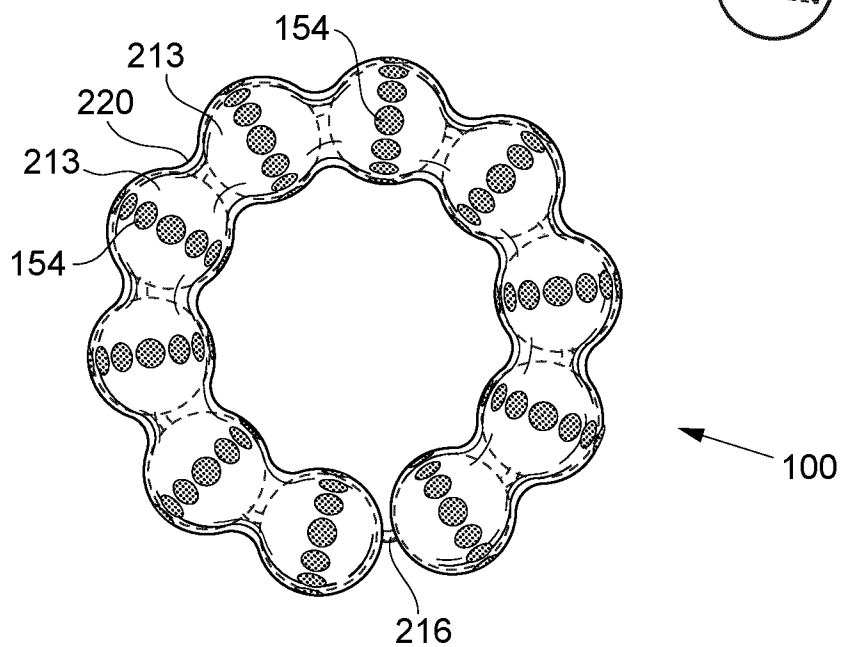
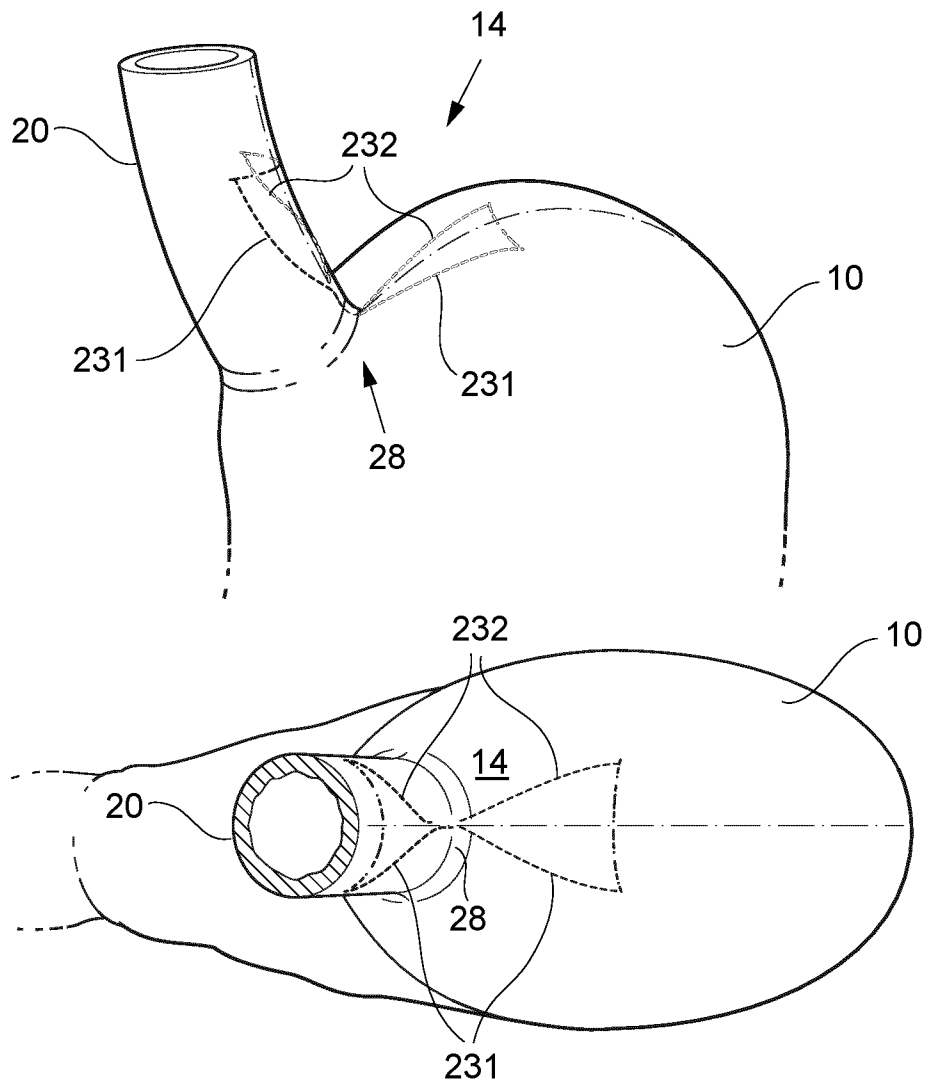
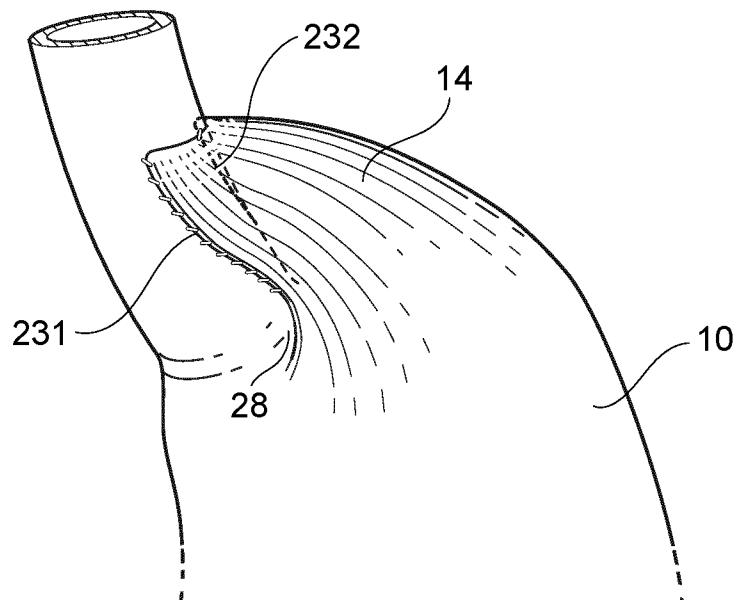


Fig. 21



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Fig.22**Fig. 23A**

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Fig.23 B

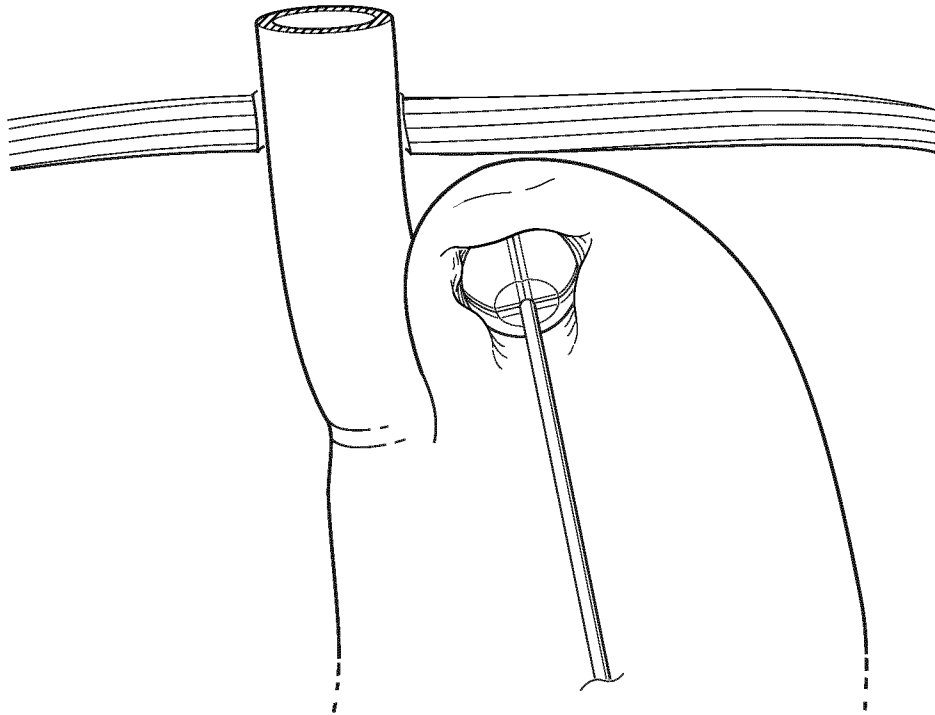
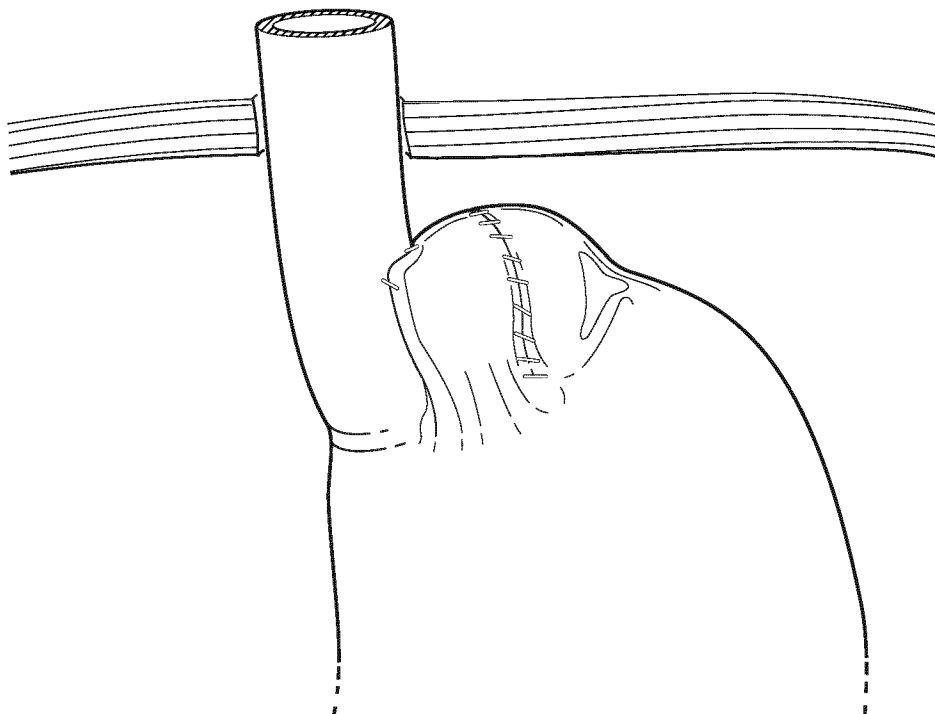


Fig.23 C



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Fig. 24

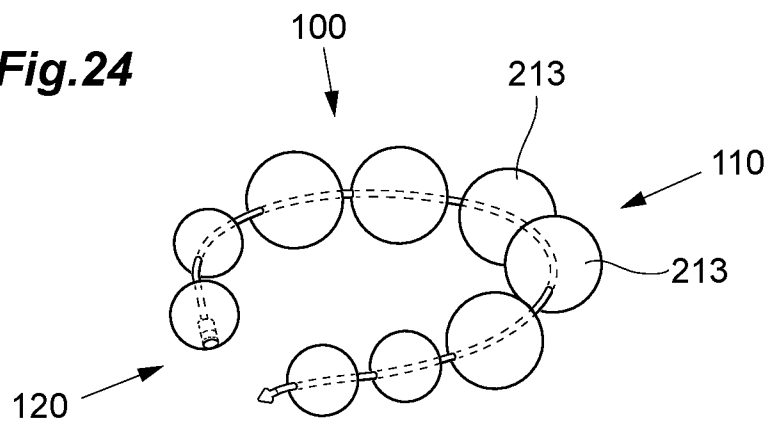


Fig. 25

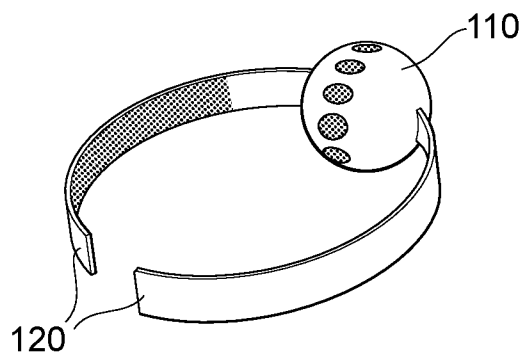


Fig. 26

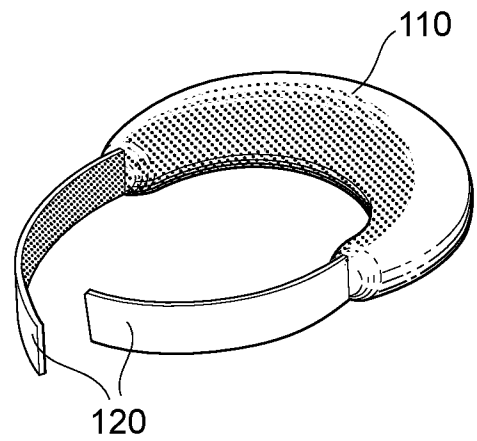
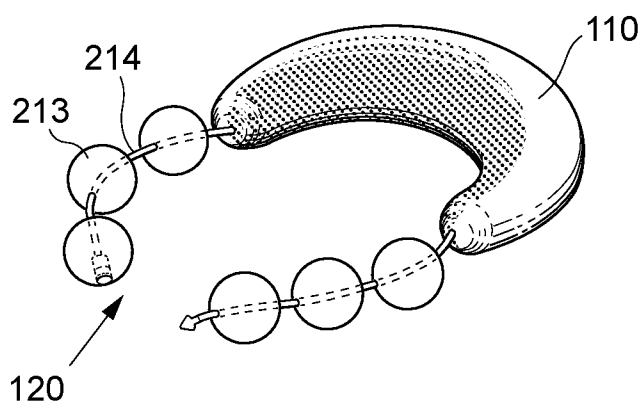
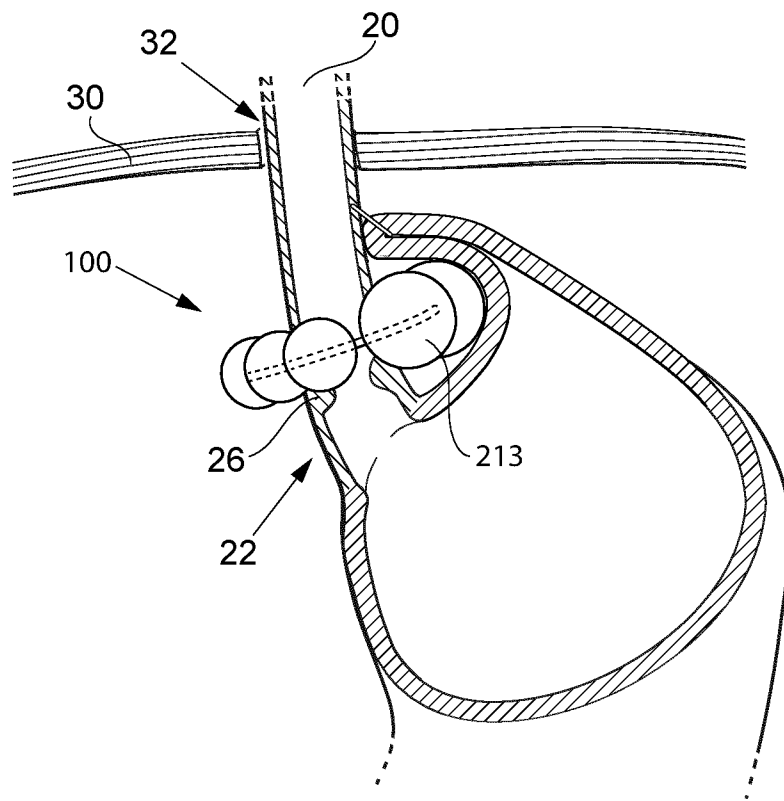


Fig. 27



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Fig.28

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Fig. 29

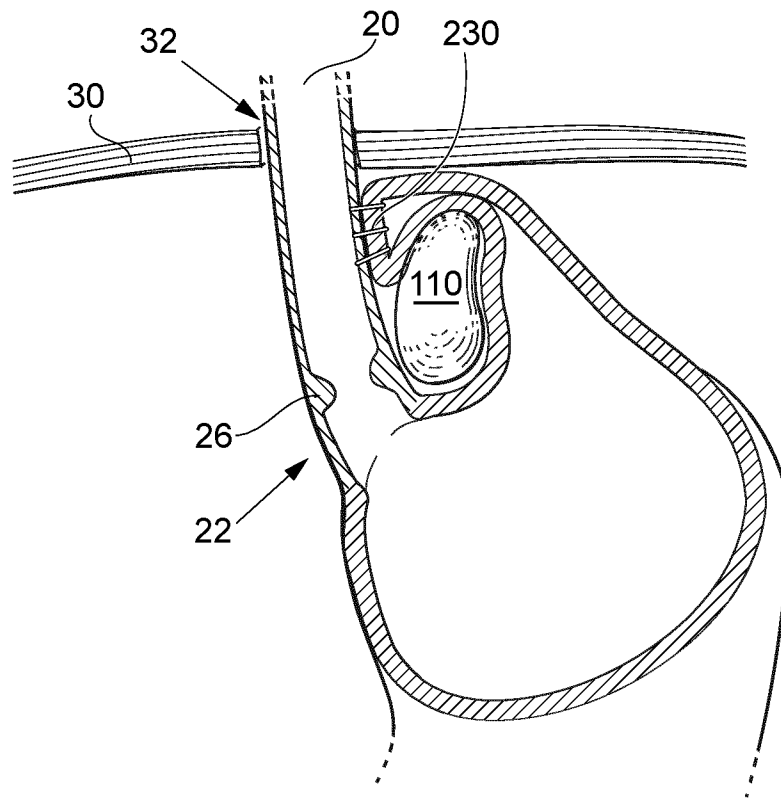
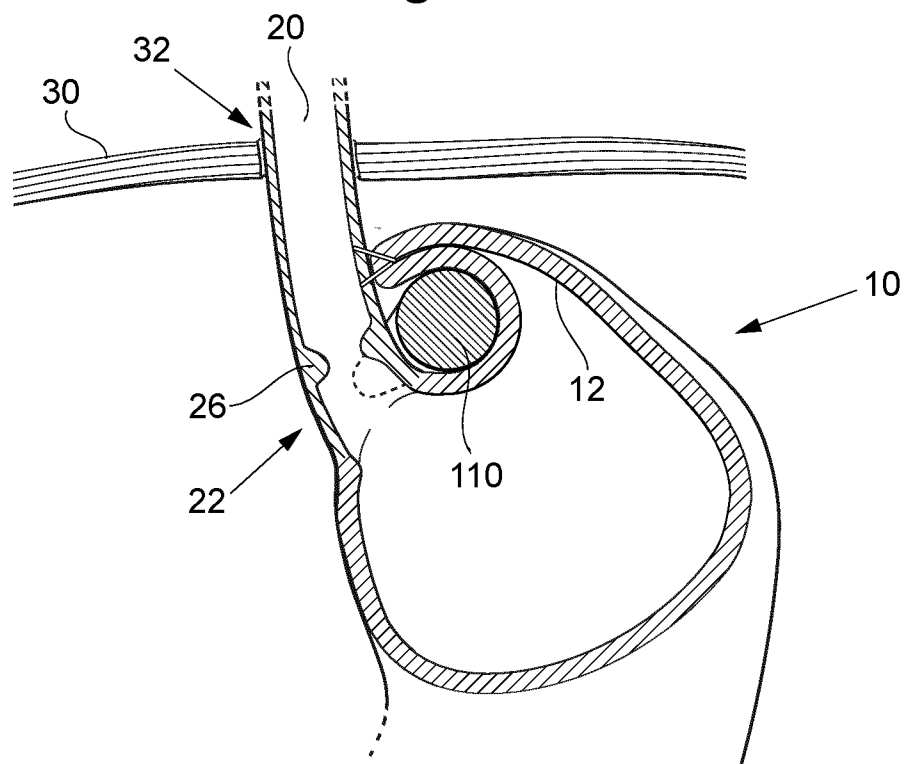


Fig. 30



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Fig. 31A

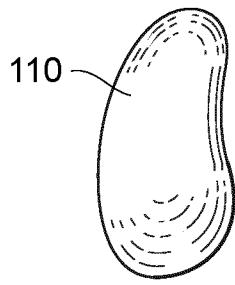


Fig. 31B

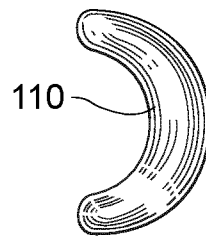


Fig. 31C

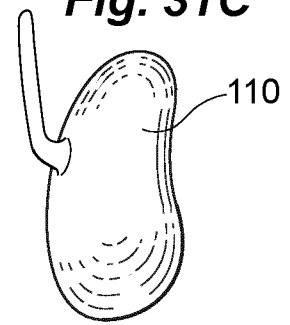


Fig. 31D

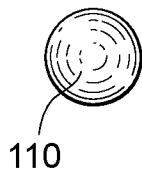


Fig. 31E

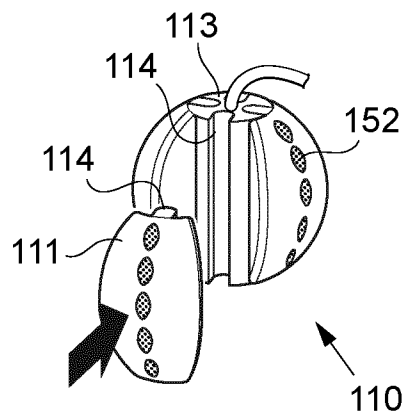


Fig. 31F

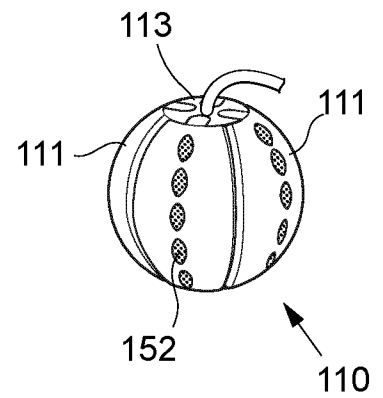
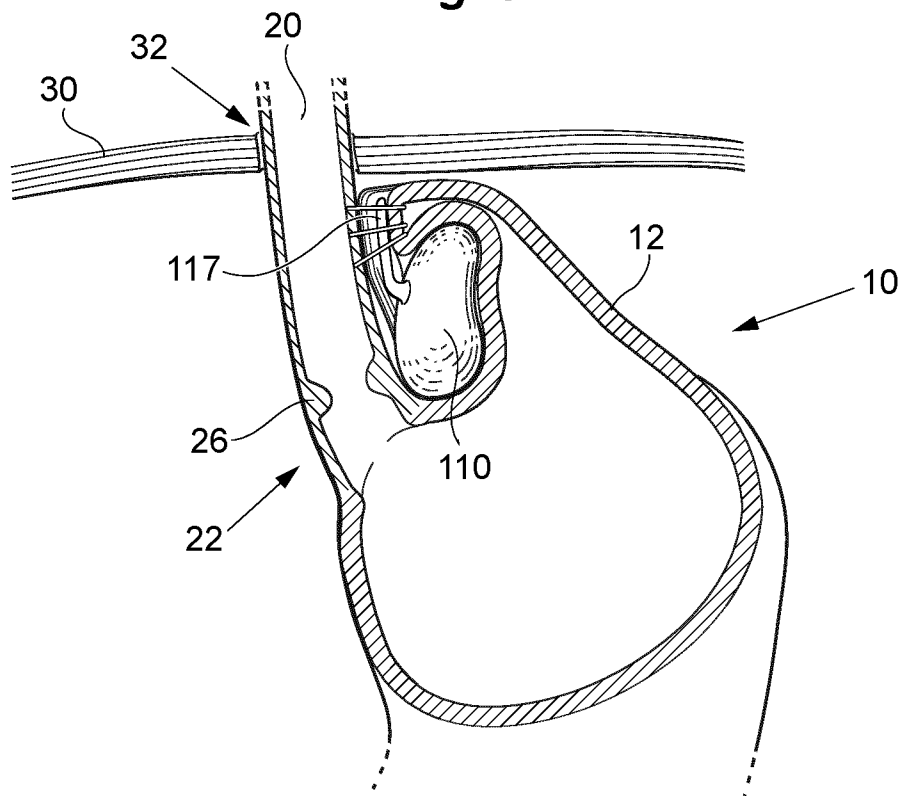


Fig. 32



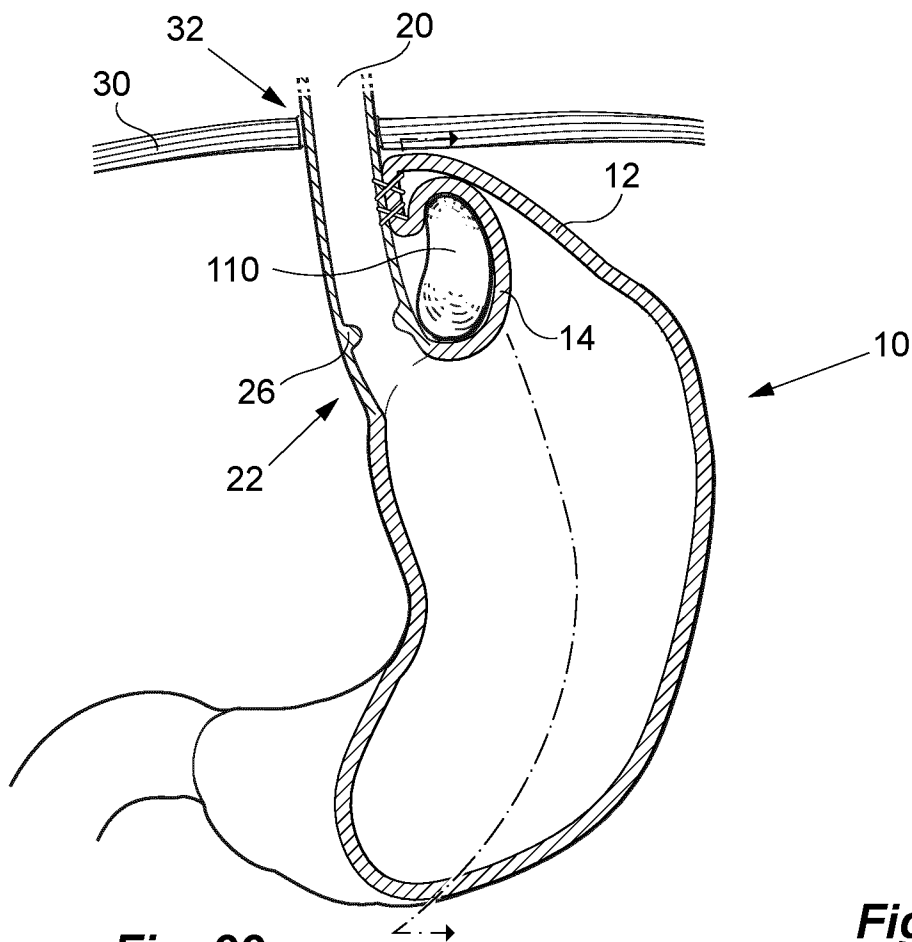


Fig. 33

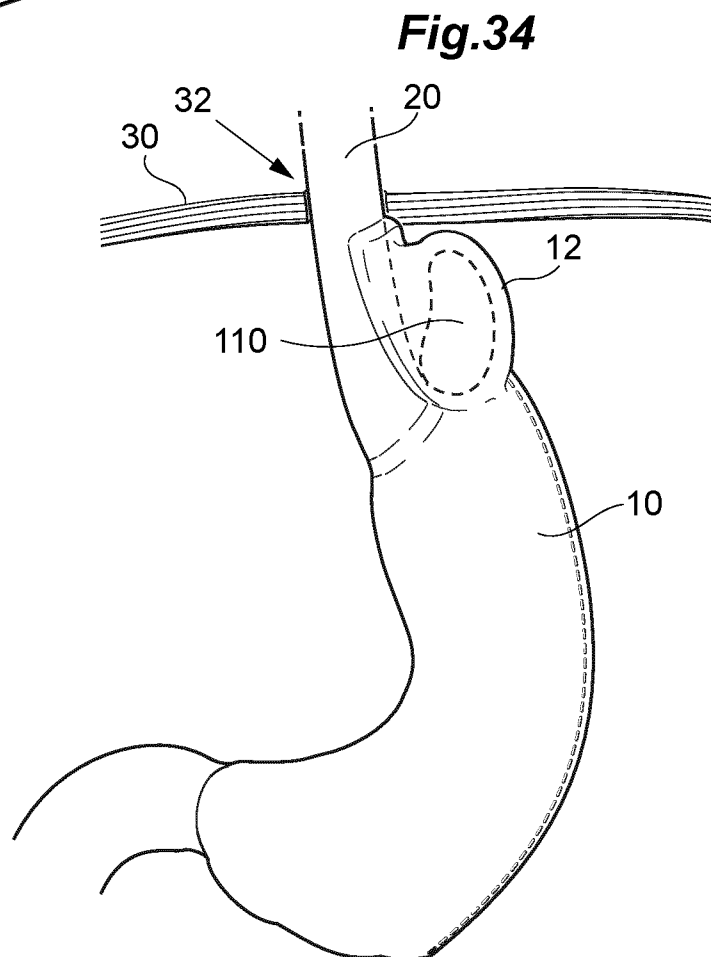


Fig. 34

Fig. 35 23/57

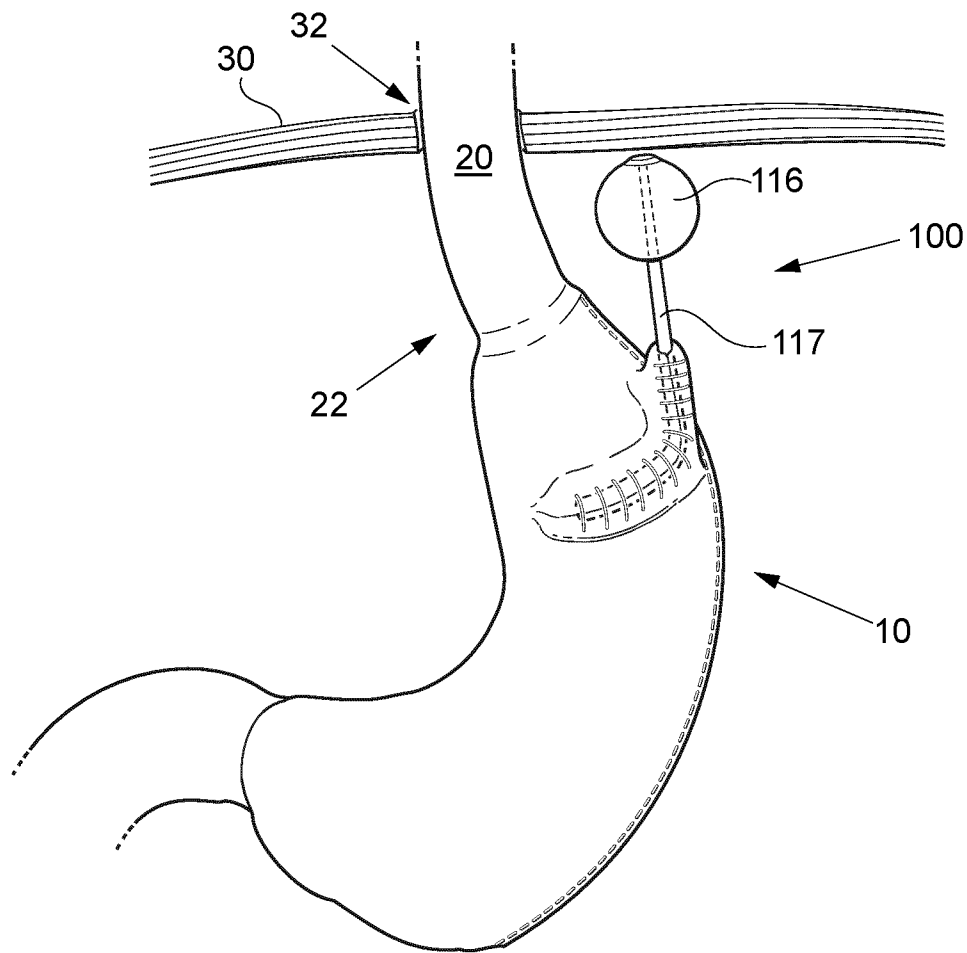


Fig. 36

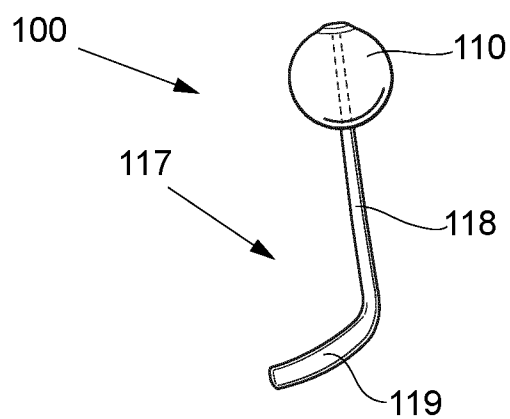
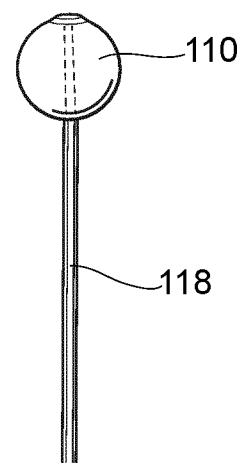
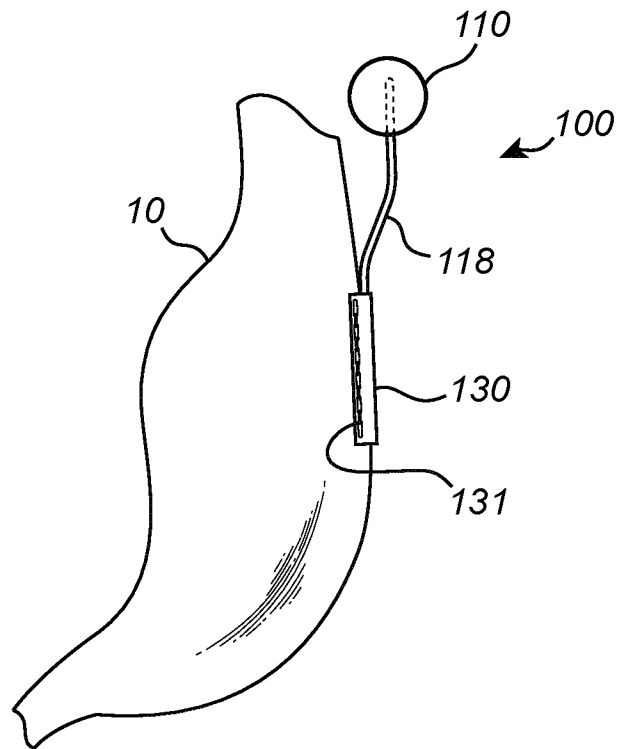
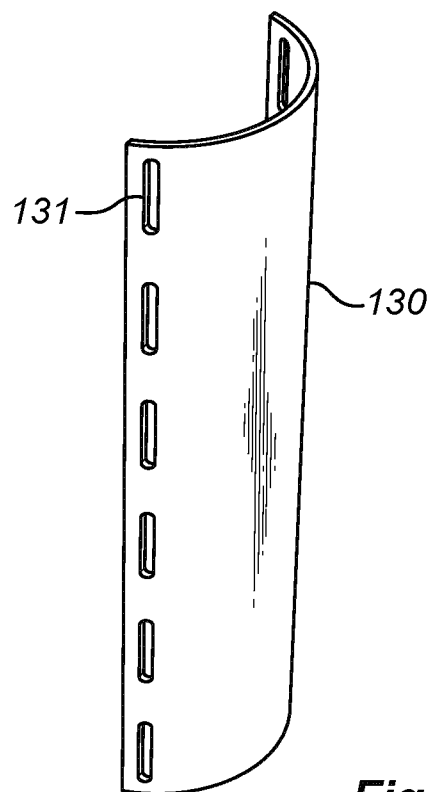


Fig. 37A



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**Fig. 37B****Fig. 37C**

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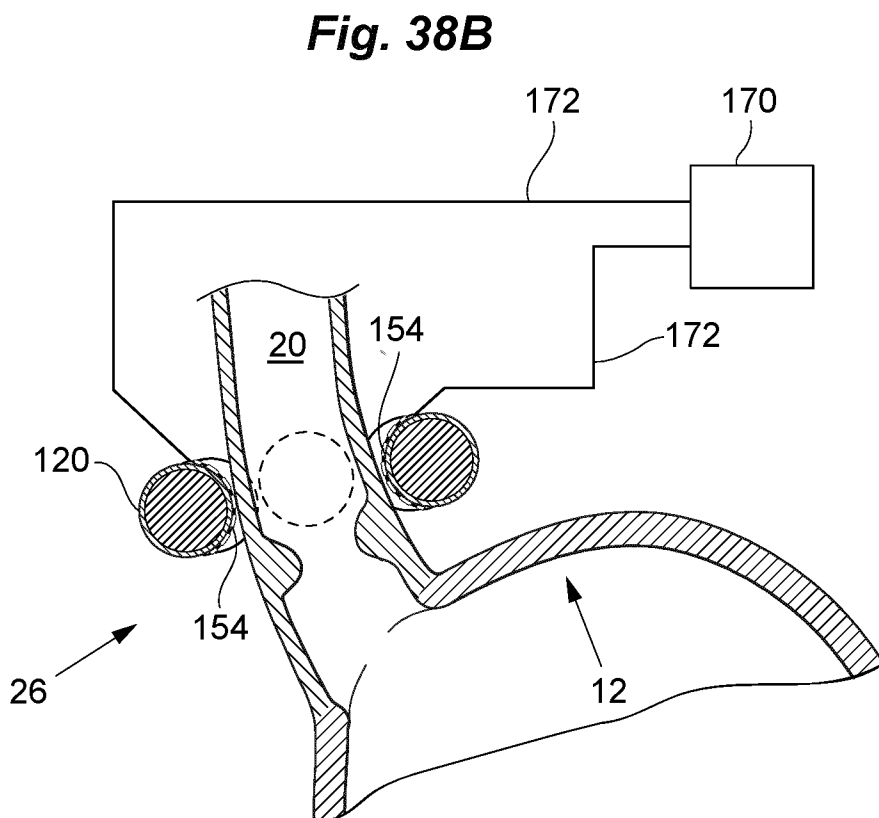
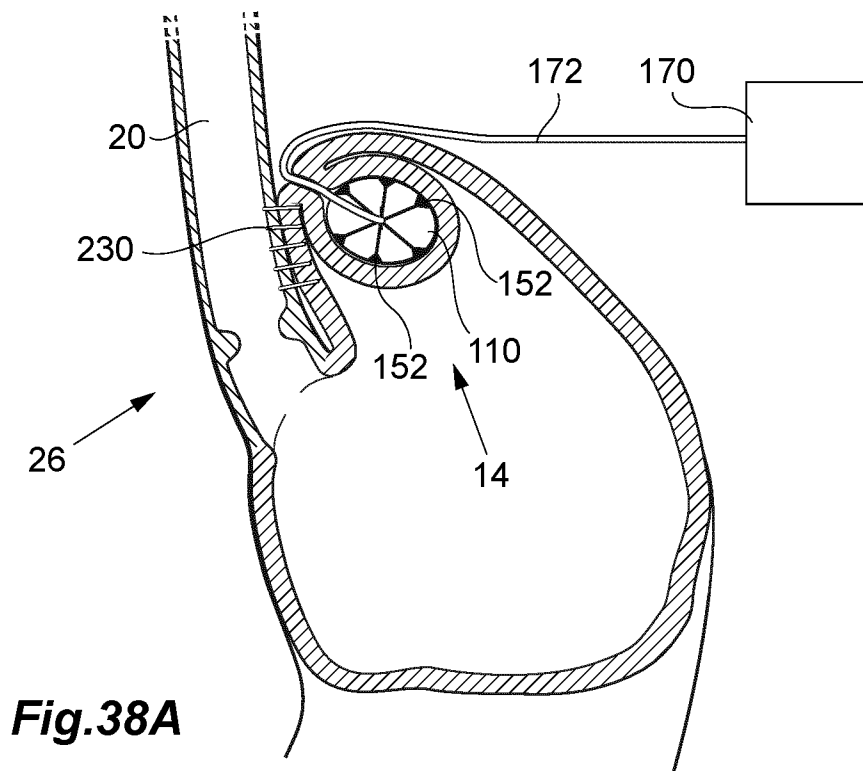
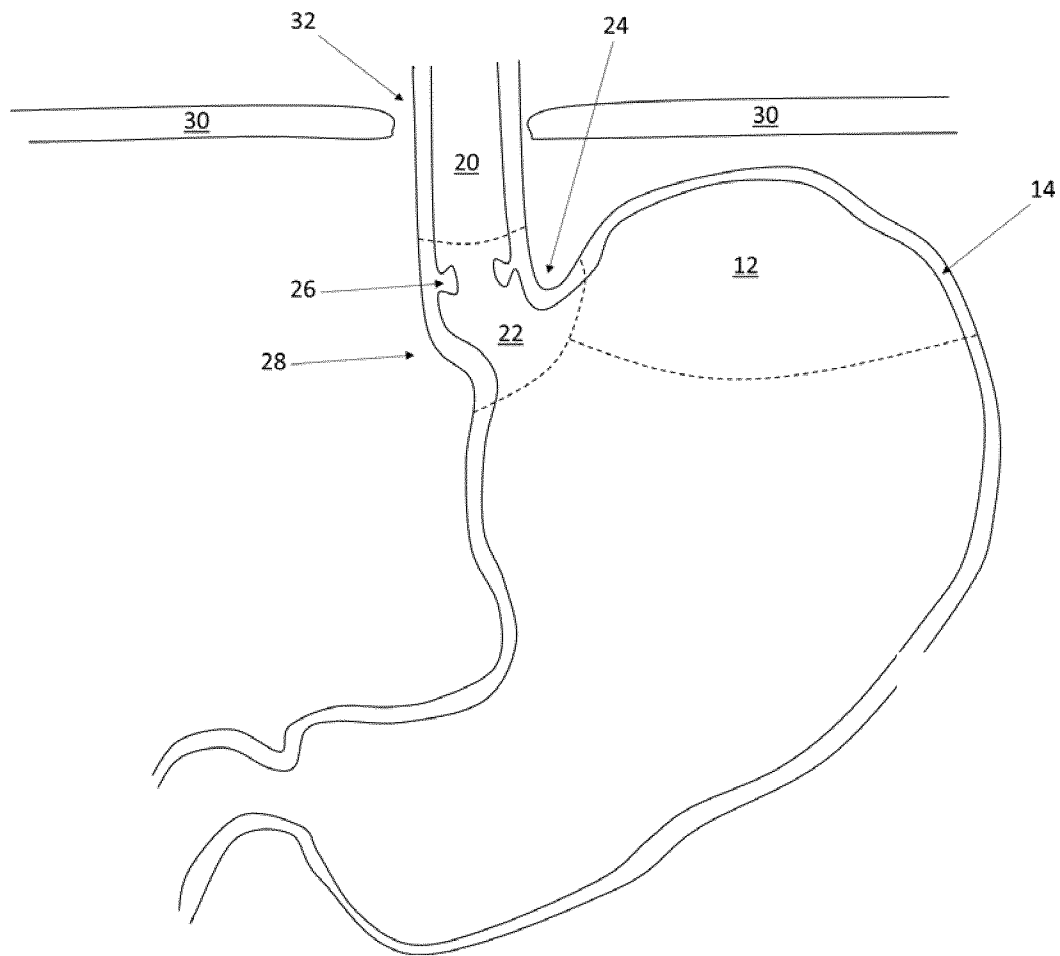


Fig. 39

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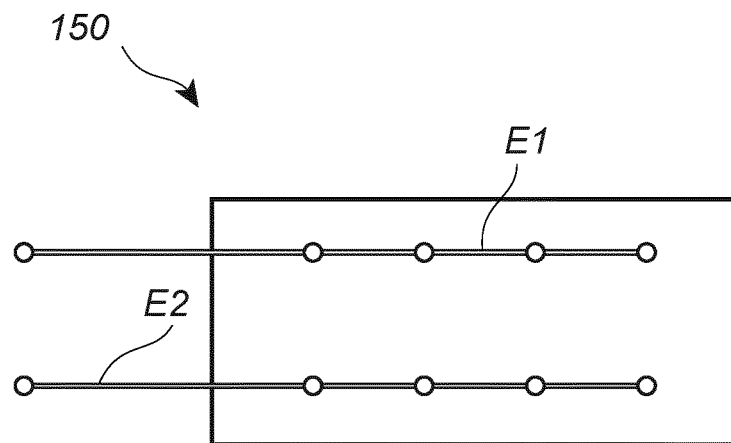
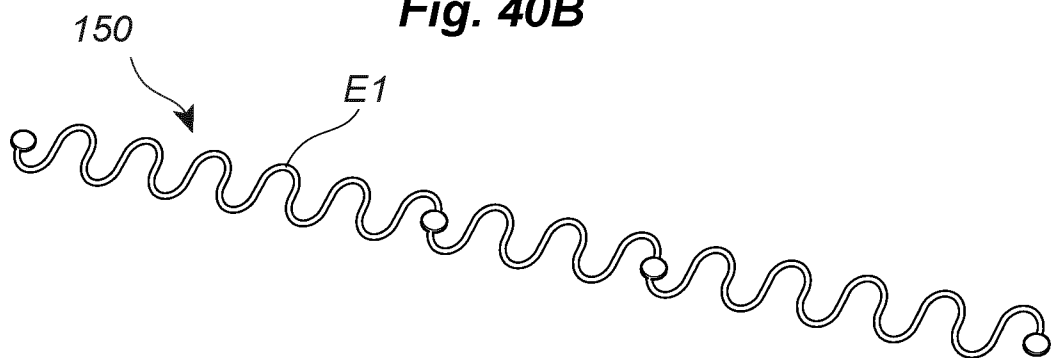
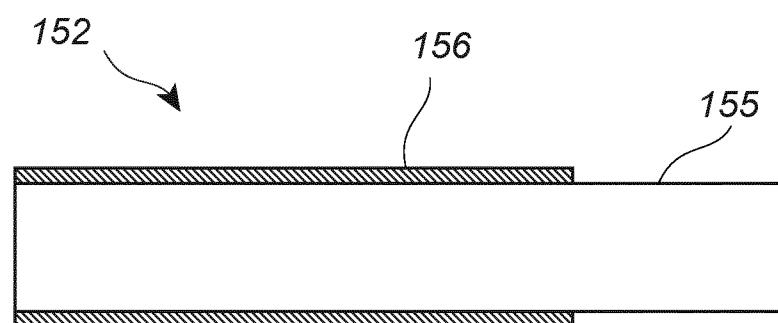
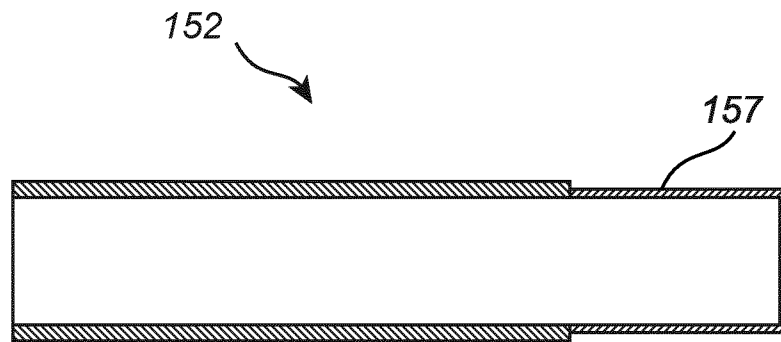
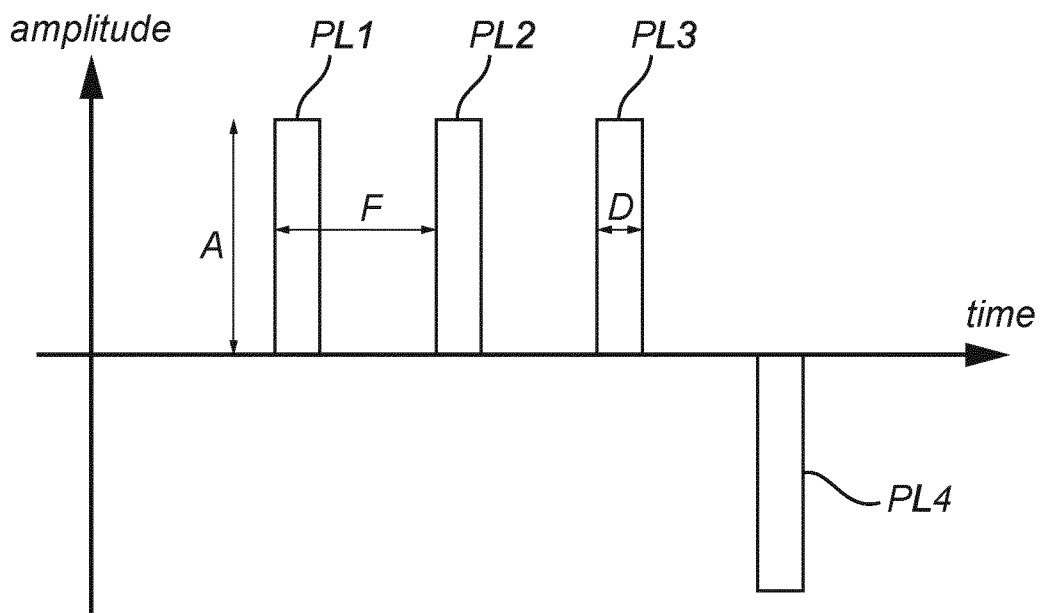
Fig. 40A**Fig. 40B****Fig. 40C**

Fig. 40D**Fig.41**

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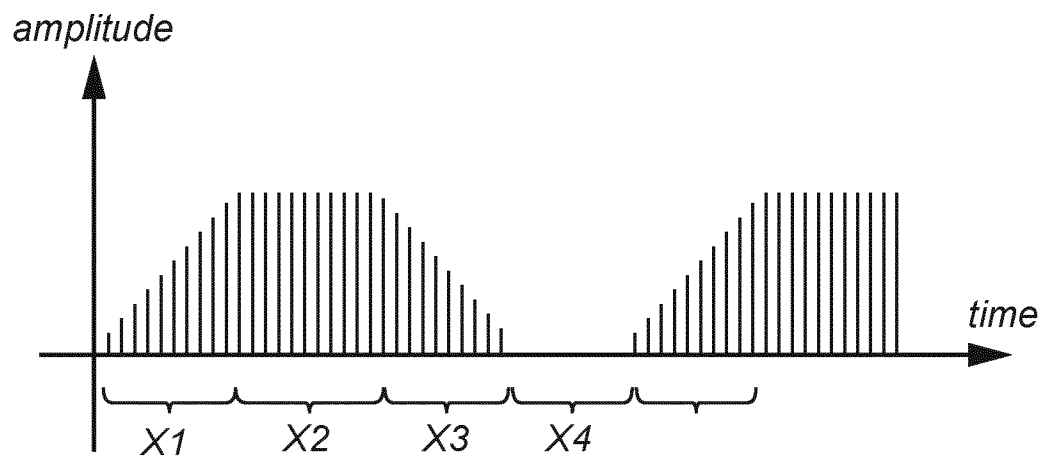
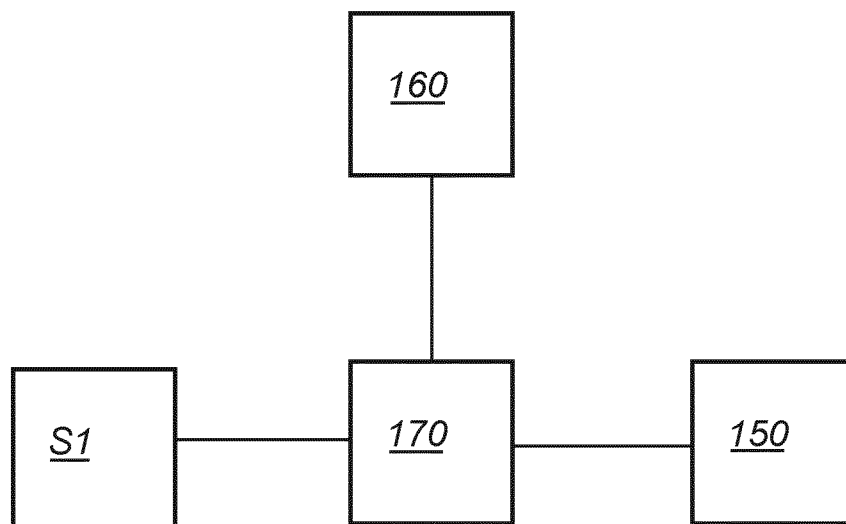
Fig.42**Fig.43**

Fig.44

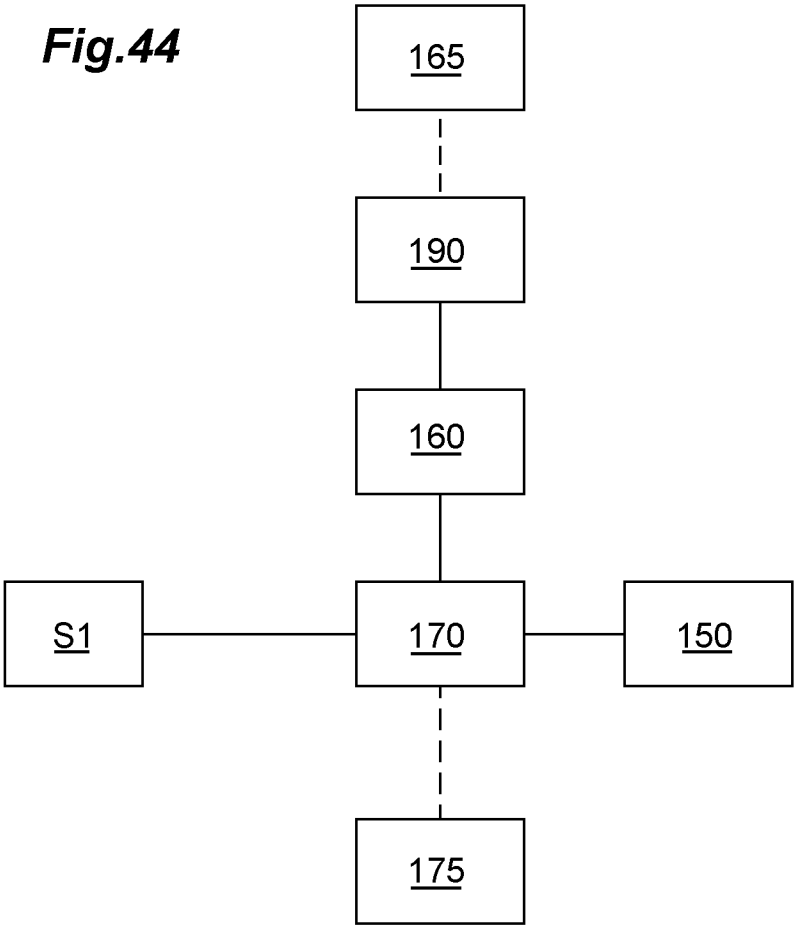
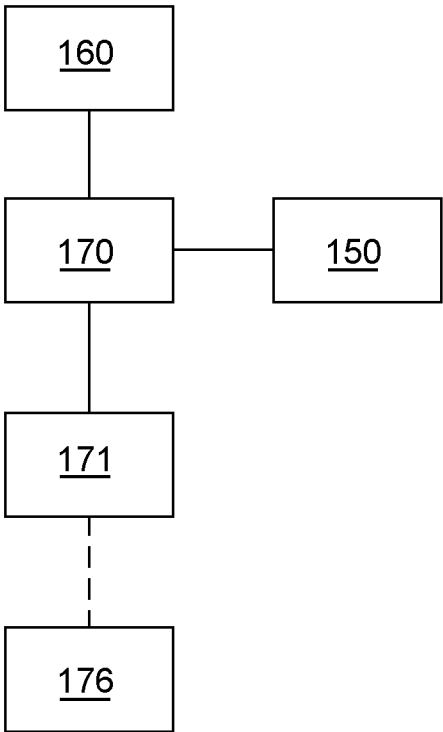


Fig. 45



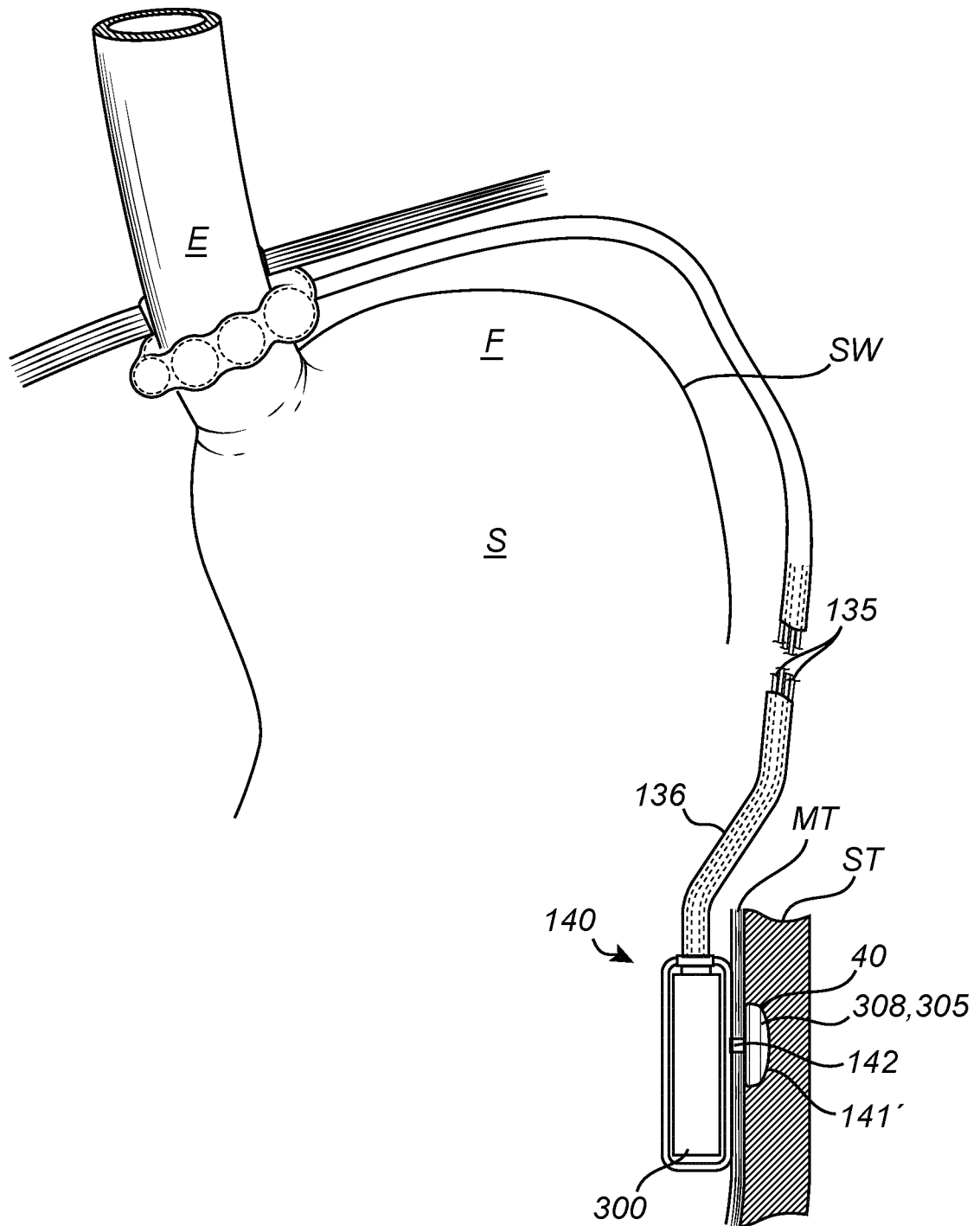
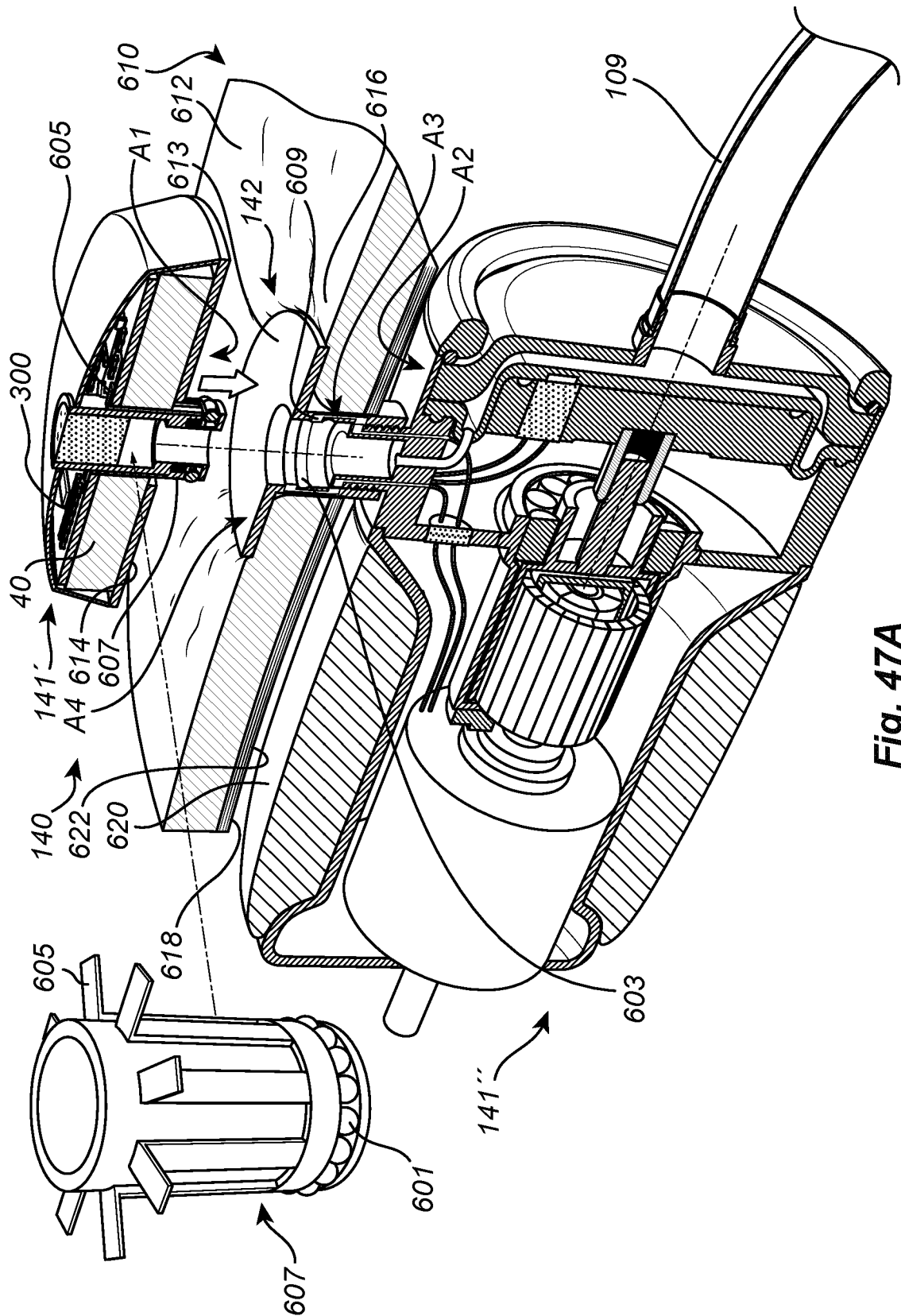


Fig. 46



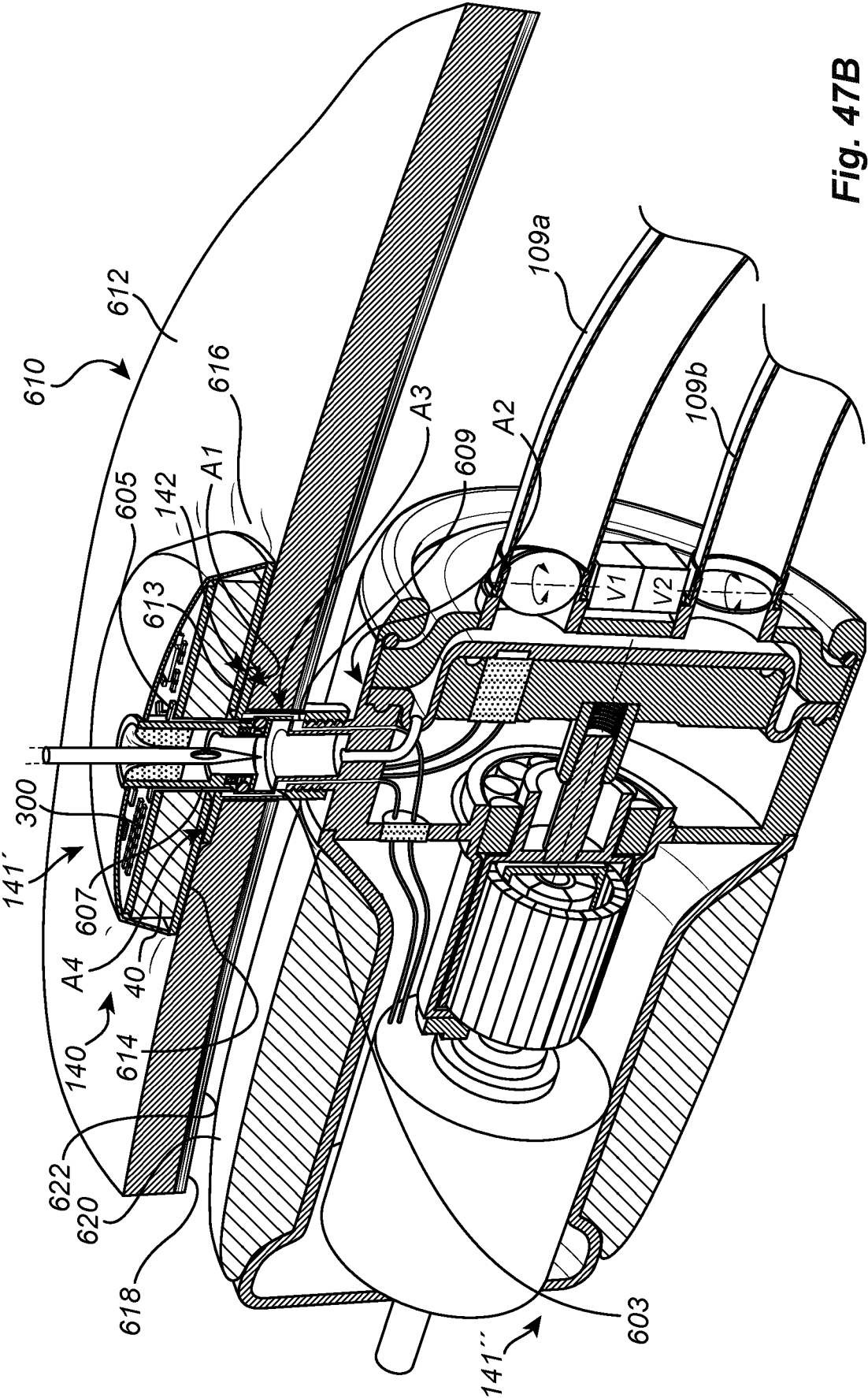
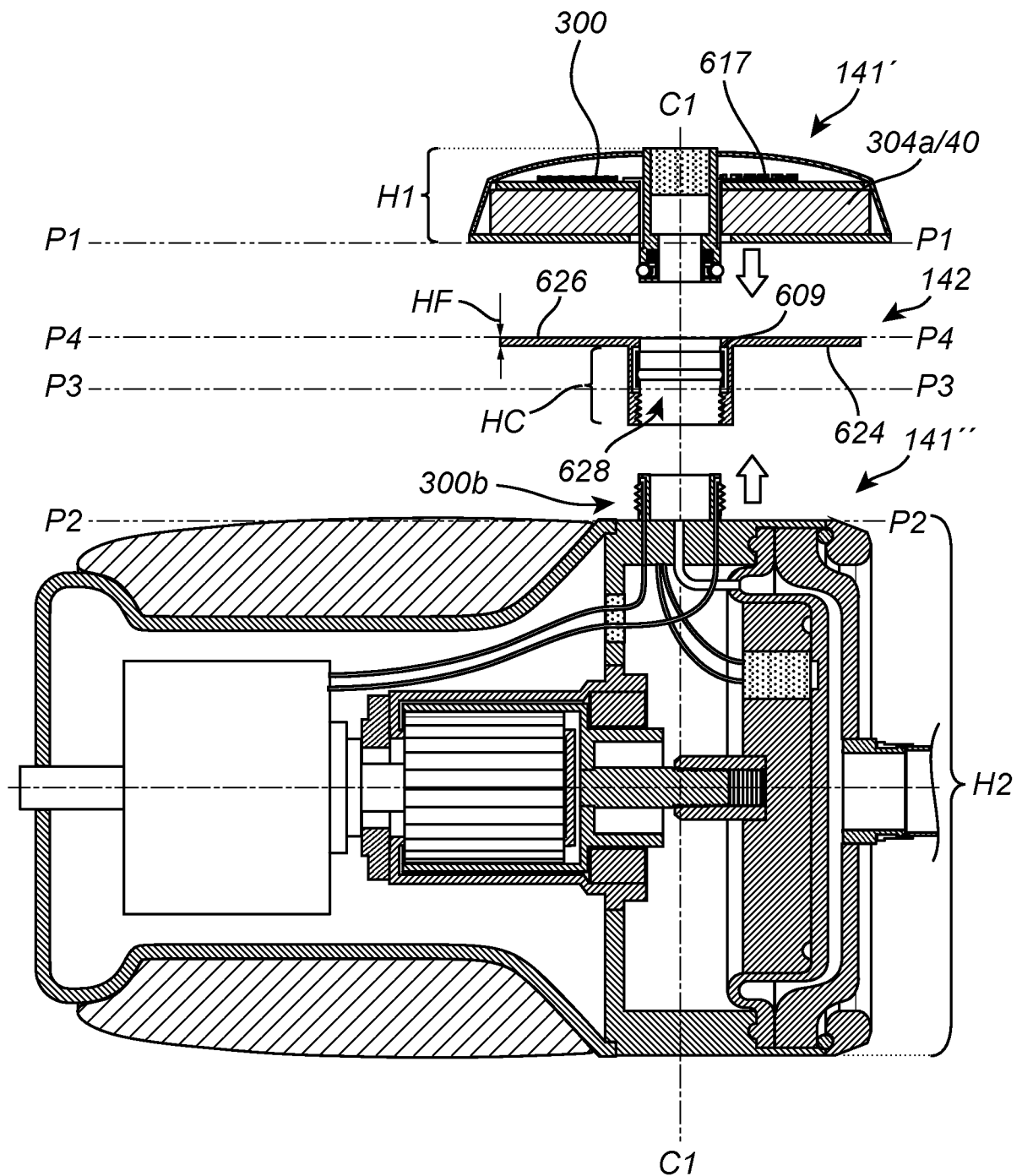


Fig. 47B

**Fig. 48**

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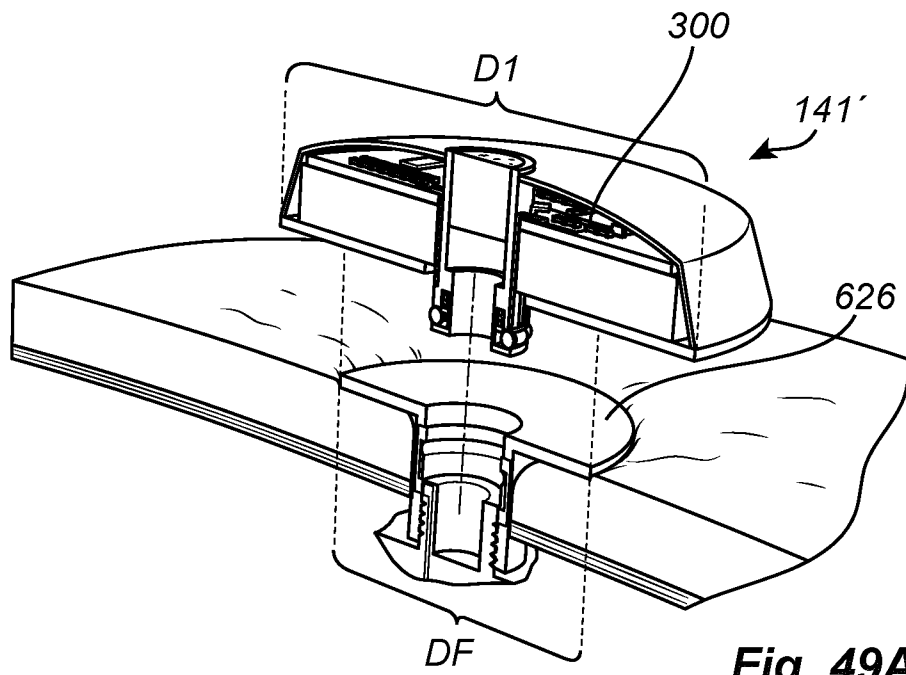


Fig. 49A

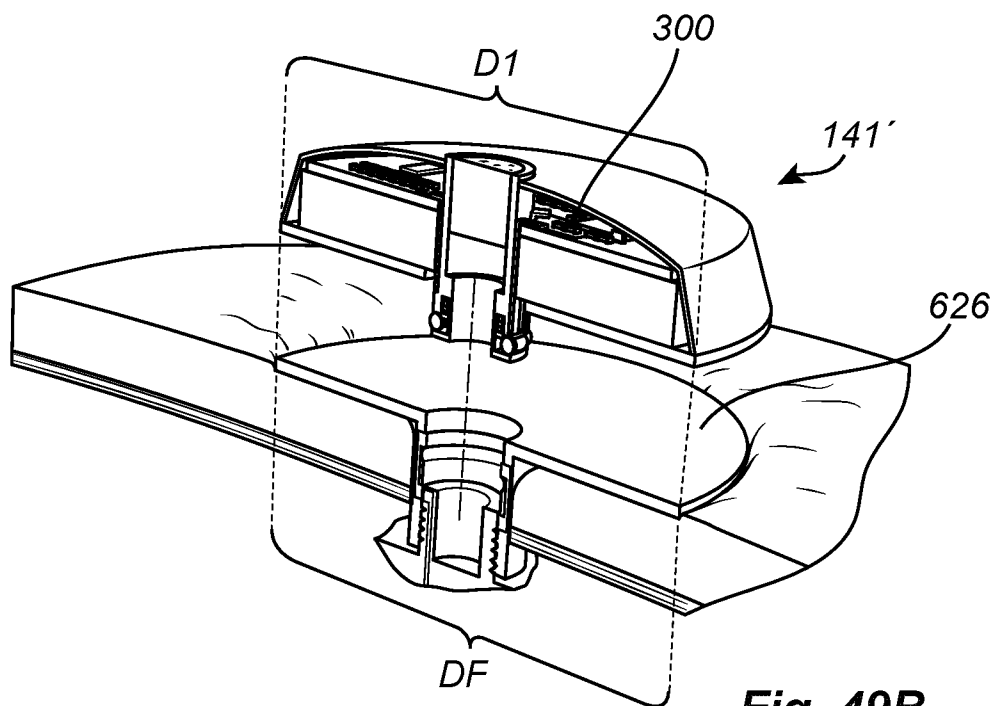


Fig. 49B

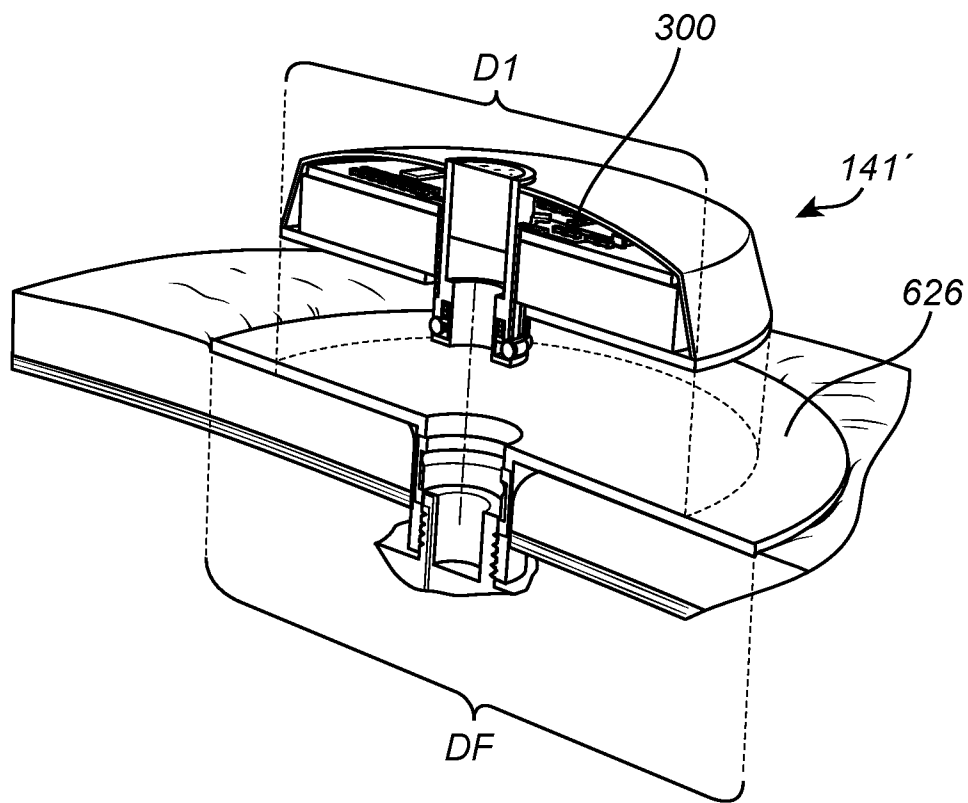


Fig. 49C

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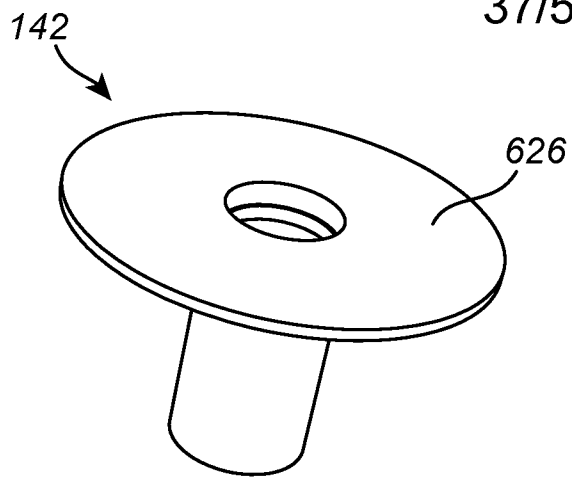


Fig. 50A

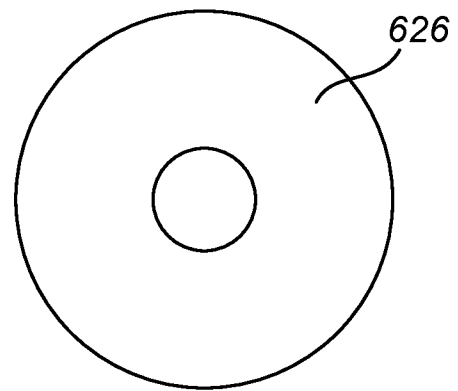


Fig. 50B

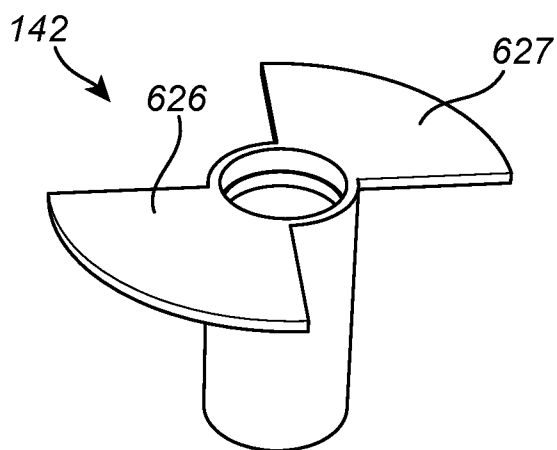


Fig. 51A

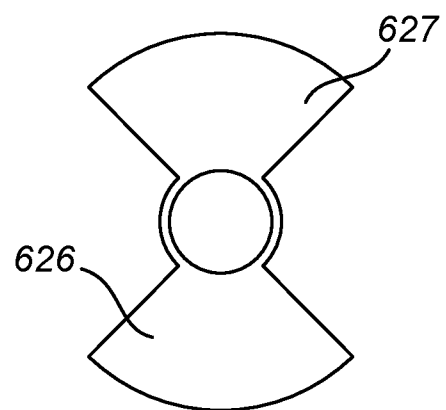


Fig. 51B

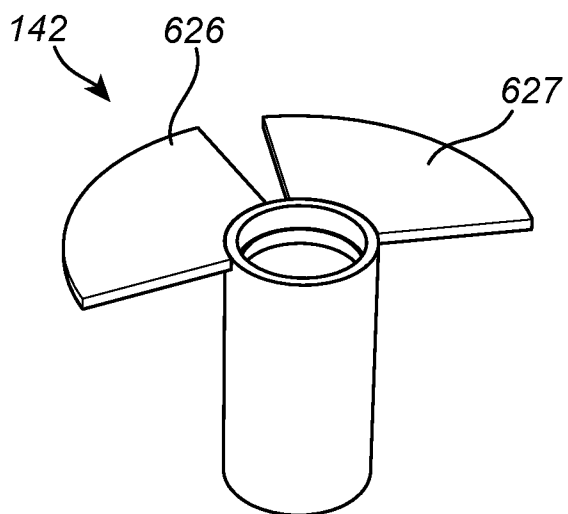


Fig. 52A

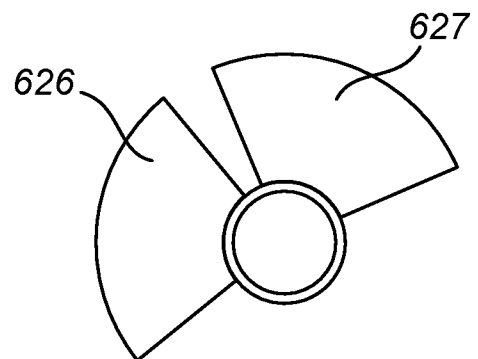


Fig. 52B

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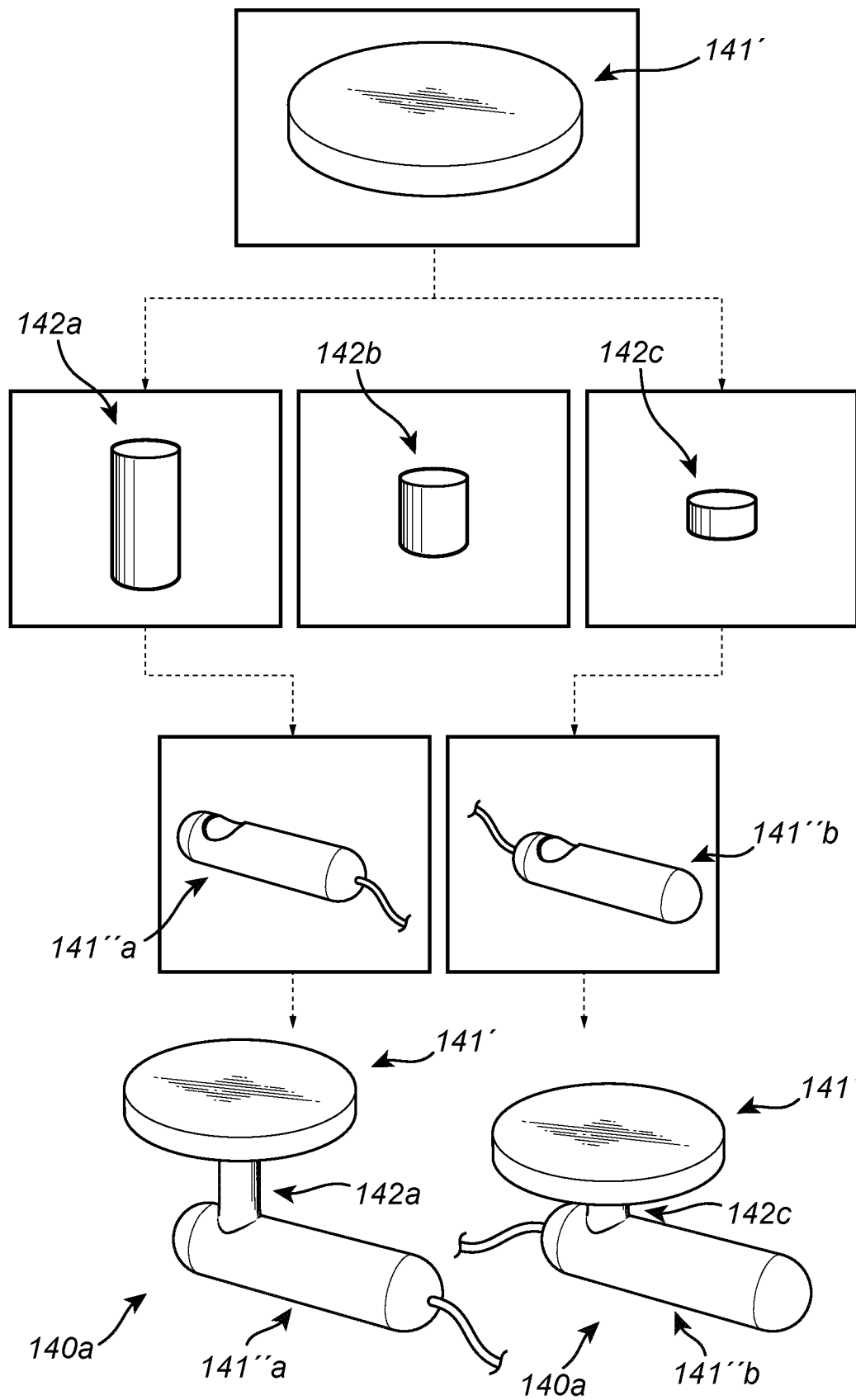
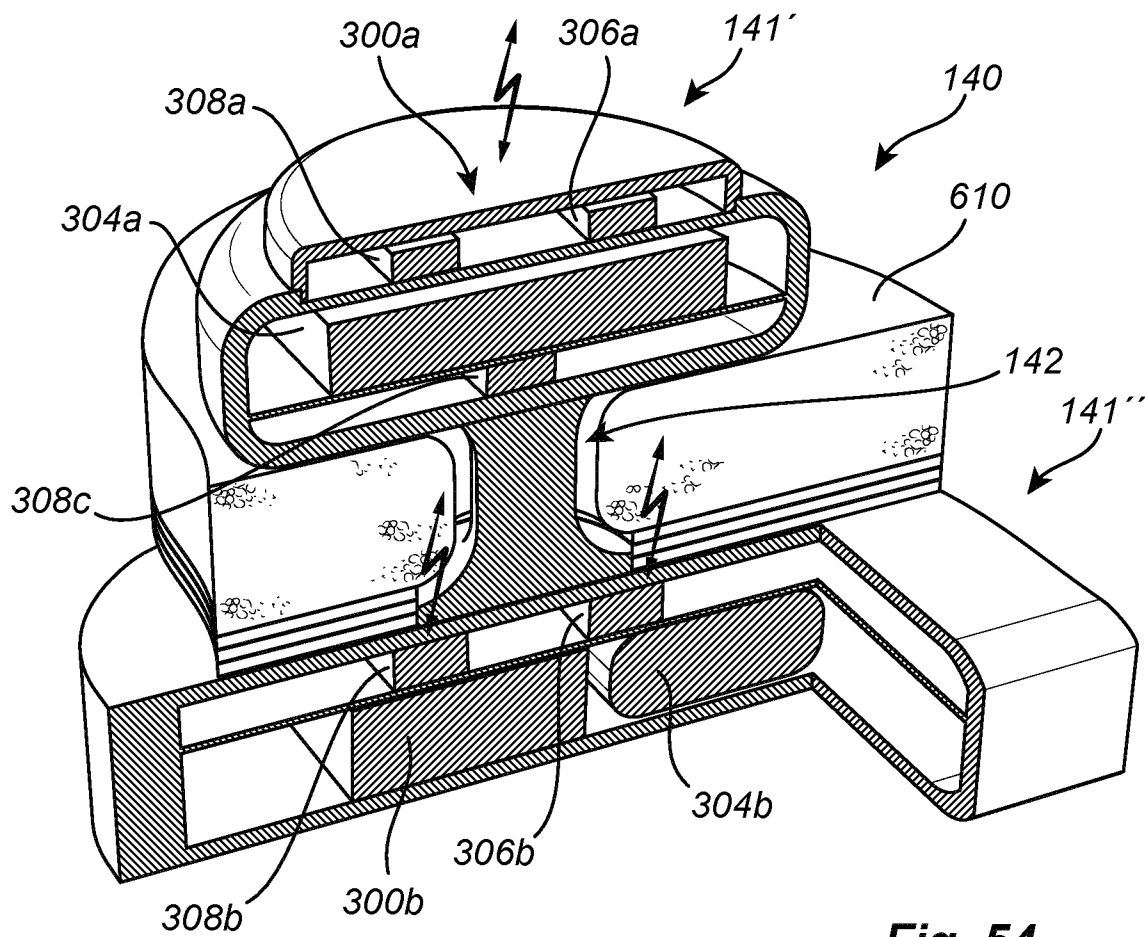


Fig. 53



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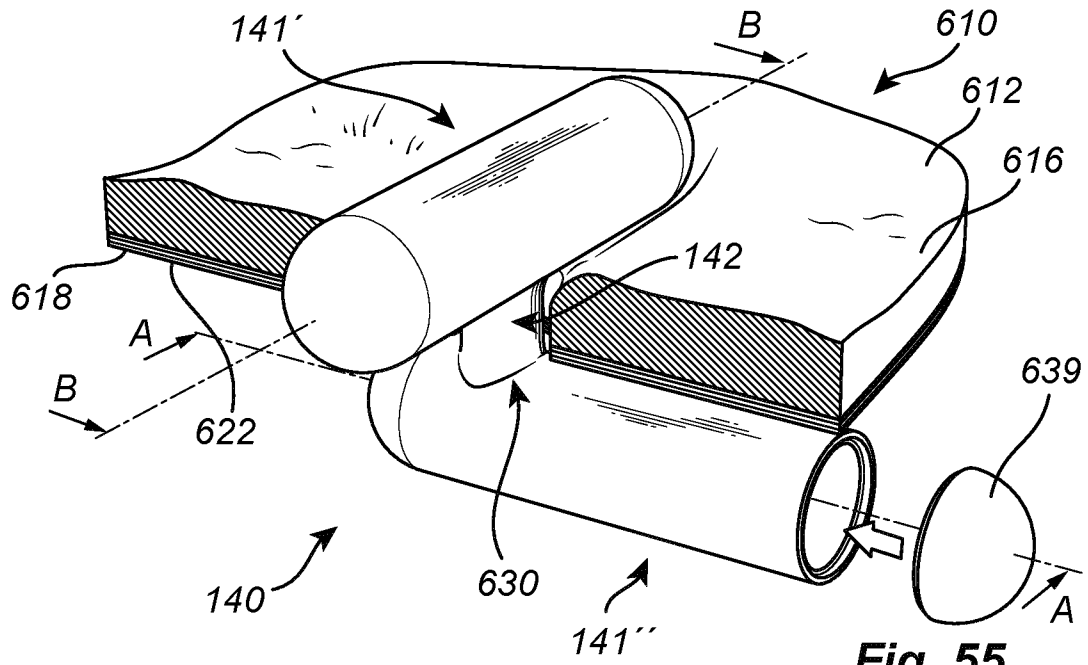


Fig. 55

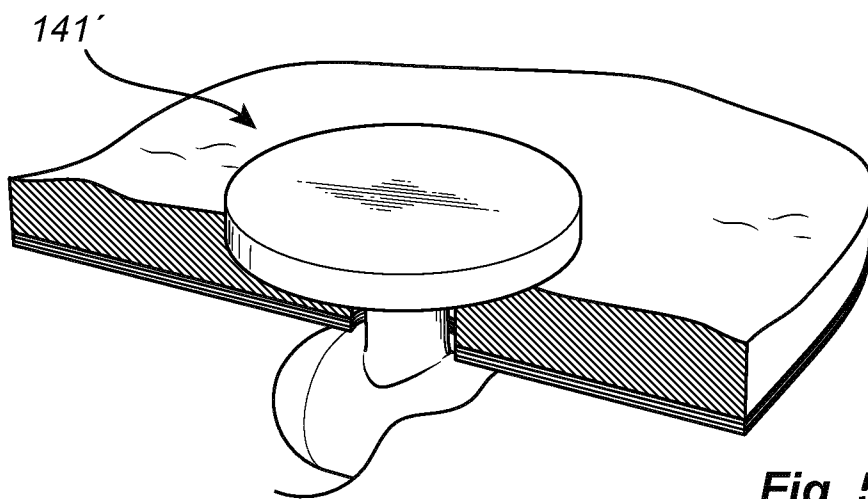


Fig. 56

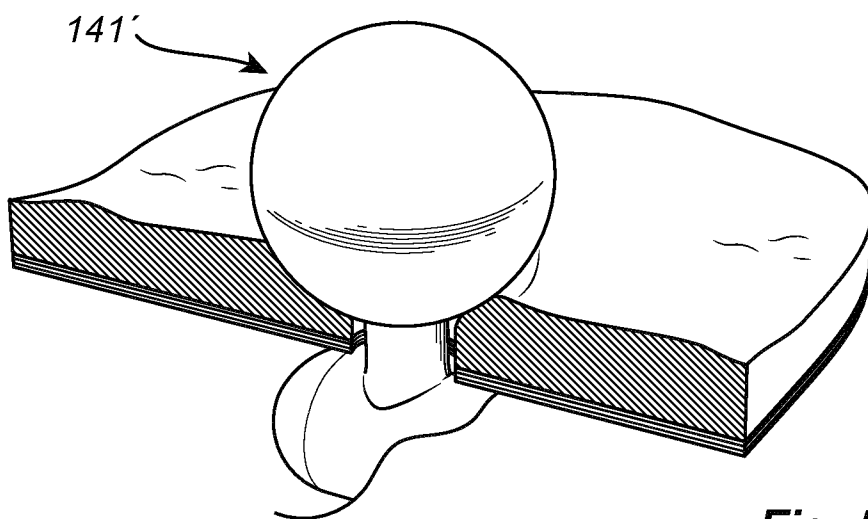
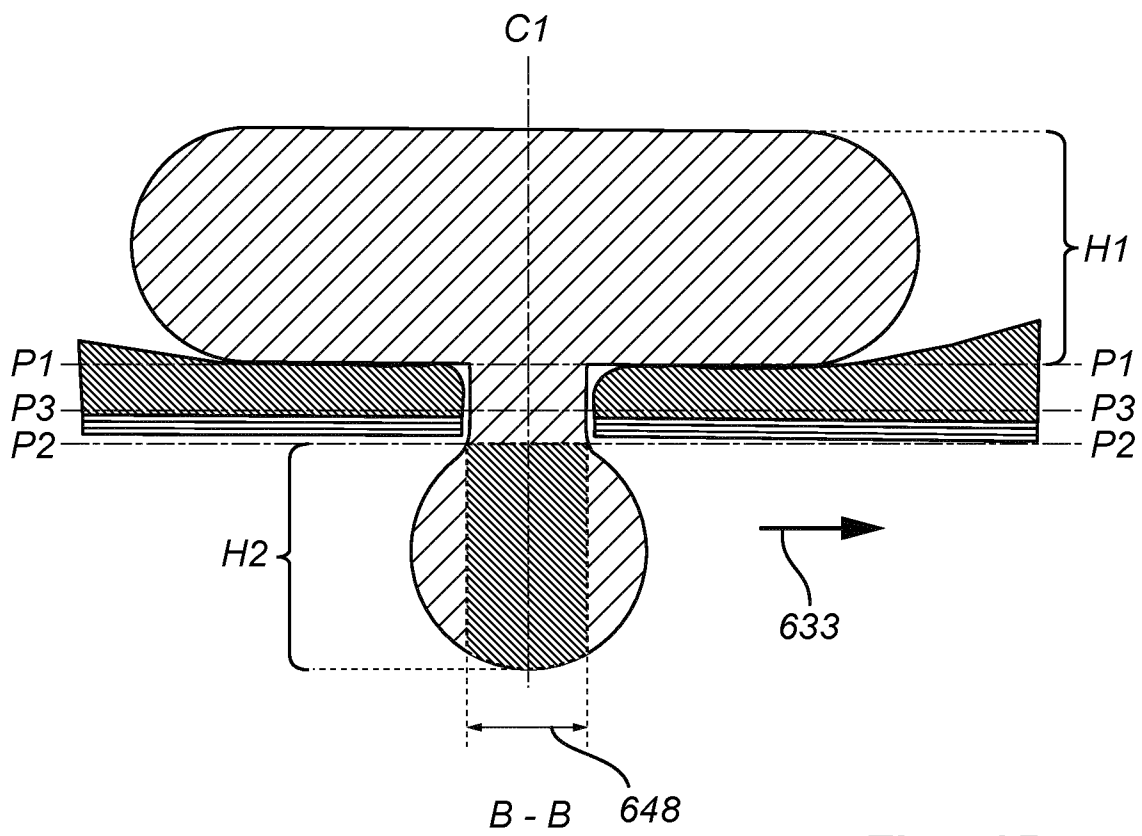
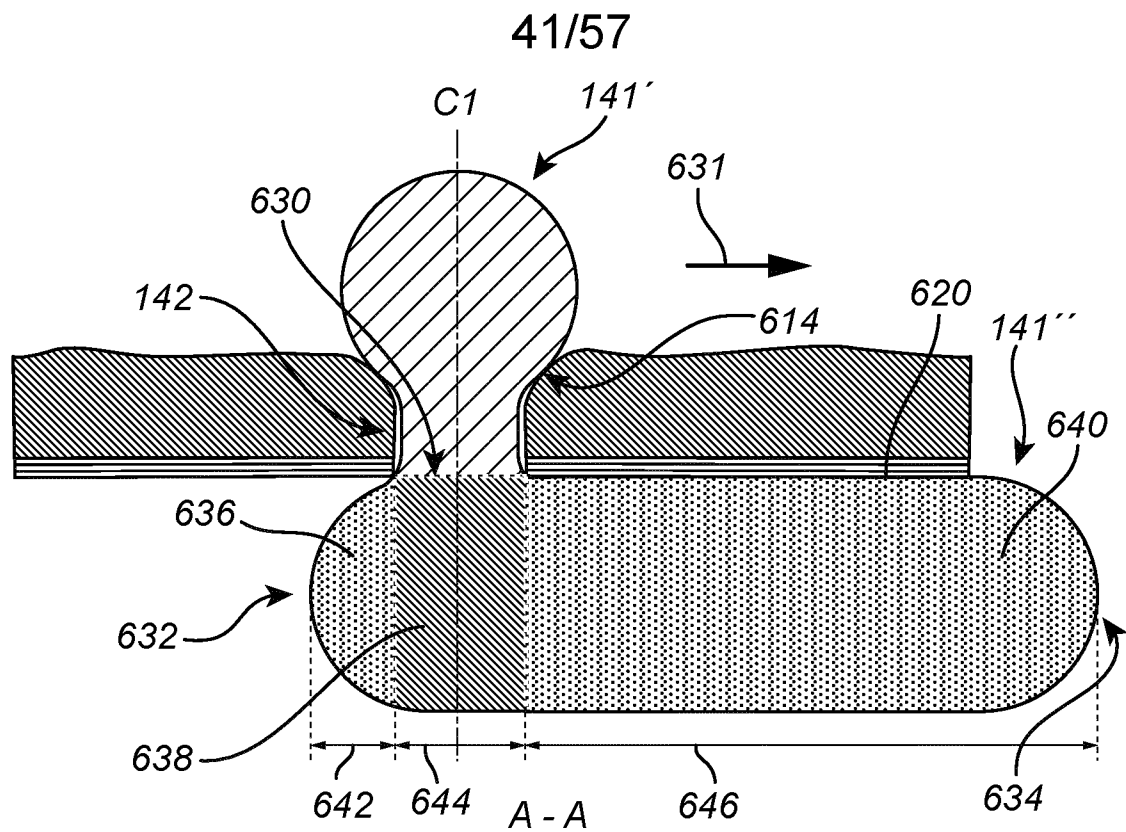


Fig. 57



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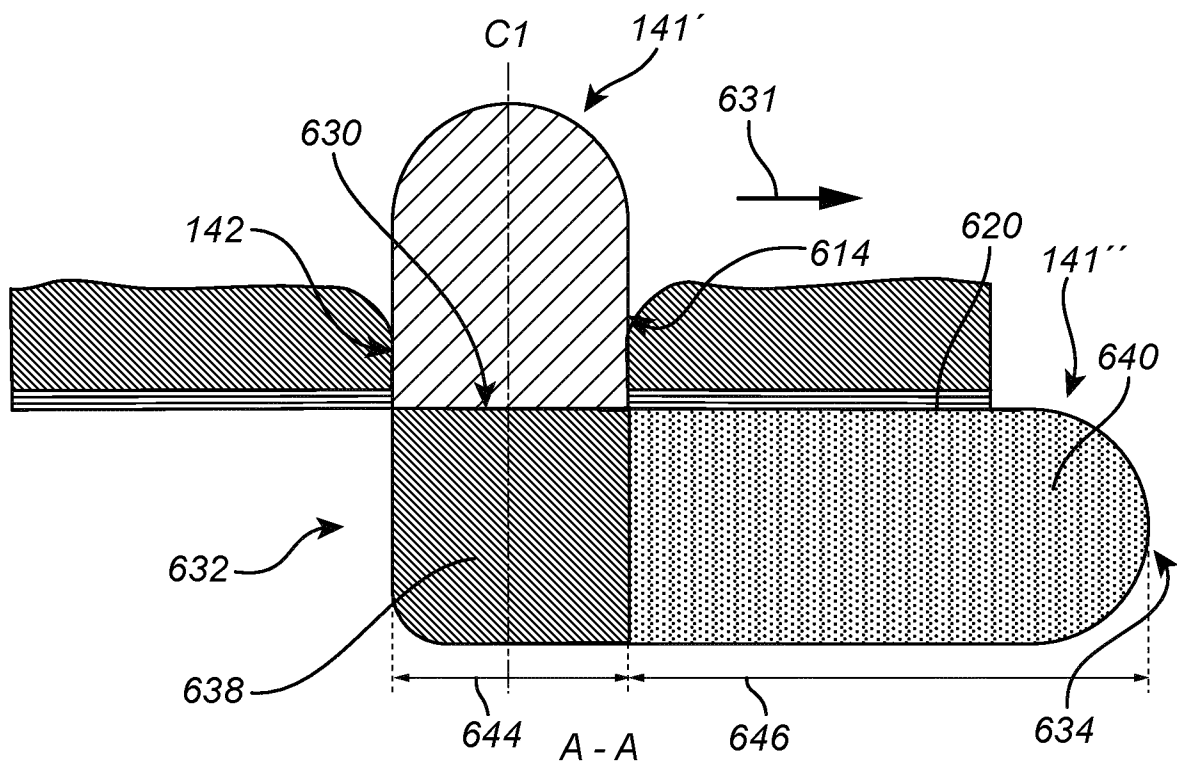


Fig. 58C

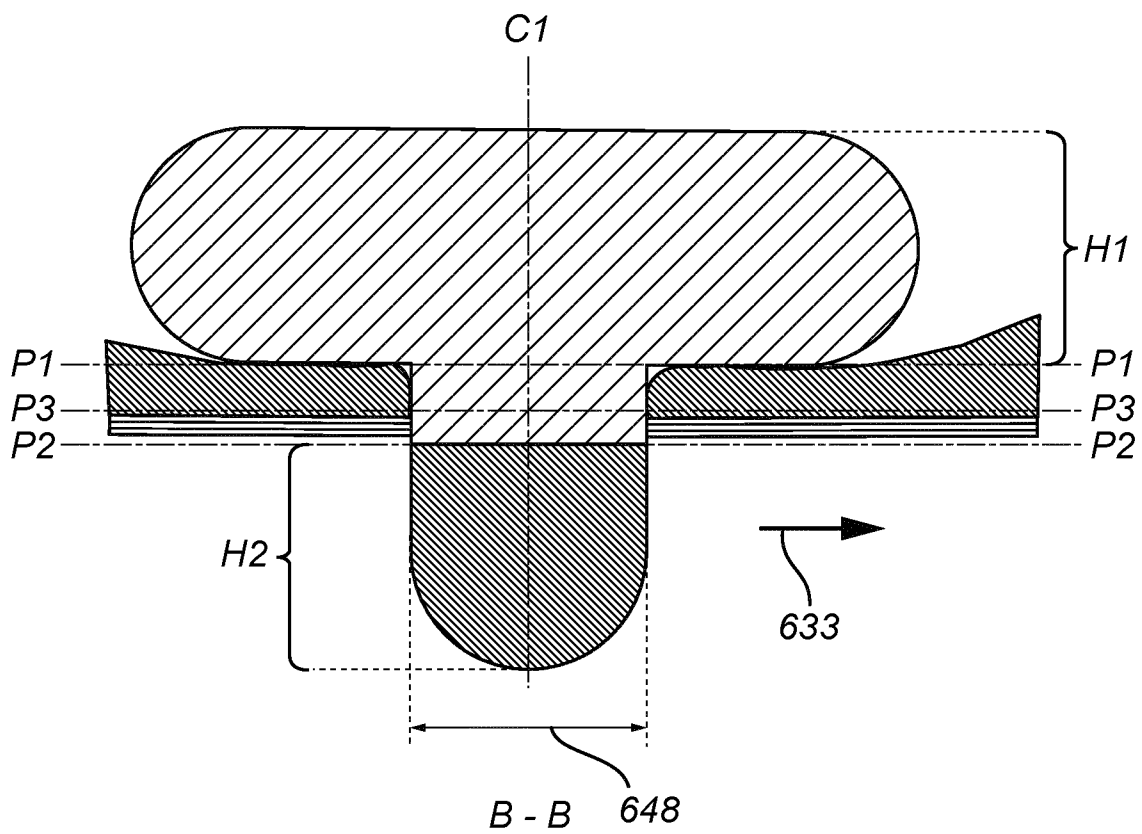


Fig. 58D

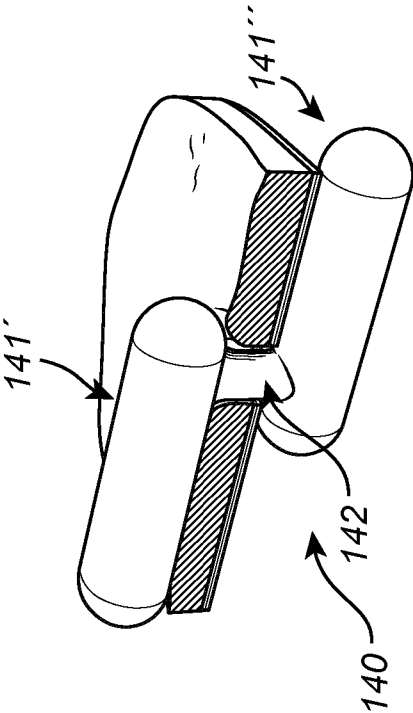


Fig. 59A

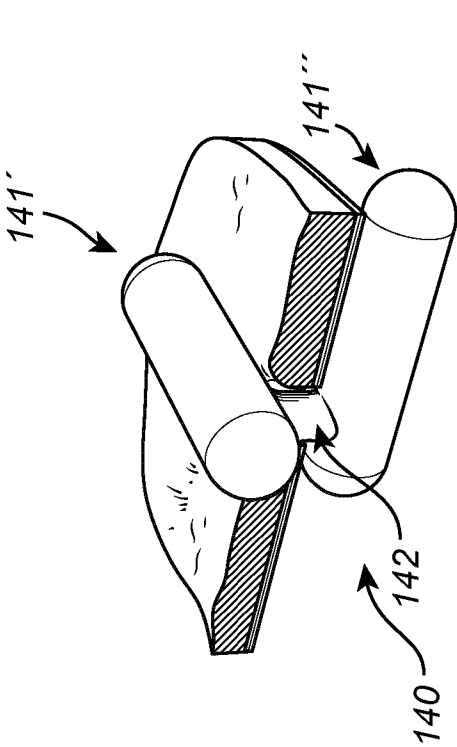


Fig. 59B

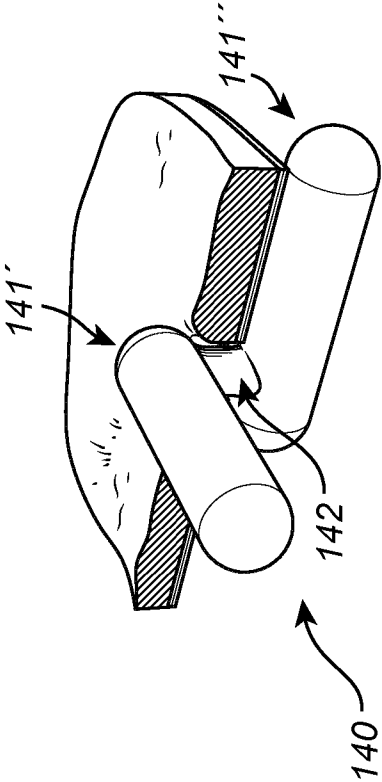


Fig. 59C

Fig. 59D

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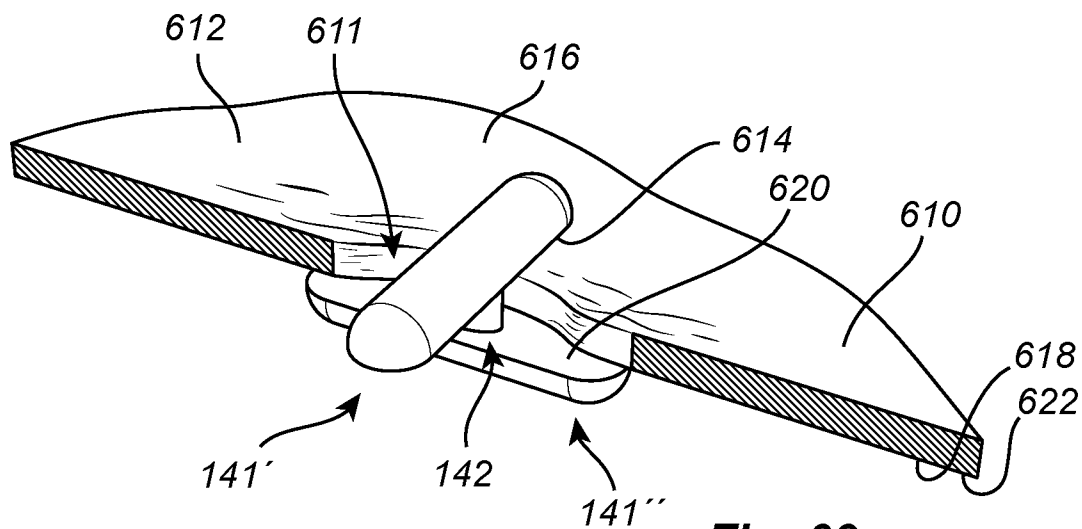


Fig. 60

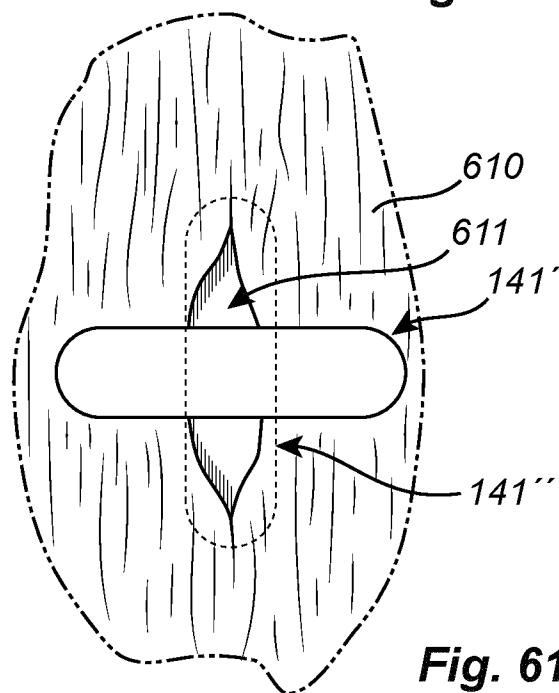


Fig. 61

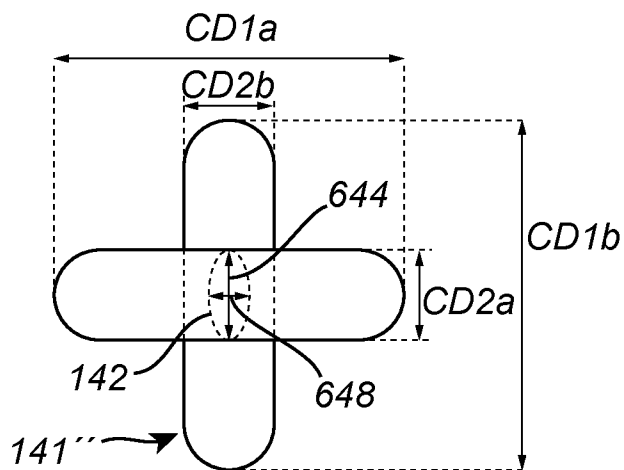


Fig. 62A

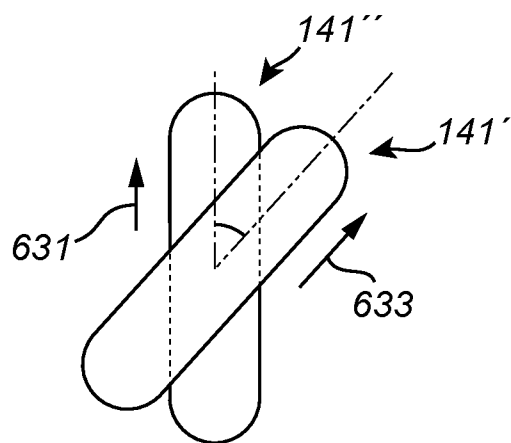


Fig. 62B

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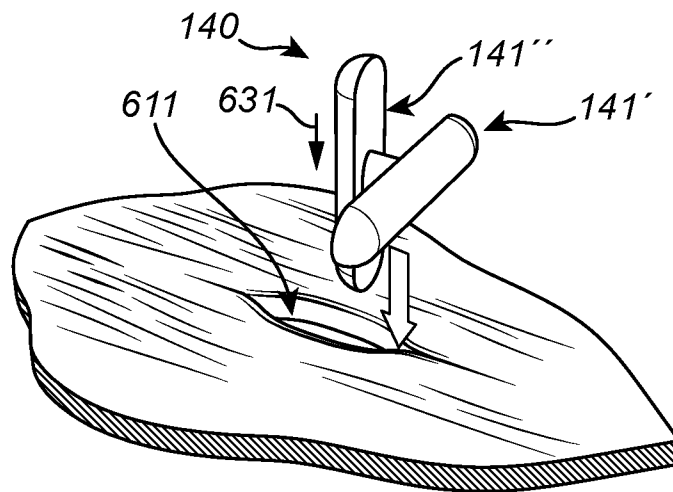


Fig. 63A

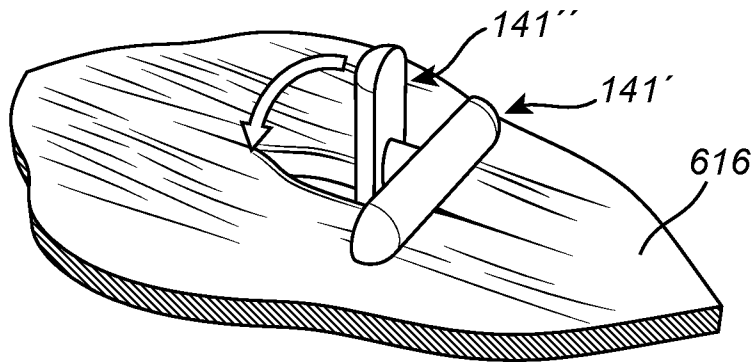


Fig. 63B

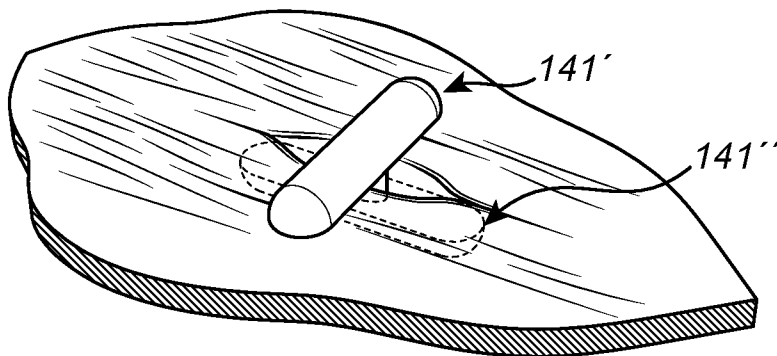


Fig. 63C

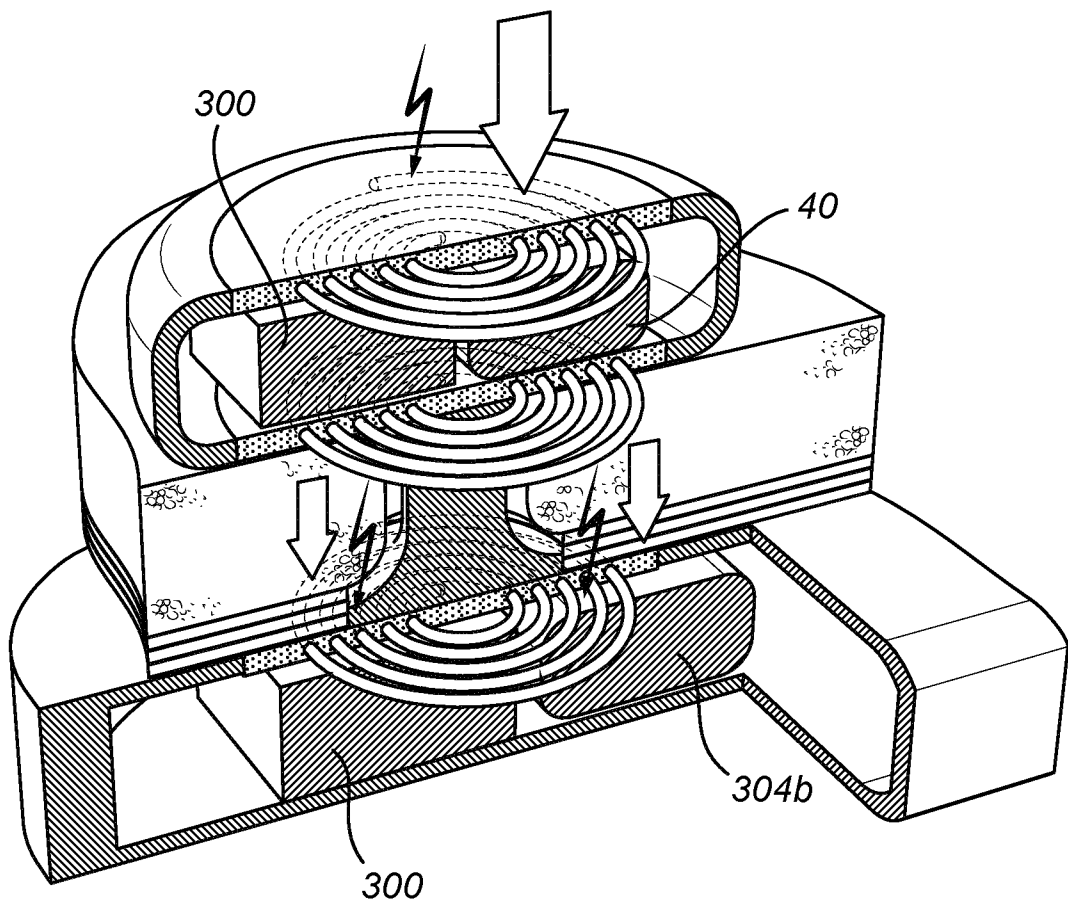


Fig. 64

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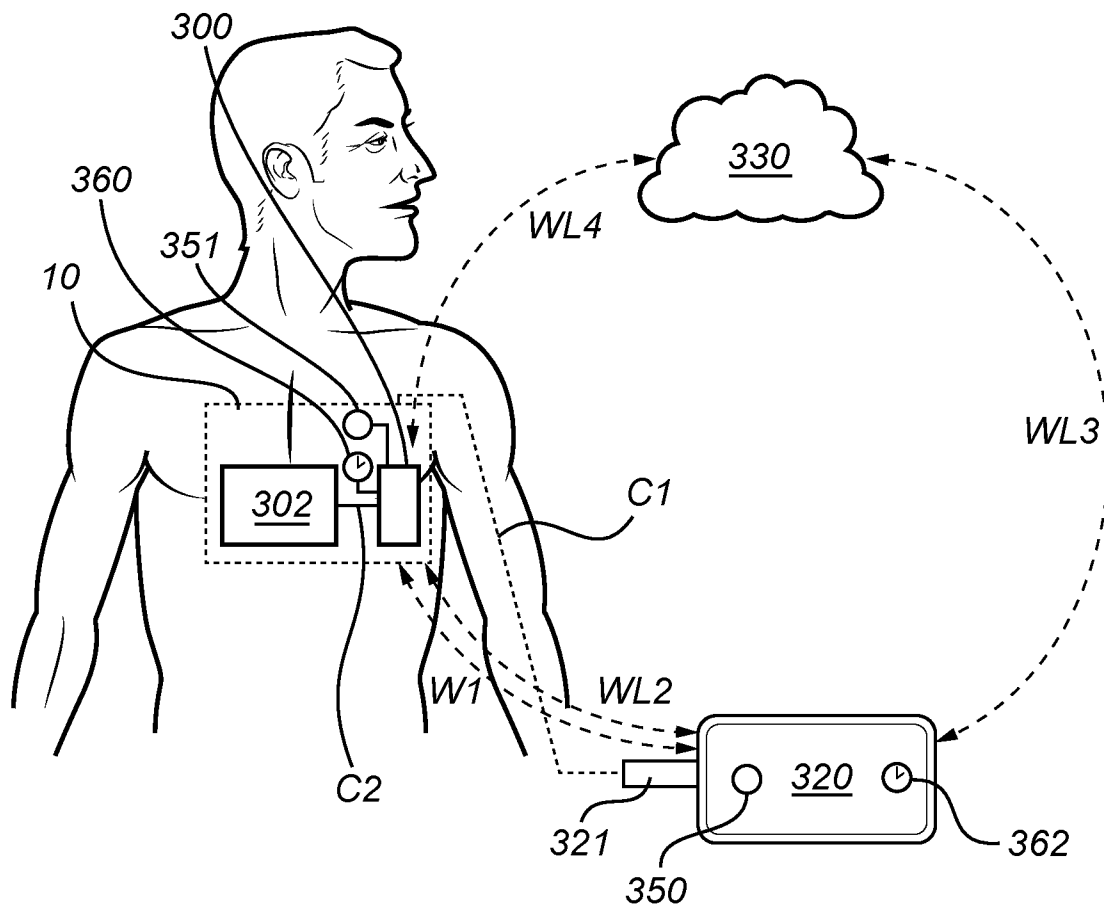


Fig. 65A

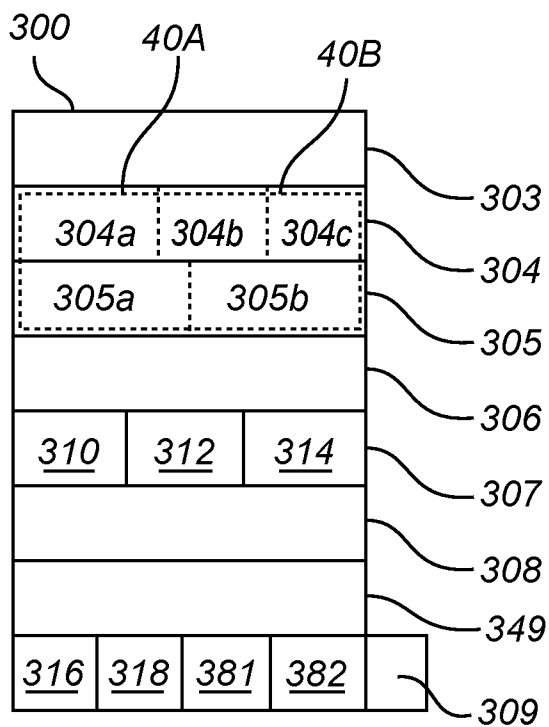


Fig. 65B

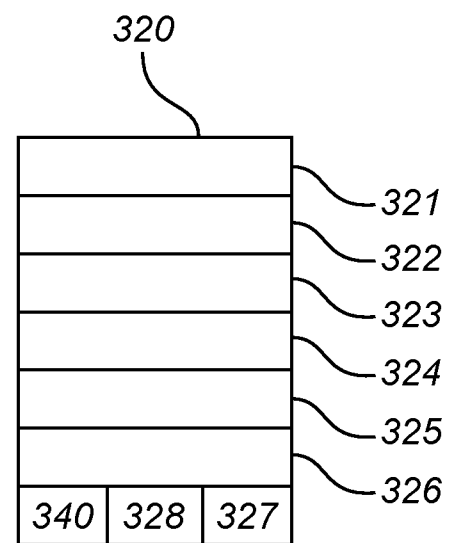


Fig. 65C

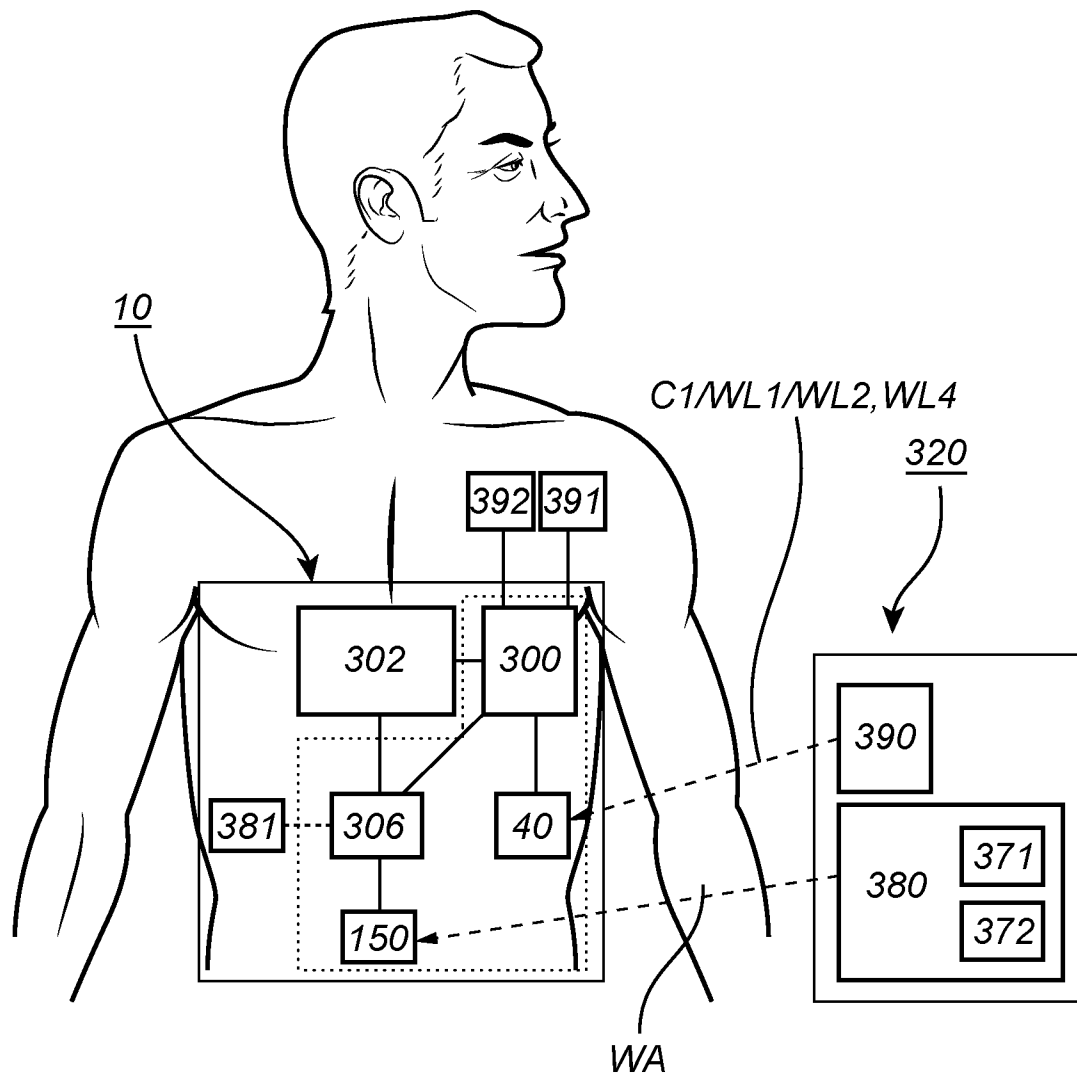
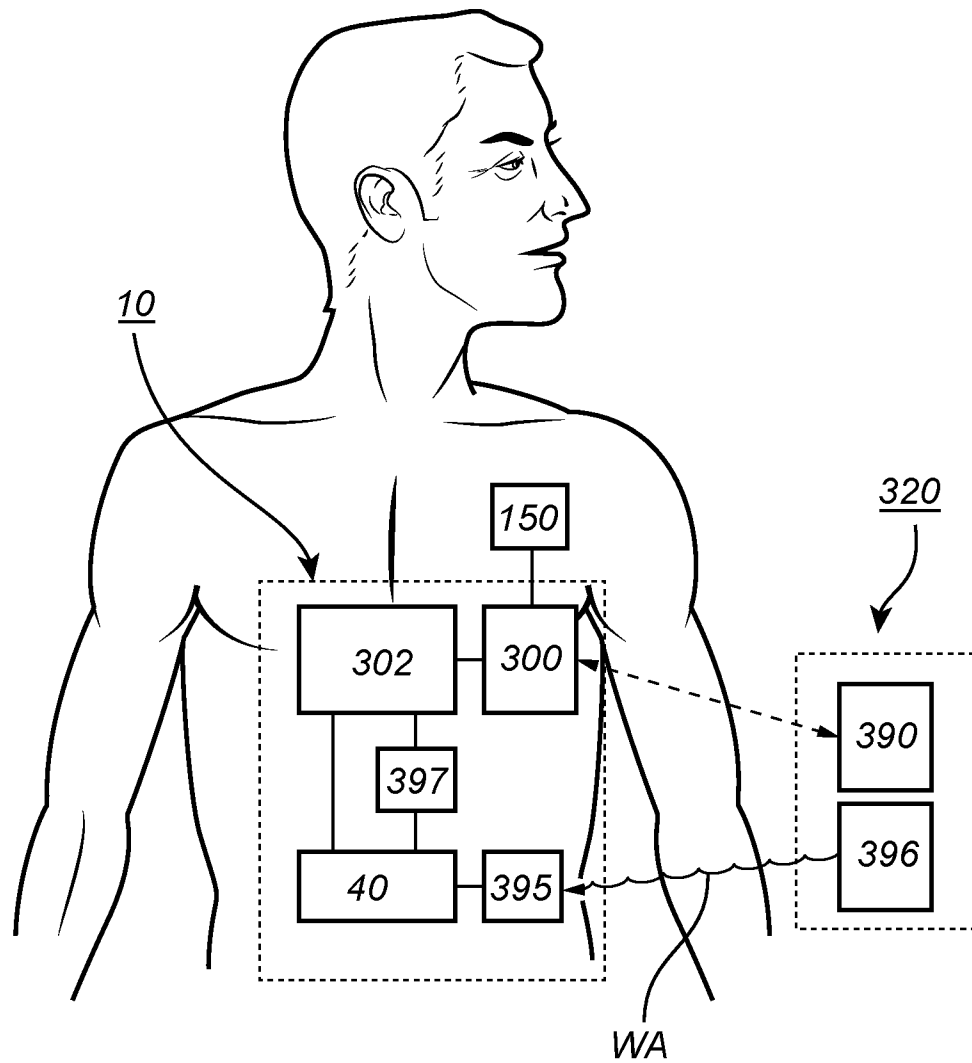


Fig. 65D

**Fig. 65E**

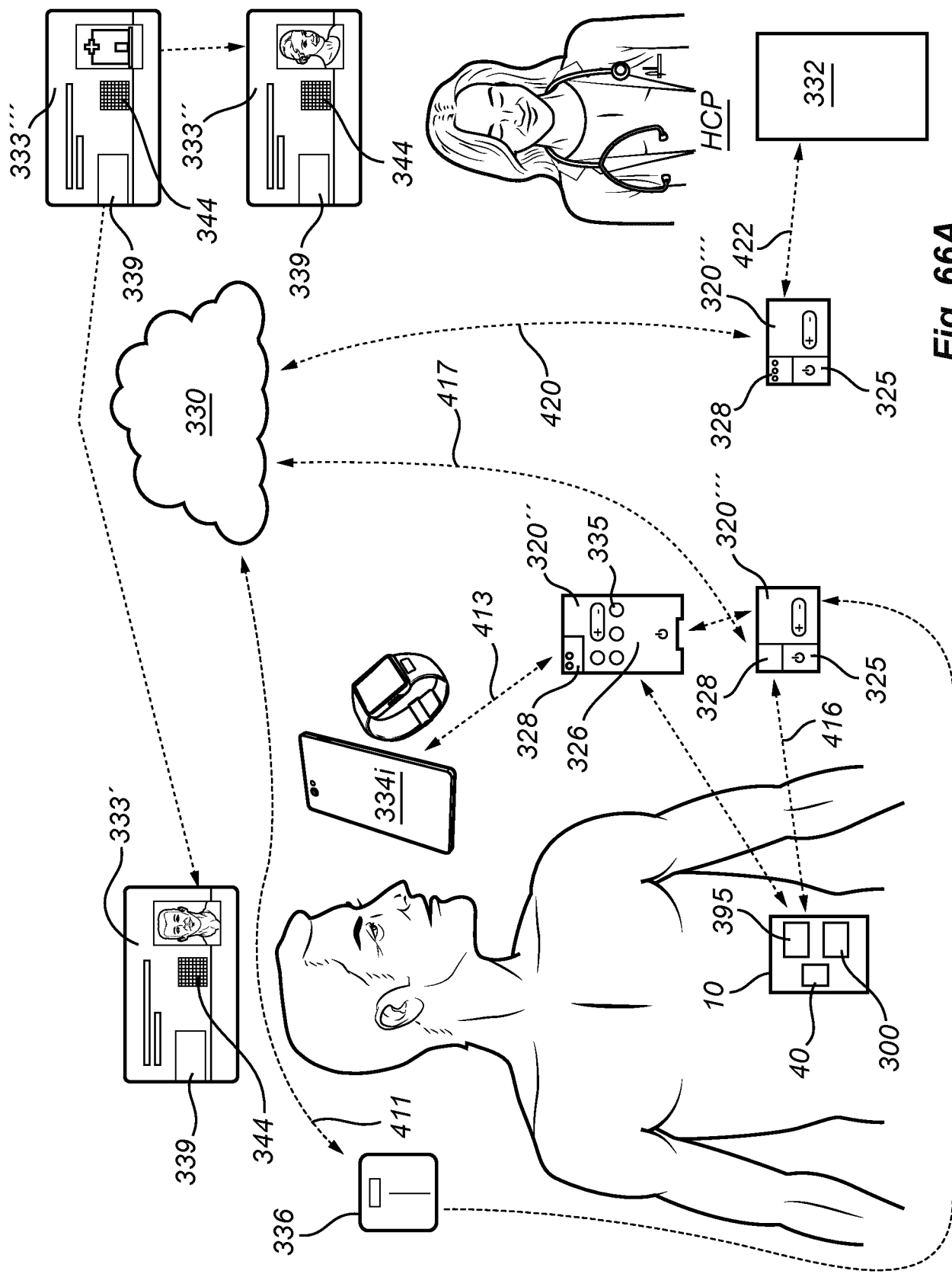


Fig. 66A

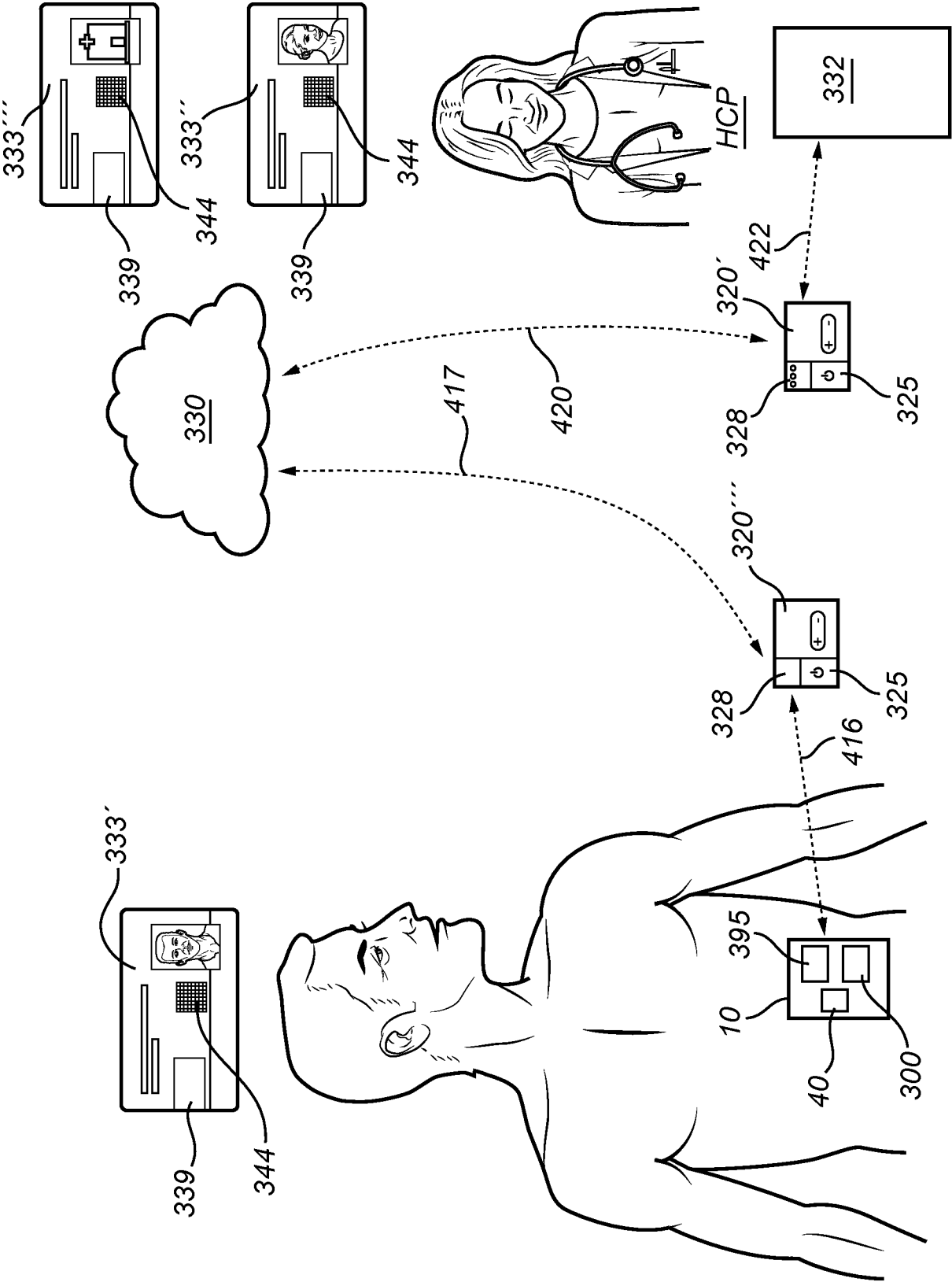


Fig. 66B

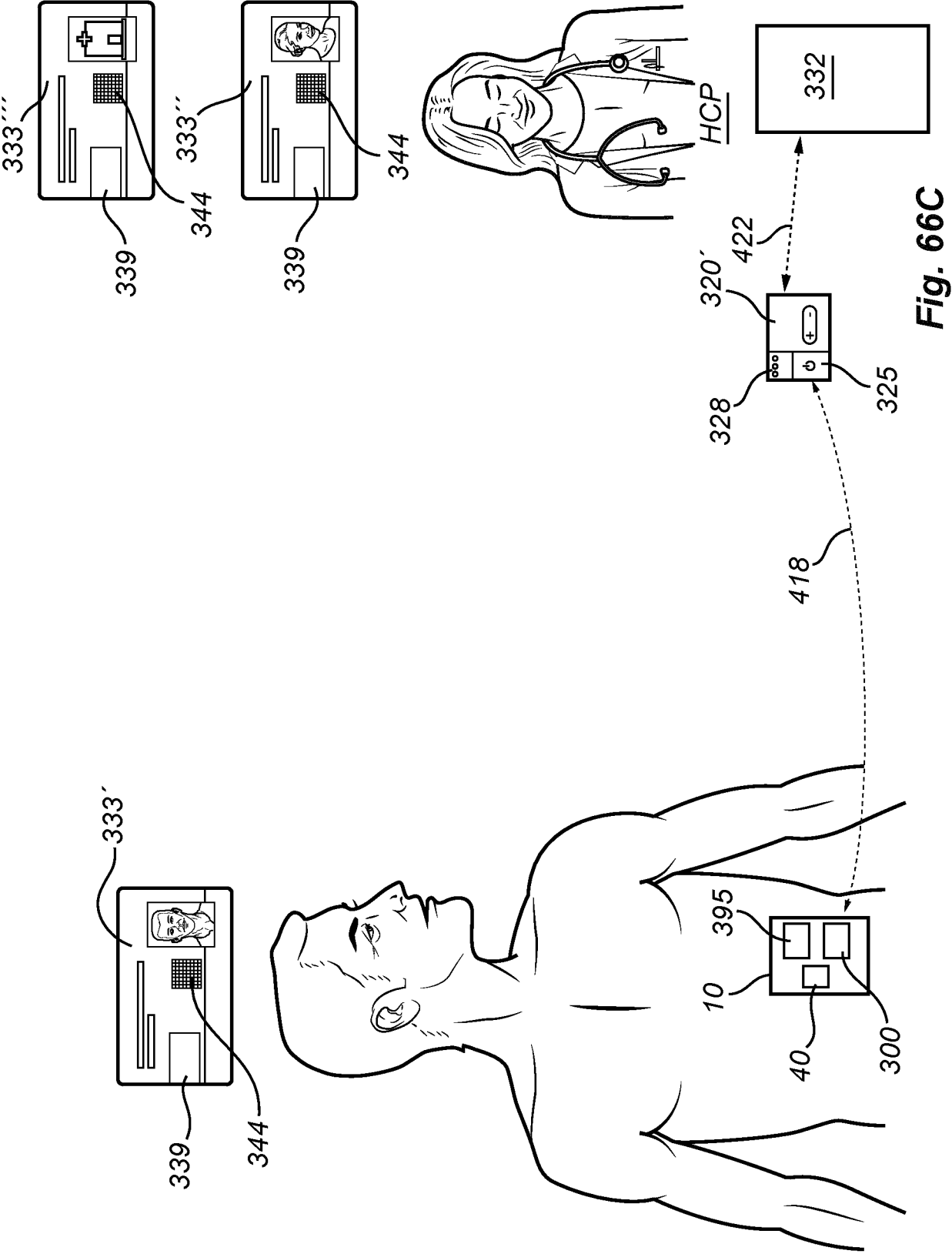


Fig. 66C

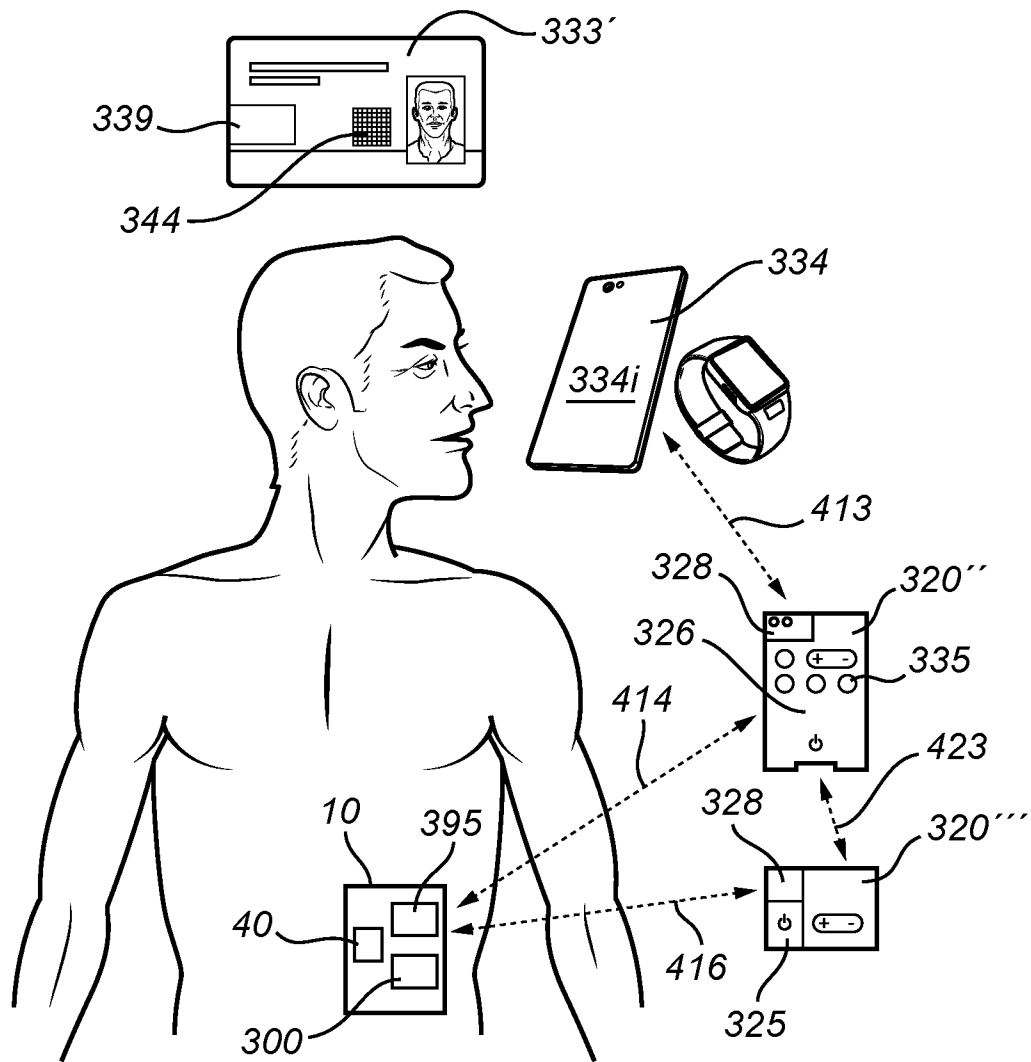


Fig. 66D

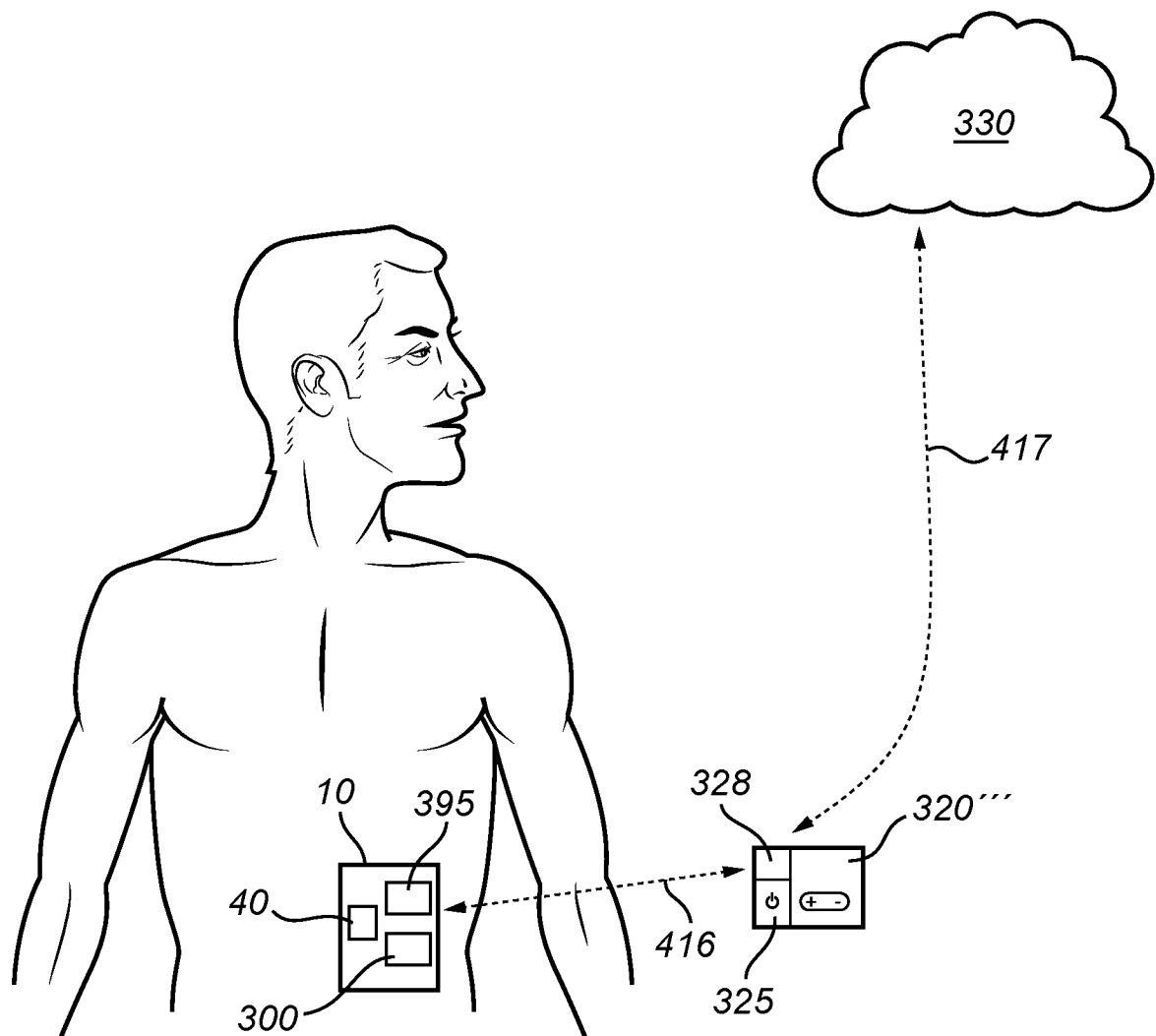


Fig. 66E

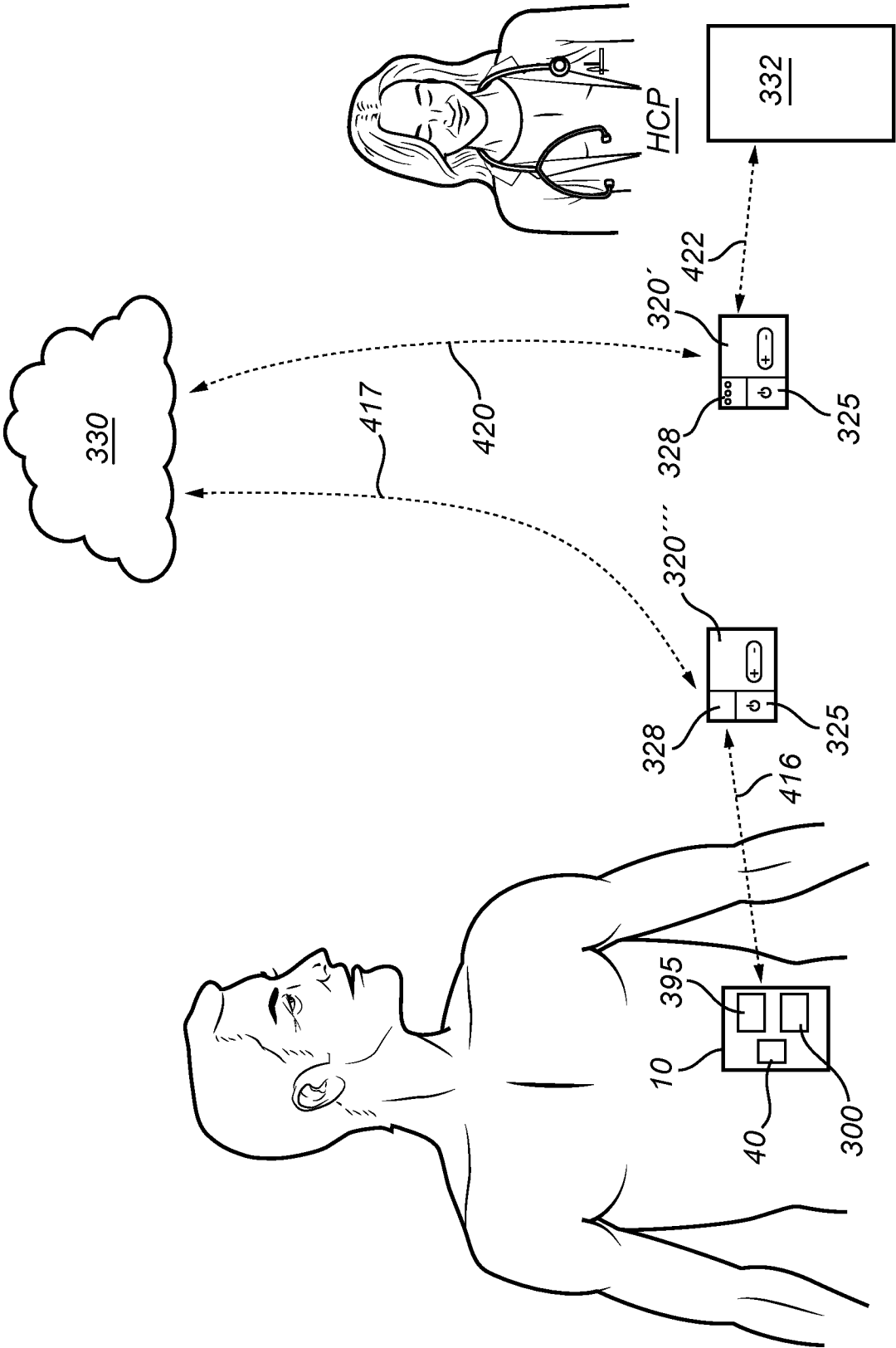
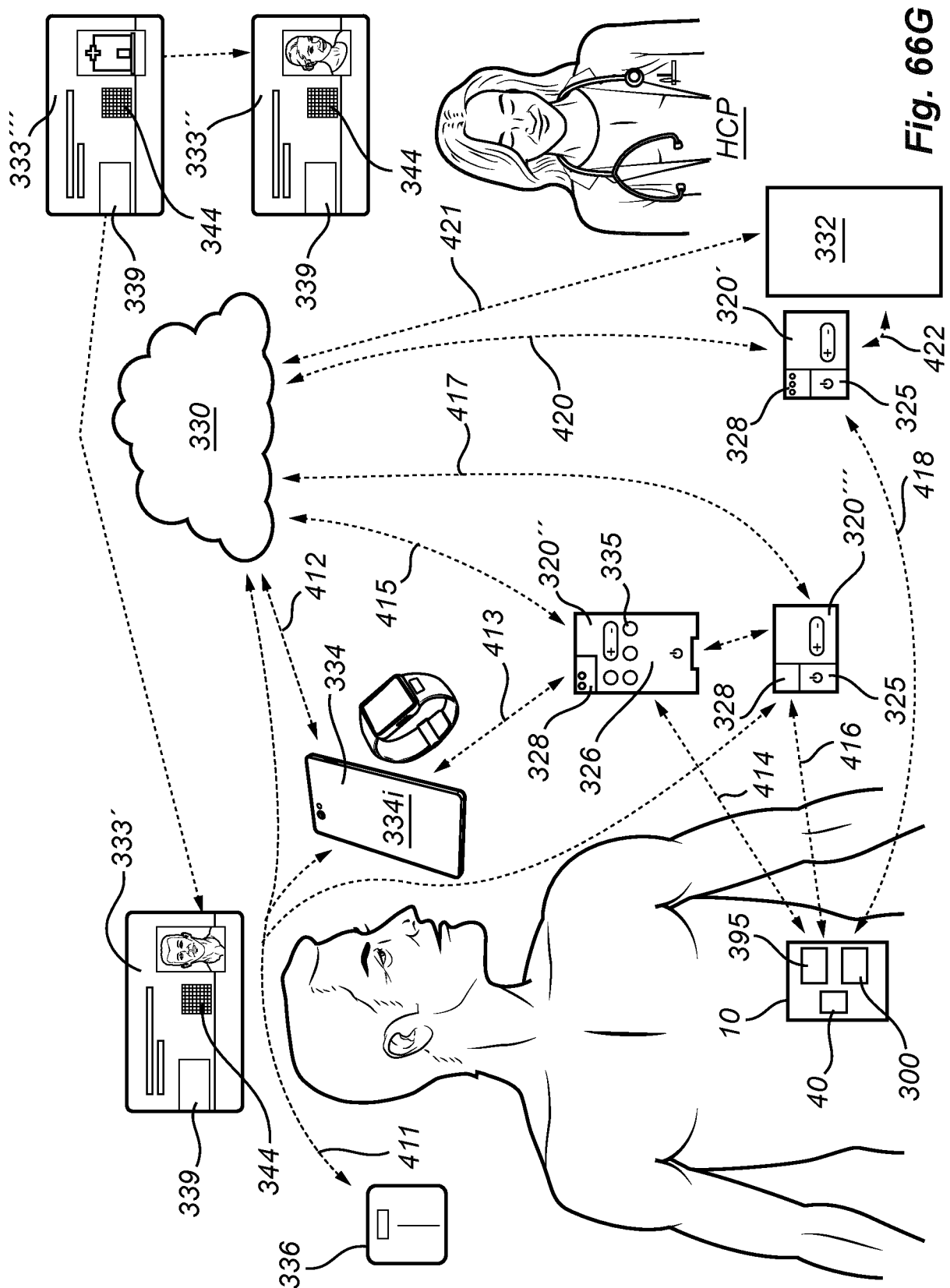


Fig. 66F



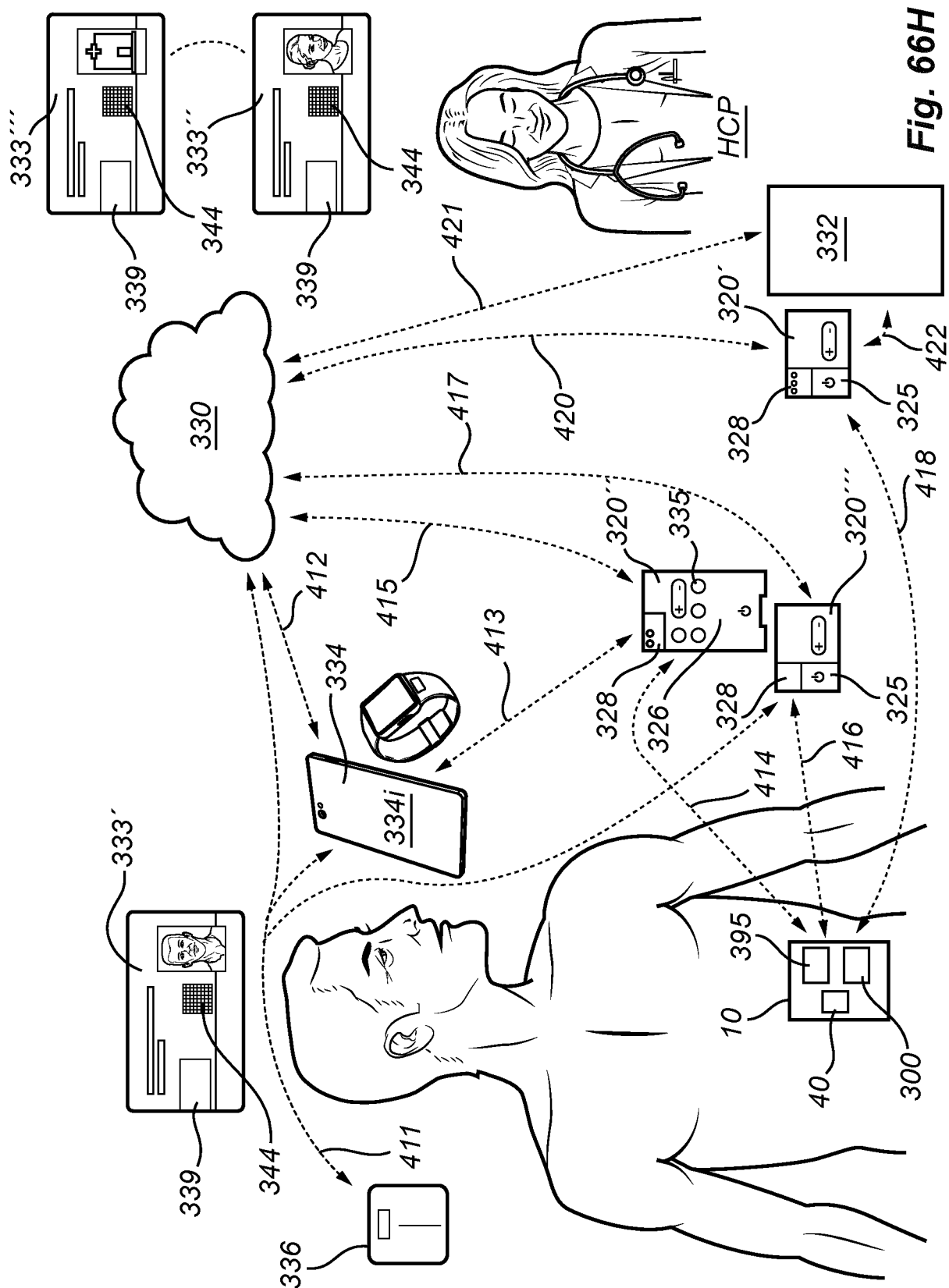


Fig. 66H

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2022/068601

A. CLASSIFICATION OF SUBJECT MATTER		
INV.	A61N1/36	A61N1/05
ADD.	A61B17/00	A61F5/00
		A61B17/12
		A61N1/372
		A61N1/378
		G16H40/60
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)		
A61N A61B G16H		
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)		
EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2021/000627 A1 (FORSELL PETER [CH]) 7 January 2021 (2021-01-07) paragraphs [0066] - [0131], [0422] - [0426], [0434] - [0438], [0584] - [0600]; figures 5A-5B, 10-27, 56-64 -----	1-24
X	US 2004/193229 A1 (STARKEBAUM WARREN L [US] ET AL) 30 September 2004 (2004-09-30) paragraphs [0038] - [0049], [0058] - [0062], [0069] - [0123], [0134] - [0135]; figures 1A-4B, 7-8B -----	1-24
X	US 2014/012348 A1 (STARKEBAUM WARREN L [US] ET AL) 9 January 2014 (2014-01-09) paragraphs [0044] - [0073], [0100], [0105] - [0114], [0129] - [0133], [0150] - [0154]; figures 1-2, 19A-19B -----	1-24
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "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
20 October 2022		31/10/2022
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Fischer, Olivier

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2022/068601

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **25–28**
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 25-28

The subject-matter of claims 25-28 has not been searched since it relates to a method for treatment of the human or animal body by therapy (Rule 39.1(iv) PCT). The method of claim 25 comprises the step of electrically stimulating patient's smooth muscle for treating reflux disease, therefore being of therapeutical character. Accordingly, claims 25-28 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the subject-matter of these claims (Article 34(4) (a) (i) PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2022/068601

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2021000627 A1	07-01-2021	AU 2009209519 A1	06-08-2009
		AU 2009209524 A1	06-08-2009
		AU 2009209536 A1	06-08-2009
		AU 2009302908 A1	15-04-2010
		AU 2009302938 A1	15-04-2010
		AU 2016210736 A1	25-08-2016
		AU 2018204936 A1	02-08-2018
		AU 2020239792 A1	29-10-2020
		AU 2022204717 A1	11-08-2022
		BR PI0906746 A2	07-07-2015
		BR PI0906747 A2	07-07-2015
		BR PI0906748 A2	07-07-2015
		CA 2749778 A1	06-08-2009
		CA 2749782 A1	06-08-2009
		CA 2749792 A1	06-08-2009
		CA 2776424 A1	15-04-2010
		CA 2776479 A1	15-04-2010
		CA 3108927 A1	06-08-2009
		CA 3109478 A1	06-08-2009
		CA 3109855 A1	06-08-2009
		CA 3135644 A1	15-04-2010
		CN 101980673 A	23-02-2011
		CN 101980674 A	23-02-2011
		CN 102245133 A	16-11-2011
		CN 104323877 A	04-02-2015
		CN 105361986 A	02-03-2016
		CN 105997315 A	12-10-2016
		CY 1120620 T1	11-12-2019
		DK 2240130 T3	18-10-2021
		DK 2240131 T3	23-07-2018
		DK 2240135 T3	08-11-2021
		DK 2240137 T3	07-06-2021
		DK 2349132 T3	15-03-2021
		DK 2405869 T3	08-11-2021
		DK 3072480 T3	26-07-2021
		DK 3476371 T3	04-04-2022
		EP 2240127 A1	20-10-2010
		EP 2240128 A1	20-10-2010
		EP 2240129 A1	20-10-2010
		EP 2240130 A1	20-10-2010
		EP 2240131 A1	20-10-2010
		EP 2240132 A1	20-10-2010
		EP 2240133 A1	20-10-2010
		EP 2240134 A1	20-10-2010
		EP 2240135 A1	20-10-2010
		EP 2240136 A1	20-10-2010
		EP 2240137 A1	20-10-2010
		EP 2240138 A1	20-10-2010
		EP 2240139 A1	20-10-2010
		EP 2240140 A1	20-10-2010
		EP 2249752 A1	17-11-2010
		EP 2249753 A1	17-11-2010
		EP 2349131 A1	03-08-2011
		EP 2349132 A1	03-08-2011
		EP 2349133 A1	03-08-2011
		EP 3072480 A1	28-09-2016
		EP 3417837 A1	26-12-2018
		EP 3421015 A2	02-01-2019

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2022/068601

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		EP 3434230 A1	30-01-2019
		EP 3470024 A1	17-04-2019
		EP 3476371 A1	01-05-2019
		EP 3871639 A1	01-09-2021
		EP 3895670 A1	20-10-2021
		EP 3900681 A1	27-10-2021
		EP 3922220 A1	15-12-2021
		EP 3925579 A1	22-12-2021
		EP 3925580 A1	22-12-2021
		EP 3928749 A1	29-12-2021
		EP 3957284 A1	23-02-2022
		EP 3967281 A1	16-03-2022
		ES 2695374 T3	04-01-2019
		ES 2857901 T3	29-09-2021
		ES 2858476 T3	30-09-2021
		ES 2873998 T3	04-11-2021
		ES 2894290 T3	14-02-2022
		ES 2894291 T3	14-02-2022
		ES 2896278 T3	24-02-2022
		ES 2896299 T3	24-02-2022
		ES 2915677 T3	24-06-2022
		FI 3476371 T3	15-06-2022
		HR P20181111 T1	05-10-2018
		HR P20210345 T1	30-04-2021
		HR P20210905 T1	03-09-2021
		HR P20211176 T1	29-10-2021
		HR P20211597 T1	18-03-2022
		HR P20211663 T3	15-04-2022
		HR P20220431 T3	10-06-2022
		HU E035306 T2	02-05-2018
		HU E053476 T2	28-06-2021
		HU E054386 T2	28-09-2021
		HU E055034 T2	28-10-2021
		HU E056279 T2	28-02-2022
		HU E056697 T2	28-03-2022
		HU E058231 T2	28-07-2022
		JP 6110441 B2	05-04-2017
		JP 6403698 B2	10-10-2018
		JP 6527186 B2	05-06-2019
		JP 6640926 B2	05-02-2020
		JP 7036790 B2	15-03-2022
		JP 2011510740 A	07-04-2011
		JP 2012505023 A	01-03-2012
		JP 2015198991 A	12-11-2015
		JP 2016047475 A	07-04-2016
		JP 2017104640 A	15-06-2017
		JP 2018164743 A	25-10-2018
		JP 2020044442 A	26-03-2020
		JP 2022033345 A	28-02-2022
		JP 2022069501 A	11-05-2022
		LT 2240130 T	11-10-2021
		LT 2240131 T	10-10-2018
		LT 2240135 T	10-11-2021
		LT 2240137 T	25-06-2021
		LT 2349132 T	26-04-2021
		LT 3072480 T	25-08-2021
		LT 3476371 T	11-04-2022
		PL 2240130 T3	27-12-2021

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2022/068601

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		PL 2240131 T3	30-11-2018
		PL 2240135 T3	10-01-2022
		PL 2240137 T3	04-10-2021
		PL 2349132 T3	17-05-2021
		PL 3072480 T3	02-11-2021
		PT 2240130 T	15-10-2021
		PT 2240135 T	04-11-2021
		PT 2240137 T	15-06-2021
		PT 2349132 T	12-03-2021
		PT 3072480 T	03-08-2021
		RU 2011114564 A	20-11-2012
		SE 0900997 A1	11-04-2010
		SE 0901007 A1	11-04-2010
		SE 0901009 A1	11-04-2010
		SE 0901027 A1	11-04-2010
		SI 2240130 T1	30-11-2021
		SI 2240131 T1	30-10-2018
		SI 2240135 T1	31-12-2021
		SI 2240137 T1	31-08-2021
		SI 2349132 T1	30-04-2021
		SI 3072480 T1	30-09-2021
		SI 3476371 T1	31-05-2022
		US 2010312047 A1	09-12-2010
		US 2010312048 A1	09-12-2010
		US 2010312049 A1	09-12-2010
		US 2010312050 A1	09-12-2010
		US 2010312356 A1	09-12-2010
		US 2010324360 A1	23-12-2010
		US 2010324361 A1	23-12-2010
		US 2010324362 A1	23-12-2010
		US 2010331614 A1	30-12-2010
		US 2010331615 A1	30-12-2010
		US 2010331616 A1	30-12-2010
		US 2010331617 A1	30-12-2010
		US 2010331945 A1	30-12-2010
		US 2010332000 A1	30-12-2010
		US 2011009894 A1	13-01-2011
		US 2011009896 A1	13-01-2011
		US 2011009897 A1	13-01-2011
		US 2011172693 A1	14-07-2011
		US 2011196197 A1	11-08-2011
		US 2011196391 A1	11-08-2011
		US 2011196411 A1	11-08-2011
		US 2011218394 A1	08-09-2011
		US 2012022561 A1	26-01-2012
		US 2012029551 A1	02-02-2012
		US 2014148645 A1	29-05-2014
		US 2014236212 A1	21-08-2014
		US 2014330075 A1	06-11-2014
		US 2015305851 A1	29-10-2015
		US 2016022462 A1	28-01-2016
		US 2016166418 A1	16-06-2016
		US 2016324673 A1	10-11-2016
		US 2016374843 A1	29-12-2016
		US 2017165092 A1	15-06-2017
		US 2017209292 A1	27-07-2017
		US 2017348128 A1	07-12-2017
		US 2018042746 A1	15-02-2018

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2022/068601

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2018085241 A1	29-03-2018
		US 2018243118 A1	30-08-2018
		US 2018353313 A1	13-12-2018
		US 2019000654 A1	03-01-2019
		US 2019380854 A1	19-12-2019
		US 2020060856 A1	27-02-2020
		US 2020085602 A1	19-03-2020
		US 2020246169 A1	06-08-2020
		US 2020323671 A1	15-10-2020
		US 2020337874 A1	29-10-2020
		US 2020390578 A1	17-12-2020
		US 2021000627 A1	07-01-2021
		US 2021045905 A1	18-02-2021
		US 2021059847 A1	04-03-2021
		US 2021137716 A1	13-05-2021
		US 2021186508 A1	24-06-2021
		US 2021186729 A1	24-06-2021
		US 2021186730 A1	24-06-2021
		US 2021186731 A1	24-06-2021
		US 2021186732 A1	24-06-2021
		US 2021236317 A1	05-08-2021
		US 2021236318 A1	05-08-2021
		US 2021251790 A1	19-08-2021
		US 2021322195 A1	21-10-2021
		US 2021330482 A1	28-10-2021
		US 2022039982 A1	10-02-2022
		WO 2009096857 A1	06-08-2009
		WO 2009096858 A1	06-08-2009
		WO 2009096859 A1	06-08-2009
		WO 2009096860 A1	06-08-2009
		WO 2009096861 A1	06-08-2009
		WO 2009096862 A1	06-08-2009
		WO 2009096863 A1	06-08-2009
		WO 2009096864 A1	06-08-2009
		WO 2009096865 A1	06-08-2009
		WO 2009096866 A1	06-08-2009
		WO 2009096867 A1	06-08-2009
		WO 2009096868 A1	06-08-2009
		WO 2009096869 A1	06-08-2009
		WO 2009096870 A1	06-08-2009
		WO 2009096871 A1	06-08-2009
		WO 2009096872 A1	06-08-2009
		WO 2009096873 A1	06-08-2009
		WO 2009096874 A1	06-08-2009
		WO 2010042015 A1	15-04-2010
		WO 2010042061 A1	15-04-2010
		WO 2010042062 A1	15-04-2010
		WO 2010042063 A1	15-04-2010

US 2004193229	A1	30-09-2004	NONE

US 2014012348	A1	09-01-2014	EP 2408517 A1 25-01-2012
			US 2010228313 A1 09-09-2010
			US 2014012348 A1 09-01-2014
			WO 2010101877 A1 10-09-2010
