(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 August 2009 (06.08.2009)

PCT

(10) International Publication Number
WO 2009/096867 A1

(51) International Patent Classification:
A61F 5/00 (2006.01) *A61F 2/04* (2006.01)

(21) International Application Number:
PCT/SE2009/000052

(22) International Filing Date: 29 January 2009 (29.01.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/006,719 29 January 2008 (29.01.2008) US
0802138-8 10 October 2008 (10.10.2008) SE

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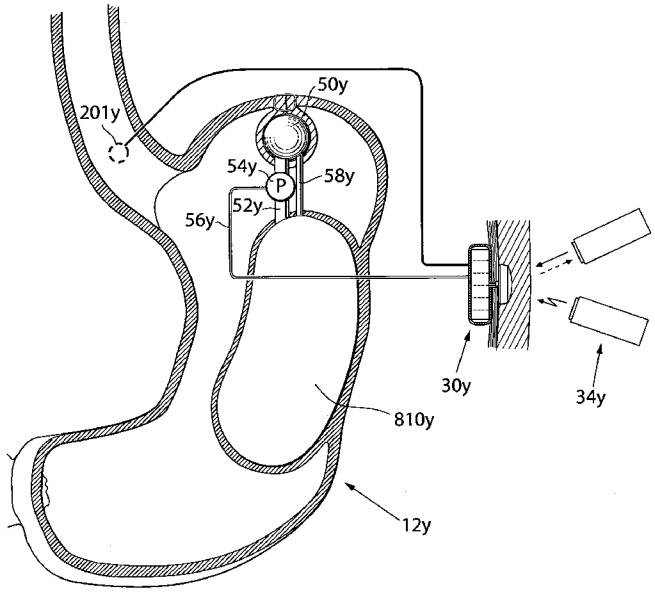
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(54) Title: APPARATUS AND METHOD FOR TREATING OBESITY

Fig.76a



(57) Abstract: The present invention relates to a reflux disease treatment apparatus comprising an implantable movement restriction device that maintains cardia in the correct position and an implantable stimulation device adapted to engage with the cardia sphincter of a patient. The invention further comprises a control device for controlling the stimulation device to stimulate the cardia sphincter. The invention can be combined with various methods for treating obesity, in particular methods that creats satiety by stretching the wall of the stomach or fills out a volume of the stomach.

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APPARATUS AND METHOD FOR TREATING OBESITY

TECHNICAL FIELD

The present invention relates to an apparatus for treating Obesity.

BACKGROUND

Obesity has been treated by gastric banding a band placed around the stomach to create a stoma, a restricted opening, to restrict the flow of food down to below the band. There has also been tried to use electrical stimulation of the stomach wall to cause the patient to feel satiety.

In the past, obese patients have been treated by gastric reduction surgery to restrict the food intake of the patient. At present, two gastric restriction procedures for treating obesity are most commonly performed, namely Adjustable Gastric Banding (AGB) and Vertical Banded Gastroplasty (VBG).

In AGB, a constricting band is placed completely around an obese patient's surgically intact stomach near the upper end thereof, just below the junction of stomach and esophagus, to restrict the food intake of the patient. As the band constricts the stomach, a small gastric pouch is formed above the band and a reduced permanent stoma in the stomach. The idea being that a small amount of food filling the small pouch causes the patient to sense fullness, i.e., satiety. Examples of AGB are disclosed in U.S. Patent No. 4,592,339 and European Patent No. 0611561,

In VBG, typically the stomach is stapled vertically with four rows of linear staples, which compartmentalize the stomach into an elongate proximal smaller compartment adjacent the esophagus and a distal larger compartment, so that the volume of the smaller compartment is about 10% of the volume of the stomach. A circular hole is punched-out in the stomach at the lower end of the rows of linear staples and several

circular rows of staples are placed on the stomach around the circular hole. A band is placed through the circular hole and is secured around the stomach, whereby the band defines a narrow outlet opening from the smaller compartment into the larger compartment of the stomach. Once secured, the band prevents the stomach from stretching at the outlet opening, which results in that the outlet opening over time maintains its initial small diameter. Food that the patient takes in is held up in the smaller compartment causing the sensation of fullness. Then, the food empties slowly through the outlet opening into the larger compartment where digestion takes place normally. Examples of VBG are disclosed in U.S. Patent Nos. 5,345,949 and 5,549,621.

There are few complications associated with AGB and VBG. However, it is important that the patient very carefully chews food completely before swallowing it, so that food pieces collected in the smaller compartment of the stomach are able to pass through the narrow outlet opening of the smaller compartment. If food pieces were stuck in the outlet opening it might cause the patient to vomit and feel sick. In such a case the patient should have to visit a doctor or nurse. Another complication associated with AGB and VBG is that the patient may suffer from acid stomach reflux at night.

The use of electrical stimulation of the stomach wall to cause the patient to feel satiety has also been used.

SUMMARY OF THE INVENTION

The object of the present invention to provide an obesity treatment apparatus and system with improved long term properties.

This object and others are obtained by an apparatus described in the appended claims. Thus, there is provided an obesity treatment apparatus comprising at least one volume filling device adapted to be at least substantially invaginated by a stomach wall portion of the patient and having an outer surface that includes a biocompatible material, wherein the volume filling device is adapted to be placed outside of the stomach wall with the outer surface of the volume filling device resting against the outside of the stomach wall, such that the volume of the food cavity is reduced in size by a volume substantially exceeding the volume of the volume filling device, the volume filling device having a maximum circumference of at least 30 millimeters, at least one operable stretching device implantable in the obese patient and adapted to stretch a portion of the patient's stomach wall, and an operation device for operating the stretching device when implanted to stretch the stomach wall portion such that satiety is created.

Accordingly, the patient's appetite is affected by both the volume filling device and the stretching device, whereby a significantly strong appetite reducing effect is obtained. Besides, the invagination of the volume filling device by the stomach wall protects the volume filling device from the stomach acids and will thus remain functioning for a very long time.

Preferably, the volume filling device is adapted to be completely invaginated by the stomach wall of the patient and to be placed outside the stomach wall via a gastroscopic instrument. To this end the volume filling device may comprise an attachment device adapted to co-operate with a gripping instrument. Suitably, the volume filling device is adapted to be non-invasively adjustable postoperatively.

The apparatus may comprise a fixation device, suitably two or more fixation devices, adapted to be involved in the fixation of the volume filling device to the stomach wall. The volume filling device may comprise a holding device adapted to

be held by an instrument, suitably two or more holding devices, to simplify the implantation of the device.

At least a part of the volume filling device may be made of a material which is not destructible by stomach acid. The volume filling device may be destructible by acids, for example hydrochloric acid.

In an embodiment, the volume filling device is inflatable to an expanded state and comprises an enclosure wall defining a chamber, wherein the volume filling device is inflated with a gel or fluid supplied into the chamber. At least one tube may be connected to the volume filling device for supplying gel or fluid to the chamber. An injection port connectible with the tube may be provided. Alternatively, the volume filling member may be provided with an inlet port for a fluid or a gel connectible to a gastroscopic instrument, wherein the inlet port comprises a fluid connection adapted to interconnect the inflatable device and the gastroscopic instrument.

The volume filling device may include a homogenous material, such as gel having a shure value of less than 15. The device may also be a solid body.

The volume filling device may comprise a rigid, elastic or flexible outer surface. Where the outer surface is rigid, it is rigid enough to maintain non-deformed when subject to forces created by stomach movements. The volume filling device may comprise a flexible non-elastic material.

In accordance with a first general design of the volume filling device, the device has a maximum circumference as seen in a plane perpendicular to an axis through the device. The circumferences of the device as seen in other planes perpendicular to said axis are equal to the maximum circumference or decrease as seen along said axis in the direction from the maximum circumference. For example, the device may be substantially egg shaped, spherically shaped, or substantially shaped like an egg with an indented middle section or like a bent egg.

In accordance with a second general design of the device, the circumference of the device as seen in a plane perpendicular to an axis through the device increases and decreases at least two times as the plane is displaced along said axis, or decreases

and increases at least one time as the plane is displaced along said axis. For example, the device may be substantially shaped like a kidney.

The volume filling device have an elongated, rounded, bent and/or curved shape.

The volume filling device has a circumference of at least 120, 150, 180 or 220 mm.

The volume filling device has a volume in the range of 0.0001 to 0.001 m^3 , or 0.00001 to 0.001 m^3, or 0.00001 to 0.0002 m^3. The volume of the volume filling device has a volume of less than 0.0002 m^3.

The the volume filling device may comprise at least two interconnectable portions adapted to be placed inside the stomach as separate portions.

The volume filling device may comprises an elastic material, a bio-compatible material and/or silicone.

Suitably, the volume filling device is provided with a coating. For example, a metal coating, a Parylene coating, a polytetrafluoroethylene coating or a polyurethane coating. The coating may be a multi-layer coating. Suitably, one of the layers may be made of made of metal, silicon or PTFE. The volume filling device may comprise an outer surface layer of polyurethane, Teflon®, or PTFE, or a combination thereof.

The volume filling device may comprise a fluid adapted to be transformed into solid state or fixed form. Such a fluid may be liquid polyurethane or iso-tonic. The fluid may comprises large molecules, such as iodine molecules, to prevent diffusion.

The volume filling device may have a maximum circumference of at least 50 millimeters, preferably at least 80 millimeters. Suitably, the volume filling device is deformable to a maximum diameter, so as to be insertable into a laparoscopic trocar.

Preferably, the volume filling device is adapted to be kept in place by stomach-to-stomach sutures or staples to invaginate the device in the stomach wall. Advantageously, the volume filling device has varying circumference to better be kept in place invaginated in the stomach wall of the patient. The stomach-to-stomach sutures or staples may be provided with fixation portions exhibiting a structure

adapted to be in contact with the stomach wall to promote growth in of human tissue to secure long term placement of the volume filling device attached to the stomach wall. The structure may comprise a net like structure.

In an embodiment of the invention, the apparatus comprises a stretching device placed outside the stomach wall and adapted to stretch a portion of the stomach wall, thereby affecting the patient's appetite. Where the volume filling device is inflatable, the apparatus may comprise a fluid connection interconnecting the stretching device and the volume filling device.

In an embodiment, the apparatus comprises a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall and an operation device for operating the stretching device when implanted to stretch the stomach wall portion such that satiety is created.

In an embodiment, the apparatus comprises at least one operable stretching device implantable in the patient and adapted to stretch a portion of the patient's stomach wall, and an implantable control unit for automatically controlling the operable stretching device, when the control unit and stretching device are implanted, to stretch the stomach wall portion in connection with the patient eating such that satiety is created.

In an embodiment, the apparatus comprises a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall, wherein said stretching device comprising an expandable stretching reservoir and an operation device for operating the stretching device when implanted to stretch the stomach wall portion, wherein the volume filling device is inflatable and in fluid connection with said stretching reservoir, wherein said operation device comprises a pump for pumping fluid between said main reservoir and said stretching reservoir to stretch said stomach wall portion such that satiety is created. A control device may be provided for controlling said stretching device including said pump. The

control device may comprise a wireless remote control adapted to control the stretching device from the outside of the patient's body, or an implantable control unit for controlling said stretching device. Alternatively, the control device may comprise a subcutaneously placed switch or reservoir adapted to control the stretching device from the outside of the patient's body. A sensor or sensing device to be implaned in the patient body may be provided, wherein the implantable control unit is adapted to control the stretching device from the inside of the patient's body using information from said a sensor or sensing device, adapted to sense, direct or indirect, the food intake of the patient.

In an embodiment, the volume filling device comprises a main volume filling reservoir, a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall, wherein said stretching device comprising an expandable reservoir, adapted to be invaginated in the stomach wall at the upper part of the stomach, higher up than the inflatable main volume filling device when the patient is standing, wherein the volume filling device is inflatable and in fluid connection with said stretching reservoir, wherein normal contractions of the stomach wall, related to food intake, cause fluid to flow from said invaginated main volume filling reservoir lower placed onto the stomach wall adapted to cause said stretching reservoir to stretch said stomach wall portion such that satiety is created. The fluid connection between the main volume filling device reservoir and the stretching reservoir comprises a non-return valve. The fluid connection between the main volume filling device reservoir and the stretching reservoir comprises a release function adapted to release the volume in the stretching reservoir back to the main volume filling device reservoir. Said release function may comprise a fluid return connection of a substantially smaller area than said fluid connection, to slowly release back fluid to said main volume filling device reservoir from the stretching reservoir to release said stretching of the stomach wall portion. A further manual control device comprising a subcutaneously placed reservoir adapted to control the stretching device from the outside of the patient's body may be provided to further affect the stretching device to stretch the stomach wall portion.

In an embodiment, the a main volume filling device reservoir adapted to be inflatable may be provided, wherein the volume filling device further comprises an expandable structure, adapted to expand, when the device is invaginated in the stomach wall, wherein said structure comprising a bellow adapted to take into account the fibrosis surrounding the device when implanted, such that the movement of the bellow is substantially un-affected of said fibrosis.

In an embodiment, the apparatus comprises a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall and wherein the stretching device comprising a expandable structure, adapted to expand and stretch the stomach wall portion, when the device is invaginated in the stomach wall, wherein said structure comprising a special bellow adapted to take into account the fibrosis surrounding the device when implanted, such that the movement of the bellow is substantially un-affected of said fibrosis. An operation device for operating the stretching device may be provided to stretch the stomach wall portion such that satiety is created. The apparatus may comprise an implantable control unit for automatically controlling the operable stretching device, when the control unit and stretching device are implanted, to stretch the stomach wall portion in connection with the patient eating such that satiety is created.

In an embodiment, the apparatus comprises a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall such that satiety is created. The control device may comprise a wireless remote control adapted to control the stretching device from the outside of the patient's body or an implantable control unit for controlling said stretching device. Alternatively, said control device may comprise a subcutaneously placed switch or reservoir adapted to control the stretching device from the outside of the patient's body. A sensor or sensing device adapted to be implaned in the patient body may be provided, wherein the implantable control unit is adapted to control the stretching device from the

inside of the patient's body using information from said sensor or sensing device, adapted to sense, direct or indirect, the food intake of the patient.

In an embodiment, the apparatus is further adapted to treat reflux disease. To this end, it further comprises an implantable movement restriction device adapted to be at least partly invaginated by the patient's stomach fundus wall and having an outer surface that includes a biocompatible material, wherein a substantial part of the outer surface of the movement restriction device is adapted to rest against the stomach wall without injuring the latter in a position between the patient's diaphragm and at least a portion of the lower part of the invaginated stomach fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is invaginated, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm.

In another embodiment, the apparatus is further adapted to treat reflux disease. To this end, it further comprises an implantable movement restriction device having an outer surface including a biocompatible material, wherein the movement restriction device is adapted to rest with at least a part of its outer surface against the patient's stomach fundus wall, in a position between the patient's diaphragm and the fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is implanted in the patient, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, wherein the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, and an afixation device adapted to secure the movement restriction device in said position, when the movement restriction device is implanted.

In another embodiment, the apparatus is further adapted to treat reflux disease. To this end, it further comprises an implantable movement restriction device adapted to be at least partly invaginated by the patient's stomach fundus wall and having an outer surface that includes a biocompatible material, wherein a substantial part of the outer surface of the movement restriction device is adapted to rest against the stomach wall without injuring the latter in a position between the patient's diaphragm and at least a portion of the lower part of the invaginated stomach fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is invaginated, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, further comprising a stretching device comprising at least one operable stretching device implantable in the obese patient and adapted to stretch a portion of the patient's stomach wall such that satiety is created.

In another embodiment, the apparatus is further adapted to treat reflux disease. To this end, it further comprises an implantable movement restriction device having an outer surface including a biocompatible material, wherein the movement restriction device is adapted to rest with at least a part of its outer surface against the patient's stomach fundus wall, in a position between the patient's diaphragm and the fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is implanted in the patient, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, wherein the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, and a fixation device adapted to secure the movement restriction

device in said position, when the movement restriction device is implanted, further comprising a stretching device comprising at least one operable stretching device implantable in the obese patient and adapted to stretch a portion of the patient's stomach wall such that satiety is created.

In an embodiment, the apparatus further comprises a stretching device comprising three or more mechanical parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling to the stomach wall or invaginating the mechanical parts in the stomach wall part with stomach to stomach sutures, wherein the three or more mechanical parts are adapted to move in relation to each other adapted to stretch three different wall portions, the stretching device further adapted to having said wall portions stretched independently from each other both regarding force used for stretching the stomach wall portion as well as, time periods the stretching is applied, and when the stretching is applied.

In an embodiment, the apparatus further comprises a stretching device comprising two or more hydraulic parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling to hydraulic part to the stomach wall or invaginating the hydraulic parts in the stomach wall part, with stomach to stomach sutures, wherein the two or more hydraulic parts are adapted to move in relation to each other adapted to stretch three different wall portions, the stretching device further adapted to having said wall portions stretched independently from each other both regarding force used for stretching the stomach wall portion as well as, time periods the stretching is applied, and when the stretching is applied.

In an embodiment, the apparatus further comprises a stretching device which is engaged with a part of the stomach wall, including suturing or stapling the stretching device to the stomach wall or invaginating the stretching devcie in the stomach wall part, with stomach to stomach sutures, wherein the stretching device is further adapted to stretch a stomach wall portion controlling force used

for stretching the stomach wall portion as well as, time periods the stretching is applied, and when the stretching is applied.

In an embodiment, the apparatus further comprises a stretching device comprising two parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling the parts to the stomach wall or invaginating the parts in the stomach wall part, with stomach to stomach sutures, wherein the stretching device further adapted to have different wall portions stretched independently from each other controlling force used for stretching the stomach wall portion as well as, time periods the stretching is applied, and when the stretching is applied.

In an embodiment, the apparatus further comprises an external control unit for controlling the volume filling device from the outside of the patient's body. The external control unit may comprise a wireless remote control adapted to control the device from the outside of the patient's body. Alternatively, the external control unit may comprise a subcutaneously placed switch or reservoir adapted to control the device from the outside of the patient's body.

In an embodiment, the apparatus further comprises a sensor or sensing device adapted to be implaned in the patient body, wherein the implantable control unit is adapted to control the device from the inside of the patient's body using information from said a sensor or sensing device, adapted to sense, direct or indirect, the food intake of the patient.

The stretching device of the apparatus may be kept in contact with the stomach wall by stomach-to-stomach sutures or staplers, in a position in which the stretching device is capable of stretching the stomach wall. Specifically, the stretching device may be invaginated by the stomach wall by means of stomach-to-stomach sutures or staplers.

The stretching device may be adapted to be placed in the stomach cavity. To this end, the stretching device may be adapted to be inserted into the stomach cavity via a gastroscope or intraluminar instrument, and be adapted to be attached to the stomach

wall by surgery. Alternatively, the stretching device may be adapted to be placed on the outside of the stomach.

In an embodiment of the invention, the stretching device comprises a first engaging member adapted to engage a first part of the stomach wall and a second engaging member adapted to engage a second part of the stomach wall close to but spaced from the first stomach part. The operation device is adapted to operate the first and second engaging member to move away from each other to stretch the stomach wall portion between the first and second parts of the stomach such that satiety is created. At least one of the first and second engaging members may be adapted to at least in part be invaginated by the stomach wall by stomach-to-stomach sutures or staplers holding the engaging member in place. In addition, at least one of the first and second engaging members may be adapted to be kept in place by sutures or staplers between the engaging member and the stomach wall. Suitably, at least one of the first and second engaging members comprises a tissue growth promoting structure, preferably a net like structure, adapted to be in contact with the stomach wall to secure long term attachment of the stretching device to the stomach wall.

In another embodiment of the invention, the stretching device comprises at least one expandable body adapted to be invaginated by a portion of the patient's stomach wall, and the operation device comprises a fluid reservoir, which is in fluid communication with a chamber of the body. The operation device is non-invasively operable to distribute fluid from the fluid reservoir to the chamber of the body to expand the body such that the stomach wall portion is stretched, when the body is invaginated. The fluid reservoir may be operated by manually pressing it. The operation device may comprise a reverse servo, wherein a small volume of fluid in the fluid reservoir is compressed with a higher force and the chamber of the body creates a movement of a larger total volume with less force per unit of volume. The fluid reservoir may be placed subcutaneously or in the abdomen, and may be regulated by moving a wall of the reservoir, for example by a motor. Alternatively, a pump may be provided for pumping fluid or air from the reservoir to the body's chamber.

The term "reversed servo means" encompasses the definition of a device that is controlled with a higher force and a small stroke i.e. for example movement of a small amount of fluid with a high force controls a larger amount of fluid moving by means of very smaller force, but may alternatively or additionally encompass the definition of a mechanism that transfers a strong force acting on a moving element having a short stroke into a small force acting on another moving element having a long stroke. The reversed servo means is preferably used when manual control of the device through intact skin is possible.

In another embodiment of the invention, the device comprises a large chamber in contact with one or more smaller chambers. The chambers are adapted to communicate with fluid or air being distributed between the chambers. A reversed servo for distributing fluid between the chambers may be provided, wherein a small volume of fluid in the large chamber is compressed with a higher force and the smaller chamber creates a movement of a larger total volume with less force per unit of volume. The large chamber may be adapted to be invaginated in the patient's fundus stomach wall to also treat reflux disease by restricting movement of the cardiac notch towards the diaphragm muscle of the patient, whereas the small chambers function as stretching devices to treat obesity. The large chamber may distribute fluid or air to the small chambers to cause them to expand and stretch the stomach fundus wall.

In another embodiment of the invention, the stretching device comprises a mechanical stretching device, wherein a motor for mechanically regulating the stretching device may be provided. The mechanically regulated stretching device may be adapted to engage a first part of the stomach wall and a second part of the stomach, wherein the mechanically regulated stretching device comprises a joint mechanism adapted to be moved by the operation device. Alternatively, the stretching device may comprise a first engaging member adapted to engage a first part of the stomach wall and a second engaging member adapted to engage a second part of the stomach wall close to but spaced from the first stomach part, wherein the mechanical stretching device regulates the distance between the first and second parts of the stomach wall.

As an alternative, the hydraulic means described above may be used for regulating such a mechanical stretching device by the hydraulic distribution of fluid or air.

The stretching device may be non-invasively adjustable postoperatively.

The operation device for operating the stretching device may in its simplest form comprise a subcutaneous switch adapted to be non-invasively operated by manually pressing the switch for the operation of the stretching device.

At least two operable stretching devices adapted to stretch at least two different portions of the stomach wall may be provided, wherein the device is adapted to be postoperatively and non-invasively regulated. Specifically, the device may be regulated from time to time such that at a first time one of the stretching devices stretches one of the portions of the stomach wall and at a second time the other of the stretching devices stretches the other portion of the stomach wall.

In another embodiment of the invention, the stretching device comprises a body adapted to fill out a volume defined by wall portions of the stomach. The body suitably has rounded contours without too sharp edges that would be damaging to the patient's stomach wall. Where the body is to be invaginated it may have varying circumference to better be kept in place invaginated by stomach wall portions of the patient. The body may be shaped like an egg or like a kidney.

Generally, any kind of mechanical construction may be used. Any mechanical construction driven mechanically or hydraulically or any pneumatic construction may be used. Any motor or any pump or moving material changing form when powered may be used to achieve the simple goal of stretching a part of the stomach wall by moving at least two part s of the stomach wall away from each other.

Any kind of hydraulic operation may be used. It will be appreciated that instead of hydraulic operation, pneumatic operation can be used, wherein air instead of hydraulic fluid is moved between a reservoir and a chamber formed by the stretching device. Preferably the reservoir has a locking position to keep it in the desired position if it is handled by the patient. To compress the reservoir it preferably stays compressed and releases after pressing again.

Any kind of hydraulic solution may be used for the stretching device. The hydraulic solution may be driven by both mechanically and powered with any motor or pump as well as manual.

Of course just expanding an invaginated part of the stomach also stretches away the stomach wall which also may be achieved both mechanically, hydraulically, pneumatically and both being powered with a motor or pump or by manual force.

According to one embodiment, a device for treating obesity of a patient is provided, the device comprises at least one operable stretching device implantable in the patient and adapted to stretch a portion of the patient's stomach wall. The device further comprises an implantable control unit for automatically controlling the operable stretching device, when the control unit and stretching device are implanted, to stretch the stomach wall portion in connection with the patient eating such that satiety is created.

According to another embodiment the device further comprises at least two stretching devices, a first stretching device and a second stretching device, or three or more stretching devices. According to yet another embodiment the device further comprises an operation device for operating the stretching device, wherein the control unit controls the operation device to stretch the stomach wall portion, when the control unit and stretching device are implanted.

According to yet another embodiment the device further comprising a sensing device including a sensor for sensing a physical parameter of the patient or a functional parameter of the stretching device, wherein the sensing device sends information relating to the parameter to the control unit, and the control unit controls the stretching device based on the information. The device could be adapted to control the stretching device to intermittently stretch the stomach wall, when the control unit and stretching device are implanted.

According to one embodiment the implantable control unit is adapted to control the amount of stretching performed by the stretching device on the stomach wall,

according to one embodiment by vary over time, the amount of stretching of the stomach wall and/or to stretch the stomach during a predetermined time period.

According to one embodiment the implantable control unit is adapted to control the stretching device based on the patient's food intake, the implantable control unit could be programmable to include any of: a predetermined time period during which the stretching device is controlled to stretch the stomach wall, and the magnitude of stretching applied on the stomach wall. The operation device could be a mechanical operation device, hydraulic operation device, a hydraulically operated mechanical operation device or a mechanically operated hydraulic operation device.

According to one embodiment the sensor of the sensing device senses the patient's food intake directly or indirectly, and the implantable control unit controls the operation device to stretch the stomach wall in response to signals from the sensor.

According to yet another embodiment the implantable control unit is adapted to control the operation device to stretch the stomach wall using more than one stretching device. This could be done by the implantable control unit being adapted to control the first stretching device, during a first time period, to stretch a first portion of the stomach wall, and the second stretching device, during a second time period, to stretch a second portion of the stomach wall different from said first portion of the stomach, to allow longer relaxation of the stomach wall in between stretching periods.

According to one embodiment the sensor of the sensing device is adapted to sense a parameter related to the patients food intake such as esophagus movement, esophagus bending, esophagus motility, esophagus stretching, esophagus pressure, food passing esophagus, food in the stomach, neural activity, vagus activity, muscle activity, hormonal activity, stomach motility, stomach stretching, stomach pressure, stomach bending, stomach filling, and/or acidity in the stomach. The sensing device could also be adapted to senses motility, stretching, bending, pressure, movement, a hormone, neural activity, PH-level, acidity, volume, capacitance, resistance, volt,

ampere, light absorption or visualization, ultrasound reflection or absorption, bending metal, bimetal and PH.

According to one embodiment the device further comprises an implantable reservoir, wherein the operation device is hydraulically controlled by the reservoir. The stretching device could be adapted to be controlled from outside the patient's body using a patient control which according to one embodiment could be adapted to override the control of the implantable control unit. The implantable control unit could be adapted to be controlled from outside the patient's body by the patient.

According to one embodiment the device further comprises an external control unit for controlling the implantable control unit from outside the patient's body e.g. by means of an implantable switch operable by the patient.

According to one embodiment the device comprises a wireless remote control for controlling and/or programming the implantable control unit from outside the patient's body. The control unit could comprise a force controller, and the mechanical operation device could be controlled by the force controller.

According to one embodiment the implantable control unit comprises a pressure controller, and the hydraulic operation device is controlled by the pressure controller.

STRETCHING DEVICE

The stretching device of the apparatus according to any of the embodiments could comprise a first and a second engaging part, the first part could be adapted to be engaged to a first area of the stomach wall, and the second part could be adapted to be engaged to a second area of the stomach wall. The stretching device is thereby adapted to stretch a portion of the stomach wall between the first area and the second area. The stretching device could comprise a motor, such as an implantable electrical motor, which in turn could operate at least one joint to move the joint to stretch the stomach wall portion.

According to another embodiment the device could comprise a chamber having a variable volume; the chamber could be adapted to receive a fluid. The device could further comprise a reservoir adapted to hold a fluid and to be in fluid connection with the chamber. The stretching device could further comprise a pumping device, which could be adapted to move the fluid from the reservoir to the chamber, and thereby stretching the portion of the stomach wall. According to another embodiment the device further comprises a second fluid connection adapted to enable the fluid to flow back from the chamber to the reservoir during a predetermined time period.

HYDRAULIC

According to one embodiment the stretching device comprises a chamber adapted to have a variable volume. The chamber could comprise at least one moveable wall portion, which could be an elastic wall portion. The chamber could have an essentially round shape and could be adapted to receive a fluid.

According to another embodiment the stretching device further comprises a reservoir adapted to hold a fluid and to be in fluid connection with the chamber, the stretching device could further comprise a pumping device, which could be adapted to move the fluid from the reservoir to the chamber via a first fluid connection interconnecting the reservoir and chamber, thereby stretching the portion of the stomach wall. It is also conceivable that the stretching device further comprises a second fluid connection interconnecting the chamber and reservoir and adapted to enable the fluid to flow back from the chamber to the reservoir during a predetermined time period.

The reservoir according to any of the embodiment could be adapted to be placed subcutaneously or in the abdomen and the reservoir could be controlled by moving a wall of the reservoir which could be done using a motor adapted therefore. The chamber could also comprise an electrical motor adapted to expand the volume of the chamber.

The device could further comprise a reverse servo, wherein a small volume in the reservoir is compressed with a higher force and the chamber creates a movement of a larger total area with less force per area unit.

SENSOR

The sensor implanted in the patient according to any of the embodiments could be a functional parameter sensor sensing a functional parameter of the device, such as the transfer of energy for charging an internal energy source. In other embodiments the sensor is a physical parameter sensor sensing a physical parameter of the patient, such as the food intake of the patient. The sensor according to any of the embodiments could be at least one of body temperature sensors, pressure sensors, blood pressure sensors, blood flow sensors, heartbeat sensors, breathing sensors, electrical conductivity sensors, pH sensor, light sensitive sensors, gas detection sensors and sensors sensing mechanical strain, such as a sensor adapted to sense any of contraction and relaxation of the Cardia.

According to one embodiment the device further comprises a feedback device for sending information from inside the patient's body to the outside thereof to give feedback information related to the functional parameter.

CONTROL UNIT

According to one embodiment the device is controlled by a control unit adapted to control the stretching device. The control unit could be adapted to control the stretching device, or two or more stretching devices, in response to signals from the sensor.

According to one embodiment the control unit controls the stretching devices from time to time such that one of the stretching devices at a first time stretches a first portion of the stomach wall and another of the stretching devices at a second time stretches a second portion of the stomach wall. The control unit could be adapted to be controllable from outside of the patient's body, e.g. through a wireless remote

control, which in turn could comprises at least one external signal transmitter, which could be adapted to transmit a wireless control signal comprising a frequency, amplitude, or phase modulated signal or a combination thereof. According to one embodiment the at least one transmitter is adapted to transmit a wireless control signal comprising a analogue or a digital signal, or a combination of an analogue and digital control signal, or a wireless control signal comprising an electric or magnetic field, or a combined electric and magnetic field.

The control unit according to any of the embodiments could be adapted to be implanted subcutaneously in the human patient, and could be adapted to control a hydraulic system.

The device could further comprise a transferring member for powering the control unit, the transferring member could comprise a fluid transferring member and/or an electrical lead.

According to another embodiment the device further comprises an external data communicator and an implantable internal data communicator communicating with the external data communicator. The internal communicator could be adapted to feed data related to the device for treating obesity or the patient back to the external data communicator or the external data communicator feeds data to the internal data communicator.

ENERGIZING

For energizing the device the device could further comprise a wireless energy transmitter transmitting energy by at least one wireless energy signal, such as a wave signal, e.g. a sound wave signals, ultrasound wave signals, electromagnetic wave signals, infrared light signals, visible light signals, ultra violet light signals, laser light signals, micro wave signals, radio wave signals, x-ray radiation signals and a gamma radiation signals. The wireless energy signal could further comprise an electric or magnetic field, or a combined electric and magnetic field.

According to yet another embodiment the device comprises an energy source adapted to power the device, which could comprise an internal energy source which in turn could be adapted to receive energy from an external energy source transmitting energy in a wireless mode. The internal energy source could further comprise an accumulator, at least one voltage level guard and/or at least one constant current guard.

The device could further comprise an energy-transforming device adapted to transform energy from a first form into a second form.

FIXATION

The apparatus according to any of the embodiments could comprise a fixating member, which could be adapted to fixate the stretching device to the stomach wall of the patient. The fixating member could be adapted to be in contact with sutures or staplers for fixating the stretching device to the stomach wall of the patient. The fixating member could comprise a net like structure, which could be adapted to promote growth in of human tissue for long term fixation to the stomach wall.

SYSTEM

The present invention also provides an obesity treatment system comprising a device for treating obesity as described above. The system may comprise a subcutaneous electric switch adapted to manually and non-invasively control a function of the device for treating obesity.

The system may comprise a hydraulic device having a hydraulic reservoir, wherein the device for treating obesity is adapted to non-invasively be regulated by manually pressing the hydraulic reservoir.

The system may comprise a wireless remote control for controlling a function of the device. The wireless remote control comprises at least one external signal transmitter and an internal signal receiver may be provided to be implanted in the patient. The

wireless remote control is adapted to transmit at least one wireless control signal for controlling the device. The wireless control signal may comprise a frequency, amplitude, or phase modulated signal or a combination thereof, and an analogue or a digital signal, or a combination of an analogue and digital signal. Alternatively, the wireless control signal comprises an electric or magnetic field, or a combined electric and magnetic field. The remote control may transmit a carrier signal for carrying the wireless control signal. The carrier signal may comprise digital, analogue or a combination of digital and analog signals. The remote control may transmit an electromagnetic carrier wave signal for carrying the digital or analog control signal.

The system may comprise a wireless energy transmitter for non-invasively energizing the device with wireless energy. The energy transmitter transmits energy by at least one wireless energy signal. The wireless energy signal may comprise a wave signal selected from the following: a sound wave signal, an ultrasound wave signal, an electromagnetic wave signal, an infrared light signal, a visible light signal, an ultra violet light signal, a laser light signal, a micro wave signal, a radio wave signal, an x-ray radiation signal and a gamma radiation signal. Alternatively, the wireless energy signal comprises an electric or magnetic field, or a combined electric and magnetic field. The wireless energy transmitter may transmit a carrier signal for carrying the wireless energy signal. The carrier signal may comprise digital, analogue or a combination of digital and analog signals.

The system may comprise an energy-transforming device for transforming the wireless energy from a first form into a second form energy. The energy-transforming device may directly during energy transfer operate the device with the second form energy. The second form energy may comprise a direct current or pulsating direct current, or a combination of a direct current and pulsating direct current. The second form energy may comprise an alternating current or a combination of a direct and alternating current. An accumulator may be provided, wherein the second form energy is used at least partly to charge the accumulator. The energy of the first or second form may comprise magnetic energy, kinetic energy, sound energy, chemical energy, radiant energy, electromagnetic energy, photo energy, nuclear energy or thermal energy. One of the energy of the first form and the

energy of the second form may be non-magnetic, non-kinetic, non-chemical, non-sonic, non-nuclear or non-thermal.

The system may comprise an energy source adapted to power the device. The energy source may comprise an internal energy source adapted to receive energy from an external energy source transmitting energy in a wireless mode. The internal energy source is charged by the energy in the wireless mode.

The system may comprise a feedback device for sending information from inside the patient's body to the outside thereof to give feedback information related to a functional parameter.

The system may comprise a sensor sensing a parameter, such as a functional parameter of the system, which is correlated to the transfer of energy for charging an internal energy source. An internal control unit may be provided for controlling the operation device of the device in response to the sensor sensing a functional parameter. Alternatively, sensor senses a physical parameter of the patient. The physical parameter may be one of body temperature, blood pressure, blood flow, heartbeats and breathing. The physical parameter sensor may be a pressure or motility sensor, or a sensor sensing measure, bending, stretching or food intake. The internal control unit may control the operation device in response to the sensor sensing the physical parameter. An internal control unit may be provided for receiving information from the sensor.

The operation device of the device may comprise a motor or a pump. Specifically, the operation device may comprise an electric motor. The operation device may be electrically powered, may be a hydraulic operation device or may be a pneumatic operation device. The transmitted energy, directly in its wireless form may affect the operation device to create kinetic energy to operate the stretching device of the device during energy transfer.

The system may comprise a feedback device for sending information from inside the patient's body to the outside thereof to give feedback information related to a functional parameter.

The system may comprise an external data communicator and an implantable internal data communicator communicating with the external data communicator, wherein the internal communicator is adapted to feed data related to the device for treating obesity or the patient back to the external data communicator or the external data communicator feeds data to the internal data communicator.

The system may comprise implantable electrical components including at least one voltage level guard and/or at least one constant current guard.

METHODS

The present invention also provides methods as listed below:

a) A method for surgically treating an obese patient, the method comprising the steps of:
cutting an opening in the abdominal wall of the patient,
dissecting an area around the stomach,
placing a device for treating obesity as described above, engaging the stomach wall of the patient, and suturing the stomach wall.

The method may further comprise the additional step of: postoperatively regulating the stretching device to stretch a part of the stomach wall to affect the appetite of the patient, wherein the step of regulating the stretching device is controlled from outside the patient's body.

The method may further comprise the additional steps of: placing an additional device for treating obesity as described above, engaging the stomach wall of the patient, stretching a first part of the stomach wall by means of the device for treating obesity, and stretching a second part of the stomach wall by means of the additional device for treating obesity.

b) A method for surgically placing a device for treating obesity in a patient via a laparoscopic abdominal approach, the method comprising the steps of:
inserting a needle or a tube like instrument into the abdomen of the patient's body,
using the needle or a tube like instrument to fill the patient's abdomen with gas

thereby expanding the patient's abdominal cavity,
placing at least two laparoscopic trocars in the patient's body,
inserting a camera through one of the laparoscopic trocars into the patient's abdomen,
inserting at least one dissecting tool through one of the at least two laparoscopic trocars and dissecting an intended placement area of the patient, and
placing a device for treating obesity as described above, engaging the stomach wall.

c) A method of using the system for treating obesity as described above, comprising the step of regulating the stretching device postoperatively to stretch a portion of the stomach wall to affect the appetite of the patient, wherein the step of regulating the stretching device is performed non-invasively. The stretching device comprises a mechanical or hydraulic stretching device. The hydraulic stretching device may comprise a reservoir, for moving gel or gas or fluid to or from the stretching device. The reservoir may be placed subcutaneously for being reached by the patients hand for moving fluid manually to or from the stretching device. The stretching device may be powered by an internal energy source for stretching or releasing the stretching device, wherein by means of a control device controlling the power from an internal control unit or from the outside the patient's body. A wireless energy transmitter for wireless transfer of energy powers the operation device to get the stretching device to directly during energy transfer cause the stretching device to stretch the stomach wall. A wireless energy transmitter for wireless transfer of energy charges the internal energy source. A reversed servo may be provided, wherein moving, in a closed hydraulic system, a small amount of fluid, a larger movement of fluid is achieved in a second larger closed hydraulic system, wherein the small amount of fluid is moved with by a higher force per area unit than the large volume. An invaginated stretching device in the fundus stomach wall of the patient is adapted to be adjustable, wherein the stretching device placed invaginated in the stomach fundus wall is adapted to be adjusted and stretching the stomach fundus wall thereby creating satiety.

The method may further comprise sending feedback information from inside the body to the outside thereof to give feedback related to the functional parameters of

the device. Alternatively, the method may further comprise sending feedback information from inside the body to the outside thereof to give feedback related to the physical parameters of the patient. The functional parameter of the device may be correlated to the transfer of energy for charging the internal energy source. The device is programmable from outside the patient's body.

The method may further comprise the steps of:
sensing a physical parameter of the patient or a functional parameter of the device, and
sending sensing information to a control unit adapted for regulating the stretching device.

The method may further comprise the steps of:
sensing a physical parameter of the patient or a functional parameter of the device, and
sending sensing information to a control unit adapted for regulating the charging of the internal energy source.

The method may further comprise subcutaneously placing a reversed servo having a small control reservoir and moving a small volume from the control reservoir with a higher force per area unit, creating a larger movement of the stretching device with less force per area unit.

The method may further comprise performing the non-invasive regulation by manually pressing a subcutaneous switch.

The method may further comprise performing the non-invasive regulation by a wireless remote control.

The method may further comprise performing the non-invasive regulation by a wireless energy transmitter.

The method may further comprise powering the device for treating obesity by an internal energy source.

The method may further comprise powering the device for treating obesity by an external energy source transmitting wireless energy, wherein the energy source comprises an external energy source transmitting wireless energy.

The method may further comprise transmitting wireless energy from an external energy source to charge a rechargeable internal energy source.

d) A method of using a device as described above, wherein the stretching device comprises a main body including a large chamber in contact with one or more smaller reservoirs/chambers adapted to stretch the stomach wall, wherein the chambers are adapted to communicate with fluid or air being moved between the chambers.

e) A method of using a device as described above, wherein the large chamber are adapted to, with its main volume to be the stretching device's most important volume and wherein, the small chambers are as the stretching devices stretching the stomach wall to treat obesity, wherein the main chamber is communicating with fluid or gel to the small chambers causing the stretching effect in the stomach fundus wall thereby treating obesity.

f) A method of using a device as described above, comprising treating reflux disease by invaginating the large chamber with its main volume in the fundus stomach wall thereby restricting movement of the stomach notch towards the diafragm muscle of the patient, and stretching the stomach fundus wall using the small chambers, communicating with fluid or air from the large chamber to the small chambers causing a stretching effect in the stomach fundus wall thereby treating obesity.

A gastroscopic method of treating obesity of a patient using a device adapted to stretch a part of the stomach wall of the patient is provided. The method comprises the steps of: inserting the device into the stomach of the patient through the esophagus, placing the device in contact with the stomach wall, fixating the device to the stomach wall such that the device can stretch a part of the stomach wall.

According to one embodiment the step of fixating the device comprises the steps of: fixating a first portion of the device to a first part of the stomach wall, and fixating a second portion of the device to a second part of the stomach wall. The step of fixating the first and second portion of the device could comprise the step of invaginating the first and second portion with stomach to stomach sutures or staples.

According to one embodiment the method comprises the additional steps of: placing a second device adapted to stretch a portion of the stomach wall in contact with the stomach, fixating the second device to the stomach wall, stretching a first portion of the stomach wall using the first device, and stretching a second part of the stomach wall using the second device.

According to one embodiment the stretching of the second portion comprises the step of: time delaying stretching the second part, with a predetermined time delay.

The method according to any of the embodiment could further comprise the steps of: inserting a gastroscope into the stomach of the patient, pushing a portion of the stomach wall to prepare a pouch on the outside of the stomach, inserting the device into the pouch, placed on the inside of the stomach wall, suturing or stapling to enclose the device in the pouch before or after the insertion of the device into the pouch.

According to one embodiment the method further comprises the steps of: inserting a gastroscope into the stomach of the patient, pulling a portion of the stomach wall to prepare a pouch on the inside of the stomach, creating a hole in the stomach wall into the pouch, inserting the device into the pouch, through the hole in the stomach wall, suturing or stapling the pouch, before or after the insertion of the device through the hole.

The method could further comprise the step of placing a transferring member from the device to a control unit, which could be a fluid transferring member and/or a member adapted to transfer electrical power.

The method could further comprise the step of placing a control unit, which can be placed subcutaneously in the patient.

According to one embodiment the step of placing a transferring member from the device to a control unit comprises the steps of: cutting an opening in the abdomen of the patient, connecting the transferring member to the control unit, inserting the control unit into the opening in the skin of the patient, and fixating the control unit subcutaneously.

According to one embodiment the method further comprises the step of placing a transferring member from the device to a control unit comprises the steps of: cutting an opening in the abdomen of the patient, connecting the transferring member to the control unit, inserting the control unit into the opening in the skin of the patient, to be placed in the abdominal cavity. The step of placing the control unit could comprise the steps of: fixating the control unit to the abdominal wall.

STRECHING

According to one embodiment of the method according to any of the embodiments the method comprises the additional step of postoperatively and non-invasively regulating the device to stretch a portion of the stomach wall to affect the appetite of the patient.

The step of postoperatively and non-invasively regulating the device to stretch a part of the stomach wall comprises the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall.

According to one embodiment the step of regulating the device is performed from outside the patient's body, whereas according to other embodiments the method step of regulating the device comprises regulating the device by the implantable control unit from inside the body.

According to one embodiment the step of regulating the device comprises from time to time regulate different devices to at a first time stretch a first portion of the stomach wall and at a second time stretch a second portion of the stomach wall.

According to one embodiment the method comprises placing two or more devices in contact with the stomach and from time to time regulate different device to stretch a part of the stomach wall.

MANUELL

The step of placing a device in contact with the stomach could comprise placing a device adapted to have a variable volume in contact with the stomach, the volume could be variable through at least one moveable wall portion, which in turn could be at least one elastic wall portion.

The apparatus according to any of the embodiments could have an essentially round shape, or an egg shape.

The device could further comprise a subcutaneous switch, and the method could further comprise pressing the switch for manually and non-invasively regulating the device.

According to one embodiment the step of regulating the device comprises the step of moving a fluid from a reservoir to the device.

According to one embodiment the device could comprise a pump, and the method could comprise the step of; pumping a fluid from the reservoir to the device to stretch the stomach wall.

The step of moving a fluid from a reservoir to the device could comprise the step of moving a wall portion of the reservoir.

The step of regulating the device could comprise the step of manually pressing the reservoir, which could be placed subcutaneously or in the abdomen.

MECHANICAL

According to one embodiment the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall comprises the step of moving fluid into a chamber having a variable volume.

AUTOMATIC

According to one embodiment the step of placing a device in contact with the stomach comprises placing a device adapted to have a variable volume in contact with the stomach.

The device could be adapted to have a variable volume comprising at least one moveable wall portion, which could comprise at least one elastic wall portion.

The device could have an essentially round shape, or an essentially egg-like shape.

The device could further comprise a subcutaneous switch, and the method could further comprise pressing the switch for non-invasively regulating the device.

The step of regulating the device could comprise the step of moving a fluid from a reservoir to the device, which in turn could comprise the steps of: operating a pumping device, the pumping device moving the fluid from the reservoir to the device, and the device expanding in volume and thereby stretching the portion of the stomach wall.

The method could further comprise the step of the fluid flowing back from the device to the reservoir, thereby releasing the stretching of the stomach wall.

According to one embodiment the method could comprise the step of: sensing a variable using an implantable sensor, interpreting the sensed variable and using the interpreted variable to control the device.

According to another embodiment the step of controlling the device comprises the steps of: operating a pumping device, for moving the fluid from a reservoir to the device, and the device expanding in volume and thereby stretching the portion of the stomach wall.

According to one embodiment the method comprises the step of the fluid flowing back from the device to the reservoir thereby releasing the stretching of the stomach wall.

The step of sensing a variable could comprise the step of sensing a variable connected to the food intake of the patient, which step could comprise the step of sensing a variable connected to the food intake of the patient is resulting in a increased stretching of the stomach portion, and thereby feeling of satiety by the patient.

MECHANICAL

According to one embodiment the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall comprises the step of moving fluid into a chamber having a variable volume.

The method could further comprise the step of moving fluid from a reservoir to the chamber having a variable volume. The step of moving a fluid from a reservoir to the device could comprise the steps of: operating a pumping device, the pumping device moving the fluid from the reservoir to the device, and the device expanding in volume and thereby stretching the portion of the stomach wall.

According to one embodiment the step of operating the pumping device comprises the step of operating the pumping device using a wireless remote control.

According to one embodiment the method further comprises the step of the fluid flowing back from the device to the reservoir thereby releasing the stretching of the stomach wall.

According to one embodiment the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall comprises the step of operating a motor adapted increase the distance between the first part of the stomach wall and the second part of the stomach wall, thereby stretching a portion of the stomach wall. Operating the motor could comprise the step of operating the motor using a wireless remote control.

According to one embodiment the method further comprises the step of: sensing a variable using an implantable sensor, interpreting the sensed variable, using the interpreted variable to control the device.

According to one embodiment the method comprises the steps of: operating a pumping device, the pumping device moving the fluid from a reservoir to the chamber, and the chamber being filled with the fluid increasing the distance between the first part of the stomach wall and the second part of the stomach wall and thereby stretching the portion of the stomach wall.

According to one embodiment the method further comprises the step of the fluid flowing back from the device to the reservoir thereby releasing the stretching of the stomach wall.

According to one embodiment the step of sensing a variable comprises the step of sensing a variable connected to the food intake of the patient.

According to one embodiment the method further comprises the step of: sensing a variable using an implantable sensor, interpreting the sensed variable, using the interpreted variable to control the device. The step of sensing a variable could comprise the step of sensing a variable connected to the food intake of the patient.

The step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall could comprise the step of operating a mechanical device adapted increase the distance between the first part of the stomach wall and the second part of the stomach wall, thereby stretching a portion of the stomach wall.

According to one embodiment the device comprises mechanical members adapted to move for stretching a portion of the stomach wall between the first and second part of the stomach wall. The mechanical members could be moving for stretching a portion of the stomach wall using the motor.

According to one embodiment the step of stretching a portion of the stomach wall comprises the step of operating at least one mechanical device for stretching a portion of the stomach wall.

According to one embodiment the method comprises the step of invaginating the mechanical device in the stomach wall with stomach to stomach sutures.

According to one embodiment the method comprises the step of expanding the mechanical device in the invaginated stomach wall to stretch the stomach wall.

According to one embodiment the method comprises a motor, expanding the stomach wall, according to another embodiment the method comprise a memory metal, expanding the stomach wall.

According to another embodiment the method comprises a hydraulically controlled mechanical device, expanding the stomach wall.

PLACING

According to one embodiment the step of placing a device comprises placing the device in connection with the stomach wall, on the outside thereof, which could comprise the step of
placing the device in the stomach fundus wall of the patient.

The step of placing a device could comprise the step of placing the device in connection with the stomach wall, on the inside thereof, which could comprise the step of
placing the device in the stomach fundus wall of the patient.

FIXATION

The step of fixating the at least one device comprises suturing or stapling the at least one device to the stomach wall.

The step of fixating the at least one device could comprise in-vaginating in the stomach wall with stomach-to-stomach sutures or staples, in other embodiments the step of fixating the at least one device could comprise placing a mesh adapted to be fixated to the stomach wall by means of fibrotic tissue.

The mesh could be additionally supported by sutures or staples and could comprise a structure adapted to promote the growth in of human tissue, such as a net like structure.

An additional method is provided, the method comprising the steps of: creating a hole in the stomach wall; introducing the stretching device into the stomach by means of a instrument; moving the device through the hole and placing it on the outside of the stomach wall; creating a pouch of a portion of the stomach wall inside the stomach cavity, with the device placed against the outside of the stomach wall;

invaginating the device in the pouch to the stomach wall; and sealing the hole, preferably with sutures or staples.

An additional method is provided, the method comprising the steps of: creating a hole in the stomach wall; creating, by means of the instrument, a pouch of a portion of the stomach wall on the inside of the stomach cavity; introducing the device into the stomach by means of the instrument; moving the device through the hole and placing it on the outside of the stomach wall; introducing the device by means of the instrument into the pouch; invaginating the device to the stomach wall; and sealing the hole, preferably with sutures or staples.

According to one embodiment the method, further comprises providing a device for regulating the stretching device from the outside of the patient's body; and operating the device to regulate the device.

According to another embodiment the method further comprises the steps of: cutting the skin of the patient, inserting a tube into the abdominal cavity of the patient, connecting the tube to the volume filling device, filling the device with fluid injected through the tube.

According to another embodiment the method further comprises the steps of: subcutaneously placing an injection port and connecting the tube to the injection port.

According to another embodiment the method further comprises the step of providing a tube connected to the stretching device through the hole and further up to the abdominal wall or passing through the abdominal wall.

According to another embodiment the method further comprises the steps of: cutting the skin of the patient, receiving the tube from the abdominal cavity of the patient, connected to the stretching device, and filling the device with fluid injected through the tube.

According to another embodiment the method the method further comprises the steps of: subcutaneously placing an injection port, and connecting the tube to the injection port.

INSTRUMENT

An instrument for placing a device adapted to stretch a part of the stomach wall of a patient in connection with the stomach wall is further provided. The instrument comprises: a holding member adapted to releaseably hold the device, an insertion member adapted to insert the device through the stomach wall, and a fixating member, adapted to assist in the fixation of the device to the stomach wall, on the outside thereof.

The instrument could further comprise a cutting member for cutting a hole in the stomach wall, an optical member for viewing in the area of the stomach. The fixation member could be adapted for suturing the device to the stomach wall, on the inside thereof, or for stapling the device to the stomach wall, on the inside thereof, or for invaginating at least a part of the device in the stomach wall with stomach-to-stomach sutures, on the inside thereof, or for invaginating at least a part of the device in the stomach wall with stomach-to-stomach staplers, on the inside thereof, however the instrument could be adapted to perform the method from the outside thereof.

The instrument could further comprise a special holding device, which could comprise a special holding device adapted to hold the stomach using vacuum or using mechanical holding members.

A surgical or laparoscopic method of treating obesity of a patient using a device adapted to stretch a portion of the stomach wall of the patient is provided. The method comprises the steps of: cutting a hole in the abdominal wall of the patient, dissecting an area around the stomach, placing the device in contact with the stomach, and fixating, direct or indirect, through invagination of the stomach wall the, device to the stomach wall such that the device can stretch a portion of the stomach wall.

According to one embodiment the method the step of fixating the device comprises the steps of: fixating a first portion of the device to a first part of the stomach wall, and fixating a second portion of the device to a second part of the stomach wall, wherein the first and second portion of the device is fixated, such that the device is adapted to stretch a portion of the stomach wall between the first and second part of the stomach wall.

According to another embodiment, the device is a first device, and the method comprises the additional steps of: fixating direct or indirect through invagination of the stomach wall a second device adapted to stretch a part of the stomach wall in contact with the stomach, fixating the second device to the stomach wall, stretching a first portion of the stomach wall using the first device, and stretching a second portion of the stomach wall using the second device.

According to another embodiment the method comprises the additional step of postoperatively and non-invasively regulating the device to stretch a portion of the stomach wall to affect the appetite of the patient.

A surgical or laparoscopic method of treating obesity of a patient using a device adapted to stretch a portion of the stomach wall of the patient is further provided. The method comprises the steps of: inserting a needle or tube like instrument into the abdomen of the patients body, using the needle or tube like instrument to fill the patient's body with gas, placing at least two laparoscopic trocars in the patient's body, inserting a camera through one of the laparoscopic trocars in the patient's body, inserting at least one dissecting tool through one of the at least two laparoscopic trocars, dissecting an area of the stomach, introducing a device into the abdominal cavity, placing the device on the outside of the stomach wall, engaging the stomach wall.

According to another embodiment the method comprises the step of postoperatively and noninvasively regulating the device to stretch a part of the stomach wall

comprises the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall.

According to another embodiment the step of regulating the device is performed from outside the patient's body.

According to another embodiment the step of regulating the device comprises from time to time regulate different device to at a first time stretch a first portion of the stomach wall and at a second time stretch a second portion of the stomach wall.

According to another embodiment the method comprises placing two or more device in contact with the stomach and from time to time regulate different device to stretch a portion of the stomach wall. The step of fixating the first and second portion of the device could further comprise the step of invaginating the first and second portion with stomach to stomach sutures or staplers.

According to another embodiment, the device further comprises an implantable control unit, wherein the method step of regulating the device comprises regulating the device by the implantable control unit from inside the body.

According to another embodiment the stretching of the second portion comprises the step of:
time delaying stretching the second part, with a predetermined time delay.

MANUELL

According to another embodiment the step of placing a device in contact with the stomach comprises placing a device adapted to have a variable volume in contact with the stomach, which could be regulated by means of at least one moveable wall portion, which in turn could be an elastic wall portion. The device could have an essentially round shape, or egg shape.

According to another embodiment the device comprises a subcutaneous switch, and the method further comprises pressing the switch for manually and non-invasively regulating the device. Regulating the device could comprise the step of moving a fluid from a reservoir to the device.

According to another embodiment the device further comprises a pump, and the method further comprises the step of; pumping a fluid from the reservoir to the device to stretch the stomach wall.

According to another embodiment the step of moving a fluid from a reservoir to the device comprises the step of moving a wall portion of the reservoir, which could be done through the step of manually pressing the reservoir.

The reservoir, according to any of the embodiments could be placed subcutaneously or in the abdomen.

MECHANICAL

According to another embodiment the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall comprises the step of moving fluid into a chamber having a variable volume.

AUTOMATIC

According to another embodiment the step of placing a device in contact with the stomach comprises placing a device adapted to have a variable volume in contact with the stomach.

The device adapted to have a variable volume could comprise at least one moveable wall portion, which in turn could be an elastic wall portion.

The apparatus according to any of the embodiments could comprise a subcutaneous switch, and the method could further comprise pressing the switch for noninvasively regulating the device.

According to another embodiment the step of regulating the device comprises the step of moving a fluid from a reservoir to the device. The step of moving a fluid from a reservoir to the device could comprise the steps of: operating a pumping device, for moving the fluid from the reservoir to the device, and the device expanding in volume and thereby stretching the portion of the stomach wall.

According to another embodiment the method further comprises the step of the fluid flowing back from the device to the reservoir, thereby releasing the stretching of the stomach wall.

According to another embodiment the method further comprises the step of: sensing a variable using an implantable sensor, interpreting the sensed variable, using the interpreted variable to control the device.
According to another embodiment the step of controlling the device comprises the steps of: operating a pumping device, for moving the fluid from a reservoir to the device, and the device expanding in volume and thereby stretching the portion of the stomach wall.

According to another embodiment the method further comprises the step of the fluid flowing back from the device to the reservoir thereby releasing the stretching of the stomach wall.

The step of sensing a variable could comprise the step of sensing a variable connected to the food intake of the patient, which could result in an increased stretching of the stomach portion, and thereby
the feeling of satiety by the patient.

MECHANICAL

According to another embodiment the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall could comprise the step of moving fluid into a chamber having a variable volume.

According to another embodiment the step moving fluid into a chamber comprises the step of moving fluid from a reservoir to the chamber having a variable volume.

According to another embodiment the step of moving a fluid from a reservoir to the device comprises the steps of: operating a pumping device, the pumping device moving the fluid from the reservoir to the device, and the device expanding in volume and thereby stretching the portion of the stomach wall.

According to another embodiment the step of operating the pumping device comprises the step of operating the pumping device using a wireless remote control.

According to another embodiment the method further comprises the step of the fluid flowing back from the device to the reservoir thereby releasing the stretching of the stomach wall.

According to another embodiment the step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall comprises the step of operating a motor adapted increase the distance between the first part of the stomach wall and the second part of the stomach wall, thereby stretching a portion of the stomach wall.

The step of operating the motor could comprise the step of operating the motor using a wireless remote control.

According to another embodiment the method could further comprises the step of: sensing a variable using an implantable sensor, interpreting the sensed variable, using the interpreted variable to control the device.

According to another embodiment the step of controlling the device could comprise the steps of: operating a pumping device, for moving the fluid from a reservoir to the chamber, and the chamber being filled with the fluid increasing the distance between the first part of the stomach wall and the second part of the stomach wall and thereby stretching the portion of the stomach wall.

According to another embodiment the method further comprise the step of the fluid flowing back from the device to the reservoir thereby releasing the stretching of the stomach wall.

According to another embodiment the step of sensing a variable comprises the step of sensing a variable connected to the food intake of the patient.

According to another embodiment the method further comprises the step of: sensing a variable using an implantable sensor, interpreting the sensed variable, using the interpreted variable to control the device. The step of sensing a variable could comprise the step of sensing a variable connected to the food intake of the patient. The step of increasing the distance between the first part of the stomach wall and the second part of the stomach wall could comprise the step of operating a mechanical device adapted increase the distance between the first part of the stomach wall and the second part of the stomach wall, thereby stretching a portion of the stomach wall. The first and second portions of the device could comprise mechanical members adapted to move for stretching a portion of the stomach wall between the first and second part of the stomach wall.

According to another embodiment the method comprises a motor, wherein the mechanical members is moving for stretching a portion of the stomach wall using the motor.

According to another embodiment the step of stretching a portion of the stomach wall comprises the step of operating at least one mechanical device for stretching a portion of the stomach wall.

According to another embodiment the step of invaginating the mechanical device in the stomach wall comprises invaginating with stomach to stomach sutures.

According to another embodiment the method further comprises the step of expanding the mechanical device in the invaginated stomach wall to stretch the stomach wall.

According to another embodiment the invaginated mechanical device comprises a motor, expanding the invaginated mechanical device.

The device could further comprise a memory metal or a hydraulically controlled mechanical device, expanding the stomach wall.

PLACING

According to another embodiment the step of placing a device comprises placing the device in connection with the stomach wall, on the outside thereof, or in the stomach fundus wall, or in connection with the stomach wall, on the inside thereof.

According to another embodiment the step of placing a device in connection with the stomach wall, on the inside thereof could comprise the steps of: cutting a hole in the stomach wall, and inserting the device through the hole in the stomach wall.

According to another embodiment the step of placing a device comprises placing the device in the stomach fundus wall of the patient.

FIXATION

According to another embodiment the step of fixating the at least one device comprises suturing or stapling the at least one device to the stomach wall, e.g. by means of stomach-to-stomach sutures or staplers.

The step of fixating the at least one device could comprise placing a mesh adapted to be fixated to the stomach wall by means of fibrotic tissue. The mesh could be additionally supported by sutures or staplers and adapted to promote the growth in of human tissue, such as a net like structure.

CONTROL UNIT

According to another embodiment the method could comprise the step of placing a transferring member from the device to a control unit. The transferring member could comprise a fluid transferring member, or a transferring member adapted to transfer electrical power.

According to another embodiment the method further comprises the step of placing the control unit, which could be placed subcutaneously in the patient.

According to another embodiment the step of placing the control unit subcutaneously further comprises the steps of: inserting the control unit into the hole in the abdomen of the patient, and fixating the control unit.

An additional method is also provided, the method comprising the steps of: creating a hole in the stomach wall; introducing the stretching device into the abdomen; moving the device through the hole and placing it on the inside of the stomach wall; creating a pouch of a portion of the stomach wall outside the stomach cavity, with the device placed against the inside of the stomach wall; invaginating the device in the pouch to the stomach wall; and sealing the hole, preferably with sutures or staples.

According to another embodiment the method according to any of the embodiments could comprise the steps of: creating a hole in the stomach wall; moving the device through the hole and placing it on the inside of the stomach wall; introducing the device by means of the instrument into the pouch; and sealing the hole, preferably with sutures or staplers.

According to another embodiment the method further comprises providing a device for regulating the stretching device from the outside of the patient's body; and operating the device to regulate the device.

According to another embodiment the device comprises an implantable control unit and the method further comprises the steps of; providing an implanted control unit for regulating the stretching device from the inside of the patient's body; and operating the device to regulate the device.

The method could further comprise the steps of subcutaneously placing an injection port and connecting a tube connected to the device to the injection port.

According to another embodiment the method further comprises the step of providing a tube connected to the stretching device through the hole and further up to the abdominal wall or passing through the abdominal wall.

According to another embodiment the method further comprises the steps of: receiving a tube from the abdominal cavity of the patient, connected to the stretching device, and filling the device with fluid injected through the tube.

According to another embodiment the method could further comprise the steps of: subcutaneously placing an injection port, and connecting the tube to the injection port.

The method could further comprise the additional step of postoperatively and non-invasively regulating the device to stretch a part of the stomach wall to affect the appetite of the patient.

According to another embodiment the method comprises the additional step of filling the device with a fluid.

According to another embodiment the method could comprise the additional step of placing an internal control unit within the patient's body.

According to one embodiment the method further comprises the additional step of connecting the internal control unit to the device, which could be done hydraulically or using electrical wires.

An additional surgical or laparoscopic method of treating obesity of a patient using a device adapted to stretch a portion of the stomach wall of the patient is provided. The method comprising the steps of: inserting a needle or tube like instrument into the abdomen of the patients body, using the needle or tube like instrument to fill the patient's body with gas, placing at least two laparoscopic trocars in the patient's body, inserting a camera through one of the laparoscopic trocars in the patient's body, inserting at least one dissecting tool through one of the at least two laparoscopic trocars, dissecting an area of the stomach, introducing a device into the abdominal cavity, invaginating the device on the outside of the stomach wall with stomach to stomach sutures or staplers and postoperatively stretching the invaginated stomach wall portion by operating the device.

According to another embodiment the method comprises the additional step of; introducing a second or more device into the abdominal cavity, invaginating the second or more device on the outside of the stomach wall with stomach to stomach sutures or staplers and postoperatively stretching the invaginated stomach wall portion by operating the second or more device.

According to another embodiment the method comprises the additional step of; postoperatively stretching the invaginated stomach wall portion at the first or second or more parts of the device independent from each other.

An additional surgical or laparoscopic method of treating obesity of a patient using a device adapted to stretch a portion of the stomach wall of the patient is provided. The method comprises the steps of: inserting a needle or tube like instrument into the abdomen of the patients body, using the needle or tube like instrument to fill the patient's body with gas, placing at least two laparoscopic trocars in the patient's body, inserting a camera through one of the laparoscopic trocars in the patient's body, inserting at least one dissecting tool through one of the at least two laparoscopic trocars, dissecting an area of the stomach, introducing a device into the abdominal cavity, invaginating a first part of the stretching device placed on the outside of the stomach wall with stomach to stomach sutures or staplers and invaginating a second part of the stretching device, separate from the first part, placed on the outside of the stomach wall with stomach to stomach sutures or staplers and postoperatively stretching the stomach wall portion between the first and second part by operating the device.

According to another embodiment the method comprises the additional step of; introducing a second or more device into the abdominal cavity, invaginating a first part of the stretching second or more device placed on the outside of the stomach wall with stomach to stomach sutures or staplers, invaginating a second part of the second or more stretching device, separate from the first part, placed on the outside of the stomach wall with stomach to stomach sutures or staplers, and postoperatively stretching the stomach wall portion between the first and second part by operating the second or more device.

According to another embodiment the method comprises the additional steps of; invaginating a third or more part of the stretching device placed on the outside of the stomach wall, separate from the first or second part, with stomach to stomach sutures or staplers and postoperatively stretching the stomach wall portion between any

combination of the first and second part and third or more parts, by operating the device.

A surgical method of treating obesity of a patient using a device adapted to stretch a portion of the stomach wall of the patient, the method comprising the steps of: cutting the skin of a human patient, dissecting an area of the stomach, introducing a device into the abdominal cavity, invaginating the device on the outside of the stomach wall with stomach to stomach sutures or staplers, and postoperatively stretching the invaginated stomach wall portion by operating the device.

The method could further comprise the additional step of; introducing a second or more device into the abdominal cavity, invaginating the second or more device on the outside of the stomach wall with stomach to stomach sutures or staplers, and postoperatively stretching the invaginated stomach wall portion by operating the second or more device.

According to another embodiment the method comprises the additional steps of; postoperatively stretching the invaginated stomach wall portion at the first or second or more parts of the device independent from each other.

An additional surgical method of treating obesity of a patient using a device adapted to stretch a portion of the stomach wall of the patient is provided. The method comprising the steps of: cutting the skin of a human patient, dissecting an area of the stomach, introducing a device into the abdominal cavity, invaginating a first part of the stretching device placed on the outside of the stomach wall with stomach to stomach sutures or staplers, invaginating a second part of the stretching device, separate from the first part, placed on the outside of the stomach wall with stomach to stomach sutures or staplers, and postoperatively stretching the stomach wall portion between the first and second part by operating the device.

According to another embodiment the method comprises the additional step of; introducing a second or more device into the abdominal cavity, invaginating a first

part of the stretching second or more device placed on the outside of the stomach wall with stomach to stomach sutures or staplers, invaginating a second part of the second or more stretching device, separate from the first part, placed on the outside of the stomach wall with stomach to stomach sutures or staplers, and postoperatively stretching the stomach wall portion between the first and second part by operating the second or more device.

According to another embodiment the method further comprises the steps of invaginating a third or more part of the stretching device placed on the outside of the stomach wall, separate from the first or second part, with stomach to stomach sutures or staplers, and postoperatively stretching the stomach wall portion between any combination of the first and second part and third or more parts, by operating the device.

According to another embodiment the method comprises the additional steps of postoperatively and noninvasively regulating the device to stretch a part of the stomach wall to affect the appetite of the patient.

The method according to any embodiment could further comprise the step of filling the device with a fluid.

According to another embodiment the method comprises the additional step of placing an internal control unit within the patient's body, and connecting the internal control unit to the device, which could be done hydraulically or using electrical wires.

INSTRUMENT

An instrument for placing a device adapted to stretch a part of the stomach wall of a patient in connection with the stomach wall is further provided. The instrument comprises: a holding member adapted to releaseably hold the device, and a fixating

member, adapted to assist in the fixation of the device to the stomach wall, on the outside thereof.

The instrument could further comprise an optical member for viewing in the area of the stomach.

The instrument could comprise a fixation member adapted to suturing the device to the stomach wall, on the outside thereof.

According to another embodiment the fixation member is adapted for stapling the device to the stomach wall, on the outside thereof, and in other embodiments the fixation member is adapted for invaginating at least a part of the device in the stomach wall with stomach-to-stomach sutures, on the outside thereof.

According to another embodiment the fixation member could be adapted for invaginating at least a part of the device in the stomach wall with stomach-to-stomach staplers, on the outside thereof.

An instrument for placing a device adapted to stretch a part of the stomach wall of a patient in connection with the stomach wall is further provided. The instrument comprises: a holding member adapted to releaseably hold the device, an insertion member adapted to insert the device through the stomach wall, and a fixating member, adapted to assist in the fixation of the device to the stomach wall, on the inside thereof.

The instrument could further comprise a cutting member for cutting a hole in the stomach wall, an optical member for viewing in the area of the stomach. The fixation member could be adapted for suturing the device to the stomach wall, on the inside thereof, or for stapling the device to the stomach wall, on the inside thereof, or for invaginating at least a part of the device in the stomach wall with stomach-to-stomach sutures, on the inside thereof, or for invaginating at least a part of the device in the stomach wall with stomach-to-stomach staplers, on the inside thereof.

The instrument could further comprise a special holding device, which could comprise a special holding device adapted to hold the stomach using vacuum or using mechanical holding members.

A stretching device, adapted to post-operatively be adjustable and comprising at least one expandable section, wherein the stretching device is adapted to be adjustable between a first collapsed state and a second expanded state. In the first collapsed state the expandable section is collapsed, and in the second expanded state, the expandable section is expanded. The outer surface of said expandable section does at least partly comprise a surface structure having elevated areas alternating with lowered areas. The expandable section is adapted to have, in at least one of said first collapsed and second expanded states a first distance between adjacent elevated areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent elevated areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said stretching device. The expandable section further comprising connecting areas between adjacent elevated and lowered areas, further adapted to have, in at least one of said first collapsed and second expanded states, a second distance between adjacent connecting areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent connecting areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said stretching device.

According to one embodiment the expandable section is hollow or comprises a hollow body.

According to another embodiment the stretching device is substantially completely hollow or comprises a hollow body extending along substantially the complete length and/or complete volume of said stretching device.

Fibrotic tissue can often have an extension or thickness of about 0,5 mm to about 1,5 mm and hence the distances between relevant surfaces of the elements of

the surface structure are suitably greater than about 3 mm, hence greater than about 2 x 1,5 mm. But depending on the circumstances also distances greater than about 1,0 mm to about 3 mm may be sufficient. In cases where the fibrotic tissue can be expected to have an extension or thickness greater than about 1.5 mm the distances between relevant surfaces of the elements of the surface structure are adapted in a suitable manner.

The surface structure may comprise elevated and lowered areas and it may be suitable that also a distance between the different planes of the elevated and lowered areas is bigger than a certain threshold to facilitate the collapsible and/or expandable functionality of the stretching device. If said distance is too small, the collapsible and/or expandable functionality of the stretching device may be limited. A suitable interval for said distance is around 0,5 to 10 mm, more suitable around 2-8 mm and most suitable around 3-7 mm The surface structure may comprise different geometrical elements or shapes and any combination of such elements or shapes as long as the above mentioned conditions for the distances can be met. The surface structure may e.g. comprise ridges and grooves of different shapes. The ridges and grooves may each have a cross-section that is e.g. wedge-shaped, polygonal, square-formed, pyramidal-shaped, truncated pyramidal-shaped or. Further may the ridges and grooves have cross-sections of different shapes. The surface structure may as well in general comprise a bellows-shaped structure or a surface structure where geometrical objects of the same or different kind(s) are placed on a surface. The geometrical objects may be practically randomly placed on the surface or according to some scheme.

One type of stretching devices where this type of surface structure may be suitable, is stretching devices where the stretching device should have the ability to change shape and/or size substantially. Hence, this is a case where the presence of fibrotic tissue substantially could hinder or impede the function of the stretching device. But the surface structure may be used by any stretching device where the characteristics of the surface structure would be advantageous for the stretching device.

SURFACE STRUCTURE

The surface structure of the various implants of the invention will now be described.

The present invention concerns an implant, adapted to post-operatively be adjustable and comprising at least one expandable section, wherein the implant is adapted to be adjustable between a first collapsed state and a second expanded state. In the first collapsed state the expandable section is collapsed, and in the second expanded state, the expandable section is expanded. The outer surface of said expandable section does at least partly comprise a surface structure having elevated areas alternating with lowered areas. The expandable section is adapted to have, in at least one of said first collapsed and second expanded states a first distance between adjacent elevated areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent elevated areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said implant. The expandable section further comprising connecting areas between adjacent elevated and lowered areas, further adapted to have, in at least one of said first collapsed and second expanded states, a second distance between adjacent connecting areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent connecting areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said implant.

According to one embodiment the expandable section is hollow or comprises a hollow body.

According to another embodiment the implant is substantially completely hollow or comprises a hollow body extending along substantially the complete length and/or complete volume of said implant.

Fibrotic tissue can often have an extension or thickness of about 0,5 mm to about 1,5 mm and hence the distances between relevant surfaces of the elements of the surface structure are suitably greater than about 3 mm, hence greater than about 2 x 1,5 mm. But depending on the circumstances also distances greater than about 1,0

mm to about 3 mm may be sufficient. In cases where the fibrotic tissue can be expected to have an extension or thickness greater than about 1.5 mm the distances between relevant surfaces of the elements of the surface structure are adapted in a suitable manner.

The surface structure may comprise elevated and lowered areas and it may be suitable that also a distance between the different planes of the elevated and lowered areas is bigger than a certain threshold to facilitate the collapsible and/or expandable functionality of the implant. If said distance is too small, the collapsible and/or expandable functionality of the implant may be limited. A suitable interval for said distance is around 0,5 to 10 mm, more suitable around 2-8 mm and most suitable around 3-7 mm The surface structure may comprise different geometrical elements or shapes and any combination of such elements or shapes as long as the above mentioned conditions for the distances can be met. The surface structure may e.g. comprise ridges and grooves of different shapes. The ridges and grooves may each have a cross-section that is e.g. wedge-shaped, polygonal, square-formed, pyramidal-shaped, truncated pyramidal-shaped or. Further may the ridges and grooves have cross-sections of different shapes. The surface structure may as well in general comprise a bellows-shaped structure or a surface structure where geometrical objects of the same or different kind(s) are placed on a surface. The geometrical objects may be practically randomly placed on the surface or according to some scheme.

One type of implants where this type of surface structure may be suitable, is implants where the implant should have the ability to change shape and/or size substantially. Hence, this is a case where the presence of fibrotic tissue substantially could hinder or impede the function of the implant. But the surface structure may be used by any implant where the characteristics of the surface structure would be advantageous for the implant.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will now be described in more detail by way of non-limiting examples, and with reference to the accompanying drawings, in which:

Figs. 1A-C are schematic views of various embodiments of an apparatus for treating Gastroesophageal Reflux Disease implanted in a human patient.

Figs. 2A-B are schematic views of various embodiments of an apparatus for treating Gastroesophageal Reflux Disease implanted in a human patient.

Figs. 3A-B are schematic views of various embodiment of an apparatus for treating Gastroesophageal Reflux Disease implanted in a human patient.

Figs. 4A-B are schematic views of embodiments of an apparatus for treating Gastro-esophageal Reflux Disease and obesity implanted in a human patient.

Fig. 5 is a schematic view of an embodiment of an apparatus for treating Gastro-esophageal Reflux Disease implanted in a human patient.

Figs. 6A-D and 7-9 show alternative shapes of a movement restriction device for treating Gastroesophageal Reflux Disease adapted to be implanted in a human patient.

Fig. 10 is an overall view of a patient with an implanted movement restriction device for treating Gastroesophageal Reflux Disease.

Figs. 11 – 27 are schematic views of various ways of powering an apparatus for treating Gastroesophageal Reflux Disease.

Figs. 28 – 34 are schematic views of various ways of arranging the hydraulic or pneumatic powering of an apparatus of the invention for treating Gastroesophageal Reflux Disease.

Fig. 35 is a flowchart illustrating steps performed when implanting a movement restriction device for treating Gastroesophageal Reflux Disease.

Figs. 36-41 shows methods for restoring the location of the cardia and the fundus in a patient suffering from Gastroesophageal Reflux Disease.

Figs. 42-46 show different shapes and features of a reflux treatment device comprised in an apparatus according to the invention,

Figs. 47a-d show a deflated inflatable reflux treatment device comprised in an apparatus according to the invention and an instrument for placing the reflux treatment device on the outside of the stomach wall of the patient.

Figs. 48a-i illustrate different steps of invaginating the inflatable device of Fig. 47a on the outside of a stomach wall of a patient,

Fig. 49 shows an embodiment wherein the reflux treatment apparatus is also adapted to treat obesity.

Figs. 50-51 show an embodiment wherein the reflux treatment apparatus adapted also for treating obesity.

Figs. 52a-h illustrate different steps of invaginating the inflatable device of Fig. 47a on the inside of a stomach wall of a patient,

Figs 53a-c shows an instrument for creating an invagination of the wall of the stomach.

Figs. 54-55 show an abdominal method for treating reflux disease.

Fig. 56 is a schematic block diagram illustrating an embodiment of the reflux disease apparatus of the invention, in which wireless energy is released from an external source of energy for use in the power of a stimulation device;

Fig. 57 is a schematic block diagram illustrating another embodiment of the invention, in which wireless energy is released from an internal source of energy;

Figs. 58 to 61 are schematic block diagrams illustrating four embodiments, respectively, of the invention, in which a switch is implanted in the patient for directly or indirectly switching the power of the stimulation device;

Fig. 62 is a schematic block diagram illustrating conceivable combinations of implantable components for achieving various communication options;

Fig. 63 illustrates the apparatus in accordance with the invention implanted in a patient; and

Fig. 64 is a block diagram illustrating remote control components of an embodiment of the invention.

Figs. 65-68 are views of embodiments of an apparatus for treating obesity by stretching the wall of the stomach that can be combined the reflux treatment apparatus implanted in a human patient.

Fig. 69 is a general description of the surface structure of any implanted device of the invention.

Fig. 70-76 are views of various embodiments of an apparatus for treating obesity that can be combined with the reflux treatment apparatus implanted in a human patient .

Figs. 77-93 show various ways of powering an apparatus for treating obesity that can be combined with an apparatus for treating reflux implanted in a human patient.

Figs. 94-100 show various ways of arranging hydraulic or pneumatic powering of an apparatus for treating obesity implanted in a human patient.

Figs 101-105 show various instruments for treating reflux and obesity.

Figs 106-107 show methods for surgery for treating reflux and obesity.

DETAILED DESCIRPTION OF THE DRAWINGS

MOVEMENT RESTRICTION DEVICE

Fig. 1A is a schematic view depicting an apparatus 11, including a movement restriction device 10 of a biocompatible material, for treating reflux disease, in accordance with the invention, implanted in a human patient. In Fig. 1A, the device 10 is invaginated in the fundus. The device 10 comprises a body 13 having an outer surface 15 suitable for resting against a portion of the outside wall 16a of the stomach fundus wall 16 in a position between the patient's diaphragm 18 and at least a portion of the lower part of the invaginated stomach fundus wall 16. Thus, with the device 10 invaginated in this fashion, movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, thereby the cardia is prevented from sliding through the patient's diaphragm opening into the patient's thorax 20 and the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen is maintained

The body 13 is inflatable and adapted to be inflated with a gel or fluid. A fluid or gel receiving member for receiving fluid to inflate said movement restriction device may be provided. Alternatively, the body 13 includes a homogenous material and be a solid body. Alternatively, the body 13 includes an outer wall in the form of an enclosure wall defining a chamber. The outer wall may be rigid, elastic or flexible. Where the outer wall is rigid, it is rigid enough to maintain non-deformed when subject to forces created by stomach movements.

The body 13 of the movement restriction device 10 can be affixed to the wall 16a of the fundus 16 in a number of different ways. In the embodiment shown in Fig. 1A, the device 10 is invaginated in the fundus stomach wall from outside the stomach. After invagination, a first fixation device consisting of a number of stomach-to-stomach sutures or staples 22a is applied to keep the invagination in tact in the short term. This allows the growth of human tissue to keep the invagination in tact over the long term.

There may optionally be a second fixation device consisting of a number of sutures or staples 22b that are provided between the wall 16a of the fundus 16 and the wall 24a of the oesophagus 24 to hold the device 10 in said position between the patient's diaphragm 18 and at least a portion of the lower part of the invaginated stomach fundus wall 16. Thus, the device 10 is affixed in this position by this second fixation apparatus. A direct or indirect affixation of the device 10 to the diaphragm muscle 18 or associated muscles may be provided. As an alternative, a direct or indirect affixation of the device 10 to the oesophagus His can be provided. Alternatively, or additionally, there may be a third fixation device in the form of sutures or staples 22c provided between the wall 16a of the fundus 16 and the diaphragm 18 to hold the device 10 in said position.

Figure 1B shows an embodiment substantially similar to the one shown in Figure 1A. In figure 1B the body 13 and invagiation are, in addition to the affixation 22, fixed by means of sutures and/or staples 22c between the reflux body 13 and the diaphragm 18, to hold the device in position above the cardia 14.

Figure 1C shows another embodiment substantially similar to the one shown in figure 1A. In figure 1C the reflux treatment device is held in place by stomach-to-stomach sutures or staplers 22a that connects the wall 16a of the fundus 16 to the wall 16a of the fundus 16. In addition the reflux treatment device 10 is held in place by sutures 22b or staplers from the wall 16 of the fundus 16a to the wall of the esophagus 24a, and by sutures or staples from the wall of the fundus 16a to the diaphragm.

An alternative embodiment of an apparatus 17 for the treatment of reflux disease in accordance with the invention is depicted in Fig. 2A. This embodiment is, in many aspects, similar to the one described above with reference to Fig. 1A-C. Thus, a movement restriction device 10 is shown implanted in a human patient and invaginated in the fundus. However, in the embodiment shown in Fig. 2A, the device 10 is invaginated from the inside of the stomach, instead of from outside of the stomach, as in Fig. 1A-C. The movement restriction device 10 comprises a body 13 adapted to rest against a portion of the inside wall of the stomach fundus wall 16 in a position between the patient's diaphragm 18 and at least a portion of the lower

part of the invaginated stomach fundus wall 16. In this embodiment, the body 13 is situated above the cardia area 14 of a standing human or animal mammal patient. The body 13 of the device 10 is shaped to rest against the wall 16a of the fundus 16, and further, has an outer surface 15 suitable to rest against this fundus wall. Thus, with the device 10 invaginated in this fashion as described above in connection with Fig. 1A, movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, thereby the cardia is prevented from sliding through the patient's diaphragm opening into the patient's thorax 20 and the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen is maintained.

After invagination, a number of stomach-to-stomach sutures or staples 33a comprising a first fixation device are applied from inside the stomach 16 to keep the invagination in tact in the short term. This allows the growth of human tissue, keeping the invagination in tact over the long term. Additional sutures or staples 22b comprising a second fixation device can be provided between a wall portion 16b of the fundus 16 forming part of the invagination of the device 10 and the wall 24a of the oesophagus 24 to hold the device 10 in said position. Similarly, a third fixation device in the form of sutures or staples 22c can be provided between another wall portion 16c of the fundus 16 forming part of the invagination of the device 10 and the diaphragm 18 to hold the device 10 in said position.

An alternative embodiment is shown in Figure 2B. This embodiment is in many aspects similar to the one described with reference to Fig 2A. However, here the sutures and staples 22b and 33a are all connected to the fixator of the reflux treatment device 10. This embodiment lacks stomach-to-diaphragm sutures or staples.

An alternative an apparatus 19 for the treatment of reflux disease is depicted in Fig. 3A. This alternative is in many aspects similar to the ones described above with reference to Figs. 1A-C and 2 A-B. Thus, a movement restriction device 10 is shown implanted in a human patient. The device 10 comprises a body 13 adapted to rest against a portion of the stomach fundus wall 16 in a position between the patient's diaphragm 18 and stomach fundus wall 16. However, in this alternative, the device

10 is not invaginated in the stomach 16. Instead, the affixation of the device 10 comprises an attachment structure 10a, preferably a net like-structure that is adapted to be in contact with the fundus stomach wall 16a to promote the growth of human tissue to secure long term placement of the reflux disease treatment device attached to the stomach wall. In the short term, a first fixation device in the form of sutures or staples 44a may be provided between the attachment structure 10a and the fundus wall 16a to keep the attachment structure 10a in place.

The attachment structure 10a may be adapted for a second fixation device in the form of sutures or staples 44b that are provided between the wall 16a of the fundus 16 and the wall 24a of the oesophagus 24 to hold the device 10 in said position between the patient's diaphragm 18 and stomach fundus wall 16. Similarly, the attachment structure 10a may also be adapted for a third fixation device in the form of sutures or staples 44c that are provided between the wall 16a of the fundus 16 and the diaphragm 18, again, to hold the device 10 in said position.

An alternative embodiment is shown in Figure 3B. This embodiment is in many aspects similar to the one described with reference to Fig 3A. In this embodiment, the reflux treatment device 10 is, like in figure 2A-B invaginated from the inside of the stomach. The attachment structure 10a is positioned on the wall 16a of the fundus 16 above and around the invagination created by the reflux treatment device 10.

A alternative embodiment of an apparatus 21 for treatment of reflux disease in accordance with the invention is depicted in Fig. 4A. This embodiment is in many aspects similar to the one described above with reference to Fig. 1A-C. In Fig. 4A, a view of a device 10 for treatment of reflux disease in accordance with the invention is shown implanted in a human patient. In Fig. 4A, the movement restriction device 10 is again invaginated in the fundus 16. The device 10 comprises a body 13 having an outer surface 15 suitable for resting against a portion of the outside wall 16a of the stomach fundus wall 16 in a position between the patient's diaphragm 18 and at least a portion of the lower part of the invaginated stomach fundus wall 16. The body 13 is shaped to rest against the outside wall 16a of the fundus 16. Thus, with the device 10 invaginated in this fashion, movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, thereby the cardia is prevented

from sliding through the patient's diaphragm opening into the patient's thorax 20 and the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen is maintained.

In the embodiment of Fig. 4A, as in the embodiment of Fig. 1A, after invagination of the device 10 in the fundus 16, a first fixation device consisting of a number of stomach-to-stomach sutures or staples 22a is applied to keep the invagination in tact in the short term. A second fixation device consisting of a number of sutures or staples 22b is provided to hold the device 10 in said position between the patient's diaphragm 18 and at least a portion of the lower part of the invaginated stomach fundus wall 16. Additionally, a third fixation device in the form of sutures or staples 22c may be provided between the wall 16a of the fundus 16 and the diaphragm 18, again, to hold the device 10 in said position.

In the embodiment depicted in Fig. 4A, the size of the movement restriction device 10 can be regulated while being implanted. The device 10 is associated with a hydraulic reservoir 52 connected to the device 10 by a lead 52b, whereby a non-invasive regulation can be performed by manually pressing the reservoir 52. The device 10 is, in turn, connected to one or more smaller chambers 10b.

Furthermore, the embodiment above may alternatively be used to also treat obesity. The apparatus may, in this embodiment, be adapted to treat obesity by using the volume of the movement restriction body 13 to contain a fluid, and further using one or more smaller chambers 10b connected to the body 13 with a pump to be filled with fluid to stretch the fundus wall to create satiety. The small chambers 10b are also adapted to be invaginated to in the fundus stomach wall, and when filled with fluid, an expansion occurs that results in human sensor feedback creating satiety. By placing the small hydraulic reservoir/pump subcutaneously in the patient, the patient is able to pump hydraulic fluid to fill the small chambers to feel full on request.

An alternative embodiment is shown in figure 4B. This embodiment is substantially similar to the one shown in figure 4A but differs in how the reflux treatment device 10 and chambers 10b are controlled. Here, the chambers 10b are not controlled by a subcutaneous pump but a powered internal control unit 56. The internal control unit

56 comprises means for the patient to control the device 10 in how it shall be used regarding treatment of reflux and/or obesity. It may also comprise means of supplying power to the device.

The internal control unit 56 may comprise a battery 70, an electric switch 72, a motor/pump 44, a reservoir 52, an injection port 1001. An energy transmission device 34 with a remote control is adapted for controlling and powering the device. The items being selected depending on the circumstances, e.g. if the device is electrically, hydraulically, pneumatically or mechanically operated.

The control unit may receive input from any sensor 76, specially a pressure sensor. Any type of sensor may be supplied. The internal control unit 56 preferable includes intelligence in forms of a FPGA or MCU or ASIC or any other circuit, component or memory (For a more extensive description see below under "system").

Figure 4C shows essentially the same as figure 4A with the difference that there is one small chamber 10b instead of two small chambers as in 4A. Figure 4C shows the small chamber 10b in its empty state whereas figure 4D shows the small chambers 10b when it has been filled and enlarged to create satiety.

Yet an alternative embodiment of an apparatus 23 for the treatment of reflux disease in accordance with the invention is depicted in Fig. 5A. This embodiment is, again, in many aspects similar to the one described above with reference to Fig. 1A-C. Thus, as in the embodiment of Fig. 1A, a movement restriction device 10, which is invaginated in the fundus, is comprised of a body 13 having an outer surface 15 suitable for resting against a portion of the outside wall 16a of the stomach fundus wall 16 in a position between the patient's diaphragm 18 and at least a portion of the lower part of the invaginated stomach fundus wall 16. The body 13 of the device 10 is shaped to rest against the outside wall 16a of the fundus 16 and has a generally smooth outer surface 15 suitable for resting against this fundus wall. And, again, after invagination of the device 10 in the fundus 16, a first fixation device consisting of a number of stomach-to-stomach sutures or staples 22a is applied to keep the invagination in tact in the short term. A second fixation device consisting of a

number of sutures or staples 22b applied between the wall 16a of the fundus 16 and the wall 24a of the oesophagus 24 is provided to hold the device 10 in said position.

In the alternative embodiment shown in Fig. 5A, the apparatus 23 further comprises a stimulation device 26 for sending out stimulation pulses adapted to stimulate the cardia muscle to further close the cardia to additionally prevent reflux disease. The apparatus 23 comprises at least one conductor 26a and at least one electrode 26b adapted to receive the stimulation pulses.

The stimulation device 26 preferably comprises an electronic circuit and an energy source, which in the preferred embodiment is provided in the device 10.

The stimulation device 26 preferably sends stimulation pulses as a train of pulses, wherein the pulse train is adapted to be repeated with a time break in between, the break extending the break between each pulse in the pulse train.

Figure 5B shows essentially the same embodiment as in figure 5A, with the addition of an internal control unit 56, a remote control 28 and an external energy transmission device 34. The internal control unit 56 is connected to the stimulation device with a power lead 56b.The internal control unit 57 may comprise a battery 70 and an electric switch 72 and other components described below under "system".

The reflux disease treatment device 10 can, in accordance with one embodiment of the present invention, be formed as a generally egg shaped body, as is shown in Fig. 6A. The reflux disease treatment device 10 can, in accordance with another embodiment of the present invention, also be formed as an egg or sphere shaped body with an indent in its middle, as is shown in Fig. 6B. The reflux disease treatment device 10 can, in accordance with yet another embodiment of the present invention, further be formed as a slightly bent egg shaped body as shown in Fig. 6C.

The reflux disease treatment device 10 can, in accordance with a further embodiment of the present invention, be formed as a generally spherically-shaped body, as shown in Fig. 6D.

As discussed above, the reflux treatment device 10 is fixed in a position which is above the esophagus in a standing patient. To enable this, one embodiment of the reflux treatment shown in Figure 7 comprises a fixator 10d that may, for example, serve as an attachment point for sutures or staples. The fixator may be a loop or a ridge with or without holes or have any other shape that makes it suitable for fixating the reflux treatment device 10.

Figure 8 show an embodiment of the reflux treatment device 10 where it is adjustable by a hydraulic mean, and 10e is an injection port where hydraulic fluid can be in order to expand the device. Alternatively, in one embodiment the reflux treatment device 10 can be inflated from a small size to a larger size during a surgical procedure where it is advantageous that the device is initially of small size, for example during a laparoscopic procedure. In such an embodiment, any filling material, solid, liquid or gas many injected trough the injection port 10e in order for the reflux treatment device 10 to achieve its final shape.

Figure 9 shows an embodiment where the reflux treatment device 10 has a sunken ridge 10f adapted to being held with a surgical tool. This is to be used, for example, during a surgical procedure when the reflux treatment device is implanted.

When the reflux disease treatment device 10 is generally spherical, whereby it can be made to wholly or partly encompass the esophagus, the inner diameter D of the reflux disease treatment device 10, is preferably such that it can encompass the esophagus and at least a part of the fundus so that the device does not rest directly against the wall of the esophagus when implanted.

The movement restriction device 10 may take any form that enables the device 10 to rest in a position in which movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, thereby the cardia is prevented from sliding through the patient's diaphragm opening into the patient's thorax and the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen is maintained.

System

An energy and operation system, generally designated 28, to be incorporated in the apparatus according to the invention, will now be described with reference to Figs. 10-27.

The system 28 shown in Fig. 10 comprises an internal energy source in the form of an implanted energy transforming device 30 adapted to supply energy consuming components of the reflux disease treatment apparatus with energy via a power supply line 32. An external energy transmission device 34 includes a wireless remote control transmitting a wireless signal, which is received by a signal receiver which may be incorporated in the implanted energy transforming device 30, or be separate. The implanted energy transforming device 30 transforms energy from the signal into electric energy which is supplied via the power supply line 32.

The system 28 of Fig. 10 is shown in a more generalized block diagram form in Fig. 11, wherein the patient's skin 36, generally shown by a vertical line, separates the interior of the patient 29 to the right of the line from the exterior to the left of the line.

Fig. 11 shows a simplified block diagram showing the movement restriction device 10, the energy transforming device 30 powering the device 10 via power supply line 32, and the external energy transmission device 34.

Fig. 12 shows an embodiment of the invention identical to that of Fig. 11, except that a reversing device in the form of an electric switch 38 operable by polarized energy also is implanted in the patient 29 for reversing the device 10. The wireless remote control of the external energy transmission device 34 transmits a wireless signal that carries polarized energy and the implanted energy transforming device 30 transforms the wireless polarized energy into a polarized current for operating the electric switch 38. When the polarity of the current is shifted by the implanted energy transforming device 30 the electric switch 38 reverses the function performed by the device 10.

Fig. 13 shows an embodiment of the invention identical to that of Fig. 11, except that an operation device 40 implanted in the patient for regulating the reflux disease

treatment device 10 is provided between the implanted energy transforming device 30 and the device 10. This operation device can be in the form of a motor 40, such as an electric servomotor. The motor 40 is powered with energy from the implanted energy transforming device 30, as the remote control of the external energy transmission device 34 transmits a wireless signal to the receiver of the implanted energy transforming device 30.

Fig. 14 shows an embodiment of the invention identical to that of Fig. 11, except that it also comprises an operation device is in the form of an assembly 42 including a motor/pump unit 78 and a fluid reservoir 46 is implanted in the patient. In this case the device 10 is hydraulically operated, i.e. hydraulic fluid is pumped by the motor/pump unit 44 from the fluid reservoir 46 through a conduit 48 to the device 10 to operate thedevice, and hydraulic fluid is pumped by the motor/pump unit 44 back from the device 10 to the fluid reservoir 46 to return the device 10 to a starting position. The implanted energy transforming device 30 transforms wireless energy into a current, for example a polarized current, for powering the motor/pump unit 44 via an electric power supply line 50.

Instead of a hydraulically operated movement restriction device 10, it is also envisaged that the operation device comprises a pneumatic operation device. In this case, pressurized air can be used for regulation and the fluid reservoir is replaced by an air chamber and the fluid is replaced by air.

In all of these embodiments the energy transforming device 30 may include a rechargeable accumulator like a battery or a capacitor to be charged by the wireless energy and supplies energy for any energy consuming part of the apparatus.

The external energy transmission device 34 is preferably wireless and may include a remotely controlled control device for controlling the device 10 from outside the human body.

Such a control device may include a wireless remote control as well as a manual control of any implanted part to make contact with by the patient's hand most likely indirect for example a button to press placed under the skin.

Fig. 15 shows an embodiment of the invention comprising the external energy transmission device 34 with its wireless remote control, the device 10, in this case hydraulically operated, and the implanted energy transforming device 30, and further comprising a hydraulic fluid reservoir 52, a motor/pump unit 44 and an reversing device in the form of a hydraulic valve shifting device 54, all implanted in the patient. Of course the hydraulic operation could easily be performed by just changing the pumping direction and the hydraulic valve may therefore be omitted. The remote control may be a device separated from the external energy transmission or included in the same. The motor of the motor/pump unit 44 is an electric motor. In response to a control signal from the wireless remote control of the external energy transmission device 34, the implanted energy transforming device 30 powers the motor/pump unit 44 with energy from the energy carried by the control signal, whereby the motor/pump unit 44 distributes hydraulic fluid between the hydraulic fluid reservoir 52 and the device 10. The remote control of the external energy transmission device 34 controls the hydraulic valve shifting device 54 to shift the hydraulic fluid flow direction between one direction in which the fluid is pumped by the motor/pump unit 44 from the hydraulic fluid reservoir 52 to the device 10 to operate the device 10, and another opposite direction in which the fluid is pumped by the motor/pump unit 44 back from the device 10 to the hydraulic fluid reservoir 52 to return the device 10 to a starting position.

Fig. 16 shows an embodiment of the invention identical to that of Fig. 15, except that an internal control unit 56 controlled by the wireless remote control of the external energy transmission device 34, an accumulator 58 and a capacitor 60 also are implanted in the patient. The internal control unit 56 arranges storage of electric energy received from the implanted energy transforming device 30 in the accumulator 58, which supplies energy to the device 10. In response to a control signal from the wireless remote control of the external energy transmission device 34, the internal control unit 56 either releases electric energy from the accumulator 58 and transforms the released energy via power lines 62 and 64, or directly transforms electric energy from the implanted energy transforming device 30 via a power line 66, the capacitor 60, which stabilizes the electric current, a power line 68 and the power line 64, for the operation of thedevice 10.

The internal control unit is preferably programmable from outside the patient's body. In a preferred embodiment, the internal control unit is programmed to regulate the device 10 to stretch the stomach according to a pre-programmed time-schedule or to input from any sensor sensing any possible physical parameter of the patient or any functional parameter of the device.

In accordance with an alternative, the capacitor 60 in the embodiment of Fig. 16 may be omitted. In accordance with another alternative, the accumulator 58 in this embodiment may be omitted.

Fig. 17 shows an embodiment of the invention identical to that of Fig. 10, except that a battery 70 for supplying energy for the operation of thedevice 10 and an electric switch 72 for switching the operation of the device 10 also are implanted in the patient. The electric switch 72 is operated by the energy supplied by the implanted energy transforming device 30 to switch from an off mode, in which the battery 70 is not in use, to an on mode, in which the battery 70 supplies energy for the operation of the device 10.

Fig. 18 shows an embodiment of the invention identical to that of Fig. 16, except that an internal control unit 56 controllable by the wireless remote control of the external energy transmission device 34 also is implanted in the patient. In this case, the electric switch 72 is operated by the energy supplied by the implanted energy transforming device 30 to switch from an off mode, in which the wireless remote control is prevented from controlling the internal control unit 56 and the battery is not in use, to a standby mode, in which the remote control is permitted to control the internal control unit 56 to release electric energy from the battery 70 for the operation of the device 10.

Fig. 19 shows an embodiment of the invention identical to that of Fig. 17, except that an accumulator 58 is substituted for the battery 70 and the implanted components are interconnected differently. In this case, the accumulator 58 stores energy from the implanted energy transforming device 30. In response to a control signal from the wireless remote control of the external energy transmission device 34, the internal control unit 56 controls the electric switch 72 to switch from an off mode, in which

the accumulator 58 is not in use, to an on mode, in which the accumulator 58 supplies energy for the operation of the device 10.

Fig. 20 shows an embodiment of the invention identical to that of Fig. 18, except that a battery 70 also is implanted in the patient and the implanted components are interconnected differently. In response to a control signal from the wireless remote control of the external energy transmission device 34, the internal control unit 56 controls the accumulator 58 to deliver energy for operating the electric switch 72 to switch from an off mode, in which the battery 70 is not in use, to an on mode, in which the battery 70 supplies electric energy for the operation of the device 10.

Alternatively, the electric switch 72 may be operated by energy supplied by the accumulator 58 to switch from an off mode, in which the wireless remote control is prevented from controlling the battery 70 to supply electric energy and is not in use, to a standby mode, in which the wireless remote control is permitted to control the battery 70 to supply electric energy for the operation of the device 10.

It should be understood that the switch should be interpreted in its broadest embodiment. This means an FPGA or a DA converter or any other electronic component or circuit may switch power on and off preferably being controlled from outside the patient's body or by an internal control unit.

Fig. 21 shows an embodiment of the invention identical to that of Fig. 17, except that a motor 40, a mechanical reversing device in the form of a gear box 74, and an internal control unit 56 for controlling the gear box 74 also are implanted in the patient. The internal control unit 56 controls the gear box 74 to reverse the function performed by the device 10 (mechanically operated). Even simpler is to switch the direction of the motor electronically.

Fig. 22 shows an embodiment of the invention identical to that of Fig. 20 except that the implanted components are interconnected differently. Thus, in this case, the internal control unit 56 is powered by the battery 70 when the accumulator 58, suitably a capacitor, activates the electric switch 72 to switch to an on mode. When the electric switch 72 is in its on mode the internal control unit 56 is permitted to

control the battery 70 to supply, or not supply, energy for the operation of the device 10.

Fig. 23 schematically shows conceivable combinations of implanted components of the apparatus for achieving various communication options. Basically, there are the device 10, the internal control unit 56, motor or pump unit 44, and the external energy transmission device 34 including the external wireless remote control. As already described above the wireless remote control transmits a control signal which is received by the internal control unit 56, which in turn controls the various implanted components of the apparatus.

A feedback device, preferably in the form of a sensor 76, may be implanted in the patient for sensing a physical parameter of the patient, such as a contraction wave in the oesophagus informing the patient is eating. The internal control unit 56, or alternatively the external wireless remote control of the external energy transmission device 34, may control the device 10 in response to signals from the sensor 76. A transceiver may be combined with the sensor 76 for sending information on the sensed physical parameter to the external wireless remote control. The wireless remote control may comprise a signal transmitter or transceiver and the internal control unit 56 may comprise a signal receiver or transceiver. Alternatively, the wireless remote control may comprise a signal receiver or transceiver and the internal control unit 56 may comprise a signal transmitter or transceiver. The above transceivers, transmitters and receivers may be used for sending information or data related to the device 10 from inside the patient's body to the outside thereof.

Alternatively, the sensor 76 may be arranged to sense a functional parameter of the device 10.

Where the motor/pump unit 44 and battery 70 for powering the motor/pump unit 44 are implanted, the battery 70 may be equipped with a transceiver for sending information on the condition of the battery 70. To be more precise, when charging a battery or accumulator with energy feed back information related to said charging process is sent and the energy supply is changed accordingly.

Fig. 24 shows an alternative embodiment wherein the device 10 is regulated from outside the patient's body. The system 28 comprises a movement restrictiondevice 10 connected to a battery 70 via a subcutaneous switch 80. Thus, the regulation of the device 10 is performed non-invasively by manually pressing the subcutaneous switch, whereby the operation of the device 10 is switched on and off. It will be appreciated that the shown embodiment is a simplification and that additional components, such as an internal control unit or any other part disclosed in the present application can be added to the system.

Fig. 25 shows an alternative embodiment, wherein the system 28 comprises a movement restriction device 10 in fluid connection with a hydraulic fluid reservoir 52. Non-invasive regulation is performed by manually pressing the hydraulic reservoir connected to the device 10.

A further embodiment of a system to be incorporated in the apparatus according to the invention comprises a feedback device for sending information from inside the patient's body to the outside thereof to give feedback information related to at least one functional parameter of the movement restriction device or apparatus or a physical parameter of the patient, thereby optimizing the performance of the apparatus.

One preferred functional parameter of the device is correlated to the transfer of energy for charging the internal energy source.

In Fig. 26, an arrangement is schematically illustrated for supplying an accurate amount of energy to a system 28 implanted in a patient, whose skin 36 is indicated by a vertical line. A movement restriction device 10 is connected to an implanted energy transforming device 30, likewise located inside the patient, preferably just beneath the patient's skin 36. Generally speaking, the implanted energy transforming device 30 may be placed in the abdomen, thorax, muscle fascia (e.g. in the abdominal wall), subcutaneously, or at any other suitable location. The implanted energy transforming device 30 is adapted to receive wireless energy E transmitted from an external energy source 34a provided in the external energy

transmission device 34 located outside the patient's skin 36 in the vicinity of the implanted energy transforming device 30.

As is well known in the art, the wireless energy E may generally be transferred by means of any suitable Transcutaneous Energy Transfer (TET) device, such as a device including a primary coil arranged in the external energy source 34a and an adjacent secondary coil arranged in the implanted energy transforming device 30. When an electric current is fed through the primary coil, energy in the form of a voltage is induced in the secondary coil which can be used to operate a movement restriction device, e.g. after storing the incoming energy in an energy storing device or accumulator, such as a battery or a capacitor. However, the present invention is generally not limited to any particular energy transfer technique, TET devices or energy storing devices, and any kind of wireless energy may be used.

The amount of energy received inside the body to the device may be compared with the energy used by the device. The term used by the device is then understood to include also energy stored by the device. The amount of transferred energy can be regulated by means of an external control unit 34b controlling the external energy source 34a based on the determined energy balance, as described above. In order to transfer the correct amount of energy, the energy balance and the required amount of energy can be determined by means of an internal control unit 56 connected to the reflux disease treatment device 10. The internal control unit 56 may thus be arranged to receive various measurements obtained by suitable sensors or the like, not shown, measuring certain characteristics of the r10, somehow reflecting the required amount of energy needed for proper operation of the device 10. Moreover, the current condition of the patient may also be detected by means of suitable measuring devices or sensors, in order to provide parameters reflecting the patient's condition. Hence, such characteristics and/or parameters may be related to the current state of the device 10, such as power consumption, operational mode and temperature, as well as the patient's condition reflected by, *e.g.*, body temperature, blood pressure, heartbeats and breathing.

Furthermore, an energy storing device or accumulator 58 may optionally be connected to the implanted energy transforming device 30 for accumulating received

energy for later use by the device 10. Alternatively or additionally, characteristics of such an accumulator, also reflecting the required amount of energy, may be measured as well. The accumulator may be replaced by a battery, and the measured characteristics may be related to the current state of the battery, such as voltage, temperature, *etc.* In order to provide sufficient voltage and current to the device 10, and also to avoid excessive heating, it is clearly understood that the battery should be charged optimally by receiving a correct amount of energy from the implanted energy transforming device 30, *i.e.*, not too little or too much. The accumulator may also be a capacitor with corresponding characteristics.

For example, battery characteristics may be measured on a regular basis to determine the current state of the battery, which then may be stored as state information in a suitable storage means in the internal control unit 56. Thus, whenever new measurements are made, the stored battery state information can be updated accordingly. In this way, the state of the battery can be "calibrated" by transferring a correct amount of energy, so as to maintain the battery in an optimal condition.

Thus, the internal control unit 56 is adapted to determine the energy balance and/or the currently required amount of energy, (either energy per time unit or accumulated energy) based on measurements made by the above-mentioned sensors or measuring devices on the reflux disease treatment device 10, or the patient, or an energy storing device if used, or any combination thereof. The internal control unit 56 is further connected to an internal signal transmitter 82, arranged to transmit a control signal reflecting the determined required amount of energy, to an external signal receiver 34c connected to the external control unit 34b. The amount of energy transmitted from the external energy source 34a may then be regulated in response to the received control signal.

Alternatively, sensor measurements can be transmitted directly to the external control unit 34b wherein the energy balance and/or the currently required amount of energy can be determined by the external control unit 34b, thus integrating the above-described function of the internal control unit 56 in the external control unit 34b. In that case, the internal control unit 56 can be omitted and the sensor measurements are supplied directly to the internal signal transmitter 82 which sends the measurements

over to the external signal receiver 34c and the external control unit 34b. The energy balance and the currently required amount of energy can then be determined by the external control unit 34b based on those sensor measurements.

Hence, the present solution employs the feed back of information indicating the required energy, which is more efficient than previous solutions because it is based on the actual use of energy that is compared to the received energy, e.g. with respect to the amount of energy, the energy difference, or the energy receiving rate as compared to the energy rate used by the device 10. The device 10 may use the received energy either for consuming or for storing the energy in an energy storage device or the like. The different parameters discussed above would thus be used if relevant and needed and then as a tool for determining the actual energy balance. However, such parameters may also be needed per se for any actions taken internally to specifically operate the device.

The internal signal transmitter 82 and the external signal receiver 34c may be implemented as separate units using suitable signal transfer means, such as radio, IR (Infrared) or ultrasonic signals. Alternatively, the internal signal transmitter 82 and the external signal receiver 34c may be integrated in the implanted energy transforming device 30 and the external energy source 34a, respectively, so as to convey control signals in a reverse direction relative to the energy transfer, basically using the same transmission technique. The control signals may be modulated with respect to frequency, phase or amplitude.

To conclude, the energy supply arrangement illustrated in Fig. 26 may operate basically in the following manner. The energy balance is first determined by the internal control unit 56. A control signal reflecting the required amount of energy is also created by the internal control unit 56, and the control signal is transmitted from the internal signal transmitter 82 to the external signal receiver 34c. Alternatively, the energy balance can be determined by the external control unit 34b instead depending on the implementation, as mentioned above. In that case, the control signal may carry measurement results from various sensors. The amount of energy emitted from the external energy source 34a can then be regulated by the external control unit 34b, based on the determined energy balance, e.g. in response to the

received control signal. This process may be repeated intermittently at certain intervals during ongoing energy transfer, or may be executed on a more or less continuous basis during the energy transfer.

The amount of transferred energy can generally be regulated by adjusting various transmission parameters in the external energy source 34a, such as voltage, current, amplitude, wave frequency and pulse characteristics.

A method is thus provided for controlling transmission of wireless energy supplied to an electrically operable reflux disease treatment device implanted in a patient. The wireless energy E is transmitted from an external energy source located outside the patient and is received by an internal energy receiver located inside the patient, the internal energy receiver being connected to the device 10 for directly or indirectly supplying received energy thereto. An energy balance is determined between the energy received by the internal energy receiver and the energy used for the device 10. The transmission of wireless energy E from the external energy source is then controlled based on the determined energy balance.

A system is also provided for controlling transmission of wireless energy supplied to an electrically operable movement restriction device 10 implanted in a patient. The system is adapted to transmit the wireless energy E from an external energy source located outside the patient which is received by an implanted energy transforming device located inside the patient, the implanted energy transforming device being connected to the device 10 for directly or indirectly supplying received energy thereto. The system is further adapted to determine an energy balance between the energy received by the implanted energy transforming device and the energy used for the device 10, and control the transmission of wireless energy E from the external energy source, based on the determined energy balance.

The functional parameter of the device is correlated to the transfer of energy for charging the internal energy source.

In yet an alternative embodiment, the external source of energy is controlled from outside the patient's body to release electromagnetic wireless energy, and released electromagnetic wireless energy is used for operating the device 10.

In another embodiment, the external source of energy is controlling from outside the patient's body to release non-magnetic wireless energy, and released non-magnetic wireless energy is used for operating the device 10.

Those skilled in the art will realize that the above various embodiments according to Figs. 14-26 could be combined in many different ways. For example, the electric switch 38 operated polarized energy could be incorporated in any of the embodiments of Figs. 12, 15-21, the hydraulic valve shifting device 54 could be incorporated in the embodiment of Fig. 24, and the gear box 74 could be incorporated in the embodiment of Fig. 33. It should be noted that the switch simply could mean any electronic circuit or component.

Wireless transfer of energy for operating the movement restriction device 10 has been described to enable non-invasive operation. It will be appreciated that the device 10 can be operated with wire bound energy as well. One such example is shown in Fig. 26, wherein an external switch 84 is interconnected between the external energy source 34a and an operation device, such as an electric motor regulating the device 10, by means of power lines 86 and 88. An external control unit 34b controls the operation of the external switch to effect proper operation of the device 10.

Hydraulic or pneumatic powering

Figs. 28-31 show in more detail block diagrams of four different ways of hydraulically or pneumatically powering a movement restriction device according to the invention.

Fig. 28 shows a system for treating reflux disease as described above with. The system comprises a device 10 and further a separate regulation reservoir 46, a one way pump 44 and an alternate valve 54.

Fig. 29 shows the device 10 and a fluid reservoir 46. By moving the wall of the regulation reservoir or changing the size of the same in any other different way, the adjustment of the device may be performed without any valve, just free passage of fluid any time by moving the reservoir wall.

Fig. 30 shows the device 10, a two way pump 44 and the regulation reservoir 46.

Fig. 31 shows a block diagram of a reversed servo system with a first closed system controlling a second closed system. The servo system comprises a regulation reservoir 46 and a servo reservoir 90. The servo reservoir 90 mechanically controls a movement restriction device 10 via a mechanical interconnection 94. The device 10 has an expandable/contactable cavity. This cavity is preferably expanded or contracted by supplying hydraulic fluid from the larger adjustable reservoir 92 in fluid connection with the device 10. Alternatively, the cavity contains compressible gas, which can be compressed and expanded under the control of the servo reservoir 90.

The servo reservoir 90 can also be part of the device itself.

In one embodiment, the regulation reservoir is placed subcutaneous under the patient's skin and is operated by pushing the outer surface thereof by means of a finger. This reflux disease treatment system is illustrated in Figs 32-c. In Fig. 31, a flexible subcutaneous regulation reservoir 46 is shown connected to a bulge shaped servo reservoir 90 by means of a conduit 48. This bellow shaped servo reservoir 90 is comprised in a flexible movement restriction device 10. In the state shown in Fig. 32, the servo reservoir 90 contains a minimum of fluid and most fluid is found in the regulation reservoir 46. Due to the mechanical interconnection between the servo reservoir 90 and the device 10, the outer shape of the device 10 is contracted, *i.e.*, it occupies less than its maximum volume. This maximum volume is shown with dashed lines in the figure.

Fig. 32 shows a state wherein a user, such as the patient in with the device is implanted, presses the regulation reservoir 46 so that fluid contained therein is brought to flow through the conduit 48 and into the servo reservoir 90, which, thanks to its bellow shape, expands longitudinally. This expansion in turn expands the device 10 so that it occupies its maximum volume, thereby stretching the stomach wall (not shown), which it contacts.

The regulation reservoir 46 is preferably provided with means 46a for keeping its shape after compression. This means, which is schematically shown in the figure, will thus keep the device 10 in a stretched position also when the user releases the regulation reservoir. In this way, the regulation reservoir essentially operates as an on/off switch for the reflux disease treatment system.

An alternative embodiment of hydraulic or pneumatic operation will now be described with reference to Figs. 33and 34. The block diagram shown in Fig. 33 comprises with a first closed system controlling a second closed system. The first system comprises a regulation reservoir 46 and a servo reservoir 90. The servo reservoir 90 mechanically controls a larger adjustable reservoir 92 via a mechanical interconnection 94. A movement restriction device 10 having an expandable/contactable cavity is in turn controlled by the larger adjustable reservoir 92 by supply of hydraulic fluid from the larger adjustable reservoir 92 in fluid connection with the device 10.

An example of this embodiment will now be described with reference to Fig. 34. Like in the previous embodiment, the regulation reservoir is placed subcutaneous under the patient's skin and is operated by pushing the outer surface thereof by means of a finger. The regulation reservoir 46 is in fluid connection with a bellow shaped servo reservoir 90 by means of a conduit 48. In the first closed system 46, 48, 90 shown in Fig. 32a, the servo reservoir 90 contains a minimum of fluid and most fluid is found in the regulation reservoir 46.

The servo reservoir 90 is mechanically connected to a larger adjustable reservoir 92, in this example also having a bellow shape but with a larger diameter than the servo reservoir 90. The larger adjustable reservoir 92 is in fluid connection with the device

10. This means that when a user pushes the regulation reservoir 46, thereby displacing fluid from the regulation reservoir 46 to the servo reservoir 90, the expansion of the servo reservoir 90 will displace a larger volume of fluid from the larger adjustable reservoir 92 to the device 10. In other words, in this reversed servo, a small volume in the regulation reservoir is compressed with a higher force and this creates a movement of a larger total area with less force per area unit.

Like in the previous embodiment described above with reference to Figs. 32a-c, the regulation reservoir 46 is preferably provided with means 46a for keeping its shape after compression. This means, which is schematically shown in the figure, will thus keep the device 10 in a stretched position also when the user releases the regulation reservoir. In this way, the regulation reservoir essentially operates as an on/off switch for the reflux disease treatment system.

In Fig. 35, a flow chart illustrating steps performed when implanting a device in accordance with the present invention. First in a step 102, an opening is cut in the abdominal wall. Next, in a step 104 an area around the stomach is dissected. Thereupon, in a step 106 at least one movement restriction device in accordance with the invention is placed in contact with the stomach wall, in particular the fundus wall. The stomach wall is then sutured in a step 108.

Method for the restoration of the location of the cardia and the fundus

Figure 36 shows how an instrument 200 having at least one flexible part 201 is introduced into the esophagus 24 of a patient that is suffering from a hiatal hernia 202 where a part of the esophagus 24 and fundus 16 that is supposed to be located below the diaphragm 18 has moved through the hiatus opening 18a to a position above the diaphragm 18.

In figure 37 it is shown how, in a subsequent step, a member 203 having a larger cross sectional area than said instrument 200 is released from the instrument 200. The member 203 is adapted as to have a cross-sectional that is larger than the opening of the cardia 14. This can be achieved by radial expansion of the member

203. The instrument 200 is then pushed in a proximal direction so that the cardia 14 and the fundus 16, or part of fundus 16, incorrectly located above diaphragm 18, slide through the hiatus opening 18a back to a correct position below the diaphragm 18.

Figure 38 shows an alternative method to the one shown in Fig. 37 which is an embodiment of the invention. In many aspects, this figure is similar to fig 37. In figure 38, the instrument 200 is adapted to release a balloon member 204 at the proximal end 205 of the instrument 200 in the lower part of the stomach 206, and using the balloon member 204 to push the instrument 200 against the lower wall part of the stomach 207 so that the cardia 14 and the fundus 16 or part of fundus 16 slide through the hiatus opening 18a to a position below the diaphragm 18.

Figure 39 shows yet an alternative method which is an embodiment of the invention. Again, this figure is in many aspects similar to fig 37. However, in figure 39 the method involves attaching the member 203 to the wall of the stomach 207 by a fixation 208. As described above the instrument is then pushed in a proximal direction so the cardia 14 and the fundus 16 or, part of fundus 16, slides below the diaphragm 18.

Figure 40 shows how the fundus 16 and cardia 14 is located in a position below the diaphragm 18 after having been pushed through the hiatal opening 18a by the instrument 200.

Figure 41 shows a subsequent step of the method. After the fundus 16 and cardia 14 has been pushed into its correct position below the diaphragm 18, the wall of the fundus 16a is affixed to the lower part of the oesophagus 24. This is carried out by using a member 209 in the proximal part 205 of the instrument 200 which is capable of providing sutures or staples 210. The fixation hinders the movement of the cardia 14 and the fundus 16 to a postion above the diaphragm 18.

Other methods according to the invention are briefly described below.

A method of treating reflux disease of a patient comprises the step of implanting a reflux disease treatment system according to the invention into the patient's body.

A method of using the system for treating reflux disease according to the invention comprises the step of regulating the device postoperatively to prevent reflux.

A method for surgically placing a movement restriction device according to the invention in a patient comprises the steps of cutting an opening in the abdominal wall of the patient, dissecting the area around the stomach, placing a movement restriction device attached to the stomach wall, and suturing the stomach wall.

A method of using a reflux disease treatment system, postoperatively controlled from outside the body, regulating the device, comprises the steps of filling out a volume attached to a part of the stomach wall, and regulating the device from outside the patient's body to affect the reflux of the patient.

A method of using a movement restriction device comprises the steps of filling out a volume in a first part of the stomach wall by placing a first part of the device, filling out a volume in a second part of the stomach wall by placing a second part of the device, and regulating the devices from outside the patient's body to affect the reflux of the patient.

A method of treating reflux disease in a patient comprises the steps of inserting a needle or a tube like instrument into the abdomen of the patient's body, using the needle or tube like instrument to fill the patient's abdomen with gas thereby expanding the abdominal cavity, placing at least two laparoscopic trocars in the patient's body, inserting a camera through one of the laparoscopic trocars into the patient's abdomen, inserting at least one dissecting tool through one of said at least two laparoscopic trocars and dissecting an intended placement area of at least one portion of the stomach of the patient, placing a movement restrictiondevice according to the invention on the stomach fundus wall, invaginating the device in the stomach fundus wall, suturing the stomach wall to itself to keep the device in place, suturing the fundus of the stomach towards the lower part of the oesophagus, and preventing the cardia to slide up through the diaphragm into the thorax. Using the method and device as described herein will provide a treatment of Gastroesophageal Reflux Disease which is very effective and which does not suffer from complications such as damaging of tissue and undesired migration of non tissue into tissue.

The filling body of the device can be adapted to be pushed or pulled through a trocar for laparoscopic use, where the trocar has a diameter that is smaller than the relaxed diameter of the body. The filling body can include an outer wall and a hollow gas filled inner part that allow the body to pass through the trocar. Alternatively, the filling body can include an outer wall and a hollow fluid filled inner part that allow the body to pass through the trocar. In this latter case, the fluid can be a gel. The filling body can further include multiple parts that can be inserted into the trocar, and that can then be put together into one unitary piece inside the patient's body, allowing the filling body to pass through the trocar. The filling body can include an outer wall and a hollow compressed inner part that is filled with a fluid or gel after insertion into the patient's body. The can further include an injection port that can be used to fill the filling body with a fluid after insertion into the patient's body through the injection port.

The filling body of the device can be an elastic compressible material, allowing the filling body to pass through the trocar. The filling body can be made from a material that is softer than 25 shure, or even 15 shure.

The filling body can also include an outer wall substantially taking the shape of a ball. The filling body can also include at least one holding device adapted to be used for pushing or pulling the filling body through a trocar for laparoscopic use. The holding device can be adapted to hold a prolongation of the device that is adapted to be held by a surgical instrument. The holding device can also hold a tread or band inserted through the holding device. The holding device can also be at least partly placed inside the outer wall of the filling body. The filling body of the device can preferably has a size that is larger than the intestinal outlet from the stomach. to avoid ileus if the ball, as a complication, should enter into the stomach. Preferably, the body has a smallest outer diameter between 30 mm and 40 mm or larger. Preferably, the body has a smallest outer circumference between 30 mm and 150 mm.

Preferred embodiments of a device for treating reflux disease, a system comprising a device for treating reflux disease, and a method according to the invention have been described. A person skilled in the art realizes that these could be varied within the

scope of the appended claims. Thus, although the different features have been described in specific embodiments, it will be appreciated that they can be combined in different configurations when applicable. For example, although hydraulic control has been described in association with the device configuration of Fig. 4 A-B, it can also be applied to the device configurations of Figs. 2 A-B and 3A-B.

It is important that the implanted reflux treatment device is firmly kept in place in the stomach wall in which it is invaginated. To this end, the reflux treatment device can be provided with one or more through holes adapted for receiving sutures or staples used for fixation of the invagination. Such an embodiment is shown in Fig. 42, where the reflux treatment device 10 is provided with a row of holes 10i provided on a protruding flange-like protrusion on the reflux treatment device. In this embodiment, the row of holes extend along the longitudinal axis of the reflux treatment device.

Fig. 43 illustrates how sutures 314 are provided so that they run through the stomach wall 12a and through the holes 10i. In this way, the reflux treatment device is fixed in place in the pouch created from the stomach wall and will thus be prevented from sliding.

Although a plurality of holes is illustrated in the Fig. 42, it will be appreciated that one single hole is sufficient to obtain improved fixation of the reflux treatment device 10.

Fig. 44 illustrates a reflux treatment device provided with an inlet port 10h. The reflux treatment device is invaginated in the stomach wall and the inlet port 10h is available for connection to a tube or the like from the abdominal area of the patient.

Fig. 45 illustrates an invaginated reflux treatment device wherein, instead of an inlet port, a fixed tube 10g extends into the abdominal area of the patient.

Fig. 46 is a figure similar to Fig. 44 but also illustrating tunneling of a connection tube 10g in the stomach wall between the inlet port 10h and the reflux treatment device 10.

It has been shown that the shape of the reflux treatment device can take many different forms. It will be appreciated that also the material of the reflux treatment device can vary. It is preferred that the reflux treatment device is provided with a coating, such as a Parylene, polytetrafluoroethylene (PTFE), or polyurethane coating, or a combination of such coatings, i.e., a multi-layer coating. This coating or multi-layer coating improves the properties of the reflux treatment device, such as its resistance to wear.

In one embodiment, the reflux treatment device comprises an inflatable device expandable to an expanded state. In this case, the inflatable device is provided with an inlet port for a fluid and is adapted to be connected to a gastroscopic instrument. This embodiment will now be described in detail with reference to Figs. 47a-47d.

An inflatable reflux treatment device in its non-expanded state is shown in Fig. 47a. It is essentially a balloon-like, deflated device 10 having an inlet port 10h. In this state, the inflatable device has a diameter of a few millimeters at the most, allowing it to be inserted into the stomach through the esophagus of the patient by means of a gastroscopic, tube-like instrument 600, depicted in figure 47b. The instrument comprises an outer sleeve 600a and an inner sleeve 600b which can be displaced longitudinally relatively to the outer sleeve. The inner sleeve is provided with a cutter in the form of a cutting edge 615 at the distal end thereof. This cutting edge can be used for cutting a hole in the stomach wall, as will be explained in detail in the following.

When the instrument reaches a stomach wall, see Fig. 47c, the inner sleeve is brought forward from its position in the outer sleeve and into contact with the stomach wall 12a. The cutting edge 615 of the inner sleeve then cuts a hole in the stomach wall so as to allow subsequent insertion of the reflux treatment device 10 into and through this hole, see Fig. 47d. In order to push the reflux treatment device through the hole, a piston 602 may be provided in the instrument. Thus, the instrument further comprises a piston 602 adapted for pushing a deflated reflux treatment device 10 out from a position in the inner sleeve, this position being shown in Fig. 47b, to a position outside of the inner sleeve, this being shown in Fig. 47d.

In order to protect the deflated reflux treatment device 10 from the cutting edge 615 of the inner sleeve, a further protective sleeve (not shown) can be provided around the reflux treatment device.

An intraluminar method of invaginating a reflux treatment device 10 on the outside of the stomach wall 12a will now be described with reference to Figs. 48a-i. Initially, an instrument 600, preferably a gastroscopic instrument, is inserted into the mouth of the patient, see Fig. 48a. The instrument comprises an injection device 601, 602 for injecting either fluid or a device into the stomach of the patient. The instrument 600 further comprises a control unit 606 adapted for controlling the operation of the instrument. To this end, the control unit 606 comprises one or more steering devices, in the embodiment shown in the figure in the form of two joysticks 603 and two control buttons 604. A display 605 is provided for displaying the image provided by a camera (not shown) arranged at the outer end of the elongated member 607, see Figs. 48e-i. The camera may be assisted by a light source (not shown).

The instrument is further inserted into the esophagus and into the stomach of the patient, see Fig. 48b. By means of the instrument 600, a hole 12b is created in the wall of the stomach 12. To this end, the instrument is provided with one or more cutters 615 at the distal end thereof, for example in the way described above with reference to Figs. 47a-d. These cutters can of course be designed in different ways, such as a toothed drum cutter rotating about the center axis of the tube-like instrument. The instrument 600 is hollow providing a space for the reflux treatment device 10 in its deflated state.

After cutting a hole in the stomach wall, the distal end of the instrument 600 is inserted into and through the hole 12b so that it ends up outside the stomach wall 12a. This is shown in Fig. 48c, showing a side view of the stomach 12, and Fig. 48d, which is a sectional view through the stomach of Fig. 48c taken along the lines Vd – Vd. The deflated reflux treatment device 10 is then inserted in the abdominal area.

The instrument 600 is adapted to create a "pocket" or "pouch" on the outside of the stomach 12 around the hole 12b in the stomach wall. Such an instrument and the method of providing the pouch will now be described.

Figs. 48e-i show a gastroscopic or laparoscopic instrument for invaginating a reflux treatment device 10 in the stomach wall 12a of the patient by creating a pouch of stomach wall 12a material in which the reflux treatment device is placed. The instrument, generally designated 600, and which may comprise the features described above with reference to Figs. 47a-d, comprises an elongated member 607 having a proximal end and a distal end, the elongated member 607 having a diameter less than that of the patient's esophagus and being flexible such as to allow introduction of the flexible elongated member 607 with its distal end first through the patient's throat, esophagus and into the stomach 12 to the stomach wall 12a.

The stomach penetration device or cutter 615 is provided on the elongated member 607 at the distal en thereof for penetrating the stomach wall 12a so as to create a hole in the stomach wall 12a, to allow introduction of the elongated member 607 through the hole. The stomach penetration device 615 could be adapted to be operable for retracting said stomach penetration device 615 after the stomach fundus wall 12a has been penetrated, for not further damaging tissue within the body. The instrument further comprises a special holding device 609 provided on the elongated member 607 on the proximal side to the penetration device 615.

The elongated member further comprises an expandable member 611 which is adapted to be expanded after the elongated member has penetrated the stomach wall 12a and thereby assist in the creation of a cavity or pouch adapted to hold the reflux treatment device 610. The expandable member 611 may comprise an inflatable circular balloon provided circumferentially around the distal end portion of the flexible elongated member 607.

The method steps when invaginating the reflux treatment device will now be described in detail. After the instrument 600 has been inserted into the stomach 12, the stomach penetration device 615 is placed into contact with the stomach wall 12a, see Fig. 48e. The stomach penetration device or cutter 615 is then brought to create the hole 12b in the stomach wall, whereafter at least the expandable member 611 is brought through the hole 12b in the stomach wall. The special holding device 609 is in this step brought to a holding state wherein it expands radially so as to form an essentially circular abutment surface to the stomach wall 12a, see Fig. 48f. In this

way, the insertion of the stomach penetration device 615 and the expandable member 611 through the hole 12a in the stomach wall is limited to the position shown in Fig. 48f.

The expandable member 611 is then expanded. In the case the expandable member comprises a balloon or the like, air or other fluid is injected into it.

The part of the elongated member 607 comprising the expandable member 611 is then retracted in the proximal direction, as indicated by the arrow in Fig. 48g, thereby pulling the stomach wall 612 into a basket like structure created by the special holding device 609.

A suturing or stapling device 608 is further provided, either as a device connected to the elongated member 607 or as a separate instrument. The suturing or stapling member comprises a suturing or stapling end 613 which is adapted to close the cavity or pouch by means of stomach to stomach sutures or staples 14.

In a further step, illustrated in Fig. 48h, an inflatable reflux treatment device 10 is placed in its deflated state in the basket like structure. The reflux treatment device 10 is then inflated to its inflated or expanded state, see Fig. 48i. This inflation of the reflux treatment device 10 can be accomplished by injecting a fluid or a gel into the deflated reflux treatment device. It can also be accomplished by injecting a material which is allowed to cure, thereby forming a solid device 10. Thus, the reflux treatment device 10 shown in Figs. 48h and 48i can illustrate either a balloon-like device which is subsequently filled with fluid or gel or alternatively a material which is simply injected into the basket like structure formed by the stomach wall 12a.

The fluid which is used to fill the reflux treatment device 10 could be any suitable fluid suitable to fill the inflatable device 10, such as a salt solution. In another embodiment, when this fluid is a fluid which is adapted to be transformed into solid state, the fluid could be liquid polyurethane.

In order to minimize or entirely eliminate leakage, the fluid is iso-tonic, i.e., it has the same osmolarity as human body fluids. Another way of preventing diffusion is to provide a fluid which comprises large molecules, such as iodine molecules.

The stomach-to-stomach sutures or staples are preferably provided with fixation portions exhibiting a structure, such as a net like structure, adapted to be in contact with the stomach wall to promote growth in of human tissue to secure the long term placement of the reflux treatment device attached to the stomach wall.

After the inflatable device 10 has been inflated, partly or fully, the inlet port 10b (not shown in Figs. 48h and 48i) of the reflux treatment device 10, is sealed and the instrument 600 is retracted from the hole 12b, which is subsequently closed in some suitable way, such as by means of the instrument 600. The instrument is then removed from the stomach 600 and the inflatable device 10 in its inflated or expanded state is invaginated by a stomach wall portion of the patient on the outside of the stomach wall. During one or more of the above described steps, the stomach may be inflated with gas, preferably by means of the gastroscopic instrument.

The reflux treatment device 10 described above with reference to Figs. 48a-i has been described as an inflatable reflux treatment device. It will be appreciated that is also can be an elastic reflux treatment device with an elasticity allowing compression so as to be inserted into a gastroscopic instrument and which expands to an expanded state after leaving the instrument.

COMBINATION OF A REFLUX TREATMENT DEVICE AND A VOLUME FILLING DEVICE

The apparatus for treating reflux can have the additional functionality of treating obsesity. In such an embodiment, the reflux treatment device may be a volume filling device that fills a volume of the stomach and thereby creating satiety.

An embodiment having this function is shown in Fig. 49, wherein a combined reflux treatment device and obesity treatment device 310 is invaginated in the stomach wall close to and at least partially above the patient's cardia 14 when the patient is in a standing position and is fixed to a position above the cardia area 14c by a fixation,

such as sutures or staples 22. For example a direct or indirect fixation to the diaphragm muscle or associated muscles may be provided. As an alternative a direct or indirect fixation to the esophagus above and close to the angle of His can be provided. In this alternative embodiment, the combined device 310 rests in a position against stomach wall of the fundus when implanted and which also fills a volume above the cardia area 14c between the cardia and the diaphragm muscle so that the cardia is prevented from slipping up into the thorax cavity, whereby reflux disease is prevented.

Such a combined device 310 may be used for keeping electronics and/or an energy source and/or hydraulic fluid. Hydraulic fluid from that device may be distributed to several smaller inflatable device areas to vary the stretching area from time to time avoiding any possible more permanent stretching effect of the stomach wall. Even mechanically several stretching areas may be used.

In an alternative embodiment, which is shown in Fig. 50, the volume of an inflatable reflux treatment device 310 may be in fluid connection with one or more preferably smaller inflatable devices or chambers 10b. These chambers are adapted to communicate with fluid or air being moved between the chambers.

Thus, the large chamber 310 is adapted to, with its main volume to be a reflux treatment device for reducing the size of the food cavity and for treating reflux disease and the one or several small chambers are adapted to function as the inflatable devices to treat obesity, wherein the main chamber is adapted to communicate with fluid or air to the small chambers causing a stretching effect in the stomach wall thereby further treating obesity.

Fig 51 show an embodiment with a combination of a volume filling device invaginated in the central or lower portion of the stomach and a stretching device invaginated in the upper portion or fundus of the patient's stomach. These two devices serve to treat obesity.

The volume filling device 399 fills a volume of the stomach creating satiety. The stretching device stretches the wall of the stomach. This stretches the tissue setting

off a endogenous signaling that creates satiety. This mimics the stretching effect of filling the stomach with food. Thus, in Fig. 51 there is shown an adjustable volume filling device 399, which is invaginated in the stomach wall of a patient's stomach 312. Additionally, an adjustable stretching device 350 with the previously described function is invaginated in the stomach fundus wall of the patient. It is preferred that the volume filling device 399 is substantially larger than the stretching device 350.

The volume filling device 399 and the stretching device 350 can be adapted to treat reflux. In one embodiment, the volume filling device and the stretching device are positioned to prevent the cardia 14 from slipping upwards trough the opening of the hernia 18a to a position above the diaphragm 18.

The volume filling device 399 and the stretching device 350 are in fluid communication with each other via a first fluid tube 352, in which a pump 354 is provided. The pump 354 is under the control from an energy transforming device 330, which is adapted to supply the pump 350 with energy via a power supply line 356. The energy transforming device 330 is also connected to a sensor 319 provided in the esophagus of the patient so that food intake can be detected.

The reflux treatment device 10 and the stretching device 350 are also in fluid communication with each other via a second fluid tube 358, which preferably has a smaller cross-sectional area than the first fluid tube 352.

The operation of this arrangement is as follows. The volume filling device 399 functions as in the above described embodiments, i.e., it reduces the size of the food cavity of the patient's stomach 12. Additionally, when the stretching device 350 is enlarged by pumping fluid from the volume filling device 10 and to the stretching device 350 by means of the pump 354, the stomach fundus wall is stretched, creating a feeling of satiety for the patient. Thus, for example when food intake is detected by means of the sensor 319, fluid is automatically pumped into the stretching device 350 to increase the feeling of satiety and thereby limit the food intake.

When fluid has been injected into the stretching device 350, the internal pressure therein is higher than the internal pressure in the reflux treatment device 399. This

difference in pressure will create a flow of fluid in the second, preferably narrower tube 358 from the stretching device 350 to the reflux treatment device 399. The flow rate will be determined by among other things the difference in pressure and the cross-sectional area of the second tube 358. It is preferred that the second tube is so dimensioned, that the pressures in the volume filing device 399 and the stretching device 350 will return to equilibrium after 3 hours after fluid has been injected into the stretching device 350 to create the feeling of satiety.

In this embodiment, the function of the second tube 358 is to allow fluid to return from the stretching device 350 to the volume filling device 399. It will be appreciated that this function also can be performed by the pump 354 in the first tube 352 and that the second tube 358 then can be omitted.

Fig. 51b illustrates an embodiment similar to the one illustrated in Fig. 51a. Thus, there is provided an adjustable volume filling device 310, which is invaginated in the stomach wall of a patient's stomach 312. Additionally, an adjustable stretching device 350 with the previously described function is invaginated in the stomach fundus wall of the patient. It is preferred that the volume filling device 310 is substantially larger than the stretching device 350.

The volume filling device 310 and the stretching device 350 are in fluid communication with each other via a first fluid tube 352, and a second fluid tube, which preferably has a smaller cross-sectional area than the first tube. However, instead of a pump, there is provided a non-return valve 360 in the first fluid tube 352 instead of an energized pump. This non-return valve 360 allows fluid to flow in the direction from the volume filling device 310 and to the stretching device 10 but not vice verse. This means that this embodiment may be entirely non-energized. Instead, it operates according to the following principles.

When the food cavity of the stomach 312 is essentially empty, there is a state of equilibrium between the internal pressure of the volume filling device 310 and the stretching device 350. In this state, the stretching device is in a non-stretch state, i.e., it does not stretch a part of the stomach fundus wall and thus does not create a feeling of satiety.

When the patient starts to eat, food will enter the food cavity of the stomach 312. This will create increased pressure on the stomach wall in which the volume filling device 310 is invaginated and the internal pressure therein will increase. Also, the stomach wall muscles will begin to process the food in the food cavity by contraction, which also contributes to an increased internal pressure in the volume filling device 310.

Since the internal pressure in the stretching device 350 will remain essentially unchanged, because it is located in the upper part of the stomach 312 where no food is exerting a pressure on the stomach wall, a fluid flow will be created through the first and second fluid tubes 352, 358 in the direction from the volume filling device 310 and to the stretching device 350. This in turn will increase the volume of the stretching device 350, which, by stretching the stomach fundus wall, will provide a feeling of satiety to the patient.

A fluid flow from the stretching device 350 to the volume filling device 310 through the second tube 358 will return the pressure of these devices to equilibrium as described above with reference to Fig. 51a

Similarly, Fig.51c illustrates an embodiment wherein the stretching device 350 can be actively regulated by manually pressing an adjustment reservoir which is provided subcutaneously below the patient's skin. Thus, a regulation reservoir 317 for fluids is connected to the inflatable device by means of a conduit 318 in the form of a tube. The stretching device 350 is thereby adapted to be regulated, non-invasively, by moving liquid or air from the regulation reservoir 317 to the chamber formed by the inflatable device. The regulation of the stretching device 350 preferably comprises a reversed servo, i.e., a small volume is actuated for example by the patient's finger and this small volume is in connection with a larger volume.

The volume filling device 310 preferably has an essentially round shape to not damage the stomach wall. An example thereof is shown in Fig. 51-3a, wherein the volume filling device is essentially egg-shaped. In another preferred embodiment, the volume filling device is slightly bent, such as the embodiment shown in Fig. 51-3b. However, since the stomach wall is strong many different shapes, forms, and

dimensions may be used. In one embodiment, the volume filling device has a diameter of about 40 millimeters and a length of about 120 millimeters, resulting in a volume that is about half the volume of the patient's stomach. However, it is preferred that the maximum circumference of the volume filling device is at least 30 millimeters, more preferably at least 50 millimeters, and even more preferably at least 80 millimeters.

It is not necessary that the volume filling device is elongated. In the embodiment shown in Fig. 51-3c, the volume filling device 310 is essentially spherical or ball-shaped. In order to fill out the stomach, two or more such volume filling devices may be combined to achieve the desired decrease of the food cavity of the patient's stomach.

It has been mentioned that the volume filling device is secured by the stomach-to-stomach sutures or staples. In order to further improve the fixation, the volume filling device may be provided with a waist portion having smaller diameter that the maximum diameter of the volume filling device. Such volume filling device having a waist portion 10a is shown in Fig.51-3d.

The volume filling device 10 may consist of at least two interconnectable portions so that each portion is easier to insert into the stomach and further through a hole in the stomach wall. Thus, Fig. 51-3e shows a volume filling device comprising two more or less spherical sub-parts 310b, 310c interconnected by a portion with which preferably has smaller diameter. The portion with smaller diameter may comprise an interconnection means with a reversible function allowing subsequent disconnection of the two interconnected sub-parts 310b, 310c. Such means may comprise a bayonet socket, a screw connection or the like, designated 310d in the figure. Alternatively, the portion with smaller diameter may comprise a fixed interconnection, such as resilient locking hooks provided on one of the sub-parts 310b, 310c and engaging the rim of a hole provided in the other one of the sub-parts 310b, 310c.

The configuration of the volume filling device 10 is not limited to one waist portion 310a. Thus, in Fig. 51-3f a volume filling device with two waist portions is shown.

In order to facilitate positioning of the volume filling device, an attachment means in the form of a handle or the like may be provided on the outer surface of the volume filling device. One example thereof is shown in Fig. 51-3g, wherein also a detail view of a handle 51-10e is shown. In a preferred embodiment, the attachment means is provide at an end portion of the volume filling device 310. In order to avoid protruding portion on the surface of the volume filling device 310, the handle 310e is provided flush with the outer surface of the volume filling device 310 and a recess 310f is arranged to allow a gripping tool or instrument (not shown in Fig. 51-3g) to achieve firm gripping around the handle 310e.

The volume filling device may comprise a tube for filling or emptying the volume filling device of a fluid or gel. By injecting fluid or gel into the volume filling device 310, the volume filling device is inflated to an inflated state, as will be described below. The size of the volume filling device can also be adjusted by moving fluid or gel therefrom to a different reservoir.

A volume filling device 310 adapted for this is shown in Fig. 51-3h. A tube 310g is fixedly attached to the volume filling device. This tube can be attached to a suitable instrument (not shown) or an injection port, which will be explained in detail below.

Instead of having a fixedly attached tube, the volume filling device 310 may comprise an inlet port 10h adapted for connection of a separate tube (not shown in this figure).

It is important that the implanted volume filling device is firmly kept in place in the stomach wall in which it is invaginated. To this end, the volume filling device can be provided with one or more through holes adapted for receiving sutures or staples used for fixation of the invagination. Such an embodiment is shown in Fig. 51-3j, where the volume filling device 310 is provided with a row of holes 10i provided on a protruding flange-like protrusion on the volume filling device. In this embodiment, the row of holes extend along the longitudinal axis of the volume filling device.

Method for placing a reflux treatment device on the inside of the stomach wall

In the following a method and an instrument for placing a reflux treatment device on the inside of the stomach wall will be described.

The invagination instrument described in Fig. 52a-1 generally designated 630, comprises an elongated tube member 632 similar to the elongated member 607 described above with reference to Figs. 48a-i. Thus, it can be connected to a control unit 606, see Fig. 48a. The invagination instrument 630 further comprises a perforated suction portion 634, which preferably is elongated. The suction portion 634 exhibits a plurality of small holes 636, into which air will be sucked by providing suction in the tube member 632. This suction effect will be used to create a "pocket" or "pouch" in a part of a stomach wall, generally designated 12a.

In other words, when the tip of the suction portion 634 is pressed against the stomach wall 12a, see Fig. 52a, a small recess will be formed therein. When the suction portion 634 is further pressed against the stomach wall 12a, see Fig. 52b, a larger recess will be formed. The part of the stomach wall 12a that forms the recess will, due to the suction effect, adhere to the suction portion 634 of the invagination instrument 630. As the suction portion 634 is further pressed into the stomach wall 12a, see Fig. 52c, a deeper recess will be formed until the entire suction portion 634 is embedded in the recess, see Fig. 18d.

The rim of the recess will at this stage be fixated by means of fixation elements 638 and the suction portion be removed from the instrument, see Fig. 52e. A compressed elastic reflux treatment device 10 will subsequently be inserted into the recess, see Fig. 52f, for example in the way described above with reference to Fig. 47d. This compressed reflux treatment device is then expanded to its final shape, see Fig. 52g, where after the pouch is sealed by suturing or stapling by means of the fixations elements, see Fig. 52h.

All the alternatives described above with reference to Figs. 1-51 are also applicable to the embodiment described with reference to Figs. 52a-1, i.e., to the embodiment where the reflux treatment device is invaginated on the inside of the stomach wall.

Figs 53 a-c show an instrument for creating an invagiation of the wall of the stomach that can either be placed on the outside of the wall of the stomach or on the inside of the wall of the stomach depending if the reflux treatment device is place on the inside or the outside of the wall. The instrument uses vacuum to such a portion of the wall of the stomach into the cup of the instrument.

It has been described how the reflux treatment device 10 is invaginated in the stomach wall by means of a gastroscopic instrument. The gastroscopic instrument can be used for either placing the reflux treatment device on the outside of the wall of the stomach as shown in figure 1A or on the inside of the stomach as shown in figure 2A. In the latter case, the instruments will be used to make an incision in the wall of the stomach from the inside of the stomach.

It will be appreciated that abdominal operation methods can be used as well. Such methods will now be described in with reference to Figs. 54-55.In figure 54 it is shown how the stomach is accessed by creating an incision 380 n the abdomen of the patient. In figure 55 it is shown how an instrument 381 is inserted into the abdomen of the patient. Any of the instruments and methods described can be selected an adapted for this purpose. Thus, for example, the reflux treatment device can be placed on the outside of the stomach as shown in figure 1A or on the inside as shown in figure 2A. In the later case an incision is made in the wall of the stomach.

STIMULATION - DETAILED DESCRIPTION

FIGURE 56 schematically shows an embodiment of the heartburn and reflux disease apparatus of the invention having some parts implanted in a patient and other parts located outside the patient's body. Thus, in FIGURE 56 all parts placed to the right of the patient's skin 2x are implanted and all parts placed to the left of the skin

2x are located outside the patient's body. The apparatus of FIGURE 56 comprises an implanted electric stimulation device 4, which engages the patient's cardia sphincter to provide electric connection thereto. An implanted control unit 6x controls the stimulation device 4x via a control line 8x. An external control unit 10x includes an external source of energy and a wireless remote control transmitting a control signal generated by the external source of energy. The control signal is received by a signal receiver incorporated in the implanted control unit 6x, whereby the control unit 6x controls the implanted stimulation device 4x in response to the control signal. The implanted control unit 6x also uses electric energy drawn from the control signal for powering the stimulation device 4x via a power supply line 12x.

FIGURE 57 shows an embodiment of the invention identical to that of FIGURE 56, except that an implanted internal electric source of energy in the form of a battery 42x is substituted for the external source of energy. Thus, an external control unit 40x without any source of energy is used in this embodiment. In response to a control signal from the external control unit 40x the implanted control unit 6x powers the stimulation device 4x with energy from the battery 42x.

FIGURE 58 shows an embodiment of the invention comprising the stimulation device 4x, the external control unit 10x, and an implanted source of energy 236x and an implanted switch 238x. The switch 238x is operated by wireless energy released from the external source of energy of the external control unit 6x to switch between an off mode, in which the implanted source of energy 236x is not in use, and an on mode, in which the implanted source of energy 236x supplies energy for the power of the stimulation device 4x.

FIGURE 59 shows an embodiment of the invention identical to that of FIGURE 58, except that also the control unit 6x is implanted, in order to receive a control signal from the wireless remote control of the external control unit 10x. The switch 238x is operated by the wireless energy from the external source of energy 10x to switch between an off mode, in which the implanted source of energy 236x and the wireless remote control of the external control unit 10x are not in use, *i.e.* the control unit 6x is not capable of receiving the control signal, and a standby mode, in which the wireless remote control is permitted to control the internal source of energy 236x, via the implanted control unit 6x, to supply energy for the power of the stimulation device 4x.

FIGURE 60 shows an embodiment of the invention identical to that of FIGURE 59, except that an energy transforming device for transforming the wireless energy into storable energy is incorporated in the implanted control unit 6x and that the implanted source of energy 236x is of a type that is capable of storing the storable energy. In this case, in response to a control signal from the external control unit 10x, the implanted control unit 6 controls the switch 238x to switch from an off mode, in which the implanted source of energy 236x is not in use, to an on mode, in which the source of energy 36x supplies energy for the power of the stimulation device 59x.

FIGURE 61 shows an embodiment of the invention identical to that of FIGURE 60, except that an energy storage device 240x also is implanted in the patient for storing the storable energy transformed from the wireless energy by the transforming device of the control unit 6x. In this case, the implanted control unit 6x controls the energy storage device 240 to operate the switch 238x to switch between an off mode, in which the implanted source of energy 236x is not in use, and an on mode, in which the implanted source of energy 236x supplies energy for the power of the stimulation device 4x.

FIGURE 62 schematically shows conceivable combinations of implanted components of the apparatus for achieving various communication possibilities. Basically, there are the implanted stimulation device 4x, the implanted control unit 6x and the external control unit 10x including the external source of energy and the wireless remote control. As already described above the remote control transmits a control signal generated by the external source of energy, and the control signal is received by a signal receiver incorporated in the implanted control unit 6x, whereby the control unit 6x controls the implanted stimulation device 4x in response to the control signal.

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

outside thereof. For example, the battery 32x may be equipped with a transceiver for sending information on the charge condition of the battery.

Those skilled in the art will realise that the above various embodiments according to FIGURES 56-61 could be combined in many different ways.

FIGURE 63 illustrates how any of the above-described embodiments of the heartburn and reflux disease treatment apparatus of the invention may be implanted in a patient. Thus, an assembly of the apparatus implanted in the patient comprises a stimulation device in the form of a band 56x, which is wrapped around the cardia 58x. The band 58x is provided with conductors that electrically contact the cardia sphincter and an operation device 60x for operating the stimulation device 56x. An implanted control unit 60x is provided for controlling the supply of electricity to the band 56x. There is an implanted energy transforming device 62x for transforming wireless energy into electric energy. The transforming device 62x also includes a signal receiver. An external control unit 64x includes a signal transmitter for transmitting a control signal to the signal receiver of the implanted transforming device 62x. The transforming device 62x is capable of transforming signal energy from the control signal into electric energy for powering the stimulation device 60x and for energising other energy consuming implanted components of the apparatus.

FIGURE 64 shows the basic parts of a wireless remote control of the apparatus of the invention including an implanted electric stimulation device 4x. In this case, the remote control is based on the transmission of electromagnetic wave signals, often of high frequencies in the order of 100 kHz - 1 gHz, through the skin 130x of the patient. In FIGURE 64, all parts placed to the left of the skin 130x are located outside the patient's body and all parts placed to the right of the skin 130x are implanted. Any suitable remote control system may be used.

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

An external control unit 136x comprises a microprocessor, a high frequency electromagnetic wave signal generator and a power amplifier. The microprocessor of the control unit 136x is adapted to switch the generator on/off and to modulate signals generated by the generator to send digital information via the power amplifier and the antennas 132x,134x to an implanted control unit 138x. To avoid that accidental random high frequency fields trigger control commands, digital signal codes are used. A conventional keypad placed on the external control unit 136x is connected to the microprocessor thereof. The keypad is used to order the microprocessor to send digital signals to either power or not power the stimulation device. The microprocessor starts a command by applying a high frequency signal on the antenna 132x. After a short time, when the signal has energised the implanted parts of the control system, commands are sent to power the stimulation device. The commands are sent as digital packets in the form illustrated below.

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

The commands may be sent continuously during a rather long time period. When a new power or not power step is desired the Count byte is increased by one to allow the implanted control unit 138x to decode and understand that another step is demanded by the external control unit 136x. If any part of the digital packet is erroneous, its content is simply ignored.

Through a line 140x, an implanted energiser unit 126x draws energy from the high frequency electromagnetic wave signals received by the receiving antenna 134x. The energiser unit 126 stores the energy in a power supply, such as a large capacitor, powers the control unit 138x and powers the electric stimulation device 4x via a line 142x.

The control unit 138x comprises a demodulator and a microprocessor. The demodulator demodulates digital signals sent from the external control unit 136x. The microprocessor of the control unit 138x receives the digital packet, decodes it and, provided that the power supply of the energiser unit 126x has sufficient energy stored, powers the stimulation device 4x via a line 144x.

Alternatively, the energy stored in the power supply of the energiser unit may only be used for powering a switch, and the energy for powering the stimulation device 4x may be obtained from another implanted power source of relatively high capacity, for example a battery. In this case the switch is adapted to connect said battery to the control unit 138x in

an on mode when the switch is powered by the power supply and to keep the battery disconnected from the control unit in a standby mode when the switch is not powered.

STRECHING - DETAILED DESCRIPTION

Here follows detailed description of two embodiments of the invention where treatment of reflux is combined with treatment of obesity. First, embodiments showing a stretching device is shown.

Invaginated in the stomach wall is to be understood as an object being placed inside of a cavity made of stomach wall material. The invagination enables stomach to stomach sutures or staplers which enables the object of be enclosed by means of the human tissue healing.

Fig. 65 shows a first embodiment of an obesity treatment apparatus. The apparatus comprises a stretching device 10y implanted in a human patient. In Fig. 65 the stretching device 10y is invaginated in the wall 12y of the patient's stomach 12y and the body of the stretching device 10y is shaped to rest against the wall 12y of the stomach 12y and further has an outer surface suitable to rest against this wall 12y. This means that the stretching device 10y preferably has an essentially round shape to not damage the stomach wall. However, the stomach wall 12y is strong so many different shapes and forms may be used.

The stretching device 10y can be fixed to the wall 12ay of the stomach 12y in a number of different ways. In the embodiment shown in Fig. 65, the stretching device 10y is invaginated in the stomach wall 12ay. After in-vagination, a number of stomach-to-stomach sutures or staplers 14y are applied to keep the in-vagination in the short term. This allows growth of human tissue, keeping the in-vagination in the long term.

By enlarging the size of the stretching device, the stomach wall 12y surrounding the stretching device 10y is stretched since the circumference of the stretching device 10y is increased. By this stretching, receptors in the stomach wall indicate that the stomach is full, thereby creating a feeling of satiety to the patient. Correspondingly, when the stretching device 10y is contracted, the receptors indicate that the stomach is not full, thereby returning the feeling of hunger.

The expansion and contraction of the stretching device 10y can be performed under direct control of the patient. Alternatively, the expansion and contraction can be performed according to a pre-programmed schedule.

Returning to Fig. 65, this figure also shows a fluid operation device, i.e., a hydraulic or pneumatic operation device suited for operating the stretching device, which in the following will be described in detail.

The stretching device 10y forms a fluid chamber, in which fluid is allowed to flow. The stretching device 10y thus forms an expandable chamber that can change the volume it occupies in the stomach wall, thereby forming a hydraulically or pneumatically regulated stretching device 10y.

A regulation reservoir 16y for fluids is connected to the stretching device 10y by means of a conduit 18y in the form of a tube. The stretching device 10y is thereby adapted to be regulated, preferably non-invasively, by moving liquid or air from the regulation reservoir 16y to the chamber formed by the stretching device.

The regulation reservoir 16y can be regulated in several ways. In the embodiment shown in Fig. 65, the regulation reservoir 16y is regulated by manually pressing the regulation reservoir 16y. In other words, the regulation reservoir 16y is regulated by moving a wall of the reservoir. It is then preferred that the regulation reservoir 16y is placed subcutaneously and non-invasive regulation is thereby achieved.

When the regulation reservoir 16y is pressed, the volume thereof decreases and hydraulic fluid is moved from the reservoir to the chamber formed by the stretching device 10y via the conduit 18, enlarging or expanding the stretching device 10y. For filling and calibrating the fluid level of the apparatus an injection 1001y port is

furthermore provided. The injection port preferably comprises self sealing membrane, such as a silicone membrane.

It will be appreciated that instead of hydraulic operation, pneumatic operation can be used, wherein air instead of hydraulic fluid is moved between the reservoir 16y and the chamber formed by the stretching device 10y. Preferable the reservoir has a locking position to keep it in the desired position. If the patient compresses the reservoir 16y it preferably stays compressed and releases after pressing again.

Any kind of hydraulic solution may be used for the stretching device. The hydraulic solution may be driven by both mechanically and be powered with any motor or pump as well as manually.

Fig.65 further shows a reversed servo system which comprises a regulation reservoir 16y and a servo reservoir 90y. The servo reservoir 90y hydraulically controls a stretching device 10y via a conduit 18y. The reverse servo function is described in greater detail in figs. 97-100

Fig. 66a shows the apparatus according to another embodiment in which a motor 40y is adapted to move a wall of the regulation reservoir 16y. The powered regulation reservoir 16y is then preferably placed in the abdomen of the patient. In this embodiment, a wireless external remote control unit 34by,cy and an external energy transmission device 34ay can be provided to perform non-invasive regulation of the motor via an energy transforming device 30y, which is adapted to supply an energy consuming operation device, in the present example the motor 40y, with energy.

The remote control may comprise a wireless energy transmitter, 34ay which also can act as a regulation device for non-invasively regulating the stretching device. When the regulation is performed by means of a remote control 34y an internal power source 70y for powering the regulating device is provided. The internal energy source 70y can for example be a chargeable implanted battery or a capacitor or a device for receiving wireless energy transmitted from outside the body of the patient. Different ways of regulating the stretching device 10y will be described below with reference to Figs. 77-100.

The apparatus as shown in fig. 66a further comprises a sensor 201y sensing a parameter of the patient or the apparatus preferably connected to the food intake of the patient. The sensor is connected to a control assembly 42y by means of a sensor signal transferring member 202y. The sensor can be used to regulate said apparatus in a completely automatic way, i.e. the apparatus responds to a sensor signal connected to the food intake of the patient, thereby affecting the control assembly to operate the stretching device 10y to stretch the stomach wall 12y and thereby creating a feeling of satiety in the patient. The sensor could be adapted to measure the food intake of the patient through any of temperature, blood pressure, blood flow, heartbeats, breathing and pressure and can be placed in the stomach 12y, esophagus 203y or in connection with the cardia 204y. According to one embodiment said sensor is a strain gauge measuring contraction and/or relaxation of the cardia 204y.

The apparatus as shown in fig. 66a further comprises a second conduit 222y for backflow of hydraulic fluid. The backflow is adapted to create the desired feeling of satiety for a predetermined time whereafter the hydraulic fluid has flowed back in a quantity large enough for the stretching device not to stretch the stomach wall anymore and thereby the feeling of hunger returns to the patient. A suitable time for the process is between 1 and 6 hours. According to other embodiments the backflow takes place in the main conduit 18y by means of a valve system connected to said conduit 18y.

For filling and calibrating the fluid level of the apparatus an injection 1001y port is furthermore provided. The injection port 1001y preferably comprises self sealing membrane, such as a silicone membrane.

Fig. 66b shows the apparatus according to the embodiment of fig. 66a, in a second state in which the stretching device 10y is expanded and thereby stretches the stomach wall 12y.

Fig. 67a shows an embodiment, wherein two stretching devices 10''y are provided. Both stretching devices 10''y work according to the principles described above with reference to Fig. 65. They can be adapted to postoperatively and non-invasively be regulated and adapted to from time to time regulate different stretching devices to at

a first time stretch a first part of the stomach wall and at a second time stretch a second part of the stomach wall.

Such a stretching device 10y may be used for keeping electronics and/or an energy source and/or hydraulic fluid. Hydraulic fluid from that device may be distributed to several smaller stretching device areas to vary the stretching area from time to time avoiding any possible more permanent stretching effect of the stomach wall. Even mechanically several stretching areas may be used. The embodiment according to fig. 67a further comprises a hydraulic valve shifting device 54y, implanted in the patient, for shifting between operating the first and the second stretching device 10''y. The alternating creates a more sustainable device since the receptors in the stomach wall is stimulated gets a longer time of recovery between the stretches.

In fig. 67a the system is a manual system controlled by the patient as described before with reference to fig. 65, whereas in fig. 67b the system is energized using wireless energy as described before with reference to fig. 66a.

Fig. 68a-e shows different embodiments of the stretching device 10y adapted to be implanted in a patient. The stretching device 10y comprises a surface adapted to be in contact with the stomach wall 12y when the device is invaginated in the stomach wall. Fig. 68b shows an embodiment of the stretching device in which the stretching device comprises a fixating member 206y for suturing or stapling the stretching device to the stomach wall. The fixating member 206y could comprise holes for receiving said sutures or staplers 14y, or the fixation device 206y could be penetratable such that the sutures or staplers can penetrate the stomach wall and the fixation device 206y. 68c shows the stretching device 10y according to an embodiment in which the stretching device 10ycomprises an inlet member 207y for filling said device with a fluid. Said inlet member is preferably connected to a hydraulic conduit 18y adapted to be invaginated in the stomach wall 12y. Fig. 68d shows the stretching device 10y according to an embodiment in which the stretching device 10y comprises a holding member 208 adapted to connect to an insertion device when said stretching device 10y is inserted into an invaginated pouch of the stomach wall 12y. Fig. 68e shows the stretching device 10y according to an embodiment in which the stretching device has a slightly oval or egg-shaped shape.

Fig. 68e furthermore shows the hydraulic conduit 18 attached to said stretching device 10y. Fig. 68f shows the stretching device 10y according to an embodiment in which the stretching device is inflatable by a fluid transported through the conduit 18y. According to one embodiment shown in fig. 68f the conduit comprises two sections 18ay,by wherein the first section 18ay is used to pull the stretching device 10y into place, and to fill the device 10y with a suitable fluid, whereas the second section 18by is used for the operation of said device 10y. Fig. 68g shows the stretching device 10y according to the embodiment of fig. 68f in a deflated state. The stretching device 10y is inserted through a hole in the stomach wall 12y in its deflated state whereafter the device 10y is filled with a suitable fluid for operation. Fig. 68h shows the stretching device 10y according to an embodiment in which the stretching device 10y comprises two movable wall portion 223ay,by, which are moveable by means of a bellows structure 209y made of a flexible material. Fig. 68i shows the stretching device according to an embodiment where the stretching device is expandable by means of four expandable sections 210y symmetrically placed on four places along the surface of the stretching device, as shown in the section image of fig. 68i. The expandable sections 210y are made of a flexible material for allowing said sections 210y to expand when said stretching device 10y is filled with a hydraulic fluid.

SURFACE STRUCTURE OF IMPLANTS

The general structure of any implanted device of the invention will now be described with reference to figure 69 a-k. The present invention concerns an implant, adapted to post-operatively be adjustable and comprising at least one expandable section, wherein the implant is adapted to be adjustable between a first collapsed state and a second expanded state. In the first collapsed state the expandable section is collapsed, and in the second expanded state, the expandable section is expanded. The outer surface of said expandable section does at least partly comprise a surface structure having elevated areas alternating with lowered areas. The expandable

section is adapted to have, in at least one of said first collapsed and second expanded states a first distance between adjacent elevated areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent elevated areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said implant. The expandable section further comprising connecting areas between adjacent elevated and lowered areas, further adapted to have, in at least one of said first collapsed and second expanded states, a second distance between adjacent connecting areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent connecting areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said implant.

According to one embodiment the expandable section is hollow or comprises a hollow body.

According to another embodiment the implant is substantially completely hollow or comprises a hollow body extending along substantially the complete length and/or complete volume of said implant.

Fibrotic tissue can often have an extension or thickness of about 0,5 mm to about 1,5 mm and hence the distances between relevant surfaces of the elements of the surface structure are suitably greater than about 3 mm, hence greater than about 2 x 1,5 mm. But depending on the circumstances also distances greater than about 1,0 mm to about 3 mm may be sufficient. In cases where the fibrotic tissue can be expected to have an extension or thickness greater than about 1.5 mm the distances between relevant surfaces of the elements of the surface structure are adapted in a suitable manner.

The surface structure may comprise elevated and lowered areas and it may be suitable that also a distance between the different planes of the elevated and lowered areas is bigger than a certain threshold to facilitate the collapsible and/or expandable functionality of the implant. If said distance is too small, the collapsible and/or expandable functionality of the implant may be limited. A suitable interval for said distance is around 0,5 to 10 mm, more suitable around 2-8 mm and most suitable

around 3-7 mm. The surface structure may comprise different geometrical elements or shapes and any combination of such elements or shapes as long as the above mentioned conditions for the distances can be met. The surface structure may e.g. comprise ridges and grooves of different shapes. The ridges and grooves may each have a cross-section that is e.g. wedge-shaped, polygonal, square-formed, pyramidal-shaped, truncated pyramidal-shaped or. Further may the ridges and grooves have cross-sections of different shapes. The surface structure may as well in general comprise a bellows-shaped structure or a surface structure where geometrical objects of the same or different kind(s) are placed on a surface. The geometrical objects may be practically randomly placed on the surface or according to some scheme.

One type of implants where this type of surface structure may be suitable, is implants where the implant should have the ability to change shape and/or size substantially. Hence, this is a case where the presence of fibrotic tissue substantially could hinder or impede the function of the implant. But the surface structure may be used by any implant where the characteristics of the surface structure would be advantageous for the implant.

A first distance 708a between two elevated areas 701, see fig. 69a, is long enough so as to prevent growth of fibrotic tissue directly connecting two adjacent elevated areas 707. That is, it may be possible that fibrotic tissue grows on the surface of the elevated and lowered areas 701, 702 and the connecting areas 704. However, thanks to the extension of the first distance 708a, fibrotic tissue is prevented from growing directly from one elevated area 701 to another adjacent elevated area 701.

With the expression "growing directly from one elevated area 701 to another elevated area 701" it is e.g. meant that fibrotic tissue grows from one elevated area 701 to another while not or only to a small extent growing on a connecting area 704. As indicated at 704a in fig. 69i, the first distance 708a may be measured within an interval 704a from the level of an elevated area 701. The expression "growing directly from one elevated area 701 to another elevated area 701" also includes the situation that fibrotic tissue grows on adjacent areas, e.g. two adjacent connecting areas 704, with such a thickness that the fibrotic tissue from each adjacent area meet and bridge the distance or space between two elevated areas 701. In such a situation

the space between two elevated areas 701 may be partly or completely filled with fibrotic tissue.

It may be advantageous that also a second distance 708b corresponding to the extension of a lowered area 702 has an extension great enough so as to prevent fibrotic tissue from growing directly from one connecting area 704 to another connecting area 704. With the expression "growing directly from one connecting area 704 to another connecting area 704" it is meant that fibrotic tissue grows from one connecting area 704 to another while not or only to a small extent growing on a lowered area 702.

In fig. 69i a surface structure comprising elevated and lowered areas has been shown, but apart from elevated and lowered areas also many other geometrical structures may be used where it is possible to fulfill the above mentioned prevention of growth of fibrotic tissue. In particular, the above mentioned prevention of growth of fibrotic tissue between elevated areas and between connecting areas.

Some examples of such other geometrical structures are shown in figs. 69i-k. In a surface structure comprising ridges and grooves, the ridges and grooves may also have different sections, some examples are shown in figs. 69b-69e.

Referring mainly to Figs. 69a and b some expressions and aspects will now be explained. In this application the concept of a first distance 708a, 718a between adjacent elevated areas 701, 710 is used. With such a first distance 708a, 718a it is meant a distance that is measured substantially from the edge 706, 714 of one elevated area 701, 710 to the edge 706, 714 of an adjacent elevated area 701, 710. Measured substantially from the edge means that the measurement may be done within a first interval 704a from the level of an elevated area 701, 710, the first interval 704a extending from the level of an elevated area 701, 710 towards the level of an adjacent lowered area 702, 712.

In this application also the concept of a second distance 708b, 718b between adjacent connecting areas 704, 716 is used. With such a second distance 708b, 718b it is meant a distance that is measured substantially from the connection point

between a connecting area 704, 716 and a lowered area 702, 712 to another connection point involving an adjacent connecting area 704, 716. Measured substantially from the connection point means that the measurement may be done within a second interval 704b from the level of a lowered area 702, 712, the second interval 704b extending from the level of a lowered area 702, towards the level of an adjacent elevated area 701, 710.

With elevated and lowered areas it is meant areas that lie in different planes 703, 705, 720, 722 where the planes are separated by a distance 707, 724, 728. The planes may be parallel or substantially parallel but may also be non-parallel. If the planes are parallel, defining a distance between them is trivial. If the planes are non-parallel (as in fig. 2a) a distance between the planes may be defined by a normal 724, 728 to one of the planes 720, 722 where the normal extend to a point on an area in another plane 722, 726 and the distance between the planes is equal to the extension of the normal 724, 728. As seen in fig. 2a the normal 724, 728 extends from a plane 720, 722 to a point which is approximately equally distant from the edges of an area. There are two possible ways to define the normal or distance between the planes. Taking normal 728 as example, one may define the normal as in 728a or in 728b. It may be suitable to define the distance between two planes as the extension of the longest normal, the distance between the planes 720 and 722 would then be equal to the extension of normal 728a. This definition will be used hereafter.

The elevated and lowered areas may have different shapes, they may be plane or substantially plane but they may also have some kind of curved shape.

The elevated areas 701, 710 connect to adjacent lowered areas 702, 712 by means of connecting areas 704, 716. The connection between elevated/lowered areas and connecting areas 704, 716 may comprise a radius of different sizes, bigger or smaller radii. When the radius is very small there will substantially be an edge 706, 714 connecting the areas.

The expression "expandable section" implies that said section also is collapsible.

Suitably the implantable device 10 at least partly comprises materials which have a high degree of biocompatibility, such materials may be called physiologically inert, biologically inert or biocompatible.

Referring in particular to figs.69a-b, in the surface structure 700 there may advantageously be a specified first distance 708a, 718a between adjacent elevated areas 701, 710. The distance between adjacent elevated areas 701, 710 is chosen so that fibrotic tissue cannot bridge the first distance 708a, 718a between adjacent elevated areas 701, 710. Hence, the first distance 708a, 718a between adjacent elevated areas 701, 710 is advantageously big enough to prevent the formation of fibrotic tissue that bridges adjacent elevated areas 701, 710.

As mentioned before, there may advantageously be a specified second distance 708b, 718b between adjacent connecting areas 704, 716. The second distance 708b, 718b between adjacent connecting areas 704, 716 is chosen so that fibrotic tissue can not bridge the second distance 708b, 718b between adjacent connecting areas 704, 716. Hence, the second distance 708b, 718b between adjacent connecting areas 704, 716 is advantageously big enough to prevent the formation of fibrotic tissue that bridges adjacent connecting areas 704, 716.

It may also be advantageous that a third distance 707, 724, 728a between the different planes 703, 705, 720, 722, 726 of the elevated and lowered areas is bigger than a certain threshold to facilitate the collapsible and/or expandable functionality of the implant. If the third distance 707, 724, 728a is too small the collapsible and/or expandable functionality of the implant may be limited. A suitable interval for the third distance 707, 724, 728a is 0,5 to 10 mm, more suitable 2-8 mm and most suitable 3-7 mm. Also regarding the aspect that the fibrotic tissue should not impede the collapsible/expandable functionality of the implantable device it is advantageous that the distance 707, 724, 728a is not too small, but suitably in the interval/s as mentioned previously.

The surface structure 700 may include objects or elements of different geometrical shapes, for example ridges of different shapes, embossments of different shapes and other objects which enable a surface structure as described herein. The

area of the elevated areas 701, 710 may be very small while still resulting in a surface structure that has the desired functionality. The area of the elevated areas 701, 710 may even be almost zero, as exemplified in fig. 2d. Whereas figs. 1 and 2a-2d show cross sections of examples of surface structures 700, figs. 69i-k show examples of different surface structures 700 in perspective. The objects or elements in the surface structure 700 may be placed in rows, ordered in some other way, or may be more or less randomly distributed over the surface of the implant. Different types of objects may also be used together in the surface structure 700, e.g. a combination of pyramid shaped and cone shaped objects together with ridges of some shape.

In figs. 69f-h an embodiment of an implant 10 is shown where a surface structure 700 is used, the implant 10 is not shown in full. Fig. 69f shows a longitudinal section of the implant 10 where 740 denotes the surface structure on the upper side of the implant 10 and 742 denotes the surface structure on the under side of the implant 10. As shown in fig. 69f the surface structure 742 on the under side may have a greater extension than the surface structure 740 on the upper side of the penile prosthesis. This gives the implant 10 an up-bent position when the implant 10 is expanded. The surface structures 140 and 142 are one example of a bending portion. Fig. 69g shows a cross section of the implant 10 where the implant 10 includes a waist portion 744, where the waist portion comprises waist surface structures 746 and 748. The waist portion with the waist surface structures 746 and 748 make the implant 10 expandable also in the radial direction. The implant 10 may also have a cross section as shown in fig. 69g comprising a waist portion 744 having four waist surface structures 750, 752, 754, 756 further facilitating the ability of the implant 10 to be expandable also in the radial direction. The cross sections in figs. 69g and h are taken along the line A1-A2 in fig. 69f.

FURTHER EMBODIMENTS COMPRING A STRETCHING DEVICE.

Futher embodiments of the inventions that disclose the treatment of obesity by stretching the stomach will now be described.

Fig. 70a illustrates a stretching device 10y provided with an inlet port 18by. The stretching device 10 is invaginated in the stomach wall 12y and the inlet port 18by is available for connection to a tube or the like from the abdominal area of the patient. The tube or conduit 18y can preferably be connected to the control unit 42y or an injection port 1001y.

Fig. 70b illustrates an invaginated stretching device 10y wherein, instead of an inlet port, a conduit 18y or electrical lead extends into the abdominal area of the patient.

Fig. 70c shows a section of the stretching device 10y and part of the stomach in which the stretching device 10 yis invaginated. The conduit 18y or electric lead is invaginated in the stomach wall 12y by means of stomach to stomach sutures or staplers 14y which creates an entirely sealed pouch of stomach wall tissue in which the stretching device 10y is placed. The conduit 18y or electric lead is thereby tunneled in the stomach wall 12y between the inlet port 18byand the volume filling device 10y.

It has been shown that the shape of the stretching device 10y can take many different forms. It will be appreciated that also the material of the stretching device 10y can vary. It is preferred that the stretching device 10y is provided with a coating, such as a Parylene, polytetrafluoroethylene (PTFE), or polyurethane coating, or a combination of such coatings, i.e., a multi-layer coating. This coating or multi-layer coating improves the properties of the stretching device, such as its resistance to wear.

In another embodiment shown in Fig. 71, the stretching device 110y works according to a different principle from that described above with reference to Figs. 65-70. The

stretching device 110y here comprises a first fixation portion 110ay adapted to have a first fixation at a first position on the stomach wall 12y and a second fixation portion 110b yadapted to have a second fixation at a second position on the stomach wall 12y These fixation portions 110ay,by, which preferably have an essentially round shape and preferably are adapted to be invaginated in the stomach wall 12y, are attached to the distal end of a respective leg 211y, which in turn are attached at their respective proximal end to an operation device, such as a motor 40y. According to the embodiment shown in fig. 71 the motor is a hydraulic motor, comprising a hydraulic piston, which is connected to a manual operation device described previously with reference to fig. 65. The hydraulic piston affects the legs through their connection with a joint 212y placed in the extremity of the leg. The stretching device 110y is enclosed in a housing 214y protecting the device from the in growth of fibrotic tissue which potentially could damage the function of said device 110y. However it is equally conceivable that the motor is another hydraulic motor, a pneumatic motor or an electrical motor.

The stretching device 110y is adapted to increase the distance between the first position and the second position on the stomach wall 12y, thereby stretching the stomach wall 12y. The first and/or second fixation portions 110ay, 110by are adapted to at least partly be invaginated in the stomach wall 12y with stomach-to-stomach sutures or staplers 14y holding the fixation portions 110ay,by in place in suspension in relation to the stomach wall 12y.

Of course the first and second positions may be sutured or fixated to the stomach wall in many possible ways and the invention covers all possibilities to distend the stomach wall by moving two portions of the stomach wall away from each other and thereby first fixating the device to at least two positions on the stomach wall. However, the soft suspended connection to the stomach wall 12y where fibrotic stomach-to-stomach tissue helps to give a long term stable position is to prefer.

Of course just expanding an in-vaginated part of the stomach also stretches away the stomach wall 12y which also may be achieved both mechanically, hydraulically, pneumatically and both being powered with a motor or pump or by manual force.

Any kind of mechanical construction may be used and the mechanical embodiment disclosed is one example. Any mechanical construction driven by mechanically or hydraulically or any pneumatic construction may be used. Any motor or any pump or moving material changing form when powered may be used to achieve the simple goal of stretching a part of the stomach wall by moving at least two portions of the stomach wall away from each other.

Fig. 72 shows the stretching device 110y according to an embodiment in which the stretching device is controlled from an implantable control assembly 42y to which sensor input, as described earlier, in received. The stretching device is then regulated through the conduit 18y using a pump 44y, connected to at least one fluid reservoir 16y, 46y, and powered from a energy transforming member 30y connected to an receiver of wireless energy 205y, placed under the skin 36y, or an implantable energy source 70y, such as a rechargeable battery.

In a variant, shown in Fig. 73a, the first and/or second fixation portions 210ay, 210by, respectively, exhibit a structure adapted to be in contact with the stomach wall 12y to promote growth in of human tissue to secure the long term placement of the stretching device 110y attached to the stomach wall 12y. This structure preferably comprises a net like structure 213y. The fixation portions 210ay, 210by may be adapted to keep the stretching device 110y in place by sutures or staplers between the fixation portion and the stomach wall 12y to secure the short term placement of the stretching device 110y. In turns of mechanical operation the stretching device 110y according to the embodiment shown in fig. 73a functions in accordance with the device described with reference to fig. 71. Fig. 9by shows a fixation device 213y comprising a net like structure adapted to propagate the growth-in of fibrotic tissue to fixate the two fixating portions to the stomach wall 12y.

Fig. 73c shows the stretching device according to the embodiment of fig. 73a in a second state, in which the two fixating portions have been separated from each other and the stomach 12y has been stretched.

Fig. 74a shows the stretching device according to an embodiment in which the stretching device is an electrical mechanical stretching device connected to a control

assembly 42y through a power supply line 32'y. The power supply line 32y is connected to a power transforming device 30y in contact with a receiver of wireless energy 205y, such as a coil, which receives energy from a transmitter of wireless energy 34ay. The control assembly may furthermore comprise a battery 70y for storing energy received from the wireless energy transmission device 34ay. The control assembly receives input from a sensor 201y, which according to this embodiment is a strain gauge measuring the contraction and/or relaxation of the cardia 204y.

Fig. 74b shows the stretching device 10y in further detail. The stretching device 10y comprises a housing having a bellows structure 209y made of a flexible material so as to enable the wall portions to move. The power supply line 32y is connected to a stator 217y of an electrical motor, said motor further comprising a rotor 218y which comprises a thread that interacts with a displaceable member 219y comprising a corresponding thread. The displacing member is rotatably fixated to a housing contacting member 220y which pushes against the housing for affecting the volume of the stretching device and thereby stretching the stomach 12y.

Fig. 74c shows the stretching device according to fig. 10by in a second state, in which the stretching device is expanded and thereby stretches the stomach wall 12y.

Fig. 75a shows an embodiment in which a device adapted to treat reflux disease is combined with the stretching device according to any of the embodiments above. After invagination of the device 410 in the fundus 416, a fixation consisting of a number of stomach-to-stomach sutures or staples 422a is applied to keep the invagination intact in the short term. A second fixation consisting of a number of sutures or staples 422b is provided to hold the device 410 in position above the cardia 414. The sutures or staples 422b are applied between the wall of the fundus 416 and the wall of the esophagus 424y. Additionally, a third fixation in the form of sutures or staples 422cy may be provided between the wall of the fundus 416 and the diaphragm 418, again, to hold the device 410 in position above the cardia 414.

In this fourth embodiment depicted in Fig. 75a, the size of the reflux disease treatment device 410 can be regulated while being implanted. The reflux disease

treatment device 410 is associated with a subcutaneous hydraulic reservoir 452 connected to the reflux disease treatment device 410, by a lead 452b whereby a non-invasive regulation can be performed by manually pressing the reservoir 452. Pressing the reservoir 452 displaces hydraulic fluid from the reservoir 452 to the smaller chambers 410b via the lead 452b. The reflux disease treatment device 410 is, in turn, connected to one or more smaller chambers 410b. In this manner, the patient may adjust the size of the reflux treatment device 410 in a manner adapted to the treatment.

Furthermore, the embodiment above may alternatively be used to also treat obesity. The device may, in this embodiment, be adapted to treat obesity by using the volume of the reflux disease body to contain a fluid, and further using one or several smaller chambers 410b connected to the device body with a pump to be filled with fluid to expand and thereby stretch the fundus wall to create satiety. The small chambers 410b are also adapted to be invaginated to in the fundus stomach wall, and when filled with fluid, an expansion of the stomach occurs that results in human sensor feedback creating satiety. The subcutaneous hydraulic reservoir/pump enables the patient to conveniently pump hydraulic fluid to fill the small chambers 410b to create a feeling of satiety as he or she wishes.

An alternative embodiment is shown in figure 75b. This embodiment is substantially similar to the one shown in figure 75a but differs in how the reflux treatment device 410 and chambers 410b are controlled. Here, the chambers 410b are not controlled by a subcutaneous pump but a powered internal control unit 456. The internal control unit 456 comprises means for the patient to control the device 410 in how it shall be used regarding treatment of reflux and/or obesity. It may also comprise means of supplying power to the device.

The internal control unit 456 may comprise a battery 470, an electric switch 472, a motor/pump 444, a reservoir 452, an injection port 1001. An energy transmission device 34 with a remote control is adapted for controlling and powering the device. The items being selected depending on the circumstances, e.g. if the device is electrically, hydraulically, pneumatically or mechanically operated.. The device 410 may be used for keeping electronics and/or an energy source and/or hydraulic fluid.

Fig. 76a shows an adjustable volume filling device 810y, which is invaginated in the stomach wall of a patient's stomach 12y. The volume filling device 810y is adapted to take up space in the stomach and thereby reduce the volume in which food can be placed. Additionally, an adjustable stretching device 10y according to any of the embodiments is invaginated in the stomach fundus wall of the patient. It is preferred that the volume filling device 810y is substantially larger than the stretching device 10y.

The volume filling device 810y and the stretching device 10y are in fluid communication with each other via a first fluid tube 52y, in which a pump 54y is provided. The pump 54y is under the control from an energy transforming device 30y, which is adapted to supply the pump 54y with energy via a power supply line 56. The energy transforming device 30 is also connected to a sensor 201y provided in the esophagus of the patient so that food intake can be detected.

The volume filling device 810y and the stretching device 10y are also in fluid communication with each other via a second fluid tube 58y, which preferably has a smaller cross-sectional area than the first fluid tube 52y.

The operation of this arrangement is as follows. The volume filling device 810y functions as in the above described embodiments, i.e., it reduces the size of the food cavity of the patient's stomach 12y. Additionally, when the stretching device 10y is enlarged by pumping fluid from the volume filling device 810y and to the stretching device 10yby means of the pump 54y, the stomach fundus wall is stretched, creating a feeling of satiety for the patient. Thus, for example when food intake is detected by means of the sensor 201y, fluid is automatically pumped into the stretching device 10y to increase the feeling of satiety and thereby limit the food intake.

When fluid has been injected into the stretching device 10y, the internal pressure therein is higher than the internal pressure in the volume filling device 810y. This difference in pressure will create a flow of fluid in the second, preferably narrower tube 58y from the stretching device 10y to the volume filling device 810y. The flow

rate will be determined by among other things the difference in pressure and the cross-sectional area of the second tube 58y. It is preferred that the second tube is so dimensioned, that the pressures in the volume filling device 810y and the stretching device 10y will return to equilibrium after 3 hours after fluid has been injected into the stretching device 10y to create the feeling of satiety.

In this embodiment, the function of the second tube 58y is to allow fluid to return from the stretching device 10y to the volume filling device 810y. It will be appreciated that this function also can be performed by the pump 54y in the first tube 52y and that the second tube 58y then can be omitted.

Yet an alternative embodiment of an apparatus for treating obesity will now be described with reference to Fig. 76b, which shows a stomach 12y of a patient who is treated for obesity. The apparatus comprises a volume filling device 810y in the form of an inflatable device 10y which is invaginated in the wall 12ay of the patient's stomach 12y. However, in this case the invagination has been performed in the fundus, i.e., the upper portion of the stomach, where the number of receptors in the stomach wall is large, and the inflatable device functions as a stretching device for part of the stomach fundus wall.

A regulation reservoir for fluids is connected to the inflatable device by means of a conduit 18y in the form of a tube. The inflatable device 810y is thereby adapted to be regulated, preferably non-invasively, by moving liquid or air from the regulation reservoir to the chamber formed by the inflatable device 810y. The regulation of the inflatable device 810y preferably comprises a reversed servo, i.e., a small volume is actuated for example by the patient's finger and this small volume is in connection with a larger volume, i.e., the regulation reservoir.

Thus, the inflatable device 810y is placed outside the stomach wall and is adapted to stretch a part of the stomach fundus wall, thereby affecting the patient's appetite. By enlarging the size of the stretching device, the stomach fundus wall surrounding the inflatable stretching device 810y is stretched since the circumference of the inflatable stretching device 810y is increased. By this stretching, the receptors in the stomach wall indicate that the stomach is full, thereby creating a feeling of satiety to the

patient. Correspondingly, when the stretching device 810y is contracted, the receptors indicate that the stomach is not full, thereby returning the feeling of hunger. It will be appreciated that this embodiment combines the effects of both reducing the volume of the stomach food cavity and stretching part of the stomach wall 12y, thereby increasing the treatment effect.

The expansion and contraction of the stretching device 810y can be performed under direct control of the patient. Alternatively, the expansion and contraction can be performed according to a pre-programmed schedule.

In a preferred embodiment, shown in Fig. 76c, a sensor 201y is provided at a suitable position, such as at the esophagus. The volume filling device 810y in the form of the inflatable stretching device is similar to the one shown in Fig. 76b. By providing one or more sensors, the apparatus for treating obesity can be automated in that the size of the volume filling device 810y in the form of the inflatable stretching device is adjusted depending on the amount of food entering the food cavity of the stomach. The fluid is thereby moved between the inflatable volume filling device 810y and a fluid reservoir.

System

A obesity treatment system that can be combined with the above-mentioned system for treating reflux, generally designated 28 and comprising a stretching device as described above will now be described with reference to Figs. 77-93. The system 28 can be combined with or be the same as the system 28 for treating reflux in figures 1-64.

The system of Fig. 77 comprises a stretching device 10y placed in the abdomen of the patient. An internal energy source in the form of an implanted energy transforming device 30 is adapted to supply energy consuming components of the obesity treatment system with energy via a power supply line 32. An external energy transmission device 34 includes a wireless remote control transmitting a wireless signal, which is received by a signal receiver, which may be incorporated in the

implanted energy transforming device 30 or be separated therefrom. The implanted energy transforming device 30 transforms energy from the signal into electric energy which is supplied via the power supply line 32.

The system of Fig. 77 is shown in a more generalized block diagram form in Fig. 79, wherein the patient's skin 36, generally shown by a vertical line, separates the interior of the patient to the right of the line from the exterior to the left of the line.

Fig. 77 shows a simplified block diagram showing the stretching device 10y, the energy transforming device 30 powering the stretching device via power supply line 32, and the external energy transmission device 34.

Fig. 78 shows an embodiment of the invention identical to that of Fig. 81, except that a reversing device in the form of an electric switch 38 operable by polarized energy also is implanted in the patient for reversing the stretching device 10y. The wireless remote control of the external energy transmission device 34 transmits a wireless signal that carries polarized energy and the implanted energy transforming device 30 transforms the wireless polarized energy into a polarized current for operating the electric switch 38. When the polarity of the current is shifted by the implanted energy transforming device 30 the electric switch 38 reverses the function performed by the stretching device 10y.

Fig. 79 shows an embodiment of the invention identical to that of Fig. 78, except that an operation device 40 implanted in the patient for regulating the stretching device 10y is provided between the implanted energy transforming device 30 and the stretching device 10y. This operation device can be in the form of a motor 40, such as an electric servomotor. The motor 40 is powered with energy from the implanted energy transforming device 30, as the remote control of the external energy transmission device 34 transmits a wireless signal to the receiver of the implanted energy transforming device 30.

Fig. 80 shows an embodiment of the invention identical to that of Fig. 81, except that it also comprises an operation device is in the form of an assembly 42 including a motor/pump unit 78 and a fluid reservoir 46 is implanted in the patient. In this case

the stretching device 10y is hydraulically operated, i.e. hydraulic fluid is pumped by the motor/pump unit 44 from the fluid reservoir 46 through a conduit 48 to the stretching device 10y to operate the stretching device, and hydraulic fluid is pumped by the motor/pump unit 44 back from the stretching device 10y to the fluid reservoir 46 to return the stretching device to a starting position. The implanted energy transforming device 30 transforms wireless energy into a current, for example a polarized current, for powering the motor/pump unit 44 via an electric power supply line 50.

Instead of a hydraulically operated stretching device 10y, it is also envisaged that the operation device comprises a pneumatic operation device. In this case, pressurized air can be used for regulation and the fluid reservoir is replaced by an air chamber and the fluid is replaced by air.

In all of these embodiments the energy transforming device 30 may include a rechargeable accumulator like a battery or a capacitor to be charged by the wireless energy and supplies energy for any energy consuming part of the device.

The external energy transmission device 34 is preferably wireless and may include a remotely controlled control device for controlling the device from outside the human body.

Such a control device may include a wireless remote control as well as a manual control of any implanted part to make contact with by the patient's hand most likely indirect for example a button to press placed under the skin.

Fig. 81 shows an embodiment of the invention comprising the external energy transmission device 34 with its wireless remote control, the stretching device 10y, in this case hydraulically operated, and the implanted energy transforming device 30, and further comprising a hydraulic fluid reservoir 52, a motor/pump unit 44 and an reversing device in the form of a hydraulic valve shifting device 54, all implanted in the patient. Of course the hydraulic operation could easily be performed by just changing the pumping direction and the hydraulic valve may therefore be omitted. The remote control may be a device separated from the external energy transmission

or included in the same. The motor of the motor/pump unit 44 is an electric motor. In response to a control signal from the wireless remote control of the external energy transmission device 34, the implanted energy transforming device 30 powers the motor/pump unit 44 with energy from the energy carried by the control signal, whereby the motor/pump unit 44 distributes hydraulic fluid between the hydraulic fluid reservoir 52 and the stretching device 10y. The remote control of the external energy transmission device 34 controls the hydraulic valve shifting device 54 to shift the hydraulic fluid flow direction between one direction in which the fluid is pumped by the motor/pump unit 44 from the hydraulic fluid reservoir 52 to the stretching device 10y to operate the stretching device, and another opposite direction in which the fluid is pumped by the motor/pump unit 44 back from the stretching device 10y to the hydraulic fluid reservoir 52 to return the stretching device to a starting position.

Fig. 82 shows an embodiment of the invention identical to that of Fig. 81, except that an internal control unit 56 controlled by the wireless remote control of the external energy transmission device 34, an accumulator 58 and a capacitor 60 also are implanted in the patient. The internal control unit 56 arranges storage of electric energy received from the implanted energy transforming device 30 in the accumulator 58, which supplies energy to the stretching device 10y. In response to a control signal from the wireless remote control of the external energy transmission device 34, the internal control unit 56 either releases electric energy from the accumulator 58 and transforms the released energy via power lines 62 and 64, or directly transforms electric energy from the implanted energy transforming device 30 via a power line 66, the capacitor 60, which stabilizes the electric current, a power line 68 and the power line 64, for the operation of the stretching device 10y.

The internal control unit is preferably programmable from outside the patient's body. In a preferred embodiment, the internal control unit is programmed to regulate the stretching device 10y to stretch the stomach according to a pre-programmed time-schedule or to input from any sensor sensing any possible physical parameter of the patient or any functional parameter of the device.

In accordance with an alternative, the capacitor 60 in the embodiment of Fig. 18 may be omitted. In accordance with another alternative, the accumulator 58 in this embodiment may be omitted.

Fig. 83 shows an embodiment of the invention identical to that of Fig. 77, except that a battery 70 for supplying energy for the operation of the stretching device 10y and an electric switch 72 for switching the operation of the stretching device 10y also are implanted in the patient. The electric switch 72 is operated by the energy supplied by the implanted energy transforming device 30 to switch from an off mode, in which the battery 70 is not in use, to an on mode, in which the battery 70 supplies energy for the operation of the stretching device 10y.

Fig. 84 shows an embodiment of the invention identical to that of Fig. 83, except that an internal control unit 56 controllable by the wireless remote control of the external energy transmission device 34 also is implanted in the patient. In this case, the electric switch 72 is operated by the energy supplied by the implanted energy transforming device 30 to switch from an off mode, in which the wireless remote control is prevented from controlling the internal control unit 56 and the battery is not in use, to a standby mode, in which the remote control is permitted to control the internal control unit 56 to release electric energy from the battery 70 for the operation of the stretching device 10y.

Fig. 85 shows an embodiment of the invention identical to that of Fig. 84, except that an accumulator 58 is substituted for the battery 70 and the implanted components are interconnected differently. In this case, the accumulator 58 stores energy from the implanted energy transforming device 30. In response to a control signal from the wireless remote control of the external energy transmission device 34, the internal control unit 56 controls the electric switch 72 to switch from an off mode, in which the accumulator 58 is not in use, to an on mode, in which the accumulator 58 supplies energy for the operation of the stretching device 10y.

Fig. 86 shows an embodiment of the invention identical to that of Fig. 85, except that a battery 70 also is implanted in the patient and the implanted components are interconnected differently. In response to a control signal from the wireless remote

control of the external energy transmission device 34, the internal control unit 56 controls the accumulator 58 to deliver energy for operating the electric switch 72 to switch from an off mode, in which the battery 70 is not in use, to an on mode, in which the battery 70 supplies electric energy for the operation of the stretching device 10y.

Alternatively, the electric switch 72 may be operated by energy supplied by the accumulator 58 to switch from an off mode, in which the wireless remote control is prevented from controlling the battery 70 to supply electric energy and is not in use, to a standby mode, in which the wireless remote control is permitted to control the battery 70 to supply electric energy for the operation of the stretching device 10y.

It should be understood that the switch should be interpreted in its broadest embodiment. This means an FPGA or a DA converter or any other electronic component or circuit may switch power on and off preferably being controlled from outside the body or by an internal control unit.

Fig. 87 shows an embodiment of the invention identical to that of Fig. 83, except that a motor 40, a mechanical reversing device in the form of a gear box 74, and an internal control unit 56 for controlling the gear box 74 also are implanted in the patient. The internal control unit 56 controls the gear box 74 to reverse the function performed by the stretching device 10y (mechanically operated). Even simpler is to switch the direction of the motor electronically.

Fig. 88 shows an embodiment of the invention identical to that of Fig. 86 except that the implanted components are interconnected differently. Thus, in this case the internal control unit 56 is powered by the battery 70 when the accumulator 58, suitably a capacitor, activates the electric switch 72 to switch to an on mode. When the electric switch 72 is in its on mode the internal control unit 56 is permitted to control the battery 70 to supply, or not supply, energy for the operation of the stretching device 10y.

Fig. 89 schematically shows conceivable combinations of implanted components of the apparatus for achieving various communication options. Basically, there are the

stretching device 10yy, the internal control unit 56, motor or pump unit 44, and the external energy transmission device 34 including the external wireless remote control. As already described above the wireless remote control transmits a control signal which is received by the internal control unit 56, which in turn controls the various implanted components of the apparatus.

A feedback device, preferably in the form of a sensor 76, may be implanted in the patient for sensing a physical parameter of the patient, such as a contraction wave in the esophagus 203 informing the patient is eating. The internal control unit 56, or alternatively the external wireless remote control of the external energy transmission device 34, may control the stretching device 10y in response to signals from the sensor 76. A transceiver may be combined with the sensor 76 for sending information on the sensed physical parameter to the external wireless remote control. The wireless remote control may comprise a signal transmitter or transceiver and the internal control unit 56 may comprise a signal receiver or transceiver. Alternatively, the wireless remote control may comprise a signal receiver or transceiver and the internal control unit 56 may comprise a signal transmitter or transceiver. The above transceivers, transmitters and receivers may be used for sending information or data related to the stretching device 10y from inside the patient's body to the outside thereof.

Alternatively, the sensor 76 may be arranged to sense a functional parameter of the stretching device 10y.

Where the motor/pump unit 44 and battery 70 for powering the motor/pump unit 44 are implanted, the battery 70 may be equipped with a transceiver for sending information on the condition of the battery 70. To be more precise, when charging a battery or accumulator with energy feedback information related to said charging process is sent and the energy supply is changed accordingly.

Fig. 90 shows an alternative embodiment wherein the stretching device 10y is regulated from outside the patient's body. The obesity treatment system 28 comprises a stretching device 10y connected to a battery 70 via a subcutaneous switch 80. Thus, the regulation of the stretching device 10y is performed non-

invasively by manually pressing the subcutaneous switch, whereby the operation of the stretching device 10y is switched on and off. It will be appreciated that the shown embodiment is a simplification and that additional components, such as an internal control unit or any other part disclosed in the present application can be added to the obesity treatment system.

Fig. 91 shows an alternative embodiment, wherein the obesity treatment system 28 comprises a stretching device 10y in fluid connection with a hydraulic fluid reservoir 52. Non-invasive regulation is performed by manually pressing the hydraulic reservoir connected to the stretching device 10y.

A further embodiment of a system according to the invention comprises a feedback device for sending information from inside the patient's body to the outside thereof to give feedback information related to at least one functional parameter of the stretching device or system or a physical parameter of the patient, thereby optimizing the performance of the system.

One preferred functional parameter of the device is correlated to the transfer of energy for charging the internal energy source.

In Fig. 92, an arrangement is schematically illustrated for supplying an accurate amount of energy to a obesity treatment system 28 implanted in a patient, whose skin 36 is indicated by a vertical line. A stretching device 10y is connected to an implanted energy transforming device 30, likewise located inside the patient, preferably just beneath the patient's skin 36. Generally speaking, the implanted energy transforming device 30 may be placed in the abdomen, thorax, muscle fascia (e.g. in the abdominal wall), subcutaneously, or at any other suitable location. The the implanted energy transforming device 30 is adapted to receive wireless energy E transmitted from an external energy source 34a provided in the external energy transmission device 34 located outside the patient's skin 36 in the vicinity of the implanted energy transforming device 30.

As is well known in the art, the wireless energy E may generally be transferred by means of any suitable Transcutaneous Energy Transfer (TET) device, such as a

device including a primary coil arranged in the external energy source 34a and an adjacent secondary coil arranged in the implanted energy transforming device 30. When an electric current is fed through the primary coil, energy in the form of a voltage is induced in the secondary coil which can be used to operate a stretching device, e.g. after storing the incoming energy in an energy storing device or accumulator, such as a battery or a capacitor. However, the present invention is generally not limited to any particular energy transfer technique, TET devices or energy storing devices, and any kind of wireless energy may be used.

The amount of energy received inside the body to the device may be compared with the energy used by the device. The term used by the device is then understood to include also energy stored by the device. The amount of transferred energy can be regulated by means of an external control unit 34b controlling the external energy source 34a based on the determined energy balance, as described above. In order to transfer the correct amount of energy, the energy balance and the required amount of energy can be determined by means of an internal control unit 56 connected to the stretching device 10y. The internal control unit 56 may thus be arranged to receive various measurements obtained by suitable sensors or the like, not shown, measuring certain characteristics of the stretching device 10y, somehow reflecting the required amount of energy needed for proper operation of the stretching device 10y. Moreover, the current condition of the patient may also be detected by means of suitable measuring devices or sensors, in order to provide parameters reflecting the patient's condition. Hence, such characteristics and/or parameters may be related to the current state of the stretching device 10y, such as power consumption, operational mode and temperature, as well as the patient's condition reflected by, e.g., body temperature, blood pressure, heartbeats and breathing.

Furthermore, an energy storing device or accumulator 58 may optionally be connected to the implanted energy transforming device 30 for accumulating received energy for later use by the stretching device 10y. Alternatively or additionally, characteristics of such an accumulator, also reflecting the required amount of energy, may be measured as well. The accumulator may be replaced by a battery, and the measured characteristics may be related to the current state of the battery, such as

voltage, temperature, etc. In order to provide sufficient voltage and current to the stretching device 10y, and also to avoid excessive heating, it is clearly understood that the battery should be charged optimally by receiving a correct amount of energy from the implanted energy transforming device 30, i.e. not too little or too much. The accumulator may also be a capacitor with corresponding characteristics.

For example, battery characteristics may be measured on a regular basis to determine the current state of the battery, which then may be stored as state information in a suitable storage means in the internal control unit 56. Thus, whenever new measurements are made, the stored battery state information can be updated accordingly. In this way, the state of the battery can be "calibrated" by transferring a correct amount of energy, so as to maintain the battery in an optimal condition.

Thus, the internal control unit 56 is adapted to determine the energy balance and/or the currently required amount of energy, (either energy per time unit or accumulated energy) based on measurements made by the above-mentioned sensors or measuring devices on the stretching device 10y, or the patient, or an energy storing device if used, or any combination thereof. The internal control unit 56 is further connected to an internal signal transmitter 82, arranged to transmit a control signal reflecting the determined required amount of energy, to an external signal receiver 34c connected to the external control unit 34b. The amount of energy transmitted from the external energy source 34a may then be regulated in response to the received control signal.

Alternatively, sensor measurements can be transmitted directly to the external control unit 34b wherein the energy balance and/or the currently required amount of energy can be determined by the external control unit 34b, thus integrating the above-described function of the internal control unit 56 in the external control unit 34b. In that case, the internal control unit 56 can be omitted and the sensor measurements are supplied directly to the internal signal transmitter 82 which sends the measurements over to the external signal receiver 34c and the external control unit 34b. The energy balance and the currently required amount of energy can then be determined by the external control unit 34b based on those sensor measurements.

Hence, the present solution employs the feedback of information indicating the required energy, which is more efficient than previous solutions because it is based on the actual use of energy that is compared to the received energy, e.g. with respect to the amount of energy, the energy difference, or the energy receiving rate as compared to the energy rate used by the stretching device. The stretching device may use the received energy either for consuming or for storing the energy in an energy storage device or the like. The different parameters discussed above would thus be used if relevant and needed and then as a tool for determining the actual energy balance. However, such parameters may also be needed per se for any actions taken internally to specifically operate the stretching device.

The internal signal transmitter 82 and the external signal receiver 34c may be implemented as separate units using suitable signal transfer means, such as radio, IR (Infrared) or ultrasonic signals. Alternatively, the internal signal transmitter 82 and the external signal receiver 34c may be integrated in the implanted energy transforming device 30 and the external energy source 34a, respectively, so as to convey control signals in a reverse direction relative to the energy transfer, basically using the same transmission technique. The control signals may be modulated with respect to frequency, phase or amplitude.

To conclude, the energy supply arrangement illustrated in Fig. 28 may operate basically in the following manner. The energy balance is first determined by the internal control unit 56. A control signal reflecting the required amount of energy is also created by the internal control unit 56, and the control signal is transmitted from the internal signal transmitter 82 to the external signal receiver 34c. Alternatively, the energy balance can be determined by the external control unit 34b instead depending on the implementation, as mentioned above. In that case, the control signal may carry measurement results from various sensors. The amount of energy emitted from the external energy source 34a can then be regulated by the external control unit 34b, based on the determined energy balance, e.g. in response to the received control signal. This process may be repeated intermittently at certain intervals during ongoing energy transfer, or may be executed on a more or less continuous basis during the energy transfer.

The amount of transferred energy can generally be regulated by adjusting various transmission parameters in the external energy source 34a, such as voltage, current, amplitude, wave frequency and pulse characteristics.

A method is thus provided for controlling transmission of wireless energy supplied to an electrically operable stretching device implanted in a patient. The wireless energy E is transmitted from an external energy source located outside the patient and is received by an internal energy receiver located inside the patient, the internal energy receiver being connected to the stretching device for directly or indirectly supplying received energy thereto. An energy balance is determined between the energy received by the internal energy receiver and the energy used for the stretching device. The transmission of wireless energy E from the external energy source is then controlled based on the determined energy balance.

A system is also provided for controlling transmission of wireless energy supplied to an electrically operable stretching device implanted in a patient. The system is adapted to transmit the wireless energy E from an external energy source located outside the patient which is received by an implanted energy transforming device located inside the patient, the implanted energy transforming device being connected to the stretching device for directly or indirectly supplying received energy thereto. The system is further adapted to determine an energy balance between the energy received by the implanted energy transforming device and the energy used for the stretching device, and control the transmission of wireless energy E from the external energy source, based on the determined energy balance.

The functional parameter of the device is correlated to the transfer of energy for charging the internal energy source.

In yet an alternative embodiment, the external source of energy is controlled from outside the patient's body to release electromagnetic wireless energy, and released electromagnetic wireless energy is used for operating the stretching device.

In another embodiment, the external source of energy is controlling from outside the patient's body to release non-magnetic wireless energy, and released non-magnetic wireless energy is used for operating the stretching device.

Those skilled in the art will realize that the above various embodiments according to Figs. 17-29 could be combined in many different ways. For example, the electric switch 38 operated polarized energy could be incorporated in any of the embodiments of Figs. 11, 18-24, the hydraulic valve shifting device 54 could be incorporated in the embodiment of Fig. 16, and the gear box 74 could be incorporated in the embodiment of Fig. 15. Please observe that the switch simply could mean any electronic circuit or component.

Wireless transfer of energy for operating the stretching device has been described to enable non-invasive operation. It will be appreciated that the stretching device can be operated with wire bound energy as well. One such example is shown in Fig. 93, wherein an external switch 84 is interconnected between the external energy source 34a and an operation device, such as an electric motor regulating the stretching device 10y, by means of power lines 86 and 88. An external control unit 34b controls the operation of the external switch to effect proper operation of the stretching device 10y.

Hydraulic or pneumatic powering

Figs. 94-97 show in more detail block diagrams of four different ways of hydraulically or pneumatically powering an apparatus for treating obesity according to the invention.

Fig. 94 shows an apparatus for treating obesity as described above with reference to any of Figs. 65-70. The apparatus comprises a stretching device 10y and further a separate regulation reservoir 16, a one way pump 44 and an alternate valve 54.

Fig. 95 shows the stretching device 10y and a fluid reservoir 16. By moving the wall of the regulation reservoir or changing the size of the same in any other different

way, the adjustment of the stretching device may be performed without any valve, just free passage of fluid any time by moving the reservoir wall.

96 shows the stretching device 10y, a two way pump 44 and the regulation reservoir 16.

Fig. 97 shows a block diagram of a reversed servo system with a first closed system controlling a second closed system. The servo system comprises a regulation reservoir 16 and a servo reservoir 90. The servo reservoir 90 mechanically controls a stretching device 10y via a mechanical interconnection 94, the stretching device having an expandable/contactable cavity. This cavity is preferably expanded or contracted by supplying hydraulic fluid from the larger adjustable reservoir 92 in fluid connection with the stretching device 10y. Alternatively, the cavity contains compressible gas, which can be compressed and expanded under the control of the servo reservoir 90.

The servo reservoir 90 can also be part of the stretching device itself.

In one embodiment, the regulation reservoir is placed subcutaneous under the patient's skin 36 and is operated by pushing the outer surface thereof by means of a finger. This obesity treatment system is illustrated in Figs 98a-c. In Fig. 98a, a flexible subcutaneous regulation reservoir 16 is shown connected to a bulge shaped servo reservoir 90 by means of a conduit 18. This bellow shaped servo reservoir 90 is comprised in a flexible stretching device 10y. In the state shown in Fig. 98a, the servo reservoir 90 contains a minimum of fluid and most fluid is found in the regulation reservoir 16. Due to the mechanical interconnection between the servo reservoir 90 and the stretching device 10y, the outer shape of the stretching device 10y is contracted, i.e., it occupies less than its maximum volume. This maximum volume is shown with dashed lines in the figure.

Fig. 98b shows a state wherein a user, such as the patient in with the stretching device is implanted, presses the regulation reservoir 16 so that fluid contained therein is brought to flow through the conduit 18 and into the servo reservoir 90, which, thanks to its bellow shape, expands longitudinally. This expansion in turn expands

the stretching device 10y so that it occupies its maximum volume, thereby stretching the stomach wall (not shown) which it contacts.

The regulation reservoir 16 is preferably provided with means for keeping its shape after compression. This means, which is schematically shown as 16a in the figure, will thus keep the stretching device 10y in a stretched position also when the user releases the regulation reservoir. In this way, the regulation reservoir essentially operates as an on/off switch for the obesity treatment system.

An alternative embodiment of hydraulic or pneumatic operation will now be described with reference to Figs. 99 and 100a-c. The block diagram shown in Fig. 99 comprises with a first closed system controlling a second closed system. The first system comprises a regulation reservoir 16 and a servo reservoir 90. The servo reservoir 90 mechanically controls a larger adjustable reservoir 92 via a mechanical interconnection 94. A stretching device 10y having an expandable/contactable cavity is in turn controlled by the larger adjustable reservoir 92 by supply of hydraulic fluid from the larger adjustable reservoir 92 in fluid connection with the stretching device 10y.

An example of this embodiment will now be described with reference to Fig. 100a-c. Like in the previous embodiment, the regulation reservoir is placed subcutaneous under the patient's skin and is operated by pushing the outer surface thereof by means of a finger. The regulation reservoir 16 is in fluid connection with a bellow shaped servo reservoir 90 by means of a conduit 18. In the first closed system 16, 18, 90 shown in Fig. 34a, the servo reservoir 90 contains a minimum of fluid and most fluid is found in the regulation reservoir 16.

The servo reservoir 90 is mechanically connected to a larger adjustable reservoir 92, in this example also having a bellow shape but with a larger diameter than the servo reservoir 90. The larger adjustable reservoir 92 is in fluid connection with the stretching device 10y. This means that when a user pushes the regulation reservoir 16, thereby displacing fluid from the regulation reservoir 16 to the servo reservoir 90, the expansion of the servo reservoir 90 will displace a larger volume of fluid from the larger adjustable reservoir 92 to the stretching device 10y. In other words, in this

reversed servo, a small volume in the regulation reservoir is compressed with a higher force and this creates a movement of a larger total area with less force per area unit.

Like in the previous embodiment described above with reference to Figs. 98a-c, the regulation reservoir 16 is preferably provided with means for keeping its shape after compression. This means, which is schematically shown as 16a in the figure, will thus keep the stretching device 10y in a stretched position also when the user releases the regulation reservoir. In this way, the regulation reservoir essentially operates as an on/off switch for the obesity treatment system.

METHOD FOR THE SURGICAL TREATMENT OF A PATIENT SUFFERING FROM REFLUX AND OBESITY

A method for surgically treating an obese patient that also suffers from reflux, the method comprising the steps of cutting an opening in the abdominal wall of the patient, dissecting an area around the stomach, placing an apparatus for treating to a part of the stomach wall of the patient, and suturing the stomach wall.

The apparatus for treating obesity and reflux is preferably placed in a patient via a laparoscopic abdominal approach, comprising the steps of: inserting a needle or a tube like instrument into the abdomen of the patient's body, using the needle or a tube like instrument to fill the patient's abdomen with gas thereby expanding the patient's abdominal cavity, placing at least two laparoscopic trocars in the patient's body, inserting a camera through one of the laparoscopic trocars into the patient's abdomen, inserting at least one dissecting tool through one of said at least two laparoscopic trocars and dissecting an intended placement area of the patient, and placing an apparatus for treating obesity in connection with the stomach wall.

The methods could further comprise the step of postoperatively regulating the at least one stretching device to: stretch a part of the stomach wall and regulate the stretching device from outside the patient's body to affect the appetite of the patient.

INSTRUMENTS

An intraluminar method of invaginating a stretching device 10 on the outside of the stomach wall 12 will now be described with reference to Figs. 101a-i. Initially, an instrument 600, preferably a gastroscopic instrument, is inserted into the mouth of the patient, see Fig. 101a. The instrument comprises an injection device 601, 602 for injecting either fluid or a device into the stomach of the patient. The instrument 600 further comprises a control unit 606 adapted for controlling the operation of the instrument. To this end, the control unit 606 comprises one or more steering devices, in the embodiment shown in the figure in the form of two joysticks 603 and two control buttons 604. A display 605 is provided for displaying the image provided by an optical device for viewing inside the stomach, such as a camera (not shown) arranged at the outer end of the elongated member 607, see Figs. 101e-i. The camera, which may comprise connecting electrical wires extending along the elongated member, may be assisted by a light source (not shown) placed distally on the elongated member for illuminating the inside of the stomach. The optical device may also comprise optical fibers placed along the elongated member and leading out from the patient's body for external viewing of the inside of the stomach.

The instrument is further inserted into the esophagus and into the stomach of the patient, see Fig. 101b. By means of the instrument 600, a hole 12by is created in the wall of the stomach 12y. To this end, the instrument is provided with one or more cutters 615 at the distal end thereof. These cutters can of course be designed in different ways, such as a toothed drum cutter rotating about the center axis of the tube-like instrument.

After cutting a hole in the stomach wall, the distal end of the instrument 600 is inserted into and through the hole 2by so that it ends up outside the stomach wall 12ay. This is shown in Fig. 101c, showing a side view of the stomach 12y, and Fig.

101d, which is a sectional view through the stomach of fig. 101c taken along the lines Vd – Vd.

The instrument 600 is adapted to create a "cavity" or "pouch" on the outside of the stomach around the hole 12by in the stomach wall 12y. Such an instrument and the method of providing the pouch will now be described.

Figs. 101e-i show a gastroscopic or laparoscopic instrument for invaginating a stretching device 10 in the stomach wall 12 of the patient by creating a pouch of stomach wall 12 material in which the stretching device 10 is placed. The instrument, generally designated 600, comprises an elongated member 607 having a proximal end and a distal end, the elongated member 607 having a diameter less than that of the patient's esophagus and being flexible such as to allow introduction of the flexible elongated member 607 with its distal end first through the patient's throat, esophagus and into the stomach 12 to the stomach wall 12a.

The stomach penetration device or cutter 615 is provided on the elongated member 607 at the distal en thereof for penetrating the stomach wall 12a so as to create a hole in the stomach wall 12a, to allow introduction of the elongated member 607 through the hole. The stomach penetration device 615 could be adapted to be operable for retracting said stomach penetration device 615 after the stomach fundus wall 12a has been penetrated, for not further damaging tissue within the body. The instrument further comprises a special holding device 609 provided on the elongated member 607 on the proximal side to the penetration device 615.

The elongated member further comprises an expandable member 611 which is adapted to be expanded after the elongated member has penetrated the stomach wall 12a and thereby assist in the creation of a cavity or pouch adapted to hold the volume filling device 610. The expandable member 611 may comprise an inflatable circular balloon provided circumferentially around the distal end portion of the flexible elongated member 607.

The method steps when invaginating the volume filling device will now be described in detail. After the instrument 600 has been inserted into the stomach 12, the stomach

penetration device 615 is placed into contact with the stomach wall 12, see fig. 101e. The stomach penetration device or cutter 615 is then brought to create the hole 12b in the stomach wall, whereafter at least the expandable member 611 is brought through the hole 12b in the stomach wall. The special holding device 609 is in this step brought to a holding state wherein it expands radially so as to form an essentially circular abutment surface to the stomach wall 12, see Fig. 101f. In this way, the insertion of the stomach penetration device 615 and the expandable member 611 through the hole 12 in the stomach wall is limited to the position shown in fig. 101f.

The expandable member 611 is then expanded. In the case the expandable member comprises a balloon or the like, air or other fluid is injected into it.

The part of the elongated member 607 comprising the expandable member 611 is then retracted in the proximal direction, as indicated by the arrow in Fig. 101g, thereby pulling the stomach wall 612 into a basket or cup like structure created by the special holding device 609.

A suturing or stapling device 608 is further provided, either as a device connected to the elongated member 607 or as a separate instrument. The suturing or stapling member comprises a suturing or stapling end 613 which is adapted to close the cavity or pouch by means of stomach to stomach sutures or staples 14.

In a further step, illustrated in Fig. 101h, an inflatable stretching device 10 is placed in its deflated state in the cup like structure. The stretching device 10 is then inflated to its inflated or expanded state, see Fig. 101i. This inflation of the stretching device 10 can be accomplished by injecting a fluid or a gel into the deflated stretching device. It can also be accomplished by injecting a material which is allowed to cure, thereby forming a solid device 10. Thus, the stretching device 10 shown in Figs. 101h and 101i can illustrate either a balloon-like device which is subsequently filled with fluid or gel or alternatively a material which is simply injected into the cup like structure formed by the stomach wall 12.

The fluid which is used to fill the stretching device 10 could be any suitable fluid suitable to fill the stretching device 10, such as a salt solution. In another

embodiment, when this fluid is a fluid which is adapted to be transformed into solid state, the fluid could be liquid polyurethane.

In order to minimize or entirely eliminate leakage, the fluid is iso-tonic, i.e., it has the same osmolarity as human body fluids. Another way of preventing diffusion is to provide a fluid which comprises large molecules, such as iodine molecules.

The stomach-to-stomach sutures or staples 14 are preferably provided with fixation portions exhibiting a structure, such as a net like structure, adapted to be in contact with the stomach wall 12 to promote growth in of human tissue to secure the long term placement of the stretching device attached to the stomach wall.

Thereby is the inflatable stretching device 10 in its inflated or expanded state invaginated by a stomach wall portion of the patient on the outside of the stomach wall 12.

During one or more of the above described steps, the stomach may be inflated with gas, preferably by means of the gastroscopic instrument.

The stretching device 10 described above with reference to Figs. 101a-i has been described as an inflatable stretching device. It will be appreciated that it also can be an elastic stretching device with an elasticity allowing compression so as to be inserted into a gastroscopic instrument and which expands to an expanded state after leaving the instrument.

In one embodiment, the stretching device 10 comprises an inflatable stretching device 10 expandable to an expanded state. In this case, the inflatable stretching device 10 is provided with an inlet port 18b for a fluid and is adapted to be connected to a gastroscopic instrument. This embodiment will now be described in detail with reference to Figs. 102a-102d.

An inflatable stretching device in its non-expanded state is shown in Fig. 102a. It is essentially a balloon-like, deflated stretching device 10 having an inlet port 18b. In this state, the inflatable stretching device 10 has a diameter of a few millimeters at the most, allowing it to be inserted into the stomach through the esophagus of the

patient by means of a gastroscopic, tube-like instrument 600, or through a laparoscopic trocar in an abdominal laparoscopic method using a tube like instrument 600 depicted in figure 102b. The instrument comprises an outer sleeve 600a and an inner sleeve 600b which can be displaced longitudinally relatively to the outer sleeve. The inner sleeve is provided with a cutter in the form of a cutting edge 615 at the distal end thereof. This cutting edge can be used for cutting a hole in the stomach wall, as will be explained in detail in the following.

When the instrument reaches a stomach wall, from the inside or outside thereof, see Fig. 102c, the inner sleeve is brought forward from its position in the outer sleeve and into contact with the stomach wall 12a. The cutting edge 615 of the inner sleeve then cuts a hole in the stomach wall so as to allow subsequent insertion of the volume filling device 10 into and through this hole, see Fig. 102d. In order to push the stretching device through the hole, a piston 602 may be provided in the instrument. Thus, the instrument further comprises a piston 602 adapted for pushing a deflated stretching device 10 out from a position in the inner sleeve, this position being shown in Fig. 102b, to a position outside of the inner sleeve, this being shown in Fig. 102d.

In order to protect the deflated stretching device 10 from the cutting edge 615 of the inner sleeve, a further protective sleeve (not shown) can be provided around the stretching device.

Fig. 102a-j shows an instrument for use in a method of engaging a stretching device 10 to the stomach wall 12 of a patient. The instrument is adapted to be inserted through a narrow tube shaped object such as a gastroscope, used in an intraluminar procedure, or a laparoscopic trocar used in a laparoscopic procedure. The instrument comprises an elongated member 650 which is adapted to be flexible by means of a construction comprising multiple ring shaped members, however it is equally conceivable that said elongated member 650 is adapted to be flexible by means of said elongated member 650 being made of a flexible or adjustable material. The elongated member 650 is inserted into the body and placed in proximity to the stomach wall 12 of the patient, from the outside or inside thereof. The elongated

member 650 has a special holding device 651 adapted to hold the stomach by means of mechanical grabbing members or vacuum. The special holding device 651 comprises a first joint 652 and a second joint 653, which enables the special holding device 651 be operable in relation to the elongated member 650 and thereby place the part of the holding device 651 comprising the mechanical grabbing members or vacuum elements in contact with the stomach wall 12 of the patient. Fig. 102b shows the special holding device 651 when placed in contact with the stomach wall 12 of the human patient, after which the special holding member 651 connects to the stomach wall 12, for holding the stomach wall 12. Fig. 102c shows the instrument when the step of advancing a pushing rod 654 from the elongated member 650 is performed. The pushing rod 654 pushes the stomach wall 12 to create a cavity or pouch thereof. Fig. 102d shows the instrument turned 90° in relation to figs. 102a-c. This view shows the special holding members 651a,b operably attached to two sides of the elongated member 650 and being in contact with the stomach wall 12, holding the stomach wall 12 as the pushing rod 654 pushes to create a cavity or pouch. When the pushing rod 654 has pushed the stomach wall 12 to a desired position the special holding devices 651a,b moves towards the pushing rod 654 and thereby closes the cavity or pouch.

After the cavity or pouch has been created it needs to be sealed. Fig. 103f shows the advancement of a suturing or stapling device 655 from the elongated member 650. The suturing or stapling device 655 is positioned in connection with the stomach wall after which the suturing or stapling device commences with the suturing or stapling of the stomach wall 12, creating a seal of stomach to stomach sutures or staplers 14. The instrument is moved along the stomach wall 12 of the patient and thereby a cavity or pouch is created and sealed using the instrument, as shown in fig. 103g and 103h. When a cavity or pouch or desired size has been created and sealed an inserting member 656 is advanced from the elongated member 650. The inserting member 656 is adapted to insert a stretching device 10 being inflatable, as described earlier in this application. After the inserting member 656 has been positioned in the cavity or pouch the stretching device 10 is inserted through the inserting member 656 and into the cavity or pouch by means of a pressurized fluid or gas, or a mechanical advancement member pushing said inflatable stretching device 10 into the cavity or

pouch. The insertion member then inflates the inflatable stretching device with a fluid or gas and seals of the final section of the pouch using stomach to stomach sutures or staplers 14. The embodiment described explains the process of inserting an inflatable stretching device, however it is equally conceivable that the stretching device 10 is expandable by means of the stretching device 10 being made of an elastic material.

Fig. 104a-f shows an instrument for use in a method of engaging a stretching device 10 to the stomach wall 12 of a patient. The instrument is adapted to be inserted through a narrow tube shaped object such as a gastroscope, used in an intraluminar procedure, or a laparoscopic trocar used in a laparoscopic procedure. The instrument comprises an elongated member 660 which is adapted to be flexible by means of a construction comprising multiple ring shaped members, however it is equally conceivable that said elongated member 660 is adapted to be flexible by means of said elongated member 660 being made of a flexible or adjustable material. The elongated member 660 is inserted into the body and placed in proximity to the stomach wall 12 of the patient, from the outside or inside thereof. The elongated member 660 has multiple special holding devices 661 adapted to hold the stomach by means of mechanical grabbing members or vacuum. The special holding devices 661 are locked in a position alongside the elongated member 660 by means of a locking ring 662. The special holding devices are made of a flexible material end pre-bent to expand into a funnel-shaped device when said locking ring 662 is removed. The special holding device in its funnel shaped expandable state is shown in fig. 104b. Fig. 104b further shows the special holding device 661 when placed in contact with the stomach wall 12 of the human patient, after which the special holding member 661 connects to the stomach wall 12, for holding the stomach wall 12. Fig. 104c shows the instrument when the step of advancing a pushing rod 664 from the elongated member 660 is performed. The pushing rod 664 pushes the stomach wall 12 to create a cavity or pouch thereof. When the pushing rod 664 has pushed the stomach wall 12 to a desired position the special holding devices 661 moves towards the pushing rod 664 and thereby closes the cavity or pouch.

After the cavity or pouch has been created it needs to be sealed. Fig. 104d shows the advancement of a suturing or stapling device 665 from the elongated member 660. The suturing or stapling device 665 is positioned in connection with the stomach wall 12 after which the suturing or stapling device 665 commences with the suturing or stapling of the stomach wall 12, creating a seal of stomach to stomach sutures or staplers 14. Thereafter an inserting member 666 is advanced from the elongated member 660 and the special holding devices 661 are retracted. The inserting member 666 is adapted to insert a stretching device 10 being inflatable, as described earlier in this application. After the inserting member 666 has been positioned in the cavity or pouch the stretching device 10 is inserted through the inserting member 666 and into the cavity or pouch by means of a pressurized fluid or gas, or a mechanical advancement member pushing said inflatable stretching device 10 into the cavity or pouch. The insertion member 656 then inflates the inflatable stretching device with a fluid or gas and seals of the final section of the pouch using stomach to stomach sutures or staplers 14. The embodiment described explains the process of inserting an inflatable stretching device 10, however it is equally conceivable that the stretching device 10 is expandable by means of the stretching device 10 being made of an elastic material. Fig. 40 f shows the stretching device 10 as the stretching device 10 is invaginated in the stomach wall 12, in a cavity or pouch sealed with stomach to stomach sutures or staplers 14.

Fig. 105a shows an instrument used in a method of engaging the stretching device according to any of the embodiments of the application to the stomach wall 12. The instrument comprises an elongated member 670 which is adapted to be flexible by means of a construction comprising multiple ring shaped members, however it is equally conceivable that said elongated member 670 is adapted to be flexible by means of said elongated member 670 being made of a flexible or adjustable material. The elongated member 670 is inserted into the body and placed in proximity to the stomach wall 12 of the patient, from the inside thereof. A stomach penetrating member 672 is placed in the distal end of the elongated member 670, retractably fixated to a protective sleeve 673 adapted to protect the tissue of the body from the sharp penetrating member 672 or cutter 672 after the cutting operation has been performed.

Fig. 105b shows the instrument comprising the elongated member 670 after the cutting operation has been performed and the stomach penetrating member or cutter 672 has been retracted into the protective sleeve 673. A guiding wire 671 is pushed through the elongated member 670, through the hole made in the stomach wall 12 and out through the abdomen and placed on the inside of the patients skin, which is penetrated from the outside to enable the guiding wire 671 to exit the abdomen. The guiding wire 671 can then be used to guide a conduit 18 or a lead attached to the stretching device 10 being placed in the stomach from the inside thereof. The stretching device 10 with the conduit 18 or electrical lead being a stretching device 10 according to any of the embodiments of this application. The guiding of the conduit 18 or electrical lead enables the attachment of the conduit 18 or electrical lead to a control unit 42 placed subcutaneously in the patient from the outside of the abdomen.

Fig. 106 shows a flowchart describing the steps needed in an interluminar method of inserting an apparatus for stretching a portion of the stomach wall, the method comprises the steps of inserting an instrument into the esophagus 203 of the patient, step 1a, inserting an apparatus into the stomach of the patient through the esophagus 203 using the instrument, step 2a, placing the apparatus 10 in contact with the stomach wall 12, step 3a, fixating the apparatus to the stomach wall 12 such that the apparatus can stretch a part of the stomach wall 12. The method described could further comprise the step of non-invasively regulating the device after the placing of the apparatus has been completed.

Fig. 107 shows a flowchart describing the steps needed in an abdominal method of inserting an apparatus for stretching a portion of the stomach wall, the method comprises the steps of cutting a hole in the abdominal wall of said patient, step 1b, dissecting an area around the stomach, step 2b, placing said apparatus in contact with the stomach, step 3b and fixating direct or indirect through invagination of the stomach wall the apparatus to the stomach wall such that the apparatus can stretch a portion of said stomach wall, step 4b. The method described could further comprise the steps of closing the hole in the abdomen using sutures or staplers 14 and non-

invasively regulating the device after the placing of the apparatus has been completed.

CLAIMS

1. An apparatus for treating obesity of an obese patient having a stomach with a food cavity, the apparatus comprising:

   - at least one volume filling device adapted to be at least substantially invaginated by a stomach wall portion of the patient and having an outer surface that includes a biocompatible material, wherein the volume filling device is adapted to be placed with the outer surface of the volume filling device resting against the stomach wall, such that the volume of the food cavity is reduced in size by a volume substantially exceeding the volume of the volume filling device, the volume filling device having a maximum circumference of at least 30 millimeters,
   - at least one operable stretching device implantable in the obese patient and adapted to stretch a portion of the patient's stomach wall, and
   - an operation device for operating the stretching device when implanted to stretch the stomach wall portion such that satiety is created.

2. The apparatus according to claim 1, wherein the stretching device comprises a first engaging member adapted to engage a first part of the stomach wall and a second engaging member adapted to engage a second part of the stomach wall close to but spaced from the first stomach part.

3. The apparatus according to claim 2, wherein the operation device is adapted to operate the first and second engaging member to move away from each other, when the engaging members engage the first and second stomach parts, to stretch the stomach wall portion between the first and second parts of the stomach such that satiety is created.

4. The apparatus according to claim 3, wherein at least one of the first and second engaging members is adapted to at least in part be invaginated by the stomach wall by stomach-to-stomach sutures or staplers holding the engaging member in place.

5. The apparatus according to claim 3, wherein at least one of the first and second engaging members is adapted to be kept in place by sutures or staplers between the engaging member and the stomach wall.

6. The apparatus according to claim 5, wherein at least one of the first and second engaging members comprises a tissue growth promoting structure adapted to be in contact with the stomach wall to secure long term attachment of the stretching device to the stomach wall.

7. The apparatus according to claim 6, wherein the structure comprises a net like structure.

8. The apparatus according to claim 1, wherein the stretching device is adapted to be kept in contact with the stomach wall by stomach-to-stomach sutures or staplers, in a position in which the stretching device is capable of stretching the stomach wall.

9. The apparatus according to claim 1, wherein the stretching device is adapted to be invaginated by the stomach wall by means of stomach-to-stomach sutures or staplers.

10. The apparatus according to claim 1, wherein the stretching device is a substantially non-circumferential stomach or esophageal device.

11. The apparatus according to claim 1, wherein the stretching device is adapted to be non-invasively adjustable postoperatively.

12. The apparatus according to claim 1, wherein the stretching device comprises a body adapted to fill out a volume defined by wall portions of the stomach.

13. The apparatus according to claim 12, wherein the body has rounded contours without too sharp edges that would be damaging to the patient's stomach wall.

14. The apparatus according to claim 13, wherein the body has varying circumference to be better adapted to be kept in place invaginated by stomach wall portions of the patient.

15. The apparatus according to claim 13, wherein the body is shaped like an egg.

16. The apparatus according to claim 13, wherein the body is shaped like a kidney.

17. The apparatus according to claim 1, wherein the stretching device is adapted to be placed in the stomach cavity.

18. The apparatus according to claim 17, wherein the stretching device is adapted to be inserted into the stomach cavity via a gastroscope or intraluminar instrument.

19. The apparatus according to claim 1, further comprising at least two operable stretching devices adapted to stretch at least two different portions of the stomach wall.

20. The apparatus according to claim 19, wherein the device is adapted to be postoperatively and non-invasively regulated, and adapted to be regulated from time to time such that at a first time one of the stretching devices stretches one of the portions of the stomach wall and at a second time the other of the stretching devices stretches the other portion of the stomach wall.

21. The apparatus according to claim 1, wherein the stretching device is adapted to be attached to the stomach wall by surgery.

22. The apparatus according to claim 1, wherein the stretching device is adapted to be placed on the outside of the stomach.

23. The apparatus according to claim 1, wherein the operation device comprises a subcutaneous switch adapted to be non-invasively operated by manually pressing the switch for the operation of the stretching device.

24. The apparatus according to claim 1, wherein the stretching device comprises at least one expandable body adapted to be invaginated by a portion of the patient's stomach wall, and the operation device comprises a fluid reservoir, which is in fluid communication with a chamber of the body, the operation device being non-invasively operable to distribute fluid from the fluid reservoir to the chamber of the body to expand the body such that the stomach wall portion is stretched, when the body is invaginated.

25. The apparatus according to claim 24, wherein the fluid reservoir is operated by manually pressing the fluid reservoir.

26. The apparatus according to claim 25, wherein the operation device comprises a reverse servo, and wherein a small volume of fluid in the fluid reservoir is compressed with a higher force and the chamber of the body creates a movement of a larger total volume with less force per unit of volume.

27. The apparatus according to claim 1, further comprising a large chamber in contact with one or more smaller chambers.

28. The apparatus according to claim 27, wherein the chambers are adapted to communicate with fluid or air being distributed between the chambers.

29. The apparatus according to claim 27, comprising a reversed servo for distributing fluid between the chambers, wherein a small volume of fluid in the large chamber is compressed with a higher force and the smaller chamber creates a movement of a larger total volume with less force per unit of volume.

30. The apparatus according to claim 27, wherein the large chamber is adapted to be invaginated in the patient's fundus stomach wall to also treat reflux disease by restricting movement of the cardiac notch towards the diaphragm

muscle of the patient and wherein the small chambers are adapted to function as stretching devices to treat obesity, wherein the large chamber is adapted to distribute fluid or air to the small chambers to cause them to expand and stretch the stomach fundus wall.

31. The apparatus according to claim 25, wherein the reservoir is adapted to be placed subcutaneously.

32. The apparatus according to claim 24, wherein the reservoir is adapted to be placed in the abdomen.

33. The apparatus according to claim 24, wherein the reservoir is regulated by moving a wall of the reservoir.

34. The apparatus according to claim 33, further comprising a motor adapted to move the wall of the reservoir.

35. The apparatus according to claim 24, further comprising a pump, wherein the reservoir is regulated by the pump pumping fluid or air from the reservoir to the body's chamber.

36. The apparatus according to claim 24, wherein the hydraulic regulated device comprising a mechanical stretching device adapted to be regulated by the hydraulic distribution of fluid or air.

37. The apparatus according to claim 1, further comprising a mechanically regulated stretching device.

38. The apparatus according to claim 37, further comprising a motor for mechanically regulating the stretching device.

39. The apparatus according to claim 37, wherein the stretching device comprises a first engaging member adapted to engage a first part of the stomach wall and a second engaging member adapted to engage a second parts of the stomach wall close to but spaced from the first stomach part and

wherein the mechanical stretching device is adapted to regulate the distance between the first and second part of the stomach wall.

40. The apparatus according to claim 37, wherein the mechanically regulated stretching device is adapted to engage a first part of the stomach wall and a second part of the stomach.

41. The apparatus according to claim 40, wherein the mechanically regulated stretching device comprises a joint mechanism adapted to be moved by the operation device.

42. An obesity treatment system for treating obesity of a patient, comprising an device for treating obesity according to claim 1.

43. The system according to claim 42, further comprising a switch adapted to manually and non-invasively control a function of the device for treating obesity.

44. The system according to claim 43, wherein the switch is a subcutaneous switch.

45. The system according to claim 43, wherein the switch is an electric switch.

46. The system according to claim 42, further comprising a hydraulic device having a hydraulic reservoir, wherein the device for treating obesity is adapted to non-invasively be regulated by manually pressing the hydraulic reservoir.

47. The system according to claim 42, further comprising a wireless remote control for controlling a function of the device.

48. The system according to claim 47, wherein the wireless remote control comprises at least one external signal transmitter, further comprising an internal signal receiver implantable in the patient.

49. The system according to claim 47, wherein the wireless remote control is adapted to transmit at least one wireless control signal for controlling the device.

50. The system according to claim 49 wherein the wireless control signal comprises a frequency, amplitude, or phase modulated signal or a combination thereof.

51. The system according to claim 49, wherein the wireless control signal comprises an analogue or a digital signal, or a combination of an analogue and digital signal.

52. The system according to claim 49, wherein the wireless control signal comprises an electric or magnetic field, or a combined electric and magnetic field.

53. The system according to claim 49, wherein the remote control transmits a carrier signal for carrying the wireless control signal.

54. The system according to claim 53, wherein the carrier signal comprises digital, analogue or a combination of digital and analog signals.

55. The system according to claim 53, wherein the remote control transmits an electromagnetic carrier wave signal for carrying the digital or analog control signal.

56. The system according to claim 42, further comprising a wireless energy transmitter for non-invasively energizing the device with wireless energy.

57. The system according to claim 56, wherein the energy transmitter transmits energy by at least one wireless energy signal.

58. The system according to claim 57, wherein wireless energy signal comprises wave signals.

59. The system according to claim 58, wherein the wireless energy signal comprises a wave signal selected from the following: a sound wave signal, an

ultrasound wave signal, an electromagnetic wave signal, an infrared light signal, a visible light signal, an ultra violet light signal, a laser light signal, a micro wave signal, a radio wave signal, an x-ray radiation signal and a gamma radiation signal.

60. The system according to claim 58, wherein the wireless energy signal comprises an electric or magnetic field, or a combined electric and magnetic field.

61. The system according to claim 56, wherein the wireless energy transmitter transmits a carrier signal for carrying the wireless energy signal.

62. The system according to claim 61, wherein the carrier signal comprises digital, analogue or a combination of digital and analog signals.

63. The system according to claim 61, wherein the remote control transmits an electromagnetic carrier wave signal for carrying the digital or analog control signal.

64. The system according to claim 61, wherein the wireless energy signal comprises an analogue or a digital signal, or a combination of an analogue and digital signal.

65. The system according to claim 42, further comprising an energy source adapted to power the device.

66. The system according to claim 65, wherein the energy source comprises an internal energy source.

67. The system according to claim 65, wherein the energy source is an internal energy source adapted to receive energy from an external energy source transmitting energy in a wireless mode.

68. The system according to claim 67, wherein the internal energy source is charged by the energy in the wireless mode.

69. The system according to claim 42, further comprising a sensor sensing a parameter.

70. The system according to claim 69, wherein the sensor is a functional parameter sensor sensing a functional parameter of the system.

71. The system according to claim 69, wherein the functional parameter of the system is correlated to the transfer of energy for charging an internal energy source.

72. The system according to claim 42, further comprising a feedback device for sending information from inside the patient's body to the outside thereof to give feedback information related to a functional parameter.

73. The system according to claim 69, further comprising an internal control unit for controlling the operation device of the device in response to the sensor sensing a functional parameter.

74. The system according to claim 69, wherein the sensor is a physical parameter sensor sensing a physical parameter of the patient.

75. The system according to claim 74, wherein the physical parameter is one of body temperature, blood pressure, blood flow, heartbeats and breathing.

76. The system according to claim 74, wherein the physical parameter sensor is a pressure or motility sensor, or a sensor sensing measure, bending, stretching or food intake.

77. The system according to claim 74, further comprising an internal control unit for controlling the operation device in response to the sensor sensing the physical parameter.

78. The system according to claim 42, comprising a internal control unit receiving information from the sensor.

79. The system according to claim 1, wherein the operation device comprises a motor or a pump.

80. The system according to claim 79, wherein the operation device comprises an electric motor.

81. The system according to claim 42, wherein the operation device is electrically powered.

82. The system according to claim 42, wherein the operation device comprises a hydraulic operation device.

83. The system according to claim 42, wherein the operation device comprises a pneumatic operation device.

84. The system according to claim 56, wherein the transmitted energy, directly in its wireless form affect the operation device to create kinetic energy to operate the stretching device of the device during energy transfer.

85. The system according to claim 42, further comprising an external data communicator and an implantable internal data communicator communicating with the external data communicator, wherein the internal communicator is adapted to feed data related to the device for treating obesity or the patient back to the external data communicator or the external data communicator feeds data to the internal data communicator.

86. The system according to claim 56, further comprising an energy-transforming device for transforming the wireless energy from a first form into a second form energy.

87. The system according to claim 86, wherein the energy-transforming device directly during energy transfer operates the device with the second form energy.

88. The system according to claim 86, wherein the second form energy comprises a direct current or pulsating direct current, or a combination of a direct current and pulsating direct current.

89. The system according to claim 86, wherein the second form energy comprising an alternating current or a combination of a direct and alternating current.

90. The system according to claim 86, comprising an accumulator, wherein the second form energy is used at least partly to charge the accumulator.

91. The system according to claim 86, wherein the energy of the first or second form comprises magnetic energy, kinetic energy, sound energy, chemical energy, radiant energy, electromagnetic energy, photo energy, nuclear energy or thermal energy.

92. The system according to claim 86, wherein one of the energy of the first form and the energy of the second form is non-magnetic, non-kinetic, non-chemical, non-sonic, non-nuclear or non-thermal.

93. The system according to claim 42, further comprising implantable electrical components including at least one voltage level guard.

94. The system according to claim 42, further comprising implantable electrical components including at least one constant current guard.

95. A method for surgically treating an obese patient, the method comprising the steps of:
cutting an opening in the abdominal wall of the patient,
dissecting an area around the stomach,
placing an device for treating obesity according to claim 1, engaging the stomach wall of the patient, and
suturing the stomach wall.

96. The method according to claim 95, further comprising the additional step of: postoperatively regulating the stretching device to stretch a part of the stomach wall to affect the appetite of the patient.

97. The method according to claim 96, wherein the step of regulating the stretching device is controlled from outside the patient's body.

98. The method according to claim 95, further comprising the additional steps of:

placing an additional device for treating obesity according to claim 1,

engaging the stomach wall of the patient,

stretching a first part of the stomach wall by means of the device for treating obesity, and

stretching a second part of the stomach wall by means of the additional device for treating obesity.

99. A method for surgically placing an device for treating obesity in a patient via a laparoscopic abdominal approach, the method comprising the steps of:

inserting a needle or a tube like instrument into the abdomen of the patient's body,

using the needle or a tube like instrument to fill the patient's abdomen with gas thereby expanding the patient's abdominal cavity,

placing at least two laparoscopic trocars in the patient's body,

inserting a camera through one of the laparoscopic trocars into the patient's abdomen,

inserting at least one dissecting tool through one of the at least two laparoscopic trocars and dissecting an intended placement area of the patient, and

placing an device for treating obesity according to claim 1, engaging the stomach wall.

100. A method of using the system for treating obesity according to claim 42, comprising the step of regulating the stretching device postoperatively to stretch a portion of the stomach wall to affect the appetite of the patient.

101. The method according to claim 100, wherein the step of regulating the stretching device is performed non-invasively.

102. The method according to claim 100, wherein the stretching device comprises a mechanical stretching device.

103.The method according to claim 100, wherein the stretching device comprises a hydraulic stretching device.

104.The method according to claim 103, wherein the hydraulic stretching device comprises a reservoir, for moving gel or gas or fluid to or from the stretching device.

105.The method according to claim 104, wherein the reservoir is placed subcutaneously for being reached by the patients hand for moving fluid manually to or from the stretching device.

106.The method according to claim 100, wherein the stretching device is powered by an internal energy source for stretching or releasing the stretching device, wherein by means of a control device controlling the power from an internal control unit or from the outside the patients body.

107.The method according to claim 100, wherein a wireless energy transmitter for wireless transfer of energy is powering the operation device to get the stretching device to directly during energy transfer cause the stretching device to stretch the stomach wall.

108.The method according to claim 100, wherein a wireless energy transmitter for wireless transfer of energy is charging the internal energy source.

109.The method according to claim 100, further comprising sending feedback information from inside the body to the outside thereof to give feed back related to the functional parameters of the device.

110.The method according to claim 100, further comprising sending feedback information from inside the body to the outside thereof to give feedback related to the physical parameters of the patient.

111.The method according to claim 109, wherein the functional parameter of the device is correlated to the transfer of energy for charging the internal energy source.

112.The method according to claim 100, wherein the device is programmable from outside the patient's body.

113.The method according to claim 100, comprising the steps of:
sensing a physical parameter of the patient or a functional parameter of the device, and
sending sensing information to a control unit adapted for regulating the stretching device.

114.The method according to claim 100, further comprising the steps of:
sensing a physical parameter of the patient or a functional parameter of the device, and
sending sensing information to a control unit adapted for regulating the charging of the internal energy source.

115.A method of using an device according to claim 19, wherein the stretching device comprises a main body including a large chamber in contact with one or more smaller reservoirs/chambers adapted to stretch the stomach wall.

116.The method according to claim 115, wherein the chambers are adapted to communicate with fluid or air being moved between the chambers.

117.The method according to claim 103, further comprising subcutaneously placing a reversed servo having a small control reservoir and moving a small volume from the control reservoir with a higher force per area unit, creating a larger movement of the stretching device with less force per area unit.

118.A method of using an device according to claim 19, wherein the large chamber are adapted to, with its main volume to be the stretching device's most important volume and wherein, the small chambers are as the stretching devices stretching the stomach wall to treat obesity, wherein the main chamber is communicating with fluid or gel to the small chambers causing the stretching effect in the stomach fundus wall thereby treating obesity.

119.The method according to claim 100, comprising a reversed servo, wherein moving, in a closed hydraulic system, a small amount of fluid, a larger movement of fluid is achieved in a second larger closed hydraulic system, wherein the small amount of fluid is moved with by a higher force per area unit than the large volume.

120.The method according to claim 100, wherein an invaginated stretching device in the fundus stomach wall of the patient is adapted to be adjustable, wherein the stretching device placed invaginated in the stomach fundus wall is adapted to be adjusted and stretching the stomach fundus wall thereby creating satiety.

121.The method according to claim 100, further comprising performing the non-invasive regulation by manually pressing a subcutaneous switch.

122.The method according to claim 100, further comprising performing the non-invasive regulation by a wireless remote control.

123.The method according to claim 100, further comprising performing the non-invasive regulation by a wireless energy transmitter.

124.The method according to claim 100 further comprising powering the device for treating obesity by an energy source.

125.The method according to claim 124, wherein the energy source comprises an internal energy source.

126.The method according to claim 124, wherein the energy source comprises an external energy source transmitting wireless energy.

127.The method according to claim 124, further comprising transmitting wireless energy from an external energy source to charge a rechargeable internal energy source.

128.A method of using an device according to claim 27, comprising treating reflux disease by invaginating the large chamber with its main volume in the

fundus stomach wall thereby restricting movement of the stomach notch towards the diaphragm muscle of the patient, and stretching the stomach fundus wall using the small chambers, communicating with fluid or air from the large chamber to the small chambers causing a stretching effect in the stomach fundus wall thereby treating obesity

129. A stretching device according to claim 1, adapted to post-operatively be adjustable and comprising at least one expandable section;

- wherein said stretching device is adapted to be adjustable between a first collapsed state, in which said expandable section is collapsed, and a second expanded state, in which said expandable section is expanded, and

- wherein the outer surface of said expandable section at least partly comprises a surface structure having elevated areas alternating with lowered areas,

- wherein said expandable section is adapted to have, in at least one of said first collapsed and second expanded states,

- a first distance between adjacent elevated areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent elevated areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said stretching device, and further comprising connecting areas between adjacent elevated and lowered areas, further adapted to have, in at least one of said first collapsed and second expanded states,

- a second distance between adjacent connecting areas sufficiently extended to prevent growth of fibrotic tissue from directly interconnecting adjacent connecting areas to an extent that compromises the adjustability between a first collapsed and a second expanded state of said stretching device.

130. A stretching device according to claim 129, wherein at least said expandable section, is hollow or comprises a hollow body.

131. A stretching device according to any of the claims 129 and 130, wherein said stretching device is substantially completely hollow or comprises a hollow body extending along substantially the complete length and/or complete volume of said stretching device.

132. The apparatus according to anyone of claim 1, 2 and 5, adapted to pass through a hole in the stomach wall from the abdomen the abdomen.

133.The apparatus according to claim 132, further comprising an external control device for controlling the stretching device from the outside of the patient's body.

134.The apparatus according to claim 132, wherein the implantable control unit is adapted to control the stretching device from the inside of the patient's body.

135. The apparatus according to anyone of claim 1, 2 and 5, further comprising a tube connected to the stretching device adapted to be connected to an the injection port.

136. The apparatus according to claim 135, wherein the device is adapted to receive a fluid through the tube.

137. The apparatus according to claim 136, further comprising an injection port adapted to be connected to the tube.

138. The apparatus according to anyone of claim 1, 2 and 5, wherein said device is adapted to be postoperatively and non-invasively programmable.

139. The apparatus according to anyone of claim 1, 2 and 5, wherein the implantable control is adapted to connect to the stretching device hydraulically.

140. The apparatus according to anyone of claim 1, 2 and 5, wherein the implantable control is adapted to connect to the device with electrical wires.

141. The apparatus according to claim 1, comprising a second or more device, adapted to be invaginated, placed on the outside of the stomach wall, with stomach to stomach sutures or staplers, adapted to postoperatively stretching the invaginated stomach wall portion.

142. The apparatus according to claim 141, wherein said first stretching device and said second or more stretching device is adapted to stretch a separate portion of the stomach wall.

143. The apparatus according to anyone of claim 1, 2 and 5, comprising a first part of the stretching device adapted to be placed on the outside of the stomach wall, invaginated with stomach to stomach sutures or staplers, and a second part of the stretching device adapted to be placed on the outside of the stomach wall, invaginated with stomach to stomach sutures or staplers at a different location on the stomach wall, and the device further adapted to postoperatively stretch the stomach wall portion between the first and second part.

144. The apparatus according to anyone of claim 1, 2 and 5, further comprising a second or more stretching device, comprising a first part of the second or more device adapted to be placed on the outside of the stomach wall, invaginated with stomach to stomach sutures or staplers, and a second part of the second or more stretching device adapted to be placed on the outside of the stomach wall invaginated with stomach to stomach sutures or staplers at a different location on the stomach wall, and the device further

adapted to postoperatively stretch the stomach wall portion between the first and second parts of the second or more device.

145. The apparatus according to claim 111, comprising a third or more part of the stretching device adapted to be placed on the outside of the stomach wall, separate from said first or second part, with stomach to stomach sutures or staplers, and further adapted to postoperatively stretching the stomach wall portion between a combination of the first and second part and third or more parts.

146. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device, further comprising:

- at least one volume filling device adapted to be at least substantially invaginated by a stomach wall portion of the patient,
- wherein the volume filling device is adapted to be placed on the outside of the stomach wall, so that the volume of the food cavity is reduced in size by a volume substantially exceeding the volume of the volume filling device,
- wherein the surface of the volume filling device comprises a biocompatible material,
- wherein a substantial part of the surface of the volume filling device is adapted to rest against the outside of the stomach wall, and
- wherein the volume filling device has a maximum circumference of at least 30 millimeters volume of at least 0.00001 m^3 outside the stomach wall to reduce the inner volume of the stomach, thereby further affecting the patient's appetite.

147. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device, further comprising:

at least one implantable volume filling device, forming a volume and adapted to be completely invaginated by a stomach wall portion on the outside of the stomach of an obese patient, the device adapted to be placed on the inside of the patient's stomach wall, such that the stomach cavity is substantially reduced,
wherein said food intake reducing device is adapted to be invaginated by said stomach wall portion in a completely sealed volume separated from said remaining stomach for holding food, whereby the patient's appetite is reduced when the food intake reducing device is implanted,
wherein the surface of the device includes a biocompatible material, a substantial part of said surface being adapted to rest against the inside of the stomach wall wherein the volume filling device has a maximum circumference of at least 30 millimeters volume of at least 0.00001 m^3 outside the stomach wall to reduce the inner volume of the stomach, thereby further affecting the patient's appetite.

148. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device, further comprising an implantable movement restriction device adapted to be at least partly invaginated by the patient's stomach fundus wall and having an outer surface that includes a biocompatible material, wherein a substantial part of the outer surface of the movement restriction device is adapted to rest against the stomach wall without injuring the latter in a position between the patient's diaphragm and at least a portion of the lower part of the invaginated stomach fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is invaginated, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm.

149. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device, further comprising:
- an implantable movement restriction device having an outer surface

including a biocompatible material, wherein the movement restriction device is adapted to rest with at least a part of its outer surface against the patient's stomach fundus wall, in a position between the patient's diaphragm and the fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is implanted in the patient, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, wherein the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, and

- fixation device adapted to secure the movement restriction device in said position, when the movement restriction device is implanted.

150. The apparatus according to anyone of claim 148, wherein the stretching device, further comprising an implantable movement restriction device adapted to be at least partly invaginated by the patient's stomach fundus wall and having an outer surface that includes a biocompatible material, wherein a substantial part of the outer surface of the movement restriction device is adapted to rest against the stomach wall without injuring the latter in a position between the patient's diaphragm and at least a portion of the lower part of the invaginated stomach fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is invaginated, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm.

151. The apparatus according to anyone of claim 149, wherein the stretching device, further comprising:

- an implantable movement restriction device having an outer surface including a biocompatible material, wherein the movement restriction device is adapted to rest with at least a part of its outer surface against the patient's stomach fundus wall, in a position between the patient's diaphragm and the fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is implanted in the patient, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, wherein the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, and
- fixation device adapted to secure the movement restriction device in said position, when the movement restriction device is implanted.

152. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device comprising a expandable structure, adapted to expand and stretch the stomach wall portion, when the device being invaginated in the stomach wall, wherein said structure comprising a special bellow adapted to take into account the fibrosis surrounding the device when implanted, such that the movement of the bellow is substantially un-affected of said fibrosis.

153. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device comprising three or more mechanical parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling to the stomach wall or invaginating the mechanical parts in the stomach wall part with stomach to stomach sutures, wherein the three or more mechanical parts are adapted to move in relation to each other adapted to stretch three different wall portions, the stretching device further adapted to having said wall portions stretched independently from each other both regarding;

force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

154. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device comprising three or more hydraulic parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling to hydraulic part to the stomach wall or invaginating the hydraulic parts in the stomach wall part, with stomach to stomach sutures, wherein the three or more hydraulic parts are adapted to move in relation to each other adapted to stretch three different wall portions, the stretching device further adapted to having said wall portions stretched independently from each other both regarding;
force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

155. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device comprising three or more hydraulic parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling to hydraulic part to the stomach wall or invaginating the hydraulic parts in the stomach wall part, with stomach to stomach sutures, wherein the three or more hydraulic parts are adapted to independent of each other stretch three different wall portions, the stretching device further adapted to having said wall portions stretched independently from each other both regarding;
force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

156. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device is engaged with a part of the stomach wall, including

suturing or stapling the stretching device to the stomach wall or invaginating the stretching device in the stomach wall part, with stomach to stomach sutures, wherein the stretching device is further adapted to stretch a stomach wall portion controlling;
force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

157. The apparatus according to anyone of claim 1, 2 and 5, wherein the stretching device comprising two parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling the parts to the stomach wall or invaginating the parts in the stomach wall part, with stomach to stomach sutures, wherein the stretching device further adapted to have different wall portions stretched independently from each other controlling;
force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

158. The apparatus according to anyone of claim 1, 2 and 5, further comprising an external control unit for controlling the stretching device from the outside of the patient's body.

159.The apparatus according to anyone of claim 158, wherein the external control unit comprising a wireless remote control adapted to control the stretching device from the outside of the patient's body.

160.The apparatus according to anyone of claim 158, wherein the external control unit comprising a subcutaneously placed switch or reservoir adapted to control the stretching device from the outside of the patient's body.

161. The apparatus according to anyone of claim 1, 2 and 5, comprising a sensor or sensing device adapted to be implanted in the patient body, wherein the implantable control unit is adapted to control the stretching device from the

inside of the patient's body using information from said a sensor or sensing device, adapted to sense, direct or indirect, the food intake of the patient.

162.The apparatus according to claim 1, wherein the stretching device is provided with a coating or multi layer construction.

163. The apparatus according to claim 162, wherein the coating is a Parylene coating.

164. The apparatus according to claim 162, wherein the coating is a polytetrafluoroethylene coating.

165. The apparatus according to claim 162, wherein the coating is a polyurethane coating.

166. The apparatus according to claim 162, wherein the coating is a multi-layer coating.

167. The apparatus according to claim 162, wherein one layer is made of polyurethane.

168. The apparatus according to claim 162, wherein one layer is made of silicon.

169. The apparatus according to claim 162, wherein one layer is made of PTFE.

170. The apparatus according to claim 162, wherein the coating is a metal coating.

171. The apparatus according to claim 162, wherein one layer is made of metal.

172. The apparatus according to claim 1, wherein the volume filling device comprises an inflatable device expandable to an expanded state.

173. The apparatus according to claim 172, wherein the inflatable device has an inlet port for a fluid or a gel and is adapted to be connected to a gastroscopic instrument.

174. The apparatus according to claim 173, wherein the inlet port comprises a fluid connection adapted to interconnect the inflatable device and the gastroscopic instrument.

175. The apparatus according to claim 1, wherein the volume filling device has an elongated shape.

176. The apparatus according to claim 175, wherein the volume filling device has a rounded shape.

177. The apparatus according to claim 175, wherein the volume filling device has a bent or curved shape.

178. The apparatus according to claim 1, wherein the volume filling device comprises an elastic material.

179. The apparatus according to claim 1, wherein the volume filling device comprises a bio-compatible material.

180. The apparatus according to claim 1, wherein the volume filling device comprises silicone.

181. The apparatus according to claim 1, wherein the volume filling device is provided with a coating or a multilayer coating.

182. The apparatus according to claim 181, wherein the coating is a Parylene coating.

183. The apparatus according to claim 181, wherein the coating is a polytetrafluoroethylene coating.

184. The apparatus according to claim 181, wherein the coating is a polyurethane coating.

185. The apparatus according to claim 181, wherein the coating is a multi-layer coating.

186. The apparatus according to claim 181, wherein the coating is a polyurethane coating.

187. The apparatus according to claim 1, wherein the volume filling device comprises a fluid.

188. The apparatus according to claim 197, wherein the fluid is adapted to be transformed into solid state or fixed form.

189. The apparatus according to claim 197, wherein the fluid is liquid polyurethane.

190. The apparatus according to claim 197, wherein the fluid is iso-tonic.

191. The apparatus according to claim 197, wherein the fluid comprises large molecules to prevent diffusion.

192. The apparatus according to claim 1, wherein the volume filling device comprises a homogenous material.

193. The apparatus according to claim 1, wherein the volume filling device is a solid body.

194. The apparatus according to claim 1, wherein the volume filling device comprises an enclosure wall defining a chamber.

195. The apparatus according to claim 1, wherein the volume filling device comprises a rigid outer surface.

196. The apparatus according to claim 1, wherein the volume filling device comprises an elastic outer surface.

197. The apparatus according to claim 1, wherein the volume filling device comprises a flexible outer surface.

198. The apparatus according to claim 1, wherein the volume filling device as a maximum circumference of at least 50 millimeters.

199. The apparatus according to claim 1, wherein the volume filling device has a circumference of at least 80 millimeters.

200. The apparatus according to claim 1, wherein the volume filling device has a volume of between 0.00001 and 0.001 m^3.

201. The apparatus according to claim 1, wherein the volume filling device has a volume of between 0.00001 and 0.0002 m^3.

202. The apparatus according to claim 1, wherein the volume filling device is deformable to a maximum diameter, so as to be inserted into a laparoscopic trocar.

203. The apparatus according to claim 1, wherein the volume filling device is adapted to be kept in place by stomach-to-stomach sutures or staples to invaginate the device in the stomach wall.

204. The apparatus according to claim 203, wherein the stomach-to-stomach sutures or staples are provided with fixation portions exhibiting a structure adapted to be in contact with the stomach wall to promote growth in of human tissue to secure long term placement of the volume filling device attached to the stomach wall.

205. The apparatus according to claim 204, wherein the structure comprises a net like structure.

206. The apparatus according to claim 1, wherein the volume filling device is adapted to be non-invasively adjustable postoperatively.

207. The apparatus according to claim 1, wherein the volume filling device has varying circumference to be better adapted to be kept in place invaginated in the stomach wall of the patient.

208. The apparatus according to claim 1, comprising a stretching device placed outside the stomach wall and adapted to stretch a part of the stomach wall, thereby affecting the patient's appetite, the apparatus further comprising a fluid connection interconnecting the stretching device and the volume filling device.

209. The apparatus according to claim 207, wherein the volume filling device is adapted to be placed outside the stomach wall via a gastroscopic instrument.

210. The apparatus according to claim 1, wherein the volume filling device comprises at least two interconnectable portions adapted to be placed outside the stomach wall as separate portions.

211. The apparatus according to claim 1, wherein the volume filling device comprises an outer surface layer of polyurethane, Teflon®, or PTFE, or a combination thereof.

212. The apparatus according to claim 1, wherein the volume filling device is destructible by acid, preferably hydrochloric acid.

213. The apparatus according to claim 1, wherein the volume filling device comprises gel.

214. The apparatus according to claim 213, wherein the gel has a shure value of less than 15.

215. The apparatus according to claim 1, wherein the volume filling device comprises an attachment device adapted to co-operate with a gripping instrument.

216. The apparatus according to claim 1, wherein the volume filling device is adapted to be completely invaginated by the stomach wall of the patient.

217. The apparatus according to claim 1, comprising a fixating device adapted to fixate the volume filling device to the stomach wall to keep the volume filling device in place, when the volume filling device is implanted.

218. The apparatus according to claim 1, wherein the volume filling device has a volume of less than 0.0002 m^3.

219. The apparatus according to claim 30, wherein the volume filling device has a volume of between 0.0001 and 0.001 m^3.

220. The apparatus according to claim 1, wherein at least a part of the volume filling device is made of a material which is not destructible by acid.

221. The apparatus according to claim 1, wherein the volume filling device has a circumference of at least 120 mm.

222. The apparatus according to claim 1, wherein the volume filling device has a circumference of at least 150 mm.

223. The apparatus according to claim 1, wherein the volume filling device has a circumference of at least 180 mm.

224. The apparatus according to claim 1, wherein the volume filling device has a circumference of at least 220 mm.

225. The apparatus according to claim 1, wherein the volume filling device comprises a flexible non-elastic material.

226. The apparatus according to claim 1, further comprising a fixation device adapted to be involved in the fixation of the volume filling device to the stomach wall.

227. The apparatus according to claim 1, further comprising two or more fixation devices adapted to be involved in the fixation of the volume filling device to the stomach wall.

228. The apparatus according to claim 1, wherein the volume filling device comprises a holding device adapted to be held by an instrument and simplify the implantation of the device.

229. The apparatus according to claim 1, wherein the volume filling device comprises two or more holding devices adapted to be held by an instrument and simplify the implantation of the device.

230. The apparatus according to claim 1, wherein the volume filling device comprises an inflatable chamber, further comprising at least one tube connected to the device for supplying fluid to the chamber.

231. The apparatus according to claim 230, further comprising an injection port connectible with the tube.

232. The apparatus according to claim 1, wherein the volume filling device has a maximum circumference as seen in a plane perpendicular to an axis through the device, and wherein the circumferences of the device as seen in other planes perpendicular to said axis are equal to the maximum circumference or decrease as seen along said axis in the direction from the maximum circumference.

233. The apparatus according to claim 1, wherein the circumference of the volume filling device as seen in a plane perpendicular to an axis through the device increases and decreases at least two times as the plane is displaced along said axis, or decreases and increases at least one time as the plane is displaced along said axis.

234. The apparatus according to claim 181, wherein one layer is made of silicon.

235. The apparatus according to claim 181, wherein one layer is made of PTFE.

236. The apparatus according to claim 181, wherein the coating is a metal coating.

237. The apparatus according to claim 181, wherein one layer is made of metal.

238. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device comprising; - a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall and
- an operation device for operating the stretching device when implanted to stretch the stomach wall portion such that satiety is created.

239. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device comprising;

a. at least one operable stretching device implantable in the patient and adapted to stretch a portion of the patient's stomach wall, and

b. an implantable control unit for automatically controlling the operable stretching device, when the control unit and stretching device are implanted, to stretch the stomach wall portion in connection with the patient eating such that satiety is created.

240. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device comprising; - a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall, wherein said stretching device comprising an expandable stretching reservoir and
- an operation device for operating the stretching device when implanted to stretch the stomach wall portion, wherein the volume filling device is inflatable and in fluid connection with said stretching reservoir, wherein said operation device comprises a pump for pumping fluid between said main reservoir and said stretching reservoir to stretch said stomach wall portion such that satiety is created.

241. The apparatus for treating obesity according to claim 240, comprising a control device for controlling said stretching device including said pump.

242. The apparatus for treating obesity according to claim 71, wherein said control device comprising a wireless remote control adapted to control the stretching device from the outside of the patient's body.

243. The apparatus for treating obesity according to claim 241, wherein said control device comprising a subcutaneously placed switch or reservoir

adapted to control the stretching device from the outside of the patient's body.

244. The apparatus for treating obesity according to claim 241, wherein said control device comprising an implantable control unit for controlling said stretching device.

245. The apparatus according to claim 74, comprising a sensor or sensing device adapted to be implaned in the patient body, wherein the implantable control unit is adapted to control the stretching device from the inside of the patient's body using information from said a sensor or sensing device, adapted to sense, direct or indirect, the food intake of the patient.

246. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device comprising;

- a main volume filling reservoir,

- a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall, wherein said stretching device comprising an expandable reservoir, adapted to be invaginated in the stomach wall at the upper part of the stomach, higher up than the inflatable main volume filling device when the patient is standing, wherein the volume filling device is inflatable and in fluid connection with said stretching reservoir, wherein normal contractions of the stomach wall, related to food intake, cause fluid to flow from said invaginated main volume filling reservoir lower placed onto the stomach wall adapted to cause said stretching reservoir to stretch said stomach wall portion such that satiety is created.

247. The apparatus for treating obesity according to claim 246, wherein the fluid connection between the main volume filling device reservoir and the stretching reservoir comprises a non-return valve.

248. The apparatus for treating obesity according to claim 246, wherein the fluid connection between the main volume filling device reservoir and the stretching reservoir comprises a release function adapted to release the volume in the stretching reservoir back to the main volume filling device reservoir.

249. The apparatus for treating obesity according to claim 76, wherein said release function comprises a fluid return connection of a substantially smaller area than said fluid connection, to slowly release back fluid to said main volume filling device reservoir from the stretching reservoir to release said stretching of the stomach wall portion.

250. The apparatus for treating obesity according to anyone of claim 246, comprising a further manual control device comprising a subcutaneously placed reservoir adapted to control the stretching device from the outside of the patient's body to further affect the stretching device to stretch the stomach wall portion.

251. The apparatus according to anyone of claim 1, 3, 8 and 24, comprising a main volume filling device reservoir adapted to be inflatable, the device further comprising an expandable structure, adapted to expand, when the device is invaginated in the stomach wall, wherein said structure comprising a bellow adapted to take into account the fibrosis surrounding the device when implanted, such that the movement of the bellow is substantially un-affected of said fibrosis.

252. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device comprising; - a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall and wherein the stretching device comprising a expandable structure, adapted to expand and stretch the stomach wall portion, when the device being invaginated in the stomach wall,

wherein said structure comprising a special bellow adapted to take into account the fibrosis surrounding the device when implanted, such that the movement of the bellow is substantially un-affected of said fibrosis.

253. The apparatus for treating obesity according to claim 252, comprising;
- an operation device for operating the stretching device when implanted to stretch the stomach wall portion such that satiety is created.

254. THe apparatus for treating obesity according to claim 252, wherein the volume filling device comprising;

an implantable control unit for automatically controlling the operable stretching device, when the control unit and stretching device are implanted, to stretch the stomach wall portion in connection with the patient eating such that satiety is created.

255. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device comprising; - a stretching device comprising at least one operable stretching device implantable in an obese patient and adapted to stretch a portion of the patient's stomach wall such that satiety is created.

256. The apparatus for treating obesity according to claim 255, wherein said control device comprising a wireless remote control adapted to control the stretching device from the outside of the patient's body.

257. The apparatus for treating obesity according to claim 255, wherein said control device comprising a subcutaneously placed switch or reservoir adapted to control the stretching device from the outside of the patient's body.

258. THe apparatus for treating obesity according to claim 255, wherein said control device comprising an implantable control unit for controlling said stretching device.

259.The apparatus according to anyone of claim 258, comprising a sensor or sensing device adapted to be implaned in the patient body, wherein the implantable control unit is adapted to control the stretching device from the inside of the patient's body using information from said a sensor or sensing device, adapted to sense, direct or indirect, the food intake of the patient.

260. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further is adapted to treat reflux disease and further comprising an implantable movement restriction device adapted to be at least partly invaginated by the patient's stomach fundus wall and having an outer surface that includes a biocompatible material, wherein a substantial part of the outer surface of the movement restriction device is adapted to rest against the stomach wall without injuring the latter in a position between the patient's diaphragm and at least a portion of the lower part of the invaginated stomach fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is invaginated, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm.

261. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further is adapted to treat reflux disease and further comprising:
- an implantable movement restriction device having an outer surface including a biocompatible material, wherein the movement restriction device is adapted to rest with at least a part of its outer surface against the patient's stomach fundus wall, in a position between the patient's diaphragm and the fundus wall, such that movement of the cardiac

notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is implanted in the patient, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, wherein the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, and

- a fixation device adapted to secure the movement restriction device in said position, when the movement restriction device is implanted.

262. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further is adapted to treat reflux disease and further comprising; an implantable movement restriction device adapted to be at least partly invaginated by the patient's stomach fundus wall and having an outer surface that includes a biocompatible material, wherein a substantial part of the outer surface of the movement restriction device is adapted to rest against the stomach wall without injuring the latter in a position between the patient's diaphragm and at least a portion of the lower part of the invaginated stomach fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is invaginated, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, further comprising a stretching device comprising at least one operable stretching device implantable in the obese patient and adapted to stretch a portion of the patient's stomach wall such that satiety is created.

263. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further is adapted to treat reflux disease and further comprising;

- an implantable movement restriction device having an outer surface including a biocompatible material, wherein the movement restriction device is adapted to rest with at least a part of its outer surface against the patient's stomach fundus wall, in a position between the patient's diaphragm and the fundus wall, such that movement of the cardiac notch of the patient's stomach towards the patient's diaphragm is restricted, when the movement restriction device is implanted in the patient, to thereby prevent the cardia from sliding through the patient's diaphragm opening into the patient's thorax, so as to maintain the supporting pressure against the patient's cardia sphincter muscle exerted from the patient's abdomen, wherein the movement restriction device having a size of at least 125 mm^3 and a circumference of at least 15 mm, and

- a fixation device adapted to secure the movement restriction device in said position, when the movement restriction device is implanted, further comprising a stretching device comprising at least one operable stretching device implantable in the obese patient and adapted to stretch a portion of the patient's stomach wall such that satiety is created.

264. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further comprising; a stretching device comprising three or more mechanical parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling to the stomach wall or invaginating the mechanical parts in the stomach wall part with stomach to stomach sutures, wherein the three or more mechanical parts are adapted to move in relation to each other adapted to stretch

three different wall portions, the stretching device further adapted to having said wall portions stretched independently from each other both regarding;

force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

265. The apparatus for treating obesity according to anyone of claim1, 3, 8 and 24, wherein the volume filling device, further comprising; a stretching device comprising two or more hydraulic parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling to hydraulic part to the stomach wall or invaginating the hydraulic parts in the stomach wall part, with stomach to stomach sutures, wherein the two or more hydraulic parts are adapted to move in relation to each other adapted to stretch three different wall portions, the stretching device further adapted to having said wall portions stretched independently from each other both regarding;

force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

266. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further comprising; a stretching device is engaged with a part of the stomach wall, including suturing or stapling the stretching device to the stomach wall or invaginating the stretching devcie in the stomach wall part, with stomach to stomach sutures, wherein the stretching device is further adapted to stretch a stomach wall portion controlling;

force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and

when the stretching is applied.

267. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further comprising; a stretching device comprising two parts engaged with different parts of the stomach wall, one part each, wherein said engagement includes suturing or stapling the parts to the stomach wall or invaginating the parts in the stomach wall part, with stomach to stomach sutures, wherein the stretching device further adapted to have different wall portions stretched independently from each other controlling;
force used for stretching the stomach wall portion as well as,
time periods the stretching is applied, and
when the stretching is applied.

268. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device further comprising; an external control unit for controlling the volume filling device from the outside of the patient's body.

269. The apparatus according to claim 98, wherein the external control unit comprising a wireless remote control adapted to control the device from the outside of the patient's body.

270. The apparatus according to claim 268, wherein the external control unit comprising a subcutaneously placed switch or reservoir adapted to control the device from the outside of the patient's body.

271. The apparatus for treating obesity according to anyone of claim 1, 3, 8 and 24, wherein the volume filling device, further comprising; comprising a sensor or sensing device adapted to be implaned in the patient body, wherein the implantable control unit is adapted to control the device from the inside of the patient's body using information from said a sensor or sensing device, adapted to sense, direct or indirect, the food intake of the patient.

Fig.1A

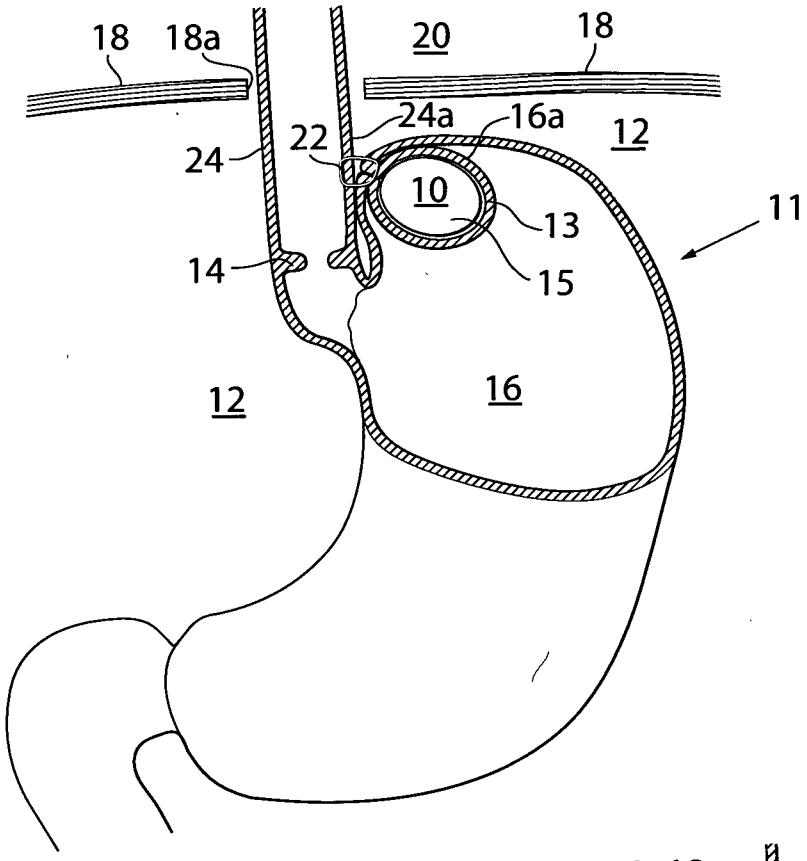

Fig.1B

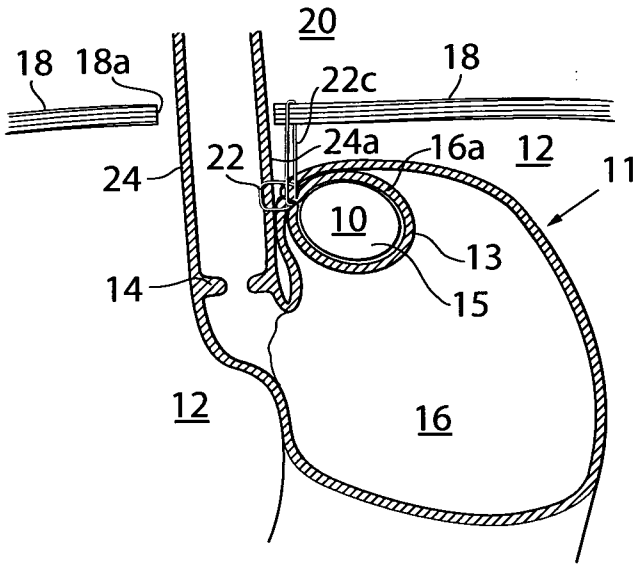

Fig.1C

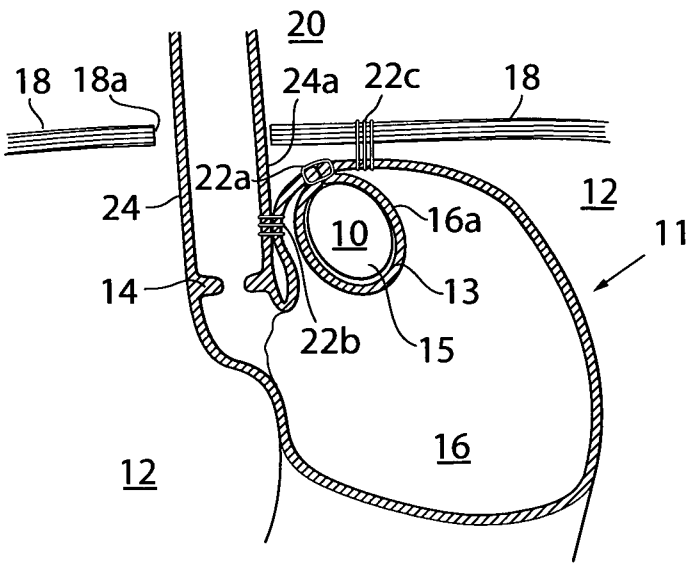

Fig.2A

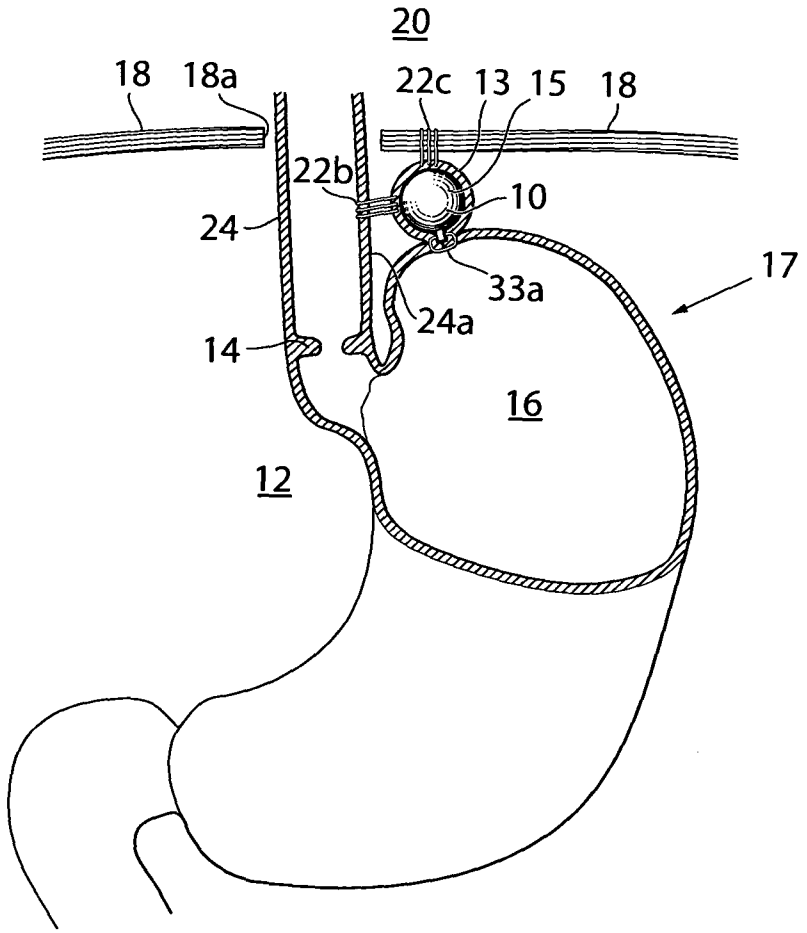
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Fig.2B

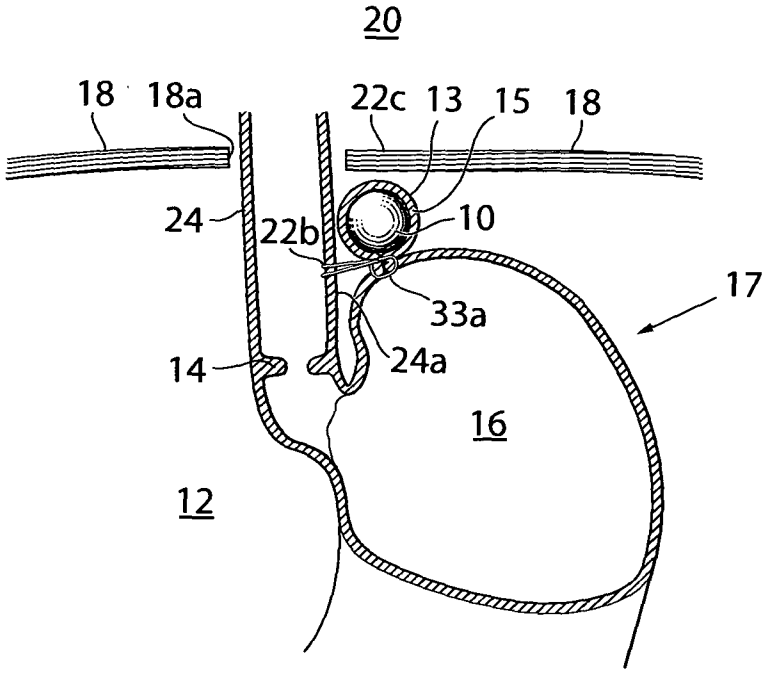
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Fig.3A

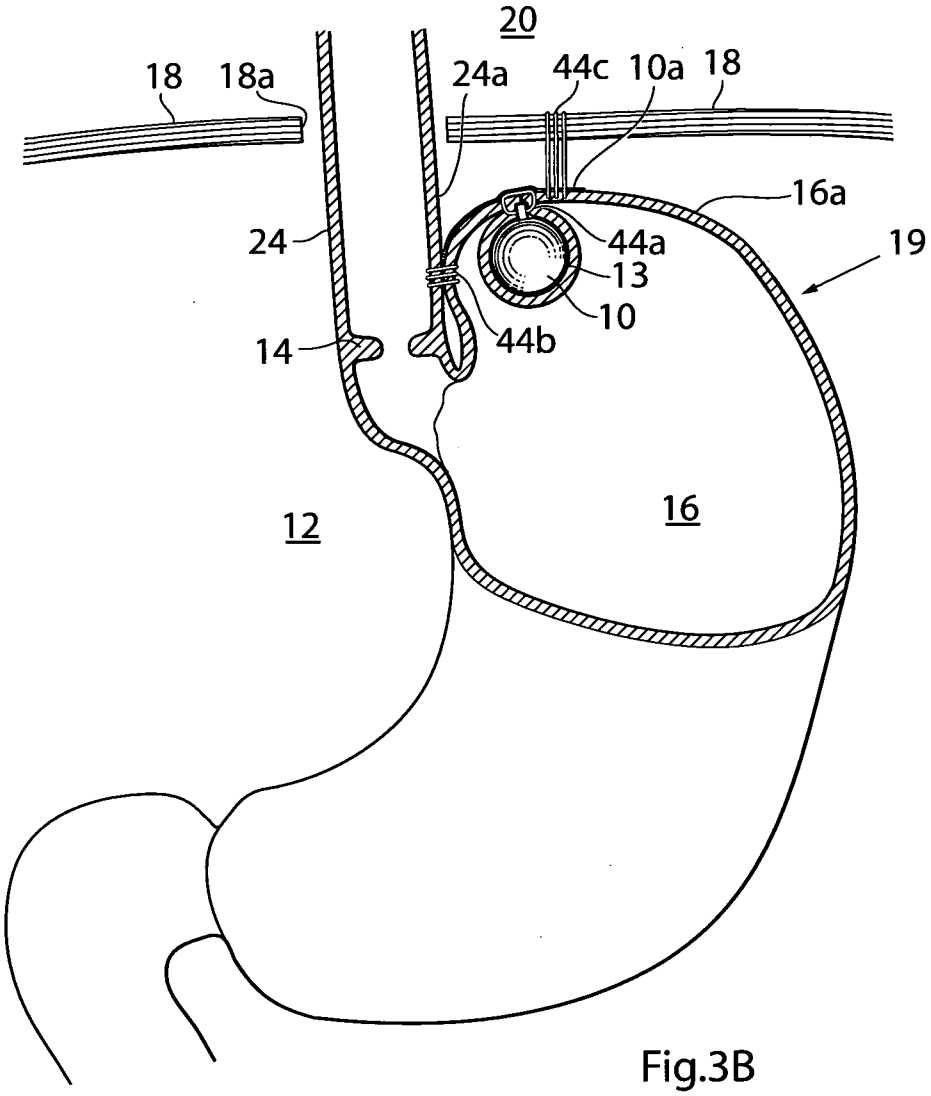
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Fig.3B

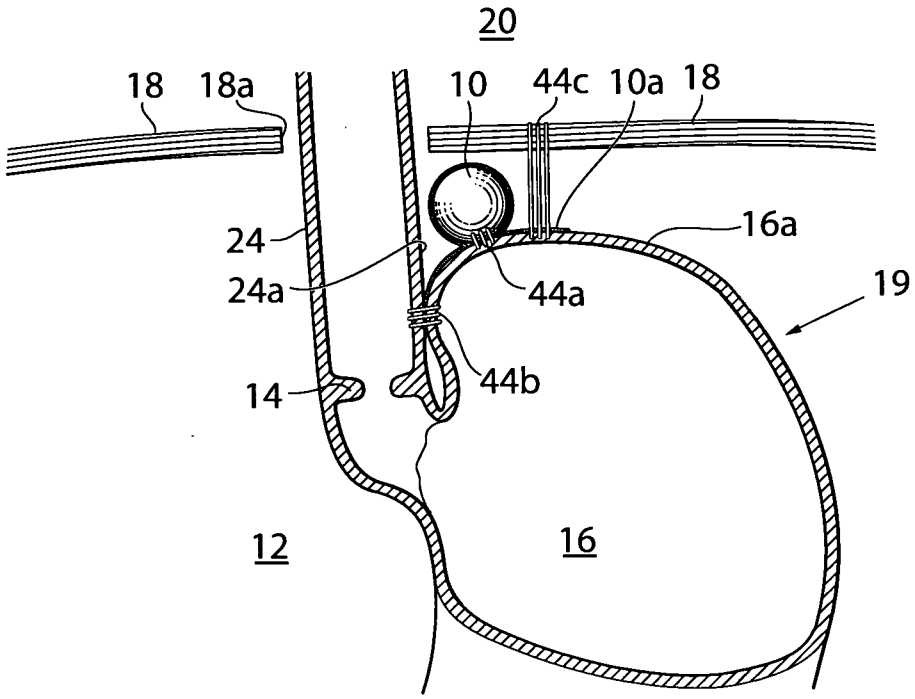
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Fig.4A

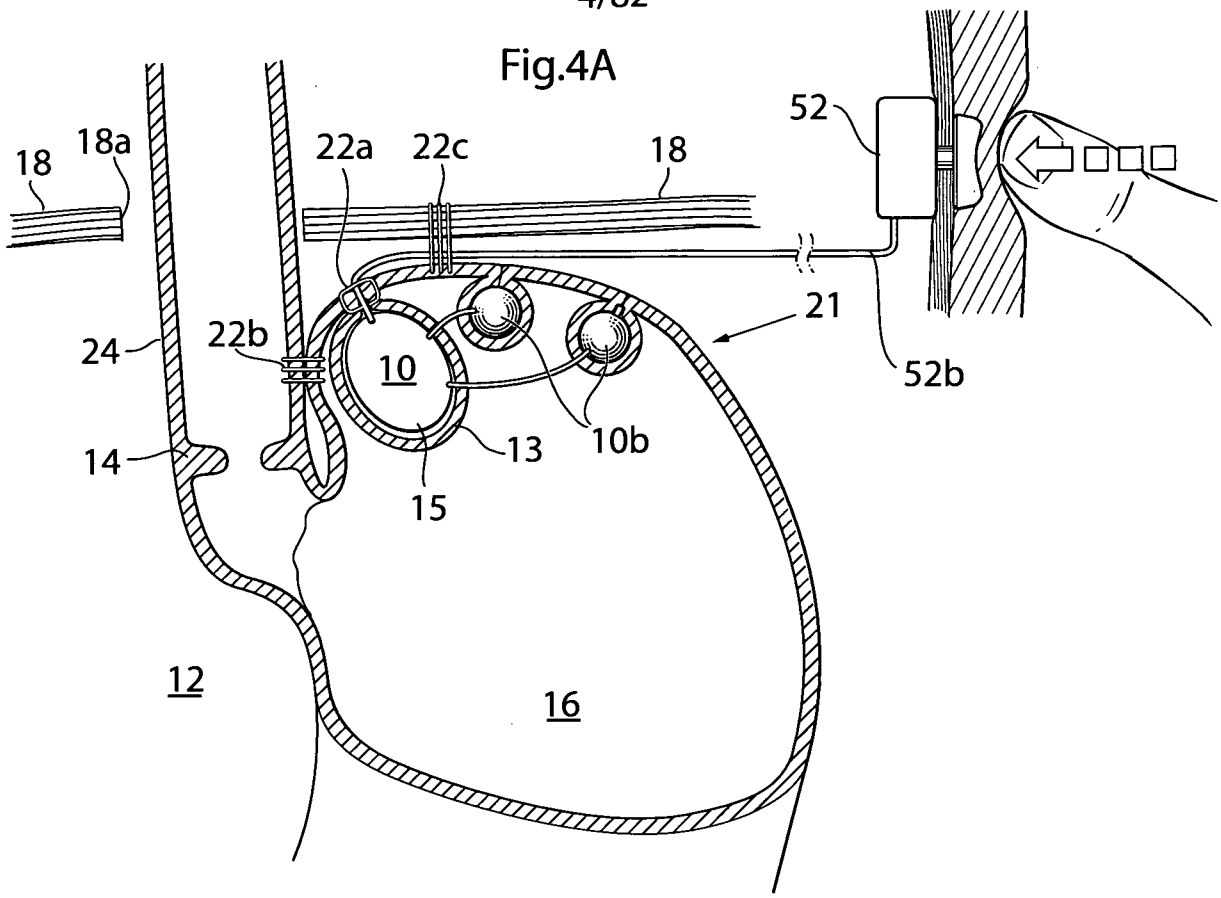
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Fig.4B

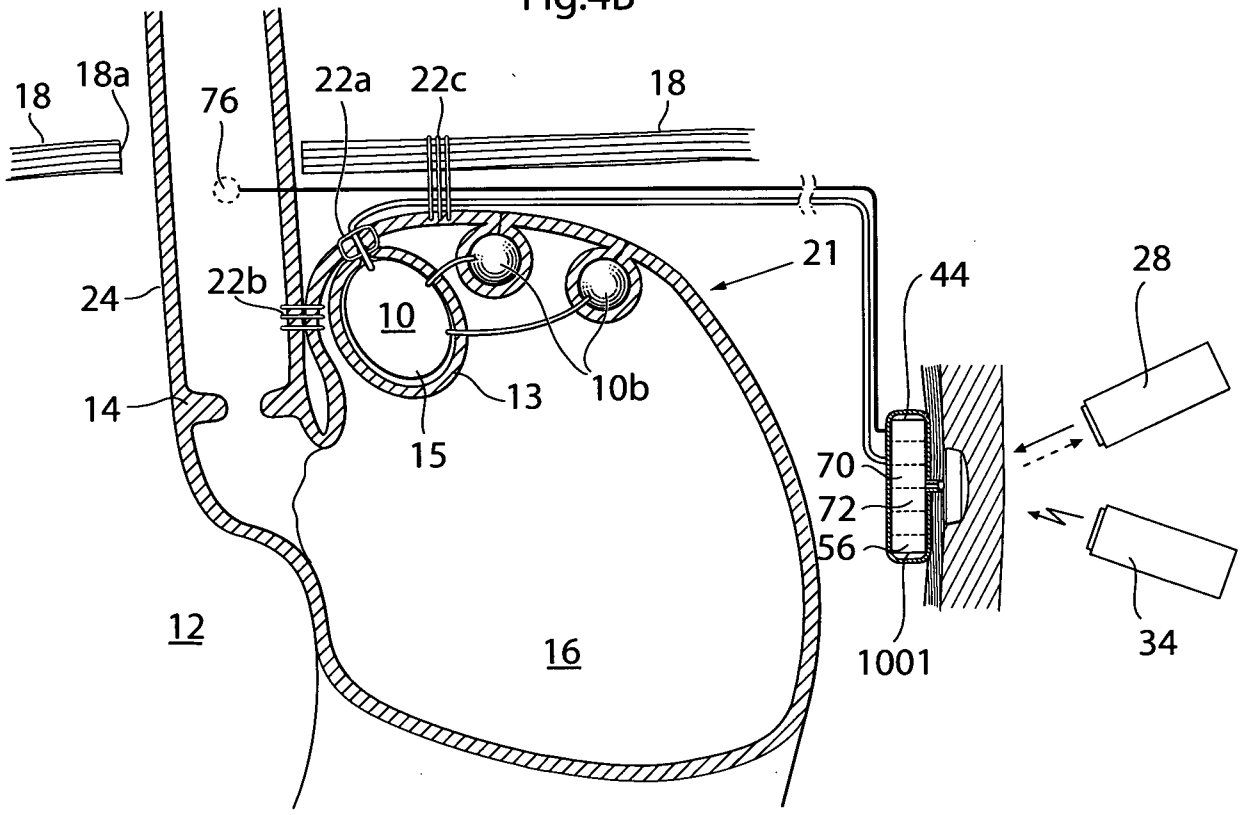
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Fig. 4C

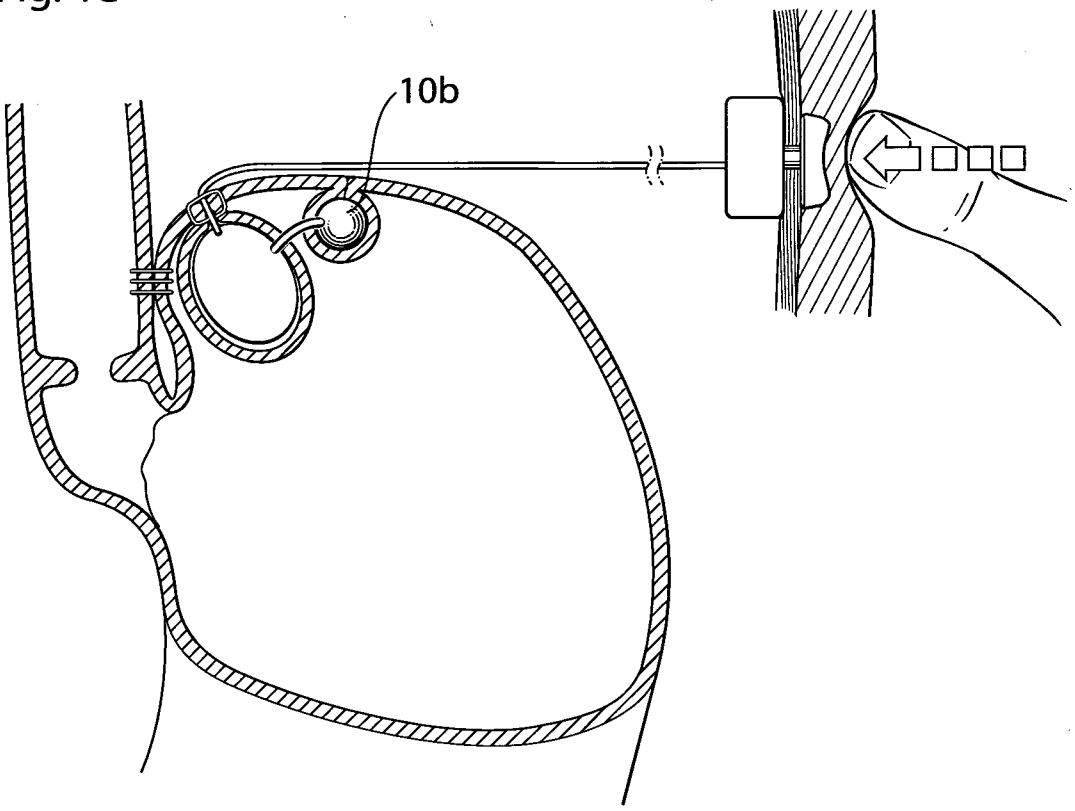

Fig. 4D

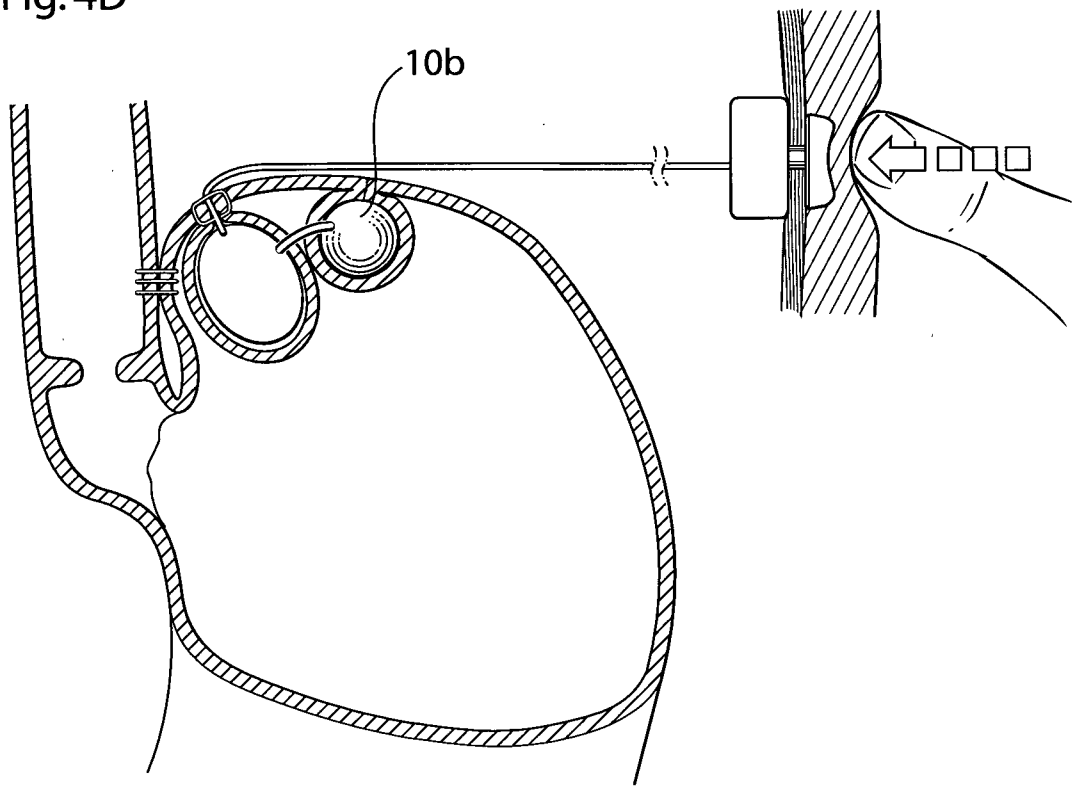

Fig.5A

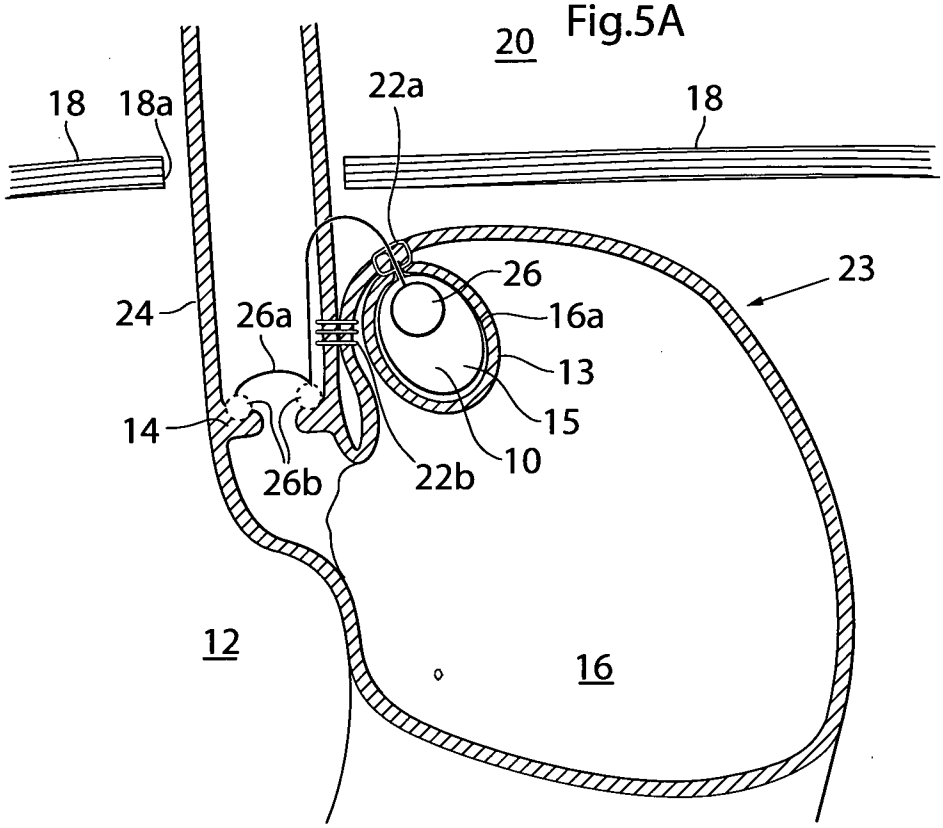
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Fig.5B

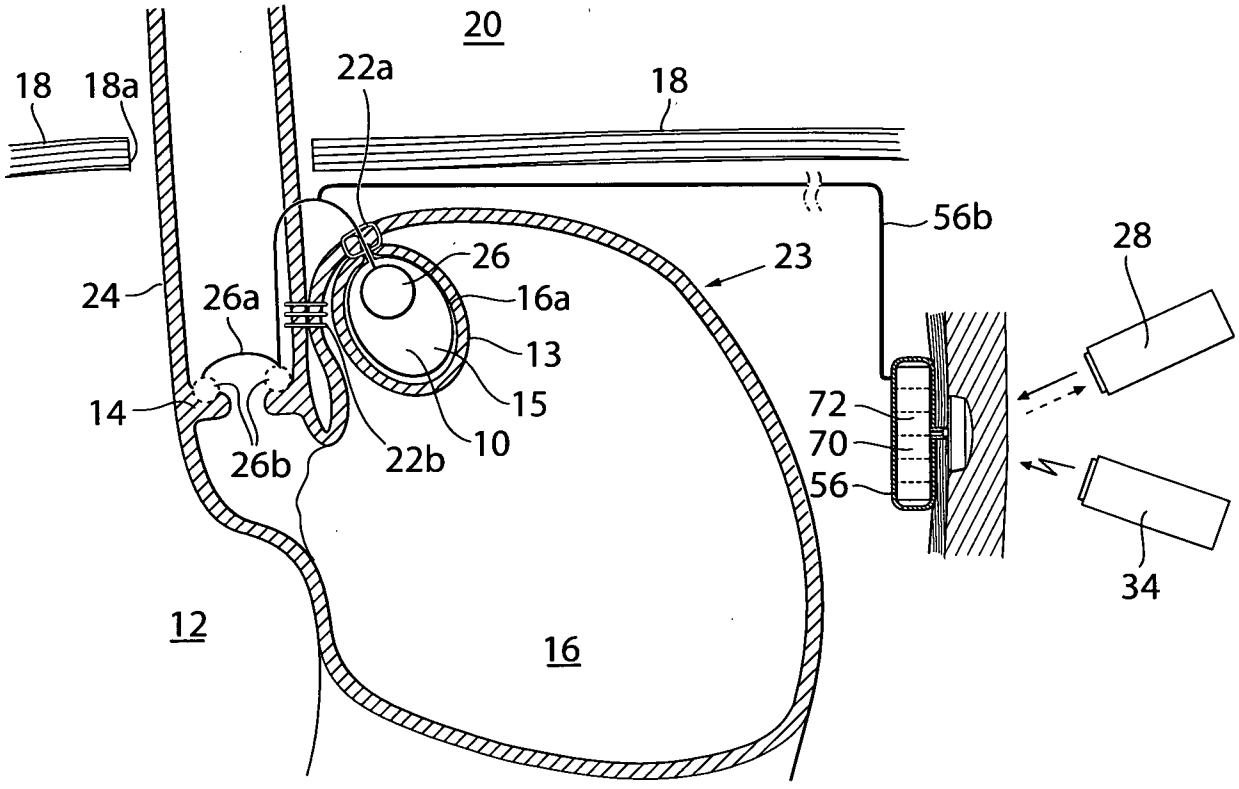
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Fig.6A

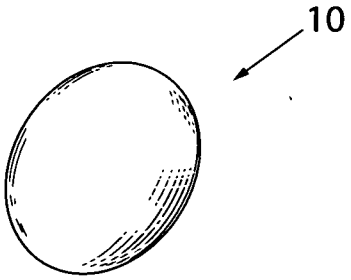


Fig.6B

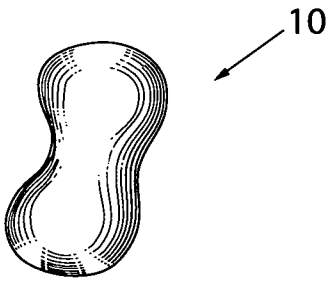


Fig.6C

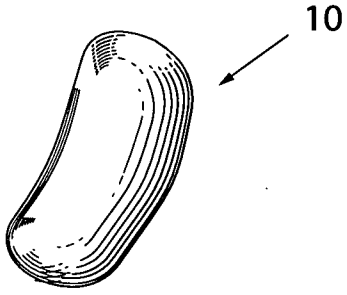


Fig.6D

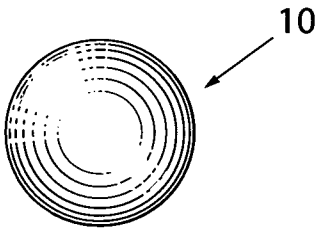


Fig.7

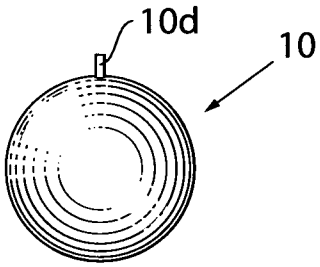


Fig.8

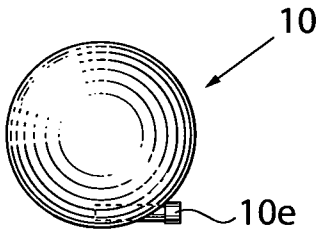


Fig.9

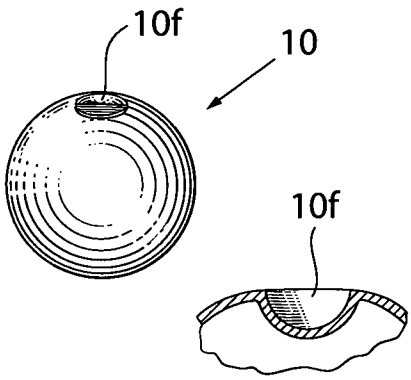


Fig.10

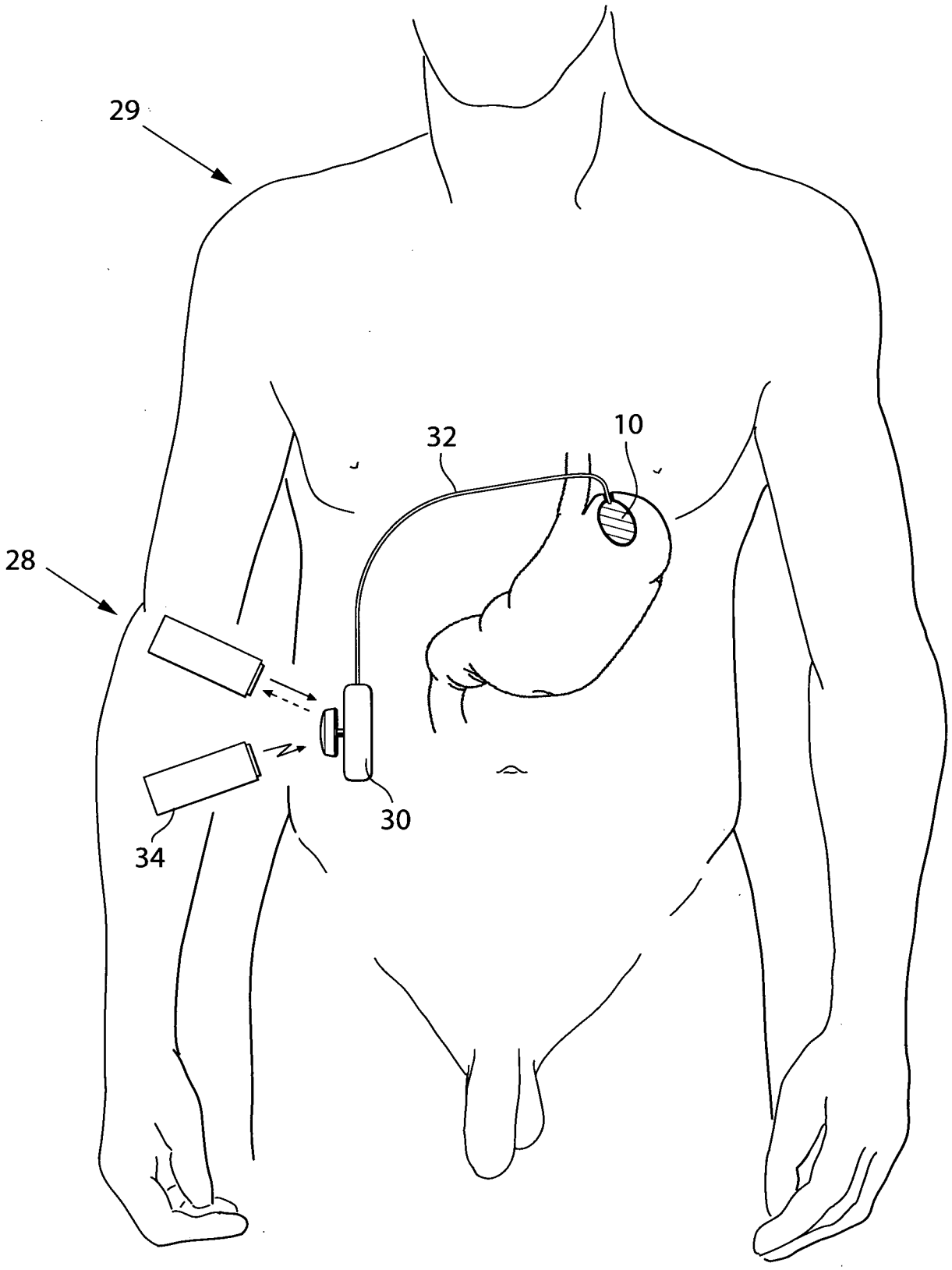


Fig.11

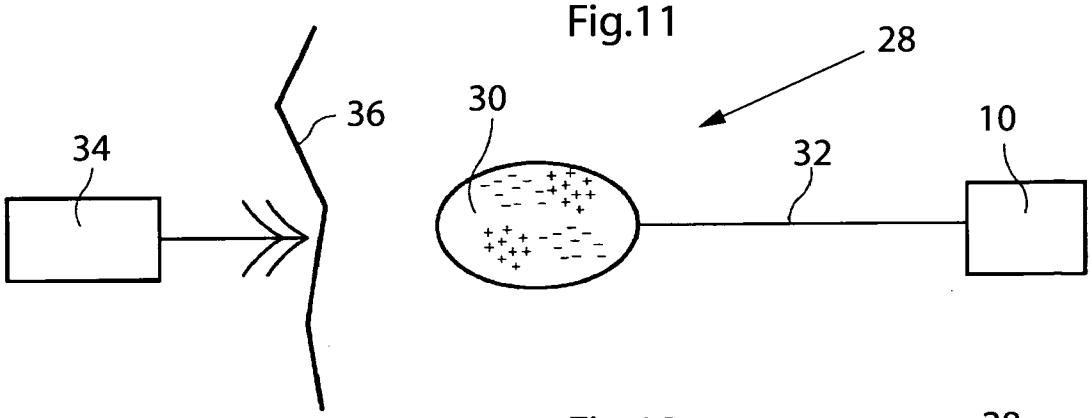


Fig.12

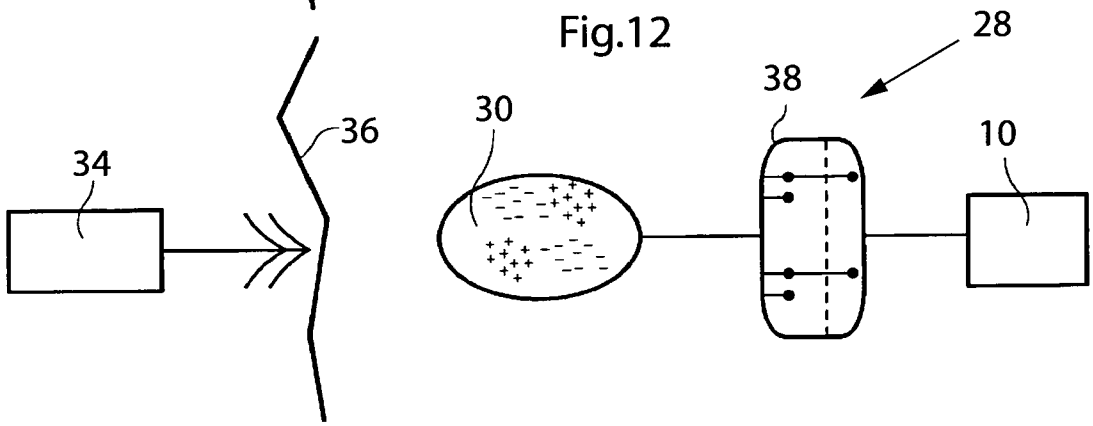


Fig.13

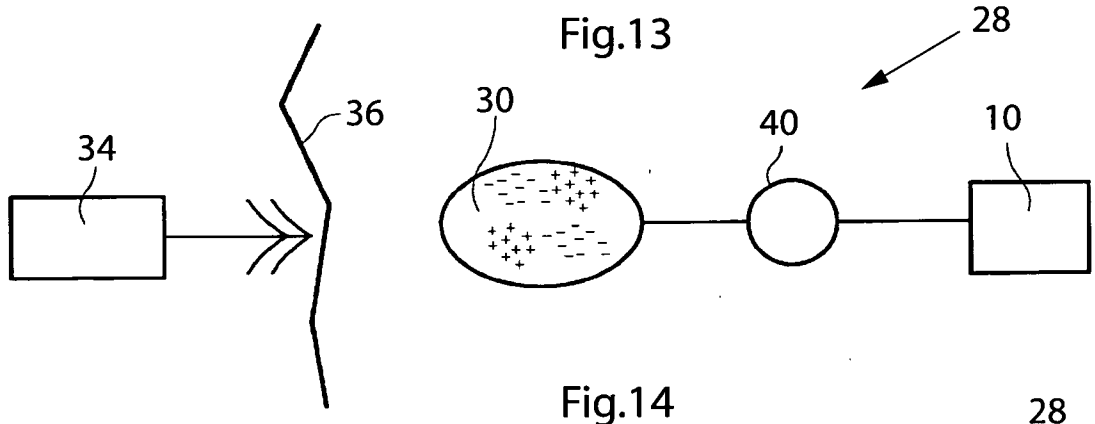


Fig.14

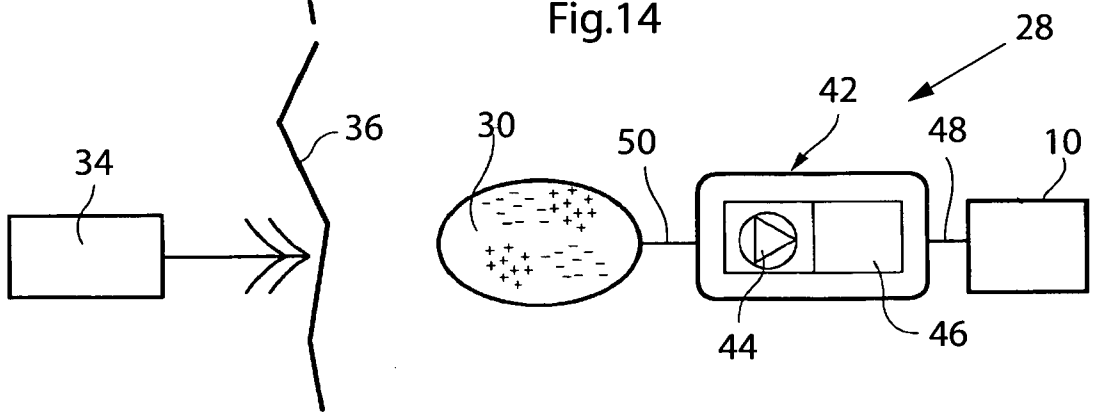


Fig.15

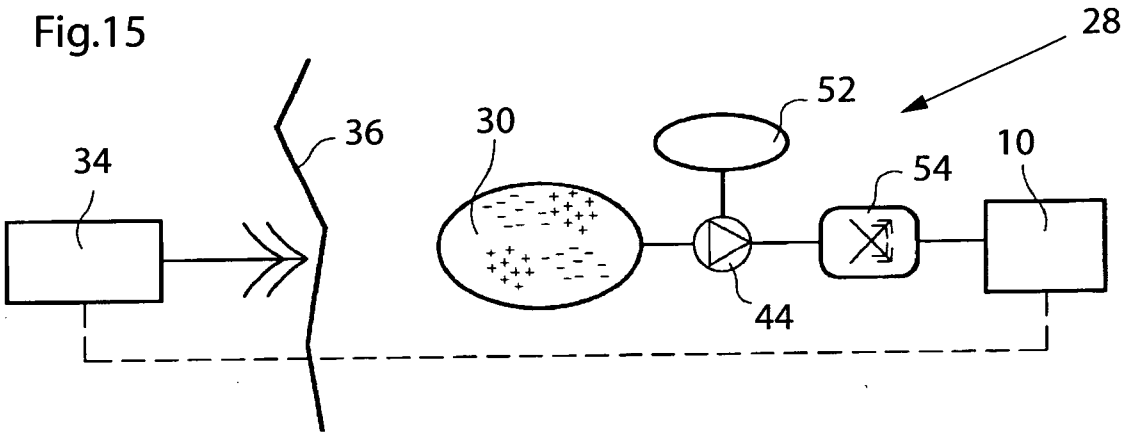


Fig.16

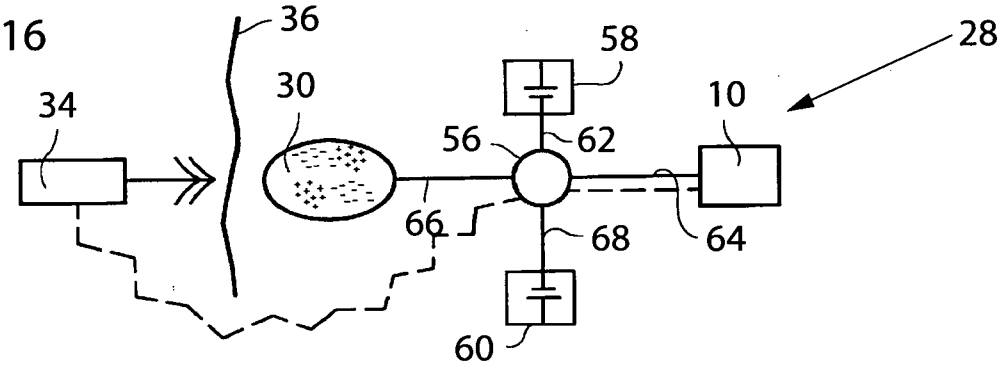


Fig.17

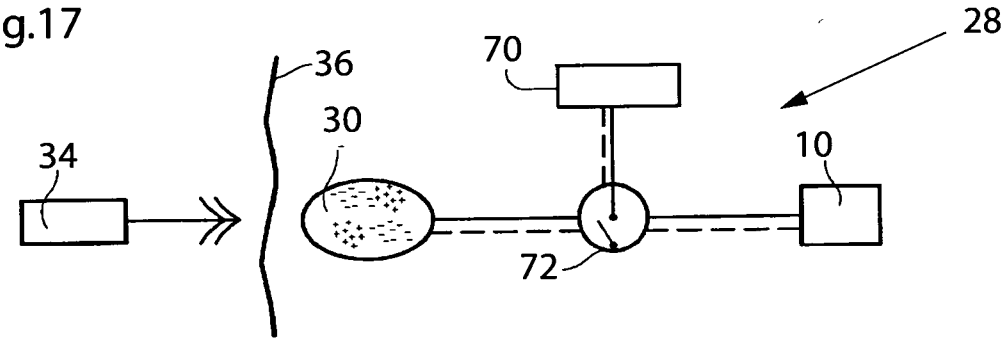
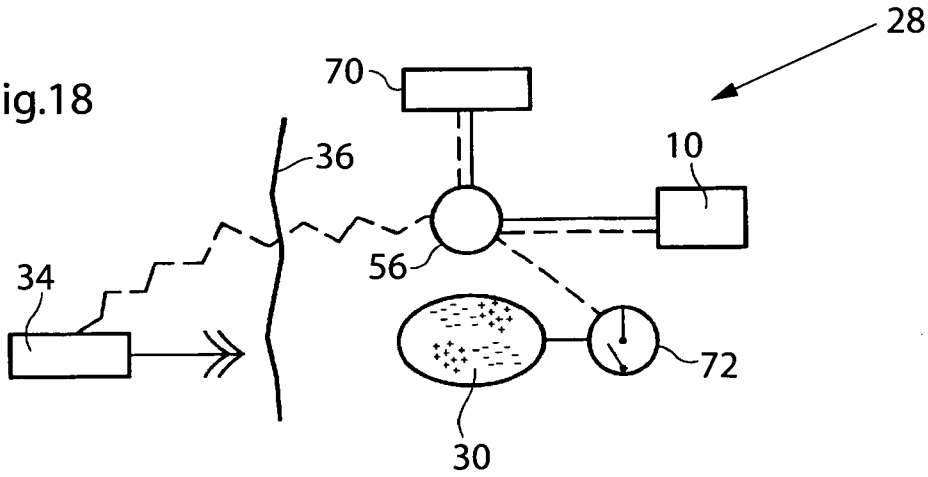


Fig.18



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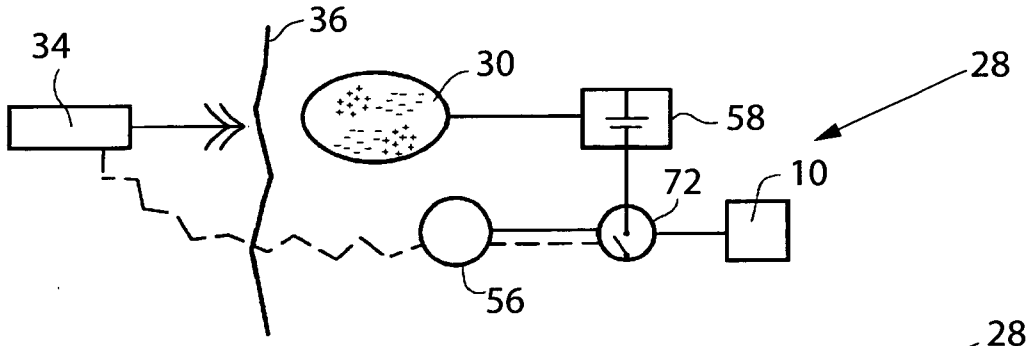


Fig.20

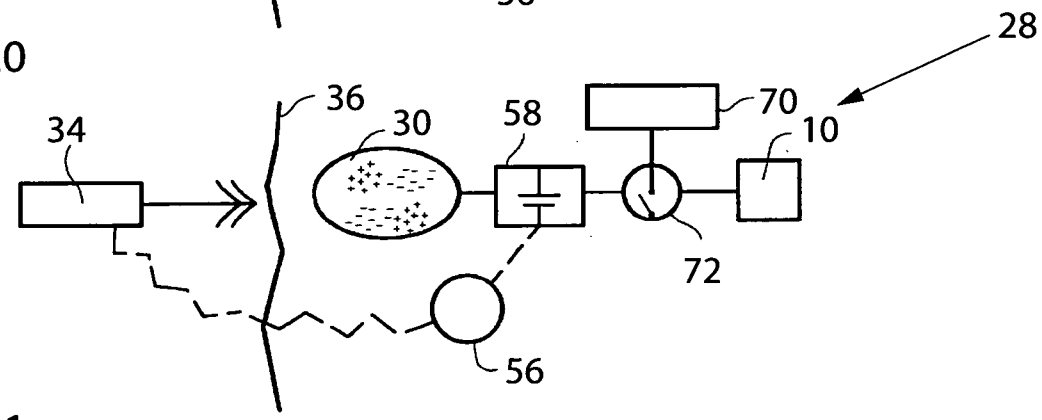


Fig.21

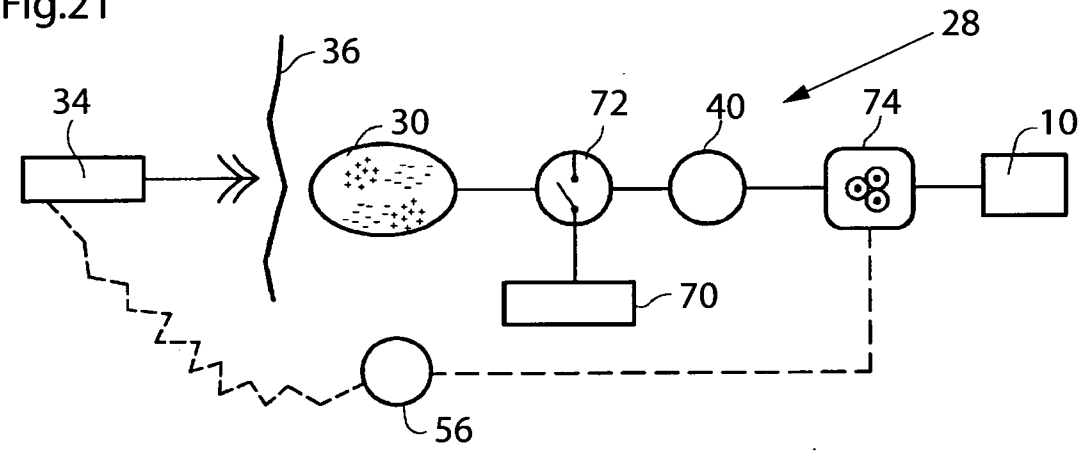


Fig.22

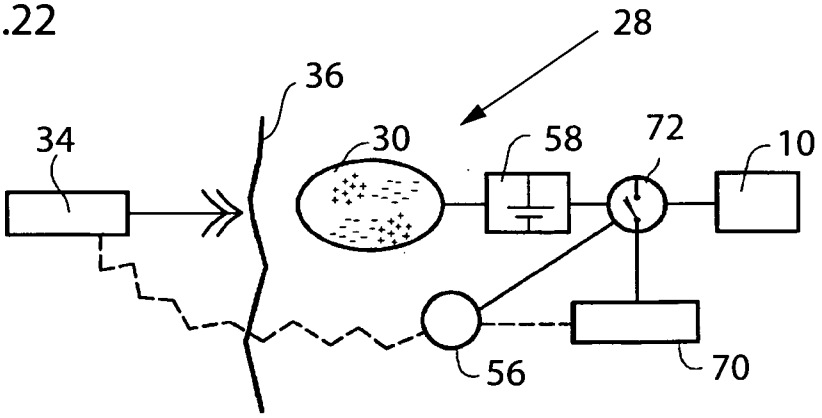


Fig.23

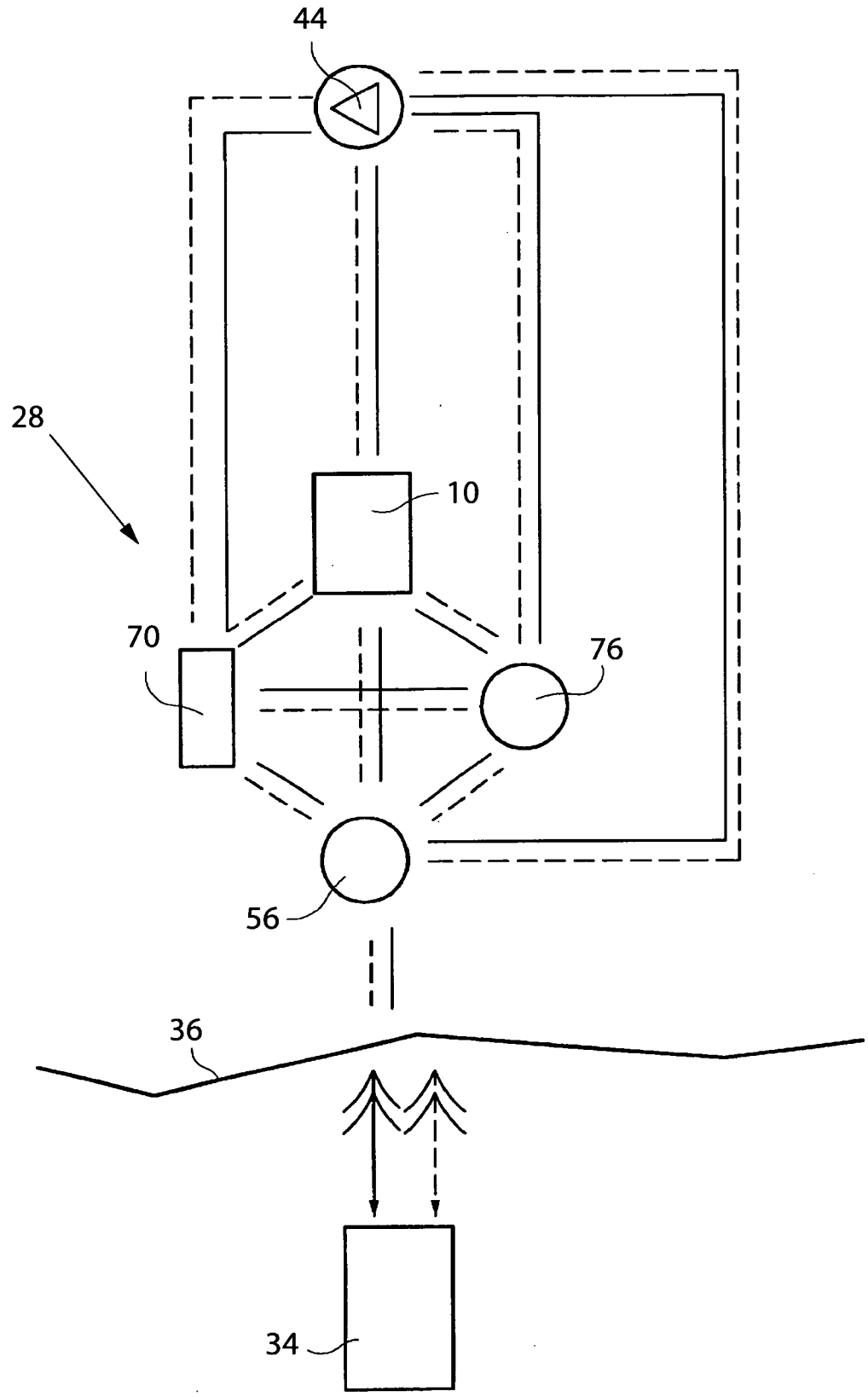


Fig.24

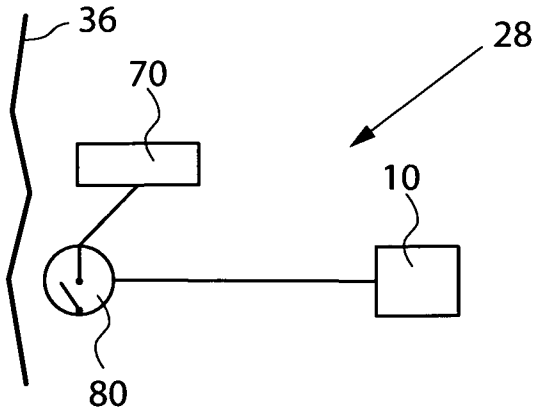


Fig.25

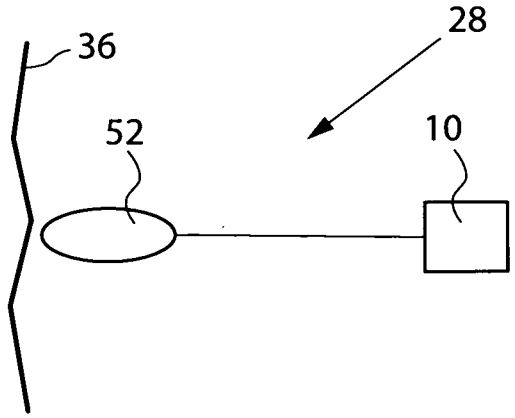


Fig.26

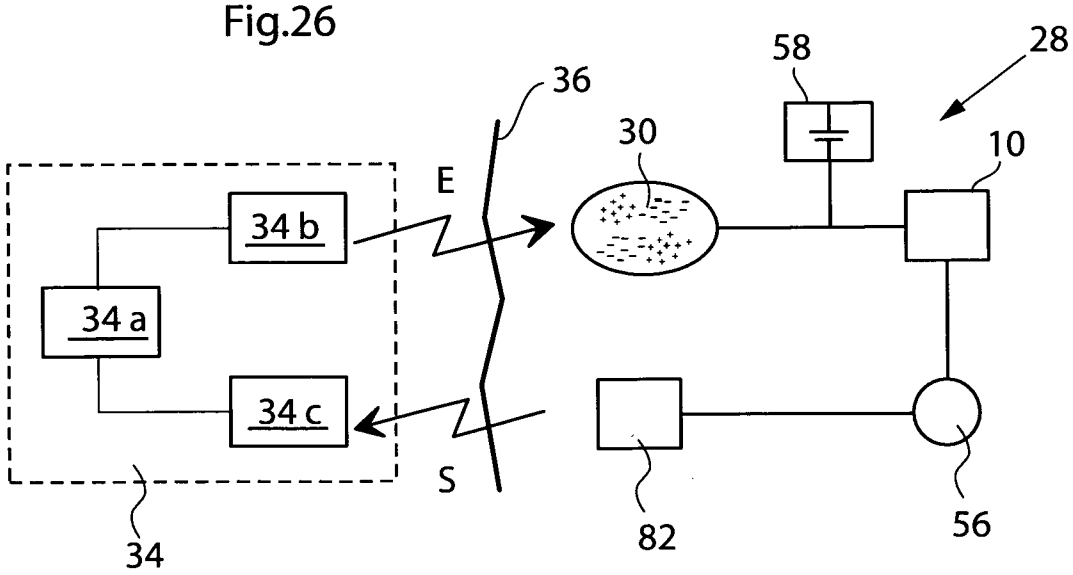


Fig.27

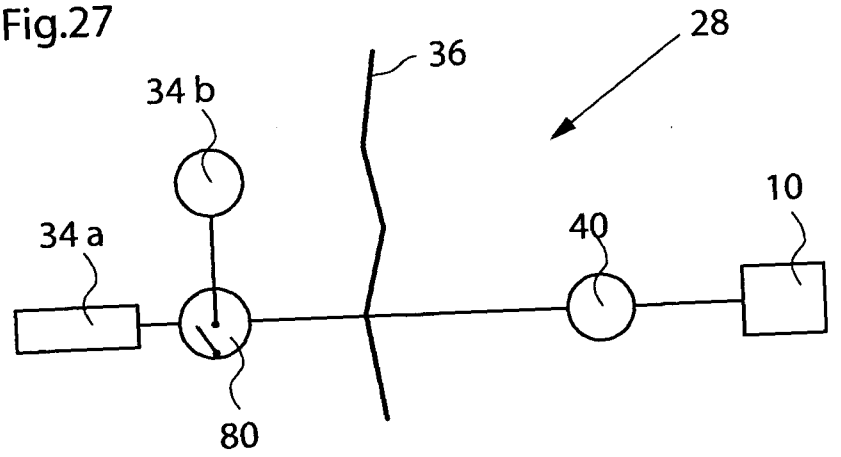


Fig.28

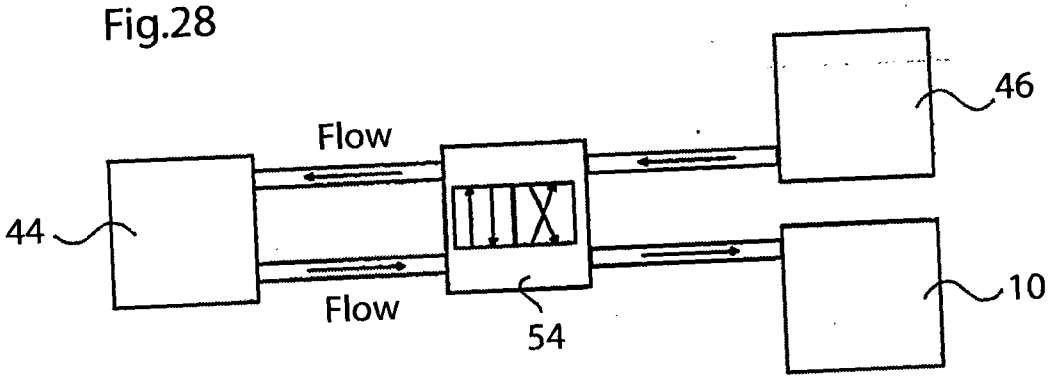


Fig.29

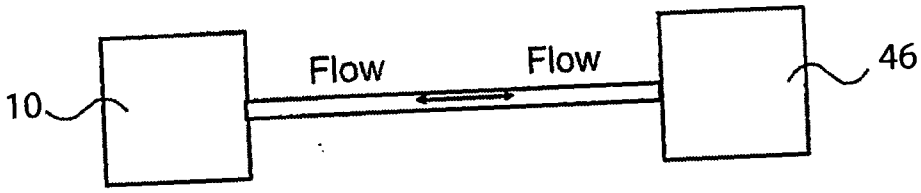


Fig.30

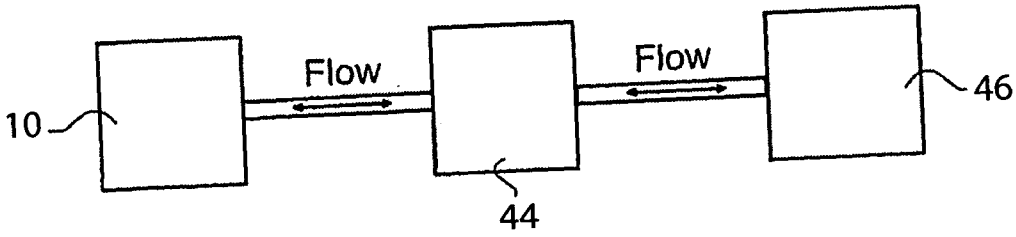


Fig.31

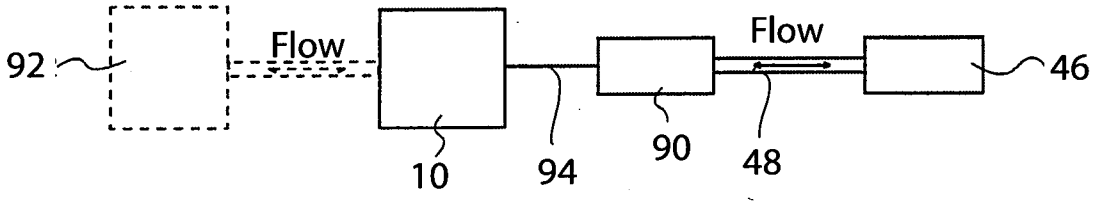


Fig.32 a

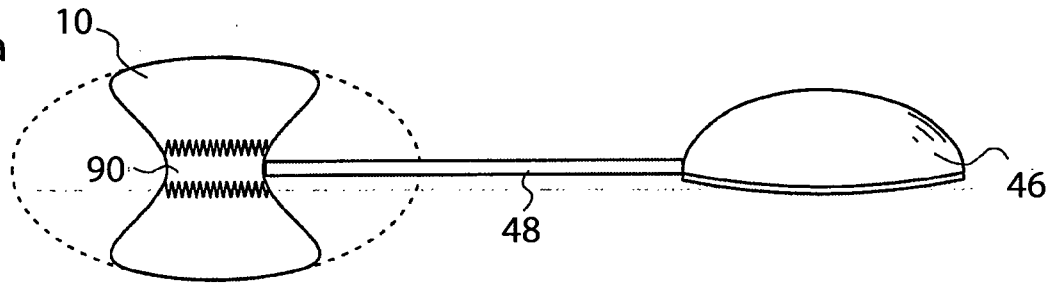


Fig.32 b

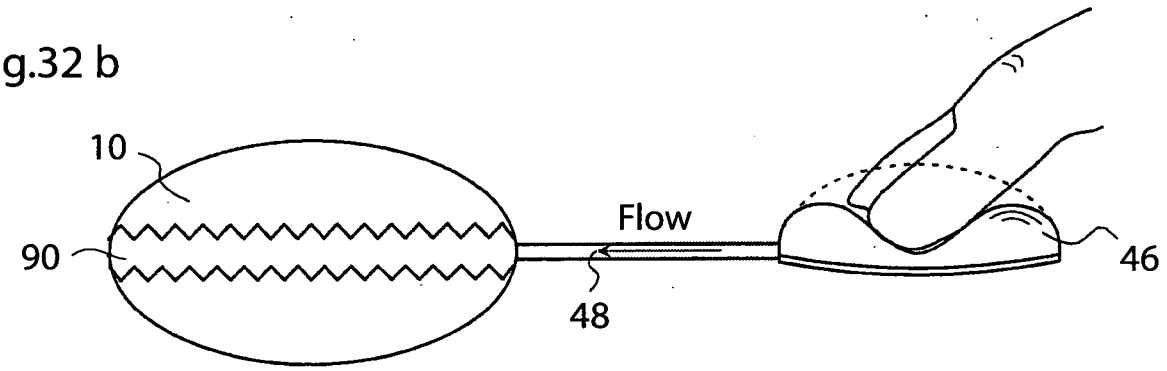


Fig.32 c

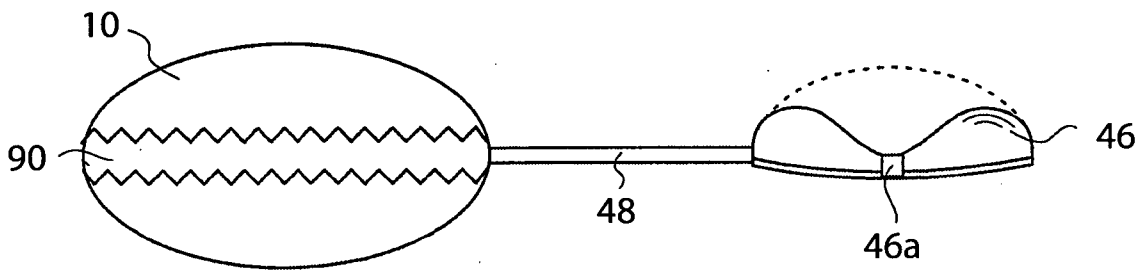


Fig.33

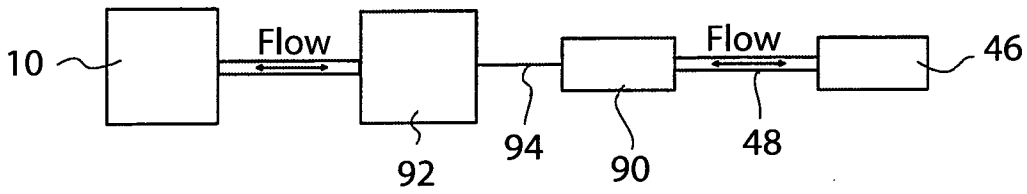


Fig.34 a

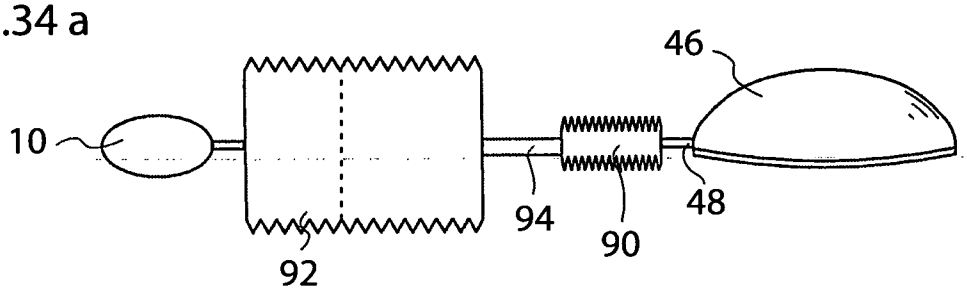


Fig.34 b

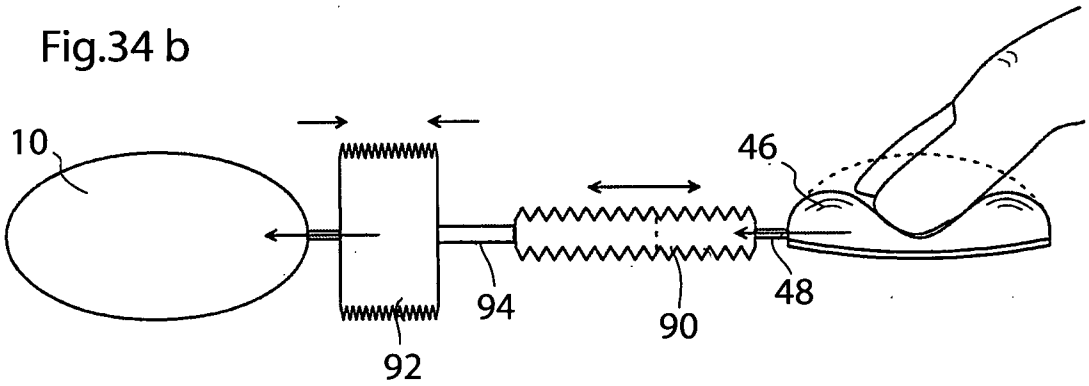


Fig.34 c

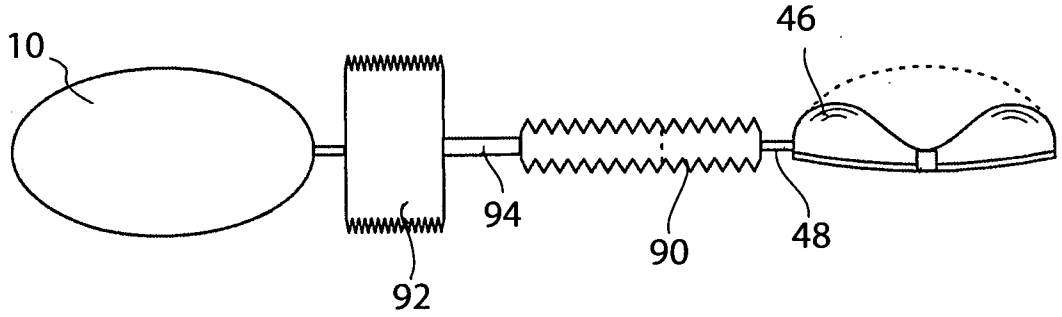


Fig.35

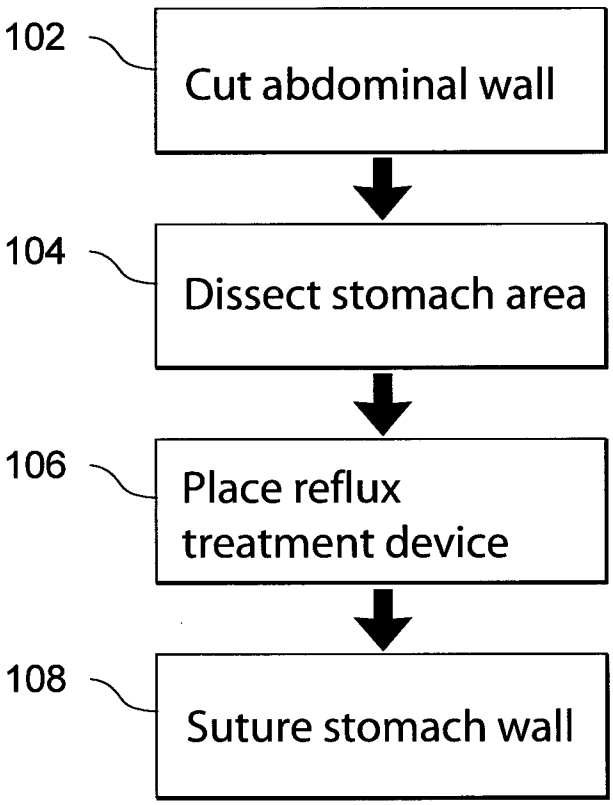

102
Cut abdominal wall
104
Dissect stomach area
106
Place reflux treatment device
108
Suture stomach wall

Fig.36

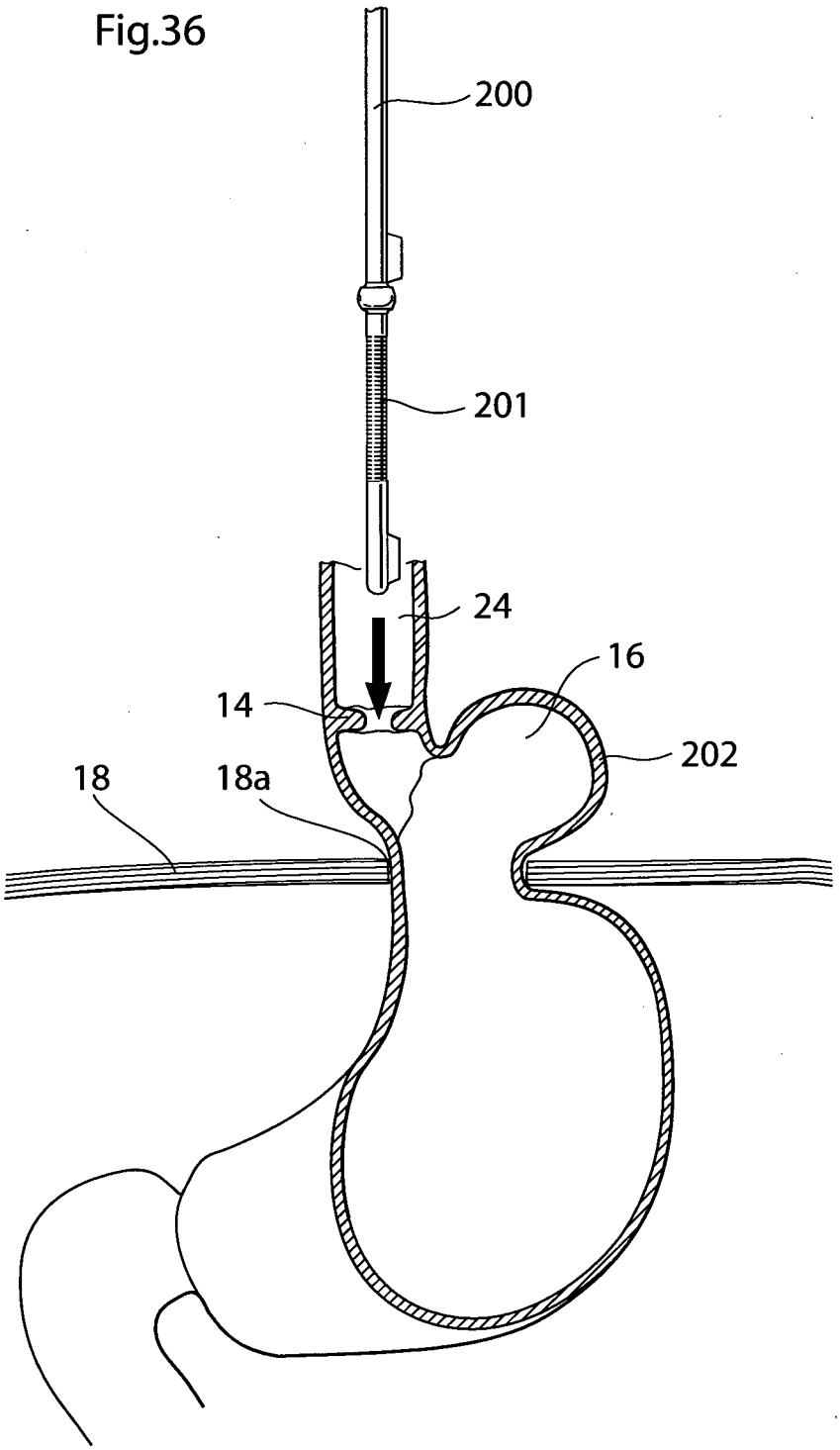


Fig.37

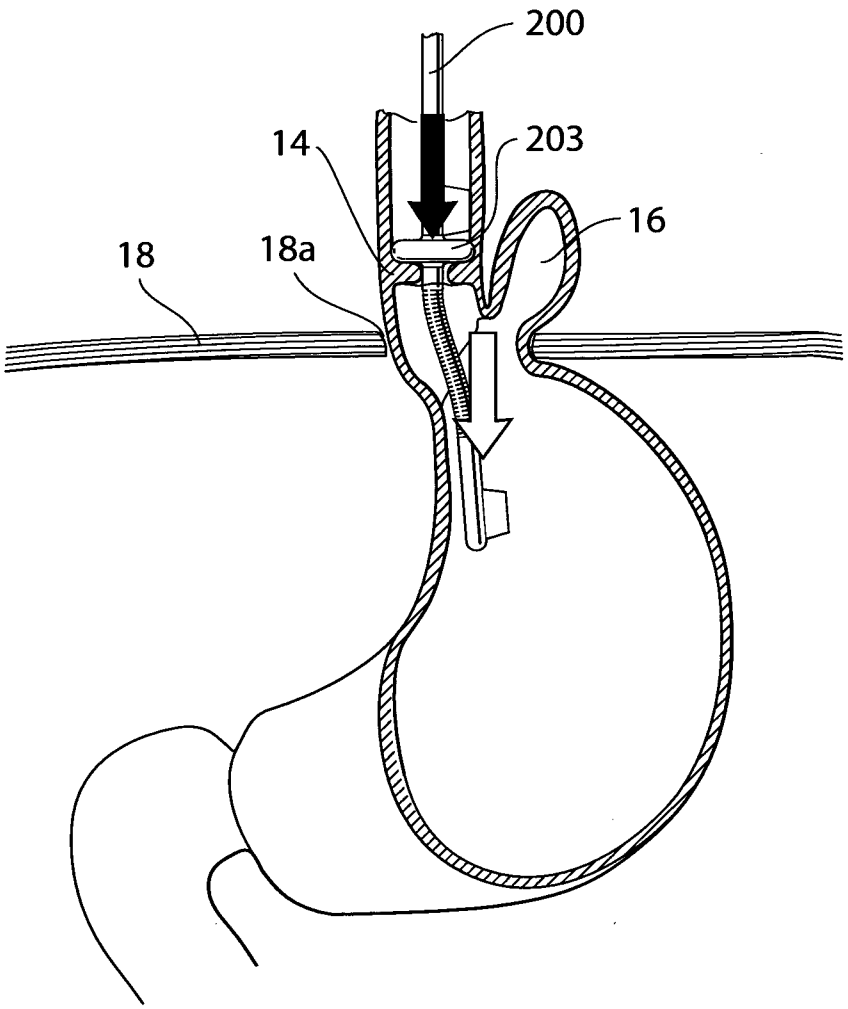


Fig.38

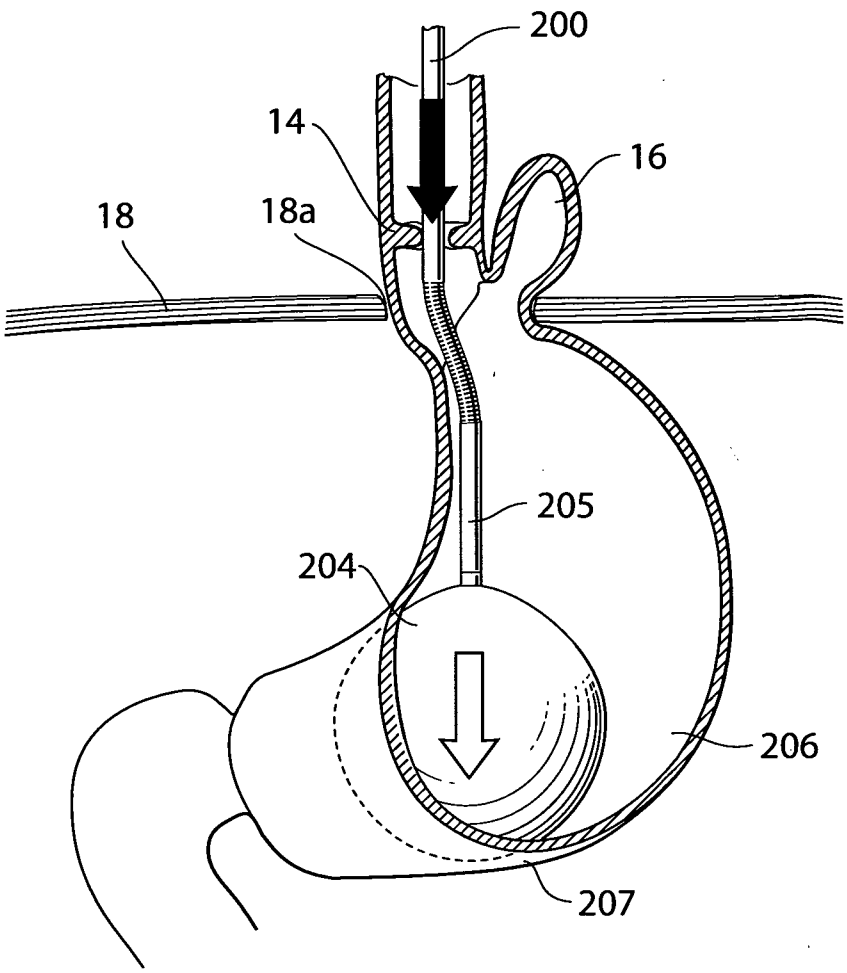


Fig.39

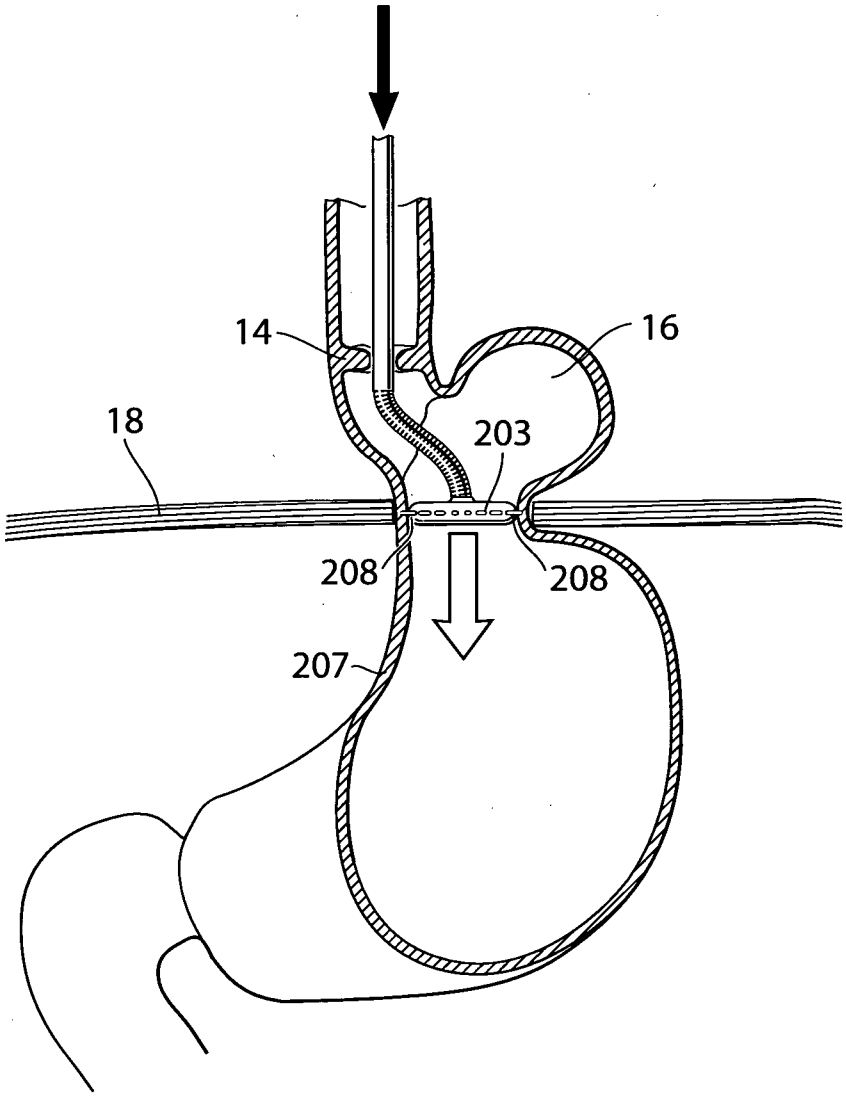


Fig.40

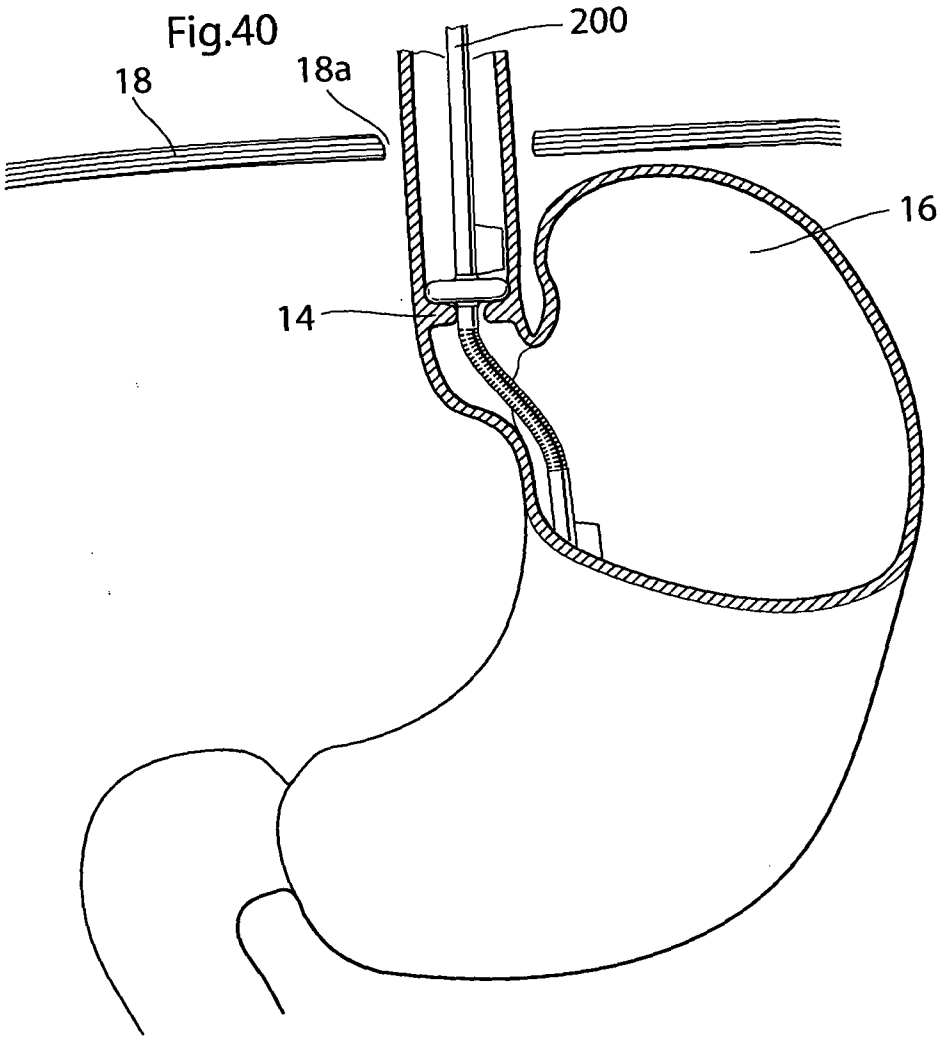


Fig.41

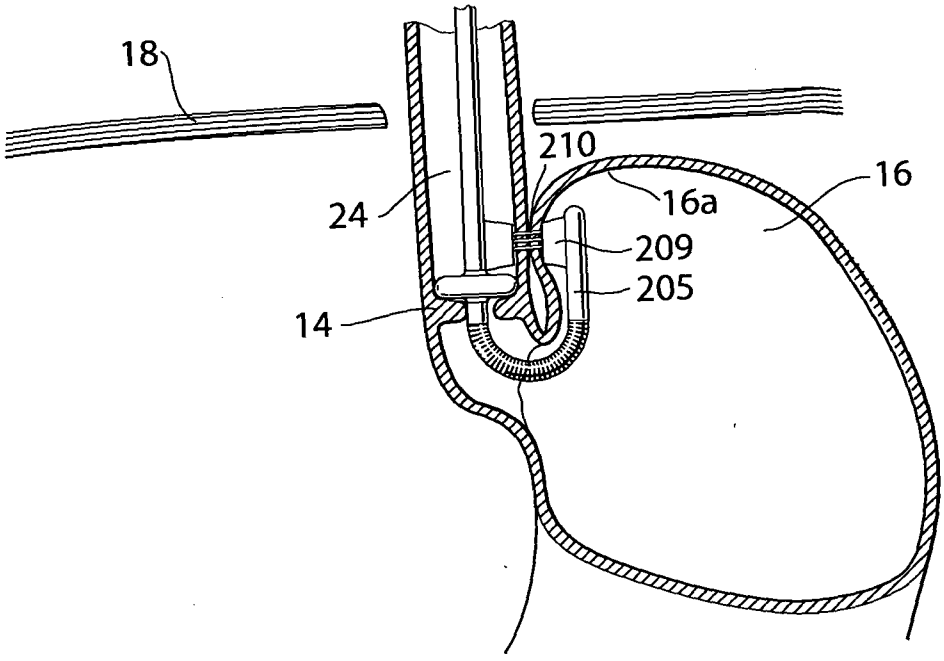


Fig.42

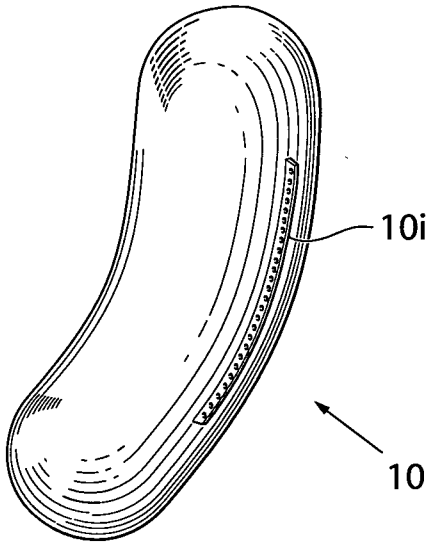


Fig.43

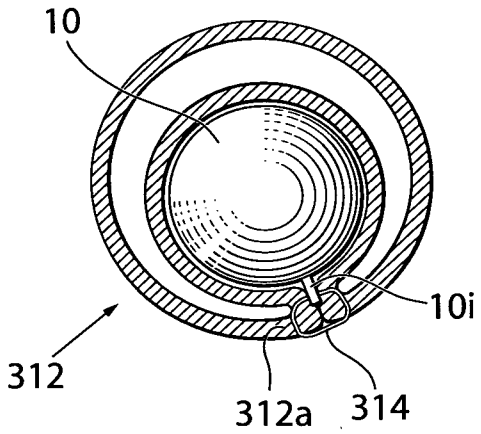


Fig.44

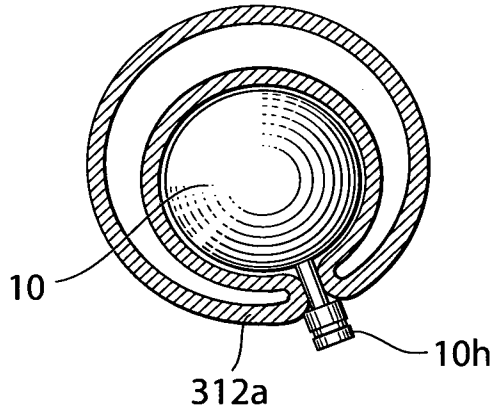


Fig.45

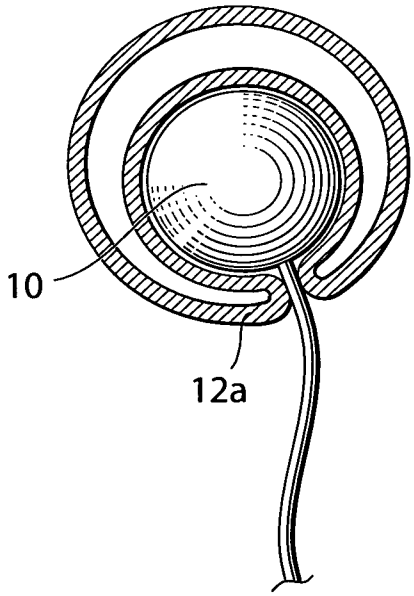


Fig.46

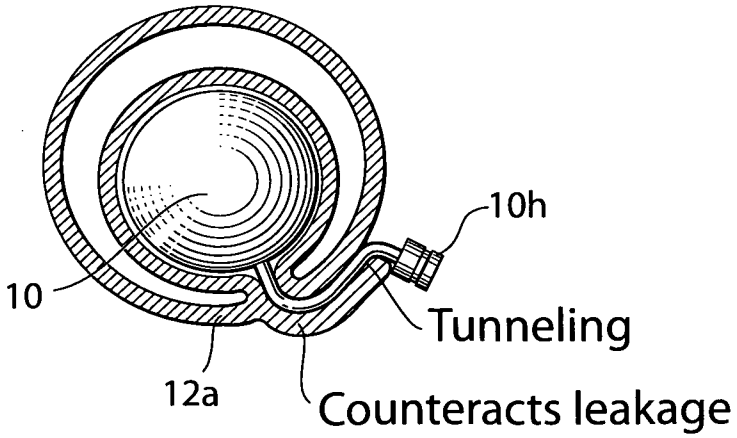


Fig.47a

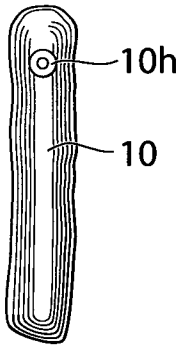


Fig.47b

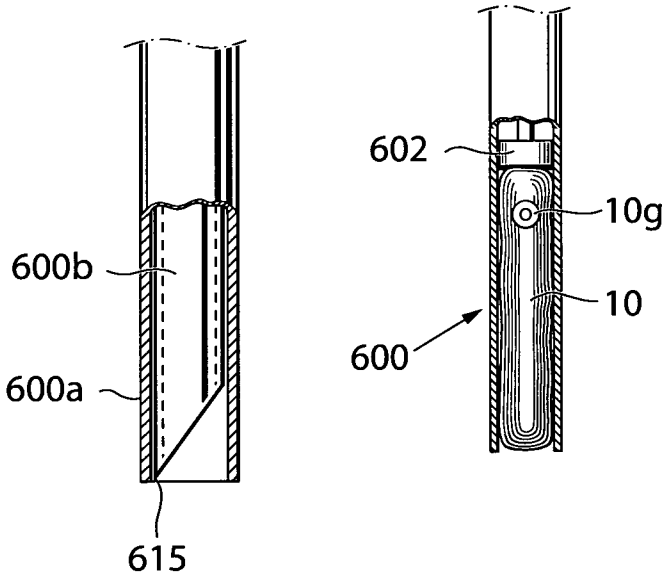


Fig.47c

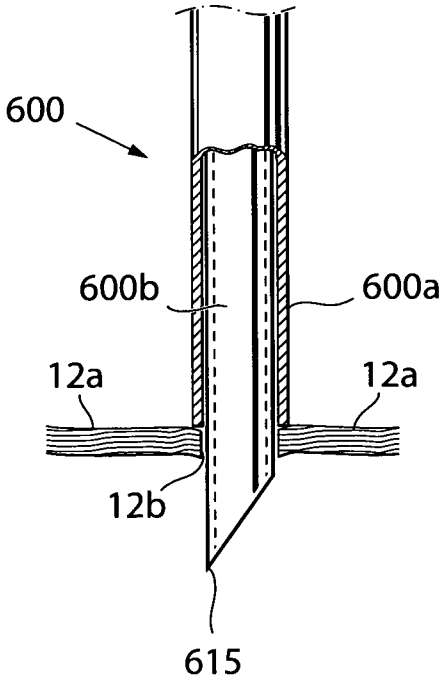


Fig.47d

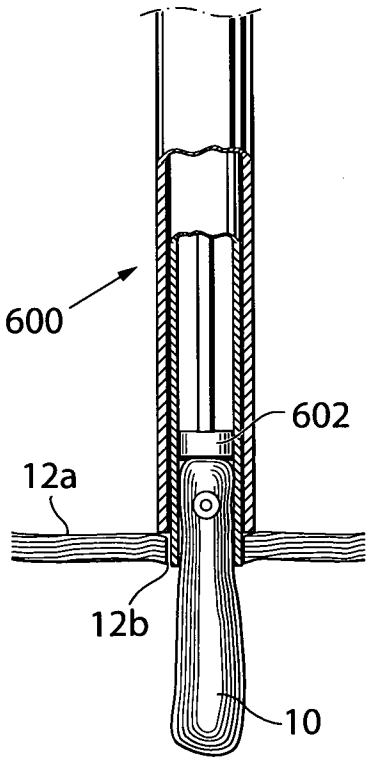


Fig.48a

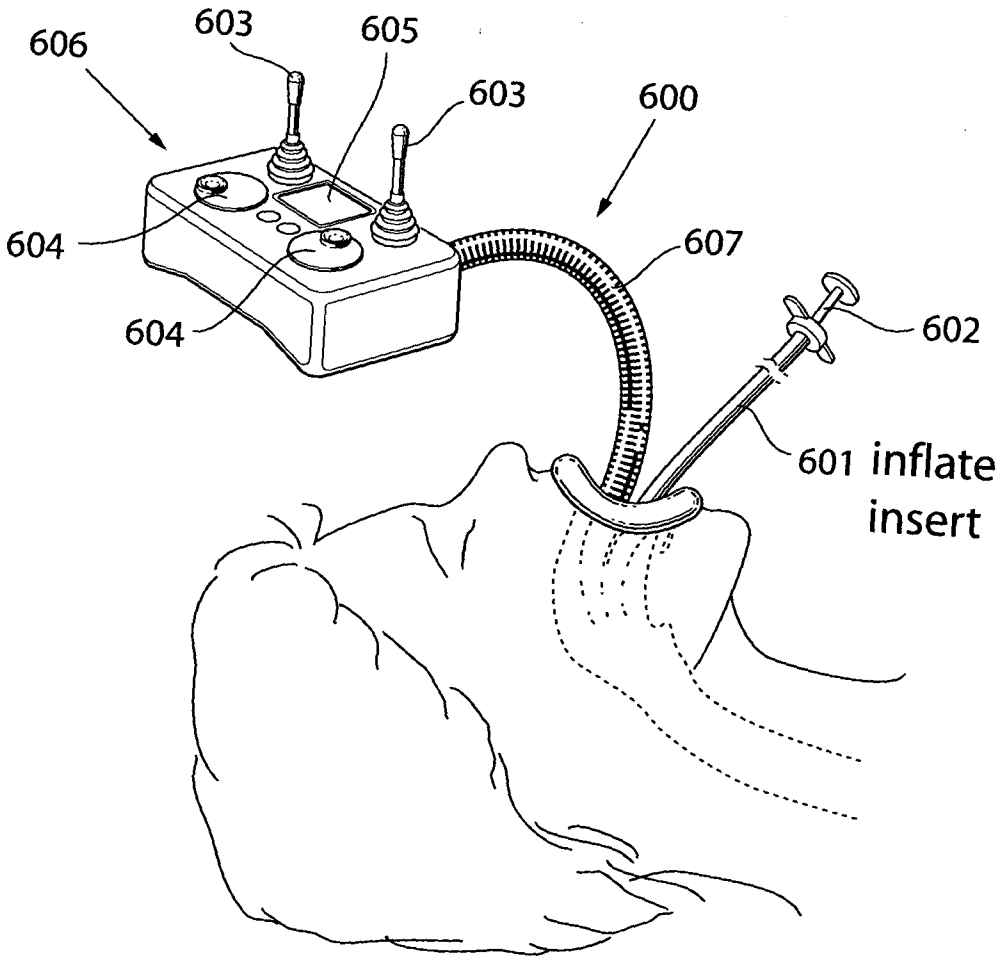


Fig.48b

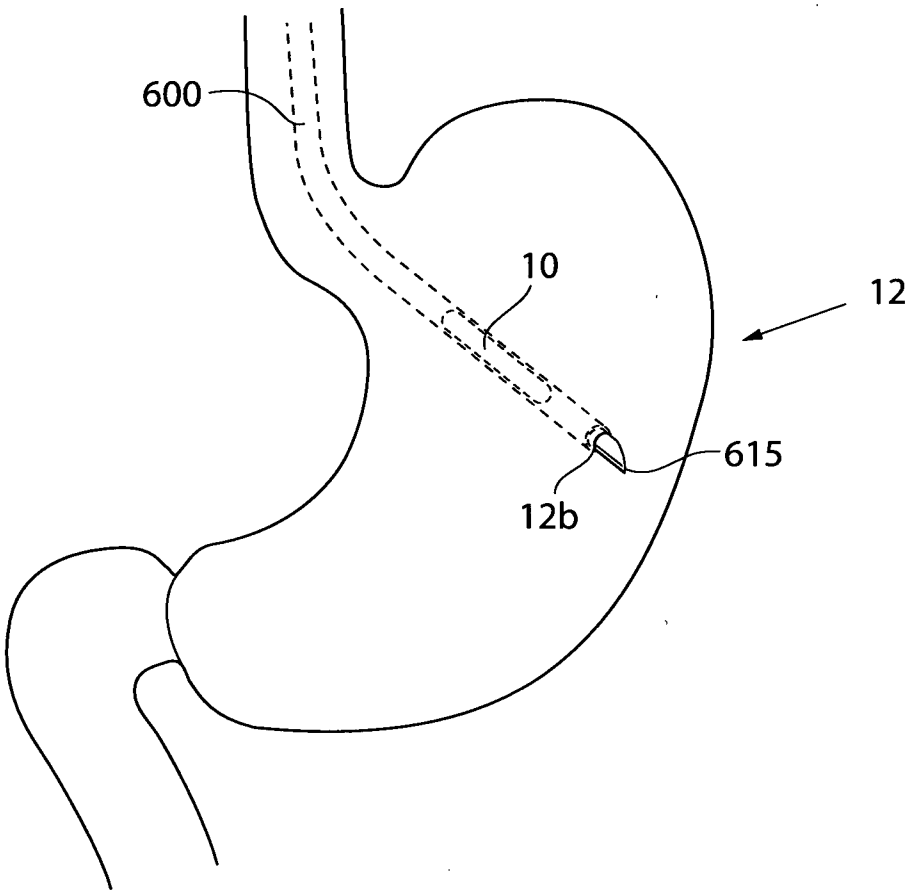


Fig.48c

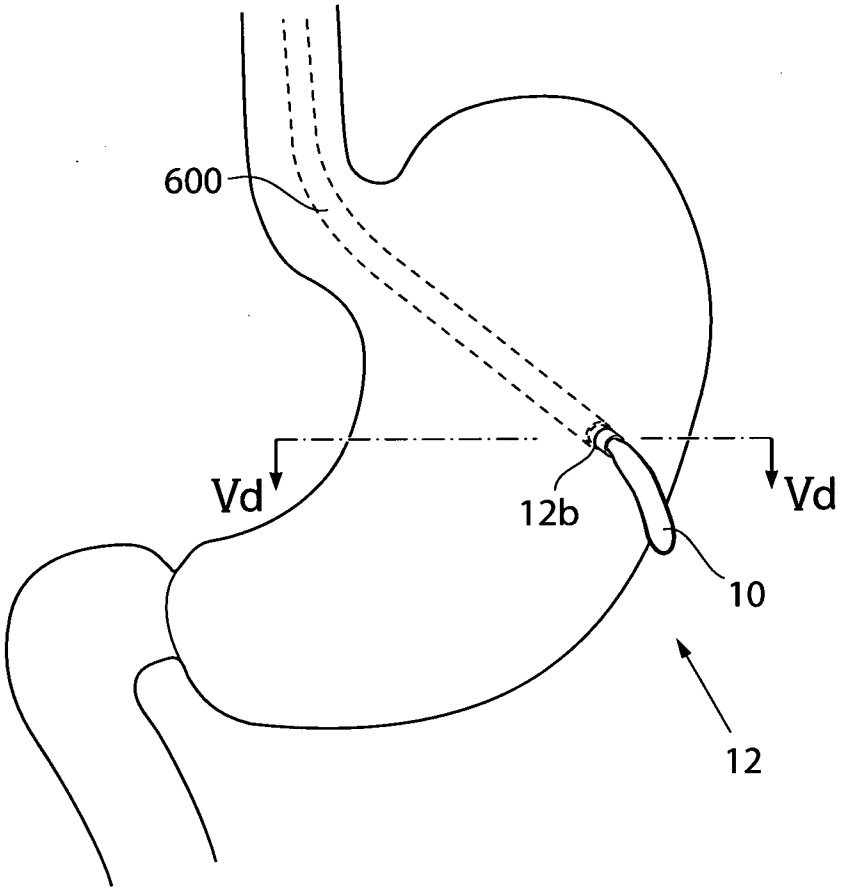


Fig.48d

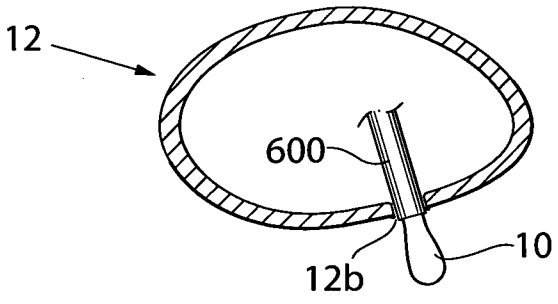


Fig.48e

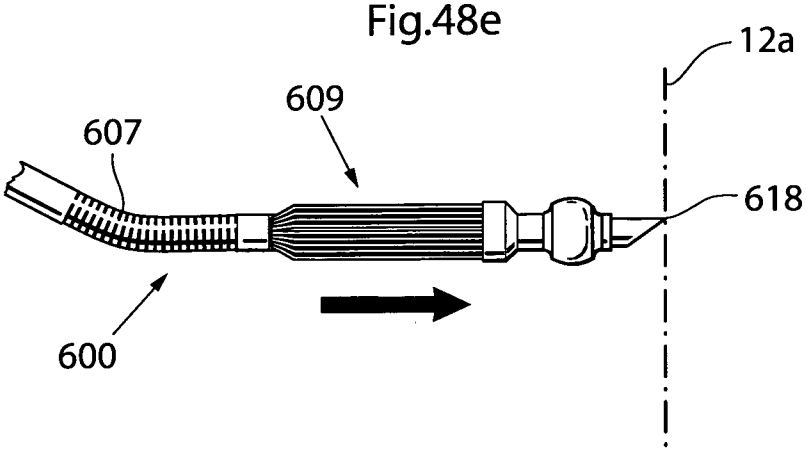


Fig.48f

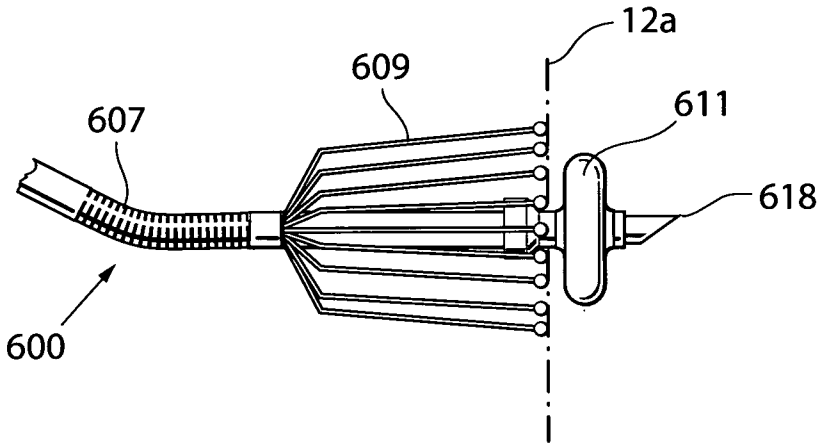


Fig.48g

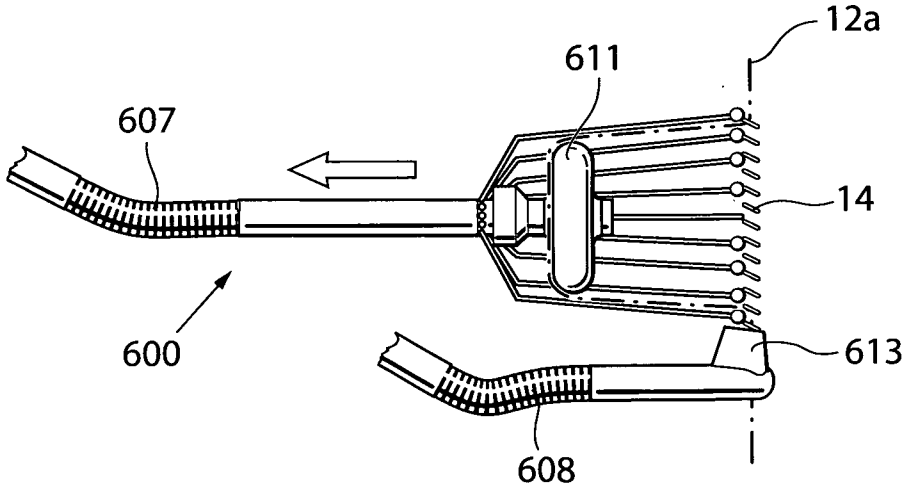


Fig.48h

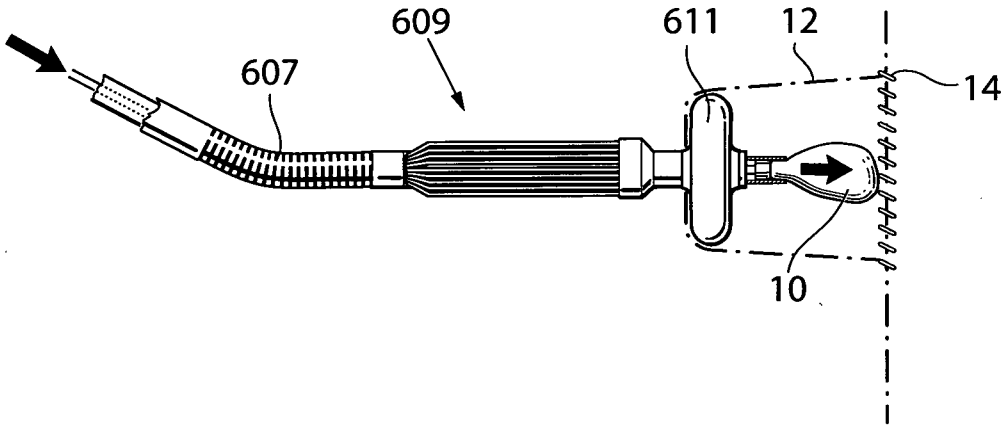


Fig.48i

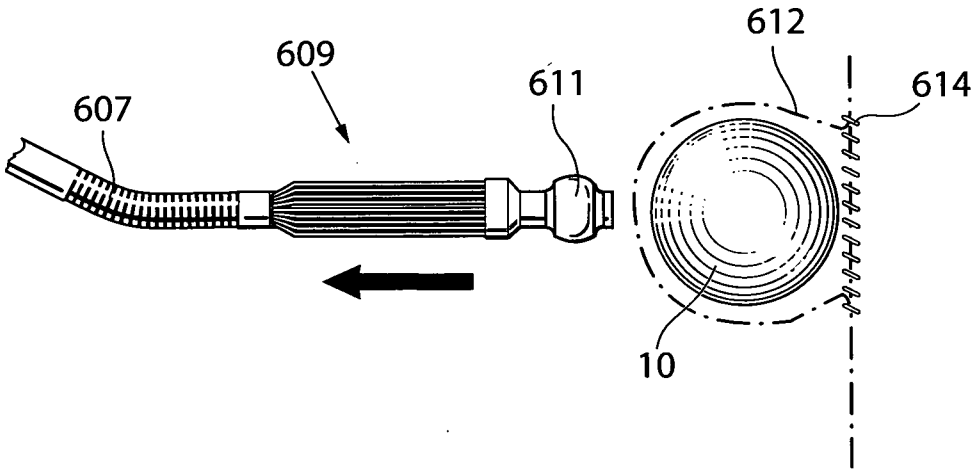


Fig.49

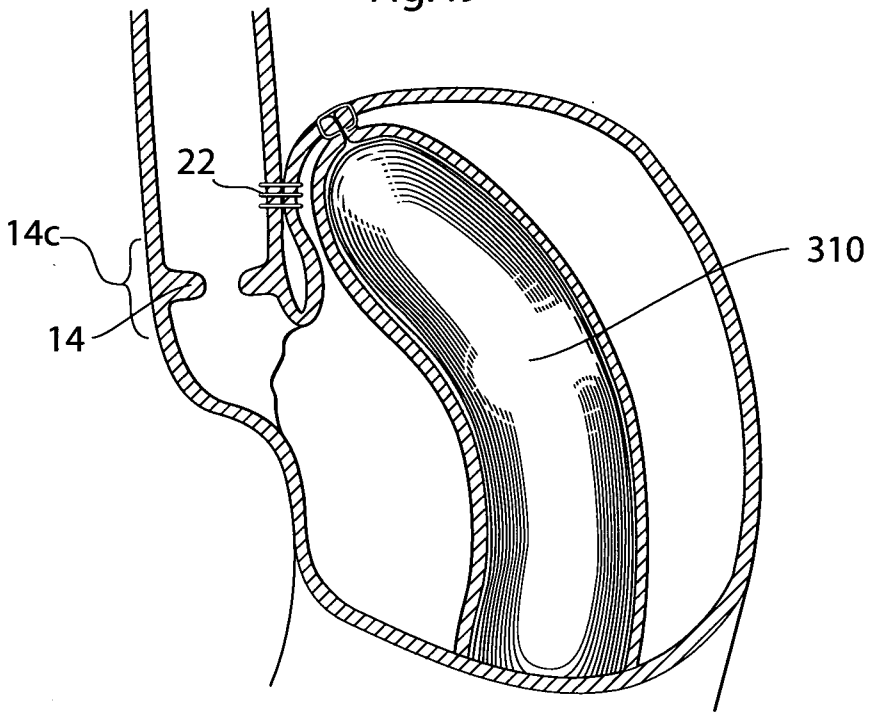


Fig.50

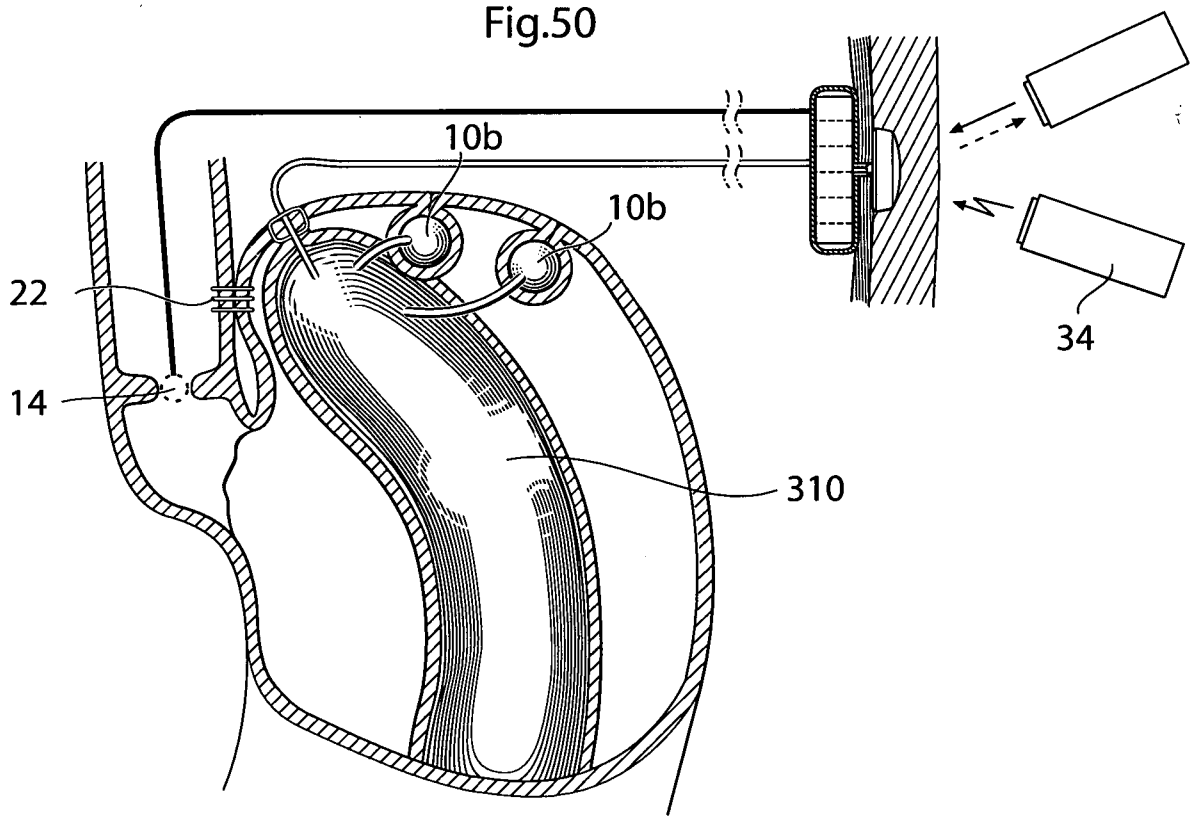


Fig.51

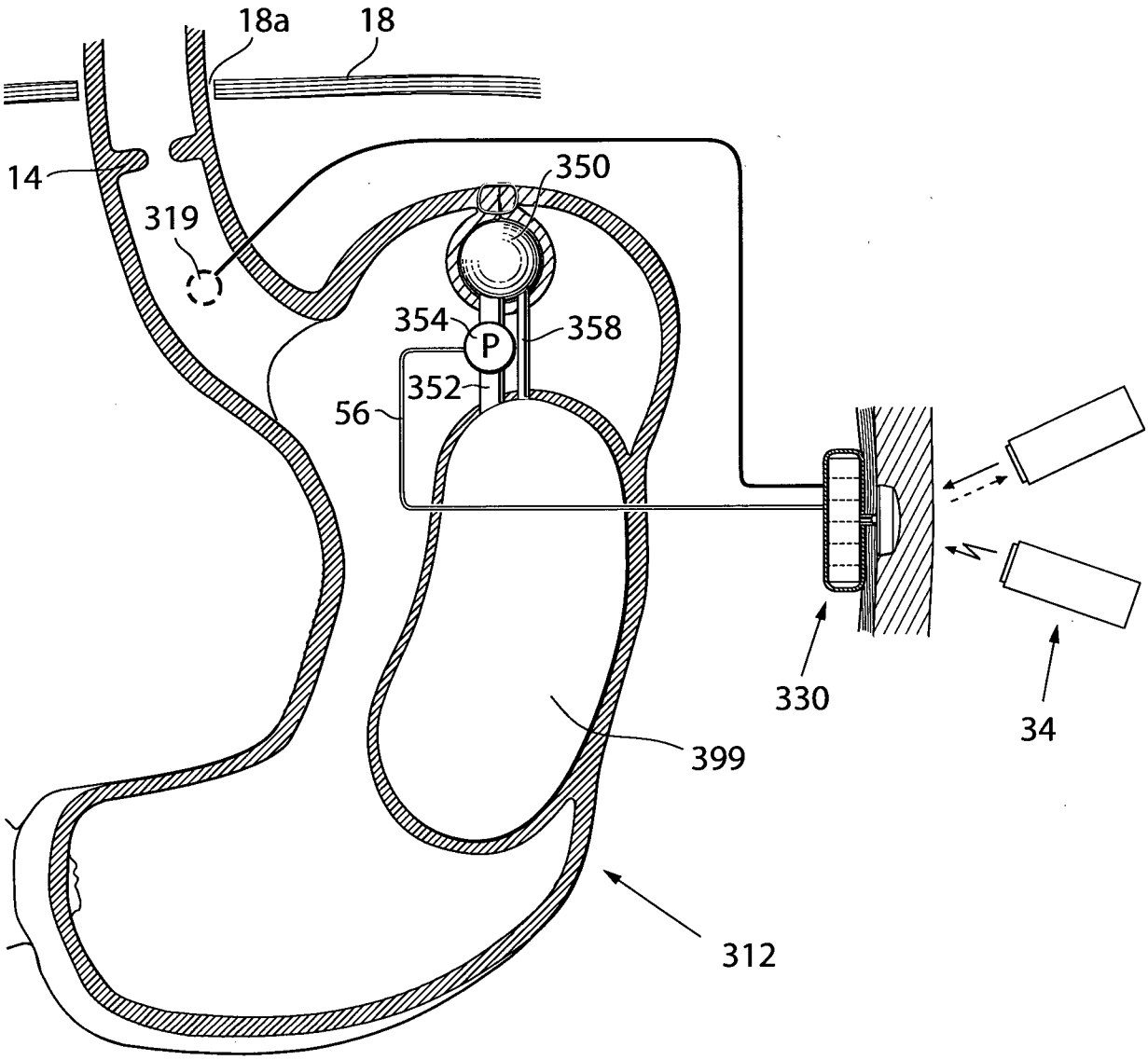


Fig.51b

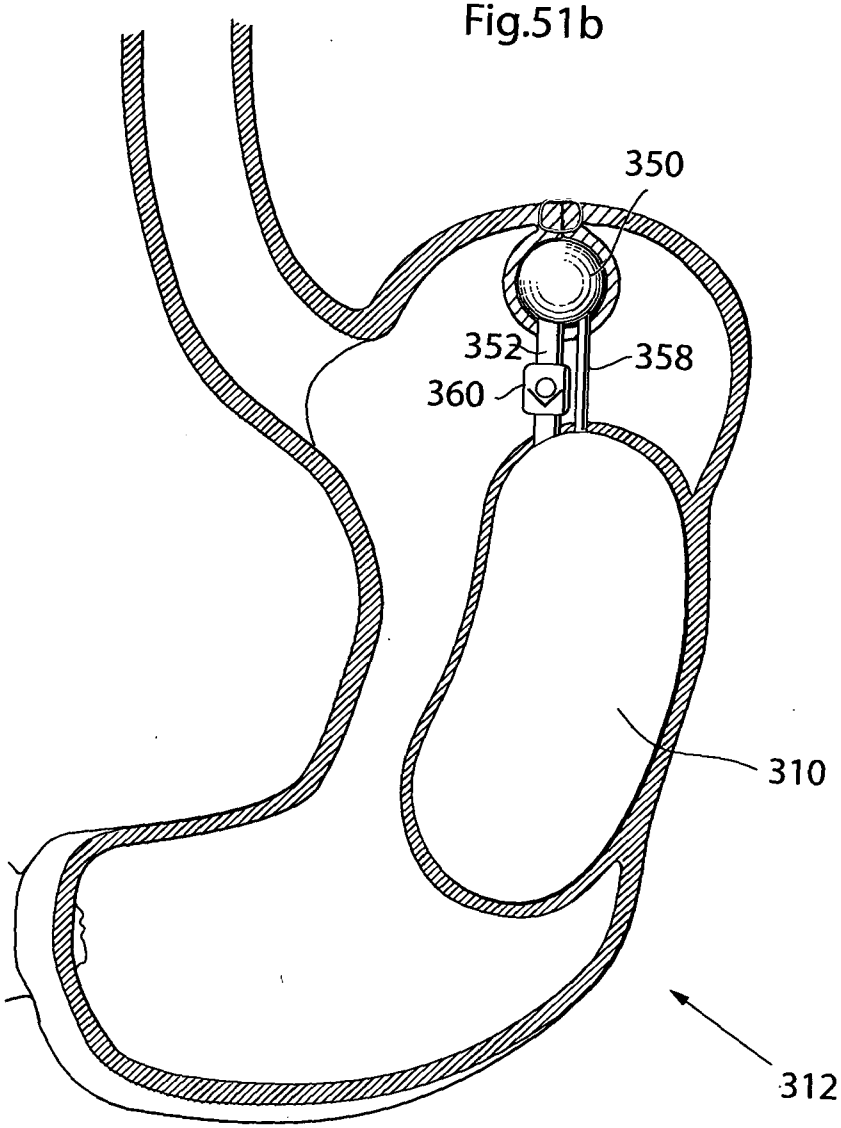


Fig.51c

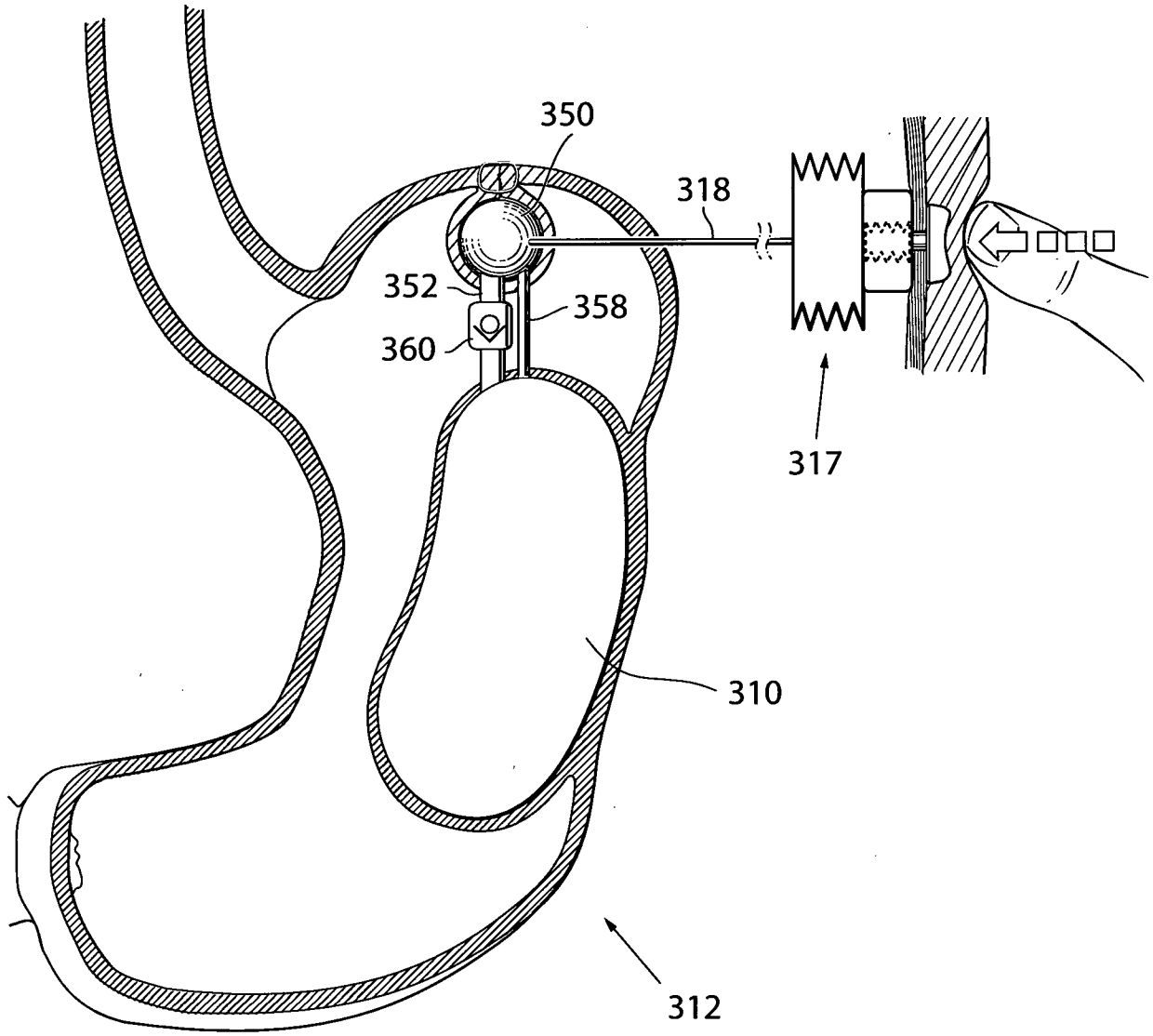


Fig.51-3a

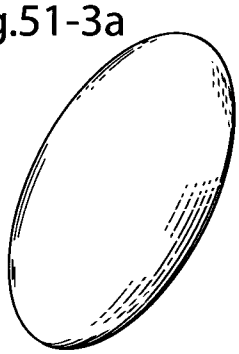


Fig.51-3b

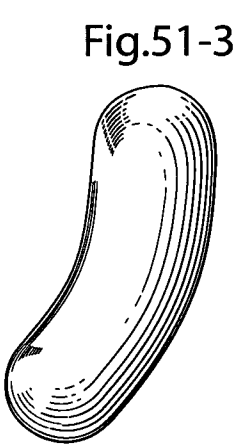


Fig.51-3c

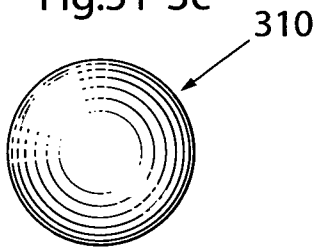


Fig.51-3d

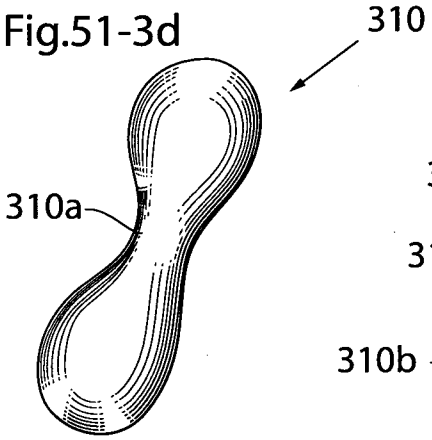


Fig.51-3e

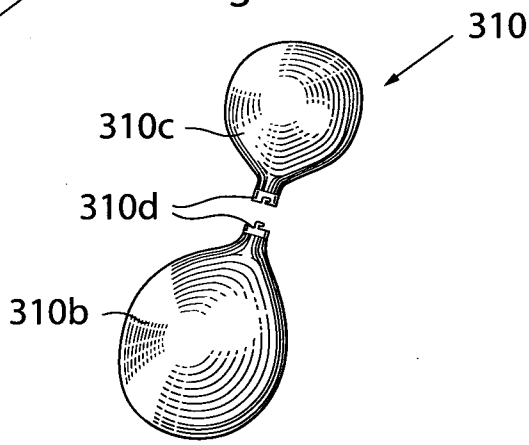


Fig.51-3f

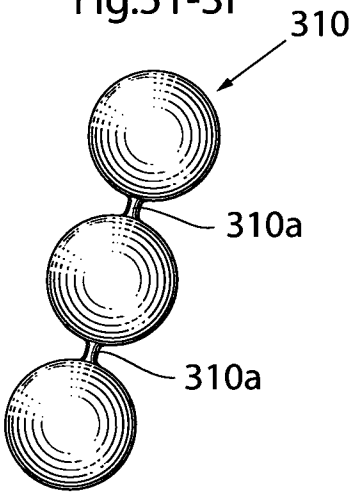


Fig.51-3g

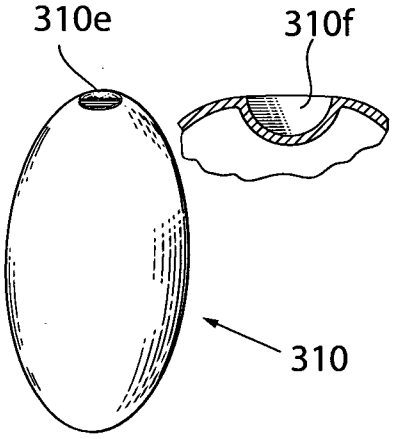


Fig.51-3h

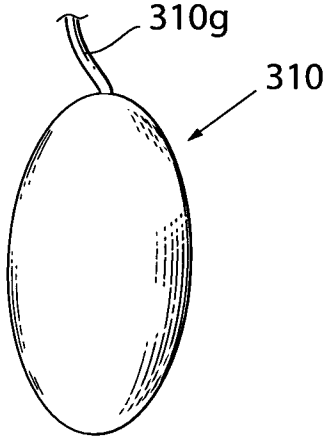


Fig.51-3i

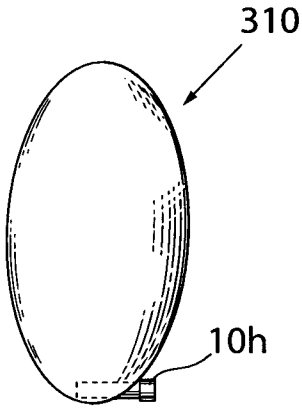


Fig.52a

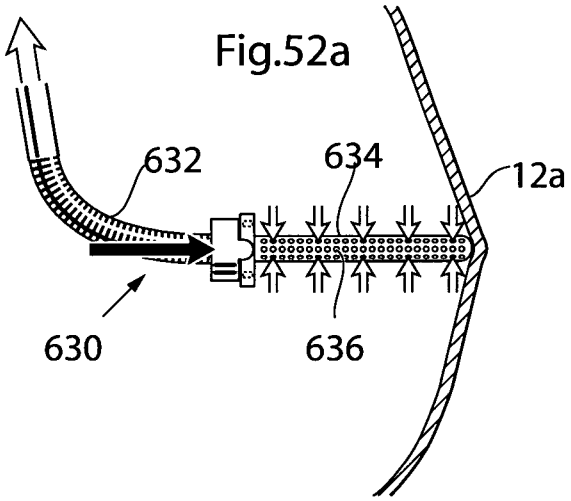


Fig.52b

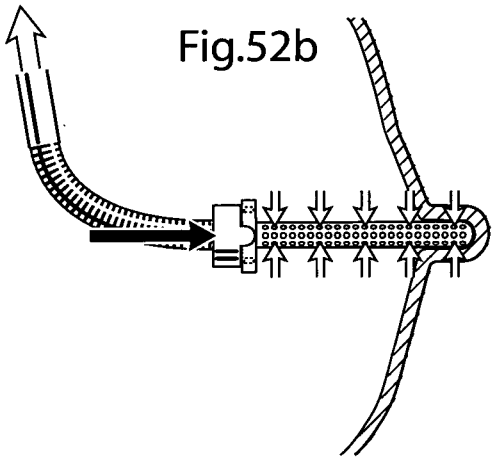


Fig.52c

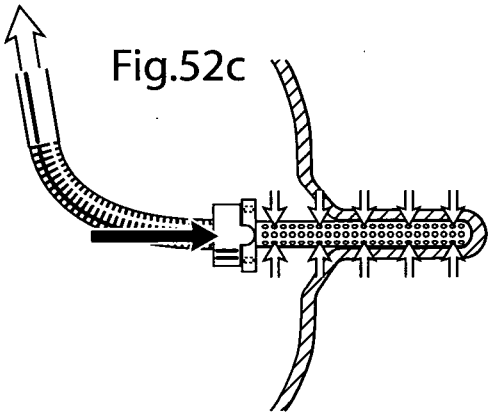


Fig.52d

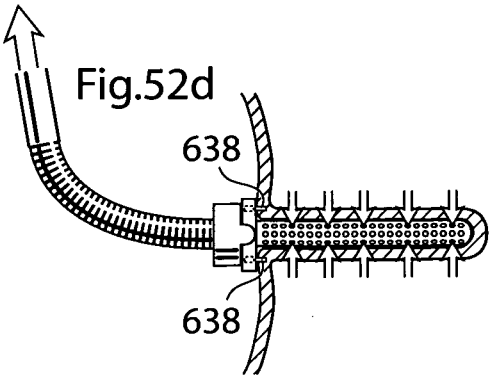


Fig.52e

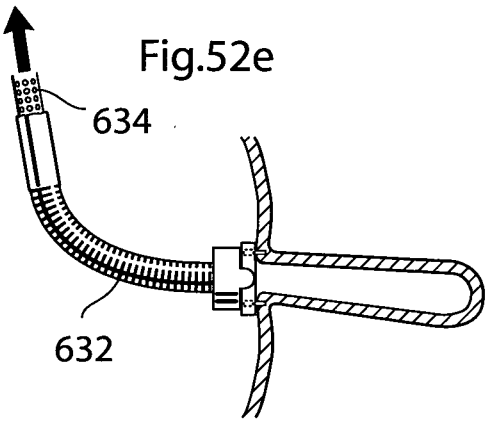


Fig.52f

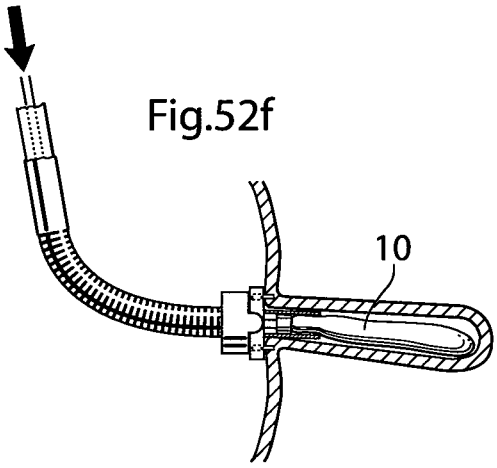


Fig.52g

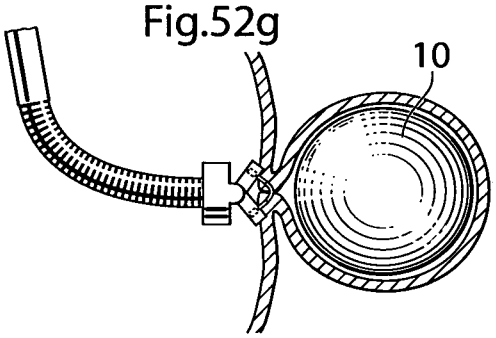


Fig.52h

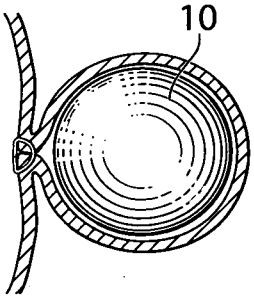


Fig. 53a

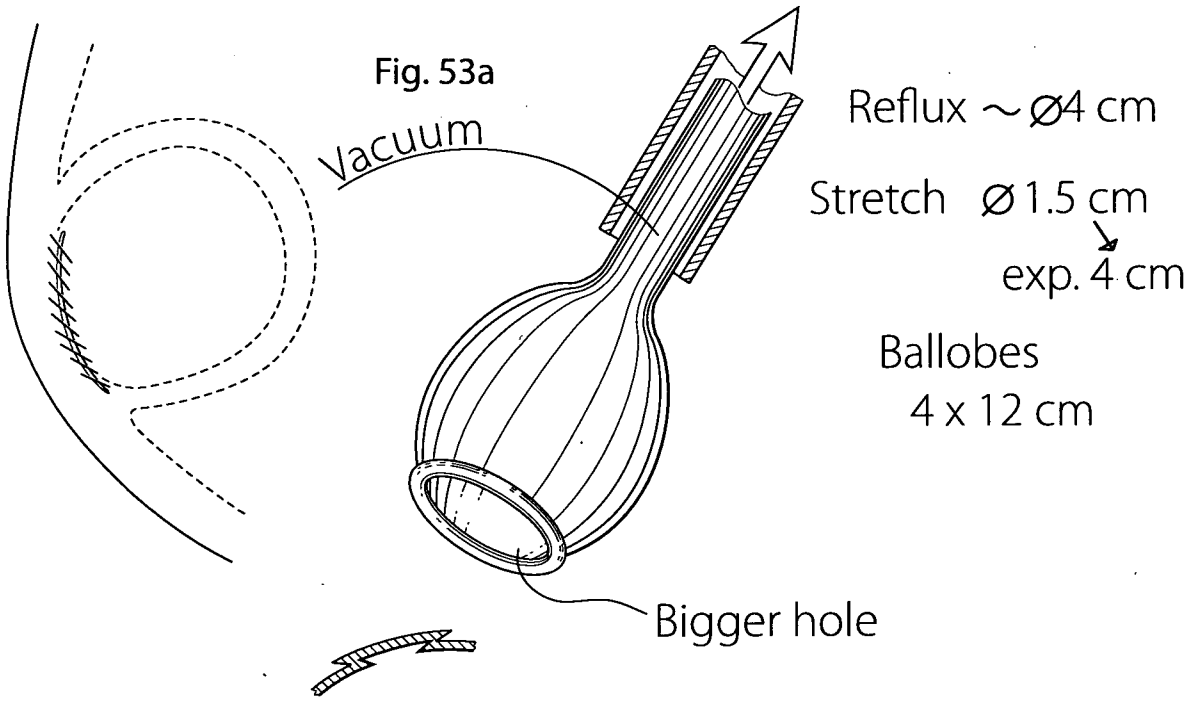


Fig. 53b

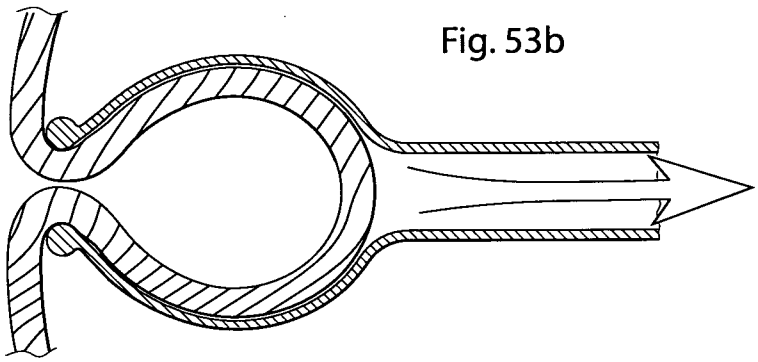


Fig. 53c

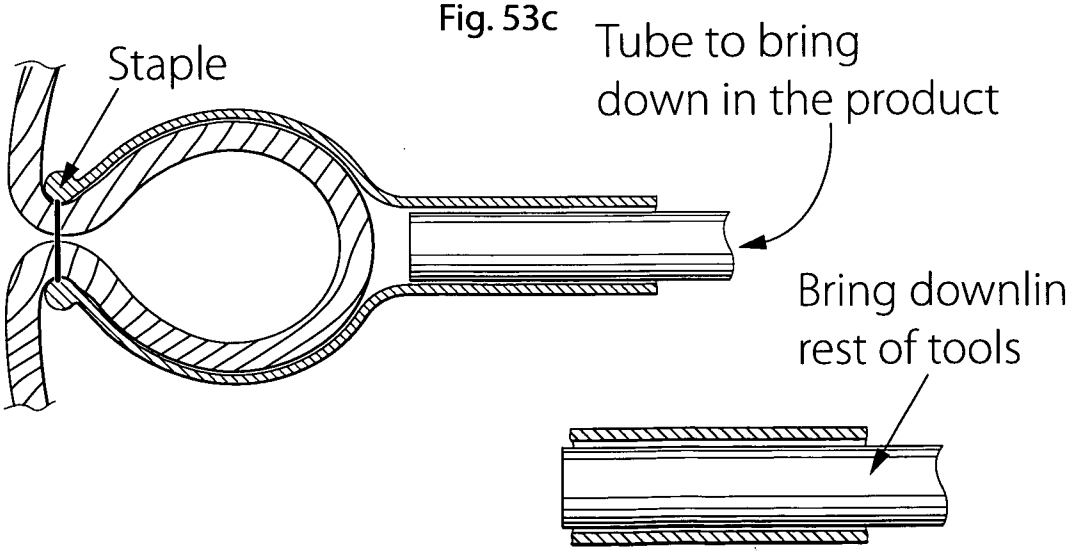


Fig.54

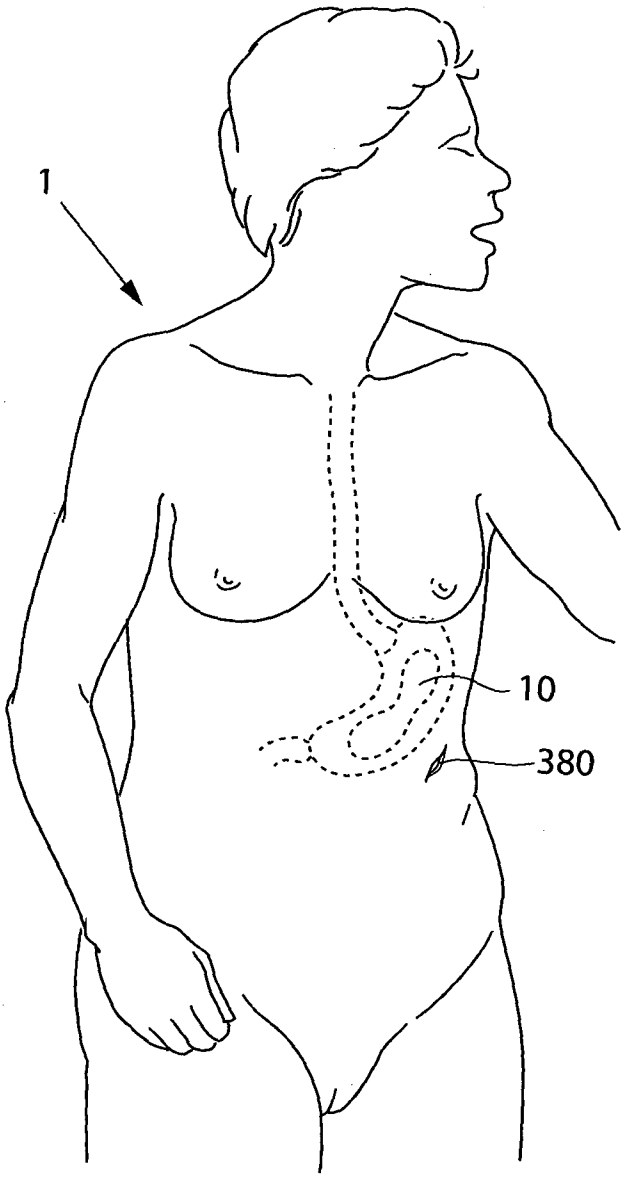


Fig.55

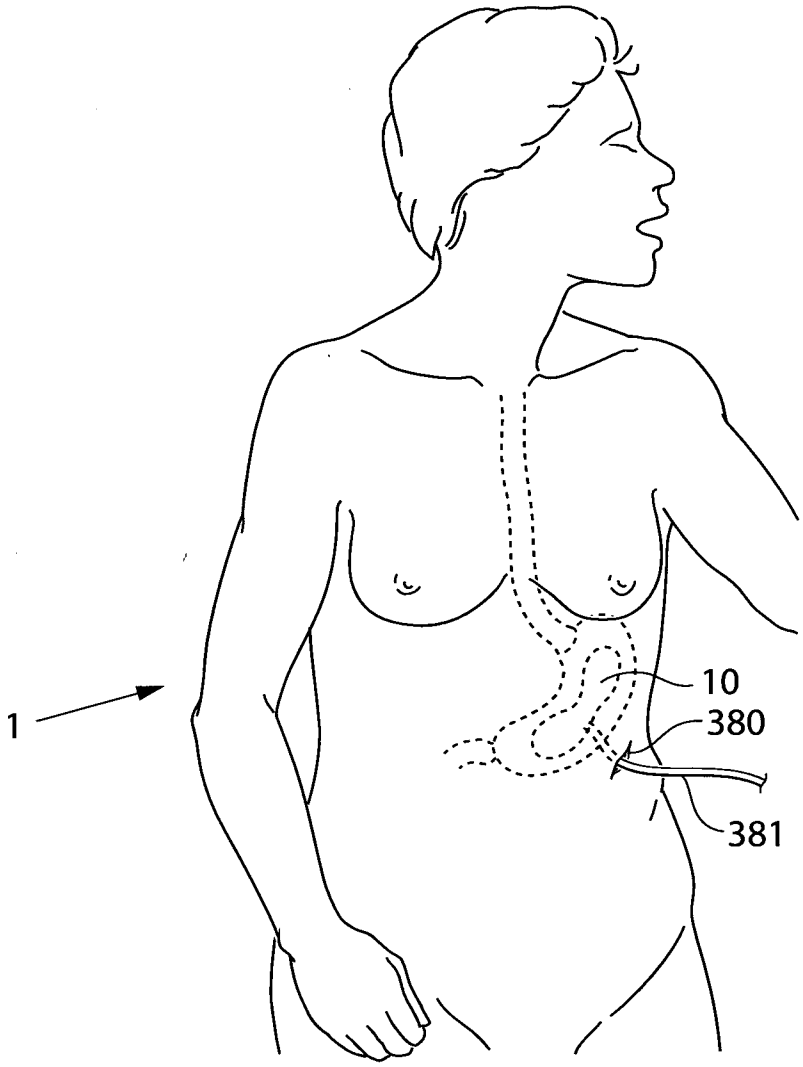


Fig.56

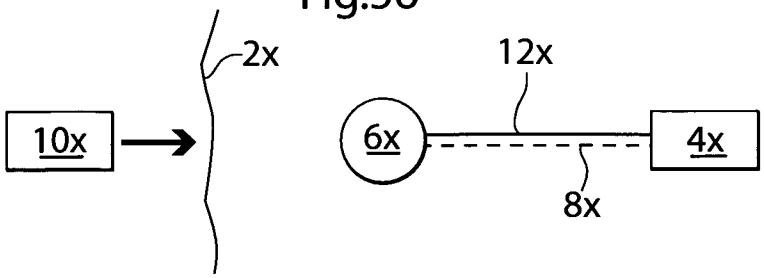


Fig.57

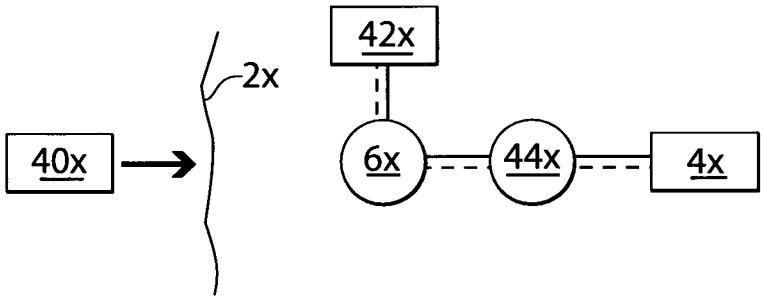


Fig.58

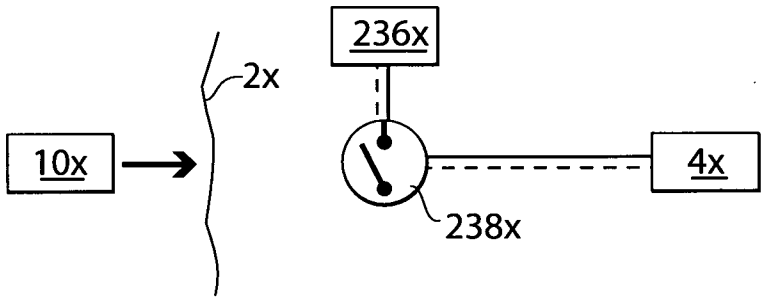


Fig.59

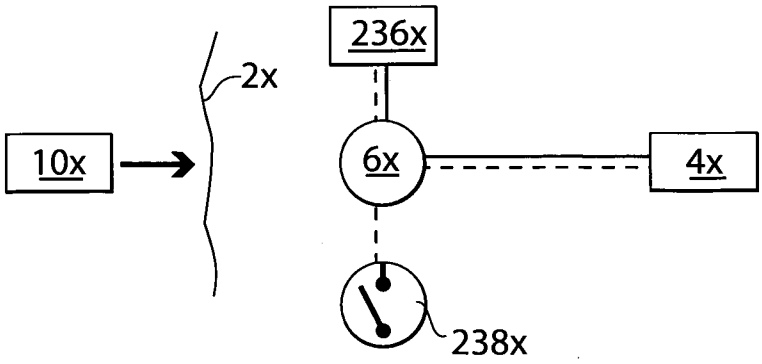


Fig.60

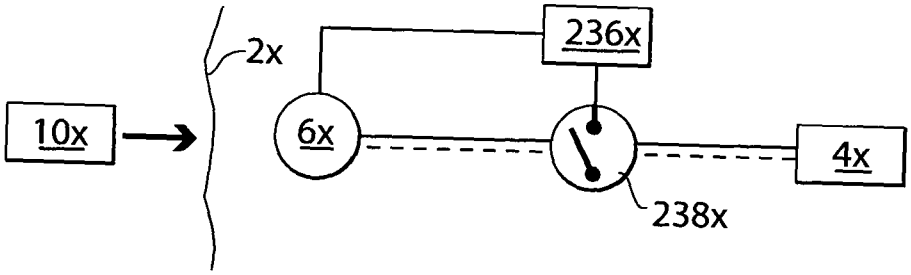


Fig.61

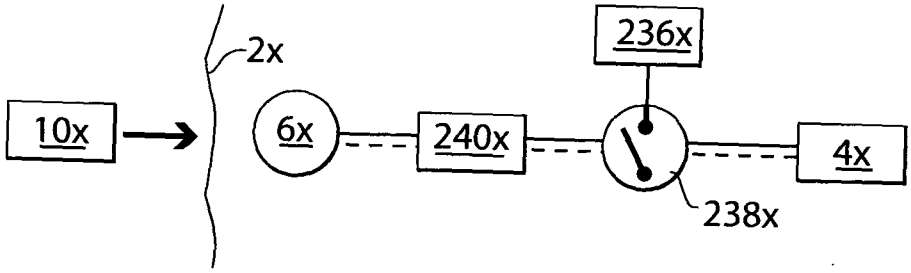


Fig.62

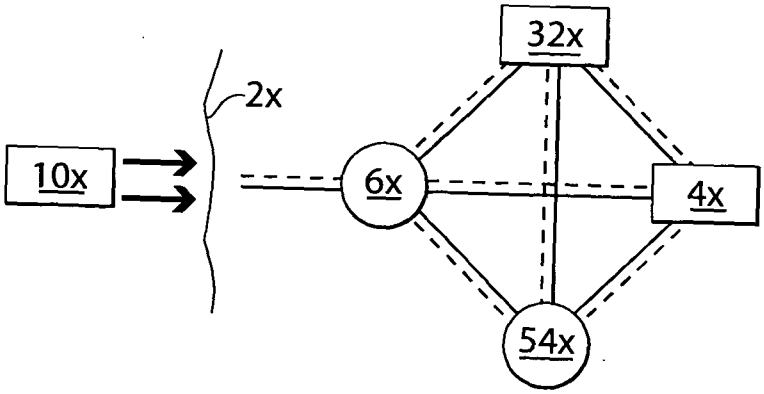


Fig.63

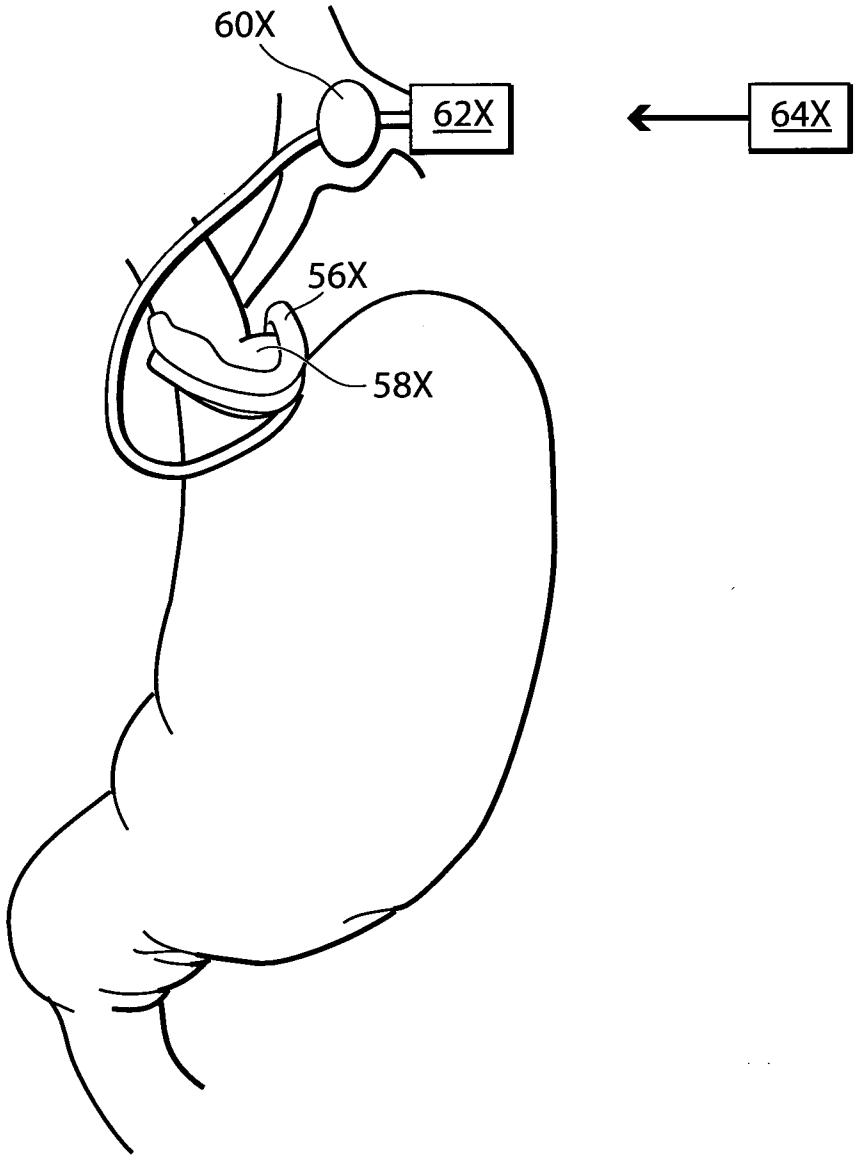


Fig.64

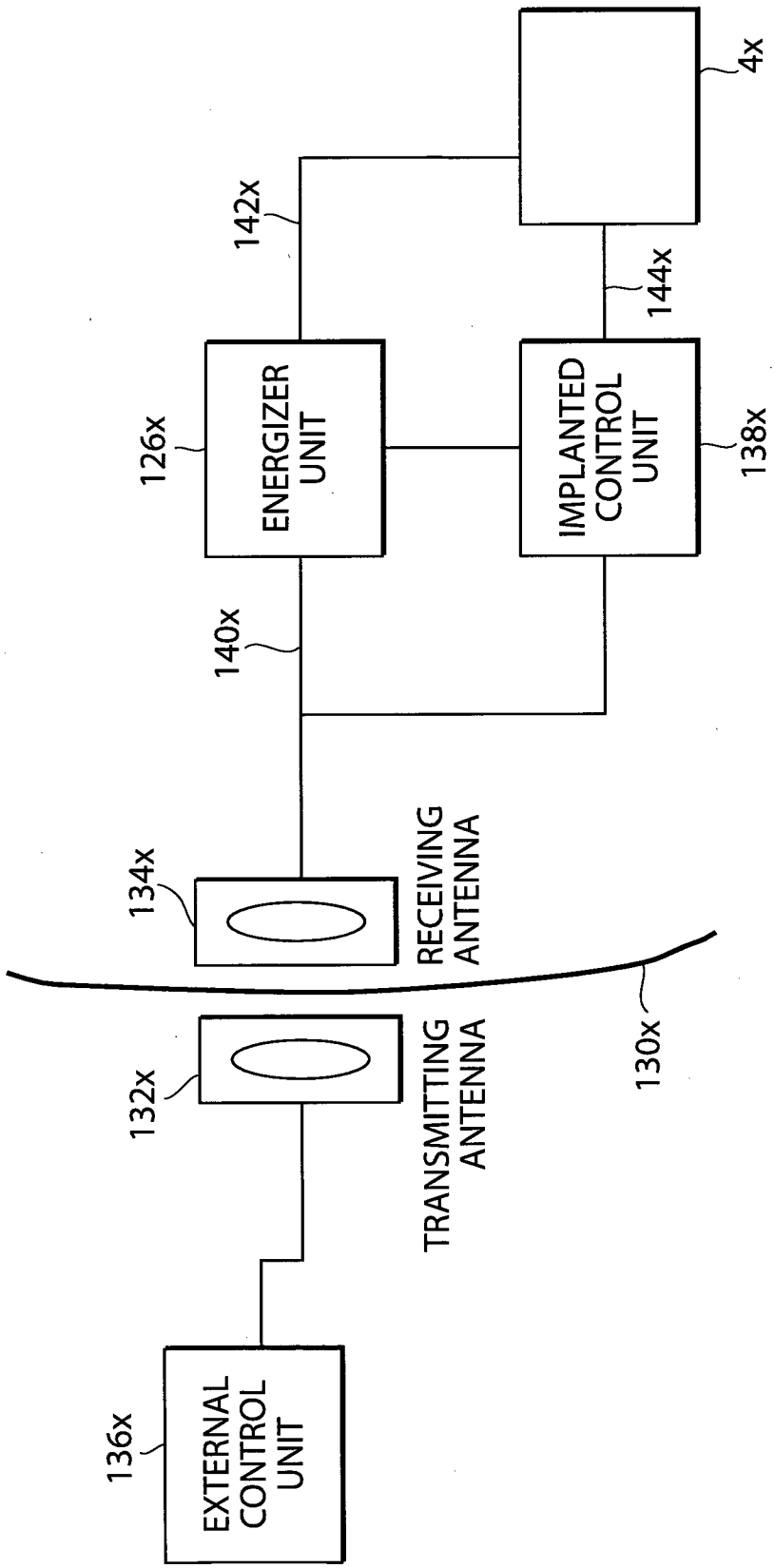

4x
142x
144x
126x
ENERGIZER UNIT
IMPLANTED CONTROL UNIT
138x
140x
134x
RECEIVING ANTENNA
130x
132x
TRANSMITTING ANTENNA
136x
EXTERNAL CONTROL UNIT

Fig.65

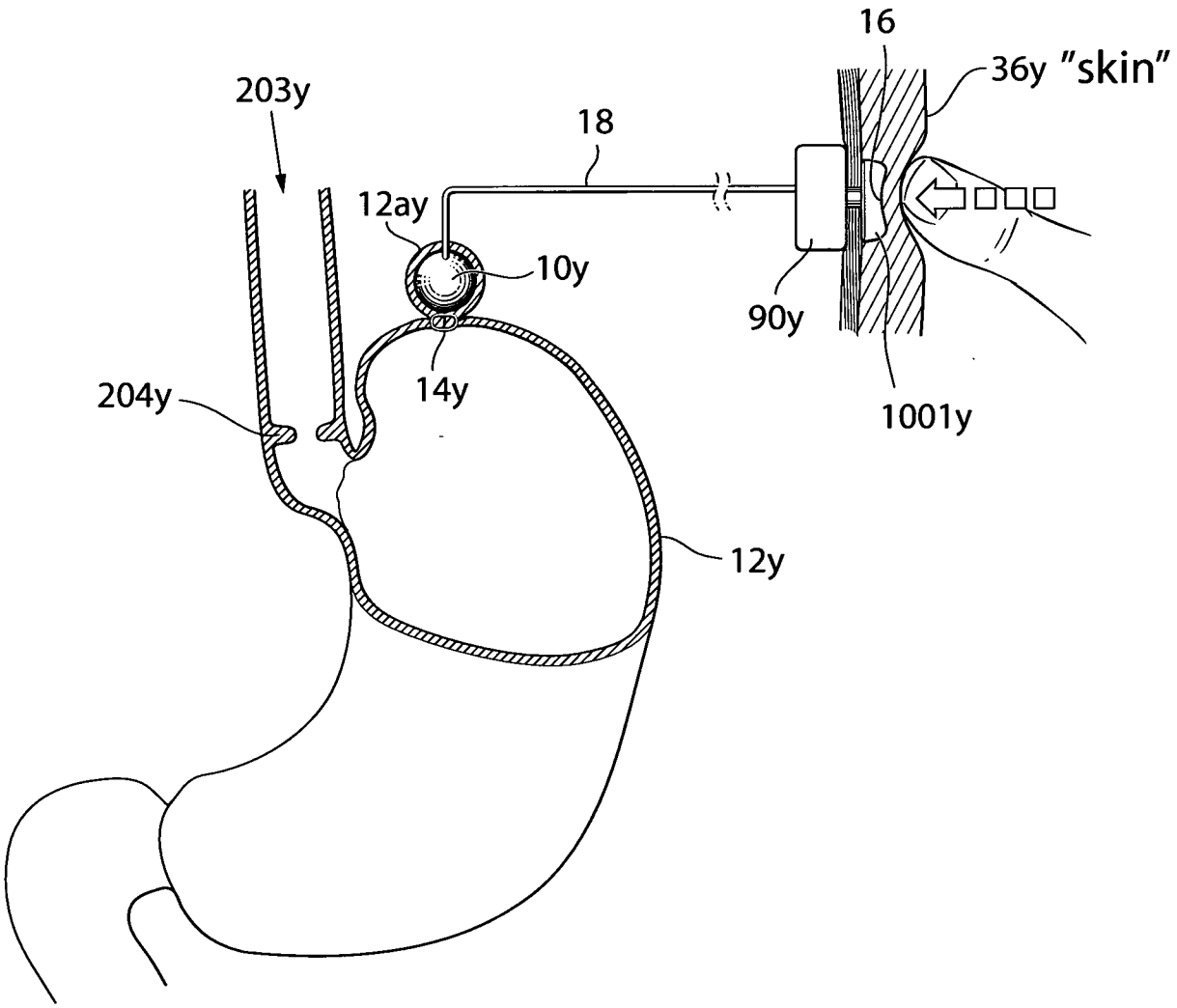


Fig.66a

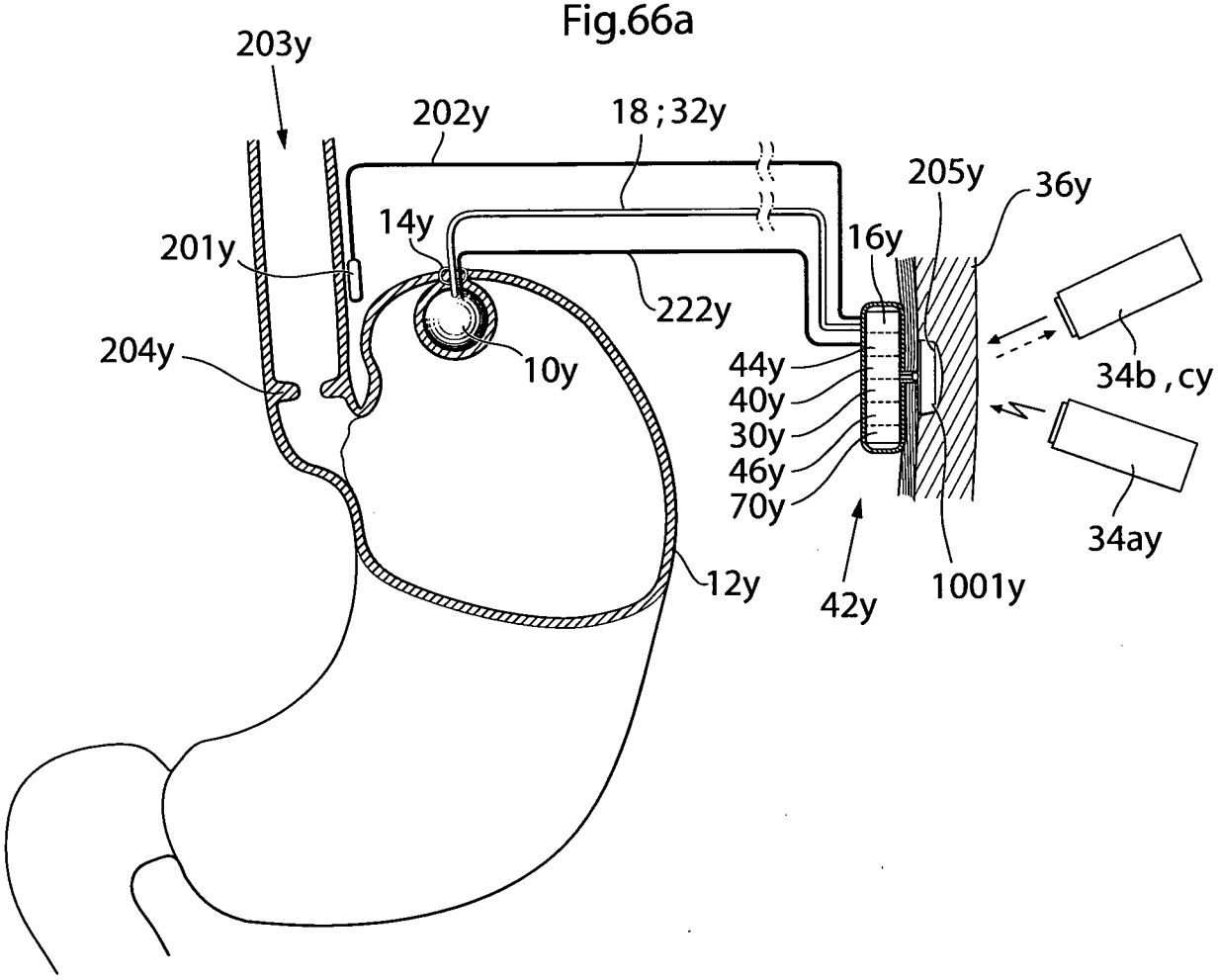


Fig.66b

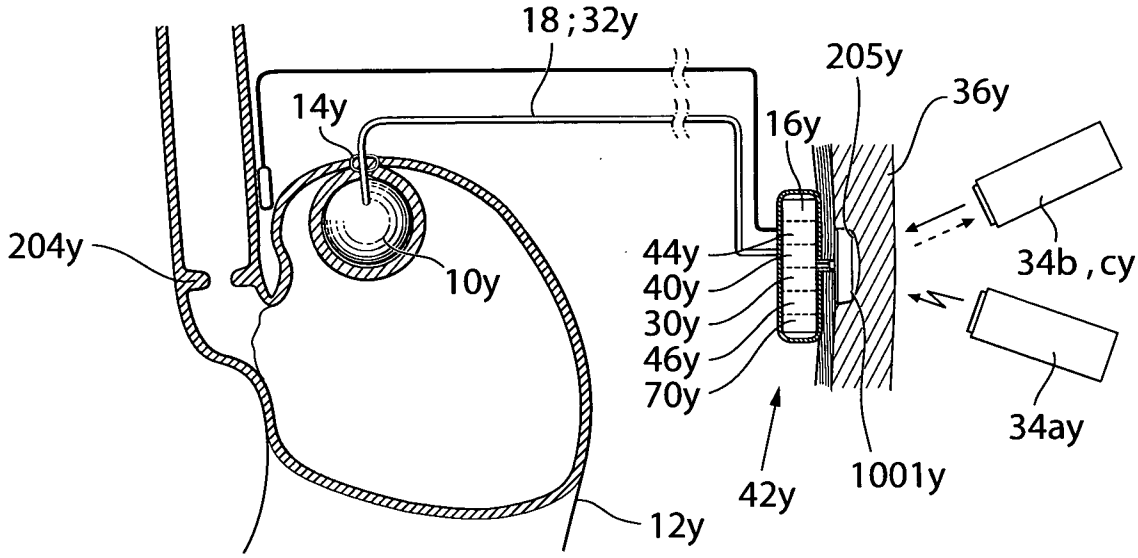


Fig.67a

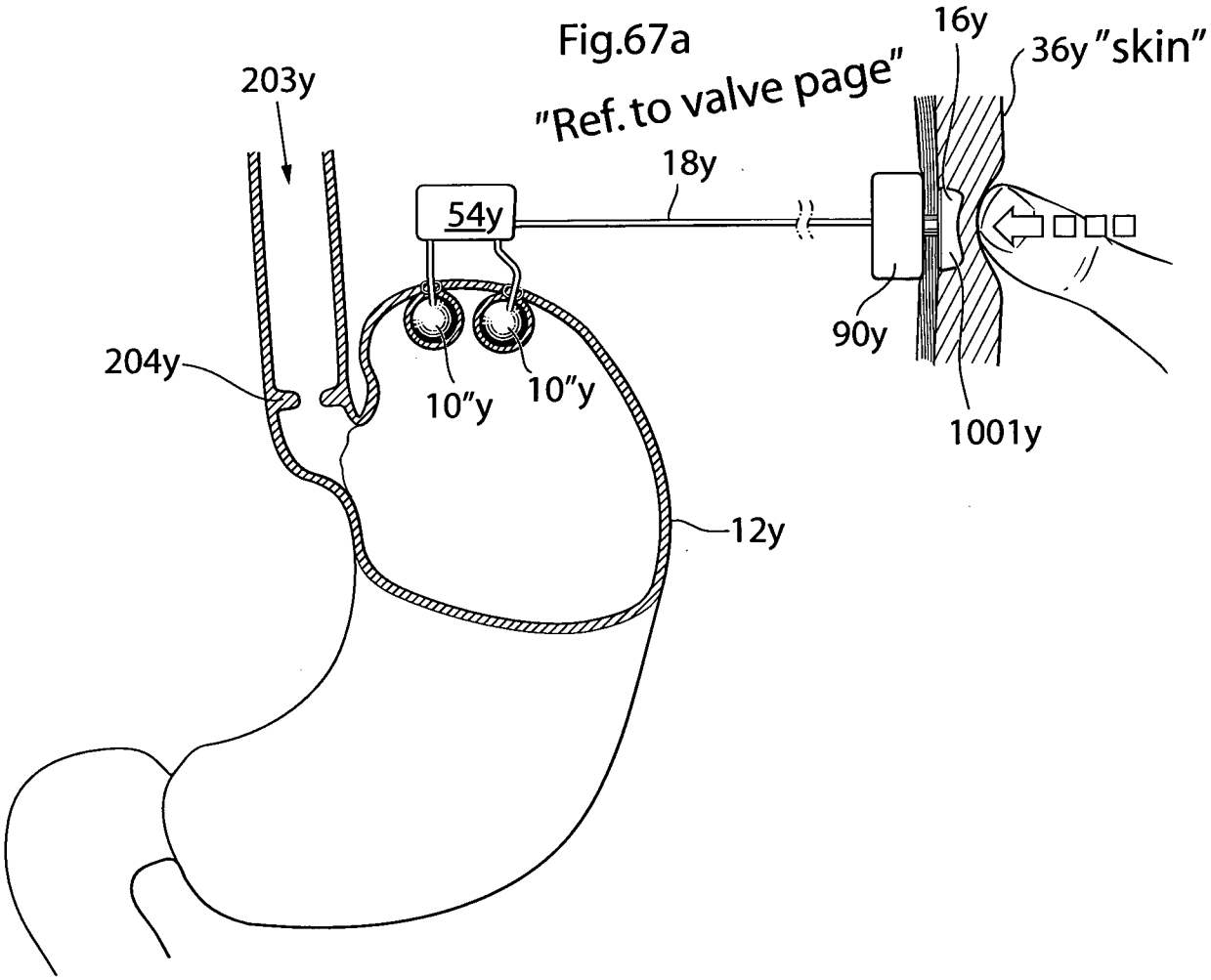


Fig.67b

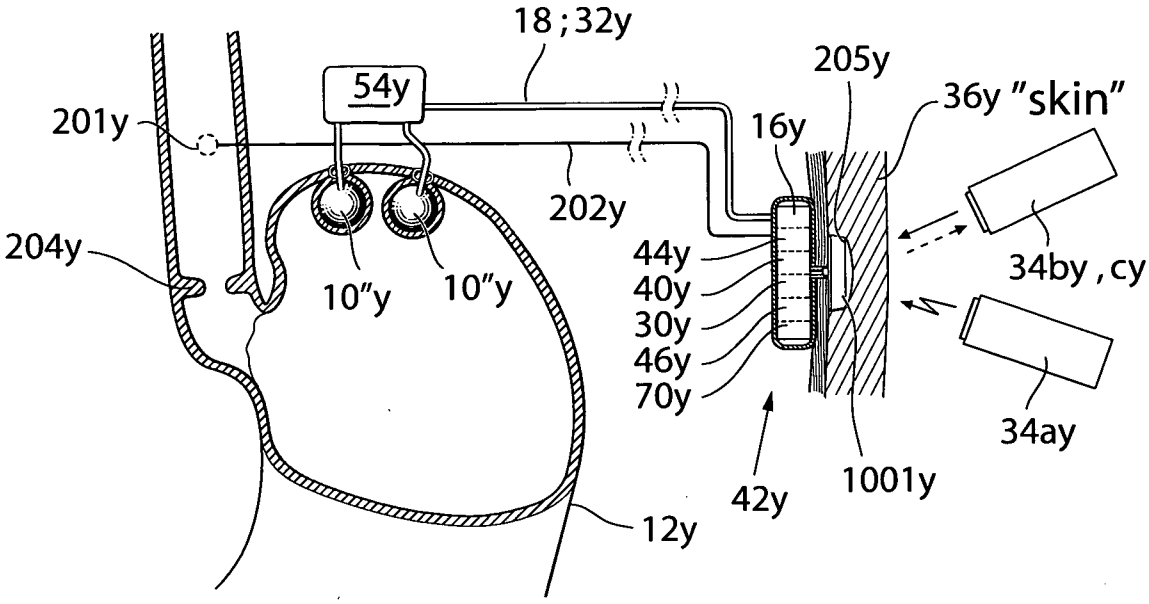


Fig.68a

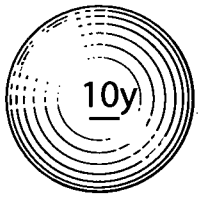


Fig.68e

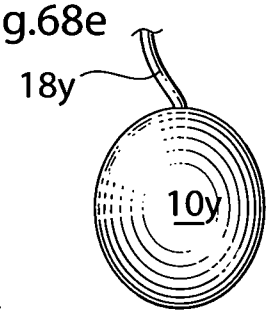


Fig.68b

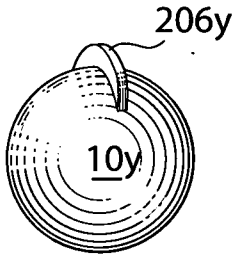


Fig.68f

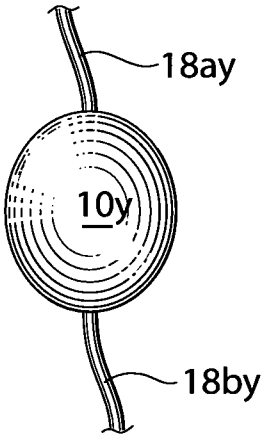


Fig.68g

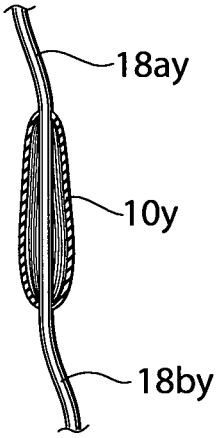


Fig.68c

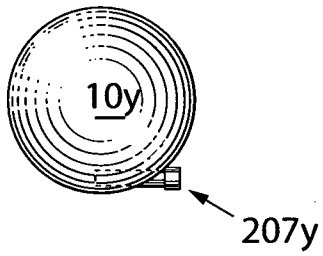


Fig.68h

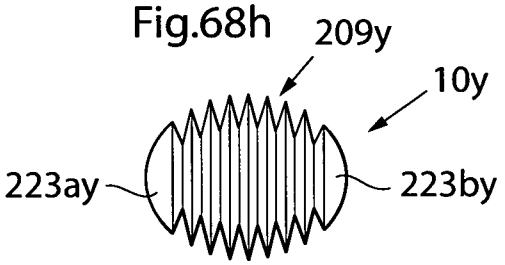


Fig.68d

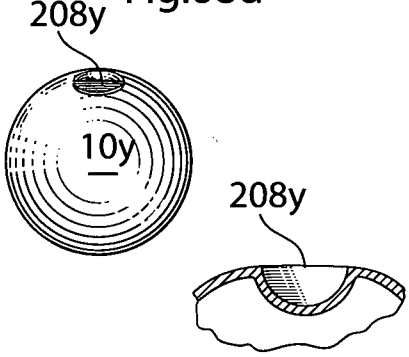


Fig.68i

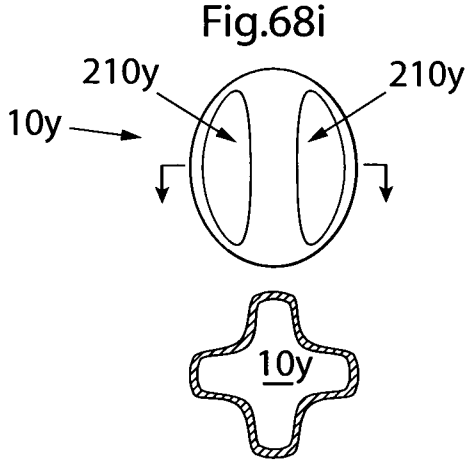


Fig.69a

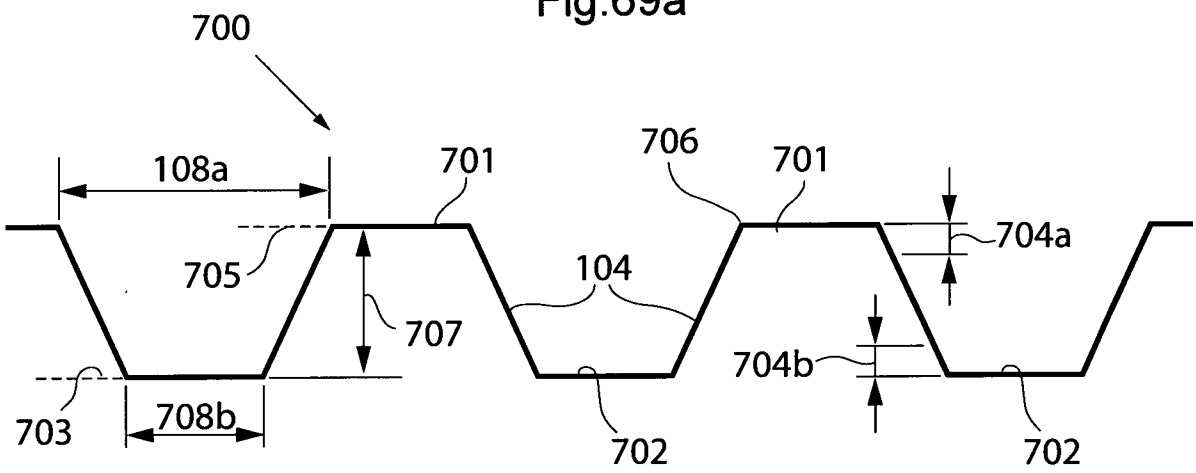


Fig.69b

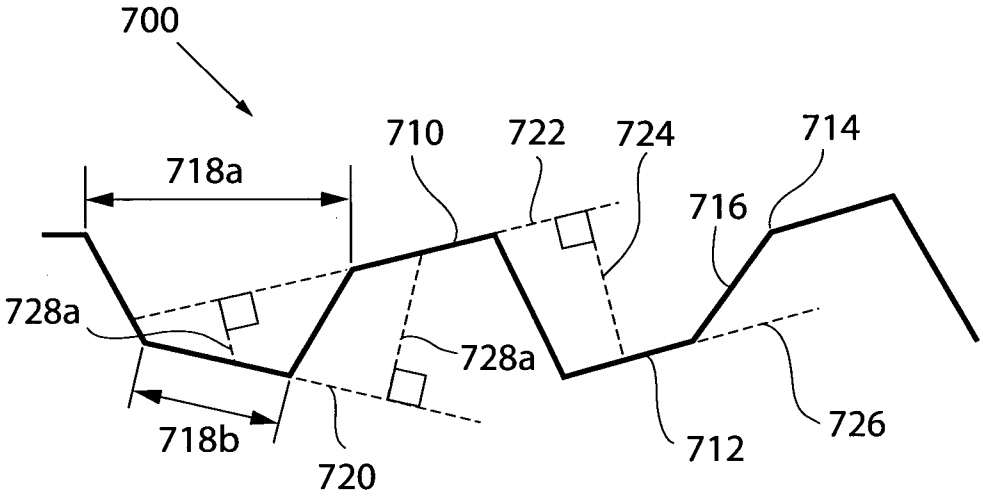


Fig.69c

Fig.69d

Fig.69e

Fig.69f

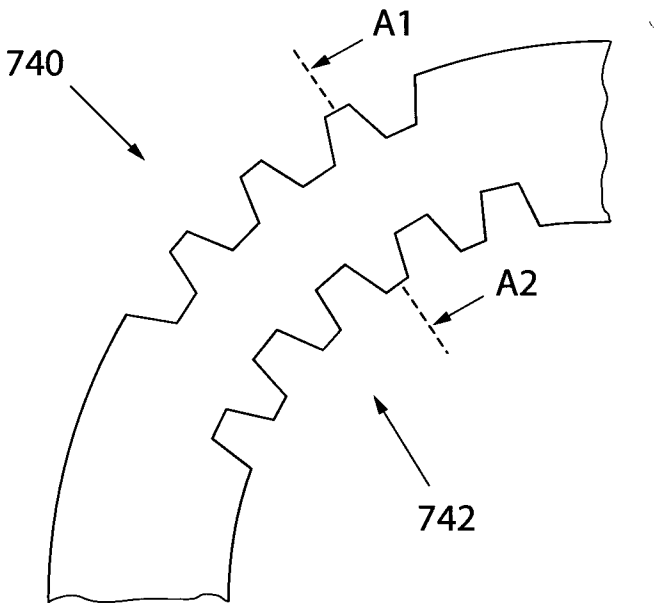


Fig.69g

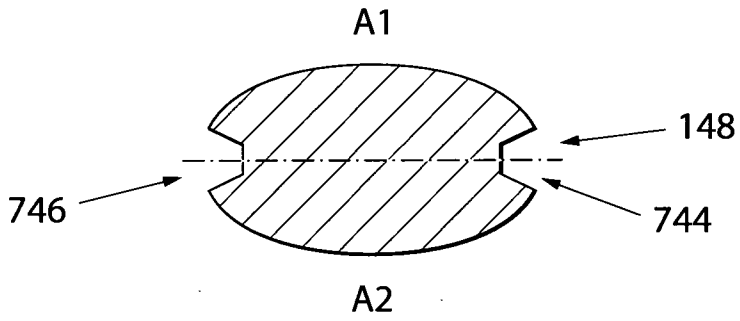


Fig.69h

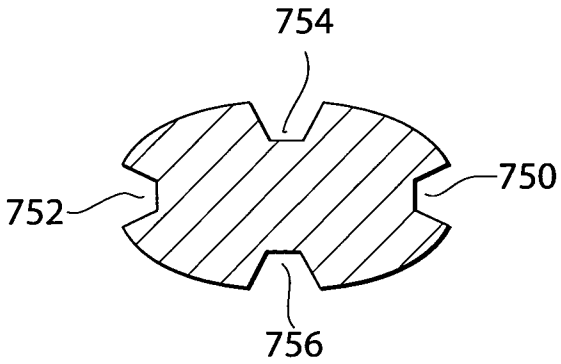


Fig.69i

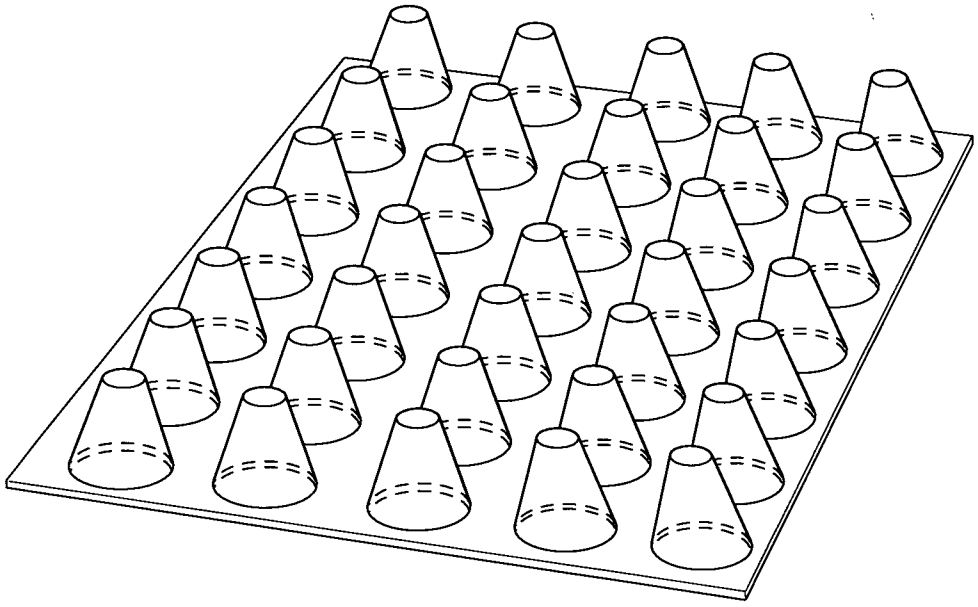


Fig.69j

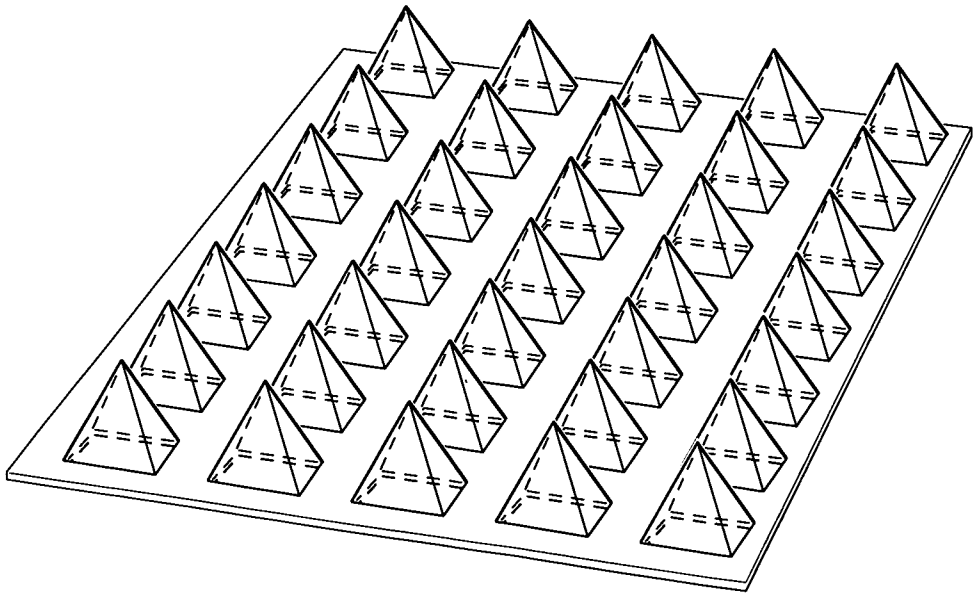


Fig.69k

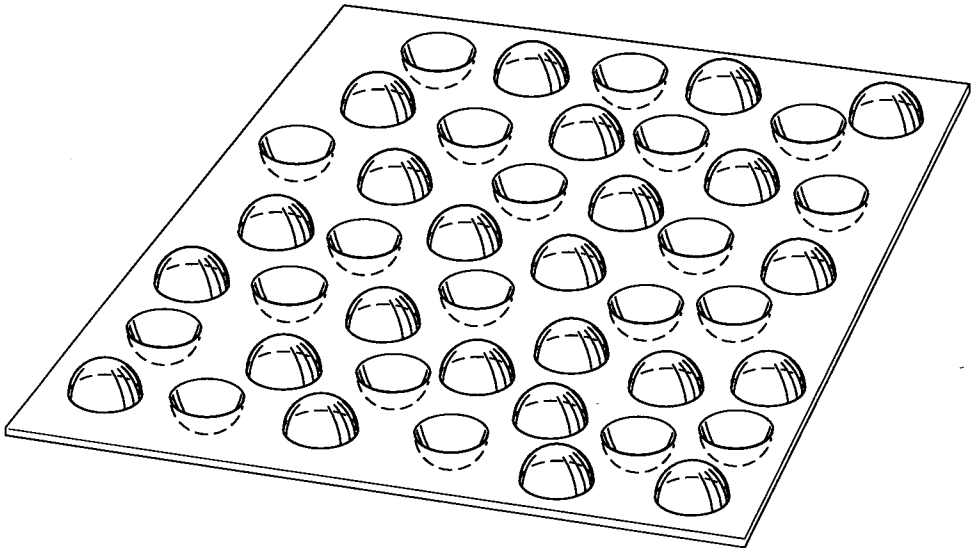


Fig.70a

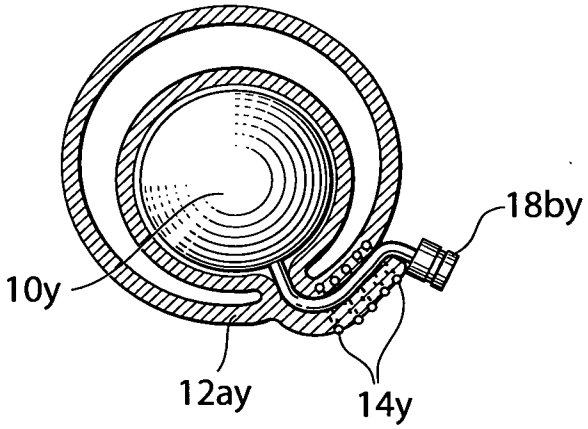


Fig.70b

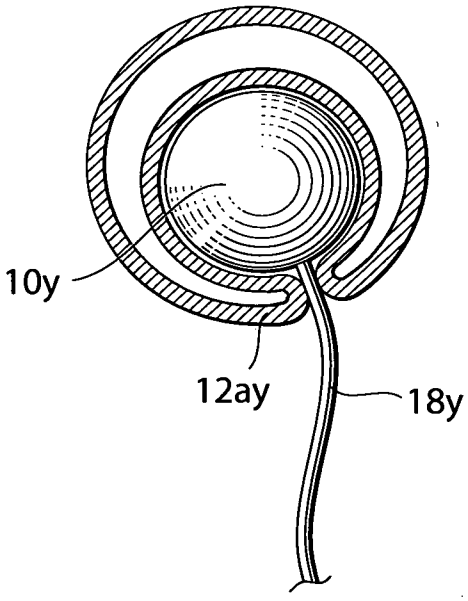


Fig.70c

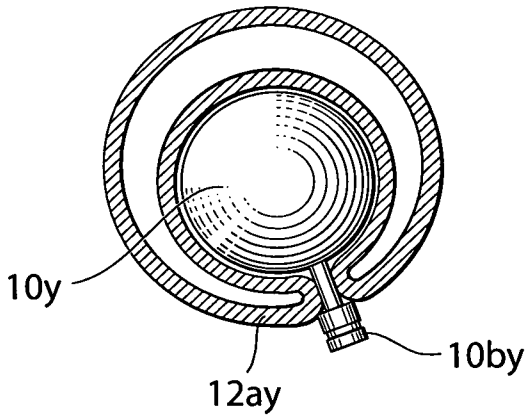


Fig.71

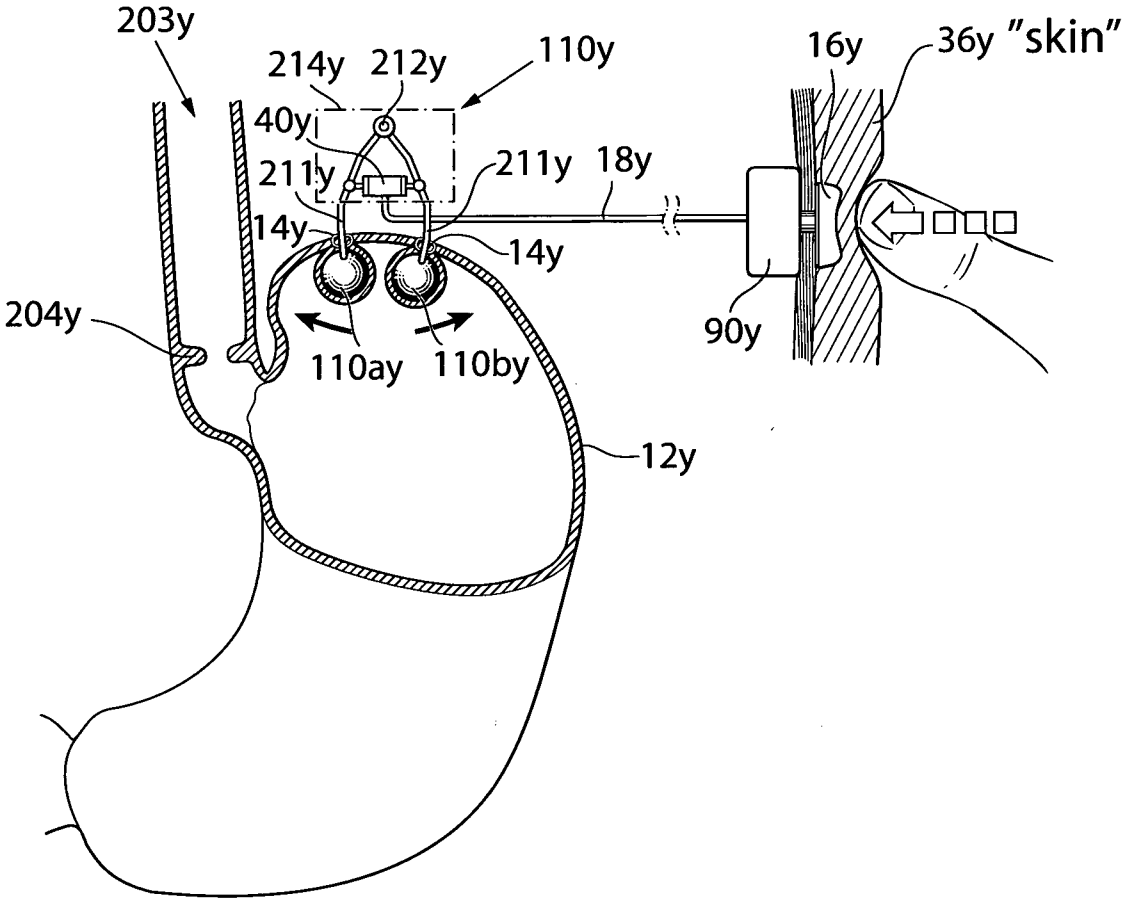

203y
214y
212y
110y
16y
36y "skin"
40y
211y
211y
18y
14y
14y
204y
110ay
110by
90y
12y

Fig.72

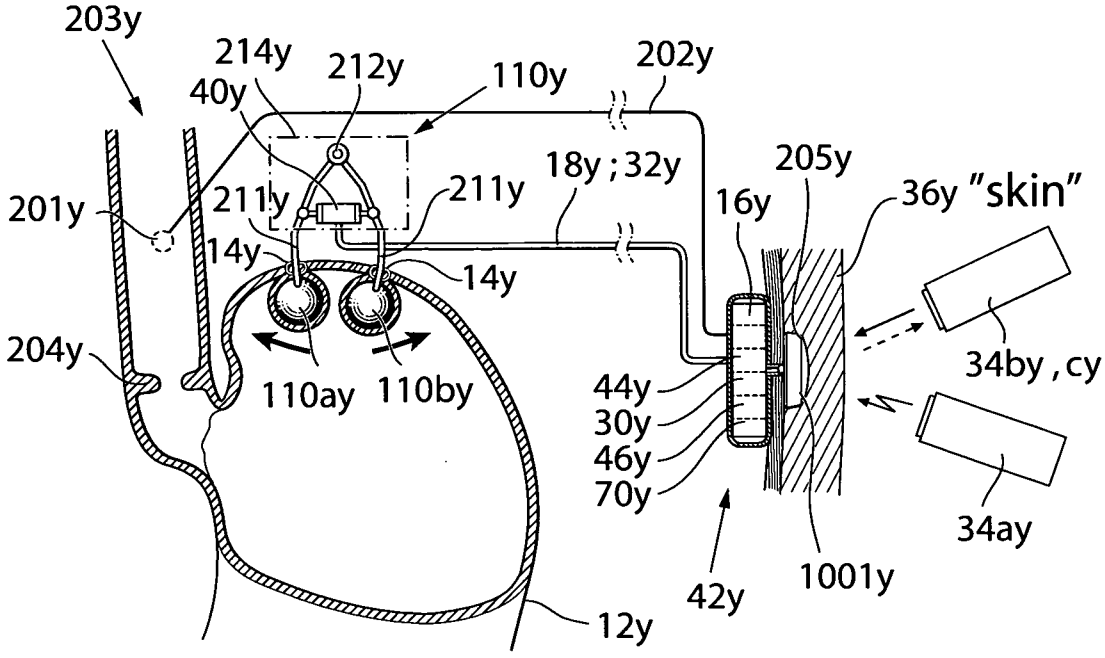

203y
214y
212y
110y
202y
40y
18y ; 32y
205y
16y
36y "skin"
201y
211y
211y
14y
14y
204y
110ay
110by
34by , cy
44y
30y
46y
70y
34ay
42y
1001y
12y

Fig.73a

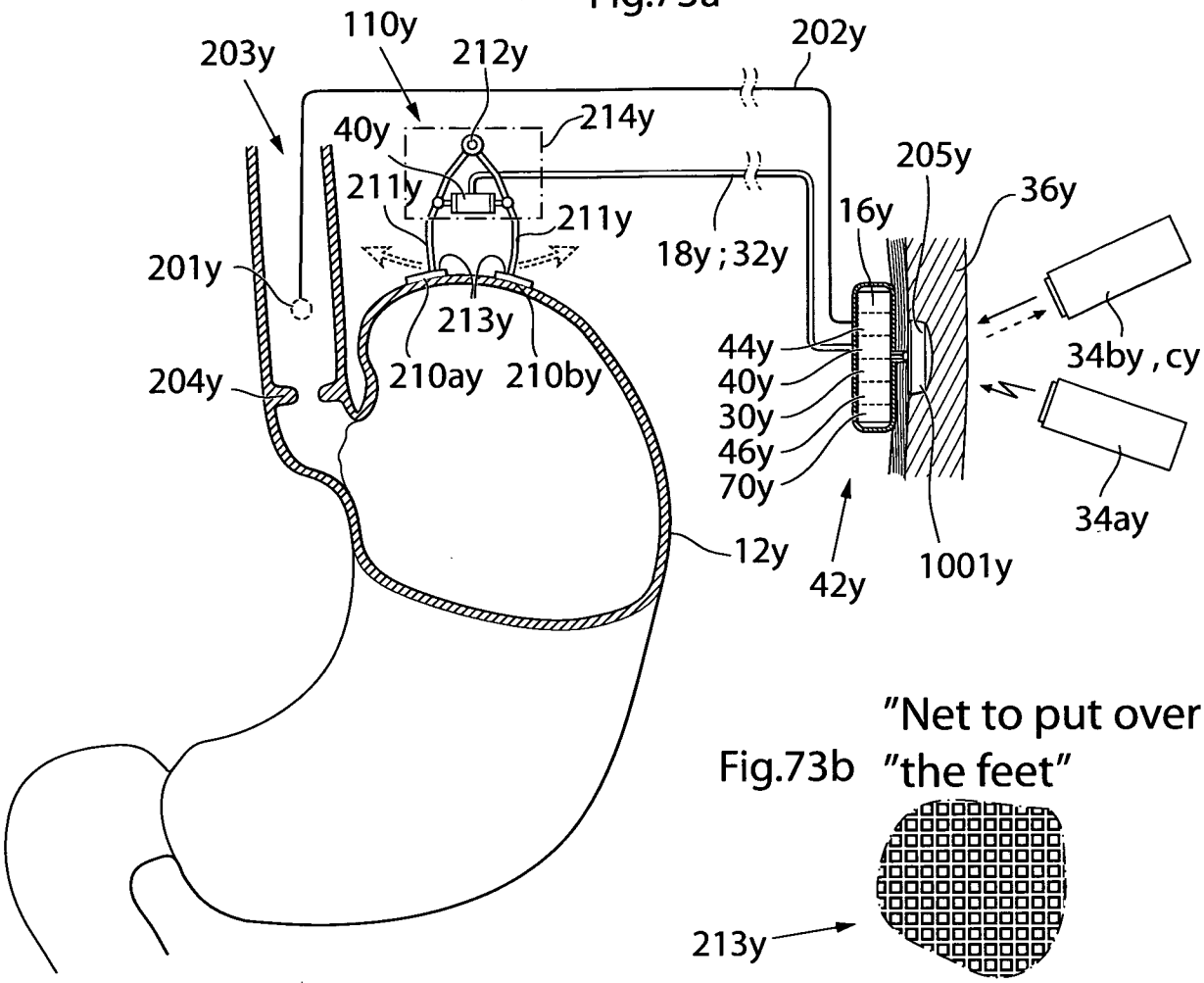
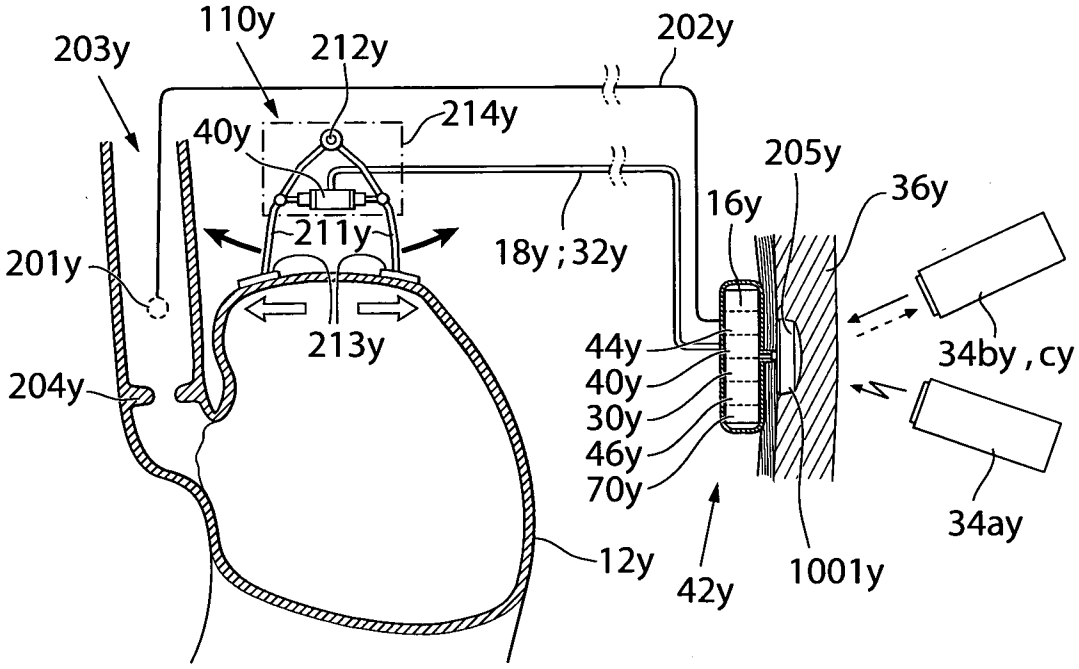


Fig.73b

"Net to put over "the feet"

Fig.73c



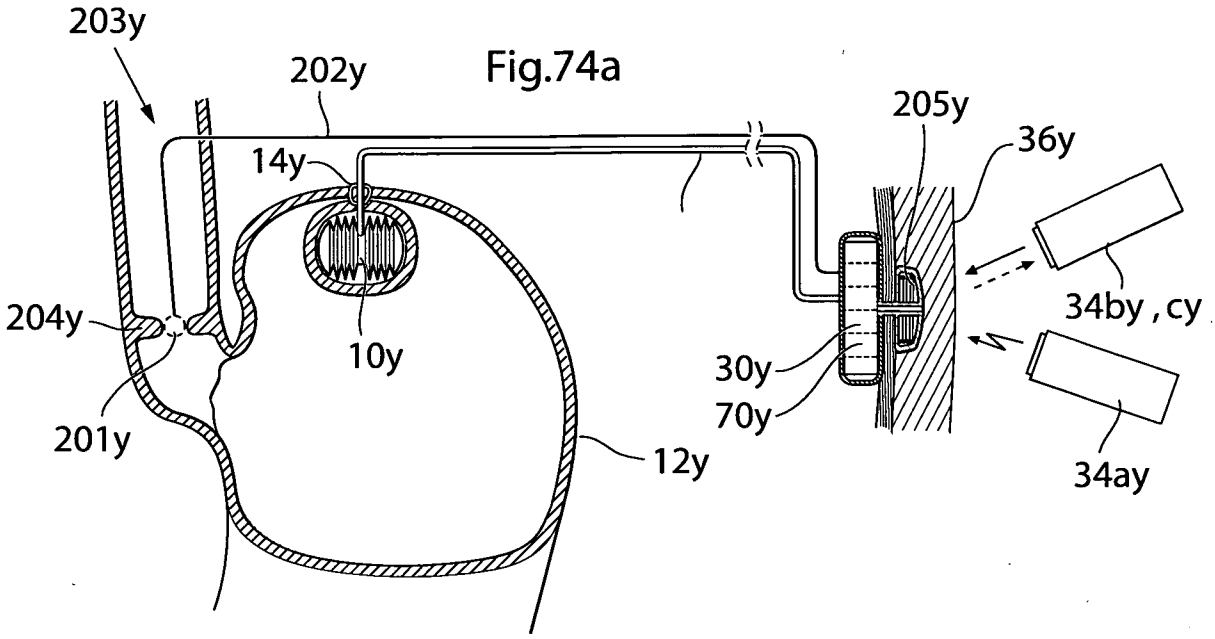


Fig.74a

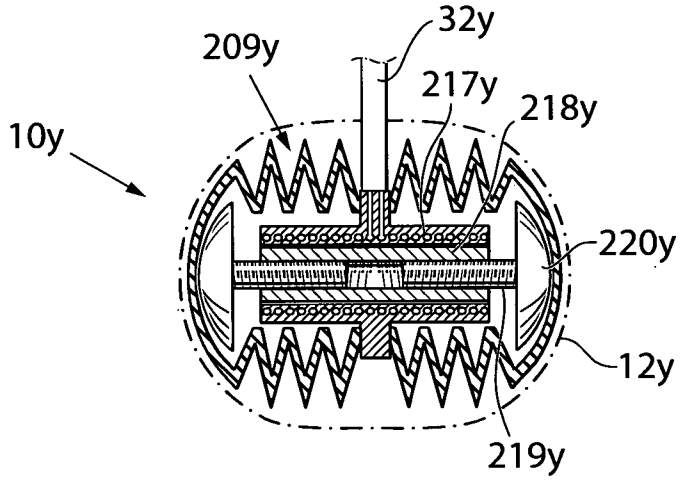


Fig.74b

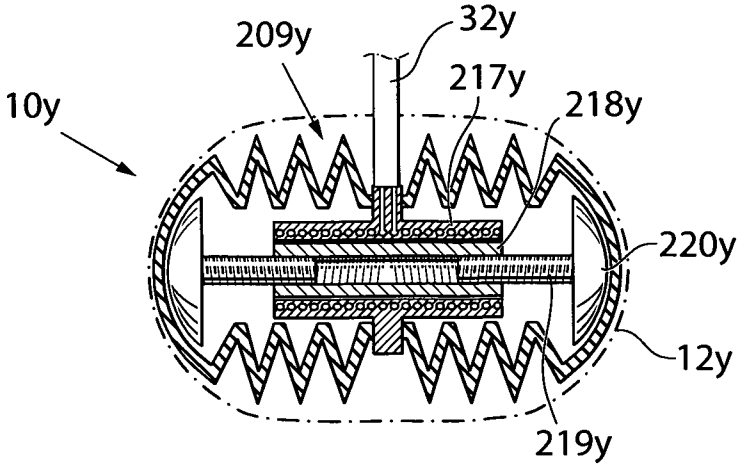


Fig.74c

Fig.75a

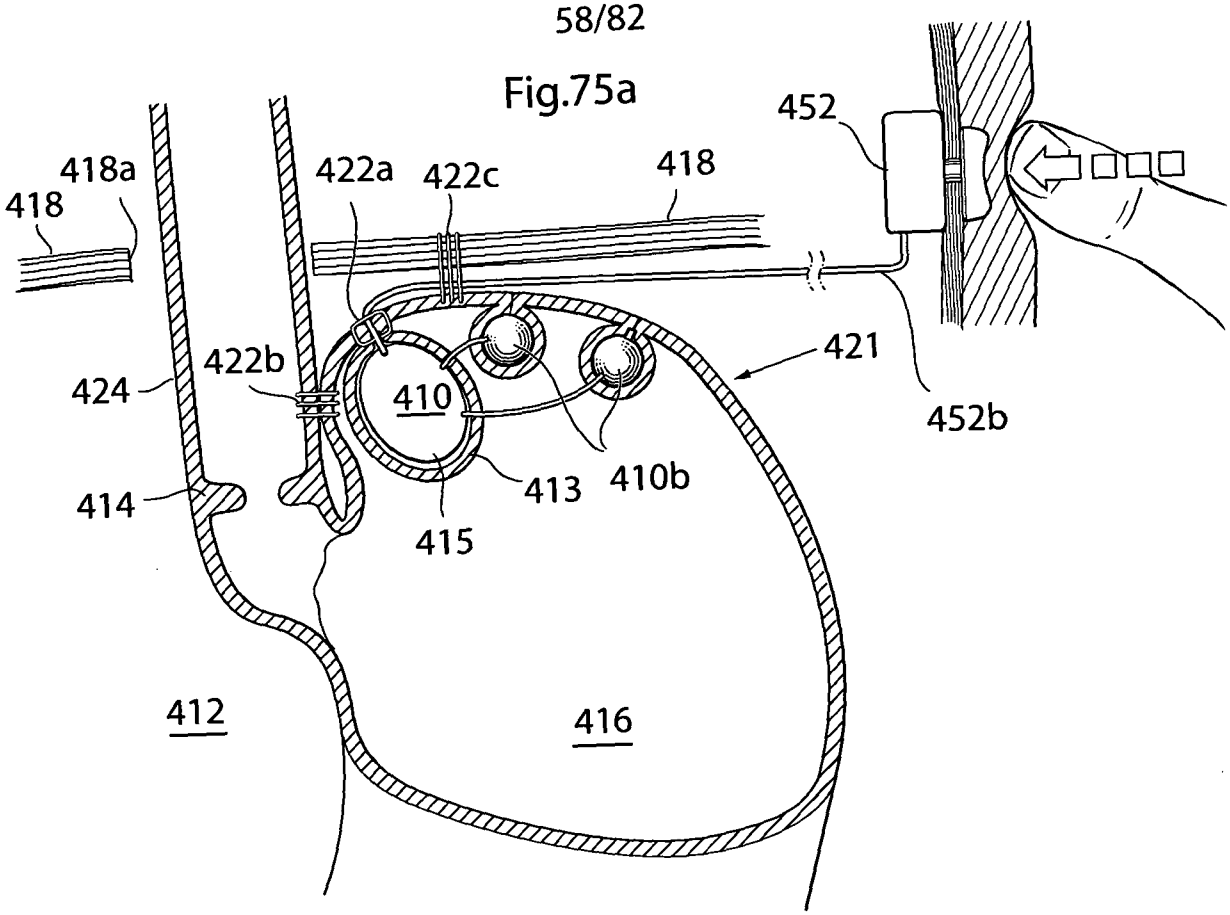


Fig.75b

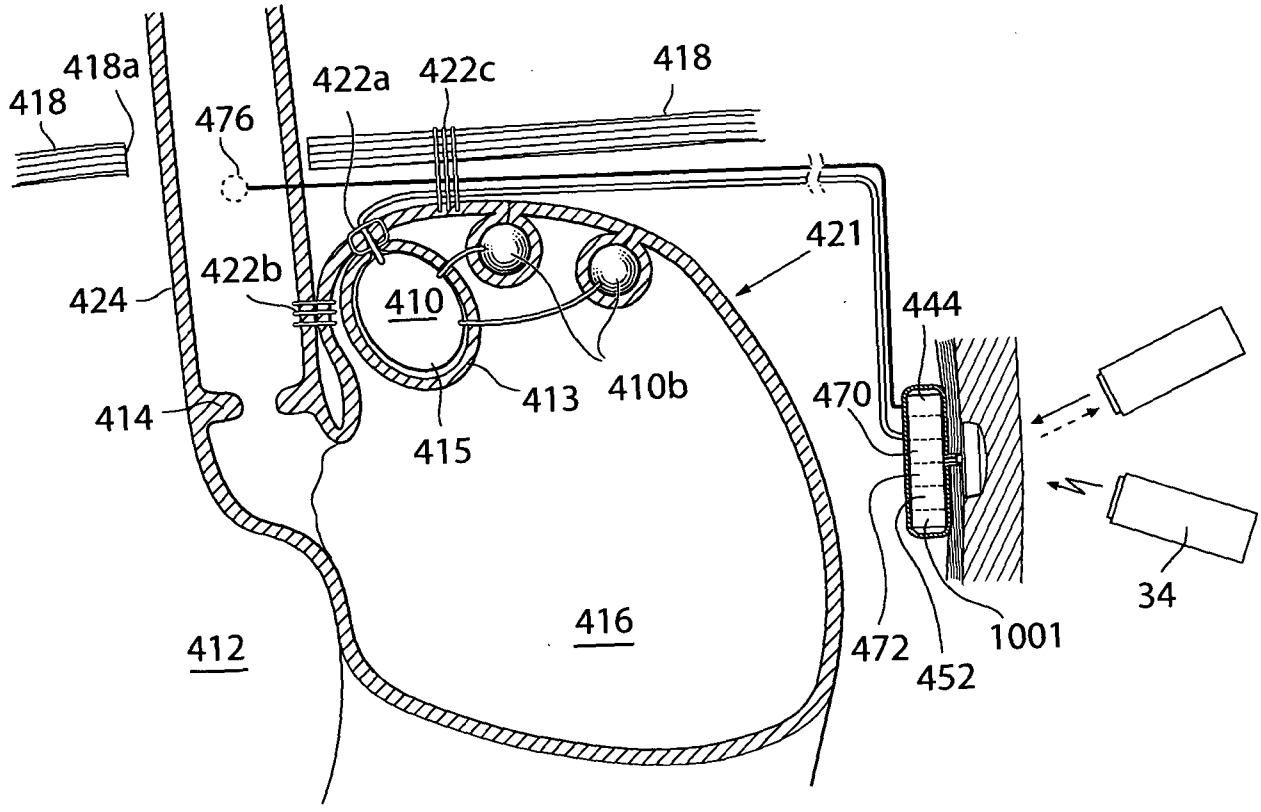


Fig.76a

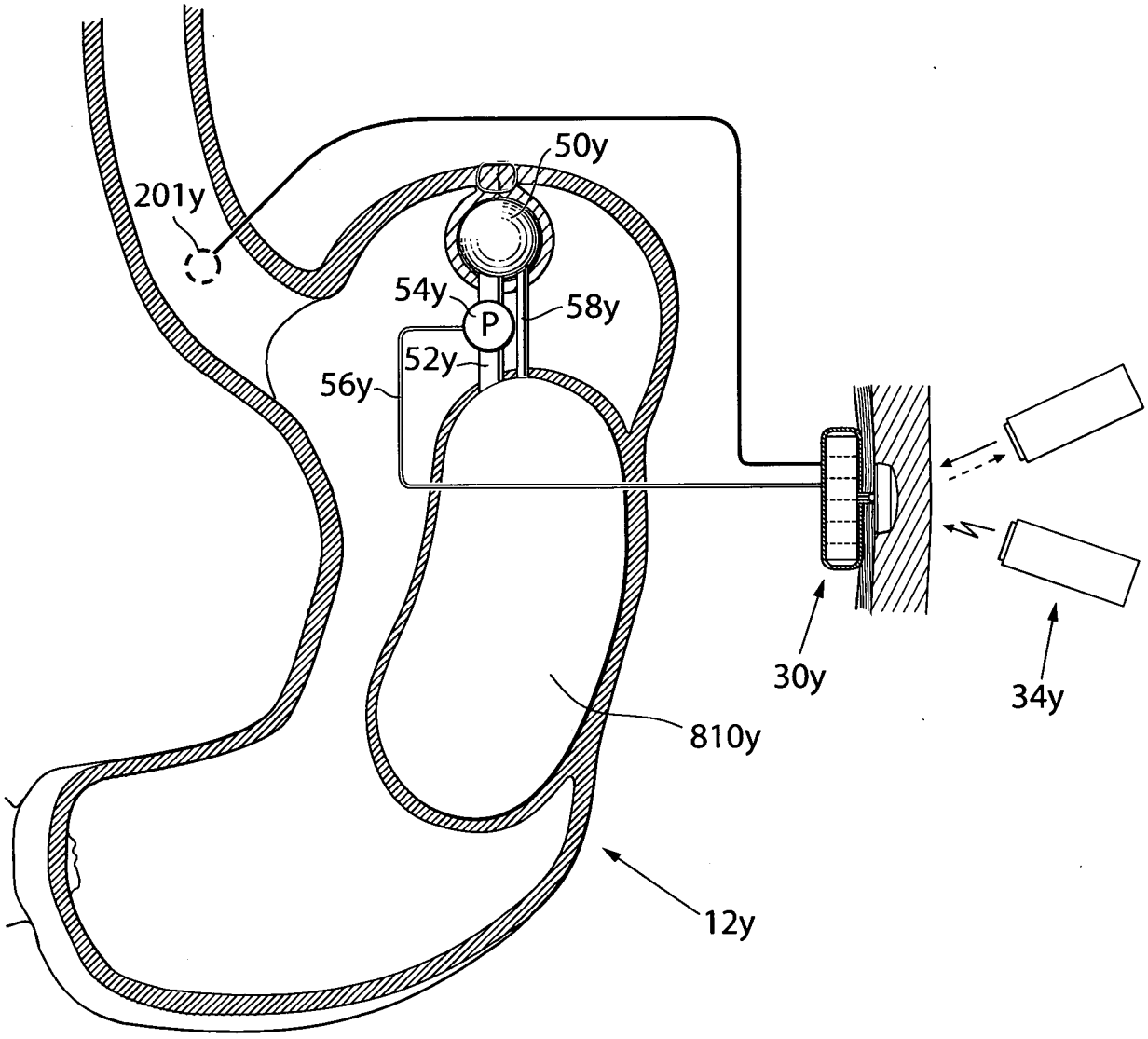


Fig.76b

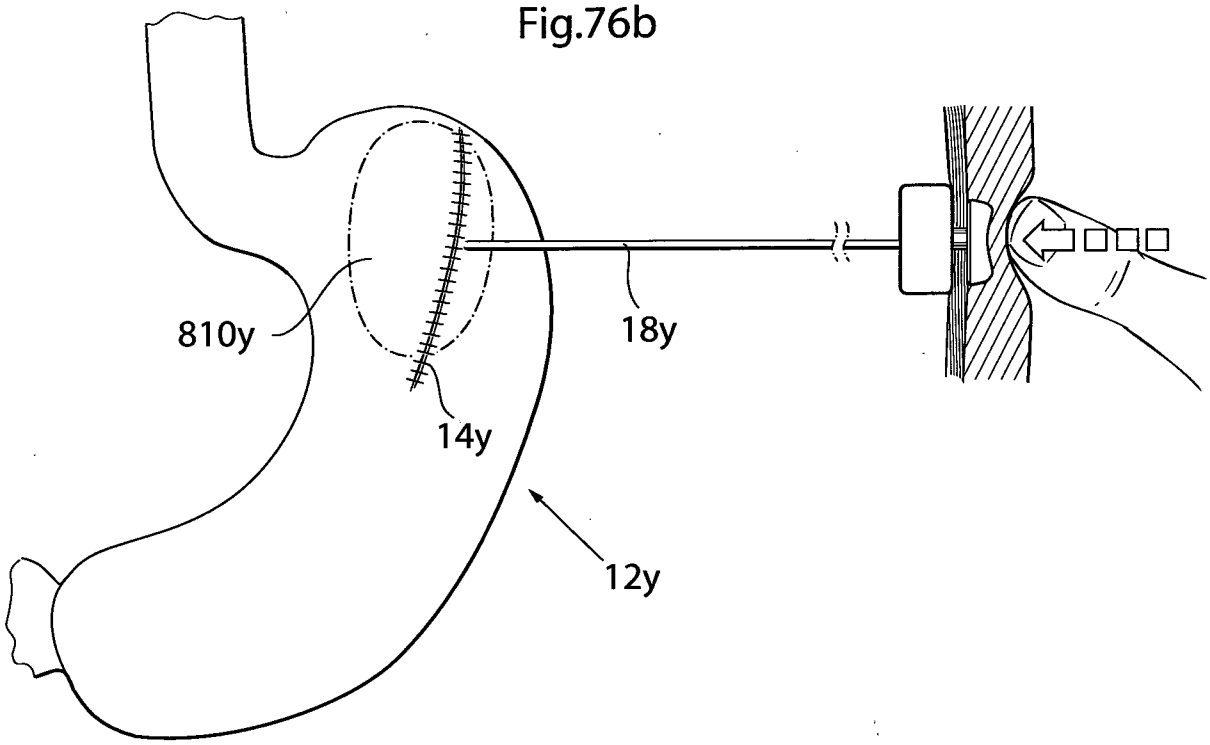


Fig.76c

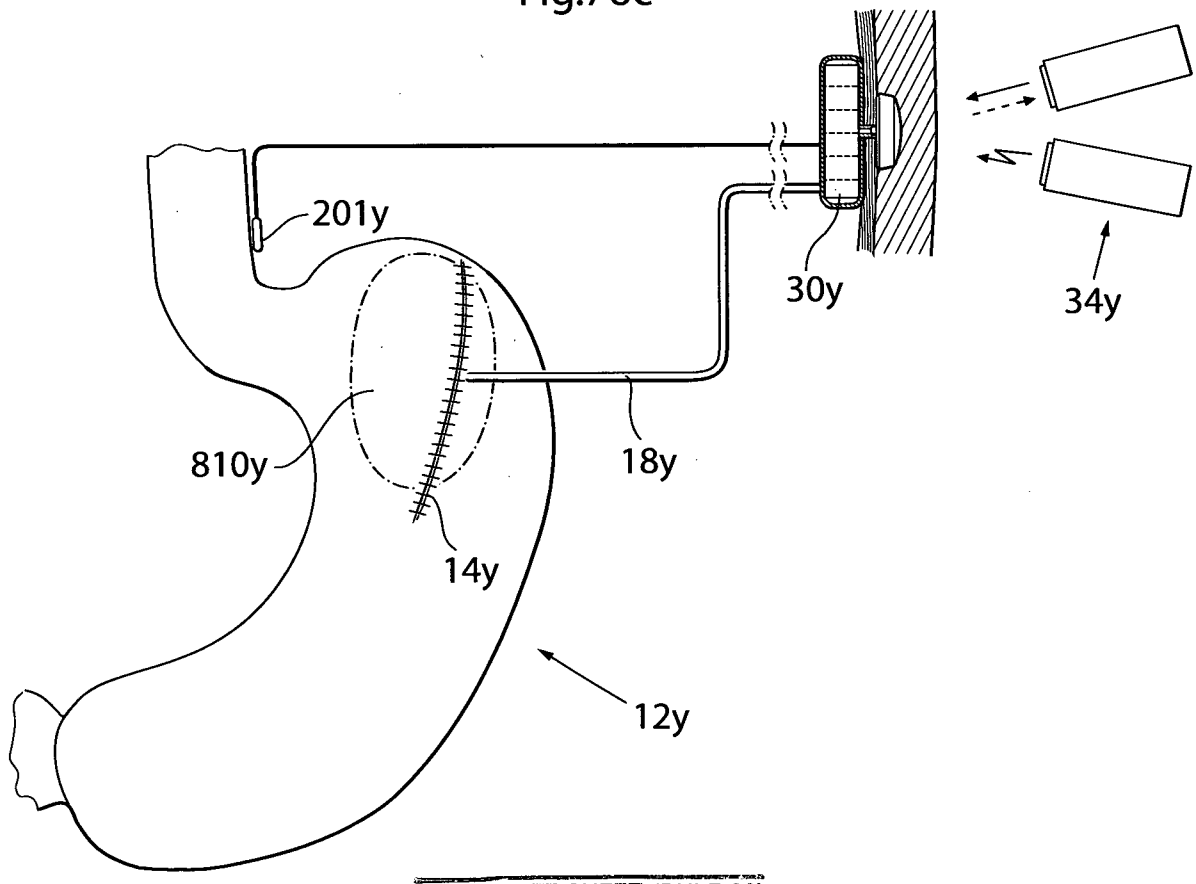


Fig.77

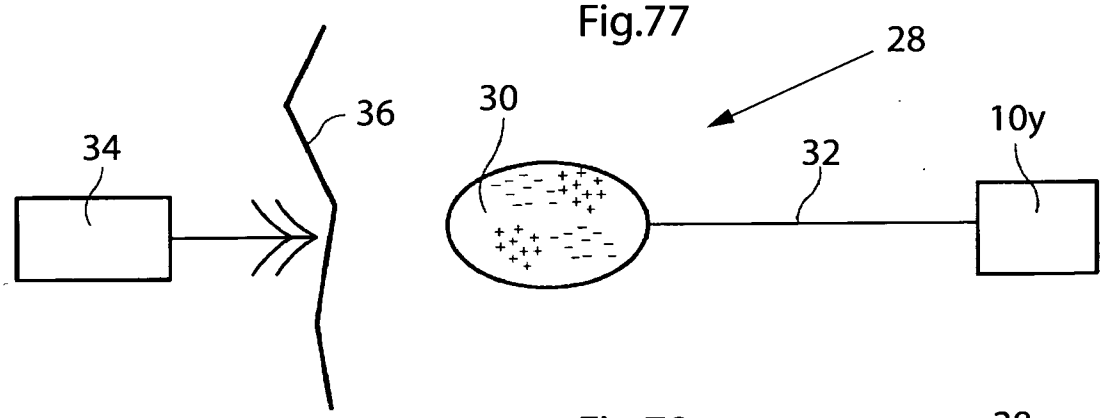


Fig.78

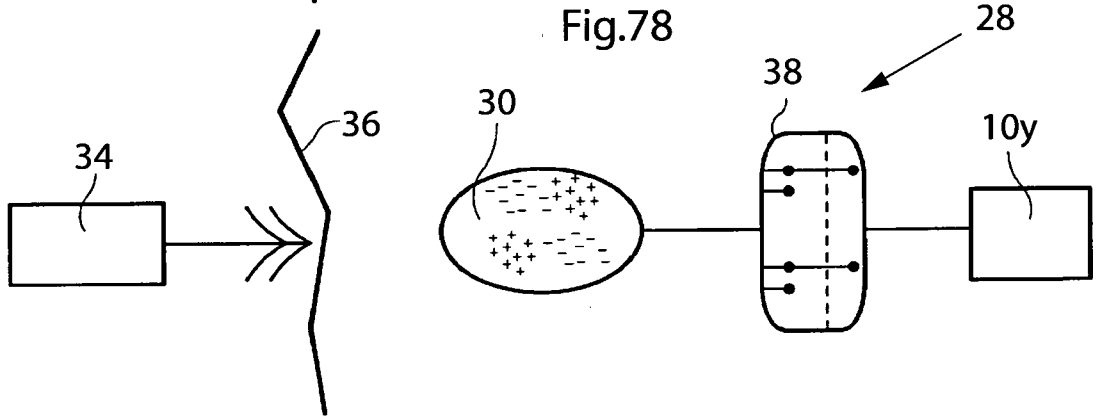


Fig.79

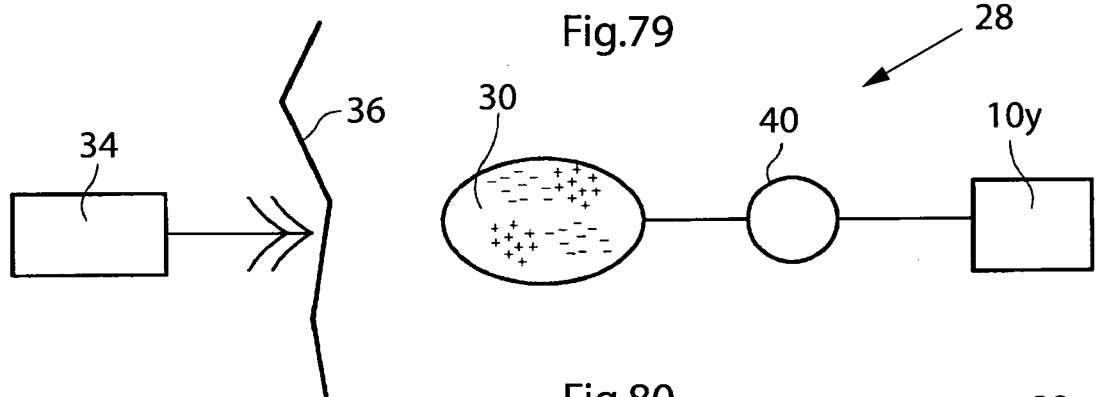


Fig.80

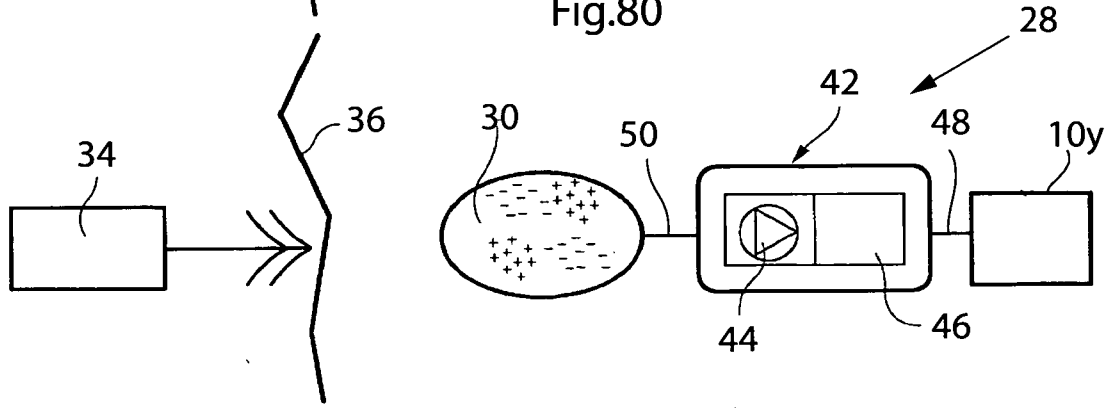


Fig.81

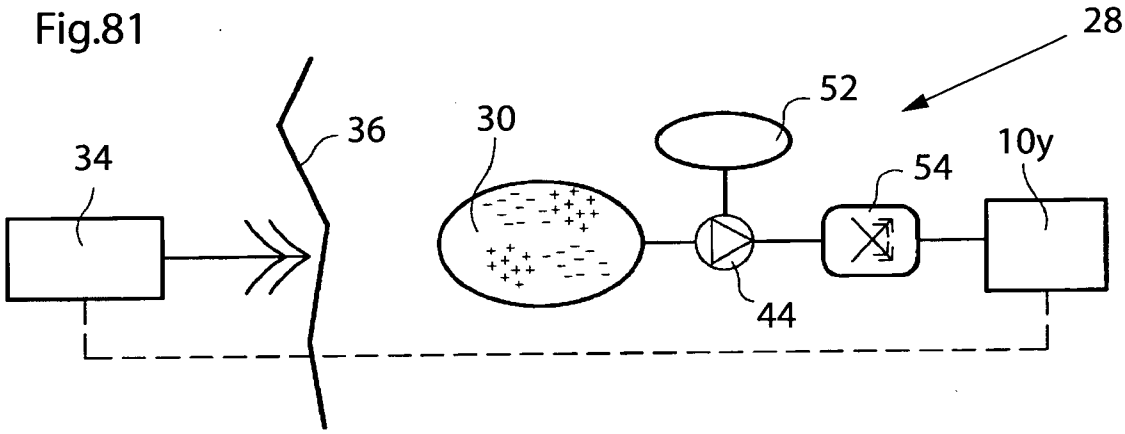


Fig.82

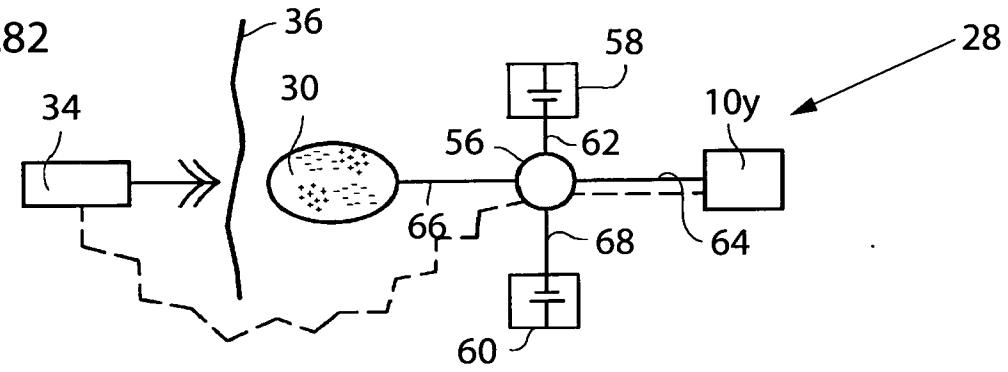


Fig.83

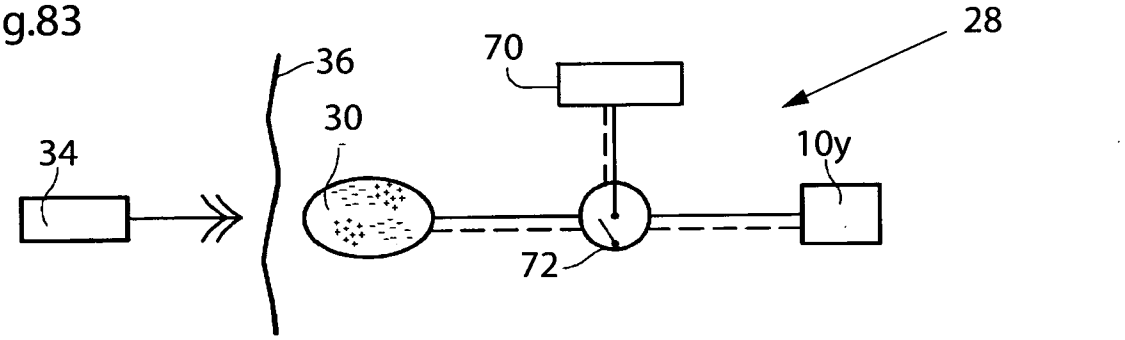


Fig.84

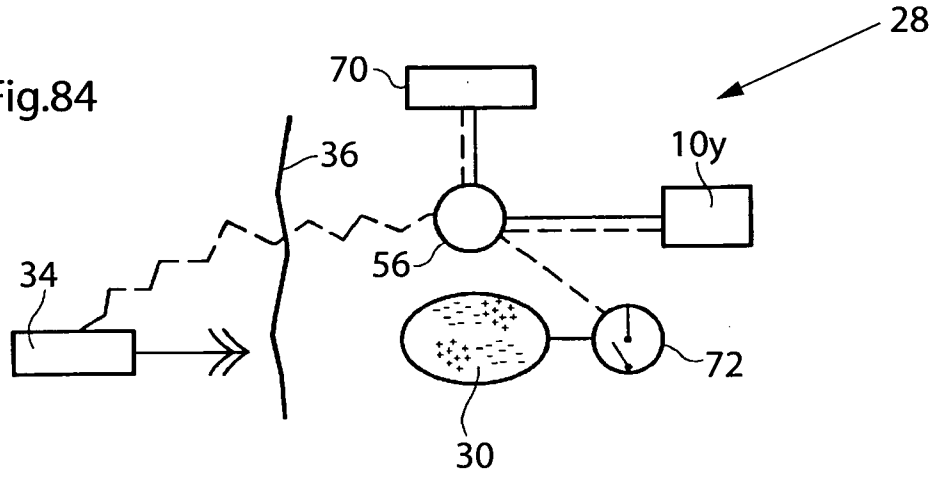


Fig.85

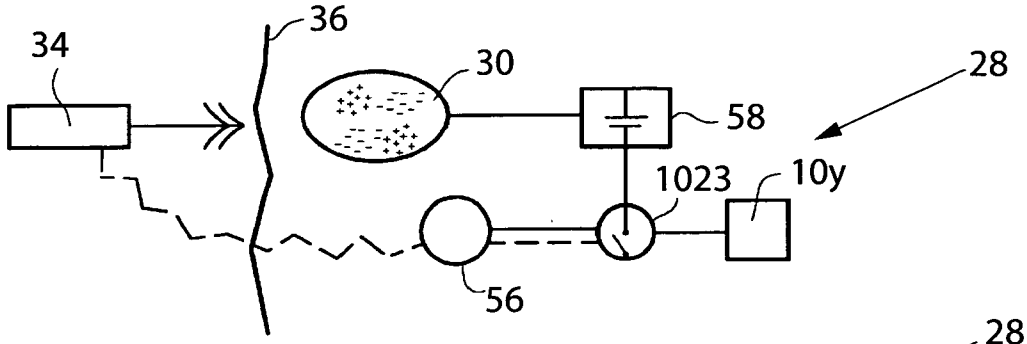


Fig.86

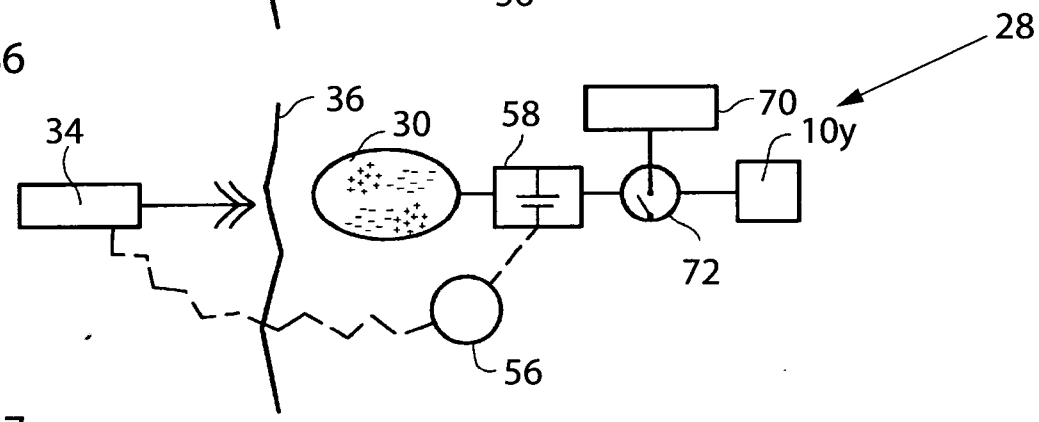


Fig.87

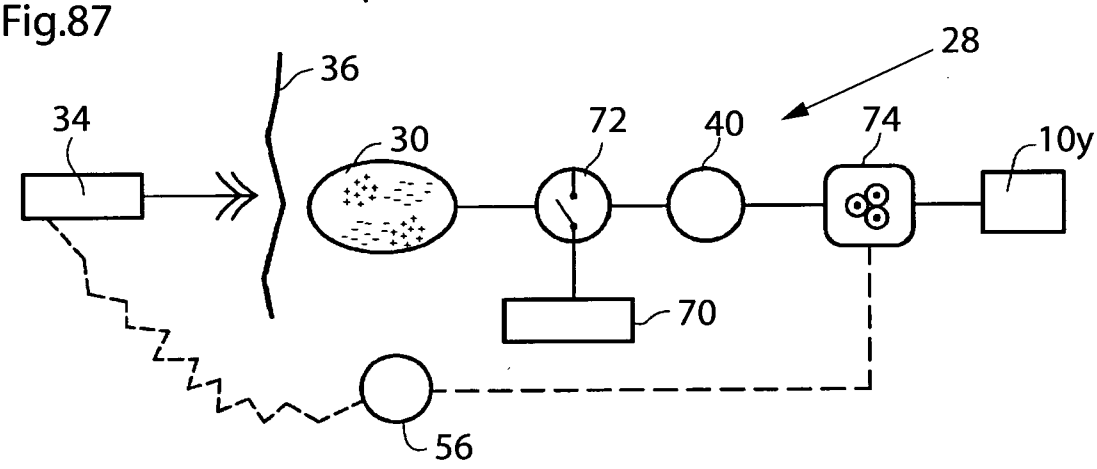


Fig.88

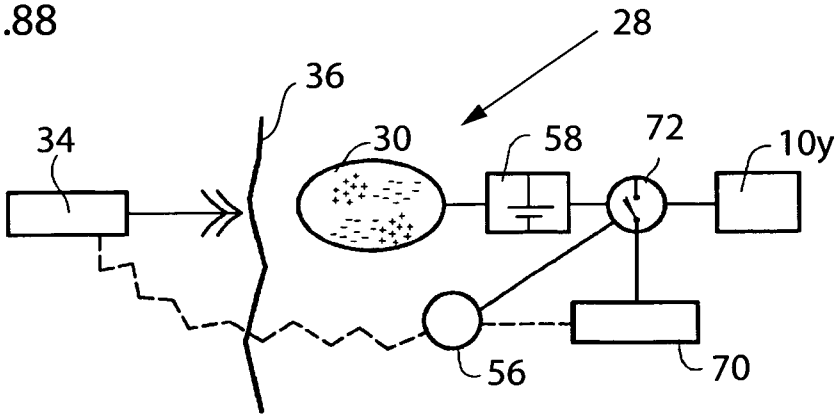


Fig.89

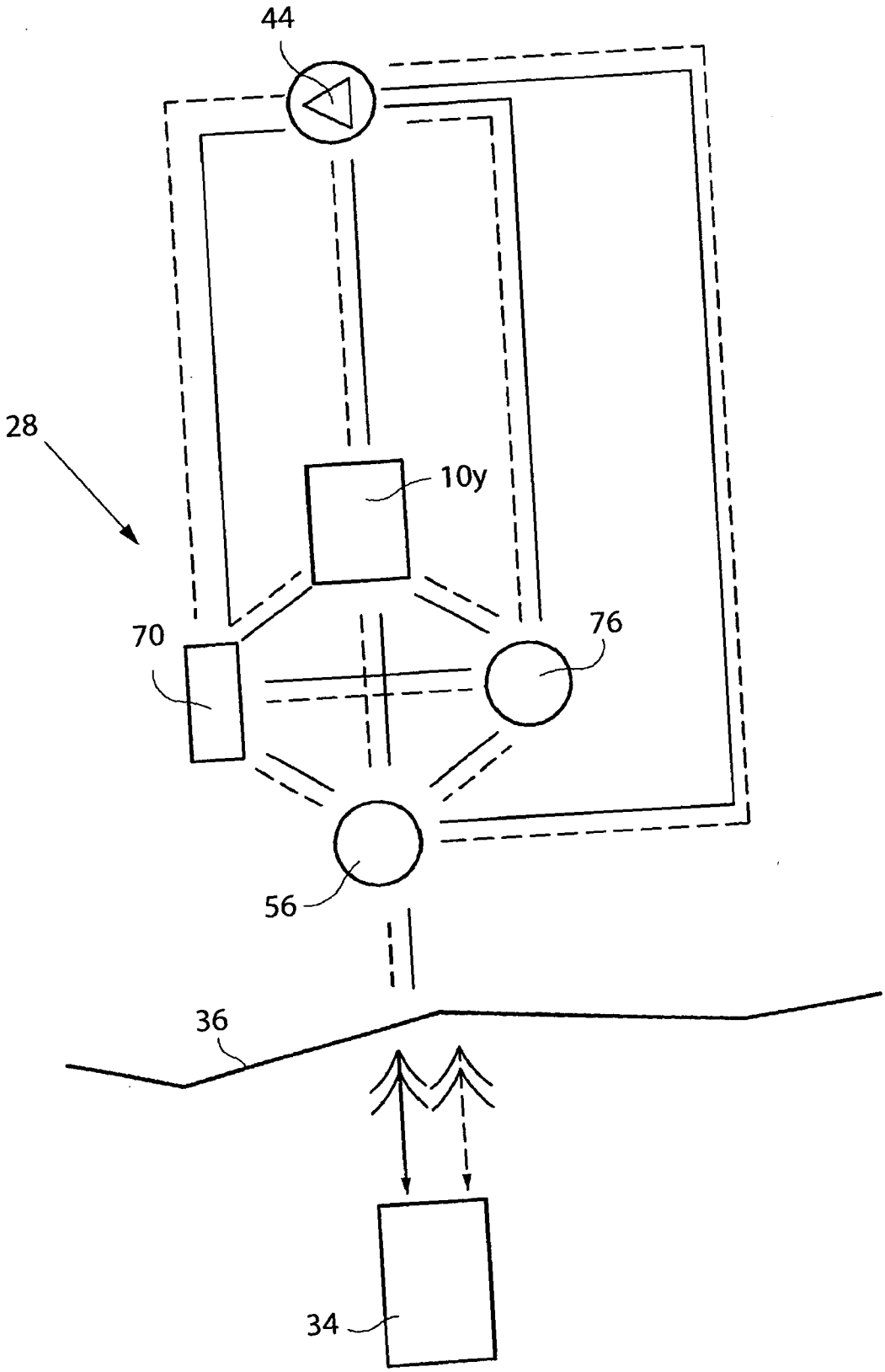


Fig.90

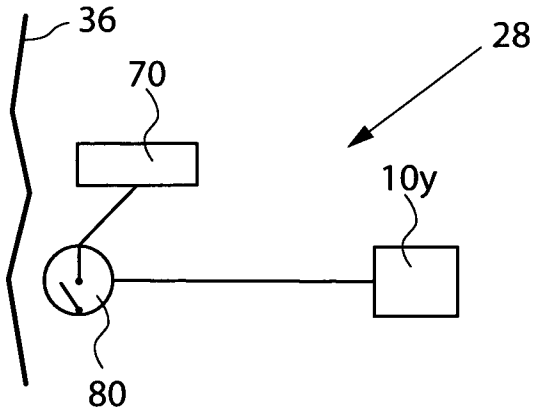


Fig.91

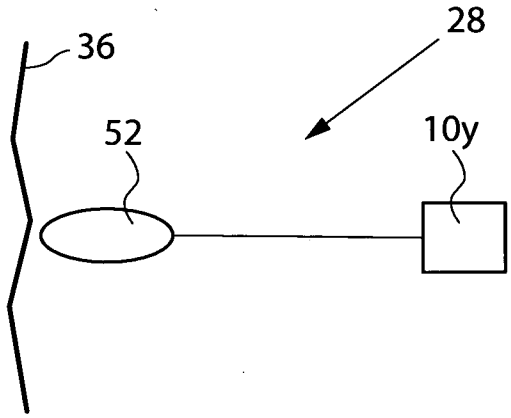


Fig.92

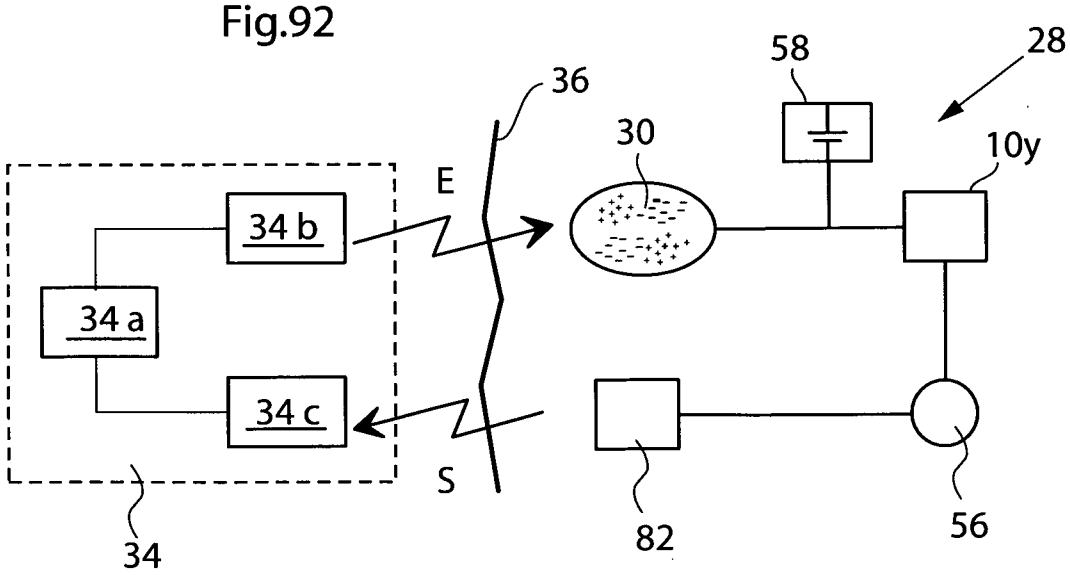


Fig.93

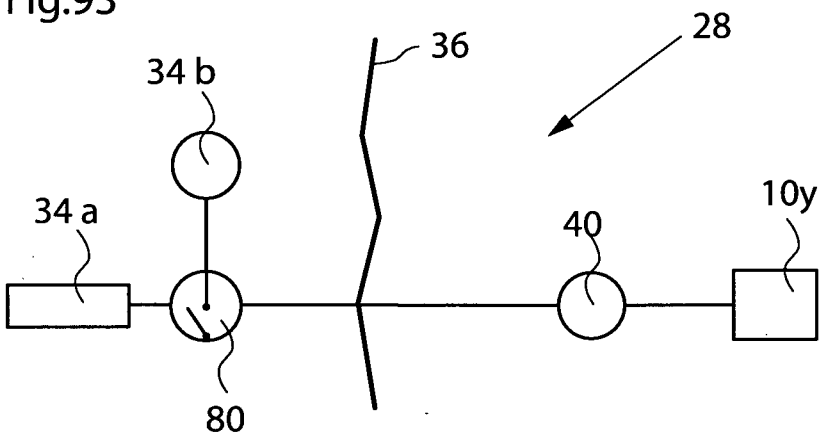


Fig.94

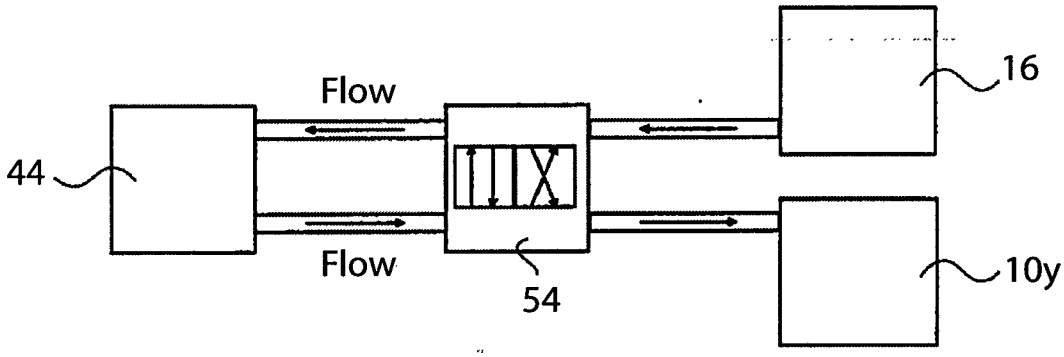


Fig.95

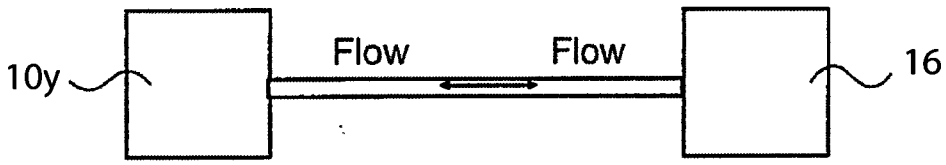


Fig.96

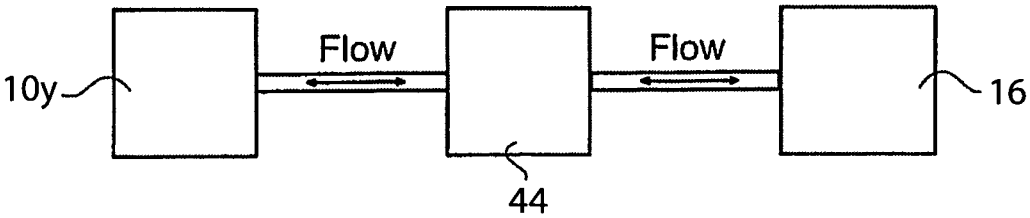


Fig.97

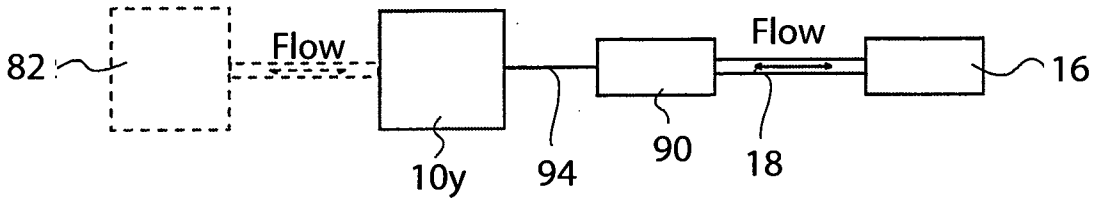


Fig.98 a

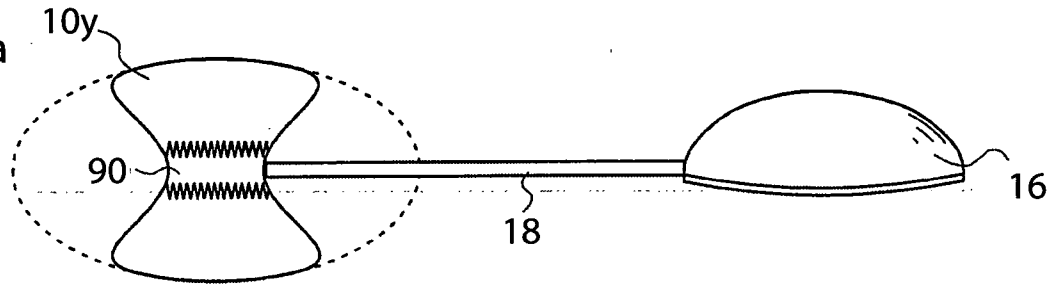


Fig.98 b

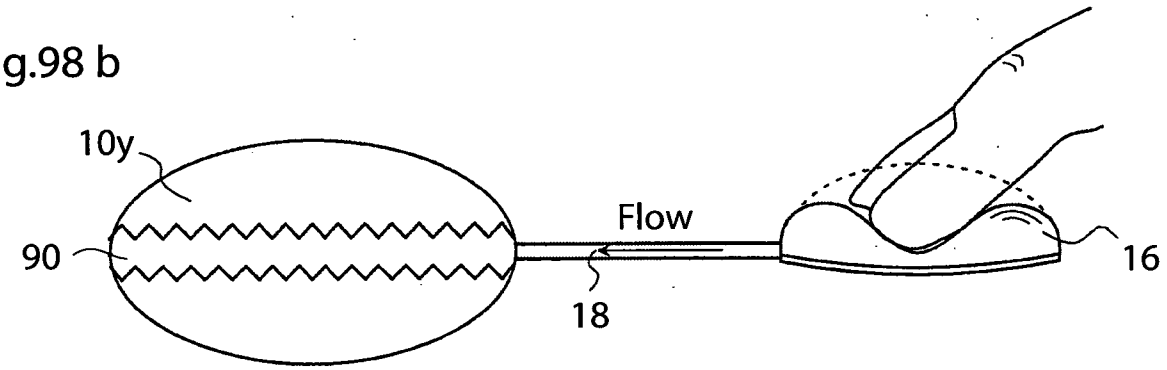


Fig.98 c

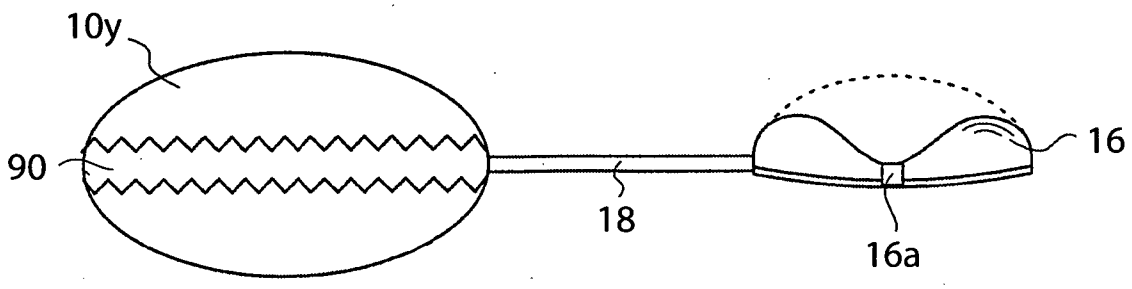


Fig.99

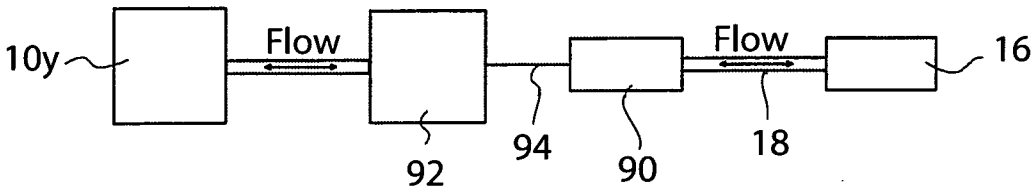


Fig.100a

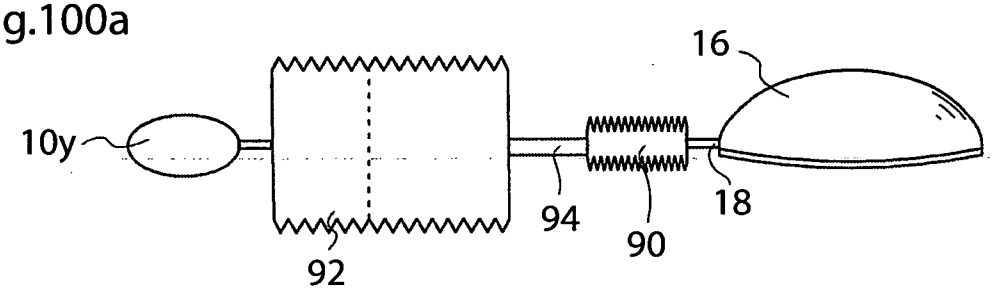


Fig.100b

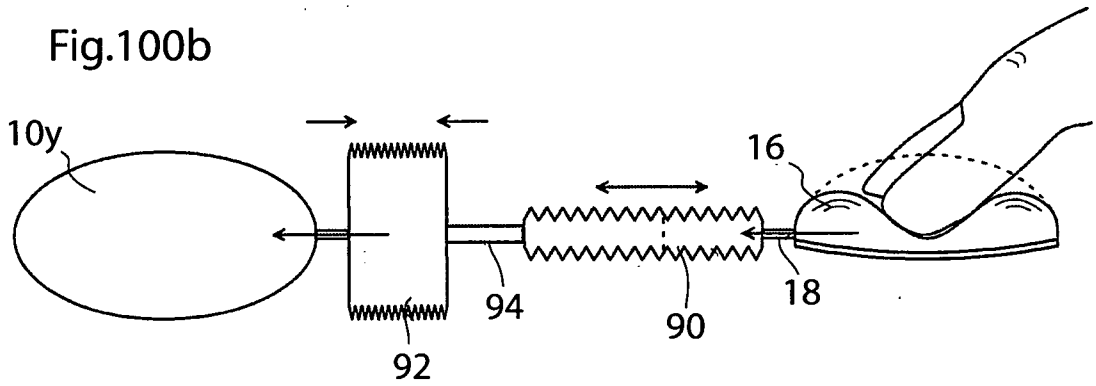


Fig.100c

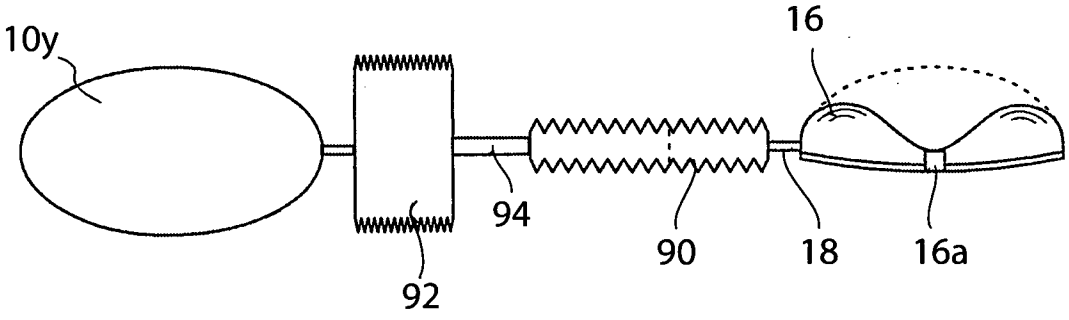


Fig.101a

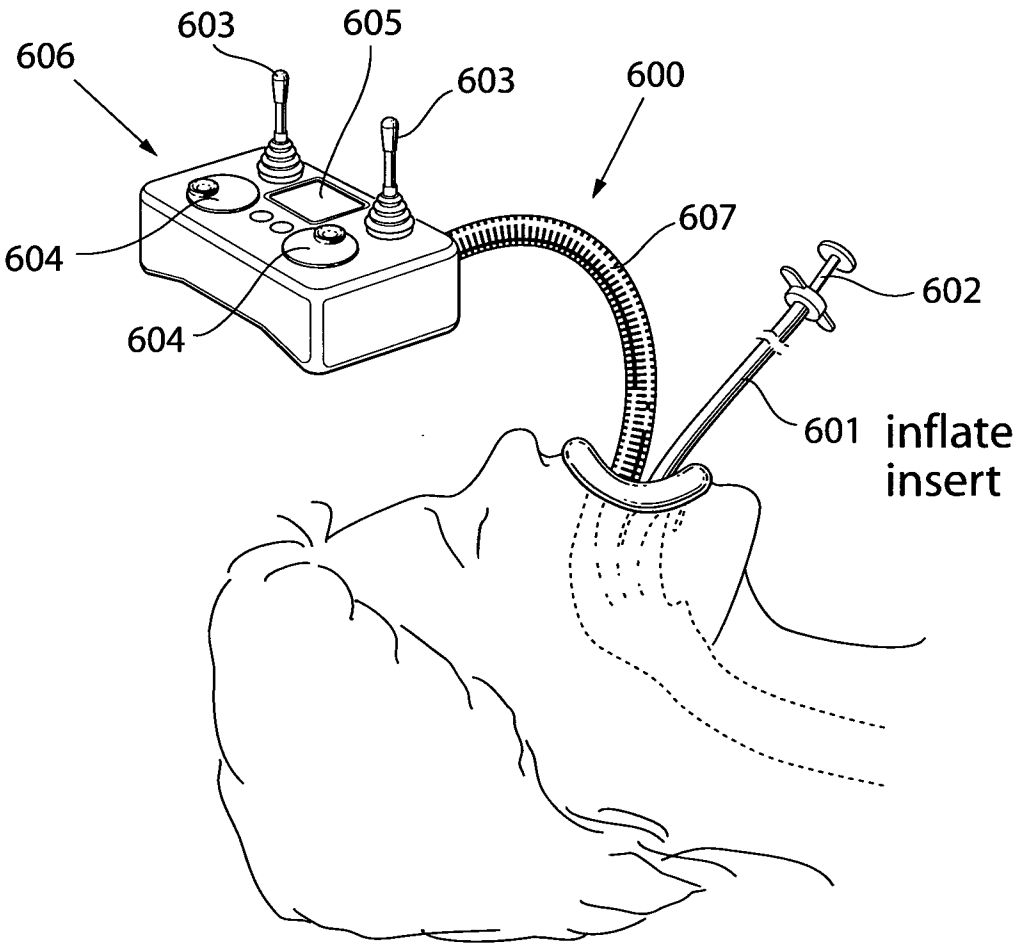


Fig.101b

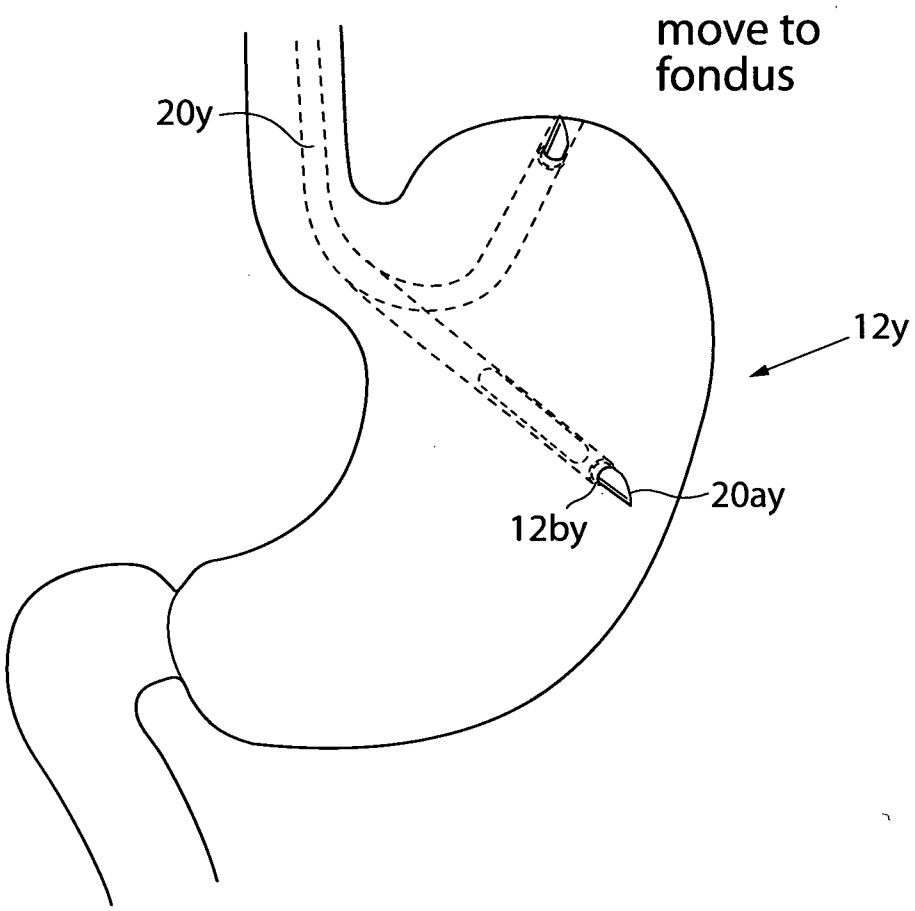


Fig.101c

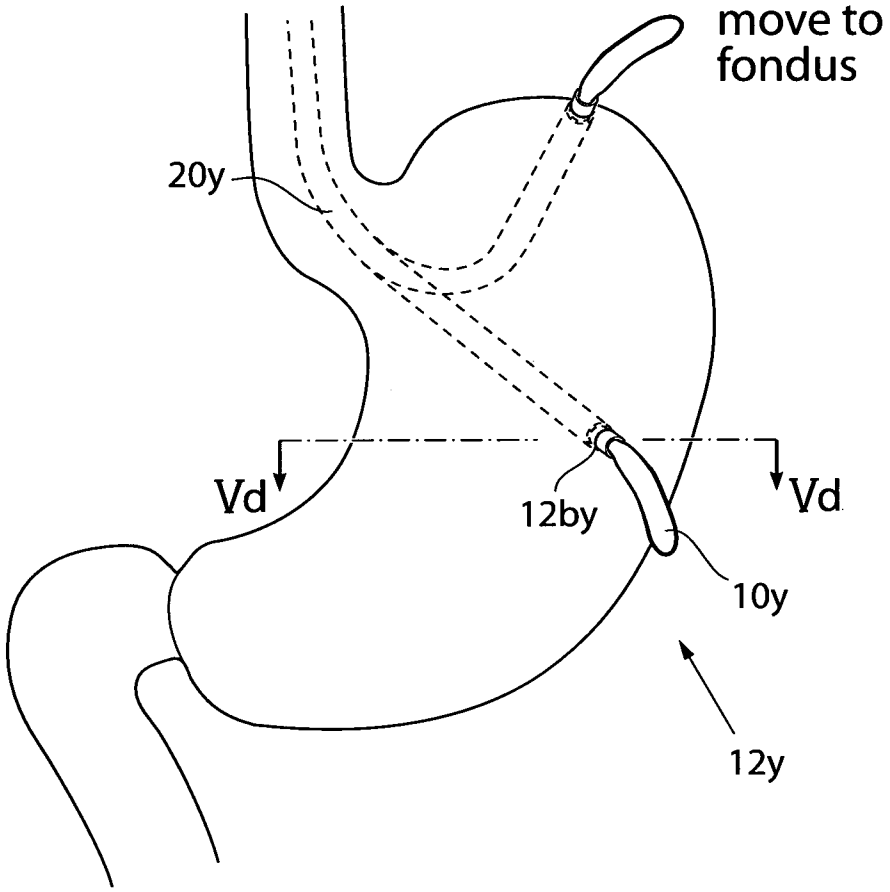


Fig.101d

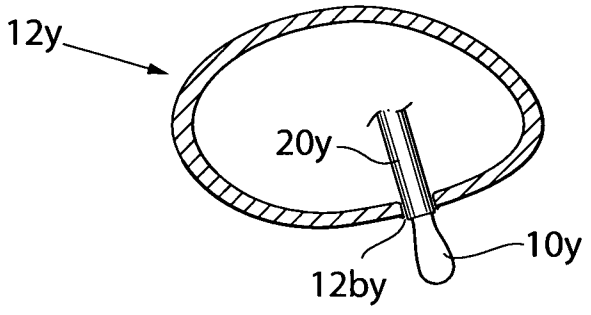


Fig.101e

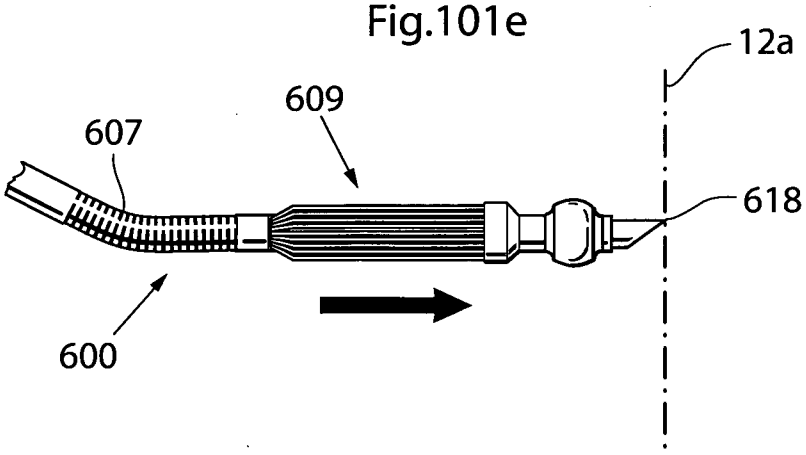


Fig.101f

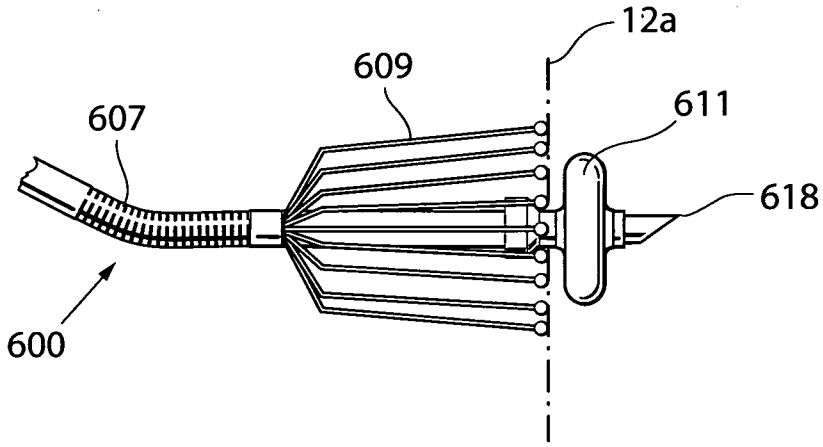


Fig.101g

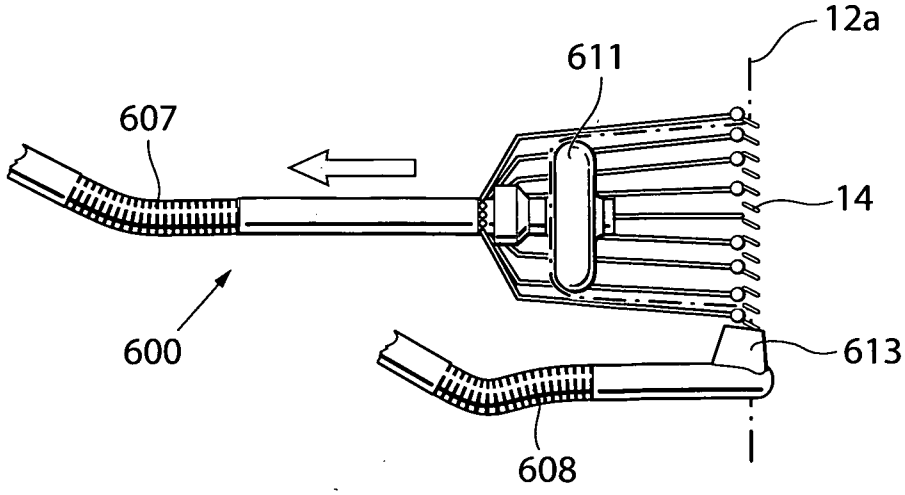


Fig.101h

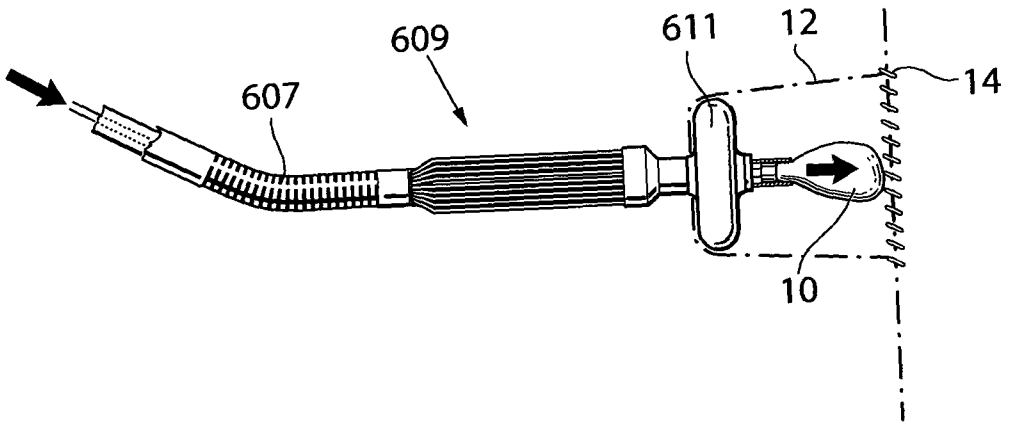


Fig.101i

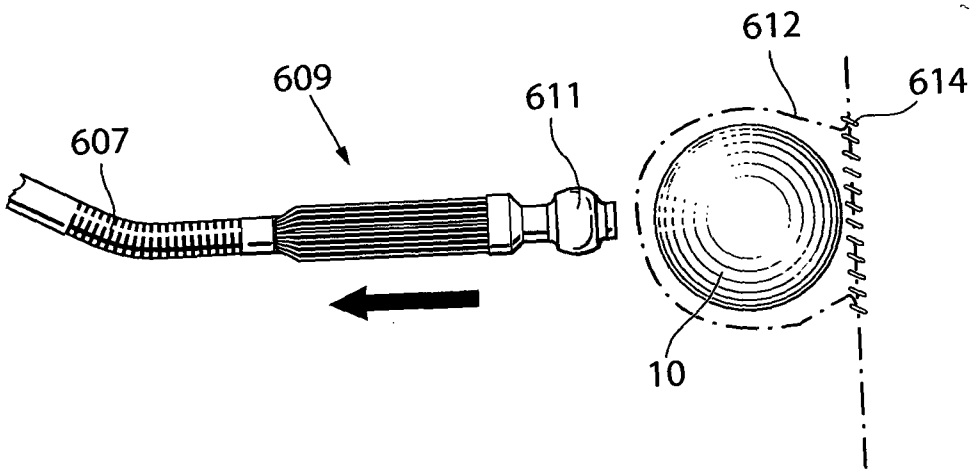


Fig.102a

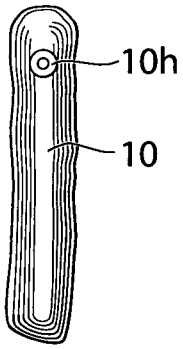


Fig.102b

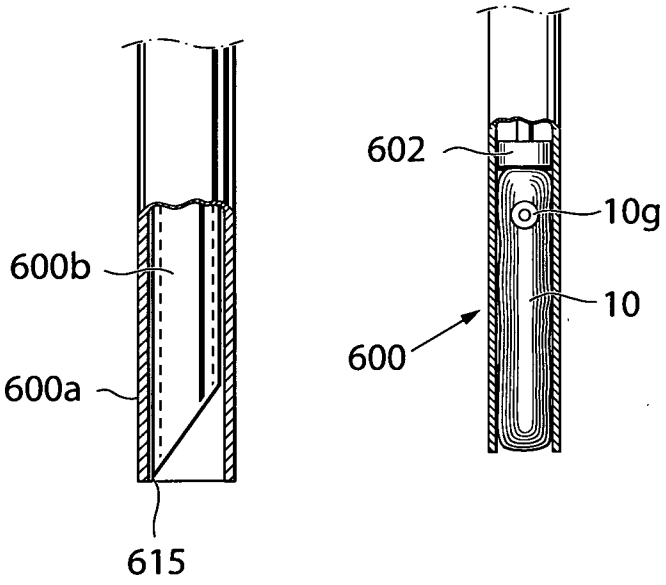


Fig.102c

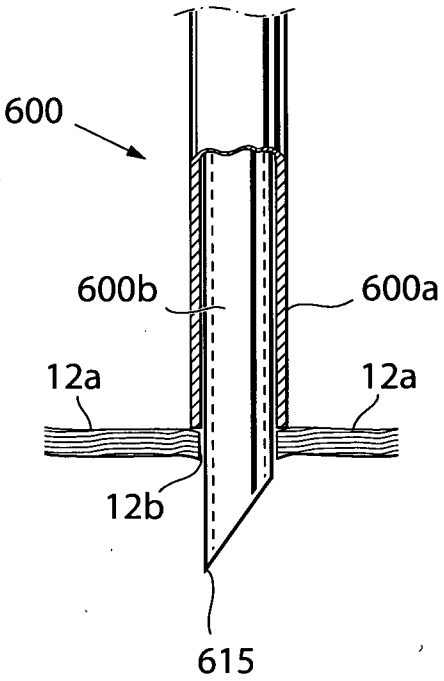


Fig.102d

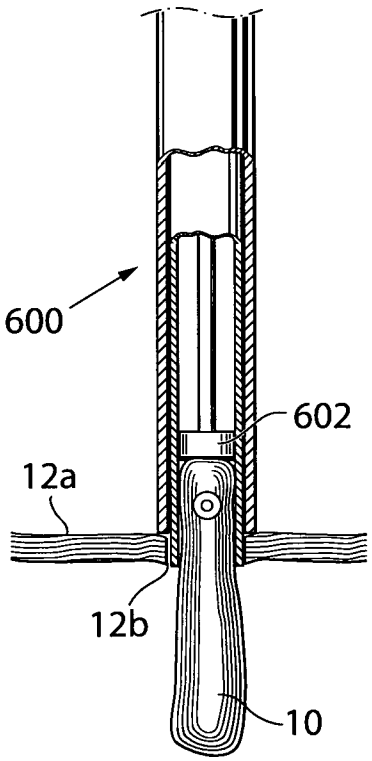


Fig.103a

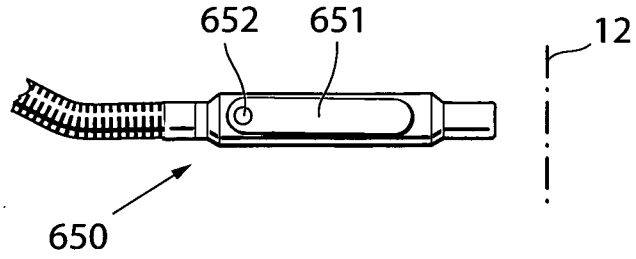


Fig.103b

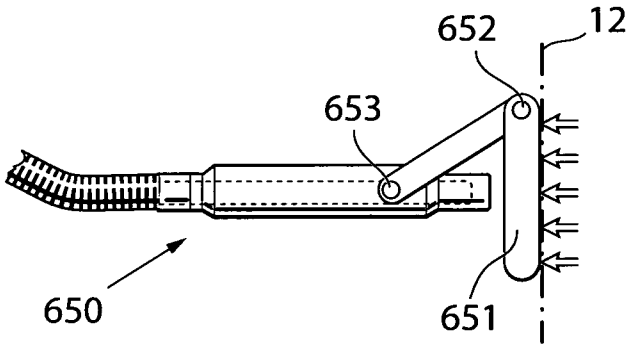


Fig.103c

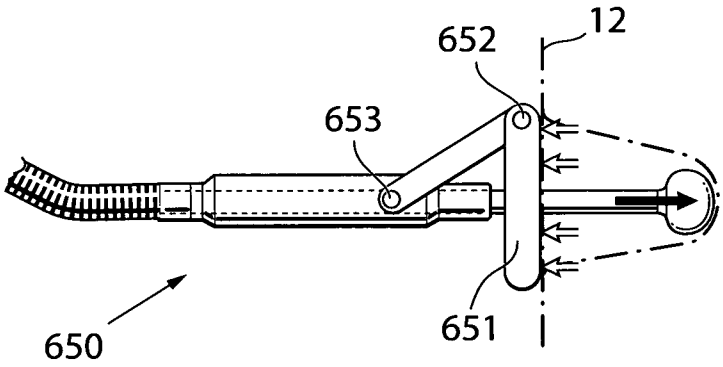


Fig.103d

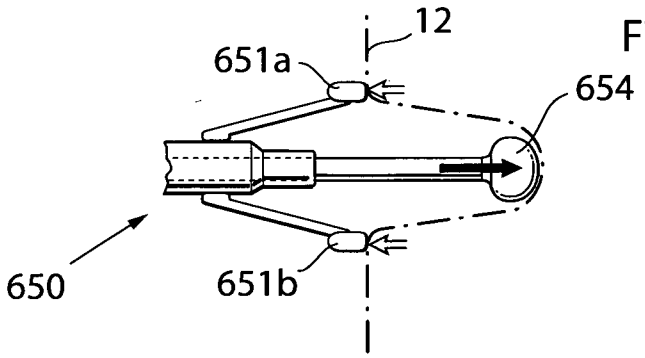


Fig.103e

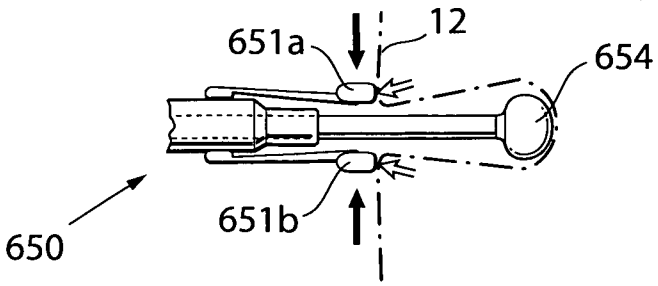


Fig.103f

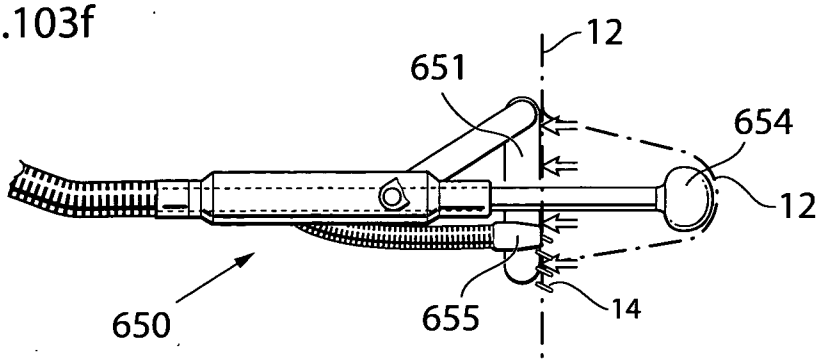


Fig.103g

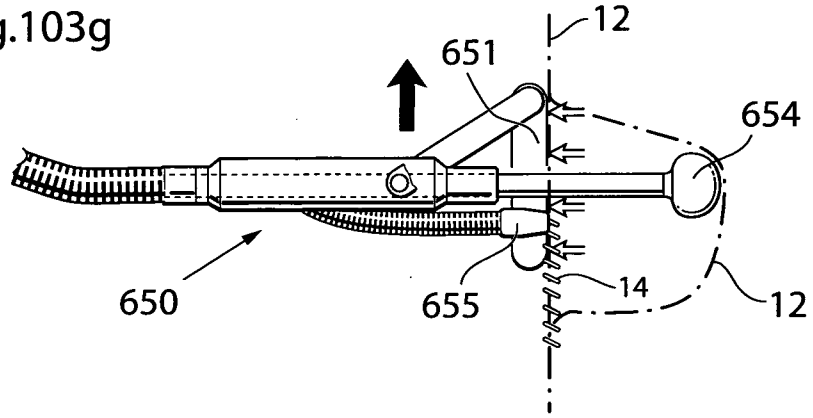


Fig.103h

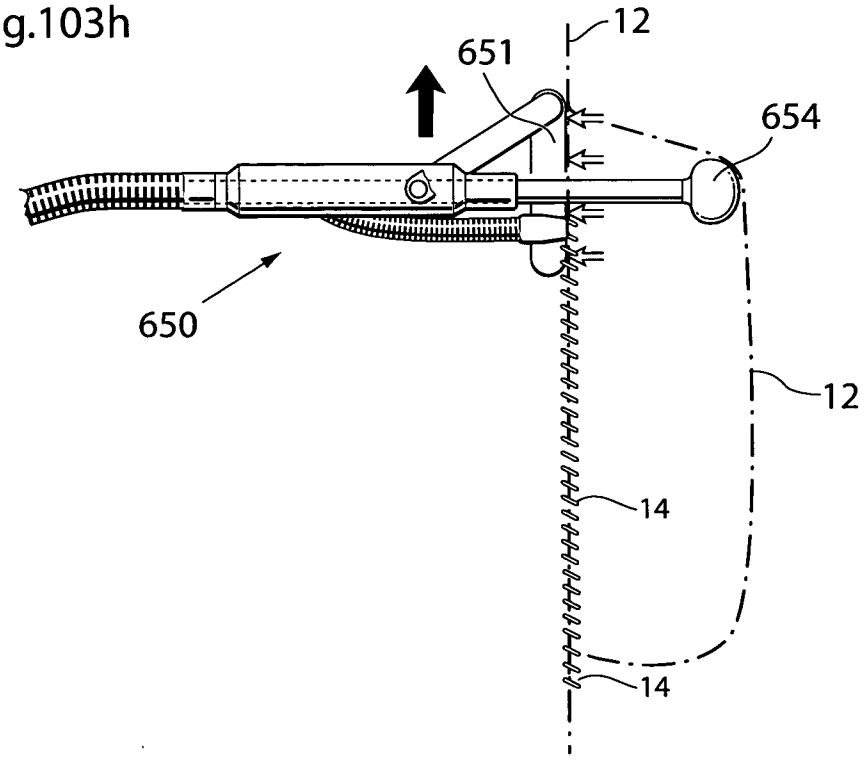


Fig.103i

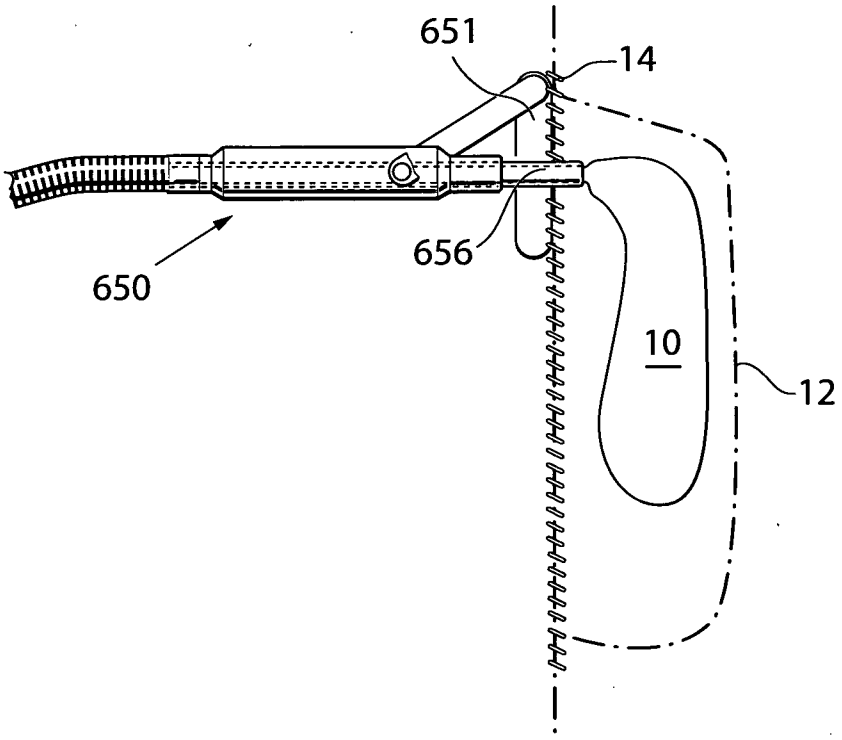


Fig.103j

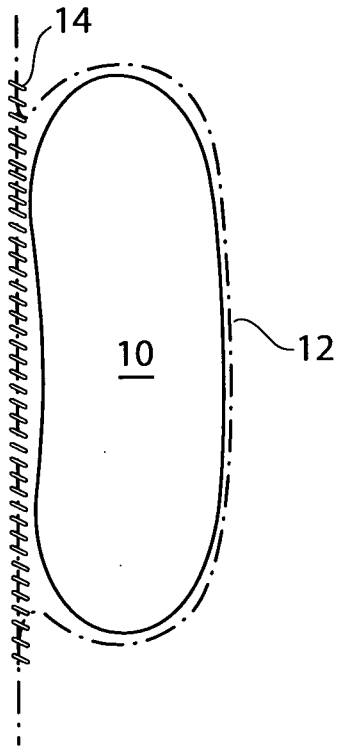


Fig.104a

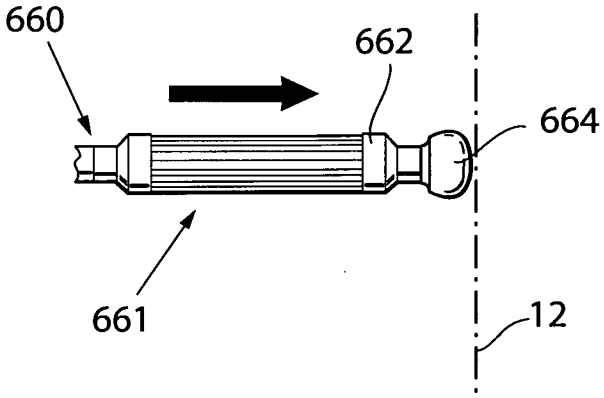


Fig.104b

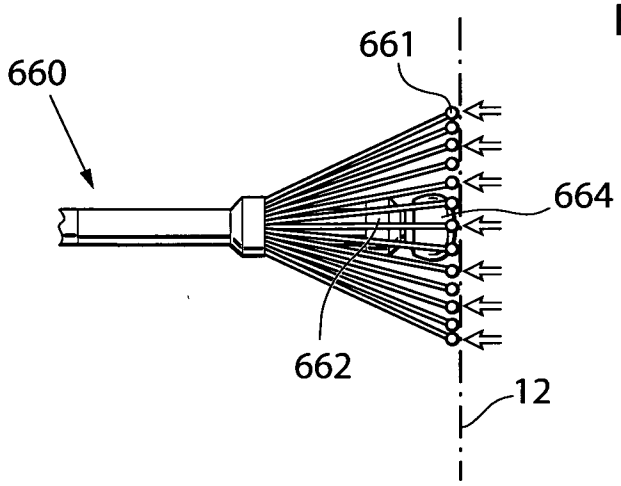


Fig.104c

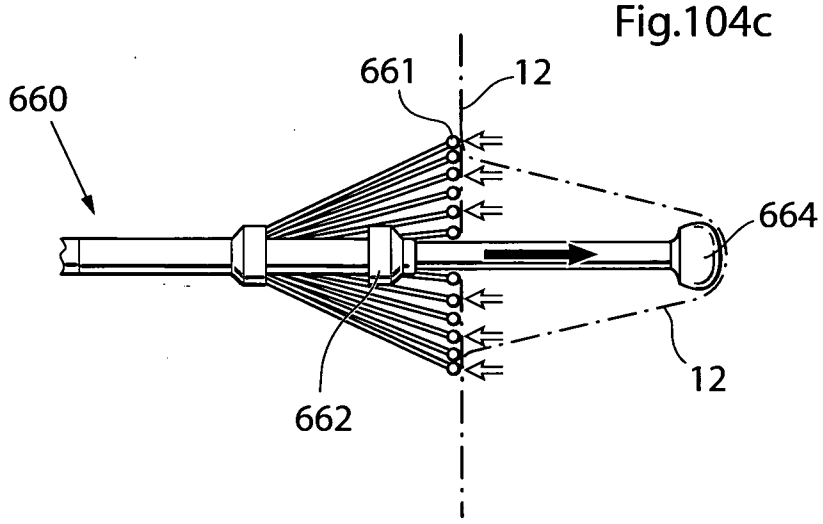


Fig.104d

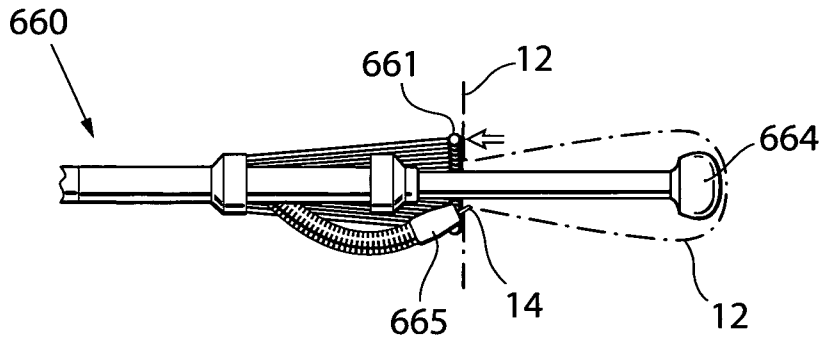


Fig.104e

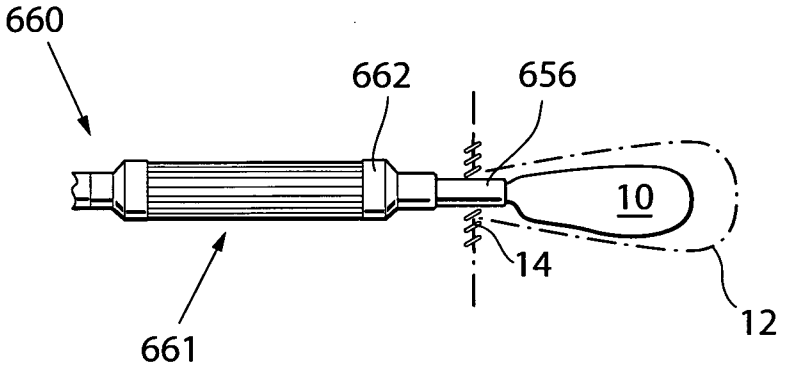


Fig.104f

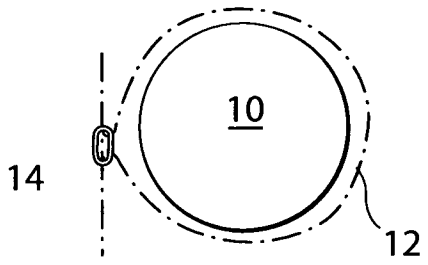


Fig. 105a

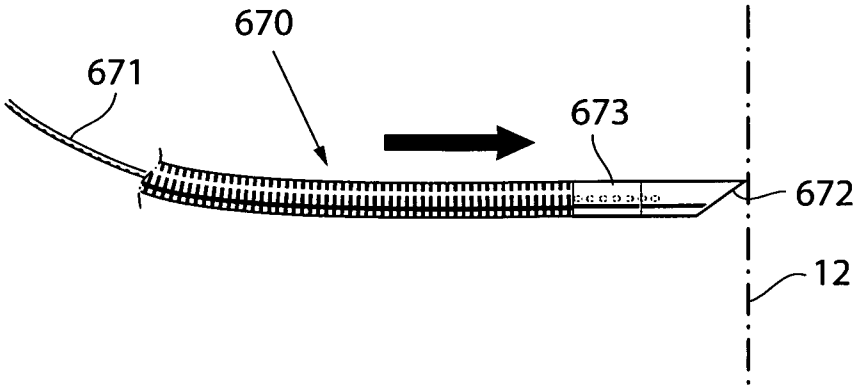


Fig. 105b

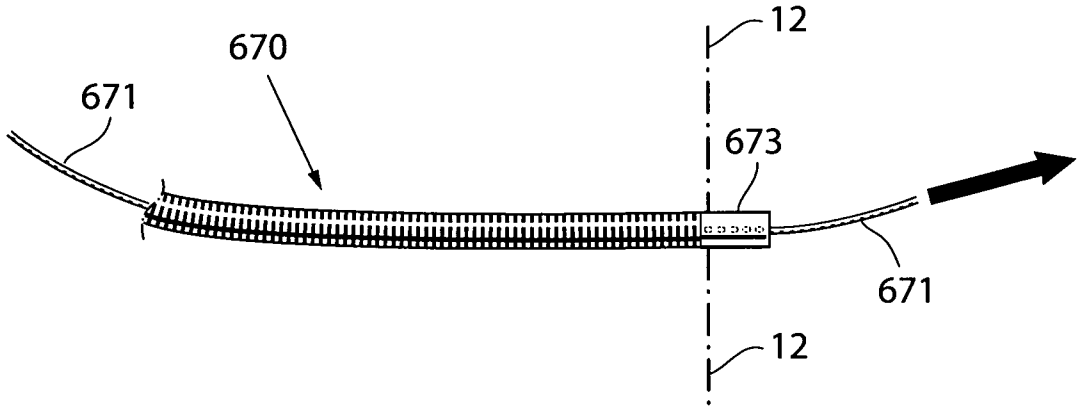


Fig.106

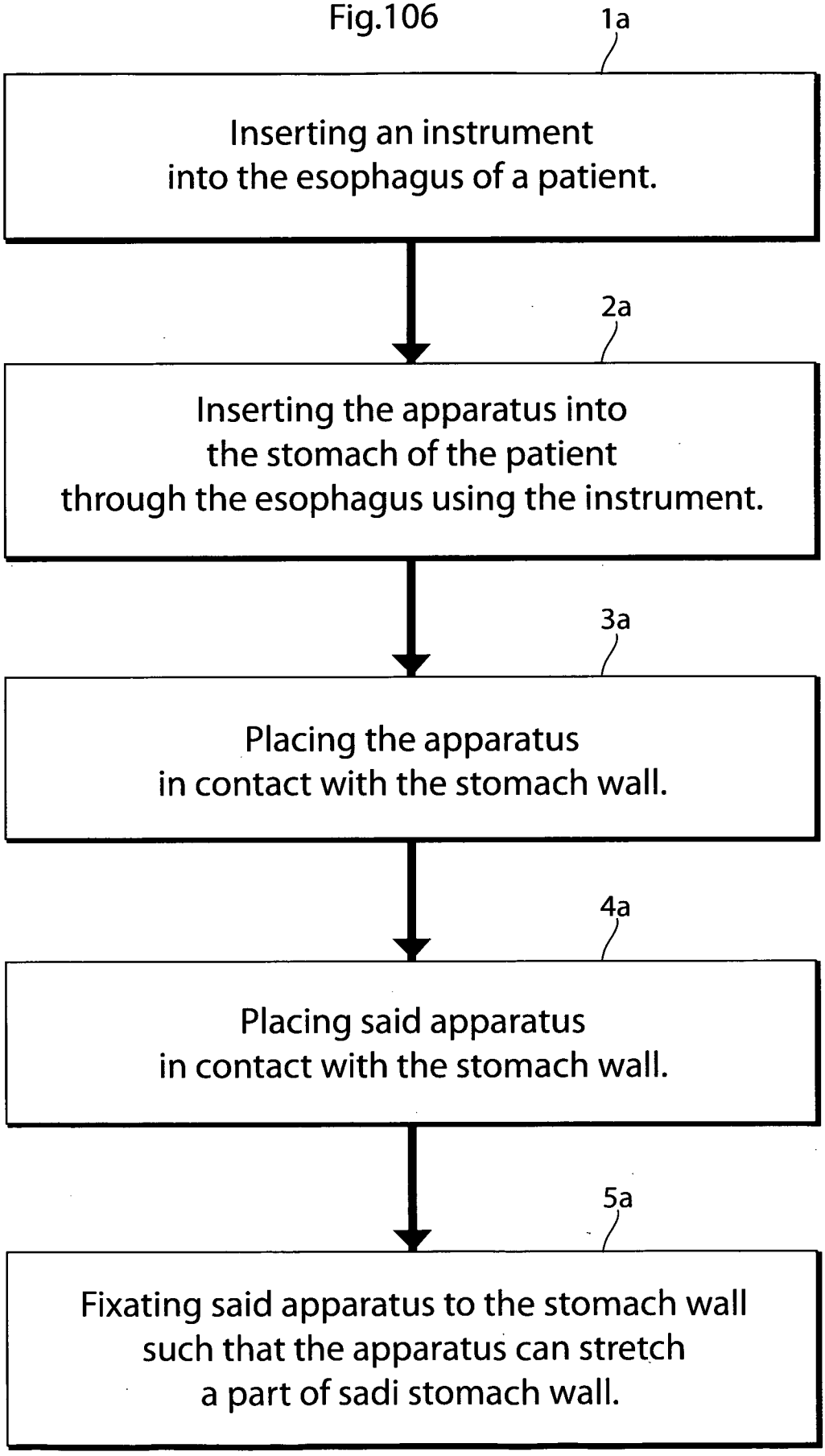
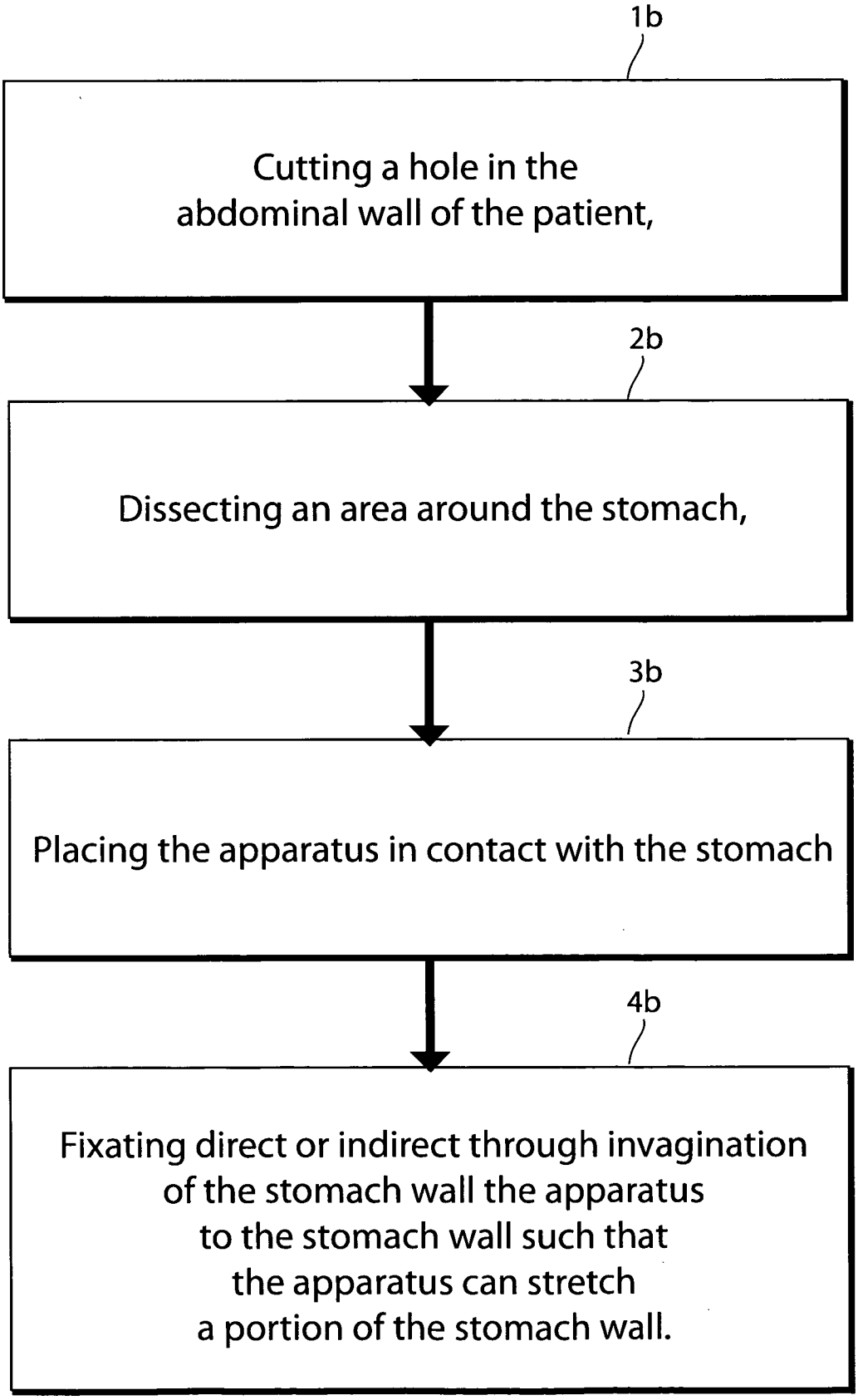

1a
Inserting an instrument into the esophagus of a patient.
2a
Inserting the apparatus into the stomach of the patient through the esophagus using the instrument.
3a
Placing the apparatus in contact with the stomach wall.
4a
Placing said apparatus in contact with the stomach wall.
5a
Fixating said apparatus to the stomach wall such that the apparatus can stretch a part of sadi stomach wall.

Fig.107


1b
Cutting a hole in the abdominal wall of the patient,
2b
Dissecting an area around the stomach,
3b
Placing the apparatus in contact with the stomach
4b
Fixating direct or indirect through invagination of the stomach wall the apparatus to the stomach wall such that the apparatus can stretch a portion of the stomach wall.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2009/000052

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
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)

IPC: A61F

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

SE,DK,FI,NO classes as above

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

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20050261712 A1 (D.J. BALBIERZ ET AL), 24 November 2005 (24.11.2005), figures 10,18,19, paragraphs (0045), (0046) --	1-271
A	WO 2005105003 A1 (SYNECOR, LLC), 10 November 2005 (10.11.2005), figures 10,18,19, abstract --	1-271
A	US 20050245957 A1 (W.L. STARKEBAUM ET AL), 3 November 2005 (03.11.2005), figures 4-9 --	1-271
A	US 5297536 A (P.J. WILK), 29 March 1994 (29.03.1994), figure 4, abstract --	96-99

[X] Further documents are listed in the continuation of Box C. [X] 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
15 June 2009	15 -06- 2009
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Tomas Lund /MRo Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2009/000052

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2004019765 A2 (SATIETY, INC.), 11 March 2004 (11.03.2004), figures 4,5, abstract ---	1-271
A	WO 0167964 A2 (MEDIGUS LTD.), 20 Sept 2001 (20.09.2001), figures 6-7,10-11 ---	1-271
A	US 20030055442 A1 (M.D. LAUFER ET AL), 20 March 2003 (20.03.2003), figures 1-8 ---	1-271
A	WO 0158391 A1 (OBTECH MEDICAL AG), 16 August 2001 (16.08.2001), figures 1-17, claims --- --------	1-271

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2009/000052

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.: 95-128
because they relate to subject matter not required to be searched by this Authority, namely:

See extra sheet.

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 any 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.

Box II.1

Claims 95-128 relates to a method for treatment of the human or animal body by surgery or by therapy, see PCT rule 39.1(iv). Nevertheless, a search has been made for these claims. The search has been directed to the technical content of the claims.

International patent classification (IPC)

A61F 5/00 (2006.01)
A61F 2/04 (2006.01)

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Use the application number as username. The password is **PJNHYXZCUU**.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.

US	20050261712	A1	24/11/2005	NONE			
WO	2005105003	A1	10/11/2005	EP	1740132	A	10/01/2007
US	20050245957	A1	03/11/2005	NONE			
US	5297536	A	29/03/1994	US	5458131	A	17/10/1995
WO	2004019765	A2	11/03/2004	AU	2003263029	A	19/03/2004
				BR	0313950	A	12/07/2005
				EP	1545311	A	29/06/2005
				US	20070118160	A	24/05/2007
				US	20070162059	A	12/07/2007
				US	20070167962	A	19/07/2007
WO	0167964	A2	20/09/2001	AT	295122	T	15/05/2005
				AU	3952501	A	24/09/2001
				AU	2001239525	B	02/12/2004
				CA	2403013	A	20/09/2001
				DE	60110761	D,T	04/05/2006
				EP	1265537	A,B	11/05/2005
				JP	2003526439	T	09/09/2003
				MX	PA02008996	A	15/10/2004
				NZ	521288	A	24/12/2004
				US	7156863	B	02/01/2007
				US	20010056282	A	27/12/2001
US	20030055442	A1	20/03/2003	NONE			
WO	0158391	A1	16/08/2001	AU	767248	B	06/11/2003
				AU	3427501	A	20/08/2001
				BR	0108140	A	05/03/2003
				CA	2398493	A	16/08/2001
				CN	1262254	C	05/07/2006
				CN	1426291	A	25/06/2003
				EP	1253884	A	06/11/2002
				MX	PA02007707	A	17/10/2002
				US	6450946	B	17/09/2002

专利名称(译)	用于治疗肥胖症的装置和方法		
公开(公告)号	EP2240137A1	公开(公告)日	2010-10-20
申请号	EP2009706524	申请日	2009-01-29
[标]申请(专利权)人(译)	米卢克斯控股股份有限公司		
申请(专利权)人(译)	MILUX HOLDING SA		
当前申请(专利权)人(译)	MILUX HOLDING SA		
[标]发明人	FORSELL PETER		
发明人	FORSELL, PETER		
IPC分类号	A61F5/00 A61F2/04 A61B1/04 A61B1/273 A61B1/313 A61B17/00 A61B17/04 A61B17/064 A61B17/068 A61B17/08 A61B17/30 A61B17/32 A61B17/34 A61N1/36		
CPC分类号	A61F5/0036 A61F5/0063 A61B17/00234 A61B17/0469 A61B17/068 A61B17/0682 A61B2017/00278 A61B2017/00561 A61B2017/00818 A61B2017/00827 A61B2017/306 A61B2017/308 A61F2/04 A61F5/0003 A61F5/0013 A61F5/0026 A61F5/003 A61F5/0033 A61F5/004 A61F5/0043 A61F5/0046 A61F5/005 A61F5/0069 A61F5/0073 A61F5/0076 A61F5/0079 A61F5/0086 A61F5/0089 A61F2005/0016 A61F2005/002 A61F2005/0023 A61F2250/0001 A61F2250/0004 A61N1/36007 A61B1/04 A61B1/2736 A61B1/3132 A61B17/00 A61B17/064 A61B17/08 A61B17/30 A61B17/320016 A61B17/3423 A61B17/3474 A61B2017/081 A61F2002/044 A61F2002/045		
优先权	61/006719 2008-01-29 US 0802138 2008-10-10 SE		
其他公开文献	EP2240137A4		
外部链接	Espacenet		

摘要(译)

本发明涉及一种回流疾病治疗装置，其包括将贲门保持在正确位置的可植入运动限制装置和适于与患者的贲门括约肌接合的可植入刺激装置。本发明还包括用于控制刺激装置以刺激贲门括约肌的控制装置。本发明可以与治疗肥胖症的各种方法组合，特别是通过拉伸胃壁或填充一定体积的胃来产生饱腹感的方法。