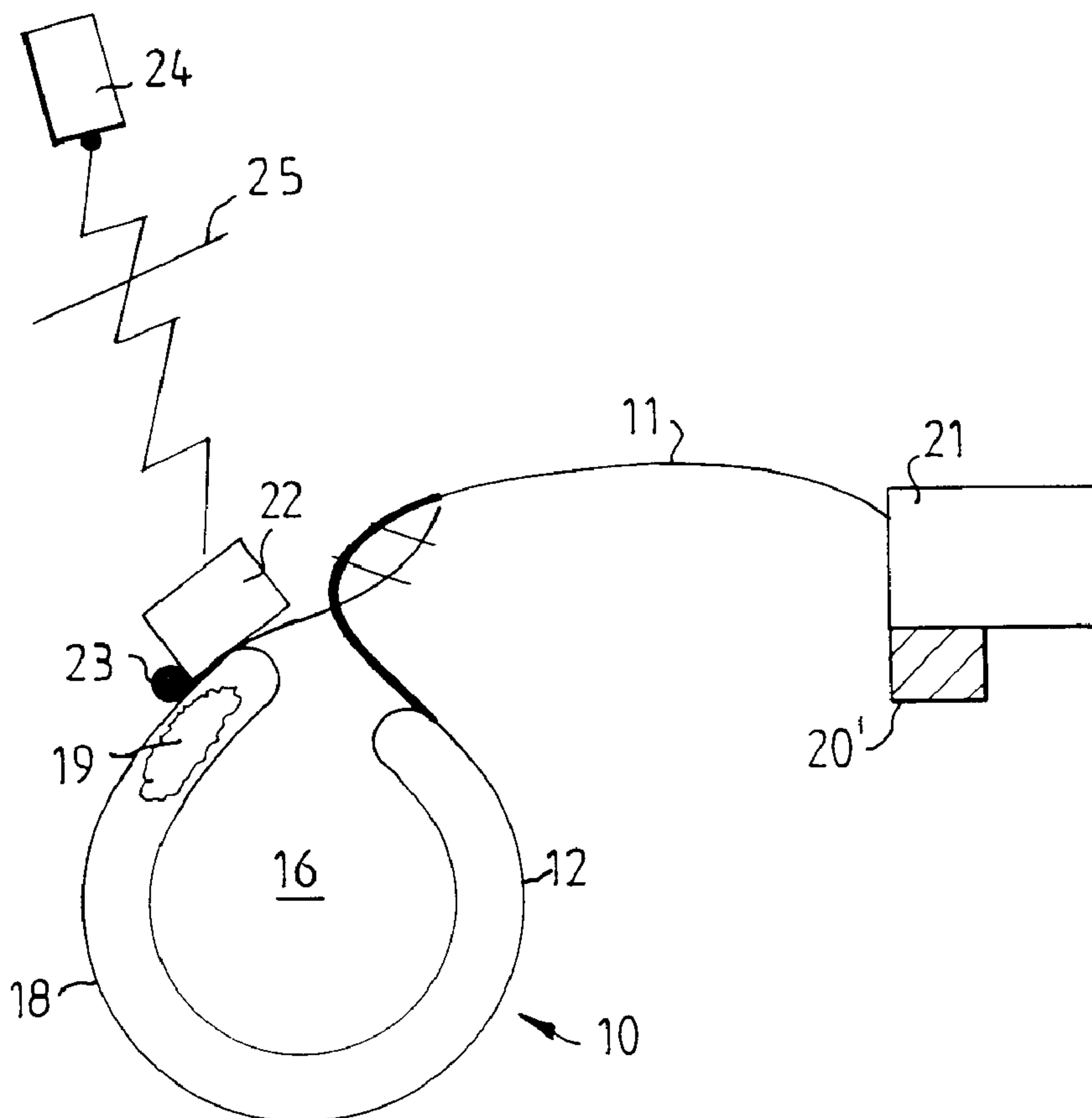




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 (54) Title: STOMA OPENING FORMING APPARATUS



(57) Abrégé/Abstract:

An apparatus for forming a stoma opening is used for the treatment of morbid obesity or heartburn and reflux disease. An implanted elongated restriction member (12) of the apparatus is formed in a substantially closed loop around a human's stomach

(57) **Abrégé(suite)/Abstract(continued):**

or esophagus to define a restriction opening (16), whereby a corresponding stoma opening is formed in the stomach or esophagus. The size of the restriction opening is adjustable by an implanted adjustment device. A control device (22) is utilized to control the adjustment device, in order to either reduce or enlarge the size of the restriction opening. Nausea in a treated obese human can be minimized or substantially eliminated as a result of the control device controlling the adjustment device to keep the restriction opening substantially fully open between meals (such as at night when the human is sleeping). A sensor (23), such as a pressure or position sensor, is surgically implanted in the human's body so that the sensor may either directly or indirectly sense a physical parameter of the human, such as the pressure in the stomach or the human's orientation with respect to the horizontal. If in response to sensing by the sensor it is determined by the control device that a significant change in the physical parameter has occurred, then the control device controls the adjustment device to either reduce or enlarge the size of the restriction opening.

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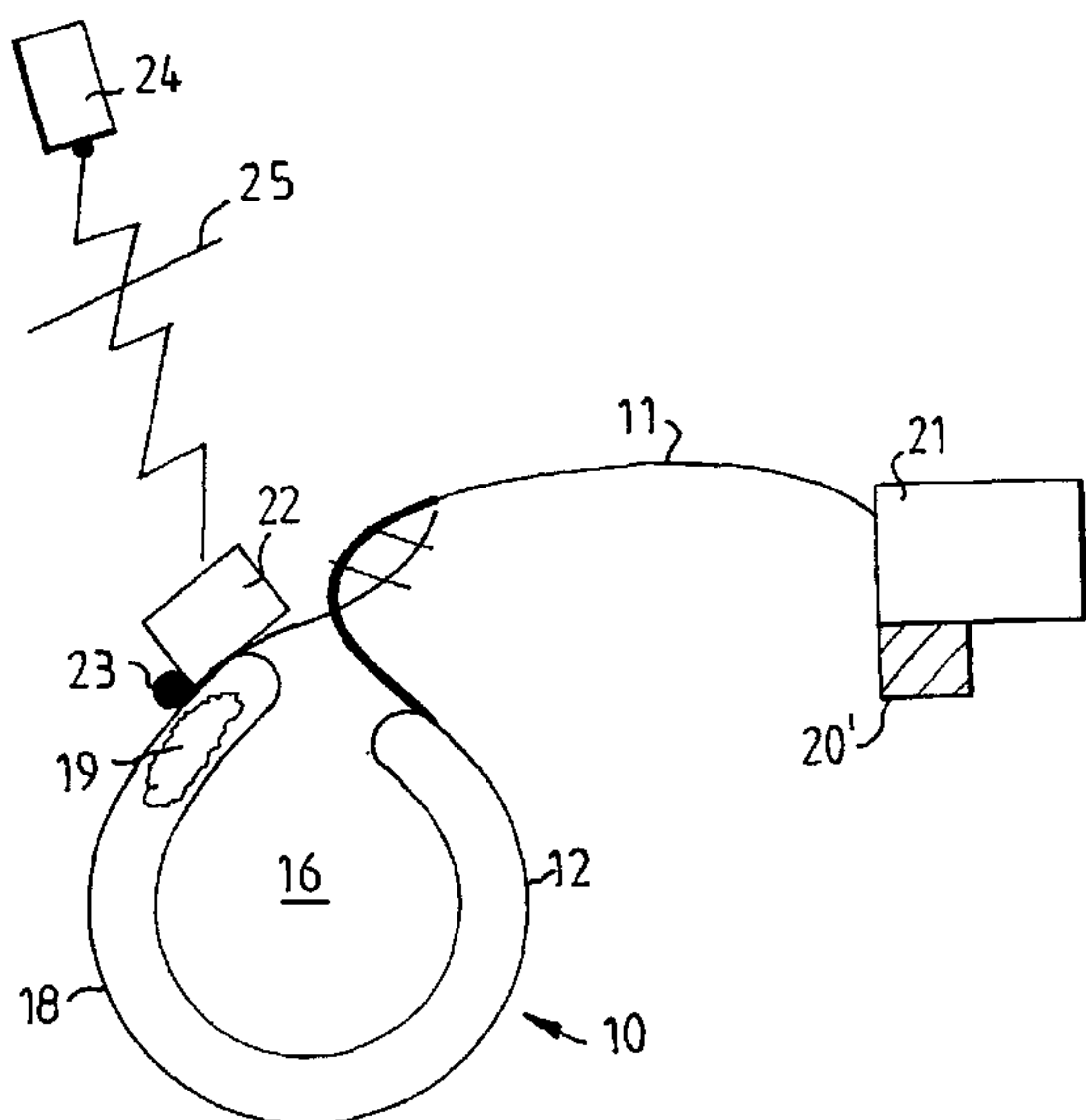
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(54) Title: STOMA OPENING FORMING APPARATUS



(57) Abstract: An apparatus for forming a stoma opening is used for the treatment of morbid obesity or heartburn and reflux disease. An implanted elongated restriction member (12) of the apparatus is formed in a substantially closed loop around a human's stomach or esophagus to define a restriction opening (16), whereby a corresponding stoma opening is formed in the stomach or esophagus. The size of the restriction opening is adjustable by an implanted adjustment device. A control device (22) is utilized to control the adjustment device, in order to either reduce or enlarge the size of the restriction opening. Nausea in a treated obese human can be minimized or substantially eliminated as a result of the control device controlling the adjustment device to keep the restriction opening substantially fully open between meals (such as at night when the human is sleeping). A sensor (23), such as a pressure or position sensor, is surgically implanted in the human's body so that the sensor may either directly or indirectly sense a physical parameter of the human, such as the pressure in the stomach or the human's orientation with respect to the horizontal. If in response to sensing by the sensor it is determined by the control device that a significant change in the physical parameter has occurred, then the control device controls the adjustment device to either reduce or enlarge the size of the restriction opening.

WO 01/12078 A1

STOMA OPENING FORMING APPARATUS

The present invention relates to an apparatus for forming a stoma opening in the stomach or esophagus of a patient. The apparatus comprises an implantable elongated restriction member adapted to be formed into a substantially closed loop around the patient's stomach or esophagus, so that the loop defines a restriction opening.

This kind of apparatus in the form of a gastric banding device, in which a band encircles a portion of a patient's stomach to restrict the food intake of the patient, have been used in surgery for morbid obesity to form a small gastric pouch above the band and a reduced stoma opening in the stomach. Although such a band is applied around the stomach to obtain an optimal stoma opening during surgery, some prior gastric banding devices are provided with an adjustment means enabling a minor post-operation adjustment of the size of the stoma opening. In all such prior art devices, such as disclosed in U.S. Patent No. 4 592 339, European Patent No. 0611561 and International Patent Application WO 94/27504, the adjustment means typically comprises an inflatable cavity in the band and an injection port in fluid connection with the inflatable cavity. The injection port is subcutaneously implanted to allow the addition of fluid to or withdrawal of fluid from the cavity by an injection needle penetrating the patient's skin and passing into the injection port. In practice, the band is made of silicone which is a material approved for implantation and the fluid is a liquid such as an isotonic salt solution mixed with other conventional materials.

Thus, the only way for a patient carrying a gastric band of the type used in the above-discussed prior art devices to have the

2

stoma opening adjusted is by visiting a doctor or nurse who is able to use an injection needle for withdrawing some liquid from or adding some liquid to the band. However, a problem with the prior art devices is that when the patient lies in bed sleeping it may
5 happen that the stoma opening is completely closed by the stomach wall, which might cause the patient to vomit and feel sick. In such a situation the patient normally has no doctor or nurse available.

The kind of apparatus presented initially has also been used for treating heartburn and reflux disease due to hiatal hernia,
10 *i.e.* a portion of the stomach immediately below the gastric fundus slides upwardly through the esophageal hiatus. In consequence, stomach acids and foods are regurgitated into the esophagus. In the late 1970s a prior art prosthesis called Angelchik, according to U.S. Patent No. 3 875 928, was used to operatively treat heartburn
15 and reflux disease. However, the Angelchik prosthesis had a major disadvantage in that it was not possible to adjust the size of the restriction opening after the operation. A further disadvantage was that the prosthesis did not satisfactorily protect the esophagus and the surrounding area against injuries due to poor shape of the
20 prosthesis. Therefore, operations using the Angelchik prosthesis are no longer practised.

An operation technique, semi-fundoduplicatio, is currently in use for treating heartburn and reflux disease. A most common operation is Nissen semi-fundoduplicatio, in which one takes the
25 fundus of the stomach and makes a three quarter of a turn around the esophagus and sutures between the stomach and esophagus. Although this operation works fairly well it has three main disadvantages. Firstly, most patients treated in accordance to semi-fundoduplicatio lose their ability to belch. Secondly, many of
30 these patients get dysphagia, *i.e.* difficulties to swallow after

30533-10

3

the operation. Thirdly, it is not possible to adjust the stoma opening in the esophagus or stomach in any way after the operation. Characteristic for these patients is the variation of their problems over the day. For example, many
5 patients have difficulties during the night when they lie down because of stomach acid leaking up into the esophagus.

The prime aspect of the present invention is to provide a new apparatus for forming a stoma opening in the stomach or esophagus of a patient, wherein the new apparatus
10 is suited for treating obese patients as well as patients suffering from heartburn and reflux disease.

Another aspect of the present invention is to provide a new convenient apparatus for forming a stoma opening, which practically eliminates the patient's need for
15 visiting a doctor or nurse in order to adjust the stoma opening so that the patient always is satisfied.

Accordingly, embodiments of the present invention provide an apparatus for forming a stoma opening in the stomach or esophagus of a patient, the apparatus comprising
20 an implantable elongated restriction member adapted to be formed into a substantially closed loop around the patient's stomach or esophagus, so that the loop defines a restriction opening, an implantable adjustment device for adjusting the
25 restriction member in the loop to change the size of the restriction opening, and a control device for controlling the adjustment device to adjust the restriction member to change the size of the restriction opening. Hereby the
patient's stoma opening will be similarly adjusted when the elongated restriction member is implanted in the patient.

30 In accordance with a preferred embodiment of the invention, the apparatus further comprises an implantable sensor for sensing

4

at least one physical parameter associated with the patient, in particular the pressure in the patient's stomach or esophagus, or the orientation of the patient with respect to the horizontal, wherein the control device is adapted to control the adjustment
5 device in response to the sensor sensing a change in the physical parameter.

The control device may comprise an implantable internal control unit for directly controlling the adjustment device in response to signals from the sensor. Alternatively, the control
10 device may comprise an external control unit outside the patient's body for directly or indirectly controlling the adjustment device in response to signals from the sensor. The external control unit may store information on the physical parameter sensed by the sensor and be manually operated to control the adjustment device
15 based on the stored information.

Conveniently, the apparatus may further comprise at least one implantable sender for sending information on the physical parameter sensed by the sensor.

In accordance with a particular embodiment of the invention,
20 the sensor comprises a pressure sensor for sensing as the physical parameter the pressure in the patient's stomach or esophagus. The pressure sensor may be any suitable known or conventional pressure sensor such as shown in U.S. patents 5 540 731, 4 846 181, 4 738 267, 4 571 749, 4 407 296 or 3 939 823; or an NPC-102 Medical
25 Angioplasty Sensor.

Preferably, the control device is adapted to control the adjustment device to change the size of the restriction opening in response to the pressure sensor sensing a change in the pressure in the stomach or esophagus.

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In the case of treating obese patients, in accordance with one embodiment of the invention the control device controls the adjustment device to reduce the restriction opening in response to the pressure sensor sensing a pressure, within a normal pressure range, equal to or exceeding a predetermined value, and to enlarge the restriction opening in response to the pressure sensor sensing a pressure below a predetermined value. The predetermined value is the pressure that normally occurs preferably in the stomach or, alternatively, in the esophagus soon after the patient has started to eat. Thus, food reaching the stomach causes an increase in the pressure in the stomach.

Between meals, for example at night, when the stomach is empty and the sensed pressure is well below the predetermined high pressure, the adjustment device can keep the restriction opening as large as possible, i.e. substantially fully open. As a result, the stoma opening will be relatively large, which minimizes the risk of the stoma opening closing completely. When the obese patient eats, so that the food entering the stomach increases the pressure therein, the restriction opening is reduced when the pressure sensor senses the predetermined value. Consequently, the obese patient's hunger is soon satisfied after a relatively small intake of food, which will lead to a reduction of the obese patient's weight.

In the case of treating patients suffering from heartburn and reflux disease, in accordance with another embodiment of the invention, the control device controls the adjustment device to enlarge the restriction opening in response to the pressure sensor sensing a pressure, within a normal pressure range, equal to or exceeding a predetermined value, and to reduce or close the restriction opening in response to the pressure sensor sensing a

6

pressure below a predetermined value. The predetermined value is the pressure that occurs preferably in the esophagus or, alternatively, in the stomach soon after the patient has started to eat. Thus, food reaching the esophagus (or stomach) causes an
5 increase in the pressure in the esophagus (or stomach).

Between meals, for example at night, when the stomach is empty and the sensed pressure is well below the predetermined value, the control device controls the adjustment device to adjust the restriction device to close the stoma opening. Consequently, the
10 restriction device will work as an artificial sphincter.

In addition to or as an alternative to the two embodiments described above related to the treatment of obese patients and patients suffering from heartburn and reflux disease in which normal pressures in the stomach or esophagus are sensed, the
15 control device may be adapted to control the adjustment device to enlarge the restriction opening in response to the pressure sensor sensing a pressure equal to or exceeding an excessively high value which is injurious to the patient. For example, an injurious pressure can occur in the stomach or esophagus if a large piece of
20 food get stuck in the stoma opening. By enlarging the restriction opening the piece of food will be able to pass through the correspondingly enlarged stoma opening.

Conveniently, the pressure sensor may indirectly sense the pressure in the stomach by sensing the pressure exerted by the
25 stomach or esophagus against the restriction member.

In accordance with another particular embodiment of the invention, the sensor comprises a position sensor for sensing as the physical parameter the orientation of the patient with respect to the horizontal. The position sensor may be a biocompatible
30 version of what is shown in U.S. patents 4 942 668 and 5 900 909.

7

In the case of treating an obese patient, the control device controls the adjustment device to increase the restriction opening in response to the position sensor sensing that the patient has assumed a substantially horizontal orientation, *i.e.* that the patient is lying.

In the case of treating a patient suffering from heartburn and reflux disease, the control device controls the adjustment device to reduce or close the restriction opening in response to the position sensor sensing that the patient has assumed a substantially horizontal orientation, *i.e.* that the patient is lying.

Alternatively, the apparatus may further comprise such a position sensor in addition to the above described pressure sensor.

The control device may control the adjustment device in response to the time of day and for that purpose it suitably comprises a clock mechanism used for controlling the adjustment device to adjust the restriction member to keep the restriction opening at different sizes during different time periods of the day. In case a sensor of any of the above described types (pressure or position sensor) is provided, the clock mechanism is used for controlling the adjustment device provided that the physical parameter sensed by the sensor does not override the clock mechanism.

Preferably, the control device comprises an internal control unit to be implanted in the patient and a wireless remote control adapted to set control parameters of the internal control unit from outside the patient without mechanically penetrating the patient, when the internal control unit is implanted in the patient. At least one of the control parameters, which is settable by the wireless remote control, is the physical parameter. Suitably, the

wireless remote control may set the above mentioned clock mechanism.

For example the wireless remote control may comprise a signal (e.g. electromagnetic or sound waves, magnetic energy, digital pulses, etc.) transmitter, an implantable signal receiver, and an implantable energizer unit for transforming wireless energy from the signals, as they are transmitted from the transmitter to the signal receiver, into energy different than the wireless energy for energizing the adjustment device and/or the sensor. Alternatively, the apparatus may comprise an implantable battery or accumulator, such as a capacitor, for energizing the adjustment device and/or the sensor.

The adjustment device may comprise an expandable cavity in the restriction member, the size of the restriction opening being reduced upon expansion of the cavity and increased upon contraction of the cavity, and a reservoir for hydraulic fluid (e.g. a salt solution). In this case the adjustment device is adapted to distribute hydraulic fluid from the reservoir to expand the cavity, and to distribute hydraulic fluid from the cavity to the reservoir to contract the cavity, to thereby change the size of the restriction opening. The reservoir may be attached or fixed to the restriction member, or integrated therewith. Further, the adjustment device comprises a pump for pumping fluid between the cavity and the reservoir, and adapted to be subcutaneously implanted in the patient remote from the restriction member. Alternatively, the pump may be attached or fixed to the restriction member. In accordance with a preferred embodiment of the invention, the reservoir, pump and restriction member form a single piece, suitably together with the sensor.

Alternatively, the restriction member may be non-inflatable, which has the advantage that the risk of fluid leaking from the restriction member is avoided. In this case it is preferred to use an adjustment device which is designed to mechanically adjust the
5 non-inflatable restriction member.

Suitably, an implantable battery or accumulator, such as a capacitor, may be provided for energizing the adjustment device and/or the sensor.

The invention is not limited to sensing the pressure in the
10 patient's stomach or esophagus, or the patient's orientation with respect to the horizontal, but may sense a wide variety of other physical parameters associated with the patient, such as parameters associated with rest or sleep, etc.

By using the apparatus of the present invention for treating
15 an obese patient it is possible to minimize or eliminate nausea in the patient. Thus, a sensor of the apparatus is surgically implanted in the patient, at least one physical parameter of the patient is sensed using the sensor, and if in response to the sensor it is determined that a significant change has occurred in
20 the physical parameter the adjustment device is controlled to enlarge the restriction opening (e.g. open it substantially fully), so that nausea is minimized or substantially eliminated. Where the sensor is a pressure sensor, the restriction opening is substantially fully open when the pressure in the stomach is at a
25 pressure value commonly occurring when the obese patient is sleeping at night, or other between meal times. Where the sensor is a position sensor, the adjustment device is controlled to enlarge the restriction opening if the obese patient is substantially horizontal.

30533-10

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An internal control unit of the control device may be implanted in the patient at substantially the same time as the sensor, so that the internal control unit is mounted on the restriction member, or at some other location associated with the implant. Suitably, the internal control unit is operated exteriorly of the patient in a non-invasive manner to control the adjustment device.

According to another aspect of the present invention, there is provided an apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising: an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus, an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening, an implanted sensor for sensing at least one physical parameter associated with the patient, and a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter; wherein said control device comprises an external control unit outside the patient's body for controlling said adjustment device in response to signals from said sensor; and wherein said external control unit directly controls said adjustment device in response to signals from said sensor.

According to another aspect of the present invention, there is provided an apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising: an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach

30533-10

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or esophagus, an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening, an implanted sensor for sensing at least one physical parameter associated with the patient, and a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter; wherein said control device comprises an external control unit outside the patient's body for controlling said adjustment device in response to signals from said sensor; and wherein said external control unit stores information on said physical parameter sensed by said sensor and is manually operated to control said adjustment device based on said stored information.

15 According to another aspect of the present invention, there is provided an apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising: an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus, an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening, an implanted sensor for sensing at least one physical parameter associated with the patient, and a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter; and at least one implanted sender for sending information on said physical parameter sensed by said sensor.

 According to another aspect of the present invention, there is provided an apparatus for controlling the food flow through the stomach or esophagus of a patient,

30533-10

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the apparatus comprising: an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus, an implanted adjustment device for adjusting
5 said restriction device to change the size of the stoma opening, an implanted sensor for sensing at least one physical parameter associated with the patient, and a control device which controls said adjustment device to adjust said restriction device to change the size of the
10 stoma opening in response to said sensor sensing a change in said physical parameter; wherein said sensor comprises a pressure sensor for sensing as said physical parameter the pressure in the patient's stomach or esophagus; and wherein said pressure sensor indirectly senses the pressure in the
15 stomach or esophagus by sensing the pressure exerted by the stomach or esophagus against said restriction member.

According to another further aspect of the present invention, there is provided an apparatus for controlling the food flow through the stomach or esophagus of a patient,
20 the apparatus comprising: an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus, an implanted adjustment device for adjusting said restriction device to change the size of the stoma
25 opening, an implanted sensor for sensing at least one physical parameter associated with the patient, and a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in
30 said physical parameter; and wherein said sensor comprises a position sensor for sensing as said physical parameter the orientation of the patient with respect to the horizontal.

30533-10

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According to another aspect of the present invention, there is provided an apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising: an implanted adjustable
5 restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus, an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening, an implanted sensor for sensing at least one
10 physical parameter associated with the patient, and a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter; and wherein said adjustment device
15 comprises an expandable cavity in said restriction device and the size of said stoma opening is reduced upon expansion of said cavity and increased upon contraction of said cavity, and further comprises a reservoir for hydraulic fluid, said adjustment device distributing hydraulic fluid
20 from said reservoir to expand said cavity and withdraw hydraulic fluid from said cavity to said reservoir to contract said cavity, to thereby change the size of said stoma opening.

According to another aspect of the present
25 invention, there is provided an apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising: an implanted adjustable restriction device engaging the patient's stomach or
esophagus to form a restricted stoma opening in the stomach
30 or esophagus, an implanted adjustment device for adjusting said restriction device to change the size of said stoma opening, and a control device which controls said adjustment device to adjust said restriction device to change the size

30533-10

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of said stoma opening in response to the time of day; and wherein said adjustment device comprises an expandable cavity in said restriction device and the size of said stoma opening is reduced upon expansion of said cavity and
5 increased upon contraction of said cavity, and further comprising a reservoir for hydraulic fluid, said adjustment device distributing hydraulic fluid from said reservoir to expand said cavity and withdraw hydraulic fluid from said cavity to said cavity to said reservoir to contract said
10 cavity, to thereby change the size of said stoma opening.

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

FIGURE 1 is a schematic perspective view of the
15 torso of an obese human having an apparatus for forming a stoma opening according to an exemplary embodiment of the invention, showing internal body portions of the human schematically for clarity of illustration;

FIGURE 2 is a schematic side view, with portions
20 cut away for clarity of illustration, of an exemplary apparatus according to the exemplary embodiment of the invention used in the human body as illustrated in FIGURE 1; and

FIGURE 3 is a view like that of FIGURE 2 only of
25 another exemplary embodiment according to the invention.

An apparatus according to the present invention for forming a stoma opening in the stomach (or esophagus) of an obese human patient is illustrated schematically at 10 in FIGURES 1 and 2. The apparatus 10 includes an elongated
30 restriction member 12, such as a gastric band, which is surgically implanted in the human body 13 around the human's

30533-10

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stomach 14 or - as shown in the embodiment of FIGURE 1 -
both the stomach and esophagus 15 to form a stoma opening
between an upper small pouch of the stomach 14 and a lower
major portion of the stomach 14. The elongated restriction
5 member

12 is formed into a substantially closed loop, the loop defining a restriction opening, such as illustrated schematically at 16 in FIGURE 2 (FIGURE 2 shows the opening 16 dimensioned, compared to the illustration in FIGURE 1, in a manner whereby it would be
5 disposed around the stomach 14 rather than the esophagus 15).

In the case of treating a human patient suffering from heartburn and reflux disease, the restriction member 12 would be applied around the esophagus or around an upper portion of the stomach close to the cardia without forming the upper pouch of the
10 stomach illustrated in FIGURE 1.

The restriction member 10 includes an adjustment device, which may be of any suitable type. In the embodiment illustrated in FIGURE 2 the adjustment device comprises an expandable element 18 integrated with the band 12 and defining an interior cavity 19. An
15 implanted pump 20 remote from the band 12 is connected thereto via a fluid conduit 11. The pump 20 is fixed to a reservoir, likewise implanted, for hydraulic fluid, shown generally at 21 in FIGURE 2. The hydraulic fluid would be any suitable substantially
incompressible fluid, which will not cause severe illness or injury
20 to the human if it were to leak from the reservoir 21 or the cavity 19, such as a salt solution. By pumping hydraulic fluid from the reservoir 21 through the conduit 11 into the cavity 19, the pump 20 causes the element 18 to expand thereby reducing the size of the opening 16, whereas by pumping hydraulic fluid out of the cavity 19
25 into the reservoir 21 the pump 20 causes the element 18 to contract, causing the opening 16 to enlarge.

The pump 20 may be controlled by a control unit 22. While the control unit 22 may be mounted exteriorly of the body 13, in the preferred embodiment the control unit 22 is mounted within the body

12

13, preferably on the elongated restriction member 12, and adjacent the cavity 19. Electrical interconnections (not shown) are provided between the control unit 22 and the pump 20. A battery for operating the control unit 22 and pump 20 may be provided right
5 within the control unit 22. Alternatively, a power source for powering the control unit 22 and the pump 20 may be located exteriorly of the body 13. Energy from such an exterior power source may be wirelessly transmitted to implanted energy consuming components.

10 A pressure sensor 23, shown schematically in FIGURE 2, is implanted in the body 13 of the human patient for sensing the pressure in the stomach 14. For example, in the embodiment illustrated in FIGURE 2 the pressure sensor 23 is mounted on the restriction member 12 and indirectly senses the pressure in the
15 stomach 14 by sensing the pressure exerted by the stomach against the expandable element 18. However, the sensor 23 may be mounted directly on the inner side of the elongated restriction member 12 at a location remote from the cavity 19 to directly abut the stomach, or any other suitable mounting may be provided as long as
20 the pressure sensor 23 is able to sense the pressure or related value within stomach 14 that is caused when food is ingested by the human patient.

The sensor 23 may be any suitable known or conventional sensor which is capable of performing the functions as set forth above.
25 Some non-limiting examples of implantable sensors include those described in U.S. patents 5 540 731, 4 846 181, 4 738 267, 4 571 749, 4 407 296 or 3 939 823, and the NPC-102 Medical Angioplasty Sensor.

Alternatively the adjustment device may mechanically adjust the restriction member 12, e.g. a motor may be provided to adjust member 12.

The control unit 22 may be of the type which communicates
5 effectively with a wireless remote control 24 illustrated schematically in FIGURE 2, with the zig-zag line between the elements 22, 24 indicating wireless communication therebetween, and the solid cross line 25 indicating that the remote control 24 is exterior of the body 13. The remote control 24 may be for setting
10 control parameters of the control unit 22 from outside the body 13 without mechanically penetrating the human patient. One of the control parameters which is settable by the device 24 may be the predetermined pressure values that the sensor 23 senses and communicates to the control unit 22 (either by electrical
15 connections, or in a wireless manner) to cause the pump 20 to operate and hydraulic fluid to be removed from or pumped into the cavity 19. Wireless energy carrying signals from the remote control 24 may be electromagnetic or sound or other types of waves, magnetic transfer, or digital pulses.

20 In one embodiment of the invention the control unit 22 may include a clock mechanism mounted on the restriction member 12 and used for controlling the adjustment device 17 to adjust the restriction member 12 to keep the restriction opening 16 at different sizes during different time periods of the day, provided
25 that the pressure sensed by the pressure sensor 23 does not exceed a predetermined value (which would indicate food in the stomach 14). For example in the middle of the night when it is expected that the obese human would have little or no food in his/her stomach 14, the control unit 22 would automatically operate the

pump 20 to pump fluid out of the cavity 19 into the reservoir 21 so as to substantially fully open the restriction opening 16, whereas at other times of the day the pump 20 could be controlled to vary the size of the restriction opening 16 from the maximum to a
5 minimum value.

The remote control 24 may be used to set the clock mechanism 22.

For example, the wireless remote control 24 may comprise a signal transmitter, and a signal receiver may be implanted within
10 the body 13 (e.g. as part of the control unit 22), and an energizer unit may also be implanted in the body 13 (e.g. as part of the control unit 22) for transforming wireless energy from the signals as they are transmitted to the signal receiver into energy different than the wave energy, for example electrical energy, for
15 energizing the adjustment device (e.g. by operating the pump 20) and sensor 23. Alternatively a battery may be implanted in the body 13 (e.g. as part of the control unit 22) for energizing the adjustment device (e.g. the pump 20) and sensor 23, or an accumulator (such as a capacitor) may be implanted in the patient
20 for energizing the adjustment device and sensor 23.

The present invention also provides a method for minimizing or eliminating nausea in an obese human having an apparatus 10, as a result of the stoma opening 16 substantially closing between meals. The method comprises: (a) Implanting (e.g. with a conventional
25 surgical procedure) the adjustment device and pressure sensor 23 in the obese human's body 13 operatively associated with the restriction opening 16. (b) Sensing the pressure in the stomach 14; and (c) if in response to (b) it is determined that the pressure is below a predetermined value (indicating little or no

food in the stomach 14), then controlling the adjustment device to substantially fully open the restriction opening 16, so that nausea is minimized or substantially eliminated. In the method (b) and (c) may be practised to substantially fully open the restriction opening 16 when the pressure in the stomach is at a pressure value commonly occurring when the human is sleeping at night.

The method may further comprise implanting the control unit 22 in the human's body 13 at substantially the same time that (a) is practised so that the control unit 22 is mounted on the restriction member 12 or at some other location associated with the implant, and operating the control unit 22 exteriorly of the human in a non-invasive manner (as by using the remote control 24) to control the adjustment device.

Furthermore, the invention provides a method of treating morbid obesity in a human comprising: (a) Surgically implanting (preferably in a laparoscopic surgery) in the human an elongated restriction member 12 defining a substantially closed loop (see FIGURE 2) around the human's stomach 14 or esophagus 15, defining a restriction opening 16. (b) Surgically implanting in the human an adjustment device which adjusts the restriction opening 16, and a pressure sensor 23 for sensing the pressure in the humans' stomach 14. (c) In response to sensing by the pressure sensor 23 of a pressure in the human's stomach 14 greater than a predetermined amount, controlling the adjustment device to reduce the size of the opening 16. And (d) in response to sensing by the pressure sensor 23 of a pressure less than a predetermined amount in the human stomach 14, controlling the adjustment device to substantially fully open the opening 16. The method may also comprise (e) controlling the adjustment device in response to the time of day

(e.g. using a clock mechanism as described above, e.g. as part of the control unit 22) to vary the restriction opening 16 unless overridden by the pressure sensor 23 sensing pressure in the stomach 14 that would cause the stoma opening to be less than fully
5 open, or "closed" (that is having a minimize size substantially preventing further passage of food particles into the stomach, or a part thereof).

FIGURE 3 shows an embodiment similar to that of FIGURE 2 with comparable components shown by the same reference numbers only
10 preceded by a "1". In the FIGURE 3 embodiment, however, two chambers 26,27 are separated from each other in a fluid tight manner by a partition wall 28, and the pump 120 pumps fluid from one chamber 26 to the other chamber 27 to change the size of the restriction opening 116. The sensor 123 may in this case be a
15 conventional position sensor, which senses the orientation of the patient with respect to the horizontal. Both the pump 120 and sensor 123 are fixed to the partition wall 28 inside the chambers 26,27. Conventional locking members 30 may be used to hold the elongated restriction member 112 in the formed loop. The control
20 unit 122 is implanted remote from the restriction member 112 and operably connected to the sensor 123 and pump 120 through a line 31. As in the other embodiments the control unit 122 may include an internal clock mechanism, and may be controlled from externally of the human by wireless remote control (like the remote control 24
25 in FIGURE 2). If desired a pressure sensor 23 may also be included.

Alternative or additional sensors which sense other physical parameters related to sleep or rest of the human in which the sensors are implanted may also or alternatively be utilized.

While the invention has been herein shown and described in a preferred practical embodiment for the treatment of obese humans, it is to be understood by those of ordinary skill in the art that also patients suffering from heartburn and reflux disease can be
5 treated with the apparatus 10 described, and many modifications may be made thereof within the scope of the invention, which scope is to be accorded the broadest interpretation of the appended claims so as to encompass all equivalent devices and methods.

30533-10

18

CLAIMS:

1. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising:

5 an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening,

10 an implanted sensor for sensing at least one physical parameter associated with the patient, and

a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a
15 change in said physical parameter;

wherein said control device comprises an external control unit outside the patient's body for controlling said adjustment device in response to signals from said sensor;
and

20 wherein said external control unit directly controls said adjustment device in response to signals from said sensor.

2. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus
25 comprising:

an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

30533-10

19

an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening,

an implanted sensor for sensing at least one physical parameter associated with the patient, and

5 a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter;

10 wherein said control device comprises an external control unit outside the patient's body for controlling said adjustment device in response to signals from said sensor; and

15 wherein said external control unit stores information on said physical parameter sensed by said sensor and is manually operated to control said adjustment device based on said stored information.

3. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising:

20 an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening,

25 an implanted sensor for sensing at least one physical parameter associated with the patient, and

a control device which controls said adjustment device to adjust said restriction device to change the size

30533-10

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of the stoma opening in response to said sensor sensing a change in said physical parameter; and

at least one implanted sender for sending information on said physical parameter sensed by said
5 sensor.

4. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising:

an implanted adjustable restriction device
10 engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening,

an implanted sensor for sensing at least one
15 physical parameter associated with the patient, and

a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter;

20 wherein said sensor comprises a pressure sensor for sensing as said physical parameter the pressure in the patient's stomach or esophagus; and

wherein said pressure sensor indirectly senses the pressure in the stomach or esophagus by sensing the pressure
25 exerted by the stomach or esophagus against said restriction member.

5. An apparatus according to claim 4, wherein said control device controls said adjustment device to change the size of said stoma opening in response to said pressure

30533-10

21

sensor sensing to a change in the pressure in the stomach or esophagus.

6. An apparatus according to claim 5, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to reduce said stoma opening in response to said pressure sensor sensing a pressure equal to or exceeding the predetermined value.

7. An apparatus according to claim 5 or 6, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to enlarge said stoma opening in response to said pressure sensor sensing a pressure below a predetermined value.

8. An apparatus according to any one of claims 5-7, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to enlarge said stoma opening in response to said pressure sensor sensing a pressure equal to or exceeding too high value.

9. An apparatus according to claim 5, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to enlarge said stoma opening in response to said pressure sensor sensing a pressure equal to or exceeding a predetermined value.

10. An apparatus according to claim 5 or 9, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to reduce or close said stoma opening in response to

30533-10

22

said pressure sensor sensing a pressure below a predetermined value.

11. An apparatus according to any one of claims 5, 9 and 10, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to enlarge or fully open said stoma opening in response to said pressure sensor pressures in the stomach esophagus.

12. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising:

an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

15 an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening,

an implanted sensor for sensing at least one physical parameter associated with the patient, and

20 a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter; and

25 wherein said sensor comprises a position sensor for sensing as said physical parameter the orientation of the patient with respect to the horizontal.

13. An apparatus according to claim 12, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to increase said stoma opening in response

30533-10

23

to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

14. An apparatus according to claim 12, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to restrict or close said stoma opening in response to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

15. An apparatus according to claim 4, further comprising a position sensor for sensing the orientation of the patient with respect to the horizontal.

16. An apparatus according to claim 15, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to increase said stoma opening in response to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

17. An apparatus according to claim 15, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to restrict or close said stoma opening in response to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

18. An apparatus according to claim 1, wherein said control device comprises a clock mechanism used for controlling said adjustment device to adjust said restriction member to keep said stoma opening at different sizes during different time periods of the day.

19. An apparatus according to claim 18, wherein said clock mechanism is used for controlling said adjustment

30533-10

24

device provided that said physical parameter sensed by said sensor does not override said clock mechanism.

20. An apparatus according to claim 1, wherein said control device comprises an implanted internal control unit and a wireless remote control which sets control parameters of said internal control unit from outside the patient.

21. An apparatus according to claim 20, wherein at least one of said control parameters, which is settable by said wireless control, is associated with said physical parameter.

22. An apparatus according to claim 20 or 21, wherein said internal control unit includes a clock mechanism used for controlling said adjustment device to adjust said restriction device to keep said stoma opening at different sizes during different time periods of the day.

23. An apparatus according to claim 22, wherein said wireless remote control is capable of setting said clock mechanism.

24. An apparatus according to claim 1, wherein said control device comprises a wireless remote control.

25. An apparatus according to claim 24, wherein said wireless remote control transmits a signal and is capable of transforming wireless energy from said signal into energy for powering implanted energy consuming components of the apparatus.

26. An apparatus according to claim 25, wherein said wireless remote control comprises a signal transmitter for transmitting said signal, an implanted signal receiver, and an implanted energizer unit for transforming wireless energy from said signal, as they are transmitted from said signal

30533-10

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transmitter to said signal receiver, into said energy for powering implanted energy consuming components of the apparatus.

27. An apparatus according to claim 25, wherein said energy transformed from said wireless energy is used for energizing said implanted sensor.

28. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising:

10 an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening,

15 an implanted sensor for sensing at least one physical parameter associated with the patient, and

a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter; and

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wherein said adjustment device comprises an expandable cavity in said restriction device and the size of said stoma opening is reduced upon expansion of said cavity and increased upon contraction of said cavity, and further comprises a reservoir for hydraulic fluid, said adjustment device distributing hydraulic fluid from said reservoir to expand said cavity and withdraw hydraulic fluid from said cavity to said reservoir to contract said cavity, to thereby change the size of said stoma opening.

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30533-10

26

29. An apparatus according to claim 28, wherein said reservoir is attached to said restriction device.

30. An apparatus according to claim 28, wherein said reservoir is fixed to said restriction device.

5 31. An apparatus according to claim 28, wherein said reservoir is integrated with said restriction device.

32. An apparatus according to any one of claims 28-31, wherein said adjustment device comprises a pump for pumping fluid between said cavity and said reservoir.

10 33. An apparatus according to claim 32, wherein said pump is attached to said restriction device.

34. An apparatus according to claim 32, wherein said pump is fixed to said restriction device.

15 35. An apparatus according to claim 32, wherein said reservoir, pump and restriction device form a single piece.

36. An apparatus according to claim 32, wherein said reservoir, pump, sensor and restriction device form a single piece.

20 37. An apparatus according to claim 32, wherein said pump is subcutaneously implanted in the patient remote from said restriction device.

38. An apparatus according to claim 1, wherein said adjustment device mechanically adjusts said restriction device.

25 39. An apparatus according to claim 1, further comprising an implanted battery for energizing said adjustment device.

30533-10

27

40. An apparatus according to claim 1, further comprising an implanted accumulator for energizing said adjustment device.

41. An apparatus according to claim 40, wherein said
5 accumulator comprises a capacitor.

42. An apparatus according to claim 1, further comprising an implanted battery for energizing said sensor.

43. An apparatus according to claim 1, further comprising an implanted accumulator for energizing said
10 sensor.

44. An apparatus according to claim 43, wherein said accumulator comprises a capacitor.

45. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus
15 comprising:

an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

an implanted adjustment device for adjusting said
20 restriction device to change the size of said stoma opening, and

a control device which controls said adjustment device to adjust said restriction device to change the size of said stoma opening in response to the time of day; and

25 wherein said adjustment device comprises an expandable cavity in said restriction device and the size of said stoma opening is reduced upon expansion of said cavity and increased upon contraction of said cavity, and further comprising a reservoir for hydraulic fluid, said adjustment

30533-10

28

device distributing hydraulic fluid from said reservoir to expand said cavity and withdraw hydraulic fluid from said cavity to said cavity to said reservoir to contract said cavity, to thereby change the size of said stoma opening.

5 46. An apparatus according to claim 45, wherein said control device comprises a clock mechanism used for controlling said adjustment device to adjust said restriction device to keep stoma opening at different sizes during different time periods of the day.

10 47. An apparatus according to claim 45, wherein said control device comprises an implanted internal control unit and a wireless remote control which sets control parameters of said internal control unit from outside the patient.

15 48. An apparatus according to claim 47, wherein said internal control unit includes a clock mechanism used for controlling said adjustment device to adjust said restriction device to keep said stoma opening at different sizes during different time periods of the day.

20 49. An apparatus according to claim 48, wherein said wireless remote control is capable of setting said clock mechanism.

50. An apparatus according to claim 45, wherein said control device comprises a wireless remote control.

25 51. An apparatus according to claim 50, wherein said wireless remote control transmits signals and is capable of transforming wireless energy from said signals into energy for powering implanted energy consuming components of the apparatus.

30 52. An apparatus according to claim 51, wherein said wireless remote control comprises a signal transmitter for

30533-10

29

transmitting said signals, an implanted signal receiver, and an implanted energizer unit for transforming wireless energy from said signals, as they are transmitted from said signal transmitter to said signal receiver, into said energy for
5 powering implanted energy consuming components of the apparatus.

53. An apparatus according to claim 45, wherein said reservoir is attached to said restriction device.

54. An apparatus according to claim 45, wherein said
10 reservoir is fixed to said restriction device.

55. An apparatus according to claim 45, wherein said reservoir is integrated with said restriction device.

56. An apparatus according to claim 45, wherein said adjustment device comprises a pump for pumping fluid between
15 said cavity and said reservoir.

57. An apparatus according to claim 56, wherein said pump is attached to said restriction device.

58. An apparatus according to claim 56, wherein said pump is fixed to said restriction device.

20 59. An apparatus according to claim 56, wherein said reservoir, pump and restriction device form a single piece.

60. An apparatus according to claim 56, wherein said pump is subcutaneously implanted in the patient remote from said restriction device.

25 61. An apparatus according to claim 45, further comprising an implanted battery for energizing said adjustment device.

30533-10

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62. An apparatus according to claim 45, further comprising an implanted accumulator for energizing said adjustment device.

63. An apparatus according to claim 62, wherein said
5 accumulator comprises a capacitor.

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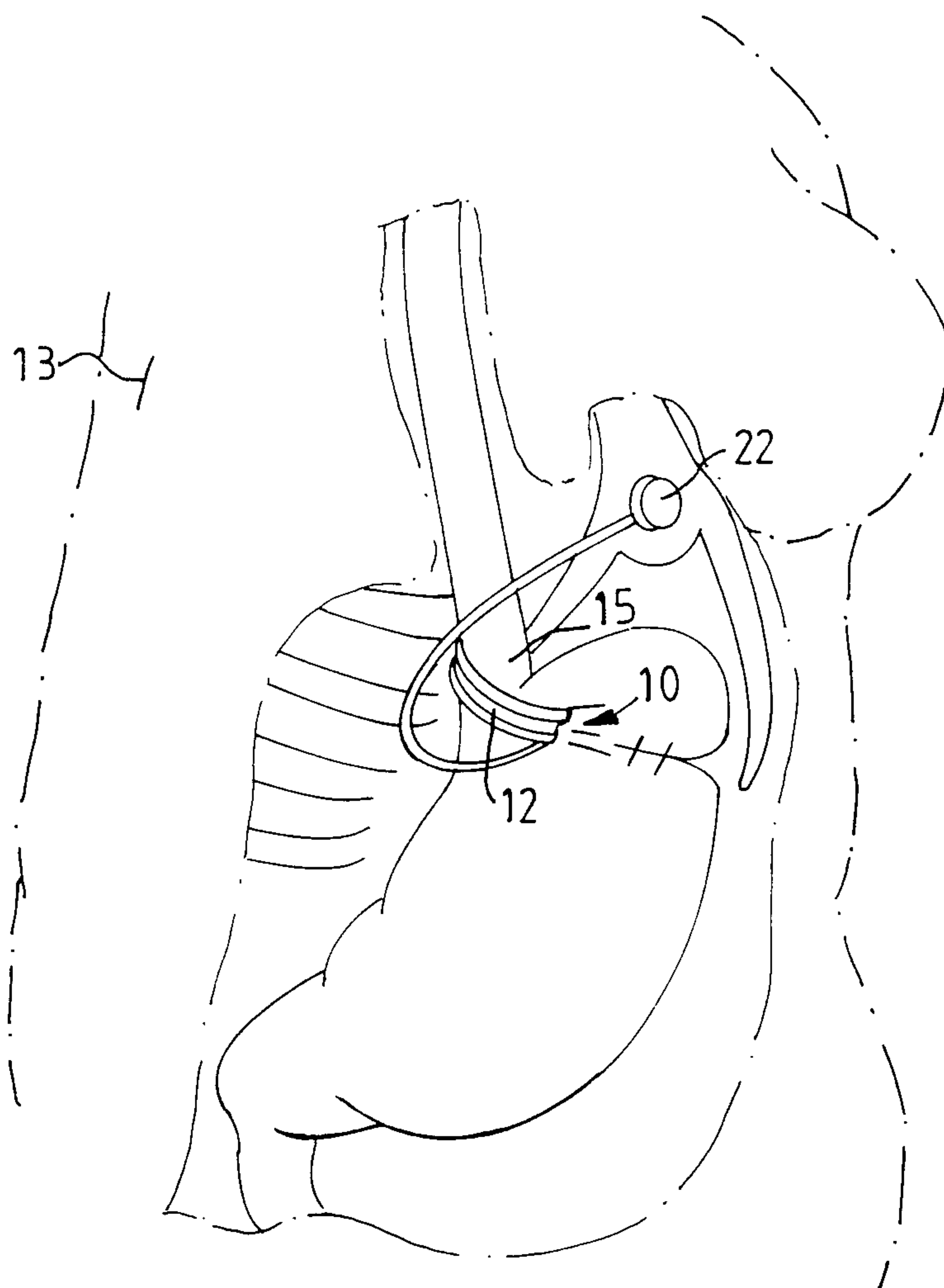


FIG.1

2 / 2

