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(54) **REMOTELY ADJUSTABLE GASTRIC BANDING DEVICE**

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Publication Classification

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(57) **ABSTRACT**

A remotely controllable gastric banding device (**10**) for placement around the stomach of a patient for the treatment of obesity. The device (**10**) comprises a gastric band (**10**) having an inflatable chamber (**16**) for adjusting the inner circumference of the band (**10**), a pressurized reservoir (**20**) with a valve (**31**) for providing fluid to inflate the inflation chamber (**16**), a valve (**32**) for releasing fluid from the inflatable chamber (**16**), and a controller (**41**) for controlling the valves (**31**, **32**). The controller (**41**) is remotely controllable from outside the patient.

Fig. 1

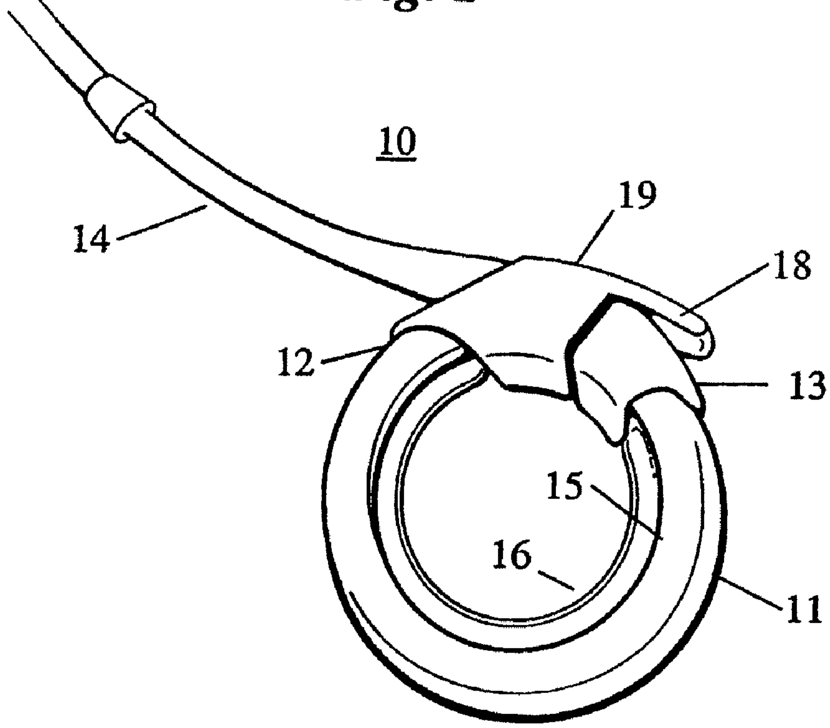
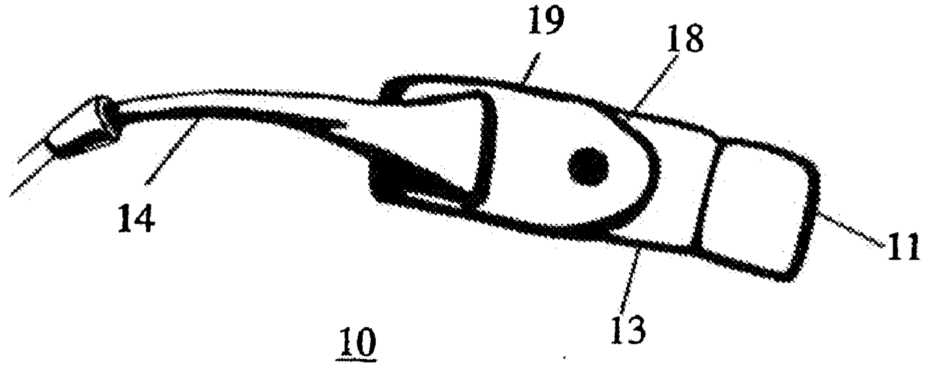


Fig. 2



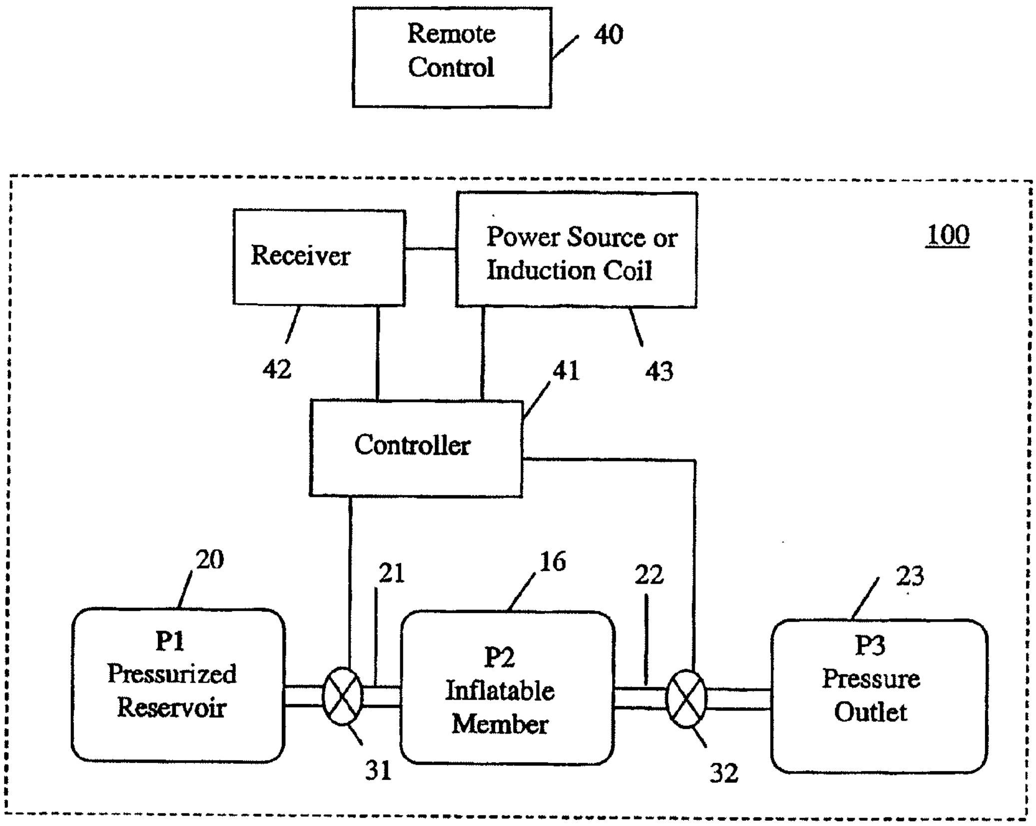

Remote
Control
40
Receiver
Power Source or
Induction Coil
100
42
41
43
Controller
20
21
16
22
23
P1
Pressurized
Reservoir
P2
Inflatable
Member
P3
Pressure
Outlet
31
32

Fig. 3

REMOTELY ADJUSTABLE GASTRIC BANDING DEVICE

RELATED APPLICATION(S)

[0001] The present application is a continuation of U.S. patent application Ser. No. 10/524,864, filed Jun. 23, 2005, now U.S. Pat. No. 7,338,433, issued Mar. 4, 2008, which was a National Stage Entry of PCT/US02/25654, filed Aug. 13, 2002.

FIELD OF THE INVENTION

[0002] The present invention relates generally to an apparatus for remotely adjusting the volume in the inflatable portion of a surgically implanted gastric band encircling the stomach. A method for treating morbid obesity utilizing a remotely adjustable gastric banding device is also disclosed.

BACKGROUND OF THE INVENTION

[0003] A belt-like gastric band for encircling the stomach to control morbid obesity is disclosed by Vincent in U.S. Pat. No. 5,601,604, incorporated herein by reference. The band comprises a belt that can be passed around the stomach and locked into an encircling position in order to create a stoma opening within the stomach. An adjustable portion of the band comprises an inflatable member which permits fine adjustment of the stoma opening after the stoma is created by locking the band in place.

[0004] The gastric banding procedure may involve placement of a calibrating apparatus in the stomach to position the stoma and size the pouch created above the stoma. The gastric band is fastened in position about the stomach to prevent slippage, usually by gastro-gastric sutures.

[0005] The stoma opening may be adjusted by injecting or withdrawing a fluid into or from an inflatable member, which is preferably coextensive with a portion of the inner stomach-contacting surface of the band. The means for injecting the fluid into the inflatable member usually comprises a fill port located beneath the skin that can be accessed extracorporeally by transdermal injection. Thus, following implantation, the gastric band can be adjusted to enlarge or reduce the stoma as required.

[0006] A potential disadvantage of prior art gastric bands is the difficulty in finely adjusting the stoma created by the implanted band. For example, the fill port located beneath the skin can be difficult to locate precisely. In addition, the fill procedure requires an invasive transdermal injection to adjust the band. Hence, repeated adjustments may be painful or worrisome to the patient. Moreover, exposure to x-rays may be required to facilitate location of the port. It would therefore be desirable to provide a band having an inflatable member that can be easily, precisely, and readily adjusted remotely, without the need to undergo an invasive procedure or radiographic exposure.

[0007] To address this problem, several prior art remote control gastric banding devices have been proposed. Klaiber et al. (U.S. Pat. No. 5,938,669) discloses a radio controlled gastric band adjusted by means of an electric pump and a balancing reservoir. Forsell (U.S. Pat. No. 6,210,347) discloses a remotely controlled and powered gastric band adjusted by a motorized mechanical or hydraulic means. Each of these proposed devices operates by pumping fluid to or from the gastric band. Unfortunately, because of their energy requirements, these devices pose problems for practical use. These devices are also not suitable for use with existing gastric banding systems, such as that disclosed by Vincent.

[0008] Recent developments in implantable drug delivery devices have shown that small, reliable, and energy-efficient implantable devices are feasible.

[0009] Drug delivery devices currently exist in which drugs are administered periodically or continuously to a patient having an implanted device by applying pressure from a pressurized reservoir and opening an outlet valve to allow a pressure differential to cause a flow of the drug. For example, Malamud et al. (U.S. Pat. No. 5,928,195) discloses a remotely controlled drug delivery device suitable for implantation in a body cavity. A pressurized gas chamber presses upon a drug storage chamber thereby administering a dose of the drug when a valve is remotely opened.

[0010] Similarly, Arzbaecher (U.S. Pat. No. 5,607,418) discloses an implantable drug apparatus having nested deformable chambers with the outer chamber being pressurized. The pressure from the outer pressurized chamber forces the drug from a reservoir chamber into an inner dispensing chamber. A remotely controlled valve is used to administer a dose of the drug from the dispensing chamber.

[0011] Further, Haller et al. (U.S. Pat. No. 6,203,523) discloses an implantable drug infusion device having a flow regulating mechanism that permits the flow rate to be independent of reservoir pressure. Some of the tradeoffs between "passive" (pressurized reservoir-based) devices and "active" (pump-based) devices are discussed in Haller, as follows:

[0012] Active drug or programmable infusion devices feature a pump or a metering system to deliver the drug into the patient's system. An example of such an active drug infusion device currently available is the Medtronic SynchroMed™ programmable pump. Such pumps typically include a drug reservoir, a peristaltic pump to pump out the drug from the reservoir, and a catheter port to transport the pumped out drug from the reservoir via the pump to a patient's anatomy. Such devices also typically include a battery to power the pump as well as an electronic module to control the flow rate of the pump. The Medtronic SynchroMed™ pump further includes an antenna to permit the remote programming of the pump. Needless to say, in view of these various components, the cost as well as the size of active drug infusion devices is greater than desired.

[0013] Passive drug infusion devices, in contrast, do not feature a pump, but rather rely upon a pressurized drug reservoir to deliver the drug. Thus such devices tend to be both smaller as well as cheaper as compared to active devices. An example of such a device includes the Medtronic IsoMed™. This device delivers the drug into the patient through the force provided by a pressurized reservoir. In particular, this reservoir is pressurized with a drug to between 20 to 40 psi (1.3 to 2.5 bar) and is used to deliver the drug into the patient's system. Typically the flow path of the drug from the reservoir to the patient includes a flow restrictor, which permits a constant flow rate. The flow rate, however, is only constant, if the pressure difference between reservoir and patient does not change. Factors that could impact this pressure difference include temperature, pressure-volume dependence of reservoir and altitude, among others. The selected pressure for the reservoir is thus typically quite high, so that absolute pressure changes only cause small and acceptable errors in flow rate. This also requires, however, the drug to be injected into the reservoir using still higher pressure. This is often a very difficult to achieve using a hand operated syringe.

[0014] The foregoing demonstrates a need for a practical, accurate and easy means of remotely adjusting an implanted gastric band.

OBJECTS OF THE INVENTION

[0015] It is therefore an object of the present invention to provide a practical, accurate and efficient means for remotely adjusting an implanted gastric band.

[0016] It is another an object of the present invention to remotely adjust an implanted gastric band having an inflatable member.

[0017] It is yet another object of the invention to provide a remote control means suitable for use with existing gastric banding devices and technology.

[0018] Still another an object of the present invention is to minimize device complexity for an implanted remotely adjustable gastric banding device to ensure maximum device longevity/durability, in light of the fact that repair would require additional surgery.

[0019] Various other objects, advantages and features of the present invention will become readily apparent from the ensuing detailed description and the novel features will be particularly pointed out in the appended claims.

SUMMARY OF THE INVENTION

[0020] The present invention applies recent developments in implantable drug delivery device technology to the field of gastric banding.

[0021] A preferred embodiment of the invention provides a gastric banding device for treatment of morbid obesity. The device has a gastric band suited for laparoscopic placement around the stomach of a patient to form an adjustable stoma opening. The gastric band has an inflatable chamber for adjusting the inner circumference of the band. The inflatable chamber is preferably substantially coextensive with an inner stomach-facing surface of the gastric band. The inflatable member does not wrinkle or fold when adjusted, thereby presenting a substantially smooth contour along the inner circumference. A fluid-filled pressurized reservoir provides a source of fluid to inflate the inflation chamber of the gastric band. First and second valves control the flow between the pressurized reservoir, the inflatable chamber, and an unpressurized or negatively pressurized outlet. A controller is used to control the valves, thereby regulating the volume change in the inflatable chamber to adjust the inner circumference of the band. The controller is remotely controllable from outside of the patient.

[0022] Other aspects of the invention include a remote control for remotely transmitting control signals to the controller, a receiver for receiving control signals from the remote control, and a power source for providing power to the controller and the valves. The power source may be an induction coil. The power source may also be a battery or capacitor charged by a piezoelectric device which converts body motion into electrical energy.

[0023] In a method according to the invention, a remotely adjustable gastric banding system may be use for the treatment of obesity. The method comprises the steps of implanting a gastric band, preferably laparoscopically, around the stomach of the patient to create a stoma; remotely transmitting control signals from outside of the patient to a controller of the implanted gastric banding device; and actuating a first valve, between a pressurized reservoir and an inflatable chamber, and/or a second valve, between the inflatable chamber and an outlet, on the basis of the control signals received by the controller to increase or decrease the fluid volume in the inflatable chamber, thereby adjusting the inner circumference of the band to adjust the stoma.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The following detailed description given by way of example, but not intended to limit the invention solely to the specific embodiments described, may best be understood in conjunction with the accompanying drawings in which:

[0025] FIG. **1** is a perspective view of a laparoscopically implantable gastric band, which may be used in the present invention, fastened in an encircling position and partially inflated;

[0026] FIG. **2** is a side view of the gastric band shown in FIG. **1**; and

[0027] FIG. **3** is a schematic diagram showing a remotely controlled fluid distribution system for a gastric band according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0028] The present invention combines the implantable drug delivery device technology discussed above with gastric banding technology. The preferred embodiments of the apparatus and method according to the present invention will be described with reference to the accompanying drawings.

[0029] Referring to FIG. **1**, a gastric band for use with the present invention is disclosed in Vincent (U.S. Pat. No. 5,601,604). This compatible gastric band, indicated as reference numeral **10**, has a body portion **11** with an inner stomach-facing surface **15**. The body portion **11** has a head end **12** and a tail end or "belt" **13**. A fill tube **14**, which is generally a tube having a single lumen coextensive therewith, is in fluid communication with an inflatable chamber **16** on the inner surface **15** of the band body **11**. Preferably, the inflatable portion **16** is substantially coextensive with the inner surface **15** of the body portion **11**. The central lumen of the fill tube **14** is in fluid communication with inflatable chamber **16**. The head end **12** of the body portion **11** has a "buckle" **19** through which the tail end of "belt" **13** is inserted and locked in place in use. Head end **12** may be provided with a pull tab **18** for use in locking the band in place about the stomach.

[0030] In use, the gastric band is placed in an encircling position around the stomach and locked in place as shown in FIG. **2**. (In FIG. **2**, the stomach is omitted for clarity.) This is accomplished by introducing the gastric band **10** through a laparoscopic cannula (not shown) in a patient's abdominal cavity. Laparoscopic placement consists of blunt dissection below the gastro-esophageal junction followed by placement of the band. The end of the fill tube **14** is passed through the dissected path around the upper stomach, and the tail end or belt **13** is passed through buckle **19**, so that the belt and buckle lock in place. A laparoscopic closure tool, such as that disclosed by Coe and Vincent in U.S. Pat. No. 5,658,298, incorporated herein by reference, may be used. Hence, with the gastric band affixed in an encircling position around the stomach, a new stoma (opening) is created within the stomach. After the band is secured in position, the size of the stoma may be adjusted by adding fluid to or withdrawing fluid from the inflatable member **16** to bring the stoma opening to the desired size. The inflatable member or chamber **16** is preferably coextensive with the inner stomach-facing surface **15** of the band between the head end **12** and the tail end **13**. The interior of the adjustable chamber **16** is in fluid communication with a fluid reservoir (not shown) by means of the central lumen of the fill tube **14**, as with prior art adjustable gastric bands. The inflatable member **16** is gradually inflated or deflated with saline or other biologically compatible fluid via the fluid reservoir such that the inflatable member **16** presses on and constricts the stomach wall or other tissue underlying the band. This results in the decrease or increase of the size of the stomach opening directly inside the encircling band.

[0031] FIG. **3** is a schematic diagram depicting a remotely adjustable gastric band **100** constructed in accordance with the present invention. In FIG. **3**, the pressure in the inflatable member **16** of the remote gastric banding system **100** is represented by the band inflation pressure P**2**. Pressure P**2** is regulated by an inlet valve **31** and an outlet valve **32**. Pressurized reservoir **20**, having a pressure P**1**, is connected to the inflatable chamber **16** through inlet valve **31** and tube **21**, which corresponds to fill tube **14** in FIG. **2**. Pressurized reservoir **20** is analogous to the pressurized reservoirs discussed above in relation to implantable drug delivery devices. This reservoir may be connected to the fill tube **21** as shown, or it may be incorporated into the body **11** of the band itself, e.g. on the outer surface, opposite the inner stomach-facing surface **15**, and communicate directly with inflatable chamber **16** though inlet valve **21**. Inflatable member **16** is also connected to outlet **23**, having a pressure P**3**, through tube **22** and valve **32**. Outlet **23** may be either a separate waste reservoir as shown in FIG. **3** or the peritoneal cavity of the patient's body. When outlet **23** is a waste reservoir, P**3** may be negative. Where pressure outlet **23** is the patient's peritoneal cavity, P**3** will be at ambient pressure within the body.

[0032] In the present invention, the pressure relationship between reservoir **20**, inflatable member **16** and outlet **23** is initially represented by the formula P**1**>P**2**>P**3**. Hence, valve **31** may be used to increase the pressure P**2** up to a maximum pressure of P**2**=P**1**, thereby inflating inflatable member **16**. Similarly, valve **32** may be used to decrease the pressure P**2** down to a minimum of P**2**=P**3**, thereby deflating inflatable member **16**. Thus, by actuating valves **31** and **32**, the fluid volume in the inflatable member **16** may be regulated, thereby adjusting the size of the stoma formed by the gastric band.

[0033] In the present invention, valves **31** and **32** are controlled by a controller **41**. The valves are preferably controlled in accordance with externally transmitted signals (not shown) received by a receiver **42** but may ultimately be controlled by any control system, including internal, mechanical, wired, or the like. The signals are preferably radio frequency (RF) signals transmitted by a remote control device **40** located external to the implanted gastric banding system. Power may be supplied to the receiver, the controller, and/or the valves either from an implanted power source **43** or from an induction coil **43** that receives power from a concentric coil external to the body, as described for instance for hearing aids in Baumann et al. (U.S. Pat. No. 5,279,292), which is hereby incorporated by reference.

[0034] The entirety of the remote gastric banding system **100** shown in FIG. **3** may be laparoscopically implanted in the patient. Subsequent adjustment of the band can be simply, quickly, and painlessly performed using a remote control device to remotely inflate/deflate the inflatable portion **16** of the band. The entire system **100** may be removed from the patient if necessary. No permanent anatomical changes should be anticipated.

[0035] The remote control device **40** can be in the form of a typical television remote control, a personal computer interfaced device, or any other format. A unique identification code may be assigned to each remotely adjustable gastric band, so that access to and control of the device is restricted. This code may be a PIN code and may also act to prevent accidental adjustment of the band.

[0036] The system may be pressurized using a saline solution, or any other biocompatible fluid. If desired, a concentrated saline solution may be used as the inflation medium, thereby allowing water from the patient's body to diffuse into the inflatable member **16** over time and further inflate the band. After repeated adjustments the reservoir **20** may be refilled through an access port (not shown) or replaced altogether. As a backup and safety measure, the system may also allow for inflation/deflation of inflatable member **16** by transdermal injection through a fill port (not shown) as in prior art gastric banding devices.

[0037] Because this system uses a pressurized reservoir rather than a mechanical pressurization means (i.e. a pump or screw), the present system is more energy-efficient than those disclosed in the existing remote-controlled adjustable gastric band systems of Klaiber or Forsell (U.S. Pat. Nos. 5,938,669 and 6,210,347). Power is only required when operating the valves **31** and/or **32**, and then only for relatively short time intervals.

[0038] Alternative embodiments of the present invention may include means for measuring fluid flow through the valves **31** and/or **32**, such as a mass flowmeter, to ensure accuracy in adjusting the stoma when inflatable member **16** is inflated or deflated. Also, the controller **41** may be positioned external to the body. An alternate gastric band design might also be used, provided that the inflation medium remains a fluid.

[0039] A further embodiment of the present invention is a method of treating obesity using the remotely adjustable gastric banding system disclosed herein. The method includes implanting a gastric band, preferably laparoscopically, around the stomach of the patient to create a stoma; remotely transmitting control signals from outside of the patient to controller **41** of the gastric banding device inside of the patient; and opening and closing valve **31**, between pressurized reservoir **20** and inflatable chamber **16**, and/or valve **32**, between the inflatable chamber and outlet **23**, on the basis of the control signals received by controller **23** to increase or decrease the pressure in the inflatable chamber, thereby adjusting the inner circumference of the band to adjust the stoma size.

[0040] Although the invention has been particularly shown and described with reference to certain preferred embodiments, it will be readily appreciated by those of ordinary skill in the art that various changes and modifications may be made therein, without departing from the spirit and scope of the invention. It is intended that the claims be interpreted as including the foregoing as well as various other such changes and modifications.

What is claimed is:

1. A passively pressurized inflatable gastric banding apparatus for treatment of obesity in a patient, comprising:

a gastric band suitable for laparoscopic placement around the stomach of the patient to create a stoma opening, the gastric band having an inflatable chamber defining an inner circumference of the band, the pressure within the inflatable chamber being denoted P**2**;

a pressurized fluid reservoir connected to provide fluid to inflate the inflation chamber, the pressurized fluid reservoir having a pressure P**1**;

an inlet valve between the pressurized fluid reservoir and the inflatable chamber;

an outlet that is not the pressurized fluid reservoir having a pressure P**3**;

an outlet valve between the inflatable chamber and the outlet; and

a controller for actuating the inlet valve and passively increasing the fluid volume in the inflatable chamber when P**1**>P**2**, or actuating the outlet valve and passively decreasing the fluid volume in the inflatable chamber when P**2**>P**3**, thereby adjusting the inner circumference of the band.

2. The gastric banding apparatus of claim **1**, wherein the controller includes a receiver and is remotely controllable from outside of the patient, and further comprising a remote control for remotely transmitting control signals to the controller.

3. The gastric banding apparatus of claim **2**, wherein the receiver is an RF receiver and the controller actuates the inlet and outlet valves in response to the received RF signals.

4. The gastric banding apparatus of claim **1**, further comprising a power source for providing power to the controller, the first valve, and the second valve.

5. The gastric banding apparatus of claim **4**, wherein the power source is selected from the group consisting of:

an induction coil,

a battery,

a capacitor, and

a piezo-electrically charged capacitor.

6. The gastric banding apparatus of claim **1**, wherein the outlet is adapted to be in fluid communication with the peritoneal cavity of the patient.

7. The gastric banding apparatus of claim **1**, wherein the outlet is a waste reservoir.

8. The gastric banding apparatus of claim **7**, wherein the waste reservoir is negatively pressurized.

9. The gastric banding apparatus of claim **1**, wherein the inflatable chamber is substantially coextensive with an inner stomach-facing surface of the gastric band to form a circular adjustable stoma opening.

10. The gastric banding apparatus of claim **1**, further including a fill tube connected to the inflatable chamber and a fill port on the end of the fill tube suitable for receiving transdermal injections of fluid, wherein the pressurized fluid reservoir is connected to the fill tube.

11. The gastric banding apparatus of claim **1**, wherein the pressurized fluid reservoir is located on the gastric band.

12. The gastric banding apparatus of claim **1**, further including a measuring device for measuring fluid flow through the inlet valve.

13. The gastric banding apparatus of claim **12**, further including a measuring device for measuring fluid flow through the outlet valve.

14. A passively pressurized inflatable gastric banding apparatus for treatment of obesity in a patient, comprising:

a laparoscopically implantable gastric band having an inflatable member for adjusting an inner circumference of the band, the pressure within the inflatable member being denoted P**2**;

a pressurized fluid reservoir connected to provide fluid to inflate the inflation member, the pressurized fluid reservoir having a pressure P**1**;

an inlet valve between the pressurized fluid reservoir and the inflatable member;

a controller remotely controllable from outside of the patient for actuating the inlet valve and passively increasing the fluid volume in the inflatable member when P**1**>P**2**, thereby reducing the inner circumference of the band.

15. The gastric banding apparatus of claim **14**, further comprising:

an outlet that is not the pressurized fluid reservoir having a pressure P**3**;

an outlet valve between the inflatable member and the outlet; and

wherein the controller actuates the outlet valve and passively decreases the fluid volume in the inflatable member when P**2**>P**3**, thereby enlarging the inner circumference of the band.

16. The gastric banding apparatus of claim **15**, wherein the outlet is adapted to be in fluid communication with the peritoneal cavity of the patient.

17. The gastric banding apparatus of claim **15**, wherein the outlet is a waste reservoir.

18. The gastric banding apparatus of claim **14**, further including a fill tube connected to the inflatable member and a fill port on the end of the fill tube suitable for receiving transdermal injections of fluid, wherein the pressurized fluid reservoir is connected to the fill tube.

19. The gastric banding apparatus of claim **14**, wherein the pressurized fluid reservoir is located on the gastric band.

20. The gastric banding apparatus of claim **14**, further including a measuring device for measuring fluid flow through the inlet valve.

* * * * *

patsnap

专利名称(译)	可远程调节的胃束带装置		
公开(公告)号	US20090182356A1	公开(公告)日	2009-07-16
申请号	US12/041547	申请日	2008-03-03
[标]申请(专利权)人(译)	COE检基大号		
申请(专利权)人(译)	COE检基大号		
当前申请(专利权)人(译)	COE检基大号		
[标]发明人	COE FREDERICK L		
发明人	COE, FREDERICK L.		
IPC分类号	A61B17/03 A61F2/02 A61F2/72 A61F5/00		
CPC分类号	A61F5/0053 A61F2250/0001 A61F5/0066		
优先权	PCT/US2002/025654 2002-08-13 WO		
外部链接	Espacenet USPTO		

摘要(译)

一种可远程控制的胃束带装置（10），用于放置在患者的胃周围，用于治疗肥胖症。该装置（10）包括胃带（10），其具有用于调节带（10）的内周的可充气室（16），带有阀（31）的加压贮器（20），用于提供流体以充气膨胀腔室（16），用于从可膨胀腔室（16）释放流体的阀门（32），以及用于控制阀门（31,32）的控制器（41）。控制器（41）可从患者外部远程控制。

Fig. 1

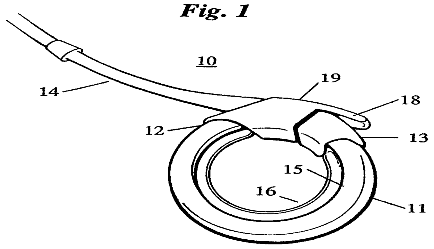


Fig. 2