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(54) **ADJUSTABLE GASTROPLASTY RING
COMPRISING A GRIP TAB**

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(57) **ABSTRACT**

(73) Assignee: **Compagnie Europeene D'Etrude et
deRecherche de Dispositifs pour
L'Implantation Par Laparoscopie**

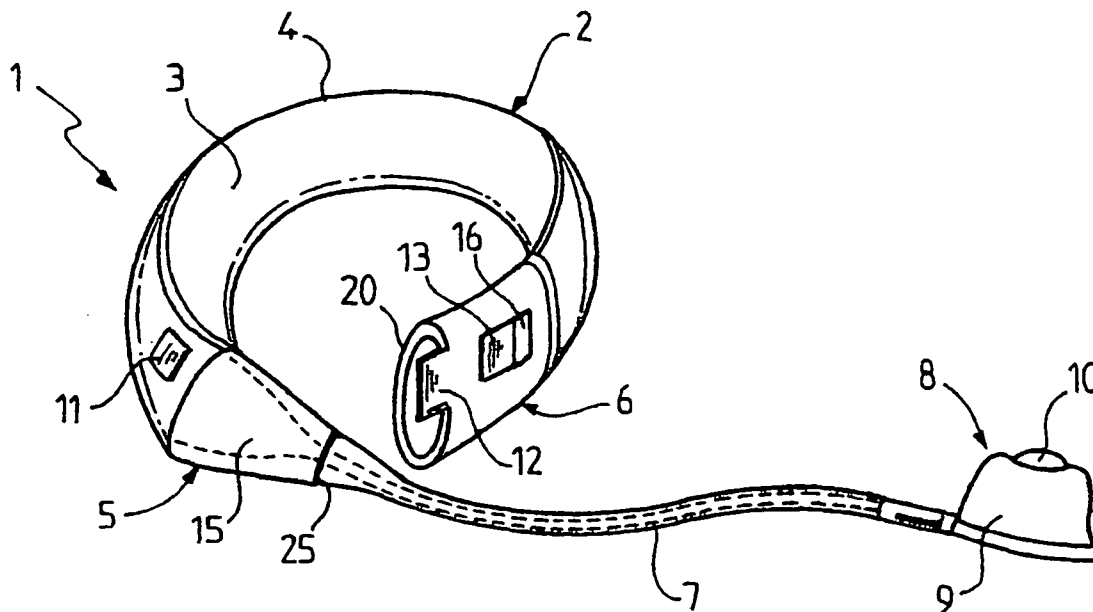
The invention relates to a gastroplasty ring formed by a flexible band (2) which comprises a first end part (5) and a second end part (6) and which is intended to be closed around the stomach toward its two end parts by a closure system in order to reduce the diameter of the opening of the stoma by forming a loop, the band comprising an adjustable-volume annular compression chamber (3) connected, at the first end part, by an adjusting catheter (7) to a device for adjusting the internal pressure of said chamber, so as to adjust its diametral expansion, the ring comprising at least one grab tab (11, 12, 13) which projects toward the outside of the loop to make it easier for the two end parts to be brought together and parted.

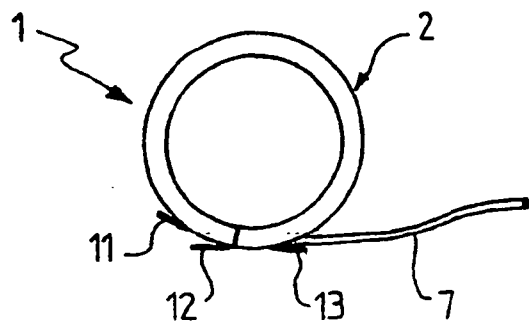
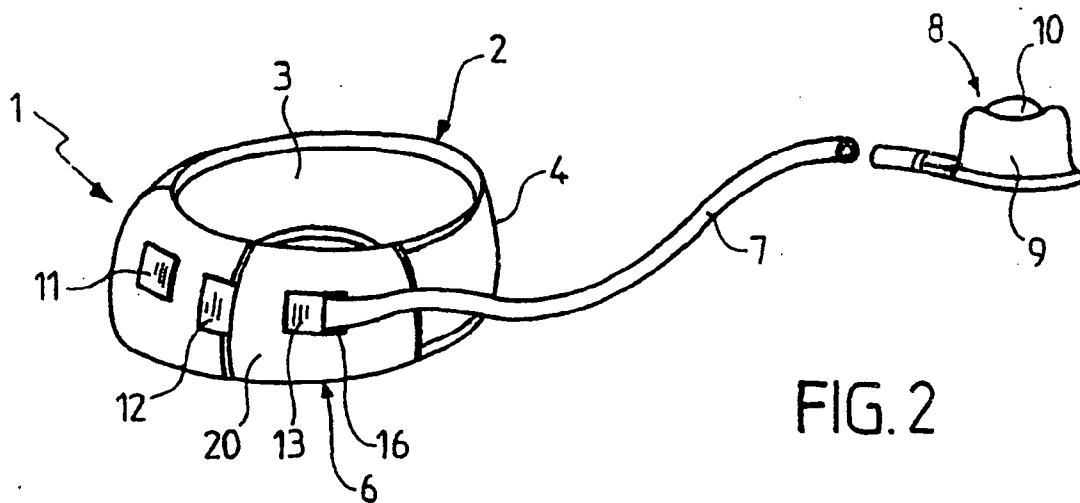
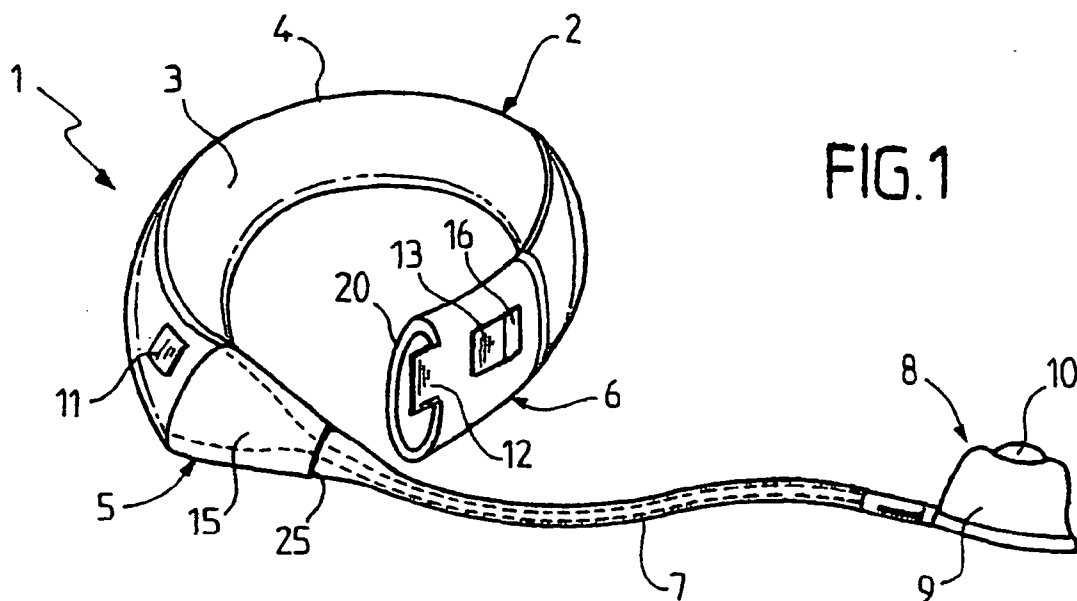
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(63) Continuation of application No. 10/275,019, filed on Jun. 26, 2003, filed as 371 of international application No. PCT/FR01/01434, filed on May 11, 2001.





**ADJUSTABLE GASTROPLASTY RING
COMPRISING A GRIP TAB**

TECHNICAL FIELD

[0001] The present invention relates to the technical field of surgical implants intended to treat obesity by implanting a flexible gastric band intended to restrict the stomach of a patient, said gastric band being equipped with an annular compression chamber, the volume of which is variable and can be adjusted via an adjusting catheter connected to an adjusting and control device implanted in the body of the patient.

[0002] The present invention relates to a gastroplasty ring formed by a flexible band which comprises a first end part and a second end part and which is intended to be closed around the stomach essentially toward and by its two ends, using a closure system so as to reduce the diameter of the opening of the stoma by forming a loop, the band comprising an adjustable-volume annular compression chamber connected, at one of the end parts, by an adjusting catheter to a device for adjusting the internal pressure of said chamber, so as to adjust its diametral expansion.

PRIOR ART

[0003] In the case of patients suffering from extremely severe obesity (morbid obesity), that is to say in the case of patients whose weight exceeds the ideal weight by at least fifty kilos, for example, it is absolutely essential to treat these patients surgically in order not only to avoid a series of health problems ensuing from this obesity, but also to avoid certain and precipitate death of such patients.

[0004] Indeed, it is acknowledged that patients suffering from morbid obesity present a significantly reduced life expectancy, the reduction being by at least some ten to fifteen years, while at the same time creating significant problems of psychological burden. Furthermore, a whole series of ancillary health phenomena are involved, having an impact on the development of cardiovascular diseases, hypertension, diabetes, and severe arthritis in particular.

[0005] It has been found that treatment based on a strict diet combined with a series of physical exercises associated with a modification in behavior, particularly eating habits, were not very well suited to such cases of morbid obesity, even though such treatment methods are the most healthy.

[0006] This is why treatments for morbid obesity which are effective and remain so in the long-term, involve surgical treatment.

[0007] In general, a distinction is made between surgical treatment techniques involving a lack of absorption of foodstuffs, that is to say a shortening of the conventional path of the food and of the digestive juices, and techniques involving gastric restriction, reducing the size of the stomach.

[0008] Surgical techniques involving a lack of absorption are, for example, those involving a technique of bypassing the small intestine or alternatively those separating the passage of the foodstuffs relative to the digestive juices. The surgical technique of bypassing may give rise to severe complications, which means that this technique is now used only very rarely. The surgical technique of separating the

passage of the alimentary bolus relative to the digestive juices does not involve particular complications, but entails a major surgical operation involving, in particular, a partial gastrectomy.

[0009] This is why the trend nowadays is to use surgical techniques employing gastric restriction to reduce the intake of food.

[0010] Such techniques conventionally involve the use of gastroplasty rings implanted around the stomach in order to reduce its size and the diameter of its passage (stoma).

[0011] Most of the known gastroplasty devices, and, for example, the one described in U.S. Pat. No. 5,074,868, employ a flexible band made of an elastomeric material and intended to be implanted around the stomach then tightened and closed into a loop of fixed diameter by a closure system. The body of the flexible band contains a variable-volume compression chamber or cavity connected by an adjusting catheter to a device for adjusting the internal pressure of the chamber so as to vary the inside diameter of the loop in order to modify or adjust the diameter of the stoma by injecting or extracting a volume of liquid into or from the chamber. Such an operation of adjusting the inside diameter of the ring is performed using conventional control devices including a miniaturized unit implanted directly under the skin of the patient and equipped with a self-sealing membrane through which the doctor injects or withdraws liquid using a syringe.

[0012] The closure system of U.S. Pat. No. 5,074,868 employs suturing, using sutures, of the two parts of the flexible band of the ring.

[0013] Such a device is generally satisfactory but, like most of the known systems, suffers from disadvantages associated essentially with the difficulty involved in any surgical operation likely to arise once the gastroplasty implant has been fitted. What has been found is that in spite of the possibility of, to a certain extent, altering the diameter of the ring without surgical intervention, using the miniaturized unit mentioned hereinabove, the fitting of such gastric implants may be accompanied by phenomena of intolerance, for example accompanied by vomiting, associated with an excessive reduction in the diameter of the stoma, or alternatively with ineffective action of the implant associated with an excessively large diameter of the stoma, or alternatively still, quite simply with discomfort or a local or generalized infection or inflammation.

[0014] This is why it is often necessary to perform a further surgical operation, either to make the patient more comfortable, or to modify or change the gastroplasty ring already implanted. Such surgical operations are particularly severe and in addition entail either a surgeon cutting the ring, or the cutting of the suture accompanied by a complete opening of the ring followed by its exchange and replacement.

[0015] Such operations are tricky to perform, are difficult for the patient to tolerate, and are therefore expensive in that they entail destroying an implant and replacing it.

SUMMARY OF THE INVENTION

[0016] The object of the invention is therefore to propose a novel gastroplasty ring making it possible to remedy the various drawbacks listed above and which is capable of

making the ring easier to handle when the implant is being fitted and when the ring is being opened and closed again during a further operation.

[0017] Another object of the invention is to propose a novel gastroplasty ring capable simply and reliably of reversibly closing the loop that makes up the ring while at the same time allowing easy unlocking of the end parts, doing so without entailing destruction of the implant.

[0018] Another object of the invention is to propose a novel gastroplasty ring capable of offering a simple and reliable means of adapting the diameter of the ring to suit each given surgical situation.

[0019] Another object of the invention is to propose a novel gastroplasty ring capable of exhibiting several implantation diameters.

[0020] Another object of the invention is to propose a novel gastroplasty ring making it possible to reduce the discomfort experienced by the patient, while at the same time being firmly held in place by the loop.

[0021] Another object of the invention is to propose a novel gastroplasty ring which is particularly easy to manufacture while at the same time having excellent overall mechanical strength.

[0022] The objects of the invention are achieved using a gastroplasty ring formed by a flexible band which comprises a first end part and a second end part and which is intended to be closed around the stomach toward its two end parts by a closure system in order to reduce the diameter of the opening of the stoma by forming a loop, the band comprising an adjustable-volume annular compression chamber connected, at the first end part, by an adjusting catheter to a device for adjusting the internal pressure of said chamber, so as to adjust its diametral expansion, characterized in that the ring comprises grab tabs which project toward the outside of the loop to make it easier for the two end parts to be brought together and parted.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Further objects and advantages of the invention will become better apparent from reading the appended description, and with the aid of the purely illustrative and informative appended drawings, in which:

[0024] FIG. 1 illustrates, in a schematic perspective view, one embodiment of a gastroplasty ring according to the invention, in the open position prior to its being implanted.

[0025] FIG. 2 illustrates, in a schematic perspective view, one embodiment of a gastroplasty ring according to the invention, in the closed position.

[0026] FIG. 3 illustrates, in a view from above, the gastroplasty ring in FIG. 2.

BEST EMBODIMENT OF THE INVENTION

[0027] FIGS. 1 and 2 illustrate a preferred embodiment of a gastroplasty ring 1 according to the invention, formed by a flexible band 2 produced, for example, by thermoforming, from an elastomeric material for surgical use, said band 2 defining, preferably essentially along its entire length, an

internal compression chamber 3 delimited by the walls 4 of the flexible band 2 and by a first end part 5 and a second end part 6.

[0028] In its position of implantation in the stomach of a patient, as illustrated in FIG. 2, the compression chamber 3 therefore forms an annular compression chamber.

[0029] As is well known in the prior art, the compression chamber 3 defines a closed volume internal to the gastroplasty ring, which is intended to form a volume which is adjustable so that the diametral expansion of the ring can be adjusted when the ring is in place so as to adapt it to suit each given surgical situation.

[0030] In the conventional way, the diametral expansion of the gastroplasty ring according to the invention is adjusted by an adjusting catheter 7 formed by a tubular element made of elastomeric material extending one of the free end parts, for example the first end part 5, of the compression chamber 3 so as to connect said chamber to a device 8 for adjusting the internal pressure of said chamber.

[0031] As is well known to those skilled in the art, the adjusting device 8 may be formed by a miniaturized unit 9 implanted under the skin of the patient. The miniaturized unit 9 comprises, for example, a self-sealing upper membrane 10 intended to be pierced by a syringe so that a certain amount of fluid can be injected or withdrawn so as to vary the volume of the compression chamber 3, in order to adjust the volume of the chamber and thus obtain the desired inside diameter of the ring. As a device such as this is well known to those skilled in the art, it will therefore not be described further in detail.

[0032] The gastroplasty ring according to the invention also comprises a closure system intended to close the gastroplasty ring in a loop around the stomach and held in position.

[0033] According to an important feature of the invention, the ring further comprises at least one grab tab which projects outward from the loop to make it easier for the two end parts to be brought together and parted when the ring is being closed and/or during a further operation in order to adjust the ring, when unlocking it or alternatively when relocking it.

[0034] As depicted in the figures, the flexible band 2 has, near the first end part 5 of the ring, at least one first grab tab 11.

[0035] As a preference, the second end part 6 comprises a second grab tab 12 and, advantageously, it also bears a third grab tab 13.

[0036] Each of the grab tabs 11, 12, 13, is preferably essentially flat and extends between a first end which is secured to the walls of the ring and a second end which is free and can be grasped by gripping so as to positively move at least one of the end parts 5 and 6.

[0037] Also as a preference, the grab tabs are flexible so that they can move out of the way when the ring is being introduced into the body of the patient. They are of rectangular shape.

[0038] Each of the grab tabs extends tangentially to the walls 4 of the ring 1 so that it is perpendicular to the plane of this ring and is of a small size with respect to the overall

dimensions of the ring. In particular, the thickness of the tabs is slender with respect to their width and to their length.

[0039] The grab tabs are formed integrally with the band and the walls of the end parts **5** and **6** or are attached and secured to these by any mechanical or chemical means, such as by bonding or overmolding, for example, while being made of a biocompatible elastomeric material.

[0040] In general, the grab tabs form protrusions which can be implanted at any point on the external surface or internal surface of the walls of the band and of the end parts, so as to be grabbed by the surgeon using any surgical instrument such as forceps, for example, so as to make the ring easier to handle, to lock and to unlock.

[0041] Also as a preference, the first grab tab **11** extends in the opposite direction to the second end part **6**. The second grab tab **12** extends in the same direction as the first tab **11**, while the third tab **13** is in the opposite direction to the other two tabs **11** and **12**.

[0042] According to one feature of the invention, the closure system according to the invention comprises means for immobilizing and slackening the ring, which means are carried by the adjusting catheter **7**, thus making it possible, starting from the position in which the ring is diametrically immobilized, corresponding to the closed and loop-shaped position as illustrated in FIG. 2, for it to be diametrically released for a moment by a relative movement of the two end parts **6**, **7** of the ring, while at the same time, if so desired, forming a closed loop around the stomach. Advantageously, the immobilizing and slackening means are reversible.

[0043] According to the invention, the immobilizing and slackening means comprise pneumatic means for closing and opening the ring, involving a fluid, for example a gas or a liquid. Recourse to pneumatic means allows simplified placement of the implant and simple control over its opening and closure.

[0044] Performing such a technical function makes it possible, in addition to the simplicity of placement and of closure of the ring that it affords, to reduce the severity and impact of any repeat surgical interventions following the placement of an implant by avoiding having to cut through and to destroy the gastroplasty ring fitted. A function such as this allows the ring to be opened up easily using the first and third grab tabs **11**, **13** and even the second tab, without destroying the loop of the ring, possibly allows the ring to be left in place, and allows subsequent re-locking using the second tab **12**.

[0045] According to a preferred alternative form of the invention, as illustrated in FIGS. 1 and 2, the gastroplasty ring according to the invention comprises a closure system, the reversible immobilizing and slackening means of which comprise at least one deformable zone **15** and an opening **16** formed in the wall **4** of the second end part **6** of the band **2**. The inflatable adjusting catheter **7** which is made of a biocompatible elastomeric material, is intended to be slipped into the opening **16**, when the ring is in the closed position, and also to act as a guide means.

[0046] The deformable zone **15** may form a protrusion if the pressure in the adjusting catheter **7** increases, said protrusion resting against the walls **4** of the end part **6** of the

band, inside the chamber **3**, so as to immobilize the ring in the closed position. The protrusion reverts to its shape at rest if the pressure inside the adjusting catheter **7** returns to normal, so as to allow said catheter to slide and be guided freely in the opening **16**, and so as to allow the loop to be slackened.

[0047] According to one particularly advantageous version of the invention, the reversible deformable zone **15** is formed by at least one zone of lesser strength and, in its shape at rest, constitutes a zone of a shape that converges toward the second end part **6**. It may, for example, be of triangular shape in cross section, that is to say in a plane of section perpendicular to the plane of the ring.

[0048] Advantageously, the deformable zone **15** may be formed by a section of the adjusting catheter **7** having a hardness of the elastomeric material of which the catheter is made, which is locally lower than the overall hardness of said catheter. In such a case, as the adjusting catheter **7** is connected to the external adjusting device **8** for pressurizing using a fluid (air or liquid), the zone **15** will tend to form a kind of balloon with a diameter greater than the internal dimensions of the band, which will diametrically immobilize the ring. The pressurizing of the balloon occurs before the band is pressurized, this being facilitated by the convergent shape of the balloon.

[0049] Advantageously, the flexible band **2** is provided at one end part, and for example at the second end part **6** opposite the first end part **5** which is extended via the adjusting catheter **7**, with a hollow sleeve **20** extending the flexible band **2**.

[0050] The hollow sleeve **20** also comprises the opening **16** which is formed in one of its faces, preferably an external face, so that the other end **5** of the flexible band **2** can be inserted in said sleeve in the closed position, the adjusting catheter **7** then passing through the opening **16** (FIG. 2) to form the loop of the ring. Such a constructional arrangement makes the withstand of the closure very reliable while at the same time allowing the compression chamber **2** to extend around the entire perimeter for clamping the stomach.

[0051] As a preference, the band **2** and the hollow sleeve **20** are of a cross section of oblong shape to make it even easier still for the deformable zone **15** to become jammed when it is pressurized.

[0052] Advantageously, the flexible band **2**, the compression chamber **3** and the hollow sleeve **20** form a one-piece unit made from one and the same elastomeric plastic, the adjusting catheter **7** then being hot-welded on.

[0053] As a preference, the third grab tab **13** extends from the external surface of the sleeve, and partly over the opening **16** without, however, impeding the passage of the catheter through this opening.

[0054] Advantageously, it is also possible for the deformable zone **15** to be made with a thickness which differs from the thickness of the flexible band **2** so as to obtain different fluid flow rates through each of these elements. These different flow rates may also be obtained by different shapes, the purpose of this being, for example, to deflate the flexible band **2** before the deformable zone **15**.

[0055] The end part **5** of the band **2** to which the adjusting catheter **7** is connected is preferably of conical shape to

make it easier to insert into the hollow sleeve 20. The deformable zone 15 is situated inside this conical shape.

[0056] Also as a preference, the adjusting catheter 7 has a limit stop 25 which is situated at the end of the conical part, near the deformable zone 15, and which is intended to pass through the opening 16 of the hollow sleeve 20. After this limit stop has clipped into the opening 16, the protrusion 15 may be immobilized by inflation.

[0057] These limit-stop means 25 consist for example of an excess of material forming a lump facing toward the outside of the ring and which prevents unwanted unfastening of the ring. The clipping of these means also makes it possible to check that the catheter has been slipped far enough into the opening 16 for the nominal ring diameter to be achieved, and also make sure that the protrusion is held in position immobilized in the hollow sleeve 20.

[0058] Furthermore, the adjusting catheter 7 is essentially rigid and is of great length by comparison with the diameter of the ring, so as to facilitate the operation of slipping and passing the catheter 7 into and through the opening 16. This also allows good placement of the band in the desired position.

[0059] Producing a gastroplasty ring in one piece makes it possible to simplify the method of manufacture of the ring and to obtain a ring which presents no risk of degradation over time.

[0060] During implantation, the ring according to the invention is set in place around the stomach in the position illustrated in FIG. 1. As the adjusting device 8 is disconnected to start with, the surgeon slips the adjusting catheter 7 into the opening 16 and passes it through the latter so as to insert the first end part 5 into the hollow sleeve 20 (FIG. 1). The surgeon then brings the limit stop 25 into the immobilizing position in the opening 16 using the second grab tab 12. He may then, using the adjusting and inflation device 8 connected to the single catheter 7, immobilize the ring in position. The surgeon then adjusts the internal diameter of the ring by injecting or removing the appropriate amount of liquid through the catheter 7. It will be noted that all of these operations are carried out using one single solitary catheter 7.

[0061] In the event of a further surgical operation, it is possible, by virtue of the gastroplasty ring according to the invention, for the operation to be confined to a superficial external examination of the situation of the implant using celioscopy or laparoscopy, simply by optical inspection using a camera. As appropriate, if the situation so demands, it is possible in a first instance, to unlock the catheter using simple celioscopy. To do this, all that is required is for the catheter 7 to be put under depression, which leads to deflation of the band and to a release of the balloon. All that is then required is for the two end parts 5 and 6 to be detached by action on the first and third locking tabs 11, 13. The tabs therefore allow the limit stop 25 to be disengaged from the opening 16. The catheter may then be slid through the opening 16. It is also possible to use the second grab tab 12 to extract the limit stop and to open out the ring; the ring is then turned back on itself in the opposite direction to the first grab tab 11.

[0062] Such sliding is accompanied by a partial and momentary slackening of the ring, without having to perform a serious operation on the patient.

[0063] It may be pointed out that the gastroplasty ring according to the invention has grab tabs which, during unlocking, are manipulated in opposite directions so that the ring experiences essentially symmetric opposed forces. During unlocking, the ring therefore does not have a tendency to move the part of the stomach around which it is placed.

[0064] It is then possible, also by a simple laparoscopic examination and operation, to close the ring again and immobilize it in the closed position in a very simple way, because the loop of the ring has never been destroyed.

[0065] It will therefore be understood that the grab tabs 11 to 13 have the function of facilitating the locking of the ring and of making it possible to unlock the ring without destroying this ring.

INDUSTRIAL APPLICABILITY

[0066] The invention finds its industrial application in the production and use of gastroplasty rings.

1. A surgical method for releasing a gastric band from a releasable immobilized position, the gastric band including a first end portion comprising an opening for receiving a second end portion of the gastric band to form a loop around a stomach at a time when in the releasable immobilized position, the method comprising:

grasping a first grabbing element positioned at the first end portion of the gastric band that is formed into the loop around the stomach; and

manipulating the first grabbing element to separate the first and second end portions of the gastric band.

2. The surgical method of claim 1, further comprising:

grasping a second grabbing element positioned at the second end portion of the gastric band; and

manipulating the first and second grabbing elements to separate the first and second ends of the gastric band.

3. The surgical method of claim 2, wherein the first grabbing element is positioned between the opening and the second grabbing element at a time when the gastric band is in its releasable immobilized position.

4. The surgical method of claim 2, wherein the second grabbing element extends outwardly from of the ring.

5. A surgical method comprising:

grasping a first grabbing element positioned at a first end portion of a gastric band that is formed into a loop around a stomach;

grasping a second grabbing element positioned proximate a second end portion of the gastric band; and

manipulating the first and second grabbing elements to separate the first and second end portions of the gastric band.

6. The surgical method of claim 5, wherein manipulating the first and second grabbing elements to separate the first and second ends of the gastric band includes manipulating the first and second grabbing elements in opposite directions to separate the first and second ends of the gastric band.

7. The surgical method of claim 6, wherein manipulating the first and second grabbing elements in opposite directions includes manipulating the first and second grabbing elements using substantially symmetric opposed forces.

8. The surgical method of claim 5, wherein the first grabbing element is located proximate an opening formed in the first end portion of the gastric band, the opening configured to receive the second end portion of the gastric band to form the loop around the stomach.

9. The surgical method of claim 5, further comprising, at a time before manipulating the first and second grabbing elements to separate the first and second ends of the gastric band, releasing the first and second portions of the gastric band from an immobilizing position.

10. The surgical method of claim 9, wherein releasing the first and second portion of the gastric band from an immobilizing position comprises deflating a deformable portion of the gastric band in order to release the first and second portion of the gastric bands from the immobilizing position, the deformable portion located proximate the first end portion of the gastric band.

11. The surgical method of claim 5, wherein the second grabbing element extends outwardly from the loop.

12. The surgical method of claim 5, further comprising:

inserting the first end portion of the gastric band into a second portion of the gastric band, the first portion of the gastric band comprising an adjusting catheter and the second portion comprising an opening through which the adjusting catheter can be passed to form the loop; and

manipulating at least one of the first and second grabbing elements to bring the first and second end portions of the gastric band together to form the loop around the stomach.

13. The surgical method of claim 1, wherein manipulating the first grabbing element to separate the first and second end portions of the gastric band is performed using laparoscopy or celioscopy.

14. A surgical method comprising:

forming a loop around a stomach with a flexible gastric band by inserting a first portion of the gastric band into a second portion of the gastric band, the first portion of the gastric band comprising an adjusting catheter and the second portion comprising an opening through which the adjusting catheter can be passed to form the loop; and

releasably securing the first and second portion of the gastric bands in an immobilizing position.

15. The surgical method of claim 14, further comprising:

positioning the first and second portions of the gastric band in the immobilizing position using a first grabbing element extending outwardly from the second portion of the gastric band.

16. The surgical method of claim 15, further comprising:

positioning the first and second portions of the gastric bands in the immobilizing position by manipulating the

first grabbing element and a portion of the first end of the gastric band in opposite directions to bring the first and second ends of the gastric band together to form the loop.

17. The surgical method of claim 16, further comprising:

positioning the first and second portions of the gastric bands in the immobilizing position by manipulating the first grabbing element and a second grabbing element located on the portion of the first end of the gastric band in opposite directions to bring the first and second ends of the gastric band together to form the loop.

18. The surgical method of claim 15, wherein the second grabbing element extends outwardly from the loop.

19. The surgical method of claim 15, further comprising:

inflating a deformable portion of the gastric band in order to releasably secure the first and second portions of the gastric band in the immobilizing position, the deformable portion located proximate the first portion of the gastric band.

20. The surgical method of claim 19, wherein at least a portion of the deformable portion of the gastric band, located proximate the first portion of the gastric band, extends through the opening of the second portion of the gastric band at a time when the first and second portions of the gastric band are in the immobilizing position, and upon inflation of the deformable portion, releasably secures the first portion of the gastric band to the second portion of the gastric band.

21. The surgical method of claim 14, further comprising:

adjusting the internal diameter of the ring by injecting a fluid into the adjusting catheter using an inflation device.

22. The surgical method of claim 14, further comprising releasing the first and second portions of the gastric band from the immobilizing position by:

grasping a first grabbing element positioned proximate of the first end portion of the gastric band, the first grabbing element extending outwardly from the loop;

grasping a second grabbing element positioned on the second end portion of the gastric band; and

manipulating the first and second grabbing elements to separate the first and second ends of the gastric band.

23. The surgical method of claim 22, wherein manipulating the first and second grabbing elements includes manipulating the first and second grabbing elements in opposite directions using substantially symmetric opposed forces.

24. The surgical method of claim 22, wherein releasing the first and second portions of the gastric band from the immobilizing position is performed using laparoscopy or celioscopy.

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