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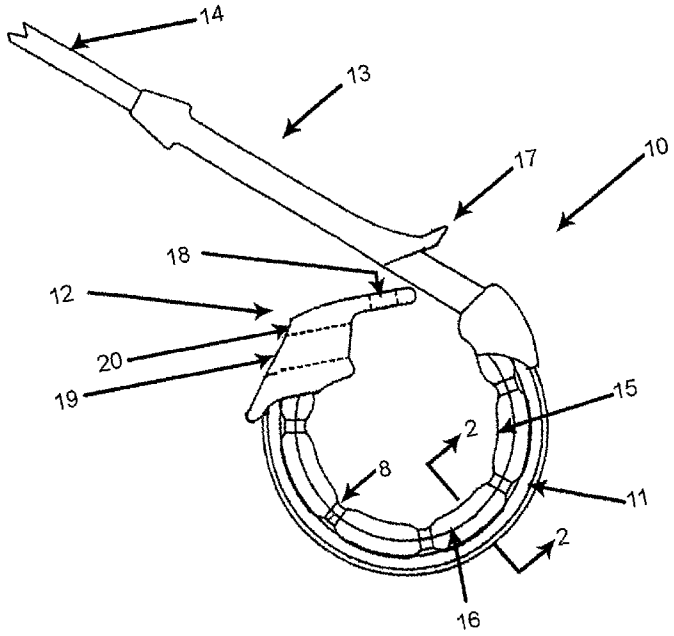
(54) Title: FATIGUE-RESISTANT GASTRIC BANDING DEVICE



(57) Abstract: A fatigue-resistant inflatable gastric banding device suitable for laparoscopic placement around the stomach of a patient for the treatment of obesity and a method for such treatment are disclosed. The device includes a gastric band having a chambered inflatable member, substantially coextensive with an inner stomach facing surface of the band, that does not crease, wrinkle or fold when adjusted, so as to present a substantially smooth contour along the inner circumference, and to avoid fatigue or failure of the member itself. A gastric band having multiple inflatable compartments or chambers, which may be inflated together or individually is also disclosed.

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FATIGUE-RESISTANT GASTRIC BANDING DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of Provisional Patent Application Serial No. 60/407,219, filed August 28, 2002 with the United States Patent and Trademark Office, and which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates generally to surgically implanted gastric bands for encircling the stomach having notches, ribs and/or chambers in the inflatable portion to reduce fatigue or crease fold failure in the device, while increasing the range of adjustment. A method for treating morbid obesity utilizing a fatigue-resistant gastric banding device is also disclosed.

2. DESCRIPTION OF THE RELATED ART

A belt-like gastric band for encircling the stomach to control morbid obesity is disclosed by Vincent in U.S. Pat. 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. The stoma opening may be adjusted by injecting or withdrawing a fluid into or from an inflatable member. 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.

The gastric band is implanted surgically, via open or laparoscopic surgery, which 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 imbricated in position about the stomach to prevent slippage, usually by gastro-gastric sutures (*i.e.* tissue is wrapped over the band and sutured to itself).

As disclosed by Vincent, the inflatable member or shell is preferably substantially coextensive with an inner stomach-facing surface of the gastric band.

Furthermore, it has been observed that the inflatable member should not wrinkle or fold when adjusted, so as to present a substantially smooth contour along the inner circumference. This ensures not only that stomach tissue will not be pinched by the inflatable member, which could lead to discomfort or necrosis, but also protects the shell from a phenomenon known as crease fold failure, which may occur if it is inflated beyond its intended range of adjustment. In the field, it has been observed that silicone or other elastomeric materials commonly used in the manufacture of gastric bands can fatigue or fail if repeatedly compressed, folded, wrinkled, buckled under stress or creased by, for example, over-inflation. This failure mode, which may include abrasion of the opposing surfaces against one another, abrasion of the inner surface of the fold "peak" against the opposing chamber wall, or fatigue of the material at folder intersections (the most highly-stressed areas), is sometimes referred to as crease fold failure.

In some cases, it has also been noted that existing adjustable gastric bands do not provide the overall size or range of adjustment desirable for use in particular patients. For instance, existing gastric bands may be either too large or too small to encircle a patient's stomach, while still allowing for a properly sized stoma. This may be due, for instance, to variations from patient to patient and their individual internal physiologies. Thus, gastric bands are now available in several different sizes, measured according to the circumference of the band (*e.g.* 9.75 cm, 11 cm, etc.). But due to variations in not only patient physiology, but also in the location and encircling position of the band, the surgical technique used, etc., it may not be evident what size band is necessary until a patient is undergoing surgery. Rather than have a variety of different sizes of gastric bands on hand during the surgical procedure, it would be desirable to have one universal size gastric band available that is adjustable over a wider range than those bands known in the prior art.

If the overall size of the gastric band is increased, the inflatable shell portion may not be capable of being adjusted to form a relatively small stoma without creases, wrinkles or folds forming on the inner stomach-facing surface, which may lead to fatigue or failure of the inflatable member, necessitating additional surgery. It would therefore be desirable to provide a universal size of a fatigue-resistant

gastric band having an inflatable member that can be adjusted over a wide range of stoma openings.

OBJECTS OF THE INVENTION

The foregoing demonstrates a need for a surgically implantable gastric band having a universal size and offering a range of adjustability suitable for use in a variety of patients.

It is therefore an object of the present invention to provide a gastric band universally sized for use in patients with varying internal physiologies.

It is another object of the present invention to provide a gastric band having an inflatable member adjustable over a wider range of stoma openings than currently available devices.

It is yet another object of the invention to provide a gastric band having an inflatable member that is substantially coextensive with an inner stomach-facing surface of the gastric band.

Still another object of the present invention is to provide a gastric band having an inflatable member that does not wrinkle or fold when adjusted over a wide range, so as to present a substantially smooth contour along the inner circumference, and to avoid fatigue or failure of the member itself.

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

A preferred embodiment of the invention provides a fatigue-resistant gastric banding device for the 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 a multi-chambered inflatable member for adjusting the inner circumference of the band. The inflatable member is preferably substantially coextensive with an inner stomach-facing surface of the gastric band. The inflatable member is chambered so as to not wrinkle or fold when

adjusted over its range of adjustment, thereby presenting a substantially smooth contour along the inner circumference and reducing fatigue or failure of the device.

Another embodiment of the present invention is a gastric band having an inflatable shell including a plurality of chambers. Separating the chambers is at least one notch and/or reinforcing rib. Upon inflation of the gastric band, the chambers ribs and/or notches eliminate creasing, folding or wrinkling of said inflatable shell, thereby reducing fatigue on the device.

Yet another embodiment of the present invention is a method of treating morbid obesity. The method of treatment includes the steps of providing a gastric band having an inflatable shell with a plurality of chambers, ribs and/or notches. A further step requires placing the gastric band around the stomach of a patient to be treated for morbid obesity; and inflating the gastric band to form a stoma.

The fatigue-resistant gastric band of the present invention may be adjusted by adding fluid to or removing fluid from the chambered inflatable member or shell by means of a subcutaneous access port, via a remotely controllable pump, using pressurized fluid or through other means well known to one skilled in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

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:

Figure 1 is a top view of a gastric band according to one embodiment of the present invention;

Figure 2 is a cross-sectional view of the gastric band shown in Figure 1 taken along line 2-2;

Figure 3 is a top and side view of the encircling portion of a fatigue-resistant inflatable shell of the gastric band of Figure 1;

Figure 4 is a cross-sectional top view of the fatigue-resistant inflatable shell of Figure 3 taken along line 4-4;

Figure 5 is a close up cross-sectional view of a convolution point of the fatigue-resistant inflatable shell of Figure 4 taken in area 5.

Figure 6 is a cross-sectional view of the fatigue-resistant inflatable shell of Figure 3 taken along line 6-6 showing the relative thickness of a reinforcing rib;

Fig. 7 is a perspective view of the encircling portion of a fatigue-resistant inflatable shell of a gastric band according to the present invention; and

Figure 8 is a top and side view of a portion of the gastric band of Figure 1 straightened to show the width and projection of the chambers in relation to the inner band portion.

DETAILED DESCRIPTION OF CERTAIN PREFERRED EMBODIMENTS

An inflatable gastric band **10** according to the present invention is shown in FIG. 1. The gastric band **10** has a body portion **11** and an inflatable portion or shell **16**. The body portion **11** has a head end **12** and a tail end **13**. The head end **12** of the body portion **11** has a buckle **19** with a pull-tab **18**. The tail end **13** includes a belt tab **17**. Upon insertion of the tail end **13** including a fill tube **14** through the buckle **19**, the tail end **13** is drawn through the buckle **19** until the belt tab **17** catches on the exit side **20**. In this position the gastric band **10** is releasably locked in a closed loop position and secured by the buckle **19** and the belt tab **17**.

The fill tube **14**, which is generally a tube having a single lumen (not shown) coextensive therewith, is connected to an end of the gastric band **10**. In FIG. 1 it is shown attached to the tail end **13** and in fluid communication with an inflatable shell **16**. It will be apparent to one of skill in the art that other arrangements of the fill tube **14** could be made including attachment to the head end **12** without departing from the scope of the present invention.

The inflatable shell **16** is formed to receive the body portion **11** as shown in FIG. 2, which is a cross sectional view of FIG. 1 taken along line 2-2. The inflatable shell **16** is preferably substantially coextensive with the body portion **11**, as shown in FIG. 1. The body portion **11** may be attached to the interior of the inflatable shell **16** through the use of adhesives compatible for use within the body or other methods known to those skilled in the art of implantable medical device manufacture. The inflatable shell **16** includes an inner stomach-facing surface **15** that forms a stoma

when placed around the stomach. It is this surface that has traditionally been the location of failure due to crease fold fatigue.

To reduce the potential for crease fold failure or high stresses in the inner surface **15**, the inflatable shell **16** has pre-formed stress-reducing notches **8** separating chambers **6**. FIG. 3 shows a top view of the inflatable shell **16** of gastric band **10** with plurality of chambers **6** each separated by a respective notch **8**. FIG. 3 differs from FIG. 1 in that it shows just the inflatable shell **16** without the inner portion **11** of the gastric band **10**.

Similarly, FIG. 4 shows a cross-sectional top view of the inflatable shell **16** shown in FIG. 3. In FIG. 4, the inside of the inflatable shell **16** is depicted with reinforcing ribs 7 at each of the notches **8** separating each of the chambers **6**. However, as shown in FIG. 3 the first chamber **24** and last chamber **26** of the inflatable shell **16** may be formed with only one rib 7.

The band may be formed with a single notch **8** along the inner stomach-facing surface **15** of the inflatable shell **16**, or more preferably, with multiple notches **8**. Similarly, the band may be formed with a single reinforcing rib 7 inside the inflatable shell **16**, or more preferably, with multiple ribs 7. Most preferably, the inflatable shell **16** is formed with corresponding ribs 7 and notches **8**. The notches **8**, chambers **6**, and ribs 7 are formed in the inflatable shell **16** during the manufacturing process and are a feature of the inflatable shell **16** of the gastric band **10** whether filled or unfilled (*i.e.* whether the band is inflated or un-inflated). This helps to ensure that upon initial positioning of the gastric band **10** there is no pinching of the stomach.

FIG. 6 shows a cross sectional view of the inflatable shell **16** of FIG. 3 taken along line 6-6. In FIG. 6 the thickness of the rib 7 can be seen relative to the thickness of the inflatable shell **16**. FIG. 6 also shows that the width of the chambers **6** may extend beyond the width of an outer surface **22** of the inflatable shell **16**. Similarly, FIG. 8 shows the chambers **6** extending beyond the width of the body portion **11** (designated by the dotted line). The greater size of the chambers **6** relative to the body portion **11** helps to evenly distribute the forces applied to the stomach through the inflation of the gastric band **10**.

FIG. 5 shows a close-up view of a notch **8** and rib **7** of the inflatable shell **16**. Also shown in FIG. 5 are chambers **6** on either side of the rib **7**. From FIG. 5 it can be seen that the portions of the inner surface **15** immediately adjacent to the notches **8** will not come in contact with one another upon inflation of a gastric band **10** having a inflatable shell **16** so designed. This prevents wear and rubbing of the inner surface **15**. Also as a result of the notch **8**, a crease will not form in the inner surface **15** of the inflatable shell **16**. Further, because of this the chamber **6** can be inflated to a much greater volume forming a smaller stoma than similar sized gastric bands known in the prior art.

The effects of the notch **8** can be described as follows: the notch **8** acts as a pre-formed crease in the inflatable shell **16**. The notch **8** acts similarly to the crease that may form in gastric bands known in the prior art as it provides a point around which the body portion **11** is allowed to bend the inner surface **15** of the gastric band **10** to form a substantially circular band. One with basic geometry skills will understand that the inner surface **15** and the body portion **11** have substantially similar lengths. As a result of this, if the body portion **11** and inflatable shell **16** are not pre-formed in a circle, when they are subsequently bent into a circular form, the interior surface **15** must in some fashion eliminate a portion of its overall length to form a circle having a smaller inner circumference than outer circumference. This reduction in circumference has heretofore occurred in prior art gastric bands through the formation of undesirable creases on the inner stomach-facing surface of the gastric band, resulting in a reduced range of inflation for such bands. The formation of these creases alleviates the material stresses in forming the circular shape, but causes point loading at the top and bottom of the creases as well as providing a point of friction between two facing sides of the crease. By forming the inflatable shell **16** in a circle with pre-formed notches **8**, the aforementioned stresses are drastically reduced because the notch **8**, alone or in combination with a rib **7**, is formed in a fashion that prevents opposing sides of the notch **8** from buckling and reduces stress, while allowing for a great range of inflation versus prior art devices. Additionally, the effects of the point loading associated with the extremities of the crease can be

alleviated by the notch **8**, especially when the notch **8** is formed in conjunction with a reinforcing rib **7**.

In practice, the gastric band is placed in an encircling position around the stomach using known surgical techniques, including, preferably laparoscopy. Laparoscopic placement is accomplished by introducing the fill tube **14** through a laparoscopic cannula (not shown) into the patient's abdomen. Laparoscopic placement begins with blunt dissection behind the stomach, usually two to three centimeters below the gastro-esophageal junction. Typically, the end of the fill tube **14** and tail end **13** are passed around the stomach and drawn through the buckle **19**, past the exit side **20** so that the belt tab **17** and buckle **19** are releasably locked together. In this sense, the band is a "one-size-fits-all" device—like that described by Vincent—but because of its notched design, the gastric band is adjustable over a greater range without creasing or folding than Vincent and other known prior art bands.

The stoma—the narrow opening in the stomach created by the band—may be adjusted after the band is secured in this single position. Prior art gastric bands employ an adjustable balloon portion that is used for post-operative adjustment of the stoma as necessary. These adjustable balloons, as discussed above, are prone to creasing. The pre-formed notches **8**, chambers **6** and ribs **7** of the inflatable gastric band **10** described herein provide for increased fill volumes, *e.g.* up to 10 cc, without wrinkles or folds forming in the shell. As in the Vincent band, the inflatable shell **16** is preferably coextensive with the inner stomach-facing surface **15** of the band between the belt tab **17** and buckle **19**. The interior of the inflatable shell **16** is in fluid communication with an injection reservoir, remote pump, pressure reservoir or other adjustment means (not shown) via fill tube **14**, as with prior art adjustable gastric bands. The inflatable shell **16** is gradually inflated with saline or other biocompatible fluid via the adjustment means such that the inflatable shell **16**, and in particular the inner surface **15** thereof presses on and constricts the stomach underlying the band. This results in a decrease of the opening (stoma) inside the stomach directly under the encircling gastric band **10**.

During inflation of the gastric band **10**, the notches **8** and the ribs **7** resist deflection. At the same time, the chambers **6** do not comparatively resist deflection. This results in the areas of the inflatable shell **16** where the ribs **7** are located forming deeper notches **8** upon inflation. Accordingly, these notches **8** reduce the stresses in the inflatable shell **16** and reduce the potential for crease fold failure by eliminating contact between the two sides of the notch **8**.

Despite the addition of the notches **8** and ribs **7**, the gastric band **10** forms a substantially circular constriction around the stomach upon inflation. The chambers **6** of the inflatable shell **16** direct the locations of inflation. Because of the greater deflections of the inflatable shell **16** in the chambers **6** as compared to the area of the notches **8** and ribs **7**, the gastric band **10**, and in particularly the inner surface **15** is prevented from pinching the surface of the stomach between two chambers **6** when in its inflated state, thereby reducing the potential for patient discomfort and necrosis.

The gastric band **10,** as shown in FIG. 1, allows for greater adjustability and fill volume range than current gastric bands, while reducing the potential for fatigue failure, crease fold failure, or pinching of the stomach. Through the use of the chambers **6,** notches **8,** and the elimination of crease points, the inflatable shell **16** is provided a greater expandable range and is able to produce a smaller opening without fear of pinching the stomach. Similarly, because the crease points are eliminated, the likelihood of crease fold failure is also reduced. It is the possibility of pinching the stomach, and the potential for crease-fold failure that limit the operable range of currently known devices. The reduction of these possibilities increases the range of the stoma opening that may be formed with a single gastric band, while safely treating the obese patient.

Another embodiment of the present invention is an inflatable gastric band with an inflatable shell that is separated into multiple, isolated inflatable compartments or chambers. The inflation of the isolated chambers may or may not be circular, but will not crease, wrinkle or fold. Each isolated chamber may be inflated separately or simultaneously with other isolated chambers and will expand without creasing, wrinkling or folding. A compartmentalized gastric band allows for

even greater adjustability and fill volume ranges than current gastric bands while reducing the potential for fatigue failure or crease fold failure.

For example, it may be desirable to reduce the size of the stoma in a particular direction. In such instances, a chamber on that side of the gastric band could be inflated without changing the size of the remaining chambers. Accordingly, greater flexibility is available in a device having isolated chambers that may be independently filled and adjusted. Such an arrangement requires independent filling pathways for each chamber.

The design of the present invention has been described for use in gastric banding devices, but may also be incorporated into any inflatable or expandable device that uses silicone or other elastomeric or polymeric materials where there may be a concern over crease fold failure.

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.

CLAIMS

1. A gastric band for the treatment of obesity suitable for laparoscopic placement around the stomach of a patient to create a stoma comprising:

a body portion for encircling the stomach; and

a multi-chambered inflatable member substantially coextensive with said body portion of said gastric band when said band is placed around the stomach, wherein said chambers eliminate creasing, folding or wrinkling along an inner stomach-facing surface of said inflatable member, thereby reducing fatigue on the inflatable member.

2. The gastric band of claim 1, wherein said chambers are in fluid communication with one another and defined by at least one notch along said inner stomach-facing surface of said inflatable member.

3. The gastric band of claim 1, wherein said chambers are in fluid communication with one another and defined by at least one rib inside said inflatable member.

4. The gastric band of claim 2, further comprising at least one rib adjacent to said at least one notch.

5. The gastric band of claim 1, wherein said chambers are in fluid isolation from one another.

6. An gastric band comprising:

an inflatable shell having a plurality of chambers; and

at least one notch defining said plurality of chambers, wherein upon inflation of the gastric band, said chambers and said at least one notch eliminate creasing, folding or wrinkling of said inflatable shell, thereby reducing fatigue on the inflatable shell.

7. The gastric band of claim 6 further comprising a body portion affixed to said inflatable shell.

8. The gastric band of claim 7, wherein said chambers extend beyond the width of said body portion.

9. The gastric band of claim 6 further comprising a fill tube for inflation of said inflatable shell.

10. The gastric band of claim 7 further comprising a buckle for receiving a portion of said body portion to secure said gastric band in a circle.

11. The gastric band of claim 10, wherein said gastric band is releasably secured.

12. The gastric band of claim 6 further comprising at least one rib.

13. A method of treating morbid obesity comprising the steps of:

providing a gastric band having an inflatable shell including a plurality of chambers and at least one notch defining said plurality of chambers;

placing the gastric band around the stomach of a patient to be treated; and

inflating the gastric band to form a stoma.

14. The method of claim 13, wherein the gastric band is placed around the stomach laparoscopically.

15. The method of claim 13, wherein the gastric band further comprises at least one rib.

16. The method of claim 13, wherein upon inflation of the gastric band the chambers and the at least one notch eliminate creasing, folding or wrinkling of the inflatable shell.

17. The method of claim 13, wherein the gastric band is inflated with a pressurized fluid.

18. The method of claim 17, wherein the pressurized fluid is saline.

19. The method of claim 13, wherein the gastric band is inflated via a subcutaneous access port.

20. The method of claim 13, wherein the gastric band is inflated via remote control of fluid transfer from a separate location.

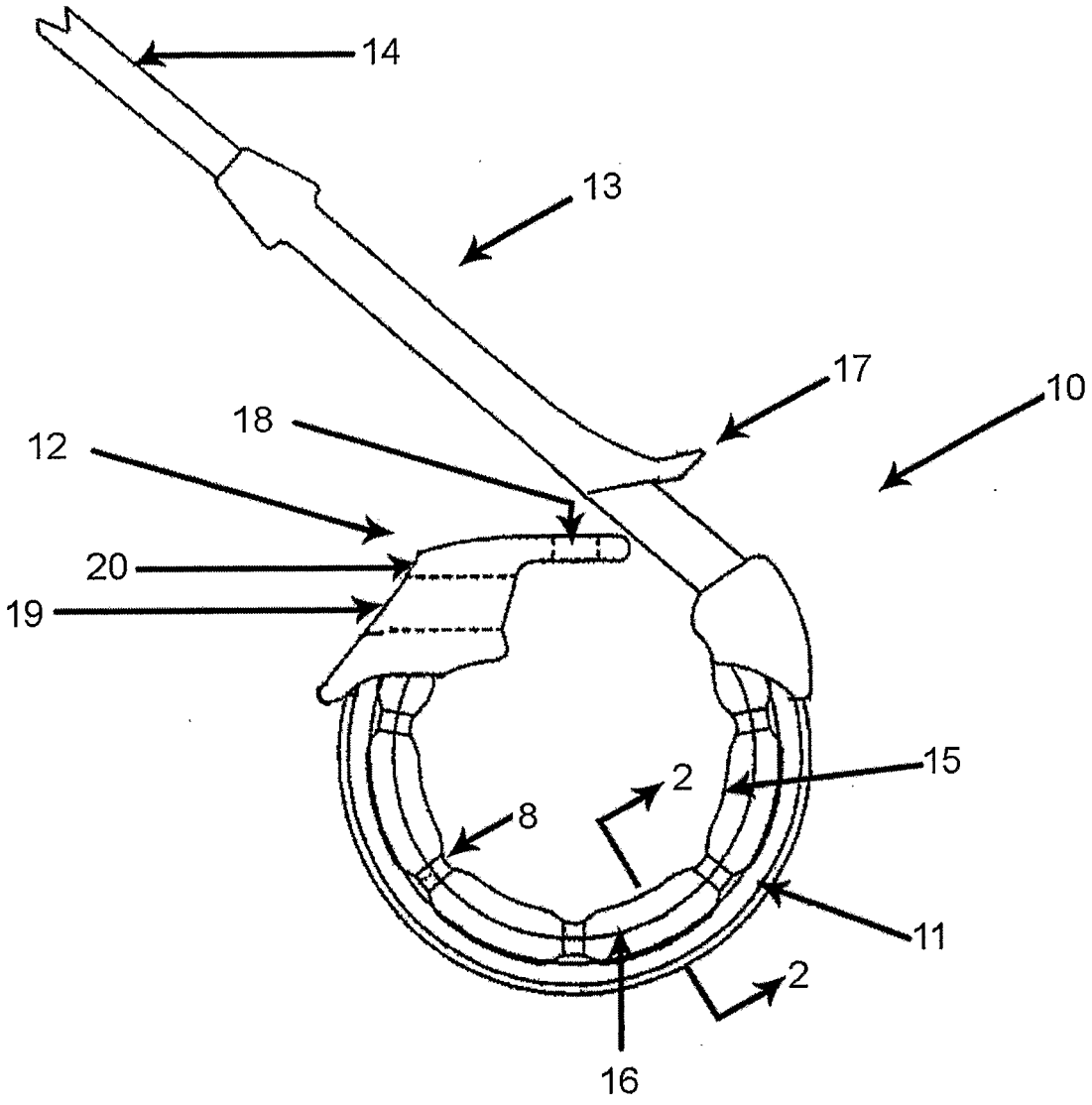

FIG. 1

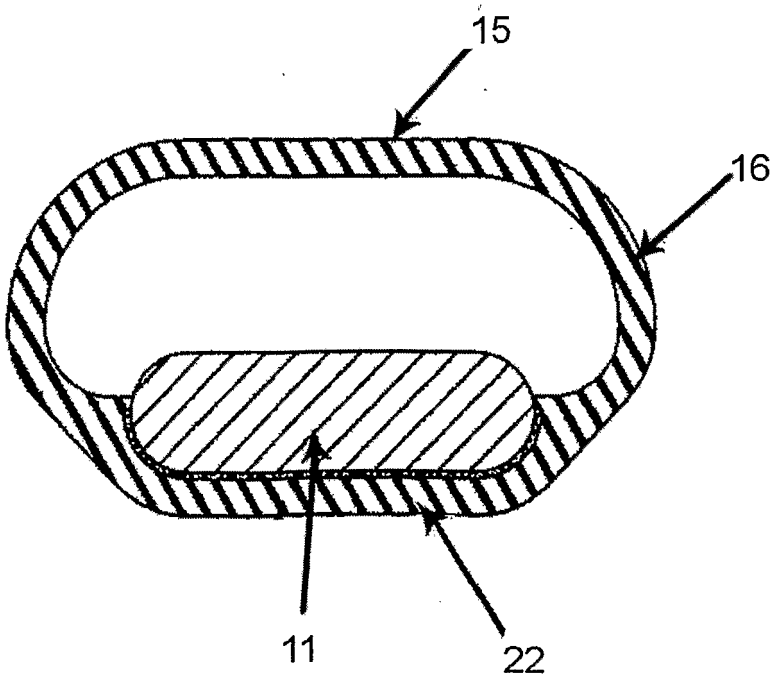

FIG. 2

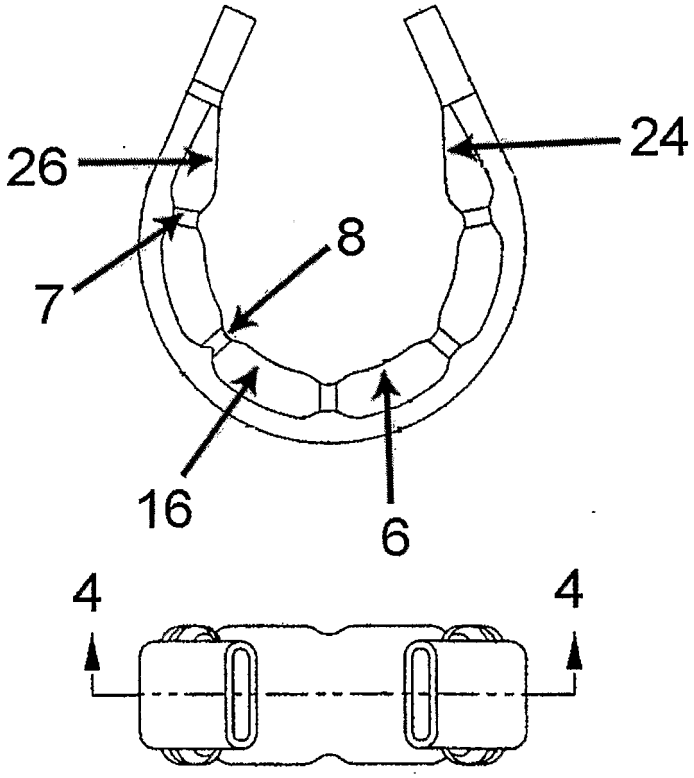

FIG. 3

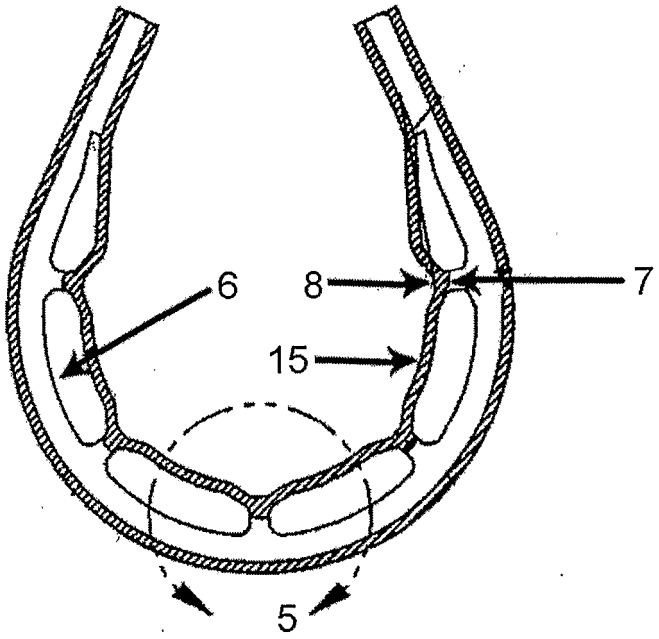

FIG. 4

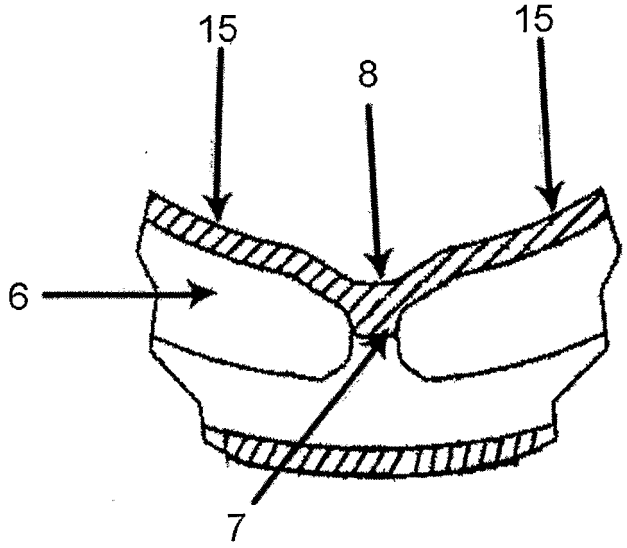

FIG. 5

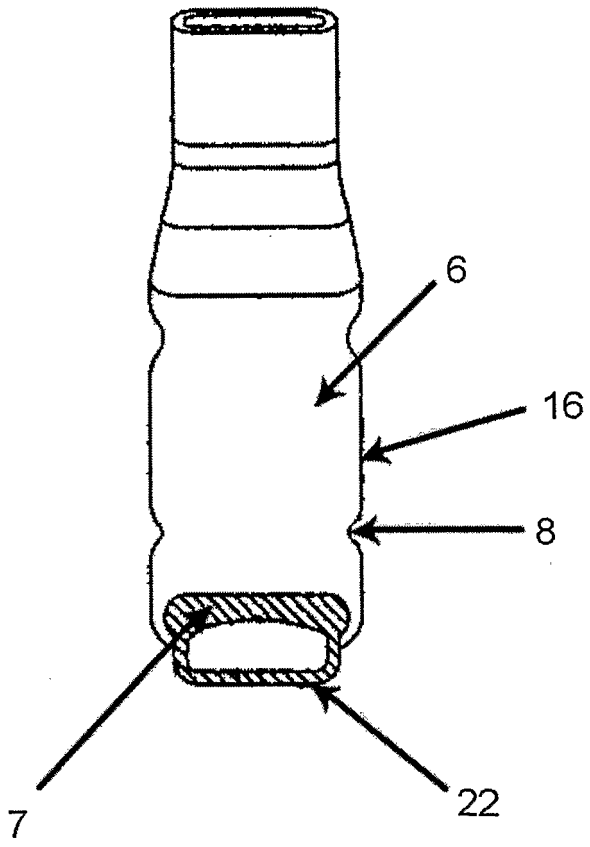

FIG. 6

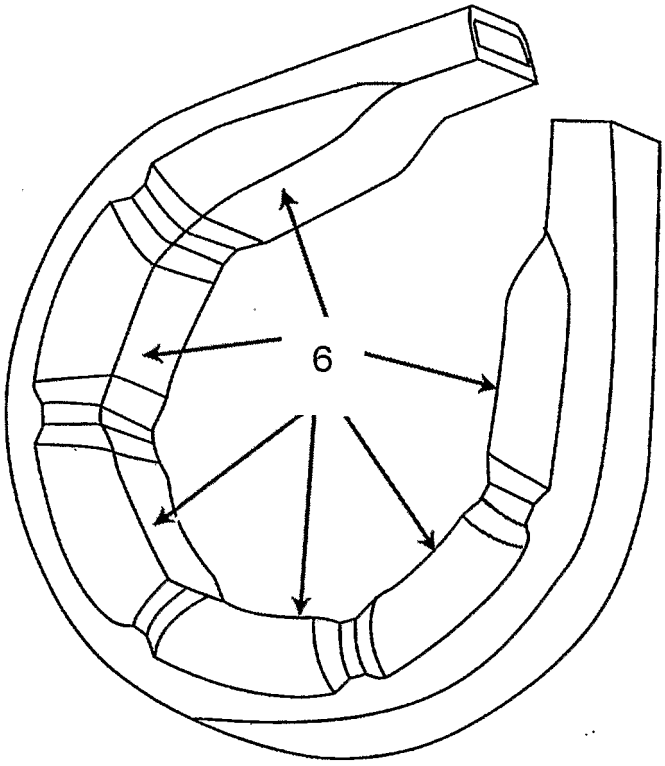

FIG. 7

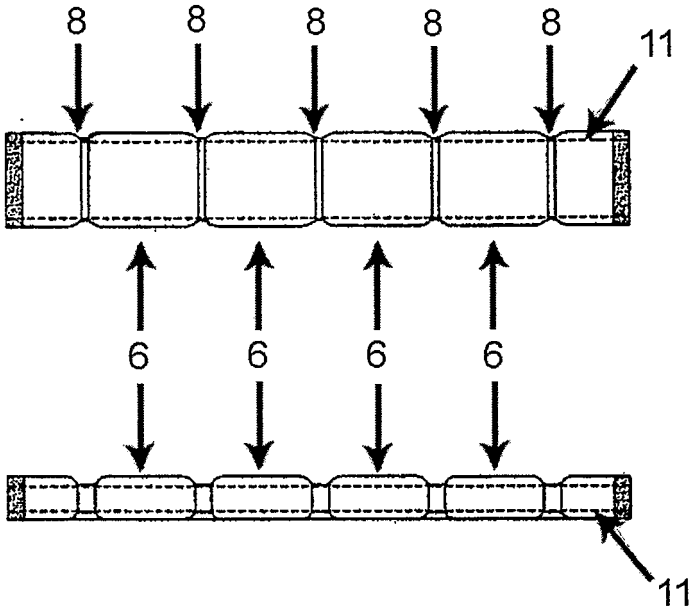

FIG. 8

专利名称(译)	抗疲劳胃束带装置		
公开(公告)号	EP1553878A2	公开(公告)日	2005-07-20
申请号	EP2003791781	申请日	2003-08-26
[标]申请(专利权)人(译)	INAMED医疗PROD		
申请(专利权)人(译)	INAMED医疗产品公司		
当前申请(专利权)人(译)	ALLERGAN，INC.		
[标]发明人	BIRK JANEL		
发明人	BIRK, JANEL		
IPC分类号	A61B17/08 A61F5/00 A61M29/00		
CPC分类号	A61F5/0066 A61F5/0033 A61F5/005		
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其他公开文献	EP1553878A4 EP1553878B1		
外部链接	Espacenet		

摘要(译)

公开了一种抗疲劳的可充气胃束带，其适于腹腔镜放置在患者的胃周围以治疗肥胖症。该装置包括胃带（2），该胃带（2）具有回旋的可充气构件（16），其基本上与带的面向胃的内表面共同延伸，在调节时不会折皱，起皱或折叠，从而呈现基本上光滑的轮廓。沿着内圆周（8），以避免构件本身的疲劳或失效。