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(54) **GASTRIC SPACE FILLER DELIVERY SYSTEM AND RELATED METHODS**

**Publication Classification**

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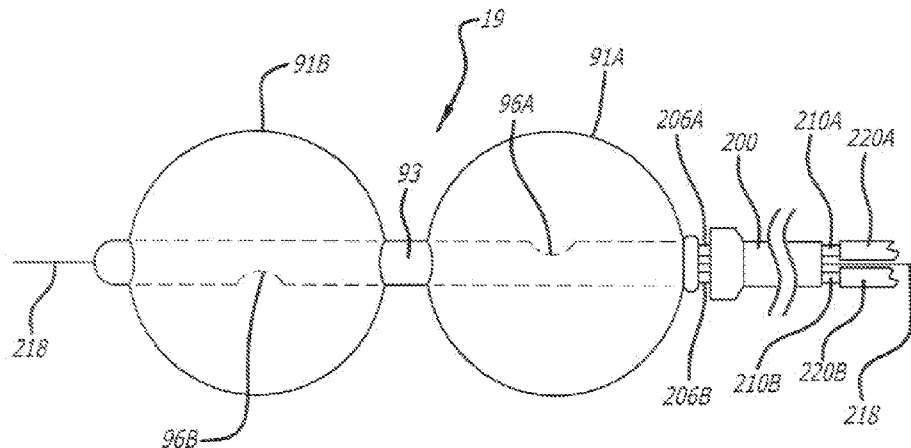
(57) **ABSTRACT**

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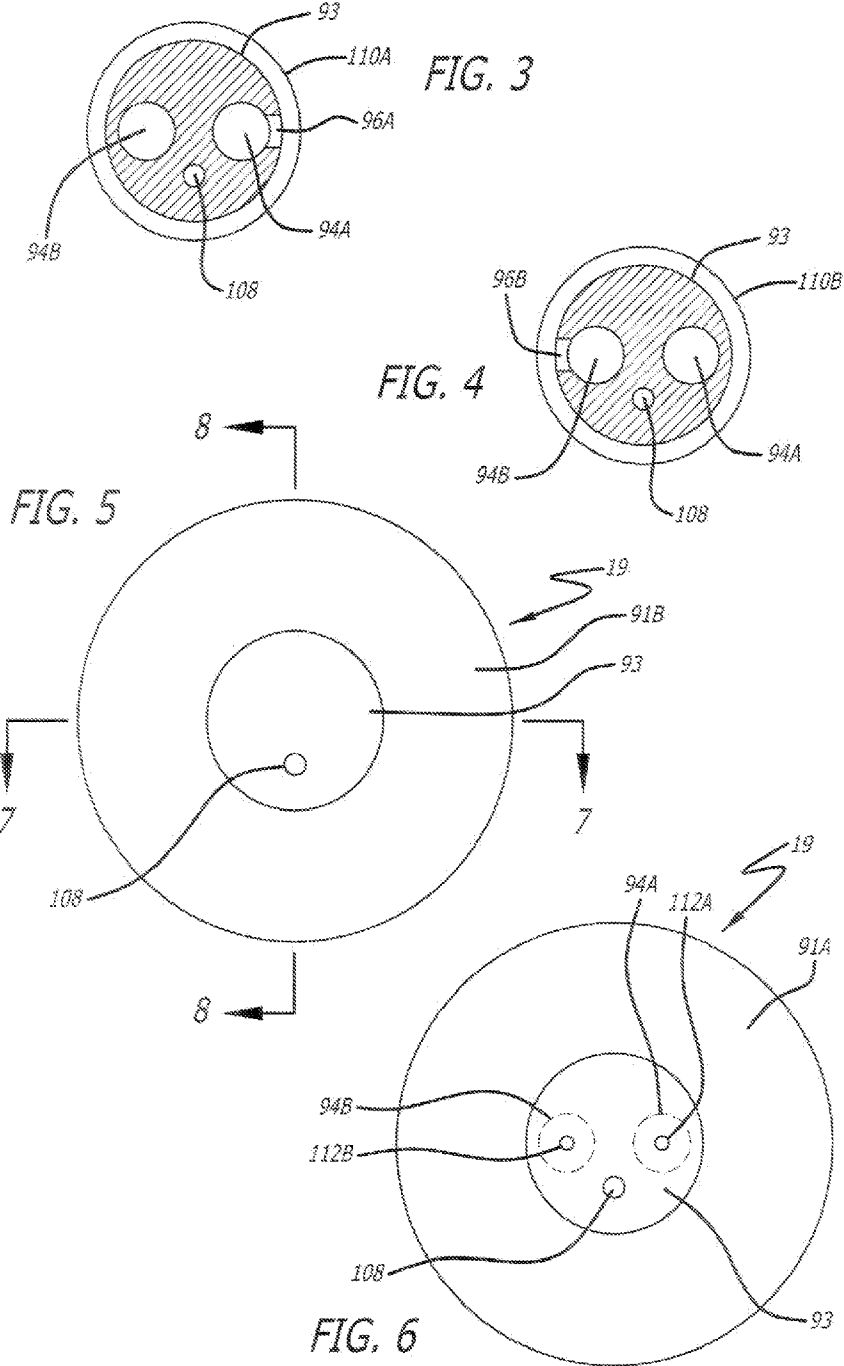
According to features of the present disclosure, a gastric space filler device and methods effective for reducing stomach volume are disclosed. A gastric space filler comprising at least one inflatable space filler and a sleeve to prevent leakage out of the gastric space filler device is disclosed. The gastric space filler device may be inflated with an insufflation fluid and with mineral oil, which further has the effect of reducing leakage. Delivery systems and methods for inserting a gastric space filler device into a patient are also disclosed. Sheaths and methods for covering a gastric space filler device during delivery into a patient are also disclosed.

**Related U.S. Application Data**

(63) Continuation of application No. 13/074,956, filed on Mar. 29, 2011, which is a continuation of application No. 11/768,152, filed on Jun. 25, 2007, now Pat. No. 8,142,469.







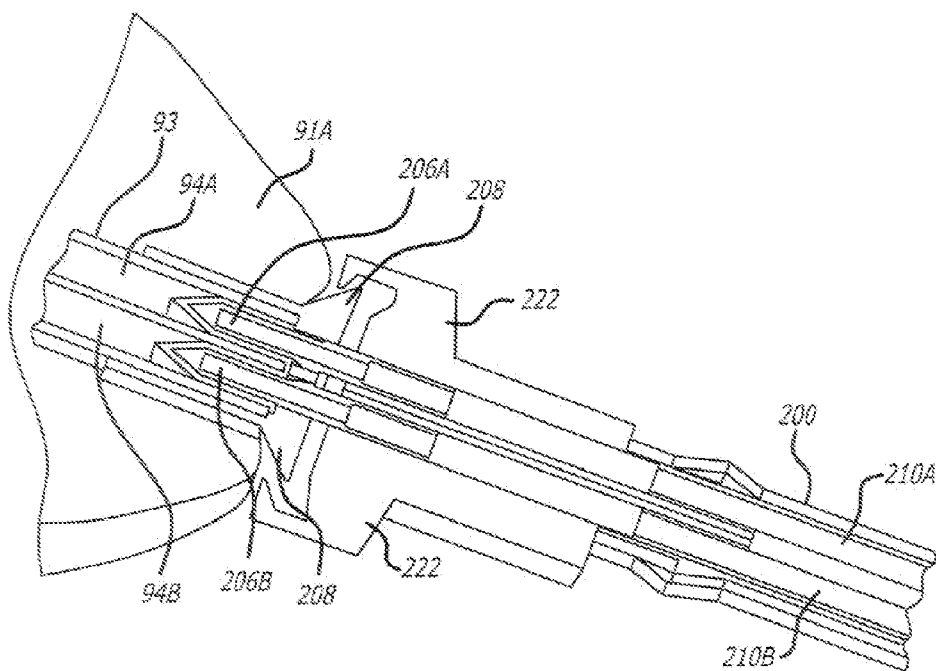


FIG. 7

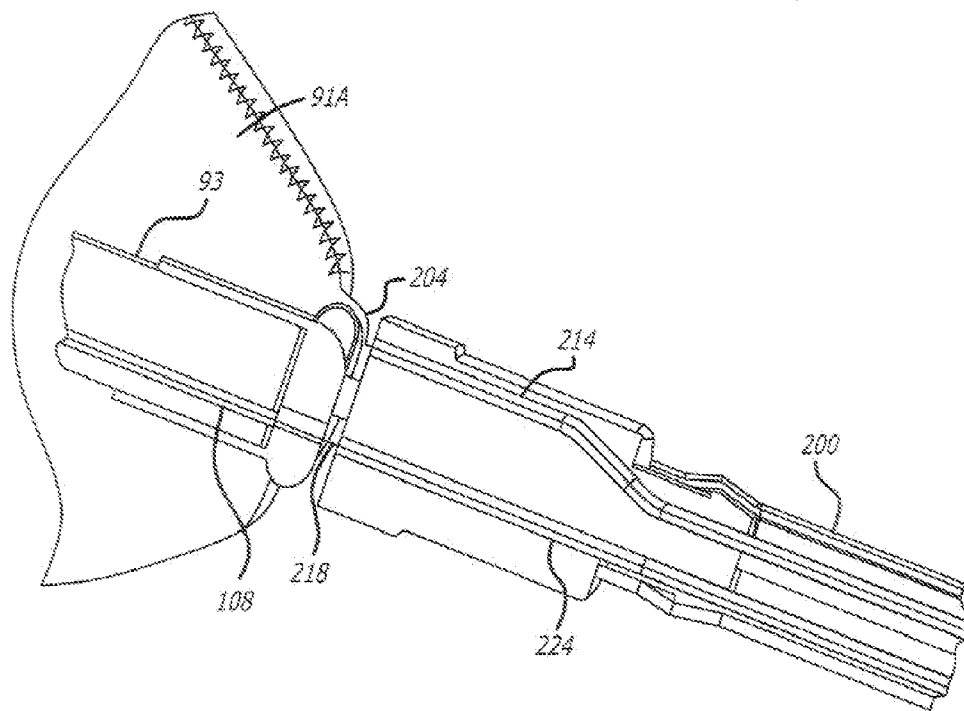


FIG. 8

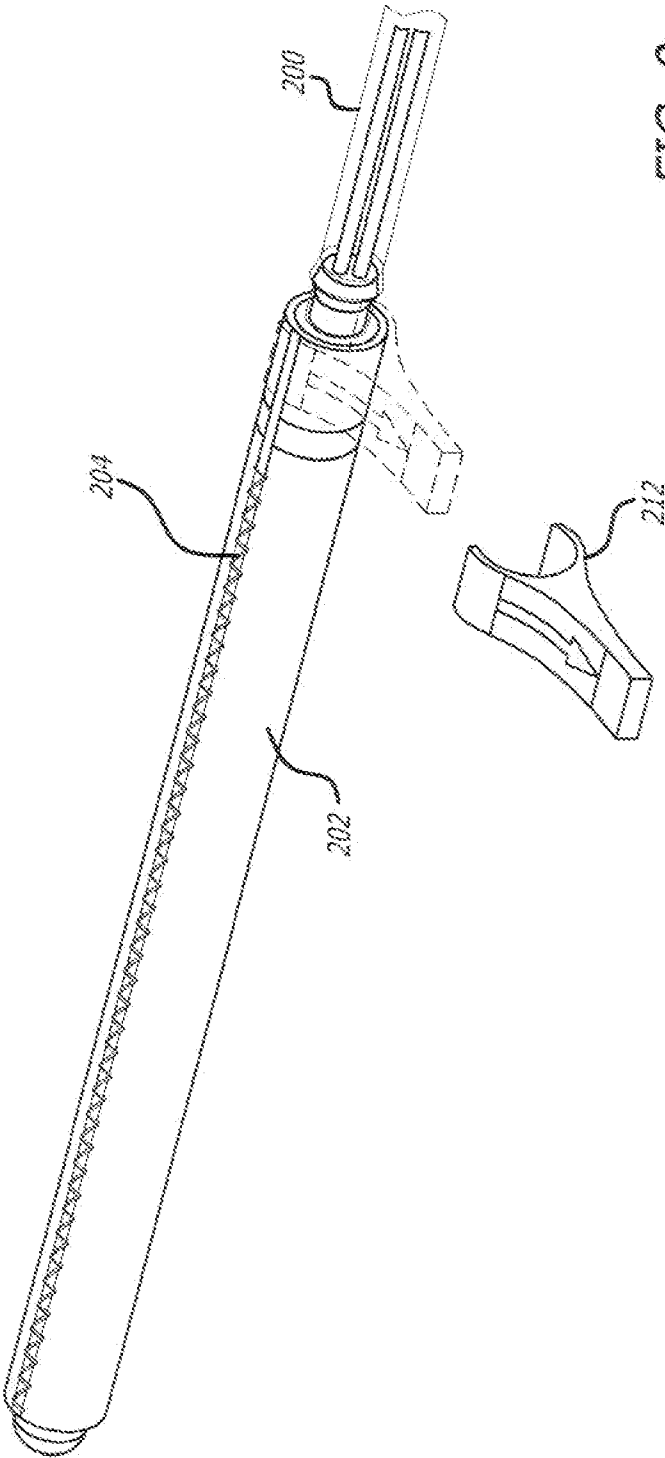


FIG. 9

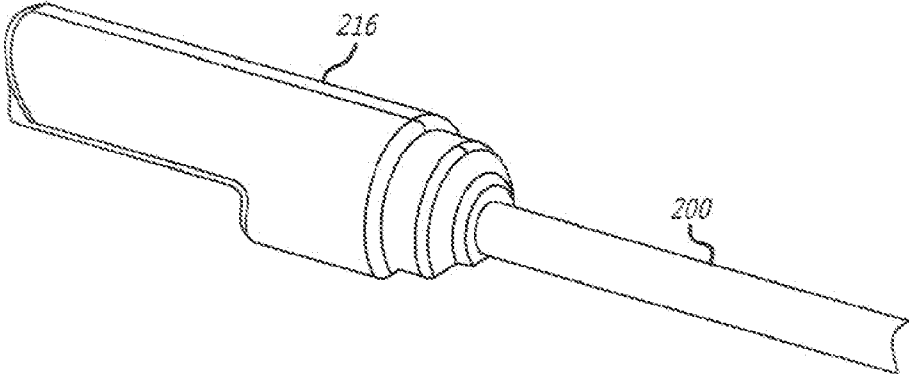


FIG. 10A

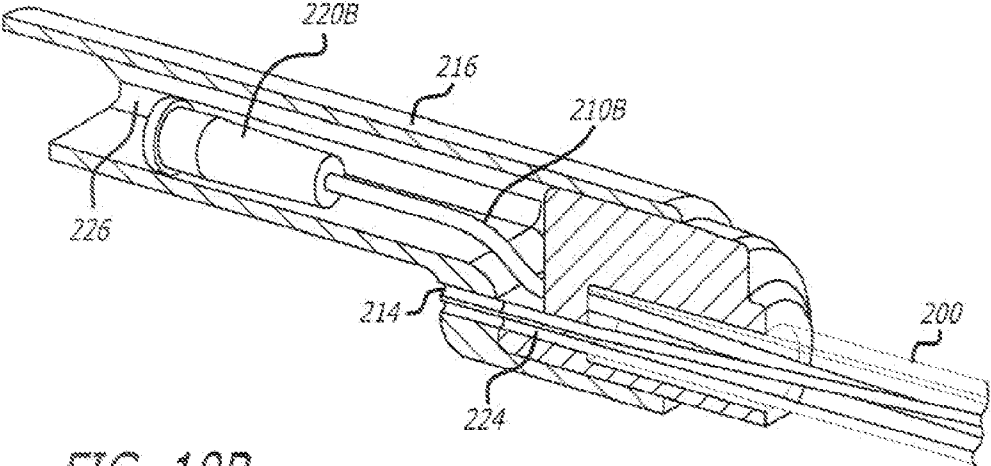


FIG. 10B

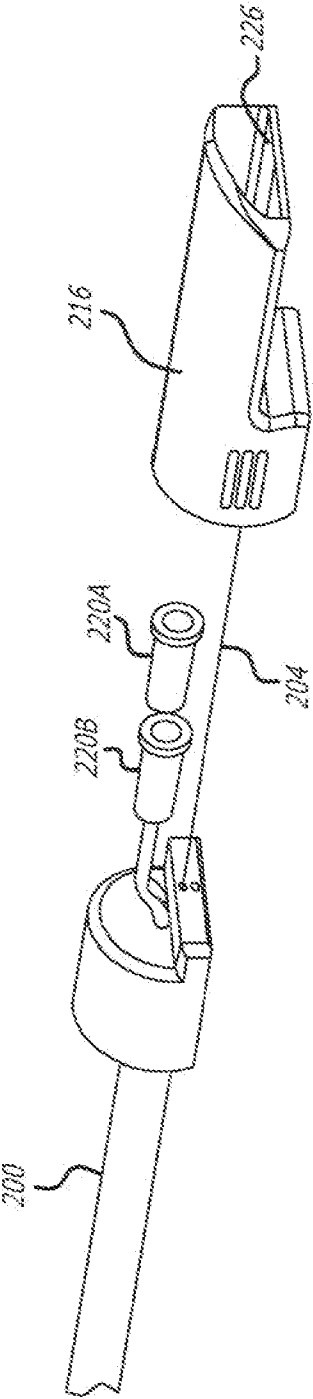


FIG. 10C

FIG. 11A

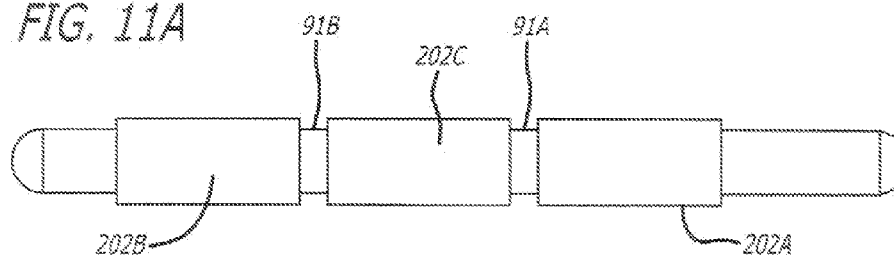


FIG. 11B

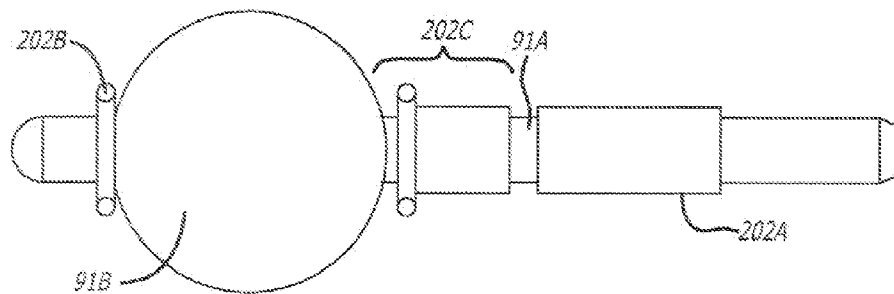
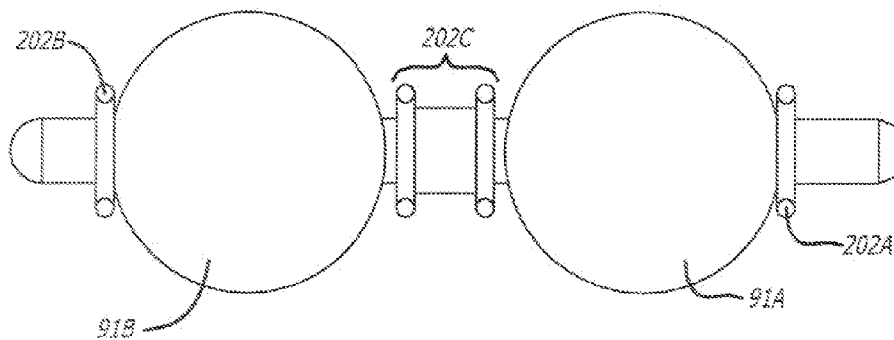


FIG. 11C





**GASTRIC SPACE FILLER DELIVERY SYSTEM AND RELATED METHODS**

**RELATED APPLICATION**

**[0001]** This application claims full Paris Convention benefit of and priority to U.S. patent application (a) Ser. No. 11/694,536, filed Mar. 30, 2007 and PCT applications (b) Serial No. PCT/US06/142,336, filed Oct. 31, 2006, (c) Serial No. PCT/US06/42711, filed Oct. 31, 2006, and (d) Serial No. PCT/US06/42710, filed Oct. 31, 2006, and (e) Serial No. PCT/US06/48647, filed Dec. 20, 2006, the contents of which are hereby incorporated by reference in their entirety, as if fully set forth herein.

**BACKGROUND**

**[0002]** 1. Field

**[0003]** This disclosure relates to implantable weight control devices. More particularly, this disclosure relates to a gastric space filler device which is retrievably implantable in a patient, an improved device and method for delivery of a gastric space filler device, and a method and device for retaining fluid in a gastric space filler device, among other things.

**[0004]** 2. General Background

**[0005]** Gastric space fillers used for achieving loss of weight in extremely obese persons have been known in the art. Some gastric space fillers utilized for this purpose function on the principle that an empty bag or space filler is placed into the stomach through the esophagus. Thereafter, the bag or space filler is fully or partially filled with a suitable insufflation fluid, such as saline solution, through a filler tube or catheter which is inserted into the stomach through the mouth or the nose. The space filler occupies space in the stomach thereby leaving less room available for food and creating a feeling of satiety for the obese person. Clinical experience has shown that, for many obese patients, reducing the size of the gastric compartment with gastric space fillers significantly helps to control appetite and accomplish weight loss. The present disclosure is directed to a device which non-operatively reduces the size of the gastric compartment and which is easily removed. Artisans shall readily appreciate that emergency operative morbidity rates and co-morbidity statistics relating to such devices which have migrated beyond the stomach underscore the need for an effective medical device that can be removed.

**SUMMARY**

**[0006]** According to features of the present disclosure, a gastric space filler device and methods effective for reducing stomach volume are disclosed. A gastric space filler comprising at least one inflatable space filler and a sleeve to prevent leakage out of the gastric space filler device is disclosed. The gastric space filler device may be inflated with an insufflation fluid and with mineral oil, which further has the effect of reducing leakage. Delivery systems and methods for inserting a gastric space filler device into a patient are also disclosed. Sheaths and methods for covering a gastric space filler device during delivery into a patient are also disclosed.

**[0007]** According to embodiments of the instant teachings, there is disclosed a gastric space filler device comprising a space filler, an opening to inflate the space filler, and a sleeve that is configured to receive mineral oil between the sleeve and the opening. According to at least one embodiment, the sleeve is disposed between the opening and the outer periph-

ery of the space filler. According to at least one embodiment, the sleeve allows fluid to enter the space filler during inflation, but does not allow fluid to exit the space filler when mineral oil is received between the sleeve and the opening.

**[0008]** According to embodiments of the instant teachings, there is disclosed a gastric space filler device comprising a space filler and a sheath, wherein the sheath at least partially covers the space filler. According to at least one embodiment, the sheath is secured around the space filler with a stitch that can be released by pulling on the stitch. According to at least one embodiment, the sheath automatically uncovers the space filler as the space filler is inflated.

**[0009]** According to embodiments of the instant teachings, there is disclosed a delivery system comprising a delivery lumen, a barb configured for coupling with an infusing lumen of a gastric space filler device, and a docking clip configured for securely attaching the delivery system to the gastric space filler device. According to at least one embodiment, the delivery system contains a handle that, when removed from the infusing lumen, pulls a stitch to release a space filler and simultaneously uncovers a luer for infusing a fluid into the gastric space filler device.

**[0010]** According to embodiments of the instant teachings, there is disclosed a method for treating obesity challenged patients comprising providing a gastric space filler device comprising a space filler, an opening to inflate the space filler with a fluid, and a sleeve disposed between the opening and an outer periphery of the space filler; allowing the fluid to enter the space filler through the opening; and preventing the fluid from exiting the space filler through the opening.

**[0011]** According to embodiments of the instant teachings, there is disclosed a method for emplacing a gastric space filler device in a patient comprising providing a delivery system attached to a gastric space filler device comprising a space filler; covering at least part of the space filler with a sheath; and delivering the delivery system and the gastric space filler device through an esophagus into a stomach of a patient.

**DRAWINGS**

**[0012]** The above-mentioned features and objects of the present disclosure will become more apparent with reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals denote like elements and in which:

**[0013]** FIG. 1 shows an embodiment of a gastric space filler device and delivery system;

**[0014]** FIG. 2A shows an embodiment of an infusing member without proximal sleeve or distal sleeve;

**[0015]** FIG. 2B shows an embodiment of an infusing member with a proximal sleeve and a distal sleeve;

**[0016]** FIG. 3 shows a cross-sectional view of an embodiment of an infusing member, a proximal sleeve, and a proximal opening;

**[0017]** FIG. 4 shows a cross-sectional view of an embodiment of an infusing member, a distal sleeve, and a distal opening;

**[0018]** FIG. 5 shows a rear view of an embodiment of a gastric space filler device containing a distal space filler;

**[0019]** FIG. 6 shows a front view of an embodiment of a gastric space filler device containing a proximal space filler;

**[0020]** FIG. 7 shows a cross-sectional view of an embodiment of a gastric space filler device and a delivery system containing a proximal delivery lumen and a distal delivery lumen;

[0021] FIG. 8 shows a cross-sectional view of an embodiment of a gastric space filler device and a delivery system containing a stitch channel and a delivery guide wire channel;

[0022] FIG. 9 shows an embodiment of a gastric space filler device and a delivery system containing a sheath, a stitch, and a sheath release cap;

[0023] FIG. 10A shows an embodiment of a delivery system containing a handle;

[0024] FIG. 10B shows a cross-sectional view of an embodiment of a delivery system containing a handle;

[0025] FIG. 10C shows an embodiment of a delivery system and a handle detached from delivery system;

[0026] FIG. 11A shows an embodiment of a gastric space filler device and sheaths wherein a proximal space filler and a distal space filler are deflated;

[0027] FIG. 11B shows an embodiment of a gastric space filler device, wherein a distal space filler is inflated;

[0028] FIG. 11C shows an embodiment of a gastric space filler device, wherein a proximal space filler is inflated.

#### DETAILED DESCRIPTION

[0029] According to an embodiment as schematically depicted in FIG. 1, gastric space filler device 19 comprises proximal space filler 91A, distal space filler 91B, and infusing member 93. Proximal space filler 91A is filled with an insufflation fluid through proximal opening 96A of infusing member 93, and distal space filler 91B is filled with fluid from distal opening 96B of infusing member 93. Delivery system 200 infuses and expands gastric space filler device 19.

[0030] According to an illustrative embodiment, proximal space filler 91A and distal space filler 91B are spaced apart and secured to each other by infusing member 93. According to an illustrative embodiment, the distance between the two space fillers is between at least about 10 to approximately 40 mm. The overall axial length of gastric space filler device 19 is between about 100 and about 300 mm. According to an illustrative embodiment, infusing member 93 may be made of semi-flexible or flexible material. The semi-flexible material may be selected from space filler-compatible polymer, such as, polyethylene, polystyrene, polyurethane, silicone, fluoropolymer, and co-polymers thereof.

[0031] According to an illustrative embodiment, the longitudinal length of proximal space filler 91A is between about 70 and about 80 mm, preferably about 75 mm. Proximal space filler 91A may be expanded to a space volume of between about 100 and about 600 cc. In an embodiment, the longitudinal length of distal space filler 91B is between about 60 and about 70 mm, preferably about 65 mm.

[0032] Distal space filler 91B may be expanded to a space volume of between about 100 and about 400 cc. According to a further embodiment, a radial diameter of proximal space filler 91A may be expanded to a diameter between about 40 and about 60 mm, and a radial diameter of distal space filler 91B may be expanded to a diameter between about 20 and about 40 mm. According to an illustrative embodiment, proximal space filler 91A is substantially larger than distal space filler 91B in gastric space filler device 19 to take the advantage of the restricted space at the entrance region of the stomach and to create a better feeling of satiety for the patient. According to an illustrative embodiment, the thickness of proximal space filler 91A and distal space filler 91B is between about 0.2 and about 1.0 mm, effectively between about 0.3 to about 0.5 mm.

[0033] According to an embodiment as depicted in FIG. 2B, infusing member 93 contains proximal sleeve 110A that wraps around infusing member 93 and covers proximal opening 96A, which connects proximal space filler 91A to proximal infusing lumen 94A. Infusing member 93 also contains distal sleeve 110B that wraps around infusing member 93 and covers distal opening 96B, which connects distal space filler 91B to distal infusing lumen 94B.

[0034] According to an embodiment as depicted in FIG. 3, proximal infusing lumen 94A of infusing member 93 has proximal opening 96A that provides fluid communication between infusing lumen 94A and proximal space filler 91A. According to an embodiment as depicted in FIG. 4, distal infusing lumen 94B of infusing member 93 has distal opening 96B that provides fluid communication between distal infusing lumen 94B and distal space filler 91B. Proximal space filler 91A and proximal infusing lumen 94A are not in fluid communication with either distal space filler 91B or distal infusing lumen 94B. According to an illustrative embodiment, infusing member 93 has an inner diameter of between about 1 and about 6 mm. According to an illustrative embodiment, proximal infusing lumen 94A is substantially larger than distal infusing lumen 94B.

[0035] According to an illustrative embodiment, proximal opening 96A connects proximal space filler 91A to proximal infusing lumen 94A. According to an illustrative embodiment, proximal sleeve 110A wraps around infusing member 93 and covers proximal opening 96A. Proximal sleeve 110A may be disposed between proximal opening 96A and outer periphery of proximal space filler 91A.

[0036] As proximal space filler 91A is being inflated, proximal sleeve 110A allows an insufflation fluid to enter proximal space filler 91A from proximal infusing lumen 94A through proximal opening 96A. According to an illustrative embodiment, proximal sleeve 110A allows an insufflation fluid to enter proximal space filler 91A by moving at least part of proximal sleeve 110A away from proximal opening 96A. According to an illustrative embodiment, at least part of proximal sleeve 110A is moved away from proximal opening 96A as a result of higher pressure outside proximal space filler 91A in relation to pressure inside proximal space filler 91A.

[0037] According to an illustrative embodiment, after proximal space filler 91A is inflated, proximal sleeve 110A is pressed against proximal opening 96A; thus proximal sleeve 110A does not allow fluid to exit proximal space filler 91A through proximal opening 96A. According to an illustrative embodiment, higher pressure inside proximal space filler 91A, relative to pressure outside proximal space filler 91A, presses proximal sleeve 110A against proximal opening 96A.

[0038] According to another embodiment, proximal sleeve 110A is not wrapped around infusing member 93, but is attached to infusing member 93 and is configured to move at least partially away from proximal opening 96A while proximal space filler 91A is being inflated and is also configured to block proximal opening 96A after proximal space filler 91A has been inflated.

[0039] According to an embodiment as depicted in FIG. 4, distal sleeve 1103 covers distal opening 96B. Distal sleeve 110B allows inflation of distal space filler 91B through distal opening 96B and prevents deflation of distal space filler 91B through distal opening 96B while distal space filler 91B is

inflated. Appropriate materials for proximal sleeve 110A or distal sleeve 110B include any elastomeric material, such as silicone.

[0040] According to an illustrative embodiment, an insufflation fluid, such as a saline solution, is used to inflate proximal space filler 91A or distal space filler 91B to a desired volume effective to fill the desired portion of a stomach of a patient and create the desired feeling of satiety. When proximal space filler 91A is inflated to this point, mineral oil is infused through proximal opening 96A and received between proximal sleeve 110A and proximal opening 96A. The mineral oil displaces the insufflation fluid in the area between proximal sleeve 110A and proximal opening 96A. Mineral oil has the effect of decreasing leakage of the insufflation fluid out of proximal space filler 91A through proximal opening 96A. According to an illustrative embodiment, an effective amount of mineral oil is the amount of mineral oil with volume equal to the volume of the insufflation fluid to be displaced by the mineral oil. According to an illustrative embodiment, mineral oil is received between distal sleeve 110B and distal opening 96B. Unexpectedly, this teaching substantially improves leakage and has yet to have been disclosed.

[0041] According to an embodiment as depicted in FIG. 6, proximal infusing lumen 94A contains proximal gate 112A, and distal infusing lumen 94B contains distal gate 112B, disposed at proximal end of infusing member 93. Proximal gate 112A prevents at least some of any fluid from traveling into or out of proximal infusing lumen 94A until proximal barb 206A is inserted through proximal gate 112A and into proximal infusing lumen 94A. Similarly, distal gate 112B prevents at least some of any fluid from traveling into or out of distal infusing lumen 94B until distal barb 206B is inserted through distal gate 112B and into distal infusing lumen 94B. Proximal gate 112A or distal gate 112B may be made of a flexible material that substantially covers proximal infusing lumen 94A or distal infusing lumen 94B and can be manipulated to allow insertion of proximal barb 206A or distal barb 206B.

[0042] According to an embodiment as depicted in FIG. 7, after gastric space filler device 19 is delivered to the stomach of a patient, delivery system 200 is inserted through the mouth to securely couple with proximal end of gastric space filler device 19. According to another embodiment, delivery system 200 is securely coupled to gastric space filler device 19 before gastric space filler device 19 and delivery system 200 are delivered to the stomach of a patient. According to an illustrative embodiment, delivery system 200 may be coupled to gastric space filler device 19 by docking clip 222 of delivery system 200, which is configured to securely attach to docking notch 208 of gastric space filler device 19.

[0043] According to an illustrative embodiment, delivery system 200 contains proximal barb 206A and distal barb 206B. Proximal barb 206A is in fluid communication with proximal delivery lumen 210A, and distal barb 206B is in fluid communication with distal delivery lumen 210B. When delivery system 200 is securely coupled with proximal end of gastric space filler device 19, proximal barb 206A and distal barb 206B are at least partially inserted into proximal infusing lumen 94A and distal infusing lumen 94B, respectively.

[0044] Proximal space filler 91A may be inflated by delivering an insufflation fluid into proximal delivery lumen 210A, thereby delivering insufflation fluid through proximal barb

206A and into proximal infusing lumen 94A. Similarly, distal space filler 91B may be inflated by delivering an insufflation fluid into distal delivery lumen 210B, thereby delivering insufflation fluid through distal barb 206B and into the distal infusing lumen 94B.

[0045] According to an embodiment as depicted in FIG. 8, gastric space filler device 19 contains filler guide wire channel 108, and delivery system 200 contains delivery guide wire channel 224. According to an illustrative embodiment, guide wire 218 is laid along a path to be traveled by gastric space filler device 19 or delivery system 200. Guide wire 218 is then threaded through at least one of guide wire channel 108 of gastric space filler device 19 and delivery guide wire channel 224 of delivery system 200. Once threaded, gastric space filler device 19 or delivery system 200 may travel along guide wire 218.

[0046] According to an embodiment as depicted in FIG. 9, sheath 202 at least partially covers proximal space filler 91A and distal space filler 91B before or during insertion through an esophagus of a patient. Sheath 202 may be made from flexible or semi-flexible materials, including mesh fabric and silicone. According to an illustrative embodiment, sheath 202 is secured to gastric space filler device 19 by stitch 204. Various stitching patterns are known in the art. Stitch 204 may comprise an easily releasable stitching pattern, such as one that may be released by pulling on one end of stitch 204. When proximal space filler 91A or distal space filler 91B is ready to inflate, stitch 204 is removed.

[0047] According to an illustrative embodiment, at least part of stitch 204 is secured by sheath release clip 212 until gastric space filler device 19 is ready to be inserted into patient. Sheath release clip 212, while engaged, secures at least part of stitch 204, such that stitch 204 may not be released. When sheath release clip 212 is removed, stitch 204 is capable of being released.

[0048] According to an illustrative embodiment, at least part of stitch 204 is located inside stitch channel 214 of delivery system 200. This allows stitch 204 to be pulled away from gastric space filler device 19 without additional instruments. Where stitch 204 is released from sheath 202 by pulling on an end of stitch 204, stitch 204 may be released by pulling stitch 204 through stitch channel 214.

[0049] According to an embodiment as depicted in FIG. 10A, delivery system 200 may contain handle 216, which may be removably attached to delivery system 200. According to an embodiment as depicted in FIG. 10B, handle 216 contains inner compartment 226. Proximal luer 220A and distal luer 220B may be contained within inner compartment 226 while handle is attached to delivery system 200. While handle 216 is attached to delivery system 200, proximal luer 220A and distal luer 220B may not be accessed to infuse fluid into proximal space filler 91A or distal space filler 91B.

[0050] According to an embodiment as depicted in FIG. 100, stitch 204 may be attached to handle 216, such that when handle 216 is removed from delivery system 200, stitch 204 is pulled away from sheath 202, thereby releasing sheath 202 from covering proximal space filler 91A or distal space filler 91B. Likewise, removal of handle 216 exposes proximal luer 220A and distal luer 220B, such that proximal space filler 91A and distal space filler 91B can be infused only when handle 216 is removed. In this embodiment, proximal space filler 91A and distal space filler 91B cannot be inflated until sheath 202 is released.

[0051] According to an embodiment as depicted in FIG. 11A, FIG. 11B, and FIG. 110, gastric space filler device 19 is at least partially covered by three sheaths: proximal sheath 202A, central sheath 202C, and distal sheath 202B. Distal sheath 202B at least partially covers distal portion of distal space filler 91B, central sheath 202C at least partially covers proximal portion of distal space filler 91B and distal portion of proximal space filler 91A, and proximal sheath 202A at least partially covers proximal portion of proximal space filler 91A.

[0052] As distal space filler 91B is inflated, distal sheath 202B is rolled onto itself toward distal end of gastric space filler device 19 and distal portion of central sheath 2020 is rolled onto itself toward center of gastric space filler device 19. As proximal space filler 91A is inflated, proximal sheath 202A is rolled onto itself toward proximal end of gastric space filler device 19, and proximal portion of central sheath 2020 is rolled onto itself toward center of gastric space filler device 19. In an illustrative embodiment, as proximal space filler 91A is inflated, proximal sheath 202A is rolled onto itself toward delivery system 200 attached to proximal end of gastric space filler device 19, such that when proximal space filler 91A is inflated, proximal sheath 202A is rolled onto delivery system 200 and when delivery system 200 is detached and removed, proximal sheath 202A is removed with delivery system 200.

[0053] In an illustrative embodiment, gastric spacer filler device 19 is at least partially covered by two sheaths: proximal sheath 202A and distal sheath 202B. Distal sheath 202B at least partially covers distal space filler 91B until distal space filler 91B is inflated, which causes distal sheath 202B to be rolled onto itself, either toward distal end of gastric space filler device 19 or toward center of gastric space filler device 19. Similarly, proximal sheath 202A at least partially covers proximal space filler 91A until proximal space filler 91A is inflated, which causes proximal sheath 202A to be rolled onto itself, either toward proximal end of gastric space filler device 19 or toward the center of gastric space filler device 19.

[0054] In an illustrative embodiment, gastric space filler device 19 is at least partially covered by a single sheath: central sheath 202C. Central sheath 202C at least partially covers each of proximal space filler 91A and distal space filler 91B. As distal space filler 91B is inflated, central sheath 2020 is rolled onto itself from proximal end of gastric space filler device 19 toward center of gastric space filler device 19 until central sheath 202C no longer covers distal space filler 91B. As proximal space filler 91A is inflated, central sheath 202C is rolled onto itself from proximal end of gastric space filler device 19 toward center of gastric space filler device 19 until central sheath 2020 no longer covers proximal space filler 91A. Alternatively, as proximal space filler 91A is inflated, central sheath 202C may be rolled from center of gastric space filler device 19 toward proximal end of gastric space filler device 19.

[0055] While the apparatus and method have been described in terms of what are presently considered to be the most practical embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and

similar structures. The present disclosure includes any and all embodiments of the following claims.

1-20. (canceled)

21. A gastric space filler device, comprising:

a flexible, elongate infusing member having a proximal end, a distal end, and a guide wire channel extending completely through the infusing member from the proximal end to the distal end; and

a plurality of inflatable gastric space fillers secured to the infusing member, wherein the infusing member extends completely through the gastric space fillers, and wherein the inflatable gastric space fillers are configured to be implanted and inflated in a stomach of a human patient.

22. The gastric space filler device of claim 21, further comprising a delivery system configured to be releasably attached to the gastric space filler device, wherein the delivery system comprises:

a proximal barb positioned to engage a proximal delivery lumen of the infusing member and provide fluid communication between the delivery system and a proximal inflatable space filler coupled to the infusing member; and

a distal barb positioned to engage a distal lumen of the infusing member and provide fluid communication between the delivery system and a distal inflatable space filler coupled to the infusing member.

23. The gastric space filler device of claim 22 wherein the delivery system is configured to be attached to the gastric space filler device with the proximal barb and/or the distal barb of the delivery system inserted into a gate at the proximal end of the infusing member.

24. The gastric space filler device of claim 22 wherein the delivery system further comprises a delivery guide wire channel aligned with the guide wire channel when the delivery system is releasably attached to the gastric space filler device.

25. The gastric space filler device of claim 24, further comprising a guidewire threaded through the filler guide wire channel and the delivery guide wire channel.

26. The gastric space filler device of claim 21 wherein at least one of the gastric space fillers has an outer diameter of at least about 40 mm when inflated with a fluid.

27. The gastric space filler device of claim 21 wherein the gastric space fillers are configured to at least partially fill a portion of the stomach of the human patient to create a feeling of satiety.

28. The gastric space filler device of claim 22 wherein the infusing member comprises a gate at the proximal end, and wherein the gate is configured to close when the proximal barb and/or the distal barb is removed from the proximal end of the infusing member.

29. The gastric space filler device of claim 21 wherein the gastric space filler device is configured to be at least partially covered with a sheath before guiding the gastric space filler device along a guide wire.

30. The gastric space filler device of claim 21 wherein: the infusing member includes a docking notch; and wherein the gastric space filler device further comprises a delivery system having a docking clip configured to be releasably attached over the docking notch of the infusing member.

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