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(54) **SLEEVE GASTRECTOMY CALIBRATION TUBE AND METHOD OF USING SAME**

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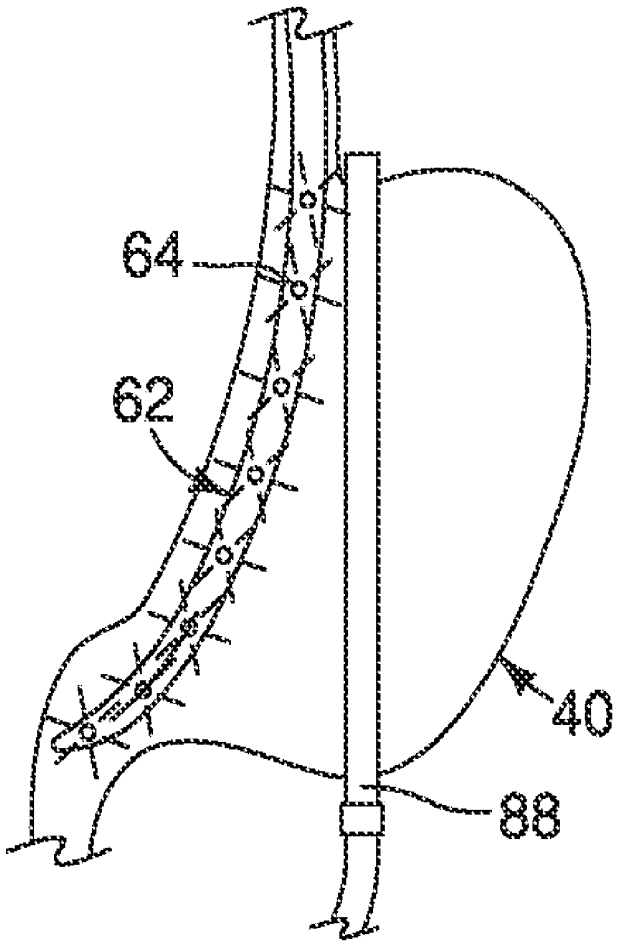
CPC ***A61F 5/0083*** (2013.01); ***A61F 5/0076*** (2013.01); ***A61B 19/46*** (2013.01); ***A61F 5/0089*** (2013.01); *A61B 17/07207* (2013.01)

(57) **ABSTRACT**

One or more medical devices may be provided that may be used, for example, in bariatric surgery including a vertical sleeve gastrectomy. The one or more medical devices may include a laparoscopic sleeve gastrectomy stapling guide in conjunction with a calibration tube in accordance with one or more examples. According to an example, the calibration tube may be a flared, multi-diameter calibration tube. The flared, multi-diameter calibration tube may have a first diameter along a portion of the tube and a second diameter that may larger than the first diameter along at least another portion of the tube. The calibration tube may be used in conjunction with the stapling guide to align stomach such that it may be stapled along the stapling guide (e.g., to perform the vertical sleeve gastrectomy).



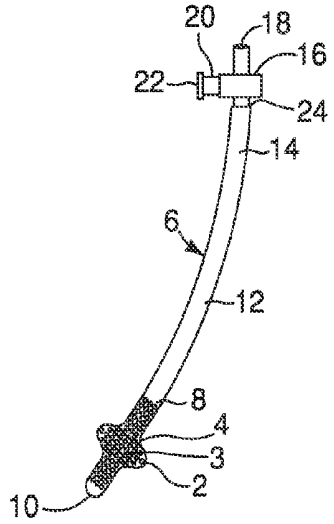


FIG. 1

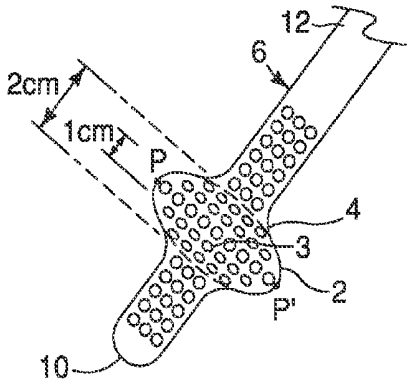


FIG. 2

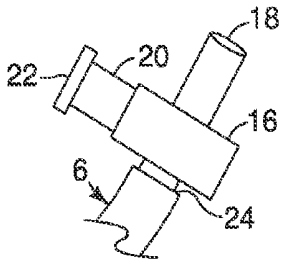


FIG. 3A

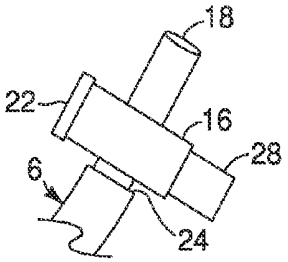


FIG. 3B

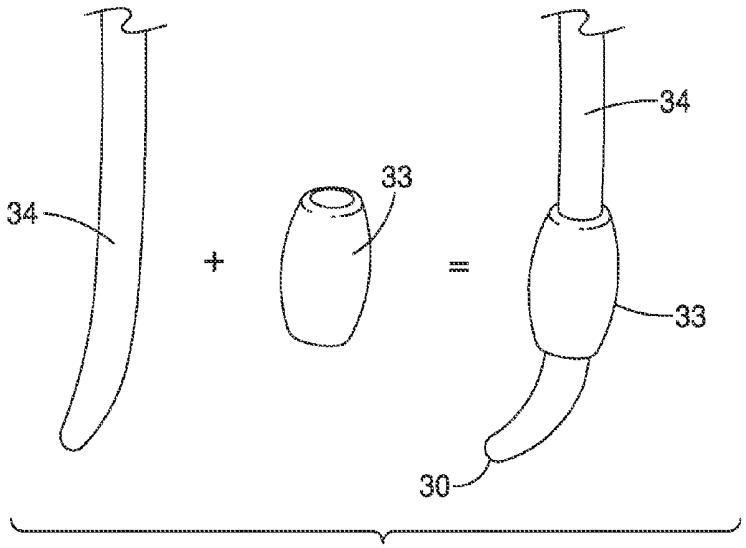


FIG. 4

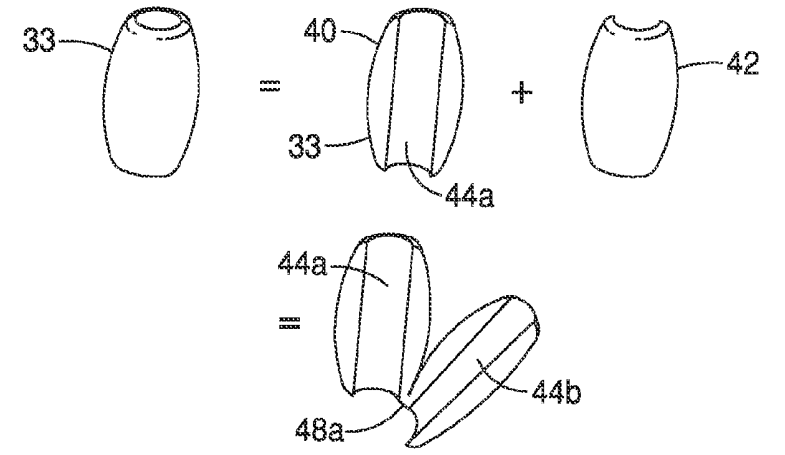


FIG. 5A

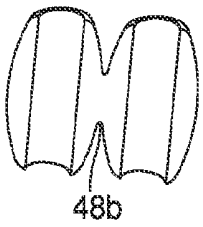


FIG. 5B

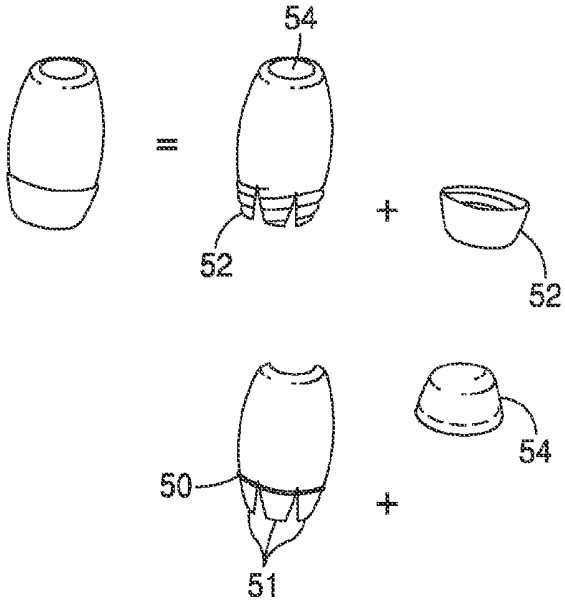


FIG. 6

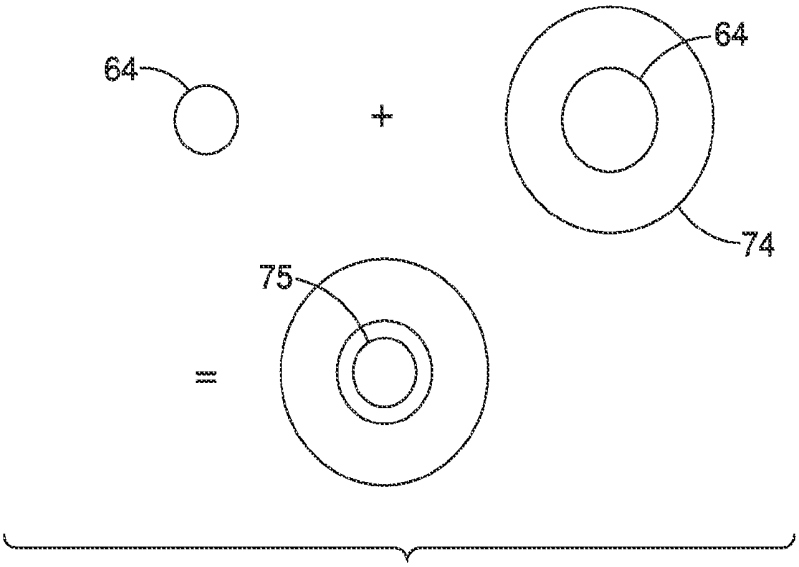


FIG. 7

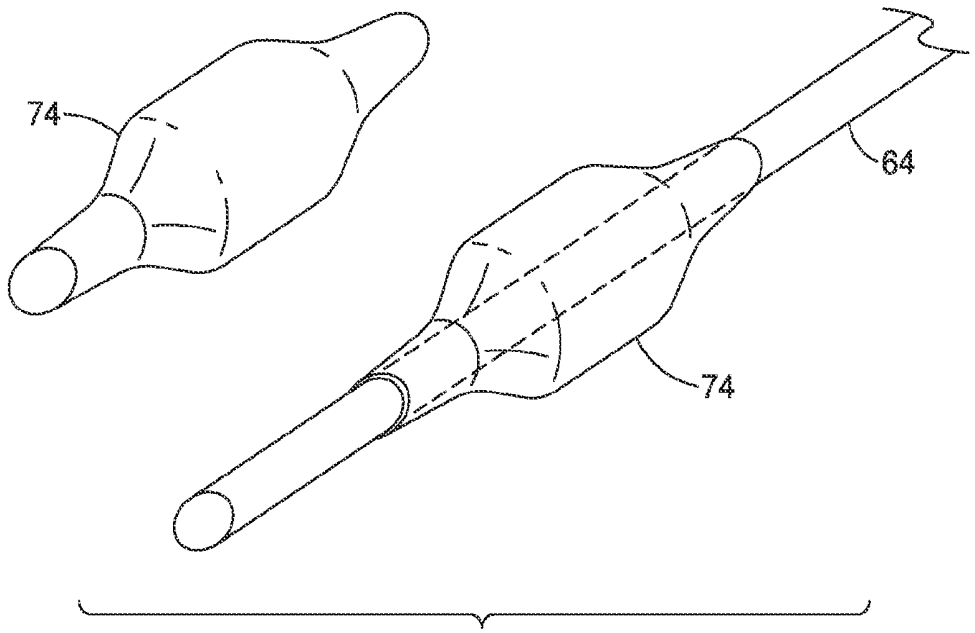


FIG. 8

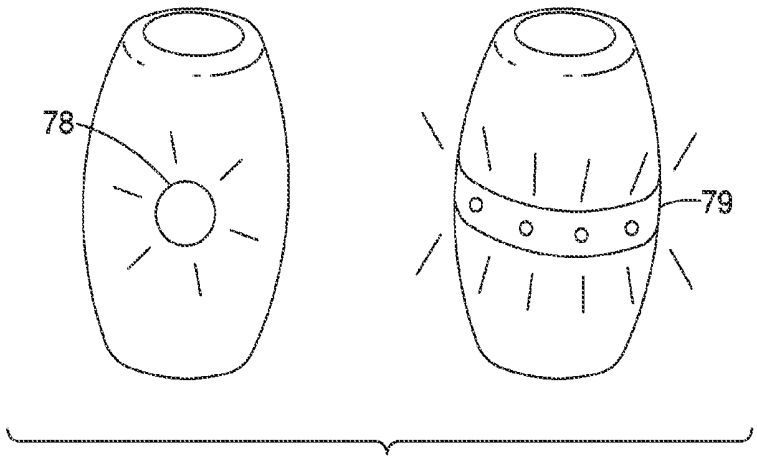


FIG. 9

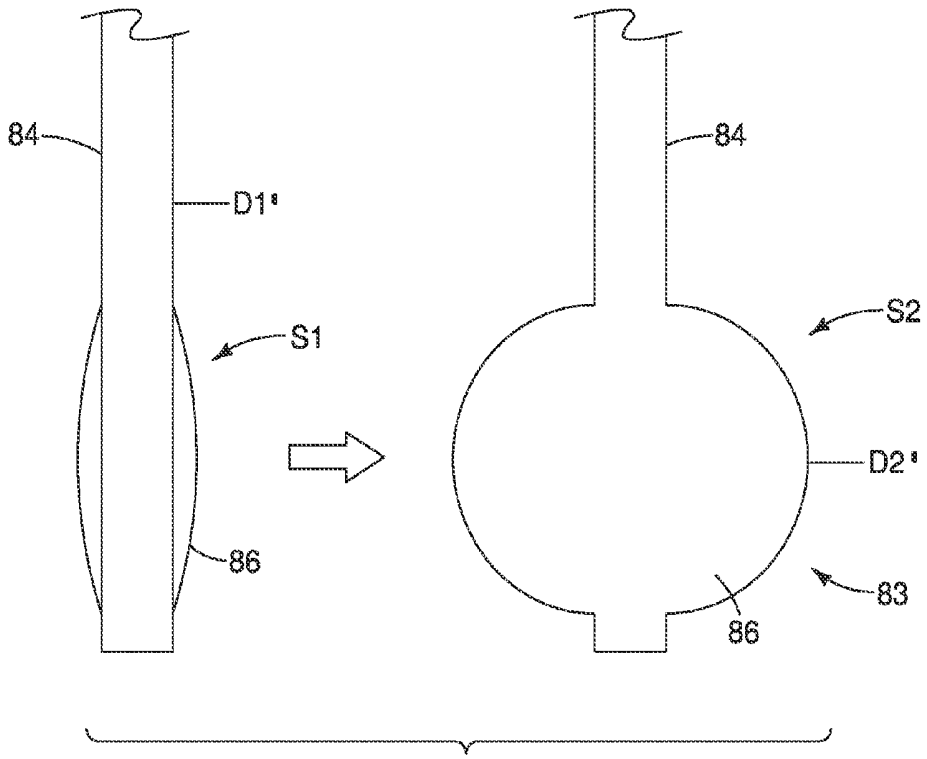


FIG. 10

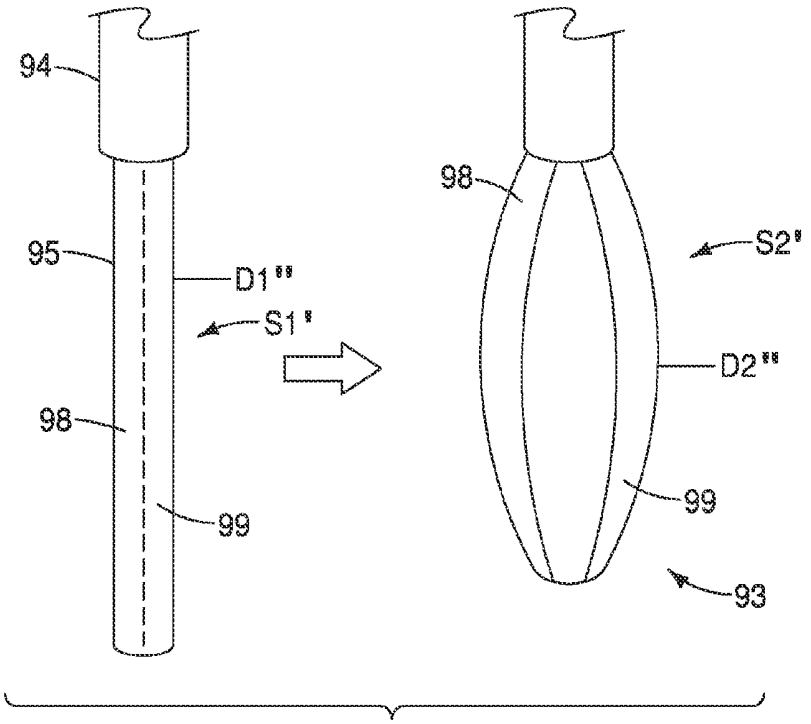


FIG. 11

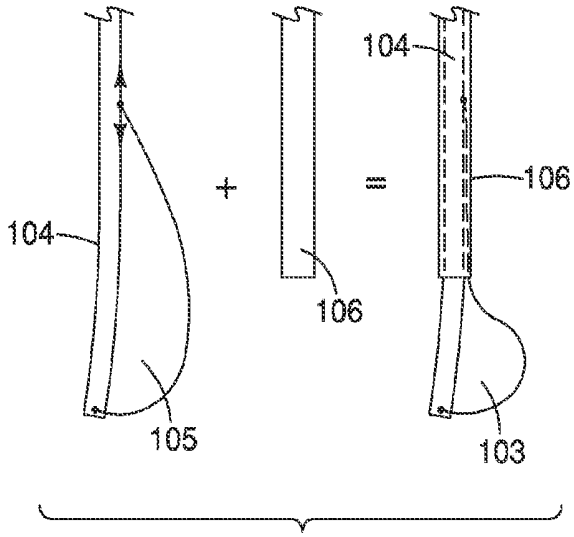


FIG. 12A

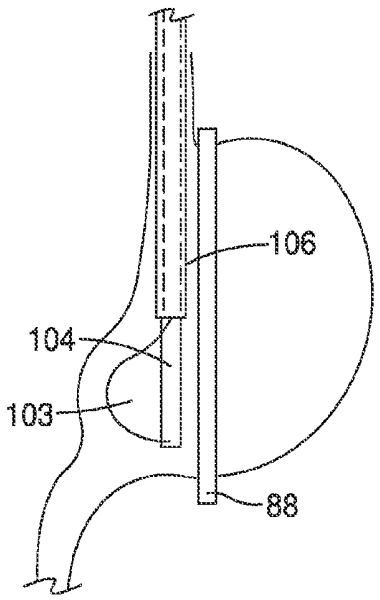


FIG. 12B

F1

$$C_1 + 2L_1 = C_2$$

FIG. 13A

F2

$$D_1 + \frac{2L_1}{\pi} = D_2$$

FIG. 13B

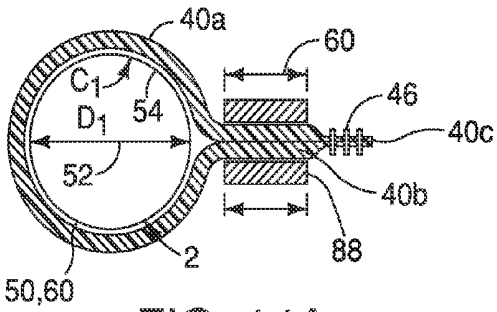


FIG. 14A

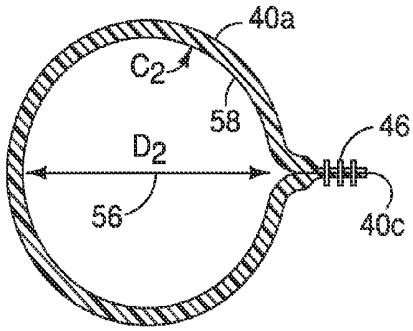


FIG. 14B

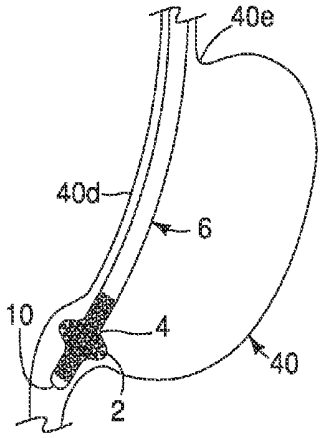


FIG. 15

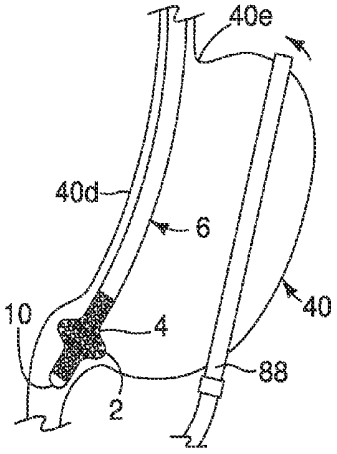


FIG. 16

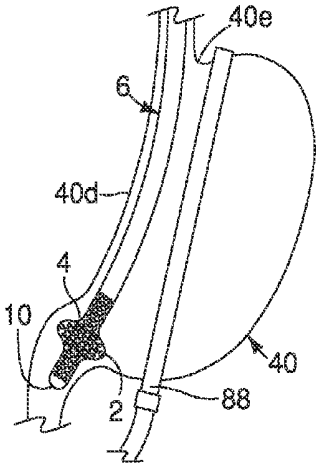


FIG. 17

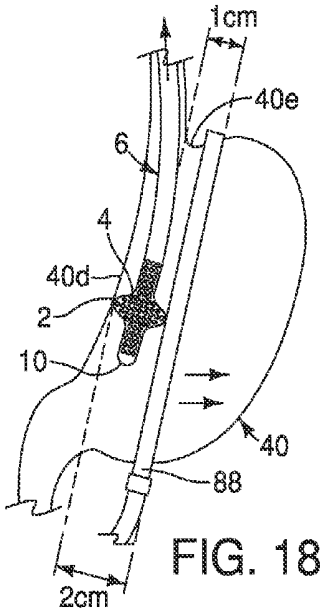


FIG. 18

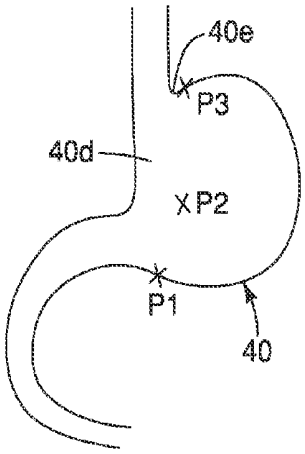


FIG. 19

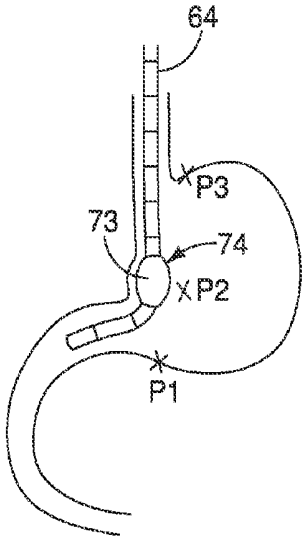


FIG. 20

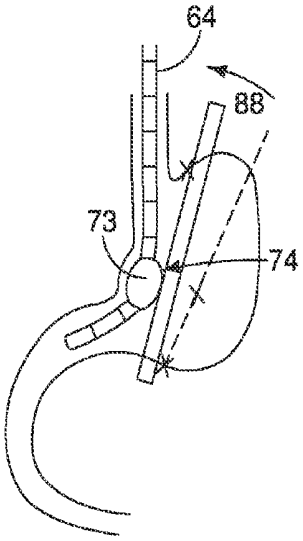


FIG. 21

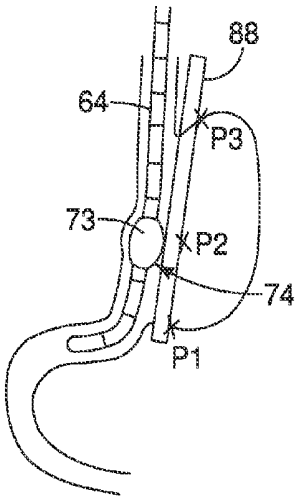


FIG. 22

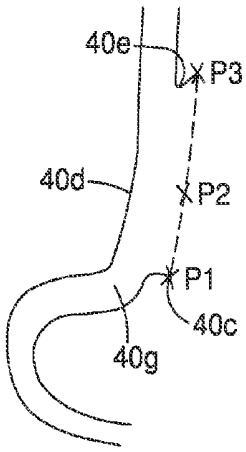


FIG. 23

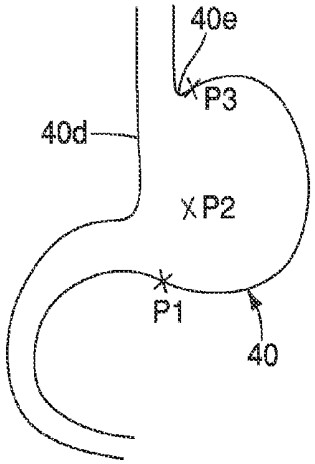


FIG. 24

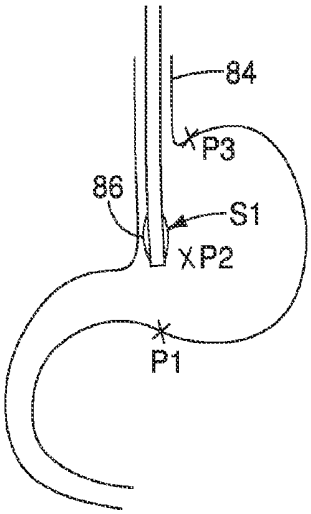


FIG. 25

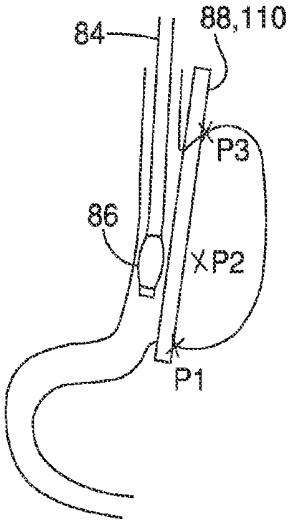


FIG. 26

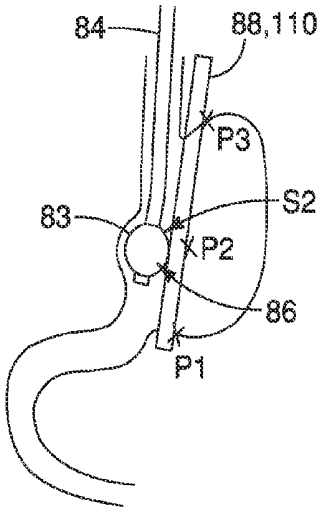


FIG. 27

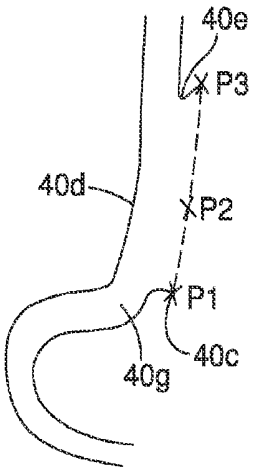


FIG. 28

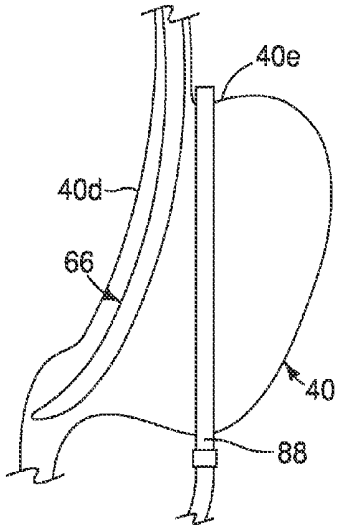


FIG. 29

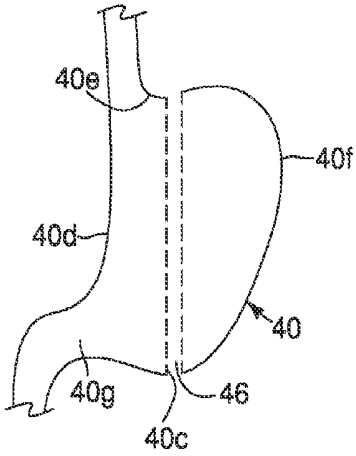


FIG. 30

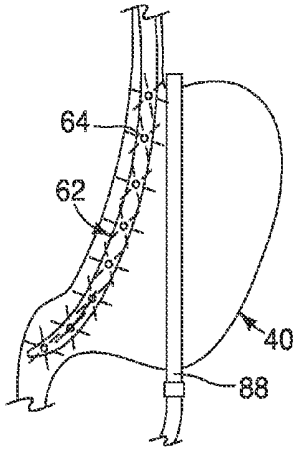


FIG. 31

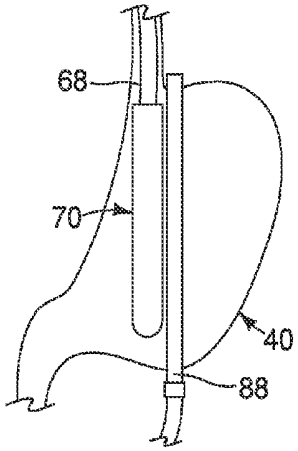


FIG. 32

Tube size (Fr)	Clamp Width (mm)									
	0	5	6	7	8	9	10			
10	10.00	19.55	21.46	23.37	25.28	27.19	29.10			
12		21.55	23.46	25.37	27.28	29.19	31.10			
14		23.55	25.46	27.37	29.28	31.19	33.10			
16		25.55	27.46	29.37	31.28	33.19	35.10			
18		27.55	29.46	31.37	33.28	35.19	37.10			
20		29.55	31.46	33.37	35.28	37.19	39.10			
22		31.55	33.46	35.37	37.28	39.19	41.10			
24		33.55	35.46	37.37	39.28	41.19	43.10			
26		35.55	37.46	39.37	41.28	43.19	45.10			
28		37.55	39.46	41.37	43.28	45.19	47.10			
30		39.55	41.46	43.37	45.28	47.19	49.10			
32		41.55	43.46	45.37	47.28	49.19	51.10			
34		43.55	45.46	47.37	49.28	51.19	53.10			
36		45.55	47.46	49.37	51.28	53.19	55.10			
38		47.55	49.46	51.37	53.28	55.19	57.10			
40		49.55	51.46	53.37	55.28	57.19	59.10			
42		51.55	53.46	55.37	57.28	59.19	61.10			
44		53.55	55.46	57.37	59.28	61.19	63.10			
46		55.55	57.46	59.37	61.28	63.19	65.10			
48		57.55	59.46	61.37	63.28	65.19	67.10			
50		59.55	61.46	63.37	65.28	67.19	69.10			
52		61.55	63.46	65.37	67.28	69.19	71.10			
54		63.55	65.46	67.37	69.28	71.19	73.10			
56		65.55	67.46	69.37	71.28	73.19	75.10			
58		67.55	69.46	71.37	73.28	75.19	77.10			
60		69.55	71.46	73.37	75.28	77.19	79.10			

FIG. 33

SLEEVE GASTRECTOMY CALIBRATION TUBE AND METHOD OF USING SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/046,598, filed Sep. 5, 2014, the disclosures of which are incorporated herein by references in their entirety.

TECHNICAL FIELD

[0002] The examples herein may be directed to a sleeve gastrectomy, and more particularly to a calibration tube inserted into the stomach and used in conjunction with a sleeve gastrectomy stapling guide or a sleeve gastrectomy stapler such as a full length sleeve gastrectomy stapler. The example devices herein may provide a minimum safe distance from the incisura angularis and other stomach landmarks during the creation of a vertical sleeve gastrectomy.

BACKGROUND

[0003] Obesity is a disease that affects a significant portion of the world's population and leads to multiple chronic medical conditions and premature death from cardiovascular events and cancer. In particular, the United States has a current, and worsening obesity epidemic. The U.S. Centers for Disease Control and Prevention (CDC) reports that over 33% of the U.S. population is obese, with a Body Mass Index (BMI) of over 30, and another 35-40% of the US population is overweight, with a BMI of 25-30. The CDC reports that the percent of the US population being either overweight or obese by 2018 will be 75%. The CDC also reports that obesity directly costs the U.S. economy $147 billion currently, and projects that the costs will approach $315 billion by 2020.

[0004] Further, obesity has environmental, genetic and behavioral origins but is intractable to most medical and behavioral interventions. To help reduce obesity and/or facilitate weight loss, bariatric surgery may be an option for some patients that may be overweight. Typically, bariatric surgery may be an effective long-term treatment option for patients with a BMI greater than 35. Despite the 20 million patients who are eligible for weight loss surgery in the U.S., the number of procedures per year has plateaued at about 200 thousand, eliminating any public health effect of surgery.

[0005] In recent years, a popular form of bariatric surgery may include a laparoscopic vertical sleeve gastrectomy (e.g., which may remove approximately 80% of the stomach). Laparoscopic vertical sleeve gastrectomy may be a procedure that may be safer and more effective for patients eligible for weight loss surgery. In fact, it has been accepted as the surgery that should be offered to most morbidly obese patients over, for example, laparoscopic adjustable gastric banding and laparoscopic Roux-en-Y gastric bypass. As such, the surgery has been adopted by bariatric surgeons and is now the most commonly performed weight loss surgery.

[0006] Vertical sleeve gastrectomy is typically performed using standard laparoscopic equipment. The greater curvature of the stomach is mobilized using vessel-sealing devices, sealing the gastric branches of the gastroepiploic vessels and the short gastric vessels. The posterior adhesions of the stomach are also divided so the stomach is fully mobilized while the blood supply to the lesser curvature remains intact.

[0007] Following mobilization of the stomach a calibration tube is typically introduced into the stomach through the mouth. Resection is accomplished by applying a series of staples from a laparoscopic linear surgical stapler, for example, along the calibration tube in a staple line. The staple line may be important in sleeve gastrectomy as the amount of weight lost and complications or consequences may be a direct result of the quality of the resultant sleeve gastrectomy pouch formed from the staple line (e.g., the portion of the stomach not rescinded by the staple line). The complications or consequences may include gastroesophageal reflux disorder (GERD), weight loss failure or weight regain, food intolerance, staple line bleed, leak, and/or the like.

[0008] To help produce a repeatable sleeve gastrectomy pouch (e.g., from the staple line), a sleeve gastrecotomy stapling guide and calibration tube with a constant diameter may be used. Although the combination of the stapling guide and calibration tube may help produce a better staple line and, thus, sleeve gastrectomy pouch, a surgeon may still need to estimate or envision an adequate distance from one or more parts of the stomach such as the IA to not create a stricture at that point with the staple line. Other efforts, devices, and techniques such as balloon catheters, bougies, and/or the like have been made to improve the calibration and, thus, location of the staple line such thereby needing less estimation by the surgeon. Unfortunately, such efforts still make it difficult for a surgeon to envision the staple line and may not help ensure that proper distances are maintained from each landmark along the stomach as the surgeon may still need to estimate distances to create the staple line.

SUMMARY

[0009] In an example herein, one or more medical devices may be provided that may be used, for example, in bariatric surgery including a vertical sleeve gastrectomy. The one or more medical devices may include a laparoscopic sleeve gastrectomy stapling guide in conjunction with a calibration tube in accordance with one or more examples. According to an example, the calibration tube may be a flared, multi-diameter calibration tube. The flared, multi-diameter calibration tube may have a first diameter along a portion of the tube and a second diameter that may larger than the first diameter along at least another portion of the tube. The calibration tube may be used in conjunction with the stapling guide to align stomach such that it may be stapled along the stapling guide (e.g., to perform the vertical sleeve gastrectomy). In examples herein, the one or more devices (e.g., the calibration tube and/or the stapling guide) may provide a proper distance (e.g., a minimum safe distance) from the incisura angularis and other stomach landmarks during the creation of a staple line for the vertical sleeve gastrectomy and may be used to create a repeatable resultant sleeve size of the stomach. For example, a surgeon may have a good idea of what size the resultant sleeve size should be, but the shortcoming of current methods, medical devices, and/or the like may lie in how they may be used to create and repeat such a sleeve—both between different surgeons, and for each surgeon from patient to patient. The use of the flared, calibration tube (e.g., with the different diameters) along with the staple guide may enable a surgeon to create the resultant sleeve size they desire, and a size they know works for effective weight loss while at the same time may improve a surgeon's ability to line up each staple fire and create the resultant sleeve that may be more consistent and repeatable.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. **1** depicts the flared calibration tube complete with a valve for regulated suction and perforations to allow for suction and injection of material into the stomach.

[0011] FIG. **2** depicts a zoomed-in look at the tip of the flared calibration tube, indicating the cylindrical flared portion along with the perforations.

[0012] FIG. **3**A depicts the suction regulation valve of the flared calibration tube in the "open" position.

[0013] FIG. **3**B depicts the suction regulation valve of the flared calibration tube in the "closed" position.

[0014] FIGS. **4-9** depicts an enlarged view of one or more additional or alternative examples of a flared portion that may be included in the flared, calibration tube.

[0015] FIGS. **10-12**B depicts an enlarged view of one or more additional or alternative examples of a flared portion that may be included in the flared, calibration tube.

[0016] FIG. **13**A is the formula used to calculate resultant sleeve circumference based on stapling guide width and calibration tube circumference.

[0017] FIG. **13**B is the formula used to calculate resultant sleeve diameter based on stapling guide width and calibration tube diameter.

[0018] FIG. **14**A depicts a cross-section view of what the calibration tube and stapling guide combination will look like, with the adjacent resection line along the guide.

[0019] FIG. **14**B then depicts the resultant size of the sleeve once the calibration tube and stapling guide have been removed.

[0020] FIG. **15** depicts the flared calibration tube once it has been inserted to the pylorus of the stomach.

[0021] FIG. **16** depicts the stapling guide being positioned around the stomach.

[0022] FIG. **17** depicts the stapling guide being positioned at the gastroesophageal junction, in the approximate location of where the resection line will occur.

[0023] FIG. **18** depicts the calibration tube being pulled up from the pylorus and positioned along the incisura angularis, forcing the stapling guide to move laterally into the appropriate position to prepare for stapling and cutting.

[0024] FIGS. **19-23** illustrate an additional or alternative example method or procedure that may be performed using the flared, calibration tube in one or more examples.

[0025] FIGS. **24-28** illustrate an additional or alternative example method or procedure that may be performed using the flared, calibration tube in one or more examples.

[0026] FIG. **29** depicts a calibration tube that is meant to generally represent the alternative embodiments listed above, used in conjunction with the stapling guide to assist in guide and resection line alignment.

[0027] FIG. **30** depicts the resultant sleeve after the stapling and cutting has been executed. The resection line is about 2 cm off the incisura angularis, about 1 cm off of the GE junction, is vertical, and has complete fundus removal.

[0028] FIG. **31** depicts a calibration tube in accordance with another embodiment of the invention and used in conjunction with a stapling guide to assist in guide and resection line alignment.

[0029] FIG. **32** depicts a calibration tube in accordance with another embodiment of the invention and used in conjunction with a stapling guide to assist in guide and resection line alignment.

[0030] FIG. **33** depicts a table illustrating different sizes of the flared, calibration tube and/or the stapling guide that may provide different sizes to a resultant sleeve of a stomach in one or more examples herein.

DETAILED DESCRIPTION

[0031] As described herein, systems and/or methods may be provided for performing a sleeve gastrectomy. For example, a first medical device may be positioned in an interior of the stomach. The first medical device may include or have a first diameter along a first portion thereof (e.g., a calibration or medical tube) and a second diameter that may be larger than the first diameter along a second portion thereof (e.g., a flared portion or a radially-outward projecting portion of a medical tube). The first medical device may be positioned, for example, by inserting the first medical device into a mouth of a patient to access the interior of the stomach and positioning the second portion at a landmark (e.g., a first landmark such as an incisura angularis (IA)) of the stomach. According to an example, the first medical device may be moved proximally and/or distally (e.g., from a first position to a second position) to position the first medical device at the landmark.

[0032] Further, in one example, a second medical device such as a clamp or stapler may be positioned on an exterior of the stomach relative to or based on an interaction with the first medical device (e.g., adjacent to, near, in proximity to, and/or interaction with the second portion of the first medical device) such that the second medical device may be configured to demonstrate or create a path such as a resection line or staple line) along the stomach at which the sleeve gastrectomy may be performed. As such, the first medical device may be used as a reference to position the second medical device. For example, an interaction (e.g., positioning the second medical device relative to the first medical device may position the second medical device in a desired position to demonstrate or provide the path. In one example, movement of the first medical device causes a corresponding movement or sliding of the second medical device (e.g., from a first position to a second position) along the exterior of the stomach to position the second medical device in the desired position to demonstrate the path. The second medical device may be fixed relative to another landmark and/or additional landmarks of the stomach (e.g., a second and/or a third landmark) as part of its positioning to create and/or demonstrate the path.

[0033] In additional examples, the first medical device itself may create and/or demonstrate the path to perform the sleeve gastrectomy as described herein (e.g., without use of the second medical device). In such an example the path may be demonstrated and/or created along the second portion (e.g., the flared portion) of the first medical device (e.g., the tube).

[0034] The sleeve gastrectomy (e.g., resection of part of the stomach) may be performed along the path thereby producing a resultant sleeve of the stomach. For example, a resection or staple line may be created (e.g., using a surgical stapler) along the path thereby producing the resultant sleeve. In one or more examples herein, the resultant sleeve of the stomach that may be created by the path (e.g., the resection or staple line) may include a diameter of approximately to 3 cm near the first landmark (e.g., the IA), approximately 2 to 6 cm near a second landmark (e.g., a pylorus) of the stomach, and approximately 0 to 2 cm near a third landmark (e.g., a gastroesophageal junction (GEJ) or GE junction) of the stomach.

[0035] In one example, the first medical device may be a flared, multi-diameter calibration tube and may include a tube that may include a flared portion at a distal end thereof. In an example, the tube may be the first portion and the flared portion may be the second portion. The tube may have or include a first diameter (e.g., a constant diameter as described herein) that may be proximal and distal to the flared portion. The flared portion may have or include a second diameter (e.g., a maximum diameter as described herein) that may be larger than the first diameter. As described herein, the tube (e.g., that may be the first medical device or part of the first medical device) may be configured to be inserted or may be inserted into an interior of the stomach and the flared portion may be positioned at a first landmark thereof (e.g., the IA) such that the flared portion that may be positioned at the first landmark may be configured to facilitate alignment of a resection line or staple line (e.g., the path) during the sleeve gastrectomy that produces the resultant sleeve described herein. For example, the flared portion may include a first point and a second portion at an opposite end thereof forming the second diameter thereacross. The first point of the flared portion may be configured to be positioned near the first landmark as described herein and the second point of the flared portion may be configured to form the resection line (e.g., a line that includes the second point) that produces the resultant sleeve.

[0036] In an example, alignment of resection or staple line may further be facilitated by the second medical device (e.g., a clamp or stapler) positioned relative to the first medical device. For example, the flared portion may include a first point and a second point at an opposite end thereof forming the second diameter thereacross. The first point of the flared portion may be configured to be positioned near the first landmark as described herein and the second medial device may be configured to be positioned near the second point of the flared portion to form the resection line (e.g., a line along a side of the clamp opposite of the side positioned near the second point) that produces the resultant sleeve.

[0037] FIG. **1** depicts the flared calibration tube complete with a valve for regulated suction and perforations to allow for suction and injection of material into the stomach. As shown in FIG. **1**, a flared, calibration tube **12** (e.g., a first medical device) in accordance with one or more examples herein may be provided. According to an example herein, the flared, calibration tube **12** may be used in conjunction with a second medical device (e.g., a clamp or a surgical stapler) as described herein (not shown in FIG. **1** but an example of which may be shown as stapling guide **88** in FIGS. **15-32**) to perform a vertical sleeve gastrectomy. In an example, the flared, calibration tube **12** may have a first diameter along a portion thereof that may be constant (e.g., **6**) and a second diameter along another portion thereof (e.g., **2**) that may be larger than the first diameter as described herein.

[0038] For example, as shown, the flared, calibration tube **12** may include a tube **14** (e.g., a first portion of the first medical device or calibration tube) and a suction regulation valve **16** that may cap the tube **14** (e.g., a body of the tube **14**). As shown, the tube **14** may be generally cylindrical in shape and may be made of, for example, rubber, silicone, polyurethane, a plastic polymer, and/or any other suitable material. The tube may be hollow, solid, and/or the like in one or more examples. The tube **14** may include a proximal end PE that may be closer to a surgeon that may interact with the flared, calibration tube **12** to a distal end DE that may be farther away from the surgeon. As shown, the tube **14** may include a lower tip **10** at the distal end DE and a flared out portion **3** (e.g., a second portion of the first medical device or calibration tube) and may be capped off by the suction regulation valve **16** at the proximal end PE.

[0039] The lower tip **10** of the tube **14** may be long enough to allow for easy insertion into the mouth, esophagus, and stomach, and/or may enable or allow the tube **14** of the flared, calibration tube **12** to be navigated down to the pylorus of the stomach. Moving proximally up from the lower tip **10** at the distal end DE, the tube **14** (e.g., the generally cylindrical shape of the tube **14**) may include a flared portion **3** (e.g., a cylindrical flared portion).

[0040] FIG. **2** depicts an enlarged view of the lower tip **10** of the tube **14** that may be included in the flared, calibration tube **12** including the flared portion **3**. As shown in FIG. **2**, the tube **14** may begin to flare out **4** from the constant diameter **6** until it reaches the maximum diameter **2** at which point it may begin to flare in **5** until it may return back to the constant diameter **6** thereby forming the flared out portion **3**. As described herein, the flared out portion **3** may be used to align and calibrate a stapling guide such that a more accurate staple line (e.g., path or resection line) may be formed for resection during the vertical sleeve gastrectomy according to examples herein. As shown, the maximum diameter **2** may be formed by points (e.g., a first and second point such as P and P') at opposite ends or sides of the flared portion **3**.

[0041] In an example, the flared portion **3** may be approximately 2 cm long from the beginning of the flare **4** to the end of the flare **5**. Further, as shown, the maximum diameter **2** of the flared portion **3** may be approximately. Additionally, as described herein (e.g., above), the flared portion **3** may narrow at **4** and **5** until it may return to the constant diameter **6** (e.g., that may be substantially maintained throughout the rest of the tube **14**). Example dimensional ranges of the constant diameter portion **6** of the tube may be from 0.3 cm to 1.5 cm and example dimensional ranges of the flared portion **3** are contemplated to range from 0.5 cm to 2.0 cm (e.g., including the maximum diameter **2**). Such ranges may be provided based on a spacer (e.g., the spacer **60**) that may be 1 cm in width according the formulas F**1** and F**2** described with respect to FIGS. **13**A-**13**B and **14**A-**14**B. In one or more examples, the resultant sleeve diameter range may be 1 cm (or 30 French) to 2 cm (or 60 French) for the cylindrical portion near or above the incisura angularis (e.g., a first landmark), may be 2 cm to 6 cm for the portion near the pylorus (e.g., a second landmark), and/or 0 cm to 2 cm for the portion near the GEJ (e.g., a third landmark). The flared portion **3** may have a wider resultant sleeve diameter of 1.2 cm (or 36 French) to 2.6 cm (or 78 French) according to examples herein.

[0042] As shown in FIG. **2**, according to one example, the flared portion **3** may be integrally formed as part of the tube **14**, for example, during manufacturing. In additional or alternative examples, the flared portion **3** may be separately coupled and/or fixedly attached to the tube **14** and/or may include two separate pieces (e.g., as shown in FIGS. **4-8**). In additional embodiments, the flared portion **3** may be a constant diameter (e.g., the constant diameter **6**) and/or a smaller diameter than the constant diameter **6** until use of the flared, calibration tube **12** during the vertical sleeve gastrectomy during which the flared portion **3** may be enlarged to the maximum diameter **2** by inflation and/or actuation such as mechanical actuation (e.g., as shown in FIGS. **10-12**).

[0043] In examples herein, the diameter **2** of the flared out portion **3** may be used as a form of alignment and calibration,

and/or may be the point at which a stapling guide (not shown in FIG. **1** and which may be shown as **88** in FIGS. 15-32) may be positioned adjacent to an incisura angularis (IA) (e.g., not shown in FIG. **1** and which may be shown as **40***d* in FIGS. **15-32**). As such, the flared, calibration tube **12** (e.g., via tube **14**) may include a constant diameter **6** and a maximum diameter **2** (e.g., D_1 in FIG. **13**A) of a flared portion **3** such that the flared, calibration tube **12** may enable a surgeon to more reliably create a sleeve pouch with a different (wider) diameter at the IA (e.g., D_2 in FIG. **13**B) than the GE junction. In such an example, the stapling guide may be used as a spacer, otherwise, the flared portion **3** may not fit past the narrower upper sleeve of the stomach (e.g., **40***e* as shown in FIGS. **15-18**).

[0044] In an example, as shown in FIG. **2**, the tube **14** may include one or more perforations **26**. For example, as shown, the lower tip **10**, the flared portion **3**, and/or a portion of the tube **14** proximal to the flared portion include the one or more perforations **26** therein. In an example, the one or more perforations **26** may be holes in the tube **14** that may be used to collect or suction tissue debris from the stomach that may be suctioned proximally up through the tube **14** during the vertical sleeve gastrectomy and expunged therefrom as described herein.

[0045] Referring back to FIG. **1**, the body of the tube **14** may be capped **24** by a suction control valve **16** that may be used to regulate when and how suction may be applied to the distal end DE (e.g., shown in FIG. **2**) of the tube **14**. As shown, the suction control valve **16** may include a switch **22** that may be used to open and/or close the suction control valve thereby allowing and/or not allow air flow through the tube.

[0046] FIG. **3**A depicts the suction control valve **16** of the flared, calibration tube **12** in an "open" position **20**. In an example, when the switch **22** of the valve **16** may be in the "open" position **20**, air may flow out of the tube **14** through an opening at a proximal tip **18** of the flared, calibration tube **12**. As described herein, in the "open" position **20**, the suction control valve **16** may enable tissue debris to be removed during the vertical sleeve gastrectomy and expunged therefrom as described herein. For example, the debris that may be collected by the one or more perforations **26** may be suctioned through the tube **14** and out of the opening in the proximal tip **18** when the suction control valve **16** may be in the "open" position **20**.

[0047] FIG. **3**B depicts the suction control valve **16** of the flared, calibration tube **12** in a "closed" position **28**. According to an example, when the switch **22** of the valve **16** may be in the "closed" position **28**, air may not flow out (e.g., air may be blocked) of the tube **14** through the opening at a proximal tip **18** of the flared, calibration tube **12**. In the "closed" position **28**, tissue debris may not be expunged and/or removed during the vertical sleeve gastrectomy.

[0048] FIGS. **4-8** depicts an enlarged view of one or more additional or alternative examples of the flared portion **33** that may be included in the flared, calibration tube **12**. As shown in FIGS. **4-6**, a separate, flared portion **33** (e.g., that may have the same or similar properties including the maximum diameter **2**, and/or the like as described herein with respect to the flared portion **3**) may be coupled or attached onto an existing stock gastric tube **34** (e.g., that may have the same or similar properties including the constant diameter **6**, and/or the like as described herein with respect to the tube **14**). This may enable the flared portion **33** (e.g., the add on) to be sold separately and assembled at bedside or prior to the surgery. In examples herein, the flared portion **33** may be slid onto the tube **34**, may be snapped around the tube **34**, may be glued on the tube **34**, and/or may be coupled and/or fixedly attached to the tube **34** using any other suitable coupling or attachment mechanism. The flared portion **33** may include and/or have a tapered face (e.g., similar to the flared portion **3** tapering to **4** and **5**) to slide along the oropharyngeal, esophageal and gastric mucosa without damaging the mucosal surfaces and/or getting snagged. The flared portion **13** may be made rubber, silicone, polyurethane, a plastic polymer, and/or any other suitable material.

[0049] FIGS. **5**A-**5**B illustrate examples of the flared portion **33** that may be coupled or attached onto the tube **34**. As shown in FIG. **5**A, the flared portion **33** may include a first flared portion **40** and a second flared portion **42**. As shown, the first flared portion **40** and the second flared portion **42** may have crevices **44***a*, **44***b* respectively. The crevices **44***a*, **44***b* may be convex depression that may extend along the outer diameter of the tube **34** and may when combined take the shape of the outer diameter of the tube **34**. For example, when the first and second portions **40**, **42** may coupled or attached together (e.g., connected via one or more snaps (not shown), glue, and/or the like), the crevices **44***a*, **44***b* may receive and surround the tube **34**. As shown in FIG. **5**B, the first and second portions **40**, **42** may include a hinge **48***a*, **48***b* that may be used to pivot the first and second portions, **40**, **42** to surround the tube **34**.

[0050] In an example, as shown in FIG. **6**, the flared portion **33** may be used with different diameter tubes. For example, the flared portion **33** may include and/or have a gripping surface **50** and a screw **52** and/or cap **54** that may be inserted into one or more sides of the tube **34**. The gripping surface **50** may include teeth **51** that may be used to prevent the flared portion **33** from sliding up and down the tube **34**. For example, the flared portion **33** may be slid over the tube **34** and the teeth **51** of the gripping surface **50** may help secure the flared portion **33** at the appropriate location on the tube **34** thereby preventing the flared portion **33** from sliding freely up and down the tube **34**. In one example (e.g., once the flared portion **33** may be positioned at the appropriate location), the screw may be inserted over the tube **34** and screwed, for example, in a distal end of the flared portion **33** and the cap **52** may be inserted over the tube **34** and snapped into a proximal end of the flared portion **33** thereby further securing the flared portion **33** on the tube **34** and preventing movement thereof.

[0051] According to examples, as shown in FIGS. **7-8**, a tube with two diameters (e.g., a first and second diameter) and/or a first and second tube **64**, **74** may be inserted within each other may be used to form a flared portion **73** (e.g., that may have the same or similar properties including the maximum diameter **2**, and/or the like as described herein with respect to the flared portion **3**). For example, the first tube **64** may include a 16 or 18 French polymer or latex orogastric tube that may be used as the smaller diameter tube (e.g., that may have the same or similar properties of the tube **14** including the constant diameter **6**, and/or the like). The second tube **74** may include a tapered wider section of a tube (e.g., a polymer or latex orogastric tube) with an inner diameter that may be equivalent to, larger, and/or substantially similar to the outer diameter of the tube **14** (e.g., constant diameter **6**) and an outer diameter equivalent to the diameter of the flared portion **3** (e.g., the maximum diameter **2**). Further, as shown in FIG. **8**, the tube **74** may taper similar to the tapering **4**,**5** of the flared portion **3**. According to an example, the second tube

74 may be slid over and positioned at the appropriate location on the first tube 64 (e.g., a location approximately near the distal end 10 similar to the flared portion 3). The second tube 74 (e.g., once positioned) may be fixedly attached and/or coupled to the first tube 64 via any suitable technique including solvent bonding via a solvent bond 75.

[0052] FIG. 9 illustrates an example of one or more lights that may be included in the flared portion 3, 33, and/or 73 in one or more examples. For example, the flared portion 3, 33, and/or 73 (e.g., the wider section) of the tubes 14, 34, and/or 74 (e.g., that may be combined with the tube 64) may be fitted with lights 78, 79 such as LED or fiber optic lights to better visualize the position of the tube within the stomach. According to an example, having lights 78, 79 that may indicate the flared portion may enable or the surgeon to accurately place the wider portion of the calibration tube adjacent the incisura angularis (IA).

[0053] FIGS. 10-12B depicts an enlarged view of one or more additional or alternative examples of the flared portion 83 that may be included in the flared, calibration tube 12. As shown in FIG. 10, in one example, a tube 84 that may be included in the flared, calibration tube 12 may include a first diameter D1' that may be adjustable to a second diameter D2' to form the flared portion 83. For example, the tube 84 may include a balloon 86 that may be used to form the flared portion 93. The balloon 86 may be relaxed or deflated prior to use and insertion of the flared, calibration tube 12 in the stomach. In such an example (e.g., prior to insertion and use), the tube 84 with the balloon 86 in the relaxed or deflated state S1 may have a substantially constant diameter (e.g., similar to the constant diameter 6). The first diameter D1' may be the substantially constant diameter. The balloon 86 may be inflated to an inflated state S2 upon insertion of the tube 84 that may be part of the flared, calibration tube 12 into the stomach to the appropriate position such as adjacent to the incisura angularis and interaction therewith. According to an example, the inflated state S2 may form the flared portion 83 that may have the second diameter D2' (e.g., similar to the maximum diameter 2). The tube 84 with the flared portion 83 formed by the balloon 86 may enable the staple line to be performed with a single cartridge sleeve gastrectomy stapler. For example, the tube 84 may be placed with the balloon 86 adjacent the incisura angularis (e.g., as described in FIGS. 24-28 below) in the state S1. The stapler may then placed in apposition but not fully clamped, the balloon may be inflated to the state S2 to form the flared portion 83, and the flared portion 83 formed by the balloon 86 in the state S2 may widen the area adjacent the incisura angularis prior to stapling. After stapling, the balloon 86 may be deflated to state S1 such that the tube 84 may return to the first diameter D1' and may be removed.

[0054] Further, as shown in FIG. 11, a tube 94 that may be included in the flared, calibration tube 12 may include a first diameter D1" that may be adjustable to a second diameter D2" to form the flared portion 93. For example, the tube 94 may include a split tube 95 at a distal end (e.g., the distal tip 10) and a solid portion 96 (e.g., that may have properties similar to the tube 14 including the constant diameter 6) extending proximally from the split tube 95 and the distal end. The split tube 95 may be used to form a flared portion 93 (e.g., that may have similar properties to the flared portion 3) similar to the balloon 86 used in the tube 84 described with respect to FIG. 10. In an example, the split tube 95 may include a first portion 98 and a second portion 99 that may be widened to form the flared portion 93. For example, the split tube 95 may be relaxed or compressed prior to use and insertion of the flared, calibration tube 12 in the stomach. In such an example (e.g., prior to insertion and use), the first and second portions 98, 99 of the split tube 95 may be in contact with each other in a relaxed or compressed state S1' such that the split tube 95 may have a substantially constant diameter (e.g., that may be similar and/or smaller than the constant diameter 6) that may be diameter D1". The split tube 95 may be widened (e.g., the first and second portions 98, 99 may be separated) from the relaxed or compressed state S1' to an expanded state S2' that may form the flared portion 93 upon insertion of the tube 94 into the stomach to the appropriate position such as adjacent to the incisura angularis and interaction therewith (e.g., similar to that described in FIGS. 24-28). Such an interaction may include, for example, shortening a distance from the distal tip to the solid portion of the tube 94 by pulling on a control element (e.g., at the proximal end of the tube 94 not shown). As shown, in the second state S2', the first and second portions 98, 99 of the split tube 95 may be adjusted from the first diameter D1" to a second diameter D2" (e.g. may become wider along an x-axis) the first and second portions 98, 99 may be wider along the x axis. In additional or alternative examples, the split tube 95 may include three portions, four portions, and/or the like that may be expanded and/or become wider along the x and z axes to form the flared portion 93.

[0055] In an example as shown in FIG. 12A-12B, a tube 104 may include a bowing out portion that may be used to form the flared portion 103 that may be included in the flared, calibration tube 12. As described herein the tube 104 may include one or more properties similar to the tube 4 such as the constant diameter 6, and/or the like. Similarly, the flared portion 103 that may be formed may include one or more properties similar to the flared portion 3 such as the maximum diameter 2 (e.g., upon actuation and/or insertion). The flared portion 103 may be formed from bowing out a sail 105 attached to the tube 104 using a sheath 106. For example, the tube 104 may have a sail portion 105 (e.g., a portion that bows out) that may be connected to the tube 104 at the distal end and a second point 20 to 30 cm proximally. Alternatively, the sail portion 105 is connected distally and extends beyond the proximal end of tube 104. In this configuration, the sail portion 105 is extendable when portion extending beyond tube 104 is pushed into tube 104 and retractable when portion extending beyond tube 104 is lengthened. The sail portion 105 may be adjusted to form the fared portion 103, for example, by applying force thereto using a sheath 106, and/or the like. For example, the flared, calibration tube 12 may include a sheath 106. The sheath 106 may be inserted over the tube 104 at the proximal end (e.g., PE) to apply the force to the sail portion 105 thereby adjusting the sail portion 105 to form the flared portion 103 relative to tube 104. In an example, the tube 104 with the sail portion 105 may be inserted into the stomach and positioned such that the flared portion 103 when formed may be adjacent to the incisura angularis. The sheath 106 may then be pushed distally down the tube 104, and may be moved distally and/or proximally to form and adjust the area that bows out to form the flared portion 103. In an example, the sail portion 105 may be combined with either a stapler or a stapling guide to make the flared portion 103 and/or the resultant sleeve formed thereby wider at the incisura angularis.

[0056] FIGS. 13A-13B depict example formulas, F1 and F2, that may be used to calculate a resultant sleeve circum-

ference and diameter, respectively, based on stapling guide width and calibration tube circumference, respectively.

[0057] As described herein, using the flared, calibration tube with a sleeve gastrectomy stapling guide may help to create a repeatable sleeve gastrectomy anatomy based on a size a surgeon may want to achieve for their patient. The formulas F**1**, $C_1+2L_1=C_2$, and F**2**,

$$D_1+\frac{2L_1}{\pi}=D_2,$$

may be used such that the flared, calibration tube and the stapling guide or clamp may create a reproducible sleeve diameter. In examples, D_1 represents the diameter of the calibration tube used and C_1 represents its circumference (e.g., at the IA, or the narrowest point), L_1 represents the distance/width of the (e.g., top and bottom) stapling guide, D_2 represents the diameter of a resultant sleeve size, and/or C_2 represents its resultant circumference.

[0058] For example, a surgeon may aim or want to create a resultant sleeve size equivalent to using that of a 36 French (Fr) bougie (or 1.2 cm), which may be D_2. If the stapling guide may be 1 cm in width (L_1), using the formula F**2**, the diameter of the calibration tube may be approximately 0.5634 cm (D_1), or 16.9014 Fr. As such, to create a sleeve size resultant of using a 36 Fr bougie, a 16.9 Fr flared, calibration tube should be used in conjunction with a stapling guide.

[0059] As described herein, one of the main focuses of this process, and the calibration tube, is the fact that it keeps the resection line at least 2 cm off of the IA. The desired resultant diameter above was 36 Fr, but this is only equivalent to 1.2 cm. While 36 Fr is a good estimate of the average diameter of the various calibration tubes used, surgeons achieve the 2 cm IA offset by inserting their calibration tube, and stapling (i.e. estimating) slightly off the calibration tube, guessing at where they think 2 cm is.

[0060] To overcome this, the calibration tube may configured to flair out at its widest point (e.g., the maximum diameter **2** of the flared portion **3**, **13**, and/or **23**), which may be the same point where it may be lined up adjacent to the IA and the stapling guide, and may create a resultant diameter of 2 cm. Inserting 2 cm as D_2 into F**1**, with L_1 still 1 cm, D_1 may be calculated as 1.3634 cm, or 40.9014 Fr. Thus, at its widest point, the flared, calibration tube may be about 41 Fr. The rest of the tube may narrow as it moves proximally (e.g., to **4**) until it reaches the constant diameter or a smaller diameter such that this point in the tube, for example, the flared portion or maximum diameter thereof may be emphasized and easier to see from the surgeon's perspective. The 41 Fr flair may subsequently narrow to something closer to the examples described herein, of around 15 or 16 Fr, so the rest of the tube may not be as wide thereby facilitating fundus removal, which may be important to the procedure. This narrowing from the maximum diameter (e.g., to **4** and/or **5**) may also allow the stapling guide to be positioned at the GEJ. Based on the width and shape of the stapling guide along with the diameter of the flared, calibration tube, a 1 cm offset from the GEJ and a squared off final cut may be provided (e.g., ensured). As such, in an example, with a 10 mm stapling guide as a spacer, a calibration tube with a 41 Fr flare portion and 16.9 Fr body, a surgeon may be able to achieve a safe distance from the incisura angularis and create a sleeve gastrectomy tube with a consistent resultant diameter of 36 Fr.

[0061] Further, in one or more examples, other surgeons may want 1.5 cm or 2.5 cm offset (e.g., even though a 2 cm offset at the IA may be believed to be ideal) or some other distance along their staple line, so various sizes of flared, calibration tubes may be used in one or more examples herein to accommodate surgeon needs to maximize what they think is the best, most effective sleeve. A table as shown in FIG. **33** with the different sizes D_1, D_2, L_1, C_1, and/or C_2 may be provided to assist a surgeon in knowing the resultant sleeve volume with different sizes of the flared, calibration tube and/or the stapling guide. As such, according to examples herein, different flared, calibration tubes with different diameters may be used with a stapling guide with a particular width to achieve a resultant sleeve diameter using the formulas F**1** and F**2** (e.g., calculated thereby).

[0062] FIG. **14**A depicts a cross-section view of what the calibration tube and stapling guide combination will look like, with the adjacent resection line along the guide. In an example herein, the formula F**1** illustrated in FIG. **13**A may be used to calculate the resultant sleeve circumference **58** (C_2) from the circumference **54** of the calibration tube **50** used (C_1) and the width **60** (L_1) of a stapling guide **88** used as shown in FIG. **14**A.

[0063] FIG. **14**B depicts the resultant size of the sleeve once the calibration tube and stapling guide may be removed. In one or more examples herein, the formula F**2** as described herein may be used. Here, the diameter **56** (D_2) of the resultant sleeve **40***g* may be calculated from the diameter **52** (D_1) of the calibration tube **50** used and the width **60** (L**1**) of the stapling guide **88** used.

[0064] FIG. **15-18** depicts an example method or procedure that may be performed using the flared, calibration tube **12** in one or more examples. As shown in FIG. **15**, the calibration tube **12** may be positioned into an interior of a stomach. For example (e.g., to position), the calibration tube **12** may be inserted into a stomach **40** through the mouth and esophagus, and passed down into the pylorus. A stapling guide **88** may be positioned on an exterior of the stomach relative to the calibration tube **12**. For example, the stapling guide **88** may be passed around the stomach **40** as shown in FIG. **15** until it may be placed into position, with the proximal portion being on the GE junction **40***e* as shown in FIG. **17**. In examples, the stapling guide **88** may be inserted through a trocar or laparoscopic device to be positioned on the exterior of the stomach. The flared, calibration tube **12** may then be pulled up by the surgeon until the flared portion **3** (e.g., the maximum diameter **2** thereof) of the tube **14** may reach the incisura angularis **40***d* as shown in FIG. **18**. Because the gap between the incisura angularis **40***d* and the stapling guide **88** may be narrower than the flared portion **3** of the tube **14**, as the flared portion **3** moves vertically, it (e.g., via the point P') may push (e.g., a side of) the stapling guide **88** to the anatomic left that the stapling guide **88** may be positioned relative to. The surgeon may hold the stapling guide **88** in place at the GE junction **40***e*, so that the stapling guide **88** may swing over and create a line (e.g., along point P**1**, P**2**, and P**3** as shown in FIGS. **18** and **19** and opposite to a side positioned relative to the calibration tube **12**) up the stomach **40**. In examples, P**1** may be the distance from the pylorus, which may vary from surgeon to surgeon, but may typically be 2-6 cm from the pylorus on the gastric antrum along the greater curve (e.g., and may be **40***c* of the resultant sleeve in FIG. **30**), P**2** may be adjacent to the incisura angularis, and P**3** may be the distance from the gastroesophageal junction (GEJ) (e.g., and may be **40***e* in

FIGS. **15-18** and the resultant sleeve of FIG. **30**). Further, P**2** may be defined by an internal diameter of the flared portion **3** of the tube **14** plus the spacer effect of the stapling guide (e.g., using the formula F**1** and F**2** described with respect to FIGS. **13**A-**13**B). The edge of the stapling guide **88** (e.g., where a surgical stapler may be deployed and the staple line formed along P**1**, P**2**, and P**3**) may then be approximately 2 cm off of the incisura angularis **40***d* and approximately 1.0 cm off of the GE junction **40***e* (e.g., which as described herein may be ideal for the surgeon).

[0065] In an example (e.g., when the stapling guide **88** may be so aligned), the stomach portions may be separated and reconnected along the edge of the stapling guide **88** at the path, staple line, resection line, or line (e.g., formed by P**1**, P**2**, and P**3**) using the surgical stapler such as a conventional surgical stapler. In the example described above, the stapling guide and the surgical stapler may be separate elements. In an additional or alternative embodiment, however, the stapling guide and the surgical stapler may be integrated into a single device. Once that device may be aligned, such as with the calibration tube described above, it may be activated as described herein to form the staple line along the vertical line thereby separating and reconnecting the stomach portions without further positioning.

[0066] The resultant sleeve **40***g*, post stapling, may be illustrated in FIG. **30**. The example dimensions (e.g., about 2 cm off of the incisura angularis **40***d* and about 1 cm off of the GE junction **40***e*) may be provided for the resultant sleeve **40***g*. For example, the resultant sleeve **40***g* created or provided by the path, resection line, staple line, or line may include a diameter of 1 to 3 cm near the first landmark (e.g., the IA **40***d*), 2 to 6 cm near a second landmark (e.g., a pylorus near **40***c*) of the stomach, and 0 to 2 cm near a third landmark (e.g., a gastroesophageal junction (GEJ) or GE junction **40***e*) of the stomach.

[0067] FIGS. **19-23** illustrate another or additional example method or procedure that may be performed using the flared, calibration tube **12** in one or more examples. As shown, in examples, the method or procedure shown in FIGS. **19-23** may be used with the tubes **64**, **74** with the flared portion **73** described with respect to FIGS. **7-8** and/or the tube **34** with the flared portion **33** described with respect to FIGS. **4-6** (not shown). FIG. **19** shows the points P**1**, P**2**, and P**3** on the stomach that a surgeon may want to form a staple line as described herein (e.g., in FIGS. **15-18**) to create a sleeve gastrectomy associate with such points. As described herein, in one or more examples, different surgeons may have different methods and distances that they may be trying to achieve but they may want it wider at P**2** to prevent kinking around the bend although the width may vary from 50% wider to 300% wider between the surgeons. Further, with respect to P**3** (e.g., **40***c* in FIGS. **18** and **30**), the surgeons may try to stay 0.5 cm to 1 cm away from the GEJ to preserve the sling fibers of the cardia, which play a role in the antireflux mechanism.

[0068] As shown in FIG. **20**, an orogastric tube (e.g., as shown the first and second tubes **64**, **74**) with a flared portion (e.g., the flared portion **73**) may be positioned in an interior of the stomach. For example (e.g., to position), the first and second tubes **64**, **74** may be inserted into the stomach **40** through the mouth and esophagus, and passed down into the pylorus. The tubes **64**, **74** may be placed along the lesser curve such that the flared portion **73** with the wider diameter (e.g., the maximum diameter **2**) may be placed at the incisura angularis **40***d*. The stapling guide **88** may be positioned on an exterior of the stomach relative to the tubes **64**, **74**. For example, the stapling guide **88** may be passed around the stomach **40** as shown in FIG. **21** until it may be placed into position (e.g., near point P'), with the proximal portion being on the GE junction **40***e* as shown in FIG. **22**. For example, as shown in FIG. **21**, the stapling guide **88** may be placed just medial to the desired resection line, staple line, or line that may be defined by P**1** to P**2**. In an example, P**2** may be defined by an internal diameter of the flared portion **23** of the orogastric tube (e.g., **64** and **74**) plus the spacer effect of the stapling guide (e.g., using the formula F**1** and F**2** described with respect to FIGS. **13**A-**13**B). As shown in FIGS. **21** and **22**, the surgeon may move the stapling guide **88** relative to the stomach **40** to align P**2** with P**3** such that P**1**, P**2**, and P**3** may be in alignment and adjacent to a lateral edge or side of the surgical clamp **88** (e.g., opposite to an edge or side near or adjacent to the point P') ready to be stapled therealong to form or create the staple line, line, resection line, or path. As described herein, the edge of the stapling guide **88** (e.g., where a surgical stapler may be deployed and the staple line formed) may be approximately 2 cm off of the incisura angularis **40***d* and approximately 1.0 cm off of the GE junction **40***e* (e.g., which as described herein may be ideal for the surgeon) as shown in FIG. **22**. The surgical stapler may be actuated along the line defined by P**1**, P**2**, and P**3** as described herein.

[0069] The resultant sleeve **40***g*, post stapling along the line of P**1**, P**2**, and P**3**, may be illustrated in FIG. **23**. The resultant sleeve **40***g* and its dimensions (e.g., about 2 cm off of the incisura angularis **40***d* and about 1 cm off of the GE junction **40***e*) may be provided. For example, the resultant sleeve **40***g* created or provided by the path, resection line, staple line, or line may include a diameter of 1 to 3 cm near the first landmark (e.g., the IA **40***d*), 2 to 6 cm near a second landmark (e.g., a pylorus near **40***c*) of the stomach, and 0 to 2 cm near a third landmark (e.g., a gastroesophageal junction (GEJ) or GE junction **40***e*) of the stomach. In an example, the lengths of the lines defined by P**1** to P**2** and P**2** to P**3** may be changed during clamping thereby enabling the formation of the resultant sleeve **40***g* and its dimensions. The orientation and position of the stomach may be changed in examples by the placement of the tubes **64**, **74** and the stapling guide **88** and the stomach may snap back into shape after the manipulation and stapling. Thus, the interaction between the clamp **88** and the flared calibration tube **64**, **74** aligns the points P**1**, P**2** and P**3** to enable a straight staple line to become a curved resultant sleeve.

[0070] FIGS. **24-28** illustrate another or additional example method or procedure that may be performed using the flared, calibration tube **12** in one or more examples. As shown, in examples, the method or procedure shown in FIGS. **24-28** may be used with the tubes **84** with the flared portion **83** described with respect to FIG. **10** and/or the tubes **94**, **104** with the flared portion **93**,**103** described with respect to FIGS. **11-12**B (not shown). As shown in FIG. **24**, similar to the method or procedure described above with respect to FIGS. **15-18** and **19-23**, a surgeon may want to form a staple line or resection line along the line defined by P**1**, P**2**, and P**3**.

[0071] In FIG. **25**, a calibration tube such as the tube **84** with a balloon such as the balloon **86** on the distal end (e.g., in state S**1** as described above) that may form the flared portion **83** may be positioned in an interior of the stomach. For example, the tube **84** may be inserted into the stomach **40** through the mouth and esophagus, and passed down into the pylorus. The tube **84** may be inserted such that the balloon **86**

that may form the flared portion **83** may be placed along the lesser curve adjacent the incisura angularis **40***d*.

[0072] In an example, as shown in FIG. **26**, a single cartridge stapler **110** or the stapling guide **88** may be positioned on an exterior of the stomach. For example, the stapler **110** may be placed along P**1** and P**3** or the stapling guide **88** may be placed medial to P**1** and P**3**. P**1** and P**3** may be stabilized by partial clamping the stapler **110** or positing the stapling guide **88** as described herein (e.g., above), and/or using similar stabilization with accessory instruments.

[0073] As shown in FIG. **27**, the balloon **86** may be inflated (e.g., from state S**1** to state S**2** as described above) to form the flared portion **83**. The flared portion **83** formed by the balloon **86** may align P**2** with P**1** and P**3** as described herein by moving or the stapler **110** and/or the stapling guide **88** and/or the stomach to create or demonstrate the stapling line, resection line, path, and/or the like. For example, the flared portion **83** via the point P' that may be near an edge or side of the stapler **110** or stapling guide **88** may move the stapler **110** or stapling guide **88** to create the staple line, resection line, path, line, and/or the like (e.g., with the points P**1**, P**2**, and P**3**) along the edge of the stapler **110** or stapling guide **110** opposite of the edge near the point P'. As described herein, the edge of the stapler **110** or the stapling guide **88** (e.g., where a surgical stapler may be deployed and the staple line formed) may be approximately 2 cm off of the incisura angularis **40***d* and approximately 1.0 cm off of the GE junction **40***e* (e.g., which as described herein may be ideal for the surgeon) as shown in FIG. **22**. The stapler may be actuated along the line defined by P**1**, P**2**, and P**3** as described herein above. This may also be illustrated for the tube **104** in FIG. **12**B.

[0074] The resultant sleeve **40***g*, post stapling along the vertical line of P**1**, P**2**, and P**3**, may be illustrated in FIG. **28**. The resultant sleeve **40***g* and its dimensions (about 2 cm off of the incisura angularis **40***d* and about 1 cm off of the GE junction **40***e*) may be provided. For example, the resultant sleeve **40***g* created or provided by the path, resection line, staple line, or line may include a diameter of 1 to 3 cm near the first landmark (e.g., the IA **40***d*), 2 to 6 cm near a second landmark (e.g., a pylorus near **40***c*) of the stomach, and 0 to 2 cm near a third landmark (e.g., a gastroesophageal junction (GEJ) or GE junction **40***e*) of the stomach. After the stapler may be removed, the stomach may return to a curved shape after resection as described herein.

[0075] FIG. **29** may illustrate a representation of what an example method or procedure may include if one of several alternative or additional examples may be used. Here, the example device **66** may be used similar to the flared calibration tube **12** in that it may help align the stapling guide **88** and create proper spacing as described herein to provide a resultant sleeve **40***g*.

[0076] Additional or alternative examples of the calibration tubes that may be used in FIG. **29** may be provided in FIGS. **31** and **32**. FIG. **31** illustrates a calibration tube **62** with lights **64** running down the length of the tube **62**. The lights **64** may assist the surgeon in seeing the placement and outline of the tube and improve their understanding of what their resultant sleeve will look like. The exact number and spacing of the lights **64** may vary to achieve the desired illumination. Further, FIG. **32** illustrates a specialized balloon bougie **68** that may be inflated to create a variable-sized balloon **70** that may be used to regulate the spacing to the stapling guide or single cartridge sleeve gastrectomy stapler and the volume of the sleeve. According to examples herein, the balloon **70** may be configured to have a consistent size and shape such that the sleeve may be sized and shaped to this template with the use of the stapling guide or single cartridge sleeve gastrectomy stapler. Thus, the balloon **70** may act as a mold from which to create the resultant sleeve lumen at a constant pressure (15 to 100 cm of water). Using either the tube **62** or the bougie **68**, a resultant sleeve may be provided with the dimensions described herein as shown by **40***g* in FIG. **30** or similar dimensions to that of **40***g*.

[0077] While several devices and components thereof have been discussed in detail above, it should be understood that the components, features, configurations, and methods of using the devices discussed are not limited to the contexts provided above. In particular, components, features, configurations, and methods of use described in the context of one of the devices may be incorporated into any of the other devices. Furthermore, not limited to the further description provided below, additional and alternative suitable components, features, configurations, and methods of using the devices, as well as various ways in which the teachings herein may be combined and interchanged, will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0078] Versions of the devices described above may be actuated mechanically or electromechanically (e.g., using one or more electrical motors, solenoids, etc.). However, other actuation modes may be suitable as well including but not limited to pneumatic and/or hydraulic actuation, etc. Various suitable ways in which such alternative forms of actuation may be provided in a device as described above will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0079] Versions of the devices described above may have various types of construction. By way of example only, any of the devices described herein, or components thereof, may be constructed from a variety of metal and/or plastic materials.

[0080] Having shown and described various versions in the present disclosure, further adaptations of the methods and systems described herein may be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the examples, versions, geometrics, materials, dimensions, ratios, steps, and the like discussed above are illustrative and are not required. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited to the details of structure and operation shown and described in the specification and drawings.

1. A method of performing a sleeve gastrectomy on a stomach of a patient, comprising:

positioning a first medical device in the interior of the stomach, the first medical device including a first diameter along a first portion thereof and a second diameter larger than the first diameter along a second portion thereof, the first medical device being positioned by inserting the first medical device into the mouth of the patient to access the interior of the stomach and positioning the second portion at a landmark of the stomach;

positioning a second medical device on the exterior of the stomach relative to the first medical device such that the second medical device is configured to demonstrate a path along the stomach at which the sleeve gastrectomy is performed; and

performing the sleeve gastrectomy along the path.

2. (canceled)

3. The method of claim 1, wherein the first medical device is further positioned by moving the first medical device such that the second portion of the first medical device is positioned approximately at the landmark.

4. (canceled)

5. The method of claim 1, wherein positioning the second medical device further comprises using the first medical device as a reference for positioning the second medical device.

6. (canceled)

7. The method of claim 1, wherein positioning the second medical device further comprises:

moving the first medical device from a first position to a second position,

wherein the movement of the first medical device from the first position to a second position causes a corresponding movement of the second medical device from a first position to a second position.

8. (canceled)

9. The method of claim 1, wherein positioning the second medical device further comprises fixing a portion of the second medical device relative to a another landmark of the stomach.

10.-13. (canceled)

14. A flared, multi-diameter calibration tube for a sleeve gastrectomy, the calibration tube comprising:

a tube comprising a flared portion at a distal end thereof, the tube having a first diameter therealong proximal and distal to the flared portion and the flared portion having a second diameter larger than the first diameter, the tube being configured to be inserted into an interior of a stomach and the flared portion positioned at a first landmark thereof such that the flared portion positioned at the first landmark is configured to facilitate alignment of a resection line during the sleeve gastrectomy that produces a resultant sleeve of the stomach comprising a diameter of approximately 1 to 3 cm near the first landmark, approximately 2 to 6 cm near a second landmark of the stomach, and approximately 0 to 2 cm near a third landmark of the stomach.

15. The calibration tube of claim 14, wherein the first landmark is an incisura angularis of the stomach.

16. The calibration tube of claim 14, wherein the second landmark is a pylorus of the stomach.

17. The calibration tube of claim 14, wherein the third landmark is a gastroesophageal junction (GEJ) of the stomach.

18. The calibration tube of claim 14, wherein the flared portion comprises a first point and a second point at an opposite end thereof forming the second diameter thereaccross.

19. The calibration tube of claim 18, wherein the first point of the flared portion is configured to be positioned near the first landmark, and the second point of the flared portion is configured to facilitate formation of the resection line that produces the resultant sleeve.

20. The calibration tube of claim 14, wherein the flared portion comprises a balloon that is configured to be inflated and deflated from the proximal end of the calibration tube.

21. A medical device for a sleeve gastrectomy, the medical device comprising:

a first medical device comprising a tube and a flared portion at a distal end of the tube, the tube having a first diameter therealong proximal and distal to the flared portion and the flared portion having a second diameter larger than the first diameter, the tube being configured to be inserted into an interior of a stomach and the flared portion positioned at a first landmark thereof; and

a second medical device being configured to be positioned on an exterior of the stomach relative to the flared portion of the first medical device such that the flared portion of the first medical device positioned at the first landmark and the second medical device positioned relative to the first medical device at the flared portion is configured to facilitate alignment of a resection line during the sleeve gastrectomy that produces a resultant sleeve of the stomach comprising a diameter of approximately 1 to 3 cm near the first landmark, approximately 2 to 6 cm near a second landmark, and approximately 0 to 2 cm near a third landmark.

22. The medical device of claim 21, wherein the first landmark is an incisura angularis of the stomach.

23. The medical device of claim 21, wherein the second landmark is a pylorus of the stomach.

24. The medical device of claim 21, wherein the third landmark is a gastroesophageal junction (GEJ) of the stomach.

25. The medical device of claim 21, wherein the flared portion comprises a first point and a second point at an opposite end thereof forming the second diameter thereaccross.

26. The medical device of claim 25, wherein the first point of the flared portion is configured to be positioned near the first landmark, and the second medical device is configured to be positioned near the second point of the flared portion to facilitate formation of the resection line that produces the resultant sleeve.

27. (canceled)

28. (canceled)

29. The medical device of claim 21, wherein the flared portion comprises a balloon that is configured to be inflated and deflated from the proximal end of the calibration tube.

30. A medical device for a sleeve gastrectomy,

the medical device comprising:

a first medical device comprising a tube, the tube being configured to be inserted into an interior of a stomach; and

a second medical device being configured to be positioned on an exterior of the stomach relative to the first medical device such that a resection line for the sleeve gastrectomy is configured to be created by the first medical device and the second medical device positioned relative thereto.

31. (canceled)

32. The medical device of claim 30, wherein the first medical device further comprises a flared portion at a distal end of the tube, and wherein the tube comprises a first diameter therealong proximal and distal to the flared portion and the flared portion comprises a second diameter larger than the first diameter.

33. The medical device of claim 32, wherein the flared portion is configured to be positioned at a first landmark in the interior of the stomach.

34. The medical device of claim 33, wherein the flared portion of the first medical device positioned at the first landmark and the second medical device positioned relative to the first medical device at the flared portion is configured to create the resection line.

35. The medical device of claim **34**, wherein the flared portion comprises a first point and a second point at an opposite end thereof forming the second diameter thereaccross.

36. The medical device of claim **35**, wherein the first point of the flared portion is configured to be positioned near the first landmark, and the second medical device is configured to be positioned near the second point of the flared portion to create the resection line along the second medical device.

37. The medical device of claim **32**, wherein the flared portion comprises a balloon that is configured to be inflated and deflated from the proximal end of the calibration tube.

38. The medical device of claim **30**, wherein the resection line upon performing the sleeve gastrectomy produces a resultant sleeve of the stomach comprising a diameter of approximately 1 to 3 cm near the first landmark, approximately 2 to 6 cm near a second landmark, and approximately 0 to 2 cm near a third landmark.

39. The medical device of claim **38**, wherein the first landmark is an incisura angularis of the stomach.

40. The medical device of claim **38**, wherein the second landmark is a pylorus of the stomach.

41. The medical device of claim **38**, wherein the third landmark is a gastroesophageal junction (GEJ) of the stomach.

42. (canceled)

43. (canceled)

* * * * *

专利名称(译)	袖套胃切除术校准管及其使用方法		
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[标]申请(专利权)人(译)	标准肥胖病学股份有限公司		
申请(专利权)人(译)	标准肥胖病学，INC.		
当前申请(专利权)人(译)	标准肥胖病学，INC.		
[标]发明人	THOMPSON JONATHAN MCKEOWN JACK THOMPSON BEN		
发明人	THOMPSON, JONATHAN MCKEOWN, JACK THOMPSON, BEN		
IPC分类号	A61F5/00 A61B19/00		
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摘要(译)

可以提供一种或多种医疗装置，其可以用于例如减肥手术，包括垂直套管胃切除术。根据一个或多个示例，一个或多个医疗装置可以包括腹腔镜套管胃切除术吻合器引导件以及校准管。根据一个示例，校准管可以是喇叭形多直径校准管。扩口的多直径校准管可以具有沿着管的一部分的第一直径和可以沿着管的至少另一部分大于第一直径的第二直径。校准管可以与吻合导向器结合使用以对准胃，使得它可以沿着吻合导向器被钉合（例如，以执行垂直套管胃切除术）。