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(54) Title: DEVICES AND METHODS FOR GASTROINTESTINAL BYPASS

(57) Abstract: Devices and methods for gastrointestinal bypass are described. A gastrointestinal bypass device includes a gastrointestinal cuff and a gastrointestinal sleeve. The cuff may be configured to be attached in the esophagus, and may be sufficiently flexible to expand and collapse to conform with the inside of the esophagus to allow the esophagus to function substantially normally. The sleeve is configured to be coupled to the cuff, and may be made of a material that is floppy or flaccid but does not substantially expand radially.

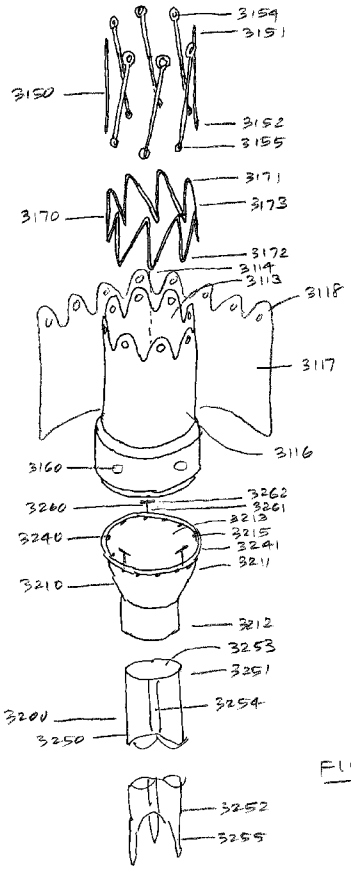

FIG 3B

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DEVICES AND METHODS FOR GASTROINTESTINAL BYPASS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application serial nos. 13/485,887, 13/485,889, 13/485,893, 13/485,896, and 13/485,898, all filed on May 31, 2012. This application is also a continuation-in-part of U.S. patent application serial nos. 13/743,285 and 13/743,287, both filed on January 16, 2013. This application also claims priority to U.S. patent application serial no. 13/896,838, filed May 17, 2013. The applications listed above are hereby incorporated by reference in their entireties.

BACKGROUND

[0002] Diabetes, heart disease, and other obesity-related conditions may be treated surgically with bariatric procedures such as jejuno-ileal bypass, jejuno-colic bypass, biliopancreatic diversion, gastric bypass, and gastroplasty. These procedures may be effective for weight control and treatment of chronic conditions. However, these procedures carry with them substantial shortcomings, including the risk of infection and other risks accompanying surgery. Some of these procedures induce radical permanent changes to the gastrointestinal anatomy, thus foreclosing subsequent surgical intervention.

[0003] What is needed are devices and methods that use non-surgical techniques that avoid the risks associated with gastrointestinal bypass surgery. What is also needed are devices and methods for gastrointestinal bypass that allow for additional or revision procedures to be performed. What is also needed are devices and methods for gastrointestinal bypass that are reversible.

SUMMARY

[0004] A method of treating a patient is described. In one embodiment, the method comprises providing a gastrointestinal bypass device including a gastrointestinal cuff and a gastrointestinal sleeve. A distal portion of the gastrointestinal cuff may be coupled to a proximal portion of the gastrointestinal sleeve. The method also comprises delivering the gastrointestinal sleeve to position a distal portion of the gastrointestinal sleeve in an intestine of the patient, positioning a proximal portion of the gastrointestinal cuff in an esophagus of the patient, and providing a tissue anchor. The tissue anchor may include a tension element, a proximal retention element coupled to a proximal portion of the tension element, and a distal retention element coupled to a distal portion of the tension element. The proximal retention element may be configured to be coupled to the gastrointestinal cuff. The distal retention element may be configured to be deployed on a distal side of a wall of the esophagus. The method also comprises delivering the distal retention element through the gastrointestinal cuff and through a wall of the esophagus at an attachment point to anchor the gastrointestinal cuff to the wall of the esophagus.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] FIGURES 1A-1C show one embodiment of a gastrointestinal bypass device 1000. FIGURE 1D shows an enlarged view of a strut 1150.

[0006] FIGURES 2A-2C show another embodiment of a gastrointestinal bypass device 2000. FIGURE 2D shows an enlarged view of a hook 2160.

[0007] FIGURES 3A-3C show yet another embodiment of a gastrointestinal bypass device 3000. FIGURE 3D shows still another embodiment of a gastrointestinal bypass device 3000A. FIGURES 3E-3F show top views of cuff 3100 in an open and a closed position. FIGURES 3G-3H show enlarged views of strut 3150. FIGURES 3I-3J show side views of cuff 3100 normally and subjected to a retrograde force. FIGURES 3K-3L show other embodiments of sleeve 3200.

[0008] FIGURES 4A-4B show one embodiment of a tissue anchor 1300. FIGURES 4C-4D show another embodiment of a tissue anchor 1300A.

[0009] FIGURES 4E-4G show one embodiment of a method for delivering tissue anchor 1300.

[0010] FIGURES 5A-5C show one embodiment of a tissue marking device 1400.

[0011] FIGURES 6A-6D show one embodiment of a method for using tissue marking device 1400.

[0012] FIGURE 7A shows one embodiment of a tissue marking device 2400. FIGURES 7B-7D show various embodiments of marking surface 2420. FIGURE 7E shows various embodiments of openings 2426.

[0013] FIGURES 8A-8F show one embodiment of a method for using tissue marking device 2400.

[0014] FIGURES 9A-9C show one embodiment of a sleeve delivery device 1500.

[0015] FIGURES 9D-9G show one embodiment of a method for loading sleeve delivery device 1500.

[0016] FIGURES 10A-10C show another embodiment of a sleeve delivery device 2500.

[0017] FIGURES 10D-10G show one embodiment of a method for loading sleeve delivery device 2500.

[0018] FIGURES 11A-11C show yet another embodiment of a sleeve delivery device 3500.

[0019] FIGURES 11D-11G show one embodiment of a method for loading sleeve delivery device 3500.

[0020] FIGURES 12A-12C show one embodiment of an anchor delivery device 1600.

[0021] FIGURES 13A-13E show one embodiment of a method for using anchor delivery device 1600.

[0022] FIGURES 14A-14C show one embodiment of a stent 1690.

[0023] FIGURES 15A-15G show another embodiment of an anchor delivery device 2600.

[0024] FIGURES 16A-16F show one embodiment of a method for using anchor delivery device 2600.

[0025] FIGURES 17A-17H show one embodiment of a method for implanting a gastrointestinal bypass device 1000.

[0026] FIGURES 18A-18J show one embodiment of a method for implanting a gastrointestinal bypass device 3000.

[0027] FIGURES 19A-19H show one embodiment of a method for exchanging a sleeve 2200 of a gastrointestinal bypass device 2000.

[0028] FIGURE 20A shows one embodiment of gastrointestinal cuff with one or more attachment openings 3160 and a gastrointestinal sleeve with one or more attachment elements 3260. FIGURES 20B-20E show various embodiments of attachment openings 3160. FIGURES 20F-20G, 20H-20I, and 20J-20K show various embodiments of an attachment element 3260.

[0029] FIGURES 21A-21F show one embodiment of a method for using attachment element 3260 to attach a device through an attachment opening 3160 formed in a wall.

[0030] FIGURES 22A-22D show another embodiment of a tissue anchor 2300.

[0031] FIGURES 22E-22G show one embodiment of a method for delivering tissue anchor 2300.

[0032] FIGURES 22H-22J show tissue anchor 2300 with various embodiments of a tissue ingrowth element 2360.

[0033] FIGURES 23A-23C show another embodiment of a tissue anchor 3300.

[0034] FIGURES 24A-24D show another embodiment of a tissue anchor 4300.

[0035] FIGURES 24E-24G show one embodiment of a method for delivering tissue anchor 4300.

[0036] FIGURES 24H-24K show tissue anchor 4300 with various embodiments of a tissue ingrowth element 4360.

[0037] FIGURES 25A-25D show various embodiments of attachment points which may be used with the devices and methods described above. Tissue anchors may be passed through the attachment points to retain a gastrointestinal bypass device.

DESCRIPTION

[0038] FIGURES 1A-1C show one embodiment of a gastrointestinal bypass device 1000. FIGURE 1A shows a perspective view of gastrointestinal bypass device 1000. FIGURE 1B shows an exploded view of gastrointestinal bypass device 1000. FIGURE 1C shows a cross-sectional view of gastrointestinal bypass device 1000. FIGURE 1D shows an enlarged view of a strut 1150.

[0039] Gastrointestinal bypass device 1000 may include a gastrointestinal cuff 1100 and a gastrointestinal sleeve 1200.

[0040] Cuff 1100 may be configured to be attached in the esophagus. Cuff 1100 may be attached at or near the gastroesophageal junction. Alternatively, cuff 1100 may be attached proximal to the gastroesophageal junction, in the proximal stomach, or at some other location. For example, cuff 1100 may be attached within about 3 cm, 2.5 cm, 2 cm, 1.5 cm, 1 cm, 0.5 cm, above, below, or at the GEJ or squamocolumnar junction (SCJ or Z-line). As another example, cuff 1100 may be attached up to 5 cm above the diaphragm. Some non-limiting locations for attachment can be found, for example, in U.S. Pat. Pub. No. 2007/0198174 to Dann et al., which is hereby incorporated by reference in its entirety (e.g., at paras. [0131] to [0147]). Cuff 1100 may be sufficiently flexible to expand and collapse to conform with the inside of the esophagus. Cuff 1100 directs food and liquids into sleeve 1200, and provides a structure to which sleeve 1200 may be attached. Cuff 1100 may be attached using tissue anchors.

[0041] Cuff 1100 may include a liner 1110, a plurality of anchor holes 1130, and a plurality of struts 1150.

[0042] Liner 1110 may include a proximal portion 1111, a distal portion 1112, a lumen 1113, and a longitudinal axis 1114. Liner 1110 may be tubular and may have a uniform width. Alternatively, liner 1110 may taper or change in width. Liner 1110 may be made of material that is flexible. This flexibility allows the attachment area, such as the lower esophageal sphincter, to open and close substantially normally. Liner 1110 may be made of a material that is thin, allowing it to collapse into a smaller profile. This smaller profile allows the attachment area, such as the lower esophageal sphincter, to close substantially normally, and also helps liner 1110 to be collapsed for delivery. Liner 1110 may include a single layer of material. Alternatively, liner 1110 may include a

plurality of layers. Liner 1110 may be at least semi-permeable to liquids and/or solids. This semi-permeability may allow some food to reach the stomach, and may help the stomach maintain some residual functionality. This semi-permeability may allow medications to reach the stomach. Liner 1110 may be made of DACRON or any other suitable material. In one embodiment, liner 1110 may have a length of approximately 20 mm to 80 mm. Liner 1110 may include a sleeve-coupling element, e.g., suture holes 1115 formed at distal portion 1112.

[0043] A coupling mechanism, e.g., anchor holes 1130 may be formed at or near proximal portion 1111 of liner 1110. Anchor holes 1130 are configured to receive tissue anchors. Anchor holes 1130 may be marked with a contrasting color, radiopaque marker, or other means to aid visualization. Anchor holes 1130 may be marked with stitching, ink, or other suitable marking. Anchor holes 1130 may be used as a placement template for tissue anchors. Anchor holes 1130 may be evenly spaced about a circumference of liner 1110. Evenly spaced anchor holes 1130 may help to distribute forces among the tissue anchors, prevent concentration of forces in a small number of tissue anchors, and enhance conformance of liner 1110 to an inside (e.g., luminal wall) of the esophagus. Alternatively, anchor holes 1130 may be spaced in any manner about a circumference of liner 1110. Anchor holes 1130 may be substantially coplanar. Anchor holes 1130 may be arranged in a plane substantially perpendicular to longitudinal axis 1114, or angled to longitudinal axis 1114. A substantially coplanar arrangement may help to prevent concentration of forces in a small number of tissue anchors. Alternatively, anchor holes 1130 may be arranged in a staggered fashion.

[0044] Struts 1150 each include a proximal portion 1151 and a distal portion 1152. Struts 1150 may be elongate and substantially straight. Alternatively, struts 1150 may be curved or any other suitable shape. Struts 1150 may be coupled to an inner surface of liner 1110. Alternatively, struts 1150 may be coupled to an outer surface of liner 1110 or between layers of liner 1110 to reduce obstructions on an inner surface of liner 1110. Struts 1150 may be coupled to liner 1110 longitudinally. Alternatively, struts 1150 may be coupled to liner 1110 at an angle of 1 to 30 degrees or more with respect to longitudinal axis 1114 of liner 1110. Struts 1150 may include a first attachment element, e.g., an anchor hole 1154 at or near proximal portion 1151. Anchor holes 1154 of struts

1150 may be aligned with anchor holes 1130 of liner 1110. Anchor holes 1154 of struts 1150 may reinforce anchor holes 1130 of liner 1110 and prevent tissue anchors from pulling through. Struts 1150 may include a second attachment element, .e.g., suture holes 1155, and struts 1150 may be coupled to liner 1110 with sutures stitched through suture holes 1155 and liner 1110. Alternatively, struts 1150 may be coupled to liner 1110 with adhesives, thermal bonding, ultrasonic or laser welding, pockets formed between layers of liner 1110, or other suitable ways. Struts 1150 may have a uniform cross-section. Alternatively, struts 1150 may have a non-uniform cross-section which varies wider, narrower, thicker, and/or thinner. For example, struts 1150 may each have a proximal portion 1151 and/or a distal portion 1152 which are thinner. This thinner cross-section allows proximal portion 1151 and/or distal portion 1152 to be more flexible. Struts 1150 may be made of a plastic such as PEEK, a metal, or any other suitable material.

[0045] Struts 1150 may reduce longitudinal stretching of liner 1110. Prograde forces such as peristaltic forces at distal portion 1112 of liner 1110 are transferred by struts 1150 to anchor holes 1154 and tissue anchors, to advantageously redistribute forces and minimize focal wear or failure points. Struts 1150 may also prevent inversion of liner 1110. Retrograde forces such as vomiting or retching forces at distal portion 1112 of liner 1110 are resisted by struts 1150, helping to maintain liner 1110 in proper implanted position.

[0046] Sleeve 1200 is configured to be coupled to cuff 1100, either in an integrally formed or removably coupled manner. Sleeve 1200 directs food and liquids into the intestine. Sleeve 1200 may include a coupling 1210 and a tube 1250.

[0047] Coupling 1210 directs food and liquids from cuff 1100 to tube 1250. Coupling 1210 includes a proximal portion 1211, a distal portion 1212, and a lumen 1213. A coupling element, e.g., suture holes 1215 may be formed at or near proximal portion 1211 to allow coupling 1210 be coupled with sutures to a complementary cuff-coupling element, e.g., suture holes 1115 in liner 1110. Proximal portion 1211 may have a width that is the same or substantially the same as liner 1110, or in some embodiments taper down in width to restrict the flow of food and liquids through coupling 1210, which may help to create a feeling of fullness. Distal portion 1212 may have a uniform width. Alternatively, proximal portion 1211 and distal portion 1212 may have a uniform width.

Coupling 1210 may be made of a material that is flexible, but does not stretch substantially in a radial or longitudinal direction. Coupling 1210 may be made of a polyurethane elastomer such as PELLETHANE, or any other suitable material.

[0048] Tube 1250 includes a proximal portion 1251, a distal portion 1252, and a lumen 1253. Proximal portion 1251 of tube 1250 may be coupled to distal portion 1212 of coupling 1210 with an interference fit, heat bonded, and/or other suitable methods. Alternatively, tube 1250 may be formed integrally with coupling 1210. Tube 1250 may have a uniform width. Alternatively, tube 1250 may taper or change in width. Tube 1250 may allow food and liquids to bypass the stomach and/or part of the intestine. Tube 1250 may allow foods and liquids to be bypassed into the duodenum, jejunum, or other part of the intestine. In one embodiment, tube 1250 may have a length of approximately 80 cm to 450 cm, a diameter of approximately 15 mm to 25 mm, and/or a thickness of about 0.05 mm to about 0.5 mm, such as about 0.15 mm.

[0049] Tube 1250 may be made of a material that is floppy or flaccid, but does not stretch substantially in a radial direction. Thus, tube 1250 may be flexible and compliant inwardly to allow peristaltic forces to act on its contents, but will not balloon outwardly. Tube 1250 may also not stretch substantially in a longitudinal direction. Tube 1250 may be made of a polyurethane elastomer such as PELLETHANE, or any other suitable material. Tube 1250 may be impermeable or semi-permeable. Tube 1250 may allow nutrients and medications inside tube 1250 to pass outward. Alternatively or in addition, tube 1250 may allow digestive juices and hormones outside tube 1250 to pass inward. Tube 1250 or portions of tube 1250 may be biodegradable. Tube 1250 with a plurality of biodegradable portions may be configured such that each portion degrades at a different rate.

[0050] Tube 1250 may include one or more coatings to resist calcification, deliver medications, provide lubriciousness, and/or provide other desired properties. These coatings may include parylene, polyvinylpyrrolidone (PVP), and/or other suitable materials. Tube 1250 may include an electrical stimulation element to resist calcification and promote motility and satiety. Various electrical stimulation elements that can be utilized or modified for use with the systems and methods disclosed herein are described, for example, in U.S. Pat. No. 7,881,797 to Griffin et al., which is hereby incorporated by

reference in its entirety. Tube 1250 may be made up of one or more sections which may be coupled or uncoupled to adjust a length of tube 1250. Tube 1250 may include one, two, or more additional lumens interior to, exterior to, or within walls of tube 1250 for delivery of medications, access for imaging devices for visual monitoring, and access for diagnostic sampling. Tube 1250 may have additional lumens which open at different points along the length of tube 1250 for targeted delivery or access.

[0051] Tube 1250 may include a radiopaque marker 1254. Radiopaque marker 1254 may be one or more longitudinal stripes which run along all or part of the length of tube 1250. Radiopaque marker 1254 may be configured to help prevent or reduce kinking and twisting of tube 1250. For example, radiopaque marker 1254 may be thicker and/or wider toward proximal portion 1251 of tube 1250, where kinking and twisting may be more pronounced. Alternatively, radiopaque marker 1254 may be a helical stripe, circumferential bands, or other suitable configuration. Radiopaque marker 1254 may be coupled to an inside surface of tube 1250 to help maintain at least some patency of lumen 1253 and prevent lumen 1253 from closing completely when tube 1250 is kinked or twisted. Alternatively, radiopaque marker 1254 may be coupled to an outside surface of tube 1250. Various embodiments, features, materials and parameters of cuffs, sleeves, anchors, and other components that can be used or modified for use with those disclosed herein are described, for example, in the following patents and publications, each of which are incorporated by reference in their entireties: U.S. Pat. Pub. No. 2007/0198074 to Dann et al., U.S. Pat. No. 8,070,743 to Kagan et al., U.S. Pat. Pub. No. 2009/0149871 to Kagan et al., U.S. Pat. Pub. No. 2004/0092892 to Kagan et al., U.S. Pat. Pub. No. 2006/0155375 to Kagan et al., U.S. Pat. Pub. No. 2006/0015125 to Swain, U.S. Pat. Pub. No. 2006/0020254 to von Hoffmann, U.S. Pat. No. 8,118,774 to Dann et al., U.S. Pat. Pub. No. 2009/0012553 to Swain et al., U.S. Pat. Pub. No. 2009/0012544 to Thompson et al., and U.S. Pat. Pub. No. 2009/0012541 to Dahl et al.

[0052] Tube 1250 may include one, two, three, or more tails 1255 at distal portion 1252. Tails 1255 may be folded over each other and cinched with a grasping element, such as a loop snare, to seal distal portion 1255 of tube 1250 during deployment of sleeve 1200. Tails 1255 may be as described, for example, in U.S. Pat. No. 8,118,774 to Dann et al., which is hereby incorporated by reference in its entirety.

[0053] FIGURES 2A-2C show another embodiment of a gastrointestinal bypass device 2000. FIGURE 2A shows a perspective view of gastrointestinal bypass device 2000. FIGURE 2B shows an exploded view of gastrointestinal bypass device 2000. FIGURE 2C shows a cross-sectional view of gastrointestinal bypass device 2000. FIGURE 2D shows an enlarged view of a hook 2160.

[0054] Gastrointestinal bypass device 2000 may include a gastrointestinal cuff 2100 and a gastrointestinal sleeve 2200.

[0055] Cuff 2100 may be configured to be attached in the esophagus. Cuff 2100 may be attached at or near the gastroesophageal junction. Alternatively, cuff 2100 may be attached proximal to the gastroesophageal junction, in the proximal stomach, or at some other location. For example, cuff 2100 may be attached within about 3 cm, 2.5 cm, 2 cm, 1.5 cm, 1 cm, 0.5 cm, above, below, or at the GEJ or squamocolumnar junction (SCJ or Z-line). As another example, cuff 1100 may be attached up to 5 cm above the diaphragm. Some non-limiting locations for attachment can be found, for example, in U.S. Pat. Pub. No. 2007/0198174 to Dann et al., which is hereby incorporated by reference in its entirety (e.g., at paras. [0131] to [0147]). Cuff 2100 may be sufficiently flexible to expand and collapse to conform with the inside of the esophagus. Cuff 2100 directs food and liquids into sleeve 2200, and provides a structure to which sleeve 2200 may be attached. Cuff 2100 may be attached using tissue anchors.

[0056] Cuff 2100 may include a liner 2110, a plurality of anchor holes 2130, a retainer 2140, a plurality of struts 2150, and one or more hooks 2160.

[0057] Liner 2110 may include a proximal portion 2111, a distal portion 2112, a lumen 2113, and a longitudinal axis 2114. Liner 2110 may be tubular and may have a uniform width. Alternatively, liner 2110 may taper or change in width. Liner 2110 may be made of material that is flexible. This flexibility allows the attachment area, such as the lower esophageal sphincter, to open and close substantially normally. Liner 2110 may be made of a material that is thin, allowing it to collapse into a smaller profile. This smaller profile allows the attachment area, such as the lower esophageal sphincter, to close substantially normally, and also helps liner 2110 to be collapsed for delivery. Liner 2110 may include a single layer of material. Alternatively, liner 2110 may include a plurality of layers. Liner 2110 may be at least semi-permeable to liquids and/or solids.

This semi-permeability may allow some food to reach the stomach, and may help the stomach maintain some residual functionality. This semi-permeability may allow medications to reach the stomach. Liner 2110 may be made of DACRON or any other suitable material. In one embodiment, liner 2110 may have a length of approximately 20 mm to 80 mm.

[0058] A coupling mechanism, e.g. anchor holes 2130 may be formed at or near proximal portion 2111 of liner 2110. Anchor holes 2130 are configured to receive tissue anchors. Anchor holes 2130 may be marked with a contrasting color, radiopaque marker, or other means to aid visualization. Anchor holes 2130 may be marked with stitching, ink, or other suitable marking. Anchor holes 2130 may be used as a placement template for tissue anchors. Anchor holes 2130 may be evenly spaced about a circumference of liner 2110. Evenly spaced anchor holes 2130 may help to distribute forces among the tissue anchors, prevent concentration of forces in a small number of tissue anchors, and enhance conformance of liner 2110 to an inside (e.g., luminal wall) of the esophagus. Alternatively, anchor holes 2130 may be spaced in any manner about a circumference of liner 2110. Anchor holes 2130 may be substantially coplanar. Anchor holes 2130 may be arranged in a plane substantially perpendicular to longitudinal axis 2114, or angled to longitudinal axis 2114. A substantially coplanar arrangement may help to prevent concentration of forces in a small number of tissue anchors. Alternatively, anchor holes 2130 may be arranged in a staggered fashion.

[0059] Retainer 2140 may be coupled to distal portion 2112 of liner 2110. Retainer 2140 may be collapsible radially inwardly but not expandable radially outwardly. Retainer 2140 may be a circumferential channel formed in distal portion 2112 of liner 2110 by one or more folds 2141. Folds 2141 may be secured by a suture 2142, adhesive, or other means. Folds 2141 may be made more rigid by applying a stiffening substance to distal portion 2112 and/or folds 2141. The stiffening substance may be silicone or other suitable substance. Alternatively, retainer 2140 may be made of plastic or other suitable material, and coupled to distal portion 2112 of liner 2110.

[0060] Struts 2150 each include a proximal portion 2151 and a distal portion 2152. Struts 2150 may be elongate and substantially straight. Alternatively, struts 2150 may be curved or any other suitable shape. Struts 2150 may be coupled to an inner surface of

liner 2110. Alternatively, struts 2150 may be coupled to an outer surface of liner 2110 or between layers of liner 2110 to reduce obstructions on an inner surface of liner 2110. Struts 2150 may be coupled to liner 2110 longitudinally. Alternatively, struts 2150 may be coupled to liner 2110 at an angle of 1 to 30 degrees or more with respect to longitudinal axis 2114 of liner 2110. Struts 2150 may include a first attachment element, e.g., an anchor hole 2154 at or near proximal portion 2151. Anchor holes 2154 of struts 2150 may be aligned with anchor holes 2130 of liner 2110. Anchor holes 2154 of struts 2150 may reinforce anchor holes 2130 of liner 2110 and prevent tissue anchors from pulling through. Struts 2150 may include a second attachment element, e.g., suture holes 2155, and struts 2150 may be coupled to liner 2110 with sutures stitched through suture holes 2155 and liner 2110. Alternatively, struts 2150 may be coupled to liner 2110 with adhesives, thermal bonding, ultrasonic or laser welding, pockets formed between layers of liner 2110, or other suitable ways. Struts 2150 may have a uniform cross-section. Alternatively, struts 2150 may have a non-uniform cross-section which varies wider, narrower, thicker, and/or thinner. For example, struts 2150 may each have a proximal portion 2151 and/or a distal portion 2152 which are thinner. This thinner cross-section allows proximal portion 2151 and/or distal portion 2152 to be more flexible. Struts 2150 may be made of a plastic such as PEEK, a metal, or any other suitable material.

[0061] Struts 2150 may reduce longitudinal stretching of liner 2110. Prograde forces such as peristaltic forces at distal portion 2112 of liner 2110 are transferred by struts 2150 to anchor holes 2154 and tissue anchors, to advantageously redistribute forces and minimize focal wear or failure points. Struts 2150 may also prevent inversion of liner 2110. Retrograde forces such as vomiting or retching forces at distal portion 2112 of liner 2110 are resisted by struts 2150, helping to maintain liner 2110 in proper implanted position.

[0062] Hooks 2160 may each include a proximal portion 2161 and a distal portion 2162. Proximal portion 2161 may be coupled to distal portion 2152 of strut 2150. Hooks 2160 may include one or more suture holes 2164 for stitching to liner 2110 and/or distal portion 2152 of strut 2150. Alternatively, hooks 2160 may be coupled to liner 2110 or one or more struts 2150 with an adhesive or other suitable methods. Alternatively, hooks 2160 may be formed as part of one or more struts 2150. Hooks 2160 may each include a

retainer 2165 and a barb 2166. Distal portions 2162 may be configured so that they do not substantially protrude beyond struts 2150 into an interior of liner 2110. Distal portion 2112 of liner 2110 may be enlarged in diameter or otherwise configured to accommodate hooks 2160.

[0063] Sleeve 2200 is configured to be coupled to cuff 2100, either in an integrally formed or removably coupled manner. Sleeve 2200 directs food and liquids into the intestine. Sleeve 2200 may include a coupling 2210, a ring 2240, a tube 2250, and a halo 2260.

[0064] Coupling 2210 directs food and liquids from cuff 2100 to tube 2250. Coupling 2210 includes a proximal portion 2211, a distal portion 2212, and a lumen 2213. Drawstring holes 2215 may be formed at or near proximal portion 2211. Proximal portion 2211 may have a width that is the same or substantially the same as liner 2110, or in some embodiments taper down in width to restrict the flow of food and liquids through coupling 2210, which may help to create a feeling of fullness. Distal portion 2212 may have a uniform width. Alternatively, proximal portion 2211 and distal portion 2212 may have a uniform width. Coupling 2210 may be made of a material that is flexible, but does not stretch substantially in a radial or longitudinal direction. Coupling 2210 may be made of a polyurethane elastomer such as PELLETHANE, or any other suitable material.

[0065] Ring 2240 may be coupled to proximal portion 2211 of coupling 2210. Ring 2240 may be a thickened portion of coupling 2210, or a separate structure operably attached to coupling 2210. Ring 2240 may be sufficiently flexible to deform inwardly, but sufficiently rigid to spring back to its original shape. Ring 2240 is configured to interface with retainer 2140. Ring 2240 may have an interference fit with retainer 2140, or other form of attachment. Sleeve 2200 is thus coupled to cuff 2100 by ring 2240 and retainer 2140. Ring 2240 may deform when sleeve 2200 is pulled distally to allow sleeve 2200 some travel, provide some shock absorption, and more evenly distribute forces to tissue anchors. Sleeve 2200 can be exchanged for a new, second sleeve having the same or one, two, or more differing properties by inwardly deforming ring 2240 and removing sleeve 2200. Ring 2240 may be inwardly deformed using a drawstring 2241 threaded through drawstring holes 2215. Other properties of sleeves, cuffs, cuff-sleeve attachment interfaces, and sleeve exchange methods can be found, for example, in U.S. Pat. Pub. No.

2007/0198074 to Dann et al., and U.S. Pat. No. 8,070,743 to Kagan et al., each of which are hereby incorporated by reference in their entireties.

[0066] Tube 2250 includes a proximal portion 2251, a distal portion 2252, and a lumen 2253. Proximal portion 2251 of tube 2250 may be coupled to distal portion 2212 of coupling 2210 with an interference fit, heat bonded, and/or other suitable methods. Alternatively, tube 2250 may be formed integrally with coupling 2210. Tube 2250 may have a uniform width. Alternatively, tube 2250 may taper or change in width. Tube 2250 may allow food and liquids to bypass the stomach and/or part of the intestine. Tube 2250 may allow foods and liquids to be bypassed into the duodenum, jejunum, or other part of the intestine. In one embodiment, tube 2250 may have a length of approximately 80 cm to 450 cm, a diameter of approximately 15 mm to 25 mm, and/or a thickness of about 0.05 mm to about 0.5 mm, such as about 0.15 mm.

[0067] Tube 2250 may be made of a material that is floppy or flaccid, but does not stretch substantially in a radial direction. Thus, tube 2250 may be flexible and compliant inwardly to allow peristaltic forces to act on its contents, but will not balloon outwardly. Tube 2250 may also not stretch substantially in a longitudinal direction. Tube 2250 may be made of a polyurethane elastomer such as PELLETHANE, or any other suitable material. Tube 2250 may be impermeable or semi-permeable. Tube 2250 may allow nutrients and medications inside tube 2250 to pass outward. Alternatively or in addition, tube 2250 may allow digestive juices and hormones outside tube 2250 to pass inward. Tube 2250 or portions of tube 2250 may be biodegradable. Tube 2250 with a plurality of biodegradable portions may be configured such that each portion degrades at a different rate.

[0068] Tube 2250 may include one or more coatings to resist calcification, deliver medications, provide lubriciousness, and/or provide other desired properties. These coatings may include parylene, polyvinylpyrrolidone (PVP), and/or other suitable materials. Tube 2250 may include an electrical stimulation element to resist calcification and promote motility and satiety. Various electrical stimulation elements that can be utilized or modified for use with the systems and methods disclosed herein are described, for example, in U.S. Pat. No. 7,881,797 to Griffin et al., which is hereby incorporated by reference in its entirety. Tube 2250 may be made up of one or more sections which may

be coupled or uncoupled to adjust a length of tube 2250. Tube 2250 may include one, two, or more additional lumens interior to, exterior to, or within walls of tube 2250 for delivery of medications, access for imaging devices for visual monitoring, and access for diagnostic sampling. Tube 2250 may have additional lumens which open at different points along the length of tube 2250 for targeted delivery or access.

[0069] Tube 2250 may include a radiopaque marker 2254. Radiopaque marker 2254 may be one or more longitudinal stripes which run along all or part of the length of tube 2250. Radiopaque marker 2254 may be configured to help prevent or reduce kinking and twisting of tube 2250. For example, radiopaque marker 2254 may be thicker and/or wider toward proximal portion 2251 of tube 2250, where kinking and twisting may be more pronounced. Alternatively, radiopaque marker 2254 may be a helical stripe, circumferential bands, or other suitable configuration. Radiopaque marker 2254 may be coupled to an inside surface of tube 2250 to help maintain at least some patency of lumen 2253 and prevent lumen 2253 from closing completely when tube 2250 is kinked or twisted. Alternatively, radiopaque marker 2254 may be coupled to an outside surface of tube 2250. Various embodiments, features, materials and parameters of cuffs, sleeves, anchors, and other components that can be used or modified for use with those disclosed herein are described, for example, in the following patents and publications, each of which are incorporated by reference in their entireties: U.S. Pat. Pub. No. 2007/0198074 to Dann et al., U.S. Pat. No. 8,070,743 to Kagan et al., U.S. Pat. Pub. No. 2009/0149871 to Kagan et al., U.S. Pat. Pub. No. 2004/0092892 to Kagan et al., U.S. Pat. Pub. No. 2006/0155375 to Kagan et al., U.S. Pat. Pub. No. 2006/0015125 to Swain, U.S. Pat. Pub. No. 2006/0020254 to von Hoffmann, U.S. Pat. No. 8,118,774 to Dann et al., U.S. Pat. Pub. No. 2009/0012553 to Swain et al., U.S. Pat. Pub. No. 2009/0012544 to Thompson et al., and U.S. Pat. Pub. No. 2009/0012541 to Dahl et al.

[0070] Tube 2250 may include one, two, three, or more tails 2255 at distal portion 2252. Tails 2255 may be folded over each other and cinched with a grasping element, such as a loop snare, to seal distal portion 2255 of tube 2250 during deployment of sleeve 2200. Tails 2255 may be as described, for example, in U.S. Pat No. 8,118,774 to Dann et al., which is hereby incorporated by reference in its entirety.

[0071] Halo 2260 may be coupled to proximal portion 2211 of coupling 2210 by one or more standoffs 2261. Standoffs 2261 may be coupled to proximal portion 2211 of coupling 2210 using an adhesive or other suitable methods. Halo 2260 may be made of suture or other suitable material. Halo 2260 is configured to be coupled to hooks 2160. Halo 2260 and hooks 2160 may provide a primary or backup coupling between sleeve 2200 and cuff 2100. Halo 2260 and hooks 2160 are configured to keep sleeve 2200 coupled to cuff 2100 if the coupling between retainer 2140 and ring 2240 should fail. Halo 2260 may be cut between standoffs 2261 to release sleeve 2200 for removal or exchange. Distal portion 2112 of liner 2110 may be enlarged in diameter or otherwise configured to accommodate halo 2260 and standoffs 2261.

[0072] FIGURES 3A-3C show yet another embodiment of a gastrointestinal bypass device 3000. FIGURE 3A shows a perspective view of gastrointestinal bypass device 3000. FIGURE 3B shows an exploded view of gastrointestinal bypass device 3000. FIGURE 3C shows a cross-sectional view of gastrointestinal bypass device 3000. FIGURE 3D shows still another embodiment of a gastrointestinal bypass device 3000A. FIGURES 3E-3F show top views of cuff 3100 in an open and a closed position. FIGURES 3G-3H show enlarged views of strut 3150. FIGURES 3I-3J show side views of cuff 3100 normally and subjected to a retrograde force. FIGURES 3K-3L show other embodiments of sleeve 3200.

[0073] Gastrointestinal bypass device 3000 may include a gastrointestinal cuff 3100 and a gastrointestinal sleeve 3200.

[0074] Cuff 3100 may be configured to be attached in the esophagus. Cuff 3100 may be attached at or near the gastroesophageal junction. Alternatively, cuff 3100 may be attached proximal to the gastroesophageal junction, in the proximal stomach, or at some other location. For example, cuff 3100 may be attached within about 3 cm, 2.5 cm, 2 cm, 1.5 cm, 1 cm, 0.5 cm, above, below, or at the GEJ or squamocolumnar junction (SCJ or Z-line). As another example, cuff 1100 may be attached up to 5 cm above the diaphragm. Some non-limiting locations for attachment can be found, for example, in U.S. Pat. Pub. No. 2007/0198174 to Dann et al., which is hereby incorporated by reference in its entirety (e.g., at paras. [0131] to [0147]). Cuff 3100 may be sufficiently flexible to expand and collapse to conform with the inside of the esophagus. Cuff 3100

directs food and liquids into sleeve 3200, and provides a structure to which sleeve 3200 may be attached. Cuff 3100 may be attached using tissue anchors.

[0075] Cuff 3100 may include a liner 3110, an edge with one, two, or more projections, e.g., a scalloped edge 3120, a plurality of anchor holes 3130, a retainer 3140, a plurality of struts 3150, one or more attachment openings 3160, and a scaffold 3170.

[0076] Liner 3110 may include a proximal portion 3111, a distal portion 3112, a lumen 3113, and a longitudinal axis 3114. Liner 3110 may be tubular and may have a uniform width. Alternatively, liner 3110 may taper or change in width. Liner 3110 may be made of material that is flexible. This flexibility allows the attachment area, such as the lower esophageal sphincter, to open and close substantially normally. Liner 3110 may be made of a material that is thin, allowing it to collapse into a smaller profile. This smaller profile allows the attachment area, such as the lower esophageal sphincter, to close substantially normally, and also helps liner 3110 to be collapsed for delivery. Liner 3110 may include an inner layer 3116 and an outer layer 3117. Alternatively, liner 3110 may include a single layer of material, or any number of layers. Inner layer 3116 and outer layer 3117 may be sealed at proximal portion 3111 with an edge seal 3118. Edge seal 3118 may be silicone or other suitable material. Edge seal 3118 may be radiopaque. Alternatively, inner layer 3116 and outer layer 3117 may be formed from a single layer of material folded over. Inner layer 3116 and outer layer 3117 may be at least partially coupled together by sutures, thermal bonding, ultrasonic or laser welding, or other ways. Liner 3110 may be at least semi-permeable to liquids and/or solids. This semi-permeability may allow some food to reach the stomach, and may help the stomach maintain some residual functionality. This semi-permeability may allow medications to reach the stomach. Liner 3110 may be made of DACRON or any other suitable material. In one embodiment, liner 3110 may have a length of approximately 20 mm to 80 mm.

[0077] Scalloped edge 3120 may include a plurality of peaks 3121 and valleys 3122 formed at the edge of proximal portion 3111 of liner 3110. Peaks 3121 and valleys 3122 may be of uniform shape and size. Alternatively, peaks 3121 and valleys 3122 may be of varying shapes and sizes. Scalloped edge 3120 allows peaks 3121 to open wider than the rest of liner 3110, as shown in FIGURE 3E. This enhances conformance of scalloped edge 3120 to an inside of the esophagus and reduces the amount of food and

liquids which pass outside of scalloped edge 3120 and into the stomach (and thus outside of the cuff and sleeve). Reducing the amount of food or liquid that passes outside of the cuff and sleeve can in some cases advantageously improve clinical endpoints (e.g., improved weight loss, improved glycemic, lipid profile, blood pressure, etc.). Valleys 3122 may include a webbing which may be thinner than liner 3110. Scalloped edge 3120 reduces bunching of liner 3110 when the esophagus is closed, and reduces the profile of liner 3110 when the esophagus is closed, as shown in FIGURE 3F.

[0078] A coupling mechanism, e.g., anchor holes 3130 may be formed in the peaks 3121 of scalloped edge 3120. Anchor holes 3130 are configured to receive tissue anchors. Anchor holes 3130 may be marked with a contrasting color, radiopaque marker, or other means to aid visualization. Anchor holes 3130 may be marked with stitching, ink, or other suitable marking. Anchor holes 3130 may be used as a placement template for tissue anchors. Anchor holes 3130 may be evenly spaced about a circumference of liner 3110. Evenly spaced anchor holes 3130 may help to distribute forces among the tissue anchors, prevent concentration of forces in a small number of tissue anchors, and enhance conformance of liner 3110 to an inside (e.g., luminal wall) of the esophagus. Alternatively, anchor holes 3130 may be spaced in any manner about a circumference of liner 3110. Anchor holes 3130 may be substantially coplanar. Anchor holes 3130 may be arranged in a plane substantially perpendicular to longitudinal axis 3114, or angled to longitudinal axis 3114. A substantially coplanar arrangement may help to prevent concentration of forces in a small number of tissue anchors. Alternatively, anchor holes 3130 may be arranged in a staggered fashion.

[0079] Retainer 3140 may be coupled to distal portion 3112 of liner 3110. Retainer 3140 may be collapsible radially inwardly but not expandable radially outwardly. Retainer 3140 may be a circumferential channel formed in distal portion 3112 of liner 3110 by one or more folds 3141. Folds 3141 may be secured by a suture 3142, adhesive, or other means. Folds 3141 may be made more rigid by applying a stiffening substance to distal portion 3112 and/or folds 3141. The stiffening substance may be silicone or other suitable substance. Alternatively, retainer 3140 may be made of plastic or other suitable material, and coupled to distal portion 3112 of liner 3110.

[0080] Struts 3150 each include a proximal portion 3151 and a distal portion 3152. Struts 3150 may be elongate and substantially straight. Alternatively, struts 3150 may be curved or any other suitable shape. Struts 3150 may be coupled to liner 3110 between layers of liner 3110. Alternatively, struts 3150 may be coupled to an inner surface or an outer surface of liner 3110. Struts 3150 may be coupled to liner 3110 at an angle of 1 to 30 degrees or more with respect to longitudinal axis 3114 of liner 3110. Alternatively, struts 3150 may be coupled to liner 3110 longitudinally without an angle. Struts 3150 may include a first attachment element, e.g., an anchor eyelet 3154 at proximal portion 3151. Struts 3150 may include a second attachment element, e.g., a suture eyelet 3155 at distal portion 3152. Anchor eyelets 3154 may be aligned with anchor holes 3130 of liner 3110 to reinforce anchor holes 3130 of liner 3110 and prevent tissue anchors from pulling through. Struts 3150 may be coupled to liner 3110 with pockets formed by stitching together layers of liner 3110, and stitching through suture eyelets 3155. Alternatively, struts 3150 may be coupled to liner 3110 with sutures, adhesives, thermal bonding, ultrasonic or laser welding, or other suitable ways. Struts 3150 may have a uniform cross-section. Alternatively, struts 3150 may have a non-uniform cross-section which varies wider, narrower, thicker, and/or thinner. For example, struts 3150 may have a proximal portion 3151 and/or a distal portion 3152 which are thinner and/or wider, as shown in FIGURES 3G-3H. This varying cross-section allows proximal portion 3151 and/or distal portion 3152 to be more flexible. Struts 3150 may include a notch 3157. Struts 3150 may be made of a plastic such as PEEK, a metal, or any other suitable material.

[0081] Struts 3150 may reduce longitudinal stretching of liner 3110. Prograde forces such as peristaltic forces at distal portion 3112 of liner 3110 are transferred by struts 3150 to anchor eyelets 3154 and tissue anchors, to advantageously redistribute forces and minimize focal wear or failure points. Struts 3150 may also prevent inversion of liner 3110. Retrograde forces such as vomiting or retching forces at distal portion 3112 of liner 3110 cause liner 3110 and angled struts 3150 to twist or corkscrew about longitudinal axis 3114 and prevents inversion of liner 3110, as shown in FIGURES 3I-3J, helping to maintain liner 3110 in proper implanted position. This twisting or corkscrewing may also at least partially close lumen 3113 of liner 3110.

[0082] Attachment openings 3160 may be formed at distal portion 3112 of liner 3110. Attachment openings 3160 may be marked with a contrasting color to aid visualization. Attachment openings 3160 may be marked with stitching, ink, or other suitable marking.

[0083] Scaffold 3170 may be coupled to liner 3110 between layers of liner. Alternatively, scaffold may be coupled to an inner surface or an outer surface of liner 3110. Scaffold 3170 may be coupled to liner 3110 with sutures, adhesives, or other suitable ways. Scaffold 3170 may have any desired wall pattern, and in some embodiments resemble a sawtooth wave, sine wave, square wave, triangle wave, or other wave. Scaffold 3170 may include a plurality of proximal segments 3171 and a plurality of distal segments 3172 connected by a plurality of connecting segments 3173. Alternatively, scaffold 3170 may be a mesh, ring, or other suitable device. Scaffold 3170 may be coupled to struts 3150, or formed integrally with struts 3150. Scaffold 3170 may cross each strut 3150 through notch 3157.

[0084] Scaffold 3170 provides an outward bias to enhance conformance of liner 3110 to the luminal wall of the esophagus. This outward bias may be large enough to open liner 3110 when the esophagus opens, but not so large as to prevent the esophagus from closing. Scaffold 3170 is not necessarily meant to hold cuff 3100 in the esophagus. Scaffold 3170 may have a geometry, such as length and thickness, selected to create a desired amount of outward bias. Scaffold 3170 may be made of a material selected to create a desired amount of outward bias. Scaffold 3170 may be made of plastic such as PEEK, metal, or any other suitable material. Proximal segments 3171 may be placed at or near valleys 3122. This placement positions outward bias at valleys 3122. Any portion of scaffold 3170 may be placed across struts 3150. The placement of scaffold 3170 across struts 3150 may be selected to create a desired amount of outward bias. For example, distal segments 3172 may be placed across struts 3150. This placement provides a pivot point for connecting segments 3173 of scaffold 3170. This placement may also fold or rotate peaks 3121 when liner 3110 closes, resulting in a smaller closed profile, as shown in FIGURES 3E-3F.

[0085] Sleeve 3200 is configured to be coupled to cuff 3100, either in an integrally formed or removably coupled manner. Sleeve 3200 directs food and liquids

into the intestine. Sleeve 3200 may include a coupling 3210, a ring 3240, a tube 3250, and one or more attachment elements 3260.

[0086] Coupling 3210 directs food and liquids from cuff 3100 to tube 3250. Coupling 3210 includes a proximal portion 3211, a distal portion 3212, and a lumen 3213. Drawstring holes 3215 may be formed at or near proximal portion 3211. Proximal portion 3211 may have a width that is the same or substantially the same as liner 3110, or in some embodiments taper down in width to restrict the flow of food and liquids through coupling 3210, which may help to create a feeling of fullness. Distal portion 3212 may have a uniform width. Alternatively, proximal portion 3211 and distal portion 3212 may have a uniform width. Coupling 3210 may be made of a material that is flexible, but does not stretch substantially in a radial or longitudinal direction. Coupling 3210 may be made of a polyurethane elastomer such as PELLETHANE, or any other suitable material.

[0087] Ring 3240 may be coupled to proximal portion 3211 of coupling 3210. Ring 3240 may be a thickened portion of coupling 3210, or a separate structure operably attached to coupling 3210. Ring 3240 may be sufficiently flexible to deform inwardly, but sufficiently rigid to spring back to its original shape. Ring 3240 is configured to interface with retainer 3140. Ring 3240 may have an interference fit with retainer 3140, or other form of attachment. Sleeve 3200 is thus coupled to cuff 3100 by ring 3240 and retainer 3140. Ring 3240 may deform when sleeve 3200 is pulled distally to allow sleeve 3200 some travel, provide some shock absorption, and more evenly distribute forces to tissue anchors. Sleeve 3200 can be exchanged for a new, second sleeve having the same or one, two, or more differing properties by inwardly deforming ring 3240 and removing sleeve 3200. Ring 3240 may be inwardly deformed using a drawstring 3241 threaded through drawstring holes 3215. Other properties of sleeves, cuffs, cuff-sleeve attachment interfaces, and sleeve exchange methods can be found, for example, in U.S. Pat. Pub. No. 2007/0198074 to Dann et al., and U.S. Pat. No. 8,070,743 to Kagan et al., each of which are hereby incorporated by reference in their entireties.

[0088] Tube 3250 includes a proximal portion 3251, a distal portion 3252, and a lumen 3253. Proximal portion 3251 of tube 3250 may be coupled to distal portion 3212 of coupling 3210 with an interference fit, heat bonded, and/or other suitable methods. Alternatively, tube 3250 may be formed integrally with coupling 3210. Tube 3250 may

have a uniform width. Alternatively, tube 3250 may taper or change in width. Tube 3250 may allow food and liquids to bypass the stomach and/or part of the intestine. Tube 3250 may allow foods and liquids to be bypassed into the duodenum, jejunum, or other part of the intestine. In one embodiment, tube 3250 may have a length of approximately 80 cm to 450 cm, a diameter of approximately 15 mm to 25 mm, and/or a thickness of about 0.05 mm to about 0.5 mm, such as about 0.15 mm.

[0089] Tube 3250 may be made of a material that is floppy or flaccid, but does not stretch substantially in a radial direction. Thus, tube 3250 may be flexible and compliant inwardly to allow peristaltic forces to act on its contents, but will not balloon outwardly. Tube 3250 may also not stretch substantially in a longitudinal direction. Tube 3250 may be made of a polyurethane elastomer such as PELLETHANE, or any other suitable material. Tube 3250 may be impermeable or semi-permeable. Tube 3250 may allow nutrients and medications inside tube 3250 to pass outward. Alternatively or in addition, tube 3250 may allow digestive juices and hormones outside tube 3250 to pass inward. Tube 3250 or portions of tube 3250 may be biodegradable. Tube 3250 with a plurality of biodegradable portions may be configured such that each portion degrades at a different rate.

[0090] Tube 3250 may include one or more coatings to resist calcification, deliver medications, provide lubriciousness, and/or provide other desired properties. These coatings may include parylene, polyvinylpyrrolidone (PVP), and/or other suitable materials. Tube 3250 may include an electrical stimulation element to resist calcification and promote motility and satiety. Various electrical stimulation elements that can be utilized or modified for use with the systems and methods disclosed herein are described, for example, in U.S. Pat. No. 7,881,797 to Griffin et al., which is hereby incorporated by reference in its entirety. Tube 3250 may be made up of one or more sections which may be coupled or uncoupled to adjust a length of tube 3250. Tube 3250 may include one, two, or more additional lumens interior to, exterior to, or within walls of tube 3250 for delivery of medications, access for imaging devices for visual monitoring, and access for diagnostic sampling. Tube 3250 may have additional lumens which open at different points along the length of tube 3250 for targeted delivery or access.

[0091] Tube 3250 may include a radiopaque marker 3254. Radiopaque marker 3254 may be one or more longitudinal stripes which run along all or part of the length of tube 3250. Radiopaque marker 3254 may be configured to help prevent or reduce kinking and twisting of tube 3250. For example, radiopaque marker 3254 may be thicker and/or wider toward proximal portion 3251 of tube 3250 as shown in FIGURE 3K, where kinking and twisting may be more pronounced. Alternatively, radiopaque marker 3254 may be a helical stripe as shown in FIGURE 3L, circumferential bands, or other suitable configuration. Radiopaque marker 3254 may be coupled to an inside surface of tube 3250 to help maintain at least some patency of lumen 3253 and prevent lumen 3253 from closing completely when tube 3250 is kinked or twisted. Alternatively, radiopaque marker 3254 may be coupled to an outside surface of tube 3250. Various embodiments, features, materials and parameters of cuffs, sleeves, anchors, and other components that can be used or modified for use with those disclosed herein are described, for example, in the following patents and publications, each of which are incorporated by reference in their entireties: U.S. Pat. Pub. No. 2007/0198074 to Dann et al., U.S. Pat. No. 8,070,743 to Kagan et al., U.S. Pat. Pub. No. 2009/0149871 to Kagan et al., U.S. Pat. Pub. No. 2004/0092892 to Kagan et al., U.S. Pat. Pub. No. 2006/0155375 to Kagan et al., U.S. Pat. Pub. No. 2006/0015125 to Swain, U.S. Pat. Pub. No. 2006/0020254 to von Hoffmann, U.S. Pat. No. 8,118,774 to Dann et al., U.S. Pat. Pub. No. 2009/0012553 to Swain et al., U.S. Pat. Pub. No. 2009/0012544 to Thompson et al., and U.S. Pat. Pub. No. 2009/0012541 to Dahl et al.

[0092] Tube 3250 may include one, two, three, or more tails 3255 at distal portion 3252. Tails 3255 may be folded over each other and cinched with a grasping element, such as a loop snare, to seal distal portion 3255 of tube 3250 during deployment of sleeve 3200. Tails 3255 may be as described, for example, in U.S. Pat No. 8,118,774 to Dann et al., which is hereby incorporated by reference in its entirety.

[0093] Attachment elements 3260 are configured to be coupled to attachment openings 3160. Attachment elements 3260 and attachment openings 3160 may provide a first, e.g., a primary, or second, e.g., a backup, coupling between sleeve 3200 and cuff 3100. Attachment elements 3260 and attachment openings 3160 may be configured to

keep sleeve 3200 coupled to cuff 3100 if the coupling between retainer 3140 and ring 3240 should fail.

[0094] FIGURE 20A shows one embodiment of cuff 3100 with one or more attachment openings 3160 and sleeve 3200 with one or more attachment elements 3260. FIGURES 20B-20E show various embodiments of attachment openings 3160. FIGURES 20F-20G, 20H-20I, and 20J-20K show enlarged and exploded views of various embodiments of an attachment element 3260.

[0095] Attachment openings 3160 may be round, oval, or any other suitable shape. Attachment openings 3160 may be deformable or substantially rigid. Attachment openings 3160 may include one or more flaps 3161 that cover attachment openings 3160 which are not in use to reduce leakage through attachment openings 3160. As shown in FIGURES 20B-20E, flaps 3161 may be arranged in a t-, T-, X-, or slit-like configuration, respectively, or any other suitable configuration. Flaps 3161 may be flexible to allow attachment element 3260 to pass through. Flaps 3161 may be made of a similar or different material as the rest of liner 3110. For example, flaps 3161 may be made of silicone or other suitable material.

[0096] Attachment element 3260 may include an elongate member 3261, a tension element 3265, and at least one grasping aid 3268. The number of attachment elements 3260 may be equal or unequal to the number of attachment openings 3160. In other applications, attachment element 3260 may be used to couple any device through an attachment opening 3160 formed in a wall of a mating device or tissue wall by deploying attachment element 3260 on an opposite side of the wall.

[0097] Elongate member 3261 includes a central portion 3262. Elongate member 3261 is configured to be passed longitudinally through attachment opening 3160 from the inside of liner 3110, and deployed transversely on the outside of liner 3110. Elongate member 3261 is of a length or other physical dimensions which will not be pulled through attachment opening 3160 after being deployed. Elongate member 3261 may be straight, curved, or any other suitable shape. Elongate member 3261 may include one or more holes 3263 through which tension element 3265 may be coupled. Elongate member 3261 may include one or more holes 3264 through which grasping aid 3268 may be coupled. One or more holes 3264 may be in communication with one or more holes 3263,

as shown in FIGURES 20F-20G and 20H-20I. Elongate member 3261 may be at least partially radiopaque to aid in placement and monitoring.

[0098] Tension element 3265 includes a proximal portion 3266 and a distal portion 3267. Proximal portion 3266 may be coupled to sleeve 3200. Distal portion 3267 may be flexibly coupled to central portion 3262 of elongate member 3261. Tension element 3265 may be a loop of suture passed through holes 3263 in elongate member 3263 and holes in sleeve 3200 and secured with one or more knots. Alternatively, tension element 3265 may be made of a length of suture, or any other suitable material. Alternatively, tension element 3265 may be a tube, stick, or other suitable element. Tension element 3265 may be substantially flexible or substantially rigid. Tension element 3265 may be stretchable to allow sleeve 3200 some travel, provide some shock absorption, and to more evenly distribute forces to tissue anchors. Tension element 3265 may be cut to release sleeve 3200 for removal or exchange.

[0099] Grasping aid 3268 may be grasped by a grasper, hook, or other suitable tool and advanced through attachment opening 3160 along with elongate member 3261 and distal portion 3267 of tension element 3265. Attachment opening 3160 may be sized or otherwise configured to allow the tool, elongate member 3261, and distal portion 3267 of tension element 3265 to pass through together. Grasping aid 3268 may be coupled to or near at least one end of elongate member 3261. Grasping aid 3268 may include a loop of suture or a length of suture. Alternatively, grasping aid 3268 may include a substantially rigid extension or stub flexibly or rigidly coupled to or near at least one end of elongate member 3261.

[0100] Tension element 3265 and grasping aid 3268 may be formed from a continuous piece of suture or other material which passes through holes 3263 and holes 3264 and is secured by one or more knots 3269, as shown in FIGURES 20F-20G and 20H-20I. Alternatively, tension element 3265 and grasping aid 3268 may be include separate pieces of suture, or similar or dissimilar materials, as shown in FIGURES 20J-20K. Grasping aid 3268 may be secured by one or more knots 3269.

[0101] FIGURES 21A-21F show one embodiment of a method for using attachment element 3260 to attach a device through an attachment opening 3160 formed in a wall.

[0102] FIGURE 21A shows advancing a tool, in this embodiment a grasper G, from the working channel of an endoscope E.

[0103] FIGURE 21B shows using the grasper G to grasp grasping aid 3268.

[0104] FIGURE 21C shows advancing the grasper G toward attachment opening 3160 from the inside of liner 3110. Grasper G may include a working end that is pre-curved and/or steerable to aid in manipulating elongate member 3261 through attachment opening 3160.

[0105] FIGURE 21D shows advancing the grasper G through attachment opening 3160 to pass grasping aid 3268 through attachment opening 3160 from the inside of liner 3110. Because grasping aid 3268 is coupled to or near an end of elongate member 3261 and pulls on or near the end of elongate member 3261, elongate member 3261 becomes aligned to pass longitudinally through attachment opening 3160. Because distal portion 3267 of tension element 3265 may be flexibly coupled to elongate member 3261, elongate member 3261 may move or rotate with respect to tension element 3265.

[0106] FIGURE 21E shows continuing to advance the grasper G through attachment opening 3160 to pass elongate member 3261 longitudinally through attachment opening 3160. Also passed through attachment opening 3160 are the grasper G and the distal portion 3267 of tension element 3265.

[0107] FIGURE 21F shows releasing grasping aid 3268 to deploy elongate member 3261 transversely on the outside of liner 3110. Elongate member 3261 is passed through attachment opening 3160 completely. Releasing grasping aid 3268 generally causes elongate member 3261 to catch or deploy transversely on the outside of liner 3110. If elongate member 3261 passes back through attachment opening 3160, the grasper G may be used to grasp grasping aid 3268 or other part of elongate member 3261 and attempt deployment again.

[0108] One or more safety sutures may be used to provide a backup coupling between sleeve 3200 and cuff 3100. Safety sutures may be cut to release sleeve 3200 for removal or exchange.

[0109] FIGURES 4A-4B show one embodiment of a tissue anchor 1300. FIGURE 4A shows a perspective view of tissue anchor 1300. FIGURE 4B shows a cross-sectional view of tissue anchor 1300.

[0110] FIGURES 4C-4D show another embodiment of a tissue anchor 1300A. FIGURE 4C shows a perspective view of tissue anchor 1300A. FIGURE 4D shows a cross-sectional view of tissue anchor 1300A.

[0111] The cuffs and/or sleeves described above may be anchored, for example, using tissue anchors 1300 and tissue anchors 1300A, or any other suitable tissue anchor. Other tissue anchors or features of tissue anchors that may be used with systems and methods as described herein can be found, for example, in U.S. Pat. Pub. No. 2009/0012541 to Dahl et al., which is hereby incorporated by reference in its entirety.

[0112] Tissue anchor 1300 and tissue anchor 1300A are configured to pass through a tissue wall to retain a device. For example, tissue anchor 1300 and tissue anchor 1300A may be configured to pass through an anchor hole in a cuff and transmurally through the wall of the esophagus to retain a cuff in the esophagus.

[0113] Tissue anchor 1300 and tissue anchor 1300A each include a proximal retention element 1310, a distal retention element 1320, and a tension element 1350.

[0114] Proximal retention element 1310 is configured to be deployed on a proximal side of a tissue wall. Proximal retention element 1310 may be a button, a bar, or other suitable shape. In one embodiment, proximal retention element 1310 may be a button having a diameter of approximately 2 mm to 5 mm, and a thickness of approximately 0.25 mm to 1 mm. Proximal retention element 1310 may include one or more holes 1311. Proximal retention element 1310 may be at least partially radiopaque to aid in placement and monitoring.

[0115] Distal retention element 1320 is configured to be deployed on a distal side of a tissue wall. Distal retention element 1320 may include a hub 1330 and a plurality of petals 1340.

[0116] Hub 1330 includes a proximal end 1331, a distal end 1332, and a longitudinal axis 1333. Hub 1330 includes an inner tube 1334 having a central lumen 1335. Hub 1330 also includes an outer tube 1336. Inner tube 1334 and outer tube 1336 form an annular space 1337. Inner tube 1334 and outer tube 1336 may be substantially

the same length, or be of different lengths. Inner tube 1334 and outer tube 1336 may be made of a stainless steel or other suitable material.

[0117] Petals 1340 each include a proximal side 1341, a distal side 1342, an open area 1344, a hub portion 1345, an inclined portion 1346, and a tissue contact portion 1347. Hub portion 1345 is coupled to tissue contact portion 1347 by inclined portion 1346. Hub portion 1345 is at least partially positioned within annular space 1337. Hub portion 1345 may be coupled to inner tube 1334 and outer tube 1336 with an adhesive 1338, solder or weld joint, laser weld, compression fit, or other suitable ways. Adhesive 1338 may be a two-part epoxy or other suitable material or adhesive. In one embodiment, hub portion 1345 may have a length of approximately 0.5 mm to 2 mm. Inclined portion 1346 extends from proximal end 1331 of hub 1330. In one embodiment, inclined portion 1346 may be inclined at an angle of approximately 30 to 60 degrees with respect to longitudinal axis 1333. Alternatively, inclined portion 1346 may be inclined at a variable angle between 0 and 90 degrees with respect to longitudinal axis 1333. In one embodiment as shown in FIGURES 4A-4B, inclined portion 1346 may have a length of approximately 3 mm to 4 mm. In another embodiment as shown in FIGURES 4C-4D, inclined portion 1346 may have a length of approximately 2 mm to 3 mm.

[0118] Tissue contact portion 1347 is configured to contact a distal surface of a tissue wall. Tissue contact portion 1347 may be substantially flat, or it may be configured to curve away from the distal surface of a tissue wall. Tissue contact portion 1347 may be substantially perpendicular to longitudinal axis 1333. Alternatively, tissue contact portion 1347 may be slightly curved to conform to the distal surface of a tissue wall. Tissue contact portion 1347 may be proximal to proximal end 1331 of hub 1330 to prevent hub 1330 from contacting the distal surface of a tissue wall. Tissue contact portion 1347 may have an open structure which reduces the amount of material coming into contact with a distal surface of a tissue wall. This open structure may reduce a response by a tissue wall to tissue contact portion 1347. In one embodiment as shown in FIGURES 4A-4B, tissue contact portion 1347 may have a footprint having an outside diameter of approximately 7 mm to 8 mm, and an inside diameter of approximately 4 mm to 5 mm. In another embodiment as shown in FIGURES 4C-4D, tissue contact portion

1347 may have a footprint having an outside diameter of approximately 8 mm to 10 mm, and an inside diameter of approximately 4 mm to 5 mm.

[0119] Petals 1340 may be sufficiently flexible to be collapsed into a delivery configuration for delivery inside a needle and expanded into a deployed configuration on a distal side of a tissue wall. Petals 1340 may be sufficiently flexible to provide shock absorption. Petals 1340 may be formed of one or more loops or lengths of wire, cut from one or more sheets of material, or made using any other suitable method. In one embodiment, petals 1340 may be formed of wire having a diameter of approximately 0.1 mm to 0.2 mm. Petals 1340 may be made of nitinol or other suitable material. Petals 1340 may be coated or treated with an antibiotic or other therapeutic agent.

[0120] In one embodiment, distal retention element 1320 may have a height of approximately 1 mm to 5 mm.

[0121] Tension element 1350 includes a proximal portion 1351 and a distal portion 1352. Proximal portion 1351 is coupled to proximal retention element 1310. Proximal portion 1351 may pass through hole 1311 of proximal retention element 1310 and coupled with one or more knots. Distal portion 1352 is positioned within central lumen 1335 of inner tube 1334. Distal portion 1352 may be coupled to inner tube 1334 with an adhesive 1339, solder or weld joint, laser weld, compression fit, or other suitable ways. Adhesive 1339 may be a two-part epoxy or other suitable material or adhesive. Distal portion 1352 may also be coupled to inner tube 1334 with one or more knots. Tension element 1350 is configured to pass through a tissue wall. Tension element 1350 may have a reduced width or thickness in order to decrease the size of the hole through a tissue wall, which may lower the likelihood of infection or other response. In one embodiment, tension element 1350 may have a diameter of approximately 0.2 mm to 0.5 mm. Tension element 1350 may be elastic or inelastic. Tension element 1350 may include a suture, wire, superelastic polymer, or other suitable material or device. Tension element 1350 may be coated or treated with an antibiotic agent. Alternatively, tension element 1350 may include an ultrathin coated stent that is stretchable and presents no interstitial spaces to surrounding tissue.

[0122] FIGURES 4E-4G show one embodiment of a method for delivering tissue anchor 1300. For clarity, a pushrod is not shown. FIGURE 4E shows tissue anchor 1300

packaged inside a delivery needle N in a collapsed or delivery configuration. FIGURE 4F shows tissue anchor 1300 being pushed out of the delivery needle N. FIGURE 4G shows tissue anchor 1300 completely pushed out of delivery needle N and into an expanded or deployed configuration.

[0123] FIGURES 22A-22D show another embodiment of a tissue anchor 2300. FIGURE 22A shows a perspective view of tissue anchor 2300. FIGURE 22B shows a bottom view of distal retention element 2320 of tissue anchor 2300. FIGURE 22C shows a side view of tissue anchor 2300. FIGURE 22D shows a cross-sectional view of distal retention element 2320 of tissue anchor 2300.

[0124] The cuffs and/or sleeves described above may be anchored, for example, using tissue anchors 2300 or any other suitable tissue anchor. Other tissue anchors or features of tissue anchors that may be used with systems and methods as described herein can be found, for example, in U.S. Pat. Pub. No. 2009/0012541 to Dahl et al., which is hereby incorporated by reference in its entirety.

[0125] Tissue anchor 2300 is configured to pass through a tissue wall to retain a device. For example, tissue anchor 2300 may be configured to pass through an anchor hole in a cuff and transmurally through the wall of the esophagus to retain a cuff in the esophagus.

[0126] Tissue anchor 2300 includes a proximal retention element 2310, a distal retention element 2320, and a tension element 2350.

[0127] Proximal retention element 2310 is configured to be deployed on a proximal side of a tissue wall. Proximal retention element 2310 may be a button, a bar, or other suitable shape. In one embodiment, proximal retention element 2310 may be a button having a diameter of approximately 2 mm to 5 mm, and a thickness of approximately 0.25 mm to 1 mm. Proximal retention element 2310 may include one or more holes 2311. Proximal retention element 2310 may be at least partially radiopaque to aid in placement and monitoring.

[0128] Distal retention element 2320 is configured to be deployed on a distal side of a tissue wall. Distal retention element 2320 may include a proximal side 2321, a distal side 2322, a hub 2330, and a plurality of petals 2340.

[0129] Hub 2330 includes a proximal end 2331, a distal end 2332, and a longitudinal axis 2333. Hub 2330 includes an inner tube 2334 having a central lumen 2335. Hub 2330 also includes an outer tube 2336. Inner tube 2334 and outer tube 2336 form an annular space 2337. Inner tube 2334 and outer tube 2336 may be substantially the same length, or be of different lengths. Inner tube 2334 and outer tube 2336 may be made of a stainless steel or other suitable material.

[0130] Petals 2340 each include a proximal side 2341, a distal side 2342, an open area 2344, hub portion 2345, a connecting portion 2346, and a tissue contact portion 2347. Hub portion 2345 is coupled to tissue contact portion 2347 by connecting portion 2346. Hub portion 2345 is at least partially positioned within annular space 2337. Hub portion 2345 may be coupled to inner tube 2334 and outer tube 2336 with an adhesive 2338, solder or weld joint, laser weld, compression fit, or other suitable ways. Adhesive 2338 may be a two-part epoxy or other suitable material or adhesive. In one embodiment, hub portion 2345 may have a length of approximately 0.5 mm to 2 mm. Connecting portion 2346 extends from distal end 2332 of hub 2330. Connecting portion 2346 may include a first curved portion 2348 and a second curved portion 2349. First curved portion 2348 may couple hub portion 2345 to connecting portion 2346. First curved portion 2348 may extend from distal end 2332 of hub 2330 substantially parallel to longitudinal axis 2333, and curve approximately 135 to 180 degrees away from longitudinal axis 2333. Second curved portion 2349 may couple connecting portion 2346 to tissue contact portion 2347. Second curved portion 2349 may curve approximately 45 to 90 degrees away from longitudinal axis 2333. Thus, tissue contact portion 2347 may extend outward away from longitudinal axis 2333. Connecting portion 2346 may have a length of approximately 3 mm to 5 mm.

[0131] Tissue contact portion 2347 is configured to contact a distal surface of a tissue wall. Tissue contact portion 2347 may be substantially flat, or it may be configured to curve away from the distal surface of a tissue wall. Tissue contact portion 2347 may be substantially perpendicular to longitudinal axis 2333. Alternatively, tissue contact portion 2347 may be slightly curved to conform to the distal surface of a tissue wall. Tissue contact portion 2347 may be proximal to proximal end 2331 of hub 2330 to prevent hub 2330 from contacting the distal surface of a tissue wall. Tissue contact

portion 2347 may have an open structure which reduces the amount of material coming into contact with a distal surface of a tissue wall. This open structure may reduce a response by a tissue wall to tissue contact portion 2347. In one embodiment, tissue contact portion 2347 may have a footprint having an outside diameter of approximately 7 mm to 8 mm, and an inside diameter of approximately 4 mm to 5 mm. In another embodiment, tissue contact portion 2347 may have a footprint having an outside diameter of approximately 8 mm to 10 mm, and an inside diameter of approximately 4 mm to 5 mm.

[0132] Petals 2340 may be sufficiently flexible to be collapsed into a delivery configuration for delivery inside a needle and expanded into a deployed configuration on a distal side of a tissue wall. Petals 2340 may be sufficiently flexible to provide shock absorption. Petals 2340 may be formed of one or more loops or lengths of wire, cut from one or more sheets of material, or made using any other suitable method. In one embodiment, petals 2340 may be formed of wire having a diameter of approximately 0.1 mm to 0.2 mm. Petals 2340 may be made of nitinol or other suitable material. Petals 2340 may be coated or treated with an antibiotic or other therapeutic agent.

[0133] Petals 2340, especially first curved portions 2348 of connecting portions 2346, may form a distal side 2322 which is rounded or substantially flat, which may be less traumatic to surrounding tissue. Also, because petals 2340 extend from distal end 2332 of hub 2330, hub 2330 may be positioned closer to the distal surface of a tissue wall and distal retention element 2320 may have a reduced height, which may lessen the likelihood of tumbling or tipping over. In one embodiment, distal retention element 2320 may have a height of approximately 1 mm to 5 mm.

[0134] Tension element 2350 includes a proximal portion 2351 and a distal portion 2352. Proximal portion 2351 is coupled to proximal retention element 2310. Proximal portion 2351 may pass through hole 2311 of proximal retention element 2310 and coupled with one or more knots. Distal portion 2352 is positioned within central lumen 2335 of inner tube 2334. Distal portion 2352 may be coupled to inner tube 2334 with an adhesive 2339, solder or weld joint, laser weld, compression fit, or other suitable ways. Adhesive 2339 may be a two-part epoxy or other suitable material or adhesive. Distal portion 2352 may also be coupled to inner tube 2334 with one or more knots.

Tension element 2350 is configured to pass through a tissue wall. Tension element 2350 may have a reduced width or thickness in order to decrease the size of the hole through a tissue wall, which may lower the likelihood of infection or other response. In one embodiment, tension element 2350 may have a diameter of approximately 0.2 mm to 0.5 mm. Tension element 2350 may be elastic or inelastic. Tension element 2350 may include a suture, wire, superelastic polymer, or other suitable material or device. Tension element 2350 may be coated or treated with an antibiotic agent. Alternatively, tension element 2350 may include an ultrathin coated stent that is stretchable and presents no interstitial spaces to surrounding tissue.

[0135] FIGURES 22E-22G show one embodiment of a method for delivering tissue anchor 2300. FIGURE 22E shows tissue anchor 2300 packaged inside a delivery needle N in a collapsed or delivery configuration. FIGURE 22F shows tissue anchor 2300 being pushed out of the delivery needle N. FIGURE 22G shows tissue anchor 2300 completely pushed out of delivery needle N and into an expanded or deployed configuration. Because petals 2340 extend from distal end 2332 of hub 2330, tissue anchor 2300 may be configured with a shorter tension element 2350 and may be deployed with less needle penetration.

[0136] FIGURES 22H-22J show tissue anchor 2300 with various embodiments of a tissue ingrowth element 2360. Tissue ingrowth element 2360 may be coupled to distal retention element 2320. Tissue ingrowth element 2360 may allow at least a portion of a tissue surrounding distal retention element 2320 to at least partially grow into and help secure distal retention element 2320. The tissue may include tissue in the vicinity of or adjacent to a tissue wall. The tissue may include one or more layers of the tissue wall itself. Tissue ingrowth element 2360 may reduce migration or movement of tissue anchor 2300 after delivery.

[0137] FIGURE 22H shows tissue anchor 2300 with one embodiment of a tissue ingrowth element 2360. Tissue ingrowth element 2360 may include a cover 2365. Cover 2365 may at least partially cover proximal side 2321 and/or distal side 2322 of distal retention element 2320. Cover 2365 may conform to distal retention element 2320. Alternatively, cover 2365 may span across proximal side 2321 of distal retention element 2320. Cover 2365 may be stitched or otherwise coupled to itself or to petals 2340.

Alternatively, cover 2365 may be configured to retain itself over distal retention element 2320. For example, cover 2365 may be sufficiently elastic to fit over distal retention element 2320 and retain itself over distal retention element 2320. Cover 2365 may be coupled to proximal end 2331 and/or distal end 2332 of hub 2330, such as to inner tube 2334 of hub 2330. Cover 2365 may be coupled to hub 2330 by melt welding, or any other suitable method. Cover 2365 may be sufficiently compressible and/or collapsible to allow distal retention element 2320 to collapsed into and delivered with a delivery needle.

[0138] FIGURE 22I shows tissue anchor 2300 with another embodiment of a tissue ingrowth element 2360. Tissue ingrowth element 2360 may include one or more covers 2366. Each cover 2366 may at least partially cover proximal side 2341 and/or distal side 2342 of a petal 2340. Covers 2366 may be stitched or otherwise coupled to themselves or to petals 2340. Alternatively, covers 2366 may be configured to retain themselves over petals 2340. For example, covers 2366 may be sufficiently elastic to fit over petals 2340 and retain themselves over petals 2340. Covers 2366 may be coupled to proximal end 2331 and/or distal end 2332 of hub 2330, such as to inner tube 2334 of hub 2330. Covers 2366 may be coupled to hub 2330 by melt welding, or any other suitable method. Covers 2366 may be sufficiently compressible and/or collapsible to allow distal retention element 2320 to collapsed into and delivered with a delivery needle.

[0139] FIGURE 22J shows tissue anchor 2300 with another embodiment of a tissue ingrowth element 2360. Tissue ingrowth element 2360 may include a webbing 2367. Webbing 2367 may be formed at least partially in open area 2344 of one or more petals 2340. Alternatively, or in addition, webbing 2367 may be formed at least partially in one or more areas between petals 2340. Webbing 2367 may be coupled to petals 2340 by melt welding, or any other suitable method. Webbing 2367 may be sufficiently compressible and/or collapsible to allow distal retention element 2320 to collapsed into and delivered with a delivery needle.

[0140] Tissue ingrowth element 2360 may be used with any suitable tissue anchor, such as a T-tag. Tissue ingrowth element 2360 may be used with any suitable distal retention element, such as those described in U.S. Patent Nos. 8,070,743 and 8,182,459, and U.S. Patent Application Publication 2009/0012541. Tissue ingrowth element 2360

may be used with any suitable frame or structure that is collapsible, compressible, and/or may be delivered inside a delivery needle.

[0141] Tissue ingrowth element 2360 may include a mesh made of fabric, plastic, metal, or any other suitable material. For example, tissue ingrowth element 2360 may include a knitted or woven material made of a polyester or polypropylene. Tissue ingrowth element 2360 may have a mesh size that allows or promotes tissue ingrowth, such as a mesh size ranging from about 6 μm to about 2.5 mm. Tissue ingrowth element 2360 may also have a mesh size large enough to permit macrophages to pass through, such as a mesh size greater than about 80-100 μm.

[0142] FIGURES 23A-23C show another embodiment of a tissue anchor 3300. FIGURE 23A shows a perspective view of tissue anchor 3300. FIGURE 23B shows a top view of tissue anchor 3300. FIGURE 23C shows a side view of tissue anchor 3300.

[0143] The cuffs and/or sleeves described above may be anchored, for example, using tissue anchors 3300 or any other suitable tissue anchor. Other tissue anchors or features of tissue anchors that may be used with systems and methods as described herein can be found, for example, in U.S. Pat. Pub. No. 2009/0012541 to Dahl et al., which is hereby incorporated by reference in its entirety.

[0144] Tissue anchor 3300 is configured to pass through a tissue wall to retain a device. For example, tissue anchor 3300 may be configured to pass through an anchor hole in a cuff and transmurally through the wall of the esophagus to retain a cuff in the esophagus.

[0145] Tissue anchor 3300 includes a proximal retention element 3310, a distal retention element 3320, and a tension element 3350.

[0146] Proximal retention element 3310 is configured to be deployed on a proximal side of a tissue wall. Proximal retention element 3310 may be a button, a bar, or other suitable shape. In one embodiment, proximal retention element 3310 may be a button having a diameter of approximately 2 mm to 5 mm, and a thickness of approximately 0.25 mm to 1 mm. Proximal retention element 3310 may include one or more holes 3311. Proximal retention element 3310 may be at least partially radiopaque to aid in placement and monitoring.

[0147] Distal retention element 3320 is configured to be deployed on a distal side of a tissue wall. Distal retention element 3320 may include a proximal side 3321, a distal side 3322, a hub 3330, and a plurality of petals 3340.

[0148] Hub 3330 includes a proximal end 3331, a distal end 3332, and a longitudinal axis 3333.

[0149] Petals 3340 each include a proximal side 3341, a distal side 3342, an open area 3344, a connecting portion 3346 and a tissue contact portion 3347. Tissue contact portion 3347 is coupled to hub 3330 by connecting portion 3346. Connecting portion 3346 extends from distal end 3332 of hub 3330. Connecting portion 3346 may include a first curved portion 3348 and a second curved portion 3349. First curved portion 3348 may couple hub 3330 to connecting portion 3346. First curved portion 3348 may extend from distal end 3332 of hub 3330 substantially parallel to longitudinal axis 3333, and curve approximately 135 to 180 degrees away from longitudinal axis 3333. Second curved portion 3349 may couple connecting portion 3346 to tissue contact portion 3347. Second curved portion 3349 may curve approximately 45 to 90 degrees away from longitudinal axis 3333. Thus, tissue contact portion 3347 may extend outward away from longitudinal axis 3333. Connecting portion 3346 may have a length of approximately 3 mm to 5 mm.

[0150] Tissue contact portion 3347 is configured to contact a distal surface of a tissue wall. Tissue contact portion 3347 may be substantially flat, or it may be configured to curve away from the distal surface of a tissue wall. Tissue contact portion 3347 may be substantially perpendicular to longitudinal axis 3333. Alternatively, tissue contact portion 3347 may be slightly curved to conform to the distal surface of a tissue wall. Tissue contact portion 3347 may be proximal to proximal end 3331 of hub 3330 to prevent hub 3330 from contacting the distal surface of a tissue wall. Tissue contact portion 3347 may have an open structure which reduces the amount of material coming into contact with a distal surface of a tissue wall. This open structure may reduce a response by a tissue wall to tissue contact portion 3347. In one embodiment, tissue contact portion 3347 may have a footprint having an outside diameter of approximately 7 mm to 8 mm, and an inside diameter of approximately 4 mm to 5 mm. In another embodiment, tissue contact portion 3347 may have a footprint having an outside diameter

of approximately 8 mm to 10 mm, and an inside diameter of approximately 4 mm to 5 mm.

[0151] Petals 3340 may be sufficiently flexible to be collapsed into a delivery configuration for delivery inside a needle and expanded into a deployed configuration on a distal side of a tissue wall. Petals 3340 may be sufficiently flexible to provide shock absorption. Petals 2340 may be formed of one or more loops or lengths. Petals 2340 may have a thickness of approximately 0.1 mm to 0.2 mm. Hub 3330 and petals 3340 may be laser cut, stamped, or otherwise manufactured from a single piece of material, such as a sheet or tube of material. Petals 3340 may be set into a desired shape by heat setting, cold working, or other suitable ways. Hub 3330 and petals 3340 may be made of nitinol or other suitable material. Petals 3340 may be coated or treated with an antibiotic or other therapeutic agent.

[0152] Petals 3340, especially first curved portions 3348 of connecting portions 3346, may form a distal side 3322 which is rounded or substantially flat, which may be less traumatic to surrounding tissue. Also, because petals 3340 extend from distal end 3332 of hub 3330, hub 3330 may be positioned closer to the distal surface of a tissue wall and distal retention element 3320 may have a reduced height, which may lessen the likelihood of tumbling or tipping over. In one embodiment, distal retention element 3320 may have a height of approximately 1 mm to 5 mm.

[0153] Tension element 3350 includes a proximal portion 3351 and a distal portion 3352. Proximal portion 3351 is coupled to proximal retention element 3310. Proximal portion 3351 may pass through hole 3311 of proximal retention element 3310 and coupled with one or more knots. Distal portion 3352 is positioned within central lumen 3335 of inner tube 3334. Distal portion 3352 may be coupled to inner tube 3334 with an adhesive 3339, solder or weld joint, laser weld, compression fit, or other suitable ways. Adhesive 3339 may be a two-part epoxy or other suitable material or adhesive. Distal portion 3352 may also be coupled to inner tube 3334 with one or more knots. Tension element 3350 is configured to pass through a tissue wall. Tension element 3350 may have a reduced width or thickness in order to decrease the size of the hole through a tissue wall, which may lower the likelihood of infection or other response. In one embodiment, tension element 3350 may have a diameter of approximately 0.2 mm to 0.5

mm. Tension element 3350 may be elastic or inelastic. Tension element 3350 may include a suture, wire, superelastic polymer, or other suitable material or device. Tension element 3350 may be coated or treated with an antibiotic agent. Alternatively, tension element 3350 may include an ultrathin coated stent that is stretchable and presents no interstitial spaces to surrounding tissue.

[0154] FIGURES 24A-24D show another embodiment of a tissue anchor 4300. FIGURE 24A shows a perspective view of tissue anchor 4300. FIGURE 24B shows a top view of distal retention element 4320 of tissue anchor 4300. FIGURE 24C shows a side view of tissue anchor 4300. FIGURE 24D shows a cross-sectional view of tissue anchor 4300.

[0155] The cuffs and/or sleeves described above may be anchored, for example, using tissue anchors 4300 or any other suitable tissue anchor. Other tissue anchors or features of tissue anchors that may be used with systems and methods as described herein can be found, for example, in U.S. Pat. Pub. No. 2009/0012541 to Dahl et al., which is hereby incorporated by reference in its entirety.

[0156] Tissue anchor 4300 is configured to pass through a tissue wall to retain a device. For example, tissue anchor 4300 may be configured to pass through an anchor hole in a cuff and transmurally through the wall of the esophagus to retain a cuff in the esophagus.

[0157] Tissue anchor 4300 includes a proximal retention element 4310, a distal retention element 4320, and a tension element 4350.

[0158] Proximal retention element 4310 is configured to be deployed on a proximal side of a tissue wall. Proximal retention element 4310 may be a button, a bar, or other suitable shape. In one embodiment, proximal retention element 4310 may be a button having a diameter of approximately 2 mm to 5 mm, and a thickness of approximately 0.25 mm to 1 mm. Proximal retention element 4310 may include one or more holes 4311. Proximal retention element 4310 may be at least partially radiopaque to aid in placement and monitoring.

[0159] Distal retention element 4320 is configured to be deployed on a distal side of a tissue wall. Distal retention element 4320 may include a proximal side 4321, a distal side 4322, a hub 4330, and a plurality of petals 4340.

[0160] Hub 4330 includes a proximal end 4331, a distal end 4332, and a longitudinal axis 4333. Hub 4330 includes an inner tube 4334 having a central lumen 4335. Hub 4330 also includes an outer tube 4336. Inner tube 4334 and outer tube 4336 form an annular space 4337. Inner tube 4334 and outer tube 4336 may be substantially the same length, or be of different lengths. Inner tube 4334 and outer tube 4336 may be made of a stainless steel or other suitable material.

[0161] Petals 4340 each include a proximal side 4341, a distal side 4342, an open area 4344, hub portion 4345, a connecting portion 4346, and a tissue contact portion 4347. Hub portion 4345 is coupled to tissue contact portion 4347 by connecting portion 4346. Hub portion 4345 is at least partially positioned within annular space 4337. Hub portion 4345 may be coupled to inner tube 4334 and outer tube 4336 with an adhesive 4338, solder or weld joint, laser weld, compression fit, or other suitable ways. Adhesive 4338 may be a two-part epoxy or other suitable material or adhesive. In one embodiment, hub portion 4345 may have a length of approximately 0.5 mm to 2 mm. Connecting portion 4346 extends from distal end 4332 of hub 4330. Connecting portion 4346 may include a first curved portion 4348 and a second curved portion 4349. First curved portion 4348 may couple hub portion 4345 to connecting portion 4346. First curved portion 4348 may extend from distal end 4332 of hub 4330 substantially parallel to longitudinal axis 4333, and curve approximately 60 to 120 degrees away from longitudinal axis 4333. Second curved portion 4349 may couple connecting portion 4346 to tissue contact portion 4347. Second curved portion 4349 may curve approximately 150 to 210 degrees proximally toward longitudinal axis 4333. Thus, tissue contact portion 4347 may extend inward toward longitudinal axis 4333. Connecting portion 4346 may have a length of approximately 3 mm to 7 mm.

[0162] Tissue contact portion 4347 is configured to contact a distal surface of a tissue wall. Tissue contact portion 4347 may be substantially flat, or it may be configured to curve away from the distal surface of a tissue wall. Tissue contact portion 4347 may be substantially perpendicular to longitudinal axis 4333. Alternatively, tissue contact portion 4347 may be slightly curved to conform to the distal surface of a tissue wall. Tissue contact portion 4347 may be proximal to proximal end 4331 of hub 4330 to prevent hub 4330 from contacting the distal surface of a tissue wall. Tissue contact

portion 4347 may have an open structure which reduces the amount of material coming into contact with a distal surface of a tissue wall. This open structure may reduce a response by a tissue wall to tissue contact portion 4347. In one embodiment, tissue contact portion 4347 may have a footprint having an outside diameter of approximately 7 mm to 8 mm, and an inside diameter of approximately 4 mm to 5 mm. In another embodiment, tissue contact portion 4347 may have a footprint having an outside diameter of approximately 8 mm to 10 mm, and an inside diameter of approximately 4 mm to 5 mm.

[0163] Petals 4340 may be sufficiently flexible to be collapsed into a delivery configuration for delivery inside a needle and expanded into a deployed configuration on a distal side of a tissue wall. Petals 4340 may be sufficiently flexible to provide shock absorption. Petals 4340 may be formed of one or more loops or lengths of wire, cut from one or more sheets of material, or made using any other suitable method. In one embodiment, petals 4340 may be formed of wire having a diameter of approximately 0.1 mm to 0.2 mm. Petals 4340 may be made of nitinol or other suitable material. Petals 4340 may be coated or treated with an antibiotic or other therapeutic agent.

[0164] Petals 4340, especially connecting portions 4346, may form a distal side 4322 which is rounded or substantially flat, which may be less traumatic to surrounding tissue. Also, because petals 4340 extend from distal end 4332 of hub 4330, hub 4330 may be positioned closer to the distal surface of a tissue wall and distal retention element 4320 may have a reduced height, which may lessen the likelihood of tumbling or tipping over. In one embodiment, distal retention element 4320 may have a height of approximately 1 mm to 5 mm.

[0165] Tension element 4350 includes a proximal portion 4351 and a distal portion 4352. Proximal portion 4351 is coupled to proximal retention element 4310. Proximal portion 4351 may pass through hole 4311 of proximal retention element 4310 and coupled with one or more knots. Distal portion 4352 is positioned within central lumen 4335 of inner tube 4334. Distal portion 4352 may be coupled to inner tube 4334 with an adhesive 4339, solder or weld joint, laser weld, compression fit, or other suitable ways. Adhesive 4339 may be a two-part epoxy or other suitable material or adhesive. Distal portion 4352 may also be coupled to inner tube 4334 with one or more knots.

Tension element 4350 is configured to pass through a tissue wall. Tension element 4350 may have a reduced width or thickness in order to decrease the size of the hole through a tissue wall, which may lower the likelihood of infection or other response. In one embodiment, tension element 4350 may have a diameter of approximately 0.2 mm to 0.5 mm. Tension element 4350 may be elastic or inelastic. Tension element 4350 may include a suture, wire, superelastic polymer, or other suitable material or device. Tension element 4350 may be coated or treated with an antibiotic agent. Alternatively, tension element 4350 may include an ultrathin coated stent that is stretchable and presents no interstitial spaces to surrounding tissue.

[0166] FIGURES 24E-24G show one embodiment of a method for delivering tissue anchor 4300. FIGURE 24E shows tissue anchor 4300 packaged inside a delivery needle in a collapsed or delivery configuration. FIGURE 24F shows tissue anchor 4300 being pushed out of the delivery needle. FIGURE 24G shows tissue anchor 4300 completely pushed out of delivery needle and into an expanded or deployed configuration. Because petals 4340 extend from distal end 4332 of hub 4330, tissue anchor 4300 may be configured with a shorter tension element 4350 and may be deployed with less needle penetration.

[0167] FIGURES 24H-24K show tissue anchor 4300 with various embodiments of a tissue ingrowth element 4360. Tissue ingrowth element 4360 may be coupled to distal retention element 4320. Tissue ingrowth element 4360 may allow at least a portion of a tissue surrounding distal retention element 4320 to at least partially grow into and help secure distal retention element 4320. The tissue may include tissue in the vicinity of or adjacent to a tissue wall. The tissue may include one or more layers of the tissue wall itself. Tissue ingrowth element 4360 may reduce migration or movement of tissue anchor 4300 after delivery.

[0168] FIGURES 24H-24I shows tissue anchor 4300 with one embodiment of a tissue ingrowth element 4360. Tissue ingrowth element 4360 may include a cover 4365. Cover 4365 may at least partially cover proximal side 4321 and/or distal side 4322 of distal retention element 4320. Cover 4365 may conform to distal retention element 4320, as can be seen in the cross-sectional view shown in FIGURE 24I. Alternatively, cover 4365 may span across proximal side 4321 of distal retention element 4320. Cover 4365

may be stitched or otherwise coupled to itself or to petals 4340. Alternatively, cover 4365 may be configured to retain itself over distal retention element 4320. For example, cover 4365 may be sufficiently elastic to fit over distal retention element 4320 and retain itself over distal retention element 4320. Cover 4365 may be coupled to proximal end 4331 and/or distal end 4332 of hub 4330, such as to inner tube 4334 of hub 4330. Cover 4365 may be coupled to hub 4330 by melt welding, or any other suitable method. Cover 4365 may be sufficiently compressible and/or collapsible to allow distal retention element 4320 to collapsed into and delivered with a delivery needle.

[0169] FIGURE 24J shows tissue anchor 4300 with another embodiment of a tissue ingrowth element 4360. Tissue ingrowth element 4360 may include one or more covers 4366. Each cover 4366 may at least partially cover proximal side 4341 and distal side 4342 of a petal 4340. Covers 4366 may be stitched or otherwise coupled to themselves or to petals 4340. Alternatively, covers 4366 may be configured to retain themselves over petals 4340. For example, covers 4366 may be sufficiently elastic to fit over petals 4340 and retain themselves over petals 4340. Covers 4366 may be coupled to proximal end 4331 and/or distal end 4332 of hub 4330, such as to inner tube 4334 of hub 4330. Covers 4366 may be coupled to hub 4330 by melt welding, or any other suitable method. Covers 4366 may be sufficiently compressible and/or collapsible to allow distal retention element 4320 to collapsed into and delivered with a delivery needle.

[0170] FIGURE 24K shows tissue anchor 4300 with another embodiment of a tissue ingrowth element 4360. Tissue ingrowth element 4360 may include a webbing 4367. Webbing 4367 may be formed at least partially in open area 4344 of one or more petals 4340. Alternatively, or in addition, webbing 4367 may be formed at least partially in one or more areas between petals 4340. Webbing 4367 may be coupled to petals 4340 by melt welding, or any other suitable method. Webbing 4367 may be sufficiently compressible and/or collapsible to allow distal retention element 4320 to collapsed into and delivered with a delivery needle.

[0171] Tissue ingrowth element 4360 may be used with any suitable tissue anchor, such as a T-tag. Tissue ingrowth element 4360 may be used with any suitable distal retention element, such as those described in U.S. Patent Nos. 8,070,743 and 8,182,459, and U.S. Patent Application Publication 2009/0012541. Tissue ingrowth element 4360

may be used with any suitable frame or structure that is collapsible, compressible, and/or may be delivered inside a delivery needle.

[0172] Tissue ingrowth element 4360 may include a mesh made of fabric, plastic, metal, or any other suitable material. For example, tissue ingrowth element 4360 may include a knitted or woven material made of a polyester or polypropylene. Tissue ingrowth element 4360 may have a mesh size that allows or promotes tissue ingrowth, such as a mesh size ranging from about 6 μm to about 2.5 mm. Tissue ingrowth element 4360 may also have a mesh size large enough to permit macrophages to pass through, such as a mesh size greater than about 80-100 μm.

[0173] FIGURES 5A-5C show one embodiment of a tissue marking device 1400. FIGURE 5A shows a perspective view of tissue marking device 1400. FIGURE 5B shows an enlarged cross-sectional view of a distal portion of tissue marking device 1400. FIGURE 5C shows an enlarged end view of a distal portion tissue marking device 1400.

[0174] Tissue marking device 1400 may be used for aiding the placement of tissue anchors, identifying cancerous tissue, marking tissue before surgery, and other purposes where a temporary or permanent marking of the anatomy is desired. In some embodiments, tissue marking device 1400 may be used for purposes other than marking, such as for pinpoint delivery of a diagnostic or therapeutic agent into tissue, such as a chemotherapeutic drug for example.

[0175] Tissue marking device 1400 may include a marking tube 1410, a marking tip 1420, a dye source 1444, and a vacuum source 1460.

[0176] Marking tube 1410 includes a proximal portion 1411 and a distal portion 1412. Marking tube includes an inlet lumen 1413 and an outlet lumen 1415. Marking tube 1410 is configured to access a part of the body where the tissue is located. Marking tube 1410 may be configured to be used in a working channel of an endoscope or other device.

[0177] Marking tip 1420 may be formed at distal portion 1412 of marking tube 1410. Marking tip 1420 includes a passage 1421 formed in a wall 1414 between inlet lumen 1413 and outlet lumen 1415. Marking tip 1420 includes an opening 1426. Opening 1426 may be circular, cross-shaped, X-shaped, or any other suitable size and

shape as desired for a particular tissue identification, and in some embodiments could have a first opening shape to mark a first tissue, and a second opening shape to mark a second tissue. Opening 1426 may be chamfered on the inside and/or outside. Marking tip 1420 is configured to be placed against a tissue to be marked. Marking tip 1420 may be any suitable size or shape depending on the tissue to be marked. Opening 1426 could be on a distal-facing surface of marking tip 1420 as illustrated, or on a sidewall of the marking tip 1420 in other embodiments, such as described in connection with FIGURES 7A-7E below.

[0178] Dye source 1444 may be coupled to inlet lumen 1413. Dye source 1444 may be a reservoir containing a dye for marking tissue. The dye may be gentian violet or any other suitable ink or dye. Dye source 1444 may be a syringe or other device which allows the flow of the dye to be controlled.

[0179] Optionally, a rinse source 1445 may be coupled to inlet lumen 1413. Rinse source 1445 may be a reservoir containing a rinse solution such as saline or water. Rinse source 1445 may be a syringe or other device which allows the flow of the rinse solution to be controlled.

[0180] A single solution may be used which performs both functions of the dye and the rinse solution.

[0181] A manifold 1450 may be used to couple dye source 1444 and rinse source 1445 to inlet lumen 1413. Manifold 1450 may include one or more valves 1451 which allow dye source 1444 and rinse source 1445 to be turned on and off independently.

[0182] Vacuum source 1460 may be coupled to outlet lumen 1415. Vacuum source 1460 may be a pump or other suitable device. Vacuum source 1460 is configured to draw a tissue placed against marking tip 1420 and create a seal between opening 1426 and the tissue. Vacuum source 1460 is also configured to fill marking tip 1420 with a dye from dye source 1444 and a rinse solution from rinse source 1445. Vacuum source 1460 may include controls for adjusting or programming time and pressure of vacuum applied.

[0183] Tissue marking device 1400 may be a sealed system, which allows for a given fluid to be maintained in marking tip 1420 as long as a vacuum is applied and a seal with the tissue is maintained.

[0184] Tissue marking device 1400 may be used by first applying a vacuum to marking tip 1420 to draw a portion of the tissue against opening 1426, and then providing a dye to marking tip 1420 to at least partially fill marking tip 1420 with the dye and allow the dye to contact the portion of the tissue and mark the tissue. Tissue marking device 1400 may also be used to provide a rinse solution to marking tip 1420 to at least partially fill marking tip 1420 with the rinse solution and rinse the portion of the tissue. Tissue marking device 1400 may also be used to provide a prep solution to marking tip 1420 to at least partially fill marking tip 1420 with the prep solution and prepare the portion of the tissue before providing the dye.

[0185] FIGURES 6A-6D show one embodiment of a method for using tissue marking device 1400.

[0186] FIGURE 6A shows positioning marking tip 1420 against a tissue to be marked. An endoscope S may be used to place marking tip 1420 against the tissue.

[0187] FIGURE 6B shows drawing the tissue against marking tip 1420. Vacuum source 1460 is turned on to create a vacuum in marking tip 1420. Vacuum source 1460 draws the tissue against marking tip 1420, creating a seal between opening 1426 and the tissue.

[0188] FIGURE 6C shows marking the tissue. Valve 1451 for dye source 1444 is opened and vacuum source 1460 fills marking tip 1420 with a dye from dye source 1444 to mark the tissue exposed through opening 1426. Vacuum source 1460 may be used to maintain the dye in marking tip 1420 for a length of time to allow the dye to penetrate into the tissue. The dye may then be evacuated from marking tip 1420.

[0189] Optionally, rinsing marking tip 1420 and/or the tissue may be performed. Valve 1451 for rinse source 1445 is opened and vacuum source 1460 fills marking tip 1420 with a rinse solution from rinse source 1445.

[0190] FIGURE 6D shows marking tip 1420 removed from the tissue, showing the tissue mark.

[0191] FIGURE 7A shows one embodiment of a tissue marking device 2400. FIGURES 7B-7D show various embodiments of marking surface 2420. FIGURE 7E shows various embodiments of openings 2426.

[0192] Tissue marking device 2400 may be used for aiding the placement of tissue anchors, identifying cancerous tissue, marking tissue before surgery, and other purposes. In some embodiments, tissue marking device 2400 may be used for purposes other than marking, such as for pinpoint delivery of a diagnostic or therapeutic agent into tissue, such as a chemotherapeutic drug for example.

[0193] Tissue marking device 2400 may include an access element 2410, a marking interface 2420, a positioning element 2430, a dye source 2444, and a vacuum source 2460.

[0194] Access element 2410 includes a proximal portion 2411 and a distal portion 2412. Access element 2410 may include an inlet tube 2413 and an outlet tube 2415. Access element 2410 is configured to access a part of the body where the tissue is located. In one embodiment, an access element 2410 used for esophageal access may be a catheter of suitable length and diameter to access the gastroesophageal junction or other part of the esophagus. Access element 2410 may be configured to be used with a visualization device. In other embodiments, access element 2410 may be an endoscope, a solid elongate member, or other suitable device used to access the esophagus or other bodily cavities.

[0195] Marking surface 2420 may be coupled to distal portion 2412 of access element 2410. Alternatively, marking surface 2420 may be coupled to any suitable part of access element 2410. Marking surface 2420 includes a lumen 2421 having an inlet 2423 and an outlet 2425. Inlet 2423 and outlet 2425 may be coupled to inlet tube 2413 and outlet tube 2415. Lumen 2421 may be linear, meandering, or U-shaped, as shown in FIGURES 7B-7D, or any other suitable configuration. Lumen 2421 may include one or more gaps 2422 for visualization. Marking surface 2420 includes one or more openings 2426. Openings 2426 may be arranged in one or more rows that can be regularly or irregularly spaced apart. Regularly spaced apart rows may be advantageous, for example, for calibration or measuring of distances. Openings 2426 may be circular, cross-shaped, X-shaped, or any other suitable size and shape as desired for a particular tissue identification, and in some embodiments could have a first opening shape to mark a first tissue, and a second opening shape to mark a second tissue. Openings 2426 may be chamfered on the inside and/or outside. Marking surface 2420 is configured to be placed

against a tissue to be marked. Marking surface 2420 may be any suitable size or shape depending on the tissue to be marked. In one embodiment, marking surface 2420 may simply be a tube with one or more openings 2426 formed in a side of the tube.

[0196] Positioning element 2430 may be coupled to distal portion 2412 of access element 2410. Positioning element 2430 may be an expandable element, such as balloon, expandable mesh, or other suitable device. Positioning element 2430 may be coupled a known distance proximal or distal to marking surface 2420. Positioning element 2430 may be used to position marking surface 2420 with respect to an anatomical feature. In one embodiment, positioning element 2430 is a balloon configured to be expanded in the stomach, and configured to position marking surface 2420 in the esophagus a known distance from the opening of the stomach.

[0197] Optionally, a first rinse source 2441 may be coupled to inlet tube 2413. First rinse source 2441 may be a reservoir containing a first rinse solution such as saline or water. First rinse source 2441 may be a syringe or other device which allows the flow of the first rinse solution to be controlled.

[0198] Optionally, a second rinse source 2442 may be coupled to inlet tube 2413. Second rinse source 2442 may be a reservoir containing a second rinse solution such as acetic acid. Second rinse source 2442 may be a syringe or other device which allows the flow of the second rinse solution to be controlled.

[0199] Optionally, a prep source 2443 may be coupled to inlet tube 2413. Prep source 2443 may be a reservoir containing a prep solution such as isopropyl alcohol. Prep source 2443 may be a syringe or other device which allows the flow of the prep solution to be controlled.

[0200] Dye source 2444 may be coupled to inlet tube 2413. Dye source 2444 may be a reservoir containing a dye for marking tissue. The dye may be gentian violet or any other suitable ink or dye. Dye source 2444 may be a syringe or other device which allows the flow of the dye to be controlled.

[0201] Optionally, a third rinse source 2445 may be coupled to inlet tube 2413. Third rinse source 2445 may be a reservoir containing a third rinse solution such as saline or water. Third rinse source 2445 may be a syringe or other device which allows the flow of the third rinse solution to be controlled.

[0202] A single solution may be used which performs two or more functions of the first rinse solution, second rinse solution, prep solution, dye, and third rinse solution.

[0203] A manifold 2450 may be used to couple first rinse source 2441, second rinse source 2442, prep source 2443, dye source 2444, and third rinse source 2445 to inlet tube 2413. Manifold 2450 may include one or more valves 2451 which allow first rinse source 2441, second rinse source 2442, prep source 2443, dye source 2444, and third rinse source 2445 to be turned on and off independently.

[0204] Vacuum source 2460 is coupled to outlet tube 2415. Vacuum source 2460 may be a pump or other suitable device. Vacuum source 2460 is configured to create a vacuum within lumen 2421 of marking surface 2420. Vacuum source 2460 is configured to draw a tissue placed against marking surface 2420 and create a seal between openings 2426 and the tissue. Vacuum source 2460 is configured to fill lumen 2421 with a first rinse solution from first rinse source 2441, a second rinse solution from second rinse source 2442, a prep solution from prep source 2443, a dye from dye source 2444, and/or a third rinse solution from third rinse source 2445. Vacuum source 2460 may include controls for adjusting or programming time and pressure of vacuum applied.

[0205] Tissue marking device 2400 may be a sealed system, which allows for a given fluid to be maintained in lumen 2421 as long as a vacuum is applied and a seal with the tissue is maintained.

[0206] Tissue marking device 2400 may be used to first apply a vacuum to outlet 2425 of lumen 2421 to draw a portion of the tissue against opening 2426, and then to provide a dye to inlet 2423 of lumen 2421 to at least partially fill lumen 2421 with the dye and allow the dye to contact the portion of the tissue and mark the tissue. Tissue marking device 2400 may also be used to provide a rinse solution to inlet 2423 of lumen 2421 to at least partially fill lumen 2421 with the rinse solution and rinse the portion of the tissue. Tissue marking device 2400 may also be used to provide a prep solution to inlet 2423 of lumen 2421 to at least partially fill lumen 2421 with the prep solution and prepare the portion of the tissue before providing the dye.

[0207] FIGURES 8A-8F show one embodiment of a method for using tissue marking device 2400.

[0208] FIGURE 8A shows introducing access element 2410 into a first location, e.g., the esophagus and introducing positioning element 2430 into a second location, e.g., the stomach which in some embodiments may be distal to the first location.

[0209] FIGURE 8B shows expanding positioning element 2430 in the stomach.

[0210] FIGURE 8C shows seating positioning element 2430 against the opening of the stomach to position marking surface 2420 a known distance from the opening of the stomach in the esophagus. Alternatively, marking surface 2420 may be positioned using an initial mark made previously by tissue marking device 1400.

[0211] FIGURE 8D shows drawing the tissue against marking surface 2420. Vacuum source 2460 is turned on to create a vacuum in lumen 2421. Vacuum source 2460 draws the tissue against marking surface 2420, creating a seal between openings 2426 and the tissue.

[0212] Optionally, rinsing the tissue may be performed one or more times. Valve 2451 for first rinse source 2441 is opened and vacuum source 2460 fills lumen 2421 with a first rinse solution from first rinse source 2441 to rinse the tissue exposed through openings 2426. Valve 2451 for second rinse source 2442 is opened and vacuum source 2460 fills lumen 2421 with a second rinse solution from second rinse source 2442 to rinse the tissue exposed through openings 2426.

[0213] Optionally, preparing the tissue may be performed. Valve 2451 for prep source 2443 is opened and vacuum source 2460 fills lumen 2421 with a prep solution from prep source 2443 to prepare the tissue exposed through openings 2426.

[0214] FIGURE 8E shows marking the tissue. Valve 2451 for dye source 2444 is opened and vacuum source 2460 fills lumen 2421 with a dye from dye source 2444 to mark the tissue exposed through openings 2426. Vacuum source 2460 may be used to maintain the dye in lumen 2421 for a length of time to allow the dye to penetrate into the tissue. The dye is then evacuated from lumen 2421.

[0215] Optionally, rinsing lumen 2421 and/or the tissue may be performed. Valve 2451 for third rinse source 2445 is opened and vacuum source 2460 fills lumen 2421 with a third rinse solution from third rinse source 2445 to rinse lumen 2421 and/or the tissue exposed through openings 2426.

[0216] FIGURE 8F shows marking surface 2420 removed from the tissue, showing the tissue marks.

[0217] FIGURES 9A-9C show one embodiment of a sleeve delivery device 1500. FIGURE 9A shows a perspective view of sleeve delivery device 1500. FIGURE 9B shows an enlarged view of a distal portion of sleeve delivery device 1500. FIGURE 9C shows a cross-sectional view of sleeve delivery device 1500.

[0218] Sleeve delivery device 1500 may be used to deliver a gastrointestinal sleeve. Sleeve delivery device 1500 may also be used to deliver a gastrointestinal cuff together with or apart from a gastrointestinal sleeve.

[0219] Sleeve delivery device 1500 may include a handle 1510, a delivery catheter 1520, a sealing element 1540, a release element 1550, and a pump 1570.

[0220] Handle 1510 may include a sealing port 1514, a release port 1515, a pump port 1517, and a snare port 1518. Snare port 1518 is configured to receive a loop snare or other grasping device.

[0221] Delivery catheter 1520 includes a proximal portion 1521 and a distal portion 1522. Proximal portion 1521 is coupled to handle 1510. Distal portion 1522 is configured to receive a proximal portion of a gastrointestinal sleeve. Distal portion 1522 may be curved to facilitate placement into the pylorus and/or intestine. Delivery catheter 1520 includes a delivery lumen 1523, a sealing lumen 1524, and a release lumen 1525. Delivery lumen 1523 is configured to receive at least a distal portion of a gastrointestinal sleeve which may be inverted inside delivery lumen 1523. Sealing lumen 1524 is in communication with a sealing opening 1534 formed in a side of distal portion 1522. Release lumen 1525 is in communication with a release opening 1535 formed in a side of distal portion 1522.

[0222] Sealing element 1540 is configured to form a substantially fluid-tight seal between a proximal portion of a sleeve, such as a gastrointestinal sleeve, and distal portion 1522 of delivery catheter 1520, when a proximal portion of a gastrointestinal sleeve is placed over distal portion 1522 of delivery catheter 1520. Sealing element 1540 is also configured to retain a gastrointestinal sleeve to delivery catheter 1520 during delivery. Sealing element 1540 may be, for example, a suture, wire, or other means that

runs through sealing lumen 1524, exits out of sealing opening 1534, and wraps one or more times around a proximal portion of a gastrointestinal sleeve placed over distal portion 1522 of delivery catheter 1520. Sealing element 1540 may include a distal portion 1542 having a loop or a ring.

[0223] Release element 1550 is slidably disposed in release lumen 1525. Release element 1550 is configured to retain a distal portion 1542 of sealing element 1540. Release element 1550 is exposed at release opening 1535. Release element 1550 may be a wire. Alternatively, release element 1550 may be a suture or other suitable device.

[0224] Pump 1570 is configured to be coupled to pump port 1517. Pump 1570 is configured to pump a fluid such as water into delivery lumen 1523 to evert a gastrointestinal sleeve loaded onto delivery catheter 1520. Pump 1570 may include controls for pressure, volume, flow rate, time, or other parameters.

[0225] FIGURES 9D-9G show one embodiment of a method for loading sleeve delivery device 1500. FIGURE 9D shows placing a proximal portion of a gastrointestinal sleeve over distal portion 1522 of delivery catheter 1520. FIGURE 9E shows wrapping sealing element 1540 around the proximal portion of the gastrointestinal sleeve. FIGURE 9F shows securing distal portion 1542 of sealing element 1540 in release opening 1535 using release element 1550. FIGURE 9G shows tightening of sealing element 1540 around the proximal portion of the gastrointestinal sleeve. The loading may be completed by inserting a grasper, such as a loop snare through delivery lumen 1523 and the gastrointestinal sleeve, sealing a distal portion of the gastrointestinal sleeve, and using the loop snare to pull the distal portion of the gastrointestinal sleeve into delivery lumen 1523 to invert the gastrointestinal sleeve into delivery lumen 1523. Further examples of everting systems and methods that can be used with the systems and methods disclosed herein can be found, for example, in U.S. Pat. No. 8,118,774 and U.S. Pat. Pub. No. 2007/0198074, both of which are incorporated by reference in their entireties.

[0226] FIGURES 10A-10C show another embodiment of a sleeve delivery device 2500. FIGURE 10A shows a perspective view of sleeve delivery device 2500. FIGURE 10B shows an enlarged view of a distal portion of sleeve delivery device 2500. FIGURE 10C shows a cross-sectional view of sleeve delivery device 2500.

[0227] Sleeve delivery device 2500 may be used to deliver a gastrointestinal sleeve. Sleeve delivery device 2500 may also be used to deliver a gastrointestinal cuff together with or apart from a gastrointestinal sleeve.

[0228] Sleeve delivery device 2500 may include a handle 2510, a delivery catheter 2520, a sealing element 2540, one or more rings 2550, and a pump 2570.

[0229] Handle 2510 may include a sealing port 2514, a pump port 2517, and a snare port 2518. Snare port 2518 is configured to receive a loop snare or other grasping device.

[0230] Delivery catheter 2520 includes a proximal portion 2521 and a distal portion 2522. Proximal portion 2521 is coupled to handle 2510. Distal portion 2522 is configured to receive a proximal portion of a gastrointestinal sleeve. Distal portion 2522 may be curved to facilitate placement into the pylorus and/or intestine. Delivery catheter 2520 includes a delivery lumen 2523 and a sealing lumen 2524. Delivery lumen 2523 is configured to receive at least a distal portion of a gastrointestinal sleeve which may be inverted inside delivery lumen 2523. Sealing lumen 2524 is in communication with a sealing opening 2534 formed in a side of distal portion 2522.

[0231] Sealing element 2540 is configured to form a substantially fluid-tight seal between a proximal portion of a sleeve, such as a gastrointestinal sleeve, and distal portion 2522 of delivery catheter 2520, when a proximal portion of a gastrointestinal sleeve is placed over distal portion 2522 of delivery catheter 2520. Sealing element 2540 is also configured to retain a gastrointestinal sleeve to delivery catheter 2520 during delivery. Sealing element 2540 may be, for example, a suture, wire, or other means that runs through sealing lumen 2524, exits out of sealing opening 2534, and wraps one or more times around a proximal portion of a gastrointestinal sleeve placed over distal portion 2522 of delivery catheter 2520. Sealing element 2540 may include a distal portion 2542 that may be tied to sealing element 2540 with a releasable knot.

[0232] Rings 2550, which may include any radially outwardly protruding structure, may be formed or coupled around distal portion 2522 of delivery catheter 2520. Rings 2550 may be coupled with heat shrink tubing, an adhesive, or other suitable methods. Rings 2550 are configured to fit inside a proximal portion of a gastrointestinal sleeve. Rings 2550 may cooperate with sealing element 2540 to help seal and retain a

proximal portion of a gastrointestinal sleeve around distal portion 2522 of delivery catheter 2520.

[0233] Pump 2570 is configured to be coupled to pump port 2517. Pump 2570 is configured to pump a fluid such as water into delivery lumen 2523 to evert a gastrointestinal sleeve loaded onto delivery catheter 2520. Pump 2570 may include controls for pressure, volume, flow rate, time, or other parameters.

[0234] FIGURES 10D-10G show one embodiment of a method for loading sleeve delivery device 2500. FIGURE 10D shows placing a proximal portion of a gastrointestinal sleeve over distal portion 2522 of delivery catheter 2520 and over rings 2550. FIGURE 10E shows wrapping sealing element 2540 around the proximal portion of the gastrointestinal sleeve between two rings 2550. FIGURE 10F shows securing sealing element 2540 to itself by tying a knot that will release when pulled, such as a slip knot. FIGURE 10G shows tightening of sealing element 2540 around the proximal portion of the gastrointestinal sleeve. The loading may be completed by inserting a grasper, such as a loop snare, through delivery lumen 2523 and the gastrointestinal sleeve, sealing a distal portion of the gastrointestinal sleeve, and using the loop snare to pull the distal portion of the gastrointestinal sleeve into delivery lumen 2523 to invert the gastrointestinal sleeve into delivery lumen 2523. Further examples of everting systems and methods that can be used with the systems and methods disclosed herein can be found, for example, in U.S. Pat. No. 8,118,774 and U.S. Pat. Pub. No. 2007/0198074, both of which are incorporated by reference in their entireties.

[0235] FIGURES 11A-11C show yet another embodiment of a sleeve delivery device 3500. FIGURE 11A shows a perspective view of sleeve delivery device 3500. FIGURE 11B shows an enlarged view of a distal portion of sleeve delivery device 3500. FIGURE 11C shows a cross-sectional view of sleeve delivery device 3500.

[0236] Sleeve delivery device 3500 may be used to deliver a gastrointestinal sleeve. Sleeve delivery device 3500 may also be used to deliver a gastrointestinal cuff together with or apart from a gastrointestinal sleeve.

[0237] Sleeve delivery device 3500 may include a handle 3510, a delivery catheter 3520, a balloon 3540, a boot 3560, and a pump 3570.

[0238] Handle 3510 may include an inflation port 3514, a boot release port 3516, a pump port 3517, and a snare port 3518. Inflation port 3514 is configured to be coupled to an inflation source. Snare port 3518 is configured to receive a loop snare or other grasping device.

[0239] Delivery catheter 3520 includes a proximal portion 3521 and a distal portion 3522. Proximal portion 3521 is coupled to handle 3510. Distal portion 3522 is configured to receive a proximal portion of a gastrointestinal sleeve. Distal portion 3522 may be curved to facilitate placement into the pylorus and/or intestine. Delivery catheter 3520 includes a delivery lumen 3523, an inflation lumen 3524, and a boot release lumen 3526. Delivery lumen 3523 is configured to receive at least a distal portion of a gastrointestinal sleeve which may be inverted inside delivery lumen 3523. Inflation lumen 3524 is in communication with balloon 3540. Boot release lumen 3526 is in communication with a boot release opening 3536 formed in a side of distal portion 3522.

[0240] Balloon 3540 is coupled to distal portion 3522 of delivery catheter 3520. Balloon 3540 is configured to form a substantially fluid-tight seal between a proximal portion of a sleeve, such as a gastrointestinal sleeve, and distal portion 3522 of delivery catheter 3520, when a proximal portion of a gastrointestinal sleeve is placed over distal portion 3522 of delivery catheter 3520. Balloon 3540 is also configured to retain a gastrointestinal sleeve to delivery catheter 3520 during delivery. Balloon 3540 may be a circumferential balloon coupled around distal portion 3522 of delivery catheter 3520.

[0241] Boot 3560 is configured to wrap around a proximal portion of a gastrointestinal sleeve placed over distal portion 3522 of delivery catheter 3520. Boot 3560 is configured to prevent damage to or snagging of a proximal portion of a gastrointestinal sleeve during delivery. Boot 3560 has an outside profile configured to minimize trauma and damage to esophagus and other tissue during delivery. Boot 3560 may also help to retain a gastrointestinal sleeve to delivery catheter 3520. Boot 3560 includes a boot release 3561. Boot release 3561 may be, for example, a suture, wire, or other means that runs through boot release lumen 3526, exits out of boot release opening 3536, and attaches to boot 3560. Boot release 3561 is configured to unzip, tear open, cut, degrade, or otherwise disassociate boot 3560 to release it from delivery catheter 3520. Boot 3560 may include perforations 3562 and a tongue 3563 to facilitate release. Boot

3560 may be made of plastic, fabric, or other suitable material. When sleeve delivery device 3500 is used to deliver a gastrointestinal cuff together with a gastrointestinal sleeve, boot 3560 may be long enough to wrap around both the gastrointestinal cuff and the proximal portion of the gastrointestinal sleeve. A boot 3560 may also be used with sleeve delivery devices 1500 and 2500.

[0242] Pump 3570 is configured to be coupled to pump port 3517. Pump 3570 is configured to pump a fluid such as water into delivery lumen 3523 to evert a gastrointestinal sleeve loaded onto delivery catheter 3520. Pump 3570 may include controls for pressure, volume, flow rate, time, or other parameters.

[0243] FIGURES 11D-11G show one embodiment of a method for loading sleeve delivery device 3500. FIGURE 11D shows placing a proximal portion of a gastrointestinal sleeve over distal portion 3522 of delivery catheter 3520 and over balloon 3540. FIGURE 11E shows folding the proximal portion of the gastrointestinal sleeve around distal portion 3522 of delivery catheter 3520. The loading may be continued by inserting a grasper, such as a loop snare, through delivery lumen 3523 and the gastrointestinal sleeve, sealing a distal portion of the gastrointestinal sleeve, and using the loop snare to pull the distal portion of the gastrointestinal sleeve into delivery lumen 3523 to invert the gastrointestinal sleeve into delivery lumen 3523. FIGURE 11F shows wrapping boot 3560 around the now folded proximal portion of the gastrointestinal sleeve and attaching boot 3560 to boot release 3561. FIGURE 11G shows inflating balloon 3540. Further examples of everting systems and methods that can be used with the systems and methods disclosed herein can be found, for example, in U.S. Pat. No. 8,118,774 and U.S. Pat. Pub. No. 2007/0198074, both of which are incorporated by reference in their entireties.

[0244] FIGURES 12A-12C show one embodiment of an anchor delivery device 1600. FIGURE 12A shows a perspective view of anchor delivery device 1600. FIGURE 12B shows an exploded view of anchor delivery device 1600. FIGURE 12C shows an enlarged cross-sectional view of a distal portion of anchor delivery device 1600 with a tissue anchor loaded.

[0245] Anchor delivery device 1600 includes a handle 1610, a sheath 1650, a delivery needle 1660, and a stylet 1670.

[0246] Handle 1610 includes a needle control 1616 and a stylet control 1617.

[0247] Sheath 1650 includes a proximal portion 1651, a distal portion 1652, and a sheath lumen 1655. Proximal portion 1651 of sheath 1650 may be coupled to handle 1610. Sheath 1650 is configured to be slidably disposed in a working lumen of an endoscope.

[0248] Delivery needle 1660 is slidably disposed in sheath lumen 1655. Delivery needle 1660 includes a proximal portion 1661, a distal portion 1662, and a needle lumen 1665. Proximal portion 1661 may be coupled to needle control 1616. Distal portion 1662 may include a tip 1668 that is sharp. Alternatively, tip 1668 may be atraumatic and coupled to an RF or other energy source. Distal portion 1662 may be advanced out of and retracted into sheath 1620. Distal portion 1662 may be preformed with a curve, or made of a shape memory material. This curve may be straightened out when distal portion 1662 is retracted into sheath 1620. Distal portion 1662 may be made of the same material as the rest of delivery needle 1660. Alternatively, distal portion 1662 may be made of a different material for greater curve and/or flexibility. For example, distal portion 1662 may be made of a polyamide and the rest of delivery needle 1660 may be made of nitinol. Delivery needle 1660 is configured to receive a tissue anchor collapsed into a delivery configuration.

[0249] Stylet 1670 is slidably disposed in needle lumen 1665. Stylet 1670 includes a proximal portion 1671 and a distal portion 1672. Proximal portion 1671 may be coupled to stylet control 1617. Distal portion 1672 may be advanced out of and retracted into delivery needle 1660. Stylet 1670 is configured to push out a tissue anchor loaded in delivery needle 1660.

[0250] FIGURES 13A-13E show one embodiment of a method for using anchor delivery device 1600. Other systems and methods that can be used or modified for use with anchor delivery devices as described herein can be found, for example, in U.S. Pat. Pub. No. 2009/0012541 to Dahl et al., which is hereby incorporated by reference in its entirety.

[0251] FIGURE 13A shows loading anchor delivery device 1600 with a tissue anchor, e.g., tissue anchor 1300. Tissue anchor 1300A, tissue anchor 2300, tissue anchor 3300, tissue anchor 4300, and/or any other suitable tissue anchor may also be used. Delivery needle 1660 is retracted inside sheath 1650. A distal retention element of a tissue anchor is loaded into delivery needle 1660. A proximal retention element of tissue anchor 1300 hangs outside of delivery needle 1660. A therapeutic agent, e.g., an antibiotic gel, may also be loaded into delivery needle 1660.

[0252] FIGURE 13B shows advancing delivery needle 1660 through sheath 1650 and transmurally through a tissue wall W. The proximal retention element is maintained on a proximal side of the tissue wall W, e.g., on a mucosal surface. In other embodiments tissue anchor 1300 may be placed through a plication.

[0253] FIGURE 13C shows advancing stylet 1640 through delivery needle 1630 to deploy the distal retention element on a distal side of the tissue wall W, e.g., on a serosal surface. The antibiotic gel may also be pushed out.

[0254] FIGURE 13D shows positioning and/or turning over tissue anchor 1300 as necessary using laparoscopic instruments positioned on the distal side of the tissue wall W.

[0255] FIGURE 13E shows retracting delivery needle 1660 back through the tissue wall and back into sheath 1650, leaving a tension element of tissue anchor 1300 in place through the tissue wall W.

[0256] FIGURES 14A-14C show one embodiment of a stent 1690. FIGURE 14A shows a top view of stent 1690. FIGURE 14B shows stent 1690 in an collapsed configuration coupled to a gastrointestinal cuff. FIGURE 14C shows stent 1690 in an expanded configuration coupled to a gastrointestinal cuff.

[0257] Stent 1690 may be removably coupled to a gastrointestinal cuff to create a working space inside the esophagus. Stent 1690 may also be used without being coupled to the gastrointestinal cuff. Stent 1690 may be used in conjunction with anchor delivery device 1600.

[0258] Stent 1690 includes a plurality of proximal segments 1691 and a plurality of distal segments 1692 connected by connecting segments 1693. Proximal segments 1691 may include proximal drawstring holes 1694. A proximal drawstring 1695 may be

threaded through proximal drawstring holes 1692. A proximal drawstring control 1696 may be coupled to proximal drawstring 1695. Proximal drawstring control 1696 is configured to loosen and tighten proximal drawstring 1695 to expand and collapse a proximal portion of stent 1690. Distal segments 1692 may include distal drawstring holes 1697. A distal drawstring 1698 may be threaded through distal drawstring holes 1697. A distal drawstring control 1699 may be coupled to distal drawstring 1698. Distal drawstring control 1699 is configured to loosen and tighten distal drawstring to expand and collapse a distal portion of stent 1690.

[0259] Stent 1690 may be removably coupled to an inner surface of a proximal portion of a gastrointestinal cuff. Stent 1690 may be sutured to the gastrointestinal cuff. Stent 1690 may be delivered in a collapsed configuration together with the gastrointestinal cuff, and expanded at an attachment point to create a working space. When the working space is no longer needed, the sutures may be cut and removed, and stent 1690 collapsed and removed.

[0260] Stent 1690 may also be used without being coupled to a gastrointestinal cuff. Stent 1690 may be delivered in a collapsed configuration into a previously placed gastrointestinal cuff, and expanded to create a working space. When the working space is no longer needed, the stent 1690 may be collapsed and removed.

[0261] FIGURES 15A-15G show another embodiment of an anchor delivery device 2600. FIGURE 15A shows a perspective view of anchor delivery device 2600. FIGURE 15B shows an exploded view of anchor delivery device 2600. FIGURE 15C shows a side cross-sectional view of a distal portion of anchor delivery device 2600. FIGURE 15D shows a side cross-sectional view of a distal portion of sled 2650. FIGURE 15E shows a side view of a delivery needle 2660, a pushrod 2670, and a holder 2680. FIGURE 15F shows an enlarged view of a delivery needle 2660 and a pushrod 2670. FIGURE 15G shows an end cross-sectional view of a distal portion of anchor delivery device 2600.

[0262] Anchor delivery device 2600 includes a handle 2610, a catheter 2620, a side port 2630, a sled 2650, a delivery needle 2660, pushrod 2670, and a holder 2680.

[0263] Handle 2610 includes a needle control 2616, a pushrod control 2617, and a holder control 2618.

[0264] Catheter 2620 includes a proximal portion 2621, a distal portion 2622, and a longitudinal axis 2623. Catheter 2620 also includes a central lumen 2625. Distal portion 2622 may include a nose 2626 having an opening 2627. Nose 2626 may be soft and flexible. Nose 2626 may be elongate. Nose 2626 may be curved. Opening 2627 may be configured to allow an endoscope or other tool to pass through. Distal portion 2622 may also include an alignment slot 2628 and a stop 2629.

[0265] Side port 2630 is formed in a side of distal portion 2622 of catheter 2620. Side port 2630 includes a proximal side 2631 and a distal side 2632. Side port 2630 may optionally include a tissue brace 2634 slidably disposed within a brace lumen of catheter 2620. Tissue brace 2634 may be configured to removably cover side port 2630 to prevent tissue from prematurely entering side port 2630. Side port 2630 may be coupled to a vacuum source. Side port 2630 may be configured to be placed against and draw in a tissue wall. Side port 2630 may be sized larger to allow enough of a tissue wall to be drawn in for single-wall (transmural) anchor delivery, or sized smaller for double-wall (plication) anchor delivery. For single-wall anchor delivery, side port 2630 may have a length of 10 mm to 50 mm or greater, such as a length of 20 mm to 30 mm.

[0266] Sled 2650 is slidably disposed in central lumen 2625. Sled 2650 includes a sheathing channel 2655 having a proximal opening 2656. Sled 2650 may be coupled to a sled control rod 2657 configured to move sled 2650. Sled control rod 2657 may be coupled to handle 2610. Sled 2650 may include an alignment tab 2658 which cooperates with alignment slot 2628 to align proximal opening 2656 with side port 2630. Sled 2650 may be configured to slide in central lumen 2625 distally until it reaches stop 2629. When sled 2650 has reached stop 2629, proximal opening 2656 of sheathing channel 2655 may be positioned at distal side 2632 of side port 2630. Sled 2650 may be removed from catheter 2620 for reloading.

[0267] Delivery needle 2660 is slidably disposed in sheathing channel 2655. Delivery needle 2660 includes a distal control portion 2661, a proximal delivery portion 2662, and a needle lumen 2665. Distal control portion 2661 may be coupled to a needle control rod 2667. Needle control rod 2667 may be coupled to needle control 2616. Proximal delivery portion 2662 includes a tip 2668 that is sharp. Alternatively, tip 2668 may be atraumatic and coupled to an RF or other energy source. Delivery needle 2660

has a reverse orientation, with tip 2668 pointed proximally (e.g., toward the oropharynx, when the device 2600 is deployed transesophageally via an endoscopic technique) and movable from a first, e.g., distal retracted position to a second, e.g., proximal position for delivering a tissue anchor across a body luminal wall. Proximal delivery portion 2662 may be advanced out of and retracted into sheathing channel 2655. When advanced out of sheathing channel 2655, proximal delivery portion 2662 may enter distal side 2632 of side port 2630. Delivery needle 2660 is configured to receive a tissue anchor collapsed into a delivery configuration. Delivery needle 2660 may include a slot 2669 configured to allow a tension element of a tissue anchor to pass through.

[0268] Pushrod 2670 is slidably disposed in needle lumen 2664. Pushrod 2670 includes a distal control portion 2671 and a proximal delivery portion 2672. Distal control portion 2671 may be coupled to a pushrod control rod 2677. Pushrod control rod 2677 may be coupled to pushrod control 2617. Pushrod 2670 has a reverse orientation, with proximal delivery portion 2672 pointed proximally. Proximal delivery portion 2672 may be advanced out of and retracted into delivery needle 2660. Pushrod 2670 is configured to push out a tissue anchor loaded in delivery needle 2660. Pushrod 2670 may include at least a portion, e.g., proximal delivery portion 2672, sized small enough to push against a hub of a tissue anchor without damaging the tissue anchor or a portion thereof, e.g., the petals. Pushrod 2670 may include a channel 2679 configured to allow a tension element of a tissue anchor to pass through. Channel 2679 of pushrod 2670 may be aligned with slot 2669 of delivery needle 2660.

[0269] Holder 2680 may be coupled to a holder control rod 2687. Holder control rod 2687 may be coupled to holder control 2618. Holder 2680 may be configured to hold an anchor hole of a gastrointestinal cuff over proximal opening 2656 of sheathing channel 2655. Holder 2680 may be configured to hold an anchor hole of a gastrointestinal cuff over tip 2668 of delivery needle 2660. Holder 2680 may be slidably and/or rotatably manipulated. Holder 2680 may be stowed when not in use.

[0270] The control rods may be arranged coaxially. For example, sled control rod 2657 may be slidably disposed in a hollow pushrod control rod 2677, which is slidably disposed in a hollow needle control rod 2667, which is slidably disposed in a hollow holder control rod 2687, as shown in FIGURE 15G. As another example, pushrod

control rod 2677 may be slidably disposed in a hollow needle control rod 2667, which is slidably disposed in a hollow sled control rod 2657, which is slidably disposed in a hollow holder control rod 2687. Alternatively, the control rods may be arranged non-coaxially, such as in a multi-lumen carrier tube. In some embodiments, anchor delivery device 2600 may also include an integrated vacuum port operably connected to a source of vacuum. In some embodiments, the vacuum may be delivered via a port on a separate endoscope or other device.

[0271] FIGURES 16A-16F show one embodiment of a method for using anchor delivery device 2600. Sheathing lumen 2655 is represented by the cross-hatched area. For clarity, only delivery needle 2660 and pushrod 2670 are shown.

[0272] FIGURE 16A shows loading delivery needle 2660. Sled 2650 is removed from catheter 2620. Pushrod 2670 is taken out of delivery needle 2660. An antibiotic gel may be loaded into delivery needle 2660, which may reduce the likelihood of infection when delivery needle 2660 bridges non-sterile and sterile fields. A distal retention element of a tissue anchor, e.g., tissue anchor 1300, is loaded through distal control portion 2661. Tissue anchor 1300A, tissue anchor 2300, tissue anchor 3300, tissue anchor 4300, and/or any other suitable tissue anchor may also be used. A tension element of tissue anchor 1300 is passed through slot 2669 and channel 2679. A proximal retention element is positioned outside of delivery needle 2660.

[0273] FIGURE 16B shows loading catheter 2620. Pushrod 2670 is inserted into delivery needle 2660. The distal retention element is positioned inside tip 2668. Sled 2650 is inserted into catheter 2620 and seated in distal portion 2622. Proximal opening 2656 of sheathing channel 2655 is positioned at distal side 2632 of side port 2630.

[0274] FIGURE 16C shows capturing the gastrointestinal cuff. Holder 2680 may be used to hold an anchor hole of the gastrointestinal cuff over proximal opening 2656 of sheathing channel 2655. Delivery needle 2660 may be advanced a small amount so that tip 2668 threads through the anchor hole. A tissue wall W is drawn in through side port 2630 using a vacuum source. The tissue wall W at proximal side 2631 of side port 2630 may be at least partially drawn up into central lumen 2625 of catheter 2620. Tissue marks made previously, such as those made by tissue marking device 1400 and/or tissue marking device 2400, may be used to position delivery needle 2660.

[0275] FIGURE 16D shows advancing delivery needle 2660. Delivery needle 2660 is advanced through the tissue wall W at distal side 2632 of side port 2630. Pushrod 2670 is also advanced, but is not moved relative to delivery needle 2660. Handle 2610 and needle control 2616 may be configured to preset the distance delivery needle 2660 is advanced to reduce the risk of penetrating the tissue wall W through proximal side 2631 of side port 2630.

[0276] FIGURE 16E shows retracting the delivery needle 2660. Delivery needle 2660 is retracted while keeping pushrod 2670 in place to deploy the distal retention element. The antibiotic gel may also be released.

[0277] FIGURE 16F shows stowing delivery needle 2660 and pushrod 2670. Delivery needle 2660 and pushrod 2670 are retracted into sheathing channel 2655. Anchor delivery device 2600 includes a delivery needle 2660 with a reverse throw, which makes it convenient for use with anchor holes on a proximal portion of a gastrointestinal cuff. The reverse throw avoids the need to draw more of the gastrointestinal cuff into side port 2630. This and other anchor delivery systems and methods used herein can be used to accurately deliver one or a plurality of tissue anchors through a single transmural wall or to create or reinforce one or a plurality of tissue plications. Furthermore, anchor delivery system 2600 may advantageously reduce the risk of puncturing other body structures in close proximity, e.g., the aorta. In some embodiments, anchor delivery systems as described herein can be used via a pure endoscopic approach, e.g., as illustrated in connection with FIGURES 18A-18J below, without necessarily requiring laparoscopic assistance.

[0278] FIGURES 17A-17H show one embodiment of a method for implanting a gastrointestinal bypass device 1000. The method may also be used with other gastrointestinal bypass devices such as gastrointestinal bypass device 2000 and gastrointestinal bypass device 3000.

[0279] Sleeve delivery device 1500 is mounted with cuff 1100 and sleeve 1200. Sleeve delivery device 2500 or sleeve delivery device 3500 may also be used. Stent 1690 is coupled to cuff 1100. Stent 1690 is cinched around sleeve delivery device 1500.

[0280] FIGURE 17A shows introducing sleeve delivery device 1500. Sleeve delivery device 1500 may position sleeve 1200 at or near the pylorus. Sleeve delivery device 1500 may be introduced with or without an overtube. An endoscope may be used for guidance and visualization.

[0281] FIGURE 17B shows deploying sleeve 1200. A fluid is pumped into delivery device 1500 to evert sleeve 1200 past the pylorus and into the intestine.

[0282] FIGURE 17C shows positioning cuff 1100 and sleeve 1200 at the attachment point. Sleeve delivery device 1500 pulls cuff 1100 and sleeve 1200 proximally up to the gastroesophageal junction or other attachment points, some of which are described elsewhere in the application.

[0283] FIGURE 17D shows releasing cuff 1100 and sleeve 1200 from sleeve delivery device 1500. Sleeve delivery device 1500 is then withdrawn.

[0284] FIGURE 17E shows introducing a laparoscopic tool L. Laparoscopic tool L is positioned on a distal side of the attachment point. Laparoscopic tool L may be used to clear tissue around the esophagus to create a working space.

[0285] FIGURE 17F shows introducing anchor delivery device 1600. Anchor delivery device 1600 may be used in the working lumen of an endoscope. Anchor delivery device 1600 may be introduced with or without an overtube. Anchor delivery device 1600 is positioned on a proximal side of the attachment point. Stent 1690 is opened to create a working space.

[0286] FIGURE 17G shows delivering tissue anchors 1300. Anchor delivery device 1600 is delivers tissue anchors 1300 through cuff 1100 and the wall of the esophagus. Tissue anchor 1300A, tissue anchor 2300, tissue anchor 3300, tissue anchor 4300, and/or any other suitable tissue anchor may also be used. Tissue marks made earlier by tissue marking device 1400 may be used as a guide. Laparoscopic tool L may be held against the distal side of the attachment point to reduce tenting. Laparoscopic tool L may be used to flip over distal retention element 1320 of tissue anchor 1300.

[0287] FIGURE 17H shows removing stent 1690 from cuff 1100. The sutures used to couple stent 1690 to cuff 1100 may be cut and removed. Stent 1690 may be cinched using proximal drawstring 1695 and/or distal drawstring 1698 and removed. Stent 1690 may be removed with or without an overtube.

[0288] FIGURES 18A-18J show yet another embodiment of a method for implanting a gastrointestinal bypass device 3000. The method may also be used with gastrointestinal bypass device 1000 and gastrointestinal bypass device 2000.

[0289] Sleeve delivery device 1500 is mounted with cuff 3100 and sleeve 3200. Sleeve delivery device 2500 or sleeve delivery device 3500 may also be used.

[0290] FIGURE 18A shows introducing sleeve delivery device 1500. Sleeve delivery device 1500 may position sleeve 3200 at or near the pylorus. Sleeve delivery device 1500 may be introduced with or without an overtube. An endoscope may be used for guidance and visualization.

[0291] FIGURE 18B shows deploying sleeve 3200. A fluid is pumped into delivery device 1500 to evert sleeve 3200 past the pylorus and into the intestine.

[0292] FIGURE 18C shows positioning cuff 3100 and sleeve 3200 in the stomach. Sleeve delivery device 1500 pulls cuff 3100 and sleeve 3200 into the stomach.

[0293] FIGURE 18D shows releasing cuff 3100 and sleeve 3200 from sleeve delivery device 1500. Sleeve delivery device 1500 is then withdrawn.

[0294] FIGURE 18E shows introducing catheter 2620 of anchor delivery device 2600. Catheter 2260 of anchor delivery device 2600 is introduced through the esophagus. An endoscope may be used for guidance and visualization.

[0295] FIGURE 18F shows grasping cuff 3100. A grasping tool is introduced through catheter 2260 to grasp cuff 3100 and pull cuff 3100 over catheter 2260. Sled 2650 is introduced into catheter 2260 and used to hold cuff 3100.

[0296] FIGURE 18G shows positioning cuff 3100 and sleeve 3200 at an attachment point. Catheter 2620 pulls cuff 3100 and sleeve 3200 proximally up to the gastroesophageal junction or other attachment points, some of which are described elsewhere in the application.

[0297] FIGURE 18H shows drawing a portion of a tissue wall into side port 2630 of anchor delivery device 2620. A vacuum may be applied through the working lumen of an endoscope placed in central lumen 2625.

[0298] FIGURE 18I shows delivering tissue anchor 1300. Anchor delivery device 2600 is used to deliver tissue anchors 1300 through cuff 3100 and the wall of the esophagus. Tissue anchor 1300A, tissue anchor 2300, tissue anchor 3300, tissue anchor

4300, and/or any other suitable tissue anchor may also be used. Tissue marks made earlier by tissue marking device 1400 may be used as a guide.

[0299] FIGURE 18J shows removing anchor delivery device 2600.

[0300] Alternatively, the method may include first deploying sleeve 3200 without cuff 3100, then anchoring cuff 3100 at the attachment point, and then grasping sleeve 3200 to attach sleeve 3200 to cuff 3100.

[0301] FIGURES 25A-25D show various embodiments of attachment points which may be used with the devices and methods described above. Tissue anchors may be delivered through a wall of the esophagus at an attachment point to retain a gastrointestinal bypass device. The size and relative locations of the opening O of the stomach S, the squamocolumnar junction SCJ, the diaphragm D, and the lower esophageal sphincter LES may vary from patient to patient, and one or more of these anatomical features may be referenced separately or in combination to select an attachment point.

[0302] FIGURE 25A shows one embodiment of an attachment point 1710. The esophagus E and the opening O of the stomach S are shown. Attachment point 1710 may be approximately 5 mm to approximately 25 mm above the opening O of the stomach S.

[0303] FIGURE 25B shows another embodiment of an attachment point 1720. The esophagus E and the squamocolumnar junction SCJ, also known as the Z-line, are shown. Attachment point 1720 may be approximately 0 mm to approximately 20 mm above the squamocolumnar junction SCJ.

[0304] FIGURE 25C shows yet another embodiment of an attachment point 1730. The esophagus E and the diaphragm D are shown. Attachment point 1730 may be approximately 20 mm below to approximately 50 mm above the diaphragm D. The diaphragm D may be located using imaging techniques and/or other methods before and/or during the delivery of the tissue anchors. The diaphragm D may be located by locating the diaphragmatic pinch in the esophagus E.

[0305] FIGURE 25D shows still another embodiment of an attachment point 1740. The esophagus E and the lower esophageal sphincter LES are shown. Attachment point 1740 may be at an upper or proximal portion of the lower esophageal sphincter LES.

[0306] FIGURES 19A-19F show one embodiment of a method for exchanging a sleeve 2200. The method may also be used for exchanging a sleeve 3200. In some embodiments, anchor delivery device 2600 may be used to replace tissue anchors 1300, such as those that may have pulled out of tissue, without necessarily requiring exchange of sleeve 3200 and/or cuff 3100.

[0307] FIGURE 19A shows a cuff 2100 and a sleeve 2200 implanted in an esophagus. A grasping tool is introduced into the esophagus.

[0308] FIGURE 19B shows removing sleeve 2200. The grasping tool passes through cuff 2100 to grasp sleeve 2200. The grasping tool may be configured to pull drawstring 2241 to cinch ring 2240 of sleeve 2200. Halo 2260 or attachment elements 3260 may be cut. Sleeve 2200 is pulled out.

[0309] FIGURE 19C shows introducing sleeve delivery device 1500. Sleeve delivery device 1500 passes through cuff 2100 and may position sleeve 2200 at or near the pylorus. Sleeve delivery device 1500 may be introduced with or without an overtube. Sleeve delivery device 2500 or sleeve delivery device 3500 may also be used. An endoscope may be used for guidance and visualization.

[0310] FIGURE 19D shows deploying sleeve 2200. A fluid is pumped into delivery device 1500 to evert sleeve 2200 past the pylorus and into the intestine.

[0311] FIGURE 19E shows positioning sleeve 2200 in the stomach. Sleeve delivery device 1500 pulls sleeve 2200 into the stomach.

[0312] FIGURE 19F shows releasing sleeve 2200 from sleeve delivery device 1500. Sleeve delivery device 1500 is then withdrawn.

[0313] FIGURE 19G shows grasping sleeve 2200. A grasping tool may be passed through cuff 2100 to grasp sleeve 2200. The grasping tool may be configured to pull drawstring 2241 to cinch ring 2240 of sleeve 2200.

[0314] FIGURE 19H shows attaching sleeve 2200 to cuff 2100. The grasping tool pulls ring 2240 of sleeve 2200 into cuff 2100 so that ring 2240 may be coupled to retainer 2140. Halo 2260 or attachment elements 3260 may be coupled to hooks 2160 or through attachment openings 3160, respectively.

[0315] While the foregoing has been with reference to particular embodiments of the invention, it will be appreciated by those skilled in the art that changes in these embodiments may be made without departing from the principles and spirit of the invention, including embodiments that do not provide all the features and benefits described herein. It will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative or additional embodiments and/or uses and obvious modifications and equivalents thereof. In addition, while a number of variations have been shown and described in varying detail, other modifications, which are within the scope of the present disclosure, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the present disclosure. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the present disclosure. Thus, it is intended that the scope of the present disclosure herein disclosed should not be limited by the particular disclosed embodiments described above. For all of the embodiments described above, the steps of any methods need not be performed sequentially.

CLAIMS

What is claimed is:

1. A gastrointestinal cuff device configured to be attached in a gastrointestinal lumen, the device comprising:

a liner having a proximal portion and a distal portion, the proximal portion including a scalloped edge having a plurality of peaks and valleys, the liner configured to open and close with the gastrointestinal lumen; and

a scaffold coupled to the liner distal to the scalloped edge, the scaffold having a plurality of proximal segments and distal segments coupled by connecting segments, the proximal segments positioned in a vicinity of the valleys, the scaffold configured to provide an outward bias to increase conformance of the liner to an inside surface of the gastrointestinal lumen.

2. The device of claim 1, wherein the peaks and the valleys are substantially similar in size and shape.

3. The device of claim 1, wherein the peaks and the valleys vary in size and shape.

4. The device of claim 1, wherein the peaks each include an anchor hole.

5. The device of claim 1, wherein the proximal portion is capable of opening wider than a remainder of the liner.

6. The device of claim 1, wherien the scaffold is shaped like a wave.

7. The device of claim 1, wherein the scaffold is shaped like a sawtooth wave.

8. The device of claim 1, wherein the scaffold is shaped like a sine wave.

9. The device of claim 1, wherein the scaffold is coupled to an inner surface of the liner.

10. The device of claim 1, wherein liner includes an inner layer and an outer layer, and wherein the scaffold is coupled to the liner between the inner layer and the outer layer.

11. The device of claim 1, wherein the outward bias is large enough to open the liner when the gastrointestinal lumen is open.

12. The device of claim 1, wherein the outward bias is not large enough to prevent the gastrointestinal lumen from closing.

13. A gastrointestinal cuff device configured to be attached in a gastrointestinal lumen, the device comprising:

a liner having a proximal portion, a distal portion, and a longitudinal axis; and

a plurality of struts coupled to the liner at an angle to the longitudinal axis, wherein the struts are configured to twist the liner about the longitudinal axis to prevent the liner from inverting when a retrograde force is applied to the distal portion of the liner.

14. The device of claim 13, wherein the struts are coupled to an inner surface of the liner.

15. The device of claim 13, wherein the liner includes an inner layer and an outer layer, and wherein the struts are coupled to the liner between the inner layer and the outer layer.

16. The device of claim 13, wherein the angle is between 1 and 30 degrees.

17. The device of claim 13, wherein one or more of the struts includes a first eyelet at a proximal portion of the strut, the first eyelet configured to receive a tissue anchor.

18. The device of claim 17, wherein the proximal portion of the liner includes an anchor hole, and wherein the first eyelet is aligned with the anchor hole.

19. The device of claim 13, wherein one or more of the struts includes a second eyelet at a distal portion of the strut, the second eyelet configured to be coupled to the liner.

20. The device of claim 13, wherein one or more of the struts includes a proximal portion that is more flexible.

21. The device of claim 13, wherein one or more of the struts includes a distal portion that is more flexible.

22. The device of claim 13, wherein the liner is made of a first material, and the struts are made of a second, different material.

23. The device of claim 13, wherein the liner includes a lumen which at least partially closes when the struts twist the liner about the longitudinal axis.

24. The device of claim 13, wherein the distal portion of the liner is substantially cylindrical.

25. A gastrointestinal cuff device configured to be attached in a gastrointestinal lumen, the device comprising:

a liner having a proximal portion and a distal portion, the liner configured to open and close with the gastrointestinal lumen;

a plurality of struts coupled to the liner; and

a scaffold coupled to the liner, the scaffold having a plurality of proximal segments and distal segments coupled by connecting segments, the distal segments positioned across the struts, the scaffold configured to provide an outward bias to increase conformance of the liner to an inside surface of the gastrointestinal lumen.

26. The device of claim 25, wherein the scaffold is shaped like a wave.

26. The device of claim 25, wherein the scaffold is shaped like a sawtooth wave.

28. The device of claim 25, wherein the scaffold is shaped like a sine wave.

29. The device of claim 25, wherein the scaffold is a mesh.

30. The device of claim 25, wherein the scaffold is coupled to an inner surface of the liner.

31. The device of claim 25, wherein the liner includes an inner layer and an outer layer, and wherein the scaffold is coupled to the liner between the inner layer and the outer layer.

32. The device of claim 25, wherein the outward bias is large enough to open the liner when the gastrointestinal lumen is open.

33. The device of claim 25, wherein the outward bias is not large enough to prevent the gastrointestinal lumen from closing.

34. The device of claim 25, wherein one or more of the struts are formed as a single piece with the scaffold.

35. The device of claim 25, wherein the scaffold is configured to rotate the struts when the liner closes.

36. The device of claim 25, wherein one or more of the struts includes a notch configured to be coupled to the scaffold.

37. A device for marking a tissue, the device comprising:

a marking surface having a lumen, the lumen having an inlet and an outlet, the marking surface configured to contact the tissue,

at least one opening formed in the marking surface;

a vacuum source coupled to the outlet, the vacuum source configured to create a vacuum in the lumen and create a seal between the opening and the tissue; and

a dye source coupled to the inlet, the dye source having a dye.

38. The device of claim 37, further comprising:

a rinse source coupled to the inlet, the rinse source having a rinse solution.

39. The device of claim 38, wherein the rinse solution includes saline.

40. The device of claim 38, wherein the rinse solution includes acetic acid.

41. The device of claim 37, further comprising:

a prep source coupled to the inlet, the prep source having a prep solution.

42. The device of claim 41, wherein the prep solution includes isopropyl alcohol.

43. The device of claim 37, wherein the dye source is coupled to the inlet through a manifold.

44. The device of claim 37, wherein the dye includes gentian violet.

45. The device of claim 37, wherein the marking surface includes a distal portion of a tube, the tube having an inlet lumen and an outlet lumen separated by a wall, and wherein the lumen of the marking surface includes a passage formed in the wall at the distal portion of the tube..

46. The device of claim 37, wherein the marking surface is an exterior surface of a tube, and wherein the lumen of the marking surface is a lumen of the tube.

47. A method for marking a tissue, the method comprising:

placing a marking surface against the tissue, the marking surface having a lumen and at least one opening;

applying a vacuum to an outlet of the lumen to draw a portion of the tissue against the opening; and

providing a dye to an inlet of the lumen to at least partially fill the lumen with the dye and allowing the dye to contact the portion of the tissue and mark the tissue.

48. The method of claim 47, wherein providing a dye includes maintaining the dye in the lumen for a period of time.

49. The method of claim 47, further comprising:

providing a rinse solution to the inlet of the lumen to at least partially fill the lumen with the rinse solution and rinse the portion of the tissue.

50. The method of claim 49, wherein providing the rinse solution is performed before providing the dye.

51. The method of claim 49, wherein providing the rinse solution is performed after providing the dye.

52. The method of claim 49, wherein the rinse solution includes saline.

53. The method of claim 49, wherein the rinse solution includes acetic acid.

54. The method of claim 47, further comprising:

providing a prep solution to the inlet of the lumen to at least partially fill the lumen with the prep solution and prepare the portion of the tissue, wherein providing the prep solution is performed before providing the dye.

55. The method of claim 54, wherein the prep solution includes isopropyl alcohol.

56. The method of claim 47, wherein the dye includes gentian violet.

57. A device for delivering a tissue anchor through a tissue wall, the device comprising:

a catheter having a central lumen, the catheter having a side port formed in a distal portion of the catheter, the side port having a proximal side and a distal side;

a sled slidably disposed in the central lumen, the sled having a sheathing channel, the sheathing channel having a proximal opening configured to be positioned at the distal side of the side port;

a delivery needle slidably disposed in the sheathing channel, the delivery needle having a needle lumen configured to receive the tissue anchor, the delivery needle having a tip pointed proximally, the delivery needle configured to be advanced proximally through the distal side of the side port; and

a pushrod slidably disposed in the needle lumen.

58. The device of claim 57, further comprising:

a sled control rod coupled to the sled, the sled control rod configured to slide the sled in the central lumen;

a needle control rod coupled to a distal control portion of the delivery needle, the needle control rod configured to slide the delivery needle in the sheathing channel; and

a pushrod control rod coupled to a distal control portion of the pushrod, the pushrod control rod configured to slide the pushrod in the needle lumen.

59. The device of claim 58, wherein the sled control rod, the needle control rod, and the pushrod control rod are coaxial.

60. The device of claim 57, further comprising:

a holder coupled to the sled, the holder configured to hold a portion of a gastrointestinal cuff over the proximal delivery portion of the delivery needle.

61. The device of claim 57, further comprising:

a holder control rod coupled to the holder, the holder control rod configured to rotate and slide the holder.

62. The device of claim 57, further comprising:

a vacuum source configured to generate a vacuum in the central lumen and draw a portion of the tissue wall through the side port.

63. The device of claim 57, further comprising:

a tissue brace slidably disposed within a brace lumen of the catheter, the tissue brace configured to removably cover the side port.

64. The device of claim 57, wherein the delivery needle includes a longitudinal slot.

65. The device of claim 64, wherein the pushrod includes a longitudinal channel substantially aligned with the longitudinal slot.

66. The device of claim 57, wherein the pushrod includes a proximal delivery portion that is tapered.

67. A method for delivering a tissue anchor through a tissue wall, the method comprising:

loading the tissue anchor in a delivery needle, the tissue anchor having a proximal retention element and a distal retention element;

providing a catheter having a side port;

positioning the delivery needle on a distal side of the side port, the delivery needle pointed proximally;

drawing the tissue wall through the side port;

advancing the delivery needle and a pushrod through the tissue wall from the distal side of the side port; and

withdrawing the delivery needle while keeping the pushrod in place to deploy the distal retention element on a distal side of the tissue wall.

68. The method of claim 67, wherein drawing the tissue wall through the side port includes using a vacuum source to generate a vacuum in a central lumen of the catheter.

69. The method of claim 67, wherein advancing the delivery needle includes moving the delivery needle proximally.

70. The method of claim 67, wherein withdrawing the delivery needle includes moving the delivery needle distally.

71. The method of claim 67, further comprising:

withdrawing the pushrod to deploy the proximal retention element on a proximal side of the tissue wall.

72. An attachment element for attaching a gastrointestinal sleeve through an attachment opening formed in a liner of a gastrointestinal cuff, the attachment element comprising:

an elongate member configured to be passed longitudinally through the attachment opening from an inside of the liner, the elongate member configured to be deployed transversely on an outside of the liner;

a tension element having a proximal portion coupled to the gastrointestinal sleeve, the tension element having a distal portion flexibly coupled to a central portion of the elongate member; and

a grasping aid coupled to or near at least one end of the elongate member, the grasping aid capable of being passed through the attachment opening.

73. The attachment element of claim 72, wherein the tension element includes a suture.

74. The attachment element of claim 72, wherein the grasping aid includes a length of suture.

75. The attachment element of claim 72, wherein the grasping aid includes a loop of suture.

76. The attachment element of claim 72, wherein the grasping aid is substantially flexible.

77. The attachment element of claim 72, wherein the grasping aid is flexibly coupled to the elongate member.

78. The attachment element of claim 72, wherein the grasping aid is substantially rigid.

79. The attachment element of claim 72, wherein the grasping aid is rigidly coupled to the elongate member.

80. A method for attaching a gastrointestinal sleeve through an attachment opening formed in a liner of a gastrointestinal cuff, the method comprising:

providing the attachment element of claim 72;

grasping the grasping aid;

passing the grasping aid through the attachment opening from an inside of the liner;

passing the elongate member longitudinally through the attachment opening; and

releasing the grasping aid to deploy the elongate member transversely on an outside of the liner.

81. A method for attaching a gastrointestinal sleeve through an attachment opening formed in a liner of a gastrointestinal cuff, the method comprising:

providing the attachment element of claim 72;

using a tool to grasp the grasping aid;

advancing the tool through the attachment opening to pass the grasping aid through the attachment opening from an inside of the liner;

continuing to advance the tool through the attachment opening to pass the elongate member longitudinally through the attachment opening; and

releasing the grasping aid and withdrawing the tool back through the attachment opening to deploy the elongate member transversely on an outside of the liner.

82. An attachment element for attaching a device through an attachment opening formed in a wall, the attachment element comprising:

an elongate member configured to be passed longitudinally through the attachment opening, the elongate member configured to be deployed transversely on an opposite side of the wall;

a tension element having a proximal portion coupled to the device, the tension element having a distal portion flexibly coupled to a central portion of the elongate member; and

a grasping aid coupled to or near at least one end of the elongate member, the grasping aid capable of being passed through the attachment opening.

83. The attachment element of claim 82, wherein the tension element includes a suture.

84. The attachment element of claim 82, wherein the grasping aid includes a length of suture.

85. The attachment element of claim 82, wherein the grasping aid includes a loop of suture.

86. The attachment element of claim 82, wherein the grasping aid is substantially flexible.

87. The attachment element of claim 82, wherein the grasping aid is flexibly coupled to the elongate member.

88. The attachment element of claim 82, wherein the grasping aid is substantially rigid.

89. The attachment element of claim 82, wherein the grasping aid is rigidly coupled to the elongate member.

90. The attachment element of claim 82, wherein the attachment opening is formed in a mating device.

91. The attachment element of claim 82, wherein the attachment opening is formed in a tissue wall.

92. A method for attaching a device through an attachment opening formed in a wall, the method comprising:

providing the attachment element of claim 82;

grasping the grasping aid;

passing the grasping aid through the attachment opening;

passing the elongate member longitudinally through the attachment opening; and

releasing the grasping aid to deploy the elongate member transversely on an opposite side of the wall.

93. A method for attaching a device through an attachment opening formed in a wall, the method comprising:

providing the attachment element of claim 82;

using a tool to grasp the grasping aid;

advancing the tool through the attachment opening to pass the grasping aid through the attachment opening;

continuing to advance the tool through the attachment opening to pass the elongate member longitudinally through the attachment opening; and

releasing the grasping aid and withdrawing the tool back through the attachment opening to deploy the elongate member transversely on an opposite side of the wall.

94. A tissue anchor, comprising:

a proximal retention element;

a distal retention element having a hub and a plurality of petals extending from a distal end of the hub, each of the petals having a tissue contact portion, the distal retention element having a collapsed configuration for delivery inside a hollow needle and an expanded configuration wherein each of the tissue contact portions is substantially perpendicular to a longitudinal axis of the hub and proximal to a proximal end of the hub; and

a tension element having a proximal portion coupled to the proximal retention element, the tension element having a distal portion coupled to the hub of the distal retention element.

95. The tissue anchor of claim 94, wherein the tissue contact portions extend outward away from the longitudinal axis of the hub.

96 The tissue anchor of claim 94, wherein the tissue contact portions extend inward toward the longitudinal axis of the hub.

97. The tissue anchor of claim 94, wherein the hub and the petals are formed from a single piece of material.

98. The tissue anchor of claim 94, wherein the hub and the petals are laser cut from a single piece of material.

99. The tissue anchor of claim 94, wherein the hub and the petals are formed from separate pieces of material.

100. The tissue anchor of claim 94, wherein the petals are formed from open loops of wire.

101. The tissue anchor of claim 94, wherein the petals are set into a desired shape.

102. The tissue anchor of claim 94, wherein each of the petals includes a connecting portion coupling the hub to the tissue contact portion.

103. The tissue anchor of claim 102, wherein the connecting portion includes a first curved portion coupled to the hub and a second curved portion coupled to the tissue contact portion.

104. The tissue anchor of claim 103, wherein the first curved portion extends from the distal end of the hub substantially parallel to the longitudinal axis of the hub.

105. The tissue anchor of claim 103, wherein the first curved portion curves approximately 135 to 180 degrees away from the longitudinal axis of the hub.

106. The tissue anchor of claim 105, wherein the second curved portion curves approximately 45 to 90 degrees away from the longitudinal axis of the hub.

107. The tissue anchor of claim 103, wherein the first curved portion curves approximately 60 to 120 degrees away from the longitudinal axis of the hub.

108. The tissue anchor of claim 107, wherein the second curved portion curves approximately 150 to 210 degrees proximally toward the longitudinal axis of the hub.

109. The tissue anchor of claim 72, wherein the distal retention element includes a distal portion that is rounded.

110. The tissue anchor of claim 72, wherein the distal retention element includes a distal portion that is substantially flat.

111. The tissue anchor of claim 72, wherein the distal retention element has a height of approximately 1mm to 5mm.

112. A method of treating a patient, the method comprising:

providing a gastrointestinal bypass device including a gastrointestinal cuff and a gastrointestinal sleeve, a distal portion of the gastrointestinal cuff being coupled to a proximal portion of the gastrointestinal sleeve;

delivering the gastrointestinal sleeve to position a distal portion of the gastrointestinal sleeve in an intestine of the patient;

positioning a proximal portion of the gastrointestinal cuff in an esophagus of the patient;

providing a tissue anchor including a tension element, a proximal retention element coupled to a proximal portion of the tension element, and a distal retention element coupled to a distal portion of the tension element, the proximal retention element

configured to be coupled to the gastrointestinal cuff, the distal retention element configured to be deployed on a distal side of a wall of the esophagus; and

delivering the distal retention element through the gastrointestinal cuff and through a wall of the esophagus at an attachment point to anchor the gastrointestinal cuff to the wall of the esophagus.

113. The method of claim 112, wherein the attachment point is in the esophagus approximately 5 mm to approximately 25 mm above an opening of a stomach of the patient.

114. The method of claim 112, wherein the attachment point is in the esophagus approximately 0 mm to approximately 20 mm above a squamocolumnar junction of the patient.

115. The method of claim 112, wherein the attachment point is in the esophagus approximately 20 mm below to approximately 50 mm above a diaphragm of the patient.

116. The method of claim 112, wherein the attachment point is in the esophagus at a proximal portion of a lower esophageal sphincter of the patient.

117. A method of treating a patient, the method comprising:

delivering a gastrointestinal sleeve to position at least a distal portion of the gastrointestinal sleeve in an intestine of the patient;

positioning at least a portion of gastrointestinal cuff in an esophagus of the patient, a distal portion of the gastrointestinal cuff being coupled to a proximal portion of the gastrointestinal sleeve; and

delivering a tissue anchor through the gastrointestinal cuff and through a wall of the esophagus at an attachment point to anchor the gastrointestinal cuff to the wall of the esophagus.

118. The method of claim 117, wherein the attachment point is in the esophagus approximately 5 mm to approximately 25 mm above an opening of a stomach of the patient.

119. The method of claim 117, wherein the attachment point is in the esophagus approximately 0 mm to approximately 20 mm above a squamocolumnar junction of the patient.

120. The method of claim 117, wherein the attachment point is in the esophagus approximately 20 mm below to approximately 50 mm above a diaphragm of the patient.

121. The method of claim 117, wherein the attachment point is in the esophagus at a proximal portion of a lower esophageal sphincter of the patient.

122. A method of treating a patient, the method comprising:

providing a gastrointestinal cuff configured to be anchored in an esophagus of the patient, the gastrointestinal cuff including a plurality of anchor holes; and

anchoring the gastrointestinal cuff in the esophagus of a patient by delivering one or more tissue anchors through the anchor holes and through a wall of the esophagus at an attachment point.

123. The method of claim 122, wherein the attachment point is in the esophagus approximately 5 mm to approximately 25 mm above an opening of a stomach of the patient.

124. The method of claim 122, wherein the attachment point is in the esophagus approximately 0 mm to approximately 20 mm above a squamocolumnar junction of the patient.

125. The method of claim 122, wherein the attachment point is in the esophagus approximately 20 mm below to approximately 50 mm above a diaphragm of the patient.

126. The method of claim 122, wherein the attachment point is in the esophagus at a proximal portion of a lower esophageal sphincter of the patient.

127. A tissue anchor comprising:

a tension element;

a proximal retention element coupled to a proximal portion of the tension element;

a distal retention element coupled to a distal portion of the tension element, the distal retention element configured to be deployed on a distal side of a tissue wall; and

a tissue ingrowth element coupled to the distal retention element, the tissue ingrowth element configured to allow ingrowth from at least a portion of tissue surrounding the distal retention element.

128. The tissue anchor of claim 127, wherein the tissue ingrowth element includes a cover at least partially covering a proximal side of the distal retention element.

129. The tissue anchor of claim 127, wherein the tissue ingrowth element includes a cover at least partially covering a distal side of the distal retention element.

130. The tissue anchor of claim 127, wherein the tissue ingrowth element includes a cover at least partially covering a proximal side and a distal side of the distal retention element.

131. The tissue anchor of claim 127, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes one or more covers at least partially covering a proximal side of one or more of the petals.

132. The tissue anchor of claim 127, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes one or more covers at least partially covering a distal side of one or more of the petals.

133. The tissue anchor of claim 127, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes one or more covers at least partially covering a proximal side and a distal side of one or more of the petals.

134. The tissue anchor of claim 127, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes webbing formed at least partially in an open area of one or more of the petals.

135. The tissue anchor of claim 127, wherein the distal retention element includes a T tag, and wherein the tissue ingrowth element includes a cover at least partially covering the T-tag.

136. The tissue anchor of claim 127, wherein the distal retention element includes a frame or structure, and wherein the tissue ingrowth element includes a cover at least partially covering the frame or structure.

137. A method for using a tissue anchor, the method comprising:

providing a tissue anchor having a tension element, a proximal retention element coupled to a proximal portion of the tension element, a distal retention element coupled to a distal portion of the tension element, and a tissue ingrowth element coupled to the distal retention element;

deploying the distal retention element on a distal side of a tissue wall;

passing the tension element through the tissue wall;

deploying the proximal retention element on a proximal side of the tissue wall;

allowing a tissue surrounding the distal retention element to at least partially grow into the tissue ingrowth element.

138. The method of claim 137, further comprising:

coupling a device to the proximal retention element after the tissue has at least partially grown into the tissue ingrowth element.

139. The method of claim 137, wherein the tissue ingrowth element includes a cover at least partially covering a proximal side of the distal retention element.

140. The method of claim 137, wherein the tissue ingrowth element includes a cover at least partially covering a distal side of the distal retention element.

141. The method of claim 137, wherein the tissue ingrowth element includes a cover at least partially covering a proximal side and a distal side of the distal retention element.

142. The method of claim 137, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes one or more covers at least partially covering a proximal side of one or more of the petals.

143. The method of claim 137, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes one or more covers at least partially covering a distal side of one or more of the petals.

144. The method of claim 137, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes one or more covers at least partially covering a proximal side and a distal side of one or more of the petals.

145. The method of claim 137, wherein the distal retention element includes a plurality of petals, and wherein the tissue ingrowth element includes webbing formed at least partially in an open area of one or more of the petals.

146. The method of claim 137, wherein the distal retention element includes a T tag, and wherein the tissue ingrowth element includes a cover at least partially covering the T-tag.

147. The method of claim 137, wherein the distal retention element includes a frame or structure, and wherein the tissue ingrowth element includes a cover at least partially covering the frame or structure.

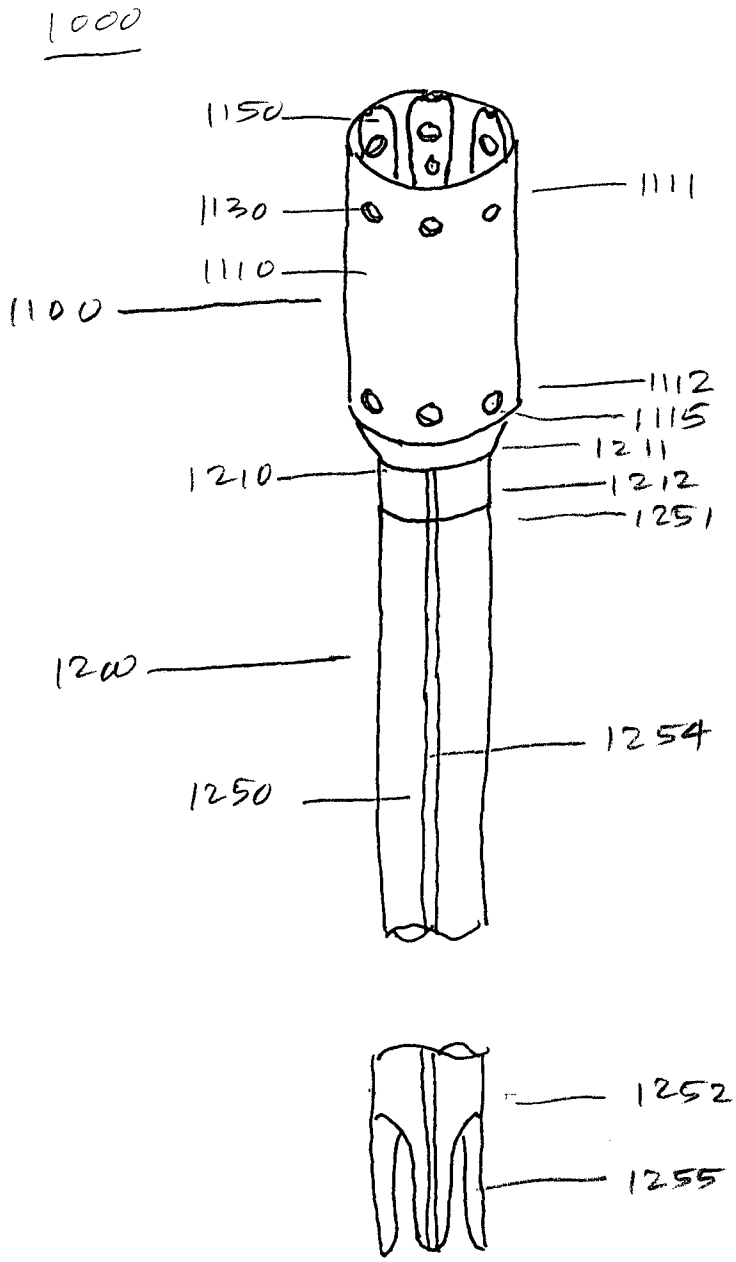
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FIG. 1A

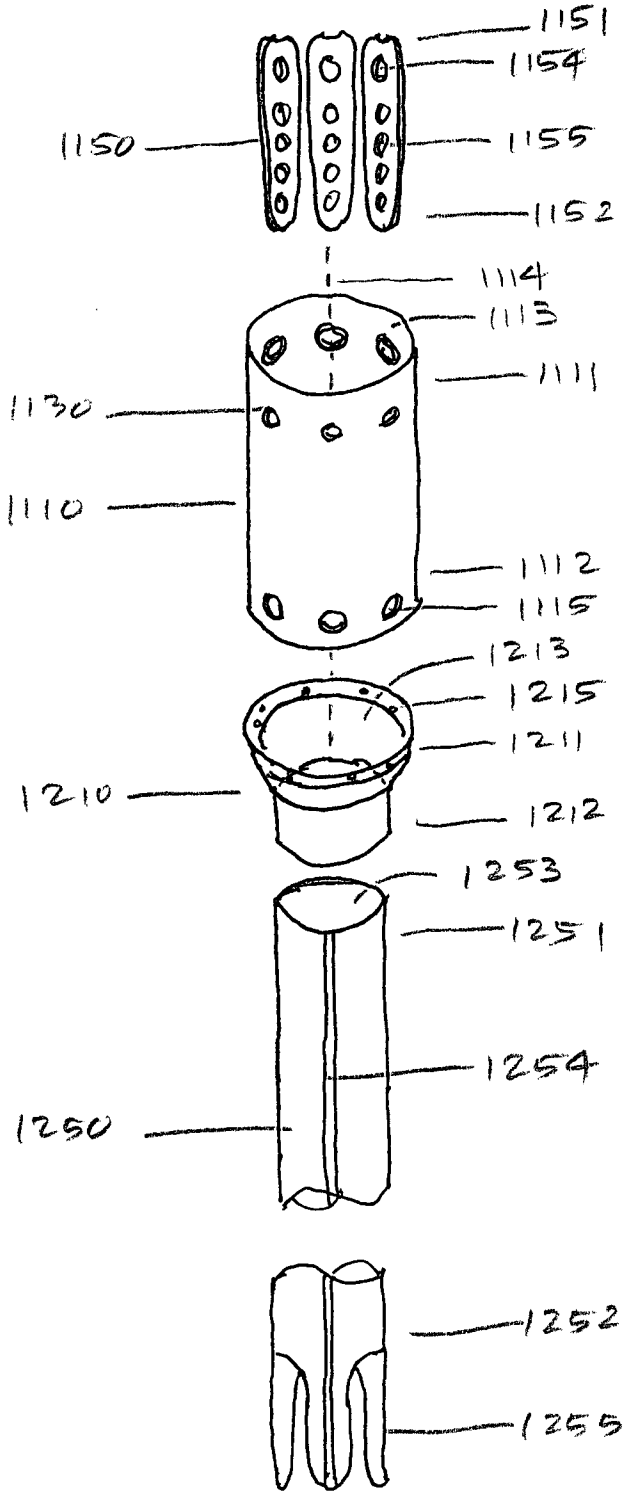
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FIG. 1B

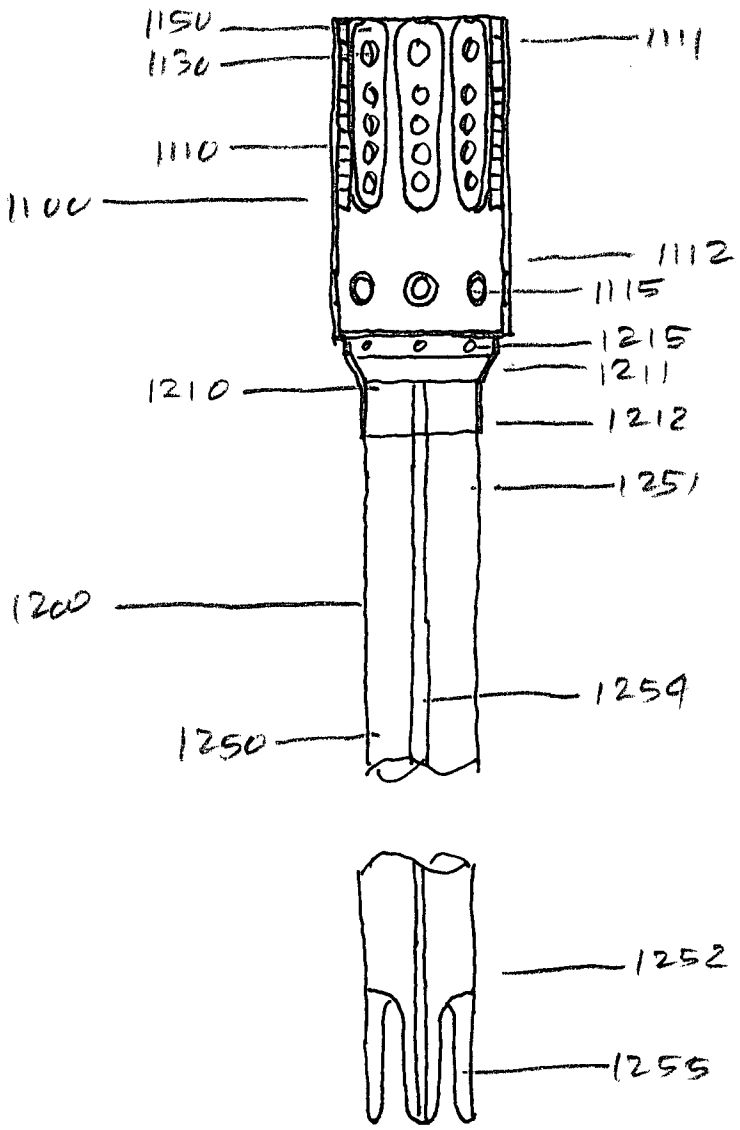
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FIG. 1C

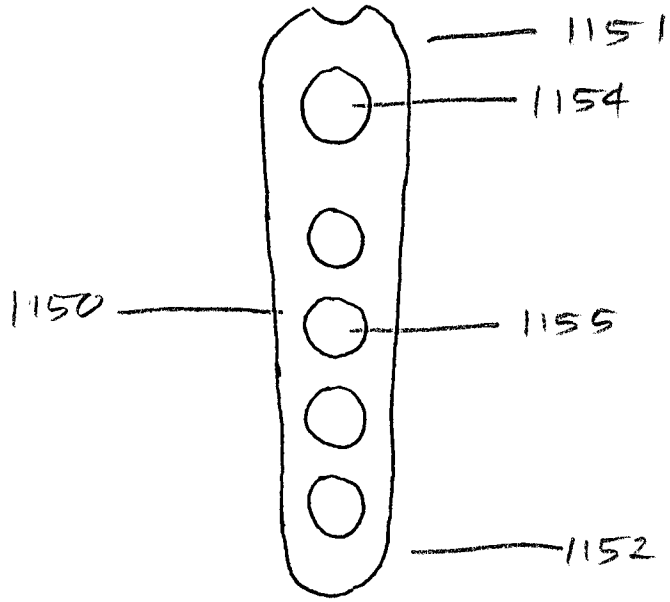

FIG. 1D

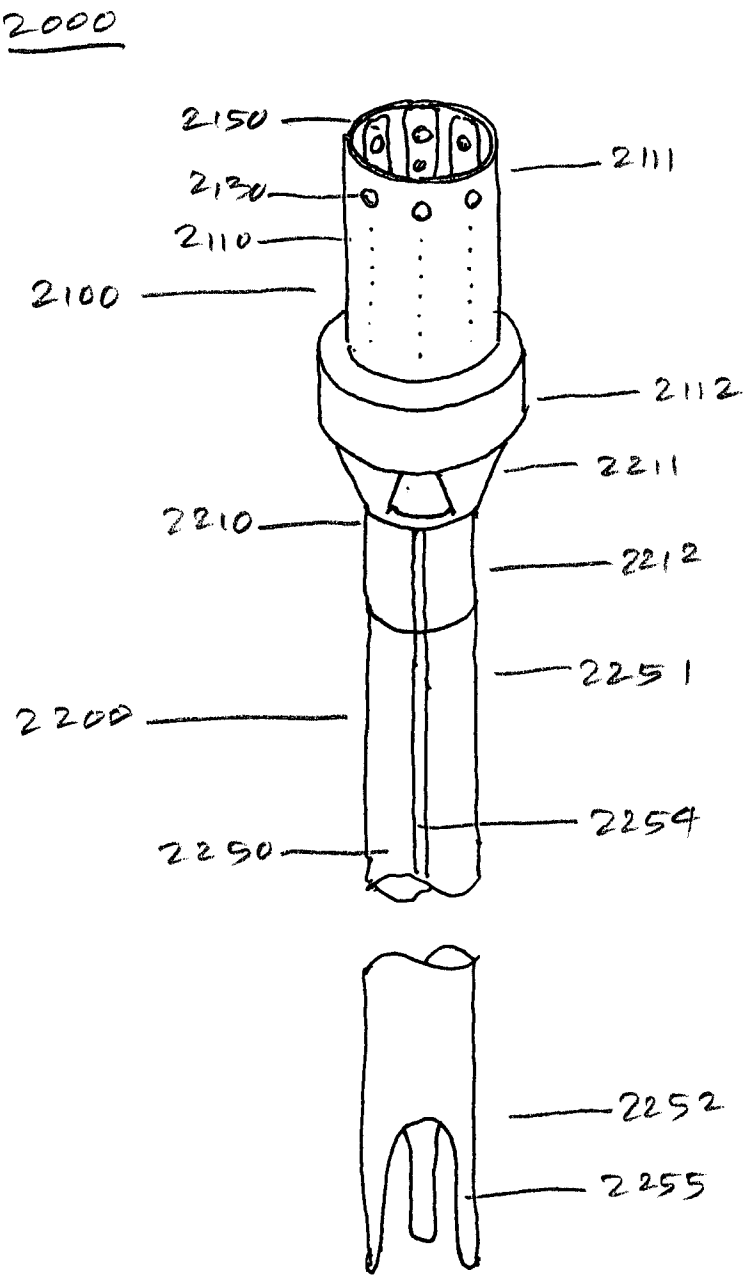
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FIG. 2A

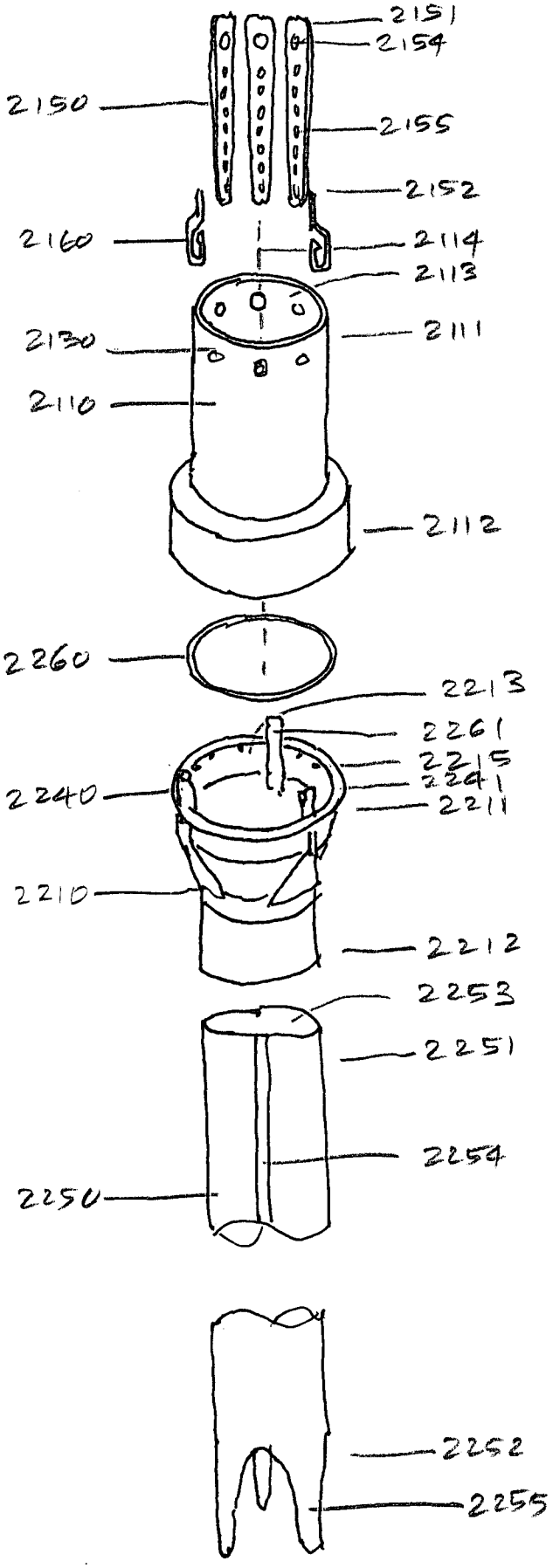
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FIG. 2B

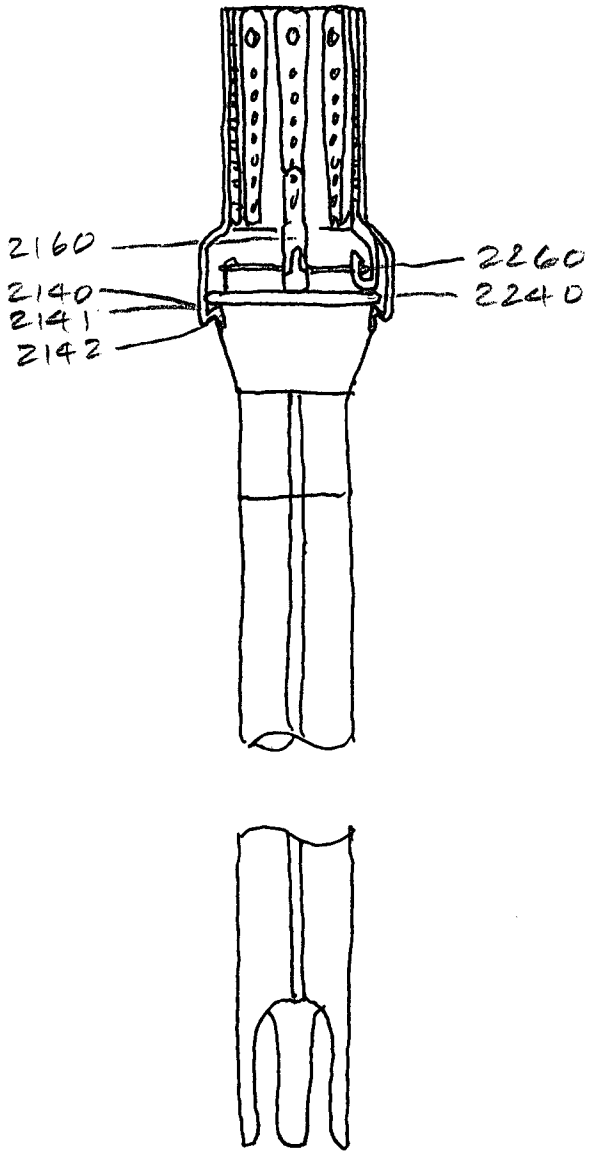

FIG. 2C

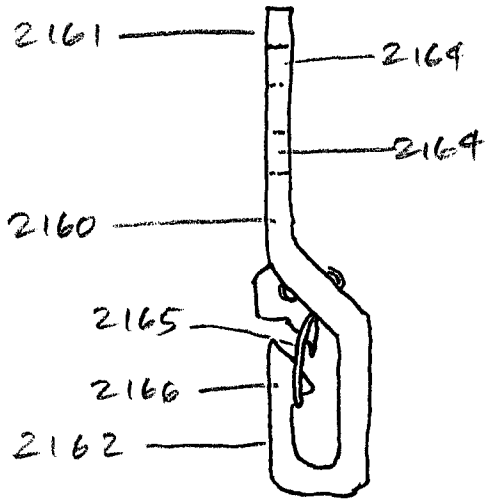

FIG. 2D

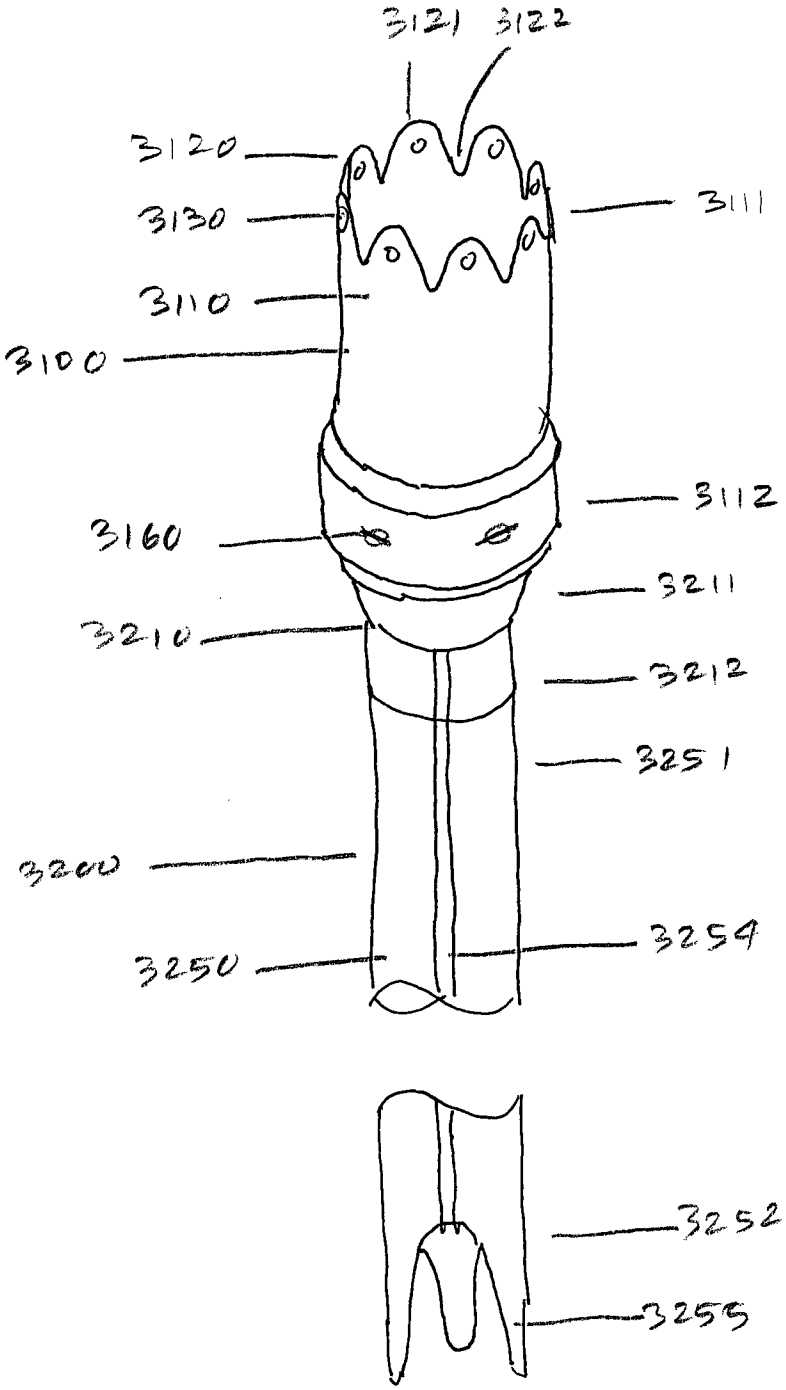
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FIG. 3A

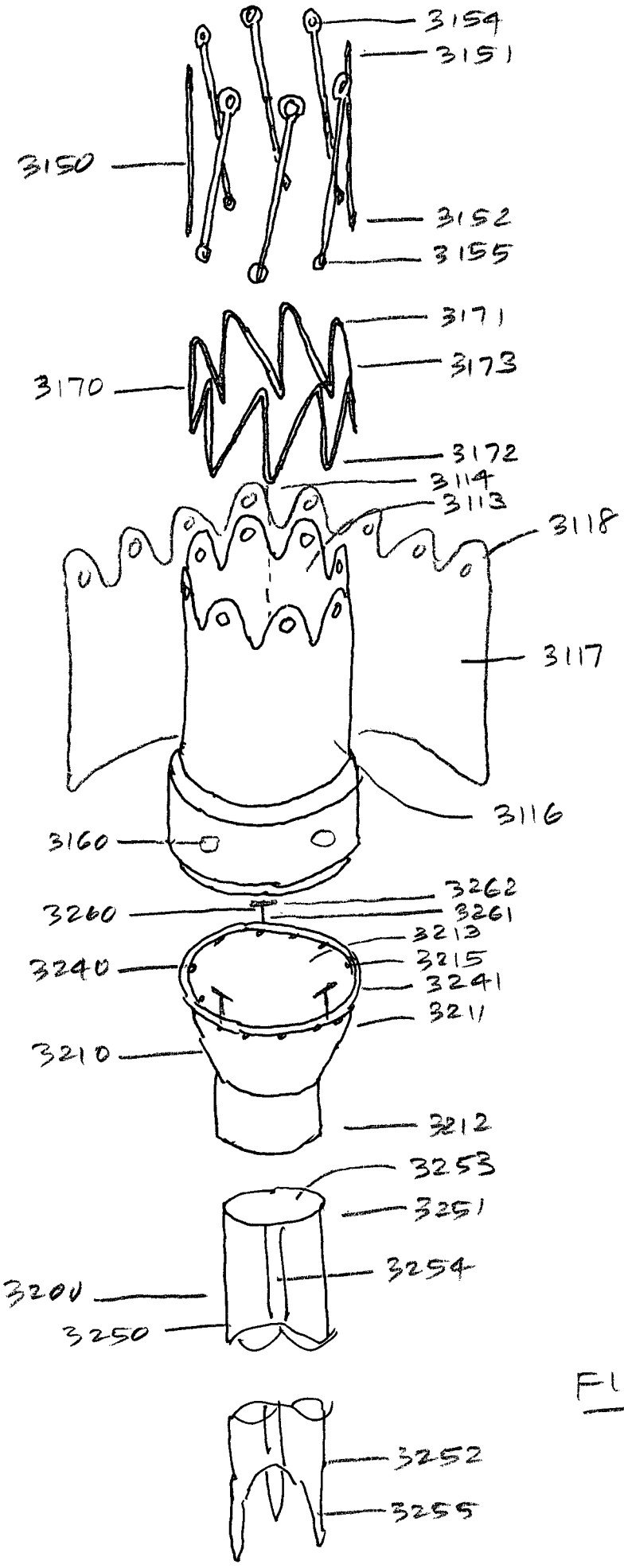
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FIG 3B

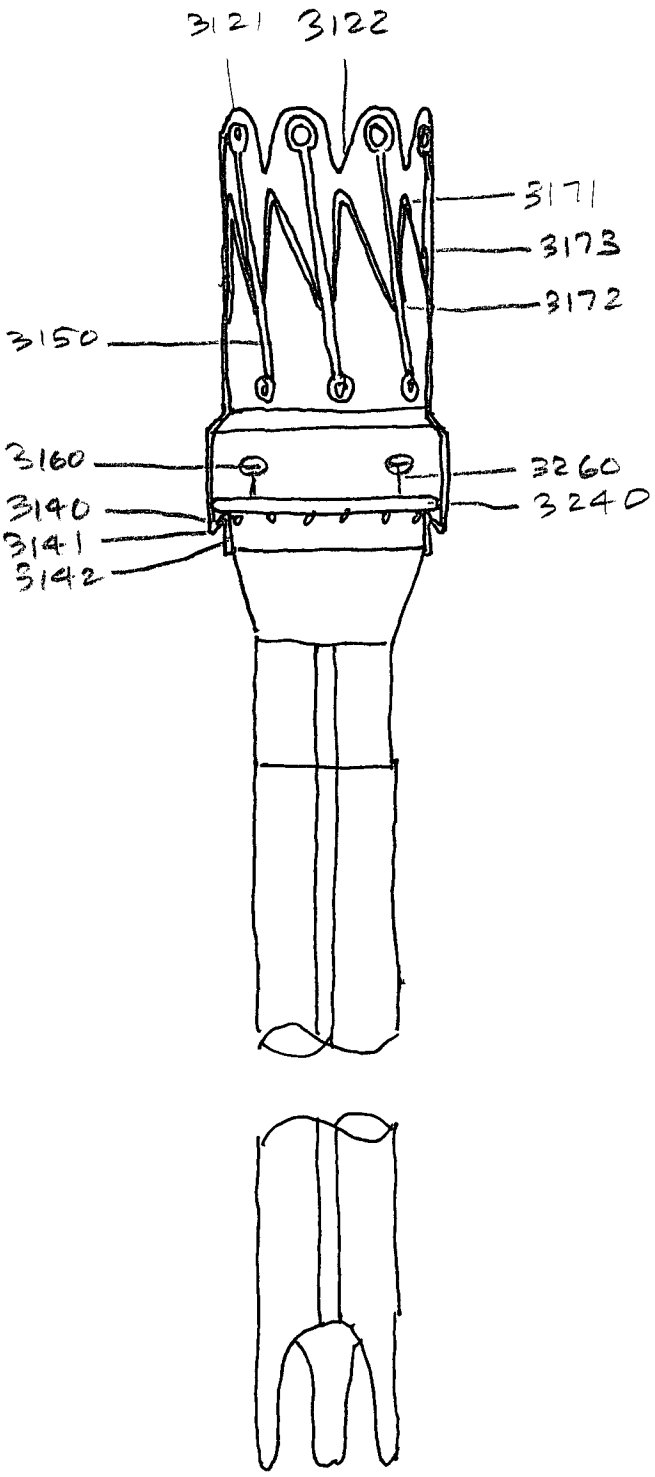

FIG. 3C

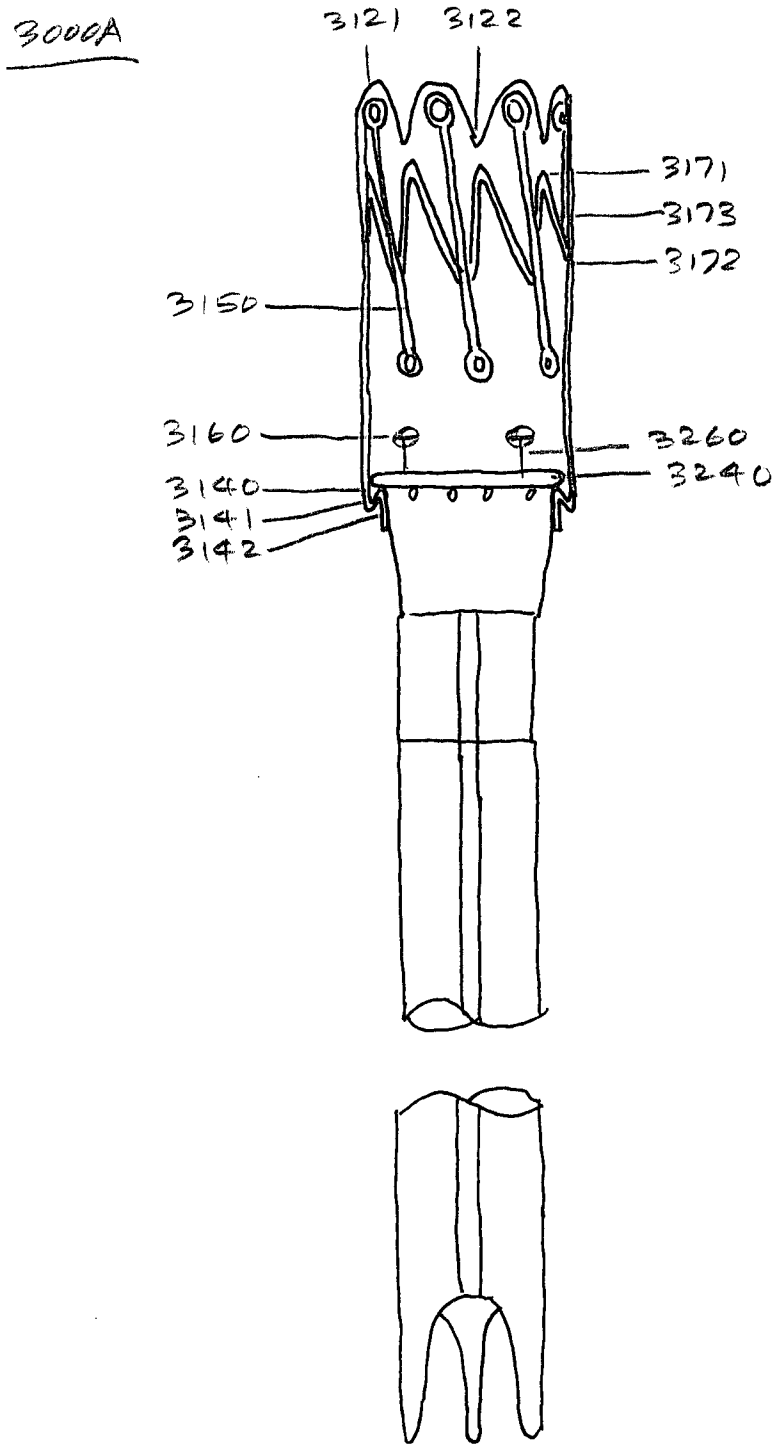
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FIG. 3D

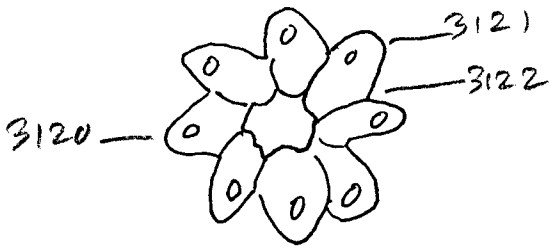

FIG. 3E

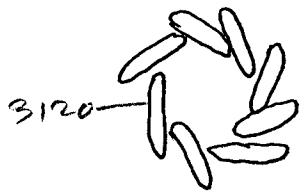

FIG. 3F

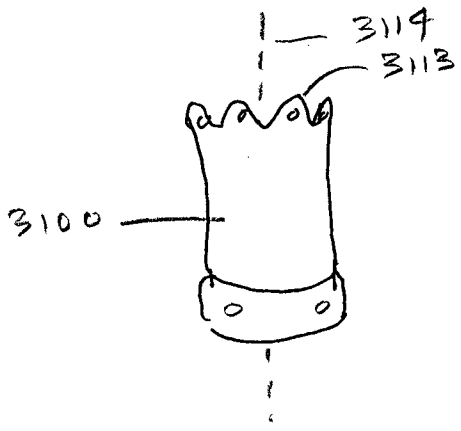

FIG. 3I

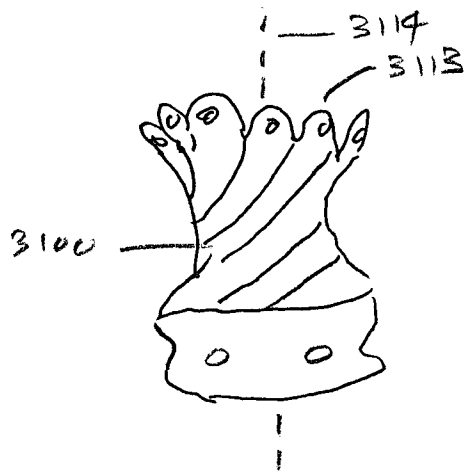

FIG. 3J

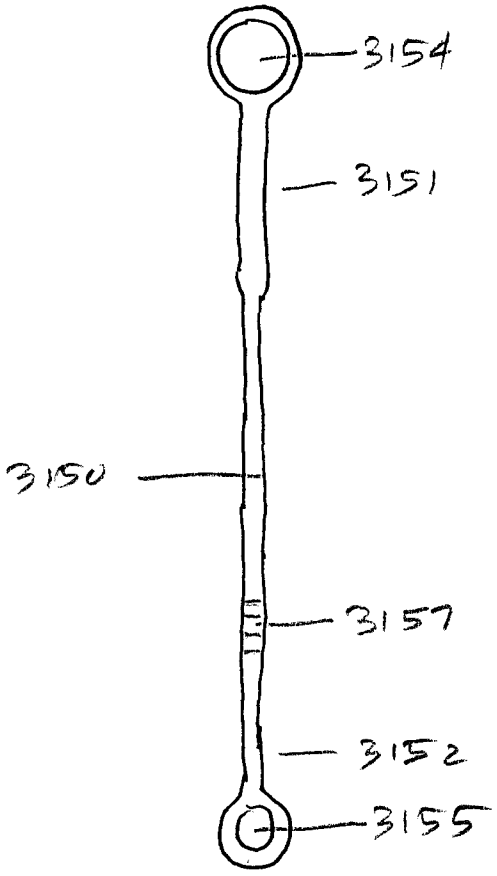

FIG. 3G

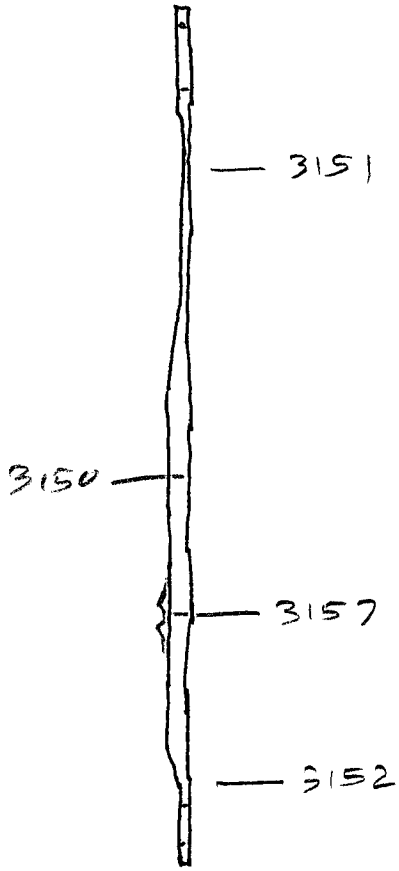

FIG. 3H

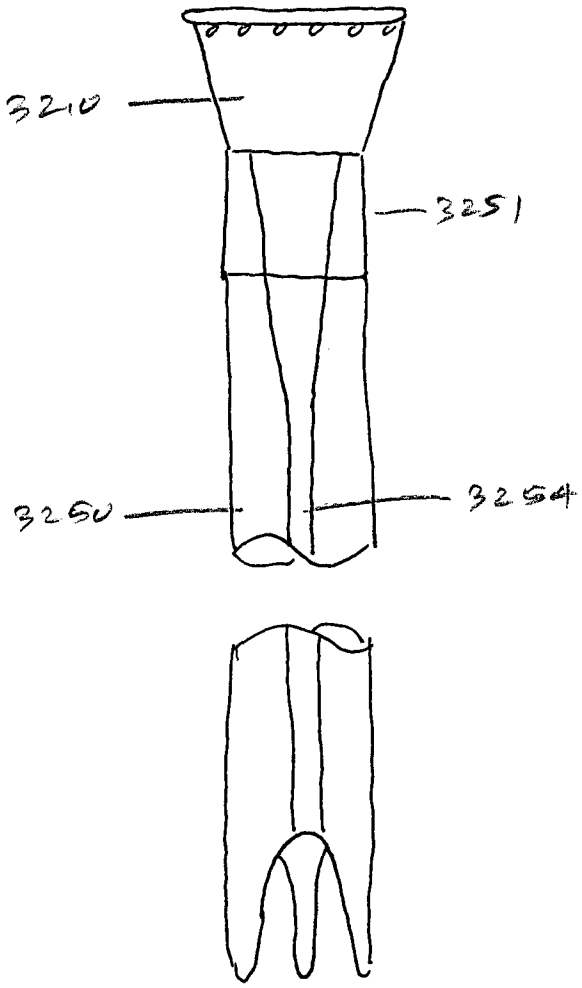

FIG. 3K

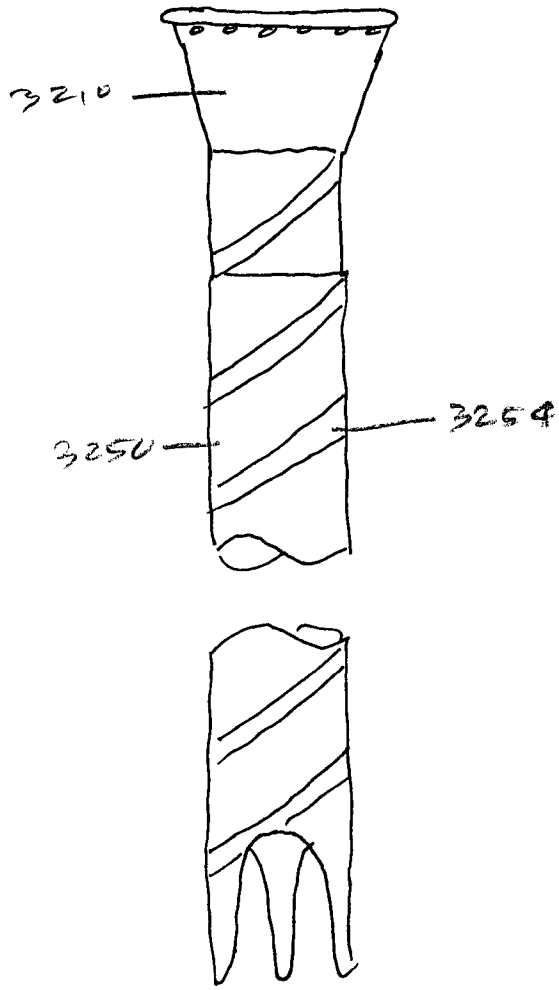

FIG. 3L

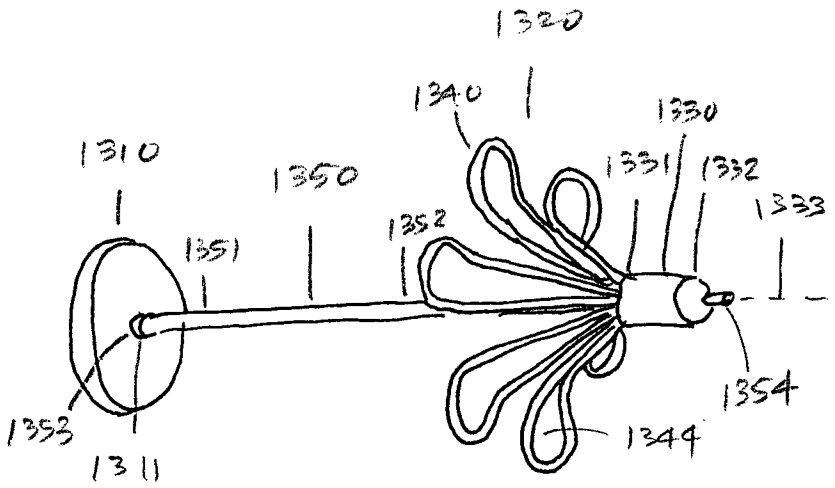
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FIG. 4A

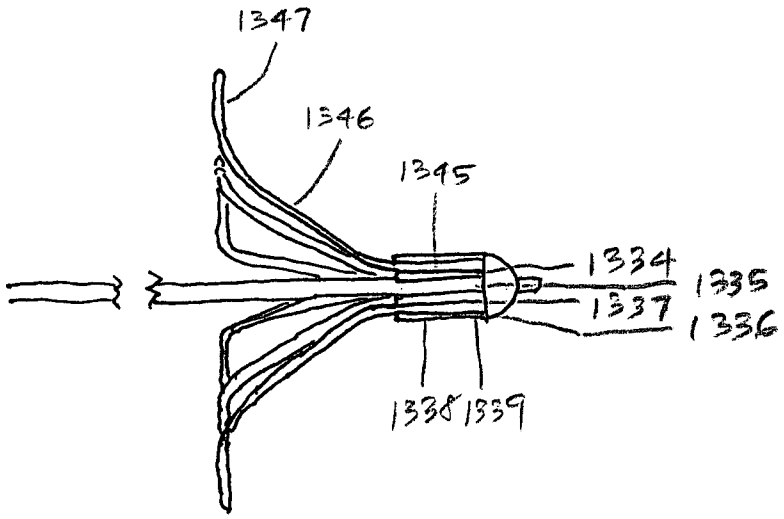
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FIG. 4B

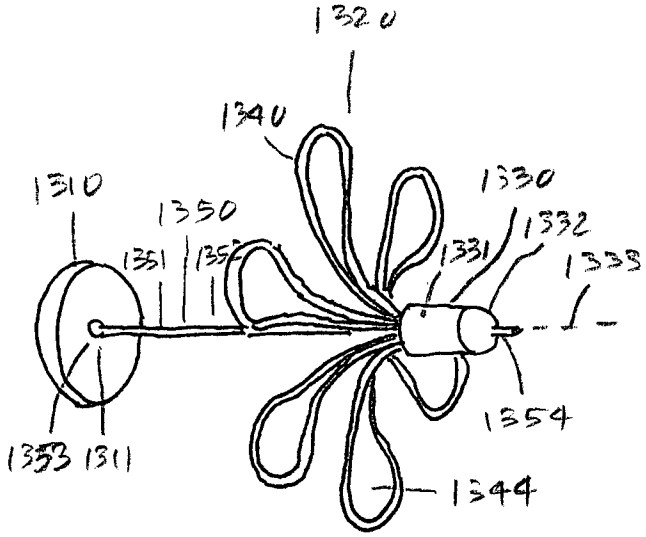
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FIG. 4C

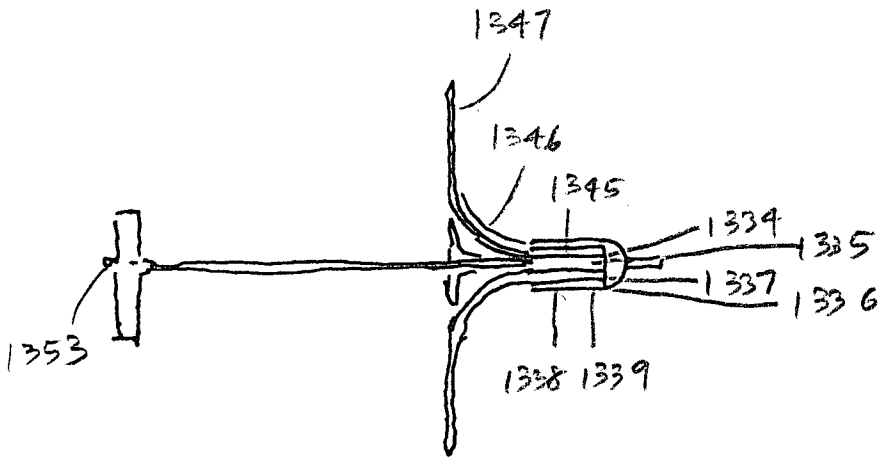
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FIG. 4D

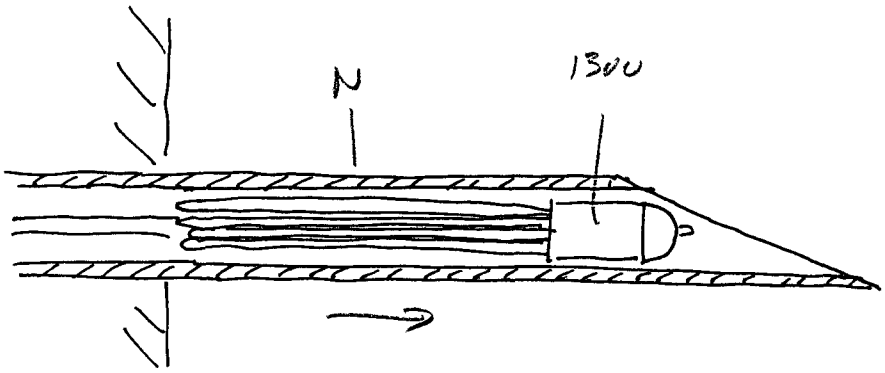

FIG 4E

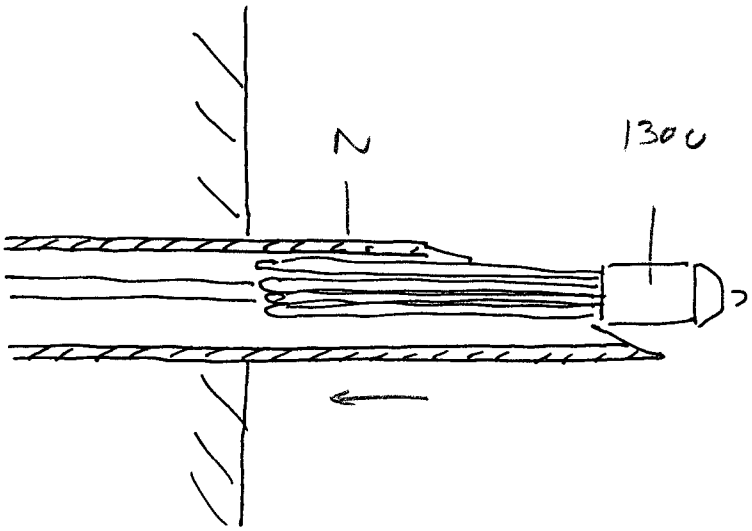

FIG. 4F

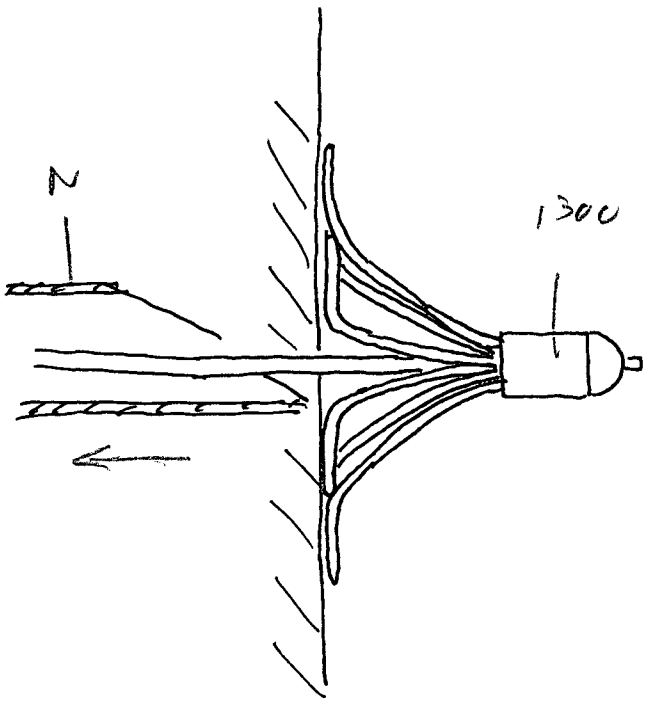

FIG. 4G

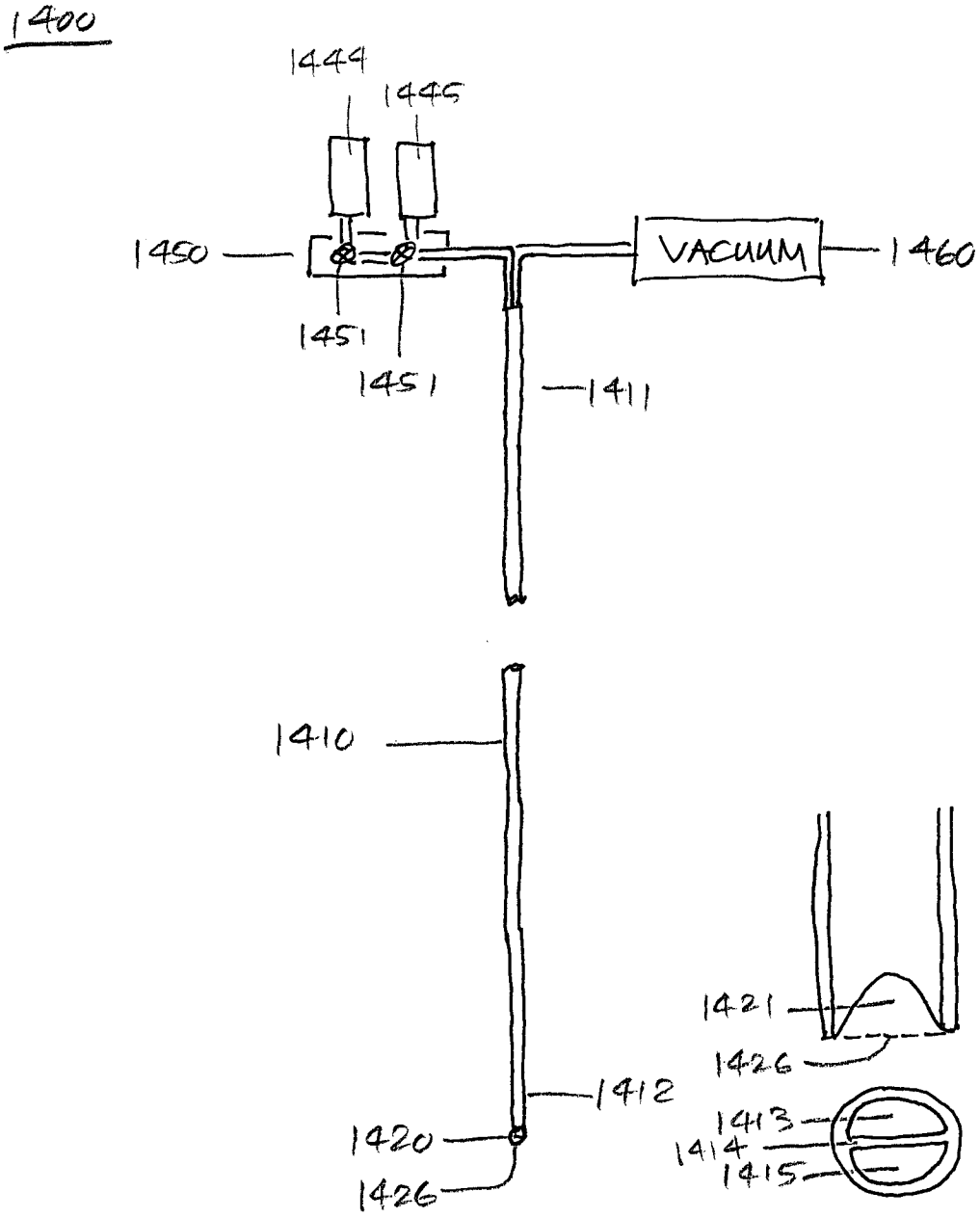

FIG. 5A

FIG. 5B

FIG. 5C

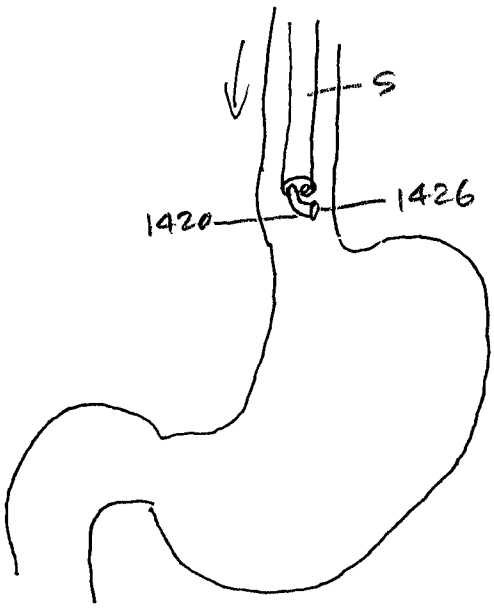

FIG. 6A

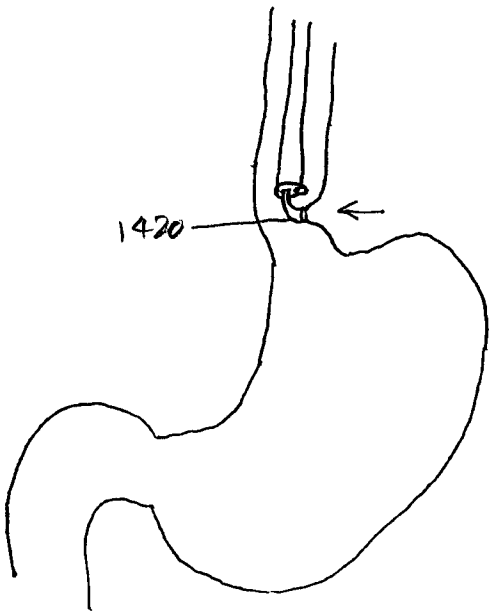

FIG. 6B

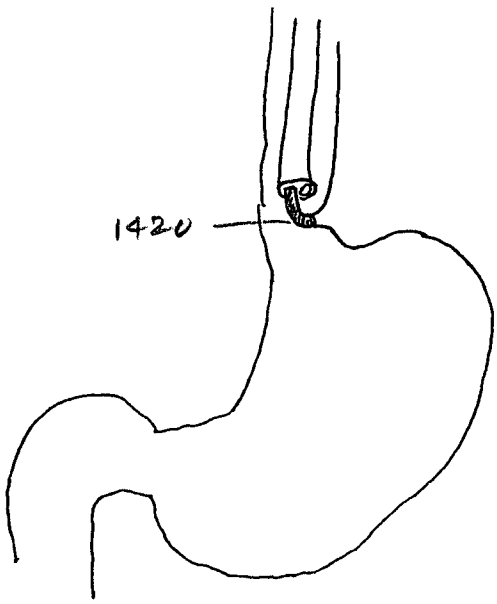

FIG. 6C

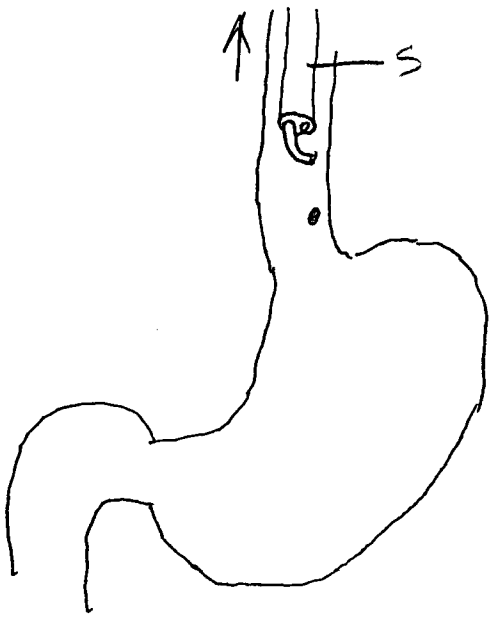

FIG. 6D

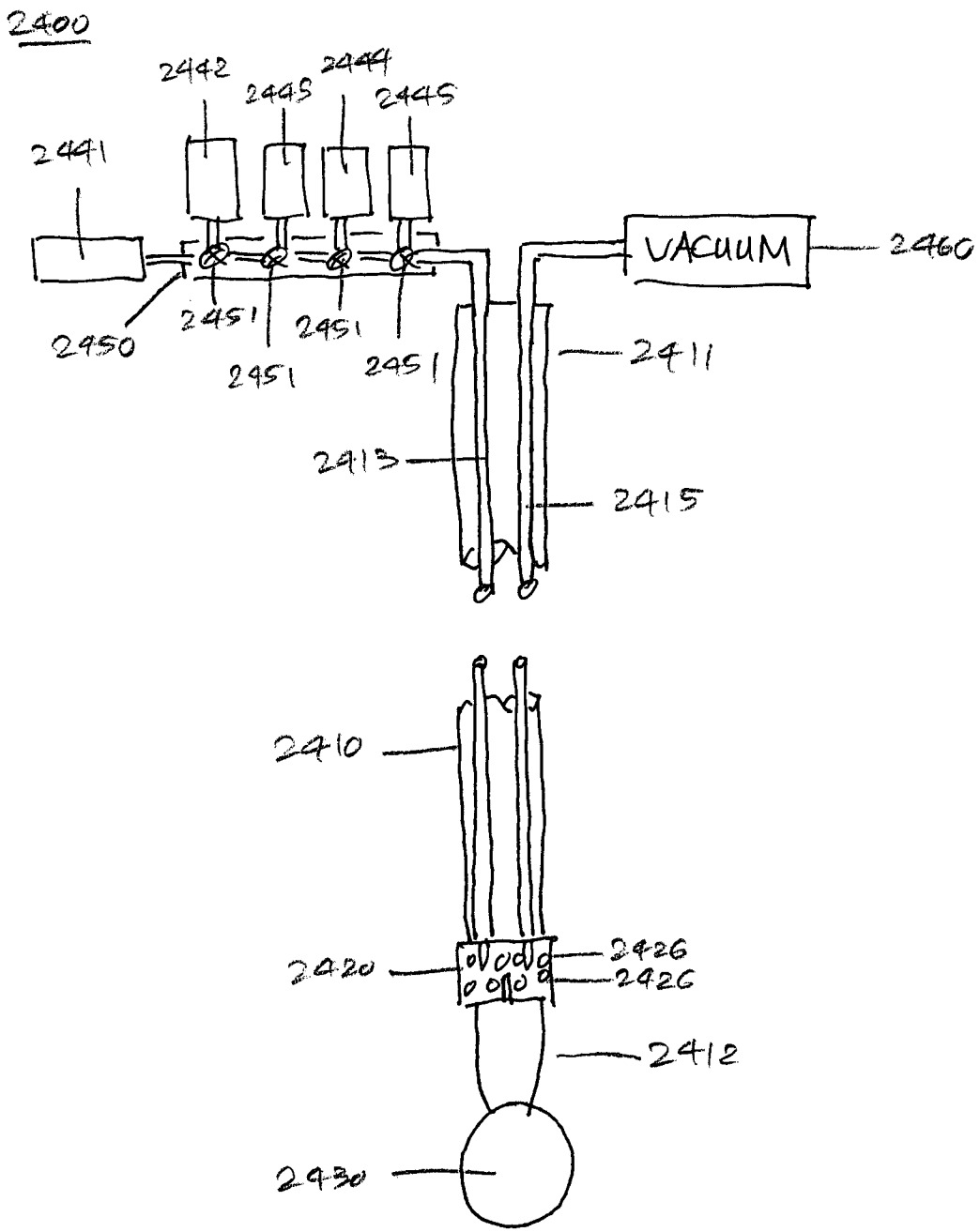
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FIG. 7A

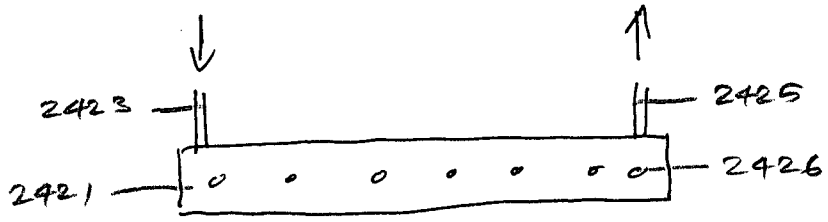


FIG. 7B

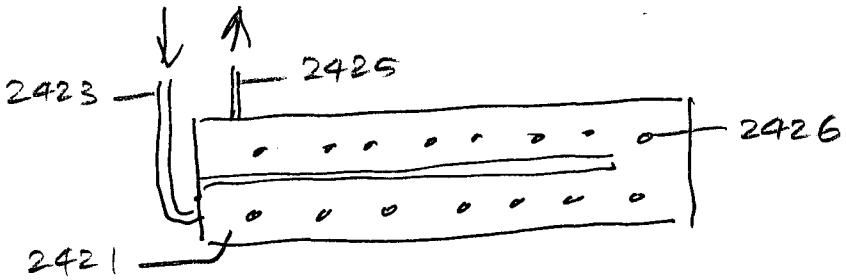


FIG. 7C

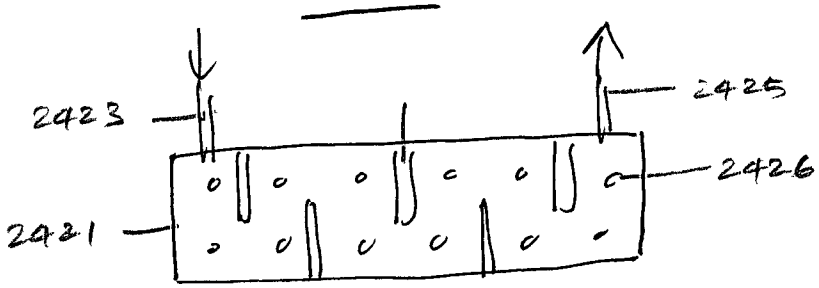


FIG. 7D

FIG. 7E

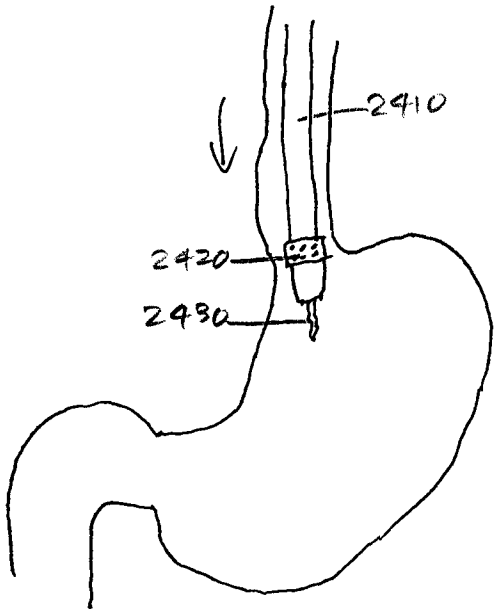


FIG. 8A

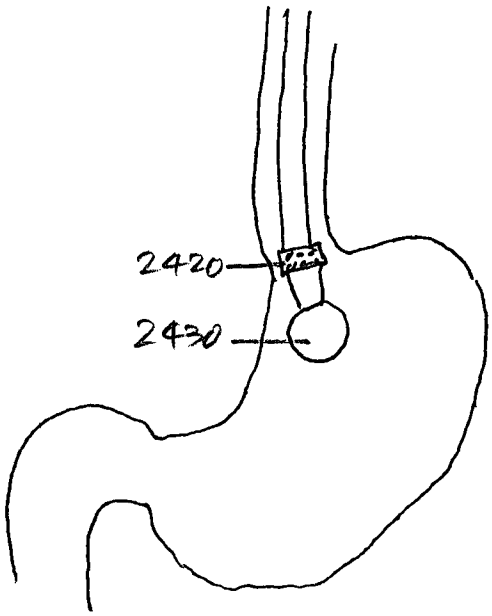


FIG. 8B

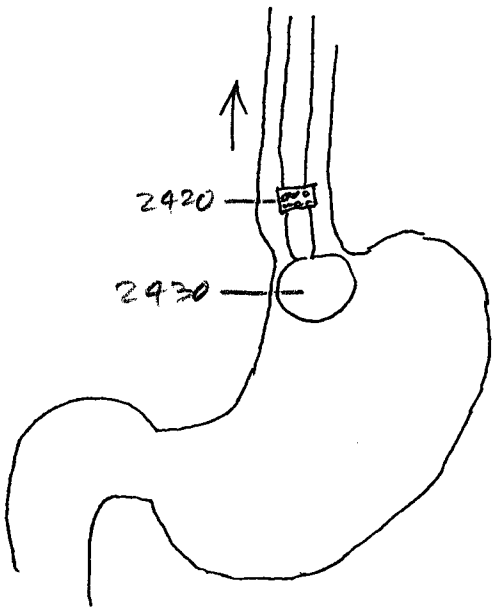


FIG. 8C

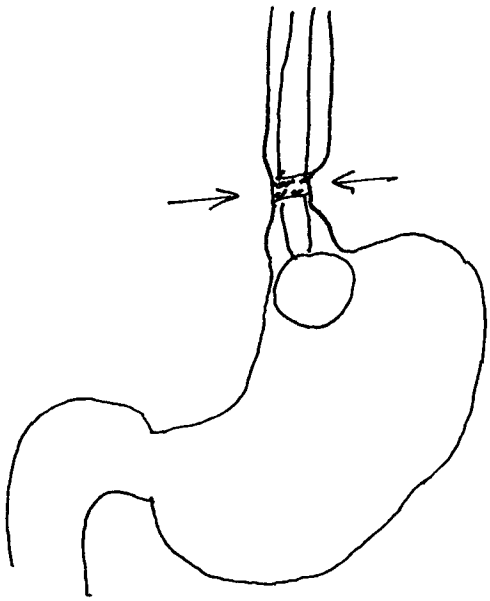


FIG. 8D

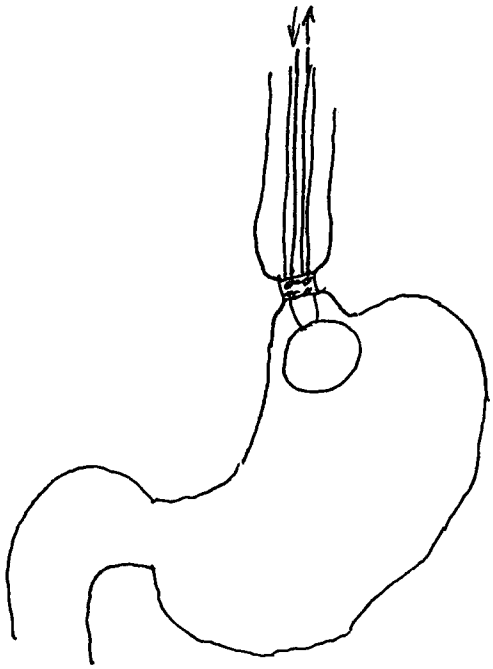


FIG. 8E

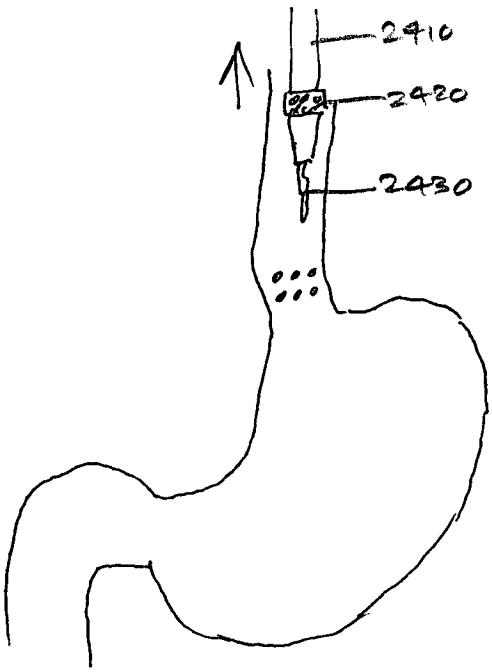


FIG. 8F

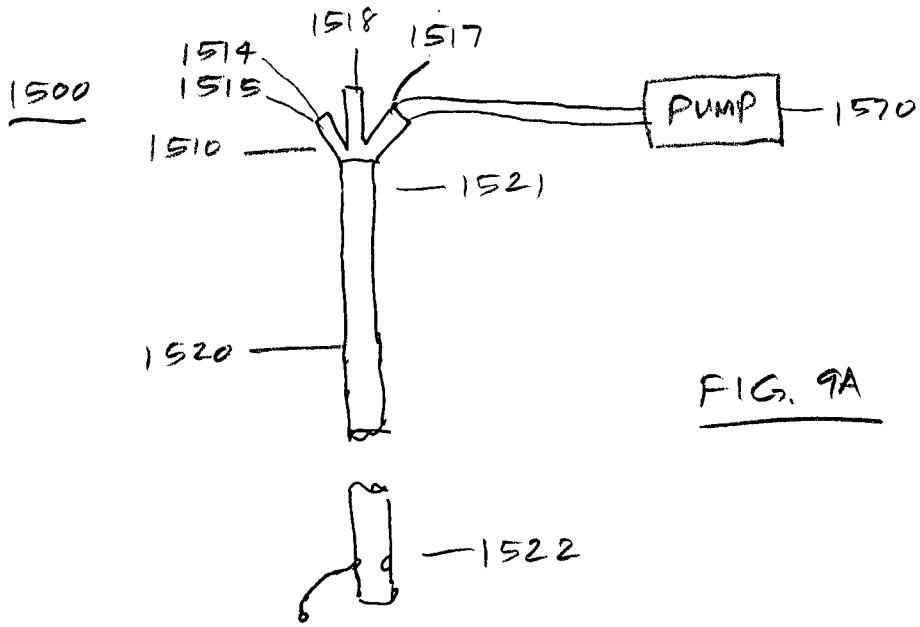


FIG. 9A

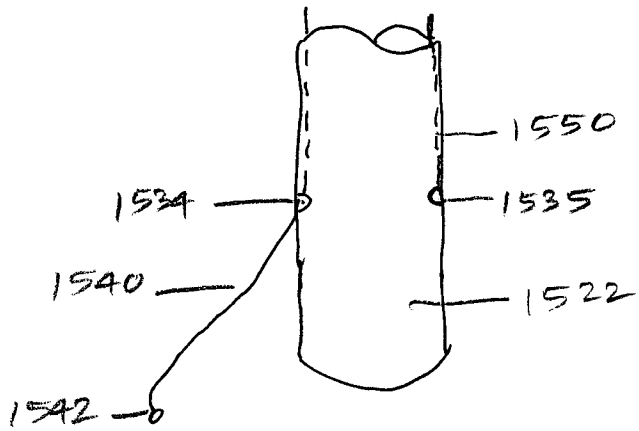


FIG. 9B

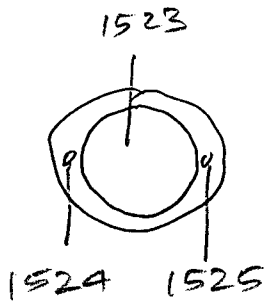


FIG. 9C

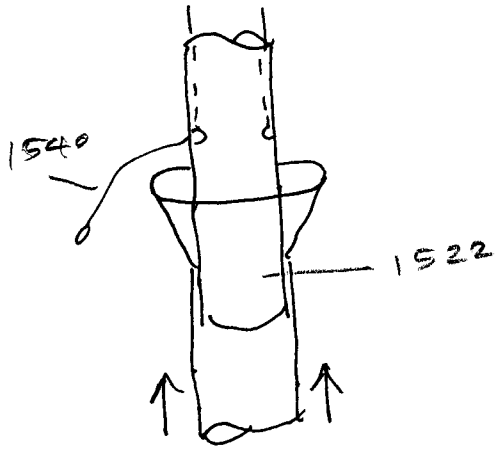


FIG. 9D

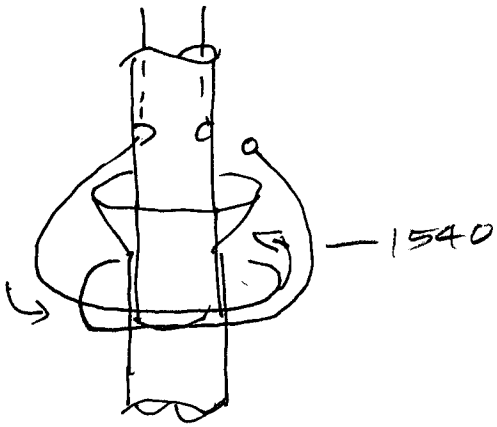


FIG. 9E

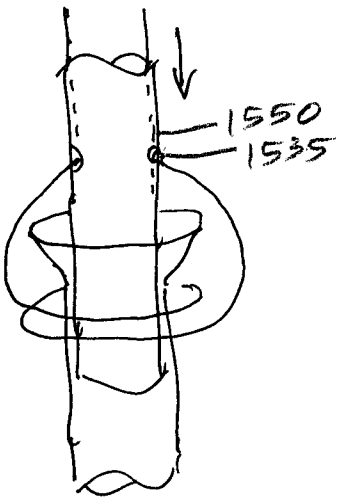


FIG. 9F

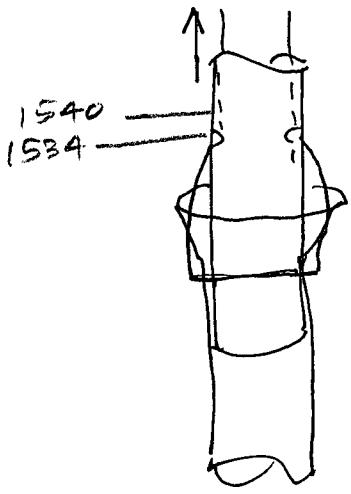


FIG. 9G

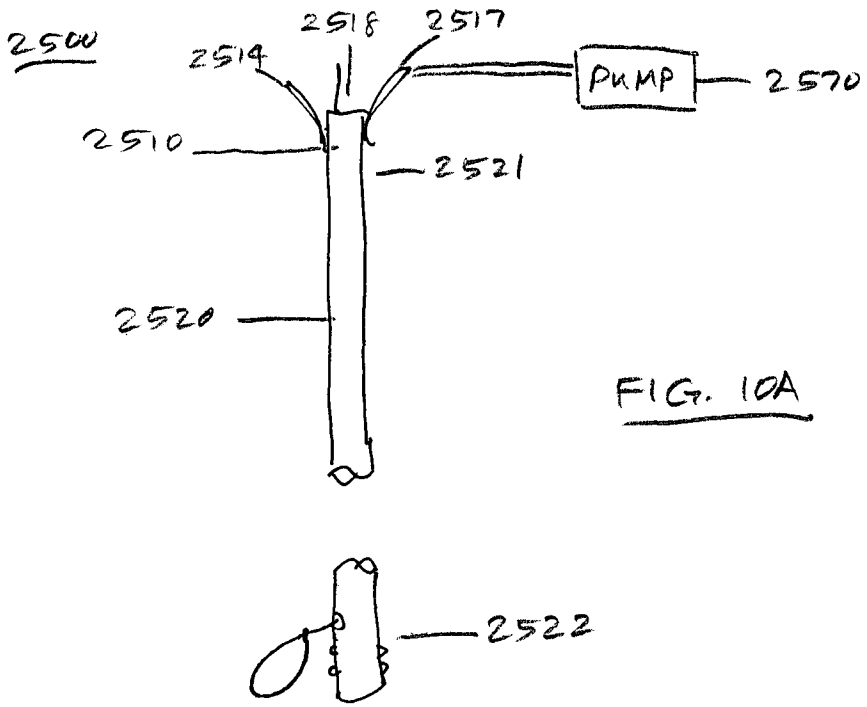


FIG. 10A

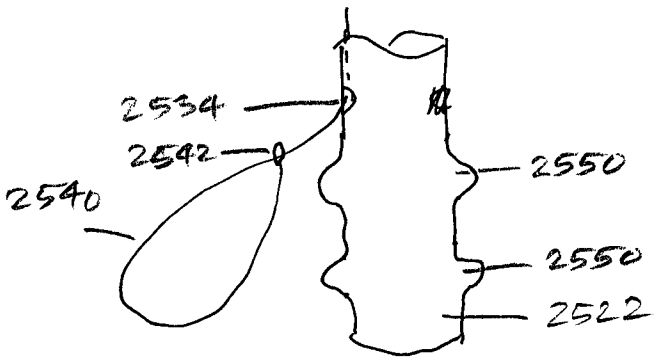


FIG. 10B

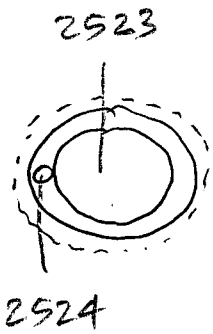


FIG. 10C

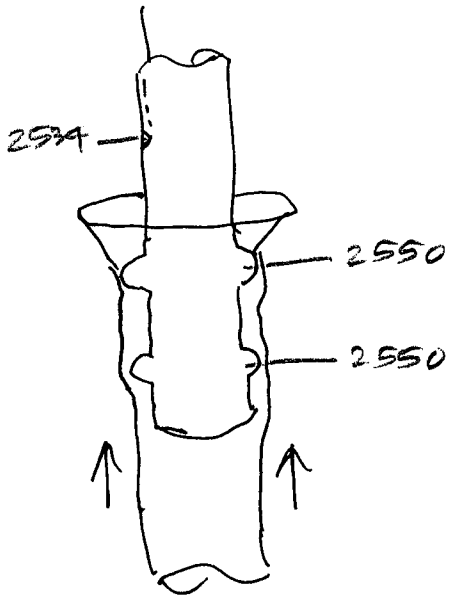


FIG. 10D

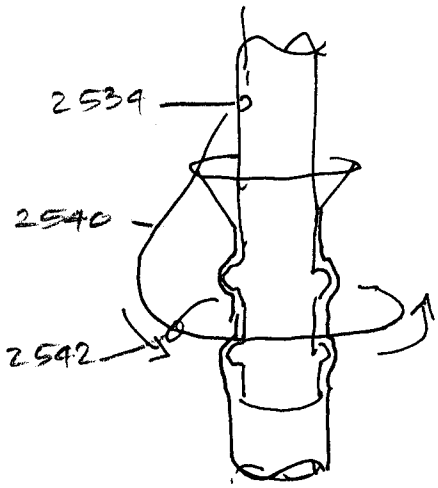


FIG. 10E

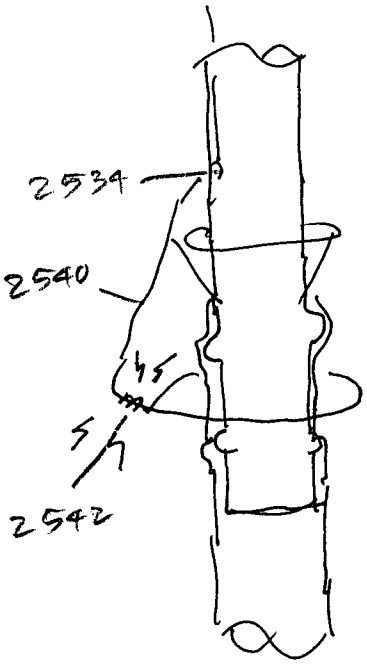


FIG. 10F

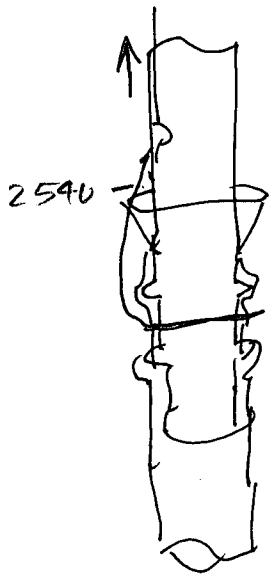


FIG. 10G

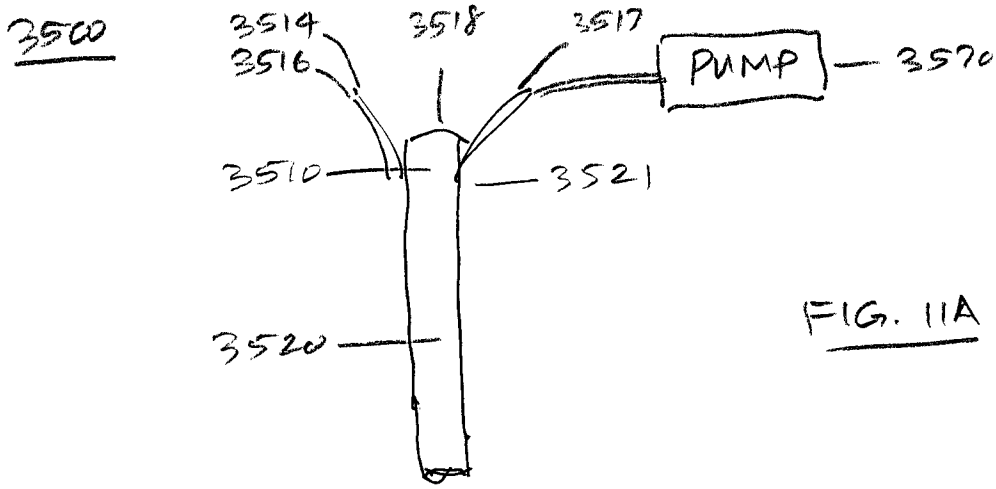
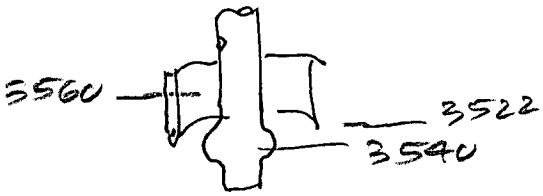


FIG. 11A



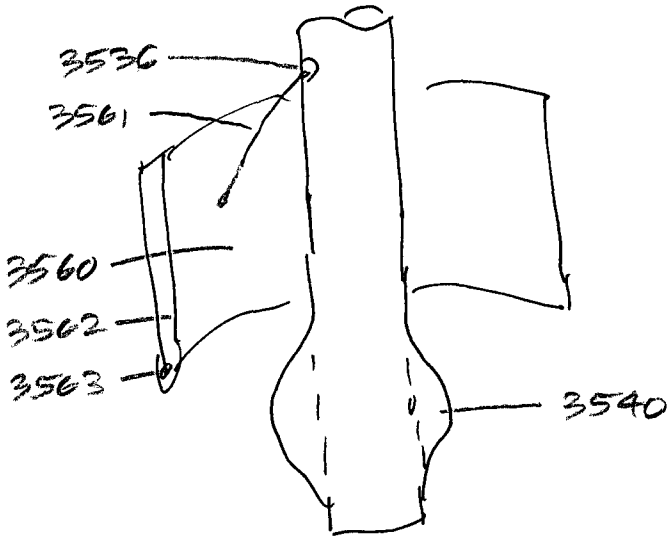


FIG. 11B

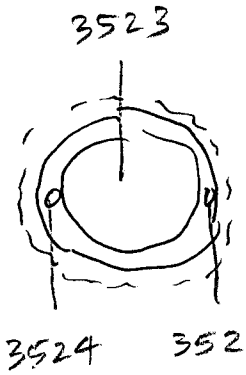


FIG. 11C

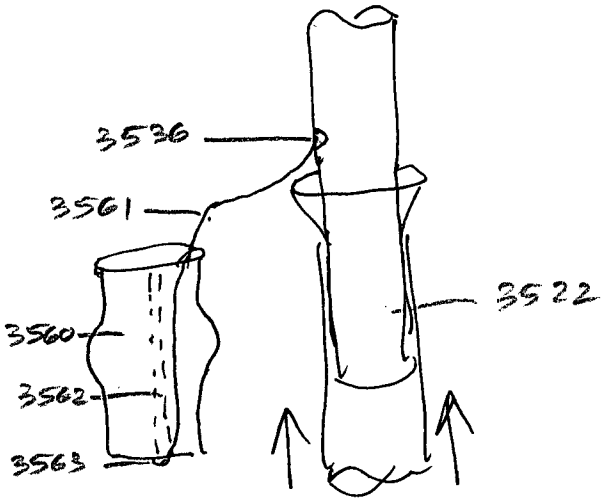


FIG. 11D

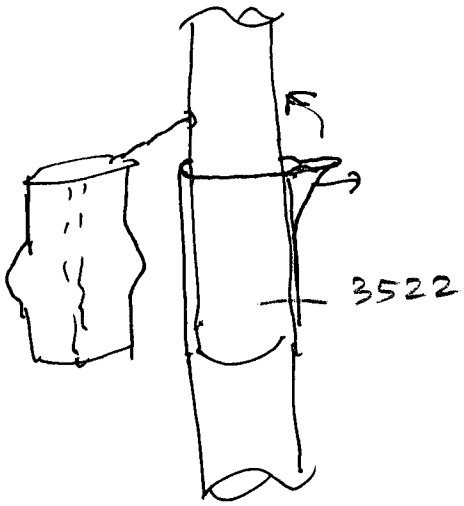


FIG. 11E

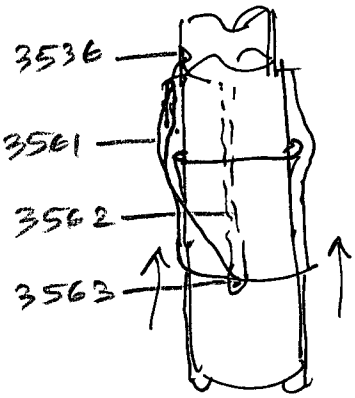


FIG. 11F

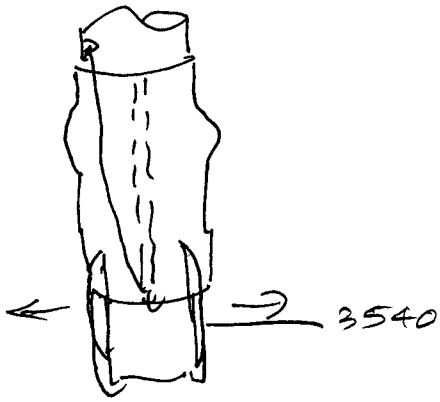


FIG. 11G

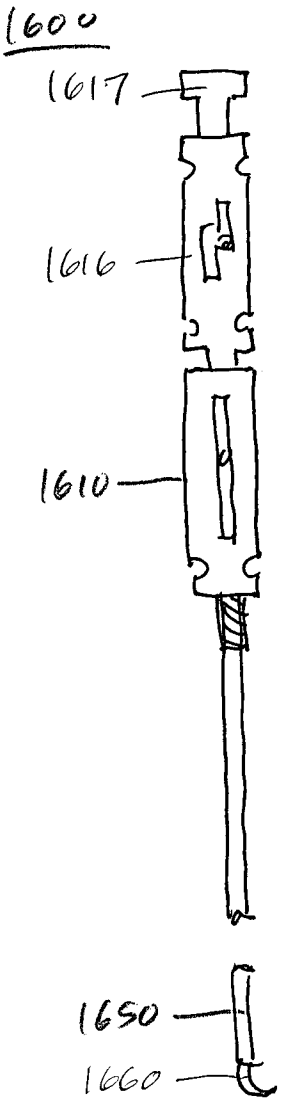


FIG. 12A

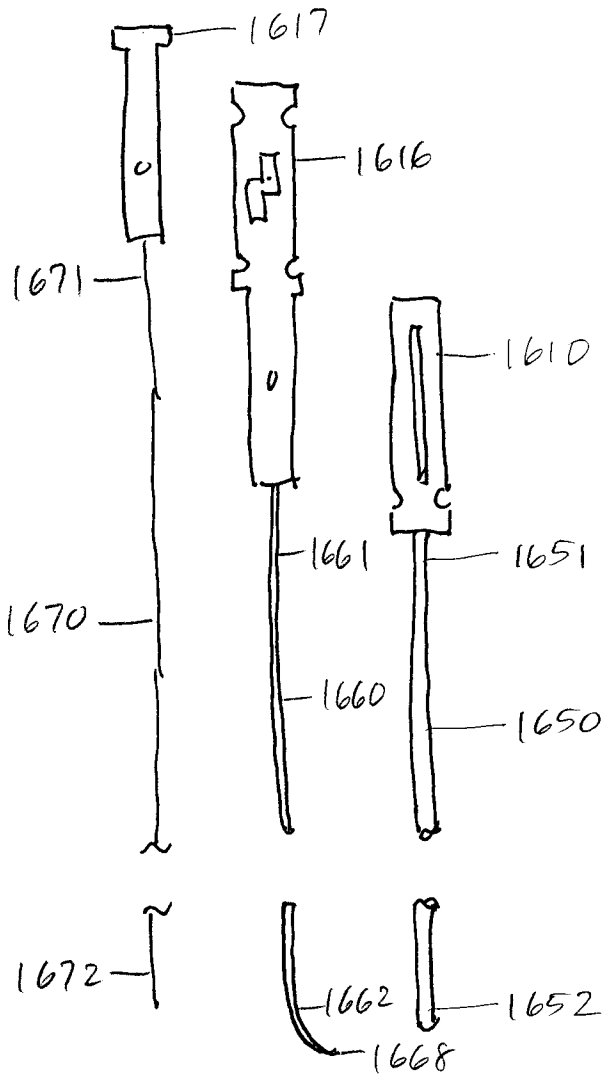


FIG. 12B

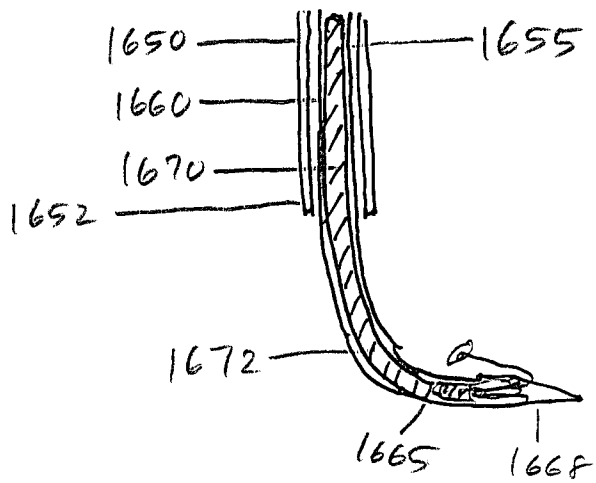


FIG. 12C

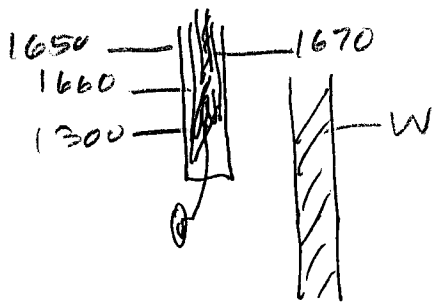


FIG. 13A

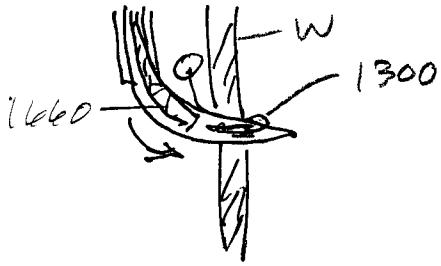


FIG. 13B

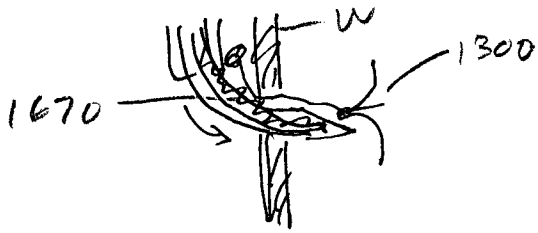


FIG. 13C

FIG. 13D

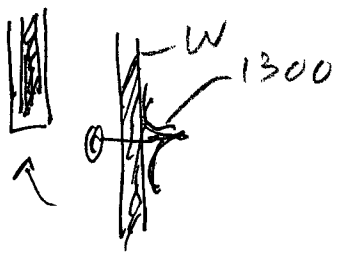


FIG. 13E

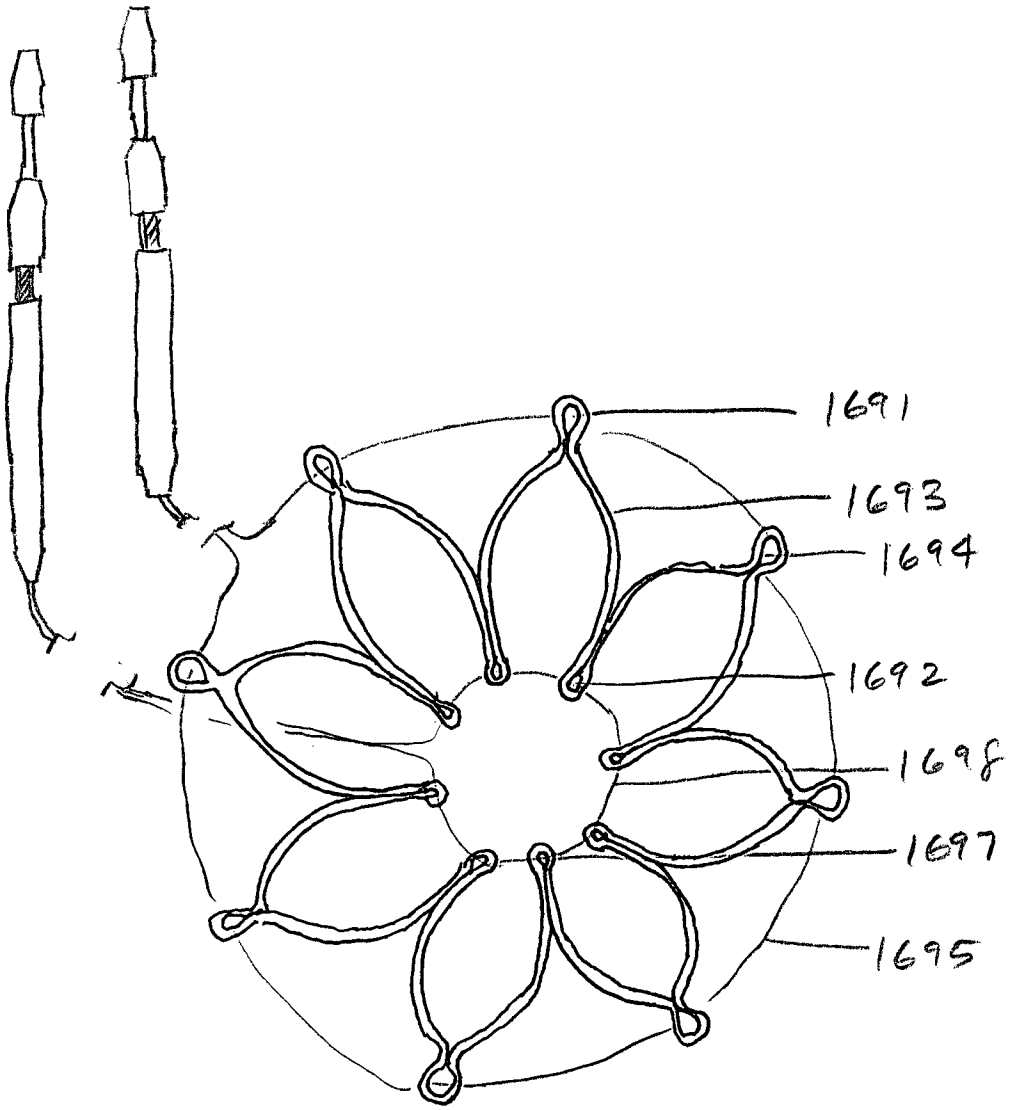


FIG. 14A

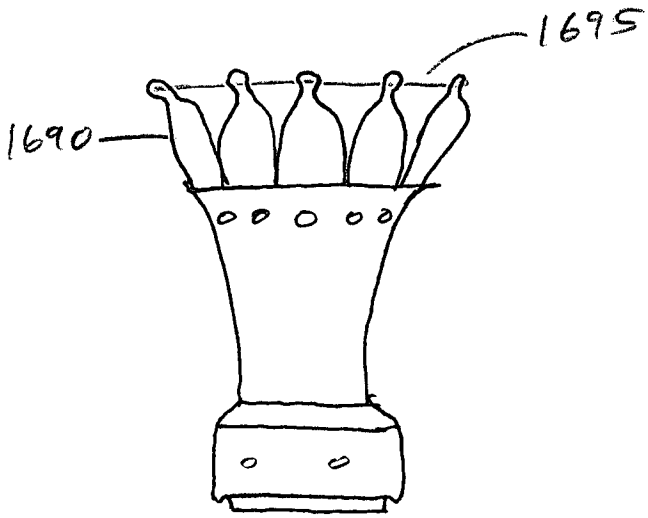


FIG. 14B

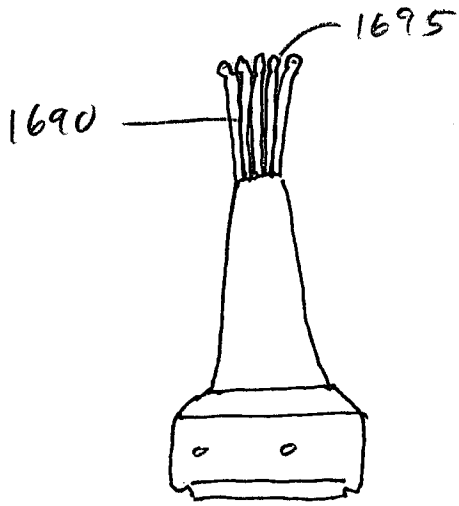


FIG. 14C

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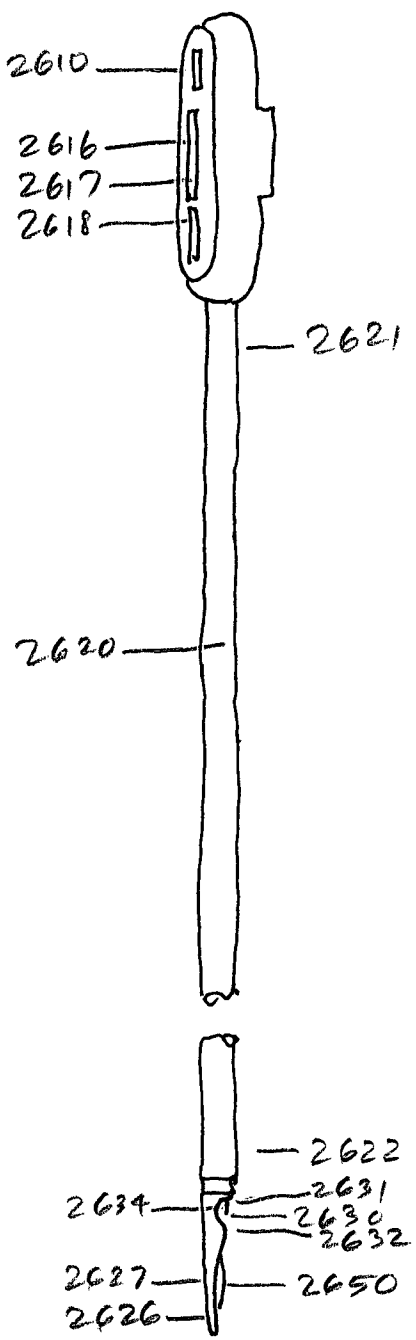

FIG. 15A

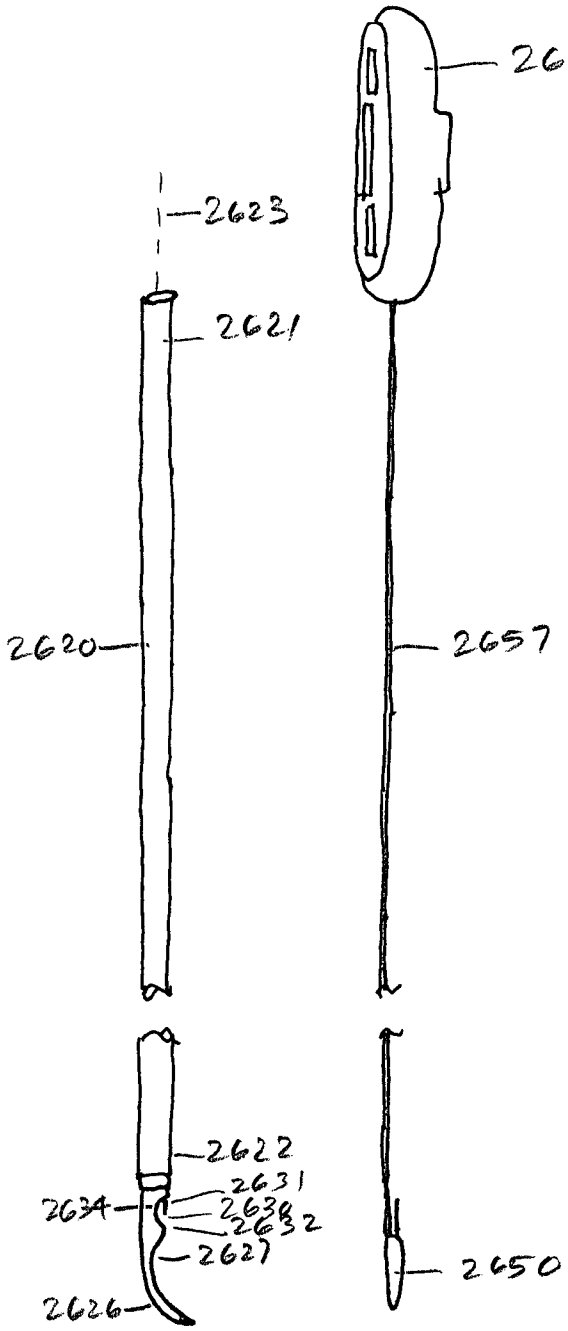

FIG. 15B

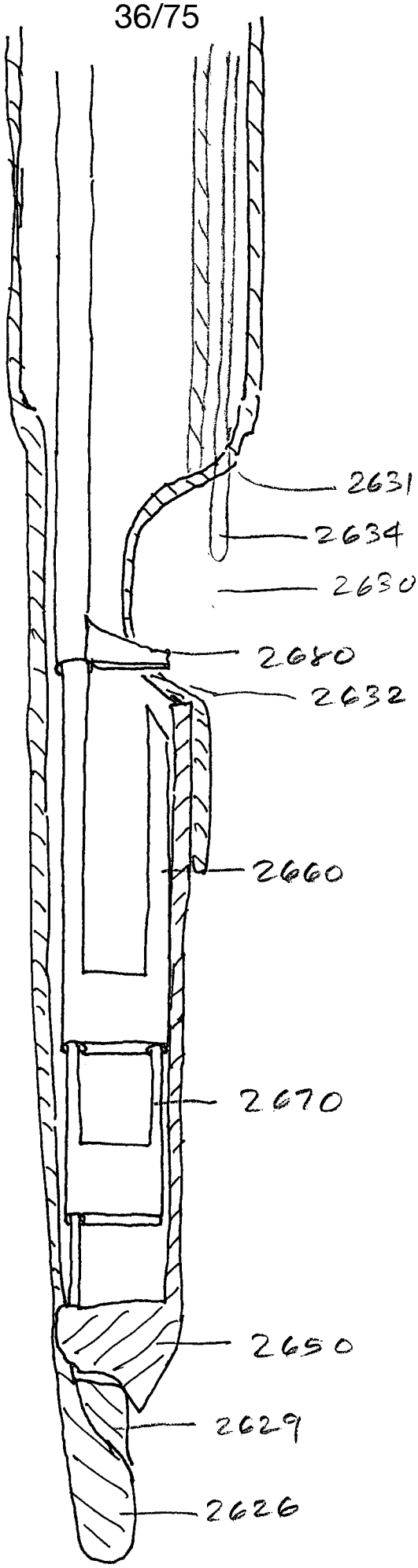

FIG. 15C

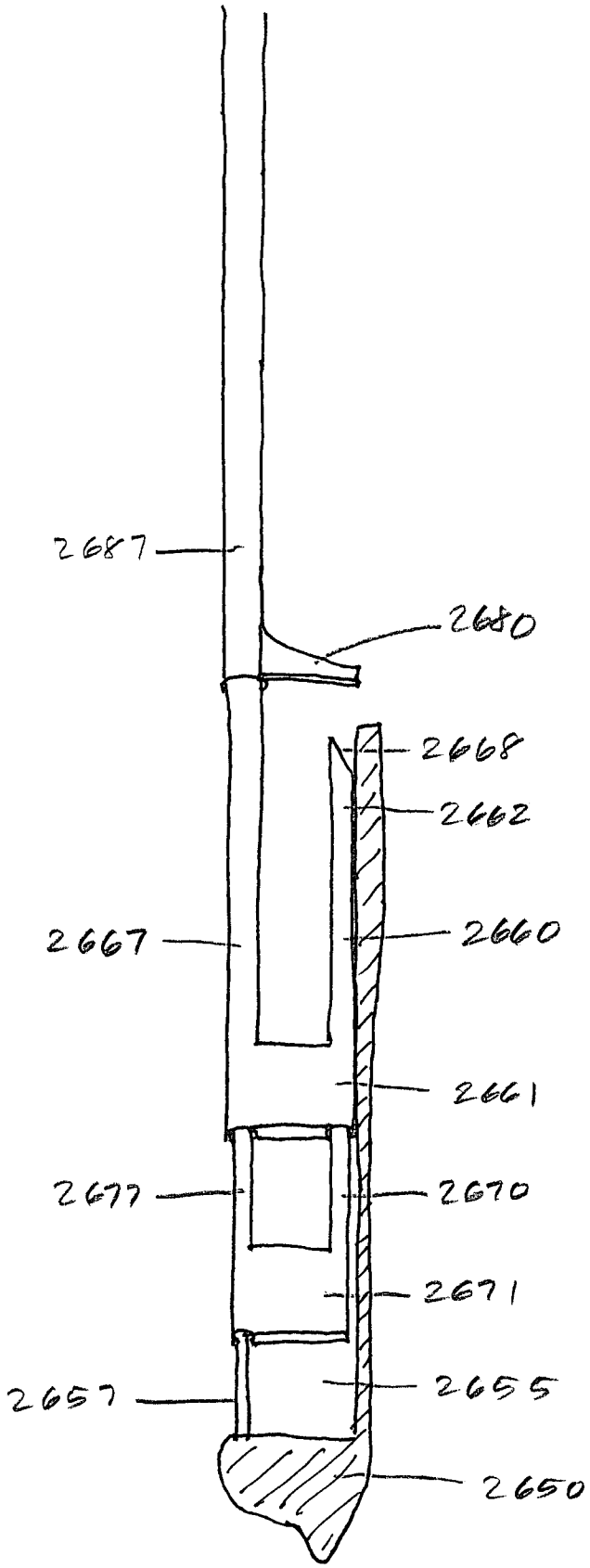
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FIG. 15D

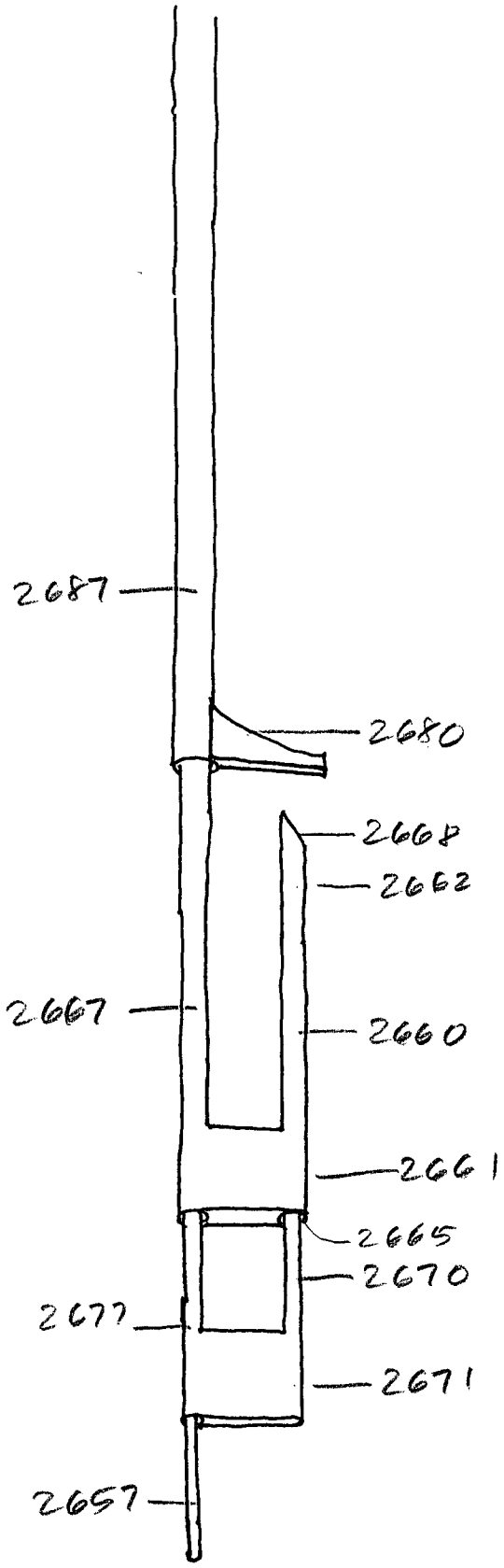

FIG. 15E

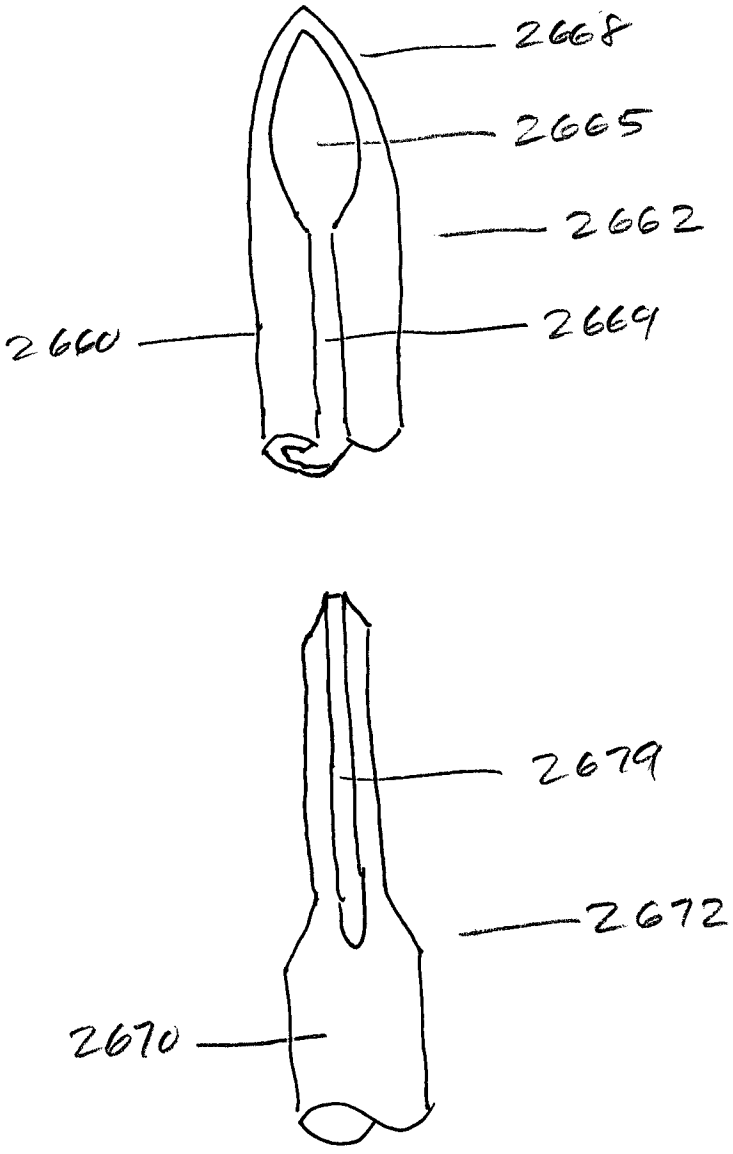

FIG. 15F

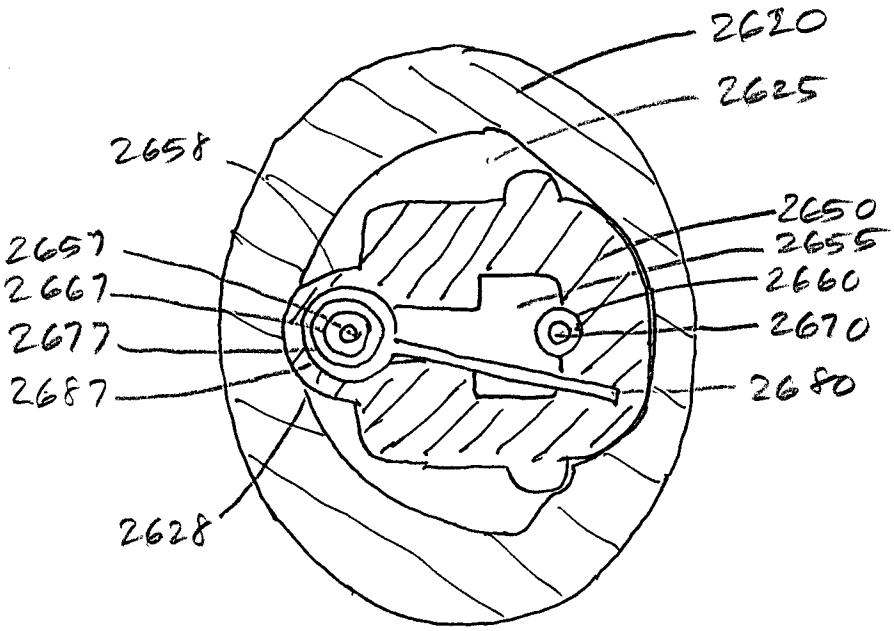
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FIG. 15G

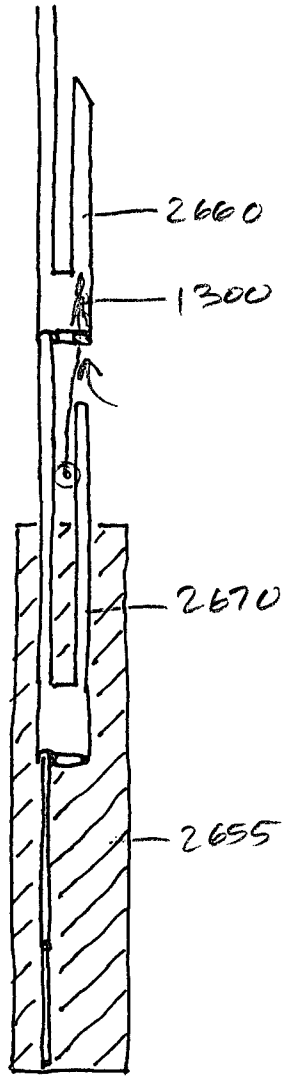


FIG. 16A

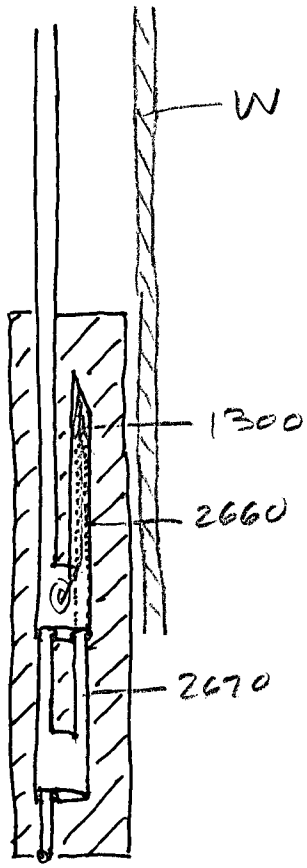


FIG. 16B

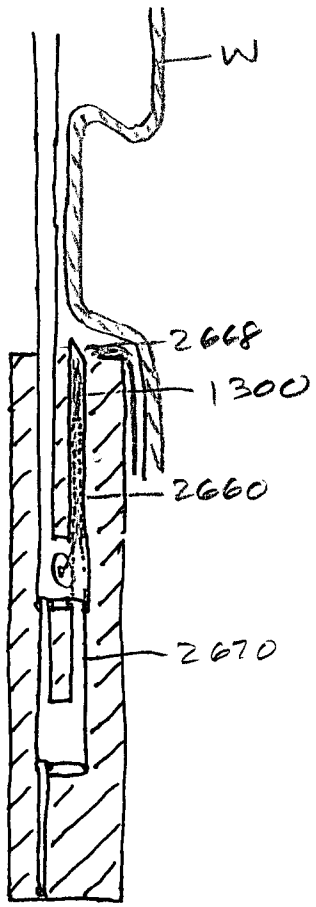


FIG. 16C

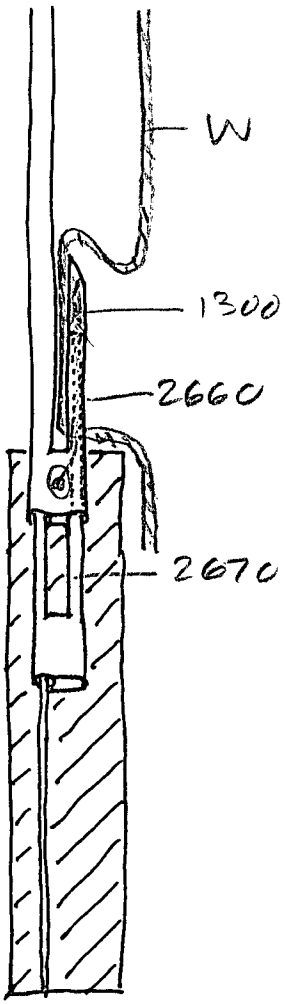


FIG. 16D

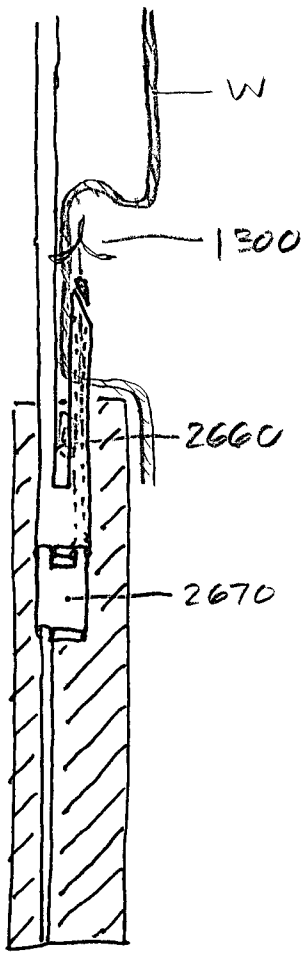


FIG. 16E

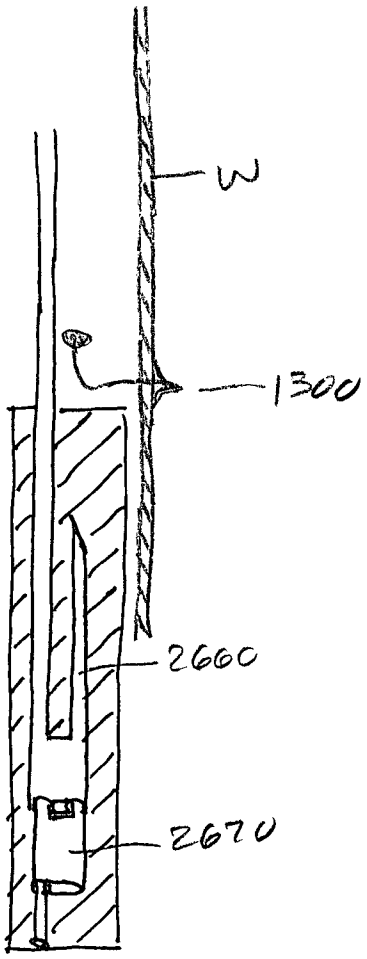


FIG. 16F

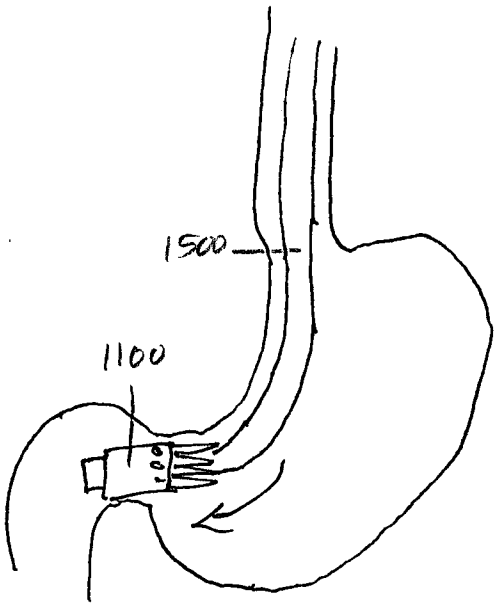


FIG. 17A

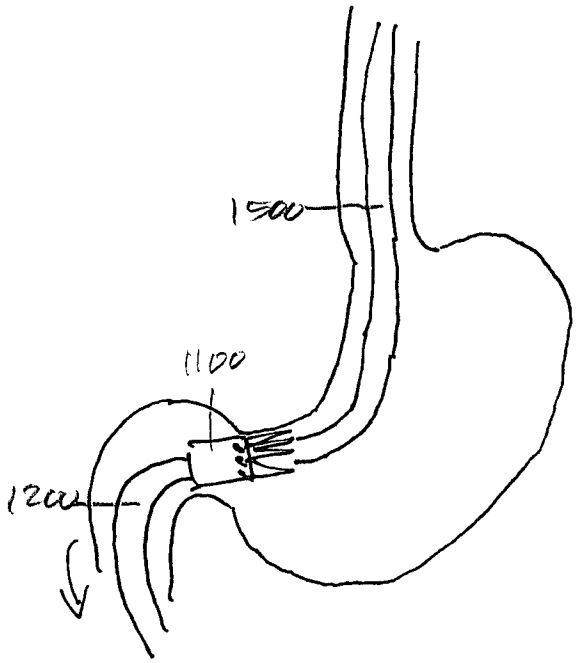


FIG. 17B

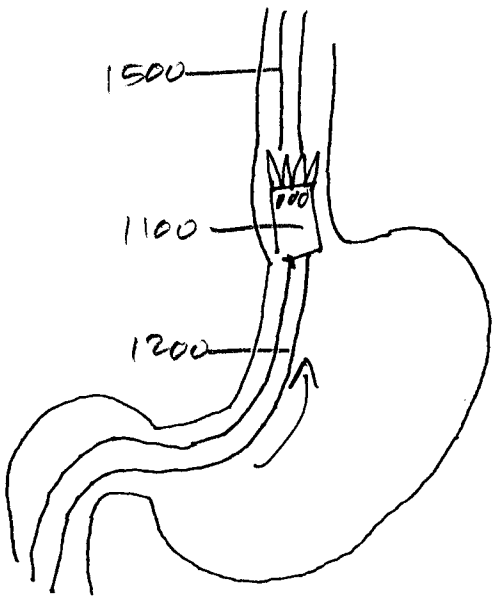


FIG. 17C

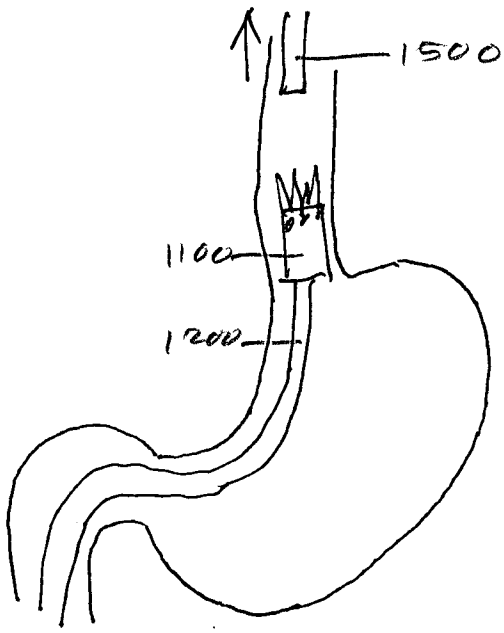


FIG. 17D

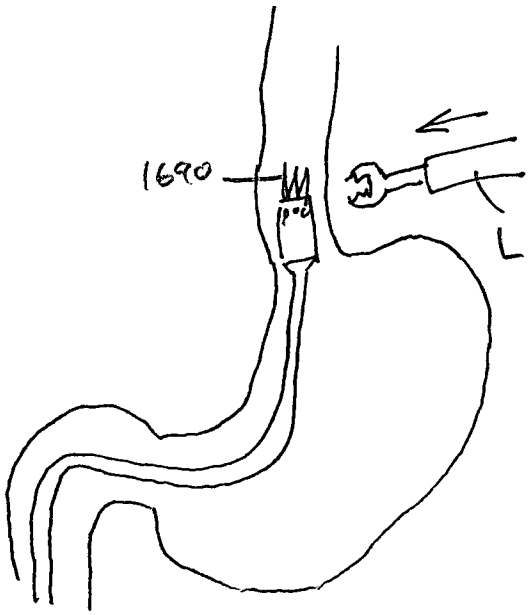


FIG. 17E

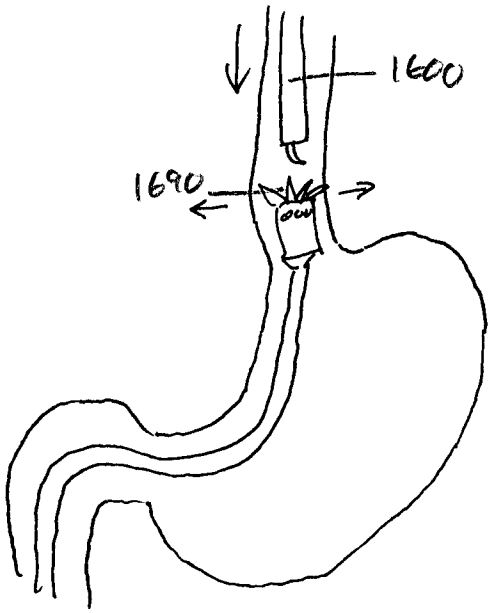


FIG. 17F

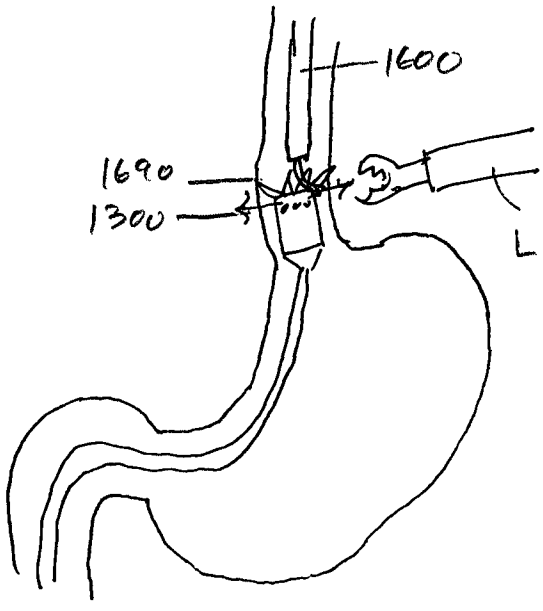


FIG. 17G

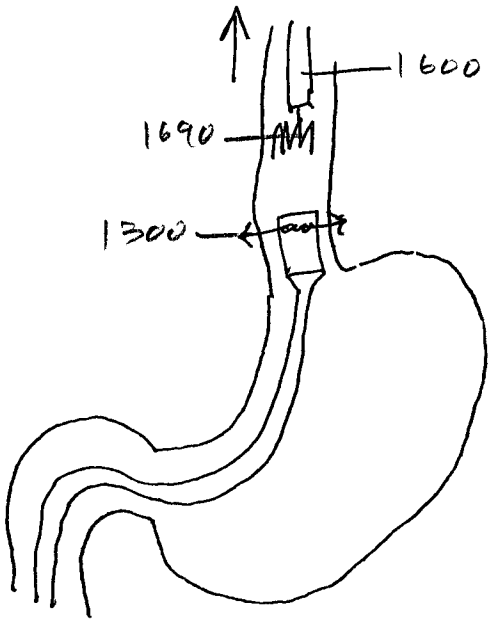


FIG. 17H

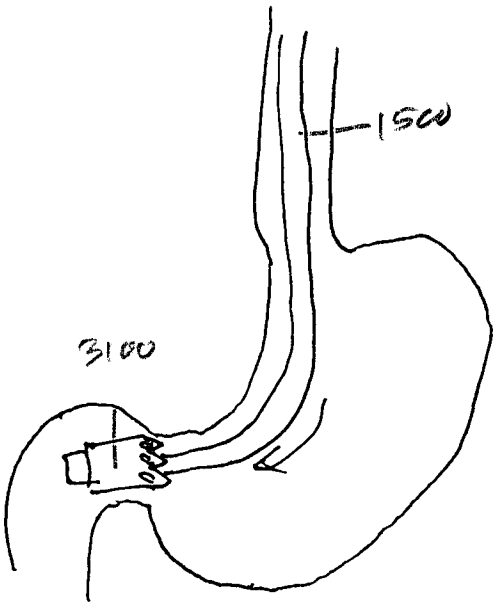


FIG. 18A

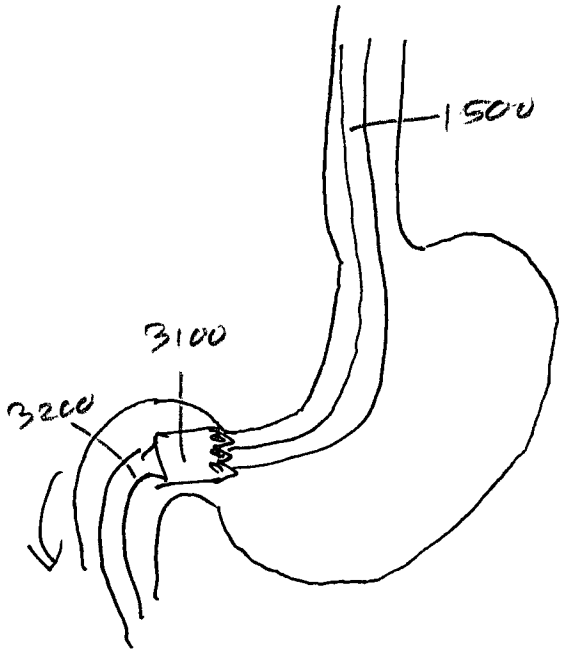


FIG. 18B

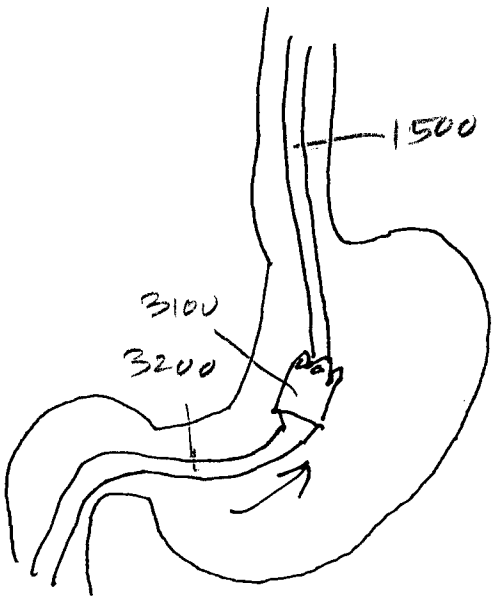


FIG. 18C

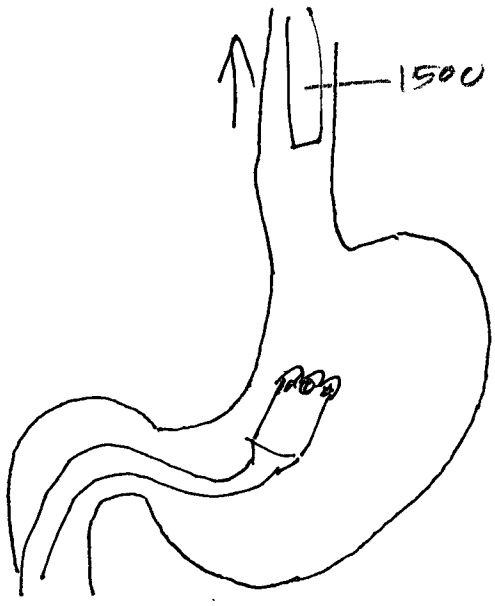


FIG. 18D

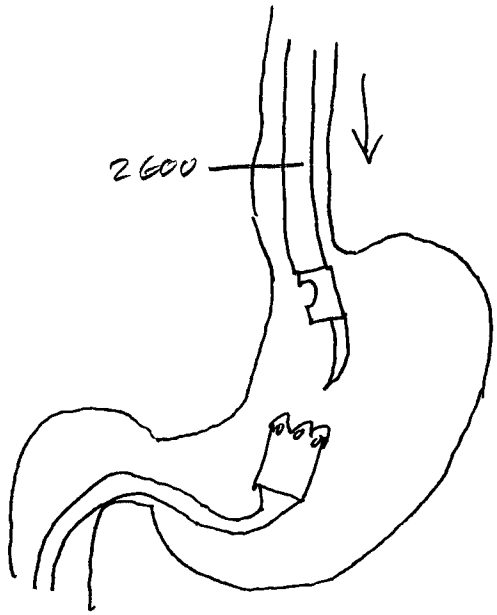


FIG. 18E

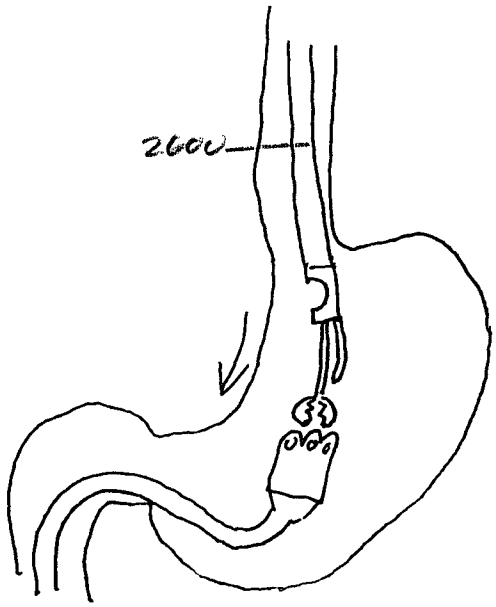


FIG. 18F

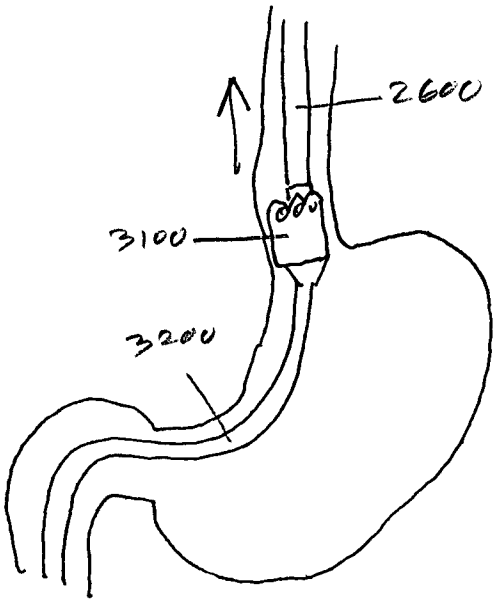


FIG. 18G

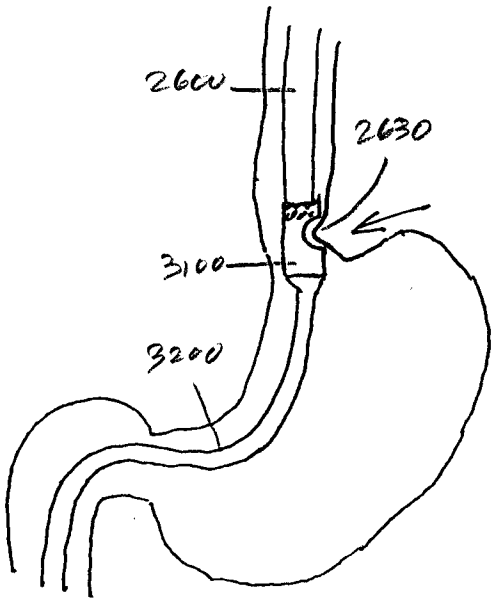


FIG. 18H

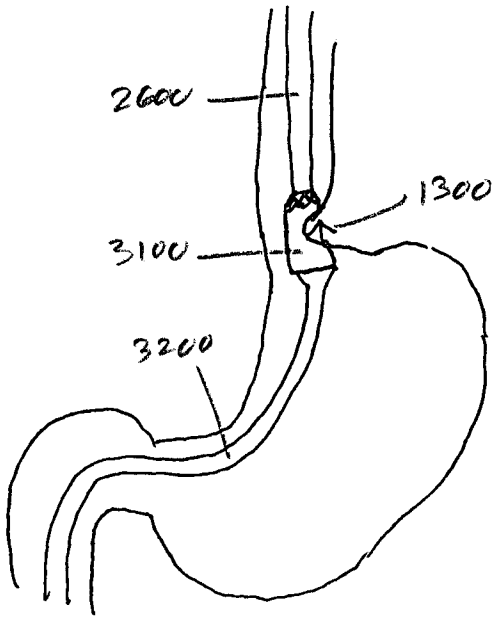


FIG. 18I

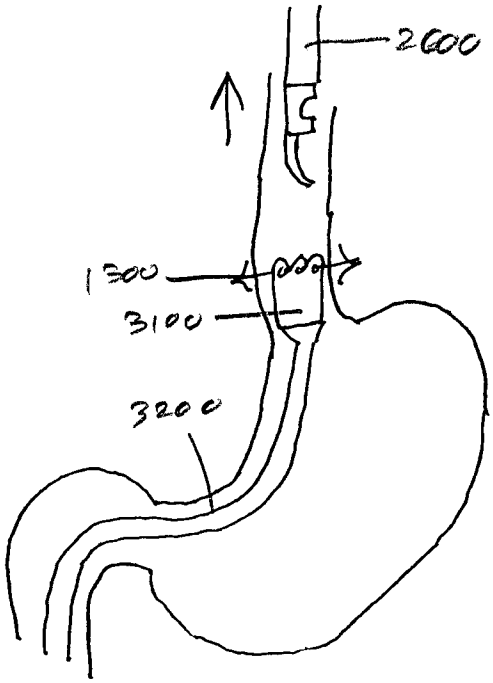


FIG. 18J

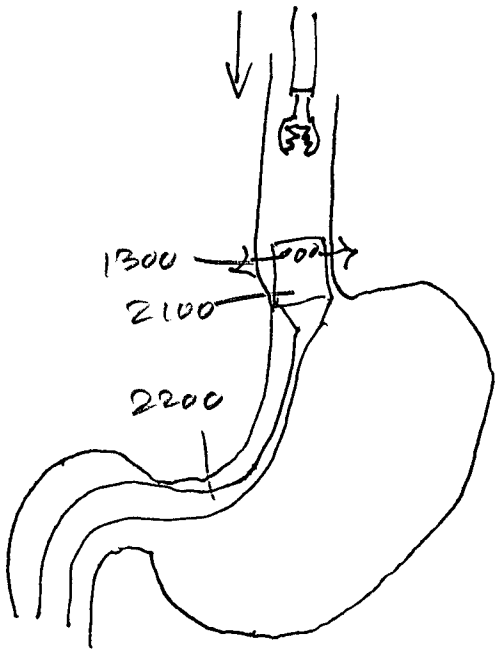


FIG. 19A

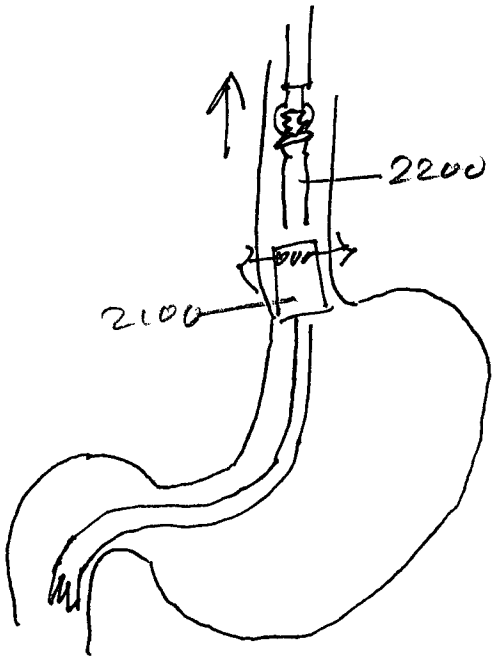


FIG. 19B

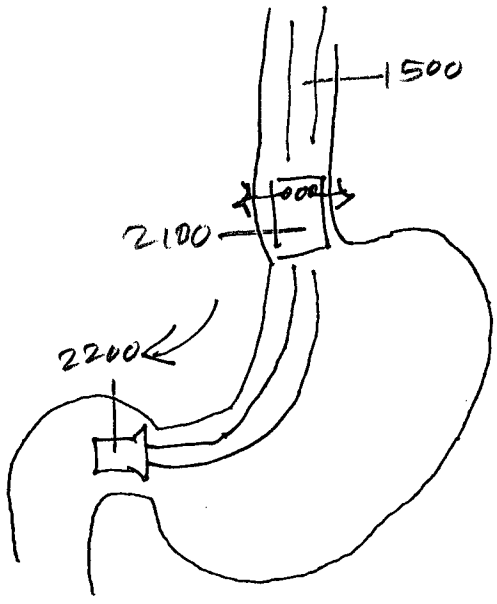


FIG. 19C

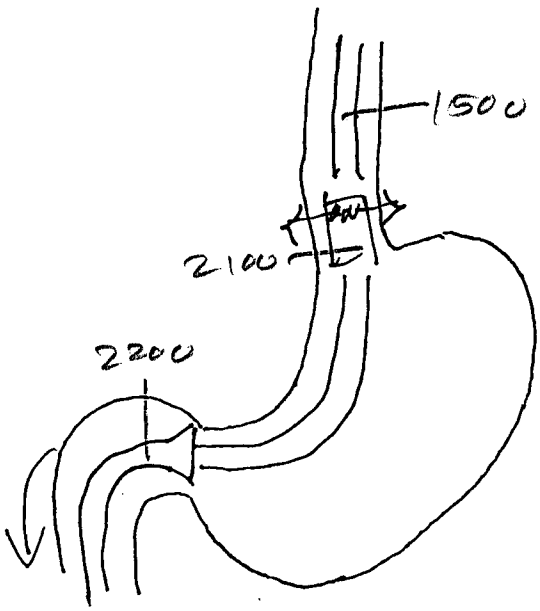


FIG. 19D

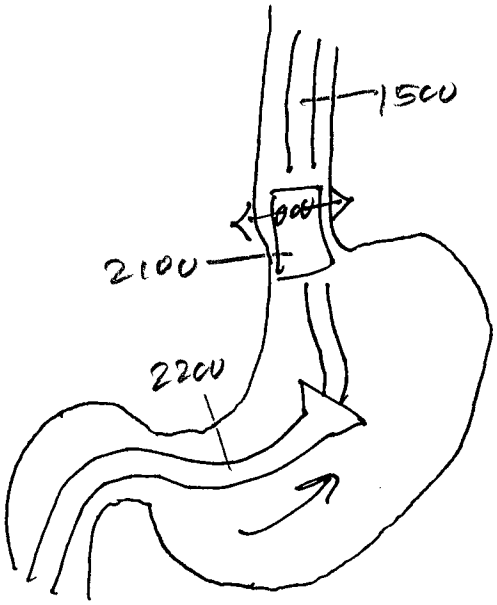


FIG. 19E

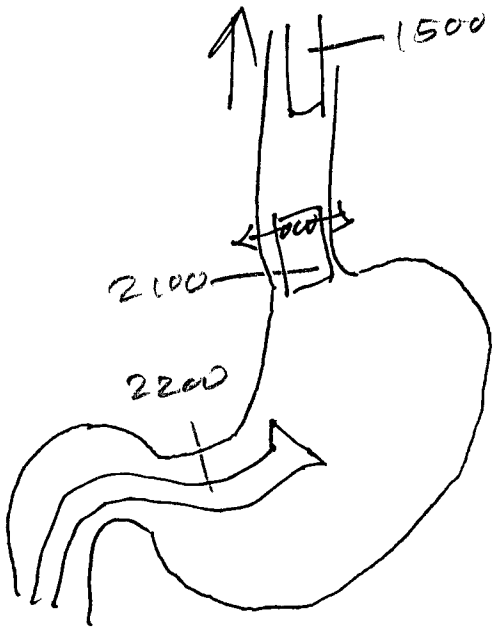


FIG. 19F

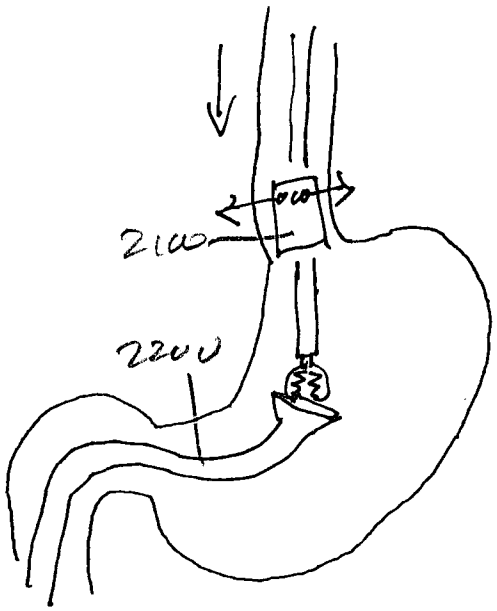


FIG. 19G

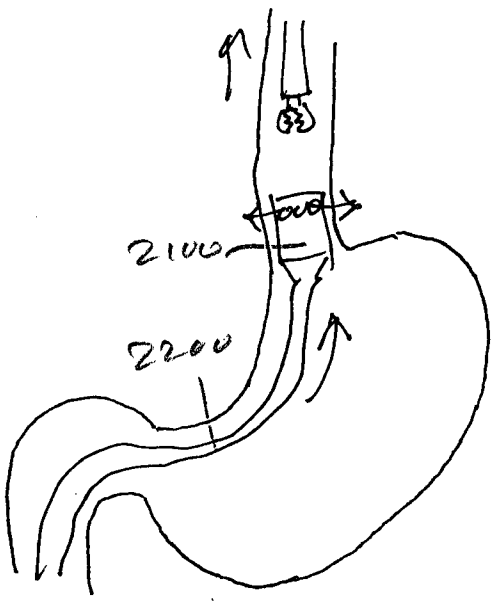


FIG. 19H

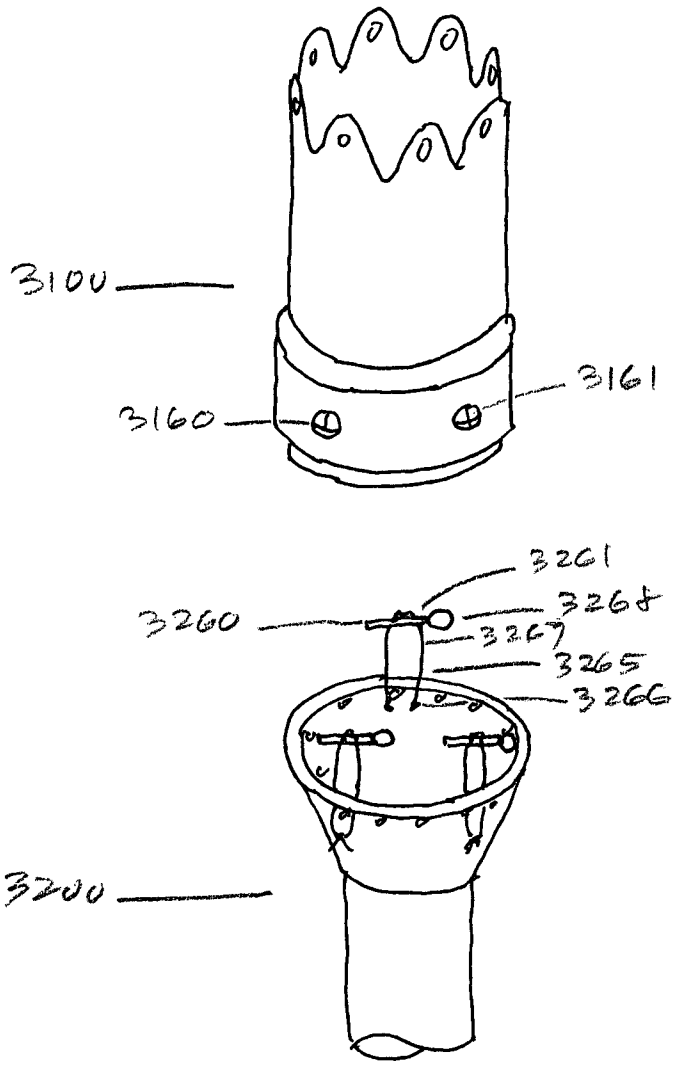


FIG. 20A

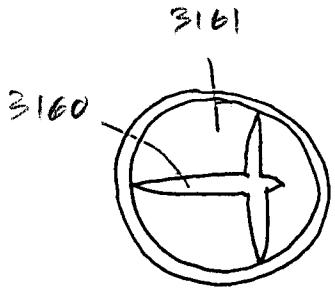


FIG. 20B

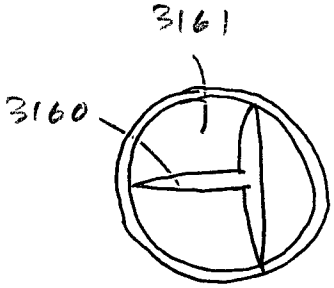


FIG. 20C

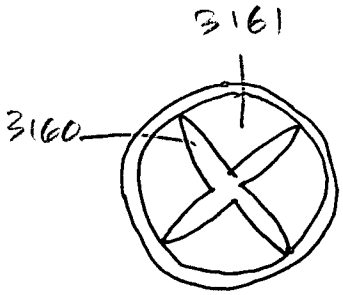


FIG. 20D

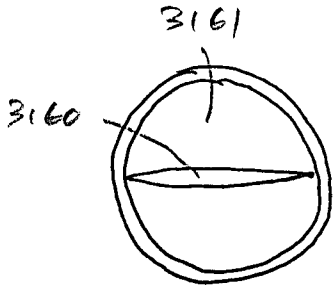


FIG. 20E

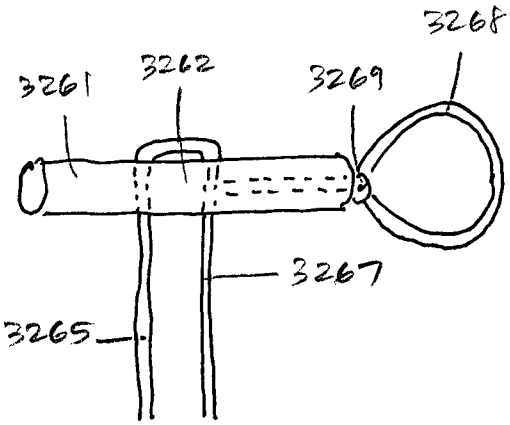


FIG. 20F

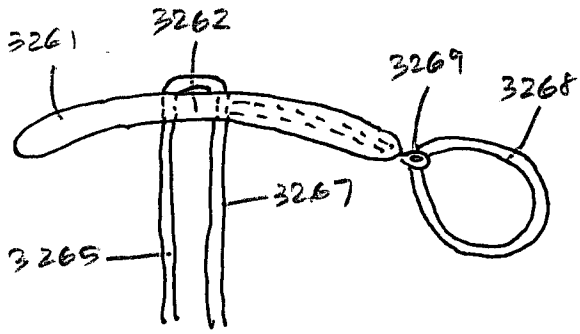
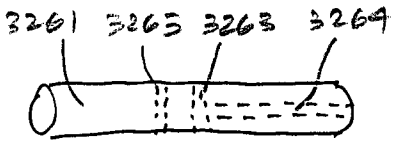
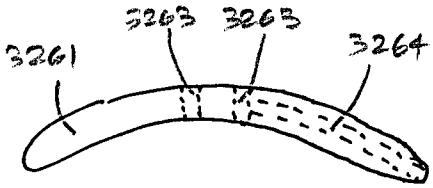


FIG. 20H





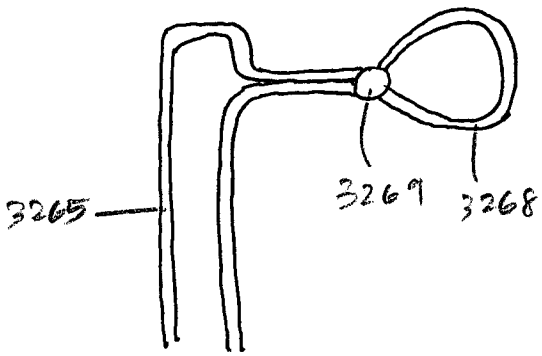


FIG. 20G

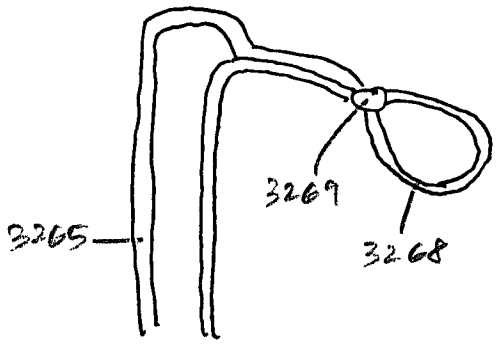


FIG. 20I

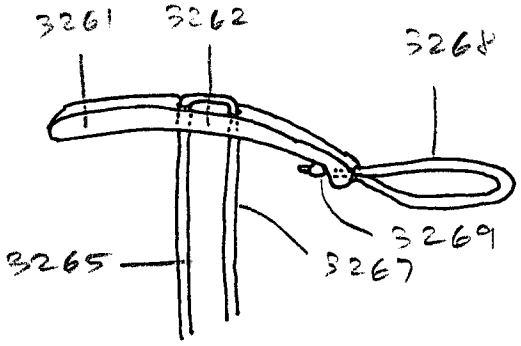


FIG. 20J

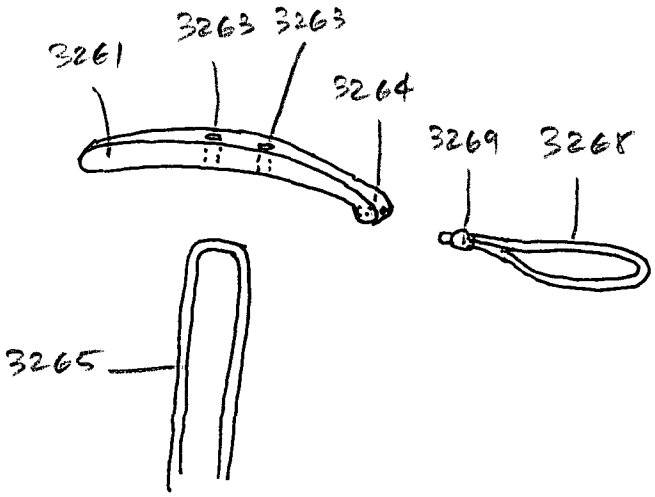


FIG. 20K

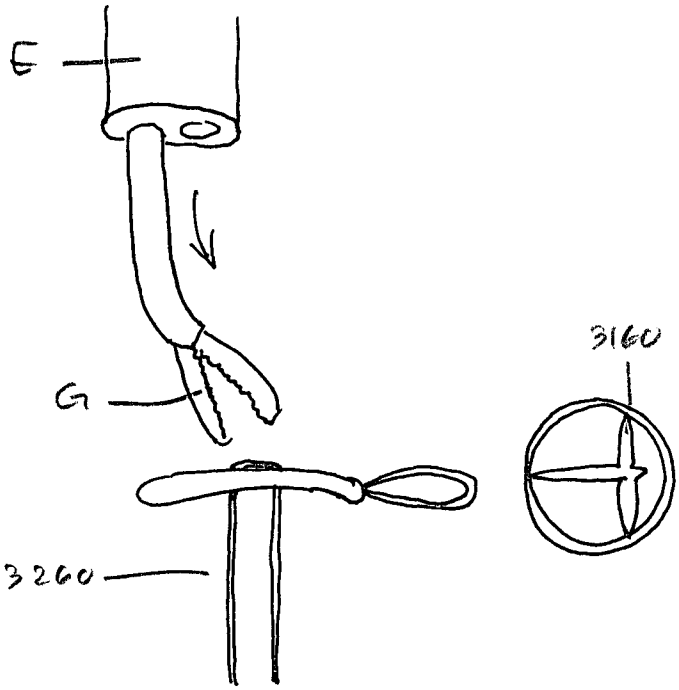


FIG. 21A

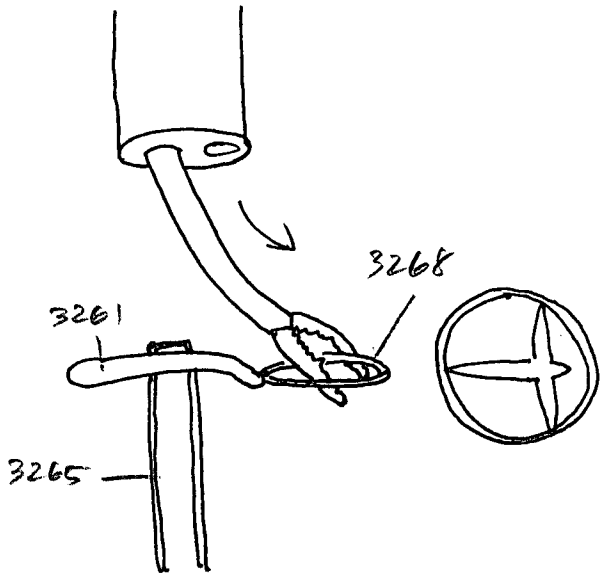


FIG. 21B

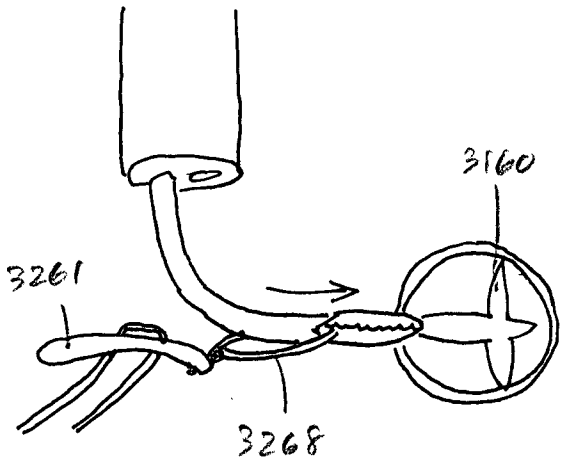


FIG. 21C

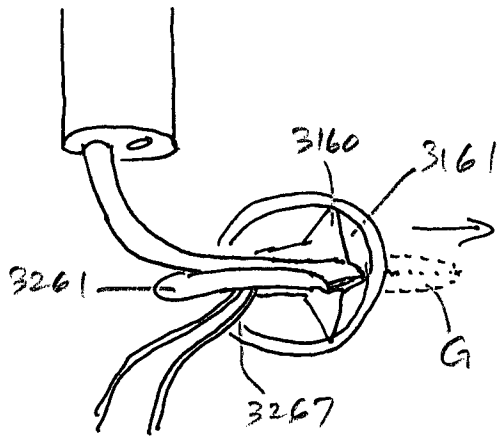


FIG. 21D

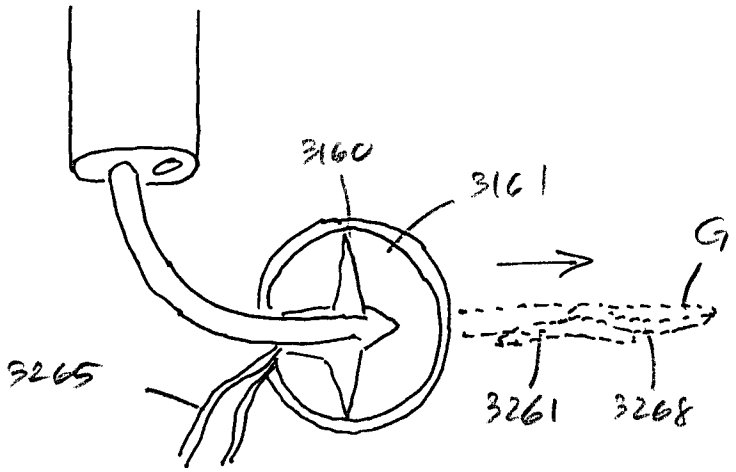


FIG. 21E

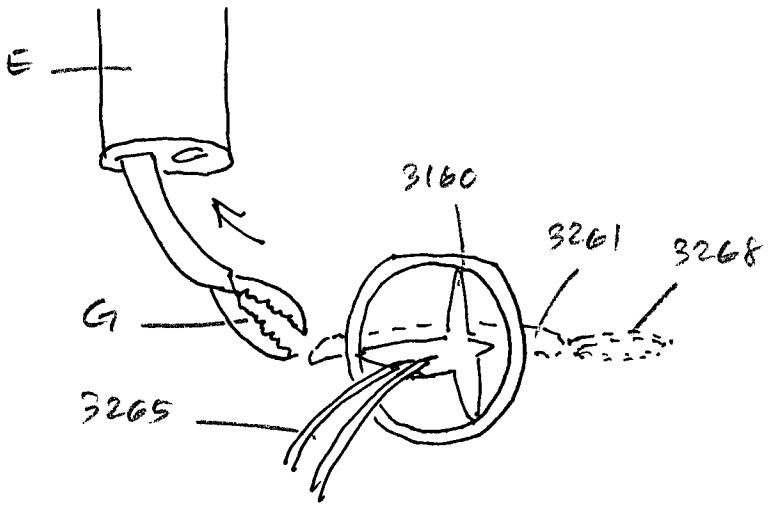


FIG. 21F

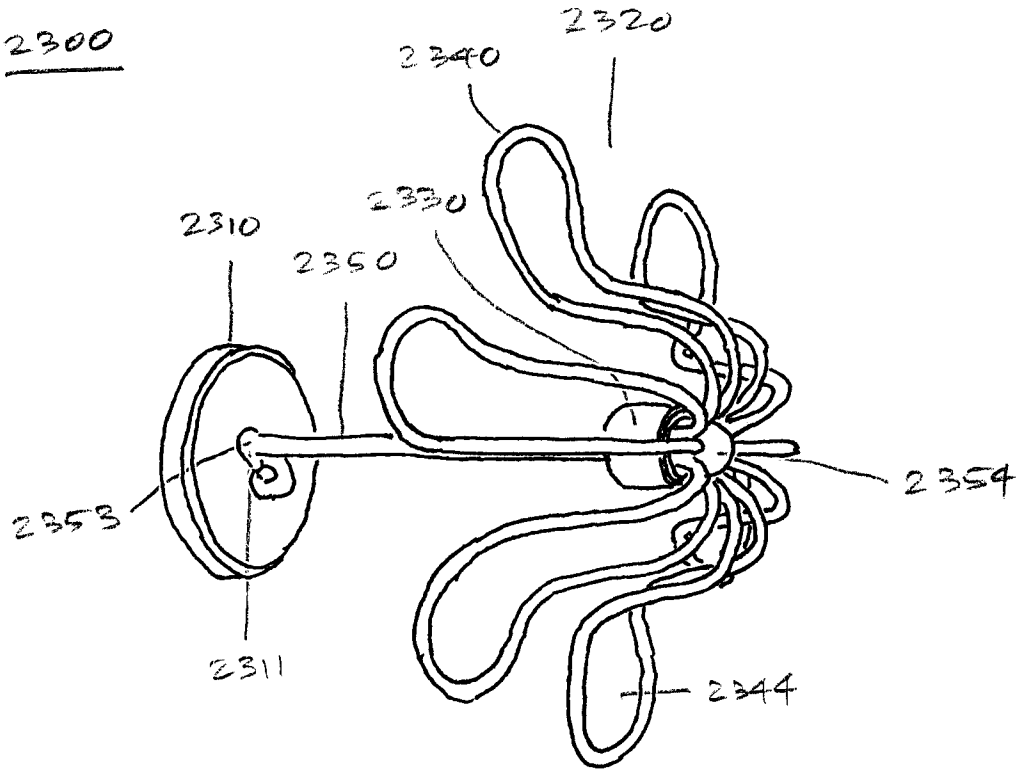


FIG. 22A

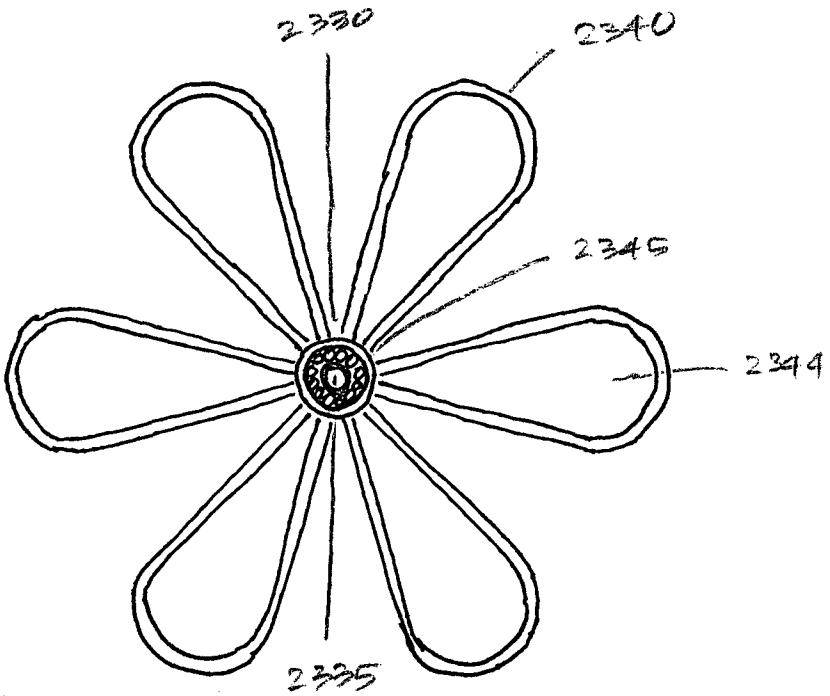


FIG. 22B

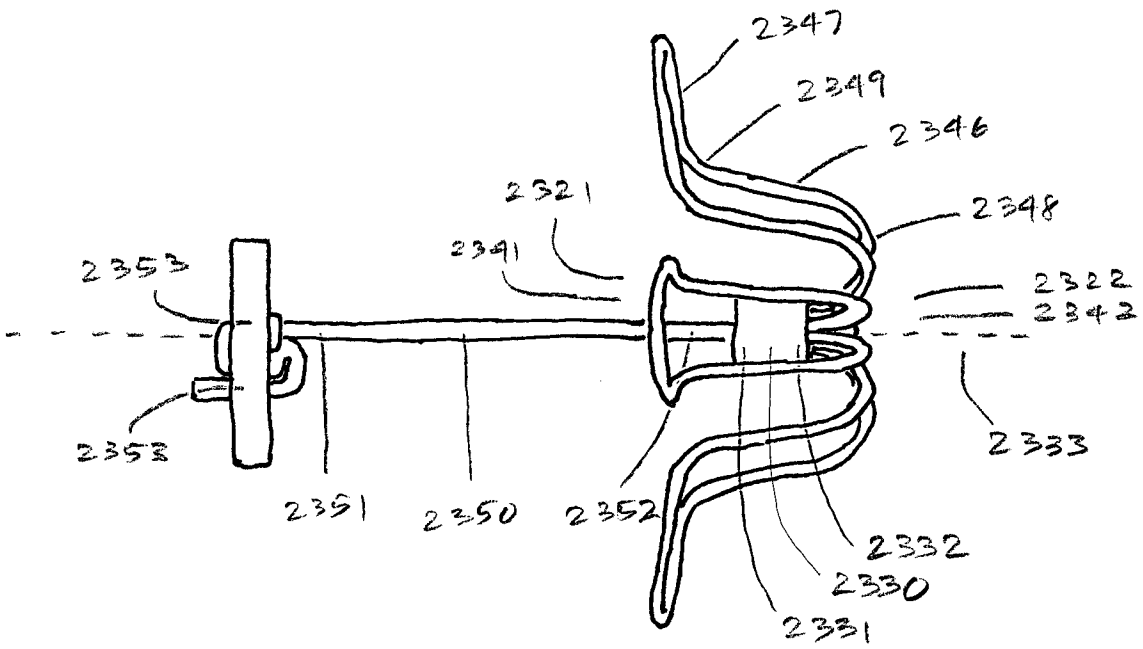


FIG. 22C

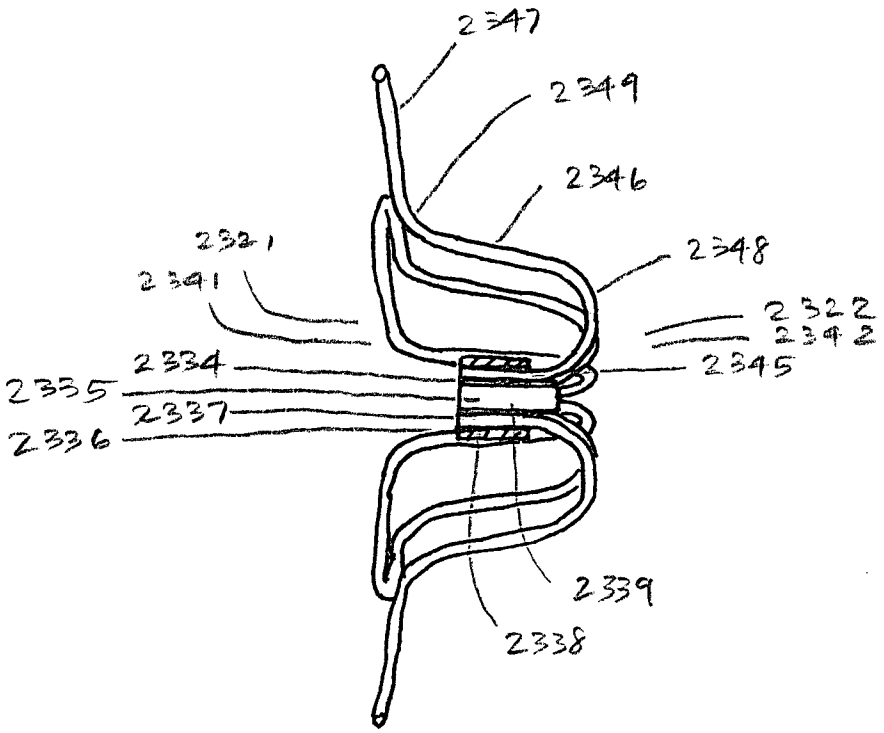


FIG. 22D

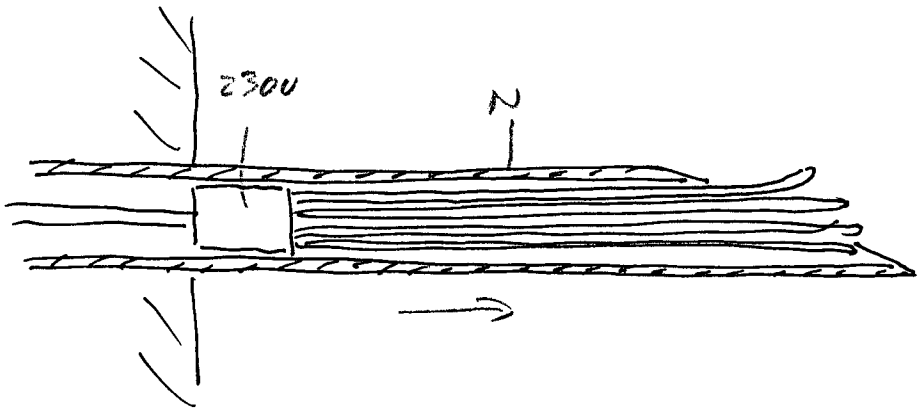


FIG. 22E

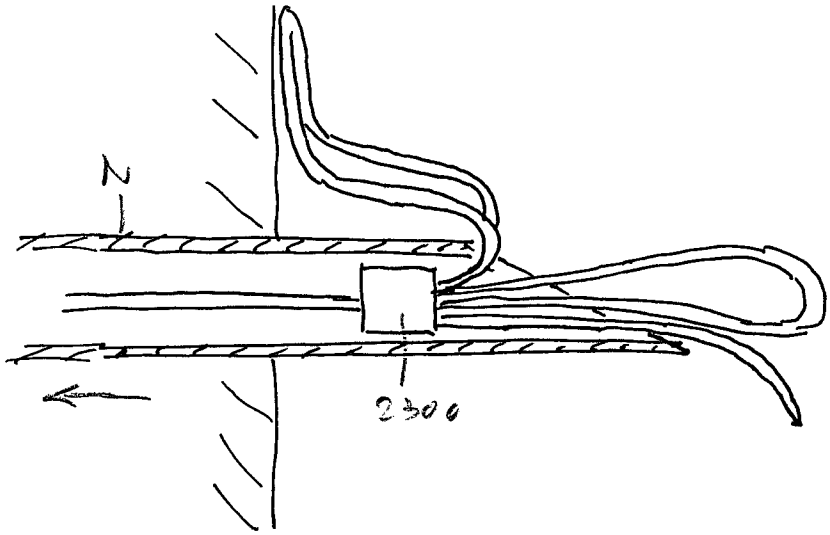


FIG. 22F

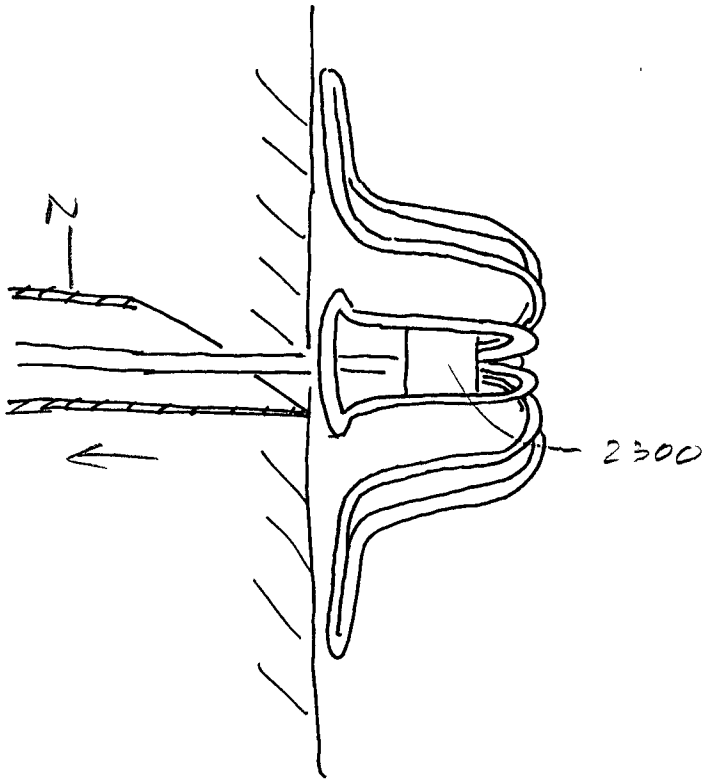


FIG 22G

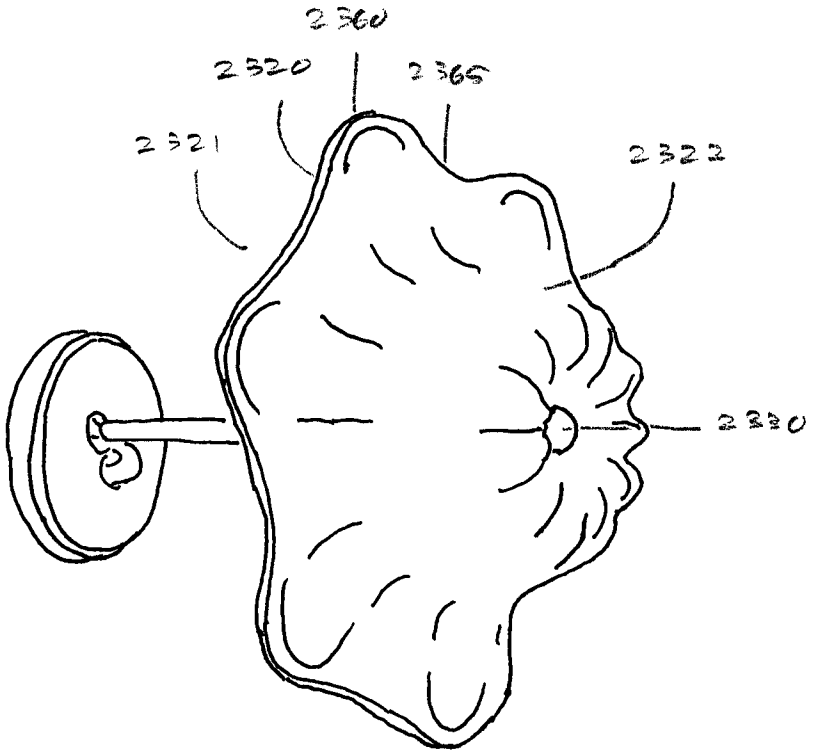


FIG. 22H

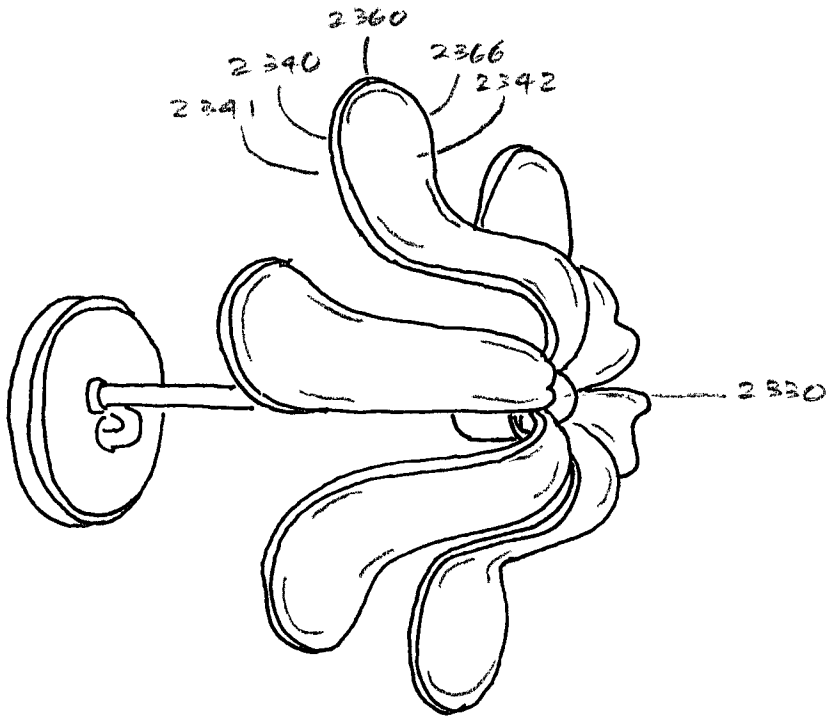


FIG. 22I

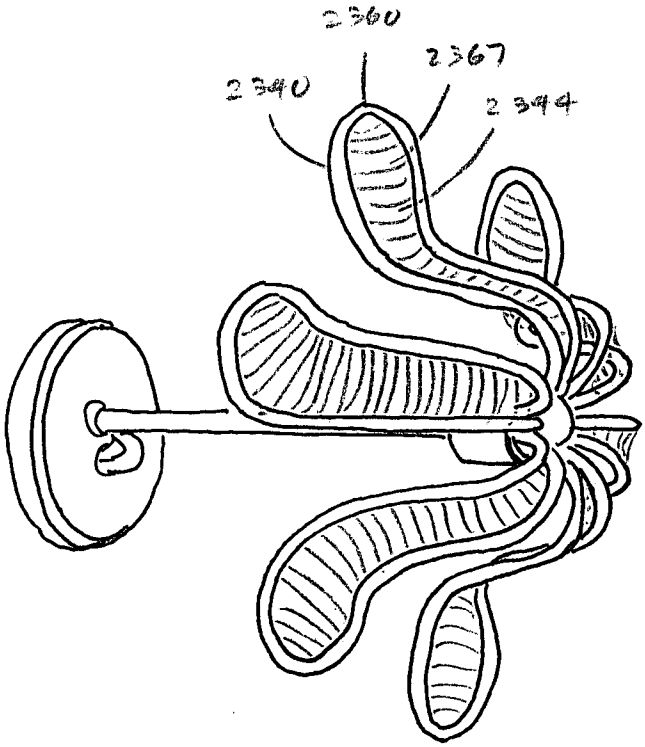


FIG. 22J

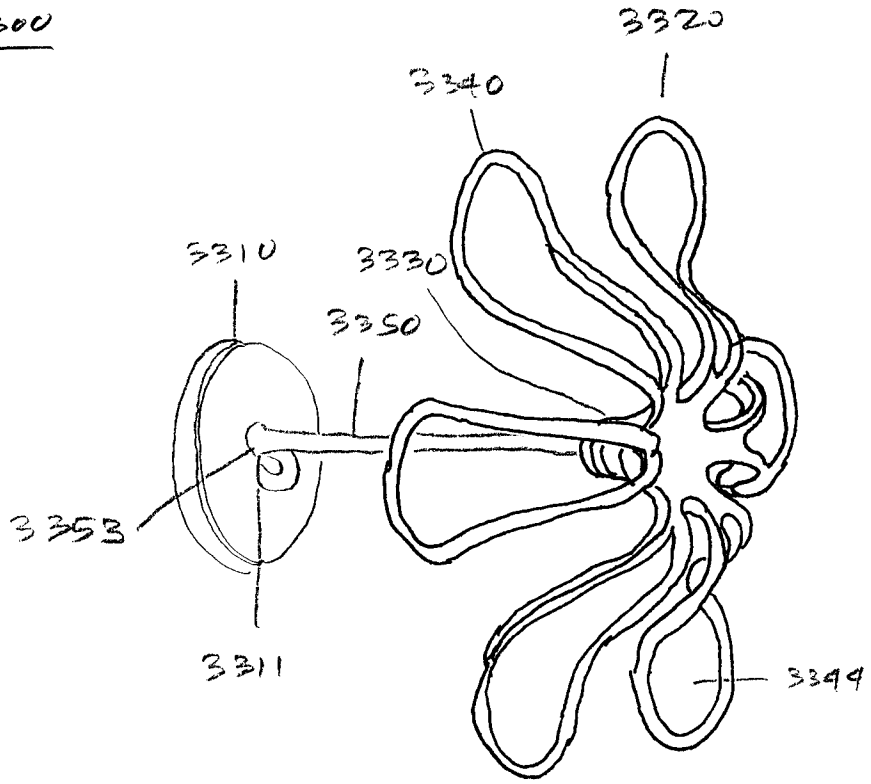


FIG. 23A

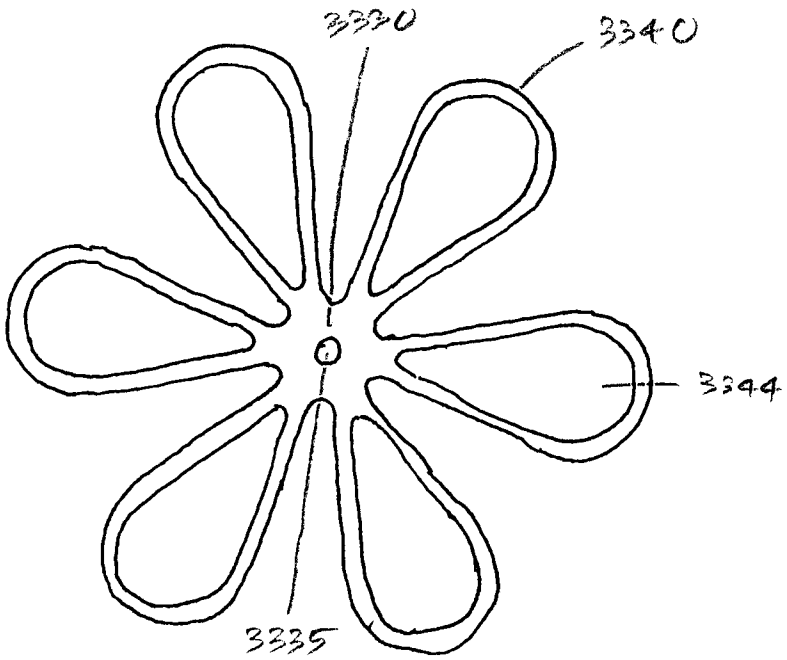


FIG. 23B

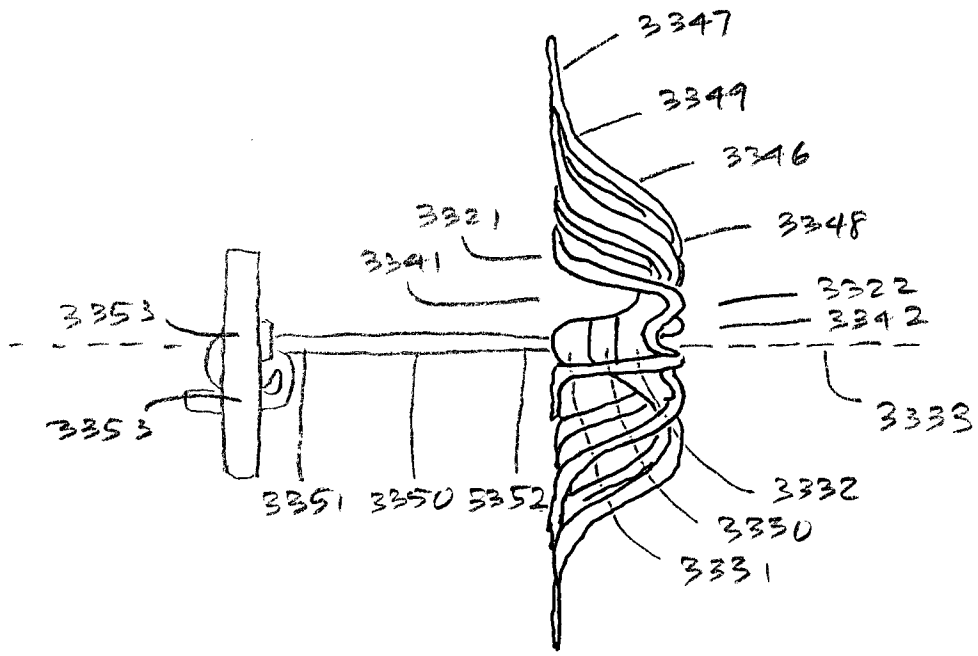

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FIG. 23C

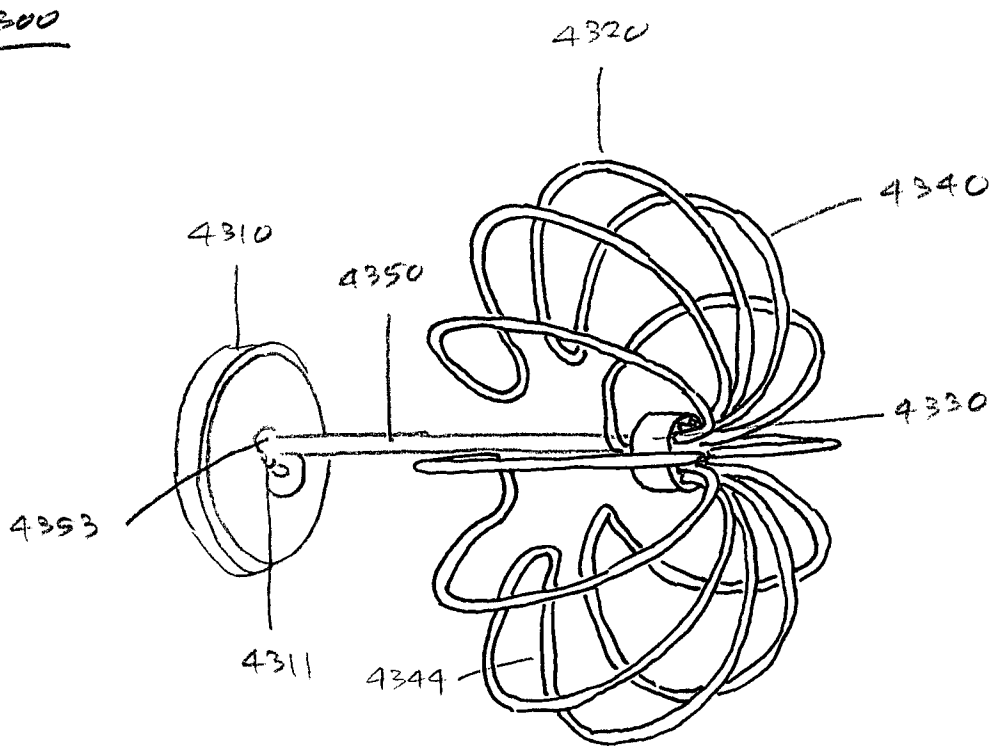

FIG. 24A

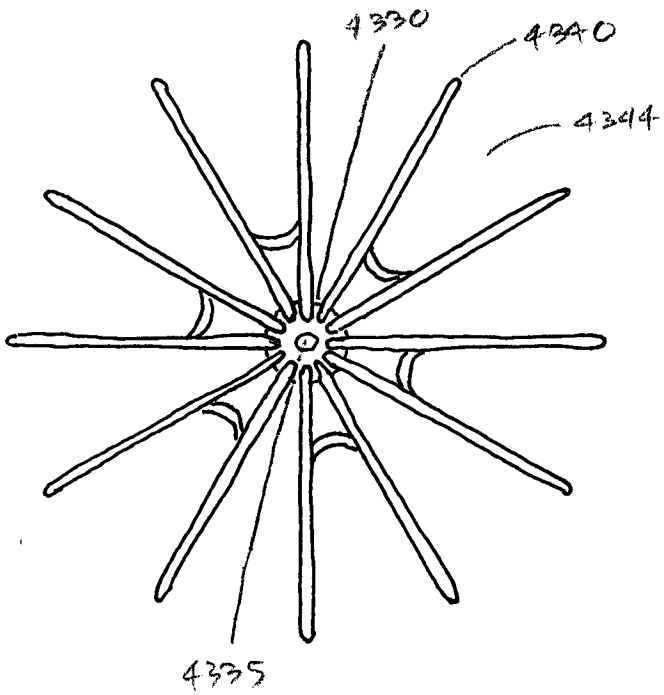

FIG. 24B

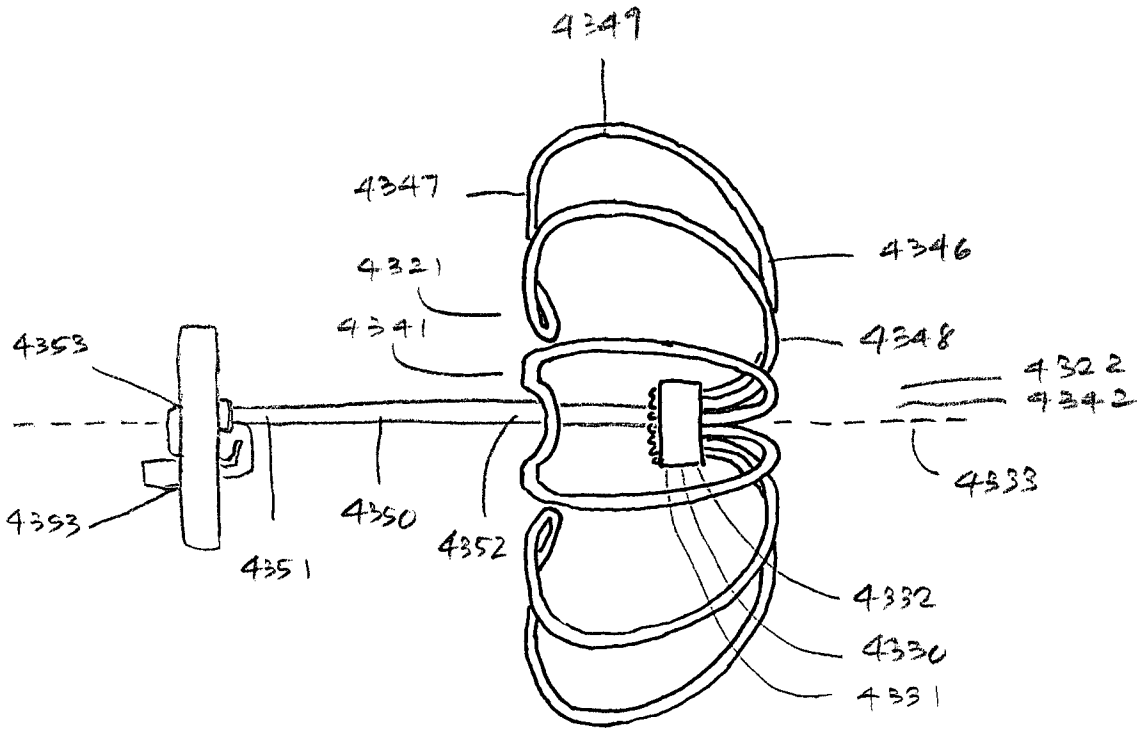

FIG. 24C

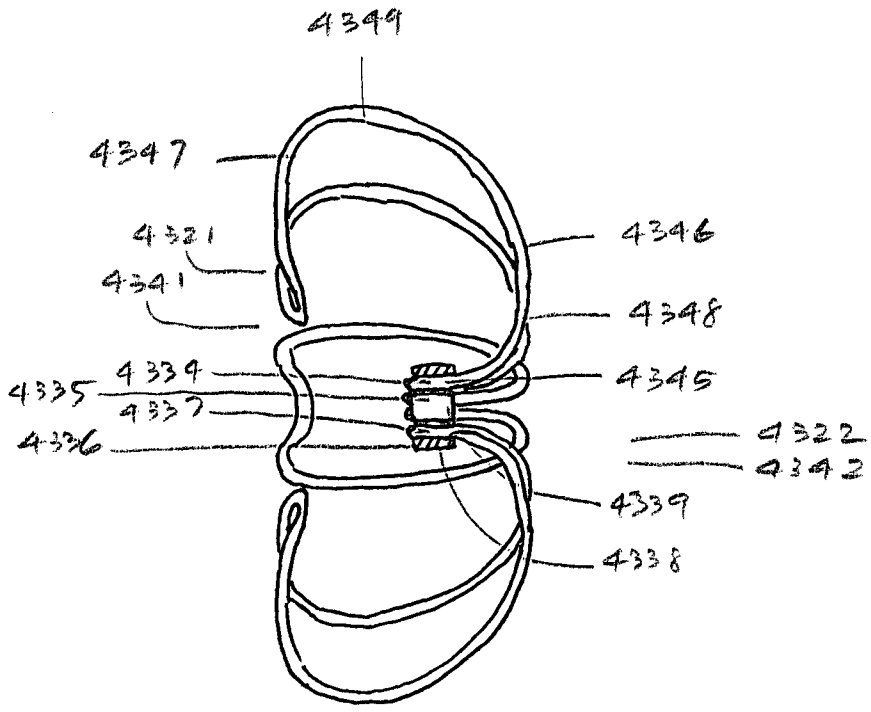

FIG. 24D

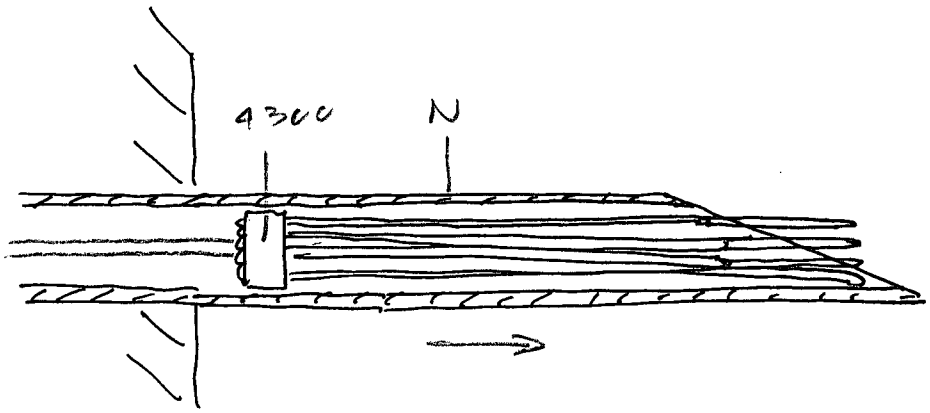

FIG. 24E

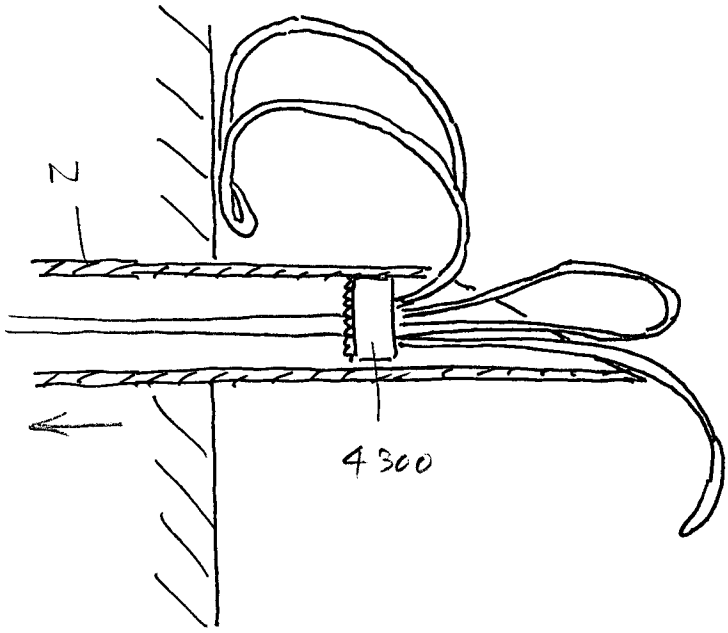

FIG. 24F

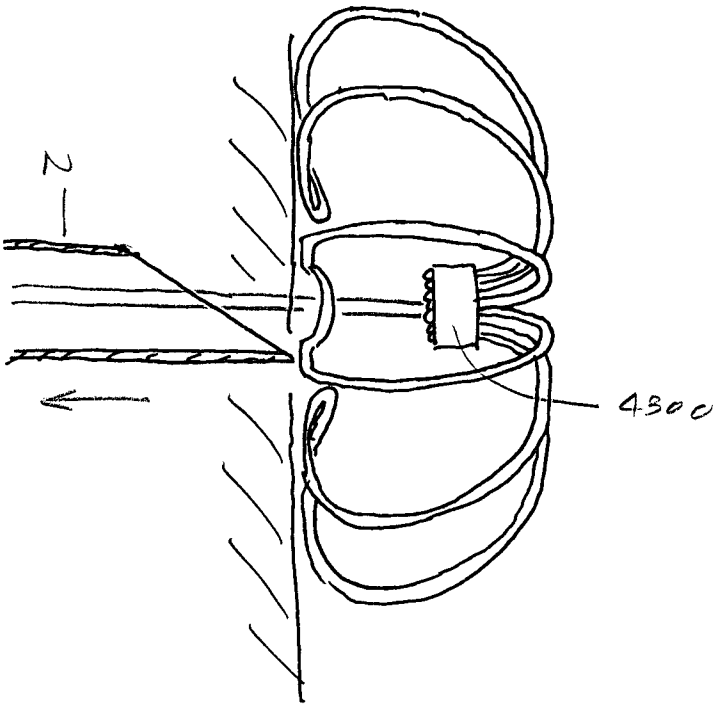

FIG. 24G

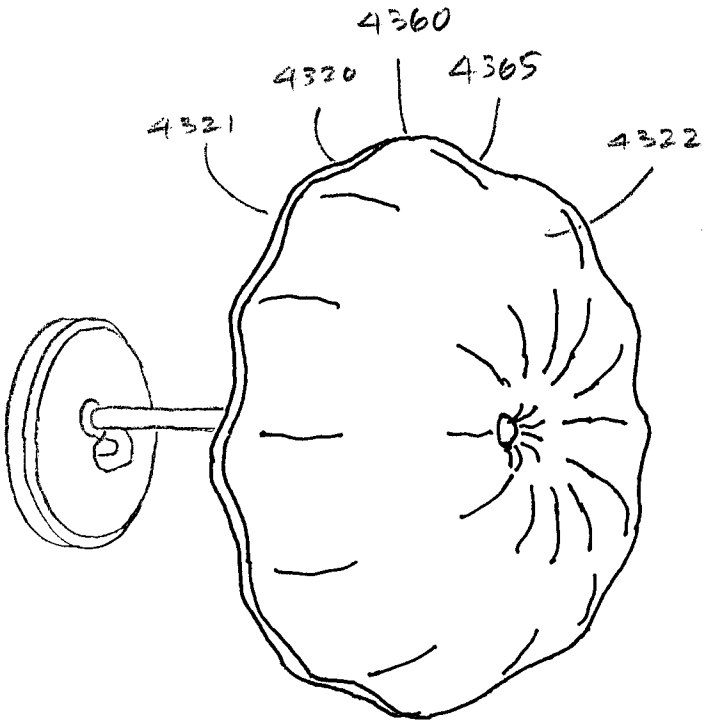

FIG. 24H

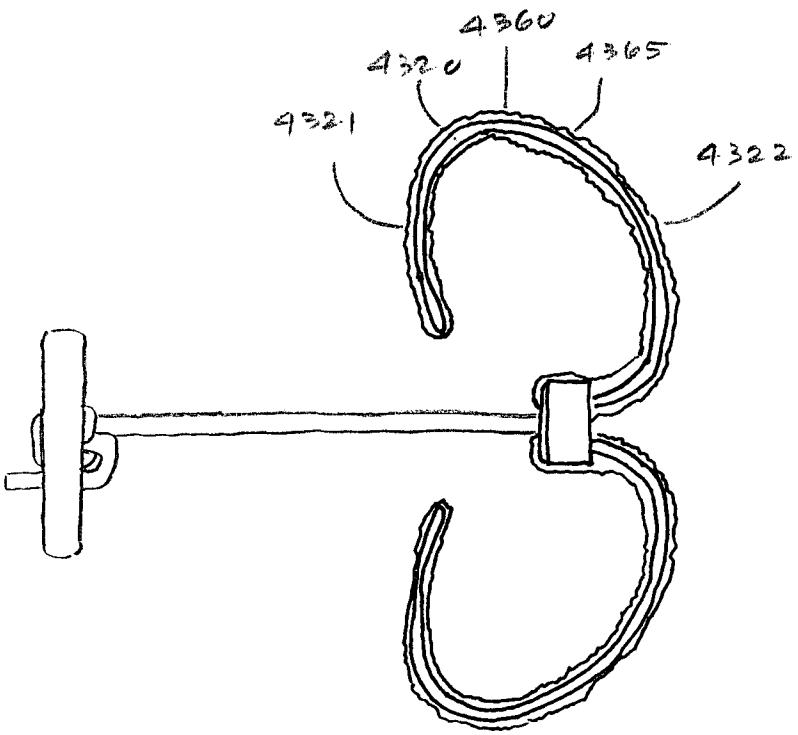

FIG. 24I

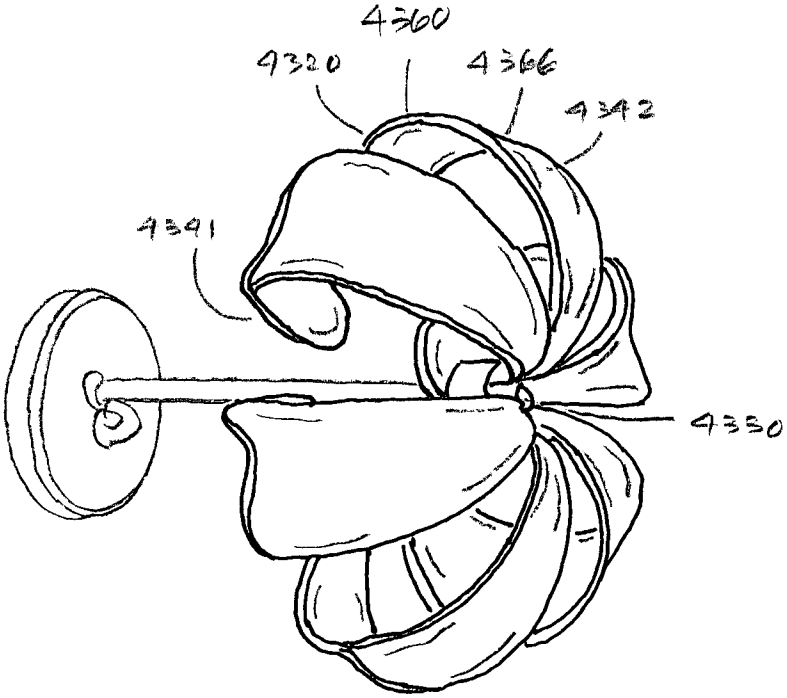

FIG. 24J

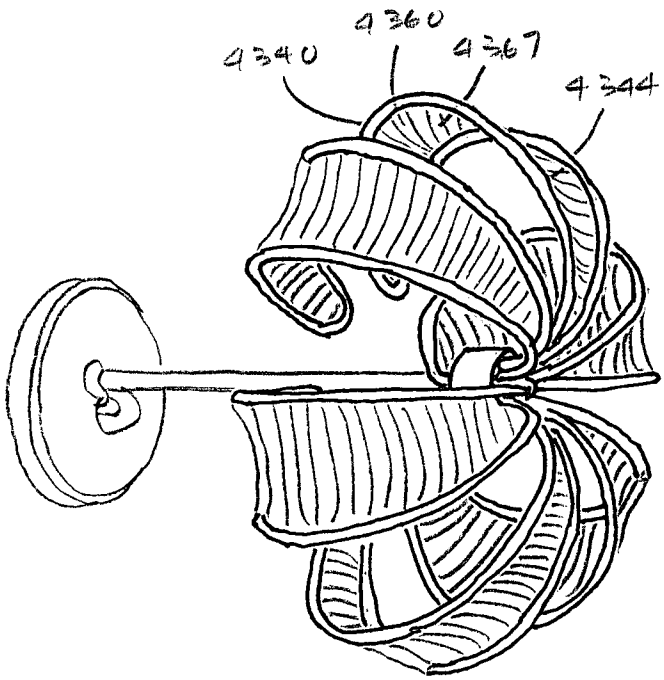

FIG. 24K

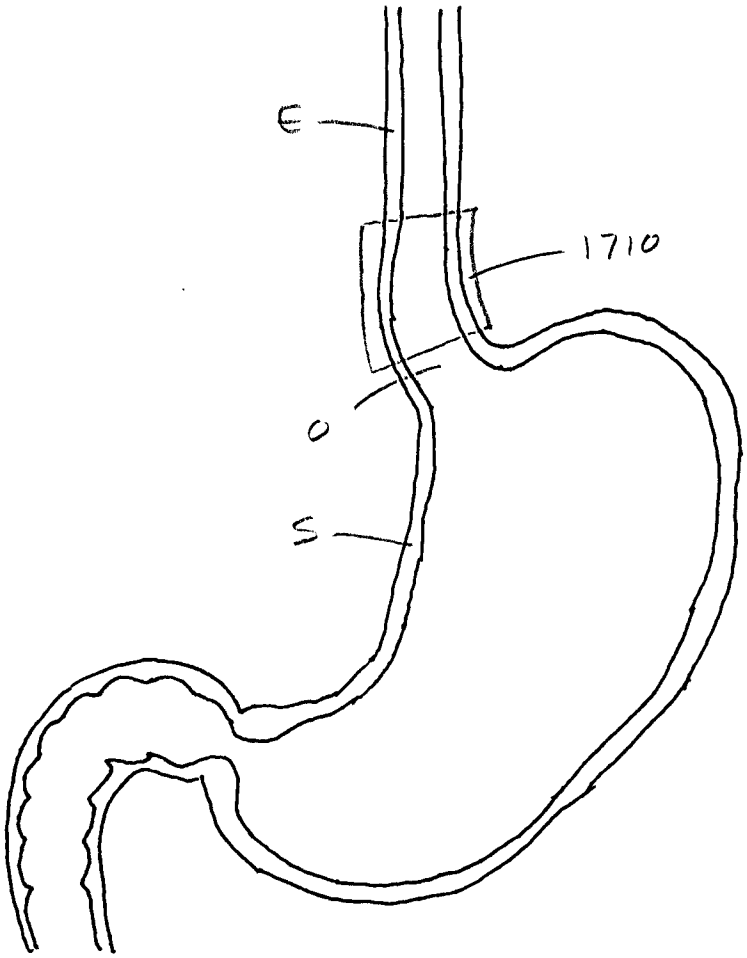

FIG. 25A

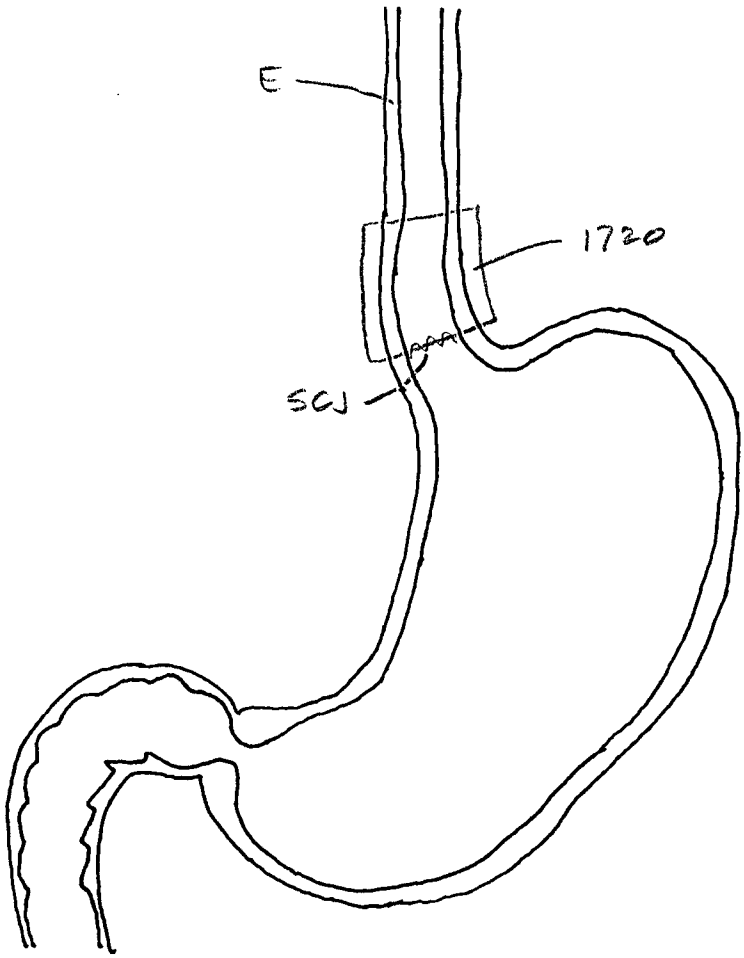

FIG. 25B

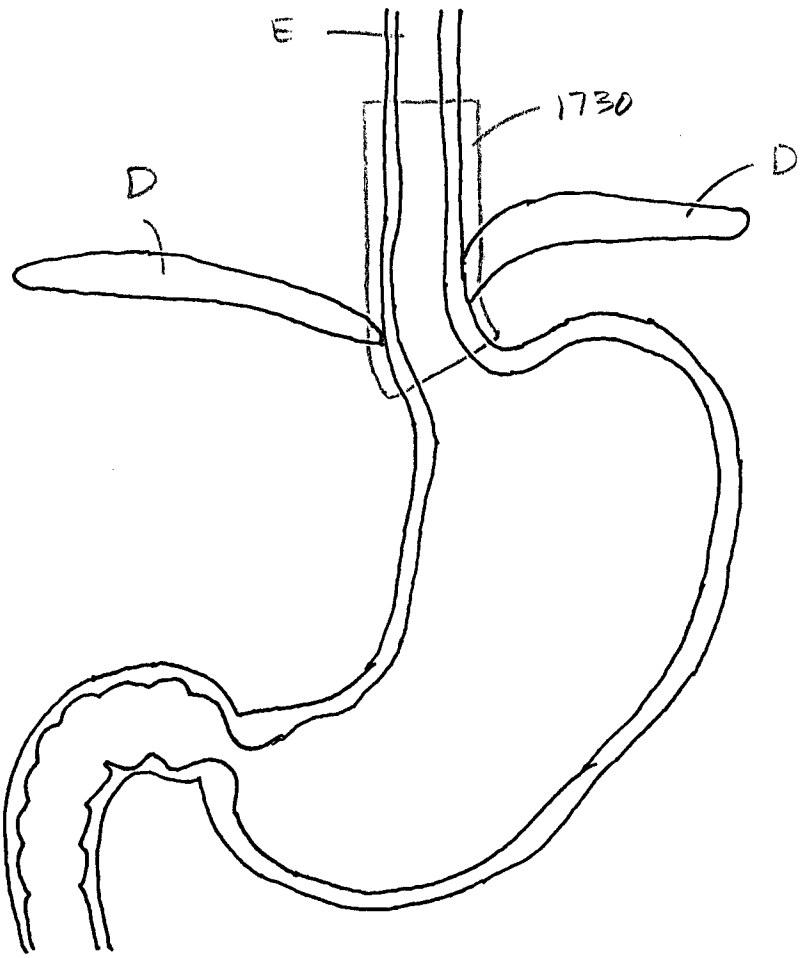

FIG. 25C

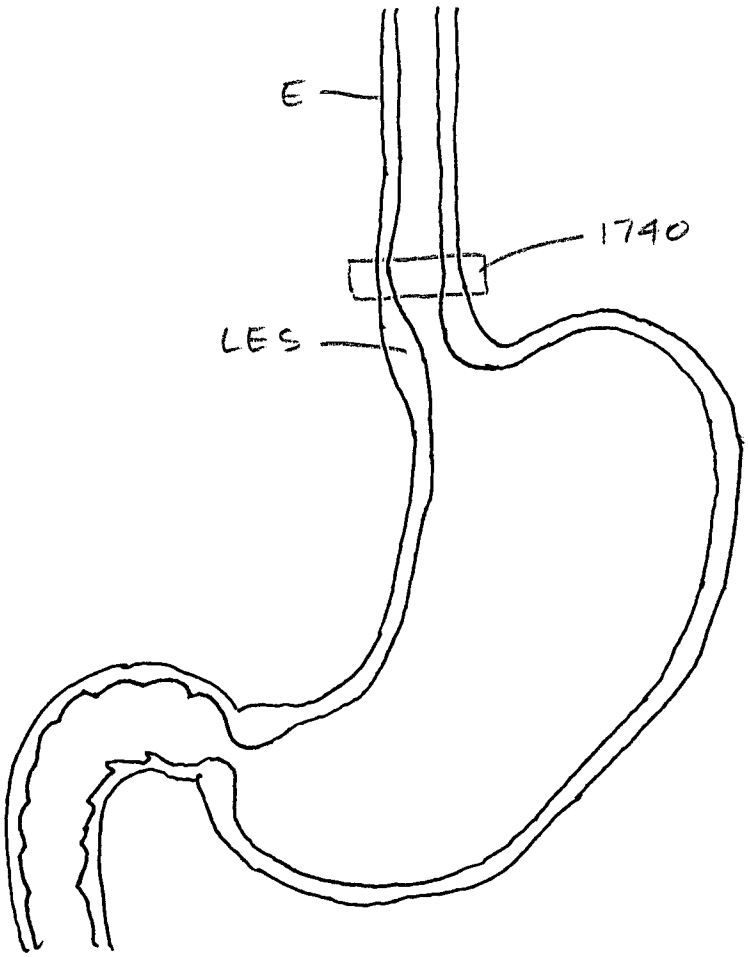

FIG. 25D