US 20090024143A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2009/0024143 A1**

(43) **Pub. Date: Jan. 22, 2009**

Crews et al.

(54) **ENDOSCOPIC IMPLANT SYSTEM AND METHOD**

(76) Inventors: **Samuel T. Crews**, Woodside, CA (US); **Bretton Swope**, Gaithersburg, MD (US); **Justen England**, San Francisco, CA (US)

Correspondence Address:
STALLMAN & POLLOCK LLP
353 SACRAMENTO STREET, SUITE 2200
SAN FRANCISCO, CA 94111 (US)

(21) Appl. No.: **12/175,242**

(22) Filed: **Jul. 17, 2008**

Related U.S. Application Data

(60) Provisional application No. 60/950,584, filed on Jul. 18, 2007, provisional application No. 61/042,862, filed on Apr. 7, 2008.

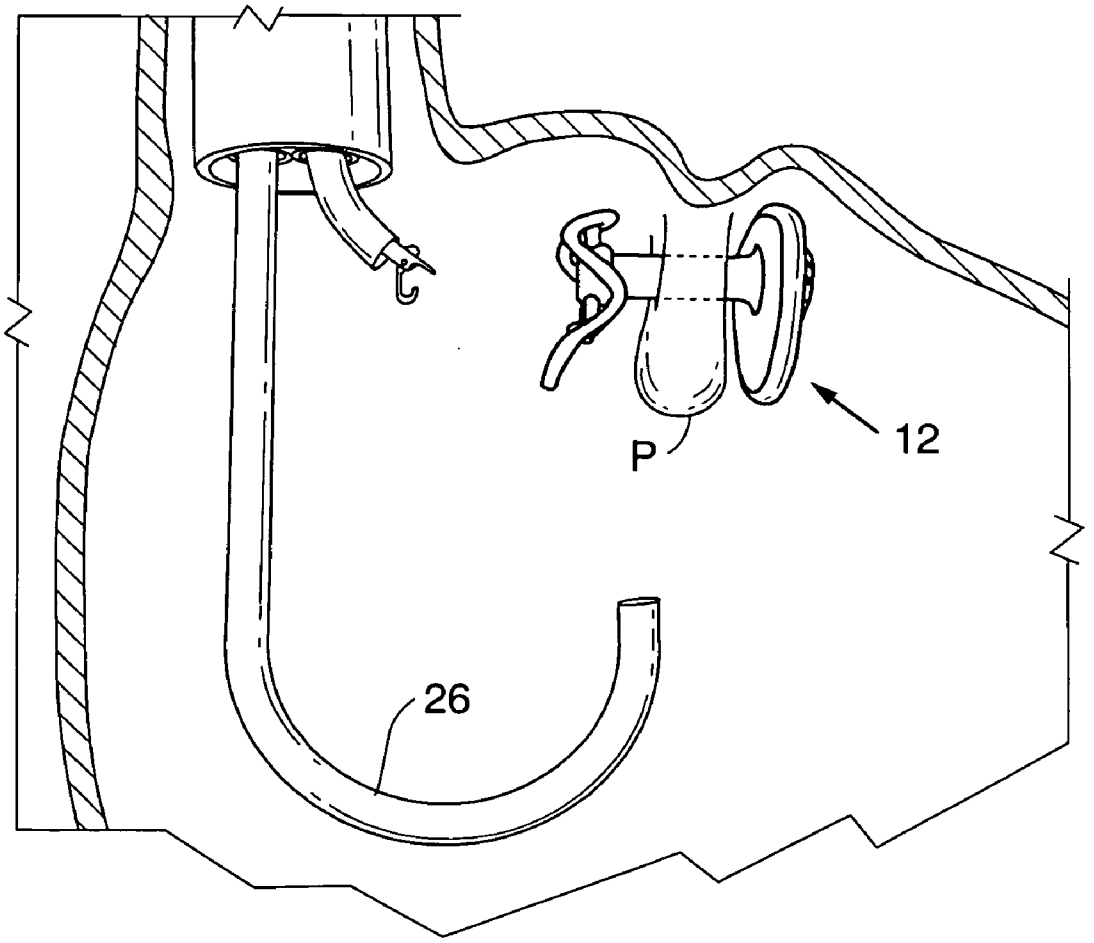
Publication Classification

(51) **Int. Cl.**
A61B 17/122 (2006.01)
A61B 17/32 (2006.01)

(52) **U.S. Cl.** **606/139**; 606/167

(57) **ABSTRACT**

Disclosed is a system for endoscopically implanting a medical implant within a body cavity such as a human stomach. The system includes one or more anchors positionable within one or more openings formed in tissue within the body cavity, such as cutouts formed in plicated body tissue. Tools are disclosed for positioning the anchors within the openings, and for coupling the implant to the anchors.



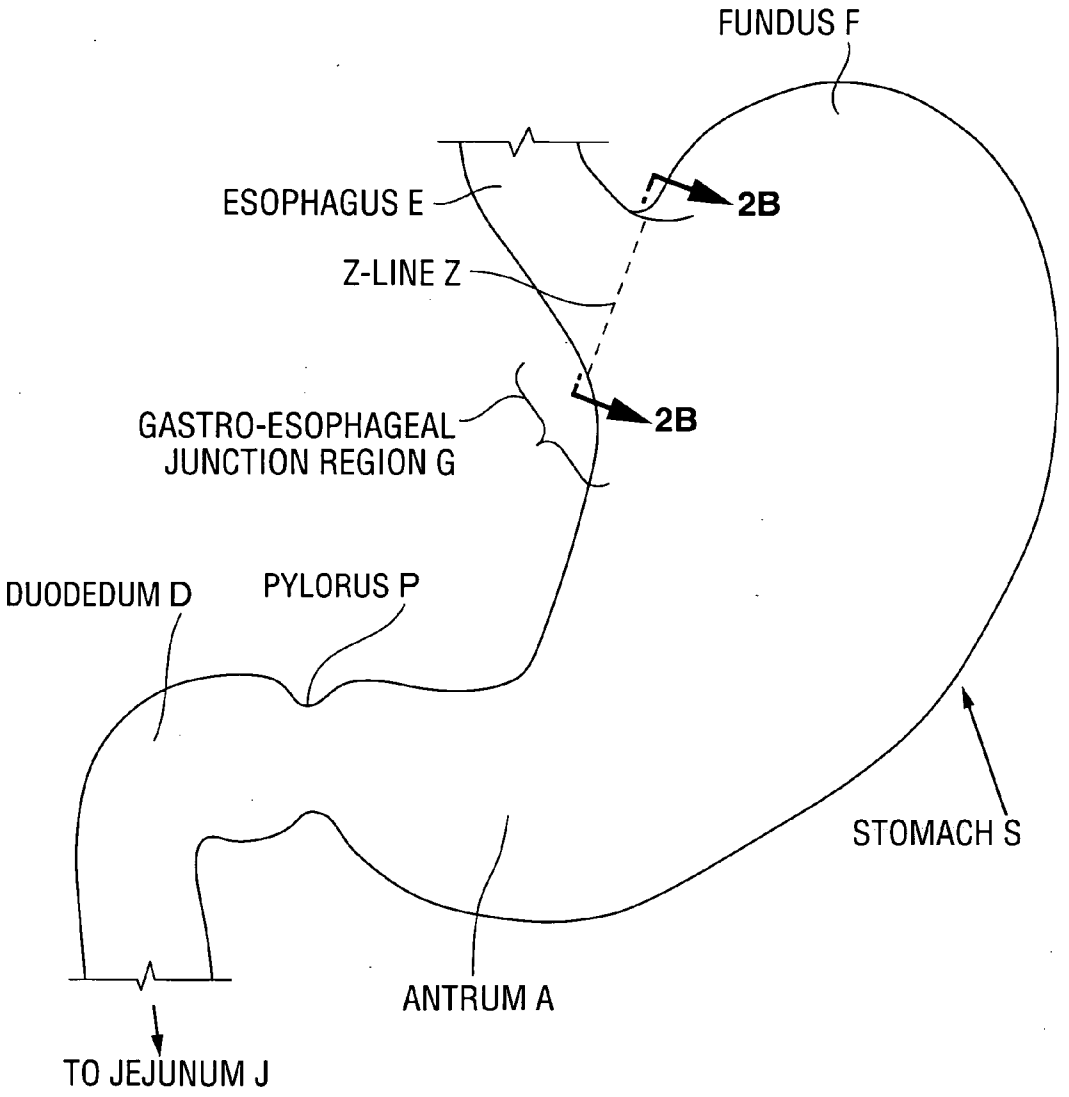

FUNDUS F
ESOPHAGUS E
2B
Z-LINE Z
2B
GASTRO-ESOPHAGEAL
JUNCTION REGION G
DUODEDUM D
PYLORUS P
STOMACH S
ANTRUM A
TO JEJUNUM J

FIG. 1

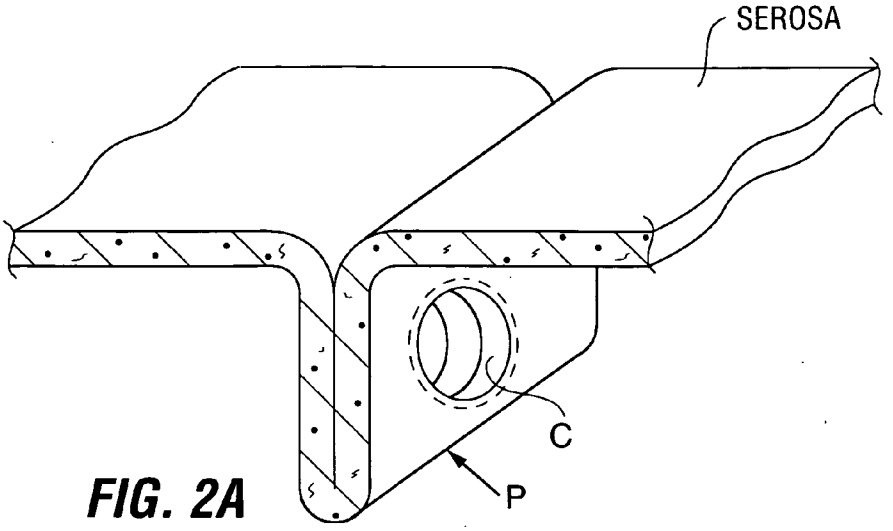


FIG. 2A

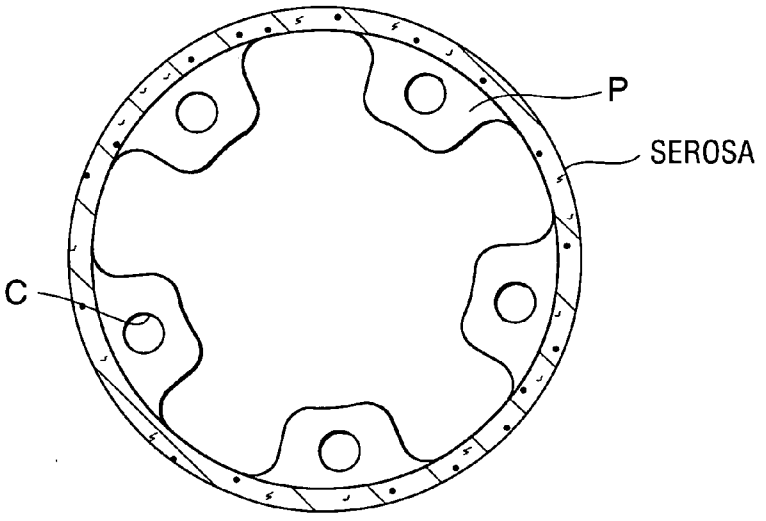


FIG. 2B

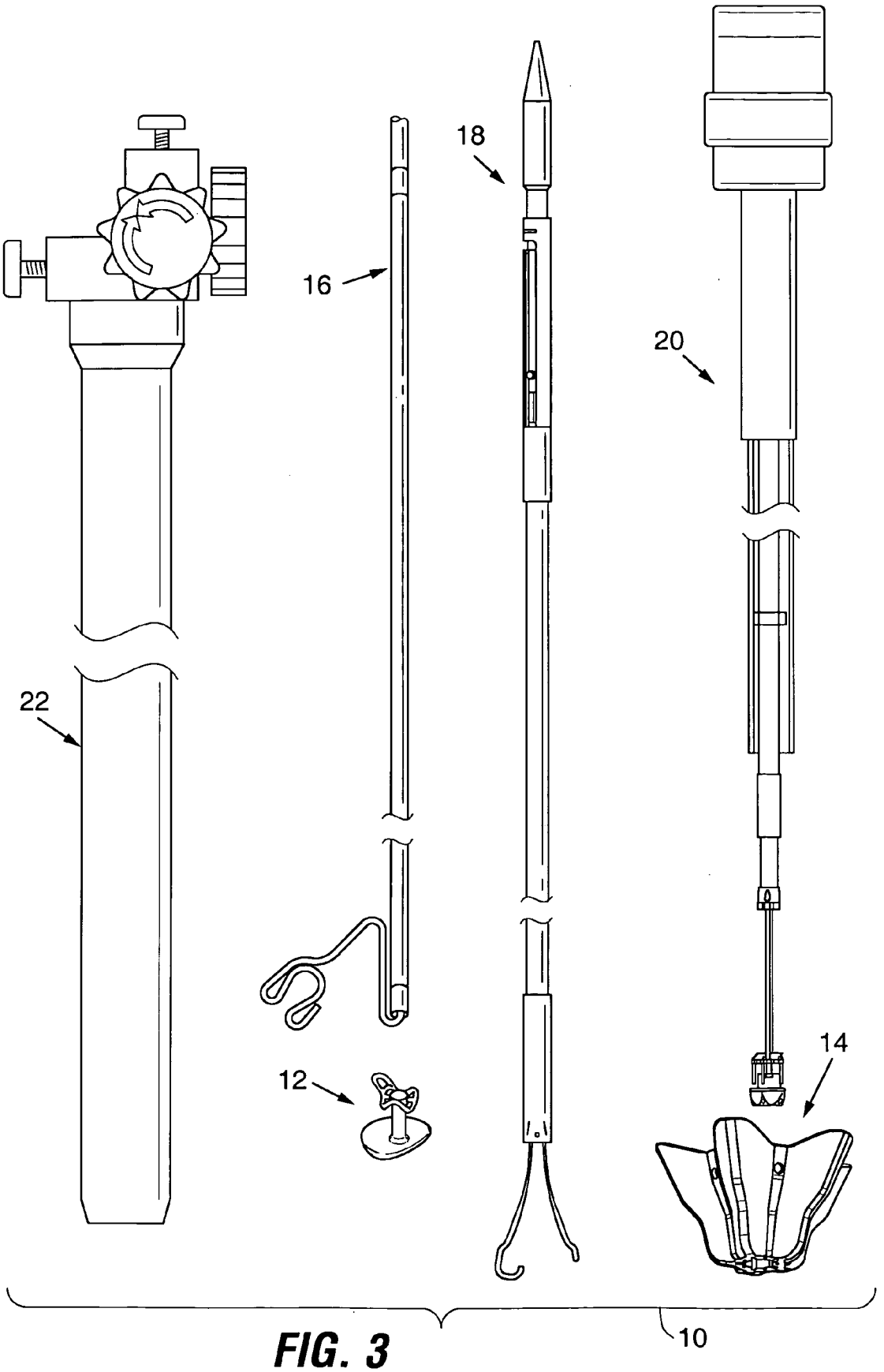


FIG. 3

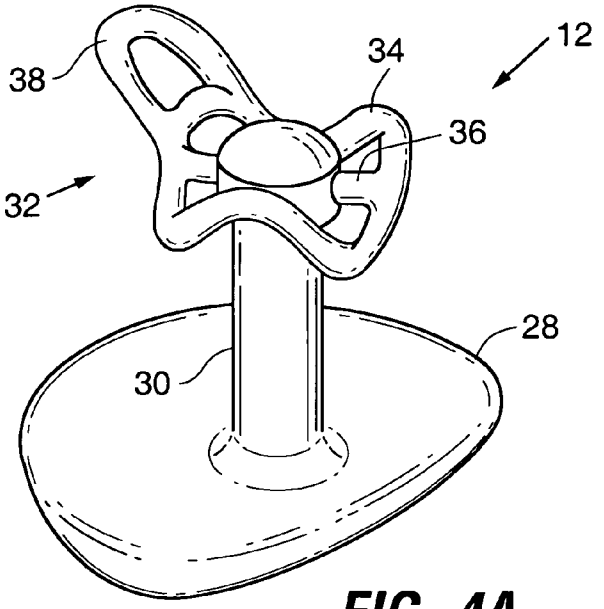


FIG. 4A

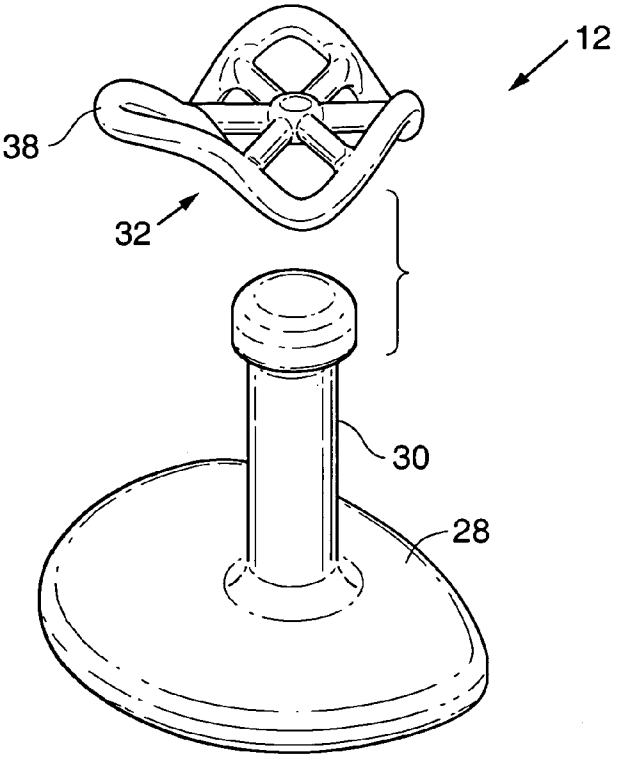


FIG. 4B

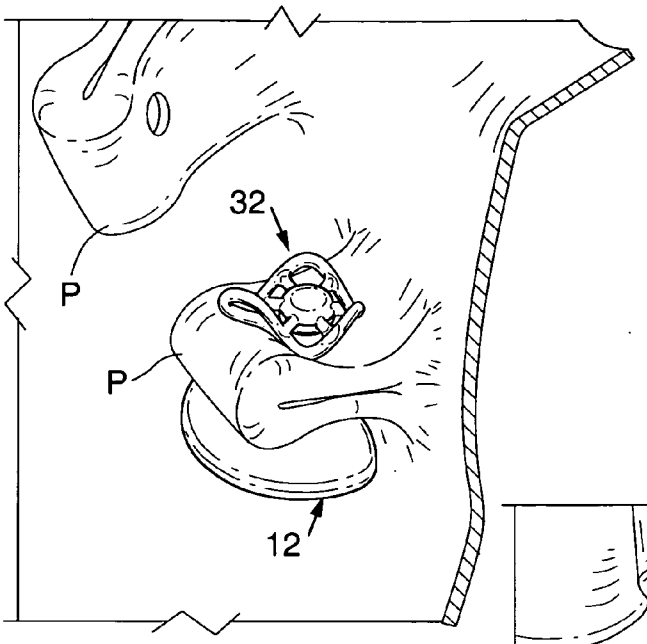


FIG. 5

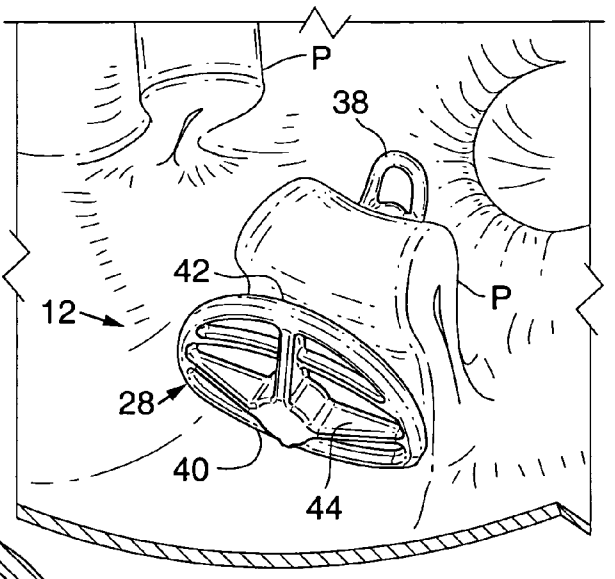


FIG. 6

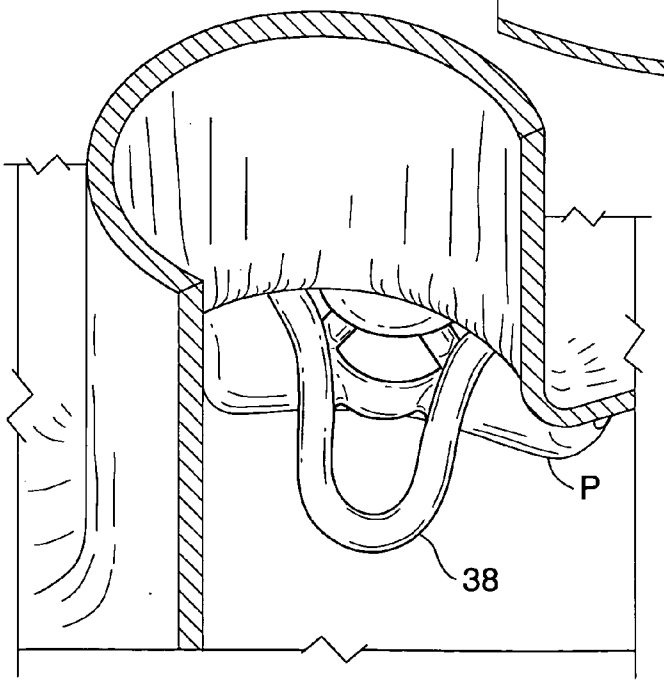


FIG. 7

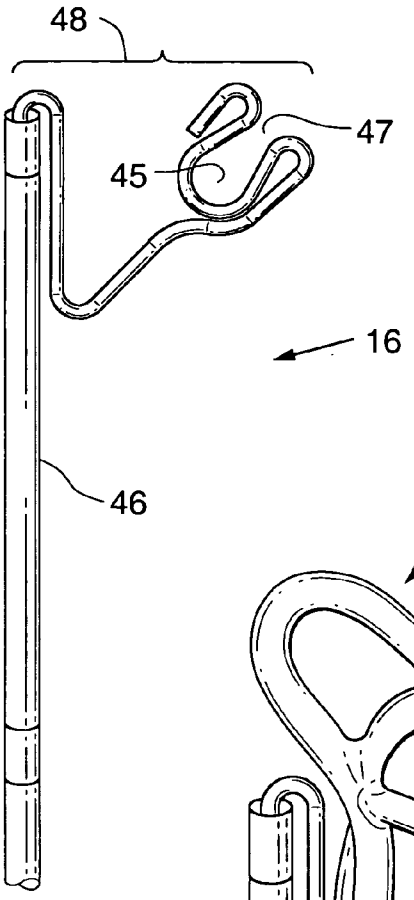


FIG. 8A

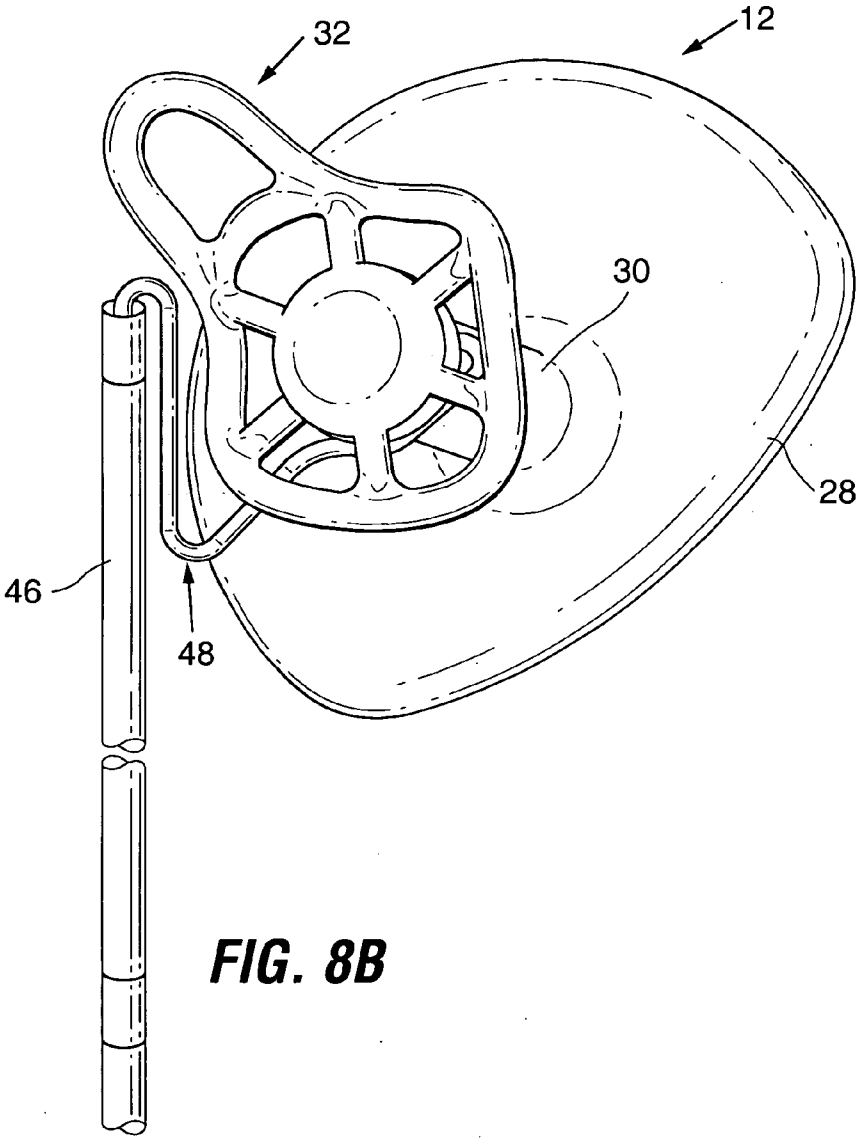


FIG. 8B

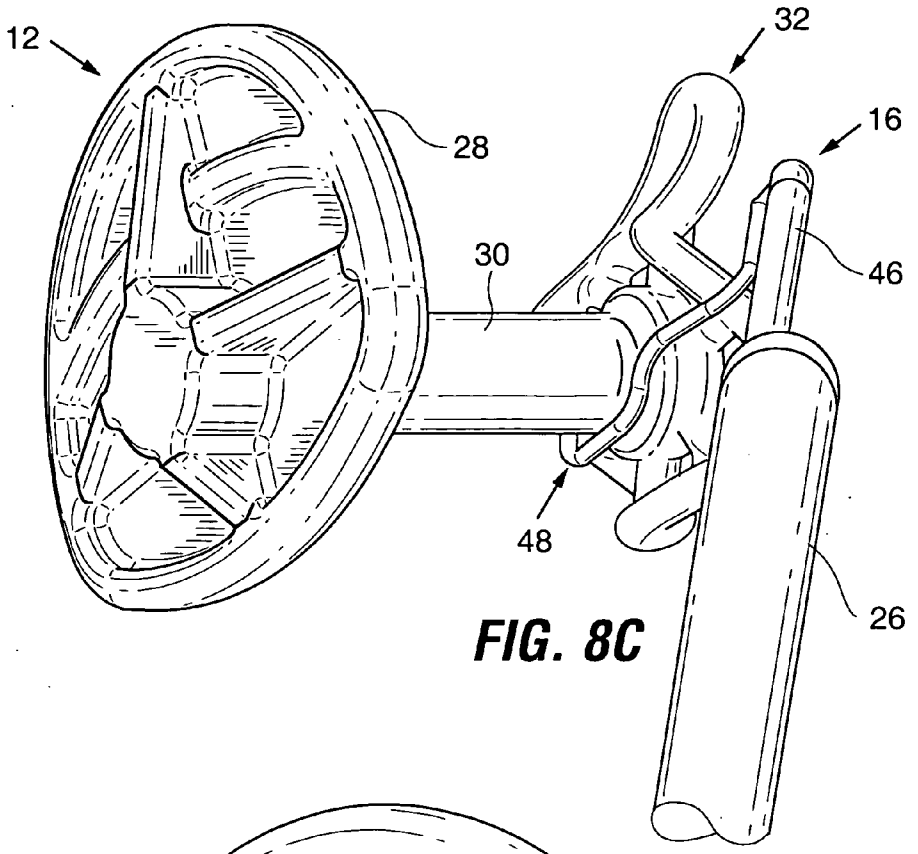


FIG. 8C

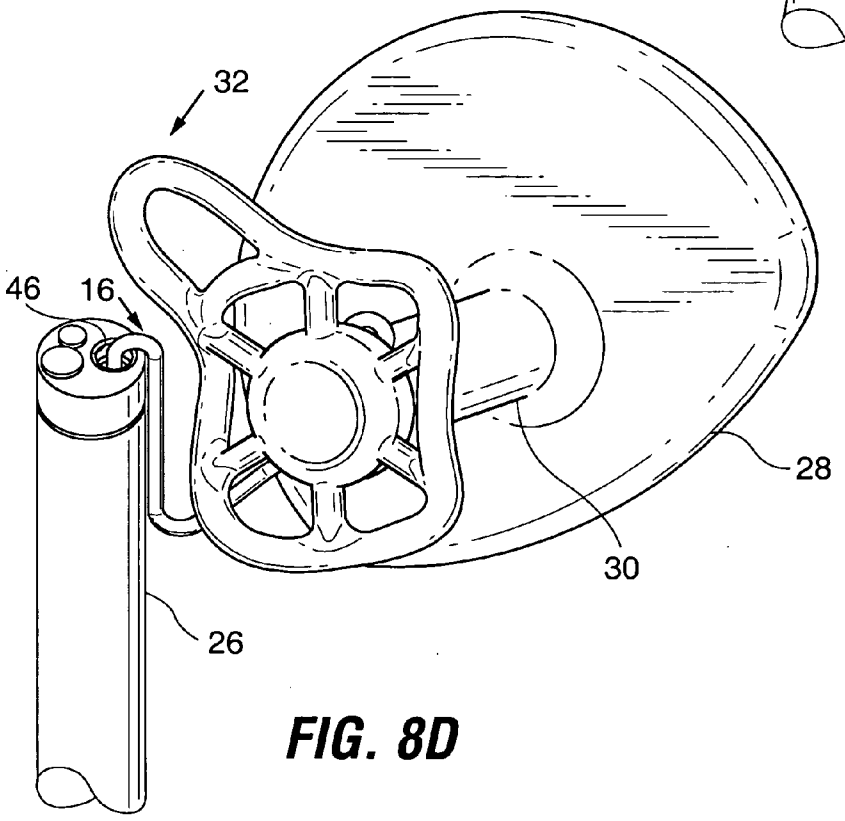


FIG. 8D

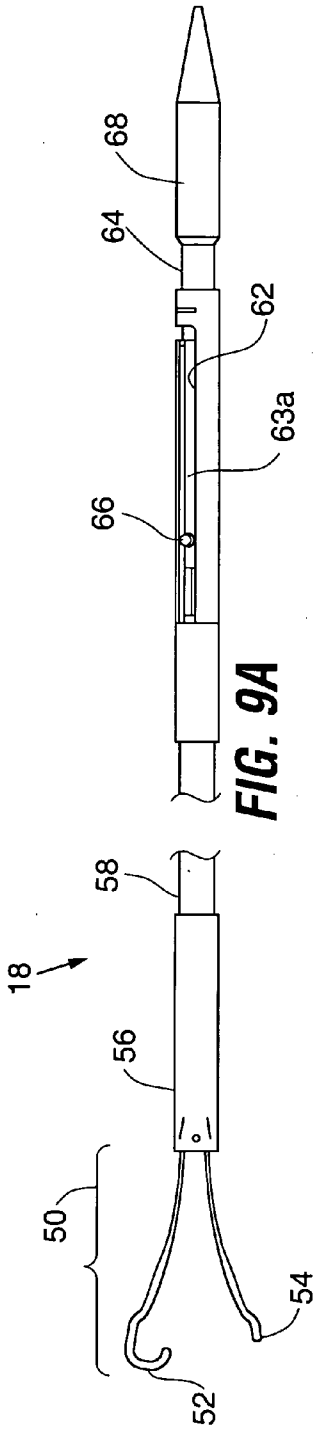


FIG. 9A

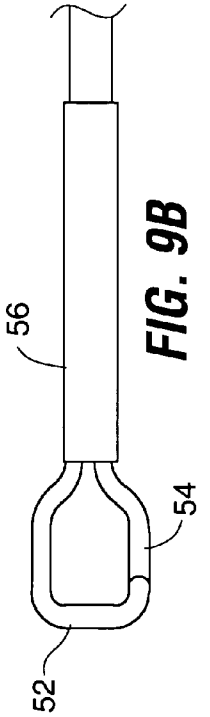


FIG. 9B

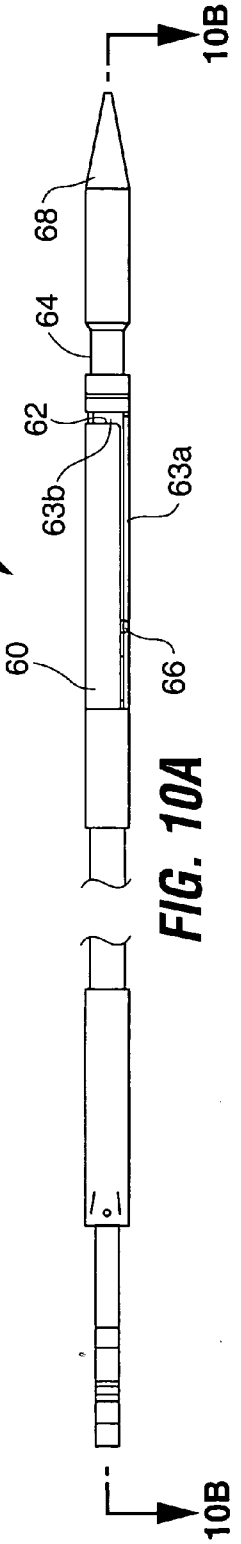


FIG. 10A

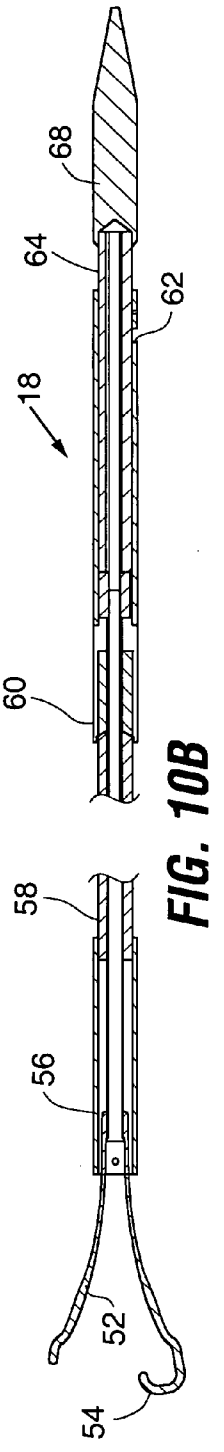


FIG. 10B

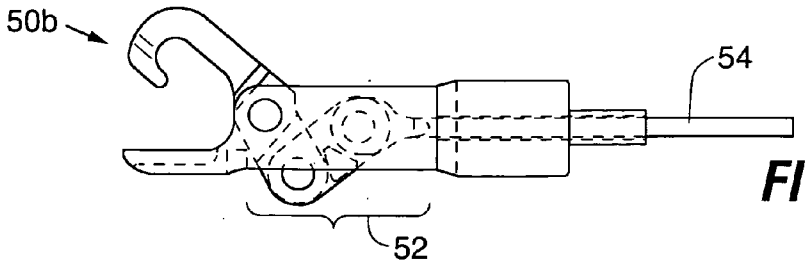


FIG. 11A

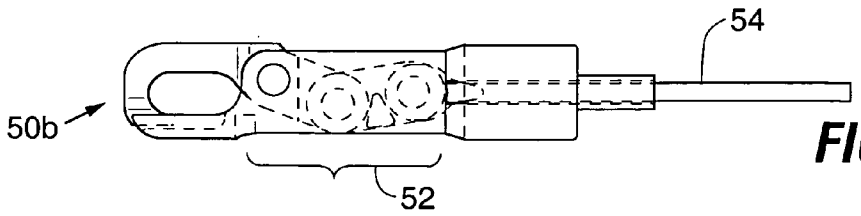


FIG. 11B

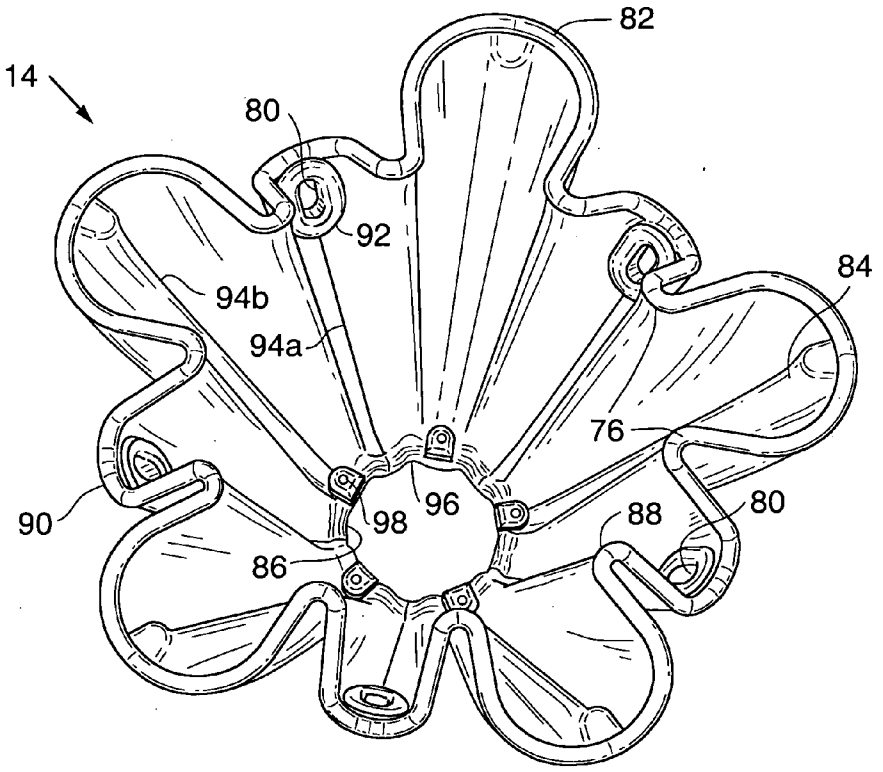


FIG. 12A

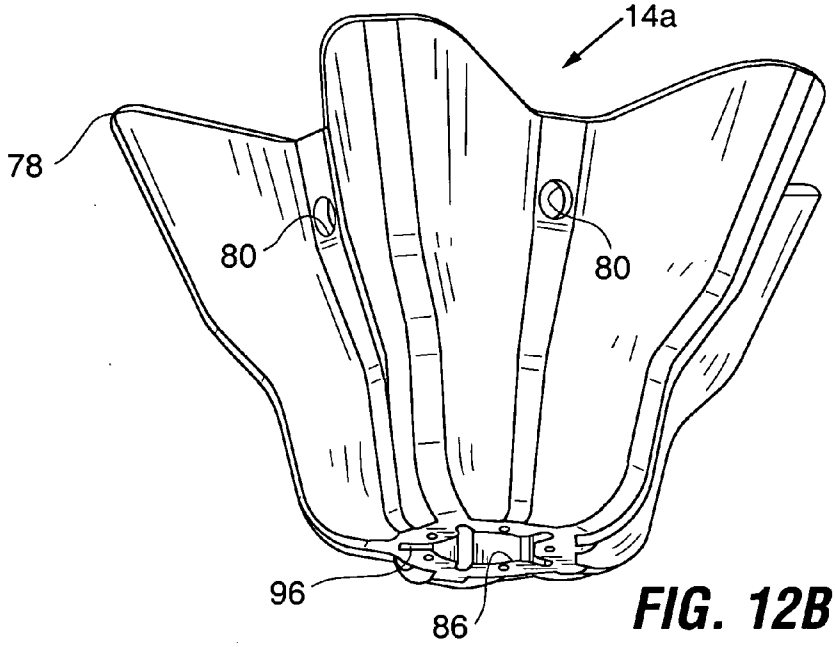


FIG. 12B

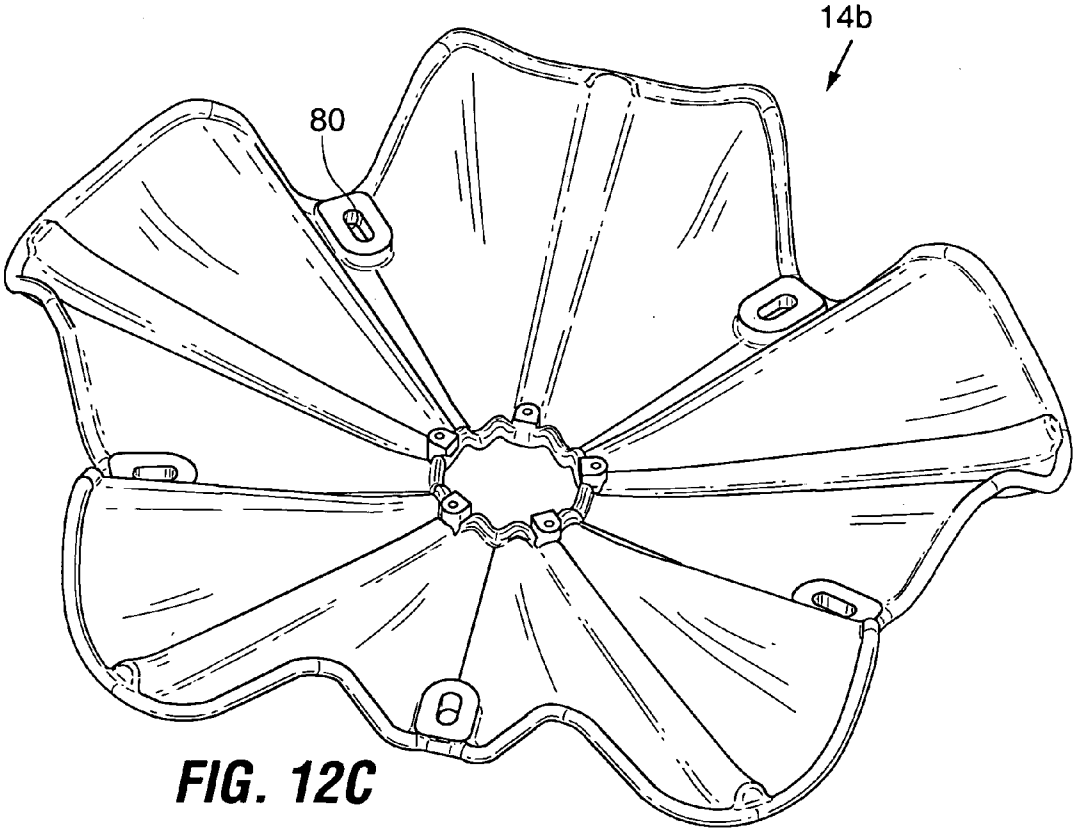


FIG. 12C

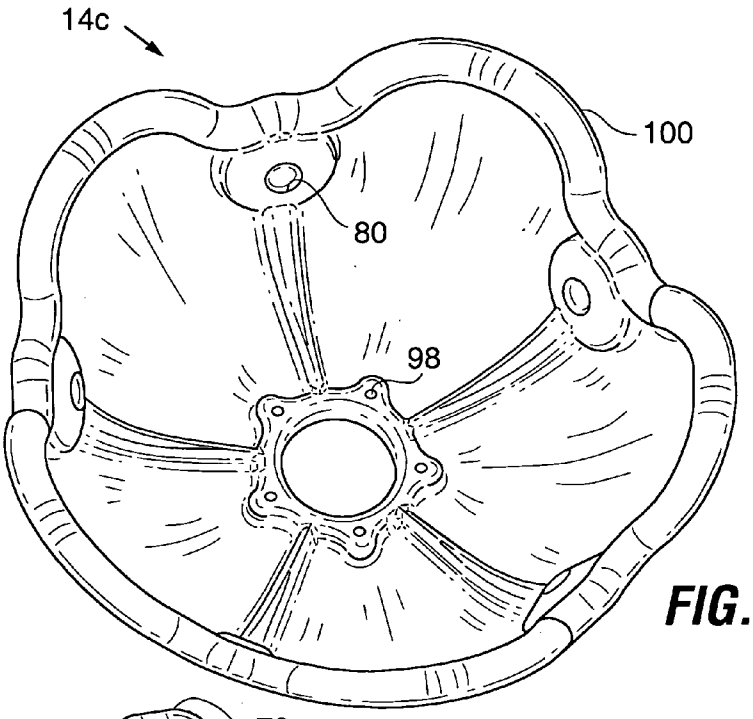


FIG. 13

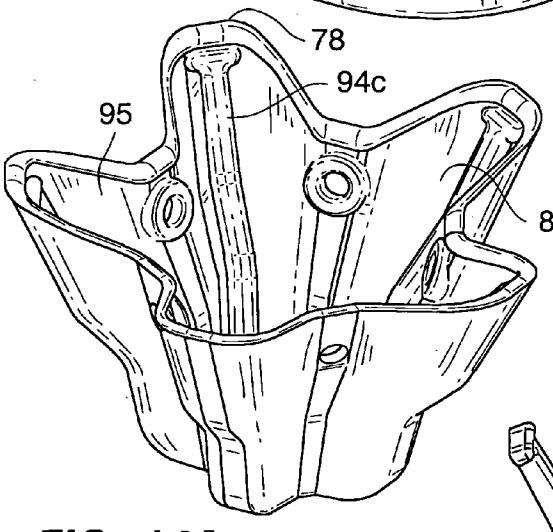


FIG. 14A

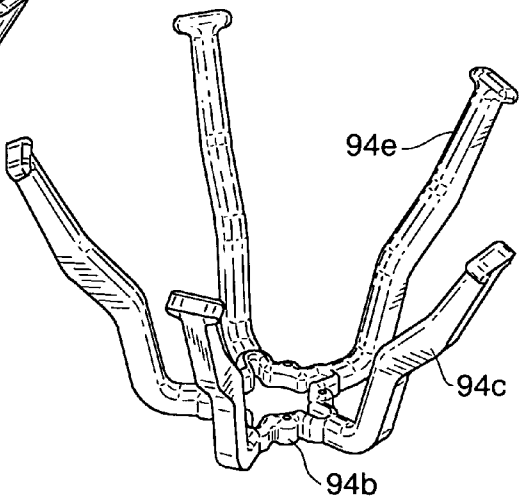


FIG. 14B

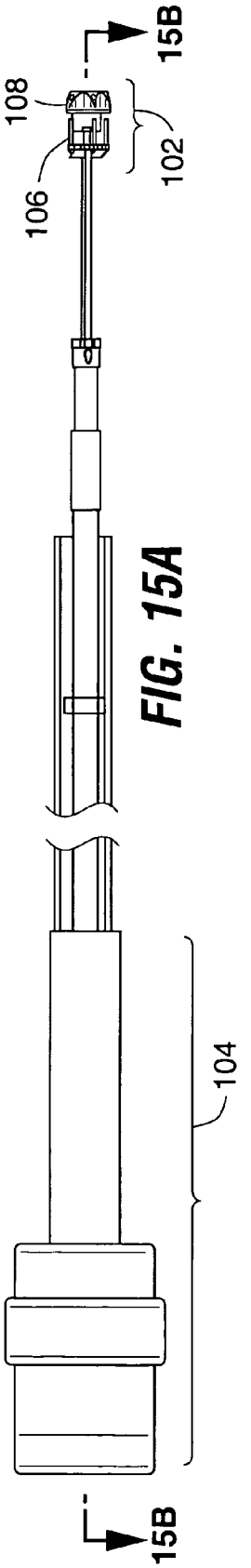


FIG. 15A

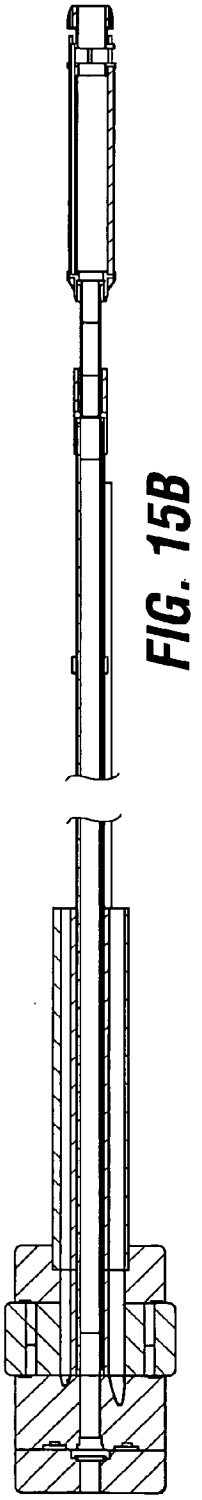


FIG. 15B

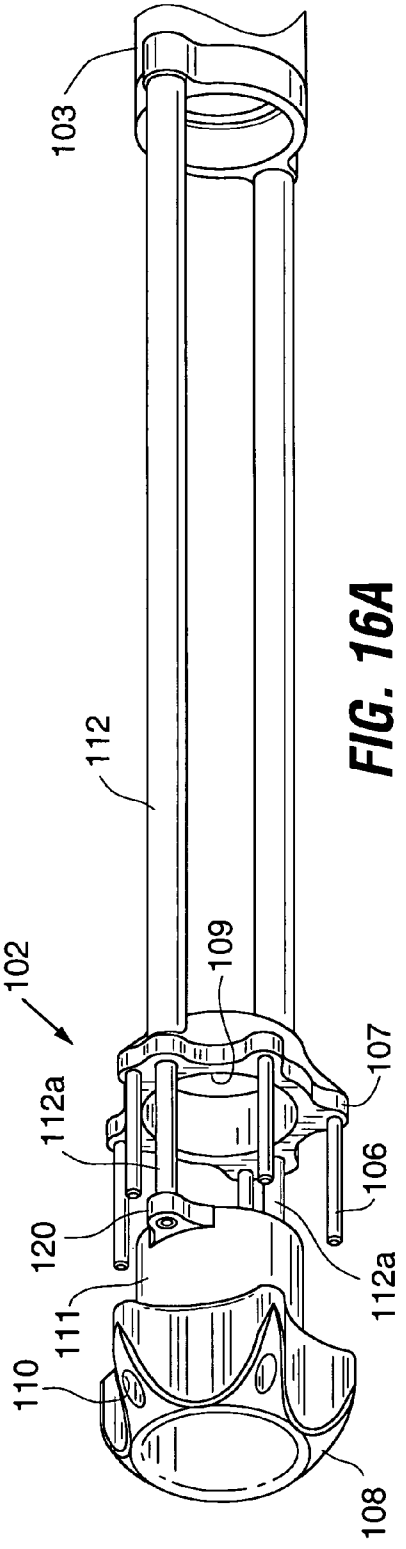


FIG. 16A

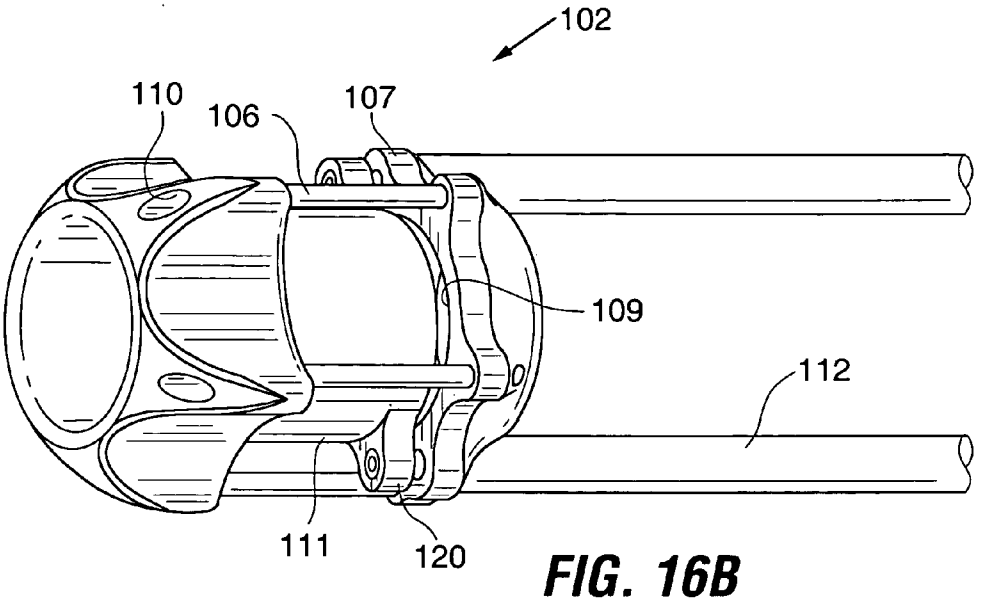


FIG. 16B

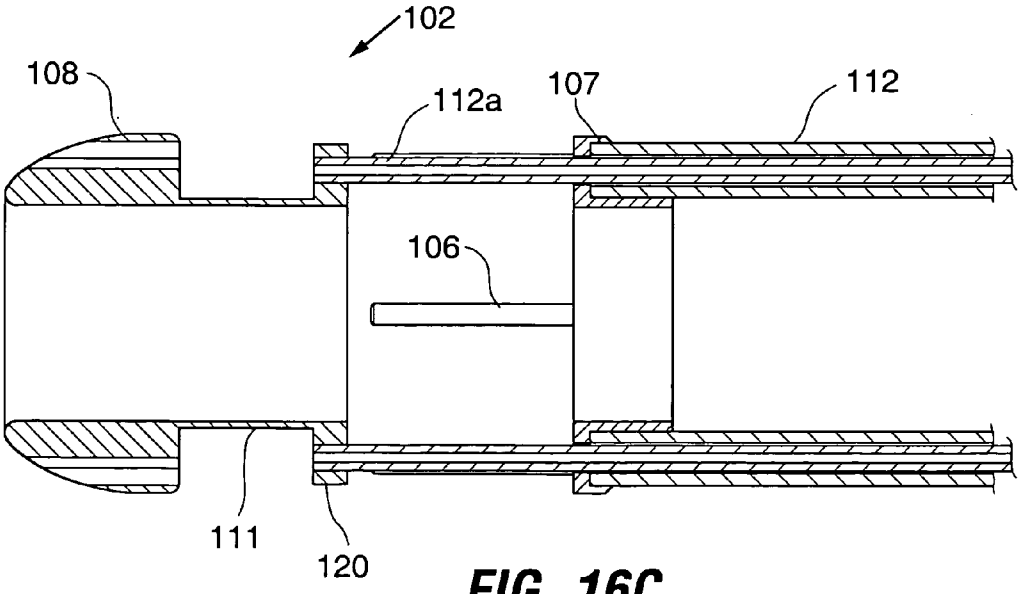


FIG. 16C

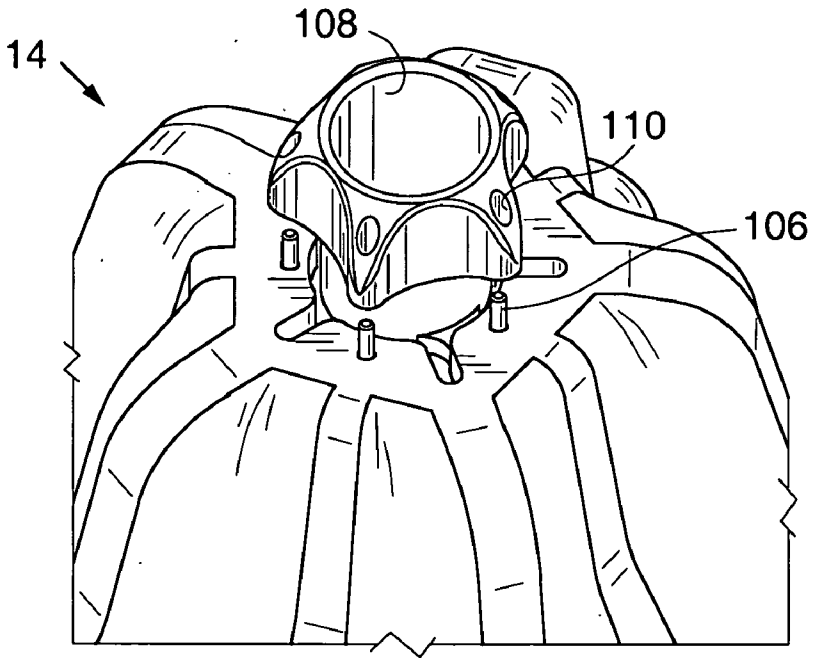


FIG. 17A

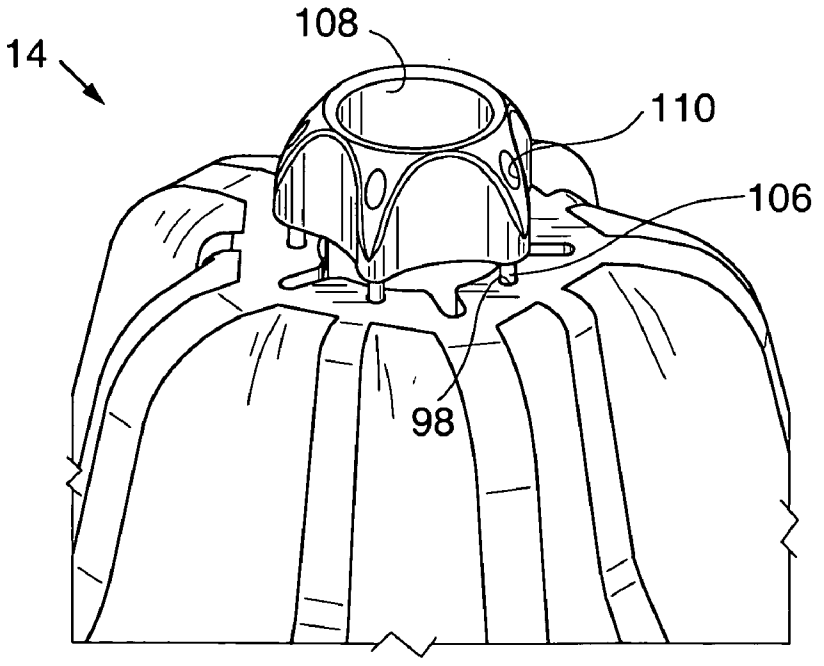


FIG. 17B

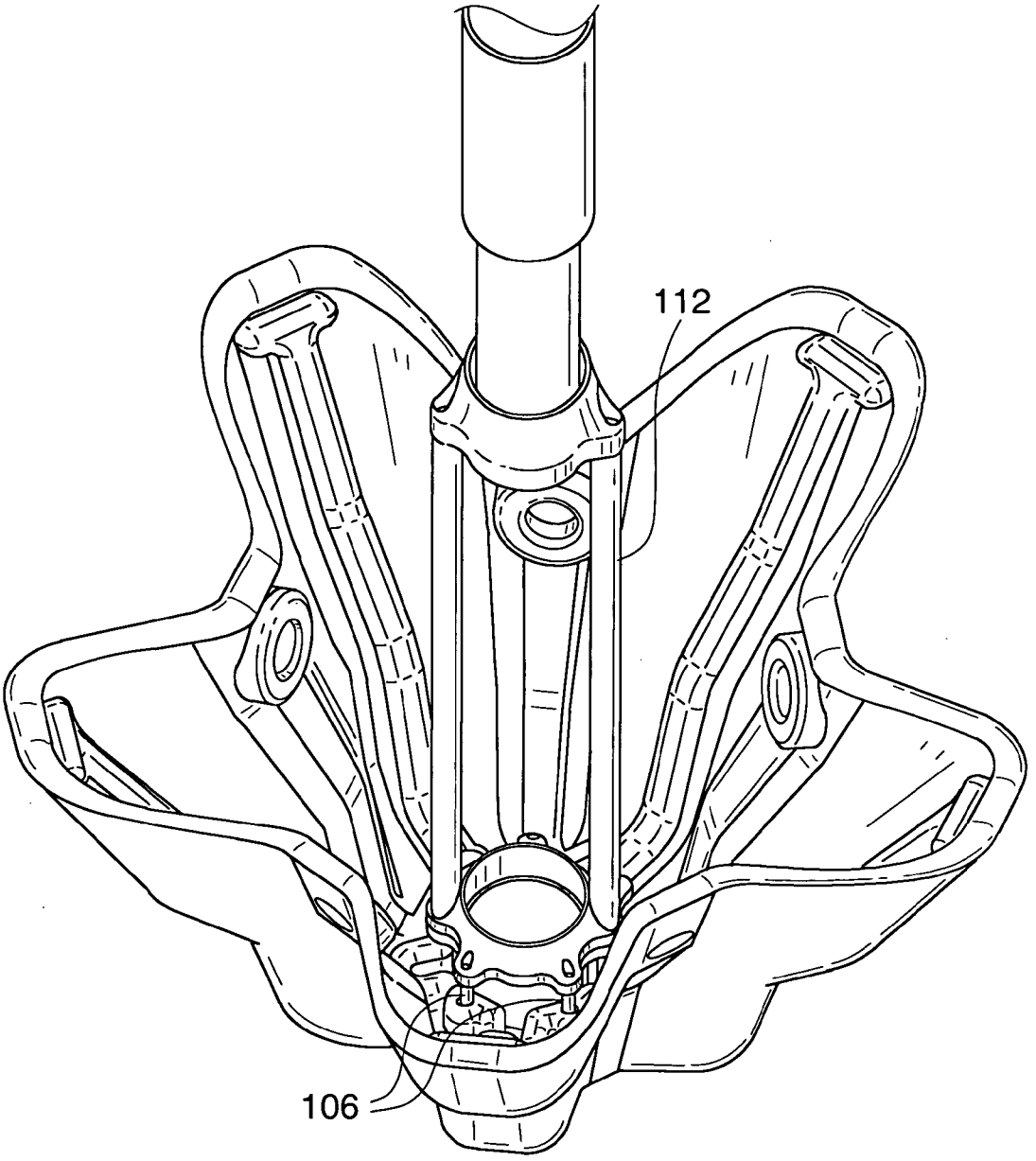


FIG. 17C

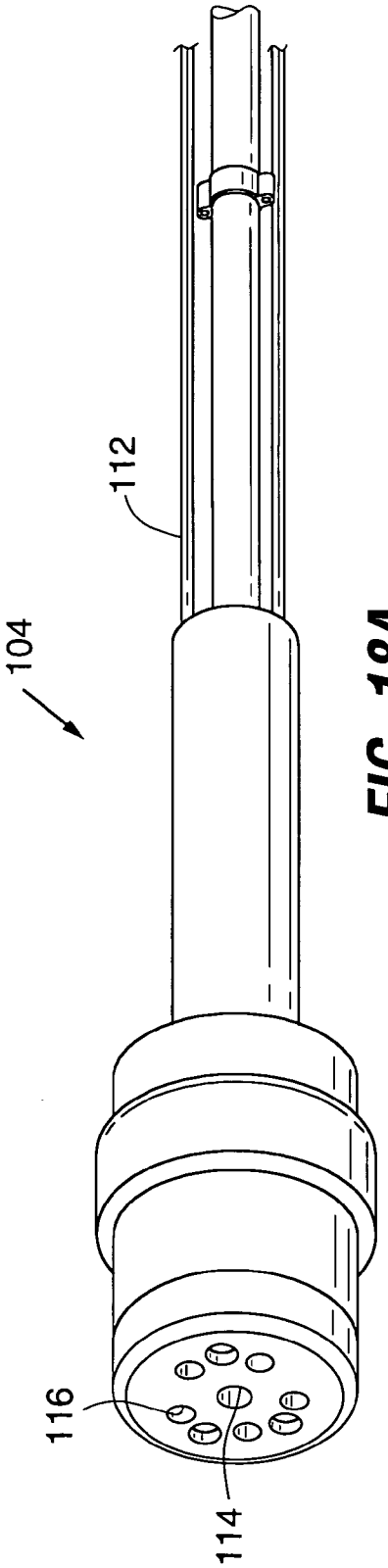


FIG. 18A

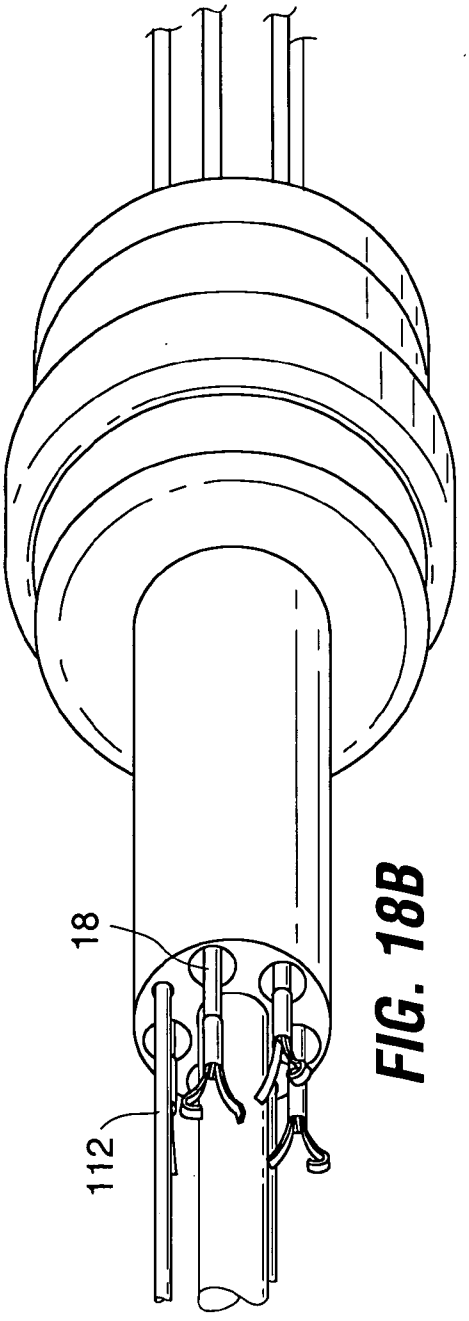


FIG. 18B

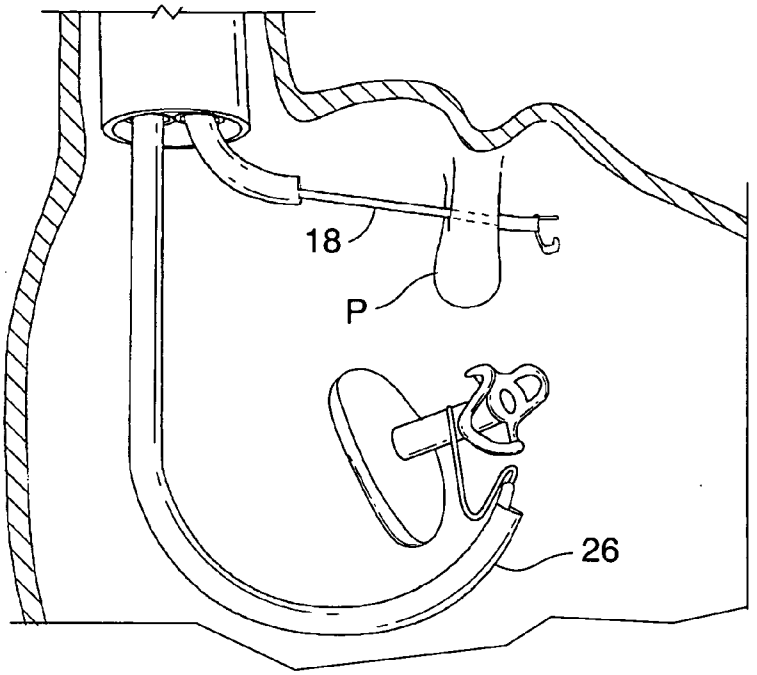


FIG. 19A

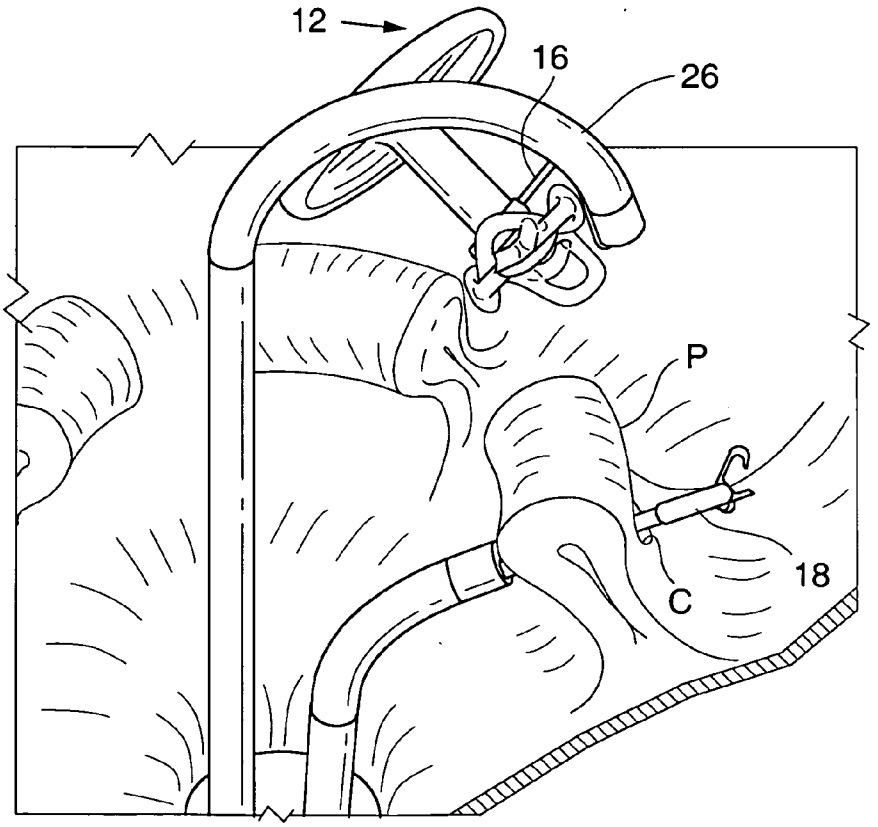


FIG. 19B

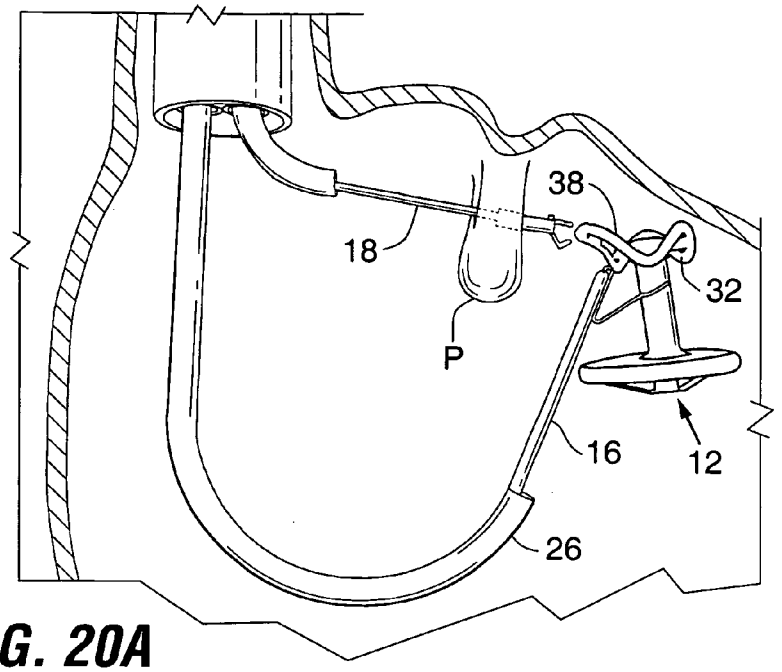


FIG. 20A

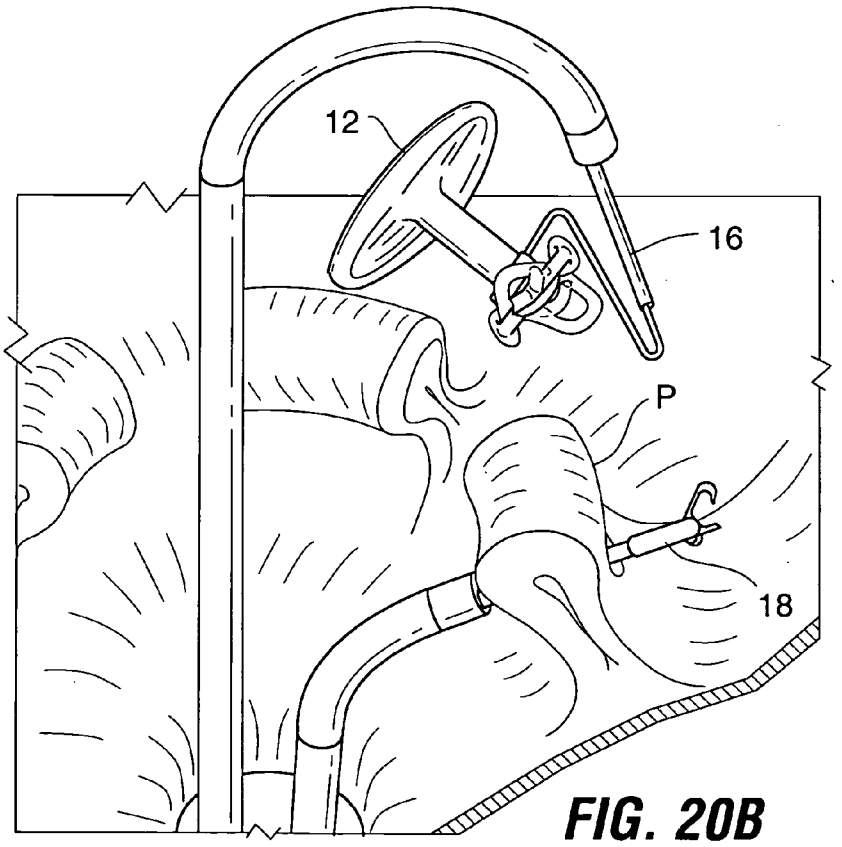


FIG. 20B

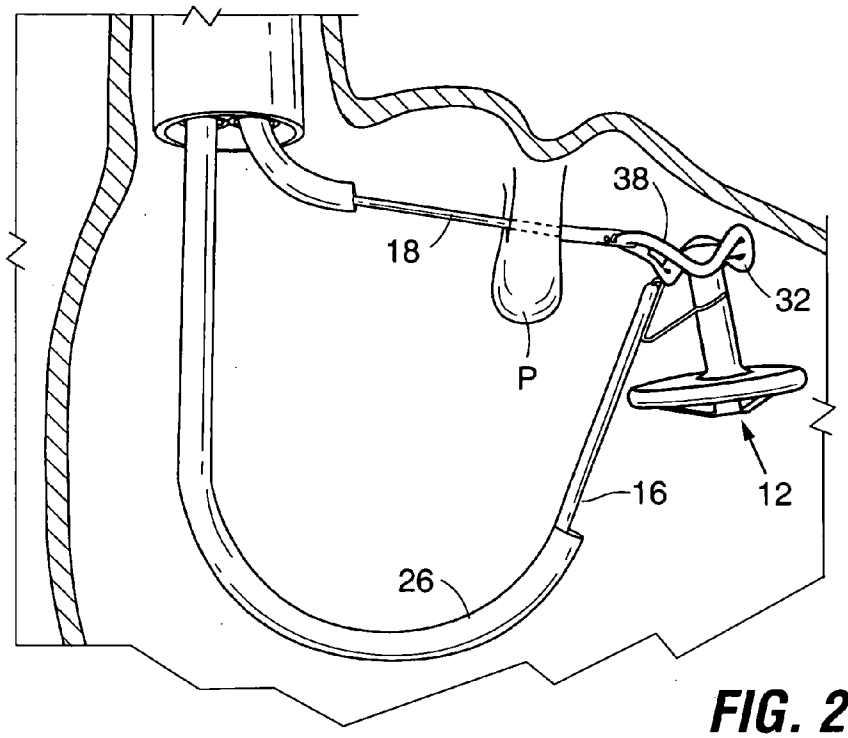


FIG. 20C

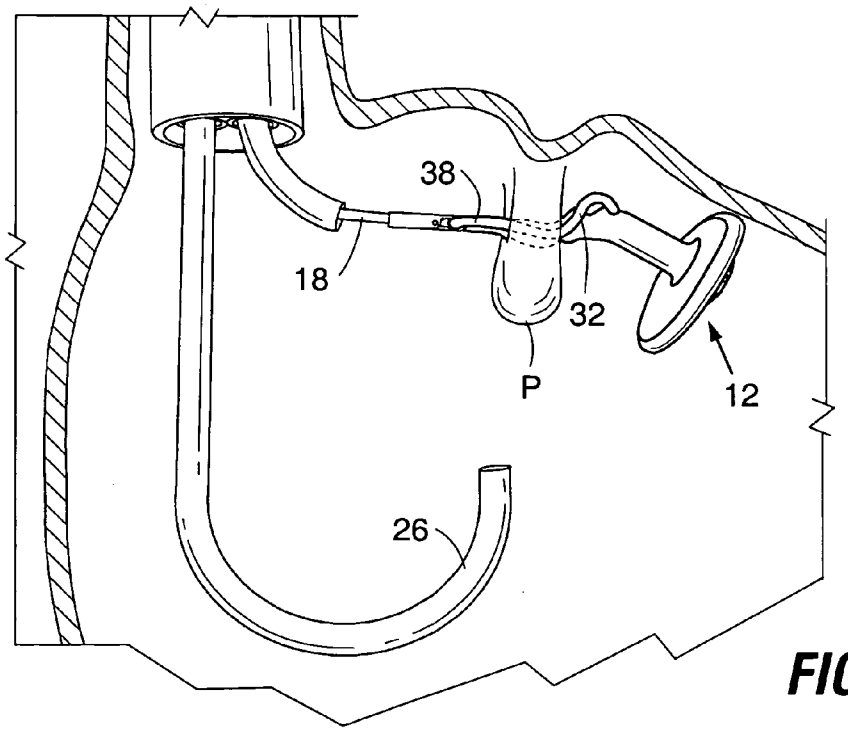


FIG. 20D

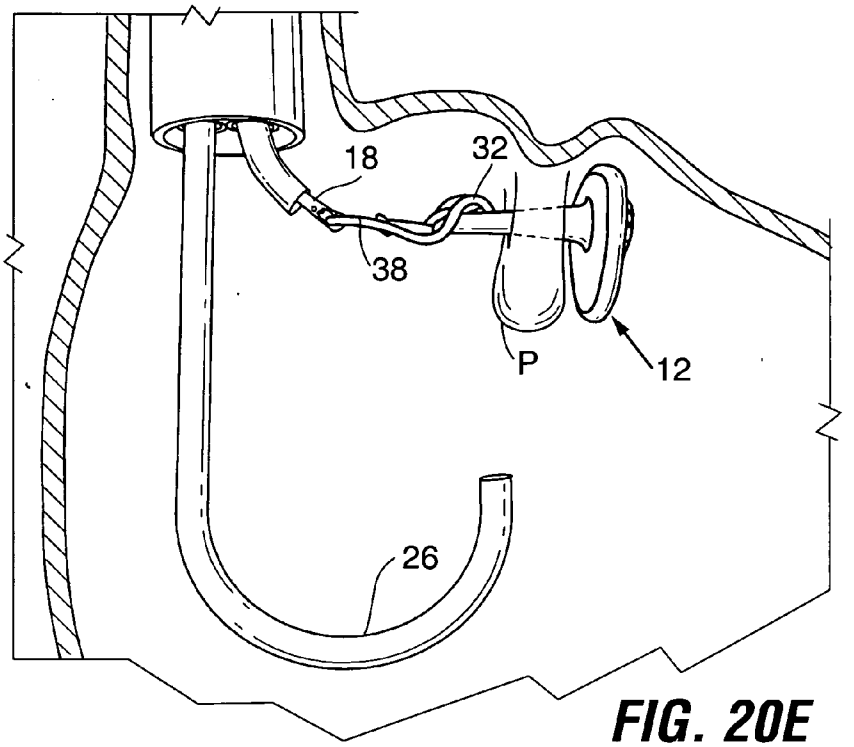


FIG. 20E

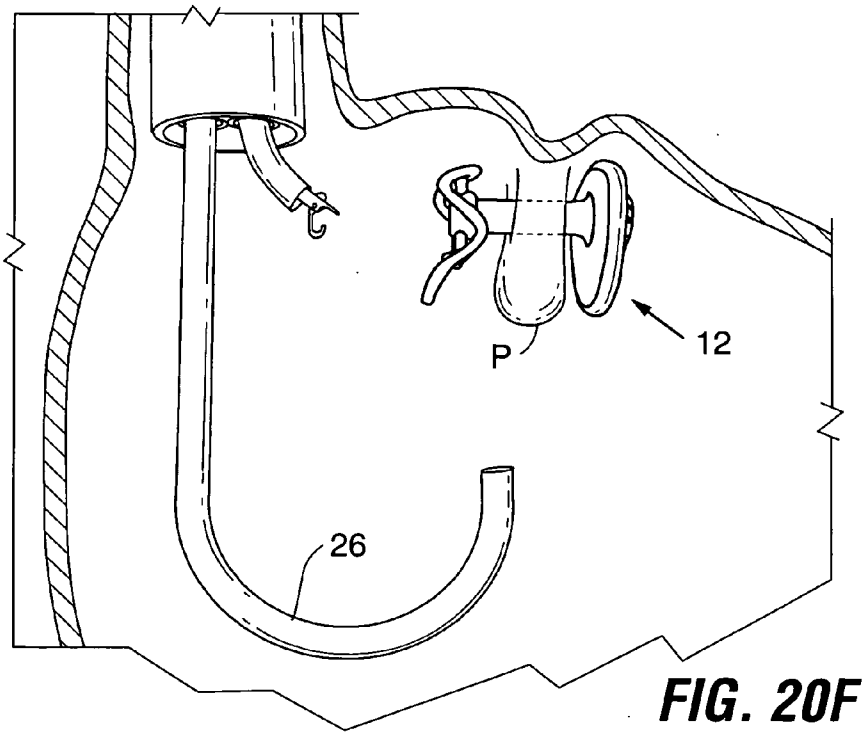


FIG. 20F

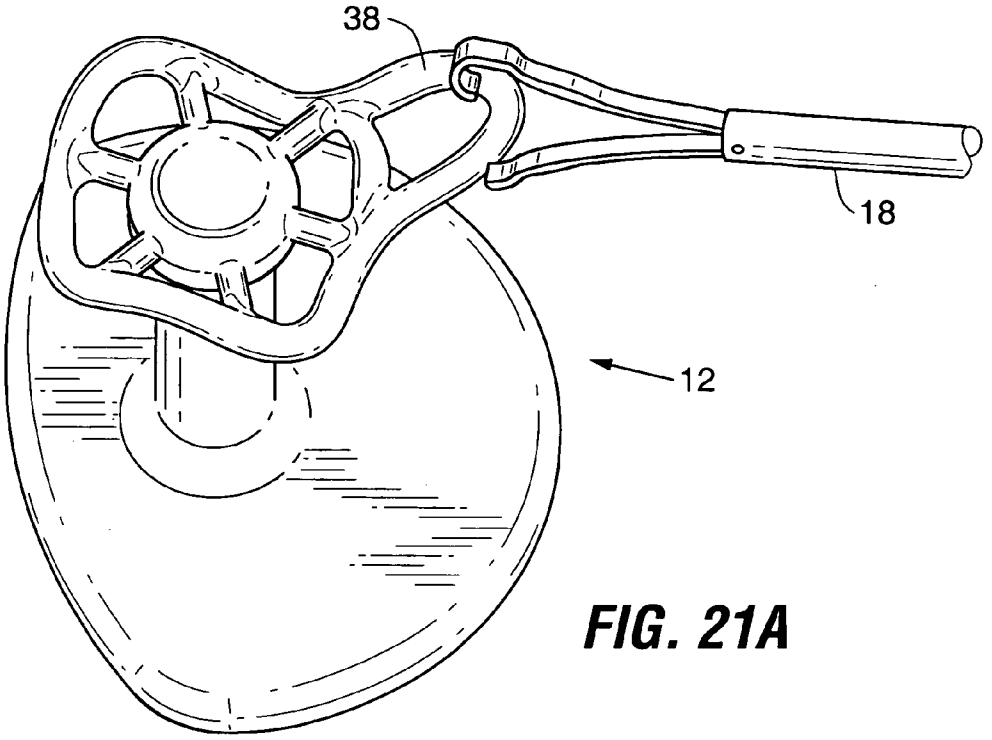


FIG. 21A

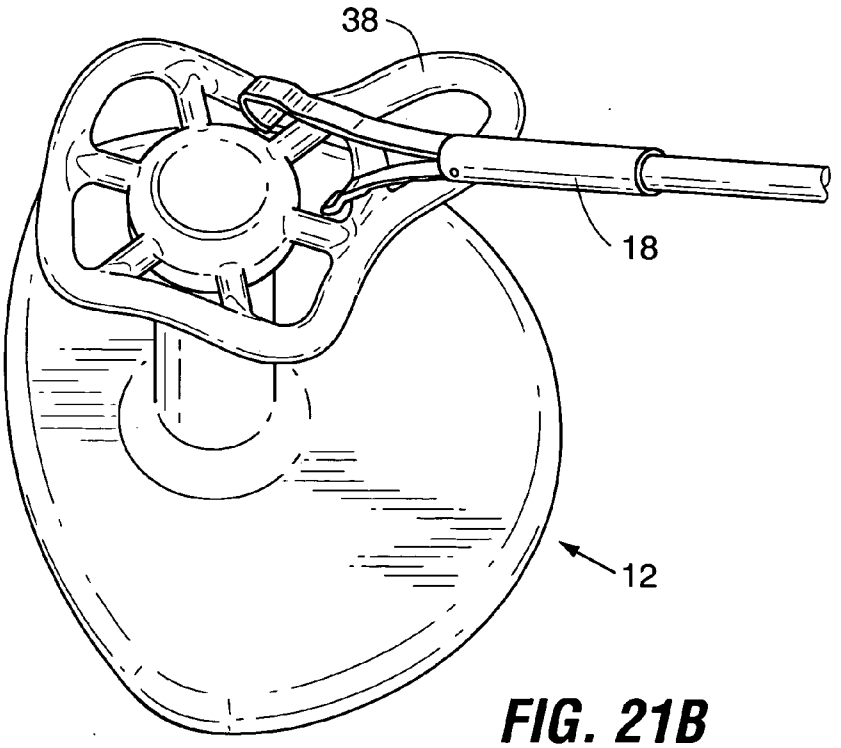


FIG. 21B

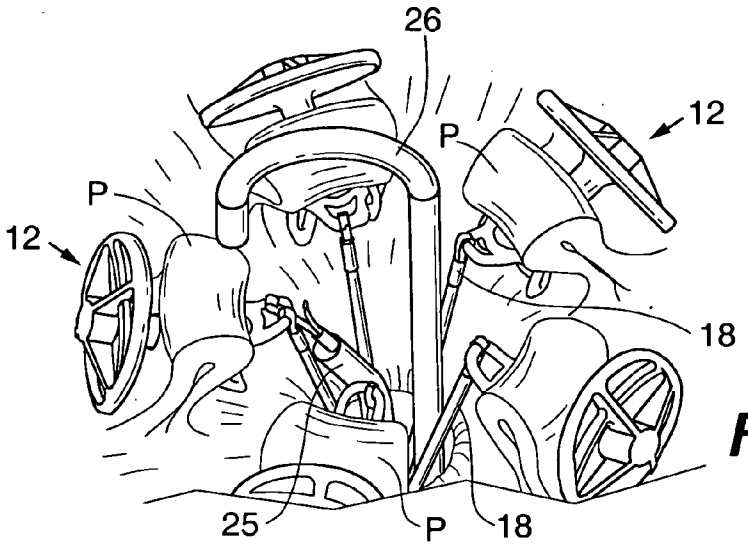


FIG. 22A

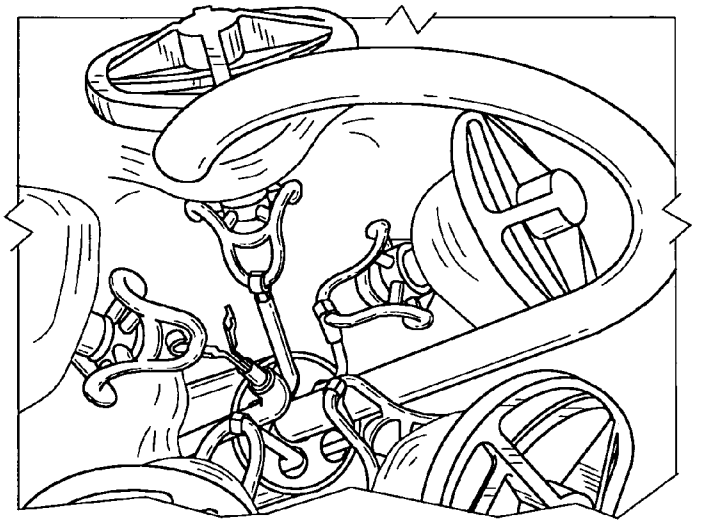


FIG. 22B

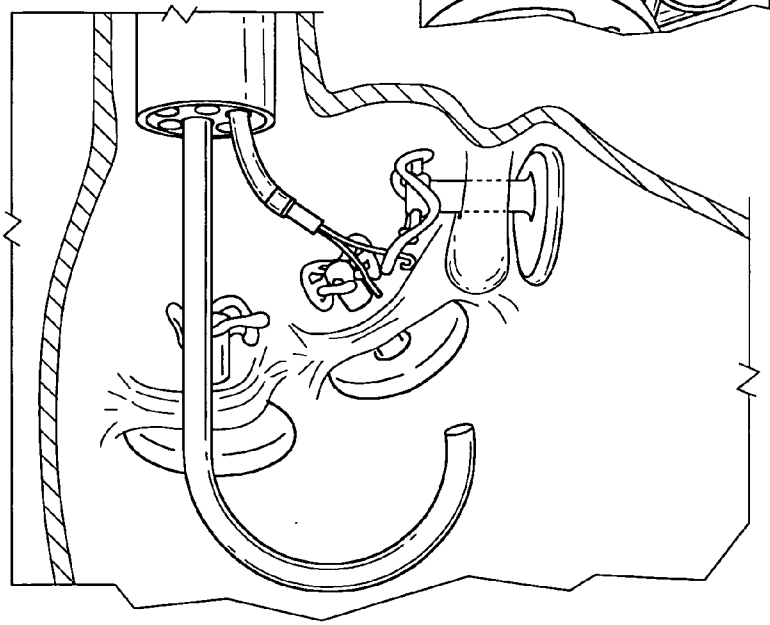


FIG. 22C

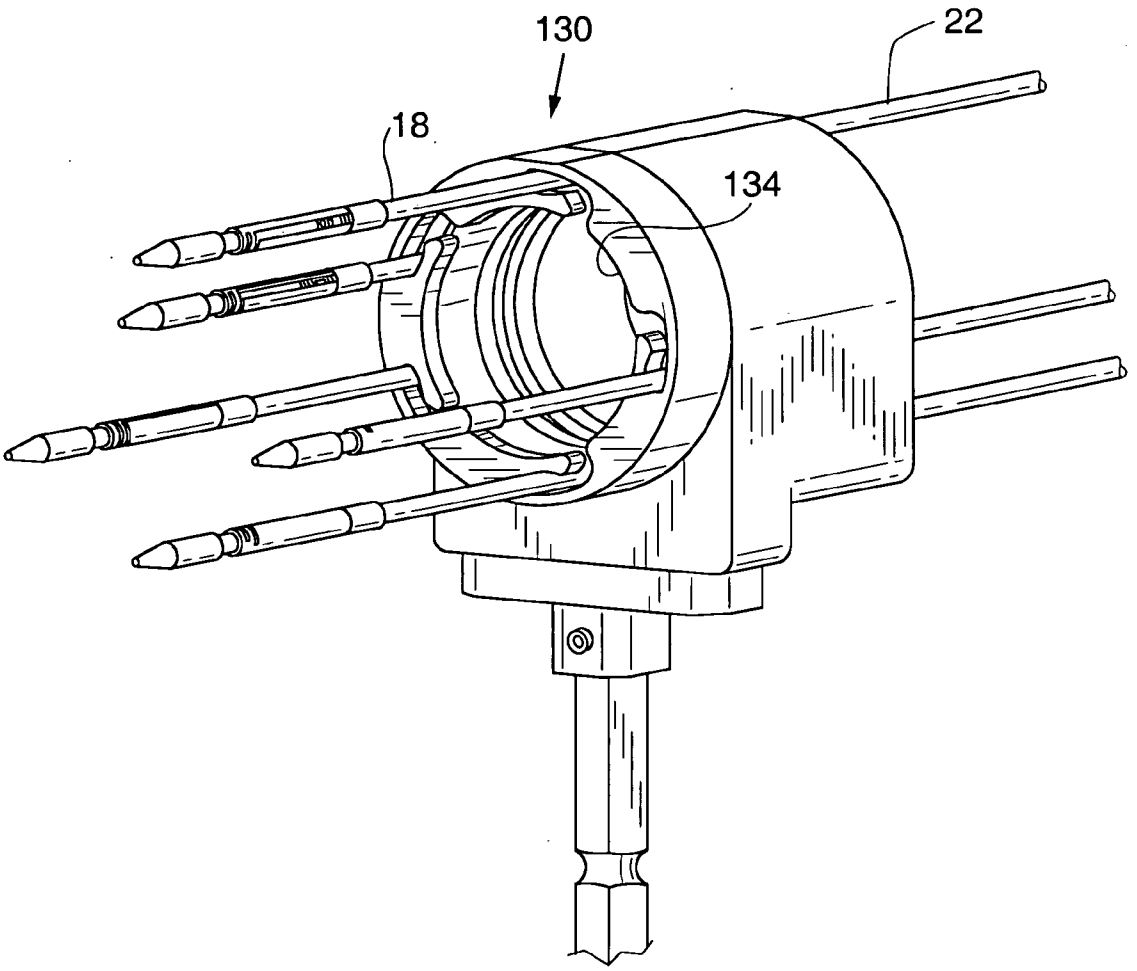


FIG. 23

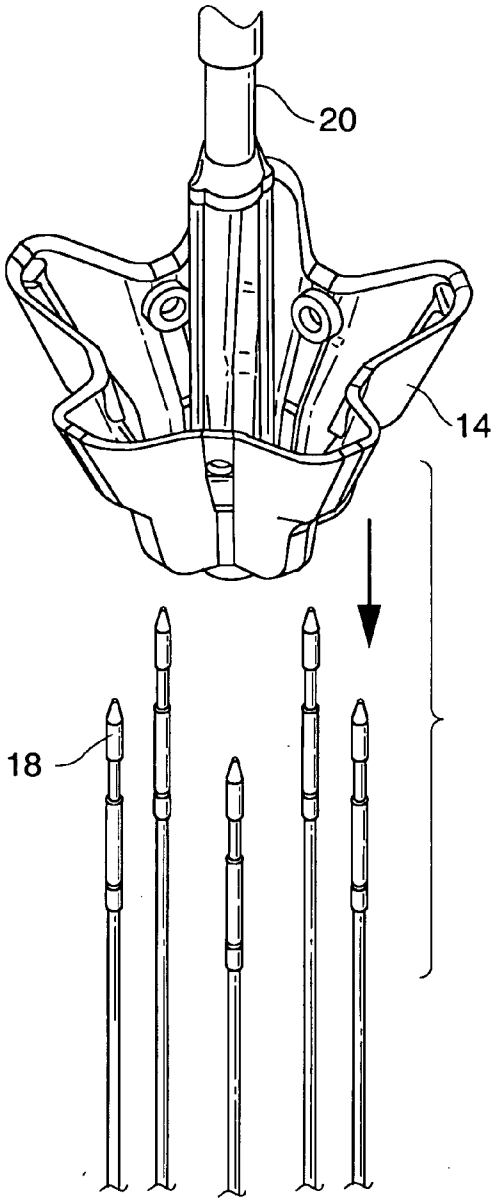


FIG. 24A

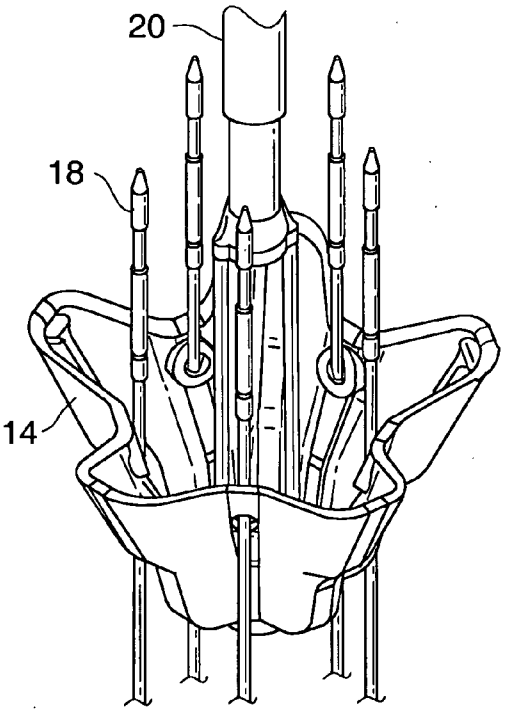


FIG. 24B

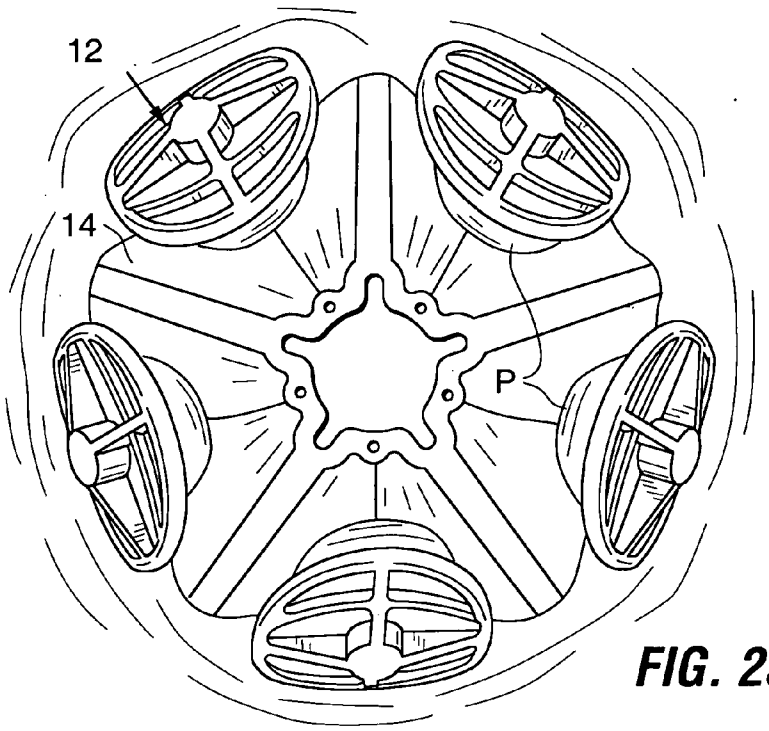


FIG. 25A

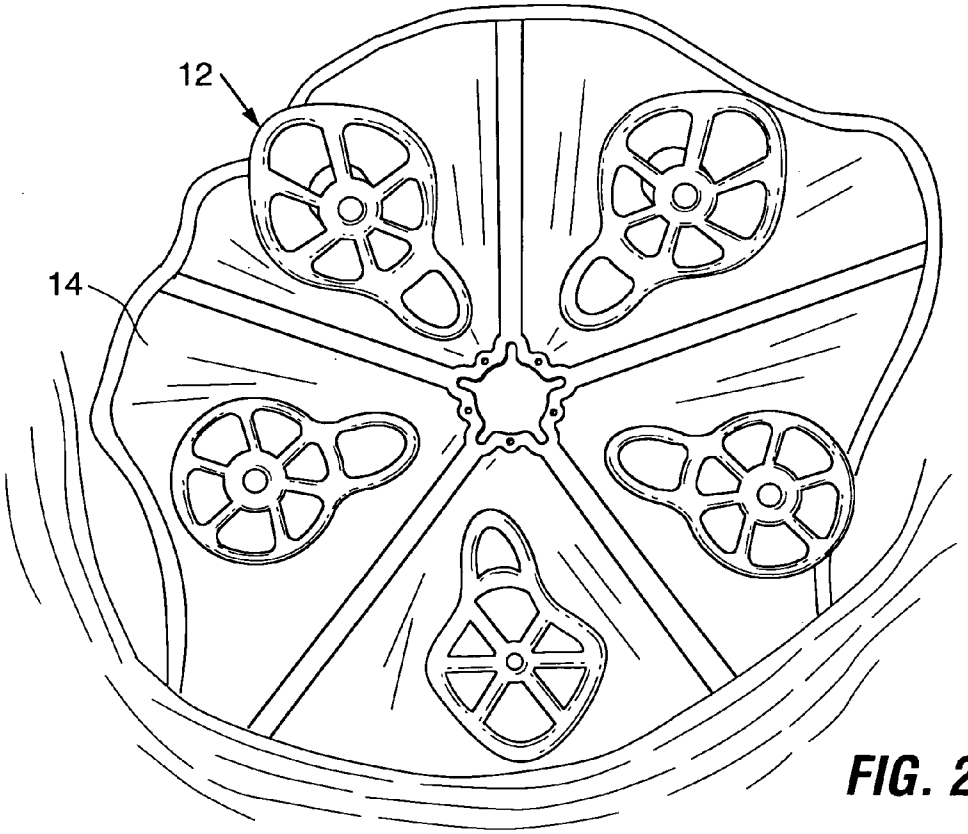


FIG. 25B

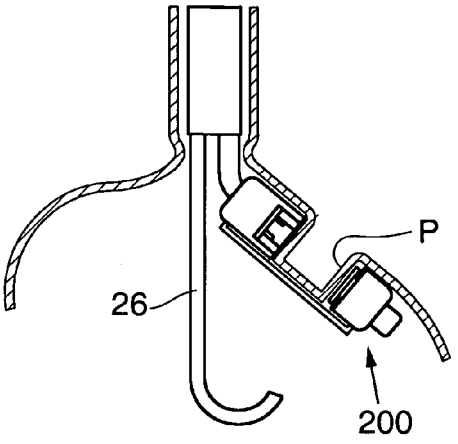


FIG. 26A

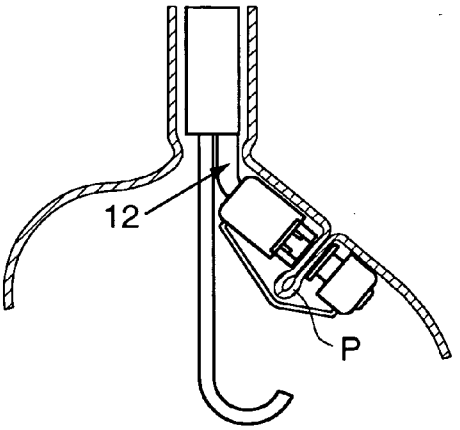


FIG. 26B

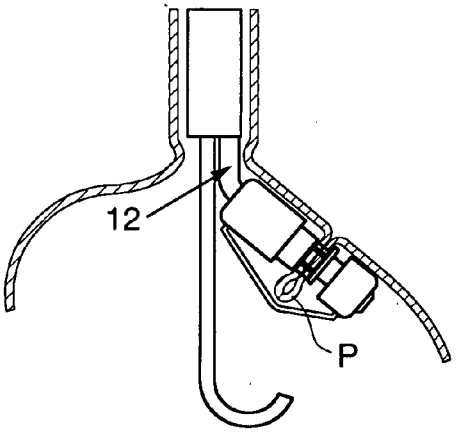


FIG. 26C

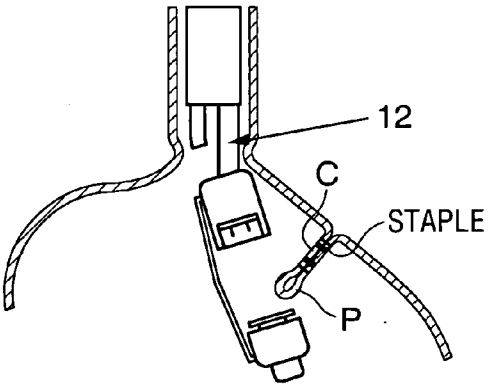


FIG. 26D

ENDOSCOPIC IMPLANT SYSTEM AND METHOD

PRIORITY

[0001] This is application claims priority to U.S. Provisional Application No. 60/950,584, filed Jul. 18, 2007, and U.S. Provisional Application No. 61/042,862, filed Apr. 7, 2008.

TECHNICAL FIELD OF THE INVENTION

[0002] The present invention relates to the field of systems for use in endoscopically implanting devices within the gastrointestinal system.

BACKGROUND

[0003] An anatomical view of a human stomach S and associated features is shown in FIG. **1**. The esophagus E delivers food from the mouth to the proximal portion of the stomach S. The z-line or gastro-esophageal junction Z is the irregularly-shaped border between the thin tissue of the esophagus and the thicker tissue of the stomach wall. The gastro-esophageal junction region G is the region encompassing the distal portion of the esophagus E, the z-line, and the proximal portion of the stomach S.

[0004] Stomach S includes a fundus F at its proximal end and an antrum A at its distal end. Antrum A feeds into the pylorus P which attaches to the duodenum D, the proximal region of the small intestine. Within the pylorus P is a sphincter that prevents backflow of food from the duodenum D into the stomach. The middle region of the small intestine, positioned distally of the duodenum D, is the jejunum J.

[0005] Several prior applications, including U.S. Publication No. US 2007/0276432 having a priority date of Oct. 8, 2004 and U.S. Publication No. US 2008/0065122, filed May 23, 2006 describe methods according to which medical implants are coupled to tissue structures, such as plications or folds, formed within the stomach. Examples of methods and devices for forming such tissue structures are described in U.S. Publication No. US 2007/0219571 (entitled ENDOSCOPIC PLICATION DEVICES AND METHOD), filed Oct. 3, 2006, U.S. application Ser. No. 11/900,757 (entitled ENDOSCOPIC PLICATION DEVICE AND METHOD), filed Sep. 13, 2007, and U.S. application Ser. No. 12/050,169 (entitled ENDOSCOPIC STAPLING DEVICES AND METHODS), filed Mar. 18, 2008. Each of the referenced publications and applications is incorporated herein by reference.

[0006] As disclosed in these prior applications, more robust and long lasting coupling between the implant and the surrounding stomach wall tissue is achieved when the plications/folds are formed by retaining regions of serosal tissue (i.e., the tissue on the exterior surface of the stomach) in contact with one another. Over time, adhesions form between the opposed serosal layers. These adhesions help to create strong bonds that can facilitate retention of the plication/fold over extended durations, despite the forces imparted on them by stomach movement and implanted devices

[0007] Several of the disclosed methods for forming tissue plications include a step in which a hole or cut is formed in the plication, using the plication device or other devices. An example of this type of plication is shown in FIG. **2**A. This application discloses a system for attaching a medical implant to cutouts of this type, or to other types of openings in the plications (e.g., cuts, slits, perforations, tissue tunnels, etc.).

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. **1** is a schematic illustration of a human stomach and a portion of the small intestine.

[0009] FIG. **2**A is a partial section of a stomach wall showing a stomach wall plication having an opening formed in it.

[0010] FIG. **2**B is a cross-section view taken along the plane designated **2**B-**2**B in FIG. **1**, and illustrating five plications formed in a gastro-esophageal junction region of the stomach.

[0011] FIG. **3** shows an endoscopic implant system.

[0012] FIG. **4**A is a perspective view of the anchor of the implant system of FIG. **3**.

[0013] FIG. **4**B is a perspective view of the anchor of FIG. **4**A, showing the head separated from the stem.

[0014] FIGS. **5-7** are partial section views of a human stomach schematically illustrating the anchor of FIG. **4**A positioned in an opening in a stomach wall plication.

[0015] FIG. **8**A is a perspective view of an anchor hand-off tool.

[0016] FIGS. **8**B and **8**C are perspective views showing the anchor coupled to the anchor hand-off tool.

[0017] FIG. **9**A is a side elevation view of an anchor grasper in the open position.

[0018] FIG. **9**B shows the distal end of the anchor grasper of FIG. **9**A in the closed position.

[0019] FIG. **10**A is a top plan view of the anchor grasper of FIG. **9**A.

[0020] FIG. **10**B is a cross-section view taken along the plane designated **10**B-**10**B in FIG. **10**A.

[0021] FIGS. **11**A and **11**B are side elevation views of the distal end of an alternative anchor grasper.

[0022] FIG. **12**A shows a top perspective view of a first embodiment of a restrictor.

[0023] FIG. **12**B shows a side perspective view of a second embodiment of a restrictor.

[0024] FIG. **12**C shows a top perspective view of a third embodiment of a restrictor.

[0025] FIG. **13** shows a top perspective view of a fourth embodiment of a restrictor.

[0026] FIG. **14**A shows a side perspective view of a fifth embodiment of a restrictor.

[0027] FIG. **14**B is a perspective view of the embodiment of FIG. **14**A, showing only the rib structure.

[0028] FIG. **15**A is a side elevation view of a restrictor guide.

[0029] FIG. **15**B is a cross-section view of the restrictor guide taken along the plane designated **15**B-**15**B in FIG. **15**A.

[0030] FIG. **16**A is a perspective view of the distal portion of the restrictor guide, showing the mount in the open configuration.

[0031] FIG. **16**B is similar to FIG. **16**A and shows the mount in the closed configuration.

[0032] FIG. **16**C is a cross-section view of the mount in the open configuration.

[0033] FIG. **17**A is a perspective view of a restrictor, showing the restrictor positioned on the restrictor guide, with the mount in the open configuration.

[0034] FIG. **17**B is similar to FIG. **17**A but shows the mount in the closed configuration.

[0035] FIG. **17**C is a perspective showing the interior of a restrictor positioned on the restrictor guide.

[0036] FIG. **18**A is a perspective view showing the proximal end of the restrictor guide.

[0037] FIG. **18**B is a perspective view showing the distal portion of the multi-lumen portion of the restrictor guide.

[0038] FIGS. **19**A and **19**B schematically illustrate elements of the system positioned in the stomach in preparation for transferring an anchor from an anchor hand-off to the anchor grasper that will then draw the anchor through the opening in the plication.

[0039] FIGS. **20**A-**20**F schematically illustrate transfer of the anchor from the anchor hand-off to the anchor grasper within the stomach.

[0040] FIGS. **21**A and **21**B are perspective views showing the anchor grasper engaging different portions of the anchor head.

[0041] FIGS. **22**A-**22**C schematically illustrate a plurality of anchors that have been placed in plications in the stomach, together with elements of the disclosed system.

[0042] FIG. **23** is a perspective view of the proximal end of the endogastric tube, showing use of the tool organizer.

[0043] FIG. **24**A is a perspective view of a restrictor being advanced onto proximal ends of a collection of anchor graspers.

[0044] FIG. **24**B is a perspective view similar to FIG. **24**A showing the restrictor advanced further along the anchor graspers.

[0045] FIG. **25**A is a schematic illustration showing the downstream side of a restrictor within the stomach, anchored to plications using anchors.

[0046] FIG. **25**B is a schematic illustration showing the upstream side of a restrictor within the stomach, anchored to plications using anchors.

[0047] FIGS. **26**A-**26**D schematically illustrate use of the plicator for forming tissue plications and for forming holes in the plicated tissue.

DETAILED DESCRIPTION

[0048] FIG. **2**B is a schematic cross-section view of the stomach, looking distally into the stomach interior. In this view, five tissue plications P having openings such as cutouts C are shown to have been formed in the stomach wall tissue. This view would seem to illustrate clear access via the esophagus to the plications and cutouts using endoscopic instruments. However, the natural undulations and folds of the actual stomach tissue, and the constant movement of the stomach, limit the visibility of the cutouts and even the plications themselves, rendering it difficult to endoscopically access the cutouts in an actual human subject. The disclosed system facilitates access to the cutouts, and provides for an efficient method for coupling an implant to the cutouts.

[0049] FIG. **3** illustrates an embodiment of an endoscopic implant system **10** that may be used for this purpose. In general, system **10** includes multiple anchors **12** (one shown) that are implanted in the cutouts and an implant **14** to be coupled to the anchors **12**. The implant can be any type of implant to be anchored within the stomach. In the disclosed embodiment, the implant is a restrictor **14** designed to slow the rate at which food can enter the stomach from the esophagus.

[0050] An anchor hand-off **16** delivers the anchors into the stomach, and anchor graspers **18** (one shown) are used to position the anchors within the tissue openings and also to guide the restrictor **14** to the implanted anchors. A restrictor guide **20** is provided for advancing the restrictor into position in the stomach. An endogastric overtube **22** is provided for establishing a working channel between the mouth and the stomach. Other tools shown elsewhere in the drawings, such as a multi-lumen guide **24** (FIG. **19**A), articulated guides **25** (FIG. **19**A), and one or more endoscopes **26** (FIG. **19**A) are additionally provided.

Anchor

[0051] One embodiment of an anchor **12** is shown in FIG. **4**. A preferred anchor will pass though the opening C in the plication cutout with relative ease and minimal tissue trauma, but will resist pulling out of the opening in the cutout when subjected to the stresses imparted to it by the restrictor. Moreover, a preferred anchor will minimize the stress and strain on the stomach wall and distribute a given stress as evenly as possible so as to prevent the stomach's natural defense from engaging in an attempt to eliminate the anchors and restrictor.

[0052] Referring to FIG. **4**A, the general features of the anchor **12** include a base **28**, a stem **30**, and a head **32**. The anchor is formed using materials that are durable within the stomach environment. In one embodiment, the head **32** is molded out of a higher durometer compliant material (such as 50 shore A durometer Silicone) while the stem **30** and base **28** are molded out of a softer compliant material (such as 5 shore A durometer Silicone). Since the loading on the anchor from the restrictor implant can be seen as shear against the edges of the opening in the plication, the stem **30** is formed to have a relatively large diameter (2 mm-8 mm) to minimize stress and abrasion on the stomach wall tissue inside the opening. The edges of the anchor are molded with generous fillet radii to minimize abrasion of stomach wall tissue.

[0053] Head **32** includes a ring **34** and a plurality of struts **36** coupling the ring **34** to the stem **30**, and an elongate loop **38** extending from the ring **34**. The anchor is elastically deformable to an elongated shape (see FIGS. **20**D and **20**E) in response to application of tension to the ring **34** or loop **38** (collectively referred to as the "rim"). This allows the anchor to be drawn into a streamlined shape so that it can be drawn through the opening in the plication and also through an opening in the restrictor. When the anchor is pulled from the rim, its shape lengthens and slims down to fit through a much smaller hole. For example in one embodiment, in its natural state the anchor has an outer head diameter of approximately 0.600 inch (15 mm), but in its streamlined orientation it can fit through a plication opening of 0.200 inch (5 mm). However, once implanted, the anchor's shape resists pull-out force to a higher degree since the rim is not being pulled and lengthened directly. Also in this embodiment, the base is designed so it will not pull through the hole and may have an outer diameter of approximately 1 inch (25.4 mm)

[0054] Referring to the top view of the anchor **12** shown in FIG. **5**, when an anchor is implanted in a plication opening, the anchor's proximity to the wall of the stomach with its enveloping rugae can make it difficult to find and grab onto the anchor when it is time to couple the restrictor implant to the anchors. The head **32** is shaped to have an undulating profile to enhance its visibility and accessibility when the anchor is positioned in a plication opening. The undulation of the head forces several of the elements of the head away from the wall to make them more visible and also to allow a grasping tool to latch onto one of those elements without also grabbing adjacent tissue.

[0055] Referring to FIG. **6**, the base **28** is preferably formed to have an asymmetrical shape. In the illustrated example, one

edge **40** of the base is formed to have a flatter curvature than that of the other edge **42** of the base. When implanted, the anchor self-orients to position the flatter edge **40** against the adjacent stomach wall as shown. Since the loop **38** of the head extends in a direction opposite to the side of the anchor on which the flatter edge **40** is position, this self-alignment causes the loop **38** to extend towards the center of the stomach as shown in FIG. **7**. This makes it easier to find segments of the anchor head amongst the folds of the stomach which can envelope other segments.

[0056] Referring again to FIG. **6**, the base **28** preferably includes a relatively large surface area (e.g., approximately 1 square inch) so as to distribute the stress of holding the restrictive implant in place over a large percentage of the surface area of the tissue plication. Reinforcing ribs **44** may be positioned on the underside of the base, radiating from the stem to the edges of the base, to facilitate distribution of stress while minimizing the overall weight of the base.

Anchor Hand-Off Tool

[0057] Anchor hand-off **16** is an instrument used to deliver individual anchors to the implantation site, and to hand-off each anchor to an anchor grasper which pulls the anchor through an opening in a plication.

[0058] Referring to FIG. **8**A, one embodiment of an anchor hand-off **18** includes a torqueable elongate shaft **46** having a wire element **48** extending from its distal end and attachable to an anchor.

[0059] In one embodiment, the anchor hand-off **16** has a horseshoe shaped form with an opening **45** that narrows to form a constriction **47**. The stretchable nature of the anchor stem **30** allows it to be squeezed through the constriction **47** and thus held in place by friction. See FIGS. **8**B-**8**D. Upon pulling on the head portion **32** by the anchor grasper, **18**, the stem **30** elongates and passes out of the horseshoe shaped constriction.

[0060] Shaft **46** is slidably disposed in an articulating guide **49** that will articulate in response to actuation using pull wires or other means known to those skilled in the art. The articulating guide **26** may be one with video capability, for example it might be an articulating endoscope. In one embodiment, wire element **48** is detachable from the shaft **46** of the anchor hand-off **16** to allow shaft **48** to pass through a small diameter tool channel in the articulating guide **26**. Once the distal end of the shaft **46** reaches the distal end of the guide **26**, the wire element **48** is coupled to the shaft **46**.

[0061] Furthermore, the anchor hand-off tool **16** may be designed to hold the anchor behind (or axially off-set from) the distal tip of the articulating guide **26** with video capability. This facilitates greater visibility at the target site/plication by positioning the held anchor out of the endoscope's field of view as shown in FIGS. **8**C and **8**D. To perform the actual hand-off of the anchor **12**, the user can extend and torque the hand-off tool **16** to position at least a portion of the anchor head **32** within the field of view.

Anchor Grasper Tool

[0062] Anchor grasper **18** is designed to couple to or engage a portion of the head **32** of an anchor **12**. It is used to pull the anchor **12** through an opening in a plication, and to pull the anchor through a corresponding opening in a restrictor that is to be implanted. The anchor grasper **18** may have a variety of designs that allow these functions to be carried out. One such design is shown in FIGS. **9**A and **9**B an employs a coupling/grasping element **50** that takes the form of a hook **52** having a gate **54** that closes against the opening in the hook **52**. The hook and gate are naturally biased in the open position shown in FIG. **9**A.

[0063] A closure tube **56** is longitudinally slidable over the hook and gate to lock them in the closed position, thus preventing them from separating. The collar and associated features are proportioned to ensure that when the grasping element **50** is to be locked, bending of the shaft of the anchor grasper **18** does not cause the closure tube **56** to slide into a position that will release the grasping element **50** from the locked position.

[0064] Referring to FIG. **10**B, the closure tube **56** is mounted to a torqueable element **58** (preferably a coil), which in turn is coupled to outer tubing **60**. An L-shaped slot **62** is formed in the outer tubing **60**. As best shown in FIG. **10**A, slot **62** includes a longitudinal segment **63***a* and a partially circumferential segment **63***b*.

[0065] Hypotube **64** is slidably and rotatably disposed within outer tubing **60**, and includes a pin **66** disposed within the slot **62**. Hypotube **64** is mounted to a tapered handle **68**. A cable **70** has a distal end coupled to the grasping element **50** and a proximal end mounted to the handle **68**.

[0066] To close and lock the grasping element, the outer tube **60** is advanced distally relative to the handle **68**. Advancement of the outer tube **60** pushes the coil **58** and thus the closure tube **56** in a distal position until the closure tube **56** moves the grasping element **50** to the closed position shown in FIG. **9**B. As the outer tube **60** moves distally, longitudinal segment **63***a* of the slot **62** slides over pin **66**. The outer tube **60** is then rotated to cause positioning of pin **66** within the circumferential segment **63***b* of the slot **62**, and to thereby lock the outer tube **60** in the distal position. To unlock the grasper element **50**, the outer tube **60** is rotated in the opposite direction to release the pin **66** from the circumferential segment **63***b*. Since the closure tube is no longer locked in the distal position, the grasping element **50** moves to the open position due to its natural bias, thereby pushing the outer tube **60** in a proximal direction.

[0067] FIGS. **11**A and **11**B show an alternative grasper element **50***a* which is moved between open and closed positions using a system **72** of linkages pivoted using a longitudinally slidable push rod **74**.

Restrictor

[0068] The restrictor is an implant designed to slow the passage of food from the esophagus into the stomach. The illustrated embodiments, the restrictor is positioned in the stomach such that food enters the restrictor through a proximal opening and exits the restrictor through a distal opening. The restrictor and/or openings are proportioned to slow the rate at which food can move into or through the restrictor, and/or from the restrictor into the rest of the stomach.

[0069] A preferred restrictor is proportioned to be coupled to anchors that have been coupled to plications in the gastroesophageal junction region of the proximal stomach. In a preferred design, the restrictor **14** includes features that minimize pulling against the anchors when the restrictor encounters stress as a result of food moving through the restrictor and/or movement of the stomach. Minimizing pulling at the anchors is beneficial for minimizing stress on the stomach wall tissue coupled to the anchors. In general, the restrictor **14** is designed to have compliance between the

anchor points (i.e., the points at which the implant is coupled to the tissue directly or using the anchors). This compliance may be achieved using the geometry of the restrictor **14** and/or using restrictor materials selected to give compliance between anchor points.

[0070] In a first embodiment shown in FIG. **12**A, the restrictor **14** is a sleeve having a wall and a plurality of anchor openings **80** formed in the wall. The restrictor wall is an undulating wall defining multiple folds **76** that give it compliance even when molded from a relatively more stiff material (such as 30 shore A silicone). When viewed from the side (see the second embodiment **14***a* in FIG. **12**B), it can be seen that the proximal edge of the restrictor **14** undulates to define peaks **78** in the profile of the proximal edge. When viewed from the top (FIG. **12**A), it can be seen that the circumferential profile of the restrictor also includes peaks **82** extending radially outwardly. These peaks **82** define chutes **84** extending from the proximal peaks **78** towards a distal orifice **86**. When the restrictor is implanted, the chutes **84** help to channel ingested material towards the distal orifice **86**.

[0071] Anchor openings **80** are positioned between the radial peaks **82**. These openings may be positioned in the portion of the wall that is at the most radially inward position as on the restrictor **14***a* of FIG. **12**B, or the undulations in the wall may be such that the openings **80** are in a section of wall that is positioned between some inwardly extending folds **88** as in FIG. **12**A (or that, in other words, forms smaller radial peaks **90** than the radial peaks **82**).

[0072] Openings **80** may be surrounded by reinforced sections **92** formed using thicker regions of silicone, or a stronger material embedded in or attached to the silicone. Additional reinforcements such as ribs **94***a*, **94***b* may extend from the openings **80** towards the orifice **86** and/or from the proximal peaks **78** towards the orifice **86** and may be formed using similar techniques.

[0073] The edge of the wall defining the orifice **86** preferably includes folds or undulations **96**, allowing the orifice to be compliant as well. In addition, small holes **98** are arranged around the orifice to allow the restrictor **14** to be coupled to the restrictor guide used to deliver the restrictor into the stomach.

[0074] An alternative restrictor **14***b* shown in FIG. **12**C is similar to the restrictor of FIG. **12**A, but is molded to be flat for ease of manufacturing, but assumes its undulating configuration at the folds when coupled to anchors at anchor openings **80**.

[0075] Yet another alternative restrictor **14***c* (FIG. **13**) is molded out of highly compliant material (such as 40 shore 00 silicone) to put minimal stress on attached stomach tissue. This embodiment includes a reinforced proximal rim **100**.

[0076] An additional restrictor **14***d* is molded out of a combination of high and low compliance material (such as 50 shore A plus 40 shore 00 silicones) in different areas of the restrictor to achieve optimal performance. A rib structure **94***c* (see FIG. **14**B) out of stiffer material serves to maintain the restrictor shape in the open position within the stomach. IN this example, rib structure **94***c* includes an undulating ring **94***d* encircling the orifice **86**, and ribs **94***e* extending to peaks **78**. In this manner, the rib structure **94***c* maintains apposition of the restrictor against the wall of the stomach in order to improve the effectiveness of catching food, particularly in the chutes **84**. In addition to the stiffer rib structure, the assembled restrictor contains a very soft web **95** of material that forms the funnel shape and also serves to link together the anchor points **80** (see FIG. **14**A). The soft compliant nature of the web material minimizes the stress to the plication tissue by allowing full flexibility.

Restrictor Guide Tool

[0077] Restrictor guide **20** generally includes a tubular shaft **101**, a distal portion comprising a coupling element/mount **102** and a proximal portion **104**.

[0078] In a preferred restrictor guide, the mount **102** is designed to support the restrictor **14** during delivery of the restrictor into the stomach and coupling of the restrictor **12** to the stomach wall (directly or using anchors or other means as disclosed herein). In the illustrated embodiment, mount **102** includes a collar **103** on the distal end of the shaft **101**. A pair of tubes **112** extend distally between the collar **103** and a ring **107**. Ring **107** includes a plurality of distally extending pins **106** and a central opening **109**. A tube **111** is positioned co-axially with the opening **109**. A distal cap **108** is mounted to the distal end of the tube **111**. Cap **108** includes an opening positioned in alignment with the opening of the ring **107** and the lumen of the tube **111**. Bores **110** in the cap are positioned so that proximal advancement of the cap **108** relative to the ring **107** causes pins **106** to enter the bores **110**.

[0079] Referring to FIG. **17**A, pins **106** are arranged to allow a user to couple the restrictor **14** to the restrictor mount by threading the holes **98** surrounding the orifice in the restrictor **14** over the pins **106** as shown. When the restrictor **14** is mounted in this way, the tube **111** is disposed in the orifice **86** of the restrictor, and the cap **108** is positioned distal to the restrictor. Restrictor **14** is retained on the mount **102** by moving the cap **108** in a proximal direction until bores **110** slide over the pins **106**, thus capturing the restrictor **14** between the cap **108** and the ring **107** by preventing the restrictor from sliding off the pins. See FIG. **17**B.

[0080] Drive rods **112***a* (FIG. **16**A) extend through the tubes **112** and are coupled at their distal ends to flanges **120** on the proximal end of tube **111**. The proximal ends of the drive rods **112***a* are advanceable by an actuator at the proximal end of the restrictor guide. Manipulation of the actuator will cause the drive rods **112***a* to move distally relative to the tubes **112**, causing distal movement of the cap **108** relative to the ring **107**. In one current embodiment, rotation of a threaded nut on the proximal handle moves a threaded piece inside the handle that is connected to wires or cables that communicate with the drive rods **112***a*. In another embodiment, the drive rods **112***a* may be lead screws, and the actuator may include a knob and associated gearing for rotating the lead screws such that they advance the cap **108** distally. Alternatively, the actuator may include a spring that is initially locked in a compressed position using a latch. According to this embodiment, a button or other element is manipulated by the user to disengage the latch, thus releasing the spring from the compressed position to drive the drive rods distally. Other alternatives include pneumatic or hydraulic actuation of the cap **108**. In other embodiments, the actuator may be a handle that allows the user to manually advance the drive rods to advance the cap.

[0081] Proximal portion **104** of the restrictor guide **20** is a multi-lumen guide having a central lumen **114** through which the tubular shaft **101** extends, and a plurality of peripheral lumens **116** arranged around the central lumen. The peripheral lumens **116** are proportioned to accommodate the anchor graspers **18**. Each of the peripheral lumens **116** has a proximal port fitted with a seal (which may be, for example, a duck bill

seal) that will seal around the shaft of a grasper **18** positioned in the lumen, and that will self-seal when the grasper **18** is removed from the lumen.

Exemplary Procedure

[0082] Use of the system **10** to implant a restrictor **14** will next be described. According to one embodiment, the method is performed following an initial procedure in which a plurality of plications P having cutouts or other openings C are formed. In another embodiment, after each plication is formed, an anchor **12** is implanted in that plication's opening for the dual purpose of marking the location of the plication as well as ensuring that the opening does not close in the natural healing process of the tissue. The anchor implantation procedure may immediately precede restrictor implantation, or may instead be performed in advance of the restrictor implantation procedure to allow reinforcement of the plications through the body's healing process.

[0083] In the initial phase of the restrictor implantation procedure, anchors **12** are positioned in the openings of the plications P. Referring to FIG. **19**A, the endogastric tube **22** is introduced into the mouth and through the esophagus, and parked with its distal opening in a portion of the stomach or esophagus that is proximal to the plications P. After each plication with opening is created, a multi-lumen (or cannulation) guide tube **24** may be passed through the endogastric tube **22**. Multi-lumen guide tube **24** may have a central lumen **24***a* and peripheral lumen **24***b* in a similar arrangement to the lumen of the restrictor guide **20** (FIG. **18**B).

[0084] Outside the body, an anchor hand-off **16** is passed through a tool channel of an endoscope **26** such that the anchor engaging wire **48** extends from the endoscope lumen. With the engaging wire in this position, an anchor **12** is coupled to the engaging wire **48**, and the endoscope **26**, anchor hand-off **16**, and anchor **12** are together passed through the central lumen **24***a* of the multi-lumen guide tube **24** and into the stomach as shown in FIGS. **19**A and **19**B. The endoscope **26** is retroflexed within the stomach to provide visualization of the plication P.

[0085] Next, an articulating guide **25** is advanced through a peripheral lumen **24***b* of the multi-lumen guide tube **24** and into the stomach. An anchor grasper **18** is positioned in the lumen of the guide **25**. Under visualization using endoscope **26** (with anchor hand-off **18** retracted so that the anchor is out of view), guide **25** is articulated to orient the grasper **18** towards the opening C in the plication, and the grasper **18** is then advanced through the opening as also shown in FIGS. **19**A and **19**B. The grasping element **50** of the grasper **18** is moved into the open position.

[0086] Referring to FIGS. **20**A, **20**B and **20**C, anchor hand-off **16** is advanced further from the endoscope **26** until the head **32** of the anchor is positioned within reach of the grasping element **50**. Grasping element **50** is manipulated to engage the head **32**. While it is preferable to engage the loop **38** as shown in FIG. **21**A, the structure of the head **32** allows for engagement of other portions of the head such as the struts **36** as shown in FIG. **21**B, or the ring surrounding the struts **36**. Engagement between the anchor and the anchor grasper is secured by moving the grasping element **50** into the locked position. Next, the anchor hand-off is retracted into the endoscope in order to separate it from the anchor grasper. This action results in stretching the anchor stem and thus causing it to release from the horseshoe shaped form. See FIG. **20**D. The handle of the anchor grasper **18** is then withdrawn to pull the head **32** of the anchor through the opening C in the plication as in FIG. **20**E. As discussed above, application of tension to the head **32** causes the anchor to elongate to a narrow profile that will pass readily through the opening C in the plication. The jaws of the anchor grasper **18** are opened to release the anchor **12**. FIG. **20**F.

[0087] The endoscope **26** and anchor hand-off **16** are withdrawn from the guide tube **24** along with the multiple lumen guide and articulating guide. After another plication is created, the process is repeated for each anchor that is to be implanted. See FIGS. **22**A-**22**C.

[0088] As each anchor is implanted, its corresponding anchor grasper is preferably left coupled to the ring of the anchor, although it may instead be withdrawn from the body. At the end of the anchor-positioning phase of the procedure, each anchor is positioned extending through a plication opening (FIG. **22**A). If the anchor graspers were left in place coupled to the rings of each anchor, the handles of each separate anchor grasper **18** extend out of the body. Organization of the anchor graspers **18** is maintained by the multi-lumen cannula **24**.

[0089] If the anchor graspers **18** are not left in place following implantation of the individual anchors **12**, the graspers **18** are re-coupled to the anchors prior to the restrictor-positioning phase. Specifically, each of the graspers **18** is reintroduced into the stomach and endoscopically guided by its corresponding articulated guide **25** into engagement with the head **32** of one of the anchors. As discussed in the Anchors section above, orientation of the loop **38** to extend in a direction opposite to the asymmetrical base **28** helps to orient the loop **38** centrally within the stomach so that the loops **38** may be more easily seen and engaged by the graspers **18**.

[0090] The restrictor-positioning phase of implantation begins with each anchor that is to be coupled to the restrictor having a separate anchor grasper **18** coupled to it. If the multi-lumen guide **24** is still in use at this point, with individual ones of the graspers **18** in the peripheral lumen **24***b*, the guide **24** is withdrawn from the endogastric tube **22** and removed from the handles of the anchor graspers. The tapered proximal ends of the anchor graspers **18** allow the lumens **24***b* of the guide **24** to pass easily over them. Before the multiple lumen guide is completely removed from the endogastric tube **22**, the anchor grasper tool shafts are locked into a tool organizer **130** at the proximal end of the endogastric tube **22** as shown in FIG. **23**. Organizer **130** includes slots **132** positioned to receive the shafts of the graspers **18**, leaving them arranged around the main lumen **134** of the endogastric tube. This serves to maintain the relative clocking of each grasper at the proximal end to a corresponding anchor location at the distal end.

[0091] The restrictor **14** is prepared for implantation by threading anchor openings **80** in the restrictor over the tapered proximal ends of the anchor graspers **18**, which at this point are still extending out of the endogastric tube **22**. FIG. **24**A. The restrictor **14** is mounted to the mount **102** of the restrictor guide **20** in the manner disclosed in the Restrictor Guide section above. This step may be performed before or after the restrictor is threaded over the anchor graspers.

[0092] Next, the restrictor guide **20** is advanced over the tapered proximal ends of the anchor graspers **18**, which are still extending out of the endogastric tube **22**. The restrictor guide **20** is positioned so that each of its peripheral lumens **116** advances over a separate one of the anchor graspers **18**. FIG. **24**B. Continued distal advancement of the guide **20**

advances the guide **20** and restrictor **14** through the endogastric tube **22** and into the stomach.

[0093] In a final step, the anchors **12** are pulled through the anchor openings **80** to couple the restrictor **14** to the anchors **12**. In this step, distally-oriented pressure is applied to the restrictor guide **20** while the anchor graspers **18** are one-by-one pulled proximally, causing the anchors **12** to elongate sufficiently to pass through the openings **90**. Coupling between each anchor and its corresponding opening **80** is confirmed visually and/or by tactile feedback reflecting the "pop" of the anchor moving through the opening **80**. Once the restrictor **14** has been coupled to the anchors **12**, the cap **108** of the restrictor guide **20** is advanced distally to release the restrictor as described in the Restrictor Guide section above. The anchor graspers **18** are unlocked and separated from the anchors. The restrictor guide **20**, anchor graspers **18**, guides, etc. are withdrawn from the body, leaving the restrictor **14** and anchors **12** in place as shown in FIGS. **25**A and **25**B.

[0094] The system of FIG. **3** may additionally include one or more tools for use in forming plications in the stomach wall tissue and for forming holes in the plicated tissue. Examples of such plicators are found in the following co-pending U.S. patent applications: U.S. Publication No. US 2007/0219571 (entitled ENDOSCOPIC PLICATION DEVICES AND METHOD), filed Oct. 3, 2006, U.S. application Ser. No. 11/900,757 (entitled ENDOSCOPIC PLICATION DEVICE AND METHOD), filed Sep. 13, 2007, and U.S. application Ser. No. 12/050,169 (entitled ENDOSCOPIC STAPLING DEVICES AND METHODS), filed Mar. 18, 2008.

[0095] Use of one such tool is generally illustrated in FIGS. **26**A-**26**D and includes drawing stomach wall tissue into a vacuum chamber of a plication head (FIG. **26**A), compressing the tissue (FIG. **26**B), advancing fasteners such as staples through the compressed tissue and forming a cut or hole in the compressed tissue (FIG. **26**C), and releasing the tissue from the plication tool, leaving the plication with a hole or cut out through the plicated tissue. In one staple arrangement, a pair of annular staple patterns encircle the cut/hole. Anchors can be subsequently positioned within the hole/cutout as disclosed above.

[0096] Although the disclosed system has been described in the context of implanting a restrictor implants implantable in the stomach for limiting limit intake of food by the patient, the systems and methods may be used to implant other types of implants for a variety of purposes. These implants include, but are not limited to obstructive gastric implants that obstruct flow of food into the stomach, gastric space occupiers for limiting effective stomach volume, prosthetic valves for the treatment of gastro-esophageal reflux disease, gastric stimulators, pH monitors and drug eluting devices that release drugs, biologics or cells into the stomach or elsewhere in the GI tract. Such drug eluting devices might include those which release leptin (a hormone which creates feelings of satiety), Ghrelin (a hormone which creates feelings of hunger), octreotide (which reduces Ghrelin levels and thus reduces hunger), Insulin, chemotherapeutic agents, natural biologics (e.g., growth factor, cytokines) which aid in post surgery trauma, ulcers, lacerations, etc. Still other implants might be of a type which might provide a platform to which specific cell types can adhere, grow and provide biologically-active gene products to the GI tract, and/or a platform for radiation sources that can provide a local source of radiation for therapeutic purposes, or provide a platform whereby diagnostic ligands are immobilized and used to sample the GI tract for evidence of specific normal or pathological conditions, or provide an anchor point for imaging the GI tract via cameras and other image collecting devices. Additionally, the disclosed anchors and restrictors are shown positioned and anchored near the gastro-esophageal junction region of the proximal stomach, but may be positioned and/or anchored elsewhere in the stomach or GI system.

[0097] It should also be recognized that a number of variations of the above-identified embodiments will be obvious to one of ordinary skill in the art in view of the foregoing description. Accordingly, the invention is not to be limited by those specific embodiments and methods of the present invention shown and described herein. Rather, the scope of the invention is to be defined by the following claims and their equivalents.

[0098] Any and all patents and patent applications referred to herein, including for purposes of priority, are incorporated herein by reference.

We claim:

1. A method of coupling an implant to tissue having an opening formed therein, the method comprising:
providing an anchor having a head and a base;
drawing the head through the opening in the tissue to position the head on a first side of the plication and the base on a second side of the plication, and
coupling an implant to the anchor.

2. The method of claim **1**, wherein the method includes, after drawing the head through the opening, expanding the head to a diameter larger than the diameter of the opening.

3. The method of claim **1**, wherein drawing the head deforms the head for passage through the opening, an wherein expanding the head includes allowing the head to assume the larger diameter.

4. The method of claim **2**, wherein the method includes:
coupling the anchor to a first tool;
advancing the first tool into a body cavity;
advancing a second tool into the body cavity and passing the second tool through the opening;
after passing the second tool through the opening, engaging the anchor using the second tool;
withdrawing the second tool from the opening to draw the head through the opening; and
releasing the anchor from the first tool.

5. The method of claim **4**, wherein coupling the implant to the anchor includes passing the implant over the second tool and over the head.

6. The method of claim **2**, wherein the method includes coupling a tool to the head, and wherein coupling an implant to the anchor includes, with the tool coupled to the head and with a portion of the anchor disposed in the tissue opening, advancing the implant over the tool and into engagement with the anchor.

7. The method of claim **6**, wherein the implant includes an opening, and wherein advancing the implant over the tool and into engagement with the anchor includes threading the opening of the implant onto the tool and advancing the implant over the tool and the head.

8. The method of claim **1**, wherein coupling the implant to the anchor includes coupling the implant to the anchor after drawing the head through the tissue opening.

9. The method of claim **4**, wherein advancing the first tool into the body cavity includes advancing the first tool with the anchor thereon into the body cavity.

10. The method of claim **4**, wherein the anchor is coupled to the first tool after the first tool is advanced into the body cavity.

11. The method of claim **7**, wherein the method includes providing a plurality of the anchors and drawing the heads of the plurality of the anchors through a plurality of tissue openings, coupling a plurality of tools to the heads of the plurality of anchors, and advancing the implant over the plurality of tools and into engagement with the anchors.

12. The method of claim **6**, wherein the tissue opening is in a plication extending from a tissue wall and wherein:

providing the anchor includes providing the head to include a laterally-extending loop

the method further includes positioning the anchor within the tissue opening such that the loop extends generally away from the most proximate second of the tissue wall.

13. The method of claim **12**, wherein:

providing the anchor further includes providing the base to include a first edge having a first curvature and a second edge having a second, flatter curvature, the loop extending laterally in a direction opposite to the second edge of the base, and

positioning the anchor includes positioning the anchor with the second edge in contact with the wall to cause the loop to extend generally away from the most proximate section of the tissue wall.

14. The method of claim **12**, wherein the tissue opening is in a plication in a stomach wall, and wherein positioning the anchor includes transorally introducing the anchor into the stomach and positioning the anchor with the second edge in contact with the interior wall of the stomach.

15. The method of claim **1**, wherein the tissue opening is in a plication in a stomach wall, and wherein the method includes introducing the anchor and the implant transorally into the stomach.

16. The method of claim **15**, wherein the method is further for forming the opening in the tissue structure, and further includes:

forming a plication in the wall of the stomach;

forming an opening in the plication.

17. The method of claim **16**, wherein the method includes introducing a plication tool transorally into the stomach and forming the plication with the plication tool.

18. The method of claim **17**, wherein the method includes forming the opening in the plication with the plication tool.

19. A medical implant system for coupling an implant to an opening formed in body tissue, comprising:

an anchor comprising a head coupled to a base, the head having a first, natural, position in which the head has a diameter larger than a diameter of the opening, and a second, elongated, position in which the head is deformed for passage through the opening; and

an implant having an opening, the opening of the implant proportioned to allow passage of the head when the head is in the second position, and to resist passage of the head when the head is in the first position.

20. The medical implant system of claim **19**, wherein the anchor head is moveable from the first position to the second position in response to application of tension in a generally longitudinal direction between the head and the base.

21. The medical implant system of claim **19**, wherein the anchor head is moveable to a third position in response to application of tension to the head in a generally transverse direction, wherein in the third position the head is proportioned to resist passage through the opening.

22. The medical implant system of claim **19**, wherein the head is more elastic than the base.

23. The medical implant system of claim **19**, wherein the anchor includes a stem extending between the head and the base.

24. The medical implant system of claim **23**, wherein the stem is more elastic than the base.

25. The medical implant of claim **23**, wherein the head includes a ring coupled to the stem.

26. The medical implant system of claim **25**, wherein the ring has an undulating surface.

27. The medical implant system of claim **25**, wherein the head includes a loop extending laterally from the ring.

28. The medical implant system of claim **23**, wherein at least one of the head and the base is asymmetrical relative to the longitudinal axis of the stem.

29. The medical implant system of claim **19**, wherein the head includes a laterally-extending loop.

30. The medical implant system of claim **19**, wherein the base has a first edge having a first curvature and a second edge having a second, flatter curvature.

31. The medical implant system of claim **29**, wherein the head has a loop extending laterally in a direction opposite to the second edge of the base.

32. The medical implant system of claim **19**, wherein the body cavity is a stomach and the opening is in stomach tissue and wherein the system further includes a tool proportioned for transoral insertion into the body cavity and for extension through the opening in the stomach tissue, the tool engageable with the head to deform the head into the second position, the opening of the implant slidable over the tool through an oral cavity into position within the stomach.

33. The medical implant system of claim **32**, wherein the head includes a loop and wherein the tool is engageable with the loop.

34. The medical implant system of claim **33**, wherein the tool includes a jaw having an open position and a closed position.

35. The medical implant system of claim **32**, wherein:

the system includes a plurality of the anchors;

the implant includes a plurality of openings; and

the system includes a plurality of tools each transorally insertable into the stomach and extendable through separate openings formed in stomach tissue, each tool engageable with the head of a corresponding one of the anchors to deform the head into the second position, the opening of the implant slidable over the plurality of tools into engagement with the anchors.

36. The medical implant system of claim **32**, wherein the system is further for forming the opening in the stomach tissue, and wherein the system further includes a plication tool and a tissue cutting element, wherein the anchor is positionable within an opening formed by the tissue cutting element in a plication formed by the plication tool.

37. The medical implant system of claim **36**, wherein the tissue cutting element is on the plication tool.

38. The medical implant system of claim **37**, wherein the plication tool includes a plurality of staples advanceable through tissue for forming a plication.

39. The medical implant system of claim **19**, wherein the implant comprises a wall bounding an interior, and wherein the opening is formed in the wall.

40. The medical implant system of claim **39**, wherein the implant is a flow-restrictive implant proportioned for implantation within a stomach having the tissue opening formed in tissue of the stomach.

41. The medical implant system of claim **35**, further including:

an implant pusher having at least one engaging pin on a distal portion of the implant pusher, the implant pusher proportioned for transoral advancement into the stomach with the implant coupled to the engaging pin.

42. The medical implant system of claim **32**, further including instructions for use instructing the user to implant the anchor and implant according to the following steps:

coupling the anchor to the tool;

transorally advancing the tool into the stomach;

advancing a second tool into the stomach and passing the second tool through the tissue opening;

after passing the second tool through the opening, engaging the anchor using the second tool;

withdrawing the second tool from the opening to draw the head through the opening;

releasing the anchor from the first tool; and

passing the implant over the second tool and over the head.

43. A restrictive stomach implant, comprising:

a wall including a plurality of anchor points and compliant sections between the anchor points.

44. The restrictive stomach implant of claim **43**, wherein the compliant sections include at least one fold positioned between each pair of anchor points.

45. The restrictive stomach implant of claim **43**, wherein the wall is formed of first regions of a first material and second regions of a second material, the first regions more compliant than the second regions.

46. The restrictive implant of claim **45**, wherein the wall is formed of the first material, and wherein the second regions include sections of the second material positioned on the first material.

47. The restrictive implant of claim **46**, wherein the sections of second material include longitudinal ribs.

48. The restrictive implant of claim **45**, wherein the wall includes a distal orifice, and wherein the sections of second material include a ring of second material encircling the distal orifice.

49. The restrictive implant of claim **43**, wherein the wall defines a sleeve having a proximal edge, the proximal edge including proximally extending peaks.

50. The restrictive implant of claim **49**, wherein the peaks define chutes for directing ingested food material from a proximal portion of the implant towards a distal portion of the implant.

51. The restrictive implant of claim **43**, wherein the wall includes a distal orifice defined by an edge, wherein the edge includes a plurality of folds.

52. The restrictive implant of claim **43**, wherein the anchor points comprise a plurality of anchor openings formed in the wall.

53. The restrictive implant of claim **52**, wherein each of the anchor openings includes a circumferential reinforcement.

54. A medical implant system for use in a patient comprising:

an anchor configured to be coupled to tissue within a body cavity;

a first tool having a proximal portion, a distal portion, and a shaft between the proximal and distal portions, the distal portion including a coupling element operable to couple the first tool to the anchor, the first tool proportioned such that when the coupling element is coupled to the anchor within the body cavity, the proximal portion of the first tool extends out of the patient; and

an implant having an opening proportioned to slide over the shaft and distal end of the first tool and into engagement with the anchor.

55. The medical implant system according to claim **54** wherein the opening and the first tool are proportioned to allow the opening to slide over a proximal tip of the first tool.

56. The medical implant system according to claim **55**, wherein the proximal tip is tapered in a proximal direction.

57. The medical implant system according to claim **54**, further including a second tool having a distal end with a coupling element adapted to be detachably coupled to the implant, the implant opening slidable over the shaft of the first tool when the implant is coupled to the coupling element of the second tool, the second tool proportioned such that a proximal end of the second tool remains outside the patient during advancement of the implant over the distal end of the first tool and into engagement with the anchor within the body cavity.

58. The medical implant system according to claim **57**, wherein the coupling element of the second tool includes at least one longitudinally-extending pin extendable through a portion of the implant.

59. The medical implant system according to claim **58**, wherein the pin includes a free distal end, and wherein the coupling element further includes a distal containment element positioned such that relative movement of the free distal end of the pin and the distal containment element towards one another to a first position prevents detachment of the implant from the pin, and such that relative movement of the free distal end of the pin away from one another to a second position exposes the pin to allow detachment of the implant from the pin.

60. The medical implant system according to claim **59**, wherein the coupling element of the second tool includes a plurality of longitudinally-extendable pins extendable through the implant, and wherein in the second position the distal containment element is positioned to detachment of the implant from the plurality of pins.

61. The medical implant system according to claim **60**, wherein the implant includes a base, a wall coupled to the base and surrounding an interior, a first opening in the base, and a plurality of second openings surrounding the exit port, and wherein the plurality of pins are positionable within the plurality of second openings, with a shaft of the second tool extending through the exit port.

* * * * *