US008641729B2

(12) **United States Patent**
Filipi et al.

(10) **Patent No.: US 8,641,729 B2**
(45) **Date of Patent: Feb. 4, 2014**

(54) **SYSTEMS AND TECHNIQUES FOR MINIMALLY INVASIVE GASTROINTESTINAL PROCEDURES**

(75) Inventors: **Charles J. Filipi**, Omaha, NE (US); **Scott D. Klopfenstein**, Phoenix, AZ (US); **Jason L. Addink**, Gilbert, AZ (US)

(73) Assignee: **Creighton University**, Omaha, NE (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1642 days.

(21) Appl. No.: **11/457,442**

(22) Filed: **Jul. 13, 2006**

(65) **Prior Publication Data**

US 2007/0129735 A1 Jun. 7, 2007

Related U.S. Application Data

(60) Provisional application No. 60/698,748, filed on Jul. 13, 2005, provisional application No. 60/742,826, filed on Dec. 6, 2005, provisional application No. 60/757,694, filed on Jan. 10, 2006.

(51) **Int. Cl.**
A61B 17/04 (2006.01)

(52) **U.S. Cl.**
USPC **606/144**; 606/139; 606/148

(58) **Field of Classification Search**
USPC 606/139, 1, 142, 144–148, 151, 153, 606/158; 128/898
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,803,985	A	2/1989	Hill	
4,841,888	A	6/1989	Mills et al.	
4,927,428	A	5/1990	Richards	
5,037,021	A	8/1991	Mills et al.	
5,080,663	A	1/1992	Mills et al.	
5,437,681	A	8/1995	Meade et al.	
5,540,705	A	7/1996	Meade et al.	
5,545,148	A	8/1996	Wurster	
5,643,293	A	7/1997	Kogasaka et al.	
5,755,730	A	5/1998	Swain et al.	
5,792,153	A	8/1998	Swain et al.	
5,908,429	A *	6/1999	Yoon	606/144
5,947,983	A *	9/1999	Solar et al.	606/144

(Continued)

FOREIGN PATENT DOCUMENTS

EP	1 518 507 A1	3/2005
EP	1 584 294 A2	10/2005

(Continued)

OTHER PUBLICATIONS

European Patent Application 11163638.7 Extended Search Report mailed Nov. 21, 2011.

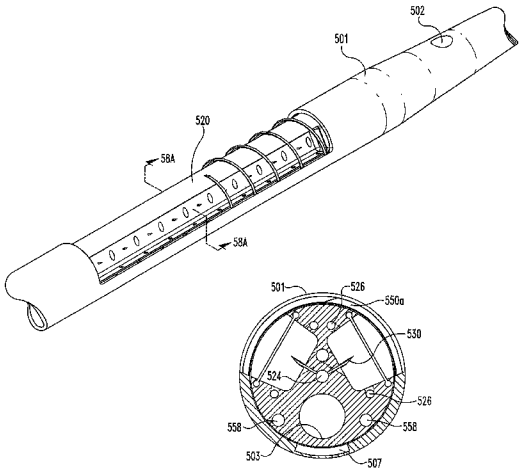
(Continued)

Primary Examiner — Corrine M McDermott
Assistant Examiner — Mark Mashack
(74) *Attorney, Agent, or Firm* — Woodard, Emhardt, Moriarty, McNett & Henry LLP

(57) **ABSTRACT**

A surgical system for performing gastroplasty is disclosed. The system includes an elongated body adapted to be inserted into the esophagus with a proximal end extending from a body orifice. A working member includes a pair of elongated suction cavities that capture and excise portions of the anterior and posterior stomach walls and apply sutures to the captured tissue, which, when drawn tight, serve to create a modified lumen in the stomach.

16 Claims, 43 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

5,972,153	A	10/1999	Focke et al.	
6,071,289	A	6/2000	Stefanchik et al.	
6,494,888	B1	12/2002	Laufer et al.	
6,506,196	B1	1/2003	Laufer et al.	
6,543,456	B1	4/2003	Freeman	
6,558,400	B2 *	5/2003	Deem et al.	606/151
6,572,629	B2	6/2003	Kalloo et al.	
6,592,593	B1	7/2003	Parodi et al.	
6,656,194	B1	12/2003	Gannoe et al.	
6,663,639	B1	12/2003	Laufer et al.	
6,719,763	B2	4/2004	Chung et al.	
6,746,460	B2	6/2004	Gannoe et al.	
6,755,843	B2	6/2004	Chung et al.	
6,773,440	B2	8/2004	Gannoe et al.	
6,773,441	B1	8/2004	Laufer et al.	
6,800,081	B2	10/2004	Parodi	
6,821,285	B2	11/2004	Laufer et al.	
6,835,200	B2	12/2004	Laufer et al.	
6,923,819	B2	8/2005	Meade et al.	
2001/0049497	A1	12/2001	Kalloo et al.	
2002/0055757	A1	5/2002	Torre et al.	
2002/0193816	A1	12/2002	Laufer et al.	
2003/0065359	A1 *	4/2003	Weller et al.	606/213
2003/0120289	A1	6/2003	McGuckin et al.	
2003/0139752	A1	7/2003	Pasricha et al.	
2003/0181924	A1	9/2003	Yamamoto et al.	
2003/0208209	A1 *	11/2003	Gambale et al.	606/144
2003/0216613	A1	11/2003	Suzuki et al.	
2003/0216749	A1	11/2003	Ishikawa et al.	
2003/0225312	A1	12/2003	Suzuki et al.	
2003/0229296	A1	12/2003	Ishikawa et al.	
2003/0236535	A1	12/2003	Onuki et al.	
2004/0034371	A1	2/2004	Lehman et al.	
2004/0044353	A1	3/2004	Gannoe	
2004/0044354	A1	3/2004	Gannoe et al.	
2004/0044357	A1	3/2004	Gannoe et al.	
2004/0054347	A1	3/2004	Zadno-Azizi et al.	
2004/0082963	A1	4/2004	Gannoe et al.	
2004/0087996	A1	5/2004	Gambale et al.	
2004/0092892	A1	5/2004	Kagan et al.	
2004/0092965	A1	5/2004	Parihar	
2004/0092974	A1	5/2004	Gannoe et al.	
2004/0138682	A1	7/2004	Onuki et al.	
2004/0147941	A1	7/2004	Takemoto et al.	
2004/0158125	A1	8/2004	Aznoian et al.	
2004/0167546	A1	8/2004	Saadat et al.	
2004/0181238	A1	9/2004	Zarbatany et al.	
2004/0193117	A1	9/2004	Laufer et al.	
2004/0193184	A1	9/2004	Laufer et al.	
2004/0193193	A1	9/2004	Laufer et al.	
2004/0193194	A1	9/2004	Laufer et al.	
2004/0194790	A1	10/2004	Laufer et al.	
2004/0210243	A1	10/2004	Gannoe et al.	
2004/0225191	A1	11/2004	Sekine et al.	
2004/0249395	A1	12/2004	Mikkaichi et al.	
2005/0004431	A1	1/2005	Kogasaka et al.	
2005/0033325	A1	2/2005	May et al.	
2005/0033328	A1	2/2005	Laufer et al.	
2005/0049455	A1	3/2005	Ootawara et al.	
2005/0049614	A1	3/2005	Cendan	
2005/0049617	A1	3/2005	Chatlynne et al.	
2005/0055038	A1	3/2005	Kelleher et al.	
2005/0065483	A1	3/2005	Nakao	
2005/0080438	A1	4/2005	Weller et al.	
2005/0090862	A1	4/2005	McDevitt et al.	
2005/0096673	A1 *	5/2005	Stack et al.	606/151
2005/0096750	A1	5/2005	Kagan et al.	
2005/0113869	A1	5/2005	Price	
2005/0149067	A1	7/2005	Takemoto et al.	
2005/0165419	A1	7/2005	Sauer et al.	
2005/0177176	A1	8/2005	Gerbi et al.	
2005/0192599	A1	9/2005	Demarais	
2005/0192601	A1	9/2005	Demarais	
2005/0192615	A1	9/2005	Torre et al.	
2005/0203488	A1	9/2005	Michlitsch et al.	
2005/0203500	A1	9/2005	Saadat et al.	
2005/0203547	A1	9/2005	Weller et al.	
2005/0203548	A1	9/2005	Weller et al.	
2005/0209612	A1	9/2005	Nakao	
2005/0216040	A1	9/2005	Gertner et al.	
2005/0251153	A1	11/2005	Sakamoto et al.	
2005/0251175	A1	11/2005	Weisenburgh et al.	
2006/0253127	A1 *	11/2006	Bjerken	606/139

FOREIGN PATENT DOCUMENTS

WO	WO 01/89370	A2	11/2001
WO	WO 02/062200		8/2002
WO	WO 2004/103157		12/2004
WO	WO 2005/011463		2/2005
WO	WO 2005/020802		3/2005
WO	WO 2005/086945	A	9/2005
WO	PCT/US06/61665		6/2007

OTHER PUBLICATIONS

U.S. Appl. No. 12/134,685 to Filipi et al., Office Action mailed May 25, 2012.

EP search report for EP 06840122.3 dated Apr. 15, 2009.

* cited by examiner

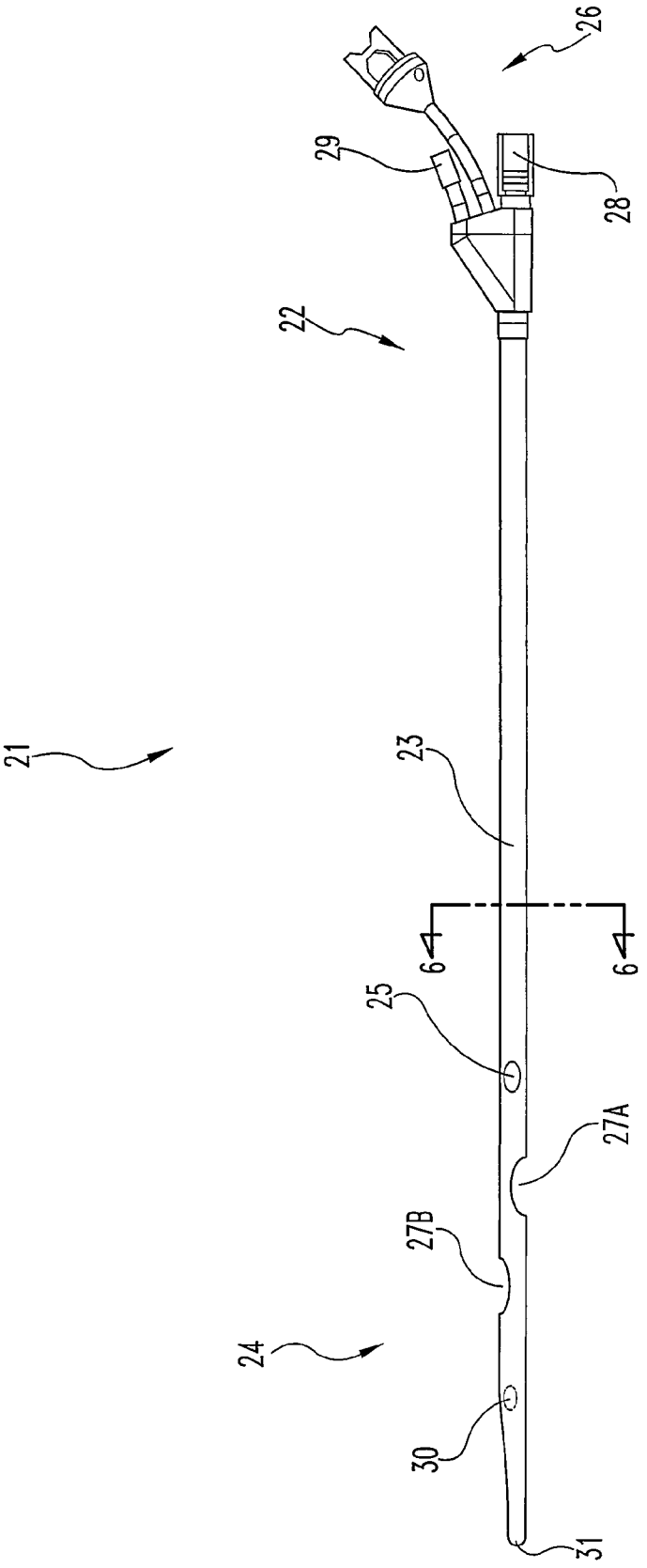


Fig. 1

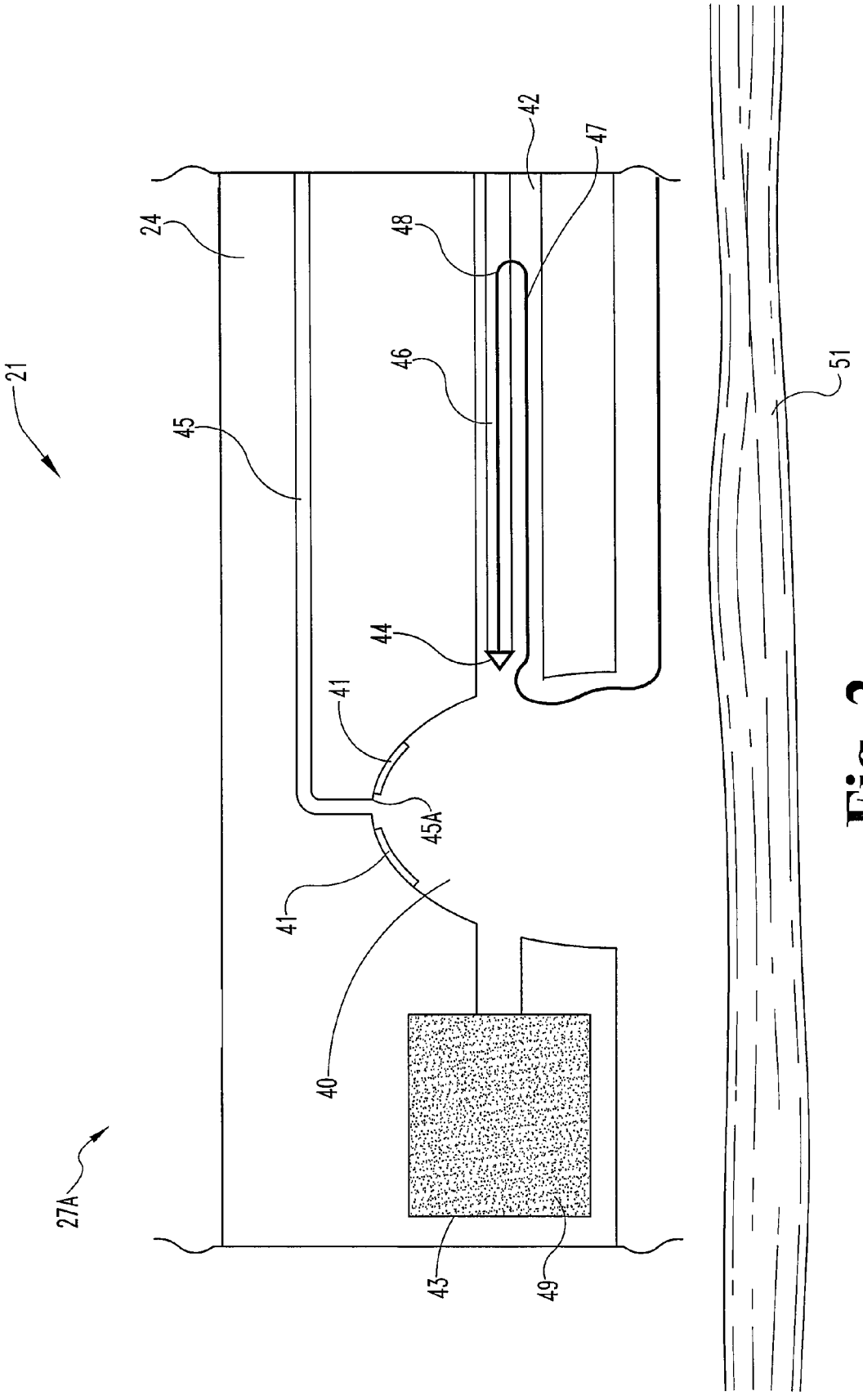


Fig. 2

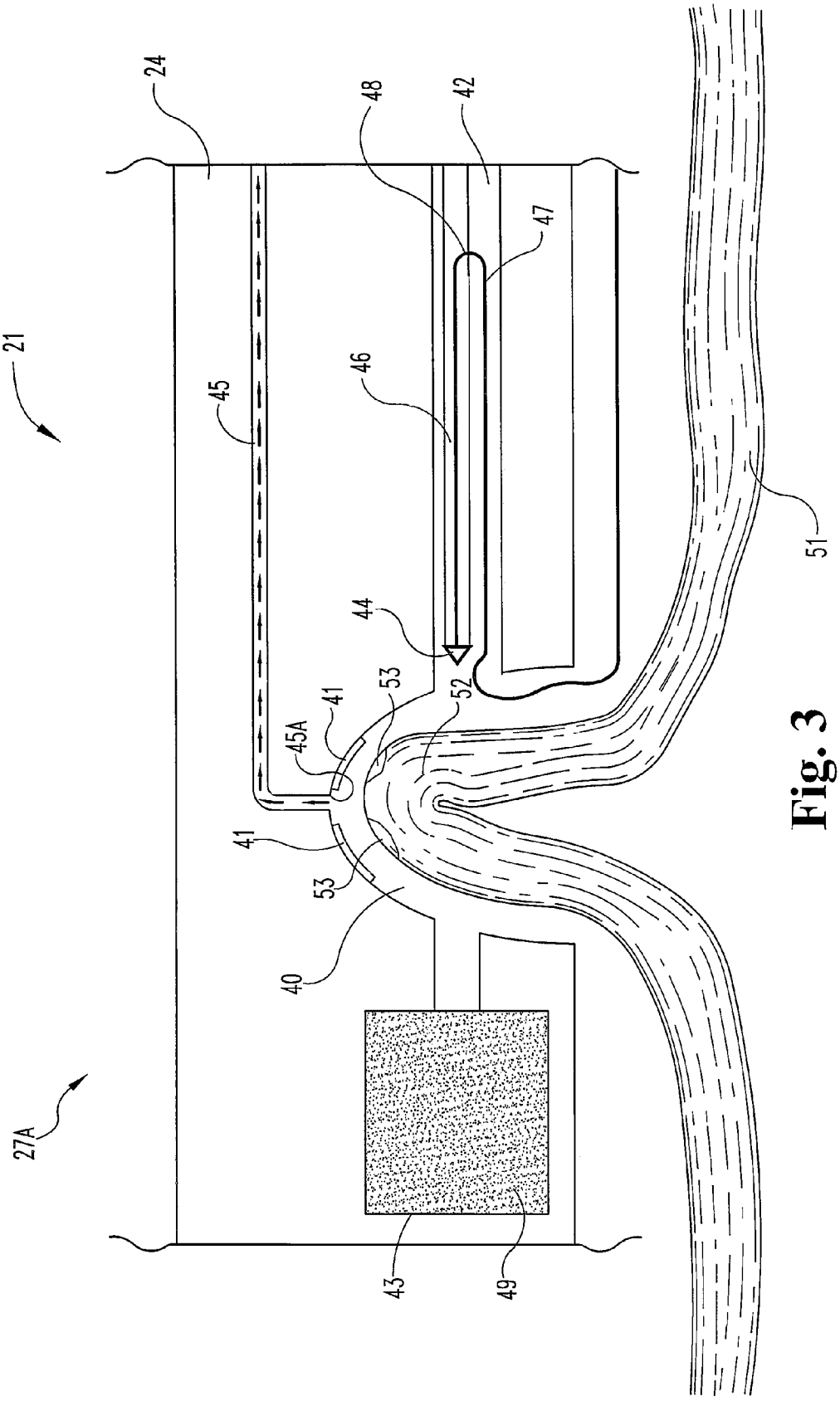


Fig. 3

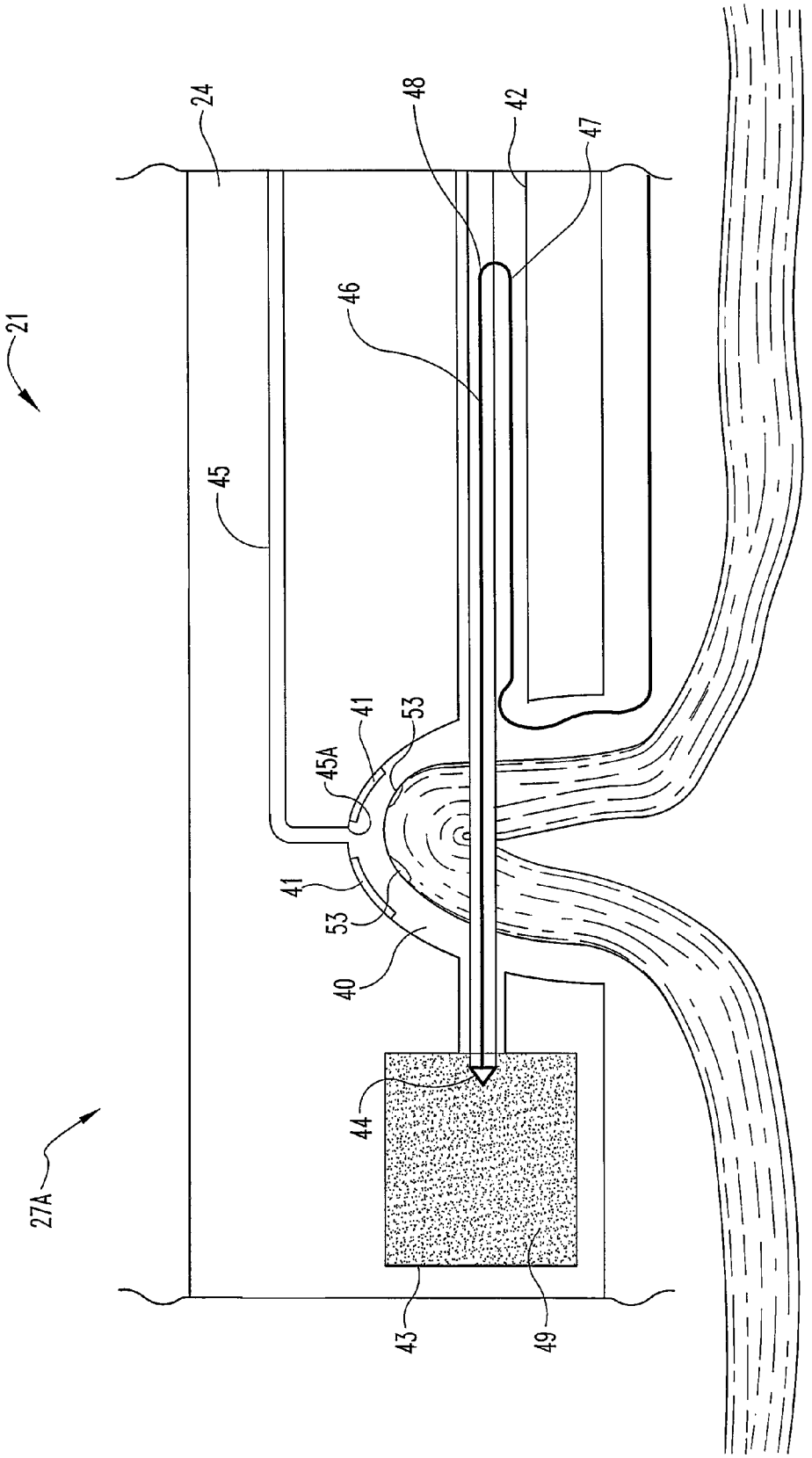


Fig. 4

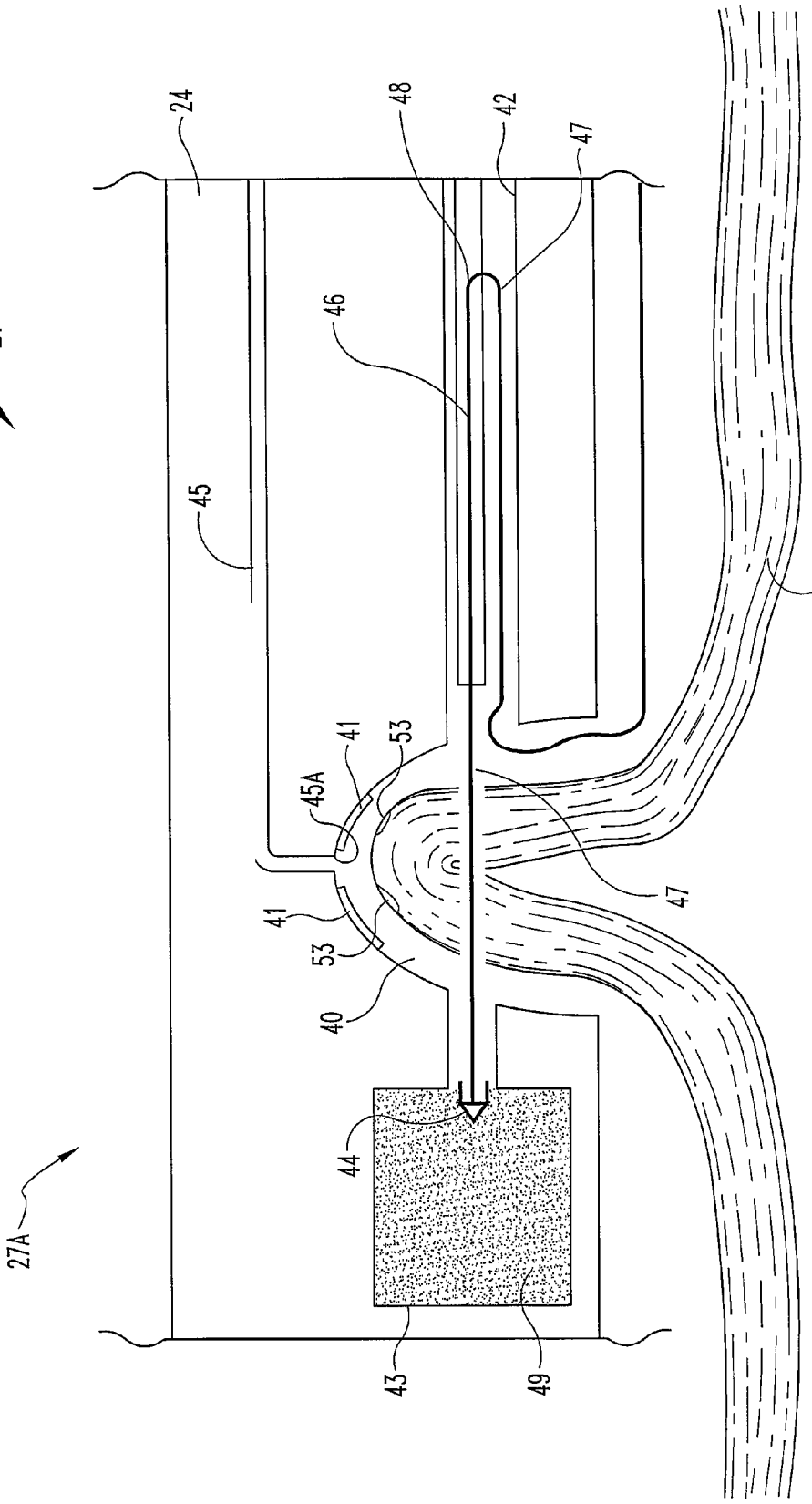


Fig. 5

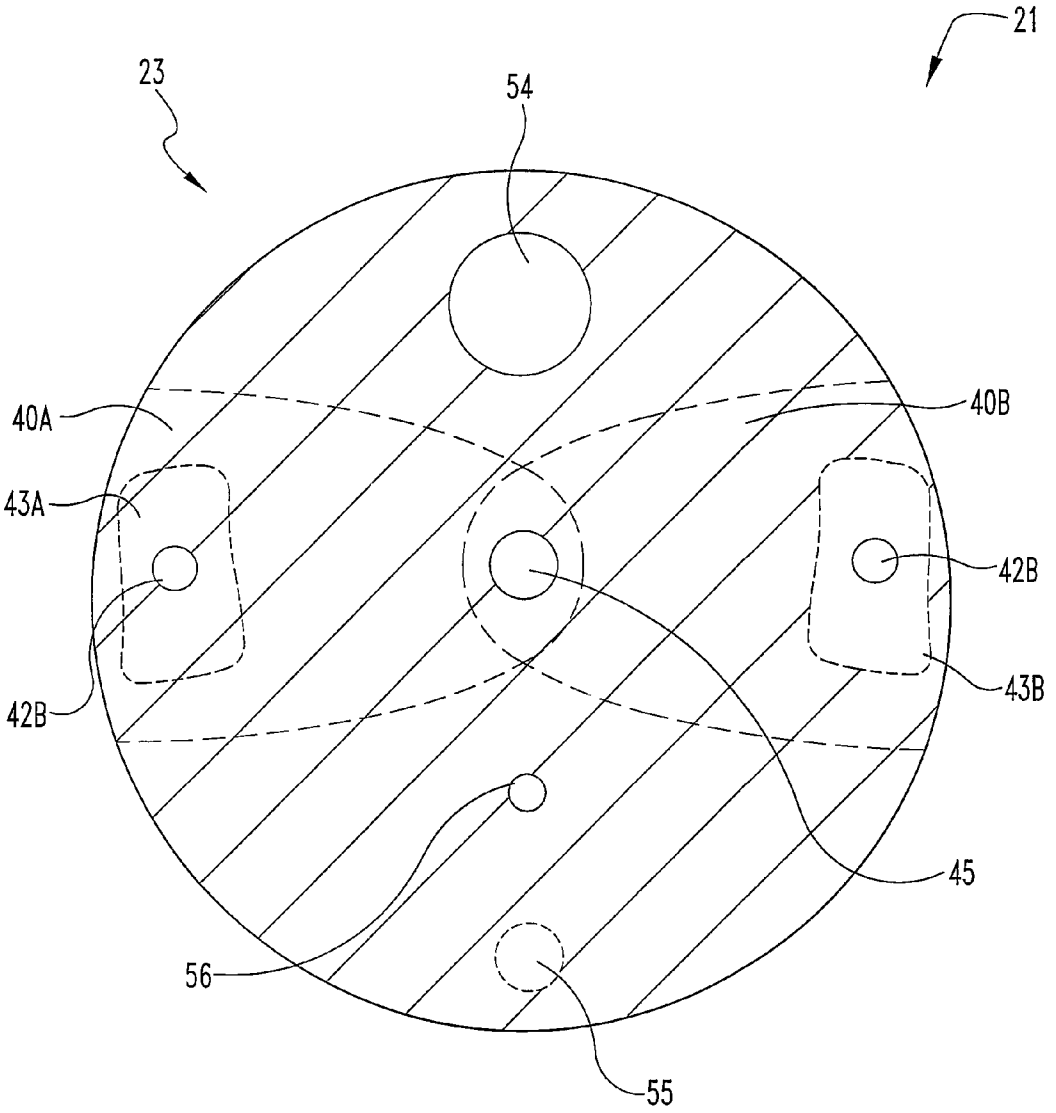


Fig. 6

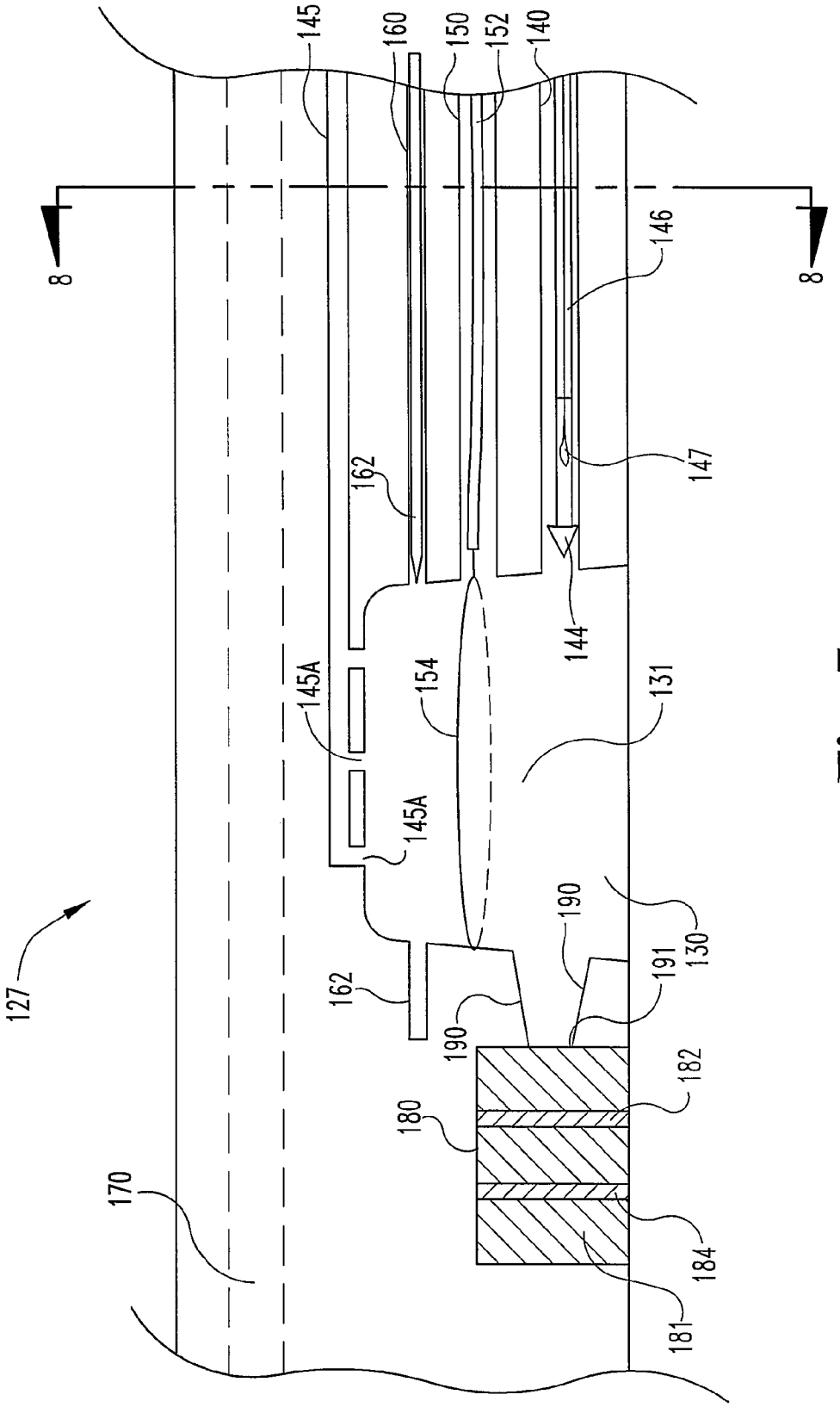

145
160
150
152
140
8
8
146
147
162
144
154
131
145A
145A
190
130
191
162
190
182
180
170
184
181
127

Fig. 7

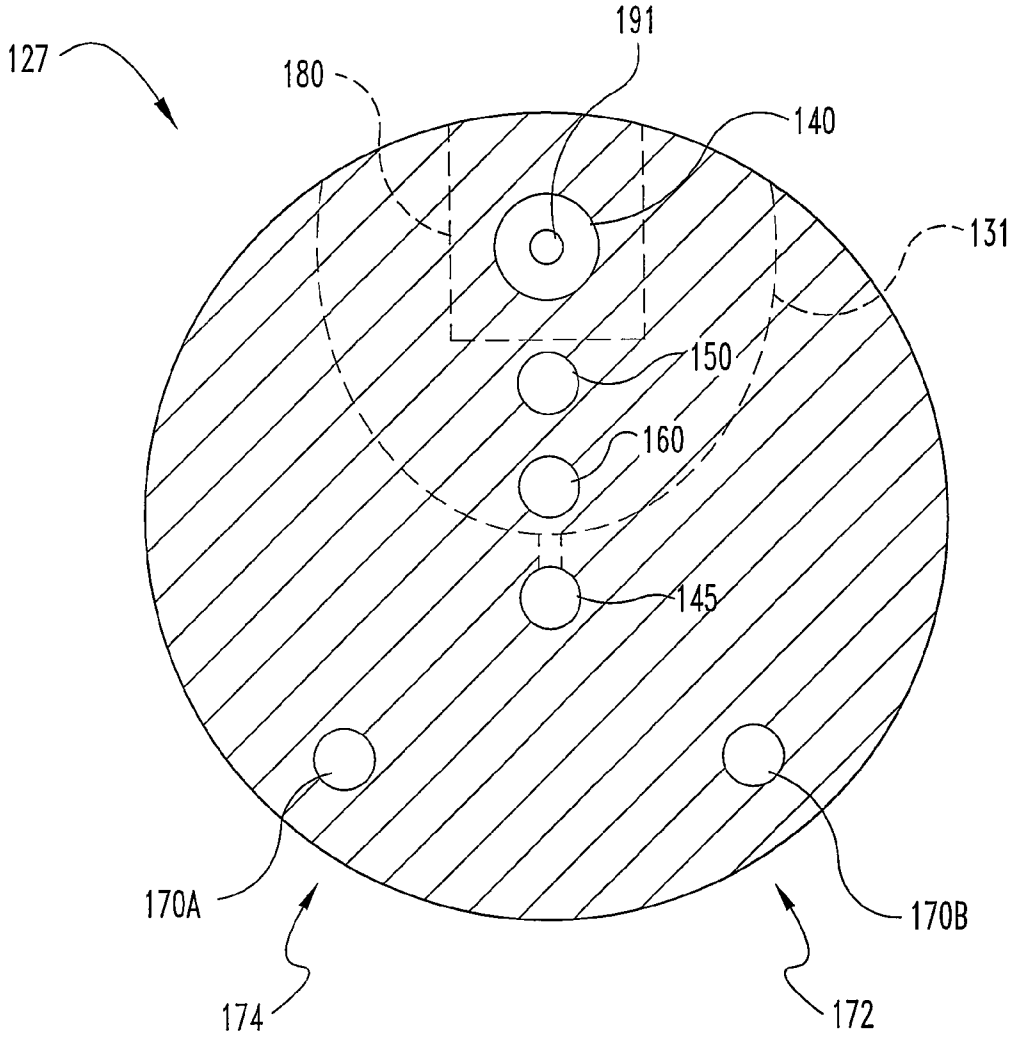


Fig. 8

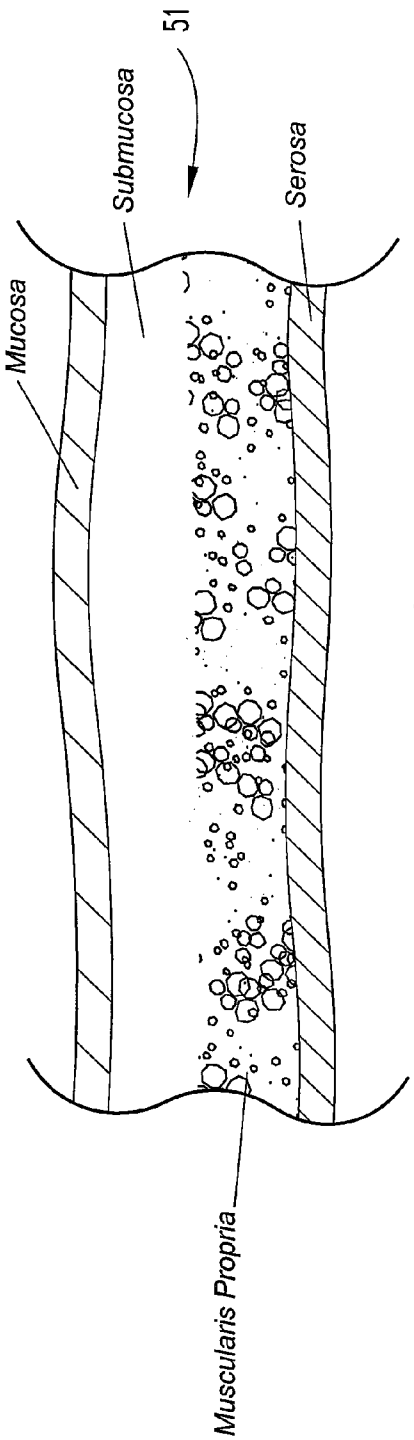


Fig. 9

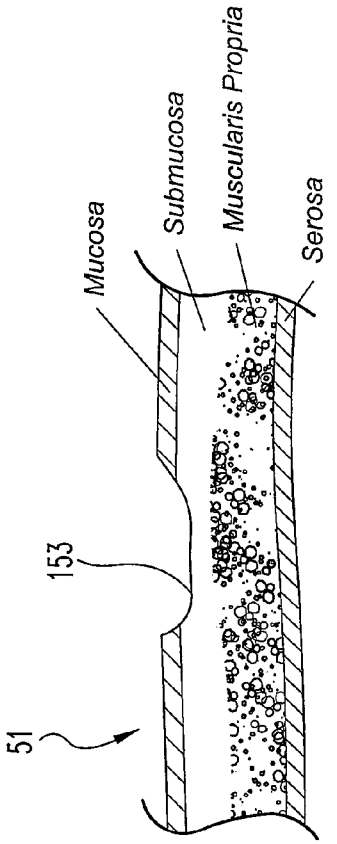


Fig. 11

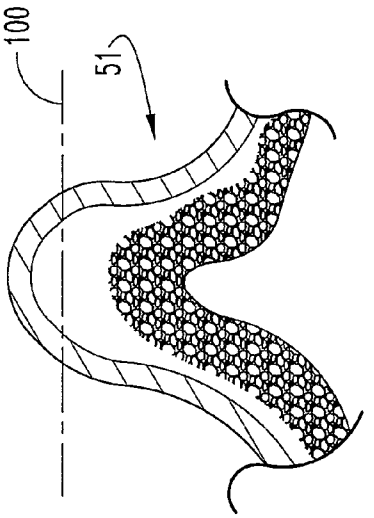


Fig. 10

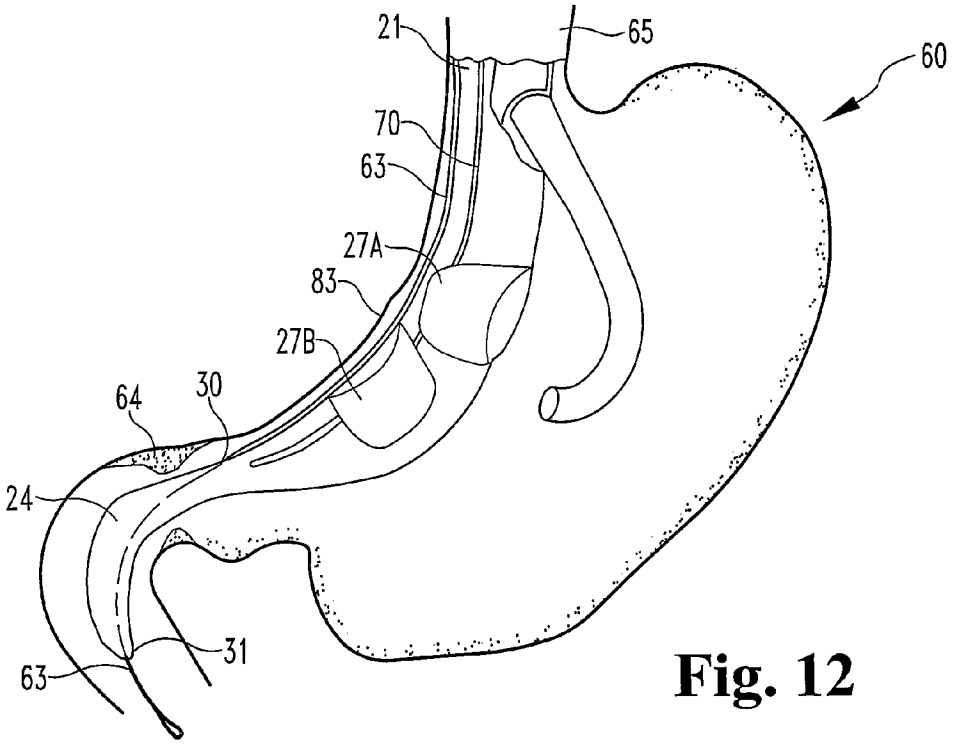


Fig. 12

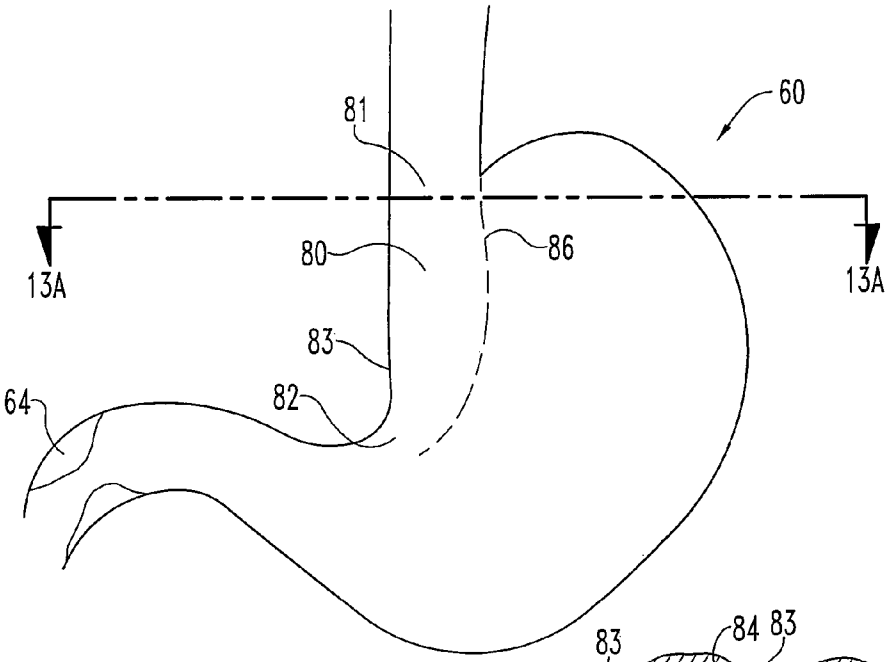


Fig. 13

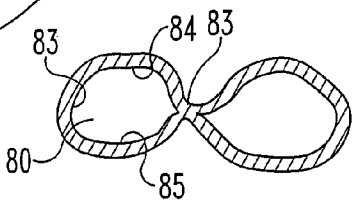


Fig. 13A

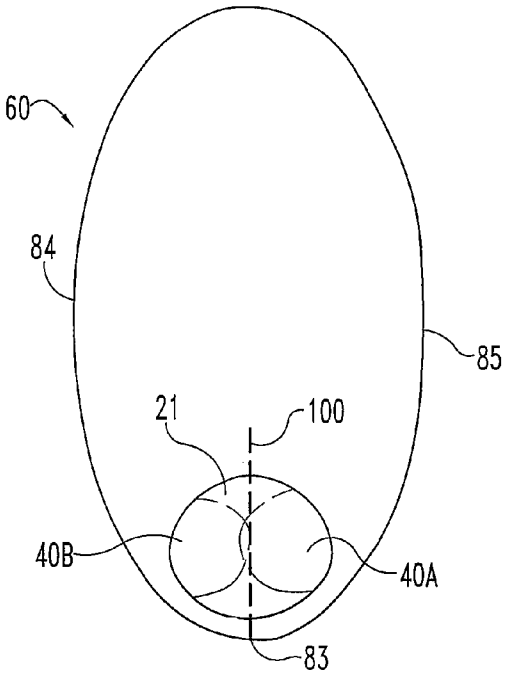


Fig. 14

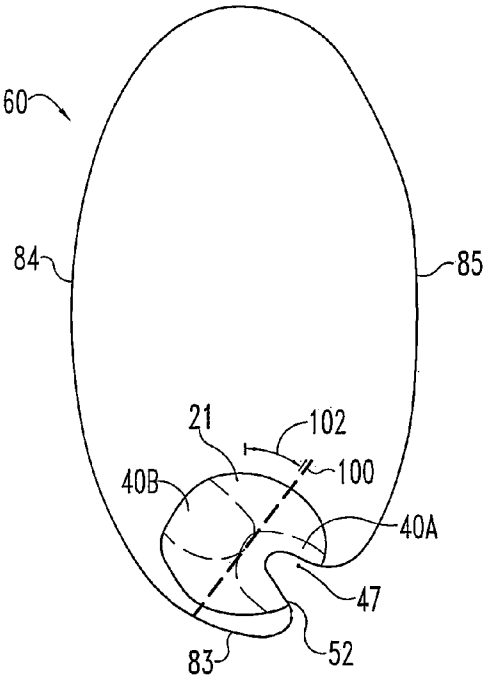


Fig. 15

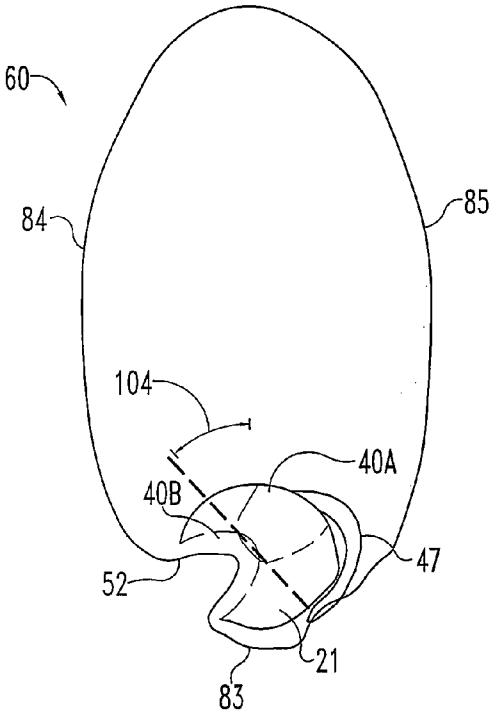


Fig. 16

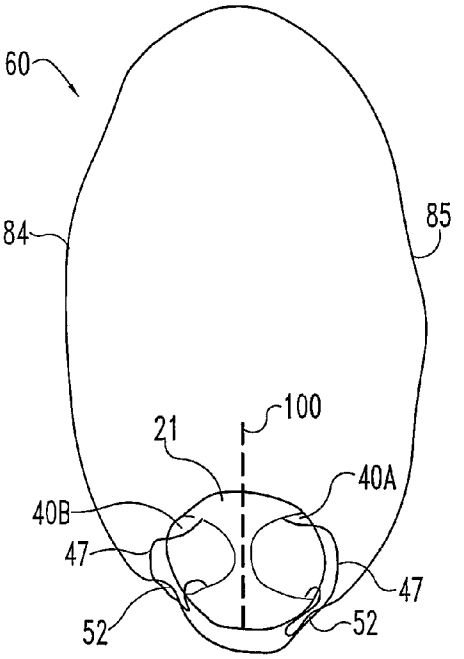


Fig. 17

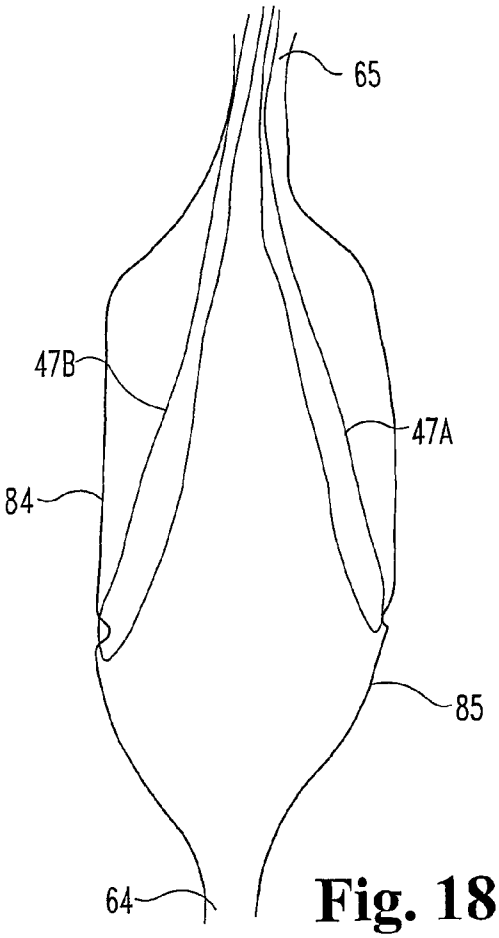


Fig. 18

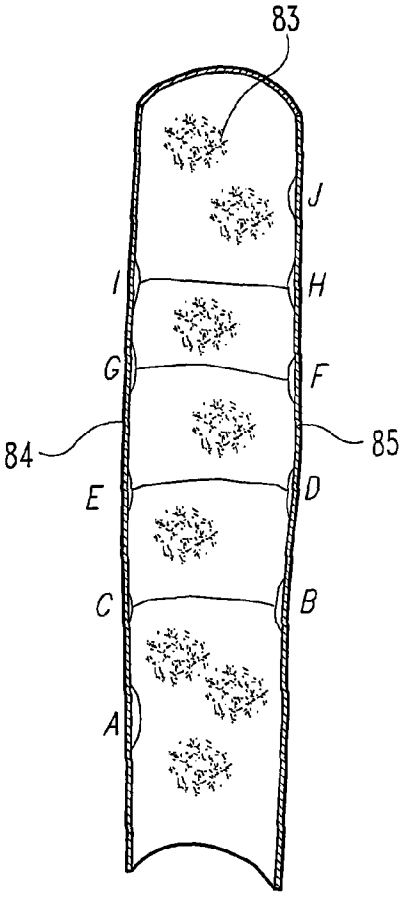


Fig. 19

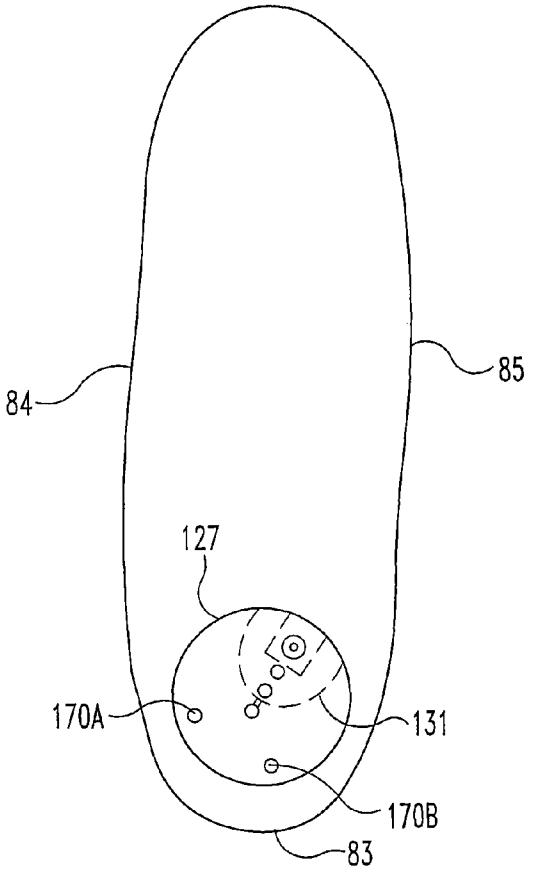


Fig. 20

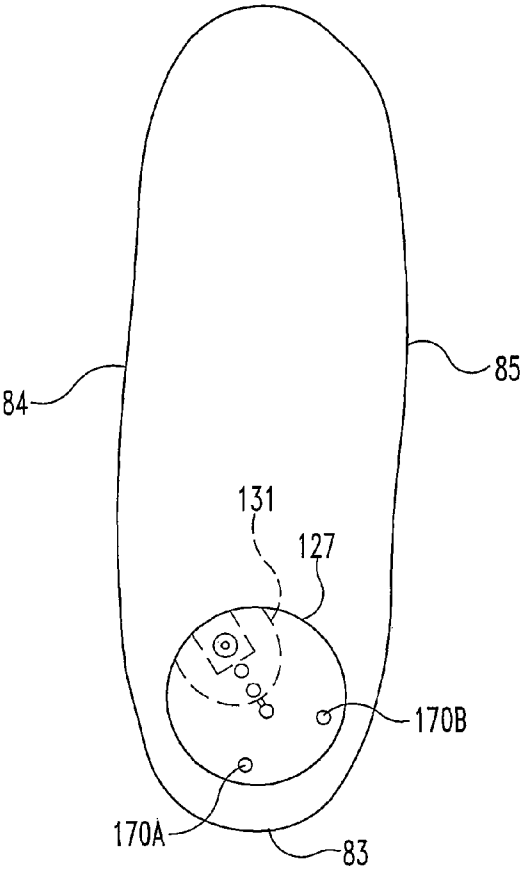


Fig. 21

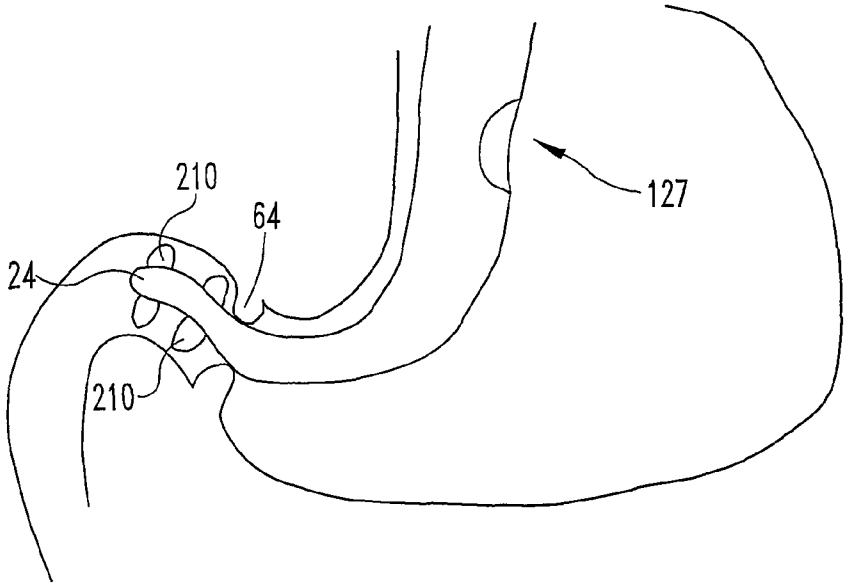


Fig. 22

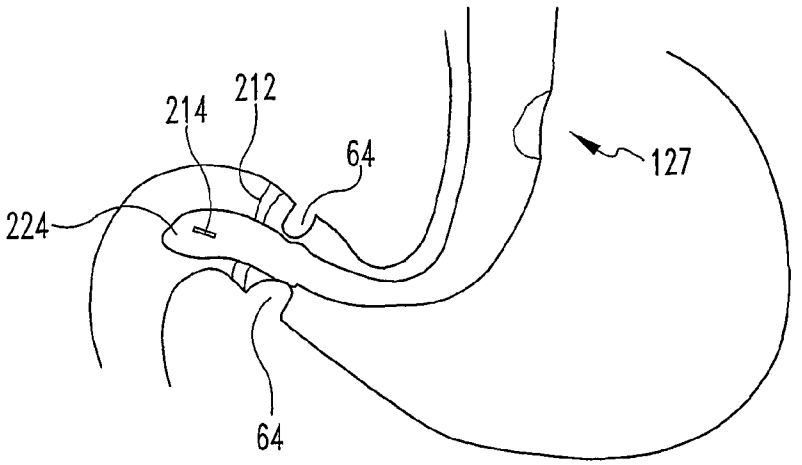


Fig. 23

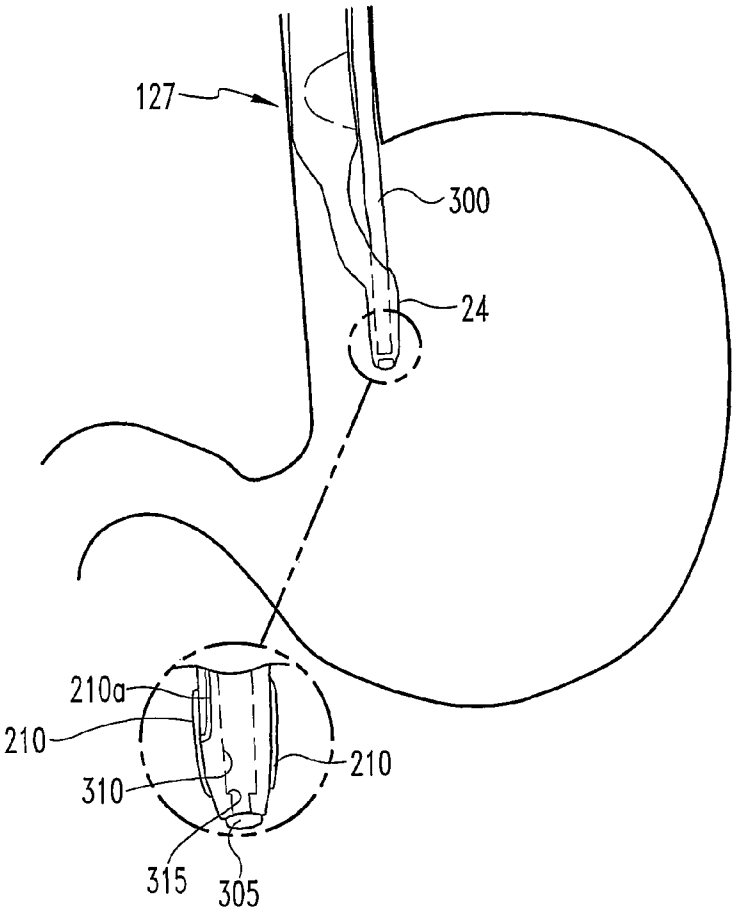


Fig. 24

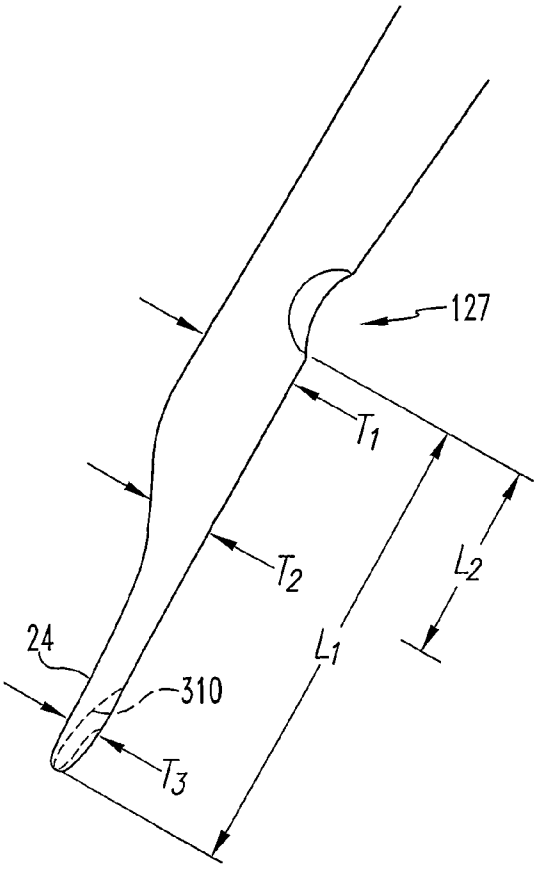


Fig. 25

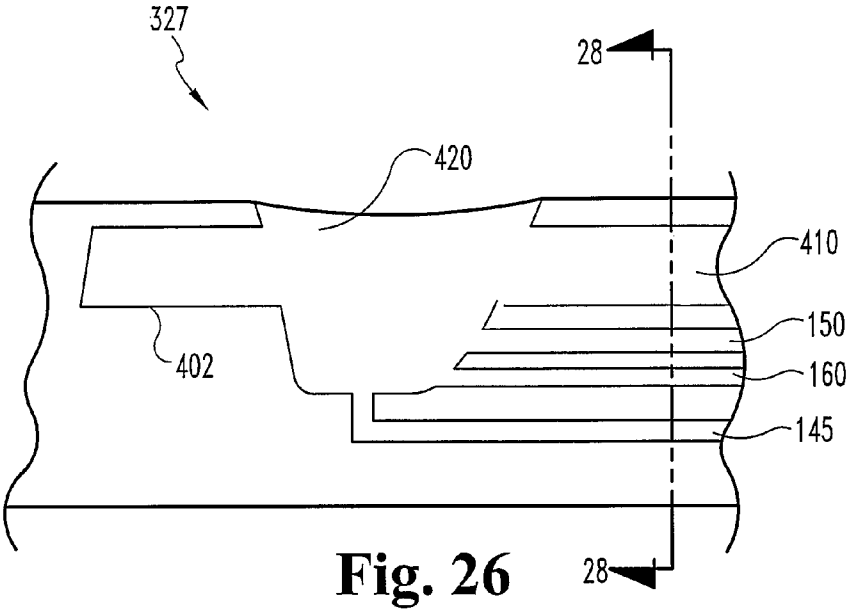


Fig. 26

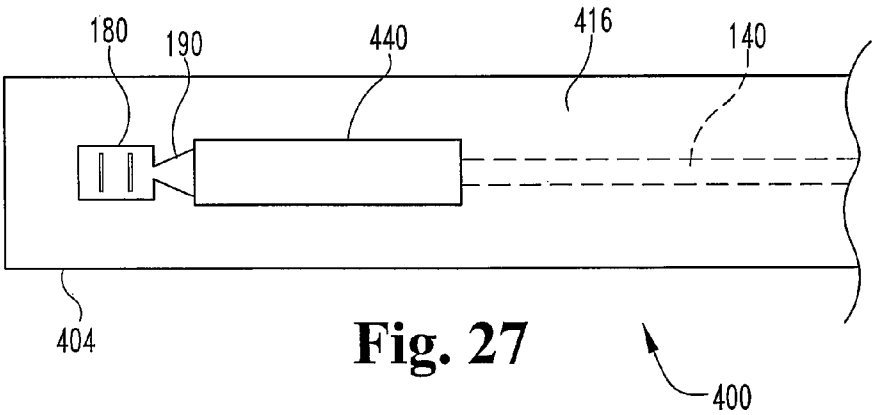


Fig. 27

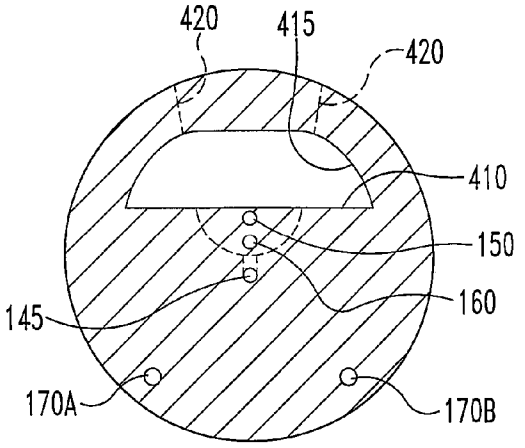


Fig. 28

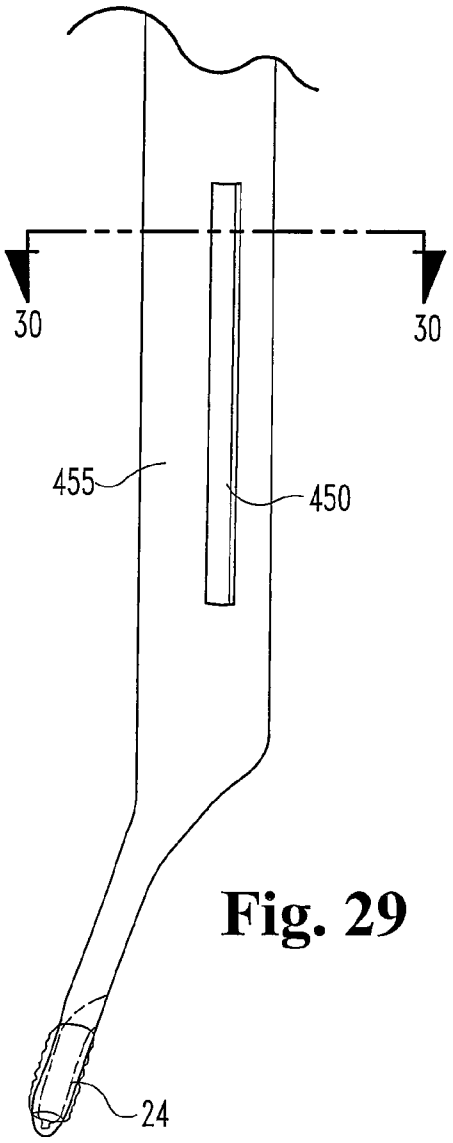


Fig. 29

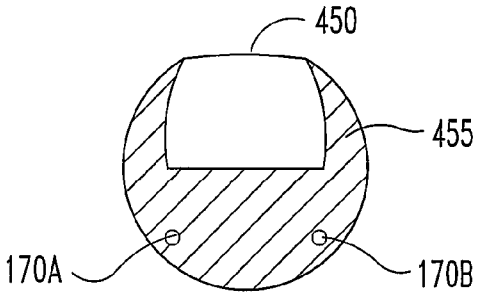


Fig. 30

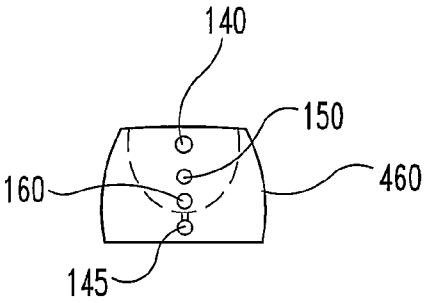


Fig. 31

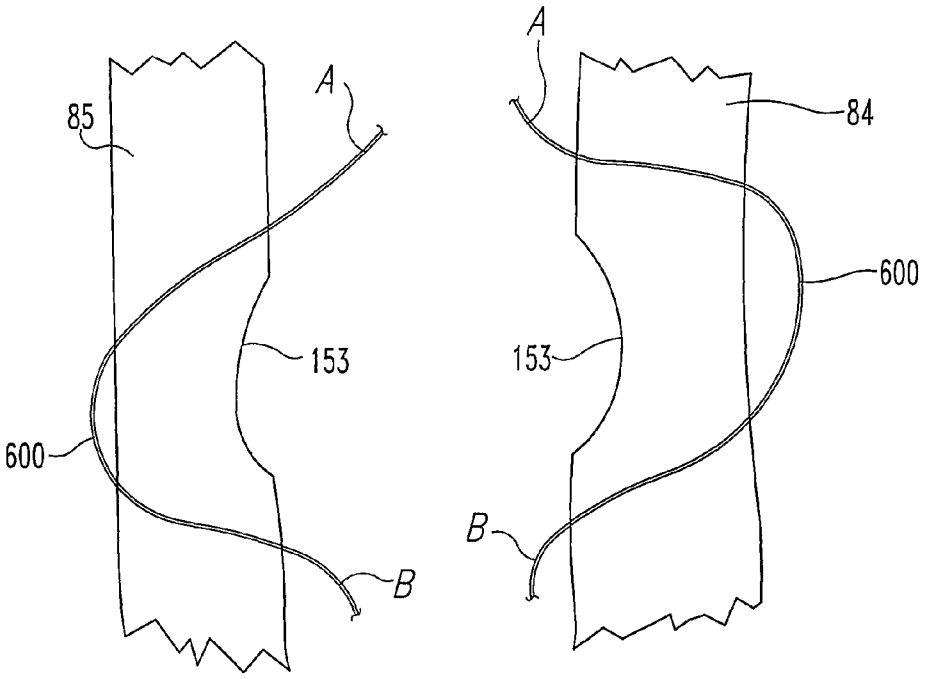


Fig. 32

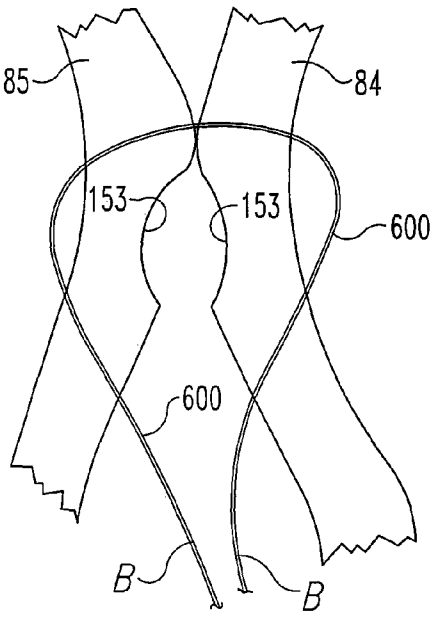


Fig. 33

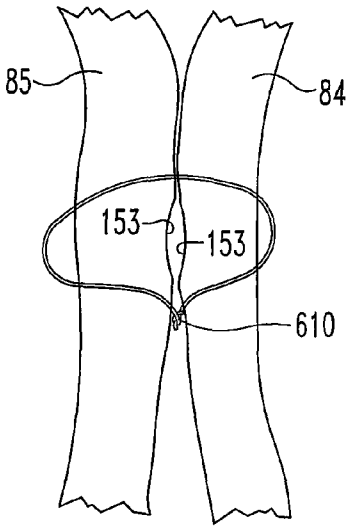


Fig. 34

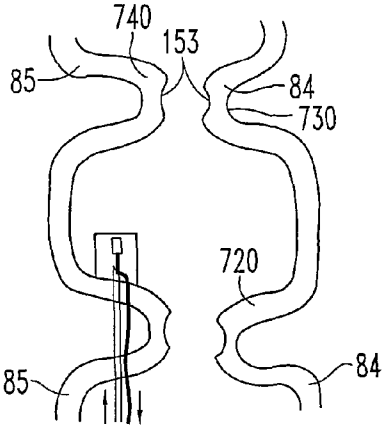


Fig. 35A

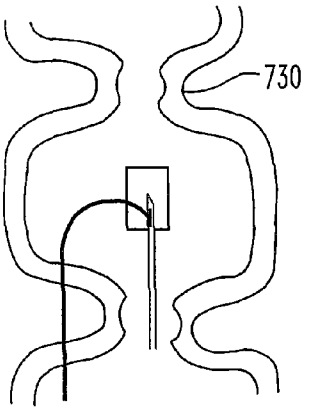


Fig. 35B

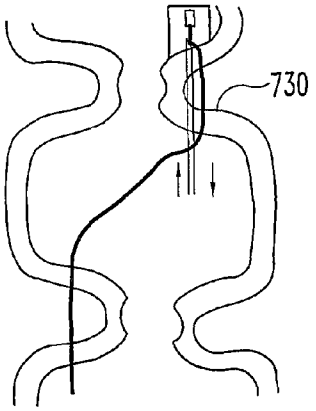


Fig. 35C

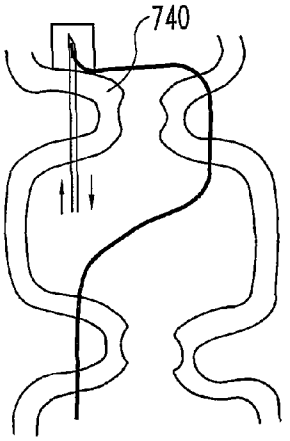


Fig. 35D

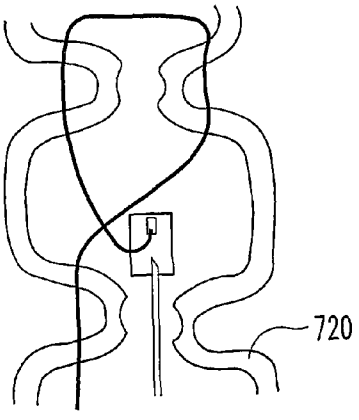


Fig. 35E

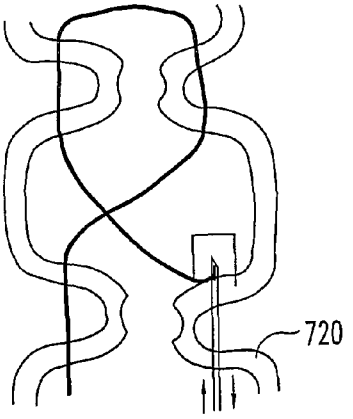


Fig. 35F

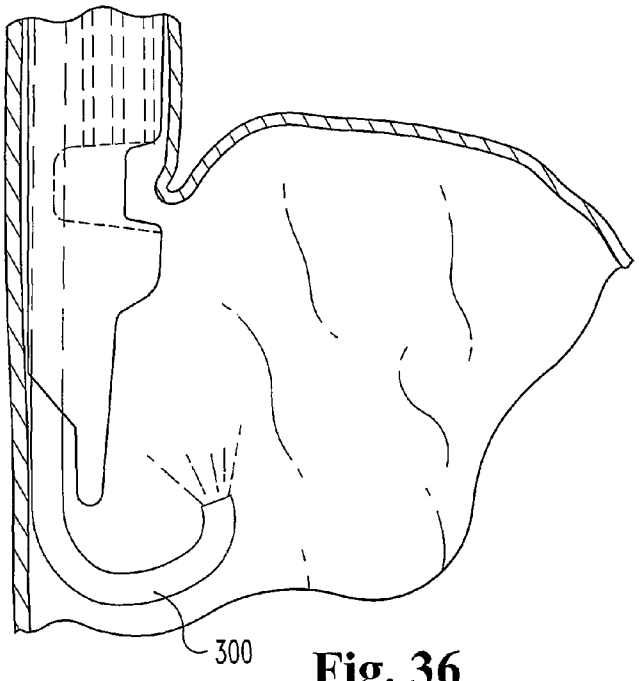


Fig. 36

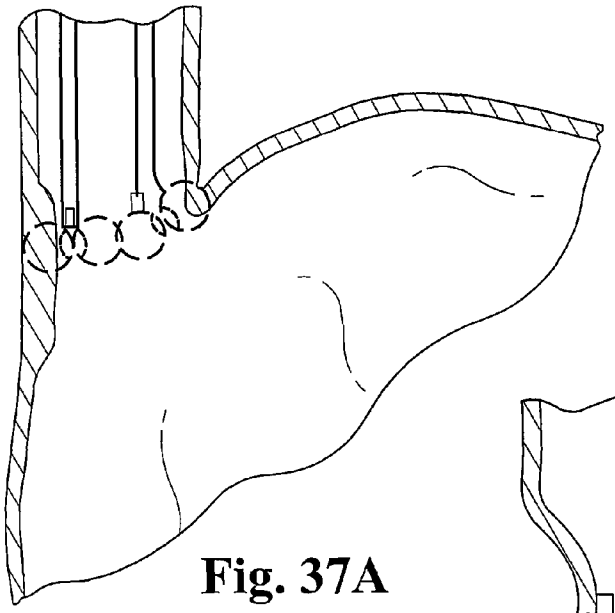


Fig. 37A

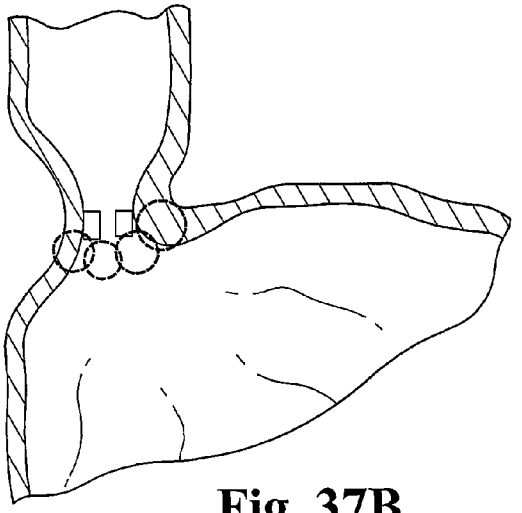


Fig. 37B

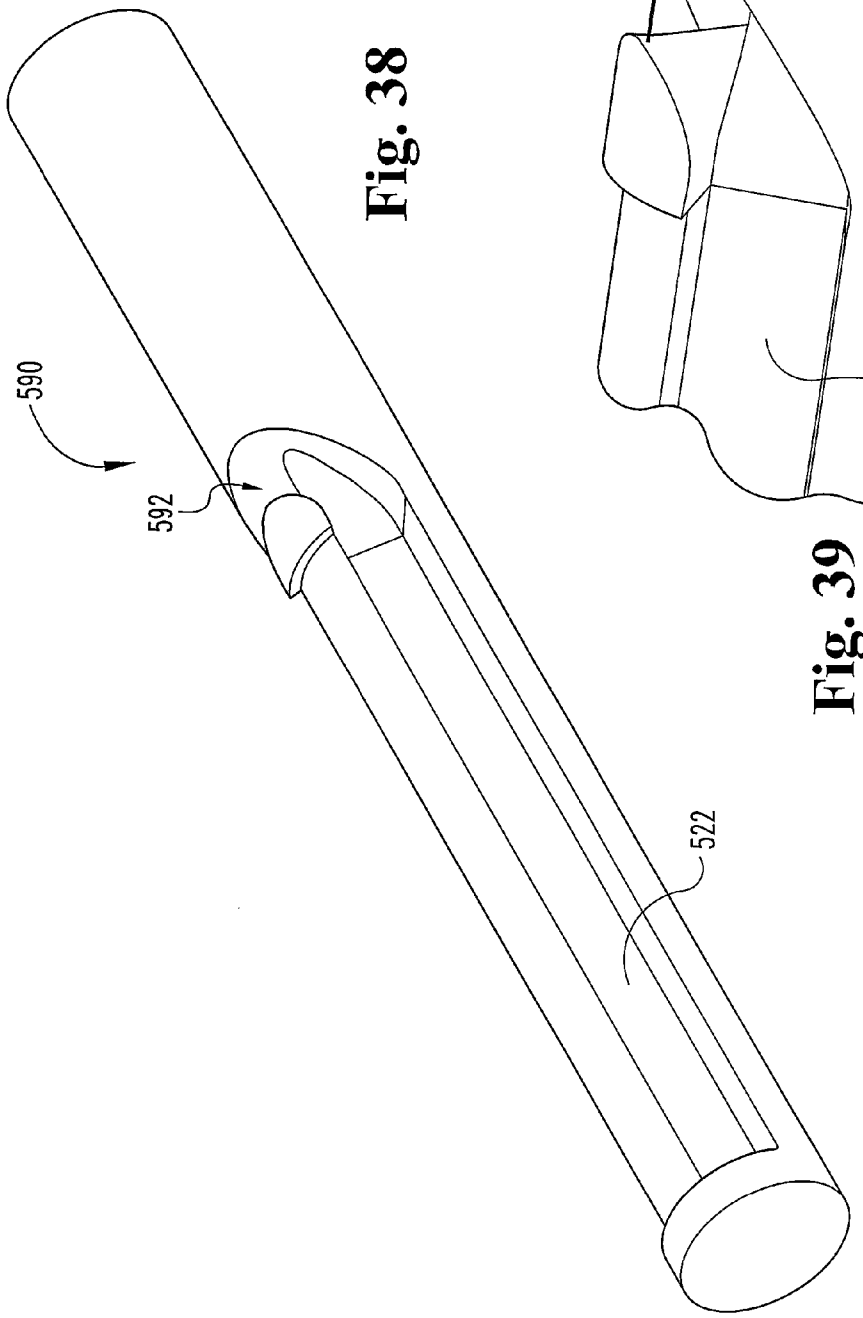


Fig. 38

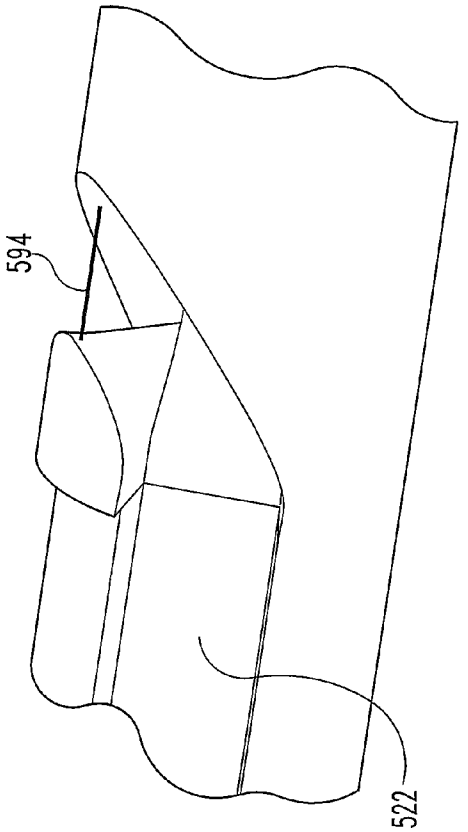


Fig. 39

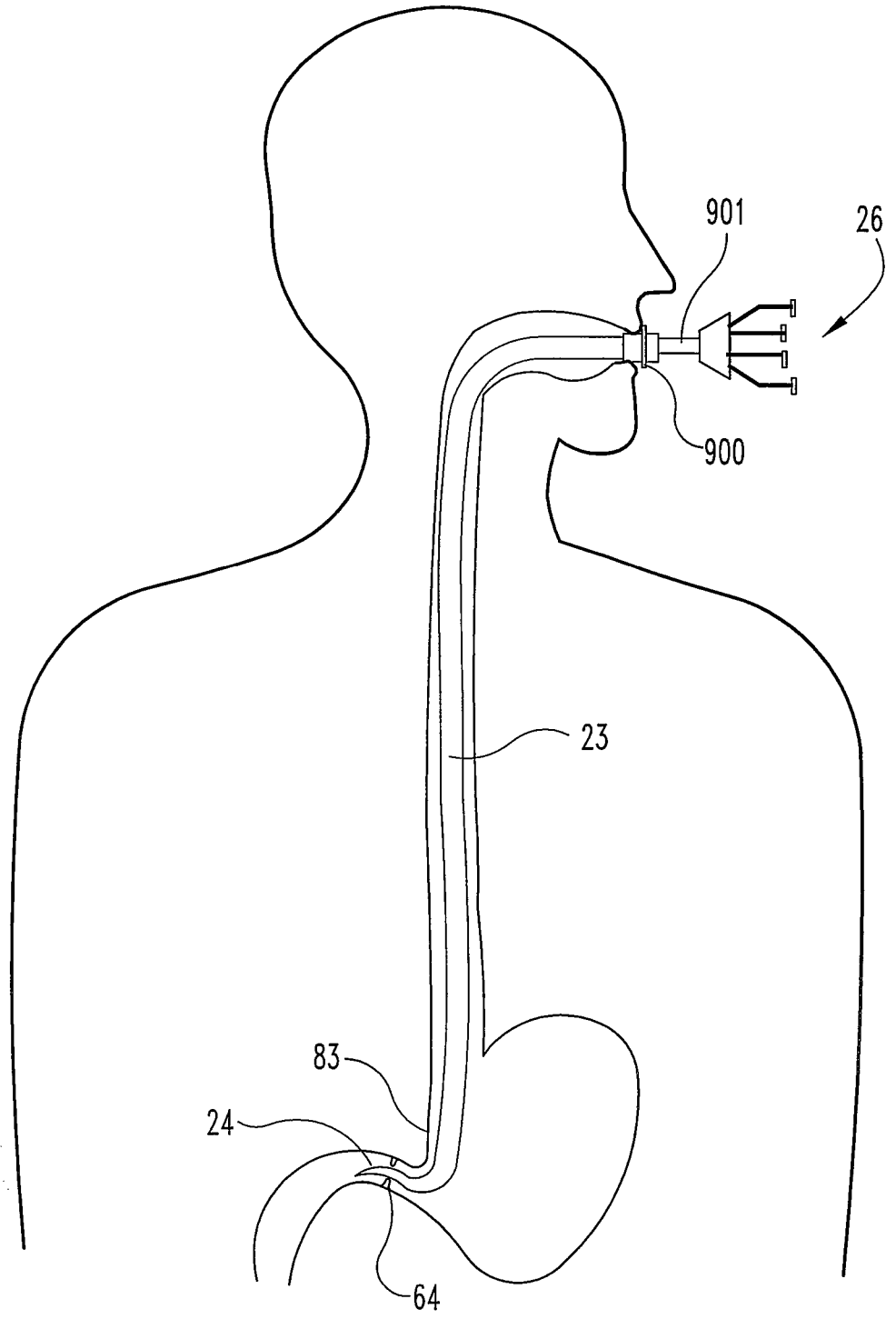


Fig. 40

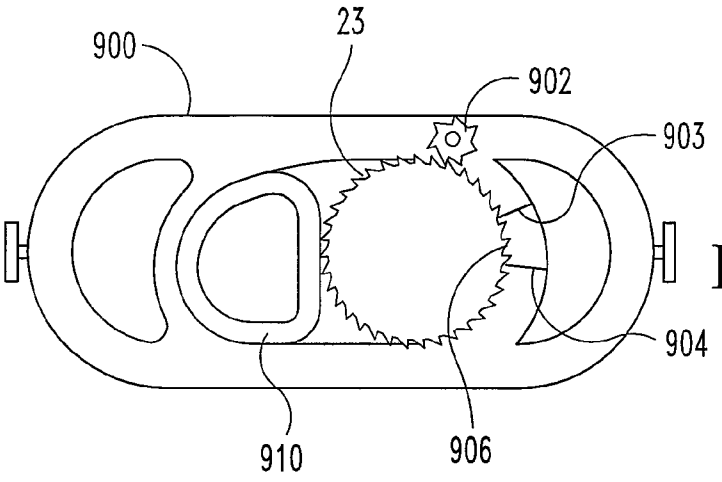


Fig. 41A

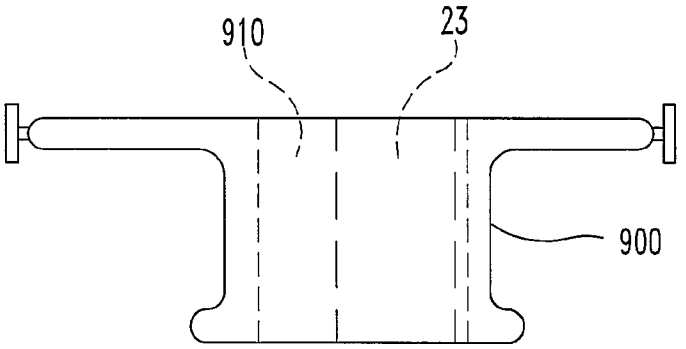


Fig. 41B

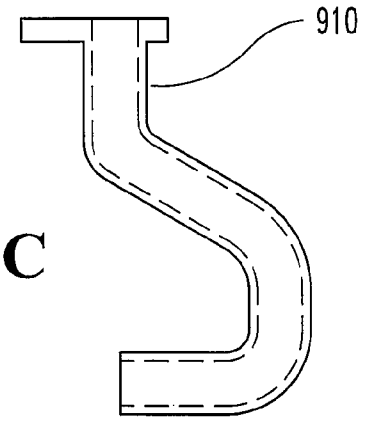


Fig. 41C

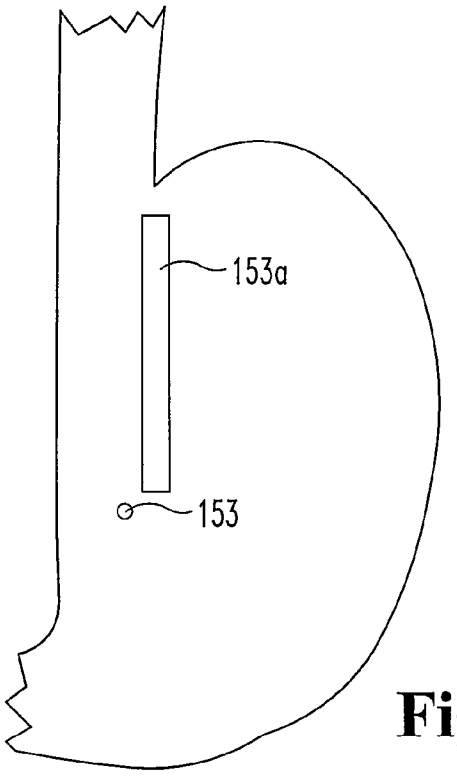


Fig. 43

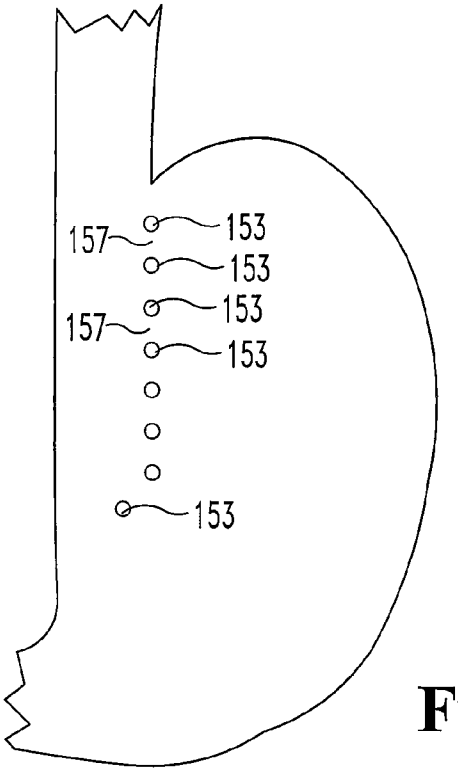


Fig. 42

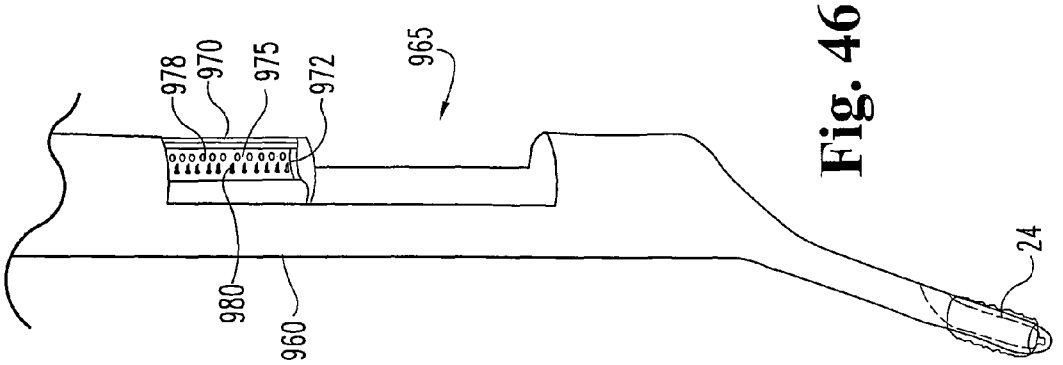


Fig. 46

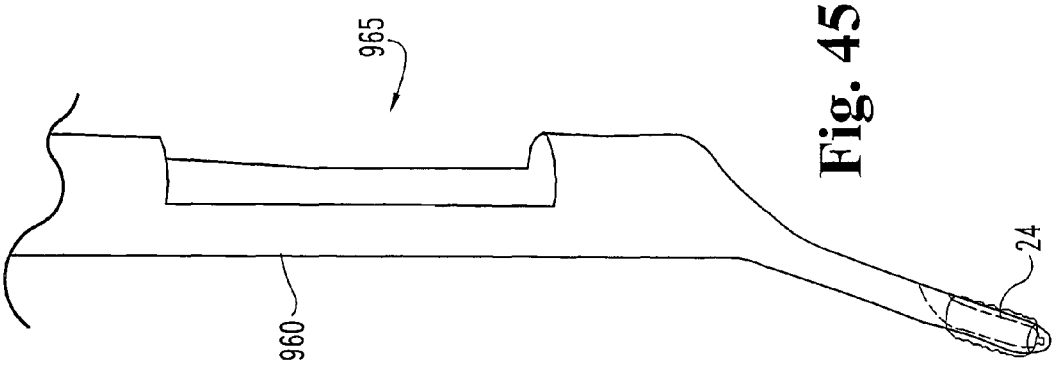


Fig. 45

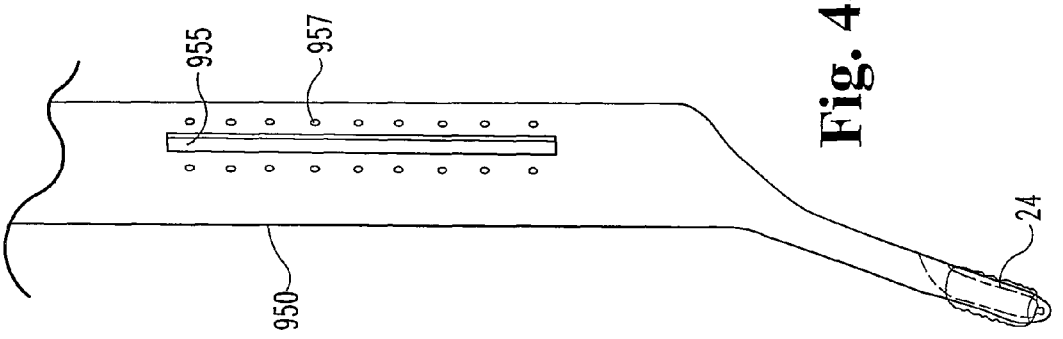


Fig. 44

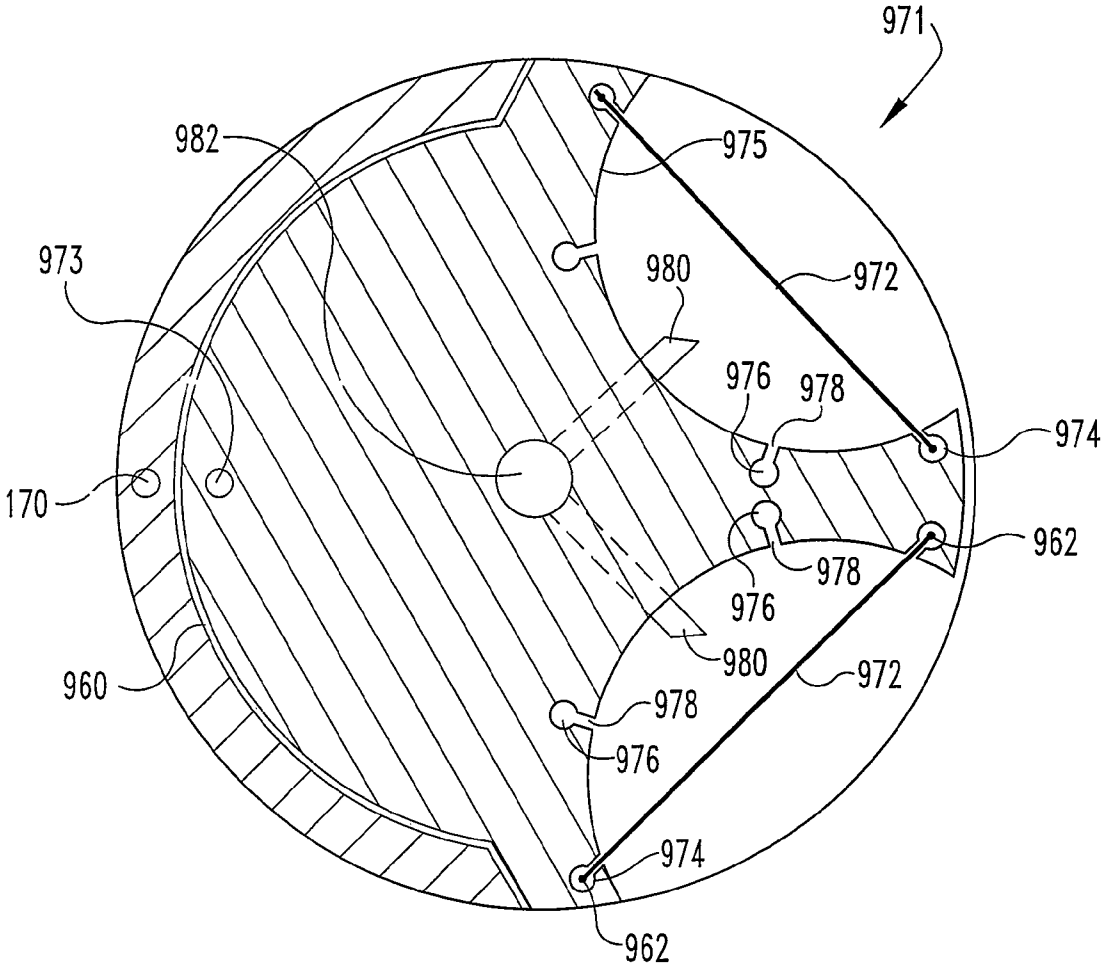

971
982
975
973
980
972
976
978
974
170
962
978
976
960
980
972
978
976
974
962

Fig. 47

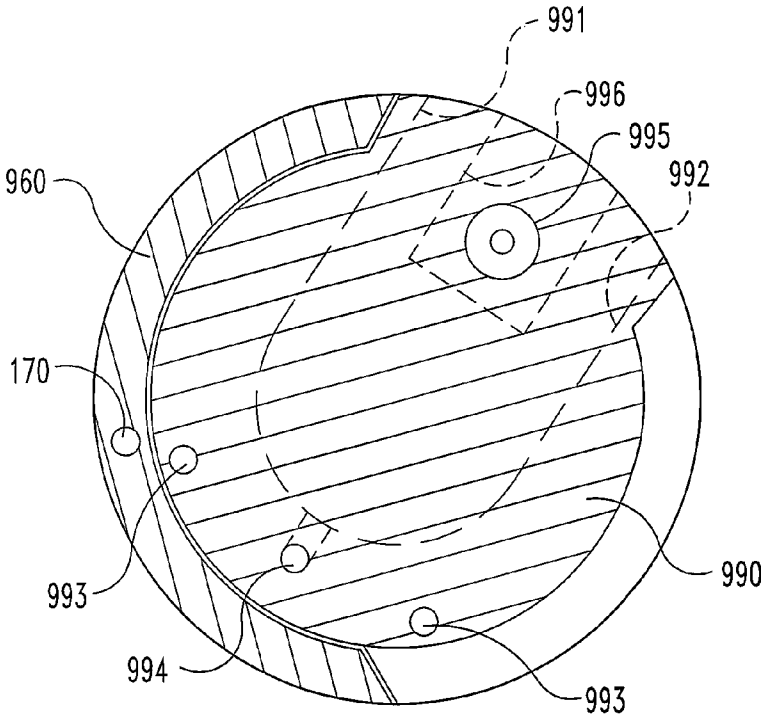

991
996
995
992
960
170
990
993
994
993

Fig. 48

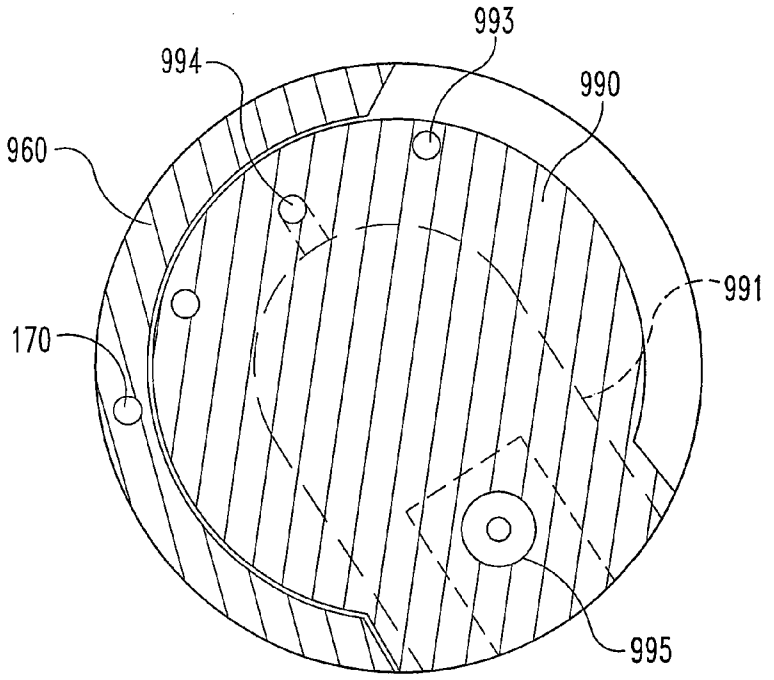

993
994
990
960
991
170
995

Fig. 49

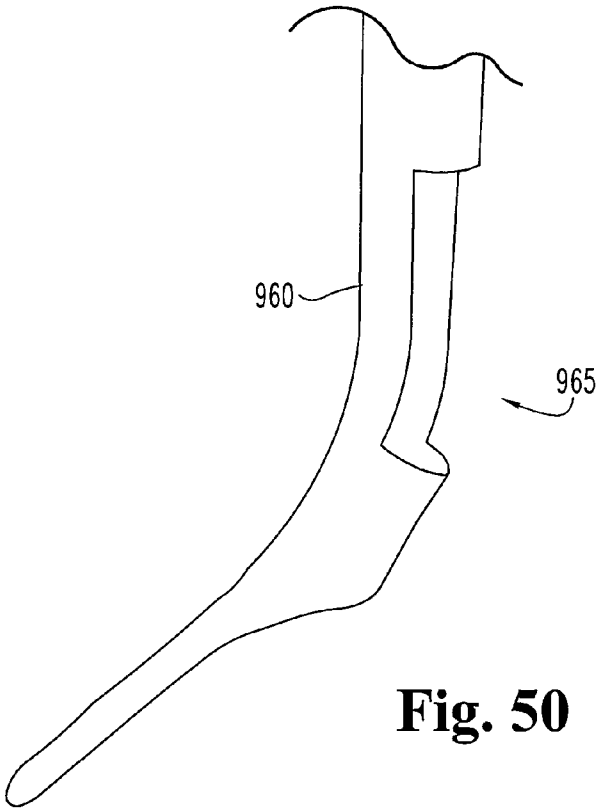


Fig. 50

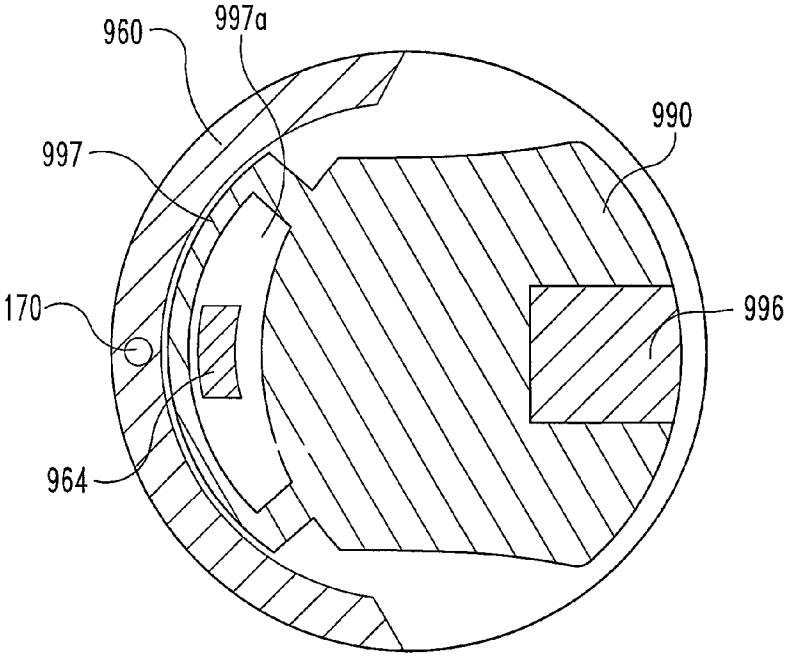


Fig. 51

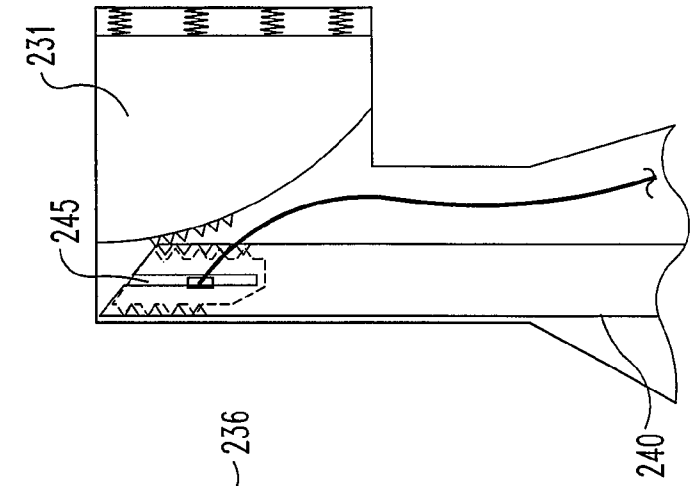


Fig. 54

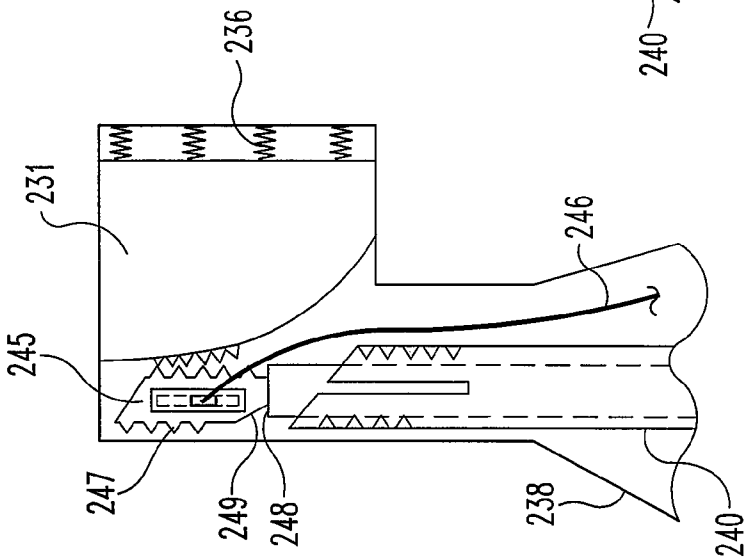


Fig. 53

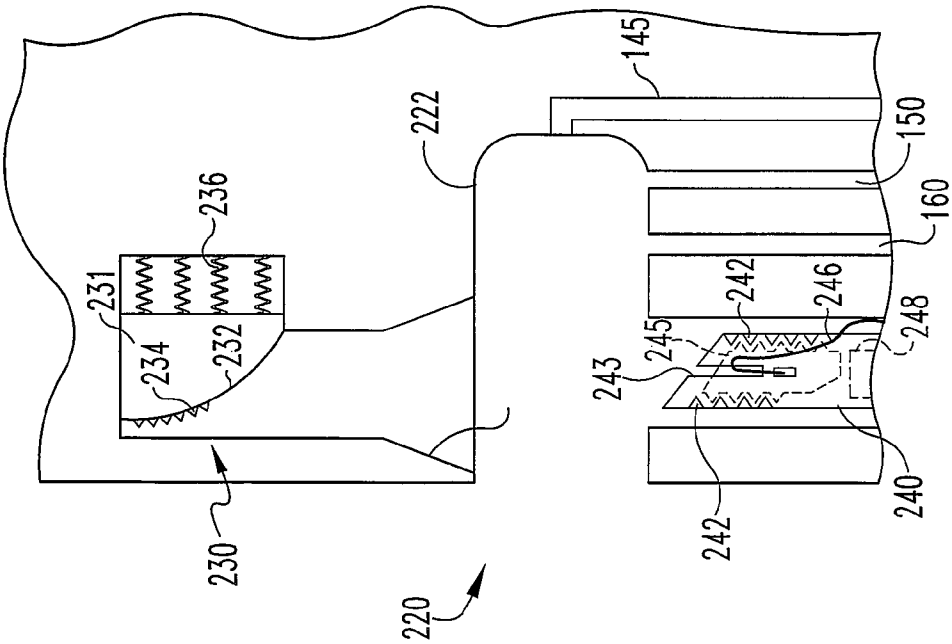


Fig. 52

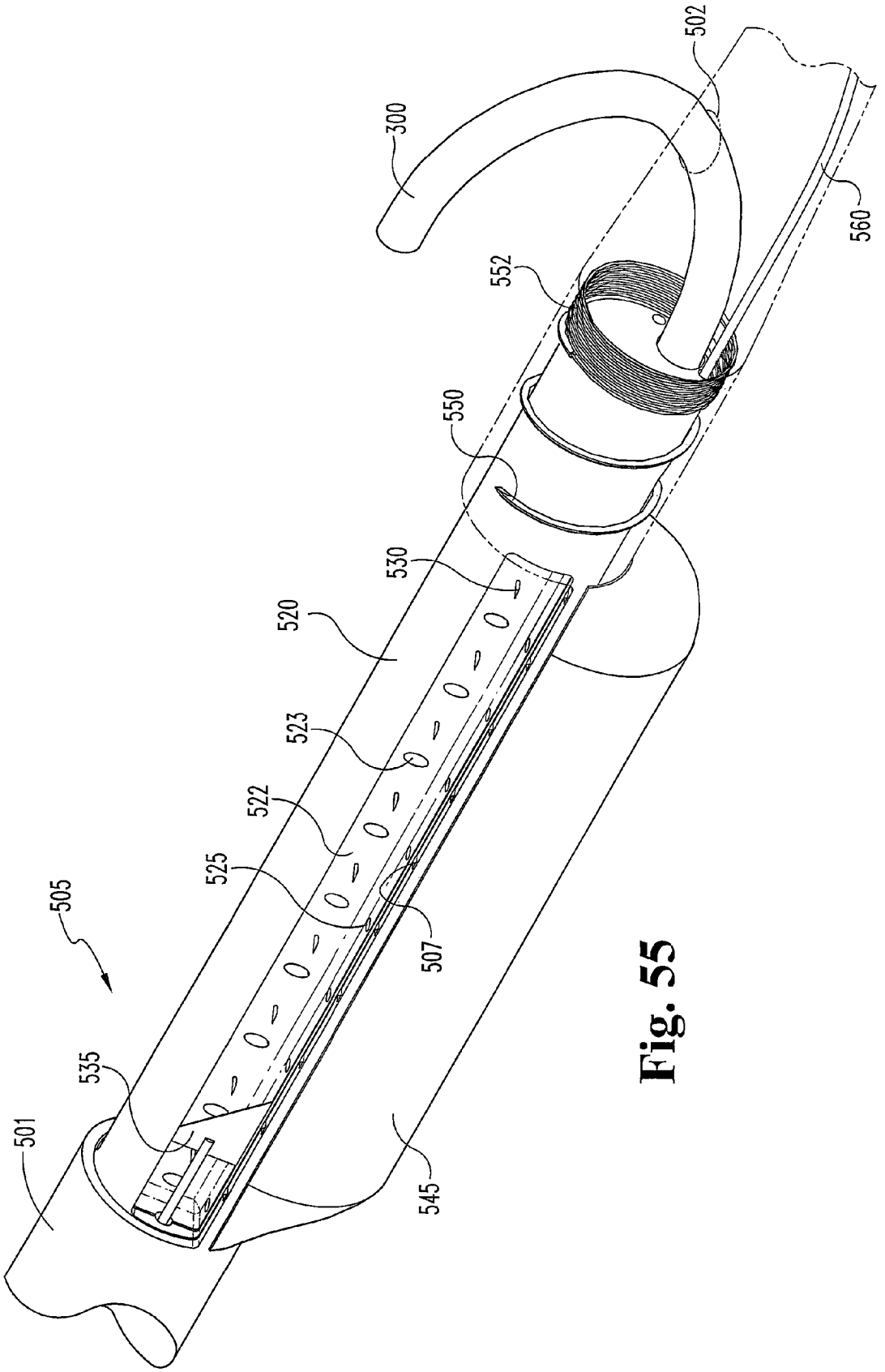


Fig. 55

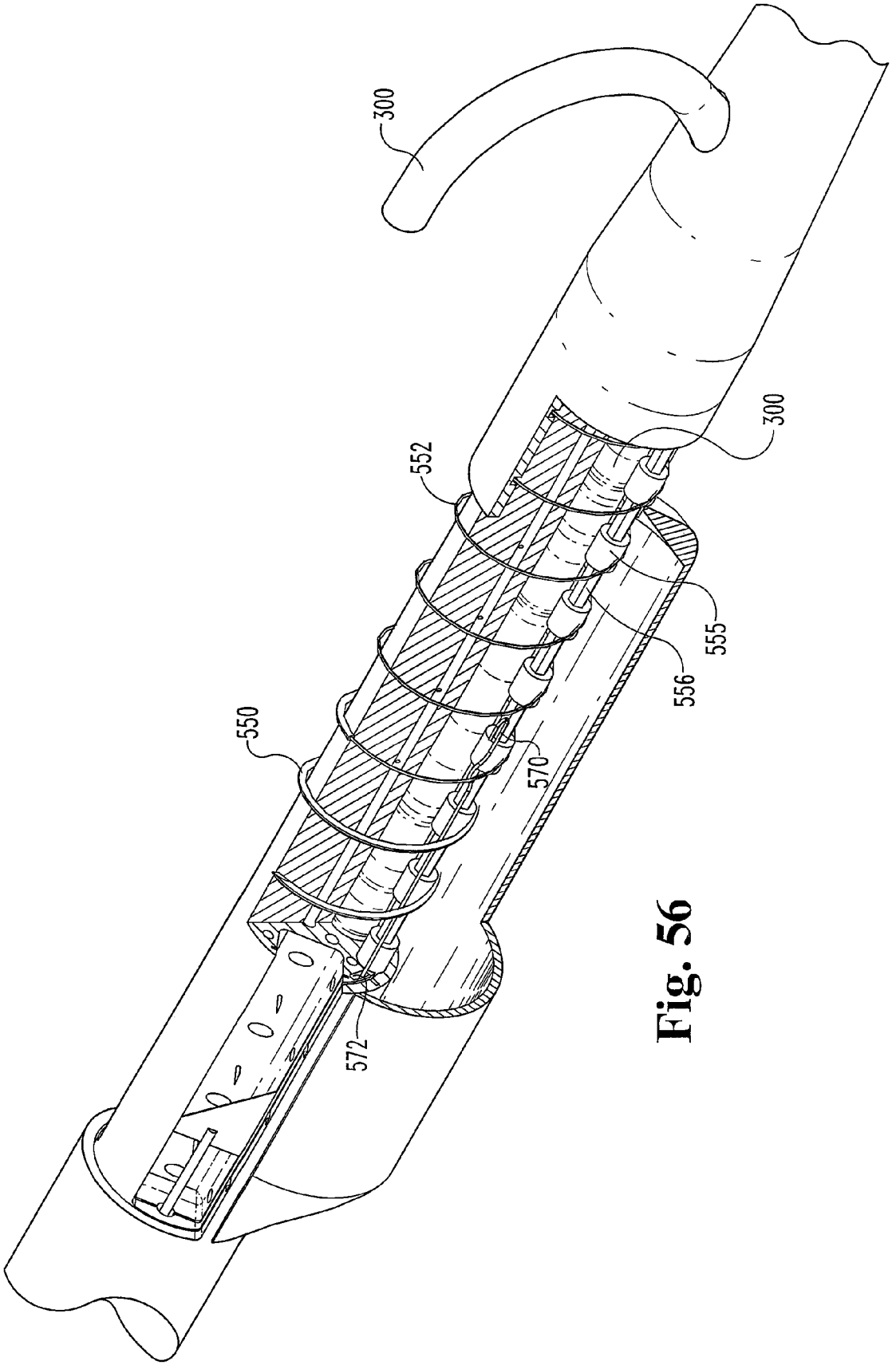


Fig. 56

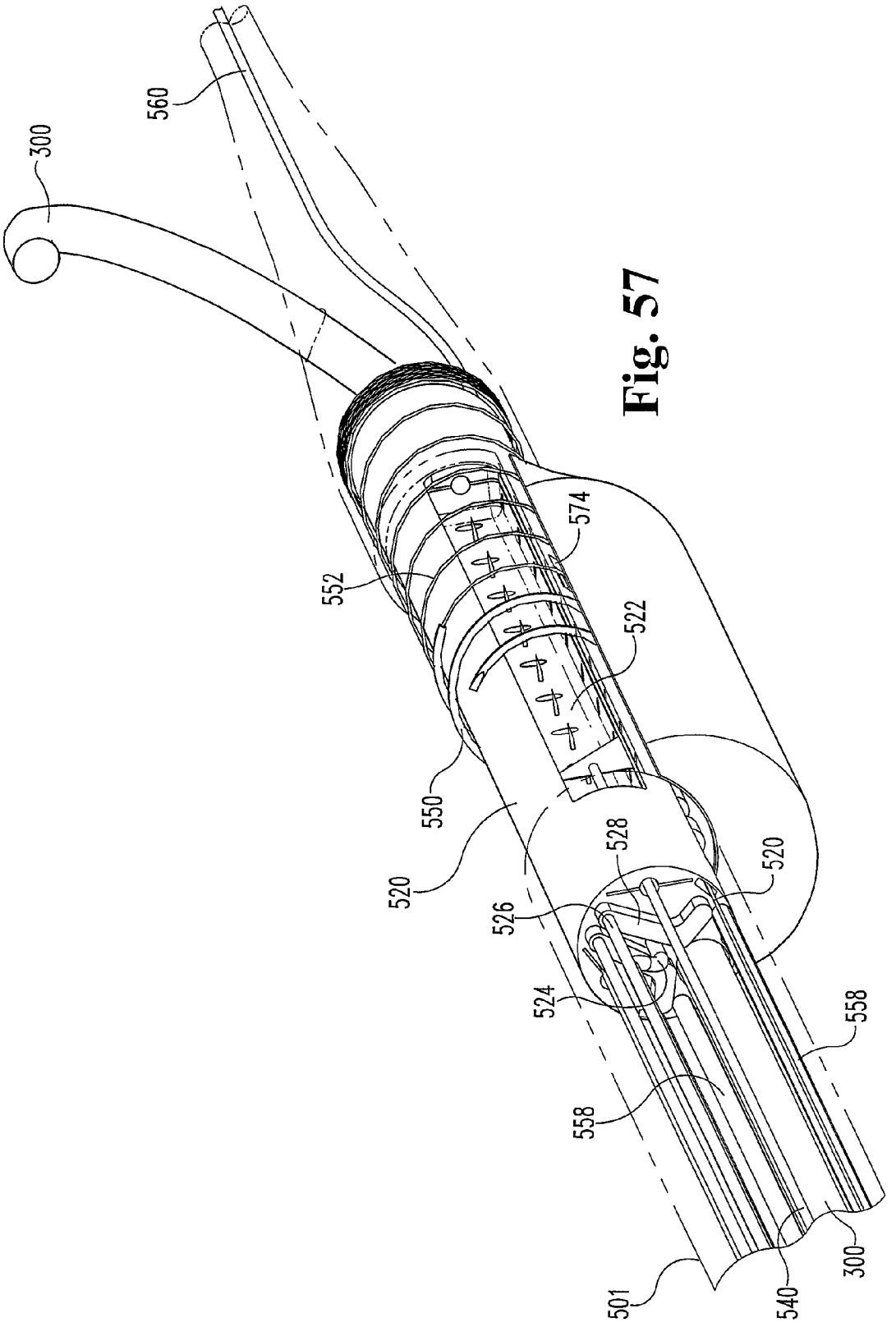


Fig. 57

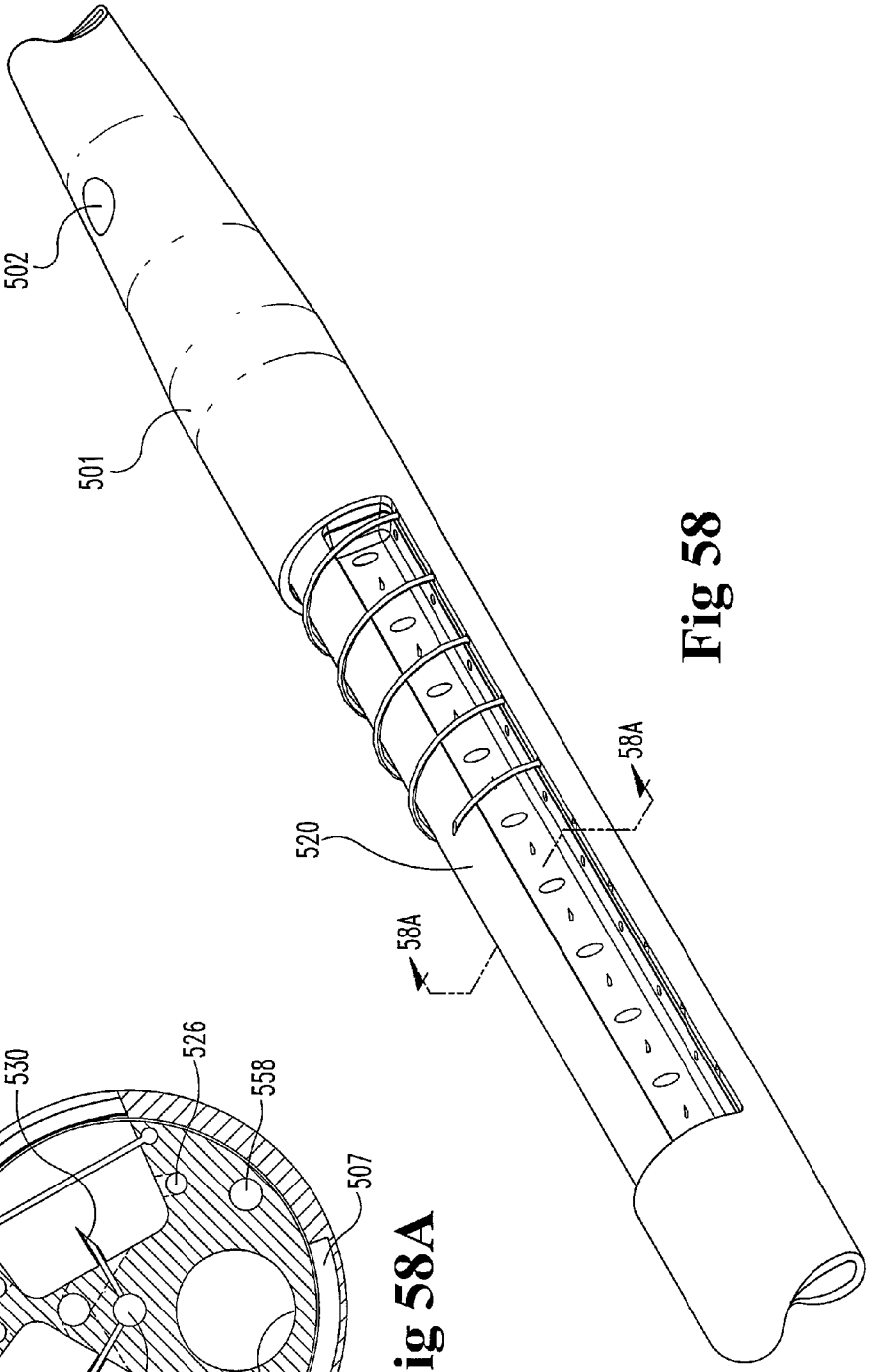


Fig 58

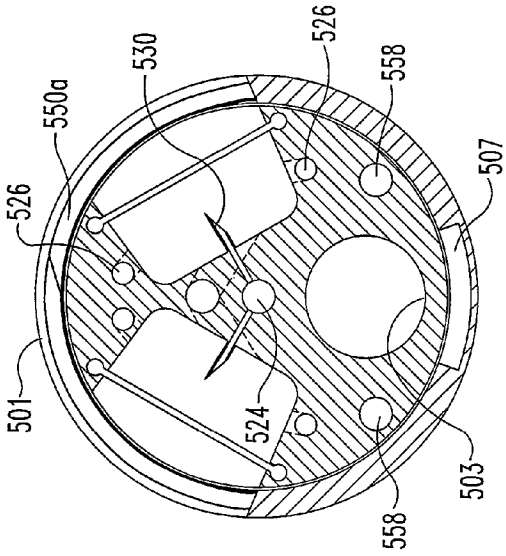


Fig 58A

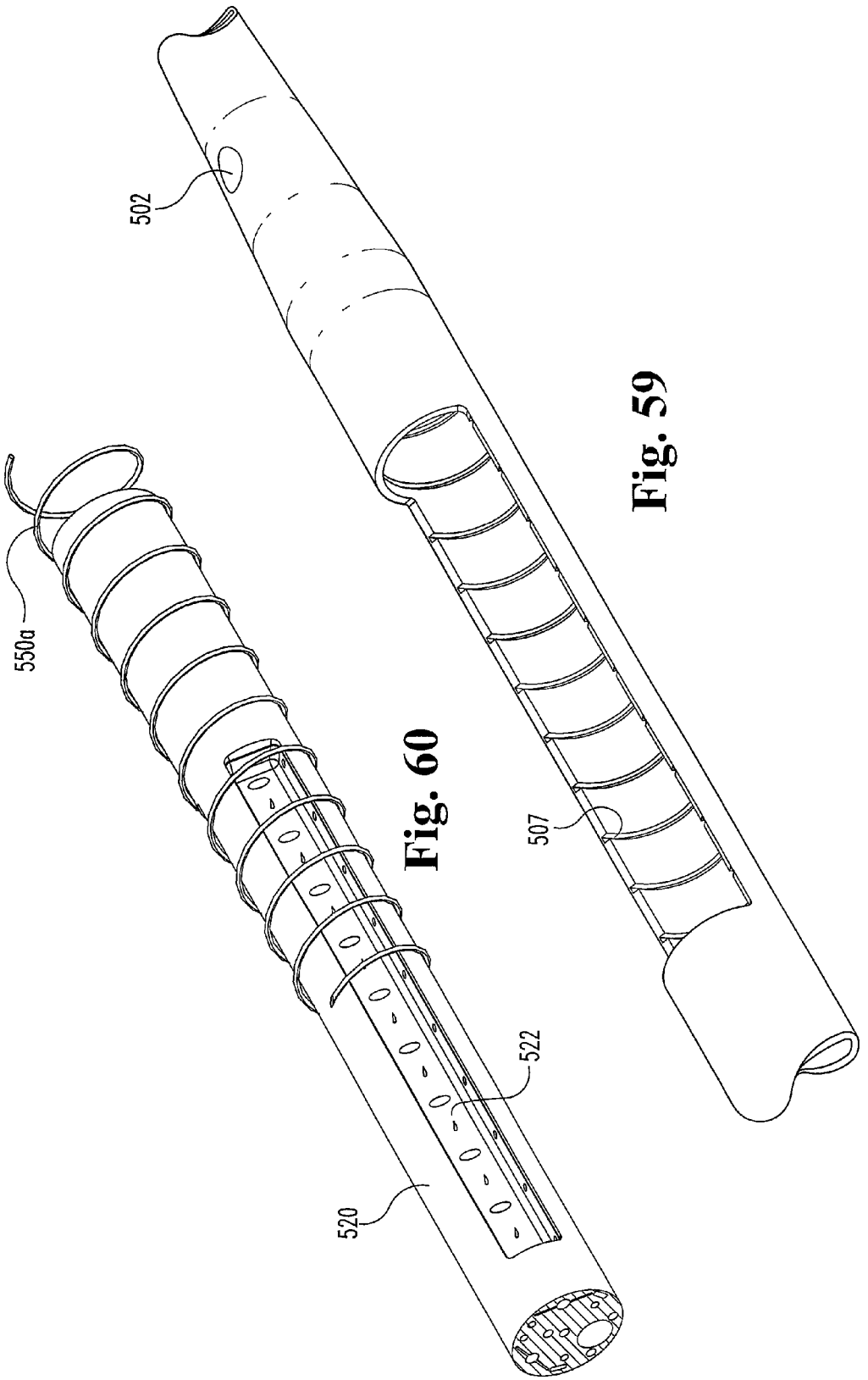


Fig. 59

Fig. 60

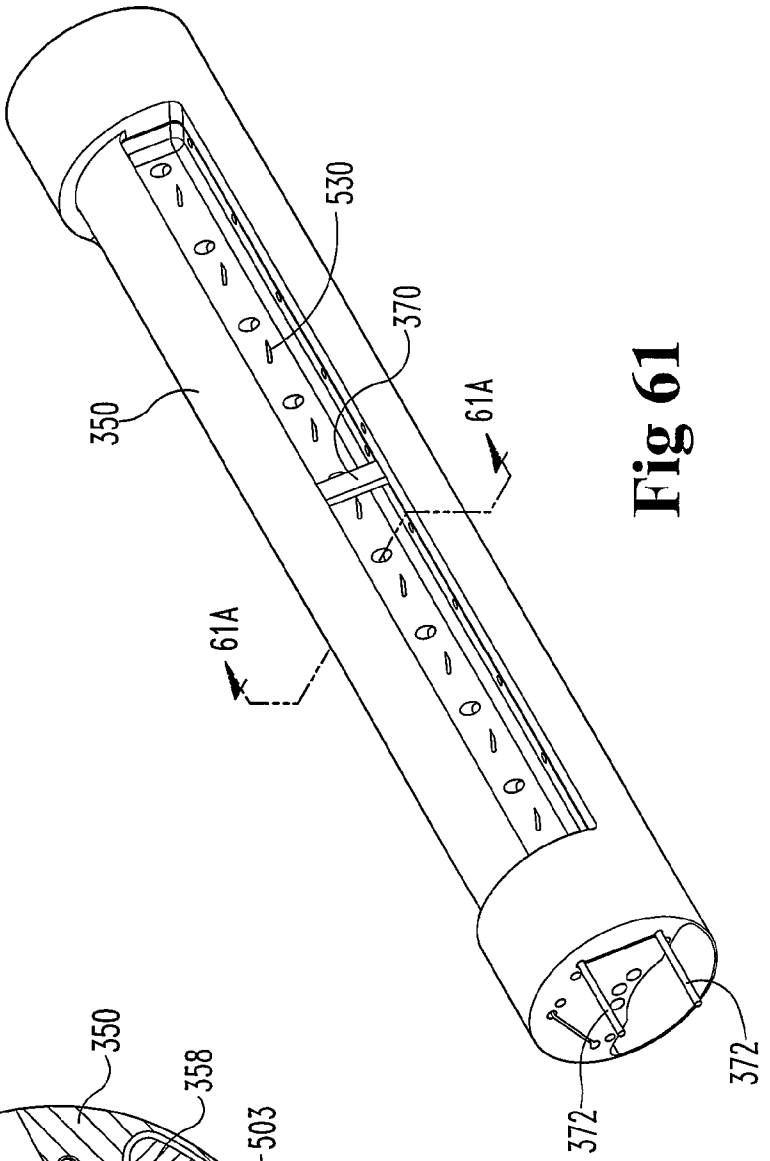


Fig 61

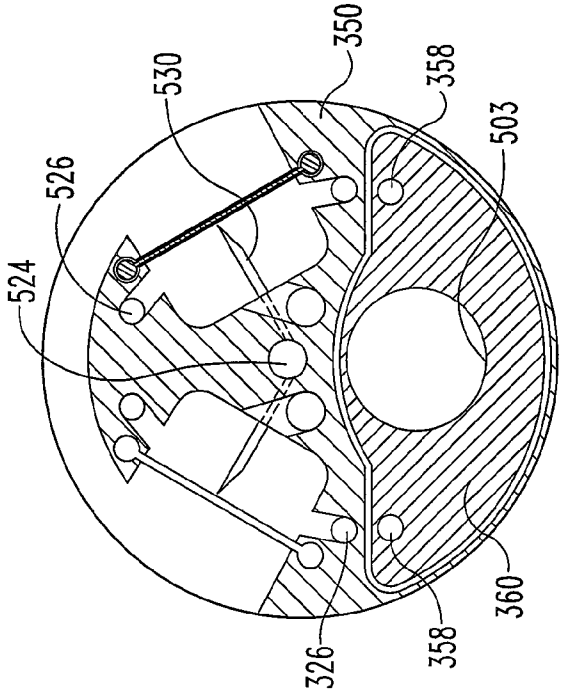


Fig 61A

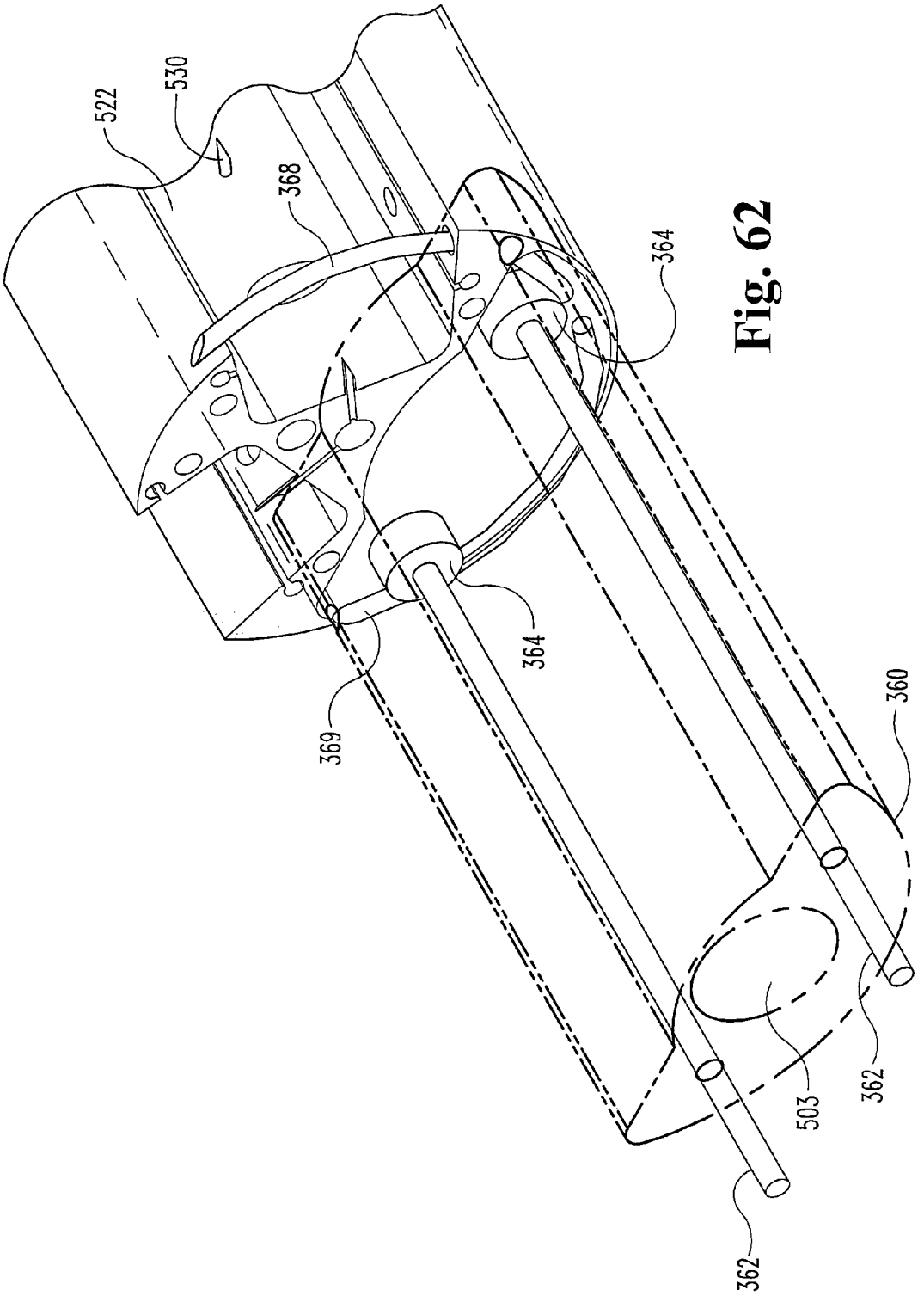


Fig. 62

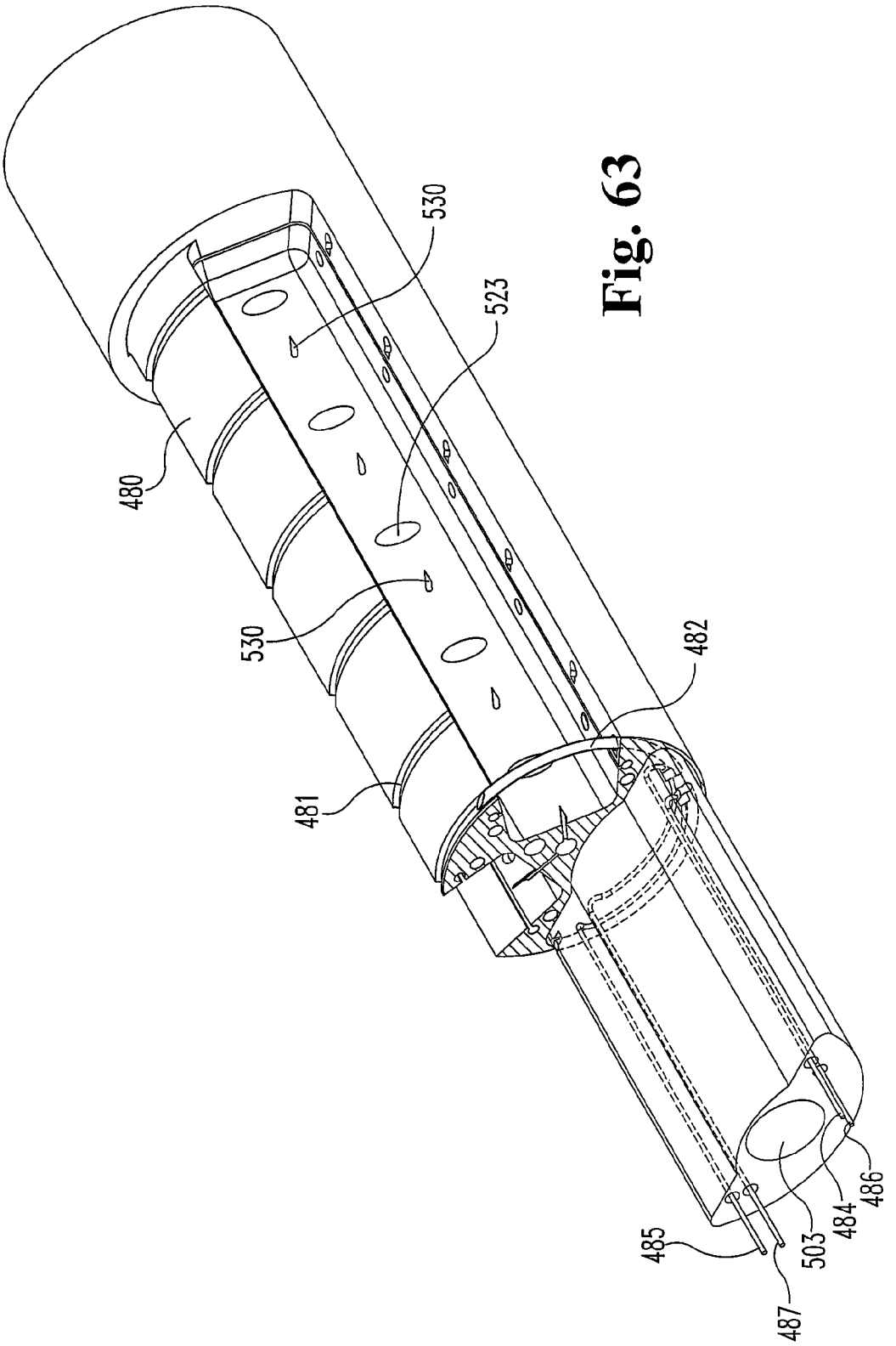


Fig. 63

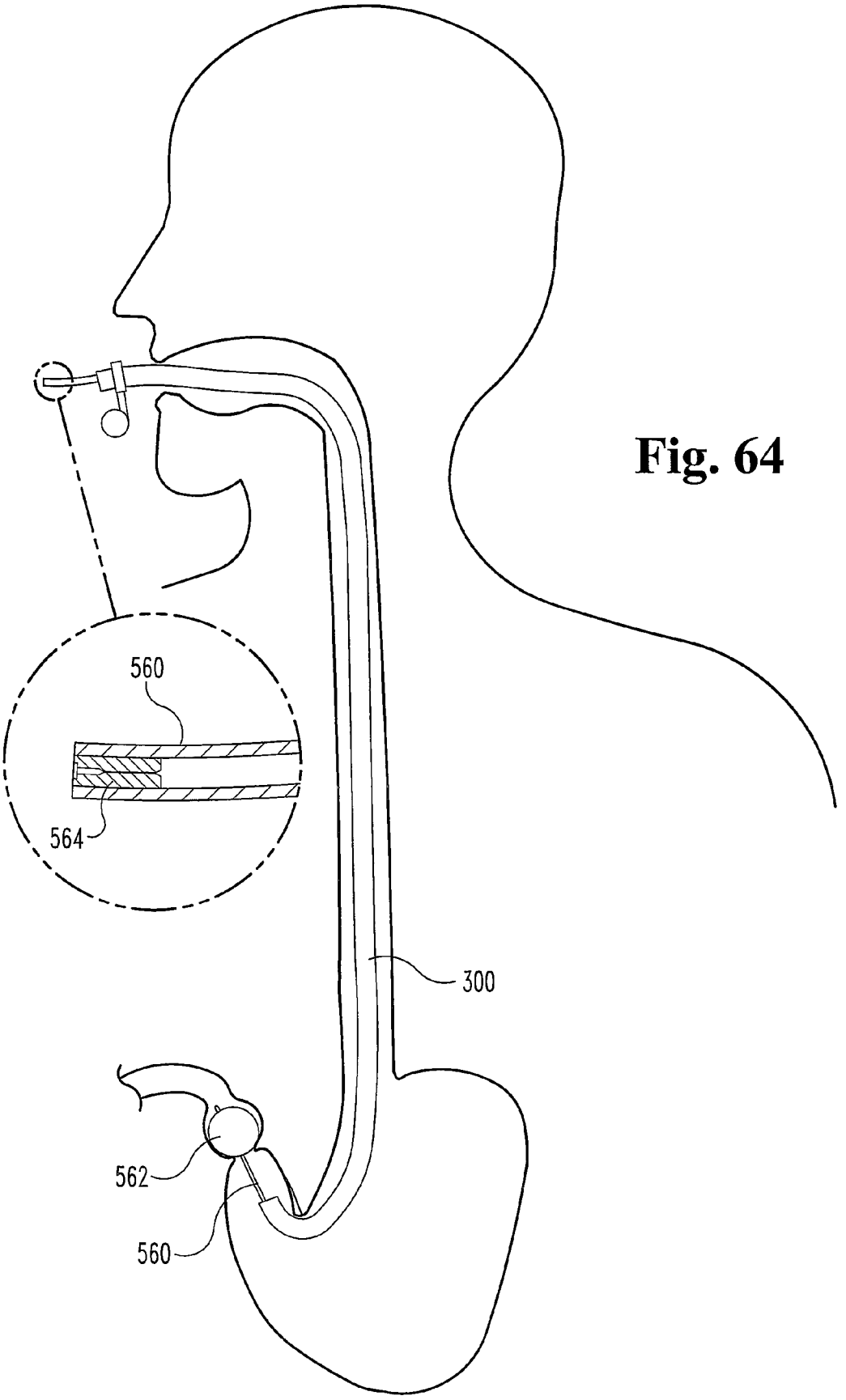


Fig. 64

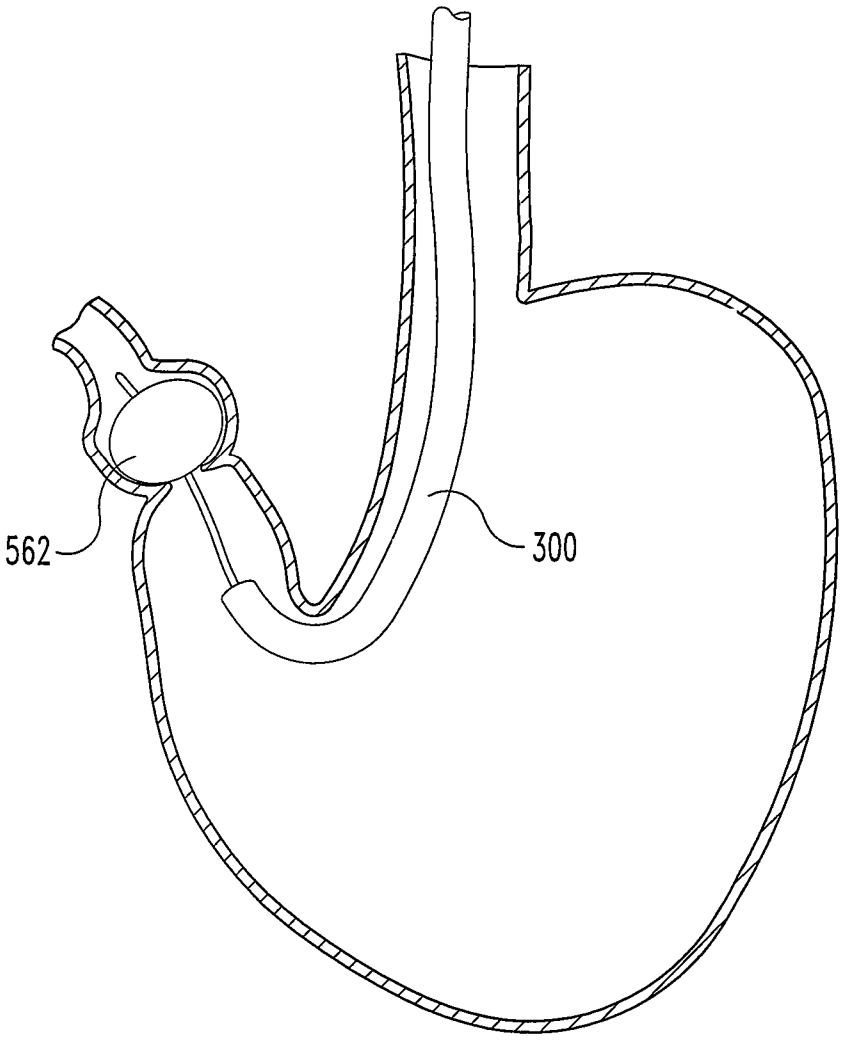


Fig. 65A

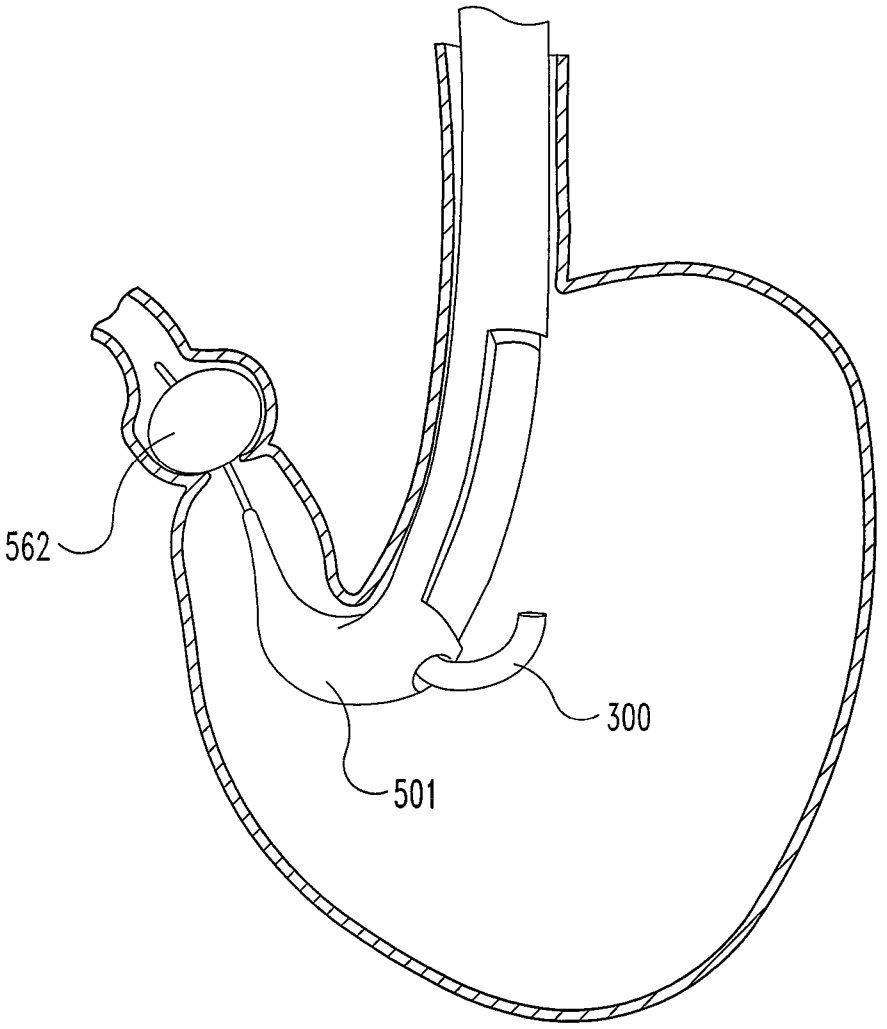


Fig. 65B

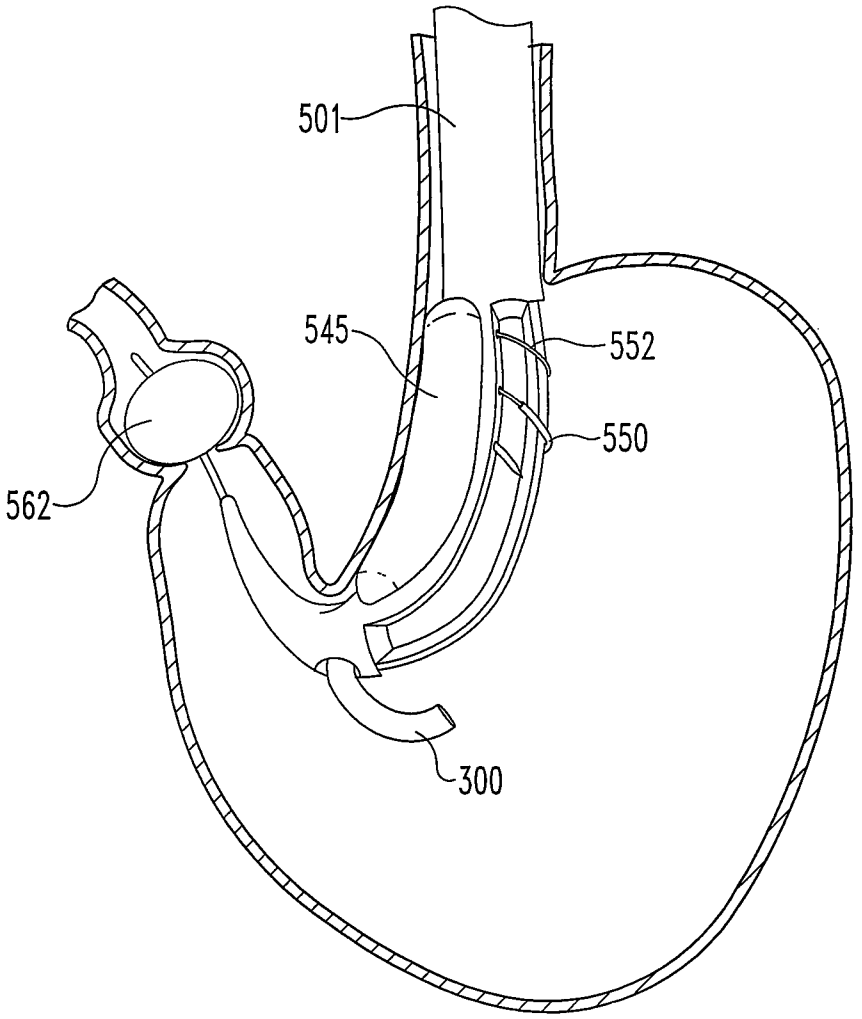


Fig. 65C

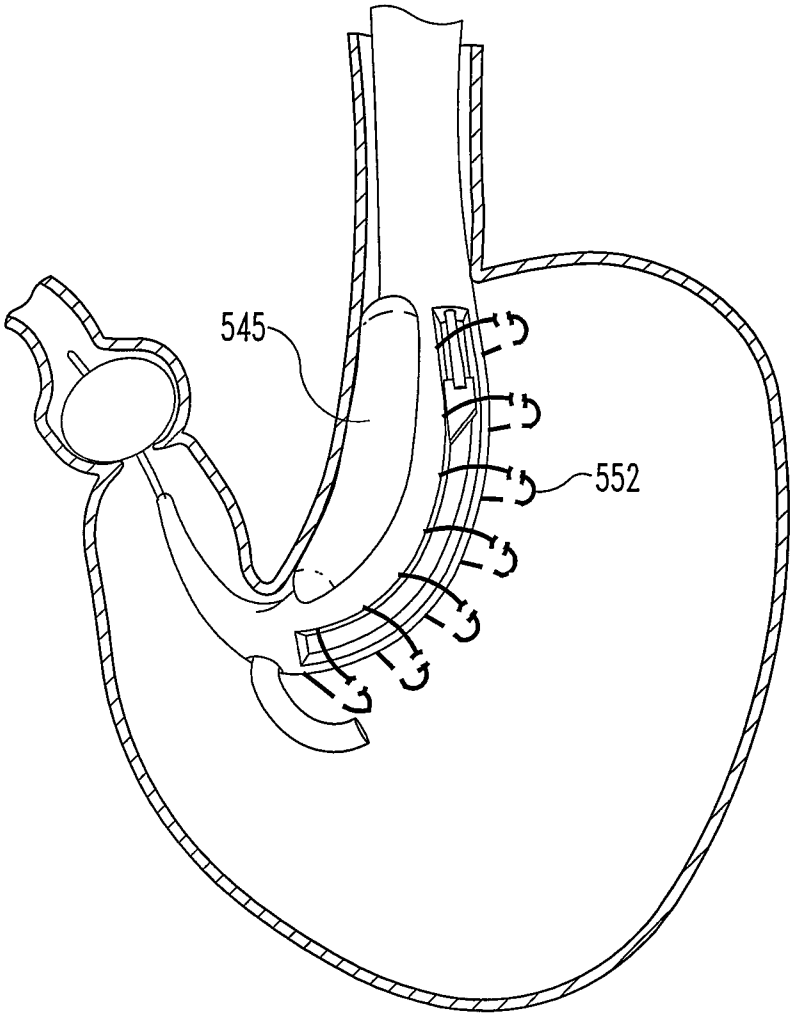


Fig. 65D

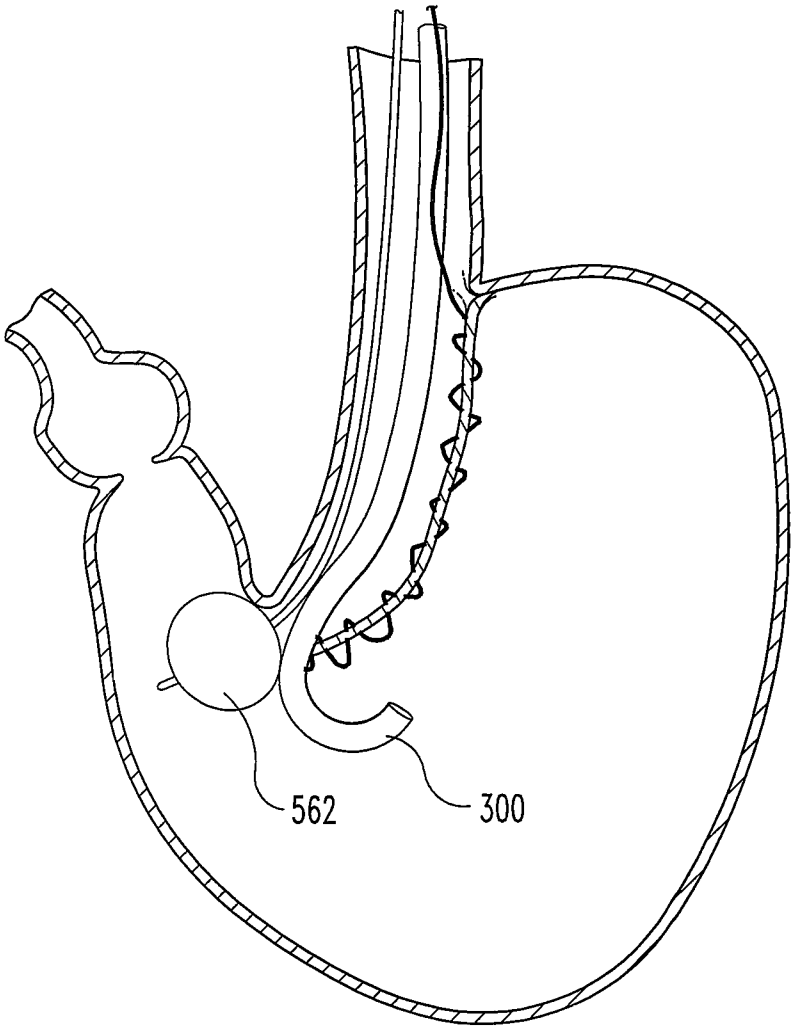


Fig. 65E

SYSTEMS AND TECHNIQUES FOR MINIMALLY INVASIVE GASTROINTESTINAL PROCEDURES

RELATED APPLICATION DATA

This application claims the benefit of Provisional Application 60/698,748 filed Jul. 13, 2005, 60/742,826 filed Dec. 6, 2005, and 60/757,694 filed Jan. 10, 2006, the disclosures of which are each incorporated herein by reference.

BACKGROUND

The present invention relates generally to gastrointestinal procedures such as bariatric surgery. More particularly, but not exclusively, it relates to surgical devices and techniques for excising mucosa in the stomach or esophagus and/or for securing portions of the stomach and esophagus together, e.g. to reduce the size of the stomach in connection with the treatment obesity in humans.

Gastric reduction surgery is conventionally performed to restrict food intake of a patient by decreasing the size of the stomach. The objective is to limit the receptive capacity of the stomach and promote weight loss in patients with severe obesity. Various surgical techniques have been developed, such as laparoscopic banding, where a device is used to constrict a portion of the stomach, vertical banded gastroplasty (VBG), or the more invasive Roux-en-Y Gastric Bypass which effects a permanent reduction in the volume of the stomach. It is desirable to develop surgical instruments and techniques that can be used to achieve gastric reduction in a minimally invasive manner. The present invention is generally directed to addressing this need, but aspects of the invention can be usefully applied in other endoscopic procedures, for example in the diagnosis or treatment of Barrett's esophagus and in the treatment of gastoresophegael reflex disease (GERD).

SUMMARY

A novel approach to gastroplasty and other medical procedures has been developed. In a preferred form, this approach can be used to achieve a reduction in the size of the stomach without the need for any external surgical incisions. A useful surgical system for implementing this approach can be a single device or a combination of devices working together which includes a main elongated body adapted to be transorally inserted into a patient's stomach. The body has a smooth outer surface and is preferably shaped similar to a conventional dilator or bougie for ease of insertion into the patient's stomach. When used to create a lumen in the patient's stomach, the outer diameter of the device may be chosen based on the size of the gastric lumen to be created, with a larger diameter device being used to create larger diameter gastric lumens. Alternatively the device may be provided with a spacing balloon along its length so as to be able to enlarge the effective outer diameter of a desired section after the device has been inserted into the stomach.

The device may have a distal anchoring section, and at least one suturing section may be provided along the length of the body proximal to the anchoring section. In use, the elongated body may be positioned along the lesser curvature of the stomach with the distal section used to anchor the device. One purpose of anchoring the device is to provide secure positioning for the suturing section as it is used to attach sutures to the anterior and posterior stomach walls. Anchoring of the distal section also facilitates modifying the shape of the device while it is in the stomach, for example to cause the device to assume a predetermined shape or orientation. With the device securely in position, opposed sutures are attached to the stomach walls and then drawn together to attach the anterior and posterior walls to form a partition or lumen in the stomach. Certain gastroplasty approaches may forgo anchoring of the device, and operations on the esophagus or esophageal junction (e.g. treating Barrett's esophagus or forming tissue plications to treat GERD) may anchor in a different location, if at all.

In one form, anchoring is accomplished at least in part by lodging the distal section through the pyloric sphincter and into the first portion of the duodenum. In another form, the distal portion of the device is not itself lodged or otherwise anchored in the patient's digestive tract, but rather it is engaged with a separate device that is lodged or otherwise anchored therein. A separate anchoring balloon at the distal end of a balloon catheter may be used for this purpose. The separate anchoring balloon may be preinserted into position (e.g. via the working channel of an endoscope) with its catheter extending proximally into the stomach and out the esophagus. After the anchoring balloon is inserted into position, inflated, and then the insertion endoscope removed, the distal end of the device may be inserted over the distal end of the catheter and guided into position in the stomach. With the cathether in a lumen of the device, application of tension to the catheter may be used to bias the device into a desired orientation or position (e.g. press it against the lesser curvature). Alternatively or in addition, the device may be clamped or otherwise releasably affixed to the catheter.

Alternatively or in addition to its uses of guiding the device during insertion and/or anchoring the device during application of the sutures, the anchoring balloon may be used to test for leaks during or after creation of the gastric lumen. When used for leak checking, the balloon is positioned (or repositioned) to plug the distal end of the lumen to be tested. With the balloon plugging the distal end, a testing fluid (such as methlyene blue) may be injected into the lumen with the presence of leaks being checked, for example, via endoscopic visualization.

The balloon catheter may be sized to fit through the working channel of the endoscope (e.g. 5 mm), and the distal end of the balloon catheter is preferably constructed to facilitate the insertion and removal of instruments from it (e.g. the endoscope used for insertion and the keeper). To accomplish this, valves and any actuating mechanism(s) may be removably coupled at the distal end so that they can be removed to reduce the effective diameter of the distal end to less than, e.g. 5 mm, so as to accommodate the insertion and removal of devices. In one form, the distal end is provided with a self closing valve. The self closing valve may be constructed such that when a fluid injection device is coupled to the valve, fluid communication with the balloon is established; and when the injection device is uncoupled from the valve, fluid communication with the balloon is interrupted (e.g. to keep the balloon inflated without external fluid pressure application). A suitable self closing valve includes a deformable material that allows a hollow needle to pass and closes when the needle is removed.

In a typical configuration, the suturing section(s) will include a side disposed suction cavity constructed to capture a fold of tissue suitable for receiving at least one suture, preferably a series of sutures. The suturing section will also include a puncturing member, such as a needle, that is operative to place a suture through at least one fold of tissue that has

been captured in the suction cavity, though preferably the suturing section is capable of placing multiple sutures at a series of locations.

In gastroplasty, a general purpose of the surgical system is to provide endoscopic access for the placement of sutures along the anterior and posterior stomach walls in a desired pattern. For a typical procedure, the suture pattern will be such that sutures are positioned in opposing locations along the anterior and posterior stomach walls in such a way that, when the tissue of the suture sites is drawn together with the tissue of an opposing suture site, a seam is formed in the stomach generally extending from near the pylorus to the esophagus. In a typical application, sutures will be placed along complimentary paths on the anterior and posterior walls with the longitudinal axis of the device providing the general orientation of the paths.

To locate sutures along paths generally corresponding to the longitudinal axis of the device, the distal anchoring section may be withdrawn and repositioned, so as to locate the suturing section either closer or further from the esophagus. In order to reduce the number of times such repositioning would be needed, and thus to further speed the procedure, the suturing section(s) can be constructed so as to be operable to apply sutures at several positions along the longitudinal axis of the device. In this way, a series of sutures can be placed along the longitudinal axis of the device while the distal section remains anchored in a single position. This can be accomplished by providing several suturing sections at different positions along the length of the device and/or by constructing at least a portion of the suturing section to be translatable relative to the anchoring section, for example by being slidably disposed in a lumen of the elongated body. In one implementation, at least a portion of the suturing section is constructed such that it can be wholly or partially withdrawn from the patient while the elongated body remains in place, facilitating the rapid adjustment, tying, or reloading of sutures during the procedure.

In a preferred form, surgical instrumentation includes an outer elongated body, or keeper, that is guided into location (i.e. into the stomach via the catheter on an anchoring balloon). The keeper includes one or more working lumens leading to a window section that is positioned in the patient's stomach. The window section provides access to the stomach walls for the elements needed during the particular procedure. If the objective of the procedure is to perform tissue resection under endoscopic visualization, such as may be employed in the diagnosis or treatment of Barrett's esophagus, only a tissue capture and excision device (described below) need be provided through the working lumen to the window to capture, for example, esophageal tissue for later biopsy. For gastroplasty and formation of tissue plications to treat GERD, both a tissue capture and excision device and a suture activating mechanism are employed. These elements may be integrally or separately provided.

In one design for gastroplasty, the keeper has a main elongated body and the working components are configured to have a pair of elongated suction cavities for capturing a line of tissue in each cavity, the lines being from the anterior and posterior stomach walls respectively. Sutures are then applied between the captured tissue lines such that, once the tissue is released from the suction cavities, the sutures may be drawn tight to draw the anterior and posterior stomach walls together. A curved needle follows a helical or corkscrew shaped path through the device, with the axis of the helix generally corresponding to the elongated axis of the device, may be used to apply sutures between the captured tissue lines. One or more rollers may be used to drive the needle along its helical/corkscrew path.

As an aid for positioning and orientation, the elongated body or keeper may be configured to receive one or more orientation wires or shape memory rods in one or more orientation wire lumens. These orientation wires may be used to establish a desired curvature or positioning of the elongated body (for example positioning it against the lesser curvature of the stomach). Alternatively or in addition, the orientation wire may be used to provide flexion orientation for the suturing section, for example to selectively dispose the suturing section near the lesser curvature. A mechanism for accomplishing rotational orientation via an orientation wire may be by providing two orientation wire lumens, each offset from the centerline of the body. Positioning of the orientation wire in the first orientation wire lumen may be used to flex/bend the device along the lesser curvature for anterior suture placement, with the second used to flex/bend the device for posterior suture placement.

Prior to drawing the anterior and posterior stomach walls together (to form the seam), it is desirable to prepare the tissue sections to be joined so as to promote their adhesion. One method of tissue preparation is to cauterize or abrade one or both of the tissue surfaces to be joined. The surgical system can be configured with a separate cautery or abrading device used for this purpose, or a cautery or abrading surface may be provided adjacent and/or inside the suction cavity of the suturing section, to cauterize or abrade the tissue in connection with the suturing. Such cautery or abrading techniques are described in US 2004/0034371 in the context of the treatment of GERD and these techniques may be beneficially used in the present procedure.

An alternative technique for preparing the tissue to be joined so as to promote adhesion has also been developed. This technique is based on tissue removal, for example sectioning or slicing a thin layer of tissue to expose the submucosa of the stomach wall, and it is believed that this approach is superior to the mere modification of existing tissue in the cauterizing or abrading of the mucosa described in US 2004/0034371. More specifically, it is expected that by exposing the submucosa of the stomach, and by placing areas of exposed submucosa in contact, stomach tissue will heal together and form a secure bond without some of the drawbacks of prior approaches.

A desirable way of exposing submucosa is via a cutting means, such as a blade, a knife, a wire, a loop, or a high frequency snare, that is operable to slice tissue that has been acquired in a suction cavity, such as the suction cavity of the suturing section. Prior to sectioning, the captured tissue may be injected with a preparatory material, such as adrenaline saline solution, via an injection needle. To assist in reliably sectioning the appropriate tissue thickness, the injection needle and/or the suturing needle (when present) may be used to fixate the captured tissue.

While a wide variety of suturing mechanisms and suturing patterns can be employed to join the anterior and posterior stomach walls, the suturing pattern is preferably selected to press together the prepared tissue portions to be joined, rather than tending to close up the individual sections of prepared tissue. For example, four folds of tissue (two opposed pairs) with prepared sections near the fold may be joined with a stitching pattern resembling a FIG. **8**.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view of a device according to a first embodiment.

FIGS. **2-5** are partial sectional views of the suturing section of the first embodiment during operation.

FIG. **6** is a cross section of the FIG. **1** device at the location indicated in FIG. **1**

FIG. **7** is a partial sectional view of a variation of another embodiment of the suturing section.

FIG. **8** is a cross section of the FIG. **7** suturing section at the location indicated in FIG. **7**.

FIG. **9** is an illustrative cross section of stomach tissue showing the various layers.

FIG. **10** is a cross section showing a desirable resecting line **100** for preparing a fold of tissue to promote adhesion.

FIG. **11** is the FIG. **10** tissue after resection along line **100**.

FIG. **12** is a perspective view of the FIG. **1** in a patient's stomach.

FIG. **13** is an anterior view of a stomach that has been partitioned by the techniques described herein.

FIG. **13**A is a cross section of the portioned stomach of FIG. **13**.

FIGS. **14-17** are cross sectional views looking down the device illustrating the attachment of sutures to the anterior and posterior stomach walls.

FIG. **18** is a side view of two sutures attached to the anterior and posterior stomach walls with the ends of the sutures extending up the esophagus.

FIG. **19** is a cutaway view of the stomach looking at the lesser curvature and illustrating the positioning and attachment of opposing sutures on the anterior and posterior walls.

FIGS. **20** and **21** are sectional views corresponding to FIGS. **14-17** illustrating the use of two orientation wire lumens to rotate the device.

FIGS. **22** and **23** are anterior views of the stomach showing the distal anchoring portion of different embodiments anchored in the first portion of the duodenum.

FIG. **24** is an anterior view of the stomach showing insertion of the distal anchoring section via an endoscope and including an enlargement showing details of the distal tip.

FIG. **25** is a side view of a device showing dimensional features.

FIG. **26** is a side view of a suturing section that utilizes a removable shuttle.

FIG. **27** is a top view of the removable shuttle used in the FIG. **26** suturing section.

FIG. **28** is a sectional view of the suturing section at the location indicated in FIG. **26**

FIG. **29** is a side view of a device according to another embodiment.

FIG. **30** is a sectional view of the FIG. **29** device.

FIG. **31** is a sectional view of the shuttle used with the FIG. **29** device.

FIG. **32-34** are side views of two tissue sections being joined.

FIGS. **35**A-**35**F are a series of side views of the joining of 4 tissue folds in a FIG. **8** suture pattern utilizing the needle shuttle concept for bidirectional application of a suture.

FIG. **36** is a sectional view of an embodiment used to form tissue plications at the esophageal junction.

FIG. **37**A schematically illustrates the sutures placed with the FIG. **36** device and

FIG. **37**B schematically illustrates the formation of plications with the sutures.

FIG. **38** is a perspective view of a suction cavity arrangement to cut an arch in the stomach near the esophagus.

FIG. **39** is an enlarged view of the arch cutting section of the FIG. **38** device.

FIG. **40** is a side cutaway of a patient with a surgical system inserted into the stomach.

FIG. **41** shows a top and side view of the bite block used in FIG. **40** with the lower left corner illustrating a side view of the airway.

FIG. **42** shows a cutaway of the stomach with a useful pattern of discretely prepared tissue sites for partitioning the stomach.

FIG. **43** is a cutaway of the stomach with a continuous slot of prepared tissue replacing some of the discretely prepared sites of FIG. **42**.

FIG. **44** is a device for forming the slot of prepared tissue of FIG. **43**.

FIG. **45** is a side view of an applicator according to another embodiment.

FIG. **46** is a side view of the FIG. **45** applicator with a slicing device partially inserted into its main lumen.

FIG. **47** is a cross section of a slicing device positioned in the working opening of the FIG. **45** applicator.

FIGS. **48** and **49** are cross sections of a suturing device positioned in the working opening of the FIG. **45** applicator.

FIG. **50** is a side view of the FIG. **45** applicator positioned with a curve near the distal end of working opening.

FIG. **51** is a cross section of the distal portion of the suturing device in the FIG. **45** applicator.

FIGS. **52-54** are side views showing the operation of a suturing mechanism using a thread shuttle that is passed back and forth across a suction chamber by a hollow needle.

FIG. **55** is a perspective view of an alternative embodiment incorporating an expandable spacer and a short helical needle. The distal portion of the outer elongated body, or keeper, is shown in phantom lines to illustrate the detail within.

FIG. **56** is a cutaway in partial section corresponding the FIG. **55** embodiment and view.

FIG. **57** is a perspective view looking towards the distal end of the FIG. **55** embodiment with the keeper shown in phantom lines.

FIG. **58** is perspective view of an alternative embodiment using a longer helical needle, and FIG. **58**A is an end sectional view along the line indicated in FIG. **58**.

FIG. **59** corresponds to the keeper as depicted in FIG. **58** with the internal helical needle and the internal tissue capture, excision, and needle activation components removed and shown in FIG. **60**.

FIG. **61**. is a perspective view of an alternative configuration for the internal tissue capture, excision and needle activation components for use with a FIG. **59** keeper.

FIG. **61**A is a sectional view as indicated in FIG. **61** and illustrating needle activation shuttle slideably disposed within the tissue capture and excision component.

FIG. **62** is a schematic illustrating the working arrangement for needle activation via rollers for the slideably disposed shuttle of FIG. **61**.

FIG. **63** is a cutaway view of an alternative shuttle configuration for needle activation via pull wires for a slideably disposed shuttle.

FIG. **64** is a schematic illustration of an anchoring balloon catheter extending through the working channel of an endoscope and with the anchoring balloon inflated in the duodenum and showing detail of the self closing valve at the proximal end of the catheter.

FIGS. **65**A-E schematically illustrate exemplary stages of a gastroplasty procedure beginning from the placement of the anchoring balloon as shown in FIG. **64**.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the

embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described embodiments, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

A novel approach to gastroplasty and other medical procedures has been developed. This general approach is described herein with reference to various instruments and devices, some of which have been developed specifically for the implementation of this approach in performing gastric reduction from within the stomach wall via the esophagus. While some of the devices described are particularly adapted to this procedure, it is to be understood that commercially available devices and others known in the art may be adapted and used to advantage in implementing the inventive processes described herein. The provision and use of devices specially adapted to this procedure may, however, facilitate its successful implementation. As will also be appreciated and understood from the disclosure to follow, the instruments and devices developed for the implementation of this approach may also be used to advantage for the conduct of other medical procedures. Thus, those novel instruments and devices are not to be construed as limited to the uses therefore described herein with reference to gastric reduction. For example, the suturing devices described herein may be used in forming tissue plications for the treatment of GERD.

Devices and techniques for tissue acquisition and fixation, and methods of using them are described. In general, the gastroplasty techniques and devices described herein may be utilized for creating a partition within a hollow body organ, such as the stomach or other portions of the gastrointestinal tract. The gastroplasty devices may be advanced through a variety of methods, i.e. transesophageally (transorally or transnasally) and/or endoscopically to create a gastric lumen within the stomach. Further, the gastroplasty devices may be assisted through the use of laparoscopic or endoscopic visualization to ensure proper operation of the devices.

The gastroplasty techniques and devices described herein allow for the creation of a smaller gastric lumen through a minimally invasive procedure taking place entirely within the stomach cavity. This effectively reduces the time that a patient must be hospitalized and allows the patient to return to work or normal activity sooner. Further, by eliminating the needs for abdominal incisions, the complications that result from the large quantity of fat layers that must be cut through and eventually replaced are prevented.

Turning now to the Figures, FIG. **1** shows a side view of one illustrative embodiment of a device useful in transoral gastroplasty. Device **21** is generally comprised of an elongate flexible tubular member **24** having a control assembly **26** connected at its proximal end **22**. Control assembly **26** is illustrated with several structures for controlling the operation of the devices on the distal working portion **24** of member **23**. Control assembly **26** may include endoscopic inlet port **28** for the insertion of an endoscope (not shown) to provide visualization. Control assembly **26** may further include vacuum connection **29** for connection of a vacuum source (not shown). Elongate member **24** preferably has a circular or elliptical cross sectional area to create an atraumatic surface during insertion into the body.

Distal portion **24** of member **23** includes a guide wire outlet **30** and guide wire inlet **31** to allow the surgeon to place device **21** over a guidewire which has been preinserted into the patient's gastrointestinal tract. Suturing sections **27**A and **27**B are provided along member **23** for acquiring and securing apposed tissue once device **21** has been properly positioned. Device **21** further includes endoscopic outlet port **25** to allow the surgeon to position an endoscope outside of device **21** once device **21** has been positioned within a hollow organ to provide visualization of the surgical procedure.

FIG. **2** is a schematic showing details of the suturing section **27**A. It will be understood that suturing section **27**B is similar to section **27**A, the difference being their relative positions on the device. A suction chamber **40** is recessed into elongate member **23** of device **21**. Cautery surfaces **41** are disposed within suction chamber **40** on either side of a vacuum port **45**A. The cautery surfaces **41** are heating elements coupled to electrical lines (not shown), and they are used to cause slight trauma to the external layer of the tissue which is suctioned into chamber **40** by a vacuum supplied by vacuum line **45**.

Also included adjacent to chamber **40**, in longitudinal alignment on opposing sides of chamber **40**, are needle lumen **42** and entrapment chamber **43**. Needle lumen **42** contains a needle head **44** mounted to needle pusher rod **46** which is oriented longitudinally such that the tip of needle head **44** is aligned with the proximal wall of suction chamber **40**. Optionally, an adhesion surface may exist between needle head **44** and pusher rod **46** to ensure that needle head **44** remains in place during insertion of device **21** and articulation of elongate member **23**. Attached to needle head **44** there is a suture **47**. Suture **47** could be a 2-0 or 0 monofilament suture, or other suitable suture material, such as silk thread or polypropylene (e.g. PROLENE suture, marketed by Ethicon, Cincinnati Ohio). Suture **47** can reside in a longitudinal guide groove **48** of pusher rod **46**.

Referring to FIG. **3**, suturing section **27**A includes a side disposed suction chamber **40** for tissue acquisition. Vacuum line **45** is connected to an external vacuum source through port **29** and applies sufficient suction to draw a fold **52** of tissue **51** into suction chamber **40**. Once the tissue fold is acquired, cautery surfaces **41** are activated to cauterize the tissue and create cauterized areas **53** of tissue on fold **52**. These cauterized areas **53** are designed to promote subsequent tissue adhesion. This approach to promoting tissue adhesion is analogous to the techniques described in the context of a surgical treatment for GERD in U.S. application Ser. No. 10/275,521 (US 2004/0034371) titled "Method of Promoting Tissue Adhesion" and naming the present inventor as a co-inventor, which is incorporated by reference to the extent not inconsistent with the present disclosure

Referring to FIG. **4**, with the fold **52** of tissue **51** still held in place within chamber **40** by the suction force, pusher rod **46** longitudinally projects needle **44** through suction chamber **40** and the contained tissue fold **52** and into entrapment chamber **43**. Once there, the acquisition material **49** within entrapment chamber **43** holds needle head **44** as well as the attached suture **47** on the opposite side of the chamber **40**.

Referring now to FIG. **5**, the pusher rod **46** is next extracted from the tissue fold **52** and drawn back into the needle chamber **42**. The result is that suture **47** has been passed through tissue fold **52**. The entire apparatus **21** may then be withdrawn from the patient and the surgeon may acquire the distal end of suture **47** by removing needle head **44** from entrapment material **49**. Having maintained control over the proximal end of suture **47** throughout the procedure, the surgeon will now have both ends of a suture that has been attached to the interior stomach wall.

FIG. **6** shows a cross-section view of elongate member **23**. Elongate member **23** includes vacuum line **45** which is in fluid connection with vacuum connection **29**. Elongate mem-

ber **23** also includes endoscopic channel **54**, guidewire channel **55**, and orientation wire lumen **56**. Endoscopic channel **54** runs through elongate member **23** from endoscopic inlet port **28** to endoscopic outlet port **25**. Guidewire channel **54** runs from guidewire inlet **30** to guidewire outlet **31** at the extreme distal end of elongate member **23**. As also shown, suction chambers **40**A and **40**B are recessed into elongate member **23** and needle chambers **42** and entrapment chambers **43** are arranged in longitudinal alignment on opposing sides of chambers **40**.

Referring now to FIG. **7**, an alternative arrangement for suturing section is depicted. Suturing section **127** includes a side disposed suction cavity **130** having several suction ports **145** in its closed end such that a vacuum may be applied to cavity **130** via vacuum line **145** to capture a fold of tissue (not shown). Moving from the open to the closed end of the cavity, a suture needle lumen **140**, a sectioning device lumen **150**, and an injection needle lumen **160** each provide access to the cavity for their respective instruments, the operation of which is described below. It is to be understood that FIG. **8** is a sectional view of the suturing section indicated showing the relative orientation of the lumens but with their instruments removed.

The suture needle lumen **140** provides access for the puncturing device **144** that is pushed through captured tissue by a pusher rod **146**. The puncturing device **144** carries a suture thread **147**, and is received in the receiving chamber **180** on the distal side of the cavity **130**. Ramped guide surfaces **190** are provided at the entrance to receiving chamber **180**. These surfaces **190** are tapered to guide the puncturing device **144** into the chamber **180** once the puncturing device **144** has been passed through the captured tissue.

The receiving chamber **180** is configured to retain the puncturing device (and/or the suture thread **147**) until released by the surgeon. As illustrated, the receiving chamber **180** is configured to have parallel pieces **182** and **184** of a relatively firm, puncturable material (such as leather) retained in a softer filler material **181** (such as a polymer, foam, or rubber). In operation, the tip of puncturing device **144** will penetrate one or both of pieces **182** and **184** and become captured in chamber **180**. The receiving chamber **180** can be snap fit in place, and a release mechanism (not shown) may optionally be provided to assist in removing the chamber **180** with the captured puncturing device **144**.

Other mechanisms for passing a suture through tissue captured in a suction cavity could also be employed. For example, U.S. application Ser. No. 10/275,521 (US 2004/0034371), U.S. application Ser. No. 10/430,071 (US 2003/0236535) titled "Apparatus for Ligating/Suturing Living Tissues and System for Resecting/Suturing Living Tissues", U.S. application Ser. No. 10/658,135 (US 2004/0158125), U.S. application Ser. No. 11/085,703 (US 20005/0165419), and U.S. Pat. No. 5,792,153 to Swain describe mechanisms that are operable to pass a thread longitudinally through captured tissue in an endoscopic arrangement, and these devices may be adapted for use in the procedures described herein. Alternatively, the suturing section may be adapted to apply the sutures radially or circumferentially relative to the axis of the device, for example as described in U.S. Pat. No. 5,947,983 to Solar et al.

The sectioning device lumen **150** provides access for a sectioning device **152** to slice a thin layer from the tissue (not shown) that has been captured in the suction cavity **130**. As illustrated, the section device **152** includes a wire loop **154** that is disposed about the periphery of the cavity **130** such that, when a fold of tissue is captured in the suction cavity, it passes through the loop **154**. Optionally, the loop **154** can be received in a retaining recess (not shown) in the wall **131** of the cavity **130**. With the captured tissue inside the loop, the sectioning device **152** is used to pull the loop **154** proximally through the tissue, which has the effect of slicing or sectioning the tissue. The wire loop **154** can include utilize high frequency or electrical current to facilitate slicing through the tissue. Alternatively, the sectioning device could be configured as a straight wire, a blade or other cutting means suitable for slicing a tissue section captured in the chamber.

In one implementation, the purpose of the sectioning device is to remove the mucosa from the tissue portions to be joined so as to expose the underlying submucosa. Referring to FIG. **9**, there is generally considered to be four different tissue layers in human stomach tissue. Beginning with the interior-facing layer, these layers are termed mucosa, submucosa, muscularis propria, and serosa. It is believed that removing the thin mucosal layer of stomach tissue to expose the underlying submucosa provides a tissue site that promotes adhesion with other stomach tissue, and particular other stomach tissue with exposed submucosa. Accordingly, the sectioning device may be arranged to take a thin slice of tissue that removes a portion of the mucosa to expose underlying submucosa, but otherwise leaves the tissue intact.

FIG. **10** illustrates an appropriate sectioning line **100** for resecting a fold of tissue captured in a suction cavity, and FIG. **11** illustrates the resulting sectioned area **153** having exposed submucosa that would result from resection along line **100** in FIG. **10** once the tissue has been released from the cavity. While the boundary between mucosa and submucoas is not uniform, and injecting the tissue will typically cause it to swell (i.e. edema), orienting the sectioning device relative to the depth of the cavity so as to section about 3 to 4 mm of captured/injected tissue, should be suitable for many patients. While it is believed that sectioning into the submucosa is particularly advantageous, it may not be necessary in all situations, and sectioning of less than the full thickness of the mucosa could be employed.

Turning back to FIG. **7**, the injection needle lumen **160** provides access for an injection needle **162** to inject the tissue that has been captured in the cavity **130**. One use for the injection needle **162** is to inject a material that will swell the captured tissue prior to it being sectioning with the sectioning device **152** described above. Adrenaline with saline or other therapeutic substances, such as materials designed to minimize bleeding or reduce chances of infection, may be injected.

An additional use for the injection needle **162** is to assist in fixating the captured tissue during sectioning. To assist in this fixating, a recess **162** may optionally be provided on the distal side of the cavity **130** opposite the needle channel **160** for receiving the injection needle **162**. During use, the injection needle **162** can be pushed through the captured tissue and into the recess **162**, and in this position can serve to assist in holding the captured tissue in place. Alternatively or in addition, the suturing needle **147** and/or the vacuum provided via line **145** can be used to provide fixation during the tissue sectioning.

Referring now to FIGS. **12** and **13**, device **21** is preferably used to create a seam **86** which joins the anterior and posterior walls to form a partition **80** within the patient's stomach **60**. The partition **80** is preferably sized to have a diameter of about 2.5 cm at the top segment **81** near the esophagus. The lower section **82** near the pylorus is preferably tapered to a diameter of around 1 cm in width. It is to be appreciated that the location of the sutures along the anterior and posterior stomach walls (which are then drawn together) determine the ending diameter of the partition. As explained more fully

below, with the elongated body positioned generally at the midline of the stomach (e.g. against the lesser curvature) the angular orientation of the suturing section may be set to establish the desired relative location of the sutures.

Referring to FIG. **12**, the procedure to create partition **80** begins with a guidewire **63** inserted transorally through the patient's gastrointestinal tract so that is it below the pyloric sphincter **64**. The guidewire **63** is then inserted into the guidewire inlet **31** in the rounded distal portion of member **23** of device **21**. The guidewire **63** passes through the guidewire channel **55** and exits through the guidewire outlet **30**. Alternatively, the guidewire outlet **30** may be on the proximal end **22** of device **21** so that guidewire channel **55** runs through a larger length of elongate member **23**. The device **21** is then advanced through the patient's gastrointestinal tract until the distal end of elongate member **23** is forced through the pyloric sphincter **64**. Once through, pyloric sphincter **64** serves as a frictional anchor for device **21**. As explained more fully below, the distal section **23** may optionally be provided with means for assisting anchoring, such as retractable barbs, inflatable balloon(s), or a magnet that cooperates with an external magnet.

Once device **21** is located within the patient's stomach **60**, the elongate member **23** is oriented against the lesser curvature **83** of the patient's stomach **60** by insertion of orientation wire **70** into orientation wire lumen **56**. Orientation wire **70** is of sufficient rigidity (or controllable to have sufficient ridigidy) to cause the device to conform to the lesser curvature **83**. Orientation wire **70** made be constructed of shape memory material or a flexion material or any other material sufficient to impart orientation to the elongated body. With the orientation wire **70** remaining in place to establish shape and orientation, device **21** can be longitudinally repositioned (i.e. moved axially up and down the orientation wire **70**) while maintaining the shape of the lesser curvature **83** as indicated by the orientation wire **70**.

With the device **21** in place and aligned along the lesser curvature **83**, the suturing sections **27**A and **27**B are used to attach two sutures, one in the anterior wall and another in the posterior wall of the stomach. Referring to FIG. **14** which shows overhead views of the stomach looking up from the pelvis, device **21** can be seen in its initial position with device centerline **100** corresponding to the centerline of the stomach, i.e. facing neither the posterior **84** nor anterior wall **85** of stomach **60**. Because the suturing sections are disposed at different angular orientations relative to the centerline of the device (in other words, section **27**A is disposed anteriorially and section **27**B is disposed posteriorially), device **21** only uses a single orientation wire lumen. The device **21** is axially positioned so that the suturing sections **27**A and **27**B are located near the bottom of lesser curvature **83** to begin the creation of partition **80**. The device **21** is rotated clockwise, as shown in FIG. **15**, so that centerline **100** is offset by angle **102**. Suturing section **27**A is then used to draw in a fold **52** of tissue from the anterior wall **85**, and the surgeon proceeds to prepare the captured tissue (e.g. by cauterizing it via cautery surfaces **41**) and to place a suture.

The device **21** is then returned to its original position with the centerline **100** parallel to both the posterior **84** and anterior wall **85** of stomach **60**, and then the device **21** is rotated counterclockwise by an amount corresponding to angle **104** (see FIG. **16**). Once device **21** is in position, suturing section **27**B draws in a section of tissue from the posterior wall **84**, cauterizes the tissue surface, and attaches a suture.

As shown in FIG. **12**, once the two sutures **47** have been passed through the portions of the anterior **85** and posterior wall **84**, the device **21** is withdrawn over the guidewire **63** so that the surgeon may acquire the distal ends of the sutures, having retained their proximal ends throughout the process. Due to the longitudinal offset of suturing section **27**B toward the distal end of member **23**, the two sutures **47**A and **47**B created during the first iteration are offset as indicated in FIG. **13**. Suture **47**B on the posterior wall is located relatively closer to the pylorus **64** than suture **47**A, which is located on the anterior wall and is relatively closer to the esophagus **65**.

The creation of partition **80** within the patient's stomach **60** typically will require a series of sutures (e.g. 8-14) in a stitching pattern such as depicted in FIG. **19**, with the pairing of sutures that are tied together and joined indicated by the connecting lines (i.e. C to B, E to D, etc.). This series of sutures can be created by repeating the procedure multiple times, with reloading of each suturing section (**27**A, **27**B) and repositioning of the device **21** between iterations. For example, in the first iteration sutures A and B would be attached. Device **21** would be axially slid up orientation wire **70** and the procedure repeated to attach sutures C and D. To create a taper, the angles **102** and **104** can be adjusted such that sutures are placed successively further away from the lesser curvature.

Once the first four sutures are in place, the surgeon may then couple the two sutures B and C together by an attachment means. For example, a means of attachment includes a surgical knot, a clamp, or any other means that may occur to one skilled in the art. The means of attachment are then slid into place and the two sutures are drawn together, creating contact between the two folds of tissue which have been modified or removed (i.e. having been cauterized or abraded, or having a surface portion sectioned and removed). It is believed that the resulting areas of modified or removed tissue will then develop scar tissue to facilitate formation of a relatively permanent bond.

The procedure has been described so far in connection with a device **21** with two suturing sections that are radially offset (i.e. one faces anteriorially while the other faces posteriorally) and a single orientation wire lumen. Devices with only one suturing section or with suturing sections that are not radially offset may also be employed. For such devices, multiple orientation wire lumens can be used to provide the proper curvature to the device when it is rotated anteriorially or posterially.

For example, as shown in FIG. **8**, suturing section **127** has orientation wire lumens **170**A and **170**B that are each offset from the centerline of the elongated body. More specifically, lumen **170**B is nearer surface portion **172** whereas lumen **170**A is nearer surface portion **174**. When the suturing section **127** is rotated anteriorially, as depicted in FIG. **20**, an orientation wire located in lumen **170**B is activated biased towards the lesser curvature **83** so as to have the surface portion **172** that is closest to lumen **170**B in contact with the lesser curvature **83**. Likewise, when the device is rotated posteriorially as shown in FIG. **21**, an orientation wire in lumen **170**A is activated to provide the desired curvature of the device.

With reference to FIGS. **40** and **41**, one mechanism for rotating the device is by manually grasping and rotating the proximal portion **901** that is extending from the patients mouth. The body **23** can be constructed of appropriately stiff material such that this turning is translated down its length to also turn the operating portions located inside the patient's stomach.

In typical operation, a bite block **900** will be positioned in the patient's mouth and a head strap (not shown) attached to either side of the bite block **900** will be wrapped around the patients head to further secure the bite block **900** in position. The bite block **900** may be used to accommodate both the

elongated body **23** used to perform the surgical operation on the stomach as well as a conduit **910** for providing an airway. Once in position, the elongated body **23** may be clamped or otherwise secured to the bite block to keep the proximal portion in position. Alternatively or in addition, the bite block **900** can be configured to assist in rotating the device, for example by the provision of gears **902** or a ratcheting mechanism that engage corresponding surface portions of the body **23** to assist in its relative rotation. Gradations or markings **903**, **904** on the bite block **900** can also be provided to match up with corresponding markings **906** on the proximal portion of body **23** to indicate the relative angular orientation of the device.

The orientation wires may remain in place and be activated and deactivated as needed. Alternatively, they can be withdrawn and inserted when needed. The orientation wires can be activated by manual pulling or cable gathering (similar to the operation of endoscope control) or, when constructed from shape memory material (e.g. nitinol) then can be activated by heating (e.g. application of electrical energy). In place of or in addition to the orientation wires, an alternative mechanism for aligning and orienting the elongated body **23** along the lesser curvature can be used. For example, a series of suction ports may be provided along that portion of the body which is to be in contact with the lesser curvature. A suction force may then be applied to these ports to draw the body against the lesser curvature of the stomach wall. It is to be understood that these suction ports are used for purposes of alignment and not tissue capture, and thus they would operate independently from the suction chamber used to capture the tissue for suturing. Where different angular orientations of the body are utilized (i.e. where the device is rotated in an anterior or posterior direction as described above) these suction ports can be arranged in two longitudinally extending lines wherein suction can be applied to each line individually.

It is to be appreciated that one purpose of the distal anchoring section is to provide secure anchoring of the device against axial movement (e.g. being prematurely withdrawn from the pylorus) while the suturing section is attaching sutures to the stomach walls. Referring to FIGS. **22** and **23**, the distal section **24** may be provided with means for enhancing anchoring, such as retractable wires **212**, inflatable balloons **210**, and/or a magnetic material **214** that cooperates with an external magnet (not shown). As illustrated, these anchoring structures can be provided on the portion of distal section **24** that extends past the pylorus **64**. They serve to retain the distal section **24** in place while the suturing section **127** is operating on the stomach walls. Alternatively, anchor assisting means can be provided on either side of the pylorus **64** or only on the portion proximal from the pylorus **64**.

While the distal section **24** has been described as being placed into its initial position (e.g. being anchored in the pylorus) by being threaded over a guidewire, other means of positioning the device may be employed. For example, referring to FIG. **24**, the distal section **24** may be configured to receive an endoscope **300**, for example a 5 mm endoscope, and the endoscope **300** may be used to guide the distal portion **24** into position. In this arrangement, an endoscope lumen **310** is provided in portion **24** with a visualization port **305** (or a see-through closure) at its distal end. When inserted in the lumen **310**, the endoscope contacts a stepoff **315** at the distal end and, while also using the endoscope for visualization, the operator uses the endoscope to push the distal portion **24** through the stomach and into the pylorus. The detail in FIG. **24** of the distal tip also illustrates balloon **210** in a deflated configuration. Once placed, the balloon **210** can be inflated via an inflation lumen **210***a*. Alternatively, the balloon can be inflated and deflated during insertion as a means of assisting to advance the distal portion into position.

A useful aspect of the devices described herein is their ability to be distally anchored while the suturing section operates on the stomach walls. FIG. **25** illustrates general dimensional aspects that assist in this implementation. The length L**1** is the length corresponding to the distal anchoring section, measured from the distal-most portion of the suction chamber of suturing section **127** to the distal tip of the anchoring section. This length L**1** will generally be in the range of 10-20 cm, for example about 15 cm. Thickness T**1** refers to the diameter of the suturing section, and this will generally range from 15-20 mm. The distal anchoring section will typically include a taper down to a thickness T**2** of about half the thickness T**1**. This taper may be used to occlude the pylorus. The distance L**2** from the distal most portion of the suction chamber to this taper may be in the range of about 0.5 to 2 cm. The portion of the distal anchoring section that extends into the pylorus may have a thickness T**3** of about 7 mm so as to be able to accommodate the 5 mm endoscope used for insertion.

Turning now to FIGS. **26-28**, a variation on the suturing section **127** illustrated in FIG. **7** is depicted. Suturing section **327** is identical to suturing section **127** except that the needle lumen **140** and the receiving chamber **180** are provided in a removable shuttle **400** that is slideably received in a shuttle lumen **410** of the device. As shown in the top view of FIG. **27**, the shuttle **400** has an opening **440** that aligns with vacuum cavity **420** when the distal portion of shuttle **404** is positioned in the distal portion of shuttle lumen **410**. Rounded shoulders **416** extend along the length of the shuttle on either side of opening **440**, and corresponding guide surfaces **415** extend along the length of lumen **410**.

With shuttle **400** inserted in lumen **410** and the opening **440** aligned with cavity, the suturing section operates in the same manner as suturing section **127** of FIG. **7**. A vacuum is drawn via line **145**, the captured tissue is injected via lumen **160** and sectioned via lumen **150**, and a suture is passed through the captured tissue via lumen **140** and captured in chamber **180**. However, once the tissue has been released, the shuttle **400** can be withdrawn from its lumen **410**. This allows the operator to remove the captured needle from the chamber **180** without removing the entire device.

While only the needle lumen **140** is shown on the removable shuttle **400** in FIGS. **26-28**, it is to be appreciated that one or more of the sectioning lumen **150**, the injection lumen **160** and even the vacuum lumen **145** can be integrated into the removable shuttle **400**.

When the vacuum lumen is included in the removable shuttle, a positioning device **455** can be configured to have an elongated slot **450**, as depicted in FIG. **29-30**. In this variation, the removable shuttle **460** will contain all of the operative mechanisms for suturing, as depicted in the cross section of FIG. **31**. In use, the shuttle **460** can be positioned anywhere along the longitudinal length of the slot **450** to position a suture. To assist in longitudinal positioning, the proximal portion of the shuttle **460** (not shown) can be marked (i.e. with gradations or markings) so as to measure how far into the lumen the shuttle has been extended. Knowing the relative dimensions of the device, the operator can then determine where along the slot **450** the shuttle is positioned. Alternatively or in addition, stops can be provided on the shuttle **460** or in the lumen of the device **455** to aid in positioning. For example, a series of extension members (not shown) can be attached to the distal end of the shuttle **460** to control how far into the lumen the shuttle can extend. In other words, a 1 cm

extension member would make the shuttle stop 1 cm from the end, a 2 cm extension member would make the shuttle stop 2 cm from the end, etc.

It is to be appreciated that the instruments and techniques described here are suitable for providing a suture through stomach tissue that has been prepared for joining with other stomach tissue. For example, as shown in FIG. **32**, two strands of suture thread may be attached to the anterior **85** and posterior **84** stomach walls such that their free ends A and B extend from opposite sides of prepared tissue areas **153**. From outside the body, the operating physician can attach the A ends together and, by pulling on the B ends, bring the walls **85** and **84** together, as shown in FIG. **33**. The B ends may then be joined and a knot or crimp **610** slid down to the tissue to complete the attachment as shown in (FIG. **34**). The process may be repeated as often as necessary until enough tissue sections have been joined to form an adequate seam **86** (see FIG. **13**).

To reduce the number of sutures that need to be tied together in this way by the surgeon, the device can be constructed such that a single suture thread is attached at multiple tissue sites. For example, U.S. Pat. No. 5,792,153 to Swain illustrates one such mechanism for attaching a single thread to multiple tissue sites. The general approach of the Swain device, and of other known devices of this type, is to configure the suturing section as a type of sewing machine, wherein the suture is carried by a thread carrier that is passed back and forth across the suction chamber by a hollow needle. Alternatively, instead of capturing the thread on the far side of the suction chamber via a thread carrier, the thread can be directly captured, for example by catching a loop of the thread with a spring loaded latch, as is also know in the art. Furthermore, while many of the longitudinally operable needles described so far generally begin operation on the proximal side of the suction cavity, it is to be understood that these suturing devices can be modified so as to begin operation on the distal side as convenient.

FIG. **34** illustrates a useful suturing pattern when a sewing machine type device is employed. For ease of illustration, four folds of tissue **710**, **720**, **730**, **740**, two each on the anterior **85** and posterior walls **84** are illustrated. However it is to be understood that the folds of tissue depicted in FIG. **34** are each created by the suction chamber at the time the suture is passed through the respective tissue fold. In illustrated step **1**, the suture shuttle (which carries the suture thread) is passed through fold **710** on the anterior wall **85** from a proximal to distal direction by a hollow needle. In step **2**, the suture shuttle is reinserted into the hollow needle, and in step **3** the suture shuttle is passed through fold **730** on the posterior wall **84** also from a proximal to distal direction. With the suture shuttle still on the distal side of the suction chamber (not shown) the suture is passed through fold **740** in a distal to proximal direction. The suture shuttle is then repositioned on the distal side of the chamber and in step **6** passed through fold **720** in a distal to proximal direction. The end result is to produce a suture pattern across the four folds that resemble a "figure 8", with the free ends (extending from bottom of page in step **6**) being tied together to complete the lower loop of the "figure 8".

FIG. **36** is another illustration of this "figure 8" suturing pattern, and FIG. **37** shown alternative suturing patterns and techniques that use plugs and anchors to either join suture threads or provide the initial suture location. It is to be understood that the shaded areas indicated areas of sectioned or cauterized tissue and that the left and right sides of the figures correspond to the anterior and posterior stomach walls (or vice versa). FIG. **38** shows a still further variation of useful suturing patterns. The FIG. **38** suturing pattern begins with a plug or pledget anchoring the first end of a suture thread attached to the posterior wall. The suture pattern of FIG. **38** may be used in connection with curvilinear needles, as depicted in FIG. **39**, that serve to attach sutures radially or circumferentially relative to the axis of the device.

It is to be understood that the procedure has so far been described in connection with interior stomach tissue that is operated on to promote joining (i.e. has been cauterized or abraded, or wherein a portion of the surface tissue has been sectioned or removed) in a spot type fashion. In other words, referring to FIG. **42** which shows the relative position of sites **153** of resected or removed tissue (which could alternatively be cauterized or abraded tissue) on the posterior wall **84** useful for joining to corresponding anterior wall portions so as to form seam **86** (see FIG. **13**), there may be sections of unaltered tissue **157** between the sectioned sites **153**. Referring to FIG. **43**, in alternative implementations, the stomach walls may be prepared (i.e. cauterized or abraded, or alternatively sectioned or removed) in a pattern resembling a strip **153***a*. In the illustrated implementation, the strip **153***a* corresponds to the upper generally constant width portion of the partition, and an isolated spot portion **153** is formed to create the narrower distal portion of the partition. In further variations, the strip can be angled so to form a taper.

Referring to FIG. **44**, one mechanism for creating the strip **153***a* of prepared tissue is with device, such as device **950**, which has a cautery surface **955** in the shape of the desired strip **153**. In use, suction is applied through vacuum holes **957** on either side of surface **955** to bring the stomach wall into contact with surface **955**, and surface **955** is activated to cauterize the stomach wall.

Referring now to FIGS. **45-51**, another variation on a surgical system for performing gastroplasty is disclosed. In this variation, the surgical system includes an applicator **960** that is inserted into the patient's stomach and aligned along the lesser curvature. The proximal portion (not shown) can be secured to a bite block at the patient's mouth, and the distal portion **24** can be anchored (e.g. in the pylorus) as described above. The applicator **960** has a main lumen (not shown) that extends at least from a proximal entrance to an elongated side working opening **965**. With the applicator **960** in position a slicing device **970** and a suturing device **990** may be inserted into the main lumen so as to access the anterior and posterior stomach walls via working opening **965**. During the initial insertion of applicator **960** into the patient, a filler block (not shown) may be inserted in the main lumen to fill the opening **965** and provide structure integrity to the applicator **960** and/or provide a smooth surface at opening **965**.

Referring in particular to FIGS. **46** and **47**, a slicing device **970** may be inserted through the main lumen of applicator **960** and used to resect a portion of the anterior and posterior stomach walls to prepare them for being joined (e.g. so as to expose submucosa). The slicing device has two slicing portions **971** for forming strips of resected tissue on the anterior and posterior stomach walls. Each slicing portion **971** has a cavity **975** with a series of vacuum ports **978** and injection needles **980**. The injection needles **980** are all coupled to a common injection lumen **982** and a common vacuum source feeds the vacuum ports **978** via a series of vacuum lumens **976**. When suction is applied, tissue (not shown) is drawn into the cavities **975**, and the force of the suction causes needles **980** to puncture the captured tissue. An adrenaline saline solution may then be injected into the captured tissue via lumen **982**. The cross section of lumen **982** may be configured to promote the even distribution of fluid along the length of

the slicing portions, for example with the cross section at the distal end being smaller that at the proximal end.

A wire **972** extends across each cavity **975** and has an enlarged head **962** slideably received in channels **974** at each side of the cavity **975**. With the tissue captured in the slicing portions **971** (via the vacuum), the operating physician pulls proximally on lines (not shown) coupled to each head **962** to pull the wire **972** through the tissue.

To assure proper positioning during use, orientation wire (s) may be used in orientation wire lumen **973** of the tissue sectioning device **970** and/or in orientation wire lumen **170** of the applicator **960**.

With the stomach walls sectioned, tissue sectioning device **970** may be withdrawn and a suturing device **990** inserted into the main lumen of applicator **960**. As illustrated, the suturing device is of the type that employs a longitudinally operable needle, but a suturing device having a circumferentially operable needle could be used. Suturing device **990** includes a vacuum lumen **994** for drawing a vacuum in cavity **992** and a needle lumen **995** for driving a suture through the tissue captured in cavity **992**. A removable needle capture chamber **996** is provided on the distal side of the cavity **992** to capture the needle and/or the suture once it has been passed through the tissue.

As illustrated, the suturing device **990** is configured to attach a single suture and to be axially rotated within the applicator **960** so as to be disposed towards the anterior or posterior walls, as illustrated in FIGS. **48** and **49**. A pair of orientation wire lumens **993** are provided in the suturing device **990** and may be used to rotate the suturing device.

With the applicator **960** conforming to the lesser curvature of the stomach, the distal end of the working opening **965** in applicator **960** may be curved during use, as depicted in FIG. **50**. To assure that the devices **970** and **990** stay oriented in the main lumen of the applicator **960** while they are being inserted, orientation wires may be used in the orientations wire lumens of the slicing device **970** and the suturing device **990**. Alternatively or in addition, the distal portions of the devices **970**, **990** may be adapted to engage with the applicator **960** near the distal portion of the opening **965**. One such mechanism for accomplishing this engagement is illustrated in FIG. **51**, which shows in cross section the distal portion of suturing device **990** engaged with the applicator **960** near the distal end of opening **965**. More specifically, a retention member **997** extends from the side of device **990** opposite the suction cavity **991** and receiving chamber **996** and defines a receiving opening **997***a*. A catch **964** is secured at the distal end of extends on the interior surface of applicator **960** and extends proximally. As the suturing device **990** is advanced towards the distal end of opening **965**, catch **964** slides into receiving opening **997***a* to assure that the suturing device **990** conforms to the curvature of the applicator **960**.

As mentioned above, for example in connection with FIG. **35**, a suture can be attached to multiple sites by passing a thread carrier back and forth across the suction chamber via a hollow needle. Turning now to FIGS. **52-54**, a suitable mechanism for accomplishing this is shown. Suturing section **220** includes a tissue acquisition cavity **222** to which suction is applied by vacuum line **145**, an injection needle lumen **160** and a resection device lumen **150** (or alternative the resection may be via **160** and the injection via **150**). Referring to FIG. **52**, a tread shuttle **254** having a suture thread **246** attached or embedded therein is contained in a hollow needle **240** in a needle lumen on the proximal side of the cavity **222**. On the distal side of the cavity, an entrapment section **230** is provided for selectively capturing the thread shuttle **245** and retaining it on the distal side of the cavity **222**. The entrapment section includes a member **231** having a ramped cam surface **232** and being biased leftward (per FIG. **52**) by compression springs **236**.

Before being passed to the distal side (i.e. FIG. **52**), the shuttle **245** is retained in the hollow needle **240** via frictional engagement with inside surfaces **242** of the needle **240**. The shuttle **245** may also include engagement members **247** (FIG. **53**), such as a textured or rubberized surface, for engagement with corresponding features on inside surface **242**. To pass the shuttle to the distal side, the distal tip of the hollow needle **240** is advanced across the cavity **222** and a pusher rod **248** slides the shuttle **245** distally against the ramped surface **232**. This causes member **231** to move rightward and compress springs **236**, and the restoring force of springs **236** frictionally holds the shuttle **245** in the entrapment section **230**, as shown in FIG. **53**. Engagement members **234** may be provided on member **231** to improve the frictional adhesion.

To bring the shuttle back to the proximal side of the cavity **222**, the hollow needle is advanced into the entrapment section **230** over the shuttle **245** and the interior surfaces **242** of needle frictionally grab the shuttle **245**. The distal portion of the shuttle **245** can be provided with a tapered surface **249** to facilitate the proper alignment of the needle **240** over the shuttle **245**, and the needle **240** has a distal slot **243** for accommodating the free end of the thread **246**. The entrance **238** to the entrapment section is also tapered to facilitate smooth insertion.

Other mechanisms for holding the thread shuttle in place (inside the hollow needle and/or in the entrapment portion) may be utilized in place of or in addition to the friction fitting described above. For example, magnets, shape memory materials or mechanical latches can be used to supplement or replace the friction pads on the thread shuttle and the inside of the hollow needle. In one particular example, the thread shuttle includes magnetic material and the entrapment section applies a magnetic force to selectively capture the thread shuttle. An electromagnet or a moveable permanent magnet may be employed in the entrapment section to selectively provide the magnetic force used to capture the thread shuttle. In another example, an entrapment mechanism may be constructed from a shape memory material that selectively engages the thread shuttle when heated, for example by an electrical current.

A variety of other suturing arrangements may be advantageously employed for joining the anterior and posterior walls, and reference is made to the alternative patterns depicted in U.S. Ser. No. 60/757,694 filed Jan. 10, 2006 and the use of one or more curved or transverse needles therein, for example for the joining of excised strips via a continuous thread in an ascending corkscrew pattern. For example, a device having multiple transverse curved needles along an elongated suction cavity (like cavity **975** in FIGS. **46** and **47**) is envisioned. The series of needles may be constructed to be simultaneously or successively activated to pass sutures through tissue that has been captured in the elongated suction cavity. Such an arrangement would allow multiple sutures to be attached in a row with a predetermined spacing.

Referring now to FIGS. **55-57** an alternative embodiment incorporating an expandable spacer and a short helical needle is depicted. An elongated body or keeper **501** has a window section **505** for allowing the working components, in this case device **520**, access to the stomach walls. Device **520** includes a pair of elongated suction cavities **522** for capturing tissue via suction applied to ports **523**, **525** along the bottom and sides of cavities **522**. A suction lumen **526** delivers a vacuum and a manifold **528** serves to allocate the vacuum pressure to the ports **523**, **525**. Lumen **524** provides the infusate into

injection needles **530** to inject the captured tissue, and once injected, an excision blade **535** is driveably distally via a driving rod **540** to excise the captured and infused tissue.

A helical needle **550** carrying a suture tread **552** is driven along its axis in a distal to proximal direction by two sets of rollers **555**, which are driven by a pair of driving rods **558**. Rollers **555** are evenly spaced based on the pitch of the helical pitch of the needle **550** and connected by narrower diameter connecting portions **556** which enhance the flexibility of the device. As illustrated, needle **550** includes two complete helical turns and thus would remain in contact with at least four rollers at all times as it is advanced proximally up its path, contributing to a stable and predictable path of the needle through the tissue. As an additional aid to the stability and guidance of needle **555**, the inner surface of keeper **501** is provided with guiding grooves in the shape of the intended needle path. In addition to or in place of conventional needle materials, to enhanced workability, the helical needle **550** may be constructed of a superelastic material, such as Nitinol.

An endoscope **300** extends though the keeper **501** and device **520** and exits through opening **502** distal to window **505** and may be used to visualize the procedure and spot issues that may develop. As illustrated, an emergency wire catch **570** extends through lumen **572** of device **520** and may exit at one or more openings **574** to address problems that might be so identified, for example to address snags or to pull any necessary slack in the suture thread. Alternatively or in addition, instruments (not shown) may be inserted through the working channel of the endoscope for this purpose.

A balloon catheter **560** extends through the keeper **501** and exits through the distal end of the keeper (not shown). A balloon on the distal end of the cathether (see FIG. **64**) is anchored in the pylorus. An inflatable balloon **545** is provided along the length of the working section of the keeper **501** and may be inflated after insertion into the stomach to increase the effective diameter of the keeper. In use, the balloon **545** is positioned toward the lesser curvature and, with tension applied to the catheter **560**, the keeper is biased into the desired position. Careful selection of the outer diameter of the keeper and/or control of the same via the balloon **545**, together with anchoring and positioning as described herein, facilitates creation of a lumen of the desired size and shape.

In it to be appreciated that, as illustrated, the axis of the helix is generally coaxial with the axis of the keeper **501**. Offset configurations and configurations wherein a portion of the helixal path extends outside the outer dimension of keeper **501** are also contemplated. Generally useful confugrations will typically involve the axis of the helical path residing within the local outer dimensions of the keeper **501**.

Additionally, as illustrated, side suction ports **525** are located in cavity **522** on the same side of (i.e. below) the resecting plane defined by the excision blade **535** as are bottom ports **523**. As a result, as the captured tissue is excised, ports **523**, **525** may both be beneficially used to retaining the excised tissue, but their usefulness in retaining the unexcised tissue is substantially reduced. Placing the suture before or during the excision is one mechanism to address this issue. Alternatively, or in addition, side ports **525** may be located above the tissue excision plane.

In a still further variation, side ports are above the tissue excision plane and made controllable independent of the lower ports. Separate control of the suction cavities would allow, for example, the lower ports to hold onto the excised tissue while the side ports release the tissue.

In a still further variation, mechanical clamping members may be provided along the suction cavities **522**. Such clamping members may be used to supplement or replace the acquisition and retaining function of the cavities **522**.

FIGS. **58-60** illustrate an embodiment similar to that depicted in FIGS. **55-57** save the use of a needle with more turns of the helix and the removal of the inflatable balloon **545**. FIG. **59** corresponds to the keeper **501** as depicted in FIG. **58** with the internal helical needle and the internal tissue capture, excision, and needle activation components removed and shown in FIG. **60**. FIG. **58**A shows the relative size and orientation of the various lumens. By way of reference, in one embodiment, the endoscope lumen **503** may be sized to accommodate a 5 mm endoscope and the overall outer dimension of the keeper may be in the range of 15-25 mm, for example about 20 mm not including any expansion provided by the expandable balloon **545**.

FIG. **61** is a perspective view of an alternative configuration for the internal tissue capture, excision and needle activation components for use with a keeper such as keeper **501**, with additional details of the needle activation shown in FIG. **62**. The tissue acquisition and sectioning components of device **350** operate identically to those of device **520** save that the excision blade **370** is operated by pulling a pair of cords **372** attached to the outer edges of blade **370** rather than pushing a centrally mounted actuating rod **540**.

The suture activation of device **350** is provided by a shuttle **360** slidably disposed in device **350**. The endoscope lumen **503** and a pair of needle actuation lumens **358** are provided in the shuttle **360**. Referring to FIG. **62**, rods **368** extend through lumens **358** and are coupled to rollers **364** which drive needles **368** and **369** back and forth across the suction cavities.

In place of rollers, needles may be advanced back and forth across the suction cavities via pull wires **484**, **485**, **486**, **487** as depicted with respect to device **480** of FIG. **63**, which may also be used with keeper **501**. For example, as depicted, wires **484** is pulled proximally to advance needle **482** across the cavity, and wire **487** is pulled to bring needle **482** back into the shuttle. Device **480** includes a series of channels **481** in the bridging area dividing the suction cavities. The channels **481** may be used as places to exchange a thread carrier between the right side and left side needles, either directly or via a drop-off pick-up arrangement. Alternatively, applying sutures via a removable shuttle facilitates the reloading of needles for outside the body, as described above.

FIG. **64** is a schematic illustration of an anchoring balloon catheter extending through the working channel of an endoscope and with the anchoring balloon inflated in the duodenum and showing detail of the self closing valve at the proximal end of the catheter.

FIGS. **65**A-E schematically illustrate the performance of a gastroplasty procedure. The procedure begins with the placement of the anchoring balloon **562** via the working channel of endoscope. The endoscope is withdrawn leaving the balloon in place and the keeper is backloaded over the proximal end of the catheter. The endoscope is then inserted through the keeper. Under visualization of the endoscope and with the assistance of the expandable positioning balloon and/or the anchoring catheter, the keeper is positioned against the lesser curvature and captures portions of the anterior and posterior walls in the suction cavities.

The helical needle is then used to apply a suture to the tissue portions, which is shown in FIG. **65**C in a proximal to distal direction. The tissue is excised after an epinephrine injection, and then it is released with the sutures attached. The position balloon **545** on the keeper **501** is deflated and the working components (e.g. the tissue acquisition and excision components) are slid proximally so as to be removed from the

working window. The keeper may then been removed and the helical suture pulled tight. The anchoring balloon **562** is then repositioned at the distal opening of the newly created lumen (or pouch) in the stomach. With the endoscope positioned on the outside as shown in FIG. **65**E, the lumen is filled with liquid, such as methlyene blue, such the absence of any leaks may be visually determined.

One potential complication in creating a leakless seam is that, while in the middle of the stomach one is joining opposing walls together, near the esophageal junction (i.e. where the seam meets the esophagus) the "walls" start to resemble "ceilings." FIGS. **38** and **39** depict one approach to avoiding leaks where the seam meets the esophagus involving excising this "ceiling" tissue. The excision may be accomplished by adding an arch section **592** to effectively join the elongated suction cavities **522** on the left and right sides of the device. In use, this arch section would be positioned where the seam is to meet the esophagus. An arch cutter **594**, such as a wire or rotating blade, may be configured to cut tissue acquired in this arch section. Alternatively the blades or excision wires used to excise along the length of the channels may begin or end its path by cutting the arch. For example, two blades can act together as one to cut the arch portion and then split and follow their separate paths in the elongated cavities.

As will be appreciated by those of skill in the art, what has been disclosed includes a novel method for joining stomach walls to reduce the interior volume of the stomach utilizes a surgical system comprising an elongated body or keeper and at least one working member operably associated with the elongated body, the working member including first and second suction cavities. The method may involve capturing an anterior portion of the stomach wall with the first suction cavity and applying a first suture thereto, capturing a posterior portion of the stomach wall with the second suction cavity and applying a second suture thereto, and then drawing the first and second sutures together to join the anterior and posterior wall portions. During some or all of the capturing, the elongated body may be aligned along the lesser curvature of the stomach by any of the anchoring and/or orientation techniques described herein. Preferably, though not essentially, the anchoring is via a balloon catheter with desired orientation imparted to the device via tension applied to the balloon catheter.

The working member may be slideably disposed within the elongated body capture the stomach wall portions through at least one opening along the length of the elongated body.

The elongated body may be used to occlude the proximal portion of the stomach and a balloon used to occludes the distal portion of the stomach. Then, gas may be fed into or removed from the stomach to expand or contract the stomach walls. Similarly, the balloon may be moved into position to plug the lumen once it is created to check for leaks in the seam.

Prior to drawing the sutures together the captured portions of the stomach walls may be partially excised, for example via a cutting device in the suction cavity. Prior to excision, an infusate may be injected, for example via injection needles in the suction cavities. Suction may be controllably applied to the upper and lower portions of the suction cavities independently, for example such to hold the unexcised tissue when the lower portion of the tissue is being cut away.

What has also been disclosed is a novel method for joining stomach walls to reduce the interior volume of the stomach using an elongated body having a proximal end extending from a body orifice, at least one working member operably associated with a working portion of the elongated body, and an anchoring device distal to the working portion for orienting the elongated body along the lesser curvature. The at least one working member may define at least one suction cavity and excision device for capturing and excising and the method may include capturing and excising an anterior portion of the stomach wall, capturing and excising a posterior portion of the stomach wall with the suction cavity and excision device, then joining the excised anterior and posterior wall portions. Infusate may be injected to prepare the tissue for excision swelling or promote healing and the suction may be controlled across portions of the cavities. During some or all of the procedure, the elongated body may be oriented along the lesser curvature.

The excised anterior and posterior wall portions may be joined with a plurality of sutures applied to the captured and excised anterior and posterior wall portions to create a modified lumen in the stomach. In one form, tissue is captured in two elongated suction cavities and a plurality of sutures are applied via a needle carrying a suture thread along a generally helical path. The generally helical path may have an axis inside the elongated body and/or helical grooves in an interior surface of the elongated body may define the path.

After excision and application of the sutures, the captured wall portions may be released and allowed to fall away from the device and then drawn together by drawing the suture tight. Depending on the device orientation, if the thread is wrapped around the device it may be necessary to slidingly withdraw the suturing device after applying the sutures.

If the cross sectional area of the device is not ideal for the particular application or merely as a mechanism for improving the orientation of the device, a spacing member along the length of the elongated body may be employed. The spacing member may be expandable to increase the effective cross sectional area of the elongated body at any point along its length but would typically be used against the lesser curvature. An expandable bladder or balloon may be used. As an additional mechanism for retaining the tissue captured in the suction cavities, one or more clamping members may be employed to grasp the tissue in the cavity.

What has also been described is a novel method for joining stomach walls to reduce the interior volume of the stomach utilizing a surgical system inserted inside the stomach via the esophagus. The system may include an elongated body having a proximal end extending from a body orifice and at least one working member operably associated with a working portion of the elongated body, the at least one working member comprising first and second elongated suction channels and a helical needle suturing device. The procedure may involve capturing an anterior portion of the stomach wall in the first suction channel, capturing a posterior portion of the stomach wall with the second suction channel, and then helically suturing the captured anterior portion to the captured posterior portion with the suturing device. During some or all of the procedure, the elongated body may be anchored in position as described above. The suturing may be along a generally helical path having an axis inside the working portion of the elongated body and it may be in a distal to proximal or proximal to distal direction. The suturing device may be integral with or slideably disposed within the working portion of the elongated body.

What has also been described is a novel surgical system comprising an elongated body adapted to be inserted into an esophagus with a proximal end extending from a body orifice, the elongated body including a tapered distal portion and a working portion having an outer surface defining at least one side opening therein, at least one working member disposed within the working portion of the elongated body, the at least one working member comprising at least two tissue acquisi-

tion and excision assemblies, the assemblies each comprising a suction cavity open to the at least one side opening and an excision device for excising at least the mucosal layer of tissue captured in the cavity.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. Only certain embodiments have been shown and described, and all changes, equivalents, and modifications that come within the spirit of the invention described herein are desired to be protected. Any experiments, experimental examples, or experimental results provided herein are intended to be illustrative of the present invention and should not be considered limiting or restrictive with regard to the invention scope. Further, any theory, mechanism of operation, proof, or finding stated herein is meant to further enhance understanding of the present invention and is not intended to limit the present invention in any way to such theory, mechanism of operation, proof, or finding. Thus, the specifics of this description and the attached drawings should not be interpreted to limit the scope of this invention to the specifics thereof. It is to be understood that when words such as "a", "an", and "at least one" are used, there is no intention to limit to only one item unless specifically stated to the contrary. Furthermore, when the language "at least a portion" and/or "a portion" is used, a portion and/or the entire item may be present. Finally, all publications, patents, and patent applications cited in this specification are herein incorporated by reference to the extent not inconsistent with the present disclosure as if each were specifically and individually indicated to be incorporated by reference and set forth in its entirety herein.

What is claimed is:

1. A method for joining gastric tissue, comprising:

(a) capturing a first portion of gastric tissue with a first elongated suction cavity of an elongated member introduced via the esophagus, wherein the gastric tissue is in the stomach or at the esophageal junction;

(b) excising at least the mucosal layer of the captured first portion so as to create a first elongated exposed tissue section;

(c) capturing a second portion of the gastric tissue with a second elongated suction cavity introduced via the esophagus;

(d) excising at least the mucosal layer of the captured second portion so as to create a second elongated exposed tissue section; and

(e) suturing the first and second portions together at multiple locations with sutures applied to the tissue in a direction transverse to the elongation direction of the elongated member, wherein the applied sutures are drawn together to bring the tissue portions into position with the first elongated exposed tissue section facing the second elongated exposed tissue section wherein prior to excising in (b) and (d), the captured tissue is injected with an infusate with at least one needles extending in a direction transverse to a longitudinal axis of the elongated member, the at least one needle disposed in a bottom surface of the first elongated suction cavity.

2. The method of claim **1** wherein the excising in (b) and (d) involves advancing a cutting device along guiding slots provided in opposed sidewalls of the elongated suction cavities.

3. The method of claim **2** wherein the cutting device is a wire or a blade.

4. The method of claim **3** wherein the cutting device is a blade.

5. The method of claim **1** wherein the sutures are applied with a curved needle.

6. The method of claim **5** wherein the sutures are applied with a generally helical needle.

7. The method of claim **5** wherein the elongated member comprises an endoscope lumen which terminates in an endoscope exit hole, the method further comprising providing endoscopic visualization via an endoscope extending from the endoscope exit hole in the device.

8. The method of claim **7** wherein the endoscope exit hole is distal to the first elongated suction cavity.

9. The method of claim **7** wherein the endoscope exit hole is proximal to the first elongated suction cavity.

10. The method of claim **1** wherein the tissue is stomach tissue and the anterior and posterior walls of the stomach are joined to create a modified lumen in the stomach.

11. The method of claim **1** wherein the first elongated suction cavity is provided on a device having an endoscope lumen which terminates in an endoscope exit hole, the method further comprising providing endoscopic visualization via an endoscope extending from the endoscope exit hole in the device.

12. The method of claim **11** wherein the endoscope exit hole is distal to the first elongated suction cavity.

13. The method of claim **11** wherein the endoscope exit hole is proximal to the first elongated suction cavity.

14. The method of claim **13** wherein the excising in (b) and (d) involves advancing a cutting device along guiding slots provided in opposed sidewalls of the elongated suction cavities.

15. The method of claim **1** wherein the at least one of the first elongated suction cavity and the second elongated suction cavity is provided on an elongated body which is aligned along the lesser curvature of the stomach during the capturing.

16. The method of claim **1** wherein plications are formed at the esophageal junction.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,641,729 B2
APPLICATION NO. : 11/457442
DATED : February 4, 2014
INVENTOR(S) : Charles J. Filipi

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Col. 24, line 3, replace "needles" with --needle--

Signed and Sealed this
Twenty-ninth Day of April, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office