US007708181B2

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Cole et al.

(10) **Patent No.: US 7,708,181 B2**
(45) **Date of Patent: May 4, 2010**

(54) **ENDOSCOPIC STAPLING DEVICES AND METHODS**

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(73) Assignee: **Barosense, Inc.**, Redwood City, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **12/052,885**

(22) Filed: **Mar. 21, 2008**

(65) **Prior Publication Data**

US 2009/0236394 A1 Sep. 24, 2009

Related U.S. Application Data

(62) Division of application No. 12/050,169, filed on Mar. 18, 2008.

(51) **Int. Cl.**
A61B 17/068 (2006.01)

(52) **U.S. Cl.** **227/176.1**; 227/19; 227/175.2; 227/180.1; 606/139; 606/219

(58) **Field of Classification Search** 227/19, 227/176.1, 180.1, 175.2; 606/139, 219
See application file for complete search history.

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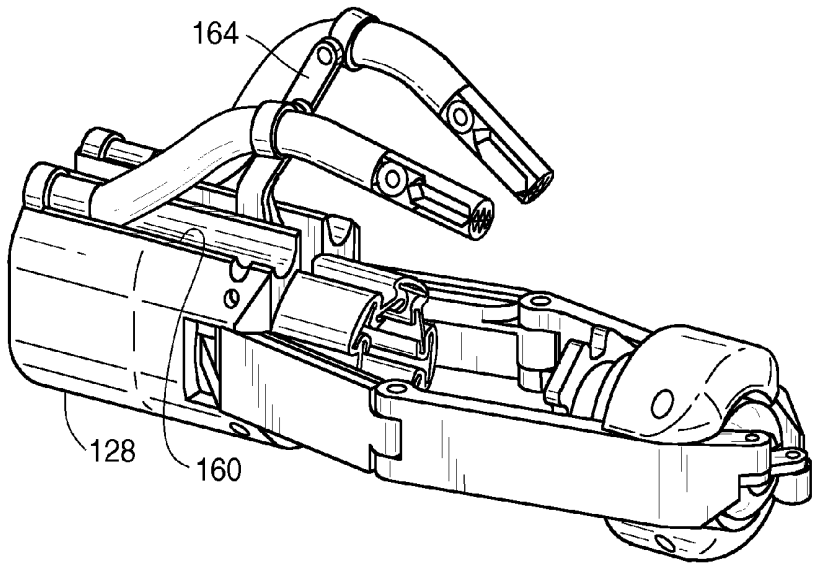
Primary Examiner—Scott A Smith
(74) *Attorney, Agent, or Firm*—King & Spalding LLP; Peter J. Dehlinger; Kathleen A. Frost

(57) **ABSTRACT**

Described herein are endoscopic staplers used to apply one or more fasteners to body tissue. In one embodiment, a fastener-applying device, which is preferably a stapler, is passed transorally into the stomach and used to plicate stomach tissue by engaging tissue from inside of the stomach and drawing it inwardly. In the disclosed embodiments, the tissue is drawn inwardly into a vacuum chamber, causing sections of serosal tissue on the exterior of the stomach to be positioned facing one another. The disclosed staplers allow the opposed sections of tissue to be moved into contact with one another, and preferably deliver staples for maintaining contact between the tissue sections at least until serosal bonds form between them. Each of these steps may be performed wholly from the inside of the stomach and thus can eliminate the need for any surgical or laparoscopic intervention. After one or more plications are formed, medical devices may optionally be coupled to the plication(s) for retention within the stomach.

24 Claims, 22 Drawing Sheets



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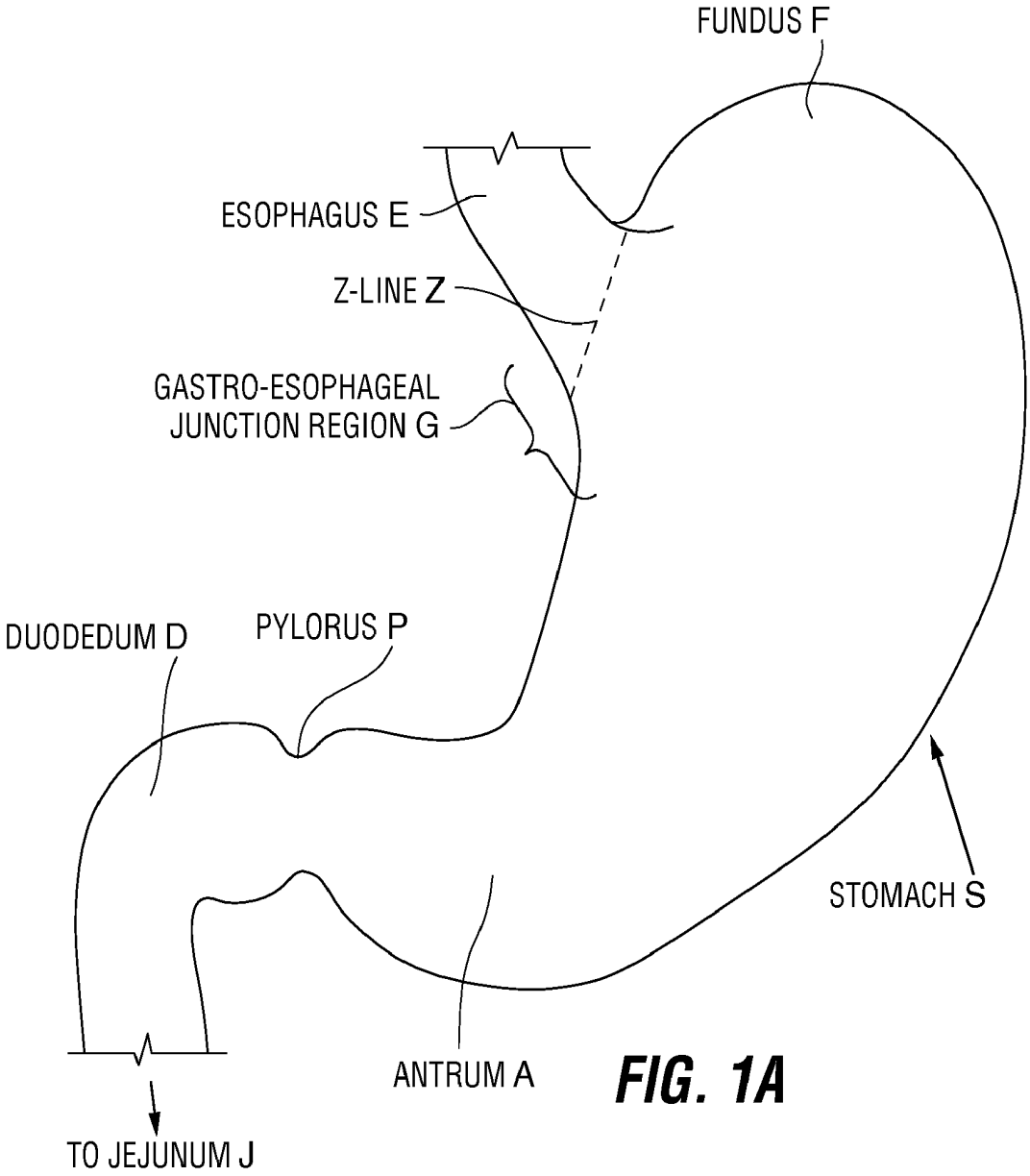
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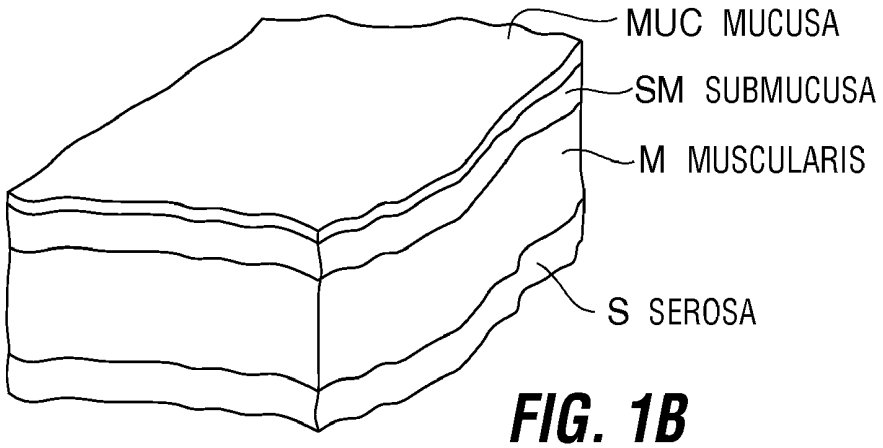
STOMACH S
ANTRUM A
TO JEJUNUM J

FIG. 1A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M MUSCULARIS
S SEROSA

FIG. 1B

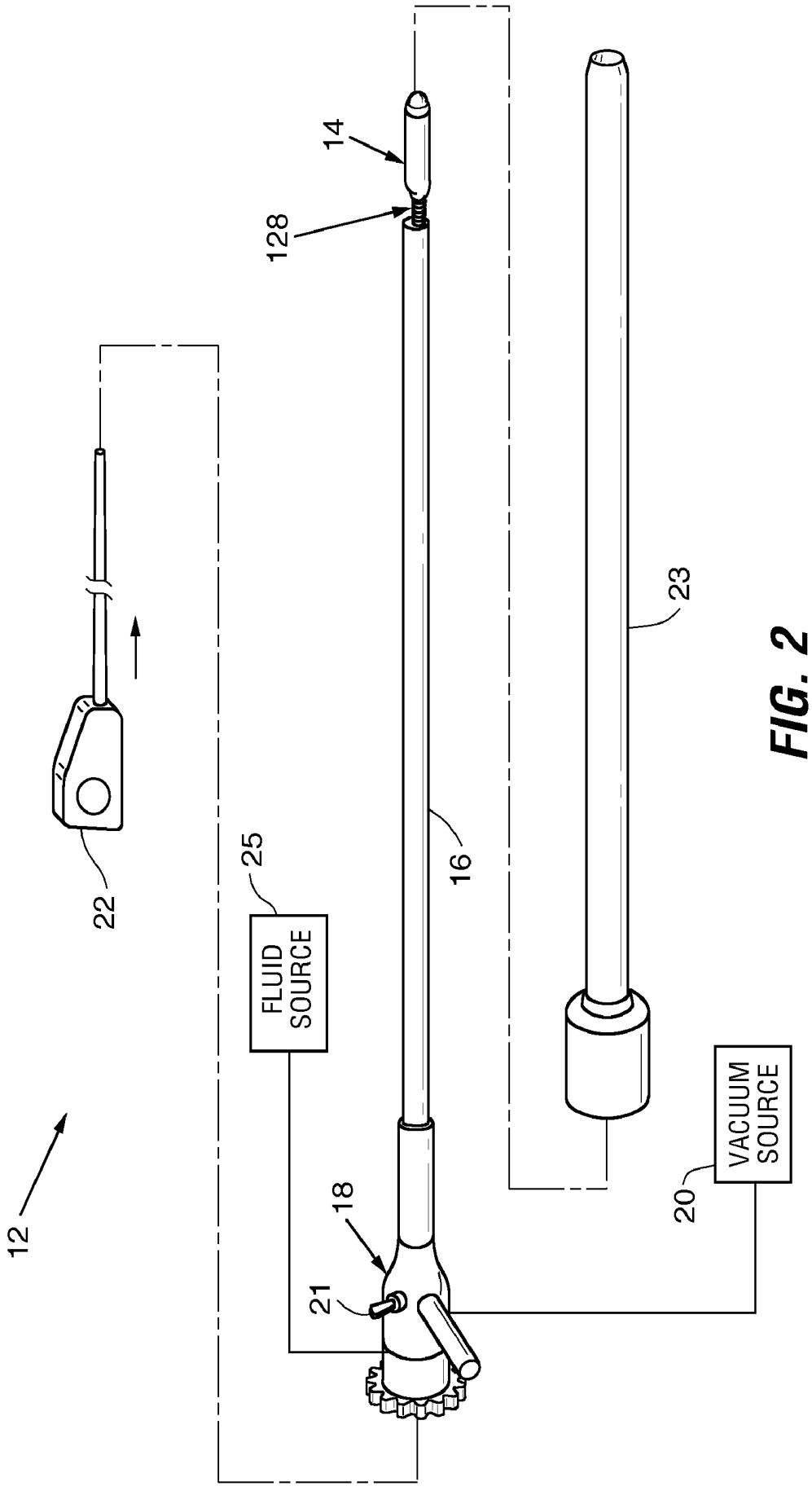


FIG. 2

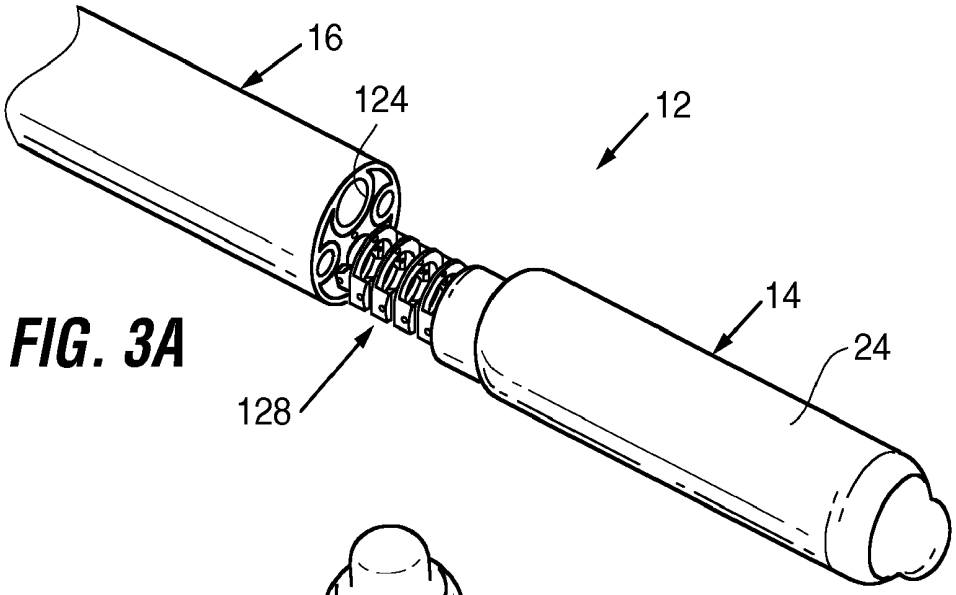


FIG. 3A

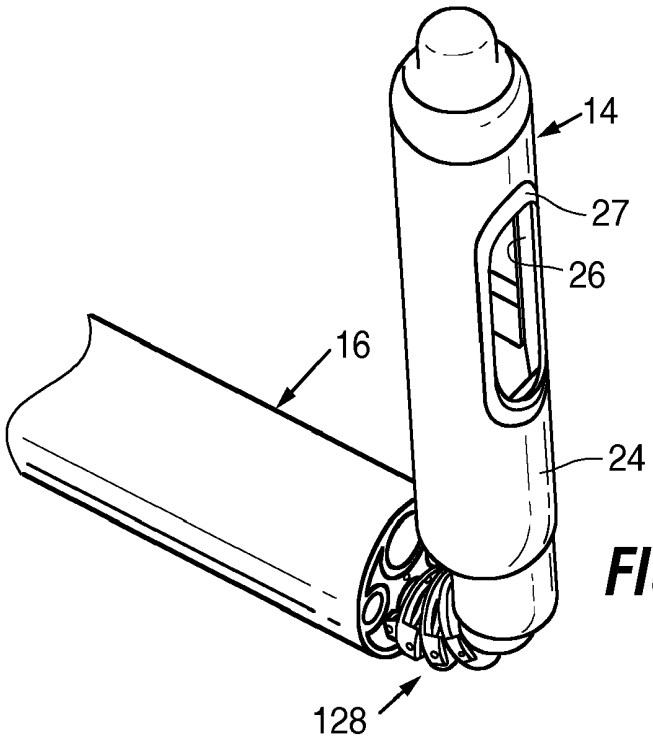


FIG. 3B

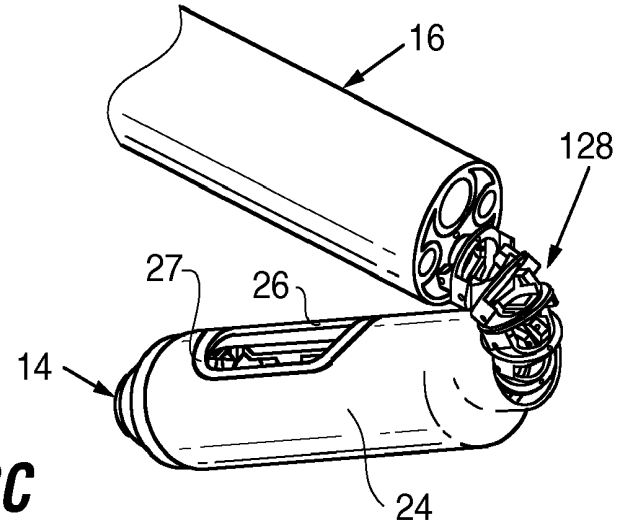
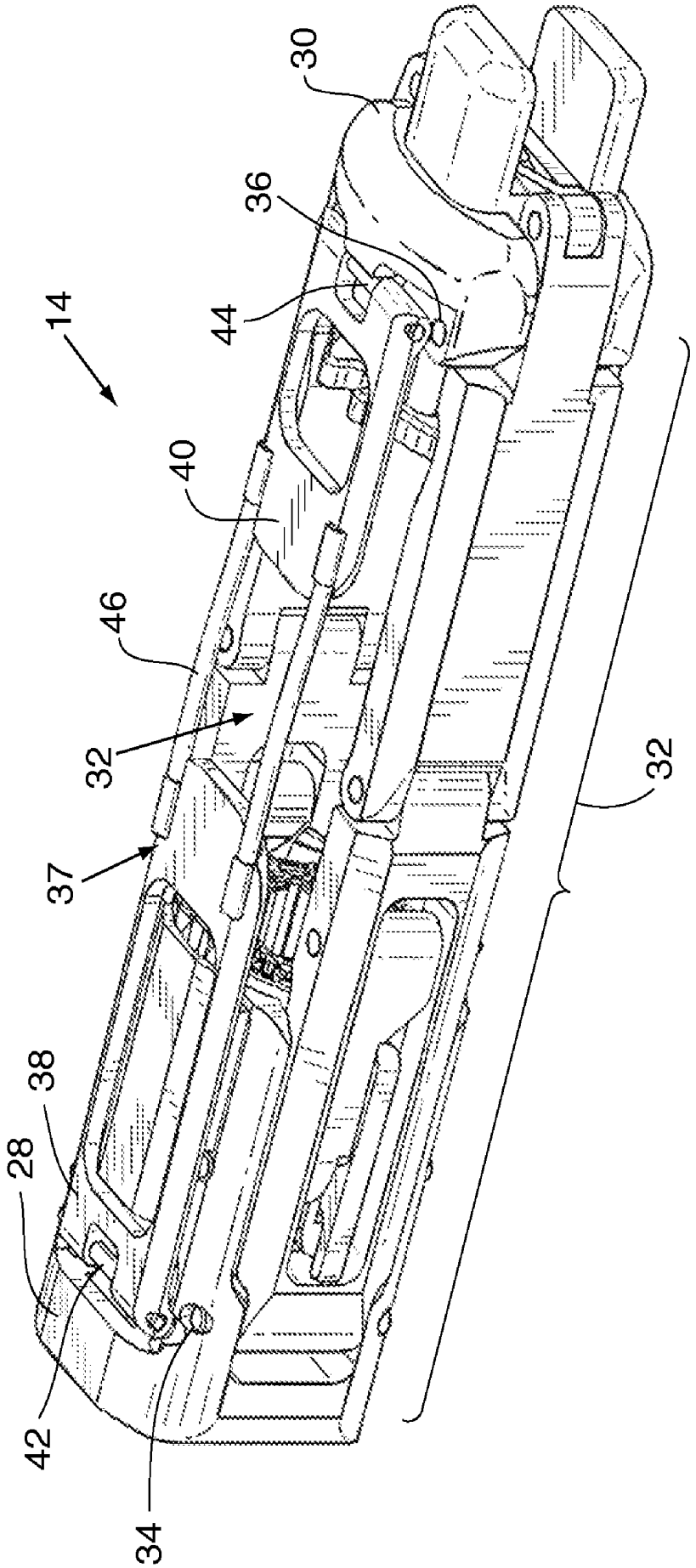


FIG. 3C



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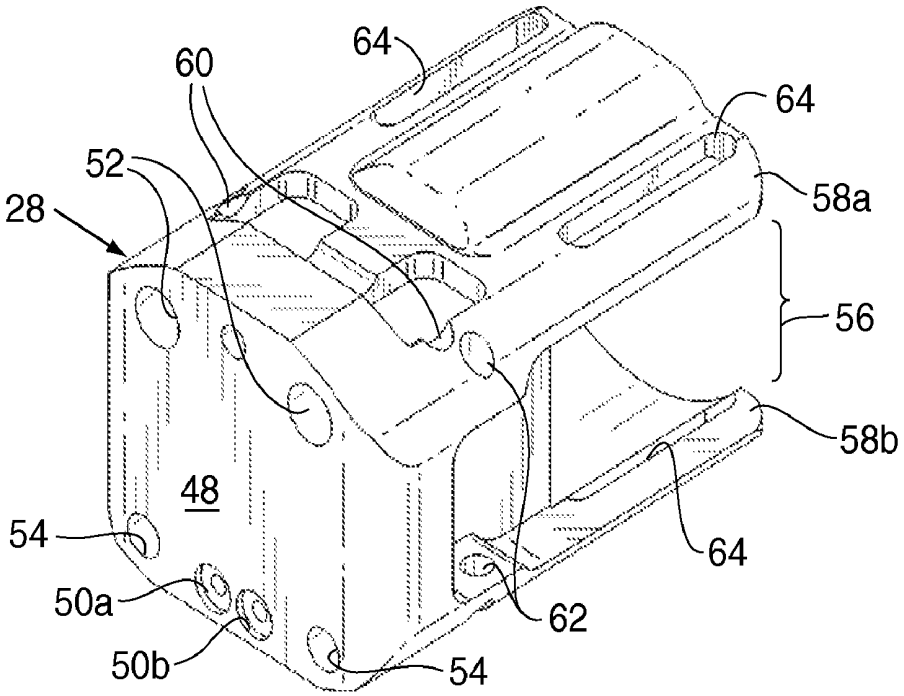
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50a
62
50b
54

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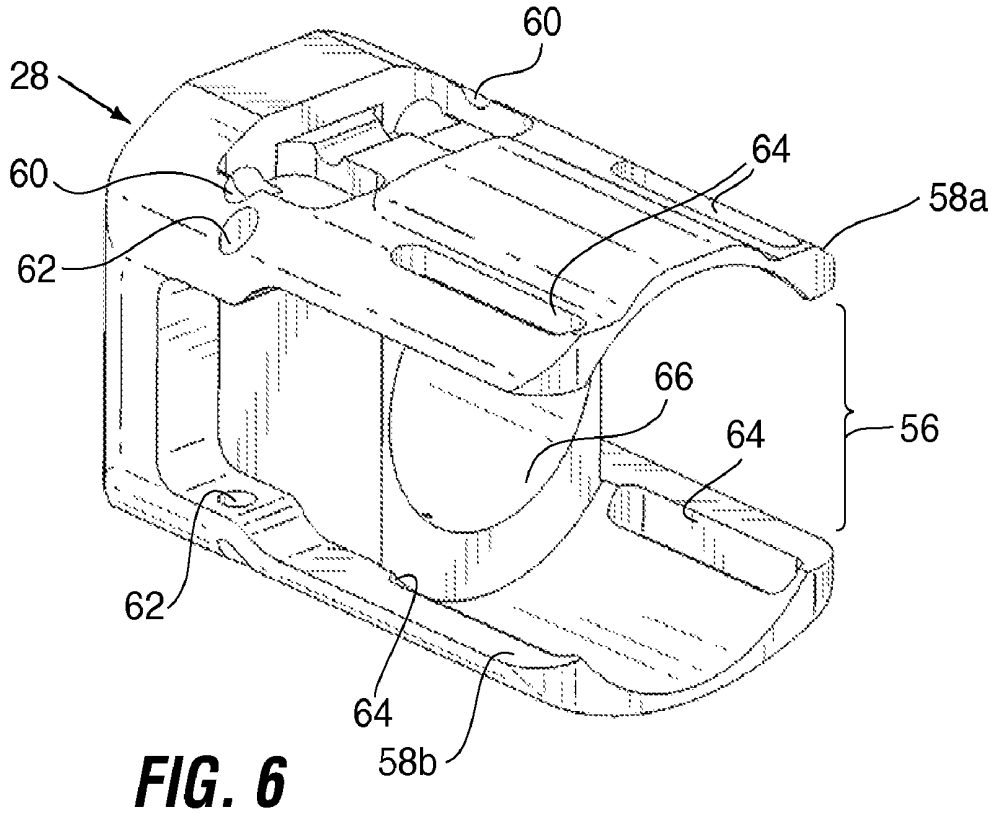
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FIG. 6

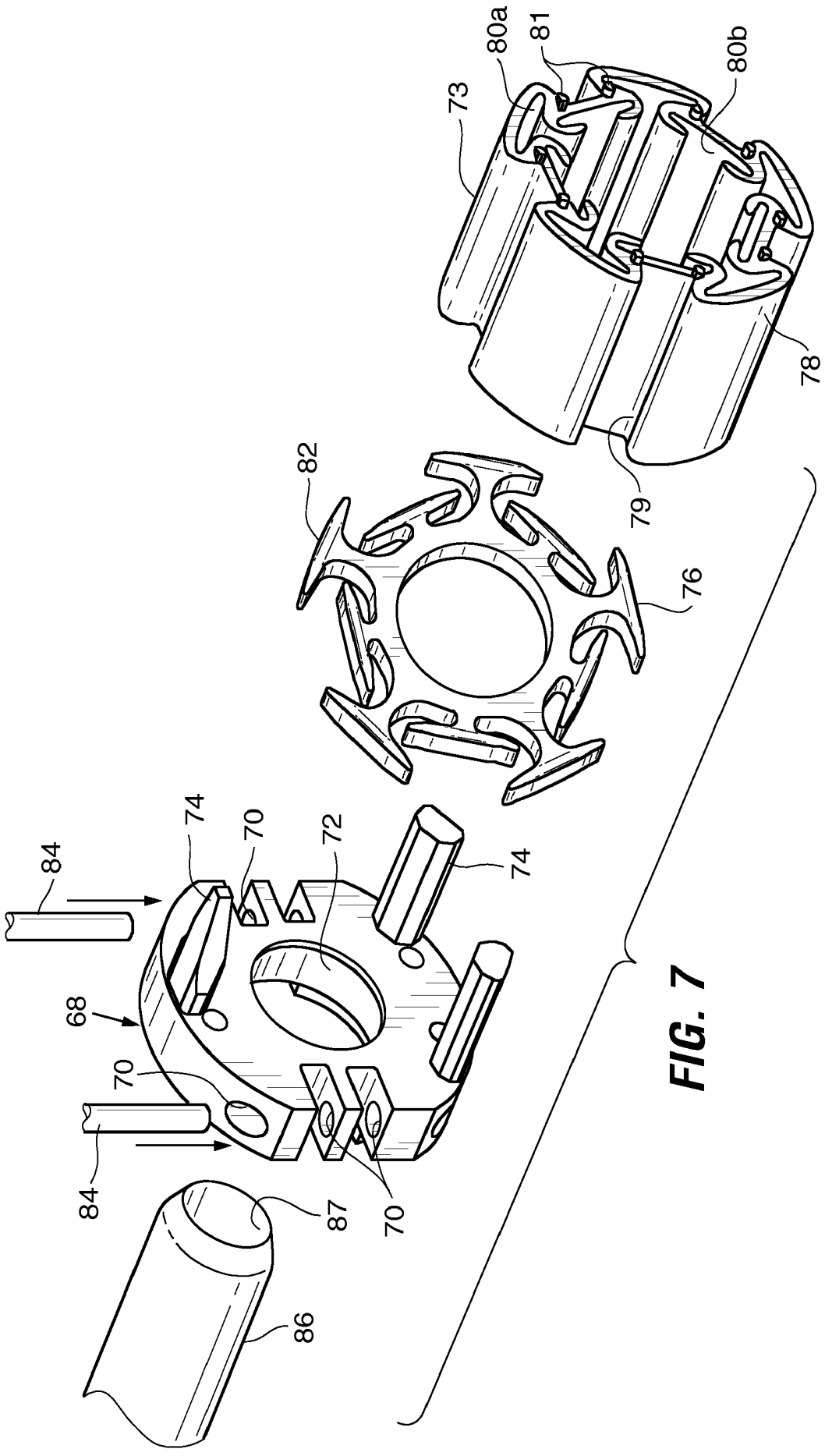


FIG. 7

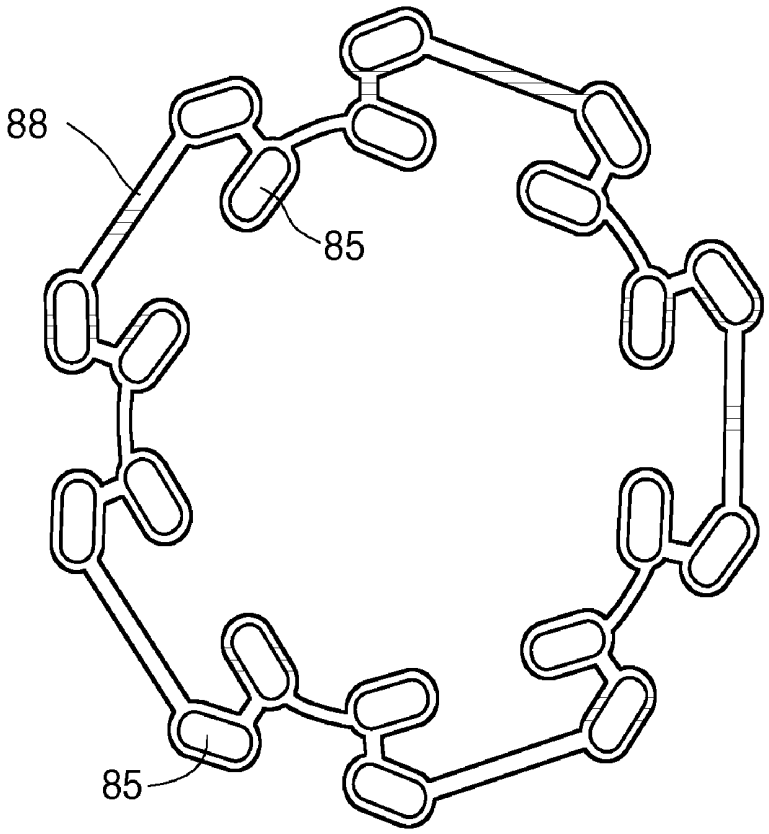


FIG. 8

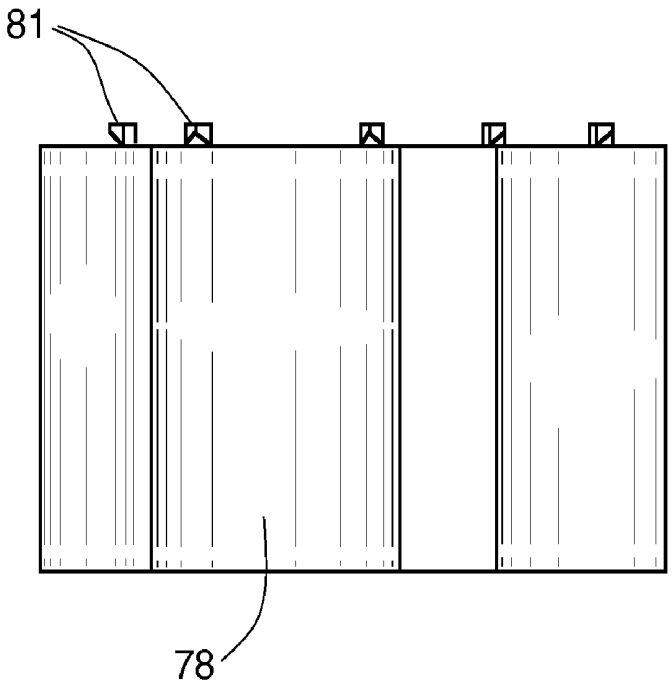


FIG. 9

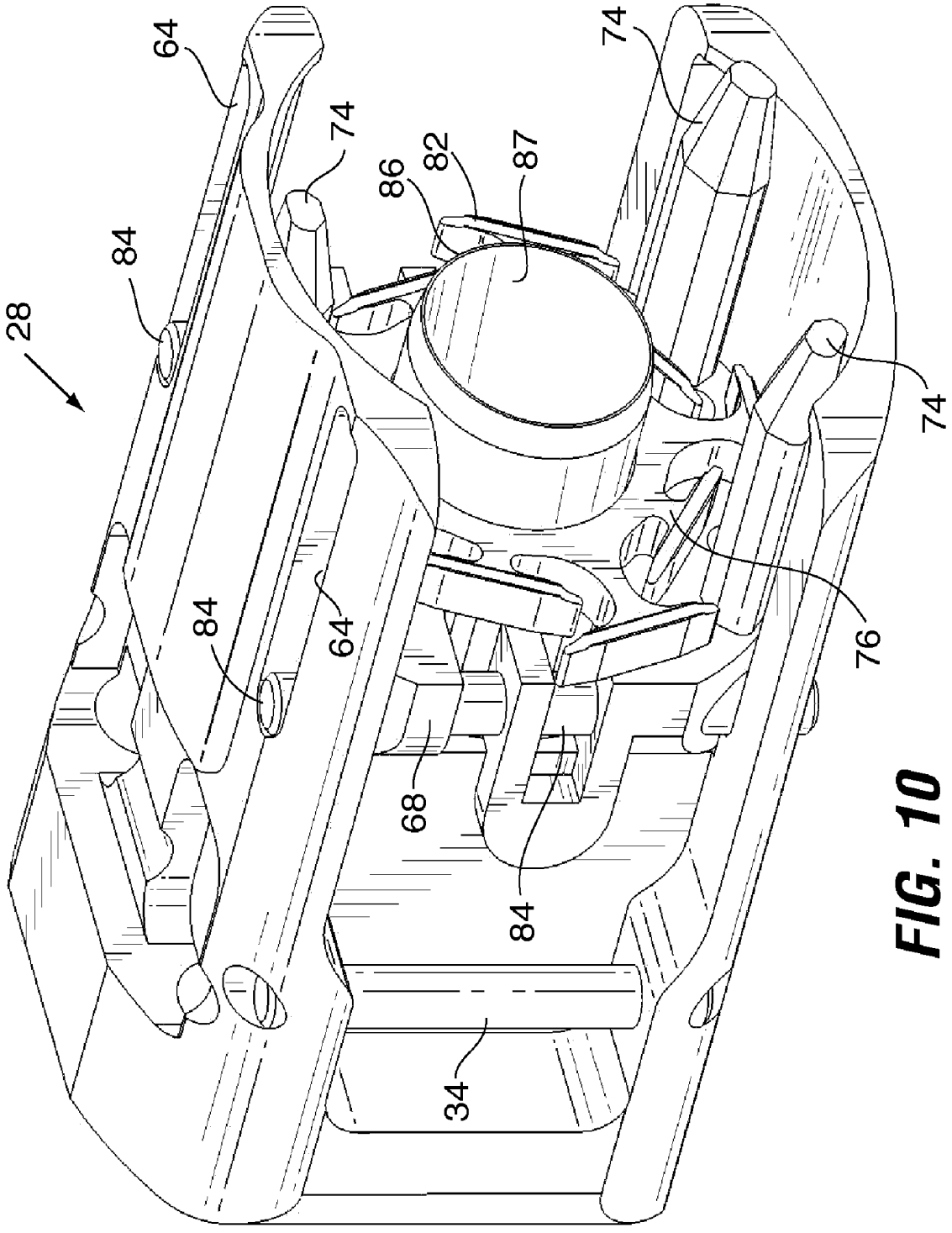


FIG. 10

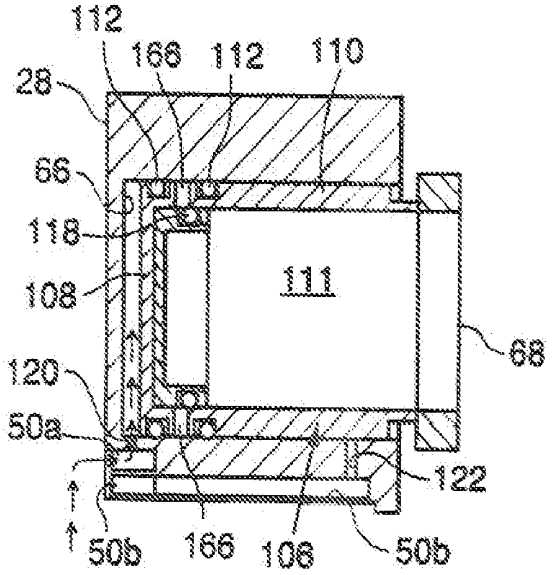


FIG. 11A

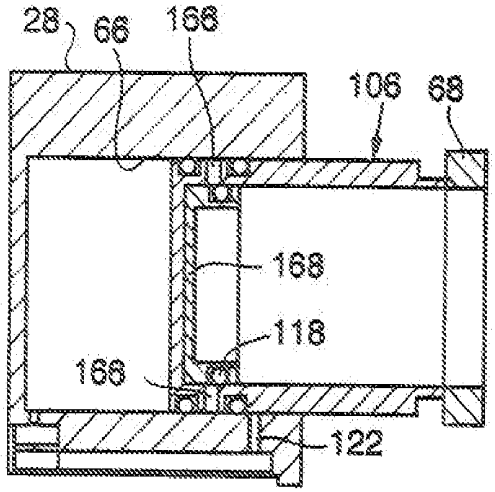


FIG. 11B

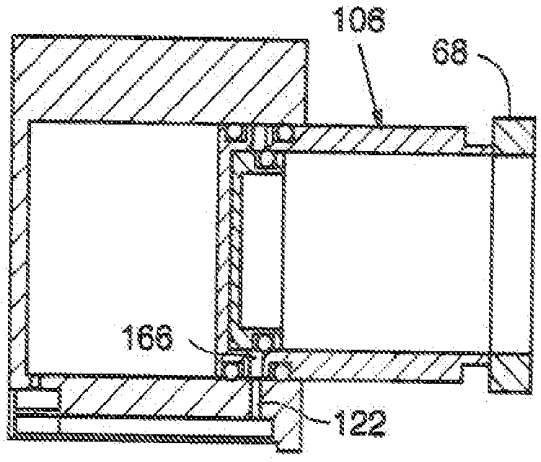


FIG. 11C

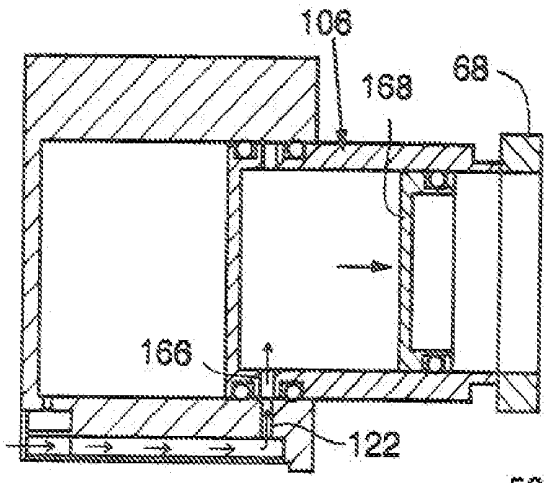


FIG. 11D

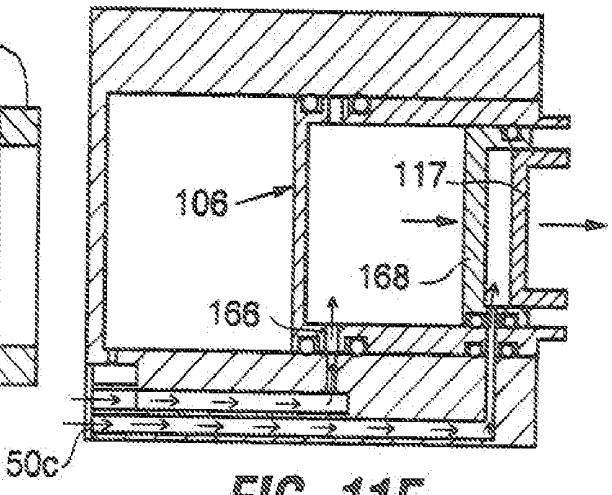
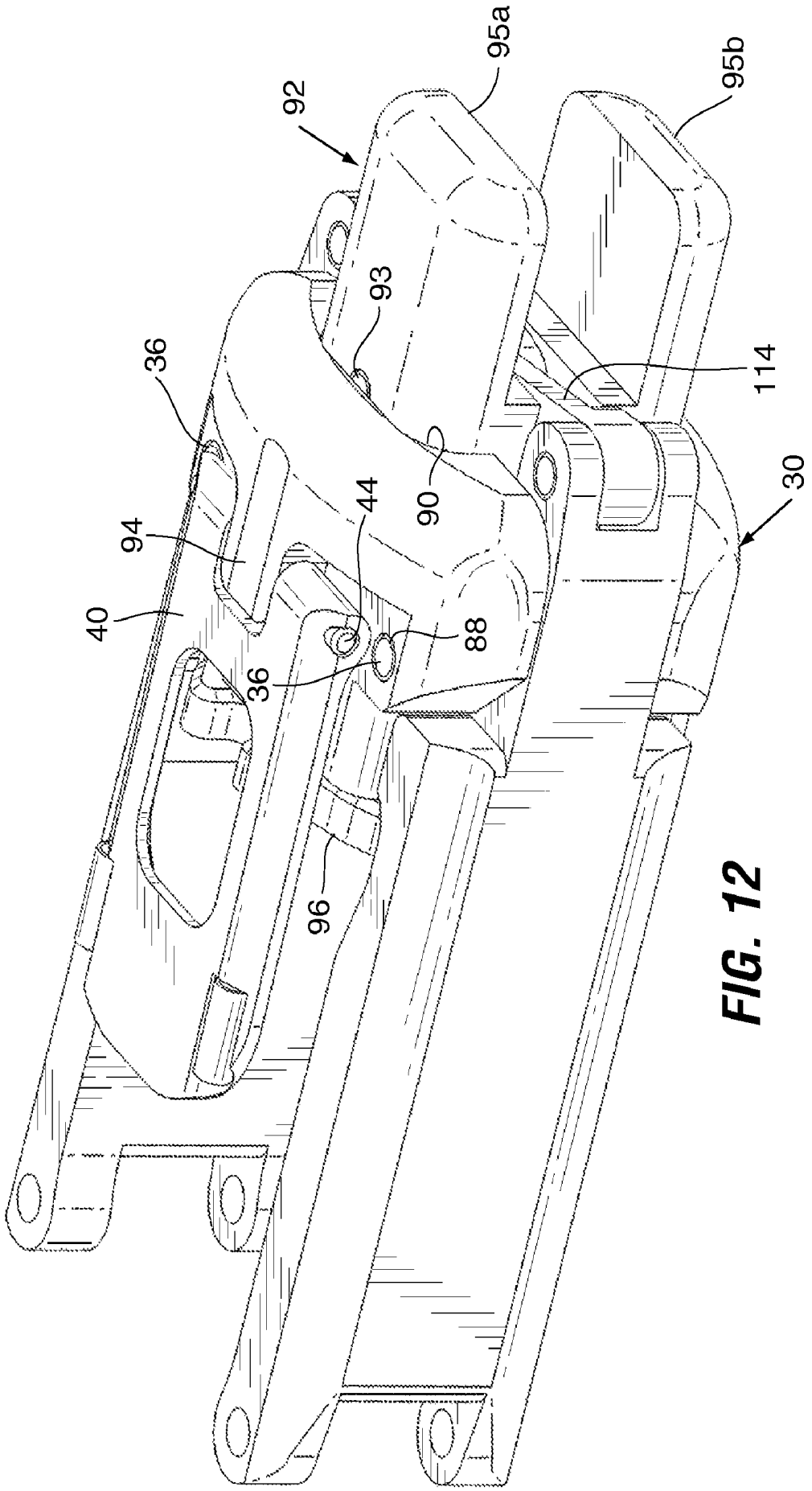


FIG. 11E



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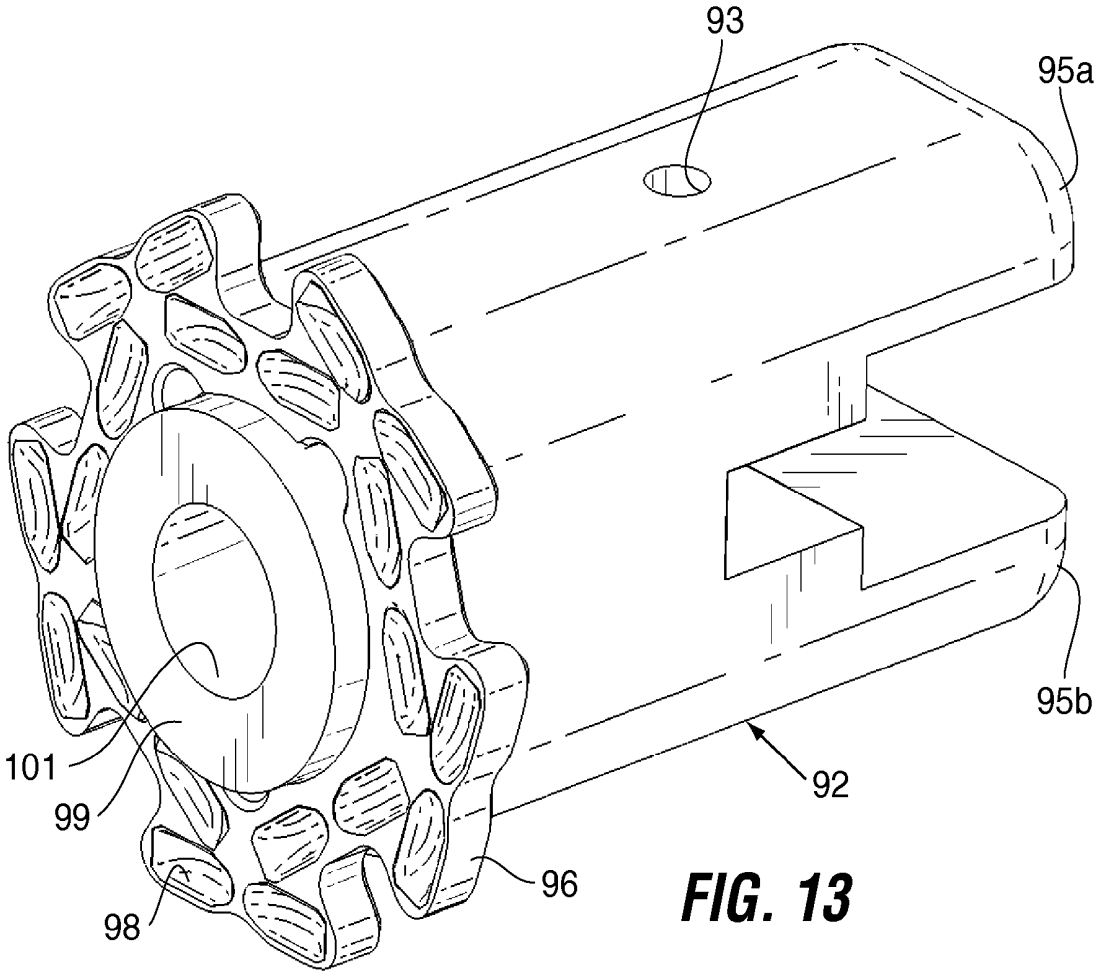

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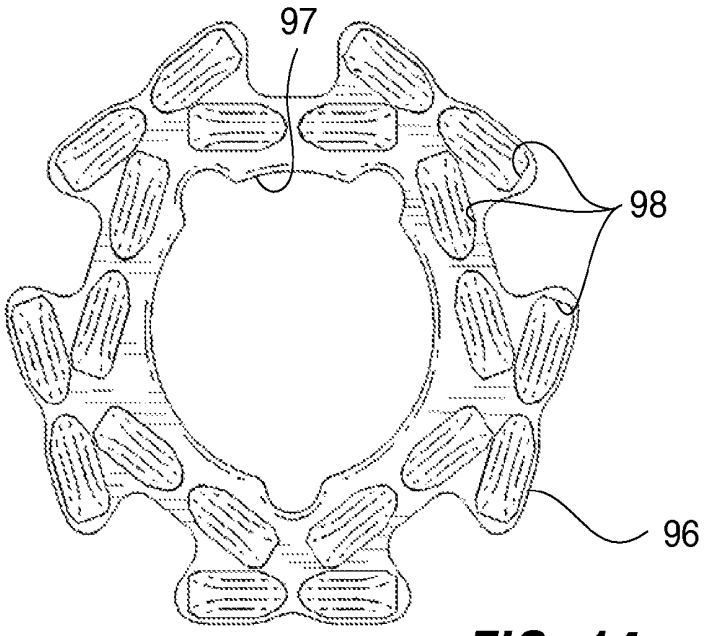

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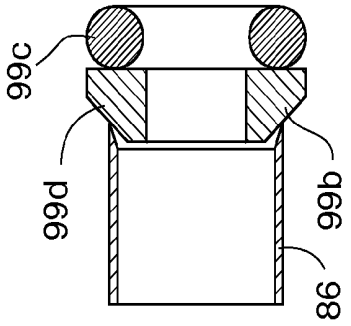


FIG. 15B

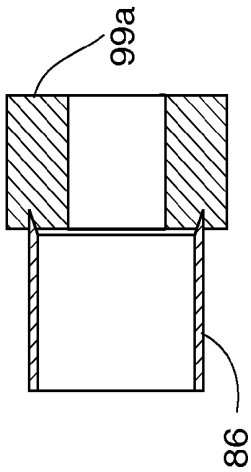
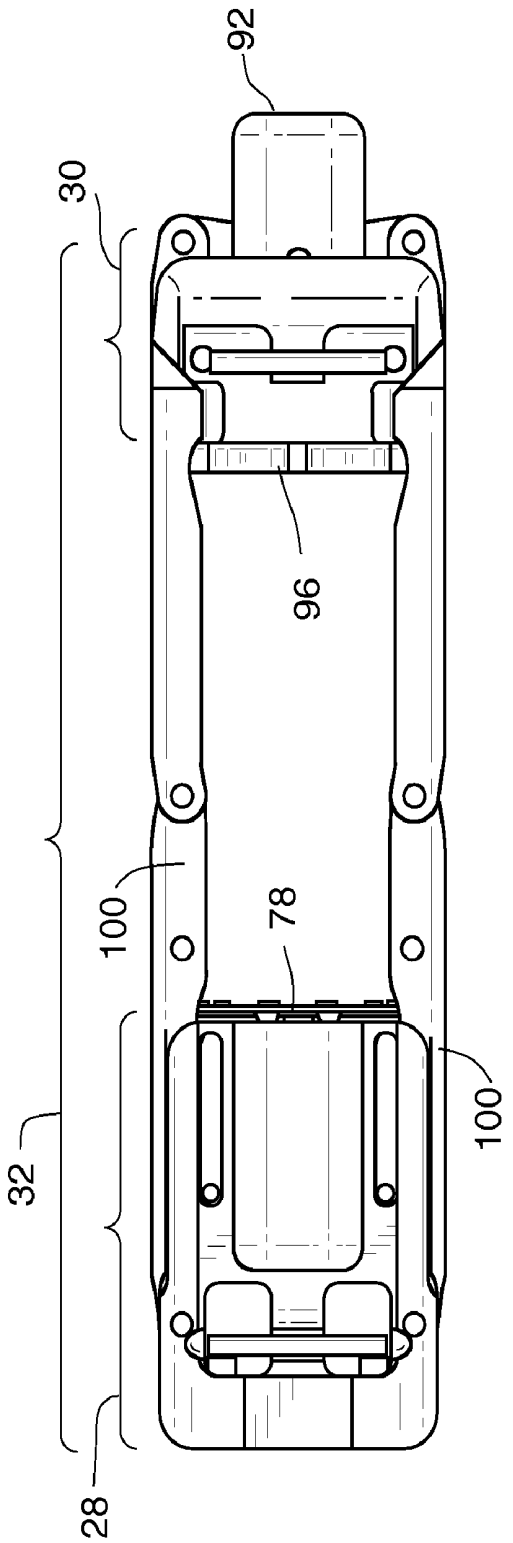


FIG. 15A

FIG. 16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30
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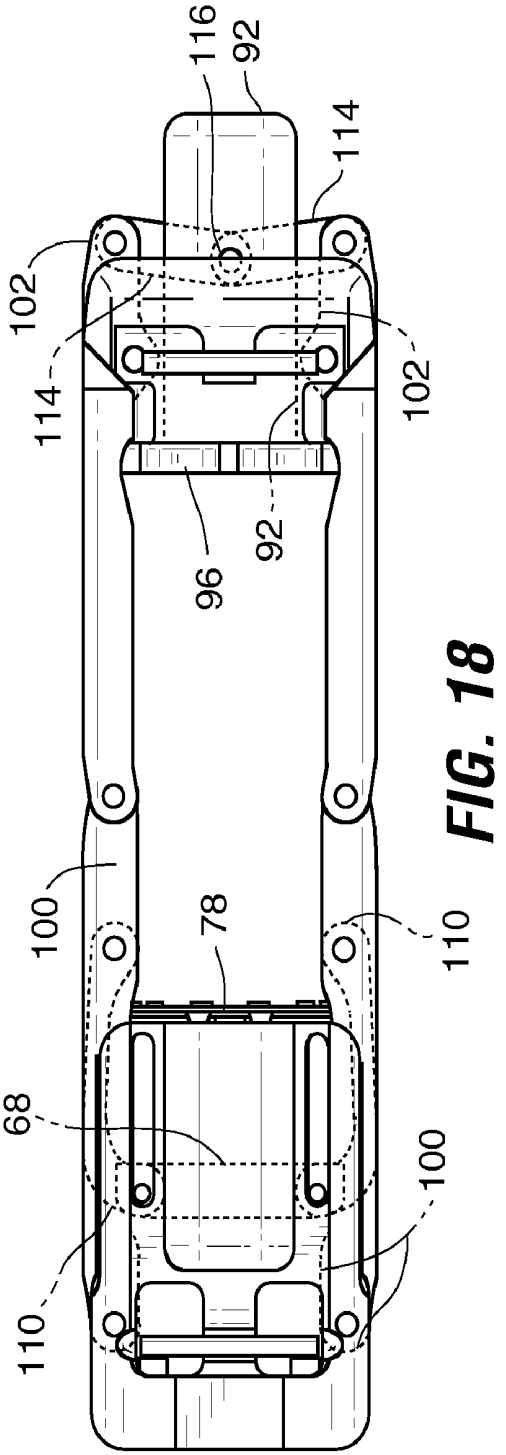
100
78
100
32
28

FIG. 17


116
92
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102
114
102
92
96
100
78
110
68
100
110

FIG. 18

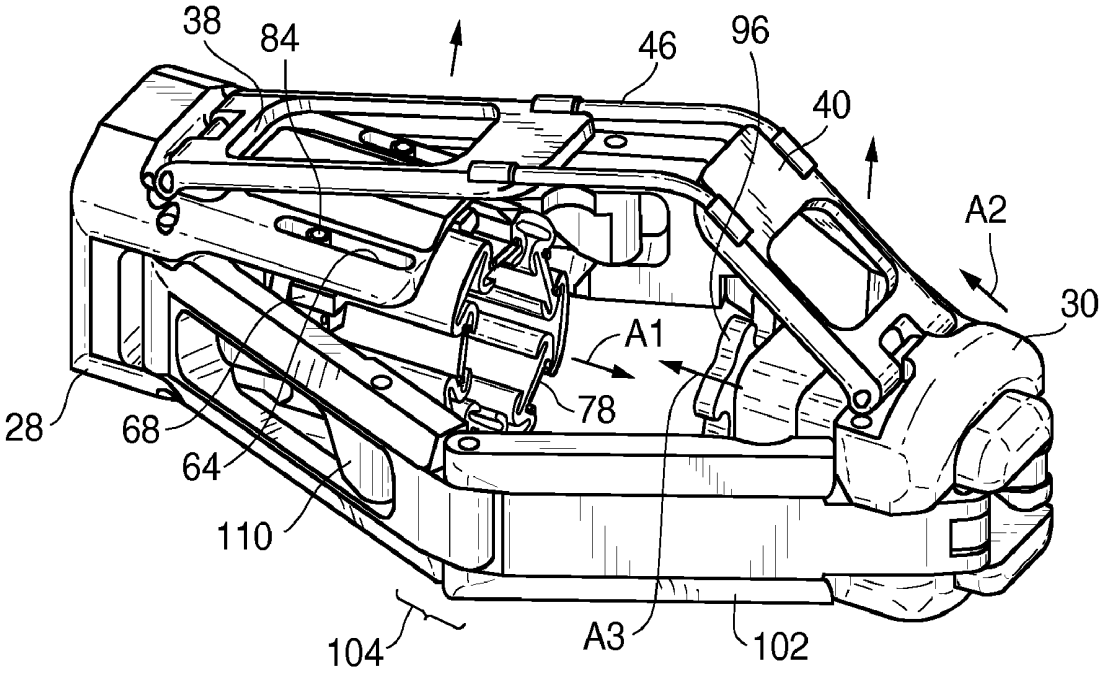
38
84
46
96
40
A2
30
A1
78
28
68
64
110
104
A3
102

FIG. 19

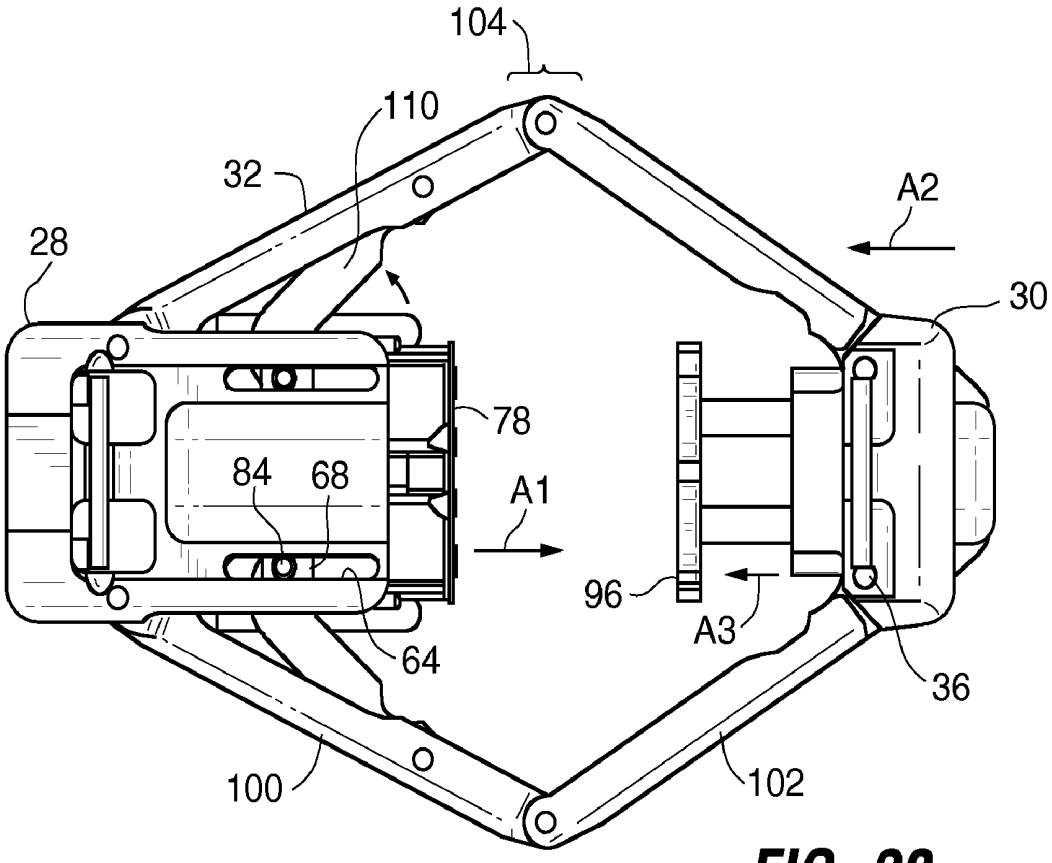
104
110
32
A2
28
30
78
84
68
A1
96
A3
64
36
100
102

FIG. 20

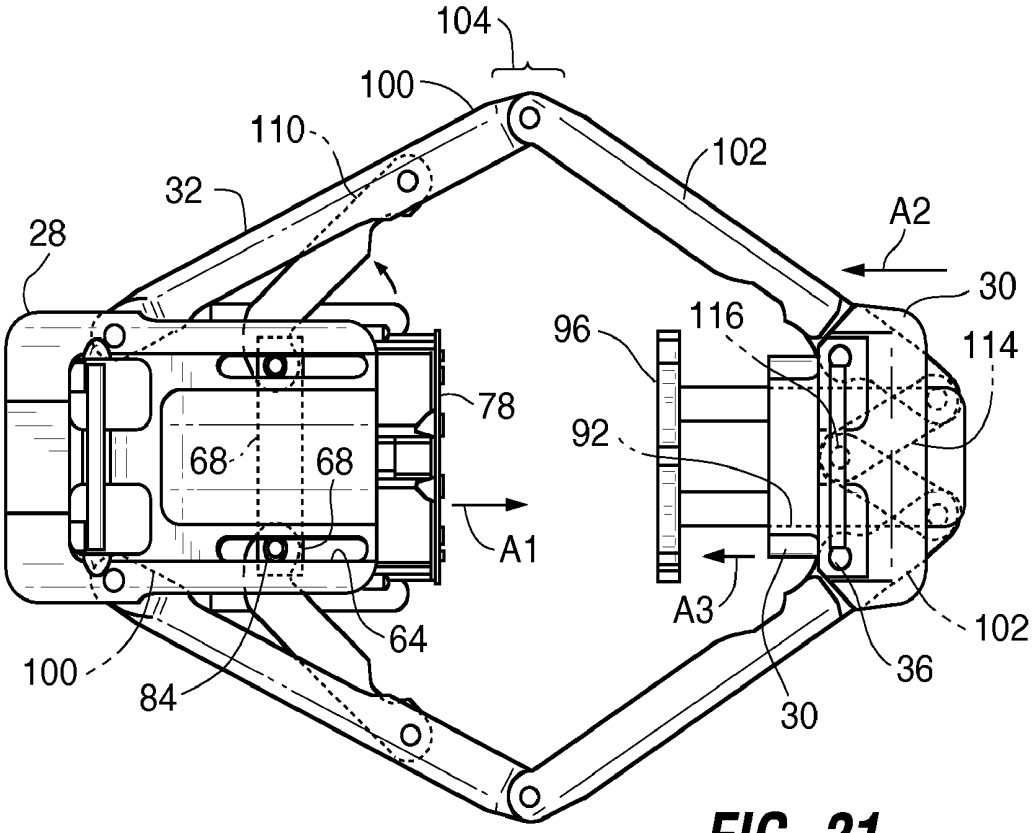
104
100
110
32
28
102
A2
30
96
116
114
78
92
68
68
A1
A3
64
100
84
36
102
30

FIG. 21

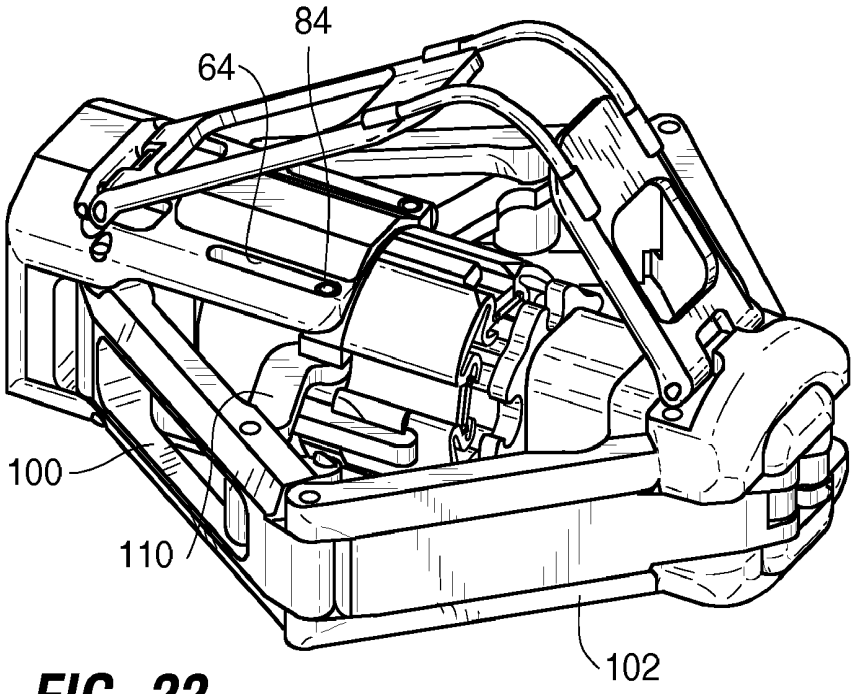
84
64
100
110
102

FIG. 22

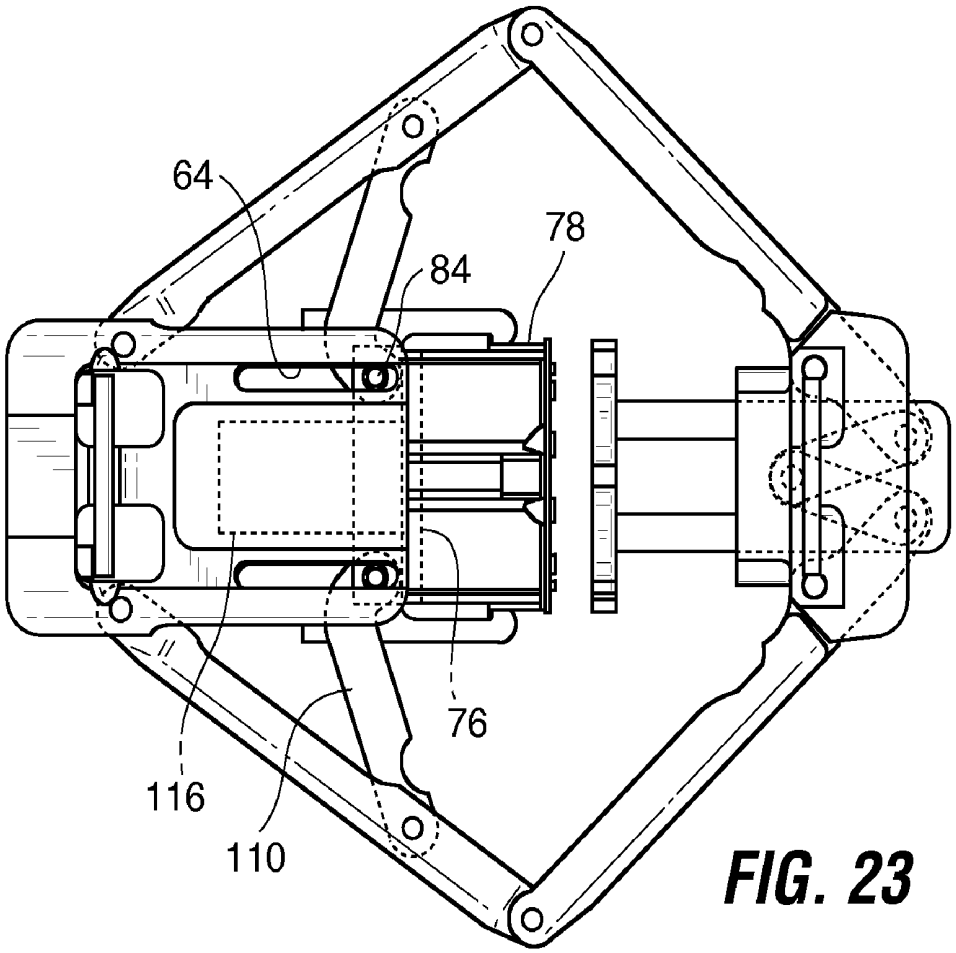

FIG. 23

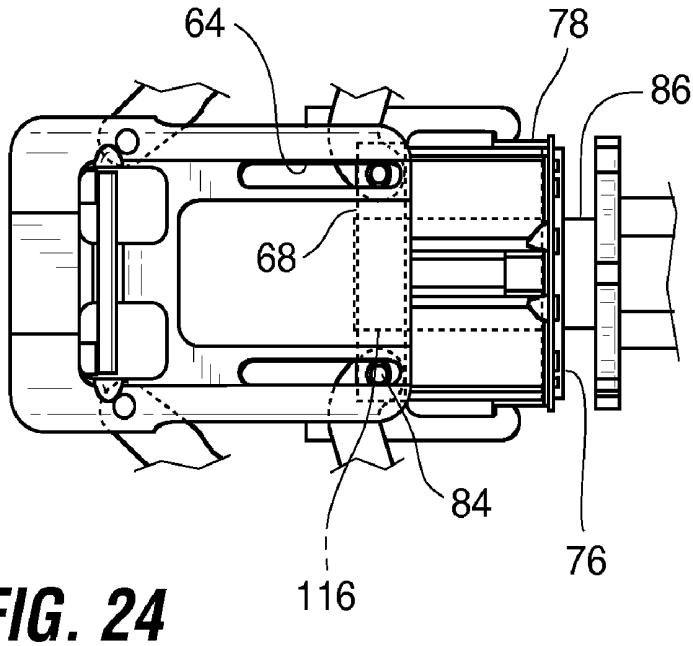

FIG. 24

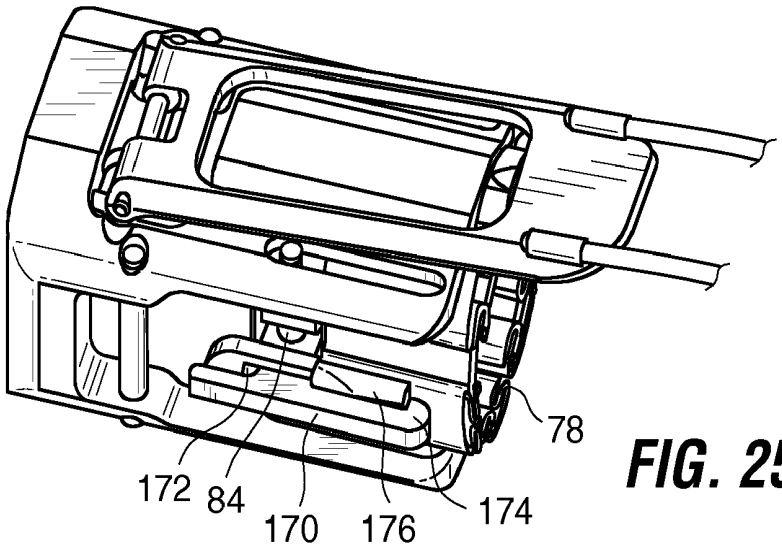

FIG. 25A

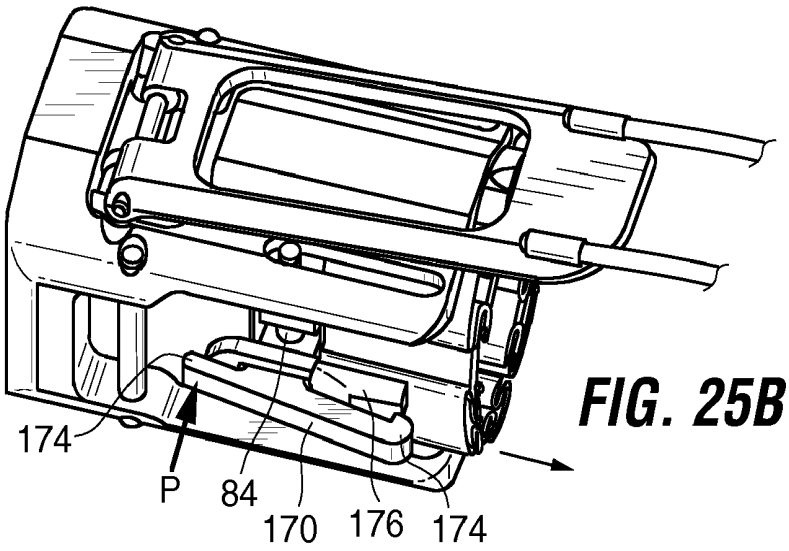

FIG. 25B

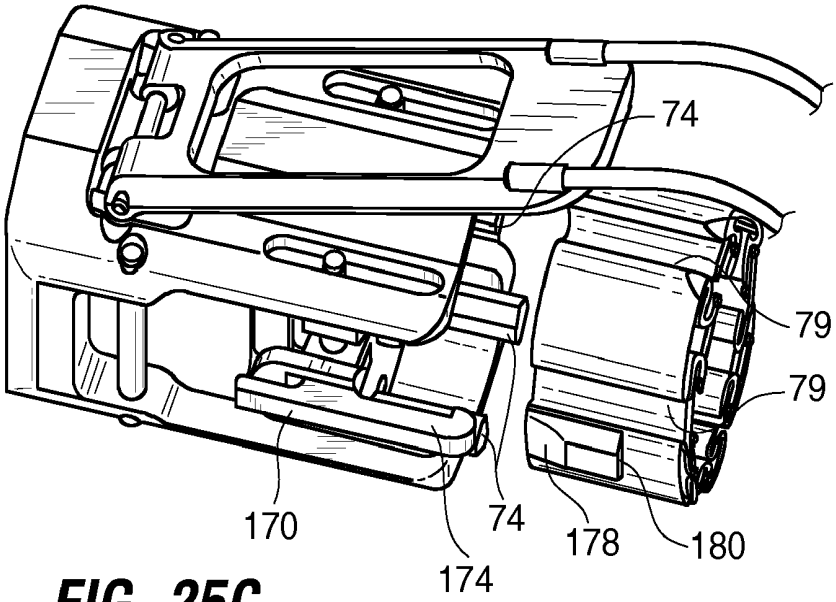

FIG. 25C

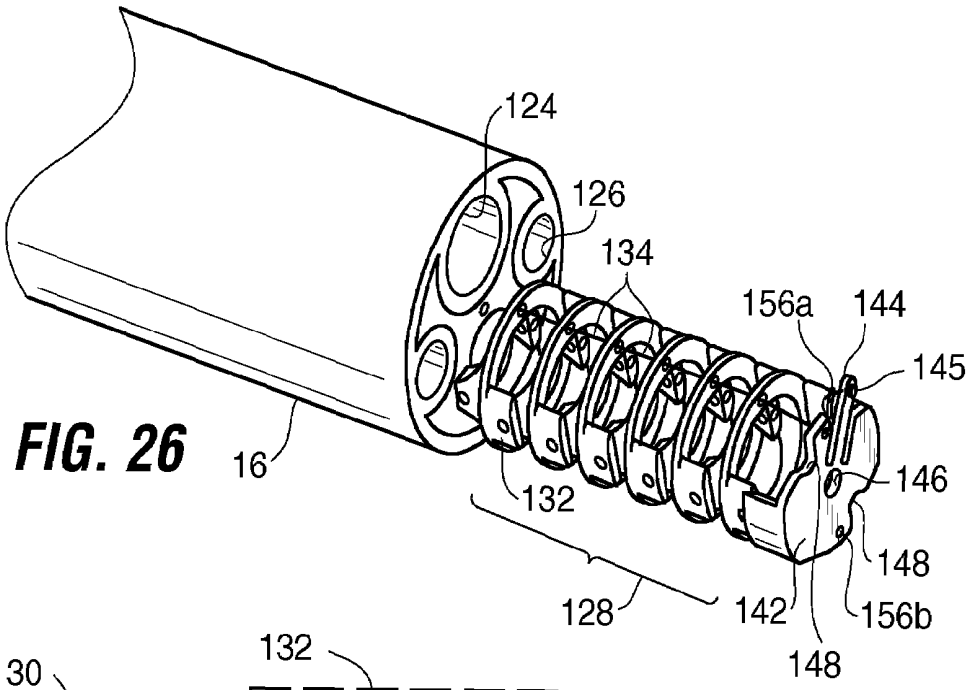

FIG. 26

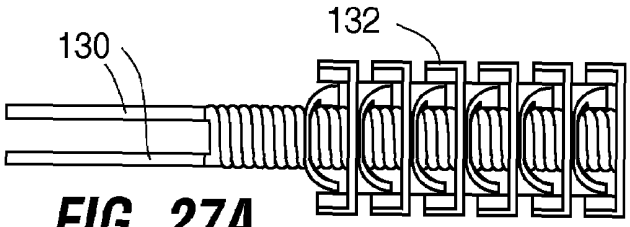

FIG. 27A

FIG. 27B

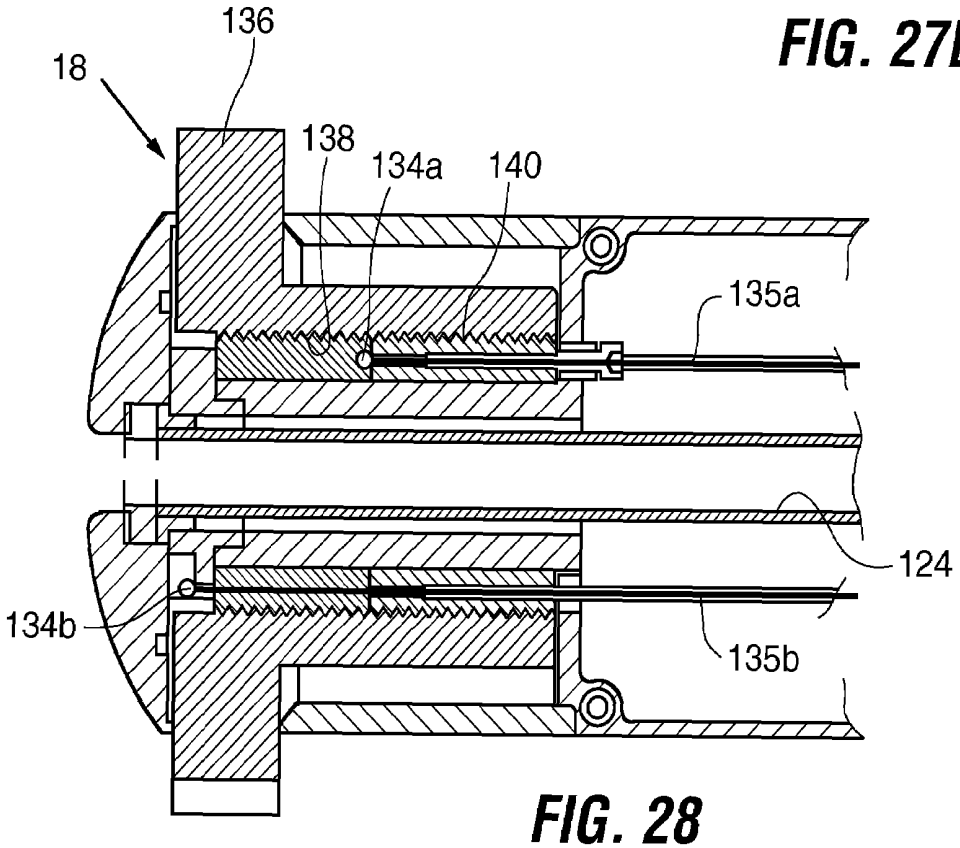

FIG. 28

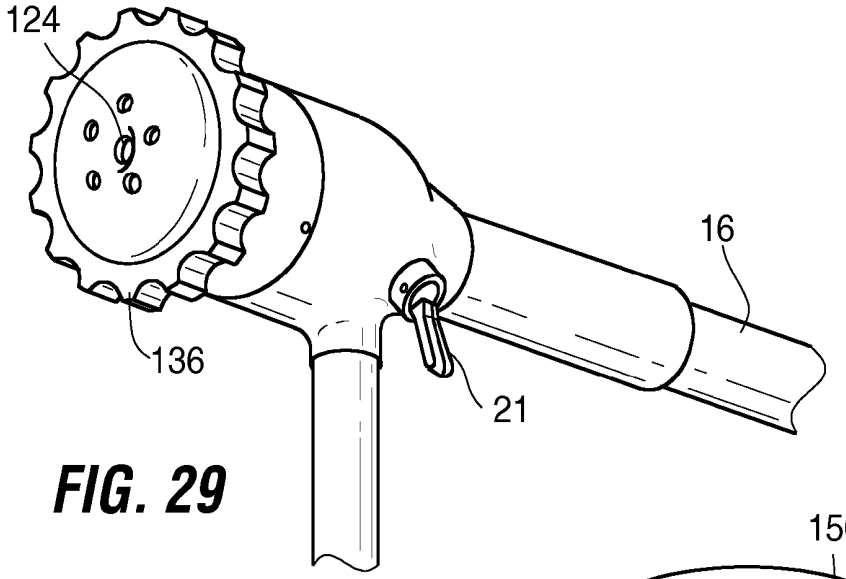

FIG. 29

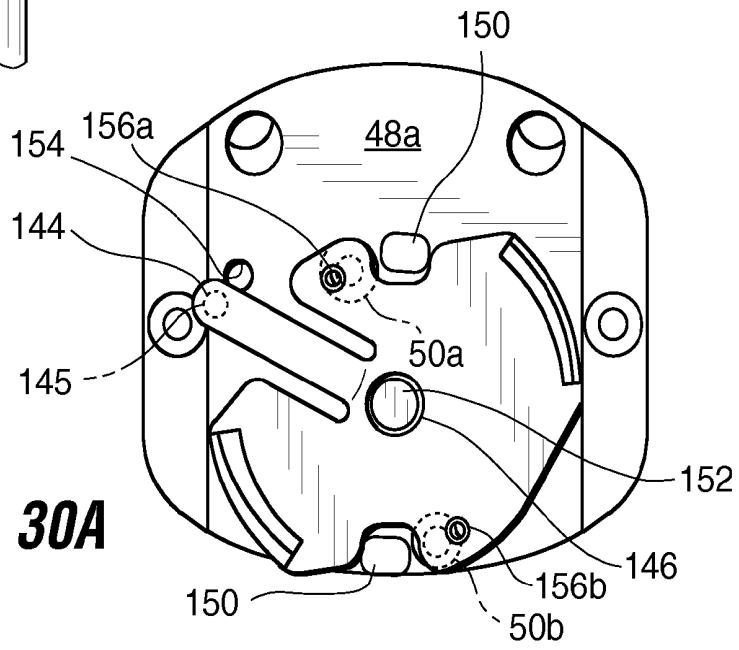

FIG. 30A

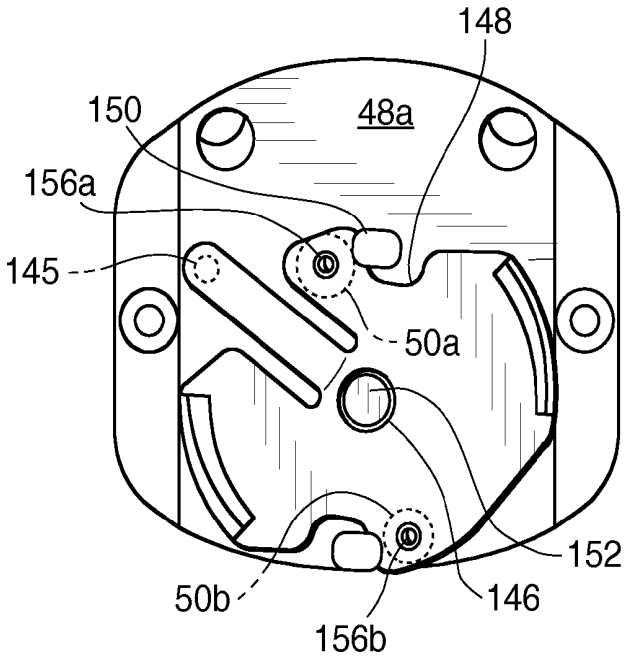

FIG. 30B

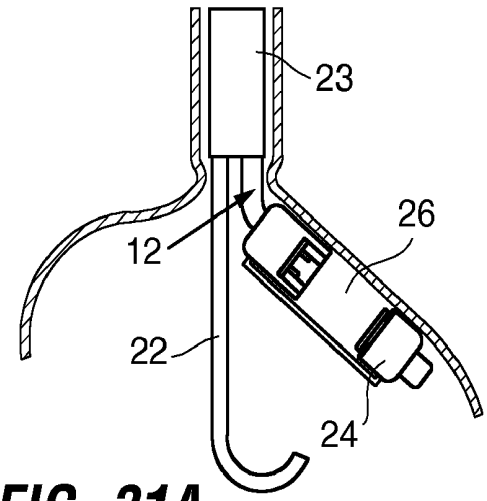

FIG. 31A

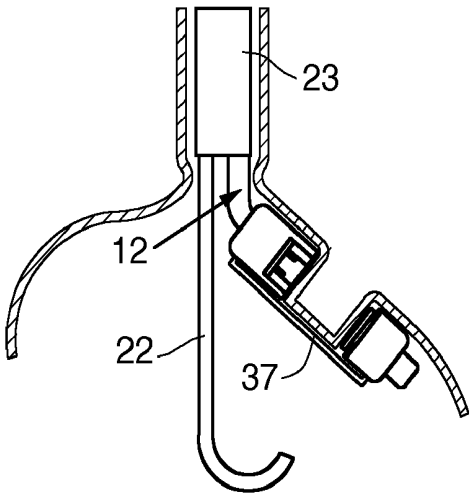

FIG. 31B

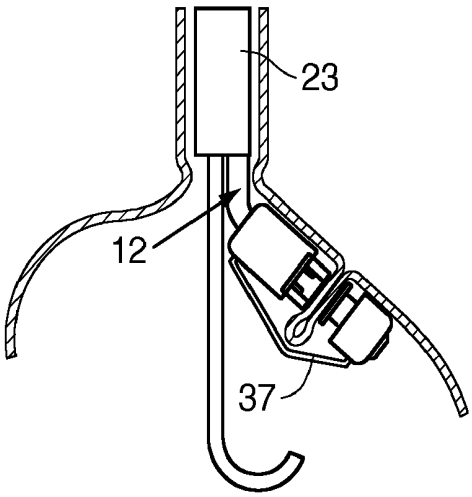

FIG. 31C

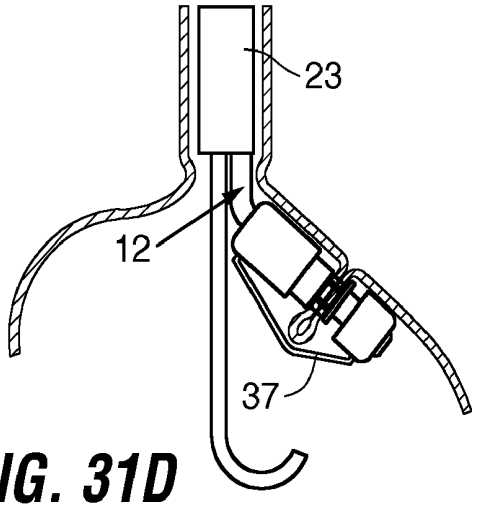

FIG. 31D

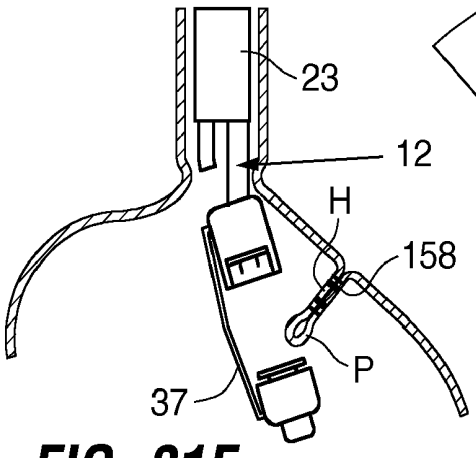

FIG. 31E

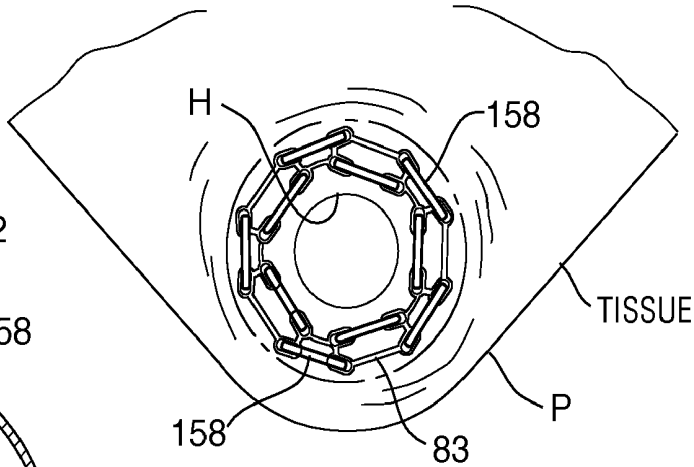

FIG. 33

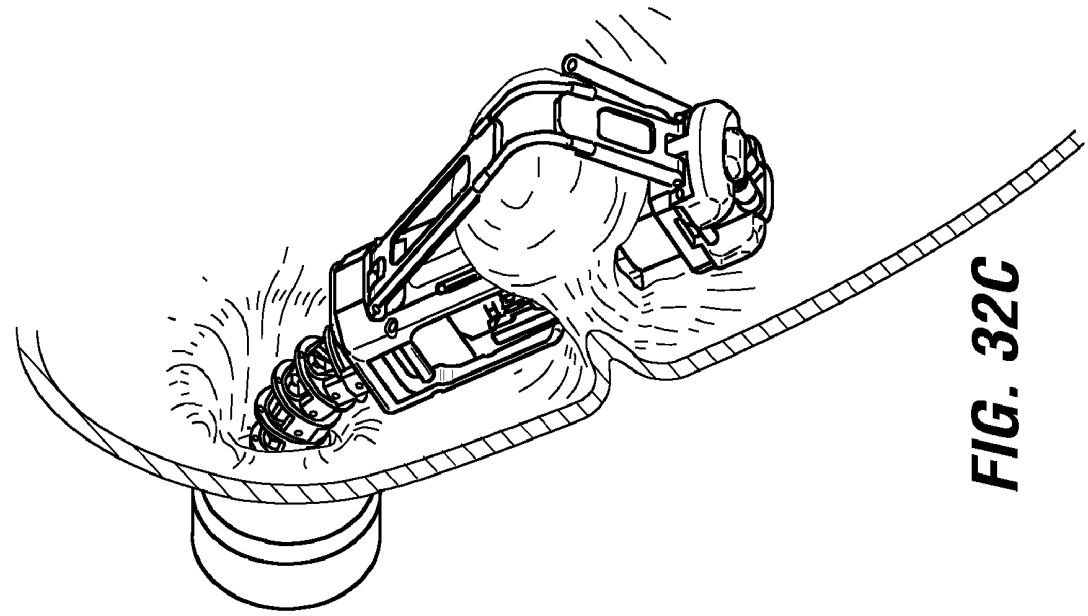

FIG. 32C

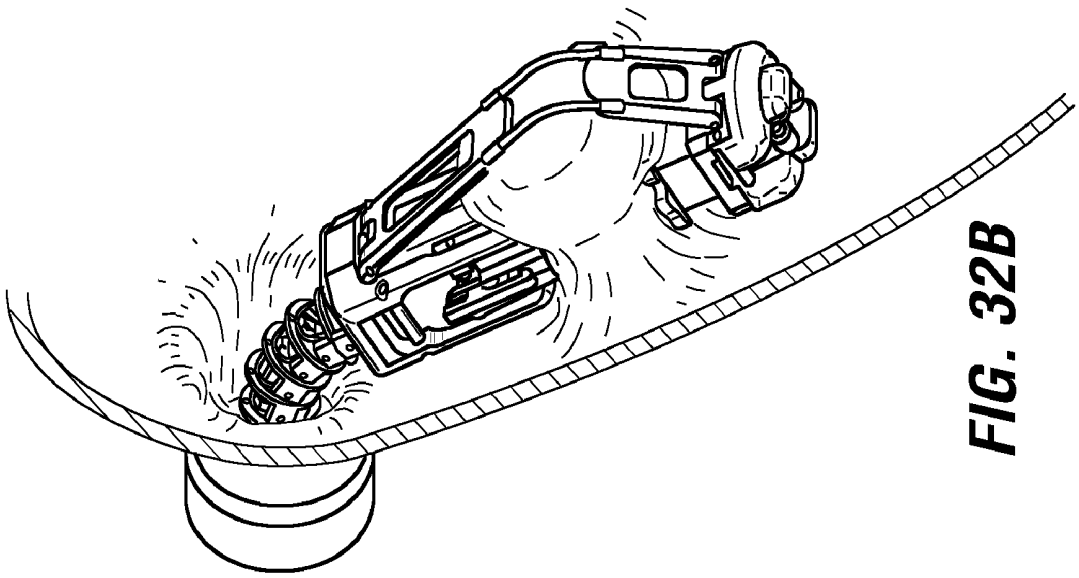

FIG. 32B

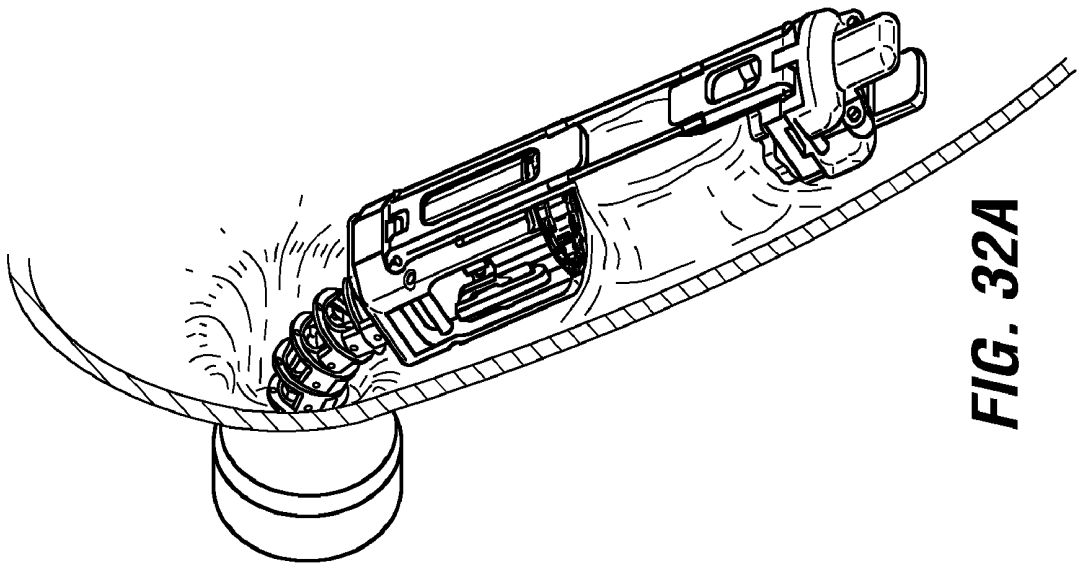

FIG. 32A

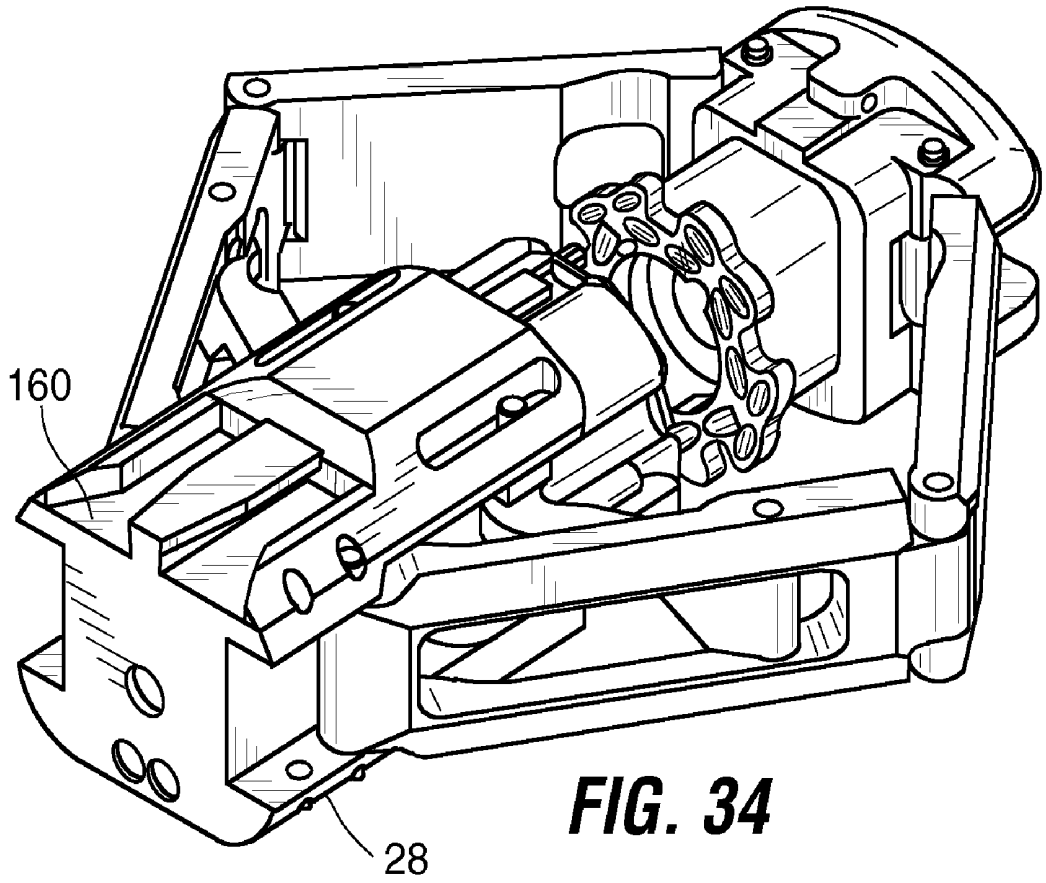

FIG. 34

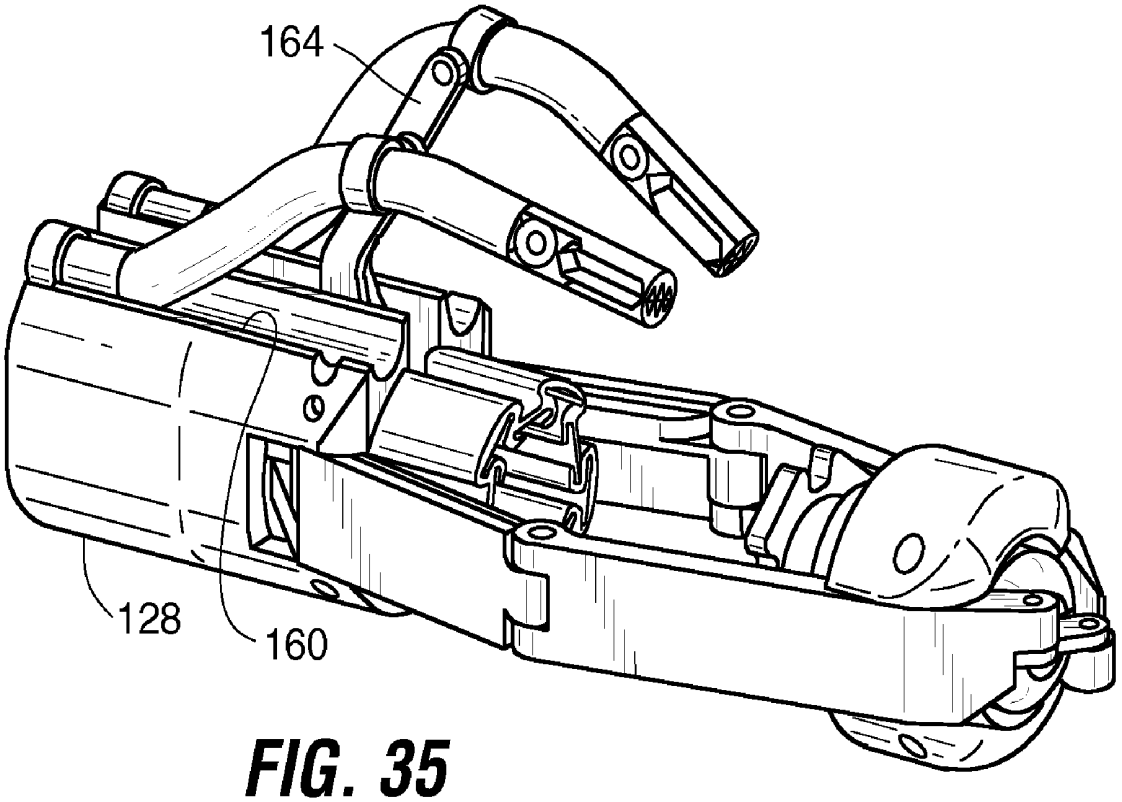

FIG. 35

ENDOSCOPIC STAPLING DEVICES AND METHODS

PRIORITY

This application is a divisional of U.S. patent application Ser. No. 12/050,169, filed Mar. 18, 2008, pending, entitled ENDOSCOPIC STAPLING DEVICES AND METHODS, and is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of systems and methods for performing endoscopic surgery, and specifically to systems and methods for endoscopic stapling of tissue within body cavities.

BACKGROUND OF THE INVENTION

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

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

FIG. **1**B illustrates the tissue layers forming the stomach wall. The outermost layer is the serosal layer or "serosa" S and the innermost layer, lining the stomach interior, is the mucosal layer or "mucosa" MUC. The submucosa SM and the multi-layer muscularis M lie between the mucosa and the serosa.

There are a number of applications for endoscopic application of fasteners such as staples to tissue within a body cavity. Some of those applications involve forming tissue structures such as plications or folds in tissue of the body cavity.

Several prior applications, including International Application No. WO 2005/037152 having an international filing date of Oct. 8, 2004 and U.S. application Ser. No. 11/439,461, filed May 23, 2006 (both incorporated herein by reference) describe methods according to which medical implants are coupled to tissue structures formed within the stomach. According to these applications, devices for inducing weight loss (e.g. by restricting and/or obstructing flow of food into the stomach, and/or by occupying a portion of the stomach volume) may be coupled to tissue tunnels or plications formed from stomach tissue.

For example, U.S. application Ser. No. 11/439,461 describes a restrictive and/or obstructive implant system for inducing weight loss. In one embodiment, flexible loops are coupled to tissue plications formed in the gastroesophageal junction region of the stomach. An implant, such as a flow restrictive and/or obstructive implant, is passed through the loops **2** and thus retained in the stomach.

In other instances, tissue plications may themselves be sufficient to provide the necessary treatment. For example, the plications may be used to reduce stomach volume or form a flow restriction within the stomach as disclosed in WO 2005/037152 and in Applicants' co-pending application Ser. No. 11/542,457, filed Oct. 3, 2006, U.S. Publication No. 2007-0219571, which is incorporated herein by reference.

Other types of implants may be coupled to such plications or other tissue structures for a variety of purposes. These implants include, but are not limited to prosthetic valves for the treatment of gastro-esophageal reflux disease, gastric stimulators, pH monitors and drug eluting devices that release drugs, biologics or cells into the stomach or elsewhere in the GI tract. Such drug eluting devices might include those which release leptin (a hormone which creates feelings of satiety), Ghrelin (a hormone which creates feelings of hunger), octreotide (which reduces Ghrelin levels and thus reduces hunger), Insulin, chemotherapeutic agents, natural biologics (e.g. growth factor, cytokines) which aid in post surgery trauma, ulcers, lacerations etc. Still other implants might be of a type which might provide a platform to which specific cell types can adhere, grow and provide biologically-active gene products to the GI tract, and/or a platform for radiation sources that can provide a local source of radiation for therapeutic purposes, or provide a platform whereby diagnostic ligands are immobilized and used to sample the GI tract for evidence of specific normal or pathological conditions, or provide an anchor point for imaging the GI tract via cameras and other image collecting devices.

The prior applications listed above, address the desirability of forming tissue plications, pockets or tunnels in a way that regions of serosal tissue (i.e. the tissue on the exterior surface of the stomach) are retained in contact with one another. Over time, adhesions formed between the opposed serosal layers create strong bonds that can facilitate retention of the plication/pocket/tissue over extended durations, despite the forces imparted on them by stomach movement and implanted devices.

Regardless of the application for which a plication is being formed, it is highly desirable to form that plication using steps carried out from within the stomach using instruments passed down the esophagus, rather than using more invasive surgical or laparoscopic methods. The present application describes endoscopic staplers which may be passed transorally into the stomach and used to form serosal-to-serosal plications in a stomach wall.

BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. **1**B is a cross-sectional perspective view of a portion of a stomach wall, illustrating the layers of tissue forming the wall.

FIG. **2** illustrates an endoscopic stapling system.

FIGS. **3**A-**3**C are perspective views showing the stapler head of the stapling system of FIG. **2** in three different positions.

FIG. **4** is a perspective view of the stapler head, with the membrane removed.

FIG. **5** is a perspective view of the proximal end of the staple housing of the stapler head of FIG. **4**.

FIG. **6** is a perspective view of the distal end of the staple housing of the stapler head of FIG. **4**.

FIG. **7** is an exploded perspective view showing elements advanceable within the staple housing during compression and stapling operations.

FIG. **8** is a plan view of a staple reinforcement device.

FIG. **9** is a side elevation view of a staple cartridge.

FIG. **10** is a perspective view of the staple housing similar to FIG. **6**, but showing some of the elements of FIG. **7** within the housing.

FIGS. **11**A-**11**D are a series of schematic representations of the hydraulic chamber and pistons, illustrating operation of an exemplary hydraulic system during tissue compression and stapling.

FIG. **11**E is similar to FIG. **11**D and shows an alternative piston configuration.

FIG. **12** is a perspective view of the anvil housing of the stapler head of FIG. **4**.

FIG. **13** is a perspective view of the anvil support.

FIG. **14** is a plan view of the anvil.

FIG. **15**A is a cross-sectional side view of the cutting device and a first embodiment of a cutting board.

FIG. **15**B is a cross-sectional side view of the cutting device and a second embodiment of a cutting board.

FIG. **16** is a perspective view of the hinged arm assemblies of the stapler head of FIG. **4**.

FIG. **17** is a top plan view of the stapler head of FIG. **4** in the streamlined position for introduction into the body. Both the membrane and the membrane raiser are not shown for purposes of clarity.

FIG. **18** is similar to FIG. **17** and illustrates hidden features of FIG. **17**.

FIG. **19** is a perspective view of the stapler head in an intermediate, partially expanded, position.

FIG. **20** is a plan view similar to FIG. **17** but showing the stapler head in the intermediate position.

FIG. **21** is similar to FIG. **20** and illustrates hidden features of FIG. **20**.

FIG. **22** is a perspective view of the stapler head in a fully expanded, full compression position.

FIG. **23** is a plan view similar to FIG. **20** but showing the stapler head in the full compression position.

FIG. **24** is similar to FIG. **23** and illustrates hidden features of FIG. **24**.

FIGS. **25**A-**25**C are perspective views showing the staple housing, cartridge and a portion of the membrane raiser. These figures illustrate the steps of detaching a staple cartridge from the staple housing.

FIG. **26** is a perspective view of the stapler of FIG. **2**, with the staple head removed.

FIG. **27**A is a plan view of the articulating section of the stapler of FIG. **2**, showing the drive fluid lines.

FIG. **27**B shows a drive fluid line having an alternate longitudinally expandable shape.

FIG. **28** is a cross-sectional side view of the handle of the stapler of FIG. **2**.

FIG. **29** is a perspective view of the handle of the stapler of FIG. **2**.

FIGS. **30**A and **30**B are plan views of the proximal face of the staple housing, showing a method for attaching the end plate of the stapler handle to the staple housing.

FIGS. **31**A-**31**E are a series of drawings schematically illustrating use of the system of FIG. **2** to form a plication in a stomach.

FIGS. **32**A-**32**C are a series of perspective views illustrating use of the stapler of FIG. **2** to acquire, compress, and then staple stomach wall tissue to form a plication in the stomach. The membrane is not shown in these drawings.

FIG. **33** is a top plan view of a plication formed in body tissue.

FIGS. **34** and **35** are perspective views of an alternative stapler head equipped to carry additional tools.

DETAILED DESCRIPTION OF THE DRAWINGS

The present application describes endoscopic fastener-applying devices which in preferred embodiments may be passed transorally into the stomach and used to plicate stomach tissue.

In the disclosed embodiments, tissue is drawn inwardly into a vacuum chamber, although tissue may be drawn inwardly using other components (e.g. graspers) that do not involve the use of a vacuum. When a portion the interior stomach wall is drawn inwardly, sections of serosal tissue on the exterior of the stomach are positioned facing one another. The disclosed fastener applying device allows the opposed sections of tissue to be moved into contact with one another, and delivers fasteners that will hold the tissue sections together until at least such time as serosal bonds form between them. Each of these steps may be performed wholly from the inside of the stomach and thus can eliminate the need for any surgical or laparoscopic intervention. After one or more plications is formed, medical devices (including, but not limited to any of the types listed above) may be coupled to the plication(s) for retention within the stomach.

The disclosed embodiments include an optional feature that forms a hole or cut in a plication using the fastener-applying device. This hole or cut might be formed so that a portion of a medical implant may be passed through or linked to the hole/cut, or it may be formed so as to provoke a healing response that will contribute to the strength of the resulting tissue bond.

In the description of the embodiments given below, the fastener-applying devices are described as being staplers, and exemplary methods are given with respect to the formation of plications in stomach tissue. It should be understood, however, that the embodiments described herein include features having equal applicability for applying other types of fasteners, and for applying staples or other fasteners for purposes other than formation of plications. The disclosed embodiments and methods will also find use in parts of the body outside the GI system. Additionally, although the disclosed embodiment features circular stapling and cutting of a concentric hole, modifications are conceivable in which linear stapling can be accomplished, as well as circular or linear stapling without cutting.

FIG. **2** illustrates one embodiment of a system **10** for tissue stapling that is suitable for endoscopic use, as well as surgical or laparoscopic use if desired.

Generally speaking, system **10** includes a stapler **12** having a stapler head **14** positioned on a distal portion of a shaft **16**. A handle **18** on the shaft **16** controls articulation of the stapler head **14** and actuation of the tissue acquisition, tissue compression, and stapling functions of the stapler head **14**. Vacuum and fluid sources **20**, **25** are fluidly coupled to the handle **18** for use in tissue acquisition, compression and stapling as discussed below. The vacuum source **20** may be the "house vacuum" accessible through a coupling on the wall of the operating room, or an auxiliary suction pump. The stapler may include a switch **21** allowing the user to control airflow between the vacuum source and stapler.

The fluid source **25** may be a single source of drive fluid (e.g. water, saline, oil, gas) or multiple sources, but in each case the fluid source preferably includes two actuators separately used to control flow into each of two hydraulic lines (one for tissue compression and one for stapling). An endoscope **22** insertable through a lumen in the shaft **16** permits

visualization of the plication procedure. The system may optionally include an overtube, such an endoscopic guide tube **23**, having a lumen for receiving the stapler **12**.

Referring to FIG. **3**A, a covering or membrane **24** encloses the stapler head **14** to form a vacuum chamber within the stapler head **14**. The side exposed to the tissue to be plicated remains uncovered by the membrane **24** to allow tissue to be drawn into the chamber during use. For example, the membrane **24** may include a side opening **26** as shown in FIG. **3**B. Membrane **24** is preferably formed of silicone, elastomeric material, or any other inelastic or elastic flexible or deformable biocompatible material capable of forming a vacuum chamber that will expand in volume to accommodate tissue drawn into the chamber.

At least a portion of the membrane is at least partially transparent. In being at least partially transparent, the membrane is formed of a material, or includes sections of material, that will allow the user to see through the membrane well enough to confirm (via endoscopic observation) that an appropriate volume of tissue has been acquired into the stapler head prior to staple application. The opening **26** may be surrounded by a reinforced section **27** formed of material that will strengthen the area around the opening **26**. Reinforced section **27** may be formed of a thicker section of the membrane material, and/or a higher durometer material. Alternatively, reinforcing ribs or other structures or elements may be formed into or onto the membrane material, or embedded in the membrane material.

Stapler Head

The stapler head **14** is designed to have a minimum profile during insertion to the plication site, and to then transform into a much larger profile device having a large internal volume. For example, in one embodiment the vacuum chamber might have an initial internal volume of 0.2 cubic inches, and an expanded volume of 0.6 cubic inches (i.e. the internal chamber volume after subtracting the volume occupied by the stapler head components positioned within the vacuum chamber). This large internal volume allows a large volume of tissue to be drawn into the vacuum chamber and stapled. In this way, the stapler head creates a large plication without requiring invasive techniques for insertion. The unique features of the stapler head allow in situ volumetric expansion of the stapler head using a minimum of motion and force input.

Features of the stapler head are shown in FIGS. **4**-**10**. For clarity, the membrane is not shown in these figures. Referring to FIG. **4**, stapler head **14** generally includes a first member comprising a proximal staple housing **28**, a second member comprising a distal anvil housing **30**, and at least one elongate member but preferably a pair of hinged arm assemblies **32**.

The staple housing and anvil housing are arranged to allow tissue to be compressed between contact surfaces on each of the staple housing and the anvil housing. In the disclosed embodiment, the contact surfaces are on a staple holding portion of the staple housing and an anvil on the anvil housing.

The arm assemblies **32** extend between the staple housing **28** and anvil housing **30** on opposite sides of the stapler head **14**. Proximal and distal pins **34**, **36** pivotally couple each arm assembly **32** to the staple housing **28** and the anvil housing **30**. An expansion member comprising a membrane raiser **37** also extends between the staple housing **28** and the anvil housing **30**. Although the membrane **24** is not shown in FIG. **4**, it should be understood that the membrane raiser **37** is positioned opposite the opening **26** (FIG. **3**B) in the membrane. In the illustrated embodiment, membrane raiser **37** includes a link **38** pivotally mounted to the staple housing by a pin **42**, a corresponding link **40** pivotally mounted to the anvil housing by pin **44**, and spring wires **46** coupling the links **38**, **40** to one another.

Staple Housing

Turning to a more detailed discussion of the stapler head components, the staple housing **28** can be seen separated from other components in FIGS. **5** and **6**. As shown in FIG. **5**, proximal face **48** of the staple housing includes input ports **50***a*, **50***b* through which fluid is directed for hydraulic actuation of the tissue compression, stapling, and optional cutting operations of the stapler head. Seals **51** surround the ports **50***a*, **50***b* to minimize fluid leakage.

Vacuum ports **52** are fluidly coupled to a vacuum source **20** (FIG. **2**) that is selectively activated to create negative pressure in the vacuum chamber for tissue acquisition. The vacuum ports **52** are connected to the vacuum source **20** by flexible tubing (not shown) in the stapler shaft **16** (FIG. **2**). Mounting holes **54** are used to mount the stapler head **14** to the shaft **16**.

The staple housing **28** includes upper and lower sections **58***a*, **58***b* above and below open side sections **56**. The upper section **58***a* includes a recess **60** within which the pivot pin **42** for link **38** (FIG. **4**) is mounted. As best shown in FIG. **6**, bores **62** are positioned in the upper and lower sections **58***a*, **58***b* to receive pins **34** (FIG. **4**) that serve as the proximal pivot points for arm assemblies **32**. Guide slots **64** extend longitudinally through the upper and lower sections **58***a*, **58***b*.

Referring to FIG. **6**, a hydraulic chamber **66** is disposed within the staple housing **28**. Within the hydraulic chamber **66** (FIG. **6**) is a dedicated hydraulic circuit for driving the tissue compression and stapling functions of the stapler. Chamber **66** is fluidly coupled to the fluid input ports **50***a*, **50***b* (FIG. **5**). As will be discussed in detail in connection with FIGS. **11**A-**11**D, fluid driven into the hydraulic chamber **66** via input ports **50***a*, **50***b* sequentially advances a system of hydraulic pistons (not shown) that act on other components to compress the tissue, and that drive the staples and cutting element through the compressed tissue.

FIG. **7** illustrates components of the stapler head that are driven by the hydraulic system for compression, stapling, and cutting. For clarity, these components are shown separated from the staple housing and from each other. In this discussion, the components that are driven by the hydraulic system will be described. The hydraulic system itself is described in a later section in connection with FIGS. **11**A-**11**D.

In particular, FIG. **7** illustrates a drive member which takes the form of a disk **68** in the staple housing. In the assembled housing, disk **68** is positioned such that it will be pushed distally by a hydraulic compression piston (not shown). The drive member is coupled to the arm assemblies **32**, anvil housing, and staple housing so that advancing the drive member distally effects tissue compression by bringing the contact surfaces of the staple housing and anvil housing relatively towards one another.

Disk **68** includes mounting bores **70**, a central opening **72**, and alignment posts **74**. Referring briefly to FIG. **10**, in the assembled stapler head, disk **68** is coupled to the stapler housing **28** using pins **84** that extend through the housing's guide slots **64** and through mounting bores **70** in the disk **68**.

A portion of the staple housing **28** contains staples to be fired into the tissue. The staples are contained within a staple holder on the staple housing. The staple holder may have a number of different configurations. For example, it may be an integral portion of the staple housing, or a separate part mounted or attached to the staple housing, and/or it may be moveable relative to the body of the staple housing to effect tissue compression prior to stapling. In any of these examples,

the staple holder may be a removeable/replaceable cartridge, and/or it may be refillable by inserting additional staples into it. In other embodiments, the staple holder may be neither replaceable nor refillable.

In the disclosed embodiment, the staple holder is a removeable staple cartridge **78** that can be replaced with another cartridge after staple filing. In this embodiment, the staple cartridge is moveable relative to the body of the staple housing to compress the tissue prior to staple firing.

Referring again to FIG. **7**, staple cartridge **78** is positionable within the staple housing, distal to the disk **68**, such that distal advancement of the disk by the compression piston pushes the cartridge distally to compress tissue disposed between the cartridge and anvil. Grooves **79** on the exterior of the cartridge slide over corresponding ones of the alignment posts **74** during insertion of the cartridge into the stapler head. FIG. **10** shows the alignment posts prior to loading of a cartridge into the staple housing. As shown, the alignment posts **74** may have tapered ends to facilitate loading of the cartridge over the posts.

Again referring to FIG. **7**, cartridge **78** includes a number of staple locations **80**, each housing a staple. The staple cartridge is equipped with bosses **81** to retain a staple line reinforcement device **83** of the type shown in FIG. **8** and disclosed in detail in commonly-owned U.S. application Ser. No. 11/542,457, entitled ENDOSCOPIC PLICATION DEVICES AND METHODS, filed Oct. 3, 2006, and published Sep. 20, 2007 as US 2007-0219571. To summarize briefly, this type of reinforcement device **83** may be a ring or other element positionable against the distal face of the staple cartridge. When the ring is placed on the cartridge, openings **85** in the ring align with prongs of some of the staples in the cartridge. When staples are driven from the cartridge, these prongs pass through associated ones of the openings **85** and capture the ring **83** against the adjacent body tissue.

Referring to FIGS. **7** and **9**, a number of undercut bosses **81** on the anvil-facing side of the cartridge may be used to lock the reinforcement device **83** in place on the face of the staple cartridge. Other positive shapes, such as mushrooms, hooks, and tilted bosses could be used to accomplish the same end. Negative shapes, such as pockets or grooves formed into the surface of the cartridge, may also be employed to engage corresponding features on the reinforcement device **83**. As another alternative, the reinforcement device may be held in place on the cartridge using adhesives.

A cutter element **86** extends through the central opening **72** (FIG. **7**) of the disk **68**. The cutter element is shown as a tubular punch having a sharpened wall and a lumen **87**, but may be provided in alternative forms. A staple pusher **76** is mounted to the cutter element, distally of the disk as can be seen in the assembled view of FIG. **10**. Staple pusher **76** includes pusher elements **82** proportioned to slide into the cartridge's staple locations **80** as the staple pusher **76** is advanced into the staple cartridge **78**, thus driving the staples from the cartridge. A hydraulically-driven staple piston (not shown in FIG. **7**) in the hydraulic chamber **66** is coupled to the cutter element **86** such that advancement of the stapler piston advances the staple pusher **76** and cutter element **86** in a distal direction.

Fluid Drive System

The fluid drive system used to actuate compression, stapling and cutting may be configured in various ways. The following paragraphs describe one exemplary configuration for the fluid drive system, which in this embodiment is a hydraulic system. FIGS. **11**A and **11**B schematically show the fluid flow in the hydraulic chamber **66** of the staple housing **28** during both compression and stapling stages of actuation. Referring to FIG. **11**A, compression piston **106** is disposed within hydraulic chamber **66**. Disk **68** (also shown in FIGS. **7** and **10**) is positioned in contact with or slightly distal to piston **106**. Compression piston **106** is generally cup-shaped, having a rear wall **108** and a side wall **110** enclosing an interior **111**. O-ring seals **112** are spaced-apart on a proximal portion of the side wall **110**. Channels **166** are formed through the side wall **110**, between the o-ring seals **112**.

A second piston, referred to as the staple piston **168**, is positioned in the interior **111** of compression piston **106**, against the rear wall **108**. Although not shown in FIGS. **11**A-**11**D, cutting element **86** (FIG. **7**), with the staple pusher **76** thereon, is positioned in contact with or slightly distal to the staple piston **168**. An o-ring seal **118** surrounds a portion of the staple piston **168** that is distal to the channels **166** in the compression piston.

A first fluid channel **120** extends from fluid port **50***a* in the stapler housing **28** to a proximal section of the hydraulic chamber **66**. A second fluid channel **122** extends from fluid port **50***b* in the stapler housing to a more distal section of the hydraulic chamber **66**. Fluid flow from port **50***a* and fluid channel **120** against the compression piston cylinder is shown in FIG. **11**A. Fluid pressure within the hydraulic chamber **66** advances the compression piston **106**, with the stapler piston **168** within in it, in a distal direction. FIG. **11**B shows the compression piston **106** approaching the end of its travel. Once the compression piston reaches the end of its travel as shown in FIG. **11**C, channel **166** in the compression piston **106** aligns with channel **122** in the housing, allowing fluid introduced through fluid port **50***b* to enter the interior of the compression piston **106** via channel **122**. The fluid entering the interior of the compression piston drives the staple piston distally as shown in FIG. **11**D. In an alternative embodiment shown in FIG. **11**E, a third piston **117** is provided for separately driving the cutting element **86**. In this embodiment, fluid introduced into a third drive fluid port **50***c* causes advancement of the third piston **117**. The pistons **106**, **168** and **117** and associated fluid paths may be arranged so that fluid cannot enter the interior of the stapler piston to advance the cutting piston **117** until compression piston **106** has traveled to the tissue-compression position and stapler piston **168** has in turn traveled to the stapling position.

The anvil housing (identified by numeral **30** in FIG. **4**) will next be described with reference to FIG. **12**. The anvil housing **30** includes mounting bores **88** for receiving pivot pins **36** at the distal end of the hinged arm assemblies **32**. The upper section of the anvil housing **30** includes a section **94** through which the pivot pin **44** for link **40** (FIG. **4**) is mounted.

A central bore **90** extends longitudinally through the anvil housing **30**. An anvil support **92** is longitudinally slidable within the bore. Both the bore **90** and the anvil support **92** are preferably formed to have non-circular cross-sections (such as the illustrated rectangular cross-section) with flat bearing surfaces to prevent rotation of the piston within the bore.

FIG. **13** shows the anvil support **92** separated from the anvil housing **30**. The distal portion of the anvil support **92** is split into upper and lower plates **95***a, b*. Plate **95***a* has a bore **93** axially aligned with a similar bore in plate **95***b*. The proximal portion of the anvil support **92** carries the anvil **96**. As shown in FIG. **14**, anvil **96** includes a plurality of indentations **98** positioned such when staples are driven from the staple cartridge, each staple leg engages one of the indentations, which causes the staple leg to fold. A central opening **97** extends through the anvil **96** and is contiguous with a lumen in the anvil support **92**.

The anvil **96** and the staple cartridge **78** (FIG. **7**) are the two parts of the stapler head which exert force on the tissue to be

stapled. As shown in FIGS. **9** and **14**, the preferred anvil and cartridge are designed to use a minimal amount of material surrounding the indentations **98** of the anvil **96** and the staple locations **80** of the cartridge **78**—so that the amount of anvil/cartridge surface area contacting the tissue is as small as possible. When subjected to a constant force, a smaller footprint will damage less tissue than would a larger footprint, since a smaller area of tissue is squeezed between the anvil and cartridge. However, the tissue that does get squeezed experiences more pressure from the given force because the force is distributed over a smaller area. In other words, the minimized footprint creates more pressure on the tissue with less force. This is advantageous from a mechanical standpoint because the stapler head need not supply or withstand as much force as would be needed with a larger-footprint cartridge and anvil.

Referring to FIG. **7**, in the illustrated embodiments, the staple cartridge **78** has an outer wall that tracks the contours of the staples housed within it, thus forming a number of pedals **73** surrounding the outer staple positions or slots **80***a*, with the grooves **79** disposed between the pedals, adjacent to the inner staple positions **80***b*. Rather than providing each staple position to be fully surrounded by cartridge material, the staple positions **80***a*, **80***b* preferably each include a back wall **71***a* and a retaining element attached to the wall and positioned to retain a staple between the retaining element and the back wall. In FIG. **7**, the retaining element comprises a pair of wings **71***b* that curve inwardly from the back wall **71** to define a slot that is sufficiently bounded to retain a staple within the staple position, but that is preferably not bounded around its full circumference. The anvil has a similar pedal arrangement, as shown in FIG. **13**.

Referring again to FIG. **13**, a plate **99** is positioned on the anvil **96** such that the distally-advancing cutting element **86** will advance into contact with the plate **99** during tissue cutting. In one embodiment, the plate **99** may be seated within the opening **97** in the anvil. The plate **99**, which will also be referred to as the "cutting board", has a hole **101** in it which relieves the pressure of the captured tissue and prevents hydraulic locking, a condition in which the punch and plate create a closed volume. If it is desired to move the cutting element **86** after contact is made, pressure will increase inside this closed volume and it will resist further motion. This may prevent or adversely affect tissue cutting.

The cutting board is preferably designed so as to not serve as a hard stop against advancement of the cutting element **86**. If the cutting element **86** is stopped by the cutting board, the stapling piston will also be stopped and incomplete staple formation may result. Therefore, it is preferred that the cutting element **86** is allowed to penetrate or displace the cutting board during and after the tissue is cut.

FIGS. **15**A and **15**B illustrate the cutting element **86** advanced into contact with two different embodiments of cutting boards. In the FIG. **15**A embodiment, the material of cutting board **99***a* is a relatively soft material, such as an elastomeric silicone, which is cut by the advancing cutting element as shown. This material allows the sharp distal end of the cutting element to move into the cutting board during the final stage of staple formation. In the FIG. **15**B embodiment, the cutting board **99***b* can be made of a harder material positioned with a compressible object such as an elastomeric spring **99***c* behind it. In the figure, this spring is an o-ring. Advancement of the cutting element **86** against the cutting board **99***b* causes the cutting board to be displaced distally against the spring **99***c*. The advancing cutting element **86** experiences increasing resistance as the o-ring is compressed. Other spring shapes and materials, such as coiled wire, spring washers and leaf springs can be used to achieve the same result. The chamfer **99***d* on the surface of the cutting board **99***b* may help to align the cutting element **86** as it is forced into contact with the cutting board.

Arm Assemblies

Following is a discussion of the features of the arm assemblies **32**. FIG. **16** shows the arm assemblies **32** separated from the other elements of the stapler head. In general, each arm assembly has a first arm section pivotally coupled to the staple housing and a second arm section pivotally coupled between the first arm section and the anvil housing. While not present in the illustrated embodiment, additional arm sections may be positioned between the first and second arm sections.

Each arm assembly includes a proximal arm **100** and a distal arm **102** joined to one another to form a hinge **104**. Each of the proximal arms **100** has a longitudinal cutout **108** and a spreader arm **110** pivotally mounted within the cutout **108**. The distal end of each spreader arm **110** includes a bore **112**. Pin **84** is positioned within the bore **112**. As disclosed in connection with FIG. **10**, this pin **84** extends through the disk **68** and has ends that ride within the slots **64** (FIG. **6**) on the lower and upper sections of the stapler housing. Longitudinal movement of the disk **68** within the stapler housing will thus advance the pins **84** within their corresponding slots **64**, causing the spreader arms **110** to pivot relative to the pins **84** and to thus drive the arm assemblies **32** outwardly. Additional specifics concerning movement of the arm assemblies **32** is set forth in the section entitled Stapler Head Operation.

Distal arms **102** of the arm assemblies include pins **36** which, as discussed, are pivotally mounted to the anvil housing **30** (FIG. **4**). A pair of drive links **114** are provided, each of which has a first end pivotally attached to a corresponding one the distal arms **102** and a second end pivotally coupled to a common pin **116**. In the assembled stapler head, pin **116** is positioned in the bores **93** of the upper and lower plates **95***a*, **95***b* of the anvil support (see plates **95***a, b* in FIG. **12**). As detailed in the Stapler Head Operation section below, when the spreader arms **110** drove the arm assemblies **32** outwardly, drive links **114** act on the pin **116** to push the anvil support in a proximal direction, causing the anvil to advance proximally towards the staple cartridge.

Stapler Head Operation

The following discussion centers on the manner in which the arm assemblies function to expand the vacuum chamber and to compress tissue that has been drawn into the chamber using suction. As an initial step preceding chamber expansion, the stapler head is positioned with the opening **26** in the membrane **24** in contact with tissue at the location at which plication creation is desired. Vacuum source **20** (FIG. **2**) is activated to apply vacuum to the inside of the vacuum chamber defined by the membrane. Tissue in contact with the opening **26** (FIG. **3**B) will be drawn into the vacuum chamber between the staple housing **28** and the anvil housing **30**. After the tissue is drawn in, the stapler profile is changed, expanding the volume of the chamber within the membrane.

The streamlined position of the stapler head **28** prior to expansion is shown in FIGS. **4**, **17** and **18**. In particular, the hinged arm assemblies **32** and membrane raisers **37** are in generally straight orientations. The proximal arms **100** serve as the drive arms for chamber expansion and tissue compression. Motion of these arms is initiated when water under pressure is forced into the hydraulic circuit of the staple housing. Referring to FIG. **19**, the fluid pressure advances disk **68** (by action of the compression piston **106**, not shown in FIG. **19**). Disk **68** in turn pushes the staple cartridge **78**

toward the anvil **96** as shown in FIGS. **19-21**, causing the staple cartridge **78** to extend further from the staple housing **28**.

Both the disk **68** and the arm spreaders **110** are coupled to the pins **84**. For this reason, the longitudinal movement of the disk **68** within the stapler housing **28** will carry the pins **84** distally within their corresponding slots **64**. The arm spreaders **110** will consequently pivot relative to the pins **84**, driving the proximal arms **100** outwardly. Outward movement of proximal arms **100** at hinge **104** causes the distal arms **102** to also pivot outwardly at hinge **104**, forming an angle between the proximal and distal arms **100**, **102**. Naturally, formation of the angle between the arms **100**, **102** shortens the effective length between the remote ends of the arms, causing the distal pins **36** of the distal arms **102** to carry the anvil housing **30** towards the staple cartridge. The pivoting movement of the distal arms **102** further causes drive links **114** to act on pin **116** to push the anvil support in a proximal direction. This moves the anvil support relative to the anvil housing in a proximal direction at the same time the anvil housing is also moving proximally.

In essence, one motion, that of the hydraulically driven compression piston, creates at least three motions, illustrated by arrows A**1**, A**2** and A**3** in FIGS. **19-21**. These three motions include: the staple cartridge **78** moving relative to the staple housing in a direction towards the anvil **96** (arrow A**1**), the anvil housing **30** moving toward the staple housing **28** (arrow A**2**) and the anvil **96** itself moving relative to the anvil housing **30** in a direction towards the cartridge (arrow A**3**). This compound motion of the anvil toward the staple cartridge enables a small displacement of the compression piston to quickly compress tissue in the grip of stapler. The multiplication of motion also enhances force transmission between the two housings by keeping the angle at hinge **104**, between the proximal (driven) arm and the distal (drive) arm, as large as possible.

The relative motion of the two housings **28**, **30** toward each other also drives upward links **38**, **40** and their interconnecting spring wires **46** on the top of the stapler head **14**. Together, the links and spring wires raise the top of the membrane, creating more volume to accommodate expansion of the tissue during compression.

Compression of the tissue is halted when the pins **84** traveling in slots **64** in the staple housing **28** reach the limit of travel, as shown in FIGS. **22-24**. Thus, the slots and associated components are dimensioned to set the desired separation distance between the tissue contact surfaces on the stapler side and the anvil side of the stapler head. Exemplary separation distances for use in stomach wall plications might include approximately 0.06-0.07 inches (e.g. for use with staples having legs of 5.5 mm length) or 0.109 inches for 6.5 mm leg length staples. Application of additional pressure into the hydraulic circuit will not compress the tissue any further.

Moreover, because of the piston arrangement, the stapling function is effectively locked out until tissue compression is complete. With this arrangement, fluid introduced via the fluid port **50***b* (FIG. **11**A) into the staple fluid channel **122** prior to completion of tissue compression will leak until the two o-rings **112** of the compression piston **106** are straddling the inlet **166**. This design prevents premature staple firing.

At the fully compressed position, the arm spreaders **110** are nearly perpendicular to the longitudinal centerline of the stapler head. Once tissue is compressed between cartridge **78** and anvil **96**, the tissue is ready for stapling.

Stapling is initiated by introducing hydraulic fluid through port **50***b* (FIG. **5**). The staple piston advances, pushing cutting element **86** (FIGS. **7** and **10**) towards the anvil **96**. Because the staple pusher **76** is mounted to the cutter **86**, this action carries the staple pusher **76** through the cartridge **78** where it simultaneously pushes all staples through the tissue. Staple piston travel is limited by internal stops, and is preset to yield optimal staple formation.

During compression, as the angle at the hinge **104** of arm assemblies **32** reaches its minimum, the force required to resist separation of the staple and anvil housings increases. These forces increase further when the forces of staple crushing are exerted on the anvil by the staple piston. To compensate, the arm spreaders **110** serve as displacement struts to channel at least a portion of these forces into the disk **68**. These forces, if not reacted by the pusher disk, would pull in the arms **100**, **102** and potentially release the compression on the tissue, causing incomplete staple formation or tissue cutting. In this way, a truss-like structure is created for force displacement.

When staples have been formed, staple pressure is released and a spring (not shown) returns the staple pusher **72** to its base position. Releasing fluid pressure will allow the deflected spring wires **46** on membrane raiser **37** to return the staple head to its minimum profile configuration and release the plication from the stapler. Once outside the patient, the used staple cartridge can be ejected and a new one installed.

FIGS. **25**A-**25**C illustrate one method for retaining a removable staple cartridge **78** within the staple housing. The cartridge is spring-loaded into the staple housing and retained by two latches **170** (one visible), each pivotable relative to a fulcrum **172**. As shown, the fulcrum **172** may be coupled to the disk **68** by pin **84**. Each latch **170** includes a catch **174** which engages a corresponding catch **176** on the cartridge. The latch **170** is preferably spring biased to urge the catch **174** inwardly towards the cartridge.

Depressing the proximal end **175** of each latch **170** as shown by arrow P in FIG. **25**B pivots the latch against this bias, causing ejection of the staple cartridge. A new staple cartridge may then be positioned with its grooves **79** aligned with alignment posts **74** as shown in FIG. **25**C and then pushed towards the staple housing. As the new cartridge slides into position, catch **174** rides over the tapered proximal portion **178** of the catch **176**. Once catch **174** passes over the distal end **180** of the catch **176**, it drops inwardly towards the cartridge due to its spring bias, thus engaging the cartridge. When the cartridge is properly seated, a click will be felt or heard as the latches engage the new cartridge.

Stapler Shaft and Handle

Referring again to FIG. **2**, the stapler shaft **16** connecting the handle **18** and the stapler head **14** is flexible enough to conform to the curvature of the upper digestive tract, yet maintains the ability to transmit enough torque to rotate the stapler head. The shaft is formed with sufficient stiffness to allow it to be pushed down esophageal guide tube **23**. Suitable materials include

FIG. **26** shows a distal portion of the shaft **16**, with the stapler head removed from the shaft. As shown, shaft **16** includes an endoscope lumen **124** through which an endoscope is advanced to allow visualization of a stapling operation. Side lumens **126** may also be provided for receiving other instruments useful during the procedure.

An articulating section **128** is positioned at the distal end of the shaft **16**, between the shaft **16** and the stapler head **14** so as to allow the stapler head to be articulated relative to the shaft. Tubing coupled to the vacuum source and the source of hydraulic fluid extends from the handle and through the shaft **16** and the articulating section **128**.

FIG. **27**A shows one configuration that may be used for the hydraulic fluid lines **130**. During use, the hydraulic fluid lines

are subjected to significant deflection and elongation in the articulating section of the stapler. They are also subjected at times to fluid pressure which may be in excess of 1000 psi. Typically, hydraulic lines in industrial applications are flexible and have a working loop of extra tubing that accommodates length changes during use. The illustrated configuration for the hydraulic lines is a lower profile solution particularly suitable for an endoscopic device having space constraints. A preferred hydraulic line is a tube **130** having a portion that is shaped into a longitudinally expandable shape so that it can accommodate effective length changes during bending. The longitudinally expandable portion of the tube is preferably disposed within the articulating section **128** of the stapler **12**. In a preferred design, the longitudinally expandable shape is a coil shape as shown in FIG. **27**A. In alternate embodiments, the tube **130** may be formed into other longitudinally expandable shapes, such as regular or irregular undulating shapes (FIG. **27**B).

The preferred material for the tubes **130** is stainless steel hypotube, although other materials may instead be used. In the preferred stapler configuration, two drive fluid lines are provided, one for actuating tissue compression, and the other for staple application (and cutting when used). In the present embodiment, the tubes are coiled together as shown in FIG. **27**A. In alternate embodiments, two or more coiled tubes may be nested one inside the other. As the articulating section bends, it forces the coiled tubes **130** to bend and to change length in response to bending. The coiled tubes behave just as coiled wires would during these motions and are thus able to change length, deflect, and follow the contour of the articulating section without compromising flow through the lumens of the tubes or imparting undue stress to the connections at either end of the hydraulic system.

The longitudinally expandable shapes for the fluid lines may be suitable for use in allowing delivery of fluid to the operative ends of other types of articulating medical devices, such as catheters or endoscopic devices for delivering therapeutic agents or irrigation fluids past an articulating or bendable section of the device.

Referring again to FIG. **26**, articulating section **128** is comprised of a spine formed of a plurality of links **132** strung over a pair of pull cables **134** (only one shown in FIG. **26**). In one embodiment, engagement of the pull cables allows the stapler head **14** to be articulated in two directions through a range of motion of approximately 90 degrees in one direction (see FIG. **3**B) to 175 degrees in the opposite direction (see FIG. **3**C). Each pull cable is anchored at or near the stapler head, such as at the distalmost link **132** of the stapler housing **28**.

The more proximal portions of the pull cables **134** extend the length of the shaft **16** and terminate in the handle **18**. Referring to FIG. **28**, the handle **18** includes a rotating knob **136** that may be selectively rotated in a clockwise or counterclockwise to articulate the stapler head up or down. Rotation in one direction applies tension to one of the pull cables to cause the stapler head to bend downwardly, whereas rotation in the opposite direction puts tension on the other cable, causing the head to bend upwardly.

In a preferred handle configuration, the knob **136** includes an internal threaded bore **138**. Knob **136** is partially restrained within the handle **18** so that it remains fixed within the handle but can rotate freely. A carriage **140** having a threaded exterior surface is positioned within the threaded bore **128** of the knob. The threads within the bore **138** are engaged with the threads on the carriage **140** so that rotation of the knob causes the carriage **140** to translate, but not rotate, within the handle.

Each of the two pull cables, identified in FIG. **28** as cables **134***a* and **134***b*, is terminated on a different member in the handle. Cable **134***a* is mounted on the sliding carriage and cable **134***b* is mounted to a stationary part of the handle **18**. Each cable extends through a corresponding sheath. Cable **134***a* extends through a sheath **135***a* having a proximal end fixed to a stationary part of the handle **18**. Cable **134***b* extends through a sheath **135***b* having a proximal end mounted to the sliding carriage.

The cables **134***a,b* and sheaths **135***a,b* are arranged such that translation of the carriage in one direction will cause deflection of the stapler head in one direction, and translation of the carriage on the other direction will deflect the stapler head in another direction.

Referring to FIG. **28**, if knob **136** is rotated to causes the carriage **140** to translate to the left of the page, cable **134***a* will be tensioned and cable **134***b* will slacken, causing the stapler head to articulate in a first direction (e.g. upwardly). Rotation of the knob **136** in the opposite direction will advance the carriage to the right of the page, releasing tension on cable **134***a* and pushing sheath **135***b* over the cable **134***b* towards the distal end of the staple head, causing articulation in the second direction (e.g. downwardly) as the sheath **135***b* is advanced against a distal portion of the shaft **16**. The proximal portion of sheath **135***b* is provided with sufficient working length prevent it from being placed under tension when the carriage moves distally. The positioning of the knob is advantageous in that the hand movement required for stapler articulation is always the same, regardless of the rotational orientation of the stapler. Also, the use of the threaded knob can prevent unintentional relaxation of the deflection angle, even if the knob is provided without a lock to retain its rotational position.

Referring to FIGS. **28** and **29**, the endoscope lumen **124** extends along the center axis of the stapler. The positioning of the lumen and the coaxial relationship of the articulation knob in relative to the endoscope **124** allows the endoscope and stapler to be rotated independently without one interfering with one another. Thus, if the user chooses to change the rotational orientation of the stapler head **14** within the body, s/he may rotate the handle **18** and shaft **16** while maintaining the rotational position of the endoscope.

For cost efficiency, the stapler **12** may be designed to permit the stapler head **14** to be discarded while allowing the shaft **16** and handle **18** to be sterilized and re-used. One mechanism for removably coupling the stapler head to the shaft **16** is illustrated, although others are readily conceivable (e.g. a slip coupling type arrangement). Referring to FIG. **26**, an end plate **142** is mounted to the distalmost one of the links **132**. Each of the end plate **142** and the corresponding rear surface of the stapler head are provided with latch features that allow the end plate and stapler head to be engaged to one another.

End plate **142** includes a cantilevered pin **144** having a peg **145** (which may be a spring pin), a central opening **146**, and a pair of u-shaped catches **148** along its edges. Hydraulic feed holes **156***a, b* are formed through the end plate **142**. The hydraulic tubes that deliver hydraulic fluid to the stapler head (see tubes **130** of FIG. **27**) are preferably welded to the end plate to allow fluid from the tubes to be directed through the feed holes **156***a, b*.

FIGS. **30**A and **30**B show the rear surface **48***a* of the staple housing, which has been somewhat modified relative to FIG. **5**. In this variation of the rear surface **48***a*, the hydraulic input ports **50***a*, **50***b* are repositioned as shown. Additionally, the

rear surface **48***a* has been modified to include a pair of catches in the form of undercut bosses **150**, plus an aligning pin **152**, and a hole **154**.

FIGS. **30**A and **30**B show the end plate **142** positioned against the rear surface **48***a* of **25** the staple housing. The other features of the articulating section **128** are not shown in FIGS. **30**A and **30**B for clarity. To attach the stapler head to the shaft **16**, the plate **142**, attached to the handle assembly, is pressed against the rear surface **48***a* of the staple housing as shown in FIG. **30**A. As the plate is pushed, it is rotated in a clockwise direction, causing the peg **145** (FIG. **26**) of the cantilevered pin **144** to engage hole **154** in the rear surface of the staple housing. When this latch is engaged, hydraulic feed holes **156***a, b* of the end plate **142** are lined up with the hydraulic inlets **50***a*, **50***b* on the staple head as shown in FIG. **30**B. At the same time, portions of the end plate surrounding u-shaped catches **148** slide beneath the undercut bosses **152**. Pressing the plate compresses the face-sealing o-rings surrounding the hydraulic input ports **50***a*, **50***b*. Compression on the o-rings is maintained by engagement of the catches and the undercut bosses overhanging the end plate. To remove the stapler head from the housing, the stapler housing is twisted in a counterclockwise direction to disengage the end plate **142** from the rear surface **48***a*. The stapler shaft and handle may then be sterilized in preparation for mounting of a fresh stapler head.

Exemplary Procedure

One example of a method for using the system **10** will next be described in the context of formation of plications in stomach wall tissue.

As an initial step (FIG. **2**), endoscopic guide tube **23** is advanced into the stomach via the mouth and esophagus. The endoscope **22** is inserted into the endoscope channel in the stapler handle (not shown) and advanced down the lumen of the stapler handle. The stapler/endoscope are simultaneously passed through the endoscopic guide tube towards the stomach. Once the stapler and endoscope reach the gastroesophageal junction region of the stomach, the position of the stapler is maintained while the endoscope is advance further into the stomach.

The stapler head **14** is advanced to the desired depth and location in the stomach. Using the articulation controls on the stapler handle, the angular orientation of the stapler head is adjusted to allow positioning of the stapler head **12** at the pre-identified target tissue as shown in FIG. **31**A. The opening **26** in the membrane **24** is positioned against the target tissue. The endoscope **22** is placed in a retroflexed position as shown.

The vacuum source **20** (FIG. **2**) is coupled to the vacuum port on the handle external to the body, and vacuum pressure is applied to draw tissue through the opening **26** and into the vacuum chamber defined by membrane **24** as shown in FIGS. **31**B and **32**A. Acquisition of the target tissue will be readily identified endscopically through the wall of transparent membrane **24** on the stapler head.

The fluid source (is shown) is coupled to the handle. Once it has been visually confirmed that a sufficient amount of tissue has been acquired, fluid is introduced to cause compression of the tissue and expansion of the arm assemblies **32** and membrane raiser **37** as shown in FIGS. **32**B and **31**C. As can been seen, the expansion of the arm assemblies and the membrane allows a large volume of tissue to be acquired into the vacuum chamber and displaced further into the chamber during tissue compression.

Once the tissue has been compressed, additional hydraulic fluid is introduced to cause stapling and cutting of the tissue as shown in FIGS. **31**D and **32**C, forming a plication P. The compression and stapling hydraulic sources are then deactivated to release fluid pressure within the hydraulic circuit. With the hydraulic pressure relieved, the spring wires of the membrane raiser **37** help to restore the stapler head **14** to its original streamlined configuration, allowing the stapler head to be withdrawn from the tissue as shown in FIG. **31**E. The stapler head may be articulated relative to the shaft to assist in moving the stapler head away from the plication P.

In a preferred plication configuration shown in FIG. **33** the staples **158** are arranged in two concentric rings of five staples, with the staple reinforcement device **83** retained by the staples and distributing forces around the staple pattern as shown. The plication P includes a hole H formed by the cutting element, through which various implants or anchors for various implants can be placed.

If multiple plications are needed, the stapler **12** is briefly withdrawn from the endoscopic guide tube and the staple cartridge is replaced in the manner described in connection with FIGS. **25**A-**25**C. The procedure is repeated until all desired plications have been formed.

The system may be packaged with instructions for use instructing the user to use the various disclosed features to perform a stapling procedure using methods disclosed herein.

Alternate Embodiments

The basic architecture of the stapler disclosed above can be used as a foundation for other stapling tools. FIGS. **34-35** show a modified stapler in which the membrane and membrane raiser have been removed, and in which the staple housing **28** has been modified for the attachment of tools. As shown in FIG. **34**, the staple housing **28** includes a pair of grooves **160** proportioned to receive tools **162**. Tools **162** may be seated in these grooves **160** and mounted to the staple housing as shown in FIG. **35**. This attachment will provide for a stable base from which to actuate the tools. The tools may be self-articulating, or the staple housing **28** may be equipped with devices **164** for moving the tools between streamlined positions for insertion of the assembly into a body cavity, and a deployed position such as that shown in FIG. **35**. Tools similar to those in FIG. **35** might be used for tissue acquisition, by reaching between the cartridge and anvil and used to engage tissue and pull the tissue into position between the cartridge and anvil so that it may be stapled, or otherwise affected by various features added to or in place of the anvil and cartridge. Procedures which may benefit from adaptation of the stapler include, but are not limited to gastroplasty, stoma adjustment, polyectomy, lead placement, bleeding control, perforation or hole closure, biopsy and tumor removal.

The disclosed systems provide convenient embodiments for carrying out the disclosed compression and stapling functions. However, there are many other widely varying instruments or systems may alternatively be used within the scope of the present invention. Moreover, features of the disclosed embodiments may be combined with one another and with other features in varying ways to produce additional embodiments. Thus, the embodiments described herein should be treated as representative examples of systems useful for forming endoscopic tissue plications, and should not be used to limit the scope of the claimed invention.

Any and all patents, patent applications and printed publications referred to above, including those relied upon for purposes of priority, are incorporated herein by reference.

We claim:

1. A medical instrument for applying a fastener to a tissue comprising:

a fastener device comprising:

a first member having a staple housing and a fastener holder that is independently moveable with respect to the staple housing, the holder carrying at least one fastener;

a second member having an anvil housing and an anvil carried on the anvil housing;

a drive assembly including a drive member operatively connected to the fastener holder for movement within the staple housing from a retracted position to an extended position the drive member including a feature positioned to move into contact with a stop when the drive member reaches the extended position, such that the stop prevents further movement of the drive member; and

an arm assembly operatively coupled to the first and second members such that movement of the drive member from its retracted to its extended position is effective to (i) move the fastener holder with respect to the staple housing toward the anvil, and (ii) move the second member toward the first member.

2. The medical instrument of claim **1**, wherein the drive member further comprises a fastener driver moveable to drive a fastener from the fastener member towards the anvil, wherein the fastener driver is inoperable to drive the fastener except when the first and second members are in the second relative position.

3. The medical instrument of claim **1**, wherein:

the drive member includes a disc that travels within the staple housing and carries at least one pin that moves within a slot in the staple housing, and the stop is an end of the slot;

wherein the slot is proportioned such that the pin abuts an end of the slot when the first and second members reach the second relative position to prevent further movement of the drive member.

4. The medical instrument of claim **3**, further including at least one arm spreader pivotally connecting said disc to the arm assembly for spreading the arm assembly outwardly as the disc travels within the staple housing.

5. The medical instrument of claim **1**, wherein:

the fastener holder and the anvil have confronting surfaces that define, in combination with the arm assembly, a chamber, and wherein the drive member comprises a piston moveable within the chamber, wherein the effect of movement of the drive member from its retracted to its extended position is to squeeze tissue captured within the chamber to form a captured tissue fold.

6. The medical instrument of claim **5** wherein the fastener device includes a fluid inlet port fluidly coupled to the chamber.

7. The medical instrument of claim **5**, wherein the chamber is covered by a membrane allowing tissue to be drawn into the chamber with application of a vacuum to the membrane.

8. The medical instrument of claim **7**, wherein the membrane has an opening on one side thereof for sucking tissue into the chamber, and movement of the drive member from its retracted to extended position along with application of vacuum to the chamber is effective to draw tissue into the side of the chamber opposite the opening.

9. The medical instrument of claim **1**, wherein the first member is coupled to the drive member such that movement of the drive member advances at least a portion of the first member towards the second member.

10. The medical instrument of claim **1**, wherein the second member is coupled to the drive member such that movement of the drive member advances at least a portion of the second member towards the first member.

11. The medical instrument of claim **1**, wherein the anvil is independently moveable in the anvil housing and the arm assembly is operatively coupled to the anvil such that movement of the drive member is effective to (i) move the fastener holder with respect to the staple housing toward the anvil, (ii) move the second member toward the first member, and (iii) move the anvil with respect to the anvil housing toward the fastener holder.

12. The medical instrument of claim **1**, wherein the second member includes drive links operatively connected to the arm assembly for moving the anvil toward the fastener holder as the drive assembly is moved from its retracted to its extended position.

13. The medical instrument of claim **12**, further comprising:

a tissue cutter mounted on the fastener piston, said cutter being adapted to cut a hole in a tissue fold held between the fastener holder and anvil, as the tissue fold is being stapled by movement of the fastener piston from its retracted to its extended position.

14. The medical instrument of claim **13**, wherein the second member includes a compressible cutting board allowing the cutter to be advanced by movement of the fastener piston beyond its point of initial contact with the cutting board.

15. The medical instrument of claim **14**, wherein the cutting board is formed of a material that can be penetrated by the cutter.

16. The medical instrument of claim **15**, wherein the cutting board is formed of silicone.

17. The medical instrument of claim **14**, wherein the cutting board is spring biased in the direction opposing movement of the cutter.

18. The medical instrument of claim **1**, wherein the drive member further includes a drive piston connected to a disc, and

wherein the drive member further includes a fastener piston carried for movement within the drive piston between retracted and extended positions and a staple pusher adapted to engage one or more fasteners in the fastener holder and eject the one or more fasteners from the holder against the anvil when the staple pusher is moved with the fastener piston from a retracted to an extended position.

19. The medical instrument of claim **18**, wherein said fastener holder is designed to hold an annular array of fasteners and said staple pusher is adapted to engage the array of fasteners in the fastener holder and eject the array of fasteners simultaneously.

20. The medical instrument of claim **19**, wherein the fastener holder is a replaceable staple cartridge adapted to be inserted into the staple housing to travel therein with the drive member between retracted and extended positions.

21. The medical instrument of claim **20**, wherein the disc has at least one axially extending post adapted to engage the staple cartridge and prevent angular movement of the cartridge within the staple housing.

22. The medical instrument of claim **21**, further comprising:

a cartridge-side reinforcing ring disposed against the cartridge and having openings for receiving staples therethrough, for attaching the reinforcing ring to the side of stapled tissue facing the cartridge.

23. The medical instrument of claim **18**, further comprising:

an alignment pin carried on one of the first or second members; and

an opening on the other of the first or second members, said pin and opening being positioned such that movement of the fastener piston toward its extended position causes the pin to mate with the opening, thus to engage the two members in axial alignment.

24. The medical instrument of claim **1**, wherein the fastener device is carried at the distal end of a shaft carrying hydraulic fluid to the device, wherein the first and second members are proximal and distal members, respectively, with the shaft being operatively connected to the proximal member of the device.

* * * * *

专利名称(译)	内窥镜缝合装置和方法		
公开(公告)号	US7708181	公开(公告)日	2010-05-04
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[标]申请(专利权)人(译)	COLE DAVID ANDREW SMITH		
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外部链接	Espacenet USPTO		

摘要(译)

本文描述了用于将一个或多个紧固件施加到身体组织的内窥镜缝合器。在一个实施例中，紧固件施加装置（优选为吻合器）经口部通入胃中并用于通过从胃内部接合组织并将其向内拉入而使胃组织复位。在所公开的实施例中，组织被向内抽入真空室，使得胃外部上的浆膜组织的部分彼此面对地定位。所公开的订书机允许组织的相对部分移动成彼此接触，并且优选地递送钉以维持组织部分之间的接触，至少直到它们之间形成浆膜结合。这些步骤中的每一个可以完全从胃内部进行，因此可以消除对任何手术或腹腔镜介入的需要。在形成一个或多个褶皱之后，可任选地将医疗装置连接到褶皱以保留在胃内。