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(54) **TISSUE RECONFIGURATION**

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(73) Assignee: **ndo Surgical, Inc., a Massachusetts corporation**

(21) Appl. No.: **10/819,965**

(22) Filed: **Apr. 8, 2004**

Related U.S. Application Data

(63) Continuation of application No. 09/859,579, filed on May 18, 2001, which is a continuation-in-part of application No. 09/574,424, filed on May 19, 2000, now Pat. No. 6,494,888, which is a continuation-in-part of application No. 09/520,273, filed on Mar. 7, 2000, now Pat. No. 6,663,639, and which is a continuation-in-part of application No. 09/519,945, filed on Mar. 7, 2000, now Pat. No. 6,506,196.

(60) Provisional application No. 60/140,492, filed on Jun. 22, 1999.

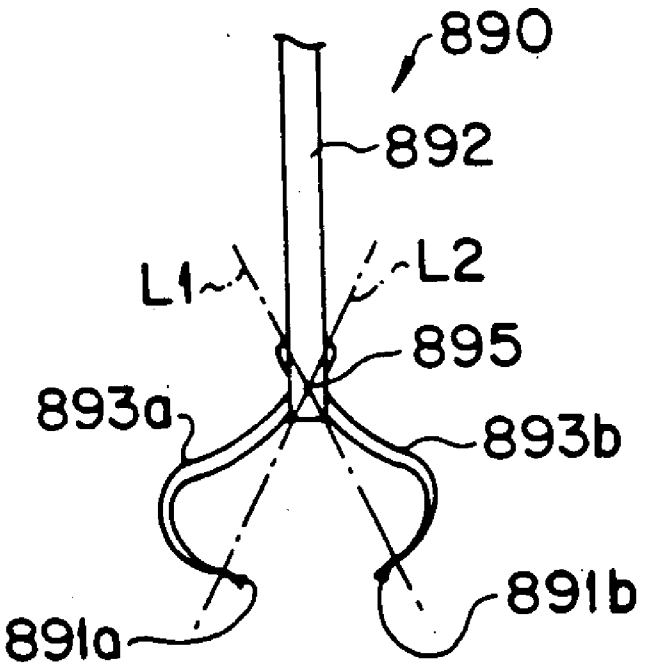
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/08**

(52) **U.S. Cl.** **604/222**; 606/153

(57) **ABSTRACT**

A medical instrument for engaging tissue includes a flexible shaft, a tissue piercing coil at a distal portion of the shaft, and a tissue stabilizer positioned over the shaft and biased in a distal direction such that as the tissue piercing coil enters tissue, the tissue stabilizer is urged against a surface of the tissue. A medical instrument for reconfiguring tissue includes a flexible shaft defining a lumen housing actuating controls, and a distal actuating assembly with a sealing portion configured to substantially seal the shaft lumen from contact with bodily fluids. A cartridge assembly includes first and second members configured for releasable attachment to a medical instrument, and a holder configured to receive the first and second members and to be released from the first and second members upon action of the first and second members attaching to the medical instrument.



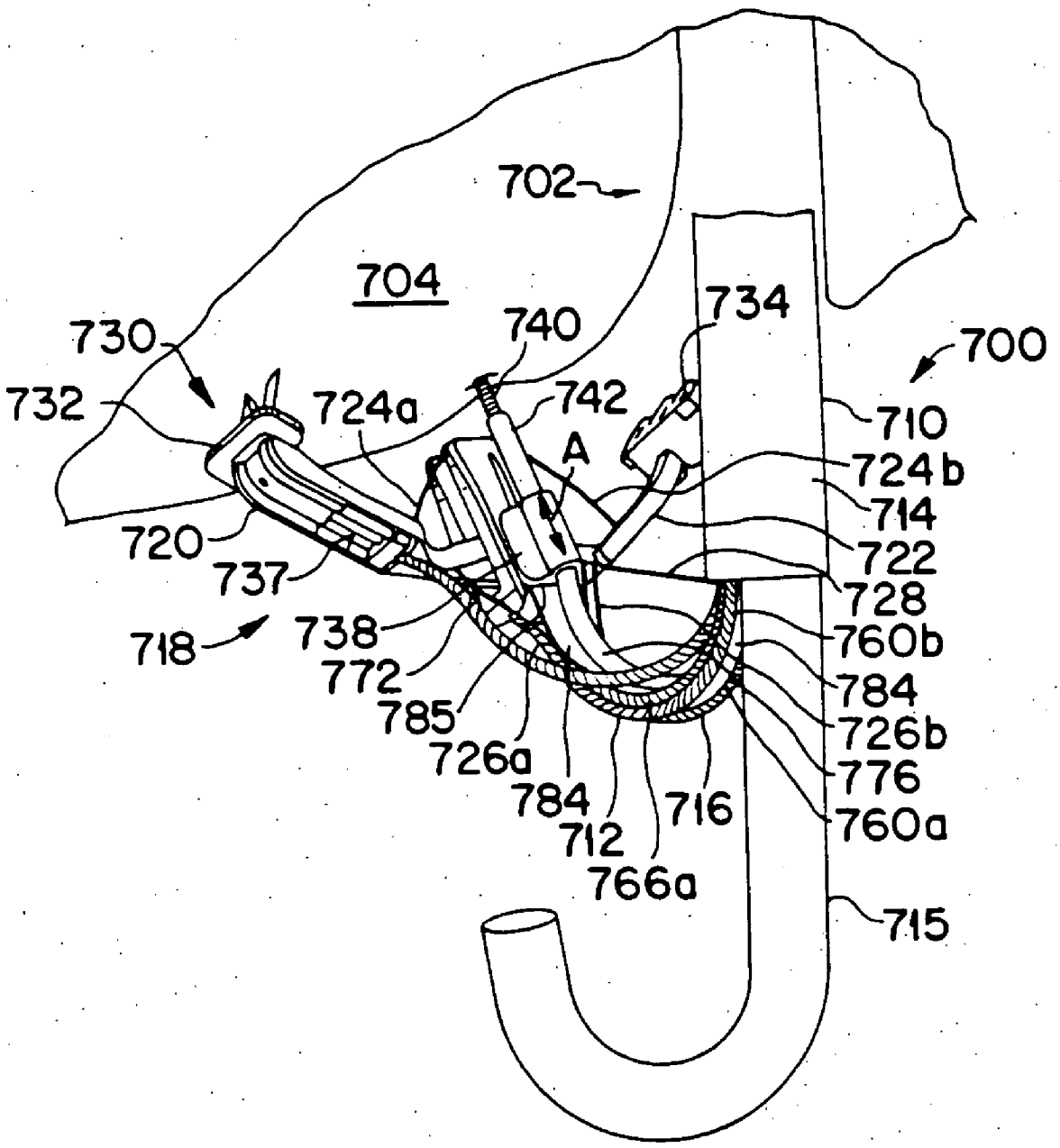

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FIG. 1

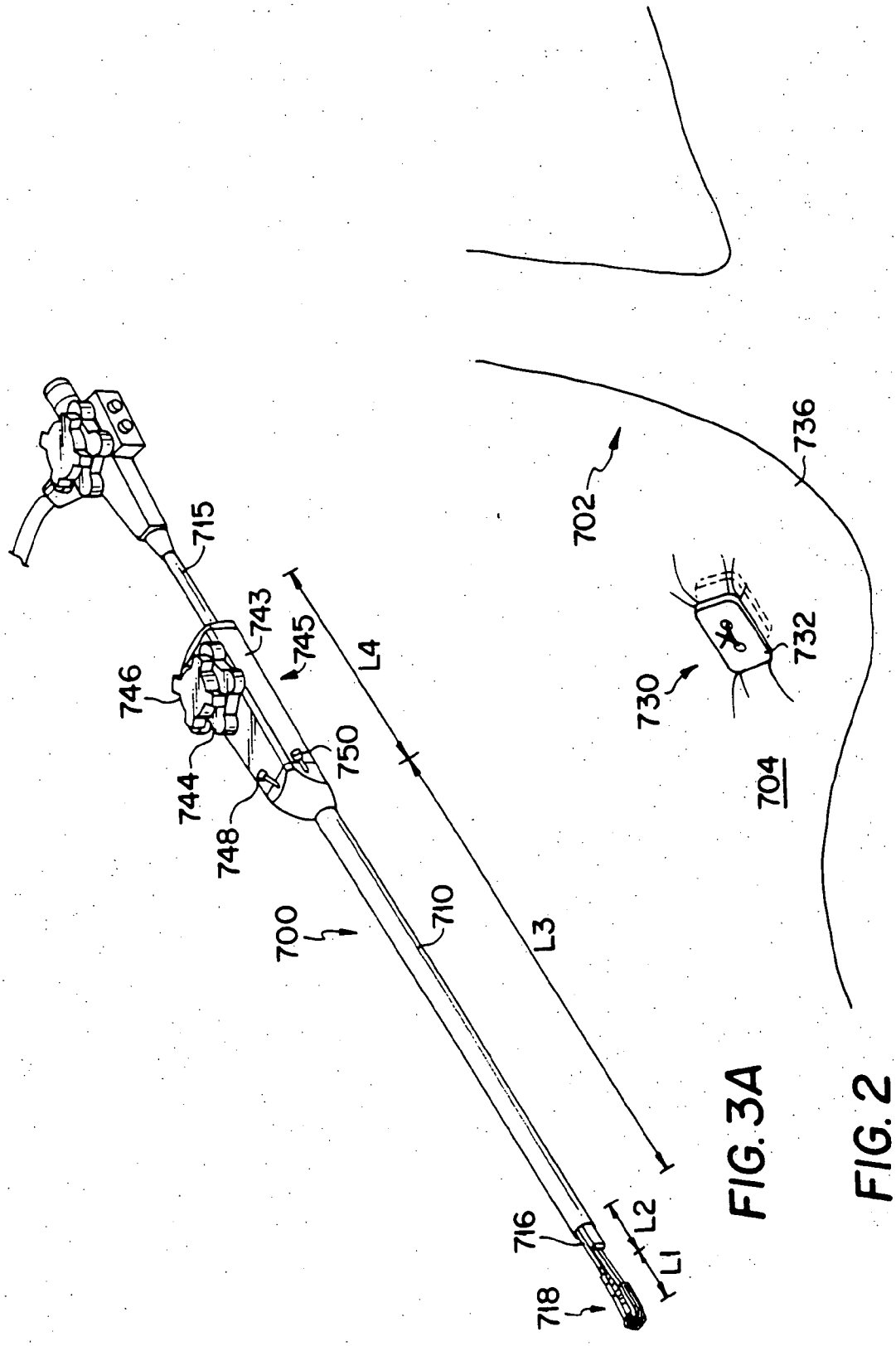

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FIG. 3A

FIG. 2

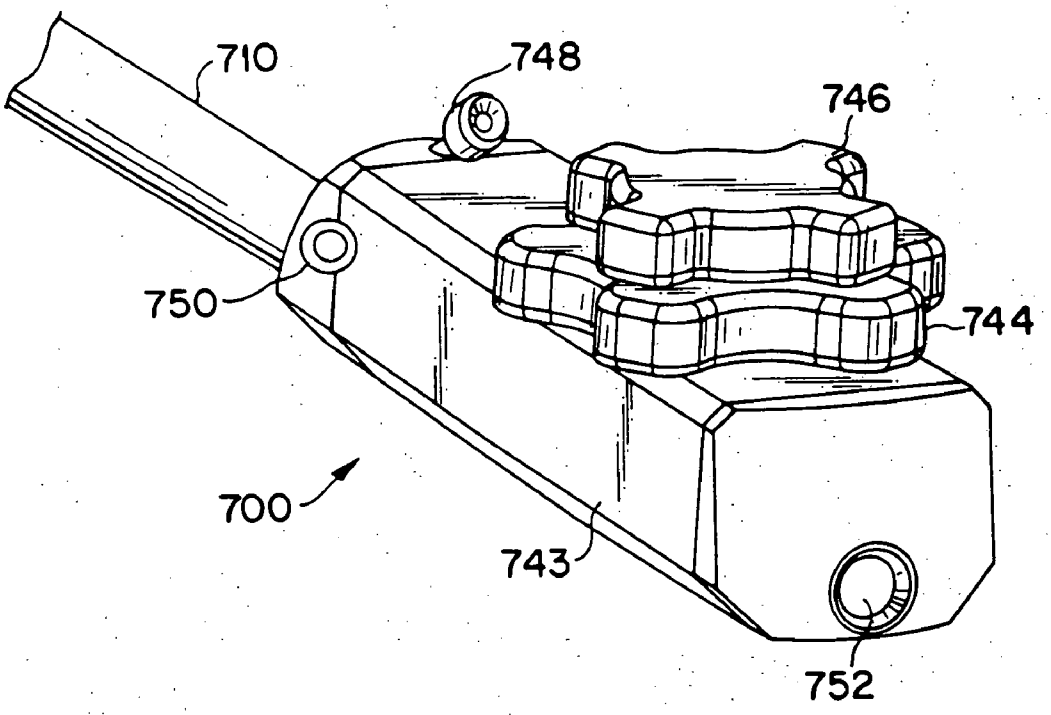


FIG. 3B

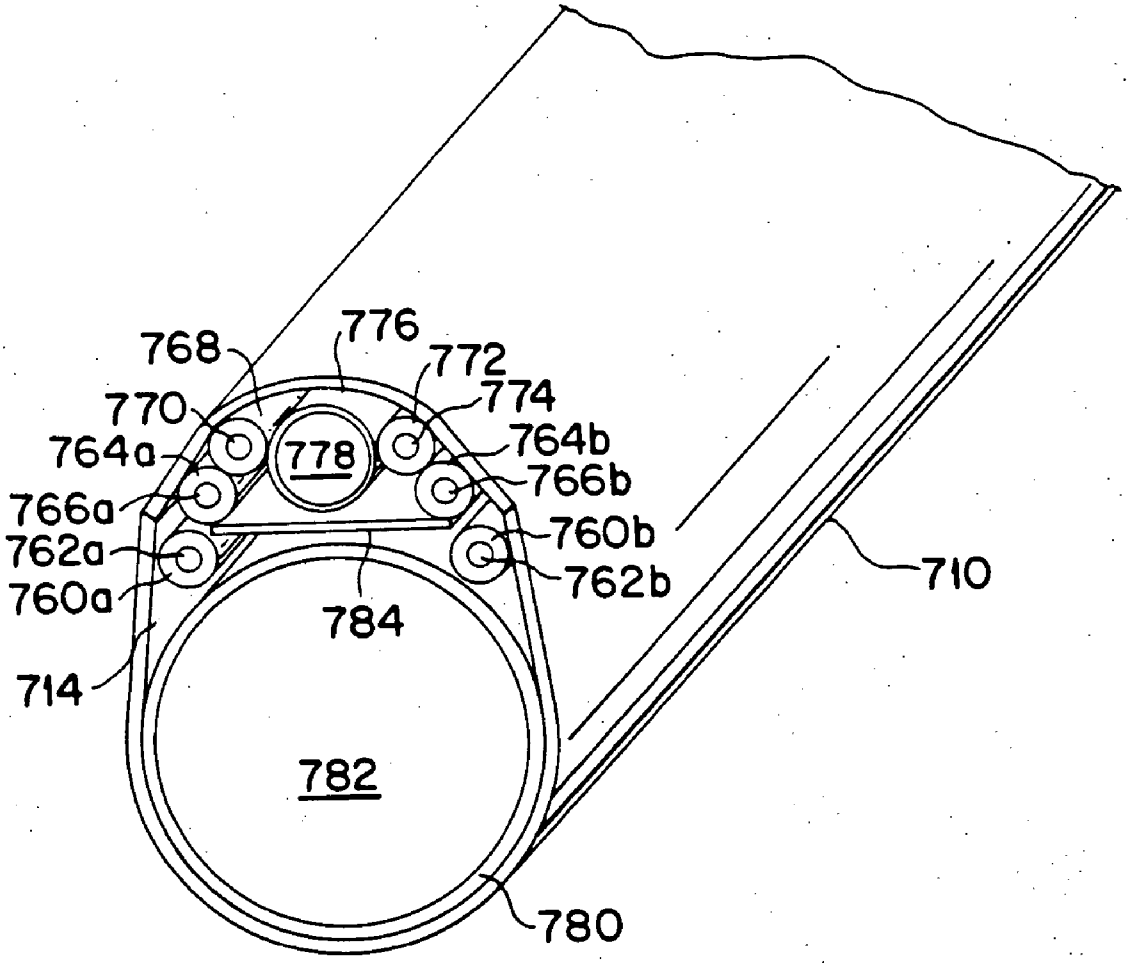

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FIG. 3C

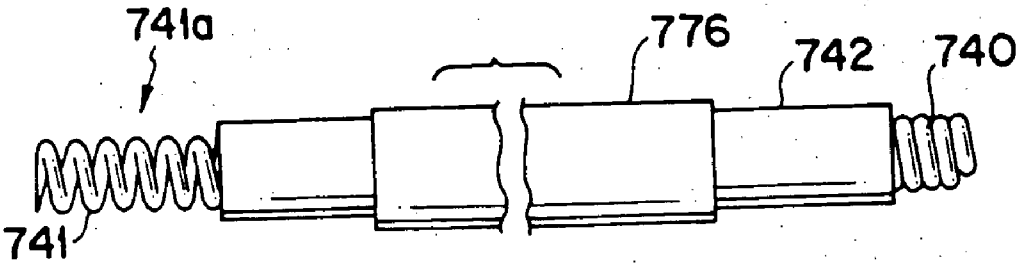

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FIG. 3D

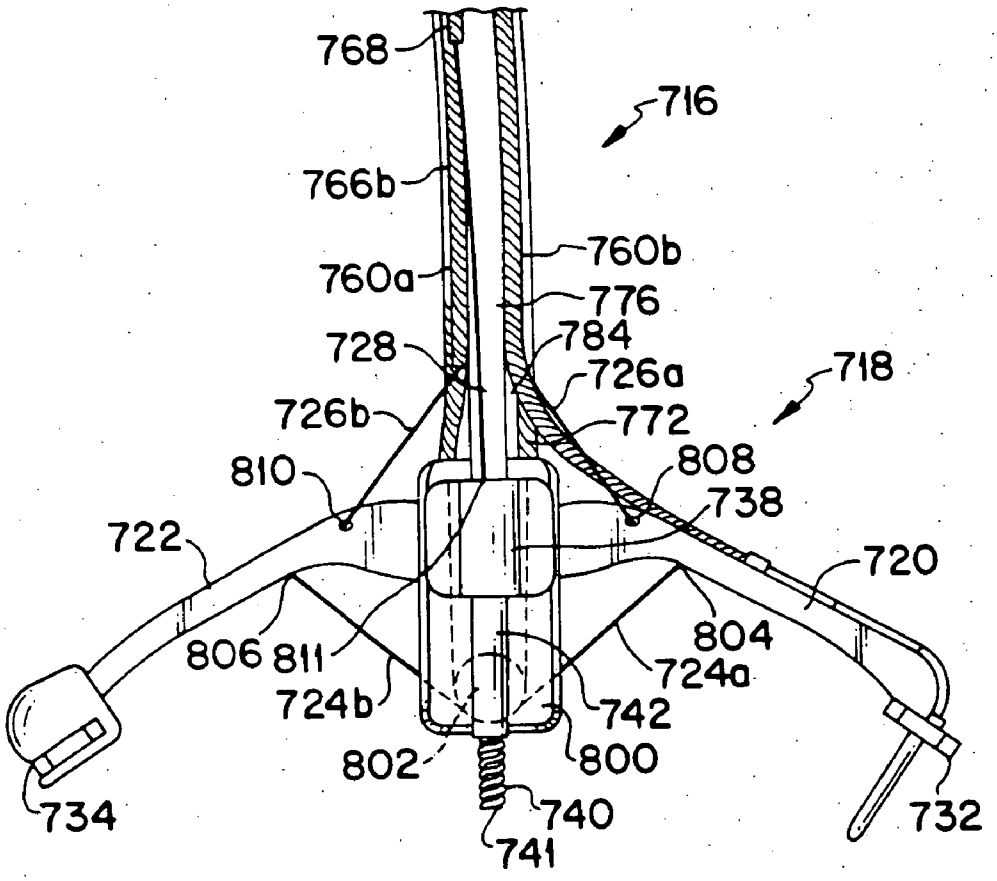

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FIG. 4A

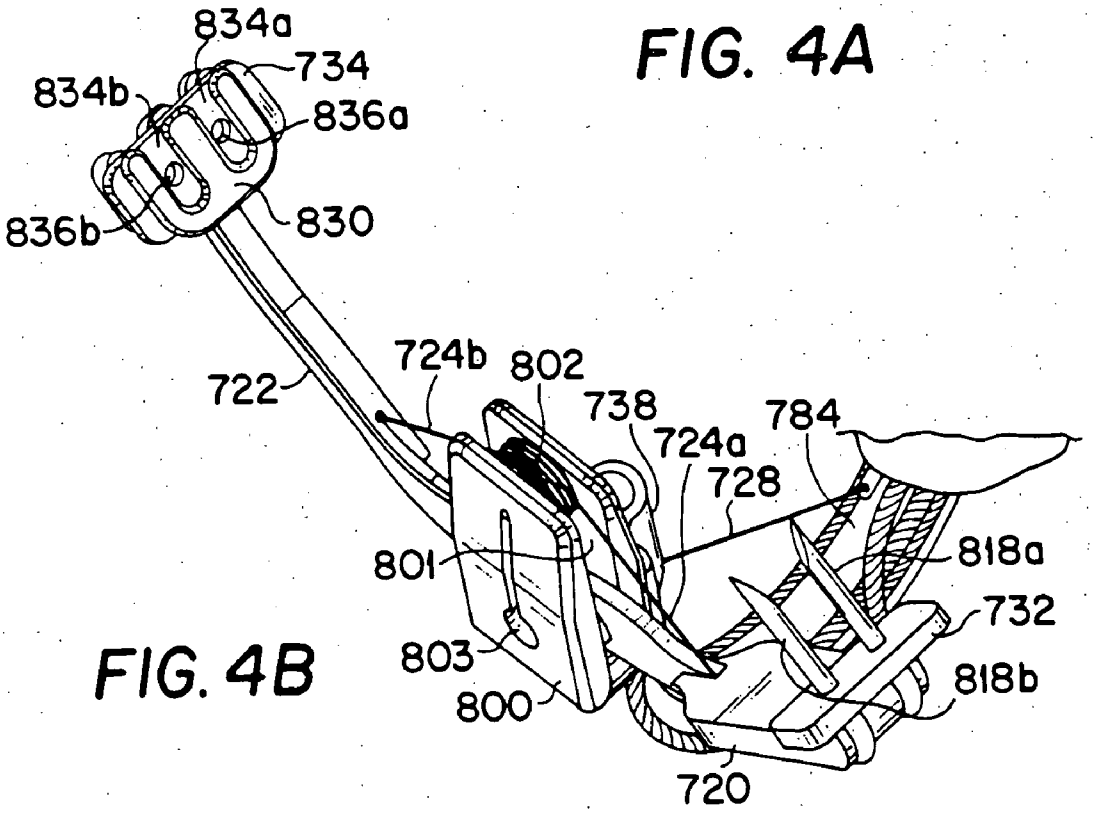

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FIG. 4B

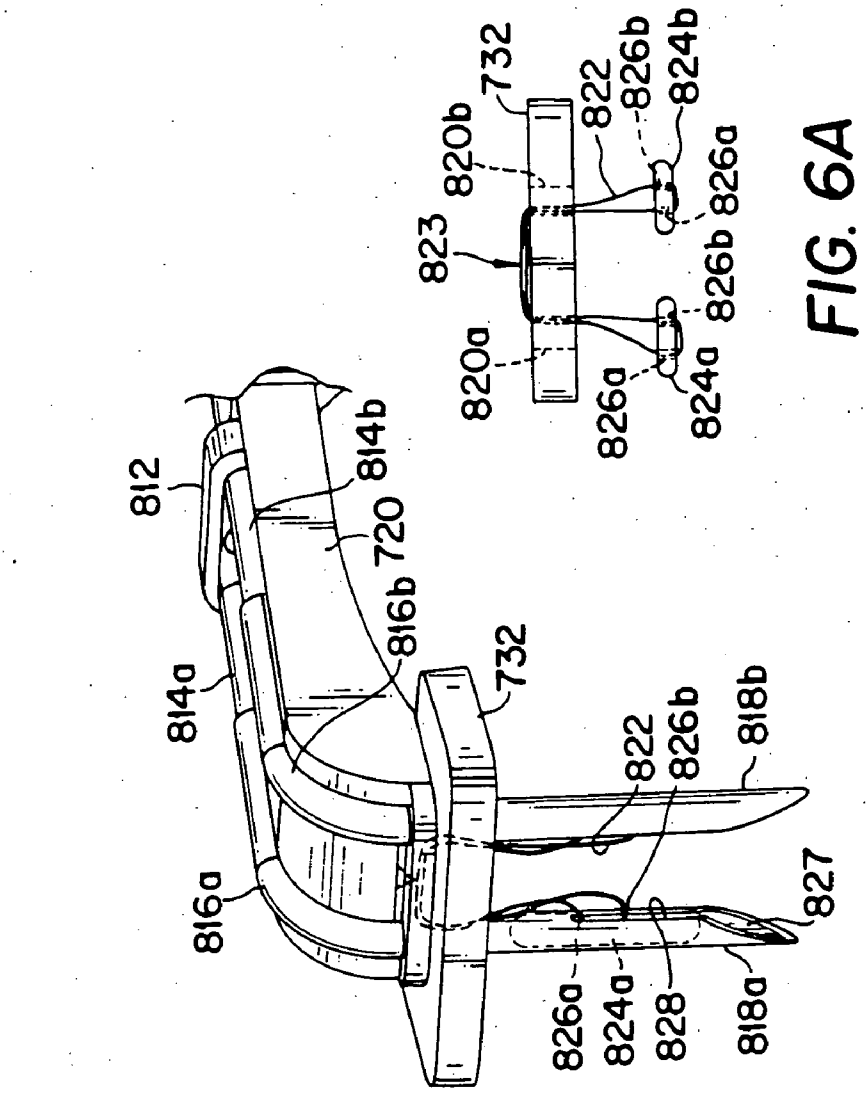


FIG. 6A

FIG. 6B

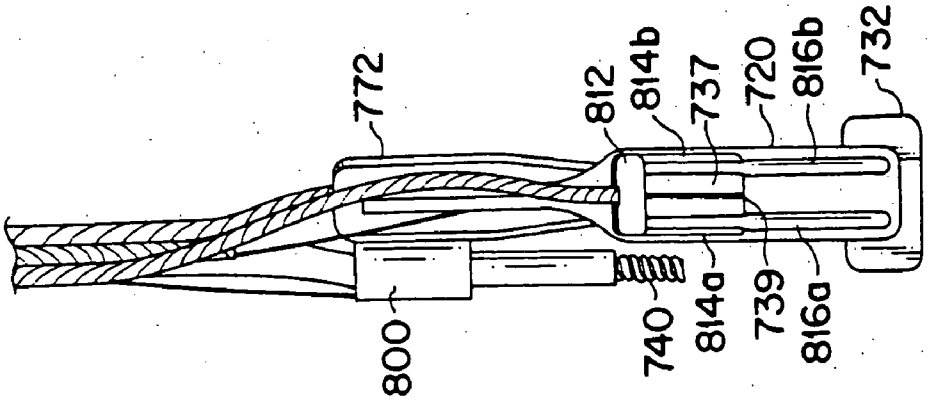


FIG. 5

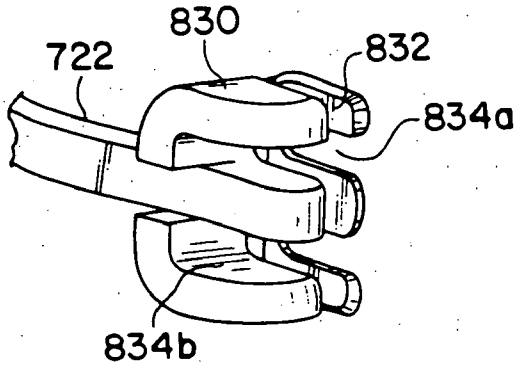


FIG. 7

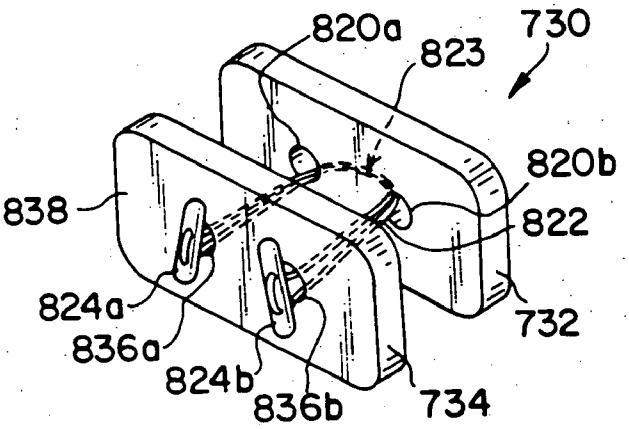


FIG. 8

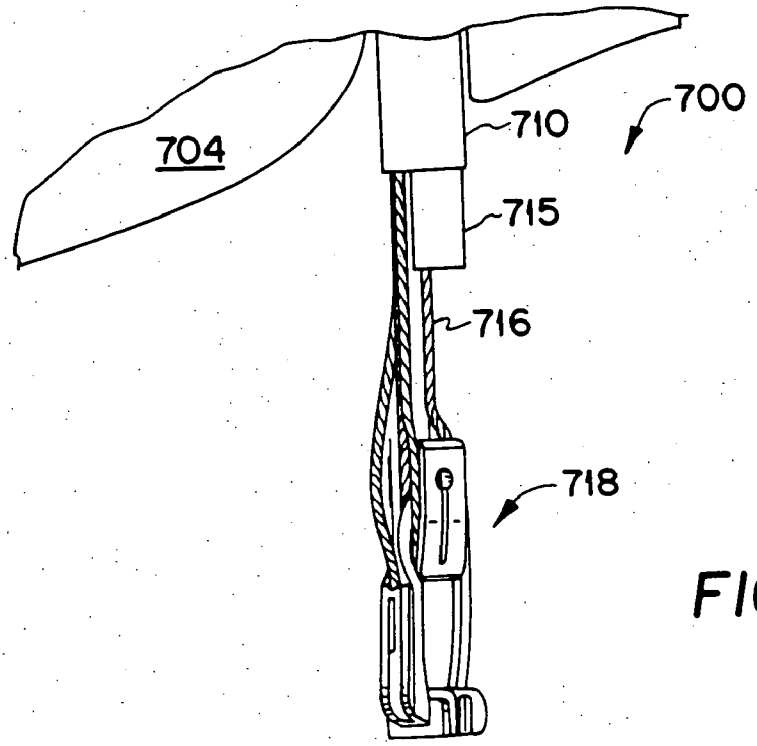


FIG. 9A

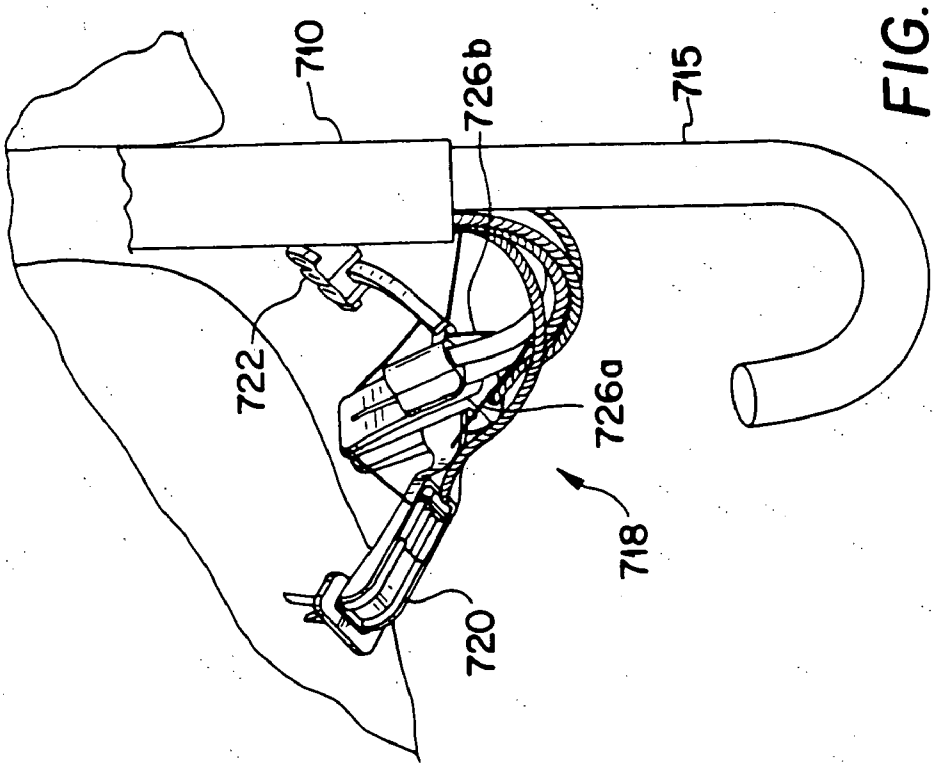


FIG. 9C

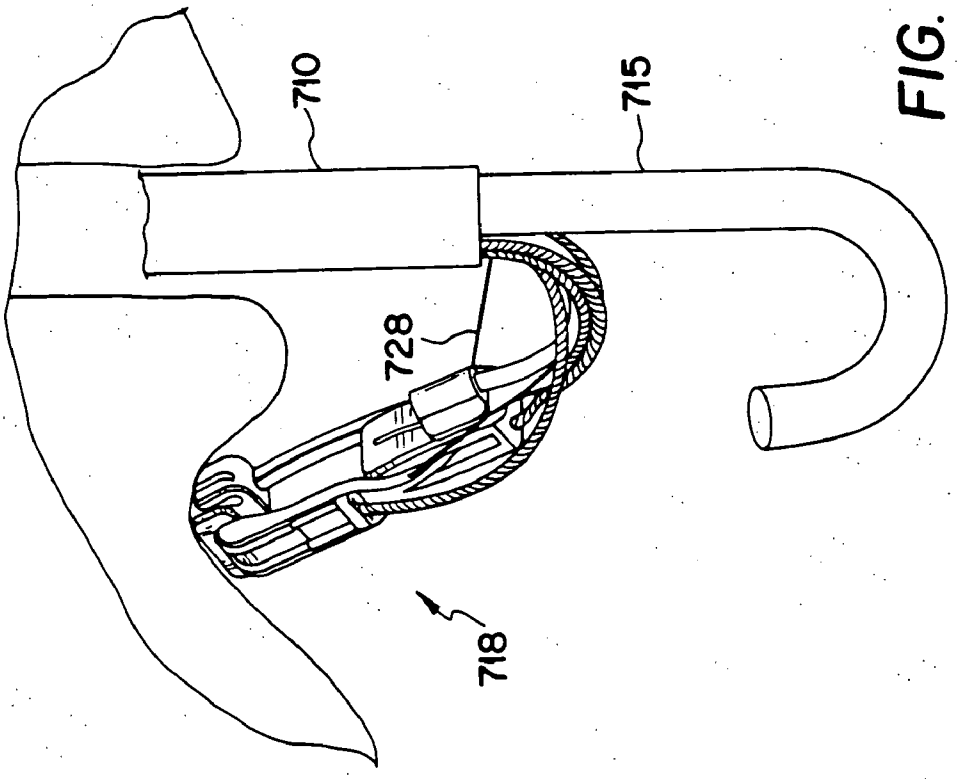


FIG. 9B

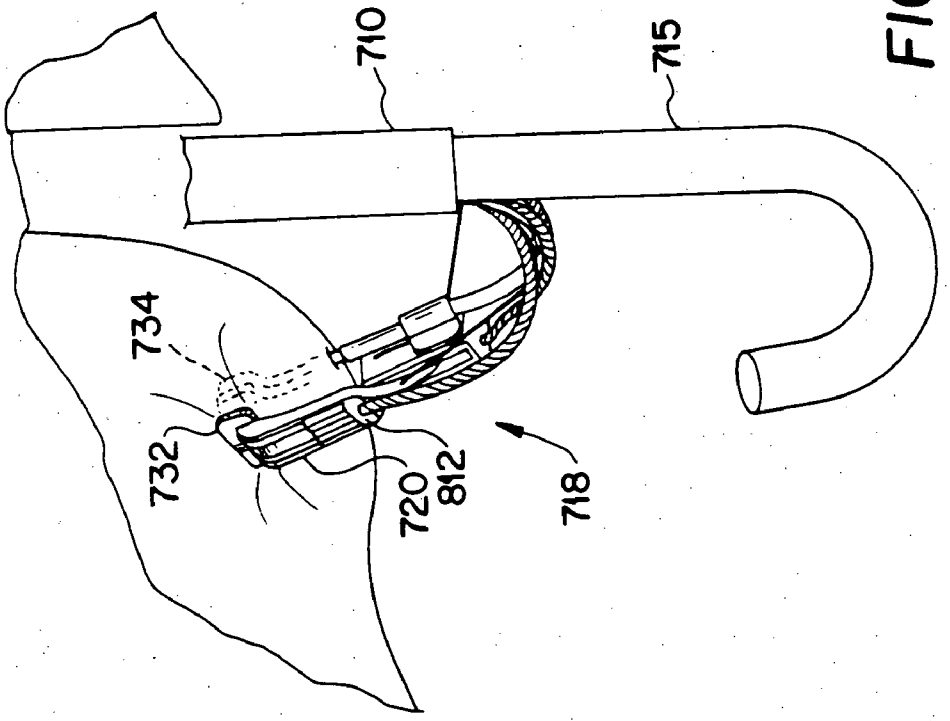

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FIG. 9E

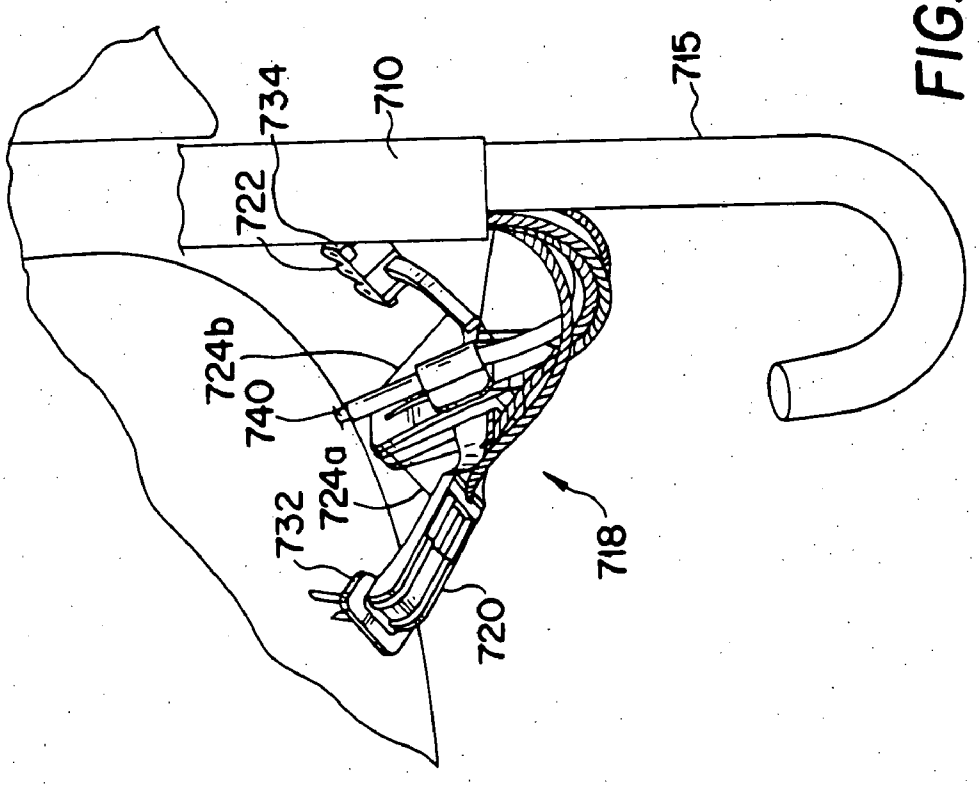

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FIG. 9D

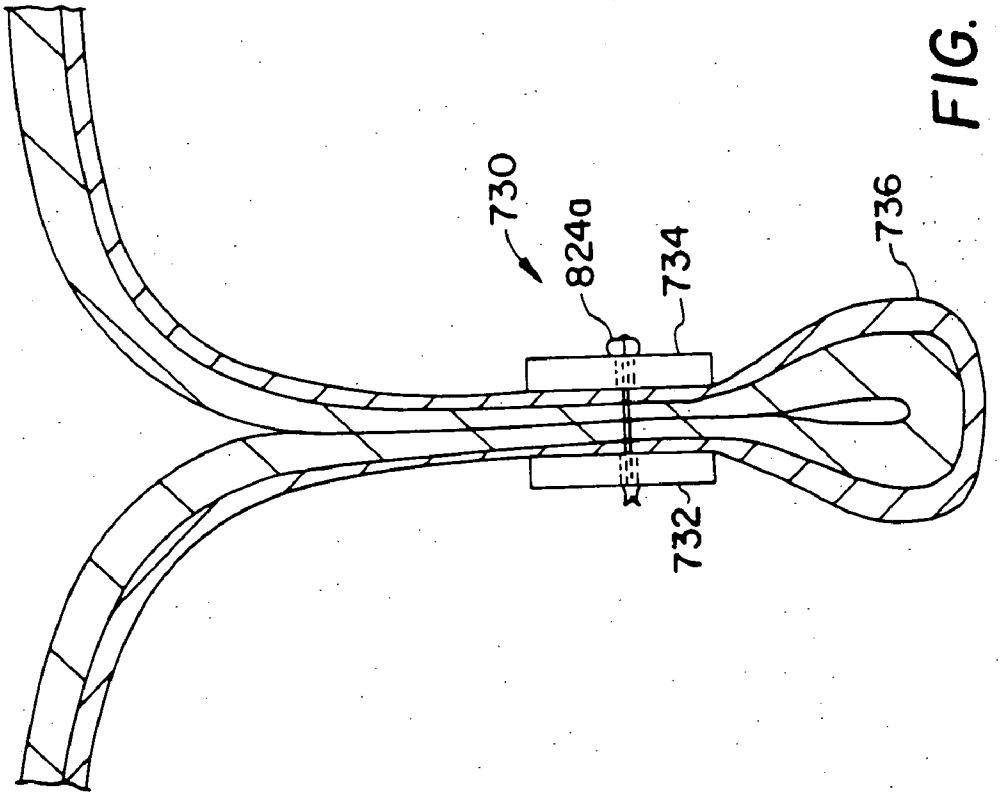


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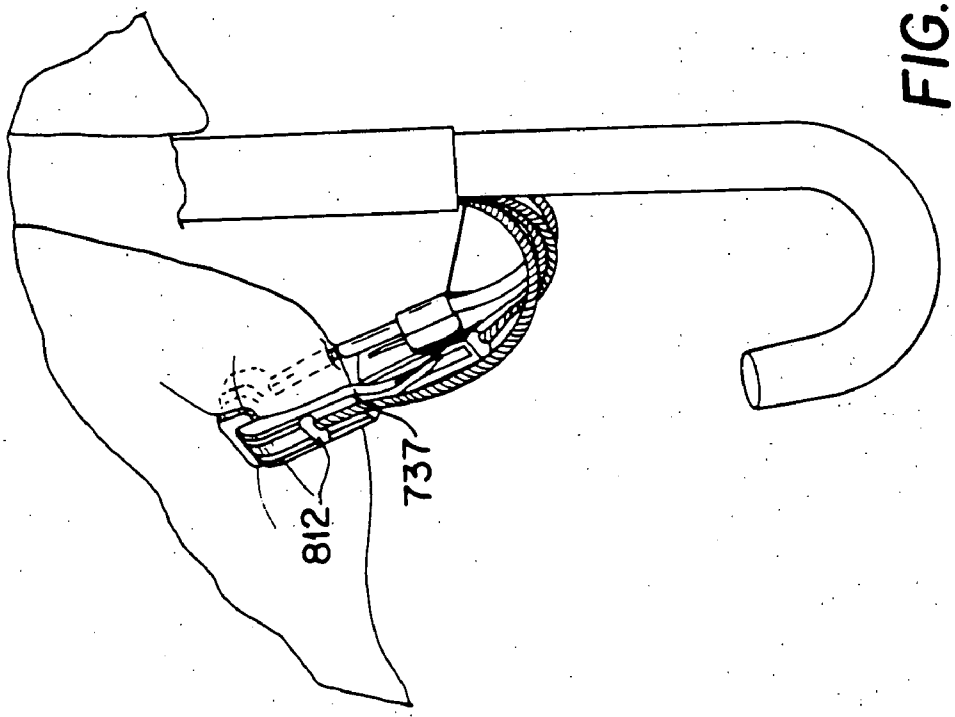


FIG. 9F

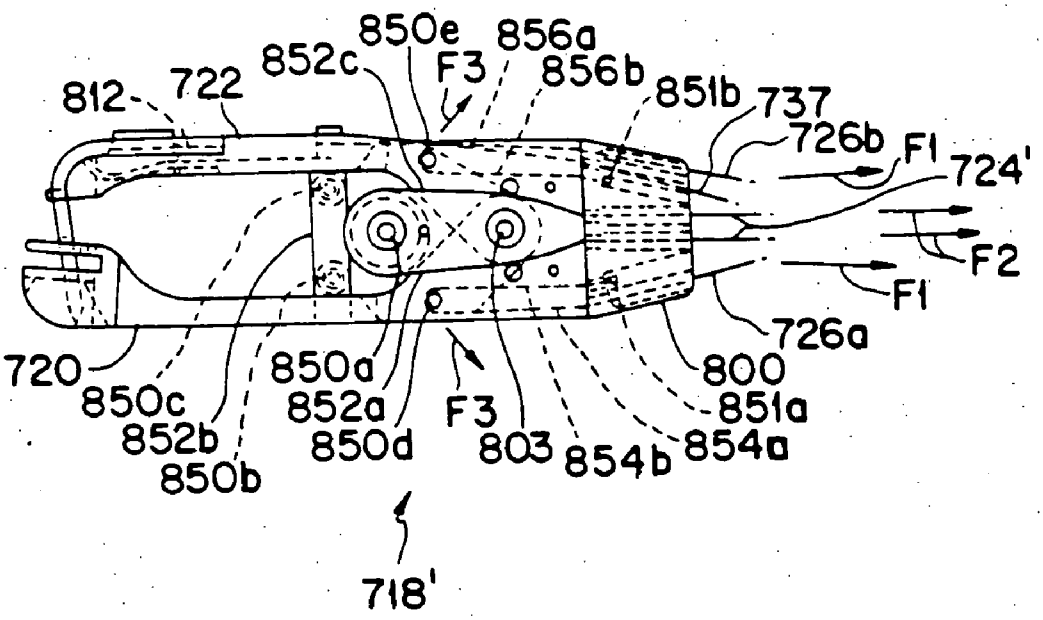


FIG. 11A

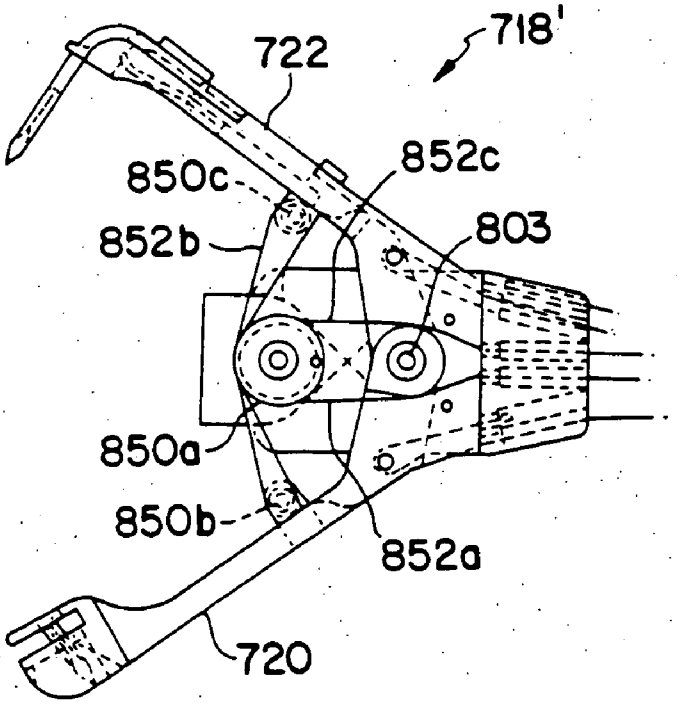


FIG. 11B

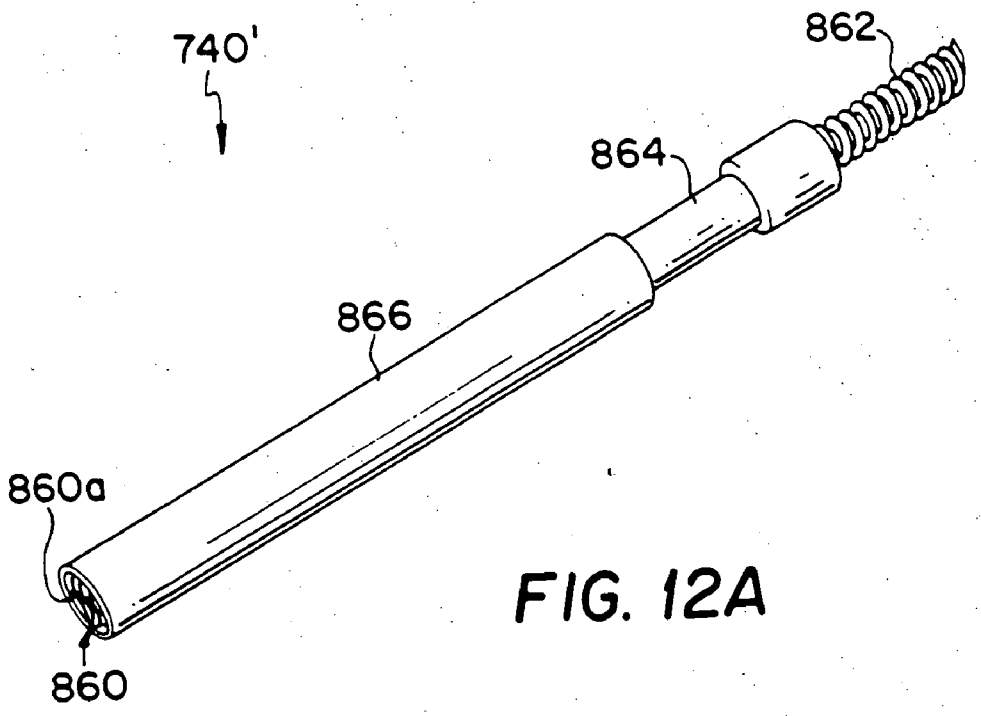


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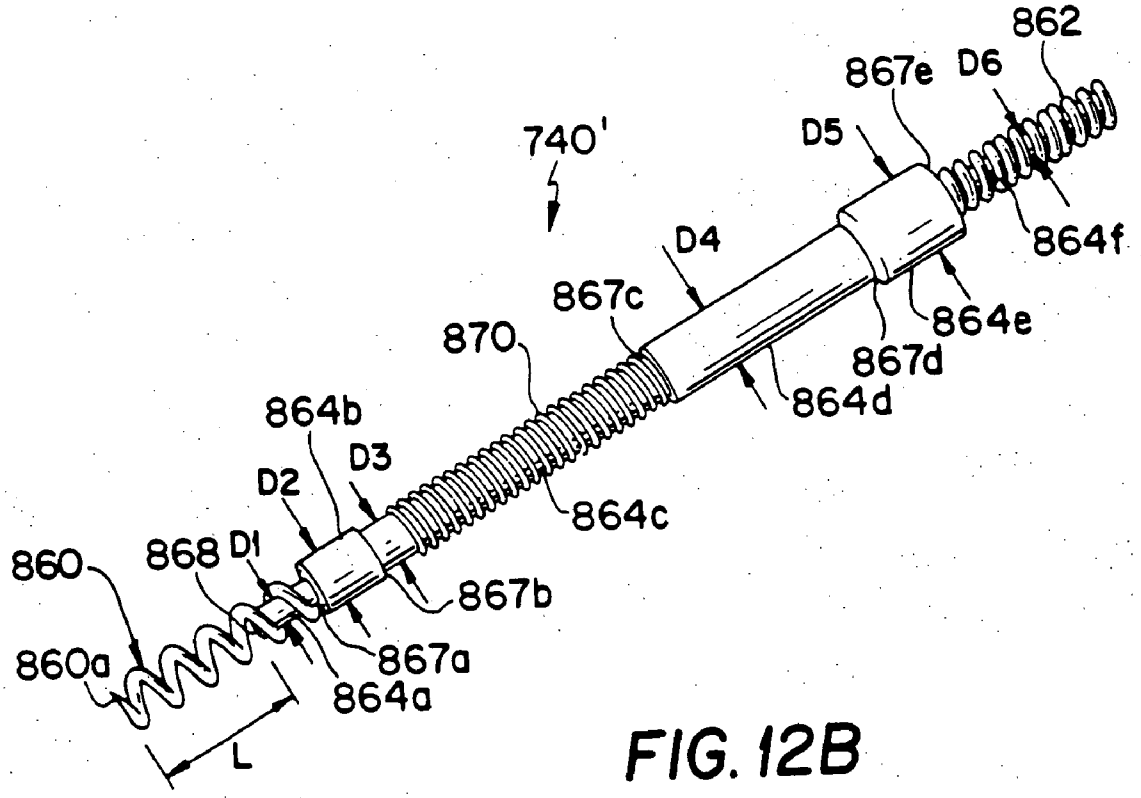


FIG. 12B

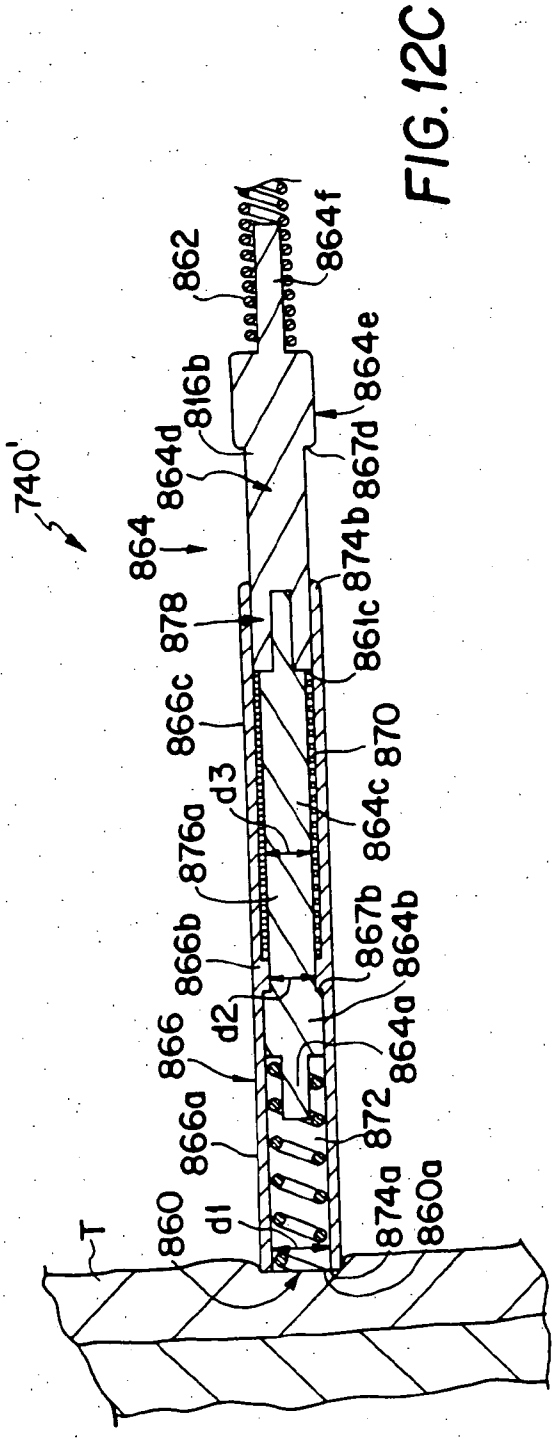


FIG. 12C

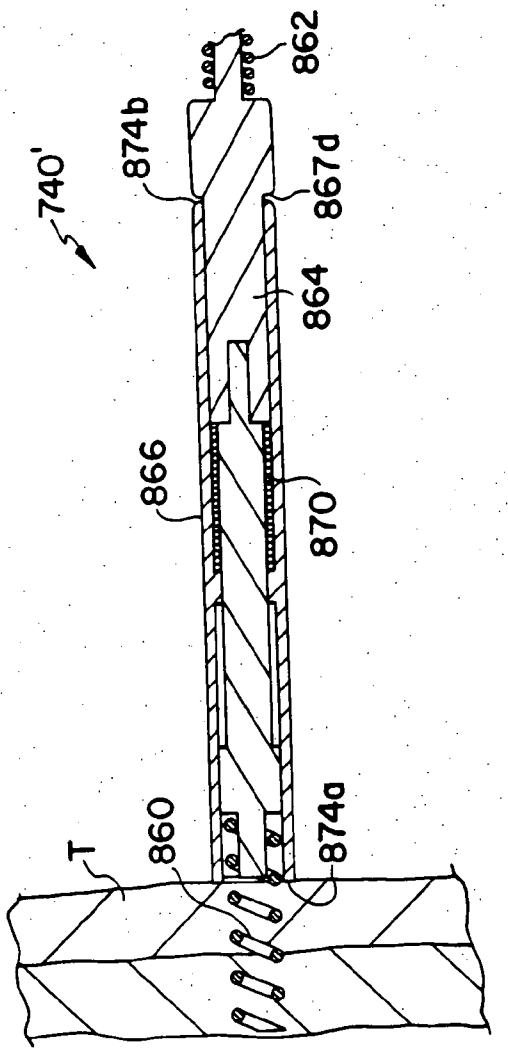


FIG. 12D

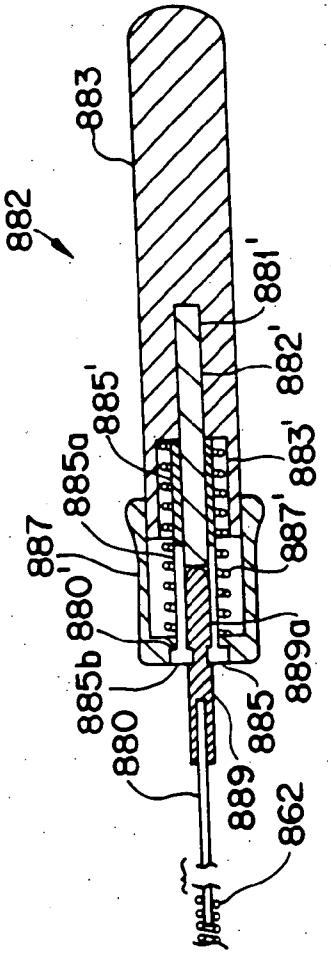


FIG. 13B

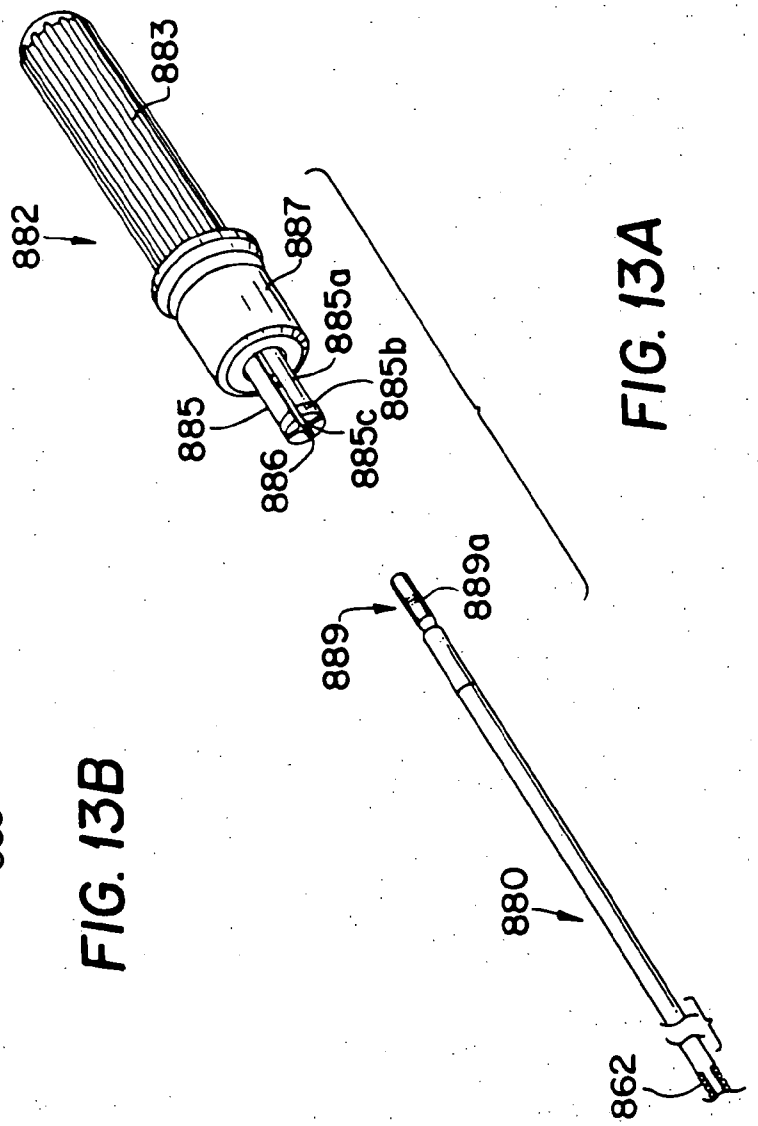


FIG. 13A

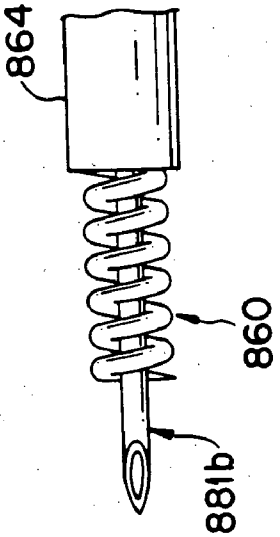


FIG. 14B

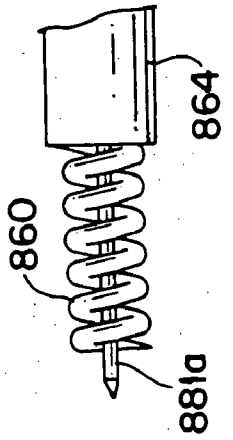


FIG. 14A

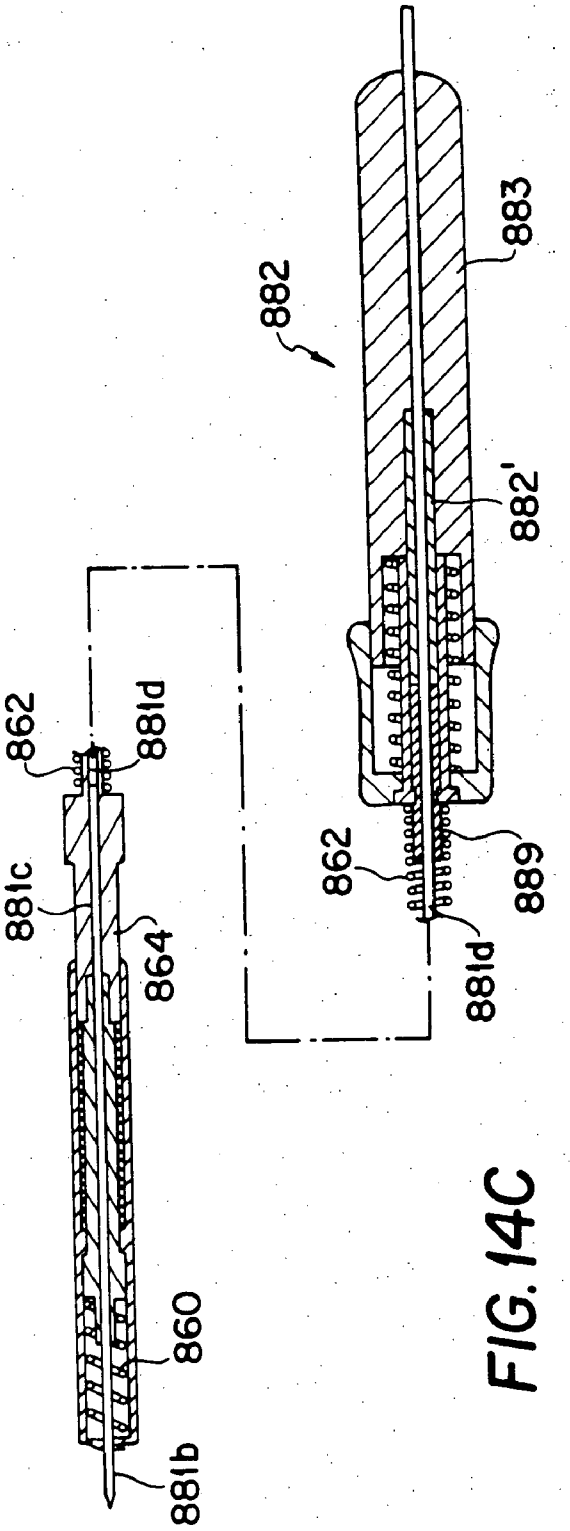


FIG. 14C

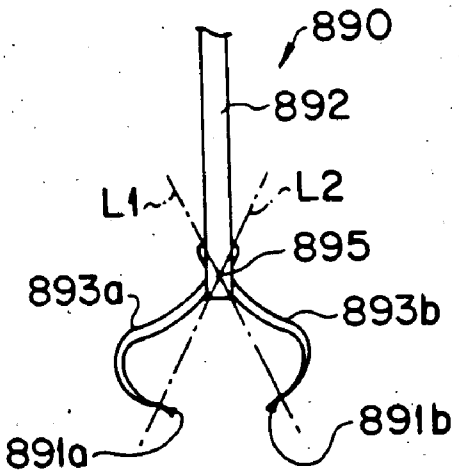


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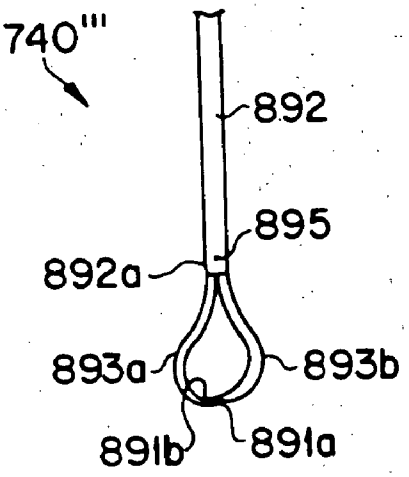


FIG. 15B

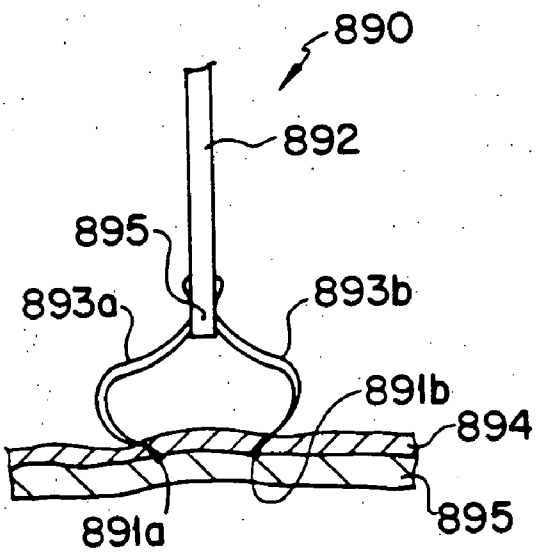


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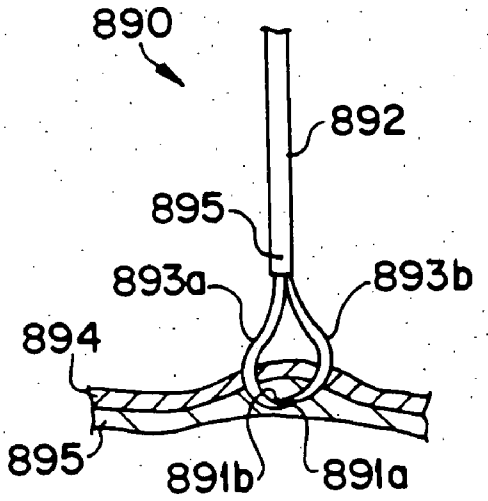


FIG. 15D

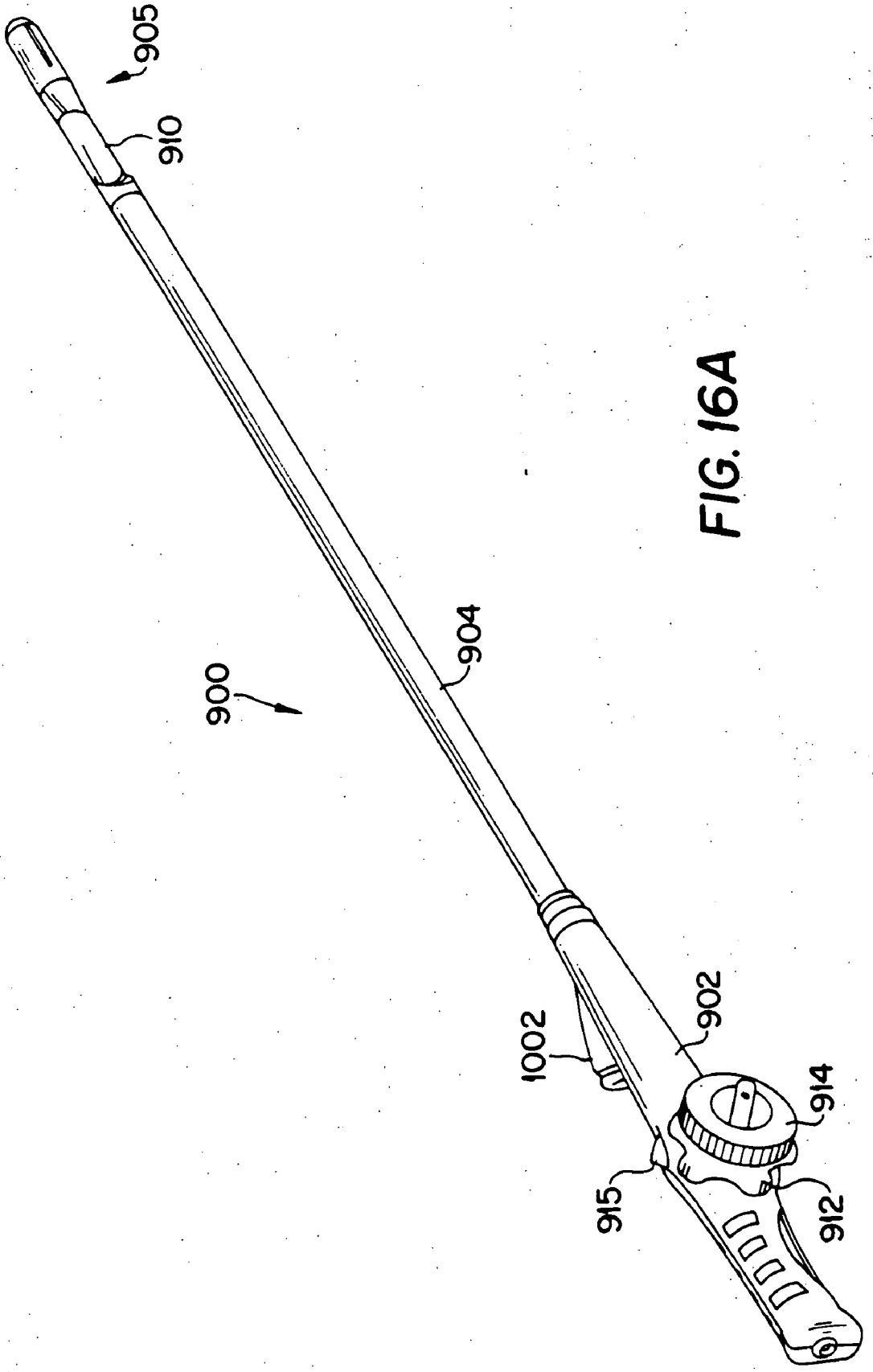


FIG. 16A

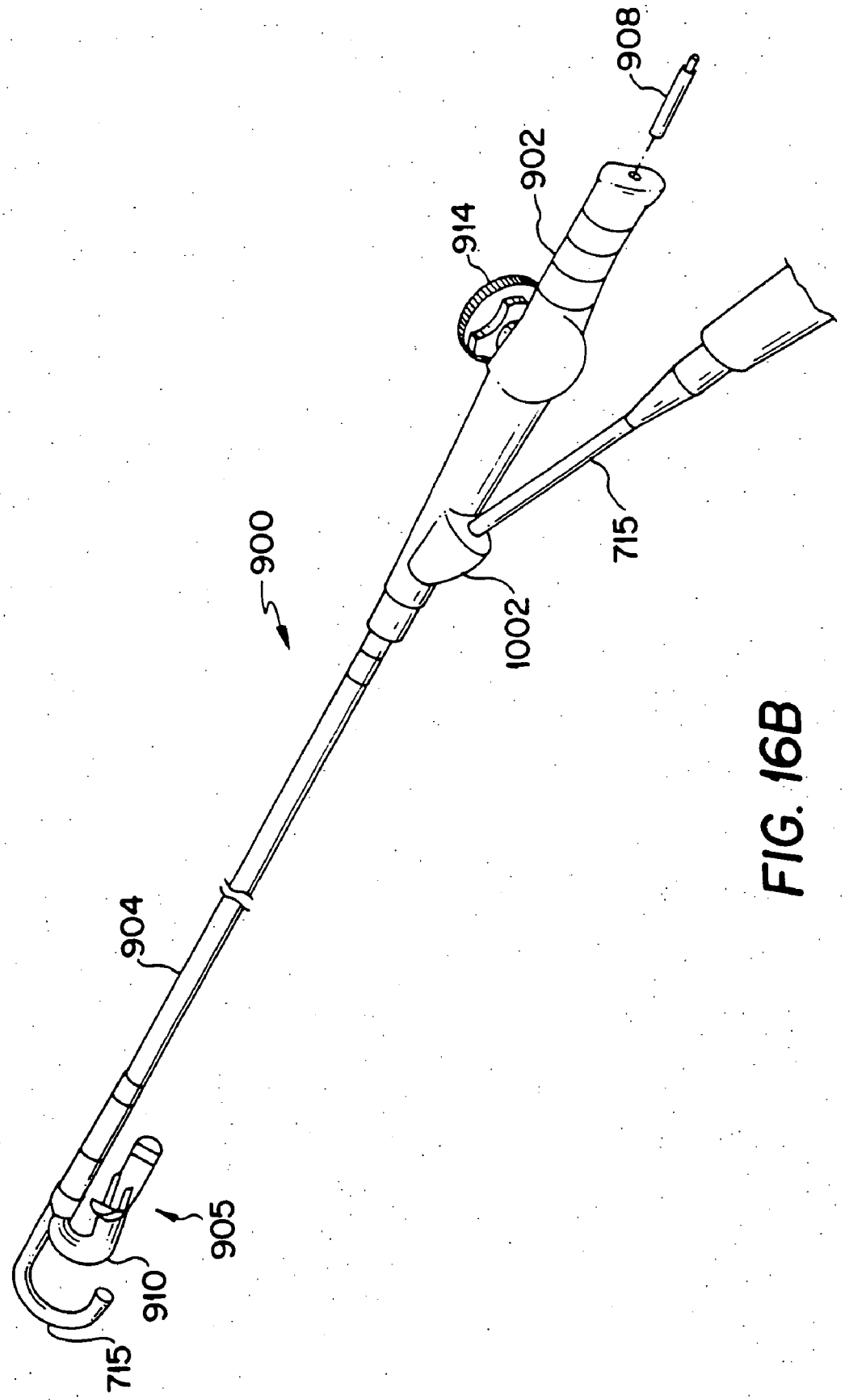


FIG. 16B

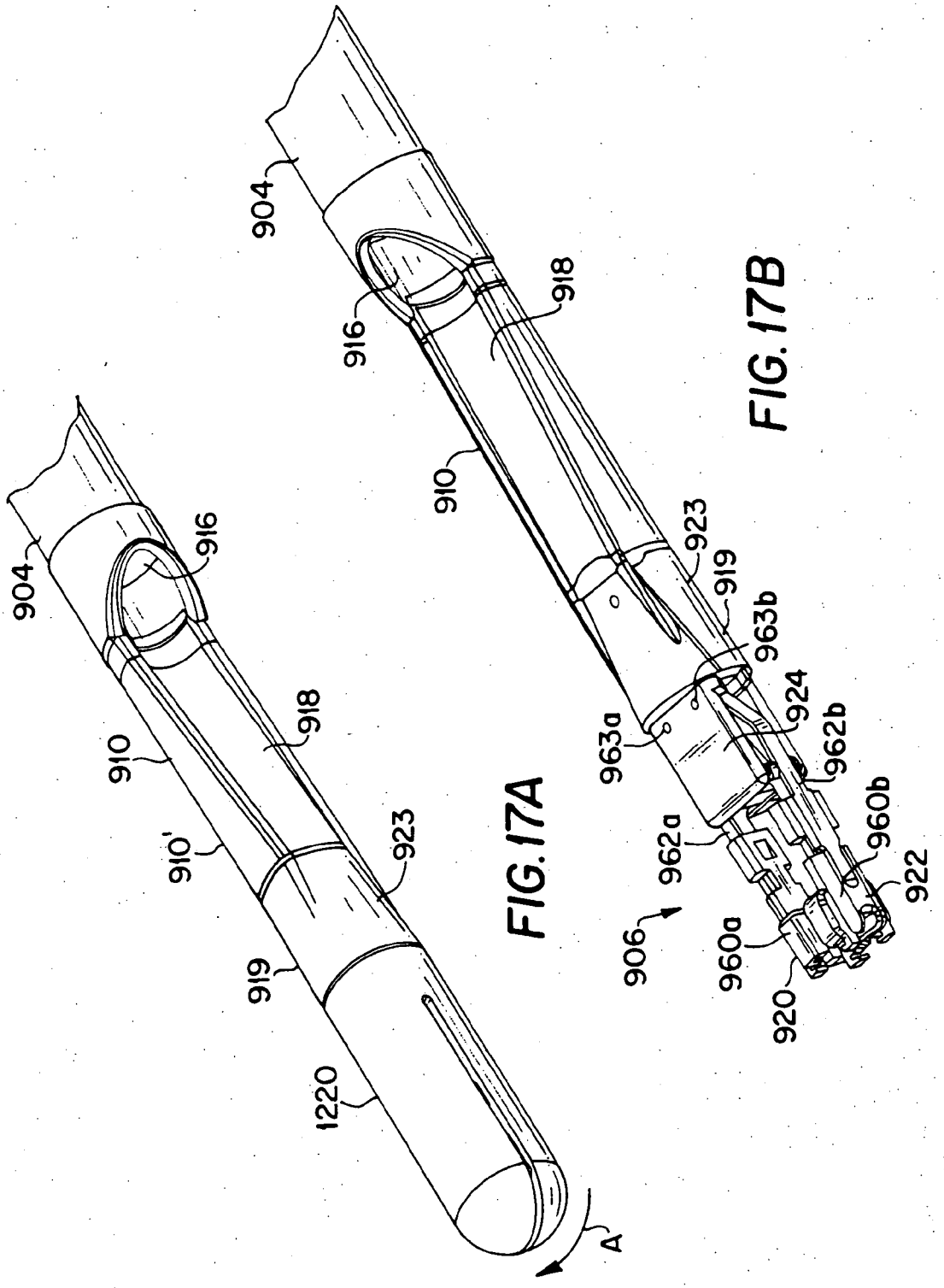


FIG. 17A

FIG. 17B

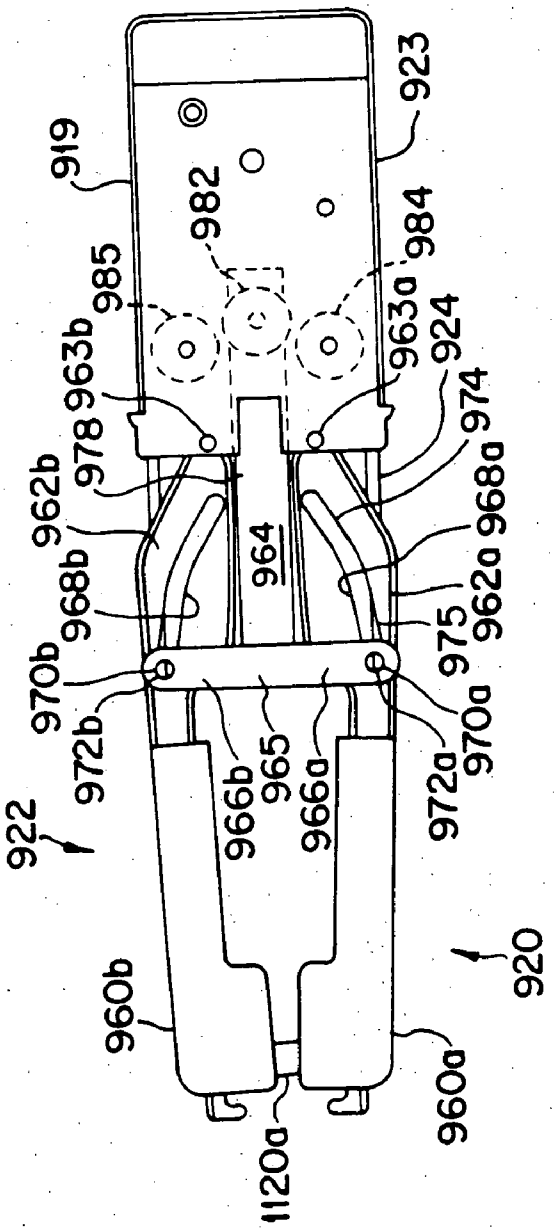


FIG. 17C

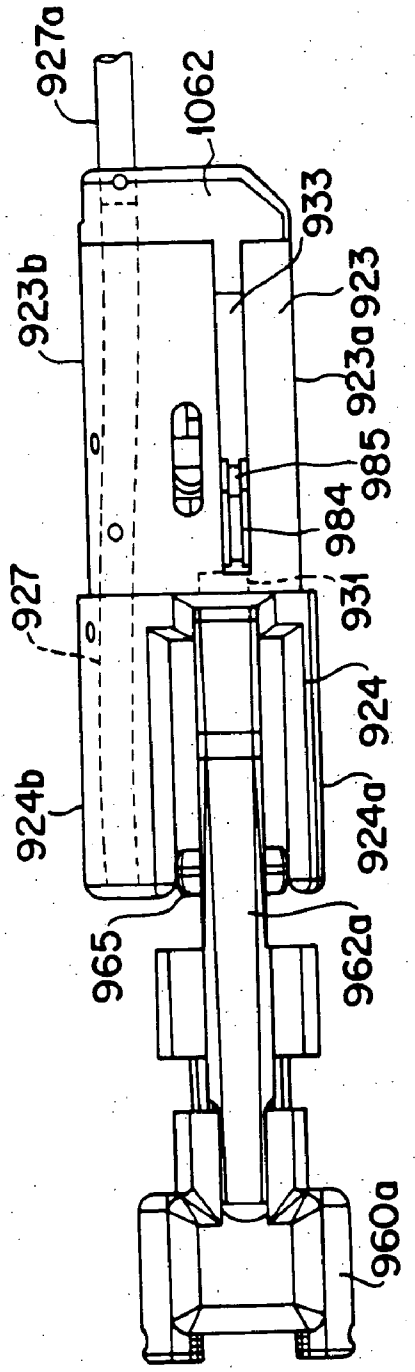


FIG. 17D

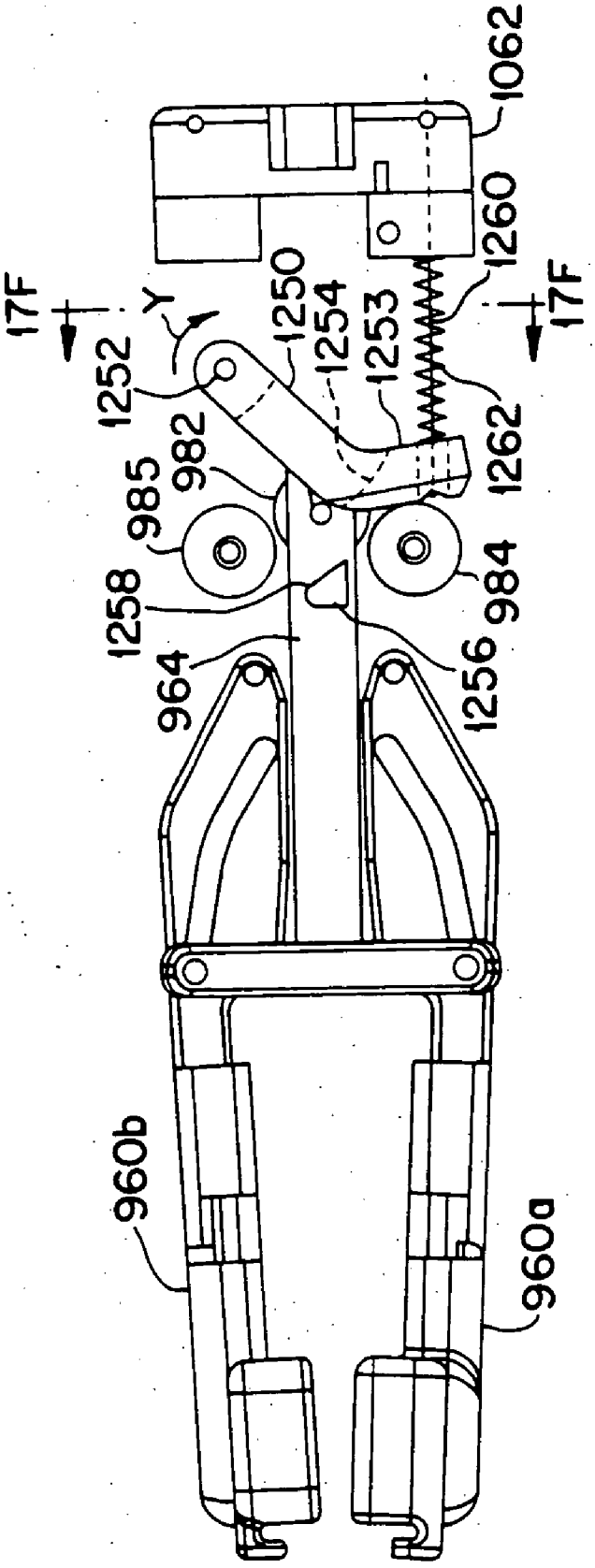


FIG. 17E



FIG. 17F

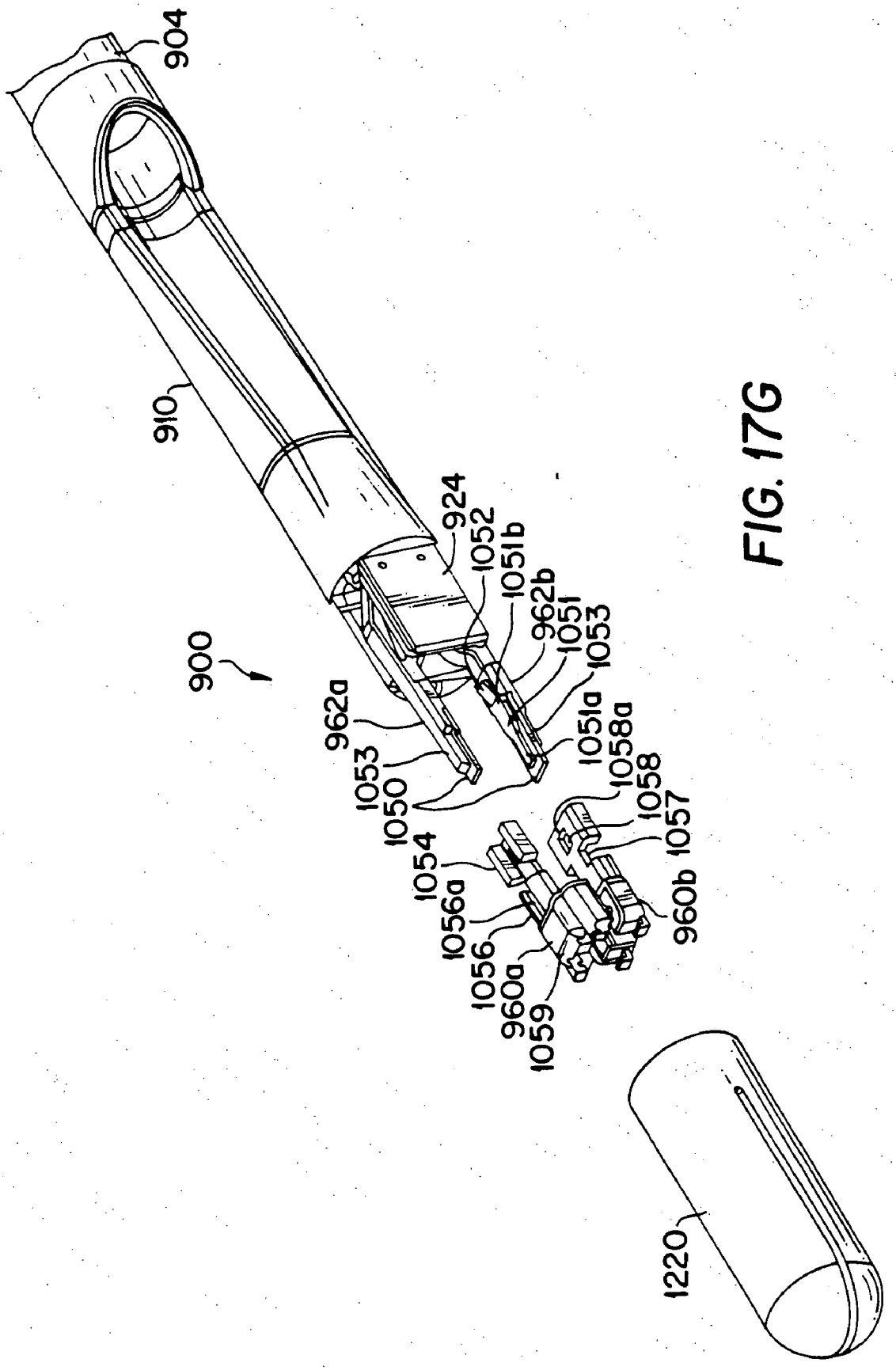

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FIG. 17G

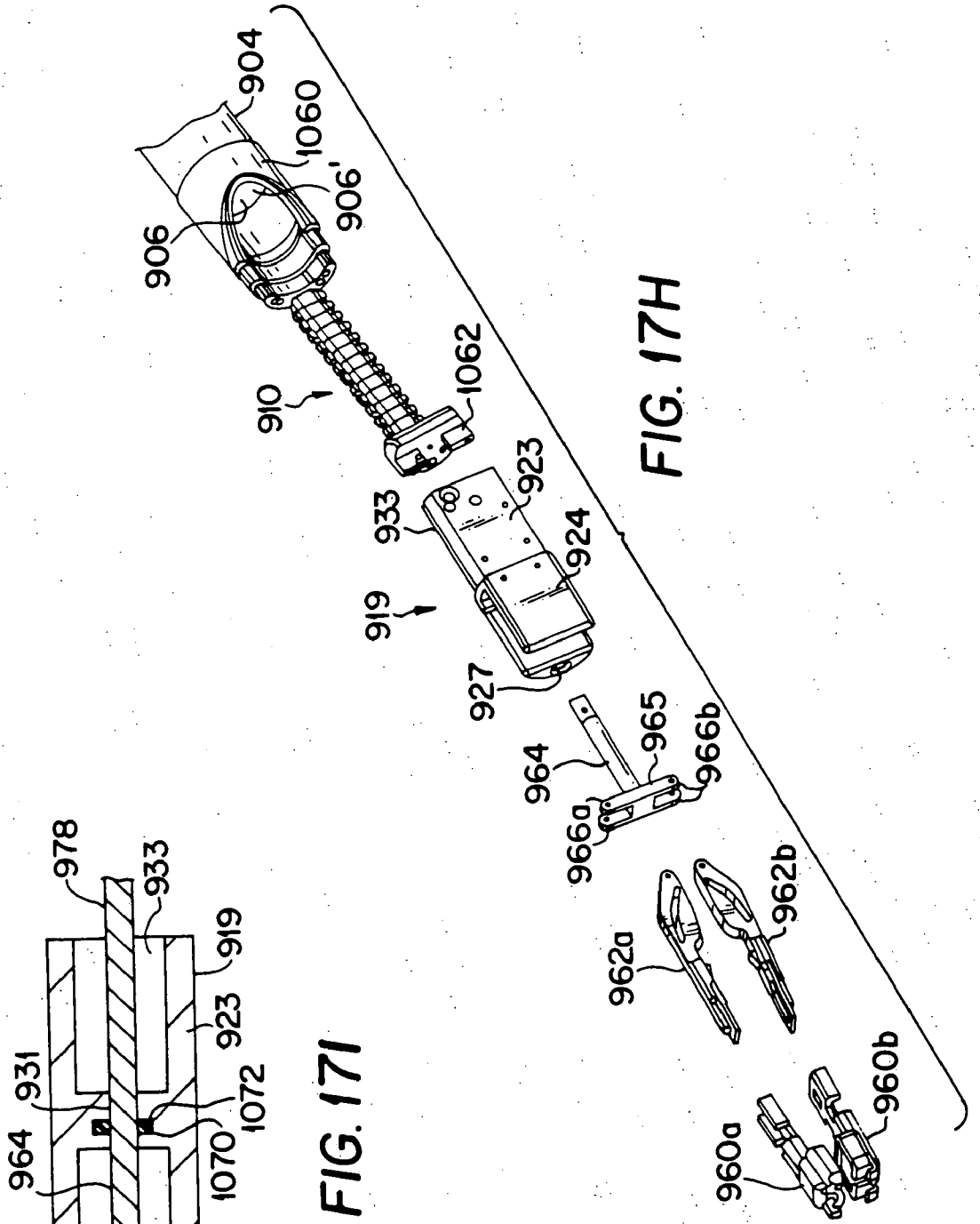


FIG. 17H

FIG. 17I

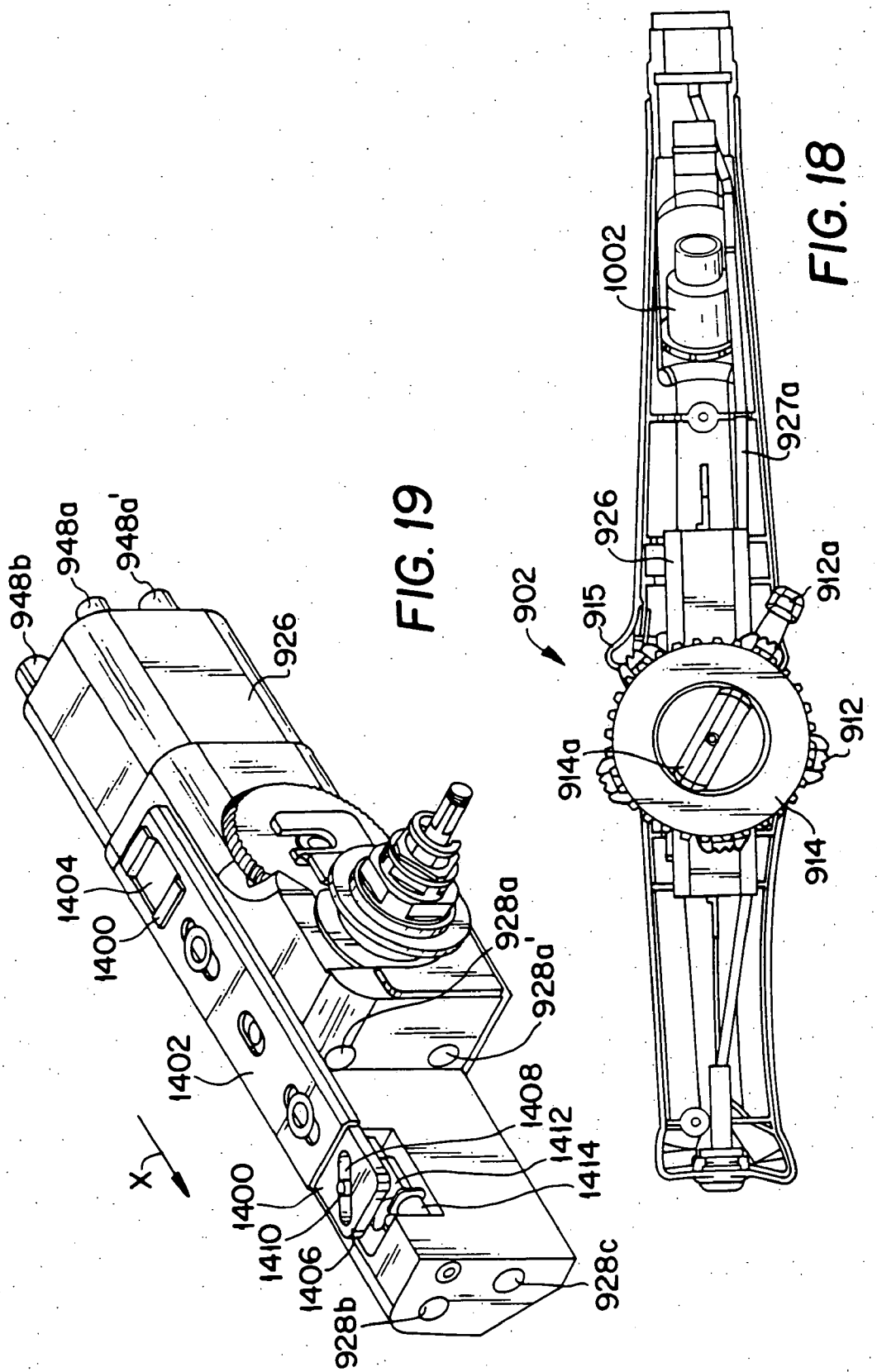

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FIG. 18

FIG. 19

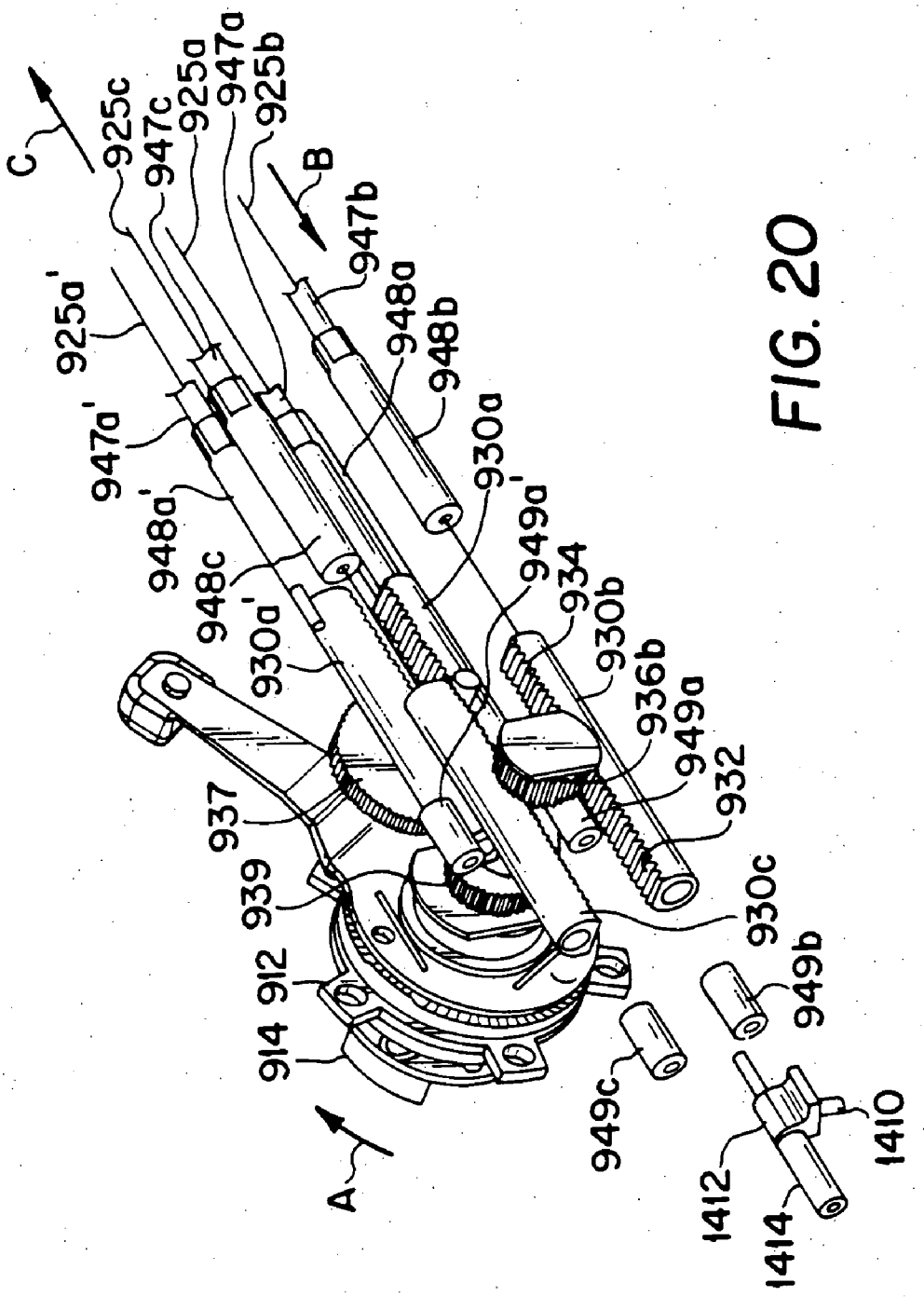

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FIG. 20

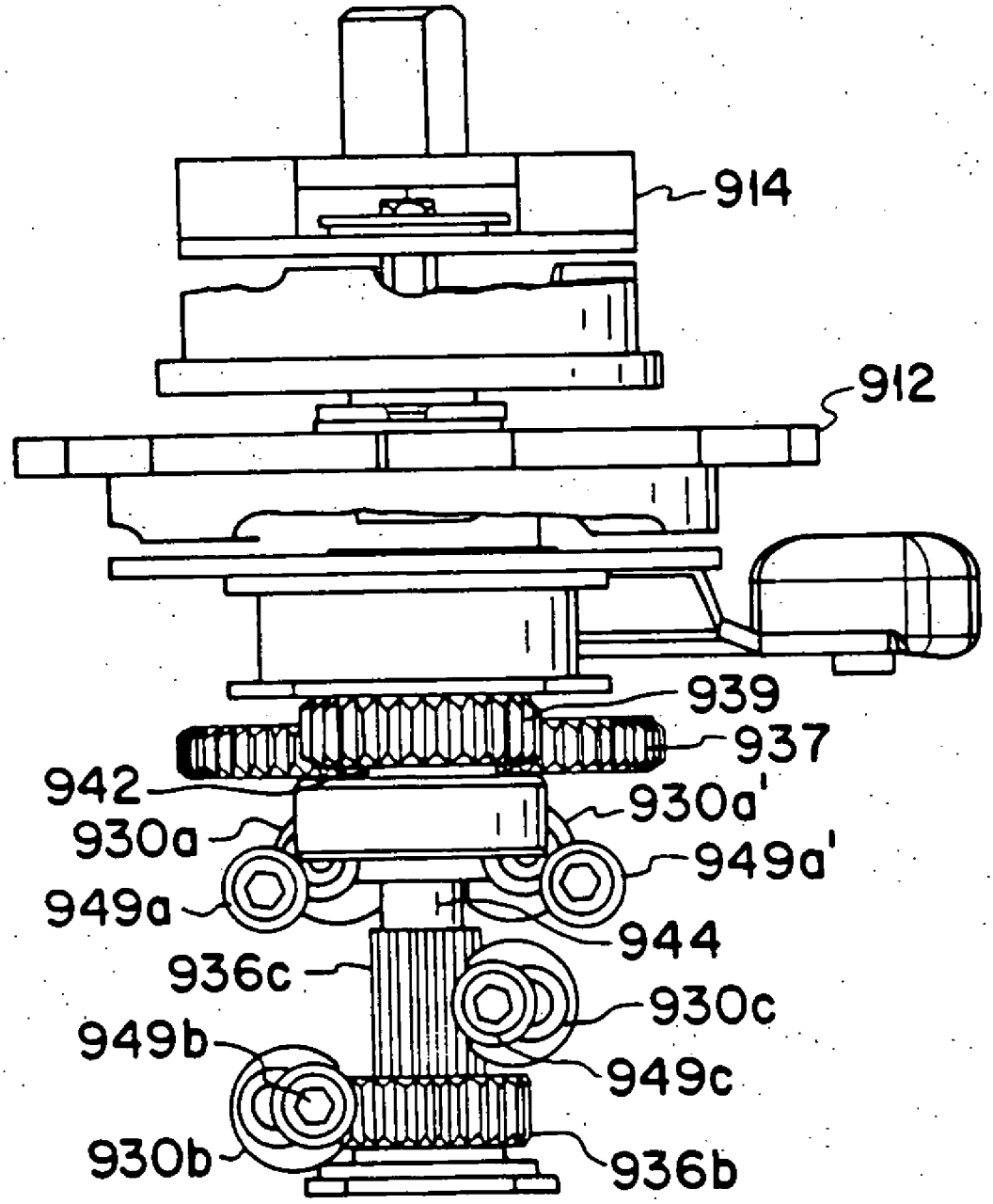

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FIG. 21A

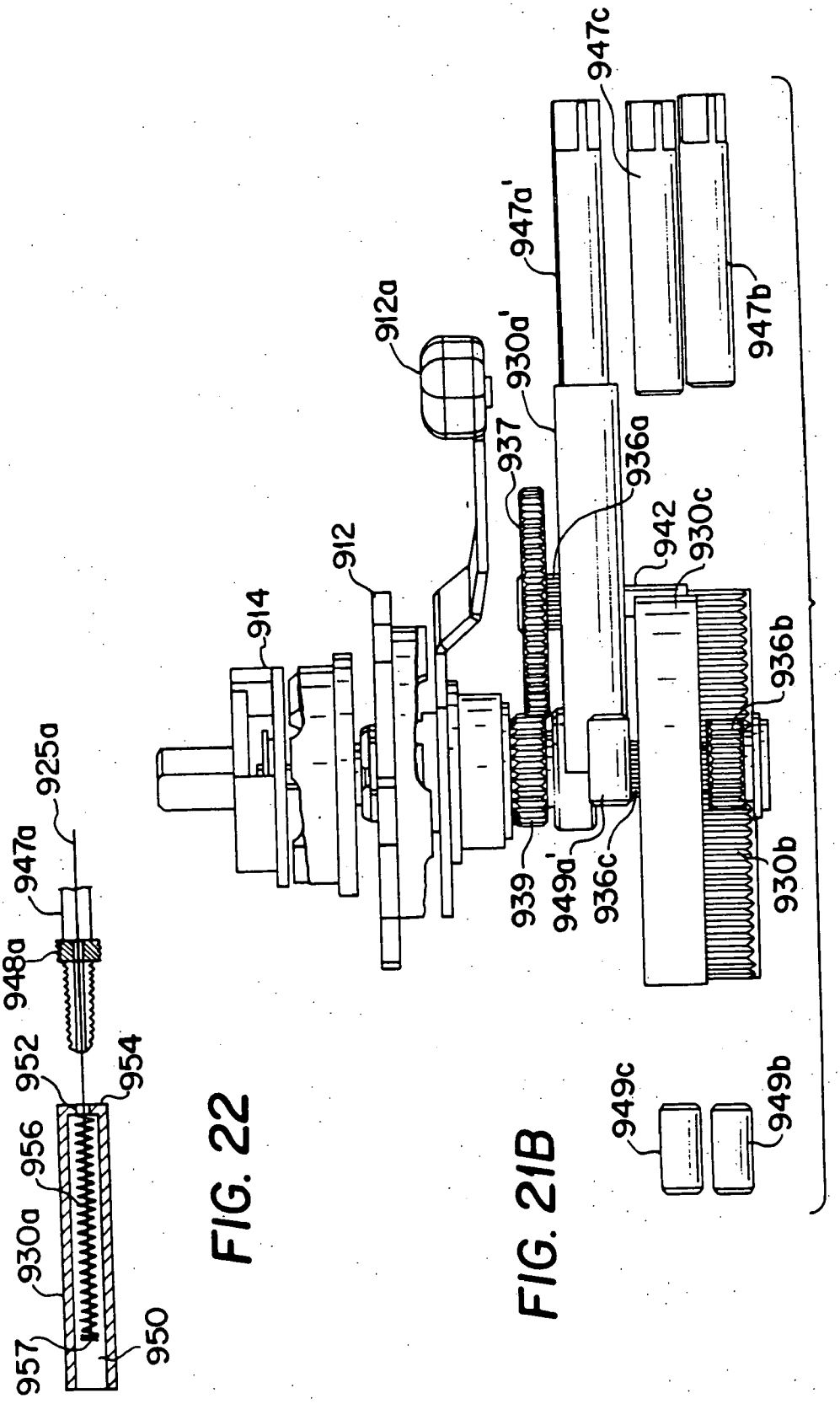


FIG. 22

FIG. 21B

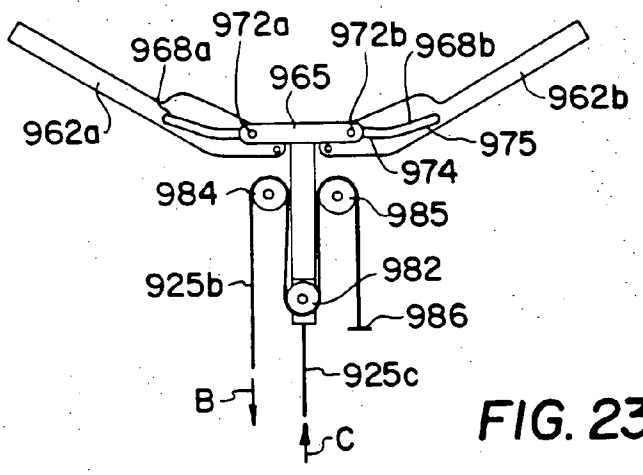


FIG. 23A

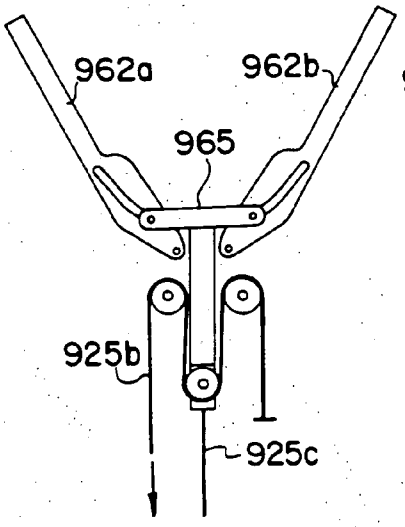


FIG. 23B

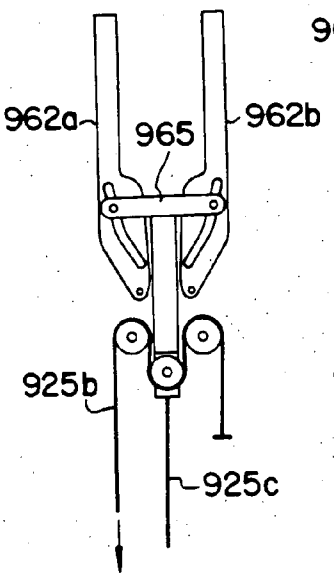


FIG. 23C

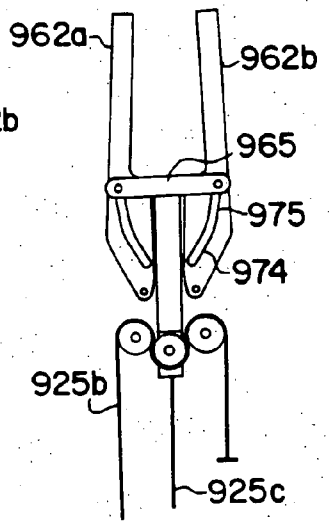


FIG. 23D

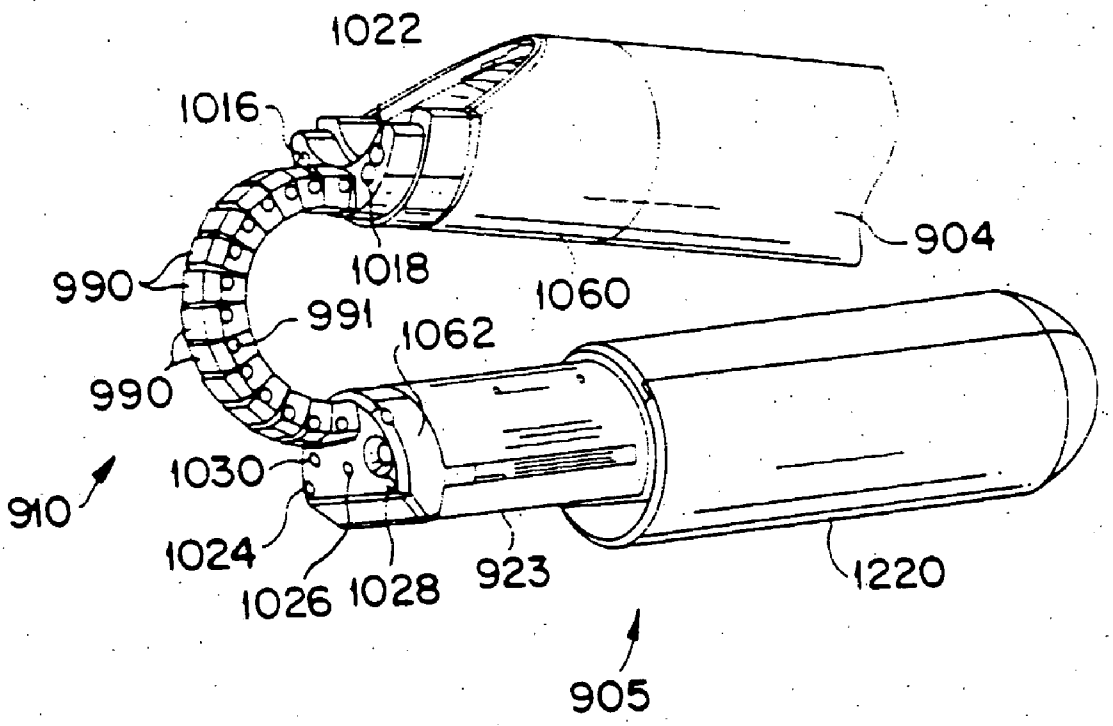


FIG. 24A

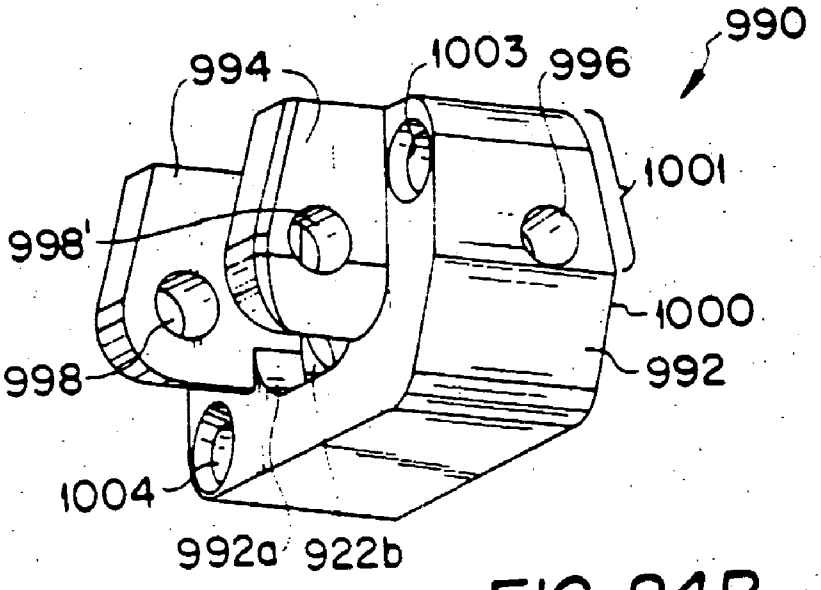


FIG. 24B

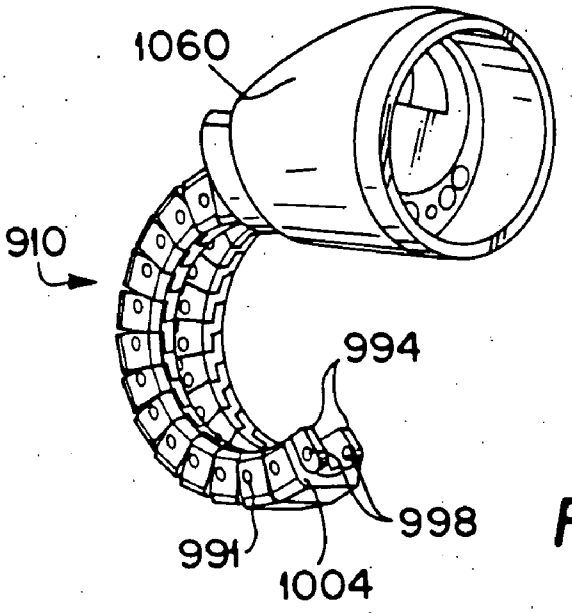


FIG. 24C

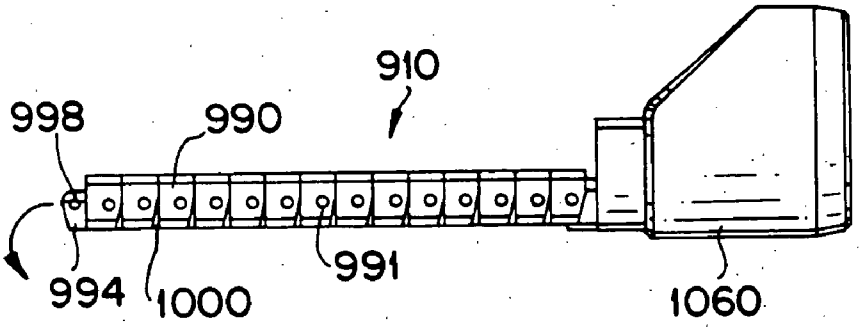


FIG. 24D

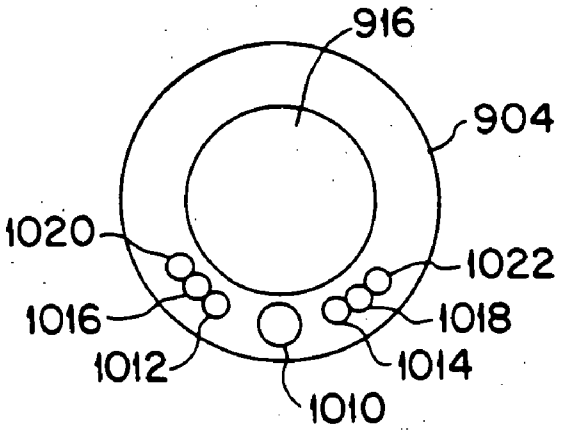


FIG. 25

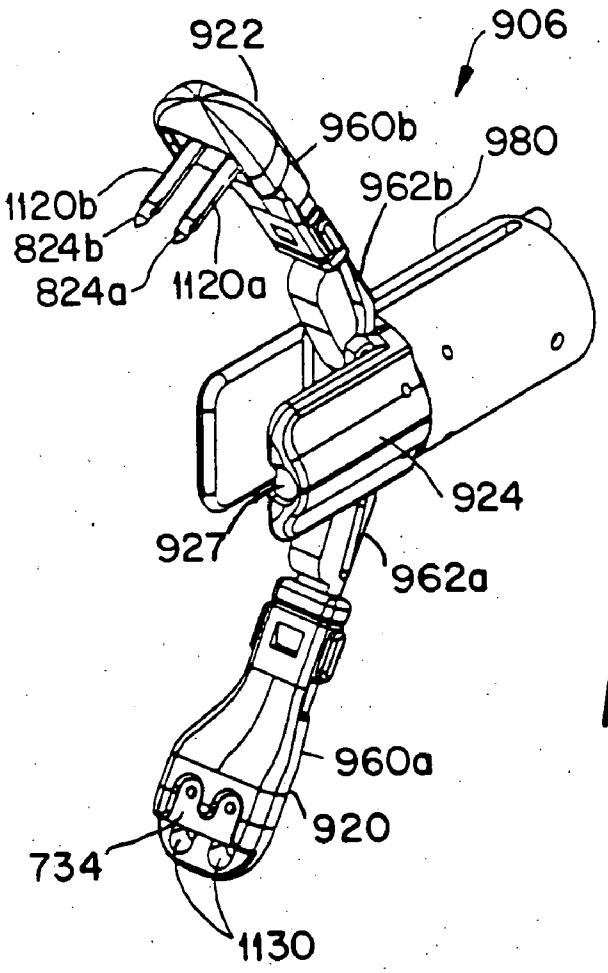

922
906
960b
980
962b
1120b
824b
824a
1120a
924
927
962a
960a
920
734
1130

FIG. 26

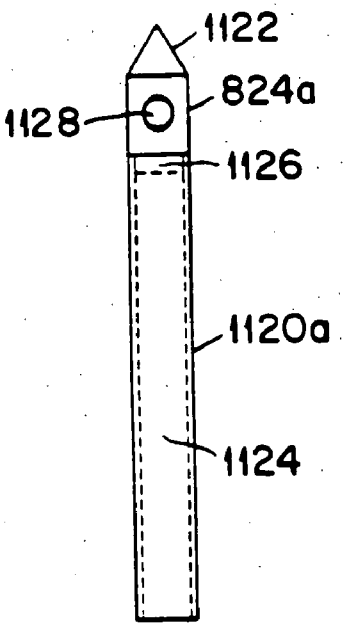

1122
824a
1128
1126
1120a
1124

FIG. 27

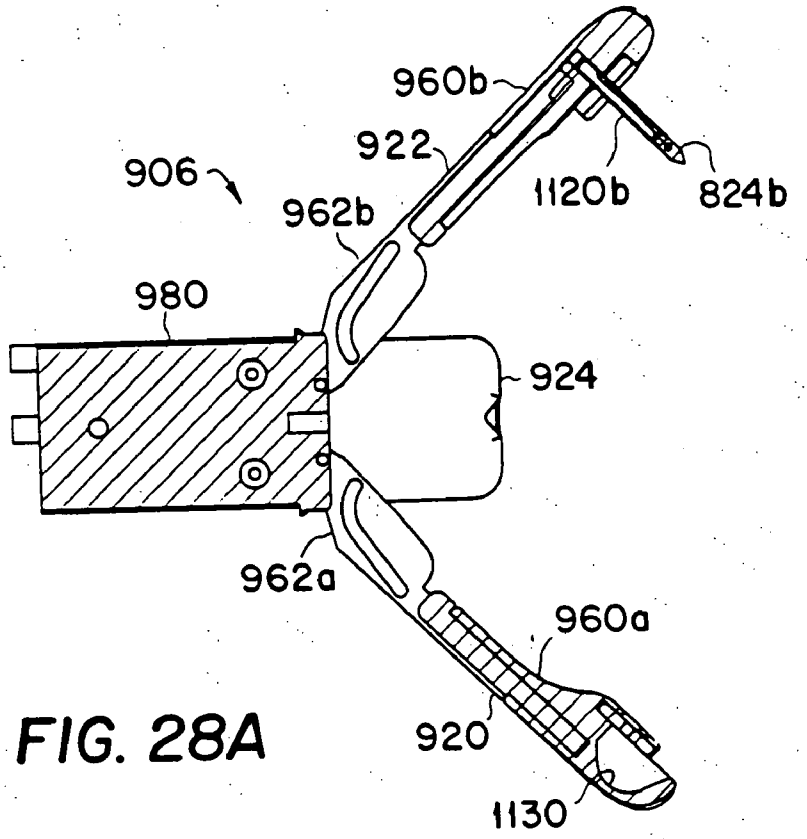


FIG. 28A

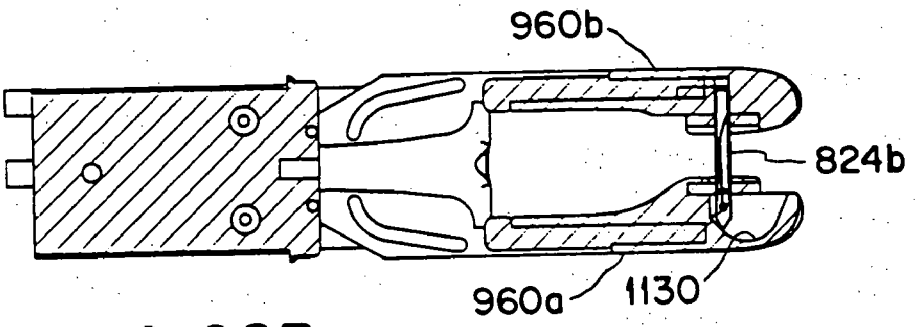


FIG. 28B

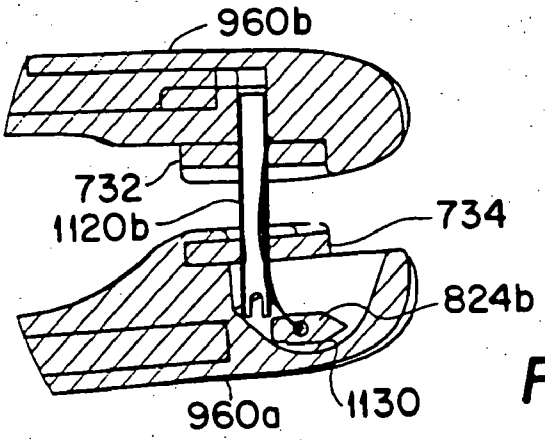


FIG. 28C

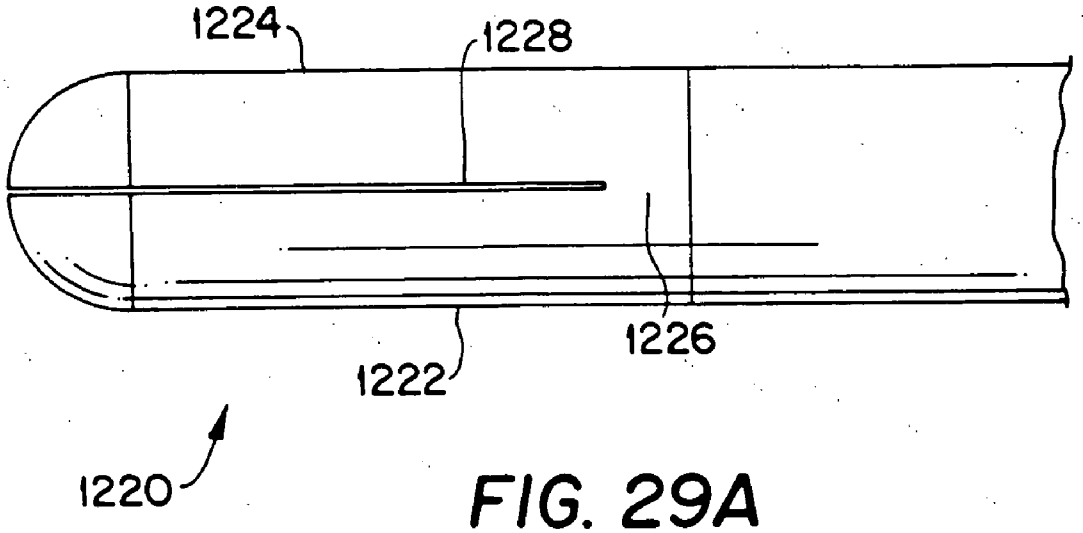


FIG. 29A

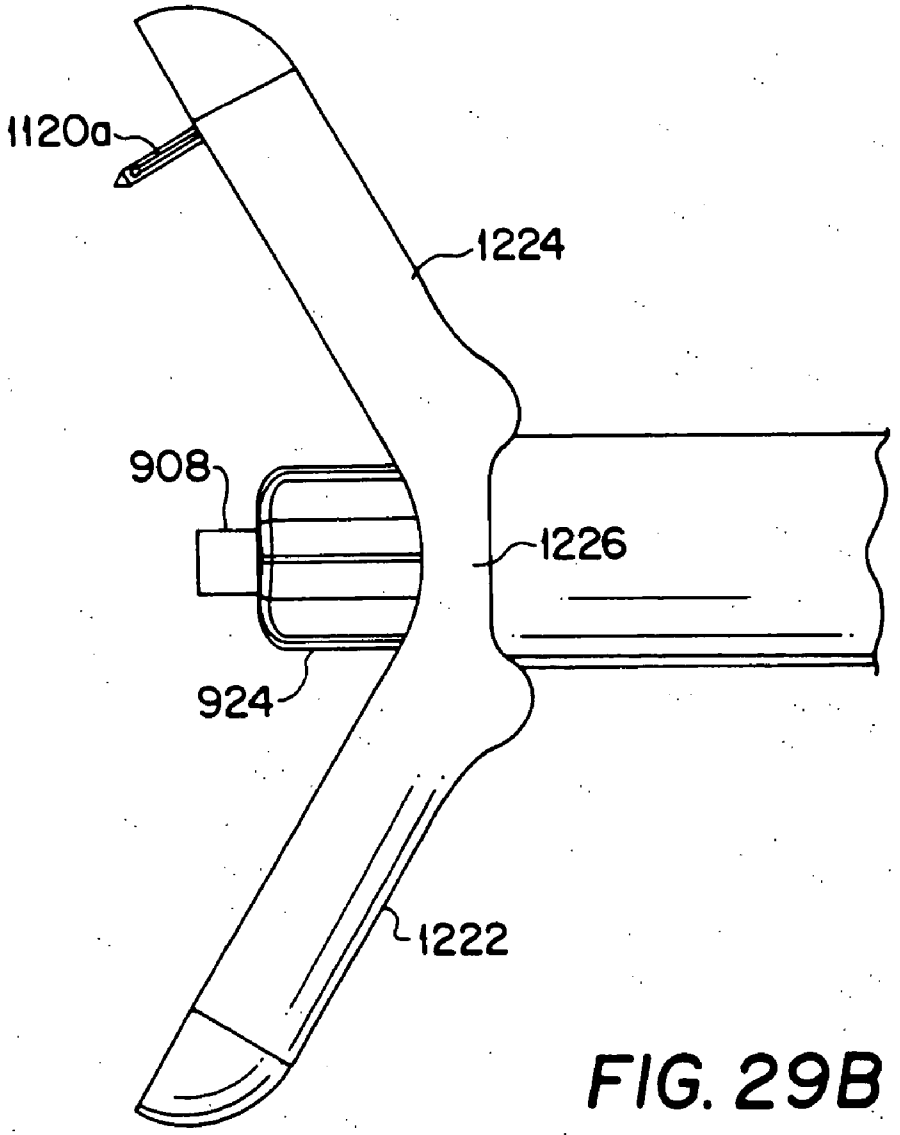


FIG. 29B

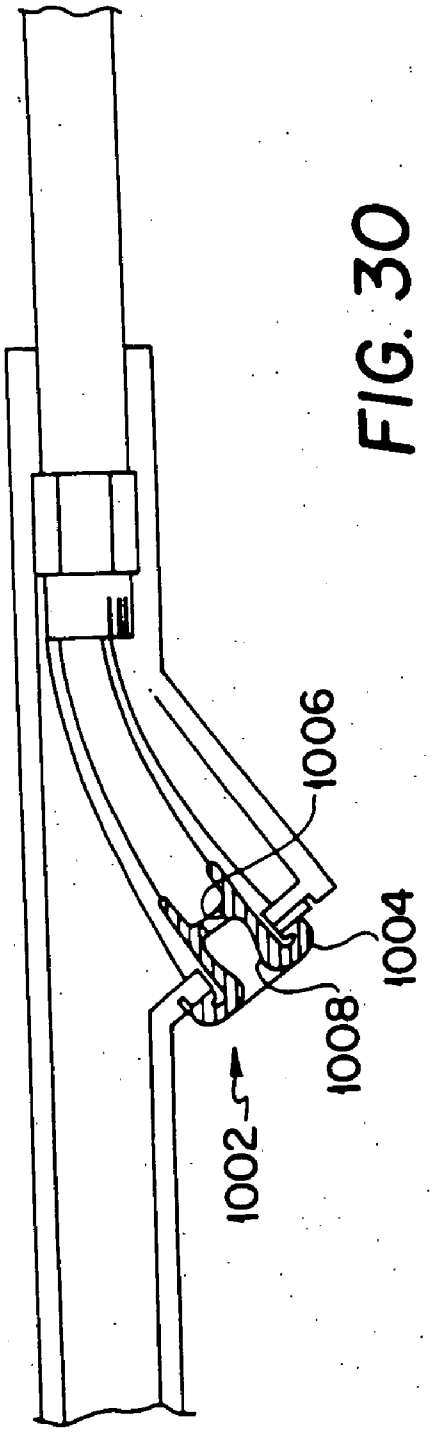


FIG. 30

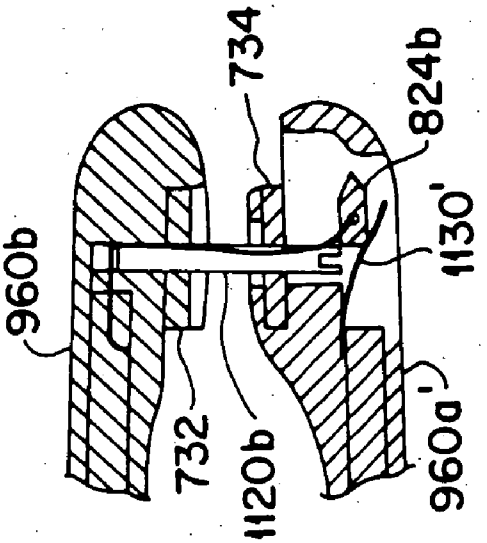


FIG. 31

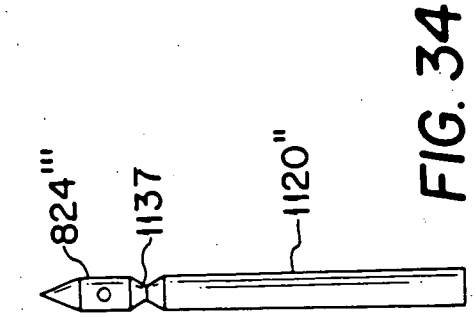


FIG. 34

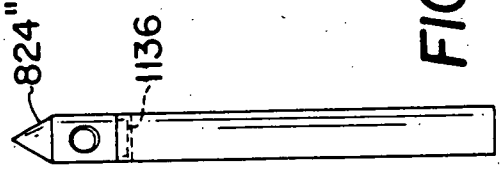


FIG. 33

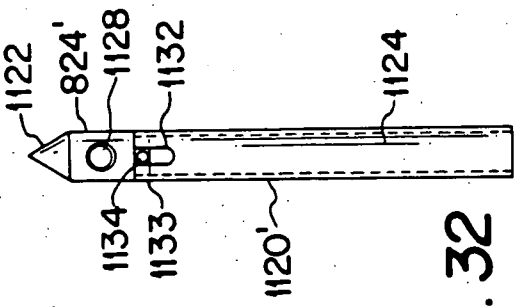


FIG. 32

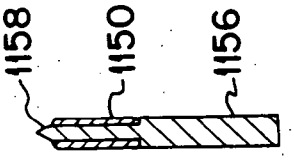


FIG. 35B

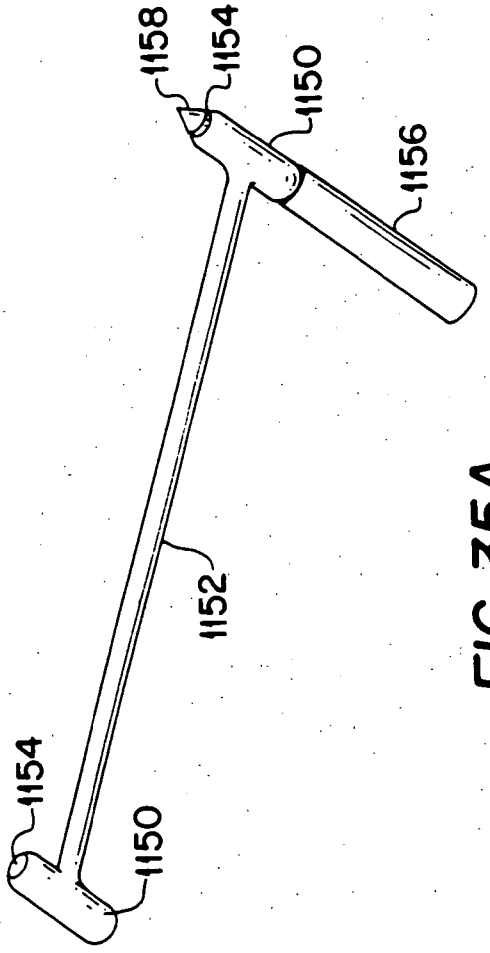


FIG. 35A

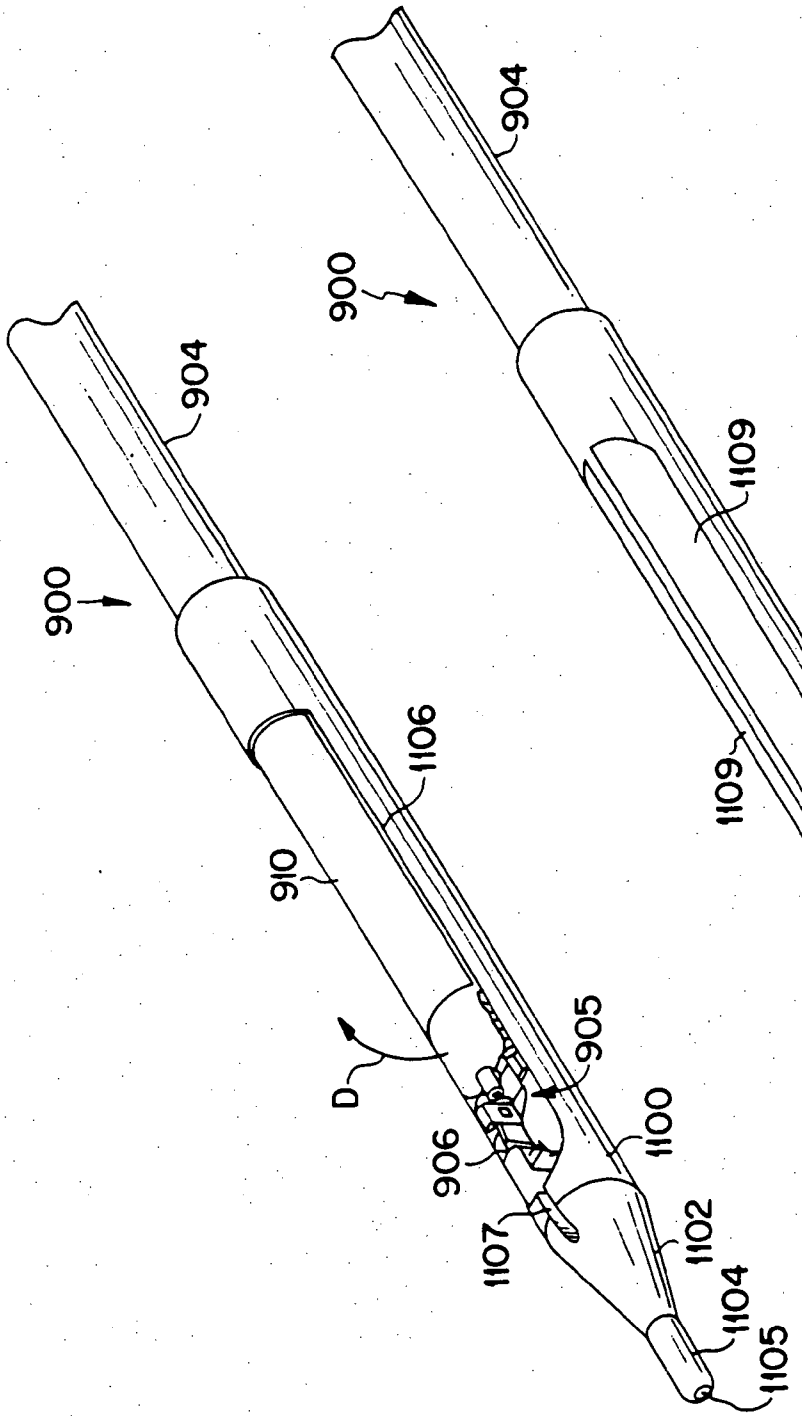


FIG. 36A

FIG. 36B

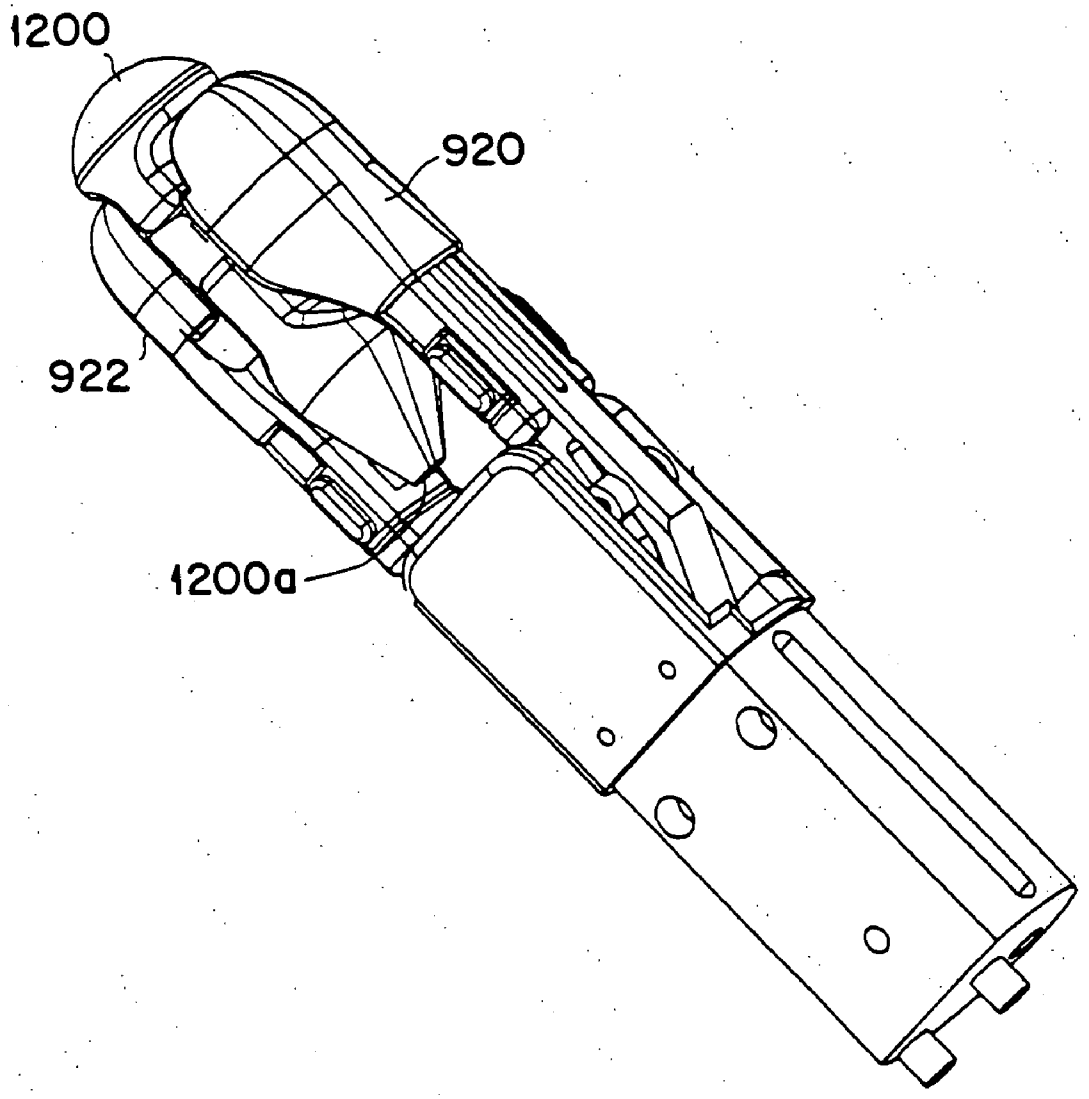


FIG. 37

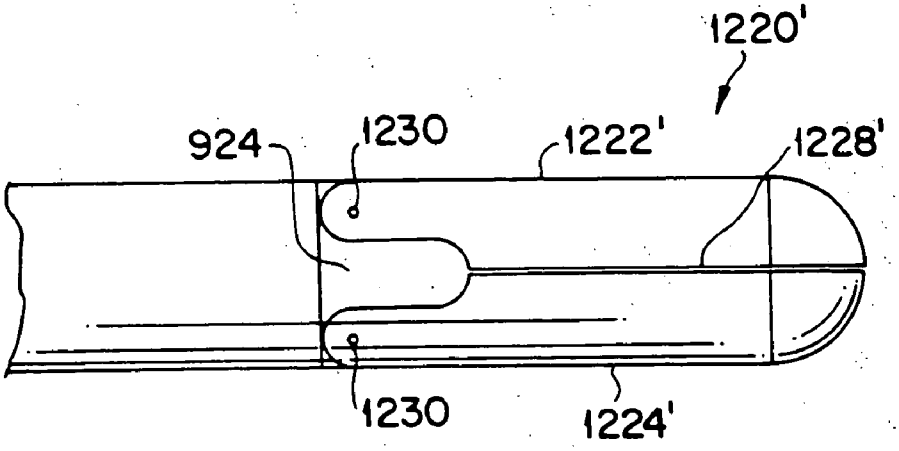


FIG. 38

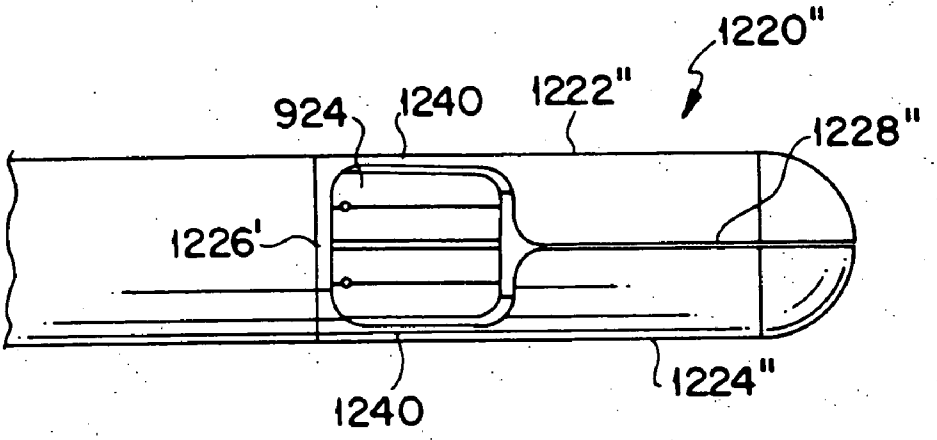


FIG. 39

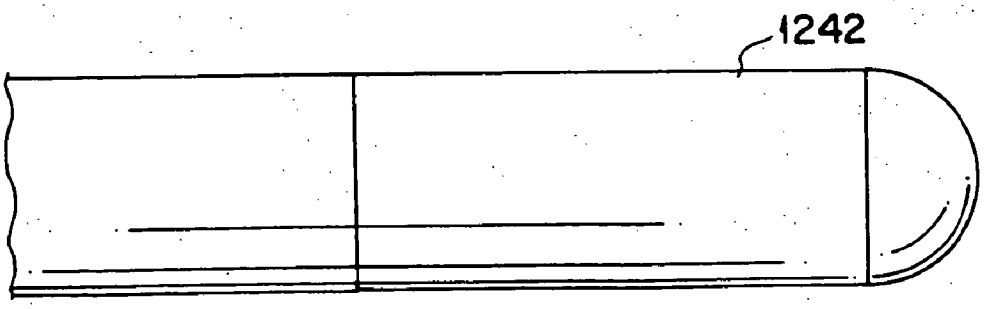


FIG. 40

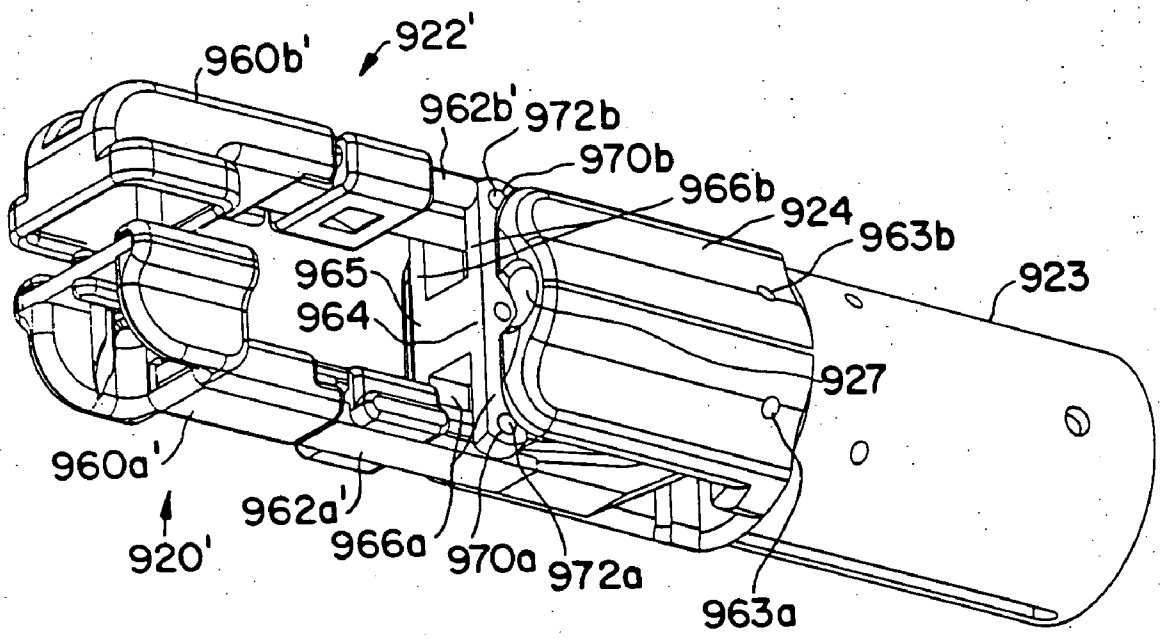


FIG. 41A

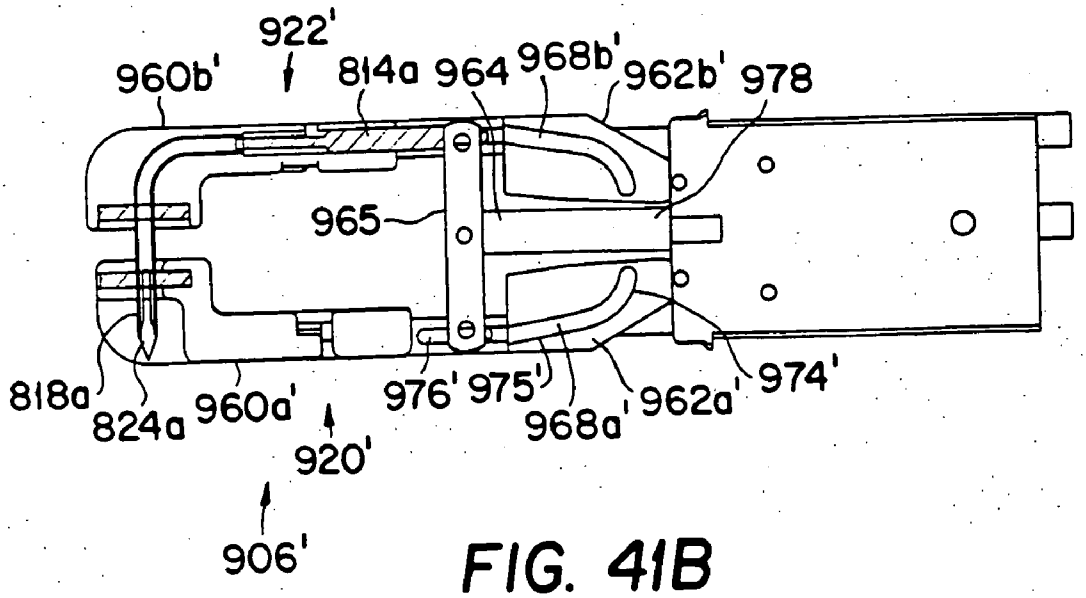


FIG. 41B

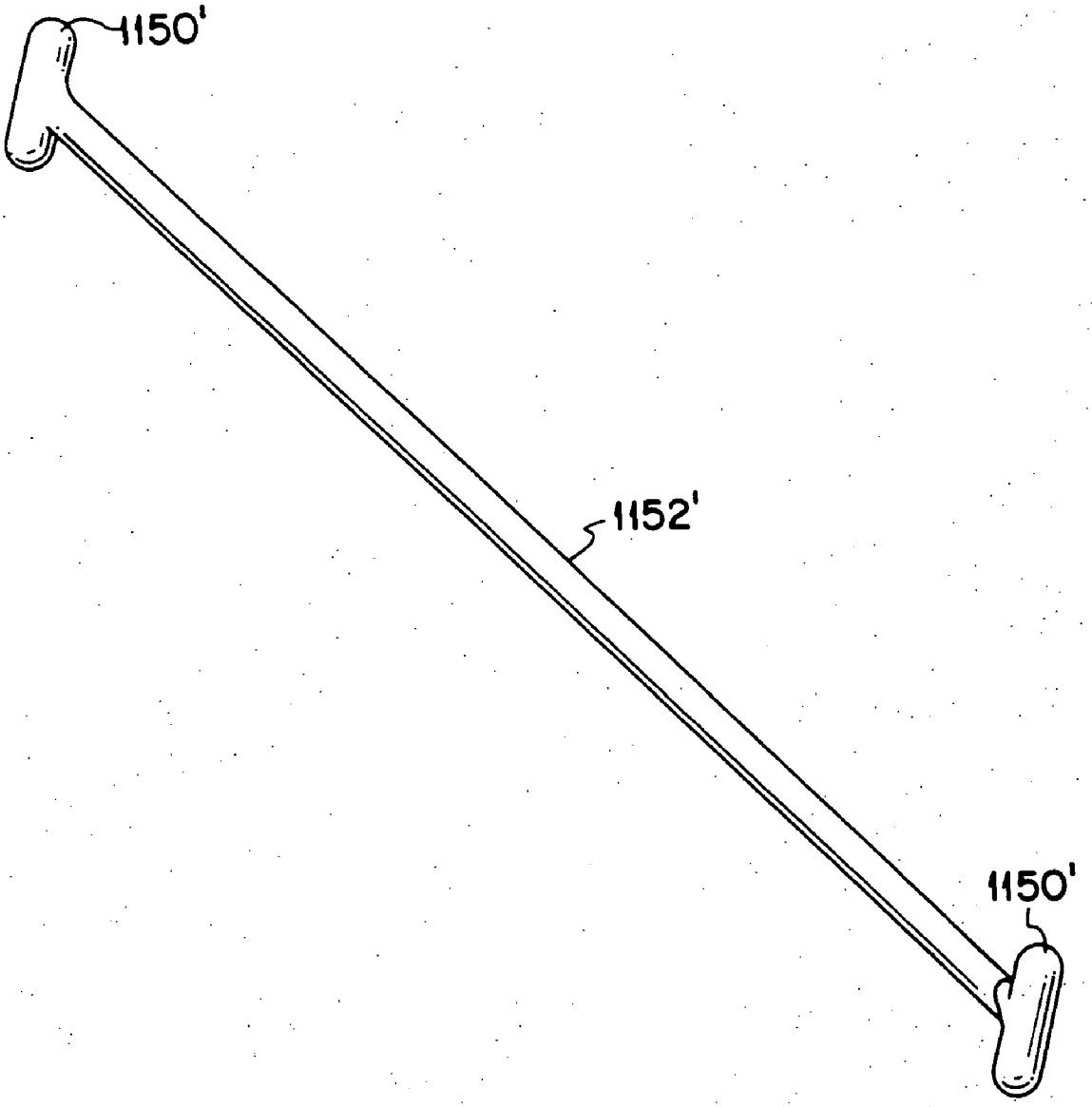


FIG. 42

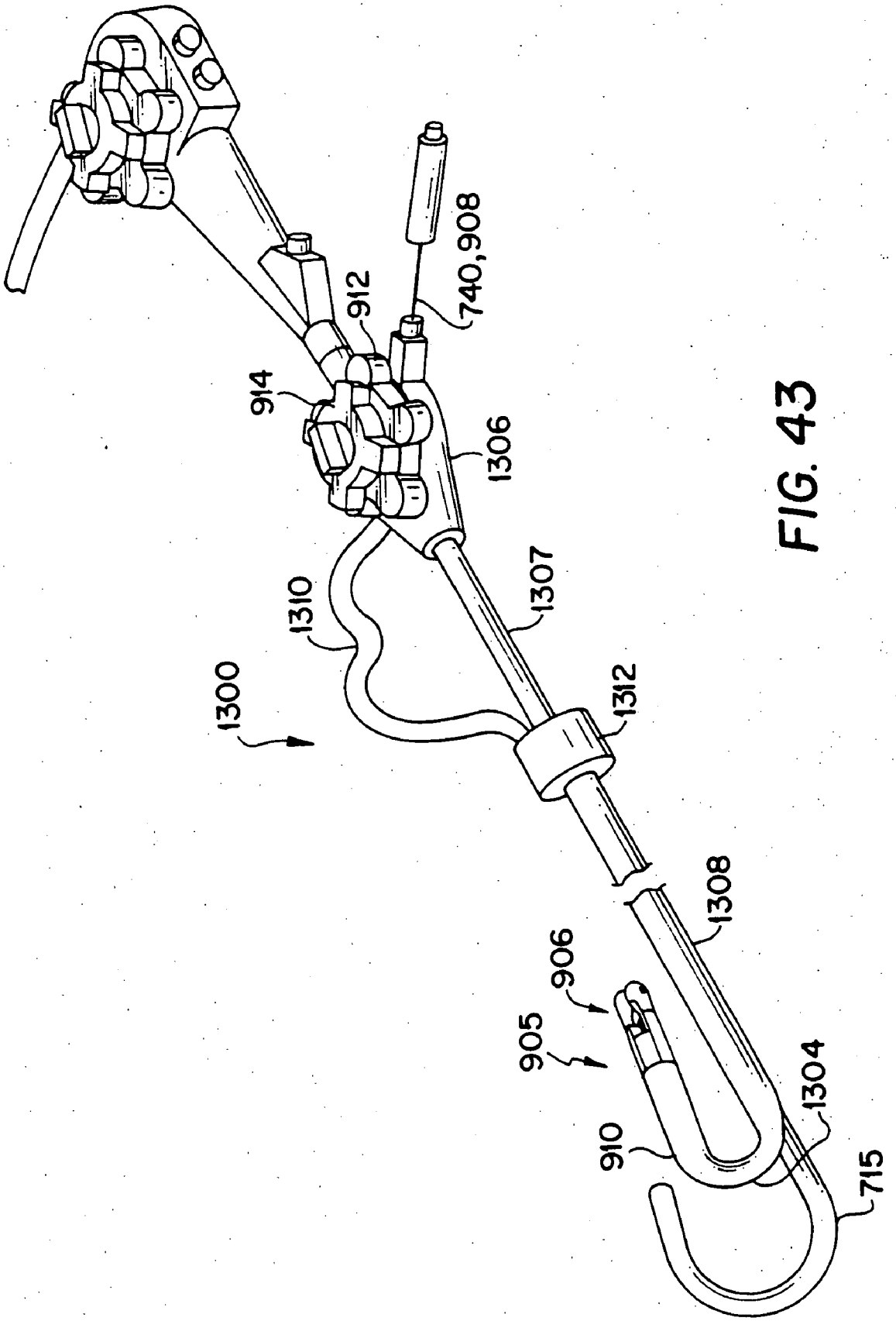

740,908
912
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1304
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715

FIG. 43

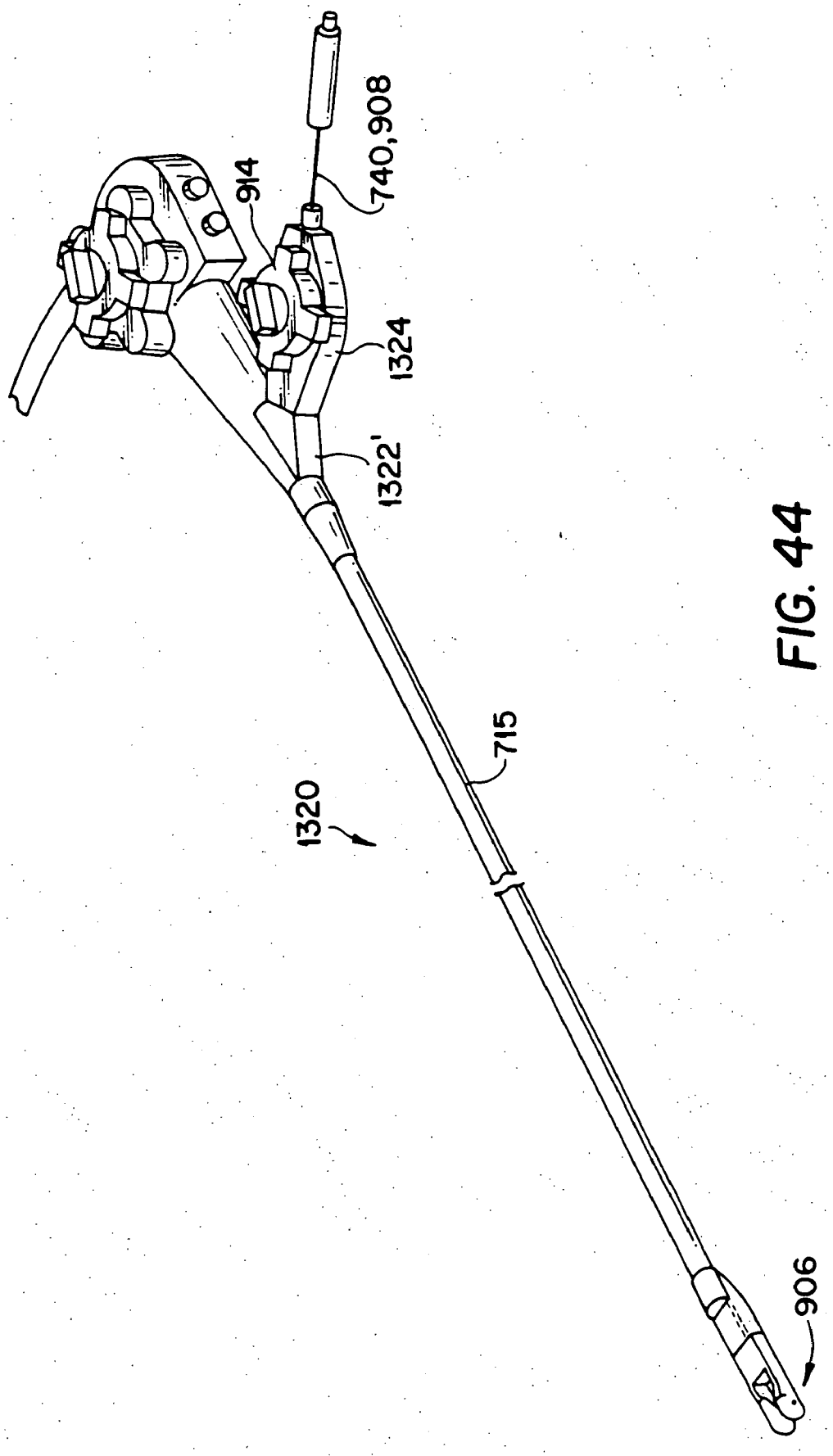


FIG. 44

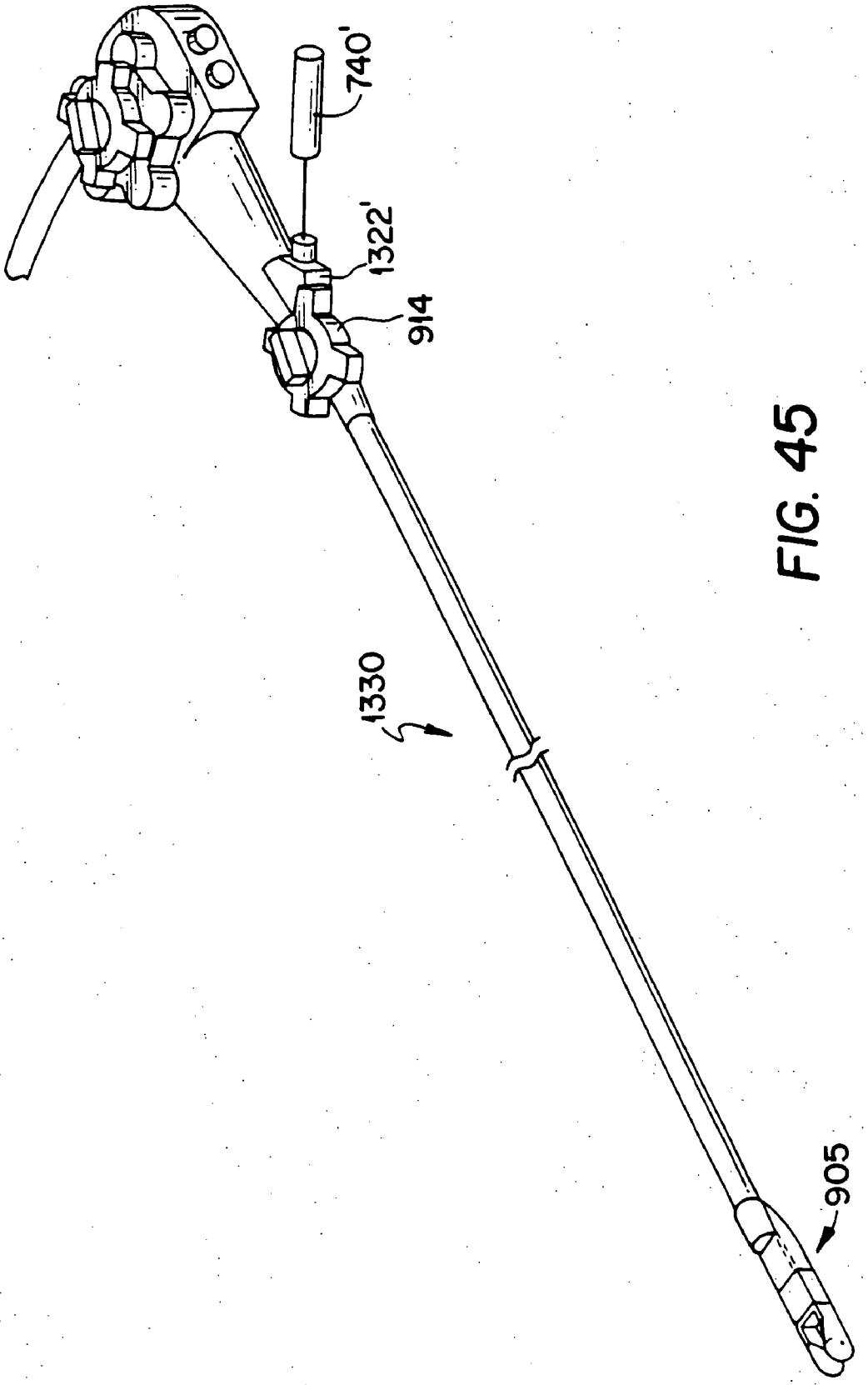


FIG. 45

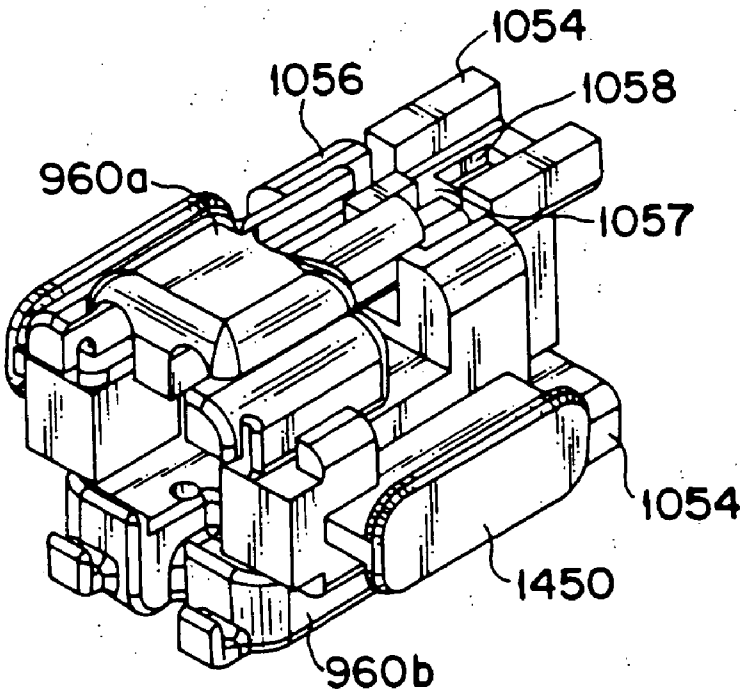


FIG. 46A

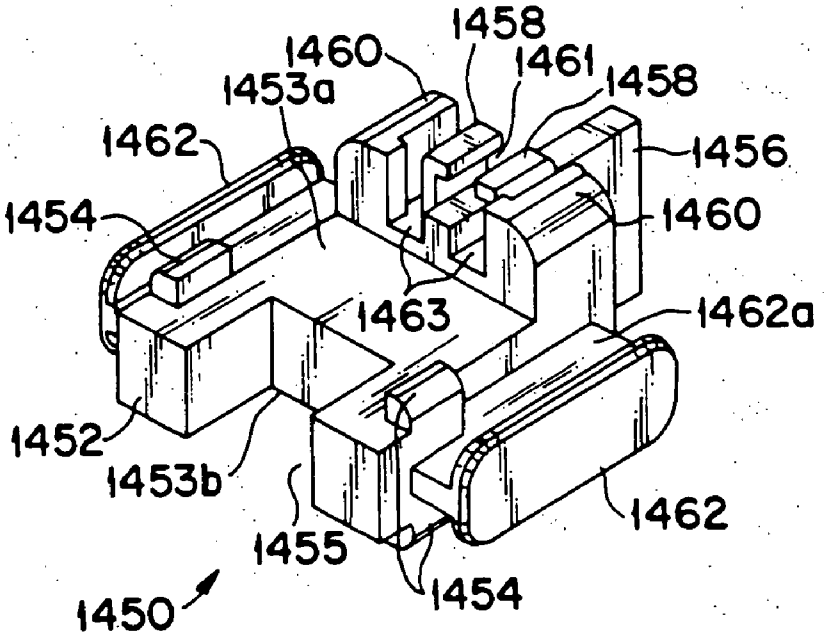


FIG. 46B

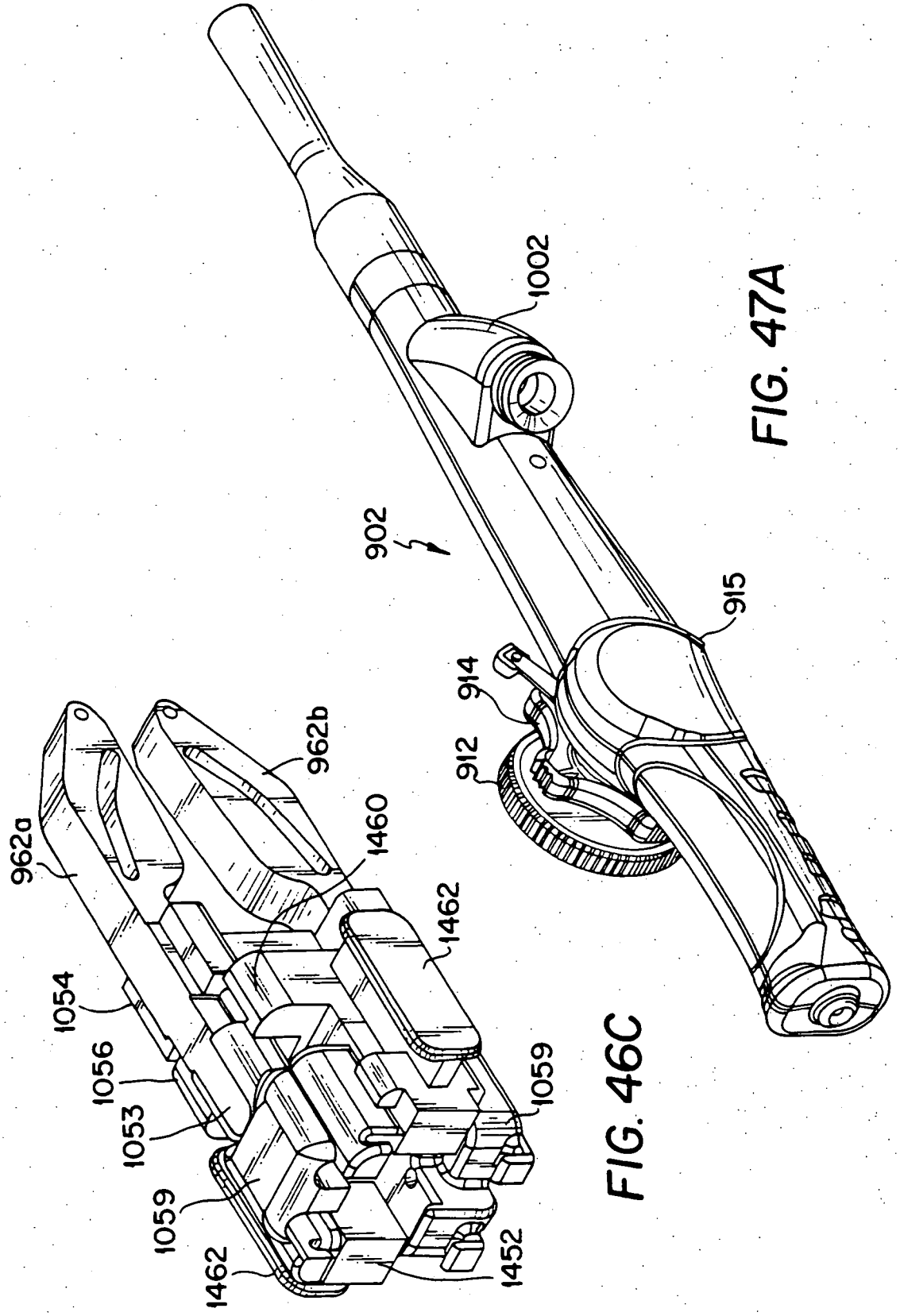


FIG. 47A

FIG. 46C

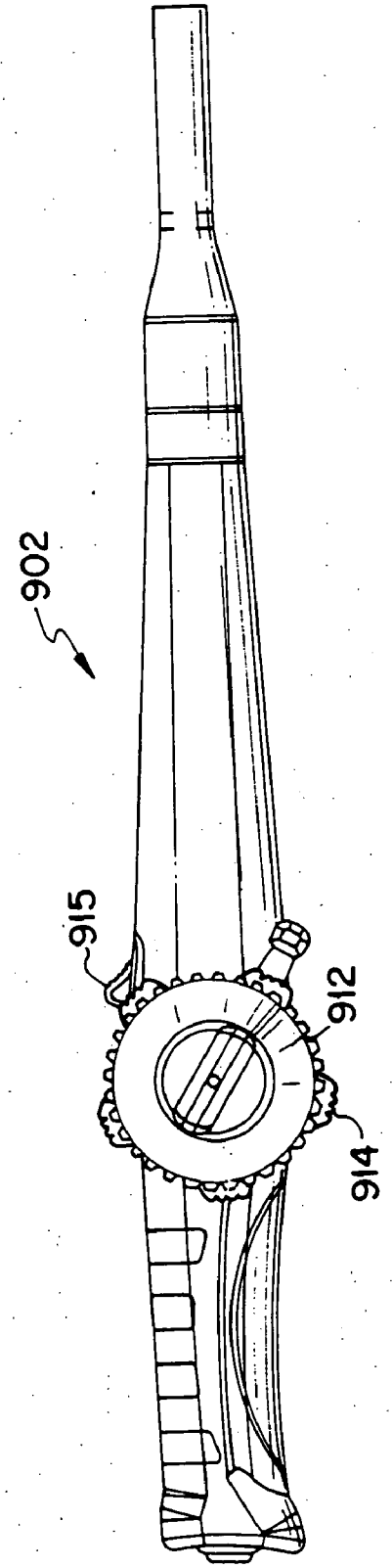


FIG. 47B

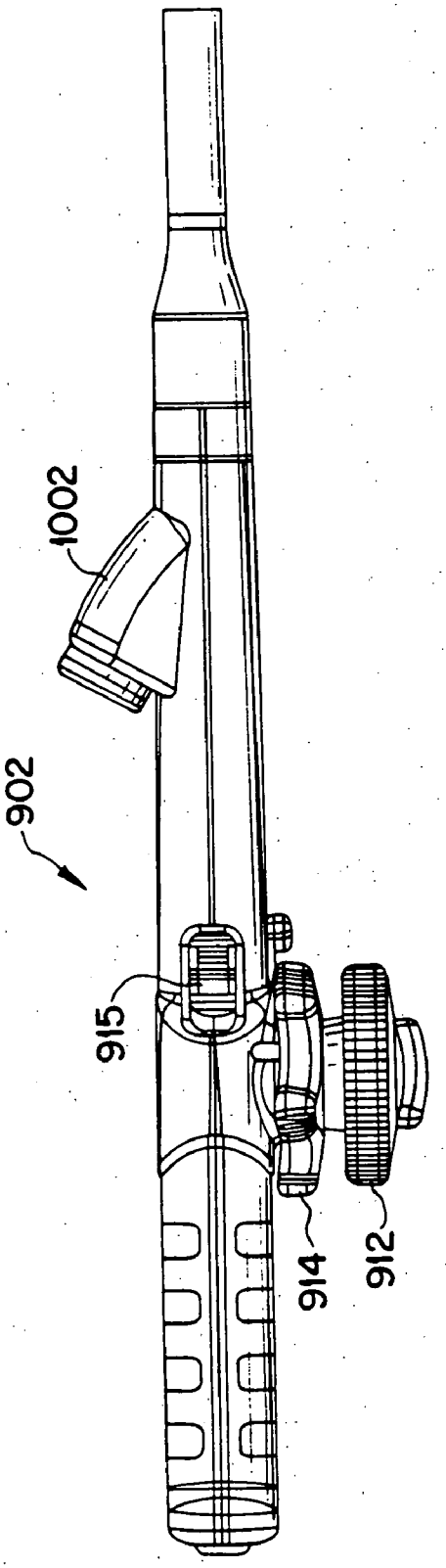


FIG. 47C

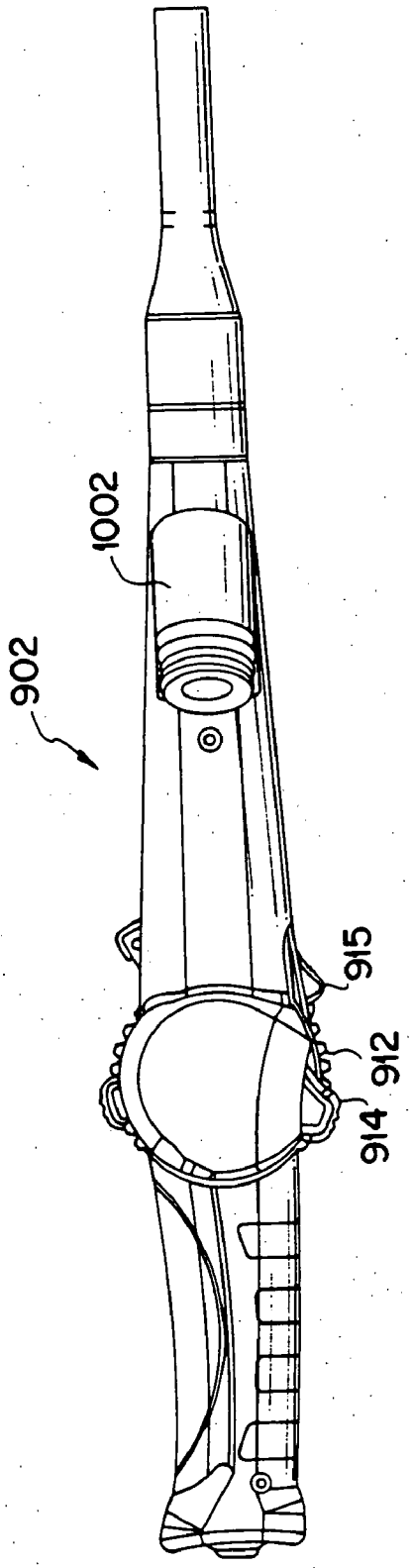


FIG. 47D

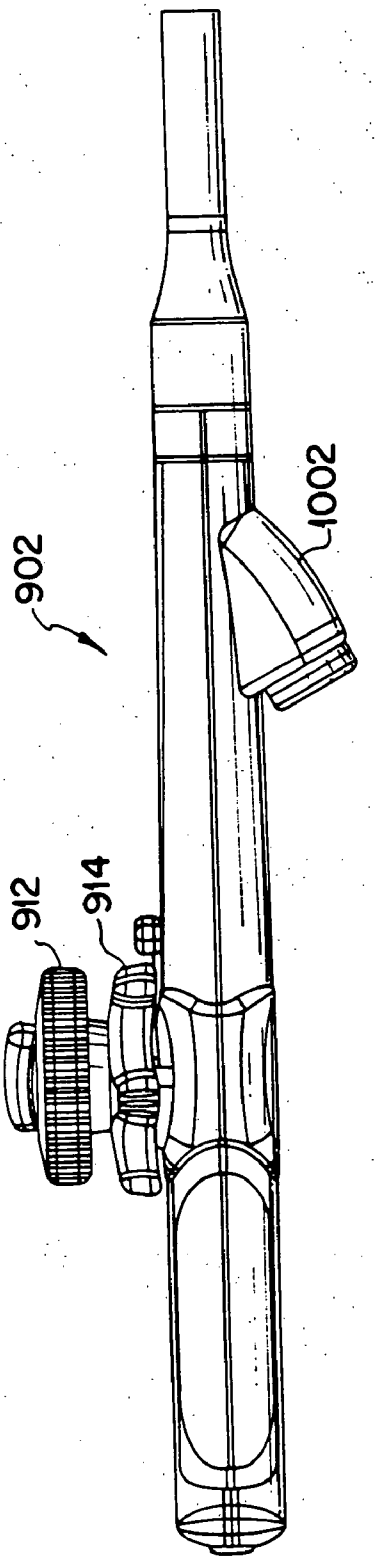


FIG. 47E

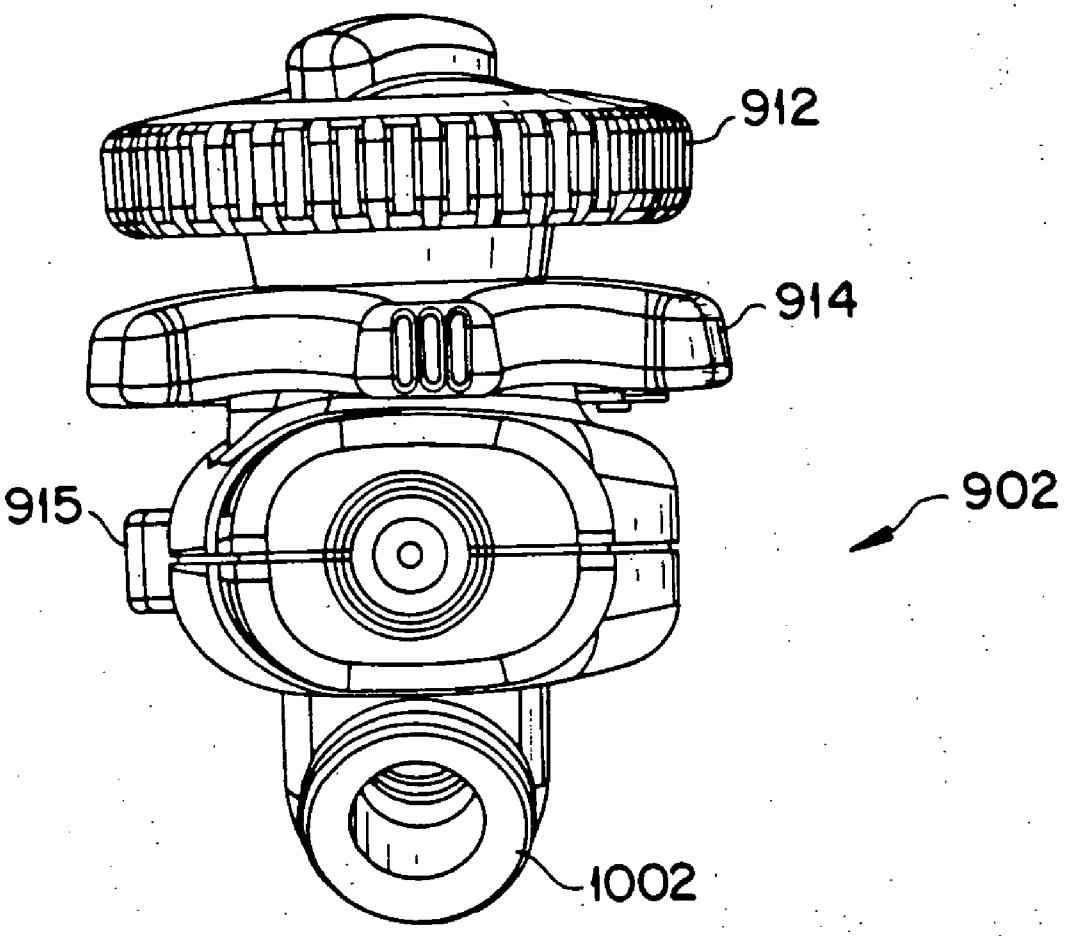


FIG. 47F

TISSUE RECONFIGURATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 09/859,579, filed May 18, 2001, which is a continuation-in-part of U.S. application Ser. No. 09/574,424, filed May 19, 2000, which is a continuation-in-part of U.S. application Ser. No. 09/520,273, filed Mar. 7, 2000, and U.S. application Ser. No. 09/519,945, filed Mar. 7, 2000, which claim priority from U.S. Application No. 60/140,492, filed Jun. 22, 1999, all hereby incorporated by reference in their entirety.

BACKGROUND

[0002] This invention relates to methods and apparatus for reconfiguring tissue, and more particularly to reconfiguring tissue in the vicinity of the gastroesophageal junction.

[0003] Gastroesophageal reflux disease (GERD) is a common upper-gastrointestinal disorder in which acidic contents of the stomach flow inappropriately from the stomach into the esophagus. Backflow of gastric contents into the esophagus results when gastric pressure is sufficient to overcome the resistance to flow that normally exists at the gastroesophageal junction (GEJ) or when gravity acting on the contents is sufficient to cause flow through the GEJ. Medication, open surgical procedures, minimally invasive surgical techniques, and endoscopic techniques are known for treating GERD.

SUMMARY

[0004] According to one aspect of the invention, a medical instrument for engaging tissue includes a flexible shaft, a tissue piercing coil at a distal portion of the shaft, and a member positioned over the shaft. The member and the coil are coupled for relative movement.

[0005] Embodiments of this aspect of the invention may include one or more of the following features. The member is biased, e.g., by a spring, in a distal direction. The shaft includes a length of coil. The shaft coil and the tissue piercing coil are wound in opposite directions.

[0006] According to another aspect of the invention, a medical instrument for engaging tissue includes a flexible shaft, a tissue piercing member at a distal portion of the shaft, and a tissue stabilizer coupled to the shaft for movement relative to the tissue piercing member. The tissue stabilizer is biased in a distal direction such that as the tissue piercing member enters tissue, the tissue stabilizer is urged against a surface of the tissue.

[0007] According to another aspect of the invention, a medical instrument for engaging tissue includes a tissue piercing coil, and a tissue stabilizer coupled to the coil for movement relative to the coil. The tissue stabilizer is biased in a distal direction such that as the coil enters tissue, the tissue stabilizer is urged against a surface of the tissue.

[0008] According to another aspect of the invention, a method of treatment includes advancing a flexible shaft to a treatment site, and piercing tissue with a coil portion of the shaft.

[0009] According to another aspect of the invention, a method of treatment includes advancing a flexible shaft to a treatment site, piercing tissue with a member located at a distal portion of the shaft, and stabilizing tissue being pierced by contacting a surface of the tissue with a tissue stabilizer biased in a distal direction such that as the tissue piercing member enters tissue, the tissue stabilizer is urged against the surface of the tissue.

[0010] According to another aspect of the invention, a method of treatment includes piercing tissue with a coil, and stabilizing tissue being pierced by contacting a surface of the tissue with a tissue stabilizer biased in a distal direction such that as the coil enters tissue, the tissue stabilizer is urged against the surface of the tissue.

[0011] According to another aspect of the invention, a medical instrument for reconfiguring tissue includes a flexible shaft defining a lumen housing actuating controls, and a distal actuating assembly. The distal actuating assembly includes a sealing portion configured to substantially seal the shaft lumen from contact with bodily fluids, and a tissue manipulator located distal of the sealing portion. The actuating member is coupled to the tissue manipulator such that the tissue manipulator is actuatable to deploy an implant located distal of the sealing portion.

[0012] Embodiments of this aspect of the invention may include one or more of the following features. The distal actuating assembly includes an implant located distal of the sealing portion. The sealing portion includes a cover over a section of the assembly. The sealing portion includes a seal surrounding an actuating member extending through the seal.

[0013] According to another aspect of the invention, a medical device includes first and second members and each member includes a body having a first attachment portion and a second attachment portion. The first attachment portion includes a member with a side wall defining a slot and a mating contour having a straight, proximal edge for releasably attaching the body to a distal portion of a medical instrument such that the body can be exchanged with a replacement body. The second portion is configured to releasably receive an implant.

[0014] Embodiments of this aspect of the invention may include one or more of the following features. The first attachment portion includes a flexing section between the side wall and the mating contour. The second portion includes tubes configured to pass through tissue.

[0015] According to another aspect of the invention, a medical device includes an implant including a suture, and first and second members configured to releasably attach to a distal portion of a medical instrument such that the members can be exchanged with replacement members. At least one of the members is configured to releasably receive the implant for delivery of the implant to a treatment site.

[0016] According to another aspect of the invention, a cartridge assembly includes first and second members configured for releasable attachment to a medical instrument, and a holder configured to receive the first and second members and to be released from the first and second members upon action of the first and second members attaching to the medical instrument.

[0017] The instrument and method of the invention advantageously provide an endoscopic approach to treating GERD that does not require the surgical formation of portals to access the GEJ. The procedure can be performed as an outpatient procedure done under sedation, without general anesthesia being required. The procedure can be performed by gastroenterologists rather than a surgeon, and takes less time, has fewer complications and side-effects and has lower overall procedure costs than surgical methods. The procedure recreates or augments the natural anatomy, and is easily reversible. The procedure creates a gastric plication without the need for the operator to tie knots.

[0018] Of particular advantage is that portions of the instrument that engage tissue can be provided sterile, while the remainder of the instrument only need be disinfected between procedures. In addition, a tissue engagement member of the instrument provides a safe and reliable means for remotely retracting tissue.

[0019] Other features, objects, and advantages of the invention will be apparent from the following detailed description, and from the claims.

DESCRIPTION OF DRAWINGS

[0020] **FIG. 1** is a diagrammatic representation of an instrument in use to reconfigure tissue in the vicinity of the gastroesophageal junction of the stomach;

[0021] **FIG. 2** shows a tissue fixation device deployed by the instrument of **FIG. 1** in use to secure a bulge formed in the tissue;

[0022] **FIG. 3A** is an illustration of the instrument of **FIG. 1**;

[0023] **FIG. 3B** shows a proximal end of the instrument;

[0024] **FIG. 3C** shows the working channels in a shaft of the instrument;

[0025] **FIG. 3D** is an illustration of a coil assembly of the instrument;

[0026] **FIG. 4A** is a top view of a distal end of the instrument, shown with first and second jaw members in an open position;

[0027] **FIG. 4B** shows the distal end of the instrument located off-axis relative to a shaft of the instrument;

[0028] **FIG. 5** is a side view of the distal end of the instrument, turned **90** degrees relative to **FIG. 4A**;

[0029] **FIG. 6A** is an illustration of a first part of the tissue fixation device of **FIG. 2**;

[0030] **FIG. 6B** is an illustration of the first jaw member with the first part of the tissue fixation device mounted to the jaw member;

[0031] **FIG. 7** is an illustration of the second jaw member;

[0032] **FIG. 8** is an illustration of the tissue fixation device of **FIG. 2**;

[0033] **FIGS. 9A-9F** show the instrument of **FIG. 1** in use;

[0034] **FIG. 10** is an illustration of tissue secured with the tissue fixation device of **FIG. 2**;

[0035] **FIGS. 11A and 11B** are illustrations of an alternative cable routing for an end effector;

[0036] **FIG. 12A** is an isometric view of a tissue engaging member;

[0037] **FIG. 12B** is an isometric view of the tissue engaging member of **FIG. 12A** shown with an outer sheath removed;

[0038] **FIG. 12C** is a cross-sectional view of the tissue engaging member of **FIG. 12A**;

[0039] **FIG. 12D** is a cross-sectional view of the tissue engaging member of **FIG. 12A** shown piercing tissue;

[0040] **FIG. 13A** is an isometric view of a proximal end the tissue engaging member of **FIG. 12A** and a torque generator;

[0041] **FIG. 13B** is a cross-sectional view of the torque generator of **FIG. 13A**;

[0042] **FIG. 14A** is an illustration of an alternative tissue engaging member;

[0043] **FIG. 14B** is an illustration of an alternative tissue engaging member including a tissue bulking needle;

[0044] **FIG. 14C** is a further illustration of the tissue engaging member of **FIG. 14B**;

[0045] **FIGS. 15A-15D** are illustrations of an additional alternative tissue engaging member;

[0046] **FIG. 16A** is an isometric view of an instrument for reconfiguring tissue;

[0047] **FIG. 16B** shown the instrument of **FIG. 16A** receiving a gastroscope;

[0048] **FIG. 17A** is an isometric view of the distal end portion of the instrument of **FIG. 16AFIG. 17B** shows the distal end portion of the instrument with a hood member removed;

[0049] **FIGS. 17C-17E** are side views of an end effector of the instrument of **FIG. 16A**;

[0050] **FIG. 17F** is a side view of a lock arm taken along lines **17**F-17F in **FIG. 17E**;

[0051] **FIG. 17G** is an illustration of disposable components of the instrument of **FIG. 16A**;

[0052] **FIG. 17H** is an exploded view of the instrument of **FIG. 16A**;

[0053] **FIG. 17I** is a cross-sectional view of a coupling member of the end effector;

[0054] **FIG. 18** is a side view of a handle of the instrument of **FIG. 16A**, shown with a cover removed;

[0055] **FIG. 19** is an isometric view of a gearbox located in the handle of **FIG. 18**;

[0056] **FIG. 20** is an illustration of the mechanism inside the gearbox of **FIG. 19**;

[0057] **FIGS. 21A and 21B** are end and side views, respectively, of the mechanism of **FIG. 20**;

[0058] **FIG. 22** is a cross-sectional view of a rack of the mechanism of **FIG. 20**;

[0059] **FIGS. 23A-23D** illustrate the closing of jaw members of the end effector;

[0060] **FIG. 24A** is an illustration of the distal end portion in a flexed position;

[0061] **FIG. 24B** is an isometric view of a link of a retroflex portion of the distal end portion; **FIGS. 24C and 24D** show the retroflex portion flexed and straight, respectively;

[0062] **FIG. 25** is a cross-sectional view of a shaft of the instrument of **FIG. 16A**;

[0063] **FIG. 26** is an isometric view of the distal end portion with the jaw members open;

[0064] **FIG. 27** is an illustration of an implant bar of a tissue fixation device shown coupled to a tube of the jaw member;

[0065] **FIGS. 28A-28C** illustrate deployment of the implant bar of **FIG. 27**;

[0066] **FIGS. 29A and 29B** are illustrations of the hood member with the jaw members closed and open, respectively;

[0067] **FIG. 30** is an illustration of a seal on the handle of **FIG. 18**;

[0068] **FIG. 31** is an illustration of an alternative deployment mechanism;

[0069] **FIGS. 32-34** are illustrations of alternative means for coupling the implant bar to the tube of the jaw member;

[0070] **FIG. 35A** is an isometric view and **FIG. 35B** is a cross-sectional view of an alternative tissue fixation device;

[0071] **FIGS. 36A-40** are illustrations of alternative means for providing an atraumatic distal end on the instrument of **FIG. 16A**;

[0072] **FIG. 41A** is an isometric view and **FIG. 41B** is a side view in partial cross-section of an alternative embodiment of an end effector;

[0073] **FIG. 42** is an illustration of a tissue fixation device for use with the end effector of **FIGS. 41**;

[0074] **FIGS. 43-45** are illustrations of alternative configurations of an instrument for reconfiguring tissue;

[0075] **FIGS. 46A-46C** are illustrations of a cartridge assembly to which the disposable cartridges of **FIG. 17F** are mounted for handling and attachment to the instrument; and

[0076] **FIGS. 47A-47F** are isometric, four side views, and an end view, respectively, of the handle of **FIG. 18**.

DETAILED DESCRIPTION

[0077] Referring to **FIG. 1**, an instrument **700** for reconfiguring stomach tissue, e.g., stomach tissue in the vicinity of the gastroesophageal junction (GEJ) **702**, such as tissue **704** of the lesser curvature of the stomach or any portion of the stomach within about **2** cm of the GEJ, is shown. The GEJ is the region of transition from the esophagus and the stomach. The lesser curvature of the stomach is a portion of the stomach located beyond the GEJ. Instrument **700** includes an elongated shaft **710** dimensioned to permit transoral access to the stomach, and a tissue manipulator **712** for manipulating stomach tissue. Positioned within a lumen **714** defined by shaft **710** is a standard GI endoscope **715** providing visual guidance of the reconfiguring procedure. Instrument **700** is particularly adapted for treating GERD. Using instrument **700**, as described below, a bulge, plication or tissue wrap is formed in the vicinity of gastroesophageal junction **702** to reduce reflux of stomach fluids into the esophagus.

[0078] Tissue manipulator **712** has an elongated cable assembly **716** housed within lumen **714** of shaft **710**, and a distal end effector **718** actuated to perform the various steps in the tissue reconfiguring procedure by cable assembly **716**. End effector **718** includes first and second jaw members **720**, **722** which engage tissue **704**. Cable assembly **716** includes first and second cable pairs **724***a*, **724***b*, and **726***a*, **726***b* for moving jaws **720**, **722** relatively toward and away from one another, respectively, in a first plane, and a third cable **728** for moving end effector **718** relative to shaft **710** in a second plane generally transverse to, and preferably perpendicular to, the first plane, as described further below. During insertion into the stomach, end effector **718** is aligned with shaft **710** (as shown in **FIG. 3A**). Once positioned in the stomach, cable **728** is actuated to articulate end effector **718** out of alignment with shaft **710** (as shown in **FIG. 1**).

[0079] Cable assembly **716** includes a spring beam **784**, formed from, e.g., stainless steel or Nitinol, extending into shaft **710**. End effector **718** is attached to beam **784** at a distal end **785** of beam **784**. Beam **784**, in its rest state, is biased toward a straight alignment. Pulling cable **728** bends beam **784**. When cable **728** is released, beam **784** returns toward the straight alignment.

[0080] Referring also to **FIG. 2**, mounted to first jaw **720** is a first part **732** of a tissue securement member, e.g., a fixation device **730**, and mounted to second jaw **722** is a second part **734** of tissue fixation device **730**. As described further below, after jaws **720**, **722** engage tissue **704** and manipulate the tissue in a wrapping action to create a bulge **736** in, e.g., the lesser curvature of the stomach, tissue fixation device **730** is deployed to secure the engaged tissue together. Cable assembly **716** includes a fourth cable **737** for deploying fixation device **730**, as described further below.

[0081] End effector **718** further includes a tube **738** and a third tissue engaging member, e.g., a coil **740**, received within tube **738**, for purposes described below. Coil **740** is housed within an overtube **742**, and coil **740** and overtube **742** can be moved axially proximally and distally relative to jaws **720**, **722**, along the axis, A, of cable assembly **716**. Coil **740** can be rotatably advanced into tissue.

[0082] Referring to **FIG. 3A**, instrument **700** has, at its proximal end **745**, a handle **743** with a control knob **744** for controlling cables **724***a*, **724***b*, **726***a*, **726***b* to close and open jaws **720**, **722**, and a control knob **746** for controlling cable **728** to move end effector **718**. Handle **743** includes a port **748** through which coil **740** and overtube **742** can be introduced into shaft lumen **714**, and a pull-knob **750** for deploying tissue fixation device **730**, as described below. As shown in **FIG. 3B**, handle **743** defines a channel **752** through which endoscope **715** is introduced into shaft lumen **714**.

[0083] Referring to **FIGS. 1 and 3**C, which shows the working channels in shaft **710** for receiving the various cables, overtube **742** and endoscope **715**, within lumen **714**

of shaft **710** are cable housings **760***a*, **760***b* defining channels **762***a*, **762***b* in which cables **724***a*, **724***b* for closing jaws **720**, **722** are received, and cable housings **764***a*, **764***b* defining channels **766***a*, **766***b* in which cables **726***a*, **726***b* for opening jaws **720**, **722** are received. Within lumen **714** are also a cable housing **768** defining a channel **770** in which cable **728** for bending end effector **718** is received, and a cable housing **772** defining a channel **774** in which cable **737** for deploying fixation device **730** is received. Coil **740** and overtube **742** are received in a channel **778** defined in a coil housing **776** in lumen **714**. Housing **776** extends from port **748** to tube **738**. As shown in **FIG. 3D**, coil **740** has a tissue penetrating tip **741** and a distal section **740***a* having a looser wound coil than the remainder of coil **740**. Endoscope **715** is received in a channel **782** defined in an endoscope housing **780** in lumen **715**.

[**0084**] Spring beam **784** is located generally between cable housing **776** and endoscope housing **780**, and extends about 4 inches into shaft **710** from the distal end of the shaft where beam **784** is mounted to shaft **710** by, e.g., silicone adhesive/sealant. The various cable housings and spring beam **784** do not move relative to shaft **710** and handle **743**. It is the movement of the cables within the cable housings that actuate end effector **718**. Shaft **710** is preferably formed from, e.g., heat-shrink tubing.

[**0085**] Referring again to **FIG. 3A**, end effector **718** has a length, L**1**, of about 2 inches, cable assembly **716** extends axially by a length, L**2**, of about 2.5 inches from shaft **710**, shaft **710** has a length, L**3**, of about 23.5 inches, and handle **743** has a length, L**4**, of about 5 inches. Cable assembly **716**, spring beam **784**, and shaft **710** have the necessary flexibility to permit transoral placement of instrument **700** into the stomach. The length, L**1**, of relatively rigid end effector **718** is minimized to ensure the necessary flexibility of instrument **700** is maintained. The distance that cable assembly **716** extends axially from shaft **710** is selected to cantilever beam **784** permitting the desired bending of end effector **718** relative to shaft **710** to position jaws **720**, **722** against the inner surface of the stomach in the vicinity of the GEJ.

[**0086**] Distal end effector **718** is sized to fit through a 12-16 mm diameter channel (corresponding to the diameter of the esophagus) and shaft **710** has an outer diameter of about 12 to 16 mm to enable transoral passage of instrument **700** into the stomach. Scope channel **782** has a diameter of either about 8 mm or 10 mm. An 8 mm diameter scope channel allows passage of 7.9 mm pediatric gastroscope, and a 10 mm diameter scope channel allows passage of a 9.8 mm adult gastroscope. Channel **778** has a diameter of about 2-3 mm for receiving cable **742**.

[**0087**] Distal end effector **718** is shown in more detail in **FIGS. 4A and 4B**. End effector **718** includes a central mount **800** defining a slot **801**. Spanning slot **801** and supported by mount **800** is a pin **803** to which **720**, **722** are pivotally mounted. Central mount **800** also houses two pulleys **802** over which cables **724***a*, **724***b* are respectively passed for closing jaws **720**, **722**. Cables **724***a*, **724***b* terminate at points **804**, **806** on jaws **720**, **722**, respectively. Cables **726***a*, **726***b* for opening jaws **720**, **722** terminate at points **808**, **810** on jaws **720**, **722**, respectively, proximal of points **804**, **806**. Tube **738** of end effector **718** for receiving coil **740** and overtube **742** is attached to mount **800**, and cable **728** for bending end effector **718** terminates at point **811** on tube **738**.

[**0088**] Pulling cables **724***a*, **724***b* proximally moves jaws **720**, **722** toward one another generally in a first plane (in the plane of the paper in **FIG. 4A**). Pulling cables **726***a*, **726***b* proximally moves jaws **720**, **722** away from one another generally in the first plane. Pulling cable **728** proximally bends beam **784** moving end effector **718** in a second plane (out of the plane of the paper in **FIG. 4A**) generally perpendicular to the first plane.

[**0089**] Referring also to **FIG. 5**, jaw **720** includes two guide tubes **816***a*, **816***b* and a slider **812** including two push rods **814***a*, **814***b* guided within tubes **816***a*, **816***b*, respectively. Slider **812** is mounted to jaw **720** to slide relative to jaw **720**. Tubes **816***a*, **816***b* curve about jaw **720** to terminate in tissue penetrating tips **818***a*, **818***b* (**FIG. 6B**), respectively. Push rods **814***a*, **814***b* can be formed from molded plastic such as polyethylene or polypropylene or as a braided stainless steel cable to provide the flexibility to follow the curve of tubes **816***a*, **816***b*. Cable housing **772** is attached to slider **812** and cable **737** terminates at a fixed point **739** on jaw **720**. Actuation of cable **737** pushes slider **812** distally, as described below.

[**0090**] First part **732** of tissue fixation device **730** is shown in more detail in **FIGS. 6A and 6B**. First part **732** of tissue fixation device **730** defines through holes **820***a*, **820***b* (**FIG. 6A**), and part **732** is loaded onto jaw **720** with tips **818***a*, **818***b* received in through holes **820***a*, **820***b*, respectively. Connected to part **732** with a suture **822** are two securing elements, e.g., bars **824***a*, **824***b*. Each bar **824***a*, **824***b* defines two through holes **826***a*, **826***b*. Suture **822** is threaded through holes **826***a*, **826***b* of the bars and through holes **820***a*, **820***b* of part **732**, and is tied together forming a knot **823** to secure bars **824***a*, **824***b* to part **732**. Tubes **818***a*, **818***b* each define a channel **827** for receiving one of bars **824***a*, **824***b*, and a slot **828** communicating with channel **827** for receiving suture **822** therethrough.

[**0091**] Referring particularly to **FIGS. 4B and 7**, jaw **722** has a distal member **830** defining a slot **832** for receiving second part **734** of fixation device **730**, and slots **834***a*, **834***b* for receiving tissue penetrating tips **818***a*, **818***b*. Second part **734** of fixation device **730** defines through holes **836***a*, **836***b* for receiving tips **818***a*, **818***b*. When jaws **720**, **722** are closed, tips **818***a*, **818***b* pass through slots **834***a*, **834***b* and holes **836***a*, **836***b*. Actuation of fixation device deployment cable **737** after closing jaws **720**, **722** pushes slider **812** and push rods **814***a*, **814***b* distally, advancing bars **824***a*, **824***b* out of tissue penetrating tips **818***a*, **818***b*, and locating bars **824***a*, **824***b* on the far side **838** of second part **734** of fixation device **730**, as shown in **FIG. 8**.

[**0092**] Referring to **FIGS. 9A-9F**, in use, under endoscopic guidance, the physician advances instrument **700** transorally to position end effector **718** in the stomach. During advancement into the stomach, end effector **718** is generally aligned along the axis of shaft **710**, as shown in **FIG. 9A**. The physician then turns control knob **746** to pull cable **728** proximally, thereby bending beam **784** moving end effector **718** out of alignment with shaft **710** to the position shown in **FIG. 9B**. By then turning control knob **744** to pull cables **726***a*, **726***b*, jaws **720**, **722** are pivoted about pins **803** to the open position shown in **FIG. 9C**.

[**0093**] The physician then advances coil **740** and overtube **742** by pushing the coil and overtube distally in channel **778** advancing coil **740** and overtube **742** out of tube **738** and

into contact with stomach tissue, preferably stomach tissue beyond the gastroesophageal junction, as shown in **FIG. 1**. With overtube **742** pressing against the tissue to stabilize the tissue, the physician rotates coil **740** while applying slight distal pressure to advance the coil into the tissue, as shown in **FIG. 9D**. Coil **740** and overtube **742** are then pulled proximally to pull tissue between jaws **720**, **722**. Jaws **720**, **722** are then closed by turning control knob **744** to pull cables **724***a*, **724***b* proximally, as shown in **FIG. 9E**. The turning of the control knob can also be the action that pulls coil **740** and overtube **742** proximally, ensuring that coil **740** and overtube **742** are positioned out of the way of the closing of the jaws. A lockout can be incorporated to prevent the jaws from closing if coil **740** and overtube **742** are not in their proximal position.

[**0094**] The closing of the jaws places parts **732**, **734** of fixation device **730** in contact with two tissue sections, e.g., against two spaced tissue surfaces in the stomach, and causes tissue penetrating tips **818***a*, **818***b* to penetrate through the tissue and into holes **836***a*, **836***b* in second part **734** of fixation device **730**. To deploy fixation device **730**, the physician pulls cable **737** proximally removing slack from cable **737**. Because cable housing **772** is of fixed length and is non-movably attached to the handle, removing slack from cable **737** causes cable housing **772** to move distally, advancing slider **812** to push t-bars **824***a*, **824***b* out of tissue penetrating tips **818***a*, **818***b*, as shown in **FIG. 9F**.

[**0095**] The physician then opens the jaws, disengages jaw **722** from second part **734**, returns the distal end effector to its original position generally aligned with shaft **710**, closes the jaws and removes instrument **700**. **FIG. 10** shows a cross-section of the tissue with fixation device **730** in place securing bulge **736**.

[**0096**] Other embodiments are within the scope of the following claims. For example, rather than a coil **740**, alternative tissue penetrating or grasping elements such as a T-bar suture or two small grasping jaws can be employed. Instrument **700** can be used without the third tissue engaging member.

[**0097**] Referring to **FIGS. 11A and 11B**, an end effector **718'** includes an alternative cable routing for actuating jaws **720**, **722**. End effector **718'** includes cables **726***a*, **726***b* for opening jaws **720**, **722**, a single cable **724'** for closing jaws **720**, **722**, and cable **737** for advancing slider **812**. End effector **718'** also includes pivot **803** and a series of pulleys **850***a*, **850***b*, **850***c*, **850***d*, and **850***e* around which the cables are routed.

[**0098**] Cable **724'** has a first portion **852**a that is routed under (as viewed in **FIGS. 11A and 11B**) pulley **850***a* and over pulley **850***c*; a second portion **852***b* that extends between pulleys **850***c* and **850***b*; and a third portion **852***c* routed under pulley **850***b* and over pulley **850***a*. Cable **726***a* has a first portion **854***a* that extends to pulley **850***d* and a second portion **854***b* that extends between pulley **850***d* and anchor **851***a* fixed to central mount **800**. Cable **726***b* has a first portion **856***a* that extends to pulley **850***e* and a second portion **856***b* that extends between pulley **850***d* and anchor **851***b* fixed to central mount **800**.

[**0099**] To open jaws **720** and **722**, the user applies a tensile force F**1** to cables **726***a* and **726***b* (by turning control knob **744**). The tensile force F**1** draws the first portions **854***a* and **856***a* of cables **726***a* and **726***b* proximally in the same direction as force F**1** and draws the second portions **854***b* and **856***b* of cables **726***a* and **726***b* distally around respective pulleys **850***e* and **850***d*. Turning knob **744** also produces slack in cable **724'**. A net force F**3** results and draws jaws **720**, **722** open.

[**0100**] To close jaws **720**, **722**, the user applies a tensile force F**2** to portions **852***a* and **852***b* ' of cable **724'** (by turning control knob **744** in the opposite direction, which also relieves tension in cables **726***a*, **726***b*). The tensile force F**2** acts to shorten portion **852***b* of cable **724'**, thereby drawing pulleys **850***c* and **850***b* together and jaws **720**, **722** closed.

[**0101**] Referring to **FIG. 12A**, in an alternative embodiment, a third tissue engagement member **740'** includes a tissue-engaging coil **860** with a tissue piercing end **860***a*, a helical drive shaft **862**, and a coupling member **864** for translating a torque applied by drive shaft **862** to coil **860**. Helical drive shaft **862** is preferably wound in a direction opposite that of tissue engaging coil **860**, for reasons described below. Positioned over and axially movable relative to coupling member **864** is a sprung sheath **866**. Tissue engagement member **740'** can be used alone or can replace tissue engagement member **740** of **FIG. 1**. Coil **860** has, e.g., six loops with a pitch of 1 ½ mm from loop-to-loop and a diameter of 2 mm. Other configurations can be used, e.g., one loop and greater with the number of loops times the pitch corresponding to the desired penetration depth into the tissue.

[**0102**] Referring to **FIG. 12B**, in which tissue engagement member **740'** is shown without spring sheath **866**, coupling member **864** includes a first, distal-most section **864***a* with a diameter, D**1**; a second section **864***b* with a diameter D**2** larger than D**1**; a third section **864***c* with a diameter D**3** between D**1** and D**2**; a fourth section **864***d* with a diameter D**4** about equal to D**2**; a fifth section **864***e* with a diameter D**5** larger than D**4**; and a proximal-most section **864***f* having a diameter D**6** about equal to D**1**. Diameters D**1**-D**6** are, for example, about 0.04", 0.09", 0.06", 0.09", 0.12" and 0.04", respectively. Defined between sections **864***a* and **864***b* is a shelf **867***a*; defined between sections **864***b* and **864***c* is a shelf **867***b*; defined between sections **864***c* and **864***d* is a shelf **867***c*; defined between sections **864***d* and **864***e* is a shelf **867***d*; and defined between sections **864***e* and **864***f* is a shelf **867***e*. Drive shaft **862** is received over coupling member section **864***f* and coil **860** is received over coupling member section **864***a*. Drive shaft **862** and coil **869** are attached to coupling member **864** by, for example, soldering. Coil **860** has a coil length, L, of, for example, about 0.25", extending beyond the distal end **868** of section **864***a*. Positioned on coupling member section **864***c* between shelves **867***b* and **867***c* is a spring **870** that biases sprung sheath **866** distally.

[**0103**] Referring to **FIG. 12C**, sprung sheath **866** defines a lumen **872** and has a first section **866***a* with an inner diameter d**1**, a second hub section **866***b* with an inner diameter d**2** less than d**1**, and a third section **866***c* with an inner diameter d**3** about equal to d**1**. Coil **860** is received within lumen **872** in sheath section **866***a*. Spring **870** is located within lumen **872** radially between coupling member section **864***c* and section **866***c* of sheath **866** and axially between hub **866***b* and shelf **867***c*. Sheath hub **866***b* is biased

against shelf **867***b* by spring **870**. The spacing between coupling member shelf **867***d* and a proximal end **874***b* of sheath **866** permits axial, proximal movement of sheath **866** against the action of spring **870**.

[**0104**] To facilitate assembly of tissue engaging member **740'**, coupling member **864** is formed from two parts **876***a*, **876***b* having mating fingers **878** joined, for example, by compression fitting. This configuration permits sheath **866** to be slid over part **876**a prior to joining part **876***b* to **876***a*.

[**0105**] Referring also to **FIG. 12D**, in operation, the user places distal end **874***a* of sheath **866** against tissue T to be pierced to stabilize the tissue. The user then applies distal and rotational forces to drive shaft **862**, which causes coupling member **864** and coil **860** to move distally and rotate into the tissue, for example, the mucosal layer of tissue. As coil **860** advances into the tissue, distal end **874***a* of sheath **866** remains on the surface of the tissue, spring **870** is compressed, and shelf **867***d* advances toward sheath proximal end **874***b*. When coil **860** has been anchored in the tissue, for example, the muscle layer of tissue underlying the mucosal layer (which takes about 3 or 4 turns of the coil into the tissue), the user can manipulate the tissue with tissue engaging member **740'**. By engaging multiple layers of tissue, member **740'** provides a secure grasp on the tissue.

[**0106**] Sprung sheath **866** acts to stabilize both the tissue and coil **860** when coil **860** is advanced into the tissue. Sheath **866** compresses the tissue, facilitating initial penetration of the coil into the tissue, and helps keep the tissue from twisting as the coil rotates. Furthermore, the coil **860** tends to want to go off-axis as it rotates into the tissue. Sprung sheath **866** provides enough force against the tissue and has enough friction against the tissue surface to limit movement of sheath **866** as coil **860** is advanced into the tissue. This counteracts the tendency of the coil to want to go off-axis.

[**0107**] Due to the opposed winding of drive shaft **862** and coil **860**, the rotational force applied to drive shaft **862** causes a decrease in the diameter of drive shaft **862** upon encountering torsional resistance. This decrease in the diameter of drive shaft **862** limits contact of drive shaft **862** with the wall of an associated working channel in which drive shaft **862** is located and thus possible jamming in the working channel.

[**0108**] Referring to **FIGS. 13A and 13B**, to apply the distally and rotationally directed forces to drive shaft **862**, a torque generator **882** held by the user and a drive rod **880** releasably attached to torque generator **882** and extending through handle **743** are coupled to drive shaft **862**. Drive rod **880** runs a majority of the length of instrument **700** to provide high torque, with drive shaft **862** extending in the area of the retroflex region to provide high flexibility. Drive rod **880** and drive shaft **862** are coupled, e.g., by soldering. Torque generator **882** includes a handle **883**, a collet **885**, and a spring loaded cap **887**. Collet **885** includes a circumferential section **885'** and four legs **885***a* extending from section **885'**, each with an enlarged end **885***b*. Each leg **885***a* has a flat, inner facing surface **885***c* that together define a square opening **886**. Drive rod **880** has a coupling member **889** with four flat sides **889***a*. Coupling member **889** is received within opening **886** with flat sides **889***a* aligned with surfaces **885***c* such that when closed, torque generator **882** and drive rod **880** are rotationally locked.

[**0109**] Handle **883** defines a bore **881'** in which a pin **882'** is received, and a larger diameter bore **883'** in which pin **882'**, collet **885** and a spring **887'** are received. Cap **887** is biased distally by spring **887'**. Pin **882'** is press fit into bore **881'** and into circumferential section **885'** of collet **885**. To attach drive rod **880** to torque generator **882**, cap **887** is moved proximally against the force of spring **887'**, which allows legs **885***a* to be flexed outward permitting coupling member **889** to be positioned in opening **886**. The user releases cap **887**, and spring **887'** acts to move cap **887** distally closing legs **885***a* around coupling member **889**. Distal motion of cap **887** is limited by contact of a shelf **880'** of cap **887** against enlarged leg ends **885***b*.

[**0110**] Tissue engaging member **740'** is preferably a single use disposable product supplied sterile to the user. Member **740'** can be loaded into the instrument from the distal end of the instrument and then attached to torque generator **882**. This preserves the sterility of the distal end of member **740'**.

[**0111**] Referring to **FIG. 14A**, in an alternative embodiment, rather than stabilizing tissue with sprung sheath **866** of **FIG. 12A**, positioned within coil **860** is a solid needle **881***a*. Needle **881** a extends from coupling member **864**. Needle **881** a facilitates the initial engagement of coil **860** with the tissue, and is particularly applicable to situations in which coil **860** approaches the tissue surface at an angle. Referring to **FIGS. 14B and 14C**, rather than a solid needle, positioned within coil **860** and extending to the proximal end of the tissue engagement member is a matter injector needle **881***b*, which can be advanced through coil **860**. Matter injector needle **881***b* has a. metal tip **881***c* on a flexible, plastic tube **881***d*. Coupling member **864**, coupling member **889**, pin **882'**, and hand grip **883** define aligned through bores that slidably receive needle **881***b*. Needle **881***b* replaces drive rod **880**, and drive shaft **862** extends the length of the instrument.

[**0112**] Matter injector needle **881***b* can be used in "bulking" procedures to augment tissue in a selected region by injecting a biocompatible material, such as described, e.g., in U.S. Pat. No. 5,336,263 to Ersek et al., hereby incorporated by reference in its entirety. In use, coil **860** acts to anchor needle **881***b* in the tissue to counteract pressure created by the material injection, which would tend to push needle **881***b* out of the tissue. For matter injection, the tissue engaging instrument can be used through a working channel of an endoscope, or in conjunction with instrument **700**. Alternatively, the wire forming coil **860** can define a lumen and matter injected through the wire lumen.

[**0113**] Referring to **FIGS. 15A and 15B**, an alternative third tissue engagement member **740'"** includes an elongate member **892** that passes through a working channel of instrument **700** and a pair of pincers **893***a* and **893***b* pivotably mounted at a pivot **895** to the distal end **892***a* of elongate member **892**. Pincers **893***a* and **893***b* each include a respective pincer tip **891***a* and **891***b* suitable for piercing tissue. Pincers **893***a* and **893***b* are actuated, e.g., by one or more guidewires (not shown), as is described, e.g., in U.S. Pat. No. 5,613,499 to Palmer et al., hereby incorporated by reference in its entirety.

[**0114**] Pincers **893***a* and **893***b* are generally arcuate in shape with pincer tips **891***a* and **891***b* oriented substantially normal to lines L1, L2 defined by pivot point **895** and the end of each respective pincer tip. Pincers **893***a* and **893***b* are

made from a rigid, sterilizable material capable of maintaining pincer tips **891***a* and **891***b* suitable for puncturing tissue and withstanding at least short term exposure to operating environments such as the stomach. As such, pincers **893***a* and **893***b* can be made from metals such as stainless steel and Co—Cr alloys.

[**0115**] Referring to **FIG. 15C and 15D**, in operation, with pincers **893***a* and **893***b* in their opened position, the user advances tissue engagement member **740**''' into contact with a tissue surface such as a mucosal layer **894** on a muscle layer **895** in the stomach. The user then closes pincers **893***a* and **893***b* such that the pincer tips **891***a* and **891***b* penetrate through the mucosal layer **894** and into muscle layer **895**. Once the pincer tips **891***a* and **891***b* have been drawn together, the user retracts the pincers **893***a* and **893***b* from the engaged tissue using the elongate member **892**. Plication and/or bulking of the retracted tissue can follow as described elsewhere herein.

[**0116**] Due to the arcuate shape of pincers **893***a* and **893***b*, the initial closing of the pincers results in substantially distal translation of pincer tips **891***a*, **891***b*, with further closing of the pincers resulting in substantially transverse motion of pincer tips **891***a*, **891***b*. This distributes the retraction load applied by the pincers **893***a* and **893***b* for plication over a relatively large area of tissue, limiting the possibility of tearing the tissue during retraction.

[**0117**] Referring to **FIGS. 16A and 16B**, in accordance with another embodiment of the invention, an instrument **900** for reconfiguring stomach tissue includes a handle **902**, an elongated instrument shaft **904**, and a distal actuating assembly **905**. As discussed below, the configuration of assembly **905**, and the means of attachment of assembly **905** to instrument shaft **904**, substantially seals a lumen of shaft **904** that houses the actuating cables from contact with bodily fluids. As a result, only a disposable portion of assembly **905** need be supplied to the user in a sterile condition. The remainder of the instrument can simply be disinfected by manual cleaning and soaking in a disinfecting solution between procedures.

[**0118**] As in embodiments discussed above, instrument **900** receives gastroscope **715** and a tissue engagement member **908** (such as coil **740** or **740**' described above). Assembly **905** includes a retroflex portion **910** that is manipulated by the user to orient assembly **905** (as shown in **FIG. 16B**). Handle **902** includes control knobs **912**, **914** that actuate assembly **905**, and a switch **915** that disengages a lock mechanism, as described below.

[**0119**] Referring to **FIGS. 17A and 17B**, shaft **904** defines a lumen **916** through which the end of gastroscope **715** protrudes. Retroflex portion **910** has a sloping curved wall section **918** against which the end of gastroscope **715** is received. When flexed, retroflex portion **910** is bent in a direction away from section **918** (arrow A). Assembly **905** further includes a coupling member **919** and an end effector **906**. Coupling member **919** includes a first portion **923** that attaches to retroflex portion **910**, and a mount **924** to which end effector **906** is pivotally mounted. End effector **906** includes jaw members **920**, **922**, each of which includes a tissue manipulating cartridge **960***a*, **960***b*, respectively, releasable mounted to a respective actuating arm **962***a*, **962***b*.

[**0120**] Covering retroflex portion **910** and coupling member portion **923** is a cover **910**', and covering mount **924** and end effector **906** is a hood **1220**, discussed further below. Hood **1220** provides an atraumatic distal end for transoral placement of instrument **900**, and cover **910**' seals retroflex portion **910** and coupling member portion **923** from contact with bodily fluids.

[**0121**] In use, with gastroscope **715** in instrument lumen **916** and the end of the gastroscope residing in section **918**, the user advances instrument **900** transorally into the stomach. Once in the stomach, gastroscope **715** is independently manipulated to obtain the desired view. The user flexes instrument **900** (as shown in **FIG. 16B**), opens jaws **920**, **922**, advances the tissue engagement member into engagement with the tissue to stabilize the tissue, closes jaws **920**, **922** such that cartridges **960***a*, **960***b* manipulate the tissue into a bulge, and deploys an implant, as described further below.

[**0122**] Referring to **FIG. 17C** (coupling member **919** has been partially removed from **FIG. 17C** for clarity), actuating arms **962***a*, **962***b* are pivotally coupled to mount **924** at pivots **963***a*, **963***b*, respectively. A pair of cables, discussed below, for opening and closing jaws **920**, **922** are coupled to the jaws via a yoke **964**. Yoke **964** has a generally H-shaped section **965** with two legs **966***a* straddling arm **962***a*, and two legs **966***b* straddling arm **962***b*. Each arm **962***a*, **962***b* defines a slot **968***a*, **968***b*, and each leg **966***a*, **966***b* defines a through hole **970***a*, **970***b*. Received within slot **968***a* and holes **970***a* is a pin **972***a*, and received within slot **968***b* and holes **970***b* is a pin **972***b*. Slots **968***a*, **968***b* each have first and second sections **974**, **975**. Slot sections **974** are orientated at a greater angle relative to the axis of the instrument than that of slot sections **975**, for purposes described below. Yoke **964** includes a post **978** extending proximally from section **965**. Post **978** extends into coupling member **980**. Mounted to post **978** is a first pulley **982**, and mounted to coupling member **980** are two pulleys **984**, **985**, which a jaw closing cable is routed over, as described below.

[**0123**] Portion **923** and mount **924** of coupling member **919** have flat sides **923***a*, **924***a* and rounded sides **923***b*, **924***b*, as shown in **FIG. 17D**. Rounded sides **923***b*, **924***b* define a through bore **927** for passage of the tissue engagement member. Mount **923** also defines a through bore **931** through which yoke **964** extends.

[**0124**] Referring to **FIGS. 17E and 17F**, located in portion **923** is a lock arm **1250** pivotally mounted at **1252**. Lock arm **1250** has a ridge **1253** with curved wall **1254** and yoke **964** defines a notch **1256** with a correspondingly shaped curved wall **1258**. After a predetermined amount of distal travel of yoke **964**, curved wall **1254** of ridge **1253** engages with curved wall **1258** of notch **1256** to limit further distal travel of yoke **964**. Lock arm **1250** is biased by a compression spring **1262** to rotate clockwise about pivot **1252** (arrow Y) such that when notch **1256** passes under lock arm **1250**, lock arm **1250** is rotated under the force of spring **1262** to engage curved walls **1254**, **1258**. Attached to lock arm **1250** is a cable **1260** for moving arm **1260** out of engagement with yoke **964** to allow further distal travel of yoke **964**.

[**0125**] **FIG. 17G** illustrates the replaceable nature of cartridges **960***a*, **960***b*. Arms **962***a*, **962***b* each include a flat, rectangular member **1050** and a clip **1052**. Member **1050** has formations **1051**, **1053** extending from either side of member **1050**. Formations **1051** have a thin distal section **1051***a* that slopes to a wider proximal section **1051***b*, for purposes

described below with reference to **FIGS. 46**. Cartridges **960***a*, **960***b* each include a first pair of side walls **1054**, a second pair of side walls **1056** defining slots **1056***a*, an opening **1058**, and a head **1059**. Opening **1058** is rectangular in shape, here shown square, though other shapes are suitable that have a mating contour with a flat proximal edge **1058***a*. Instead of an opening **1058**, an indentation in the cartridge that corresponds to the shape of clip **1052** can be employed. Side walls **1054**, **1056** are separated by a thin section **1057** which allows the cartridge to flex.

[**0126**] To attach cartridges **960***a*, **960***b* to arms **962***a*, **962***b*, respectively, the cartridge is slid over the arm with side walls **1054** aligning the cartridge to the arm. Rectangular member **1050** is received in slots **1056***a* while the cartridge flexes over clip **1052** such that clip **1052** is received within opening **1058** to lock the cartridge to the arm. To remove the cartridge, the user pushes on side walls **1054** to flex the cartridge away from clip **1052**, and the cartridge is then slid off the arm.

[**0127**] Referring to the exploded view of **FIG. 17H**, retroflex portion **910** has a proximal mount **1060** that is, e.g., glued onto the end of shaft **904**, and a distal mount **1062** that is received within a slot **933** in mount **923**. Mounts **1062**, **923** are attached, e.g., by screws. Mount **1062** is preferably metal and coupling member **919** is preferably plastic.

[**0128**] Referring to **FIG. 171**, the only member of instrument **900** that extends from retroflex region **910** through the sealed section formed by cover **910'** is yoke **964**. To limit access of bodily fluids to retroflex portion **910**, coupling member portion **923** defines a space **1070** in which an o-ring **1072** is positioned to seal off through bore **931**.

[**0129**] Referring to **FIGS. 18-20**, to control retroflex portion **910** and end effector **906**, knobs **912**, **914** interface with a series of cables **925***a*, **925***a*', **925***b*, **925***c* (**FIG. 20**) through a gear block mount **926** located in handle **902**. Block mount **926** defines through bores **928***a*, **928***a*', **928***b*, **928***c* within each of which a rack **930***a*, **930***a*', **930***b*, **930***c*, respectively, is located. Each rack **930***a*, **930***a*', **930***b*, **930***c* is connected to a respective cable **925***a*, **925***a*', **925***b*, **925***c*, as described below, and has a flat side **932** defining teeth **934**. Referring particularly to **FIGS. 21A and 21B**, associated with racks **930***a*, **930***a*' is a pinion **936***a*, and associated with each rack **930***b*, **930***c* is a respective pinion **936***b*, **936***c*. Racks **930***a*, **930***a*' are on opposite sides of pinion **936***a*, and racks **930***b*, **930***c* are on opposite sides of pinions **936***b*, **936***c*. Pinion **936***c* is preferably twice the diameter of pinion **936***b*, for reasons discussed below. Pinion **936***a* is driven by a reduction gear set **937**, **939**. Gear **939** is mounted to a shaft **942** that is integral with retroflex knob **912**. Pinions **936***b*, **936***c* are mounted to a shaft **944** that is integral with jaw actuating knob **914**, and passes through shaft **942**.

[**0130**] To manipulate retroflex portion **910**, the user turns knob **912**, which causes shaft **942** and pinion **936***a* to turn. Since racks **930***a*, **930***a*' are on opposite sides of shaft **946**, rotation of pinion **936***a* causes opposed linear motion of racks **930***a*, **930***a*', which moves cables **925***a*, **925***a*' to flex and straighten retroflex portion **910**, as described further below. To manipulate the jaws, the user turns knob **914**, which causes shaft **946** and pinions **936***b*, **936***c* to rotate. Since racks **930***b*, **930***c* are on opposite sides of shaft **946**, rotation of pinions **936***b*, **936***c* causes opposed linear motion of racks **930***b*, **930***c*, which moves cables **925***b*, **925***c* to open and close the jaws, as described further below. Associated with knob **912** is a tension adjustment knob **912***a*, and associated with knot **914** is a tension adjustment lever **914***a*, as is well known in the art.

[**0131**] Referring to **FIGS. 20 and 22**, mounted over each cable **925***a*, **925***a*', **925***b*, **925***c* is a cable housing **947***a*, **947***a*', **947***b*, **947***c*, respectively, and a cable housing adjustment screw **948***a*, **948***a*', **948***b*, **948***c*, respectively. Cable housing adjustment screws **948***a*, **948***a*', **948***b*, **948***c* are threadably received within respective block through bores **928***a*, **928***a*', **928***b*, **928***c* (as shown in **FIG. 19**). Rotation of screws **948***a*, **948***a*', **948***b*, **948***c* translates cable housings **947***a*, **947***a*', **947***b*, **947***c* distally and proximally along respective cables **925***a*, **925***a*', **925***b*, **925***c* to provide an optimal working length for transmitting actuating forces. Cables **925***a*, **925***a*', **925***b*, **925***c* move freely through their respective housings and screws.

[**0132**] On the opposite side of racks **930***a*, **930***a*', **930***b*, **930***c* from screws **948***a*, **948***a*', **948***b*, **948***c* are stops **949***a*, **949***a*', **949***b*, **949***c* received within respective block through bores **928***a*, **928***a*', **928***b*, **928***c*. Stops **949***a*, **949***a*', **949***b*, **949***c* limit the travel of racks **930***a*, **930***a*', **930***b*, **930***c*, respectively.

[**0133**] Referring particularly to **FIG. 22**, cable **925***a* is received within a bore **950** defined in rack **930***a*. Cable **925***a* extends through a hole **952** defined in an end wall **954** of rack **930***a* into bore **950**. Located within bore **950** is a spring **956**. Cable **925***a* extends through spring **956** and has an enlarged terminal end **957** that maintains the position of cable **925***a* relative to spring **956**. Spring **956** acts to continually exert a slight tensile force upon cable **925***a* to keep the cable taught. Cables **925***b*, **925***c* are likewise coupled to racks **930***b*, **930***c*, respectively.

[**0134**] Referring again to **FIG. 19**, attached to block mount **926** is a slide lever **1400** mounted within a bracket **1402**. Switch **915** is received within an opening **1404** in lever **1400** such that movement of switch **915** moves lever **1400**. Lever end **1406** defines a diagonal slot **1408** in which a pin **1410** is received. Pin **1410** is attached to a stop member **1412** that contacts a stop **1414** after jaw closing rack **930***b* has traveled a pre-set distance. Movement of lever **1400** in the direction of arrow X causes pin **1410** and stop member **1412** to rotate about the axis of stop member **1412**, disengaging stop member **1412** from stop **1414** to allow further movement of rack **930***b*. Cable **1260** attached to lock arm **1250** is attached at its opposite end to switch **915**. When switch **915** is moved in the direction of arrow X, cable **1260** moves lock arm **1250** to disengage lock arm **1250** (**FIG. 17E**) from yoke **964** (discussed further below with reference to **FIGS. 23**). Bracket **1402** can be adjusted to fine tune the positioning of switch **915** relative to pin **1410** and lock arm **1250**.

[**0135**] As shown in **FIGS. 23A-23D**, jaw closing cable **925***b* is wound around pulleys **984** and **982**, and terminates at a fixed point **986** connected to distal mount **1062** (**FIG. 17G**). Jaw opening cable **935***c* is connected in a fixed relationship to post **978**. To close jaws **920**, **922**, the user turns knob **914** in the direction of arrow, A (**FIG. 20**), which moves cable **925**b in the direction of arrow, B, and permits slack in cable **925***c* allowing yoke **965** to move distally, in the direction of arrow, C. Due to the 2:1 ratio between pinions **936***b* and **936***c*, cable **925***b* moves twice the distance

of cable **925***c*. (This is required due to the routing of cable **925***b* around pulleys **982**, **984**.) Pins **972***a*, **972***b* slide along slots **968***a*, **968***b* causing jaws **920**, **922** to close. To open the jaws, the user turns knob **914** in the direction opposite arrow, A, which tensions cable **925***c* and permits slack in cable **925***b*. The tension on cable **925***c* moves yoke **964** proximally, arrow, E, opening jaws **920**, **922**. Due to the orientation of slot sections **974**, **975**, during the initial stage of jaw closing **(FIG. 23B)** when the yoke is sliding along slot section **974**, there is a greater ratio of jaw closing for the distance the piston moves than during the later stage **(FIG. 23C)** when the yoke is sliding along slot section **975**. There provides faster jaw closing with lower mechanical advantage when less closing force is needed (because the jaws are not yet contacting the tissue), and slower jaw closing with higher mechanical advantage when more closing force is needed as the jaws grasp the tissue and pierce through the tissue. After the jaws have reached the position of **FIG. 23C**, pin hits stop in handle and lock arm notch **1254** and yoke notch **1256** engage to limit further closing of the jaws. The user then pushes switch **915** proximally to move stop member out of the way and to disengage lock arm **1250** from yoke **964**, this permits knob **914** to be further turned to completely close the jaws and deploy the implant **(FIG. 23D)**.

[0136] Referring to **FIGS. 24A-24D**, retroflex portion **910** includes a series of links **990** that are hinged together with pins **991**. Each link **990** includes a generally U-shaped body **992** with a first section **992***a* defining a U-shaped opening and second section **992***b* defining a larger U-shaped opening. Extending from body **992** are two mating prongs **994**. Body **992** defines two transverse holes **996** (only one hole **996** being shown in **FIG. 24B**), and each prong **994** defines a transverse hole **998**. When two links **990** are mated, prongs **994** lie within the U-shaped opening defined by section **992***b*. Holes **996**, **998** are aligned, and pin **991** is passed through holes **996**, **998** to join the two links. Body **992** has a side wall **1000** with a portion **1001** of the side wall set at an angle to allow the joined links to flex. Links **990** also define axial holes **1003**, **1004** for receiving cables **924***a*, **924***a*'. Cables **924***a*, **924***a*' terminate on mount **1062**. Pulling cable **924***a* flexes portion **910**, and pulling cable **924***a*' straightens portion **910**. Cover **910'** **(FIG. 17A)** covers the links.

[0137] Referring also to **FIG. 25**, in addition to lumen **916** for receiving gastroscope **715**, shaft **904** and mount **1060** define a lumen **1010** for receiving tissue engaging member **908**, a lumen **1012** for receiving flexing cable **924***a*, a lumen **1014** for receiving straightening cable **924***a*', a lumen **1016** for receiving closing cable **925***b*, a lumen **1018** for receiving opening cable **925***c*, a lumen **1020** for receiving locking cable **1260**, and an extra lumen **1022** if needed. Mount **1062** includes holes **1024** and **1026** for passage of cables **925***b*, **925***c*, respectively, a hole **1028** at which the end of closing cable **925***b* terminates, and a hole **1030** for passage of locking cable **1260**.

[0138] Tissue engaging member **908** is located in the U-shaped openings defined by U-shaped bodies **992** in retroflex portion **910**. Pins **991** are centered along the central axis of tissue engaging member **908** such that when flexed, tissue engaging member **908** is flexed along is central axis. Tissue engaging member **908** is surrounded by a sheath **927***a* **(FIGS. 17D and 18)**. Sheath **927***a* runs from handle inlet **1002** to the proximal end of through bore **927** in coupling member **919**. Sheath **927***a* is sealed at one end to handle **902** and at the other end to coupling member **919**. This effectively seals the remainder of the instrument from contact with fluid that enters tissue engaging member **908**. Shaft lumen **906** likewise is lined with a sheath **906'** that seals the remainder of the instrument from contact with bodily fluids that enter lumen **906**.

[0139] Referring to **FIGS. 26 and 27**, end effector **906** is configured for deployment of a tissue fixation member upon closing of jaws **920**, **922** without requiring further actuation. Cartridge **960***b* of jaw **922** includes tissue passing tubes **1120***a*, **1120***b*. Removably coupled to each tube **1120***a*, **1120***b* is a tissue fixation bar **824***a*, **824***b* having a pointed tip **1122** for penetrating tissue. Each tube **1120***a*, **1120***b* defines a through bore **1124**, and each bar **824***a*, **824***b* has a hub **1126** that fits within bore **1124**. Tubes **1120***a*, **1120***b* and bars **824***a*, **824***b* have the same outer diameter for ease of penetrating tissue. Bars **824***a*, **824***b* each define a through hole **1128** for receiving, for example, a suture (not shown), which is passed through both holes and tied off to itself. Bars **824***a*, **824***b* can be coupled to tubes **1120***a*, **1120***b*, respectively by a press fit, crimp, or spot laser welding. Crimping can be done around the entire perimeter of the bar, at two (opposing) sides of the bar, or at a single point along the perimeter of the bar.

[0140] Bars **824***a*, **824***b* are configured to detach from tubes **1120***a*, **1120***b* under the force applied by the closing of jaws **920**, **922**. Referring to **FIGS. 26 and 28**A-28C, cartridge **960***a*defines two arcuate walls **1130** against which bars **824***a*, **824***b* are positioned upon closing of jaws **920**, **922**. As shown in **FIG. 28C**, upon closure of jaws **920**, **922**, the arcuate walls **1130** apply a lateral force (i.e., substantially normal to the long axis of the tubes) to bars **824***a*, **824***b*, which causes the bars to be released from the respective tubes. When jaws **920**, **922** are opened, and instrument **900** pulled proximally, bars **824***a*, **824***b* and parts **732**, **734** (discussed above with reference to **FIG. 8**) of the tissue fixation member are released from jaws **920**, **922**.

[0141] Referring to **FIGS. 29A and 29B**, jaws **920**, **922** are covered with hood **1220** formed from halves **1222** and **1224** connected at a region **1226** and defining a seam **1228** therebetween. Each half **1222**, **1224** covers a respective jaw **920**, **922**. When the jaws are closed, as shown in **FIG. 29A**, hood **1220** provides an atraumatic distal end for delivery through the esophagus. When the jaws are opened, as shown in **FIG. 29B**, halves **1222**, **1224** separate at seam **1228**. Hood **1220** limits trauma to the tissue during transoral insertion of the instrument and eliminates the need for an outer sheath extending the length of the instrument.

[0142] Referring to **FIG. 30**, handle **902** defines an inlet **1002** through which gastroscope **715** is introduced. Located at inlet **1002** is a seal **1004** for providing a hermetic seal between handle **902** and gastroscope **715**. Seal **1004** has a sealing area **1006** of restricted diameter, and an alignment area **1008** of restricted diameter spaced about 10 mm from area **1006**. Area **1006** has a diameter of about 9 mm, which is about the same or slightly smaller than (about 90% of) the diameter of gastroscope **715** (typically about 10 mm). Area **1008** has a diameter of about 11 mm, which is also about the same or slightly larger than (about 110% of) the diameter of gastroscope **715**. Alignment area **1008** provides support for

gastroscope **715** to maintain a hermetic seal at sealing area **1006** during motion of the gastroscope. Seal **1004** is made from, e.g., rubber or other deformable material.

[**0143**] Other embodiments are within the scope of the following claims.

[**0144**] For example, referring to **FIG. 31**, instead of curved surfaces **1130** of **FIGS. 28**, cartridge **960***a*' includes a spring member **1130**'. When bars **824***a*, **824***b* contacts members **1130**', member **1130**' deflects forming a curved surface resulting in a lateral force being applied to bars **824***a*, **824***b* that acts to dislodge the bars from needles **1120***a*, **1120***b*.

[**0145**] Referring to **FIGS. 32**, in an alternative embodiment, tubes **1120**' include a pair of radially opposed slots **1132** that impart flexibility to end **1133** of the tube to aid in release of the bars from the tubes. Bars **824**' can include a pair of guide nubs **1134** received in slots **1132** to radially orients bars **824**' relative to tubes **1120**' . Referring to **FIG. 33**, bars **824**" include a bump or undercut **1136** that determine the force needed to remove the bars from the tubes. The tubes can be formed from plastic and molded as an integral component of the cartridges, and the bars can be insert molded into the tubes. Referring to **FIG. 34**, bars **824**'" are connected to tubes **1120**' by a weak area **1137** of decreased diameter that breaks upon application of lateral force to bars **824**'".

[**0146**] Referring to **FIGS. 35A and 35B**, instead of bars attached by suture, the tissue fixation member includes bars **1150** connected by a flexible spanning member **1152**. Bars **1150** define through bores **1154** and are received on members **1156** having tissue penetrating tips **1158**. Members **1156** replace tubes **1120**.

[**0147**] Referring to **FIG. 36A**, to aid in insertion of instrument **900** through the esophagus, end effector **906** and retroflex portion **910** are partially covered with an atraumatic hood **1100**. Hood **1100** has a tapered distal end **1102** terminating in a small diameter lead portion **1104**. Hood **1100** includes an opening **1106** through which end effector **906** and retroflex portion **910** are deployed, in the direction of arrow, D, after insertion of instrument **900** through the esophagus. Distal end **1102** defines a channel **1105** extending from lead portion **1104** to a slot **1107**. Instrument **900** can be introduced transorally over a guidewire (not shown) by threading the guidewire through channel **1105** entering at lead portion **1104** to exiting at slot **1107**. Hood **1100** is made from, e.g., metal, plastic, or elastomeric materials such as rubber, polyurethane or silicone.

[**0148**] As shown in **FIG. 36B**, to further ensure trauma to tissue as the instrument is introduced transorally is avoided, a pair of flaps **1109** are provided covering assembly **905**. The flaps part when retroflex portion **910** is deployed.

[**0149**] Referring to **FIG. 37**, rather than a hood covering end effector **906**, placed between jaws **920**, **922** is volume-filling bullet **1200** that creates a relatively smooth surface at the distal end of the instrument to facilitate insertion of the instrument into a patient. Bullet **1200** defines a through hole **1200***a* for delivery over a guidewire. Volume-filling bullet **1200** can be dissolvable in the operating environment, retrievable from the operating environment, or abandonable in the operating environment. For example, the guidewire can have a tip with a larger diameter than hole **1200***a* such that bullet **1200** is retained on the guidewire and removable therewith.

[**0150**] Referring to **FIG. 38**, in another embodiment, a hood **1220**' includes halves **1222**', **1224**' that are connected to mount **924** at pivots **1230**. When the jaws are opened, halves **1222**', **1224**' pivot about pivots **1230** to separate at seam **1228**'. In **FIG. 39**, halves **1222**", **1224**" of a hood **1220**" include spring beams **1240** joined in a region **1226**'. When the jaws are opened, halves **1222**" , **1224**" separate at seam **1228**" and spring beams **1240** deform.

[**0151**] Alternatively, as shown in **FIG. 40**, to provide an atraumatic distal end, an end cap **1242** is placed over the jaws. End cap **1242** can be removed by pushing it off distally using the tissue engagement member, can be dissolvable (e.g., made out of starch or gelatin), or can "break-away." when the jaws are opened. Providing a perforation along the length of cap **1242** can aid in break-away. After removal, cap **1242** can be abandoned in the operating environment, where it is dissolved or passed, or it can be retained by a guidewire so that it is withdrawn when the instrument is withdrawn.

[**0152**] Referring to **FIGS. 41A and 41B**, in an alternative embodiment, an end effector **906**' includes jaw members **920**', **922**', each of which includes a tissue manipulating cartridge **960***a*', **960***b*', respectively, releasable mounted to a respective actuating arm **962***a*', **962***b*'. Jaw **922**' contains a pusher rods **814***a*, **814***b* for deploying bars **824***a*, **824***b* as described above with reference to **FIG. 5**. However, rather than employing a separate mechanism for actuating pusher rods **814***a*, **814***b*, pusher rods **814***a*, **814***b* are actuated by yoke **964**. Each arm **962***a*', **962***b*' defines a slot **968***a*', **968***b*" having a first arcuate section **974**', a second generally linear, angled section **975**', and a third generally linear, parallel section **976**'. Movement of yoke **964** along slot sections **974**' and **975**' closes jaws **920**', **922**'. To deploy tissue fixation device **730** (**FIG. 2**), movement of yoke **964** along section **976**' of slots **968***a*, **968***b* moves pusher rods **814***a*, **814***b* distally advancing bars **824***a*, **824***b* out of tissue penetrating tips **818***a*, **818***b* to deploy fixation device **730**, as described above with reference to **FIGS. 4A and 4B**.

[**0153**] Referring to **FIG. 42**, an alternative tissue fixation member for use with the embodiments of **FIGS. 2 and 41**, includes bars **1150**' connected by a flexible spanning member **1152**.' Bars **1150**' replace bars **824***a*, **824***b*.

[**0154**] The instruments embodied in **FIGS. 43-45** are configured to allow one person to control both the gastroscope and the tissue reconfiguring instrument. Referring particularly to **FIG. 43**, an instrument **1300** for reconfiguring tissue includes a standard gastroscope **715** and a tissue manipulator **1304** mounted to gastroscope **715**. Tissue manipulator **1304** includes a control mount **1306** which the user mounts to gastroscope tube **1307** by, e.g., a friction fit. Control mount **1306** includes knobs **912**, **914**, described above. End effector **906** and retroflex portion **910** of assembly **905** are mounted to a sleeve **1308** through which gastroscope tube **1307** extends. Sleeve **1308** defines conduits for the control cables as described above. Connecting control mount **1306** and sleeve **1308** is a flexible conduit **1310** enclosing the various cables for controlling end effector **906** and retroflex portion **910**, as discussed above. Sleeve **1308** includes a hand grip **1312**. Conduit **1310** permits axial movement of gastroscope **715** relative to tissue manipulator

1304. In use, the operator holds the gastroscope handle with one hand, and operates all the controls and manipulates grip **1312** with the other hand, permitting a single operator to control all functions.

[**0155**] Referring to **FIG. 44**, an instrument **1320** for reconfiguring tissue includes a standard gastroscope **715** to which the user mounts end effector **906**. Cables for actuating the jaws are attached to a jaw control mount **1324**. The cables are received in the standard biopsy channel **1322'** of the gastroscope. Retroflexing action is provided by gastroscope **715** and is controlled by the gastroscope controls. Jaw control mount **1324** includes knob **914** for actuating the jaw control cables. In the embodiment of **FIG. 45**, rather than mounting the tissue reconfiguring instrument to a standard gastroscope, an integral instrument **1330** includes a knob **914** mounted directly to gastroscope **1330**. The control cables for actuating the jaws are integrated with the gastroscope control cables. The tissue engaging member, e.g., member **740'** of **FIGS. 12**, is introduced through the gastroscope channel **1322'**.

[**0156**] Referring to **FIGS. 46A and 46B**, cartridges **960***a*, **960***b* are supplied to the medical personnel in a holder **1450**. Holder **1450** includes a base section **1452** having a first side **1453***a* for receiving head **1059** of cartridge **960***a*, and a second side **1453***b* for receiving head **1059** of cartridge **960***b*. Base section **1452** defines an opening **1455** where tubes **1120***a*, **1120***b* are located. Extending from either side of base section **1452** are two sets of detents **1454** that are positioned on either side of the cartridge head **1059**. Extending proximally from base section **1452** is a fin **1456** with spring beams **1458** on either side of fin **1456** on both sides of base section **1452**. Located on either side of spring beams **1458** are guide rails **1460**. Between the spring beams is a slot **1461** and between each spring beam **1458** and guide rail **1460** is a slot **1463**. Holder **1450** includes finger grips **1462** for ease of handling. Hood **1220** is provided to the user with holder **1450**. To allow the user to hold finger grips **1462**, finger grips **1462** are attached to the remainder of the holder by a thin section **1462***a* over which the slot in the hood is positioned.

[**0157**] To load cartridges **960***a*, **960***b* in holder **1450**, each cartridge is in turn positioned over base section **1452** with thin section **1057** of the cartridge aligned with slot **1461**. By pushing down on the cartridge, spring beams **1458** are forced apart and thin section **1057** snaps into place in slot **1461**, with spring beams **1458** holding the cartridge in place. Cartridge head **1059** is located between detents **1454**, and side walls **1056** are partially within slots **1463** to align the cartridge and help hold the cartridge in position. With base section **1452** located between cartridges **960***a*, **960***b*, the cartridges are spaced such that the implant will not deploy (corresponding to the position shown in **FIG. 23C**).

[**0158**] Referring also to **FIG. 46C**, to attach cartridges **960***a*, **960***b* to arms **962***a*, **962***b*, respectively, while holding finger grips **1462**, the user slides the cartridges over the arms (with the arms positioned as shown in **FIG. 23C**). Initially, formation **1051** on the inner surfaces of the arms slide between spring beams **1458** forcing the spring beams apart. Further sliding of the cartridge over the arms, positions rectangular member **1050** under arms **1056** and locates clip **1052** in hole **1058**. The cartridges are now attached to the arms. Because spring beams **1458** have been forced apart by formation **1051**, holder **1450** can now be released from cartridges **960***a*, **960***b* by opening the jaws and the instrument is ready for use.

[**0159**] Holder **1450** is preferably formed from plastic, and holder **1450** with cartridges **960***a*, **960***b*, hood **1220** and the implant are supplied to the surgical personnel in a sterile condition.

[**0160**] **FIGS. 47A-47F** are various views of handle **902**.

What is claimed is:

1. An apparatus comprising:

first and second members configured to be operable at a distal portion of a flexible device, at least one of the first and second members including an implant having two rigid components coupled in a fixed relation by a flexible member, the first and second members configured to interact to deploy the implant in a patient.

2. The apparatus of claim 1 wherein the flexible member is formed of a material different than that of the rigid components.

3. The apparatus of claim 1 wherein the flexible member comprises suture.

4. The apparatus of claim 1 wherein the first and second members each form part of a jaw.

5. The apparatus of claim 1 wherein at least one of the first and second members is actuatable to deploy the implant in the patient.

6. The apparatus of claim 1 wherein at least one of the members includes a tissue piercing element.

7. The apparatus of claim 6 wherein the tissue piercing element is a needle.

8. The apparatus of claim 1 wherein at least one of the members includes two tissue piercing elements.

9. The apparatus of claim 8 wherein the tissue piercing elements are oriented parallel with each other.

10. The apparatus of claim 1 wherein both the first and second members include a part of implant.

11. The apparatus of claim 1 wherein at least one of the rigid components includes a bar defining two holes.

12. An apparatus comprising:

a member configured to pierce tissue and including an implant having rigid portions connected in a fixed relation by a flexible portion, the member configured to be operable at a distal portion of a flexible device to deploy the rigid portions of the implant through body tissue.

13. The apparatus of claim 12 wherein the flexible portion comprises suture.

14. The apparatus of claim 12 wherein the member includes a tissue piercing element.

15. The apparatus of claim 14 wherein the tissue piercing element is a needle.

16. The apparatus of claim 12 wherein the member includes two tissue piercing elements.

17. The apparatus of claim 16 wherein the tissue piercing elements are parallel with each other.

18. The apparatus of claim 12 wherein at least one of the rigid portions includes a bar defining two holes.

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