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(54) **SUTURE LOCKING AND CUTTING DEVICES AND METHODS**

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(57) **ABSTRACT**

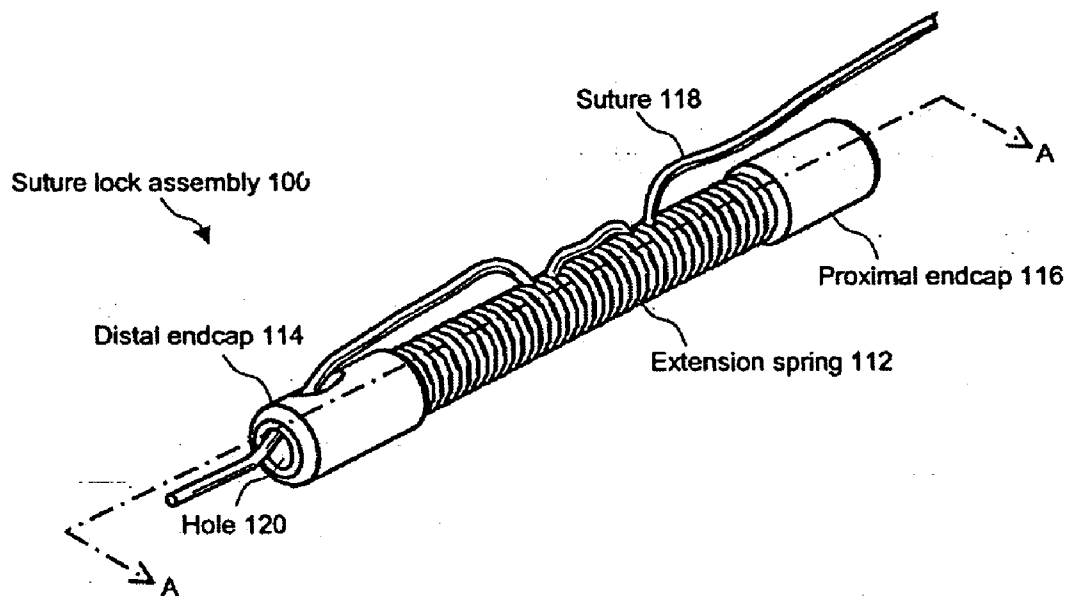
Suture holding devices and methods are disclosed, including devices and methods useful in performing a transoral surgical procedure, such as a posterior gastropexy procedure. A device is disclosed which can be used by a physician in a medical procedure to automatically lock and cut a suture in one motion and without the need for additional cutting instrumentation, rather than perform separate locking and cutting actions.

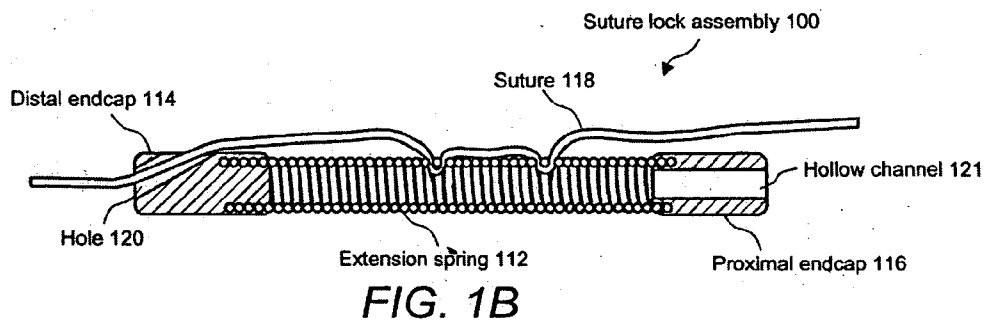
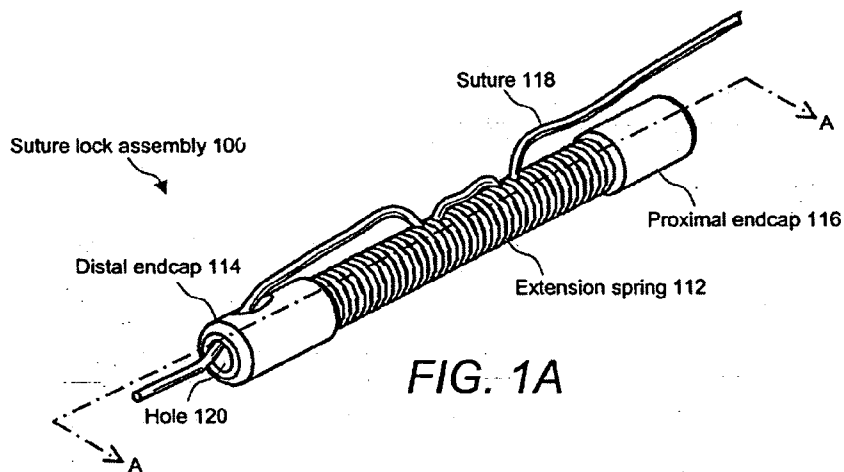
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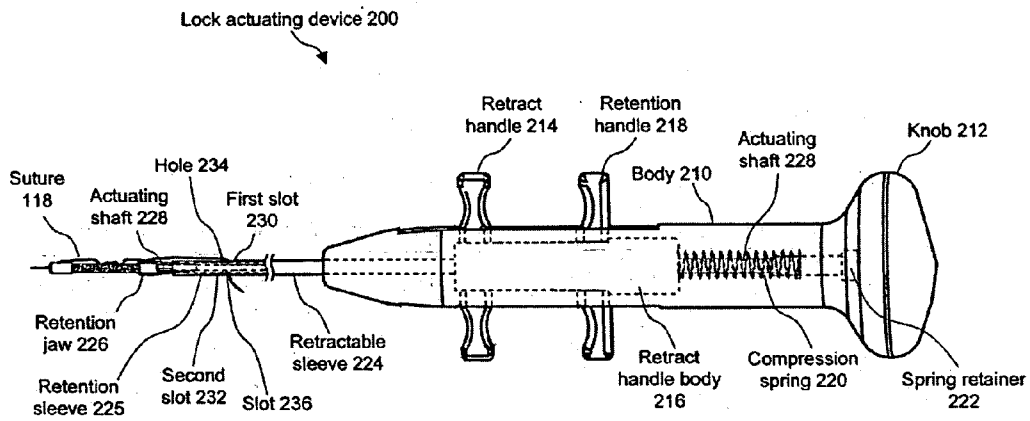


FIG. 2

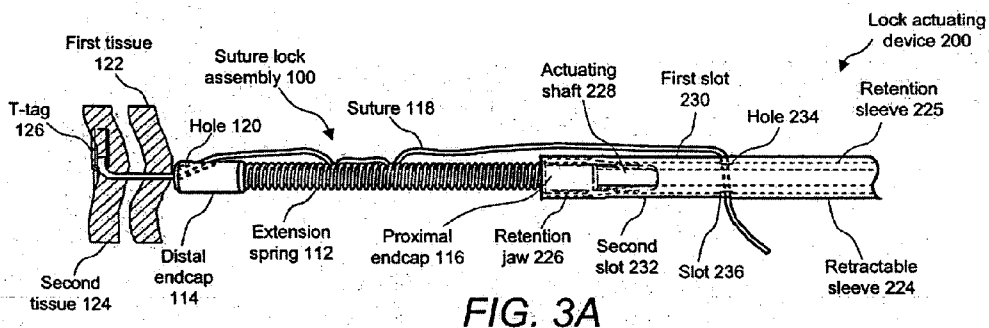


FIG. 3A

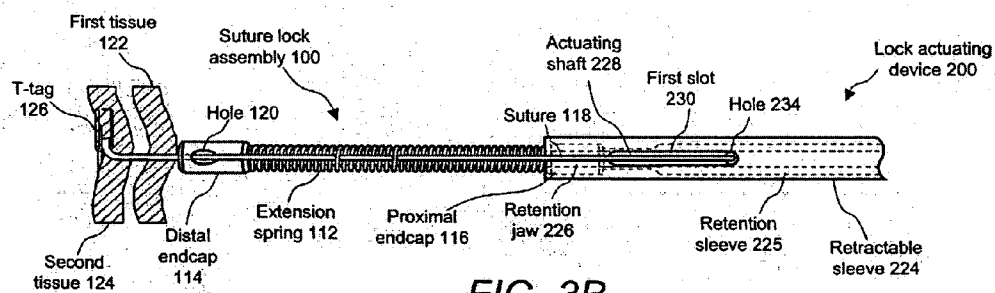


FIG. 3B

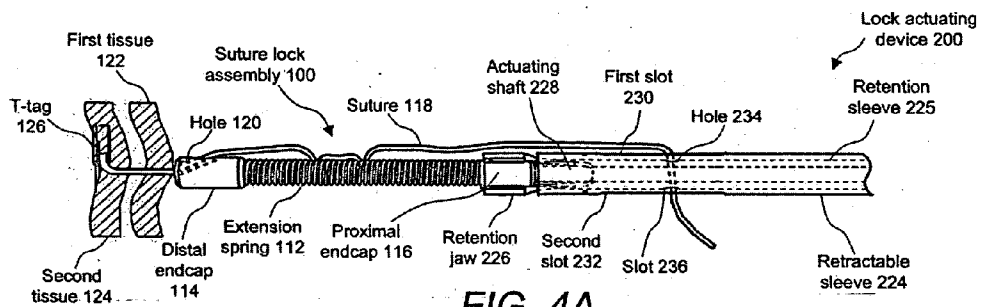


FIG. 4A

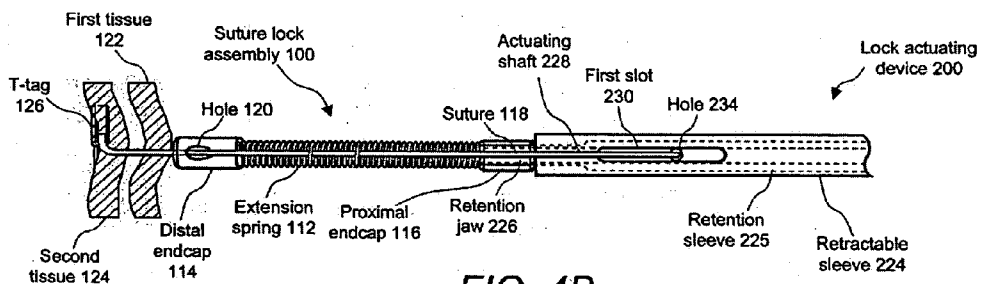


FIG. 4B

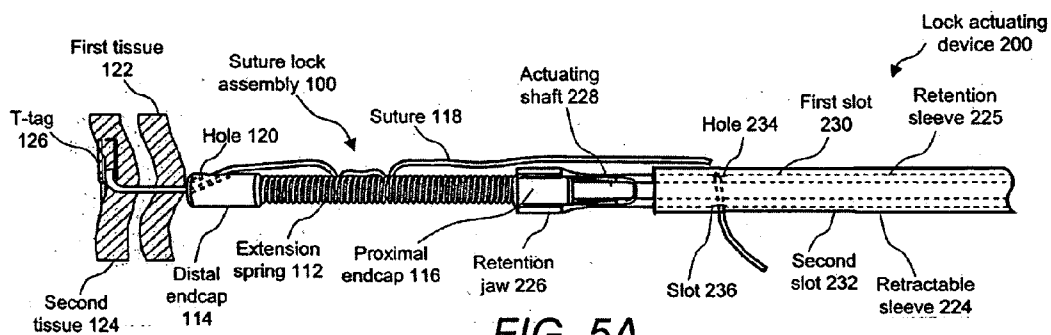


FIG. 5A

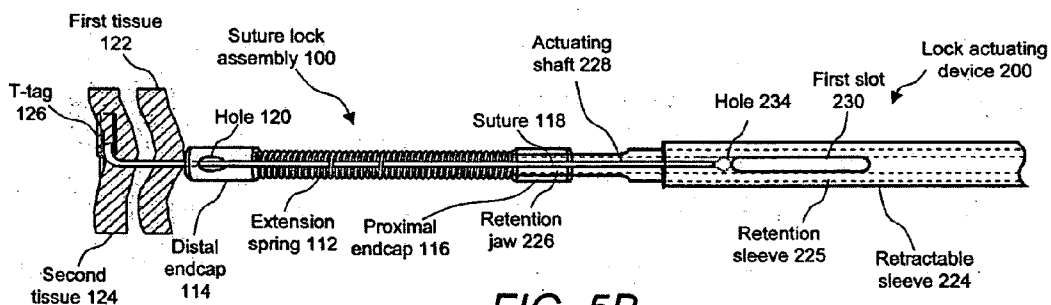


FIG. 5B

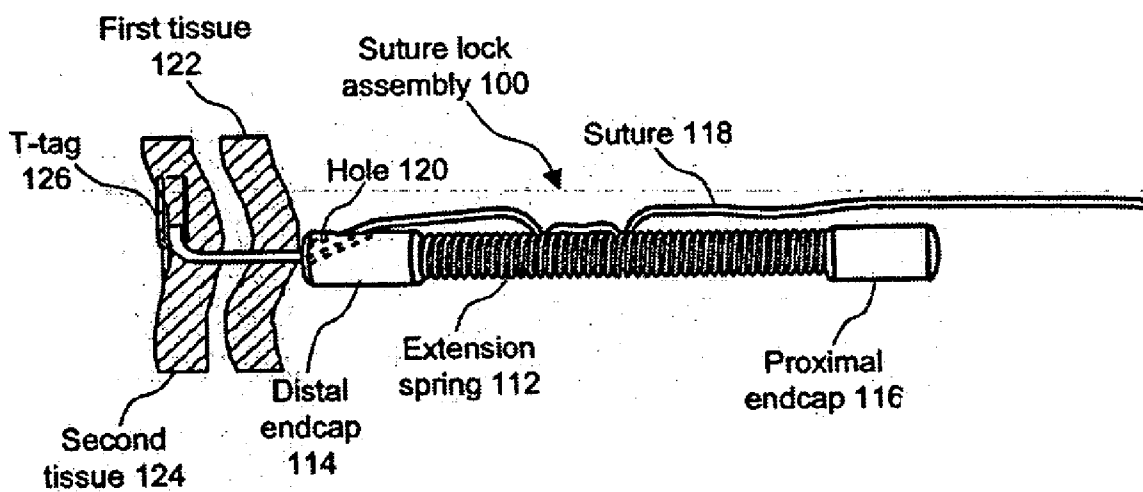
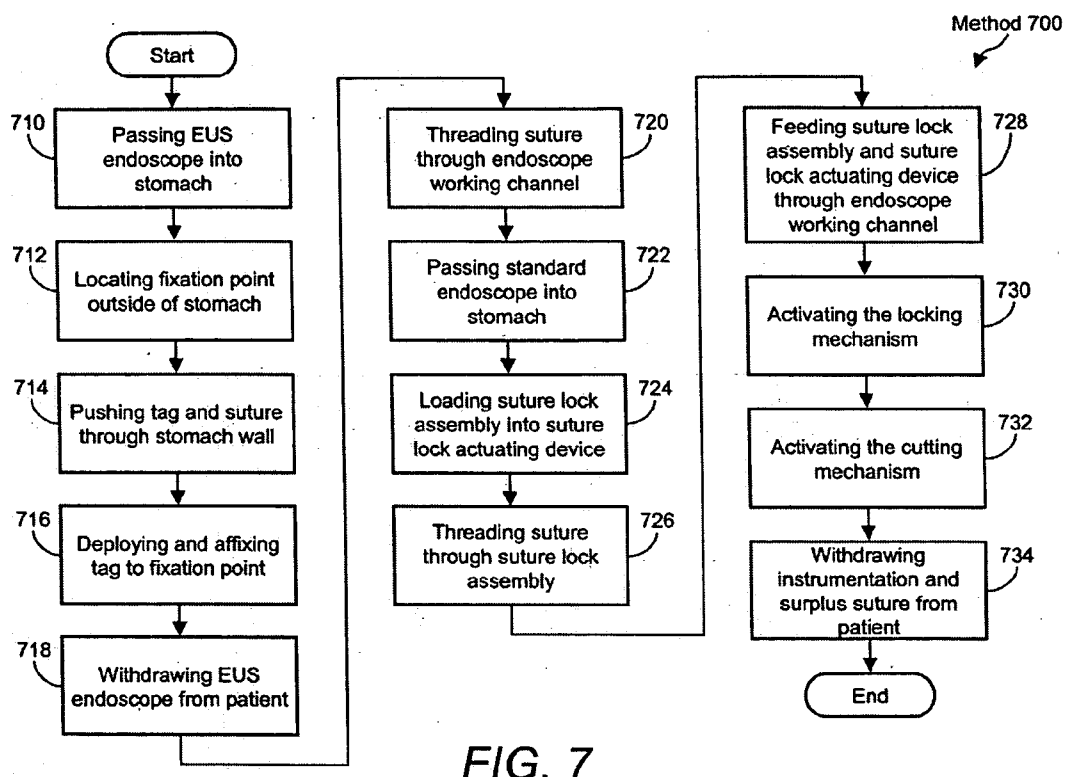


FIG. 6





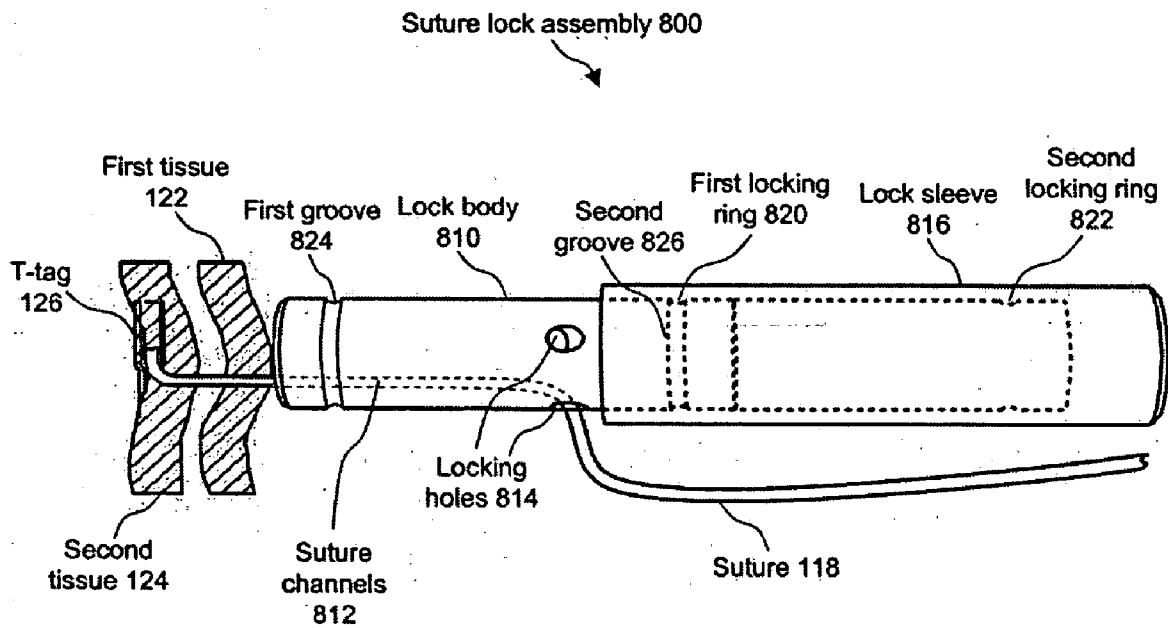


FIG. 8

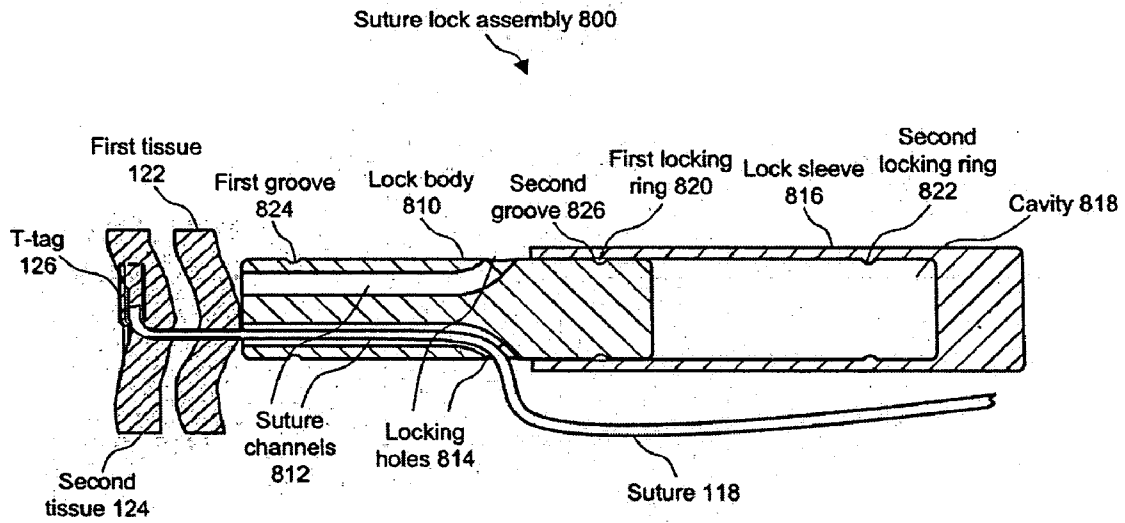


FIG. 9

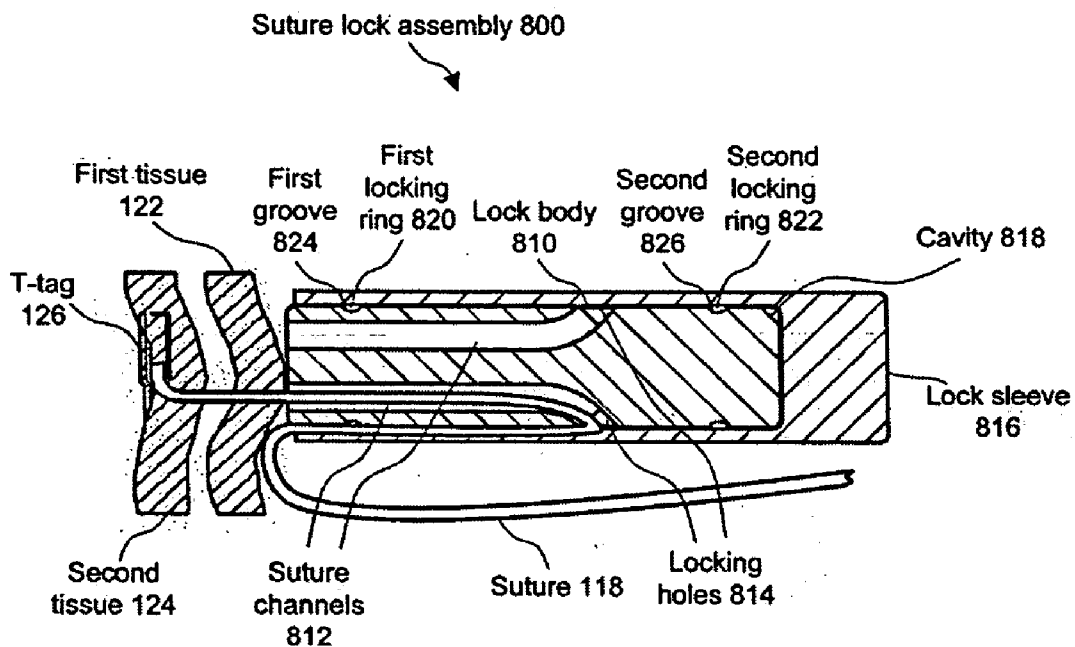


FIG. 10

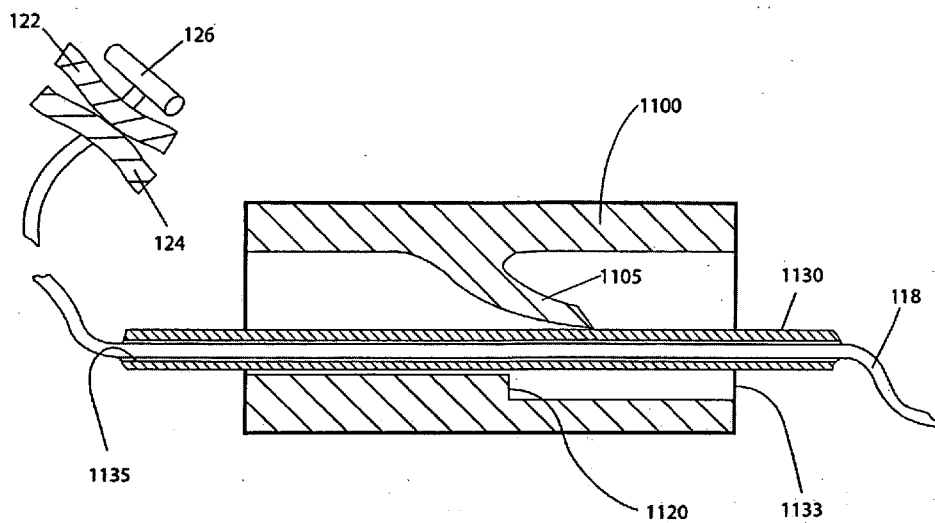


Figure 11A

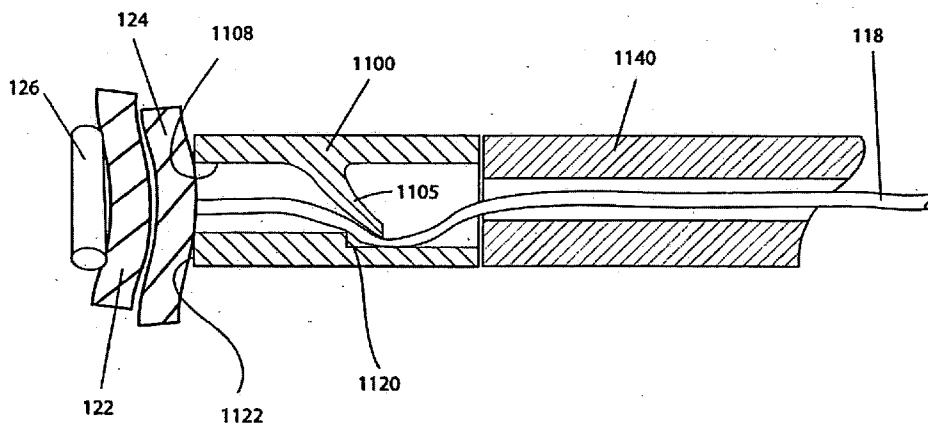


Figure 11B

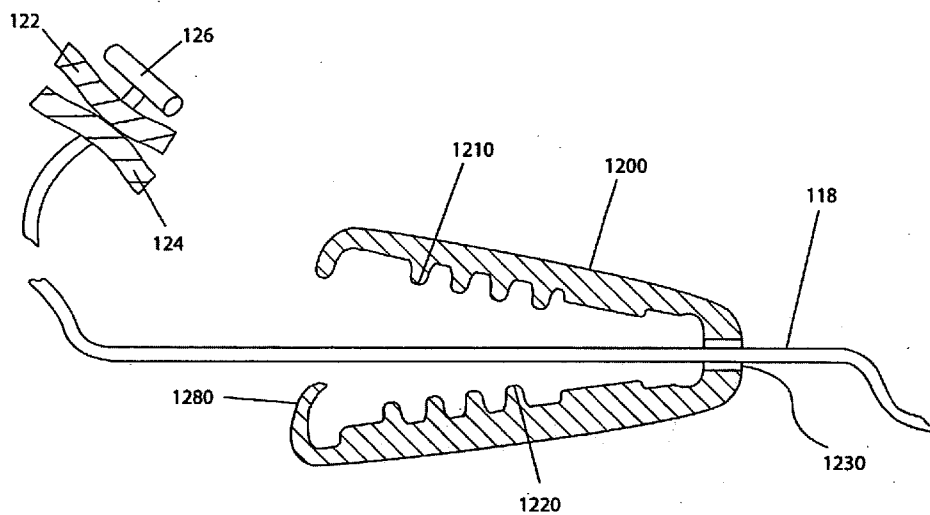


Figure 12A

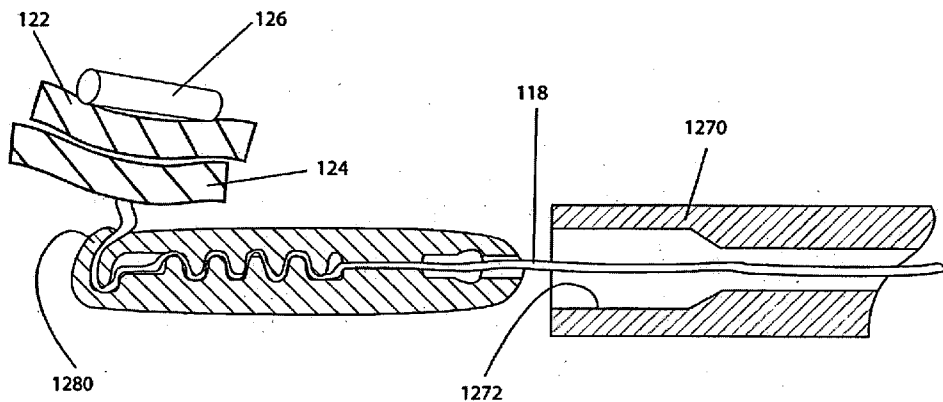


Figure 12B

## SUTURE LOCKING AND CUTTING DEVICES AND METHODS

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and incorporates by reference the following applications: U.S. Provisional Application 60/571,117 filed May 14, 2004; U.S. provisional Application 60/571,119 filed May 14, 2004; and U.S. Provisional Application 60/571,000 filed May 14, 2004.

### FIELD OF THE INVENTION

[0002] This invention relates to endoscopic suturing devices and methods, including devices and methods which may pass through or be employed in connection with the working channel of various endoscopic and ultrasound devices.

### BACKGROUND

[0003] Application of sutures in the gastrointestinal tract is required for several different types of medical procedures, for example, for transoral endoscopic valvuloplasty for gastroesophageal reflux disease (GERD), gastroplasty, fundoplication, anterior gastropexy, posterior gastropexy, suturing esophageal perforations, or closure of the esophageal side of the tracheo-esophageal fistula. Traditionally, these procedures are performed by physicians, such as gastroenterologists or surgeons, either by laparoscopy or open surgical techniques. Such procedures are invasive, as laparoscopy requires that small access incision(s) be made in the body of the patient, through which a laparoscope and other surgical enabling tools are provided, while open surgical techniques are traditionally invasive and can have complications and cause long patient recovery periods.

[0004] The solution to these problems is to perform these medical procedures through the gastroesophageal tract via the mouth or other naturally occurring orifice. Already available flexible endoscopes, commonly called gastroscopes, can be provided through the gastroesophageal tract and enable illumination and visualization of tissue along the gastroesophageal tract on a video display for diagnostic purposes. These flexible endoscopes also provide an instrumentation means for applying sutures in tissue, such as in the wall of the stomach. What is needed are improved methods of providing a totally transoral surgical procedure, such as a posterior gastropexy procedure, and thereby avoid more invasive laparoscopic procedures.

[0005] New endoscopic suturing methods performed through the gastroesophageal tract as an alternative to the invasive laparoscopic method of, for example, a posterior gastropexy procedure, are currently being developed. For example, suturing methods under the control of endoscopic ultrasound (EUS) are being evaluated. EUS is a procedure that combines endoscopy and ultrasound. In particular, a Mar. 14, 2003 publication authored by Fritscher-Ravens, Mosse, Mukherjee, Yazaki, Park, Mills, and Swain, entitled, "Transgastric gastropexy and hiatal hernia repair for GERD under EUS control: a porcine model," (American Society for Gastrointestinal Endoscopy) describes how endoluminal operations for gastroesophageal reflux are currently limited by the inability of the surgeon to visualize and manipulate structures outside the wall of the gut. The publication

describes a way to define the EUS anatomy of structures outside the gut that influence reflux, to place stitches in the median arcuate ligament, to perform posterior gastropexy, and to test the feasibility of crural repair, under EUS control, in pigs. More specifically, by using a linear-array EUS, the median arcuate ligament and part of the right crus were identified and punctured with a needle, which served as a carrier for a tag and suture. These were anchored into the muscle. An endoscopic sewing device was used, which allowed stitches to be placed through a 2.8-mm accessory channel to any predetermined depth.

[0006] The publication also describes new methods of knot tying and suture cutting through the 2.8-mm channel of the EUS. More specifically, stitches were placed through the gastric wall into the median arcuate ligament, and one stitch was placed just beyond the wall of the lower esophageal sphincter. The stitches were tied together and locked against the gastric wall, and the surplus length of suture material was then cut and removed. While this publication describes a suitable transgastric gastropexy and hiatal hernia repair procedure, further improvements in methodology and equipment to perform such procedures would be beneficial. For example, the publication describes a process for locking and cutting the suture from inside the stomach. However, the suture requires that a separate suture cutting step, along with its associated cutting instrumentation, be available via the working channel of the endoscope. This may result in multiple passes of instrumentation back and forth through the working channel of the endoscope. What is needed is a way to both lock and cut a suture automatically with a single device and thereby simplify the medical procedure, such as a posterior gastropexy procedure.

[0007] Additionally, the locking mechanism described in the publication is too large to pass through the working channel of an endoscope and, thus, it must be inserted into the patient separately from the endoscope, which again adds complexity to the medical procedure. What is needed are suture locking and cutting mechanisms that are small enough to pass through the working channel of various endoscopic and ultrasound devices (typical working channel diameter is 2.8-3.4 mm).

### SUMMARY OF THE INVENTION

[0008] Applicants recognize the desirability of providing improved methods of performing a totally transoral surgical procedure, such as a posterior gastropexy procedure, and thereby avoid more-invasive laparoscopic procedures. Applicants also recognize the desirability of providing a single mechanism for automatically locking and cutting a suture and thereby simplifying medical procedures, such as, but not limited to, a posterior gastropexy procedure; and the desirability of providing suture locking and cutting mechanisms that are small enough to pass through the working channel of various endoscopic and ultrasound devices.

[0009] Certain embodiments of the present invention are directed to providing improved methods of performing a totally transoral surgical procedure, such as a posterior gastropexy procedure, and thereby avoiding more-invasive laparoscopic procedures. One embodiment of the present invention provides a device and method that allows a physician in a medical procedure to automatically lock and cut a suture in one motion and without the need for additional cutting instrumentation, rather than perform separate locking and cutting actions.

[0010] In one embodiment of the invention, a suture lock assembly in combination with a lock actuating device is provided. The lock comprises an extension spring arranged between two endcaps, wherein one or more sutures are locked within the coils thereof. Extending the extension spring allows for one or more sutures to be threaded there-through and, by relaxing the extension spring, provides a clamping action upon the sutures and a tortuous path within the coils. The lock actuating device provides a cutting mechanism. Furthermore, both the suture lock assembly, in combination with a lock actuating device, are suitably small enough to pass through the working channel of various endoscopic and ultrasound devices.

[0011] In another embodiment of the invention, a suture lock assembly is provided that forms a hollow body, within which a clamp device is engaged and through which one or more sutures is threaded. Depending upon the slidable position of the clamp device within the body, the suture within the clamp device is engaged to clamp the suture permanently. The suture lock assembly of this embodiment is likewise suitably small enough to pass through the working channel of various endoscopic and ultrasound devices.

[0012] The various embodiments of the invention can be employed with various types of suture, including without limitation monofilament suture and braided suture.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0013] While the novel features of the invention are set forth with particularity in the appended claims, the invention, in all its embodiments, may be more fully understood with reference to the following description and accompanying drawings.

[0014] FIG. 1A illustrates a perspective view of a suture lock assembly in accordance with a first embodiment of the invention;

[0015] FIG. 1B illustrates a cross-sectional view of the suture lock assembly in accordance with a first embodiment of the invention;

[0016] FIG. 2 illustrates a side view of an exemplary lock actuating device according to the first embodiment;

[0017] FIGS. 3A and 3B illustrate a side view and a top view, respectively, of the distal end of the lock actuating device with the suture lock assembly of the first embodiment engaged therein in the default state;

[0018] FIGS. 4A and 4B illustrate a side view and a top view, respectively, of the distal end of the lock actuating device with the suture lock assembly of the first embodiment engaged therein in the lock state;

[0019] FIGS. 5A and 5B illustrate a side view and a top view, respectively, of the distal end of the lock actuating device with the suture lock assembly of the first embodiment engaged therein in the cut state;

[0020] FIG. 6 illustrates a side view of the suture lock assembly of the first embodiment engaged therein in the release state;

[0021] FIG. 7 illustrates a flow diagram of an example method of using the suture lock assembly of the first embodiment in combination with the lock actuating system;

[0022] FIG. 8 illustrates a perspective view of a suture lock assembly in accordance with a second embodiment of the invention.

[0023] FIG. 9 illustrates a cross-sectional view of the suture lock assembly of the second embodiment in the unlocked state.

[0024] FIG. 10 illustrates a cross-sectional view of the suture lock assembly of the second embodiment in the locked state.

[0025] FIGS. 11A and 11B illustrate cross section views of an alternative locking device with a one-way flap inside a tubular segment, in a loading state, and a locked state, respectively.

[0026] FIGS. 12A and 12B show a cross section view of alternative one-piece clip in a default state, and a cross section view of the one-piece clip in a locked state, respectively.

#### DETAILED DESCRIPTION OF THE INVENTION

[0027] FIG. 1A illustrates a perspective view of a suture lock assembly 100 in accordance with a first embodiment of the invention. Suture lock assembly 100 includes an extension spring 112 arranged between a distal endcap 114 and a proximal endcap 116.

[0028] Extension spring 112 is formed of any nontoxic, noncorrosive metal, such as stainless steel, and distal endcap 114 and proximal endcap 116 are formed of, for example, molded plastic or stainless steel. Also shown in FIG. 1 is a suture 118 threaded first through a hole 120 in distal endcap 114 and then through multiple coils of extension spring 112, wherein suture 118 is clamped because of the pressure of the coils and the tortuous path within the coils. Suture lock assembly 100 is not limited to a single suture 118 installed therein; a plurality of sutures 118 may be engaged within a single suture lock assembly 100.

[0029] FIG. 1B illustrates a cross-sectional view of suture lock assembly 100 taken along line AA of FIG. 1A. This view shows that proximal endcap 116 further includes a hollow channel 121 that runs through its center. Furthermore, hole 120 in distal endcap 114 is angled from the center of an outer end of distal endcap 114 toward the sidewall of distal endcap 114, which thereby allows suture 118 to exit distal endcap 114 external to extension spring 112. Distal endcap 114 and proximal endcap 116 may be insert-molded onto extension spring 112 or use other methods or procedures of providing a smooth, trauma free extension of spring coils.

[0030] In operation, suture 118 is threaded first through hole 120 in distal endcap 114; extension spring 112 is then extended and suture 118 is threaded through multiple coils of extension spring 112; extension spring 112 is then relaxed, which thereby applies a tortuous path in addition to a clamping or locking action upon suture 118 between the coils thereof. The overall diameter of suture lock assembly 100 is suitably small enough to allow it to pass through the working channel of various endoscopic and ultrasound devices, which is typically between 2.8 and 3.4 mm in diameter. See Table 1 for example dimensions of suture lock assembly 100.

TABLE 1

Example dimensions of suture lock assembly 100	
	Example Dimension
Suture lock assembly 100 overall length	0.70 in
Extension spring 112 outside diameter	0.060 in
Extension spring 112 inside diameter	0.040 in
Distal endcap 114 outside diameter	0.07 in
Distal endcap 114 length	0.15 in
Proximal endcap 116 outside diameter	0.07 in
Proximal endcap 116 length	0.125 in
Hollow channel 121 diameter	0.04 in
Hole 120 diameter	0.04 in
Hole 120 angle	45 degrees

[0031] FIG. 2 illustrates a side view of a lock actuating device 200, which is exemplary only and representative of any suitable actuating device for use with suture lock assembly 100. In this example, lock actuating device 200 includes a body 210 that has a knob 212 arranged at its proximal end for grasping by the user. Mechanically coupled to body 210 is a retract handle 214, which has a retract handle body 216 and a retention handle 218 that is slidably arranged within retract handle body 216. Furthermore, a compression spring 220 is mechanically coupled between a spring retainer 222, which is coupled to knob 212, and the proximal end of retract handle body 216. Mechanically coupled to the distal end of retract handle body 216 is a hollow retractable sleeve 224, within which is first arranged a hollow retention sleeve 225, which has a retention jaw 226 at its distal end. Furthermore, arranged within retention sleeve 225 is an actuating shaft 228. FIG. 2 also shows that arranged within the distal end of retractable sleeve 224 is a first slot 230 that is aligned opposite a second slot 232. Also, arranged within the distal end of retention sleeve 225 is a hole 234 that is aligned opposite a slot 236.

[0032] Actuating shaft 228 of a fixed length is mechanically coupled at one end to the distal end of spring retainer 222 while passing through spring retainer 222. Actuating shaft 228 passes through a hollow channel within retract handle body 216, then passes through the hollow channel of retention jaw 226 within retractable sleeve 224. The tip of actuating shaft 228 extends through an opening at the distal end of retention jaw 226 within retractable sleeve 224. Using retract handle 214 and retention handle 218, retractable sleeve 224 and retention sleeve 225 are slidable along the length of actuating shaft 228. As a result, the relative axial position of retractable sleeve 224, retention jaw 226, and actuating shaft 228 may vary one to another under user control. Lock actuating device 200 may include well-known mechanical methods and elements (not shown) for holding retractable sleeve 224 and retention jaw 226 at various positional states.

[0033] The operation of suture lock assembly 100 in combination with lock actuating device 200 for automatically locking and cutting a suture includes a sequential transition from a default state (i.e., undeployed state) to a lock state, a cut state and, finally, a release state (i.e., deployed state), as described in reference to FIGS. 3A, 3B, 4A, 4B, 5A, 5B, 6, and 7. Additionally, FIGS. 3A, 3B, 4A, 4B, 5A, 5B, and 6 show suture lock assembly 100 in use and, therefore, it includes suture 118, which runs through the center of suture lock assembly 100 and approximates a first

tissue 122 and a second tissue 124. Suture 118 is anchored to second tissue 124 with a T-tag 126, which is a well-known medical device for anchoring a suture into body tissue.

[0034] FIGS. 3A and 3B illustrate a side view and a top view, respectively, of the distal end of lock actuating device 200 with suture lock assembly 100 engaged therein in the default state, which is described as follows.

[0035] Default state: In the default or undeployed state, extension spring 112 is extended suitably to allow suture 118 to slide freely through its coils. This is accomplished by the physician's passing actuating shaft 228 through hollow channel 121 of proximal endcap 116, then through the center of extension spring 112, until the tip of actuating shaft 228 abuts the inner surface of distal endcap 114. By using retention handle 218, which is attached to the proximal end of retention sleeve 225, the physician extends retention jaw 226 to allow it to grip proximal endcap 116 and then pull proximal endcap 116 into the tip of retractable sleeve 224, as shown in FIGS. 3A and 3B, which thereby extends extension spring 112, relative to the tip of actuating shaft 228. The distance between the tip of actuating shaft 228 and the tip of retractable sleeve 224 is predetermined to suitably extend extension spring 112. Additionally, suture 118 is threaded first through hole 120 in distal endcap 114, then within the extended coils of extension spring 112 is wrapped multiple times around actuating shaft 228, through first slot 230 of retractable sleeve 224, through hole 234 of retention sleeve 225, passes around actuating shaft 228, through slot 236 of retention sleeve 225 and, finally, through second slot 232 of retractable sleeve 224.

[0036] FIGS. 4A and 4B illustrate a side view and a top view, respectively, of the distal end of lock actuating device 200 with suture lock assembly 100 engaged therein in the lock state, which is described as follows.

[0037] Lock state: In the lock state, extension spring 112 is relaxed, which allows its coils to clamp against suture 118 and thereby prevent suture 118 from sliding freely between the coils of extension spring 112. By using retention handle 218, which is attached to the proximal end of retention sleeve 225, the physician extends retention jaw 226 while gripping proximal endcap 116 in a direction toward distal endcap 114 and while maintaining the relative distance between the tip of actuating shaft 228 and the tip of retractable sleeve 224, as set in the default state. Although the relative position of hole 234 and slot 236 to first slot 230 and second slot 232, respectively, is changed, suture 118 is intact and passing freely through first slot 230 of retractable sleeve 224, through hole 234 of retention sleeve 225, passes around actuating shaft 228, through slot 236 of retention sleeve 225, and through second slot 232 of retractable sleeve 224, as shown in FIGS. 4A and 4B.

[0038] FIGS. 5A and 5B illustrate a side view and a top view, respectively, of the distal end of lock actuating device 200 with suture lock assembly 100 engaged therein in the cut state, which is described as follows.

[0039] Cut state: In the cut state, the relative distance between the tip of actuating shaft 228 and the tip of retention jaw 226 is maintained, as set in the lock state. By using retract handle 214, which is attached to the proximal end of retractable sleeve 224, the physician retracts tip of retractable sleeve 224 in a direction away from the tip of retention



jaw 226, which causes the position of hole 234 and slot 236 within retention sleeve 225 to change, relative to first slot 230 and second slot 232, respectively, such that suture 118 within hole 234 is cut as hole 234 passes underneath the edge of first slot 230, which has a ground edge suitable for cutting suture 118.

[0040] FIG. 6 illustrates a side view of suture lock assembly 100 in the release state, which is described as follows.

[0041] Release state: In the release state, the physician manipulates the grasp of retention jaw 226 and proximal endcap 116 is released, which allows all instrumentation, such as lock actuating device 200 and the endoscope, as well as the surplus length of suture 118, to be removed. Extension spring 112 remains relaxed and, thus, the locking action upon suture 118 is maintained indefinitely within the patient.

[0042] In an alternative embodiment, rather than wrapping the suture 118 multiple times around shaft 228 within the extended coils of spring 112, the suture 118 can be manually threaded through or otherwise positioned between the extended coils, such as in a serpentine fashion, so that the coils hold the suture when the coils are permitted to close together. Such manual positioning of the suture through the coils may be employed if the shaft 228 is not employed or is otherwise not positioned within the spring 112 when the suture is positioned with respect to the coils of spring 112.

[0043] FIG. 7 illustrates a flow diagram of an example method 700 of using suture lock assembly 100 in combination with lock actuating device 200 in accordance with the invention. More specifically, method 700 provides an example of a posterior gastropexy procedure that uses suture lock assembly 100 of the present invention. The use of suture lock assembly 100 is not limited to a posterior gastropexy procedure; suture lock assembly 100 may be used in any of various, similar medical procedures. Furthermore, method 700 is not limited to a single suture 118 installed within suture lock assembly 100; a plurality of sutures 118 may be engaged within a single suture lock assembly 100.

[0044] At step 710, a physician passes an EUS endoscope through a patient's mouth and esophagus and into the stomach. Example EUS endoscopes include endoscope model GF-UC160P-AT8 manufactured by Olympus Europe (Hamburg, Germany) and endoscope model EG-3630U manufactured by Pentax Medical Company (Orangeburg, N.Y.). The working channel of the EUS endoscope is preloaded with a standard EUS needle, such as is manufactured by Wilson-Cook (Winston-Salem, N.C.), that serves as a carrier for a tag and suture, such as T-tag 126 and suture 118. Suture 118 may run either through the needle or outside the needle, but still inside the working channel of the EUS endoscope.

[0045] At step 712, under the guidance of the EUS endoscope, the physician locates and identifies structures outside the stomach wall and selects a fixation point, such as the median arcuate ligament.

[0046] At step 714, under the guidance of the EUS endoscope, the physician pushes the EUS needle, which is carrying T-tag 126 and suture 118, through the stomach wall, which is represented by first tissue 122 in FIGS. 3A, 3B, 4A, 4B, 5A, 5B, and 6.

[0047] At step 716, under the guidance of the EUS endoscope, the physician deploys and affixes T-tag 126, with suture 118 attached thereto, to the fixation point, such as to the median arcuate ligament, which is represented by second tissue 124 in FIGS. 3A, 3B, 4A, 4B, 5A, 5B, and 6.

[0048] At step 718, the physician withdraws the EUS endoscope and associated instrumentation from the patient, but leaves a length of suture 118 still threaded through the patient's gastroesophageal tract and anchored to second tissue 124 (e.g., median arcuate ligament). The length of suture 118 extends out of the patient's mouth and is accessible to the physician.

[0049] At step 720, the physician threads the length of suture 118 that is extending out of the patient's mouth into the distal end and out of the proximal end of the working channel of a standard endoscope that has a standard vision system (i.e., not an EUS endoscope).

[0050] At step 722, while holding tension on suture 118, the physician passes the endoscope through the patient's mouth and esophagus and into the stomach. A length of suture 118 is left extending out of the proximal end of the working channel of the endoscope and is accessible to the physician.

[0051] At step 724, the physician loads suture lock assembly 100 into the distal end of lock actuating device 200 and sets suture lock assembly 100 into the default state, as described in reference to FIGS. 3A and 3B.

[0052] At step 726, with suture lock assembly 100 in the default state and loaded into lock actuating device 200, the physician first threads the length of suture 118 that is extending out of the proximal end of the endoscope through hole 120 in distal endcap 114, then within the extended coils of extension spring 112 is wrapped multiple times around actuating shaft 228, then threaded through hole 234 of retention sleeve 225, then threaded through first slot 230 of retractable sleeve 224, then threaded through second slot 236 of retention sleeve 225 and, finally, threaded through second slot 232 of retractable sleeve 224, as shown in FIGS. 3A and 3B.

[0053] At step 728, while holding tension on suture 118, which is extending out of second slot 232 of retractable sleeve 224, the physician passes the suture lock assembly 100 and retractable sleeve 224 of lock actuating device 200 through the working channel of the endoscope and into the patient's stomach. Suture lock assembly 100 is sliding freely along suture 118 in the default state, until distal endcap 114 is firmly abutted against the inside of the stomach wall, which is represented by first tissue 122 in FIGS. 3A, 3B, 4A, 4B, 5A, 5B, and 6.

[0054] At step 730, having determined that the desired geometry change between the stomach and the median arcuate ligament (represented by first tissue 122 and second tissue 124) is achieved and while continuing to hold tension on suture 118, the physician sets suture lock assembly 100 into the lock state by using retention handle 218, as described in reference to FIGS. 4A and 4B, which causes the coils of extension spring 112 to relax and create a torturous path and, thus, clamp against suture 118, as shown in FIGS. 4A and 4B.

[0055] At step 732, having secured suture lock assembly 100 against first tissue 122 with suture 118, the physician

sets suture lock assembly **100** into the cut state by using retract handle **214**, as described in reference to Figures SA and 5B, which causes suture **118** to be cut as hole **234** passes underneath the edge of first slot **230**, which has a geometry suitable for cutting suture **118**, as shown in FIGS. 5A and 5B.

[0056] At step **734**, having secured suture lock assembly **100** against first tissue **122** and having cut suture **118**, the physician releases retention jaw **226** from proximal endcap **116** of suture lock assembly **100**, which allows all instrumentation, such as lock actuating device **200** and the endoscope, and the surplus length of suture **118**, to be withdrawn from the patient, while suture **118** remains firmly clamped, as shown in FIG. 6. Method **700** ends.

[0057] FIG. 8 illustrates a perspective view of a suture lock assembly **800** in accordance with a second embodiment of the invention. Suture lock assembly **800** includes a cylindrical-shaped lock body **810** that further includes a plurality of suture channels **812** that run therethrough, and which have an associated plurality of locking holes **814** arranged on the outer surface of lock body **810**. Suture lock assembly **800** further includes a lock sleeve **816** that further includes a cavity **818** (shown in FIGS. 9 and 10) within which lock body **810** is inserted. Lock body **810** further includes a first groove **824** and a second groove **826**, which are detents formed around the outer perimeter of lock body **810**. Lock sleeve **816** further includes a first locking ring **820** and a second locking ring **822**, which are raised regions protruding from the inside perimeter of cavity **818** that are sized to lock within the detents formed by first groove **824** and second groove **826** of lock body **810**.

[0058] Also shown in FIG. 8 is suture **118**, which is anchored to second tissue **124** with T-tag **126** passes through first tissue **122** and into one of the suture channels **812**, and exits lock body **810** via one of associated locking holes **814**. Only a small portion of the distal end of lock body **810** is inserted into cavity **818**, such that locking holes **814** are not within cavity **818** of lock sleeve **816**. Lock body **810** and lock sleeve **816** are formed of, for example, molded plastic or stainless steel.

[0059] FIG. 9 illustrates a cross-sectional view of a suture lock assembly **800** and shows suture **118** passing through one of the suture channels **812** and existing lock body **810**. FIGS. 8 and 9 are representative of suture lock assembly **800** in the default, unlocked state wherein one or more sutures **118** may be threaded freely through lock body **810**. In the default or unlocked state first locking ring **820** of lock sleeve **816** is engaged within second groove **826** of lock body **810**, as shown in FIGS. 8 and 9.

[0060] FIG. 10 illustrates a cross-sectional view of a suture lock assembly **800** in a locked state wherein one or more sutures **118** is threaded through lock body **810** and locked therein. More specifically, in the lock state, lock sleeve **816** is pushed over the entire length of lock body **810**, such that suture **118** is clamped between the outer surface of lock body **810** and the wall of cavity **818** of lock sleeve **816**, after which any surplus suture **118** material is cut, which leaves suture lock assembly **800** secured against first tissue **122**. In order to achieve the locked state enough force is applied to lock sleeve **816** against lock body **810** such that first locking ring **820** of lock sleeve **816** disengages from within second groove **826** of lock body **810**. In doing so, lock sleeve **816**

slides upon lock body **810** until first locking ring **820** and second locking ring **822** are engaged within first groove **824** and second groove **826**, respectively, of lock body **810**, as shown in FIG. 10. The mechanical features of suture lock assembly **800** for coupling lock sleeve **816** to lock body **810** are exemplary only and are not limited to first locking ring **820**, second locking ring **822**, first groove **824**, and second groove **826**. Any well-known coupling method that allows a default and lock state by sliding lock sleeve **816** upon lock body **810** may be used.

[0061] The overall diameter of suture lock assembly **800** is suitably small enough to allow it to pass through the working channel of various endoscopic and ultrasound devices, which is typically between 2.8 and 3.4 mm in diameter. See Table 2 for example dimensions of suture lock assembly **800**.

TABLE 2

Example dimensions of suture lock assembly 800	
	Example Dimension
Lock body 810 length	0.35 in
Lock body 810 outside diameter	0.07 in
Suture channels 812 diameter	0.015 in
Lock sleeve 816 length	0.38 in
Lock sleeve 816 inside diameter	0.07 in
Suture lock assembly 800 overall length when locked	0.39 in

[0062] The method of using suture lock assembly **800**, in combination with suture **118**, T-tag **126**, first tissue **122**, and second tissue **124**, is generally the same as described in FIG. 7, in reference to suture lock assembly **100**, in that it is fed down the working channel of an endoscope and into, for example, a patient's stomach, in much the same manner. However, suture lock assembly **800** requires no special actuating device; instead, it may be pushed through the working channel of an endoscope with, for example, the tip of a standard catheter. Additionally, its use differs from suture lock assembly **100**, in that suture lock assembly **800** requires separate instrumentation for cutting the one or more sutures **118** engaged therein.

[0063] FIGS. 11A and 11B illustrate an alternative locking device similar in function to those previously mentioned. The locking device of FIGS. 11A and 11B are designed to lock onto suture **118**, when used in conjunction with the endoscope. The locking device of FIGS. 11A and 11B may be placed on suture **118** attached to T-tag **126**, that has been placed through first tissue **122** and second tissue **124** using the previously-described technique.

[0064] This embodiment comprises a tubular sleeve **1100**, a flap **1105**, and a detent **1120**. Tubular sleeve **1100** may have an outer diameter of about 2.6 mm and an inner diameter of about 1 mm, and may be injection molded from a suitable polymer, such as polycarbonate, as a single piece or as separate pieces which are then fused together to form a unitary structure. In a resting state, flap **1105** is biased toward contact with detent **1120**. Therefore, to load suture **118** into tubular segment **1100**, an introducer **1130** may be used to create space between flap **1105** and detent **1120** as shown in FIG. 11A. Introducer **1130** may be placed into tubular segment **1100** by pushing from a distal end **1122** of

tubular segment **1100**, so that flap is moved away from detent **1120**. Suture may be placed through a central lumen **1135** of introducer **1130**, so that ultimately suture **118** is positioned within tubular segment **1100**. Introducer **1130** is then removed by pulling it out of tubular segment **1100** from a proximal end **1133**, so that introducer **1130** is not trapped between tubular segment **1100** and second tissue **124**.

[0065] After introducer **1130** is removed, tubular segment **110** may be pushed along suture **118** toward second tissue **124** with a pusher **1140** especially designed for that purpose, as shown in **FIG. 11B**. Tension on suture **118** acts to pull flap **1105** partially away from detent **1120** during advancement. When distal end **1122** of tubular segment **1100** reaches second tissue **124**, pusher **1140** is withdrawn and flap **1105** traps suture **118** against detent **1120** so that tubular segment **1100** is held securely in place.

[0066] **FIGS. 12A and 12B** show another alternative concept for locking onto suture **118**. **FIG. 12A** shows a perspective view of a clip **1200** comprising a first gripping surface **1210**, a second gripping surface **1220**, an opening **1230**, and a clasp **1240**. In a default state, clip **1200** is open as shown in **FIG. 12A**, so that suture **118** can pass freely through opening **1230**. Clip **1200** may be placed on suture **118** attached to T-tag **126**, that has been placed through first tissue **122** and second tissue **124** using the previously-described technique. Clip **1200** may be placed onto suture **118** so that clasp **1280** is directed toward second tissue **124** and opening **1230** is directed toward the user. Clip **1200** may be pushed down suture **118** using a long flexible tube, such as an endoscope.

[0067] To lock clip **1200** onto suture **118**, a horn **1270** including a tapered surface **1272** may be used to apply force at a proximal end of clip **1200**, so that first gripping surface **1210** mates with second gripping surface **1220** to securely hold onto suture **118**, while clasp **1280** holds clip **1200** closed. Clip **1200** may be made from any suitable polymer material, such as nylon. Clip **1200** may be injection molded as a unitary piece with a "living hinge" that biases the part to an open position in which a first gripping surface **1210** is held away from second gripping surface **1220** in a default open state or assembled from multiple pieces.

[0068] While the present invention has been illustrated by description of various embodiments, it is not the intention of the applicants to restrict or limit the spirit and scope of the appended claims to such detail. Numerous other variations, changes, and substitutions will occur to those skilled in the art without departing from the scope of the invention. Moreover, the structure of each element associated with the present invention can be alternatively described as a means for providing the function performed by the element. It will be understood that the foregoing description is provided by way of example, and that other modifications may occur to those skilled in the art without departing from the scope and spirit of the appended Claims.

1. A medical device for locking onto suture comprising:
  - a first endcap, wherein said first endcap includes a hole bored at an oblique angle to a central axis;
  - a second endcap; and
  - an extension spring extending from said first endcap to said second endcap.

2. The medical device of claim 1 wherein first endcap and said second endcap have an outer diameter of no more than about 0.07 inch.

3. The medical device of claim 1 wherein said hole has a diameter of about 0.04 inch, and is bored at an angle of about 45 degrees to the central axis.

4. A medical device for locking onto suture comprising:
  - an endcap; and

- an extension spring associated with said endcap, wherein said spring coils are biased in a compressed state; and
- a length of suture held by said spring.

5. The medical device of claim 4 wherein said endcap has an outer diameter of no more than about 0.07 inch.

6. The medical device of claim 4 wherein the suture is monofilament.

7. The medical device of claim 4 wherein the suture is braided.

8. A medical device comprising:

- a first endcap, wherein said endcap includes a hole bored at an oblique angle to the central axis of said endcap;

- a second endcap;

- a spring disposed intermediate the first and second endcaps; and

- a suture extending through said hole in said first endcap.

9. A method of holding suture comprising the steps of:

- providing a first member having a suture receiving hole;

- providing a second member associated with the first member, the second member comprising a plurality of coils;

- providing a length of suture;

- threading a suture through said hole in said first member;

- spreading the coils of said second member; and

- holding the suture with coils of the second member.

10. The method of claim 7 further comprising the step of:

- spreading the coils apart to loosen tension in said suture.

11. A medical device for locking onto suture comprising:

- a body portion, wherein said body portion includes at least one suture channel;

- a lock sleeve positioned over an outer surface of said body portion;

- wherein said lock sleeve has an inner surface that closely matches the outer surface of said body portion; and

- a means for locking said body portion within said lock sleeve.

12. The medical device of claim 11, wherein said locking means comprises a groove in said body portion and a ring projection in said locking sleeve.

13. The medical device of claim 11, wherein there is a clearance of about 0.001 inch or less between the outer surface of said body portion and the inner surface of said locking sleeve.

14. A method of using a medical device to lock onto suture comprising the steps:

- providing a device comprising a body portion, wherein said body portion includes at least one suture channel;

a lock sleeve positioned over an outer surface of said body portion, wherein said lock sleeve has an inner surface that closely matches the outer surface of said body portion; and a means for locking said body portion within said lock sleeve;

threading a suture through said suture channel;

pushing said locking sleeve over said body portion to trap said suture in a tortuous path; and

locking said locking sleeve to said body portion.

**15.** A medical device for locking onto suture comprising:

a tubular sleeve including an inner channel;

a flap disposed within said inner channel of said tubular sleeve; and

a detent, wherein said detent is positioned within said inner channel such that said flap is biased to press against said detent.

**16.** A medical device for locking onto suture comprising:

A first gripping surface including a plurality of projections;

a second gripping surface, wherein said second grip surface is not in contact with said first grip surface in a default state; and

a clasp, wherein said clasp holds said first gripping surface against said second gripping surface in a locked state.

\* \* \* \* \*