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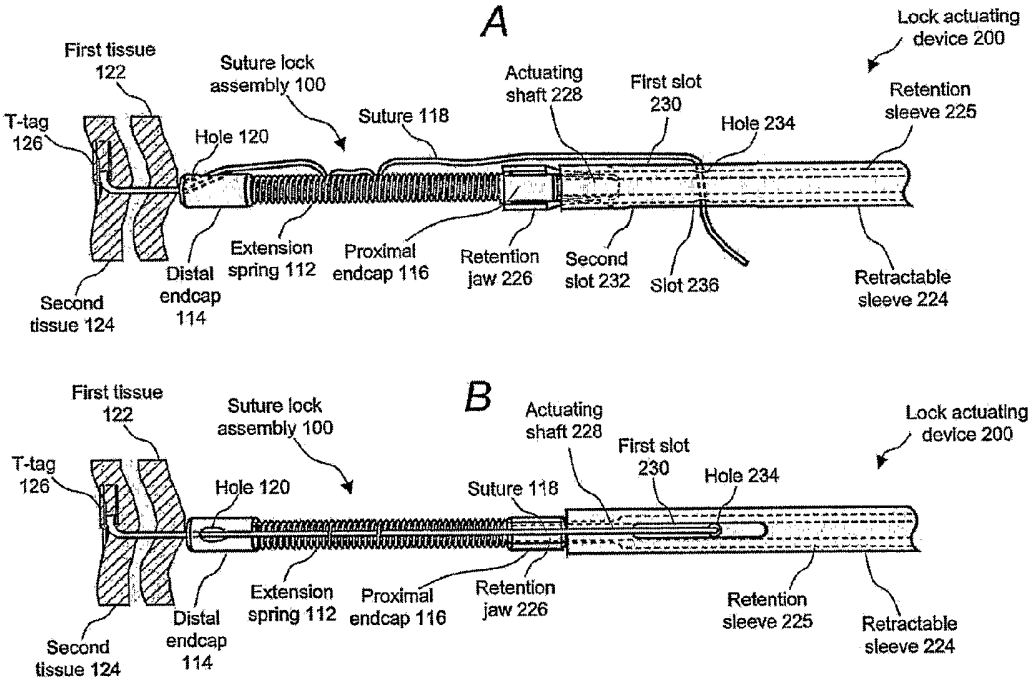

(57) Abstract: Suture holding devices and methods are disclosed, including devices and methods useful in performing a transoral surgical procedure, such as a posterior gastropexy procedure. A device is disclosed which can be used by a physician in a medical procedure to automatically lock and cut a suture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

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U.S. PATENT APPLICATION

SUTURE LOCKING AND CUTTING DEVICES AND METHODS

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SUTURE LOCKING AND CUTTING DEVICES AND METHODS

[0001] **Cross-References to Related Applications**

[0002] This application claims priority to and incorporates by reference the following applications: US Provisional Application 60/571,117 filed May 14, 2004; US provisional Application 60/571,119 filed May 14, 2004; and US Provisional Application 60/571,000 filed May 14, 2004.

[0003] **Field of the Invention**

[0004] 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.

[0005] **Background**

[0006] 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.

[0007] 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.

[0008] 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 March 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.

[0009] 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.

[0010] 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).

[0011] **Summary of the Invention**

[0012] 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.

[0013] 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.

[0014] 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 therethrough and, by relaxing the extension spring, provides a clamping action upon the sutures and a torturous 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.

[0015] 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.

[0016] The various embodiments of the invention can be employed with various types of suture, including without limitation monofilament suture and braided suture.

[0017] **Brief Description of the Drawings**

[0018] 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.

[0019] **Figure 1A** illustrates a perspective view of a suture lock assembly in accordance with a first embodiment of the invention;

[0020] **Figure 1B** illustrates a cross-sectional view of the suture lock assembly in accordance with a first embodiment of the invention;

[0021] **Figure 2** illustrates a side view of an exemplary lock actuating device according to the first embodiment;

[0022] **Figures 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;

[0023] **Figures 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;

[0024] **Figures 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;

[0025] **Figure 6** illustrates a side view of the suture lock assembly of the first embodiment engaged therein in the release state;

[0026] **Figure 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;

[0027] **Figure 8** illustrates a perspective view of a suture lock assembly in accordance with a second embodiment of the invention.

[0028] **Figure 9** illustrates a cross-sectional view of the suture lock assembly of the second embodiment in the unlocked state.

[0029] **Figure 10** illustrates a cross-sectional view of the suture lock assembly of the second embodiment in the locked state.

[0030] **Figure 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.

[0031] **Figure 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.

[0032] **Detailed Description of the Invention**

[0033] **Figure 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**. 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 **Figure 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**.

[0034] **Figure 1B** illustrates a cross-sectional view of suture lock assembly **100** taken along line AA of **Figure 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.

[0035] 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**.

	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

Table 1 Example dimensions of suture lock assembly **100**

[0036] **Figure 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**. **Figure 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**.

[0037] 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.

[0038] 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 **Figures 3A, 3B, 4A, 4B, 5A, 5B, 6**, and **7**. Additionally, **Figures 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.

[0039] **Figures 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.

[0040] 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 **Figures 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**.

[0041] **Figures 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.

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 **Figures 4A** and **4B**.

[0042] **Figures 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.

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**.

[0043] **Figure 6** illustrates a side view of suture lock assembly **100** in the release state, which is described as follows.

[0044] 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.

[0045] 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.

[0046] **Figure 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**.

[0047] 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, NY). The working channel of the EUS endoscope is preloaded with a standard EUS needle, such as is manufactured by Wilson-Cook (Winston-Salem, NC), 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.

[0048] 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.

[0049] 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 **Figures 3A, 3B, 4A, 4B, 5A, 5B,** and **6**.

[0050] 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 **Figures 3A, 3B, 4A, 4B, 5A, 5B,** and **6**.

[0051] 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.

[0052] 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).

[0053] 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.

[0054] 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 **Figures 3A** and **3B**.

[0055] 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 **Figures 3A** and **3B**.

[0056] 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 **Figures 3A, 3B, 4A, 4B, 5A, 5B,** and **6**.

[0057] 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 **Figures 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 **Figures 4A** and **4B**.

[0058] 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 5A** 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 **Figures 5A** and **5B**.

[0059] 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 **Figure 6**. Method **700** ends.

[0060] **Figure 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 **Figures 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**.

[0061] Also shown in **Figure 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.

[0062] **Figure 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**. **Figures 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 **Figures 8** and **9**.

[0063] **Figure 10** illustrates a cross-sectional view of a suture lock assembly **800** in a locked state wherein 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 **Figure 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.

[0064] 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**.

	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

Table 2 Example dimensions of suture lock assembly **800**

[0065] 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 **Figure 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.

[0066] Figures 11A and 11B illustrate an alternative locking device similar in function to those previously mentioned. The locking device of Figures 11A and 11B are designed to lock onto suture 118, when used in conjunction with the endoscope. The locking device of Figures 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.

[0067] This embodiment comprises a tubular sleeve 1100, a flap 1105, and a detent 1120. Tubular sleeve 1100 may have an outer diameter of about 2.6mm and an inner diameter of about 1mm, 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 Figure 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.

[0068] 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 Figure 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.

[0069] Figures 12A and 12B show another alternative concept for locking onto suture 118. Figure 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 Figure 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 suture118 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.

[0070] 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.

[0071] 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.

What is Claimed is:

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.

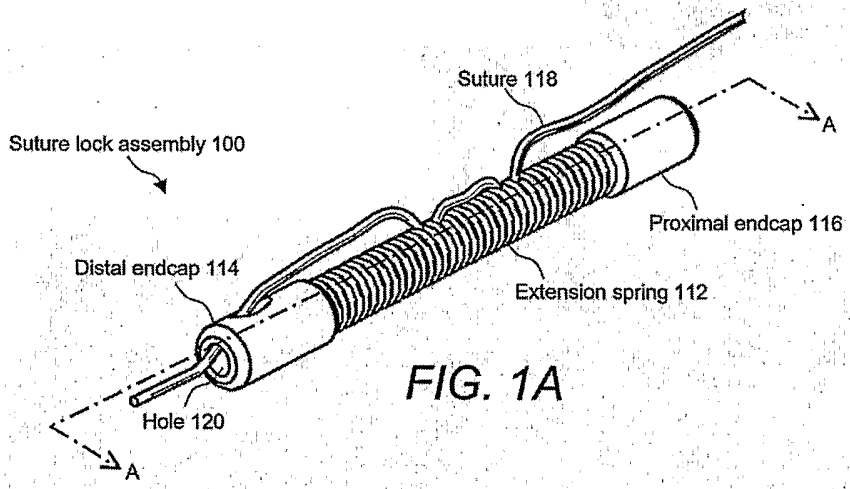
Suture 118
A
Suture lock assembly 100
Proximal endcap 116
Distal endcap 114
Extension spring 112
Hole 120
A

FIG. 1A

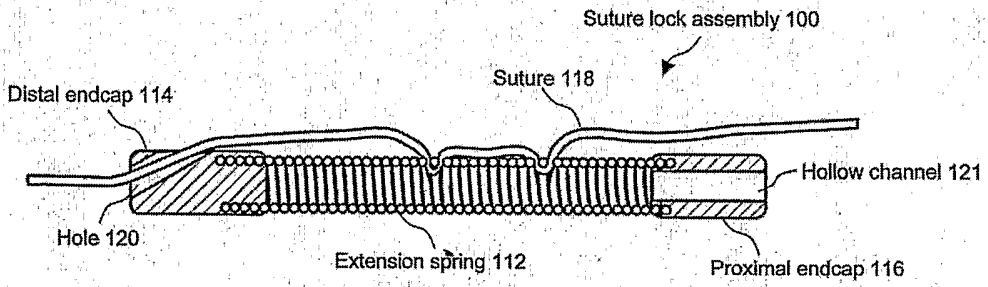
Suture lock assembly 100
Suture 118
Distal endcap 114
Hollow channel 121
Hole 120
Extension spring 112
Proximal endcap 116

FIG. 1B

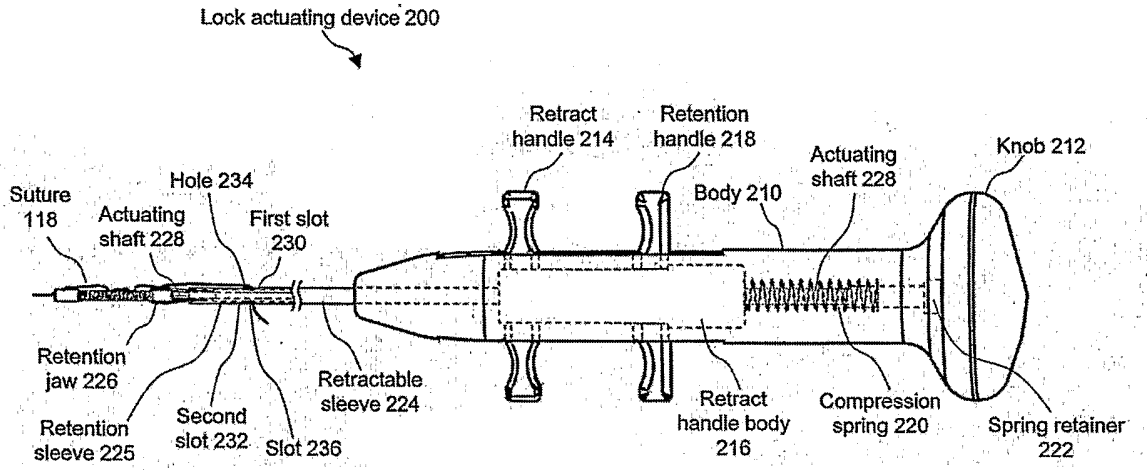
Lock actuating device 200
Retract handle 214
Retention handle 218
Actuating shaft 228
Knob 212
Suture 118
Hole 234
Actuating shaft 228
First slot 230
Body 210
Retention jaw 226
Retention sleeve 225
Second slot 232
Slot 236
Retractable sleeve 224
Retract handle body 216
Compression spring 220
Spring retainer 222

FIG. 2

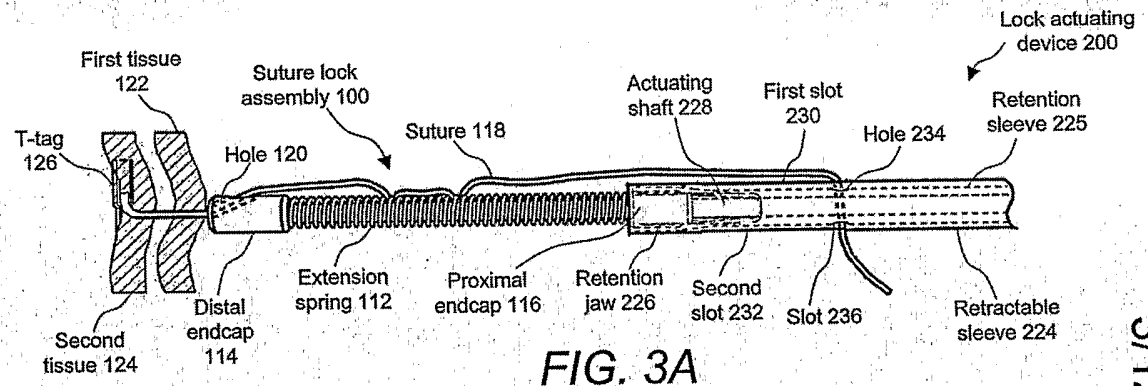
First tissue 122
Suture lock assembly 100
Suture 118
Actuating shaft 228
First slot 230
Hole 234
Lock actuating device 200
Retention sleeve 225
T-tag 126
Hole 120
Extension spring 112
Proximal endcap 116
Retention jaw 226
Second slot 232
Slot 236
Retractable sleeve 224
Distal endcap 114
Second tissue 124

FIG. 3A

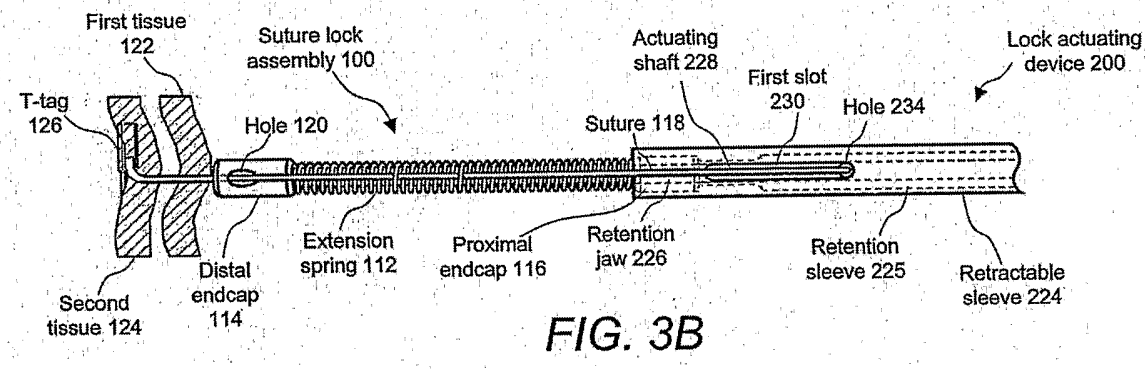
First tissue 122
Suture lock assembly 100
Actuating shaft 228
First slot 230
Hole 234
Lock actuating device 200
T-tag 126
Hole 120
Suture 118
Extension spring 112
Proximal endcap 116
Retention jaw 226
Retention sleeve 225
Retractable sleeve 224
Distal endcap 114
Second tissue 124

FIG. 3B

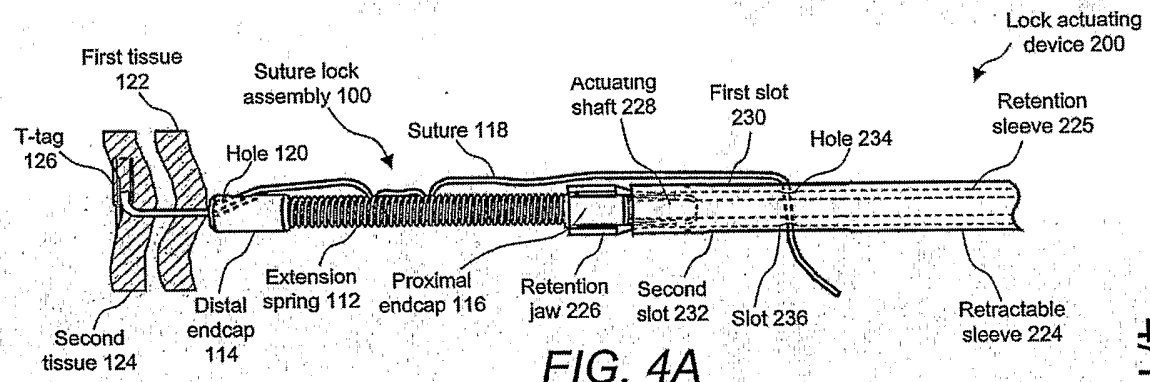
First tissue 122
Suture lock assembly 100
Actuating shaft 228
First slot 230
Lock actuating device 200
T-tag 126
Hole 120
Suture 118
Hole 234
Retention sleeve 225
Extension spring 112
Proximal endcap 116
Retention jaw 226
Second slot 232
Slot 236
Distal endcap 114
Second tissue 124
Retractable sleeve 224

FIG. 4A

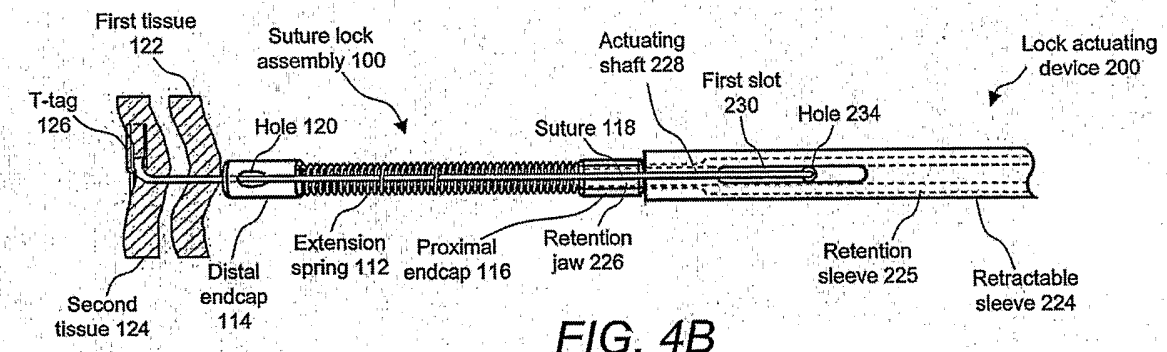
First tissue 122
Suture lock assembly 100
Actuating shaft 228
First slot 230
Lock actuating device 200
T-tag 126
Hole 120
Suture 118
Hole 234
Extension spring 112
Proximal endcap 116
Retention jaw 226
Retention sleeve 225
Distal endcap 114
Second tissue 124
Retractable sleeve 224

FIG. 4B

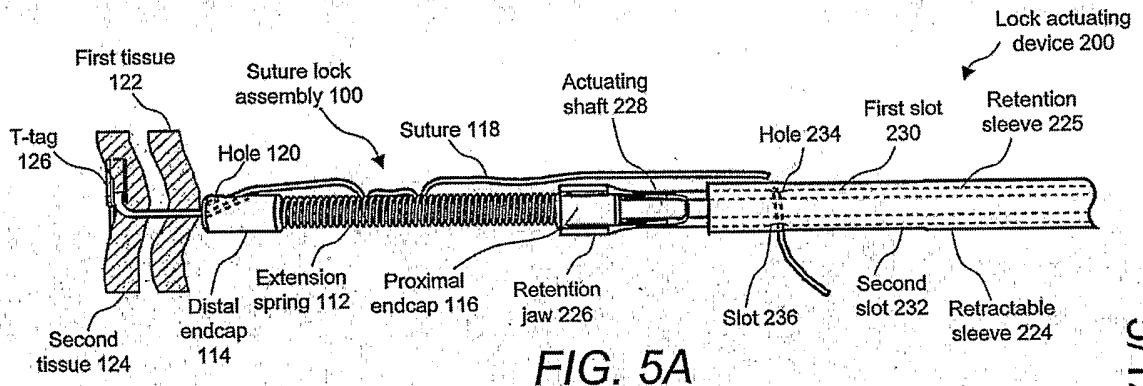
First tissue 122
Suture lock assembly 100
Actuating shaft 228
Lock actuating device 200
T-tag 126
Hole 120
Suture 118
Hole 234
First slot 230
Retention sleeve 225
Extension spring 112
Proximal endcap 116
Retention jaw 226
Slot 236
Second slot 232
Retractable sleeve 224
Second tissue 124
Distal endcap 114

FIG. 5A

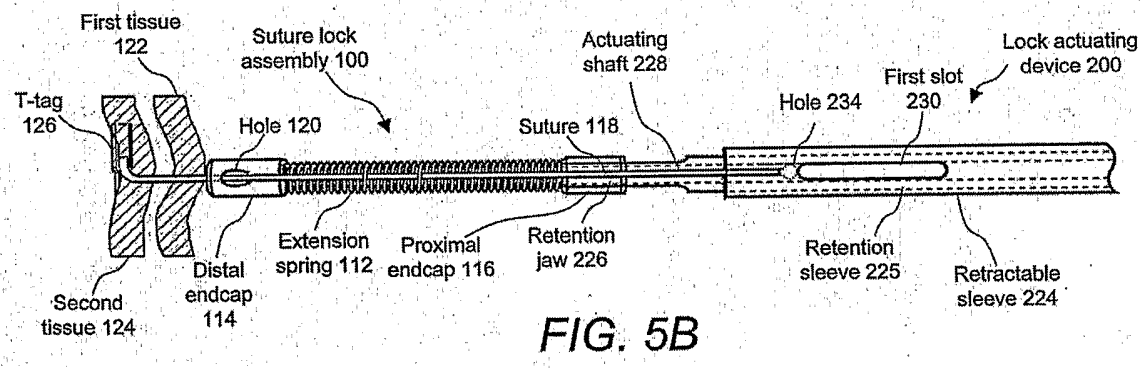
First tissue 122
Suture lock assembly 100
Actuating shaft 228
Lock actuating device 200
T-tag 126
Hole 120
Suture 118
Hole 234
First slot 230
Extension spring 112
Proximal endcap 116
Retention jaw 226
Retention sleeve 225
Retractable sleeve 224
Second tissue 124
Distal endcap 114

FIG. 5B

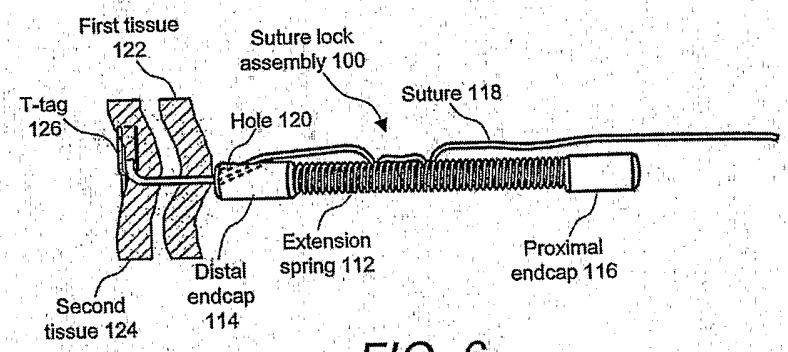
First tissue
122
Suture lock
assembly 100
Suture 118
T-tag
126
Hole 120
Extension
spring 112
Proximal
endcap 116
Distal
endcap
114
Second
tissue 124

FIG. 6

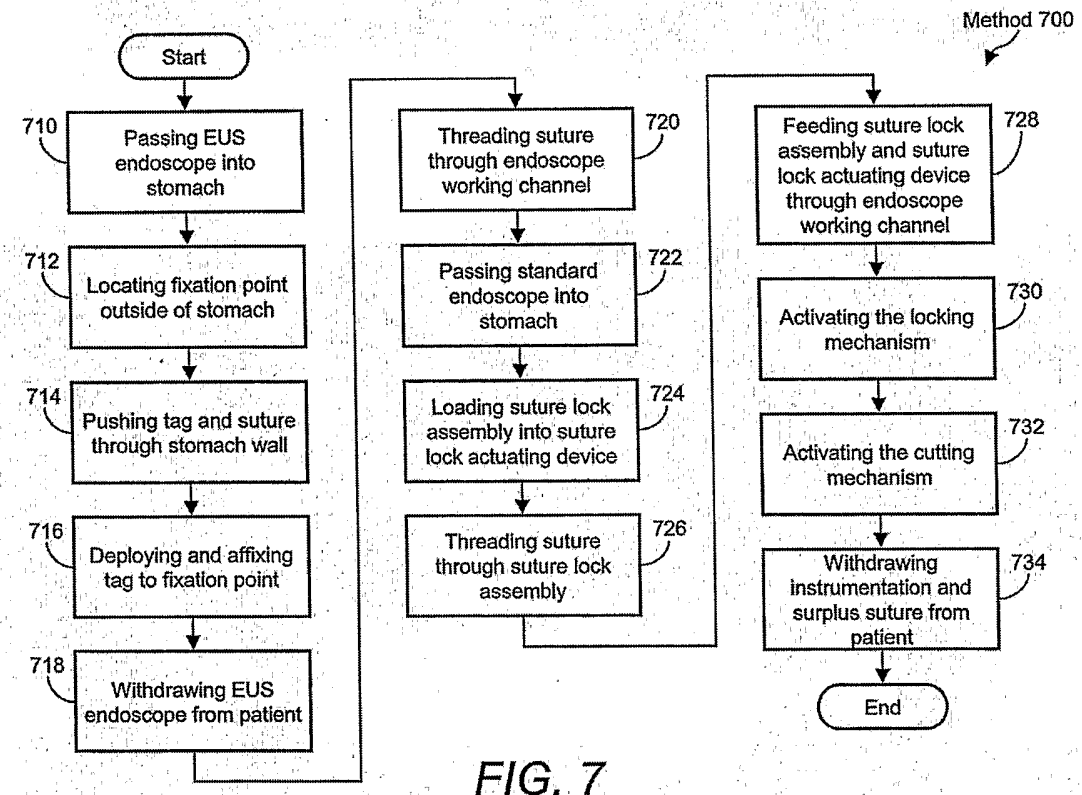
Method 700
Start
710
Passing EUS endoscope into stomach
712
Locating fixation point outside of stomach
714
Pushing tag and suture through stomach wall
716
Deploying and affixing tag to fixation point
718
Withdrawing EUS endoscope from patient
720
Threading suture through endoscope working channel
722
Passing standard endoscope into stomach
724
Loading suture lock assembly into suture lock actuating device
726
Threading suture through suture lock assembly
728
Feeding suture lock assembly and suture lock actuating device through endoscope working channel
730
Activating the locking mechanism
732
Activating the cutting mechanism
734
Withdrawing instrumentation and surplus suture from patient
End

FIG. 7

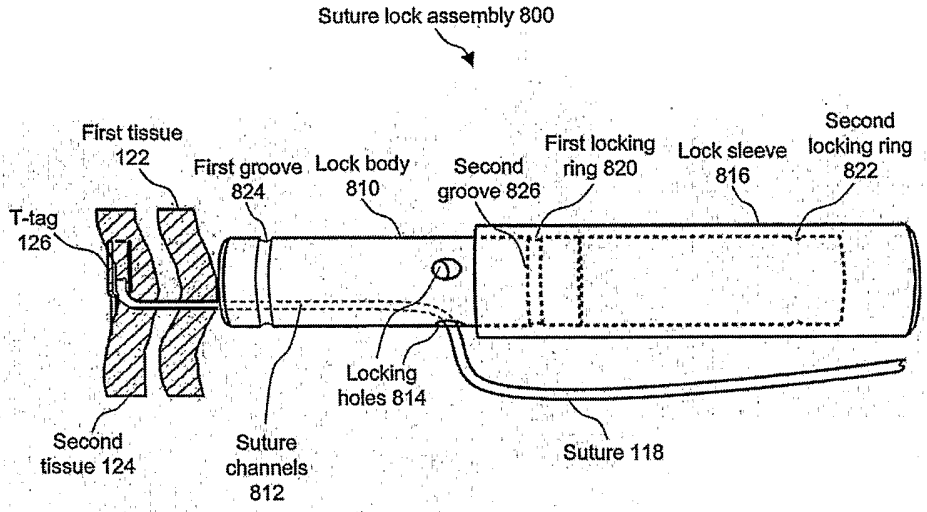
Suture lock assembly 800
First tissue 122
First groove 824
Lock body 810
Second groove 826
First locking ring 820
Lock sleeve 816
Second locking ring 822
T-tag 126
Locking holes 814
Second tissue 124
Suture channels 812
Suture 118

FIG. 8

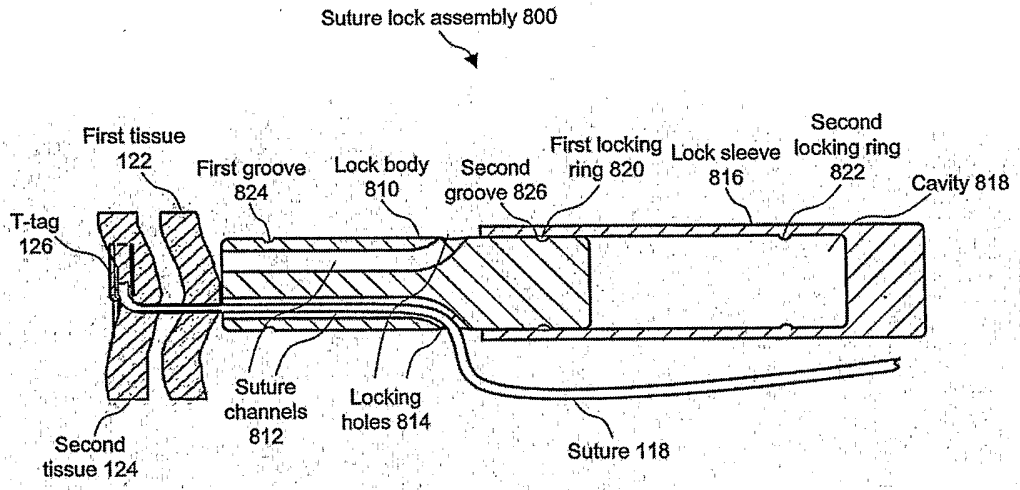
Suture lock assembly 800
First tissue 122
First groove 824
Lock body 810
Second groove 826
First locking ring 820
Lock sleeve 816
Second locking ring 822
Cavity 818
T-tag 126
Suture channels 812
Locking holes 814
Second tissue 124
Suture 118

FIG. 9

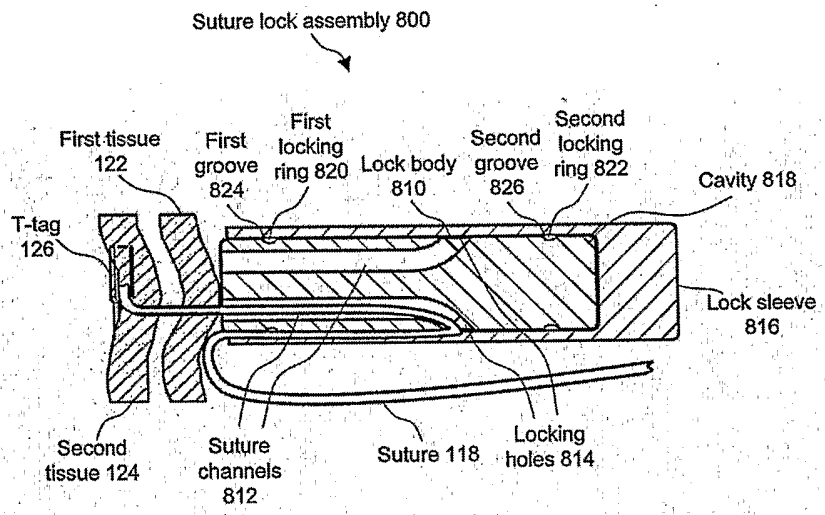
Suture lock assembly 800
First tissue 122
First groove 824
First locking ring 820
Lock body 810
Second groove 826
Second locking ring 822
Cavity 818
T-tag 126
Lock sleeve 816
Second tissue 124
Suture channels 812
Suture 118
Locking holes 814

FIG. 10

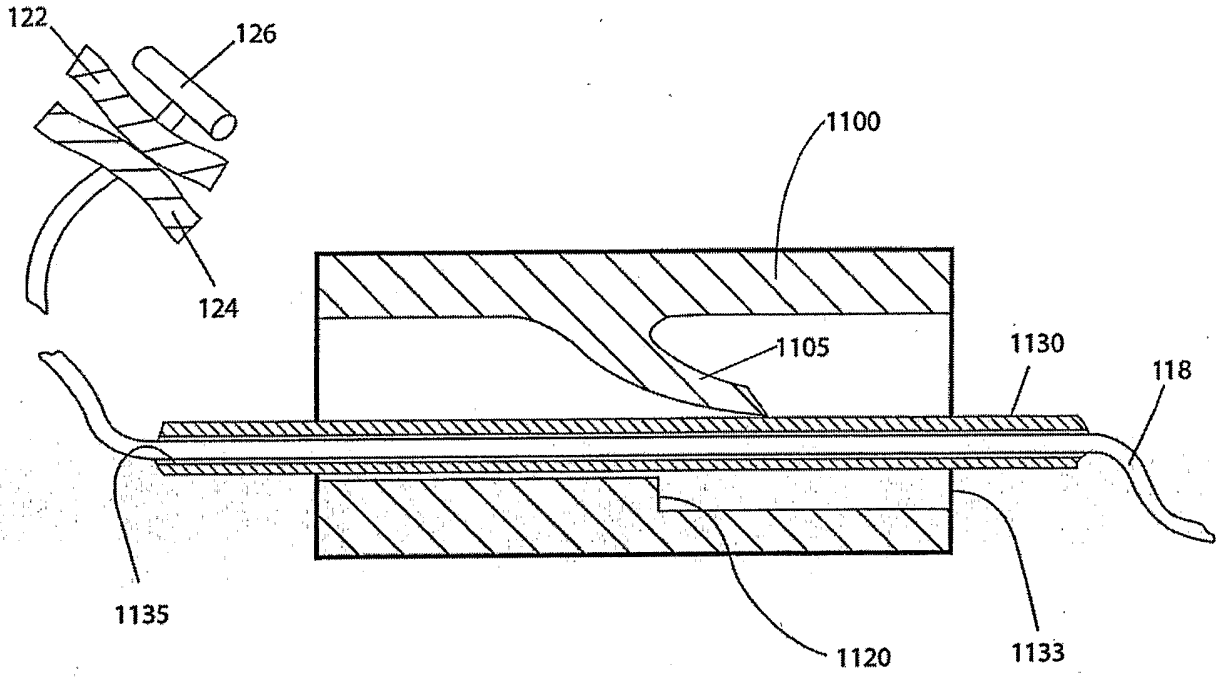

Figure 11A

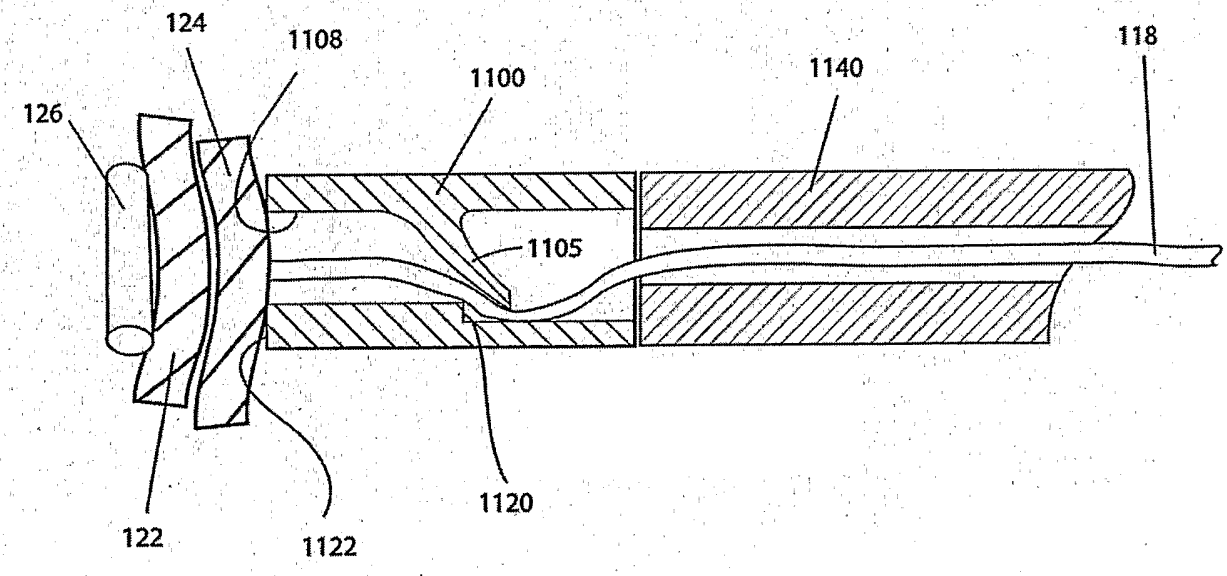

Figure 11B

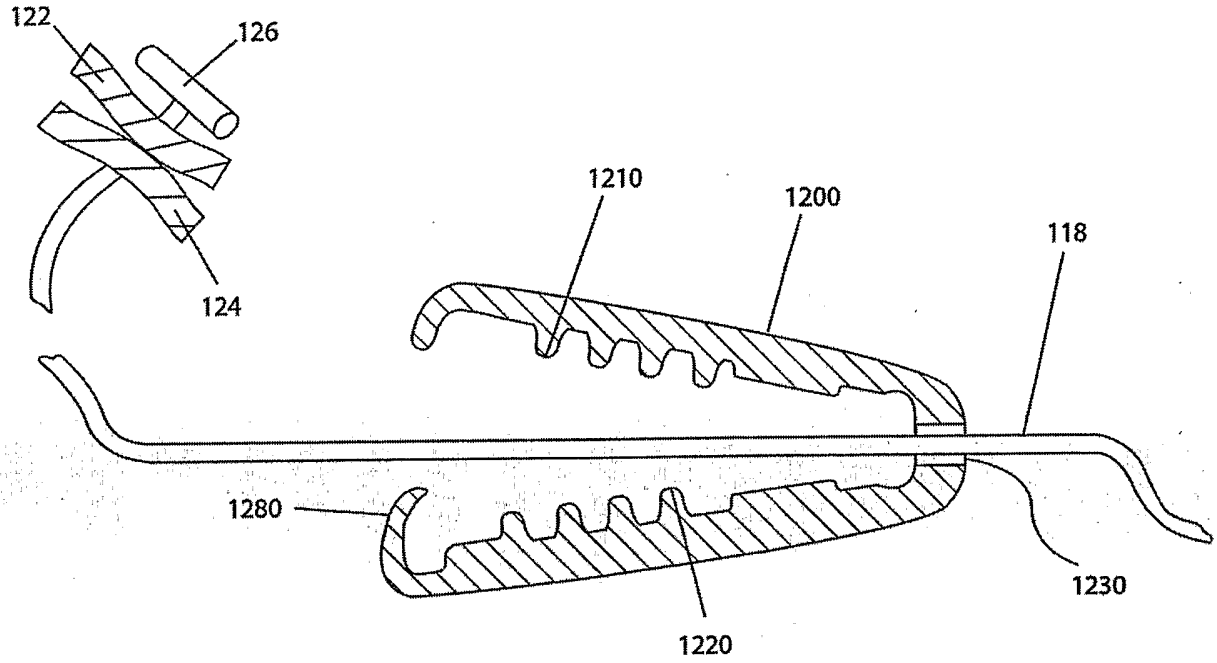

Figure 12A

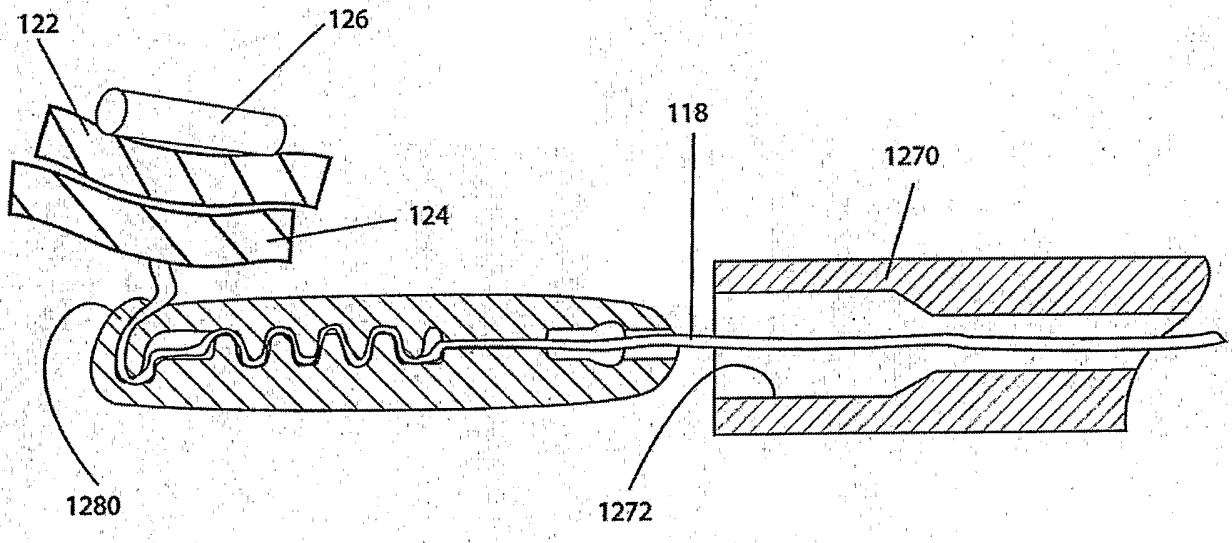

Figure 12B