US 20080228199A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2008/0228199 A1**

(43) **Pub. Date: Sep. 18, 2008**

Cropper et al.

(54) **ENDOSCOPIC TISSUE APPROXIMATION METHOD**

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(21) Appl. No.: **11/687,477**

(22) Filed: **Mar. 16, 2007**

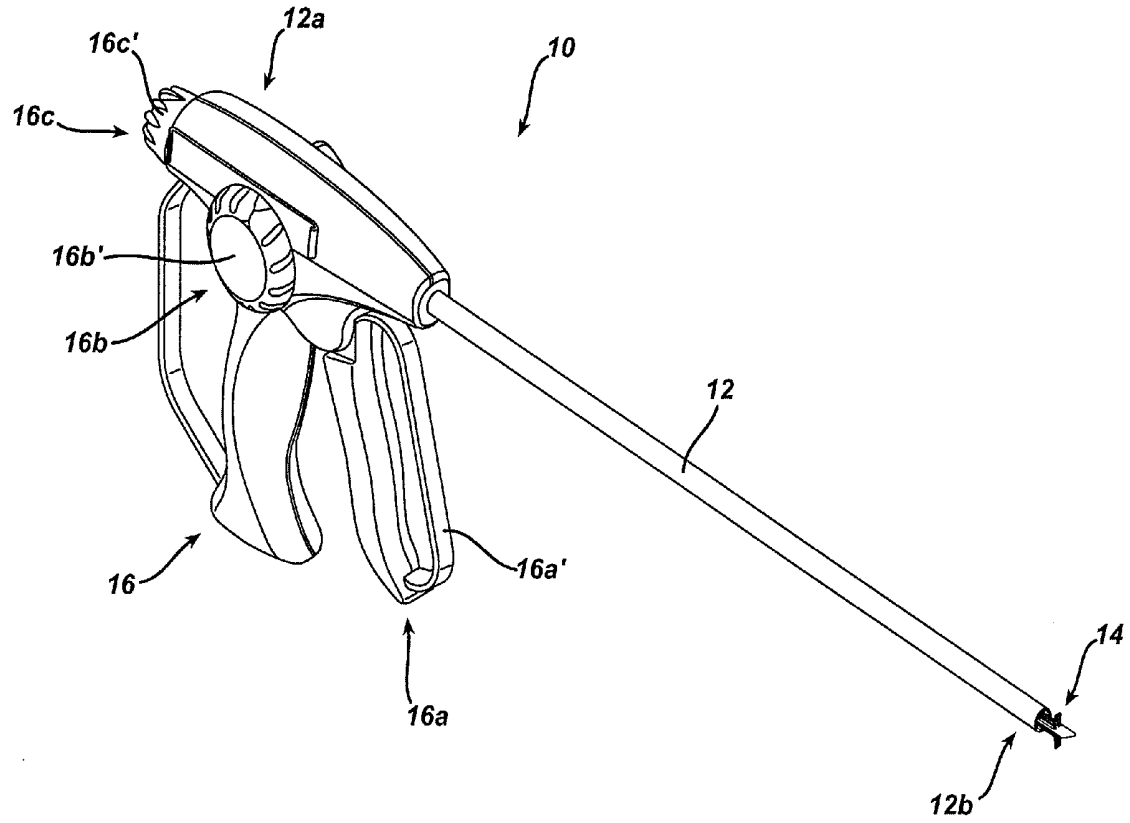
Publication Classification

(51) **Int. Cl.**
A61B 17/128 (2006.01)

(52) **U.S. Cl.** **606/139**

(57) **ABSTRACT**

The present invention generally provides methods and devices for approximating tissue. The methods and devices utilize a device for applying an implantable tissue fastener and a variety of implantable tissue fasteners. The tissue-fastening device can be delivered endoscopically and can be adapted to function along side or in conjunction with a flexible endoscope. In general, the device can include a flexible shaft having an implantable tissue fastener applier disposed at a distal end thereof and a handle for operating the implantable tissue fastener applier disposed at a proximal end thereof. A variety of implantable tissue fasteners can be used with the tissue fastener applier device including single and multi-anchor embodiments.



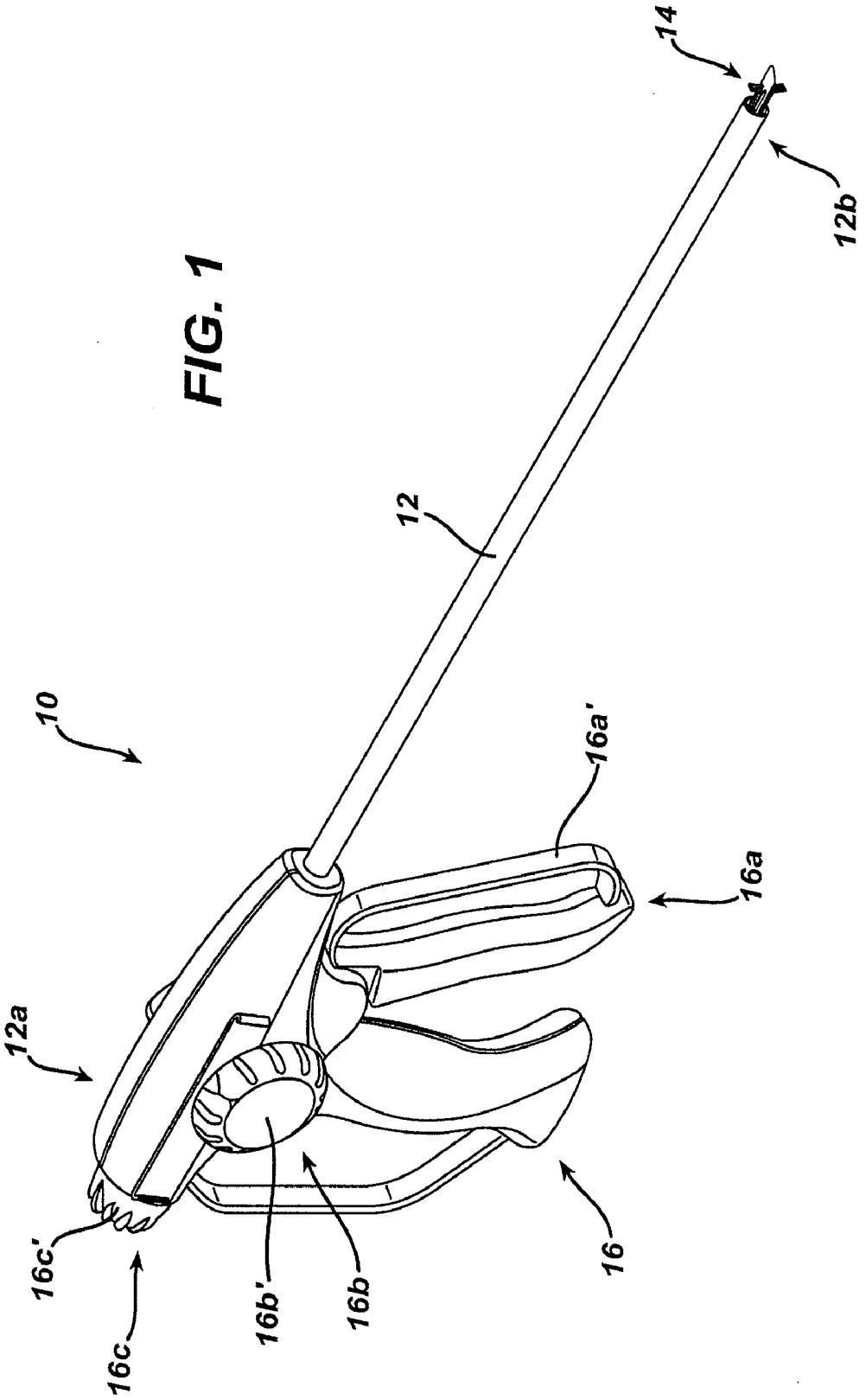


FIG. 1

FIG. 2

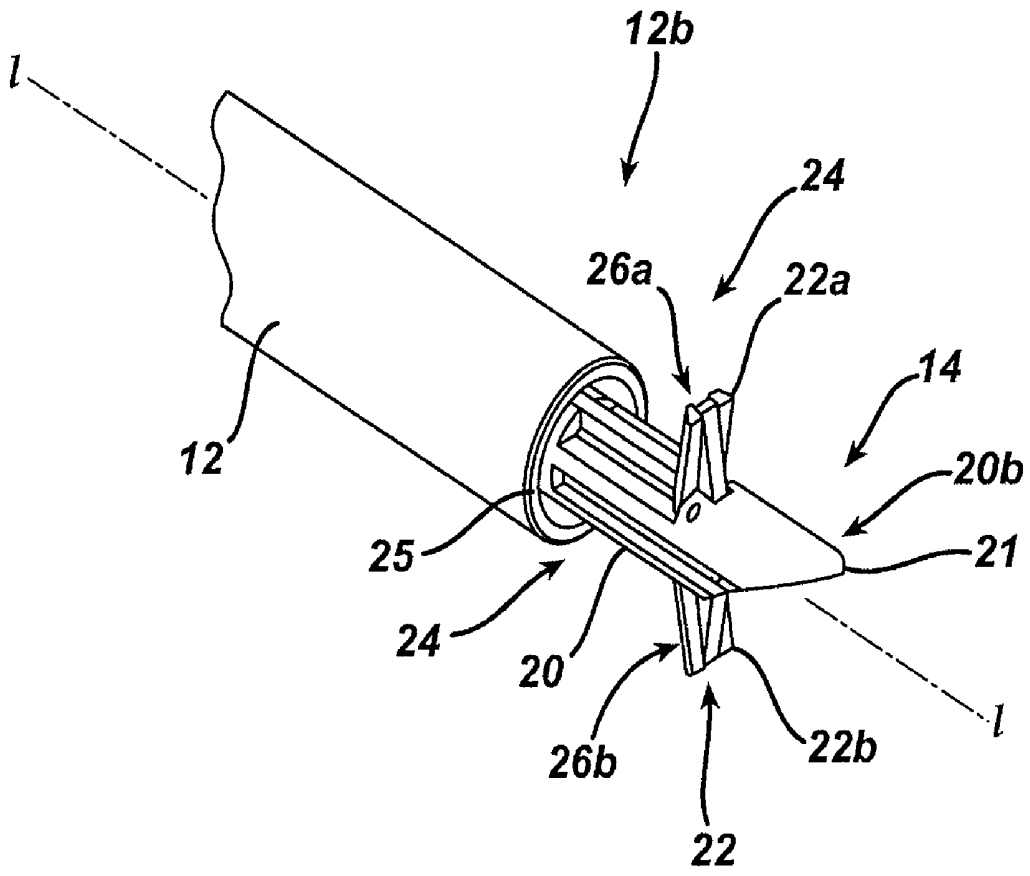


FIG. 3A

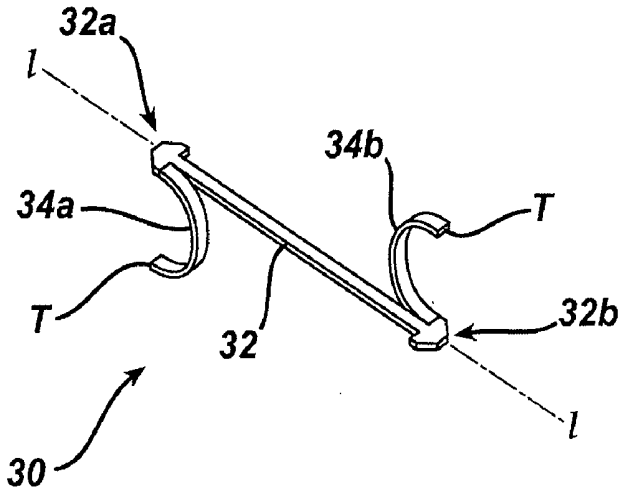


FIG. 3B

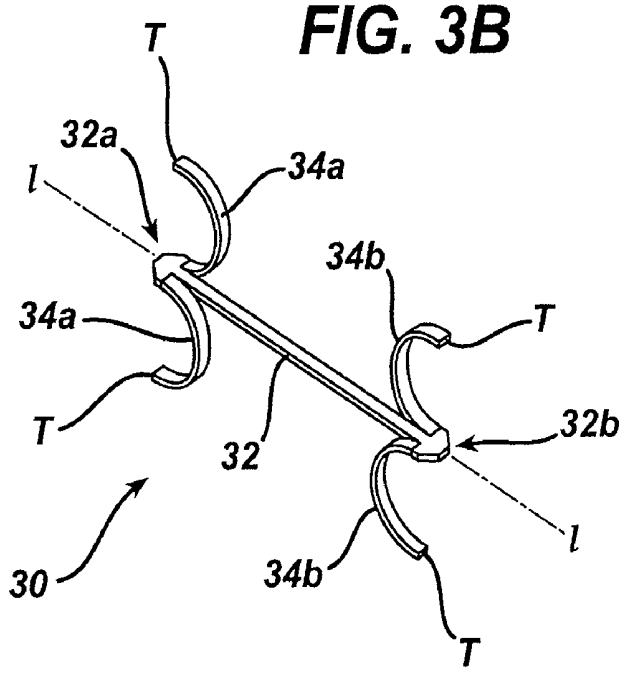


FIG. 3C

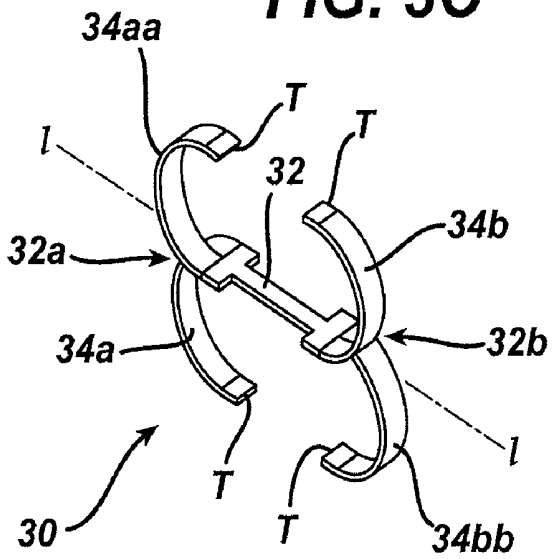

34aa
T
T
l
32
34b
32a
32b
34a
l
T
T
34bb
30

FIG. 3D

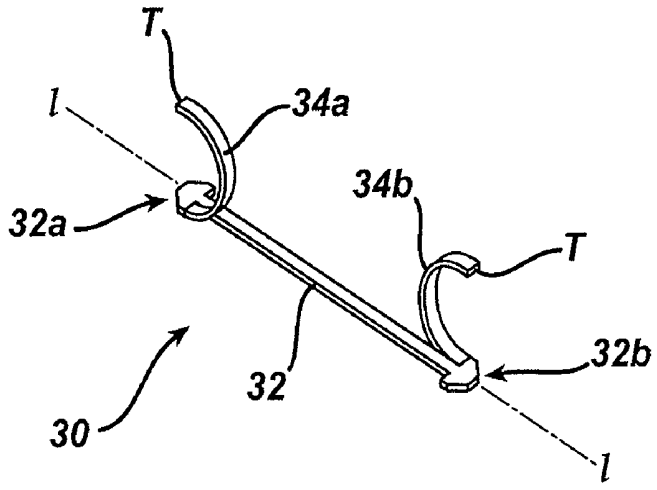

T
l
34a
34b
32a
T
32b
32
30
l

FIG. 3E

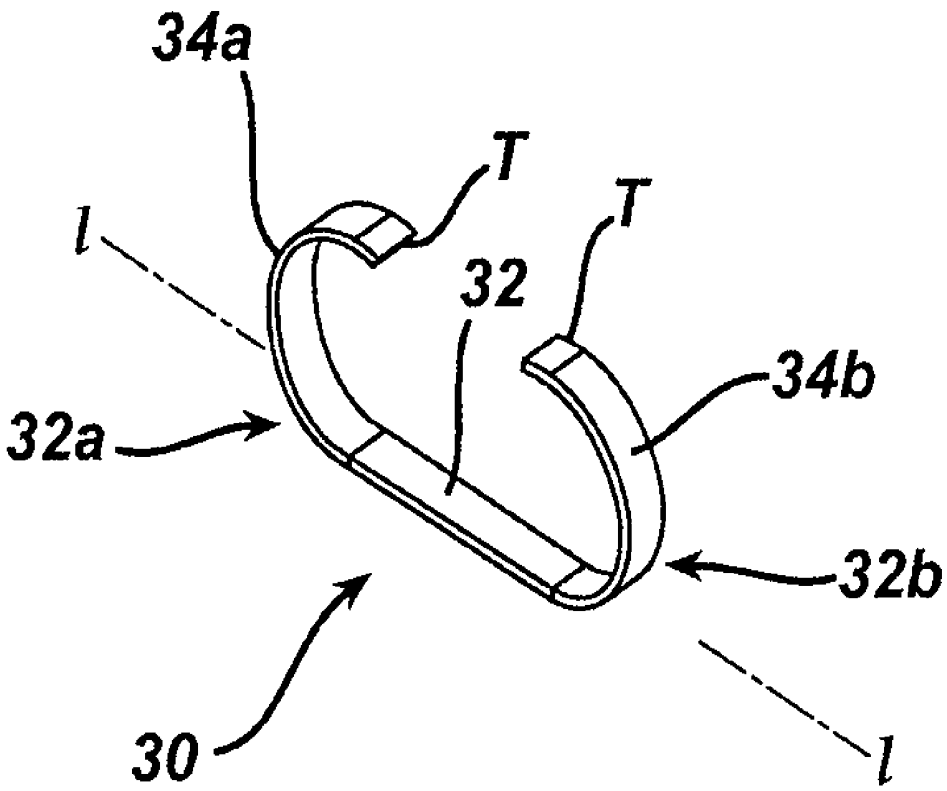


FIG. 4A

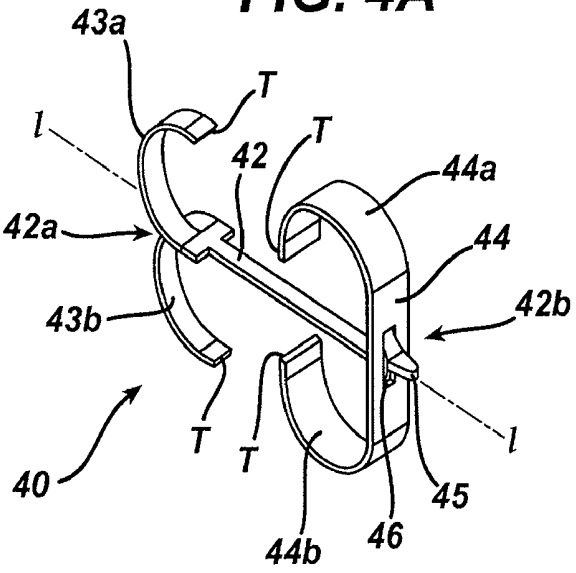

43a
T
l
T
42
44a
42a
44
43b
42b
T
T
l
40
45
44b
46

FIG. 4B

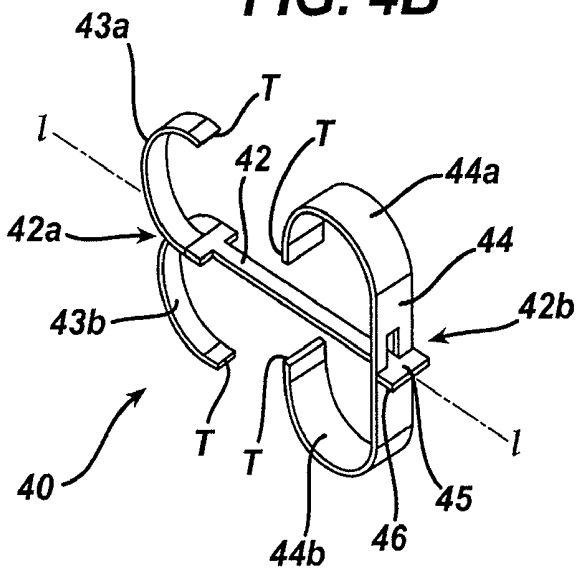

43a
T
l
T
42
44a
42a
44
43b
42b
T
T
l
40
45
44b
46

FIG. 5A

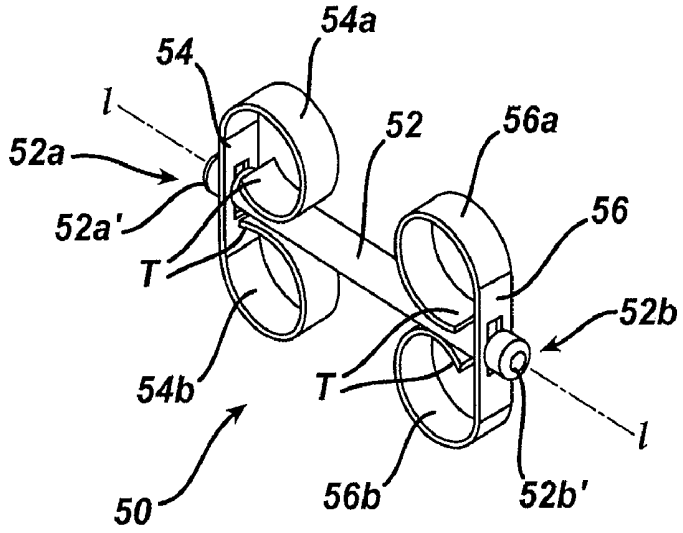
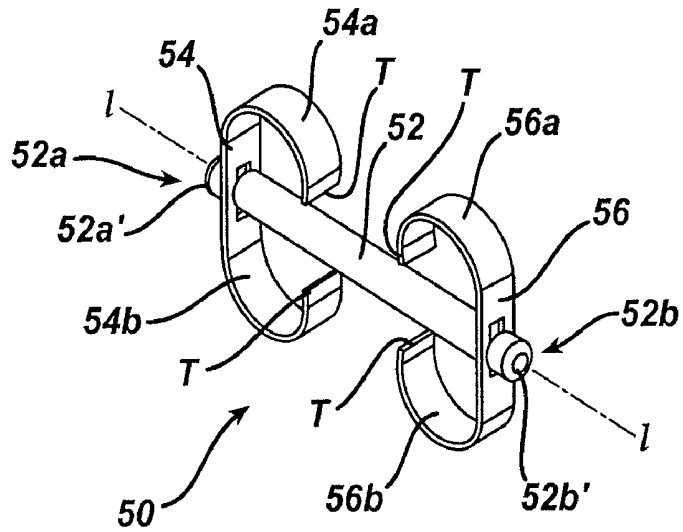

54a
54
l
52
56a
52a
56
52a'
52b
T
T
54b
l
50
56b
52b'

FIG. 5B


54a
54
T
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l
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56a
52a
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52a'
52b
54b
T
T
l
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56b
52b'

FIG. 5C

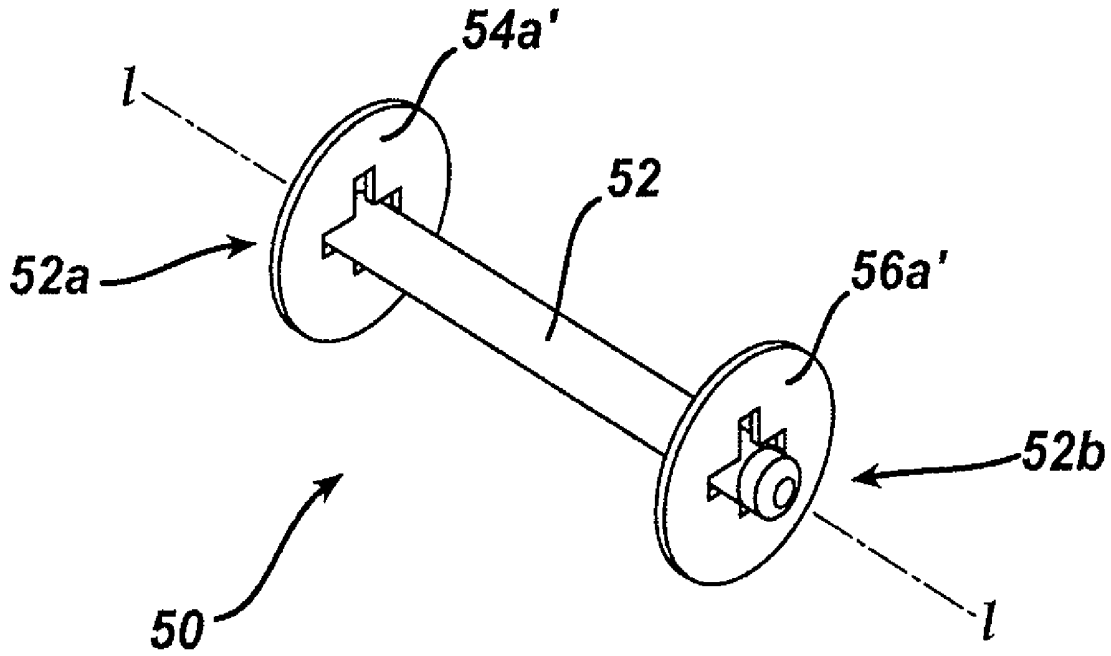
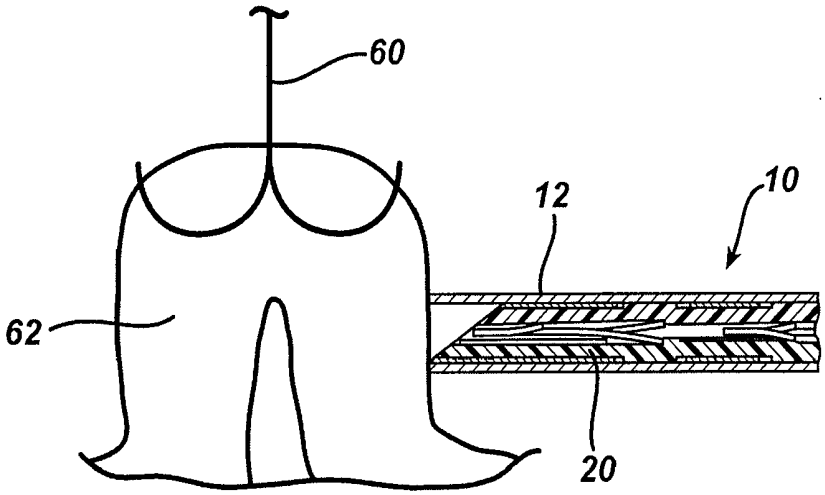


FIG. 6A



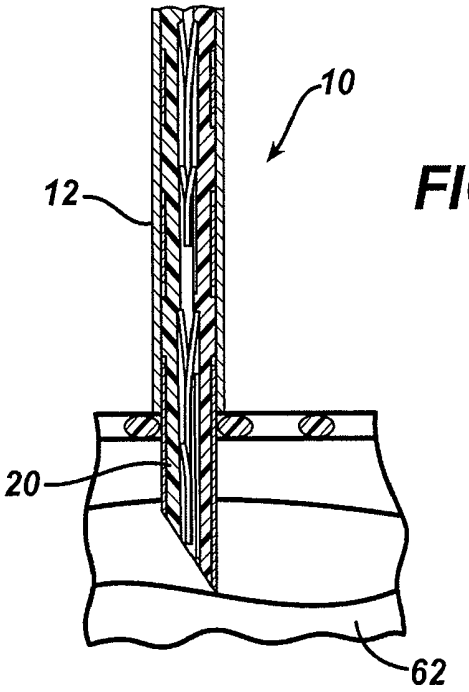


FIG. 6B

FIG. 6C

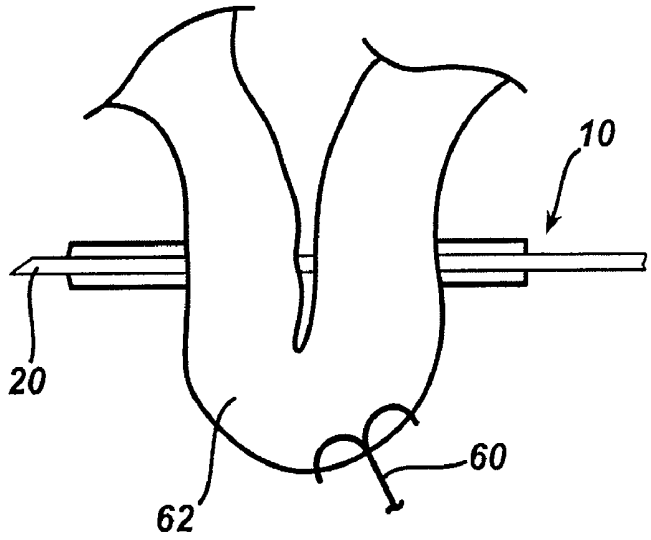


FIG. 6D

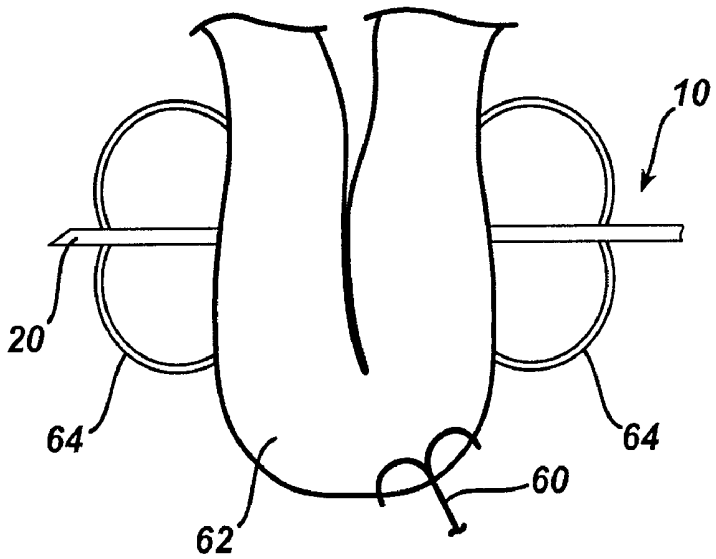


FIG. 6E

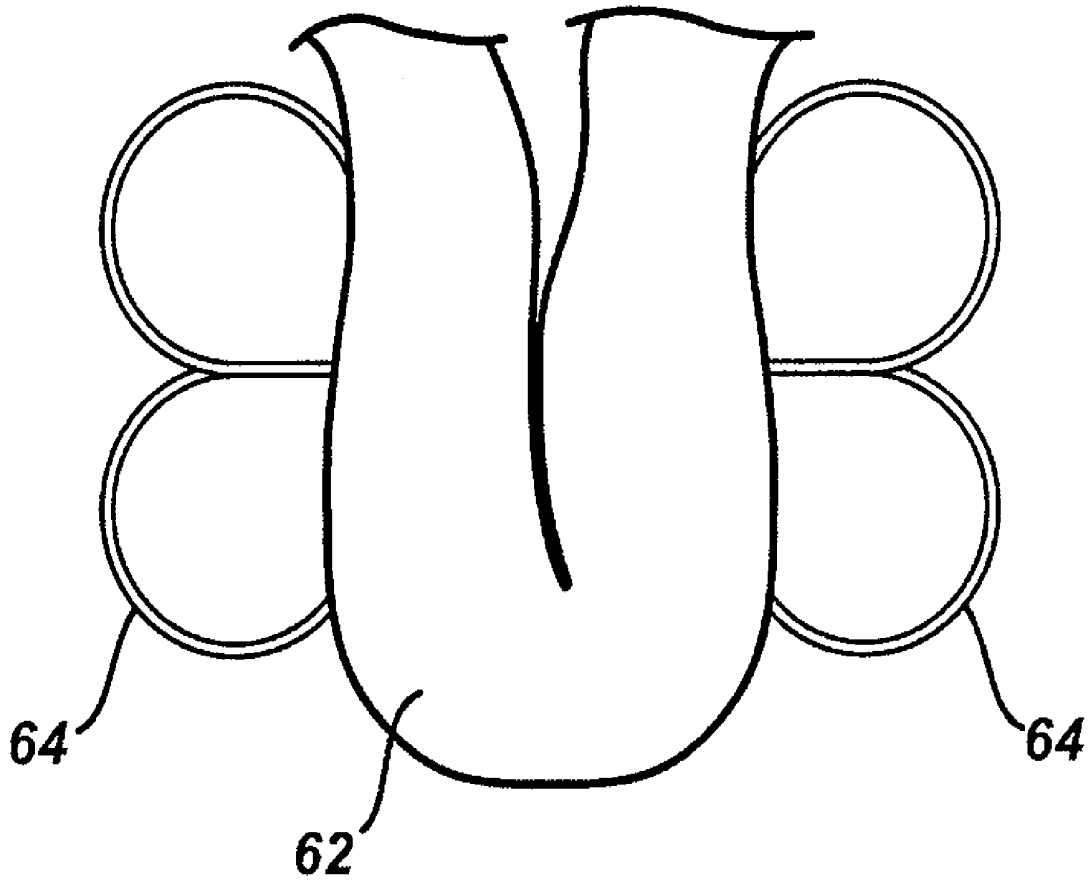


FIG. 7A

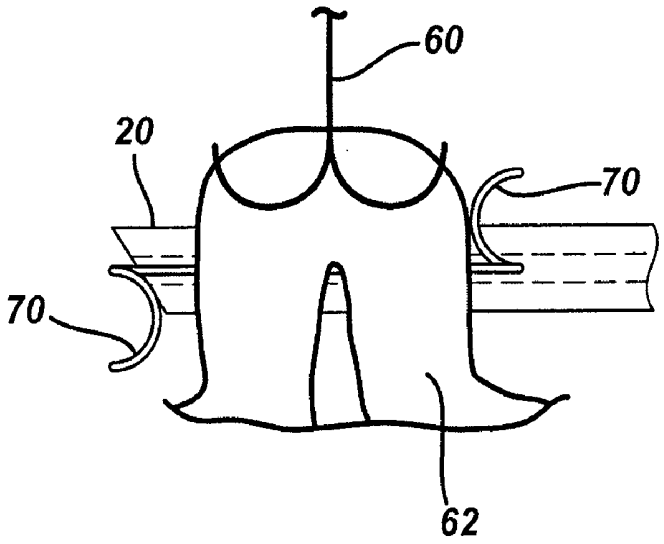


FIG. 7B

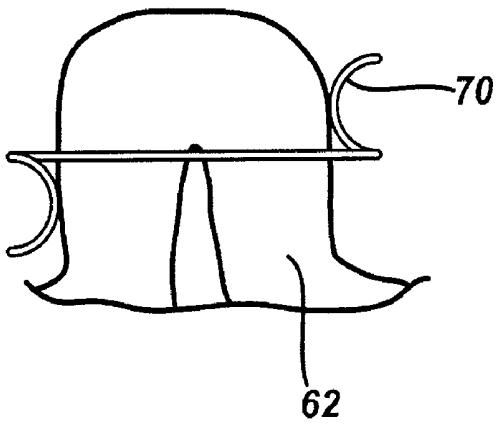


FIG. 8A

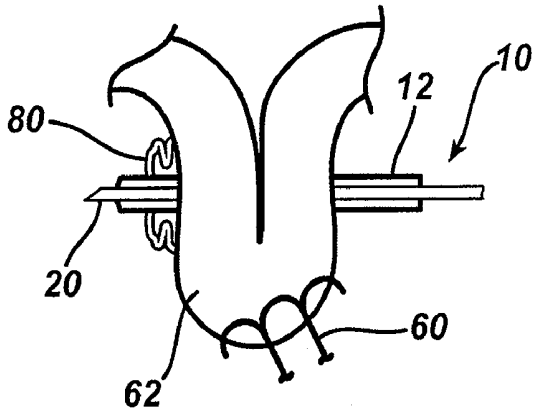


FIG. 8B

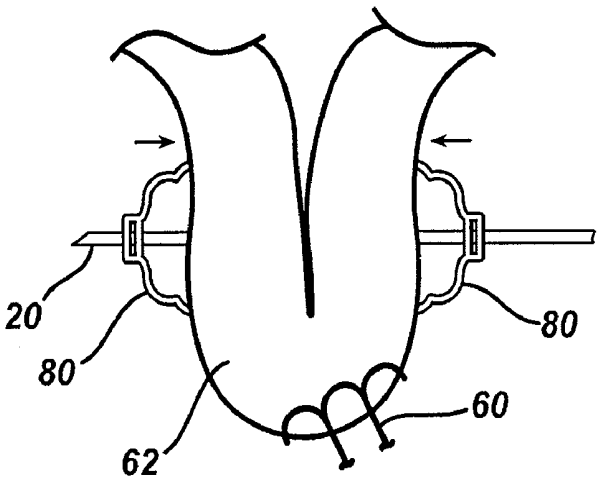
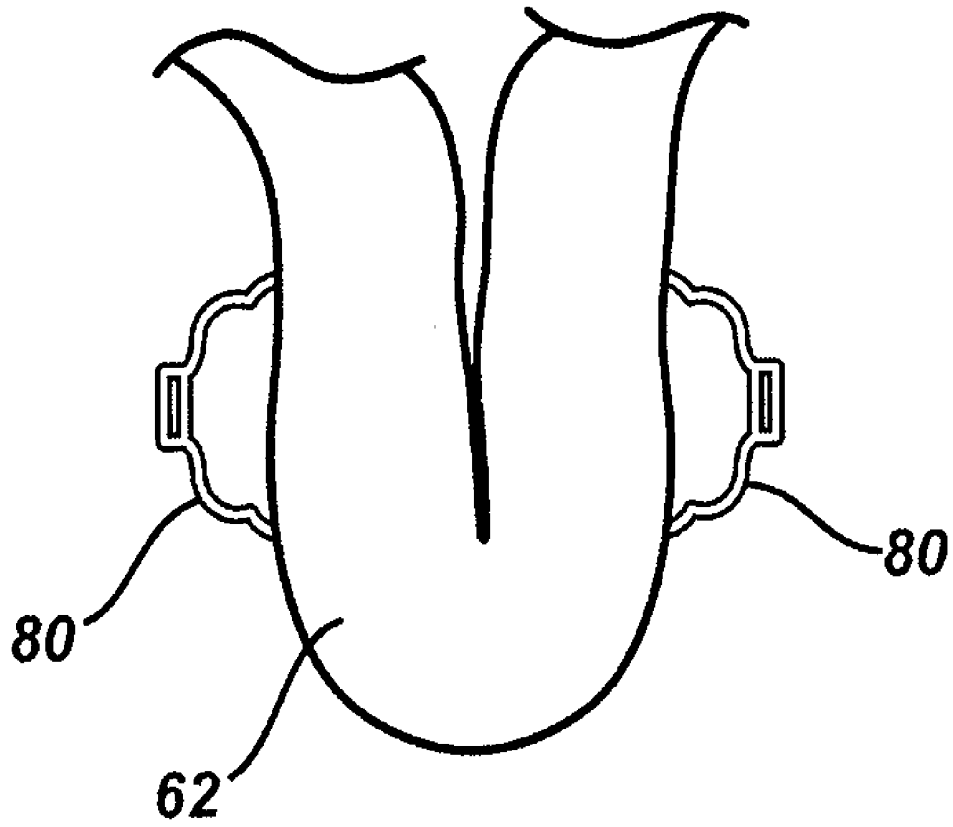


FIG. 8C



ENDOSCOPIC TISSUE APPROXIMATION METHOD

FIELD OF THE INVENTION

[0001] The present invention relates to methods and devices for approximating tissue.

BACKGROUND OF THE INVENTION

[0002] Gastroesophageal reflux disease (GERD) is a common upper gastrointestinal disorder. GERD is a condition in which acidic contents of the stomach flow inappropriately from the stomach into the esophagus. Chronic irritation of the esophagus leads to inflammation of the esophagus, known as esophagitis. In addition to esophagitis, complications of GERD include Barrett's esophagus, esophageal stricture, intractable vomiting, asthma, chronic bronchitis, and aspiration pneumonia. Pharmacological therapy is available and commonly used. However, this therapy does address the fundamental problem of stomach content flowing in the inappropriate retrograde and into the esophagus.

[0003] Normally, the lower esophageal sphincter (LES) allows food to pass from the esophagus to the stomach, while otherwise remaining closed, thus preventing reflux. Closure of the LES is an active process, requiring a combination of proper mechanics and intact innervation. Additionally, the diaphragm may act on the esophagus normally to keep it closed at the LES. Backflow of gastric contents into the esophagus results when gastric pressure is sufficient to overcome the pressure gradient that normally exists at the gastroesophageal junction (GEJ) or when gravity acting on the contents is sufficient to cause flow, retrograde through the GEJ. This situation arises when the gastric pressure is elevated or when the competence of the LES is comprised. Gastric pressure is elevated in association with eating, bending at the waist, squatting, constriction of the waist by clothing, obesity, pregnancy, partial or complete bowel obstruction, etc. Gravitational effects occur when a patient with this condition becomes recumbent. Incompetence of the LES can be functional or anatomic in origin. Function incompetence is associated with hiatus hernia, denervation, myopathy, scleroderma, and chemical or pharmacological influences (smoking, smooth muscle relaxants, caffeine, fatty foods, and peppermint). Anatomic incompetence is associated with congenital malformation, surgical disruption (myotomy, balloon dilatation or bouginage), neoplasm, etc.

[0004] The principal types of operations that address the issues with GERD have included some type of reconstruction of the antireflux barrier, which may include a gastric wrap, as in classic Nissen fundoplication, Toupet fundoplication, a nongastric wrap, e.g., the Angelchik prothesis, a ligamentum teres cardiopexy, and fixation of a part of the stomach to an immobile structure, e.g., the preaortic fascia, as in the Hill repair or the anterior rectus sheath. Several of these operations also include a crural repair of the esophageal hiatus in the diaphragm.

[0005] Other clinical studies have shown that tightening the LES helps reduce GERD. The requirement is to gather tissue from various locations forming a serosa-to-serosa plication, and securing the tissue position until the tissue unites. The resulting tightening in the LES will increase competency in preventing acid reflux.

[0006] Typically, these procedures are performed surgically through an open incision or with traditional laparoscopic and laparotomy techniques. Accordingly, a need exists for methods and devices for approximating tissue using an endoscopic approach.

SUMMARY OF THE INVENTION

[0007] The present invention generally provides devices and methods for approximating tissue. In one embodiment, a device for applying an implantable tissue fastener is provided having an elongate sheath, a handle that can be disposed at a proximal end of the elongate sheath, and a hollow needle that can be disposed within the elongate sheath and be adapted to move independent of the sheath. The elongate sheath can be flexible or it can be rigid. The device can also include a first actuator mechanism that is disposed on the handle and can be operatively associated with the needle such that actuation of the first actuator mechanism is effective to extend the needle from the elongate sheath. A second actuator mechanism can be disposed on the handle and be adapted to deploy a tissue fastener that is disposed within the needle. In one embodiment, the device can further include a tissue backstop that is associated with the hollow needle. A third actuator mechanism can be provided to deploy the tissue backstop. In another embodiment, the device can also include a tissue grasping member that is associated with the elongate sheath and is adapted to engage and manipulate a target region of tissue.

[0008] A variety of implantable tissue fasteners are also provided. In one exemplary embodiment, an implantable tissue fastener is provided having an anchor member that includes a continuous body with proximal and distal ends and a longitudinal axis extending therebetween. At least one proximal extension member can be disposed at the proximal end of the anchor member and can extend at an angle with respect to the longitudinal axis of the anchor member. The one-piece fastener can also include at least one distal extension member that is disposed at the distal end of the anchor member and can extend at an angle with respect to the longitudinal axis of the anchor member. The proximal and distal extension members can be configured such that they extend away from the anchor member. In one embodiment, the anchor member can include at least two proximal extension members and at least two distal extension members to form an I-shaped fastener.

[0009] In another embodiment, an implantable tissue fastener is provided that can include a first anchor member and a second anchor member. The first anchor member can have a continuous body with a longitudinal axis extending between proximal and distal ends. The proximal end can have at least one extension member extending at an angle with respect to the longitudinal axis of the first anchor member. The second anchor member can be removably matable to the first anchor member and can include at least one extension member extending therefrom. In one embodiment, the first anchor member can have at least two extension members that extend away from the longitudinal axis of the first anchor member to form a substantially T-shaped anchor member. The second anchor member can also have at least two extension members that extend away from the longitudinal axis of the first anchor member to form a substantially C-shaped anchor member.

[0010] In yet another embodiment, an implantable tissue fastener is provided that can include first, second, and third anchor members. The first anchor member can have a continuous body with a longitudinal axis extending between proximal and distal ends. The second and third anchor members can be removably matable to the proximal and distal ends

of the first anchor member, respectively, and can include at least one extension member extending at an angle with respect to the longitudinal axis of the first anchor member.

[0011] In general, the extension members associated with the implantable tissue fasteners can have an arcuate shape. A variety of configurations are available for the terminal ends of the extension members. For example, in one embodiment, the terminal ends can be blunt or rounded. In another embodiment, the terminal ends can be sharp or pointed such that they are adapted to penetrate tissue. The implantable tissue fastener can be formed from a variety of materials. For example, exemplary fasteners can be formed from materials including, but not limited to, stainless steel, titanium, and superelastic alloys such as a nickel titanium alloy. The fastener can be formed entirely from one material or can be formed from any combination of materials.

[0012] In another aspect of the invention, a method for approximating tissue is provided and can generally include inserting a device for applying an implantable tissue fastener, positioning the device adjacent a targeted tissue, actuating the device to extend a hollow needle that is disposed within an elongate sheath of the device to penetrate the targeted tissue, reconfiguring the targeted tissue in a desired orientation, and actuating the device to deploy a tissue fastener to penetrate the reconfigured tissue to secure the reconfigured tissue in the desired orientation. In one embodiment, the device can be used in conjunction with an endoscope to facilitate viewing of at least a portion of the method for approximating and can be inserted translumenally through a working channel of the endoscope or through an accessory channel that is mated to the endoscope. In another embodiment, the device can be used in conjunction with a laparoscope and can be inserted through a trocar that extends from an access port. A variety of configurations are available for the approximating device, but the device can generally include an elongate sheath, a hollow needle that is slidably disposed within the sheath, and at least one selectively deployable tissue fastener.

[0013] In one embodiment, actuating the device can include partially deploying the tissue fastener so as to engage the targeted tissue with the tissue fastener in a partially deployed configuration. In this embodiment, reconfiguring the targeted tissue can include manipulating the engaged tissue with the partially deployed tissue fastener. In another embodiment, the method can include actuating the device to deploy a tissue backstop disposed on a distal portion of the hollow needle. Reconfiguring the targeted tissue can include compressing the engaged tissue between a proximal surface of the tissue backstop and a distal surface of the elongate sheath. In general, reconfiguring the targeted tissue can include engaging and manipulating an inner surface of the targeted tissue to change the shape of the targeted tissue. The method can further include repeating the steps of reconfiguring the targeted tissue and actuating the device to deploy the tissue fastener.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0015] FIG. **1** is a perspective view of one embodiment of a device for applying an implantable tissue fastener;

[0016] FIG. **2** is a perspective view of the distal end of the device shown in FIG. **1**;

[0017] FIG. **3**A is a perspective view of one embodiment of an implantable tissue fastener;

[0018] FIG. **3**B is a perspective view of another embodiment of an implantable tissue fastener;

[0019] FIG. **3**C is a perspective view of another embodiment of an implantable tissue fastener;

[0020] FIG. **3**D is a perspective view of another embodiment of an implantable tissue fastener;

[0021] FIG. **3**E is a perspective view of another embodiment of an implantable tissue fastener;

[0022] FIG. **4**A is a perspective view of one embodiment of an implantable tissue fastener;

[0023] FIG. **4**B is a perspective view of another embodiment of an implantable tissue fastener;

[0024] FIG. **5**A is a perspective view of one embodiment of an implantable tissue fastener;

[0025] FIG. **5**B is a perspective view of another embodiment of an implantable tissue fastener;

[0026] FIG. **5**C is a perspective view of another embodiment of an implantable tissue fastener;

[0027] FIG. **6**A is a perspective view of one embodiment of a device for applying an implantable tissue fastener positioned adjacent a target tissue;

[0028] FIG. **6**B is a perspective view of one embodiment of a device for applying an implantable tissue fastener penetrating a target tissue;

[0029] FIG. **6**C is a perspective view of one embodiment of a device for applying an implantable tissue fastener penetrated through a target tissue;

[0030] FIG. **6**D is a perspective view of one embodiment of a device for applying an implantable tissue fastener deploying a tissue fastener to a target tissue;

[0031] FIG. **6**E is a perspective view of one embodiment of an implantable tissue fastener deployed in a target tissue;

[0032] FIG. **7**A is a perspective view of another embodiment of a device for applying an implantable tissue fastener penetrating a target tissue;

[0033] FIG. **7**B is a perspective view of another embodiment of an implantable tissue fastener deployed in a target tissue;

[0034] FIG. **8**A is a perspective view of another embodiment of a device for applying an implantable tissue fastener penetrating a target tissue;

[0035] FIG. **8**B is a perspective view of the device shown in FIG. **8**A applying an implantable tissue fastener deploying a tissue fastener to a target tissue; and

[0036] FIG. **8**C is a perspective view of another embodiment of an implantable tissue fastener deployed in a target tissue.

DETAILED DESCRIPTION OF THE INVENTION

[0037] Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those skilled in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments.

Such modifications and variations are intended to be included within the scope of the present invention.

[0038] The present invention generally provides methods and devices for approximating tissue. The methods and devices utilize a device for applying an implantable tissue fastener and a variety of implantable tissue fasteners. The tissue-fastening device can be delivered endoscopically and can be adapted to function along side of or in conjunction with a flexible endoscope. In general, the device can include a flexible shaft having an implantable tissue fastener applier disposed at a distal end thereof and a handle for operating the implantable tissue fastener applier disposed at a proximal end thereof. For example, in an exemplary embodiment, the device can have a flexible elongate sheath, a handle that is disposed at a proximal end of the elongate sheath, and a hollow needle that is disposed within the elongate sheath and is adapted to move independent of the sheath. At least one actuator mechanism can be disposed on the handle for actuating various operations of the device. For example, a first actuator mechanism can be operatively associated with the needle such that actuation of the first actuator mechanism is effective to extend the needle from the elongate sheath. The device can further include a second actuator mechanism that is adapted to deploy a tissue fastener disposed within the needle. Although the device is shown and described for endoscopic use, one skilled in the art will appreciate that device could include a rigid shaft for laproscopic use.

[0039] FIGS. **1** and **2** illustrate one exemplary embodiment of a device **10** for applying an implantable tissue fastener. As indicated above, the device can generally include a flexible elongate sheath **12** having an implantable tissue applier **14** disposed at a distal end **12***b* thereof and a handle **16** for operating the implantable tissue applier **14** at a proximal end **12***a* thereof. The implantable tissue applier **14** can have a variety of configurations, but in one exemplary embodiment, shown in FIGS. **1** and **2**, the tissue applier **14** takes the form of a hollow needle **20** (FIG. **2**) that is slidably disposed within the flexible elongate sheath **12**. The hollow needle **20** can have a variety of shapes and sizes, but can generally be sized and shaped such that it can slidably move with respect to the sheath **12** and retain an implantable tissue fastener therein. The hollow needle **20** can also be adapted such that it can move independent of the sheath **12**.

[0040] FIG. **2** shows the hollow needle **20** in a deployed position wherein the hollow needle **20** is advanced distally with respect to the sheath **12** such that the hollow needle **20** extends beyond the distal end **12***b* of the sheath **12**. As illustrated in FIG. **2**, the distal end **20***b* of the hollow needle **20** includes a tissue penetrating tip **21** that can allow the hollow needle **20** to pierce a target region of tissue to approximate. The distal portion **20***b* of the hollow needle **20** can also be adapted to release or deploy at least one implantable tissue fastener that is disposed therein.

[0041] The hollow needle **20** can further include a tissue backstop **22** to aid in isolating and compressing a target tissue. The backstop **22** can have a variety of configurations, but in one exemplary embodiment, shown in FIG. **2**, the backstop **22** includes first and second stop members **22***a*, **22***b* that are positioned near the distal end **20***b* of the hollow needle **20**. The first and second stop members **22***a*, **22***b* can be contained within and/or seated flush with an outer surface **23** of the hollow needle **20** when not in use. For compressing a target tissue, the first and second stop members **22***a*, **22***b* can be deployed such that they extend transverse to a longitudinal axis L of the hollow needle **20**. FIG. **2** illustrates that such a configuration forms a compression region **24** between a distal facing surface **25** of the elongate sheath **12** and a proximal facing surface **26***a*, **26***b* of the first and second stop members **22***a*, **22***b*. The device can be adapted to deploy the first and second stop members **22***a*, **22***b* simultaneously and/or sequentially depending on the desired use. Although the tissue backstop **22** is shown and described as first and second stop members **22***a*, **22***b*, one skilled in the art will appreciate that any combination of stop members can be incorporated into the device **10**. Additionally, the device **10** need not have a tissue backstop **22**. In such a configuration, the target tissue can be isolated and compressed using a tissue grasping member **60** (shown in FIGS. **6**A, **6**C-**6**D, **7**A, and **8**A-**8**B) or a partially deployed tissue fastener.

[0042] The handle portion **16** of the device can have a variety of configurations but is generally positioned at a proximal end **12***a* of the elongate sheath **12** and is configured to operate the implantable tissue applier **14** described above. In one exemplary embodiment, the handle **16** can include one or more actuator mechanisms for actuating various operations of the tissue approximating procedure. As shown in FIG. **1**, the device includes a first actuator mechanism **16***a* for moving the hollow needle **20** with respect to the sheath **12**, a second actuator mechanism **16***b* for deploying the tissue backstop **22** associated with the hollow needle **20**, and a third actuator mechanism **16***c* for deploying an implantable tissue fastener that can be disposed within the hollow needle **20**. In the embodiment shown, the first actuator mechanism **16***a* takes the form of a trigger **16***a*' that is adapted to advance the hollow needle **20** from the sheath **12** upon compression of the trigger **16***a*'. The second and third actuator mechanisms **16***b*, **16***c* are shown as knobs **16***b*', **16***c*' that can be rotated to deploy the tissue backstop **22** and tissue fastener, respectively. Although the device **10** is shown and described as having three separate actuator mechanisms **16***a*, **16***b*, **16***c*, one skilled in the art will appreciate that a variety of combinations and configurations of actuator mechanisms can be used to carry out the operations of the tissue approximating procedure.

[0043] A variety of implantable tissue fasteners can be used with the tissue fastener applier device described above. For example, in one exemplary embodiment, shown in FIGS. **3**A-**3**E, the implantable tissue fastener is in the form of a one-piece fastener **30** that includes an anchor member **32** with at least one proximal and one distal extension member **34***a*, **34***b*. The anchor member **32** can have a continuous body with proximal and distal ends **32***a*, **32***b* and a longitudinal axis l extending therebetween. At least one proximal extension member **34***a* can be disposed at the proximal end **32***a* of the anchor member **32** and can extend at an angle with respect to the longitudinal axis l of the anchor member **32**. The fastener **30** can also include at least one distal extension member **34***b* that is disposed at the distal end **32***b* of the anchor member **32** and extends at an angle with respect to the longitudinal axis l of the anchor member **32**.

[0044] The proximal and distal extension members **34***a*, **34***b* can extend away from the anchor member **32** to form the one-piece fastener **32**. In one embodiment, shown in FIG. **3**A, the proximal and distal extension members **34***a*, **34***b* extend away from the anchor member **32** on opposite sides of the anchor **32** to form a Z-shaped fastener. In another embodiment, shown in FIGS. **3**D-**3**E, the extension members **34***a*, **34***b* extend away from the anchor member **32** on the same side of the anchor **32** to form a U-shaped fastener. The one-piece

fastener **30** is not limited to one proximal and one distal extension member, as in some embodiments the anchor member **32** can include at least two proximal extension members **34***a*, **34***aa* and/or at least two distal extension members **34***b*, **34***bb*. FIGS. **3**B-**3**C illustrate that such a configuration yields an I-shaped fastener. Although the one-piece fastener **30** is shown and described as either a Z, U, or I-shaped fastener, one skilled in the art will appreciate that any number of extension members can be used to form fasteners having a variety of shapes and configurations.

[0045] FIGS. **4**A-**4**B illustrate another exemplary embodiment of an implantable tissue fastener wherein the tissue fastener is formed from two separate fastener components. The two-piece tissue fastener **40** can include a first anchor member **42** and a second anchor member **44**. As shown in FIGS. **4**A-**4**B, the first anchor member **42** has a continuous body with a longitudinal axis l extending between proximal and distal ends **42***a*, **42***b*. The proximal end **42***a* can have at least one extension member **43***a* extending at an angle with respect to the longitudinal axis **1** of the first anchor member **42**. The second anchor member **44** can be removably matable to the first anchor member **42** and can include at least one extension member **44***a* extending therefrom. FIGS. **4**A-**4**B illustrate first and second anchor members **42**, **44** having first and second extension members **43***a*, **43***b*, **44***a*, **44***b* extending therefrom. As shown, the first anchor member **42** has at least two extension members **43***a*, **43***b* that extend at an angle with respect to the longitudinal axis l of the first anchor member **42** to form a substantially T-shaped anchor member. The second anchor member **44** can also have at least two extension members **44***a*, **44***b* that extend at an angle with respect to the longitudinal axis l of the first anchor member **42** to form a substantially C-shaped anchor member. The distal end **42***b* of the first anchor member **42** can include a mating element **45** that is formed thereon and is adapted to mate to a complementary mating element **46** disposed on the second anchor member **44**. The mating elements can have a variety of configurations. For example, in an exemplary embodiment, shown in FIGS. **4**A-**4**B, the mating element **45** disposed on the distal end **42***b* of the first anchor member **42** is a blunt tab that is adapted to slidably engage an opening formed in the second anchor member **44**. As shown in FIG. **4**B, the opening is sized and shaped such that blunt tab can achieve a snap fit when received by the second anchor member **44**. Other exemplary embodiments for the mating elements include, but are not limited to, threaded fasteners, twist locks, and interference fits.

[0046] FIGS. **5**A-**5**C illustrate another exemplary embodiment of an implantable tissue fastener wherein the tissue fastener is formed from three separate fastener components. The three-piece tissue fastener **50** can include first, second, and third anchor members **52**, **54**, **56**. The first anchor member **52** can have a continuous body with a longitudinal axis l extending between proximal and distal ends **52***a*, **52***b*. As shown in FIGS. **5**A-**5**C, the first anchor member **52** is an elongate member with mating elements **52***a*', **52***b*' disposed on the proximal and distal ends **52***a*, **52***b*. The second and third anchor members **54**, **56** can be removably matable to the proximal and distal ends **52***a*, **52***b* of the first anchor member **52**, respectively. In one exemplary embodiment, shown in FIGS. **5**A-**5**B, the second and third anchor members **54**, **56** include at least one extension member **54***a*, **54***b*, **56***a*, **56***b* extending at an angle with respect to the longitudinal axis l of the first anchor member **52**. In another embodiment, shown in FIG. **5**C, the extension members **54***a*', **56***a*' are disks that can be mated to the proximal and distal ends **52***a*, **52***b* of the first anchor member **52** so as to form a barbell type fastener when assembled. The second and third extension members **54**, **56** can be mated to the first anchor member **52** using any of the techniques described above with reference to the two-piece fastener **40**.

[0047] In general, the extension members associated with the implantable tissue fasteners **30**, **40**, **50** can have an arcuate shape. When deployed, the arcuate shape can provide a rounded surface for contacting and applying a fastening load to the tissue. The length of the extension member can vary such that the arcuate extension member can be substantially circular (FIG. **5**A) or semi-circular (FIGS. **3**A-**3**E, **4**A-**4**B, and **5**B) in shape. The orientation of the arcuate extension members can also vary. In one exemplary embodiment, shown in FIGS. **3**C, **3**E, **4**A-**4**B, and **5**A-**5**B, the arcuate extension member is oriented such that the terminal ends T of the members curve inward or toward each other. In another exemplary embodiment, shown in FIGS. **3**A-**3**B and **3**D, the arcuate shape is oriented such that the terminal ends T curve outward or away from each other. A variety of configurations are available for the terminal ends of the extension members. For example, in one embodiment, the terminal ends can be blunt or rounded, as it is not necessary for the terminal ends to penetrate tissue. Alternatively, the terminal ends can be sharp or pointed such that they are adapted to penetrate tissue.

[0048] The implantable tissue fastener can be formed from a variety of materials. For example, exemplary fasteners can be formed from materials including, but not limited to, stainless steel, titanium, and superelastic alloys such as a nickel titanium alloy. The fastener can be formed entirely from one material or can be formed from any combination of materials. For example, in an exemplary embodiment, the anchor member can be formed from stainless steel and the proximal and distal extension members can be formed from a superelastic alloy. Such a configuration can allow the fastener to be retained within the hollow needle in a constrained position and revert to its unconstrained shape upon deployment or release from the needle. The materials can also be selected such that the fastener can be used as a marker when deployed in a target tissue.

[0049] The present invention also provides methods of approximating a target region of tissue. The method can include inserting a device for applying an implantable tissue fastener translumenally. The device can be used in conjunction with an endoscope to facilitate viewing of at least a portion of the method for approximating and can be inserted through a working channel of the endoscope or through an accessory channel that is mated to the endoscope. The approximating device can take the form of any of the embodiments described above but can generally include an elongate sheath, a hollow needle that is slidably disposed within the sheath, and at least one selectively deployable tissue fastener. FIGS. **6**A-**6**E illustrate one exemplary embodiment of approximating a target region of tissue. As shown in FIG. **6**A, the approximating device **10** is positioned adjacent the target tissue **62** of an internal organ such as the stomach. Once the device **10** is positioned adjacent the target tissue **62**, the device **10** can be actuated to extend the hollow needle **20** from the elongate sheath **12** and penetrate the targeted tissue **62** as is shown in FIGS. **6**B-**6**C.

[0050] The target tissue can then be reconfigured in a desired orientation. Reconfiguring the targeted tissue can

include engaging and manipulating an inner surface of the targeted tissue to change the shape of the targeted tissue. The reconfigured tissue can take a variety of shapes including, for example, a fold, a bulge, a mound, a plication, a ridge, a tube, a cone, and a horn. FIGS. **6**A-**6**C show the target tissue **62** being reconfigured or manipulated by a separate tissue grasping member **60** or retractor; however, the method need not include such a step. In one exemplary embodiment, the approximating device **10** can include a tissue backstop for manipulating the target tissue. In such an embodiment, once the device is actuated to penetrate the targeted tissue, the device can be actuated to deploy the tissue backstop. The target tissue can then be manipulated by compressing the tissue between a proximal facing surface of the tissue backstop and a distal facing surface of the sheath.

[0051] After manipulating the tissue to reconfigure the tissue in a desired orientation, the device **10** can be actuated to deploy a tissue fastener **64** to the target tissue to penetrate the reconfigured tissue to secure the tissue in the reconfigured orientation. In one embodiment, shown in FIG. **6**D, actuating the device **10** is effective to fully deploy the fastener **64**. For example, fastener **64** can be retained within the hollow needle **20** in a constrained position such that upon deployment or release from the needle the fastener will revert to its unconstrained shape to engage and secure the reconfigured tissue. In another embodiment, actuating the device can be effective to partially deploy the tissue fastener so as to engage the targeted tissue with the tissue fastener in a partially deployed configuration. In this embodiment, the target tissue can be manipulated and reconfigured using the partially deployed fastener. Once the desired orientation is achieved, the device can again be actuated to fully deploy the partially deployed fastener and secure the tissue in the reconfigured orientation.

[0052] The steps of reconfiguring the target tissue and actuating the device to deploy a tissue fastener can be repeated as needed. Once the target tissue is reconfigured and secured as desired, the needle can be retracted within the sheath and the device can be removed from the treatment site. FIG. **6**E shows an exemplary embodiment of a reconfigured target tissue **62** secured by a fastener **64** following the removal of the device **10**. A fastener of the type shown in FIGS. **3**A-**3**E is illustrated in FIGS. **7**A-**7**B which demonstrate the deployment of a one-piece, Z-shaped fastener **70**.

[0053] FIGS. **8**A-**8**C illustrate the deployment of a three-piece barbell type fastener **80**. FIG. **8**A shows the barbell fastener being partially deployed and used to manipulate and reconfigure the target tissue. A variety of techniques can be used to implant a multi-piece fastener. For example, in one exemplary embodiment the first, second, and third anchor members can all be contained within the hollow needle and released individually to engage the target tissue. Such a configuration can allow all or some of the anchor members to be used to manipulate and reconfigure the target tissue. In one embodiment, the first and second anchor members can be deployed and used to reconfigure the tissue. Once the tissue is reconfigured as desired, the third anchor member can be deployed from the hollow needle and can be mated to the first and second anchor members to secure the reconfigured tissue. Although the method is described above as delivering an entire multi-piece fastener via the approximating device **10**, one skilled in the art will appreciate that the hollow needle **20** need not carry each anchor member of a multi-piece fastener, as a separate device can be used to deliver one or more anchor members if desired.

[0054] A person skilled in the art will appreciate that the present invention has application in conventional endoscopic and open surgical instrumentation as well application in robotic-assisted surgery.

[0055] The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[0056] Preferably, the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

[0057] It is preferred that device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam.

[0058] One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A method for approximating tissue, comprising:

inserting to a target site a device for applying an implantable tissue fastener, the device having an elongate sheath, a hollow needle slidably disposed within the sheath, and at least one selectively deployable tissue fastener;

positioning the device adjacent the targeted tissue;

actuating the device to extend the hollow needle from the elongate sheath and penetrate the targeted tissue;

reconfiguring the targeted tissue in a desired orientation; and

actuating the device to deploy the tissue fastener to penetrate the reconfigured tissue to secure the reconfigured tissue in the desired orientation.

2. The method of claim **1**, wherein actuating the device includes partially deploying the tissue fastener so as to engage the targeted tissue with the tissue fastener in a partially deployed configuration.

3. The method of claim 2, wherein reconfiguring the targeted tissue comprises manipulating the engaged tissue with the partially deployed tissue fastener.

4. The method of claim 1, further comprising actuating the device to deploy a tissue backstop disposed on a distal portion of the hollow needle.

5. The method of claim 4, wherein reconfiguring the targeted tissue comprises compressing the engaged tissue between a proximal surface of the tissue backstop and a distal surface of the elongate sheath.

6. The method of claim 2, further comprising actuating the device to fully deploy the tissue fastener.

7. The method of claim 1, further comprising repeating the steps of reconfiguring the targeted tissue and actuating the device to deploy the tissue fastener.

8. The method of claim 1, wherein reconfiguring the targeted tissue comprises engaging and manipulating an inner surface of the targeted tissue to change the shape of the targeted tissue.

9. The method of claim 8, wherein the targeted tissue is reconfigured to be in the shape selected from the group consisting of a fold, a bulge, a mound, a plication, a ridge, a tube, a cone, and a horn.

10. The method of claim 1, wherein reconfiguring and approximating the targeted tissue are performed using only the tissue fastener delivery device.

11. The method of claim 1, wherein inserting the device comprises inserting the device translumenally.

12. The method of claim 1, wherein inserting the device comprises inserting the device laparoscopically.

13. The method of claim 1, further comprising endoscopically viewing at least a portion of the method for approximating.

14. The method of claim 1, wherein the tissue fastener is a one piece fastener.

15. The method of claim 1, wherein the tissue fastener comprises first and second anchor members.

16. The method of claim 1, wherein the tissue fastener comprises first, second, and third anchor members.

17. The method of claim 1, wherein inserting the device for applying an implantable tissue fastener comprises inserting the device through a working channel of an endoscope.

18. The method of claim 1, wherein inserting the device for applying an implantable tissue fastener comprises inserting the device through an accessory channel mated to an endoscope.

19. The method of claim 1, wherein the targeted tissue is an internal organ that is endscopically accessed.

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专利名称(译)	内窥镜组织近似方法		
公开(公告)号	US20080228199A1	公开(公告)日	2008-09-18
申请号	US11/687477	申请日	2007-03-16
[标]申请(专利权)人(译)	伊西康内外科公司		
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IPC分类号	A61B17/128		
CPC分类号	A61B17/0643 A61B17/0644 A61B17/068 A61B2017/0647 A61B2017/00349 A61B2017/00827 A61B17/1285 A61B2017/0645		
优先权	11/687484 2007-03-16 US		
外部链接	Espacenet USPTO		

摘要(译)

本发明一般地提供用于近似组织的方法和装置。该方法和装置利用用于施加可植入组织紧固件和各种可植入组织紧固件的装置。组织紧固装置可以内窥镜输送并且可以适于沿着侧面或与柔性内窥镜结合起作用。通常，该装置可包括柔性轴，该柔性轴具有设置在其远端的可植入组织紧固件施加器和用于操作设置在其近端的可植入组织紧固件施加器的手柄。各种可植入组织紧固件可与组织紧固件施加器装置一起使用，包括单锚和多锚实施例。