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(54) **TISSUE PENETRATION AND GRASPING APPARATUS**

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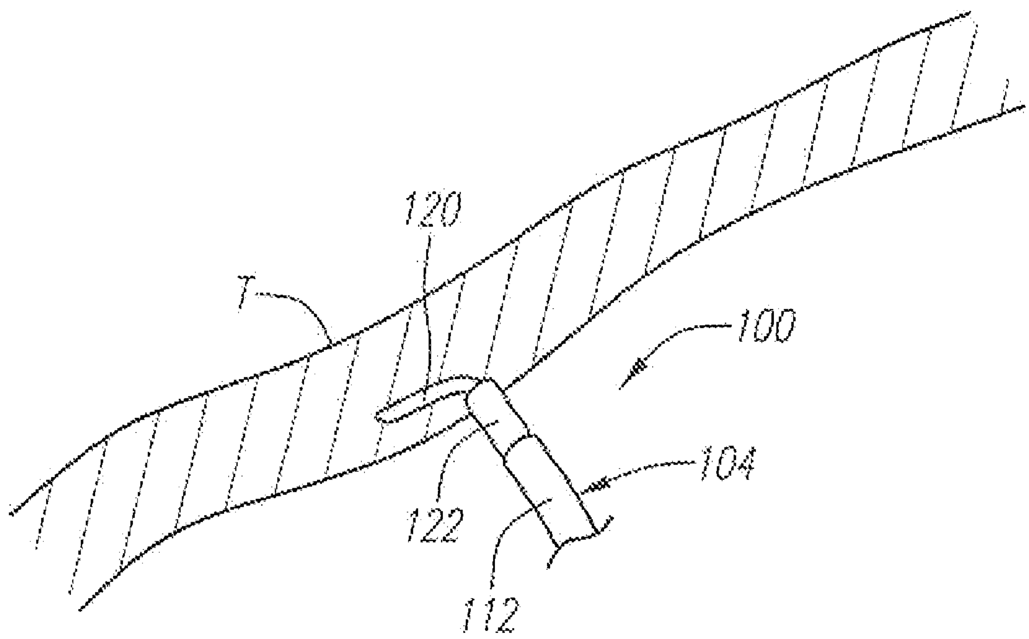
(57) **ABSTRACT**

A tissue grasping apparatus includes a control member, an elongated shaft, and a tissue penetrating and grasping member attached to the distal end of the elongated shaft. An activation mechanism provides an user-operable connection between the control member and the tissue penetrating and grasping member. In an embodiment, the tissue penetrating and grasping member includes a rigid penetrating member that is rotatably attached to the distal end of the elongated shaft. In an embodiment, the activation mechanism includes a flexible drive wire attached to the penetrating member.



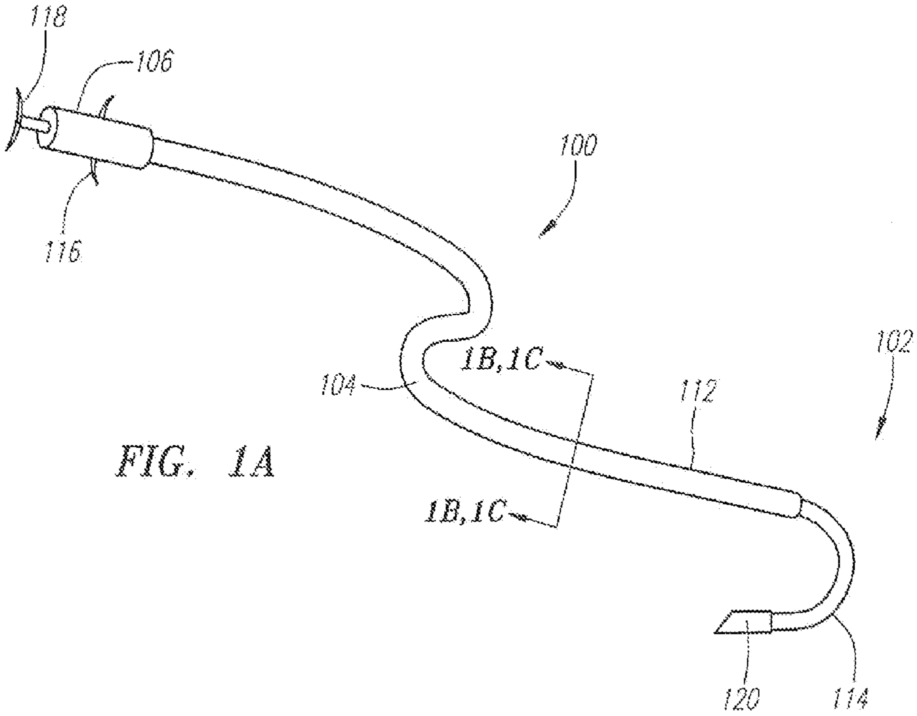


FIG. 1A

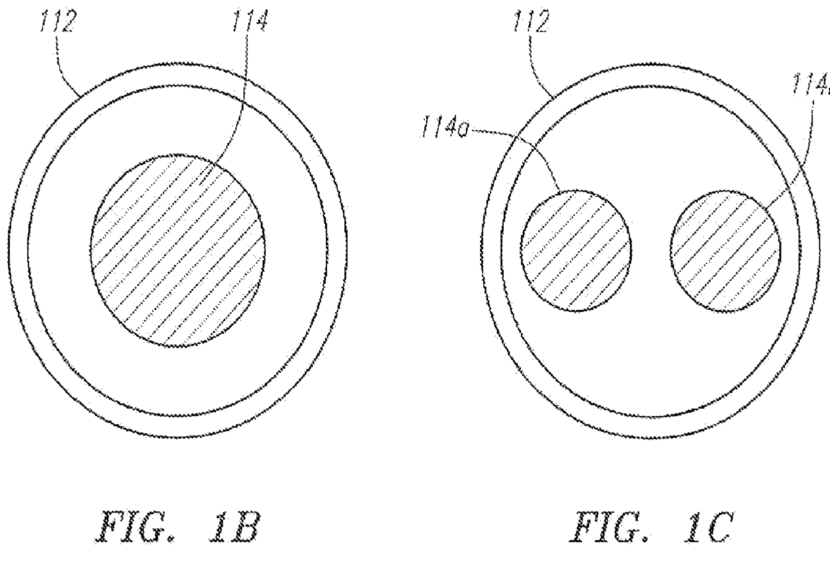


FIG. 1B

FIG. 1C

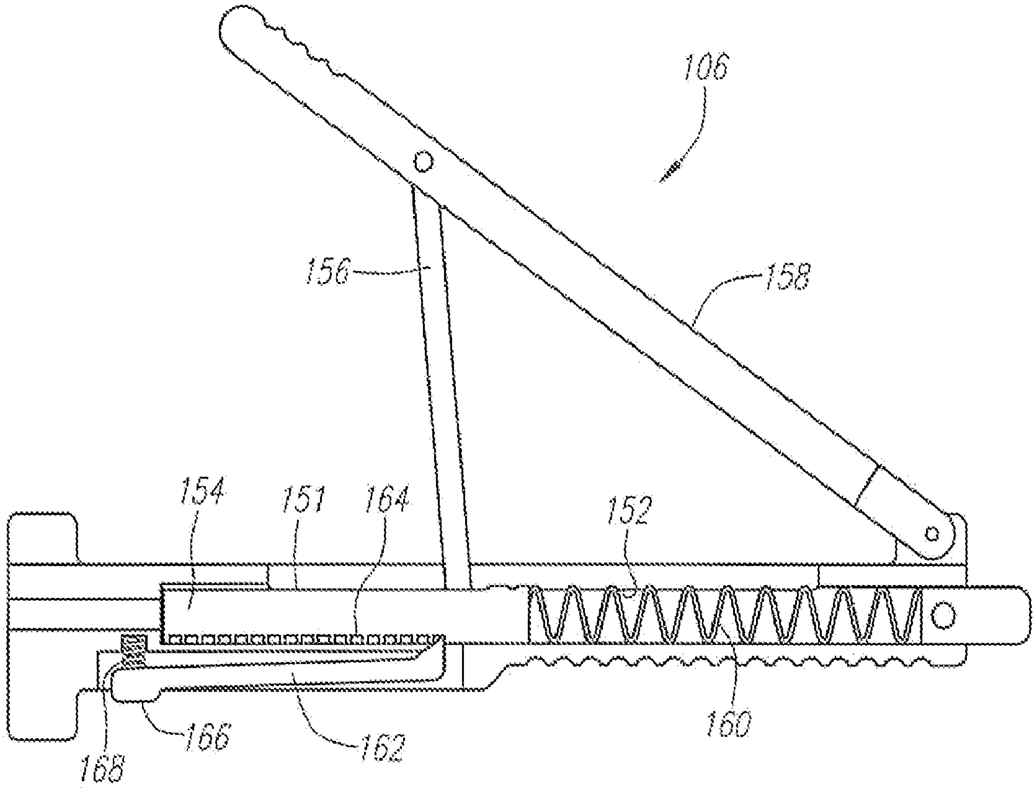


FIG. 1D

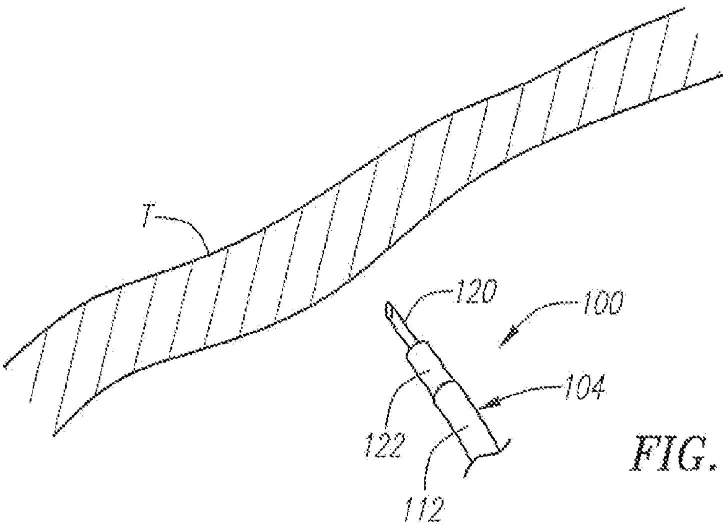


FIG. 2A

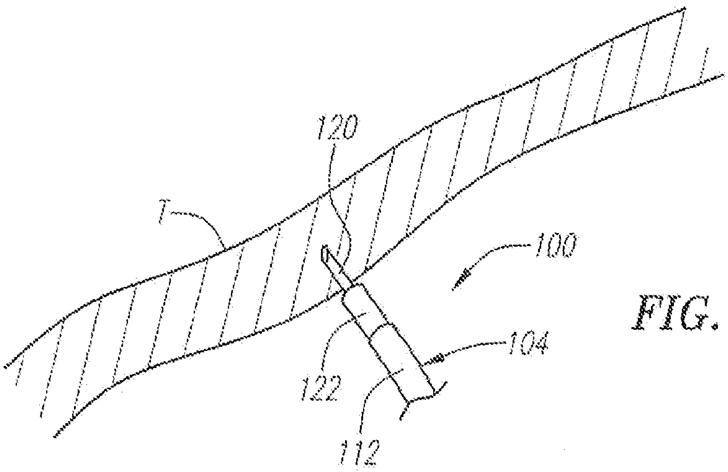


FIG. 2B

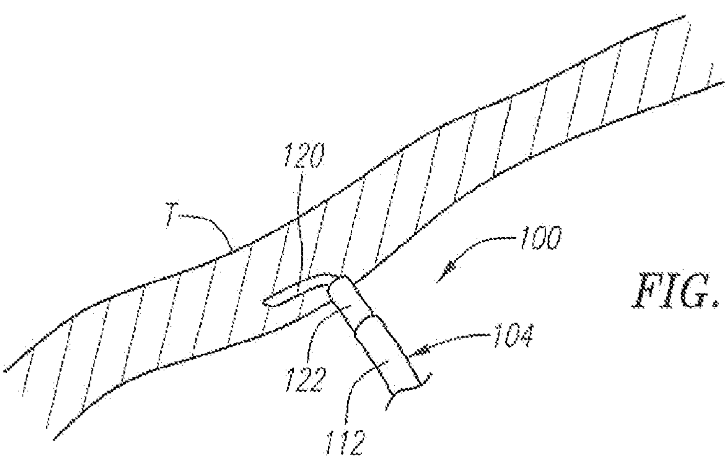


FIG. 2C

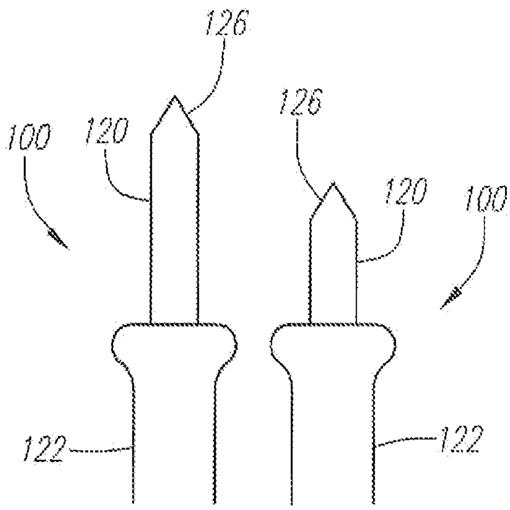


FIG. 3A

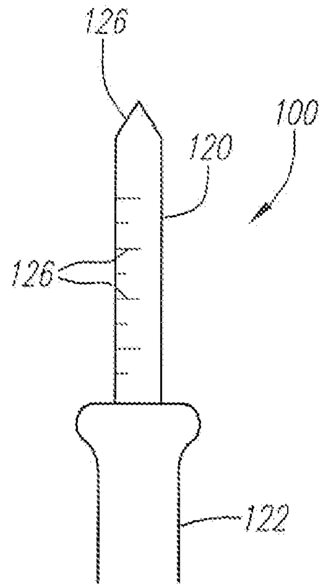


FIG. 3B

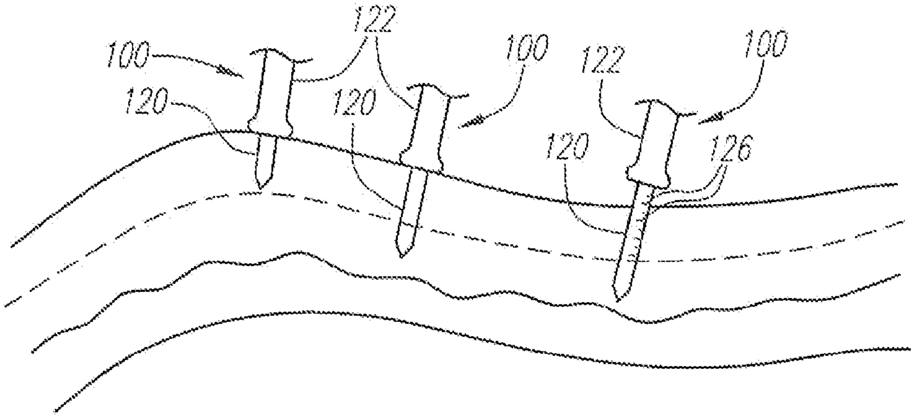


FIG. 3C

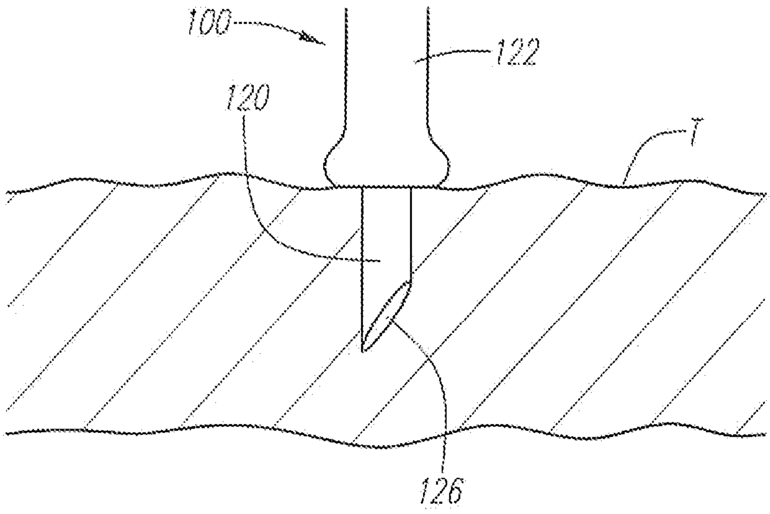


FIG. 4A

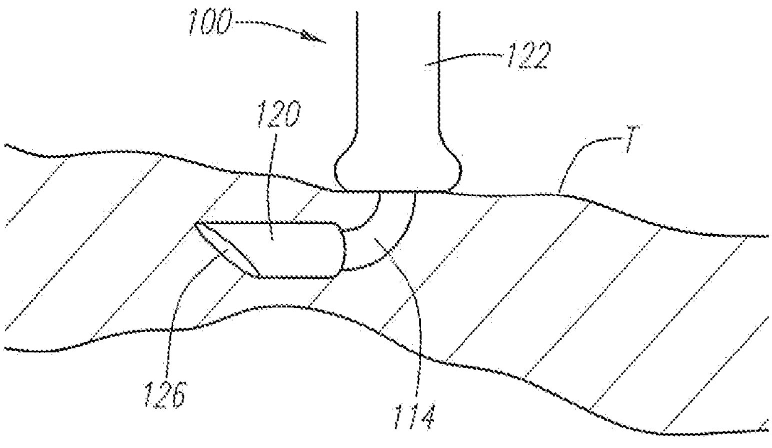


FIG. 4B

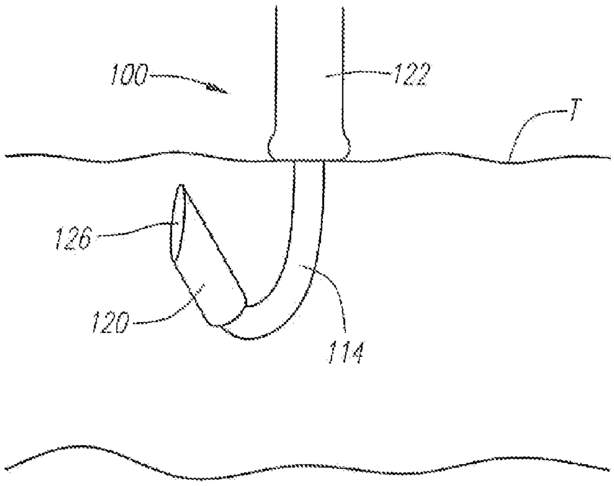


FIG. 5A

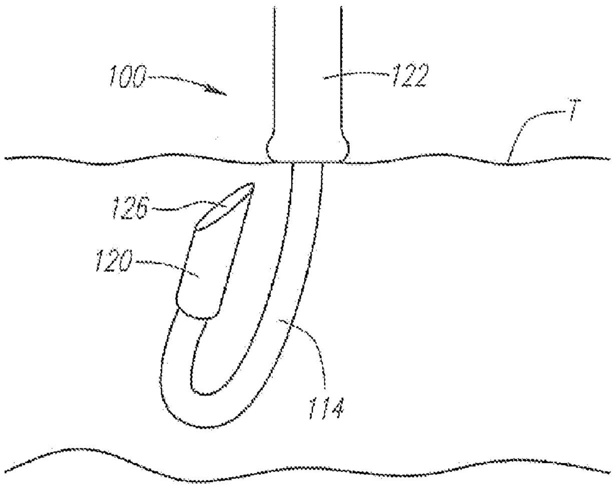


FIG. 5B

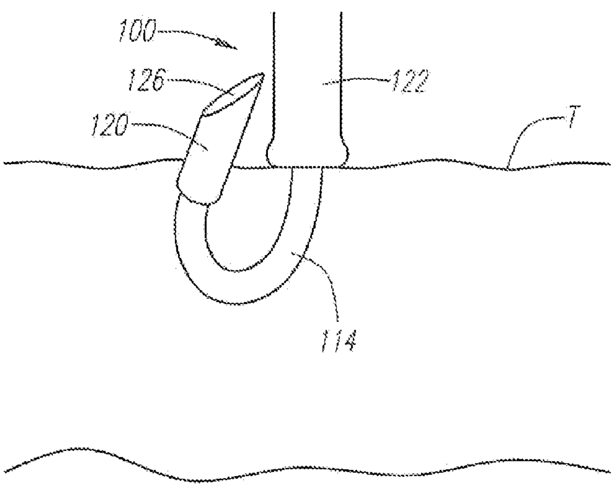


FIG. 5C

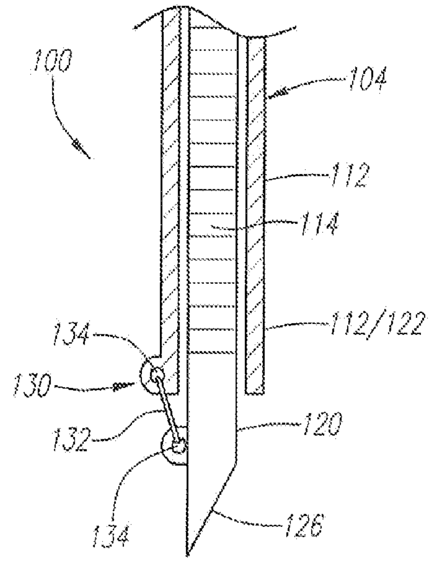


FIG. 6A

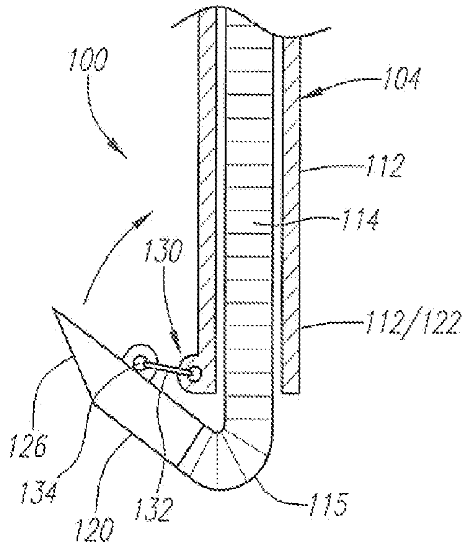


FIG. 6B

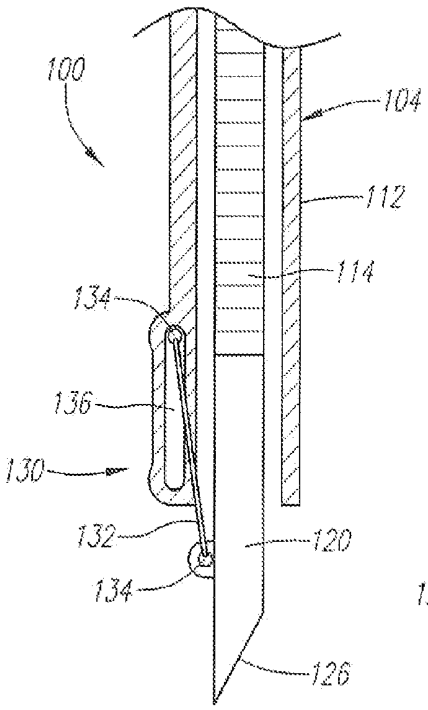


FIG. 7A

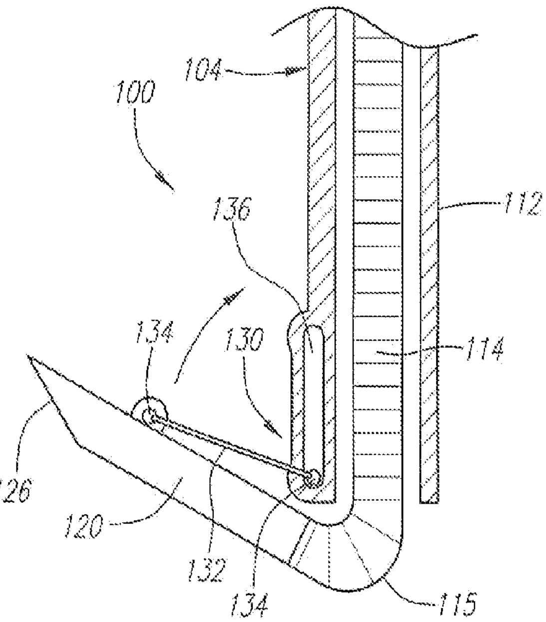


FIG. 7B

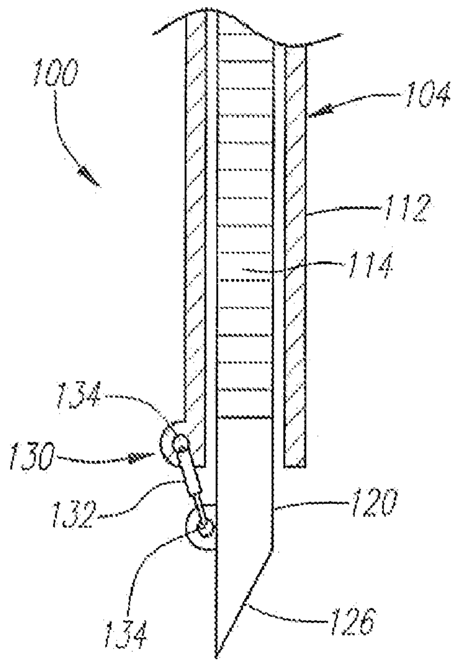
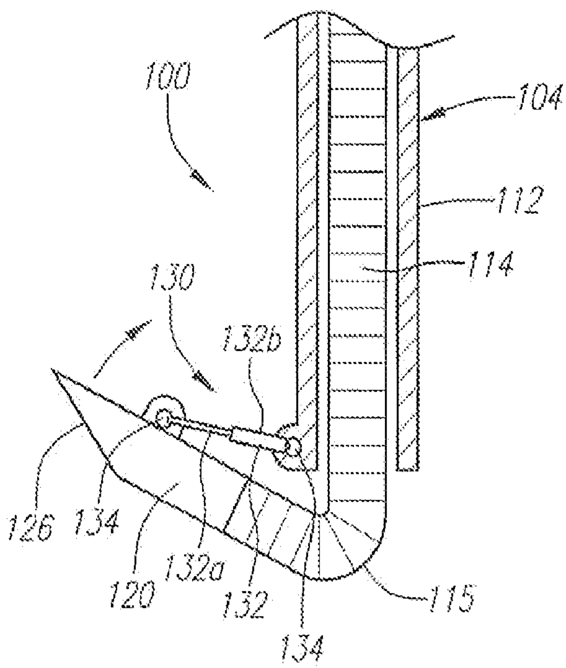

100
104
112
114
134
130
132
120
134
126

FIG. 8A


100
104
112
114
130
132b
126
134
120
132a
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115

FIG. 8B

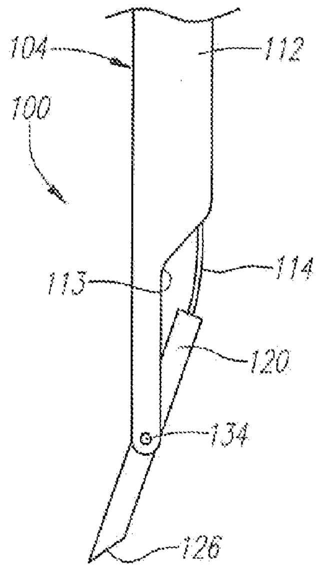


FIG. 9A

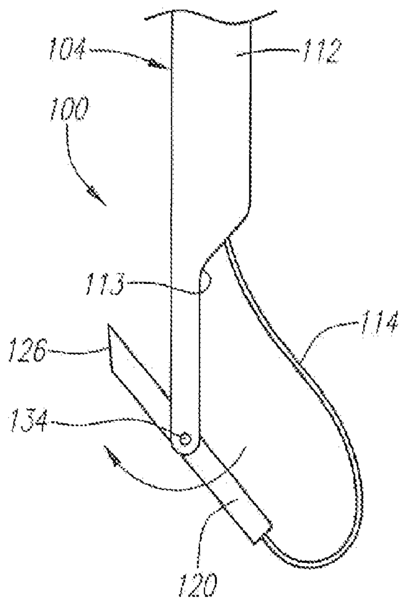


FIG. 9B

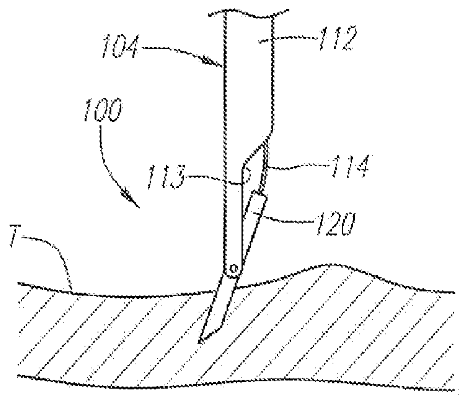


FIG. 9C

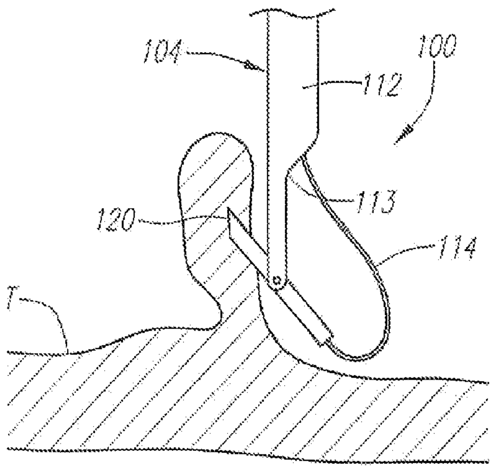


FIG. 9D

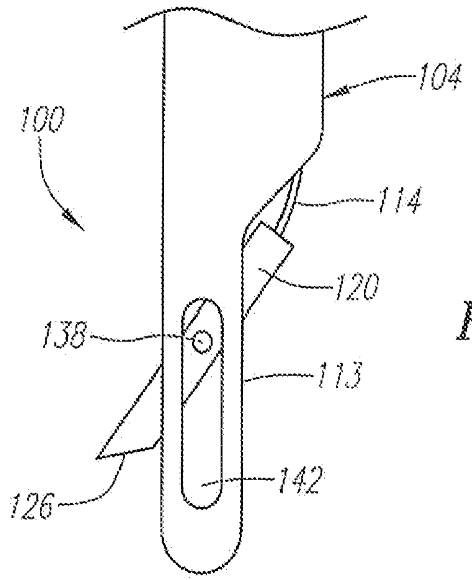


FIG. 10A

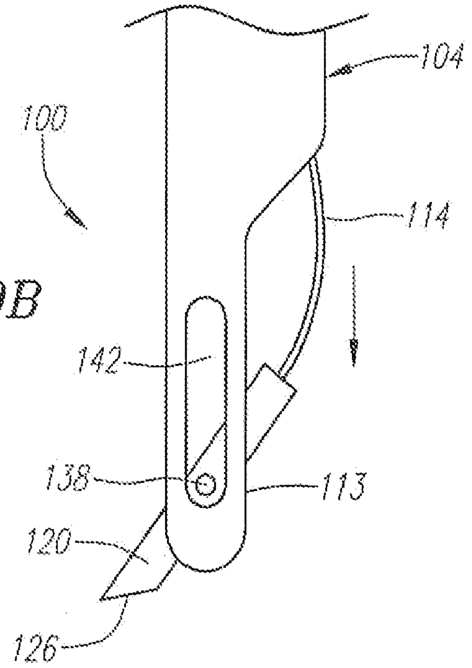


FIG. 10B

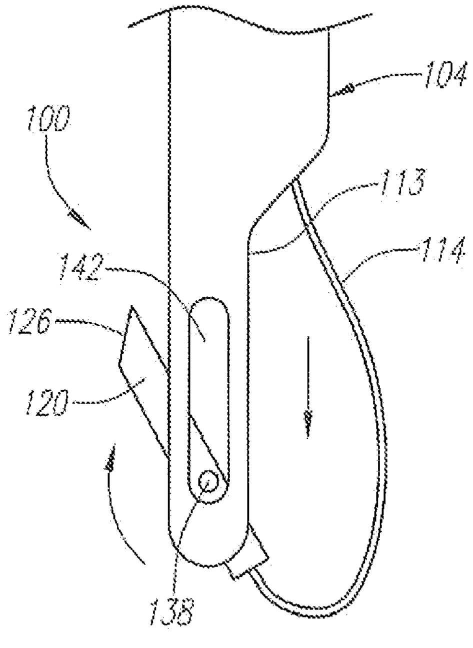
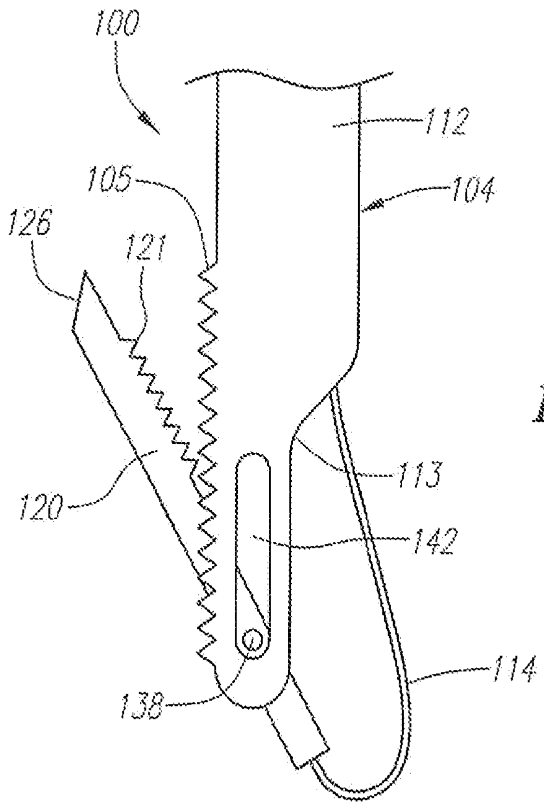


FIG. 10C


100
112
105
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121
113
120
142
114
138

FIG. 11

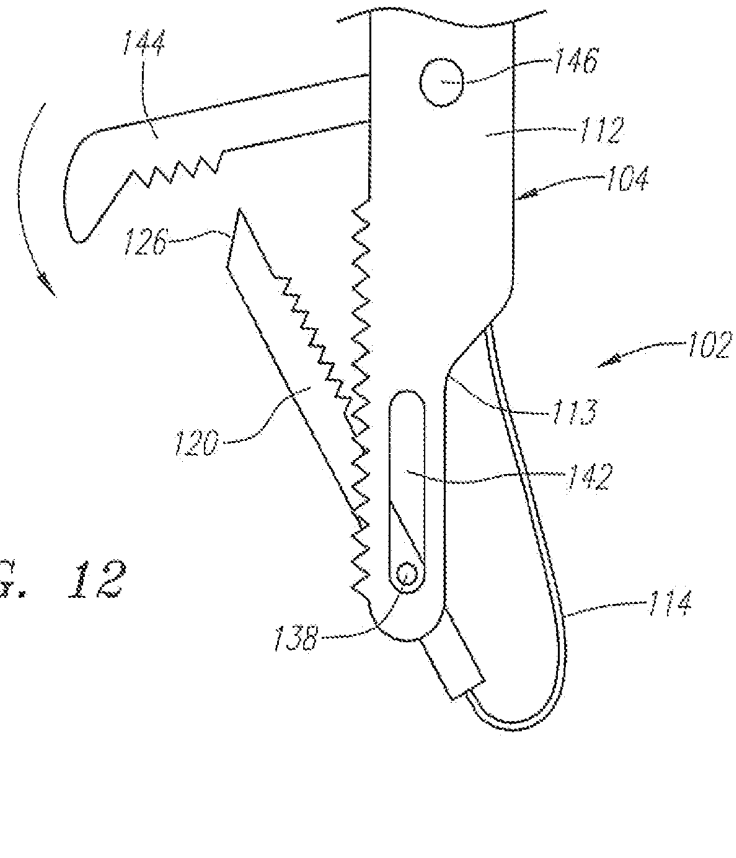
144
146
112
104
126
102
113
120
142
114
138

FIG. 12

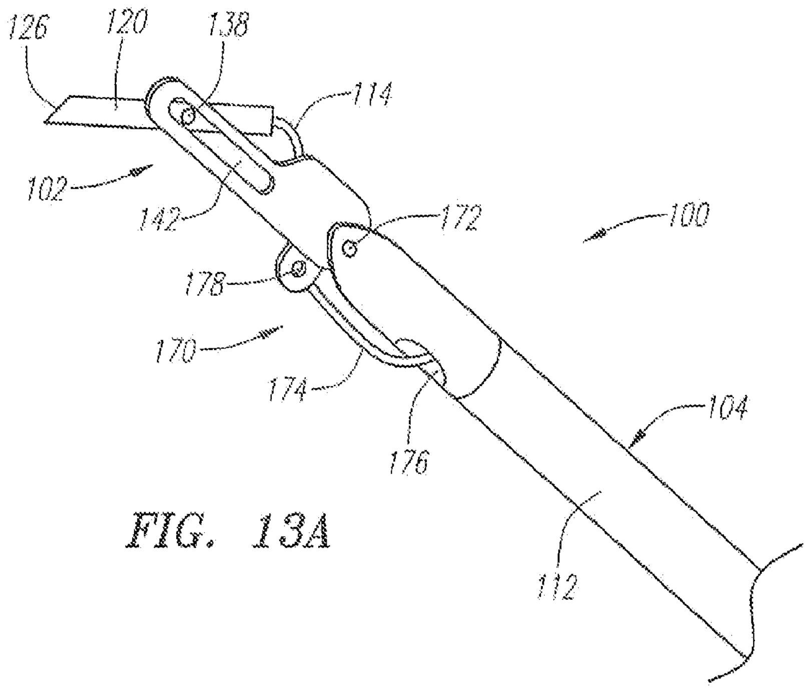

FIG. 13A

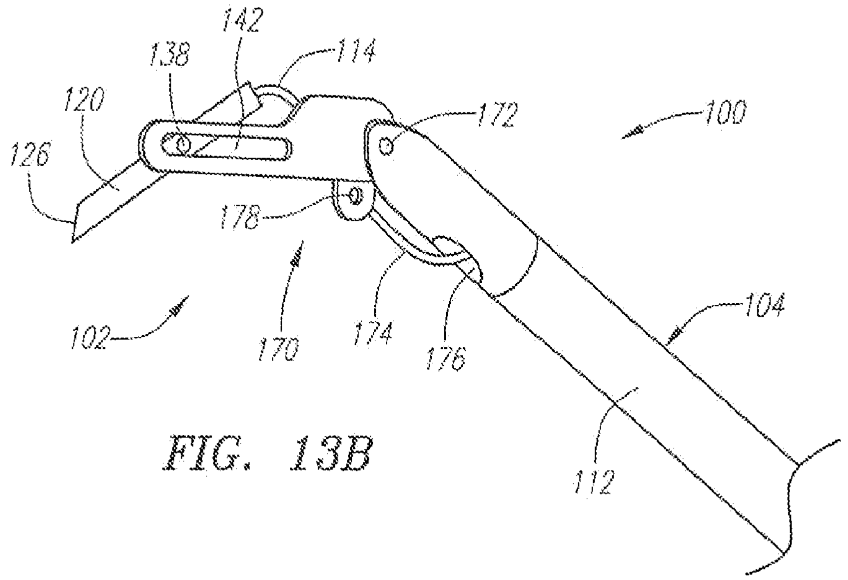

FIG. 13B

TISSUE PENETRATION AND GRASPING APPARATUS

RELATED APPLICATION DATA

[0001] None.

FIELD OF THE INVENTION

[0002] The present invention relates to surgical instruments used to engage, penetrate, grasp, or manipulate tissue, and methods of their use.

BACKGROUND OF THE INVENTION

[0003] Tissue engaging, grasping, and manipulating instruments are used during open surgery, laparoscopic surgery, endoscopic surgery, or translumenal surgery. A common type of instrument available for endolumenal acquisition of stomach tissue is an endoscopic grasper. A typical endoscopic grasper includes a pair of hinged jaws located at the distal end of a flexible shaft. The jaws are actuated between open and closed positions. Typically, the jaws are actuated using a push/pull rod or wire that extends through the flexible shaft to connect to the jaws via a mechanical linkage. When the jaws are opened, they assume a wide "V" shape. The jaws are then brought into contact with tissue, after which the jaws are actuated to the closed position. Closing the jaws causes the jaws to catch on, pinch, or entrap the tissue.

[0004] Conventional hinged jaw-type endoscopic graspers like those described above have several limitations. For example, the mechanical linkages used to actuate the jaws in typical endoscopic graspers are unable to drive the jaws open to or beyond an included angle (the angle formed between the jaws) of 180 degrees. This limitation reduces the effectiveness of these graspers in circumstances in which a wider throw (having an included angle equal to or greater than 180 degrees) is desirable. In addition, the mechanical linkages must be configured such that they do not reach a point of linear alignment during actuation to the closed position, otherwise the closure force will drop to zero and the jaws will be inoperable.

[0005] Another common type of endoscopic grasper includes two or more spring biased jaws that are actuated using an external sleeve. The jaws comprise flats of spring steel that have opposing curved or angled surfaces that have a spring bias toward the open position relative to one another. The external sleeve is slidable over the jaws. As the external sleeve is translated distally toward the ends of the spring biased jaws, the external sleeve causes the jaws to move toward one another to the closed position.

[0006] The foregoing spring jaw-type of endoscopic grasper also has limitations. For example, the jaws of these types of graspers open passively, i.e., they open only due to and are only as strong as the inherent spring force between the jaws. They are, therefore, not well suited to open fully in constrained spaces where surrounding tissue could retard the spring open force. Also, the closure requires a relative motion that makes targeting of a selected portion of tissue (or other target) difficult due to the relative movement (e.g., retraction) of the jaws into the external sleeve. Further still, the closure force of the jaws reaches its peak as the jaws are being retracted fully into the external sleeve, at which point the jaws are unable to grasp tissue.

[0007] Yet another type of endoscopic grasper includes a tissue piercing coil member attached to the distal end of a flexible shaft. The coil member has a sharp tip and an open pitch that allows the coil member to penetrate tissue when it is rotated against the tissue with a light amount of distal force. Once tissue is penetrated, the grasper allows the user to manipulate the tissue by advancing or retracting the grasper.

[0008] The coil-type grasper has limitations in that it only grasps a single point of tissue, and cannot easily grasp or bring together multiple contact points or grasp a relatively large area of tissue. The coil-type grasper also achieves its grasp by a "blind" penetration of tissue by the coil.

SUMMARY

[0009] In one general aspect, a medical instrument according to the present invention includes a tissue engaging, penetrating, grasping, and manipulating member configured for introduction into a patient. The medical instrument is adapted for use during open surgery, laparoscopic surgery, endoscopic surgery, or translumenal surgery. In several preferred embodiments, the medical instrument has a small profile such that the tissue grasping member is able to pass through a small diameter lumen to be routed to a site within a patient's body. In several other preferred embodiments, the medical instrument has an elongated, flexible shaft that allows the instrument to be passed through tortuous anatomy, either as a standalone instrument or as an instrument to be passed through a lumen of an overtube. The tissue grasping member is used to engage, penetrate, grasp, acquire, position, or otherwise manipulate tissue within a patient. The medical instrument is suitable for use as a standalone instrument, or it may be used in combination with other instruments that provide independent or related functions.

[0010] In several embodiments, the medical instrument includes a tissue penetrating member rotatably attached to the distal end of an elongated, flexible shaft. An activation mechanism is operatively coupled to the tissue penetrating member, and is also responsive to a control member, such as a handle. The user is able to manipulate the handle to operate the tissue penetrating member.

[0011] In an embodiment, the tissue penetrating member comprises a rigid needle. The needle includes a body member and a sharp, penetrating tip portion. In several embodiments, the tip portion includes a conical shape, a pyramidal shape, or a faceted, beveled needle tip formed of stainless steel having a caliber of 18 gauge or smaller. The tissue penetrating member is attached either directly or indirectly to a distal portion of the elongated, flexible shaft such that the tissue penetrating member is able to rotate through an engagement angle relative to the longitudinal axis of the shaft. In an embodiment, the tissue penetrating member is configured to slide longitudinally within a slot formed at or near the distal end of the shaft.

[0012] In a second general aspect, a method for engaging, penetrating, grasping, and/or manipulating tissue includes the steps of providing a medical instrument having a tissue penetrating member at a location adjacent to a tissue site, moving the medical instrument to cause the tissue penetrating member to penetrate the tissue, rotating the tissue penetrating member through an engagement angle, and manipulating the medical instrument in order to push, pull, or otherwise move the tissue from its natural position. In several embodiments, the method is performed using a medical instrument that is placed near the tissue site either endoscopically, laparoscopically, or during open surgery. In an embodiment, the medical instrument is advanced to a tissue site via a natural body orifice.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. **1**A is a perspective view of a medical instrument having a tissue penetrating and grasping member in accordance with the present invention.

[0014] FIGS. **1**B and **1**C are cross-sectional views of two embodiments of a shaft in accordance with the medical instrument shown in FIG. **1**A.

[0015] FIG. **1**D is a cross-sectional view of a handle suitable for use with the medical instrument shown in FIG. **1**A.

[0016] FIGS. **2**A-C are side views of an embodiment of a medical instrument having a tissue penetrating and grasping member.

[0017] FIGS. **3**A-C are side views of additional embodiments of medical instruments having a tissue penetrating and grasping member.

[0018] FIGS. **4**A-B are side views of another embodiment of a medical instrument having a tissue penetrating and grasping member.

[0019] FIGS. **5**A-C are side views of additional embodiments of medical instruments having a tissue penetrating and grasping member.

[0020] FIGS. **6**A-B are side views of another embodiment of a medical instrument having a tissue penetrating and grasping member.

[0021] FIGS. **7**A-B are side views of another embodiment of a medical instrument having a tissue penetrating and grasping member.

[0022] FIGS. **8**A-B are side views of another embodiment of a medical instrument having a tissue penetrating and grasping member.

[0023] FIGS. **9**A-D are side views of another embodiment of a medical instrument having a tissue penetrating and grasping member.

[0024] FIGS. **10**A-C are side views of another embodiment of a medical instrument having a tissue penetrating and grasping member.

[0025] FIGS. **11** and **12** are side views of additional embodiments of medical instruments having a tissue penetrating and grasping member.

[0026] FIGS. **13**A-B are side views of another embodiment of a medical instrument having a tissue penetrating and grasping member.

DETAILED DESCRIPTION

[0027] The devices described herein include several embodiments of medical instruments that are adapted to engage, penetrate, grasp, and/or manipulate tissue. The medical instruments are adapted for use with soft tissue found in human or animals, or with other tissue such as cartilage, muscle, soft areas of bone, or others. In several embodiments, the medical instrument includes a penetrator adapted to penetrate tissue. After penetrating tissue to a desired depth, the penetrator is moved in a direction away from the direction of penetration through the tissue, such as through an arcuate or curvilinear path. The arcuate or curvilinear movement causes the penetrator to engage and/or grasp the tissue such that the tissue is able to be manipulated by the medical instrument under control of the user. After the desired manipulation is completed, the penetrator is returned to its original position so as to release the tissue.

[0028] In several embodiments, the medical instruments are configured to be able to pass through a relatively small diameter lumen such as the surgical tool lumens provided during laparoscopic, endoscopic, or translumenal surgery. In other embodiments, the instrument is configured for use during conventional open surgery, or other procedures in which the size restraints required during laparoscopic, endoscopic, or translumenal surgery are not present.

[0029] Referring to FIG. **1**A, a first embodiment of a medical instrument **100** for engaging, penetrating, grasping, and/or manipulating tissue is shown. The medical instrument shown in FIG. **1**A includes an end effector **102** attached to the distal end of a shaft **104**. In the embodiment shown in FIG. **1**A, the end effector **102** includes a tissue penetrating member and a deployment mechanism, each of which is described more fully herein. A control member, such as a handle **106**, is provided at the proximal end of the instrument, preferably coupled to the proximal end of the shaft **104**. The control member serves as an interface for the user to manipulate or control the action of the tissue grasping member **102**.

[0030] In an embodiment, the shaft **104** is an elongated, flexible member having an external sleeve **112** and an internal pusher **114**. (See FIGS. **1**B and **1**C). The sleeve **112** and pusher **114** are capable of longitudinal motion relative to one another. For example, in an embodiment, the sleeve **112** is cylindrical, defining an internal lumen in which the pusher **114** is located. The pusher is longitudinally translatable within the external sleeve, preferably slidably, thereby providing the capability for the external sleeve **112** and pusher **114** to move longitudinally relative to one another.

[0031] The external sleeve **112** is adapted to provide a flexible, operable interconnection between the handle **106** and the end effector **102**. In an embodiment, the external sleeve **112** is formed of materials having sufficient strength and other materials properties to support transmission of torque forces between the handle **106** and the end effector **102**. For example, the external sleeve **112** is capable of causing the end effector **102** to rotate around the longitudinal axis of the shaft **104** in response to a rotation of the handle **106**. In an embodiment, the external sleeve **112** also supports relative sliding movement of the pusher **114** within the sleeve with very little friction and without a large amount of longitudinal stretch or contraction of the shaft **104**. In an embodiment, the external sleeve **112** is constructed of a single material. In another embodiment, the external sleeve **112** has a composite construction that includes two or more of a main body material to provide structure and flexibility, a reinforcing material to provide torque transmission capability and/or to reduce or eliminate stretch and contraction, and a liner material to reduce friction and/or to reduce or eliminate stretch and contraction. Examples of materials that are suitable for forming the main body portion of the external sleeve include polymeric materials, such as polyester amide block copolymer (PEBAX™), nylon, polyurethane, or other similar materials commonly used for medical instrument applications. Examples of suitable reinforcing materials include polymeric or metallic braid materials and/or reinforcing wires. Examples of suitable liner materials include polytetrafluoroethylene (PTFE), polyetheretherketone (PEEK), or other suitable materials.

[0032] The pusher **114** is adapted to transfer a longitudinally-directed force applied by the user from the handle **106** to the tissue grasping member **102**. In the embodiment shown in FIG. **1**B, the pusher **114** is formed of a single solid wire, coiled wire, or similarly-shaped member that extends through the length of the lumen formed by the external sleeve **112**. As described above, the pusher **114** and external sleeve **112** are adapted to move longitudinally relative to one another. In an embodiment, the pusher **114** is a wire formed of stainless steel, nickel titanium alloy (Nitinol), or other material commonly used for medical instrument applications. In other embodiments, the pusher **114** is formed of non-continuous segments aligned end-to-end and joined together to provide the desired longitudinal translation force. In still other embodiments, such as that shown in FIG. **1**C, the pusher **114** comprises two or more continuous or non-continuous wires, rods, or similarly-shaped members **114***a*, **114***b*. In some embodiments, the two or more members are arranged coaxially within the sleeve **112**, while in other embodiments the two or more members **114***a*, **114***b* are aligned alongside one another, as shown in FIG. **1**C.

[0033] The handle **106** is configured to provide relative movement between the external sleeve **112** and the pusher **114** associated with the shaft **104**. Several common types of medical instrument handles are suitable for this purpose. In FIG. **1**A, the medical instrument **100** is illustrated with a syringe-type handle **106** having a main body **107** connected at its distal end to the proximal end of the external sleeve **112**, and a pair of finger tabs **116** extending from opposite sides of the main body **107**. A thumb tab **118** is attached to the pusher **114** and extends out of the proximal end of the handle main body **107**. The syringe-type handle **106** is a common handle used in medical instruments that require relative movement between a pair of shafts or a sleeve and pusher, such as the present device. Other handle types are suitable for use as well, as will be recognized by a person having skill in the art. For example, in other embodiments, the handle includes either a pistol grip, a grip having tabs and a thumb plunger, or other structures. In still other embodiments, the handle includes a spring providing a biasing force between the sleeve **112** and the pusher **114**, the spring causing the tissue grasping member **102** to be biased to an open or closed position. In still other embodiments, the handle **106** includes an indexing mechanism used to activate the end effector **102** to one or more predetermined positions. In still other embodiments, the handle **106** includes a locking mechanism to selectively lock the end effector **102** in a selected position.

[0034] Turning to FIG. **1**D, another embodiment of a handle **106** is illustrated. The handle **106** includes an elongated main body **150** having a central channel **152** in which a pusher block **154** is slidably received. A link arm **156** extends through a slot **151** formed on the upper surface of the main body in communication with the central channel **152**, and is pivotably attached at one end to the upper surface of the pusher block **154**, and pivotably attached at its other end to an actuation arm **158**. The actuation arm **158** is pivotably attached to the upper surface of the main body **150** near its distal end. A spring **160** is located within the central channel **152** near its distal end, and provides a spring force biasing the pusher block **154** proximally within the channel.

[0035] The main body **150** of the handle **106** is attached or otherwise connected to the external sleeve **112** of the shaft **104**. The pusher block **154** is attached or otherwise connected to the pusher **114**. Accordingly, as the pusher block **154** is advanced (distally) or withdrawn (proximally) within the central channel **152**, the pusher **114** is advanced or withdrawn relative to the external sleeve **112**. In the embodiment shown, a user applied downward force applied to the actuation arm **158** causes the pusher block **154** to advance (distally) against the force of the spring **160**, thereby advancing the pusher **114** within the sleeve **112**. When the user applied force on the actuation arm **158** is released, the spring **160** causes the pusher block **154** to withdraw, thereby withdrawing the pusher **114** relative to the sleeve **112**. As explained herein, this motion creates the actuation forces controlling the operation of the tissue grasping member **102**.

[0036] In the embodiment shown in FIG. **1**D, a ratchet mechanism is provided on the handle **106** to selectively and releasably restrict the pusher block **154** to move in only a single direction within the main body **152**. The ratchet mechanism includes a pawl **162** that is pivotably connected to the bottom surface of the main body **150** of the handle **106**, and is adapted to selectively engage one of a plurality of slots **164** formed on the underside of the pusher block **154**. A pawl spring **168** is located between the pawl **162** and the handle main body **152** and provides a force biasing the pawl **162** into engagement with the pusher block **154**. When the pawl **162** is engaged with one of the slots **164**, the pusher block **154** is unable to move proximally in the central channel **152**. The user is able to disengage the pawl **162**, thereby releasing the pusher block **154**, by applying a force on the release end **166** of the pawl, which is exposed on the underside of the handle main body. The ratchet mechanism may be reversed—i.e., to restrict distal movement of the pusher block **154** by reversing the relative engagement of the pawl **162** with the slots **164** shown in FIG. **1**D, as will be recognized by a person skilled in the art. The ratchet mechanism may be used to maintain a releasable opening or closing force on the tissue grasping member **102**, as desired.

[0037] Turning to FIGS. **2**A-C, an embodiment of an end effector **102** is shown. The end effector **102** is shown located at the distal end of the shaft **104**, and includes a penetrator **120** at the distal end of the pusher **114** and a stop member **122** at the distal end of the sleeve **112**. In the embodiment shown, the penetrator **120** is formed integrally with the pusher **114**, although in other embodiments the penetrator is formed as a separate component that is connected or otherwise attached to the distal end of the pusher **114**. The penetrator **120** includes a sharpened distal tip to facilitate penetration into tissue T. The penetrator **120** is preferably formed of a material having sufficient strength to penetrate tissue, such as a metal or polymer. Examples of suitable materials include stainless steel and nickel titanium alloy (Nitinol). In the embodiment shown, the stop member **122** is formed integrally with the sleeve **112**, although in other embodiments the stop member **122** is formed as a separate component that is connected or otherwise attached to the distal end of the sleeve **112**. The stop member **122** has a transverse dimension (e.g., diameter) that is larger than the transverse dimension of the penetrator **120** and is preferably provided with a blunt distal edge adapted to engage tissue without penetrating the tissue. In some embodiments, the stop member **122** is formed of a single material, such as the polymeric or metallic materials described herein. In other embodiments, the stop member **122** is a composite construction.

[0038] In an embodiment, the penetrator **120** is of a fixed length and position relative to the stop member **122**. In another embodiment, the penetrator **120** is movable longitudinally under a force applied by the pusher **114** from a position in which it is enclosed by the stop member to a position in which it extends a distance distally of the stop member **122**.

[0039] To operate the medical instrument **100**, the end effector **102** is advanced until it is adjacent to a tissue site, as shown in FIG. **2**A. If the end effector **102** includes a penetrator **120** that is capable of being moved inside and outside the sleeve **112**, then the penetrator **120** is advanced distally to be exposed from within the sleeve **112** and the stop member **122**. The medical instrument **100** is then advanced distally until the penetrator **120** penetrates the tissue T to a desired depth, as shown in FIG. **2**B. The penetrator **120** is then activated to change direction relative to its initial penetration direction, as shown in FIG. **2**C. This movement places the penetrator **120** at an angle relative to the tissue surface, effectively engaging, grasping, and/or trapping the tissue located above the penetrator **120**. As a result, the medical instrument **100** can then be manipulated to push, pull, or torque the engaged tissue. By transforming the penetrator back to its initial position (as shown, for example, in FIG. **2**B) or relatively similar to its initial position, the penetrator **120** is configured to be withdrawn from the tissue T.

[0040] In some embodiments, the penetrator **120** has a fixed length. Accordingly, the user is able to select a medical instrument having a penetrator **120** with a length that is suitable for the clinical environment. A pair of medical instruments **100**, each having a penetrator **120** of different length, are shown in FIG. **3**A. In the embodiments shown, the penetrator **120** is of a desired length and the stop member **122** has a size and shape that prevents the stop member **122** from penetrating tissue. In this manner, the user is able to advance the instrument into the target tissue until the stop member **122** butts up against the tissue T, at which point the penetrator **120** will have reached its desired depth. In the embodiment shown in FIG. **3**B, the penetrator **120** is provided with depth markings **124** that allow the user to visually determine the depth of penetration of the penetrator **120**. The medical instruments **100** illustrated in FIGS. **3**A and **3**B are shown engaged in tissue T in FIG. **3**C.

[0041] The penetrator **120** is constructed to penetrate tissue. In several embodiments, the penetrator **120** comprises a rod having a tissue penetrating tip, a wire having a tissue penetrating tip, or a ribbon having a tissue penetrating tip. In several embodiments, the penetrating tip **126** comprises a conical, pyramidic, beveled, or faceted needle or obturator type tip. In other embodiments, the penetrating tip **126** is blunt and is operably connected to an electrosurgical cutting current or an ultrasonic vibrator. In an embodiment, shown in FIGS. **4**A-B, the penetrating tip **126** comprises a faceted, beveled needle tip formed of stainless steel having a caliber of 18 gauge or smaller. The bevel direction is such that it angles away from the inside curve of the direction that the penetrator **120** takes during engagement. (See FIG. **4**B). This positions the bevel angle away from the direction the penetrator **120** would be pulled to manipulate tissue, thereby reducing the tendency for the tissue to initiate slipping because the holding tissue is faced with a straight surface. This direction for the bevel also facilitates return of the penetrator **120** to the straight axial position, shown in FIG. **4**A.

[0042] After tissue penetration, the penetrator **120** advances through tissue at an engagement angle and engagement direction determined by the materials and construction of the end effector **102**. In several embodiments, the engagement angle and engagement direction are constructed to provide a desired amount and type of holding strength on the tissue. In an embodiment, the engagement angle is at least 90 degrees, as shown in FIG. **5**A. In another embodiment, the penetrator takes an engagement angle of approximately 180 degrees such that the penetrator retroflexes to lie in a plane that is parallel to the plane of the longitudinal axis of the shaft **104** of the medical instrument, as shown in FIG. **5**B. In yet another embodiment, the penetrator **120** passes through an engagement angle of about 180 degrees or more and re-emerges through the top surface of the tissue T, as shown in FIG. **5**C. Preferably, the penetrator **120** forms an engagement angle sufficient to form a relatively closed loop between the penetrator **120** and the end effector **102** to provide sufficient strength for the medical instrument to manipulate tissue.

[0043] The prior art "hook"-type tissue graspers are typically formed of shape memory wire (e.g., Nitinol) that is shape set in the form of a hook. A limitation of these types of devices is the need for optimization of the "hook" portion of the device. The hook must be flexible enough to be retractable within the shaft of the device, but strong enough to hold tissue once extended. In addition, there is a limitation on the column strength of the exposed penetrator because it would be configured from the flexible shape memory material.

[0044] Accordingly, in several embodiments of the medical instruments described herein, the penetrator **120** is formed of a rigid material thereby providing sufficient column strength for penetration of tissue, cartilage, or soft bone. In several of these embodiments, the medical instrument includes an activation mechanism that is coupled to the control member **106** and that is adapted to move the penetrator **120** through its designed engagement angle.

[0045] An example of a medical instrument **100** having an activation mechanism **130** suitable for moving the penetrator **120** through an engagement angle is shown in FIGS. **6**A-B. The activation mechanism **130** includes a link **132** that is pivotably attached at a first end to the penetrator **120**, and pivotably attached at a second end to the distal end of the sleeve **112** or the stop member **122**. In an embodiment, the pivoting connectors **134** connecting the link **132** to the sleeve **112** and to the penetrator **120** are pins contained in a hole or slot formed on the respective member. In other embodiments, the connectors **134** comprise hinges or other rotating members. In an embodiment, the link **132** comprises a fixed length rigid wire, rod, or other suitable member.

[0046] In the embodiment shown in FIGS. **6**A-B, a coiled-wire type pusher **114** is housed within the sleeve **112** and is connected at its distal end to the penetrator **120**. The coiled wire pusher **114** is sufficiently flexible to be bent by the activation mechanism **130**. The penetrator **120** is rotated by the activation mechanism **130** through an engagement angle of greater than 90 degrees as the pusher **114** is advanced distally within the sleeve **112**, as shown in FIG. **6**B.

[0047] The size and shape of the engagement angle is controlled by the lengths of the penetrator **120** and of the link **132**. In another embodiment, the pusher **114** is adapted to form an elbow upon distal advancement, thereby increasing the amount of force applied by the penetrator **120** and/or enhancing the shape and stability of the end effector **102**. For example, in an embodiment, the pusher **114** includes a bending portion **115** (see FIG. **6**B) that includes a tube having transverse slots that facilitate bending of the tube while maintaining column strength and stability in the non-curling planes.

[0048] FIGS. **7**A-B illustrate another embodiment of a medical instrument **100** that includes an activation mechanism **130** having a link **132** pivotably connected to the penetrator **120** by a connector **134**. The link **132** is connected at its other end to the distal portion of the shaft **104** by a connector **134** that slides longitudinally within a slot **136** formed on the distal portion of the shaft **104**. In this manner, the penetrator **120** is configured to move distally through a longer length of travel for a given length of the link **132**, due to the travel of the connector **134** within the slot **136**.

[0049] FIGS. **8**A-B illustrate yet another embodiment of a medical instrument **100** that includes an activation mechanism **130** having a link **132** that is attached via a connector **134** at a first end to the penetrator **120** and by another connector at the other end to the distal portion of the shaft **104**. In the embodiment shown, the link **132** is a telescoping member having an inner shaft **132***a* and outer tube **132***b* that provides the link **132** with the capacity to have a variable length. Accordingly, as the penetrator **120** is advanced distally, it causes the link **132** to lengthen, thereby providing an increased penetration depth of the penetrator **120**.

[0050] Turning to FIGS. **9**A-D, another embodiment of a medical instrument **100** is shown. In the embodiment, the penetrator **120** is attached by a pivot **138** to the distal end of the shaft **104**. The pivot **138** provides the penetrator **120** with the capacity for rotating around the axis of the pivot **138**, thereby providing the ability for the penetrator to rotate through an engagement angle. A recess **113** is formed on the distal end of the shaft **104** to allow the penetrator **120** to rotate. In this embodiment, the penetrator **120** is moved through an engagement angle but does not move distally relative to the sleeve **112**. In the embodiment shown, the pusher **114** comprises a drive wire that is sufficiently flexible that it is capable of bending out of its longitudinal plane as it is extended, as shown, for example, in FIG. **9**B. This bending movement of the pusher **114** facilitates the rotation of the penetrator **120** about its fixed rotation axis and through its engagement angle.

[0051] The operation of the medical instrument is illustrated in FIGS. **9**C-D. As shown in FIG. **9**C, the medical instrument **100** is advanced first to bring the penetrator **120** to a position adjacent to the tissue T, and then advanced further to cause the penetrator **120** to penetrate the tissue T at a location of interest. After penetration, the pusher **114** is advanced to cause the penetrator **120** to rotate around the axis of the pivot **138**, thereby engaging a portion of tissue T and providing the medical instrument **100** with the ability to push, pull, or otherwise manipulate the acquired tissue.

[0052] In several of the embodiments, the pusher **114** is advanced under control of the controller, such as the handle **106**, as described above in relation to FIGS. **1**A and **1**D. The controller is actuated by the user to advance the pusher **114**, thereby activating the penetrator **120**. The activation speed is controlled by the user operating the controller (e.g., the handle **106**), so as to move the penetrator **120** through its engagement angle at a desired speed. In an embodiment, the activation speed is sufficiently fast to cause the penetrator **120** to pass through the engagement angle and engage the target tissue in a fraction of a second, such as 0.001 seconds to 0.5 seconds. An appropriate speed of the penetrator **120** for the type of target tissue T causes the penetrator **120** to more effectively engage and grasp the tissue. In another embodiment, the activation speed is less fast, causing the penetrator **120** to pass through the engagement angle and engage tissue in a time of greater than 0.5 seconds.

[0053] In FIGS. **10**A-C, another embodiment of a medical instrument **100** is shown. The medical instrument **100** is otherwise similar to the embodiment described above in relation to FIGS. **9**A-D, but is provided with a longitudinal slot **142** formed on the distal end of the shaft **104**. The penetrator pivot **138** is configured to slide longitudinally within the slot **142**, thereby providing the ability to move the penetrator **120** longitudinally relative to the shaft **104**. As a result, the user is able to retract the penetrator **120** into the shaft **104** prior to activation, thereby providing an atraumatic state for the distal end of the medical instrument **100**. The atraumatic state is useful in situations in which the device is being loaded through accessory devices or through the anatomy. The atraumatic state is also useful to allow the user to effectively cover and/or protect the penetrator **120** when the end effector **102** is in a confined or sensitive space prior to deployment of the penetrator **120**.

[0054] Operation of the device is illustrated in FIGS. **10**A-C. In FIG. **10**A, the penetrator **120** is substantially retained within the distal end of the shaft **104** and is thereby retained in a substantially atraumatic state. Although the penetrator **120** is shown in FIG. **10**A slightly rotated about the axis of the pivot **138**, the penetrator **120** is also capable of being positioned fully within the shaft **104** and aligned fully longitudinally in its atraumatic state. In FIG. **10**B, the pusher **114** has been advanced distally to cause the penetrator **120** to advance within the longitudinal slot **142** and to begin rotating through its engagement angle. In FIG. **10**C, the pusher **114** has been fully advanced so as to cause the penetrator **120** to rotate through the full extent of the engagement angle.

[0055] FIG. **11** illustrates another embodiment of the medical instrument. The medical instrument **100** is generally similar to the embodiment described above in relation to FIGS. **10**A-B, but is provided with tissue-engaging surface features on the upper surface of the penetrator **120** and the outer surface of the distal end of the shaft **104**. For example, in the embodiment shown in FIG. **11**, the upper surface of the penetrator **120** includes a plurality of ridges **121** that are adapted to enhance the tissue engaging strength of the penetrator as it is activated. In addition, a plurality of ridges **105** are formed on the outer surface of the distal end of the shaft **104**. The ridges **105** are adapted to enhance the tissue engaging strength of the shaft **104** to effectively grasp tissue that is trapped between the penetrator **120** and the shaft **104** after activation of the penetrator **120**. In other embodiments, the tissue-engaging surface features comprise teeth, knurled surfaces, roughened surfaces, notches, other suitable surface irregularities, or any combination of the same. The penetrator **120** and outer surface of the distal end of the shaft **104** are thereby provided with the capacity to operate as a reverse grasper to grasp and retain tissue between their facing surfaces.

[0056] Turning next to FIG. **12**, another embodiment of a medical instrument **100** is shown. The medical instrument is constructed similarly to the device described above in relation to FIG. **11**, but includes a proximal jaw **144** that is attached to the shaft **104** by a hinge **146**. The proximal jaw **144** is attached to the shaft **104** at a point proximal of the end effector **102**, and is oriented such that the jaw closes downward and distally of the hinge **146**, as shown in the Figure. In an embodiment, the proximal jaw **144** is positioned such that the jaw is able to engage and retain the tissue T that is retained between the penetrator **120** and the distal end of the shaft **104**.

[0057] In several embodiments, the medical instruments **100** described herein are configured to work through existing endoscopes as an accessory. Accordingly, in some embodiments, the devices has a transverse dimension of no larger than 3 mm to fit the majority of conventional endoscope tool channels having working lumens. The medical instrument is also provided with a flexible shaft, and the end effector is preferably flexible and has a minimal rigid length to facilitate loading and removal from the scope.

[0058] Although several embodiments of the medical instruments **100** described are adapted for use with a steerable endoscope or other overtube, in some embodiments the medical instrument **100** includes an articulation capability. For example, in FIGS. **13**A-B, a medical instrument **100** similar to the embodiment described above in relation to FIGS. **10**A-C is shown having an articulation mechanism **170** that is adapted to rotate the end effector **102** of the device around a joint formed at the distal end of the shaft **104**. In an embodiment, the rotation joint comprises a hinge **172** or other pivot mechanism that rotatably connects the end effector **102** to the distal end of the shaft **104**. An activator, such as a pull wire **174**, extends through an exit port **176** formed near the distal end of the shaft **104**, and extends proximally to the controller at the proximal end of the shaft **104**. The distal end of the pull wire **174** is attached to a pivoting connector **178** formed on the end effector **102**. Accordingly, as the pull wire **174** is retracted (proximally) and advanced (distally), the end effector **102** is caused to articulate through a range of motion relative to the longitudinal axis of the shaft **104**. See FIGS. **13**A-B. This articulation provides the user with the ability to move the end effector **102** to a position suitable for engaging and manipulating the tissue T.

[0059] The medical instruments described herein are adapted for use in engaging, penetrating, grasping, and manipulating tissue during open surgery, laparoscopic surgery, endoscopic surgery, or translumenal surgery. In particular, the medical instruments are adapted to engage the soft, multilayer tissue of a human or animal stomach in an endolumenal approach. Alternatively, the medical instruments may be used to engage other human or animal gastric tissue, peritoneal organs, external body surfaces, or tissue of the lung, heart, kidney, bladder, or other body tissue. The instruments are particularly useful for engaging, penetrating, grasping, and manipulating tissue that is difficult to engage using conventional graspers, which frequently occurs during translumenal surgical procedures (e.g., natural orifice translumenal endoscopic surgery, or "NOTES"). Several translumenal procedures are described in U.S. patent application Ser. No. 10/841,233, Ser. No. 10/898,683, Ser. No. 11/238,279, Ser. No. 11/102,571, Ser. No. 11/342,288, and Ser. No. 11/270,195, which are hereby incorporated by reference. The medical instruments described herein are suitable for use in combination with, for example, the endoluminal tool deployment systems described in U.S. patent application Ser. No. 10/797,485, which is hereby incorporated by reference. In particular, the tool deployment systems described in the '485 application includes one or more lumens suitable for facilitating deployment of the medical instruments described herein to perform or assist in performing endoscopic, laparoscopic, or NOTES diagnostic or therapeutic procedures. In addition, the medical instruments described herein are suitable for use in combination with, or instead of, the methods and instruments described in U.S. patent application Ser. No. 11/412,261, which is also incorporated by reference herein.

[0060] Although various illustrative embodiments are described above, it will be evident to one skilled in the art that various changes and modifications are within the scope of the invention. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. Apparatus for penetrating and engaging tissue comprising:
- a control member;
- a tissue penetrating member;
- an activation mechanism responsive to said control member and operatively coupled to said tissue penetrating member; and
- an elongated flexible member extending between and coupled to each of said control member and said tissue penetrating member;
- wherein said tissue penetrating member comprises a rigid member pivotably attached to said elongated flexible member.

2. The apparatus of claim **1**, wherein said control member comprises a handle.

3. The apparatus of claim **2**, wherein said handle comprises a ratcheting mechanism.

4. The apparatus of claim **2**, wherein said handle comprises a pusher block slidably received within a main body, and an actuation arm connected to said pusher block by a linkage.

5. The apparatus of claim **1**, wherein said elongated flexible member comprises a shaft having a sleeve and a pusher.

6. The apparatus of claim **1**, wherein said activation mechanism comprises a drive wire attached to said penetrating member and adapted to move said penetrating member around its pivotable attachment to said elongated flexible member.

7. The apparatus of claim **1**, wherein said penetrating member comprises a beveled needle.

8. The apparatus of claim **1**, further comprising a frame defining an elongated slot formed on said elongated flexible member, and wherein said penetrating member is capable of translation motion restricted by said frame.

9. The apparatus of claim **1**, wherein said activation mechanism comprises a drive wire.

10. The apparatus of claim **8**, wherein said drive wire is flexible.

11. The apparatus of claim **1**, wherein said elongated flexible member comprises a composite shaft.

12. The apparatus of claim **11**, wherein said composite shaft comprises polyetheretherketone.

13. A method for penetrating and grasping tissue, comprising:
- providing an instrument having a tissue penetrating member at a location adjacent to a tissue site;
- causing said tissue penetrating member to penetrate tissue;
- rotating said tissue penetrating member; and
- manipulating said instrument to move said tissue from its natural position.

14. The method of claim **13**, wherein the tissue site is a hollow body organ.

15. The method of claim **13**, wherein the tissue penetrating member is provided at the location endoluminally.

16. The method of claim **13**, wherein the tissue penetrating member is provided at the location laparoscopically.

17. The method of claim **13**, wherein the tissue penetrating member is provided at the location by advancing the instrument through a natural body orifice.

18. The method of claim **13**, wherein causing said tissue penetrating member to penetrate tissue includes moving said tissue penetrating member through a slot formed on said instrument.

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摘要(译)

一种组织抓握装置，包括控制构件，细长轴，以及附接到细长轴的远端的组织穿透和抓握构件。激活机构在控制构件和组织穿透和抓握构件之间提供用户可操作的连接。在一个实施例中，组织穿透和抓握构件包括刚性穿透构件，其可旋转地附接到细长轴的远端。在一个实施例中，激活机构包括附接到穿透构件的柔性驱动线。