US009931111B2

(12) **United States Patent**
Chu et al.

(10) **Patent No.: US 9,931,111 B2**
(45) **Date of Patent: *Apr. 3, 2018**

(54) **SUTURING INSTRUMENT**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 91 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/262,099**

(22) Filed: **Apr. 25, 2014**

(65) **Prior Publication Data**

US 2014/0236190 A1 Aug. 21, 2014

Related U.S. Application Data

(63) Continuation of application No. 11/935,175, filed on Nov. 2, 2007, now Pat. No. 8,709,021.
(Continued)

(51) **Int. Cl.**
A61B 17/04 (2006.01)
A61B 17/12 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/0469*** (2013.01); *A61B 17/1114* (2013.01); *A61B 2017/047* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/04; A61B 17/0469; A61B 2017/047; A61B 2017/0472;
(Continued)

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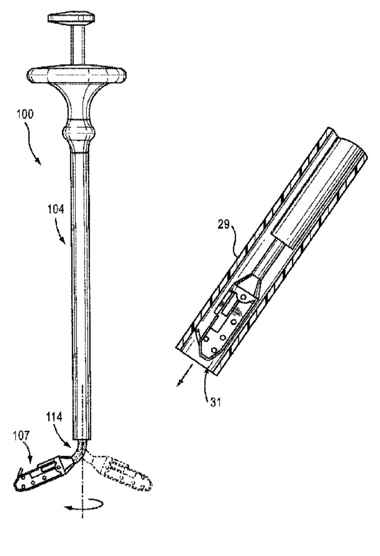
(57) **ABSTRACT**

A suturing instrument includes a suturing head that is coupled to the shaft of an elongate body member of the instrument by a connector member which may be biased in either a linear orientation along the longitudinal axis of the shaft or any one of a variety of non-linear orientations with respect to the shaft's longitudinal axis. The connector member can comprise a resilient material such that an external force may be applied to the suturing head and move the suturing head from a biased orientation (e.g., linear) to an unbiased orientation (e.g., non-linear). Once the external force is removed, the resiliency of the connector member allows the suturing head to return from the unbiased orientation to the biased orientation. Therefore, a user may adjust the shape of the instrument by applying or removing an external force on the suturing head.

20 Claims, 23 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 60/857,615, filed on Nov. 7, 2006.

(51) **Int. Cl.**
A61B 17/11 (2006.01)
A61B 17/29 (2006.01)

(52) **U.S. Cl.**
CPC *A61B 2017/0472* (2013.01); *A61B 2017/2905* (2013.01); *A61B 2017/2927* (2013.01)

(58) **Field of Classification Search**
CPC A61B 2017/2904; A61B 2017/2926; A61B 2017/2927
See application file for complete search history.

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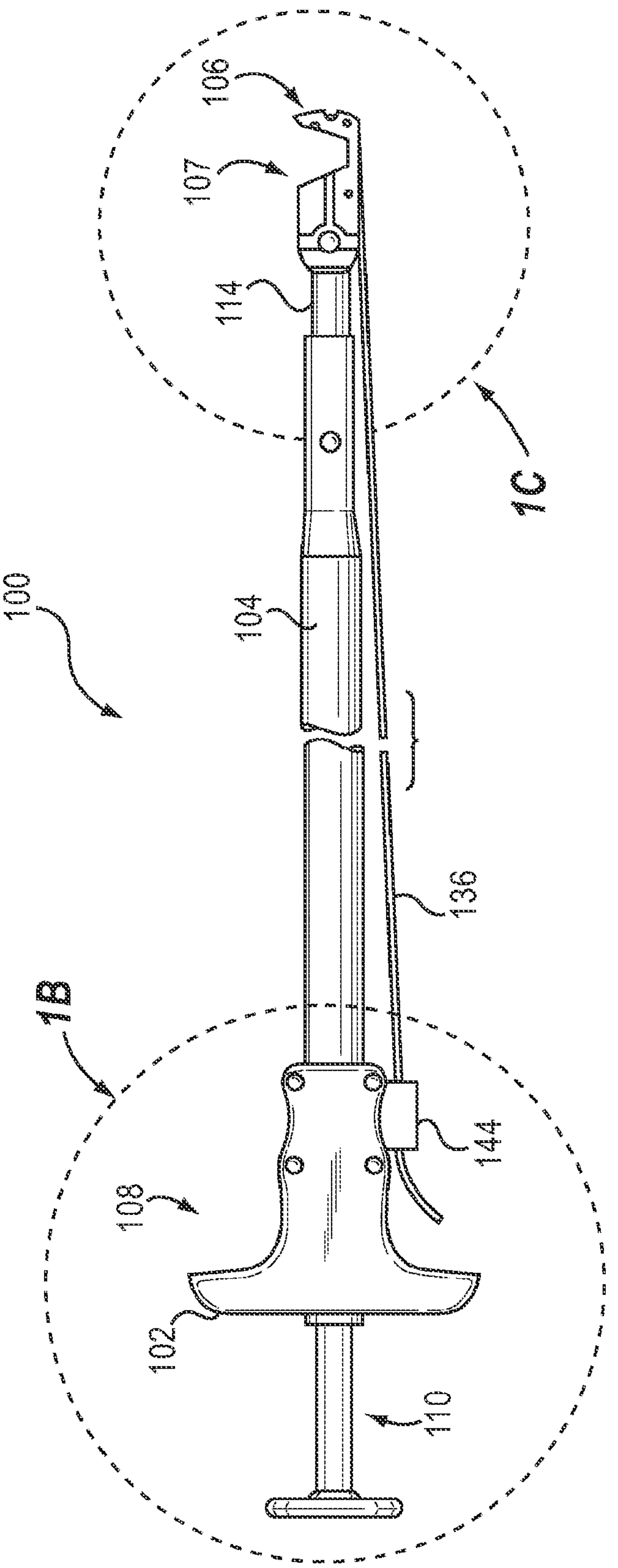

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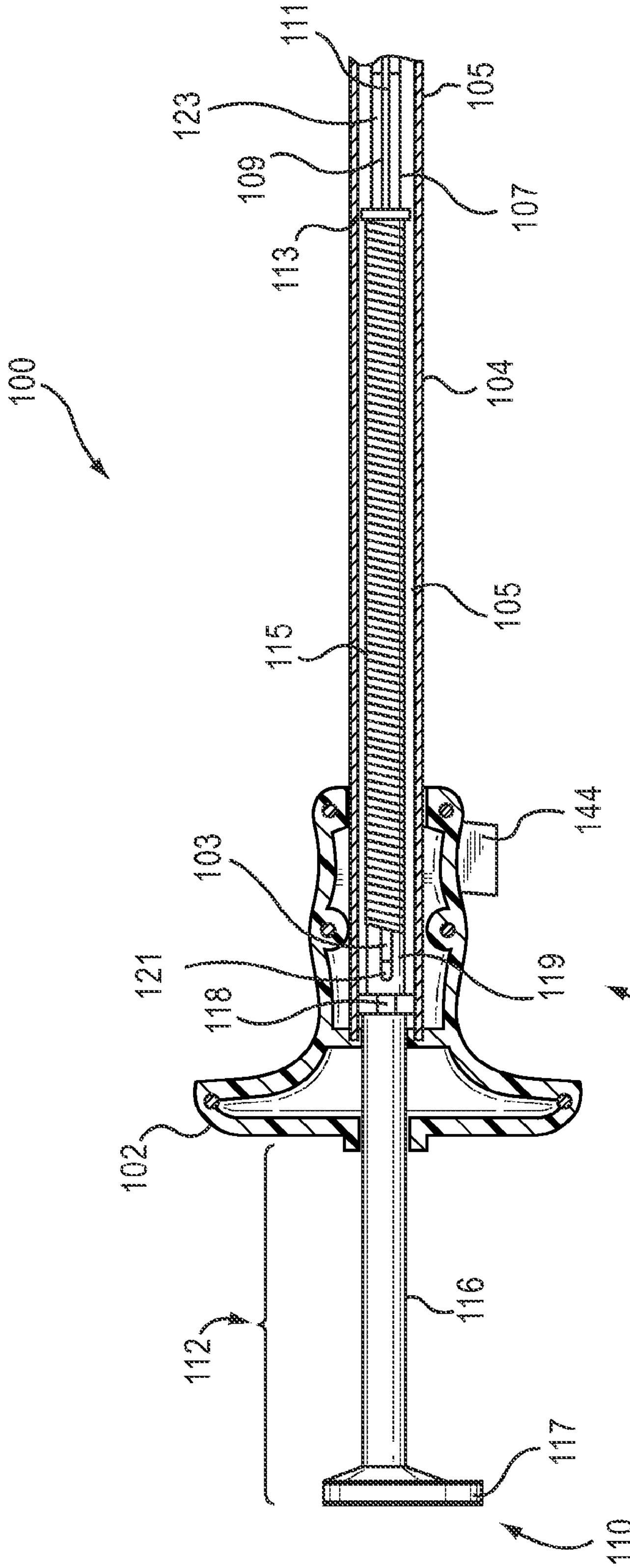

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Fig.1B

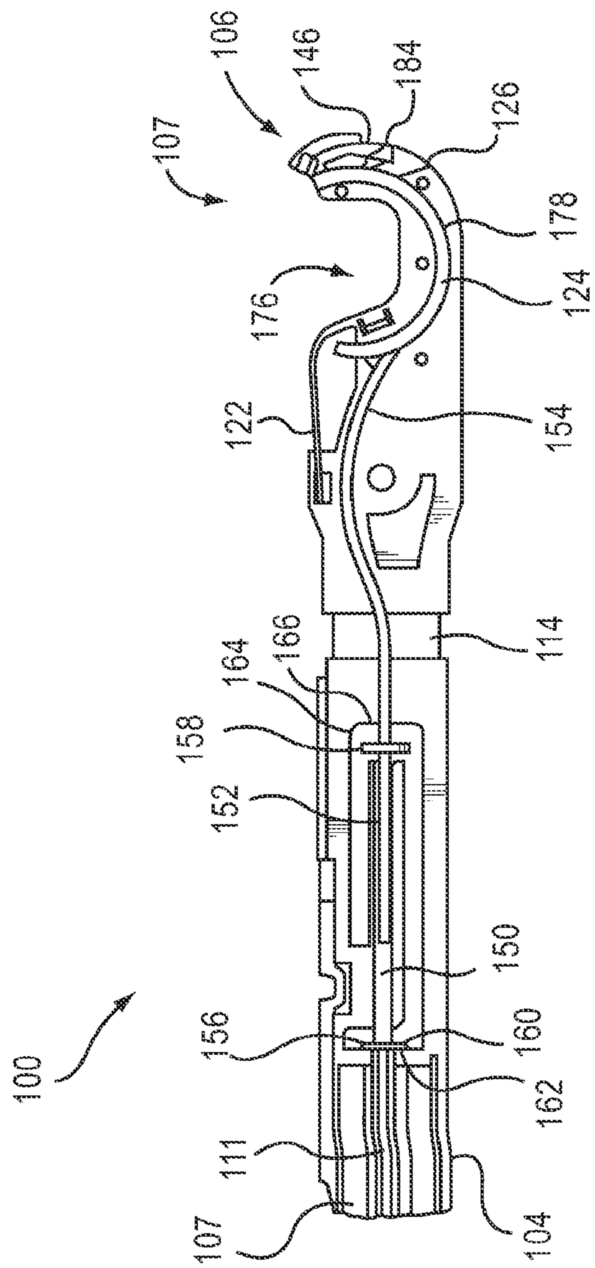
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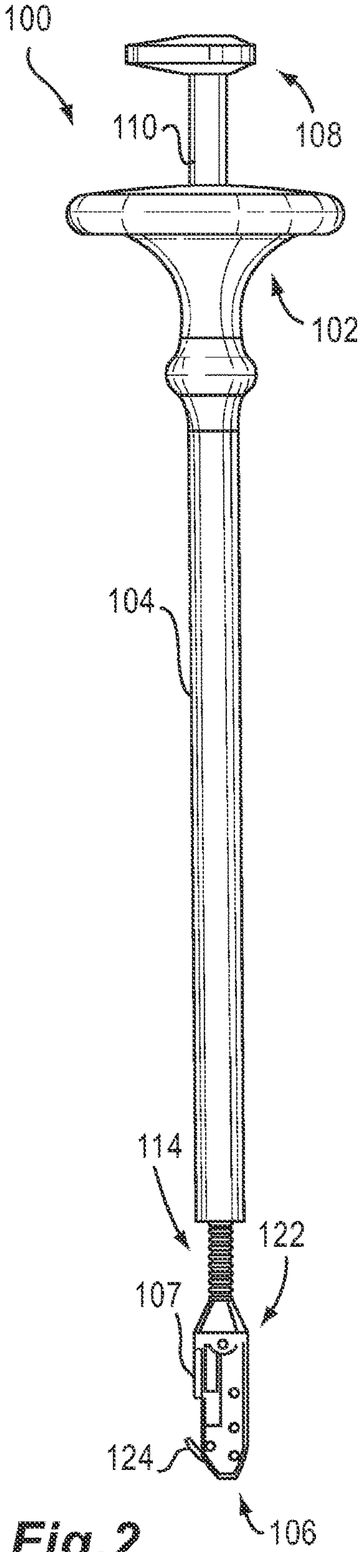
Fig.1C



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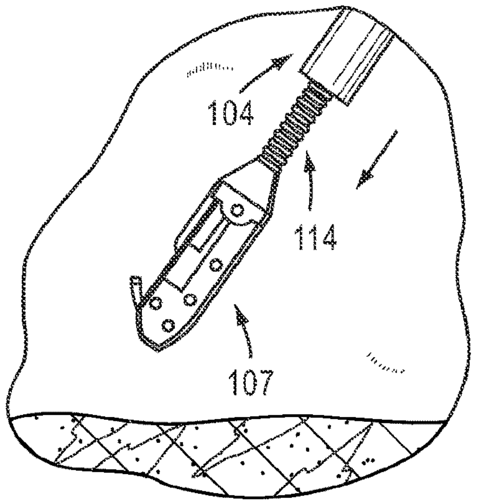
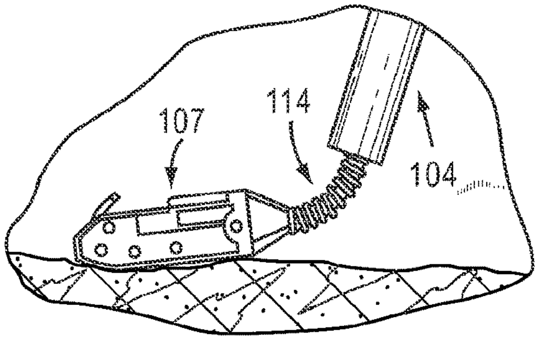


Fig.3A



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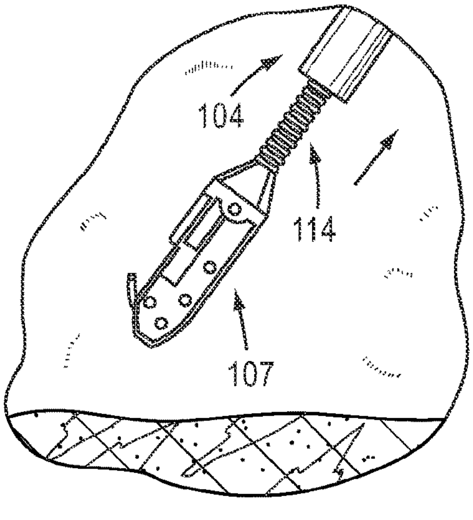

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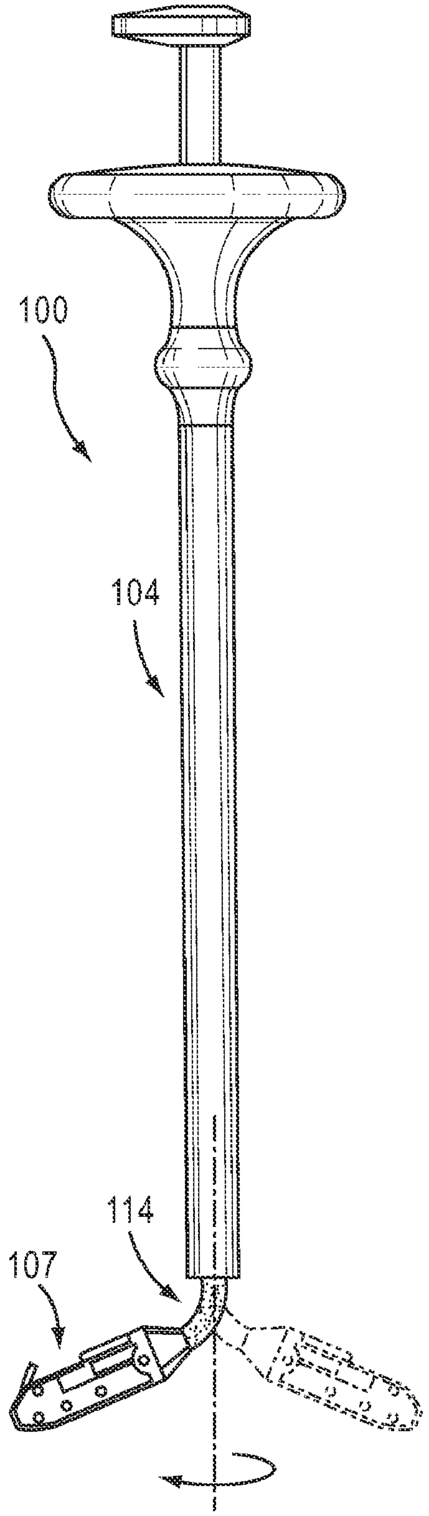


Fig.4

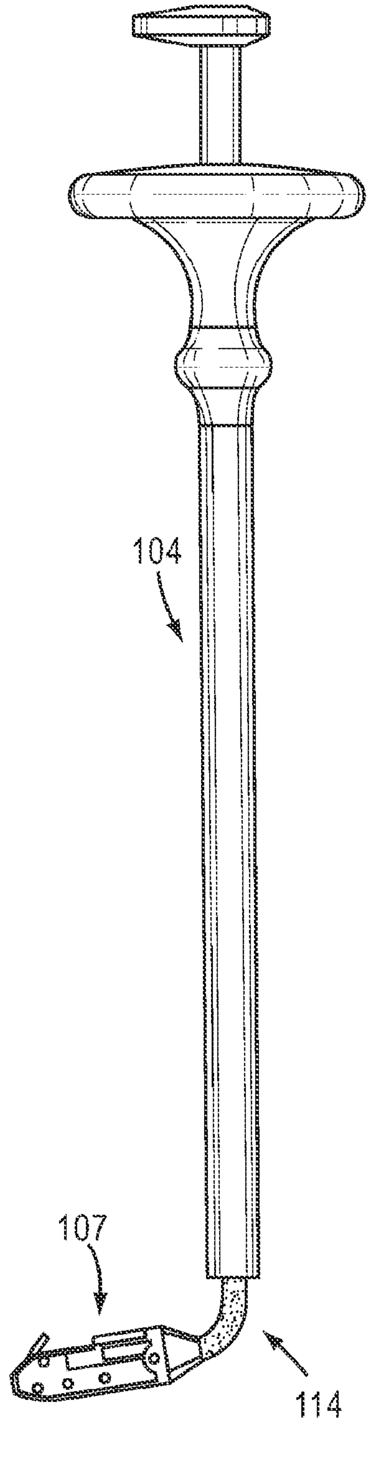
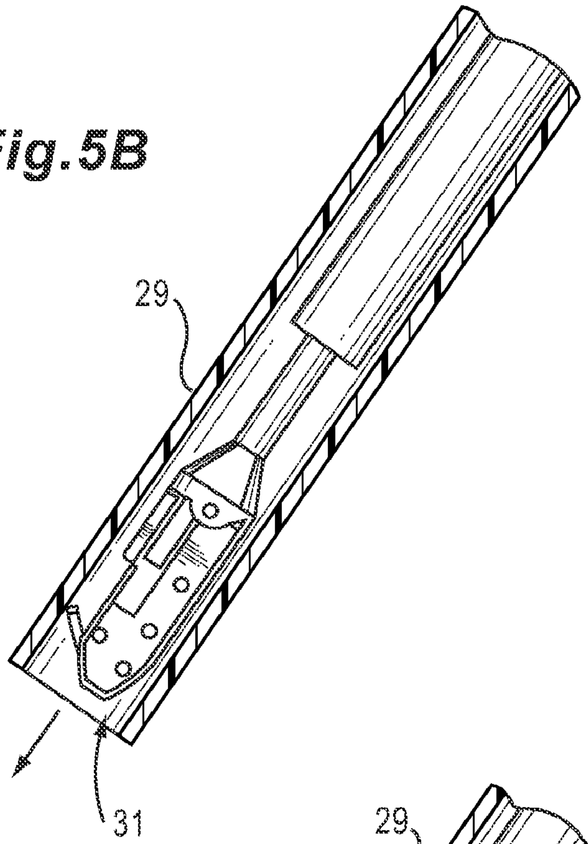


Fig.5A

Fig.5B



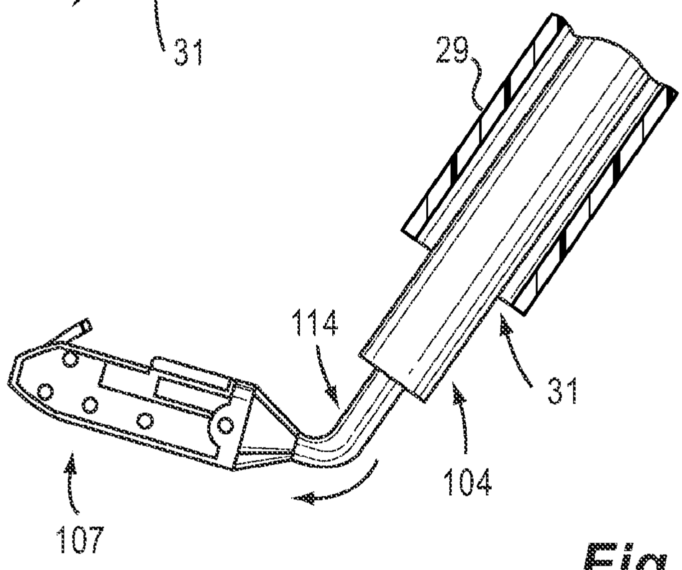


Fig.5C

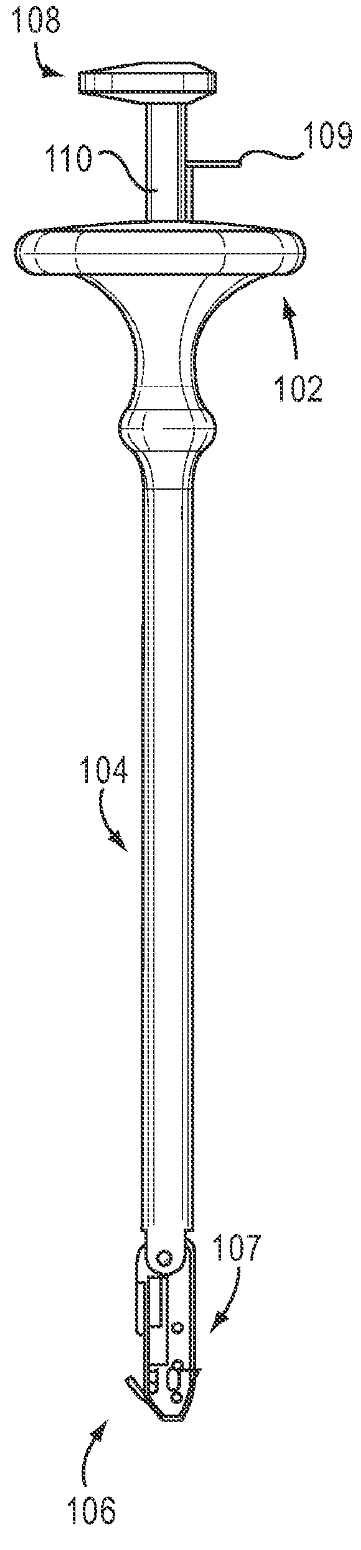


Fig.6A

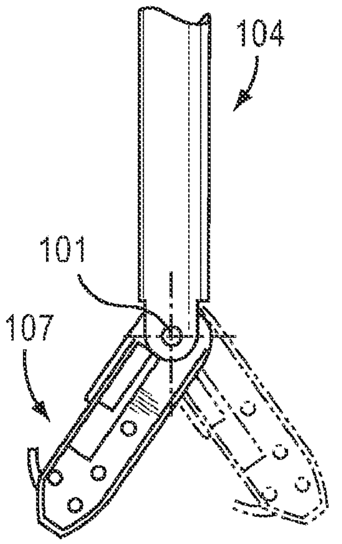


Fig.6B

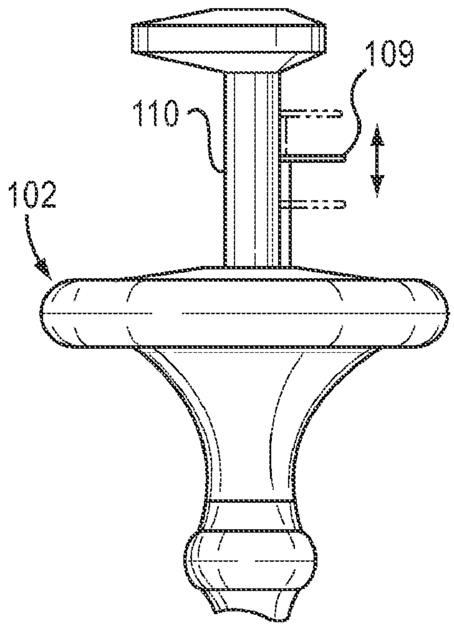


Fig.6C

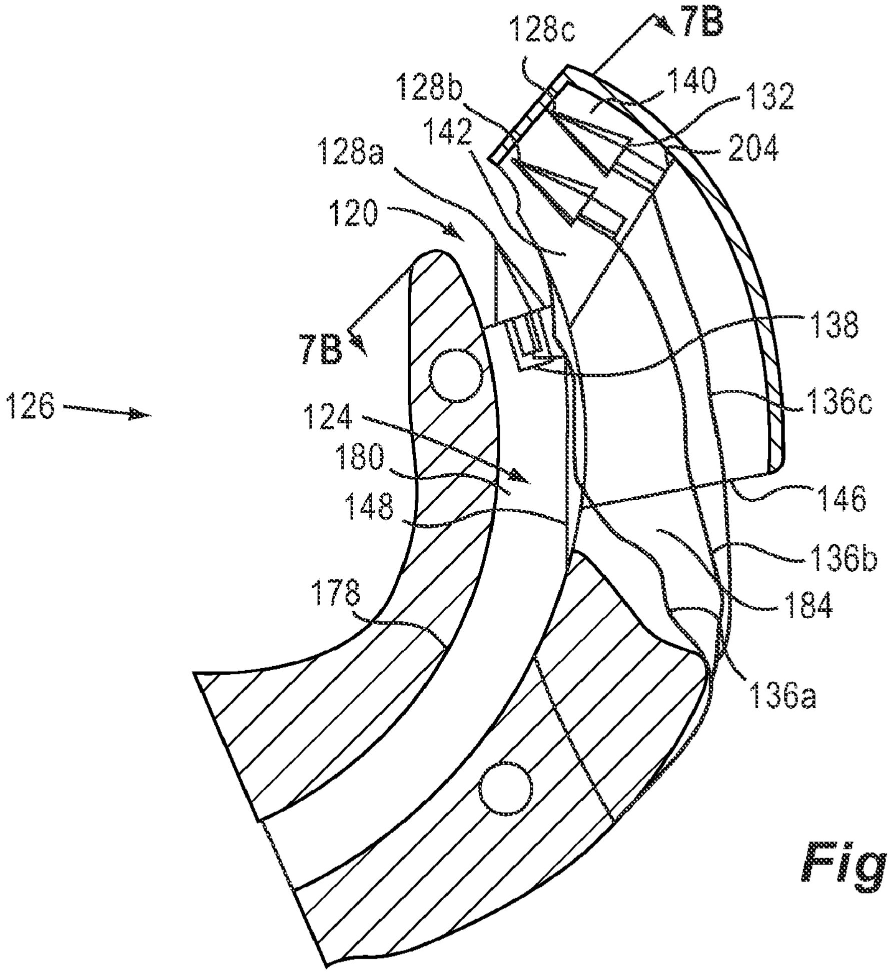

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Fig.7A

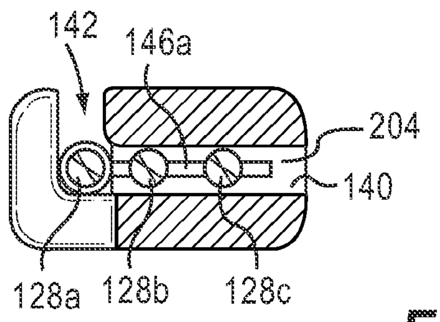
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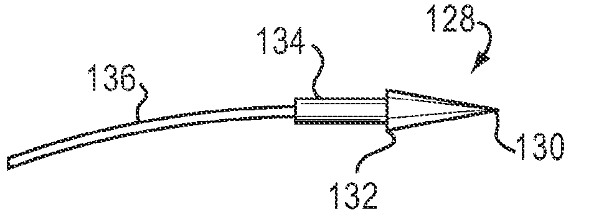
Fig.7B



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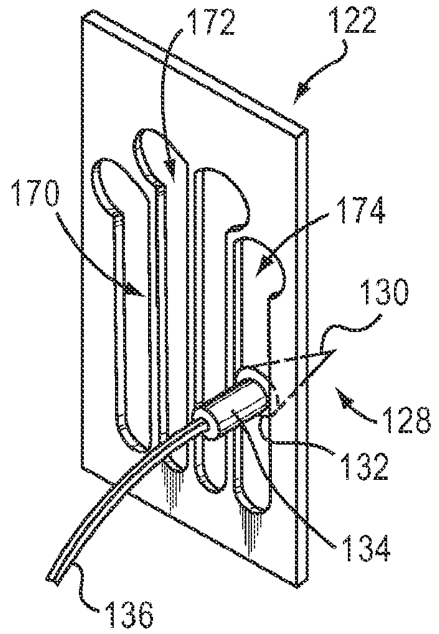

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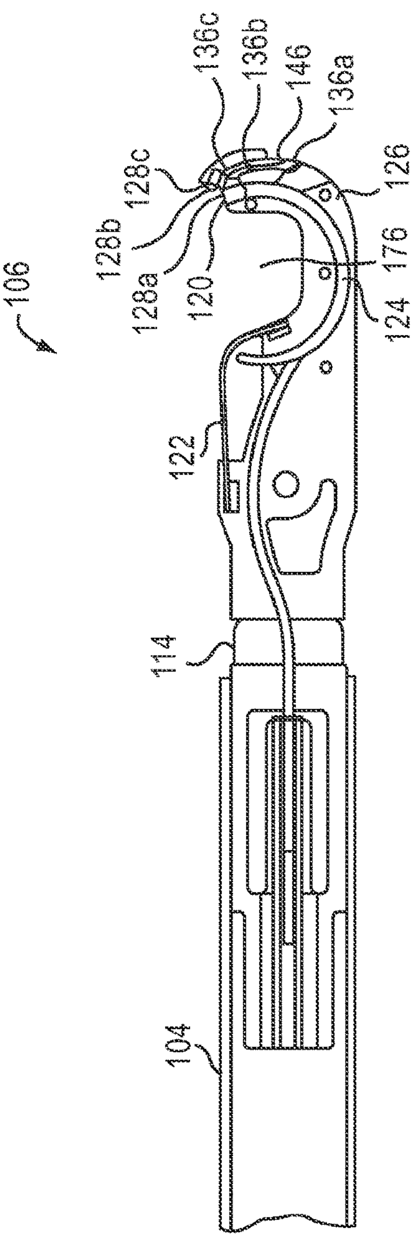
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Fig.9A

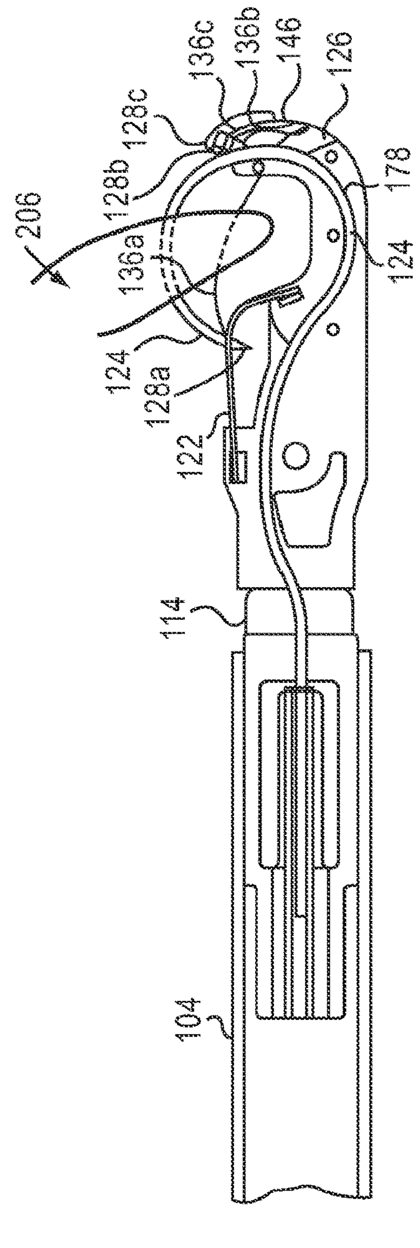
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Fig.9B

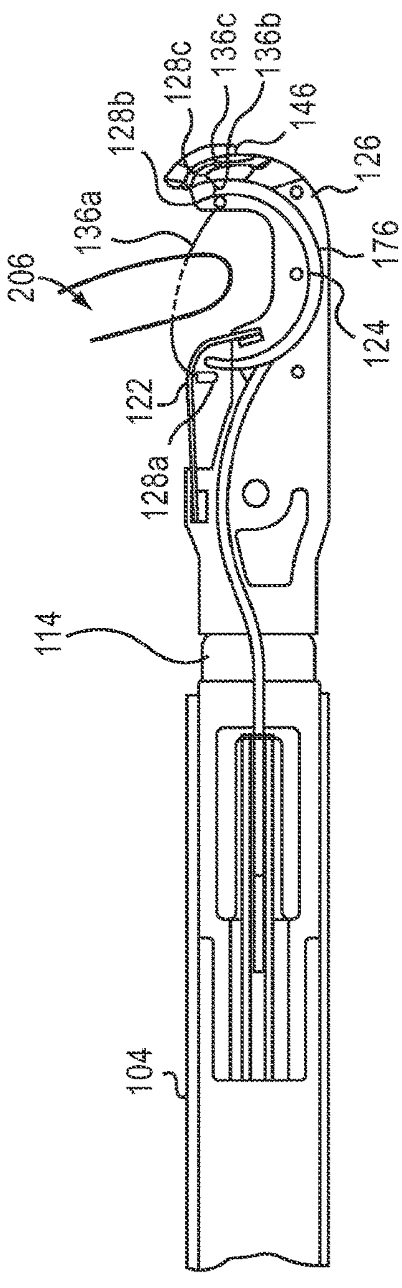
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Fig.9C

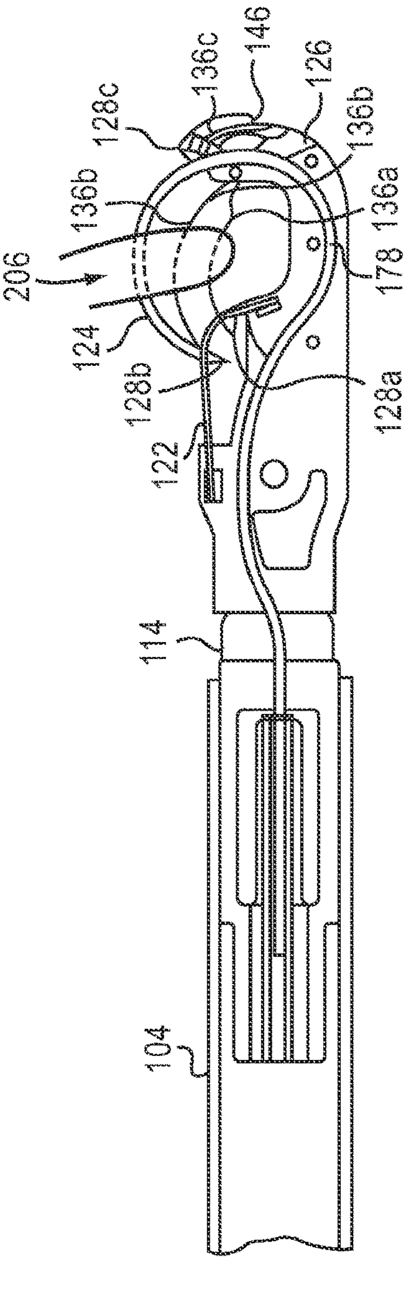
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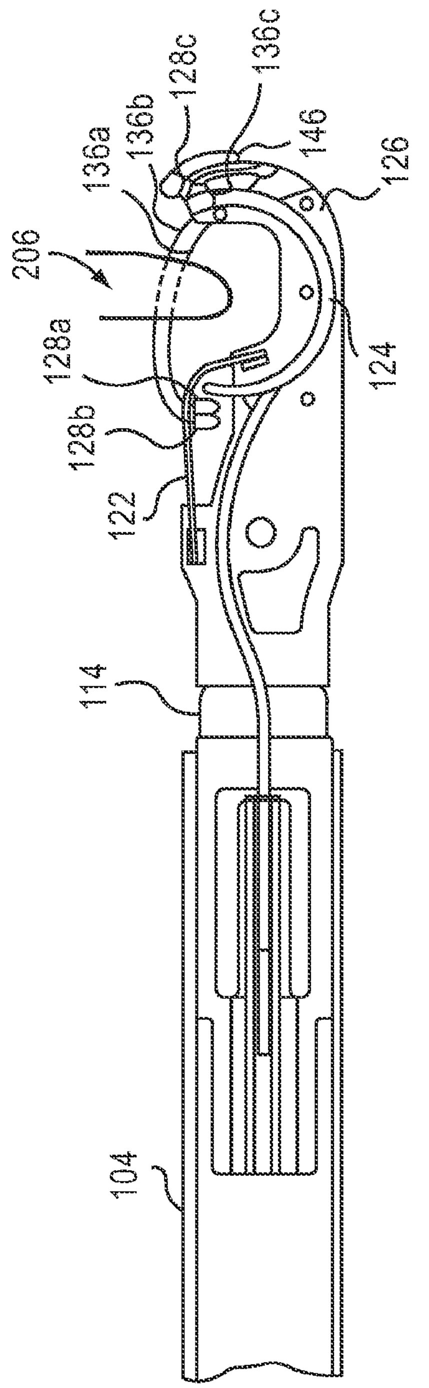
Fig.9D



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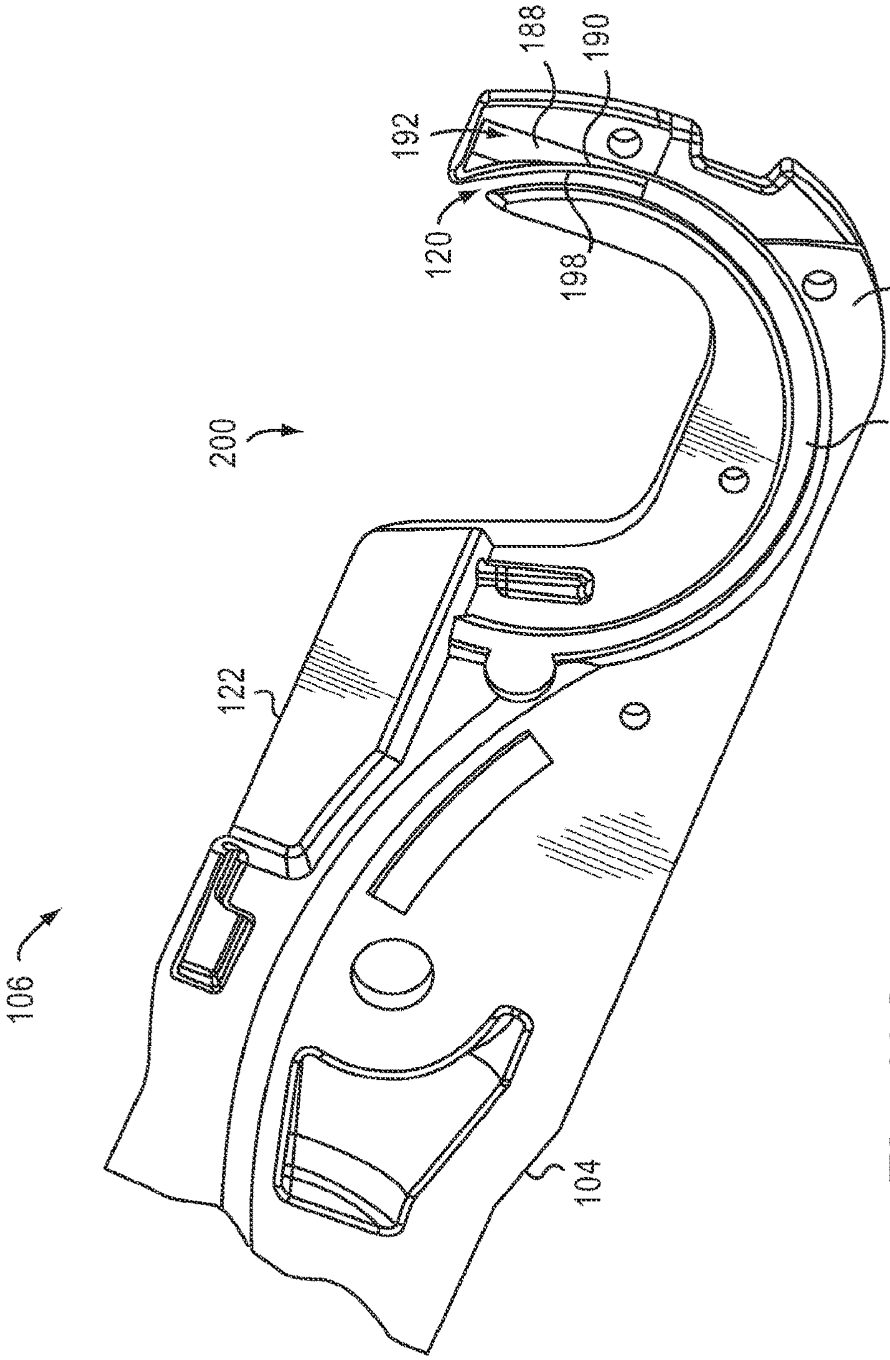

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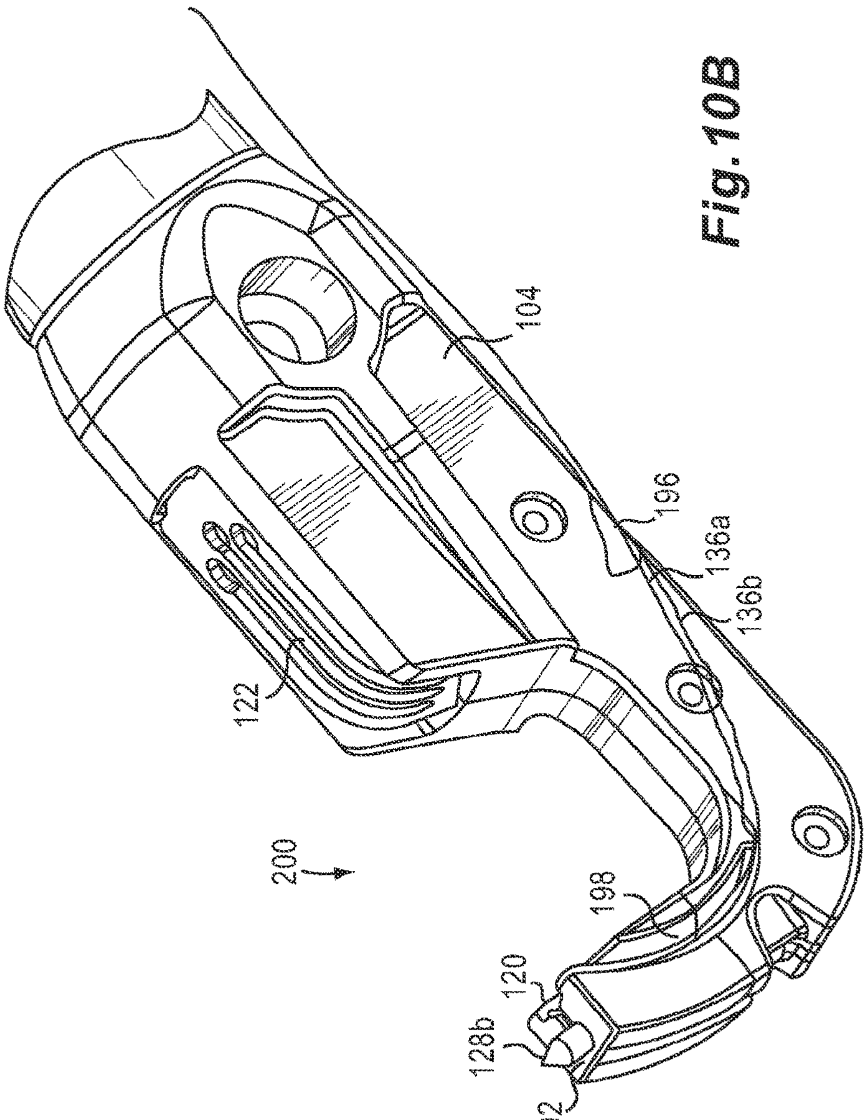

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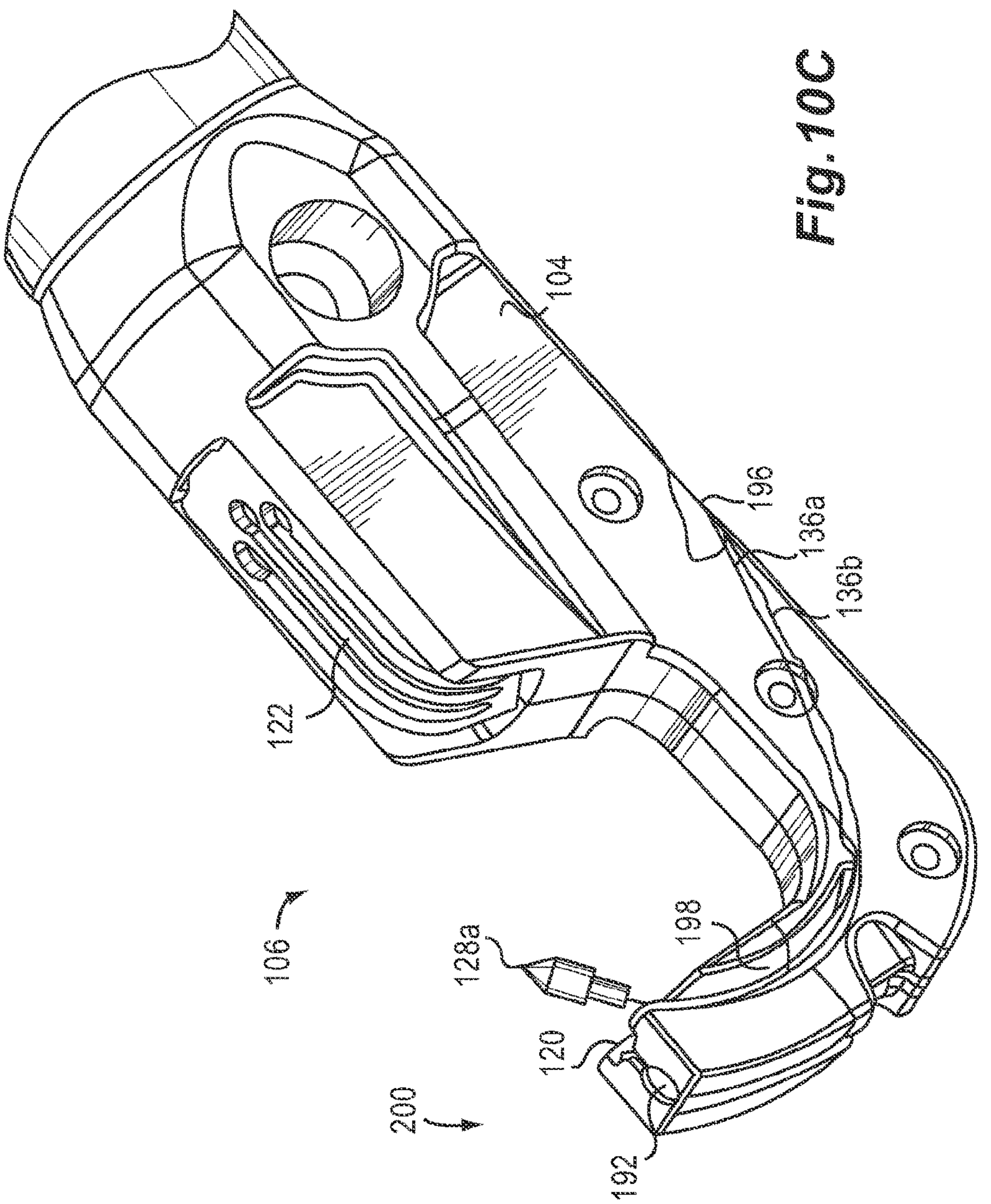

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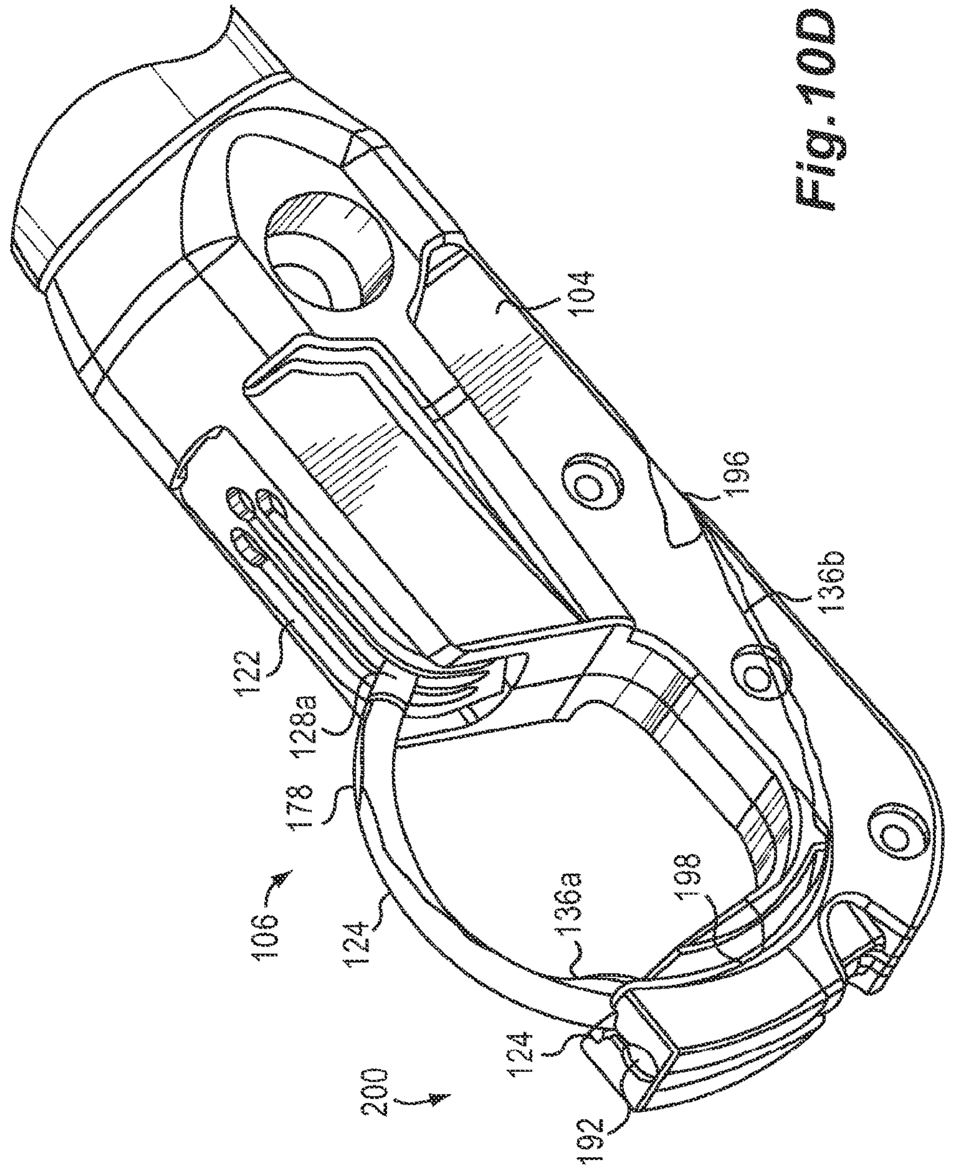

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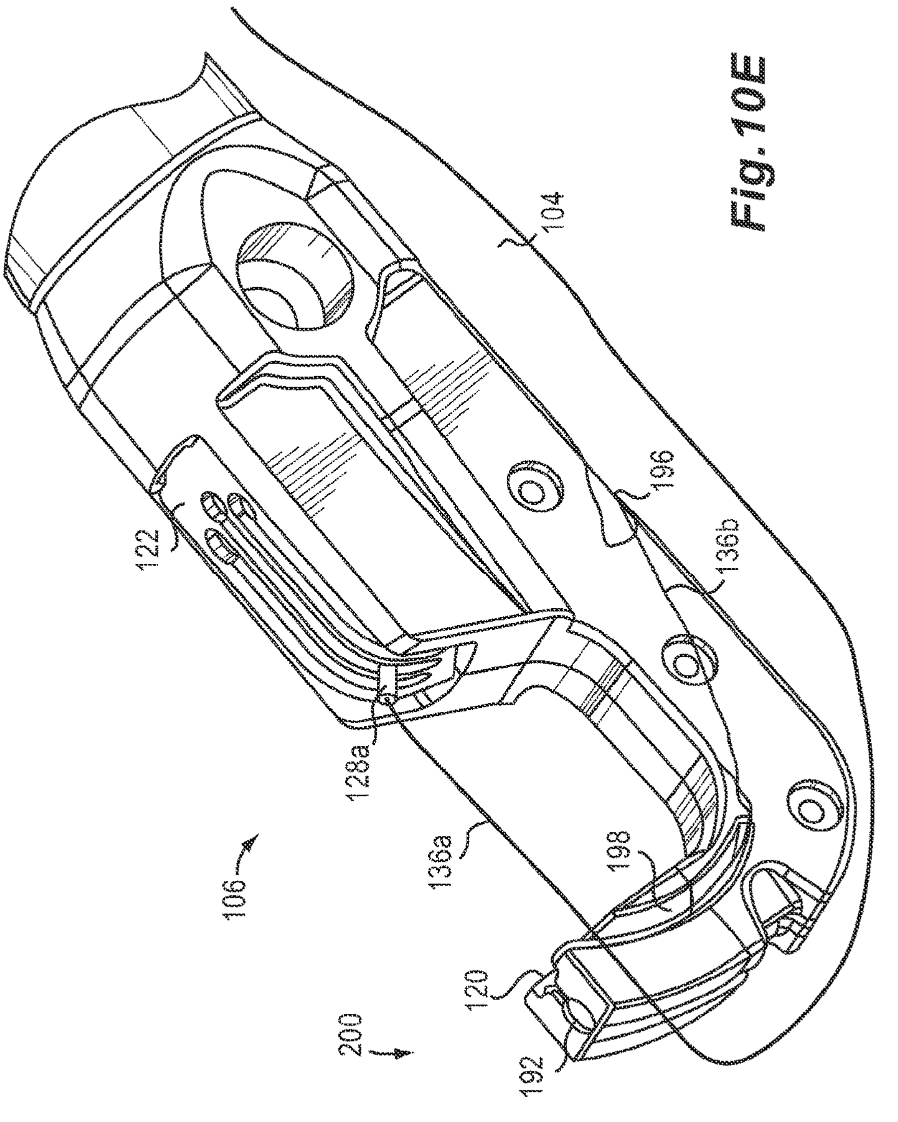

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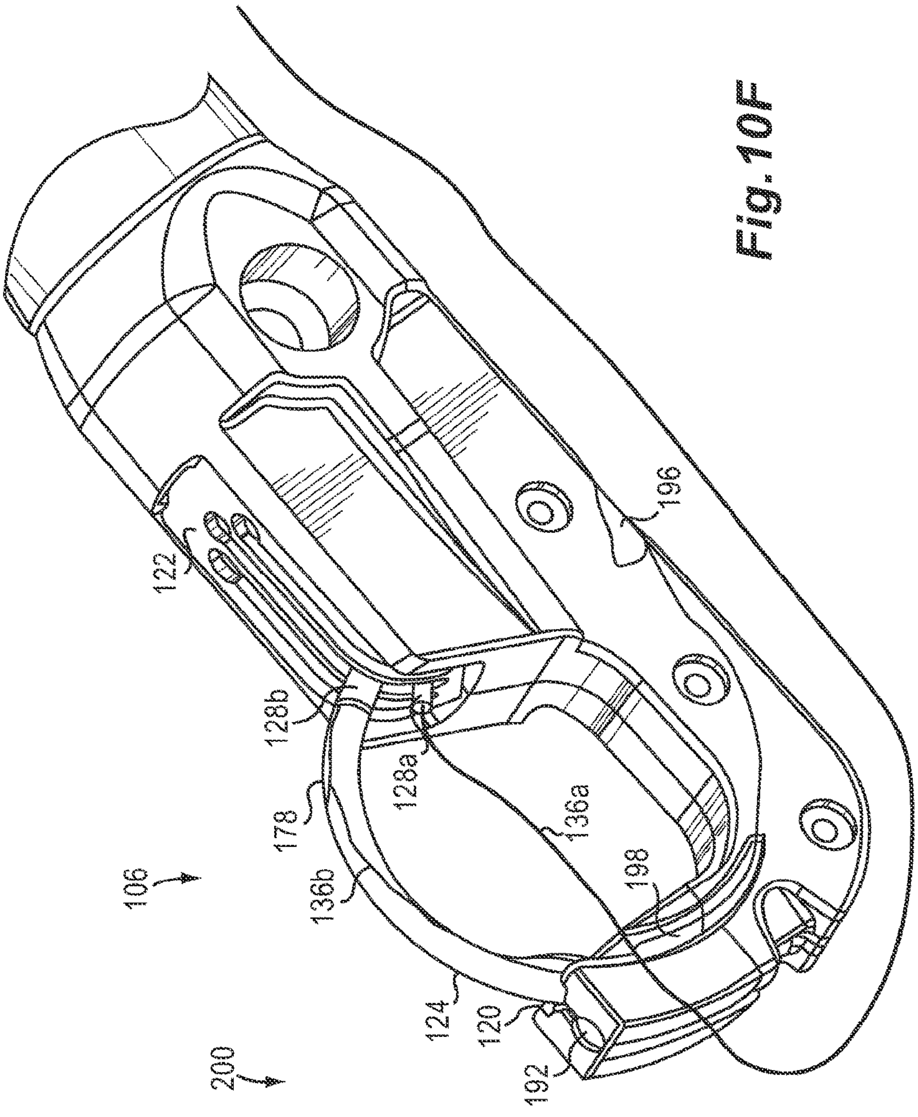

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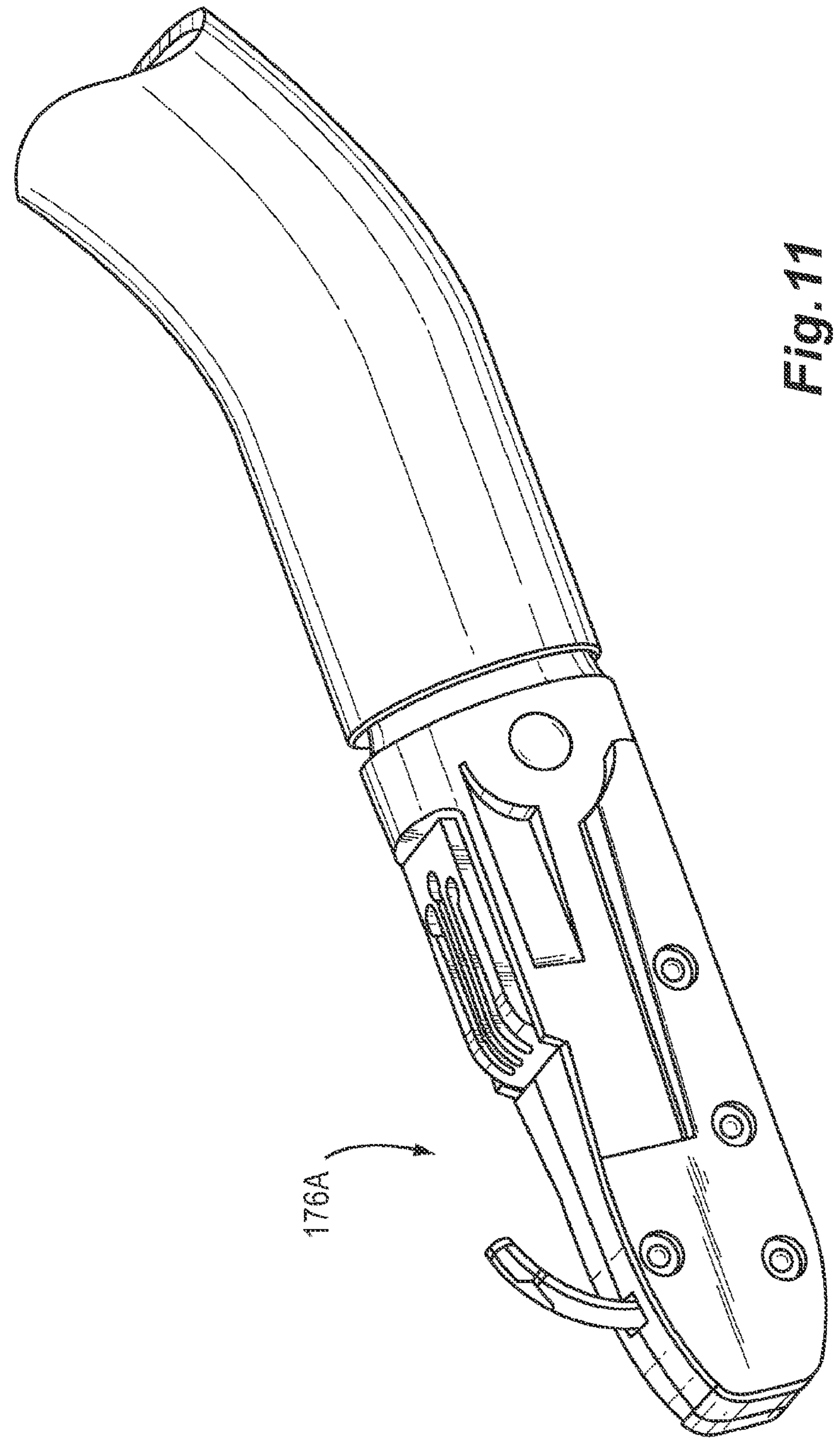


Fig.11

Fig.12

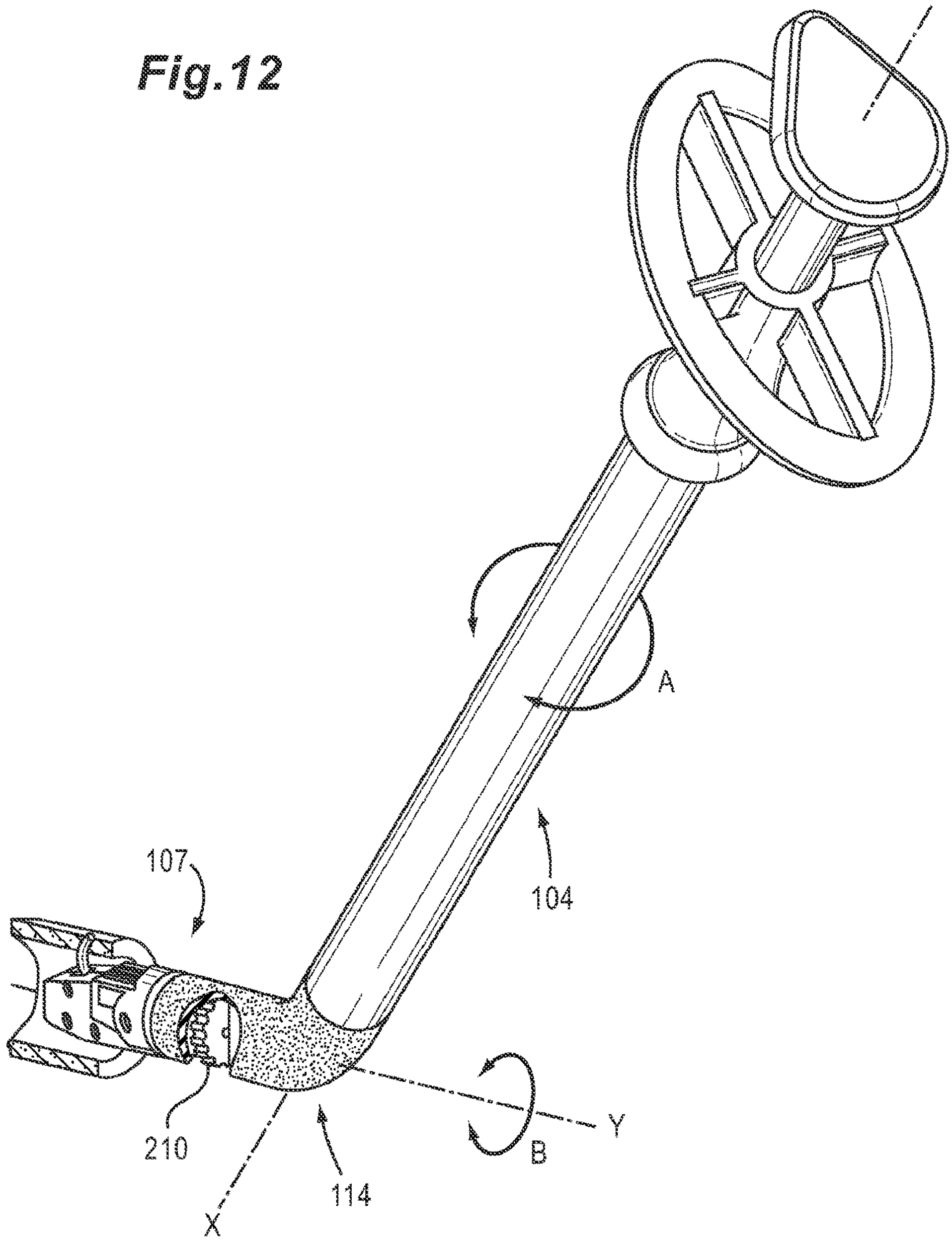


Fig.13

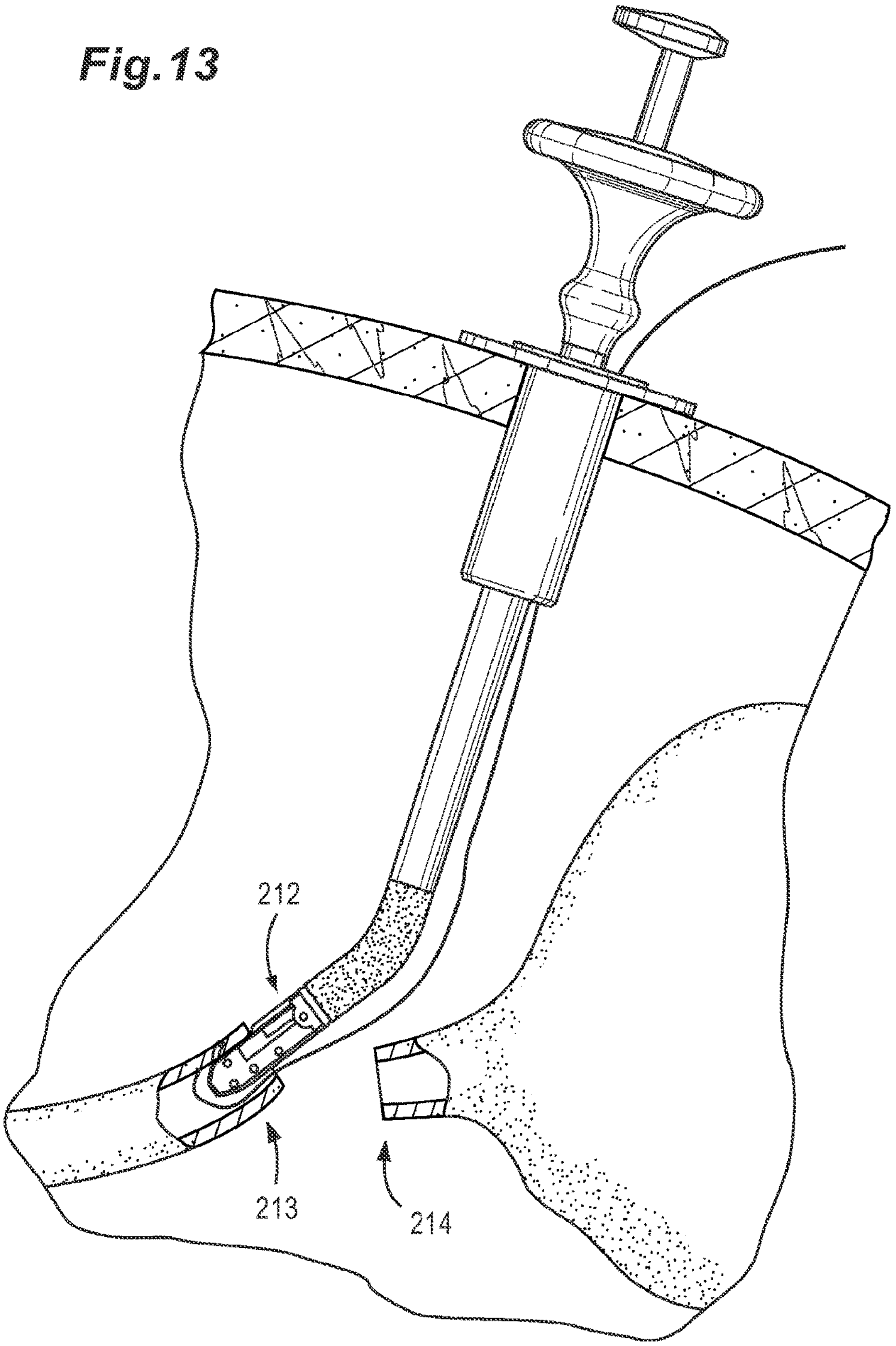
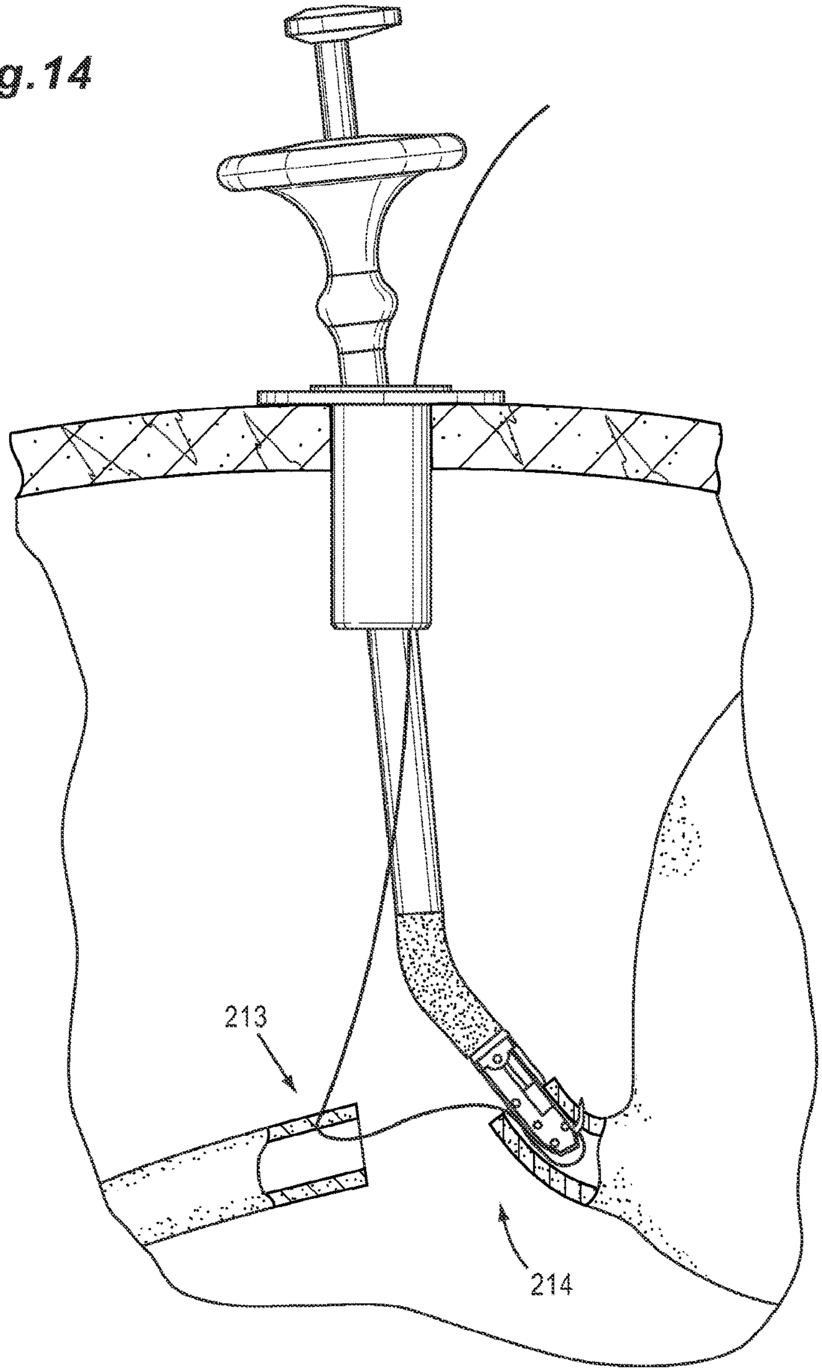


Fig.14



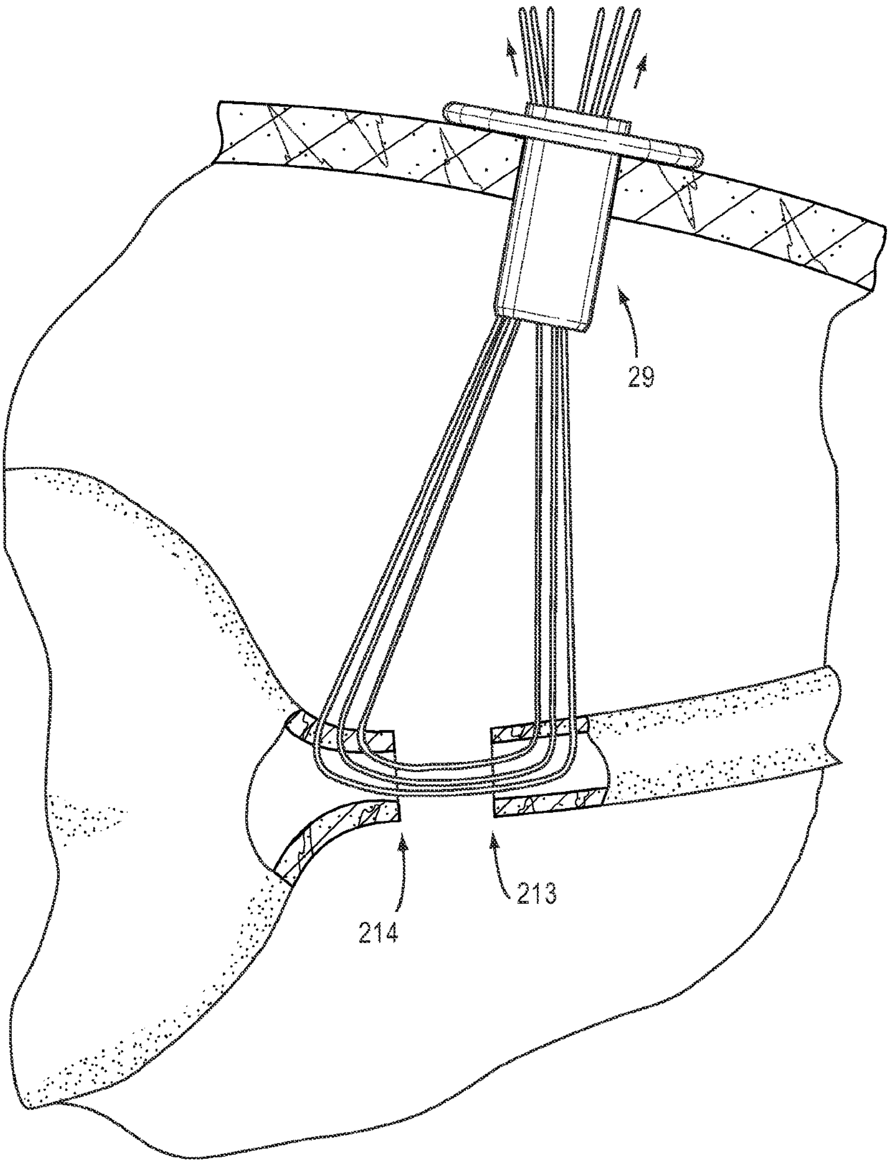


Fig.15

SUTURING INSTRUMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a Continuation of, and claims priority to, U.S. patent application Ser. No. 11/935,175, filed on Nov. 5, 2007, entitled "SUTURING INSTRUMENT", which, in turn, claims priority to U.S. Patent Application No. 60/857,615, filed on Nov. 7, 2006, entitled "DELIVERING SUTURES", the disclosures of which are incorporated by reference herein in their entirety.

TECHNICAL FIELD

The invention generally relates to placing sutures. Embodiments according to the invention can be used to navigate tortuous pathways for the purpose of accessing difficult-to-reach treatment areas within the body of a patient.

BACKGROUND INFORMATION

Suturing body tissue is a time consuming aspect of many surgical procedures. For many surgical procedures, it is necessary to make a large opening in the human body to expose the area that requires surgical repair. There are instruments available, such as endoscopes, that allow viewing of certain areas of the human body through a small puncture wound without exposing the entire body cavity. Endoscopes can be used in conjunction with specialized surgical instruments to detect, diagnose, and repair areas of the body that previously required pen surgery to access.

Some surgical instruments used in endoscopic procedures are limited by the manner in which they access the areas of the human body in need of repair. In particular, the instruments may not be able to access tissue or organs located deep within the body or that are in some way obstructed. Also, many of the instruments are limited by the way they grasp tissue, apply a suture, or recapture a needle and suture. Furthermore, many of the instruments are complicated and expensive to produce due to the numerous parts and/or subassemblies required to make them function properly.

Suturing instruments, and more specifically suturing instruments used in endoscopic procedures, are generally rigid and do not provide the operator a range of motion to access difficult-to-reach parts of the anatomical region requiring sutures. Accordingly, multiple instruments of various configurations and sizes typically are used to access all of the necessary tissue areas. These limitations of known suturing instruments complicate the endoscopic procedure for the surgeon by requiring the insertion and removal of multiple instruments from a surgical site as the target suturing area changes during the course of the surgical procedure.

SUMMARY OF THE INVENTION

The invention generally relates to suturing instruments with improved maneuverability, efficiency, and functionality for use during a surgical procedure such as an endoscopic or laparoscopic procedure. The disclosed embodiments are directed toward a suturing instrument capable of delivering a suture to a treatment area wherein the treatment area is located in a difficult-to-reach area within the body of a patient. Various medical procedures require a substantially linear instrument in order to reach the treatment area and a

non-linear instrument once the instrument reaches the treatment area. For example, the body of the instrument must be fairly linear in order to fit through the cannula of a trocar assembly. The transformation from a substantially linear instrument to a non-linear instrument can be achieved with, for example, an instrument including a head that can be positioned straight or at an angle relative to the shaft of the instrument.

Some illustrative embodiments according to the invention are directed towards a suturing instrument including a suturing head that is coupled to the shaft of an elongate body member by a connector member which may be biased in either a linear orientation along the longitudinal axis of the shaft or any one of a variety of non-linear orientations with respect to the shaft's longitudinal axis. The elongate body member can include a handle at a proximal portion that is engaged to a suturing head at a distal portion by a connector member, the suturing head including a needle carrier and a needle catch. The connector member can comprise a resilient material such that an external force may be applied to the suturing head and move the suturing head from a biased orientation (e.g., linear) to an unbiased orientation (e.g., non-linear). Once the external force is removed, the resiliency of the connector member allows the suturing head to return from the unbiased orientation to the biased orientation. Therefore, a user may adjust the shape of the instrument by applying or removing an external force on the suturing head, such as, for example, pressing the suturing head against the pelvic floor, or placing the suturing head and connector member within the confines of a cannula. An embodiment also comprises a needle partially disposed within a needle carrier, with a suture attached on one end and a tissue-penetrating tip on the other end. An actuator can be used to deliver the needle from the needle carrier to the needle catch. In another embodiment, the suturing instrument can hold and deploy a plurality of suturing needles. In a further embodiment, each suturing needle can be attached to a distinct suture, thereby allowing for the placement of a plurality of sutures prior to removal of the suturing device. The suturing head can define a recess of its surface adjacent to the concave side of the needle carrier. Alternatively, the suturing head does not define such a recess, remaining relatively flat on the surface adjacent to the concave side of the needle carrier to improve its suturing performance in certain circumstances. One such circumstance can include the anastomosis of a lumen (such as a urethra) in which the suturing head is disposed within the lumen, and the suturing needle traverses from the inside to the outside wall of the lumen.

In one embodiment, the connector member can comprise a spring or a plurality of springs, the spring being either in linear orientation or in a pre-formed non-linear or 'bent' orientation. In another embodiment, the connector member can be constructed of a polymer or a flexible plastic.

In an embodiment, the elongate body, connector member and suturing head of the suturing instrument can fit and move rotationally and slidably within a cannula. The cannula can comprise, for example, a laparoscopic trocar assembly.

A further embodiment allows the suturing head to be movable independently of the elongate body member in response to an external force. The connector member in this embodiment can comprise a spring or a plurality of springs, or a flexible polymer or plastic material. The elongate body, connector member and suturing head can be slidably disposed within a cannula. The suturing instrument can include a handle at the proximal portion of the elongate member.

In another embodiment, the suturing instrument can comprise an elongate body member coupled to a suturing head by a flexible connector member, the flexible connector member being biased such that the elongate body member is in a non-linear orientation with respect to the suturing head. The suturing head can be aligned with the elongate body member by an externally applied force, such as when it is placed within a cannula. The flexible connector can comprise a spring or a plurality of springs, or a flexible polymer or plastic.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosed embodiments will be further explained with reference to the attached drawings, wherein like structures are referred to by like numerals throughout the several views. The drawings are not necessarily to scale, the emphasis having instead been generally placed upon illustrating the principles of the invention and the disclosed embodiments.

FIG. **1**A is a schematic plan view of one embodiment of a suturing instrument in accordance with the invention;

FIGS. **1**B and **1**C are schematic cross-sectional views of a proximal portion and a distal portion of the suturing instrument of FIG. **1**A;

FIG. **2** is an embodiment of the presently disclosed suturing instrument;

FIG. **3**A shows the suturing instrument of FIG. **2** traveling to a treatment area. FIG. **3**B shows the suturing instrument of FIG. **2** engaging the treatment area. FIG. **3**C shows the suturing instrument of FIG. **2** being removed from the treatment area;

FIG. **4** shows an embodiment wherein the suturing instrument is rotated about an axis of an elongate body member;

FIG. **5**A shows an embodiment of the presently disclosed suturing instrument wherein the suturing head is biased in a non-linear orientation with respect to the elongate body member. FIG. **5**B shows the suturing instrument of FIG. **5**A being delivered to a treatment area wherein the instrument has been surrounded by a cannula from, for example, a trocar assembly. FIG. **5**C shows the suturing instrument of FIG. **5**A wherein the suturing head exits the cannula at the treatment area and thereby regains the initial non-linear orientation with respect to the elongate body member;

FIG. **6**A shows an embodiment of a suturing device wherein the suturing head is engaged to an elongate body member by a hinge pin. FIG. **6**B shows a distal portion of the suturing device of FIG. **6**A. FIG. **6**C shows a proximal portion of the suturing device of FIG. **6**A;

FIG. **7**A is an enlarged cross-sectional view of the distal portion of the suturing instrument of FIG. **1**A;

FIG. **7**B is a schematic top view of the suturing instrument of FIG. **7**A taken at line **7**B-**7**B;

FIG. **8**A is a schematic plan view of a needle coupled to a suture for use in a suturing instrument in accordance with the invention;

FIG. **8**B is a schematic perspective view of a needle catch for use with the suturing instrument of FIG. **1**A;

FIGS. **9**A-**9**E are partial schematic cross-sectional views of the distal portion of the suturing instrument of FIG. **1**A during various operational phases

FIG. **10**A is a partial schematic cross-sectional view of a distal portion of a suturing instrument in accordance with another embodiment of the invention; and

FIGS. **10**B-**10**F are partial schematic perspective views of the distal portion of the suturing instrument of FIG. **9**A.

FIG. **11** is a 3-dimensional view of a suturing head of an instrument in which the suturing head does not define a

recess adjacent to the inside arc of the needle carrier. This embodiment is useful, for example, in the anastomosis procedure depicted in FIGS. **12**-**15**.

FIG. **12** is a 3-dimensional perspective view of a suturing instrument (such as the instrument of FIG. **11**) with the suturing head angled with respect to the long axis of the instrument and inserted into the lumen of a body structure (such as a urethra).

FIG. **13** is a side-view schematic illustration of the suturing instrument of FIG. **12** inserted into the abdominal cavity, with the suturing head inserted into the proximal end of a transected urethra. In this illustration, the upper portion of the body is located on the right.

FIG. **14** is a side-view schematic illustration of the suturing instrument of FIG. **12** in the abdominal cavity oriented away from the transected urethra, with the suturing head inserted into the urethral orifice of the neck of the bladder.

FIG. **15** is a schematic illustration of the suturing material having been threaded through the urethra and the neck of the bladder, with the suture ends brought out through the laparoscopic trocar cannula for subsequent tying and approximation of the urethra with the bladder. In this illustration, the upper portion of the body is located on the left.

DESCRIPTION

Illustrative embodiments according to the invention are directed towards a suturing instrument including a suturing head that is coupled to the shaft of an elongate body member of the instrument by a connector member which may be biased in either a linear orientation along the longitudinal axis of the shaft or any one of a variety of non-linear orientations with respect to the shaft's longitudinal axis. The connector member can comprise a resilient material such that an external force may be applied to the suturing head and move the suturing head from a biased orientation (e.g., linear) to an unbiased orientation (e.g., non-linear). Once the external force is removed, the resiliency of the connector member allows the suturing head to return from the unbiased orientation to the biased orientation. Therefore, a user may adjust the shape of the instrument by applying or removing an external force on the suturing head.

As will be discussed below, the external force may be supplied by an operator (such as a surgeon or other medical professional) manipulating the shaft of the instrument, or more typically a handle connected to the shaft, to cause the suturing head to contact a treatment area within the body of a patient. The operator then applies a force that causes the connector member to give and the head to deflect. Alternatively, the external force may be applied to the suturing head by surrounding the instrument with the cannula of a trocar assembly. Any one of a wide range of external forces may be used to adjust the position and orientation of the suturing head.

By relying on an external force to adjust the suturing head as opposed to mechanically adjusting the suturing head directly (see, for example, co-owned U.S. Pat. No. 6,955,643 issued Oct. 18, 2005, and U.S. Pat. No. 6,936,054 issued Aug. 30, 2005, and co-owned pending U.S. patent application Ser. No. 11/136,805, filed on May 24, 2005, the entirety of each of which are incorporated herein by reference), the suturing head may more easily travel a tortuous pathway to a treatment area because the head will deflect when coming into contact with tissue on the way to the treatment area. As such, the presently disclosed embodiments may lead to reduced tissue damage. In addition, the presently disclosed embodiments are easier and less expensive to construct as compared to a suturing instrument wherein movement of the suturing head is controlled by mechanically coupling the suturing head to a handle of the instrument.

FIG. **1**A depicts a presently disclosed embodiment of a suturing instrument **100** including a handle **102**, an elongate body member **104**, and a needle deployment mechanism **110**. The suturing instrument **100** also includes a distal portion **106** and a proximal portion **108**. A suturing head **107** is located at the distal portion **106**. The various components of the suturing head **107** will be discussed in detail below. The elongate body member **104** is mechanically coupled to the handle **102** at the proximal portion **108** and the suturing components are at least partially disposed within the suturing head **107** of the suturing instrument **100**. The suturing instrument **100** comprises a connector member **114** which allows the suturing head **107** to move independently of the elongate body member **104**.

The handle **102** could take a variety of forms, for example, the handle **102** could be one of the types used with Boston Scientific Corporation suturing systems, in particular the Capio® Push & Catch suturing system. Generally, the needle deployment mechanism **110** extends longitudinally through the elongate body member **104** to the distal portion **106** of the suturing instrument **100**, where the needle deployment mechanism **110** is coupled to a needle **128** (FIG. **7**A). The needle deployment mechanism **110** moves the needle **128** between a retracted position and a deployed position. The needle deployment mechanism **110** is shown in greater detail in FIGS. **1**B and **1**C.

Referring to FIG. **1**B, the proximal portion **108** of the suturing instrument **100** includes the handle **102**, the elongate body member **104**, a suture clip **144**, and the needle deployment mechanism **110**. The suture clip **144** may be coupled to the handle **102** or the elongate body member **104** and is used to hold an end of one or more sutures prior to placement in a patient. The needle deployment mechanism **110** includes an actuator **112** (button **117**, shaft **116**), a bearing **118**, a button end **119**, and a hole **121**. The bearing **118** rides along a cylindrical surface **105** that is formed by the inside diameter of the elongate body member **104**. A wireform **103** is inserted into the hole **121**, coupling it to the actuator button **117**. A spring **115** encircles the wireform **103**, abuts the button end **119**, and is compressed between the button end **119** and a spring washer **113**. The spring washer **113** is seated upon a center tube **107**. The center tube **107** is housed by the cylindrical surface **105** and is constrained in the distal portion **106**. A pusher wire **111** is attached to the wireform **103** by means of a weld, a coupling, adhesive or other means, and is slidably disposed within a guidance sleeve **109**, the sleeve **109** being disposed within a cylindrical surface **123** formed by the inside diameter of the center tube **107**. In one embodiment, the pusher wire **111** is constructed of nitinol, so chosen for its combination of properties that allow for bendability and high column strength when constrained. Nitinol is a nickel-titanium alloy. Those skilled in the art will recognize that the wire may comprise various materials; these materials are all within the spirit and scope of the present invention.

Referring to FIG. **1**C, the suturing head **107** of the suturing instrument **100** of FIG. **1**A includes the elongate body member **104**, the needle deployment mechanism **110**, a connector member **114**, a curved portion **126**, and a needle catch **122**. Referring again to the needle deployment mechanism **110**, the pusher wire **111** is attached by welding or other means to a coupling **150**, which is slidably disposed within a track **152**. The coupling **150** is attached to a carrier wire **154**, which by virtue of its attachment to the coupling **150** is also slidably disposed within the track **152**. The carrier wire **154** is mechanically coupled to an extendable needle carrier **124** by means of a weld, a coupling, adhesives, or other means. The coupling **150** abuts a backstop washer **156** that is slidably disposed about the pusher wire **111** and is contained within a pocket **160** that includes a back wall **162**, against which the backstop washer **156** rests. The track **152** terminates distally in a pocket **164** that includes a wall **166**. A downstop washer **158** is slidably disposed about the carrier wire **154** and constrained within the pocket **164**.

Various medical procedures require the suturing instrument **100** to enter the body in a linear or substantially linear shape, assume a non-linear shape once the instrument has reached the treatment area, and subsequently revert to a linear or substantially linear shape prior to being removed from the body. In addition, several medical procedures require an instrument capable of traveling a tortuous pathway with minimal damage to healthy tissue. The presently disclosed suturing instrument **100** comprises a connector member **114** which allows for the suturing instrument **100** to transform from a linear shape to a non-linear shape in response to an external force applied to the suturing head **107** of the suturing device **100**. In addition, the presence of the connector member **114** allows for the suturing head **107** to easily deflect when engaging a healthy tissue while traveling to the treatment area.

FIG. **2** shows various aspects of an embodiment of the presently disclosed suturing instrument **100**. The suturing instrument **100** comprises an elongate body member **104** wherein the elongate body member **104** comprises a handle **102** at a proximal portion **108**. At a distal portion **106**, the elongate body member **104** comprises a suturing head **107** engaged to the elongate body member **104** by a connector member **114**.

The suturing instrument **100** allows for the suturing head **107** to move independently of the elongate body member **104** by essentially decoupling the suturing head **107** from the elongate body member **104** at the connector member **114**. This decoupling allows the suturing head **107** to maintain a linear orientation relative to the elongate body member **104** while the suturing instrument **100** is being delivered to the treatment area and assume a non-linear orientation relative to the elongate body member **104** once the suturing instrument **100** arrives at the treatment area and is subjected to an external force.

In an embodiment, the connector member **114** comprises a flexible spring. In an embodiment, the spring is free to bend in any direction relative to the elongate body member **104**. In an embodiment, the spring is covered with a shrink wrap material (or any other suitable material) to prevent matter from entering the suturing instrument **100** through the coils of the spring.

In an embodiment, the connector member **114** comprises a plurality of springs. In an embodiment, each of the plurality of springs comprises a distinct strength and/or stiffness.

In an embodiment, the connector member **114** comprises a flexible inner-tube and a straight outer spring. The inner-tube prevents the nitinol wire from buckling when in compression. The suturing head **107** assumes an angle with respect to the elongate body member **104** when the suturing head **107** is pressed against a treatment area, such as the pelvic floor or inside the urethra.

In an embodiment, the connector member **114** comprises a flexible inner tube and a curved outer spring. The curved outer spring maintains an angled orientation with respect to the elongate body member **104**, unless an external force is applied to place the suturing head **107** in a linear orientation with the elongate body member **104**. Such an external force can occur, for example, when the suturing head **107**, the connector **114** and the elongate body member **104** are confined within a cannula as the suturing instrument **100** is inserted into or withdrawn from a body cavity. When the suturing head **107** is in a linear orientation with the elongate body member **104**, rotating the needle deployment mechanism **110** about the axis of the elongate body member **104** of the suturing instrument **100** will cause the suturing head **107** to also rotate about the axis of the elongate body member **104**. On the other hand FIG. **12** shows that when the suturing head **107** is in an angled position relative to the elongate body member **104**, rotating the needle deployment mechanism **110** in a direction of rotation "A" about the axis "X" of the suturing instrument **100** will cause the suturing head **107** to rotate in a direction of rotation "B" about its own axis "Y". As a result, the suturing head **107** can be made to rotate to a different suturing position while remaining within the lumen of the structure being sutured (such as the urethra), as depicted in FIG. **12**.

In an embodiment, the connector member **114** comprises a flexible polymer. In an embodiment, the connector member **114** comprises a flexible plastic. Those skilled in the art will recognize that any resilient material capable of allowing the suturing head **107** to move relative to the elongate body member **104** is within the spirit and scope of the present invention.

FIG. **3**A shows an embodiment wherein the suturing instrument **100** is being delivered to a treatment area. In an embodiment, the treatment area is the pelvic floor. As shown in FIG. **7**A, the suturing head **107** is substantially linear with respect to the elongate member **104** of the suturing instrument **100** as the suturing instrument **100** navigates a tortuous path to the treatment area. In various medical procedures, a linear device is necessary to reach the treatment area; more specifically, a non-linear device could not navigate the small diameter openings (for example, the cannula of a laparoscopic trocar assembly) through which the suturing instrument **100** needs to travel to reach a desired area. However, once the suturing instrument **100** reaches the treatment area, a non-linear device is required to perform the necessary procedure; i.e., the placement of sutures **136**.

FIG. **3**B shows the suturing instrument **100** reaching the treatment area (i.e., the pelvic floor). As shown, the suturing head **107** engages the pelvic floor and is pushed against the pelvic floor. As the pelvic floor supplies an external force to the suturing head **107**, the suturing head **107** assumes a non-linear orientation with respect to the elongate body member **104**. The non-linear orientation is possible because the suturing head **107** is decoupled from the elongate body member **104** at the connector member **114**. As discussed above, the connector member **114** comprises a flexible material allowing the suturing head **107** to bend relative to the elongate body member **104** in response to an external force. Once the nonlinear orientation is assumed, the suturing instrument **100** is ready to supply sutures **136** to the treatment area (as discussed in detail below).

FIG. **3**C shows the removal of the suturing instrument **100** from the treatment area. As the suturing instrument **100** is withdrawn, the external force acting on the suturing head **107** is removed (i.e., the pelvic floor is no longer exerting a force on the suturing head **107**). With the removal of this external force, the suturing head **107** resumes the initial linear orientation with respect to the elongate body member **104**. The connector member **114** comprises a resilient, flexible material which allows the suturing head **107** to move in all directions relative to the elongate body member **104** in response to an external force; however, the resiliency of the connector member **114** allows the suturing head **107** to resume the initial linear orientation to the elongate body member **104** once the external force is removed. Once the suturing head **107** has resumed a substantially linear orientation with respect to the elongate body member **104**, the suturing instrument **100** may be retracted from the treatment area and out of the body.

FIG. **12** shows an embodiment wherein the needle deployment mechanism **110** is rotated in the "A"-direction (as shown by an arrow) about an "X" axis of the elongate body member **104**. By rotating inner tube within the elongate body member **104** about the "X" axis in the direction of arrow "A", the suturing head **107** rotates about an axis "Y" in the direction of arrow "B". The flexible inner tube can be a flexible spring **115** situated within a larger flexible polymer connector member **114**. Rotation of the needle deployment mechanism **110** causes rotation of the suturing head **107** about its axis "Y" through the rotation of the flexible inner tube within the connector member **114**. A further embodiment shown in FIG. **12** includes a ratchet assembly **210** to maintain the axial orientation suturing head **107** during insertion of the suturing instrument **100** through a cannula. In an embodiment, the suturing head **107** is rotated prior to inserting the instrument **100** into a body.

FIG. SA shows an embodiment wherein the suturing head **107** is biased towards a substantially non-linear orientation with respect to the elongate body member **104** of the suturing instrument **100**. The initial non-linear orientation is possible because the connector member **114** is pre-formed at an angle such that in the absence of an exterior force, the suturing head **107** remains in a substantially non-linear orientation with respect to the elongate body member **104**.

In an embodiment, the connector member **114** is a pre-formed bent spring. In an embodiment, the connector member **114** comprises a pre-formed polymer. In an embodiment, the connector member **114** comprises a pre-formed plastic. Those of skill in the art will recognize that the connector member **114** may comprise various materials and remain within the spirit and scope of the present invention.

FIG. **5**B shows the suturing instrument **100** of FIG. **5**A wherein the suturing instrument **100** has been partially surrounded by the cannula **29** of a trocar assembly. (As used herein, a trocar assembly consists of an obturator and a cannula, in which the obturator has a pointed end and can slide within the lumen of the cannula, and can penetrate the skin or wall of an organ, allowing the cannula to be subsequently left in place). The cannula **29** produces an external force on the connector member **114** which substantially straightens the connector member **114** thereby resulting in a substantially linear relationship between the suturing head **107** and the elongate body member **104**.

In an embodiment, the cannula **29** comprises a biocompatible plastic. In an embodiment, the cannula **29** comprises a bio-compatible polymer. In an embodiment, the cannula **29** is a laparoscopic cannula **29**. The cannula **29** comprises a material capable of supplying an external force on the suturing instrument **100** which results in a substantially linear relationship between the suturing head **107** and the elongate body member **104** of the suturing instrument **100**. Therefore, the suturing instrument **100** surrounded by the cannula **29** may be delivered to the treatment area while maintaining a substantially linear relationship between the suturing head **107** and the elongate body member **104**.

Once the cannula **29** reaches the treatment area, the suturing instrument **100** resumes a non-linear orientation by exiting the cannula **29**. FIG. **5**C shows the suturing instrument **100** exiting the cannula **29** at the distal cannula opening **31**. Once the connector member **114** substantially exits the cannula **29**, the cannula **29** is no longer supplying an external force on the connector member **114**; therefore, the connector member **114** is free to reassume a pre-formed bent configuration wherein the suturing head **107** assumes a nonlinear orientation as compared to the elongate body member **104**. Once the suturing procedure is complete, the suturing head **107** is withdrawn into the cannula **29** and regains the substantially linear orientation. Once inside the cannula **29**, the suturing instrument **100** may be withdrawn from the body.

FIG. **6**A shows an embodiment wherein the suturing head **107** is engaged to the elongate body member **104** at a hinge pin **101**. The suturing head **107** is engaged to a head adjustment rod **109** which is accessible to a user at the handle **102**. FIG. **6**B shows a view of the distal portion **106** of the suturing instrument **100**. As shown, the suturing head **107** is engaged to the elongate body member **104** at a hinge pin **101**. FIG. **6**C shows a view of the distal portion **106** of an embodiment of the suturing instrument wherein a head adjustment rod **109** is engaged to the handle **102**. In an embodiment, the head adjustment rod **109** is engaged to the suturing head **107**; as such, a user may pivot the suturing head **107** about the hinge pin **101** by applying a force to the head adjustment rod **109**.

Referring to FIGS. **7**A and **7**B, the curved portion **126** defines a channel **178**, an opening (or needle exit port **120**) including a tunnel or (needle compartment **140**), a needle input/output slot **142**, and a suture slot **146**. The curved portion **126** also defines a recess **176** for receiving tissue (FIG. **1**C). The curved portion **126** also includes a knot pusher **184**. The needle carrier **124** is disposed within the channel **178** in the curved portion **126**. A distal portion **180** of the needle carrier **124** defines a lumen **138** for holding a needle **128*a***, **128*b***, or **128*c*** (generally needle **128**). An alternative embodiment is shown in FIG. **11**, in which the suturing head **107** does not define a recess **176** as shown in FIG. **1**C and FIG. **9**A. Instead, the contour of the suturing head at **176**A of FIG. **11** is relatively flat. Absence of the recess **176** helps to prevent the prolapse of tissue inward within the inside arc of the needle carrier **124** when the suturing head **107** is placed within a lumen to suture through the wall of the lumen. The distortion created by the prolapse of tissue could otherwise disturb the proper placement of the needle **128**. This design is useful, for example, in the anastomosis of the transected urethra to the urethral orifice of the neck of the bladder during radical prostatectomy surgery, as described later and schematically illustrated in FIGS. **12** to **15**.

Referring to FIG. **8**A, in one embodiment, the needle **128** includes a tip **130** and a shaft **134** coupled to the tip **130**, thereby forming a shoulder **132**. The shaft **134** is coupled to a suture **136*a***, **136*b***, **136*c*** (generally suture **136**). The needle **128** is inserted into the lumen **138** and held by a slight friction fit. The suture **136** extends out of a needle carrier suture slot **148** and the suture slot **146**. Needles **128*b*** and **128*c*** are stored in the needle compartment **140** prior to being deployed.

Referring again to FIGS. **1**B, **1**C, **7**A, and **7**B, in operation, a user (such as a physician or other medical personnel) actuates the needle deployment mechanism **110** by pushing on the button **117**, which via the attachment to the wireform **103** which is attached to the pusher wire **111**, moves the coupling **150** along the track **152** concomitantly moving the carrier wire **154**, which slidably moves the needle carrier **124** through the needle exit port **120**. The user continues to push the button **117** until the needle **128** enters the needle catch **122**. The needle catch **122**, as shown in FIG. **8**B, includes openings **170** defined by successive ribs **172**. The needle catch **122** receives the needle **128** (coupled to the suture **136**) through opening **170**, the ribs **172** deflect slightly to allow the needle **128** to pass through. After the formed shoulder **132** has passed the ribs **172**, the ribs **172** spring back to their original position defining the openings **170**, and the needle **128** remains captured in the needle catch **122**. The user releases the button **117** and the spring **115** urges the button **117** proximally, moving the pusher wire **111**, the coupling **150**, the carrier wire **154**, and the needle carrier **124** proximally along with the button **117** to the retracted position. As the needle carrier **124** moves back to the retracted position, the needle **128** slides out of the lumen **138**. The openings **170** are chosen to be smaller in dimension than the formed shoulder **132**. This causes the needle catch **122** to retain the needle **128** because the flat rear surface of the shoulder **132** prevents the needle **128** from passing back through the opening **170**. When it is necessary to remove the needle **128** from the needle catch **122**, the needle **128** may be moved toward an enlarged portion **174** of opening **172**. The enlarged portion **174** is sized to allow the formed shoulder **132** to pass through without resistance. The needle catch **122** is preferably constructed of thin stainless steel of high temper, such as ANSI **301** full hard. The needle catch **122** may be fabricated by means of stamping, laser machining, or chemical etching.

The suturing instrument's component materials should be biocompatible. For example, the handle **102**, the elongate body member **104**, and portions of the needle deployment mechanism **110** may be fabricated from extruded, molded, or machined plastic material(s), such as polypropylene, polycarbonate, or glass-filled polycarbonate. Other components, for example the needle **128**, may be made of stainless steel. Other suitable materials will be apparent to those skilled in the art. The material(s) used to form the suture should be biocompatible. The surgeon will select the length, diameter, and characteristics of the suture to suit a particular application. Additionally, the mechanical components and operation are similar in nature to those disclosed in U.S. Pat. Nos. 5,364,408 and 6,048,351, each of which is incorporated by reference herein in its entirety.

Referring to FIGS. **7**A-**7**B and **9**A-**9**E, the present invention enables a user to place multiple sutures **136** in a patient without removing the suturing instrument **100** from the patient. The user loads the suture **136*c*** through the first suture slot **146*a*** until the suture **136*c*** emerges from the second suture slot **146*b***. The user then inserts the needle **128*c*** through the needle input/output slot **142** into the needle compartment **140**. The user repeats this process for additional sutures **136** and needles **128**. The user can repeat this process for loading the first suture **136*a*** and the first needle **128*a***, or the user can insert the first needle **128*a*** directly into the needle carrier **124**. In either case, the sutures **136*a***, **136*b***, **136*c*** extend out of the second suture slot **146*b***. If the needle **128*a*** is loaded into the needle compartment **140**, the user pulls on the first suture **136*a*** (held by the suture clip **144**) to cause the first needle **128*a*** to slide down an inclined needle shelf **204** and out of the needle compartment **140** through the needle output slot **142** into the lumen **138** of the needle carrier **124**. The suture **136*a*** extends out of the needle suture slot **148** and the second suture slot **146*b***.

In another embodiment, the suture **136***a* could be pulled by attaching the suture **136***a* to a spool mounted on the elongate body member **104** and winding the spool. In still other embodiments, the suture **136***a* could be pulled by other mechanical means known in the art, such as by a lever, for example. After the needles **128***a*, **128***b*, **128***c* and sutures **136***a*, **136***b*, **136***c* are loaded into the suturing instrument **100**, portions of the sutures **136***a*, **136***b*, **136***c* extending out the suture slot **146***b* are held by the suture clip **144** (FIG. **1**B). The needle carrier **124**, which is part of the needle deployment mechanism **110**, is sequentially connectable to the needles **128** stored in the needle compartment **140**. This means that each needle **128** stored in the needle compartment **140** is connected to, and then deployed by, the needle carrier **124** one at a time in the order the needles **128** are dispensed from the needle compartment **140**.

The user then inserts the elongate body member **104** into a patient and orients the elongate body member **104** so that the needle exit port **120** is proximate to or in contact with the tissue **206** to be sutured. The user then pushes the button **117** (FIG. **1**B), as described above. Pushing the button **117** causes the needle carrier **124** (holding the first needle **128***a*) to extend out of the needle exit port **120** and push the needle **128***a* through the tissue **206**. As the first needle **128***a* is pushed through the tissue **206**, the first needle **128***a* pulls the first suture **136***a* through the tissue **206**. As the user continues to push the button **117**, the needle carrier **124** continues to advance out of the needle exit port **120** and directs the first needle **128***a* and the first suture **136***a* toward the needle catch **122**. The user continues to push the button **117** until the first needle **128***a* contacts and becomes captured by the needle catch **122** (FIG. **9**B). The user then retracts the needle carrier **124** by releasing the button **117**, as previously described.

After the user retracts the needle carrier **124**, the first needle **128***a* and the first suture **136***a* are left captured within the needle catch **122**, with the first suture **136***a* extending through the tissue **206** (FIG. **9**C). When the needle carrier **124** returns to a fully retracted position, the user pulls on the second suture **136***b* to cause the second needle **128***b* to slide down the inclined needle shelf **204** and out of the needle compartment **140** through the needle input/output slot **142** and into the lumen **138** of the needle carrier **124**. The second suture **136***b* extends out of the needle carrier suture slot **148** and the second suture slot **146***b*. The user then advances the needle carrier **124** as described above until the second needle **128***b* is captured by the needle catch **122** (FIG. **9**D). The user then retracts the needle carrier **124** as described above leaving the second needle **128***b* and the second suture **136***b* captured by the needle catch **122** (FIG. **9**E). This procedure can be repeated for the third needle **128***c*, or for as many needles as may be stored in the needle compartment **140**.

After one or more sutures **136** have been placed, the user withdraws the suturing instrument **100** from the patient. The user detaches the suture(s) **136** from the needle(s) **128** and ties a knot or knots into the suture(s) **136**. The user can then use the knot pusher **184** (shown in FIG. **1**C) to push the knot(s) into the patient as the knot(s) is tightened.

Referring to FIGS. **10**A-**10**F, in an alternative embodiment, the distal portion **106** of the suturing instrument **100** includes a curved portion **200**. The curved portion **200** defines a needle compartment **188**, a needle output slot **190**, a needle loading slot **192**, a first suture slot **196** (FIG. **10**B), and a second suture slot **198**. In this embodiment, a needle **128***a* is inserted into the needle carrier **124** with a suture **136***a* extending through the needle carrier suture slot **148** (FIG. **7**A), the first suture slot **196** and the second suture slot **198**. An additional needle **128***b* is inserted into the needle compartment **188** through the needle loading slot **192** with a suture **136***b* extending through the first suture slot **196** and the second suture slot **198** (FIG. **10**B).

In operation, this alternative embodiment functions largely the same way as the embodiment previously described. The user advances the needle carrier **124** by pressing the button **117** (FIG. **1**A) until the first needle **128***a* along with the first suture **136***a* is driven through the tissue and captured by the needle catch **122** (FIG. **10**D). After the needle **128***a* and the suture **136***a* are captured in the needle catch **122**, the needle carrier **124** is retracted so that the second needle **128***b* can be loaded into the needle carrier **124** (FIG. **10**B). When the needle carrier **124** is fully retracted, the user pulls the second suture **136***b* causing the second needle **128***b* to slide into the needle carrier **124** from the needle compartment **188** through the needle loading slot **190**. The user again advances the needle carrier **124** out of the needle exit port **120**, through the tissue, and into the needle catch **122** (FIG. **10**F). The user then retracts the needle carrier **124** leaving the needle **128***b* and coupled suture **136***b* captured by the needle catch **122**. In other embodiments, more needles **128** and sutures **136** can be loaded into the needle compartment **188**.

FIGS. **12**-**15** schematically show an embodiment of the medical device **100** being used for laparoscopic radical prostatectomy, in which the transected urethra is anastomosed to the urethral orifice of the neck of the bladder. Because of the flexibility of the connector member **114**, the surgeon can insert the suturing instrument **100** through the cannula of a trocar in the anterior abdominal wall. Once inside the abdominal cavity, the suturing head **107** bends at an angle relative to the elongate body member **104**, either from externally applied force against the pelvic floor, or from the intrinsic properties of the connector member **114** (comprising, for example, either a pre-formed bent spring or polymeric material). As shown in FIG. **12**, the suturing head **107** can then be inserted into the lumen of the transected urethra **213**. Rotating the button **117** of the needle deployment mechanism causes the inner tube within the elongated body **104** to rotate about the long axis "X" of the elongate body member **104**. This rotational movement is transmitted within the connector **114** through a ratchet assembly **210** in the suturing head **107** and rotates the suturing head **107** about its own axis "Y". The surgeon then actuates the needle deployment mechanism **110** by pushing on the button **117**, deploying a suture in an inside-out fashion through the wall of the urethra, as shown in FIG. **13**. In an embodiment, the outside surface of the suturing head **107** can be formed with a ridge **212** on at least one side that will stop the insertion of the suturing head **107** into the urethral lumen **213** at a predefined depth, allowing the instrument to reliably take an optimally sized 'bite' of tissue with the suturing needle. As shown in FIG. **14**, after placement of a suture through the urethra, the suturing instrument **100** is turned in a proximal direction and inserted into the urethral orifice of the neck of the bladder **214**. A second suture can then be placed, again in an inside-out fashion. In an embodiment, a single line of suture material is equipped with a needle on each end (doublearmed suture), so that a single suture thread can be deployed between the distal urethra and the proximal bladder neck—one end first through the urethra, and the other end next through the urethral orifice of the bladder neck. As shown in FIG. **15**, once the suture is placed through the urethra **213** and the bladder neck **214**, the suturing instrument can then be withdrawn through the laparoscopic cannula **29**, pulling the ends of the deployed suture material out of the abdominal cavity. At that point, each needle **128** (as shown in FIG. **8**A) can then be detached from the suture material **136**, and a knot can be tied between the two ends of each suture **136**. The surgeon can then use a knot pusher to slide the knot down into the surgical field, and approximate the urethra **213** to the bladder neck **214** by applying tension on the knotted thread.

Certain embodiments according to the invention have been disclosed. These embodiments are illustrative of, and not limiting on, the invention. Other embodiments, as well as various modifications and combinations of the disclosed embodiments, are possible and are within the scope of this disclosure.

What is claimed is:

1. A suturing instrument comprising:

an elongate body member including a handle at a proximal portion and engaged to a suturing head at a distal portion by a connector member, the suturing head including a needle carrier and a needle catch, the suturing head being adjustable between a linear or substantially linear orientation relative to the elongate body member and a non-linear orientation relative to the elongate body member by application of an external force; the suturing head being biased to its non-linear orientation;

a needle partially disposed within a lumen defined by the needle carrier, the needle engaging a suture at a first end and including a tissue-penetrating tip at a second end; and

an actuator capable of delivering the needle from the needle carrier to the needle catch, wherein rotation of the actuator about a longitudinal axis of the elongate body member causes the suturing head to rotate, with respect to the elongate body member, about the longitudinal axis of the elongate body member; and

a trocar having a cannula defining a lumen, the suturing head and the connector member being retractable within the lumen such that:

the suturing head and the connector member are wholly disposed within the cannula; and

the suturing head is forced to its linear or substantially linear orientation by the cannula.

2. The suturing instrument of claim **1**, wherein the connector member comprises a spring.

3. The suturing instrument of claim **1**, wherein the connector member comprises a plurality of springs.

4. The suturing instrument of claim **1**, wherein the connector member comprises a polymer.

5. The suturing instrument of claim **1**, wherein the connector member comprises a flexible plastic.

6. The suturing instrument of claim **1**, wherein the connector member comprises a preformed non-linear spring.

7. The suturing instrument of claim **1**, wherein the trocar is a laparoscopic trocar.

8. The suturing instrument of claim **1**, further comprising a plurality of needles.

9. The suturing instrument of claim **8**, wherein each needle engages a distinct suture thereby allowing for placement of a plurality of sutures prior to removal of the suturing instrument.

10. The suturing instrument of claim **1**, wherein the suturing head includes a curved portion defining a channel, a needle exit port, a needle compartment holding a plurality of needles including the needle, and a needle output slot, the curved portion defining a recess configured to receive bodily tissue, wherein the needle is configured to be released from the needle compartment via the needle output slot, and disposed within the channel to be engaged with the needle carrier.

11. A suturing instrument comprising an elongate body member including an actuator, and a trocar having a cannula defining a lumen, the elongate body member being engaged to a suturing head by a flexible connector member, the suturing head being movable independently of the elongate body member in response to an external force, the suturing head being biased to a non-linear orientation with respect to the elongate body member, the suturing head and the connector member being retractable within the lumen such that that the suturing head and the connector member are surrounded by the cannula, and the suturing head is forced to a linear or substantially linear orientation by the cannula, wherein:

rotation of the actuator about a longitudinal axis of the elongate body member causes the suturing head to rotate, with respect to the elongate body member, about the longitudinal axis of the elongate body member; and

distal movement of the actuator causes deployment of a needle included in the suturing head.

12. The suturing instrument of claim **11**, wherein the connector member comprises a spring.

13. The suturing instrument of claim **11**, wherein the connector member comprises a plurality of springs.

14. The suturing instrument of claim **11**, wherein the connector member comprises a flexible polymer.

15. The suturing instrument of claim **11**, further comprising a handle disposed at a proximal portion of the elongate body member.

16. The suturing instrument of claim **11**, wherein the suturing head includes a curved portion defining a channel, a needle exit port, a needle compartment holding a plurality of needles including the needle, and a needle output slot, the curved portion defining a recess configured to receive bodily tissue, the suturing head including a needle carrier, wherein the needle is configured to be released from the needle compartment via the needle output slot, and disposed within the channel to be engaged with the needle carrier.

17. A suturing instrument, comprising:

an elongate body member including an actuator, the elongate body member being coupled to a suturing head by a flexible connector member, the flexible connector member being biased such that the elongate body member is in a nonlinear orientation with respect to the suturing head, wherein rotation of the actuator about a longitudinal axis of the elongate body member causes the suturing head to rotate, with respect to the elongate body member, about the longitudinal axis of the elongate body member, the suturing head including a curved portion defining a channel, a needle exit port, a needle compartment holding a plurality of needles, and a needle output slot, the curved portion defining a recess configured to receive bodily tissue, the suturing head including a needle carrier disposed within the channel; and

a trocar having a cannula defining a lumen, the suturing head and the flexible connector member being retractable within the lumen such that the suturing head and the flexible connector member are wholly disposed within the cannula, the cannula comprising a material capable of applying an external force to the suturing instrument to produce a linear or substantially linear relationship between the suturing head and the elongate body member, wherein a needle of the plurality of needles is configured to be released from the needle compartment via the needle output slot, and disposed within the channel to be engaged with the needle carrier, wherein distal movement of the actuator causes deployment of the needle carrier from a retracted position to an extended position.

18. The suturing instrument of claim **17**, wherein the flexible connector member comprises a spring.

19. The suturing instrument of claim **17**, wherein the flexible connector member comprises a plurality of springs.

20. The suturing instrument of claim **17**, wherein the flexible connector member comprises a flexible polymer.

* * * * *

patsnap

专利名称(译)	缝合仪器		
公开(公告)号	US9931111	公开(公告)日	2018-04-03
申请号	US14/262099	申请日	2014-04-25
[标]申请(专利权)人(译)	波士顿科学西美德公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED，INC.		
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IPC分类号	A61B17/04 A61B17/12 A61B17/11 A61B17/29		
CPC分类号	A61B17/0469 A61B17/1114 A61B2017/2927 A61B2017/0472 A61B2017/2905 A61B2017/047		
优先权	60/857615 2006-11-07 US		
其他公开文献	US20140236190A1		
外部链接	Espacenet USPTO		

摘要(译)

一种缝合器械包括缝合头，该缝合头通过连接器构件联接到器械的细长本体构件的轴上，该连接器构件可以沿着轴的纵向轴线以线性定向偏置，或者可以沿着轴的纵向轴线中的任何一个偏置，线性方向相对于轴的纵向轴线。连接器构件可以包括弹性材料，使得可以向缝合头施加外力并且将缝合头从偏置取向（例如线性）移动到无偏置取向（例如，非线性）。一旦外力被移除，连接器构件的弹性允许缝合头从非偏压取向返回到偏压取向。因此，使用者可以通过在缝合头上施加或移除外力来调整器械的形状。