US012390215B2

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

(10) **Patent No.: US 12,390,215 B2**
(45) **Date of Patent: Aug. 19, 2025**

(54) **SUTURING WITH AN ENDOLUMINAL GASTROPLASTY DEVICE**

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(73) Assignee: **Nitinotes Ltd.**, Caesarea (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 380 days.

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(22) PCT Filed: **Feb. 23, 2021**

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§ 371 (c)(1),
(2) Date: **Aug. 25, 2022**

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PCT Pub. Date: **Sep. 2, 2021**

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Related U.S. Application Data

(60) Provisional application No. 62/981,573, filed on Feb. 26, 2020.

(51) **Int. Cl.**
A61B 17/04 (2006.01)
A61B 17/06 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/0487*** (2013.01); ***A61B 17/06066*** (2013.01); ***A61B 17/0625*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/0401; A61B 17/0487; A61B 17/06066; A61B 17/0625;
(Continued)

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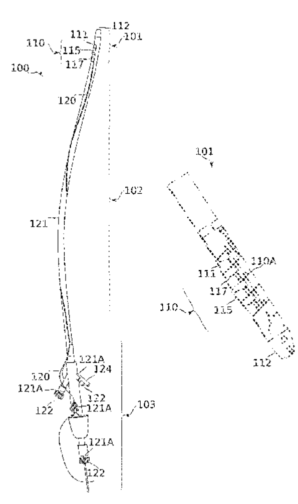
Primary Examiner — Kathleen S Holwerda

(57) **ABSTRACT**

Suture clips configured to be placed in a predetermined path of a suturing needle that advances through a device inserted to a body cavity, and remotely operated from that position to secure and clamp suturing. In some embodiments, a suture tightening device is placed in the predetermined path and configured to capture the suture and shorten a length of tissue-engaged suture by pulling on the suture. In some embodiments, sensors are placed along the needle path and used to provide an indication of needle position and/or status.

19 Claims, 13 Drawing Sheets



(51) **Int. Cl.**

A61B 17/062	(2006.01)
A61F 5/00	(2006.01)
A61B 17/00	(2006.01)
A61B 90/00	(2016.01)

(52) **U.S. Cl.**
CPC .. ***A61F 5/0086*** (2013.01); *A61B 2017/00026* (2013.01); *A61B 2017/00039* (2013.01); *A61B 2017/00561* (2013.01); *A61B 2017/0488* (2013.01); *A61B 2017/0496* (2013.01); *A61B 2017/0498* (2013.01); *A61B 2017/06076* (2013.01); *A61B 2090/064* (2016.02)

(58) **Field of Classification Search**
CPC A61B 2017/00026; A61B 2017/00039; A61B 2017/00561; A61B 2017/0488; A61B 2017/0496; A61B 2017/0498; A61B 2017/06076; A61B 17/0469; A61B 17/0491; A61F 5/0086
See application file for complete search history.

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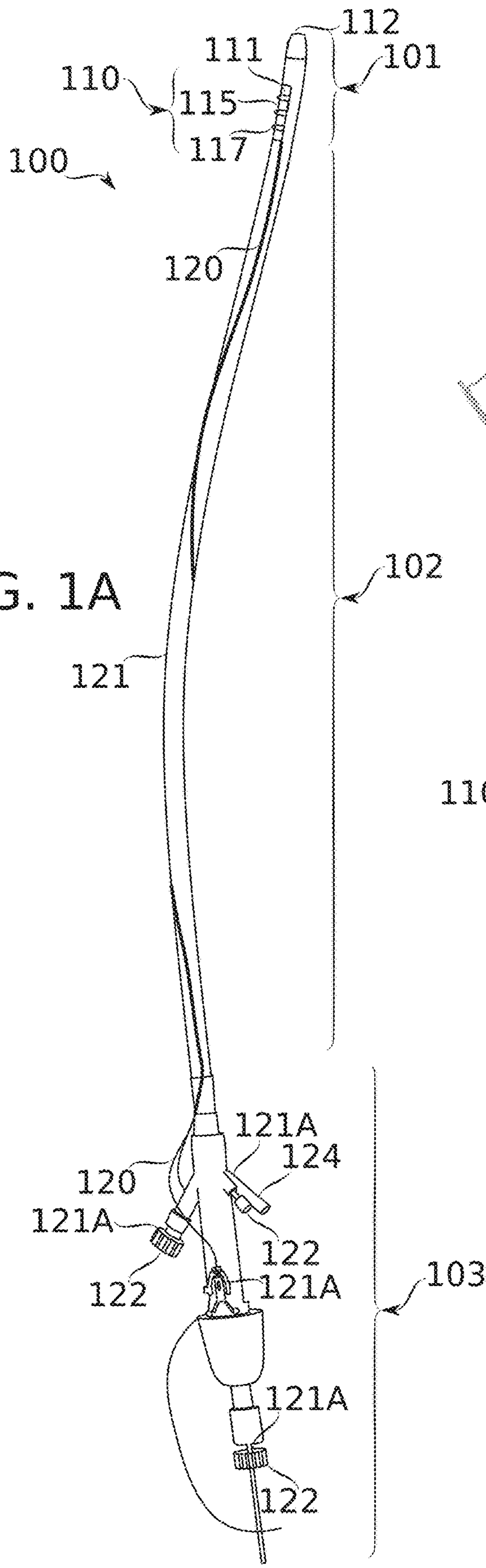
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FIG. 1A

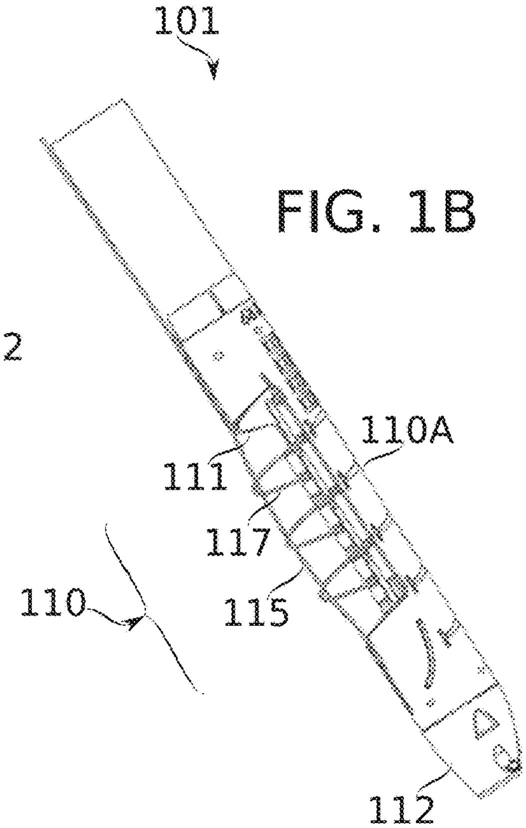
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FIG. 1B

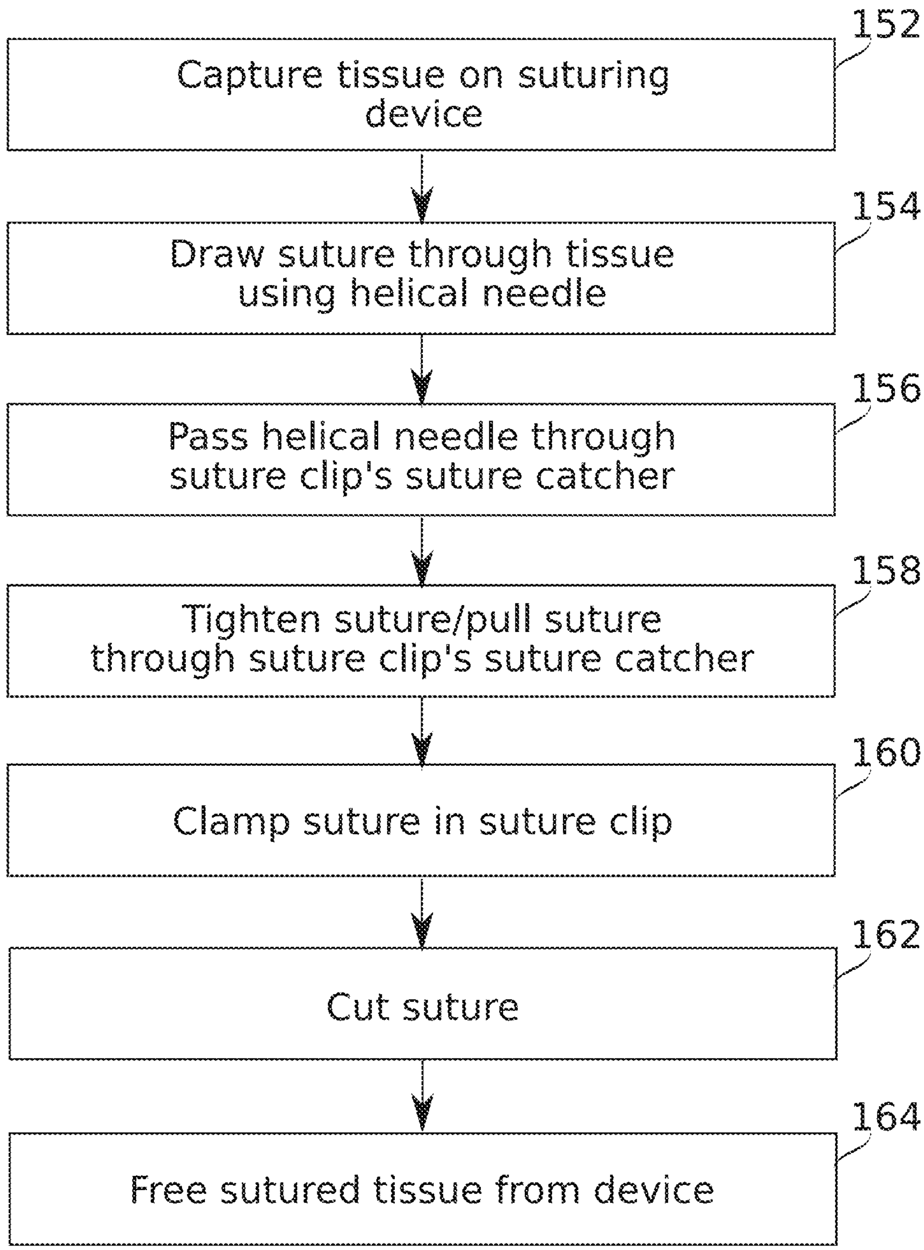
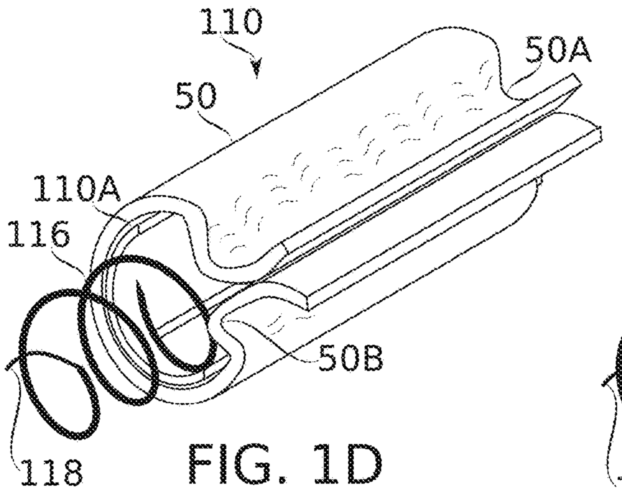

152
Capture tissue on suturing device
154
Draw suture through tissue using helical needle
156
Pass helical needle through suture clip's suture catcher
158
Tighten suture/pull suture through suture clip's suture catcher
160
Clamp suture in suture clip
162
Cut suture
164
Free sutured tissue from device

FIG. 1C



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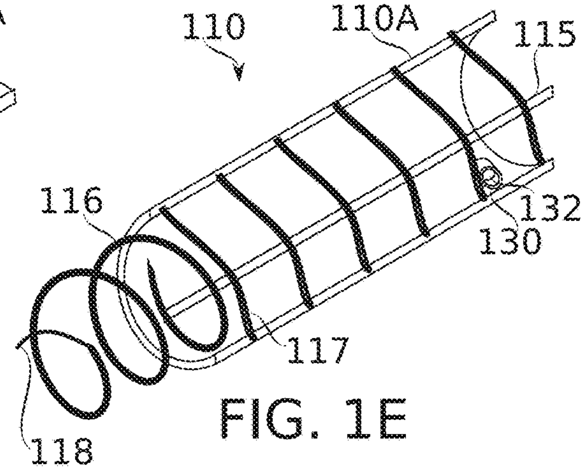
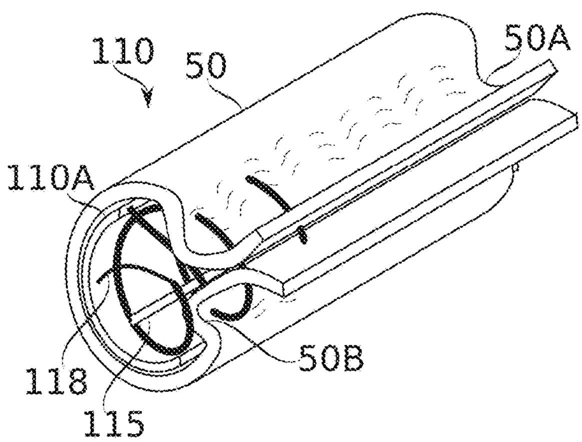


FIG. 1E



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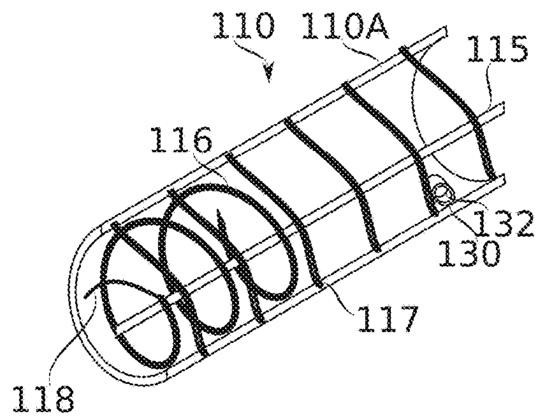


FIG. 1G

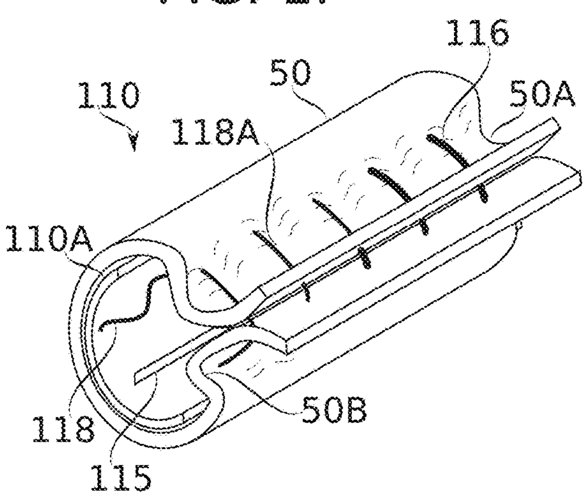


FIG. 1H

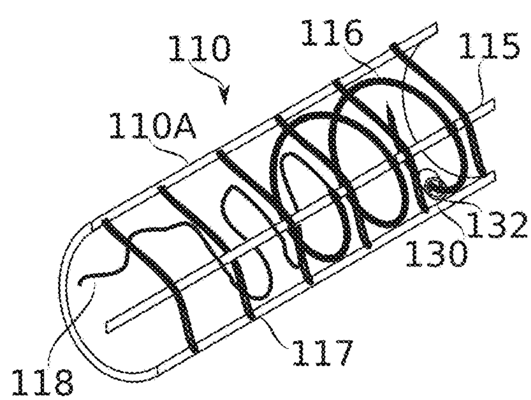


FIG. 1I

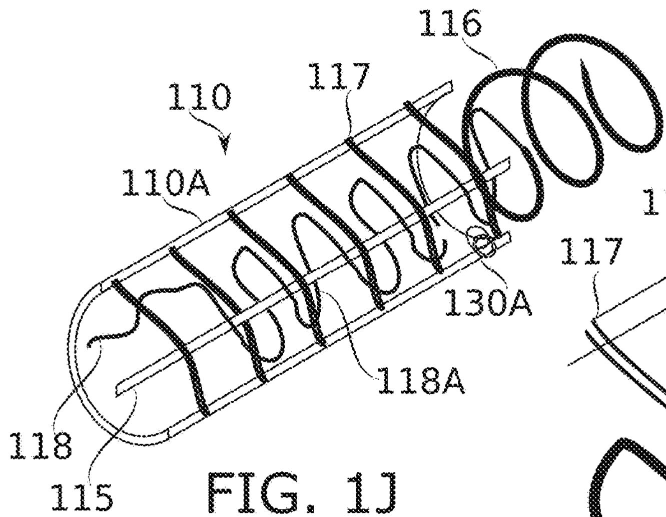


FIG. 1J

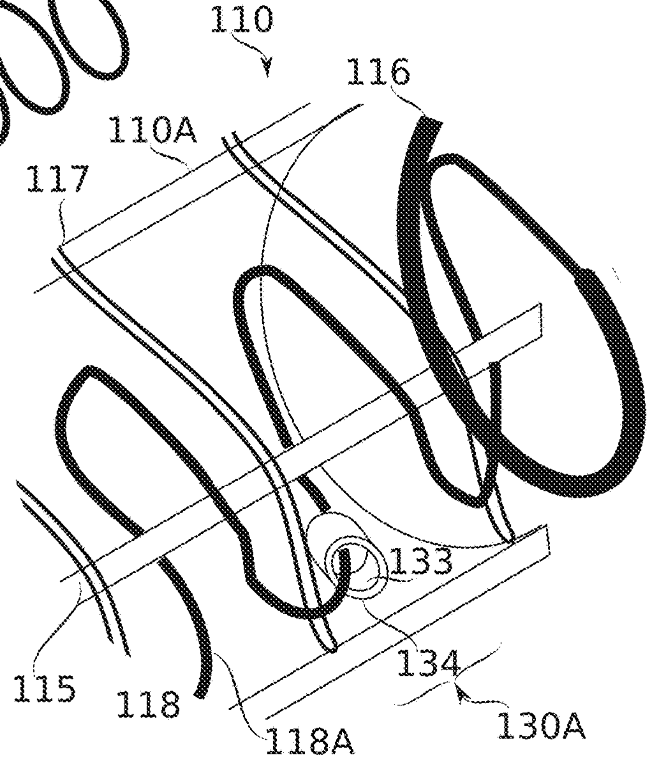


FIG. 1K

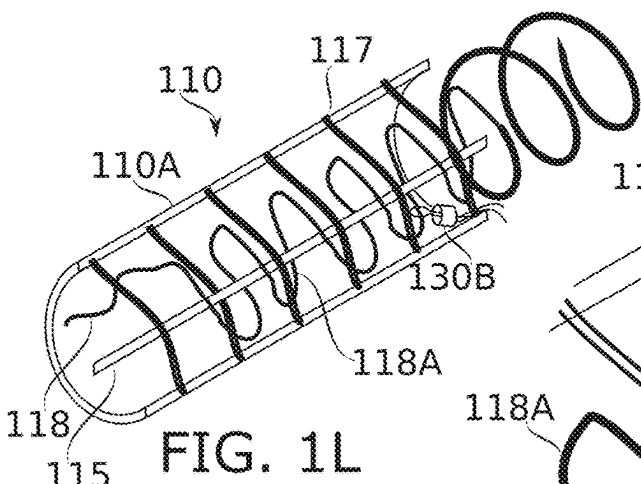


FIG. 1L

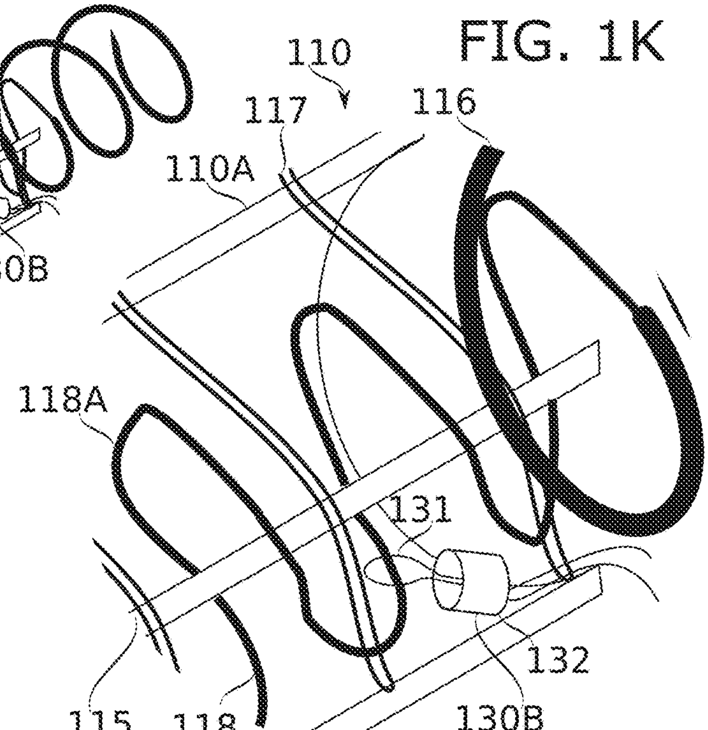


FIG. 1M

FIG. 2A

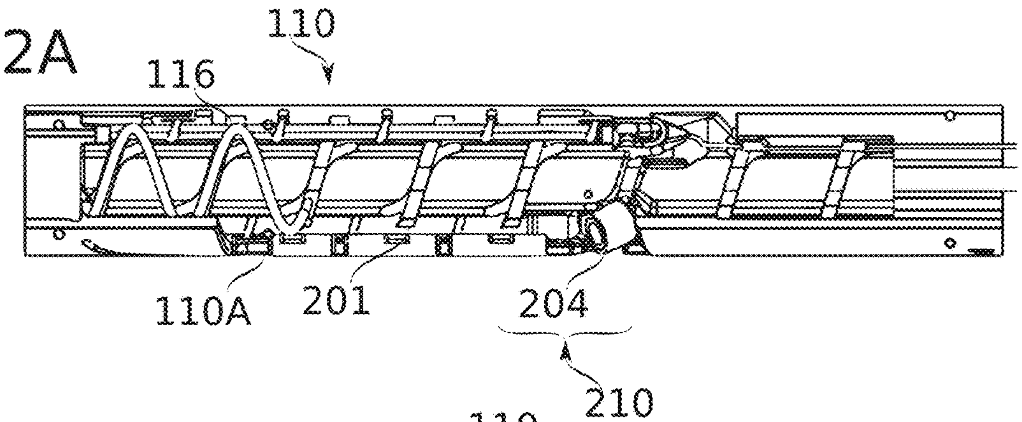


FIG. 2B

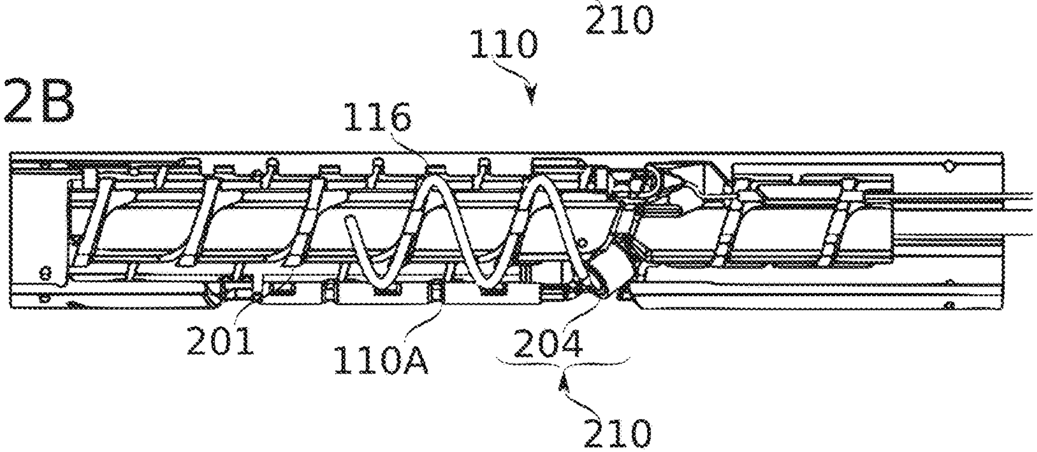


FIG. 2C

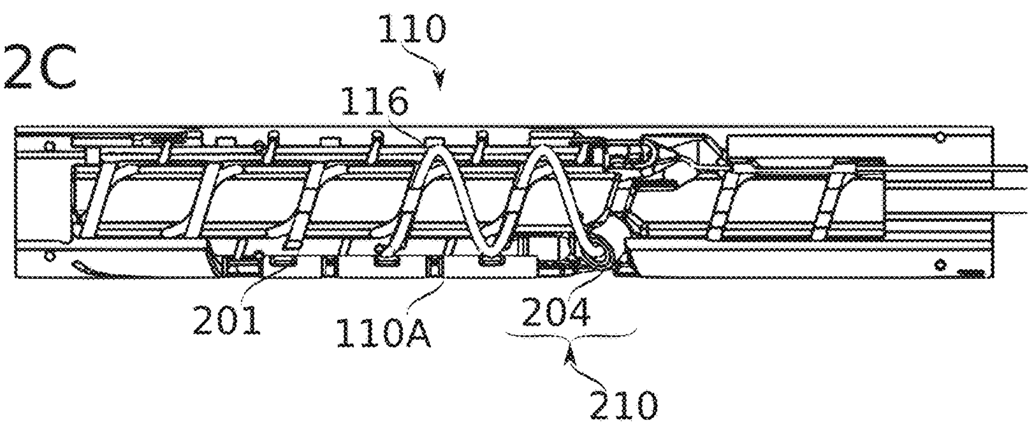
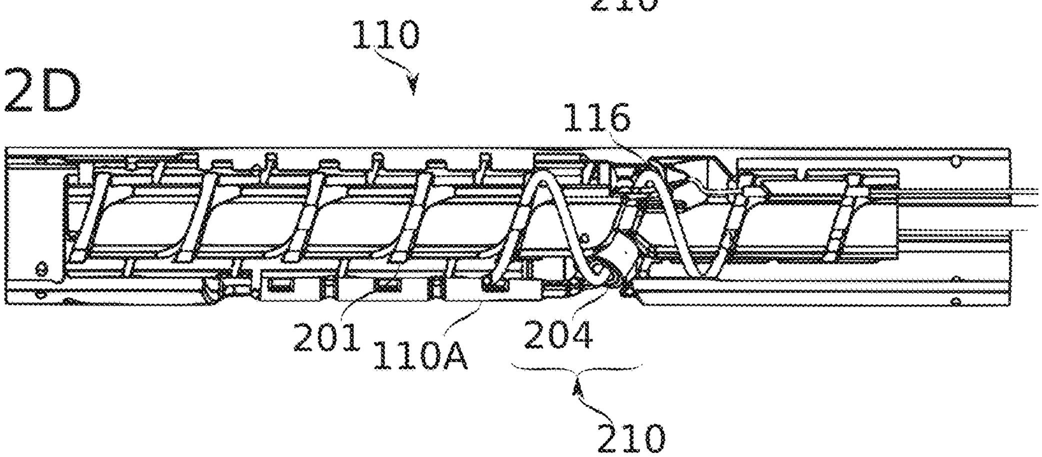


FIG. 2D



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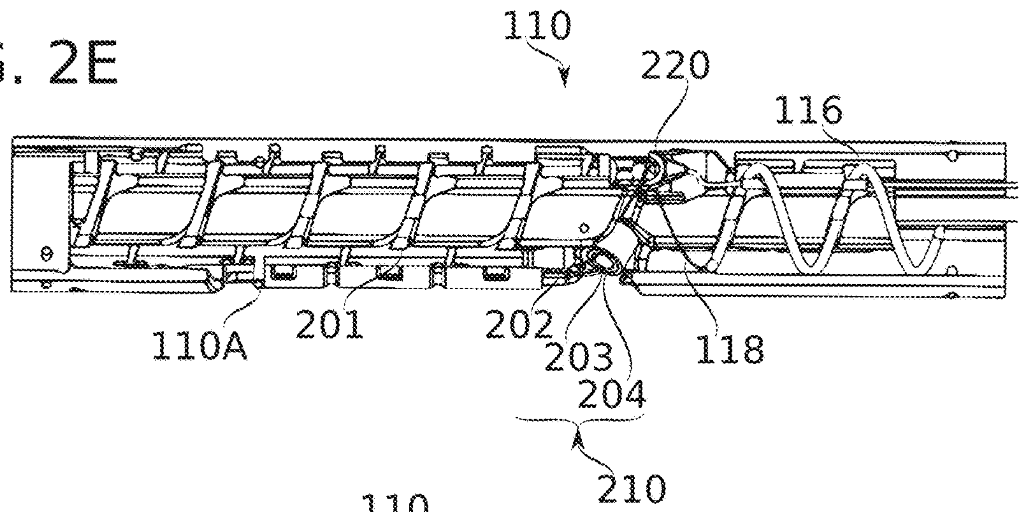

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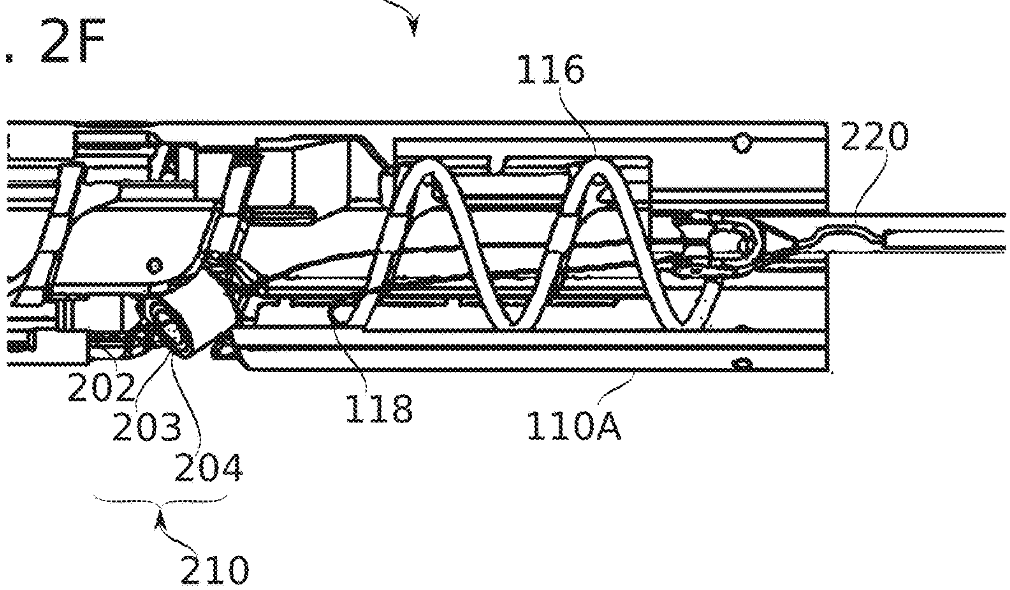

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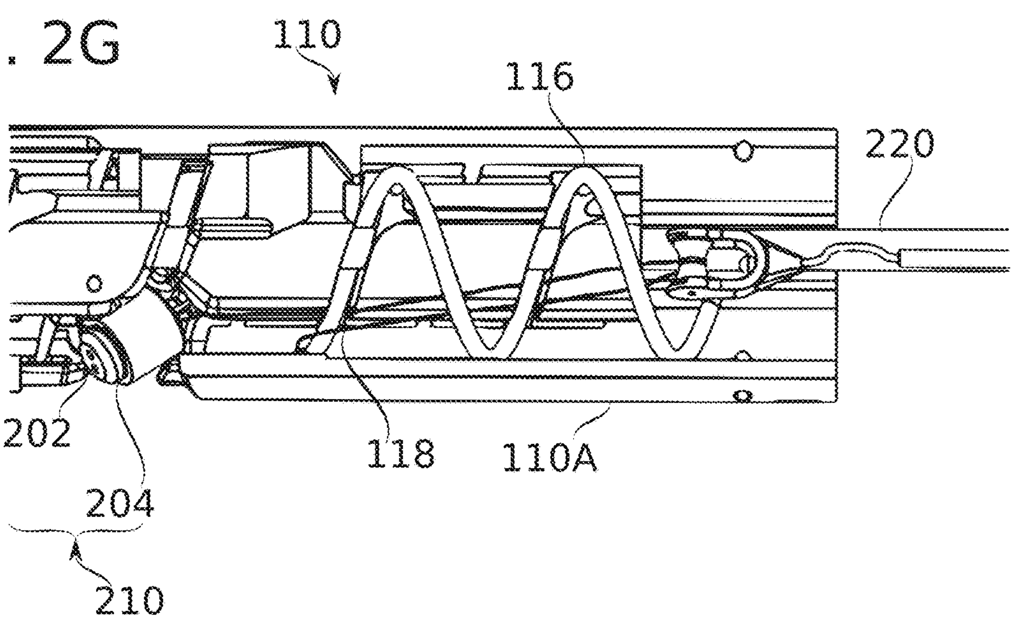


FIG. 3A

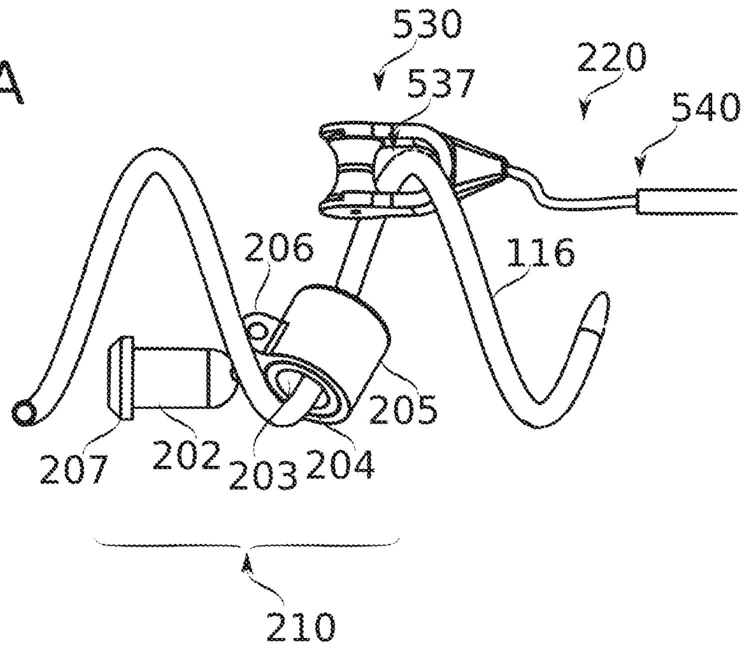


FIG. 3B

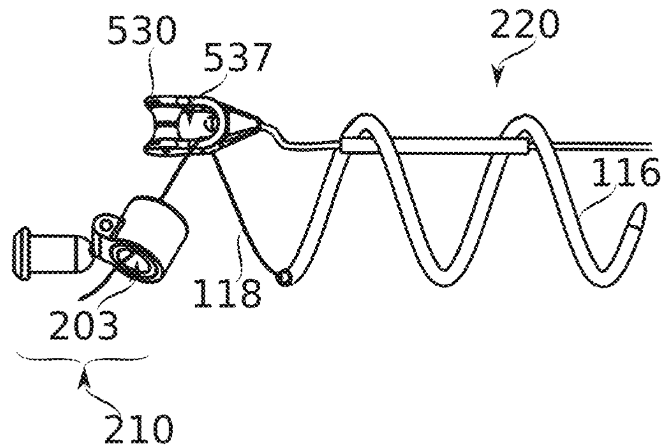


FIG. 3C

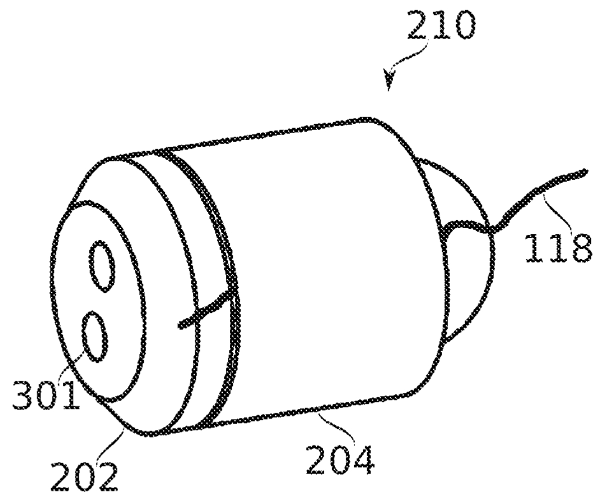
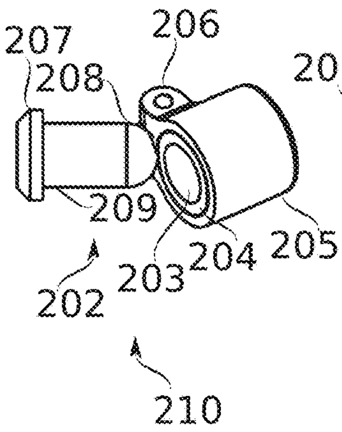


FIG. 4A



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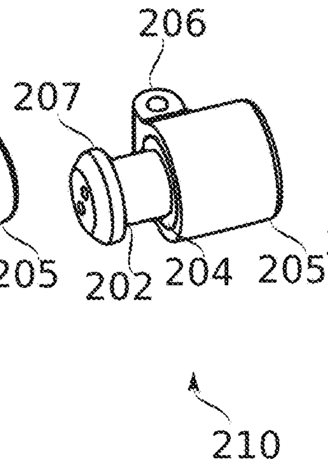

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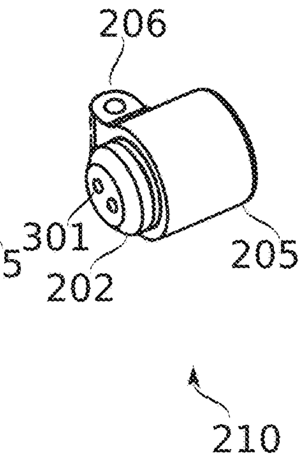

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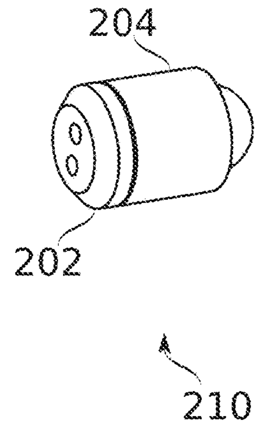
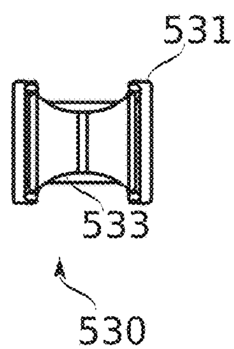


FIG. 5A



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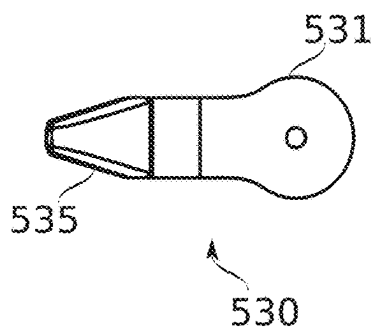

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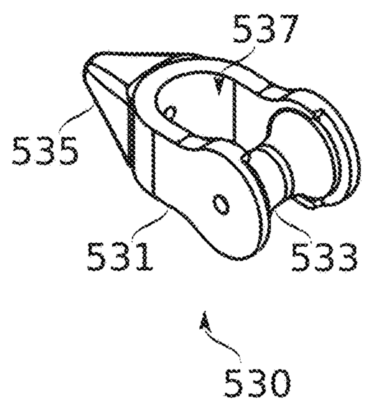

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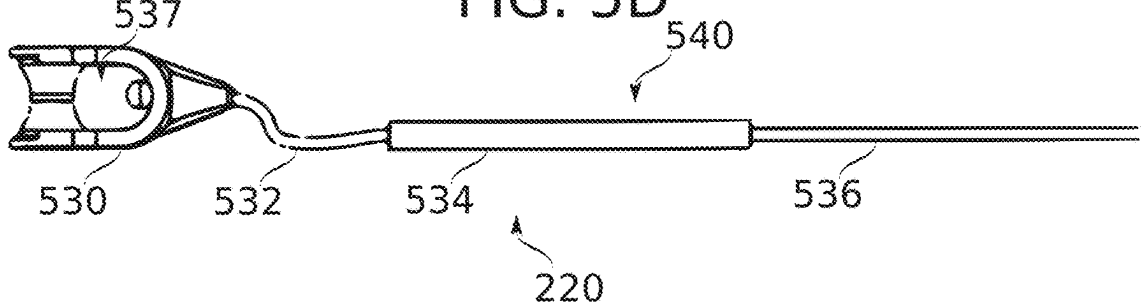


FIG. 6A

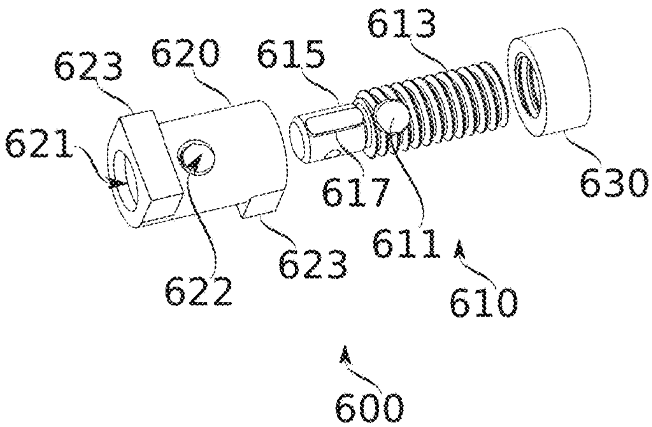
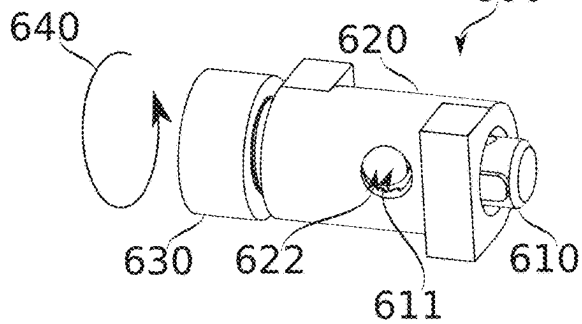


FIG. 6B



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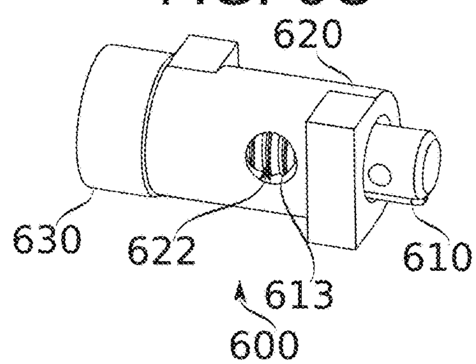

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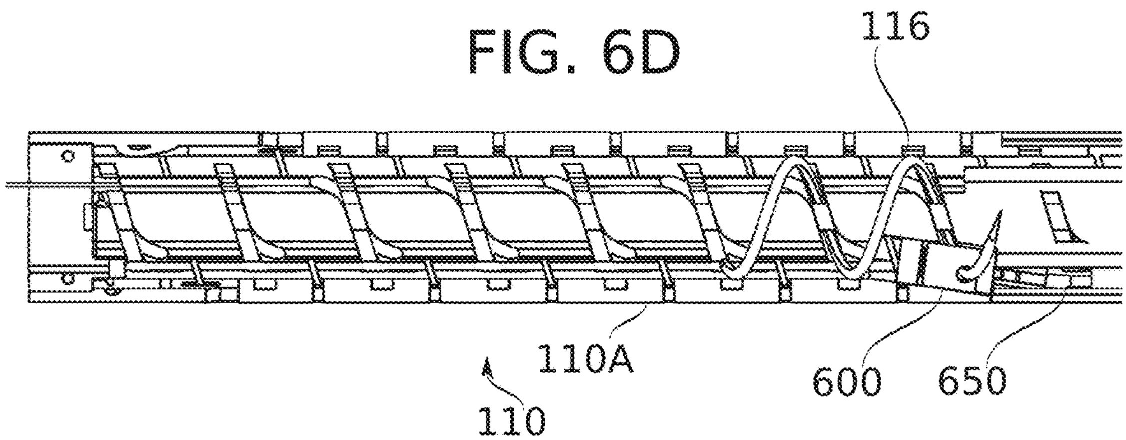


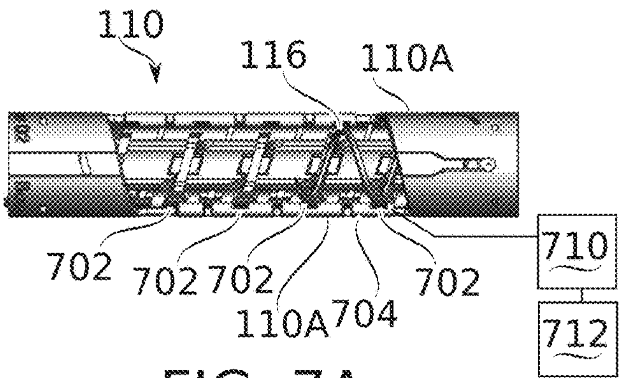
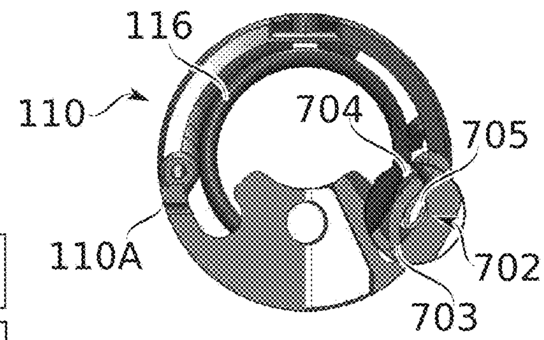


FIG. 7A



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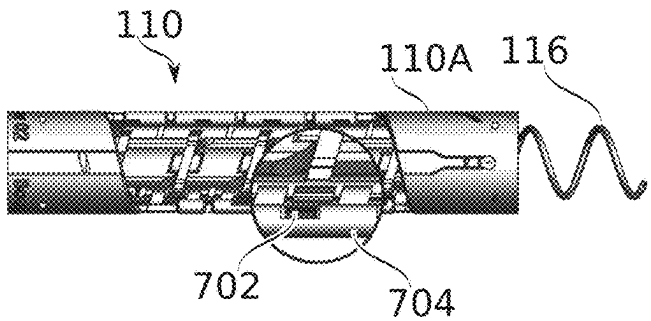

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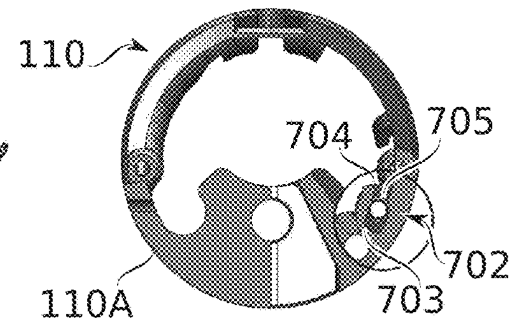

FIG. 7D

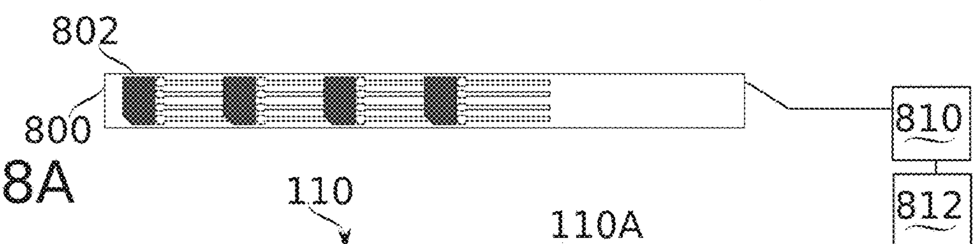

FIG. 8A

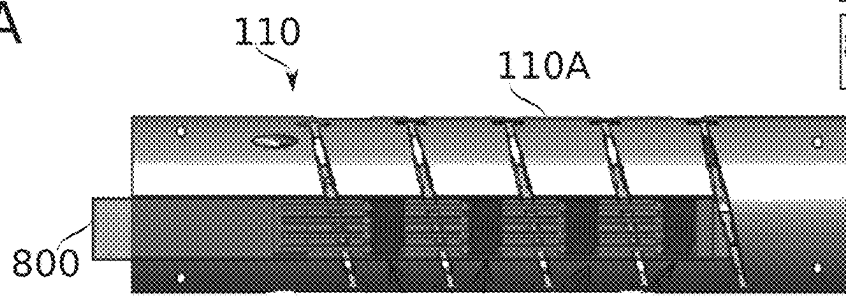

FIG. 8B

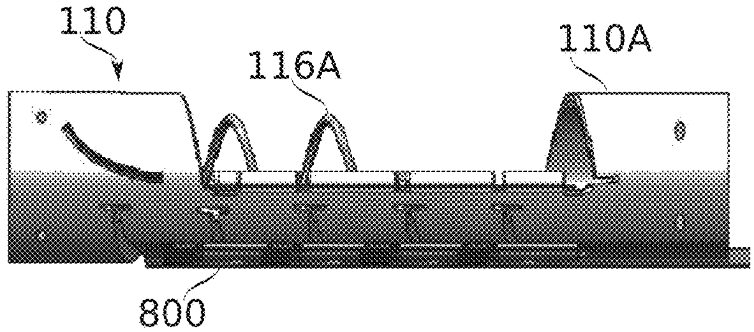

FIG. 8C

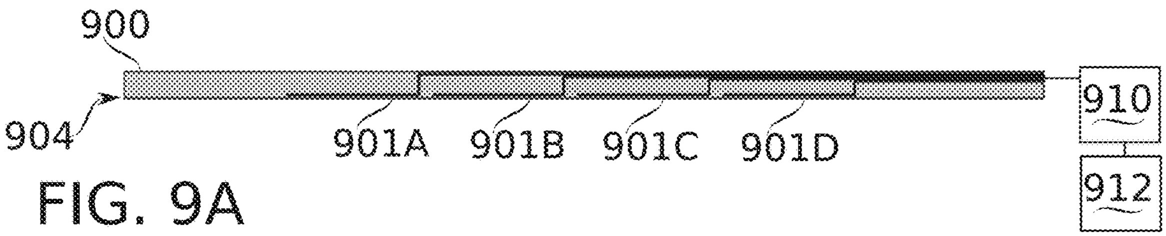

FIG. 9A

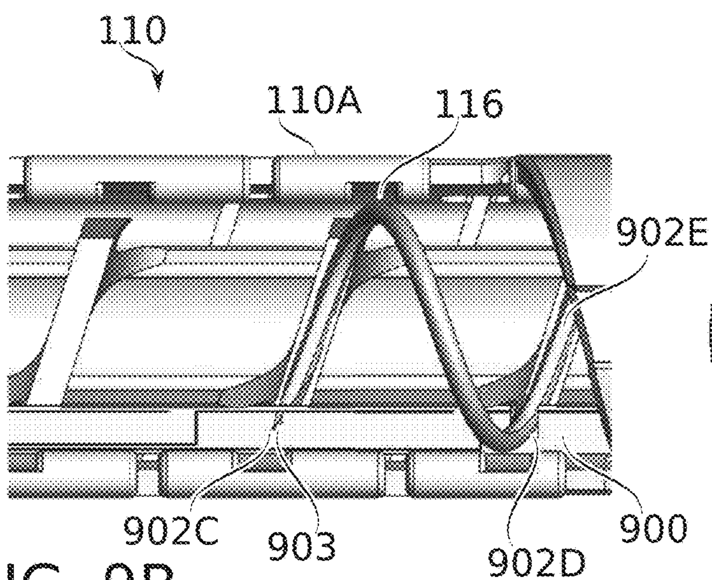

FIG. 9B

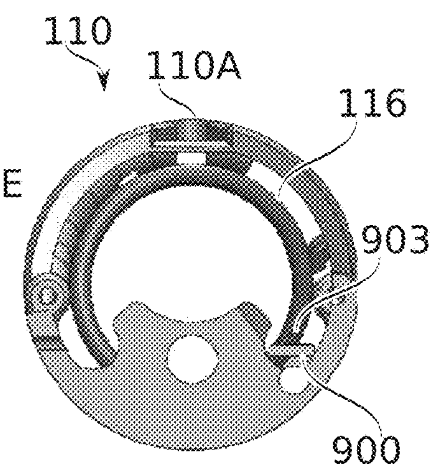

FIG. 9C

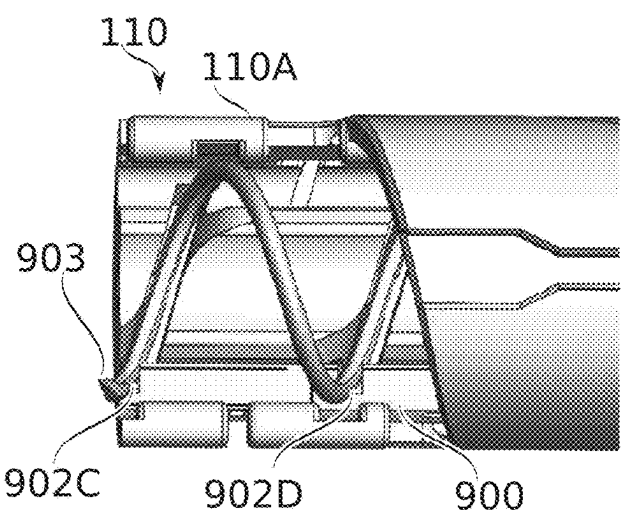

FIG. 9D

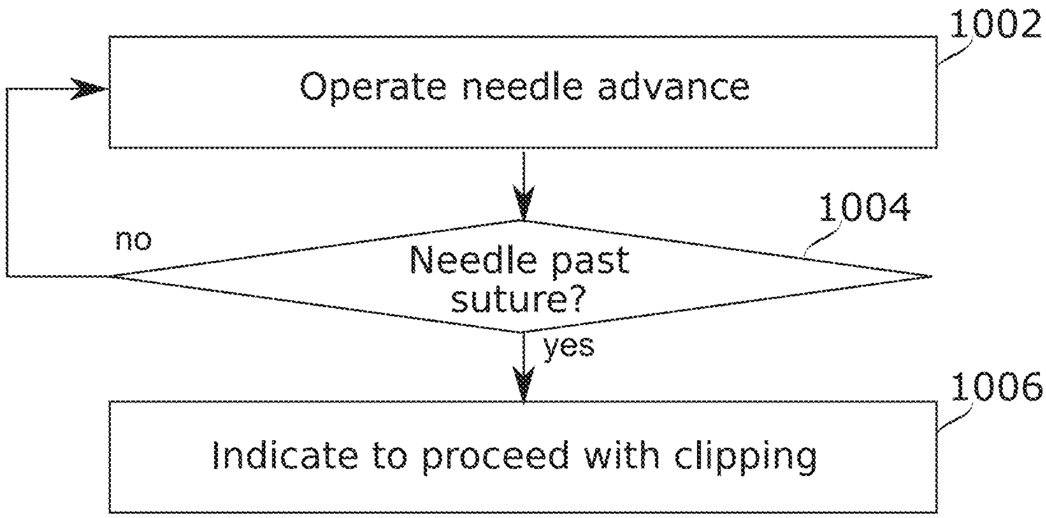
1002
Operate needle advance
1004
no
Needle past suture?
yes
1006
Indicate to proceed with clipping

FIG. 10

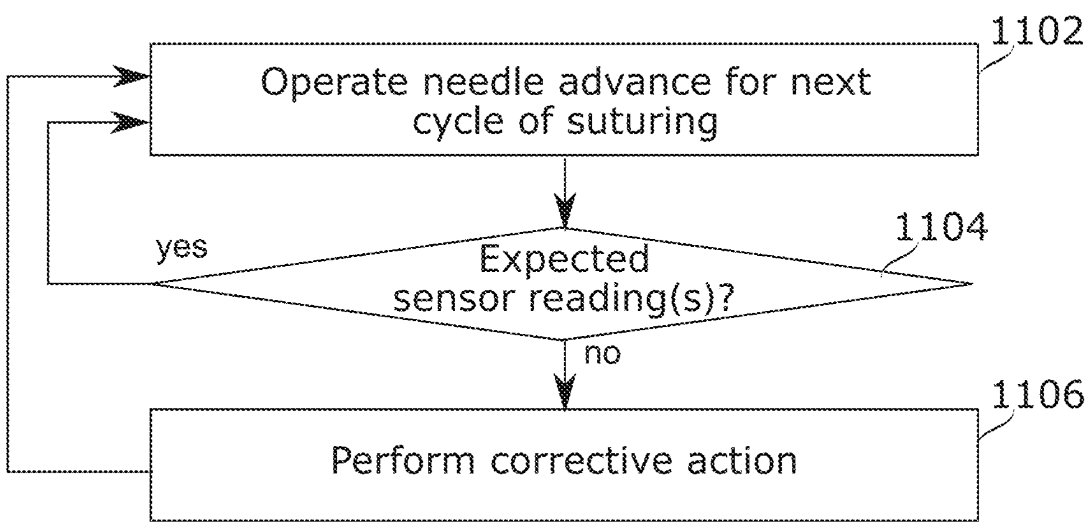
1102
Operate needle advance for next cycle of suturing
1104
yes
Expected sensor reading(s)?
no
1106
Perform corrective action

FIG. 11

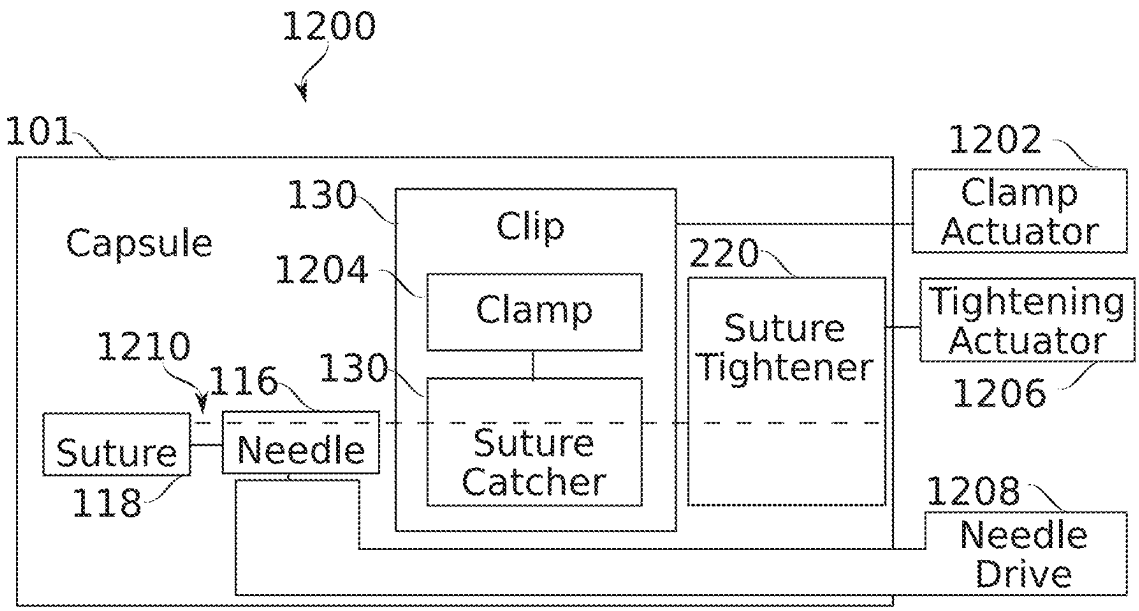
1200
101
Capsule
130
Clip
1204
Clamp
1210
116
130
Suture
Needle
Suture Catcher
118
220
Suture Tightener
1202
Clamp Actuator
Tightening Actuator
1206
1208
Needle Drive

FIG. 12

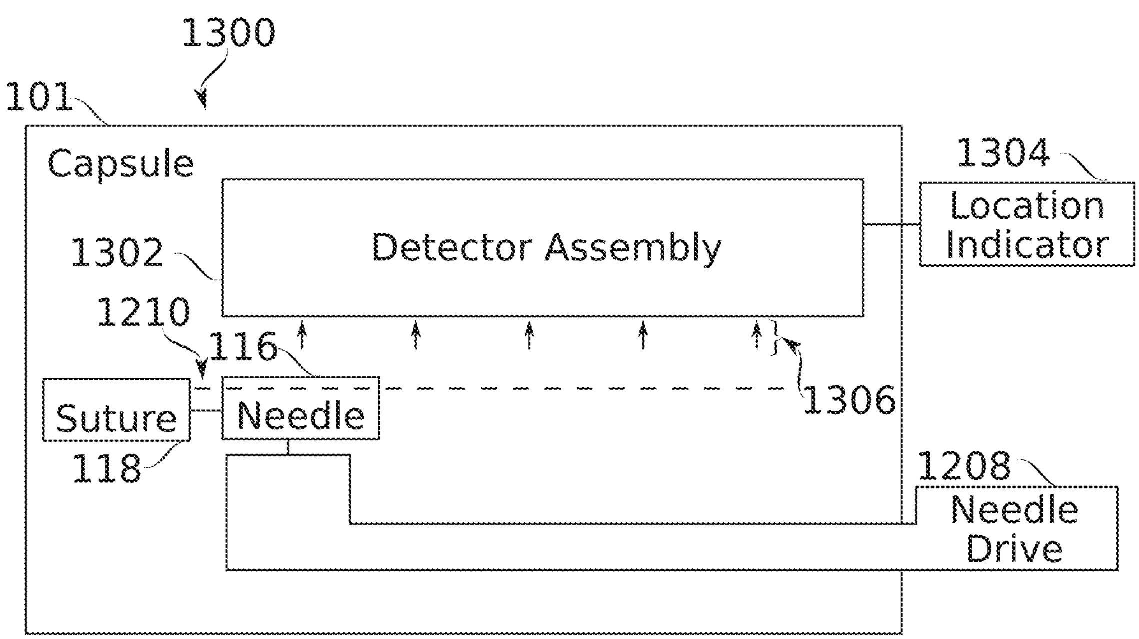
1300
101
Capsule
1302
Detector Assembly
1304
Location Indicator
1210
116
Suture
Needle
1306
118
1208
Needle Drive

FIG. 13

SUTURING WITH AN ENDOLUMINAL GASTROPLASTY DEVICE

RELATED APPLICATIONS

This application is a National Phase of PCT Patent Application No. PCT/IL2021/050208 having International filing date of Feb. 23, 2021, which claims the benefit of priority under 35 USC § 119 (e) of U.S. Provisional Patent Application No. 62/981,573 filed on Feb. 26, 2020. The contents of the above applications are all incorporated by reference as if fully set forth herein in their entirety.

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to the field of bariatric surgery; and more particularly, to endoluminal placement of gastric sutures.

Obesity and related pathologies such as type 2 diabetes are of growing concern worldwide. Gastrointestinal weight-loss surgery (bariatric surgery) has been shown to be effective in achieving sustained weight loss and amelioration of type 2 diabetes. Gastric volume reductions via open surgical- or laparoscopic sleeve-gastrectomy have proven to be one of the most effective forms of treatment.

Surgical procedures are not without risks. Complications such as procedure-related leak, severity of co-morbidities, and surgeon learning curve are but a few of the factors that have been, and will be, limiting extensive adoption of this approach.

In addition to being a relatively non-invasive form of gastric volume reduction procedure, endoluminal gastric sleeve formation carries the potential for reduced risk of leakage from the stomach. Because the stomach itself is optionally left intact, another potential advantage of an endoluminal technique over sleeve formation by surgical resection is reversibility, for example, in case of complications.

SUMMARY OF THE INVENTION

According to an aspect of some embodiments of the present disclosure, there is provided a bougie configured for placing suturing in a body cavity wall, the bougie including: a vacuum clamping domain, sized for insertion into the body cavity, and including surfaces defining an interior space, and apertures into the interior space configured to receive tissue of the body cavity wall upon application of suction thereto; a needle within the interior space, with suture attached to the needle; and a suture clip within the interior space; wherein the needle is actuatable to translate along a path within the interior space while carrying the suture through the tissue; and wherein the suture clip is positioned to capture the suture at a position along the path, and operable to clamp the captured suture.

According to some embodiments of the present disclosure, the suture clip includes a suture-catching aperture, and the predetermined path extends through the suture-catching aperture.

According to some embodiments of the present disclosure, the needle includes a helical needle, the predetermined path includes a helical path along which the helical needle translates by rotation, and the suture clip is positioned along the helical path.

According to some embodiments of the present disclosure, a suture catching portion of the suture clip is configured so that after capture of the suture, the suture remains free to loosely translate longitudinally past the suture clip.

According to some embodiments of the present disclosure, the suture clip includes a plurality of clamping portions, and the suture is clamped by movement of the clamping portions closer to one another.

According to some embodiments of the present disclosure, the clamping portions are configured to insert one inside the other, and the clamping motion includes inserting one clamping portion inside the other.

According to some embodiments of the present disclosure, the clamping movement includes rotating one of the plurality of clamping portions with respect to the other.

According to some embodiments of the present disclosure, the rotating includes moving apertures of the plurality of clamping portions out of alignment with each other.

According to some embodiments of the present disclosure, the bougie includes a suture tightener at least partially within the interior space, also positioned to capture the suture at a position along the path, and operable, from outside the bougie, to move to apply a pulling force on the suture to reduce a length of the tissue-engaged suture.

According to some embodiments of the present disclosure, the bougie includes a plurality of sensing positions, positioned along the path, each sensing position configured with a sensor configured to sense the adjacent presence of the needle.

According to an aspect of some embodiments of the present disclosure, there is provided a bougie configured for placing suturing in a body cavity wall, the bougie including: a vacuum clamping domain, sized for insertion into the body cavity, and including surfaces defining an interior space, and apertures into the interior space configured to receive tissue of the body cavity wall upon application of suction thereto; a needle within the interior space, with suture attached to the needle; and a suture tightener at least partially within the interior space; wherein the needle is actuatable to translate along a path within the interior space while carrying the suture through the tissue; and wherein the suture tightener is positioned to capture the suture at a position along the path, and operable, from outside the bougie, to move to apply a pulling force on the suture to reduce a length of the tissue-engaged suture.

According to some embodiments of the present disclosure, the captured suture slides freely with respect to the suture tightener while the suture tightener moves to reduce the length of tissue-engaged suture.

According to some embodiments of the present disclosure, the suture tightener, when moved to reduce the length of tissue-engaged suture, doubles over the suture so that both ends of the suture are on a same side of the suture tightener.

According to some embodiments of the present disclosure, the suture tightener includes a spindle over which the doubled-over suture slides.

According to some embodiments of the present disclosure, the spindle is narrower toward the middle than at the ends.

According to some embodiments of the present disclosure, the spindle is rotatably mounted to the suture tightener.

According to some embodiments of the present disclosure, the suture tightener includes an aperture positioned along the path, and the suture tightener captures the suture when the needle pulls the suture through the aperture.

According to an aspect of some embodiments of the present disclosure, there is provided a bougie configured for placing suturing in a body cavity wall, the bougie including: a vacuum clamping domain, sized for insertion into the body cavity, and including surfaces defining an interior space, and apertures into the interior space configured to receive tissue of the body cavity wall upon application of suction thereto; a needle within the interior space, with suture attached to the needle; wherein the needle is actuatable to translate along a path within the interior space while carrying the suture through the tissue; and a plurality of sensing positions, positioned along the path, each sensing position configured with a sensor configured to sense the adjacent presence of the needle.

According to some embodiments of the present disclosure, each sensing position has a separate respective sensor.

According to some embodiments of the present disclosure, the sensor includes a Hall effect sensor.

According to some embodiments of the present disclosure, the needle is magnetized.

According to some embodiments of the present disclosure, the sensor includes an electrical conductor.

According to some embodiments of the present disclosure, sensing includes detection of a break in the electrical conductor.

According to some embodiments of the present disclosure, the break detection includes sensing a change in impedance of the electrical conductor.

According to some embodiments of the present disclosure, the break detection includes sensing opening of an electrical circuit due to the break in the electrical conductor.

According to some embodiments of the present disclosure, the sensor senses electrical contact of the sensor with the needle.

According to some embodiments of the present disclosure, the plurality of sensing positions share a sensor.

According to some embodiments of the present disclosure, the sensor senses a cumulative number of the sensing positions adjacent to the needle.

According to some embodiments of the present disclosure, the sensor includes a tube extending between the sensing positions, and senses pressure within the tube.

According to some embodiments of the present disclosure, the needle includes a helical needle, the path includes a helical path along which the helical needle translates by rotation, and the plurality of sensing positions are also arranged along a longitudinal axis of the vacuum clamping domain.

According to some embodiments of the present disclosure, the bougie includes a needle position indicator, configured to indicate the position of the needle based on the presence of a portion of the needle adjacent to each of the plurality of sensing positions.

According to some embodiments of the present disclosure, the needle position indicator is configured to indicate the position of the needle in steps corresponding to the adjacent presence or adjacent absence of the needle.

According to some embodiments of the present disclosure, the bougie includes a needle position indicator configured to indicate signals produced by fluctuations in the interaction of the needle with the plurality of sensing positions, smaller than fluctuations indicating a difference between presence and absence of the needle at the sensing positions.

According to some embodiments of the present disclosure, the bougie includes a suture clip positioned within the interior space and configured to capture the suture at a position along the path, and operable to clamp the captured suture.

According to some embodiments of the present disclosure, the bougie includes a suture tightener at least partially within the interior space, positioned to capture the suture at a position along the path, and operable, from outside the bougie, to move to apply a pulling force on the suture to reduce a length of the tissue-engaged suture.

According to an aspect of some embodiments of the present disclosure, there is provided a method of securing a suture placed within a body cavity wall, the method including: translating a needle through tissue along a predetermined path within an interior space of a bougie; translating the needle through and/or alongside a suture catching portion of a suture clip pre-positioned within the interior space along the predetermined path; translating the needle past the suture catching portion, bringing a portion of the suture to a capturing zone of the suture clip defined by the suture catching portion; and actuating the suture clip to clamp the portion of the suture.

According to some embodiments of the present disclosure, the predetermined path is a helical path, and the needle is a helical needle.

According to some embodiments of the present disclosure, the method includes releasing the suture clip from the interior space.

According to some embodiments of the present disclosure, suture catching portion includes an aperture through which the predetermined path extends.

According to some embodiments of the present disclosure, the method includes translating the needle further along the predetermined path to bring the suture to a capturing portion of a suture tightener; and, before the actuating, operating the suture tightener to reduce a length of the suture engaged with tissue.

According to an aspect of some embodiments of the present disclosure, there is provided a method of monitoring the placement of suture within a body cavity wall, the method including: translating a needle through tissue along a predetermined path within an interior space of a bougie; sensing, at each a plurality of sensing positions positioned along the path, presence of the needle at the respective sensing position; and indicating the needle position, based on the sensing.

According to some embodiments of the present disclosure, the sensing includes mechanically breaking an element at least one of the plurality of sensing positions.

According to some embodiments of the present disclosure, the sensing includes detection of a pressure change induced in a tube by movement of the needle against the tube.

According to some embodiments of the present disclosure, the sensing includes detection of a magnetic field change.

According to some embodiments of the present disclosure, the sensing includes detection of an electrical contact between the needle and an electrical conductor positioned at one or more of the plurality of sensing positions.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present disclosure pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the present disclosure, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the present disclosure are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example, and for purposes of illustrative discussion of embodiments of the present disclosure. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the present disclosure may be practiced.

In the drawings:

FIGS. **1**A-**1**B schematically represent a bougie configured for shaping and intra-cavity suturing of tissue of a body cavity, according to some embodiments of the present disclosure;

FIG. **1**C is schematic flowchart of a method of suturing from within a tissue securing device, according to some embodiments of the present disclosure;

FIGS. **1**D-**1**I schematically illustrate stages in the method of suturing of FIG. **1**C, according to some embodiments of the present disclosure;

FIGS. **1**J-**1**M illustrate alternative methods of threading a suture clip, according to some embodiments of the present disclosure;

FIGS. **2**A-**2**D schematically represent stages in advancing of a needle along a suction clamping domain to enter and pass through a suture clip body, according to some embodiments of the present disclosure;

FIGS. **2**E-**2**G schematically represent stages in clamping of suture clip to a suture, according to some embodiments of the present disclosure;

FIG. **3**A shows detail of needle, in a position where it is passing by helical advance through both clip body, and an aperture of tightening head of suture tightener, according to some embodiments of the present disclosure;

FIG. **3**B shows detail of needle, in a position where it has already passed by helical advance through both clip body, and an aperture of tightening head of suture tightener, according to some embodiments of the present disclosure;

FIG. **3**C shows clip plug and clip body of suture clip in a clamped configuration, according to some embodiments of the present disclosure;

FIGS. **4**A-**4**D schematically represent components and clamping mechanism of a cylindrically clamping suture clip, according to some embodiments of the present disclosure;

FIGS. **5**A-**5**D schematically represent components and assembled configuration of a suture tightener, according to some embodiments of the present disclosure;

FIGS. **6**A-**6**D schematically represent a suture clip which clips by a rotational movement, according to some embodiments of the present disclosure;

FIGS. **7**A-**7**D schematically represent a pressure sensor arrangement for measuring movements and/or positioning of a needle, according to some embodiments of the present disclosure;

FIGS. **8**A-**8**C schematically represent a magnetic sensor arrangement for measuring movements and/or positioning of a needle, according to some embodiments of the present disclosure;

FIGS. **9**A-**9**D schematically represent a circuit board-based sensor arrangement for measuring movements and/or positioning of a needle, according to some embodiments of the present disclosure;

FIG. **10** is a schematic flowchart of a method of guiding suture clip placement within a bougie, according to some embodiments of the present disclosure;

FIG. **11** is a schematic flowchart of a method of guiding needle advance along a bougie, according to some embodiments of the present disclosure;

FIG. **12** illustrates a block diagram of a suturing subsystem comprising a needle and suturing clip, according to some embodiments of the present disclosure; and

FIG. **13** schematically represents a needle position sensing subsystem of an intrabody suturing device, according to some embodiments of the present disclosure.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to the field of bariatric surgery; and more particularly, to endoluminal placement of gastric sutures.

Overview

An aspect of some embodiments of the present disclosure relates to suture clips configured to be placed in a predetermined path of a suturing needle advancing through a device inserted to a body cavity, and remotely operated from that position to secure and clamp suturing.

The suture clip, in some embodiments, is initially placed at its position within a suturing bougie used for device-guided suturing of tissue from within a body cavity, such a stomach. More particularly, in some embodiments, the suturing bougie allows placement of a plurality of stitches in tissue of the body cavity, using a needle moving through an interior space defined by the suturing bougie, and at least partially longitudinally along the bougie. Tissue enters the bougie, for example, under suction. Optionally, the tissue is supported to obtain a particular pattern and/or depth of suturing by surfaces of the bougie arranged (for example, by a pattern of apertures or "fenestrations") to allow some tissue portions to enter the interior space, while holding adjacent tissue portions outside it.

The predetermined path, in some embodiments, is a path defined by mechanical arrangements within the interior space to guide a needle therethrough. The combined configuration of the held tissue and the predetermined path of the suturing needle through the suturing bougie determines a resulting pattern of suture stitches.

In some embodiments, the suturing needle is helical, and advances by helical rotation along a helical path. The needle may be driven by a needle drive comprising, for example, a cable, screw, ratchet, and/or other mechanism. Optionally, the needle is another shape—for example, straight or curved-planar—and moves along a path of a different shape, e.g., a straight path, a combination of straight and curved-planar paths, or another arrangement.

A device-integrated suturing clip, used with such a suturing needle configuration, encounters potential problems for reliably capturing the suture, for remote manipulation to clamp onto the suture, and for ensuring that the clip clamps at a position near to the point where the suture exits tissue that it is engaged with to create stitches.

In some embodiments, the suture clip is initially positioned along a predetermined path of the needle, so that the needle passes through a loop and/or aperture of the suture clip. This allows the suture clip to dependably capture the suture (that is, the suture is threaded through the loop and/or aperture). In some embodiments, the needle passes through or alongside a partially open-sided structure which captures the suture, for example, an arrangement of oppositely positioned hooks. The capturing comprises ensuring that some portion of the suture remains (or reliably returns to) a predetermined zone upon which the suturing clamp is later actuated to clamp down, while the suture also remain free to slide longitudinally through that zone, for example as the needle continues to move forward, and/or the suture is pulled on to tighten it. The suture clip is preferably positioned so that the clamping zone is close to the place where the needle exits tissue after forming a stitch. This helps to ensure (at least, once the suture is suitably tightened) that the suture clip is positioned close enough to the end of the stitching and/or plications of the tissue lumenal wall so that the suture stitches themselves remain tight.

In embodiments threading the suture through a loop and/or aperture, then the predetermined zone optionally comprises the confines of that loop or aperture. It is a potential advantage for the predetermined zone to be relatively small, for example, since this allows the clip to be smaller and/or operable to clamp from its original mounting position. Clamping is performed, for example, by constraining the loop/aperture area still further, e.g., adjusting a shape of the loop/aperture, by pressing another element into the loop/aperture, or another method. Optionally, clamping comprises contorting the suture, e.g., so that it bends at least one time away from a direction in which force is transmitted to the suture at the point where it enters the clamp.

In some embodiments, the suturing clip comprises a plurality of pieces, one of which is actuatable to fittingly insert into another piece, thereby pressing the suture (which threads one of the pieces) between walls of the two pieces. Additionally or alternatively, in some embodiments, the suturing clip comprises a plurality of pieces, one of which is actuatable to rotate relative to another piece, thereby contorting the suture into a shape which resists pulling.

Clamping is preferably performed while the suturing clip remains within the bougie, e.g., near to the site where suturing finishes (that is, where the needle exits the last suturing hole it makes in the tissue). One or more clips are optionally placed between sutures, e.g., to allow sutures to be clipped off individually and/or in smaller groups.

To achieve actuation remotely, in some embodiments, at least one of the suturing clip pieces is moved by a control member, e.g., by pulling on a wire, string, rod, and/or cable; rotating a socketed and/or threaded element; or another mechanism.

An aspect of some embodiments of the present disclosure relates to suture tightening devices configured to be placed in a predetermined path of a suturing needle advancing through a suturing device (e.g., a bougie) inserted to a body cavity, and remotely operated, once suture is captured, to pull on and shorten a length of suture engaged in a sutured region of tissue (tissue-engaged suture). The tightening is performed, for example, in preparation for applying a suture clip to the suture.

In some embodiments, the suture tightening device captures the suture loosely, so that the suture continues to slide freely through the suturing device while the suture tightening device pulls on and shortens the length of tissue-engaged suture. Free movement of the suture relative to the suture tightening device provides a potential advantage, by allowing the needle-attached end of the suture to remain stationary (and still attached to the needle) once the needle has finished its track.

In ordinary hand suturing, the suture needle itself is a type of "suture tightening device"—pulling on it tightens the stitches it makes (by shortening the length of tissue-engaged suture). However, mechanically driven suturing, for example using a helical needle, introduces problems for which a separate suture tightening device provides potential solutions.

A helical needle is potentially well suited to creating suture stitches e.g., insofar as its combined longitudinal and rotational path of movement passes both horizontally (due to rotation) through one or more tissue thicknesses, and longitudinally to repeat such passes. However, once the suture stitches are placed (that is, once the suture is fully engaged with tissue), it is potentially preferable to be able to tighten the stitches by simple pulling, without the complication of generating helical motion. In some embodiments, a suture tightener provides control, separate from the needle control, which allows tightening using a non-helical motion.

Compared, e.g., to a solution that transfers a helical needle from a helical driving mechanism to use with a pulling-only driving mechanism, a separate suture tightening device provides the potential advantage that the relatively cumbersome helical needle itself does not need to be navigated through the confined spaces of the bougie. The suture tightening device only needs to move the suture itself. Optionally, it is more compact than the helical needle.

In some embodiments, the suture tightening device doubles over the suture as it moves (e.g., is pulled proximally) so that both ends of the suture (e.g., a tissue-attached end and a needle-attached end) are on a same (e.g., distal) side of the suture tightening device. This is a potential advantage for shortening the tightening distance needed for the device, e.g., so that a 1 cm movement of the suture tightening device produces about a 2 cm shortening of the tissue-engaged length of suture.

In some embodiments, the suture tightening device comprises a spindle (e.g., mounted to a harness) which is shaped (e.g., flared toward the sides) so that tension on a suture line looped over the spindle tends to pull the suture toward a middle region of the spindle. This is a potential advantage for controlling the position of the suture, and/or keeping it away from sharp and/or pinching corners and crevices. In some embodiments, the spindle rotates freely (e.g., is rotatably mounted to the harness), assisting in the free motion of the suture. In some embodiments, a capturing aperture of the suture tightening device is defined at least in part by the spindle, and optionally also by a harness holding the spindle.

In some embodiments, a suturing clip and suture tightening device are arranged so that suture position relative to the suturing clip is controlled by movement of the suture tightening device, e.g., to a predetermined location. For example, the suture tightening device, as it is pulled, optionally enters a channel sized and positioned so that the portion of the suture extending directly from the suture tightening device to the location from which it exits tissue is forced to pass through the clamping zone of the suturing clip. For example, the suture is constrained to tighten against a member of the suturing clip which is involved in clamping. In such embodiments, the suturing clip need not itself comprise a loop or aperture, since capturing is managed by movement of the suture tightening device.

An aspect of some embodiments of the present disclosure relates to sensing of the position of a needle using sensors placed along a predetermined path of a suturing needle advancing through a device inserted to a body cavity.

In some embodiments, the sensors comprise a plurality of sensing sites, configured to sense and indicate the presence/absence of a needle portion at the site. In some embodiments, a plurality of sensors are placed at an interval shorter than a longitudinal length of the needle. In some embodiments, the needle is a helical needle, and the sensors are placed at intervals about the size of the longitudinal distance spanned by one helical turn of the needle, and/or a multiple thereof.

Optionally, the sensors sense needle presence/absence by a change in pressure (e.g., pressure on a tubular member), by magnetic field changes (e.g., using a Hall effect sensor), and/or by changes in electrical conductivity through the sensor (e.g., by breaking elements of the sensor, and/or by making new electrical contacts through the sensor).

In some embodiments, the position sensing is converted to indications of needle position, based on steps defined by presence/absence of the needle next to each individual sensing position. Additionally or alternatively, in some embodiments, the position sensing data is used to indicate information about needle state and/or position smaller than a step, for example by showing indications of sensor fluctuations, e.g., in response to needle movement commands.

Before explaining at least one embodiment of the present disclosure in detail, it is to be understood that the present disclosure is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings. Features described in the current disclosure, including features of the invention, are capable of other embodiments or of being practiced or carried out in various ways.

Exemplary Suture Clips

Reference is now made to FIGS. **1A-1B**, which schematically represent a bougie **100** configured for shaping and intra-cavity suturing of tissue of a body cavity, according to some embodiments of the present disclosure.

Three main sections of bougie **100** are represented as bougie capsule section **101** (distally), bougie main body **102**, and bougie control handle **103** (proximally).

Bougie capsule section **101** (herein, a bougie capsule section is also referred to herein as a "capsule"), in some embodiments, comprises a suction clamping domain **110**, which in turn comprises one or more fenestrations **111**, configured to receive tissue from the body cavity under suction, and to hold and/or position it in preparation for one or more surgical modifications such as suturing. Suction clamping domain **110**, in some embodiments, comprises supporting surfaces onto which tissue collapses when suction is applied to the device in use. The supporting surfaces comprise a body **110**A of the clamping domain **110** (formed, e.g., as a partial tube and/or spine), and/or other features along clamping domain **110** such as aperture shaping elements, optionally including longitudinal blocker **115**, and/or lateral blockers **117**. Within the supporting surfaces is defined a space (also referred to herein as a cavity) which receives and positions tissue under suction, and within which said space suturing is performed upon the positioned tissue.

During suturing, in some embodiments, a helical needle moves in a likewise helical motion along the space, suturing the positioned tissue by passing alternately, as it advances, through a first tissue portion tissue collapsed into the space from one side of the body cavity, and then through a second tissue portion from the other side of the body cavity, also collapsed into the space alongside the first tissue portion.

Herein, fenestrations **111** are moreover part of the aperture region of a bougie capsule section **101**. Fenestrations **111**, in some embodiments, are configured to be changed in size, shape, and/or topology by actuation of one or more aperture shaping elements. Such fenestrations are also referred to herein as "dynamic" fenestrations.

Aperture shaping element actuation and concomitant changes in dynamic fenestrations **111** is used, in some embodiments, to control one or more aspects of lumen tissue attachment, lumen tissue positioning, or lumen tissue suction depth (e.g., in preparation for suturing); or of tissue release. In some embodiments, tissue release includes release of suturing or other surgical material which may be attached (e.g., sewn, clipped, and/or stapled) to the lumen tissue while it is engaged with the bougie capsule section **101**.

Examples of aperture shaping elements, in some embodiments, include a longitudinal blocker **115**, and/or lateral blockers **117**.

A longitudinal blocker **115**, in some embodiments, comprises an element such as a stiffened strip or rod that longitudinally spans at least a portion of suction clamping domain **110**, substantially dividing it into two sides of fenestrations **111** which extend longitudinally alongside one another. Longitudinal blocker **115** is optionally removable, re-joining the divided fenestrations **111**. This is a potential advantage in tissue and/or suture release; for example to release of the suction clamping domain **110** from suturing which crosses between two body cavity lumen tissue portions (i.e., the first and second tissue portions mentioned hereinabove), and on an internal side of the longitudinal blocker **115** (that is, within the internal space of the suction clamping domain **110**).

Lateral blockers **117**, in some embodiments, comprise one or more elements, such as lengths of cord, which cross laterally across suction clamping domain **110** (optionally directly laterally, or diagonally). A crossing element creates a division of the suction clamping domain that separates different fenestrations **111** on either side of the element. Lateral blockers **117**, in some embodiments, are releasable and/or removable to remove the separation.

Examples of longitudinal blocker **115** and lateral blockers **117** are described, for example, in International Patent Publication No. WO 2016/056016, the contents of which are included by reference in their entirety.

In some embodiments, a distal tip **112** of bougie capsule section **101** is provided. Distal tip **112** is optionally transparent, and/or terminates in an aperture large enough (for example, about 6-8 mm in diameter) to pass the distal end of an endoscope probe or other tool out of.

Bougie main body **102**, in some embodiments, comprises a tube **121**, along which one or more longitudinally extended control members **120** pass, externally and/or internally. In some embodiments, control members **120** interconnect between actuatable elements of the bougie capsule section **101** (e.g., longitudinal blocker **115** and/or lateral blocker **117**), and the bougie control handle **103** (e.g., control knobs **122**). In some embodiments, tube **121** has an inner diameter large enough (for example, about 6-10 mm) to insert an endoscope probe or other tool through.

Any control member **120**, control knob **122** or other control device is optionally provided with an encoder **121**A which senses operation of the control member. Data from the encoder **121**A, in some embodiments, is used to determine an operating state of the bougie **100**. In some embodiments, skew between movement measured by encoder **121**A and sensed results (e.g., within the bougie capsule section **101**) is monitored. Optionally, the occurrence of measured skew is treated as an indication that there is mechanical resistance, and this is furthermore indicated to the operator, e.g., by means of logic circuitry and one or more indicators on the bougie **100** itself, or connected to the bougie **100**.

Distal tip **112** is preferably provided with a tapered shape to assist in insertion of bougie **100** along a natural body passage such as an esophagus. Bougie capsule section **101** and bougie main body **102** are preferably sized (in diameter and length) and shaped (at least in an insertion configuration) to allow insertion along a natural body passage such as an esophagus to reach a target organ such as a stomach.

Bougie control handle **103**, in some embodiments, comprises one or more control knobs **122**, configured to control manipulation of control members **120**. Optionally, one or more ports **124** are provided, sized to allow insertion of an endoscope or other tool, for passage along the lumen of tube **121** into bougie capsule section **101**, and optionally to and/or out of distal tip **112**.

Reference is now made to FIG. **1**C, which is schematic flowchart of a method of suturing from within a tissue securing device, according to some embodiments of the present disclosure. Reference is also made to FIG. **1**D-**1**I, which schematically illustrate stages in the method of suturing of FIG. **1**C, according to some embodiments of the present disclosure. Further reference is made to FIGS. **1**J-**1**M, which illustrate alternative methods of threading a suture clip, according to some embodiments of the present disclosure. Additional reference is made to FIG. **12**, which illustrates a block diagram of a suturing subsystem **1200** comprising a needle **116** and suturing clip **130**, according to some embodiments of the present disclosure.

At block **152** of FIG. **1**C, in some embodiments, tissue is captured on a suturing device, for example, by vacuum forming of stomach tissue **50** around a vacuum clamping domain **110** of a capsule **101** of a bougie **100**, supported by surfaces of body **110**A and by blockers **115**, **117**. This situation corresponds, in some embodiments, to what is shown in FIG. **1**D (optionally without needle **116** yet having been advanced to the position shown). A first portion **50**A of stomach tissue **50** is vacuum clamped along one side of the fenestrations defined by blockers **115**, **117**, and a second portion **50**B of stomach tissue **50** is vacuum clamped along the other side (i.e., on either side of longitudinal blocker **115**). Needle **116** is attached to suture **118**, and pulls suture **118** along as it is advanced. FIG. **1**E shows a bougie **100** as it would appear in FIG. **1**D without the stomach tissue **50** formed around it, revealing more of the underlying detail.

At block **154**, in some embodiments, suture **118** is drawn through tissue **118** by advancing needle **116** in a helical motion. This corresponds, in some embodiments, to the situation of FIGS. **1**F-**1**G (FIG. **1**G is a version of FIG. **1**F with the appearance of stomach tissue **50** suppressed). In some embodiments, needle **116** is advanced along a path **1210** using a needle drive **1208** (FIG. **12**). Needle drive **1208** optionally comprises, for example, cabling and/or gearing which impinge upon needle **116** and cause needle **116** to advance by corkscrew rotation when actuated (e.g., actuated by rotation and/or pulling).

At block **156**, in some embodiments, helical needle **116** is passed through and/or against a suture catcher **132** of suture clip **130**. This corresponds, in some embodiments, to the situation of FIGS. **1**H-**1**I (FIG. **1**I is a version of FIG. **1**H with the appearance of stomach tissue **50** suppressed). It is a potential advantage to mount suture clip **130** close to (e.g., within 10 mm or less) the needle exit of the last stitch. This potentially reduces slack in the suture line.

A suture catcher **132**, in some embodiments, comprises a portion of suture clip **130** through and/or against which a portion of suture **118** is reliably passed/pressed upon sufficient advancement of needle **116**. A suture catcher **132** is optionally of a loop configuration, circumferentially closed to define an aperture, which suture **118** enters by passing through an aperture of the loop. Alternatively, suture catcher **132** comprises an open-sided configuration, which allows suture **118** to enter it (e.g., across a lateral opening of the suture catcher), optionally even after the needle has passed it by.

A loop configuration has the potential advantage of capturing suture **118** as a consequence of passing needle **116** through the loop (i.e., threading of the suture through the loop), without leaving an exit allowing lateral suture escape, and while suture **118** remains loosely held. Furthermore, to obtain this capture, there is no requirement for actuation of the suture catcher **132**. Since suture **118** is only loosely held initially, it can be tightened later in the procedure, optionally without significant interference from clip friction. More particular embodiments of loop-type suture catchers **133**, **131** are shown with suture clips **130**A, **130**B in FIGS. **1**J-**1**M, as further described hereinbelow.

An open sided loop catcher configuration has the potential advantage of merely requiring the suture **118** to pass alongside (and not through) it; allowing it, for example, to be brought in from the side after needle **116** has passed. Such a configuration is furthermore compatible, for example, with implementation as a pair of clamping jaws. However, an open-sided configuration is associated with a potential risk of the suture **118** escaping the suture catcher **132** before clamping is actuated. If a separate retaining mechanism is also provided to prevent such escape, then this may itself interfere with suture release later on and/or add complexity to the device. If clamping by suture catcher **132** is at least partially actuated immediately upon passage of needle **116** (e.g., by return of a spring displaced by passage of needle **116**), this may reduce a chance for suture **118** to escape, but the suture clip **130** may itself interfere with tightening of the suture.

FIGS. **1**J-**1**K (FIG. **1**K is a magnified section of FIG. **1**J) illustrate a clip **130**A with an aperture **133** defined by a loop-type catcher configured as a cylinder **134**. Clamping (e.g., as described in relation to block **160**) optionally comprises inserting a matching plug into the cylinder **134**, for example as described in relation to FIGS. **3**C and/or **4**A-**4**D.

FIGS. **1**L-**1**M (FIG. **1**M is a magnified section of FIG. **1**L) illustrate a clip **130**B with an aperture defined by a loop-type catcher configured as a protruding loop **131**. Clamping (e.g., as described in relation to block **160**) optionally comprises withdrawing loop **134** into clip body **132**, which comprises tight confines which press on loop **134** and/or captured suture **118**.

At block **158**, in some embodiments, suture **118** is tightened. This comprises pulling on suture **118** so that the portion of it engaged within stitching length **118**A of suture **118** tightens (and, effectively, shortens, as more of suture **118** is pulled longitudinally out of the region of suture **118** engagement with tissue **50**). In some embodiments, tightening suture **118** is performed using a secondary tightening mechanism (optional suture tightener **220**, which is optionally actuated by tightening actuator **1206**), for example as described in relation to FIGS. **3**A-**3**B and/or **5**A-**5**D, herein.

At block **160**, in some embodiments, suture clip **130** is clamped. Clamping is optionally implemented mechanically in different ways. Principles of mechanism clamping used in some embodiments of the present disclosure include pressing suture **116** between surfaces to create friction, and bending clamping suture **116** to interfere with the direct transmission of pulling forces exerted on it. In some embodiments, suture clip **130** is configured so that holding power exerted through one or both of these principles is itself enhanced by pulling on the suture. Examples of suture clamping mechanisms functioning as a clamp **1204** (FIG. **12**) are described, for example, in relation to FIGS. **3**C and **4**A-**4**D; and FIGS. **6**A-**6**D.

A clamping actuator **1202** is optionally implemented mechanically in different ways in different embodiments. For example, in some embodiments, suture clip **130** comprises a plurality of parts which are moved closer to one another (e.g., closing against each other and/or inserting one inside the other) by actuation of a control member **120** (e.g., a wire or string which receives longitudinal tension from a control side of the bougie which remains outside the body cavity). Additionally or alternatively, in some embodiments, suture clip **130** comprises a plurality of parts which rotate with respect to each other, e.g., as socket and screw and/or around an axle. The rotation is optionally actuated using a control member **120** which is rotated or receives longitudinal tension from a control side of the bougie.

At block **162**, in some embodiments, suture **118** is cut. In some embodiments, a cutting edge is provided as part of bougie **100** (e.g., within the internal space of the suction clamping domain **110**, or another internal space of the bougie **110**). Optionally, clip **130** itself comprises a cutting edge.

At block **164**, in some embodiments, the sutured tissue is freed from the bougie **100**. In some embodiments, this comprises releasing suction, removing longitudinal blocker **115** (e.g., by extracting it longitudinally), and removing lateral blockers **117** (e.g., by releasing them from one side, and optionally by pulling them lose by pulling back from the other side).

While embodiments described herein relate to a helical needle **116**, it should be understood that the needle is optionally another shape, for example, a straight or curved needle. The clip suture catcher is pre-positioned within an interior space of the bougie where it receives the suture upon translation of the straight or curved needle through it (e.g., for a loop-type suture catcher) and/or alongside it (e.g., for an open-sided suture catcher).

Reference is now made to FIG. **2**A-**2**D, which schematically represent stages in advancing of a needle **116** along a suction clamping domain **110** to enter and pass through a suture clip body **204**, according to some embodiments of the present disclosure.

In FIG. **2**A, needle **116** is shown near the beginning of its longitudinal movement along suction clamping domain **110**. In some embodiments, needle **116** is helical. Optionally, advancing of needle **116** is guided by needle guide tracks **201**, which are spaced and pitched to match a helical pitch of needle **116**.

In FIG. **2**B, needle **116** has advanced to just before the position of suture clip body **204**. Suture clip body **204** is oriented so that advancing needle **116** enters it (FIG. **2**C) as a consequence of continuing its helical forward motion, and, moreover, continues to pass through it without interference with further helical forward motion (FIG. **2**D).

It is noted that display of suture **118** is suppressed in FIGS. **2**A-**2**D; it is normally attached to a trailing end of needle **116**, for example as shown in FIG. **2**E.

Reference is now made to FIG. **2**E-**2**G, which schematically represent stages in clamping of suture clip **210** to a suture **118**, according to some embodiments of the present disclosure. Suture clip **210** is a more particular example of a suture clip **130**.

In FIG. **2**E (continuing from the configuration of FIG. **2**D), needle **116** is now fully advanced through suture clip body **204**, such that suture line **118**, attached to a trailing side of needle **116**, is now threaded through suture clip body **204**. Needle **116** has also advanced through an aperture of suture tightener **220** (described further, for example in relation to FIGS. **3**A-**3**B and/or **5**A-**5**D.

Exemplary Suture Tightening and Clamping

Brief reference is made to FIG. **3**A, which shows detail of needle **116**, in a position where it is passing by helical advance through both clip body **204**, and an aperture **537** of tightening head **530** of suture tightener **220**, according to some embodiments of the present disclosure. It is noted in particular that clip body **204** is held within the predetermined pathway of needle **116** by clip case **206** (which is in turn attached to the bougie **100**, optionally fixedly attached). Tightening head **530**, also, is initially positioned at a position within the bougie along a predetermined path of needle **116**. It is not fixedly positioned, however; for example, it can be pulled proximally by exerting tension on control member **540**.

Brief reference is also made to FIG. **3**B, which shows detail of needle **116**, in a position where it has already passed by helical advance through both clip body **204**, and an aperture **537** of tightening head **530** of suture tightener **220**, according to some embodiments of the present disclosure. Suture **118** trails behind needle **116**, and is now threaded through aperture **537** of the tightening head **530**, and through aperture **203** of the suture clip **210**.

In FIG. **2**F, suture **118** has been drawn short by proximal movement of suture tightener **220**. Needle **116** acts as an anchor for one end of suture **118**, so that as suture-threaded suture tightener **220** is pulled proximally, slack is taken out of the stitches left behind by the passage (e.g., helical passage) of needle **116** through tissue **50**.

As the suture slack is taken out of the stitches, the suture line is also pulled further past and/or through suture clip **210**. It is noted that although suture clip **210** has already captured the suture line (e.g., the suture line has been threaded through it), it has not yet clamped it, so it the sliding movement of the suture is not interfered with.

In some embodiments, clamping of suture clip **210** (shown in FIG. **2**G) comprises moving clip plug **202** into an aperture **203** of clip body **204**, for example as described in relation to FIGS. **4**A-**4**D.

Brief reference is made to FIG. **3**C, which shows clip plug **202** and clip body **204** of suture clip **210** in a clamped configuration, according to some embodiments of the present disclosure. Suture **118** extends within clip body **204**, and between clip body **204** and clip plug **202**. Also shown are holes **301**; used in manipulating clip plug **202** to produce clamping, for example as explain in relation to FIGS. **4**A-**4**D, herein.

Reference is now made to FIGS. **4**A-**4**D, which schematically represent components and clamping mechanism of a cylindrically clamping suture clip **210**, according to some embodiments of the present disclosure. Aspects of suturing clip operation applicable, for example, to suture clip **210** are also described, for example, in relation to FIGS. **2**A-**2**G and **3**A-**3**C.

Suturing clamp **210**, in some embodiments, comprises a clip plug **202** and a clip body **204**, into which clip plug **202** is fittingly insertable (e.g., as shown in the sequence of FIGS. **4**A-**4**C). The fitted portion comprises clamping portion **209**, which presses against an inner wall of aperture **203** of clip body **204**. When a suture **118** is threaded through aperture **203**, clamping portion **209** and/or clip body **204** are loose and/or elastic enough to fit together even over the obstruction presented by the suture **118**; in some embodiments, the elastic deformation of the clip body **204** and/or clip plug **202** induced as a result contributes to clamping forces on suture **118**. In some embodiments, clamping portion **209** comprises a parallel cylindrical outer wall.

An aspect of the operation of suturing clip **210** is that its clamping is actuatable by manipulation of a control member (e.g., control member **120**) from a position remote from the suturing clip **210** (e.g., the suturing clip **210** can be closed by pulling on a wire or cord portion outside the body, while suturing clip **210** itself is still inside a cavity of the body, and inside bougie **100**). The control member passes through aperture **203** between clip plug **202** and a control member portion on which pulling force is exerted, so that shortening the control member brings the clip plug **202** and clip body **204** together.

In some embodiments, clip plug **202** is configured for remote actuation by embodying one or more of a plug guide tip **208**, hole(s) **301**, and insertion stop **207**.

Plug guide tip **208**, in some embodiments, is located at an inserting end of clip plug **202**, and is rounded and/or tapered to make clip plug **202** self-centering as it is advanced into aperture **203**.

One or more holes **301**, in some embodiments, are optionally open on both ends, and extend along a longitudinal axis of clip plug **202**. Holes **301** accept insertion of a control member (not shown in the figures) thereto, and optionally therethrough. Optionally, the control member is anchored to the clip plug **202**, and later released, e.g., by cutting. Alternatively, in some embodiments, a plurality of holes is configured to allow a control member to pass into the clip plug **202** from, e.g., the end comprising the plug guide tip **208**, out the other end, then back in the same end and out again on the end comprising the plug guide tip **208**. When both ends of the control member are pulled on at the same time, the clip plug is urged into the aperture **203** of the clip body **204**. If one control member end is released and the other is pulled on, the control member eventually slips entirely through both of the holes it is threaded to, releasing itself from the clip.

Insertion stop **207**, in some embodiments, comprises a widening on the trailing side of the insertion plug **202**, which prevents plug **202** from being pulled entirely through aperture **203** and out the other side.

In some embodiments, clip case **205** holds and positions clip body **204** within bougie **100**. For example, clip case **205** optionally comprises a mounting protrusion **206** which is attached to the bougie **100**, e.g., by a pin, screw, and/or other arrangement.

FIG. **4**D shows suture clip **210** released from its case **205**. In some embodiments, release of suture clip **210** from clip case **205** occurs as a consequence of withdrawing bougie **100** from the body after suture clip **210** is clamped. Tension from the tissue-attached suture retains suture clip **210**, so that it separates when bougie **100** is extracted. Optionally, clip case **205** is shaped to obstruct suture clip **210** from exiting on the wrong side, e.g., during clamping.

Reference is now made to FIGS. **5**A-**5**D, which schematically represent components and assembled configuration of a suture tightener **220**, according to some embodiments of the present disclosure. Operation of a suture tightener **220** is described, for example, in relation to FIGS. **2**E-**2**G and/or **3**A-**3**B, herein.

Suture tighter **220**, in some embodiments, comprises a control member **540** (e.g., an example of a control member **120**) and a tightening head **530**.

Tightening head **530** is configured to capture (e.g., by threading) suture **118** from a position behind the advance of needle **116**, for example by a loop or open-sided suture catcher (e.g., as described herein in relation to suture catcher **132** of a suturing clip). In the example shown, the suture **118** is captured (threaded) when needle **116** pulling an end of suture **118** passes through an aperture **537** defined by a harness **531** and a spindle **533**.

Spindle **533** is optionally fixed, or spins to form a pulley. Spindle **533**, in some embodiments, is narrower toward the middle, and flared toward the ends. This helps to center the suture **118** under tension, potentially avoiding pulling on it from a sharp interior corner of the tightening head **530**, and/or preventing getting caught in a gap between spindle **533** and harness **531**. In some embodiments, tightening head **530** is attached to its control member **540** through a strain relief **535**. Optionally, strain relief **535** is tapered, for example to assist it in entering a channel of bougie **100** along which tightening head **530** is to be drawn.

Control member **540** optionally comprises a stiffener **534**, which extends at least through a region of the bougie traversed by needle **116**. Stiffener **534** stiffens control member **540** enough to prevent control member **540** from becoming entangled with needle **116**.

Optional flexible (e.g., string or wire-like) distal section **532** of control member **540** attaches between tightening head **530** and stiffener **534**. Being flexible, it allows tightening head **530** to self-adjust its position and orientation according to the direction of pull from suture **118** during tightening. Being short, entanglement with needle **116** is potentially avoided. Proximal section **536** of control member **540** optionally comprises a wire, string, cable, or other construction. Optionally, the proximal and distal sections **532**, **536** join or are comprised in a single piece underneath stiffener **534**.

In some embodiments, cutting suture **118** is performed using a tool of an endoscope inserted through the bougie. Optionally, cutting suture **118** is performed using sharpened edge placed in the bougie **100** at a position that allows it to be pressed against, clamped over, and/or sawed on the suture, at a position between a suturing clip **130** and needle **116**. For example, the sharped edge is placed partially across an interior space of bougie **100** on a distal side of the fully advanced needle **116**. As the bougie **100** is withdrawn, the suture **118** is stretched between the needle **116** and a suture clip **130**. Once it is stretched, the bougie is moved to bring the sharpened edge against the suture **118**, cutting it. In some embodiments, the suturing clip **130** itself comprises a cutting edge.

Exemplary Rotating-Clamp Suture Clip

Reference is now made to FIGS. **6**A-**6**D, which schematically represent a suture clip **600** which clips by a rotational movement, according to some embodiments of the present disclosure.

Suture clip **600**, in some embodiments comprises clip body **620**, clip insert **610**, and optionally clip stopper ring **630**. Clip insert **610** attaches with clip body **620** by means of screw threads **613** that mate with screw threads inside clip body **620**. Clip body **620** is held attached to bougie body **110**A, e.g., by the fitted insertion of protrusions **623** into receiving locations of bougie body **110**A, or by another method.

Mounted within the bougie, suture clip **600** is positioned with apertures of holes **611** (of clip insert **610**) and **622** (of clip body **620**) aligned with each other, and moreover aligned with a predetermined path of needle **116**, so that needle **116** passes into the holes **611**, **622** as it advances; for example as shown in FIG. 6D. Clip body **620** may be said to have two holes—each opposite each other on the wall of the clip body **620**.

After passage of needle **116** through holes **611**, **622**, suture clip **600** may be operated to clamp suture **118**. For this, hole **611** is rotated relative to holes **622** (out of alignment with them), for example in direction **640**. This distorts the suture **118**, and pulls it around within clip body **620** where it is clamped between the threads of clip body **620** and clip insert **610**. Optionally, clip stopper ring **630** is attached to an end of clip insert **610**, and prevents over-rotation.

Rotational force is optionally exerted by rotation of a control member **650** (an example of a control member **120**). Control member **650** mates, for example, with a distal end **615** of insert **610**. Keying protrusion **617** mates with a matching notch in a socketed end of the control member **650**, to allow rotational force to be transmitted.

Suture clip **600**, once clamped to suture **118**, optionally slides out of its receiving locations upon removal of the bougie from the body cavity, due, e.g., to being retained by stitches made using suture **118**.

Optionally, an edge of one or more of holes **611**, **622** is sharpened. Optionally, rotating to clamp also severs suture **118** on the proximal side. Optionally, rotating by itself does not sever suture **118**; rather the suture must also be held tight, e.g., stretched using a suture tightener **220**.

Exemplary Sensor Arrangements and Operation

Reference is now made to FIG. **13**, which schematically represents a needle position sensing subsystem **1300** of an intrabody suturing device, according to some embodiments of the present disclosure.

Position sensing subsystem **1300**, in some embodiments, comprises a detector assembly **1302** positioned along needle path **1210** within a capsule section **101** of a suturing bougie. Needle **116** is configured to move along a path **1210** (e.g., actuated by needle drive **1208**) pulling suture **118**. The path **1210** may be helical. Detector assembly **1302** is configured to detect the presence, arrival, and/or departure of needle **116** at a plurality of positions **1306** along path **1210**. Location indicator **1305** interprets signals from detector assembly and provides an indication of a current location of needle **116** accordingly.

Position sensing subsystem **1300**, in some embodiments, allows tracking and/or confirmation of needle movements actuated by needle drive **1208**. A potential advantage of this is that needle drive **1208** need not itself be deterministic in how its own movements are translated into movement of needle **116**. For example, there can be slippage and/or hysteresis in the interaction between needle drive **1208** and needle **116**. Position sensing subsystem **1300** provides positive feedback that motion has actually occurred, and/or indications of how much motion has occurred. Sensing subsystem **1300** optionally comprises a single elongated sensor, or a plurality of sensors; implemented, for example, as described in relation to FIGS. **7**A-**9**D, herein.

Reference is now made to FIGS. **7**A-**7**D, which schematically represent a pressure sensor arrangement for measuring movements and/or positioning of a needle **116**, according to some embodiments of the present disclosure.

In some embodiments of the present disclosure, a suction clamping domain **110** is provided with sensing for determining the presence and/or position of a needle **116**. In some embodiments, the needle **116** is helical, and sensing is provided which allows per-turn sensing of the advance of the helical needle. Needle presence and/or position sensing provides a potential advantage in particular for verifying that the needle has passed the suction clamping domain **110**, e.g., so that further steps such as suture tightening and suture clip clamping are not performed before the stitches are fully in place.

It is a potential advantage, moreover, to know how far along the needle **116** is in its advance; for example, if it becomes stuck or slowed during advance, corrective action may be taken sooner, if there is position sensing resolution more detailed than "suturing completed/suturing not-completed". In some embodiments, needle position is measured in steps with the width of a helical winding, for example by sensing discretely at 2, 3, 4, 5, or more locations. Needle positions are optionally distinguished by a pattern of activated sensors. For example: initially none of four sensors along a longitudinal axis of helical advance. As the needed advances, one, two, three, then four sensors are activated. As the needle advances further, the trailing sensors deactivate one-by-one, until three, two, one, then no sensors are activated. Thus, in this example, eight different needle positions are identified. It should be understood that a different number of sensors is optionally used, and that sensors are optionally active at the beginning or end of the needle movement. Optionally, sensor lines are placed on the needle path at either side of the bougie body **110**A, allowing finer sensing resolution. Sensor activation patterns are optionally sensed, for example, by receiving individual inputs from each sensor, or by sensing a cumulative input from several sensors (for example, as detailed in relation to the pressure sensor of FIGS. **7**A-**7**D).

In some embodiments, a needle position sensor **700** comprises a flexible tube **705** extending longitudinally along bougie body **110**A. Tube **705** is attached to a pressure sensor **710** (e.g., at one end of the tube), and the other end of tube **705** is sealed. Accordingly, compressing tube **705** causes the sensed pressure to rise. Tube **705** is held in place (e.g., by fastening tubes **704**) so that needle **116** compresses it at intermittent sensing locations **702** as it moves (e.g., helically advances) along its predetermined path. Optionally, needle **116** directly presses an overlaying cover **703** at each sensing location **702**, and cover **703** in turn compresses tube **705**. Potential advantages of this include: cover **703** can be shaped to ensure that it protrudes enough into the interior of the bougie body **110** to be pressed against; cover **703** can be shaped to ensure that needle **116** presses it to the side instead of piercing it; cover **703** can be made longer than the width of needle **116** so that more of tube **702** is compressed (producing a larger pressure change).

Sensor indicator **712** indicates needle position status based on readings from pressure sensor **710**. Sensor indicator **712** optionally comprises a LED indicator, e.g., with a segment lit per sensing position **702** triggered. Optionally, sensor indicator **712** indicates position using tones. Optionally, sensor indicator **712** comprises a user interface for a computer configured to show a graphical and/or visual indication based on signals transmitted from pressure sensor **710**.

Optionally, a step in pressure change is registered by sensor **710** (and optionally displayed by sensor indicator **712**) for each sensing location **702** at which needle **116** begins pressing against tube **705**. This allows sensing the advance of needle **116**, first as sensing locations **702** are sequentially pressed against (increasing pressure), and then as sensing locations **702** are sequentially relieved of pressure.

Optionally, pressure sensor **710** reports small (less than a step-sized) variations in pressure as well. Optionally, sensor indicator **712** displays these small variations, which may provide hints to the device operator about needle state. For example, if the needle drive is repeatedly slipping at a particular part of the rotation cycle, there may be a corresponding (potentially small) change in pressure indication as force on the needle redistributes. An operator can respond, for example, by changing the way that advancing is controlled, and/or adjusting angulation and/or bending of the device, using the pattern of pressure changes as a guide to the effect of such adjustments. Even without slippage, there is potentially seen a pattern in pressure readings which correlates to when a needle is beginning to press against the next tissue layer, when it is sliding through it, and/or when it has successfully passed it. Optionally, the device operator adjusts operations to advance the needle and/or manipulate the angulation and/or bending of the bougie itself, based in part on such patterns.

It is noted that certain suture tighteners themselves may be used as sensors. Once a needle **116** has entered the aperture of a suture tightener, the suture tightener is partially locked into place, preventing free operation until the needle is past it again. Testing of this condition by use of gentle tugs may be used additionally or alternatively with use of dedicated sensors to determine the position of the needle **116**.

Reference is now made to FIGS. **8**A-**8**C, which schematically represent a magnetic sensor arrangement for measuring movements and/or positioning of a needle **116**A, according to some embodiments of the present disclosure.

In some embodiments, magnetic field sensors **802** (e.g., Hall effect sensors) are mounted, e.g., on a circuit board **800**, which in turn mounts to bougie body **110**A of suction clamping domain **110**. The sensors **802** are preferable placed at the location of closest approach by needle **116**A. Needle **116**A is magnetized, e.g., along its whole length (it is optionally embodied, for example, as a needle **116** which has been magnetized). As needle **116**A approaches each sensor **802** in turn, the sensor **802** registers a change in magnetic field, outputting a signal which in turn is sensed by a signal processing circuit **810**, producing a position indication displayed by sensor indicator **812** (which may produce indications, e.g., as described for sensor indicator **810**, suitably adjusted for magnetic signals rather than pressure signals).

The signals produced by sensors **802** are optionally processed and/or displayed as "present" or "not present" indications of needle proximity. Additionally or alternatively, signals components produced by sensors **802** with less than the size of a whole step are processed and/or displayed, e.g., as effectively continuous-value signals (for example, analog signals and/or digital signals encoded with a bit depth of several bits, e.g., 5 or more bits). Stresses and/or strains placed on needle **116** to advance it potentially change its shape slightly as it moves, for example as described in relation to the embodiments of FIG. **7**A-**7**D. Nearby magnetic field sensors **802** may in turn fluctuate slightly in the signals they produce. Indications of such fluctuations are optionally used by a device operator to guide device operation, for example as described in relation to FIGS. **7**A-**7**D.

Reference is now made to FIGS. **9**A-**9**D, which schematically represent a circuit board-based sensor arrangement for measuring movements and/or positioning of a needle **116**A, according to some embodiments of the present disclosure.

In some embodiments, sensor board **900** comprises a circuit board configured with a plurality of leads **901**A, **901**B, **901**C, **901**D connected to a sensing circuit **910**. A portion of each lead extends along an edge **904** of sensor board **900**, each along a different longitudinal portion of sensor board **900**.

In some embodiments, each lead **901**A-**901**D has a characteristic impedance associated with it, which changes when the lead is shortened. Additionally or alternatively, an end of each lead is connected to ground (e.g., from the other side of circuit board **900**, not shown).

Sensor board **900** is positioned on bougie body **110**A of suction clamping domain **110** at a position where a tip **902**C of needle **116** sequentially impinges, as it helically advance, on each individual lead **901**A-**901**D near edge **904** in turn. The impinging in turn breaks the impinged on lead. Optionally board **900** is weakened near the position of impingement **903** so that a notch is knocked out of the board upon impingement.

Sensing circuit **910** senses the change in impedance and/or opening of the grounded circuit, providing a signal which sensor indicator **912** in turn indicates, for example as described in relation to sensor indicator **712**.

Additionally or alternatively, in some embodiments, leads **901**A-**901**D comprise a foil, spring, or other conductive element which needle **116** contacts (and optionally deforms and/or breaks) as it rotates. Electrical contact may be established thereby between the different leads through needle **116**, and this contact used as the basis for position sensing (by sensing circuit **910**) and indicating (by sensor indicator **712**). Optionally, conductance across the area of electrical contact is subject to minor variability as the needle moves. This variation itself optionally comprises an indication of needle movement.

Optionally, needle **116** is at least partially coated with an insulating polymer (for example, on side **902**D, compared to side **902**E which may be left uncoated). The polymer coating is optionally interrupted at intervals to expose the metal. In some embodiments, this is used to allow the needle **116** to act as an encoder of its own progress, by counting events of making and/or breaking electrical contact as coated and uncoated needle portions pass over the sensor.

It is noted that a sensor at a single position can be used with such a needle **116**, e.g., by providing it with two contacts (and sensing conduction between them through the needle), or by providing it with one contact and creating a circuit that passes through the body of the needle to a conductor that maintains electrical contact with the needle, such as a wire attached to the needle, or a driver cable used to drive the needle. To track needle **116** over a distance longer than its own length, a plurality of such sensors are optionally provided.

Reference is now made to FIG. **10**, which is a schematic flowchart of a method of guiding suture clip placement within a bougie **100**, according to some embodiments of the present disclosure.

At block **1002**, in some embodiments, a needle positioned inside a body cavity is advanced. The advance is in turn controlled, in some embodiments, by operation of a control member outside the body cavity. Optionally, the needle is helical, positioned within a needle-guiding device such as a bougie **100**. The needle advances, in some embodiments, by operation (e.g., rotation) of a control member that drives the needle along a predetermined path defined by the needle-guiding device.

One or more sensors are positioned along the predetermined path, and sense the presence of the needle; for example, according to one of the embodiments of FIGS. **7**A-**9**D.

At block **1004**, in some embodiments, it is checked (e.g., by circuitry connected to the sensors) if the needle is past the region that it is configured to suture. In some embodiments, the check comprises verifying that the needle has first been sensed by at least one sensor, but now is no longer sensed by that sensor (that is, the needle has passed the sensor). Additionally or alternatively, a sensor is placed far enough along the predetermined path (e.g., about the length of the needle, measured along its direction of longitudinal travel) so that when a front portion of the needle is sensed, a back portion of the needle has passed the suturing region.

At block **1006**, in some embodiments: if the needle is not yet past the suture region, the flowchart returns to block **1002**. Otherwise, an indication is provided that the procedure can continue; e.g., with clamping of a suture clip, for example as described herein relation to blocks from block **158** onward in FIG. **1**C.

Reference is now made to FIG. **11**, which is a schematic flowchart of a method of guiding needle advance along a bougie **100**, according to some embodiments of the present disclosure.

At block **1102**, in some embodiments, a needle positioned inside a body cavity is advanced by operation of a control member outside the body cavity. The configuration of the bougie **100** and needle is, for example, as described in relation to FIG. **10**. The operation to advance the needle is performed to an extent which is considered likely to bring the needle into sensing range of a sensor (and/or move it out of sensing range of a sensor) of the bougie **100**. For example, if there is a sensor placed spaced at each turn of a helical needle, then the control member is optionally operated sufficiently that it is anticipated to advance the helical needle by about a turn, assuming that there is no restraint on needle advance that prevents this. Optionally, operation of the control member is also sensed, for example using an encoder **121**A.

At block **1104**, in some embodiments, it is checked if the needle has indeed reached and/or moved out of sensing range of the sensor(s), according to the anticipated result. If so, then the procedure returns to block **1102** and continues with further advancing of the needle.

Otherwise, at block **1106**, a corrective measure is taken. This may comprise, for example, one or more of:

- Reversing the direction of needle travel.
- Adjusting the needle drive (e.g., longitudinally translating a needle drive cable so that a different part of it works on the needle).
- Otherwise changing how force is exerted to induce needle travel (e.g., operating the needle advancing control member more quickly or more slowly).
- Changing an angulation of the bougie **100**, e.g., to change forces exerted on the needle.
- Changing bending of the bougie **100**, e.g., to change forces exerted on the needle.

After and/or while the corrective measure is taken, the flowchart returns to block **1102**. The flowchart continues until it is no longer necessary to advance the needle, e.g., until the result of block **1004** of FIG. **10** indicates to proceed with clipping.

General

As used herein with reference to quantity or value, the term "about" means "within ±10% of".

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean: "including but not limited to".

The term "consisting of" means: "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

The words "example" and "exemplary" are used herein to mean "serving as an example, instance or illustration". Any embodiment described as an "example" or "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments and/or to exclude the incorporation of features from other embodiments.

The word "optionally" is used herein to mean "is provided in some embodiments and not provided in other embodiments". Any particular embodiment of the present disclosure may include a plurality of "optional" features except insofar as such features conflict.

As used herein the term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term "treating" includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

Throughout this application, embodiments may be presented with reference to a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of descriptions of the present disclosure. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as "from 1 to 6" should be considered to have specifically disclosed subranges such as "from 1 to 3", "from 1 to 4", "from 1 to 5", "from 2 to 4", "from 2 to 6", "from 3 to 6", etc.; as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein (for example "10-15", "10 to 15", or any pair of numbers linked by these another such range indication), it is meant to include any number (fractional or integral) within the indicated range limits, including the range limits, unless the context clearly dictates otherwise. The phrases "range/ranging/ranges between" a first indicate number and a second indicate number and "range/ranging/ranges from" a first indicate number "to", "up to", "until" or "through" (or another such range-indicating term) a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numbers therebetween.

Although descriptions of the present disclosure are provided in conjunction with specific embodiments, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present disclosure. To the extent that section headings are used, they should not be construed as necessarily limiting. In addition, any priority document(s) of this application is/are hereby incorporated herein by reference in its/their entirety.

It is appreciated that certain features which are, for clarity, described in the present disclosure in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the present disclosure. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

What is claimed is:

1. A bougie configured for placing suturing in a body cavity wall, the bougie comprising:

a vacuum clamping domain, sized for insertion into the body cavity, and comprising surfaces defining an interior space, and apertures into the interior space configured to receive tissue of the body cavity wall upon application of suction thereto;

a needle within the interior space, with suture attached to the needle; and

a suture clip within the interior space;

wherein the needle is actuatable to translate along a path within the interior space while carrying the suture through the tissue; and

wherein the suture clip is positioned to capture the suture at a position along the path, and operable to clamp the captured suture

wherein said bougie comprising a suture tightener at least partially within the interior space, said suture tightener also positioned to capture the suture at a position along the path, and operable, from outside the bougie, to move to apply a pulling force on the suture to reduce a length of tissue-engaged suture; and

the suture tightener comprises an aperture positioned along the path, and the suture tightener captures the suture when the needle pulls the suture through the aperture of the suture tightener.

2. The bougie of claim **1**, wherein the suture clip comprises a suture-catching aperture, and the path extends through the suture-catching aperture.

3. The bougie of claim **1**, wherein the needle comprises a helical needle, the path comprises a helical path along which the helical needle translates by rotation, and the suture clip is positioned along the helical path.

4. The bougie of claim **1**, wherein a suture catching portion of the suture clip is configured so that after capture of the suture, the suture remains free to loosely translate longitudinally past the suture clip.

5. The bougie of claim **1**, wherein the suture clip comprises a plurality of clamping portions, and the suture is clamped by movement of the clamping portions closer to one another.

6. The bougie of claim **5**, wherein the clamping portions are configured to insert one inside another, and the clamping movement comprises inserting one clamping portion inside another clamping portion.

7. The bougie of claim **5**, wherein the clamping movement comprises rotating one of the plurality of clamping portions with respect to another one of the plurality of clamping portions.

8. The bougie of claim **7**, wherein the rotating comprises moving apertures of one of the plurality of clamping portions out of alignment with at least another one of the plurality of clamping portions.

9. The bougie of claim **1**, comprising a plurality of sensing positions, positioned along the path, each sensing position configured with a sensor configured to sense the adjacent presence of the needle.

10. The bougie of claim **9**, wherein each sensing position has a separate respective sensor.

11. The bougie of claim **9**, wherein the sensor comprises at least one of the group consisting of:

a pressure sensor,

an impedance sensor of impedance of an electrical conductor,

a contact sensor of contact with an electrical conductor,

a breakage sensor of breakage of an electrical conductor, and

a Hall effect sensor.

12. The bougie of claim **9**, wherein the plurality of sensing positions share a single sensor.

13. The bougie of claim **9**, wherein the needle comprises a helical needle, the path comprises a helical path along which the helical needle translates by rotation, and the plurality of sensing positions are also arranged along a longitudinal axis of the vacuum clamping domain.

14. The bougie of claim **1**, wherein the suture captured by the suture tightener slides freely with respect to the suture tightener while the suture tightener moves to reduce the length of tissue-engaged suture.

15. The bougie of claim **14**, wherein the suture tightener, when moved to reduce the length of tissue-engaged suture, doubles over the suture so that both ends of the suture are on a same side of the suture tightener.

16. The bougie of claim **15**, wherein the suture tightener comprises a spindle over which the suture is doubled over.

17. The bougie of claim **16**, wherein the spindle is narrower toward a middle of the spindle than at ends of the spindle.

18. The bougie of claim **16**, wherein the spindle is rotatably mounted to the suture tightener.

19. A bougie configured for placing suturing in a body cavity wall, the bougie comprising:

a vacuum clamping domain, sized for insertion into the body cavity, and comprising surfaces defining an interior space, and apertures into the interior space configured to receive tissue of the body cavity wall upon application of suction thereto;

a needle within the interior space, with suture attached to the needle; and

a suture clip within the interior space;

wherein the needle is actuatable to translate along a path within the interior space while carrying the suture through the tissue; and

wherein the suture clip is positioned to capture the suture at a position along the path, and operable to clamp the captured suture

wherein said bougie comprising a suture tightener at least partially within the interior space, said suture tightener also positioned to capture the suture at a position along the path, and operable, from outside the bougie, to move to apply a pulling force on the suture to reduce a length of tissue-engaged suture;

wherein the suture captured by the suture tightener slides freely with respect to the suture tightener while the suture tightener moves to reduce the length of tissue-engaged suture; and

wherein the suture tightener, when moved to reduce the length of tissue-engaged suture, doubles over the suture so that both ends of the suture are on a same side of the suture tightener.

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