

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 July 2007 (05.07.2007)

PCT

(10) International Publication Number
WO 2007/075310 A2

(51) International Patent Classification:
A61B 17/03 (2006.01)

(21) International Application Number:
PCT/US2006/047105

(22) International Filing Date:
8 December 2006 (08.12.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/754,172 27 December 2005 (27.12.2005) US

(71) Applicant (for all designated States except US): **EAST CAROLINA UNIVERSITY** [US/US]; 2200 Charles Boulevard, Greenville Centre, Room 2400, Greenville, North Carolina 27858 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ISHIKAWA, Norihika** [JP/JP]; 1-159 Matsumura, Kanazawa, Ishikawa 920-0348 (JP). **NIFONG, L. Wiley** [US/US]; 300 Queen Anne Road, Greenville, North Carolina 27858 (US). **SUN, You Su** [US/US]; 109 Knight Drive, Winterville, North Carolina 28590 (US).

(74) Agent: **MYERS BIGEL SIBLEY & SAJOVEC, P.A.**;
P.O. Box 37428, Raleigh, North Carolina 27627 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

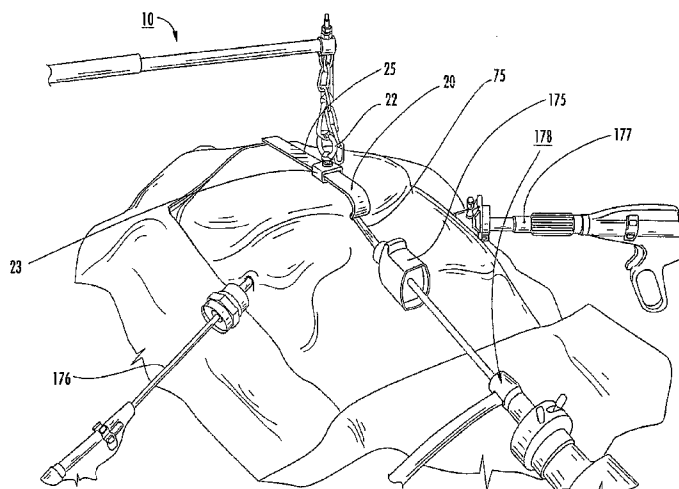
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ENDOSCOPIC FORCEPS WITH PRONGS AND RELATED METHODS



(57) Abstract: Methods and surgical devices are described that can endoscopically manipulate a length of a suture. A forceps instrument is endoscopically introduced into the body. The forceps instrument includes opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members. Each pair of prongs defines an opening therebetween. A length of suture is grasped using the forceps instrument such that the suture is captured by the pairs of prongs and a portion of the suture extends across the openings defined by the pairs of prongs. The portion of the suture that extends across the openings is grasped with another surgical instrument.

WO 2007/075310 A2

ENDOSCOPIC FORCEPS WITH PRONGS AND RELATED METHODS

RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application Serial No. 60/754,172, filed December 27, 2005, the disclosure of which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

The invention relates to medical instruments for endoscopic suture and/or tissue manipulations. The devices may be particularly suitable for use in minimally invasive cardiac surgeries.

BACKGROUND OF THE INVENTION

During surgeries, surgical tools are introduced into the body to carry out the desired cutting, forming or ablation procedure in the target location in the body. Typically, one or more retractors can be used to provide a suitable access path or increased intra-body space for the tools to be able to reach the target location.

Relatively recently, a minimally invasive, robotic-assisted surgical system has been used to carry out closed chest (rather than open heart) cardiac surgeries. The closed chest surgeries can use both major and minor surgical access paths to allow for multiple instruments to be inserted into the body and used concurrently or serially during the procedure. One example of a cardio-surgical robotic-assisted system is the da Vinci® Surgical System by Intuitive Surgical Inc. of Sunnyvale, CA.

Using the robotic-assisted surgical system, a surgeon's hands do not typically enter the patient. After set-up incisions that are used to create the major or minor access paths, the surgeon controls the instruments, including at least one miniature camera used to carry out the surgery, from a console, usually located in the operating room, to guide the instruments into position and operate the instruments to carry out their intended functions. The camera provides real time (magnified) images of the operating site or access paths on a display that allows a surgeon to "see" the tools and operative site and remotely control the surgery.

During some conventional mitral valve repairs, sutures are placed in the heart. After ligation of each suture, a "side" surgeon inserts conventional endoscopic

scissors to cut the suture excess, then grasps and removes the remnant of the suture with endoscopic forceps.

There is a need for instruments and methods that can facilitate surgeries, including, but not limited to, minimally invasive surgeries such as robotic-assisted cardiac surgeries.

SUMMARY OF EMBODIMENTS OF THE INVENTION

Embodiments of the present invention are directed to suture and tissue manipulation devices and methods that can facilitate minimally invasive endoscopic and/or robotic-assisted surgeries.

Some embodiments are directed to methods for endoscopically manipulating a length of a suture. A forceps instrument is endoscopically introduced into the body. The forceps instrument includes opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members. Each pair of prongs defines an opening therebetween. A length of suture is grasped using the forceps instrument such that the suture is captured by the pairs of prongs and a portion of the suture extends across the openings defined by the pairs of prongs. The portion of the suture that extends across the openings is grasped with another surgical instrument.

Some embodiments are directed to methods for endoscopically suturing tissue. A forceps instrument is endoscopically introduced into the body. The forceps instrument includes opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members. Each pair of prongs defines an opening therebetween. Tissue is grasped using the forceps instrument so that a portion of the tissue extends across the openings defined by the pairs of prongs. A suture is stitched in the portion of the tissue extending across the openings.

Other embodiments are directed to a forceps device including opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members. Each pair of prongs defines an opening therebetween. The forceps device is sized and configured to enter a patient's body endoscopically through an intra-body port through a closed chest access path.

Further features, advantages and details of the present invention will be appreciated by those of ordinary skill in the art from a reading of the figures and the

detailed description of the embodiments that follow, such description being merely illustrative of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side perspective view of a robotic-assisted surgery system in position for cardiac surgery according to embodiments of the present invention.

Figures 2-3 are flowcharts showing operations according to embodiments of the present invention.

Figure 4 is a side view of an endoscopic forceps instrument according to embodiments of the present invention.

Figure 5 is an enlarged perspective view of grasping members of the endoscopic forceps of **Figure 4**.

Figure 6 is a greatly enlarged perspective view of the grasping members of **Figure 5** shown capturing a suture for use with a crochet hook according to embodiments of the present invention.

Figure 7 is a greatly enlarged perspective view of the grasping members of **Figure 5** shown holding tissue together during a suturing procedure according to embodiments of the present invention.

DETAILED DESCRIPTION

The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

Like numbers refer to like elements throughout. In the figures, the thickness of certain lines, layers, components, elements or features may be exaggerated for clarity. Broken lines illustrate optional features or operations unless specified otherwise.

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the

terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items. As used herein, phrases such as "between X and Y" and "between about X and Y" should be interpreted to include X and Y. As used herein, phrases such as "between about X and Y" mean "between about X and about Y." As used herein, phrases such as "from about X to Y" mean "from about X to about Y."

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the specification and relevant art and should not be interpreted in an idealized or overly formal sense unless expressly so defined herein. Well-known functions or constructions may not be described in detail for brevity and/or clarity.

It will be understood that when an element is referred to as being "on", "attached" to, "connected" to, "coupled" with, "contacting", etc., another element, it can be directly on, attached to, connected to, coupled with or contacting the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, "directly on", "directly attached" to, "directly connected" to, "directly coupled" with or "directly contacting" another element, there are no intervening elements present. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

It will be understood that, although the terms first, second, etc. may be used herein to describe various elements, components, regions, layers and/or sections, these elements, components, regions, layers and/or sections should not be limited by these terms. These terms are only used to distinguish one element, component, region, layer or section from another region, layer or section. Thus, a first element, component, region, layer or section discussed below could be termed a second element, component, region, layer or section without departing from the teachings of

the present invention. The sequence of operations (or steps) is not limited to the order presented in the claims or figures unless specifically indicated otherwise.

Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

The term "axially" and derivatives thereof mean in a generally lengthwise direction. The term "small opening" means an opening, port or incision that is less than about 5 inches wide and/or long, typically between about 0.25-3 inches, and more typically about 10 mm. The small opening can be disposed above, below or to the side of the sternum, or through an intercostals space in the sternum when the chest is closed (no separation of the sternum is needed).

The term "endoscopically" refers to a minimally invasive surgery that uses an endoscope and/or a robotic-assisted system. The endoscope and/or robotic system can include a camera and video (for providing real-time vision of the internal site) and can include a lighted medical instrument comprising a long tube that can be inserted into the body, usually through a small incision and/or cannula defining an intraoperative access path into the body.

The term "grasping" means securely capturing and includes releaseably grasping, trapping, attaching, clasping, pinching, and the like.

The surgical instruments described herein may be particularly suitable for robotic-assisted cardiac surgeries in which the heart of the patient is arrested for a brief period while the patient is placed on a heart-lung machine so that a surgeon can operate. For example, cardiac surgeries, such as to repair mitral valves, require sutures to repair cardiac tissue. However, the surgical instruments may also be used for other surgeries, typically minimally invasive surgeries, of other target regions in the body, within or outside the mediastinum.

For clarity of description, the invention(s) will be discussed primarily below in relationship to robotic-assisted closed chest cardiac surgeries. Such surgeries are typically carried out using a small thoracotomy and several thoracoports to provide operative visibility and access to the target cardiac site. In particular, the forceps instrument may be useful for suturing procedures in robotic mitral valve repairs. However, the instruments and methods are not limited thereto as they can be useful for other surgeries and/or for other target organs or tissue, such as non-robotic endoscopic surgeries.

Generally stated, in robotic mitral repairs, sutures for annular closure, intraleaflet closure and/or annuloplasty can be placed robotically using, for example, 2-0 braided sutures and 4-0 monofilament sutures, all of which may be shortened to a desired length beforehand. A side surgeon can cut and pick up the sutures using conventional scissors and forceps after ligation of the sutures. The number of sutures can vary with a patient, but for a quadrantectomy, more than 10 sutures are typically used with the ordinary sliding technique, and in an annuloplasty, between about 10-14 sutures can be used.

Recognizing that faster interventions and reduced insertions and extractions of endoscopic instruments can provide enhanced patient treatments, particularly as myocardial function can be depressed after cardiopulmonary bypass with extended time of heart arrest, embodiments of the present invention are directed to endoscopic instruments that can facilitate manipulation of sutures and/or tissue.

Figure 1 illustrates a robotic system **100** positioned to carry out a closed chest surgical procedure. For further description of suitable systems and/or components, *see, e.g.*, U.S. Patent Nos. 6,936,042; 6,522,906; 6,371,952; 6,364,888; 6,346,072; 6,331,181; 6,312,435; 6,309,397; 6,246,200; 6,206,903; and 6,132,368, the contents of which are hereby incorporated by reference as if recited in full herein. *See also*, Ng et al., "Robotic surgery" IEEE Engineering in Medicine and Biology (1993) 120-125. As shown in **Figure 1**, an exemplary lifting retractor system **10** can be used to provide increased chest cavity access space. The system **10** includes a lifting retractor **20**, a retractor connector **22**, a mounting arm **30**, and a mounting leg **40**. A lead, such as a chain, cable or wire can extend between the connector **22** and the mounting arm **30**. The lifting retractor **20** is inserted generally lengthwise into the body under the chest wall using an opening **75** proximate the xiphoid process or tip of the sternum cavity. This increased space can help provide suitable chest cavity space for surgical access.

Other types of lifting retractors as well as cardiac (intra-wall) lifting retractors may also be used. In other embodiments, no lifting retractors are required. As such, the instruments contemplated by the instant invention can be used alone or with different lifting retractors.

Supplemental incisions for side entry via percutaneous penetration can provide additional, typically minor, surgery access paths **176, 177** to the heart or great vessel (or other target regions) to allow surgery via visualization of the target site. One or more paths **175-177** (or even additional paths) can be used by one or more surgeons for inserting tools used to carry out minimally invasive surgeries, such as endoscopic procedures. These paths **175-177** can be particularly suitable for robotic-assisted systems as noted above. Tools can be inserted serially through each path, and in some embodiments, cooperating tools can be inserted concurrently, one or more through a different access path to meet at a common location *in situ*.

One or more of the entry paths, such as the side or minor entry paths **176, 177** can be defined by an intra-body port with a cannula (also generally known as a trocar). In some embodiments, one or more intra-body ports can be provided by a small cannula, typically one that is between about 5-15 mm wide, and more typically about 10 mm wide. An example of a commercially available port suitable for providing side access paths is the THORACOPORT™, available from U.S. Surgical, Inc., a division of Tyco Healthcare, having a place of business in Norwalk, CT.

As shown in **Figure 2**, a forceps instrument can be endoscopically introduced into the body (block **100**). The forceps instrument can include opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members. Each pair of prongs defines an opening therebetween. A length of suture can be grasped using the forceps instrument such that the suture is captured by the pairs of prongs and a portion of the suture extends across the openings defined by the pairs of prongs (block **102**). The portion of the suture that extends across the openings can be grasped with another surgical instrument (block **104**). For example, the other surgical instrument can be a crochet hook, and the suture can be removed from the body through the chest wall with the crochet hook. As another example, the other surgical instrument can be used to subsequently manipulate the suture, such as to form a suture knot.

As shown in **Figure 3**, the forceps instrument described above can be endoscopically introduced into the body (block **110**), and tissue can be grasped by the

forceps instrument so that a portion of the tissue extends across the openings defined by the pairs of prongs on the forceps instrument (block 112). A suture can be stitched in the portion of the tissue extending across the openings (block 114).

Figure 4 illustrates an endoscopic forceps instrument **200** that includes two handle members **202**, an elongated body **203**, and opposing grasping members **204a**, **204b**. As shown in **Figure 5**, the grasping members **204a**, **204b** each include respective pairs of prongs **206a**, **206b** that extend away from the grasping members **204a**, **204b**. The prongs **206a**, **206b** define respective openings **208a**, **208b**. As illustrated, the prongs **206a**, **206b** are formed on plates **210a**, **210b**, which are attached to the grasping members **204a**, **204b**; however, the prongs **206a**, **206b** may also be formed as a unitary member with the grasping members **204a**, **204b**. The forceps instrument **200** can comprise a stainless steel or other biocompatible metallic material.

The handle members **202** can operate to open and close the grasping members **204a**, **204b**, for example, using operations similar to endoscopic forceps commercially available on Cardiovasive™ Chitwood Debaquey Forceps from Scanlan International, St. Paul, MN (U.S.A) and shown in U.S. Design Patent No. 369,215. However, other suitable techniques for endoscopically maneuvering grasping members on a forceps instrument may be used.

As shown in **Figure 6**, the prongs **206a**, **206b** and grasping members **204a**, **204b** of the forceps instrument **200** can be used to grasp a length of suture **260**. The prongs **206a**, **206b** can grasp the suture **260** at two spaced apart points so that a portion of the suture **260** extends across the opening **208** defined by the prongs **206a**, **206b**. In this configuration, the suture **260** can be held securely and subsequently grasped by another surgical instrument, such as a crochet hook **250**. In some embodiments, the suture **260** is a suture remnant from a suture stitch, and the crochet hook **250** can be used to pull the suture **260** out of the body through the chest wall.

Although a crochet hook **250** is shown in **Figure 6**, it should be understood that the suture **260** can be grasped and/or manipulated by other surgical instruments, such as other forceps or hooked devices. In some embodiments, other surgical instruments can be used to stitch the suture **260** bodily tissue.

As shown in **Figure 7**, the forceps instrument **200** can be used to hold bodily tissue, such as cardiac tissue, during a suturing procedure. As illustrated in **Figure 7**, two tissue portions **280**, **282** are held by prongs **206a**, **206b** to close a tissue opening

284. A portion of suture 262 is stitched in the tissue portions 280, 282 that extend across the opening 210. In this configuration, the tissue portions 280, 282 are held securely by the pairs of prongs 206a, 206b during a suturing procedure, and space is provided for a suture by the opening 210. Various stitching procedures are described, for example in co-owned Application Serial No. _____ (Attorney Docket No. 5218.139pr) filed December 7, 2005, the disclosure of which is hereby incorporated by reference in its entirety.

The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

THAT WHICH IS CLAIMED:

1. A method for endoscopically manipulating a length of a suture, comprising:
endoscopically introducing a forceps instrument into the body, the forceps instrument including opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members, wherein each pair of prongs defines an opening therebetween; and
grasping a length of suture using the forceps instrument such that the suture is captured by the pairs of prongs and a portion of the suture extends across the openings defined by the pairs of prongs.
2. A method according to Claim 1, further comprising grasping the portion of the suture that extends across the openings with another surgical instrument.
3. A method according to Claim 2, wherein the other surgical instrument is a crochet hook.
4. A method according to Claim 3, further comprising removing the suture from the body through the chest wall with the crochet hook.
5. A method according to Claim 2, further comprising forming a suture knot with the other surgical instrument.
6. A method according to Claim 1, wherein the endoscopically introducing the forceps instrument comprises introducing the forceps instrument into the body through an intra-body cannula port defining an access path using a robotic-assisted system.
7. A method according to Claim 1, wherein the introducing step comprises directing the forceps instrument through a closed chest access path that extends adjacent a left atrium of a heart.
8. A method according to Claim 7, wherein the intrabody cannula port is about a 10 mm wide cannula.

9. A method according to Claim 8, further comprising manipulating the suture to carry out a mitral valve repair.

10. A method for endoscopically suturing tissue, comprising:
endoscopically introducing a forceps instrument into the body, the forceps instrument including opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members, wherein each pair of prongs defines an opening therebetween;

grasping tissue using the forceps instrument so that a portion of the tissue extends across the openings defined by the pairs of prongs; and

stitching a suture in the portion of the tissue extending across the openings.

11. A method according to Claim 10, wherein the endoscopically introducing the forceps instrument comprises introducing the forceps instrument into the body through an intra-body cannula port defining an access path using a robotic-assisted system.

12. A method according to Claim 10, wherein the introducing step comprises directing the forceps instrument through a closed chest access path that extends adjacent a left atrium of a heart, and the tissue is cardiac tissue.

13. A method according to Claim 12, wherein the intrabody cannula port is about a 10 mm wide cannula.

14. A method according to Claim 13, further comprising manipulating the suture to carry out a mitral valve repair.

15. A method according to Claim 10, further comprising grasping a length of suture using the forceps instrument such that the suture is captured by the pairs of prongs and a portion of the suture extends across the openings defined by the pairs of prongs.

16. A method according to Claim 15, further comprising grasping the portion of the suture that extends across the openings with another surgical instrument.

17. A method according to Claim 16, wherein the other surgical instrument is a crochet hook.

18. A method according to Claim 17, further comprising removing the suture from the body through the chest wall with the crochet hook.

19. A forceps device, comprising:

opposing grasping members having respective pairs of spaced-apart prongs that extend away from the respective grasping members, wherein each pair of prongs defines an opening therebetween;

wherein the forceps device is sized and configured to enter a patient's body through an intra-body port through a closed chest access path.

20. A device according to Claim 15, wherein the device is a robotically controlled intra-heart device.

21. A device according to Claim 15, wherein the device is sized and configured to enter the body through a about a 10 mm wide cannula.

1/7

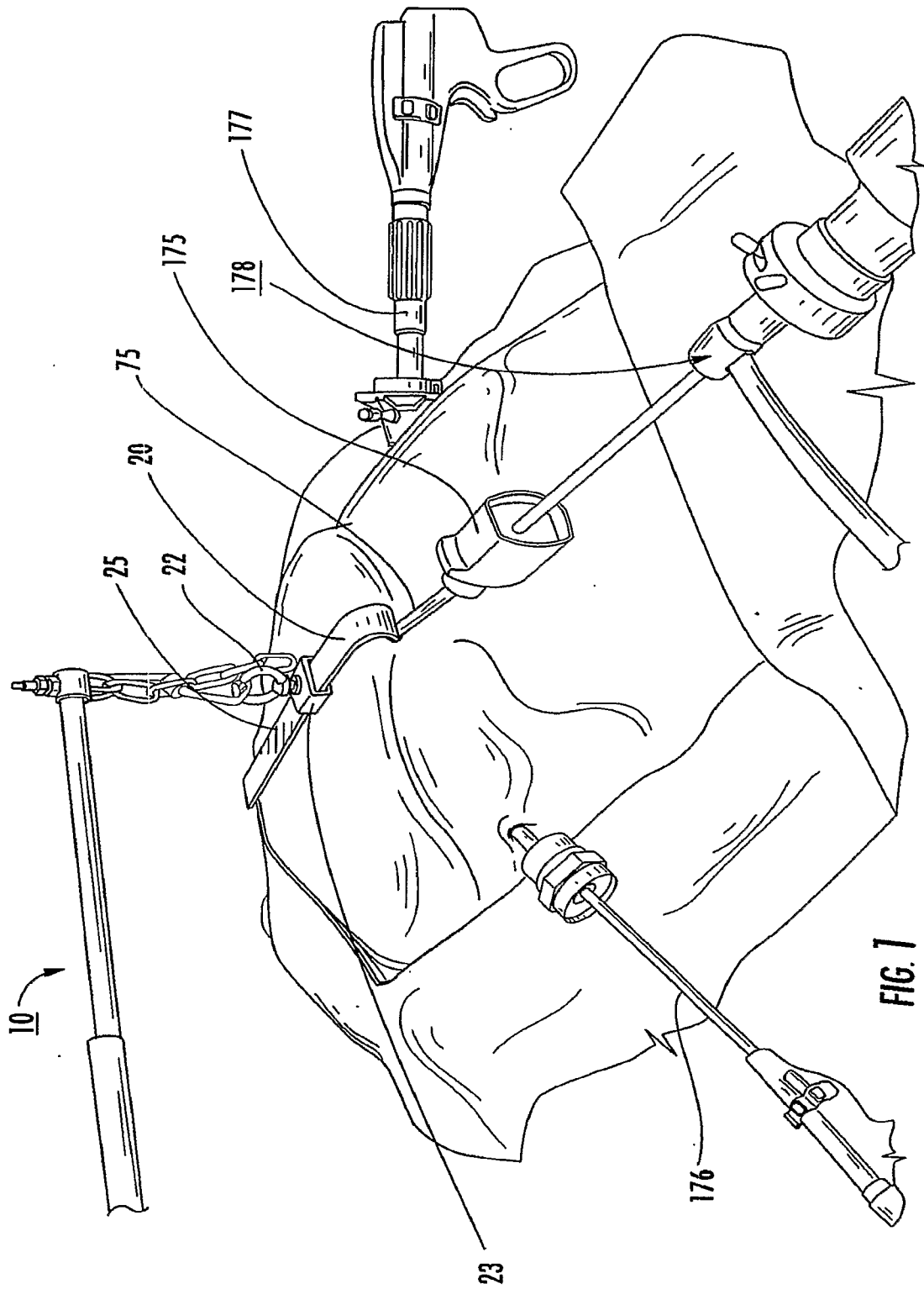


FIG. 7

2/7

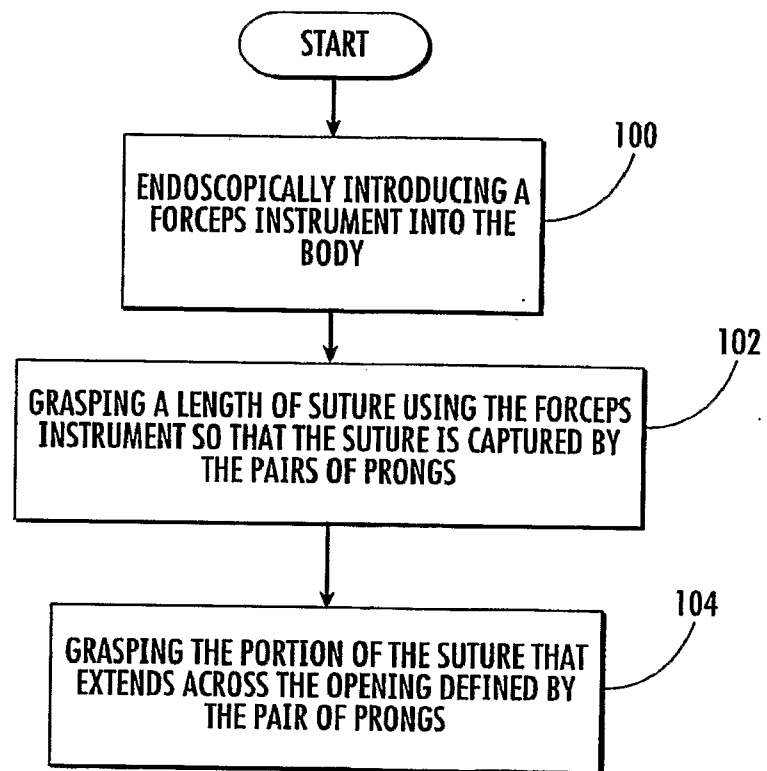


FIG. 2

3/7

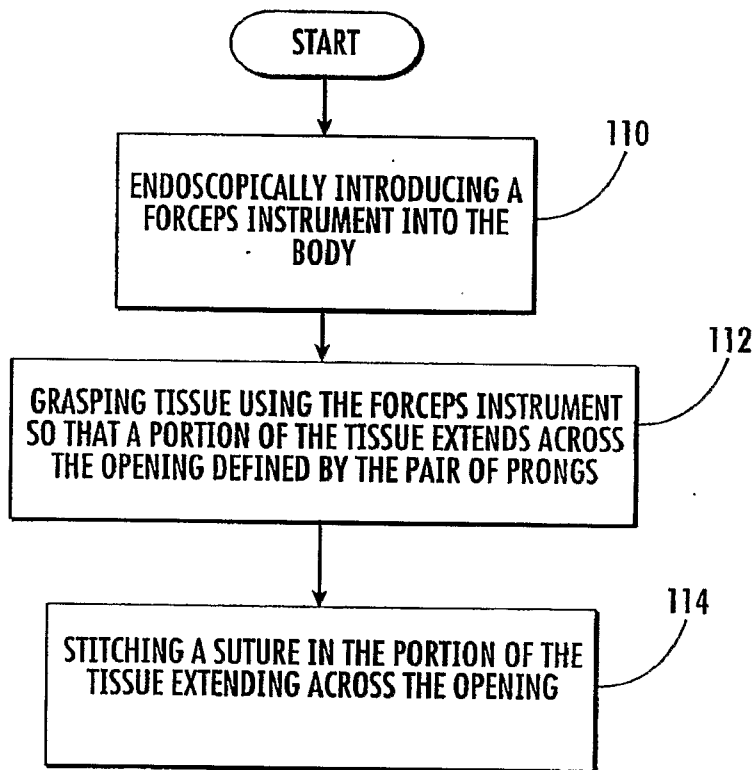


FIG. 3

4/7

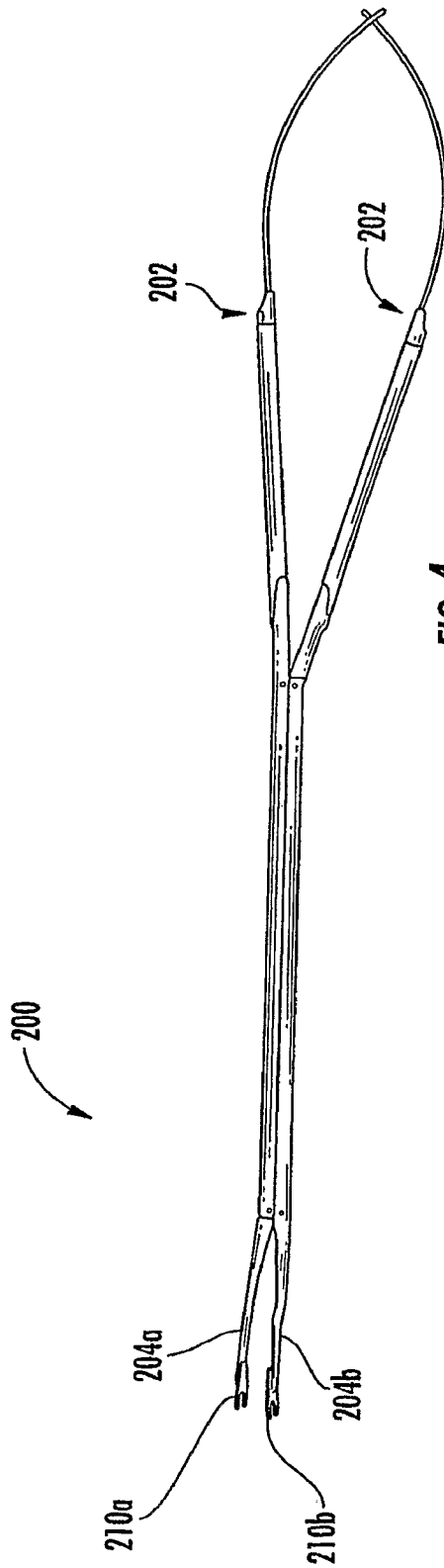


FIG. 4

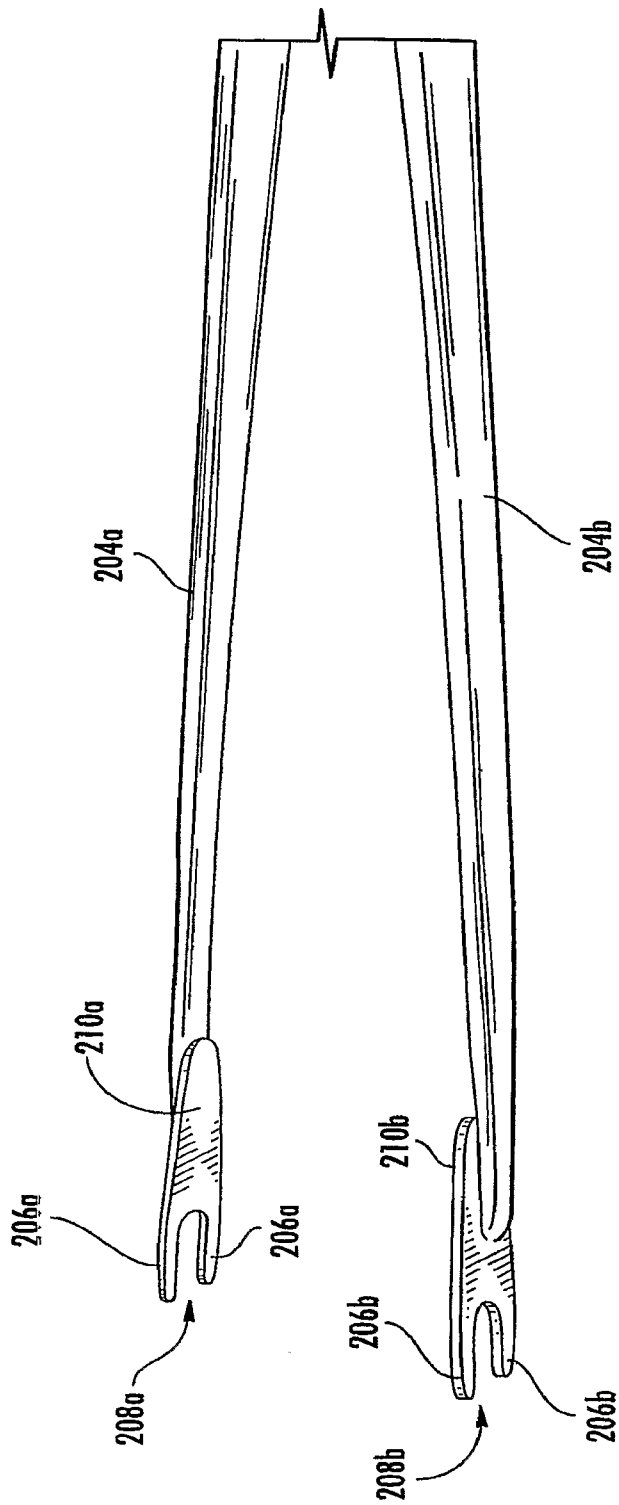
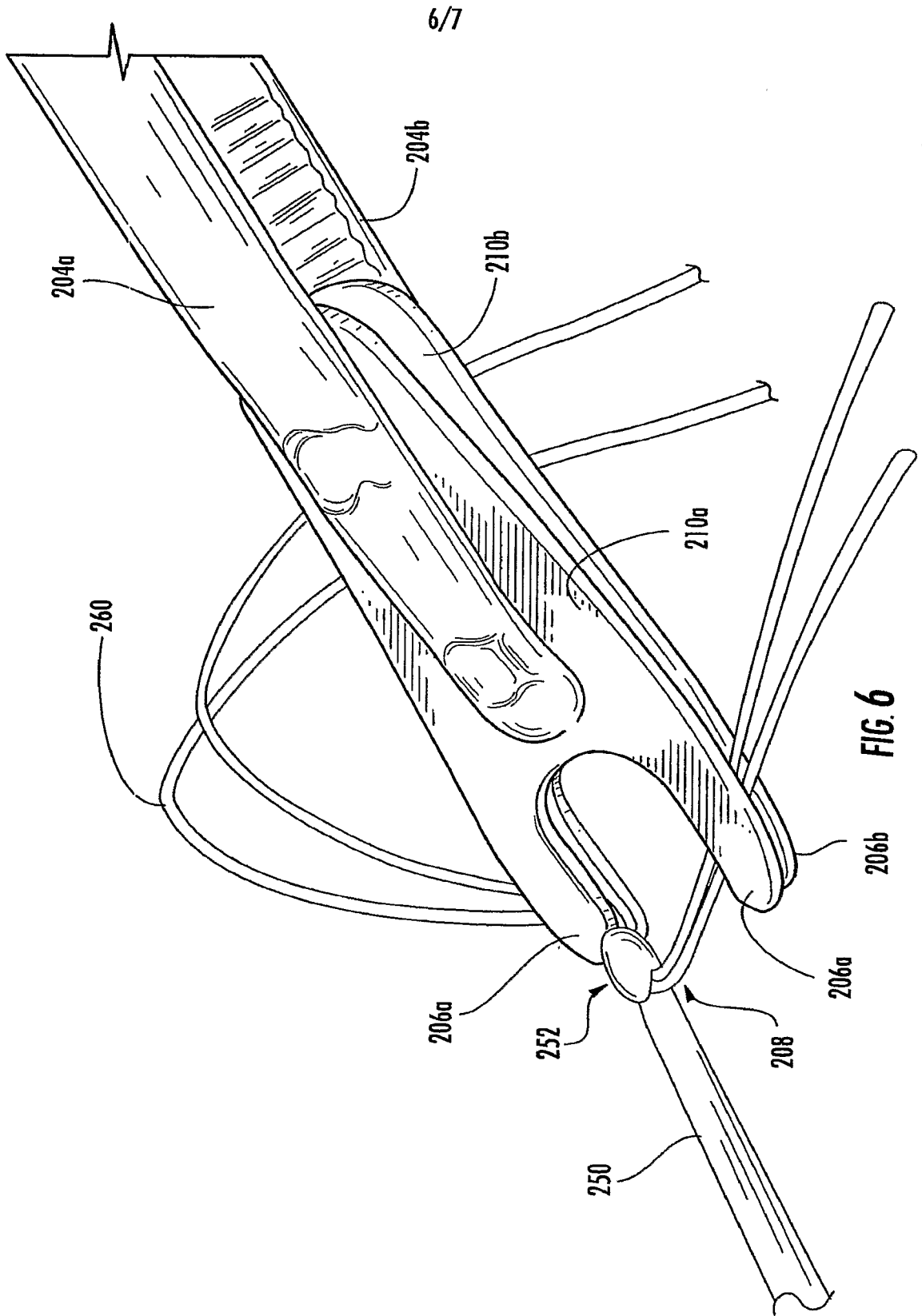


FIG. 5



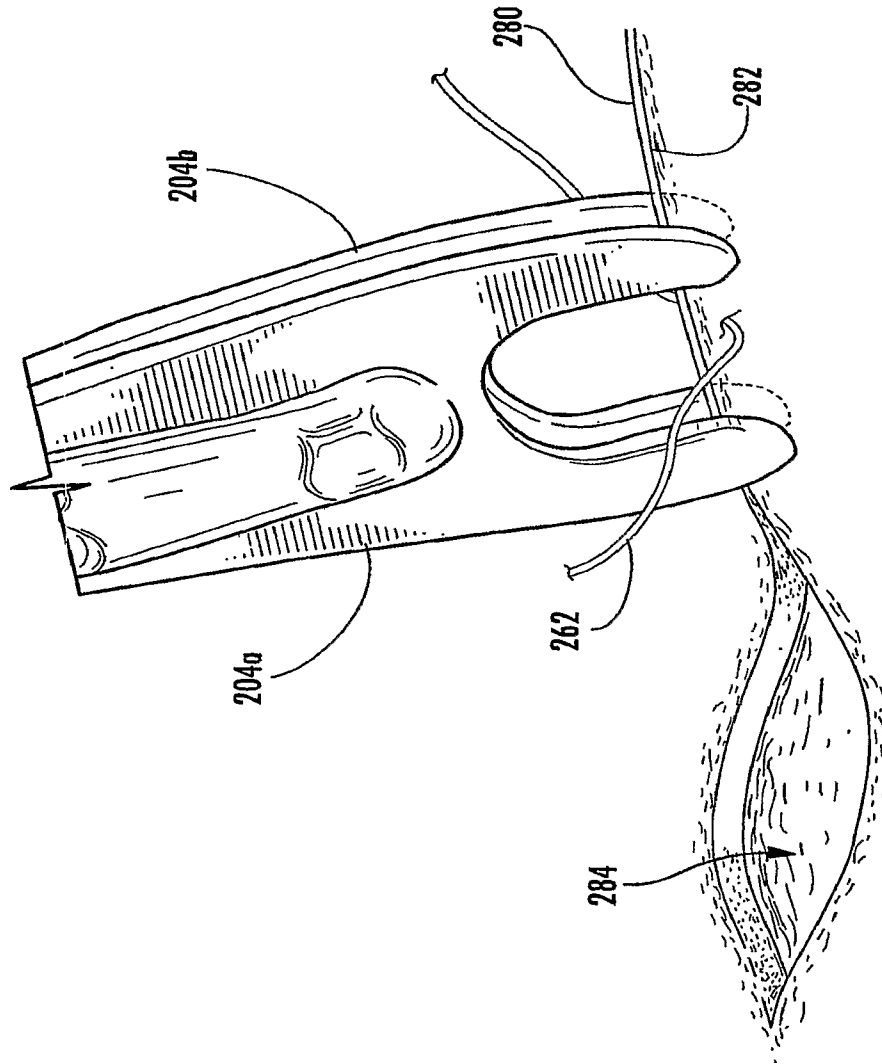


FIG. 7