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(54) **SUTURE DELIVERY TOOLS FOR ENDOSCOPIC AND ROBOT-ASSISTED SURGERY**

NAHTAUSGABEWERKZEUG FÜR ENDOSKOPISCHE UND ROBOTERGESTÜTZTE CHIRURGIE

OUTILS DE POSE DE SUTURE POUR UNE CHIRURGIE ENDOSCOPIQUE ET ASSISTÉE PAR ROBOT

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(73) Proprietor: **Ethicon LLC**
San Lorenzo, PR 00754 (US)

(72) Inventors:
- **AVELAR, Rui**
Goleta
California 93117 (US)
- **DRUBETSKY, Lev**
Coquitlam
British Columbia V3E 2S9 (CA)
- **NAIMAGON, Alexander**
Richmond
British Columbia V6Y 1M3 (CA)

(74) Representative: **Small, Gary James**
Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

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Description

FIELD OF INVENTION

[0001] The present invention relates to systems for packaging, selecting and delivering sutures to surgical sites within a patient during surgical procedures including minimally-invasive surgical procedures.

BACKGROUND OF INVENTION

[0002] Minimally invasive surgery (MIS) procedures avoid open invasive surgery in favor of closed or local surgery with less trauma. Minimally invasive surgical procedures typically involve remote manipulation of instruments with indirect observation of the surgical field through an endoscope or similar device, and are carried out through a small access port through the skin or through a body cavity or anatomical opening. Minimally invasive medical techniques thereby reduce tissue damage during diagnostic or surgical procedures, thereby reducing patient recovery time, discomfort, and deleterious side effects. Minimally invasive medical techniques consequently shorten the average length of a hospital stay for a procedure when compared to standard open surgery.

[0003] One form of minimally invasive surgery is endoscopy. Probably the most common form of endoscopy is laparoscopy, which is minimally invasive inspection and surgery inside the abdominal cavity. In standard laparoscopic surgery, a patient's abdomen is insufflated with gas, and cannula sleeves are passed through small (approximately 13 mm [½ inch]) incisions to provide access ports for laparoscopic surgical instruments. The laparoscopic surgical instruments generally include an endoscope for visualizing the surgical field and specialized surgical instruments which is, in some embodiments, passed through the access ports. The instruments can include clamps, graspers, scissors, staplers, and needle holders, for example. The surgical instruments may or may not be similar to those used in conventional (open) surgery; typically that the working end of each instrument is separated from its handle by an elongated shaft and is sized and configured to fit through the access port. To perform surgical procedures, the surgeon passes the surgical instruments through the access ports to an internal surgical site and manipulates them from outside the abdomen. The surgeon monitors the procedure by means of a monitor that displays an image of the surgical site taken from the laparoscope. Similar endoscopic techniques are employed in, e.g., arthroscopy, thoracoscopy, retroperitoneoscopy, pelviscopy, nephroscopy, cystoscopy, cisternoscopy, sinoscopy, hysteroscopy, urethroscopy, craniotomy, and natural orifice surgery (for example of the airway and gastrointestinal tract).

[0004] There are many disadvantages relating to MIS technology utilizing hand-operated instruments. For example, existing MIS instruments deny the surgeon the flexibility of instrument placement found in open surgery. Most current laparoscopic instruments have rigid shafts, so that it can be difficult to approach the surgical site through the small incision. Additionally, the length and construction of many endoscopic instruments reduces the surgeon's ability to feel forces exerted by the instrument on tissues and organs at the surgical site. The lack of dexterity and sensitivity of endoscopic instruments is an impediment to the expansion of minimally invasive surgery.

[0005] Minimally invasive telesurgery systems have been developed to increase a surgeon's dexterity when working within an internal surgical site, as well as to allow a surgeon to operate on a patient from a remote location. In a telesurgery system, the surgeon is provided with an image of the surgical site as with endoscopy. However, rather than manipulating the surgical instruments directly, the surgeon performs the surgical procedures on the patient by manipulating master input or control devices at a console. The master input and control devices control the motion of surgical instruments utilizing telemanipulators. Depending on the system, telesurgery systems may overcome some but not all of the lack of dexterity and sensitivity of endoscopic instruments. Surgical telemanipulator systems are often referred to as robotic or robotically-assisted surgery systems.

[0006] Many MIS procedures including MIS telesurgery procedures employ wound closure devices such as sutures, staples and tacks for closing wounds, repairing traumatic injuries or defects, joining tissues together (bringing severed tissues into approximation, closing an anatomical space, affixing single or multiple tissue layers together, creating an anastomosis between two hollow/luminal structures, adjoining tissues, attaching or reattaching tissues to their proper anatomical location), attaching foreign elements to tissues (affixing medical implants, devices, prostheses and other functional or supportive devices), and for repositioning tissues to new anatomical locations (repairs, tissue elevations, tissue grafting and related procedures) to name but a few examples. Sutures typically consist of a filamentous suture thread attached to a needle with a sharp point. Suture threads can be made from a wide variety of materials including bioabsorbable (i.e., that break down completely in the body over time), or non-absorbable (permanent; non-degradable) materials. Absorbable sutures have been found to be particularly useful in situations where suture removal might jeopardize the repair or where the natural healing process renders the support provided by the suture material unnecessary after wound healing has been completed; as in, for example, completing an uncomplicated skin closure. Non-degradable (non-absorbable) sutures are used in wounds where healing is, in some embodiments, expected to be protracted or where the suture material is needed to provide physical support to the wound for long periods of time; as in, for example, deep tissue repairs, high tension wounds, many orthopedic repairs and some types of surgical anastomosis. Also, a wide variety of surgical needles are available, and the shape, and size of the needle body and the configuration of the needle tip is typically selected based upon the needs of the particular application.

[0007] To use an ordinary suture, the suture needle is advanced through the desired tissue on one side of the wound and then through the adjacent side of the wound. The suture is then formed into a "loop" which is completed by tying a knot in the suture to hold the wound closed. Knot tying takes time and causes a range of complications, including, but not limited to (i) spitting (a condition where the suture, usually a knot) pushes through the skin after a subcutaneous closure), (ii) infection (bacteria are often able to attach and grow in the spaces created by a knot), (iii) bulk/mass (a significant amount of suture material left in a wound is the portion that comprises the knot), (iv) slippage (knots can slip or come untied), and (v) irritation (knots serve as a bulk "foreign body" in a wound). Suture loops associated with knot tying may lead to ischemia (knots can create tension points that can strangulate tissue and limit blood flow to the region) and increased risk of dehiscence or rupture at the surgical wound. Knot tying is also labor intensive and can comprise a significant percentage of the time spent closing a surgical wound. Additional operative procedure time is not only bad for the patient (complication rates rise with time spent under anesthesia), but it also adds to the overall cost of the operation (many surgical procedures are estimated to cost between $15 and $30 per minute of operating time). The time taken by suture tying and the range of complications is exasperated by the lack of dexterity and sensitivity of MIS instruments.

[0008] Self-retaining sutures (including barbed sutures) differ from conventional sutures in that self-retaining sutures possess numerous tissue retainers (such as barbs) which anchor the self-retaining suture into the tissue following deployment and resist movement of the suture in a direction opposite to that in which the retainers face, thereby eliminating the need to tie knots to affix adjacent tissues together (a "knotless" closure). This facilitates and expedites deployment of self-retaining sutures compared to ordinary sutures. Knotless tissue-approximating devices having barbs have been previously described in, for example, U.S. Patent No. 5,374,268, disclosing armed anchors having barb-like projections, while suture assemblies having barbed lateral members have been described in U.S. Patent Nos. 5,584,859 and 6,264,675. Sutures having a plurality of barbs positioned along a greater portion of the suture are described in U.S. Pat No. 5,931,855, which discloses a unidirectional barbed suture, and U.S. Patent No. 6,241,747, which discloses a bidirectional barbed suture. Methods and apparatus for forming barbs on sutures have been described in, for example, U.S. Patent Nos. 6,848,152. Self-retaining sutures result in better approximation of the wound edges, evenly distribute the tension along the length of the wound (reducing areas of tension that can break or lead to ischemia), decrease the bulk of suture material remaining in the wound (by eliminating knots) and reduce spitting (the extrusion of suture material - typically knots - through the surface of the skin. All of these features are thought to reduce scarring, improve cosmesis, and increase wound strength relative to wound closures using plain sutures or staples. Thus, self-retaining sutures, because such sutures avoid knot tying, allow patients to experience an improved clinical outcome, and also save time and costs associated with extended surgeries and follow-up treatments.

[0009] International patent application publication WO 2008/150773 A1 is considered the closest prior art and discloses packaging and dispensers for sutures including bi-directional sutures, the packaging and dispensers being used to reduce catching and tangling of the sutures.

SUMMARY OF INVENTION

[0010] A suture dispenser according to the present invention is defined by claim 1 and preferred embodiments are defined by the dependent claims. The present invention is generally directed to surgical instruments for delivering sutures and in particular self-retaining sutures to a surgical site in an MIS procedure including a robot-assisted MIS procedures. Despite the multitude of advantages of unidirectional and bidirectional self-retaining sutures for MIS and telesurgical MIS, there remains a need to improve upon the design of the suture such that the functionality is enhanced and/or additional functionality is provided. The present invention overcomes the problems and disadvantages of the prior art by providing packages and systems for delivering self-retaining sutures to the surgical site. The self-retaining sutures can be deployed by endoscopic and/or telesurgical instruments at the surgical site for suturing, approximating and holding tissue. The self-retaining sutures provide advantages which compensate for lack of dexterity and sensitivity present in instruments used MIS and telesurgical MIS procedures. In this way, the time taken for the procedure is reduced and the clinical outcome is enhanced.

[0011] Also disclosed is a method of performing MIS procedure in a body cavity of a patient which includes providing a suture package containing a suture or self-retaining suture and introducing the package to an operative site within a patient for use during an MIS procedure. The suture or self-retaining suture is then manipulated by the MIS instrument to suture, approximate and/or hold tissue.

[0012] In some examples, the suture package is introduced into the cavity using a telesurgical suture delivery instrument. The suture delivery instrument delivers suture to the cavity under the control of the surgeon and positions the suture such that it is, in some examples, located by the surgeon and manipulated using MIS instruments.

[0013] In some examples, the suture package is introduced into the cavity using a telesurgical suture delivery system. The telesurgical suture delivery system delivers suture to the cavity using a telemanipulator under the control of the surgeon and positions the suture such that it is, in some examples, located by the surgeon and manipulated by MIS instruments.

[0014] In some embodiments, the suture package includes a spool for the suture and self-retaining suture. The spool releasably secures one or more self-retaining sutures and surgical needles therein.

[0015] In a specific embodiment, a cartridge releasably secures one or more sutures. A cartridge is selected and attached to the suture delivery system which delivers the cartridge and suture to the surgical site. In some embodiments, a variety of different cartridges is available having different sutures.

[0016] In a specific embodiment, a cartridge releasably secures one or more sutures. A cartridge is selected and attached to the suture delivery system which delivers the cartridge and suture to the surgical site.

[0017] In some embodiments, different cartridges are available having different sutures the cartridges have features which allow them to be identified and/or selected by an automated delivery system responsive to instructions from a surgeon.

[0018] In some embodiments, suture cartridges provided with visible and/or machine readable markings, codes, tags or the like which are indicative of one or more properties of a suture loaded in the cartridge.

[0019] The details of one or more embodiments are set forth in the description below. Other features, objects and advantages will be apparent from the description, the drawings, and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] Features of the invention, its nature and various advantages will be apparent from the accompanying drawings and the following detailed description of various embodiments.

FIG. 1A shows a perspective view of a bidirectional self-retaining suture in accordance with an embodiment of the present invention.

FIG. 1B shows an enlarged views of a portion of the bidirectional suture of FIG. 1A.

FIG. 1C shows a view of a suture delivery instrument according to an embodiment of the present invention.

FIG. 1D shows an enlarged view of an embodiment of a suture spool which is, in some embodiments, used with the suture delivery instrument of FIG 1C according to an embodiment of the present invention.

FIG. 1E shows a sectional view of a subject illustrating delivery of a suture using the suture delivery instrument of FIG. 1C.

FIG. 1F shows a view of a surgical site illustrating use of the suture delivery instrument of FIG 1C.

FIG. 1G shows an image of a surgical site provided to a surgeon and illustrating use of the suture delivery instrument of FIG 1C.

FIG. 1H includes a portion of the suture of FIG. 1A also including an optional pledget.

FIG. 2A shows a suture delivery tool suitable for use with a robotically-assisted surgery system in accordance with an embodiment of the present invention; and a surgical manipulator suitable for use with the suture delivery tool.

FIGS. 2B and 2C shows introduction of a suture delivery tool by a surgical manipulator in accordance with one embodiment of the present invention.

FIG. 2D shows a side view of a suture delivery tool mounted to a surgical manipulator.

FIGS. 2E and 2F show a surgery system, and a schematic description thereof, for controlling the surgical manipulators and suture delivery tools of FIGS. 2A-2D.

FIGS. 3A and 3B show suture cartridge delivery utilizing an alternative suture delivery tool according to an embodiment of the present invention.

FIGS. 3C and 3D show internal and sectional views, respectively, of the suture delivery tool of FIGS 3A and 3B.

FIGS. 3E and 3F show different views of a suture delivery cartridge suitable for use with the suture delivery tool of FIGS. 3A through 3D according to an embodiment of the present invention.

FIGS. 4A to 4H show examples of suture cartridges.

FIGS. 5A to 5C show a suture cartridge magazine according to an embodiment of the present invention.

FIGS. 6A-6D show alternative self-retaining suture systems which have an anchor at one end.

FIGS. 6E-6F show views of a cartridge for holding one more of the alternative self-retaining suture systems of FIGS. 6A-6D.

FIGS. 6G-6H show views of a cartridge/spool for holding one more of the alternative self-retaining suture systems of FIGS. 6A-6D.

DETAILED DESCRIPTION

DEFINITIONS

[0021] Definitions of certain terms that is, in some embodiments, used hereinafter include the following.

[0022] "Self-retaining system" refers to a self-retaining suture together with devices for deploying the suture into tissue. Such deployment devices include, without limitation, suture needles and other deployment devices as well as sufficiently rigid and sharp ends on the suture itself to penetrate tissue.

[0023] "Self-retaining suture" refers to a suture that comprises features on the suture filament for engaging tissue without the need for a knot or suture anchor. Self-retaining sutures as described herein are produced by any suitable method, including without limitation, injection molding, stamping, cutting, laser, extrusion, and so forth. With respect to cutting, polymeric thread or filaments is, in some embodiments, manufactured or purchased for the suture body, and the retainers can be subsequently cut onto the suture body; the retainers are, in some embodiments, hand-cut, laser-cut, or mechanically machine-cut using blades, cutting wheels, grinding wheels, and so forth. During cutting either the cutting device or the suture thread is, in some embodiments, moved relative to the other, or both is, in some embodiments, moved, to control the size, shape and depth of cut 210. Particular methods for cutting barbs on a filament are described in U.S. Patent No. 6,848,152 (U.S. Patent Application Serial No. 09/943,733) titled "Method Of Forming Barbs On A Suture And Apparatus For Performing Same" to Genova et al., and U.S. Patent No. 8,795,332 (U.S. Patent Application Serial No. 10/065,280) titled "Barbed Sutures" to Leung et al..

[0024] "Tissue retainer" (or simply "retainer") refers to a physical feature of a suture filament which is adapted to mechanically engage tissue and resist movement of the suture in at least one axial directions. By way of example only, tissue retainer or retainers can include hooks, projections, barbs, darts, extensions, bulges, anchors, protuberances, spurs, bumps, points, cogs, tissue engagers, traction devices, surface roughness, surface irregularities, surface defects, edges, facets and the like. In certain configurations, tissue retainers are adapted to engage tissue to resist movement of the suture in a direction other than the direction in which the suture is deployed into the tissue by the physician, by being oriented to substantially face the deployment direction. In some embodiments, the retainers lie flat when pulled in the deployment direction and open or "fan out" when pulled in a direction contrary to the deployment direction. As the tissue-penetrating end of each retainer faces away from the deployment direction when moving through tissue during deployment, the tissue retainers should not catch or grab tissue during this phase. Once the self-retaining suture has been deployed, a force exerted in another direction (often substantially opposite to the deployment direction) causes the retainers to be displaced from the deployment position (i.e. resting substantially along the suture body), forces the retainer ends to open (or "fan out") from the suture body in a manner that catches and penetrates into the surrounding tissue, and results in tissue being caught between the retainer and the suture body; thereby "anchoring" or affixing the self-retaining suture in place. In certain other embodiments, the tissue retainers is, in some embodiments, configured to permit motion of the suture in one direction and resist movement of the suture in another direction without fanning out or deploying. In certain other configurations, the tissue retainer is, in some embodiments, configured or combined with other tissue retainers to resist motion of the suture filament in both directions. Typically a suture having such retainers is deployed through a device such as a cannula which prevents contact between the retainers and the tissue until the suture is in the desired location. In some embodiments, mechanical retainers are replaced and/or augmented with chemical and/or adhesive retainers which engage tissue by adhering or physically and/or chemically bonding the suture to surrounding tissue.

[0025] "Retainer configurations" refers to configurations of tissue retainers and can include features such as size, shape, flexibility, surface characteristics, and so forth. These are sometimes also referred to as "barb configurations".

[0026] "Retainer distribution" refers to the arrangement of retainers on the surface of a filament and can include variables such as orientation, pattern, pitch, and spirality angle.

[0027] "Bidirectional suture" refers to a self-retaining suture having retainers oriented in one direction at one end and retainers oriented in the other direction at the other end. A bidirectional suture is typically armed with a needle at each end of the suture thread. Many bidirectional sutures have a transition segment located between the two barb orientations.

[0028] "Transition segment" refers to a retainer-free (barb-free) portion of a bidirectional suture located between a first set of retainers (barbs) oriented in one direction and a second set of retainers (barbs) oriented in another direction. The transition segment can be at about the midpoint of the self-retaining suture, or closer to one end of the self-retaining suture to form an asymmetrical self-retaining suture system.

[0029] "Suture thread" refers to the filamentary body component of the suture. The suture thread is, in some embodiments, a monofilament, or comprise multiple filaments as in a braided suture. The suture thread is, in some embodiments, made of any suitable biocompatible material, and is, in some embodiments, further treated with any suitable biocompatible material, whether to enhance the sutures' strength, resilience, longevity, or other qualities, or to equip the sutures to fulfill additional functions besides joining tissues together, repositioning tissues, or attaching foreign elements to tissues.

[0030] "Monofilament suture" refers to a suture comprising a monofilamentary suture thread.

[0031] "Braided suture" refers to a suture comprising a multifilamentary suture thread. The filaments in such suture threads are typically braided, twisted, or woven together.

[0032] "Degradable suture" (also referred to as "biodegradable suture" or "absorbable suture") refers to a suture which, after introduction into a tissue is broken down and absorbed by the body. Typically, the degradation process is at least partially mediated by, or performed in, a biological system. "Degradation" refers to a chain scission process by which a polymer chain is cleaved into oligomers and monomers. Chain scission may occur through various mechanisms, including, for example, by chemical reaction (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination of these) or by a thermal or photolytic process. Polymer degradation is, in some embodiments, characterized, for example, using gel permeation chromatography (GPC), which monitors the polymer molecular mass changes during erosion and breakdown. Degradable suture material may include polymers such as polyglycolic acid, copolymers of glycolide and lactide, copolymers of trimethylene carbonate and glycolide with diethylene glycol (e.g., MAXONTM, Tyco Healthcare Group), terpolymer composed of glycolide, trimethylene carbonate, and dioxanone (e.g., BIOSYNTM [glycolide (60%), trimethylene carbonate (26%), and dioxanone (14%)], Tyco Healthcare Group), copolymers of glycolide, caprolactone, trimethylene carbonate, and lactide (e.g., CAPROSYNTM, Tyco Healthcare Group). A dissolvable suture can also include partially deacetylated polyvinyl alcohol. Polymers suitable for use in degradable sutures can be linear polymers, branched polymers or multi-axial polymers. Examples of multi-axial polymers used in sutures are described in U.S. Patent Application Publication Nos. 2002/0161168, 2004/0024169, and 2004/0116620. Sutures made from degradable suture material lose tensile strength as the material degrades. Degradable sutures can be in either a braided multifilament form or a monofilament form.

[0033] "Non-degradable suture" (also referred to as "non-absorbable suture") refers to a suture comprising material that is not degraded by chain scission such as chemical reaction processes (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination of these) or by a thermal or photolytic process. Non-degradable suture material includes polyamide (also known as nylon, such as nylon 6 and nylon 6,6), polyester (e.g., polyethylene terephthlate), polytetrafluoroethylene (e.g., expanded polytetrafluoroethylene), polyether-ester such as polybutester (block copolymer of butylene terephthalate and polytetra methylene ether glycol), polyurethane, metal alloys, metal (e.g., stainless steel wire), polypropylene, polyethelene, silk, and cotton. Sutures made of non-degradable suture material are suitable for applications in which the suture is meant to remain permanently or is meant to be physically removed from the body.

[0034] "Suture diameter" refers to the diameter of the body of the suture. It is to be understood that a variety of suture lengths is, in some embodiments, used with the sutures described herein and that while the term "diameter" is often associated with a circular periphery, it is to be understood herein to indicate a cross-sectional dimension associated with a periphery of any shape. Suture sizing is based upon diameter. United States Pharmacopeia ("USP") designation of suture size runs from 0 to 7 in the larger range and 1-0 to 11-0 in the smaller range; in the smaller range, the higher the value preceding the hyphenated zero, the smaller the suture diameter. The actual diameter of a suture will depend on the suture material, so that, by way of example, a suture of size 5-0 and made of collagen will have a diameter of 0.15 mm, while sutures having the same USP size designation but made of a synthetic absorbable material or a non-absorbable material will each have a diameter of 0.1 mm. The selection of suture size for a particular purpose depends upon factors such as the nature of the tissue to be sutured and the importance of cosmetic concerns; while smaller sutures is, in some embodiments, more easily manipulated through tight surgical sites and are associated with less scarring, the tensile strength of a suture manufactured from a given material tends to decrease with decreasing size. It is to be understood that the sutures and methods of manufacturing sutures disclosed herein are suited to a variety of diameters, including without limitation 7, 6, 5, 4, 3, 2, 1, 0, 1-0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0, 8-0, 9-0, 10-0 and 11-0.

[0035] "Needle attachment" refers to the attachment of a needle to a suture requiring same for deployment into tissue, and can include methods such as crimping, swaging, using adhesives, and so forth. The suture thread is attached to the suture needle using methods such as crimping, swaging and adhesives. Attachment of sutures and surgical needles is described in U.S. Patent Nos. 3,981,307, 5,084,063, 5,102,418, 5,123,911, 5,500,991, 5,722,991, 6,012,216, and 6,163,948, and U.S. Patent Application Publication No. US 2004/0088003). The point of attachment of the suture to the needle is known as the swage.

[0036] "Suture needle" refers to needles used to deploy sutures into tissue, which come in many different shapes, forms and compositions. There are two main types of needles, traumatic needles and atraumatic needles. Traumatic needles have channels or drilled ends (that is, holes or eyes) and are supplied separate from the suture thread and are threaded on site. Atraumatic needles are eyeless and are attached to the suture at the factory by swaging or other methods whereby the suture material is inserted into a channel at the blunt end of the needle which is then deformed to a final shape to hold the suture and needle together. As such, atraumatic needles do not require extra time on site for threading and the suture end at the needle attachment site is generally smaller than the needle body. In the traumatic needle, the thread comes out of the needle's hole on both sides and often the suture rips the tissues to a certain extent as it passes through. Most modern sutures are swaged atraumatic needles. Atraumatic needles is, in some embodiments, permanently swaged to the suture or is, in some embodiments, designed to come off the suture with a sharp straight tug. These "pop-offs" are commonly used for interrupted sutures, where each suture is only passed once and then tied. For barbed sutures that are uninterrupted, these atraumatic needles are preferred.

[0037] Suture needles may also be classified according to the geometry of the tip or point of the needle. For example, needles is, in some embodiments, (i) "tapered" whereby the needle body is round and tapers smoothly to a point; (ii) "cutting" whereby the needle body is triangular and has a sharpened cutting edge on the inside; (iii) "reverse cutting" whereby the cutting edge is on the outside; (iv) "trocar point" or "taper cut" whereby the needle body is round and tapered, but ends in a small triangular cutting point; (v) "blunt" points for sewing friable tissues; (vi) "side cutting" or "spatula points" whereby the needle is flat on top and bottom with a cutting edge along the front to one side (these are typically used for eye surgery).

[0038] Suture needles may also be of several shapes including, (i) straight, (ii) half curved or ski, (iii) 1/4 circle, (iv) 3/8 circle, (v) 1/2 circle, (vi) 5/8 circle, (v) and compound curve.

[0039] Suturing needles are described, for example, in US Patent Nos. 6,322,581 and 6,214,030 (Mani, Inc., Japan); and 5,464,422 (W.L. Gore, Newark, DE); and 5,941,899; 5,425,746; 5,306,288 and 5,156,615 (US Surgical Corp., Norwalk, CT); and 5,312,422 (Linvatec Corp., Largo, FL); and 7,063,716 (Tyco Healthcare, North Haven, CT). Other suturing needles are described, for example, in US Patent Nos. 6,129,741; 5,897,572; 5,676,675; and 5,693,072. The sutures described herein is, in some embodiments, deployed with a variety of needle types (including without limitation curved, straight, long, short, micro, and so forth), needle cutting surfaces (including without limitation, cutting, tapered, and so forth), and needle attachment techniques (including without limitation, drilled end, crimped, and so forth). Moreover, the sutures described herein may themselves include sufficiently rigid and sharp ends so as to dispense with the requirement for deployment needles altogether.

[0040] "Needle diameter" refers to the diameter of a suture deployment needle at the widest point of that needle. While the term "diameter" is often associated with a circular periphery, it can be understood herein to indicate a cross-sectional dimension associated with a periphery of any shape.

[0041] "Armed suture" refers to a suture having a suture needle on at least one suture deployment end. "Suture deployment end" refers to an end of the suture to be deployed into tissue; one or both ends of the suture is, in some embodiments, suture deployment ends. The suture deployment end is, in some embodiments, attached to a deployment device such as a suture needle, or is, in some embodiments, sufficiently sharp and rigid to penetrate tissue on its own.

[0042] "Wound closure" refers to a surgical procedure for closing of a wound. An injury, especially one in which the skin or another external or internal surface is cut, torn, pierced, or otherwise broken is known as a wound. A wound commonly occurs when the integrity of any tissue is compromised (e.g., skin breaks or burns, muscle tears, or bone fractures). A wound is, in some embodiments, caused by an act, such as a puncture, fall, or surgical procedure; by an infectious disease; or by an underlying medical condition. Surgical wound closure facilitates the biological event of healing by joining, or closely approximating, the edges of those wounds where the tissue has been torn, cut, or otherwise separated. Surgical wound closure directly apposes or approximates the tissue layers, which serves to minimize the volume new tissue formation required to bridge the gap between the two edges of the wound. Closure can serve both functional and aesthetic purposes. These purposes include elimination of dead space by approximating the subcutaneous tissues, minimization of scar formation by careful epidermal alignment, and avoidance of a depressed scar by precise eversion of skin edges.

[0043] "Tissue elevation procedure" refers to a surgical procedure for repositioning tissue from a lower elevation to a higher elevation (i.e. moving the tissue in a direction opposite to the direction of gravity). The retaining ligaments of the face support facial soft tissue in the normal anatomic position. However, with age, gravitational effects and loss of tissue volume effect downward migration of tissue, and fat descends into the plane between the superficial and deep facial fascia, thus causing facial tissue to sag. Face-lift procedures are designed to lift these sagging tissues, and are one example of a more general class of medical procedure known as a tissue elevation procedure. More generally, a tissue elevation procedure reverses the appearance change that results from effects of aging and gravity over time, and other temporal effects that cause tissue to sag, such as genetic effects. It should be noted that tissue can also be repositioned without elevation; in some procedures tissues are repositioned laterally (away from the midline), medially (towards the midline) or inferiorly (lowered) in order to restore symmetry (i.e. repositioned such that the left and right sides of the body "match").

[0044] "Medical device" or "implant" refers to any object placed in the body for the purpose of restoring physiological function, reducing/alleviating symptoms associated with disease, and/or repairing and/or replacing damaged or diseased organs and tissues. While normally composed of biologically compatible synthetic materials (e.g., medical-grade stainless steel, titanium and other metals or polymers such as polyurethane, silicon, PLA, PLGA and other materials) that are exogenous, some medical devices and implants include materials derived from animals (e.g., "xenografts" such as whole animal organs; animal tissues such as heart valves; naturally occurring or chemically-modified molecules such as collagen, hyaluronic acid, proteins, carbohydrates and others), human donors (e.g., "allografts" such as whole organs; tissues such as bone grafts, skin grafts and others), or from the patients themselves (e.g., "autografts" such as saphenous vein grafts, skin grafts, tendon/ligament/muscle transplants). Medical devices that can be used in procedures in conjunction with the present invention include, but are not restricted to, orthopedic implants (artificial joints, ligaments and tendons; screws, plates, and other implantable hardware), dental implants, intravascular implants (arterial and venous vascular bypass grafts, hemodialysis access grafts; both autologous and synthetic), skin grafts (autologous, synthetic), tubes, drains, implantable tissue bulking agents, pumps, shunts, sealants, surgical meshes (e.g., hernia repair meshes, tissue scaffolds), fistula treatments, spinal implants (e.g., artificial intervertebral discs, spinal fusion devices, etc.) and the like.

SUTURE DELIVERY FOR MINIMALLY-INVASIVE SURGERY

[0045] As discussed above, the present disclosure provides compositions, configurations, methods of manufacturing and methods of utilizing self-retaining sutures. The invention overcomes the problems and disadvantages of the prior art by delivering self-retaining sutures to the surgical site. The self-retaining sutures can be manipulated by endoscopic and/or robotically-assisted surgical instruments at the site for suturing, approximating and holding tissue. A number of devices have been proposed for delivery surgical elements and accessories for use in MIS procedures. Devices are disclosed, for example, in U.S. Patent 6,986,780 titled "Surgical Element Delivery System And Method" to Rudnick et al. and U.S. Patent 7,125,403 titled "in Vivo Accessories For Minimally Invasive Robotic Surgery" to Julian et al.

Endoscopic Suture Delivery System

[0046] A self-retaining suture is, in some embodiments, unidirectional, having one or more retainers oriented in one direction along the length of the suture thread; or bidirectional, typically having one or more retainers oriented in one direction along a portion of the thread, followed by one or more retainers oriented in another (often opposite) direction over a different portion of the thread (as described with barbed retainers in U.S. Patent Nos. 5,931,855 and. 6,241,747). Although any number of sequential or intermittent configurations of retainers are possible, a common form of bidirectional self-retaining suture involves a needle at one end of a suture thread which has barbs having tips projecting "away" from the needle until the transition point (often the midpoint) of the suture is reached; at the transition point the configuration of barbs reverses itself about 180° (such that the barbs are now facing in the opposite direction) along the remaining length of the suture thread before attaching to a second needle at the opposite end (with the result that the barbs on this portion of the suture also have tips projecting "away" from the nearest needle). Projecting "away" from the needle means that the tip of the barb is further away from the needle and the portion of suture comprising the barb is, in some embodiments, pulled more easily through tissue in the direction of the needle than in the opposite direction. Put another way, the barbs on both "halves" of a typical bidirectional self-retaining suture have tips that point towards the middle, with a transition segment (lacking barbs) interspersed between them, and with a needle attached to either end.

[0047] FIG. 1A illustrates a self-retaining suture system 100. Self-retaining suture system 100 comprises needles 110, 112 attached to self-retaining suture thread 102. Self-retaining suture thread 102 includes a plurality of retainers 130 distributed on the surface of a filament 120. In lead-in section 140 of filament 120 there are no retainers 130. In section 142 of filament 120, there are a plurality of retainers 130 arranged such that the suture can be deployed in the direction of needle 110, but resists movement in the direction of needle 112. In transition section 144, there are no retainers 130. Transition section 122 is, in some embodiments, provided with a marker to facilitate location of the transition section. Transition section 122, as shown, is provided with a visible band 122 to help identify the transition section. Markers are in some embodiments also provided on sections 142, 146 and/or needles 110, 112 in order to help identify the retainer location and orientation of a particular portion of self-retaining suture system 100. In section 146, there is a plurality of retainers 130 arranged such that the suture can be deployed in the direction of needle 112, but resists movement in the direction of needle 110. The retainers 130 in section 146 are larger than the retainers 130 in section 142. The larger retainers are better suited for gripping tissue that is softer and/or less dense than the smaller retainers. In lead-in section 148 of filament 120 there are no retainers 130.

[0048] A break is shown in each of sections 140, 142, 144, 146 and 148 to indicate that the length of each section is, in some embodiments, varied and selected depending upon the application for which the suture is intended to be used. For example, transition section 144 can be asymmetrically located closer to needle 110 or needle 112, if desired. A self-retaining suture having an asymmetrically located transition section 144 is, in some embodiments, favored by a physician that prefers to use his dominant hand in techniques that require suturing in opposite directions along a wound. The physician may start further from one end of the wound than the other and stitch the longer portion of the wound with the needle that is located further from the transition section 144. This allows a physician to use his dominant hand to stitch the majority of the wound with the longer arm of the suture. The longer arm of the suture is that section of suture between the transition section and the needle which is located further from the transition section.

[0049] FIG. 1B illustrates a magnified view of self-retaining suture thread 102 in section 142. As shown in FIG. 1B, a plurality of retainers 130 is distributed on the surface of filament 120. The affixation of self-retaining sutures after deployment in tissue entails the penetration of retainer ends 132 into the surrounding tissue resulting in tissue being caught between the retainer 130 and the body of suture filament 120. The inner surface 134 of the retainer 130 that is in contact with the tissue that is caught between the retainer 130 and the body of filament 120, is referred to herein as the "tissue engagement surface" or "inner retainer surface." As illustrated in FIG. 1B, each retainer 130 has a tip 132 and tissue retainer surface 134. When self-retaining suture thread 102 is moved in the direction of arrow 136, retainers 130 lies flat against the body of filament 120. However, when self-retaining suture thread 102 is moved in the direction of arrow 138, tip 132 of retainer 130 engages tissue surrounding filament 120 and causes retainer 130 to fan out from filament 120 and engage the tissue with tissue engagement surface 134 thereby preventing movement of the suture in that direction.

[0050] In alternative embodiments, a pledget can be applied to a self-retaining suture. FIG. 1H depicts a pledget 124 located in the transition zone 144 of self-retaining suture system 100. In some embodiments, a pledget 124 can carry a marker/code 128 which helps identify the suture and/or properties thereof. Pledget 124 has one or more apertures 126 through which suture thread 120 can be passed as shown. Alternatively, a pledget can be bonded and/or mechanically fixed to suture thread 120, by, for example, welding, clipping, gluing, fusing. The pledget 126 can be used for locating the transition zone, for providing a stop so that the pledget can be pulled through tissue only until the pledget contacts the tissue, and/or for providing a support to tissue and organs, to name just a few uses. The pledget 126 can take many forms including a wider section that can support tissue.

[0051] The ability of self-retaining sutures to anchor and hold tissues in place even in the absence of tension applied to the suture by a knot is a feature that also provides superiority over plain sutures. When closing a wound that is under tension, this advantage manifests itself in several ways: (i) self-retaining sutures have a multiplicity of retainers which can dissipate tension along the entire length of the suture (providing hundreds of "anchor" points this produces a superior cosmetic result and lessens the chance that the suture will "slip" or pull through) as opposed to knotted interrupted sutures which concentrate the tension at discrete points; (ii) complicated wound geometries can be closed (circles, arcs, jagged edges) in a uniform manner with more precision and accuracy than can be achieved with interrupted sutures; (iii) self-retaining sutures eliminate the need for a "third hand" which is often required for maintaining tension across the wound during traditional suturing and knot tying (to prevent "slippage" when tension is momentarily released during tying); (iv) self-retaining sutures are superior in procedures where knot tying is technically difficult, such as in deep wounds or laparoscopic/endoscopic procedures; and (v) self-retaining sutures can be used to approximate and hold the wound prior to definitive closure. As a result, self-retaining sutures provide easier handling in anatomically tight or deep places (such as the pelvis, abdomen and thorax) and make it easier to approximate tissues in laparoscopic/endoscopic and minimally invasive procedures; all without having to secure the closure via a knot. Greater accuracy allows self-retaining sutures to be used for more complex closures (such as those with diameter mismatches, larger defects or purse string suturing) than can be accomplished with plain sutures. The superior qualities of self-retaining suture are particularly beneficial in endoscopic and telesurgical procedures. Self-retaining suture help overcome the limitations of dexterity and sensitivity present in endoscopic and telesurgical instruments.

[0052] FIG. 1C shows an endoscopic suture delivery instrument 150 for delivering a self-retaining suture system 100 to a surgical site within a patient. Suture delivery instrument 150 includes, at the proximal end, a handle 152 connected by an elongated tubular member 154 to a spool 156. Handle 152 allows for positioning and operation of the suture delivery instrument 150 from outside of the body of the patient. Handle 152 may include one or more actuators 158 which is, in some embodiments, moved relative to one another and/or handle 152 for operating an effector, such as surgical scissors, a delivery spool, etc., located on the suture delivery instrument.

[0053] Elongated tubular member connects handle 152 (proximal end) to spool 156 (distal end). Elongated tubular member 154 is a rigid member which is sized to fit through an access port into the body of the patient. Preferably, the tubular member 154 is about or less than 12 mm, 8 mm and 5 mm. Elongated tubular member 154 must be long enough to reach the desired surgical site through the access port. For laparoscopic instruments, for example, elongated tubular member 154 is between 180 mm and 450 mm in length and is typically 360 mm in length for adults and 280 mm in length for pediatric surgery. Typically the access port will be 12mm in diameter in less. Preferably the access port will be 10 mm in diameter or less. In some case the access port is, in some embodiments, 8 mm or 5 mm in diameter or less. In general smaller access ports are preferred to reduce trauma to patient tissues however, the parts must be sufficiently large to permit entry of instruments having the functionality to perform the desired surgical manipulations. The diameter of the elongated tubular member 154 and spool 156 will be smaller than the inner diameter of the access port so that the distal portion of suture delivery instrument is, in some embodiments, introduce through the access port.

[0054] FIG. 1D shows a cartridge 170 which includes spool 156 and a connector 172. Connector 172 allows cartridge 170 to be releasably attached to the distal end of elongated tubular member 154. In some embodiments, an actuator 158 controls the attaching and releasing of the cartridge 170. A selection of sterile cartridges 170 is, in some embodiments, supplied for a procedure each supporting a different self-retaining suture. Thus, suture delivery instrument 150 can be used by the surgeon or assistant to select and deliver multiple self-retaining suture systems 100 in the course of a procedure. In alternative embodiments spool 156 is, in some embodiments, permanently fixed to the end of suture delivery instrument 150. As shown in FIG. 1D, spool 156 may also include one or more needle docks 157 for supporting the needles 110, 112 of self-retaining suture system 100. Needles 110, 112 are releasable attached to needle docks 157. The needle 110, 112 are removed from needle docks 157 to allow deployment of self-retaining suture thread

102. In some embodiments, needles 110, 112 are replaced in needle docks 157 to allow removal of needles 110, 112 and any surplus self-retaining suture thread 102 after deployment of self-retaining suture thread 102.

[0055] As also shown in FIG. 1D, cartridge 170 includes a marker 174. As shown in FIG. 1D, marker 174 is a QR code. A QR code is a machine-readable matrix code or two-dimensional barcode designed to allow quick decoding of its contents. In particular QR codes can be quickly recognized and decoded in camera images. The QR code in some embodiments directly identifies properties of the suture and in other cases identifies the location (URL or other) of data identifying properties of the suture. The properties of the suture are then displayed with the image of the surgical site provided to the surgeon (See FIG. 1G). The information displayed allows the surgeon to verify that the cartridge is loaded with the desired suture. Although a QR code is shown in FIG. 1D, potential markers include, but are not limited to: markers visible in the visible light frequency range; alphanumeric markers, QR code markers, markers invisible to the naked eye but which can be visualized under the conditions of surgical use; markers recognizable in the non-visible radiation frequency range; markers detectable with ultrasound; markers which are machine readable; markers which are human readable; markers which is, in some embodiments, read remotely; markers which are active markers (including RFID); and markers which are passive markers (including passive RFID). The properties of the suture which can be associated with the marker include, but are not limited to: length, diameter, material, needles, presence of retainers, absence of retainers, source/brand and/or other fixed properties. In addition to fixed or static properties, a marker can be used to identify dynamic properties. For example, movement of the cartridge and/or suture through forces being placed on the cartridge can cause the marker to move, and such movement can be noted by telesurgical system in order to track the changing location of the cartridge and the suture. Such movement can be translational movement or rotational movement. With the tracking of rotational movement of the spool, for example, the amount of suture removed from the spool can be tracked. Markings placed additionally on the suture can be used to identify the changing location of the suture and also, for example, tension placed on the suture. The markings can also be used with a voice-command telesurgical system. The surgeon speaks the type of suture desired, and the telesurgical system then loads the cartridge onto the end of a tool located on an arm of the telesurgical system for deployment into a patient.

[0056] Spool 156 is mounted on the distal end of elongated tubular member 154 and is sized so that it may slide through an access port into the body of the patient. Spool 156 supports self-retaining suture system 100 thus allowing self-retaining suture system 100 to be delivered through an access port to the surgical site within the patient. FIG. 1E shows the distal portion of suture delivery instrument 150 introduced through an access port 160 into a patient 162. Suture delivery instrument 150 is inserted through a cannula 164 at the access port 160. Suture delivery instrument 150 is, in some embodiments, slid in and out of cannula 164 as shown by arrow 166. Suture delivery instrument 150 and cannula 164 may also pivot about the access port 160 as shown by arrows 168. Thus, suture delivery instrument 150 allows spool 156 to be delivered to a surgical site within patient 162.

[0057] FIG. 1F shows delivery of a self-retaining suture system 100 to a surgical site in a patient. As shown in FIG. 1F, an endoscope 180 illuminates the surgical site with one or more light sources 182. Endoscope 180 also images the surgical site through one or more imaging devices 184. Endoscope 180 thereby illuminates the surgical site. The dashed circle 186 indicates the field of view that is, in some embodiments, transmitted to the surgeon. Note that suture delivery instrument 150 has been inserted so as to position a spool 156 of a cartridge 170 within the field of view. The end effectors (scissors, forceps and the like) of one or more endoscopic surgical instruments 190 also appear in the field of view. The surgeon may operate the endoscopic surgical instruments 190 to grasp the needles 110, 112 supported by spool 156. The surgeon may then operate the endoscopic surgical instruments 190 to deploy self-retaining suture thread 102 into tissue 192. After deployment of self-retaining suture thread 102, the surgeon may operate endoscopic surgical instruments 190 to replace needle 110, 112 in spool 156 and cut off any unused self-retaining suture thread 102. Suture delivery instrument 150 may then be removed from the surgical site thereby removing the needles and any excess self-retaining suture thread 102 from the patient's body.

[0058] FIG. 1G shows an example of an image 194 on a display 196 of the surgical site of FIG. 1F as displayed to a surgeon. The dashed circle 186 indicates the field of view available from the endoscope (not shown). Note that suture delivery instrument 150 has been inserted so as to position a spool 156 of a cartridge 170 within the field of view 186. Marker 174 of cartridge 170 is visible in the image. A computer system associated with display 196 identifies and translates marker 174. As shown in FIG. 1G, suture property information 176 associated with marker 174 is displayed to the surgeon in the image 194. The information displayed allows the surgeon to verify that the cartridge is loaded with the desired suture. The information displayed can be static or dynamic information. For example, having identified the suture the image display system can also display other suture property information 176 relevant to the suture. For example tension sensed by the endoscopic tools or otherwise can be displayed as a percentage graph of the maximum rated tension of the identified suture.

Robot-Assisted Suture Delivery System

[0059] As described above, minimally invasive telesurgical systems have been developed to increase a surgeon's dexterity when working within an internal surgical site, as well as to allow a surgeon to operate on a patient from a remote location. In a telesurgery system, the surgeon is provided with an image of the surgical site at a console. While viewing an image of the surgical site on a suitable display, the surgeon performs the surgical procedures on the patient by manipulating input devices of the console. The input devices control a robot arm which positions and manipulates the surgical instrument. During the surgical procedure, the telesurgical system can provide mechanical actuation and control of a variety of surgical instruments or instruments having end effectors such as, e.g., tissue graspers, cautery, needle drivers, or the like, that perform various functions for the surgeon, e.g., holding or driving a needle, grasping a blood vessel, or dissecting tissue, or the like, in response to manipulation of the master control devices. The Intuitive Surgical, Inc. DA VINCI® Surgical System is one example of a MIS telesurgical system.

[0060] In a telesurgical procedure, sutures, including self-retaining suture systems, can in some embodiments be introduced to the surgical site using suture delivery instrument 150 previously described with respect to FIGS. 1C-1G. The suture delivery instrument could be operated manually by the surgeon. However, this requires the surgeon to leave the workstation. Alternatively, the suture delivery instrument 150 can be operated manually by a surgical assistant. However, this requires the assistant to insert the suture delivery instrument manually without the visualization provided by the workstation. According to another embodiment of the present invention, a suture delivery instrument is provided which interfaces with the telesurgery system. The suture delivery instrument is used to deliver the self-retaining suture to the surgical site under the command of the surgeon. Such a suture delivery instrument advantageously leverages the abilities of the telesurgery system to accurately deliver the self-retaining suture to the surgical site under the control of the surgeon at the workstation and using the visualization capabilities of the telesurgery system. Moreover certain portions of the suture delivery operation is, in some embodiments, safely automated to facilitate the repeated delivery and extraction of sutures to the surgical site after initial setup under the control of the surgeon. The surgeon controls the suture delivery instrument with one or more inputs of the console, which can include, for example, switch, keyboards, motion controllers and/or voice input devices.

[0061] FIG. 2A shows a suture delivery tool 250 suitable for use with a telesurgery system. Suture delivery tool 250 includes, at the proximal end, a case 252 connected by a tool shaft 254 to an end effector including a spool 256. Case 252 can be mounted to the interface 246 of a manipulator arm 240 to allow for positioning and operation of the suture delivery tool 250 from outside of the body of the patient. Suture delivery tool 250 includes a spool 256 mounted on the distal end of tool shaft 254. Spool 256 supports self-retaining suture system 100 thus allowing self-retaining suture system 100 to be delivered through a cannula/guide 264 to the surgical site within the patient. Spool 256 is sized so that it may slide through cannula/guide 264 into the body of the patient.

[0062] Tool shaft 254 connects case 252 (proximal end) to the spool 256 (distal end). Tool shaft 254 is a rigid member which is sized to fit through an access port into the body of the patient. Alternatively, the tool shaft can be flexible. The tool shaft itself can be controlled by the telesurgical system so that the tool shaft can be "snaked" to a desired location. Tool shaft 254 must be long enough to reach the desired surgical site through the access port. The diameter of the tool shaft 254 and spool 256 must be small enough so that the distal portion of surgical tool 250 is, in some embodiments, introduced through the cannula tool guide/access port 264 into the patient. Tool shaft 254 may contain one or more mechanical linkages for transferring motion from the gears 258 in the case to an end effector at the distal end of tool shaft 254.

[0063] FIG. 2A also shows the portion of a manipulator arm 240 to which a suture delivery tool 250 is, in some embodiments, mounted. The case 252 of suture delivery tool 250 (or another tool) is, in some embodiments, releasably mounted to the interface 246 on the manipulator arm 240. Case 252 includes one or more clips 253 which engage mating structures on interface 246 to hold case 252 to interface 246. Note that interface 246 can be moved up and down track 247 to slide a tool in and out of cannula/tool guide 264. The movement of interface 246 along track 247 is effected by a transducer/actuator. Track 247 is sufficiently long that when interface 246 is moved to the proximal end of the track (the end furthest from the patient) a suture delivery tool 250 mounted to the interface is completely retracted from the cannula/tool guide 264. Thus, a suture delivery tool 250 is, in some embodiments, mated with or released from interface 246 when interface 246 is at the proximal end of the track. The suture delivery tool 250 may then be inserted through access port 264 using the transducer/actuator to advance interface 246 along track 247 towards the access port 264.

[0064] As shown in FIG. 2A, case 252 of suture delivery tool 250 may include one or more gears 258 to control movement/operation of portions of the suture delivery tool 250. Interface 246 includes a plurality of powered gears 248 which mesh with the plurality of gears 258 in case 252 when case 252 is mounted to interface 246. This allows the powered gears 248 of the interface to be utilized to rotate tool shaft 254 and/or spool 256 and/or operate other mechanical operations of the suture delivery tool. For example, suture delivery tool 250 in some embodiments includes at its distal end a grasper for grasping needles for removal from the patient or a cutter for cutting suture during the procedure; the grasper or cutter is, in some embodiments, operated by the powered gears 248 through the mating gears 258 of case 252.

[0065] FIGS. 2B and 2C show a suture delivery tool

250 mounted to a manipulator arm 240. The case 252 is held to interface 246 by one or clips 253 (not shown). One or more release levers 257 are accessible when case 252 is mounted to interface 248 to release clips 253 (not shown) when desired. Spool 256 is, in some embodiments, permanently attached to suture delivery tool 250 or may form part of a cartridge which is, in some embodiments, releasably attached to suture delivery tool 250. In some embodiments the spool is permanently or releasably attached at a fixed location of the suture delivery tool 250. Spool 256 is fixed (in this example) at the distal end of suture delivery tool 250. To introduce spool 256 to a surgical site in the subject, the interface 246 is first moved to the proximal end of the track 247 (the end furthest from the patient). The case 248 of the suture delivery tool 250 carrying the spool 256 is then mated with the interface 246 of the manipulator arm 240 as shown in FIG 2B. The interface 246 is then advanced linearly towards the patient down the track 247. The movement of the interface 246 down the track 247 inserts the spool 256 and the self-retaining suture 100 through the cannula/tool guide 264 into the patient as shown in FIG. 2C. The self-retaining suture 100 may then be positioned at the surgical site within the patient by the manipulator arm 240.

[0066] When the spool 256 has been positioned at the surgical site, the self-retaining suture 100 is positioned to be removed from the spool 256 by another instrument. In some embodiments, the needles and surplus suture are reattached to the spool after deployment of the suture. The suture delivery tool delivery tool 250 and spool 256 (and optionally the needles and excess suture) are removed from the body by retracting the interface 246 to the proximal end of the track 247 (the end furthest from the patient) as shown in FIG 2B. If another suture is required, the suture delivery tool 250 is exchanged for another suture delivery tool, or a cartridge including the spool 256 is removed and replaced with a new cartridge having a new spool 256.

[0067] FIG. 2D shows a view of manipulator arm 240 with the distal portion of suture delivery tool 250 introduced through an incision 260 into a patient 262. Suture delivery tool 250 is inserted through a cannula 264 at the incision 260. The cannula 264 is coupled to the manipulator arm 240. The suture delivery tool 250 is releasably mated with the interface 246 on the manipulator arm 240. The manipulator arm 240 can position the suture delivery tool 250 and spool 256 in three dimensions and rotate the suture delivery tool 250 about the insertion axis while constraining the motion (preventing lateral displacement) at the incision 260. Suture delivery tool 250 is slid in and out of cannula 264 as shown by arrow 266. Suture delivery tool 250 and cannula 264 is adapted to be pivoted about the incision 260 as shown by arrows 268, 269. The movements of the suture delivery tool in three or more dimensions within patient 262 are thus under the control of manipulator arm 240 allowing the spool 256 and suture 100 to be delivered to a desired position in the operative site and/or within the field of vision of the surgeon.

[0068] FIGS. 2E and 2F show an example of a telesurgical system 200 which includes a plurality of manipulator arms 240 one of which can be used to position the suture delivery tool 20 within a patient. FIG. 2E shows a perspective view of the telesurgical system whereas FIG. 2F shows a functional block diagram of the telesurgical system 200. As shown in FIGS. 2E, 2F, telesurgical system 200 comprises a patient-side manipulator system 204 and a surgeon's console 201. Patient-side manipulator system 204 includes a plurality of manipulator arms 240 mounted on an adjustable stand 242. The manipulator arms 240 comprise a plurality of mechanical linkages and a plurality of transducers/actuators. The transducers/actuators are, in some embodiments, electrical motors, for example, stepper motors and/or servo motors. In alternative embodiments, the actuators are pneumatic, hydraulic, magnetic or other transducers capable of effecting movement of the linkages in response to control signals. The position of the linkages is monitored using a plurality of sensors 270; e.g. linear or rotary optical encoders. The linkages are adapted to be moved independently by a plurality of actuators 272; e.g. stepper motors and shape-memory actuators. In some cases, the actuators 272 may also be sensors 270; for example, stepper motors function as actuators, position encoders and force sensors.

[0069] The endoscope, suture delivery instrument and one or more surgical tools are coupled to the manipulator arms 240. The number of patient-side manipulators and instruments used will vary depending on the procedure. A patient-side manipulator system 240 in some embodiments includes two mechanical manipulator arms 240 for operating surgical tools and one manipulator arm 240 for positioning the endoscope. A suture delivery tool is in this embodiment positioned and operated by one of the two manipulator arms 240 for operating surgical tools. A suture is in some cases inserted with the suture delivery tool 250 and then the suture delivery tool exchanged for another surgical tool such as a needle driver or grasper. In some systems, a fourth arm is provided. In such systems the suture delivery tool is positioned and operated by the fourth manipulator arm. The surgeon can switch between control of the surgical instruments and control of the suture delivery tool without the need for exchange of the suture delivery tool with a surgical instrument.

[0070] Surgeon's console 201 comprises a display system 212, a control system 214 and a processing system 218. The display system 212 includes a 2D or 3D video display 213 and one or more of an audio output system, force-feedback system, touchscreen display and other display elements e.g. lights, buzzers etc. The display system 212 provides the surgeon 202 with an image of the surgical site and may also provide other information in visual, audible and/or haptic formats. The control system 214 may include one or more of a variety of input devices; for example hand-operated controllers 215, joysticks, gloves, keyboards 216, buttons, case-pedals 217, touchscreen displays, mice and the like. A microphone may also be provided so that the surgeon can provide voice commands to the control system. Particular components are elements of both display system 212 and control system 214; for example, force-feedback hand controllers and touchscreen displays which both display information and receive input.

[0071] The surgeon 202 performs a minimally-invasive surgery procedure by manipulating control devices of the control system 214. The output of the control system 214 is received by a processing system 218. One function of processing system 218 is to translate the output of the control system 214 into control signals for the operation of the patient-side manipulator system 204. Surgeon's console 201 is connected by cable 206 to patient-side manipulators 240 and 242. The operation of the control devices by the surgeon 204 operates the patient-side manipulator system 204 and manipulator arms 240 to position and operate surgical tools and an endoscope coupled to the manipulator arms 240. The movement of the surgical tools is imaged by the endoscope and the image of the surgical tools is transmitted to the processing system 218. The processing system transforms the image of the surgical tools and transmits it (and other information) to display system 212 so that it can be observed by the surgeon 202.

[0072] FIGS. 3A and 3B show an alternative suture delivery tool 350 mounted to a manipulator arm 240. Suture delivery tool has a load slot 310 for receiving a cartridge 320 including a spool 356. Cartridge 320 is sized and configured to fit through load slot 310 into the tool shaft 354 as shown in FIG. 3A. Suture delivery tool 350 has a transport mechanism 312 for moving cartridge 320 from the loading slot 352 to the distal end of suture delivery tool 350 where it is accessible through delivery slot 314 for removal of the suture 100. In some embodiments, the driven gears 248 of a manipulator arm 240 operate the transport mechanism through mating gears (not shown) in the case 352. The transport mechanism 312 is for example a cable drive screw drive or similar drive for moving a cartridge linearly through the tool shaft 354.

[0073] To introduce spool 356 to a surgical site in a patient, the distal end of the suture delivery tool 350 is first positioned at the surgical site under surgeon control. Cartridge 320 is then loaded into the loading slot 310 of the suture delivery tool 350. The transport mechanism 312 is then operated to move the cartridge 320 from the loading slot 310 to the delivery slot 314 at the distal end of suture delivery tool 350 as shown by arrow 317. When cartridge 320 reaches the distal end of suture delivery tool 350, cartridge 320 is exposed sufficiently at delivery slot 314 that the suture and needles are exposed to be accessed and removed from the cartridge 320 as shown in FIG 3B. The self-retaining suture 100 is then removed from the cartridge 320 by another surgical instrument at the surgical site. In some embodiments, the spool 356 can be rotated at the delivery slot 314 in order to remove the suture from the spool. In some embodiments, the needles and surplus suture are re-attached to cartridge 320 after deployment of the self-retaining suture 100. The cartridge 320 is then removed from the body by operating the transport mechanism 356 in the opposite direction to retract the cartridge 320 from the delivery slot 314 to the loading slot 310 where the cartridge 320 is positioned to be removed and replaced with a new cartridge 320.

[0074] Advantageously, one or more cartridges 320 are delivered through suture delivery tool 350 automatically. The automatic delivery of cartridges is rendered safe by the fact that the cartridge 320 stays within the confines of the suture delivery tool 350. Additionally, the suture delivery tool itself does not change position during automatic delivery of the cartridge (only the cartridge is moved). Once the suture delivery tool has been positioned under surgeon guidance, there is little or no possibility of the insertion or retraction of a new cartridge 320 causing damage to tissue at the surgical site. Thus the presentation and removal of suture cartridges 320 is performed automatically or by the surgeon's assistant without the need to check the position for delivery of subsequent cartridge deliveries.

[0075] FIG. 3C shows one embodiment of a suture delivery tool 350 which is adapted to move a cartridge 320 from a proximal end of the shaft 354 to the distal end of the shaft 354. FIG. 3D shows a section through the tool shaft 354. FIGS. 3E and 3F show views of one embodiment of a cartridge for use with suture delivery tool 350 of FIG. 3C. FIG. 3C shows interior components of case 352 and tool shaft 354. As shown in FIG. 3C, transport mechanism comprises a threaded rod 316 which runs the length of tool shaft 354. The threaded rod 316 is supported at each end by a bushing which allows rotation of the threaded rod. A capstan 360 within case 352 is directly connected to a gear of case 352 which is adapted to be mated with a driven gear of the interface of the manipulator arm. A transmission mechanism transmits rotation of capstan 360 to rotation of threaded rod 316. The transmission mechanism is, in some embodiments, a geared mechanism or may comprise a pulley-driven system as shown in FIG. 3C. As shown in FIG. 3C a loop of cable 364 is wrapped around capstan 360 and idler pulley 364 between capstan 360 and idler pulley 364, cable 364 is also wrapped around a pulley 366 mounted to threaded rod 316. Thus, when capstan 360 is turned by a driven gear of the manipulator arm the threaded rod is rotated. When a cartridge 320 is inserted into the loading slot 310 a groove 322 in the cartridge 320 engages the threaded rod 316.

[0076] When cartridge 320 is engaged with threaded rod 316, rotation of threaded rod 316 results in movement of the cartridge up or down tool shaft 354 depending on the direction of rotation of the threaded rod 316. Threaded rod 316 can be rotated in one direction to move cartridge 320 from the load slot 310 to the delivery slot 316. Threaded rod 316 can be rotated in the opposite direction to move cartridge 320 from the delivery slot 316 back to the load slot 310 where it can be removed/replaced. Note that in some embodiments, what is shown as a cartridge in FIG. 3C is a shuttle which is an integral part of the suture delivery tool 350. In such embodiments, rather than removing and replacing a cartridge, sutures are loaded and unloaded from the shuttle to be transported to or from the distal end of the suture delivery tool 350.

[0077] FIG. 3D shows a sectional view through shaft 354 along the line D-D of FIG. 3C. The position of a cartridge 320 within the shaft is shown by the dashed line. Note that the interior of groove 322 is pushed against and engaged with threaded rod 316. Note also that shaft 354 has an internal ridge 318 which also engages groove 322 to prevent rotation of cartridge 320.

[0078] FIGS. 3E and 3F show one embodiment of a cartridge 320 suitable for use with the suture delivery tool 350 of FIGS. 3C and 3D. As shown in FIG. 3E cartridge 320 comprises a cylinder several centimeters long and having a diameter slightly less than the interior diameter of shaft 354. Cartridge 320 has a groove 322 in the back surface. Groove 322 is sized to fit over the threaded rod 316 and ridge 318 of suture delivery tool 350. Groove 322 has surface features 324 for engaging threaded rod 316. Surface features 325 include, for example, threads, ridges or similar contact points which can engage threaded rod 316 to cause linear motion of cartridge 320. Cartridge 320 has an opening 321 on the front surface through which a self-retaining suture 100 is loaded into the hollow chamber 326. Hollow chamber contains needle docks 328 for releasably securing needles 110, 112 of self-retaining suture 100. Suture thread 102 is positioned linearly within hollow chamber 326 passing around pin 329 to hold self-retaining suture 100 in position during transfer. Where longer suture is required self-retaining suture 100 is coiled up with cartridge 320. Cartridge 320 may additionally comprise more needle docks and nubs so that cartridge 320 can hold two or more self-retaining sutures 100.

C. Suture Cartridges For Suture Delivery Systems

[0079] FIGS. 4A through 4G show various suture cartridges suitable for use with MIS suture delivery tools in accordance with embodiments of the present invention. In general, the cartridge should have a diameter less than the diameter of the access port i.e. typically the cartridge should be 10 mm in diameter or less. The cartridge length will be determined by the amount of suture to be contained. As a practical matter, the cartridges will preferably be a fraction of the length of the suture delivery tool. Thus, the cartridges will preferably be 120 mm or less in length and more preferably 80 mm or less in length. In some circumstances, the cartridges are 10 mm or less in length. The cartridge should also have a coupling, aperture groove or the like for attaching the cartridge to the suture delivery tool or engaging the drive mechanism of the suture delivery tool. Each of the cartridges and spools discussed herein is adaptable for use with each of the suture delivery tools discussed herein by addition of the appropriate mating features for engaging the suture delivery tool.

[0080] FIG. 4A shows a cartridge 410 comprising a spool 412 having a helical groove 414. As shown in FIG. 4A, self-retaining suture 100 is wrapped around spool 412 within helical groove 414. In preferred embodiments, the cartridge includes a mechanism for preventing tangling of the suture or self-retaining suture. For example, with respect to cartridge 410, the retainers of section 142 facing in a given direction are spaced apart from the retainers of section 146 facing in an opposing direction (and which is separated from section 142 by transitional segment 144). The self-retaining suture 100 is, in some embodiments, wrapped sufficiently tightly around spool 412 that the retainer pluralities do not overlap with one another; for example, needles 110 and 112 at either end of self-retaining suture 100 are, in some embodiments, removably engaged in needle parks 416 and 417, respectively, in order to achieve such tension.

[0081] Note helical groove 414 is sufficiently deep that the suture 100 does not protrude above the ridges between turns of groove 414. It is to be understood that in this particular embodiment that friction engagement structures can be used to retain the suture 100 to the spool 412 in place in grooves. Note that suture 100 must be unwound from spool 412 thus requiring that spool 412 is mounted in a fashion that allows it to rotate or mounted without obstruction to unwinding the suture 100 from the spool 412. As shown in FIG. 4A, cartridge 410 has a central aperture 418 for mounting cartridge on a pin on the end of a suture delivery tool (for example suture delivery tool 150 of FIG. 1C or suture delivery tool 250 of FIG. 2A. The aperture is provided with a latching mechanism such that the pin is releasably retained within aperture 418 while still allowing rotation of cartridge 410 during removal of self-retaining suture 100.

[0082] FIG. 4B shows a partial cutaway view of a variation of cartridge 410 of FIG 4A. In the embodiment of FIG. 4B the spool 412 is provided with a cover 430 which fits over the spool 412, holding suture 100 within groove 414. Suture 100 can be removed by sliding cover 430 off spool 412 (incrementally or in one go). Alternatively, cover 430 is made of a material that can be split by the suture as the suture 100 is unwound. Cover 430 may, for example, be perforated along the groove 414 so that suture 100 is adapted to be pulled through the cover 430 as it is unwound from the spool 412. Such a cover may also be used with other cartridges described herein. A cover is useful to protect the suture during delivery to the surgical site and to retain the suture within the cartridge during delivery. In some embodiments the cover is removed by the surgeon using another surgical instrument. In other embodiments, the cover is removed by actuation of the suture delivery tool to which the cartridge is mated.

[0083] As shown in FIG. 4C, self-retaining suture 100 is wrapped around spool 422 within double helical grooves 424. The retainers of section 142 facing in a given direction are spaced apart from the retainers of section 146 facing in an opposing direction (and which is separated from section 142 by transitional segment 144). The self-retaining suture 100 is, in some embodiments, wrapped sufficiently tightly around spool 422 that the retainer pluralities do not overlap with one another. For example, needles 110 and 112 at either end of self-retaining suture 100 are, in some embodiments, removably engaged in needle parks 426 and 427 and transitional segment 144 can be wrapped around pin 423, respectively, in order to achieve such tension. Note helical groove 424 is sufficiently deep that the suture 100 does not protrude above the ridges between turns of grooves 424. It is to be understood that in this particular embodiment that friction engagement structures can be used to retain the suture 100 to the spool 422 in place in grooves. Note that suture 100 must be unwound from spool 422 thus requiring that spool 422 is mounted in a fashion that allows it to rotate or mounted without obstruction to unwinding the suture 100 from the spool 422. As shown in FIG. 4A, cartridge 420 has a central protrusion 428 for mounting cartridge on the end of a suture delivery tool, for example, suture delivery tool 150 of FIG. 1C or suture delivery tool 250 of FIG. 2A. The protrusion is provided with a latching mechanism 429 such that the protrusion is releasably retained within a suture delivery tool while still allowing rotation of cartridge 420 during removal of self-retaining suture 100.

[0084] Groove 414 or grooves 424 are, in some embodiments, provided with retaining features to releasably retain self-retaining suture 100 to manage self-retaining suture 100 while it is being unwound form a spool. For example, as shown in FIG., 4D, the groove is shaped so that the adjacent walls of the grooves are approximately parallel and slightly closer together than the diameter of the suture 100. The walls thus serve to keep suture 100 in the groove even when the tension in suture 100 is released. The walls are flexible enough that they can be pushed apart with a slight force to admit and release suture 100 as it is being wound on or off of the spool. This configuration of helical groove forms what is essentially a continuous helical clip which lightly holds suture 100 to the surface of the spool. Other configurations of groove and clips are used in alternative embodiments to hold suture 100 in place. For example, releasable clips are positioned intermittently along the helical groove. Alternatively, a releasable adhesive or gel is provided continuously or intermittently along the helical grove to retain suture 100 in the absence of tension. The spools of the various embodiments herein hold the sutures so as not to compress or reposition the retainers. Generally, the retainers on the suture are proud. That is, the retainers stand out or away from the body of the suture. In a container or cartridge such as a spool, it may be desirable that the retainers to remain away from the body of the suture and not be compressed against the body of the suture. Further, it is to be understood that some materials such as polymers, that the suture body is made up can have a memory. That is to say, the suture can develop a set shape after being help in a certain shape for awhile, such as being held in a container. With a spool, the suture can be set or have a memory of a suture with many small loops. This can be advantageous in a situation where tight radius suturing is desirable. With the suture set with tight loops, the suture can be managed as the suture is in a coil and the tight loops of the suture help facilitate sewing tissue with tight radius stitches. Further, with these cartridges, drug can be coated on the internal surfaces of the cartridges such that as the suture is removed from the cartridges, drugs coated on the surfaces of the helical grooves, for example, can rub off onto the suture for delivery to the tissue.

[0085] Cartridges 410 and 420 are preferably 10 mm or less in diameter so that they may fit through a cannula/guide into a patient. The length of cartridges 410, 420 may vary depending upon the length of self-retaining suture 100 and the number of turns of the groove required to hold self-retaining suture 100. For example, if spools 412, 422 are 10 mm in diameter, approximately 30 mm of suture will be taken up by one wrap around the spool. Thus, a suture of 70 mm total length will require less than three turns of groove around the spool. A suture of 140 mm total length will require less than five turns of groove around the spool. These three to five turns of groove may readily be provided in a cartridge 10 mm in a spool 10 mm or less in length. This allows three to five cartridges of 10 mm or less in length to be mounted to the end of a suture delivery tool to allow the introduction of multiple self-retaining sutures to a surgical site at the same time. As shown in FIG. 4E, a suture delivery tool 450 includes a spindle 452. A plurality of cartridges 454 each holding a self-retaining suture 100 including needles is received over spindle 452. Each cartridge 454 has a central aperture 455 which fits over spindle 452. Spindle 452 has at its distal end a catch 456 for releasably retaining the plurality of cartridges onto the spindle 452 during use. Additional catches 456 is, in some embodiments, provided along the length of spindle 452 so that less than the maximum number of cartridges is, in some embodiments, securely held on the spindle 452.

[0086] FIGS. 4F and 4G show two partial cutaway views of a suture cartridge 460 suitable for use with MIS suture delivery tools. In cartridge 460, self-retaining suture 100 is arranged in a linear configuration. The linear configuration is suitable for shorter sutures which are often used in MIS surgery. For example, self-retaining suture 100 is, in some examples, approximately 70 mm in total length with each of sections 142 and 146 being approximately 35 mm in length. Cartridge 460 would be approximately 40 mm in length to accommodate the 70 mm suture in the configuration of FIG 4F. In another example, self-retaining suture 100 is approximately 140 mm in total length with each or sections 142 and 146 being approximately 70 mm in length. Cartridge 460 would be approximately 80 mm in length to accommodate the 140 mm suture in the configuration of FIG 4F.

[0087] As shown in FIGS. 4F and 4G, cartridge 460 is approximately cylindrical and has a projection 462 on its proximal end for releasably engaging a suture delivery tool. Cartridge 460 has an opening 464 at its distal end for allowing access to the interior of cartridge 460. Adjacent opening 464 there are a plurality of needle docks 466 for releasably holding a plurality of needles. As shown in FIGS. 4F and 4G, a self-retaining suture 100 is contained with cartridge 460 with needles 110 and 112 releasably secured adjacent opening 464 by needle docks 466. A longitudinal divider 467 separates sections 142 and 146 of self-retaining suture 100. Section 144 of self-retaining suture 100 passes through a slot 468 in divider 467. When deployed self-retaining suture 100 can be pulled along/through slot 468 towards opening 464. Slot 468 is open with opening 464 allowing self-retaining suture 100 to be released from the cartridge 460.

[0088] The cartridge 460 may include several different sutures in similar configurations and spaced from one another by dividers or the like. As shown in FIG. 4H, multiple loops of suture 100 are separated from one anther by dividers 472 so that each suture is, in some examples, removed individually from a cartridge. The stacked sutures may then be loaded into a suture cartridge 470. Cartridge 470 has

sufficient needle docks for each of the needles of the sutures. In use, the surgeon may remove one suture and its associated needles at a time without disturbing the other sutures 100.

Suture Partridge Magazine For Suture Delivery Systems

[0089] In some situations, it is, in some embodiments, desirable to automate the delivery, loading and exchange or suture delivery cartridges to a suture delivery tool in a telesurgery system. In one example, where telesurgery is to be performed at a remote location, there is, in some embodiments, no patient-side assistant to load cartridges onto a suture delivery system. In another example, it is, in some embodiments, more expedient or reliable to let the surgeon select a suture of choice using the surgeon's console as an interface rather than relying upon communication between the surgeon and a patient-side assistant. A suture cartridge magazine holds a plurality of suture cartridges. A selector mechanism allows a surgeon to select a cartridge to be loaded into a suture delivery tool from the cartridges available in the magazine. A cartridge load/unload mechanism loads the cartridge onto/into the suture delivery tool and unloads the cartridge after deployment of the suture. This allows the surgeon to choose a suture and deploy it to the surgical site using the surgeon's console controls without the use of an assistant.

[0090] FIGS. 5A-5C show a suture cartridge magazine 500 which is adapted to select, load and unload cartridges 520 into a suture delivery tool 550 mounted to a manipulator arm 540. The case 552 of suture cartridge magazine 500 is releasably mounted to the interface 546 on the manipulator arm 540. Magazine 500 is, in this embodiment, mounted to interface 546 adjacent a load slot 522 in suture delivery tool 550. Thus, in this embodiment, magazine 500 is in a fixed position relative to suture delivery tool 550. In other embodiments, such as where a cartridge is loaded at the distal end of a suture delivery tool, magazine 500 is, in some embodiments, mounted in an affixed position relative to manipulator arm 540. In such case, the suture delivery tool retracts to place the distal end of the tool in position for loading and is then advanced into the patient.

[0091] As shown in FIGS. 5A-5C, a support 502 is mounted to interface 546. Support 502 carries a selector mechanism 504 and a load/unload mechanism 506. Magazine 500 is hooped shaped an has a plurality of spring loaded bays 508 each of which is adapted to releasably secure a cartridge. The number of bays can be selected based on the needs of the system. The bays 508 are open towards the interior and exterior of the magazine. However, a cover 510 substantially covers the magazine 500 such that only one bay 508 is exposed at an opening 512 at any time. The bays can rotate with respect to cover 510 so that any one of the bays 508 is, in some embodiments, adjacent the opening 512. Magazine 500 mounts to support 502 such that opening 512 in cover 510 is adjacent to suture delivery device 550.

[0092] Selector mechanism 504 engages magazine 500 such that it rotates bays 508 past opening 512 and suture delivery tool 550 as shown by arrow 514 of FIGS. 5A and 5B. Selector mechanism 504 may rotate bays 508 passed opening 512 for sequential loading of cartridges 520. Alternatively, as cartridges 520 is, in some embodiments, loaded with different sutures, it is, in some embodiments, desirable to allow selectable loading and unloading of any one of the cartridges. Data regarding the sutures is, in some embodiments, entered into the system manually upon loading the magazine, or more preferably, each cartridge comprises a machine readable device, such as a barcode or RFID tag, which identifies the suture loaded on the cartridge. The system can thus automatically determine the sutures available in a magazine and the position of the respective cartridges in the magazine by reading each machine readable device in sequence when the magazine is loaded. The surgeon's console should display data regarding the sutures available in cartridges available in the magazine to the surgeon and allow the surgeon to select a suture for use in the procedure. When the surgeon selects a suture, thus selector system 504 indexes magazine 500 until the desired cartridge 520 is positioned adjacent opening 512 and suture delivery tool 550. The selector system 504 is preferably operated by one or more transducers/actuators controlled by the surgeon from the surgeon's console. In some embodiments selector system 504 may coupled to a driven gear 248 (See FIG. 2A) of interface 546.

[0093] When the desired cartridge 520 is positioned adjacent opening 512 and suture delivery tool 550, load/unload mechanism 506 is activated to push the cartridge 520 from the spring-loaded bay 508 through opening 512 and into the load slot 522 of the suture delivery tool 550 (see arrow 516 in FIG 5C). The transport mechanism of the suture delivery tool can then be activated to transport cartridge 520 to the distal end of suture delivery tool 550 for deployment of the suture. After deployment, cartridge 520 is transported back to the load slot of suture delivery tool 550. Load/unload mechanism 506 is then activated to pull cartridge 520 from the load slot into the spring-loaded bay 508. A new suture may then be selected by the surgeon and the cartridge indexed and loaded automatically in response to the suture selected by the surgeon. The load/unload mechanism 506 is operated by one or more transducers/actuators controlled by the surgeon from the surgeon's console. In some embodiments load/unload mechanism 506 may coupled to a driven gear 248 (See FIG. 2A) of interface 546.

[0094] Note that all of the suture delivery systems described herein are, in some embodiments, utilized for the delivery of plain sutures. Moreover, the suture delivery systems are, in various embodiments, used for the delivery of self-retaining sutures in a wide variety of configurations including unidirectional self-retaining sutures, unidirectional self-retaining sutures having an anchor at one end and a needle at the other end; and/or bidirectional self-retaining sutures as discussed herein.

[0095] FIG. 6A illustrates an alternative example of a self-retaining suture system 600. Self-retaining suture system 600 includes needle 110 and sections 140, 142 and 144 of self-retaining suture system 100 of FIG. 1A. However, self-retaining suture system 600 is a single-armed system. As shown in FIG. 6A, filament 120 terminates following section 144 in a tissue anchor 602a. Tissue anchor 602a is a device for engaging tissue and preventing filament 120 from moving through tissue in the direction of needle 110. Tissue anchor 602a is in some examples formed in one piece with filament 120 or formed separately and subsequently attached to filament 120. As shown in FIG. 6A, tissue anchor 602a has a bar-shaped body 610a which extends approximately perpendicular to the axis of filament 120. Bar-shaped body 610a is sufficiently long and stiff to preclude movement of the distal end of filament 120 in the direction of needle 110 after tissue anchor 602a has engaged a tissue.

[0096] FIG. 6B shows an alternative anchor 602b which could be used in place of tissue anchor 602a of FIG. 6A. As shown in FIG. 6B, tissue anchor 602b comprises a conical body 610b. Conical body 610b has a pointed end 612b and tissue engaging features 614b which consist of ribs and/or barbs. Tissue anchor 602b is configured to be pushed into tissue in order to anchor filament 120 to that tissue and preclude movement of the distal end of filament 120 in the direction of needle 110.

[0097] FIG. 6C shows an alternative tissue anchor 602c which could be used in place of tissue anchor 602a of FIG. 6A. As shown in FIG. 6C, tissue anchor 602c comprises a loop 610c. Loop 610c is, in this example, formed by folding back the end 612c of filament 120 and securing end 612c to filament 120 by welding, fusing and/or adhesive. Loop 610c is thus formed from the material of filament 120. Loop 610c has an aperture 614c through which needle 110 can pass in order to create a noose/cinch which can be used to engage tissue and preclude movement of the distal end of filament 120 in the direction of needle 110.

[0098] FIG. 6D shows an alternative tissue anchor 602d which could be used in place of tissue anchor 602a of FIG. 6A. As shown in FIG. 6D, tissue anchor 602d comprises a staple-shaped body 610d. Filament 120 passes through an aperture in anchor 602d and is secured by a crimp 614d. Staple-shaped body 610d has two pointed ends 612d which can be pushed into tissue and deformed towards each other to engage the tissue and preclude movement of the distal end of filament 120 in the direction of needle 110.

[0099] FIGS. 6E and 6F show an exploded and partial cutaway views of a suture cartridge 660 suitable for use with MIS suture delivery tools. Cartridge 660 can be used to releasably hold one or more unidirectional self-retaining suture 600 with an anchor 602a-d such as described in FIGS. 6A-6D. In cartridge 660, one or more self-retaining suture systems 600 is arranged in a linear configuration. The linear configuration is suitable for shorter sutures which are often used in MIS surgery. For example, self-retaining suture system 600 is, in some examples, approximately 70 mm in total length. Cartridge 660 would be approximately 70 mm in length to accommodate the 70 mm suture in the configuration of FIG 6E. As shown in FIGS. 6E and 6F, cartridge 660 is approximately cylindrical and has a projection 662 on its proximal end for releasably engaging a suture delivery tool. Cartridge 660 has an opening 664 at its distal end for allowing access to the interior of cartridge 660. Adjacent opening 664 there are one or more needle docks 667 for releasably holding one or more needles 110. As shown in FIG. 6F one or more self-retaining suture system 600 can be contained within cartridge 660 with needles 110 releasably secured adjacent opening 664 by needle docks 666. Anchors 602a-d of self-retaining suture systems 600 are positioned towards the proximal end of the cartridge 660.

[0100] Multiple self-retaining suture systems 600 are, in some examples, loaded in a cartridge 660. As shown in FIG. 6E the self-retaining suture systems 600 are stacked and loaded through opening 664. Where multiple self-retaining suture systems 600 are loaded in a cartridge 600 they can be spaced from one another by dividers or the like to prevent entanglement. Cartridge 670 of FIG. 6G and/or dividers 669 have sufficient needle docks 667 for each of the needles 110. As shown in FIGS. 6E and 6F, multiple self-retaining suture systems 600 are separated from one another by dividers 669. Each of the plurality of self-retaining suture systems 600 can be, in some embodiments, removed individually from a cartridge 670. Cartridge 660 containing one or more self-retaining suture system 600 can be mounted to an endoscopic suture delivery tool as previously described for delivery of self-retaining suture systems 600 through a port to a desired location within a patient's body. In use, the surgeon may remove one self-retaining suture system 600 and its associated needle 110 and anchor 602a-d without disturbing the other self-retaining suture systems 600.

[0101] FIG. 6G shows a cartridge 670 which includes spool 656 and a connector 672. Connector 672 allows cartridge 670 to be releasably attached to the distal end of a tool such as an endoscopic tool. Spool 656 includes a spiral groove 658 for releasably holding a unidirectional self-retaining suture 600 with an anchor 602a-d such as described in FIGS. 6A-6D. As shown in FIG. 6G, spool 656 also includes one or more needle docks 657 for supporting the needle 110 of self-retaining suture system 600. Needle 110 is releasable attached to needle dock 657. The needle 110 is removed from needle dock 657 to allow deployment of self-retaining suture system 600. In some embodiments, needle 110 is replaced in needle dock 657 to allow removal of needle 110 and any surplus self-retaining suture thread after deployment of self-retaining suture system 600.

[0102] FIG. 6H shows cartridge 670 attached to the elongated member 682 of an endoscopic instrument 680 for insertion through a port into the body of a patient. A selection of sterile cartridges 670 is, in some embodiments, supplied for a procedure each supporting a different self-retaining suture system 100, 600. Thus, endoscopic suture delivery instrument 680 can be used by the surgeon or assistant to select and deliver multiple self-retaining suture systems 100, 600 in the course of a procedure. Handle 684 can be manipulated by a surgeon outside the body of a patient to deliver spool 656 to a desired site within the patient. In some embodiments, an actuator 686 is provided to control the attaching and releasing of the cartridge 670. In alternative embodiments spool 656 is fixed to the end of suture delivery instrument 680. Although a manual endoscopic instrument 680 is shown, cartridge 670 can also be delivered by a robotically-operated endoscopic tool as shown for example in FIG. 3A.

[0103] Although the present invention has been shown and described in detail with regard to only a few exemplary embodiments of the invention, it should be understood by those skilled in the art that it is not intended to limit the invention to the specific embodiments disclosed. Various modifications, omissions, and additions may be made to the disclosed embodiments without materially departing from the novel teachings and advantages of the invention, particularly in light of the foregoing teachings.

Claims

1. A suture dispenser, comprising:

a self-retaining suture (100) having an elongated suture body with a first segment (142) having a first plurality of retainers (130) disposed proximally to a first end, and a second segment (146) having a second plurality of retainers (130) disposed proximally to a second end; and
a spool (156, 256, 356, 412, 422), the self-retaining suture (100) being releasably secured to the spool (156, 256, 356, 412, 422);
characterized by
an elongated shaft (154, 254, 354); the spool (156, 256, 356, 412, 422) coupled to a distal end of the elongated shaft (154, 254, 354); and an actuator (158, 272) attached to a proximal end of the elongated shaft by which the dispenser can be manipulated to introduce the spool and distal end of the elongated shaft (154, 254, 354) through an access port into a surgical site within a patient.

2. The dispenser of claim 1, wherein:

the self-retaining suture (100) comprises a first needle (110) at the first end and a second needle (112) at the second end; and
the spool comprises a first needle dock (157, 328) for the first needle (110) and a second needle dock (157, 328) for the second needle (112).

3. The dispenser of claim 1, wherein:

the spool (156, 256, 356, 412, 422) comprises a plurality of suture containment regions to segregate the retainers (130) of the first segment (142) from the retainers (130) of the second segment (146).

4. The dispenser of claim 1, wherein:

the spool (156, 256, 356, 412, 422, 656) is releasably coupled to the distal end of the elongated shaft (154, 254, 354) such that the spool is adapted to be replaced by a second spool.

5. The dispenser of claim 1, wherein:

the dispenser is provided with a machine-readable code to identify a characteristic of the self-retaining suture (100).

6. The suture dispenser of claim 1 wherein:

said actuator is a mount that is adapted to mount said suture dispenser onto at least one of an endoscopic surgical tool and a laparoscopic surgical tool.

7. The suture dispenser of claim 1 wherein:

said spool (156, 256, 356, 412, 422) has a diameter about 12 mm or less.

8. The suture dispenser of claim 1 in combination with a telesurgical system.

9. The suture dispenser of claim 1 wherein said dispenser can accept and dispense a plurality of spools.

Patentansprüche

1. Nahtmaterialausgabevorrichtung, umfassend:

einen selbsthaltenden Nahtmaterialfaden (100), der einen länglichen Nahtmaterialfadenkörper hat mit einem ersten Segment (142), das eine erste Vielzahl von proximal zu einem ersten Ende angeordneten Haltevorrichtungen (130) hat, und einem zweiten Segment (146), das eine zweite Vielzahl von proximal zu einem zweiten Ende angeordneten Haltevorrichtungen (130) hat, und
eine Spule (156, 256, 356, 412, 422), wobei der selbsthaltende Nahtmaterialfaden (100) freigebbar an der Spule (156, 256, 356, 412, 422) befestigt ist,

gekennzeichnet durch

einen länglichen Schaft (154, 254, 354),
die Spule (156, 256, 356, 412, 422), die an ein distales Ende des länglichen Schafts (154, 254, 354) gekoppelt ist,
und
einen Aktuator (158, 272), der an einem proximalen Ende des länglichen Schafts angebracht ist und mittels dessen die Ausgabevorrichtung gehandhabt werden kann, um die Spule und das distale Ende des länglichen Schafts (154, 254, 354) **durch** eine Zugangsöffnung in einen Operationsort in einem Patienten einzuführen.

2. Ausgabevorrichtung nach Anspruch 1, wobei der selbsthaltende Nahtmaterialfaden (100) eine erste Nadel (110) am ersten Ende und eine zweite Nadel (112) am zweiten Ende umfasst und
die Spule eine erste Nadelandockstelle (157, 328) für die erste Nadel (110) und eine zweite Nadelandockstelle (157, 328) für die zweite Nadel (112) umfasst.

3. Ausgabevorrichtung nach Anspruch 1, wobei die Spule (156, 256, 356, 412, 422) eine Vielzahl von Nahtmaterialfaden-Einschließungsbereichen umfasst, um die Haltevorrichtungen (130) des ersten Segments (142) von den Haltevorrichtungen (130) des zweiten Segments (146) zu trennen.

4. Ausgabevorrichtung nach Anspruch 1, wobei die Spule (156, 256, 356, 412, 422, 656) freigebbar an das distale Ende des länglichen Schafts (154, 254, 354) gekoppelt ist, so dass die Spule durch eine zweite Spule ersetzt werden kann.

5. Ausgabevorrichtung nach Anspruch 1, wobei die Ausgabevorrichtung mit einem maschinenlesbaren Code versehen ist, um ein Merkmal des selbsthaltenden Nahtmaterialfadens (100) zu identifizieren.

6. Nahtmaterialausgabevorrichtung nach Anspruch 1, wobei
der Aktuator eine Montagevorrichtung ist, mit der die Nahtmaterialausgabevorrichtung an ein chirurgisches Endoskopie-Instrument und/oder ein chirurgisches Laparoskopie-Instrument montiert werden kann.

7. Nahtmaterialausgabevorrichtung nach Anspruch 1, wobei
die Spule (156, 256, 356, 412, 422) einen Durchmesser von ungefähr 12 mm oder weniger hat.

8. Nahtmaterialausgabevorrichtung nach Anspruch 1 in Kombination mit einem tele-chirurgischen System.

9. Nahtmaterialausgabevorrichtung nach Anspruch 1, wobei die Ausgabevorrichtung eine Vielzahl von Spulen annehmen und ausgeben kann.

Revendications

1. Dispositif de distribution de fil de suture, comprenant :

un fil de suture autostatique (100) comportant un corps de fil de suture allongé avec un premier segment (142) comportant une première pluralité d'éléments de retenue (130) disposés en position proximale vis-à-vis d'une première extrémité, et
un second segment (146) comportant une seconde pluralité d'élément de retenue (130) disposés en position proximale vis-à-vis d'une seconde extrémité ; et
une bobine (156, 256, 356, 412, 422), le fil de suture autostatique (100) étant fixé de manière libérable à la bobine (156, 256, 356, 412, 422) ;
caractérisé par
une tige allongée (154, 254, 354) ;
la bobine (156, 256, 356, 412, 422) étant accouplée à une extrémité distale de la tige allongée (154, 254, 354) ; et
un dispositif d'actionnement (158, 272) fixé à une extrémité proximale de la tige allongée, par

le biais duquel le dispositif de distribution peut être manipulé afin d'introduire la bobine et l'extrémité distale de la tige allongée (154, 254, 354) à travers un orifice d'accès dans un site chirurgical à l'intérieur d'un patient.

2. Dispositif de distribution selon la revendication 1, dans lequel :

   le fil de suture autostatique (100) comprend une première aiguille (110) au niveau de la première extrémité et une seconde aiguille (112) au niveau de la seconde extrémité ; et
   la bobine comprend un premier support de fixation d'aiguille (157, 328) pour la première aiguille (110) et un second support de fixation d'aiguille (157, 328) pour la seconde aiguille (112).

3. Dispositif de distribution selon la revendication 1, dans lequel :

   la bobine (156, 256, 356, 412, 422) comprend une pluralité de régions de réception de fil de suture servant à séparer les éléments de retenue (130) du premier segment (142) des éléments de retenue (130) du second segment (146).

4. Dispositif de distribution selon la revendication 1, dans lequel :

   la bobine (156, 256, 356, 412, 422, 656) est accouplée de manière libérable à l'extrémité distale de la tige allongée (154, 254, 354) de telle sorte que la bobine puisse être remplacée par une seconde bobine.

5. Dispositif de distribution selon la revendication 1, le dispositif de distribution étant pourvu d'un code lisible par machine servant à identifier une caractéristique du fil de suture autostatique (100).

6. Dispositif de distribution de fil de suture selon la revendication 1, dans lequel :

   ledit dispositif d'actionnement est une embase qui est conçue pour l'installation dudit dispositif de distribution de fil de suture sur un instrument chirurgical endoscopique et/ou instrument chirurgical laparoscopique.

7. Dispositif de distribution de fil de suture selon la revendication 1, dans lequel :

   ladite bobine (156, 256, 356, 412, 422) présente un diamètre d'environ 12 mm ou moins.

8. Dispositif de distribution de fil de suture selon la revendication 1 en combinaison avec un système de téléchirurgie.

9. Dispositif de distribution de fil de suture selon la revendication 1, ledit dispositif de distribution pouvant accepter et dévider une pluralité de bobines.

FIG. 1A

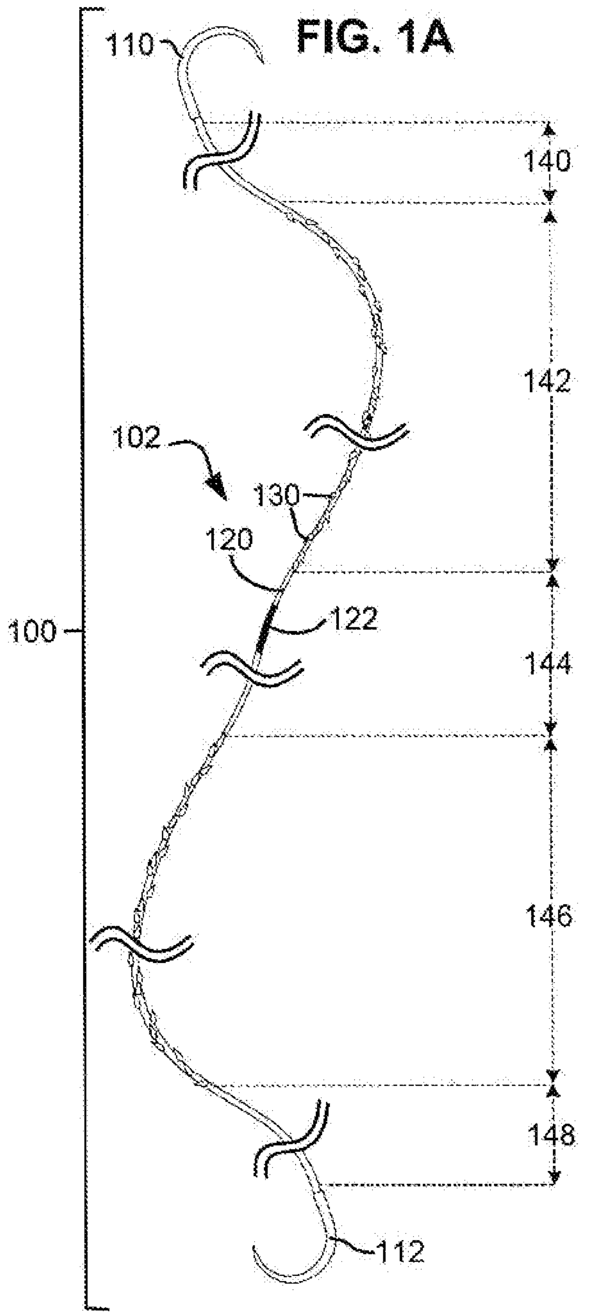


FIG. 1B

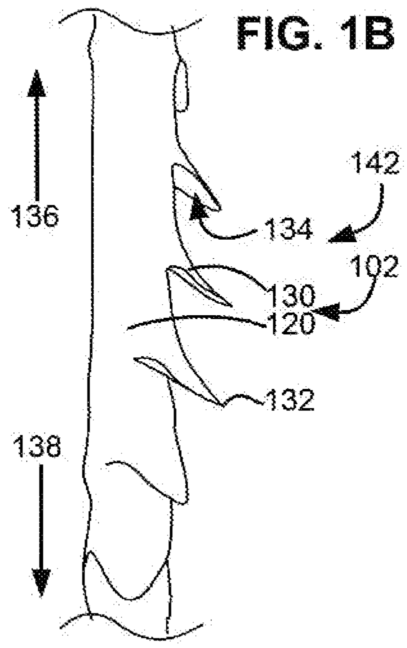


FIG. 1H

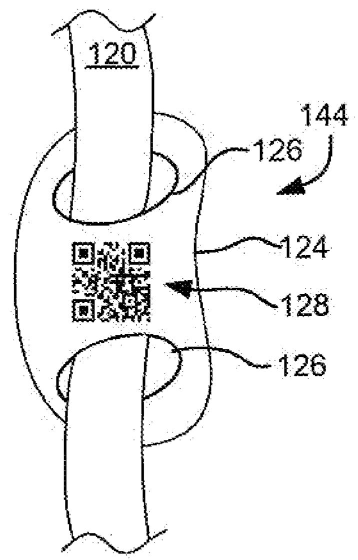


FIG. 1C

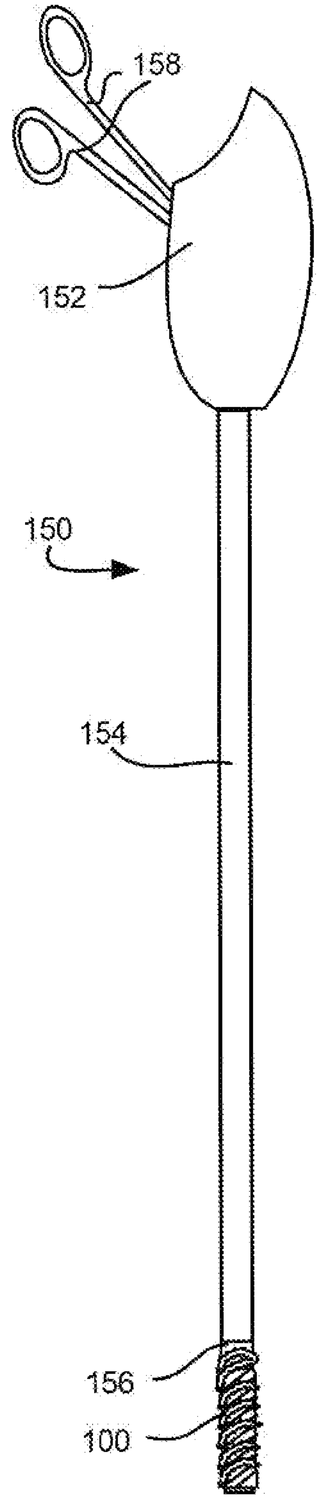


FIG. 1E

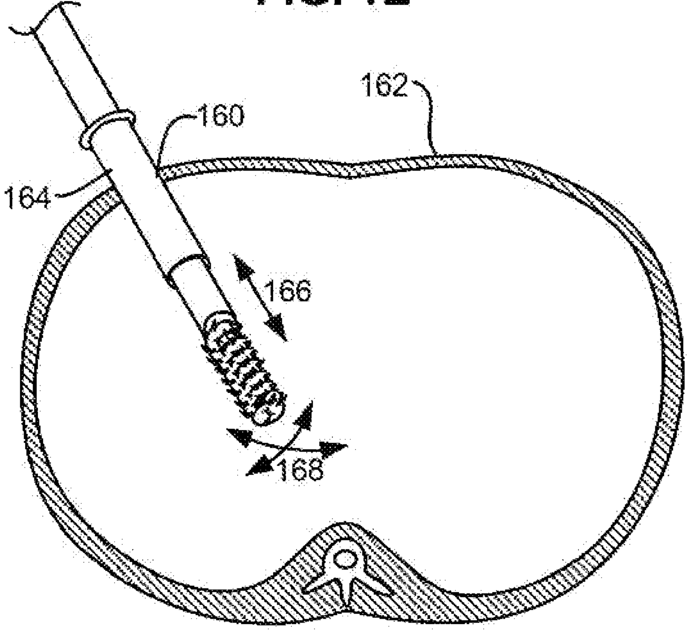


FIG. 1D

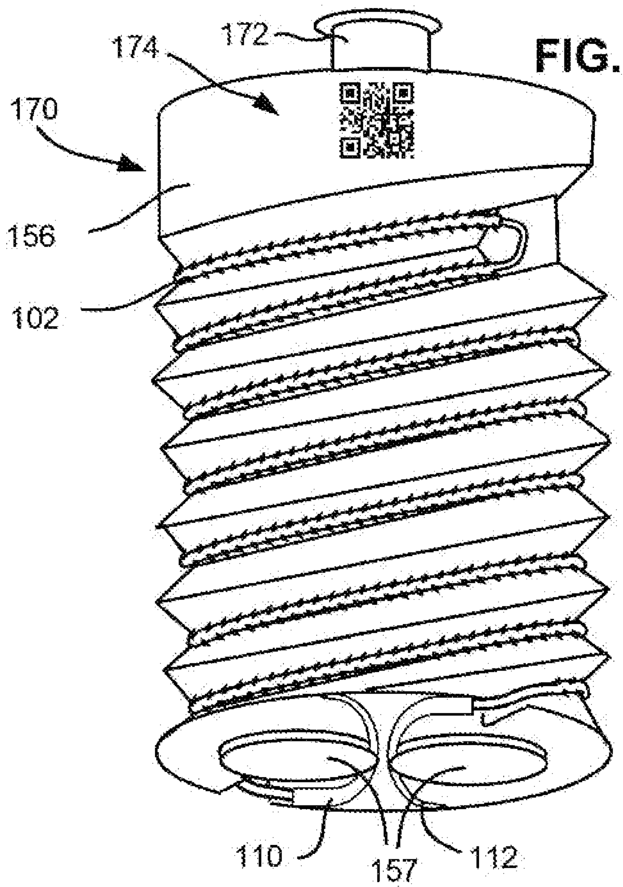


FIG. 1F

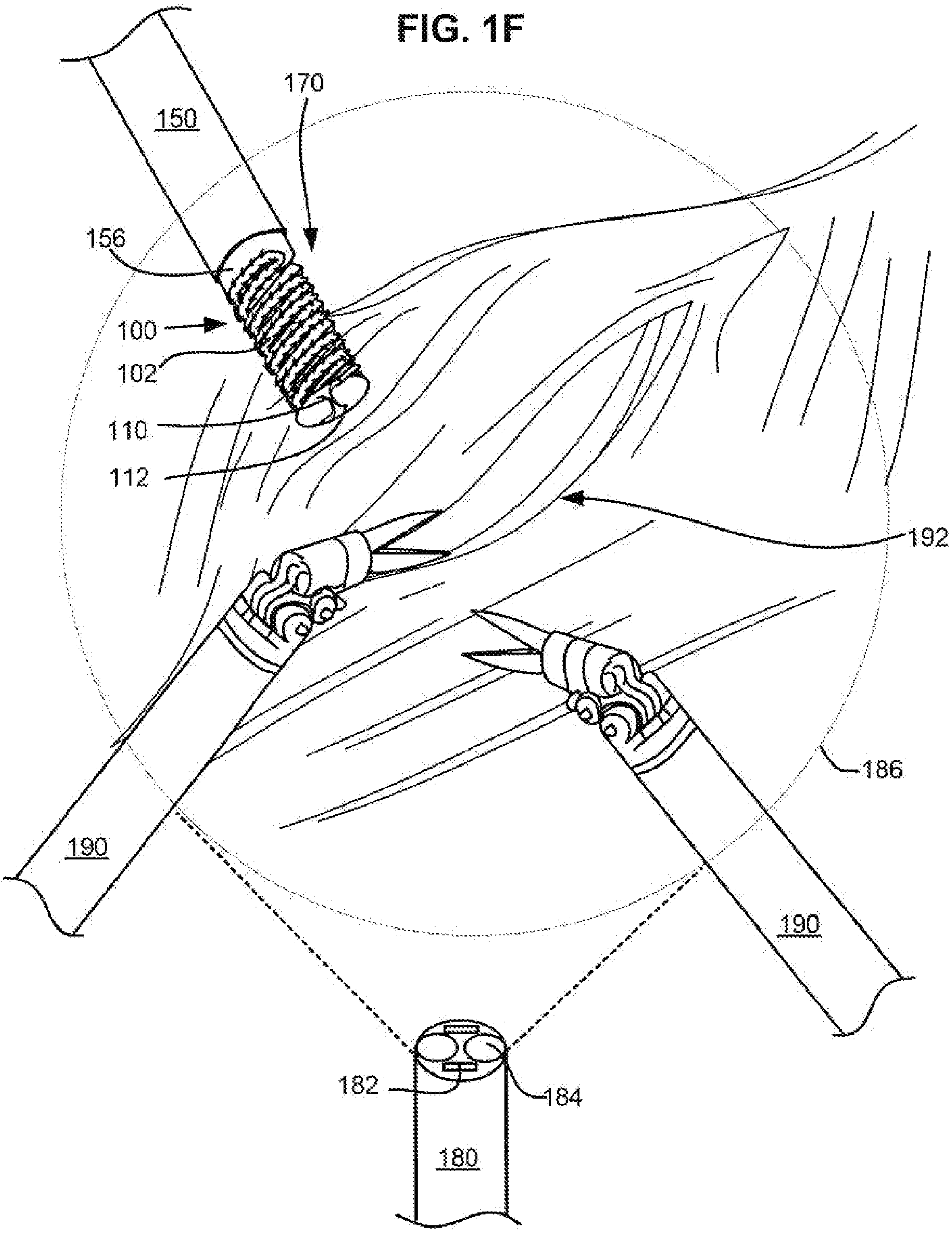


FIG. 1G

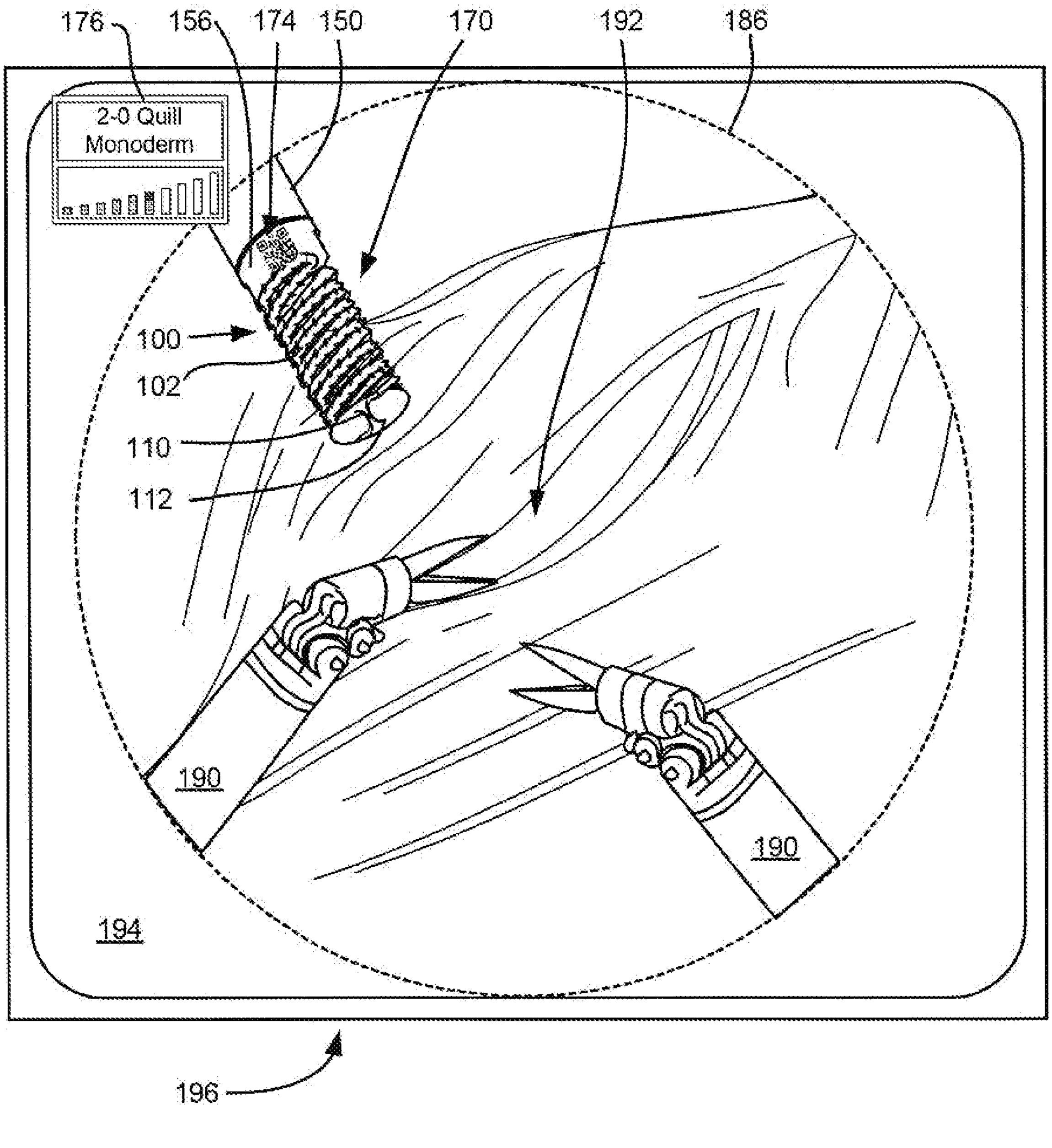
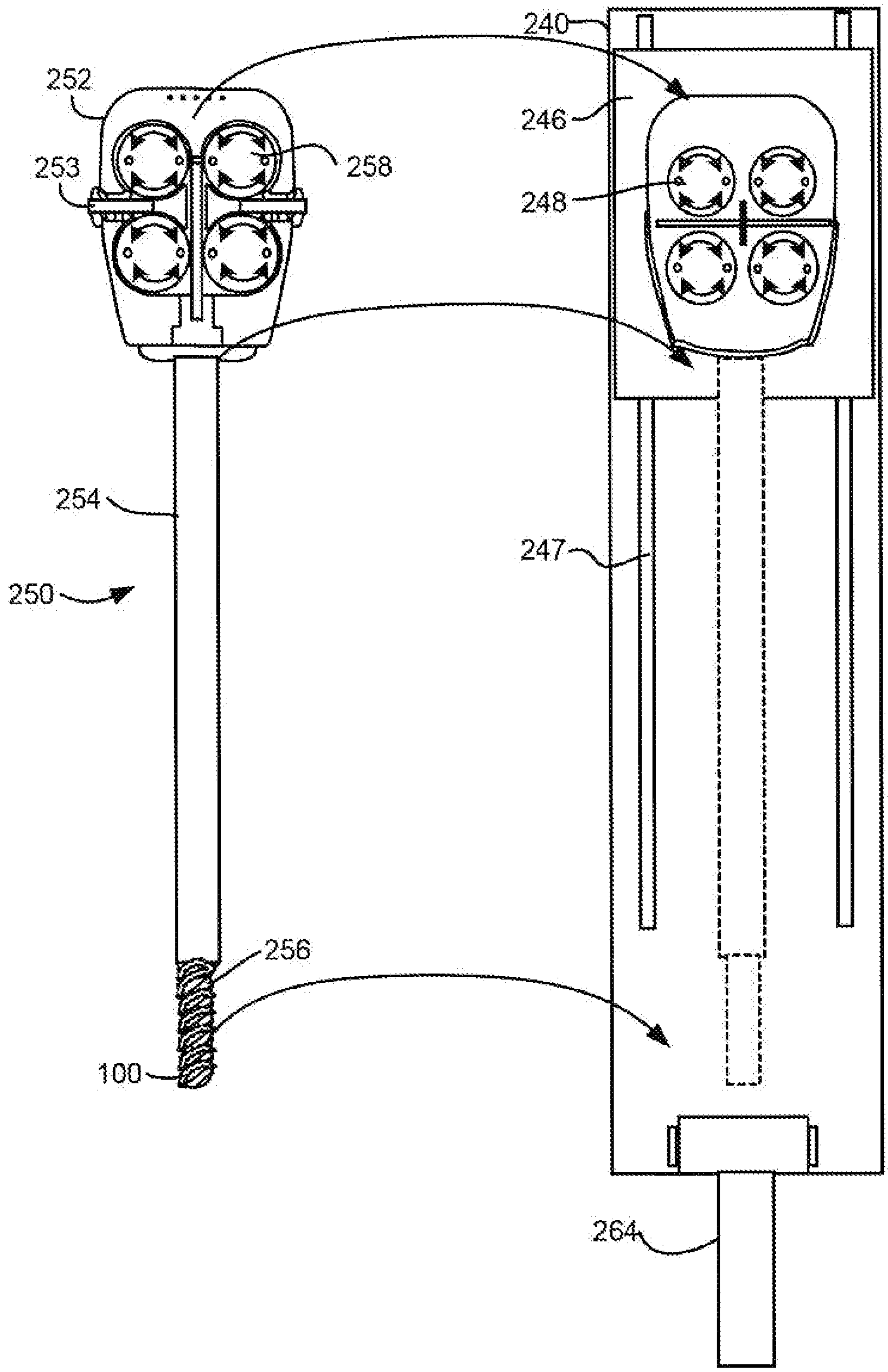
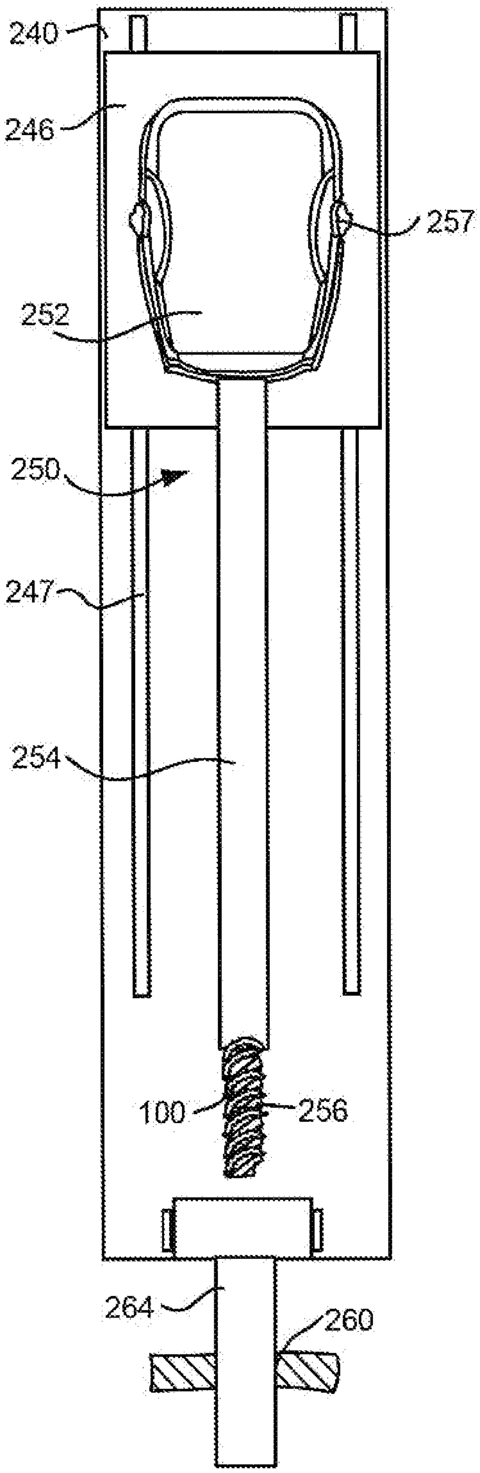

176
156
174
150
170
192
186
2-0 Quill
Monoderm
100
102
110
112
190
190
194
196

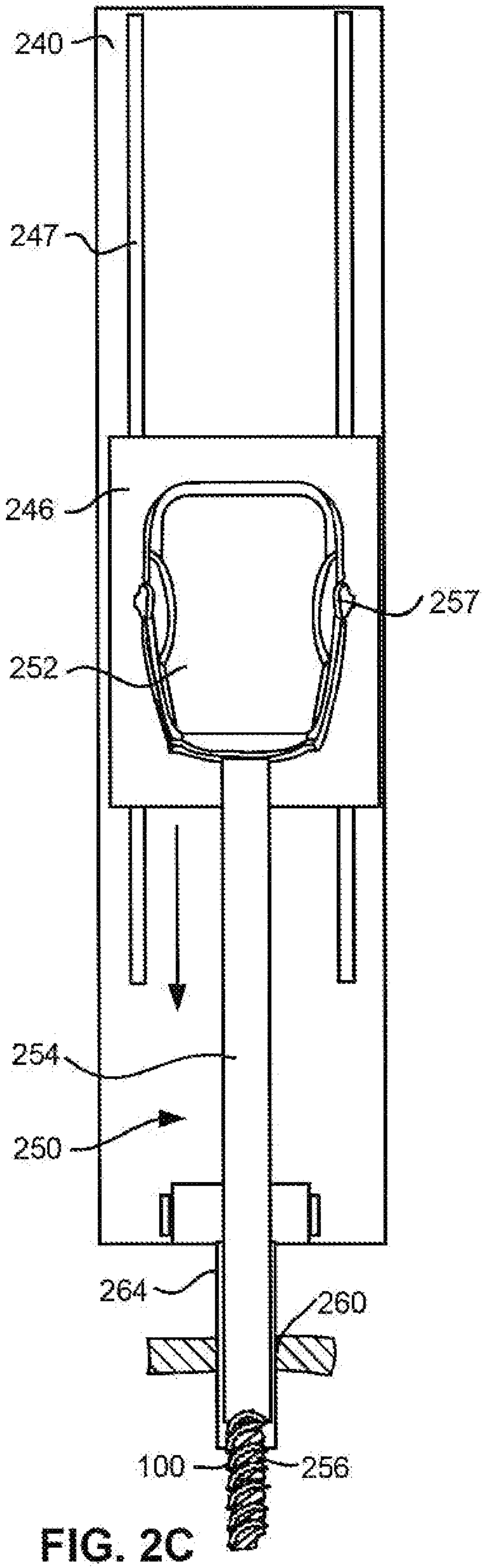
FIG. 2A





240
246
257
252
250
247
254
100
256
264
260

FIG. 2B



240
247
246
257
252
254
250
264
260
100
256

FIG. 2C

FIG. 2D

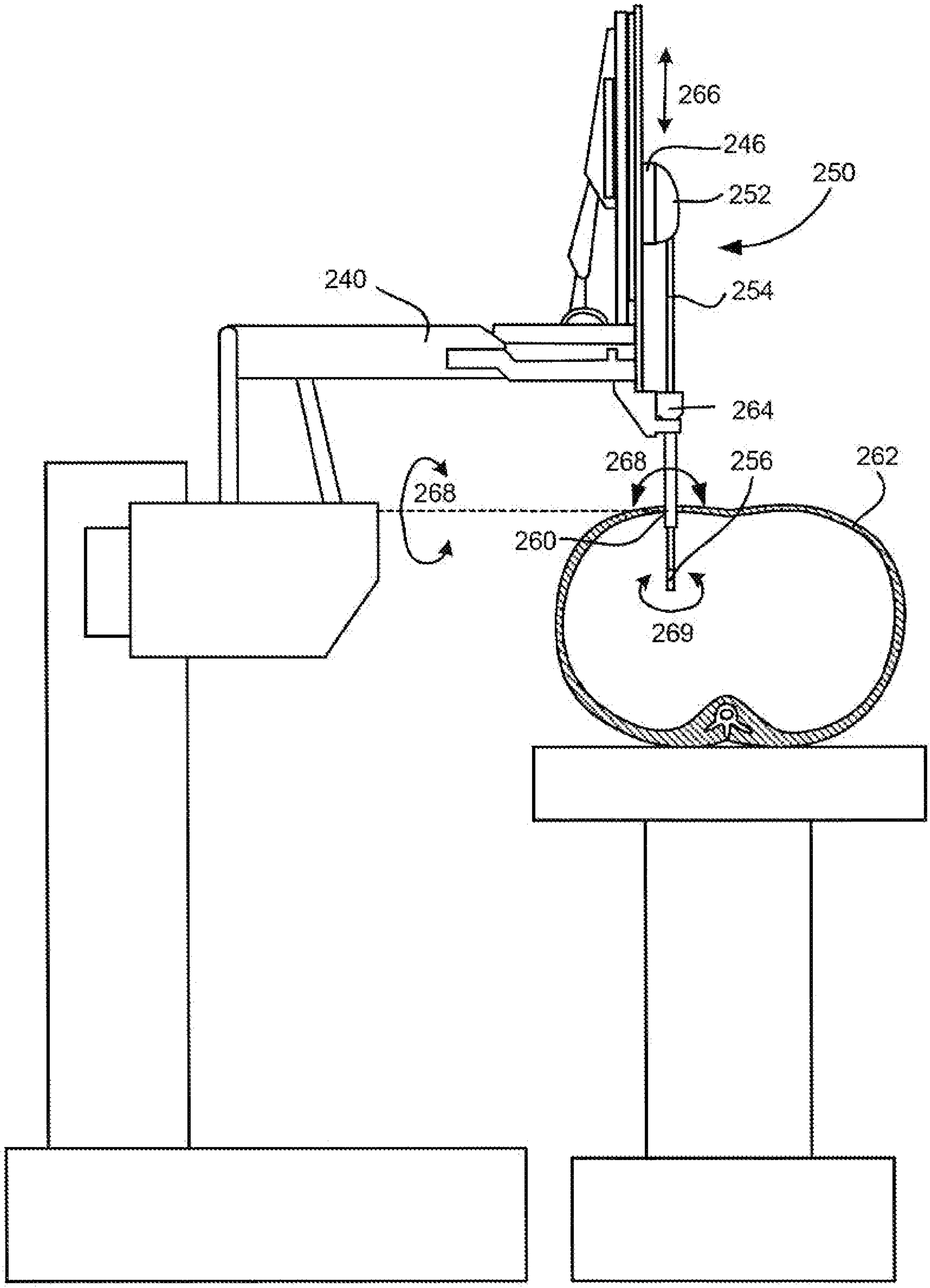
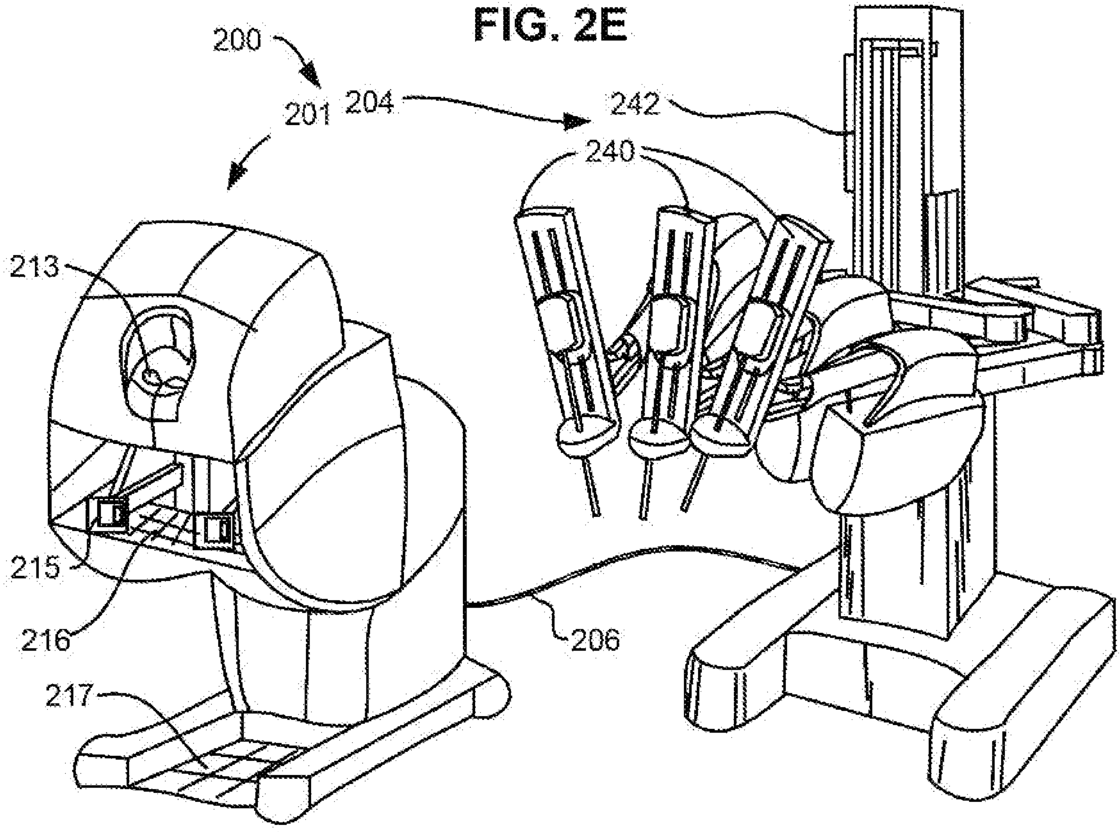


FIG. 2E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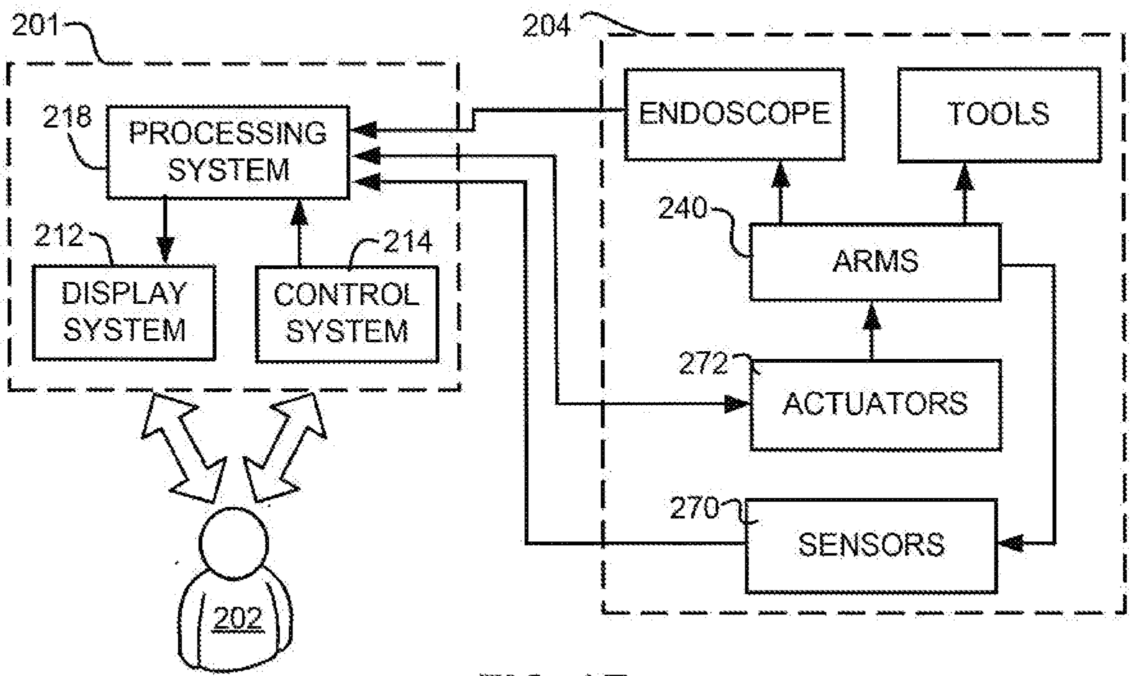
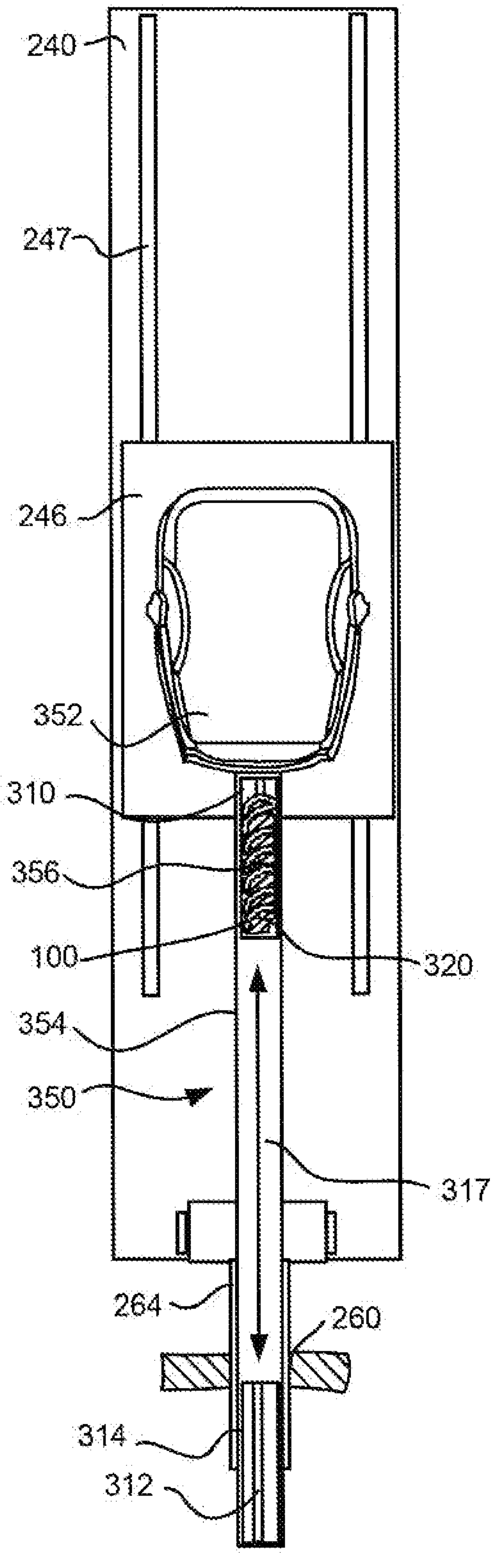

201
204
218
PROCESSING SYSTEM
212
DISPLAY SYSTEM
214
CONTROL SYSTEM
ENDOSCOPE
TOOLS
240
ARMS
272
ACTUATORS
270
SENSORS
202

FIG. 2F

FIG. 3A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247
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100
320
354
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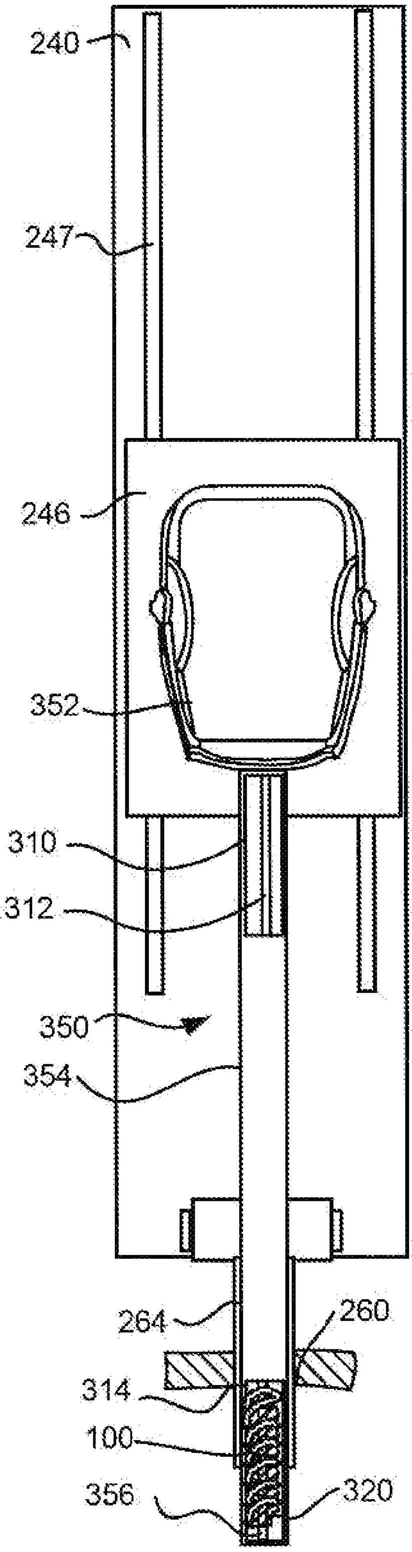
317
264
260
314
312

FIG. 3B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314
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320

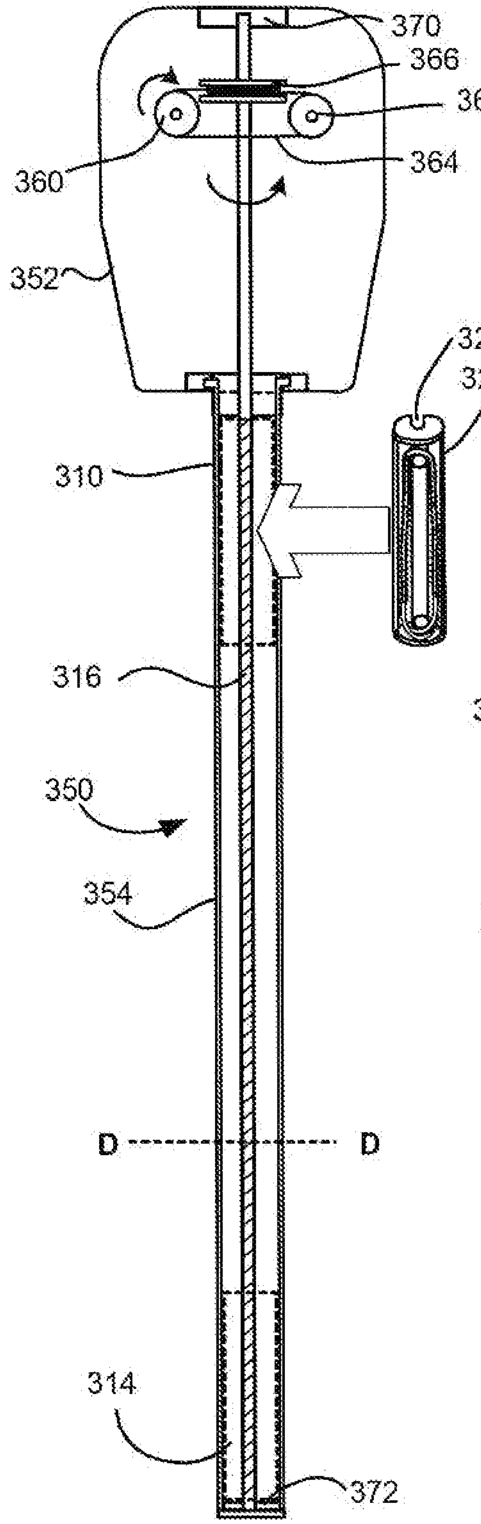


FIG. 3C

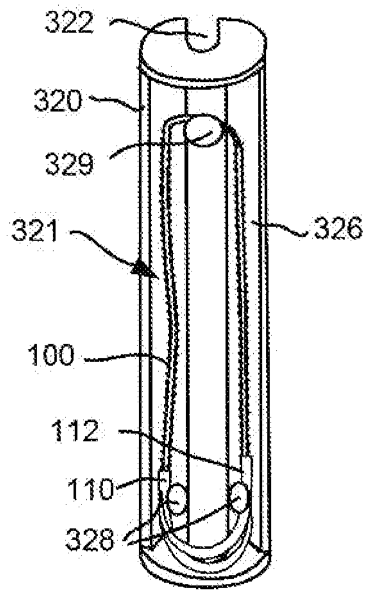


FIG. 3E

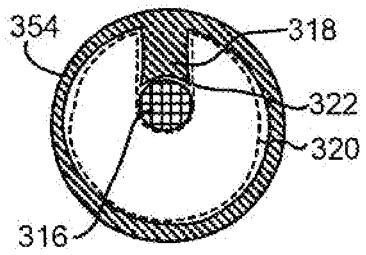


FIG. 3D

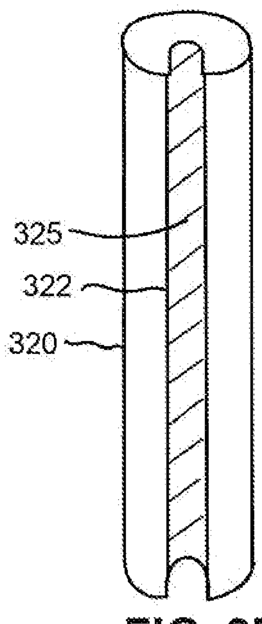


FIG. 3F

FIG. 4A

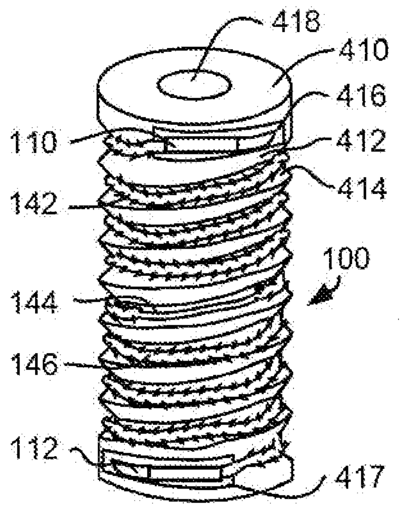


FIG. 4B

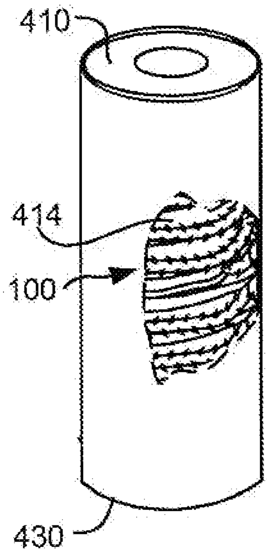
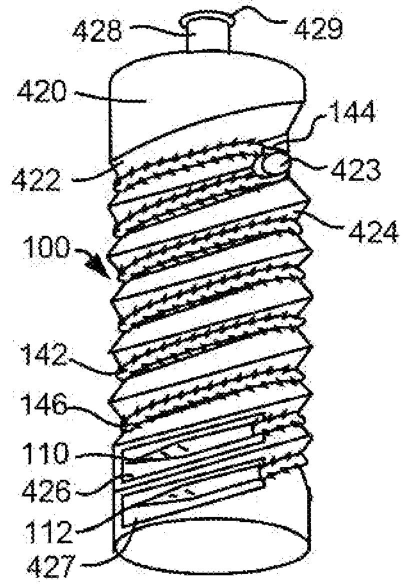


FIG. 4C



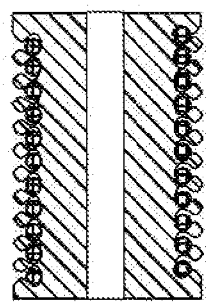


FIG. 4D

FIG. 4E

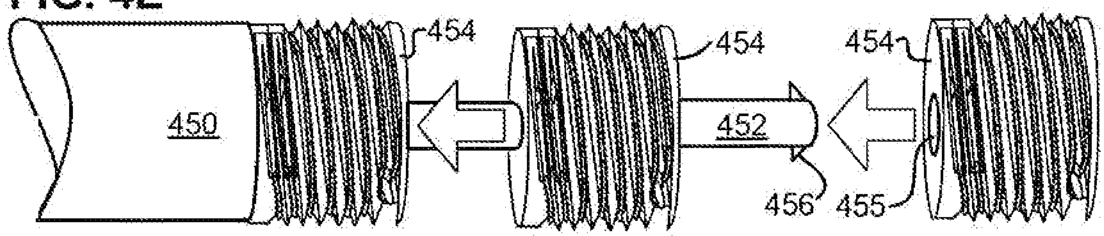


FIG. 4F

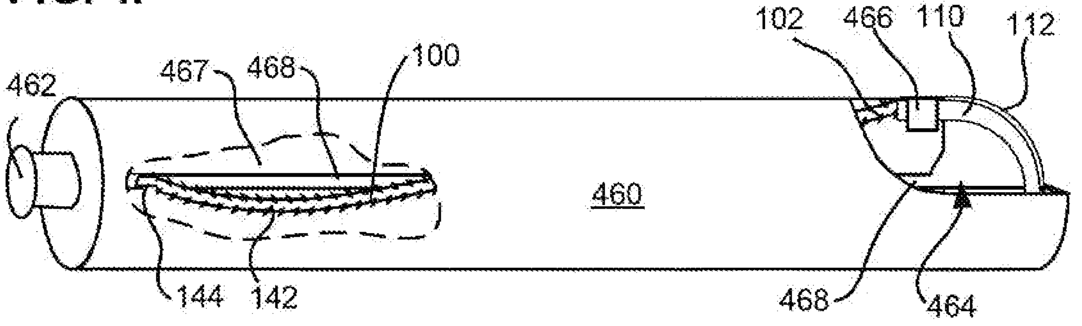


FIG. 4G

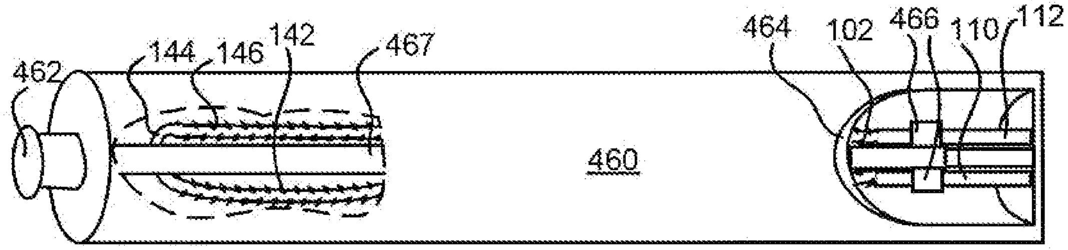


FIG. 4H

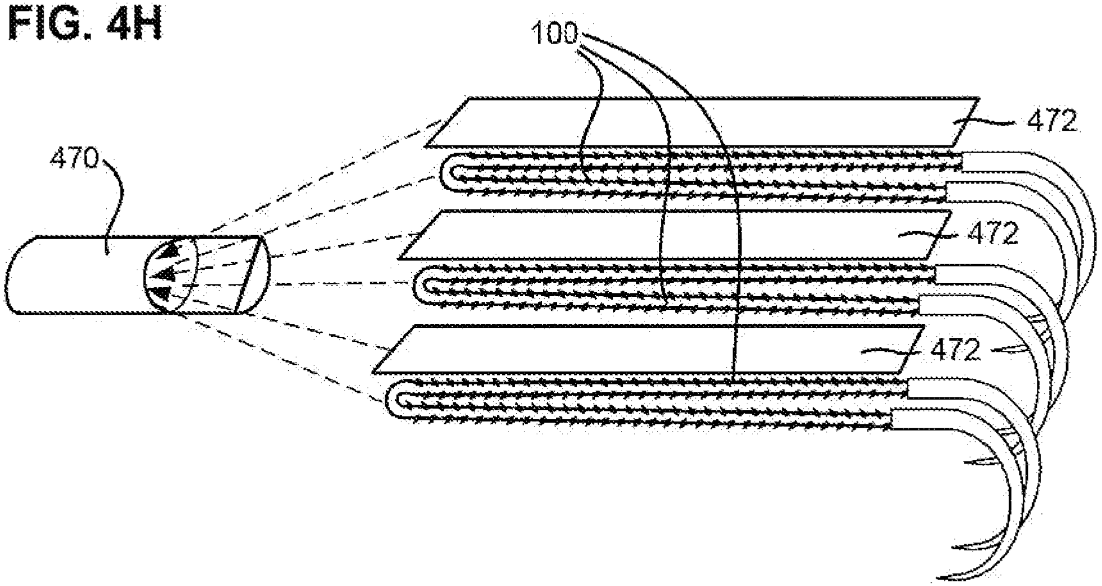


FIG. 5A

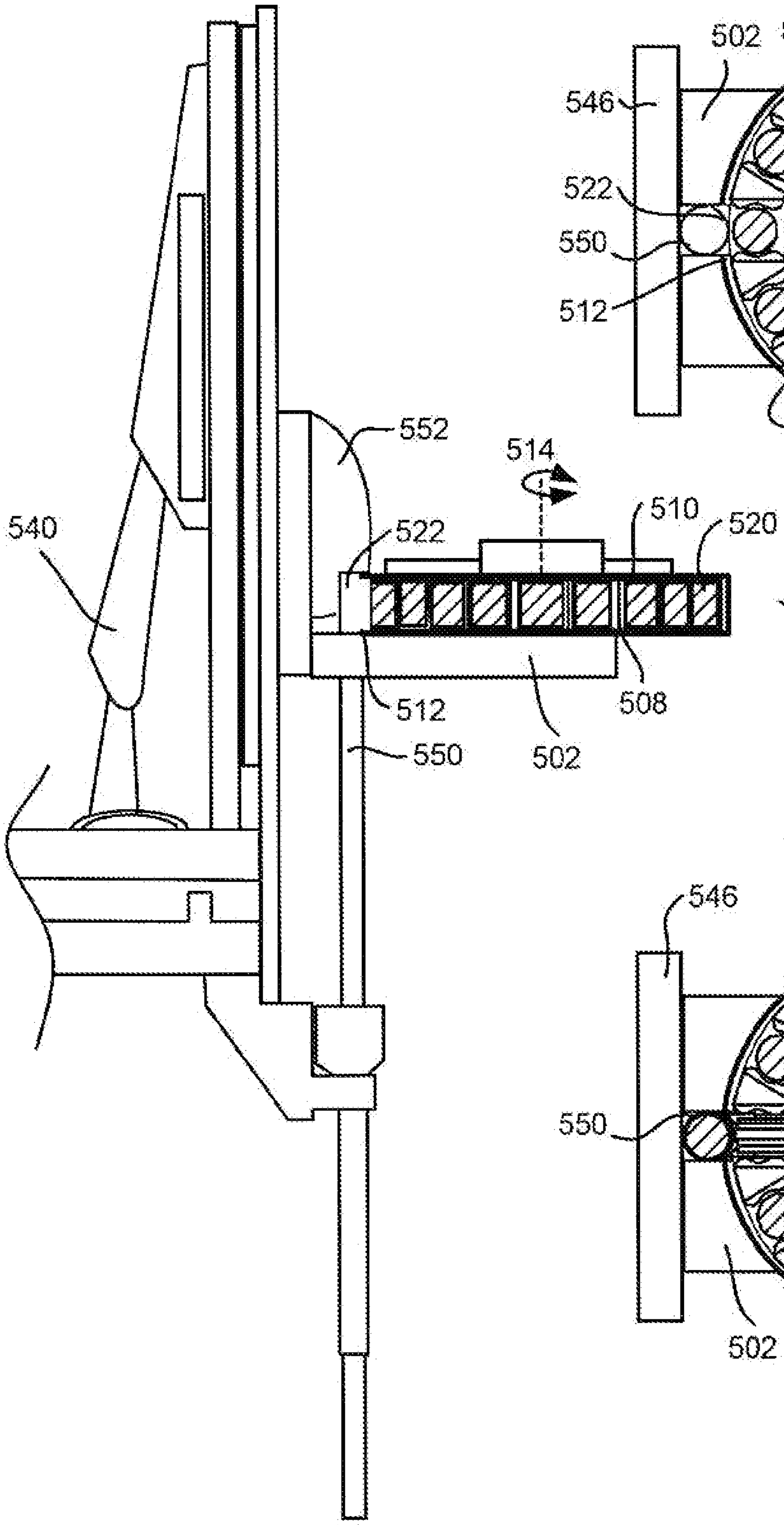


FIG. 5B

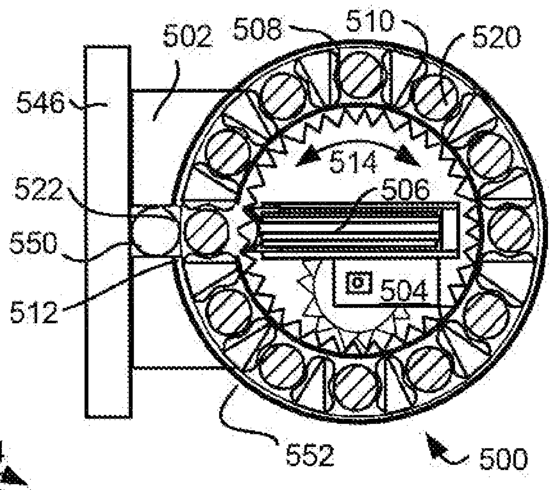


FIG. 5C

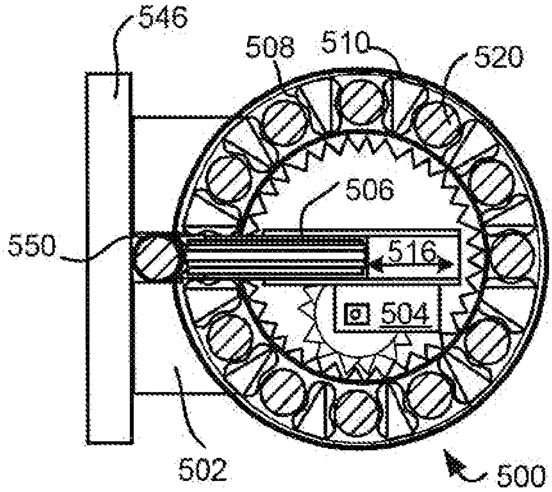
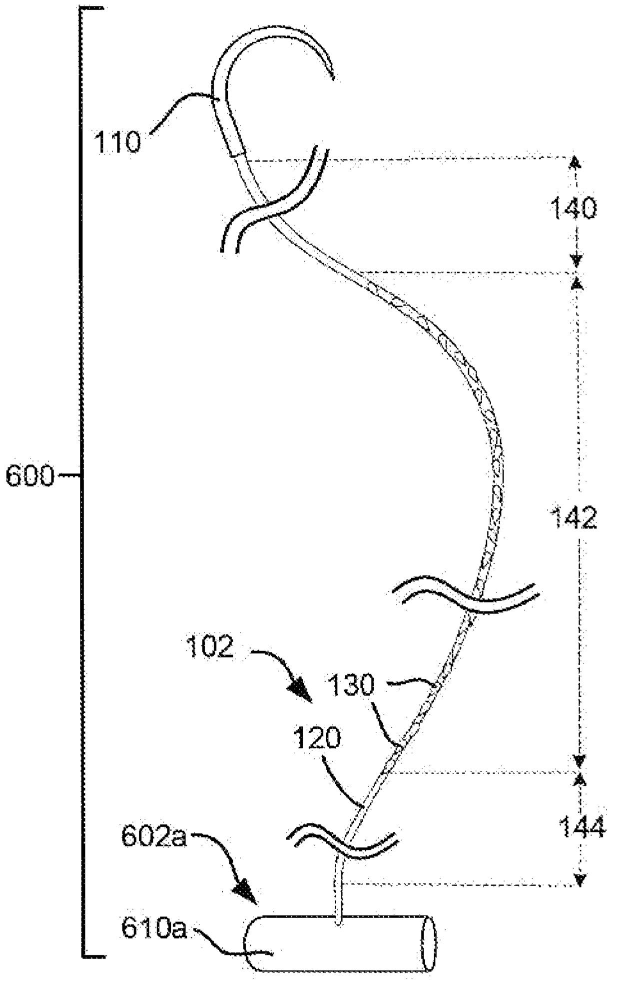


FIG. 6A



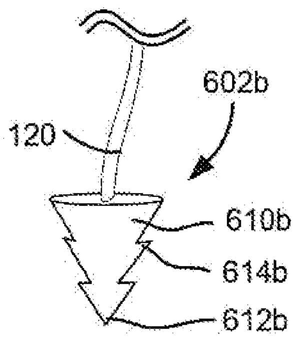


FIG. 6B

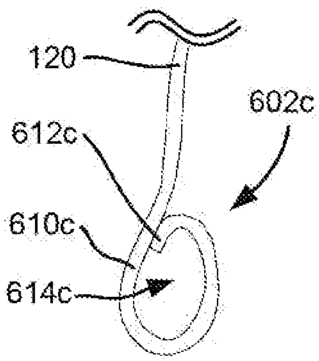


FIG. 6C

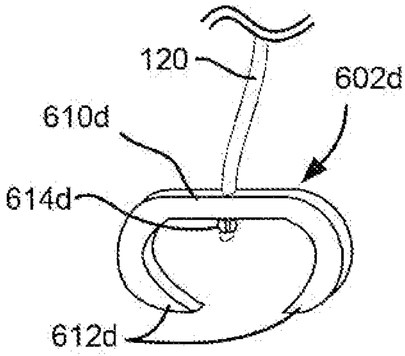


FIG. 6D

FIG. 6E

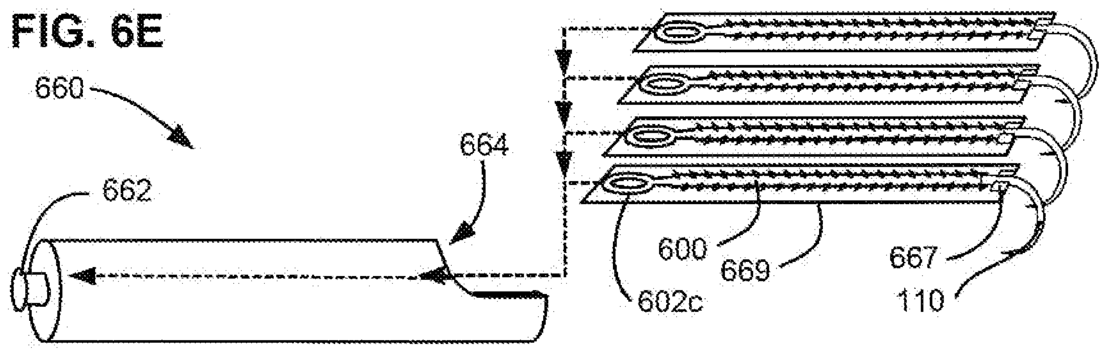


FIG. 6F

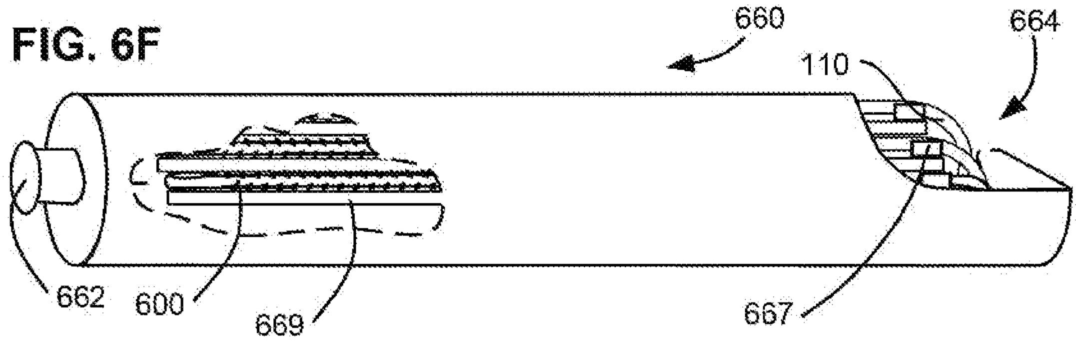


FIG. 6G

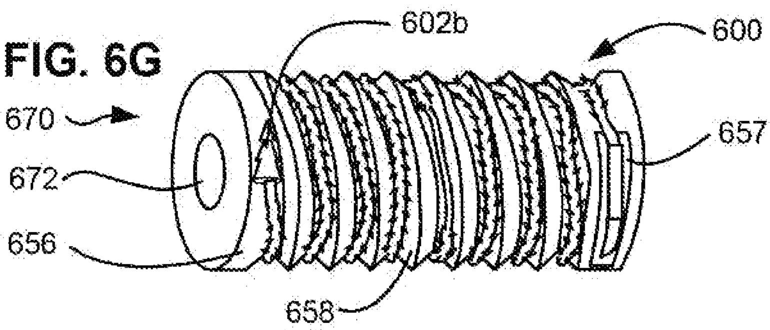
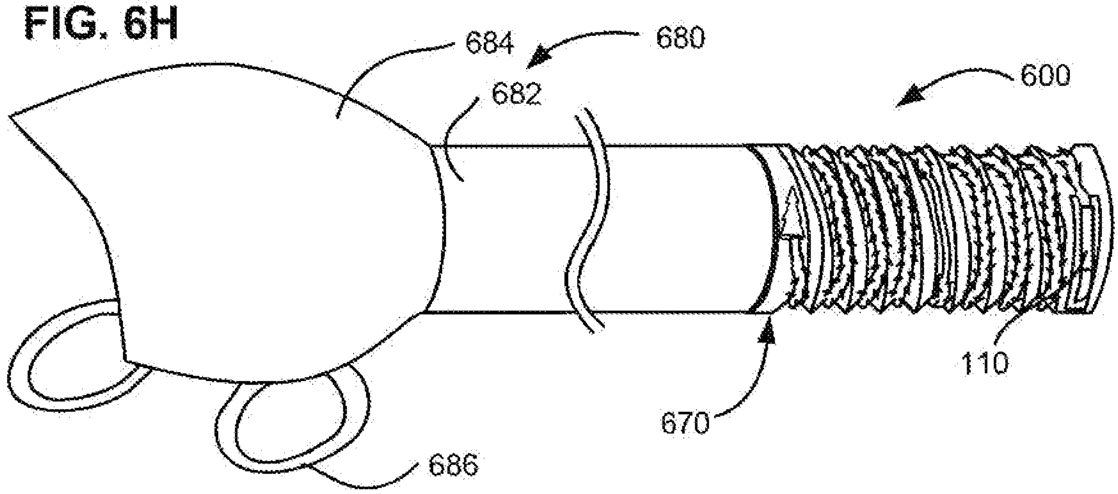


FIG. 6H



REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于内窥镜和机器人辅助手术和方法的缝合线输送工具		
公开(公告)号	EP2579787A2	公开(公告)日	2013-04-17
申请号	EP2011793252	申请日	2011-06-10
[标]申请(专利权)人(译)	ETHICON，LLC		
申请(专利权)人(译)	ETHICON LLC		
当前申请(专利权)人(译)	ETHICON LLC		
[标]发明人	AVELAR RUI DRUBETSKY LEV NAIMAGON ALEXANDER		
发明人	AVELAR, RUI DRUBETSKY, LEV NAIMAGON, ALEXANDER		
IPC分类号	A61B17/04 A61B17/062 A61B17/94 A61M25/01 A61B17/06 A61B34/30 A61B34/35 A61B90/96 A61B90/98		
CPC分类号	A61B17/04 A61B17/06128 A61B17/06166 A61B17/0644 A61B17/3421 A61B34/30 A61B34/35 A61B34/74 A61B34/76 A61B90/96 A61B90/98 A61B2017/0406 A61B2017/0412 A61B2017/0417 A61B2017/06057 A61B2017/06142 A61B2017/06176 A61B2034/302 A61B2090/036		
优先权	61/354009 2010-06-11 US		
其他公开文献	EP2579787A4 EP2579787B1		
外部链接	Espacenet		

摘要(译)

缝合线包装包括缝合线盒和可释放地固定到缝合线盒上的缝合线。缝合线盒适于通过附接到缝合线输送系统而输送到患者体内的手术部位。