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Bangera et al.

(54) **SYSTEMS AND METHODS FOR CLOSING OF FASCIA**

(75) Inventors: **Mahalaxmi G. Bangera**, Renton, WA (US); **Edward S. Boyden**, Cambridge, MA (US); **Roderick A. Hyde**, Redmond, WA (US); **Muriel Y. Ishikawa**, Livermore, CA (US); **Edward K.Y. Jung**, Bellevue, WA (US); **Eric C. Leuthardt**, St. Louis, MO (US); **Elizabeth E. Nugent**, Issaquah, WA (US); **Dennis J. Rivet**, St. Louis, MO (US); **Michael A. Smith**, Phoenix, AZ (US); **Elizabeth A. Sweeney**, Seattle, WA (US); **Clarence T. Tegreene**, Bellevue, WA (US); **Lowell L. Wood**, Bellevue, WA (US); **Victoria Y.H. Wood**, Livermore, CA (US)

Correspondence Address:
Searete LLC
Suite 110, 1756 - 114th Ave. S.E.,
Bellevue, WA 98004 (US)

(73) Assignee: **Searete LLC, a limited liability corporation of the State of Delaware**

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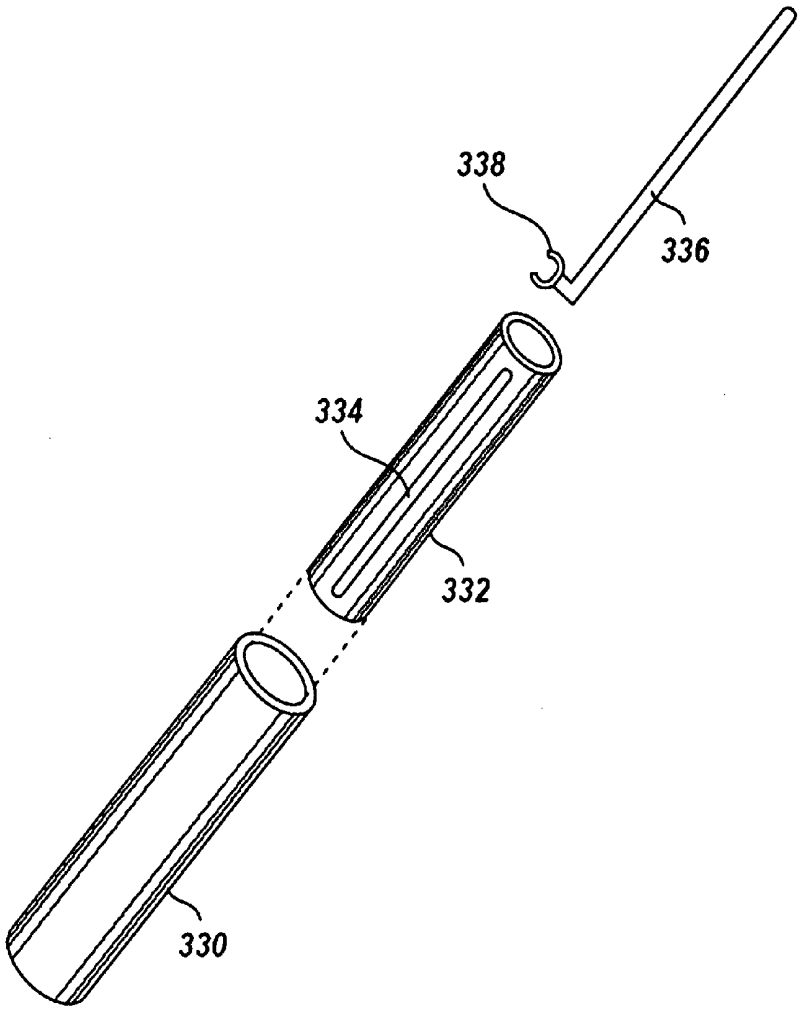
(52) **U.S. Cl.** **606/167**; 606/232

(57) **ABSTRACT**

An opening in a fascia is closed by inserting a cannula through the fascia, and attaching a tissue anchor to the fascia from the exterior or through a side of the cannula.



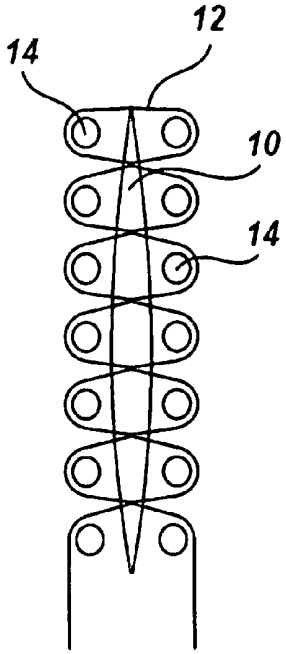


Fig. 1

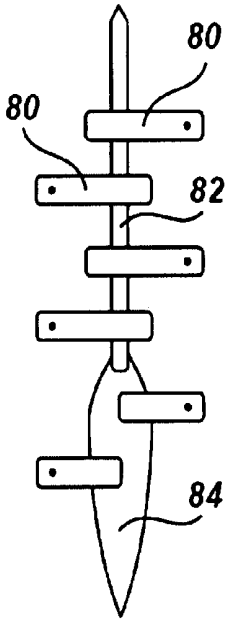


Fig. 3

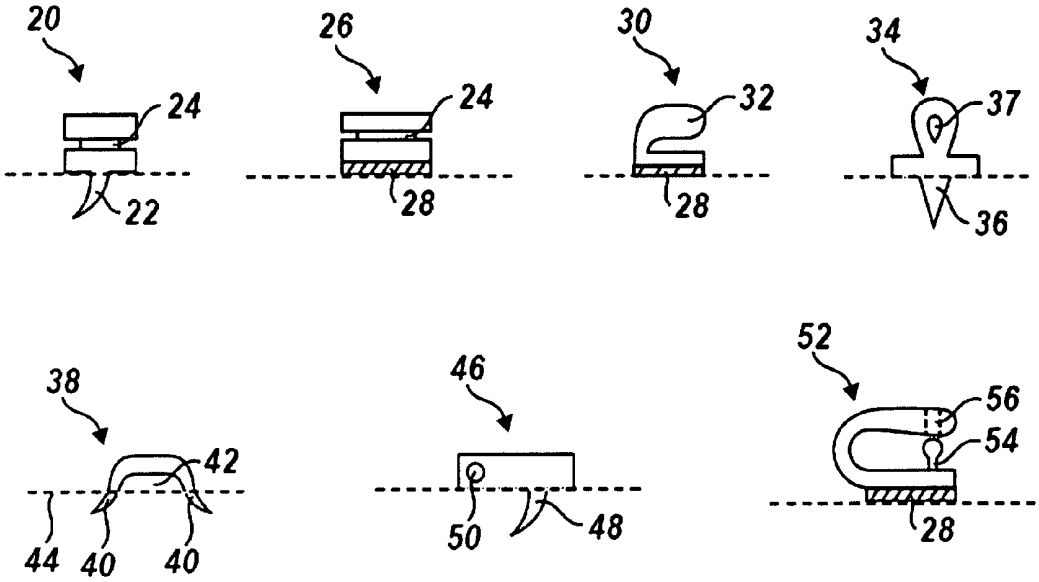
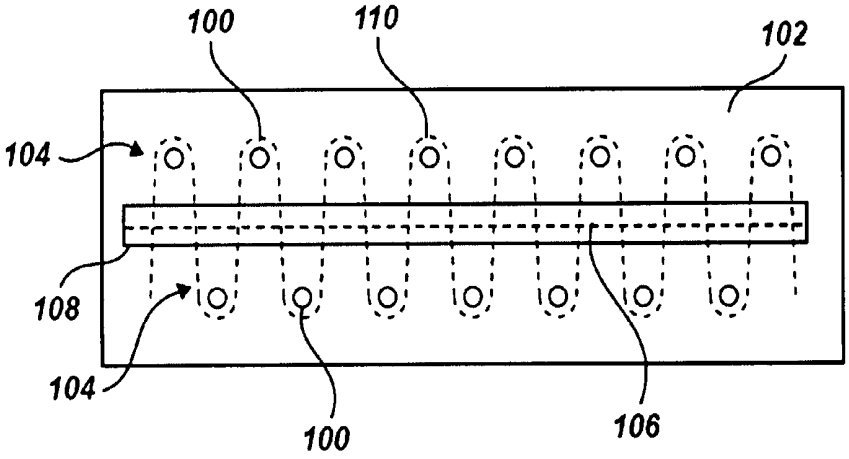


Fig. 2


100
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102
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108
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100
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Fig. 4

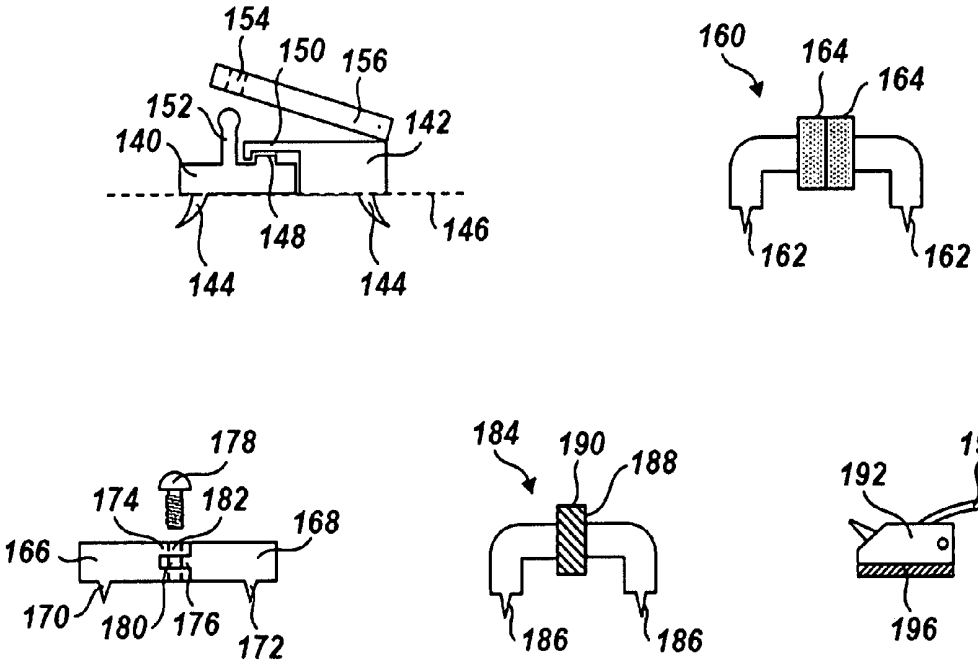
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Fig. 5

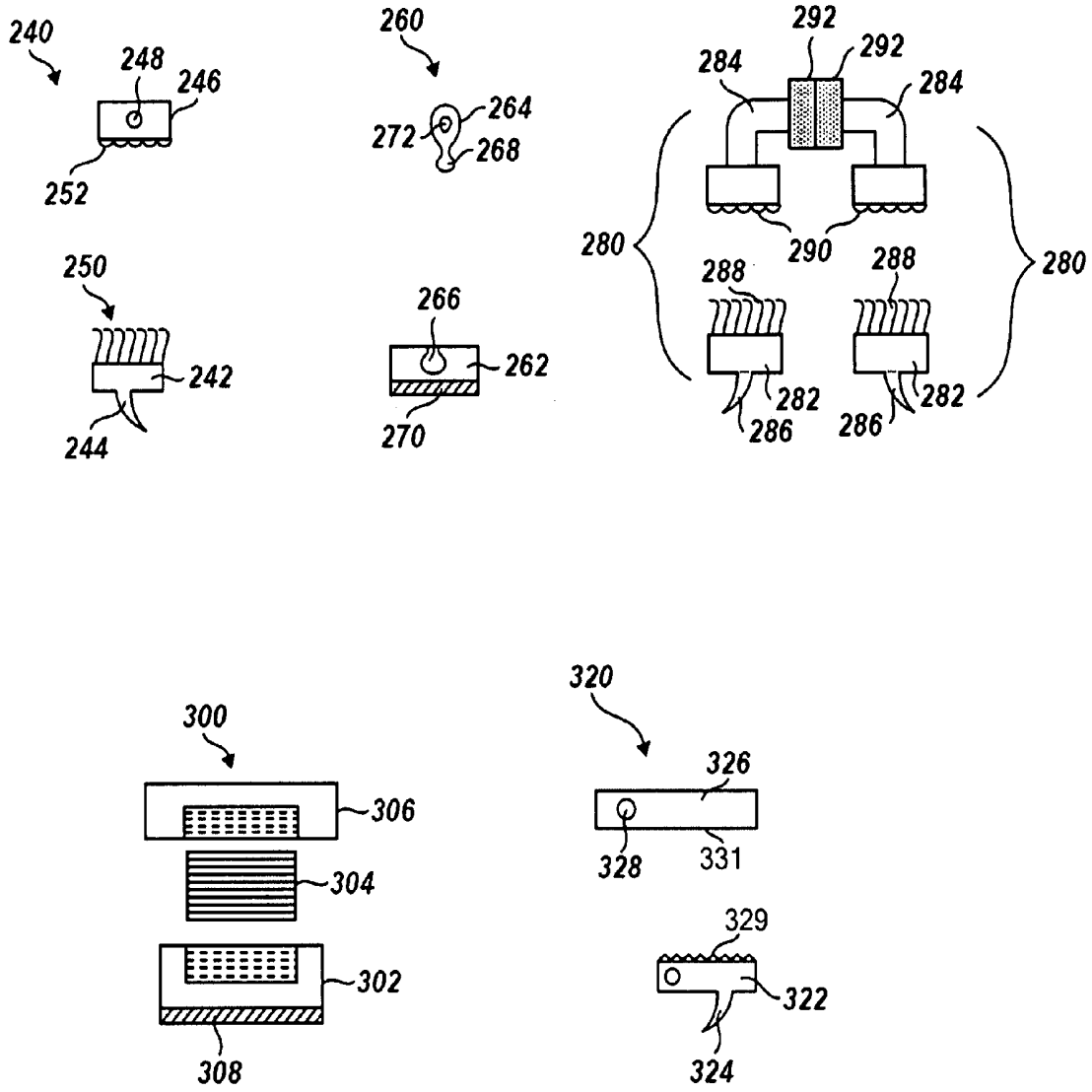
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Fig. 6

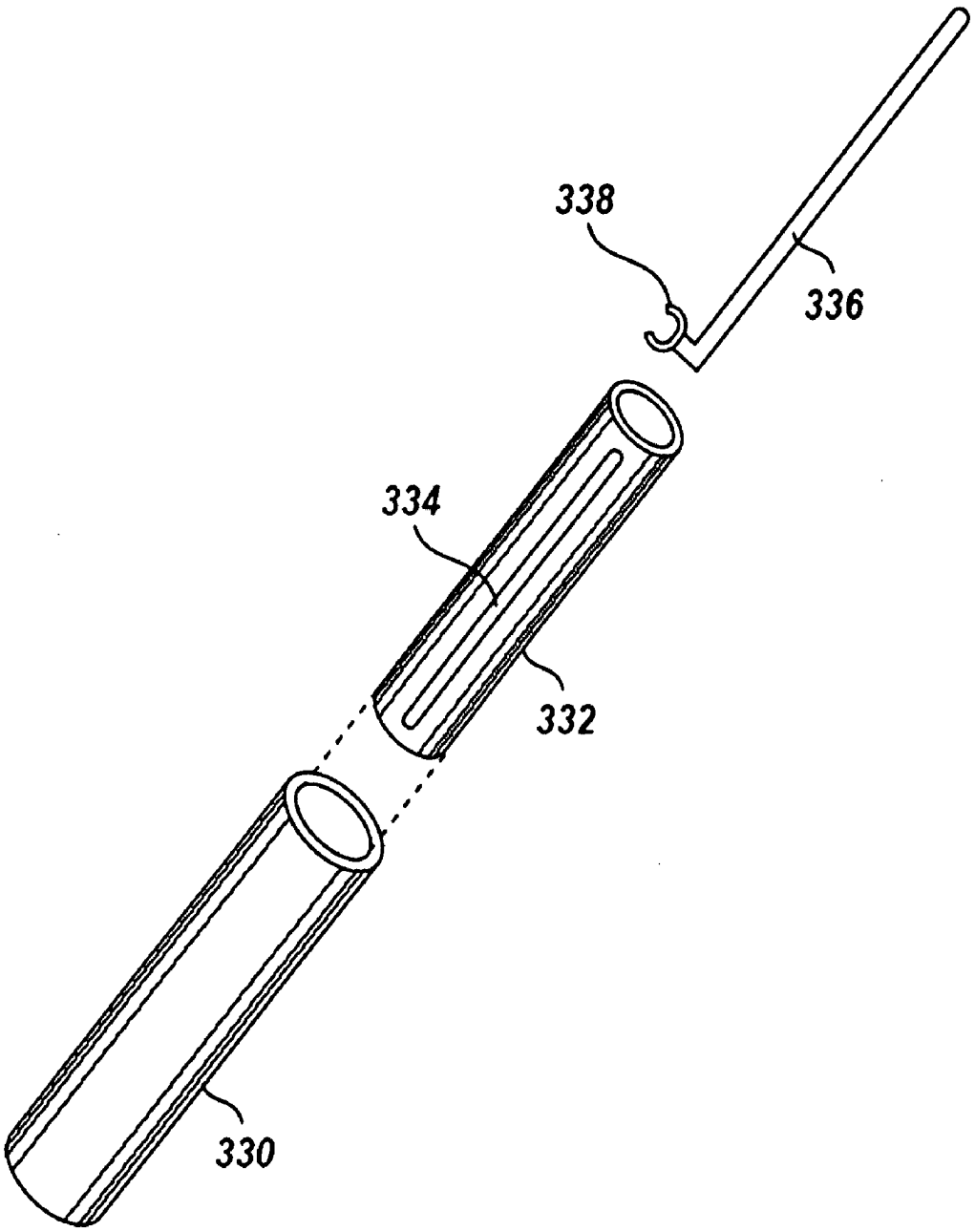


Fig. 7

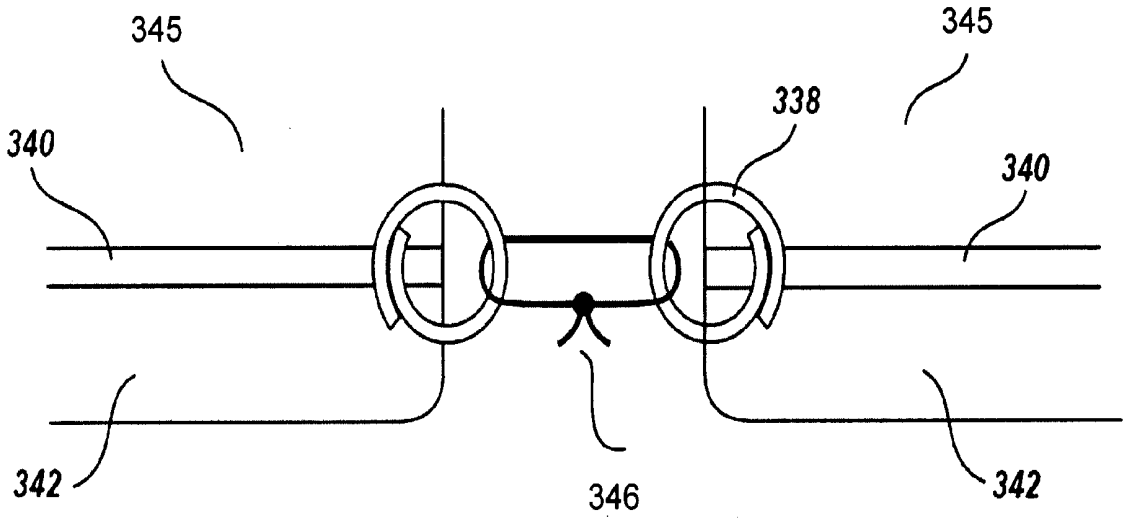


Fig. 8

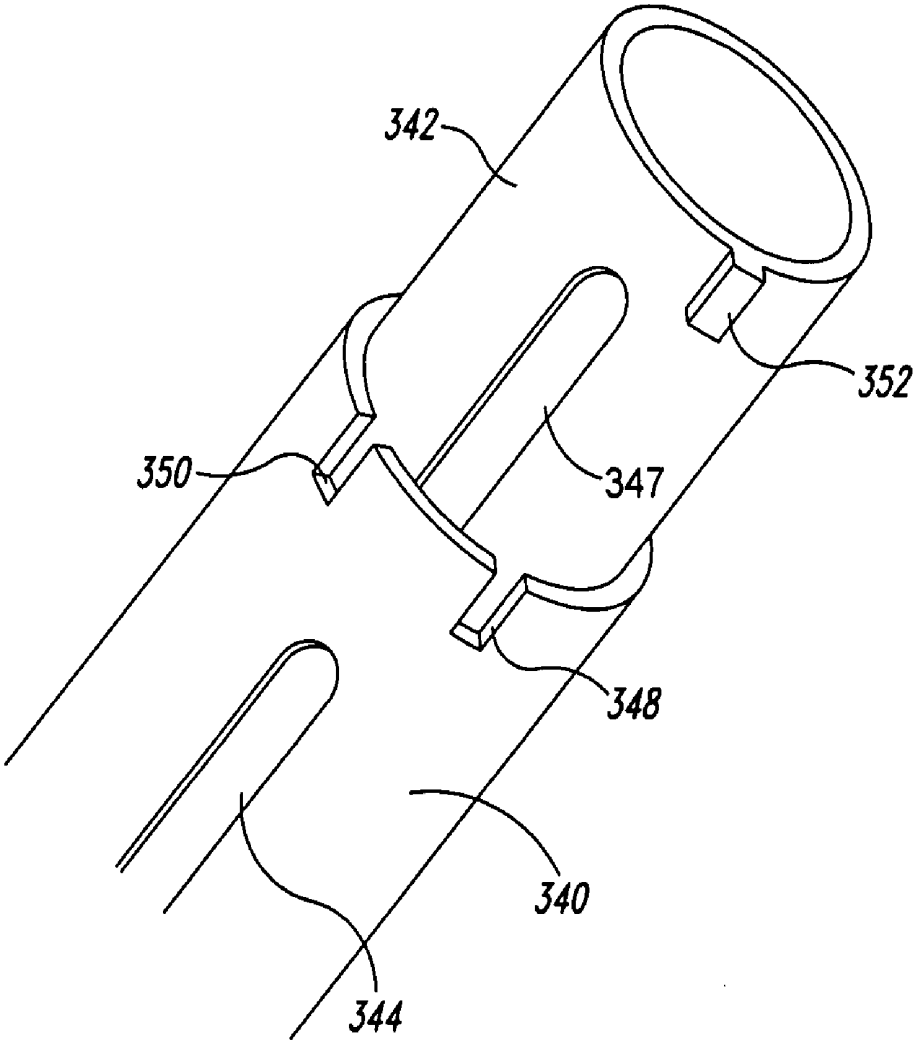


Fig. 9

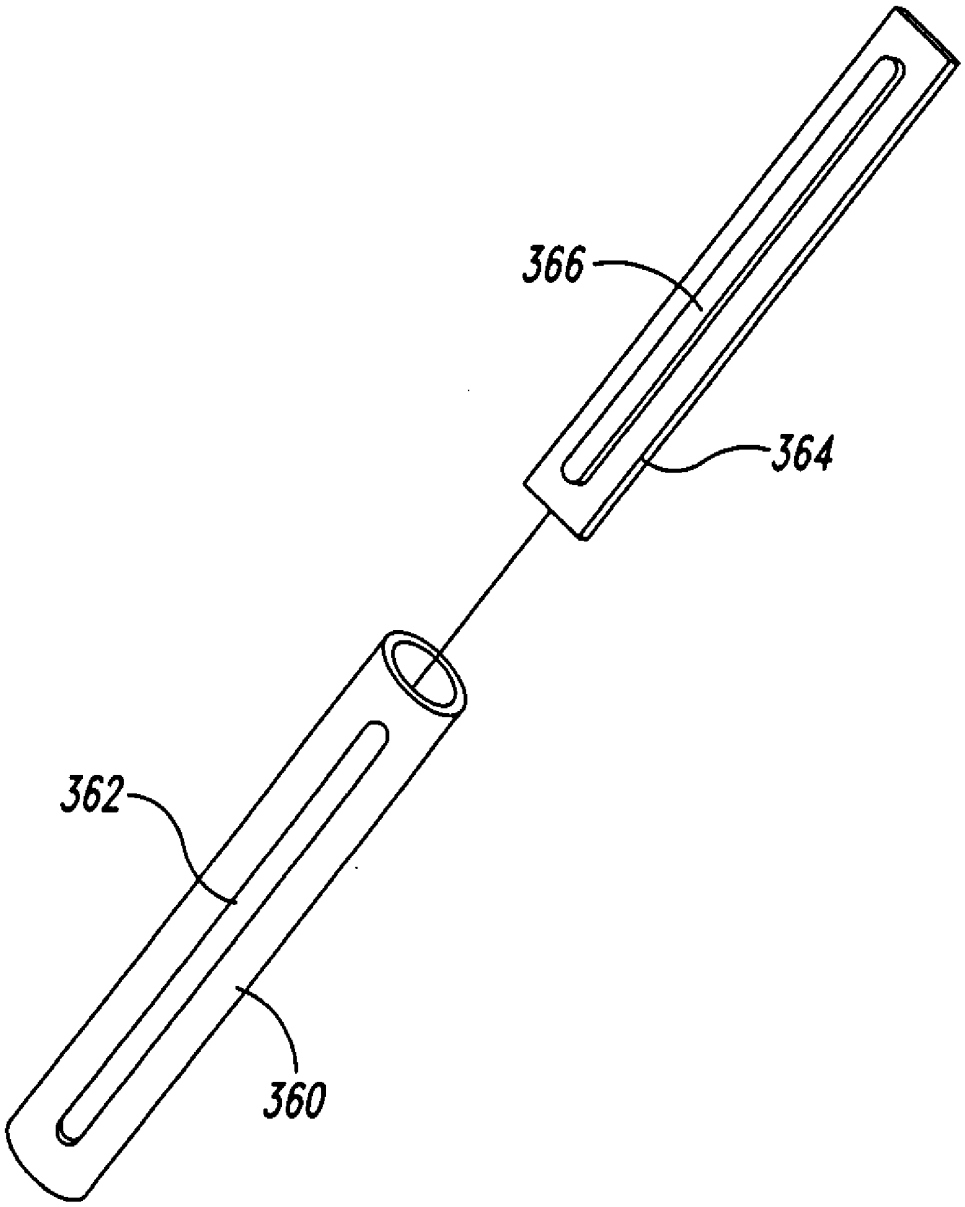


Fig. 10

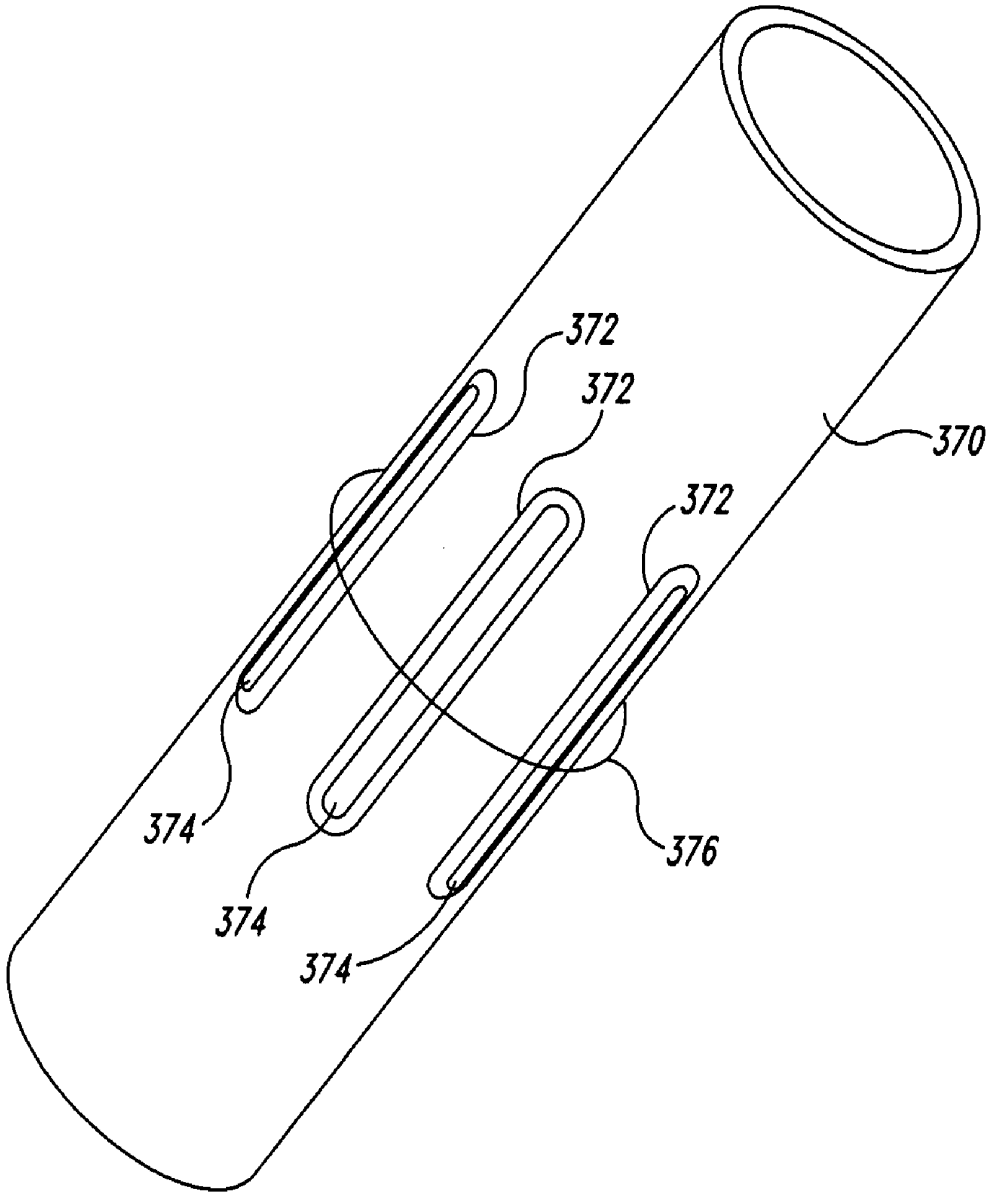


Fig. 11

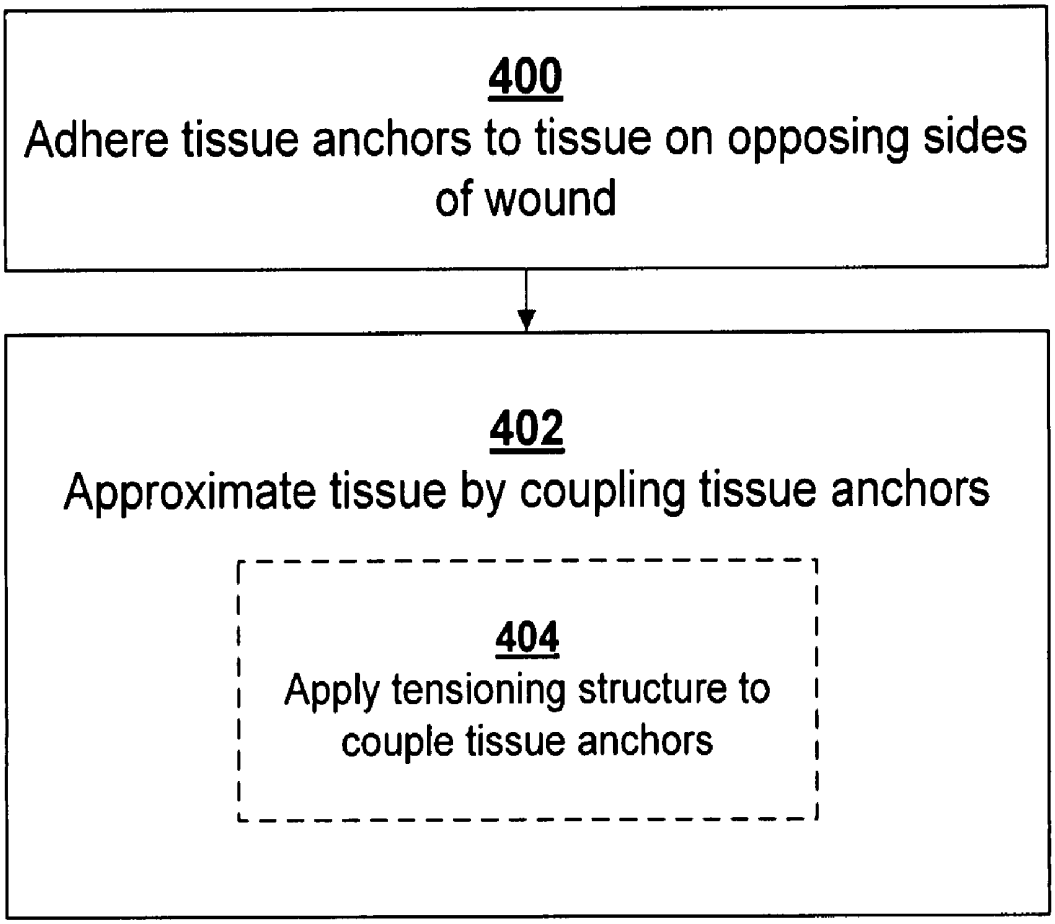

400
Adhere tissue anchors to tissue on opposing sides of wound
402
Approximate tissue by coupling tissue anchors
404
Apply tensioning structure to couple tissue anchors

Fig. 12

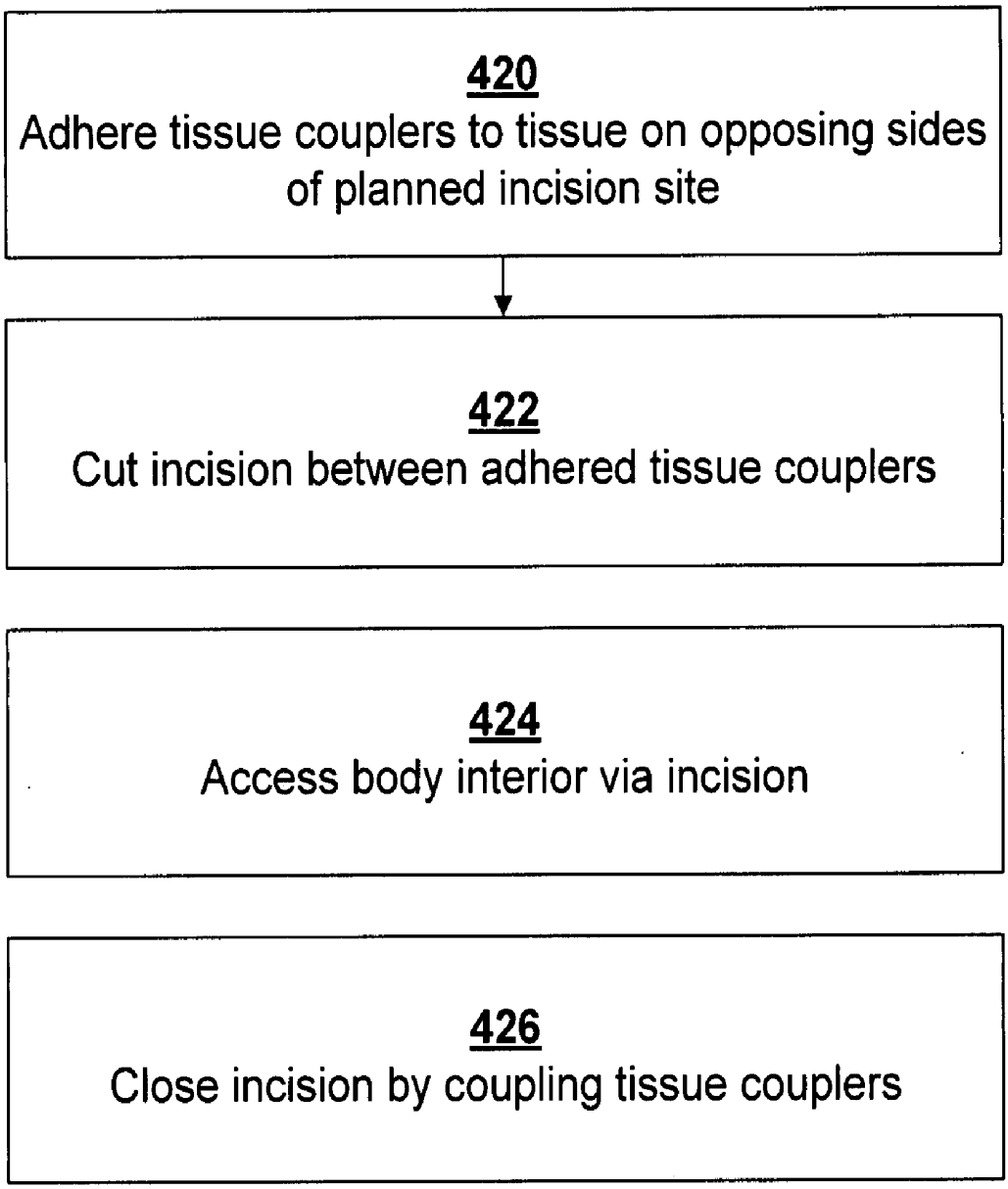

420
Adhere tissue couplers to tissue on opposing sides of planned incision site
422
Cut incision between adhered tissue couplers
424
Access body interior via incision
426
Close incision by coupling tissue couplers

Fig. 13

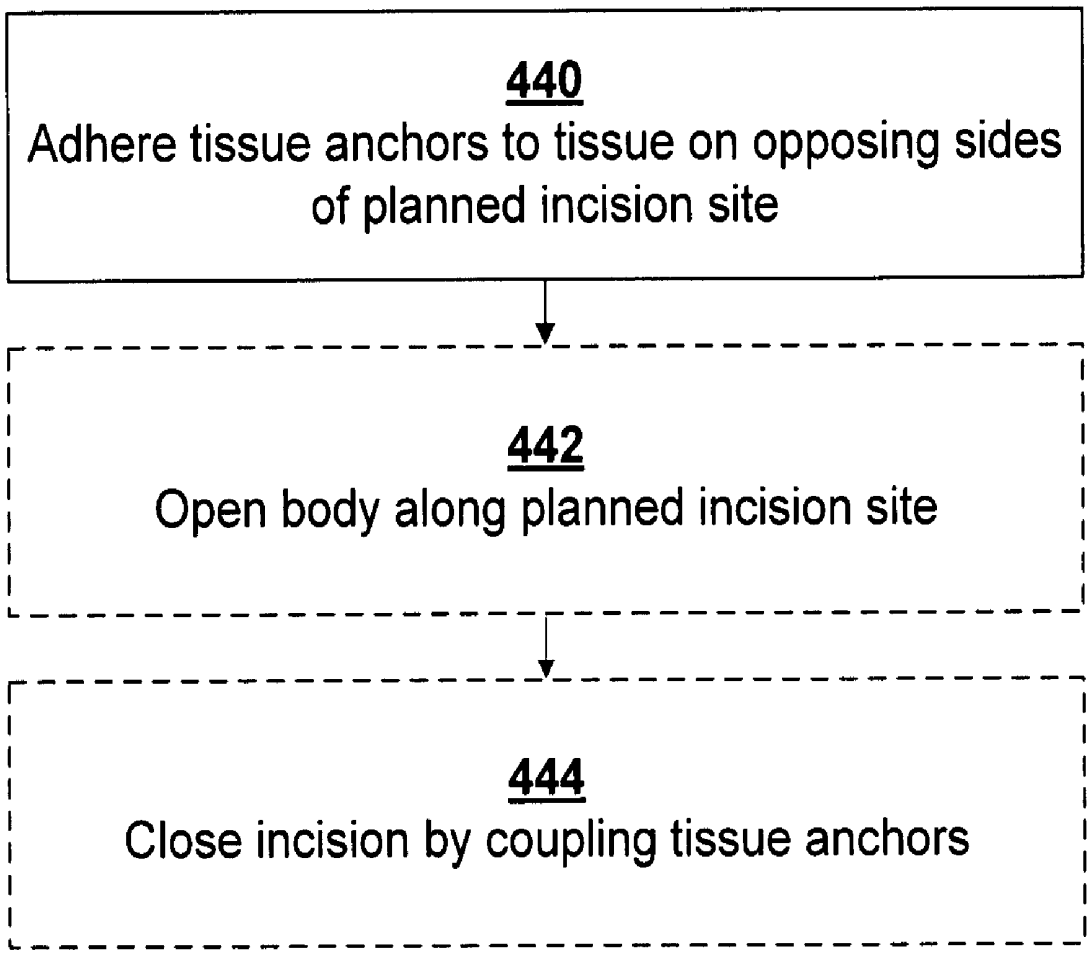

440
Adhere tissue anchors to tissue on opposing sides of planned incision site
442
Open body along planned incision site
444
Close incision by coupling tissue anchors

Fig. 14

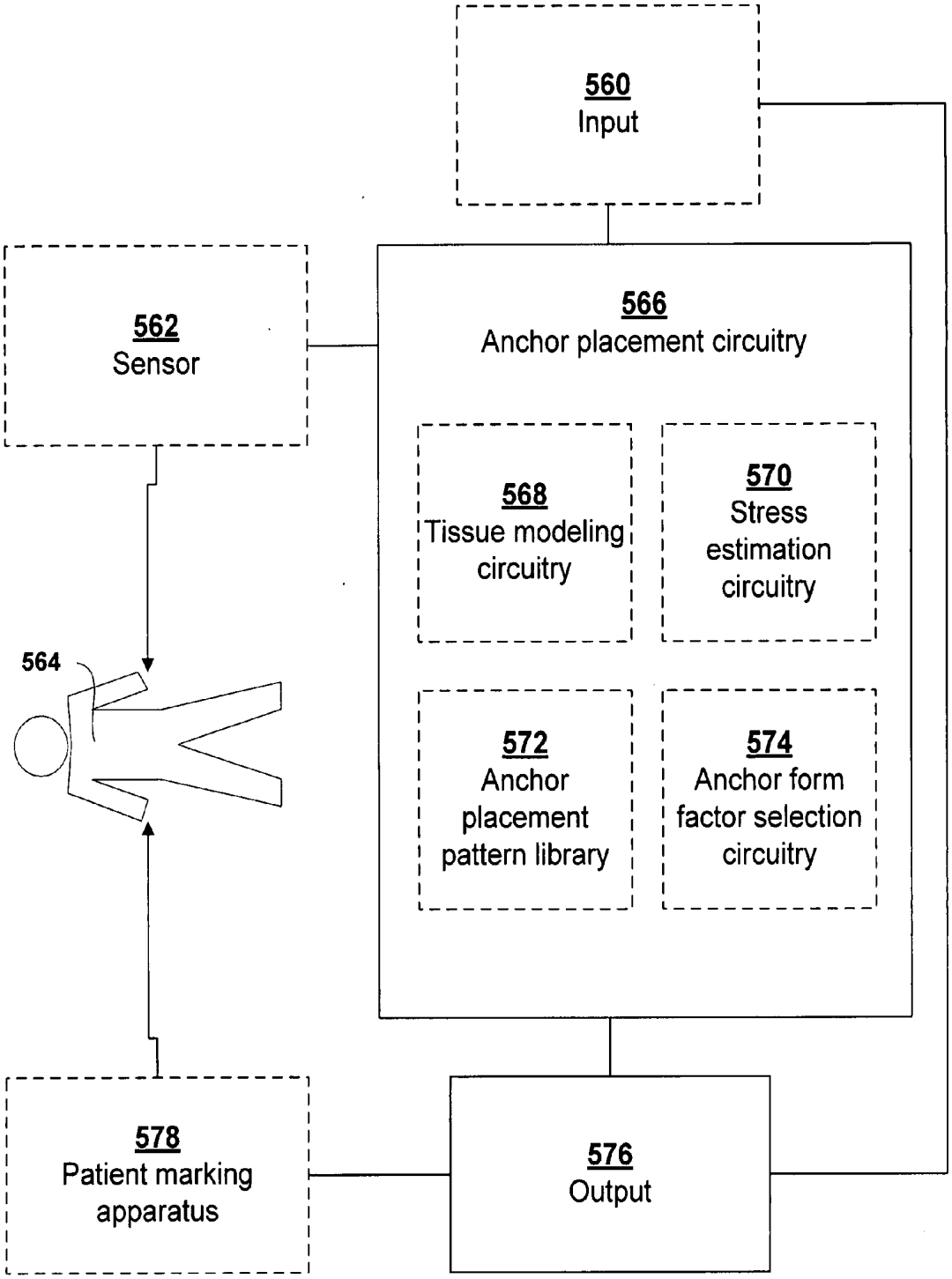

560
Input
562
Sensor
566
Anchor placement circuitry
568
Tissue modeling circuitry
570
Stress estimation circuitry
564
572
Anchor placement pattern library
574
Anchor form factor selection circuitry
578
Patient marking apparatus
576
Output

Fig. 15

SYSTEMS AND METHODS FOR CLOSING OF FASCIA

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to and claims the benefit of the earliest available effective filing date(s) from the following listed application(s) (the "Related Applications") (e.g., claims earliest available priority dates for other than provisional patent applications or claims benefits under 35 USC § 119(e) for provisional patent applications, for any and all parent, grandparent, great-grandparent, etc. applications of the Related Application(s)).

RELATED APPLICATIONS

[0002] For purposes of the USPTO extra-statutory requirements, the present application constitutes a continuation-in-part of U.S. patent application Ser. No. 11/788,767, entitled SYSTEMS AND METHODS FOR APPROXIMATING SURFACES, naming MAHALAXMI GITA BANGERA, EDWARD S. BOYDEN, RODERICK A. HYDE, MURIEL Y. ISHIKAWA, EDWARD K. Y. JUNG, ERIC C. LEUTHARDT, DENNIS J. RIVET II, MICHAEL A. SMITH, ELIZABETH A. SWEENEY, CLARENCE T. TEGREENE, LOWELL L. WOOD, JR., VICTORIA Y. H. WOOD as inventors, filed Apr. 19, 2007, which is currently co-pending, or is an application of which a currently co-pending application is entitled to the benefit of the filing date.

[0003] The United States Patent Office (USPTO) has published a notice to the effect that the USPTO's computer programs require that patent applicants reference both a serial number and indicate whether an application is a continuation or continuation-in-part. Stephen G. Kunin, *Benefit of Prior-Filed Application*, USPTO Official Gazette Mar. 18, 2003, available at http://www.uspto.gov/web/offices/com/sol/og/2003/week11/patbene.htm. The present Applicant Entity (hereinafter "Applicant") has provided above a specific reference to the application(s) from which priority is being claimed as recited by statute. Applicant understands that the statute is unambiguous in its specific reference language and does not require either a serial number or any characterization, such as "continuation" or "continuation-in-part," for claiming priority to U.S. patent applications. Notwithstanding the foregoing, Applicant understands that the USPTO's computer programs have certain data entry requirements, and hence Applicant is designating the present application as a continuation-in-part of its parent applications as set forth above, but expressly points out that such designations are not to be construed in any way as any type of commentary and/or admission as to whether or not the present application contains any new matter in addition to the matter of its parent application(s).

[0004] All subject matter of the Related Applications and of any and all parent, grandparent, great-grandparent, etc. applications of the Related Applications is incorporated herein by reference to the extent such subject matter is not inconsistent herewith.

SUMMARY

[0005] The foregoing summary is illustrative only and is not intended to be in any way limiting. In addition to the illustrative aspects, embodiments, and features described above, further aspects, embodiments, and features will become apparent by reference to the drawings and the following detailed description.

BRIEF DESCRIPTION OF THE FIGURES

[0006] FIG. **1** is a schematic of an incision being closed with a suture and a set of tissue anchors.

[0007] FIG. **2** is a schematic of several different anchor embodiments.

[0008] FIG. **3** is a schematic of an incision being closed with a securing member and a set of tissue anchors.

[0009] FIG. **4** is a schematic of anchors arranged on a stabilizing member.

[0010] FIG. **5** is a schematic of several different embodiments of multi-part couplers.

[0011] FIG. **6** is a schematic of several different multi-part anchor embodiments.

[0012] FIG. **7** is a schematic of a two-part trocar for use in closing the fascia in a laparoscopic procedure.

[0013] FIG. **8** is a schematic of fascia being closed with a suture and a set of tissue anchors.

[0014] FIG. **9** is a schematic of a portion of another two-part trocar for use in a laparoscopic procedure.

[0015] FIG. **10** is a schematic of a single-tube trocar with an openable port for use in a laparoscopic procedure.

[0016] FIG. **11** is a schematic of a single-tube trocar with tissue anchors on its exterior.

[0017] FIG. **12** is a flow chart of a method of closing a wound.

[0018] FIG. **13** is a flow chart of a method of performing surgery.

[0019] FIG. **14** is a flow chart of a method of preparing a body for surgery.

[0020] FIG. **15** is a schematic of a computer-implemented system for determining placement of tissue anchors.

DETAILED DESCRIPTION

[0021] In the following detailed description, reference is made to the accompanying drawings, which form a part hereof. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the detailed description, drawings, and claims are not meant to be limiting. Other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the subject matter presented here.

[0022] As used herein, the term "biocompatible" means a material the body generally accepts without a significant immune response/rejection or excessive fibrosis. In some embodiments, some immune response and/or fibrosis is desired. In other embodiments, vascularization is desired. In still other embodiments, vascularization is not desired. Biocompatible materials include, but are not limited to, synthetic organic materials such as clinically used nonbiodegradable and biodegradable and bioresorbable polymers including polyglycolide, optically active and racemic polylactides, polydioxanone, and polycaprolactone, polymers under clinical investigation including polyorthoester, polyanhydrides, and polyhydroxyalkanoate, early stage polymeric biomaterials including poly(lactic acid-co-lysine), and shape memory polymers (e.g., block copolymers of oligo(ϵ-caprolactone) diol and crystallisable oligo(ρ-dioxanone)diol, as described in Lendlein, et al., "Biodegradable, elastic shape-memory

polymers for potential biomedical applications," *Science,* 296 (5573):1673-1676 (2002), which is incorporated by reference herein).

[0023] As used herein, "biodegradable" materials include materials that at least partially resorb into the body or otherwise break down over time, while "nonbiodegradable" materials include those that maintain substantial mechanical integrity over their lifetime in a body. Such "biodegradable" or "nonbiodegradable" materials are well known to those having skill in the art. In general, the anchors, couplers, traction members, securing members, tensioning members, stabilizing members, and other components described herein may be either biodegradable or nonbiodegradable, or may include both biodegradable and nonbiodegradable components. In some embodiments, these elements will be biocompatible, while in other embodiments, they may be partially or fully constructed from nonbiocompatible materials.

[0024] As used herein, "antimicrobial" materials include materials that have the capacity to inhibit the growth of or destroy pathogens, including but not limited to bacteria, fungi, and viruses. Such antimicrobial materials are well known to those having skill in the art and may include materials that are coated or impregnated with an antimicrobial agent or wherein the material itself possesses antimicrobial properties.

[0025] As used herein, a material having a "therapeutic property" is one that induces or facilitates a desired biological response. Materials having a therapeutic property are well know to those having skill in the art, and include, but are not limited to cell growth promoters, cell growth inhibitors, cytokines, healing promoters, antibiotics, clotting modulators, anti-inflammatories, and anti-scarring agents.

[0026] FIG. **1** illustrates an incision **10** being closed with a suture **12** and a set of tissue anchors **14**. The tissue anchors **14** may be placed in the tissue before or after the incision **10** is made, and may be shaped to receive the suture **12**. To close the incision **10**, the suture **12** is wound around the anchors **14** as shown and pulled to tighten, approximating the body tissue in the region of the anchors **14**. In some embodiments, the edges of the incision may be brought together by other means (e.g., manually by the surgeon), and the suture **12** may be used to maintain the approximation of the edges of the incision. Those of skill in the art of surgery will recognize that there are many possible patterns for placement of the anchors **14** and for winding of the suture **12**, and will be able to select an appropriate configuration for any particular patient and incision. For example, the crossed suture **12** shown in FIG. **1** may not be desirable in all cases, and may be replaced by a suture winding that does not cross itself, such as a configuration (not shown) in which discrete sutures draw anchors **14** together pairwise across the incision **10**, or a single suture arranged in a serpentine pattern. In other embodiments, it may not be desirable to place all anchors **14** at the same distance from incision **10**, or to place the anchors **14** at regular intervals as shown in FIG. **1**. For example, an irregular pattern or a pattern with localized concentrations of anchors **14** may be appropriate for locations having differential topographies, tissue types, expected movement ranges, stresses, or contact with surfaces, such as bandages, supports, clothing, or similar. The number and placement of the anchors **14** will also vary with the incision type, with fewer anchors **14** typically (but not always) being applied for smaller incisions. While FIG. **1** illustrates an incision **10** being closed, a similar arrangement may be used to close an accidental wound or to draw tissue into a desired configuration (e.g., in a face lift or other cosmetic procedure, or in a bladder suspension), or to attach tissue to an implanted device or other object (e.g., an organ for transplant) in a body. While FIG. **1** illustrates a straight incision **10**, in other embodiments, the opening to be closed by the anchors may be curved, round, branched, stellate, and/or angled (e.g., in a sawtooth configuration).

[0027] FIG. **2** shows a variety of anchor configurations that may be used with a suture to close an incision as shown in FIG. **1**. Anchor **20** includes a piercing structure **22** for placement in a body tissue, and a groove **24** to receive a suture. Anchor **26** also includes a groove **24** to receive a suture, but is adhered to the tissue via an adhesive layer **28**. Anchor **30** is adhered to the tissue with an adhesive layer, and includes a hook **32** about which a suture may be looped. Anchor **34** includes a piercing structure **36** of a slightly different shape from that of anchor **20**, and also includes an eyelet **37** through which a suture may be threaded. The piercing structure **36** may allow the anchor to be rotated, either manually or through the natural pulling action of a threaded suture. Anchor **38** includes two piercing prongs **40** like a staple, and creates an opening **42** through which a suture may be passed in cooperation with the underlying tissue **44**. In some embodiments, this anchor may be pushed further into the tissue in a way that prevents movement of the suture, for example after the incision has been closed. Anchor **46** includes a piercing structure **48** and an eyelet **50**, the eyelet **50** being disposed distal from the piercing structure **48** and along the surface of the body tissue. In some embodiments, the eyelets **50** of adjacent anchors **46** may be aligned as the tissue is closed. Anchor **52** includes a vertical post **54** and channel **56** allowing it to be snapped closed, for example after a suture has been threaded around it. In some embodiments, this closure may be reversible, while in others, it may be irreversible. In some embodiments, closure of the anchor **52** may restrict sliding of the suture, while in other embodiments, the suture may be able to slide through the anchor **52** after closure.

[0028] The specific structures of anchors shown in FIG. **2** shall not be interpreted to limit the shape or design of the anchors described and claimed herein. By way of non-limiting example, the piercing structure **22** of anchor **20** may be used in place of the adhesive layer **28** shown with anchor **30**; the eyelet **50** of anchor **46** may be used with the adhesive layer **28** shown with anchor **30** or with the piercing structure **36** shown with anchor **34**. Various combinations of the piercing structures shown, as well as those not shown but known to those of skill in the art, can be used with any suture-holding structure or any other securing member or mechanism.

[0029] FIG. **3** shows another embodiment, in which anchors **80** are secured via insertion of a securing member **82**, which is a conformable rod in the illustrated embodiment. The illustrated anchors **80** are similar to the anchors **46** of FIG. **2**, including a piercing structure (not visible in FIG. **3**) and an eyelet through which conformable rod **82** may be inserted. As shown, the rod **82** is partially inserted through the anchors **80**, so that the incision **84** is partially closed. In other embodiments, the anchors **80** or the securing member **82** may include other attachment structures, such as hooks, mating surfaces (to which adhesive may optionally be applied), and/or mechanical fasteners (e.g., hook and loop fasteners, draw latches, screws, etc.). By way of non-limiting example, securing member **82** may include a series of hooks configured to receive anchors **80**; anchors **80** may include hooks configured to attach to securing member **82** (which may optionally

include predetermined attachment points for anchors **80**); securing member **82** may include snap fittings into which mating portions of anchors **80** may be inserted; anchors **80** and securing member **82** may include holes or other areas configured for attachment of screws or other fasteners that secure anchors **80** and securing member **82** together. In embodiments in which the securing member **82** is conformable, it may be conformed to match the shape of an incision, or it may be conformed before or after insertion in order to apply a mechanical force to tissue in order to reshape it (e.g., in cosmetic surgery). In some embodiments, the process of inserting securing member **82** may bring the anchors **80** together, while in other embodiments, the edges of the incision **84** may be brought into alignment before the securing member **82** is deployed.

[0030] FIG. **4** is a schematic of anchors **100** arranged on a stabilizing member **102**. In the embodiment shown, the stabilizing member **102** includes a flexible tape base designed to adhere to the tissue of interest. The anchors are arranged in parallel rows **104** on opposite sides of a planned incision site **106**. In some embodiments, the flexible tape base may be placed on the patient prior to making the incision. The illustrated embodiment includes an opening **108** along the planned incision site **106**, but other embodiments may omit the opening. The anchors **100** may adhere to the stabilizing member **102**, which in turn adheres to the tissue of interest, via an adhesive, or they may include mechanical fasteners or other structures to facilitate their attachment to tissue (e.g., piercing structures such as those shown in anchors **20**, **34**, **38**, **46** of FIG. **2**). In one method of use, the stabilizing member **102** is placed on the body with opening **108** positioned at the planned incision site **106**. The incision is made, and surgery is performed on the body via the incision. At the conclusion of the surgery, a suture is threaded around the anchors **100** along serpentine path **110**, and tightened to draw the anchors **100** together, thereby closing the incision (in some embodiments, the incision may be closed by other means, and the suture may maintain the closure). In other embodiments, opening **108** may be omitted, and the incision performed through the stabilizing member **102**, or the stabilizing member **102** may be placed after the incision is made (e.g., after the surgery is completed). In some embodiments, the stabilizing member **102** may be applied to a wound (e.g., an accidental wound). Rather than a suture, the incision may be closed by application of a securing member as described above in connection with FIG. **3**, or by direct connection of couplers as described below in connection with FIG. **5**. The stabilizing member **102** may be placed on the skin, or on other tissue such as muscular or vascular tissue.

[0031] FIG. **5** shows several different embodiments of couplers that may be connected without the use of a tensioning member or a securing member as described above. In some embodiments, a specialized or general purpose tool may be used to connect anchors together. Couplers **140**, **142** include piercing structures **144** that secure the couplers to underlying tissue **146**. Coupler **140** includes a temporary alignment pin **148** configured to mate with a corresponding alignment groove **150** on coupler **142**. In addition, coupler **140** includes a permanent (or, optionally, semipermanent) retaining pin **152** configured to mate with a channel **154** in hinged connector **156** on coupler **142**. In one method of use, the couplers **140**, **142** may be secured to tissue with temporary alignment structures **148**, **150** connected. The temporary alignment structures **148**, **150** may then be disconnected to permit access to an incision site, for example to open an incision after the couplers **140**, **142** have been placed. Upon closing, both temporary alignment structures **148**, **150** and permanent retaining structures **152**, **154** may be connected, permanently (or, optionally, semipermanently) closing the incision while maintaining the alignment of underlying tissue.

[0032] Couplers **160** include piercing structures **162**, and permanent magnets **164**. In use, these couplers may be placed on either side of a wound or a planned incision, and optionally rotated to increase the distance between permanent magnets **164** during access to the wound. Upon closing, the couplers **160** may be rotated (if necessary) to align the magnets, and brought into proximity to magnetically adhere them together, securing the underlying tissue. Couplers **166**, **168** include piercing structures **170**, **172** for securing them to tissue. A groove **174** in coupler **166** mates with a tongue **176** in coupler **168** to couple the couplers. This connection can be reversibly or irreversibly secured by insertion of a screw **178** through channels **180**, **182** in the couplers **166**, **168**. Couplers **184** include piercing structures **186**, and matable surfaces **188**. In use, these couplers may be placed on either side of a wound or a planned incision, and optionally rotated to orient the matable surfaces away from the work area. Upon closing, the couplers **184** may be rotated (if necessary) to align the matable surfaces, which may then be secured together with adhesive **190**. Couplers **192**, **194** include adhesive **196** for attachment to tissue (or to a stabilizing member, not shown, or other mechanism for attachment to tissue). Coupler **192** includes latch arm **198**, which engages keeper **200** on coupler **194** to form a draw latch assembly. Latch arm **198** may be rotated away from the work area during surgery, and subsequently engaged to close an underlying incision.

[0033] While the couplers illustrated in FIG. **5** are generally illustrated for coupling in pairwise configurations, in other embodiments, couplers may cooperate in larger groups to close incisions or other wounds. For example, couplers may be arranged in a "zipper" configuration to close a wound along its length. Such an arrangement may include a specialized or general-purpose coupling tool (e.g., a zipper pull) to connect couplers together and/or to separate them.

[0034] FIG. **6** is a schematic of several different multi-part anchor embodiments. Each embodiment includes a portion that adheres to tissue, and a portion that engages a suture, a stabilizing member, another anchor, or another closing mechanism. Anchor **240** includes a tissue adherent portion **242**, which is configured to adhere to tissue via piercing mechanism **244**, and connector portion **246**, which is configured to engage a suture via opening **248**. The tissue adherent portion **242** and the connector portion **246** are configured to be connected together via hook-and-loop fasteners **250**, **252** (e.g., VELCRO™). Anchor **260** includes a tissue adherent portion **262** and a connector portion **264**, which are configured to snap together via mechanical fasteners **266**, **268**. Tissue adherent portion **262** includes an adhesive layer **270** configured to adhere to tissue. Connector **264** includes an eyelet **272** configured to receive a suture (not shown). In some embodiments, mechanical fasteners **266**, **268** may be configured to form a rotatable connection, which may facilitate alignment of a suture. In either embodiment of anchors **240** or **260**, connector portions **246** or **264** may optionally be prethreaded onto a suture or a stabilizing member before they are connected to their respective tissue adherent portions **242** or

262, or they may be connected to their respective tissue adherent portions 242 or 262 and subsequently threaded with a suture or stabilizing member.

[0035] Anchors 280 each include a tissue adherent portion 282 and a connector portion 284. The tissue adherent portions 282 are configured to adhere to tissue via piercing structures 286. Connector portions 284 are configured to attach to tissue adherent portions 282 via hook-and-loop fasteners 288 and 290 (e.g., VELCRO™). Connector portions 284 are also configured to engage one another via magnets 292. In one method of use, tissue adherent portions 282 may be placed on opposing sides of an incision site, before or after cutting the incision. Upon closing, connectors 284 may be connected to tissue adherent portions 282 and their respective magnets 292 engaged (before or after connection to tissue adherent portions 282), thereby closing the incision.

[0036] Anchor 300 is a three-part anchor, including a tissue adherent portion 302, a first connector portion 304 configured to screw into tissue adherent portion 302, and a second connector portion 306 configured to screw onto connector portion 304. In one method of use, a plurality of tissue adherent portions 302 are adhered to tissue via adhesive layers 308, for example before an incision is made in the tissue. When it is desired to close the opening, first connector portions 304 are screwed into each respective tissue adherent portion 302. At this point, a suture or other tensioning member (not shown) may be wound about connector portions 304. In other embodiments, second connector portions 306 may be partially or fully screwed onto their respective first connector portions 304 before winding or before tightening of the tensioning member. In some embodiments, once the tensioning member has been tightened sufficiently to close the incision, second connector portions 306 may be further screwed onto first connector portions 304, thereby clamping the tensioning member between tissue adherent portions 302 and second connector portions 306, thereby inhibiting further movement of the tensioning member.

[0037] Anchor 320 includes tissue adherent portion 322, which adheres to tissue via piercing structure 324, and connector portion 326, which includes eyelet 328. Tissue adherent portion 322 and connector portion 326 are configured to attach to one another via van der Waals forces. In the illustrated embodiment, surface 329 includes nanotubes that adhere to flat surface 331 when they are placed in contact (see, e.g., Yurdumakan, et al., "Synthetic gecko foot-hairs from multiwalled carbon nanotubes," *Chem. Commun.,* 2005: 3799-3801, which is incorporated by reference herein). In this embodiment, eyelet 328 is located at a distal end of tissue adherent portion 322 when tissue adherent portion 322 and connector portion 326 are attached together. In some embodiments, a straight (or shaped) stabilizing element (not shown) may be threaded through eyelets 328 of a plurality of anchors 320 on opposing sides of a wound, for example in the configuration illustrated in FIG. 3.

[0038] FIG. 7 illustrates a two-part trocar for use in laparoscopic procedures. The trocar includes a first cylinder 330 having solid walls, and a second cylinder 332 having one or more longitudinal slots 334. As shown, the second cylinder 332 is sized to fit snugly within first cylinder 330. In other embodiments, the outer diameter of second cylinder 332 may be smaller than the inner diameter of first cylinder 330, producing a loose fit between the cylinders. In still other embodiments, the second cylinder 332 may be sized to fit over first cylinder 330, with either a loose or a snug fit. In still other embodiments, the first cylinder 330 may be eliminated. In such embodiments, if it is necessary to insufflate the underlying body cavity, it may be desirable that a mechanism for sealing slots 334 be integrated into second cylinder 332 in order to maintain pressure within the cavity.

[0039] In one method of use, first cylinder 330 is inserted into a body cavity (e.g., the abdominal cavity), using a round cutter (not shown) to penetrate the cavity wall. Second cylinder 332 may be integral with first cylinder 330 during insertion, or may be inserted into (or around) first cylinder 330 previously or subsequently, either before or after a laparoscopic procedure is performed. For example, the first cylinder 330 may be inserted as a conventional trocar, and a laparoscopic procedure may be performed. Subsequent to the procedure, but before closing, second cylinder 332 is then inserted into first cylinder 330, and first cylinder 330 is fully or partially retracted from the body. An anchor placement device 336, loaded with anchor 338 is then inserted into second cylinder 332. As shown, the anchor is a split ring, but any of the anchor configurations described herein may be used. In the illustrated embodiment, anchor 338 includes a shape memory alloy. The anchor 338 is inserted through the slot 334 to contact opposing sides of the fascia, and the shape memory phase change is triggered (e.g., by local heating), closing the split ring and piercing the fascia. Multiple anchors 338 may be placed, either using multiple slots 334 or by rotating second cylinder 332 in order to access different positions along the circumference of the fascial opening. Once the anchors 338 have been placed, second cylinder 332 may be fully or partially withdrawn from the opening.

[0040] FIG. 8 illustrates two split ring anchors 338 which have pierced the fascia 340 on either side of a round laparoscopic incision. As shown, the anchors 338 also at least partially penetrate peritoneum 342 and fatty tissue 345. Anchors 338 are connected by a suture 346. The suture may be threaded before or after removal of cylinders 330, 332. Tension may be applied to suture 346 to close the fascia, for example after cylinders 330, 332 have been removed from the incision. In the illustrated embodiment, the suture connects two anchors 338 on opposing sides of the incision, but it will be understood that more anchors may be connected, either by a single suture or other connector looped through all of them, or by a series of pairwise connections (or other connections of smaller subsets of the placed anchors). Tissue anchors may be analogously used to close other layers such as the peritoneum, the muscle layers, and/or the skin. While split-ring anchors 338 have been illustrated in FIG. 7 and FIG. 8, other anchor configurations may be more or less desirable for any particular tissue type and geometry. For example, a shape-memory surgical staple such as those described in U.S. Pat. Nos. 4,485,816 and 6,133,611 (both of which are incorporated by reference herein) may be used as a tissue anchor for some surgeries. In some configurations, a suture or other tensioning device may be prethreaded onto tissue anchors, or the anchors may be configured to couple to one another without use of a tensioning device.

[0041] FIG. 9 illustrates a proximal end of another two-part trocar for use in laparoscopic procedures. The illustrated trochar includes two concentric cylindrical members 340, 342, each of which includes a longitudinal slot 344, 347. The outer cylinder 340 includes two notches 348, 350, which are each configured to engage a tab 352 on the inner cylinder 342. During insufflation, tab 352 is engaged with notch 350. In this configuration, slots 344 and 347 are not aligned with one

another, so that insufflation gas does not leak from the trochar through the slots. When it is desired to access the fascia, tab **352** is disengaged from notch **350** by partially withdrawing inner cylinder **342**, as shown, and the cylinders are relatively rotated to align tab **352** with notch **348**. In this configuration, slots **344** and **347** are aligned with one another, so that the fascia may be accessed through the side of the trocar. In some embodiments, the cylinders may be transparent in at least the region of the slots, for example to aid the surgeon in visualizing the fascia.

[0042] FIG. **10** is an exploded view of a one-part trocar for use in laparoscopic procedures. The trocar includes a single cannula **360**, which includes at least one longitudinal slot **362**. The slot is configured to be sealed by insert **364**. In the illustrated embodiment, insert **364** is composed of a flexible material (e.g., silicone), and includes projection **366**, which is arranged to fit into slot **362**. In one method of use, this trocar may be inserted into a patient and used for insufflation, with projection **366** inserted into slot **362** to form a seal. When surgery is completed and insufflation is no longer required, insert **364** may be peeled back, allowing the surgeon to access the fascia via slot **362**. In some embodiments, cannula **360** may be transparent in at least the region of slot **362**, for example to aid the surgeon in visualizing the fascia.

[0043] FIG. **11** illustrates a one-part trocar with externally mounted tissue anchors. The trocar includes cannula **370**, which in some embodiments may be fully or partially transparent. The cannula includes longitudinal recesses **372**, each of which contains a tissue anchor **374**. In the illustrated embodiment, the anchors are shape-memory wires of the type depicted in FIG. **8**. Before deployment, the anchors are substantially straight and contained in recesses **372**. In the illustrated embodiment, an optional looped filament **376** (e.g., a suture, cord, or wire) surrounds the cannula **370** and anchors **374**. (For clarity, filament **376** is shown loosely wrapped about cannula **370**; in some embodiments, the filament may be tightly wrapped, for example to secure the anchors in recesses **372**.) In one method of use, the trocar is positioned for laparoscopic surgery. Before, during, and/or after surgery, the shape-memory wires of tissue anchors **374** are positioned adjacent to a fascia and activated, for example by applied heat. Upon activation, the anchors bend to pierce the tissue as shown in FIG. **8**. The cannula **370** may then be withdrawn from the patient, leaving behind anchors **374** and filament **376**. The filament **376** may be tightened to close the incision through which the cannula was inserted (for example, the filament may be a shape-memory suture which is induced to contract), or another suture or other approximating member may be used to secure the anchors together. In other embodiments, rather than shape-memory wires, other types of tissue anchors may be mounted on the exterior of cannula **370**. In some of these embodiments, the cannula may include mechanical or other deployment mechanisms. For example, in one embodiment, split-ring anchors may be opened and restrained under tension in the recesses **372**. The tension may be released, for example by removing a restraining member, allowing the anchors to pierce the tissue and close. In another embodiment, a portion of a multipart anchor (e.g., the anchors illustrated in FIG. **5**, and/or FIG. **6**, such as tissue-adherent portion **242** of anchor **240**) may be deployed on the exterior of cannula **370**.

[0044] In any of the above-described trocar arrangements, an appropriate anchor deployment device may be used to place the anchors in the fascia. For example, U.S. Pat. No. 5,392,978, which is incorporated by reference herein, describes a surgical stapler for endoscopic use which crimps staples to secure them in tissue. An analogous deployment mechanism may be used to deliver tissue anchors through the longitudinal slots of the trocars illustrated above. In other embodiments, surgical staplers such as those described in copending and commonly owned U.S. patent application Ser. No. 11/804,219, filed May 16, 2007, and entitled "STEERABLE SURGICAL STAPLER," which is incorporated by reference herein, may be used to access tissue through the trocars. In addition, it will be understood that while the openings of the above-illustrated trocars are configured as longitudinal slots, other geometries that allow access to the fascia will be apparent to those of ordinary skill in the art and are within the scope of the appended claims.

[0045] In general, the anchors, couplers, traction members, securing members, tensioning members, stabilizing members, and other components described herein may be adjustable or selectively controlled, for example to loosen tension as a joint heals and becomes more flexible or to permit expansion of skin prior to reconstructive surgery or removal for a graft. In particular, any of these components may form a part of or be configured to cooperate with the adjustable implants described in co-pending and commonly owned U.S. application Ser. Nos. 11/710,591, filed Feb. 22, 2007 and entitled, "CODED-SEQUENCE ACTIVATION OF SURGICAL IMPLANTS," and **11/710,592**, filed Feb. 22, 2007 and entitled, "CODED-SEQUENCE ACTIVATION OF SURGICAL IMPLANTS," both of which are incorporated by reference herein. Any of these components may also be controllable by changing shape or conformation so that such change results in the approximation of surfaces attached to selected anchors, for example via the use of temperature-sensitive, light-sensitive (e.g., ultraviolet light-sensitive), touch-sensitive, elastomeric (e.g., an elastomer that is configured to secure each anchor and can reconfigure in a way to approximate surfaces attached to the anchors), or remotely controllable mechanisms.

[0046] FIG. **12** is a flow chart illustrating a method of closing a wound. The method includes adhering tissue anchors (e.g., anchors such as but not limited to those described in FIG. **2**, FIG. **5**, and/or FIG. **6**) to tissue on opposing sides of a wound, **400**, and approximating the tissue by coupling the tissue anchors, **402**. For example, the tissue anchors may be coupled via a tensioning element such as a suture, **404**.

[0047] FIG. **13** is a flow chart illustrating a method of performing surgery. The method includes adhering tissue couplers (e.g., couplers such as but not limited to those described in FIG. **2**, FIG. **5**, and/or FIG. **6**) to tissue on opposing sides of a planned incision site, **420**, cutting an incision between the adhered tissue couplers, **422**, accessing the interior of the body via the incision (e.g., to perform a surgical procedure), **424**, and closing the incision by coupling the tissue couplers, **426**. The incision may be, for example, a straight incision, a curved incision, or a round incision (e.g., a round cut such as that made by a trocar). In some embodiments, couplers may be coupled together manually, while in other embodiments, couplers may be coupled together automatically. In some embodiments, the surgery may be endoscopic.

[0048] FIG. **14** is a flow chart illustrating a method of preparing a body for surgery. The method includes adhering tissue anchors to tissue, **440**, on opposing sides of a planned

incision site. The method may optionally also include opening the body along the planned incision site, **442**, and/or closing the incision by coupling the tissue anchors, **444**. The incision may be, for example, a straight incision, a curved incision, or a round incision (e.g., a round cut such as that made by a trocar).

[0049] FIG. **15** illustrates a system for determining placement of tissue anchors (or other suture attachments) for closing an incision. The system may include an input device **560** (e.g., a mouse, keyboard, touchscreen, or other machine input system), configured to allow a surgeon to specify a surgery type and/or an incision location. It may further include a sensor **562** that measures one or more physiological parameters of a patient **564** upon whom surgery will be performed. For example, the sensor **562** may include an imaging device that maps the position of organs or other physiological structures that may be taken into account in closing an incision, or it may be a reader (e.g., an optical reader) that senses a planned incision location that a surgeon has marked on the body of patient **564**. The input device **560** and/or the sensor **562** may communicate information about the body of patient **564** and/or about the planned surgery to anchor placement circuitry **566**. Anchor placement circuitry **566** may include various subcircuits or subroutines, including but not limited to tissue modeling circuitry **568**, stress estimation circuitry **570**, anchor placement pattern library **572**, and/or anchor form factor selection circuitry **574**.

[0050] Tissue modeling circuitry **568** may include circuitry configured to build a computer-based model (e.g., a finite element model and/or an analytical model) of the tissue of the patient **564**, for example including specific measurements of sensor **562** and/or physiological or other parameters specified using input device **560**. This computer-based model may be used to determine suggested placement for tissue anchors, for example by calculation of the expected response of tissue to particular anchor configurations, and/or by application of stored heuristic rules for expected tissue response. Stress estimation circuitry **570** may be configured to determine expected stresses on anchors and/or on tissue for particular anchor configurations, or it may include optimizing circuitry designed to determine an optimum anchor configuration for a specified design goal. Anchor placement pattern library **372** may include stored configurations of anchors that have been specified by an operator, previously calculated, or otherwise determined. Other portions of the anchor placement circuitry **566** (e.g. tissue modeling circuitry **568** and/or stress estimation circuitry **570**) may use the anchor placement pattern library **572** to generate initial placement patterns for calculation, including as a starting point for optimization routines. Anchor form factor selection circuitry **574** may store information about the different form factors of different anchors (such as but not limited to those described herein, e.g., in FIG. **2**, FIG. **5**, and/or FIG. **6**), and may further include information about available sizes and mechanical performance of different anchors. It may further include circuitry configured to select a suggested anchor or group of anchors for the particular surgery planned for patient **564**.

[0051] The system further includes an output device **576** (e.g., a monitor, a printer, a bar code printer, and/or a controller for a patient marking apparatus **578**), which may produce a machine-readable and/or a human-readable output. This output may include calculated anchor placement patterns, tissue responses, anchor stresses, anchor form factors, or other data relevant for placement of anchors during surgery. Output may be iterative and/or interactive, so that a user specifying input via input device **560** may modify input or specify additional inputs in response to output received via output device **576**. For example, output device **576** may output a selection of anchor placement patterns from anchor placement pattern library **572**, and a user may select from among these patterns using input device **560**. Once an anchor placement pattern has been established by anchor placement circuitry **566**, output device **576** may pass data and/or control instructions to a patient marking device **578**, which may temporarily or permanently mark desired anchor placement directly on the patient **564**, or on a tape or other stabilizing member configured to maintain relative anchor locations for attachment to the patient **564**. In other embodiments, the patient marking device may actually place anchors on a stabilizing member for application to a patient **564**.

[0052] In a general sense, those skilled in the art will recognize that the various aspects described herein which can be implemented, individually and/or collectively, by a wide range of hardware, software, firmware, or any combination thereof can be viewed as being composed of various types of "electrical circuitry." Consequently, as used herein "electrical circuitry" includes, but is not limited to, electrical circuitry having at least one discrete electrical circuit, electrical circuitry having at least one integrated circuit, electrical circuitry having at least one application specific integrated circuit, electrical circuitry forming a general purpose computing device configured by a computer program (e.g., a general purpose computer configured by a computer program which at least partially carries out processes and/or devices described herein, or a microprocessor configured by a computer program which at least partially carries out processes and/or devices described herein), electrical circuitry forming a memory device (e.g., forms of random access memory), and/or electrical circuitry forming a communications device (e.g., a modem, communications switch, or optical-electrical equipment). Those having skill in the art will recognize that the subject matter described herein may be implemented in an analog or digital fashion or some combination thereof.

[0053] Those having skill in the art will recognize that the state of the art of circuit design has progressed to the point where there is typically little distinction left between hardware and software implementations of aspects of systems. The use of hardware or software is generally a design choice representing tradeoffs between cost, efficiency, flexibility, and other implementation considerations. Those having skill in the art will appreciate that there are various vehicles by which processes, systems and/or other technologies involving the use of logic and/or circuits can be effected (e.g., hardware, software, and/or firmware), and that the preferred vehicle will vary with the context in which the processes, systems and/or other technologies are deployed. For example, if an implementer determines that speed is paramount, the implementer may opt for a mainly hardware and/or firmware vehicle. Alternatively, if flexibility is paramount, the implementer may opt for a mainly software implementation. In these or other situations, the implementer may also opt for some combination of hardware, software, and/or firmware. Hence, there are several possible vehicles by which the processes, devices and/or other technologies involving logic and/or circuits described herein may be effected, none of which is inherently superior to the other. Those skilled in the art will

recognize that optical aspects of implementations may require optically-oriented hardware, software, and or firmware.

[0054] It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.). It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of introductory phrases such as "at least one" or "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to inventions containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an" (e.g., "an anchor" should typically be interpreted to mean "at least one anchor"); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should typically be interpreted to mean at least the recited number (e.g., the bare recitation of "two anchors," or "a plurality of anchors," without other modifiers, typically means at least two anchors). Furthermore, in those instances where a phrase such as "at least one of A, B, and C," "at least one of A, B, or C," or "an [item] selected from the group consisting of A, B, and C," is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., any of these phrases would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or "B" or "A and B."

[0055] While various aspects and embodiments have been disclosed herein, other aspects and embodiments will be apparent to those skilled in the art. The various aspects and embodiments disclosed herein are for purposes of illustration and are not intended to be limiting, with the true scope and spirit being indicated by the following claims.

What is claimed is:

1. An instrument for performing surgery, comprising:

a cannula having a distal end and a proximal end connected by a substantially cylindrical body, configured to be inserted through tissue into a body cavity, wherein the cannula includes at least one openable port in a wall of the cylindrical body.

2. The instrument of claim **1**, wherein the instrument further comprises a cutting edge.

3.-**5**. (canceled)

6. The instrument of claim **1**, wherein the cannula includes at least two cylinders, and wherein the openable port is an opening in at least one of these cylinders.

7.-**8**. (canceled)

9. The instrument of claim **6**, wherein the openable port is openable by relatively rotating the at least two cylinders.

10. The instrument of claim **6**, wherein the openable port is configured to be opened by withdrawing one of the at least two cylinders.

11. The instrument of claim **6**, wherein the two cylinders are configured to lock together with the openable port open.

12. The instrument of claim **6**, wherein the two cylinders are configured to lock together with the openable port closed.

13. The instrument of claim **1**, wherein the openable port is configured to be opened by removing a block from an opening.

14. The instrument of claim **13**, wherein the block is configured to be replaced in the opening to reseal the port.

15. (canceled)

16. The instrument of claim **1**, wherein the openable port is configured to permit access to tissue when the cannula is inserted through tissue.

17. The instrument of claim **1**, further comprising an anchor deployment mechanism, configured to place a tissue anchor in tissue outside the cannula and adjacent to the openable port.

18. The instrument of claim **17**, wherein the anchor deployment mechanism is configured to be inserted into the cannula.

19.-**20**. (canceled)

21. The instrument of claim **17**, wherein the anchor deployment mechanism includes a mechanism for securing the tissue anchor to the tissue outside the cannula.

22.-**23**. (canceled)

24. An instrument for performing surgery, comprising:

a cannula having a distal end and a proximal end connected by a substantially cylindrical body, configured to be inserted through tissue into a body cavity, wherein the cannula includes a structure configured for mounting a tissue anchor on the exterior of the substantially cylindrical body.

25. The instrument of claim **24**, further comprising at least one tissue anchor mounted on the exterior of the substantially cylindrical body.

26. The instrument of claim **25**, further comprising an anchor deployment mechanism, configured to place the tissue anchor in tissue outside the cannula.

27.-**30**. (canceled)

31. The instrument of claim **25**, wherein the tissue anchor is configured to engage an approximation mechanism.

32. The instrument of claim **24**, further comprising an anchor deployment mechanism, configured to place a mounted tissue anchor in tissue outside the cannula.

33. The instrument of claim **24**, wherein the structure configured for mounting a tissue anchor includes a recess shaped to accept a tissue anchor on the exterior of the cannula.

34.-**39**. (canceled)

40. A method of performing surgery on a body, comprising:

inserting into the body a cannula having a distal end and a proximal end connected by a substantially cylindrical body, the cannula having at least one openable port in a wall of the cylindrical body, wherein inserting includes creating an opening in a fascia and passing the cannula through the opening;

accessing the body via the cannula with the openable port sealed;

opening the openable port;

applying a tissue anchor to the fascia through the opened openable port;

removing the cannula from the body; and

closing the opening via the tissue anchor.

41. The method of claim **40**, wherein the cannula includes two concentric cylindrical members.

42.-**43**. (canceled)

44. The method of claim **41**, wherein opening the openable port includes locking the two concentric cylindrical members in an open position.

45. The method of claim **41**, wherein opening the openable port includes unlocking the two concentric cylindrical members from a closed position.

46. The method of claim **40**, wherein the cannula includes a transparent portion.

47. The method of claim **46**, wherein the transparent portion is positioned to allow visualization of the fascia.

48. The method of claim **40**, wherein accessing the body includes performing surgery in the body.

49. The method of claim **48**, wherein the surgery is endoscopic.

50. The method of claim **48**, wherein the surgery is laparoscopic.

51.-**54**. (canceled)

55. A method of performing surgery on a body, comprising:

inserting into the body a cannula having a distal end and a proximal end connected by a substantially cylindrical body, the cannula having at least one tissue anchor mounted on its exterior, wherein inserting includes creating an opening in a fascia and passing the cannula through the opening;

accessing the body via the cannula;

applying the tissue anchor to the fascia;

removing the cannula from the body; and

closing the opening via the tissue anchor.

56. The method of claim **55**, wherein the cannula includes a tissue anchor deployment mechanism, and wherein applying the tissue anchor to the fascia includes activating the tissue anchor deployment mechanism.

57.-**61**. (canceled)

62. The method of claim **55**, wherein the tissue anchor is mounted in a recess on the exterior of the cannula.

63.-**64**. (canceled)

65. The method of claim **55**, wherein accessing the body includes performing surgery in the body.

66.-**69**. (canceled)

70. A method of closing an opening in a fascia, comprising:

inserting though the opening a cannula having a distal end and a proximal end connected by a substantially cylindrical body, the cannula having at least one openable port in a wall of the cylindrical body;

applying a tissue anchor to the fascia through the opened openable port;

removing the cannula from the body; and

closing the opening via the tissue anchor.

71.-**75**. (canceled)

76. The method of claim **70**, wherein the cannula includes a transparent portion.

77. (canceled)

78. The method of claim **70**, wherein accessing the body includes performing surgery in the body.

79.-**80**. (canceled)

81. The method of claim **70**, wherein the tissue anchor is configured to pierce the fascia.

82. The method of claim **70**, wherein the tissue anchor is configured to grasp the fascia.

83. A method of closing an opening in a fascia, comprising:

inserting though the opening a cannula having a distal end and a proximal end connected by a substantially cylindrical body, the cannula having at least one tissue anchor mounted on its exterior;

applying the tissue anchor to the fascia;

removing the cannula from the body; and

closing the opening via the tissue anchor.

84. The method of claim **83**, wherein the cannula includes a tissue anchor deployment mechanism, and wherein applying the tissue anchor to the fascia includes activating the tissue anchor deployment mechanism.

85.-**88**. (canceled)

89. The method of claim **83**, wherein closing the opening via the tissue anchor includes engaging the tissue anchor with an approximation mechanism.

90. The method of claim **83**, wherein the tissue anchor is mounted in a recess on the exterior of the cannula.

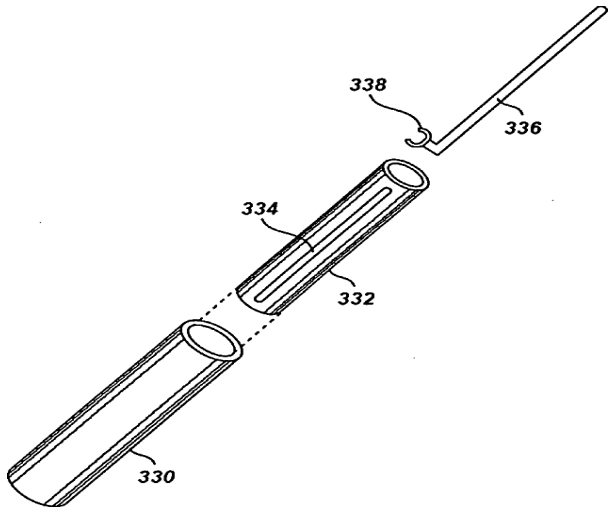
91.-**95**. (canceled)

* * * * *

专利名称(译)	用于闭合筋膜的系统和方法		
公开(公告)号	US20080262524A1	公开(公告)日	2008-10-23
申请号	US11/811885	申请日	2007-06-11
[标]申请(专利权)人(译)	特拉华州的SEARETE负债CORP		
申请(专利权)人(译)	SEARETE有限责任公司，特拉华州的有限责任公司		
当前申请(专利权)人(译)	SEARETE有限责任公司，特拉华州的有限责任公司		
[标]发明人	BANGERA MAHALAXMI G BOYDEN EDWARD S HYDE RODERICK A ISHIKAWA MURIEL Y JUNG EDWARD K Y LEUTHARDT ERIC C NUGENT ELIZABETH E RIVET DENNIS J SMITH MICHAEL A SWEENEY ELIZABETH A TEGREENE CLARENCE T WOOD LOWELL L WOOD VICTORIA Y H		
发明人	BANGERA, MAHALAXMI G. BOYDEN, EDWARD S. HYDE, RODERICK A. ISHIKAWA, MURIEL Y. JUNG, EDWARD K.Y. LEUTHARDT, ERIC C. NUGENT, ELIZABETH E. RIVET, DENNIS J. SMITH, MICHAEL A. SWEENEY, ELIZABETH A. TEGREENE, CLARENCE T. WOOD, LOWELL L. WOOD, VICTORIA Y.H.		
IPC分类号	A61B17/03 A61B17/32		
CPC分类号	A61B17/085 A61B17/10 A61B19/50 A61B2017/081 A61B2017/086 A61B34/10		
外部链接	Espacenet USPTO		

摘要(译)

通过将套管插入筋膜，并从外部或通过套管的一侧将组织锚固件连接到筋膜上来闭合筋膜中的开口。


338
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