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(54) **SURGICAL LAYER FIXATION DEVICE**

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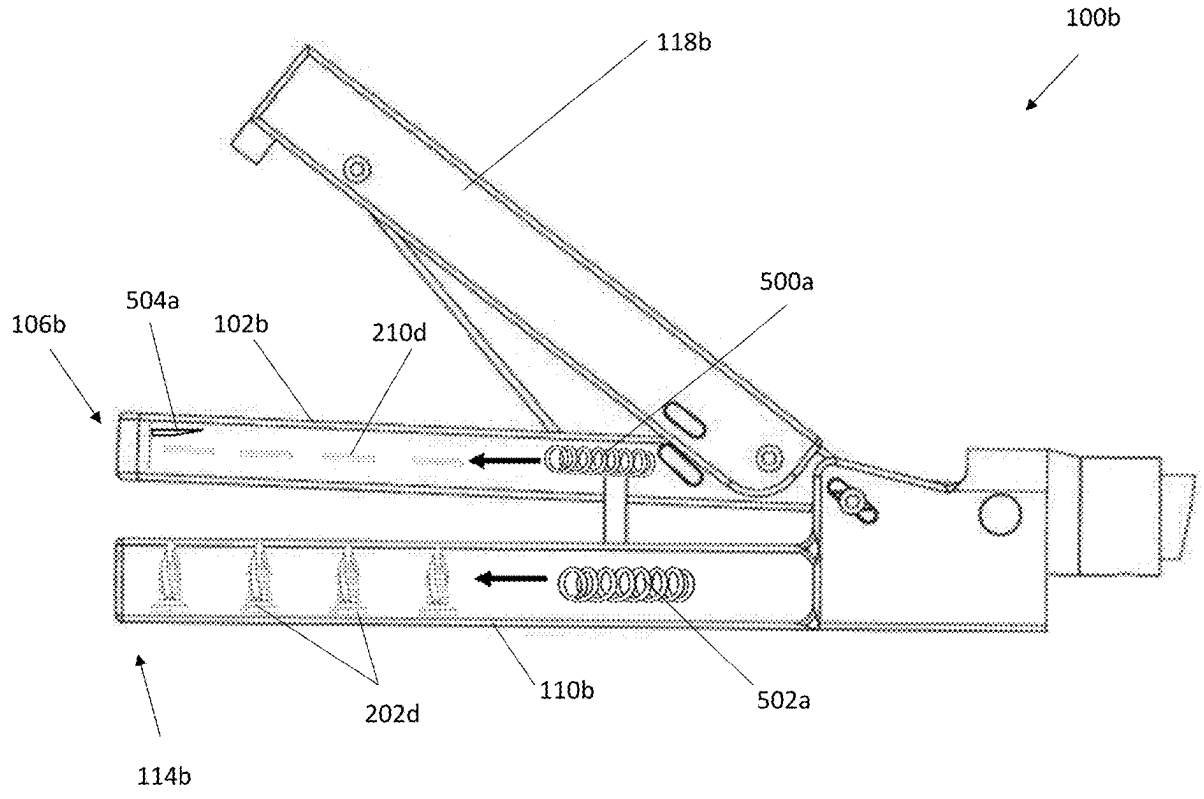
(52) **U.S. Cl.**

CPC ***A61B 17/064*** (2013.01); ***A61B 17/07207*** (2013.01); *A61B 2017/00367* (2013.01); *A61B 2017/0647* (2013.01); *A61B 2017/0649* (2013.01); *A61B 2017/07271* (2013.01); *A61B 2017/07278* (2013.01); *A61B 2017/07285* (2013.01)

(57) **ABSTRACT**

A surgical tacking system and method for fixation of soft tissues or soft prostheses during surgical procedures, such as ventral hernia repairs, e.g., between two tissues or between the tissue and the implant. The tacking system operates on a two-part fixator consisting of a penetrating tack and a retention collar to quickly and reliably deploy and fixate tissue in a closing procedure. The fastener dispenser includes a first jaw movably coupled to a second jaw that dispenses a fastener. The fastener dispenser is movable from an unclamped configuration to a clamped configuration, thereby reducing a relative spacing between the first jaw and the second jaw so as to hold the first layer relative to the second layer therebetween, while penetrating the first layer and the second layer with the elongated member to couple the elongated member to the collar to fixate the first layer to the second layer.



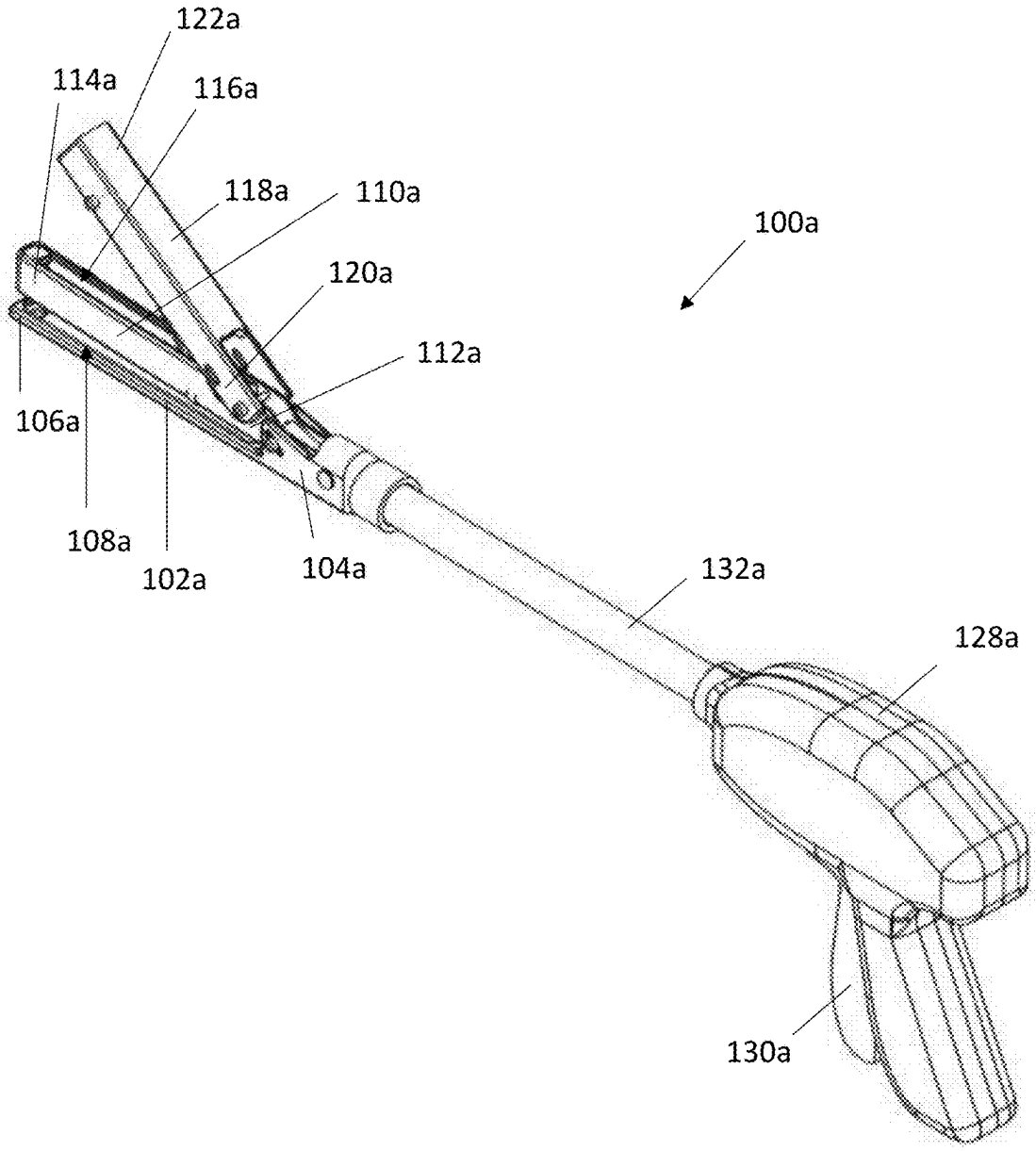

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FIG. 1A

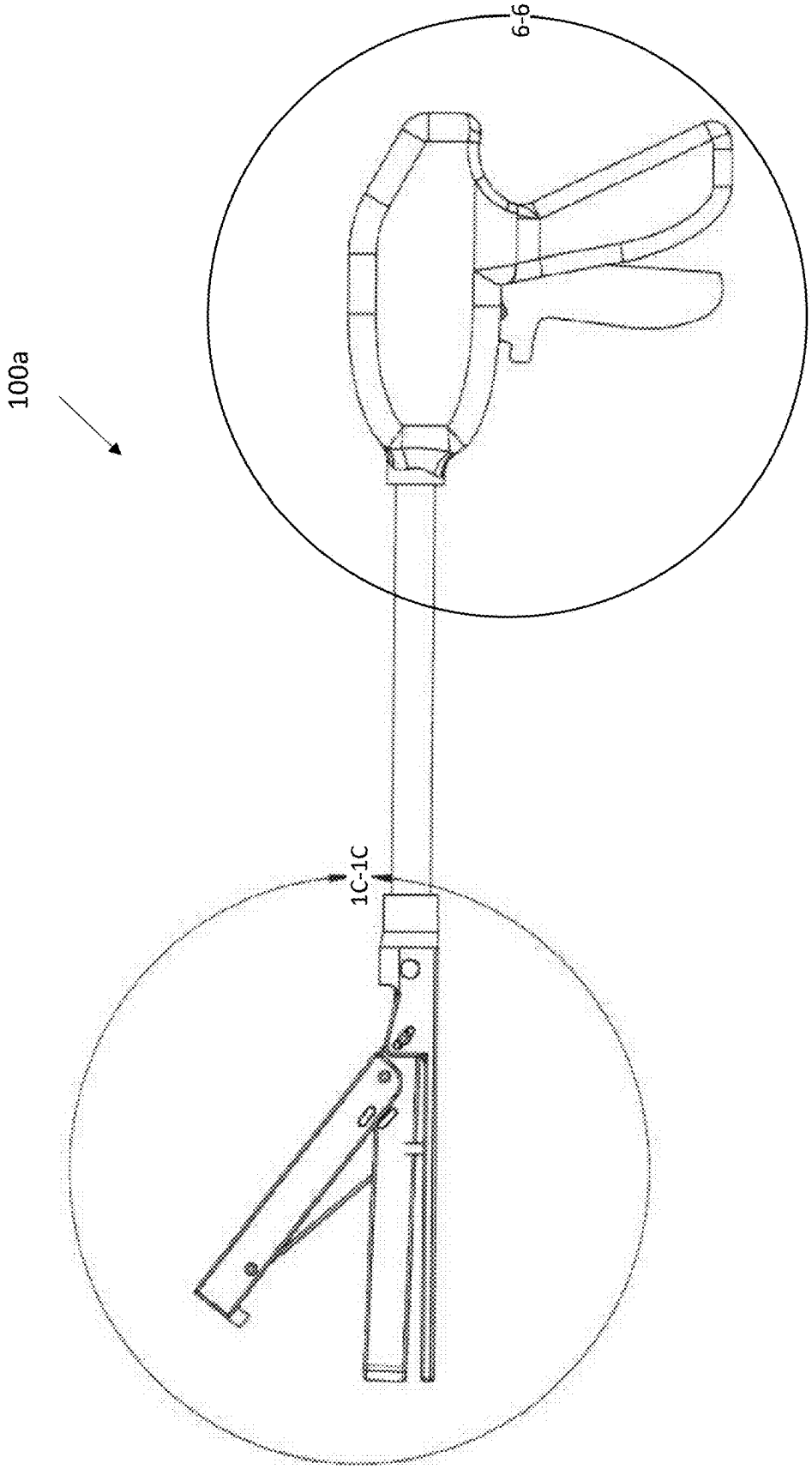

FIG. 1B

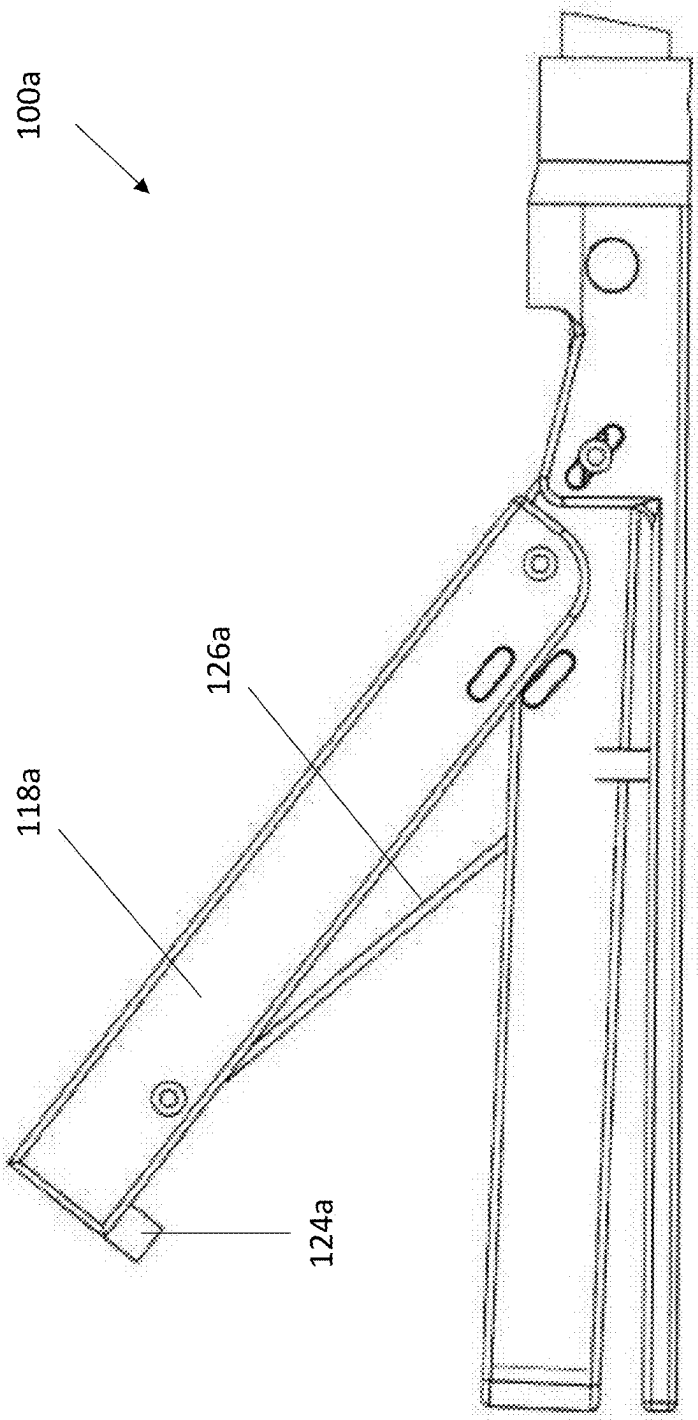

FIG. 1C

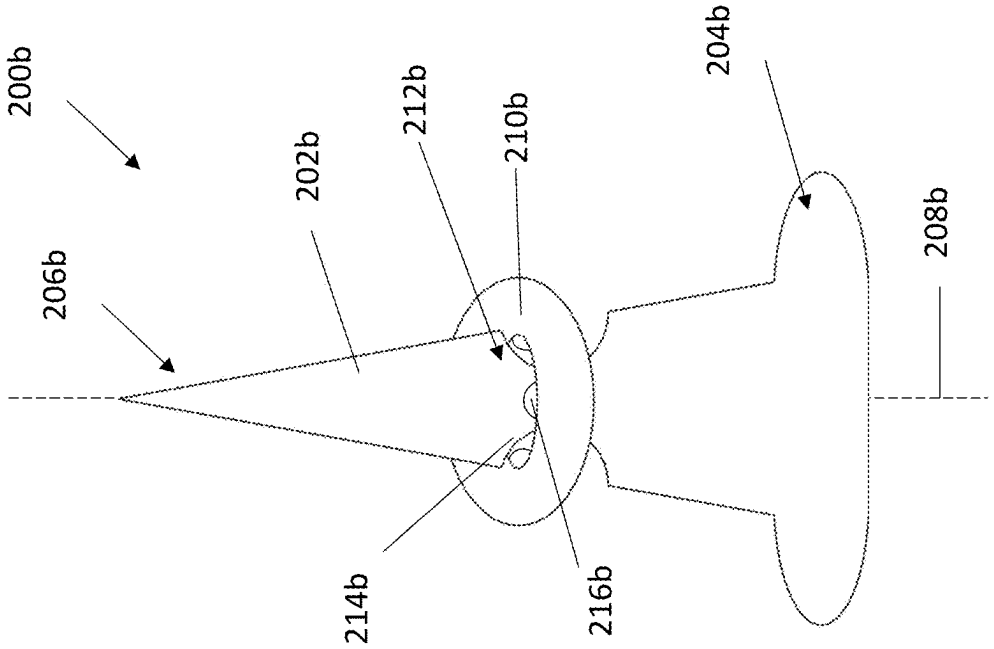
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FIG. 2B

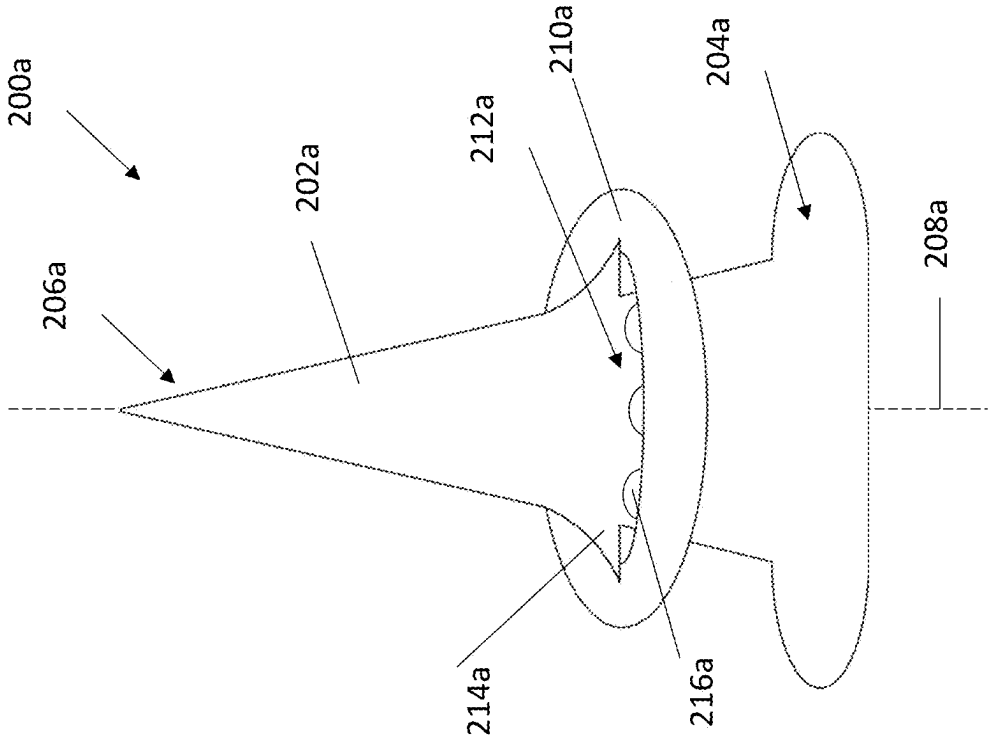
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FIG. 2A

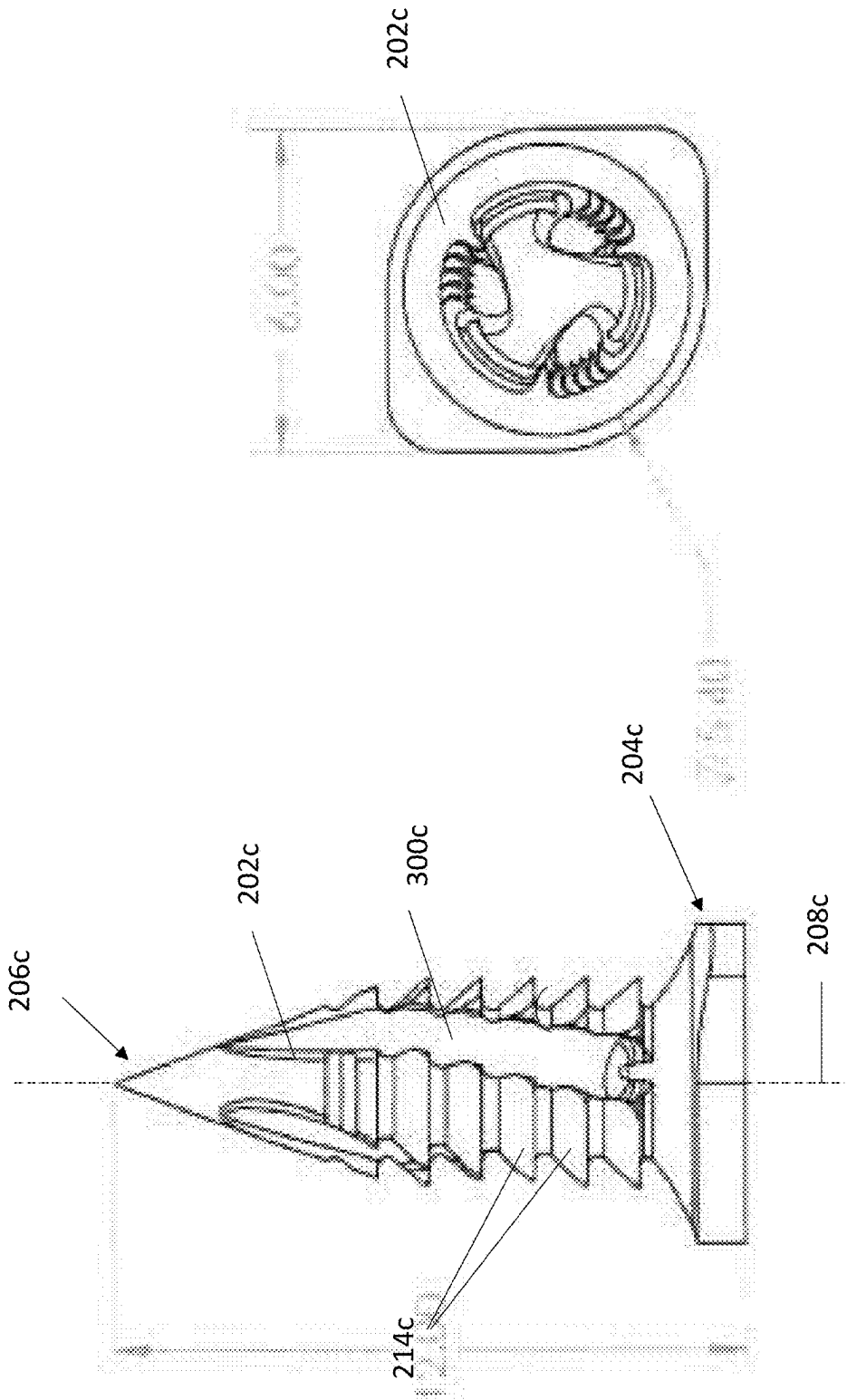


FIG. 3A

FIG. 3B

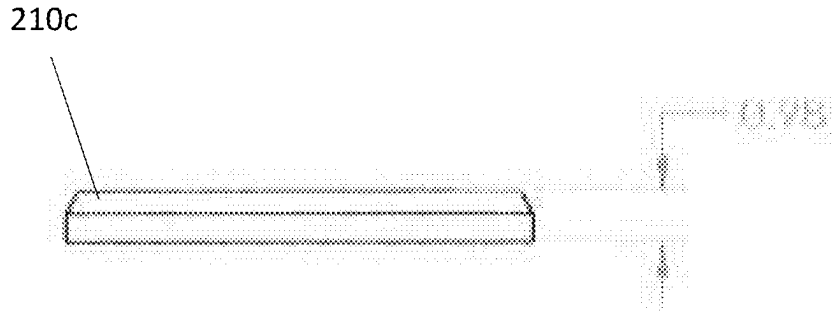


FIG. 4A

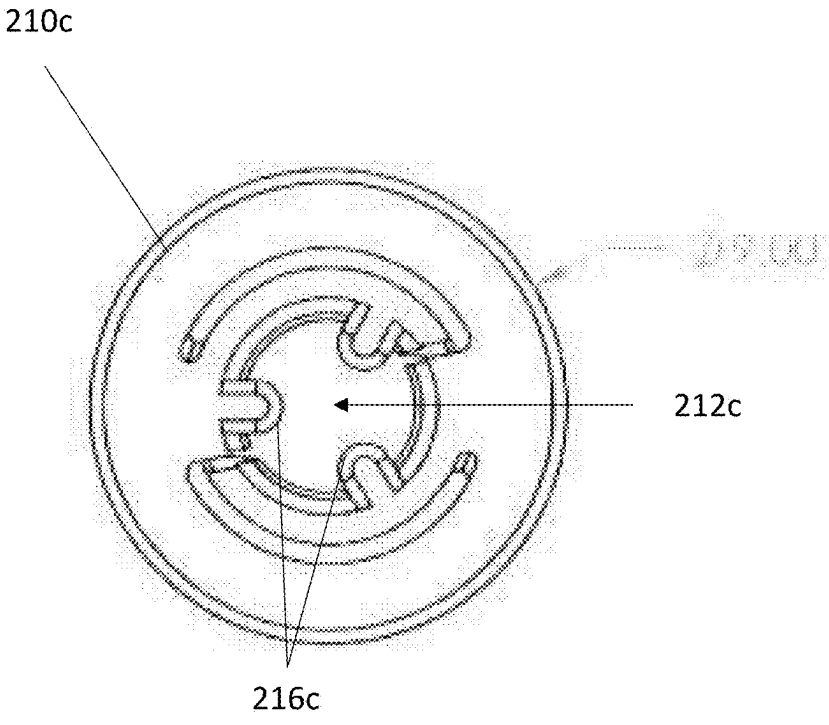


FIG. 4B

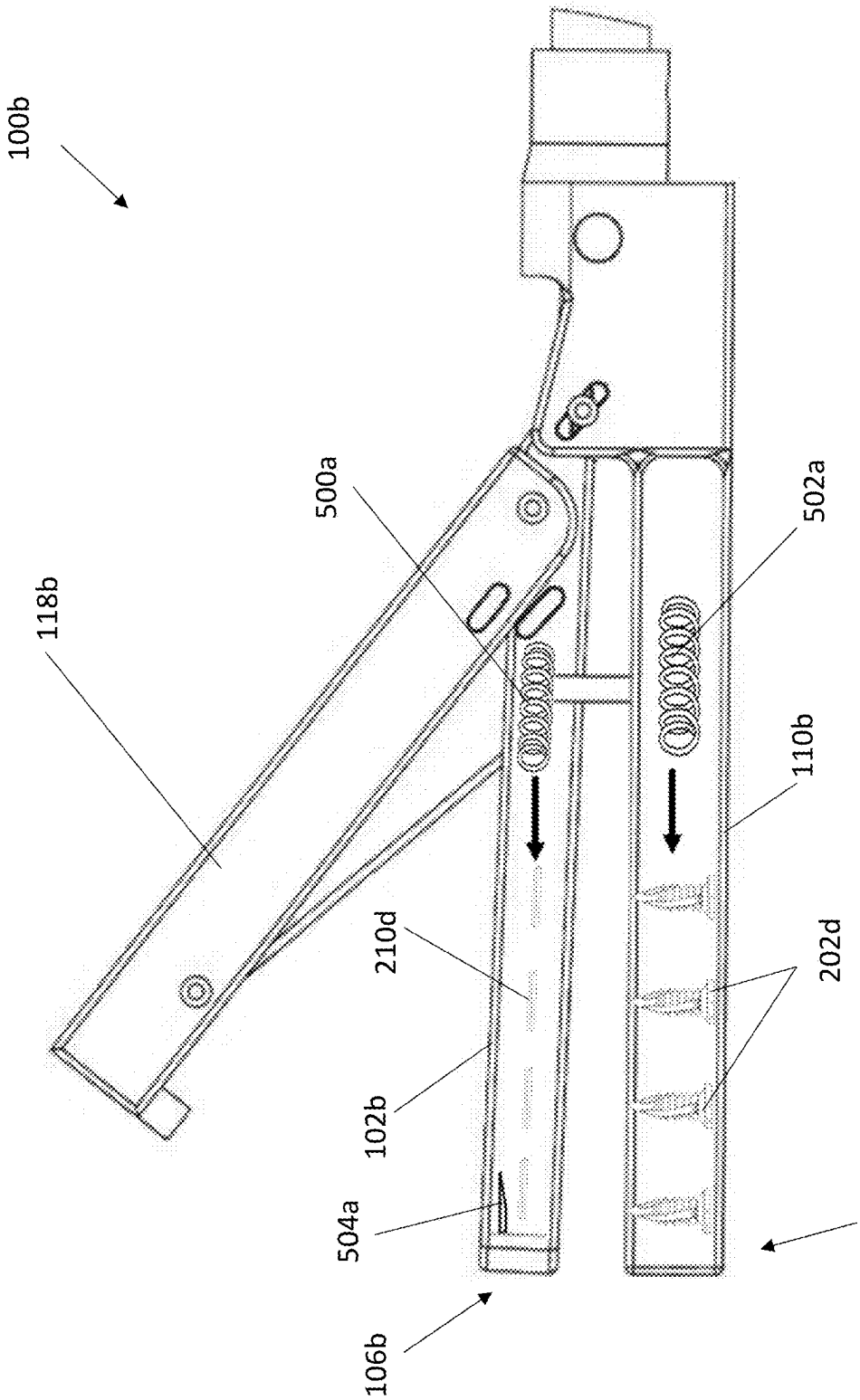


FIG. 5A

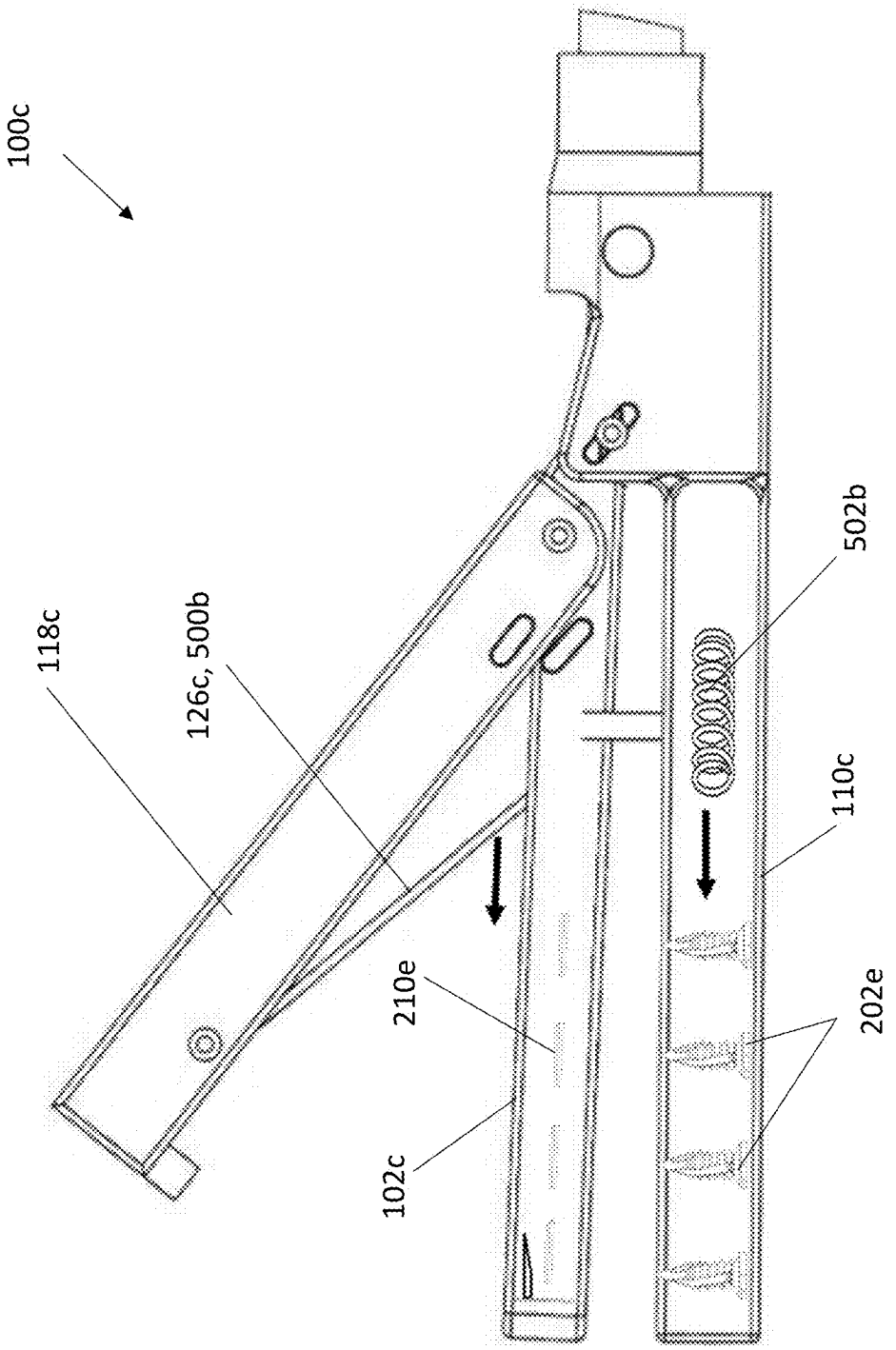


FIG. 5B

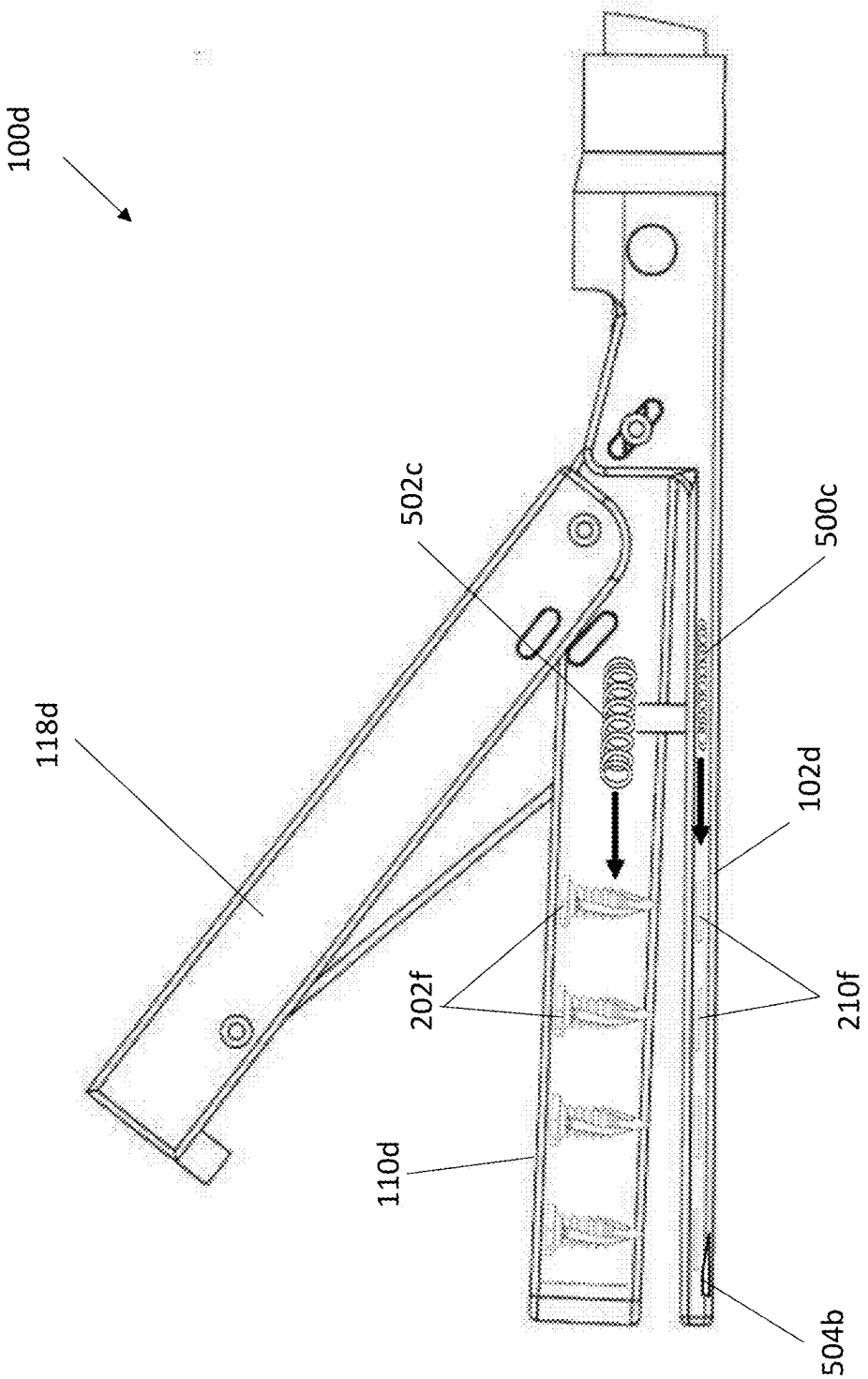


FIG. 5C

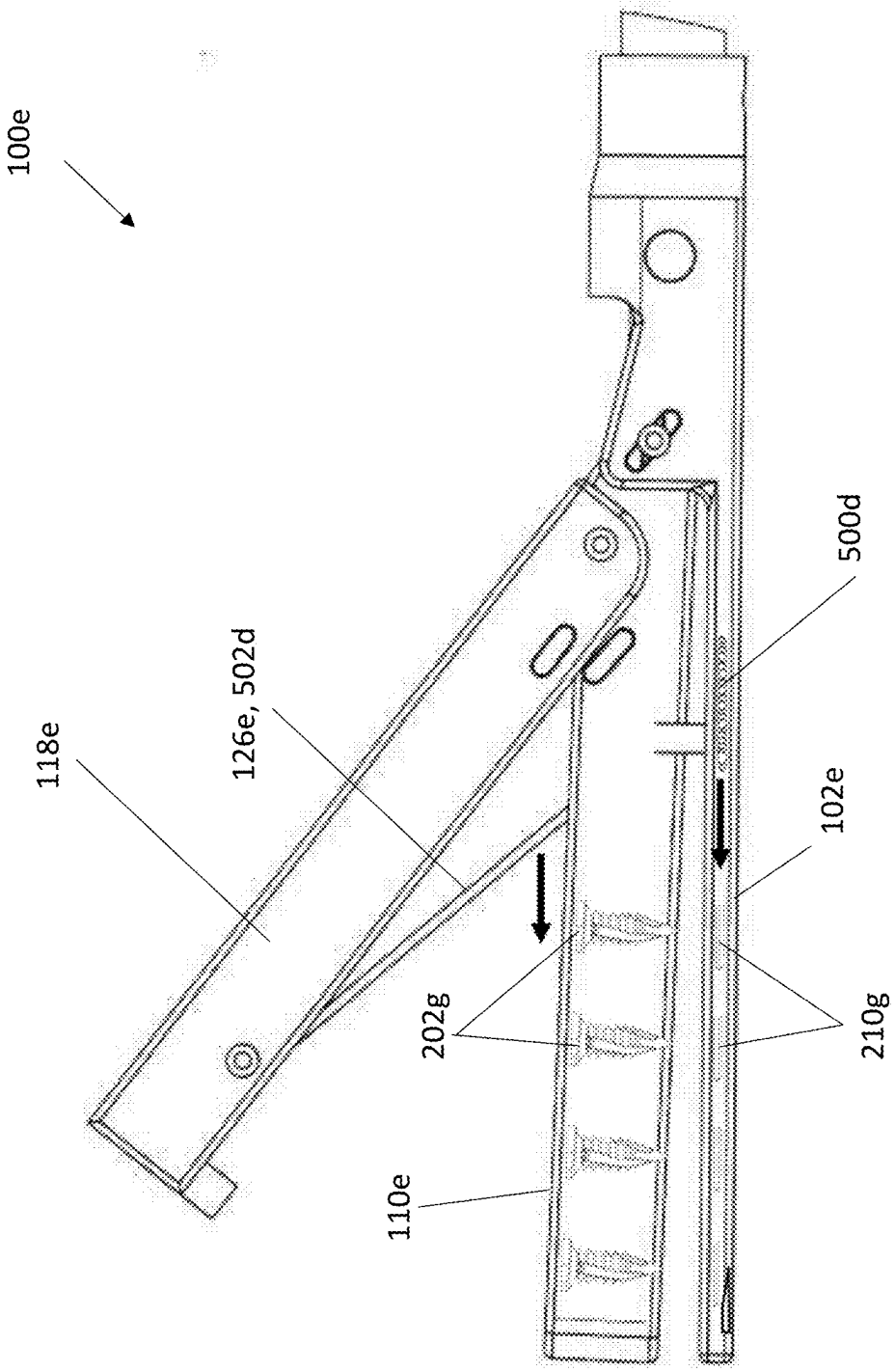


FIG. 5D

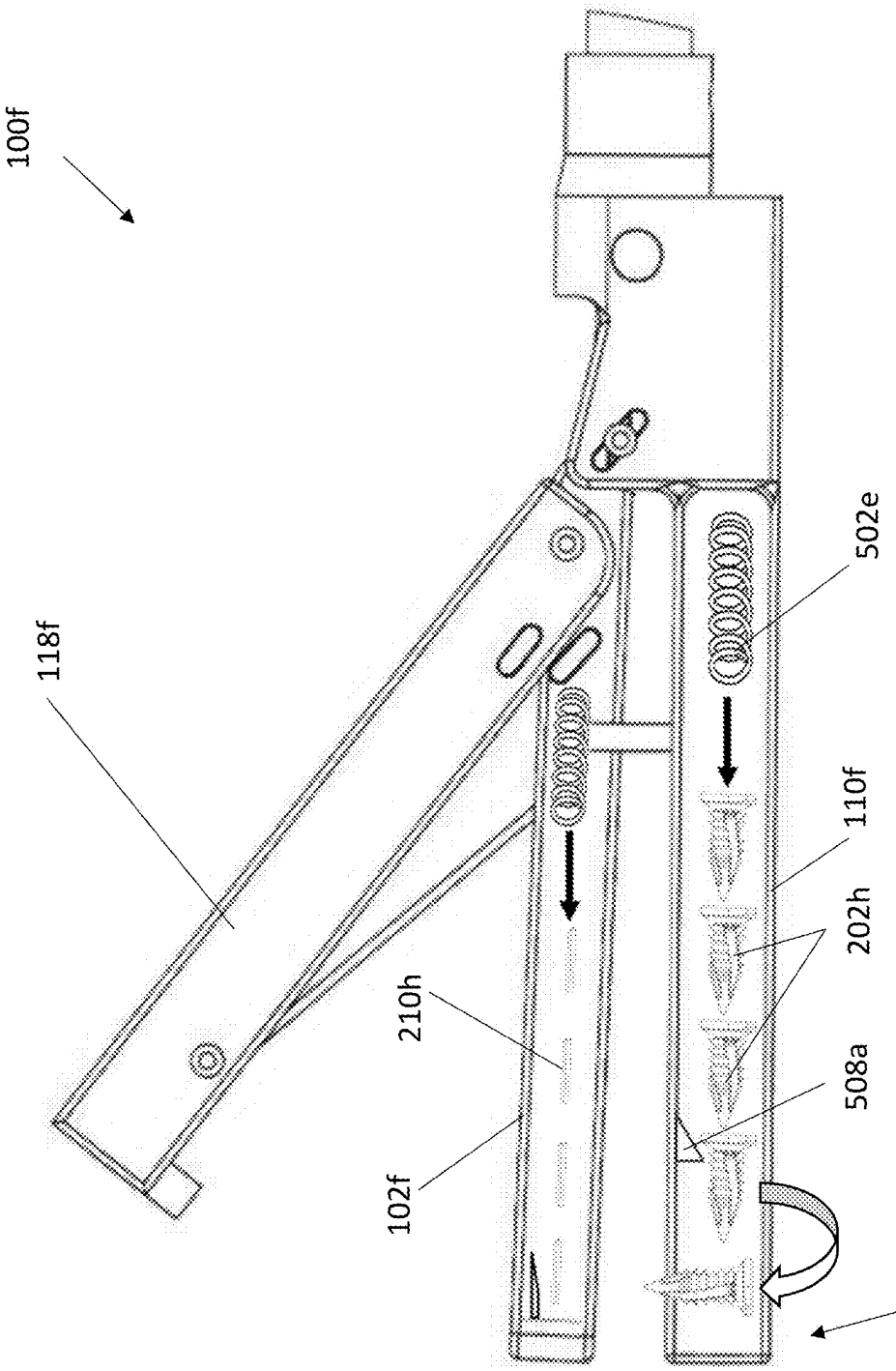


FIG. 5E

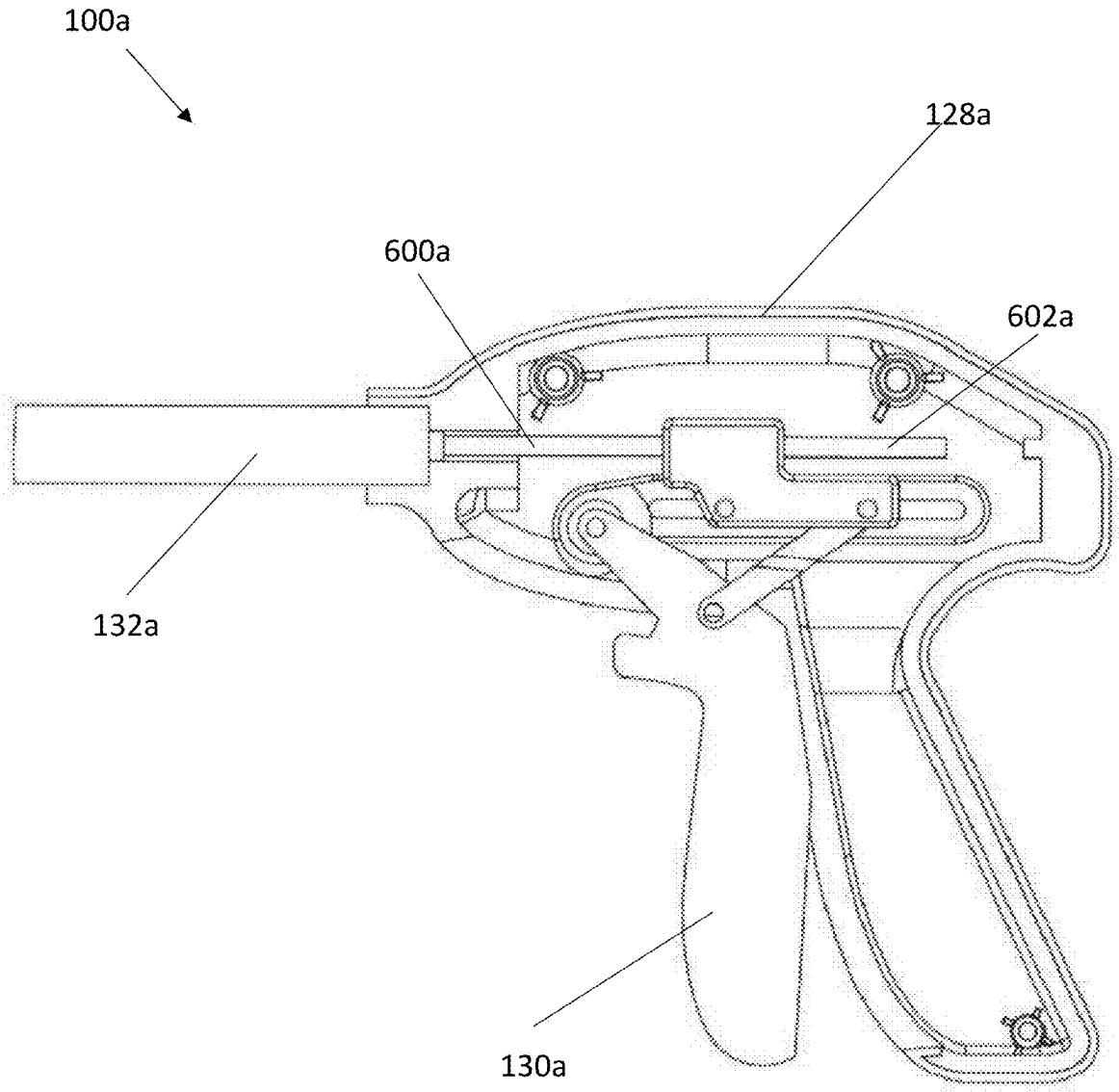


FIG. 6

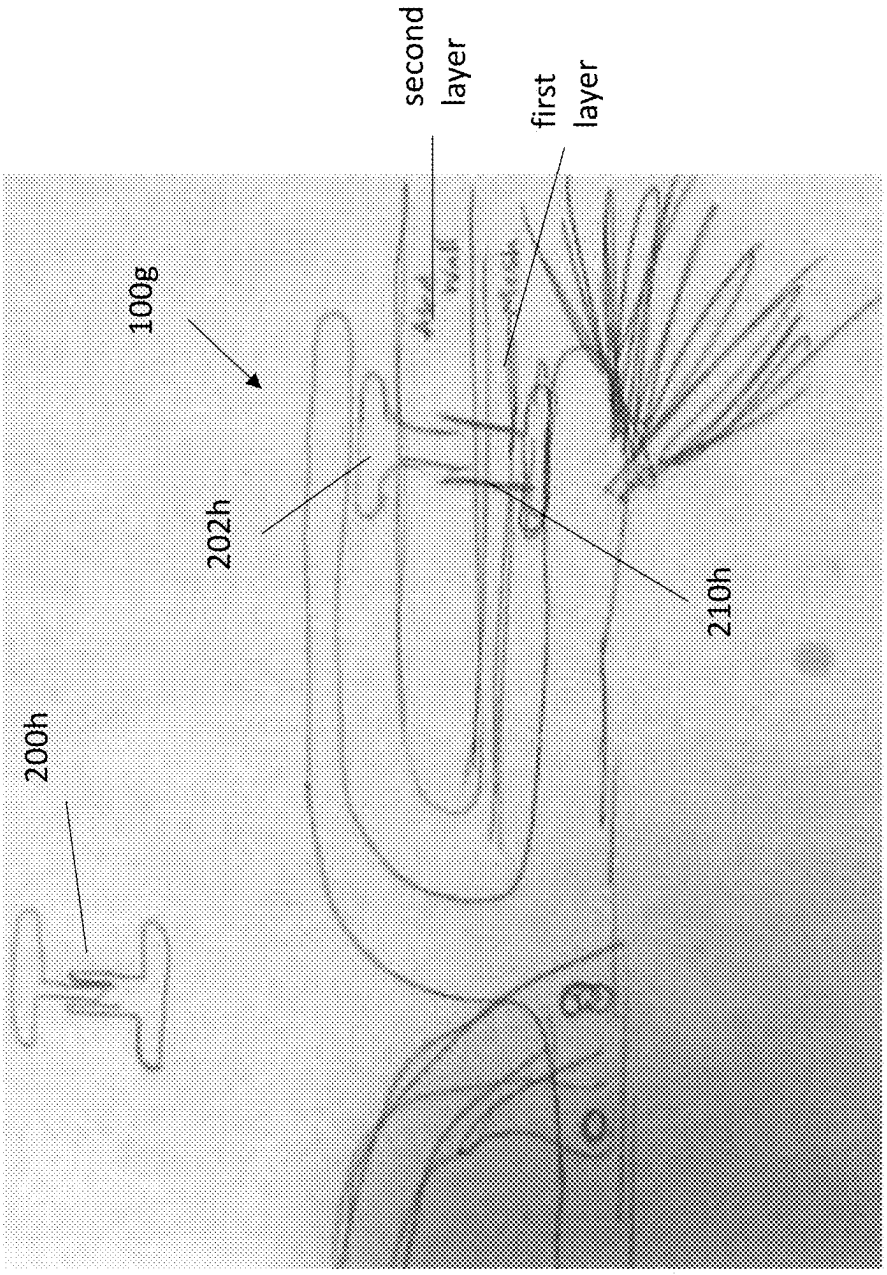


FIG. 7

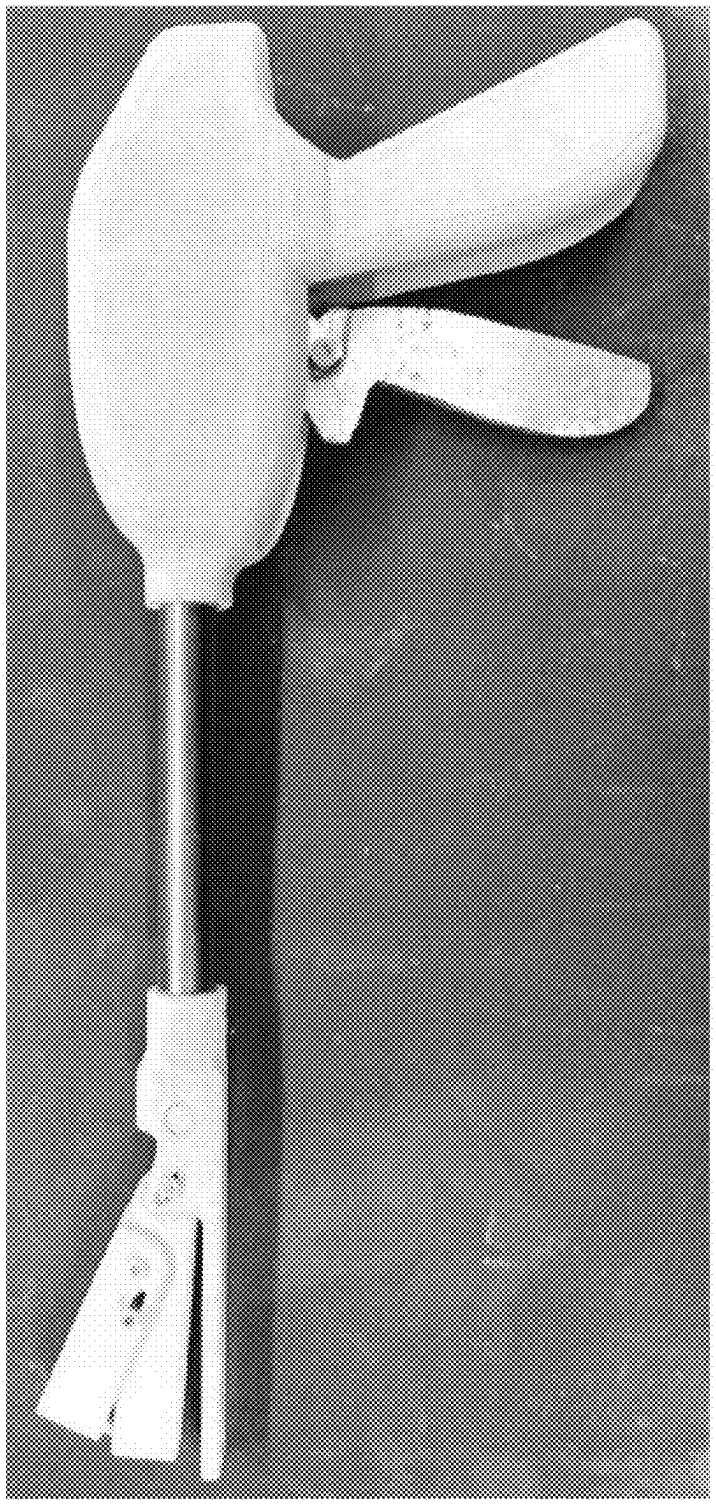


FIG. 8A

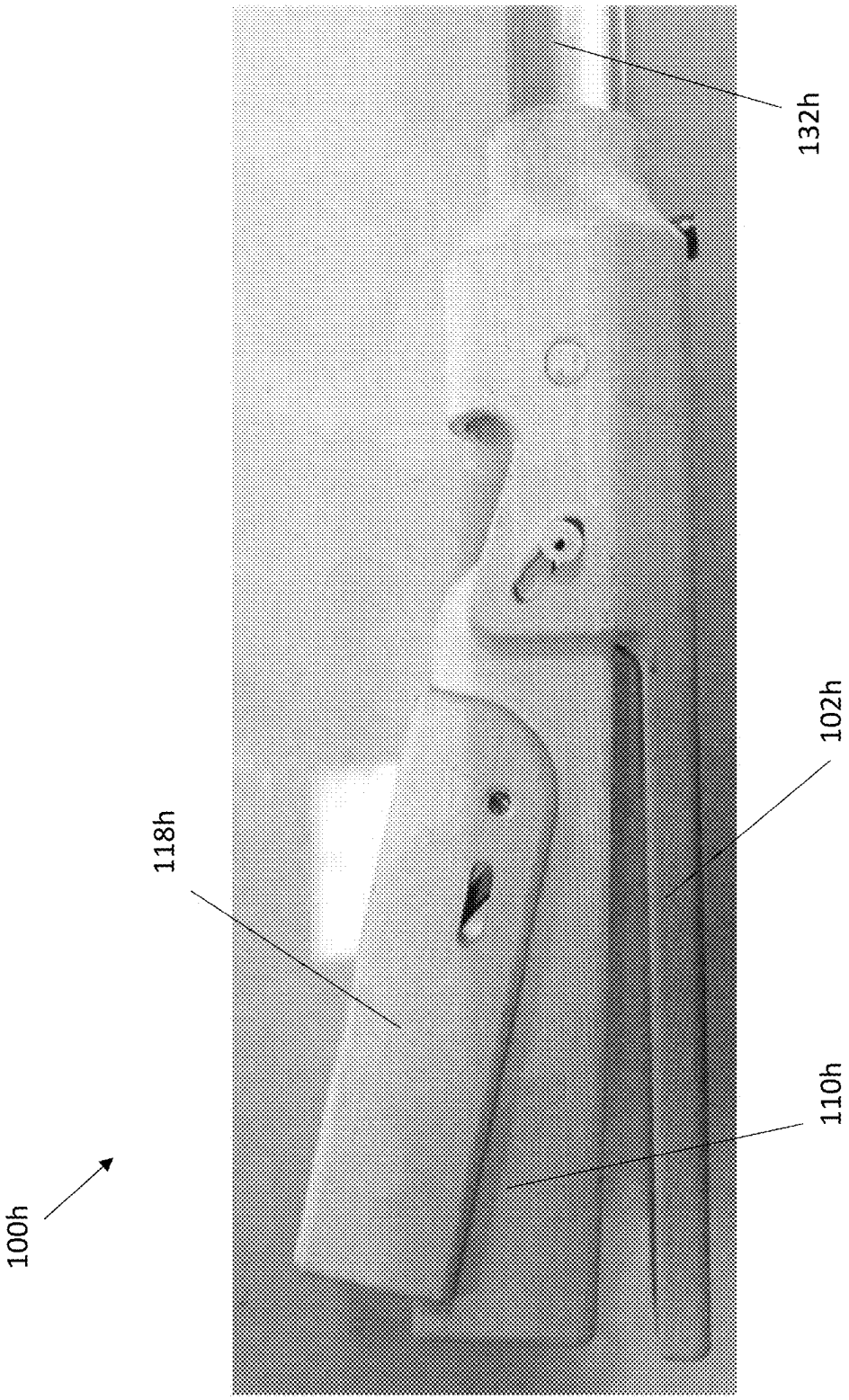


FIG. 8B

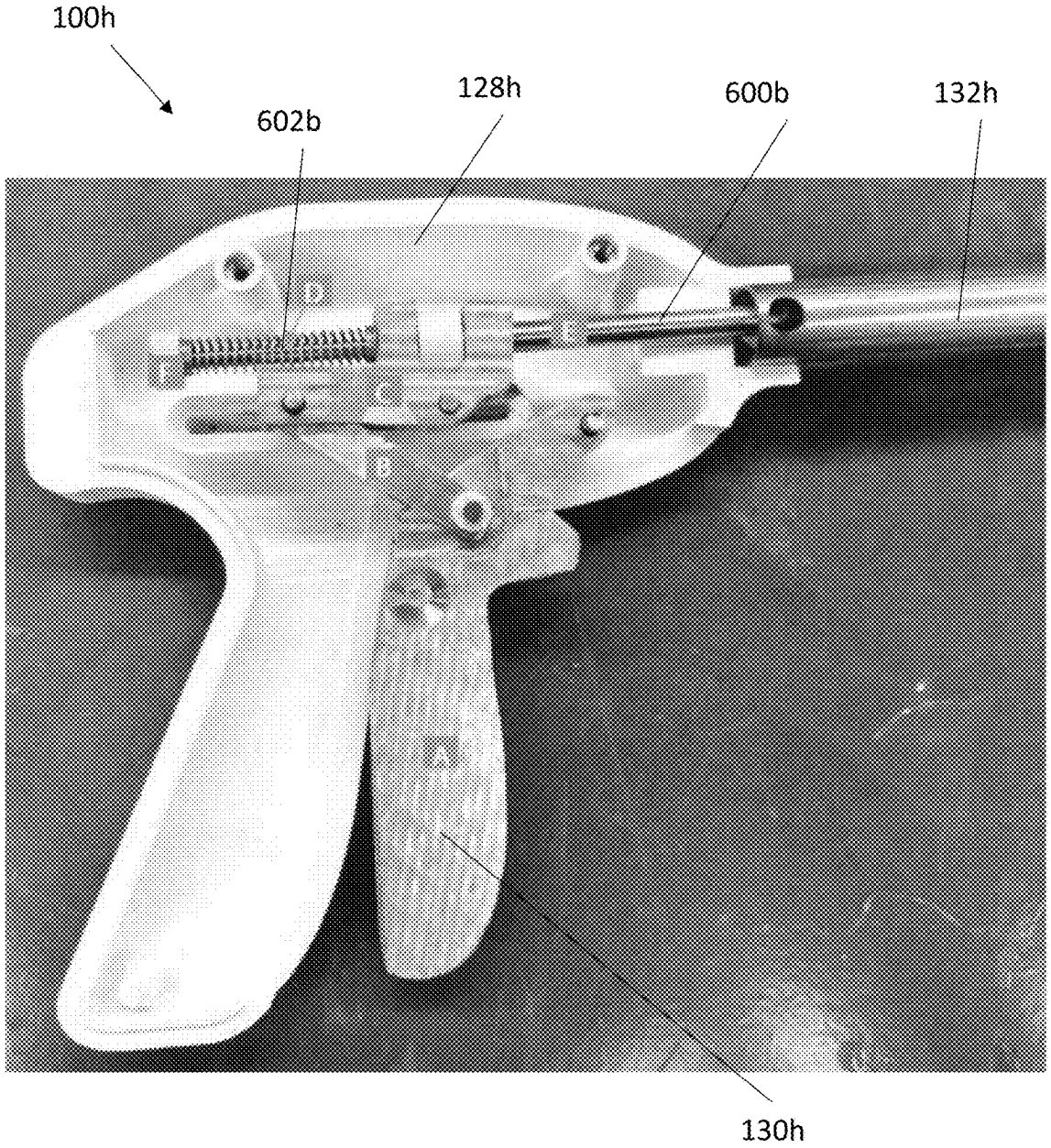


FIG. 8C

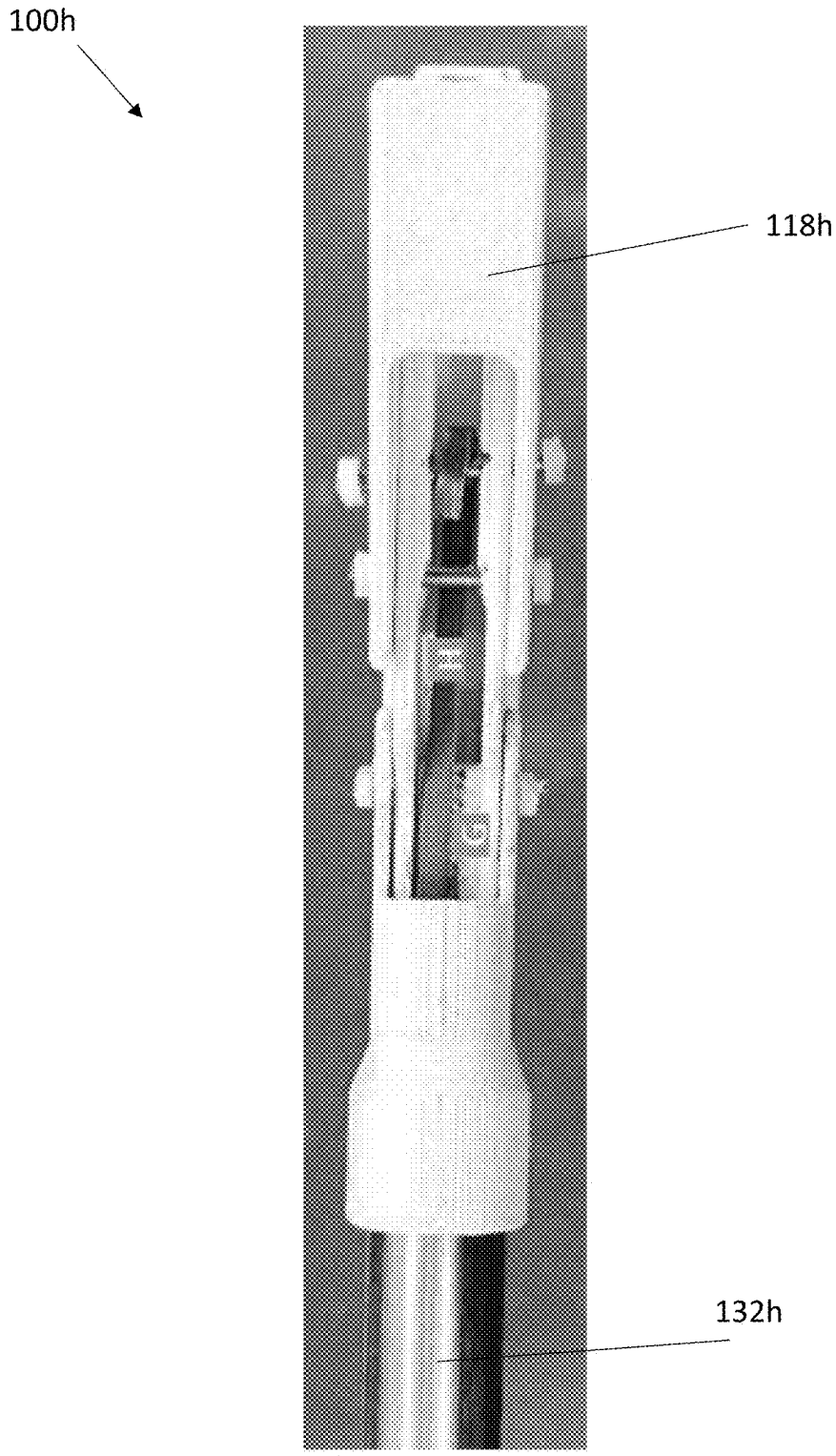


FIG. 8D

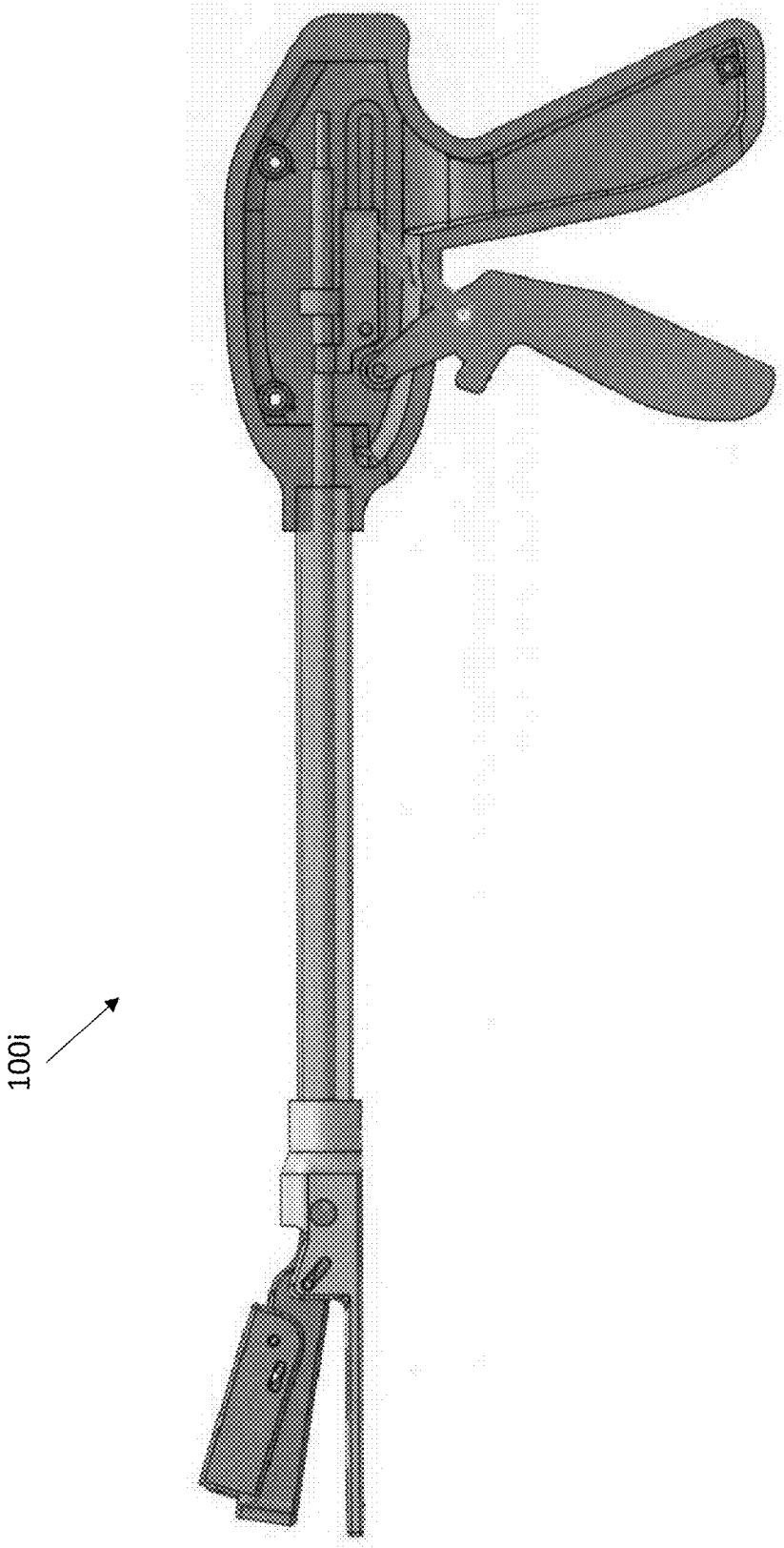


FIG. 9

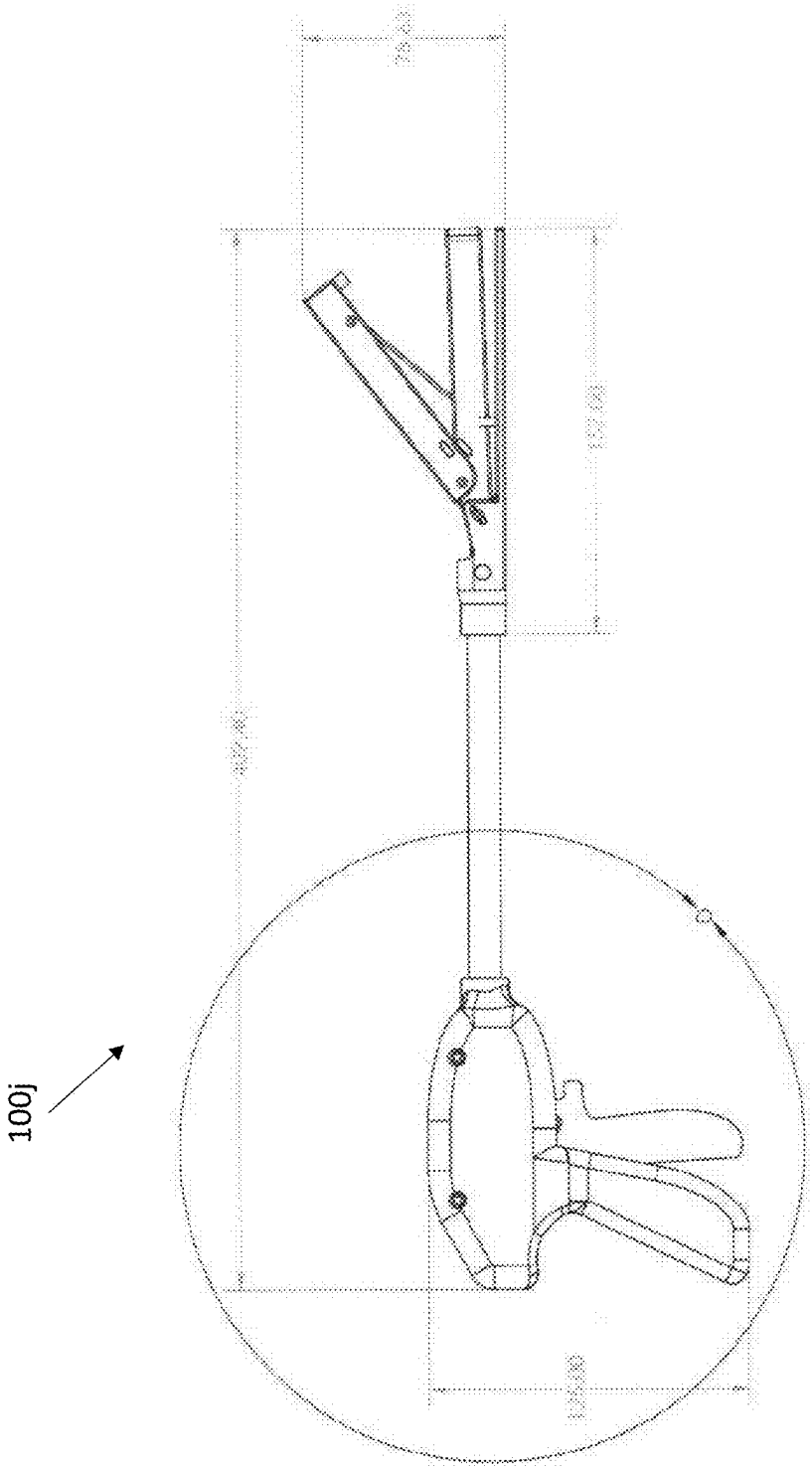


FIG. 10

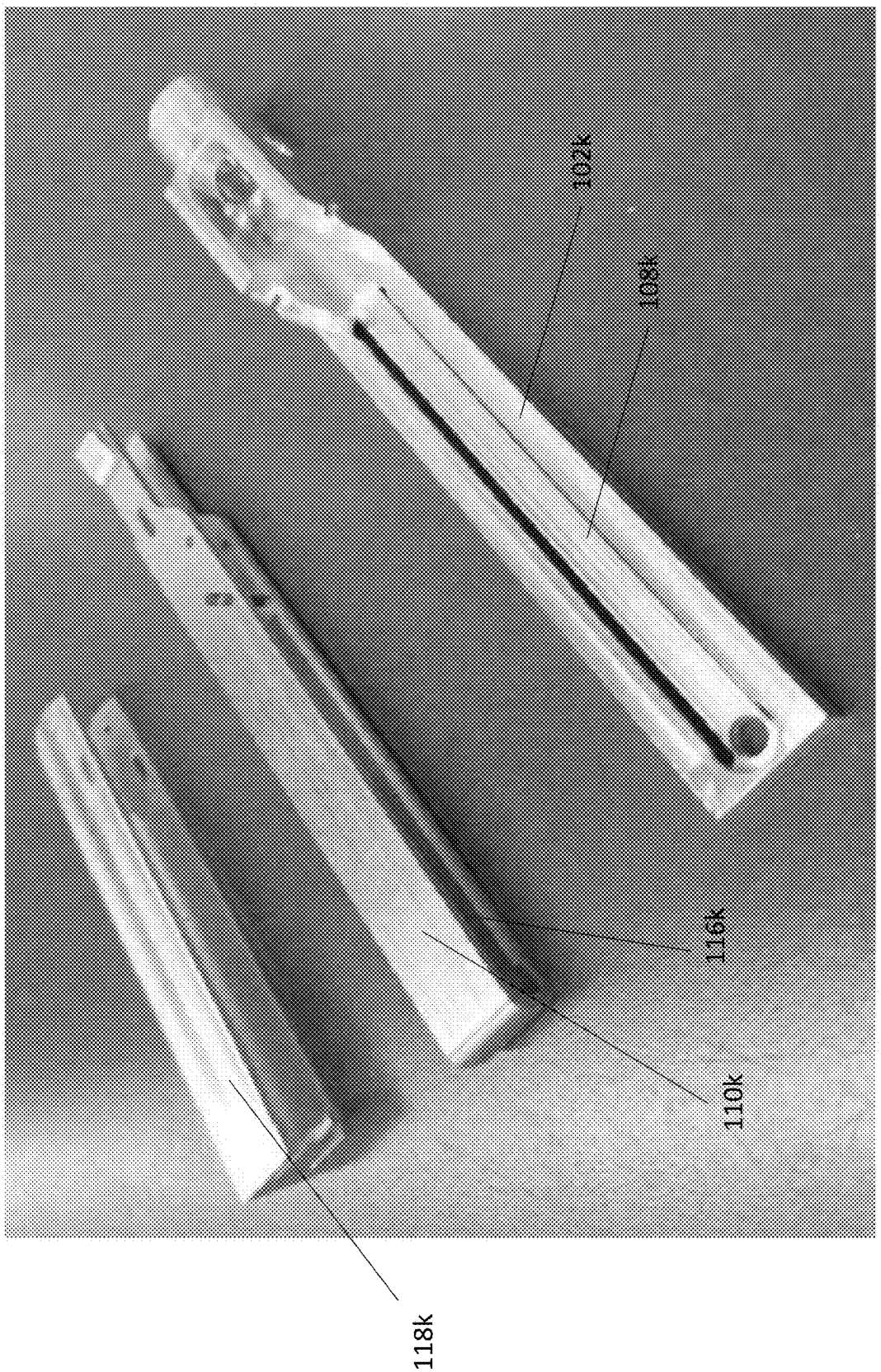


FIG. 11

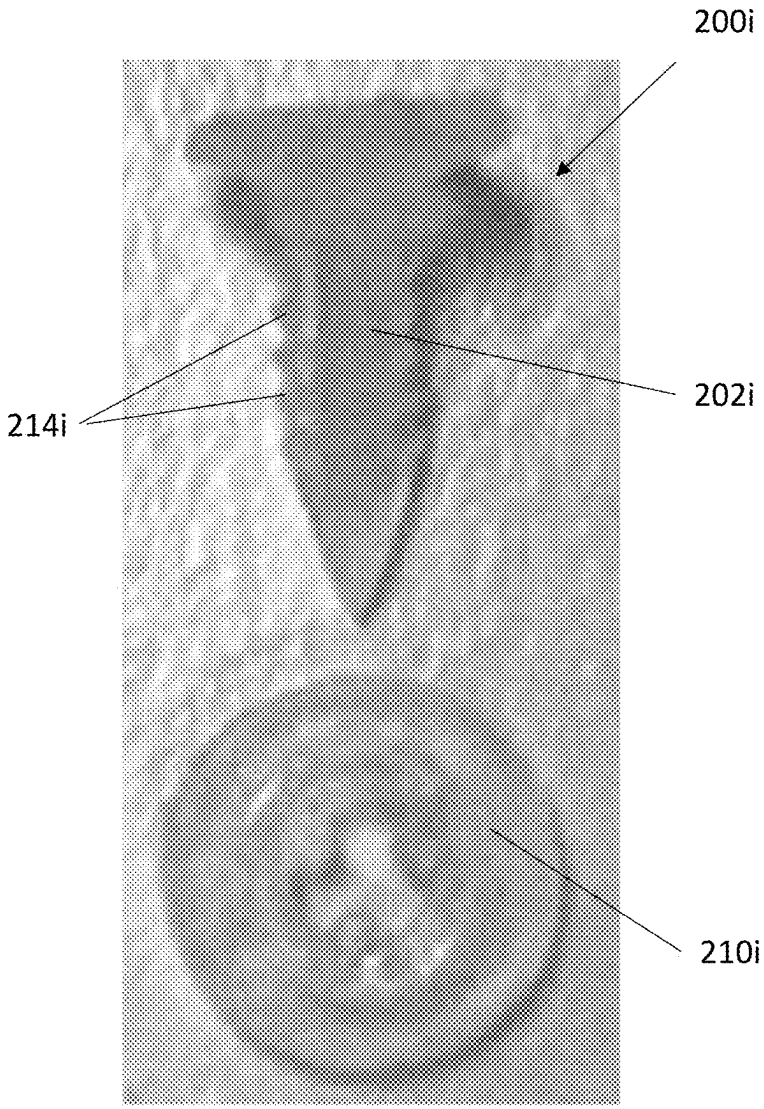


FIG. 12

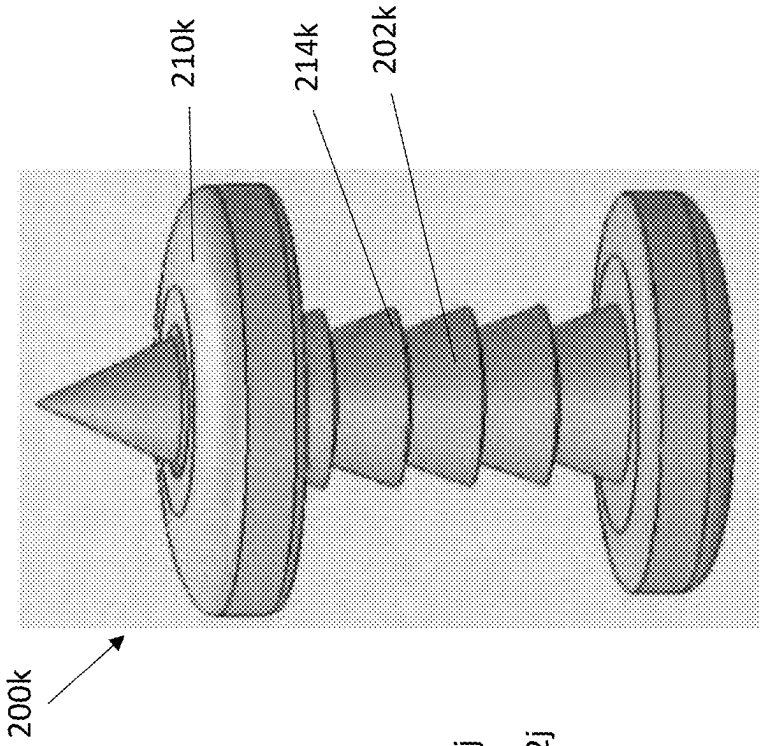


FIG. 14

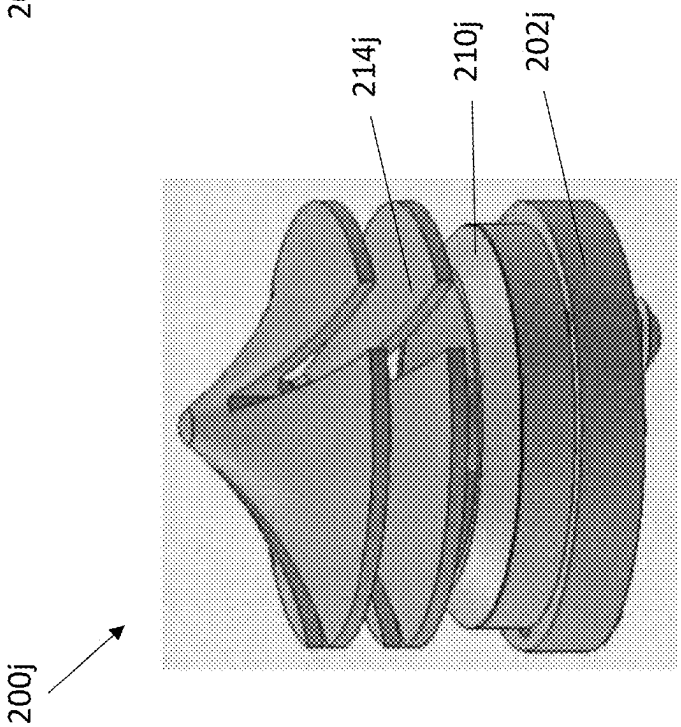
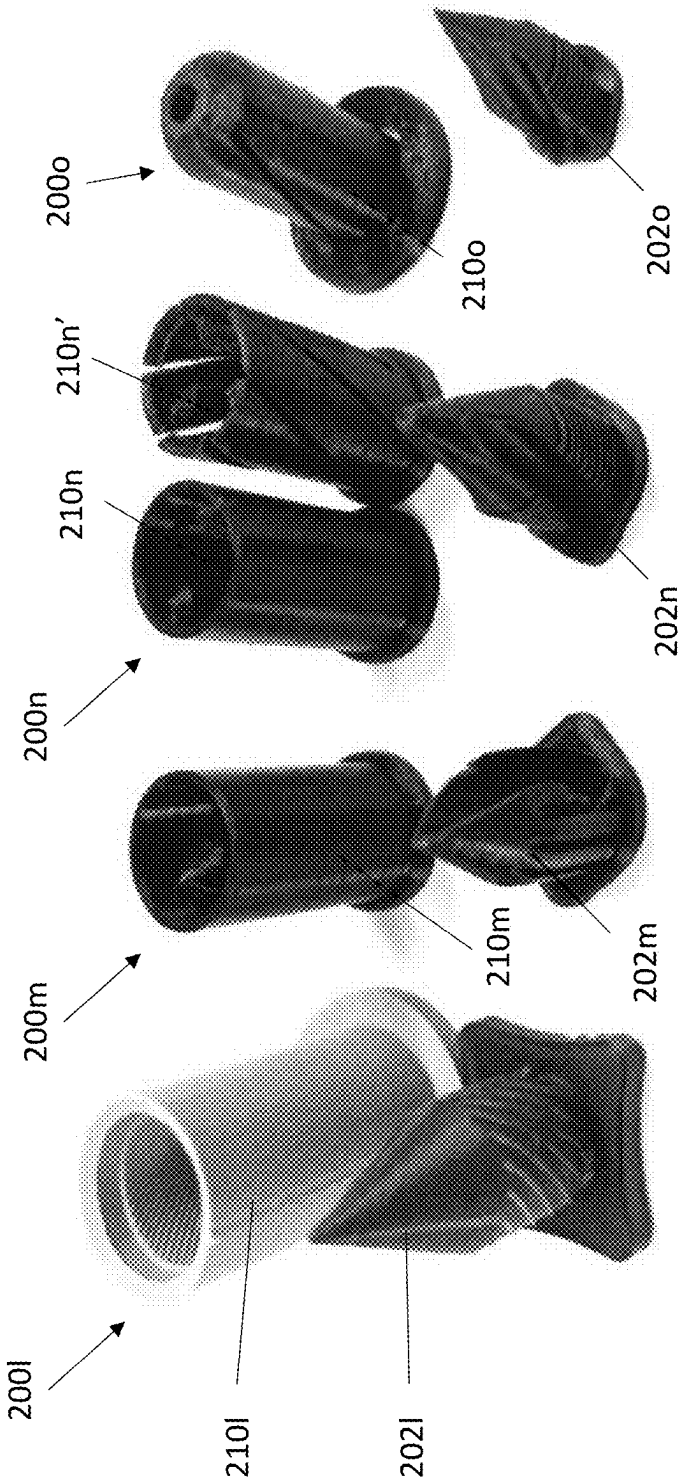


FIG. 13


200o
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210m
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200l
210l
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FIG. 15

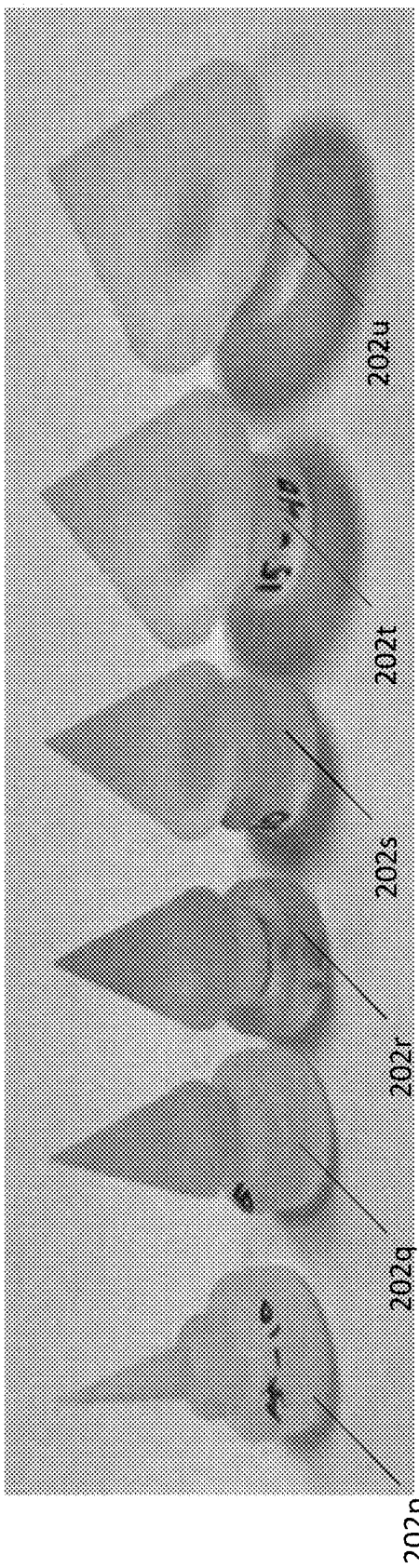


FIG. 16

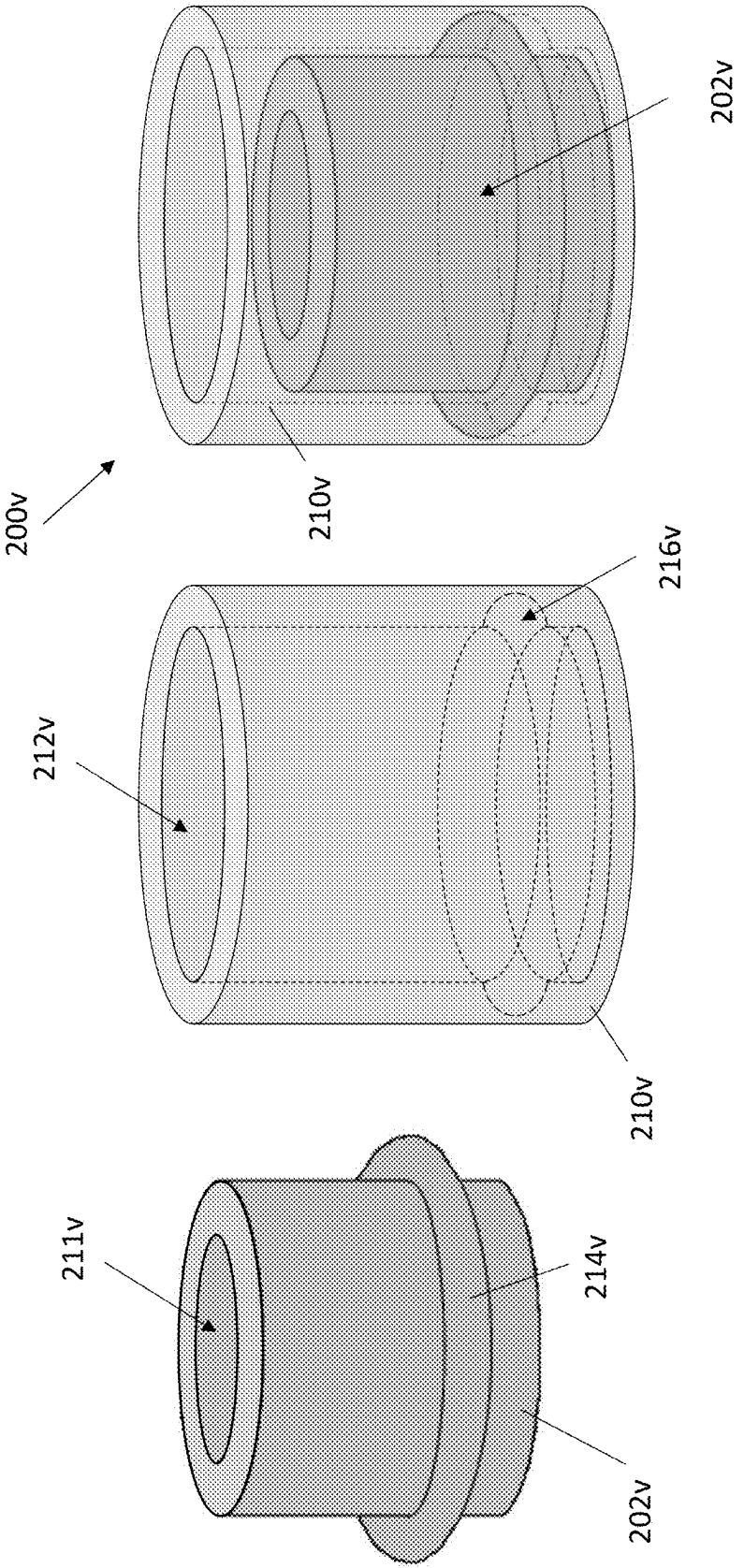


FIG. 17C

FIG. 17B

FIG. 17A

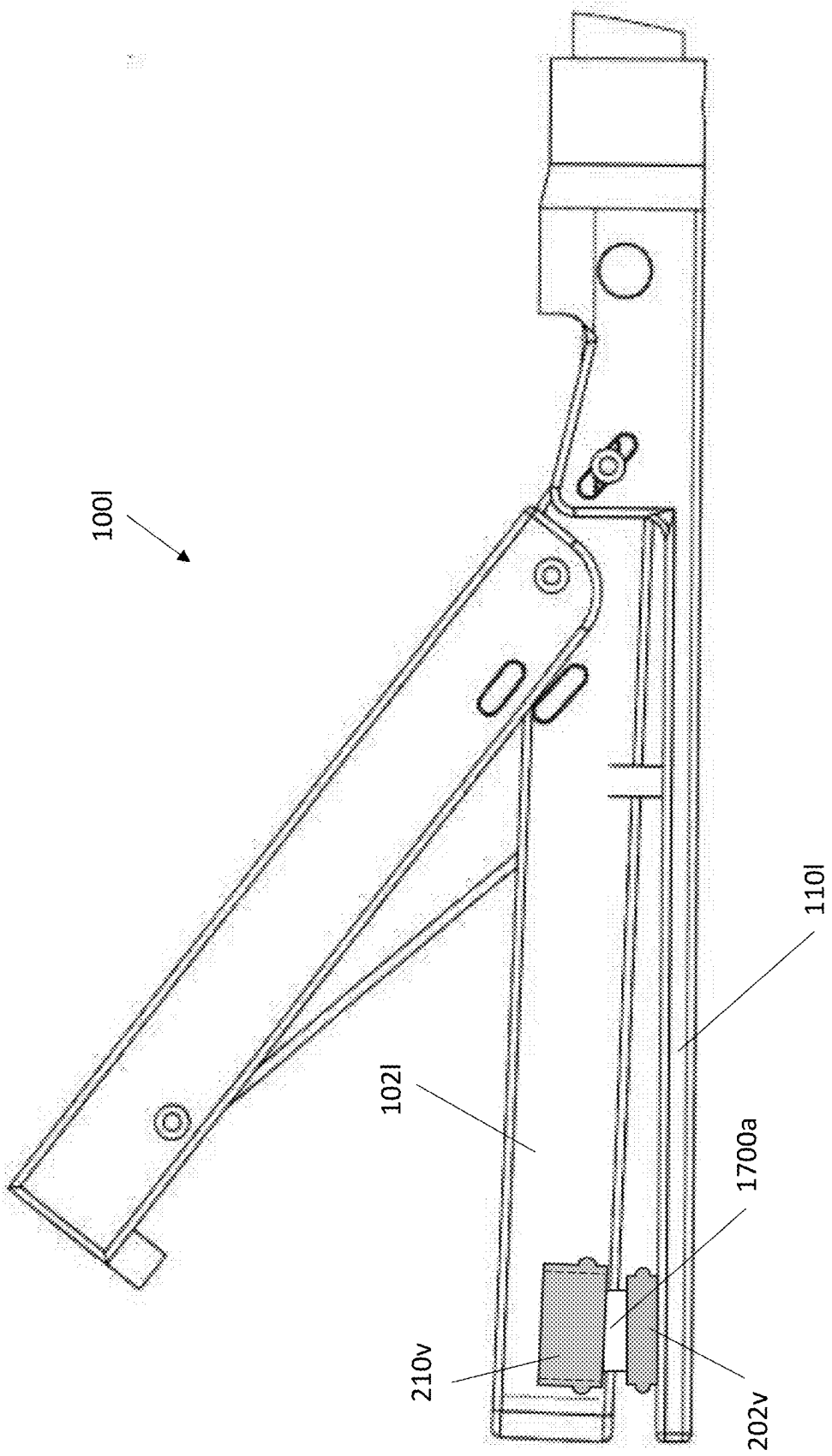


FIG. 17D

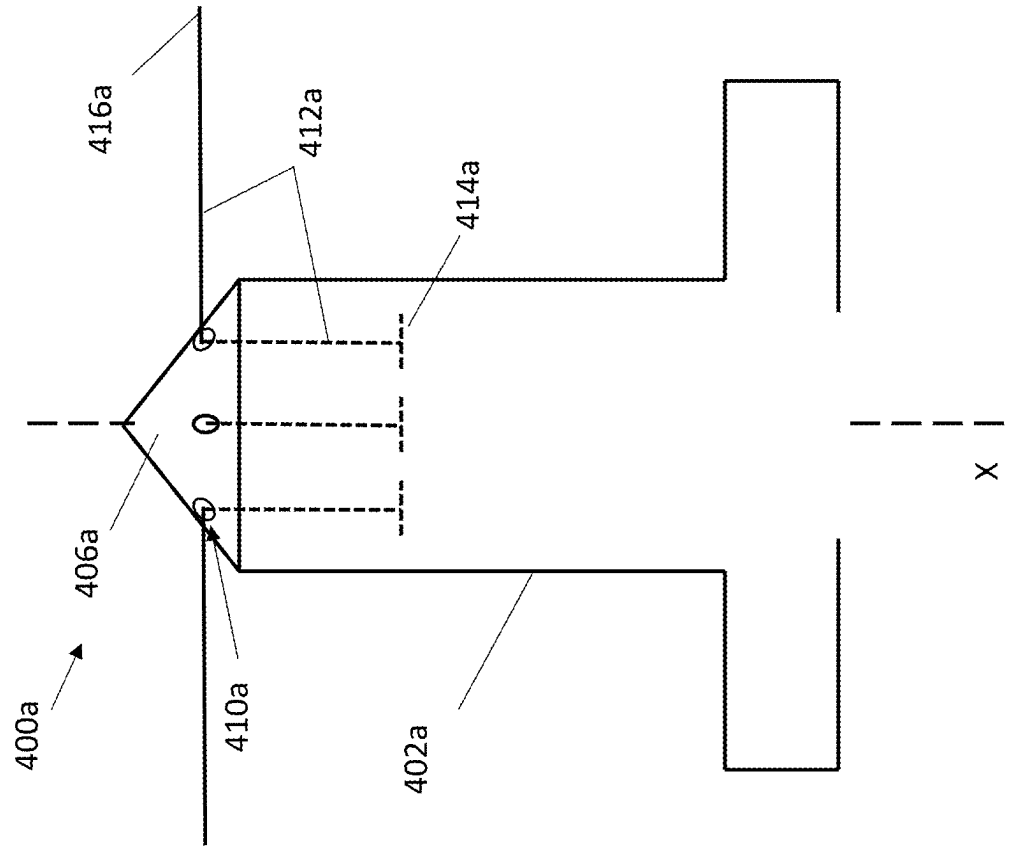


FIG. 18B

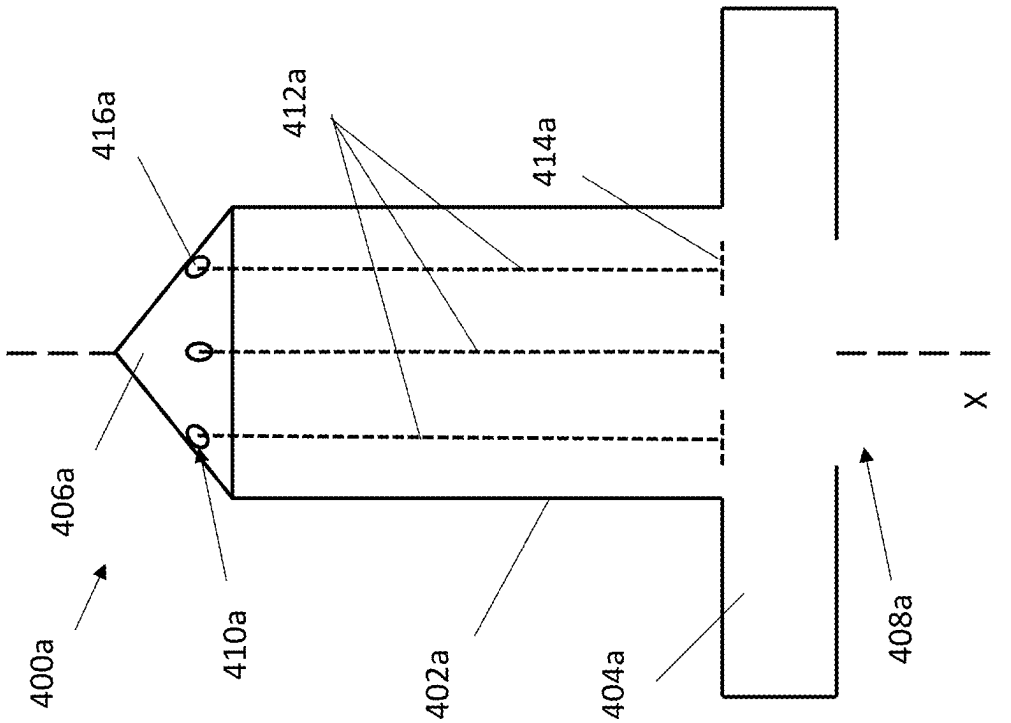
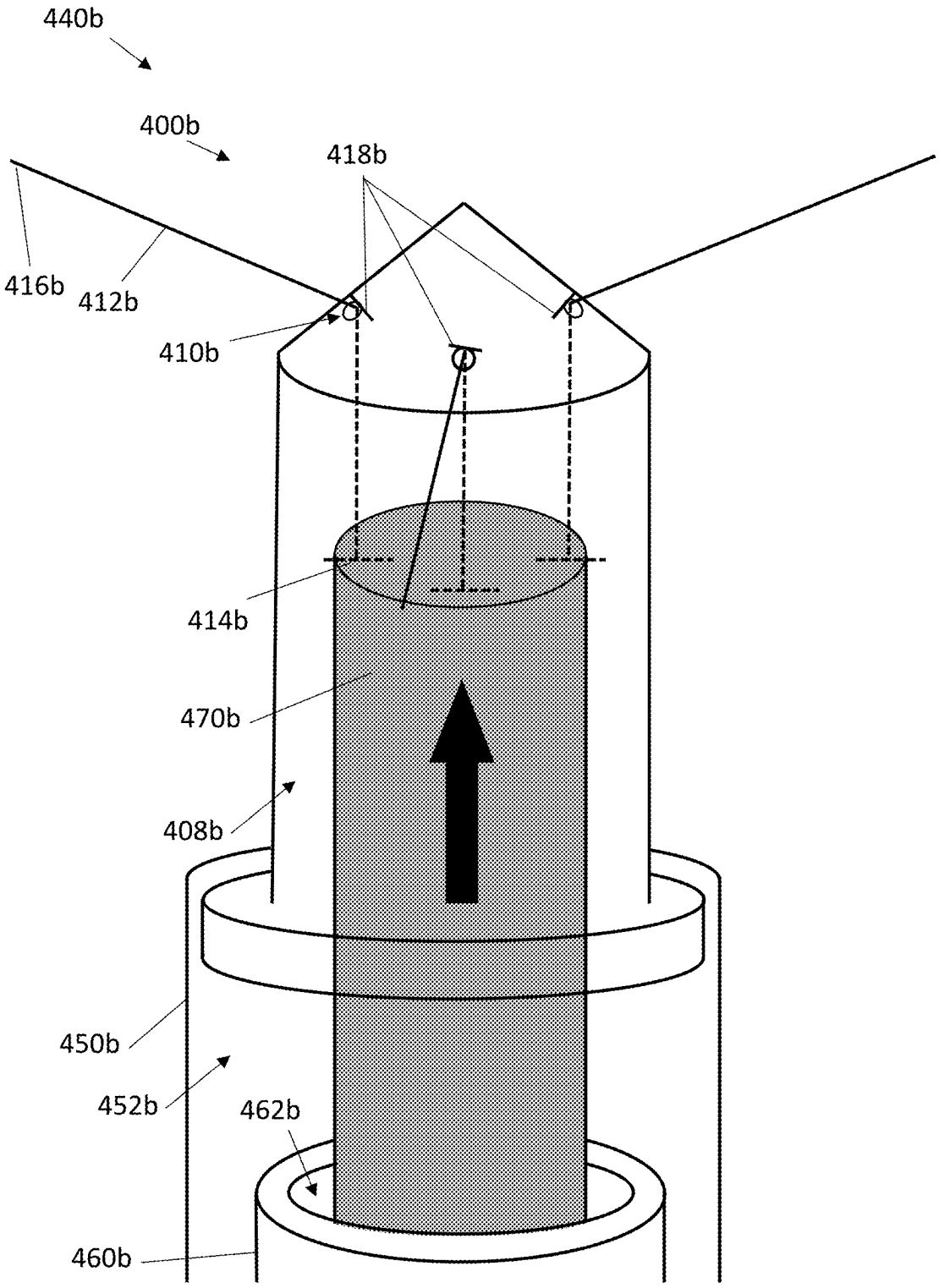


FIG. 18A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410b
414b
470b
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450b
452b
462b
460b

FIG. 19

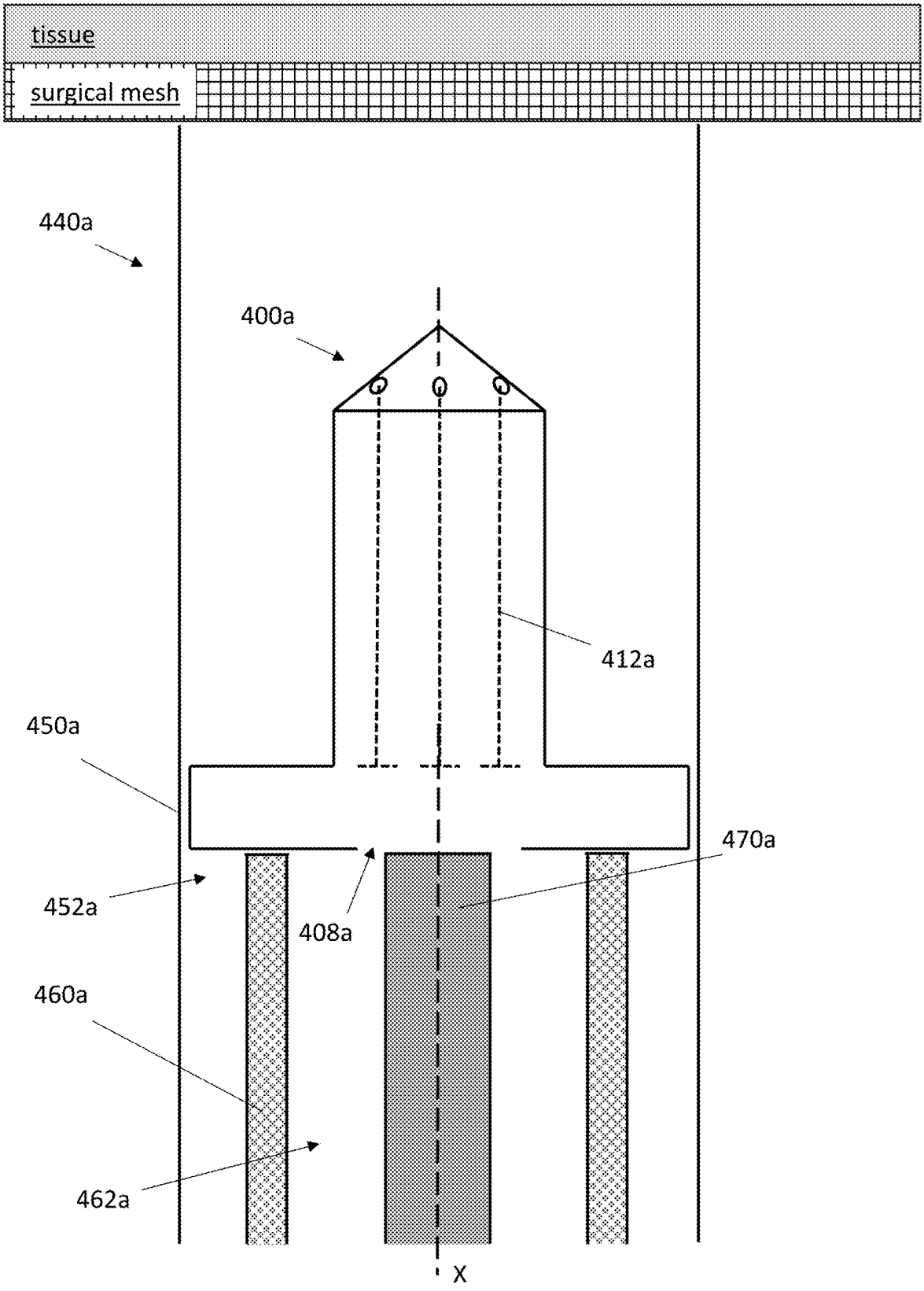

tissue
surgical mesh
440a
400a
412a
450a
470a
452a
408a
460a
462a
X

FIG. 20A

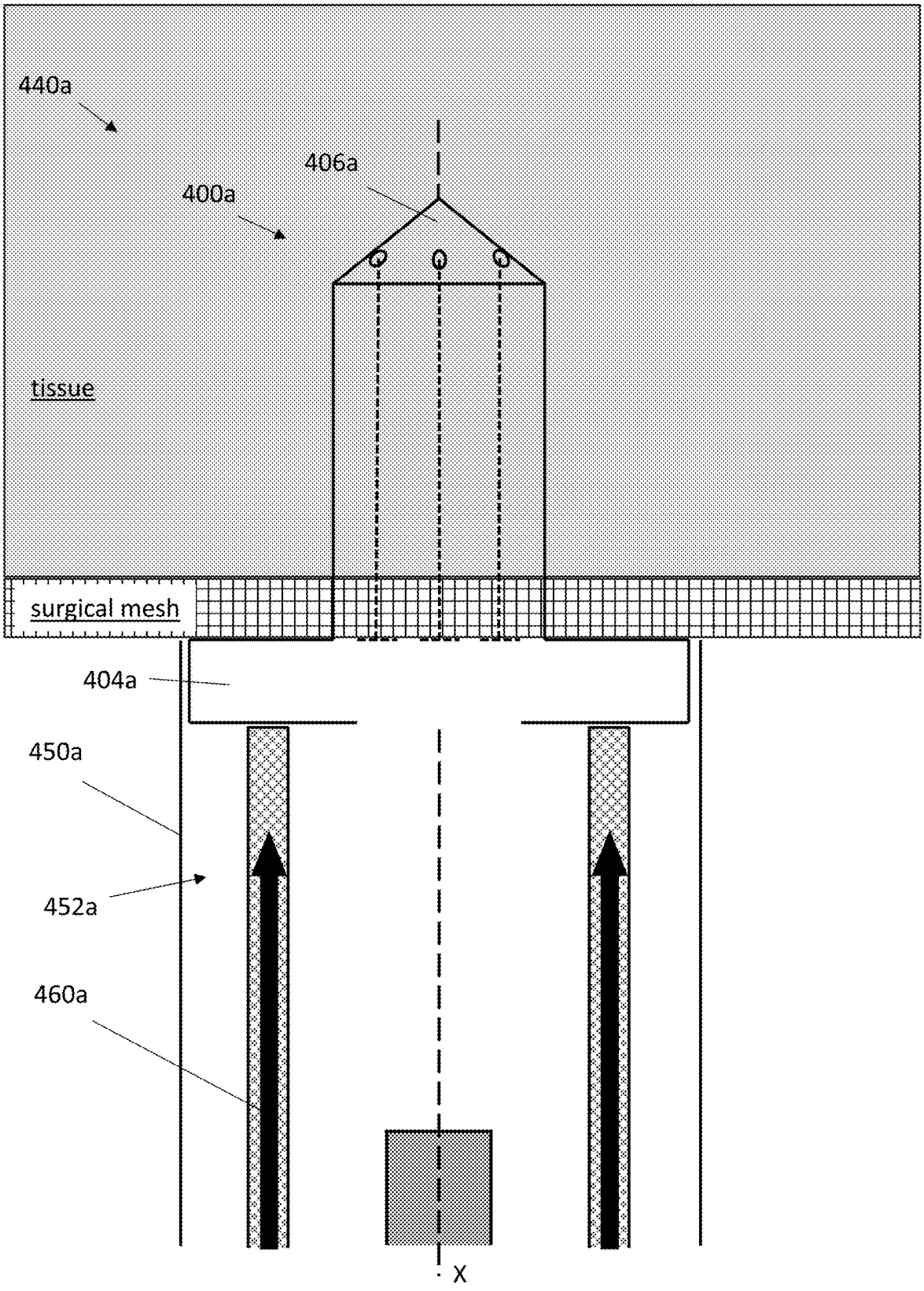
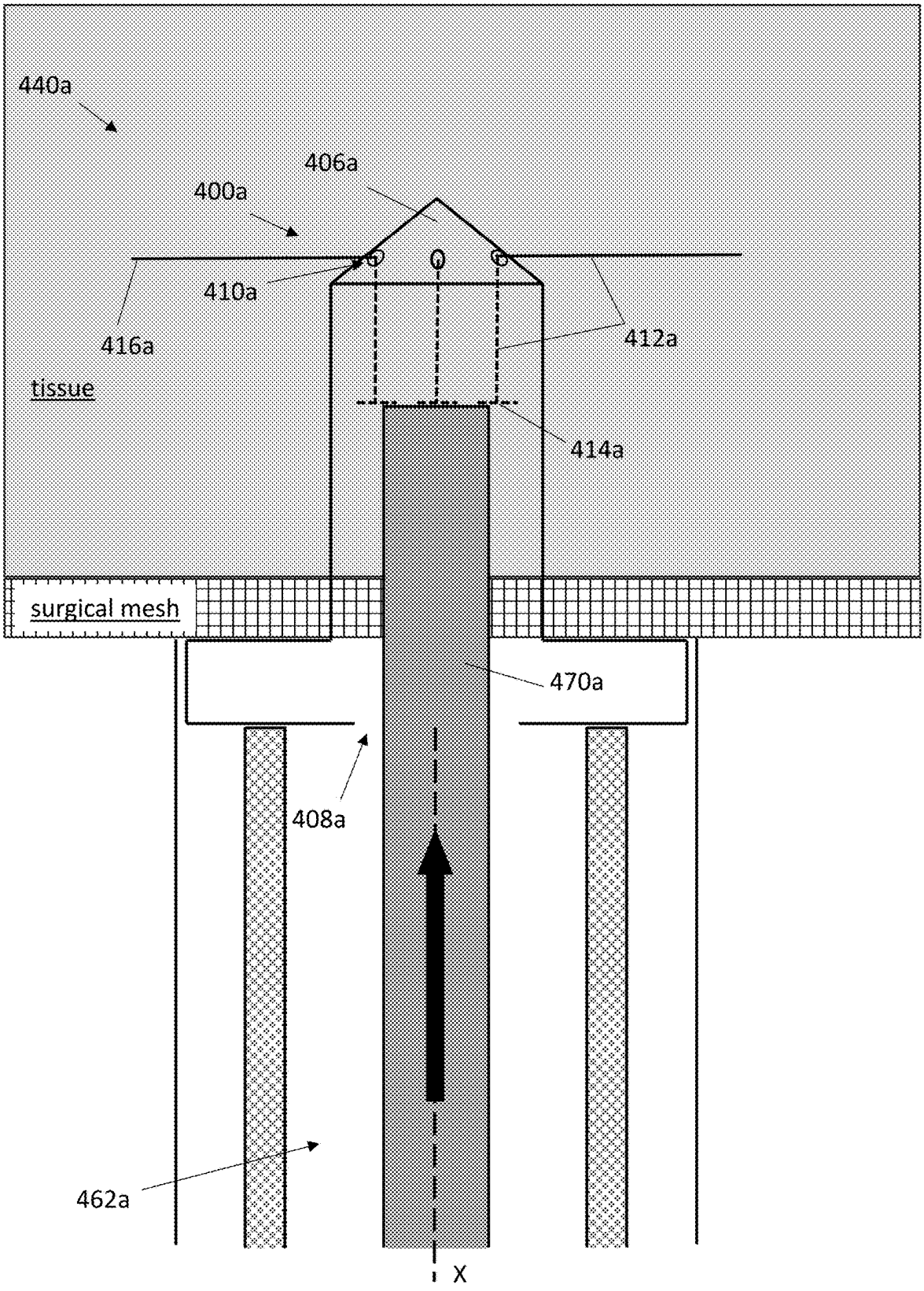


FIG. 20B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surgical mesh
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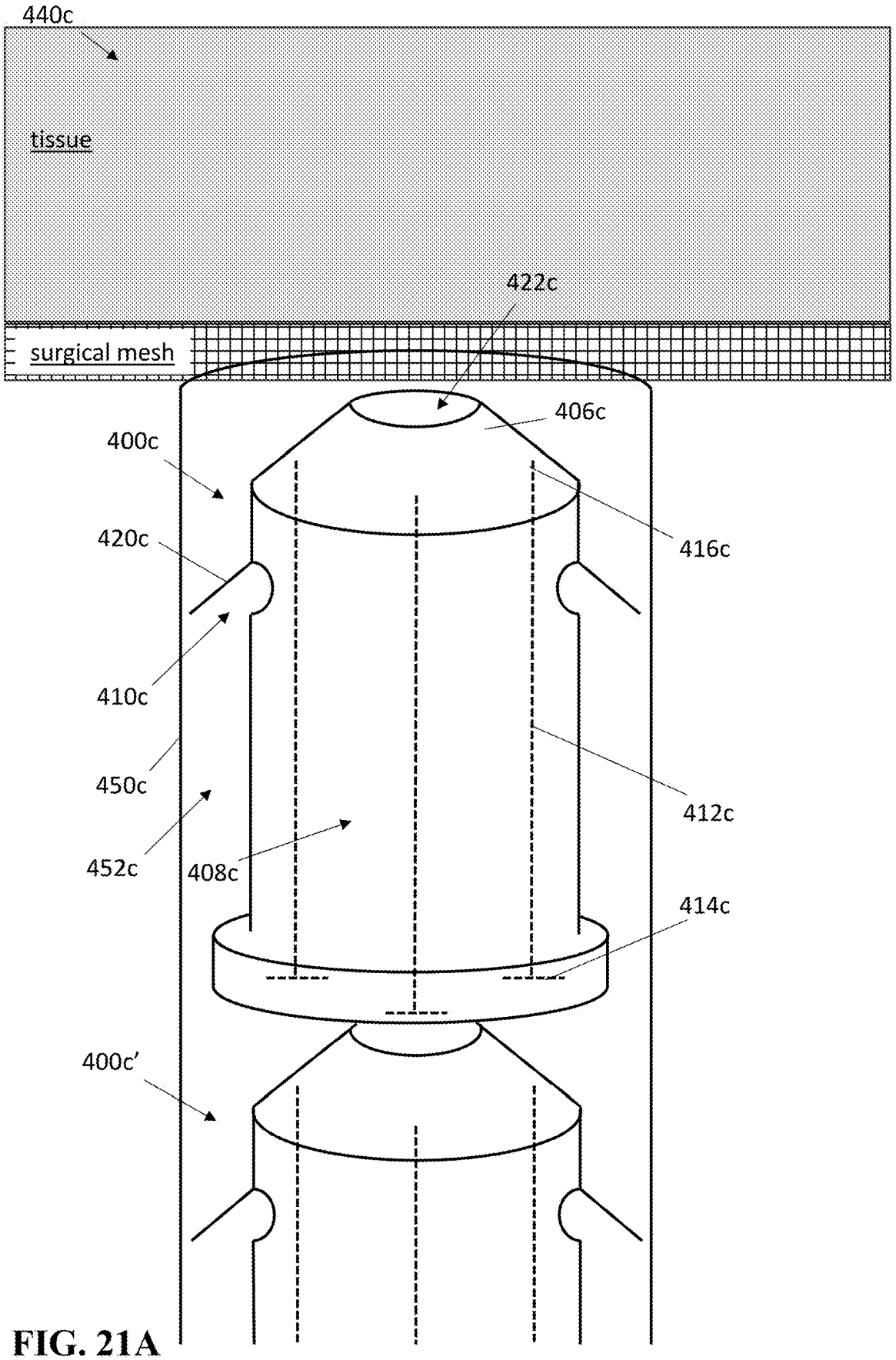
462a
X

FIG. 20C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surgical mesh
406c
400c
416c
420c
410c
450c
412c
452c
408c
414c
400c'

FIG. 21A

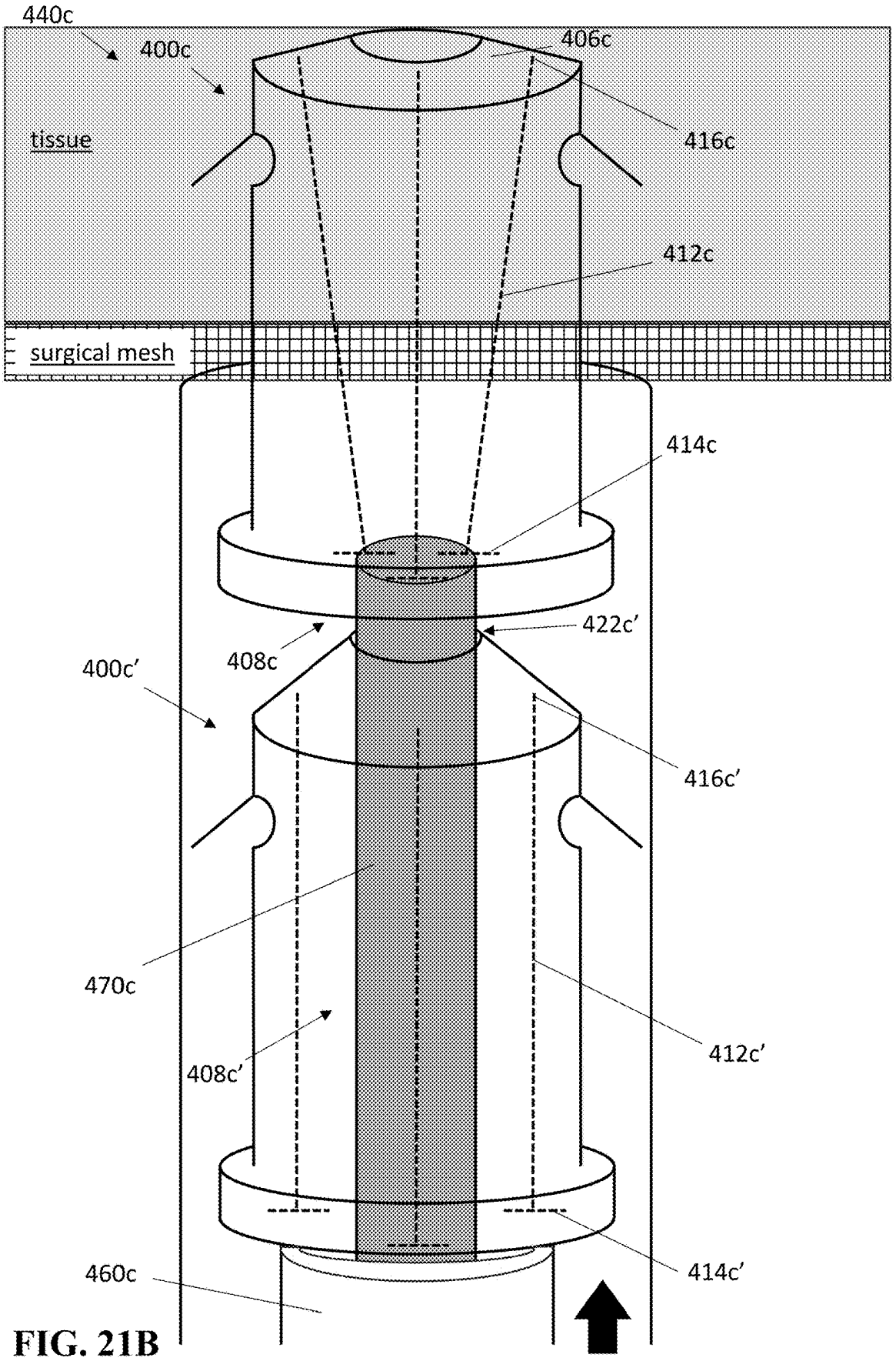
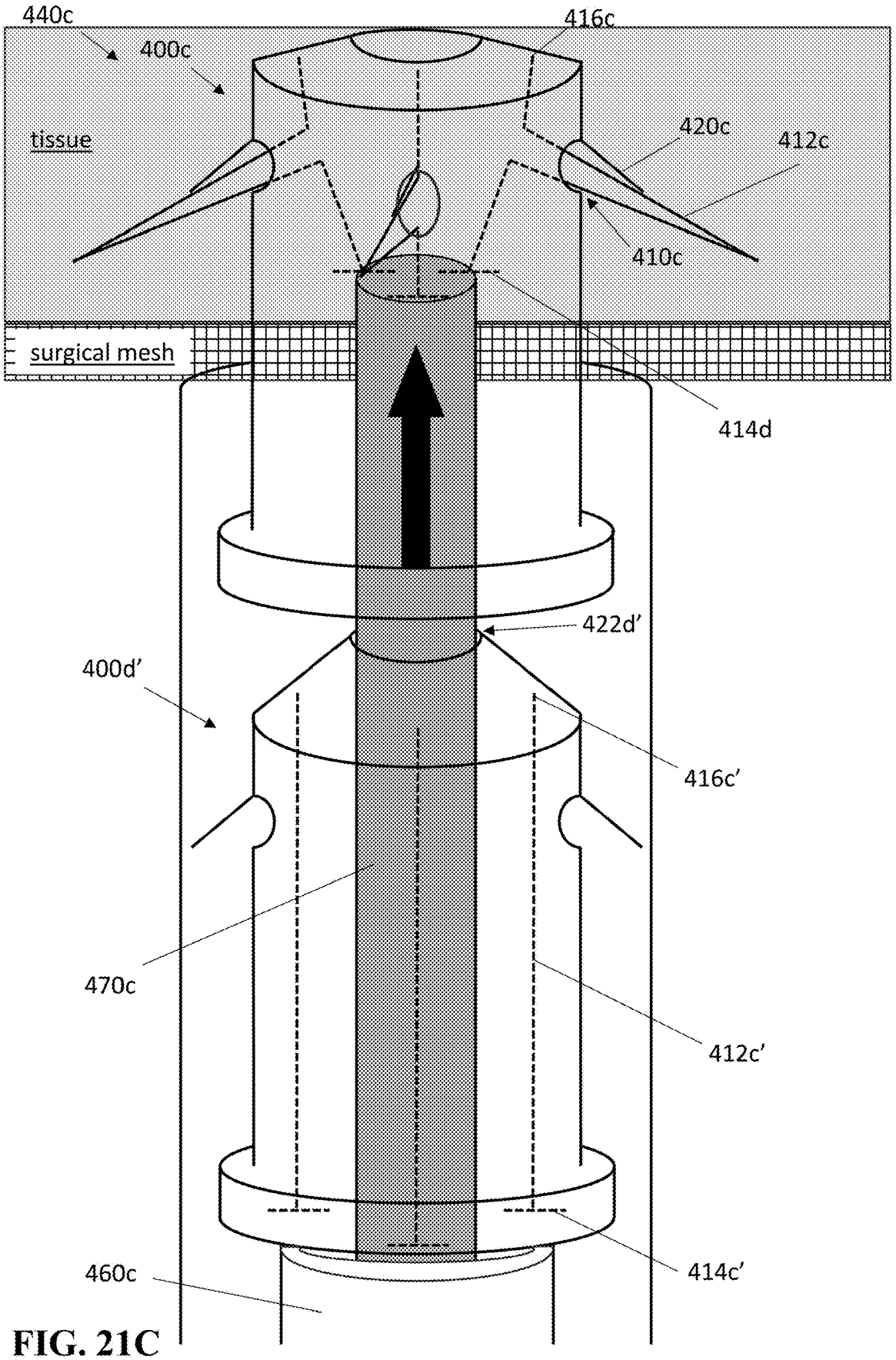

440c
400c
406c
416c
tissue
412c
surgical mesh
414c
422c'
408c
400c'
416c'
470c
412c'
408c'
460c
414c'

FIG. 21B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400c
416c
tissue
420c
412c
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surgical mesh
414d
422d'
400d'
416c'
470c
412c'
460c
414c'

FIG. 21C

SURGICAL LAYER FIXATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application No. 63/644,486, filed on May 8, 2024, the disclosure of which is expressly incorporated herein by reference in its entirety.

BACKGROUND

[0002] Hernias involve the bulging of an organ or part of an organ out of the body cavity that typically contains it. In particular, ventral hernia is a common condition that often requires surgical intervention. The surgical repair of ventral hernias is often performed in conjunction with implants such as meshes, which are designed to strengthen the repair and reduce the risk of hernia recurrence.

[0003] The current standard of care for ventral hernia repair typically involves a surgical intervention to fix meshes to the anatomy at the defect site. Specifically, the hernia is closed by accessing the site through an open or minimally invasive approach and placing a mesh (i.e., a surgical mesh, mesh implant, or mesh prosthesis) to reinforce the repaired defect. Placement and fixation of the surgical mesh may be anterior to the repaired fascia and abdominal wall muscles (i.e., onlay repair) posterior to the abdominal wall muscles (i.e., underlay repair), or posterior to the abdominal wall muscles (i.e. underlay repair) to reinforce the repaired defect. A typical technique for underlay repair entails placement of the surgical mesh in the retro-rectus position after closure of the posterior fascia, which is subsequently secured to the anterior fascia. However, underlay repair may instead involve placement of a mesh posterior to the abdominal muscles but anterior the peritoneum. When the fascial defect cannot readily be closed, a bridging mesh may be placed in line with the fascial defect (i.e., inlay repair). The mesh is fixated in place by suturing, tacking, or gluing the perimeter and the abdominal wall is then closed.

[0004] Attachment (i.e., fixing or securing) of mesh prostheses during the surgical repair of large ventral and incisional hernias is a time-consuming process. Studies conducted within the past few years report the average procedure time for open onlay and underlay repairs range from 60 to 80 minutes. Furthermore, long overall operating times are associated with mesh infection, which can necessitate reoperation. Therefore, a need exists for faster and more secure surgical mesh fixation to reduce overall operating time in hernia repairs.

SUMMARY

[0005] An exemplary surgical tacking system and method are disclosed for fixation of soft tissues or soft prostheses during surgical procedures, such as ventral hernia repairs. The fixation can be between two tissues (as attachments) or between the two tissues and the implant (e.g., mesh prostheses). The tacking system operates on a two-part fixator consisting of a penetrating tack and a retention collar to quickly and reliably deploy and fixate tissue in a closing procedure.

[0006] The tack preferably features a high-pitch spiral to aid in tissue penetration and a series of biased ribs to allow for variable thickness placements. Once the tack is placed through relevant layers, the retention disk snaps down over the tack and can be indexed at several points along the tack length to generate optimal pressure on the tissues. Tacks and disks are separately held in the upper and lower jaws of the device and are stowed as a cartridge. When the trigger is pulled, the first stage of the stroke grips the tissues, and the second stage delivers the tack and locks on the retention disk, securing tissues there between. The tack can be dispensed in an inward direction toward the patient or an outward direction away from the patient.

[0007] The exemplary system can be employed as a single-use disposable device, for a given operation that can loaded with two cartridges and reloaded via replacement cartridges, comprising the two-part fixators. The exemplary system is contemplated to improve the onlay and sublay repairs, e.g., for hernia, by 25%-50%. In addition, the exemplary system is contemplated to improve operating room safety in replacing surgical needles that are potential hazards to the surgeon and technicians with fully-enclosed fixation components.

[0008] In some aspects, the techniques described herein relate to a surgical fastening system for fixing a first layer to a second layer. The system includes a fastener dispenser including a first jaw and a second jaw. The first jaw includes a proximal end and a distal end and defines a first jaw track therein extending between the proximal end and the distal end. The second jaw includes a proximal end and a distal end and defines a second jaw track therein extending between the proximal end and the distal end. The system also includes a fastener having an elongated member and a collar. The elongated member spans the combined thickness of the first layer and the second layer and is stored within the second jaw track. The collar is stored within the first jaw track. The first jaw is movably coupled to the second jaw so that the fastener dispenser is movable from an unclamped configuration, in which the first jaw and the second jaw have a relative spacing on opposite sides of the first layer and the second layer, to a clamped configuration, in which the second jaw is moved relative to the first jaw to reduce the relative spacing between the first jaw and the second jaw. By moving from the unclamped configuration to the clamped configuration, the fastener dispenser is able to hold the first layer relative to the second layer.

[0009] In various implementations, one of the first or second jaws further includes an ejection jaw movably coupled to the one of the first or second jaws. The ejection jaw includes a protrusion configured to extend toward the track of the one of the first or second jaws to which the ejection jaw is coupled. Moving the ejection jaw toward the one of the first or second jaws engages the protrusion against one of the elongated members or the collar stored in the track of the one of the first or second jaws, thereby urging the one of the elongated member or the collar toward the other of the elongated member or the collar to couple the elongated member and the collar.

[0010] In various implementations, an ejection jaw biasing member urges the ejection jaw toward the one of the first or second jaws to which the ejection jaw is coupled.

[0011] In various implementations, the elongated member extends between a base end and a penetrating end and defines an elongated member central axis.

[0012] In various implementations, the elongated member is stored within the second jaw track such that the elongated

member central axis is parallel with or forms an acute angle with an extension axis of the second jaw track.

[0013] In various implementations, the second jaw further includes a pivoting feature configured to pivot the elongated member when the elongated member is dispensed such that the penetrating end of the elongated member extends toward the collar.

[0014] In various implementations, the system further includes a cutting blade disposed adjacent to the first jaw, the cutting blade configured to remove a portion of the penetrating end of the elongated member on a side of the collar opposite the base end of the elongated member after the elongated member is coupled to the collar.

[0015] In various implementations, the system further includes a collar cartridge configured to store and dispense the collar. In various implementations, the collar is one of a plurality of collars stored in the collar cartridge. In various implementations, the system further includes an elongated member cartridge configured to store and dispense the elongated member. In various implementations, the elongated member is one of a plurality of elongated members stored in the elongated member cartridge. In various implementations, the first jaw track is configured to receive the collar cartridge, and the second jaw track is configured to receive the elongated member cartridge. In various implementations, a first biasing member urges the collar cartridge toward the distal end of the first jaw. In various implementations, a second biasing member urges the elongated member cartridge toward the distal end of the second jaw.

[0016] In various implementations, the elongated member is formed integrally with the second jaw and extends toward the first jaw, wherein the system further includes a dispensing blade configured to remove the elongated member from the second jaw.

[0017] In various implementations, the system further includes a housing, the housing including a first actuator movable between a first unengaged position and a first engaged position, wherein movement between the first unengaged position and the first engaged position moves the fastener dispenser between the unclamped configuration to the clamped configuration, respectively. In various implementations, the housing further includes a second actuator movable between a second unengaged position and a second engaged position, wherein movement between the second unengaged position and the second engaged position moves the ejection jaw relative to one of the first or second jaws to urge one of the elongated member or the collar toward the other of the elongated member or the collar to couple the elongated member and the collar.

[0018] In various implementations, the system further includes a handle configured to move the first actuator between the first unengaged position and the first engaged position. In various implementations, the handle is further configured to move the second actuator between the second unengaged position and the second engaged position.

[0019] In various implementations, the system further includes a hollow shaft extending from the housing to the fastener dispenser. In various implementations, the first jaw is rotationally fixed to the hollow shaft. In various implementations, the fastener dispenser is detachably coupled to the hollow shaft for disposal or replacement.

[0020] In various implementations, the first layer is a surgical mesh implant, and the second layer is a patient's tissue. In various implementations, the surgical mesh implant is a hernia mesh. In various implementations, both the first layer and the second layer are a patient's tissue.

[0021] In some aspects, the techniques described herein relate to a surgical fastener for fixing a first layer to a second layer. The fastener includes an elongated member extending between a base end and a penetrating end and defining an elongated member central axis and a collar defining an opening configured to receive the penetrating end of the elongated member. The elongated member spans the combined thickness of the first layer and the second layer. The elongated member is configured to engage with the opening of the collar, thereby coupling the elongated member and the collar. The fastener operates in a system that includes a fastener dispenser, the fastener dispenser including: a first jaw including a proximal end and a distal end, the first jaw defining a first jaw track therein extending between the proximal end and the distal end; and a second jaw including a proximal end and a distal end, the second jaw defining a second jaw track therein extending between the proximal end and the distal end. The proximal end of the first jaw is pivotably coupled to the proximal end of the second jaw. The elongated member is stored within the second jaw track, and the collar is stored within the first jaw track.

[0022] In various implementations, the elongated member includes a radially extending engagement feature. In various implementations, the radially extending engagement feature of the elongated member further includes a radially outwardly extending rib. In various implementations, the opening of the collar further includes a radially extending engagement feature configured to couple with the radially extending engagement feature of the elongated member. In various implementations, the engagement feature of the elongated member further includes a radially outwardly extending rib, wherein the engagement feature of the collar defines a groove, and wherein the radially outwardly extending rib of the elongated member couples with the groove of the collar.

[0023] In some aspects, the techniques described herein relate to a method for surgically fixing a first layer to a second layer. The method includes: (i) providing a fastener dispenser including: a first jaw having a proximal end and a distal end, the first jaw defining a first jaw track therein extending between the proximal end and the distal end; a second jaw having a proximal end and a distal end, the second jaw defining a second jaw track therein extending between the proximal end and the distal end; (ii) providing a fastener including: an elongated member and a collar, the elongated member spanning the combined thickness of the first layer and the second layer, wherein the elongated member extends between a base end and a penetrating end and defines an elongated member central axis; wherein the collar defines an opening configured to receive the penetrating end of the elongated member; and wherein the elongated member is stored within the second jaw track and the collar is stored within the first jaw track; (iii) positioning the fastener dispenser so that the first layer and the second layer are disposed between the first jaw and the second jaw; (iv) moving the fastener dispenser from an unclamped configuration, in which the first jaw and the second jaw have a relative spacing on opposite sides of the first layer and the second layer, to a clamped configuration, in which the second jaw is pivoted relative to the first jaw to reduce the relative spacing between the first jaw and the second jaw, thereby holding the first layer relative to the second layer;

and (iv) coupling the elongated member with the collar, thereby clamping the first layer and the second layer between the base end of the elongated member and the collar, thereby fixing the first layer relative to the second layer. In various implementations, at least one of the first layer and second layer are a patient's tissue.

[0024] In various implementations, the method further includes: providing an ejection jaw movably coupled to one of the first or second jaws, the ejection jaw including a protrusion configured to extend toward the track of the one of the first or second jaws to which the ejection jaw is coupled.

[0025] In various implementations, coupling the elongated member with the collar further includes moving the ejection jaw toward the one of the first or second jaws to which it is coupled engaging the protrusion against one of the elongated members or the collar stored in the track of the one of the first or second jaws, thereby urging the one of the elongated member or the collar toward the other of the elongated member or the collar to couple the elongated member and the collar.

[0026] In various implementations, coupling the elongated member with the collar further includes urging the penetrating end of the elongated member through the first layer and the second layer toward the collar and engaging the elongated member with the opening of the collar.

[0027] In various implementations, the method further includes pivoting the elongated member from a storage orientation to a dispensing orientation, wherein in the storage orientation, the elongated member is stored within the second jaw track such that the elongated member central axis is parallel with or forms an acute angle with an extension axis of the second jaw track, and wherein in the dispensing orientation, the elongated member central axis is aligned with an opening of the collar.

[0028] In various implementations, the first layer is a surgical mesh implant, and the second layer is a patient's tissue.

[0029] In various implementations, the surgical mesh implant is a hernia mesh. In various implementations, both the first layer and the second layer are a patient's tissue.

[0030] In some aspects, the techniques described herein relate to a surgical fastener for fixing a first layer to a second layer. The fastener includes: an elongated member extending between a base end and a penetrating end and defining a fastener lumen therein, wherein the fastener defines a plurality of openings extending through the elongated member into the fastener lumen, and wherein the fastener defines a longitudinal axis; and a plurality of anchoring members. Each anchoring member includes a proximal end and a distal end, wherein respective proximal ends of each anchoring members are configured to translate axially toward the penetrating end of the fastener, and wherein axial translation of the respective proximal ends of plurality of anchoring members toward the penetrating end of the fastener causes the anchoring members to move from an undeployed configuration, in which the plurality of anchoring members are disposed entirely within the fastener lumen, to a deployed configuration, in which at least a portion of each anchoring member to move radially outward and extend through a respective opening of the plurality of openings.

[0031] In various implementations, in the deployed configuration, the portion of the respective anchoring member that extends through the respective opening extends at an angle less than or equal to 90 degrees relative to the longitudinal axis of the fastener.

[0032] In various implementations, the plurality of openings are arranged circumferentially around the elongated body adjacent the penetrating end.

[0033] In various implementations, in the undeployed configuration, the plurality of anchoring members extend parallel to the longitudinal axis of the fastener.

[0034] In various implementations, in the deployed configuration, the portion of the respective anchoring member that extends through the respective opening includes the distal end of the anchoring member.

[0035] In various implementations, a plurality of shelves are disposed on an inner surface of the fastener lumen, wherein each respective shelf is disposed adjacent a respective opening of the plurality of openings.

[0036] In various implementations, a plurality of shelves extend radially outward from the longitudinal body, wherein each respective shelf is disposed adjacent a respective opening of the plurality of openings.

[0037] In various implementations, the distal end of each respective anchoring member is fixed to an inner surface of the fastener lumen at the penetrating end of the fastener.

[0038] In various implementations, in the deployed configuration, the portion of the respective anchoring member that extends through the respective opening includes a section of the respective anchoring member disposed between the distal end of the anchoring member and the proximal end of the anchoring member.

[0039] In some aspects, the techniques described herein relate to a method for surgically fixing a first layer to a second layer. The method includes: (i) providing a fastener including: an elongated member extending between a base end and a penetrating end and defining a fastener lumen therein, wherein the fastener defines a plurality of openings extending through the elongated member into the fastener lumen, and wherein the faster defines a longitudinal axis; and a plurality of anchoring members. Each anchoring member includes a proximal end and a distal end. The method further includes: (ii) disposing the fastener within a central lumen of a delivery cannula; (iii) advancing the penetrating end of the fastener through the first layer and through the second layer such that the base end of the fastener abuts the second layer; and (iv) moving respective proximal ends of each anchoring members axially toward the penetrating end of the fastener, thereby moving the anchoring members from an undeployed configuration, in which the plurality of flexile anchoring members are disposed entirely within the fastener lumen, to a deployed configuration, in which at least a portion of each anchoring member to move radially outward through a respective opening, thereby fixing the first layer relative to the second layer.

[0040] In various implementations, advancing the penetrating end of the fastener through the first layer and through the second layer such that the base end of the fastener abuts the second layer includes applying a distally-directed force onto the base of the fastener via a longitudinally extending tubular fastener driver, wherein the fastener driver defines a central lumen.

[0041] In various implementations, moving the respective proximal ends of each anchoring members axially toward the penetrating end of the fastener includes applying a distally-directed force onto the respective proximal ends of

the anchoring member via a longitudinally extending anchor driver, wherein the anchor driver is disposed within the fastener driver.

[0042] In various implementations, at least one of the first layer and second layer are a patient's tissue.

[0043] In various implementations, the first layer is a surgical mesh implant, and the second layer is a patient's tissue.

[0044] In various implementations, the surgical mesh implant is a hernia mesh.

[0045] In various implementations, both the first layer and the second layer are a patient's tissue.

[0046] Additional advantages will be set forth in part in the description which follows or may be learned by practice. The advantages will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0047] FIGS. **1**A-**1**C show various views of an exemplary fastener dispenser for securing a first layer to second layer, in accordance with an illustrative embodiment. FIG. **1**A shows a perspective view of the exemplary fastener dispenser. FIG. **1**B shows a side view of the exemplary fastener dispenser of FIG. **1**A. FIG. **1**C shows a side detail view of the exemplary fastener dispenser of FIG. **1**A.

[0048] FIG. **2**A-**2**B show exemplary fasteners, in accordance with various illustrative embodiments.

[0049] FIGS. **3**A-**3**B show side and top views of an elongated member of a fastener, in accordance with various illustrative embodiments.

[0050] FIGS. **4**A-**4**B show side and top views of a collar of a fastener, in accordance with various illustrative embodiments.

[0051] FIG. **5**A-FIG. **5**E shows side partial cross-sectional views of exemplary fastener dispensers, elongated members, and collars according to various illustrative embodiments, wherein the exemplary fastener dispensers include various exemplary biasing mechanisms for advancing the elongated members and collars along the second jaw and first jaw, respectively.

[0052] FIG. **6** shows a side partial cross-sectional detail view of the exemplary fastener dispenser of FIGS. **1**A-**1**C, in accordance with an illustrative embodiment.

[0053] FIG. **7** shows a side view of an exemplary fastener dispenser coupling an exemplary elongated member and an exemplary collar to form a coupled fastener, thereby securing a surgical mesh to a patient's abdominal wall, in accordance with an illustrative embodiment.

[0054] FIG. **8**A-**8**D show various views of an exemplary fastener dispenser, in accordance with an illustrative embodiment.

[0055] FIG. **9** shows a side partial cross-sectional view of an exemplary fastener dispenser, in accordance with an illustrative embodiment.

[0056] FIGS. **10** shows an exemplary fastener dispenser, in accordance with an illustrative embodiment.

[0057] FIG. **11** shows perspective views of first, second, and ejection jaws of a fastener dispenser, in accordance with an illustrative embodiment.

[0058] FIG. **12** shows a side view of an elongated member of a fastener and a top view of a collar of a fastener, in accordance with an illustrative embodiment.

[0059] FIG. **13** shows a side-perspective view of an exemplary fastener, wherein an elongated member is coupled with a collar, in accordance with an illustrative embodiment.

[0060] FIG. **14** shows a side-perspective view of an exemplary fastener, wherein an elongated member is coupled with a collar, in accordance with an illustrative embodiment.

[0061] FIG. **15** shows various exemplary elongated members and collars, according to various illustrative embodiments.

[0062] FIG. **16** shows various exemplary elongated members according to various illustrative embodiments.

[0063] FIGS. **17**A-**17**C show perspective views of an exemplary fastener, wherein FIG. **17**A shows an exemplary elongated member, FIG. **17**B shows an exemplary collar, and FIG. **17**C shows the elongated member of FIG. **17**A coupled with the collar of FIG. **17**B, in accordance with an illustrative embodiment. FIG. **17**D shows a side view of an exemplary fastener dispenser loaded with the exemplary elongated member and collar of FIGS. **17**A-**17**C, in accordance with an illustrative embodiment.

[0064] FIGS. **18**A-**18**B show side views of an exemplary fastener for securing a first layer to second layer, in accordance with an illustrative embodiment. FIG. **18**A shows the fastener with a plurality of anchoring members in an undeployed configuration. FIG. **18**B shows the fastener and flexible anchoring members in a deployed configuration.

[0065] FIG. **19** shows a perspective view of an exemplary fastener for securing a first layer to second layer, in accordance with an illustrative embodiment and a fastener delivery system, wherein the plurality of anchoring members is in the deployed configuration.

[0066] FIGS. **20**A-**20**C show the exemplary fastener of FIG. **18**A-**18**B in use in an exemplary fastener delivery system. FIG. **20**A shows the exemplary fastener of FIG. **18**A in the exemplary fastener delivery system with the plurality of anchoring members in the undeployed configuration. FIG. **20**B shows the exemplary fastener delivery system moving the exemplary fastener into the first and second layers. FIG. **20**C shows the exemplary fastener delivery system moving the plurality of anchoring members to the deployed configuration.

[0067] FIGS. **21**A-**21**C show side perspective views of an exemplary fastener for securing a first layer to second layer, in accordance with an illustrative embodiment, and a fastener delivery system. FIG. **21**A shows the fastener within the fastener delivery system with the plurality of anchoring members in the undeployed configuration. FIG. **21**B shows the fastener moved into the first and second layers with the proximal ends of the plurality of anchoring members angled radially inward. FIG. **21**C shows the plurality of anchoring members in the deployed configuration.

[0068] Various objects, aspects, features, and advantages of the disclosure will become more apparent and better understood by referring to the detailed description taken in conjunction with the accompanying drawings, in which like reference characters identify corresponding elements throughout. In the drawings, like reference numbers generally indicate identical, functionally similar, and/or structurally similar elements.

DETAILED DESCRIPTION

Example System

[0069] In one aspect, provided herein is a surgical fastening system for fixing a first layer (e.g., an implant) to a second layer (e.g., a "target tissue" such as a hernia defect site in a patient). In some implementations, the surgical fastening system includes a fastener dispenser and a fastener. As used herein, an implant may include a soft implant, such as a surgical mesh. Throughout this disclosure, surgical meshes may also be referred to as mesh implants, mesh prostheses, or repair meshes. As used herein, these terms are interchangeable. Furthermore, in the interest of brevity, this disclosure often refers to the first layer as an implant and to the second layer as a patient's tissue. However, this disclosure also contemplates use of the surgical fastening system to fix other layers to one another. For example, the surgical fastening system may be used to fix one layer of tissue to another layer of tissue, fix one layer of an implant to another layer of another implant, or fix one layer of an implant to another layer of the same implant.

Example Fastener Dispenser

[0070] FIG. **1**A-**1**C show an exemplary fastener dispenser **100** (shown as **100***a*) for dispensing a fastener **200** (shown as **200***a*) to fixate tissue and/or implant according to various implementations.

[0071] As shown in the example of FIG. **1**A, the fastener dispenser **100** includes a first jaw **102** (shown as **102***a*), which includes a proximal end **104** (shown as **104***a*) and a distal end **106** (shown as **106***a*). A first jaw track **108** (shown as **108***a*) extends between the proximal end **104** and the distal end **106**. The fastener dispenser **100** also includes a second jaw **110** (shown as **110***a*), which includes a proximal end **112** (shown as **112***a*) and a distal end **114** (shown as **114***a*). A second jaw track **116** (shown as **116***a*) extends between the proximal end **112** and the distal end **114**. As provided herein, the fastener **200** further includes an elongated member **202** and a collar **210**. In some implementations, the elongated member **202** is stored within the second jaw track **116**, and the collar **210** is stored within the first jaw track **108**.

[0072] In FIG. **1**B and further shown in detail in FIG. **1**C, the proximal end **104** of the first jaw **102** is pivotably coupled to the proximal end **112** of the second jaw **110**. In use, the coupling allows the fastener dispenser **100** to move between an unclamped configuration, in which the first jaw **102** and the second jaw **110** have a relative spacing on opposite sides of the first layer and the second layer (e.g., opposite sides of the implant and patient's tissue), to a clamped configuration, in which the second jaw **110** is pivoted relative to the first jaw **102** to reduce the relative spacing between the first jaw **102** and the second jaw **110**. In this configuration, the first jaw **102** and the second jaw **110** are forced together and exert a clamping force to hold the first layer relative to the second layer (e.g., hold the implant relative to the patient's tissue). In some implementations, the relative spacing in the unclamped configuration may be adjusted to accommodate variations in the second layer thickness (e.g., patient tissue thickness). In such implementations, a sliding adjustment mechanism may be integrated into the coupling of the first jaw **102** and second jaw **110** to adjust their relative spacing such that the spacing between the first jaw **102** and second jaw **110** in the clamped configuration is also adjusted.

[0073] Ejection Jaw. As shown in FIG. **1**A, the fastener dispenser **100** further includes an ejection jaw **118** (shown as **118***a*) having a proximal end **120** (shown as **120***a*) and a distal end **122** (shown as **122***a*). The ejection jaw **118** is movably coupled to the second jaw **110**. Specifically, the proximal end **120** of the ejection jaw **118** is pivotably coupled to the proximal end **112** of the second jaw **110**. As shown in FIG. **1**C, the ejection jaw **118** includes a protrusion **124** (shown as **124***a*) that extends from the distal end of the ejection jaw **118** toward the second track **116** of the second jaw **110**. Specifically, the ejection jaw **118** shown is pivotably coupled to the second jaw **110** such that moving the ejection jaw **118** toward the second jaw **110** engages the protrusion **124** against the elongated member **202** stored in the second track **116** such that the protrusion **124** exerts a force upon the elongated member **202**. Accordingly, moving the ejection jaw **118** toward the second jaw **110** causes the protrusion **124** to urge the elongated member **202** toward the collar **210** stored in the first jaw track **108** of the first jaw **102**, thereby coupling the elongated member **202** with the collar **210** to form a coupled fastener **200**. In other implementations, the protrusion **124** may extend from another aspect of the ejection jaw **118** other than the distal end **122**, so long as the protrusion **124** engages the elongated member **202** and urges it toward the collar **210** as the ejection jaw **118** moves toward the second jaw **110**.

[0074] While the ejection jaw **118** shown is movably coupled to the second jaw **110**, this is not the only possible configuration. For example, in other configurations, the ejection jaw **118** may instead be movably coupled to the first jaw **102**. In such implementations, the protrusion **124** may extend toward the first track **108** of the first jaw first jaw **102**. Accordingly, the ejection jaw **118** may be instead moved toward the first jaw **102** to engage the protrusion **124** against the collar **210** stored in the first jaw track **108** such that the protrusion **124** exerts a force upon the collar **210**, thereby urging the collar **210** toward the elongated member **202** stored in the second jaw track **116** of the second jaw **110** to form a coupled fastener **200**.

[0075] Furthermore, while the ejection jaw **118** shown in FIG. **1**C is pivotably coupled to the second jaw **110**, the ejection jaw **118** may be movably coupled to the first jaw **102** or second jaw **110** in any configuration that allows the protrusion **124** to exert force on the elongated member **202** or collar **210**, depending on which jaw the ejection jaw **118** is coupled to.

[0076] In some implementations, the protrusion **124** is not necessarily associated with an ejection jaw **118** or any other additional jaw, and may be any element that can be actuated to act upon at least one of the elongated member **202** or collar **210** so as to dispense the elongated member **202** or collar **210** from the second track **116** or first track **108**, respectively, and move the elongated member **202** or collar **210** toward the other of the elongated member **202** or collar **210** to form a coupled fastener **200**.

[0077] Biasing Member. In FIG. **1**C, the ejection jaw **118** includes a biasing member **126** (shown as **126***a*) configured to urge the ejection jaw **118** toward the second jaw **110**. In other implementations, the biasing member **126** may be configured to urge the ejection jaw **118** toward the first jaw **102**. In various implementations, the biasing member **126**

may further act upon one or more of the elongated member **202** or collar **210** stored within a respective first track **108** or second track **116**.

[0078] In various implementations provided herein, the first jaw **102** may be configured for positioning posterior to the second layer (e.g., patient's target tissue), and the second jaw **110** may be configured for positioning anterior to the second layer (e.g., patient's target tissue). In implementations utilizing an ejection jaw **118**, the ejection jaw **118** may thus also be configured for positioning anterior to both the second layer (e.g., the patient's target tissue) and the second jaw **110**. In such implementations, the first jaw **102** may also be referred to as a "lower" jaw, the second jaw **110** may also be referred to as a "middle" jaw, and the ejection jaw **118** may also be referred to as an "upper" jaw, according to their relative orientations in use.

[0079] However, in various other implementations, the first jaw **102** may be configured for positioning anterior to the second layer (e.g., patient's target tissue), and the second jaw **110** may be configured for positioning posterior to the second layer (e.g., patient's target tissue). Furthermore, in implementations utilizing an ejection jaw **118**, the ejection jaw **118** may be configured for positioning either anterior or posterior to the second layer (e.g., patient's target tissue) and thus anterior or posterior to one or both of the first jaw **102** and/or second **110** jaw. Accordingly, the first jaw **102**, second jaw **110**, and ejection jaw **118** may be positioned relative to one another in various combinations of orientations within the spirit of this disclosure. Thus, relative terms including "lower," "middle," and "upper," as occasionally used herein denote arrangements characteristic of some, but not all, implementations.

[0080] In various implementations, one or more components of the fastener dispenser **100** may be formed from a polymeric material. In some implementations, one or more components of the fastener dispenser **100** may be formed from a metallic material, such as stainless steel.

Example Fasteners

[0081] FIGS. **2**A-2B show exemplary fasteners **200** (e.g., a "rivet" or a "tack", shown as **200***a* and **200***b*). In the example shown in FIG. **2**A, the fastener **200** includes an elongated member **202** (shown as **202***a* and **202***b*) and a collar **210** (shown as **210***a* and **210***b*). The elongated member **202** extends between a base end **204** (shown as **204***a* and **204***b*) and a penetrating end **206** (shown as **206***a* and **206***b*) and defines an elongated member central axis **208** (shown as **208***a* and **208***b*).

[0082] In FIG. **2**A, the elongated member **202** includes a radially extending engagement feature **214** (shown as **214***a*). Specifically, FIG. **2**A shows an elongated member **202** with a radially outwardly extending engagement feature **214***a* in the shape of a ridge. In some implementations, the radially outwardly extending engagement feature **214***a* may extend around all or only a part of the elongated member **202**. Furthermore, the radially outwardly extending engagement feature **214***a* may include various other geometries configured to facilitate one-way coupling of the elongated member **202** with the collar **210**. For example, other radially outwardly extending engagement feature **214***a* geometries include ribs, wings, bumps, or dimples extending radially outward from the elongated member **202**.

[0083] In FIG. **2**B, the radially extending engagement feature **214** (shown as **214***b*) of the elongated member **202** extends radially inward. Specifically, the exemplary implementation shown in FIG. **2**B includes a circumferential groove defined in the elongated member **202**. In some implementations, the radially inwardly extending engagement feature **214***b* may extend around all or only a part of the elongated member **202**. In some implementations, the radially inwardly extending feature may be defined by various negative space geometries (e.g., impressions) configured to facilitate the one-way coupling of the elongated member **202** with the collar **210**. Various implementations of the elongated member **202** may include a radially inwardly extending feature **214***b* with or without the addition of a radially outwardly extending feature **214***a*.

[0084] In both FIG. **2**A and FIG. **2**B, the collar **210** defines an opening **212** (shown as **212***a* and **212***b*) configured to receive the penetrating end **206** of the elongated member **202**. In some implementations, the collar **210** further includes a radially extending engagement feature **216** (shown as **216***a* and **216***b*) configured to couple with the radially extending engagement feature **214** of the elongated member **202**. Accordingly, the radially extending engagement feature **216** of the collar **210** may be radially inwardly extending or radially outwardly extending.

[0085] FIG. **3**A and FIG. **3**B show an exemplary elongated member **202** (shown as **202***c*), according to some implementations (side view and top view). As shown in FIG. **3**A, the engagement feature **214** (shown as **214***c*) of the elongated member **202** may include a plurality of engagement features **214** spaced axially along the elongated member **202**. Specifically, FIG. **3**A shows a plurality of radially outwardly extending engagement features **214** formed as ridges. Each ridge is oriented parallel to the adjacent ridge. Furthermore, the elongated member **202** shown in FIG. **3**A defines a set of three flutes **300** (shown as **300***c*) extending along the length of the elongated member **202**. As shown, the flutes **300** are spaced equidistant from each other and rotate slightly about the central axis **208** (shown as **208***c*). Other implementations of the elongated member **202** may define a different number of flutes **300** or flutes **300** arranged with different relative spacing about the elongated member **202**. Furthermore, in other implementations, the flutes **300** may be rotated more or less about the central axis **208**.

[0086] FIG. **4**A and FIG. **4**B show an exemplary collar **210** (shown as **210***c*), according to some implementations. As shown in FIG. **4**B, the collar **210** defines a plurality of radially inwardly extending (i.e., protruding toward the opening **212***c*) engagement features **216** (shown as **216***c*) configured to engage between the radially outwardly extending engagement features **214** (e.g., ridge) of the elongated member **202** shown in FIG. **3**A and FIG. **3**B.

[0087] The fastener **200** provided herein may be configured to accommodate various second-layer thicknesses (e.g., patient tissue thicknesses). For example, the length of the elongated member **202** may be sized to span the combined thickness of the first layer and the second layer (e.g., the combined thickness of the patient's tissue and the implant). For example, the elongated member **202** shown in FIG. **3**A has a total length of 12 mm. As provided herein and shown in FIG. **3**A, the engagement feature **214** of the elongated member **202** may include a plurality of radially extending engagement features **214** spaced axially along the elongated member **202**. In addition to facilitating coupling between the elongated member **202** and the collar **210**, the plurality of radially extending engagement features axially spaced along

the **202** allow the collar **210** to be coupled to the elongated member **202** at any one of several axial positions along the length of the elongated member **202**, depending on the thickness of the intervening second layer (e.g., patient tissue).

[0088] In the exemplary implementations shown in FIGS. **2**A-**2**B and FIG. **3**A, the elongated member **202** is tapered toward the penetrating end **206**. In some implementations, the taper forms an angle of 10 to 20 degrees from the central axis **208** of the elongated member **202**. In other implementations, the taper forms an angle of 30 to 40 degrees from the central axis **208** of the elongated member **202**. Furthermore, the penetrating end **206** is configured to narrow to a tip that is capable of piercing both the first layer and the second layer (e.g., piercing both the implant and the patient's tissue). In some exemplary implementations, the penetrating end **206** of the elongated member **202** may have a diameter of 15 microns. However, in other implementations, the elongated member **202** may not be tapered.

Elongated Member in Cartridge With Pivot Operation

[0089] In some implementations, and as shown in FIG. **5**A and **5**B, the elongated member **202** is stored, in a cartridge, within the second jaw track **116** such that the elongated member **202** central axis **208** is parallel with or forms an acute angle with an extension axis of the second jaw track **116**. In such implementations, the second jaw **110** further includes a pivoting feature configured to pivot the elongated member **202** when the elongated member **202** is dispensed such that the penetrating end **206** of the elongated member **202** extends toward the collar **210**. Storing the elongated member **202** in this configuration allows for a reduction in the thickness of the second jaw **110**, thereby overcoming the limited operating space available posterior to both the first layer and the second layer (e.g., posterior to both the implant and the target tissue). Thus, reducing the thickness of the second jaw **110** allows the second jaw **110** to be positioned posterior to the second layer (e.g., target tissue) as the "lower" jaw. In such implementations, the pivoting feature enables the elongated member **202** to be stored parallel or at an acute angle relative the extension axis of the second jaw track **116** and then pivot to be perpendicular with the second jaw track **116** in an orientation such that the penetrating end **206** extends anteriorly.

[0090] Orientations. As provided herein, the first jaw **102** and second jaw **110** may be configured for positioning in various orientations relative to the first layer and the second layer (e.g., relative to the implant and the patient's target tissue). In both FIG. **5**A and FIG. **5**B, the first jaw **102** and second jaw **110** (shown as **102***b,c* and **110***b,c*) are configured such that, in use, the first jaw **102** would be positioned anterior to both the first layer and the second layer (e.g., anterior to both the implant and the patient's target tissue), and the second jaw **110** would be positioned posterior to both the first layer and the second layer (e.g., posterior to both the implant and the patient's target tissue). Conversely, in both FIG. **5**C and FIG. **5**D, the first jaw **102** and second jaw **110** (shown as **102***d,e* and **110***d,e*) are configured such that, in use, the first jaw **102** would be positioned posterior to both the first layer and second layer (e.g., posterior to both the implant and the patient's target tissue), and the second jaw **110** would be positioned anterior to both the first layer and the second layer (e.g., anterior to both the implant and the patient's target tissue).

Example Biasing Members

[0091] FIG. **5**A shows fastener dispenser **100** (shown as **100***b*). As shown, the first jaw **102** (shown as **102***b*) includes a first biasing member **500** (shown as **500***a*) that urges the collar **210** (shown as **210***d*) toward the distal end **106** (shown as **106***b*) of the first jaw **102**. As shown, the collar **210** includes a plurality of collars **210** (shown as **210***d*). In such implementations, the first biasing member **500** progressively advances the plurality of collars **210** toward the distal end **106** of the first jaw **102** as successive collars **210** are dispensed from the fastener dispenser **100**. In some implementations, the biasing member **126** may also act as the first biasing member **500**. For example, FIG. **5**B shows fastener dispenser **100** (shown as **100***c*) with the biasing member **126** (shown as **126***c,* **500***b*) exerting a force on the plurality of collars **210** (shown as **210***e*), urging the plurality of collars **210** toward the distal end **106** of the first jaw **102**. Of course, the relative orientation of the first jaw **102** (and accompanying first biasing member **500**) and second jaw **110** (and accompanying second biasing member **502**) be reversed relative to FIG. **5**A, as shown, for example, in the fastener dispenser **100** (shown as **100***d*) in FIG. **5**C.

[0092] As shown in FIGS. **5**A and **5**C, the second jaw **110** (shown as **110***b*) includes a second biasing member **502** (shown as **502***a*) that urges the elongated member **202** toward the distal end **114** of the second jaw **110**. As shown, the elongated member **202** (shown as **202***d*) includes a plurality of elongated members **202**. In such implementations, the second biasing member **502** progressively advances the plurality elongated members **202** toward the distal end **114** (shown as **114***b*) of the second jaw **110** as successive elongated members **202** are dispensed from the fastener dispenser **100**. In some implementations, the biasing member **126** may also act as the second biasing member **502**.

[0093] FIG. **5**D shows fastener dispenser **100** (shown as **100***e*) where the relative orientation of the first jaw **102** (and accompanying first biasing member **500**) and second jaw **110** (and accompanying second biasing member **502**) are reversed relative to FIG. **5**A. For example, FIG. **5**D shows the biasing member **126** (shown as **126***e,* **502***d*) exerting a force on the plurality of elongated members **202**, urging the plurality of elongated members **202** toward the distal end **114** of the second jaw **110**.

Example Cutting Blade

[0094] In various implementations, the fastener **200** may further include a cutting blade **504**. As shown in FIG. **5**A, the cutting blade **504** (shown as **504***a*) is coupled to the first jaw **102**. As provided herein, the cutting blade is configured to remove a portion of the penetrating end **206** of the elongated member **202** on a side of the collar **210** opposite the base end **204** of the elongated member **202** after the elongated member **202** is coupled to the collar **210**. Specifically, the cutting blade shown in FIG. **5**A is configured to cut the penetrating end **206** after the penetrating end **206** passes anteriorly through the first layer and the second layer (e.g. anteriorly through the implant and the patient's tissue) and is coupled with the collar **210**. As shown for example in FIG. **5**C, the

cutting blade **504** (shown as **504***b*) may be oriented differently relative to the orientation of cutting blade **504***a*, depending on the orientation of the first jaw **102**. In other implementations, the cutting blade may be coupled to the first jaw **102** such that it can cut the penetrating end **206** after the penetrating end **206** passes posteriorly through the first layer and the second layer (e.g. posteriorly through the implant and the patient's tissue) and is coupled with the collar **210**. Although the cutting blade shown in FIG. **5**A is disposed within the first jaw **102**, in some implementations, the cutting blade may be disposed adjacent to the first jaw **102**, such as between the first jaw **102** and the second jaw **110**.

Example Reduced Sized Device

[0095] In some implementations, the elongated member **202** is stored within the second jaw track **116** such that the elongated member **202** central axis **208** is parallel with or forms an acute angle with an extension axis of the second jaw track **116**. For example, FIG. **5**E shows the elongated member **202** (shown as **202***h*) being stored such that the central axis **208** is parallel with the extension axis of the second jaw track **116** of the second jaw **110** (shown as **110***f*). In such implementations, the second jaw **110** further includes a pivoting feature **506** (shown as **506***a*) configured to pivot the elongated member **202** when the elongated member **202** is dispensed such that the penetrating end **206** of the elongated member **202** extends toward the collar **210**. As shown in FIG. **5**E, for example, advancing the elongated member **202** along the second jaw track **116** toward the distal end **114** (shown as **114***c*) causes the elongated member **202** to contact the pivoting feature **506**. In some examples, including the illustrated implementation, the pivoting feature **506** contacts and catches a portion of the base end **204** of an elongated member, thereby pivoting the elongated member **202** 90° from an orientation parallel with the extension axis of the second jaw track **216** to an orientation perpendicular to the extension axis of the second jaw track **216**. As shown, pivoting the elongated member **202** aligns the elongated member **202** with the opening **212** of collar **210** (shown as **210***h*). The pivoting feature **506** shown in FIG. **5**E includes an angled wedge-shaped protrusion extending from an inner aspect of the second jaw **110**. However, in other implementations, the pivoting features **506** may include other geometries, such as bumps or shoulders that extend toward the elongated member **202**. In still yet other implementations, the pivoting feature **506** may include a hinge configured to rotate the elongated member **202** as described herein.

[0096] Storing the elongated member **202** in this fashion allows for a reduction in the thickness of the second jaw **110**, thereby overcoming the limited operating space available posterior to both the first layer and the second layer (e.g., posterior to both the implant and the target tissue). Thus, reducing the thickness of the second jaw **110** allows the second jaw **110** to be positioned posterior to the second layer (e.g., target tissue) as the "lower" jaw. In such implementations, the pivoting feature enables the elongated member **202** to be stored parallel or at an acute angle relative the extension axis of the second jaw track **116** and then pivot to be perpendicular with the second jaw track **116** in an orientation such that the penetrating end **206** extends anteriorly.

Example Cartridges for Collar

[0097] In various implementations, the surgical fastening system further includes a collar cartridge configured to store and dispense the collar **210**. In some implementations the collar cartridge is configured to store a plurality of collars **210**. In some implementations, the first jaw track **108** is configured to receive the collar cartridge. In some implementations, the first biasing member is configured to urge the collar cartridge toward the distal end **106** of the first jaw **102**. In some implementations, the collar cartridge includes an opening through which the protrusion **124** may engage the collar **210** and urge the collar **210** out of the collar cartridge and toward the elongated member **202**.

[0098] In various implementations, the surgical fastening system further includes an elongated member cartridge configured to store and dispense the elongated member **202**. In some implementations the elongated member cartridge is configured to store a plurality of elongated members **202**. In some implementations, the second jaw track **116** is configured to receive the elongated member cartridge. In some implementations, the second biasing member is configured to urge the elongated member cartridge toward the distal end **114** of the second jaw **110**. In some implementations, the elongated member cartridge includes an opening through which the protrusion **124** may engage the elongated member **202** and urge the elongated member **202** out of the elongated member cartridge and toward the collar **210**.

Dispensing Blade (Elongated Member as an Extension of Fastener Dispenser)

[0099] In various implementations, the elongated member **202** may be formed integrally with (i.e., from the same bulk of material) the second jaw **110** and extend toward the first jaw **102**. Such implementations may include a plurality of elongated members **202** formed integrally with the second jaw **110**. In such implementations, the elongated member **202** dispensing the elongated member **202** from the second jaw **110** involves physically severing the elongated member **202** from the first jaw **102**. Accordingly, the fastener dispenser **100** may further include a dispensing blade configured to remove the elongated member **202** from the second jaw **110**.

Example Housing

[0100] Referring generally to the figures, FIG. **1**A and FIG. **1**B show a fastener dispenser **100** including a housing **128** (shown as **128***a*). FIG. **6** shows a detailed partial cross-sectional view of the housing **128** shown in FIG. **1**B. As shown in FIG. **6**, the housing **128** includes a first actuator **600** (shown as **600***a*) movable between a first unengaged position and a first engaged position. Movement of the first actuator **600** between the first unengaged position and the first engaged position changes the relative spacing between the first jaw **102** and the second jaw **110** such that the fastener dispenser **100** moves between the unclamped configuration and the clamped configuration, respectively. In some implementations, moving the first actuator **600** from the first unengaged position to the first engaged position reduces the relative spacing between the first jaw **102** and the second jaw **110**. As provided herein, the first actuator **600** urges the first jaw **102** and second jaw **110** together so that the jaws may exert a clamping force to hold the first layer and the second layer (e.g., hold the implant relative to the

patient's tissue). Conversely, in some implementations, moving the first actuator **600** from the first engaged position to the first unengaged position increases the relative spacing between the first jaw **102** and the second jaw **110**, thereby releasing the first layer and/or second layer from the first jaw **102** and second jaw **110**.

[0101] In various implementations, the housing **128** further includes a second actuator **602** (shown as **602***a*) movable between a second unengaged position and a second engaged position. Movement of the second actuator **602** between the second unengaged position and the second engaged position changes the relative spacing between the ejection jaw **118** and one of the first jaw **102** or the second jaw **110**. As provided herein, the second actuator **602** urges the ejection jaw **118** toward one of the elongated member **202** or the collar **210** stored within the second jaw **110** or first jaw **102**, respectively. Specifically, moving the second actuator **602** between the second unengaged position and the second engaged position engages the protrusion **124** against one of the elongated member **202** or the collar **210** such that the protrusion **124** exerts a force upon the elongated member **202** or collar **210**. Accordingly, moving the second actuator **602** between the second unengaged position and the second engaged position urges one of the elongated member **202** or the collar **210** toward the other of the elongated member **202** or the collar **210** to couple the elongated member **202** and the collar **210**, thereby forming a coupled fastener **200**. Furthermore, in various implementations, the force exerted by the protrusion **124** on the elongated member **202** or the collar **210** also dispenses the elongated member **202** or the collar **210** from the second jaw **110** or first jaw **102**, respectively.

Example Handle

[0102] As shown in the example of FIG. **6**, the housing **128** further includes a handle **130** (shown as **130***a*) configured to move the first actuator **600** between the first unengaged position and the first engaged position.

[0103] In some implementations, the handle **130** is further configured to move the second actuator **602** between the second unengaged position and the second engaged position. As such, in some implementations, the first actuator **600** and the second actuator **602** are sequentially moved by a single handle **130** as the handle **130** is engaged. For example, in some implementations, engagement of the handle **130** between a first position and a second position moves the first actuator **600** between the first unengaged position and the first engaged position and engagement of the handle **130** between a second position and a third position moves the second actuator **602** between the second unengaged position and the second engaged position. In some implementations, a second handle or other input feature may be engaged to actuate one of the first actuator **600** or second actuator **602**.

[0104] As shown, for example, in FIG. **1**A, the surgical fastening system further includes a hollow shaft **132** (shown as **132***a*) extending from the housing **128** to the fastener dispenser **100**. The hollow shaft **132** is sized and configured to allow components of the first actuator **600** and second actuator **602** to move therewithin. As shown, the hollow shaft **132** is fixed to the first jaw **102**. Specifically, the first jaw **102** is both rotationally and pivotably fixed to the hollow shaft **132**. Accordingly, tilting or maneuvering the housing **128** causes corresponding tilting or maneuvering of the first jaw **102**. Furthermore, the position of the first jaw **102** relative to the hollow shaft **132** is maintained when the first actuator **600** is moved between the first unengaged position and the first engaged position. Instead, it is the second jaw **110** that moves relative to the first jaw **102** and the hollow shaft **132** as the fastener dispenser **100** moves between unclamped and clamped configurations.

[0105] However, in other implementations, the hollow shaft **132** may be fixed to the second jaw **110**. In such implementations, the second jaw **110** is both rotationally and pivotably fixed to the hollow shaft **132**. Accordingly, tilting or maneuvering the housing **128** causes corresponding tilting or maneuvering of the second jaw **110**. Furthermore, the position of the second jaw **110** relative to the hollow shaft **132** is maintained when the first actuator **600** is moved between the first unengaged position and the first engaged position. Instead, it is the first jaw **102** that moves relative to the second jaw **110** and the hollow shaft **132** as the fastener dispenser **100** moves between unclamped and clamped configurations.

Connect/Disconnect Operation

[0106] In various implementations, the fastener dispenser **100** is detachably coupled to the hollow shaft **132** for disposal or replacement. In some implementations, the hollow shaft **132** is specifically detachably coupled to the first jaw **102**. In other implementations, the hollow shaft **132** is specifically detachably coupled to the second jaw **110**.

Example Clinical Applications

[0107] The surgical fastening system provided herein may be used in various minimally invasive and open surgical procedures. In various use cases provided herein, the surgical fastening system is employed to secure a surgical mesh corresponding to a first layer) to a target tissue (corresponding to a second layer) in the course of surgical hernia repair, such as the repair of ventral and incisional hernias. In such uses, the surgical mesh is a hernia mesh, and the target tissue corresponds to a hernia defect site. However, the surgical fastening system may be utilized to secure other soft implants to other tissues or certain layers of tissue to other layers of tissue in the course of other surgical procedures. In some implementations, the implant is formed from an absorbable material, such as synthetic polyester copolymer derived from lactic and glycolic acid. In other implementations, the implant may be nonabsorbable.

[0108] In various other use cases, the surgical fastening system may be employed to fix one segment of patient tissue (corresponding to a first layer) to another segment of patient tissue (corresponding to a second layer).

[0109] And yet other use cases, the surgical fastening system may be employed to fix one implant (corresponding to a first layer) to another implant (corresponding to a second layer) or one segment of an implant (corresponding to a first layer) to another segment of the same implant (corresponding to a second layer).

[0110] In use, the elongated member **202** is configured to engage with the opening **212** of collar **210** to form a coupling therebetween, thereby forming a two-component coupled fastener **200**. As provided herein, the fastener **200** may be implemented in a surgical fastening system that includes a fastener dispenser **100** according to any of the implementations provided herein, wherein the fastener **200** is stored in and dispensed from the fastener dispenser **100**.

Thus, in some implementations, the elongated member **202** and collar **210** of the fastener **200** are coupled by the fastener dispenser **100**.

Example Methods of Use

[0111] In another aspect, this disclosure relates to a method of fixing a first layer (e.g., an implant) to a second layer (e.g., a patient's tissue). In various implementations, the method includes: (i) positioning a first jaw **102** or a second jaw **110** of a fastener dispenser **100** posterior to a patient's tissue and an implant; (ii) positioning the other of the first jaw **102** or second jaw **110** anterior to the first and second layers; (iii) reducing a relative spacing between the first jaw **102** and the second jaw **110** so as to clamp the first layer and second layer together and hold the first layer and second layer relative to each other; (iv) penetrating the first layer and second layer with an elongated member **202** stored in the second jaw **110**; and (v) coupling the elongated member **202** with a collar **210** stored in the first jaw **102** to form a coupled fastener **200** spanning the thickness of the first layer and the second layer, thereby fixing the first layer relative to the second layer. For example, the method may entail fixing the implant relative to the patient's tissue.

[0112] The method further includes dispensing the elongated member **202** and collar **210** from the second jaw **110** and first jaw **102**, respectively. In some implementations, the steps of dispensing the elongated member **202** and/or collar **210** may occur after the coupled fastener **200** is formed. In such cases, the elongated member **202** and collar **210** are concurrently dispensed from the second jaw **110** and the first jaw **102** as a coupled fastener **200**. In other implementations, the elongated member **202** and/or collar **210** may be dispensed from the second jaw **110** and first jaw **102**, respectively, prior to coupling.

[0113] In various implementations, the method of dispensing at least one of the elongated member **202** and collar **210** from the second jaw **110** and first jaw **102**, respectively, includes engaging a protrusion **124** against the elongated member **202** or the collar **210**, thereby urging the elongated member **202** or the collar **210** out of the second jaw track **116** or first jaw track **108** in which it is stored In various implementations, the protrusion **124** extends from an ejection jaw **118** that is movably coupled to one of the first jaw **102** or second jaw **110**. In such implementations, the protrusion **124** extends toward the track of the first jaw **102** or second jaw **110**, to which the ejection jaw **118** is coupled.

[0114] In various implementations, the method includes: (i) providing a fastener dispenser **100** including: a first jaw **102** having a proximal end **104** and a distal end **106**, the first jaw **102** defining a first jaw track **108** therein extending between the proximal end **104** and the distal end **106**; a second jaw **110** having a proximal end **112** and a distal end **114**, the second jaw **110** defining a second jaw track **116** therein extending between the proximal end **112** and the distal end **114**; (ii) providing a fastener **200** including: an elongated member **202** and a collar **210**, the elongated member spanning the combined thickness of the first layer and the second layer (e.g., the combined thickness of the patient's tissue and the implant), wherein the elongated member **202** extends between a base end **204** and a penetrating end **206** and defines an elongated member central axis **208**; wherein the collar **210** defines an opening **212** configured to receive the penetrating end **206** of the elongated member **202**; and wherein the elongated member **202** is stored within the second jaw track **216** and the collar **210** is stored within the first jaw track **216**; (iii) positioning the fastener dispenser **100** so that the first layer and second layer (e.g., the implant and the patient's tissue) are disposed between the first jaw **102** and the second jaw **110**; (iv) moving the fastener dispenser **100** from an unclamped configuration, in which the first jaw **102** and the second jaw **110** have a relative spacing on opposite sides of the first and second layer (e.g., opposite sides of the implant and patient's tissue), to a clamped configuration, in which the second jaw **110** is pivoted relative to the first jaw **102** to reduce the relative spacing between the first jaw **102** and the second jaw **110**, thereby holding the first layer relative to the second layer (e.g., the implant relative to the patient's tissue); and (v) coupling the elongated member **202** with the collar **210**, thereby clamping the first layer and the second layer (e.g., clamping the implant and the patient's tissue) between the base end of the elongated member **202** and the collar **210**, thereby fixing the first layer relative to the second layer (e.g., fixing an implant relative to the patient's tissue).

[0115] Accordingly, moving the fastener dispenser **100** between the unclamped and clamped configurations involves moving the first jaw **102** and second jaw **110** relative to one another. Specifically, moving the fastener dispenser **100** from the clamped configuration to the unclamped configuration involves reducing a relative spacing between the first jaw **102** and the second jaw **110**. FIG. **7** shows an exemplary fastener dispenser **100** (shown as **100***f*) in the clamped configuration. As shown, in the clamped configuration, the second jaw **110** is pivoted relative to the first jaw **102** such that the first jaw **102** and second jaw **110** exert clamping forces toward one another to hold the patient's tissue and implant therebetween. In the unclamped configuration, the first jaw **102** and the second jaw **110** do not exert forces toward one another, thereby allowing relative movement of the fastener dispenser **100**, the patient's tissue, and the implant (i.e., before fastening) or allowing the release of the fixed implant and patient's tissue (i.e., after forming the coupled fastener **200**).

[0116] As shown, for example, in FIG. **6**, a first actuator **600** (shown as **600***a*) is provided in the housing **128** to move the fastener dispenser **100** between the clamped configuration and the unclamped configuration. As provided herein, moving the first actuator **600** from a first unengaged position to a first engaged position reduces the relative spacing between the first jaw **102** and the second jaw **110**, thereby moving the fastener dispenser **100** from the unclamped configuration to the clamped configuration. As provided herein, the first actuator **600** urges the first jaw **102** and second jaw **110** together so that the first jaw **102** and second jaw **110** exert clamping forces to hold the implant relative to the patient's tissue. Thus, the first actuator **600** is configured to generate sufficient force to maintain the fastener dispenser **100** in the clamped configuration.

[0117] The method further includes dispensing the elongated member **202** and collar **210** from the second jaw **110** and first jaw **102**, respectively. In some implementations, the steps of dispensing the elongated member **202** and/or collar **210** may occur after the coupled fastener **200** is formed. In such cases, the elongated member **202** and collar **210** are concurrently dispensed from the second jaw **110** and the first jaw **102** as a coupled fastener **200**. In other implementations,

the elongated member **202** and/or collar **210** may be dispensed from the second jaw **110** and first jaw **102**, respectively, prior to coupling.

[0118] In various implementations, the method of dispensing at least one of the elongated member **202** and collar **210** from the second jaw **110** and first jaw **102**, respectively, includes engaging a protrusion **124** against the elongated member **202** or the collar **210**, thereby urging the elongated member **202** or the collar **210** out of the second jaw track **116** or first jaw track **108** in which it is stored. In various implementations, the protrusion **124** extends from an ejection jaw **118** that is movably coupled to one of the first jaw **102** or second jaw **110**. In such implementations, the protrusion **124** extends toward the track of the first jaw **102** or second jaw **110**, to which the ejection jaw **118** is coupled.

[0119] In various implementations, urging the elongated member **202** and collar **210** toward each other includes penetrating the elongated member **202** through the relevant layers and engaging the collar **210** with the elongated member **202** such that the elongated member **202** is received within an opening **212** of the collar **210**. As provided above, the collar **210** may be indexed at several locations along the length of the elongated member **202** to generate optimal pressure on the layers.

[0120] In various implementations, coupling the elongated member **202** with the collar **210** further includes moving the ejection jaw **118** toward the first jaw **102** or second jaw **110** to which it is coupled to engage the protrusion **124** against the elongated member **202** or collar **210** stored in the track of the first jaw **102** or second jaw **110**. Thus, the protrusion **124** urges the elongated member **202** or collar **210** toward the other of the elongated member **202** or collar **210** to couple the elongated member **202** and collar **210**. In some implementations, the protrusion **124** is not necessarily associated with an ejection jaw **118** or any other additional jaw. In such implementations, the protrusion **124** may be any element that can be actuated to act upon at least one of the elongated member **202** or collar **210** so as to dispense the elongated member **202** or collar **210** from the second track **116** or first track **108**, respectively, and move the elongated member **202** or collar **210** toward the other of the elongated member **202** or collar **210** to form a coupled fastener **200**.

[0121] In various implementations, as shown, for example, in FIG. **6**, a second actuator **602** is provided in the housing **128** to move the fastener dispenser **100** between a second unengaged position and a second engaged position to engage the protrusion **124** against the he elongated member **202** or the collar **210**, thereby urging the elongated member **202** or the collar **210** toward the other of the elongated member **202** or collar **210** to couple the elongated member **202** and the collar **210**, thereby forming a coupled fastener **200**. Specifically, moving the second actuator **602** between the second unengaged position and the second engaged position engages the protrusion **124** against one of the elongated member **202** or the collar **210** such that the protrusion **124** exerts a force upon the elongated member **202** or collar **210**. Thus, the second actuator **602** is configured to generate sufficient force to couple the elongated member **202** and the collar **210** to form a coupled fastener **200**. In implementations wherein the protrusion **124** is a component of an ejection jaw, moving the second actuator **602** between the second unengaged position and the second engaged position changes the relative spacing between the ejection jaw **118** and at least one of the first jaw **102** or second jaw **110**.

[0122] Furthermore, in various implementations, the force exerted by the protrusion **124** on the elongated member **202** or the collar **210** also dispenses the elongated member **202** or the collar **210** from the second jaw **110** or first jaw **102**, respectively.

[0123] In some implementations, coupling the elongated member **202** with the collar **210** further includes urging the penetrating end **206** of the elongated member **202** through the implant and the patient's tissue toward the collar **210** and engaging the elongated member **202** with the opening **212** of the collar **210**. Thus, the second actuator **602** is configured to generate sufficient force to penetrate the patient's relevant tissues and the implant with the penetrating end **206** of the elongated member **202**.

[0124] As provided herein, the elongated member **202** may be stored within the second jaw track **116** in a storage orientation, such that the elongated member central axis **208** is parallel with or forms an acute angle with an extension axis of the second jaw track **116**. In such implementations, the method further includes pivoting the elongated member from the storage orientation to a dispensing orientation, in which the elongated member central axis **208** is aligned with opening **212** of the collar **210**.

[0125] The surgical fastening system provided herein may be used in various minimally invasive and open surgical procedures. In various use cases provided herein, the surgical fastening system is employed to fix a surgical mesh to a target tissue in the course of surgical hernia repair, such as the repair of ventral and incisional hernias. In such uses, the surgical mesh is a hernia mesh, and the target tissue corresponds to a hernia defect site. However, the surgical fastening system may be utilized to fix other soft implants to other tissues in the course of other surgical procedures. In some implementations, the implant is formed from an absorbable material, such as synthetic polyester copolymer derived from lactic and glycolic acid. In other implementations, the implant may be nonabsorbable.

[0126] In various implementations provided herein, the first jaw **102** may be positioned posterior to the patient's target tissue, and the second jaw **110** may be positioned anterior to the patient's target tissue. In implementations utilizing an ejection jaw **118**, the ejection jaw **118** may thus also positioned anterior to both the patient's target tissue and the second jaw **110**.

[0127] However, in various other implementations, the first jaw **102** is positioned anterior to the patient's target tissue, and the second jaw **110** is positioned posterior to the patient's target tissue. Furthermore, in implementations utilizing an ejection jaw **118**, the ejection jaw **118** may be positioned either anterior or posterior to the patient's target tissue and thus anterior or posterior to one or both of the first jaw **102** and/or second **110** jaw. Accordingly, the first jaw **102**, second jaw **110**, and ejection jaw **118** may be positioned relative to one another in various combinations of orientations within the spirit of this disclosure.

[0128] Accordingly, provided herein is a surgical fastening system including a fastener dispenser **100** for storing, dispensing, and coupling a two-part fastener **200**. The system enables surgeons to precisely and efficiently fix an implant to a patient's tissue, thereby reducing surgical time and improving implant fixation outcomes.

Experimental Results and Additional Examples

[0129] A study was conducted to develop systems and methods for fixing soft prostheses or tissues to fascial tissues in patients with ventral hernias through open or minimally invasive methods. In some aspects, a surgical fastener system for the fixation of soft tissues or soft prostheses during surgical procedures, such as ventral hernia repairs, is provided.

[0130] Example Fastener Dispenser. FIG. **8**A-**8**D show various views of an exemplary fastener dispenser **100** (shown as **100***g*) configured to hold and dispense a two-part fastener in accordance with an illustrative embodiment. In this implementation, tissue clamping between the first jaw **102** and the second jaw **110**, as well as fastener **200** dispensing mediated by engagement of the protrusion **124** of the ejection jaw **118** are each actuated by a single handle **130**, wherein tissue clamping is initiated by actuation of the handle **130** and dispensing of the fastener **200** is initiated once the handle **130** passes a pre-determined transition point in its range of motion.

[0131] As shown in FIG. **8**B, a slot and pin mechanism couples the first jaw **102** and the second jaw **110**, and a separate slot and pin mechanism couples the second jaw **110** and ejection jaw **118**. In implementations where the first jaw **102** and second jaw **110** are oriented opposite relative to their positions in FIG. **8**B, the ejection jaw **118** may instead be coupled to the first jaw **102**. With two separate pin and slot mechanisms, independent movement of the jaws is achieved. By pulling each through pin toward the housing, the pin slides along the overlapping slots and closes the corresponding jaw. This independent jaw motion allows for two phases of fastener **200** delivery: layer clamping and fastener **200** dispense.

[0132] As shown in FIG. **8**C, the single handle **130** (A) controls the movement of a linkage (B) and carriage (C) system responsible for moving the second actuator (e.g., "push rod") **602** (D) and first actuator (e.g., "push tube" **600**) (E) components. During the first phase of handle **130** motion (handle shown as **130***h*), the push rod **602** and push tube **600** components move as a unit until the stopper (F) contacts the back wall of the housing shell **128**; this action marks the transition from clamping to fastener dispense phases. As the handle is continually pressed, the stopper remains in contact with the back wall-ensuring clamp force is maintained-and the spring is compressed, allowing the push rod **602** to move relative to the push tube and initiate fastener **200** dispense.

[0133] The push rod **602** and push tube **600** interface with other linkages in the head of the deployment tool, shown in FIG. **8**D. To control the tissue clamping motion, the push rod **602** connects to a solid linkage (G) and through-pin. Tack dispense is controlled by the push tube **600**, which attaches to a metal ribbon (H) and corresponding through-pin. In some implementations, lubricants may be used to reduce friction between the various components.

[0134] As shown for example in FIG. **8**C, the fastener dispenser **100** includes a two-stage mechanical delivery system disposed within a housing **128** (shown as **128***h*) and an ergonomic handle **130** configured to operate the mechanical delivery system. For example, actuating the handle **130** through a first range of motion, the first jaw **102** and second jaw **110** hold the layers relative to one another. Actuating the handle further through a second range of motion ejects one of the elongated member **202** or collar **210** (e.g., by moving an ejection jaw **118**), such that the elongated member **202** and collar **210** are coupled, thereby securing the layers therebetween. In some implementations, the delivery system of the fastener dispenser **100** may include a controlled delivery mechanism, which allows for precise deployment of the tissue fasteners **200**. The mechanism is designed to prevent excessive force on the tissue by the fastener dispenser **100** and the fastener **200**, which could potentially reduce ischemia and necrosis of the surrounding tissues. With this feature, the fastener dispenser can help ensure that the tissue is not damaged during the fastening process, which may lead to better patient outcomes and lower risks of complications. While this disclosure often refers to the two-stage delivery system as mechanical, it is contemplated that the delivery system could also be electromechanical.

[0135] Additional exemplary fastener dispensers **100** (shown as **100***i* and **100***j*) are illustrated in FIGS. **9** and **10**. As shown, for example, in FIG. **11**, one component of the fastener may be stored in a first track **108** (shown as **108***k*) extending along a length of the first jaw **102** (shown as **102***k*), and a second component of the fastener may be stored in a second track **116** (shown as **116***k*) extending along the length of the second jaw **110** (shown as **110***k*).

[0136] Example Fasteners. In various implementations, the fastener **200** includes an elongated member **202** (e.g., a penetrating tack) and a retention collar **210**. In use, the fastener **200** can be deployed to fix (i.e., join) two or more soft layers. In some implementations, the elongated member **202** is tapered and includes a high-pitch spiral to aid in tissue penetration, and a series of engagement features **214** (e.g., ribs) to allow for variable thickness placements. In other words, as shown for example in FIGS. **12**, **13**, and **14**, the engagement features **214** (shown as **214***i*-**214***k*) may include a plurality of engagement features **214** extending along a length of the elongated member **202** such that the collar **210** (shown as **214***i*-**214***k*) may be coupled to the elongated member **202** at any one or more of the engagement features **214**. For example, when fixing relatively thin layers together, the collar **210** may engage with an engagement feature **214** disposed near the base end **204** of the elongated member **202**. Conversely, when fixing relatively thick layers together, the collar **210** may engage with an engagement feature **214** disposed near the penetrating end **206** of the elongated member **202**. In this way, the fastener **200** is able to accommodate variations in the thickness of the layers to be fixed together. Additional exemplary embodiments of the fastener **200** (shown as **200***l*-**200***o*) are shown in FIG. **15**.

[0137] FIG. **16** show additional implementations of the elongated member **202** (shown as **202***p*-**202***u*). In the illustrated implementation, the elongated member **202** is formed from a resin using SLA 3-Dimensional ("3D") printing. In some implementations, one or both of the elongated member **202** and collar **210** are manufactured using SLA 3-dimensional printing with a durable resin. In some implementations, the fastener components, including the elongated member **202** and collar **210**, are composed of resorbable material. However, in other implementations, non-resorbable materials may be used.

[0138] Referring generally to figures, FIGS. **17**A-**17**C show yet another exemplary fastener **200** (shown as **200***u*), including an elongated member **202** (shown as **202***v*) and a collar **210** (shown as **210***v*). In the implementation illustrated in FIG. **17**A, the elongated member **202** is formed as a tubular body and defines an opening **211** extending therethrough. Furthermore, the elongated member **202** includes a

radially extending engagement feature **214** (shown as **214***v*). Specifically, FIG. **17**A shows an elongated member **202** with a radially outwardly extending engagement feature **214** in the shape of an annular ring. The radially outwardly extending engagement feature **214** may extend all or partially around the elongated member **202** and may include various other geometries configured to facilitate one-way coupling of the elongated member **202** with the collar **210**.

[0139] As shown in FIG. **17**B, the collar **210** defines an opening **212** (shown as **212***u*) configured to receive the elongated member **202**. As shown, the collar **210** further includes a radially extending engagement feature **216** configured to couple with the radially extending engagement feature **214** of the elongated member **202**. Accordingly, the radially extending engagement feature **216** of the collar **210** may be radially inwardly extending or radially outwardly extending. In the illustrated implementation, the radially extending engagement feature **216** of the collar **210** is radially inwardly extending. FIG. **17**C shows the tubular elongated member **202** and tubular collar **210** in the coupled configuration such that the engagement features **214** and **216** are engaged.

[0140] FIG. **17**D shows an exemplary fastener dispenser **100** (shown as **100***l*). As shown, the second jaw **110** (shown as **110***l*) includes a guide member **1700** (shown as **1700***a*) extending toward the first jaw **102** (shown as **102***l*). The guide member **1700** is configured to align the elongated member **202** with the opening **212** of the collar **210**.

Example Surgical Method

[0141] In various implementations, the method for surgically fixing a first layer to a second layer includes fixing an implant mesh to patient tissue using an underlay technique. For example, in the underlay technique, the elongated member **202** may be positioned anteriorly to the implant mesh. The penetrating end **206** of the elongated member **202** penetrates through the implant mesh, fascia, and abdominal wall, the fastener collar **210** is coupled to the elongated member **202**. Accordingly, the implant mesh, fascia, and abdominal wall may be fixed between the base end **204** of the elongated member **202** and the collar **210**.

[0142] The surgical systems and methods provided herein offer several advantages. For example, use of the fastener dispenser **100** to dispense the fasteners **200** reduce surgical time, improves fixation the durability of the fixation, simplifies and standardizes the accompanying fixation procedure, and reduce physician fatigue commonly associated with large size hernia repair. As described herein, the disclosed systems and methods may be used in various other contexts. For example, the device could be used in inguinal hernia repairs or as a general tissue-to-tissue fixation system. Advantageously, the disclosed fastener **200** uses two components to perform fixation. This is advantageous in that no engagement geometries, such as screws or barbs, interface directly with the patient's tissues. Rather, any such features engage with the other components of the fastener.

[0143] The surgical fastening system provided herein is designed to be compatible with a wide range of surgical meshes. However, in some contexts of use, (e.g., fixing a surgical mesh to a patient's tissue), users may find it beneficial to make a small surgical adjustment by creating a central hole enabling the delivery tool's first jaw **102** to pass through below the surgical mesh. To minimize the risk of harming bowel tissues beneath the mesh, the first jaw **102** of the fastener dispenser may incorporate various geometries and features for the prevention of ischemia and necrosis, thereby reducing potential harm accompanying mesh insertion. By incorporating these protective measures, the fastener dispenser can help to ensure safer and more effective mesh implantation procedures. Furthermore, the surgical fastening system may be particularly suitable for use in conjunction with surgical meshes that include slotted mesh pockets on their posterior surface (e.g., Ventralex, Ventrio ST, etc.).

Additional Example Fastener and Dispenser System

[0144] In some instances, conventional tissue fasteners may not form a strong coupling between two layers of tissue targeted for fixation. This can be due at least in part to poor penetration of the fastener within the targeted tissue and/or poor retention of the fastener within the targeted tissue once placed. Furthermore, in some instances, it may be desirable to secure a first layer to a second layer (e.g., fix a surgical mesh, such as a hernia mesh, to a patient's tissue or two layers of tissue to each other) via especially minimally invasive means. Accordingly, an additional implementation of the fastener is provided herein in FIGS. **18**A-**21**C with a fastener delivered through a delivery cannula.

[0145] FIGS. **18**A-**18**B, show an exemplary fastener **400** (shown as **400***a*) for securing a first layer to a second layer. As shown in the example of FIG. **18**A, the fastener **400** includes an elongated member **402** (shown as **402***a*) that extends between a base end **404** (shown as **404***a*) and a penetrating end **406** (shown as **406***a*). The fastener **400** defines a longitudinal axis X and a fastener lumen **408** (shown as **408***a*) extending longitudinally through the elongated member **402** parallel with the longitudinal axis X. In the illustrated implementation, the fastener lumen **408** is open at the base end **404** and closed at the penetrating end **406**. In some implementations, the penetrating end **406** tapers to a pointed tip that facilitates entry into the first and second layers (e.g., patient tissue and/or surgical mesh) As shown, the elongated member **402** defines a plurality of openings **410** (shown as **410***a*) that extend between the outer surface of the elongated member **402** to the fastener lumen **408**. The plurality of openings **410** can be arranged along the tapered portion of the penetrating end **406**, as shown, or be disposed along the longitudinally extending portion of the elongated member **402**. In the illustrated implementation, the plurality of openings **410** are arranged circumferentially around the tapered region of the penetrating end **406** about the longitudinal axis X.

[0146] Although the illustrated plurality of openings **410** are ovoid, in further implementations, the plurality of openings **410** can be any shape, so long as the plurality of anchoring members **412** are able to move therethrough.

[0147] In the illustrated implementation, the fastener **400** has a length of about 2 cm as measured between the base end **404** to the penetrating end **406**. This approximately corresponds to the width of the layers that the fastener **400** is configured to secure to each other. Accordingly, the dimensions of the fastener **400** can be varied to accommodate patients, tissues, and/or implanted layers of differing sizes. For example, the length of the fastener **400** can range from about 0.5 cm to about 3.0 cm. For example, the length of the fastener 400 can range from about 1.0 cm to about 2.0 cm.

[0148] A plurality of longitudinally extending anchoring members **412** (shown as **412***a*) extend longitudinally within

the fastener lumen **408**. As shown, each anchoring member **412** includes a proximal end **414** (show as **414***a*) and a distal end **416** (shown as **416***a*). In the illustrated implementation, the anchoring members **412** are arranged circumferentially about the longitudinal axis X.

[0149] In the illustrated implementation, each anchoring member **412** is formed from a deformable polymeric material. However, in further implementations, the plurality of anchoring members **412** can be formed from any material that allows the anchoring member **412** to bend. Additionally, in some implementations, the plurality of anchoring members **412** can be formed from a biodegradable material. In specific examples, the character of the biodegradable material used to form the plurality of anchoring members **412** can be controlled to modulate degradation time.

[0150] Furthermore, each anchoring member **412** in the illustrated implementation has a rectangular cross-section. The relative cross-sectional dimensions of each anchoring member **412** can be controlled to adjust the stiffness of the respective anchoring member **412**.

[0151] As further described herein, the plurality of anchoring members **412** are movable from an undeployed configuration to a deployed configuration. In the undeployed configuration, the plurality of anchoring members **412** are disposed entirely within the fastener lumen **408**. As showed in the illustrated implementation, when in the undeployed configuration, the plurality of anchoring members **412** can extend parallel to the longitudinal axis X of the fastener **400**. In the deployed configuration, at least a portion of two or more of the anchoring members **412** move radially outward and extend through a respective opening **410**. Specifically, the plurality of anchoring members **412** are configured to move from the undeployed configuration to the deployed configuration upon axial translation of at least the proximal end of respective anchoring members **412** toward the penetrating end **406** of the fastener **400**. Advantageously, the plurality of anchoring members **412** increase the pull out force required to withdrawal the fastener **400**, thereby improving retention of the fastener **400** within the first and second layers and improving the secured coupling formed between the first layer and the second layer by the fastener **400**. In various implementations, each anchoring member **412** can extend radially outward as a distance ranging from about 0.5 cm to about 2.0 cm as measured between the outer surface of the elongated member **402** and the distal end **416**. In the illustrated implementation, each anchoring member **412** extends radially outward a distance of about 1.0 cm.

[0152] FIG. **18**B shows the exemplary fastener **400** with the plurality of anchoring members **412** in the deployed configuration. As shown, advancement of the plurality of anchoring members **412** axially toward the penetrating end **406** such that the distal ends **416** of each respective anchoring member **412** is directed through a respective opening **410** and radially outward. Although the illustrated implementation shows each anchoring member extending radially outward at a 90 degrees angle relative to the longitudinal axis, in further implementations, each anchoring member can extend radially outward so as to form an acute angle with respect to the longitudinal axis. Advantageously, this can further improve retention of the fastener **400** within the first and second layers by increasing the withdrawal force required to dislodge the fastener 400. For example, the acute angle can range from about 89 degrees to about 15 degrees. For example, the acute angle can range from about 60 degrees to about 30 degrees. For example, the acute angle can be about 45 degrees.

[0153] FIG. **19** shows another implementation of the fastener **400** (shown as **400***b*) in a part of a surgical fastening system **440** (shown as **440***b*). As shown, the illustrated fastener **400** further includes a plurality of inner shelves **418** disposed adjacent respective openings **410**. The plurality of inner shelves **418** can be protrusions formed within the fastener lumen **408** that are angled to direct the distal end **416** of the plurality of anchoring members **412** radially outward as the plurality of anchoring members **412** advances toward the penetrating end **406** when transitioning from the undeployed configuration to the deployed configuration. Advantageously, the plurality of inner shelves **418** can divert the trajectory of the plurality of anchoring members **412** away from the longitudinal axis X and radially outward into the first or second layer (e.g., patient tissue).

[0154] Furthermore, as shown in FIG. **19**, the surgical fastening system **440** includes a delivery cannula **450** (shown as **450***b*) having a central lumen **452** (shown as **452***b*) in which the fastener **400** is disposed. Disposed within the central lumen **452** of the delivery cannula **450** is a tubular fastener driver **460** (shown as **460***b*) having a central lumen **462** (shown as **462***b*). As further described herein, the fastener driver **460** is configured to move axially within the central lumen **452** of the delivery cannula **450** to apply a distally-directed axial force on the base end **404** of the fastener **400** to advance the fastener **400** out of the delivery cannula **450** and into the first and second layers.

[0155] Disposed within the central lumen **462** of the fastener driver **460** is an anchor driver **470** (shown as **470***b*) in the form of a push-rod. As shown by the arrow in FIG. **19**, the anchor driver **470** is configured to translate axially parallel to the longitudinal axis X within the central lumen **452** of the delivery cannula **450** and engage the proximal ends **414** of respective anchoring members **412**, thereby moving respective distal ends **416** of the plurality of anchoring members **412** toward respective inner shelves **418** and thus diverting the plurality of anchoring members **412** radially outward toward through respective openings **410**.

[0156] Referring now to FIGS. **20**A-**20**C, an exemplary surgical fastening system **440** (shown as **440***a*) is shown in use in conjunction with the exemplary fastener **400** (shown as **400***a*) along with the delivery system including the exemplary delivery cannula **450** and exemplary anchor driver **470**. Specifically, FIG. **20**A shows the fastener **400**, the fastener driver **460**, and the anchor driver **470** disposed within the central lumen **452** of the delivery cannula **450**. As shown, the delivery cannula **450** is positioned adjacent the first and second layers such that distal end of the delivery cannula **450** contacts whichever of the first layer or second layer is nearest the delivery cannula **450**. In the illustrated example, the first layer is a surgical mesh (e.g., hernia mesh). However, in other implementations, the first and second layer may both be layers of patient tissue. While the fastener **400** remains disposed within the central lumen **452** of the delivery cannula **450**, the plurality of anchoring members **412** are retained fully within the fastener lumen **408**.

[0157] When the delivery cannula **450** is aligned with the desired location for securing the two layers together, the fastener driver **460** is advanced axially in a distal direction, as shown by the arrows in FIG. **20**B, so that the fastener driver **460** contacts the base end **404** of the base end **404**.

The fastener driver **460** then pushes the penetrating end **406** of the fastener **400** distally parallel to the longitudinal axis X and into the first layer and second layer. In the illustrated implementation, the fastener **400** is advanced distally until the base end **404** abuts the layer nearest the delivery cannula **450**. In the particular implementation illustrated, the fastener **400** is advanced through a first layer of surgical mesh and further advanced into a second layer of patient tissue.

[0158] Once the fastener **400** is positioned so as to extend through all or part of the first and second layers, the anchor driver **470** is advanced axially in a distal direction, as shown by the arrow in FIG. **20**C, so that the anchor driver **470** contacts the respective proximal ends **414** of the plurality of anchoring members **412**. As shown, this pushes the respective proximal ends of the plurality of anchoring members **412** distally toward the penetrating end **406** and directs the respective distal end **416** of the plurality of anchoring members **412** radially outward through the plurality of openings **410** and into the first or second layer (e.g., patient's tissue), thereby holding the fastener **400** within the first or second layer and securing the first layer and second layer to each other. Once the fastener **400** is place, the remainder of the surgical fastening system **440** including the delivery cannula **450**, fastener driver **460**, and anchor driver **470** can be withdrawn.

[0159] Referring now to FIGS. **21**A-**21**C, another exemplary surgical fastening system **440** (shown as **440***c*) is shown in use in conjunction with the exemplary fastener **400** along with the delivery system including exemplary delivery cannula **450** and exemplary anchor driver **470**. The surgical fastening system **440** shown in FIGS. **21**A-**21**C is similar to the surgical fastening system **440** described with reference to FIGS. **20**A-**20**C. However, the fastener **400** in this exemplary implementation (shown as **400***c*) includes a plurality of outer shelves **420** disposed adjacent respective openings **410**. The plurality of outer shelves **420** can be protrusions formed along the outer surface of the elongated member **402** to a portion of each anchoring member **412** radially outward when transitioning from the undeployed configuration to the deployed configuration. Further still, as shown in the illustrated implementation, the plurality of outer shelves **420** are angled toward the base end **404** so as to direct the portion of each anchoring member **412** angularly toward the base end **404** so as to form an acute angle with respect to the longitudinal axis X. Advantageously, the plurality of inner shelves **418** can divert the trajectory of the plurality of anchoring members **412** away from the longitudinal axis X and radially outward into the first or second layer (e.g., patient tissue). Additionally, FIG. **21**A shows that an additional fastener **400** (shown as **400***c*') can be disposed within the delivery cannula **450** proximal to the fastener **400**. In fact, it is contemplated herein that a series of fasteners fastener **400** can be contained within the delivery cannula **450** and configured to be deployed serially at various locations across the first and second layers targeted for securement.

[0160] As shown in previous implementations, the portion of each respective anchoring member that extends radially outward in the deployed configuration can be the distal end **416** of the respective anchoring member. Such a configuration is contemplated in combination with the plurality of outer shelves **420** as described above. However, in the illustrated implementation shown in FIGS. **2**A-**21**C, the distal end **416** is fixed to an inner surface of the fastener lumen **408** at the penetrating end **406** of the fastener **400**. As shown in FIG. **21**B, in such implementations, the penetrating end penetrating end **406** of the fastener **400** is configured to collapse or depress upon engagement with the first and/or second layer. Because the distal end **416** are fixed, it is contemplated herein that such collapse of the penetrating end **406** urges the respective proximal ends **414** of the plurality of anchoring members **412** radially inward toward the longitudinal axis X.

[0161] Additionally, the fastener **400** defines a distal opening **422** (shown as **422***c*) in the penetrating end **406** such that the fastener lumen **408** extends fully through the fastener **400** between the base end **404** and the penetrating end **406**.

[0162] As shown in FIG. **21**B, the fastener **400** (shown as **400***c*) and one or more additional fasteners **400** (shown as **400***c*') can be arranged end-to-end within the delivery cannula **450**. As previously described, the fastener driver **460** translates distally within the central lumen **452** and engages the base end **404** of the fastener **400** (here, the additional fastener **400***c*') to urge the fastener **400** (or series of fasteners **400**) distally along the longitudinal axis X.

[0163] As further shown in FIG. **21**B, the anchor driver **470** configured to move axially through the fastener lumens **408** of the one or more fasteners **400** disposed in the delivery cannula **450**. For example, as shown, the anchor driver **470** extends entirely through the additional fastener **400** (shown as **400***c*'). In the illustrated implementation, this is possible because the plurality of anchoring members **412** offset from the longitudinal axis X a distance at least equal to the radius of the anchor driver **470**. Thus, the anchor driver **470** passes between respective anchoring members **412**. However, when the penetrating end **406** collapses and urges the respective proximal ends **414** of the plurality of anchoring members **412** radially inward toward the longitudinal axis X, as previously discussed, the respective proximal ends **414** are brought into alignment with the anchor driver **470** such that distal movement of the anchor driver **470** will push the respective proximal ends **414** distally. Advantageously, this arrangement enables several fasteners **400** to be stacked end-to-end within the delivery cannula **450** while facilitating deployment of the plurality of anchoring members **412** in only the distal-most fastener **400**.

[0164] Referring now to FIG. **21**C, distal advancement of the anchor driver **470** pushes the respective proximal ends **414** distally, moving the plurality of anchoring members **412** from the undeployed configuration into the deployed configuration. However, because the respective distal ends **416** of the plurality of anchoring members **412** are fixed to an inner surface of the fastener lumen **408** at the penetrating end **406** of the fastener **400**, a portion of the respective anchoring members **412** disposed between the distal end **416** end and distal end **416** is urged through the respective openings **410** and radially outward into the first or second layer (e.g., patient tissue). As shown, the portion of the respective anchoring members **412** directed radially outward through the respective openings **410** is diverted by the plurality of outer shelves **420** so as to extend at an acute angle with respect to the longitudinal axis X. Accordingly, these portions of the respective anchoring members **412** can have any of the attributes of the radially extending distal end **416** described with respect to previous implementations. In this way, the fastener **400** can effectively anchor within the first and/or second layer and thus secure the first layer and second layer to each other. Once the fastener **400** is place,

the remainder of the surgical fastening system **440** including the delivery cannula **450**, fastener driver **460**, and anchor driver **470** can be withdrawn.

[0165] Although some features of the fasteners **400** and surgical fastening systems **440** are described with respect to a single implementation (e.g., distal opening **422** and outer shelves **420** described in an embodiment having distal ends **416** fixed within the fastener lumen **408**), it is contemplated herein that the attributes of some implementations are transferrable to other implementations. For example, the implementation in which the distal end **416** are moved radially outward through the plurality of openings **410** away from the longitudinal axis can also include a distal opening **422** and outer shelves **420**.

[0166] The surgical fastening system **440** provided herein may be used in various minimally invasive and open surgical procedures. In various use cases provided herein, the surgical fastening system is employed to secure a surgical mesh to a target tissue in the course of surgical hernia repair, such as the repair of ventral and incisional hernias. In such uses, the surgical mesh is a hernia mesh, and the target tissue corresponds to a hernia defect site. However, the surgical fastening system may be utilized to secure other soft implants to other tissues or certain layers of tissue to other layers of tissue in the course of other surgical procedures. In some implementations, the implant is formed from an absorbable material, such as synthetic polyester copolymer derived from lactic and glycolic acid. In other implementations, the implant may be nonabsorbable.

Configuration of Certain Implementations

[0167] The construction and arrangement of the systems and methods as shown in the various implementations, are illustrative only. Although only a few implementations have been described in detail in this disclosure, many modifications are possible (e.g., variations in sizes, dimensions, structures, shapes, and proportions of the various elements, values of parameters, mounting arrangements, use of materials, colors, orientations, etc.). For example, the position of elements may be reversed or otherwise varied, and the nature or number of discrete elements or positions may be altered or varied. Accordingly, all such modifications are intended to be included within the scope of the present disclosure. The order or sequence of any process or method steps may be varied or re-sequenced according to alternative implementations. Other substitutions, modifications, changes, and omissions may be made in the design, operating conditions, and arrangement of the implementations without departing from the scope of the present disclosure.

[0168] As used in the specification and the appended claims, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" one particular value, and/or to "about" another particular value. When such a range is expressed, another implementation includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another implementation. It will be further understood that the endpoints of each of the ranges are significant both in relation to the other endpoint, and independently of the other endpoint.

[0169] Throughout the description and claims of this specification, the word "comprise" and variations of the word, such as "comprising" and "comprises," means "including but not limited to," and is not intended to exclude, for example, other additives, components, integers or steps. "Exemplary" means "an example of" and is not intended to convey an indication of a preferred or ideal implementation. "Such as" is not used in a restrictive sense, but for explanatory purposes.

[0170] Disclosed are components that can be used to perform the disclosed methods and systems. These and other components are disclosed herein, and it is understood that when combinations, subsets, interactions, groups, etc. of these components are disclosed that while specific reference of each various individual and collective combinations and permutations of these may not be explicitly disclosed, each is specifically contemplated and described herein, for all methods and systems. This applies to all aspects of this application including, but not limited to, steps in disclosed methods. Thus, if there are a variety of additional steps that can be performed it is understood that each of these additional steps can be performed with any specific implementation or combination of implementations of the disclosed methods.

1. A surgical fastening system for fixing a first layer to a second layer, the system comprising:

a fastener dispenser comprising:

a first jaw comprising a proximal end and a distal end, the first jaw defining a first jaw track therein extending between the proximal end and the distal end;

a second jaw comprising a proximal end and a distal end, the second jaw defining a second jaw track therein extending between the proximal end and the distal end; and

a fastener comprising an elongated member and a collar, the elongated member spanning the combined thickness of the first layer and the second layer, wherein the elongated member is stored within the second jaw track and the collar is stored within the first jaw track;

wherein the first jaw is movably coupled to the second jaw; and

wherein the fastener dispenser is movable from an unclamped configuration, in which the first jaw and the second jaw have a relative spacing on opposite sides of the first layer and the second layer, to a clamped configuration, in which the second jaw is moved relative to the first jaw to reduce the relative spacing between the first jaw and the second jaw, thereby holding the first layer relative to the second layer.)

2. The system of claim **1**, wherein one of the first or second jaws further comprises an ejection jaw movably coupled to a counterpart one of the first or second jaws, the ejection jaw comprising a protrusion configured to extend toward the track of the one of the first or second jaws to which the ejection jaw is coupled;

wherein moving the ejection jaw toward the one of the first or second jaws engages the protrusion against one of the elongated member or the collar stored in the track of the one of the first or second jaws, thereby urging the one of the elongated member or the collar toward the other of the elongated member or the collar to couple the elongated member and the collar.

3. The system of claim **2**, wherein an ejection jaw biasing member urges the ejection jaw toward the one of the first or second jaws to which the ejection jaw is coupled.

4. The system of claim **1**, wherein the elongated member extends between a base end and a penetrating end and defines an elongated member central axis.

5. The system of claim **4**, wherein the elongated member is stored within the second jaw track such that the elongated member central axis is parallel with or forms an acute angle with an extension axis of the second jaw track.

6. The system of claim **5**, wherein the second jaw further comprises a pivoting feature configured to pivot the elongated member when the elongated member is dispensed such that the penetrating end of the elongated member extends toward the collar.

7. The system of claim **4**, wherein the system further comprises a cutting blade disposed adjacent the first jaw, the cutting blade configured to remove a portion of the penetrating end of the elongated member on a side of the collar opposite the base end of the elongated member after the elongated member is coupled to the collar.)

8. The system of claim **1**, wherein the system further comprises a collar cartridge configured to store and dispense the collar, wherein the collar is one of a plurality of collars stored in the collar cartridge, and wherein a first biasing member urges the collar cartridge toward the distal end of the first jaw

9. (canceled)

10. The system of claim **8**, wherein the system further comprises an elongated member cartridge configured to store and dispense the elongated member, wherein the elongated member is one of a plurality of elongated members stored in the elongated member cartridge, and wherein a second biasing member urges the elongated member cartridge toward the distal end of the second jaw.

11. (canceled)

12. The system of claim **10**, wherein the first jaw track is configured to receive the collar cartridge, and the second jaw track is configured to receive the elongated member cartridge.

13.-**14**. (canceled)

15. The system of claim **1**, wherein the elongated member is formed integrally with the second jaw and extends toward the first jaw, wherein the system further comprises a dispensing blade configured to remove the elongated member from the second jaw.

16. The system of claim **2**, wherein the system further comprises a housing, the housing comprising a first actuator movable between a first unengaged position and a first engaged position, wherein movement between the first unengaged position and the first engaged position moves the fastener dispenser between the unclamped configuration to the clamped configuration, respectively.

17. The system of claim **16**, wherein the housing further comprises a second actuator movable between a second unengaged position and a second engaged position, wherein movement between the second unengaged position and the second engaged position moves the ejection jaw relative to one of the first or second jaws to urge one of the elongated member or the collar toward the other of the elongated member or the collar to couple the elongated member and the collar.

18. The system of claim **17**, wherein the system further comprises a handle configured to move the first actuator between the first unengaged position and the first engaged position.

19. The system of claim **18**, wherein the handle is further configured to move the second actuator between the second unengaged position and the second engaged position.

20. The system of claim **17**, wherein the system further comprises a hollow shaft extending from the housing to the fastener dispenser.

21. The system of claim **20**, wherein the first jaw is rotationally fixed to the hollow shaft.

22. The system of claim **20**, wherein the fastener dispenser is detachably coupled to the hollow shaft for disposal or replacement.

23. The system of claim **1**, wherein the first layer is a surgical mesh implant, and the second layer is a patient's tissue.

24. The system of claim **23**, wherein the surgical mesh implant is a hernia mesh.

25. The system of claim **1**, wherein both the first layer and the second layer are a patient's tissue.

26. A surgical fastener for fixing a first layer to a second layer, the fastener comprising:

an elongated member extending between a base end and a penetrating end and defining an elongated member central axis; and

a collar defining an opening configured to receive the penetrating end of the elongated member;

wherein the elongated member spans the combined thickness of the first layer and the second layer;

wherein the elongated member is configured to engage with the opening of collar, thereby coupling the elongated member and the collar; and

wherein the fastener operates in a system further comprising a fastener dispenser, the fastener dispenser comprising:

a first jaw comprising a proximal end and a distal end, the first jaw defining a first jaw track therein extending between the proximal end and the distal end; and

a second jaw comprising a proximal end and a distal end, the second jaw defining a second jaw track therein extending between the proximal end and the distal end;

wherein the proximal end of the first jaw is pivotably coupled to the proximal end of the second jaw; and

wherein the elongated member is stored within the second jaw track and the collar is stored within the first jaw track.

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

31. A method for surgically fixing a first layer to a second layer, the method comprising:

(1) providing a fastener dispenser comprising:

a first jaw having a proximal end and a distal end, the first jaw defining a first jaw track therein extending between the proximal end and the distal end;

a second jaw having a proximal end and a distal end, the second jaw defining a second jaw track therein extending between the proximal end and the distal end;

(2) providing a fastener comprising:

an elongated member and a collar, the elongated member spanning the combined thickness of the first layer and the second layer,

wherein the elongated member extends between a base end and a penetrating end and defines an elongated member central axis;

wherein the collar defines an opening configured to receive the penetrating end of the elongated member; and

wherein the elongated member is stored within the second jaw track and the collar is stored within the first jaw track;

(3) positioning the fastener dispenser so that the first layer and the second layer are disposed between the first jaw and the second jaw;

(4) moving the fastener dispenser from an unclamped configuration, in which the first jaw and the second jaw have a relative spacing on opposite sides of the first layer and the second layer, to a clamped configuration, in which the second jaw is pivoted relative to the first jaw to reduce the relative spacing between the first jaw and the second jaw, thereby holding the first layer relative to the second layer; and

(5) coupling the elongated member with the collar, thereby clamping the first layer and the second layer between the base end of the elongated member and the collar, thereby fixing the first layer relative to the second layer.

32.-**55**. (canceled)

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