



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

(21) International Application Number:
PCT/IB2010/054443

(22) International Filing Date:
1 October 2010 (01.10.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/247,638 1 October 2009 (01.10.2009) US

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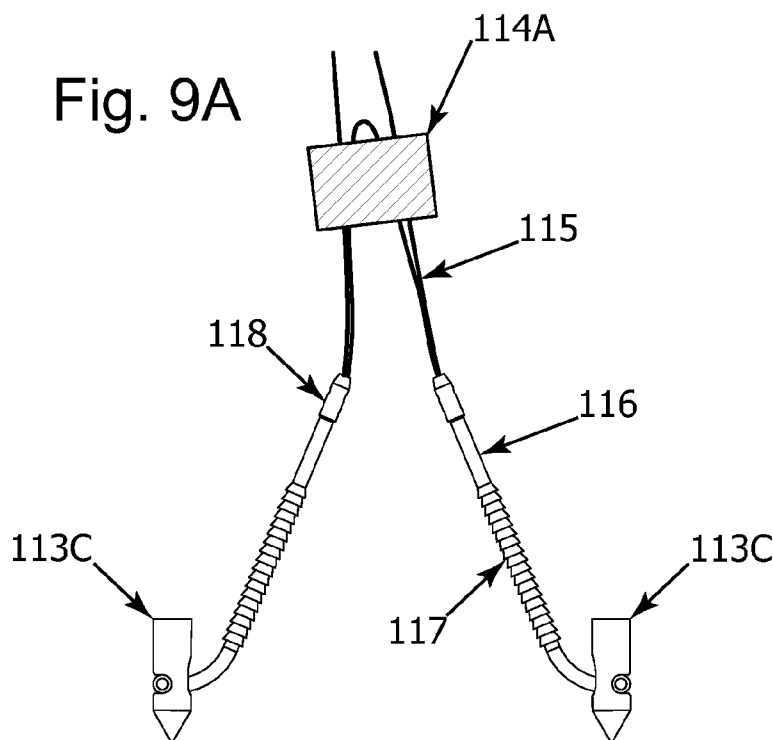
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE,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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

[Continued on next page]

(54) Title: SUTURE DEVICE AND METHOD AND ANCHOR UNIT THEREFOR



(57) Abstract: A device for approximating at least two separate tissues and including a use of a temporary needle, the device comprising a suture anchor included in a distal end of the temporary needle for penetrating the tissues; a plunger included in a proximal end of the temporary needle for pushing the anchor to penetrate the tissues, and comprising a distal end which temporarily attaches to a proximal end of the anchor to form the temporary needle; and a temporary needle driving mechanism for driving the plunger to attach to the anchor and push the anchor to penetrate the tissue.



SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, —
GW, ML, MR, NE, SN, TD, TG).

*before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))*

Published:

— *with international search report (Art. 21(3))*

SUTURE DEVICE AND METHOD AND ANCHOR UNIT THEREFOR

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

5 [001] This application claims priority from provisional patent application 61/247,638, filed on October 1, 2009.

FIELD AND BACKGROUND OF THE INVENTION

[002] The present invention, in some embodiments thereof, relates to a medical device and, more particularly, but not exclusively, to a handheld suture device for
10 performing suturing operations on human and animal tissues.

[003] Surgical procedures often require sutures to repair tissue. Generally, in a suturing operation, a suture is attached at one end to a suture needle and is passed by means of the needle through tissue portions that are to be joined together (repaired). The tissue portions are then secured together by pulling on both ends of the suture and tying a
15 knot in the suture.

[004] Open abdominal surgery typically involves an incision in the skin and the abdominal fascia in order to access the inner space of the abdomen and to perform the planned surgical procedure. Following the internal procedure, the fascia and later the skin are closed either by sutures or by staples.

20 [005] Fascial closure is often performed by suturing incision flaps with a continuous suture along the entire length of the incision. Surgeons frequently tend to use continuous sutures rather than individually tied sutures, which may provide a more secure closure as they are individually tied sutures along the length of the incision, due to a relatively longer time generally required to perform the latter method, and possibly due to
25 accompanying costs involved in operating room time.

[006] Frequently in trauma situations, a surgeon performing the fascia repair may be required to work quickly while holding the suturing needle in his/her hand, or grasping the needle with forceps. Both hands may be constantly occupied while manipulating the needle and the suture, as well as manipulating the tissue. This situation may also contribute

to reasons why surgeons often prefer to use continuous sutures in the fascia, despite risks involving needle-stick injuries to the patient's internal organs, needle-stick injury to operating room personnel, uneven and sometimes excessively high pressure on certain points along the fascia which can result in ischemia of the tissue and early post surgery evisceration of abdominal organs, as well as late post surgery herniation.

[007] Occasionally, a suture anchor is utilized during the suture operation, as described in the following publications:

[008] US 4,235,238 "Apparatus for suturing coeliac tissues" relates to a coeliac tissue-suturing apparatus comprising a flexible tubular member having a passage extending therethrough and inserted into a channel of an endoscope, a needle having one end concentrically fixed to that end of the tubular member which is inserted into the endoscope and having the other end made into a sharp tip, said needle having substantially the same outer diameter as the tubular member and adapted to protrude from a distal end of the endoscope, a first-stop receiving chamber communicating with the atmosphere and the passage of the tubular member, a first stop for setting suturing thread on tissues around a coeliac bleeding spot at the commencement of a suturing operation, said first stop being adapted to fix one end of the suturing thread extended along the tubular member, and normally received in the first-stop receiving chamber, and a pushing member inserted into the tubular member for pushing the first stop out of the first stop-receiving chamber.

[009] US 5,626,614 "T-anchor suturing device and method for using same" relates to a surgical apparatus includes a needle having an outer surface and an anchor bar disposed in sliding engagement with the needle. A suture has a first end attached to the anchor bar and a second end extending laterally of the anchor bar and outwardly of the needle. A pusher is movable coaxially of the needle to engage the anchor bar and to separate the anchor bar from the needle to form an anchor relative to a body wall. The anchor bar may have an outer surface with an inclined relationship to its longitudinal axis in order to facilitate axial insertion of the anchor bar through the body wall. An associated method for anchoring a pair of body walls includes the step of attaching a bolster to the second end of the suture and separating the anchor bar from the needle with the anchor bar and the first end of the suture disposed on one side of the body wall and the second end of the suture disposed on the other side of the body wall.

[010] US 5,085,661 "Surgical fastener implantation device" relates to a fastener implanting device used to implant a head portion of a "T" or "H"-shaped fastener within a body. The device has a needle portion and a grip portion. The needle portion has a fastener receiving cavity selectively covered by a movable sleeve. The sleeve's translational movement is controlled by a mechanism located in the device's grip portion.

[011] Additional disclosures in the field include AU 7200095, EP 1598018, US 2005/261710, EP 1749481, EP 193876, US 6,066,146, US 6,500,184, WO 2007/124773, EP 1159920, EP 1484021, US 2001/051816, WO 2007/085819, US 2006/009803, WO 9807374, US 5,810,848, US 5,041,129 and US 5,085,661.

10 SUMMARY OF THE INVENTION

[012] According to some embodiments of one aspect of the present invention there is provided a device for approximating at least two separate tissues and including a use of a temporary needle, the device comprising a suture anchor included in a distal end of the temporary needle for penetrating the tissues; a plunger included in a proximal end of the temporary needle for pushing the suture anchor to penetrate the tissues, and comprising a distal end which temporarily attaches to a proximal end of the anchor to form the temporary needle; and a temporary needle driving mechanism for driving the plunger to attach to the anchor and push the anchor to penetrate the tissue. A device for approximating at least two separate tissues, the device comprising: at least one temporary needle for penetrating said separate tissues, each temporary needle comprising: (a) a tissue penetrating suture anchor having a proximal end and a distal end and comprising a distal portion of each temporary needle; (b) a plunger having a proximal end and a distal end, the anchor's proximal end adapted for removable connection to the plunger's distal end and the plunger included in a proximal portion of each temporary needle; and (c) a tissue approximating member attached to said anchor; and a lock mechanism for securing said separate tissues in an approximated position; and a temporary needle driving mechanism for driving the plunger to connect to the anchor and push the temporary needle into said separate tissues, wherein the anchor and the plunger of each temporary needle are connected when penetrating the separate tissues and separatable after the anchor has passed through the separate tissues.

[013] In some embodiments the tissue approximating member is pivotally connected to the anchor and/or comprises a tissue holding element and a suture, the tissue holding element attached at one end thereof to the anchor and attached at the other end thereof to the suture. In some embodiments the locking mechanism includes a lock adapted to engage with lock engaging feature of the tissue approximating member and/or the approximating member comprises a plurality of ratchet ribs/segments.

[014] According to some embodiments, the distal end of the plunger comprises an opening for mating with the proximal end of the suture anchor. In some embodiments, the proximal end of the suture anchor comprises an opening for mating with the distal end of the plunger, and in other embodiments, the suture anchor comprises an anchor neck at a proximal end. According to some embodiments, the suture anchor is fixably connected to a suture, while in other embodiments, the anchor is movably connected to a suture.

[015] According to some embodiments, the device further comprises an anchor cartridge for accommodating the suture anchor housed inside an anchor unit. Optionally, the device further comprises an anchor cartridge for accommodating a plurality of anchor units. In some embodiments, a first anchor unit comprises a movable anchor connected by a suture in a loop configuration to a second movable anchor included in a second anchor unit. Additionally or alternatively, the second anchor unit comprises a looped thread for approximating the tissues by tightening the suture. Optionally, the knot is pre-tied. Additionally or alternatively, a third anchor unit comprises a looped thread for approximating the tissues by tightening the suture. Optionally, the looped thread comprises a knot.

[016] According to some embodiments, the device further comprises a body at an angle of inclination ranging from 50-240 degrees relative to a plane perpendicular to a direction of exit of the suture anchor from the device. In some embodiments, the angle of inclination ranges from 60-80 degrees.

[017] According to some embodiments of another aspect of the present invention, there is provided a method for approximating at least two separate tissues, the method comprising forming a temporary needle by attaching a distal end of a plunger into a proximal end of a suture anchor; driving the temporary needle through said separate tissues; ejecting the anchor from the temporary needle; retrieving the plunger; pulling on a

tissue approximating member attached to the anchor; and locking the tissue engaging/tying element.

[018] According to some embodiments of the present invention, the method further comprises inserting the proximal end of the anchor into an opening in the distal end of the plunger. Optionally, method further comprises inserting the distal end of the plunger into an opening in the proximal end of the anchor.

[019] According to some embodiments of a further aspect of the present invention there is provided an anchor unit, typically a single use anchor unit, for use in a device for approximating at least two separate tissues, the anchor unit comprising a suture anchor wherein a proximal end of the anchor temporarily attaches to a distal end of a plunger in the device to form a temporary needle for penetrating the tissues. In some embodiments, the anchor unit is movably connected to a suture, while in other embodiments, the anchor unit is fixably connected to a suture. In some embodiments the anchor unit further comprises a tissue approximating member attached to the anchor. In particular embodiments the tissue approximating member comprises a strip and a suture, the strip attached at one end thereof to the anchor and attached at the other end thereof to the suture; and the tissue approximating member may be pivotally connected to the anchor. In some embodiments the locking mechanism includes a lock adapted to engage with a lock engaging feature of the tissue approximating member, which may include a plurality of ratchet ribs/segments.

[020] According to some embodiments of the present invention, the anchor unit further comprises a suture lock for tightening a suture. In some embodiments, the suture lock is movably connected to the suture. Optionally, the suture lock comprises a looped thread for tightening the suture. Additionally or alternatively, the looped thread is an integral part of the suture. Optionally, the looped thread comprises a knot. Optionally, the suture lock is connected to the suture anchor by the suture.

[021] According to some embodiments of another aspect of the present invention, there is provided a method for suturing comprising driving a first movable anchor through a first tissue; driving a second movable anchor through a second tissue; and looping a thread through the two movable anchors and tightening the thread to approximate the two tissues.

[022] According to some embodiments of another aspect of the present invention, there is provided a method for suturing comprising driving a first anchor fixably connected to a first suture through a first tissue; driving a second anchor fixably connected to a second suture through a second tissue; and connecting the two sutures to a movable suture lock and tightening the suture lock to approximate the two tissues.

[023] According to some embodiments of another aspect of the present invention, there is provided a method for suturing comprising driving a first anchor fixably connected to a suture through a first tissue and a second tissue; connecting the suture to a movable suture lock; and tightening the suture lock to approximate the two tissues.

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

[001] Fig. 1A schematically illustrates a side view of an exemplary suture device, in accordance with an embodiment of the present invention;

[002] Fig. 1B schematically illustrates an orthographic top view of the suture device shown in Fig. 1A, in accordance with an embodiment of the present invention;

[003] Fig. 1C schematically illustrates a second orthographic top view of the suture device shown in Fig. 1A, in accordance with an embodiment of the present invention;

[004] Fig. 1D schematically illustrates a cut-away side view of the suture device
5 shown in Fig. 1A, in accordance with an embodiment of the present invention;

[005] Fig. 2A schematically illustrates a side view of an optional jaws opening/closing mechanism in the suture device shown in Fig. 1A, in accordance with some embodiments of the present invention;

[006] Fig. 2B schematically illustrates an orthographic top view of the optional
10 jaws mechanism in Fig. 2A, in accordance with some embodiments of the present invention;

[007] Fig. 2C schematically illustrates an orthographic top view of a structure of the optional jaws mechanism shown in Fig. 2A, in accordance with some embodiments of the present invention;

[008] Figs. 2D and 2E schematically illustrate a mode of operation of the optional
15 jaws opening/closing mechanism, in accordance with some embodiments of the present invention;

[009] Fig. 2F schematically illustrates an orthographic view of detail A in the
20 optional jaws mechanism shown in Fig. 2A, in accordance with some embodiments of the present invention;

[010] Fig. 2G schematically illustrates a side view of an optional jaws height adjustment mechanism in the exemplary suture device shown in Fig. 1A, in accordance with some embodiments of the present invention;

[011] Fig. 2H schematically illustrates an orthographic top view of the optional
25 jaws height adjustment mechanism in Fig. 2G, in accordance with some embodiments of the present invention;

[012] Figs. 2I and 2J schematically illustrate a mode of operation of the optional jaws height adjustment mechanism, in accordance with some embodiments of the present invention;

[013] Fig. 2K schematically illustrates an orthographic view of an optional bridge in the optional jaws mechanism shown in Fig. 2G, in accordance with some embodiments of the present invention;

[014] Fig. 2L schematically illustrates an orthographic view of a detail of a plunger being supported by the optional bridge in the optional jaws mechanism, in accordance with some embodiments of the present invention;

[015] Fig. 3A schematically illustrates an orthographic view of an exemplary anchor unit used in the suture device shown in Fig. 1A, in accordance with some embodiments of the present invention;

[016] Fig. 3B schematically illustrates an orthographic view of the interior of anchor unit of Fig. 3A, in accordance with some embodiments of the present invention;

[017] Fig. 3C schematically illustrates an orthographic view of an exemplary anchor cartridge including the anchor units shown in Fig. 3A, in accordance with some embodiments of the present invention;

[018] Fig. 3D schematically illustrates in a cut-away side view, a temporary needle drive operation of the suture device shown in Fig. 1A, in accordance with some embodiments of the present invention;

[019] Fig. 3E schematically illustrates an orthographic view of a detail of a plunger driving an anchor in the anchor unit shown in Fig. 3A, in accordance with some embodiments of the present invention;

[020] Figs. 3F, 3G, 3H and 3I schematically illustrate orthographic views of a temporary needle driving operation, in accordance with some embodiments of the present invention;

[021] Fig. 3J schematically illustrates a layout of an exemplary suture in the anchor unit shown in Fig. 3A, in accordance with some embodiments of the present invention;

[022] Fig. 3K schematically illustrates an exemplary tissue following a suture operation, in accordance with some embodiments of the present invention;

[023] Figs. 4A, 4B, 4C and 4D schematically illustrate an exemplary method of performing a suture operation using the suture device shown in Fig. 1A, in accordance with some embodiments of the present invention;

[024] Figs. 5A, 5B, 5C, 5D, 5E, 5F, 5G, 5H, 5I, 5J and 5K schematically illustrate an exemplary method of performing a suture operation using two anchor units similar to that shown in Fig. 3A, in accordance with some embodiments of the present invention;

[025] Figs. 6A, 6B, 6C and 6D schematically illustrate an exemplary method of performing a suture operation using three anchor units similar to that shown in Fig. 3A, in accordance with some embodiments of the present invention;

[026] Fig. 7A schematically illustrates an orthographic view of an optional anchor unit safety mechanism in the suture device shown in Fig. 1A, in accordance with some embodiments of the present invention;

[027] Figs. 7B, 7C and 7D schematically illustrate in a side view, a mode of operation of the optional anchor unit safety mechanism shown in Fig. 7A, in accordance with some embodiments of the present invention;

[028] Fig. 7E schematically illustrates an orthographic view of an optional plunger one-way mechanism in the suture device shown in Fig. 1A, in accordance with some embodiments of the present invention;

[029] Fig. 7F schematically illustrates a frontal view of the plunger one way mechanism shown in Fig. 7E, in accordance with some embodiments of the present invention;

[030] Fig. 7G schematically illustrates in a frontal view, a mode of operation of the plunger one way mechanism shown in Fig. 7A, in accordance with some embodiments of the present invention;

[031] Fig. 8A schematically illustrates an orthographic view of an exemplary suture device adapted to drive two anchors from opposing sides of a tissue, in accordance with some embodiments of the present invention;

[032] Fig. 8B schematically illustrates a pulling ring/pulling handle with two anchors, in accordance with some embodiments of the invention;

[033] Figs. 8C, 8D and 8E schematically illustrate an exemplary method of performing a suture operation using the suture device shown in Fig. 8A, in accordance with some embodiments of the present invention; and

[034] Figs. 9A-9H schematically illustrate further embodiments of anchor units of the present invention.

15 DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[035] The present invention, in some embodiments thereof, relates to a medical device and, more particularly, but not exclusively, to a handheld suture device for performing suture operations on human and animal tissues.

[036] An aspect of some embodiments of the present invention relates to a device for approximating two (or more) separate tissue portions by mechanically driving a temporarily formed needle (temporary needle) into a tissue portion and passing the suture through to a distal side of the tissue portion, the temporary needle formed by temporarily attaching a movable plunger in the device to a replaceable penetrating suture anchor (anchor). The anchor, which may be fixably or movably connected to a first end of the suture, or optionally to another location along the suture, is driven by the plunger to the distal side of the tissue where the plunger and the anchor detach. Optionally, the anchor and suture are passed to a proximal side of the tissue portion. Connected to a second end of the suture is a suture lock (lock) movably (unidirectionally) connected to the suture for tightening the suture once the anchor and suture are passed to the distal side of the tissue.

Optionally, the suture lock is connected to another location along the suture. Optionally, the suture is tightened by using a knot tightening element. Optionally, the anchor is movably attached to the first end of the suture and the lock is affixed to the second end. In some embodiments, the suture is attached to a penetrating anchor on one side and a tension anchor on the other.

[037] In some embodiments of the present invention, the device may be used with different configurations of anchor and/or lock connections for varying surgical situations. Optionally, the lock connection comprises a looped thread, optionally a knot, pre-attached to the suture and which may be tightened following deployment to approximate the tissues. For example, one configuration may be based on a loop configuration comprising at least one movable (sliding) anchor in conjunction with a pre-attached/ready-to-use stopper or looped thread. Another configuration may include two sliding anchors in the loop configuration. A third configuration may include one fixed anchor and one sliding anchor. Optionally, two separate sutures may be connectedly fixed to two anchors, the two sutures connected by a locking device.

[038] In some embodiments of the present invention, the handheld device may drive the temporary needle into two or more separate tissue portions which are clamped together, for example using forceps, so that the anchor and suture pass through the clamped tissue portions. Optionally, the device may include clamping means as described further on below. The detached plunger is retrieved and the device withdrawn leaving the anchor and the lock on opposing sides of the clamped tissue portions (connected to one another by the suture). The suturing operation is completed by removing the device from the clamped tissue portions and joining the tissue portions together by tightening the suture, movably displacing the lock in the direction of the joined tissue portions while pulling on the second end of the suture.

[039] Optionally, the handheld device may drive the temporary needle into two or more separate tissue portions passing a different anchor through to a distal side of each portion. Optionally, the anchors are passed through to a proximal side of the tissue portions. The anchors are affixed to one another and to a same lock on an opposing side to the anchors by a same suture. Optionally, each anchor is connected to the lock by a different suture. Additionally or alternatively, each anchor is connected to a different lock.

[040] Optionally, the handheld device includes a body which enables a user of the device, for example a surgeon, to insert the device into an area to be sutured and to use the device without substantially touching nor applying force on a patient's body. An angle of inclination θ of the body relative to a plane perpendicular to a direction of exit of the anchor from the device may range for example from 50-240 degrees, 50-90 degrees, 90-120 degrees, 120-150 degrees, 150-180 degrees, 180-210 degrees or 210-240 degrees.

[041] In some embodiments of the present invention, the device includes a temporary needle driving mechanism comprising the plunger, which is manipulated by an operating handle for driving the plunger into and for pushing the anchor. Optionally, the temporary needle driving mechanism may be pneumatically operated and/or electrically operated. Optionally, the plunger is inserted in the anchor. Optionally, a distance of travel of the plunger may be adjusted so that the anchor may be driven (fired) through tissue portions of varying thicknesses. Additionally or alternatively, the distance of travel may be adjusted by a bridge described further on below. Optionally, the device may include two temporary needle driving mechanisms for passing an anchor from a proximal side to a distal side in a first tissue portion, and for passing the same anchor from a distal side to a proximal side in a second tissue portion. Optionally, the anchor may be double pointing for penetrating a tissue portion from any side. Optionally, the anchor is bullet-shaped. Optionally, the plunger may be drill-shaped and provides for linear and rotational motion in a screw-shaped anchor.

[042] In some embodiments of the present invention, the attachment of the anchor and the plunger to form the temporary needle is by relatively tightly fitting a proximal end of the anchor into a hollow distal end of the plunger. Optionally, the plunger's distal end relatively tightly fits into the distal end of the anchor. Optionally, the anchor's proximal end is an anchor neck. The tight fit allows for the anchor to remain aligned when the temporary needle penetrates into the tissue. An additional aspect of some embodiments of the present invention relates to an anchor unit housing the anchor, the suture and the lock, for loading of a plurality of anchor units in the device. The anchor unit is configured such that the plunger may push the anchor out of the anchor unit and may form a temporary needle by attaching to the anchor. Optionally, the anchor unit may be configured such that the plunger may push the lock out of the anchor unit. Optionally, a single anchor unit is loaded in the device.

[043] In some embodiments of the present invention, the anchor may be housed in a first anchor unit and the lock in a second anchor unit (lock unit), the suture extending from the anchor unit to the lock unit. Optionally, for suture operations involving the use of more than one anchor, for example two anchors, a first anchor and a lock may be housed in a first anchor unit and a second anchor in a second anchor unit. Optionally, the anchors may be housed in two separate anchor units and the lock in a separate lock unit. Optionally, for continuous sutures, a quantity of $n-1$ anchor units may each include an anchor with the lock included in an n^{th} anchor unit (lock unit).

[044] In some embodiments of the present invention, the plurality of anchor units may be accommodated in an anchor cartridge included in the body of the device. Optionally, the cartridge may be external to the device and may be fitted into the body of the device. Optionally, a single anchor unit may be accommodated in the cartridge. Optionally, the anchor units may be shaped to compensate for the angle of inclination θ of the body relative to a plane perpendicular to a direction of exit of the anchor.

[045] In some embodiments of the present invention, the anchor cartridge is acted upon by a cartridge spring for pushing the anchor units in a direction towards a distal end of the body where the plunger may attach to the anchor (e.g. below the temporary needle mechanism). Optionally, other means for pushing the anchor units toward the distal end of the body may be used, for example, by turning a screw-type mechanism at a proximal end of the body, or by inserting a finger through an opening at the proximal end of the body. The cartridge spring may additionally be used for expelling an anchor unit from the device following firing of an anchor and/or a lock in the anchor unit. For convenience, hereinafter, an anchor unit whose anchor and/or lock have been fired may be referred to as a "used anchor unit". Optionally, the cartridge spring may be further used to replace the expelled unit with an unused anchor unit, allowing for relatively fast, repetitive use of the device. Optionally, the used anchor unit is removed by the user.

[046] Once expelled from the device, the anchor unit may be opened and the lock removed from the inside of the anchor unit for tightening of the suture. Optionally, the anchor unit is used to manipulate the tension of the suture while the lock is within the unit. Additionally or alternatively, the lock unit is used to manipulate the tension of the suture.

[047] In some embodiments of the present invention, the device may include at a distal end clamping means such as, for example, jaws for clamping the tissue portion. The jaws are manipulated by a jaws opening adjustment handle so that the tissue portion may be placed inside the jaws. The jaws opening adjustment handle may further be used for closing the jaws clamping the tissue portion once inside the jaws. Optionally, two (or more) tissue portions are placed inside the jaws and clamped together.

[048] In some embodiments of the present invention, the jaws may be adjusted so that tissue portions of different thicknesses may be clamped. A bridge adapted to support the jaws is further adapted to vary the height of the opening of the jaws, allowing for varying thicknesses of tissue portions to be placed in between the jaws.

[049] In some embodiments of the present invention, the device includes safety features to prevent unwanted and/or improper firing of the anchor. For example, a safety feature may include an anchor safety mechanism which blocks the path of the anchor when the tissue portion is not properly clamped by the jaw, preventing the plunger from driving the anchor through the tissue. Another safety feature may include a plunger safety mechanism adapted to enable the plunger to follow a complete trajectory, from an upper dead (pre-firing position) position to a lower dead position when the device is fired, preventing situations where the anchor may not completely penetrate through the tissue portion. Optionally, the plunger safety mechanism may be adapted to prevent unwanted firing when the plunger is being returned to its upper dead position following firing.

[050] In some embodiments of the present invention, the device is adapted to accommodate one or more anchors, the anchors optionally driven by a spring adapted to replace a fired anchor with an unfired anchor. Prior to firing, the suture is connected to the anchor. Optionally, the anchor is loaded into the device prior to firing by the user. Optionally, a pulling ring and/or a pulling handle are used to tighten the suture.

[051] In some embodiments, the device is adapted to be used as a stand alone device passed through the fascia by manual techniques and/or passed through the fascia by a dedicated applicator designed for this purpose; for example the device may be a hollow tube designed to partially grasp the penetrating anchor and pass it through the fascia, and/or a dedicated applicator designed to pass several suture anchors through the fascia one after the other. In some embodiments, the device may include various elements, for

example: (a) a hollow tube adapted to partially grasp the penetrating anchor and pass it through the fascia in a clean manner without fat and tissue debris which could hinder the grasping function of a second hollow tube designed to receive the penetrating anchor on the opposite side of the fascia tissue, the second hollow tube used to grasp the penetrating anchor on second side of the fascia; (b) a plunger adapted to push the penetrating anchor from a first side of the tissue out of the first hollow tube to second side of tissue partially into second hollow tube partially grasping the anchor on second side of the tissue; (c) a cartridge adapted to grasp a single tension anchor and housing within the wound suture and adjacent to the penetrating anchor; and (d) a staple-like device adapted to house the above elements. The staple-like device may have prongs located close to its distal edge which when approximated by closing the upper and lower segments of the stapler-like device may grasp the fascia tissue and allow the fascia tissue to be pulled as required. The staple-like device may be adapted to a mechanism which ejects, upon each pressing of handles, a single suture anchor from the cartridge.

[052] In some embodiments of the present invention, flexible anchors may be adapted to bend after penetrating the fascia and thus enable a reduction of the staple-like device profile beneath the fascia wound/incision.

[053] Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Suture Device

[054] Referring now to the drawings, Fig. 1A schematically illustrates a side view of an exemplary suture device 1, Fig. 1B schematically illustrates an orthographic top view of the suture device, Fig. 1C schematically illustrates a second orthographic top view of the suture device, and Fig. 1D schematically illustrates a cut-away side view of the suture device, all in accordance with an embodiment of the present invention.

[055] According to some embodiments of the present invention, suture device 1 is adapted to join two or more separate portions of tissue together in a suture operation by optionally clamping the tissue portions and mechanically driving a suture anchor and an

attached tissue approximating member or tissue holding member, comprising for example a suture strip, suture thread, combination thereof, or the like. In the description and claims, the term "suture" may be used to denote the aforementioned terms and includes such options for the tissue approximating/holding/tying member, feature or element, and their equivalents. Optionally, clamping of the tissue portions may be done with the aid of forceps. The suture operation is then completed by pulling on one end of the suture, tightening the tissue portions together. Suture device 1 includes an elongated body 2 and a pivotable handle 3 connected to the body, a proximal portion of the body and the handle adapted to be gripped by the surgeon during a suture operation. Body 2 may comprise an angle of inclination θ with respect to a plane 2' perpendicular to a direction of exit 2" of the anchor from the device, which allows for mechanical operation of the body and handle 3 above the surface of a target tissue (not shown) without touching the tissues which lay below the position of device 1 during its operation. The tissue portions may be human tissue or optionally animal tissue, and may include fascia. Suture device 1 is further adapted to be held in a single hand during the suture operation. Optionally, suture device 1 may be held in both hands during the suture operation.

[056] According to some embodiments of the present invention, at a distal end of body 2 are optionally jaws 6, adapted to clamp the tissue portions, and an optional bridge 7 adapted to adjust a height of the jaws so as to allow clamping of different thicknesses of tissue portion. Opening and closing of jaws 6 is controlled by a rotatable jaws opening adjustment handle 5 connected to body 2, and height adjustment of the jaws is controlled by a jaws height adjustment handle 4 on the body.

[057] According to an embodiment of the present invention, positioned above jaws 6 is a temporary needle driving mechanism comprising a plunger leading canal 8, plunger arms 81, and a plunger 82, the mechanism adapted to mechanically drive the plunger to push the suture anchor to form a temporary needle which is driven through the tissue portions. Optionally, plunger 82 is pushed into the anchor. Handle 3 includes arms 31 at a distal end which attach to plunger arms 81, the arms adapted to push down plunger 82 when the handle is rotated by the surgeon in a direction towards body 2. Optionally, plunger arm 81 may be pneumatically driven and/or electrically driven. A plunger one-way mechanism 9 ensures that plunger 82 follows a complete path along plunger arms leading canal 8 to form a temporary needle by attaching to the anchor. An anchor safety

mechanism 12 prevents driving the anchor into a tissue portion improperly clamped in jaws 6.

[058] According to an embodiment of the present invention, body 2 includes an interior compartment 10 including an anchor cartridge 11 for accommodating a plurality of aligned anchor units 111, the anchor units described in greater detail further on below. Optionally, anchor cartridge 11 is external to device 1 and may be fitted into body 2. Optionally, anchor cartridge 11 may accommodate a single anchor unit 111. Anchor cartridge 11 is pushed towards the distal end of body 2 by a cartridge spring 13 also in interior compartment 10, the cartridge spring adapted to automatically expel used anchor units 111 and to optionally automatically replace an expelled anchor unit with an unused anchor unit. Optionally, used anchor unit 111 is removed manually by the surgeon.

[059] Clamping Mechanism (Optional)

[060] Fig. 2A schematically illustrates a side view of an opening/closing mechanism in optional jaws 6 in suture device 1, Fig. 2B schematically illustrates an orthographic top view of the opening/closing mechanism, and Fig. 2C schematically illustrates an orthographic top view of a structure of the opening/closing mechanism, all in accordance with some embodiments of the present invention. The opening/closing mechanism includes optional jaws push rod 61 adapted to slidingly move along a portion of body 2 guided by an optional first jaws push rod leader 63 and an optional second jaws push rod leader 64 and further adapted to push or pull an optional jaws pivot lever 66 attached to jaws 6, opening and closing the jaws, respectively. Optionally, jaws 6 may be opened by a pulling action of jaws push rod 61, and closed by a pushing action.

[061] Jaws push rod 61 includes an optional jaws push rod pin 62 at a proximal end, the pin adapted to be inserted in an optional handle groove 51 in optional rotatable jaws opening adjustment handle 5, and further adapted to slidingly move within the slot responsive to the rotatable jaws handle pivoting around an optional axle 32 connected to body 2. Jaws push rod 61 additionally includes an optional jaws push rod slot 65 adapted to accommodate jaws pivot lever 66 and to impart a pushing/pulling action on the jaws pivot lever through an optional open stopper 68 and an optional jaws closed stopper 67, respectively. Jaws 6 is supported by an optional bridge pedestal 72 in optional bridge 7,

which comprises an optional jaws height adjustment groove 71 along which jaws pivot lever 66 may slidingly be displaced when the jaws are opened or closed.

[062] Figs. 2D and 2E schematically illustrate a mode of operation of optional jaws 6 opening/closing mechanism, and Fig. 2F schematically illustrates an orthographic view of detail A in the opening/closing mechanism, all in accordance with an embodiment of the present invention. To open jaws 6 the surgeon applies with a finger a force F on jaws opening adjustment handle 5, and rotates the handle from position a to position b. Jaws opening adjustment handle 5 applies a force on jaws push rod 61 by the contact force between a surface of the handle groove 51 and jaws push rod pin 62. The jaws push rod 61 is located between first push rod leader 63 and second push rod leader 64 that force the push rod to move forward (towards the distal end of body 2) in a straight motion. Jaws push rod 61 applies force on jaws 6 with jaws open stopper 68 on jaws push rod groove 65 forcing the jaws to rotate and to open. When closing, the surgeon pushes jaws opening adjustment handle 5 in a direction opposite to that shown by force F, so that jaws push rod 61 moves backward (towards the proximal end of body 2). Jaws push rod 61 applies force on jaws 6 with jaws close stopper 67 on jaws push rod groove 65, forcing the jaws to rotate in the opposite direction and close.

[063] Fig. 2G schematically illustrates a side view of the optional jaws 6 height adjustment mechanism in suture device 1, Fig. 2H schematically illustrates an orthographic top view of the jaws height adjustment mechanism, Fig. 2K schematically illustrates an orthographic view of optional bridge 7 in the jaws mechanism, and Fig. 2L schematically illustrates an orthographic view of a detail of plunger 82 being supported by the bridge, all in accordance with some embodiments of the present invention. The height adjustment mechanism for jaws 6 includes bridge 7 and optional jaws height adjustment locking handle 41 (included in optional jaws height adjustment handle 4).

[064] Bridge 7 includes an optional bridge pedestal 72 which, by means of optional connecting axle 73, supports jaws 6; optional jaws height adjustment groove 71 adapted to allow the bridge to be raised or lowered a distance d; optional needle arm slot 75 adapted to accommodate needle arms 81 when plunger 82 has travelled a distance in needle arms leading canal 8 required to pass the temporary needle through the tissue portion; and optional height adjustment teeth 74 adapted to allow the bridge to be locked at a height suitable to fit the tissue portion inside jaws 6.

[065] Figs. 2I and 2J schematically illustrate a mode of operation of jaws 6 height adjustment mechanism, in accordance with some embodiments of the present invention. Bridge 7 is locked in position at a selected height (selected by the surgeon) by an optional locking lever 42 included in optional jaws height adjustment locking handle 41, the locking lever adapted to fit between two optional teeth 74. To vary the height of jaws 6 in order to clamp a tissue portion of a different thickness than that for which the height is adjusted, the surgeon slides jaws height adjustment handle 4 in a direction towards the proximal end of body 2. Jaws height adjustment locking handle 41 slides together with jaws height adjustment handle 4 causing locking lever 41 to be withdrawn from between teeth 74. Bridge 7 is now free to be moved by the surgeon to a required new height. Once moved to the new height (clamping the tissue portion) the surgeon may lock bridge 7 in place by sliding jaws height adjustment handle 4 in a direction towards the distal end of body 2. Jaws height adjustment locking handle 41 also slides in the direction towards the distal end of body 2 pushing locking lever 42 to engage teeth 74 at the new height.

[066] Anchor Unit

[067] Fig. 3A schematically illustrates an orthographic view of anchor unit 111 used in suture device 1, Fig. 3B schematically illustrates an orthographic view of the interior of the anchor unit, and Fig. 3C schematically illustrates an orthographic view of anchor cartridge 11 including the plurality of aligned anchor units, all in accordance with some embodiments of the present invention. Anchor unit 111 comprises an anchor housing 112 housing the suture, the anchor housing comprising a detachable first anchor housing side 112A and second anchor housing side 112B (the anchor housing may be opened into the two sides).

[068] The suture includes a suture 115 connecting a suture anchor 113 fixedly attached to one end of the suture, the anchor adapted to attach to plunger 82 to form a temporary needle to be driven through a tissue portion during a suture operation. The suture further includes a suture lock 114 movably attached to the other end of suture 115, the lock adapted to tighten the suture as the suture is pulled through the lock. The suture may be of an absorbable material, or optionally, of a non-absorbable material, biodegradable materials, and the like as known in the art. The suture may have a dedicated stopping elements adapted to be located at fixed distances along the suture. The dedicated stopping elements adapted to a diameter larger than the diameter of the suture itself.

Optionally, a knot is used as a tightening element, the knot optionally housed in knot housing inside anchor unit 111.

[069] Anchor unit 111 is adapted to have anchor 113 forcibly pushed by plunger 82 out of anchor housing 112 responsive to the plunger being driven by pressing of operating handle 3. Optionally, plunger 82 is driven by pneumatic and/or electric operation. In some embodiments of the present invention, anchor 113 is pointed at its distal end to enable penetration through the target tissue. Optionally, anchor 113 is designed to have a slightly smaller diameter at its proximal end or alternatively to have a hollowed out proximal end. In the former, plunger 82 is optionally hollow at least at its distal end, and optionally has an internal diameter equal to or slightly smaller than a diameter of the proximal end of anchor 113. Alternatively, as in the latter anchor type, the plunger's distal end is optionally needle like, narrow and optionally enters deeply into the hollow proximal end of anchor 113. In this manner the needle-like distal end may hold the anchor aligned when it penetrates the tissue. A temporary junction between the plunger and the anchor forms a temporary needle with anchor 113 driving with its optionally pointed distal end through the target tissue.

[070] Suture 115 is adapted to be pulled out of anchor unit 111 by anchor 113 as the anchor is pushed out of anchor housing 112 and driven through the tissue portion, an end of the suture remaining inside the anchor unit attached to lock 114. Lock 114 may then be removed from anchor housing 112 by expelling, or otherwise removing, the anchor housing from suture device 1 and detaching first and second anchor housing sides 112A and 112B so that the lock may be removed and suture 115 tightened. Optionally, lock 114 may remain inside anchor unit 111 while the suture is tensioned.

[071] In some embodiments of the present invention, the suture is housed in more than one anchor unit 111. For example, anchor 113 may be housed in an anchor unit 111 and lock 114 in a lock unit (not shown), suture 115 extending from the anchor unit to the lock unit. Optionally, for suture operations involving the use of more than one anchor 113, for example two anchors, the first anchor and lock 114 may be housed in first anchor unit and 111 and the second anchor in the second anchor unit. Optionally, anchors 113 may be housed in two separate anchor units 111, and lock 114 in the lock unit. Optionally, multiple anchors are housed in multiple anchor units with one lock housed in a lock unit, for a continuous suture.

[072] Temporary Needle Driving Mechanism

[073] Fig. 3D schematically illustrates in a cut-away side view of a temporary needle drive operation in suture device 1, Fig. 3E schematically illustrates an orthographic view of a detail of plunger 82 forming a temporary needle with anchor 113 in anchor unit 111, and Figs. 3F-3I schematically illustrate orthographic views of temporary needle driving operation, all in accordance with some embodiments of the present invention.

[074] A force F is applied to operating handle 3 (for example, by the surgeon pressing on the handle) so as to cause the operating handle to rotate from a point a to a point a'. Arms 31 connecting to needle arms 81 move in a direction opposite to that in which the force F was applied, causing plunger 82 to travel in a linear path from a point h (upper dead point) to a point h' (lower dead point). While moving down from point h to point h' plunger 82 is inserted into anchor 113 in an anchor unit 111 positioned above a tissue portion optionally clamped in jaws 6. Anchor 113 is then forcibly pushed out of anchor unit 111 by plunger 82 having formed a temporary needle, and is driven out of suture device 1 through the tissue portion, a distance equivalent to that travelled by the plunger from point h to point h' (this distance should be enough for the anchor to go through the tissue portion). Suture 115 is pulled out of anchor housing 112 together with the anchor, one end remaining inside the anchor housing connected to lock 114. Operating handle 3 is then released, returning to point a by means of a spring, or optionally other type of mechanism for returning the handle which may include a hydraulic mechanism, and arm 31 pulls plunger 82 back to point h with the anchor 113 ejected from the plunger.

[075] Suture Operation

[076] Fig. 3J schematically illustrates a layout of an exemplary suture in anchor unit 111, and Fig. 3K schematically illustrates an exemplary tissue following a suture operation using the anchor, all in accordance with some embodiments of the present invention. Other suture operations are possible as should be evident to a person skilled in the art that described herein is not intended to be limiting in any form, way or manner.

[077] In this suture operation, anchor 113 is driven through two tissue portions 20 and 21 (for example, two fascia flaps formed by an incision). Suture 115 is driven together with anchor 113 through tissue portions 20 and 21 with an end remaining attached to lock 114. First anchor housing side 112A and second anchor housing side

112B are detached exposing lock 114 which is removed from second anchor housing side 112B. Suture 115 is pulled through the lock forcing the lock to move in a direction of, and joining together, two tissue portions 20 and 21. Optionally, lock 114 may be removed from first anchor housing side 112A.

5 [078] Suture Device Operation Using One Anchor Unit

[079] Figs. 4A-4D schematically illustrate an exemplary method of performing a suture operation clamping a first tissue portion 20 and a second tissue portion 21 together optionally using suture device 1, all in accordance with some embodiments of the present invention. The method described is not intended to be limiting in any form,
10 way or manner, and should be evident to a person skilled in the art that there may be numerous variations to the described method.

[080] [Optionally at 1] Jaws 6 in suture device 1 are opened in preparation to clamp two tissue portions 20 and 21 which are to be joined together (tissue repair, for example, fascia). Jaws opening adjustment handle 5 is rotationally pulled by the surgeon in
15 a direction towards the proximal end of body 2 causing jaws 6 to open. Optionally, a height of jaws 6 was previously adjusted by the surgeon using jaws height adjustment handle 4.

[081] [Optionally at 2] Suture device 1 is neared to tissue portions 20 and 21 and the two tissue portions placed inside jaws 6.

20 [082] [Optionally at 3] Jaws opening adjustment handle 5 is rotationally pushed by the surgeon in a direction towards the distal end of body 2 causing jaws 6 to close, clamping tissues 20 and 21 together. Operating handle 3 is pressed by the surgeon (rotates in a direction towards body 2) causing arm 31 to push down on needle arms 81.

[083] [Optionally at 4] Plunger 82 is driven into anchor 113 by the downward
25 motion of arm 31 on needle arms 81. Anchor 113 is fired and drives through tissue portions 20 and 21 clamped by jaws 6. Suture 115 is pulled by anchor 113 through the tissue portions 20 and 21.

[084] [Optionally at 5] Plunger 82 travels distance from the upper dead point to the lower dead point and attaches to anchor 113 forming a temporary needle passing through tissue portions 20 and 21.

[085] [Optionally at 6] Plunger 82 is pulled back to the upper dead point by the returning of operating handle 3 to its initial position (rotates in a direction away from body 2). Anchor 113 is turned so that it is locked on a far side of clamped tissues 20 and 21. Locking of anchor 113 may be manually performed by the surgeon, or optionally by a locking mechanism activated by the removal of plunger 82 from the anchor.

[086] [Optionally at 7] Suture device 1 is retrieved from the sutured tissues 20 and 21. Jaws 6 are opened by the surgeon (see 1). Anchor housing 12 of used anchor unit 111 is inside suture device 1, suture 115 connected at one end to anchor 113 and at another end to lock 114 inside the used anchor unit.

[087] [Optionally at 8] Anchor housing 12 is ejected from suture device 1 by the spring action of cartridge spring 10 on anchor cartridge 11. An unused anchor unit 111 is pushed by cartridge spring 10 and replaces the used anchor unit, allowing suture device 1 to be used quickly and repetitively. Optionally, anchor housing 12 (from the used anchor unit 111) is manually removed by the surgeon.

[088] [Optionally at 9] The surgeon separates anchor housing 12 into first anchor housing side 112A and second anchor housing side 112B, exposing lock 114. Lock 114 is removed from second anchor housing side 112B.

[089] [Optionally at 10] Suture 115 is pulled through lock 114 as the lock is forced along the suture in a direction of tissues 20 and 21, joining the tissues together. Anchor 113 and lock 114 are on opposing sides of joined tissues 20 and 21, connected by suture 115. A remaining portion of suture 115 extending beyond lock 114 may be cut and disposed of.

[090] Suture Device Operation Using Two Anchor Units

[091] Figs. 5A-5K schematically illustrate an exemplary method of performing a suture operation using a first anchor unit 111A and a second anchor unit 111B optionally using suture device 1, all in accordance with some embodiments of the present invention.

Figs. 5A and 5B show first anchor unit 111A and second anchor unit 111B as sliding anchors, respectively, in a loop configuration. Figs. 5C-5K show the actions of the sliding anchors in the suturing operation involving the loop configuration. As may be appreciated, a feature included in this loop configuration is the provision of a looped thread 115, optionally a knot, which may be tightened after deployment to approximate tissues 20 and 21. The method described is not intended to be limiting in any form, way or manner, and should be evident to a person skilled in the art that there may be numerous variations to the described method.

[092] In the suture operation described, a first anchor 113A from first anchor unit 111A is driven through a first tissue portion 20 using suture device 1, and a second anchor 113B from second anchor unit 111B is driven through a second tissue portion 21 using the suture device. The suture passes through a groove in anchor 113B in order to allow the suture to slide through the groove during the approximation process. First anchor 113A and second anchor 113B are connected together by same suture 115 connected to lock 114 included in first anchor unit 111A. Optionally, lock 114 is included in second anchor unit 111B.

[093] [Optionally at A1] Jaws 6 in suture device 1 are opened in preparation to clamp first tissue portion 20 to be joined together with second tissue portion 21 (tissue repair, for example, fascia layers). Jaws opening adjustment handle 5 is rotationally pulled by the surgeon in a direction towards the proximal end of body 2 causing jaws 6 to open. Optionally, the height of jaws 6 was previously adjusted by the surgeon using jaws height adjustment handle 4. Suture device 1 is neared to tissue portion 20 and the tissue portion placed inside jaws 6. Jaws opening adjustment handle 5 is rotationally pushed by the surgeon in a direction towards the distal end of body 2 causing jaws 6 to close, clamping tissue portion 20.

[094] [Optionally at A2] Operating handle 3 is pressed by the surgeon (rotates in a direction towards body 2) causing arm 31 to push down on needle arms 81. Needle 82 is driven into anchor 113A by the downward motion of arm 31 on needle arms 81. Anchor 113A is fired and drives through tissue portion 20. Needle 82 travels distance from the upper dead point to the lower dead point causing anchor 113A and suture 115 to pass through tissue portion 20 to an underside of the tissue portion.

[095] [Optionally at A3] Needle 82 is pulled back to the upper dead point by the returning of operating handle 3 to its initial position (rotates in a direction away from body 2). Anchor 113A is turned so that it is locked on the underside of clamped tissue 20. Locking of anchor 113A may be manually performed by the surgeon, or optionally by a locking mechanism activated by the removal of needle 82 from the anchor. Suture device 1 is retrieved from the sutured tissue 20. Jaws 6 are opened by the surgeon (see A1).

[096] The anchor housing of used (first) anchor unit 111A is inside suture device 1, suture 115 connected at one end to anchor 113A, to lock 114 inside used anchor unit 111A, and to anchor 113B in second anchor unit 111B. The anchor housing of used (first) anchor unit 111A is ejected from suture device 1 by the spring action of cartridge spring 10 on anchor cartridge 11. Second anchor unit 111B is pushed by cartridge spring 10 and replaces used anchor unit 111A. Optionally, the anchor housing of used (first) anchor unit 111A is manually removed by the surgeon. The surgeon separates the anchor housing of used (first) anchor unit 111A and removes lock 114.

[097] [Optionally at A4] Jaws 6 in suture device 1 are opened in preparation to clamp second tissue portion 21. Jaws opening adjustment handle 5 is rotationally pulled by the surgeon in a direction towards the proximal end of body 2 causing jaws 6 to open. Optionally, the height of jaws 6 was previously adjusted by the surgeon using jaws height adjustment handle 4. Suture device 1 is neared to tissue portion 21 and the tissue portion placed inside jaws 6. Jaws opening adjustment handle 5 is rotationally pushed by the surgeon in a direction towards the distal end of body 2 causing jaws 6 to close, clamping tissue portion 21.

[098] Operating handle 3 is pressed by the surgeon (rotates in a direction towards body 2) causing arm 31 to push down on needle arms 81. Plunger 82 is driven into anchor 113B by the downward motion of arm 31 on needle arms 81. Anchor 113B is fired and drives through tissue portion 20. Plunger 82 travels distance from the upper dead point to the lower dead point and attaches to anchor 113B forming a temporary needle passing through tissue portion 21 to an underside of the tissue portion.

[099] [Optionally at A5] Plunger 82 is pulled back to the upper dead point by the returning of operating handle 3 to its initial position (rotates in a direction away from body 2). Anchor 113B is turned so that it is locked on the underside of clamped tissue 21.

Locking of anchor 113B may be manually performed by the surgeon, or optionally by a locking mechanism activated by the removal of plunger 82 from the anchor. Suture device 1 is retrieved from the sutured tissue 21. Jaws 6 are opened by the surgeon (see A1).

[0100] The anchor housing of used second anchor unit 111B is ejected from suture device 1 by the spring action of cartridge spring 10 on anchor cartridge 11. Optionally, the anchor housing of used (second) anchor unit 111B is manually removed by the surgeon.

[0101] [Optionally at A6] Suture 115 is pulled through lock 114 as the lock is forced along the suture in a direction of tissues 20 and 21, joining the tissues together. Anchors 113A and 113B, and lock 114 are on opposing sides of joined tissues 20 and 21, connected by suture 115. A remaining portion of suture 115 extending beyond lock 114 may be cut and disposed of.

[0102] Suture Device Operation Using Two Anchor Units and One Lock Unit

[0103] Figs. 6A-6D schematically illustrate an exemplary method of performing a suture operation using a first anchor unit 111A, a second anchor unit 111B, and a lock unit 111C, optionally using suture device 1, all in accordance with some embodiments of the present invention. The figures show two sutures 115A and 115B, fixedly connected to first anchor unit 111A and second anchor unit 111B respectively, and the two sutures connected by locking unit 111C. The method described is not intended to be limiting in any form, way or manner, and should be evident to a person skilled in the art that there may be numerous variations to the described method.

[0104] In the suture operation described, a first anchor 113A from first anchor unit 111A is driven through a first tissue portion 20 using suture device 1, a second anchor 113B from second anchor unit 111B is driven through a second tissue portion 21 using the suture device, and a lock 114 is provided in a lock unit 111C. First anchor 113A is attached to lock 114 through a first suture 115A, and second anchor 113B is attached to lock 114 through a second suture 115B. Sutures 115A and 115B are pulled through lock 114 as the lock is forced along the sutures in a direction of tissues 20 and 21, joining the tissues together. Optionally, first anchor 113A, second anchor 113B, and lock 114, are connected through a same suture.

[0105] [Optionally at B1] Jaws 6 in suture device 1 are to be opened in preparation to clamp first tissue portion 20 which is to be joined together with second tissue portion 21. Jaws opening adjustment handle 5 is rotationally pulled by the surgeon in a direction towards the proximal end of body 2 causing jaws 6 to open. Optionally, the height of jaws 6 was previously adjusted by the surgeon using jaws height adjustment handle 4. Suture device 1 is neared to tissue portion 20 and the tissue portion placed inside jaws 6. Jaws opening adjustment handle 5 is rotationally pushed by the surgeon in a direction towards the distal end of body 2 causing jaws 6 to close, clamping tissue portion 20.

[0106] [Optionally at B2] Operating handle 3 is pressed by the surgeon (rotates in a direction towards body 2) causing arm 31 to push down on needle arms 81. Plunger 82 is driven into anchor 113A by the downward motion of arm 31 on needle arms 81, and travels a distance from the upper dead point to the lower dead point and attaches to anchor 113A forming a temporary needle passing through tissue portion 20. Plunger 82 is pulled back to the upper dead point by the returning of operating handle 3 to its initial position (rotates in a direction away from body 2). Anchor 113A is turned so that it is locked on an underside of clamped tissue portion 20. Locking of anchor 113A may be manually performed by the surgeon, or optionally by a locking mechanism activated by the removal of plunger 82 from the anchor. Jaws 6 are opened by the surgeon (see B1) and suture device 1 is retrieved from the sutured tissue 20.

[0107] [Optionally at B3] Repeat B1 and B2 for second tissue portion 21 driving second anchor 113B in second anchor unit 111B into the tissue portion.

[0108] [Optionally at B4] Eject lock unit 111C from suture device 1 by the spring action of cartridge spring 10 on anchor cartridge 11. Optionally, lock unit 111C is manually removed by the surgeon. The surgeon opens lock unit 111C exposing lock 114. Lock 114 is removed. Sutures 115A and 115B are pulled through lock 114 as the lock is forced along the s in a direction of tissues 20 and 21, joining the tissues together. A remaining portion of suture 115A and/or 115B extending beyond lock 114 may be cut and disposed of.

[0109] Anchor Unit Safety Mechanism (Optional)

[0110] Fig. 7A schematically illustrates an orthographic view of an optional anchor unit safety mechanism 12 in suture device 1, and Figs. 7B-7D schematically

illustrate in a side view, a mode of operation of the anchor unit safety mechanism shown, all in accordance with some embodiments of the present invention. Anchor safety mechanism 12, by blocking a drive path of anchor 113 with an optional movable blocking plate 121, is adapted to prevent unwanted firing of the anchor in anchor unit 111 when tissue portion 20 is not properly placed in jaws 6. Attached to movable blocking plate 121 is an optional lever 122, adapted to slidingly expose tissue portion 20 to anchor 13 when the lever is pushed back by correct insertion of the tissue portion into jaws 6.

[0111] Plunger Safety Mechanism (Optional)

[0112] Fig. 7E schematically illustrates an orthographic view of an optional plunger one-way mechanism 9 in suture device 1, and Fig. 7F schematically illustrates a frontal view of the plunger one-way mechanism, all in accordance with some embodiments of the present invention. Plunger one-way mechanism 9 (plunger safety mechanism) is adapted to allow complete movement of plunger 82 from the upper dead point to the lower dead point during driving of anchor 113, thereby ensuring that the anchor completely penetrates through the tissue portion (and does not get stuck in the tissue portion). Optionally, plunger safety mechanism 9 is further adapted to prevent unwanted firing when plunger 82 is being moved from the lower dead point to the upper dead point following firing. Plunger safety mechanism 9 includes an optional rack 91 with teeth 910, an optional lever 92, an optional spring 93, and an optional axle 94, a functional description of these components provided hereinafter with regards to Fig. 7G.

[0113] Fig. 7G schematically illustrates in a frontal view, a mode of operation of optional plunger one-way mechanism 9, in accordance with some embodiments of the present invention. The method described is not intended to be limiting in any form, way or manner, and should be evident to a person skilled in the art that there may be numerous variations to the described method.

[0114] [Optionally at C1] Plunger arms 81 are in the upper dead position. Lever 92 is locked in a horizontal position by spring 93, the lever resting on upper ledge 911. Plunger arms 81 cannot move down plunger arms leading canal 8 without a downward force being exerted by arms 31.

[0115] [Optionally at C2] When driving anchor 113, arms 31 pushing on plunger arms forces lever 92 to rotate in a counter clockwise direction against a force of spring 93.

Lever 92 engaging of teeth 910 in rack 91 is such that the teeth prevent the lever from returning to the horizontal position, restricting plunger arms 81 to movement in a downward direction (from the upper dead point to the lower dead point).

[0116] [Optionally at C3] Upon reaching the lower dead point lever 92 rotates into a horizontal position under the action of spring 93, as there are no teeth 910 preventing the rotation (lever is below lower ledge 912).

[0117] [Optionally at C4] Following driving anchor 113, operating handle 3 is returned to its initial position, arms 31 pull on plunger arms and forces lever 92 to rotate in a clockwise direction against a force of spring 93. Lever 92 engaging of teeth 910 in rack 91 is such that the teeth prevent the lever from returning to the horizontal position, restricting plunger arms 81 to movement in an upward direction (from the lower dead point to the upper dead point).

[0118] [Optionally at C5] Upon plunger arms 81 reaching the upper dead point lever 92 rotates into a horizontal position under the action of spring 93, as there are no teeth 910 preventing the rotation (lever rests on upper ledge 911). Plunger arms 81 cannot move down plunger arms leading canal 8 without a downward force being exerted by arms 31.

[0119] Double Anchor Suture Device

[0120] Fig. 8A schematically illustrates an orthographic view of an exemplary suture device 200 adapted to drive a double-pointed anchor 207 from opposing sides of a tissue, optionally from a distal side of one tissue and from a proximal side of a second tissue, and Fig. 8B schematically illustrates a pulling ring/pulling handle 205 attached to a tension anchor 209, double-pointed anchor 207, and suture 206 interconnecting the anchors, for use with the suture device, all in accordance with some embodiments of the invention. Suture device 200 is further adapted to join two or more separate portions of tissue together in a suture operation by driving double-pointed anchor 207 from one side of the tissue to the other side. Tension anchor 209 remains at a proximal side of a first tissue flap. Double-pointed anchor 207 then penetrates from a distal side of a second tissue flap to a proximal side of the second tissue flap. Suture 206 includes extrusions 208 to allow tension to be applied by one-way tension anchor 209, optionally, by any other one way tension system suitable for the application. The suture may be of an absorbable material, a

non-absorbable material, biodegradable materials, and the like as known in the art. The tension anchor 209 may be of a flexible plastic material. Optionally, the anchors and/or locks may also be of an absorbable or non-absorbable material. The tissue portions may be human tissue and/or optionally animal tissue, and may include fascia. Suture device 200 is further adapted to be held in a single hand during the suture operation. Optionally, suture device 200 may be held in both hands during the suture operation.

[0121] Suture device 200 includes a first body 201 and a first operating handle 203 adapted to drive anchor 207 through a first tissue portion, and a second body 202 and a second operating handle 204 adapted to drive anchor 207 through a second tissue portion. Optionally, suture device 200 may be adapted to accommodate one or more anchor 206 and/or anchor 207, the anchors optionally driven by a spring (not shown) such that a fired anchor may be replaced by a new one. Prior to firing, suture 208 may be connected to anchor 206 and/or anchor 207. Optionally, anchor 206 and/or anchor 207 is loaded into suture device 200 by the surgeon prior to firing. Optionally, suture 206 is connected to a handle 205 adapted to pull the suture through tension anchor 209 forcing the anchor in the direction of anchor 207 and joining the first and second tissue together.

[0122] Figs 8C-8E schematically illustrate an exemplary method of performing a suture operation optionally using suture device 200, all in accordance with some embodiments of the present invention. The method described is not intended to be limiting in any form, way or manner, and should be evident to a person skilled in the art that there may be numerous variations to the described method. In the suture operation described, first anchor 207 is first driven through a first tissue portion 20 using handle 203 in suture device 200, and then driven through a second tissue portion 21 using handle 204 in the suture device. Tension anchor 209 and first anchor 207 are connected together by suture 206 for approximating tissue portions 20 and 21 together.

[0123] [Optionally at D1] Suture device 200 is neared to first tissue portion 20 and the tissue portion is inserted between a distal end of body 201 and a distal end of body 202 positioned under anchor 207 in body 201.

[0124] [Optionally at D2] Body 201 and body 202 are pressed in a direction towards one another by the surgeon until coming in contact with first tissue portion 20.

[0125] [Optionally at D3] Surgeon fires anchor 207 by pressing operating handle 203, driving the anchor through first tissue portion 20 from a top side to an under side. Operating handle 203 is released and body 201 and body 202 are separated releasing tissue portion 20. Suture device 200 is retrieved.

5 [0126] [Optionally at D4] Suture device 200 is neared to second tissue portion 21 and the tissue portion is inserted between a distal end of body 201 and a distal end of body 202 positioned over anchor 207 in body 202. Body 201 and body 202 are pressed in a direction towards one another by the surgeon until coming in contact with second tissue portion 21. Surgeon fires anchor 207 by pressing operating handle 204, driving the anchor
10 through second tissue portion 21 from an under side to a top side. Operating handle 204 is released and body 201 and body 202 are separated releasing tissue portion 21. Suture device 200 is retrieved.

[0127] [Optionally at D5] Suture 206 is pulled, by means of pulling handle 205 (and optionally handle 210), through tension anchor 209 as the anchor is forced along the
15 suture in a direction of tissues 20 and 21, joining the tissues together. A remaining portion of suture 206 extending beyond anchor 209 may be cut and disposed of.

[0128] The tension anchor may have a hollow chamber which passes through from the proximal side to the distal side. The suture may be adapted to passes through this hollow chamber. The suture can be pulled through the chamber in one direction only. The
20 chamber has special features which allow the suture to pass in one direction but not in the other, as a result of the presence of the stopping elements on the suture. An accessory is provided which grasps the suture and facilitates pulling the suture through the tension anchor in one direction to shorten the distance between the tension anchor and the penetrating anchor in order to affect the closure of an open fascia wound/incision.

25 [0129] Figs. 9a-9h show additional embodiments of an anchor unit (a particularly preferred embodiment illustrated in Fig. 9A) wherein the unit comprises a tissue approximating member with a tissue holding or tying element, for example a strip 116 integrally formed with or pivotally connected to anchor 113c (Fig. 9C illustrates an example of an integrally formed strip and anchor), typically at the distal end of the strip. At
30 the proximal end of strip 116 is a suture engaging portion 118 (Fig. 9B). In one embodiment, suture engaging portion 118 includes a directionality portion 120, for aiding

in directing the position of the anchor unit and/or position of the tissues to be approximated; and a pulling portion 123. Suture 115 is respectively threaded in suture paths 119a and 119b of directionality portion 120 and pulling portion 123.

[0130] Strip 116 preferably includes a lock engaging feature (exemplified best in Fig. 9G), for example a plurality of ratchet ribs or segments 117. Lock 114a comprises a ratchet segment engaging member 124, in this embodiment having a pair of ratchet segment engaging elements 125 (see Fig. 9H, a partial exploded view of lock 114a which also shows a pair of lock suture paths 127 through which suture 115 is threaded).

[0131] An exemplary anchor unit housing 126 is shown in Fig. 9D. After the anchors 113c are driven through the tissue, suture 115 is pulled to direct and approximate the tissues to the point where ratchet segment engaging elements 125 are engaged with ratchet segments 117 thereby holding the tissues in their approximated positions (Fig. 9G).

[0132] Fig. 9E shows the anchor unit being driven into one tissue (flap); Fig. 9F shows the anchor unit after two anchors 113c have been driven into two respective tissue flaps, prior to pulling on suture 115 to approximate the tissues; and Fig. 9G shows the situation after pulling on the suture, whereby the anchors are parallel to the tissue surface, and at which time the suture has cleared lock 114a and the lock has engaged ratchet segments 117 to hold the tissues in place.

[0133] It is expected that during the life of a patent maturing from this application many relevant suture devices will be developed and the scope of the term suture device is intended to include all such new technologies *a priori*.

[0134] The word “optionally” is used herein to mean “is provided in some embodiments and not provided in other embodiments”. Any particular embodiment of the invention may include a plurality of “optional” features unless such features conflict.

[0135] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention.

Certain features described in the context of various embodiments are not to be considered

essential features of those embodiments, unless the embodiment is inoperative without those elements.

[0136] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will

5 be apparent to those skilled in the art.

CLAIMS

1. A device for approximating at least two separate tissues, the device comprising:
at least one temporary needle for penetrating said separate tissues, each
temporary needle comprising:

- a tissue penetrating suture anchor having a proximal end and a distal end and comprising a distal portion of each temporary needle;
- a plunger having a proximal end and a distal end, the anchor's proximal end adapted for removable connection to the plunger's distal end and the plunger included in a proximal portion of each temporary needle; and
- a tissue approximating member attached to said anchor;

and

a lock mechanism for securing said separate tissues in an approximated position;

and

a temporary needle driving mechanism for driving the plunger to connect to the anchor and push the temporary needle into said separate tissues,
wherein the anchor and the plunger of each temporary needle are connected when penetrating the separate tissues and separatable after the anchor has passed through the separate tissues.

2. The device of claim 1 comprising a pair of temporary needles.

3. The device of claim 1 wherein the tissue approximating member comprises a tissue holding element and a suture, the tissue holding element attached at one end thereof to the anchor and attached at the other end thereof to the suture.

4. The device of claim 1 wherein the tissue approximating member is pivotally connected to the anchor.

5. The device of claim 1 wherein the locking mechanism includes a lock adapted to engage with a lock engaging feature of the tissue approximating member.

6. The device of claim 5 wherein the lock engaging feature of the tissue approximating member comprises a plurality of ratchet ribs/segments.

7. The device of claim 1 wherein the distal end of the plunger comprises an opening for mating with a proximal end of the anchor.

8. The device of claim 1 wherein the proximal end of the anchor comprises an opening for mating with the distal end of the plunger.

9. The device of claim 1 wherein the anchor comprises an anchor neck at **a** proximal end thereof.

10. The device of claim 1 wherein the anchor is fixably connected to a suture.
11. The device of claim 1 wherein the anchor is movably connected to a suture.
12. The device of claim 1 further comprising an anchor cartridge for accommodating the anchor housed inside an anchor unit.
13. The device of claim 1 further comprising an anchor cartridge for accommodating a plurality of anchor units.
14. The device of claim 13 wherein a first anchor unit comprises a movable anchor connected by a suture in a loop configuration to a second movable anchor included in a second anchor unit.
15. The device of claim 14 wherein the second anchor unit comprises a looped thread for approximating said tissues by tightening the suture.
16. The device of claim 15 wherein the looped thread comprises a knot.
17. The device of claim 16 wherein the knot is pre-tied.
18. The device of claim 14 wherein a third anchor unit comprises a looped thread for approximating said tissues by tightening the suture.
19. The device of claim 18 wherein the looped thread comprises a knot.
20. The device of claim 1 further comprising a body at angle of inclination ranging from 50-240 degrees relative to a plane perpendicular to a direction of exit of the anchor from said device.
21. The device of claim 20 wherein the angle of inclination ranges from 60-80 degrees.
22. A method for approximating at least two separate tissues, the method comprising:
 - forming a temporary needle by attaching a distal end of a plunger into a proximal end of a suture anchor;
 - driving the temporary needle through said tissues;
 - ejecting the anchor from the temporary needle;
 - retrieving the plunger;
 - pulling on a tissue approximating member attached to said anchor; and
 - locking the tissue engaging/tying element.
23. The method of claim 22 further comprising inserting the proximal end of the anchor into an opening in the distal end of the plunger.
24. The method of claim 22 further comprising inserting the distal end of the plunger into an opening in the proximal end of the anchor.

25. An anchor unit for use in a device for approximating at least two separate tissues, the anchor unit comprising a tissue penetrating suture anchor wherein a proximal end of the anchor temporarily attaches to a distal end of a plunger in said device to form a temporary needle for penetrating said tissues.
26. The anchor unit of claim 25 further comprising a tissue approximating member attached to said anchor.
27. The anchor unit of claim 26 wherein the tissue approximating member comprises a strip and a suture, the strip attached at one end thereof to the anchor and attached at the other end thereof to the suture.
28. The anchor unit of claim 25 wherein the tissue approximating member is pivotally connected to the anchor.
29. The anchor unit of claim 25 wherein the locking mechanism includes a lock adapted to engage with lock engaging feature of the tissue approximating member.
30. The anchor unit of claim 25 wherein the lock engaging feature of the tissue approximating member comprises a plurality of ratchet ribs/segments.
31. The anchor unit of claim 25 wherein the anchor unit is movably connected to a suture.
32. The anchor unit of claim 25 wherein the anchor unit is fixably connected to a suture.
33. The anchor unit of claim 25 further comprising a suture lock for tightening a suture.
34. The anchor unit of claim 33 wherein the suture lock is movably connected to the suture.
35. The anchor unit of claim 33 wherein the suture lock comprises a looped thread for tightening the suture.
36. The anchor unit of claim 35 wherein the looped thread is an integral part of the suture.
37. The anchor unit of claim 35 wherein the looped thread comprises a knot.
38. The anchor unit of claim 33 wherein the suture lock is connected to the suture anchor by the suture.
39. A method for suturing comprising:
driving a first movable anchor through a first tissue;
driving a second movable anchor through a second tissue; and

looping a thread through the two movable anchors and tightening the thread to approximate the two tissues.

40. A method for suturing comprising:

driving a first anchor fixably connected to a first suture through a first tissue;

driving a second anchor fixably connected to a second suture through a second tissue; and

connecting the two sutures to a movable suture lock and tightening the suture lock to approximate the two tissues.

41. A method for suturing comprising:

driving a first anchor fixably connected to a suture through a first tissue and a second tissue;

connecting the suture to a movable suture lock; and

tightening the suture lock to approximate the two tissues.

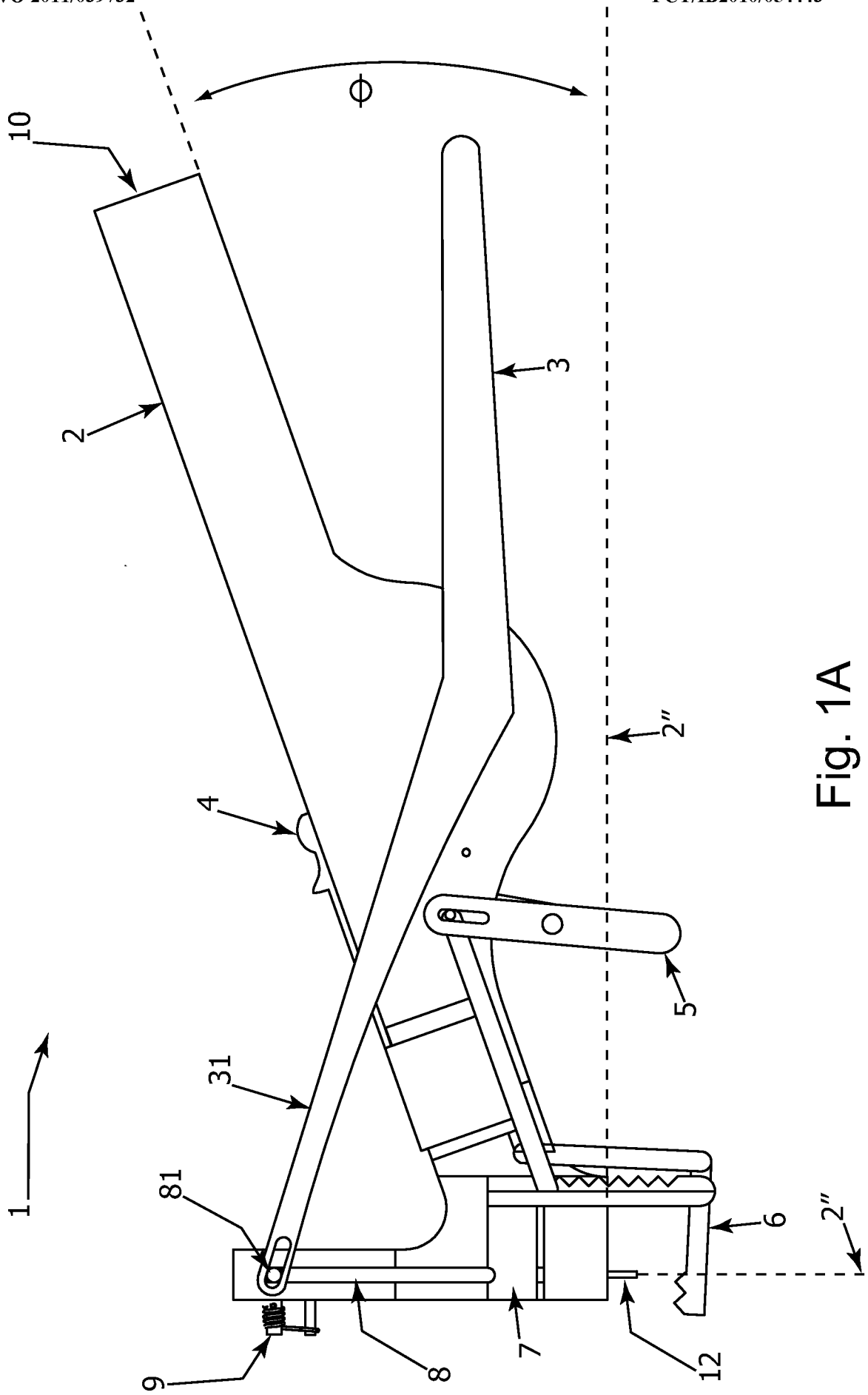


Fig. 1A

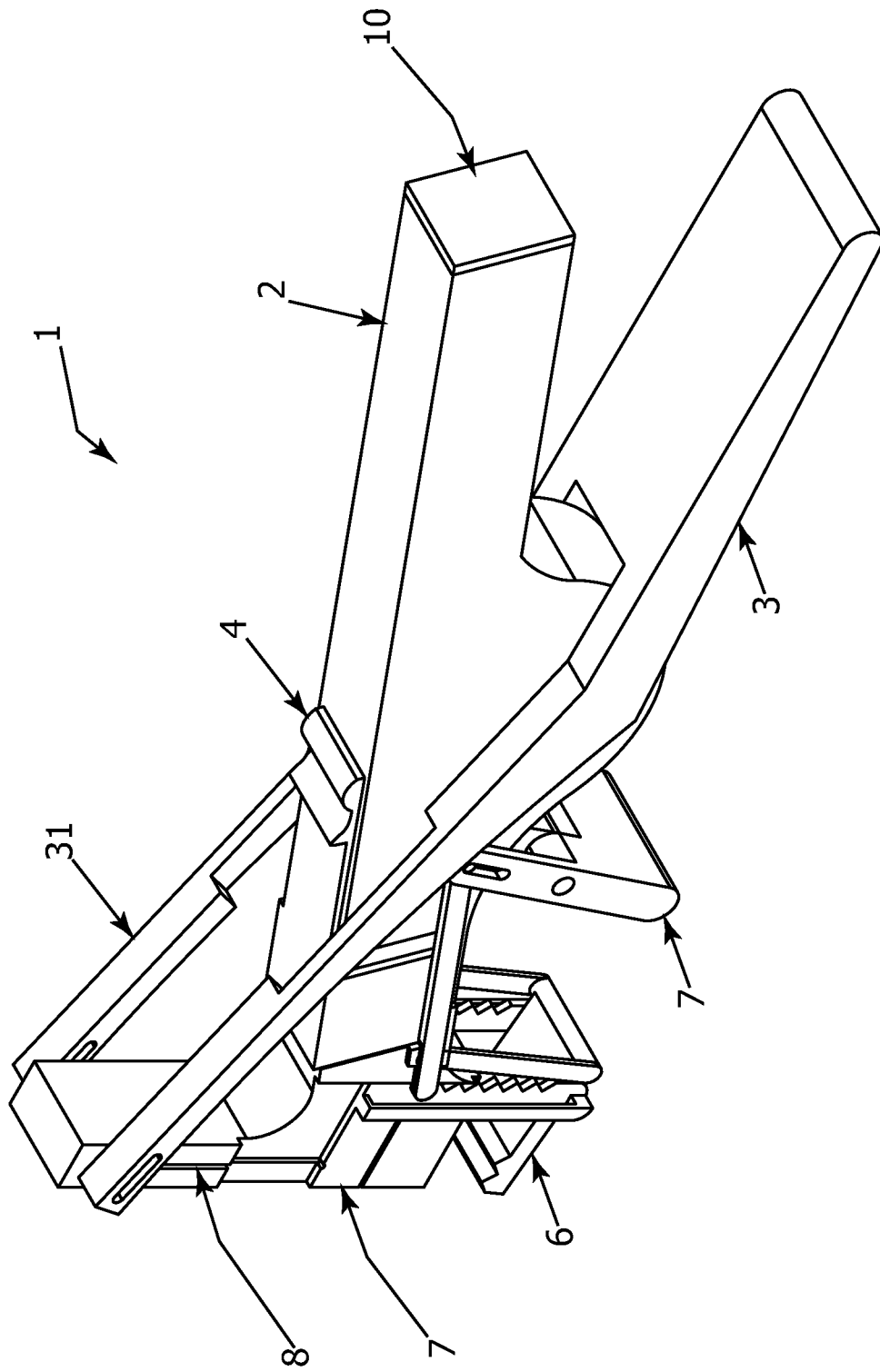
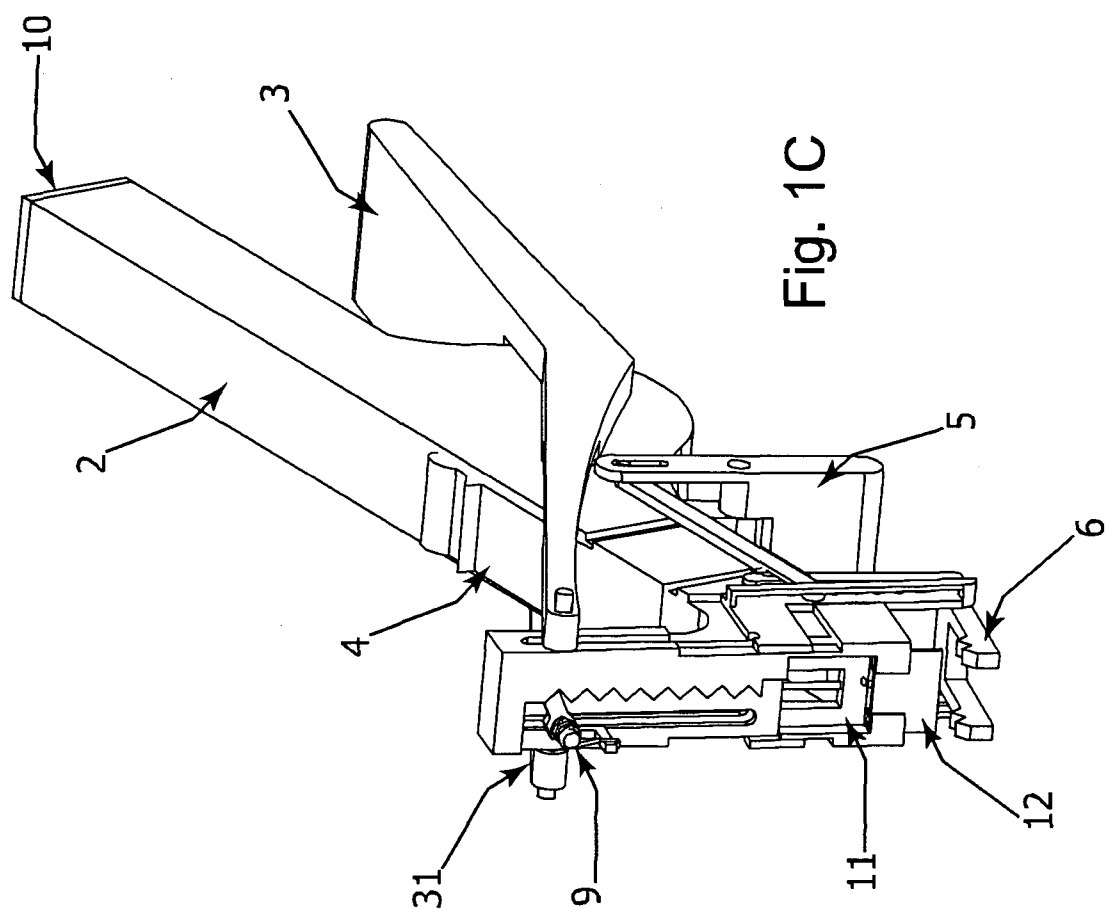


Fig. 1B



SUBSTITUTE SHEET (RULE 26)

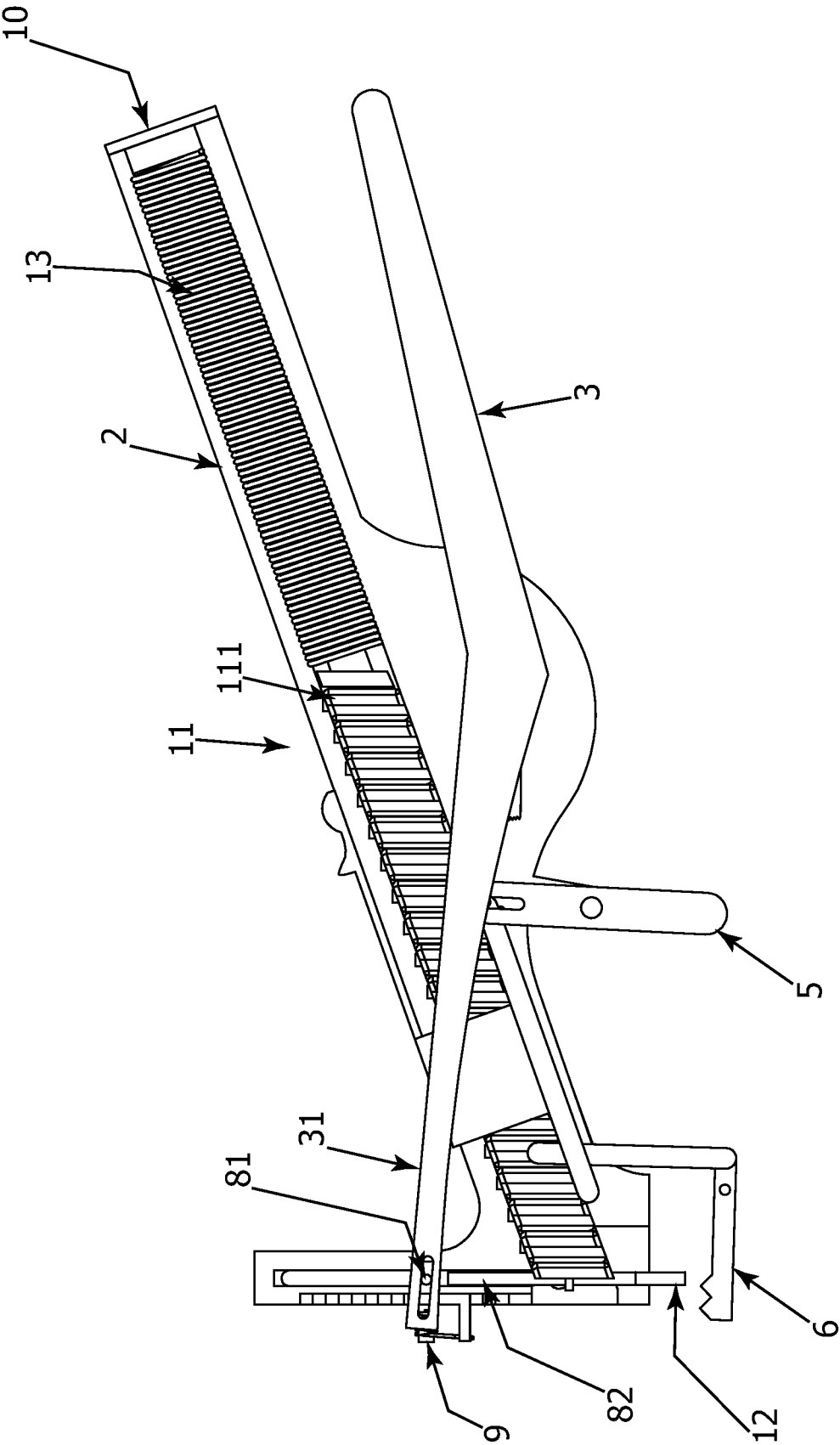


Fig. 1D

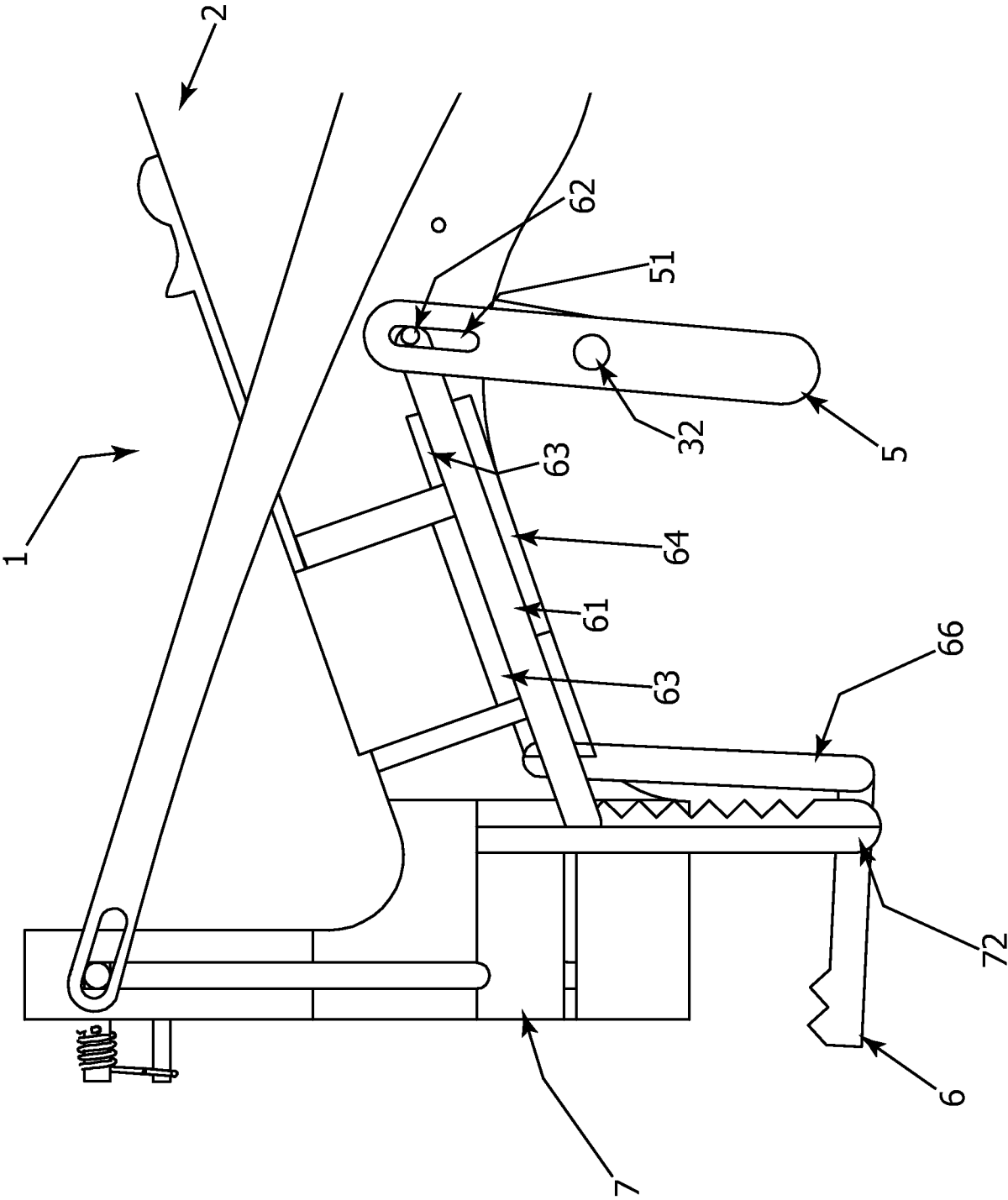


Fig. 2A

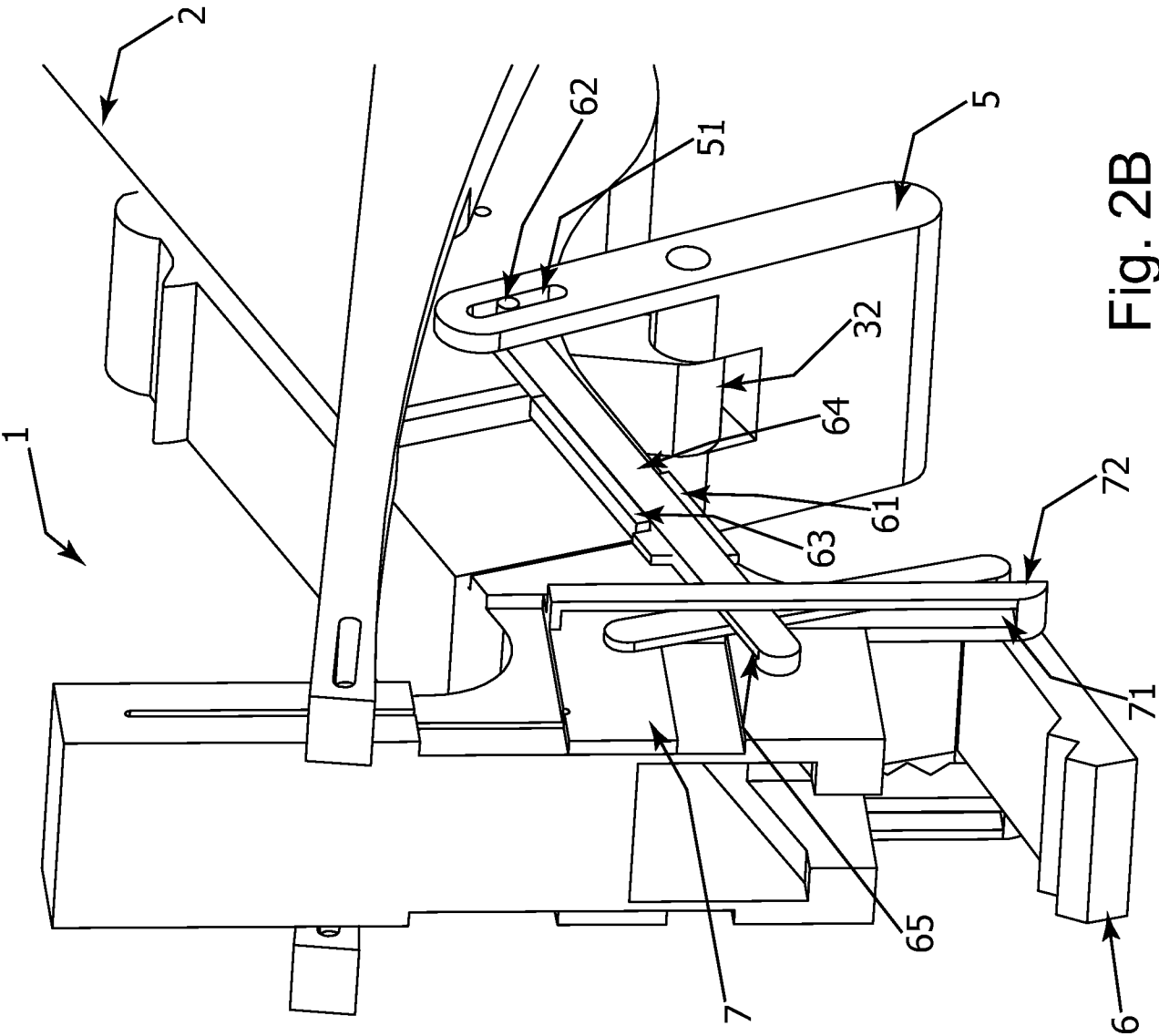


Fig. 2B

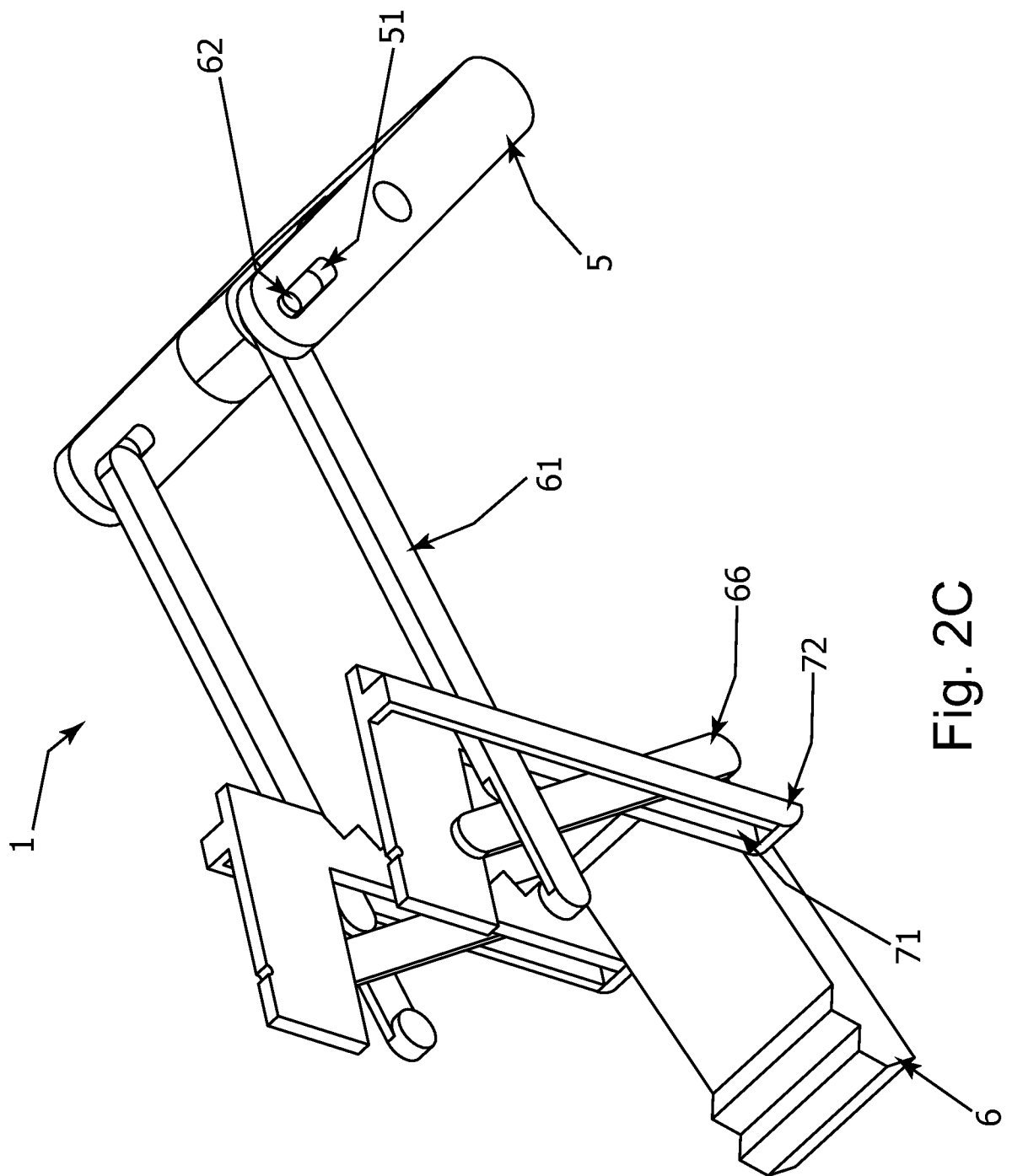
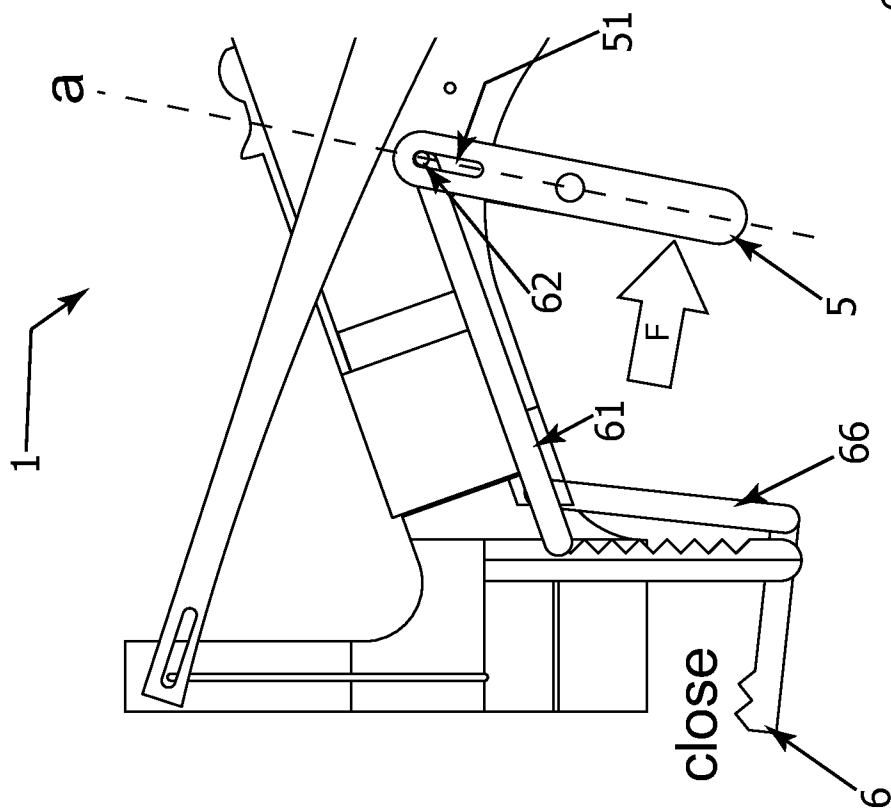
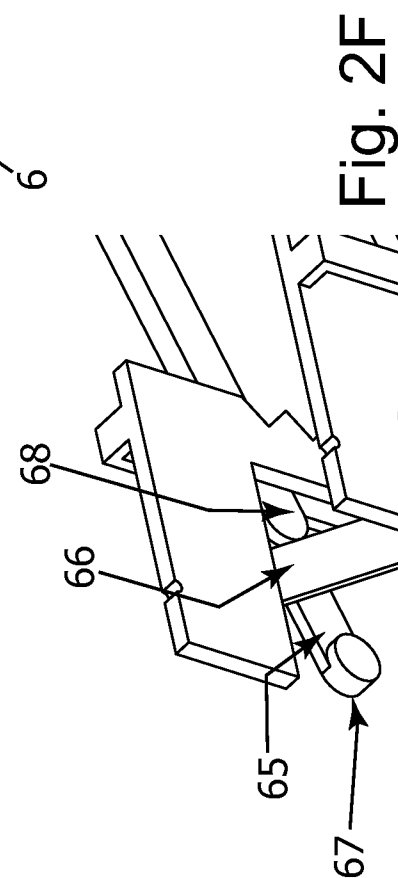
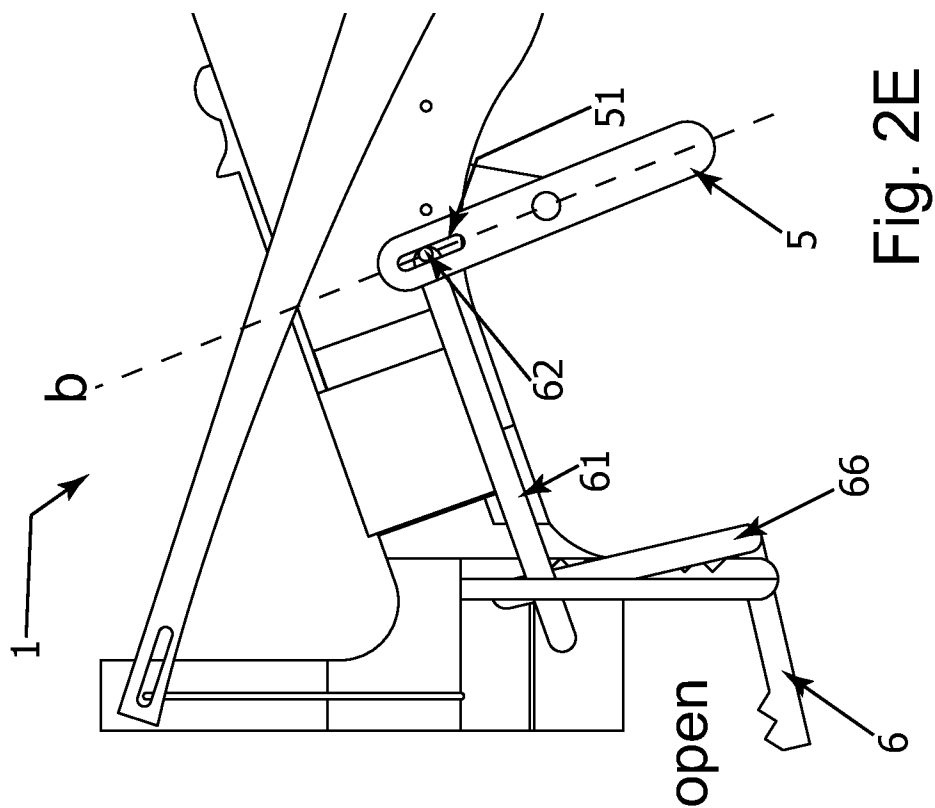


Fig. 2C



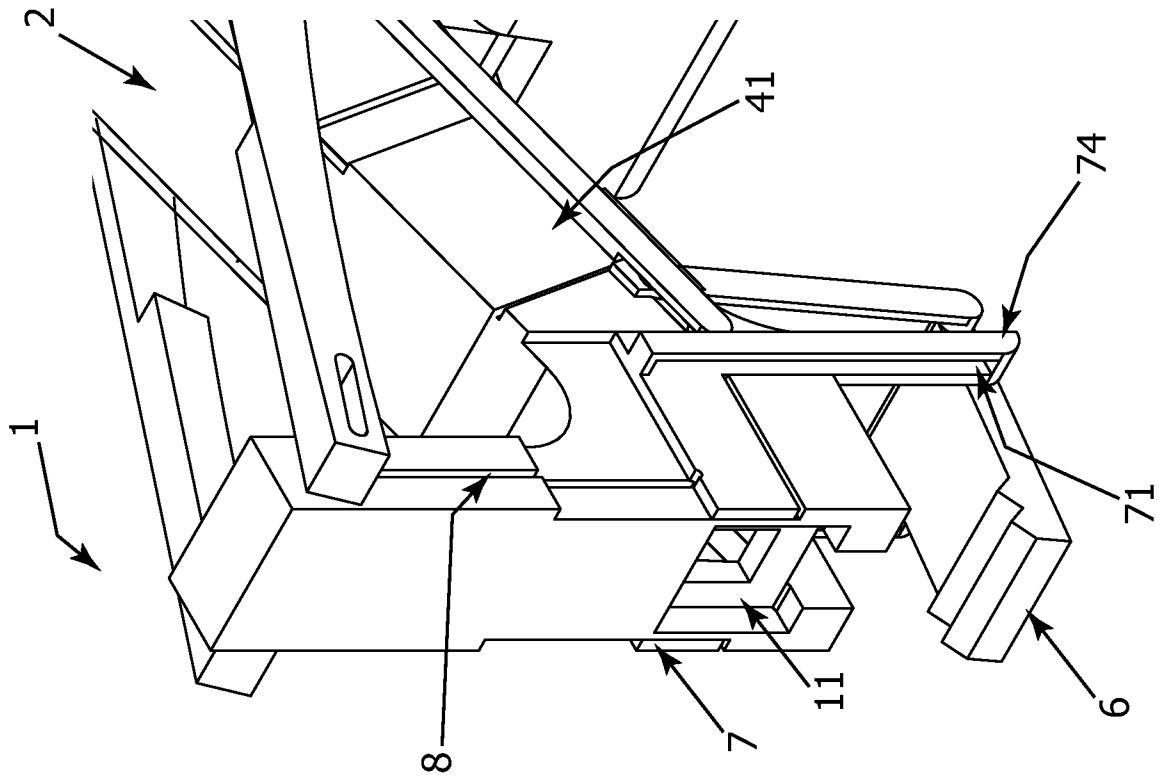


Fig. 2H

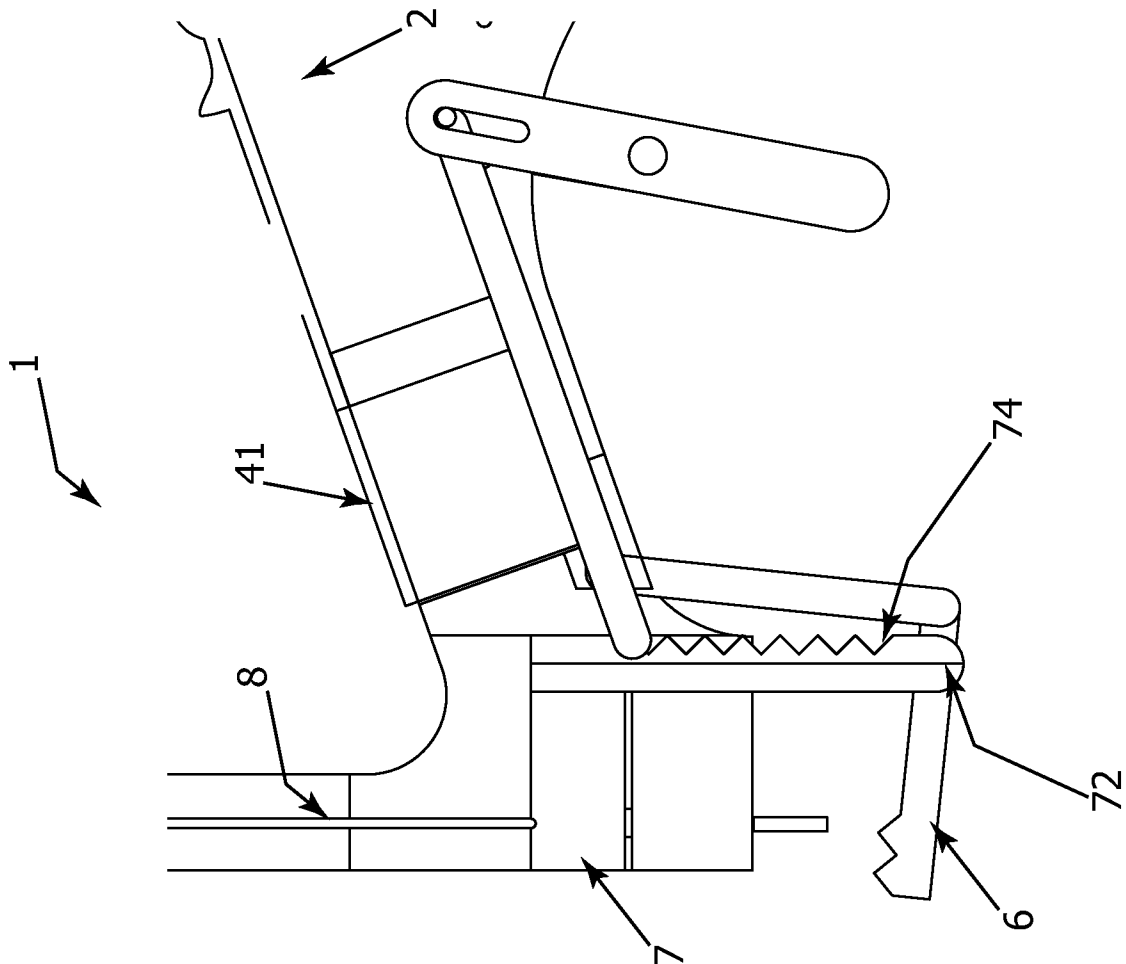


Fig. 2G

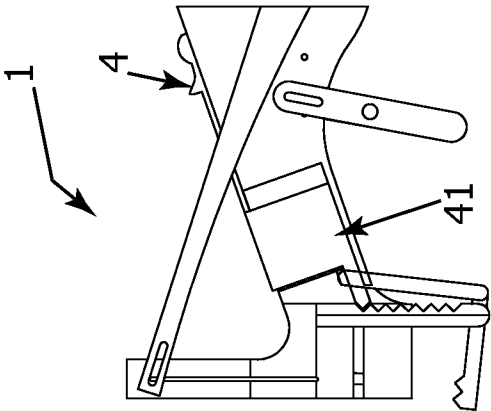
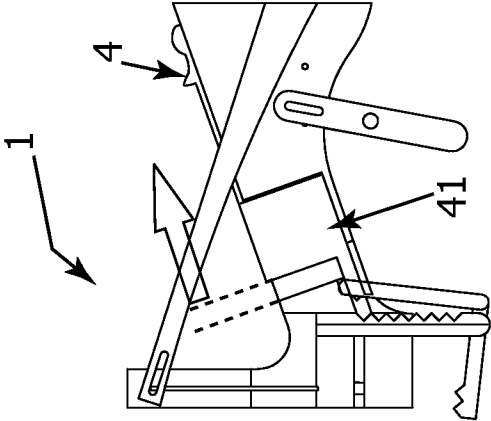
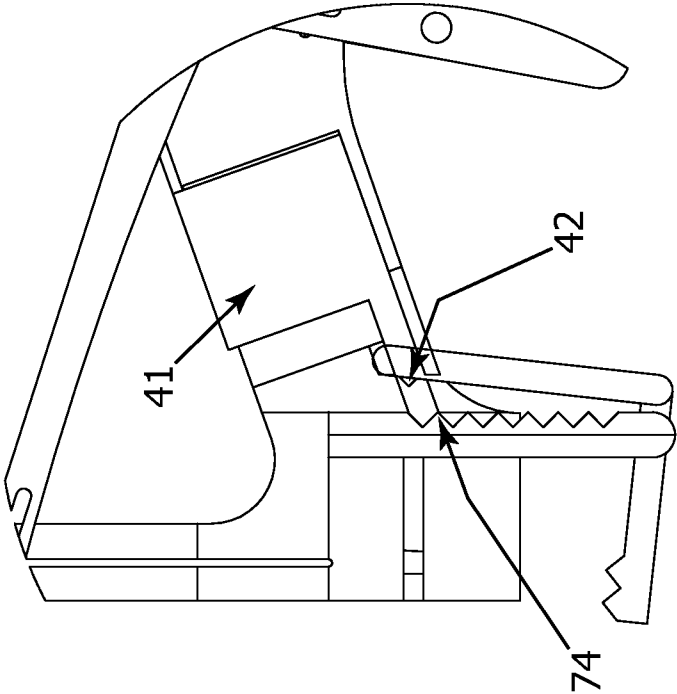
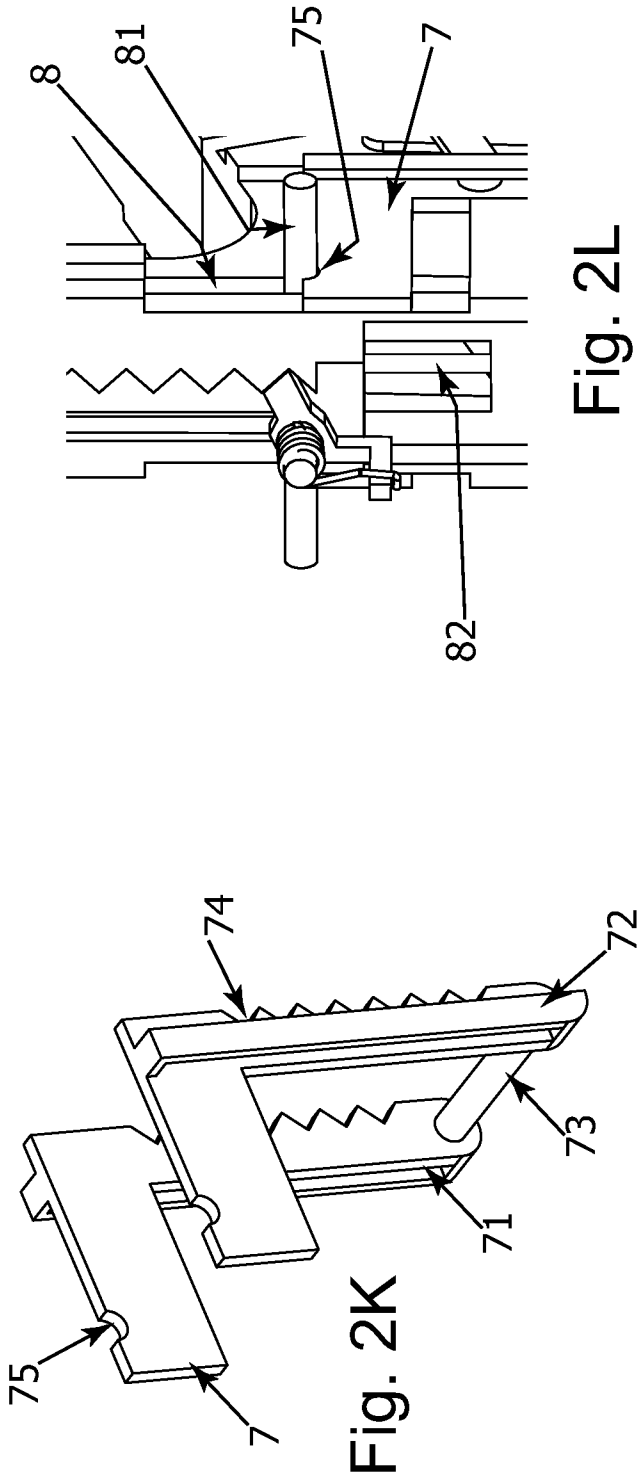
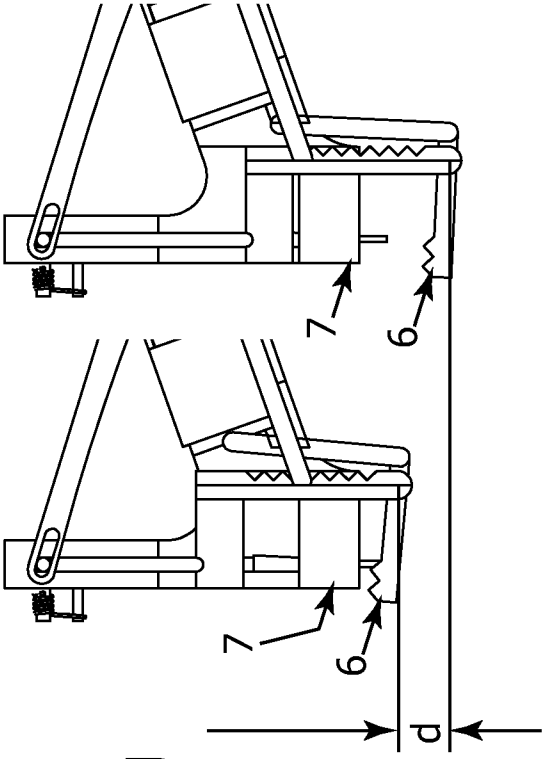


Fig. 2I



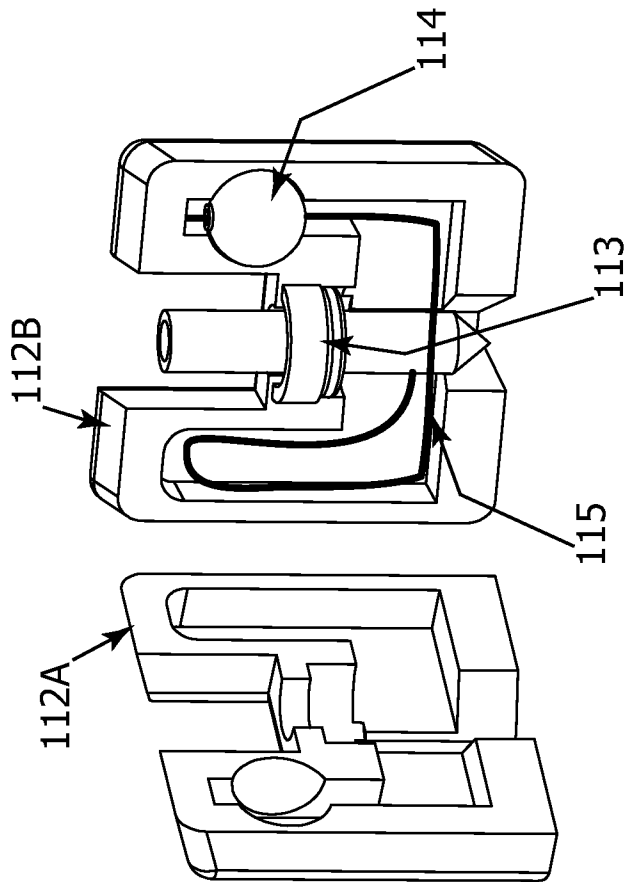


Fig. 3B

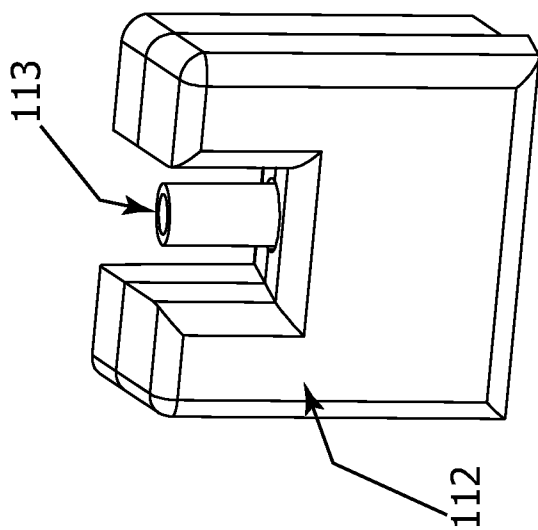


Fig. 3A

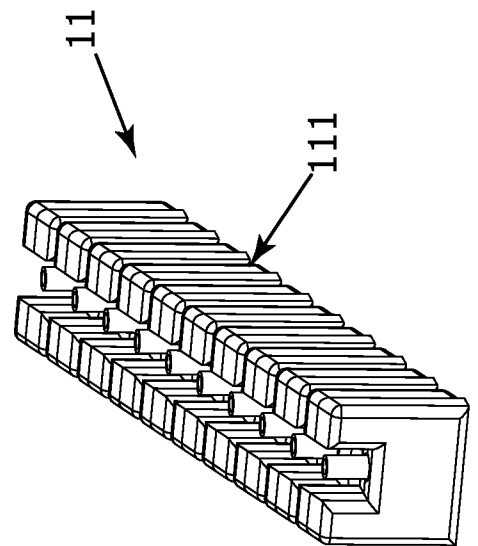


Fig. 3C

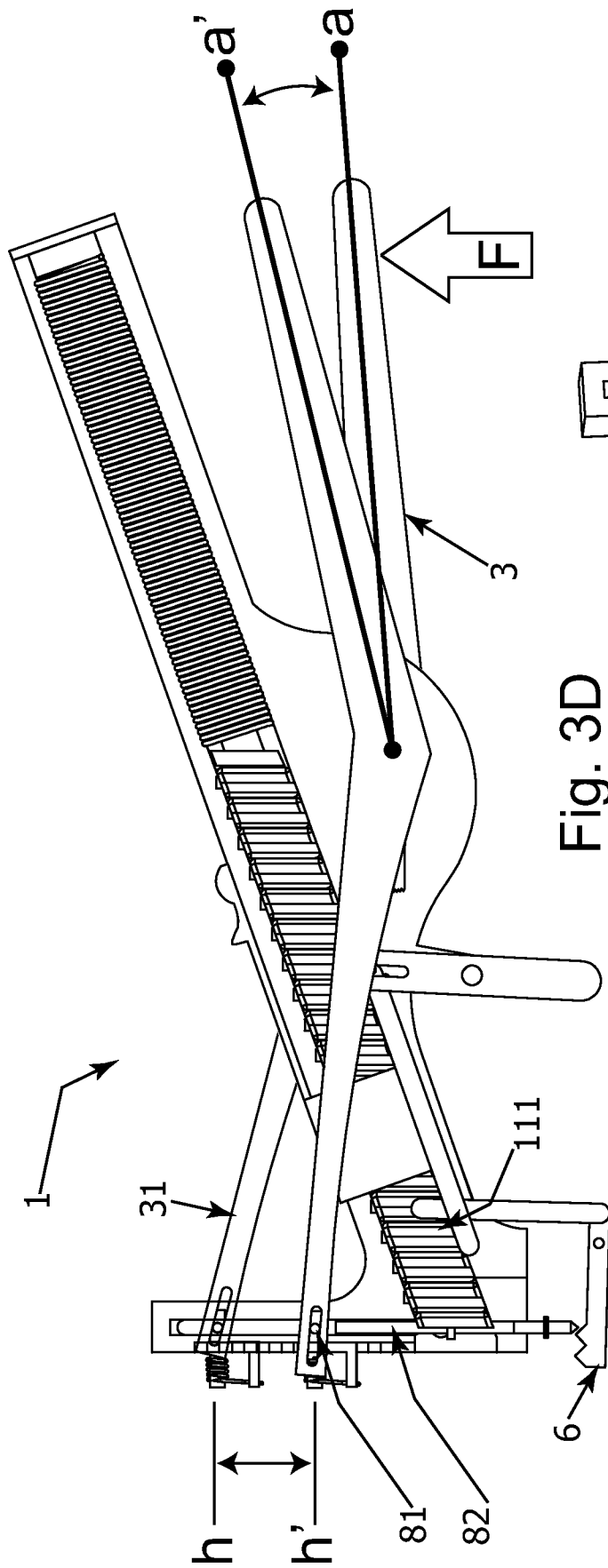


Fig. 3D

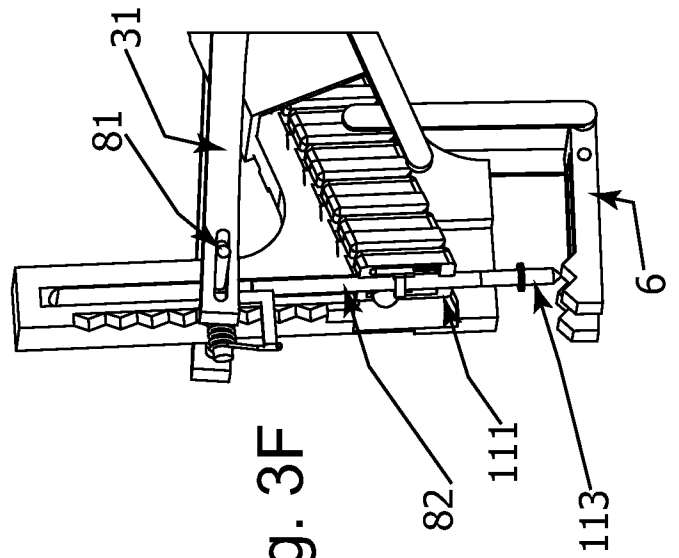


Fig. 3F

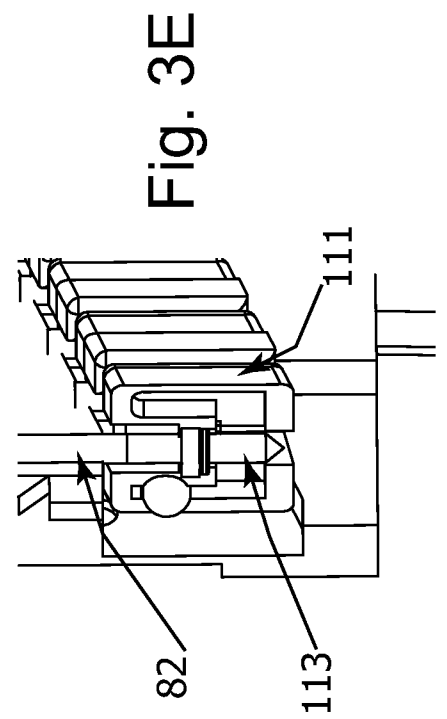


Fig. 3E

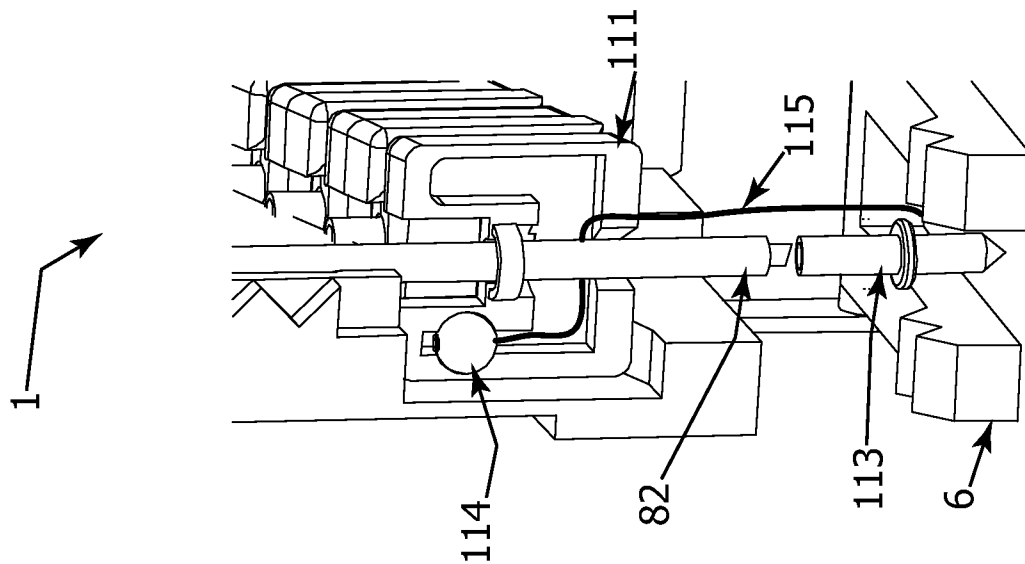


Fig. 3I

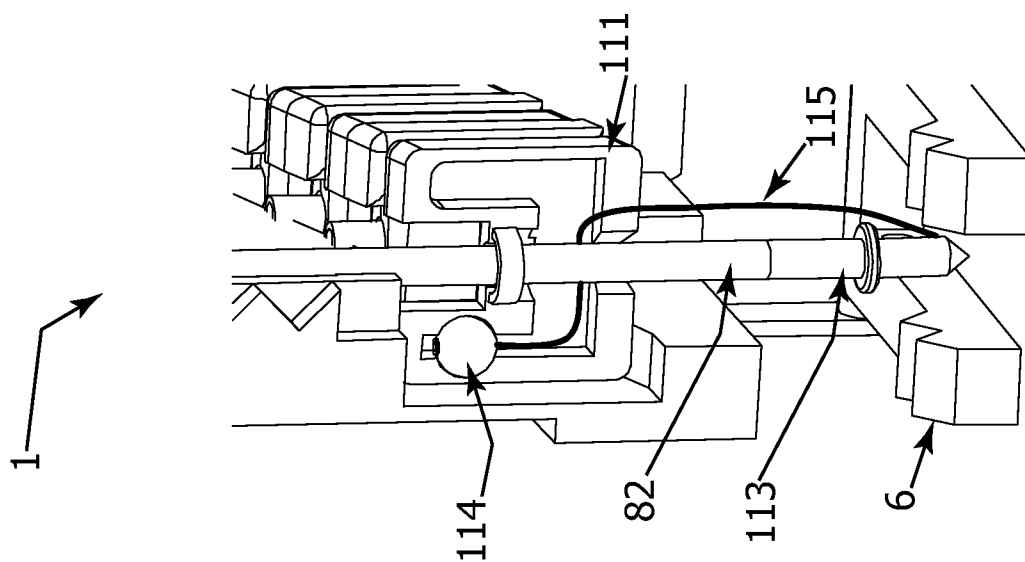


Fig. 3H

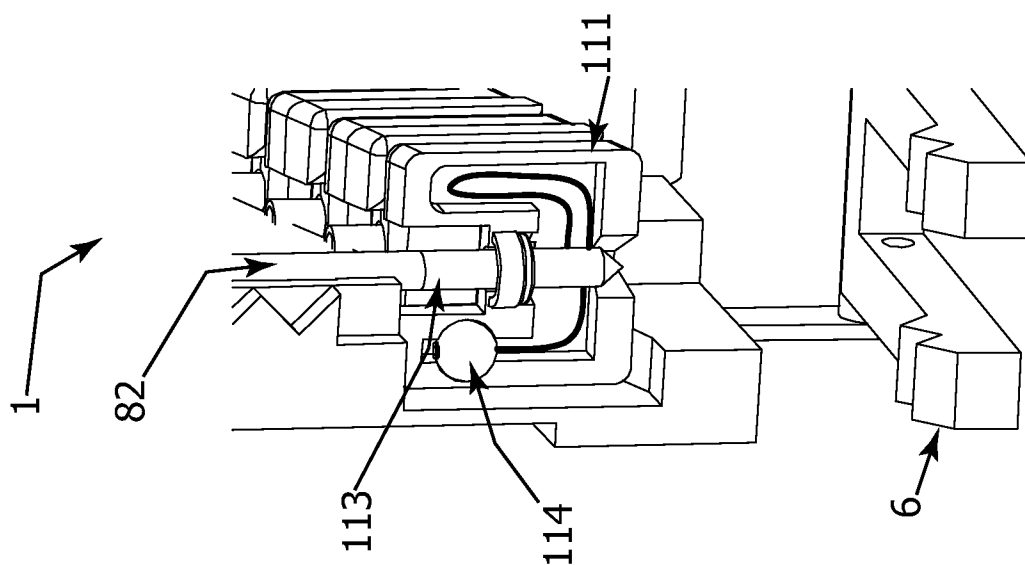


Fig. 3G

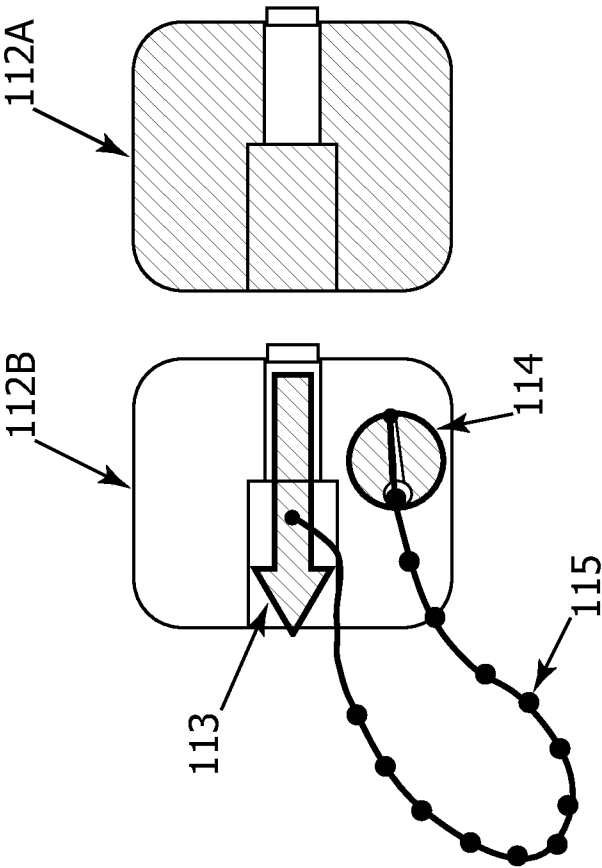


Fig. 3J

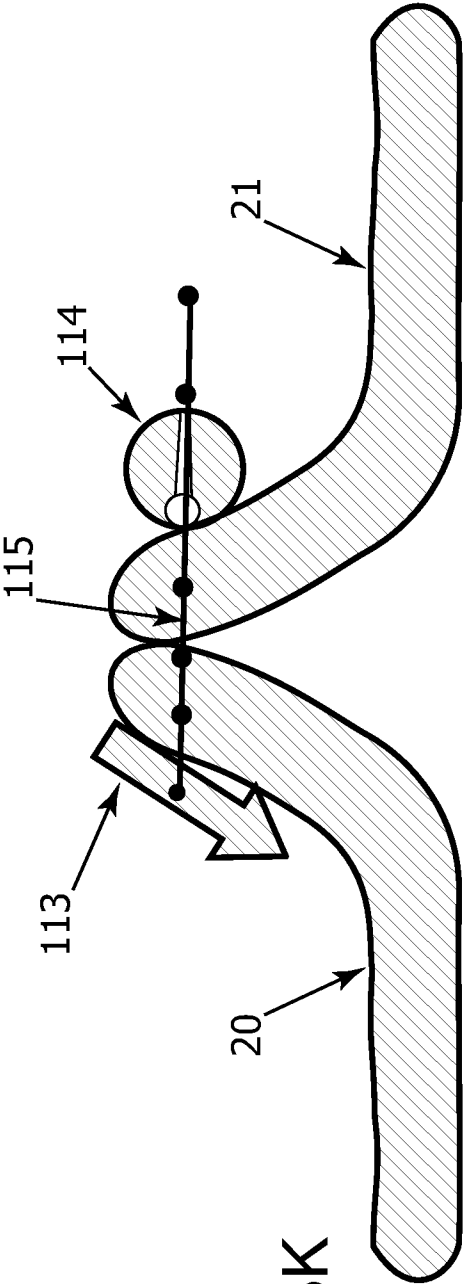


Fig. 3K

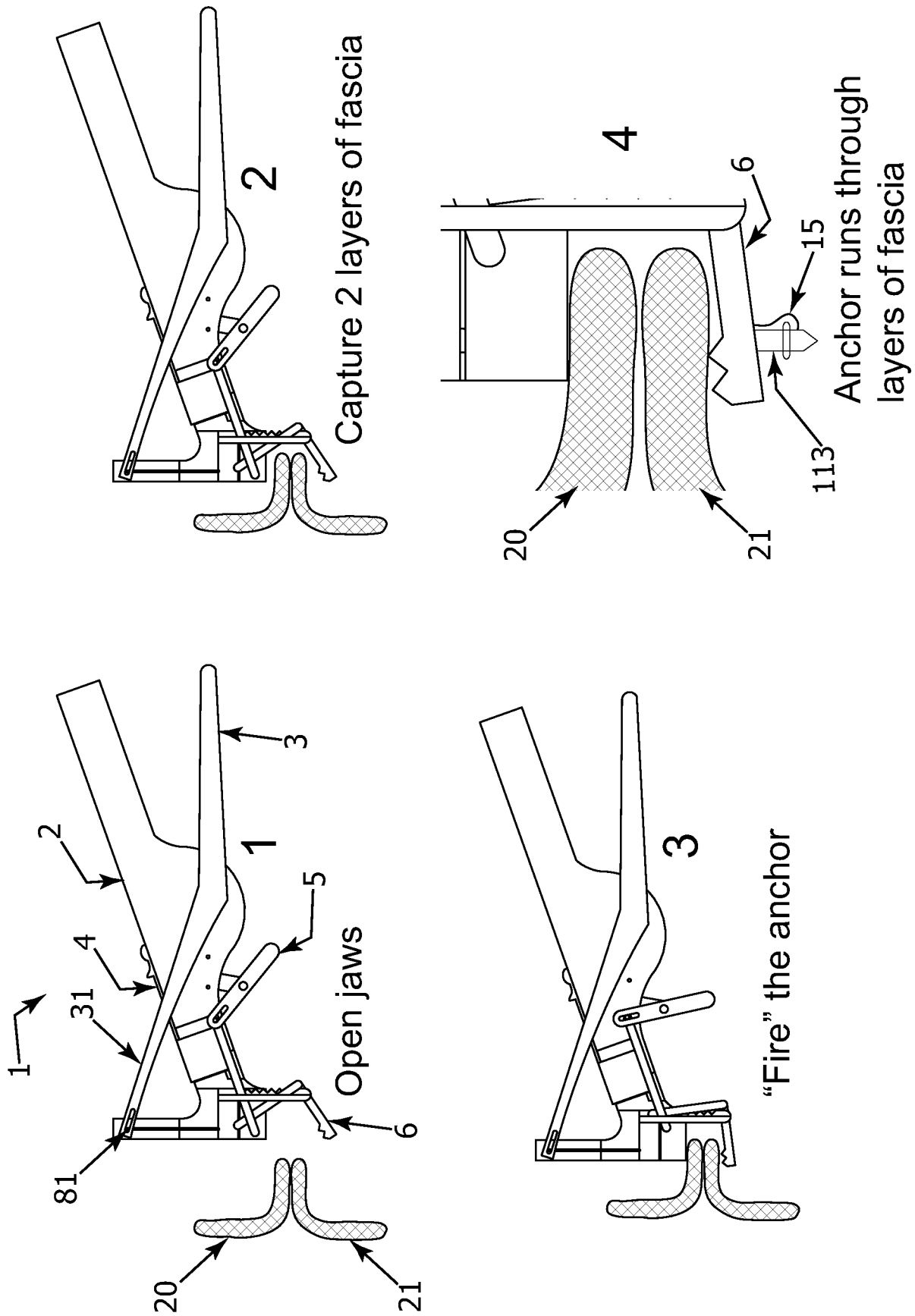
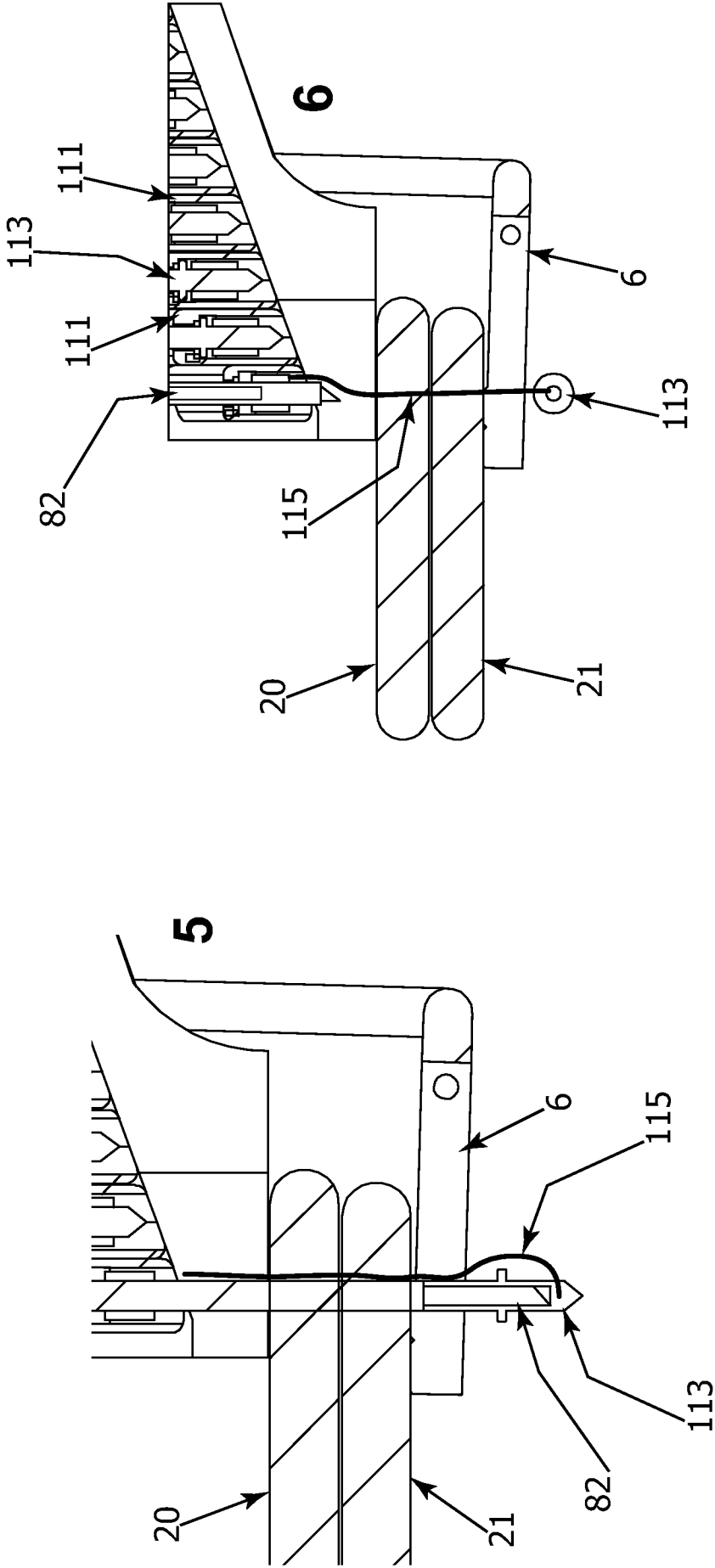


Fig. 4A



Needle tube moves back to point h (upper dead point)

Anchor with wire at point h' (lower dead point)

Fig. 4B

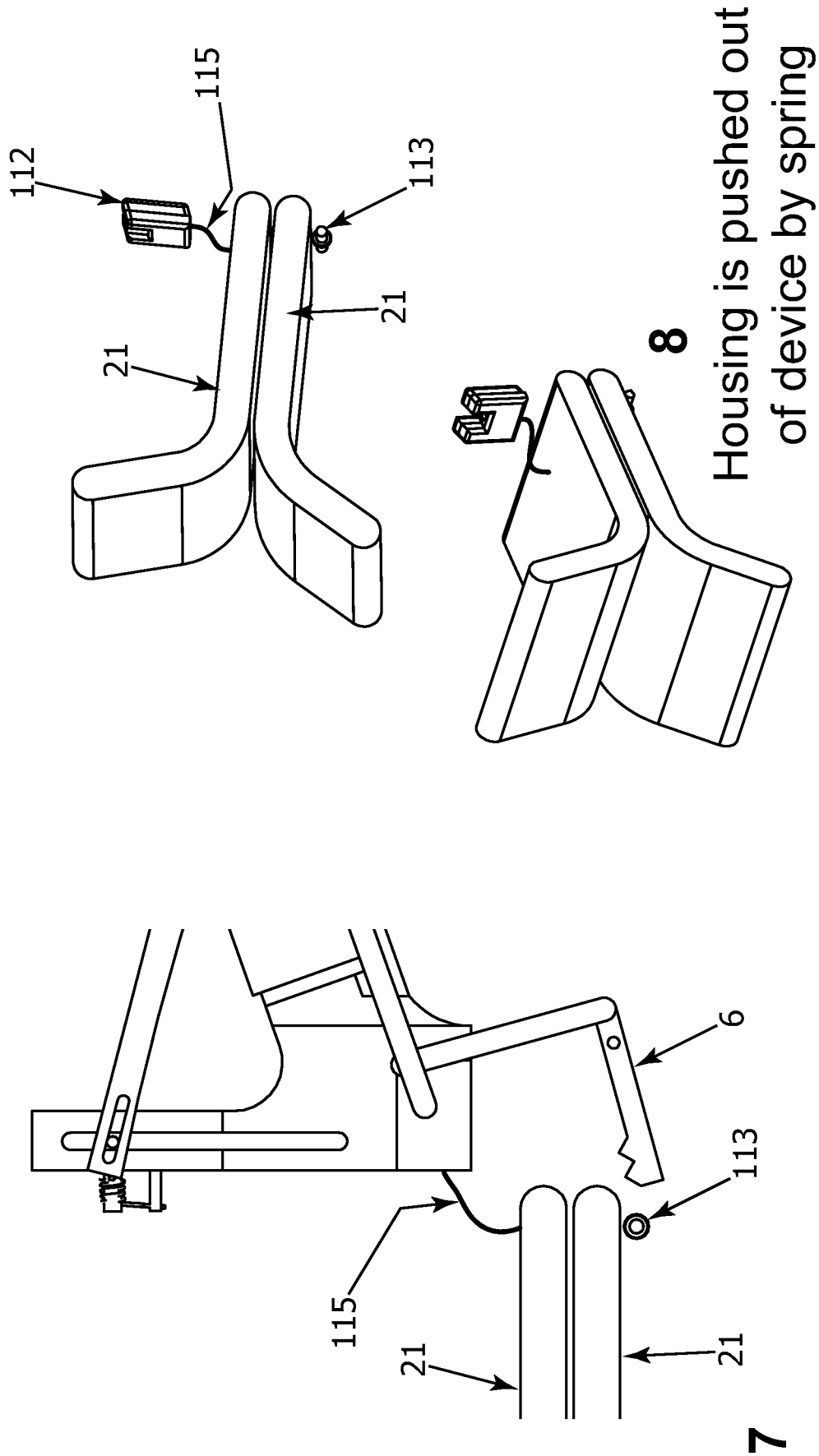
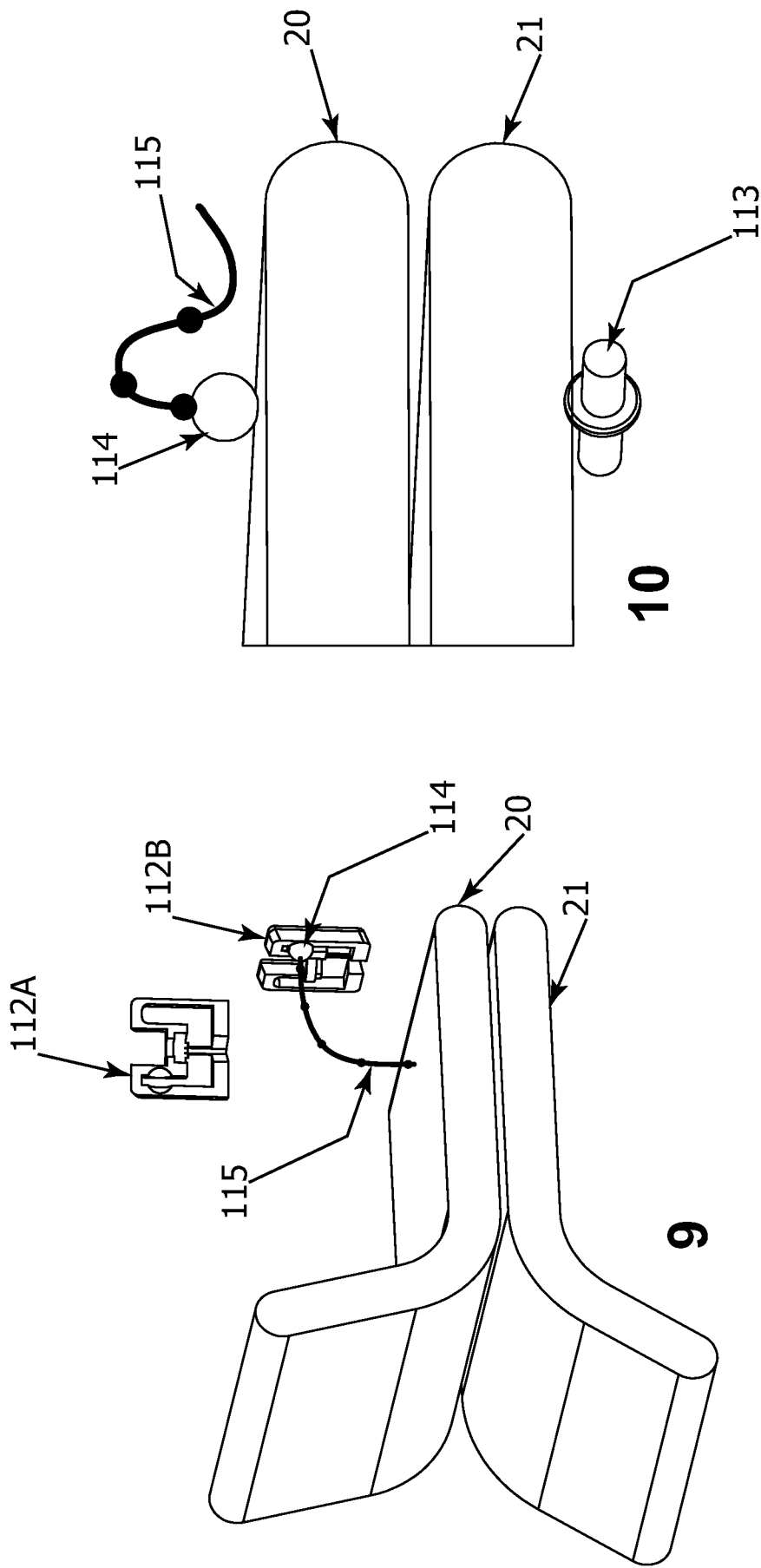


Fig. 4C



Housing separated into
2 parts exposing rest of
wire and ball

Ball forced down wire
attaching 2 layers together

Fig. 4D

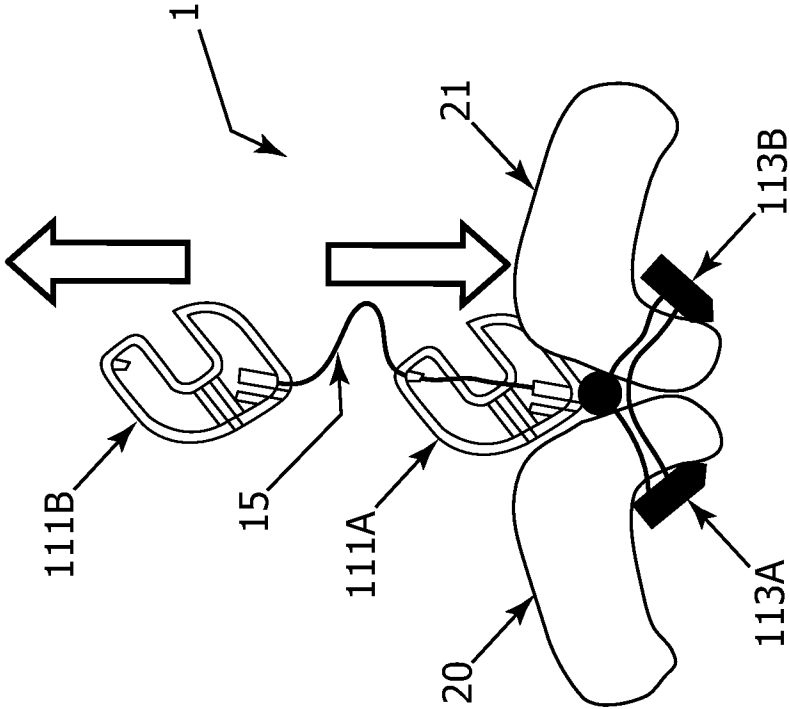


Fig. 5B

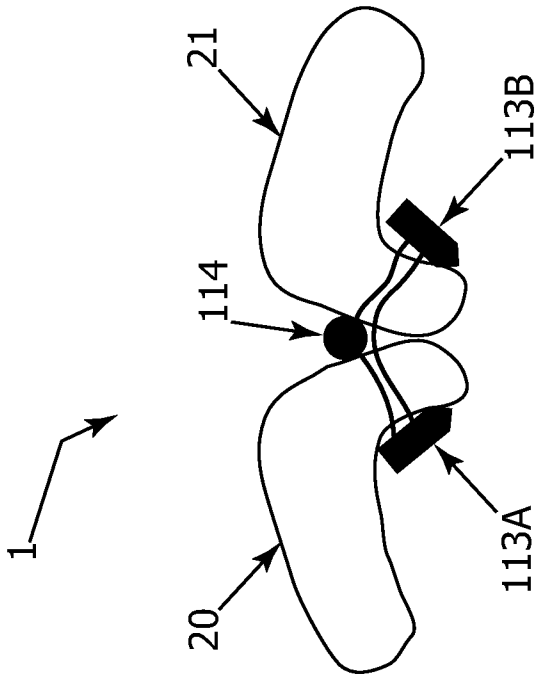


Fig. 5A

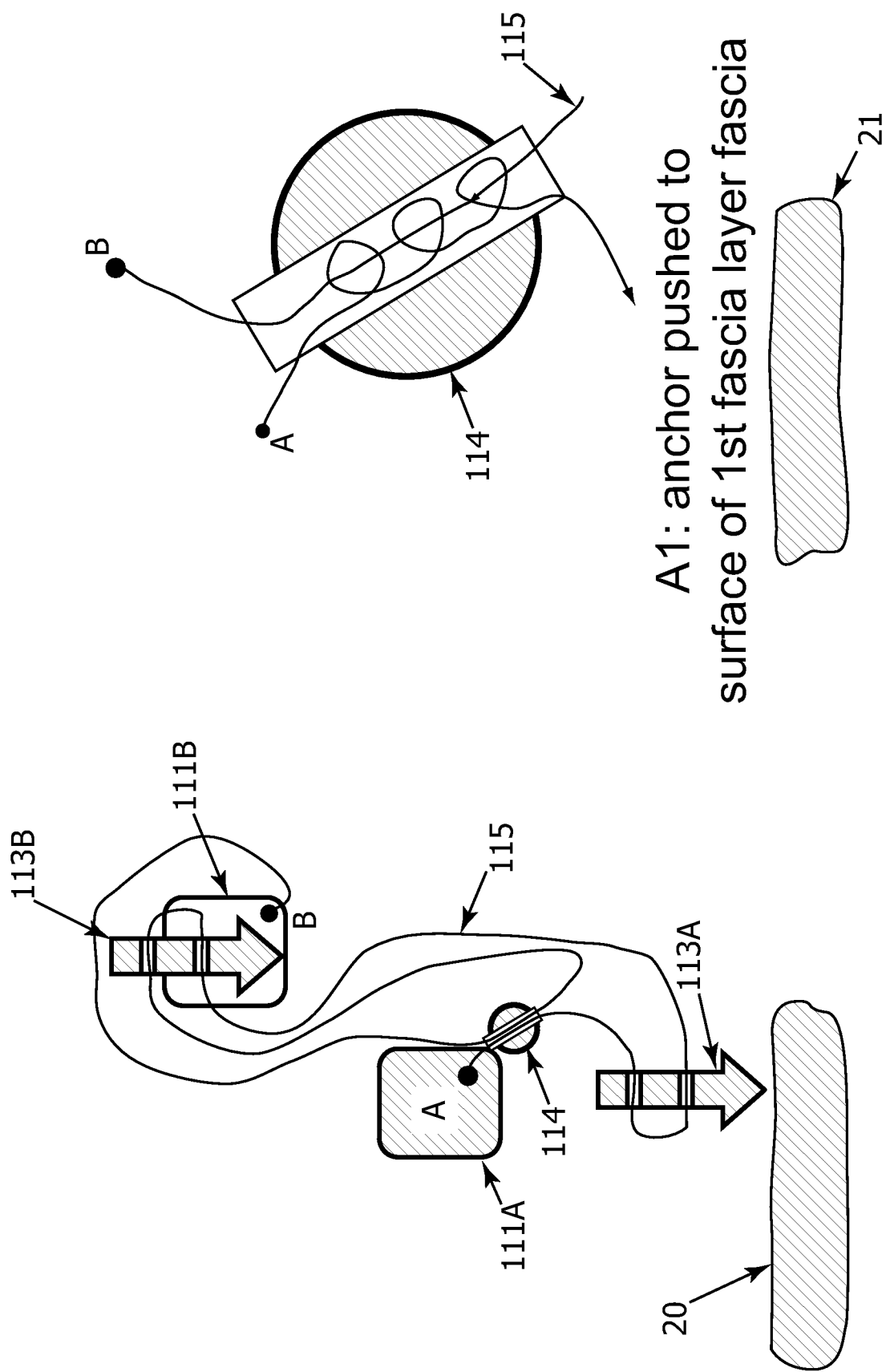


Fig. 5C

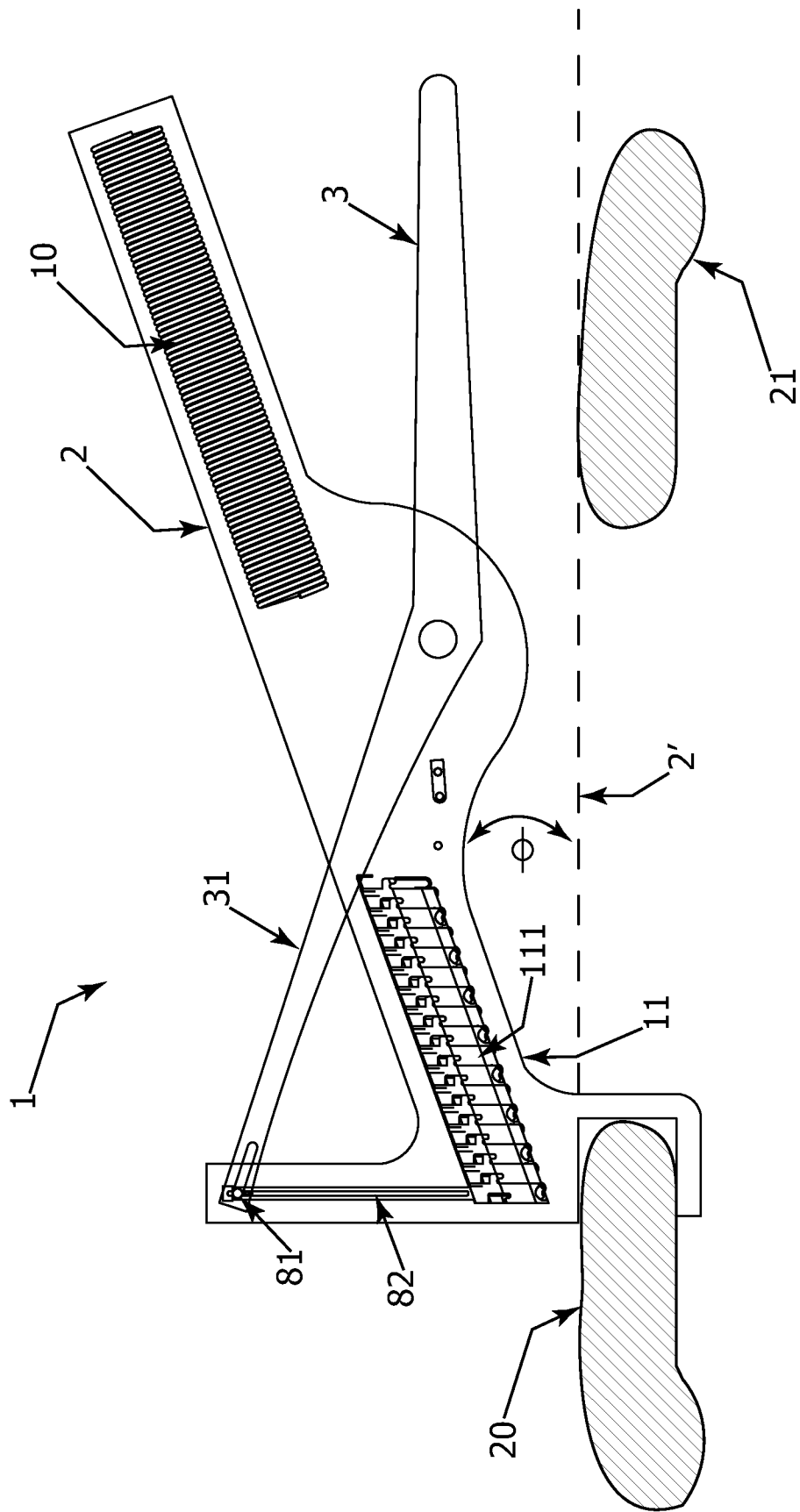


Fig. 5D

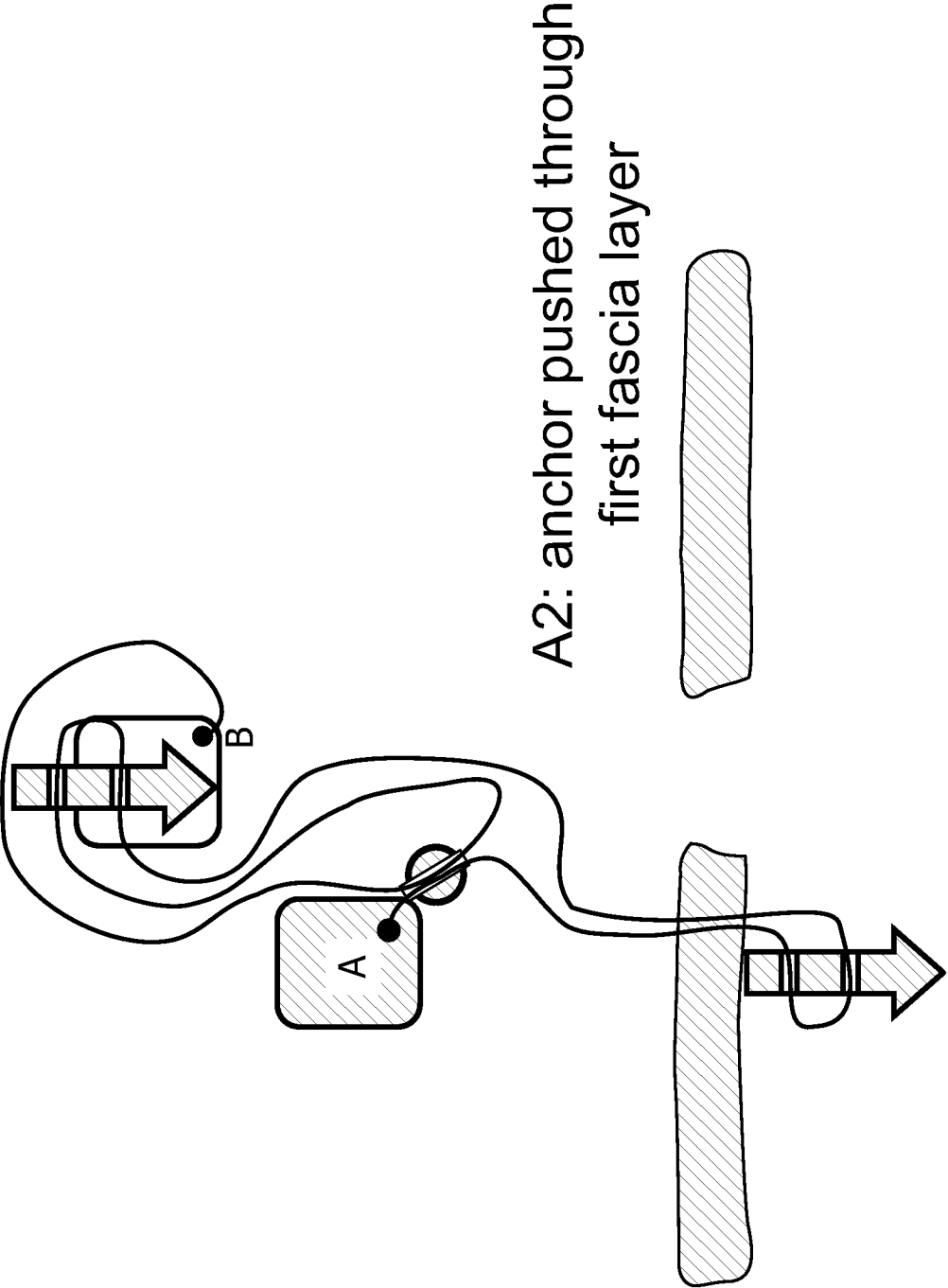
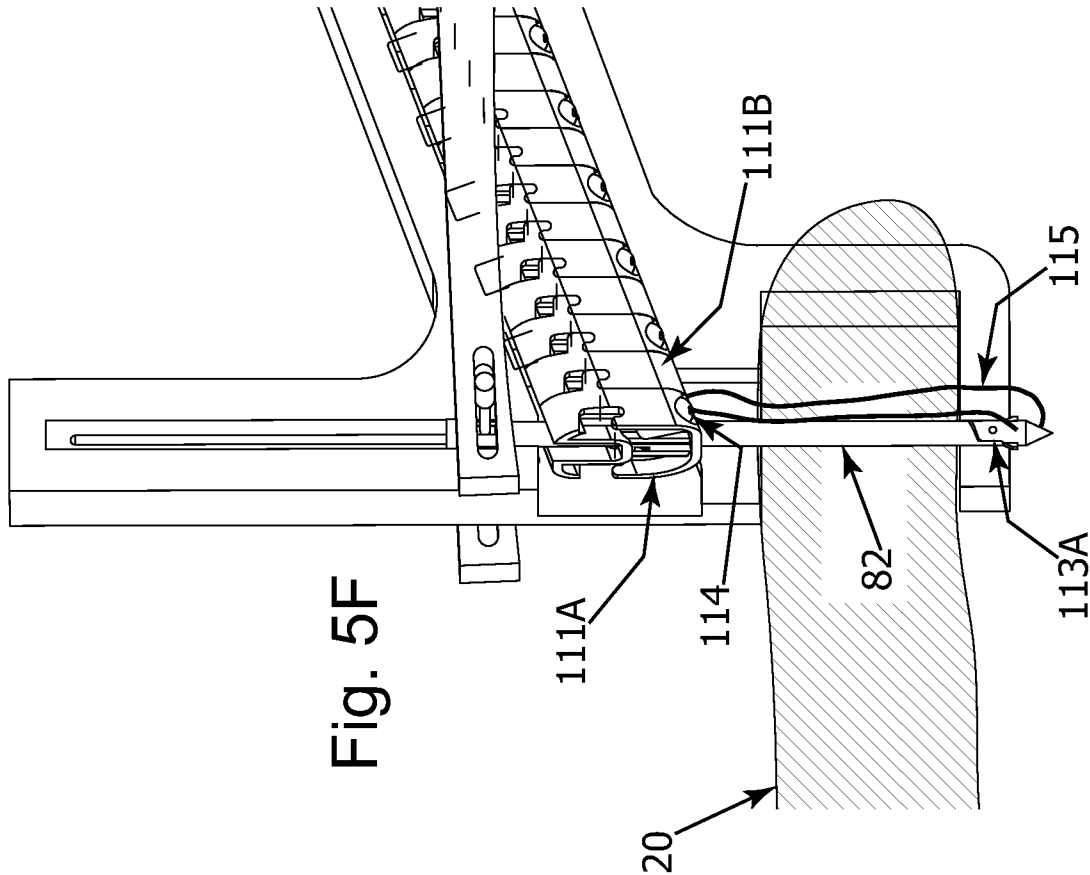
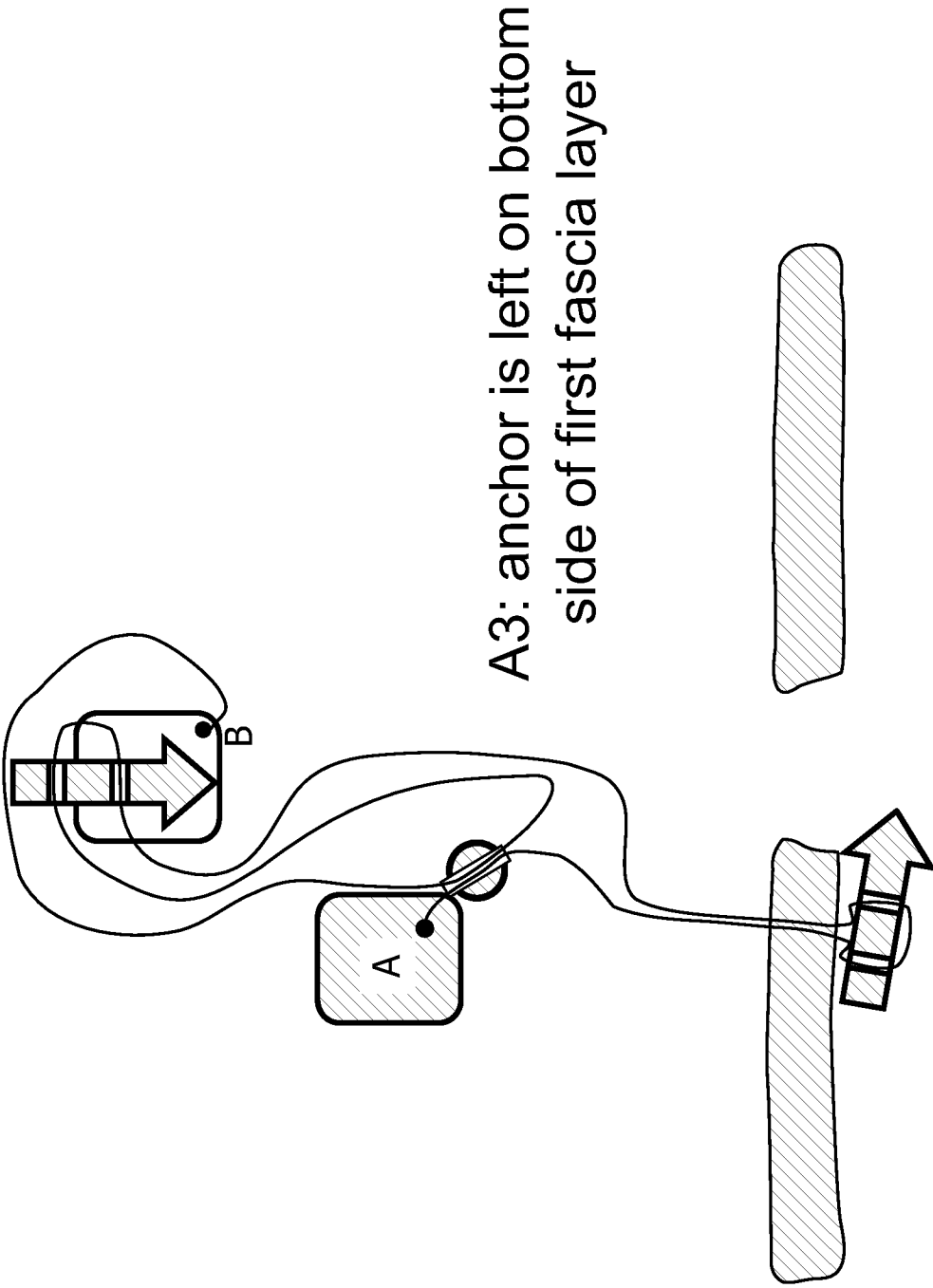


Fig. 5E





A3: anchor is left on bottom
side of first fascia layer

Fig. 5G

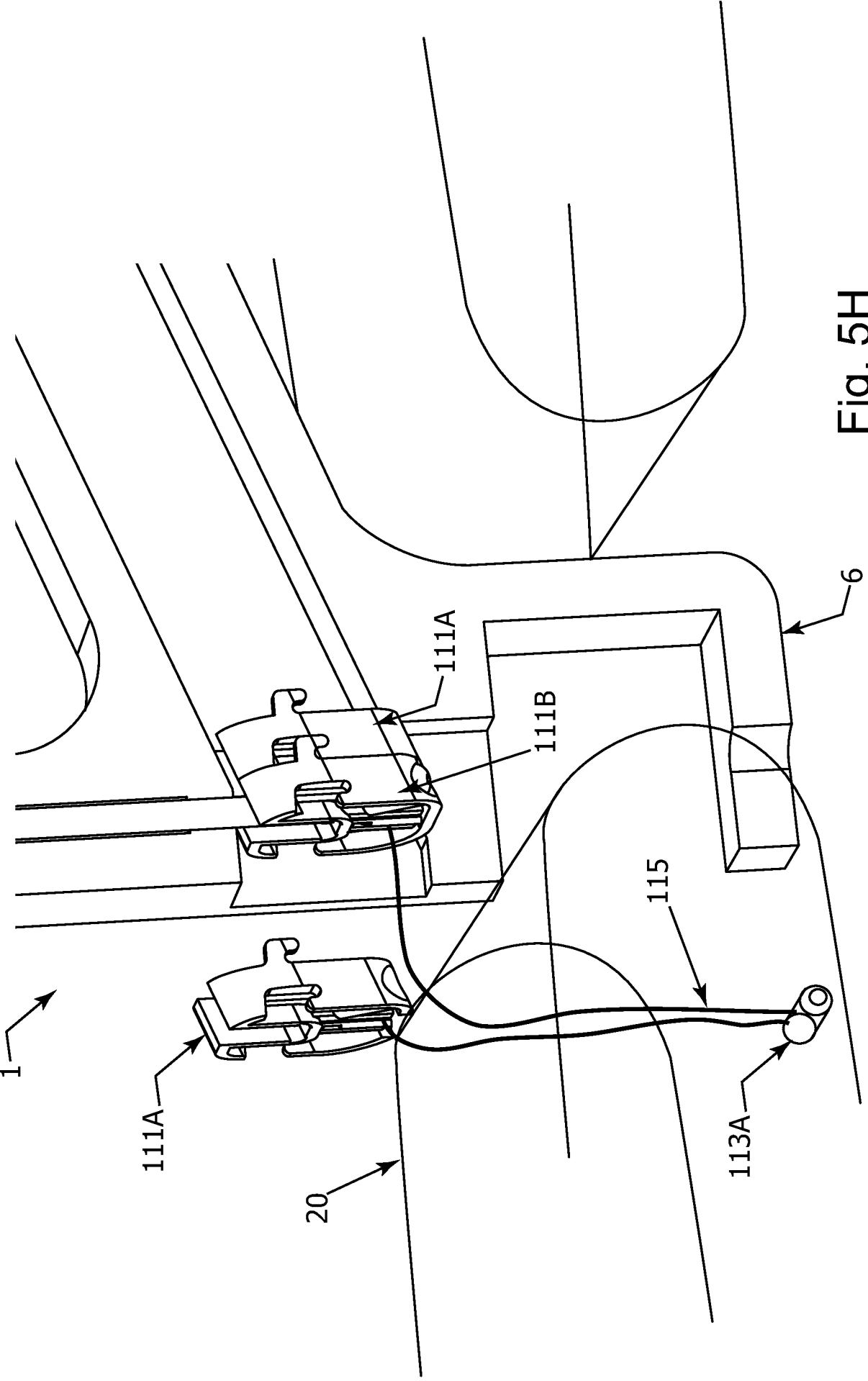


Fig. 5H

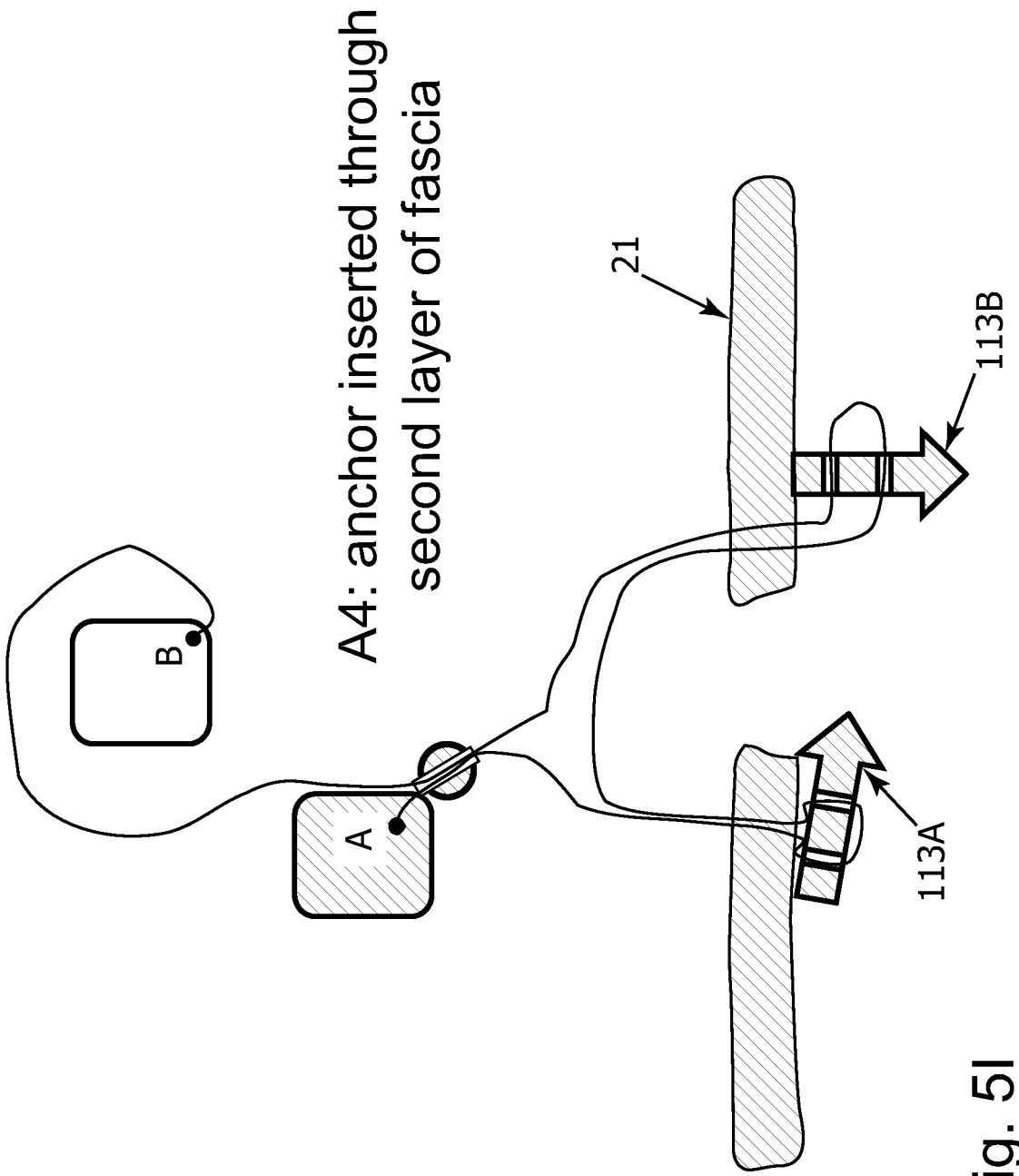


Fig. 5I

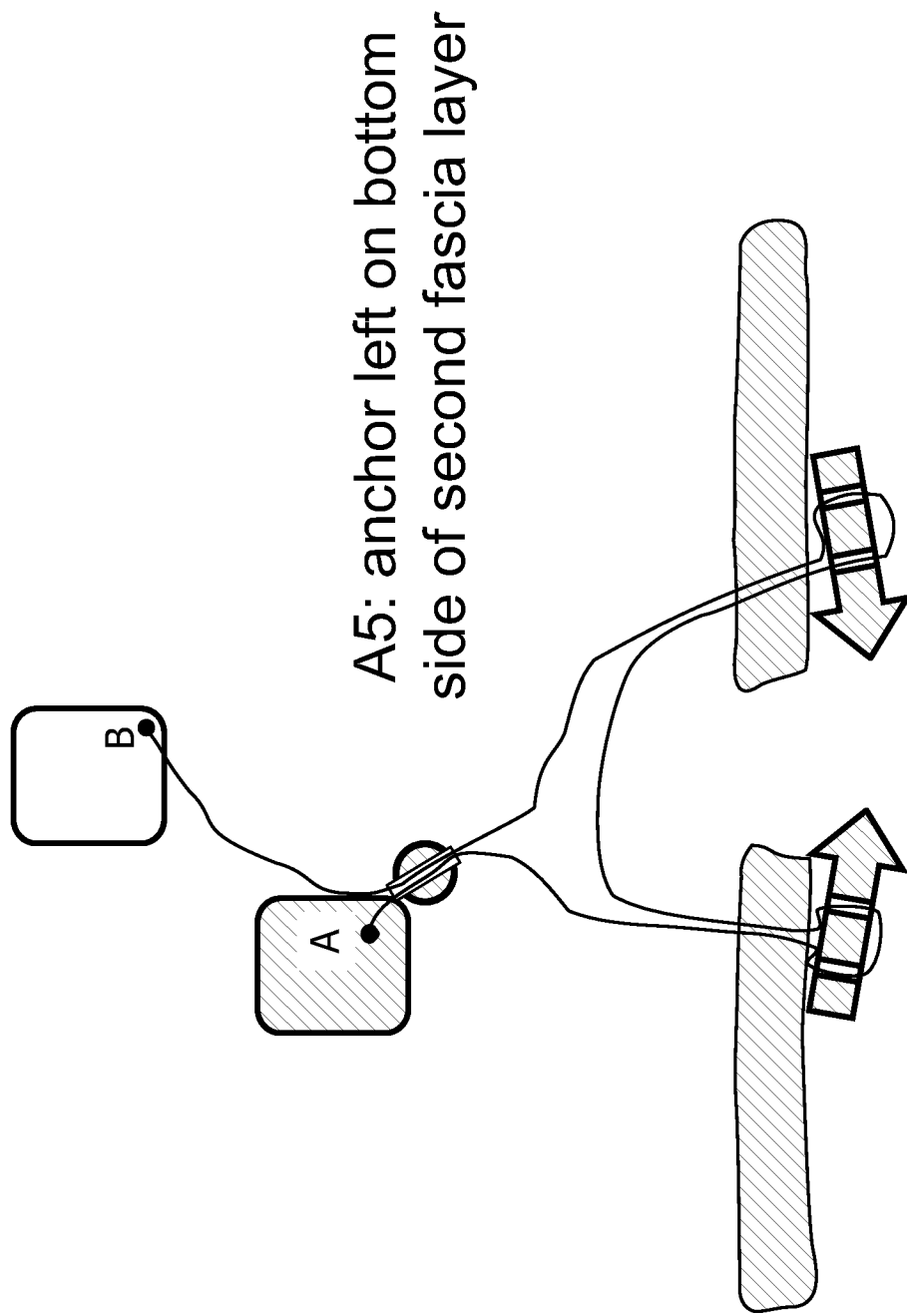


Fig. 5J

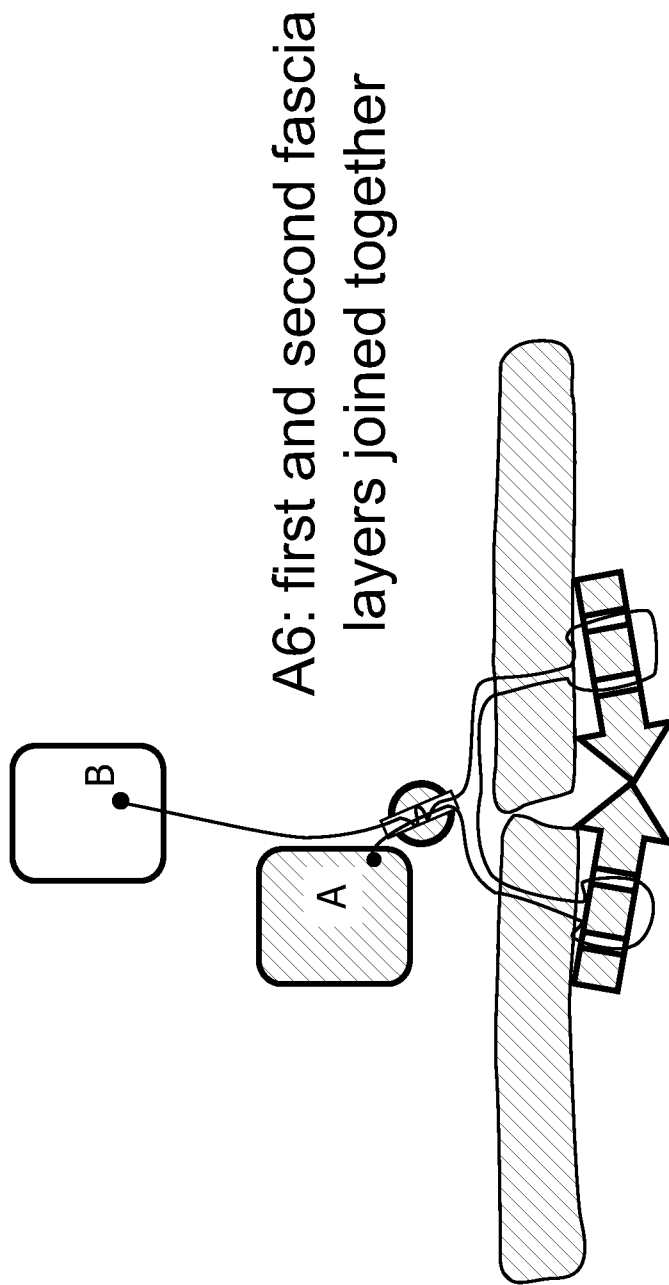


Fig. 5K

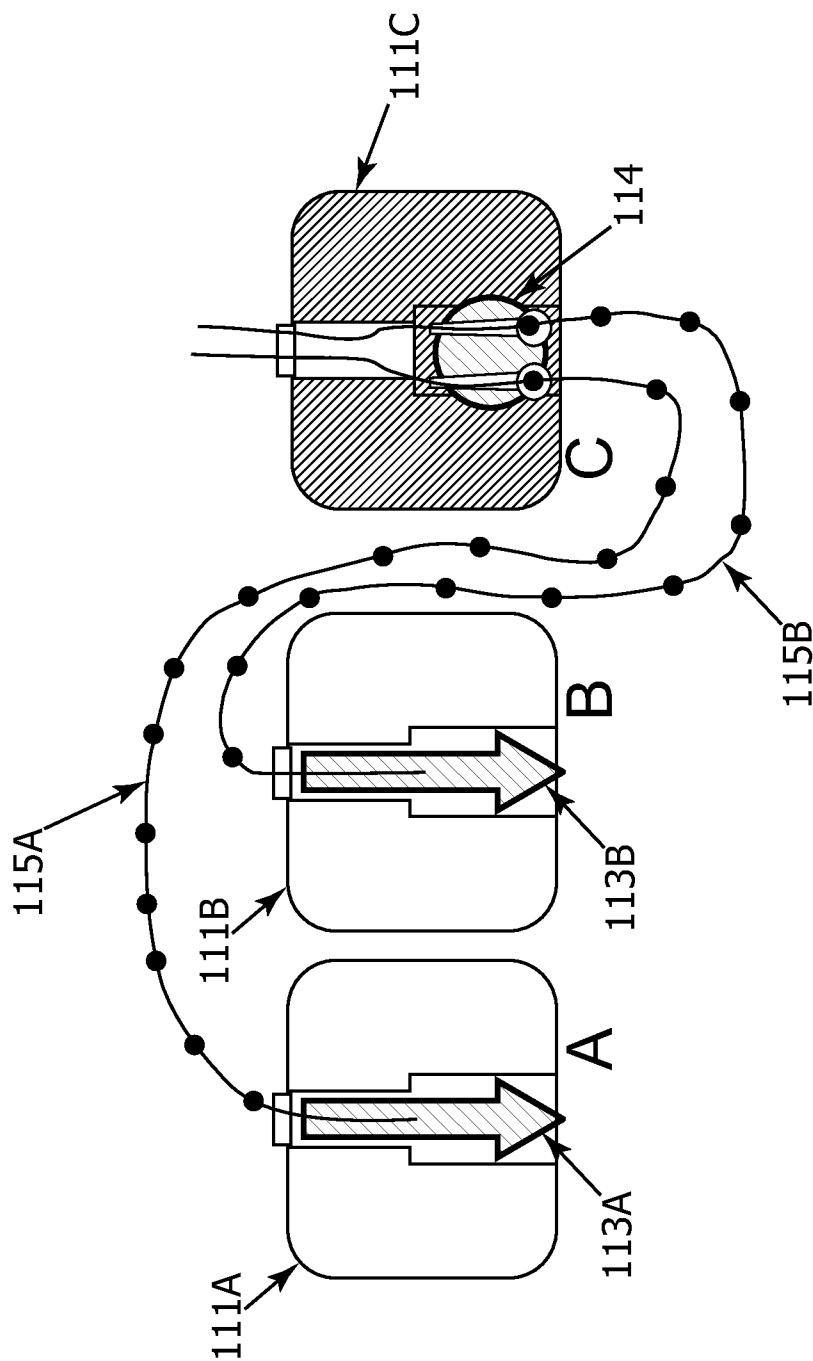


Fig. 6A

B1: device prepared for driving anchors through first and second fascia layers

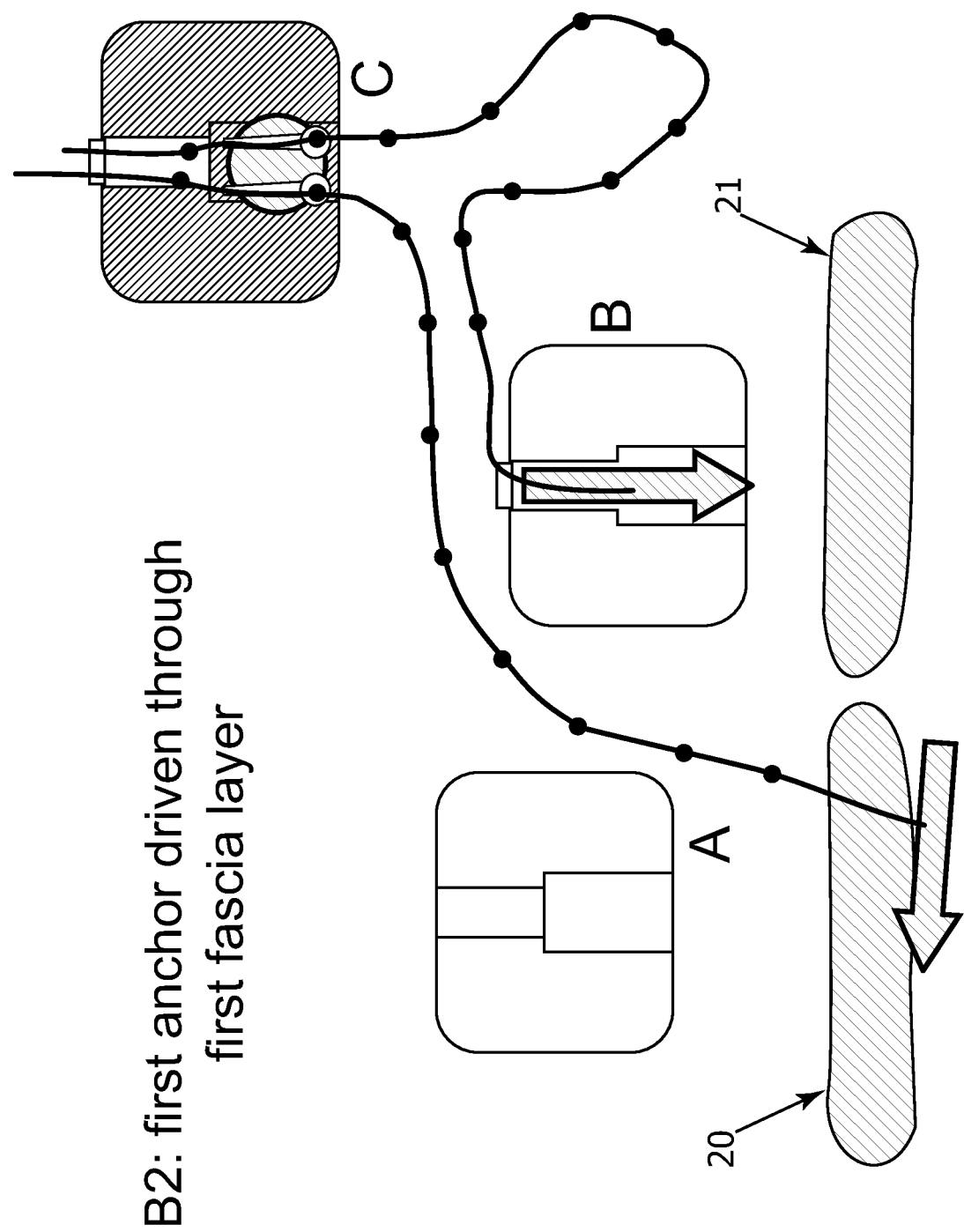


Fig. 6B

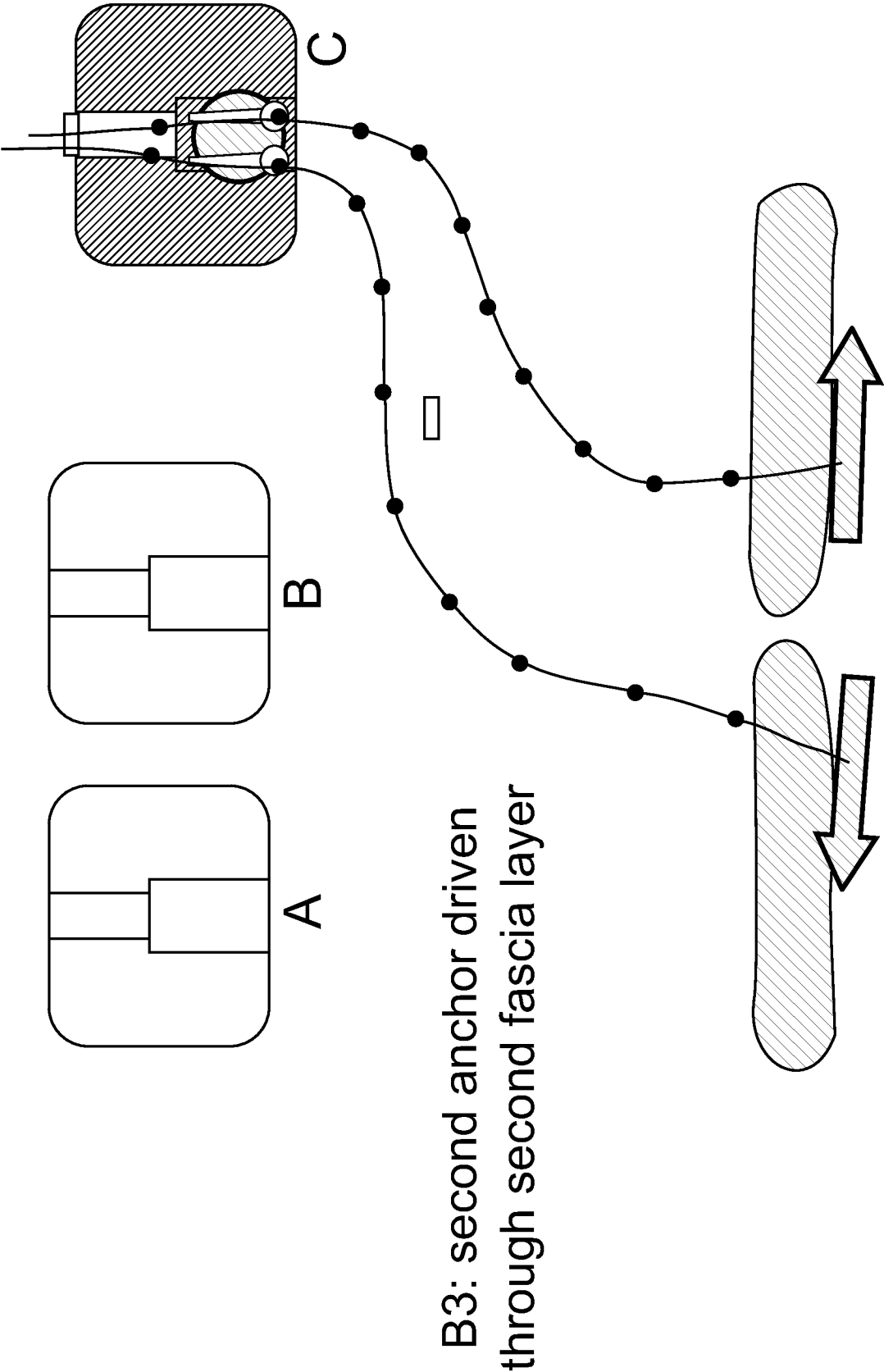


Fig. 6C

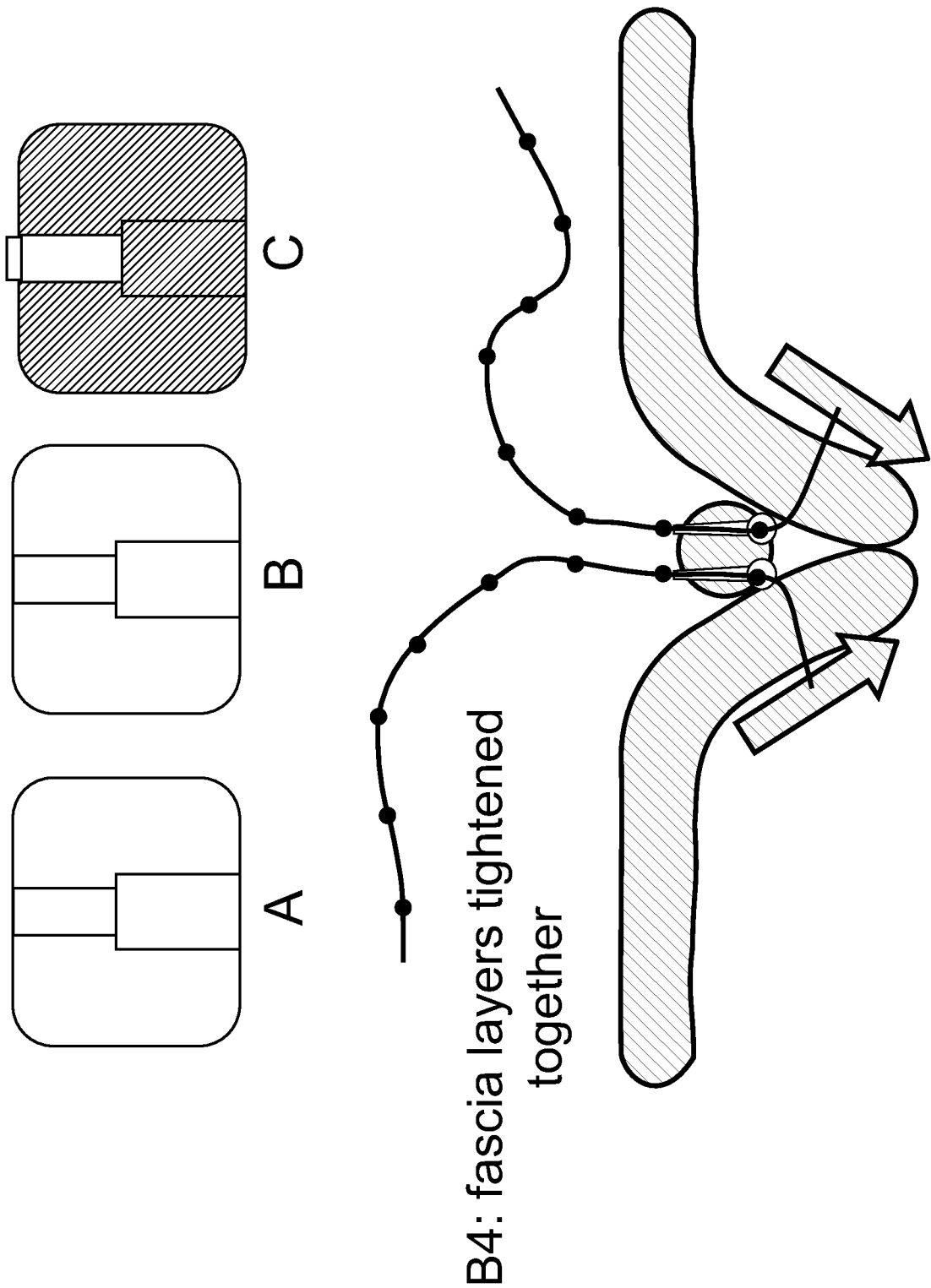
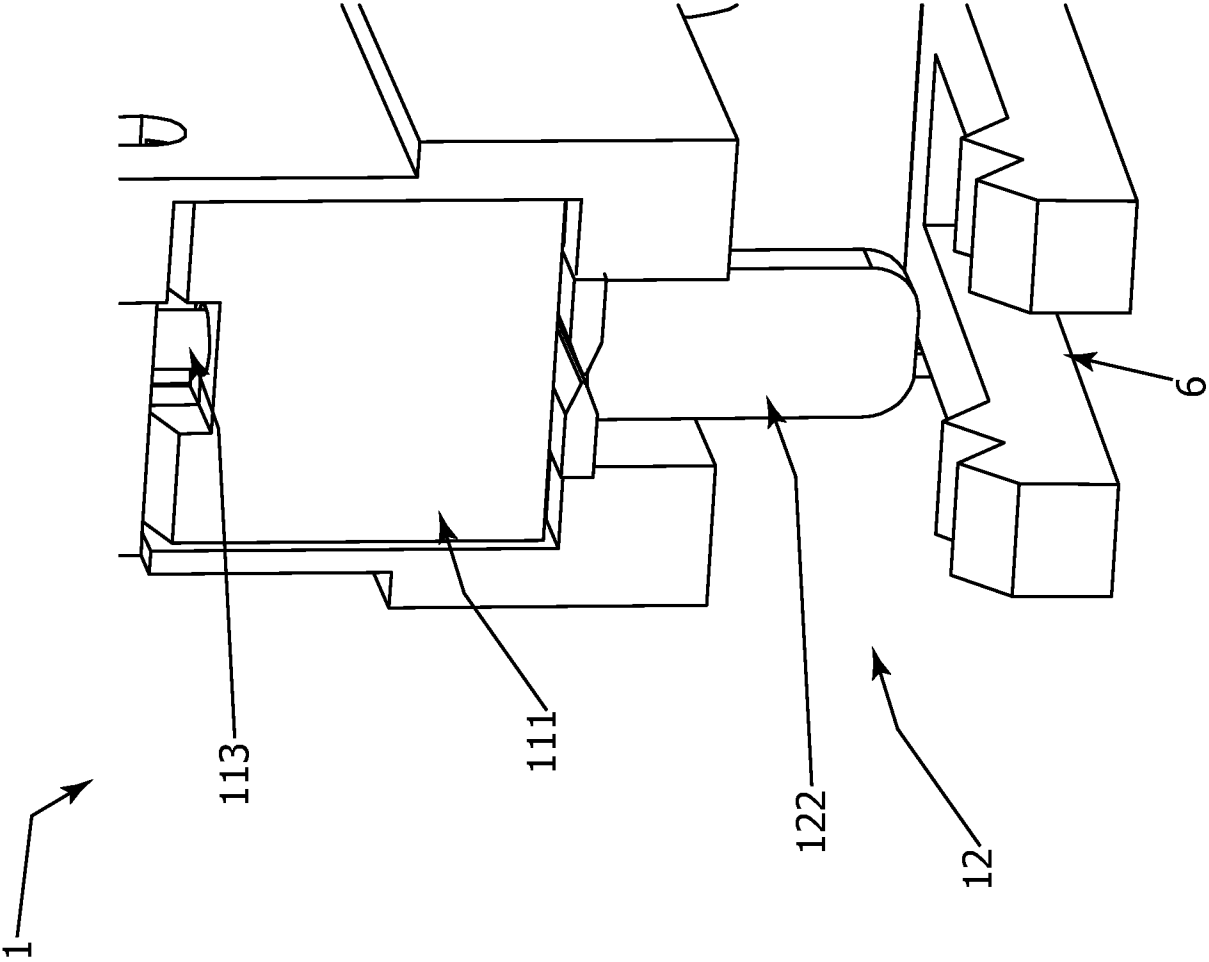
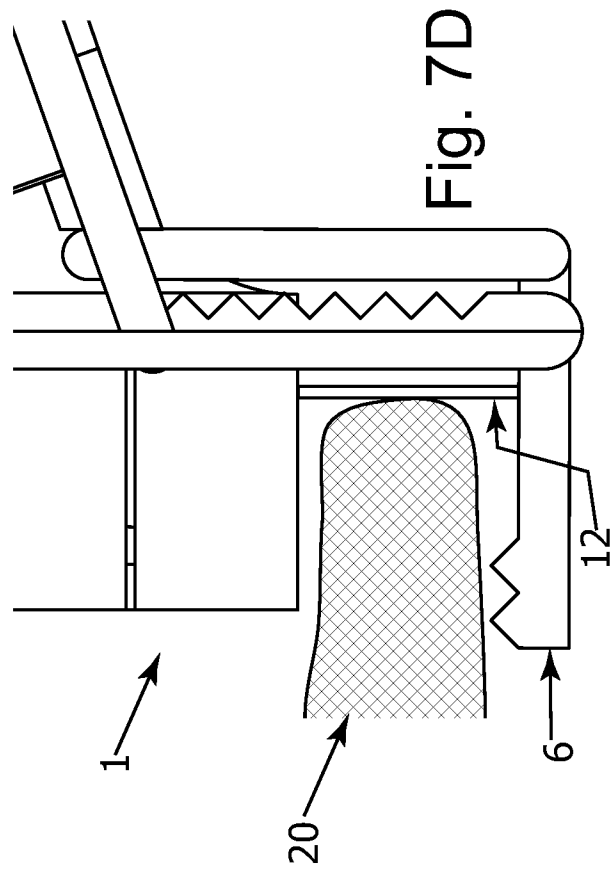
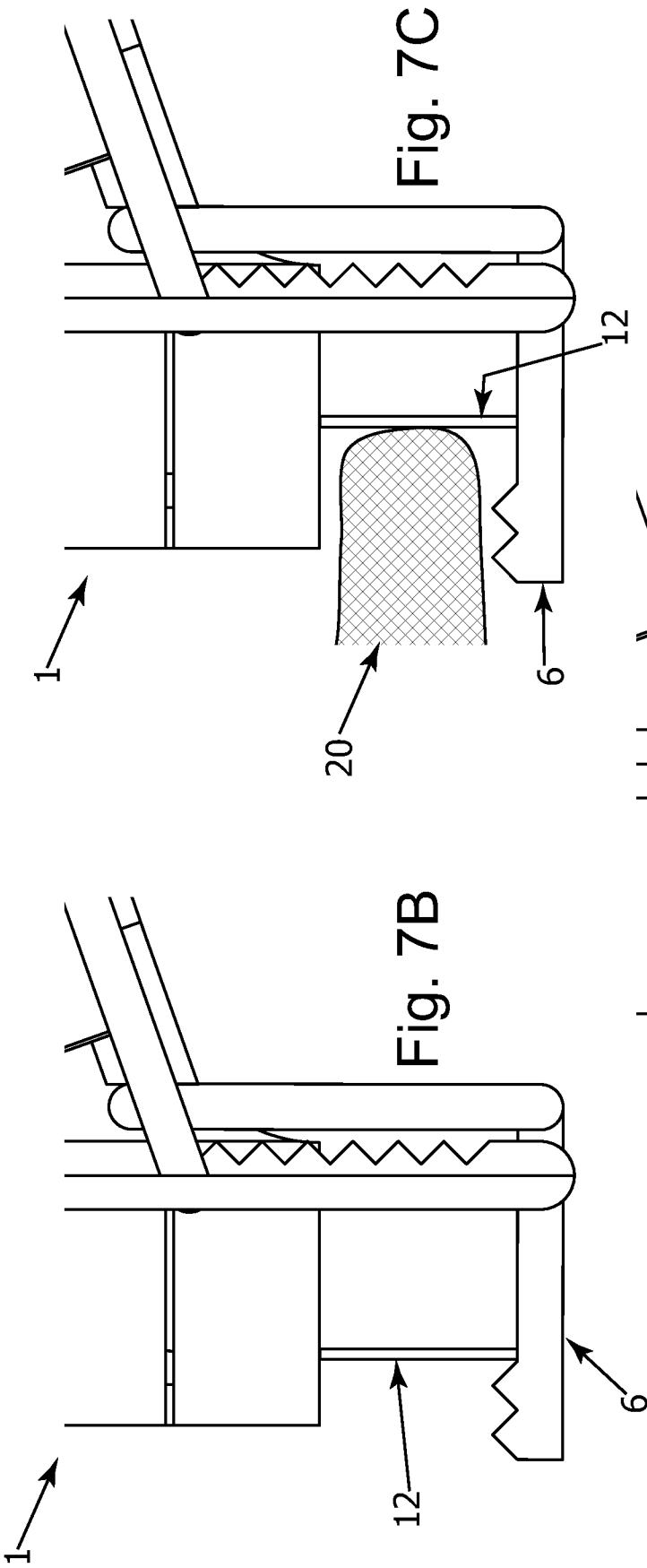


Fig. 7A





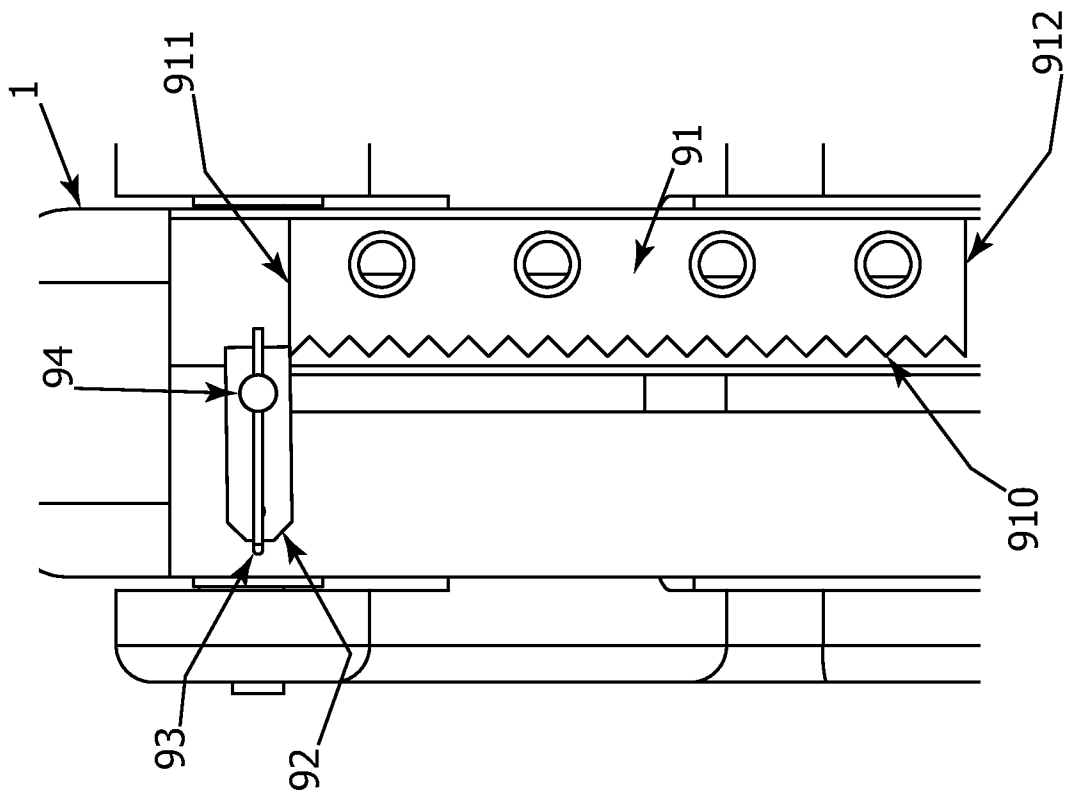


Fig. 7F

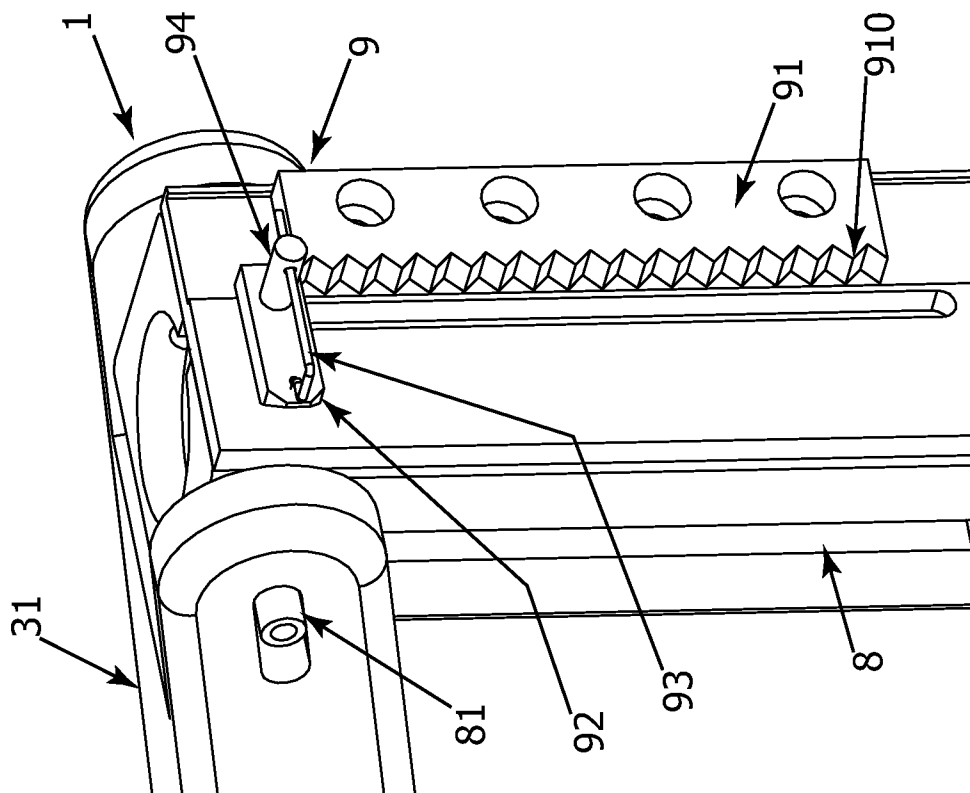


Fig. 7E

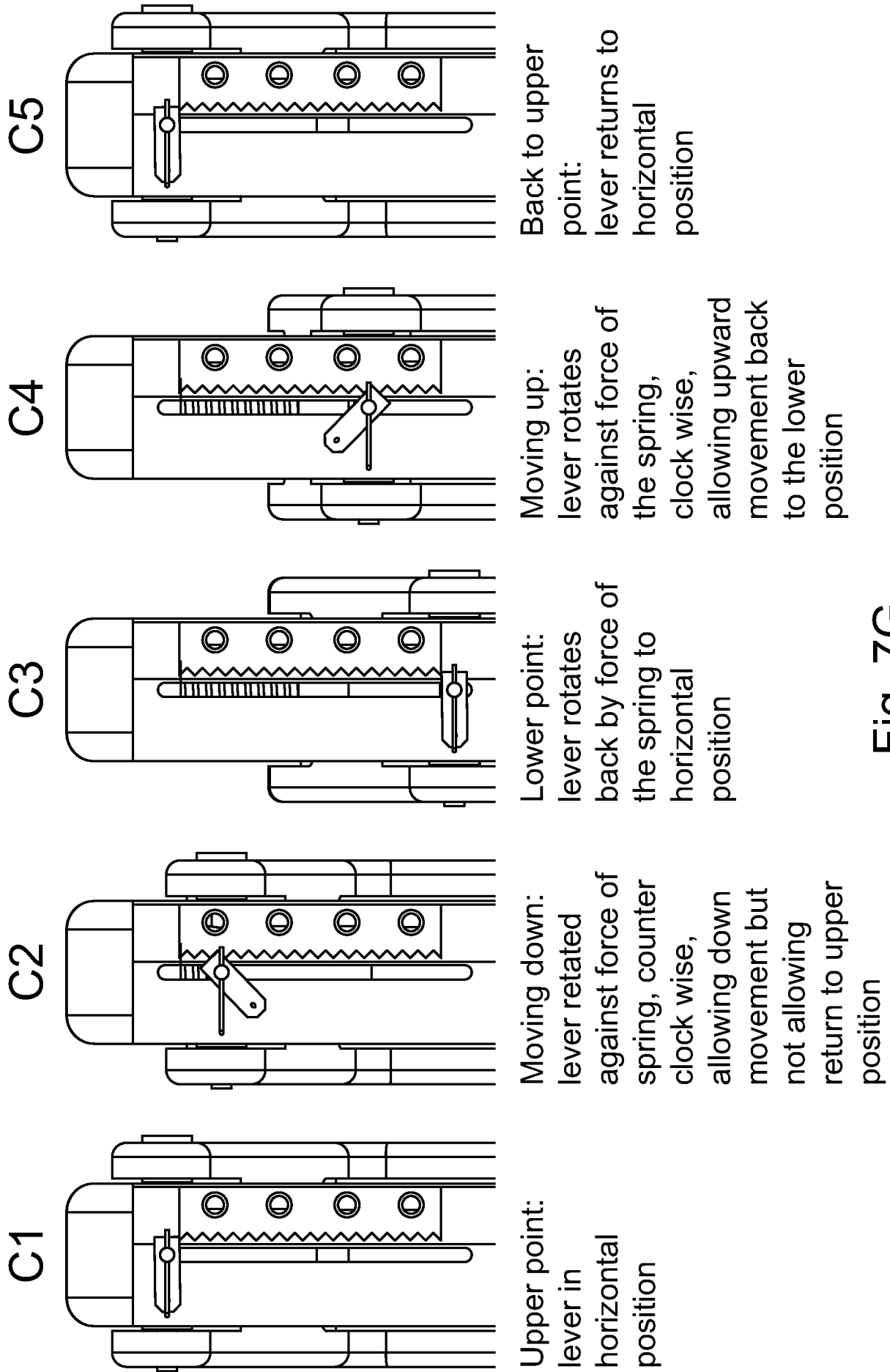


Fig. 7G

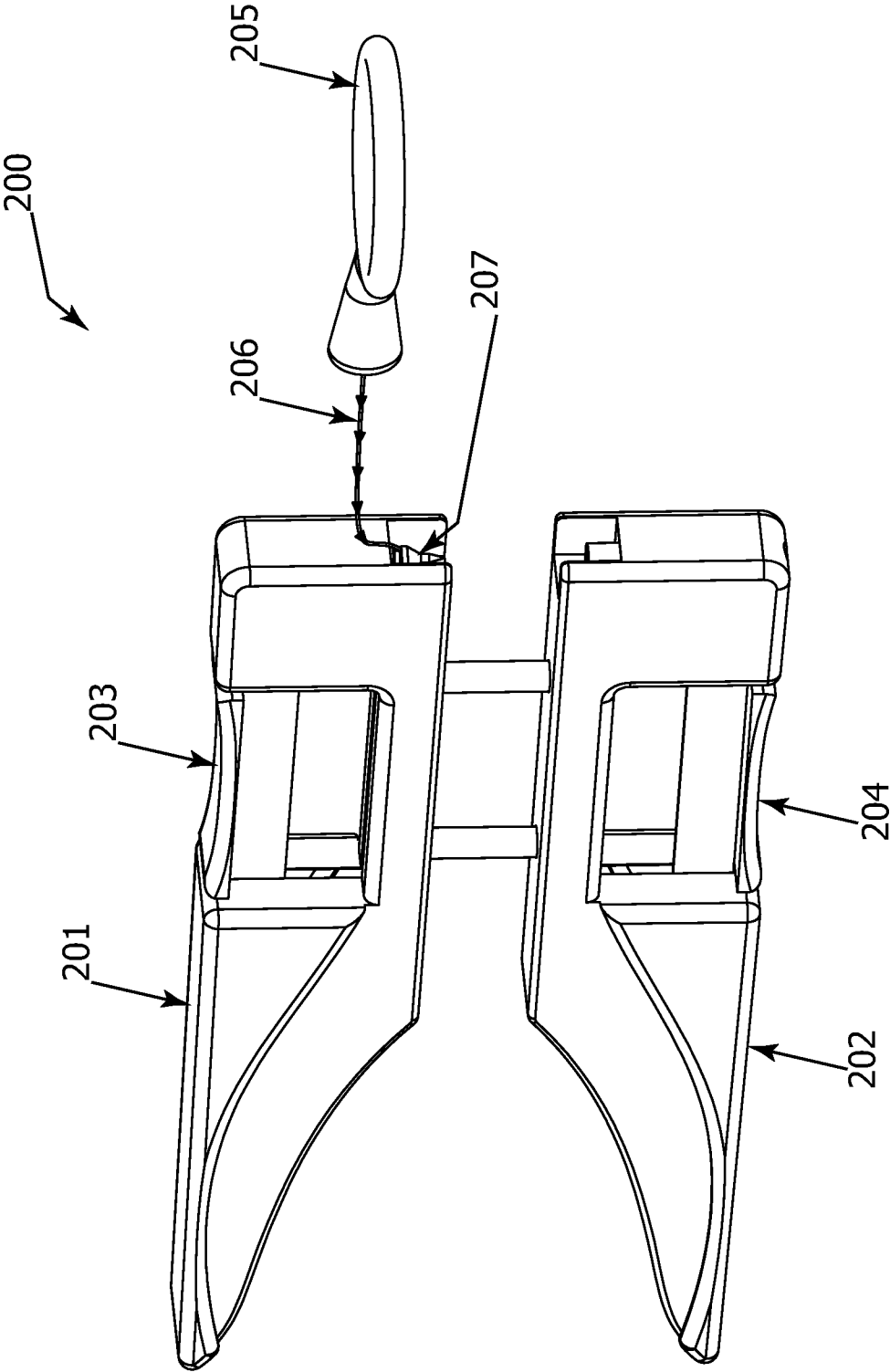


Fig. 8A

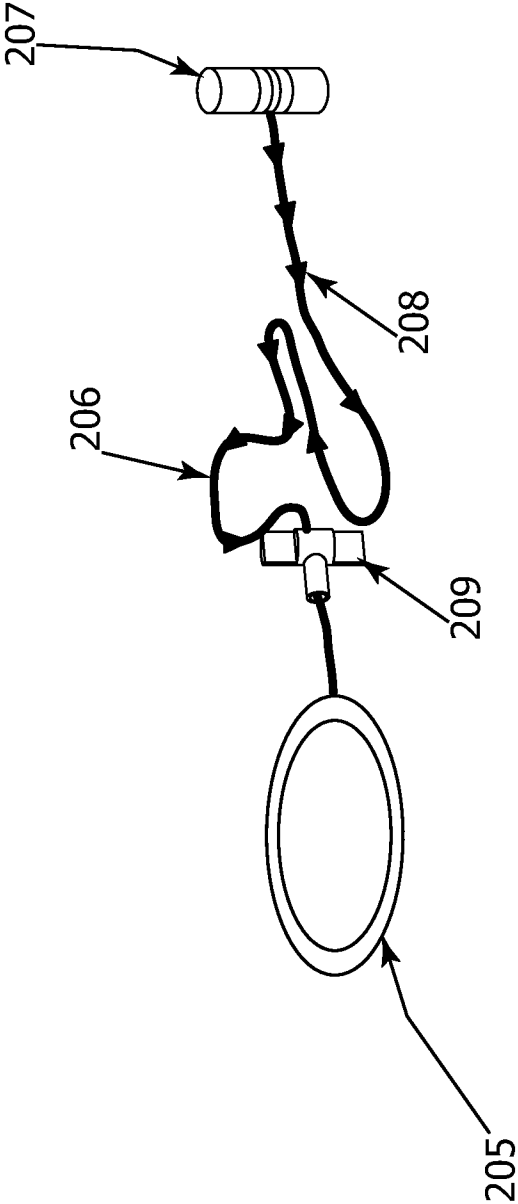
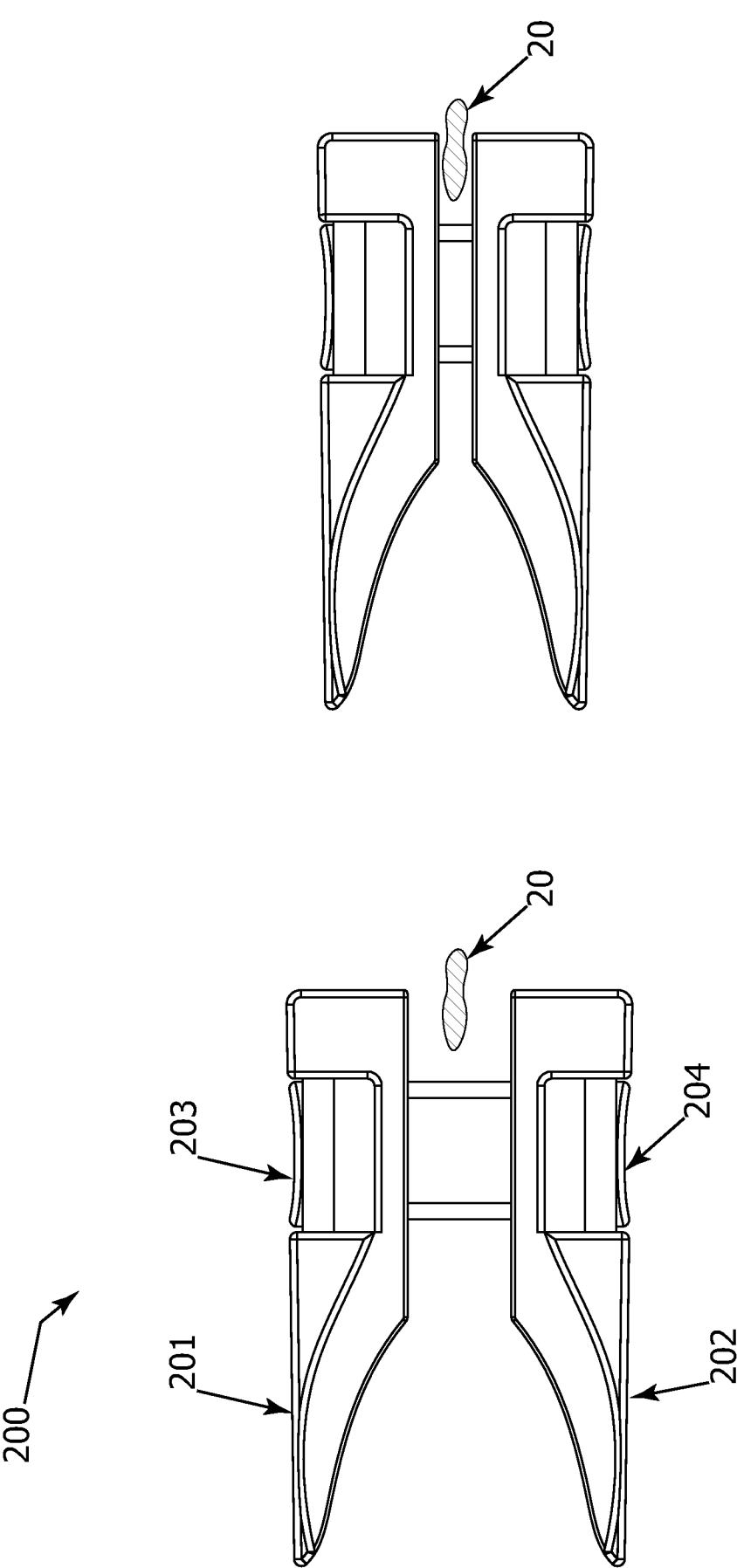
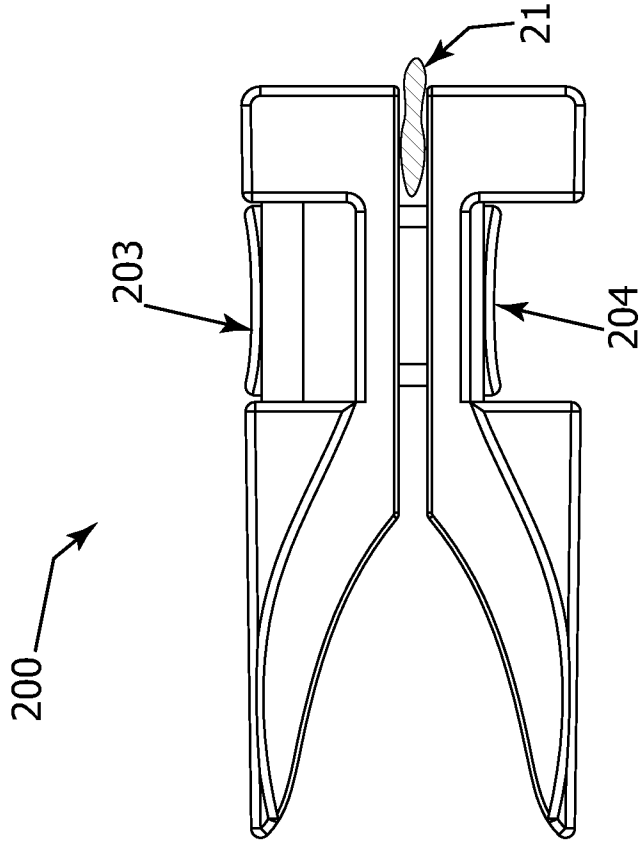


Fig. 8B

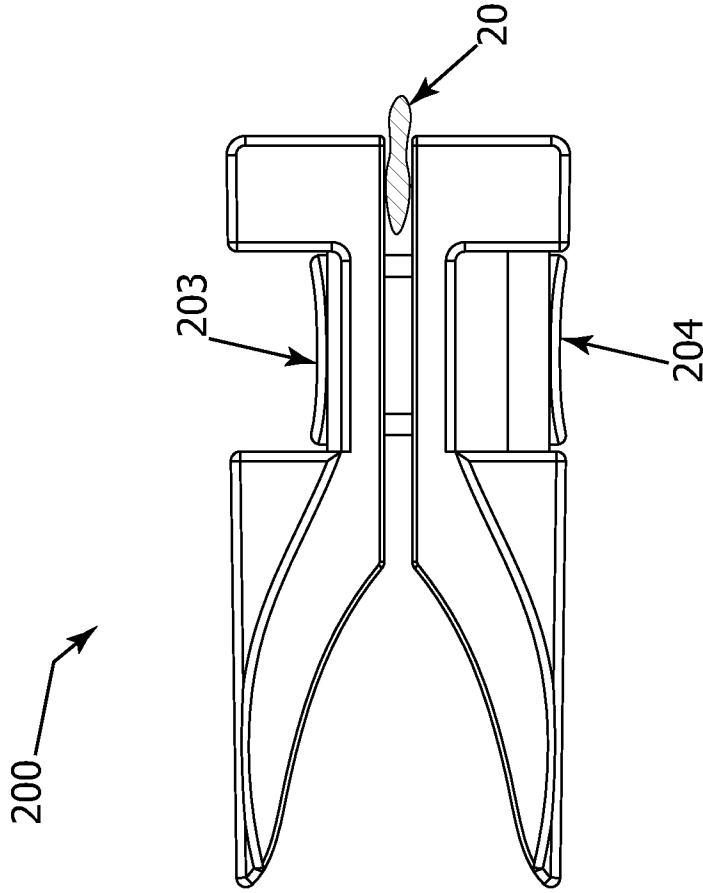


D1: tissue is brought into device D2: device is squeezed unto tissue

Fig. 8C

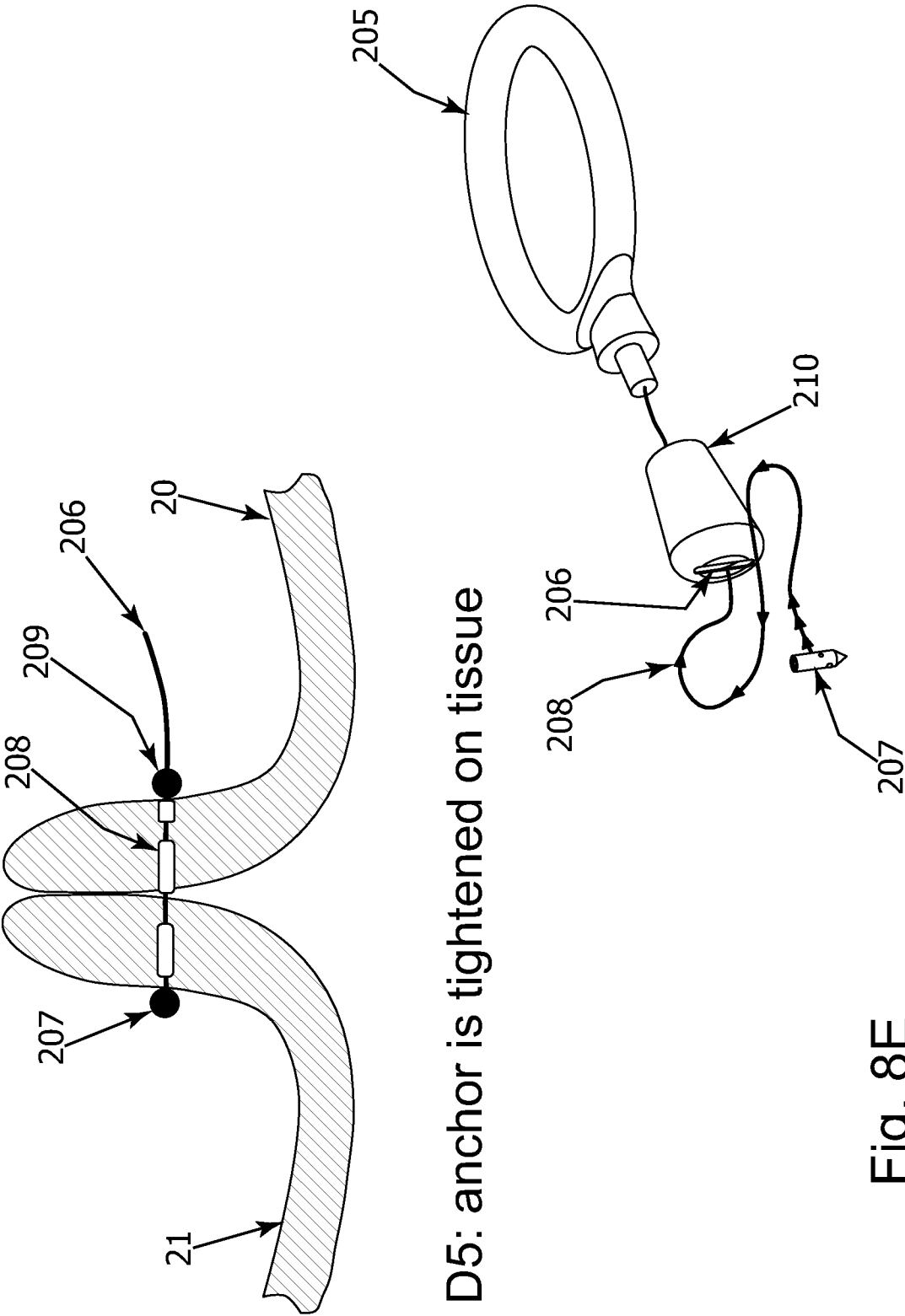


D4: device is removed to other side of tissue; anchor penetrates and passes tissue from bottom to top



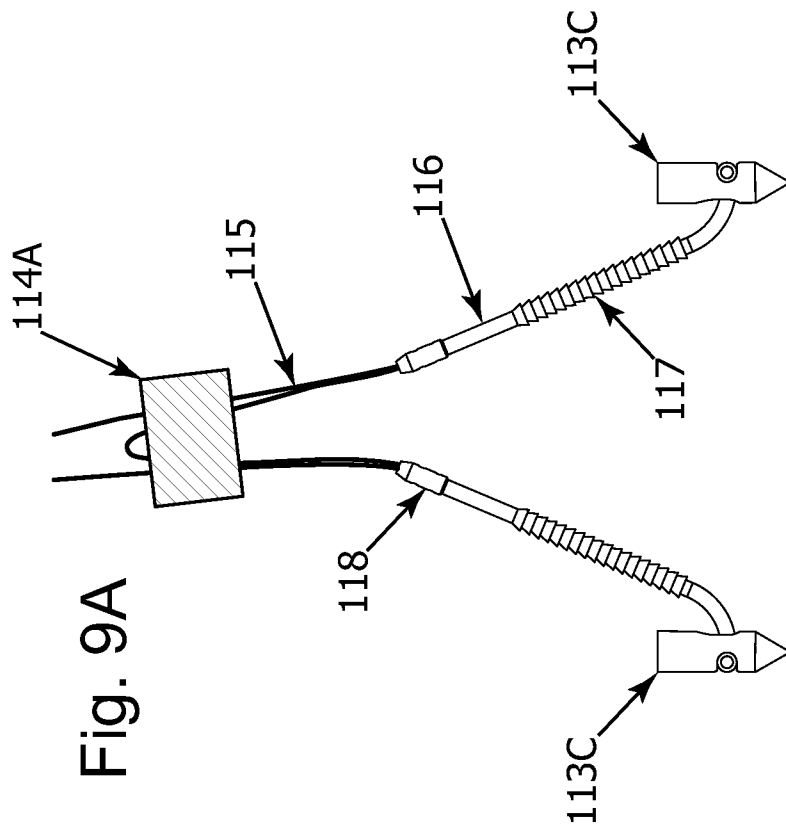
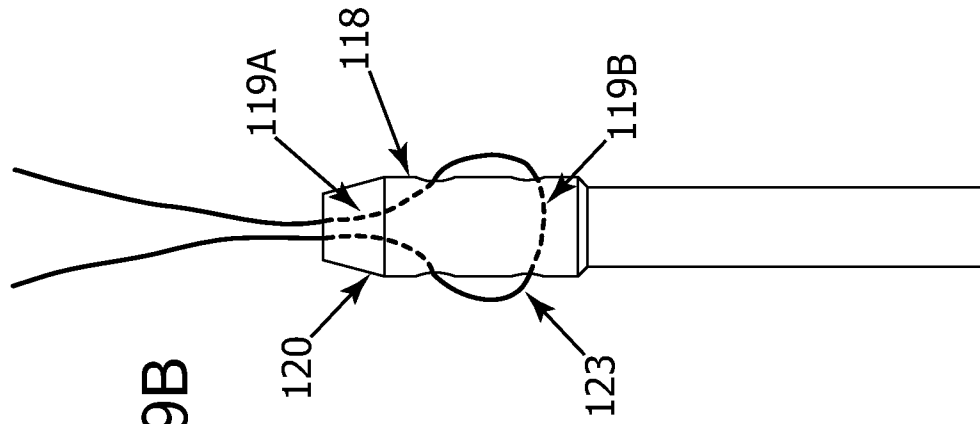
D3: anchor penetrates and passes through tissue from top to bottom

Fig. 8D



D5: anchor is tightened on tissue

Fig. 8E



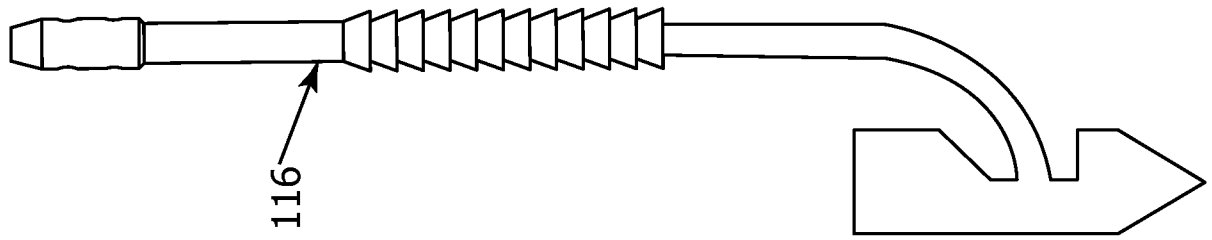


Fig. 9C

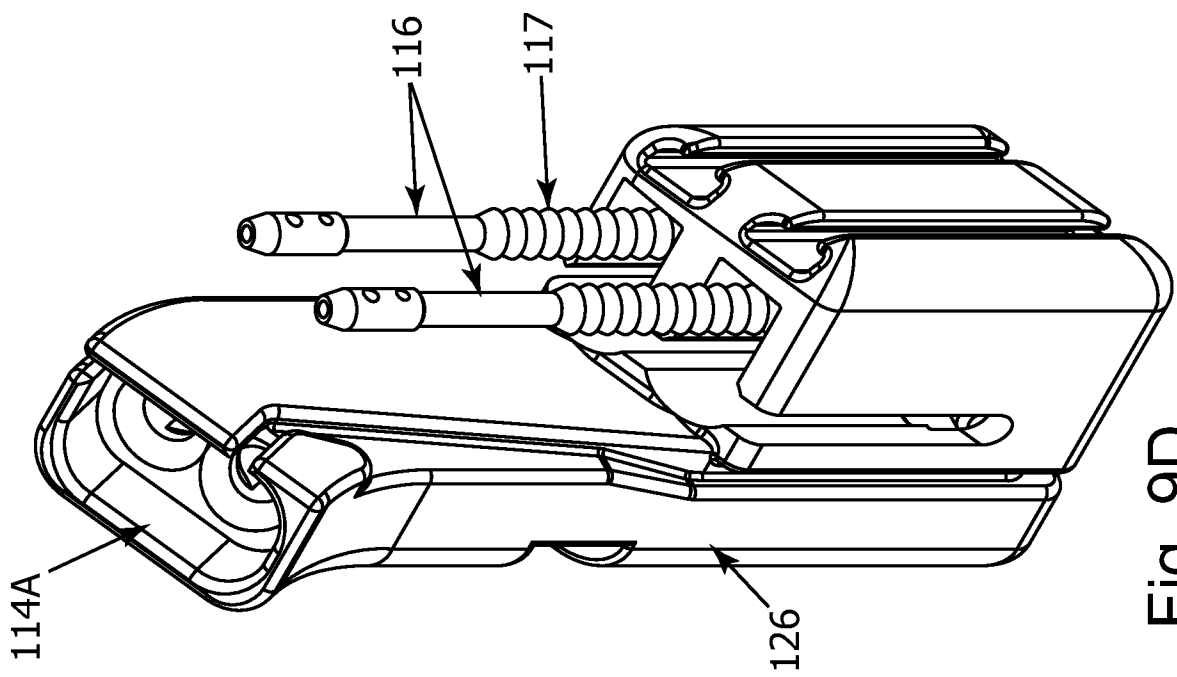


Fig. 9D

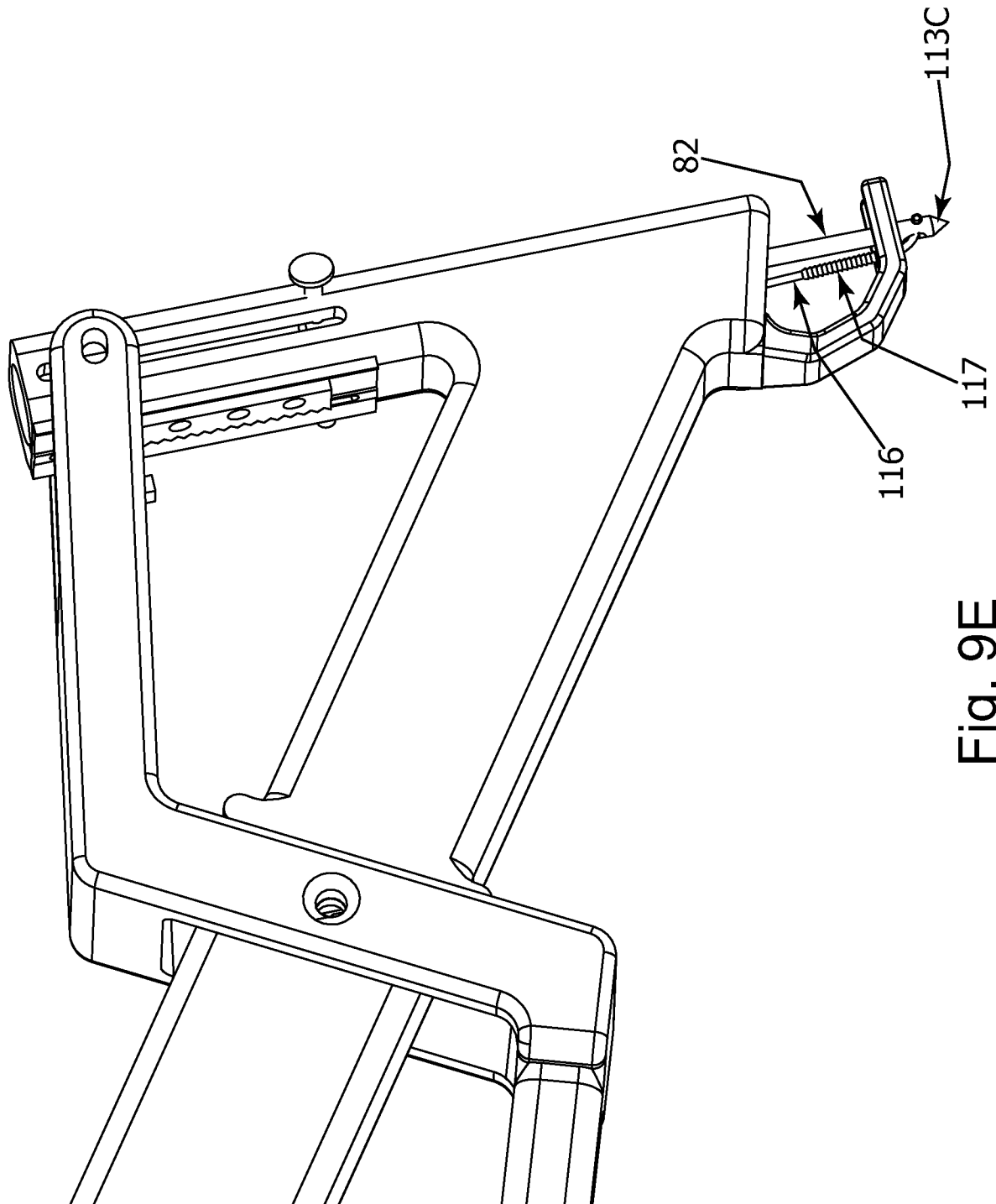


Fig. 9E

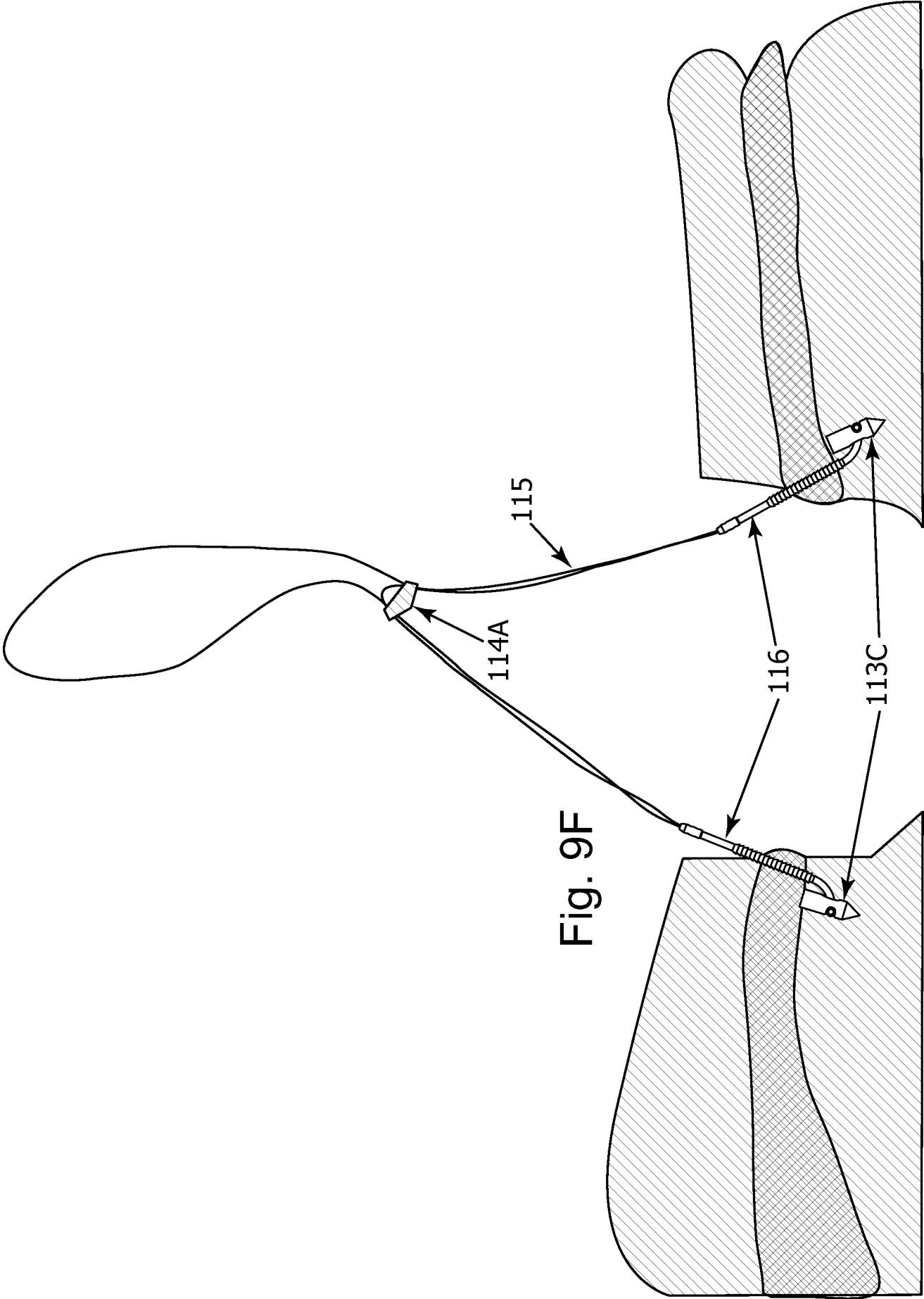
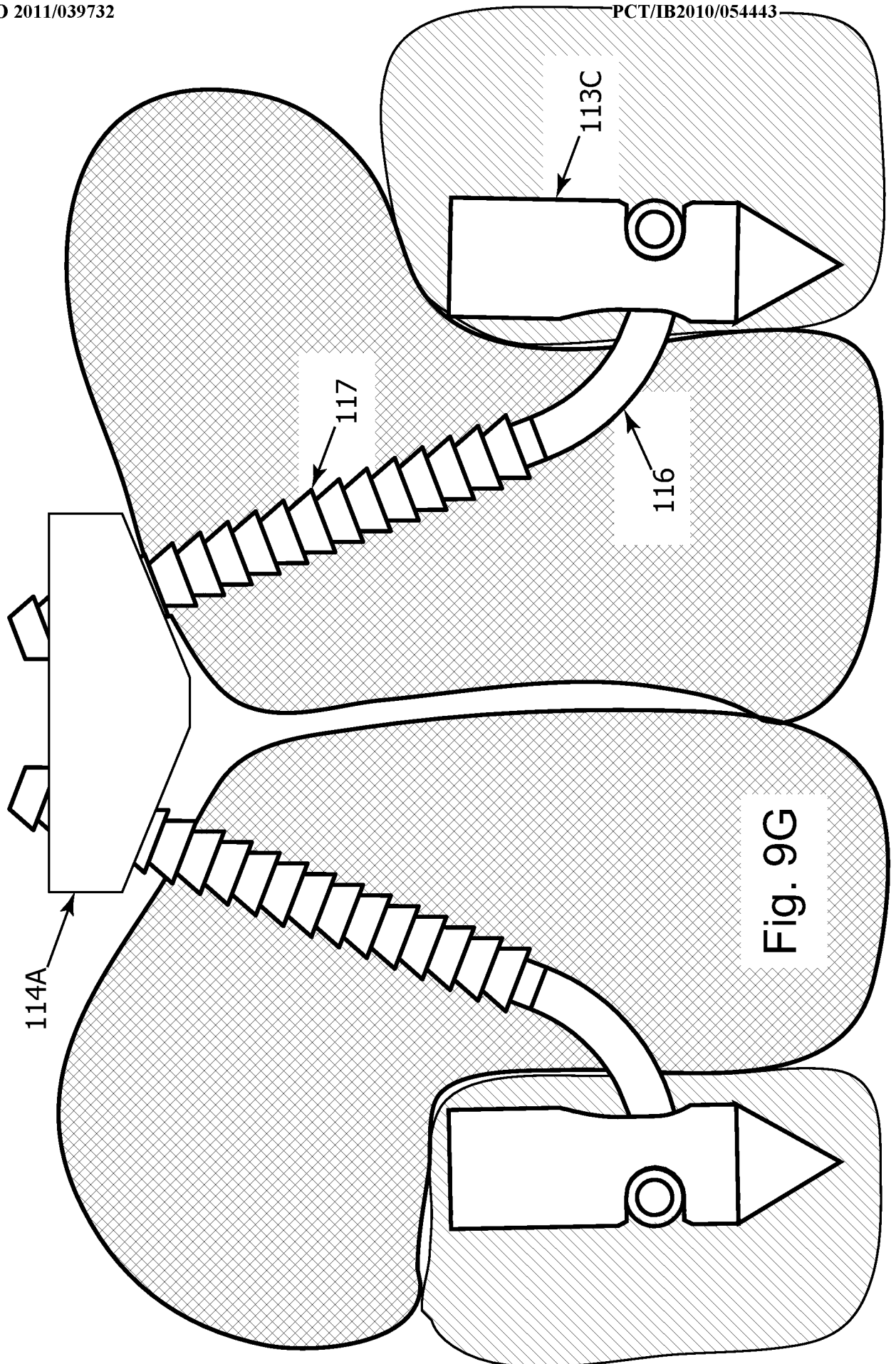


Fig. 9F



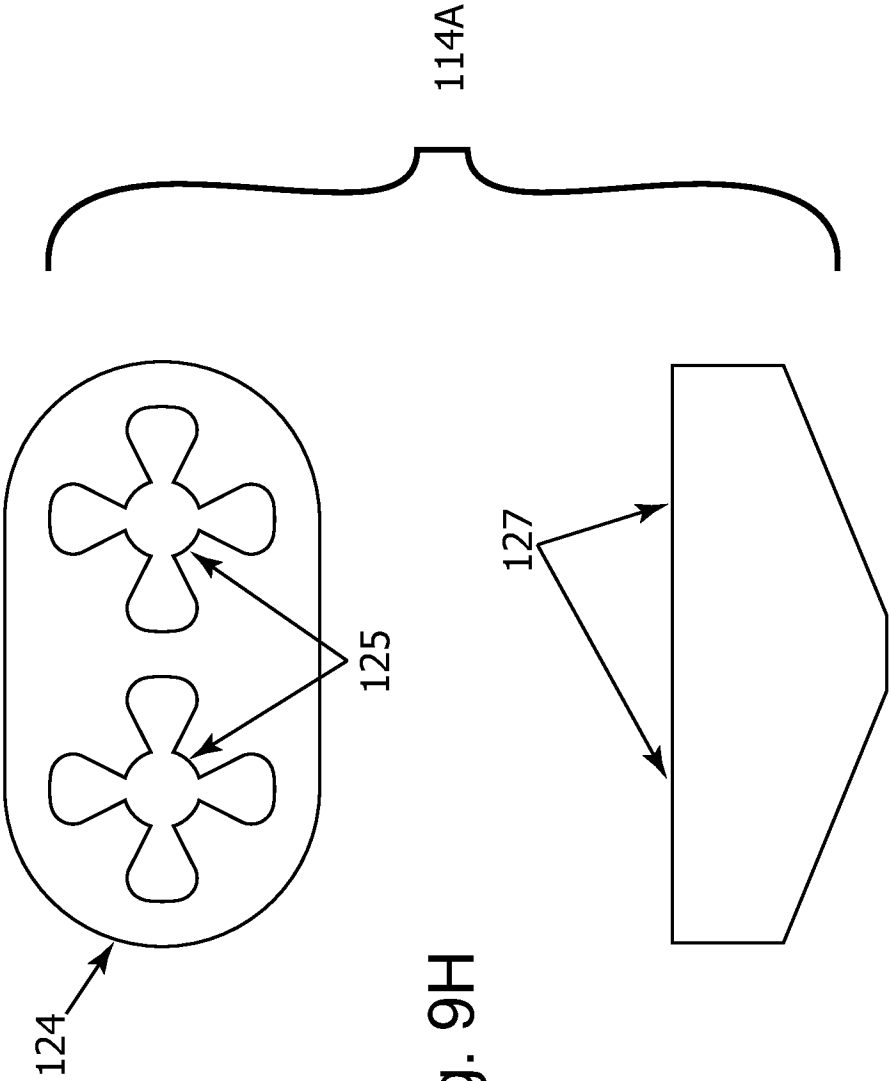


Fig. 9H

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 10/54443

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/03 (2011.01)

USPC - 606/145

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61B 17/03 (2011.01)

USPC: 606/145

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

IPC(8): A61B 17/03 (2011.01) A61B17/00

USPC: 17/04, 17/06, 17/064, 17/068, 17/072; 606/1, 139, 142, 144, 145, 148, 150, 151

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Electronic Databases Searched: Google Scholar; Google Patent; PubWest (US Patents full-text, US PGPubs USOC, full-text, EPO Abstracts, and JPO Abstracts) Search Terms Used: medical, closure, tissue, suture, suturing, temporary, needle, needles, plunger, plungers, stapler, staples, staplers, or, gun, guns, anchor, anchors, move, moving, movable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,810,848 A (HAYHURST) 22 September 1998 (22.09.1998) entire document especially Fig. 4; col 2, ln 59 to col 3, ln 51; col 5, ln 38 to col 6, ln 18	1-5, 7-8, 10, 20-29, 32
Y		6, 9, 11-19, 30-31, 33-41
Y	US 2009/0281568 A1 (CENDAN et al.) 12 November 2009 (12.11.2009) Fig. 1A; para [0036], [0045]	6, 30
Y	US 6,972,027 B2 (FALLIN et al.) 06 December 2005 (06.12.2005) Fig. 4; col 4, ln 62 to col 5, ln 9	9
Y	US 6,312,448 B1 (BONUTTI) 06 November 2001 (06.11.2001) Fig. 2; col 4, ln 66 to col 5, ln 15	11, 14-19, 31, 39
Y	US 5,871,490 A (SCHULZE et al.) 16 February 1999 (16.02.1999) Fig. 47; col 6, ln 37-67	12-19
Y	US 6,610,072 B1 (CHRISTY et al.) 26 August 2003 (26.08.2003) Fig. 19; col 11, ln 4-17	15-19, 35-37
Y	US 7,390,329 B2 (WESTRA et al.) 24 June 2008 (24.06.2008) Fig. 3E; col 14, ln 27-62	33-38, 40-41

☐ Further documents are listed in the continuation of Box C.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

08 March 2011 (08.03.2011)

Date of mailing of the international search report

14 MAR 2011

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