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[Continued on next page]

(54) Title: BARBED SUTURE DISPENSER

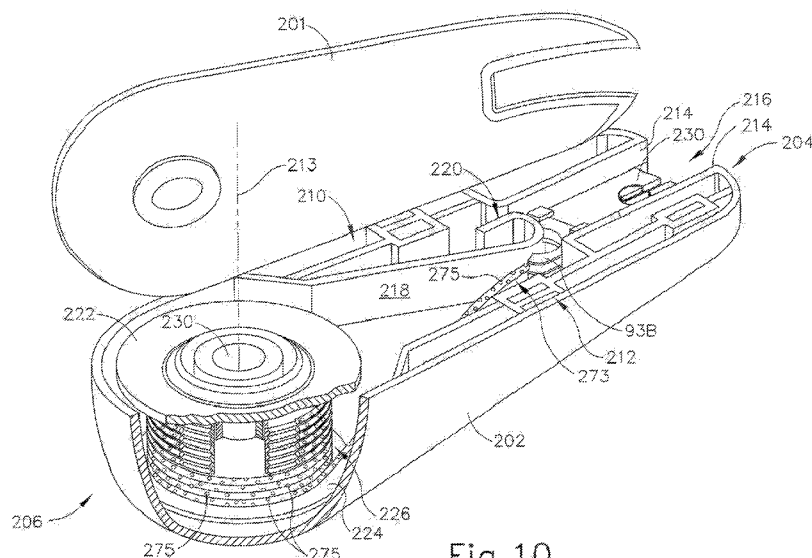


Fig.10

(57) Abstract: A packaging for a surgical needle comprises a cartridge. The cartridge comprises a surgical needle and a needle driver configured to engage and move the needle relative to the cartridge. The packaging further comprises a spool comprising a helical channel and a length of suture connected to the needle. At least a portion of the length of suture is wound around the spool. At least a portion of the length of suture is positioned within the helical channel. The suture may include a plurality of barbs.



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BARBED SUTURE DISPENSER

BACKGROUND

[0001] Sutures may be used in a wide variety of surgical procedures. Manual suturing may be accomplished by the surgeon using a fine pair of graspers to grab and hold a suture needle, pierce the tissue with the needle, let go of the needle, and re-grasp the needle to pull the needle and accompanying suture thread through the tissues to be sutured. Such needles may be curved with the suture attached to the trailing end of the needle.

[0002] Some surgical instruments automate at least part of the suturing procedure. Examples of automated suturing instruments are described in U.S. Pat. No. 8,702,732, entitled "Laparoscopic Suturing Instrument with Dual-Action Needle Graspers," issued April 22, 2014, the disclosure of which is incorporated by reference herein; U.S. Pub. No. 2011/0313433, entitled "Laparoscopic Suture Device with Asynchronous In-Line Needle Movement," published December 22, 2011, the disclosure of which is incorporated by reference herein; U.S. Pub. No. 2014/0171970, entitled "Circular Needle Applier with Articulating and Rotating Shaft," published June 19, 2014, the disclosure of which is incorporated by reference herein; and U.S. Pat. App. No. 14/297,993, entitled "Jawed Cartridge receiving assembly for Needle Cartridge," filed June 6, 2014, the disclosure of which is incorporated by reference herein.

[0003] While various kinds of suturing instruments and associated components have been made and used, it is believed that no one prior to the inventor(s) has made or used the invention described in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] While the specification concludes with claims which particularly point out and distinctly claim this technology, it is believed this technology will be better understood from the following description of certain examples taken in conjunction with the

accompanying drawings, in which like reference numerals identify the same elements and in which:

- [0005] FIG. 1 depicts a side view of an exemplary surgical suturing instrument;
- [0006] FIG. 2A depicts top perspective exploded view of a cartridge receiving assembly of the instrument of FIG. 1;
- [0007] FIG. 2B depicts bottom perspective exploded view of the cartridge receiving assembly of FIG. 2A;
- [0008] FIG. 3A depicts a top perspective view of an exemplary cartridge configured for receipt in the cartridge receiving assembly of FIG. 2A;
- [0009] FIG. 3B depicts a bottom perspective view of the cartridge of FIG. 3A;
- [0010] FIG. 4 depicts an exploded view of the cartridge of FIG. 3A;
- [0011] FIG. 5A depicts a perspective view of a drive assembly of the cartridge of FIG. 3A, with the drive assembly at one end of its stroke;
- [0012] FIG. 5B depicts a perspective view of the drive assembly of FIG. 5A, with the drive assembly at mid-stroke;
- [0013] FIG. 5C depicts a perspective view of the drive assembly of FIG. 5A, with the drive assembly at the other end of its stroke;
- [0014] FIG. 6 depicts a partial plan view of a needle driver of the cartridge of FIG. 3A engaging a needle of the cartridge of FIG. 3A;
- [0015] FIG. 7 depicts an exploded view of the cartridge of FIG. 3A with an exemplary suture dispenser;
- [0016] FIG. 8 depicts a perspective view of the cartridge receiving assembly of FIG. 2A engaged with the cartridge of FIG. 3A at the suture dispenser of FIG. 7;

- [0017] FIG. 9 depicts a perspective view of the cartridge of FIG. 3A with an exemplary alternative suture dispenser;
- [0018] FIG. 10 depicts a perspective view of the cartridge of FIG. 3A in the suture dispenser of FIG. 9, with a portion of the suture dispenser opened to reveal internal components;
- [0019] FIG. 11 depicts a side elevational view of a suture spool of the suture dispenser of FIG. 10;
- [0020] FIG. 12 depicts a perspective view of the cartridge of FIG. 3A with another exemplary alternative suture dispenser, with a portion of the suture dispenser omitted to reveal internal components;
- [0021] FIG. 13A depicts a perspective view of the cartridge receiving assembly of FIG. 2A approaching the suture dispenser of FIG. 12; and
- [0022] FIG. 13B depicts a perspective view of the cartridge receiving assembly of FIG. 2A engaged with the cartridge of FIG. 3A, pulling suture from the suture dispenser of FIG. 12.
- [0023] The drawings are not intended to be limiting in any way, and it is contemplated that various embodiments of the technology may be carried out in a variety of other ways, including those not necessarily depicted in the drawings. The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present technology, and together with the description serve to explain the principles of the technology; it being understood, however, that this technology is not limited to the precise arrangements shown.

DETAILED DESCRIPTION

- [0024] The following description of certain examples of the technology should not be used to limit its scope. Other examples, features, aspects, embodiments, and advantages of the technology will become apparent to those skilled in the art from the following

description, which is by way of illustration, one of the best modes contemplated for carrying out the technology. As will be realized, the technology described herein is capable of other different and obvious aspects, all without departing from the technology. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

[0025] I. Overview of Exemplary Surgical Suturing Instrument

[0026] FIG. 1 illustrates an example of a surgical suturing instrument (2). Instrument (2) comprises a handle assembly (10), an elongate shaft (20), and a cartridge receiving assembly (50), which is operable to receive a needle applier cartridge (30). Shaft (20) has a proximal end (21), a distal end (22), and a longitudinal axis extending therebetween. Handle assembly (10) is connected to the proximal end (21) of the shaft (20). In this example handle assembly (10) is a manual pistol grip handle. However, a variety of other manual actuators could also be used, including but not limited to a scissor grip handle, a syringe grip handle, endoscopic rotary knobs, and the like. Handle assembly (10) could also take the form of a robotic interface, such as a DAVINCI puck, or a housing comprising gears or pulleys, servomechanisms, and the like.

[0027] Needle applier cartridge (30) is connected to the distal end (22) of shaft (20) via cartridge receiving assembly (50). Needle applier cartridge (30) is operable to rotate an arced needle in a circular path enabling a surgeon to selectively apply sutures. In some alternative versions, needle applier cartridge (30) is integral with shaft (20) and handle assembly (10) as a unitary disposable instrument intended for a single surgical procedure. Needle applier cartridge (30) may also be integral with shaft (20) and handle assembly (10) as a reusable instrument. Optionally, as illustrated here, needle applier cartridge (30) may be provided in a disposable cartridge body (90) and shaft (20) includes cartridge receiving assembly (50) to releasably hold cartridge body (90). In some such versions, shaft (20) and handle assembly (10) may also be disposable or reusable. Versions with reusable components are intended to be cleaned, sterilized, and reused for a multiple surgical procedures, and may include a flush port (18) to facilitate cleaning. The preferable life cycle of a reusable instrument is at least 50 operations, more preferably at

least 150 operations, and most preferably at least 200 operations. Reusable components may be built using materials that can withstand autoclave sterilization temperatures of at least 135 degrees Celsius, although low temperature materials can also be used with low temperature sterilization techniques known in the art.

[0028] A first input (12), shown here as a trigger that pivots between opened and closed positions, may be used to selectively actuate needle applier cartridge (30). The trigger may be spring biased to return the trigger to its open position. A second input (14), shown here as a rotary knob, may be used to selectively articulate shaft (20). A third input (16), shown here as a rotary knob, may be used to selectively rotate needle applier cartridge (30) about shaft (20). Of course, the number, type, configuration, and operation of inputs (12, 14, 16) may vary.

[0029] FIGS. 2A-2B illustrate exploded views of cartridge receiving assembly (50) of the present example. Distal end (22) of shaft (20) comprises an articulation joint (23) and a rotational bearing (24). Articulation joint (23) includes a knuckle (23A) that receives pins (23B, 23C), which are connected to bearing supports (24B, 24C). Thus, pins (23B, 23C) define the pivoting axis for articulation joint (23), enabling cartridge receiving assembly (50) to articulate left and right relative the shaft (20), away from the longitudinal axis defined by shaft (20). Rods (27A, 27B) are operably connected to articulation joint (23). In this example, rods (27A, 27B) extend through shaft (20), through knuckle (23A), and connect to pins (29A, 29B) on bearing support (24C). Rods (27A, 27B) are operatively connected to second input (14) to opposingly push and pull rods (27A, 27B). In other words, second input (14) is operable to drive rods (27A, 27B) at the same time in opposite longitudinal directions, such that rod (27A) will translate distally while rod (27B) translates proximally; and such that rod (27B) will translate distally while rod (27A) translates proximally. Because pins (29A, B) are laterally spaced from the pivoting axis, the simultaneous push and pull action will in turn articulate cartridge receiving assembly (50) about joint (23) relative to shaft (20).

[0030] Rotational bearing (24) is positioned distal to articulation joint (23). Bearing (24) includes a circumferential flange (24A) that is captured between the bearing supports

(24B, 24C) such that the flange (24A) can rotate relative the bearing supports (24B, 24C) and enabling unbounded rotation of cartridge receiving assembly (50) relative shaft (20) about the longitudinal axis defined by shaft (20). A drive rod (28) extends through shaft (20). In this example, drive rod (28) comprises a proximal rigid portion (28A) and a distal bendable portion (28B) that are fixedly connected to one another. Bendable portion (28B) extends through articulation joint (23) and through bearing (24); distal end (28C) is fixedly connected to a mount (49) on a rack (45).

[0031] Rack (45) reciprocates longitudinally in lower jaw (51) with followers (45A, 45B, 45C, 45D) constrained in tracks (55A, 55B, 55C, 55D), respectively. Tracks (55A, 55B, 55C, 55D) open through lower jaw (51), providing fluid passages to the internal components within the lower jaw (51), thus facilitating easier cleaning. A pinion (47) is mounted to lower jaw (51) by the pin (46) in the rack (45) such that longitudinal reciprocation of the rack (45) is converted into rotational reciprocation of pinion (47). A key (48) communicates the reciprocating rotation to a rotary input (94) in cartridge body (90), which in turn actuates needle applier cartridge (30).

[0032] Drive rod (28) is operatively connected to first input (12) and to third input (16). Actuation of first input (12) will impart axial push and pull loads on drive rod (28) to longitudinally reciprocate rack (45) and thereby actuate needle applier cartridge (30). Actuation of third input (16) will impart a rotational load on drive rod (28) thus rotating cartridge receiving assembly (50) about bearing (24) relative to shaft (20). Accordingly, a single drive rod (28) operates to both actuate needle applier cartridge (30) as well as control distal rotation of needle applier cartridge (30) about the longitudinal axis of shaft (20). By consolidating dual functions with a single drive rod (28), the number of components is reduced, and more space is provided in the shaft (20), which may make the device less expensive to manufacture and easier to clean.

[0033] Cartridge receiving assembly (50) is dimensioned and adapted to receive and hold cartridge body (90). As shown in FIGS. 2A-2B, cartridge receiving assembly (50) of this example has upper and lower jaws (56, 51) that are operable to transition between an open configuration and a closed configuration. In the closed configuration, jaws (56, 51)

are operable to receive and retain cartridge body (90). In the open configuration, jaws (56, 51) are operable to release cartridge body (90). In the present example, lower jaw (51) is stationary and upper jaw (56) pivots. Alternatively, the arrangement could be reversed, or in some versions both jaws (56, 51) could pivot. Lower jaw (51) has two laterally offset longitudinal rails (52) that are dimensioned and adapted to receive cartridge body (90). Rails (52) help longitudinally align cartridge body (90) in cartridge receiving assembly (50) and laterally retain cartridge body (90) in jaws (51, 56). Upper jaw (56) pivots relative lower jaw (51) about a pin (53) that is received in holes (57). A tooth (59) is resiliently oriented downwardly from upper jaw (56) toward lower jaw (51) with a ramped distal face and a stepped proximal face. Tooth (59) is dimensioned and adapted to latch with cartridge body (90) and longitudinally retain cartridge body (90) in jaws (51, 56). Tooth (59) deflects by virtue of a resilient cantilevered arm extending proximally from the distal end of upper jaw (56). In this example, tooth (59) and the cantilevered arm are monolithic with upper jaw (56), thus reducing the number of components and moving pieces, which may make the device less expensive to manufacture and easier to clean.

[0034] A button (60) is operable to open and close jaws (51, 56). While button (60) could be placed on or near the handle assembly (10) in some versions, in this example button (60) is positioned adjacent cartridge receiving assembly (50), which eliminates a linkage in shaft (20) thus creating space in shaft (20) and making the device less expensive and easier to clean. The action of button (60) may vary, but in this example button (60) pivots relative to lower jaw (51) about a pin (63) that is received hole (61). A follower (62) is received by cam slots (54, 58). Pivoting button (60) proximally will open jaws (51, 56), while pivoting button (60) distally will close jaws (51, 56). A spring (64) engages and biases button (60) distally. By pulling button (60) proximally, follower (62) will drive cam slot (58) to open upper jaw (56). When button (60) is released, spring (64) will resiliently drive button (60) distally to close upper jaw (56).

[0035] FIGS. 3A-3B illustrate cartridge body (90) of the present example in greater detail. A lower face (91) of cartridge body (90) is adapted to engage lower jaw (51); and an upper face (96) to engage upper jaw (56). Poke-yoke features on cartridge body (90)

prevent improper insertion of cartridge body (90) into cartridge receiving assembly (50), but also contribute to the aesthetic appearance of cartridge body (90). For instance, lower face (91) has a pair of longitudinal notched shoulders (92) that are dimensioned to interface and mate with rails (52). In this example, notched shoulders (92) are shaped as a stepped rabbet, but a variety of other aesthetic shapes could also be employed such as chamfers and radii. In contrast, upper face (96) is asymmetrical relative lower face (91) and lacks shoulder notches, so upper face (96) would interfere with rails (52) if cartridge body (90) were inserted upside-down in cartridge receiving assembly (50). In another instance, the geometry of a proximal face (98) of cartridge body (90) is vertically asymmetrical and thus prevents cartridge body (90) from being inserted upside-down between jaws (51, 56). In this example, proximal face (98) comprises a curved surface that gently transitions to upper face (96), which matches similar geometry in cartridge receiving assembly (50); while the transition to lower face (91) has a tighter radius. Of course, a variety of other asymmetrical aesthetic geometries could also be employed that could contribute to the visual appearance and/or poke-yoke aspects of cartridge body (90).

[0036] Arms (93A, 93B) define a generally U-shaped distal end on cartridge body (90). A slot (95) and rotary input (94) are aligned and dimensioned to receive the key (48) while cartridge body (90) is being slid into cartridge receiving assembly (50). When cartridge body (90) is fully seated into cartridge receiving assembly (50), a step (99) aligns with and receives tooth (59) to latch cartridge body (90) in cartridge receiving assembly (50). Key (48) also aligns with rotary input (94), thereby providing a torsional interface that rotationally couples pinion (47) and rotary input (94). In use, the needle (70) exits arm (93A) and enters arm (93B).

[0037] As shown in FIGS. 3A-4, cartridge body (90) further comprises a lower body (81), an upper body (82), a needle (70), and a needle cover (83). Needle driver (86), rotary input (94), and a link (85) are captured between lower body (81) and upper body (82). Bodies (81, 82) may be attached to one another using a variety of known techniques, including welds, pins, adhesives, and the like to form cartridge body (90). Needle (70) has a leading end (71) and a length of suture (73) extending from the trailing

end (72). Needle (70) orbits in a circular path defined by a needle track (84) and between arms (93A, 93B). Needle (70) includes notches (74) that are configured to facilitate engagement between needle driver (86) and needle (70). Needle (70) is captured in needle track (84) by needle cover (83). A cage (87) slides over bodies (81, 82) and needle cover (83) to attach needle cover (83) against lower body (81).

[0038] FIGS. 5A-5C illustrate an example of a drive stroke of the transmission in cartridge body (90) for driving needle (70) in a circular, orbital path. However, it should be understood that needle (70) and suture (73) omitted from FIGS. 5B-5C. Needle driver (86) rides in a carrier track (88) and extends into needle track (84) to engage and drive needle (70). A link (85) connects rotary input (94) to needle driver (86). FIG. 5A shows needle driver (86) positioned at one end of its stroke in carrier track (88). As shown in FIG. 5B, counterclockwise rotation of rotary input (94) will translate needle driver (86) clockwise along carrier track (88), thereby driving needle (70) clockwise. As shown in FIG. 5C, continued counterclockwise rotation of the rotary input (94) will continue to translate needle driver (86) and thereby drive needle (70) clockwise until it reaches the other end of its stroke in carrier track (88). In this example, the drive stroke rotates the needle (70) in its circular path along an angular range of about 180 degrees. For the return stroke, the sequence can be reversed by rotating the rotary input (94) clockwise, which will translate needle driver (86) counterclockwise in carrier track (88). Needle driver (86) is disengaged from needle (70) during the return stroke until needle driver (86) reaches the end of the return stroke. Needle driver (86) will re-engage needle (70) upon completing the return stroke. Thus, a sequence of drive and return strokes will rotate the needle (70) in a circular path.

[0039] FIG. 6 illustrates a detailed view of needle driver (86) engaging needle (70). Needle driver (86) comprises a carrier (86A) and a driver (86B). Carrier (86A) is dimensioned to slideably fit in carrier track (88). Driver (86B) is attached to carrier (86A) and is operative to engage needle (70) at an oblique angle. Leftward movement of needle driver (86) will cause driver (86B) to engage proximal notch (74) of needle (70) during the drive stroke. When so engaged, needle (70) will slide in needle track (84) in unison with needle driver (86). Due to the oblique angle, rightward movement of needle driver

(86) will disengage driver (86B) from proximal notch (74) of needle (70) and slide over the stationary needle (70) during the return stroke.

[0040] Referring back to FIGS. 5A-5C, when first input (12) is depressed, closing the trigger, needle driver (86) will be actuated through its drive stroke where it orbits along an angular range of motion at least about 180 degrees counterclockwise to a driven position as shown in FIG. 5C. During the drive stroke, driver (86B) engages proximal notch (74) and will in unison rotate needle (70) about 180 degrees along an orbital path to its extended position. Needle (70) will span across arms (93A, 93B) between exit port (95) and entrance port (97). Tissue interposed between arms (93A, 93B) will be pierced by leading end (71) of needle (70).

[0041] When first input (12) is released and the spring return opens the trigger, needle driver (86) reciprocates through its return stroke where it orbits along an angular range of motion about 180 degrees clockwise back to the return position shown in FIG. 5A. During the return stroke, driver (86B) slides over the needle (70). Driver (86B) is then adjacent the distal notch (74). When first input (12) is depressed again closing the trigger, needle driver (86) will again be actuated through its drive stroke where it orbits along an angular range of motion about 180 degrees counterclockwise to the driven position as shown in FIG. 5C. During the drive stroke, driver (86B) engages distal notch (74) and will in unison drive needle (70) orbitally along an angular range of motion about 180 degrees back to its retracted position. Suture (73) will follow needle (70) and be threaded through the pierced tissue.

[0042] When first input (12) is again released and the spring return opens the trigger, needle driver (86) again reciprocates through its return stroke where it orbits along an angular range of motion about 180 degrees clockwise back to its returned position as shown in FIG. 5A. During the return stroke, driver (86B) slides over needle (70). Thus, needle (70) is driven in a complete circular path spanning an angular range of 360° in response to first input (12) being actuated twice. The sequence may be repeated as needed by the surgeon to achieve the desired suturing task.

[0043] Further details, explanations, examples, and alternative embodiments of surgical

suturing devices and subcomponents of the foregoing are disclosed in U.S. Pub. No. 2014/0171970, entitled "Circular Needle Applier with Articulating and Rotating Shaft," published June 19, 2014, the disclosure of which is incorporated by reference herein; U.S. Pat. App. No. 14/297,993, entitled "Jawed Cartridge Receiving Assembly for Needle Cartridge," filed June 6, 2014, the disclosure of which is incorporated by reference herein; and U.S. Pat. App. No. 14/298,038, entitled "Circular Needle Applier with Cleats," filed January 30, 2015, the disclosure of which is incorporated by reference herein. It should be understood that such details, explanations, examples, and alternative embodiments may be readily applied to the above-described instrument (10) and subcomponents thereof.

[0044] FIG. 7 illustrates an embodiment of packaging (100) for a cartridge (30). The cartridge (30) may be similar to any of the prior described cartridges, and contains a surgical needle, a length of suture (73) connected to the surgical needle, a needle driver (e.g., needle driver (86) (FIGS. 5A-C)) operative to engage and move the needle relative the cartridge, and a transmission operatively connected to the needle driver. Packaging (100) has an outer shell comprising a housing (102) and a top sheet (101). The needle in cartridge (30) is in its retracted position such as in the position shown in FIG. 5A. Cartridge (30) is releasably held by arms (105). Block (106) is positioned in the U-shaped distal end on cartridge (30) and prevents the needle from exiting cartridge (30). Cartridge (30) extends into gap (104). Suture (73) extends from cartridge (30) and is coiled around bobbin (108), shown here as a dynamic spool that can rotate about the axle (107). Bobbin (108) can alternatively take the form of a static bobbin, such as pegs or a track, around which suture (73) can be coiled.

[0045] As shown in FIG. 8, packaging (100) facilitates assembly of the cartridge (30) onto a suturing device (50). Packaging (100) provides an ergonomically friendly format to handle, align, and assembly cartridge (100) onto shaft (20) of suturing device (50), while keeping the needle safely isolated from the user. Once assembled and attached, withdrawing shaft (20) will pull cartridge (30) from packaging (100) and suture (73) will reel out from bobbin (108) and be ready for use.

[0046] II. Exemplary Suture Dispenser

[0047] In some situations, an operator may wish to use a barbed suture, such as the STRATAFIX™ suture by Ethicon, Inc. (Somerville, New Jersey), when operating instrument (2) during a suturing procedure. Due to the nature of the barbs of the barbed suture, an operator must be careful to prevent the barbs of the barbed suture from overlapping one another before or during use, to prevent, for example, tangling of and snagging of the suture on itself. Even when exercising the utmost care, tangling and snagging may occur, since some existing packaging such as packaging (100) may not properly accommodate barbed sutures. Therefore, the storage of barbed sutures in packaging (100) may lead to the above mentioned issues and may prevent an operator from effectively using the barbed sutures.

[0048] A. Exemplary Suture Dispenser with End Cartridge Loading

[0049] FIGS. 9-11 illustrate an example of suture dispenser packaging (200) for a cartridge (230). Cartridge (230) is configured and operable substantially similar to cartridge (30), and contains a surgical needle (e.g., needle (70)) a length of suture (273) connected to the surgical needle, a needle driver (e.g., needle driver (86) (FIGS. 5A-5C)) that is operative to engage and move the needle relative the cartridge (230), and a drive assembly that is operatively connected to the needle driver. Cartridge (230) may thus be readily received in cartridge receiving assembly (50) and may thereby be actuated by instrument (2). The needle is initially provided in cartridge (230) in a retracted position (e.g., the position shown in FIG. 5A). In the example shown, the length of suture (273) comprises barbed suture, with a plurality of barbs (275). Suture (273) is contained on a spool (208), as discussed in further detail below. However, it will be understood that packaging (200) is configured for use with all types of sutures, including barbed and non-barbed sutures.

[0050] Packaging (200) includes a housing (203) comprising a top sheet or lid (201) and a shell (202). Housing (203) has a proximal end (204) and a distal end (206). In the present example, shell (203) includes a greater depth at distal end (206) to accommodate spool (208). Housing (203) further includes a first side (210) and a second side (212).

Proximal end (204) includes a pair of opposing arms (214) defining a gap or recess (216) therebetween. As shown in the present example, cartridge (230) is received in gap (216) such that cartridge (230) is frictionally held by arms (214). In addition or in the alternative, packaging (200) may include one or more latches, clips, clamping features, and/or any other suitable kinds of features that may releasably retain cartridge (230) relative to housing (203). Packaging (200) further includes a flange (218) extending at an oblique angle relative to a central longitudinal axis of shell (202). Flange includes a hook-shaped portion (220) positioned in shell (202). Hook-shaped portion (220) is sized and configured to be at least partially received between arms (93A, 93B) of cartridge (230) such that the frictional engagement between arms (93A, 93B) and hook-shaped portion (220) also maintains cartridge (230) relative to packaging (200).

[0051] Referring to FIGS. 10-11, spool (208) includes a first flange (222), a second flange (224), and a generally cylindraceous body (226) therebetween. As shown in the present example, spool (208) includes a helical channel (228) which receives suture (273). Therefore, barbs (290) of suture (273) will be less likely to interfere with one another while suture (273) is stored in packaging (200) and while suture (273) is withdrawn from packaging (200). This is because in the present example, no portions of suture (273) overlap one another during storage, thus preventing barbs (276) of barbed suture (273) from catching on one another. As shown spool (208) includes a central channel (230) that receives a rod (not shown) extending from shell (202) that is fixed to shell (202). Spool (208) extends along an axis (213). In the example shown, spool (208) is configured to rotate about the rod and axis (213). However, in some examples, spool (208) may be fixedly connected to a rod or other structure that is configured to rotate relative to housing (203). In the present example, a leading end of suture (273) is connected to needle and trailing end of suture (273) is disposed on spool (289).

[0052] Once cartridge (230) is secured in cartridge receiving assembly (50) of instrument (2) in the manner described above, withdrawing shaft (20) will pull cartridge (230) from packaging (200), and suture (273) will reel out from spool (208). Particularly, the frictional engagement between suture (273) and helical channel (228) will cause a rotation of spool (208) upon the sufficient pulling force of suture (273). Helical channel

(228) includes a pitch angle (θ) (FIG. 11) that will not hamper the rotation of spool (208) in response to spool (208) being subjected to the tangential rotational force from the frictional engagement between spool (208) (i.e., helical channel (228)) and suture (273). In the present example, trailing end of suture (273) is removably coupled to spool (208) in a manner that allows the suture (273) to remain coupled to spool (208) absent a sufficient pulling force from an operator. However, upon the application of a sufficient force, trailing end of suture (273) may be removed from spool (208) after the remainder of suture (273) has reeled off of spool (208), and thus suture (273) will be ready for use in a suturing operation. Suturing instrument (2) with cartridge (230) loaded in cartridge receiving assembly (50) will operate in the same manner as suturing instrument (2) with cartridge (30) loaded in cartridge receiving assembly (50) as described above.

[0053] B. Exemplary Suture Dispenser with Central Cartridge Loading

[0054] FIGS. 12-13B illustrate another example of suture dispenser packaging (300) for another cartridge (330). Cartridge (330) is configured and operable substantially similar to cartridges (30, 230), and contains a surgical needle (e.g., needle (70)), a length of suture (373) connected to the surgical needle, a needle driver (e.g., needle driver (86) (FIGS. 5A-5C)) that is operative to engage and move the needle relative the cartridge (330), and a drive assembly that is operatively connected to the needle driver. Cartridge (330) may thus be readily received in cartridge receiving assembly (50) and may thereby be actuated by instrument (2). The needle initially provided in cartridge (330) in a retracted position, such as in the position shown in FIG. 5A. In the example shown, the length of suture (373) comprises a barbed suture, with a plurality of barbs (375). Suture (373) is contained on a spool (308), as discussed in further detail below. However, it will be understood that packaging (300) is configured for use with all types of sutures, including barbed and non-barbed sutures.

[0055] Packaging (300) includes a housing (302) having a first side (304) and a second side (306). Housing (302) generally defines a disk shape with the first side (304) defining a top portion, the second side (306) defining a bottom portion, and a sidewall (309) extending between the top and bottom portions, and defining a curved surface.

First side (304) includes a recess (310) extending from the first side (304) toward the second side (306). Recess (310) has a shape that complements the shape of cartridge (330) which, as shown in FIG. 12, is partially received within recess (310). Recess (312) includes a ramp that is oriented at an oblique angle (α) (FIG. 12) relative to first side (304), and at an angle ($90^\circ - \alpha$) relative to axis (313) (FIG. 13A). In the example shown, α is an acute angle. Housing (302) includes fingers (312) in recess (310) that are configured to frictionally engage one or both of arms (93A, 93B) of cartridge (330). In addition or in the alternative, packaging (300) may include one or more latches, clips, clamping features, and/or any other suitable kinds of features that may releasably retain cartridge (330) relative to housing (302).

[0056] In the present example, packaging (300) further includes a spool (308) that is enveloped by sidewall (309) and second side (306). Spool (308) of the present example is fixed relative to housing (302), such that spool (308) does not rotate relative to housing (302). In some other versions, however, spool (308) is rotatable within housing (302). As shown, an outer portion (314) of spool (308) is positioned radially inwardly of inner portion (316) of flange. Similarly, a lower portion (318) of spool (308) is positioned axially above inner portion (320) of second side (306). Therefore, in the present example, there is a space (322) defined between spool (308) and housing (302). Spool (308) includes a helical channel (323) which, as shown in the present example, receives and stores a portion of length of suture (373). Recess (310) includes an aperture (324) that provides a pathway for communication of suture (373) from space (322) to recess (310). Thus, as best seen in FIGS. 12 and 13B, the length of suture (373) extending from cartridge (330) extends through aperture (324), into space (322) along lower portion (320) of spool (308), and is wrapped around spool (308) within helical channel (323). As shown, due to the configuration of helical channel (323), no portions of suture (373) overlap one another during storage, thus preventing barbs (375) of barbed suture from catching on one another.

[0057] Referring to FIGS. 13A-13B, once cartridge (330) is secured in cartridge receiving assembly (50) of instrument (2) in the manner described above, withdrawing shaft (20) will pull cartridge (330) from packaging (300) and suture (373) will unravel

under and around spool (308). In some examples, an operator may also hold packaging (300) in a stationary position (e.g., with a hand, instrument, etc.) so that packaging (300) does not move relative to instrument (10). In some examples, a trailing end of suture (373) may be removably coupled to housing (302) or spool (308) such that absent a sufficient force, trailing end of suture (373) remains coupled to housing or spool (308). However, in response to a sufficient force, such as after most of suture (373) has unraveled from spool (308) in response to pulling on cartridge (330) with suturing device (50), the trailing end of suture (373) is configured to decouple from housing (302) or spool (308). Moreover, in some examples, at least a portion of helical channel (323) may be configured to frictionally hold at least some portions of suture (373) relative to spool (308). As another merely illustrative alternative, suture (373) may be loosely received in helical channel (323). Once suture (373) is unraveled from spool (308) and removed from packaging (300), suture (273) will be ready for use in a suturing operation. Suturing instrument (2) with cartridge (330) loaded in cartridge receiving assembly (50) will operate in the same manner as suturing instrument (2) with cartridge (30) loaded in cartridge receiving assembly (50) as described above.

[0058] III. Exemplary Combinations

[0059] The following examples relate to various non-exhaustive ways in which the teachings herein may be combined or applied. It should be understood that the following examples are not intended to restrict the coverage of any claims that may be presented at any time in this application or in subsequent filings of this application. No disclaimer is intended. The following examples are being provided for nothing more than merely illustrative purposes. It is contemplated that the various teachings herein may be arranged and applied in numerous other ways. It is also contemplated that some variations may omit certain features referred to in the below examples. Therefore, none of the aspects or features referred to below should be deemed critical unless otherwise explicitly indicated as such at a later date by the inventors or by a successor in interest to the inventors. If any claims are presented in this application or in subsequent filings related to this application that include additional features beyond those referred to below, those additional features shall not be presumed to have been added for any reason relating

to patentability.

[0060] Example 1

[0061] A packaging for a surgical needle, comprising: (a) a cartridge comprising: (i) a surgical needle, and (ii) a needle driver configured to engage and move the needle relative to the cartridge; (b) a spool comprising a helical channel; and (c) a length of suture connected to the needle, wherein at least a portion of the length of suture is wound around the spool, wherein at least a portion of the length of suture is positioned within the helical channel.

[0062] Example 2

[0063] The packaging of Example 1, wherein the suture comprises a plurality of barbs.

[0064] Example 3

[0065] The packaging of any one or more of Examples 1 through 2, further comprising a housing surrounding at least a portion of the spool.

[0066] Example 4

[0067] The packaging of Example 3, wherein the spool is fixed relative to the housing.

[0068] Example 5

[0069] The packaging of any one or more of Examples 3 through 4, wherein the spool is configured to rotate relative to the housing.

[0070] Example 6

[0071] The packaging of any one or more of Examples 1 through 5, wherein the spool extends along an axis, wherein the cartridge is coupled to the body such that the cartridge extends perpendicularly relative to the axis.

[0072] Example 7

- [0073] The packaging of any one or more of Examples 1 through 5, wherein the spool extends along an axis, wherein the cartridge is coupled to the body such that the cartridge extends at an oblique angle relative to the axis.
- [0074] Example 8
- [0075] The packaging of any one or more of Examples 1 through 7, further comprising a housing, wherein the housing comprises: (i) a top portion, (ii) a bottom portion, and (ii) a sidewall extending between the top and bottom portions.
- [0076] Example 9
- [0077] The packaging of Example 8, wherein the housing is generally disk shaped.
- [0078] Example 10
- [0079] The packaging of any one or more of Examples 8 through 9, wherein the housing surrounds the spool, wherein the packaging further comprising a space between the spool and an inner portion of the sidewall and between an inner portion of the bottom portion.
- [0080] Example 11
- [0081] The packaging of Example 10, wherein the housing comprises an aperture in communication with the space, wherein a portion of the length of suture extends through the aperture and into the space.
- [0082] Example 12
- [0083] The packaging of Example 11, wherein at least a portion of the length of suture extends along a lower portion of the spool.
- [0084] Example 13,
- [0085] The packaging of any one or more of Examples 8 through 12, wherein the top and bottom portions are parallel to one another.

[0086] Example 14

[0087] The packaging of any one or more of Examples 8 through 13, wherein the top portion includes a recess, wherein at least a portion of the cartridge is received within the recess.

[0088] Example 15

[0089] The packaging of Example 13, wherein the housing comprises engagement features in the recess, wherein the engagement features are configured to engage a portion of the cartridge to removably couple the cartridge to the housing.

[0090] Example 16

[0091] A packaging for a surgical needle, comprising: (a) a housing, wherein the housing comprises an upper portion and a lower portion; (b) a cartridge comprising: (i) a surgical needle, and (ii) a needle driver operative to engage and move the needle relative to the cartridge, wherein the cartridge is coupled to the housing, wherein the cartridge is disposed at an oblique angle relative to at least one of the upper portion or lower portion; (c) a spool, wherein at least a portion of the spool is disposed in the housing; and (d) a length of suture connected to the needle, wherein at least a portion of the length of suture is wound around the spool.

[0092] Example 17

[0093] The packaging of Example 17, wherein the housing comprises a proximal end and a distal end, wherein the housing includes a greater depth at the distal end, wherein the spool is disposed at the distal end.

[0094] Example 18

[0095] The packaging of any one or more of Examples 16 through 17, wherein the length of suture is wound helically around the spool.

[0096] Example 19

[0097] The packaging of any one or more of Examples 16 through 18, wherein a trailing end of the suture is removably coupled to the spool.

[0098] Example 20

[0099] A method for preparing an instrument for use, comprising: (a) providing an instrument, the instrument comprising an elongate shaft wherein the elongate shaft comprises a distal end; (b) providing a packaging, the packaging comprising: (i) a cartridge, comprising: (A) a surgical needle, and (B) a needle driver operative to engage and move the needle relative the cartridge, (ii) a spool comprising a helical channel, and (iii) a length of suture connected to the needle, wherein at least a portion of the length of suture is wound around the spool, wherein at least a portion of the length of suture is positioned within the helical channel; and (c) coupling the distal end of the shaft to the cartridge; and (d) directing the cartridge and the shaft away from the packaging, thereby unwinding the suture from the spool.

[00100] IV. Miscellaneous

[00101] It should also be understood that any one or more of the teachings, expressions, embodiments, examples, etc. described herein may be combined with any one or more of the other teachings, expressions, embodiments, examples, etc. that are described herein. The above-described teachings, expressions, embodiments, examples, etc. should therefore not be viewed in isolation relative to each other. Various suitable ways in which the teachings herein may be combined will be readily apparent to those of ordinary skill in the art in view of the teachings herein. Such modifications and variations are intended to be included within the scope of the claims.

[00102] It should be appreciated that any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof,

that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

[00103] Versions of the devices described above may have application in conventional medical treatments and procedures conducted by a medical professional, as well as application in robotic-assisted medical treatments and procedures. By way of example only, various teachings herein may be readily incorporated into a robotic surgical system such as the DAVINCI™ system by Intuitive Surgical, Inc., of Sunnyvale, California.

[00104] Versions described above may be designed to be disposed of after a single use, or they can be designed to be used multiple times. Versions may, in either or both cases, be reconditioned for reuse after at least one use. Reconditioning may include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, some versions of the device may be disassembled, and any number of the particular pieces or parts of the device may be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, some versions of the device may be reassembled for subsequent use either at a reconditioning facility, or by a user immediately prior to a procedure. Those skilled in the art will appreciate that reconditioning of a device may utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[00105] By way of example only, versions described herein may be sterilized before and/or after a procedure. In one sterilization technique, the device is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and device may then be placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation may kill bacteria on the device and in the container. The sterilized device may then be stored in the sterile container for later use. A device may also be sterilized using any other technique known in the art,

including but not limited to beta or gamma radiation, ethylene oxide, or steam.

[00106] Having shown and described various embodiments of the present invention, further adaptations of the methods and systems described herein may be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the examples, embodiments, geometrics, materials, dimensions, ratios, steps, and the like discussed above are illustrative and are not required. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited to the details of structure and operation shown and described in the specification and drawings.

I/We Claim:

1. A packaging for a surgical needle, comprising:
 - (a) a cartridge comprising:
 - (i) a surgical needle, and
 - (ii) a needle driver configured to engage and move the needle relative to the cartridge;
 - (b) a spool comprising a helical channel; and
 - (c) a length of suture connected to the needle, wherein at least a portion of the length of suture is wound around the spool, wherein at least a portion of the length of suture is positioned within the helical channel.
2. The packaging according to claim 1, wherein the suture comprises a plurality of barbs.
3. The packaging according to claim 1, further comprising a housing surrounding at least a portion of the spool.
4. The packaging according to claim 3, wherein the spool is fixed relative to the housing.
5. The packaging according to claim 3, wherein the spool is configured to rotate relative to the housing.
6. The packaging according to claim 1, wherein the spool extends along an axis, wherein the cartridge is coupled to the body such that the cartridge extends perpendicularly relative to the axis.
7. The packaging according to claim 1, wherein the spool extends along an axis, wherein the cartridge is coupled to the body such that the cartridge extends at an oblique angle relative to the axis.

8. The packaging according to claim 1, further comprising a housing, wherein the housing comprises:

- (i) a top portion,
- (ii) a bottom portion, and
- (ii) a sidewall extending between the top and bottom portions.

9. The packaging according to claim 8, wherein the housing is generally disk shaped.

10. The packaging according to claim 8, wherein the housing surrounds the spool, wherein the packaging further comprising a space between the spool and an inner portion of the sidewall and between an inner portion of the bottom portion.

11. The packaging according to claim 10, wherein the housing comprises an aperture in communication with the space, wherein a portion of the length of suture extends through the aperture and into the space.

12. The packaging according to claim 11, wherein at least a portion of the length of suture extends along a lower portion of the spool.

13. The packaging according to claim 8, wherein the top and bottom portions are parallel to one another.

14. The packaging according to claim 8, wherein the top portion includes a recess, wherein at least a portion of the cartridge is received within the recess.

15. The packaging according to claim 14, wherein the housing comprises engagement features in the recess, wherein the engagement features are configured to engage a portion of the cartridge to removably couple the cartridge to the housing.

16. A packaging for a surgical needle, comprising:
 - (a) a housing, wherein the housing comprises an upper portion and a lower portion;
 - (b) a cartridge comprising:
 - (i) a surgical needle, and
 - (ii) a needle driver operative to engage and move the needle relative the cartridge, wherein the cartridge is coupled to the housing, wherein the cartridge is disposed at an oblique angle relative to at least one of the upper portion or lower portion;
 - (c) a spool, wherein at least a portion of the spool is disposed in the housing; and
 - (d) a length of suture connected to the needle, wherein at least a portion of the length of suture is wound around the spool.
17. The packaging according to claim 16, wherein the housing comprises a proximal end and a distal end, wherein the housing includes a greater depth at the distal end, wherein the spool is disposed at the distal end.
18. The packaging according to claim 16, wherein the length of suture is wound helically around the spool.
19. The packaging according to claim 16, wherein a trailing end of the suture is removably coupled to the spool.
20. A method for preparing an instrument for use, comprising:
 - (a) providing an instrument, the instrument comprising an elongate shaft wherein the elongate shaft comprises a distal end;
 - (b) providing a packaging, the packaging comprising:
 - (i) a cartridge, comprising:
 - (A) a surgical needle, and
 - (B) a needle driver operative to engage and move the needle

relative the cartridge,

- (ii) a spool comprising a helical channel, and
- (iii) a length of suture connected to the needle, wherein at least a portion of the length of suture is wound around the spool, wherein at least a portion of the length of suture is positioned within the helical channel; and
- (c) coupling the distal end of the shaft to the cartridge; and
- (d) directing the cartridge and the shaft away from the packaging, thereby unwinding the suture from the spool.

1/13

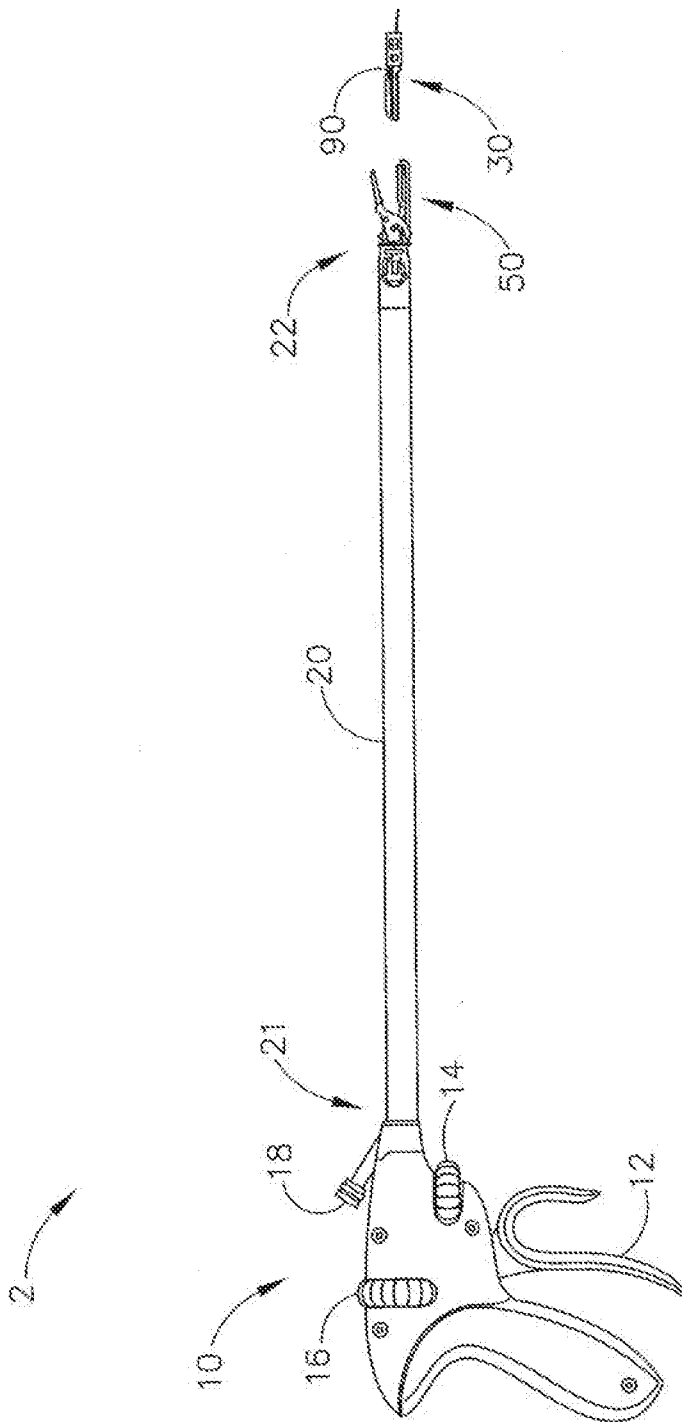


Fig. 1

2/13

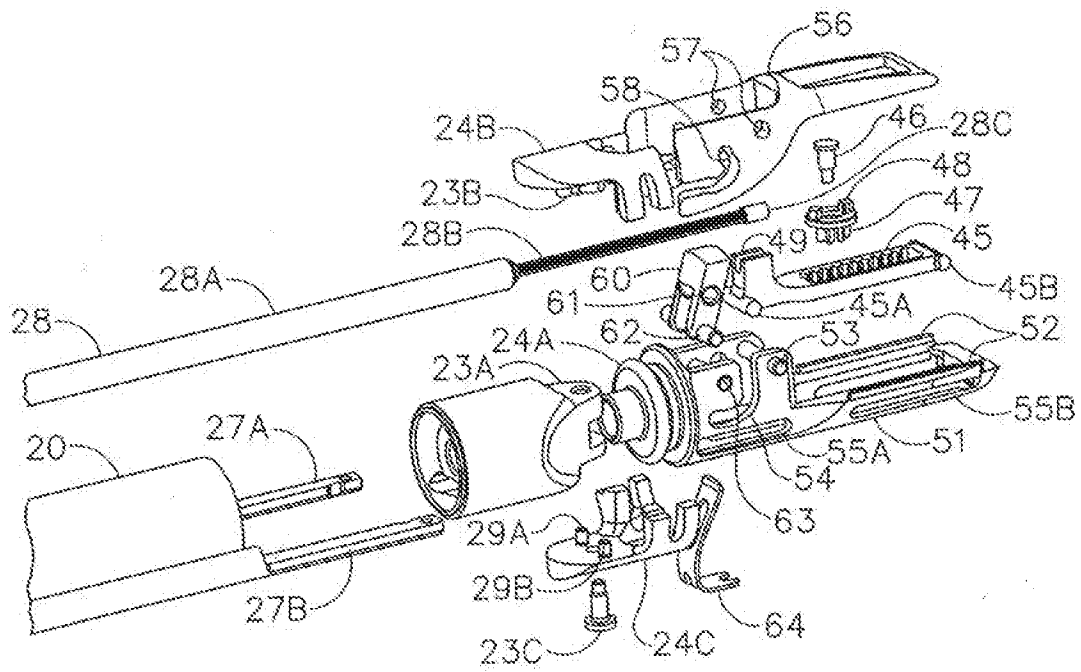


Fig.2A

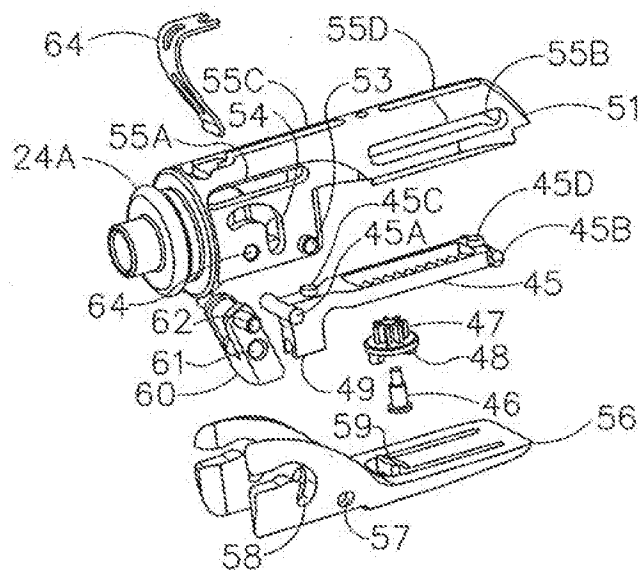


Fig.2B

3/13

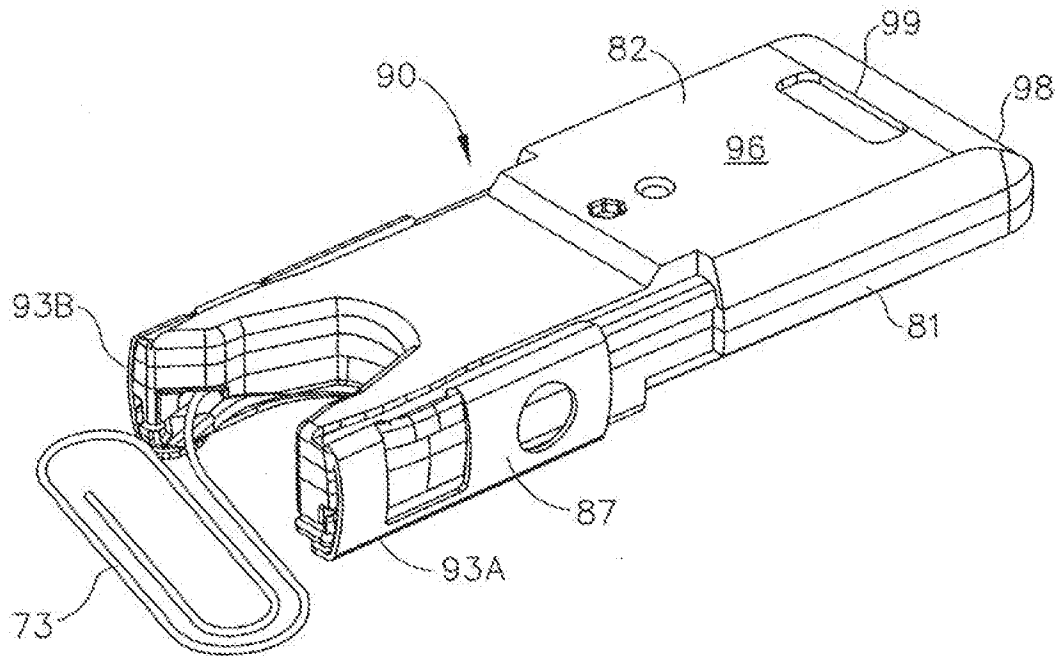


Fig.3A

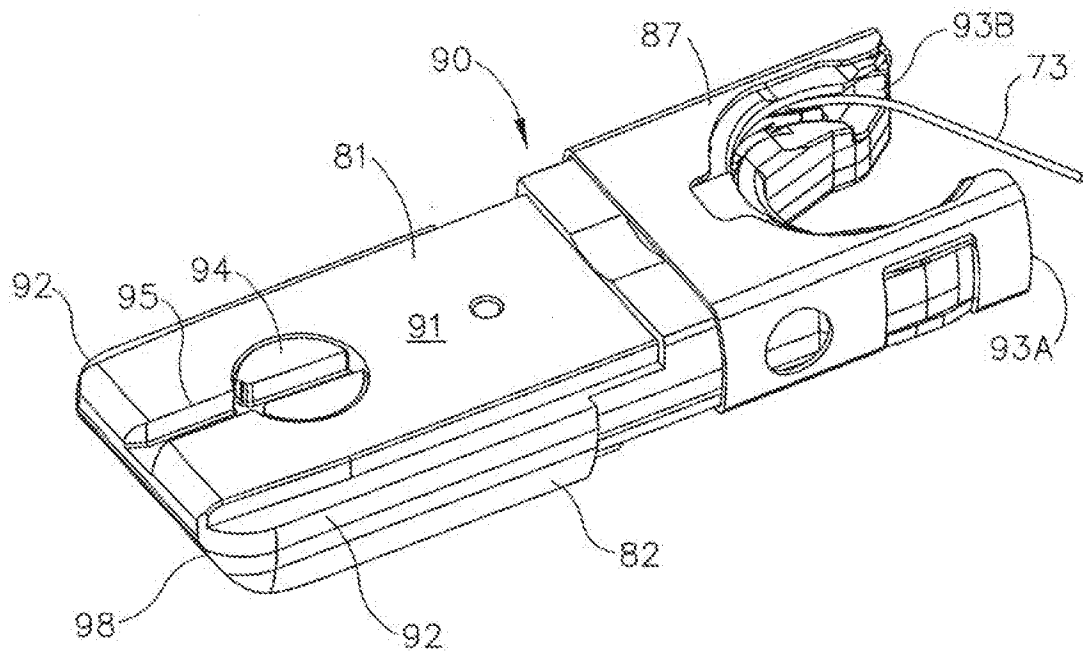


Fig.3B

4/13

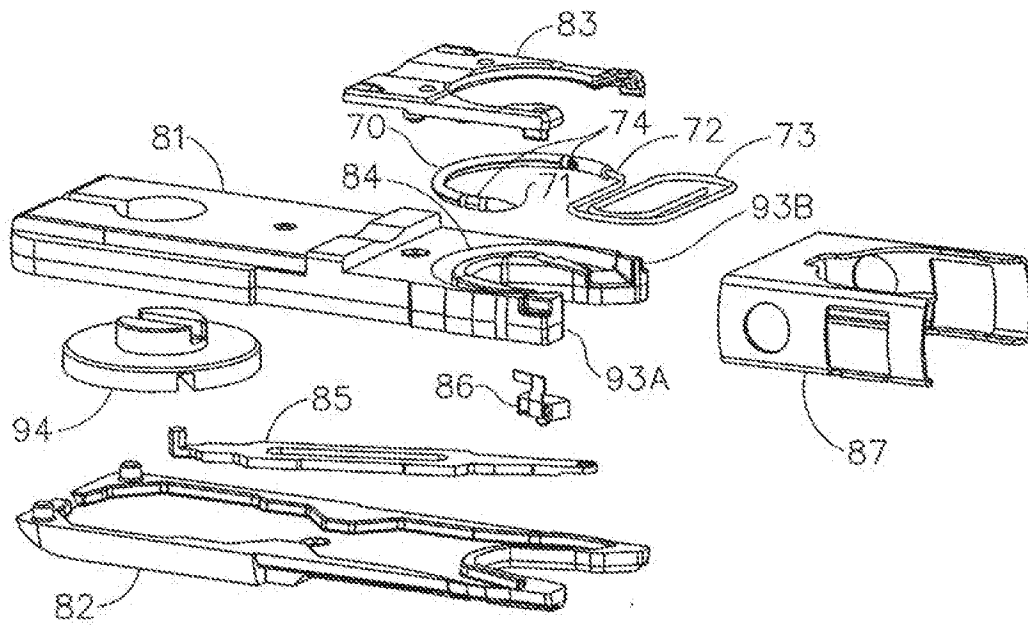


Fig.4

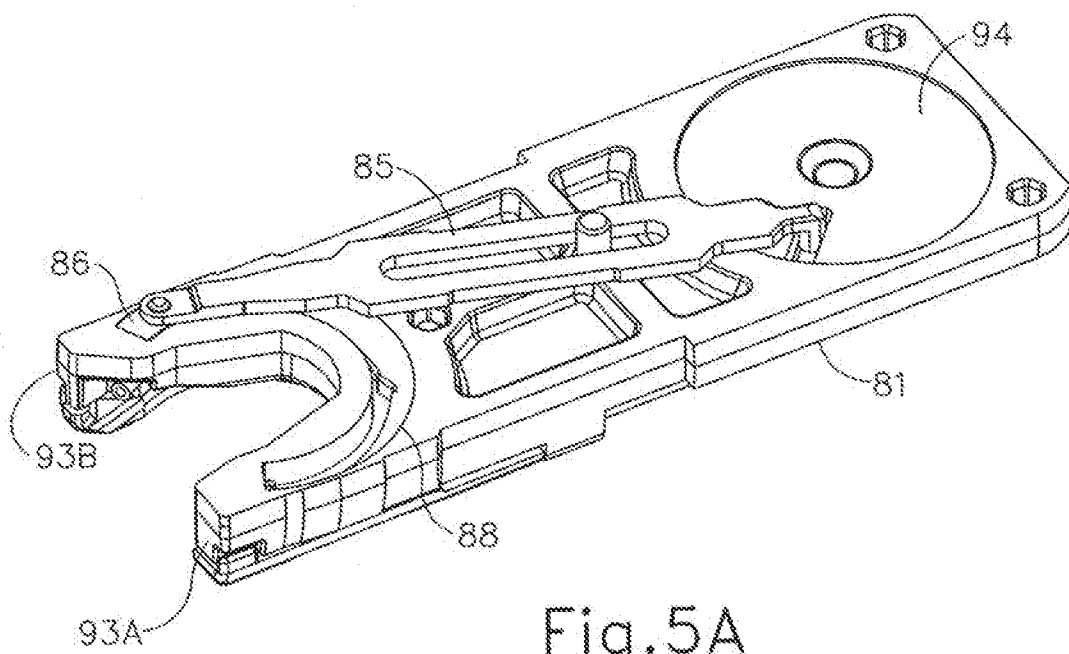


Fig.5A

5/13

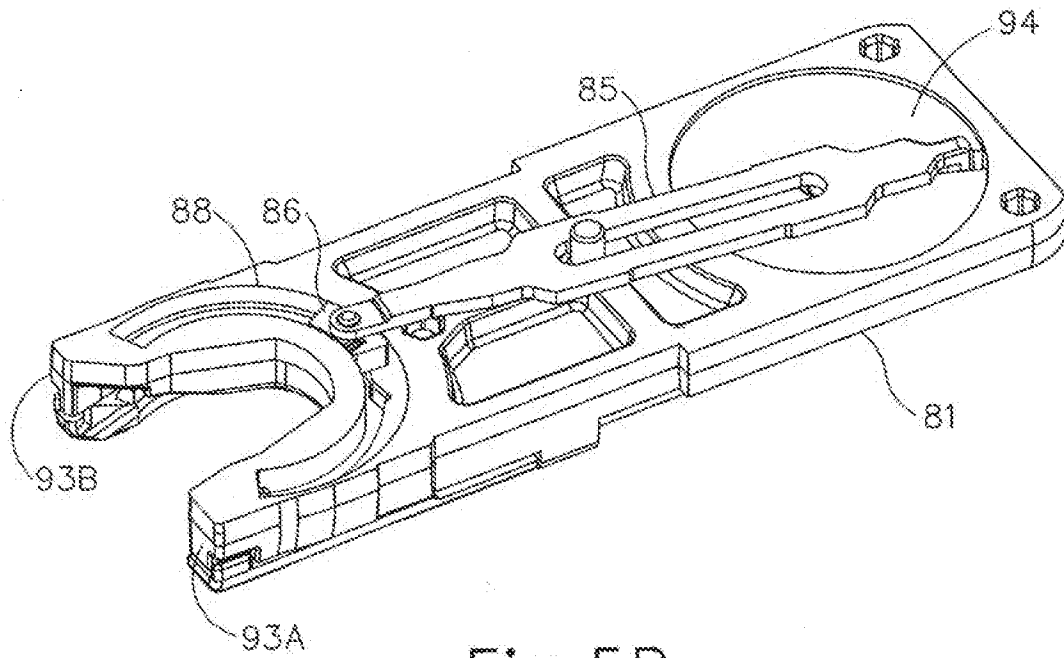


Fig.5B

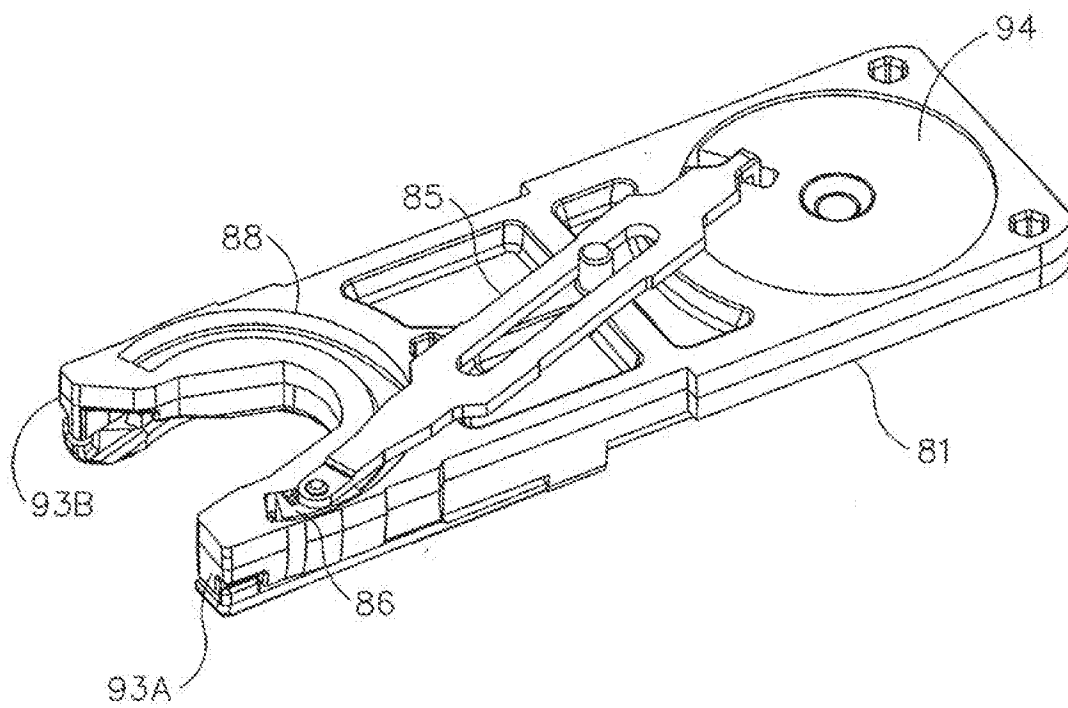


Fig.5C

6/13

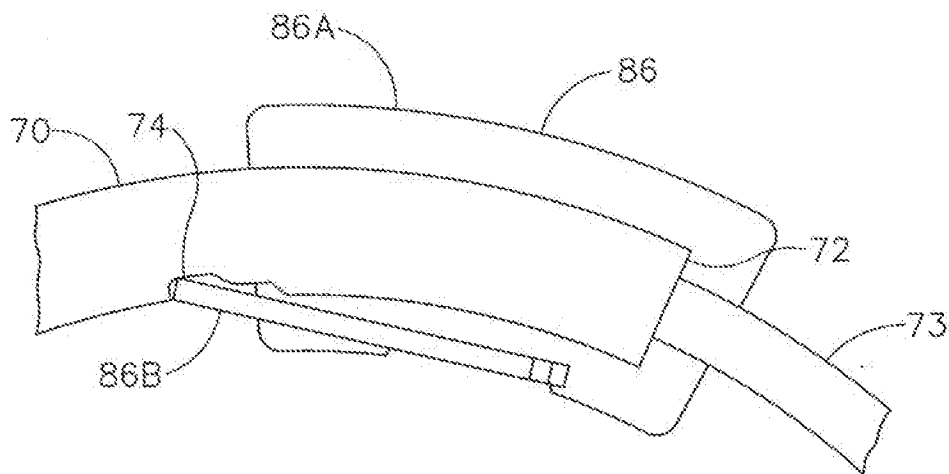


Fig.6

7/13

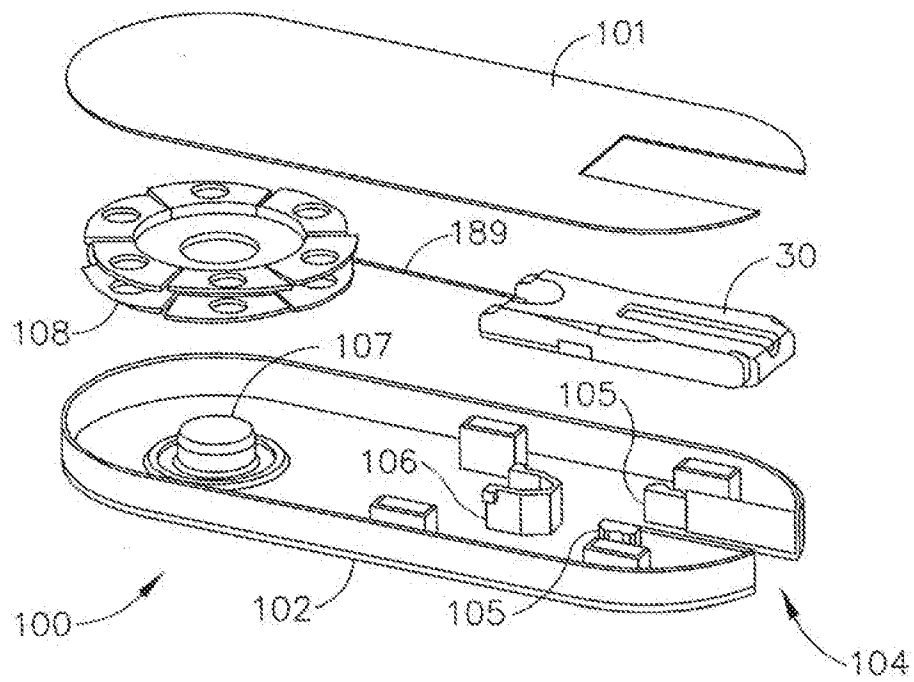


Fig.7

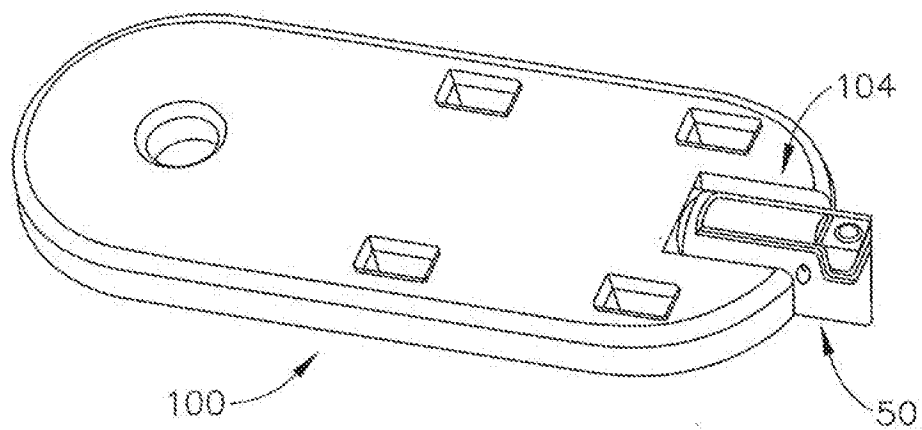


Fig.8

8/13

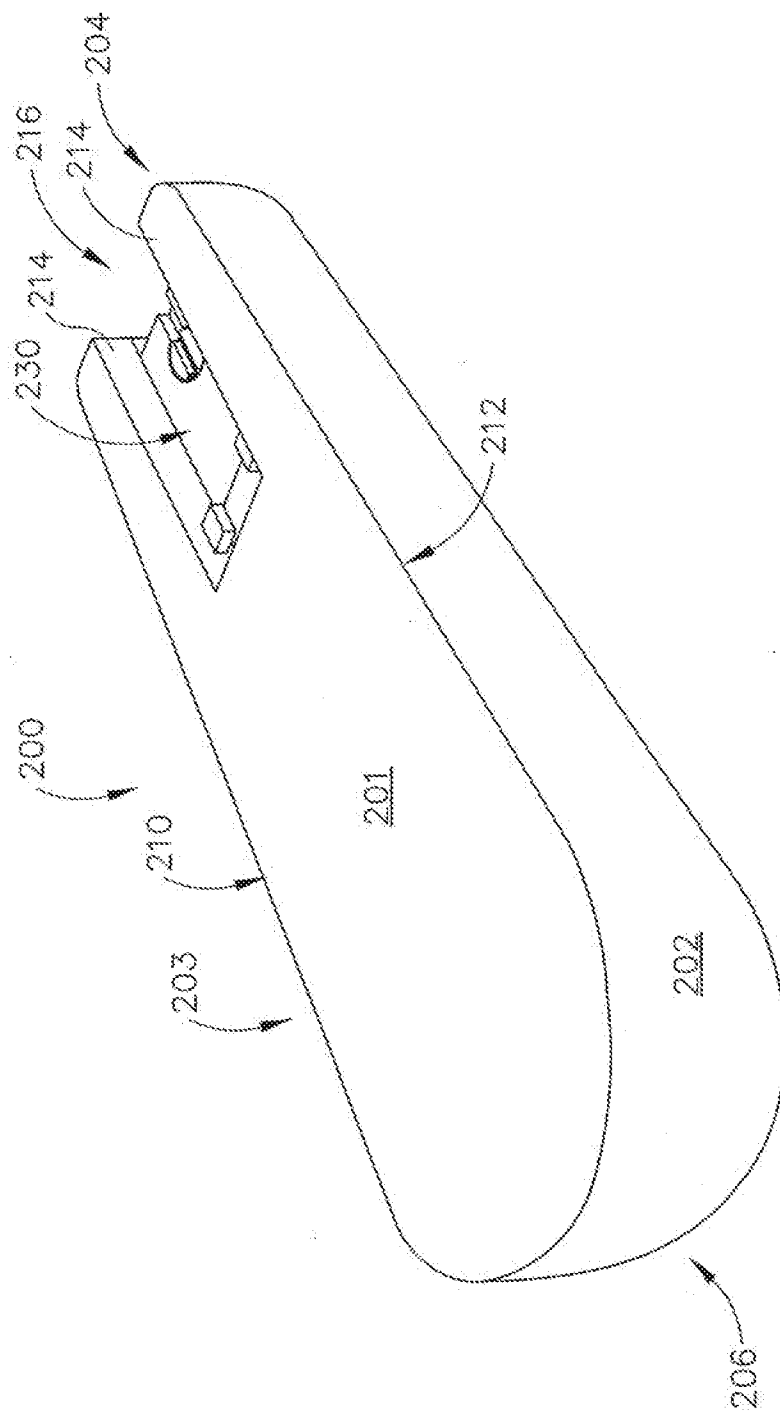
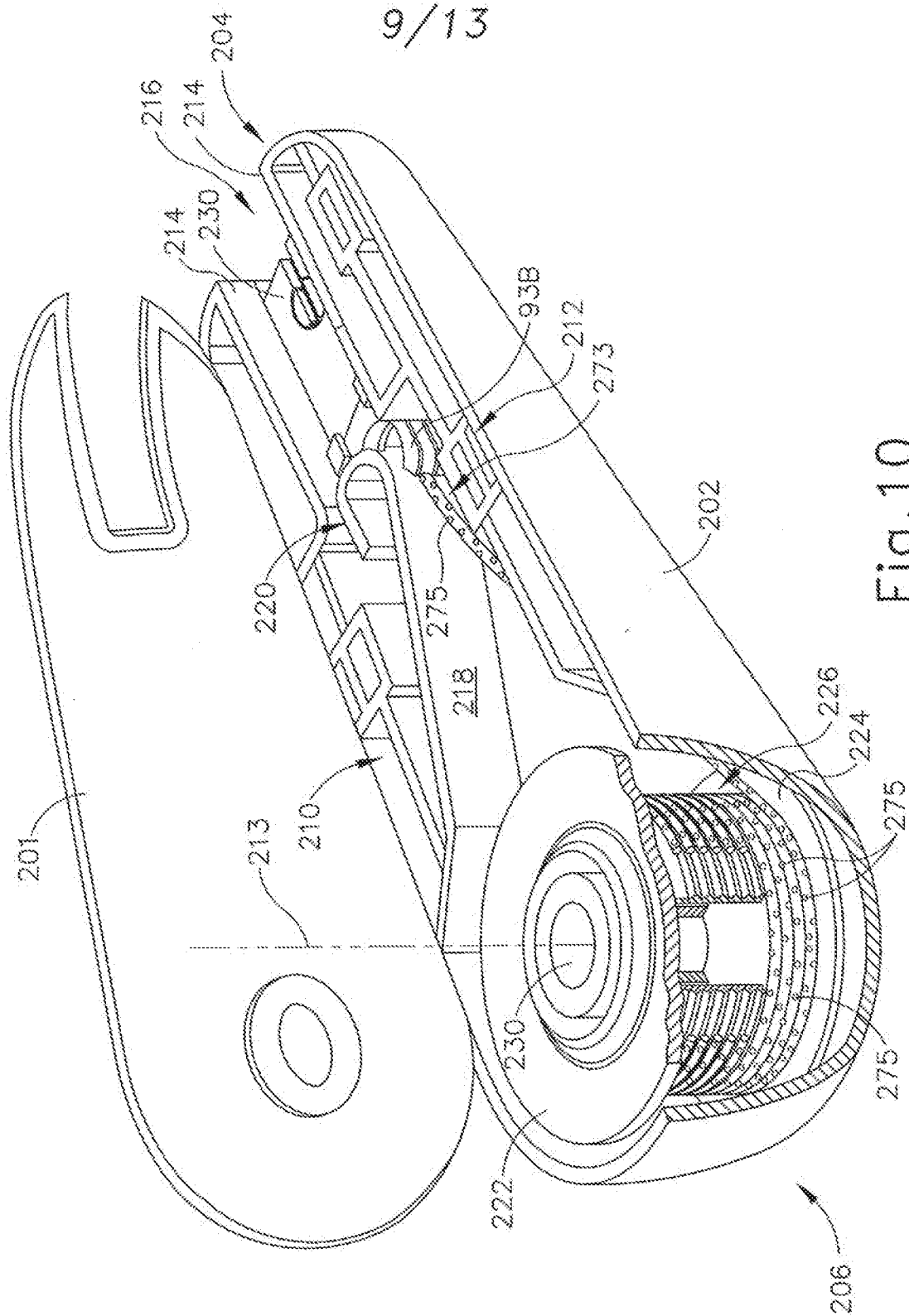


Fig. 9



11/13

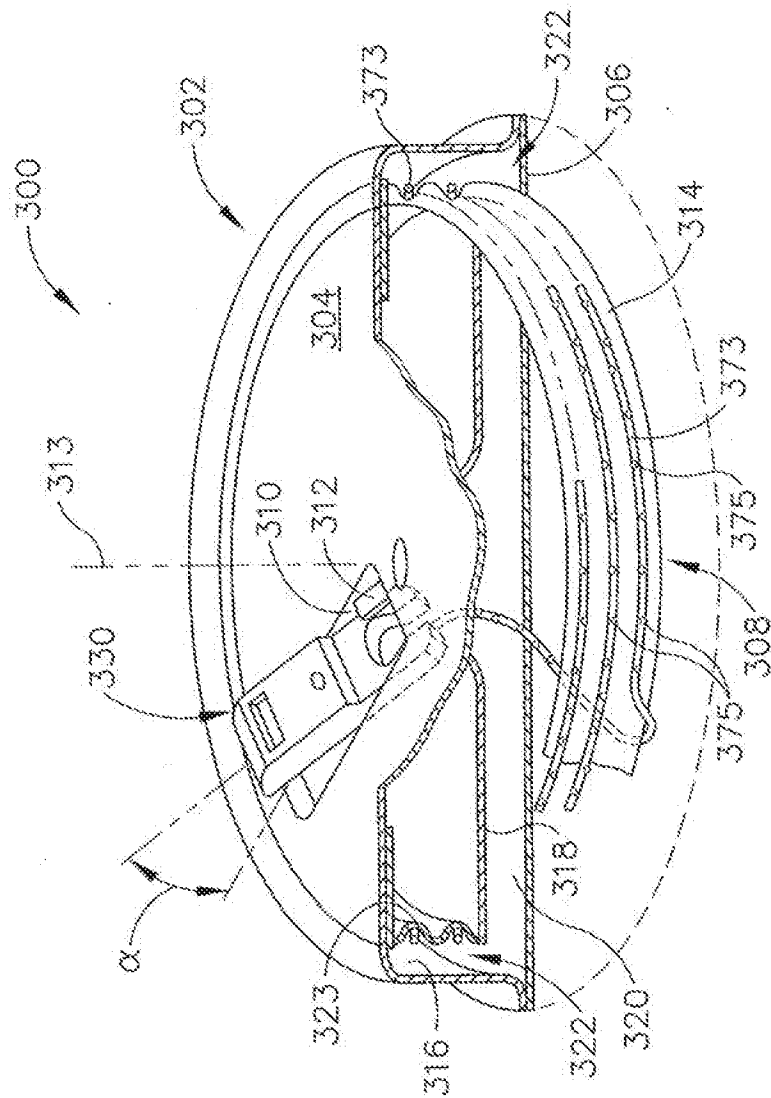


Fig.12

12/13

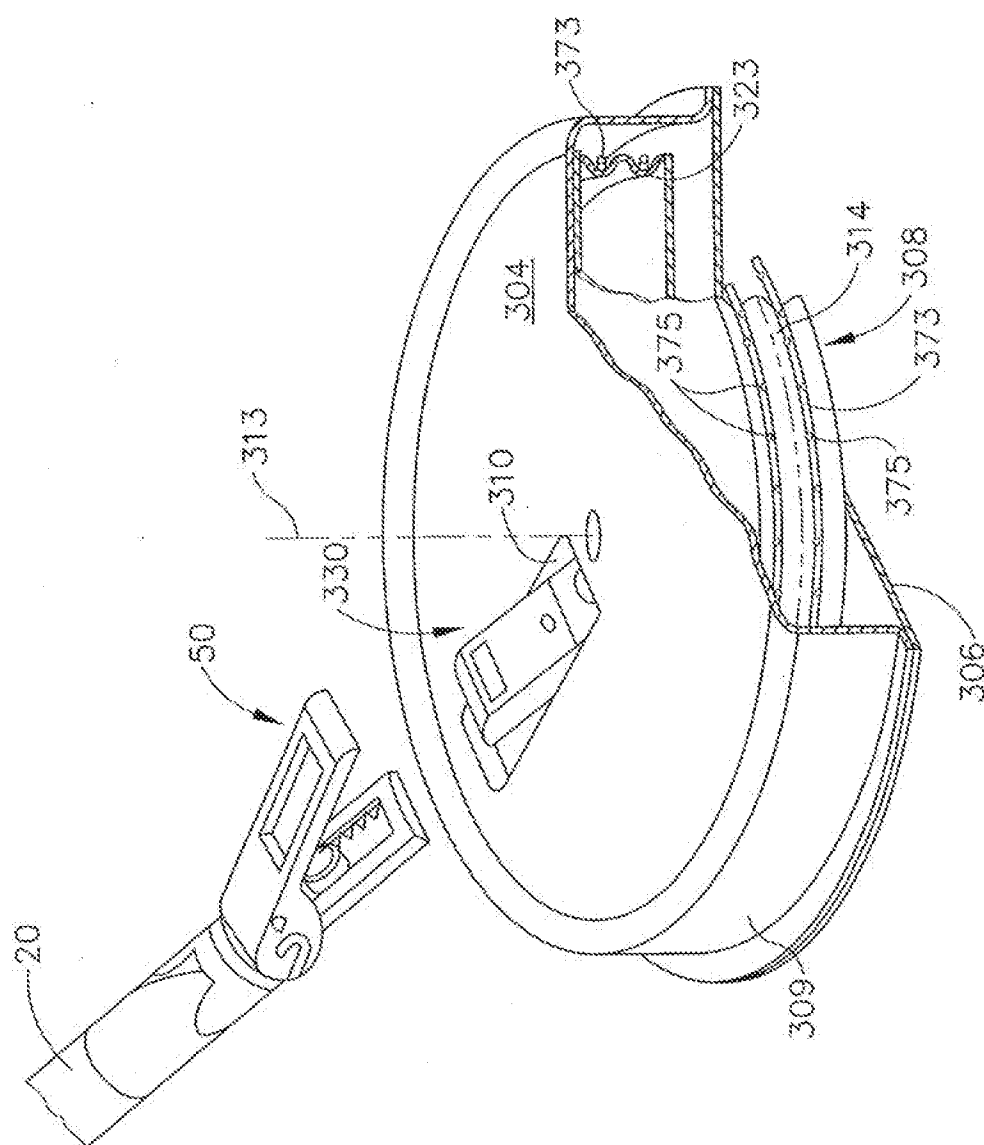


Fig. 13A

13/13

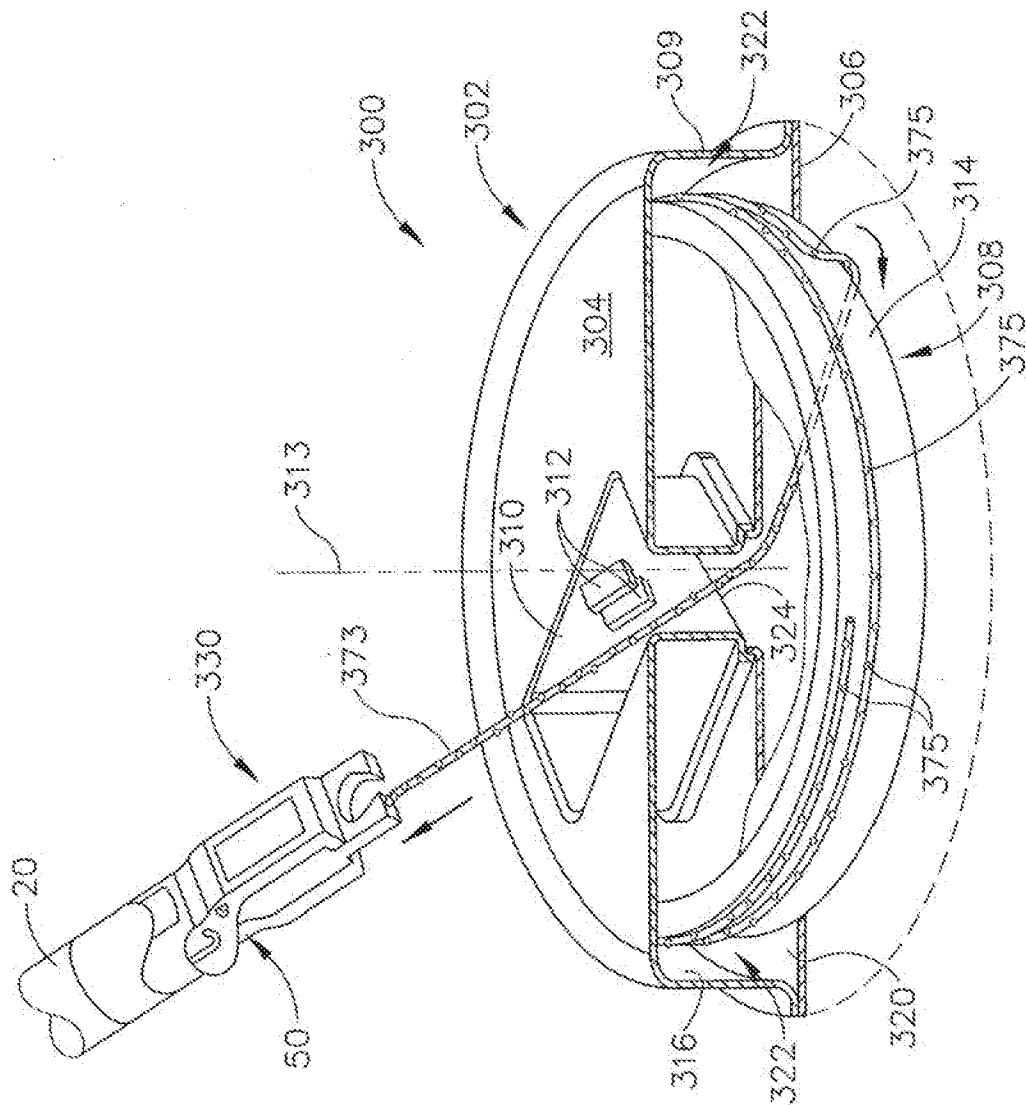


Fig. 13B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/037557

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04 A61B17/06
ADD. A61B17/00

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)
A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2014/166514 A1 (MARTIN DAVID T [US] ET AL) 19 June 2014 (2014-06-19) figures 34-36 paragraph [0152] - paragraph [0154] -----	1-15,20
Y	WO 2011/156733 A2 (ANGIOTECH PHARM INC [CA]; AVELAR RUI [US]; DRUBETSKY LEV [CA]; NAIMAGO) 15 December 2011 (2011-12-15) figures 1A-1D, 4A-4B paragraph [0069] paragraph [0075] paragraph [0099] - paragraph [0103] ----- -/-	1-15,20



Further documents are listed in the continuation of Box C.



See patent family annex.

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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

"&" document member of the same patent family

Date of the actual completion of the international search

12 August 2016

Date of mailing of the international search report

24/10/2016

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Authorized officer

Etienne, Nicolas

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/037557

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2008/150773 A1 (ANGIOTECH PHARM INC [CA]; HUNTER WILLIAM L [CA]; HERRMANN ROBERT A [CA]) 11 December 2008 (2008-12-11) figures 1, 14a-14g paragraph [0049] paragraph [0068] - paragraph [0073] -----	1-5,8, 10,20
A	US 2010/016870 A1 (CAMPBELL RICHARD A [US]) 21 January 2010 (2010-01-21) figures 1, 23 paragraph [0074] -----	1,20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/037557

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-15, 20

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15, 20

Packaging for a surgical needle comprising a spool having a helical channel.

2. claims: 16-19

Packaging for a surgical needle comprising a cartridge disposed at an oblique angle relative to the upper or lower portion of the housing.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/037557

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