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(71) Applicant: **ETHICON ENDO-SURGERY, INC.** [US/US]; 4545 Creek Road, Cincinnati, Ohio 45242 (US).

(72) Inventors: **SHELTON, IV, Frederick E.**; 245 East Main Street, Hillsboro, Ohio 45133 (US). **BEDARD, Timothy S.**; 413 Orchard Street, Sewickley, Pennsylvania 15143 (US).

(74) Agents: **PLANTZ, Bernard F.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 (US).

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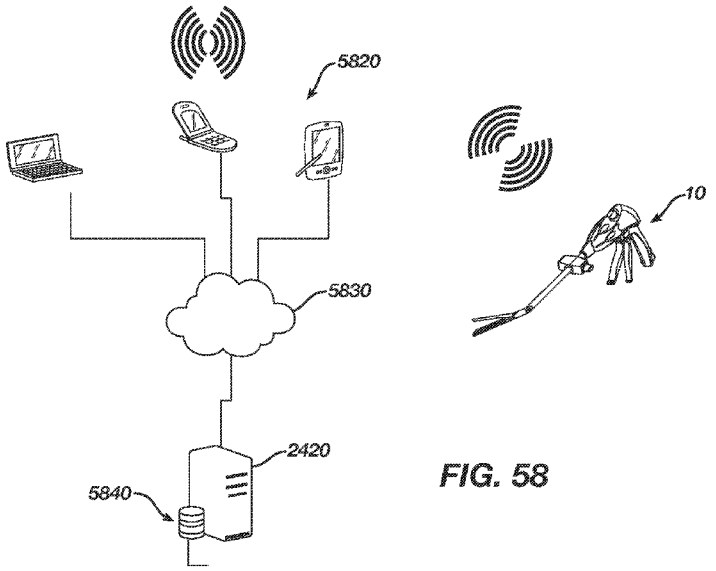


FIG. 58

(57) Abstract: A process and system are disclosed for downloading sensor data, stored in a memory device of a surgical cutting and fastening instrument (10), to an external or remote computer device (2420). The process may involve storing data from one or more sensors (2002,2004,2006,2008,2010,2012) of a surgical cutting and fastening instrument in a memory device (2001) of a control unit (2400) of the surgical cutting and fastening instrument during a surgical procedure involving the surgical cutting and fastening instrument. During the surgical procedure, the data may be transmitted to a local wireless communication device (5820) that is then transmitted to a central database (5840) for data analysis. Feedback is then communicated from the central database to a user of the surgical device via the local wireless communication device.

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PROVIDING NEAR REAL TIME FEEDBACK TO A USER OF A SURGICAL INSTRUMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to the following U.S. patent applications which are incorporated herein by reference in their entirety:

(1) MOTOR-DRIVEN SURGICAL CUTTING AND FASTENING INSTRUMENT WITH USER FEEDBACK SYSTEM, by Frederick E. Shelton, IV, John Ouwerkerk and Jerome R. Morgan, Serial No. 11/343,498;

(2) MOTOR-DRIVEN SURGICAL CUTTING AND FASTENING INSTRUMENT WITH LOADING FORCE FEEDBACK, by Frederick E. Shelton, IV, John N. Ouwerkerk, Jerome R. Morgan, and Jeffrey S. Swayze, Serial No. 11/343,573;

(3) MOTOR-DRIVEN SURGICAL CUTTING AND FASTENING INSTRUMENT WITH TACTILE POSITION FEEDBACK, by Frederick E. Shelton, IV, John N. Ouwerkerk, Jerome R. Morgan, and Jeffrey S. Swayze, Serial No. 11/344,035;

(4) MOTOR-DRIVEN SURGICAL CUTTING AND FASTENING INSTRUMENT WITH ADAPTIVE USER FEEDBACK, by Frederick E. Shelton, IV, John N. Ouwerkerk, and Jerome R. Morgan, Serial No. 11/343,447;

(5) MOTOR-DRIVEN SURGICAL CUTTING AND FASTENING INSTRUMENT WITH ARTICULATABLE END EFFECTOR, by Frederick E. Shelton, IV and Christoph L. Gillum, Serial No. 11/343,562;

(6) MOTOR-DRIVEN SURGICAL CUTTING AND FASTENING INSTRUMENT WITH MECHANICAL CLOSURE SYSTEM, by Frederick E. Shelton, IV and Christoph L. Gillum Serial No. 11/344,024;

(7) SURGICAL CUTTING AND FASTENING INSTRUMENT WITH CLOSURE TRIGGER LOCKING MECHANISM, by Frederick E. Shelton, IV and Kevin R. Doll, Serial No. 11/343,321;

(8) GEARING SELECTOR FOR A POWERED SURGICAL CUTTING AND FASTENING STAPLING INSTRUMENT, by Frederick E. Shelton, IV, Jeffrey S. Swayze, Eugene L. Timperman, Serial No. 11/343,563;

(9) SURGICAL INSTRUMENT HAVING A REMOVABLE BATTERY, by Frederick E. Shelton, IV, Kevin R. Doll, Jeffrey S. Swayze and Eugene Timperman Serial No. 11/344,020;

(10) ELECTRONIC LOCKOUTS AND SURGICAL INSTRUMENT INCLUDING SAME, by Jeffrey S. Swayze, Frederick E. Shelton, IV, Kevin R. Doll, Serial No. 11/343,439;

(11) ENDOSCOPIC SURGICAL INSTRUMENT WITH A HANDLE THAT CAN ARTICULATE WITH RESPECT TO THE SHAFT, by Frederick E. Shelton, IV, Jeffrey S. Swayze, Mark S. Ortiz, and Leslie M. Fugikawa, Serial No. 11/343,547;

(12) ELECTRO-MECHANICAL SURGICAL CUTTING AND FASTENING INSTRUMENT HAVING A ROTARY FIRING AND CLOSURE SYSTEM WITH PARALLEL CLOSURE AND ANVIL ALIGNMENT COMPONENTS, by Frederick E. Shelton, IV, Stephen J. Balek and Eugene L. Timperman, Serial No. 11/344,021;

(13) DISPOSABLE STAPLE CARTRIDGE HAVING AN ANVIL WITH TISSUE LOCATOR FOR USE WITH A SURGICAL CUTTING AND FASTENING INSTRUMENT AND MODULAR END EFFECTOR SYSTEM THEREFOR, by Frederick E. Shelton, IV, Michael S. Cropper, Joshua M. Broehl, Ryan S. Crisp, Jamison J. Float, Eugene L. Timperman, Serial No. 11/343,546; and

(14) SURGICAL INSTRUMENT HAVING A FEEDBACK SYSTEM, by Frederick E. Shelton, IV, Jerome R. Morgan, Kevin R. Doll, Jeffrey S. Swayze and Eugene Timperman, Serial No. 11/343,545.

BACKGROUND

[0002] The present invention relates in general to surgical instruments, and more particularly to minimally invasive surgical instruments capable of recording various conditions of the instrument.

[0003] Endoscopic surgical instruments are often preferred over traditional open surgical devices because a smaller incision tends to reduce the post-operative recovery time and complications. Consequently, significant development has gone into a range of endoscopic surgical instruments that are suitable for precise placement of a distal end effector at a desired surgical site through a cannula of a trocar. These distal end effectors

engage the tissue in a number of ways to achieve a diagnostic or therapeutic effect (e.g., endocutter, grasper, cutter, staplers, clip applier, access device, drug/gene therapy delivery device, and energy device using ultrasound, RF, laser, etc.).

[0004] Known surgical staplers include an end effector that simultaneously makes a longitudinal incision in tissue and applies lines of staples on opposing sides of the incision. The end effector includes a pair of cooperating jaw members that, if the instrument is intended for endoscopic or laparoscopic applications, are capable of passing through a cannula passageway. One of the jaw members receives a staple cartridge having at least two laterally spaced rows of staples. The other jaw member defines an anvil having staple-forming pockets aligned with the rows of staples in the cartridge. The instrument includes a plurality of reciprocating wedges which, when driven distally, pass through openings in the staple cartridge and engage drivers supporting the staples to effect the firing of the staples toward the anvil.

[0005] An example of a surgical stapler suitable for endoscopic applications is described in U.S. Pat. No. 5,465,895, entitled "SURGICAL STAPLER INSTRUMENT" to Knodel et al., which discloses an endocutter with distinct closing and firing actions. A clinician using this device is able to close the jaw members upon tissue to position the tissue prior to firing. Once the clinician has determined that the jaw members are properly gripping tissue, the clinician can then fire the surgical stapler with a single firing stroke, or multiple firing strokes, depending on the device. Firing the surgical stapler causes severing and stapling of the tissue. The simultaneous severing and stapling avoids complications that may arise when performing such actions sequentially with different surgical tools that respectively only sever and staple.

[0006] One specific advantage of being able to close upon tissue before firing is that the clinician is able to verify via an endoscope that the desired location for the cut has been achieved, including a sufficient amount of tissue has been captured between opposing jaws. Otherwise, opposing jaws may be drawn too close together, especially pinching at their distal ends, and thus not effectively forming closed staples in the severed tissue. At the other extreme, an excessive amount of clamped tissue may cause binding and an incomplete firing.

[0007] When endoscopic surgical instruments fail, they are often returned to the manufacturer, or other entity, for analysis of the failure. If the failure resulted in a critical class of defect in the instrument, it is necessary for the manufacturer to determine the cause of the failure and determine whether a design change is required. In that case, the manufacturer may spend many hundreds of man-hours analyzing a failed instrument and attempting to reconstruct the conditions under which it failed based only on the damage to the instrument. It can be expensive and very challenging to analyze instrument failures in this way. Also, many of these analyses simply conclude that the failure was due to improper use of the instrument.

DRAWINGS

[0008] Various embodiments of the present invention are described herein by way of example in conjunction with the following figures, wherein:

Figures 1 and 2 are perspective views of a surgical cutting and fastening instrument according to various embodiments of the present invention;

Figures 3-5 are exploded views of an end effector and shaft of the instrument according to various embodiments of the present invention;

Figure 6 is a side view of the end effector according to various embodiments of the present invention;

Figure 7 is an exploded view of the handle of the instrument according to various embodiments of the present invention;

Figures 8 and 9 are partial perspective views of the handle according to various embodiments of the present invention;

Figure 10 is a side view of the handle according to various embodiments of the present invention;

Figures 10A and 10B illustrate a proportional sensor that may be used according to various embodiments of the present invention;

Figure 11 is a schematic diagram of a circuit used in the instrument according to various embodiments of the present invention;

Figures 12-13 are side views of the handle according to other embodiments of the present invention;

Figures 14-22 illustrate different mechanisms for locking the closure trigger according to various embodiments of the present invention;

Figures 23A-B show a universal joint ("u-joint") that may be employed at the articulation point of the instrument according to various embodiments of the present invention;

Figures 24A-B shows a torsion cable that may be employed at the articulation point of the instrument according to various embodiments of the present invention;

Figures 25-31 illustrate a surgical cutting and fastening instrument with power assist according to another embodiment of the present invention;

Figures 32-36 illustrate a surgical cutting and fastening instrument with power assist according to yet another embodiment of the present invention;

Figures 37-40 illustrate a surgical cutting and fastening instrument with tactile feedback to embodiments of the present invention;

Figure 41 illustrates an exploded view of an end effector and shaft of the instrument according to various embodiments of the present invention;

Figure 42 illustrates a side view of the handle of a mechanically instrument according to various embodiments of the present invention;

Figure 43 illustrates an exploded view of the handle of the mechanically actuated instrument of Figure 42;

Figure 44 illustrates a block diagram of a recording system for recording various conditions of the instrument according to various embodiments of the present invention;

Figures 45-46 illustrate cut away side views of a handle of the instrument showing various sensors according to various embodiments of the present invention;

Figure 47 illustrates the end effector of the instrument showing various sensors according to various embodiments of the present invention;

Figure 48 illustrates a firing bar of the instrument including a sensor according to various embodiments of the present invention;

Figure 49 illustrates a side view of the handle, end effector, and firing bar of the instrument showing a sensor according to various embodiments of the present invention;

Figure 50 illustrates an exploded view of the staple channel and portions of a staple cartridge of the instrument showing various sensors according to various embodiments of the present invention;

Figure 51 illustrates a top down view of the staple channel of the instrument showing various sensors according to various embodiments of the present invention;

Figures 52A and 52B illustrate a flow chart showing a method for operating the instrument according to various embodiments;

Figure 53 illustrates a memory chart showing exemplary recorded conditions of the instrument according to various embodiments of the present invention;

Figure 54 is a block diagram of a recording system for recording various conditions of the instrument according to embodiments of the present invention;

Figure 55 is a diagram illustrating the surgical instrument in communication with a remote computer device;

Figure 56 is flow chart depicting a process according to various embodiments of the present invention;

Figure 57 is a flow chart depicting a process according to various embodiments of the present invention; and

Figure 58 is a schematic diagram of a system for transmitting from a surgical instrument to an application residing on a wireless device and a remote computer.

DETAILED DESCRIPTION

[0009] Figures 1 and 2 depict a surgical cutting and fastening instrument 10 according to various embodiments of the present invention. The illustrated embodiment is an endoscopic surgical instrument 10 and in general, the embodiments of the instrument 10

described herein are endoscopic surgical cutting and fastening instruments. It should be noted, however, that according to other embodiments of the present invention, the instrument 10 may be a non-endoscopic surgical cutting instrument, such as a laparoscopic instrument.

[0010] The surgical instrument 10 depicted in Figures 1 and 2 comprises a handle 6, a shaft 8, and an articulating end effector 12 pivotally connected to the shaft 8 at an articulation pivot 14. An articulation control 16 may be provided adjacent to the handle 6 to effect rotation of the end effector 12 about the articulation pivot 14. It will be appreciated that various embodiments may include a non-pivoting end effector, and therefore may not have an articulation pivot 14 or articulation control 16. Also, in the illustrated embodiment, the end effector 12 is configured to act as an endocutter for clamping, severing and stapling tissue, although, in other embodiments, different types of end effectors may be used, such as end effectors for other types of surgical devices, such as graspers, cutters, staplers, clip appliers, access devices, drug/gene therapy devices, ultrasound, RF or laser devices, etc.

[0011] The handle 6 of the instrument 10 may include a closure trigger 18 and a firing trigger 20 for actuating the end effector 12. It will be appreciated that instruments having end effectors directed to different surgical tasks may have different numbers or types of triggers or other suitable controls for operating the end effector 12. The end effector 12 is shown separated from the handle 6 by a preferably elongate shaft 8. In one embodiment, a clinician or operator of the instrument 10 may articulate the end effector 12 relative to the shaft 8 by utilizing the articulation control 16, as described in more detail in pending United States Patent Application Serial No. 11/329,020, filed January

10, 2006, entitled "Surgical Instrument Having An Articulating End Effector," by Geoffrey C. Hueil et al., which is incorporated herein by reference in its entirety.

[0012] The end effector 12 includes in this example, among other things, a staple channel 22 and a pivotally translatable clamping member, such as an anvil 24, which are maintained at a spacing that assures effective stapling and severing of tissue clamped in the end effector 12. The handle 6 includes a pistol grip 26 toward which a closure trigger 18 is pivotally drawn by the clinician to cause clamping or closing of the anvil 24 towards the staple channel 22 of the end effector 12 to thereby clamp tissue positioned between the anvil 24 and channel 22. The firing trigger 20 is farther outboard of the closure trigger 18. Once the closure trigger 18 is locked in the closure position as further described below, the firing trigger 20 may rotate slightly toward the pistol grip 26 so that it can be reached by the operator using one hand. Then the operator may pivotally draw the firing trigger 20 toward the pistol grip 26 to cause the stapling and severing of clamped tissue in the end effector 12. In other embodiments, different types of clamping members besides the anvil 24 could be used, such as, for example, an opposing jaw, *etc.*

[0013] It will be appreciated that the terms "proximal" and "distal" are used herein with reference to a clinician gripping the handle 6 of an instrument 10. Thus, the end effector 12 is distal with respect to the more proximal handle 6. It will be further appreciated that, for convenience and clarity, spatial terms such as "vertical" and "horizontal" are used herein with respect to the drawings. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute.

[0014] The closure trigger 18 may be actuated first. Once the clinician is satisfied with the positioning of the end effector 12, the clinician may draw back the closure trigger 18

to its fully closed, locked position proximate to the pistol grip 26. The firing trigger 20 may then be actuated. The firing trigger 20 returns to the open position (shown in Figures 1 and 2) when the clinician removes pressure, as described more fully below. A release button on the handle 6, when depressed may release the locked closure trigger 18. The release button may be implemented in various forms such as, for example, release button 30 shown in Figures 42-43, slide release button 160 shown in Figure 14, and/or button 172 shown in Figure 16.

[0015] Figures 3-6 show embodiments of a rotary-driven end effector 12 and shaft 8 according to various embodiments. Figure 3 is an exploded view of the end effector 12 according to various embodiments. As shown in the illustrated embodiment, the end effector 12 may include, in addition to the previously mentioned channel 22 and anvil 24, a cutting instrument 32, a sled 33, a staple cartridge 34 that is removably seated in the channel 22, and a helical screw shaft 36. The cutting instrument 32 may be, for example, a knife. The anvil 24 may be pivotably opened and closed at pivot pins 25 connected to the proximate end of the channel 22. The anvil 24 may also include a tab 27 at its proximate end that is inserted into a component of the mechanical closure system (described further below) to open and close the anvil 24. When the closure trigger 18 is actuated, that is, drawn in by a user of the instrument 10, the anvil 24 may pivot about the pivot pins 25 into the clamped or closed position. If clamping of the end effector 12 is satisfactory, the operator may actuate the firing trigger 20, which, as explained in more detail below, causes the knife 32 and sled 33 to travel longitudinally along the channel 22, thereby cutting tissue clamped within the end effector 12. The movement of the sled 33 along the channel 22 causes the staples (not shown) of the staple cartridge 34 to be

driven through the severed tissue and against the closed anvil 24, which turns the staples to fasten the severed tissue. In various embodiments, the sled 33 may be an integral component of the cartridge 34. United States Pat. No. 6,978,921, entitled "SURGICAL STAPLING INSTRUMENT INCORPORATING AN E-BEAM FIRING MECHANISM" to Shelton, IV et al., which is incorporated herein by reference in its entirety, provides more details about such two-stroke cutting and fastening instruments. The sled 33 may be part of the cartridge 34, such that when the knife 32 retracts following the cutting operation, the sled 33 does not retract.

[0016] It should be noted that although the embodiments of the instrument 10 described herein employ an end effector 12 that staples the severed tissue, in other embodiments different techniques for fastening or sealing the severed tissue may be used. For example, end effectors that use RF energy or adhesives to fasten the severed tissue may also be used. U.S. Pat. No. 5,709,680 entitled "ELECTROSURGICAL HEMOSTATIC DEVICE" to Yates et al., and U.S. Pat. No. 5,688,270 entitled "ELECTROSURGICAL HEMOSTATIC DEVICE WITH RECESSED AND/OR OFFSET ELECTRODES" to Yates et al., which are incorporated herein by reference in their entirety, disclose an endoscopic cutting instrument that uses RF energy to seal the severed tissue. U.S. Patent Application Serial No. 11/267,811 to Jerome R. Morgan, *et al.*, and U.S. Patent Application Serial No. 11/267,383 to Frederick E. Shelton, IV, *et. al*, which are also incorporated herein by reference in their entirety, disclose cutting instruments that uses adhesives to fasten the severed tissue. Accordingly, although the description herein refers to cutting/stapling operations and the like below, it should be recognized that this is

an exemplary embodiment and is not meant to be limiting. Other tissue fastening techniques may also be used.

[0017] Figures 4 and 5 are exploded views and Figure 6 is a side view of the end effector 12 and shaft 8 according to various embodiments. As shown in the illustrated embodiment, the shaft 8 may include a proximate closure tube 40 and a distal closure tube 42 pivotably linked by a pivot link 44. The distal closure tube 42 includes an opening 45 into which the tab 27 on the anvil 24 is inserted in order to open and close the anvil 24, as further described below. Disposed inside the closure tubes 40, 42 may be a proximate spine tube 46. Disposed inside the proximate spine tube 46 may be a main rotational (or proximate) drive shaft 48 that communicates with a secondary (or distal) drive shaft 50 via a bevel gear assembly 52. The secondary drive shaft 50 is connected to a drive gear 54 that engages a proximate drive gear 56 of the helical screw shaft 36. The vertical bevel gear 52b may sit and pivot in an opening 57 in the distal end of the proximate spine tube 46. A distal spine tube 58 may be used to enclose the secondary drive shaft 50 and the drive gears 54, 56. Collectively, the main drive shaft 48, the secondary drive shaft 50, and the articulation assembly (*e.g.*, the bevel gear assembly 52a-c) are sometimes referred to herein as the "main drive shaft assembly."

[0018] A bearing 38, positioned at a distal end of the staple channel 22, receives the helical drive screw 36, allowing the helical drive screw 36 to freely rotate with respect to the channel 22. The helical screw shaft 36 may interface a threaded opening (not shown) of the knife 32 such that rotation of the shaft 36 causes the knife 32 to translate distally or proximately (depending on the direction of the rotation) through the staple channel 22. Accordingly, when the main drive shaft 48 is caused to rotate by actuation of the firing

trigger 20 (as explained in more detail below), the bevel gear assembly 52a-c causes the secondary drive shaft 50 to rotate, which in turn, because of the engagement of the drive gears 54, 56, causes the helical screw shaft 36 to rotate, which causes the knife driving member 32 to travel longitudinally along the channel 22 to cut any tissue clamped within the end effector 12. The sled 33 may be made of, for example, plastic, and may have a sloped distal surface. As the sled 33 traverses the channel 22, the sloped forward surface may push up or drive the staples in the staple cartridge through the clamped tissue and against the anvil 24. The anvil 24 turns the staples, thereby stapling the severed tissue. When the knife 32 is retracted, the knife 32 and sled 33 may become disengaged, thereby leaving the sled 33 at the distal end of the channel 22.

[0019] As described above, because of the lack of user feedback for the cutting/stapling operation, there is a general lack of acceptance among physicians of motor-driven endocutters where the cutting/stapling operation is actuated by merely pressing a button. In contrast, embodiments of the present invention provide a motor-driven endocutter with user-feedback of the deployment, force, and/or position of the cutting instrument 32 in end effector 12.

[0020] Figures 7-10 illustrate an exemplary embodiment of a motor-driven endocutter, and in particular the handle thereof, that provides user-feedback regarding the deployment and loading force of the cutting instrument 32 in the end effector 12. In addition, the embodiment may use power provided by the user in retracting the firing trigger 20 to power the device (a so-called "power assist" mode). The embodiment may be used with the rotary driven end effector 12 and shaft 8 embodiments described above. As shown in the illustrated embodiment, the handle 6 includes exterior lower side pieces

59, 60 and exterior upper side pieces 61, 62 that fit together to form, in general, the exterior of the handle 6. A battery 64, such as a Li ion battery, may be provided in the pistol grip portion 26 of the handle 6. The battery 64 powers an electric motor 65 disposed in an upper portion of the pistol grip portion 26 of the handle 6. According to various embodiments, the motor 65 may be a DC brushed driving motor having a maximum rotation of, approximately, 25,000 RPM. Other suitable types of electric motors may also be used. The motor 65 may drive a 90° bevel gear assembly 66 comprising a first bevel gear 68 and a second bevel gear 70. The bevel gear assembly 66 may drive a planetary gear assembly 72. The planetary gear assembly 72 may include a pinion gear 74 connected to a drive shaft 76. The pinion gear 74 may drive a mating ring gear 78 that drives a helical gear drum 80 via a drive shaft 82. A ring 84 may be threaded on the helical gear drum 80. Thus, when the motor 65 rotates, the ring 84 is caused to travel along the helical gear drum 80 by means of the interposed bevel gear assembly 66, planetary gear assembly 72 and ring gear 78.

[0021] The handle 6 may also include a run motor sensor 110 (see Figure 10) in communication with the firing trigger 20 to detect when the firing trigger 20 has been drawn in (or "closed") toward the pistol grip portion 26 of the handle 6 by the operator to thereby actuate the cutting/stapling operation by the end effector 12. The sensor 110 may be a proportional sensor such as, for example, a rheostat or variable resistor. When the firing trigger 20 is drawn in, the sensor 110 detects the movement, and sends an electrical signal indicative of the voltage (or power) to be supplied to the motor 65. When the sensor 110 is a variable resistor or the like, the rotation of the motor 65 may be generally proportional to the amount of movement of the firing trigger 20. That is, if the operator

only draws or closes the firing trigger 20 in a little bit, the rotation of the motor 65 is relatively low. When the firing trigger 20 is fully drawn in (or in the fully closed position), the rotation of the motor 65 is at its maximum. In other words, the harder the user pulls on the firing trigger 20, the more voltage is applied to the motor 65, causing greater rates of rotation.

[0022] The handle 6 may include a middle handle piece 104 adjacent to the upper portion of the firing trigger 20. The handle 6 also may comprise a bias spring 112 connected between posts on the middle handle piece 104 and the firing trigger 20. The bias spring 112 may bias the firing trigger 20 to its fully open position. In that way, when the operator releases the firing trigger 20, the bias spring 112 will pull the firing trigger 20 to its open position, thereby removing actuation of the sensor 110, thereby stopping rotation of the motor 65. Moreover, by virtue of the bias spring 112, any time a user closes the firing trigger 20, the user will experience resistance to the closing operation, thereby providing the user with feedback as to the amount of rotation exerted by the motor 65. Further, the operator could stop retracting the firing trigger 20 to thereby remove force from the sensor 100, to thereby stop the motor 65. As such, the user may stop the deployment of the end effector 12, thereby providing a measure of control of the cutting/fastening operation to the operator.

[0023] The distal end of the helical gear drum 80 includes a distal drive shaft 120 that drives a ring gear 122, which mates with a pinion gear 124. The pinion gear 124 is connected to the main drive shaft 48 of the main drive shaft assembly. In that way, rotation of the motor 65 causes the main drive shaft assembly to rotate, which causes actuation of the end effector 12, as described above.

[0024] The ring 84 threaded on the helical gear drum 80 may include a post 86 that is disposed within a slot 88 of a slotted arm 90. The slotted arm 90 has an opening 92 its opposite end 94 that receives a pivot pin 96 that is connected between the handle exterior side pieces 59, 60. The pivot pin 96 is also disposed through an opening 100 in the firing trigger 20 and an opening 102 in the middle handle piece 104.

[0025] In addition, the handle 6 may include a reverse motor sensor (or end-of-stroke sensor) 130 and a stop motor (or beginning-of-stroke) sensor 142. In various embodiments, the reverse motor sensor 130 may be a limit switch located at the distal end of the helical gear drum 80 such that the ring 84 threaded on the helical gear drum 80 contacts and trips the reverse motor sensor 130 when the ring 84 reaches the distal end of the helical gear drum 80. The reverse motor sensor 130, when activated, sends a signal to the motor 65 to reverse its rotation direction, thereby withdrawing the knife 32 of the end effector 12 following the cutting operation.

[0026] The stop motor sensor 142 may be, for example, a normally-closed limit switch. In various embodiments, it may be located at the proximate end of the helical gear drum 80 so that the ring 84 trips the switch 142 when the ring 84 reaches the proximate end of the helical gear drum 80.

[0027] In operation, when an operator of the instrument 10 pulls back the firing trigger 20, the sensor 110 detects the deployment of the firing trigger 20 and sends a signal to the motor 65 to cause forward rotation of the motor 65, for example, at a rate proportional to how hard the operator pulls back the firing trigger 20. The forward rotation of the motor 65 in turn causes the ring gear 78 at the distal end of the planetary gear assembly 72 to rotate, thereby causing the helical gear drum 80 to rotate, causing the ring 84 threaded on

the helical gear drum 80 to travel distally along the helical gear drum 80. The rotation of the helical gear drum 80 also drives the main drive shaft assembly as described above, which in turn causes deployment of the knife 32 in the end effector 12. That is, the knife 32 and sled 33 are caused to traverse the channel 22 longitudinally, thereby cutting tissue clamped in the end effector 12. Also, the stapling operation of the end effector 12 is caused to happen in embodiments where a stapling-type end effector 12 is used.

[0028] By the time the cutting/stapling operation of the end effector 12 is complete, the ring 84 on the helical gear drum 80 will have reached the distal end of the helical gear drum 80, thereby causing the reverse motor sensor 130 to be tripped, which sends a signal to the motor 65 to cause the motor 65 to reverse its rotation. This in turn causes the knife 32 to retract, and also causes the ring 84 on the helical gear drum 80 to move back to the proximate end of the helical gear drum 80.

[0029] The middle handle piece 104 includes a backside shoulder 106 that engages the slotted arm 90 as best shown in Figures 8 and 9. The middle handle piece 104 also has a forward motion stop 107 that engages the firing trigger 20. The movement of the slotted arm 90 is controlled, as explained above, by rotation of the motor 65. When the slotted arm 90 rotates counter clockwise as the ring 84 travels from the proximate end of the helical gear drum 80 to the distal end, the middle handle piece 104 will be free to rotate counter clockwise. Thus, as the user draws in the firing trigger 20, the firing trigger 20 will engage the forward motion stop 107 of the middle handle piece 104, causing the middle handle piece 104 to rotate counter clockwise. Due to the backside shoulder 106 engaging the slotted arm 90, however, the middle handle piece 104 will only be able to rotate counter clockwise as far as the slotted arm 90 permits. In that way, if the motor 65

should stop rotating for some reason, the slotted arm 90 will stop rotating, and the user will not be able to further draw in the firing trigger 20 because the middle handle piece 104 will not be free to rotate counter clockwise due to the slotted arm 90.

[0030] Figures 10A and 10B illustrate two states of a variable sensor that may be used as the run motor sensor 110 according to various embodiments of the present invention. The sensor 110 may include a face portion 280, a first electrode (A) 282, a second electrode (B) 284, and a compressible dielectric material 286 between the electrodes 282, 284, such as, for example, an electroactive polymer (EAP). The sensor 110 may be positioned such that the face portion 280 contacts the firing trigger 20 when retracted. Accordingly, when the firing trigger 20 is retracted, the dielectric material 286 is compressed, as shown in Figure 10B, such that the electrodes 282, 284 are closer together. Since the distance "b" between the electrodes 282, 284 is directly related to the impedance between the electrodes 282, 284, the greater the distance the more impedance, and the closer the distance the less impedance. In that way, the amount that the dielectric 286 is compressed due to retraction of the firing trigger 20 (denoted as force "F" in Figure 42) is proportional to the impedance between the electrodes 282, 284, which can be used to proportionally control the motor 65.

[0031] Components of an exemplary closure system for closing (or clamping) the anvil 24 of the end effector 12 by retracting the closure trigger 18 are also shown in Figures 7-10. In the illustrated embodiment, the closure system includes a yoke 250 connected to the closure trigger 18 by a pivot pin 251 inserted through aligned openings in both the closure trigger 18 and the yoke 250. A pivot pin 252, about which the closure trigger 18 pivots, is inserted through another opening in the closure trigger 18 which is offset from

where the pin 251 is inserted through the closure trigger 18. Thus, retraction of the closure trigger 18 causes the upper part of the closure trigger 18, to which the yoke 250 is attached via the pin 251, to rotate counterclockwise. The distal end of the yoke 250 is connected, via a pin 254, to a first closure bracket 256. The first closure bracket 256 connects to a second closure bracket 258. Collectively, the closure brackets 256, 258 define an opening in which the proximate end of the proximate closure tube 40 (see Figure 4) is seated and held such that longitudinal movement of the closure brackets 256, 258 causes longitudinal motion by the proximate closure tube 40. The instrument 10 also includes a closure rod 260 disposed inside the proximate closure tube 40. The closure rod 260 may include a window 261 into which a post 263 on one of the handle exterior pieces, such as exterior lower side piece 59 in the illustrated embodiment, is disposed to fixedly connect the closure rod 260 to the handle 6. In that way, the proximate closure tube 40 is capable of moving longitudinally relative to the closure rod 260. The closure rod 260 may also include a distal collar 267 that fits into a cavity 269 in proximate spine tube 46 and is retained therein by a cap 271 (see Figure 4).

[0032] In operation, when the yoke 250 rotates due to retraction of the closure trigger 18, the closure brackets 256, 258 cause the proximate closure tube 40 to move distally (i.e., away from the handle end of the instrument 10), which causes the distal closure tube 42 to move distally, which causes the anvil 24 to rotate about the pivot pins 25 into the clamped or closed position. When the closure trigger 18 is unlocked from the locked position, the proximate closure tube 40 is caused to slide proximately, which causes the distal closure tube 42 to slide proximately, which, by virtue of the tab 27 being inserted in the window 45 of the distal closure tube 42, causes the anvil 24 to pivot about the pivot

pins 25 into the open or unclamped position. In that way, by retracting and locking the closure trigger 18, an operator may clamp tissue between the anvil 24 and channel 22, and may unclamp the tissue following the cutting/stapling operation by unlocking the closure trigger 20 from the locked position.

[0033] Figure 11 is a schematic diagram of an electrical circuit of the instrument 10 according to various embodiments of the present invention. When an operator initially pulls in the firing trigger 20 after locking the closure trigger 18, the sensor 110 is activated, allowing current to flow there through. If the normally-open reverse motor sensor switch 130 is open (meaning the end of the end effector stroke has not been reached), current will flow to a single pole, double throw relay 132. Since the reverse motor sensor switch 130 is not closed, the inductor 134 of the relay 132 will not be energized, so the relay 132 will be in its non-energized state. The circuit also includes a cartridge lockout sensor 136. If the end effector 12 includes a staple cartridge 34, the sensor 136 will be in the closed state, allowing current to flow. Otherwise, if the end effector 12 does not include a staple cartridge 34, the sensor 136 will be open, thereby preventing the battery 64 from powering the motor 65.

[0034] When the staple cartridge 34 is present, the sensor 136 is closed, which energizes a single pole, single throw relay 138. When the relay 138 is energized, current flows through the relay 136, through the variable resistor sensor 110, and to the motor 65 via a double pole, double throw relay 140, thereby powering the motor 65 and allowing it to rotate in the forward direction.

[0035] When the end effector 12 reaches the end of its stroke, the reverse motor sensor 130 will be activated, thereby closing the switch 130 and energizing the relay 134. This

causes the relay 134 to assume its energized state (not shown in Figure 13), which causes current to bypass the cartridge lockout sensor 136 and variable resistor 110, and instead causes current to flow to both the normally-closed double pole, double throw relay 142 and back to the motor 65, but in a manner, via the relay 140, that causes the motor 65 to reverse its rotational direction.

[0036] Because the stop motor sensor switch 142 is normally-closed, current will flow back to the relay 134 to keep it closed until the switch 142 opens. When the knife 32 is fully retracted, the stop motor sensor switch 142 is activated, causing the switch 142 to open, thereby removing power from the motor 65.

[0037] In other embodiments, rather than a proportional-type sensor 110, an on-off type sensor could be used. In such embodiments, the rate of rotation of the motor 65 would not be proportional to the force applied by the operator. Rather, the motor 65 would generally rotate at a constant rate. But the operator would still experience force feedback because the firing trigger 20 is geared into the gear drive train.

[0038] Figure 12 is a side-view of the handle 6 of a power-assist motorized endocutter according to another embodiment. The embodiment of Figure 12 is similar to that of Figures 7-10 except that in the embodiment of Figure 12, there is no slotted arm connected to the ring 84 threaded on the helical gear drum 80. Instead, in the embodiment of Figure 12, the ring 84 includes a sensor portion 114 that moves with the ring 84 as the ring 84 advances down (and back) on the helical gear drum 80. The sensor portion 114 includes a notch 116. The reverse motor sensor 130 may be located at the distal end of the notch 116 and the stop motor sensor 142 may be located at the proximate end of the notch 116. As the ring 84 moves down the helical gear drum 80 (and back),

the sensor portion 114 moves with it. Further, as shown in Figure 12, the middle piece 104 may have an arm 118 that extends into the notch 12.

[0039] In operation, as an operator of the instrument 10 retracts in the firing trigger 20 toward the pistol grip 26, the run motor sensor 110 detects the motion and sends a signal to power the motor 65, which causes, among other things, the helical gear drum 80 to rotate. As the helical gear drum 80 rotates, the ring 84 threaded on the helical gear drum 80 advances (or retracts, depending on the rotation). Also, due to the pulling in of the firing trigger 20, the middle piece 104 is caused to rotate counter clockwise with the firing trigger 20 due to the forward motion stop 107 that engages the firing trigger 20. The counter clockwise rotation of the middle piece 104 cause the arm 118 to rotate counter clockwise with the sensor portion 114 of the ring 84 such that the arm 118 stays disposed in the notch 116. When the ring 84 reaches the distal end of the helical gear drum 80, the arm 118 will contact and thereby trip the reverse motor sensor 130. Similarly, when the ring 84 reaches the proximate end of the helical gear drum 80, the arm will contact and thereby trip the stop motor sensor 142. Such actions may reverse and stop the motor 65, respectively as described above.

[0040] Figure 13 is a side-view of the handle 6 of a power-assist motorized endocutter according to another embodiment. The embodiment of Figure 13 is similar to that of Figures 7-10 except that in the embodiment of Figure 13, there is no slot in the arm 90. Instead, the ring 84 threaded on the helical gear drum 80 includes a vertical channel 126. Instead of a slot, the arm 90 includes a post 128 that is disposed in the channel 126. As the helical gear drum 80 rotates, the ring 84 threaded on the helical gear drum 80 advances (or retracts, depending on the rotation). The arm 90 rotates counter clockwise

as the ring 84 advances due to the post 128 being disposed in the channel 126, as shown in Figure 13.

[0041] As mentioned above, in using a two-stroke motorized instrument, the operator first pulls back and locks the closure trigger 18. Figures 14 and 15 show one embodiment of a way to lock the closure trigger 18 to the pistol grip portion 26 of the handle 6. In the illustrated embodiment, the pistol grip portion 26 includes a hook 150 that is biased to rotate counter clockwise about a pivot point 151 by a torsion spring 152. Also, the closure trigger 18 includes a closure bar 154. As the operator draws in the closure trigger 18, the closure bar 154 engages a sloped portion 156 of the hook 150, thereby rotating the hook 150 upward (or clockwise in Figures 14-15) until the closure bar 154 completely passes the sloped portion 156 passes into a recessed notch 158 of the hook 150, which locks the closure trigger 18 in place. The operator may release the closure trigger 18 by pushing down on a slide button release 160 on the back or opposite side of the pistol grip portion 26. Pushing down the slide button release 160 rotates the hook 150 clockwise such that the closure bar 154 is released from the recessed notch 158.

[0042] Figure 16 shows another closure trigger locking mechanism according to various embodiments. In the embodiment of Figure 16, the closure trigger 18 includes a wedge 160 having an arrow-head portion 161. The arrow-head portion 161 is biased downward (or clockwise) by a leaf spring 162. The wedge 160 and leaf spring 162 may be made from, for example, molded plastic. When the closure trigger 18 is retracted, the arrow-head portion 161 is inserted through an opening 164 in the pistol grip portion 26 of the handle 6. A lower chamfered surface 166 of the arrow-head portion 161 engages a lower sidewall 168 of the opening 164, forcing the arrow-head portion 161 to rotate

counter clockwise. Eventually the lower chamfered surface 166 fully passes the lower sidewall 168, removing the counter clockwise force on the arrow-head portion 161, causing the lower sidewall 168 to slip into a locked position in a notch 170 behind the arrow-head portion 161.

[0043] To unlock the closure trigger 18, a user presses down on a button 172 on the opposite side of the closure trigger 18, causing the arrow-head portion 161 to rotate counter clockwise and allowing the arrow-head portion 161 to slide out of the opening 164.

[0044] Figures 17-22 show a closure trigger locking mechanism according to another embodiment. As shown in this embodiment, the closure trigger 18 includes a flexible longitudinal arm 176 that includes a lateral pin 178 extending therefrom. The arm 176 and pin 178 may be made from molded plastic, for example. The pistol grip portion 26 of the handle 6 includes an opening 180 with a laterally extending wedge 182 disposed therein. When the closure trigger 18 is retracted, the pin 178 engages the wedge 182, and the pin 178 is forced downward (i.e., the arm 176 is rotated clockwise) by the lower surface 184 of the wedge 182, as shown in Figures 17 and 18. When the pin 178 fully passes the lower surface 184, the clockwise force on the arm 176 is removed, and the pin 178 is rotated counter clockwise such that the pin 178 comes to rest in a notch 186 behind the wedge 182, as shown in Figure 19, thereby locking the closure trigger 18. The pin 178 is further held in place in the locked position by a flexible stop 188 extending from the wedge 184.

[0045] To unlock the closure trigger 18, the operator may further squeeze the closure trigger 18, causing the pin 178 to engage a sloped backwall 190 of the opening 180,

forcing the pin 178 upward past the flexible stop 188, as shown in Figures 20 and 21. The pin 178 is then free to travel out an upper channel 192 in the opening 180 such that the closure trigger 18 is no longer locked to the pistol grip portion 26, as shown in Figure 22.

[0046] Figures 23A-B show a universal joint ("u-joint") 195. The second piece 195-2 of the u-joint 195 rotates in a horizontal plane in which the first piece 195-1 lies. Figure 23A shows the u-joint 195 in a linear (180°) orientation and Figure 23B shows the u-joint 195 at approximately a 150° orientation. The u-joint 195 may be used instead of the bevel gears 52a-c (see Figure 4, for example) at the articulation point 14 of the main drive shaft assembly to articulate the end effector 12. Figures 24A-B show a torsion cable 197 that may be used in lieu of both the bevel gears 52a-c and the u-joint 195 to realize articulation of the end effector 12.

[0047] Figures 25-31 illustrate another embodiment of a motorized, two-stroke surgical cutting and fastening instrument 10 with power assist according to another embodiment of the present invention. The embodiment of Figures 25-31 is similar to that of Figures 6-10 except that instead of the helical gear drum 80, the embodiment of Figures 23-28 includes an alternative gear drive assembly. The embodiment of Figures 25-31 includes a gear box assembly 200 including a number of gears disposed in a frame 201, wherein the gears are connected between the planetary gear 72 and the pinion gear 124 at the proximate end of the drive shaft 48. As explained further below, the gear box assembly 200 provides feedback to the user via the firing trigger 20 regarding the deployment and loading force of the end effector 12. Also, the user may provide power to the system via the gear box assembly 200 to assist the deployment of the end effector 12. In that sense,

like the embodiments described above, the embodiment of Figures 23-32 is another power assist motorized instrument 10 that provides feedback to the user regarding the loading force experienced by the instrument.

[0048] In the illustrated embodiment, the firing trigger 20 includes two pieces: a main body portion 202 and a stiffening portion 204. The main body portion 202 may be made of plastic, for example, and the stiffening portion 204 may be made out of a more rigid material, such as metal. In the illustrated embodiment, the stiffening portion 204 is adjacent to the main body portion 202, but according to other embodiments, the stiffening portion 204 could be disposed inside the main body portion 202. A pivot pin 207 may be inserted through openings in the firing trigger pieces 202, 204 and may be the point about which the firing trigger 20 rotates. In addition, a spring 222 may bias the firing trigger 20 to rotate in a counter clockwise direction. The spring 222 may have a distal end connected to a pin 224 that is connected to the pieces 202, 204 of the firing trigger 20. The proximate end of the spring 222 may be connected to one of the handle exterior lower side pieces 59, 60.

[0049] In the illustrated embodiment, both the main body portion 202 and the stiffening portion 204 include gear portions 206, 208 (respectively) at their upper end portions. The gear portions 206, 208 engage a gear in the gear box assembly 200, as explained below, to drive the main drive shaft assembly and to provide feedback to the user regarding the deployment of the end effector 12.

[0050] The gear box assembly 200 may include as shown, in the illustrated embodiment, six (6) gears. A first gear 210 of the gear box assembly 200 engages the gear portions 206, 208 of the firing trigger 20. In addition, the first gear 210 engages a

smaller second gear 212, the smaller second gear 212 being coaxial with a large third gear 214. The third gear 214 engages a smaller fourth gear 216, the smaller fourth gear being coaxial with a fifth gear 218. The fifth gear 218 is a 90° bevel gear that engages a mating 90° bevel gear 220 (best shown in Figure 31) that is connected to the pinion gear 124 that drives the main drive shaft 48.

[0051] In operation, when the user retracts the firing trigger 20, a run motor sensor (not shown) is activated, which may provide a signal to the motor 65 to rotate at a rate proportional to the extent or force with which the operator is retracting the firing trigger 20. This causes the motor 65 to rotate at a speed proportional to the signal from the sensor. The sensor is not shown for this embodiment, but it could be similar to the run motor sensor 110 described above. The sensor could be located in the handle 6 such that it is depressed when the firing trigger 20 is retracted. Also, instead of a proportional-type sensor, an on/off type sensor may be used.

[0052] Rotation of the motor 65 causes the bevel gears 68, 70 to rotate, which causes the planetary gear 72 to rotate, which causes, via the drive shaft 76, the ring gear 122 to rotate. The ring gear 122 meshes with the pinion gear 124, which is connected to the main drive shaft 48. Thus, rotation of the pinion gear 124 drives the main drive shaft 48, which causes actuation of the cutting/stapling operation of the end effector 12.

[0053] Forward rotation of the pinion gear 124 in turn causes the bevel gear 220 to rotate, which causes, by way of the rest of the gears of the gear box assembly 200, the first gear 210 to rotate. The first gear 210 engages the gear portions 206, 208 of the firing trigger 20, thereby causing the firing trigger 20 to rotate counter clockwise when the motor 65 provides forward drive for the end effector 12 (and to rotate counter clockwise

when the motor 65 rotates in reverse to retract the end effector 12). In that way, the user experiences feedback regarding loading force and deployment of the end effector 12 by way of the user's grip on the firing trigger 20. Thus, when the user retracts the firing trigger 20, the operator will experience a resistance related to the load force experienced by the end effector 12. Similarly, when the operator releases the firing trigger 20 after the cutting/stapling operation so that it can return to its original position, the user will experience a clockwise rotation force from the firing trigger 20 that is generally proportional to the reverse speed of the motor 65.

[0054] It should also be noted that in this embodiment the user can apply force (either in lieu of or in addition to the force from the motor 65) to actuate the main drive shaft assembly (and hence the cutting/stapling operation of the end effector 12) through retracting the firing trigger 20. That is, retracting the firing trigger 20 causes the gear portions 206, 208 to rotate counter clockwise, which causes the gears of the gear box assembly 200 to rotate, thereby causing the pinion gear 124 to rotate, which causes the main drive shaft 48 to rotate.

[0055] Although not shown in Figures 25-31, the instrument 10 may further include reverse motor and stop motor sensors. As described above, the reverse motor and stop motor sensors may detect, respectively, the end of the cutting stroke (full deployment of the knife 32) and the end of retraction operation (full retraction of the knife 32). A similar circuit to that described above in connection with Figure 11 may be used to appropriately power the motor 65.

[0056] Figures 32-36 illustrate a two-stroke, motorized surgical cutting and fastening instrument 10 with power assist according to another embodiment. The embodiment of

Figures 32-36 is similar to that of Figures 25-31 except that in the embodiment of Figures 32-36, the firing trigger 20 includes a lower portion 228 and an upper portion 230. Both portions 228, 230 are connected to and pivot about a pivot pin 207 that is disposed through each portion 228, 230. The upper portion 230 includes a gear portion 232 that engages the first gear 210 of the gear box assembly 200. The spring 222 is connected to the upper portion 230 such that the upper portion is biased to rotate in the clockwise direction. The upper portion 230 may also include a lower arm 234 that contacts an upper surface of the lower portion 228 of the firing trigger 20 such that when the upper portion 230 is caused to rotate clockwise the lower portion 228 also rotates clockwise, and when the lower portion 228 rotates counter clockwise the upper portion 230 also rotates counter clockwise. Similarly, the lower portion 228 includes a rotational stop 238 that engages a shoulder of the upper portion 230. In that way, when the upper portion 230 is caused to rotate counter clockwise the lower portion 228 also rotates counter clockwise, and when the lower portion 228 rotates clockwise the upper portion 230 also rotates clockwise.

[0057] The illustrated embodiment also includes the run motor sensor 110 that communicates a signal to the motor 65 that, in various embodiments, may cause the motor 65 to rotate at a speed proportional to the force applied by the operator when retracting the firing trigger 20. The sensor 110 may be, for example, a rheostat or some other variable resistance sensor, as explained herein. In addition, the instrument 10 may include reverse motor sensor 130 that is tripped or switched when contacted by a front face 242 of the upper portion 230 of the firing trigger 20. When activated, the reverse motor sensor 130 sends a signal to the motor 65 to reverse direction. Also, the instrument

10 may include a stop motor sensor 142 that is tripped or actuated when contacted by the lower portion 228 of the firing trigger 20. When activated, the stop motor sensor 142 sends a signal to stop the reverse rotation of the motor 65.

[0058] In operation, when an operator retracts the closure trigger 18 into the locked position, the firing trigger 20 is retracted slightly (through mechanisms known in the art, including United States Patent No. 6,978,921 to Frederick Shelton, IV *et. al* and United States Patent No. 6,905,057 to Jeffery S. Swayze *et. al*, which are incorporated herein by reference in their entirety) so that the user can grasp the firing trigger 20 to initiate the cutting/stapling operation, as shown in Figures 32 and 33. At that point, as shown in Figure 33, the gear portion 232 of the upper portion 230 of the firing trigger 20 moves into engagement with the first gear 210 of the gear box assembly 200. When the operator retracts the firing trigger 20, according to various embodiments, the firing trigger 20 may rotate a small amount, such as five degrees, before tripping the run motor sensor 110, as shown in Figure 34. Activation of the sensor 110 causes the motor 65 to forward rotate at a rate proportional to the retraction force applied by the operator. The forward rotation of the motor 65 causes, as described above, the main drive shaft 48 to rotate, which causes the knife 32 in the end effector 12 to be deployed (i.e., begin traversing the channel 22). Rotation of the pinion gear 124, which is connected to the main drive shaft 48, causes the gears 210-220 in the gear box assembly 200 to rotate. Since the first gear 210 is in engagement with the gear portion 232 of the upper portion 230 of the firing trigger 20, the upper portion 232 is caused to rotate counter clockwise, which causes the lower portion 228 to also rotate counter clockwise.

[0059] When the knife 32 is fully deployed (i.e., at the end of the cutting stroke), the front face 242 of the upper portion 230 trips the reverse motor sensor 130, which sends a signal to the motor 65 to reverse rotational directional. This causes the main drive shaft assembly to reverse rotational direction to retract the knife 32. Reverse rotation of the main drive shaft assembly also causes the gears 210-220 in the gear box assembly to reverse direction, which causes the upper portion 230 of the firing trigger 20 to rotate clockwise, which causes the lower portion 228 of the firing trigger 20 to rotate clockwise until the lower portion 228 trips or actuates the stop motor sensor 142 when the knife 32 is fully retracted, which causes the motor 65 to stop. In that way, the user experiences feedback regarding deployment of the end effector 12 by way of the user's grip on the firing trigger 20. Thus, when the user retracts the firing trigger 20, the operator will experience a resistance related to the deployment of the end effector 12 and, in particular, to the loading force experienced by the knife 32. Similarly, when the operator releases the firing trigger 20 after the cutting/stapling operation so that it can return to its original position, the user will experience a clockwise rotation force from the firing trigger 20 that is generally proportional to the reverse speed of the motor 65.

[0060] It should also be noted that in this embodiment the user can apply force (either in lieu of or in addition to the force from the motor 65) to actuate the main drive shaft assembly (and hence the cutting/stapling operation of the end effector 12) through retracting the firing trigger 20. That is, retracting the firing trigger 20 causes the gear portion 232 of the upper portion 230 to rotate counter clockwise, which causes the gears of the gear box assembly 200 to rotate, thereby causing the pinion gear 124 to rotate, which causes the main drive shaft assembly to rotate.

[0061] The above-described embodiments employed power-assist user feedback systems, with or without adaptive control (e.g., using a sensor 110, 130, and 142 outside of the closed loop system of the motor 65, gear drive train, and end effector 12) for a two-stroke, motorized surgical cutting and fastening instrument. That is, force applied by the user in retracting the firing trigger 20 may be added to the force applied by the motor 65 by virtue of the firing trigger 20 being geared into (either directly or indirectly) the gear drive train between the motor 65 and the main drive shaft 48. In other embodiments of the present invention, the user may be provided with tactile feedback regarding the position of the knife 32 in the end effector, but without having the firing trigger 20 geared into the gear drive train. Figures 37-40 illustrate a motorized surgical cutting and fastening instrument with such a tactile position feedback system.

[0062] In the illustrated embodiment of Figures 37-40, the firing trigger 20 may have a lower portion 228 and an upper portion 230, similar to the instrument 10 shown in Figures 32-36. Unlike the embodiment of Figure 32-36, however, the upper portion 230 does not have a gear portion that mates with part of the gear drive train. Instead, the instrument includes a second motor 265 with a threaded rod 266 threaded therein. The threaded rod 266 reciprocates longitudinally in and out of the motor 265 as the motor 265 rotates, depending on the direction of rotation. The instrument 10 also includes an encoder 268 that is responsive to the rotations of the main drive shaft 48 for translating the incremental angular motion of the main drive shaft 48 (or other component of the main drive assembly) into a corresponding series of digital signals, for example. In the illustrated embodiment, the pinion gear 124 includes a proximate drive shaft 270 that connects to the encoder 268.

[0063] The instrument 10 also includes a control circuit (not shown), which may be implemented using a microcontroller or some other type of integrated circuit, that receives the digital signals from the encoder 268. Based on the signals from the encoder 268, the control circuit may calculate the stage of deployment of the knife 32 in the end effector 12. That is, the control circuit can calculate if the knife 32 is fully deployed, fully retracted, or at an intermittent stage. Based on the calculation of the stage of deployment of the end effector 12, the control circuit may send a signal to the second motor 265 to control its rotation to thereby control the reciprocating movement of the threaded rod 266.

[0064] In operation, as shown in Figure 37, when the closure trigger 18 is not locked into the clamped position, the firing trigger 20 rotated away from the pistol grip portion 26 of the handle 6 such that the front face 242 of the upper portion 230 of the firing trigger 20 is not in contact with the proximate end of the threaded rod 266. When the operator retracts the closure trigger 18 and locks it in the clamped position, the firing trigger 20 rotates slightly towards the closure trigger 20 so that the operator can grasp the firing trigger 20, as shown in Figure 38. In this position, the front face 242 of the upper portion 230 contacts the proximate end of the threaded rod 266.

[0065] As the user then retracts the firing trigger 20, after an initial rotational amount (e.g. 5 degrees of rotation) the run motor sensor 110 may be activated such that, as explained above, the sensor 110 sends a signal to the motor 65 to cause it to rotate at a forward speed proportional to the amount of retraction force applied by the operator to the firing trigger 20. Forward rotation of the motor 65 causes the main drive shaft 48 to rotate via the gear drive train, which causes the knife 32 and sled 33 to travel down the

channel 22 and sever tissue clamped in the end effector 12. The control circuit receives the output signals from the encoder 268 regarding the incremental rotations of the main drive shaft assembly and sends a signal to the second motor 265 to cause the second motor 265 to rotate, which causes the threaded rod 266 to retract into the motor 265. This allows the upper portion 230 of the firing trigger 20 to rotate counter clockwise, which allows the lower portion 228 of the firing trigger to also rotate counter clockwise. In that way, because the reciprocating movement of the threaded rod 266 is related to the rotations of the main drive shaft assembly, the operator of the instrument 10, by way of his/her grip on the firing trigger 20, experiences tactile feedback as to the position of the end effector 12. The retraction force applied by the operator, however, does not directly affect the drive of the main drive shaft assembly because the firing trigger 20 is not geared into the gear drive train in this embodiment.

[0066] By virtue of tracking the incremental rotations of the main drive shaft assembly via the output signals from the encoder 268, the control circuit can calculate when the knife 32 is fully deployed (i.e., fully extended). At this point, the control circuit may send a signal to the motor 65 to reverse direction to cause retraction of the knife 32. The reverse direction of the motor 65 causes the rotation of the main drive shaft assembly to reverse direction, which is also detected by the encoder 268. Based on the reverse rotation detected by the encoder 268, the control circuit sends a signal to the second motor 265 to cause it to reverse rotational direction such that the threaded rod 266 starts to extend longitudinally from the motor 265. This motion forces the upper portion 230 of the firing trigger 20 to rotate clockwise, which causes the lower portion 228 to rotate clockwise. In that way, the operator may experience a clockwise force from the firing

trigger 20, which provides feedback to the operator as to the retraction position of the knife 32 in the end effector 12. The control circuit can determine when the knife 32 is fully retracted. At this point, the control circuit may send a signal to the motor 65 to stop rotation.

[0067] According to other embodiments, rather than having the control circuit determine the position of the knife 32, reverse motor and stop motor sensors may be used, as described above. In addition, rather than using a proportional sensor 110 to control the rotation of the motor 65, an on/off switch or sensor can be used. In such an embodiment, the operator would not be able to control the rate of rotation of the motor 65. Rather, it would rotate at a preprogrammed rate.

[0068] Figures 41-43 illustrate an exemplary embodiment of a mechanically actuated endocutter, and in particular, the handle 6, shaft 8, and end effector 12 thereof. Further details of a mechanically actuated endocutter may be found in U.S. Patent Application Serial No. 11/052,632 entitled, "Surgical Stapling Instrument Incorporating A Multi-Stroke Firing Mechanism With Automatic End Of Firing Travel Retraction," which is incorporated herein by reference in its entirety. With reference to Figure 41, the end effector 12 responds to the closure motion from the handle 6 (not depicted in Figure 41) first by including an anvil face 1002 connecting to an anvil proximal end 1004 that includes laterally projecting anvil pivot pins 25 that are proximal to a vertically projecting anvil tab 27. The anvil pivot pins 25 translate within kidney shaped openings 1006 in the staple channel 22 to open and close anvil 24 relative to channel 22. The tab 27 engages a bent tab 1007 extending inwardly in tab opening 45 on a distal end 1008 of the closure tube 1005, the latter distally terminating in a distal edge 1008 that pushes

against the anvil face 1002. Thus, when the closure tube 1005 moves proximally from its open position, the bent tab 1007 of the closure tube 1005 draws the anvil tab 27 proximally, and the anvil pivot pins 25 follow the kidney shaped openings 1006 of the staple channel 22 causing the anvil 24 to simultaneously translate proximally and rotate upward to the open position. When the closure tube 1005 moves distally, the bent tab 1007 in the tab opening 45 releases from the anvil tab 27 and the distal edge 1008 pushes on the anvil face 1002, closing the anvil 24.

[0069] With continued reference to Figure 41, the shaft 8 and end effector 12 also include components that respond to a firing motion of a firing rod 1010. In particular, the firing rod 1010 rotatably engages a firing trough member 1012 having a longitudinal recess 1014. Firing trough member 1012 moves longitudinally within frame 1016 in direct response to longitudinal motion of firing rod 1010. A longitudinal slot 1018 in the closure tube 1005 operably couples with the right and left exterior side handle pieces 61, 62 of the handle 6 (not shown in Figure 41). The length of the longitudinal slot 1018 in the closure tube 1005 is sufficiently long to allow relative longitudinal motion with the handle pieces 61, 62 to accomplish firing and closure motions respectively with the coupling of the handle pieces 61, 62 passing on through a longitudinal slot 1020 in the frame 1016 to slidingly engage the longitudinal recess 1014 in the frame trough member 1012.

[0070] The distal end of the frame trough member 1012 is attached to a proximal end of a firing bar 1022 that moves within the frame 1016, specifically within a guide 1024 therein, to distally project the knife 32 into the end effector 12. The end effector 12 includes a staple cartridge 34 that is actuated by the knife 32. The staple cartridge 34 has

a tray 1028 that holds a staple cartridge body 1030, a wedge sled driver 33, staple drivers 1034, and staples 1036. It will be appreciated that the wedge sled driver 33 longitudinally moves within a firing recess (not shown) located between the cartridge tray 1028 and the cartridge body 1030. The wedge sled driver 33 presents camming surfaces that contact and lift the staple drivers 1034 upward, driving the staples 1036. The staple cartridge body 1030 further includes a proximally open, vertical slot 1031 for passage of the knife 32. Specifically, a cutting surface 1027 is provided along a distal end of knife 32 to cut tissue after it is stapled.

[0071] It should be appreciated that the shaft 8 is shown in Figure 4 as a non-articulating shaft. Nonetheless, applications of the present invention may include instruments capable of articulation, for example, as such shown above with reference to Figures 1-4 and described in the following U.S. patents and patent applications, the disclosure of each being hereby incorporated by reference in their entirety: (1) "SURGICAL INSTRUMENT INCORPORATING AN ARTICULATION MECHANISM HAVING ROTATION ABOUT THE LONGITUDINAL AXIS", U.S. Patent Application Publication No. 2005/0006434, by Frederick E. Shelton IV, Brian J. Hemmelgarn, Jeffrey S. Swayze, Kenneth S. Wales, filed 9 Jul. 2003; (2) "SURGICAL STAPLING INSTRUMENT INCORPORATING AN ARTICULATION JOINT FOR A FIRING BAR TRACK", U.S. Patent No. 6,786,382, to Brian J. Hemmelgarn; (3) "A SURGICAL INSTRUMENT WITH A LATERAL-MOVING ARTICULATION CONTROL", U.S. Patent No. 6,981,628, to Jeffrey S. Swayze; (4) "SURGICAL STAPLING INSTRUMENT INCORPORATING A TAPERED FIRING BAR FOR INCREASED FLEXIBILITY AROUND THE ARTICULATION JOINT", U.S. Patent

No. 6,964,363, to Frederick E. Shelton IV, Michael Setser, Bruce Weisenburgh II; and (5) "SURGICAL STAPLING INSTRUMENT HAVING ARTICULATION JOINT SUPPORT PLATES FOR SUPPORTING A FIRING BAR", U.S. Patent Application Publication No. 2005/0006431, by Jeffrey S. Swayze, Joseph Charles Hueil, filed 9 Jul. 2003.

[0072] Figures 42-43 show an embodiment of the handle 6 that is configured for use in a mechanically actuated endocutter along with the embodiment of the shaft 8 and end effector 12 as shown above in Figure 41. It will be appreciated that any suitable handle design may be used to mechanically close and fire the end effector 12. In Figures 42-43, the handle 6 of the surgical stapling and severing instrument 10 includes a linked transmission firing mechanism 1060 that provides features such as increased strength, reduced handle size, minimized binding, *etc.*

[0073] Closure of the end effector 12 (not shown in Figures 42-43) is caused by depressing the closure trigger 18 toward the pistol grip 26 of handle 6. The closure trigger 18 pivots about a closure pivot pin 252 that is coupled to right and left exterior lower sidepieces 59, 60 the handle 6, causing an upper portion 1094 of the closure trigger 18 to move forward. The closure tube 1005 receives this closure movement via the closure yoke 250 that is pinned to a closure link 1042 and to the upper portion 1094 of the closure trigger 18 respectively by a closure yoke pin 1044 and a closure link pin 1046.

[0074] In the fully open position of Figure 42, the upper portion 1094 of the closure trigger 18 contacts and holds a locking arm 1048 of the pivoting closure release button 30 in the position shown. When the closure trigger 18 reaches its fully depressed position,

the closure trigger 18 releases the locking arm 1048 and an abutting surface 1050 rotates into engagement with a distal rightward notch 1052 of the pivoting locking arm 1048, holding the closure trigger 18 in this clamped or closed position. A proximal end of the locking arm 1048 pivots about a lateral pivotal connection 1054 with the pieces 59, 60 to expose the closure release button 30. An intermediate, distal side 1056 of the closure release button 30 is urged proximally by a compression spring 1058, which is compressed between a housing structure 1040 and closure release button 30. The result is that the closure release button 30 urges the locking arm 1048 counterclockwise (when viewed from the left) into locking contact with the abutting surface 1050 of closure trigger 18, which prevents unclamping of closure trigger 18 when the linked transmission firing system 1040 is in an un-retracted condition.

[0075] With the closure trigger 18 retracted and fully depressed, the firing trigger 20 is unlocked and may be depressed toward the pistol grip 26, multiple times in this embodiment, to effect firing of the end effector 12. As depicted, the linked transmission firing mechanism 1060 is initially retracted, urged to remain in this position by a combination tension/compression spring 1062 that is constrained within the pistol grip 26 of the handle 6, with its nonmoving end 1063 connected to the pieces 59, 60 and a moving end 1064 connected to a downwardly flexed and proximal, retracted end 1067 of a steel band 1066.

[0076] A distally-disposed end 1068 of the steel band 1066 is attached to a link coupling 1070 for structural loading, which in turn is attached to a front link 1072a of a plurality of links 1072a-1072d that form a linked rack 1074. Linked rack 1074 is flexible yet has distal links that form a straight rigid rack assembly that may transfer a significant

firing force through the firing rod 1010 in the shaft 6, yet readily retract into the pistol grip 26 to minimize the longitudinal length of the handle 6. It should be appreciated that the combination tension/compression spring 1062 increases the amount of firing travel available while essentially reducing the minimum length by half over a single spring.

[0077] The firing trigger 20 pivots about a firing trigger pin 96 that is connected to the handle pieces 59, 60. An upper portion 228 of the firing trigger 20 moves distally about the firing trigger pin 96 as the firing trigger 20 is depressed towards pistol grip 26, stretching a proximally placed firing trigger tension spring 222 proximally connected between the upper portion 228 of the firing trigger 20 and the pieces 59, 60. The upper portion 228 of the firing trigger 20 engages the linked rack 1074 during each firing trigger depression by a traction biasing mechanism 1078 that also disengages when the firing trigger 20 is released. Firing trigger tension spring 222 urges the firing trigger 20 distally when released and disengages the traction biasing mechanism 1078.

[0078] As the linked transmission firing mechanism 1040 actuates, an idler gear 1080 is rotated clockwise (as viewed from the left side) by engagement with a toothed upper surface 1082 of the linked rack 1074. This rotation is coupled to an indicator gear 1084, which thus rotates counterclockwise in response to the idler gear 1080. Both the idler gear 1080 and indicator gear 1084 are rotatably connected to the pieces 59, 60 of the handle 6. The gear relationship between the linked rack 1074, idler gear 1080, and indicator gear 1084 may be advantageously selected so that the toothed upper surface 1082 has tooth dimensions that are suitably strong and that the indicator gear 1084 makes no more than one revolution during the full firing travel of the linked transmission firing mechanism 1060.

[0079] As described in greater detail below, the indicator gear 1084 performs at least four functions. First, when the linked rack 1074 is fully retracted and both triggers 18, 20 are open as shown in Figure 42, an opening 1086 in a circular ridge 1088 on the left side of the indicator gear 1084 is presented to an upper surface 1090 of the locking arm 1048. Locking arm 1048 is biased into the opening 1086 by contact with the closure trigger 18, which in turn is urged to the open position by a closure tension spring 1092. Closure trigger tension spring 1092 is connected proximally to the upper portion 1094 of the closure trigger 18 and the handle pieces 59, 60, and thus has energy stored during closing of the closure trigger 18 that urges the closure trigger 18 distally to its unclosed position.

[0080] A second function of the indicator gear 1084 is that it is connected to the indicating retraction knob 1096 externally disposed on the handle 6. Thus, the indicator gear 1084 communicates the relative position of the firing mechanism 1060 to the indicating retraction knob 1096 so that the surgeon has a visual indication of how many strokes of the firing trigger 20 are required to complete firing.

[0081] A third function of the indicator gear 1084 is to longitudinally and angularly move an anti-backup release lever 1098 of an anti-backup mechanism (one-way clutch mechanism) 1097 as the surgical stapling and severing instrument 10 is operated. During the firing strokes, proximal movement of anti-backup release lever 1098 by indicator gear 1084 activates the anti-backup mechanism 1097 that allows distal movement of firing bar 1010 and prevents proximal motion of firing bar 1010. This movement also extends the anti-backup release button 1100 from the proximal end of the handle pieces 59, 60 for the operator to actuate should the need arise for the linked transmission firing mechanism 1060 to be retracted during the firing strokes. After completion of the firing strokes, the

indicator gear 1084 reverses direction of rotation as the firing mechanism 1060 retracts. The reversed rotation deactivates the anti-backup mechanism 1097, withdraws the anti-backup release button 1100 into the handle 6, and rotates the anti-backup release lever 1098 laterally to the right to allow continued reverse rotation of the indicator gear 1084.

[0082] A fourth function of the indicator gear 1084 is to receive a manual rotation from the indicating retraction knob 1096 (clockwise in the depiction of Figure 42) to retract the firing mechanism 1060 with anti-backup mechanism 1097 unlocked, thereby overcoming any binding in the firing mechanism 1060 that is not readily overcome by the combination tension/compression spring 1062. This manual retraction assistance may be employed after a partial firing of the firing mechanism 1060 that would otherwise be prevented by the anti-backup mechanism 1097 that withdraws the anti-backup release button 1100 so that the latter may not laterally move the anti-backup release lever 1098.

[0083] Continuing with Figures 42-43, anti-backup mechanism 1097 consists of the operator accessible anti-backup release lever 1098 operably coupled at the proximal end to the anti-backup release button 1100 and at the distal end to an anti-backup yoke 1102. In particular, a distal end 1099 of the anti-backup release lever 1098 is engaged to the anti-backup yoke 1102 by an anti-backup yoke pin 1104. The anti-backup yoke 1102 moves longitudinally to impart a rotation to an anti-backup cam slot tube 1106 that is longitudinally constrained by the handle pieces 59, 90 and that encompasses the firing rod 1010 distally to the connection of the firing rod 1010 to the link coupling 1070 of the linked rack 1074. The anti-backup yoke 1102 communicates the longitudinal movement from the anti-backup release lever 1098 via a cam slot tube pin 1108 to the anti-backup cam slot tube 1106. That is, longitudinal movement of cam slot tube pin 1108 in an

angled slot in the anti-backup cam slot tube 1106 rotates the anti-backup cam slot tube 1106.

[0084] Trapped between a proximal end of the frame 1016 and the anti-backup cam slot tube 1106 respectively are an anti-backup compression spring 1110, an anti-backup plate 1112, and an anti-backup cam tube 1114. As depicted, proximal movement of the firing rod 1010 causes the anti-backup plate 1112 to pivot top to the rear, presenting an increased frictional contact to the firing rod 1010 that resists further proximal movement of the firing rod 1010.

[0085] This anti-backup plate 1112 pivots in a manner similar to that of a screen door lock that holds open a screen door when the anti-backup cam slot tube 1106 is closely spaced to the anti-backup cam tube 1114. Specifically, the anti-backup compression spring 1110 is able to act upon a top surface of the plate 1112 to tip the anti-backup plate 1112 to its locked position. Rotation of the anti-backup cam slot tube 1106 causes a distal camming movement of the anti-backup cam tube 1114 thereby forcing the top of the anti-backup plate 1112 distally, overcoming the force from the anti-backup compression spring 1110, thus positioning the anti-backup plate 1112 in an untipped (perpendicular), unlocked position that allows proximal retraction of the firing rod 1010.

[0086] With particular reference to Figure 43, the traction biasing mechanism 1078 is depicted as being composed of a pawl 1116 that has a distally projecting narrow tip 1118 and a rightwardly projecting lateral pin 1120 at its proximal end that is rotatably inserted through a hole 1076 in the upper portion 230 of the firing trigger 20. On the right side of the firing trigger 20 the lateral pin 1120 receives a biasing member, depicted as biasing wheel 1122. As the firing trigger 20 translates fore and aft, the biasing wheel 1122

traverses an arc proximate to the right half piece 59 of the handle 6, overrunning at its distal portion of travel a biasing ramp 1124 integrally formed in the right half piece 59. The biasing wheel 1122 may advantageously be formed from a resilient, frictional material that induces a counterclockwise rotation (when viewed from the left) into the lateral pin 1120 of the pawl 1116, thus traction biasing the distally projecting narrow tip 1118 downward into a ramped central track 1075 of the nearest link 1072a-d to engage the linked rack 1074.

[0087] As the firing trigger 20 is released, the biasing wheel 1122 thus tractionally biases the pawl 1116 in the opposite direction, raising the narrow tip 1118 from the ramped central track 1075 of the linked rack 1074. To ensure disengagement of the tip 1118 under high load conditions and at nearly full distal travel of the pawl 1116, the right side of the pawl 1116 ramps up onto a proximally and upwardly facing beveled surface 1126 on the right side of the closure yoke 250 to disengage the narrow tip 1118 from the ramped central track 1075. If the firing trigger 20 is released at any point other than full travel, the biasing wheel 1122 is used to lift the narrow tip 1118 from the ramped central track 1075. Whereas a biasing wheel 1122 is depicted, it should be appreciated that the shape of the biasing member or wheel 1122 is illustrative and may be varied to accommodate a variety of shapes that use friction or traction to engage or disengage the firing of the end effector 12.

[0088] Various embodiments of the surgical instrument 10 have the capability to record instrument conditions at one or more times during use. Figure 44 shows a block diagram of a system 2000 for recording conditions of the instrument 10. It will be appreciated that the system 2000 may be implemented in embodiments of the instrument 10 having

motorized or motor-assisted firing, for example, as described above with reference to Figures 1-40, as well as embodiments of the instrument 10 having mechanically actuated firing, for example, as described above with reference to figures 41-43.

[0089] The system 2000 may include various sensors 2002, 2004, 2006, 2008, 2010, 2012 for sensing instrument conditions. The sensors may be positioned, for example, on or within the instrument 10. In various embodiments, the sensors may be dedicated sensors that provide output only for the system 2000, or may be dual-use sensors that perform other functions with in the instrument 10. For example, sensors 110, 130, 142 described above may be configured to also provide output to the system 2000.

[0090] Directly or indirectly, each sensor provides a signal to the memory device 2001, which records the signals as described in more detail below. The memory device 2001 may be any kind of device capable of storing or recording sensor signals. For example, the memory device 2001 may include a microprocessor, an Electrically Erasable Programmable Read Only Memory (EEPROM), or any other suitable storage device. The memory device 2001 may record the signals provided by the sensors in any suitable way. For example, in one embodiment, the memory device 2001 may record the signal from a particular sensor when that signal changes states. In another embodiment, the memory device 2001 may record a state of the system 2000, *e.g.*, the signals from all of the sensors included in the system 2000, when the signal from any sensor changes states. This may provide a snap-shot of the state of the instrument 10. In various embodiments, the memory device 2001 and/or sensors may be implemented to include 1-WIRE bus products available from DALLAS SEMICONDUCTOR such as, for example, a 1-WIRE EEPROM.

[0091] In various embodiments, the memory device 2001 is externally accessible, allowing an outside device, such as a computer, to access the instrument conditions recorded by the memory device 2001. For example, the memory device 2001 may include a data port 2020. The data port 2020 may provide the stored instrument conditions according to any wired or wireless communication protocol in, for example, serial or parallel format. The memory device 2001 may also include a removable medium 2021 in addition to or instead of the output port 2020. The removable medium 2021 may be any kind of suitable data storage device that can be removed from the instrument 10. For example, the removable medium 2021 may include any suitable kind of flash memory, such as a Personal Computer Memory Card International Association (PCMCIA) card, a COMPACTFLASH card, a MULTIMEDIA card, a FLASHMEDIA card, *etc.* The removable medium 2021 may also include any suitable kind of disk-based storage including, for example, a portable hard drive, a compact disk (CD), a digital video disk (DVD), *etc.*

[0092] The closure trigger sensor 2002 senses a condition of the closure trigger 18. Figures 45 and 46 show an exemplary embodiment of the closure trigger sensor 2002. In Figures 45 and 46, the closure trigger sensor 2002 is positioned between the closure trigger 18 and closure pivot pin 252. It will be appreciated that pulling the closure trigger 18 toward the pistol grip 26 causes the closure trigger 18 to exert a force on the closure pivot pin 252. The sensor 2002 may be sensitive to this force, and generate a signal in response thereto, for example, as described above with respect to sensor 110 and Figures 10A and 10B. In various embodiments, the closure trigger sensor 2002 may be a digital sensor that indicates only whether the closure trigger 18 is actuated or not actuated. In

other various embodiments, the closure trigger sensor 2002 may be an analog sensor that indicates the force exerted on the closure trigger 18 and/or the position of the closure trigger 18. If the closure trigger sensor 2002 is an analog sensor, an analog-to-digital converter may be logically positioned between the sensor 2002 and the memory device 2001. Also, it will be appreciated that the closure trigger sensor 2002 may take any suitable form and be placed at any suitable location that allows sensing of the condition of the closure trigger.

[0093] The anvil closure sensor 2004 may sense whether the anvil 24 is closed. Figure 47 shows an exemplary anvil closure sensor 2004. The sensor 2004 is positioned next to, or within the kidney shaped openings 1006 of the staple channel 22 as shown. As the anvil 24 is closed, anvil pivot pins 25 slides through the kidney shaped openings 1006 and into contact with the sensor 2004, causing the sensor 2004 to generate a signal indicating that the anvil 24 is closed. The sensor 2004 may be any suitable kind of digital or analog sensor including a proximity sensor, *etc.* It will be appreciated that when the anvil closure sensor 2004 is an analog sensor, an analog-to-digital converter may be included logically between the sensor 2004 and the memory device 2001.

[0094] Anvil closure load sensor 2006 is shown placed on an inside bottom surface of the staple channel 22. In use, the sensor 2006 may be in contact with a bottom side of the staple cartridge 34 (not shown in Figure 46). As the anvil 24 is closed, it exerts a force on the staple cartridge 34 that is transferred to the sensor 2006. In response, the sensor 2006 generates a signal. The signal may be an analog signal proportional to the force exerted on the sensor 2006 by the staple cartridge 34 and due to the closing of the anvil 24. Referring the Figure 44, the analog signal may be provided to an analog-to-digital

converter 2014, which converts the analog signal to a digital signal before providing it to the memory device 2001. It will be appreciated that embodiments where the sensor 2006 is a digital or binary sensor may not include analog-to-digital converter 2014.

[0095] The firing trigger sensor 110 senses the position and/or state of the firing trigger 20. In motorized or motor-assisted embodiments of the instrument, the firing trigger sensor may double as the run motor sensor 110 described above. In addition, the firing trigger sensor 110 may take any of the forms described above, and may be analog or digital. Figures 45 and 46 show an additional embodiment of the firing trigger sensor 110. In Figures 45 and 46, the firing trigger sensor is mounted between firing trigger 20 and firing trigger pivot pin 96. When firing trigger 20 is pulled, it will exert a force on firing trigger pivot pin 96 that is sensed by the sensor 110. Referring to Figure 44, In embodiments where the output of the firing trigger sensor 110 is analog, analog-to-digital converter 2016 is included logically between the firing trigger sensor 110 and the memory device 2001.

[0096] The knife position sensor 2008 senses the position of the knife 32 or cutting surface 1027 within the staple channel 22. Figures 47 and 48 show embodiments of a knife position sensor 2008 that are suitable for use with the mechanically actuated shaft 8 and end effector 12 shown in Figure 41. The sensor 2008 includes a magnet 2009 coupled to the firing bar 1022 of the instrument 10. A coil 2011 is positioned around the firing bar 1022, and may be installed; for example, along the longitudinal recess 1014 of the firing trough member 1012 (see Figure 41). As the knife 32 and cutting surface 1027 are reciprocated through the staple channel 22, the firing bar 1022 and magnet 2009 may move back and forth through the coil 2011. This motion relative to the coil induces a

voltage in the coil proportional to the position of the firing rod within the coil and the cutting edge 1027 within the staple channel 22. This voltage may be provided to the memory device 2001, for example, via analog-to-digital converter 2018.

[0097] In various embodiments, the knife position sensor 2008 may instead be implemented as a series of digital sensors (not shown) placed at various positions on or within the shaft 8. The digital sensors may sense a feature of the firing bar 1022 such as, for example, magnet 2009, as the feature reciprocates through the shaft 8. The position of the firing bar 1022 within the shaft 8, and by extension, the position of the knife 32 within the staple channel 22, may be approximated as the position of the last digital sensor tripped.

[0098] It will be appreciated that the knife position may also be sensed in embodiments of the instrument 10 having a rotary driven end effector 12 and shaft 8, for example, as described above, with reference to Figures 3-6. An encoder, such as encoder 268, may be configured to generate a signal proportional to the rotation of the helical screw shaft 36, or any other drive shaft or gear. Because the rotation of the shaft 36 and other drive shafts and gears is proportional to the movement of the knife 32 through the channel 22, the signal generated by the encoder 268 is also proportional to the movement of the knife 32. Thus, the output of the encoder 268 may be provided to the memory device 2001.

[0099] The cartridge present sensor 2010 may sense the presence of the staple cartridge 34 within the staple channel 22. In motorized or motor-assisted instruments, the cartridge present sensor 2010 may double as the cartridge lock-out sensor 136 described above with reference to Figure 11. Figures 50 and 51 show an embodiment of the cartridge present sensor 2010. In the embodiment shown, the cartridge present sensor 2010

includes two contacts, 2011 and 2013. When no cartridge 34 is present, the contacts 2011, 2013 form an open circuit. When a cartridge 34 is present, the cartridge tray 1028 of the staple cartridge 34 contacts the contacts 2011, 2013, a closed circuit is formed. When the circuit is open, the sensor 2010 may output a logic zero. When the circuit is closed, the sensor 2010 may output a logic one. The output of the sensor 2010 is provided to memory device 2001, as shown in Figure 44.

[0100] The cartridge condition sensor 2012 may indicate whether a cartridge 34 installed within the staple channel 22 has been fired or spent. As the knife 32 is translated through the end effector 12, it pushes the sled 33, which fires the staple cartridge. Then the knife 32 is translated back to its original position, leaving the sled 33 at the distal end of the cartridge. Without the sled 33 to guide it, the knife 32 may fall into lock-out pocket 2022. Sensor 2012 may sense whether the knife 32 is present in the lock-out pocket 2022, which indirectly indicates whether the cartridge 34 has been spent. It will be appreciated that in various embodiments, sensor 2012 may directly sense the present of the sled at the proximate end of the cartridge 34, thus eliminating the need for the knife 32 to fall into the lock-out pocket 2022.

[0101] Figures 52A and 52B depict a process flow 2200 for operating embodiments of the surgical instrument 10 configured as an endocutter and having the capability to record instrument conditions according to various embodiments. At box 2202, the anvil 24 of the instrument 10 may be closed. This causes the closure trigger sensor 2002 and or the anvil closure sensor 2006 to change state. In response, the memory device 2001 may record the state of all of the sensors in the system 2000 at box 2203. At box 2204, the instrument 10 may be inserted into a patient. When the instrument is inserted, the anvil

24 may be opened and closed at box 2206, for example, to manipulate tissue at the surgical site. Each opening and closing of the anvil 24 causes the closure trigger sensor 2002 and/or the anvil closure sensor 2004 to change state. In response, the memory device 2001 records the state of the system 2000 at box 2205.

[0102] At box 2208, tissue is clamped for cutting and stapling. If the anvil 24 is not closed at decision block 2210, continued clamping is required. If the anvil 24 is closed, then the sensors 2002, 2004, and/or 2006 may change state, prompting the memory device 2001 to record the state of the system at box 2213. This recording may include a closure pressure received from sensor 2006. At box 2212, cutting and stapling may occur. Firing trigger sensor 110 may change state as the firing trigger 20 is pulled toward the pistol grip 26. Also, as the knife 32 moves through the staple channel 22, knife position sensor 2008 will change state. In response, the memory device 2001 may record the state of the system 2000 at box 2013.

[0103] When the cutting and stapling operations are complete, the knife 32 may return to a pre-firing position. Because the cartridge 34 has now been fired, the knife 32 may fall into lock-out pocket 2022, changing the state of cartridge condition sensor 2012 and triggering the memory device 2001 to record the state of the system 2000 at box 2015. The anvil 24 may then be opened to clear the tissue. This may cause one or more of the closure trigger sensor 2002, anvil closure sensor 2004 and anvil closure load sensor 2006 to change state, resulting in a recordation of the state of the system 2000 at box 2017. After the tissue is cleared, the anvil 24 may be again closed at box 2220. This causes another state change for at least sensors 2002 and 2004, which in turn causes the memory

device 2001 to record the state of the system at box 2019. Then the instrument 10 may be removed from the patient at box 2222.

[0104] If the instrument 10 is to be used again during the same procedure, the anvil may be opened at box 2224, triggering another recordation of the system state at box 2223. The spent cartridge 34 may be removed from the end effector 12 at box 2226. This causes cartridge present sensor 2010 to change state and cause a recordation of the system state at box 2225. Another cartridge 34 may be inserted at box 2228. This causes a state change in the cartridge present sensor 2010 and a recordation of the system state at box 2227. If the other cartridge 34 is a new cartridge, indicated at decision block 2230, its insertion may also cause a state change to cartridge condition sensor 2012. In that case, the system state may be recorded at box 2231.

[0105] Figure 53 shows an exemplary memory map 2300 from the memory device 2001 according to various embodiments. The memory map 2300 includes a series of columns 2302, 2304, 2306, 2308, 2310, 2312, 2314, 2316 and rows (not labeled). Column 2302 shows an event number for each of the rows. The other columns represent the output of one sensor of the system 2000. All of the sensor readings recorded at a given time may be recorded in the same row under the same event number. Hence, each row represents an instance where one or more of the signals from the sensors of the system 2000 are recorded.

[0106] Column 2304 lists the closure load recorded at each event. This may reflect the output of anvil closure load sensor 2006. Column 2306 lists the firing stroke position. This may be derived from the knife position sensor 2008. For example, the total travel of the knife 32 may be divided into partitions. The number listed in column 2306 may

represent the partition where the knife 32 is currently present. The firing load is listed in column 2308. This may be derived from the firing trigger sensor 110. The knife position is listed at column 2310. The knife position may be derived from the knife position sensor 2008 similar to the firing stroke. Whether the anvil 24 is open or closed may be listed at column 2312. This value may be derived from the output of the anvil closure sensor 2004 and/or the anvil closure load sensor 2006. Whether the sled 33 is present, or whether the cartridge 34 is spent, may be indicated at column 2314. This value may be derived from the cartridge condition sensor 2012. Finally, whether the cartridge 34 is present may be indicated a column 2316. This value may be derived from cartridge present sensor 2010. It will be appreciated that various other values may be stored at memory device 2001 including, for example, the end and beginning of firing strokes, for example, as measured by sensors 130, 142.

[0107] Figures 54 and 55 show another embodiment of the system 2000. The illustrated embodiment of Figure 54 is similar to that of Figure 44, except that in Figure 54 the sensors 2002-2010 are in communication with a control unit 2400, preferably located in the handle 6 of the instrument, and more preferably in the pistol grip portion 26 of the handle 6. The control unit 2400 may comprise a processor 2402 and the memory device 2001. The memory device 2001 may comprise a read-only memory unit 2404, and a read-write memory unit 2406. The control unit 2400 may also comprise analog-to-digital converters (ADC) and digital-to-analog converters (DAC) (not shown) for communicating with the sensors 2002-2010. The read-only memory unit 2404 may comprise EPROM and/or flash EEPROM memory units. The read-write memory unit 2406 may comprise a volatile memory unit such a random access memory (RAM) unit.

The various components of the control unit 2400 may be discrete or they may be integrated in one or a few components. For example, in one embodiment, the processor 2402, ROM 2404, RAM 2406, DACs, and ADCs may be part of a microcontroller or computer-on-a-chip.

[0108] The control unit 2400 may be powered by a power source 2408, such as a battery. For instruments 10 having a DC motor for powering the end effector, the power source 2408 that powers the control unit 2400 may be the same power source that powers the motor, or different power sources may be used for the control unit 2400 and the motor 65.

[0109] Output from the various sensors may be stored in digital form in one or both of the memory units 2404, 2406. Published U.S. patent application Pub. No. 2007/0175964 A1, which is incorporated herein by reference in its entirety, discloses an endocutter having a memory device for storing and recording sensor data. The output from some of the above-mentioned sensors may be in analog form. For such types of sensors, the ADCs may be used to convert the analog sensor signals to digital form for storing in the memory units 2404, 2406. Also, the sensors may be coupled to the control unit 2400 via wired and/or wireless communication links. For example, the sensors and the control unit 2400 may communicate via a 1-WIRE or I^2C bus. For embodiments where the sensors communicate with the control unit 2400 wirelessly, the sensors may comprise transponders that communicate with a transceiver (not shown) of the control unit 2400.

[0110] Although not shown in Figure 44, the instrument 10 may also comprise one or more articulation sensors that sense the state of articulation of the end effector. For example, the articulation sensors may be located in or near the articulation pivot and

sense the relative articulation between the end effector 12 and the shaft 8. The articulation sensors may also be in communication with the control unit 2400 and the data from the articulation sensors may be stored in the memory device 2001 of the control unit 2400. U.S. patent application Serial No. 12/124,655, entitled "Surgical Instrument With Automatically Reconfigurable Articulating End Effector," filed May 21, 2008, which is hereby incorporated by reference in its entirety, provides more details regarding such articulation sensors. In addition, the sensors may include various motor-related sensors that detect conditions of the motor 65, such as RPM, etc.

[0111] According to various embodiments, the data stored in the memory device 2001 may be encrypted. For example, one of the memory units 2404, 2406, such as the ROM 2404, may stored encryption code or software that when executed by the processor 2402 causes the processor 2402 to encrypt the sensor data received from the sensors and stored in the memory device 2001.

[0112] The control unit 2400 may also have an output port 2020 that is externally accessible by a remote computer device 2420 via a communication link 2422 connected to the output port 2020. The communication link 2422 may be a wired or wireless communication link. For example, the output port 2020 may comprise a serial data port such as a USB port (including Type A, Type B, Mini-A, or Mini-B USB ports), a IEEE 1394 interface port (including IEEE 1394a, 1394b, or 1394c), a RS-232 port, a RS-423 port, a RS-485 port, an optical port, such as a SONET or SDH port, or any other suitable serial data port for a wired serial data communication link 2422. Also, the communications link 2422 may be a parallel data communications link, such as ISA, ATA, SCSI, or PCI. The output port 2020 may be a corresponding parallel data output

port in such circumstances. In addition, the communications link 2422 may be a wireless data link, such as a link that uses one of the IEEE 802.11 standards.

[0113] The remote computer device 2420 may be any device with a processor and a memory, and capable of communicating with the control unit 2400 and downloading the sensor data stored in the memory device 2001. For example, the remote computer device 2420 may be a desktop computer, a laptop computer, a server, a workstation, a palmtop computer, a minicomputer, a wearable computer, etc. That remote computer device 2420 may be external of the instrument 10 (i.e., not part of the instrument 10) and may be located relatively close to the instrument 10 when the data is downloaded to the computer device 2420, or the computer device 2420 may be located farther away from the instrument 10, such as in an adjoining room or even farther away.

[0114] Figure 56 is a flow chart illustrating a process according to various embodiments of the present invention. The process starts at step 2500 where the clinician performs a surgical procedure using the instrument 10. At step 2502, the various sensors in the instrument capture data and transmit it to the control unit 2400. At step 2504, the data may be encrypted by the control unit 2400 and, at step 2506, the encrypted data is stored in the memory unit 2001. In other embodiments, the data need not be encrypted or only a portion of the sensed data is encrypted. Then, at step 2508, a data link is established between the remote computer device 2420 and the control unit 2400, such as via the output port 2020. Then, at step 2510, some or all of the data stored in the memory unit 2001 from the sensors is downloaded to the remote computer device 2420. For embodiments where the stored data is encrypted, the remote computer device 2420 may decrypt the data before or after it is loaded to a memory device in the remote computer

device 2420. At step 2512, the data, now stored in the remote computer device 2420 may be manipulated. For example, calculations or analysis may be carried out on the data, or it could be downloaded or transferred to another storage medium.

[0115] In one expression of the devices disclosed herein, the cartridge 34 may include a means to communicate with a cartridge sensor installed in instrument 10 the type of cartridge installed. Cartridge 34 may be equipped with an RFID tag that communicates, among other things, cartridge type. For example, when stapling thin tissue, a user may select a cartridge that forms staples in a smaller height than that used when stapling thick tissue. The cartridge type determines the clearance available for tissue between the cartridge deck and the anvil. As is known and understood in the art, cartridges are manufactured in a variety of closed staple heights ranging from 2.0mm to 5.0mm.

[0116] Discrete heights are typically denoted by a unique cartridge color, which provides visual feedback to a user of the device. If a user attempts to fire a cartridge meant for thin tissue on thick tissue, the user may experience higher forces when closing the jaws and the motor may experience greater load when driving the sled 33. In this example, due to the thick nature of the tissue in the jaws, the gap between the cartridge deck and the anvil pockets may be so great as to prevent the proper formation of staples. This may lead to bleeding or staple line dehiscence. Conversely, if the user selects a cartridge adapted to be used in thick tissue, the formed staple height may not provide sufficient compressive force to prevent bleeding or leakage.

[0117] During the firing sequence, motor 65 may experience different loads depending upon the amount and type of tissue present in the jaws of instrument 10. A microprocessor or memory device 2001 may interface with motor 65 and record some of

the motor's parameters including RPM, current, voltage, capacitance or resistance as well as the duration of the firing stroke. In addition, the time and date may also be recorded along with cartridge 34 identifying information as well as instrument 10 identifying information. This data may then be stored in memory 2001 or transmitted via data port 2020 or wirelessly over a wireless protocol as is known and understood in the art.

[0118] To facilitate wireless transmission, instrument 10 may be equipped with a Bluetooth transceiver that communicates with any paired Bluetooth device within transmission range of instrument 10. In one embodiment, the receiving device may be a smart phone equipped with an application that receives the transmitted information and formats it for display and manipulation by the smart phone user. The application may transmit the received information, along with the user's name, email address, hospital name or account name and GPS location, to a central database.

[0119] Upon receiving the motor 65 parameters after a firing sequence in a central database, an algorithm may store the data according to instrument and cartridge type. The algorithm may further compare the received information against known or predicted values based upon the instrument 10 and cartridge 34 combination. For example, when firing the instrument 10 with a blue or medium tissue thickness cartridge, the algorithm may predict that the motor would draw 3-4A. If the motor drew more current than predicted, the user of instrument 10 might have selected the wrong thickness cartridge. In this case, the algorithm may transmit an alert to the smart phone that originated the message containing the motor information, alerting the user that the instrument 10 operated outside of its predicted range. The algorithm may further suggest a different

cartridge 34. This may be done in real time, or the application may generate a report that may be emailed to the user.

[0120] The application may solicit information through the smart phone interface (or any other interface on any device capable of operating the application as is known and understood in the art) such as procedure type, tissue type, surgeon name, and hospital name. This information may then be added to the central database to further refine the predicted motor parameters.

[0121] Referring now to Figure 57, a flow chart illustrating the process described above is set forth. The process starts at step 5710 where a cartridge 34 is loaded into the instrument 10 and the cartridge type is detected by cartridge sensor. At step 5720, the instrument 10 is fired and the various sensors in the instrument 10 capture motor data and store it in local memory or transmit it to the control unit 2400. At step 5730, the data may be encrypted by the control unit 2400 and, at steps 5730 and 5740, the encrypted data is stored in the memory unit 2001. In other embodiments, the data need not be encrypted or only a portion of the sensed data is encrypted. Then, at step 5750, a data link is established between the remote computer device 2420 and the control unit 2400, such as via the output port 2020. Where instrument 10 is equipped with a Bluetooth transceiver module, the data may be transmitted to a paired Bluetooth device.

[0122] Then, at step 5760, some or all of the data stored in the memory unit 2001 from the sensors is transmitted to a paired Bluetooth device having an application to receive, store and further transmit the information to a central database on a remote computer device via WiFi or over a cellular network, as is known and understood in the art. For embodiments where the stored data is encrypted, the paired Bluetooth device may

decrypt the data. At step 5770, the data, now stored in the remote computer device is compared to expected motor data for the type of cartridge employed. If, as stated above, the motor operated outside of expected parameters, the application may communicate an alert back to the device running the application that the motor operated outside of expected parameters.

[0123] Referring now to Figure 58, a system for communicating real time and near real time information between a user of instrument 10 and a remote database is disclosed. As stated above, instrument 10 is configured, in one expression, with an RF (e.g. Bluetooth) transceiver. Information captured during instrument 10 firing is transmitted via an RF link to a handheld device 5820. The handheld device 5820, in one expression, is running an application that stores the transmitted information. The application may also solicit information from the user such as type of surgical case, hospital name, surgeon name, type of tissue into which the instrument 10 was fired. The application may also automatically ascertain its GPS position as well as date and time. This information is transmitted to a remote computer 2420 via an internet 5830. A central database program 5840 on computer 2420 may then store the transmitted information, analyze the motor data as stated above and transmit information back to instrument 10 user via remote computer 2420, internet 5830 and wireless device 5820. This information may include an alert that motor 65 operated outside of predicted parameters.

[0124] The devices disclosed herein can be designed to be disposed of after a single procedure (which may comprise multiple firings), or they can be designed to be used in multiple procedures. In either case, however, the device can be reconditioned for reuse after at least one procedure. Reconditioning can include any combination of the steps of

disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can 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.

[0125] Preferably, the various embodiments of the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a thermoformed plastic shell covered with a sheet of TYVEK. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

[0126] It is preferred that the device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam and other methods.

[0127] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable

detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications may readily appear to those skilled in the art. The various embodiments of the present invention represent vast improvements over prior staple methods that require the use of different sizes of staples in a single cartridge to achieve staples that have differing formed (final) heights.

[0128] Accordingly, the present invention has been discussed in terms of endoscopic procedures and apparatus. However, use herein of terms such as "endoscopic" should not be construed to limit the present invention to a surgical stapling and severing instrument for use only in conjunction with an endoscopic tube (i.e., cannula or trocar). On the contrary, it is believed that the present invention may find use in any procedure where access is limited, including but not limited to laparoscopic procedures, as well as open procedures. Moreover, the unique and novel aspects of the various staple cartridge embodiments of the present invention may find utility when used in connection with other forms of stapling apparatuses without departing from the spirit and scope of the present invention.

[0129] Any patent, publication, or information, 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 document. As such the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference.

CLAIMS

What is claimed is:

1. 1. A system for communicating information to and from a user of a surgical instrument comprising:

a surgical instrument having a motor, a powersource, a microprocessor to control the motor and a memory;

the surgical instrument further having a means for transmitting first information to a mobile wireless device;

an application resident on the mobile wireless device capable of receiving and storing the first information transmitted from the surgical instrument, the application further capable of soliciting a second information from a user;

a remote computer in communication with the mobile wireless device;

a database on the remote computer, the database having stored information;

a program that interacts with the database resident on the remote computer that compares the transmitted first and second information with the stored information and generates a user alert information; and

the program transmits the user alert information to the mobile wireless device.

2. A system for communicating information to and from a user of a surgical instrument comprising:

a surgical instrument having a motor, a powersource, a microprocessor to control the motor and a memory;

the surgical instrument further having an RF transmitter for transmitting first information to a mobile wireless device;

an application resident on the mobile wireless device capable of receiving and storing the first information transmitted from the surgical instrument, the application further capable of soliciting a second information from a user, the application communicates the first and second information;

a remote computer in communication with the mobile wireless device;

a database on the remote computer for receiving the first and the second information, the database having stored information;

a program that interacts with the database resident on the remote computer that compares the transmitted first and second information with the stored information and generates a user alert information; and

the program transmits the user alert information to the mobile wireless device.

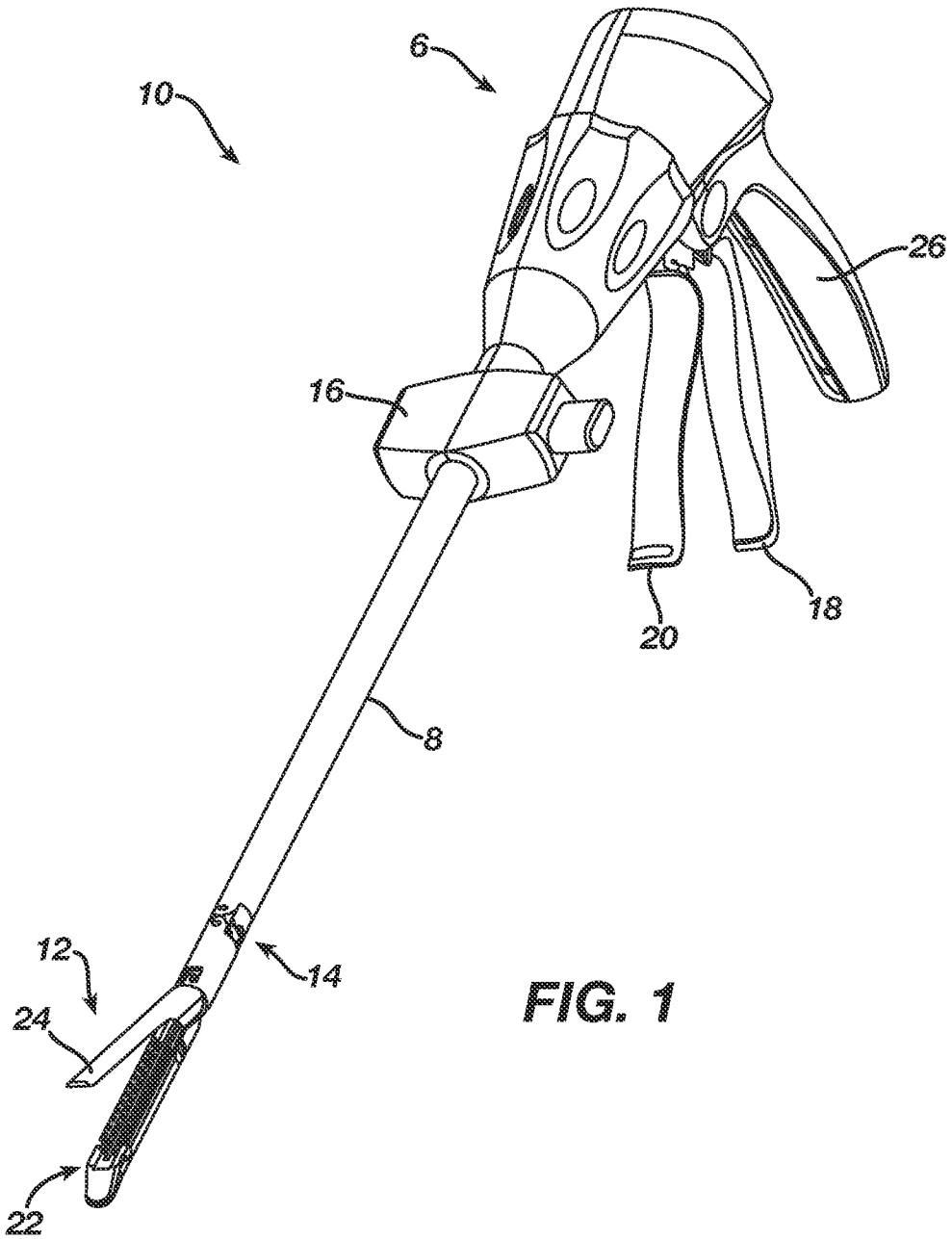


FIG. 1

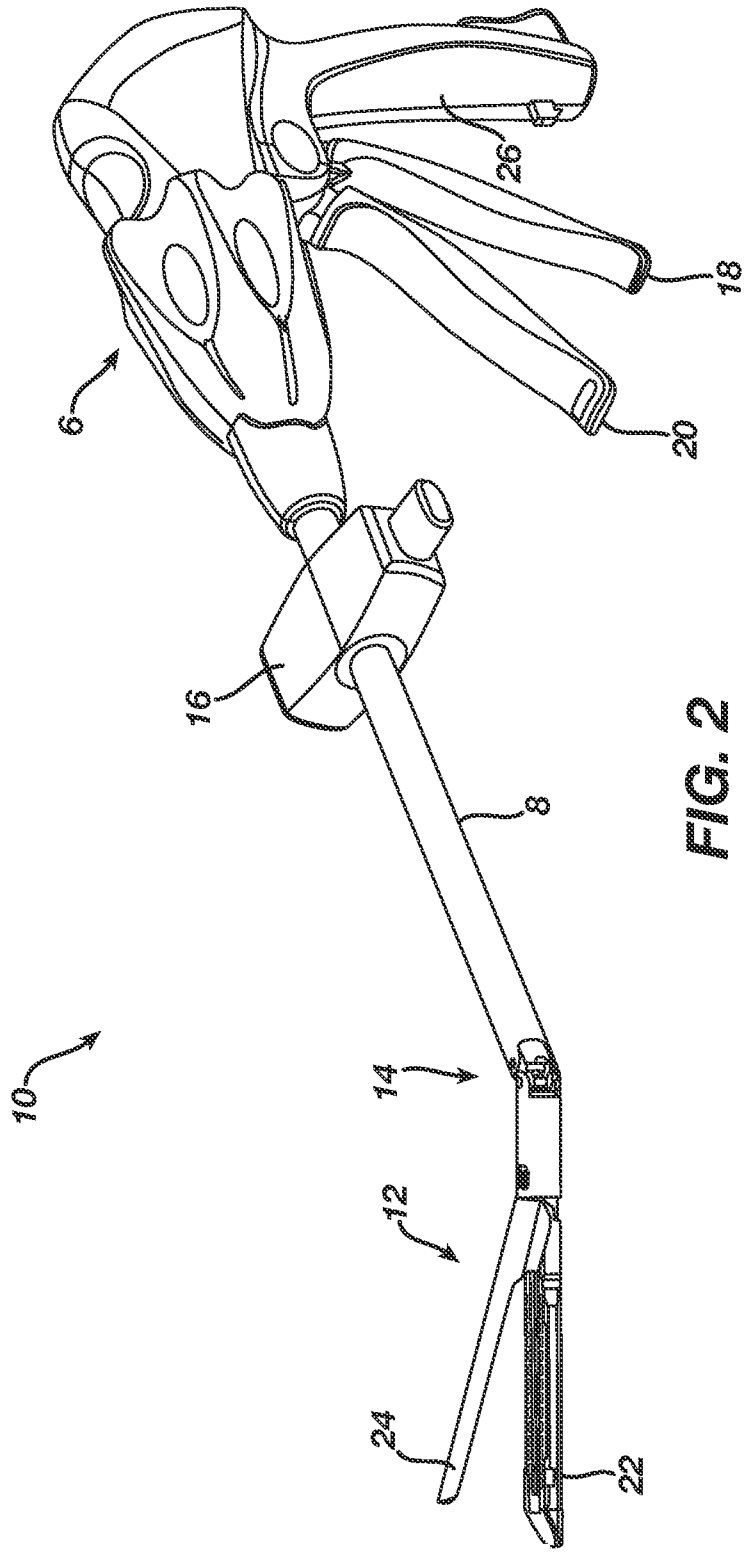


FIG. 2

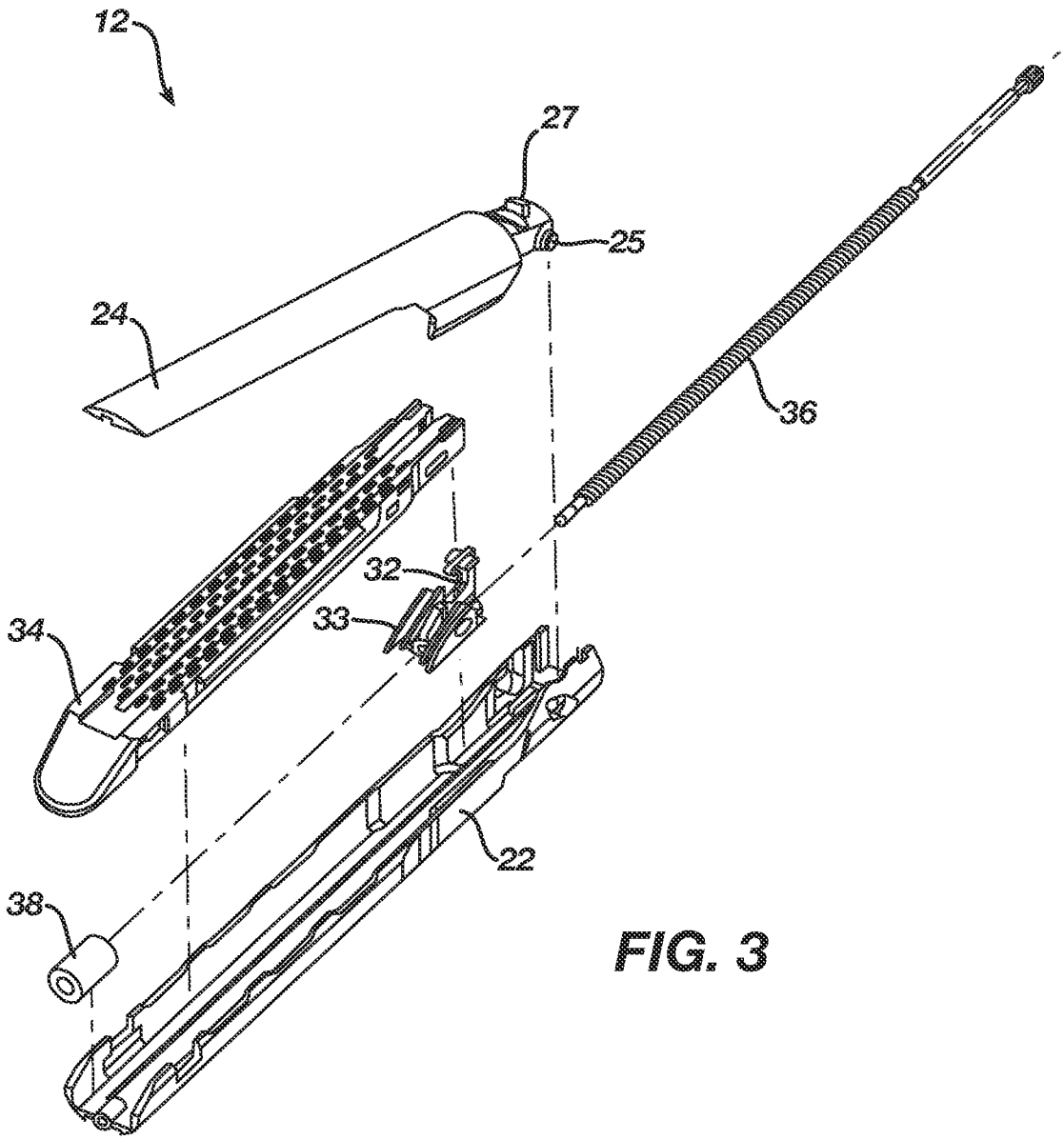


FIG. 3

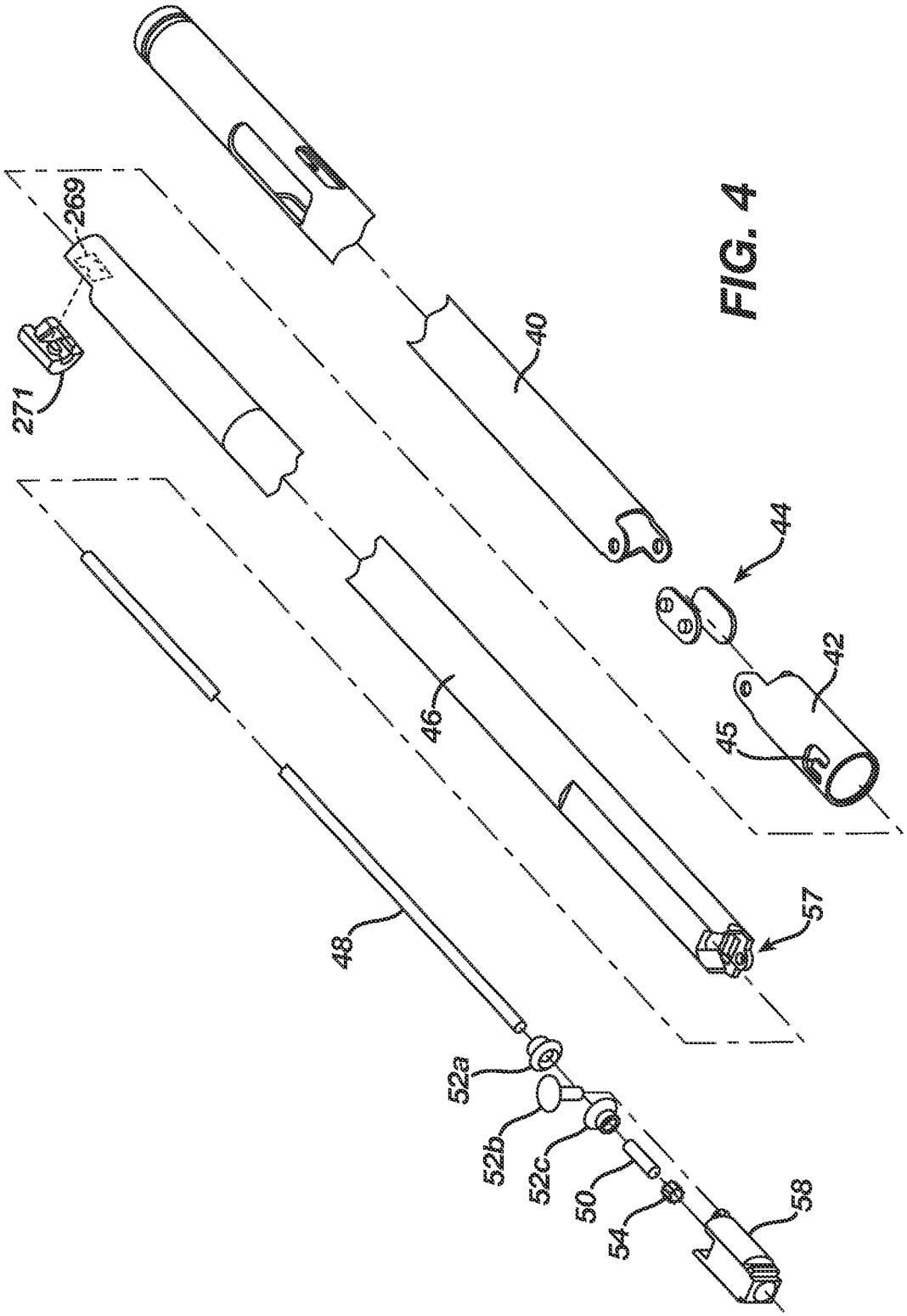


FIG. 4

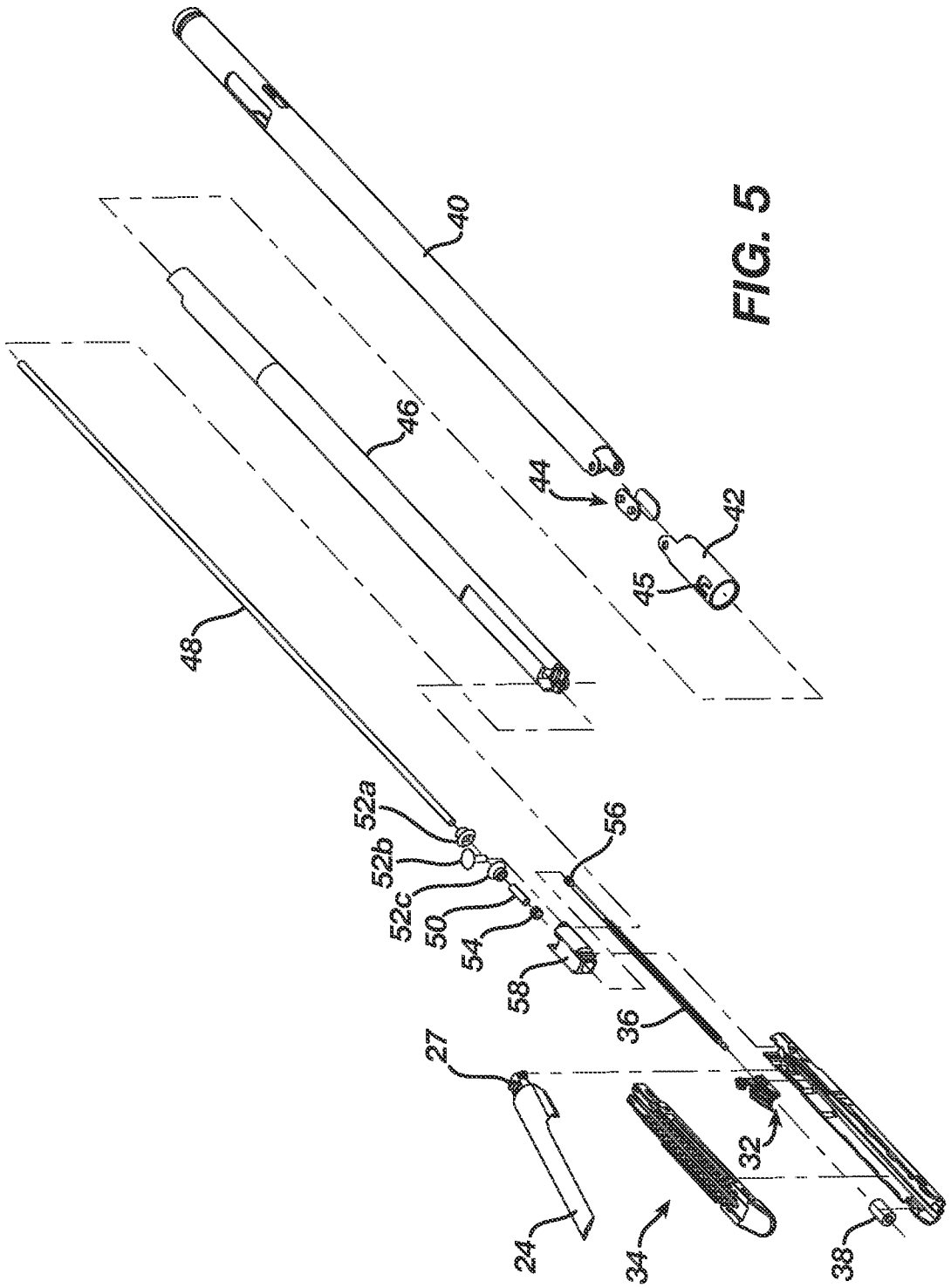


FIG. 5

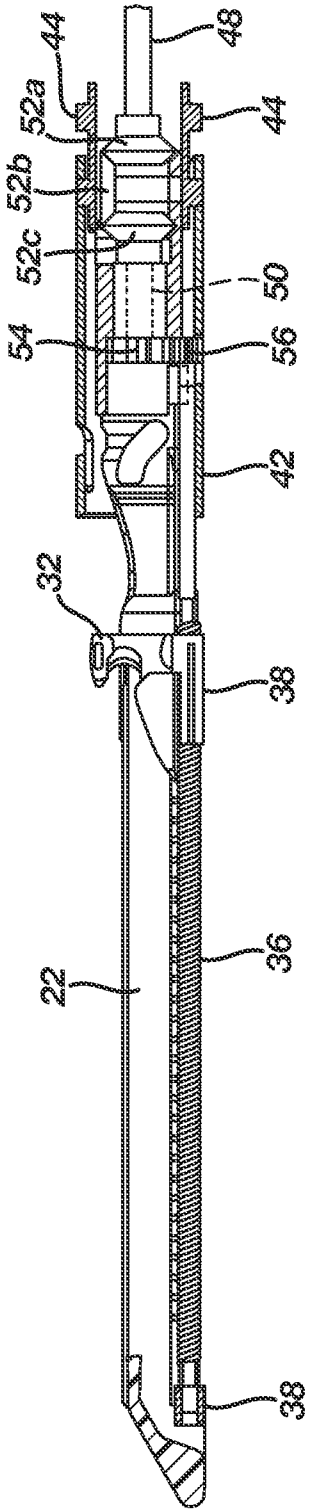


FIG. 6

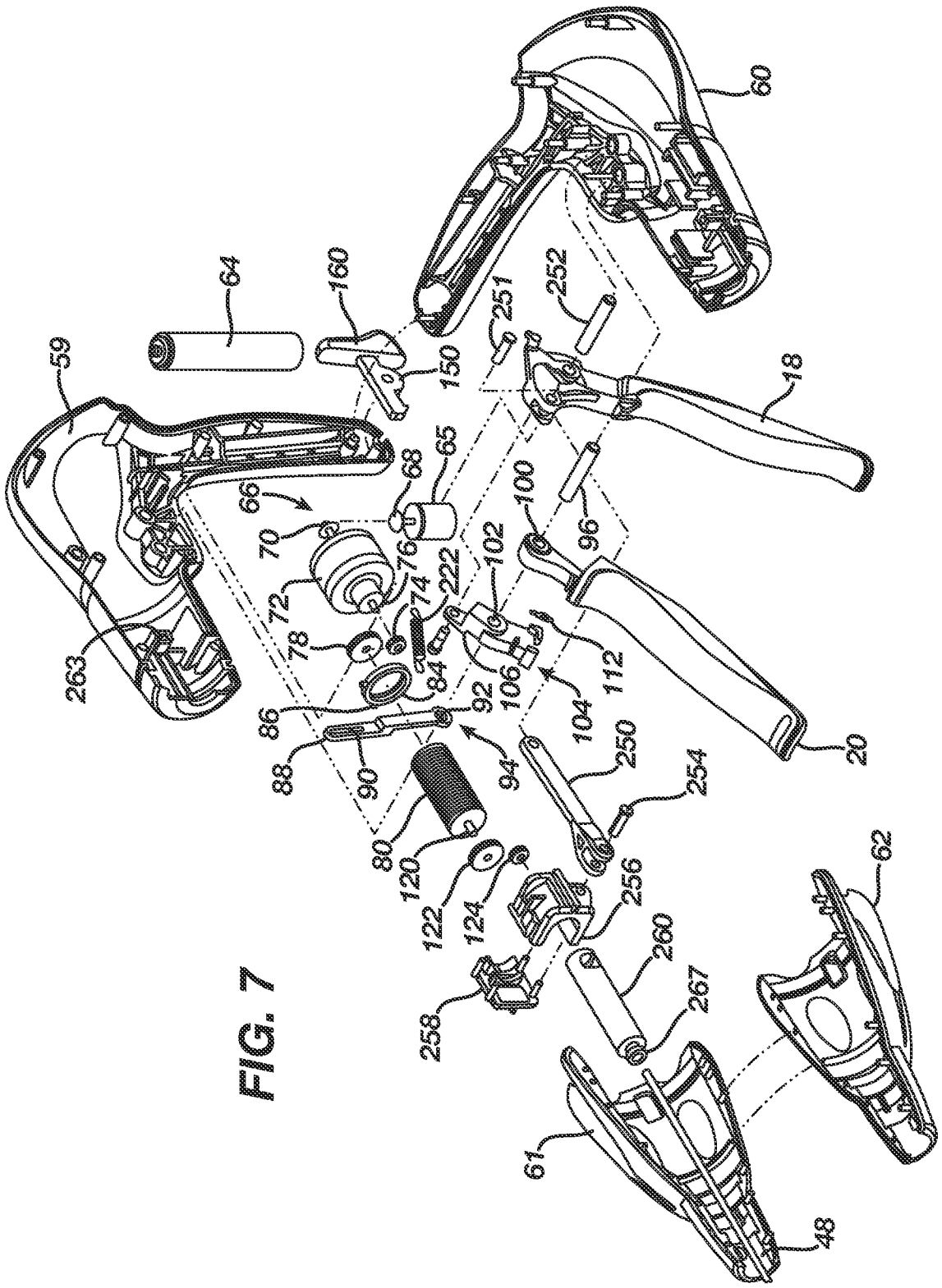

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100
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106
112
263
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FIG. 7

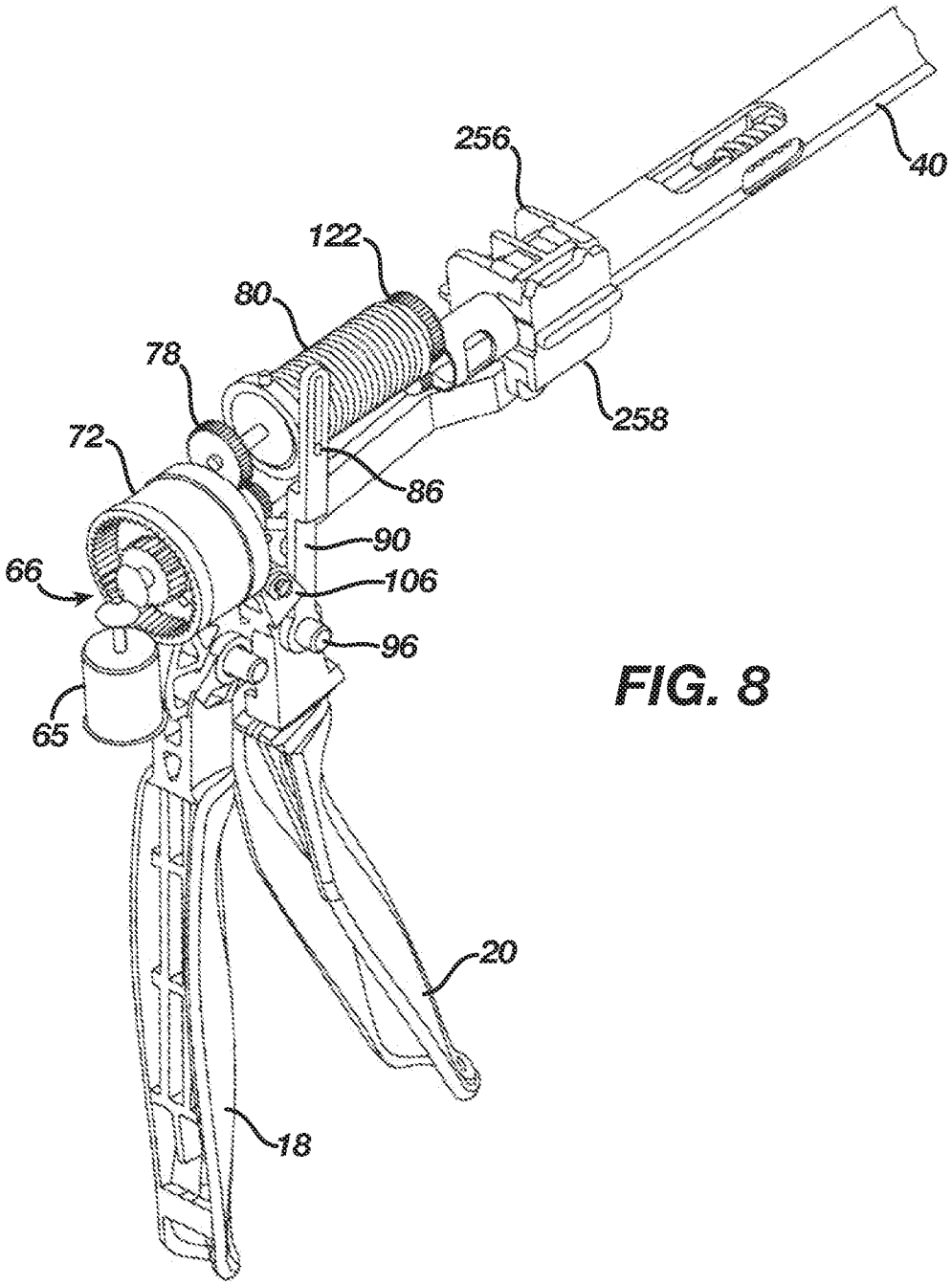


FIG. 8

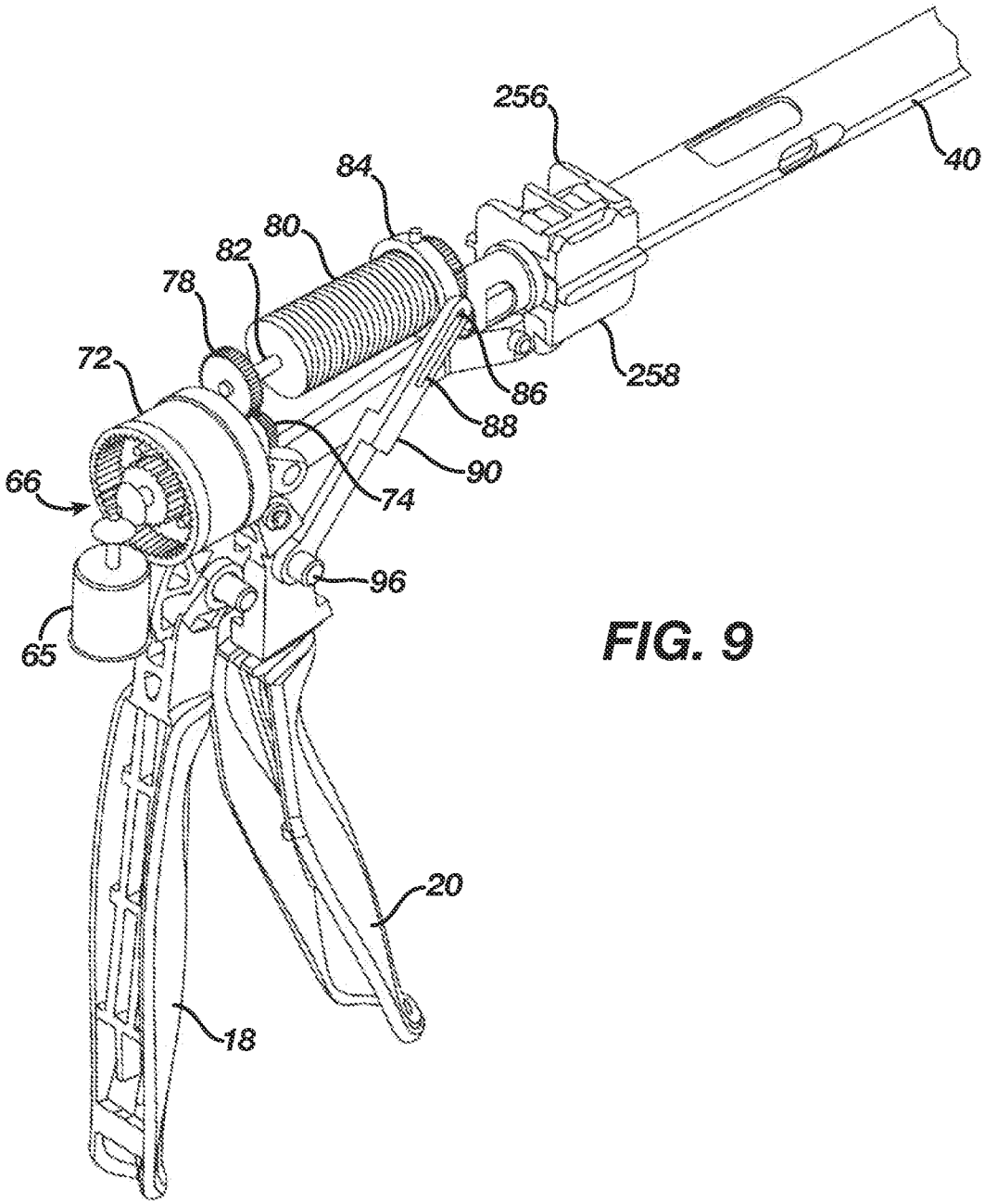


FIG. 9

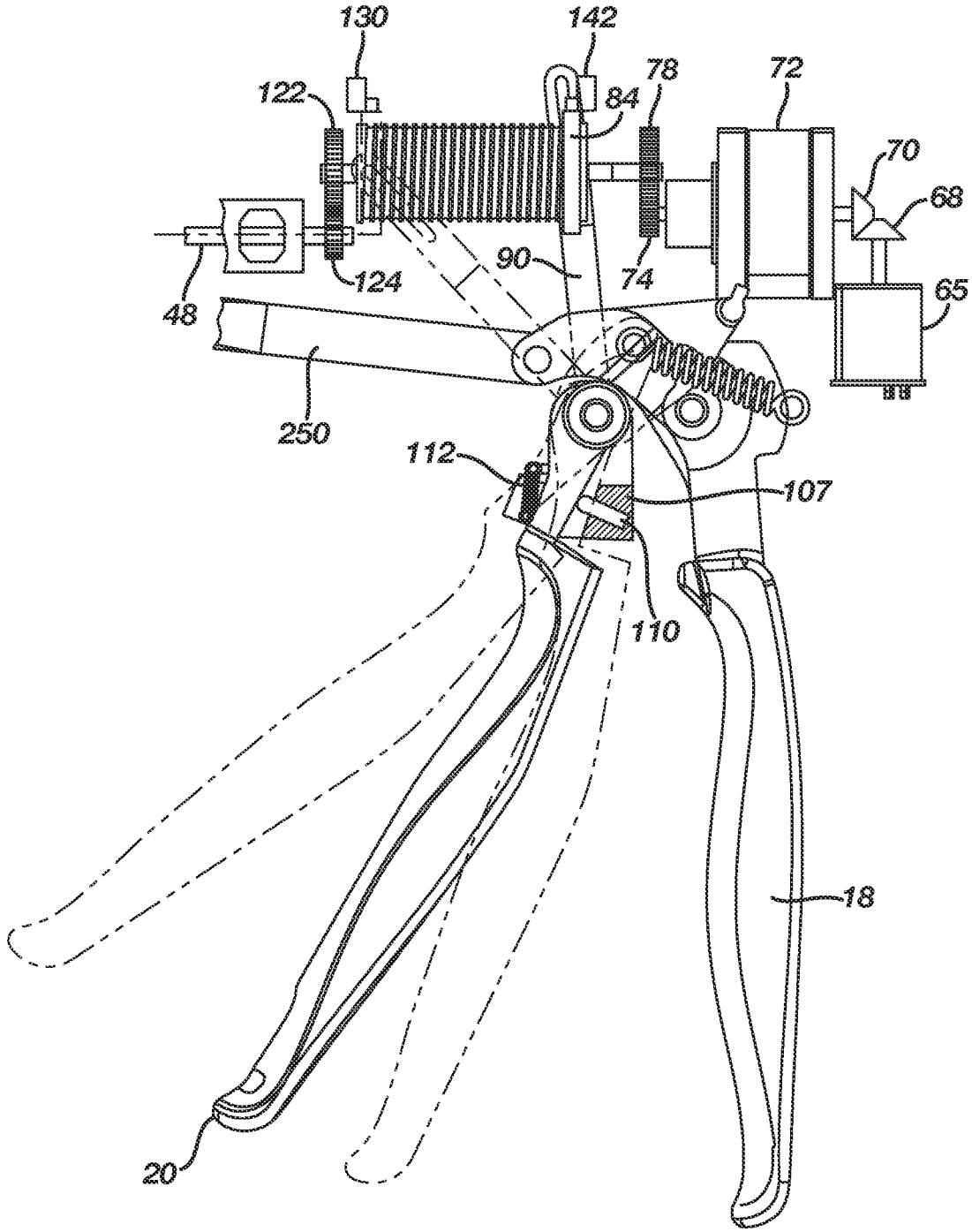


FIG. 10

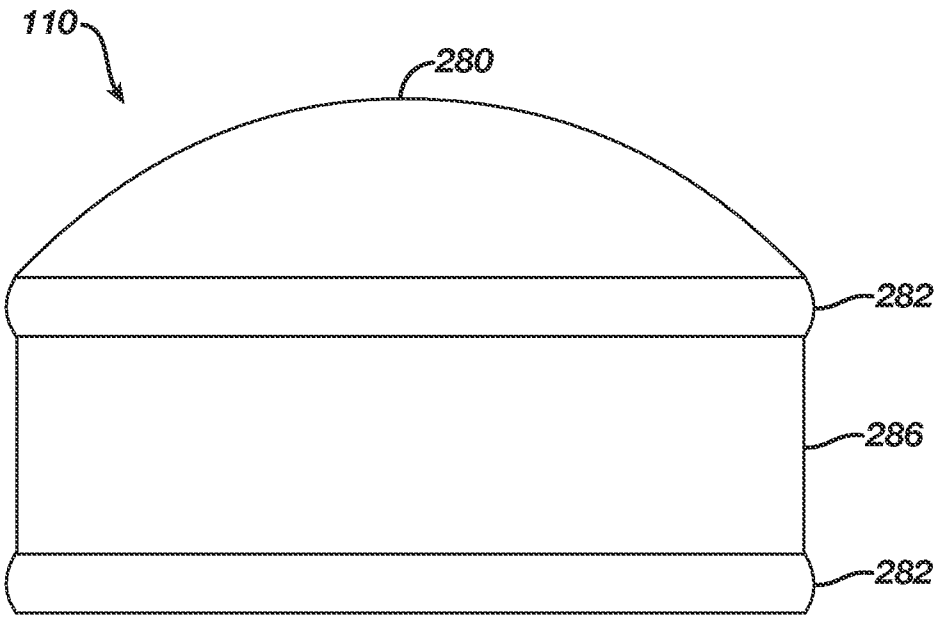


FIG. 10A

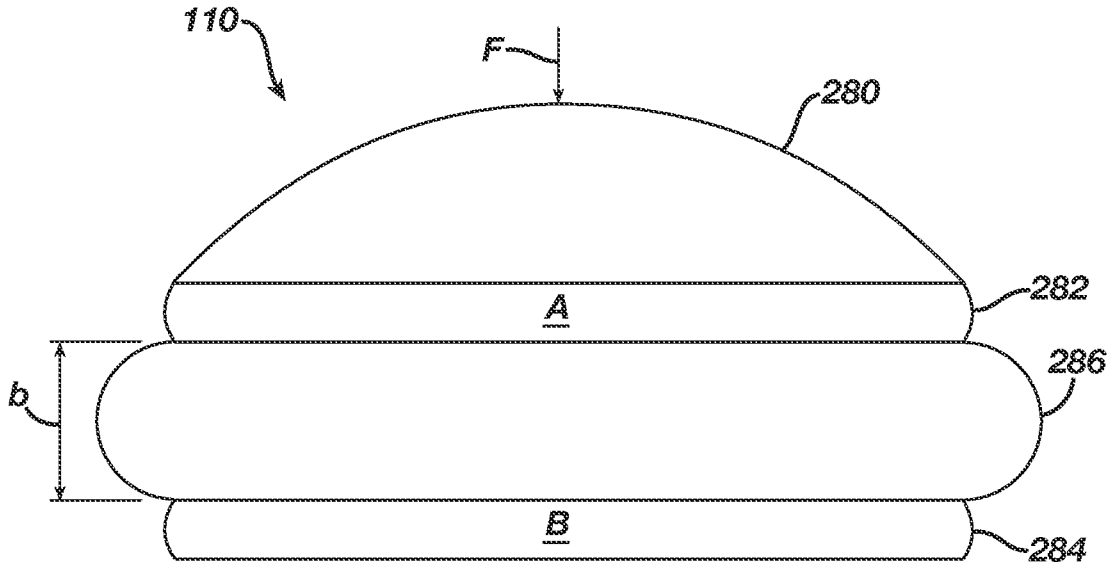


FIG. 10B

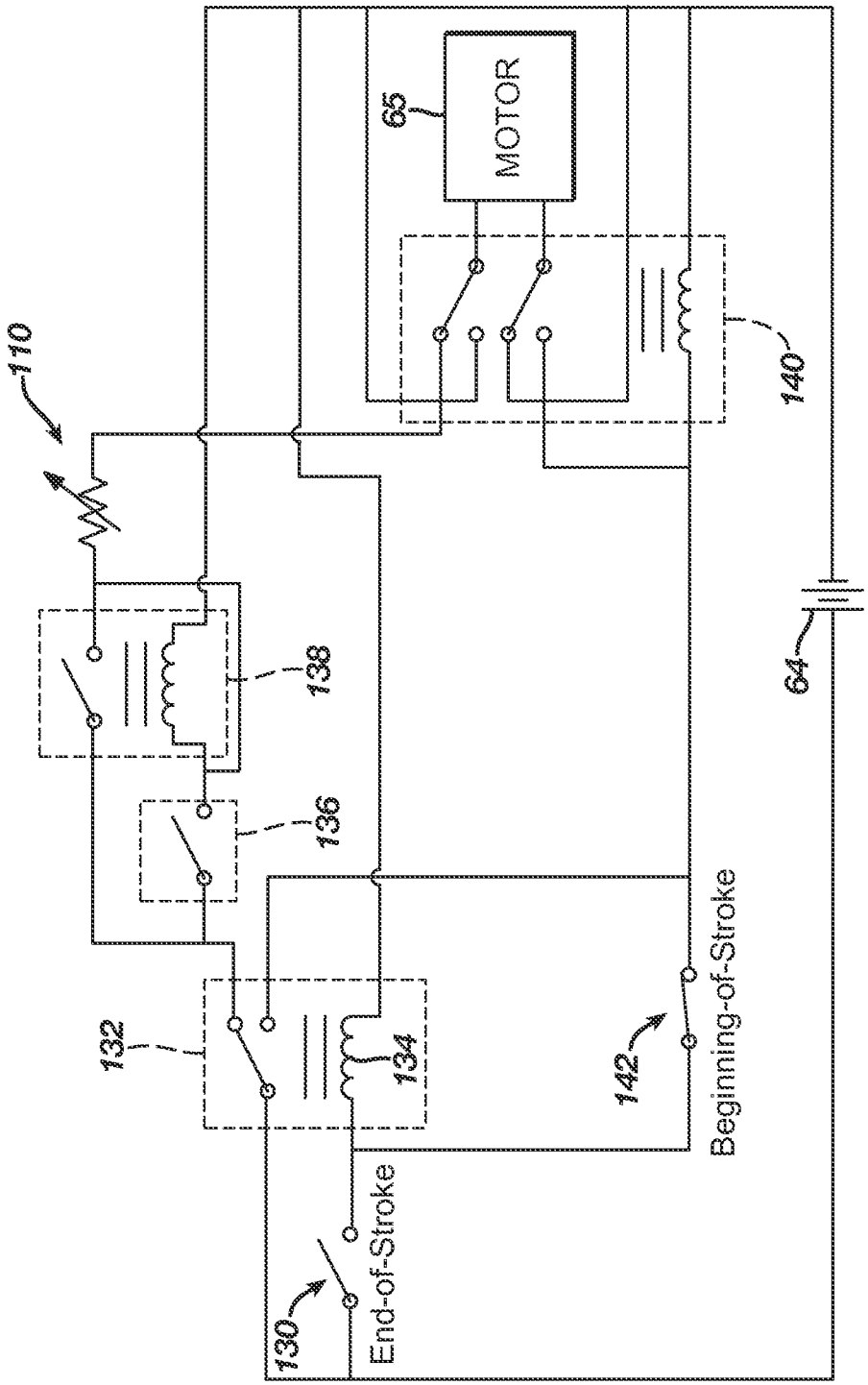

MOTOR
65
110
140
138
136
132
134
142
64
130
End-of-Stroke
Beginning-of-Stroke

FIG. 11

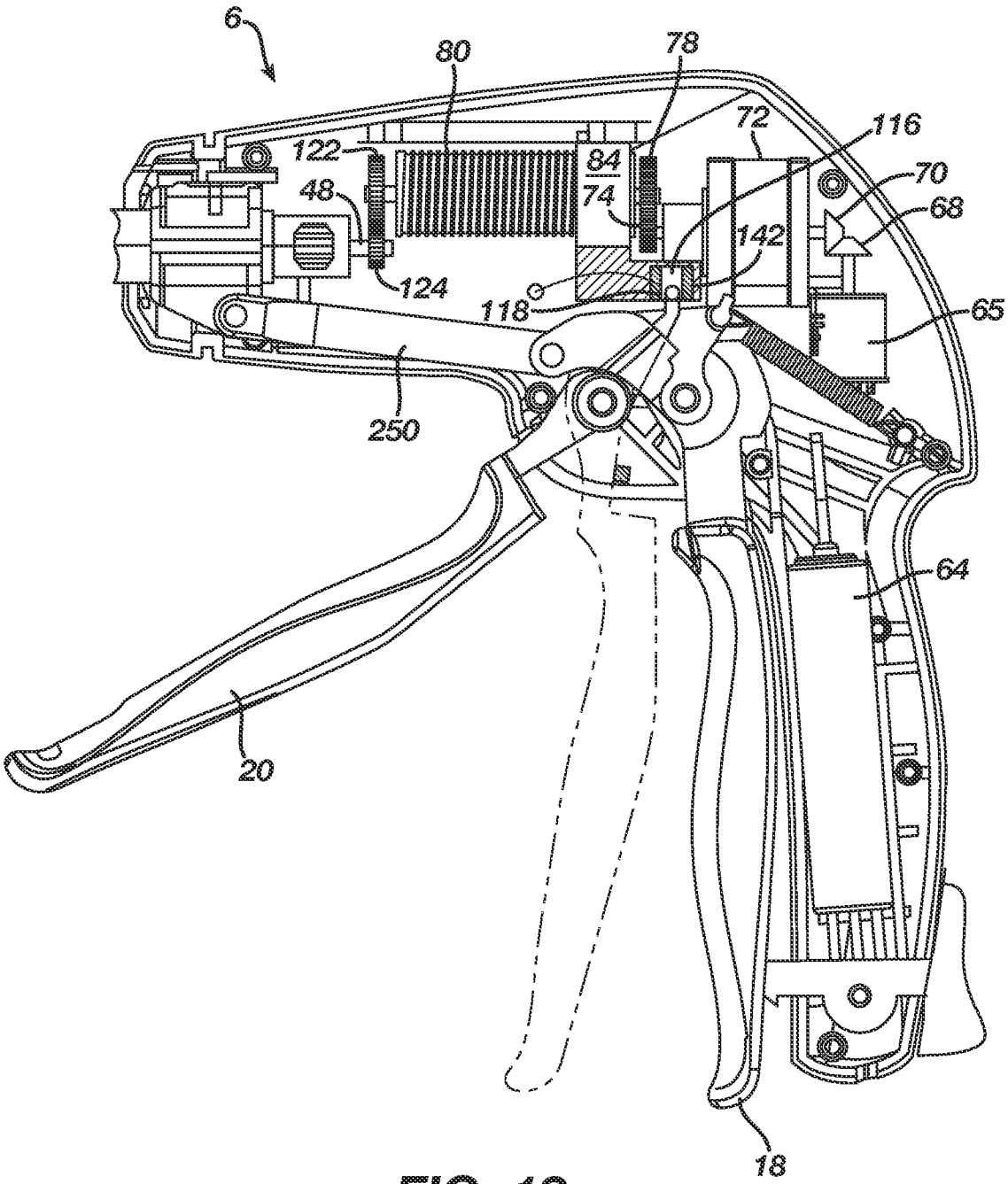


FIG. 12

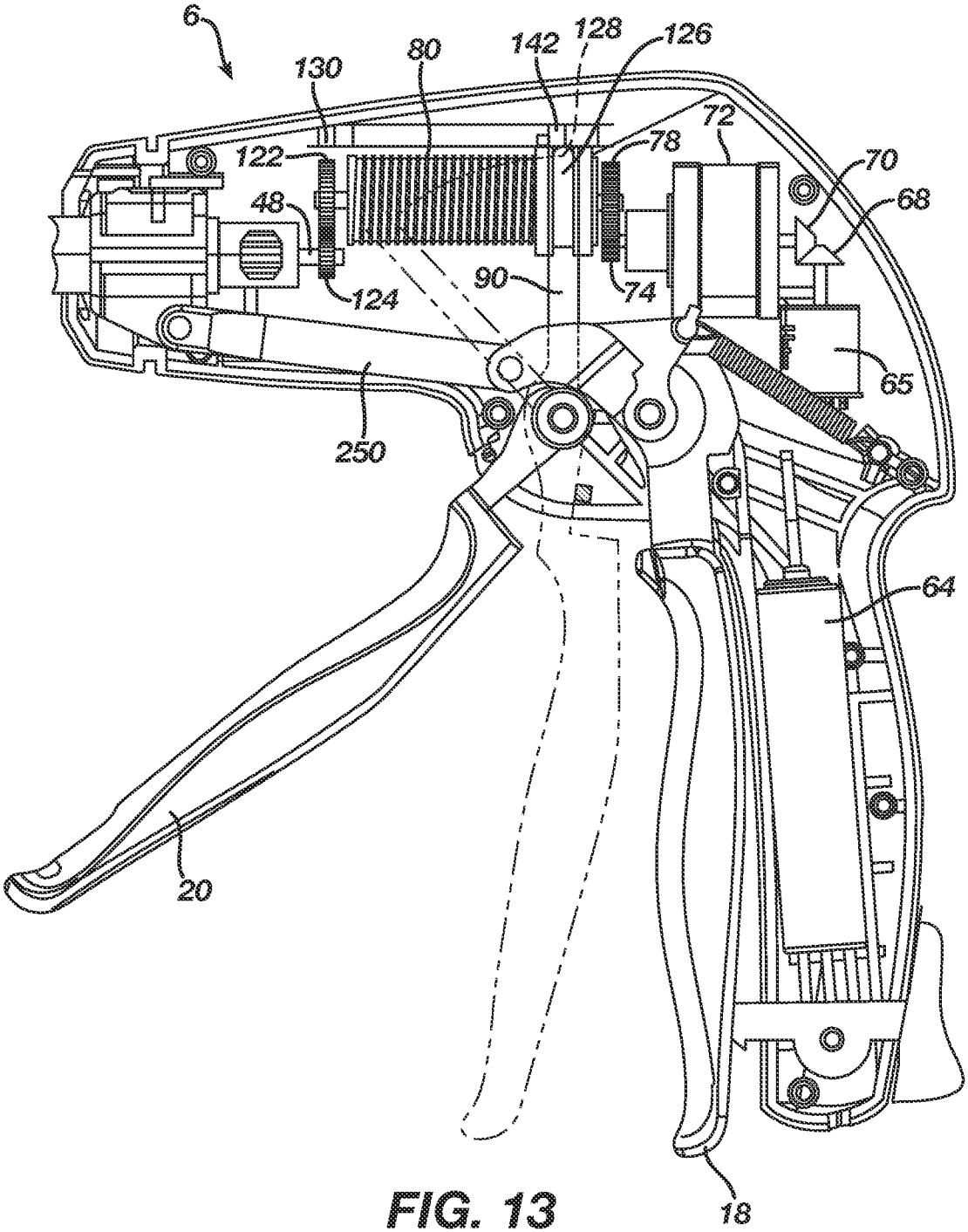


FIG. 13

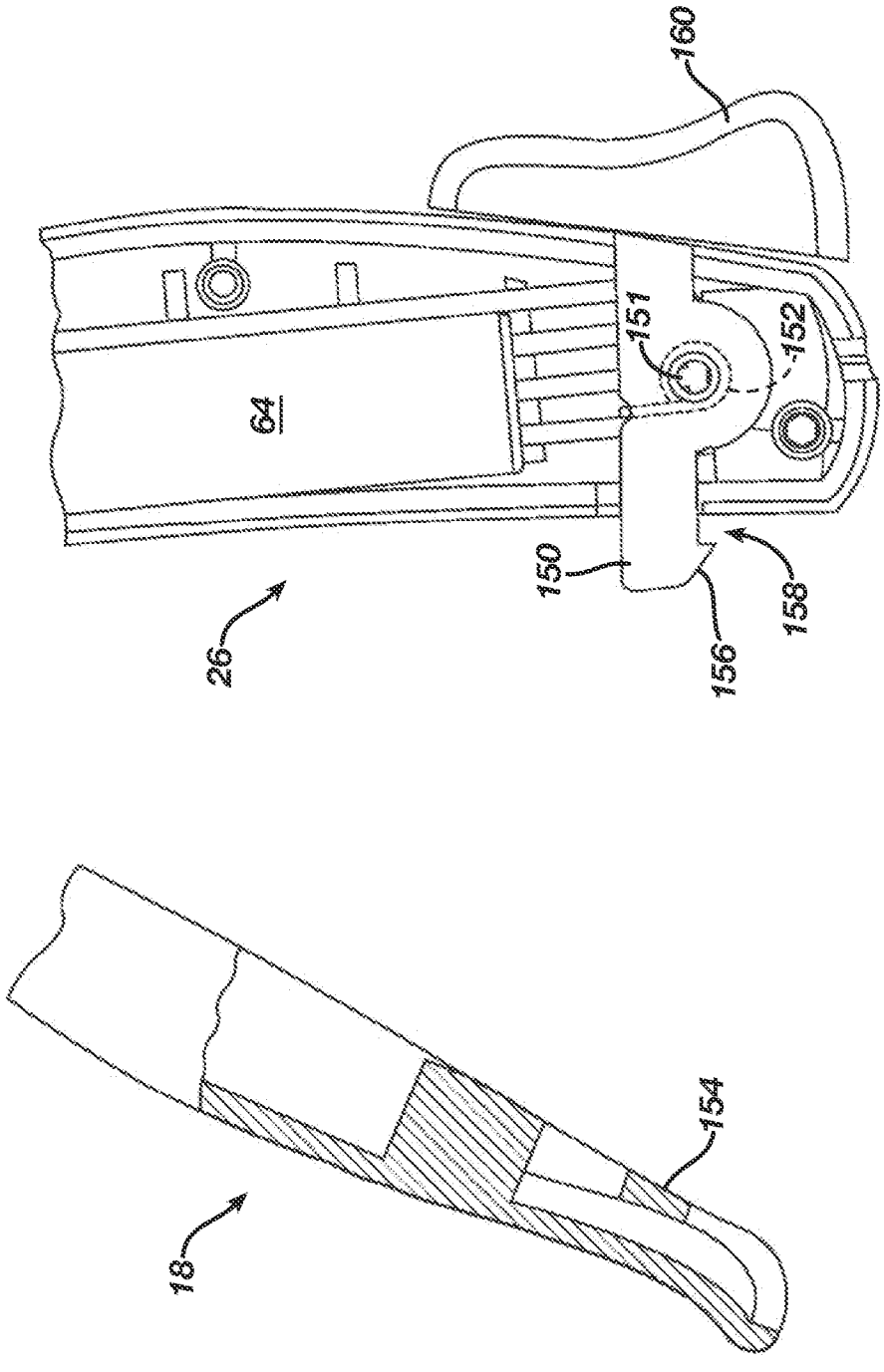


FIG. 14

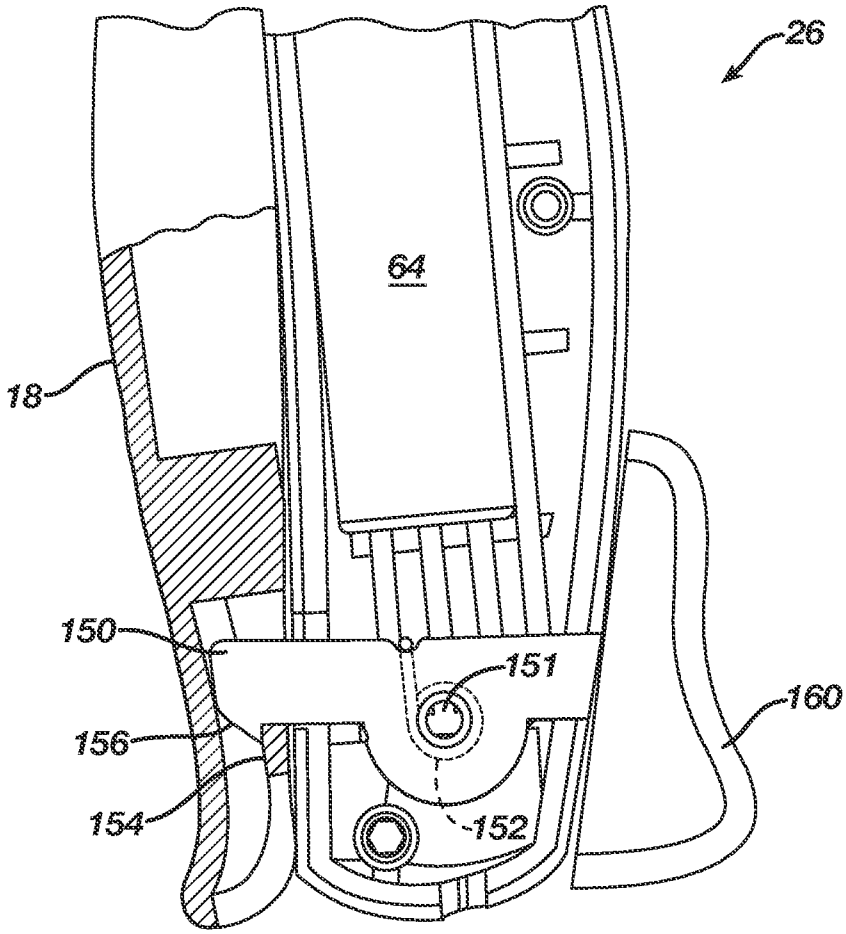


FIG. 15

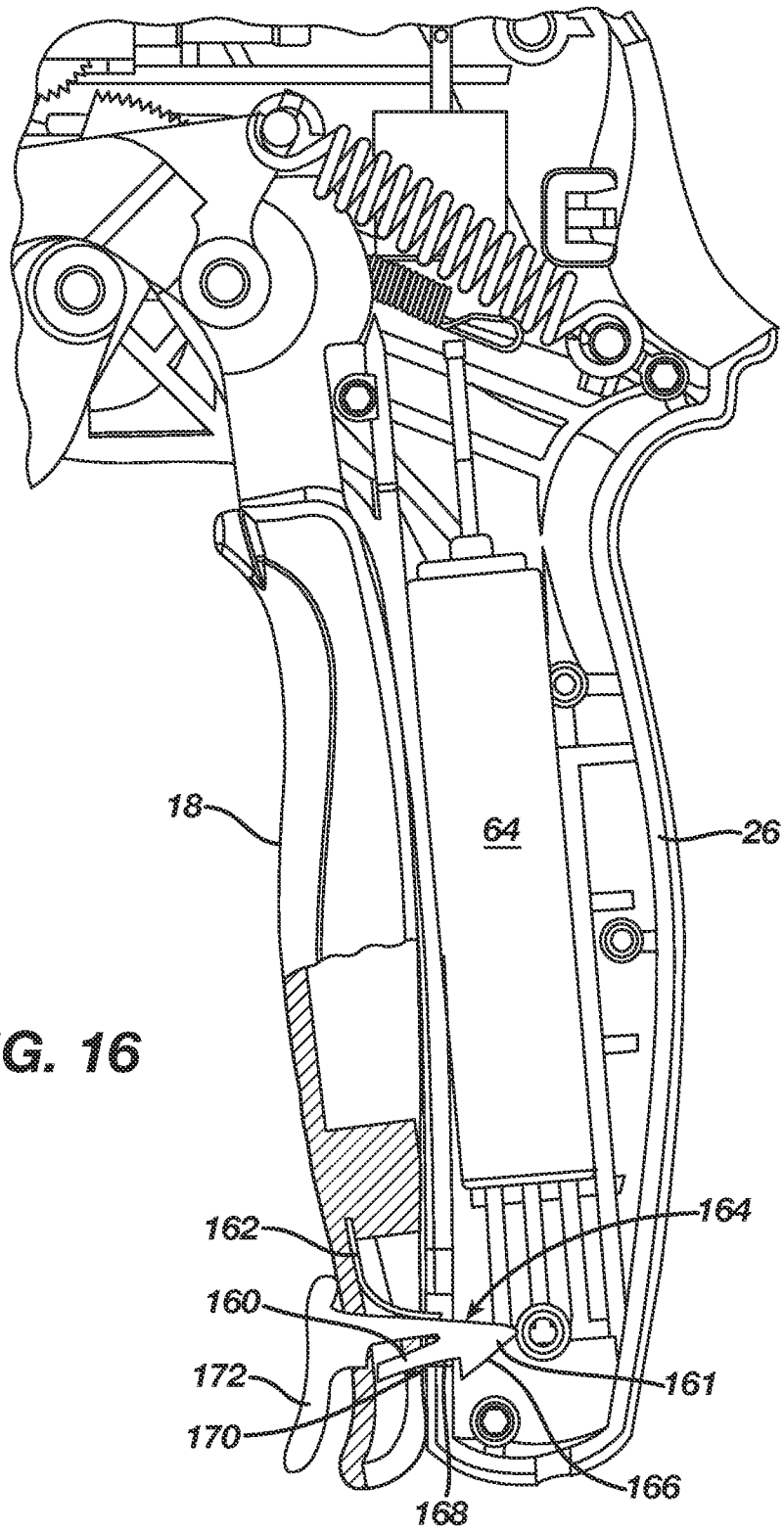


FIG. 16

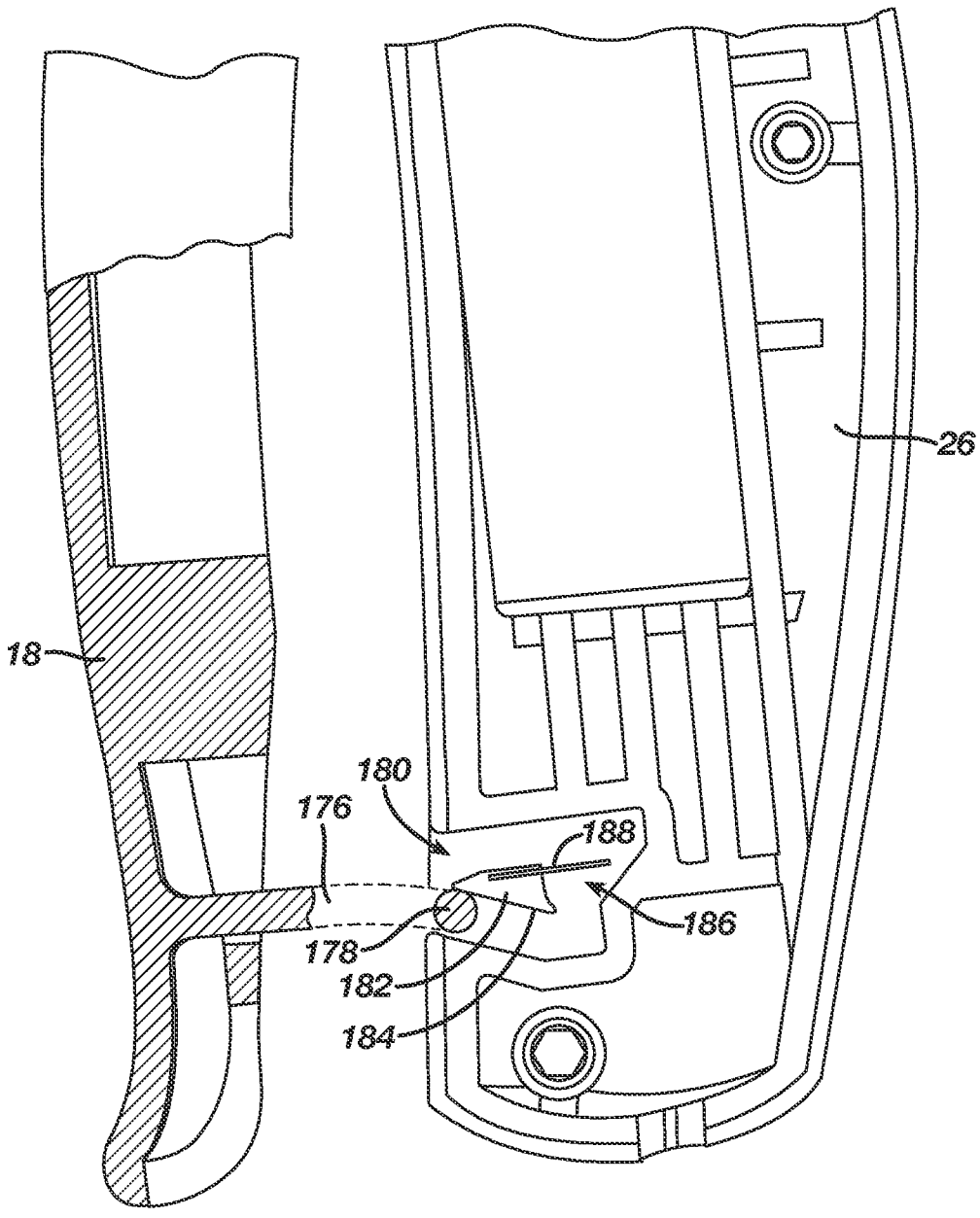


FIG. 17

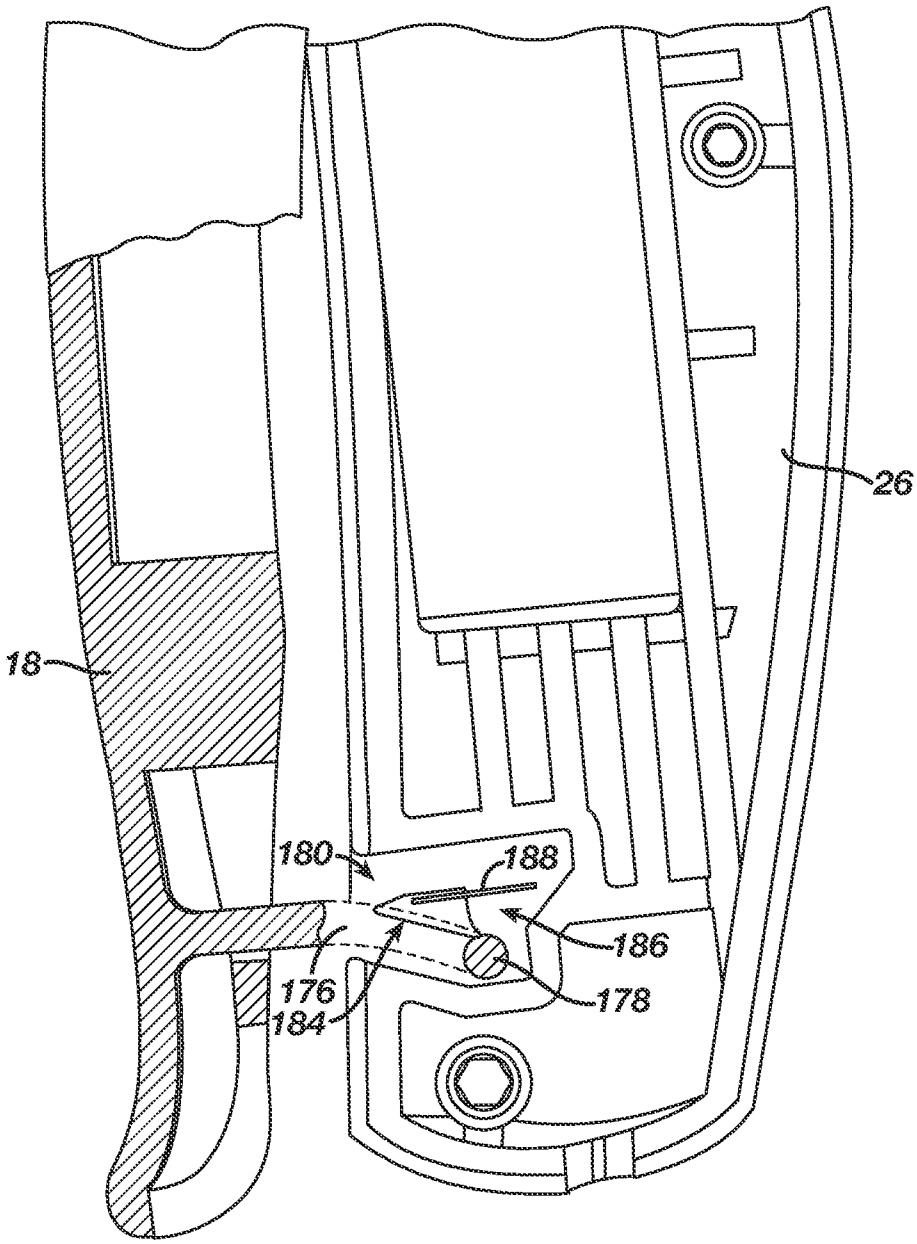


FIG. 18

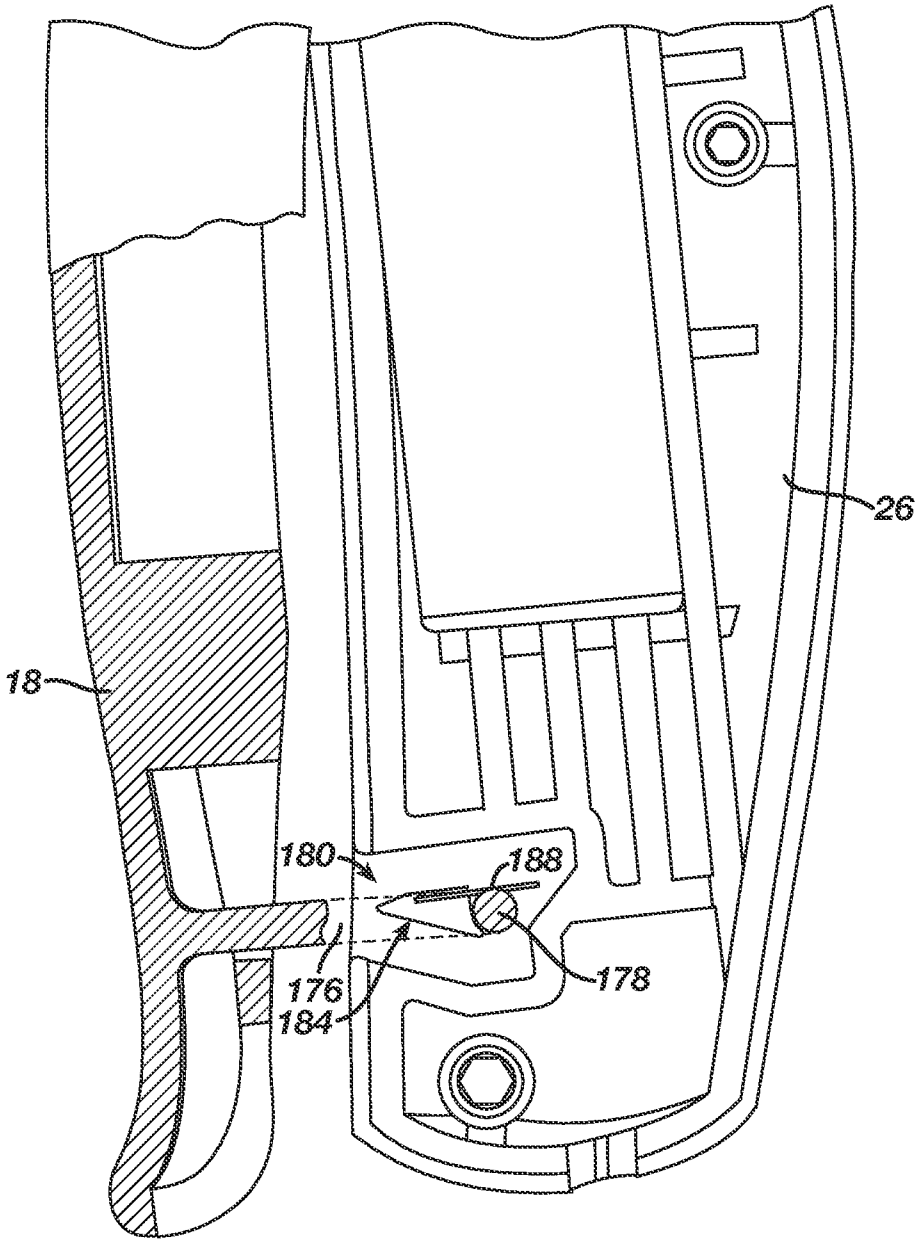


FIG. 19

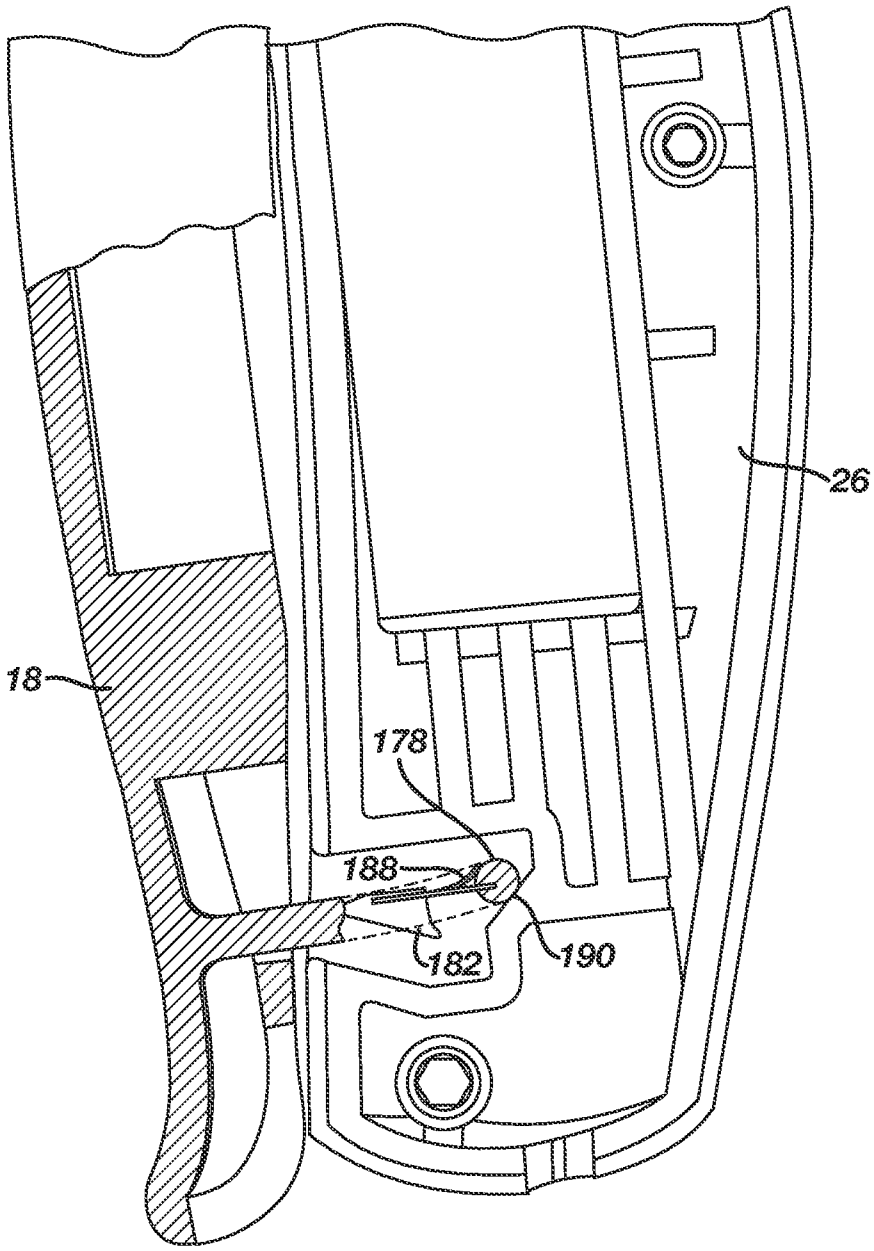


FIG. 20

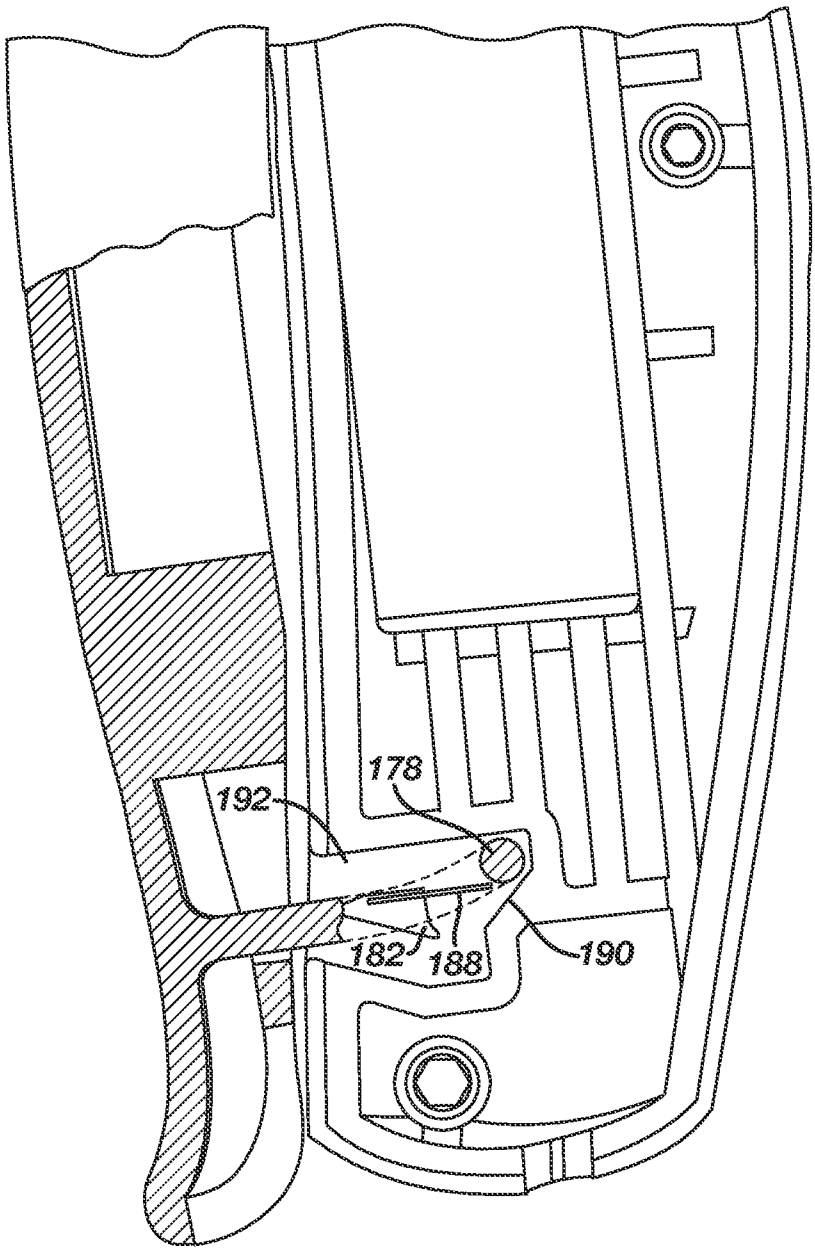


FIG. 21

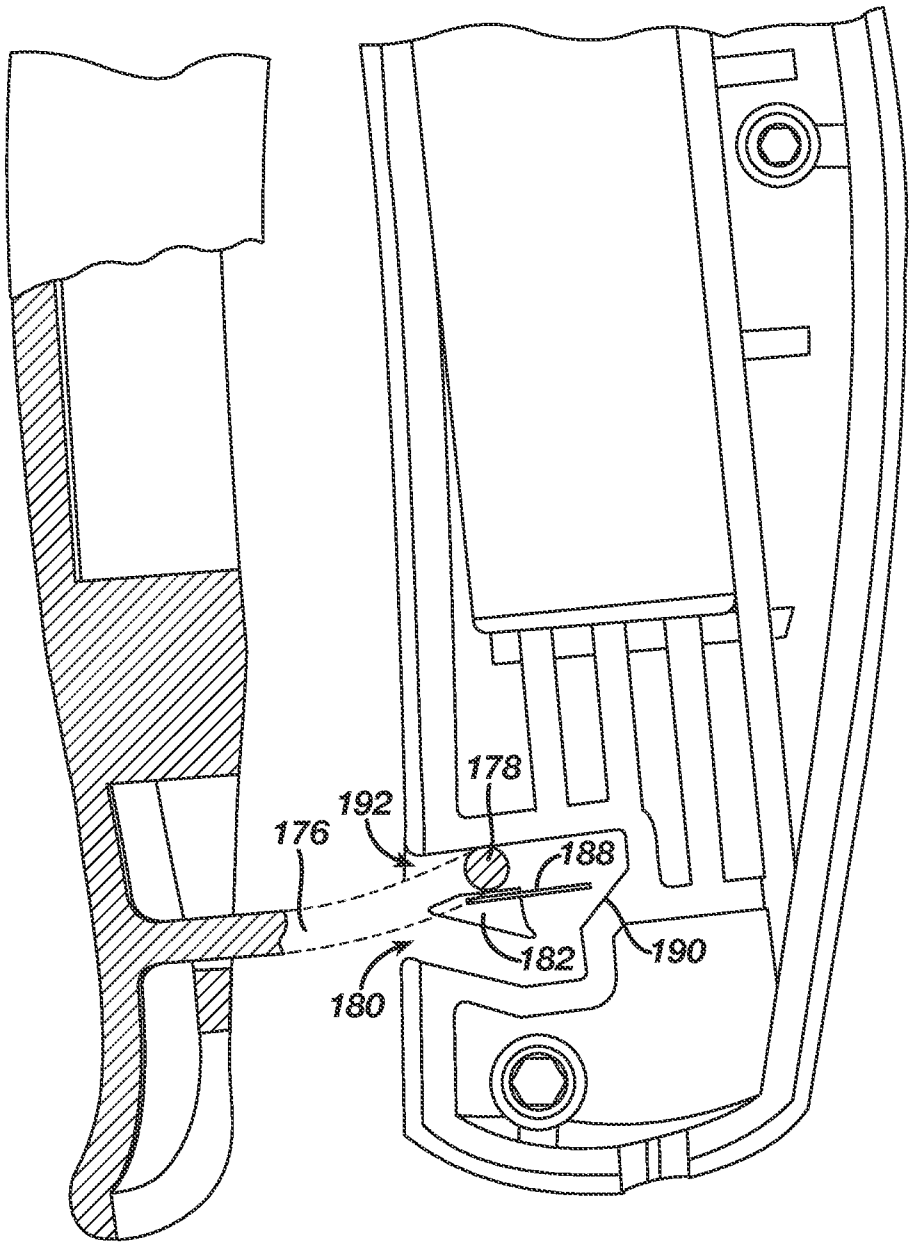


FIG. 22

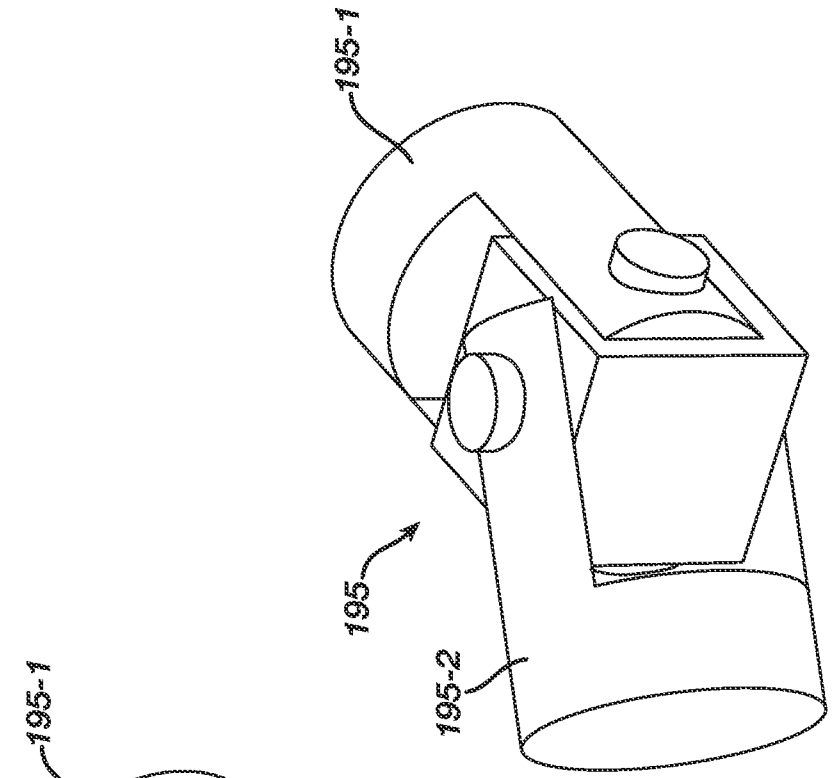


FIG. 23B

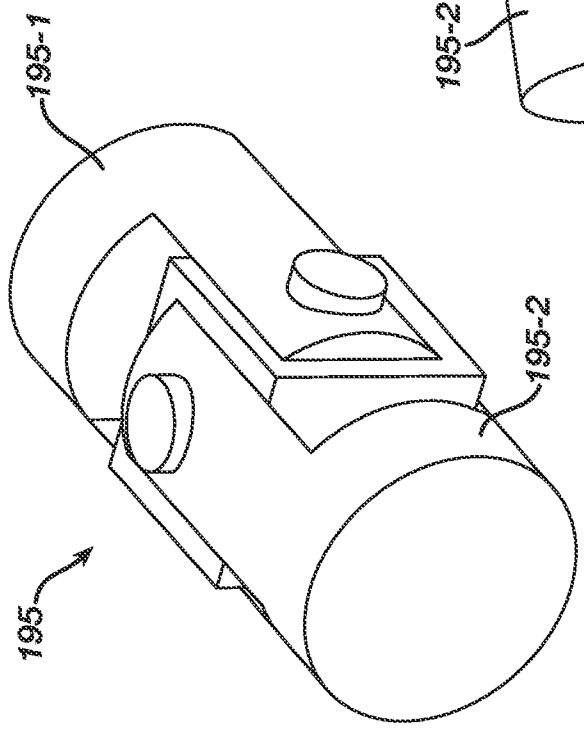


FIG. 23A

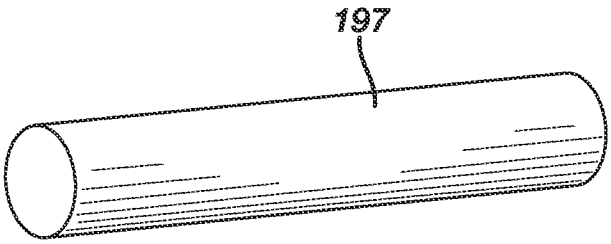


FIG. 24A

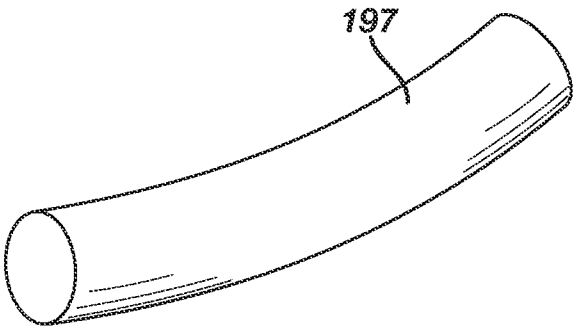


FIG. 24B

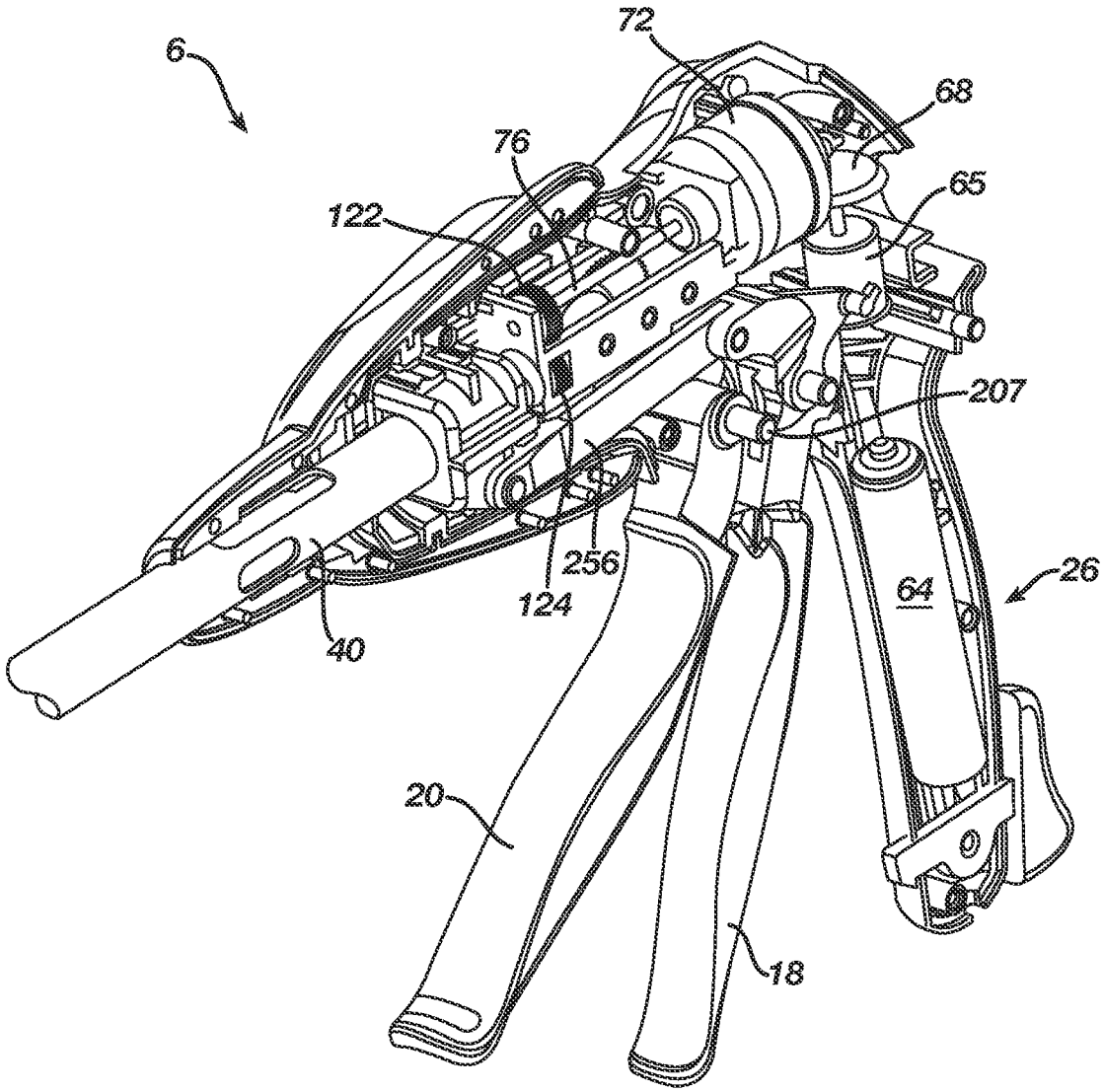
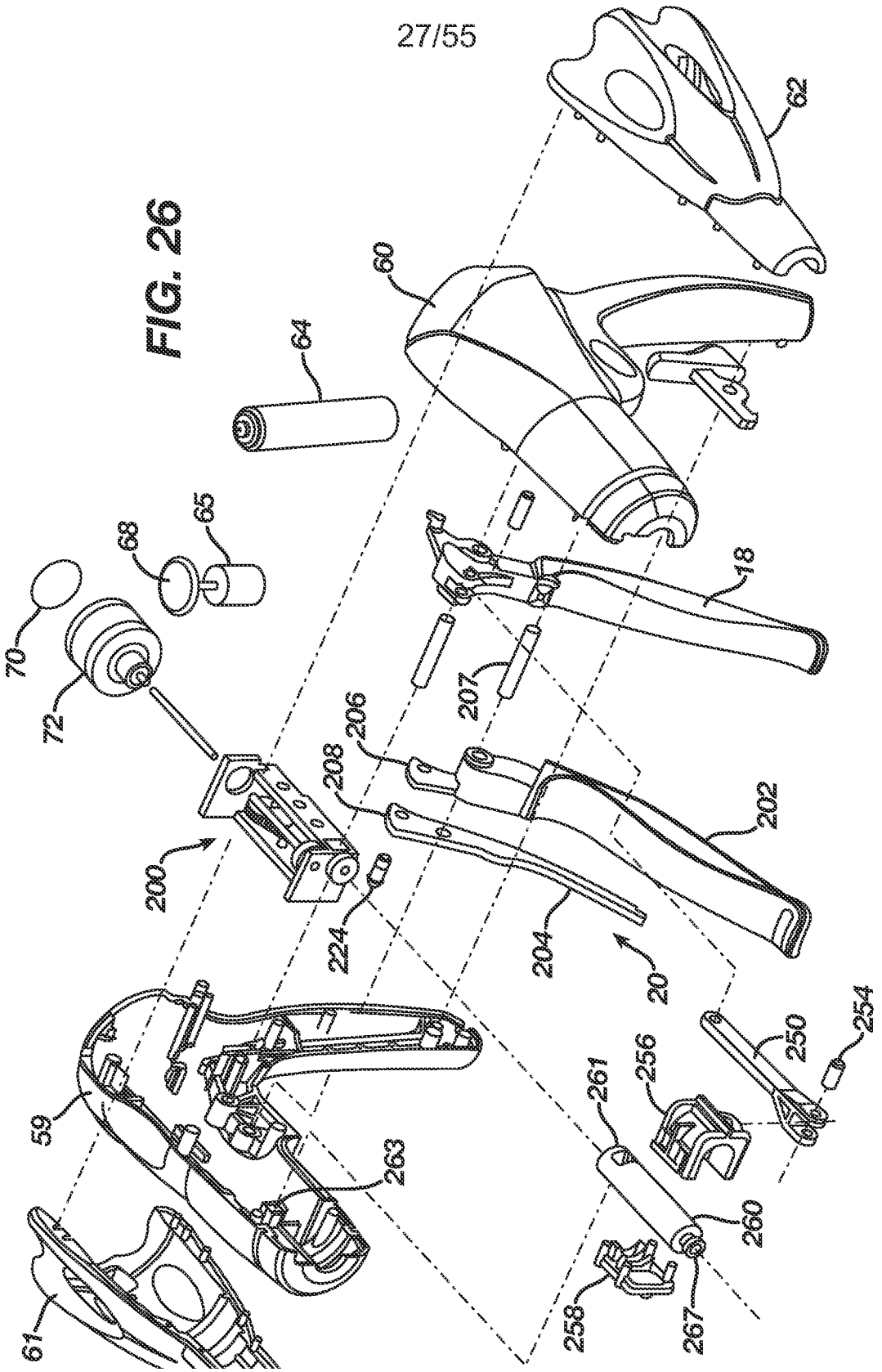


FIG. 25

FIG. 26


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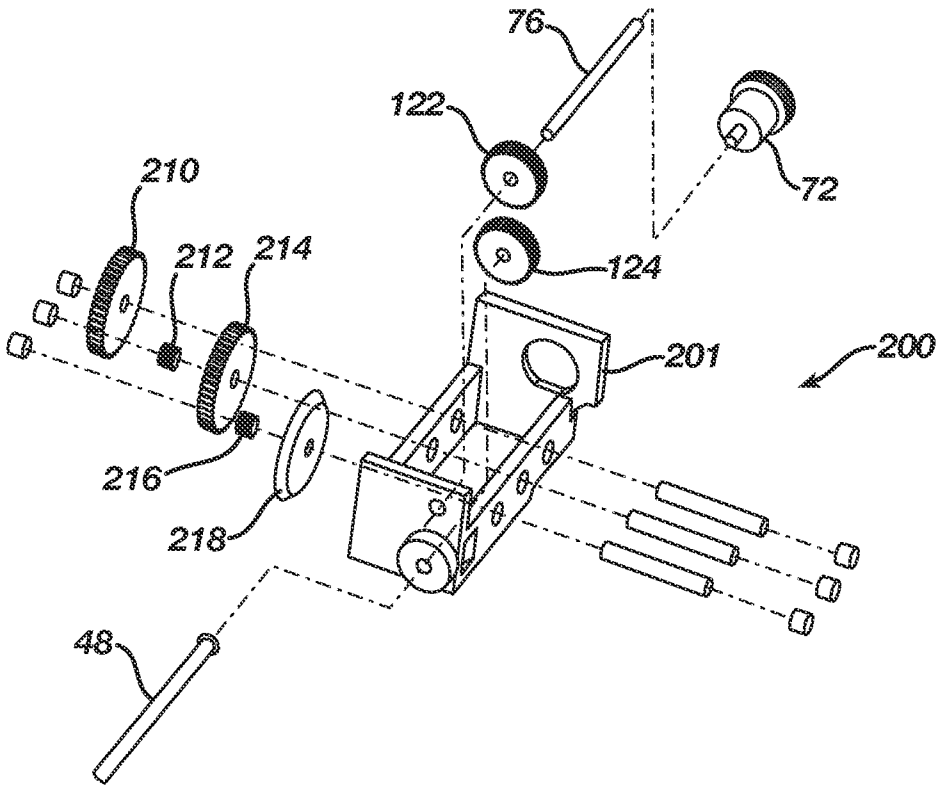


FIG. 27

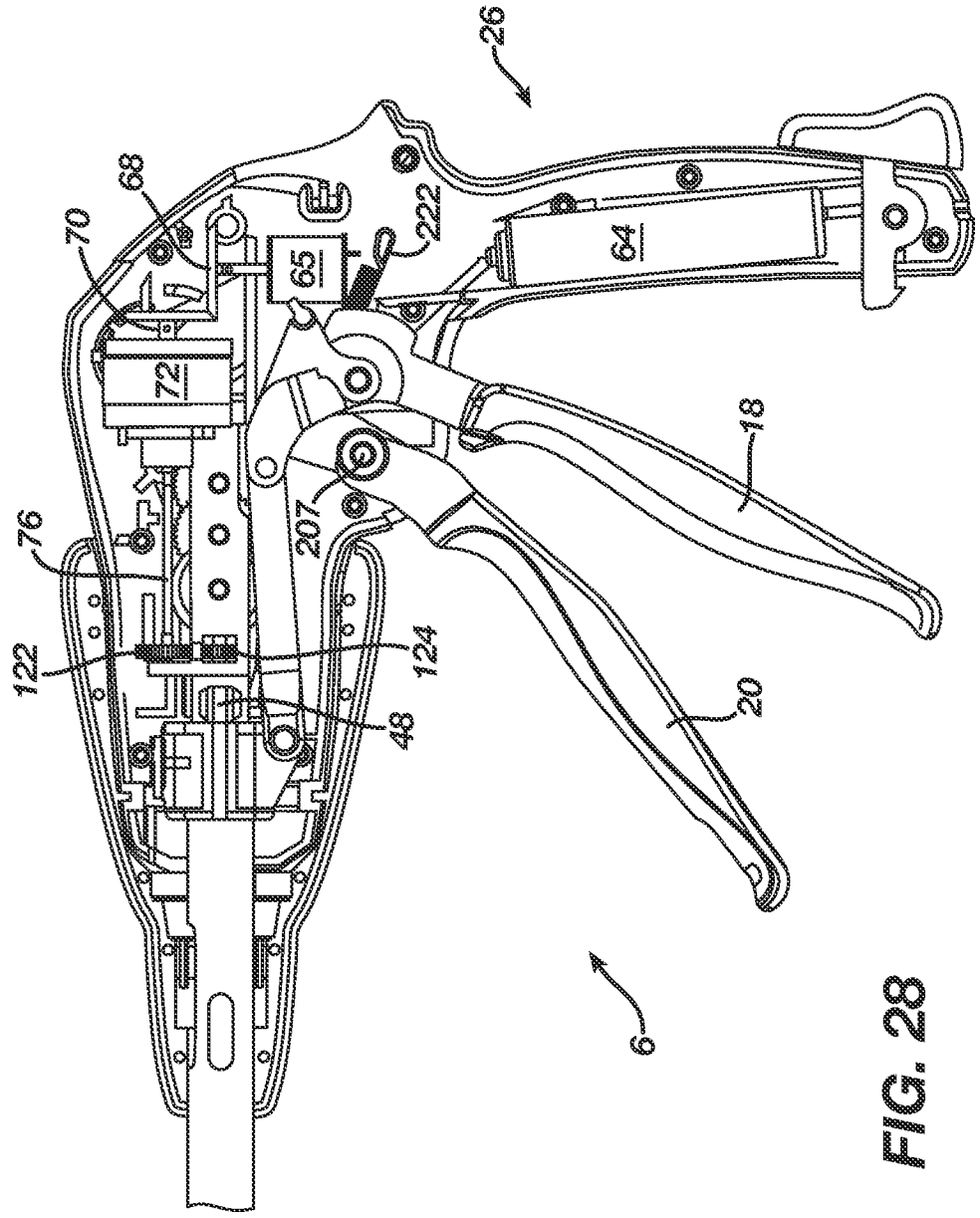


FIG. 28

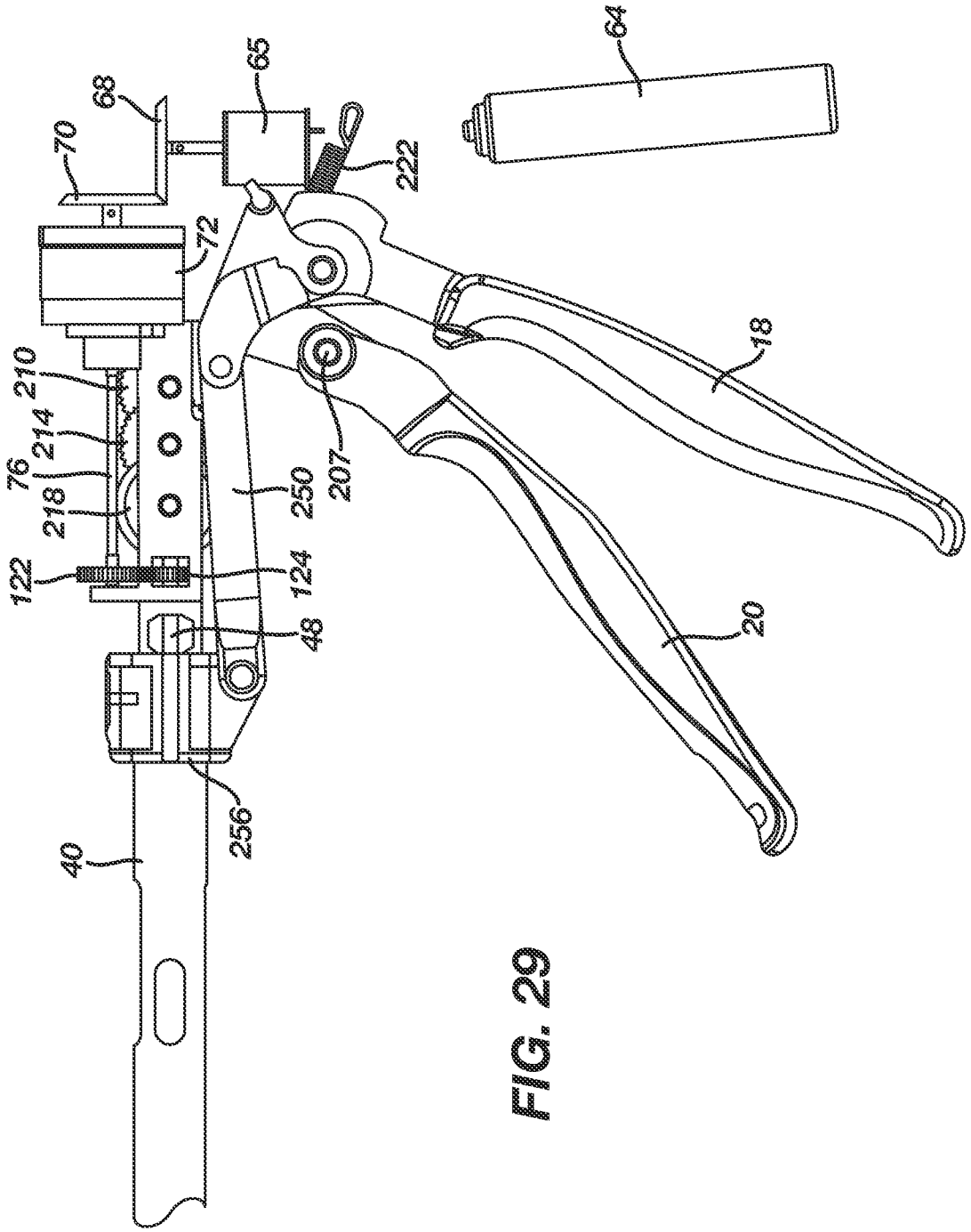


FIG. 29

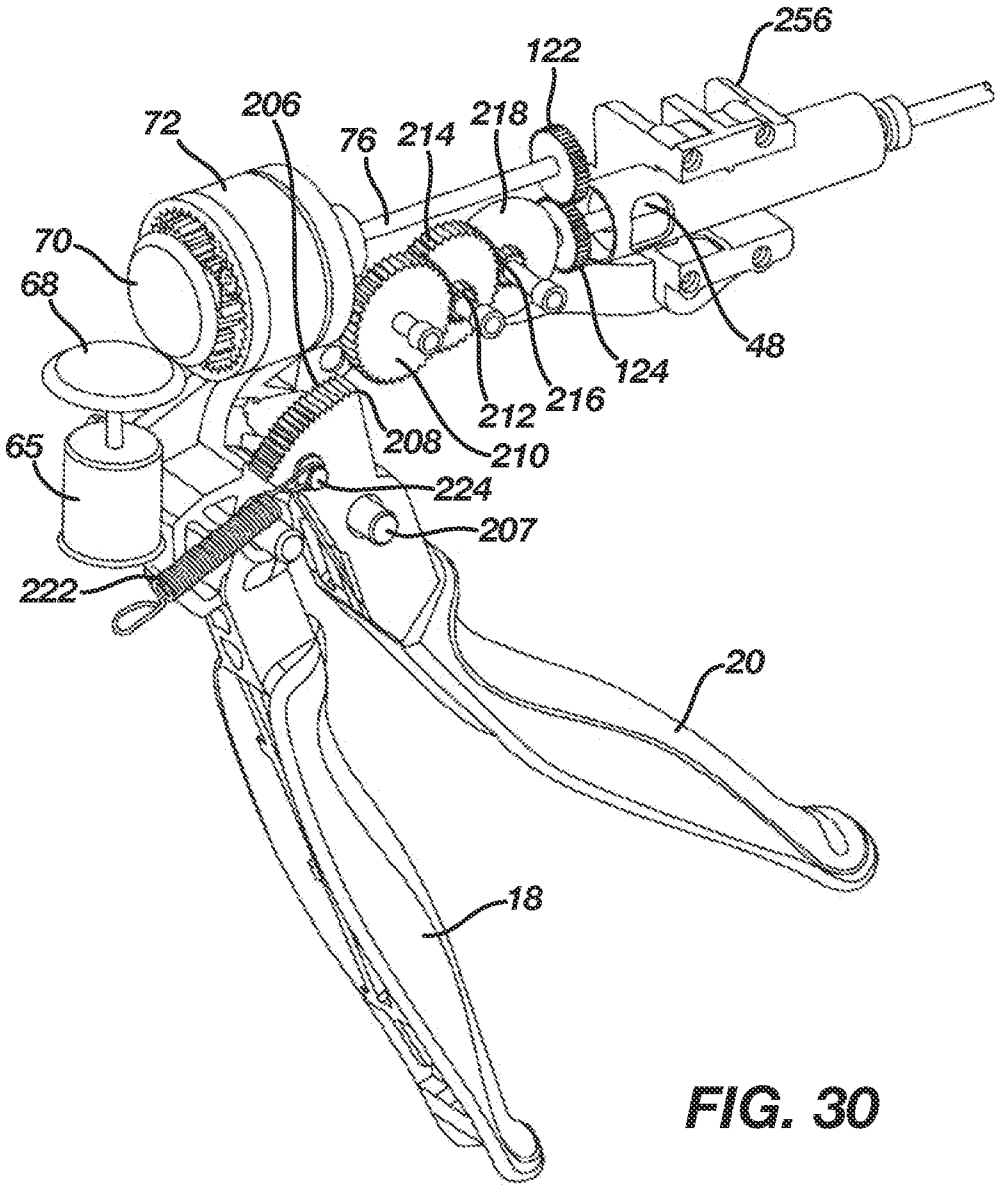

256
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FIG. 30

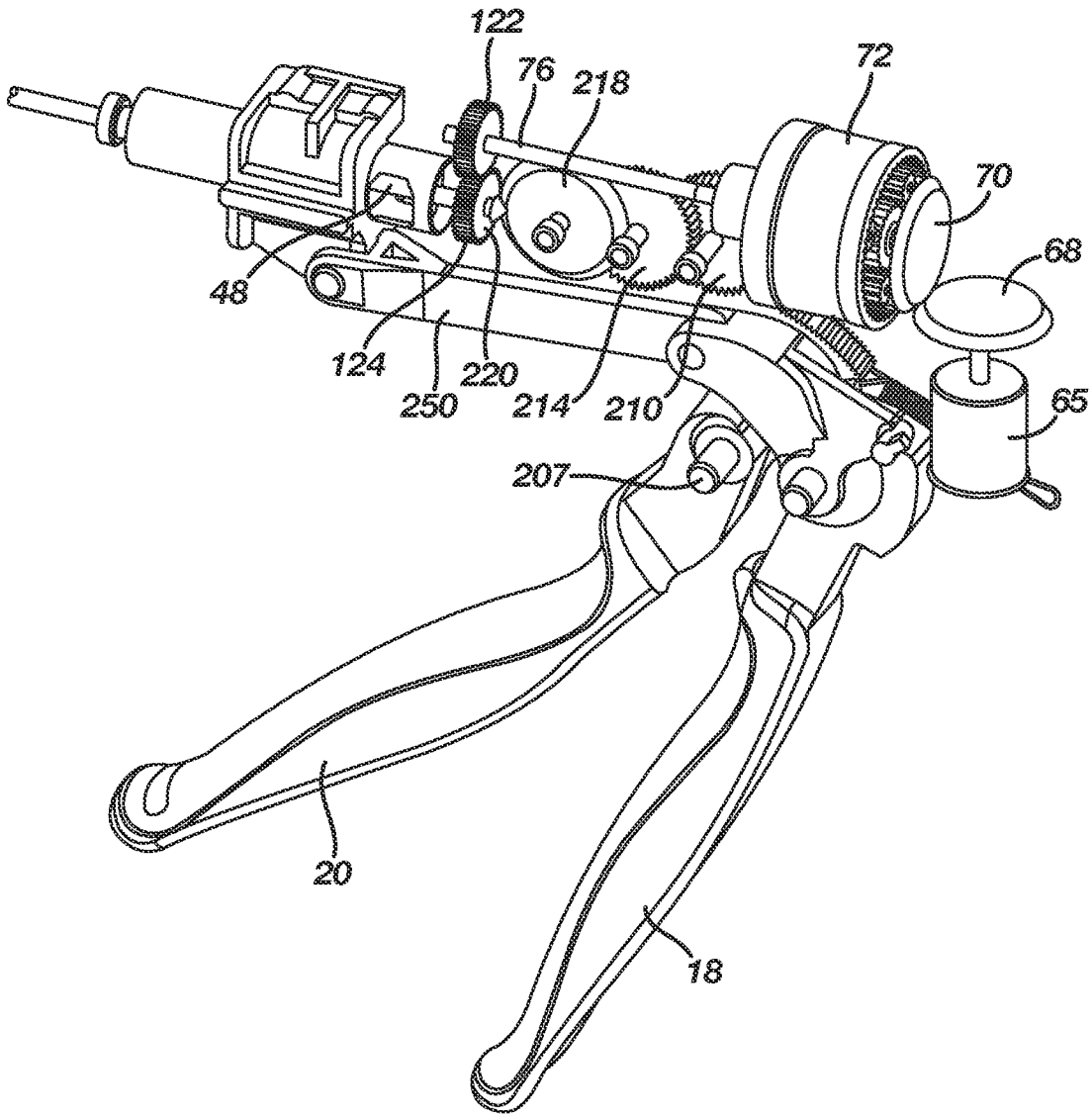


FIG. 31

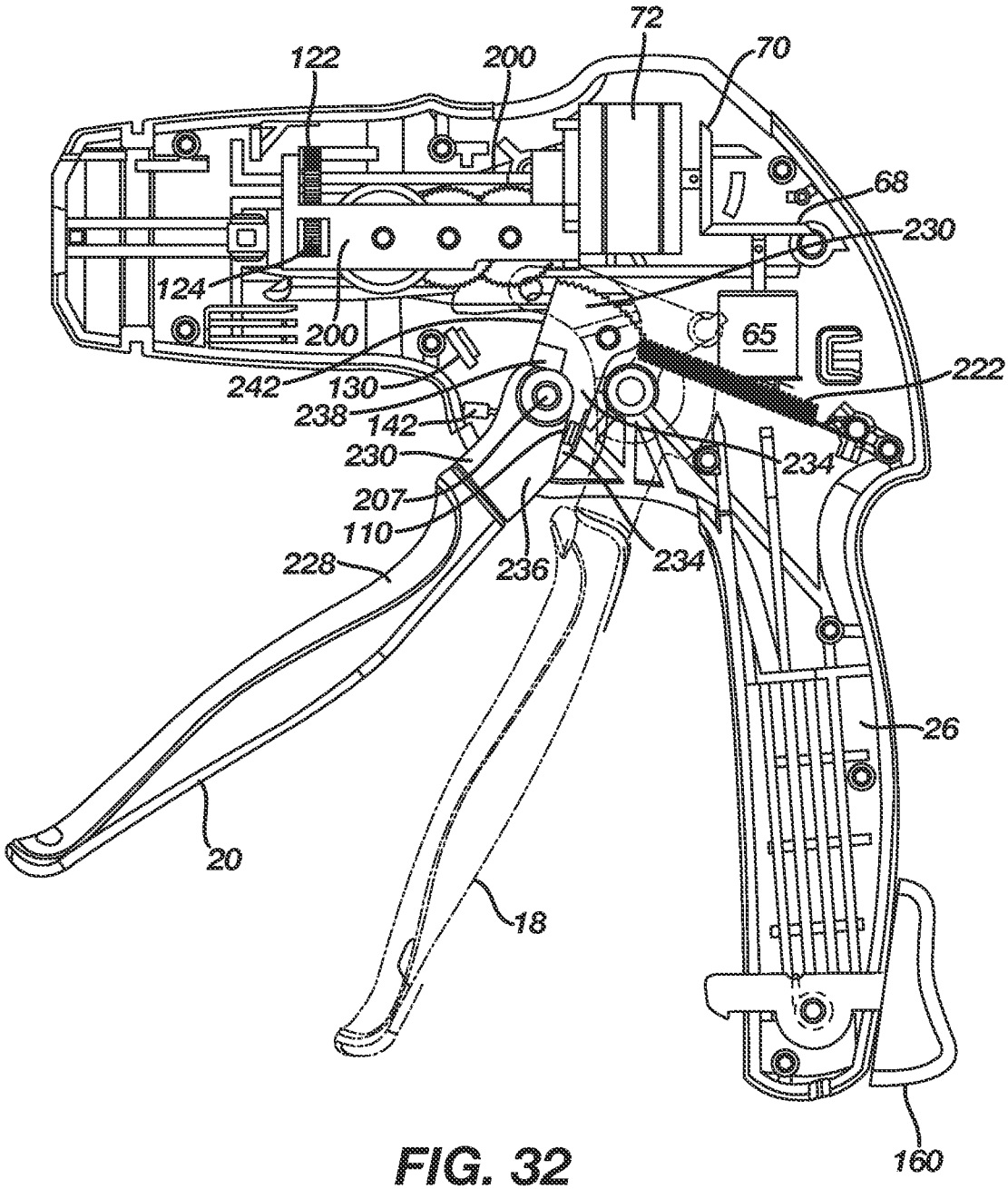

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222
242
130
238
142
230
234
207
110
228
236
234
26
20
18
160

FIG. 32

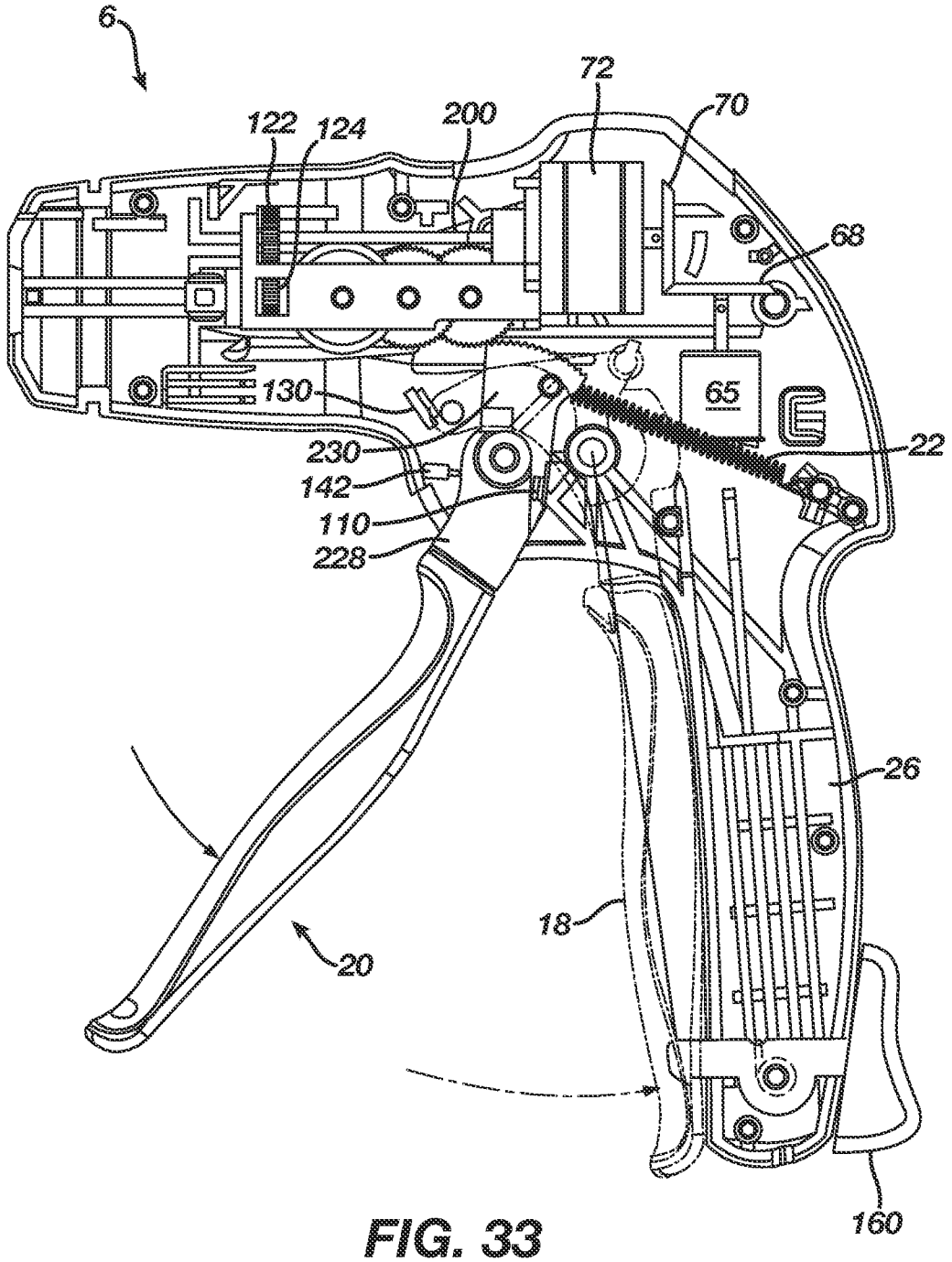


FIG. 33

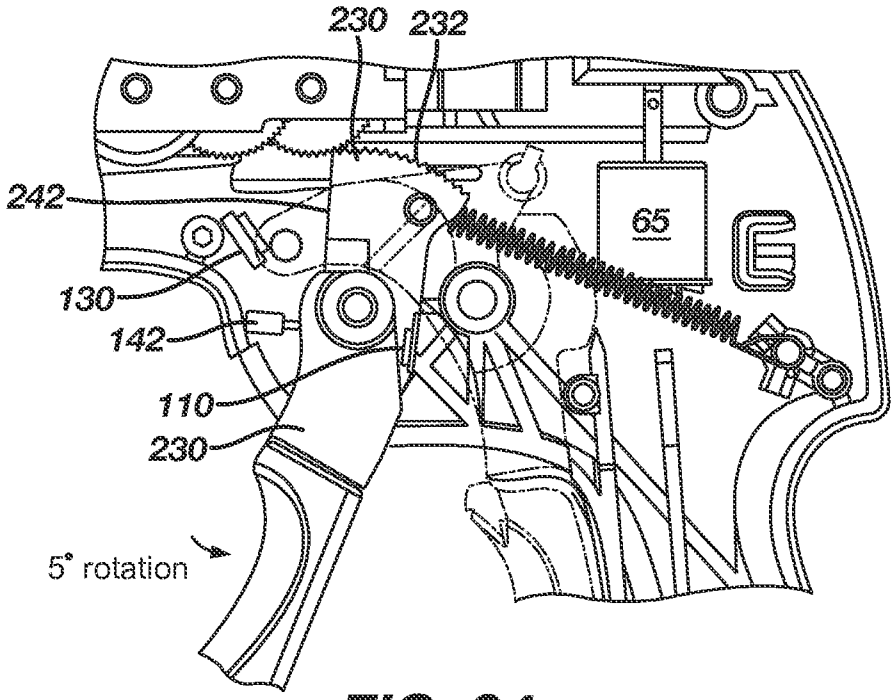

230
232
242
65
130
142
110
230
5° rotation

FIG. 34

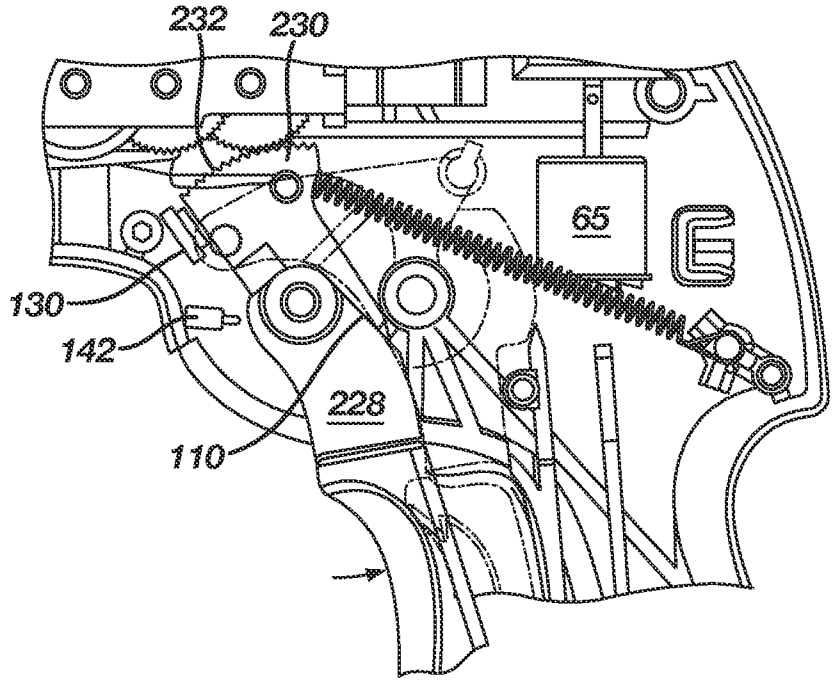

232
230
65
130
142
228
110

FIG. 35

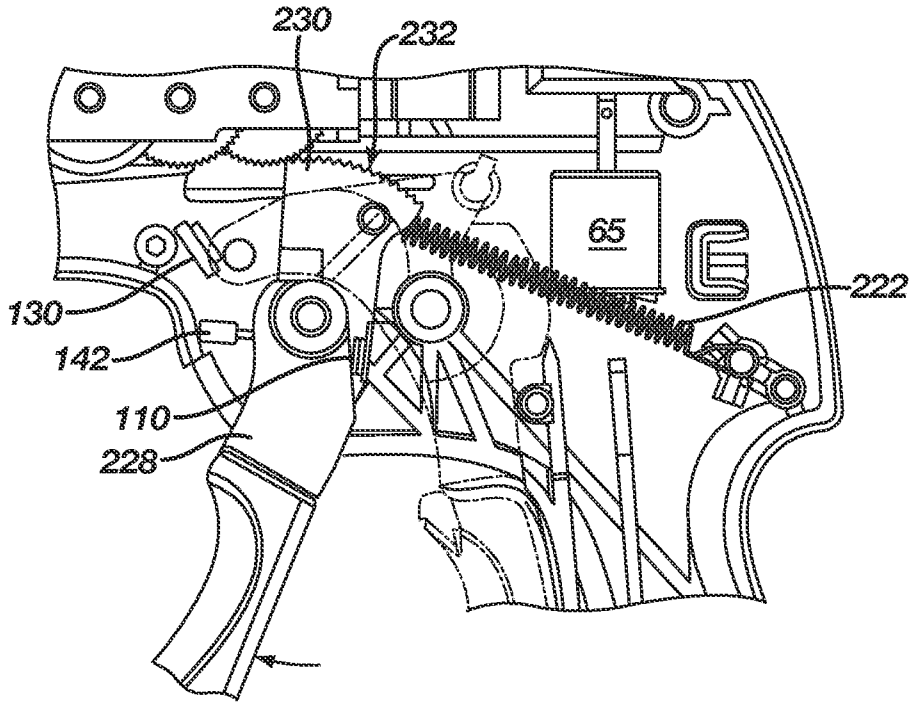


FIG. 36

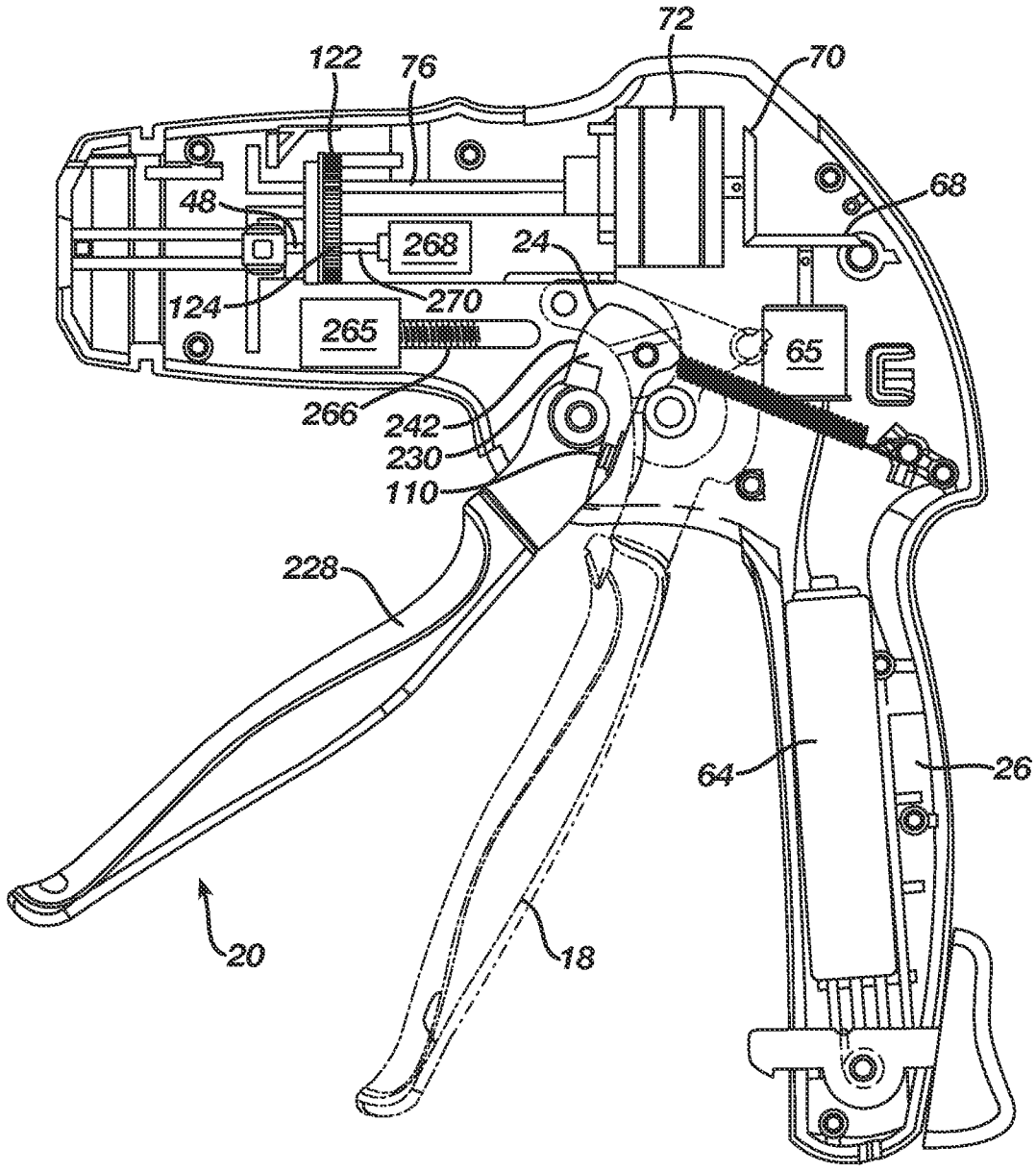

72
122
76
70
68
48
268
24
124
270
265
65
266
242
230
110
228
64
26
20
18

FIG. 37

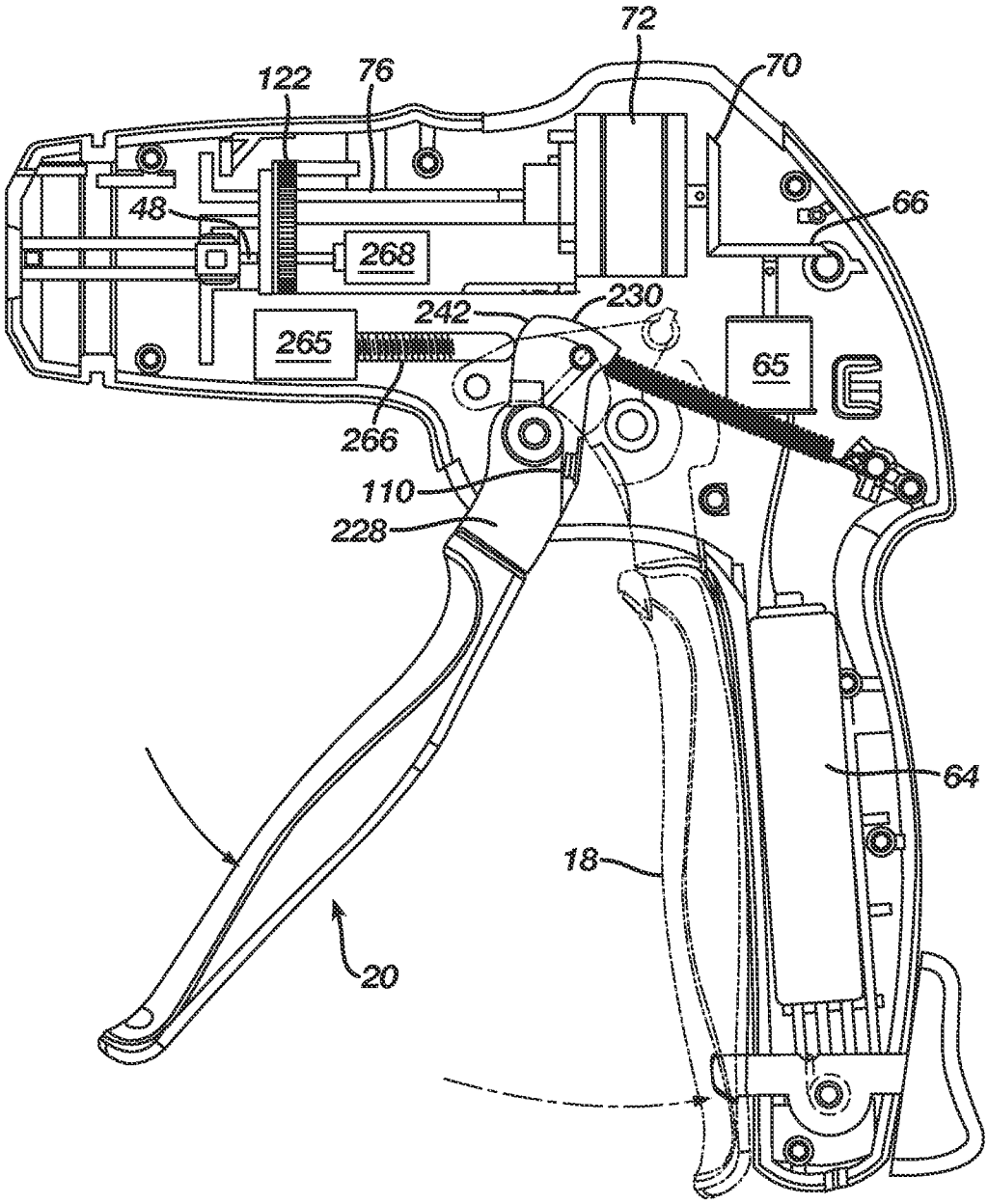


FIG. 38

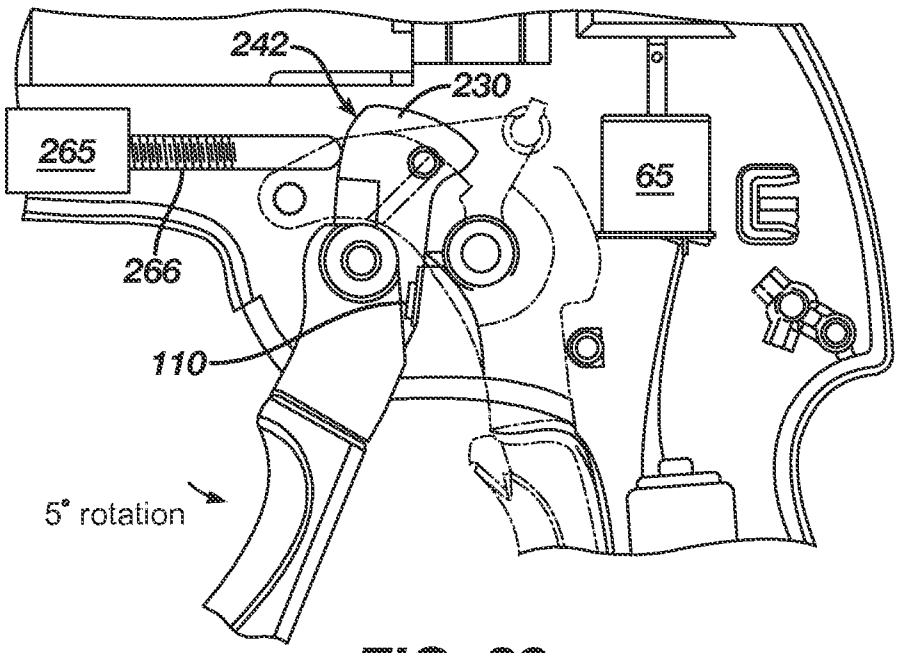


FIG. 39

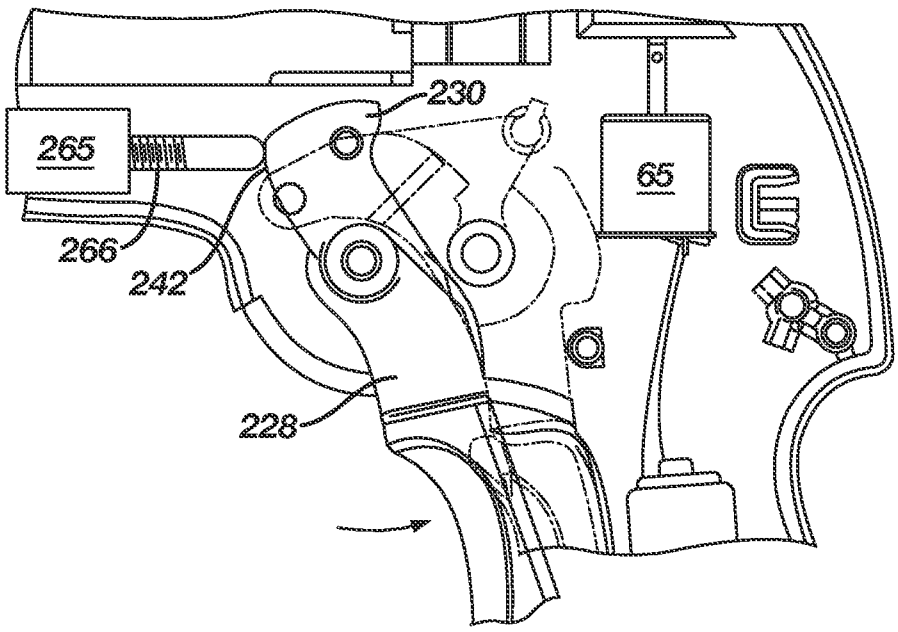


FIG. 40

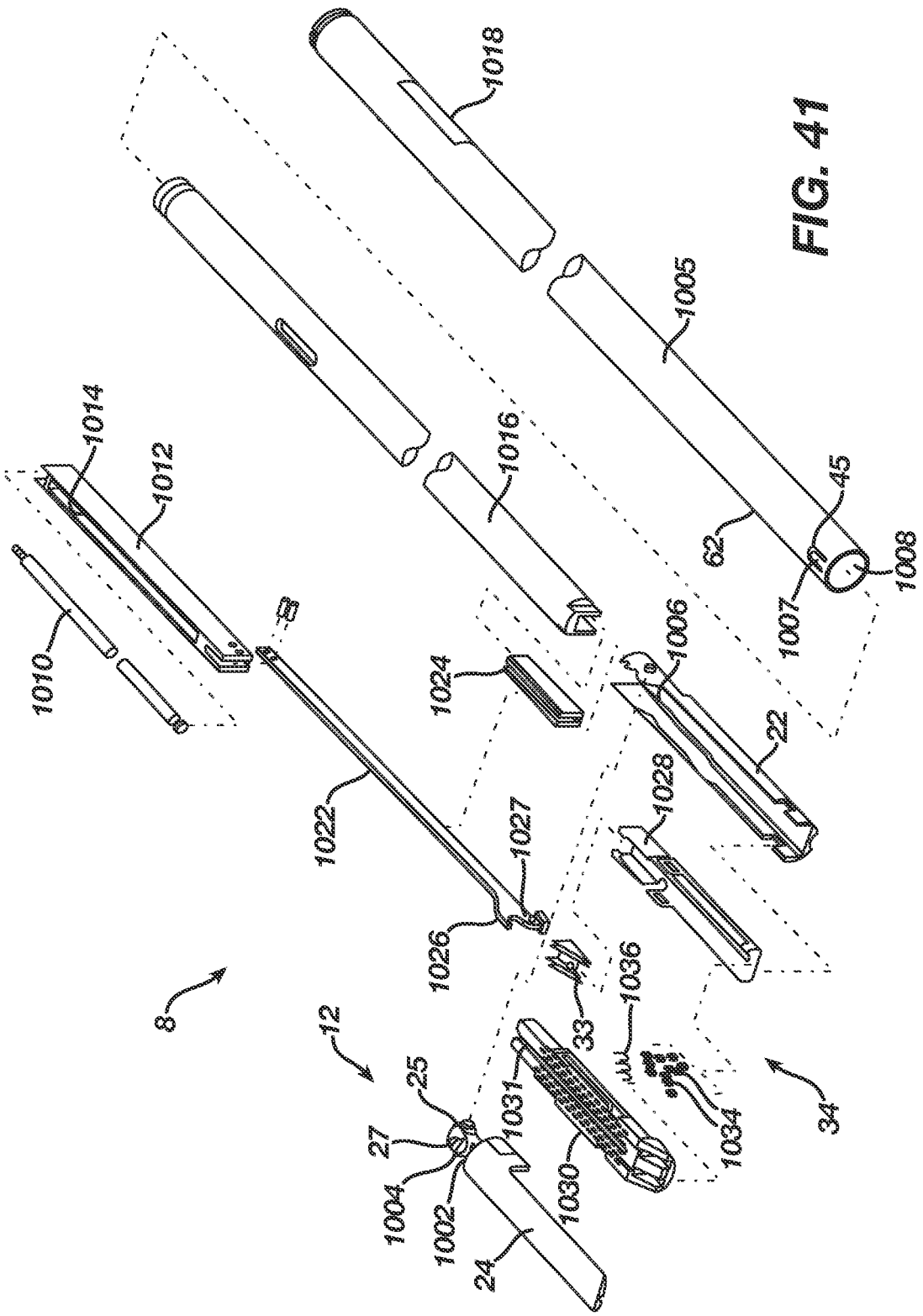

1018
1005
1014
1012
1016
1010
1024
1006
22
1028
1022
1027
1026
1036
33
8
12
25
27
1031
1004
1002
1030
1034
24
34
62
45
1007
1008

FIG. 41

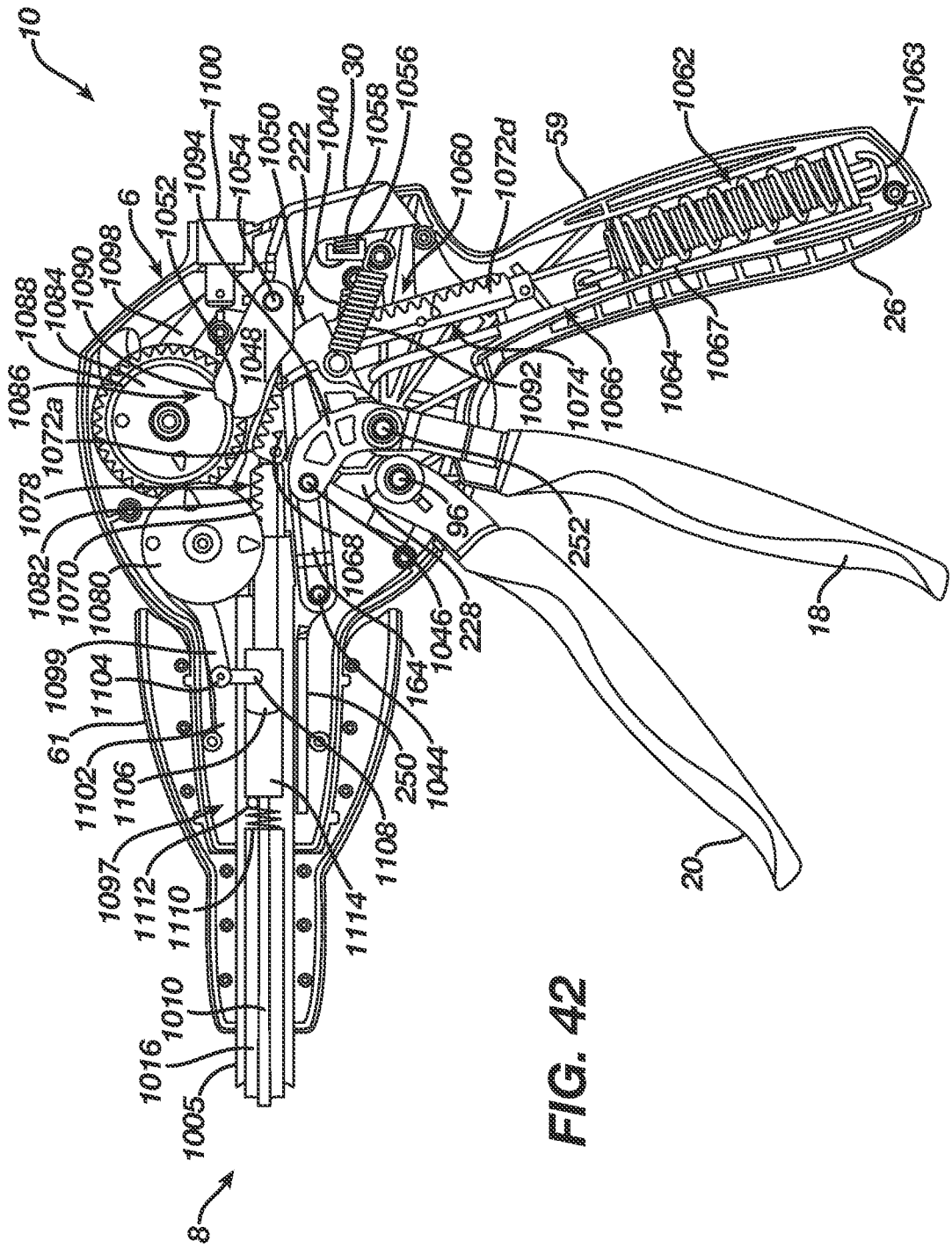

10
1100
30
1058
1056
1062
1063
1094
1054
1050
222
1040
1060
1072d
59
6
1052
1098
1090
1088
1084
1086
1072a
1078
1082
1070
1080
1099
1104
61
1102
1106
1097
1112
1110
1010
1016
1005
8
1048
1092
1074
1066
1064
1067
26
252
96
1068
1046
228
164
250
1044
1108
1114
18
20

FIG. 42

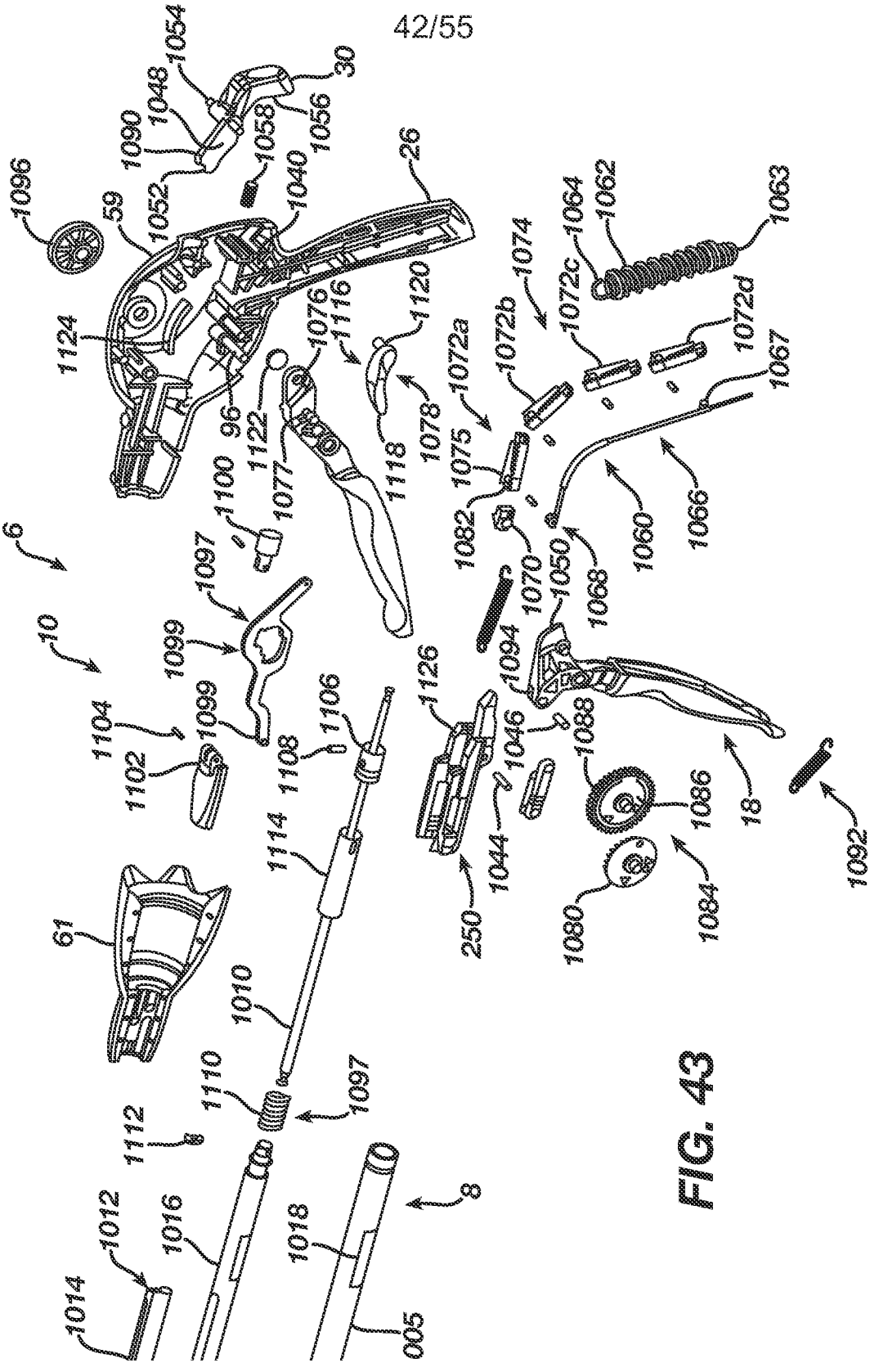

1096
59
1052
1090
1048
1054
30
1056
1058
1040
26
1124
1076
1116
1120
1072a
1072b
1074
1072c
1064
1062
1063
1072d
1067
96
1122
1077
1100
1078
1118
1075
1082
1070
1050
1068
1060
1066
6
10
1097
1099
1104
1102
1106
1108
1126
1094
1046
1088
1086
18
1092
1044
1084
1080
250
61
1114
1010
1110
1112
1097
1012
1016
1018
8
1014
005

FIG. 43

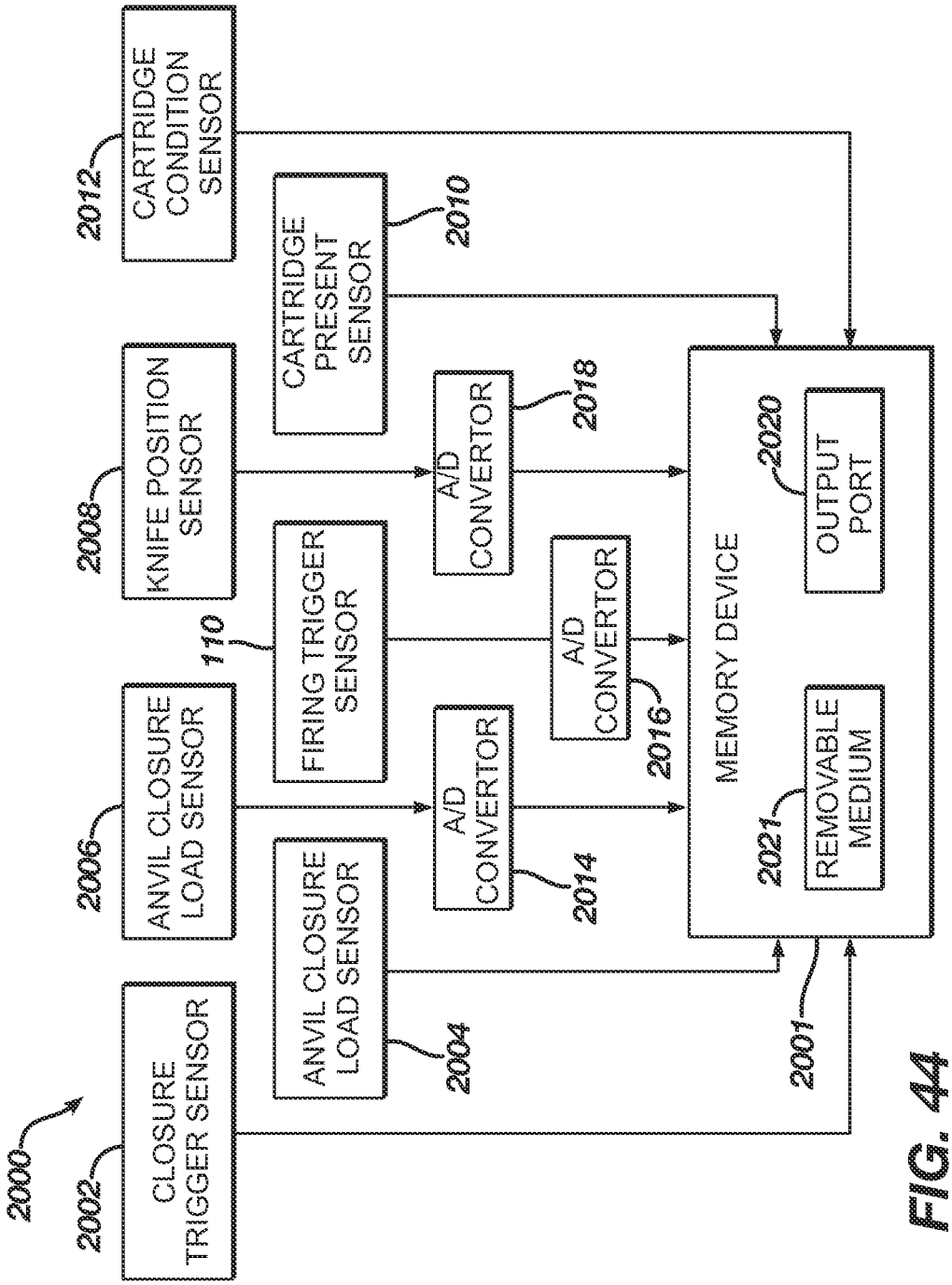

2000
2002
CLOSURE TRIGGER SENSOR
2004
ANVIL CLOSURE LOAD SENSOR
2006
ANVIL CLOSURE LOAD SENSOR
110
FIRING TRIGGER SENSOR
2008
KNIFE POSITION SENSOR
2010
CARTRIDGE PRESENT SENSOR
2012
CARTRIDGE CONDITION SENSOR
2014
A/D CONVERTOR
2016
A/D CONVERTOR
2018
A/D CONVERTOR
2001
MEMORY DEVICE
2020
OUTPUT PORT
2021
REMOVABLE MEDIUM

FIG. 44

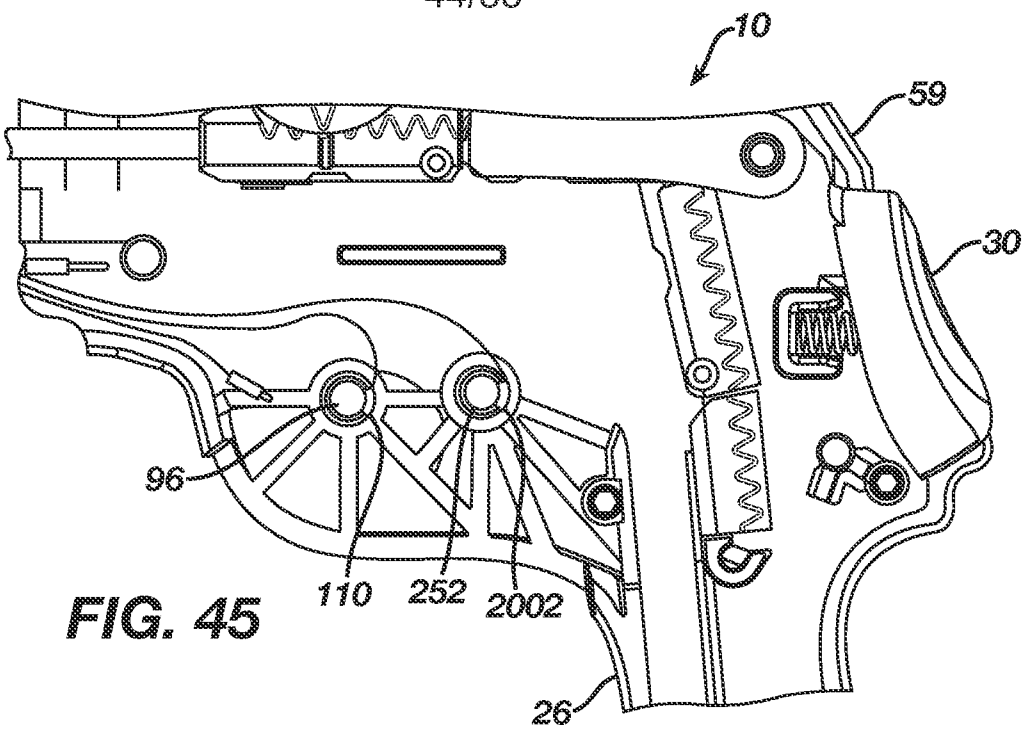


FIG. 45

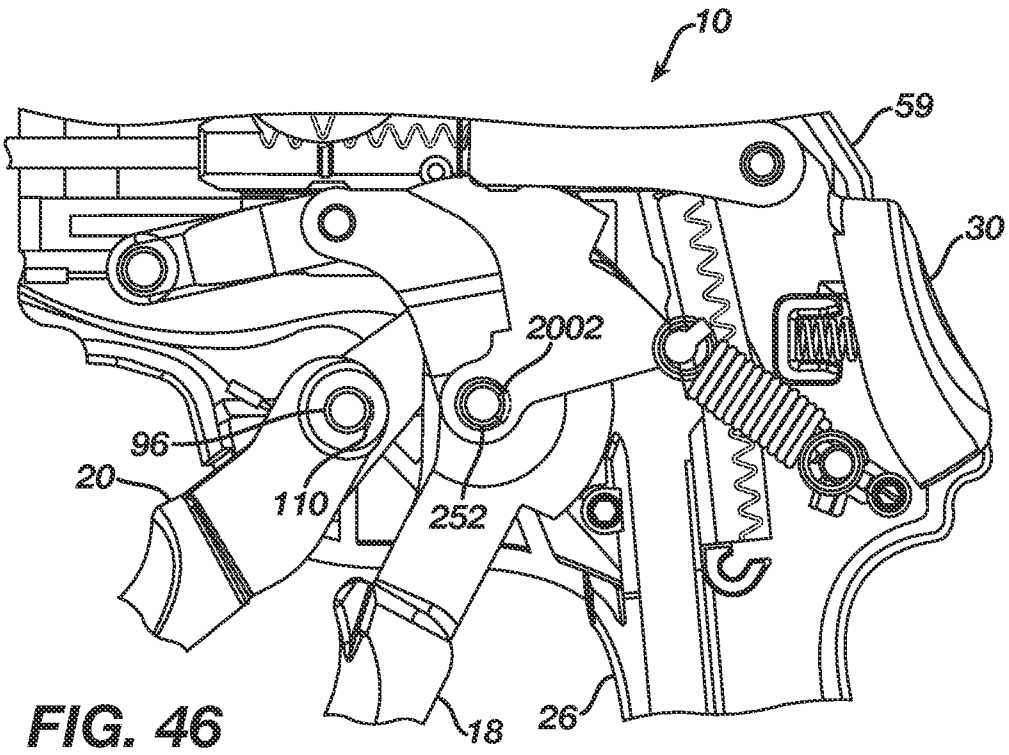


FIG. 46

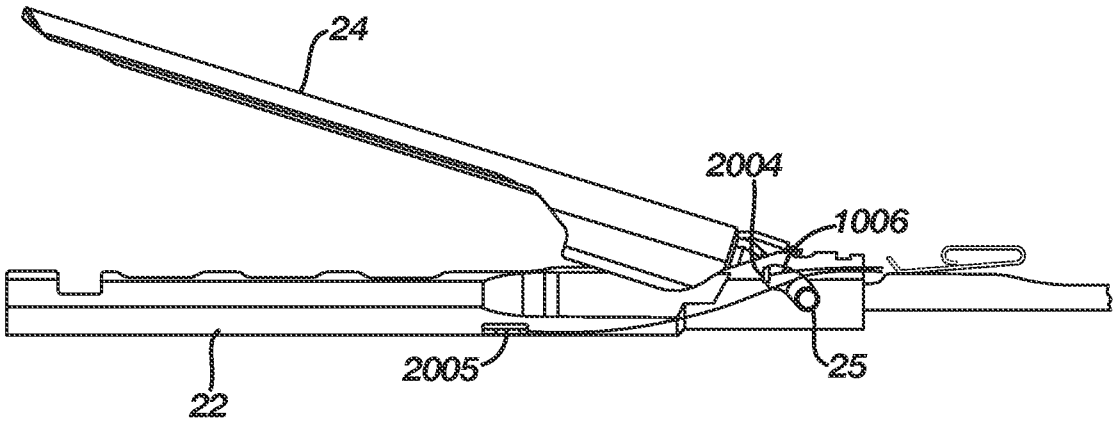


FIG. 47

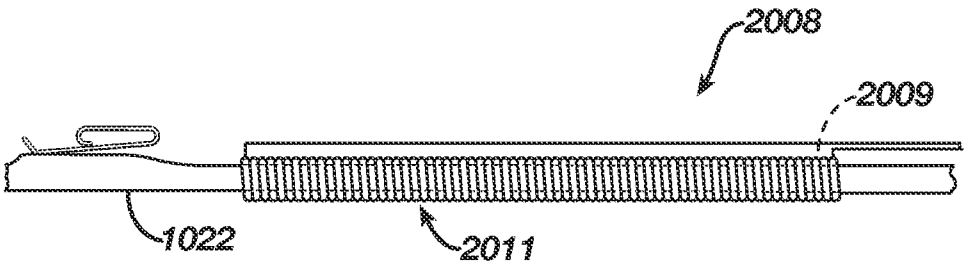


FIG. 48

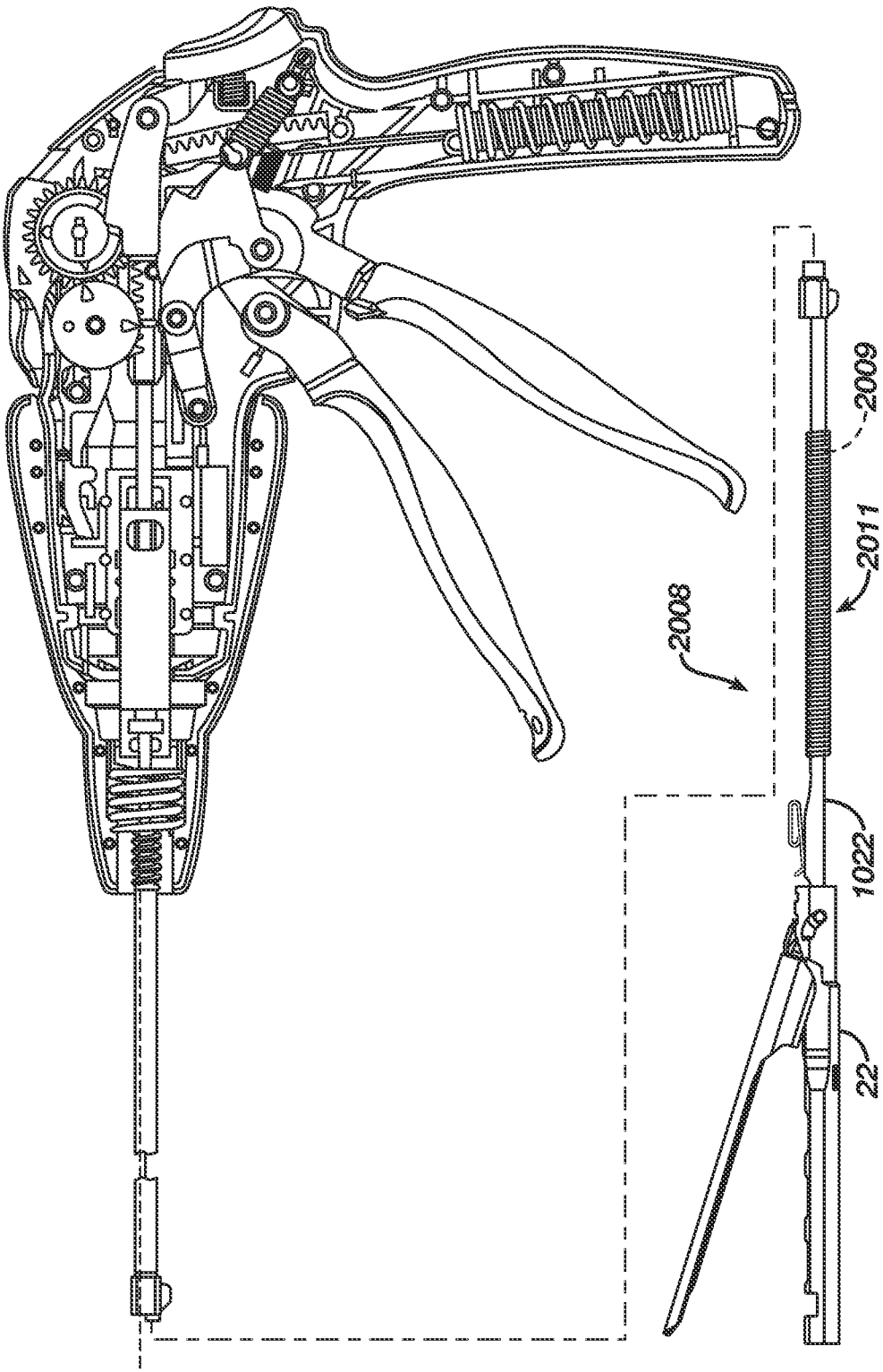


FIG. 49

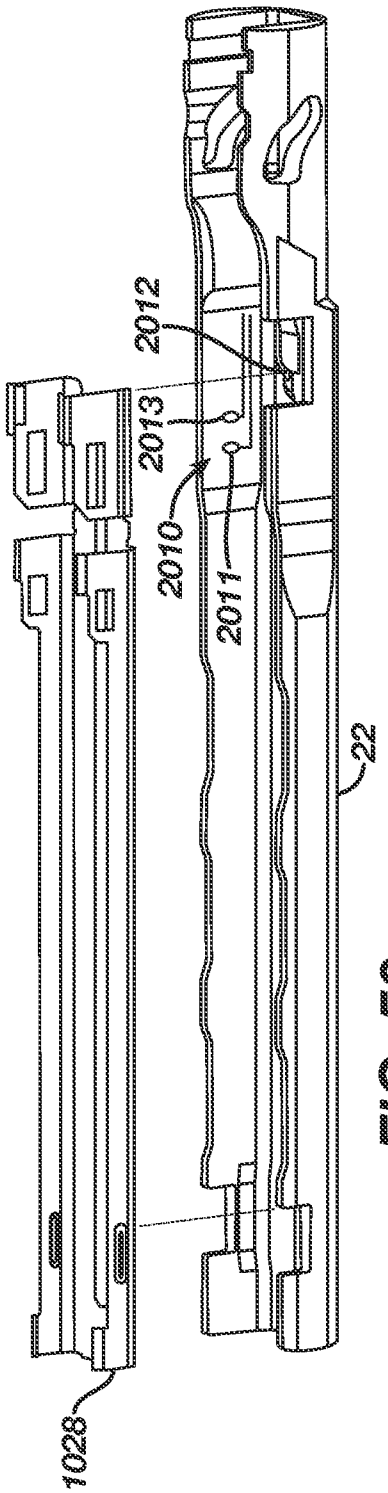


FIG. 50

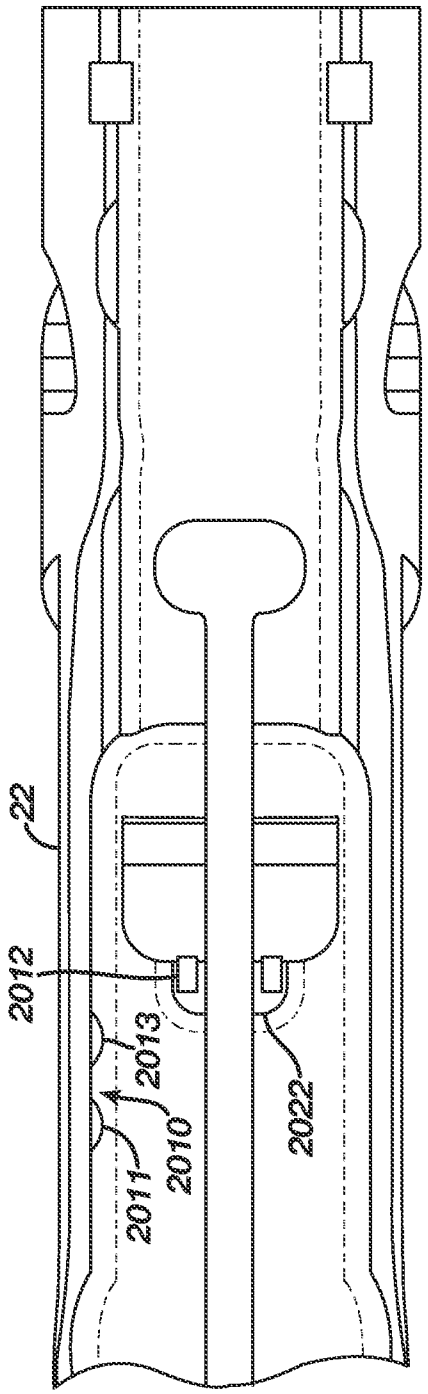


FIG. 51

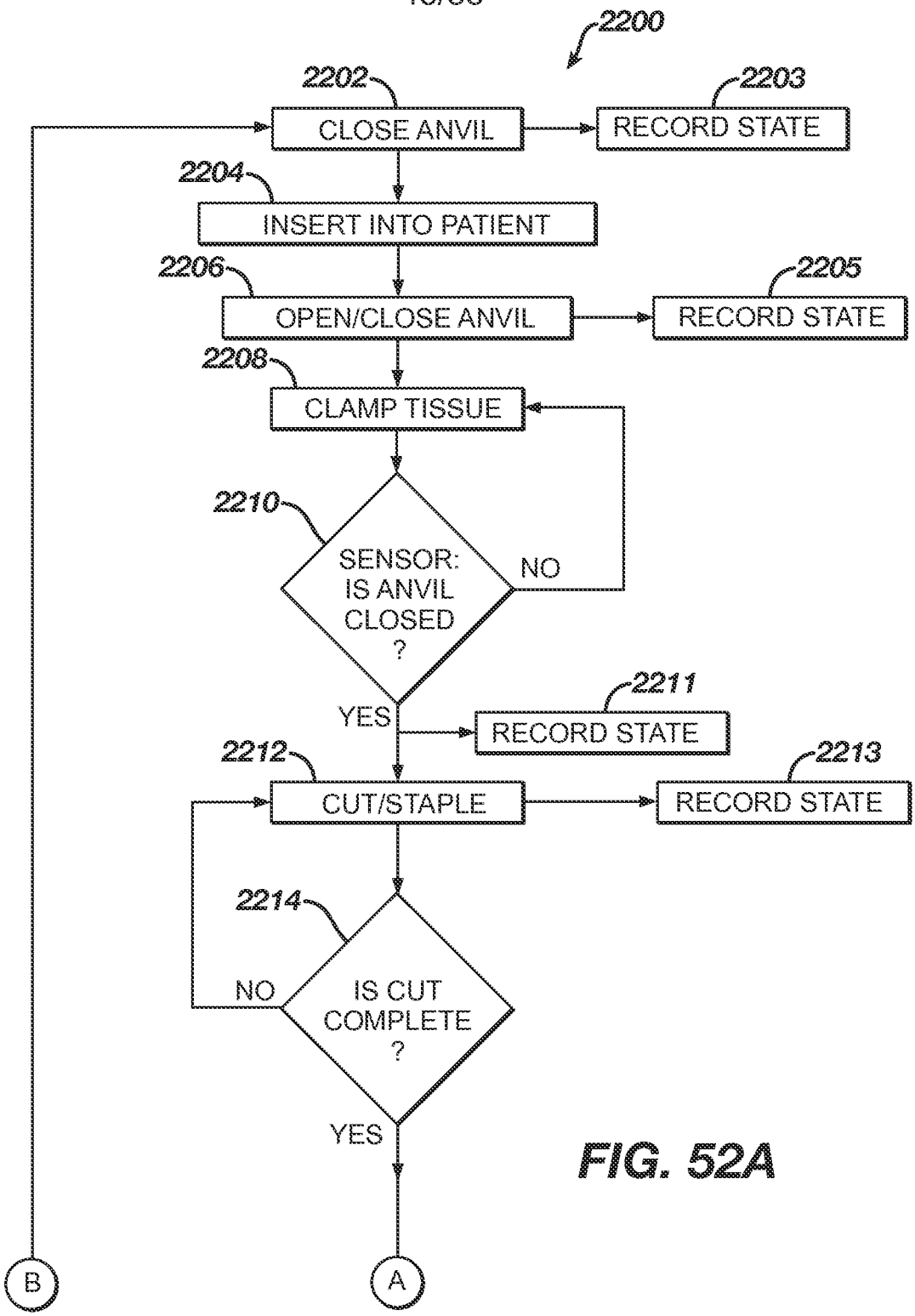

2200
2202
CLOSE ANVIL
2203
RECORD STATE
2204
INSERT INTO PATIENT
2206
OPEN/CLOSE ANVIL
2205
RECORD STATE
2208
CLAMP TISSUE
2210
SENSOR: IS ANVIL CLOSED ?
NO
YES
2211
RECORD STATE
2212
CUT/STAPLE
2213
RECORD STATE
2214
IS CUT COMPLETE ?
NO
YES
B
A

FIG. 52A

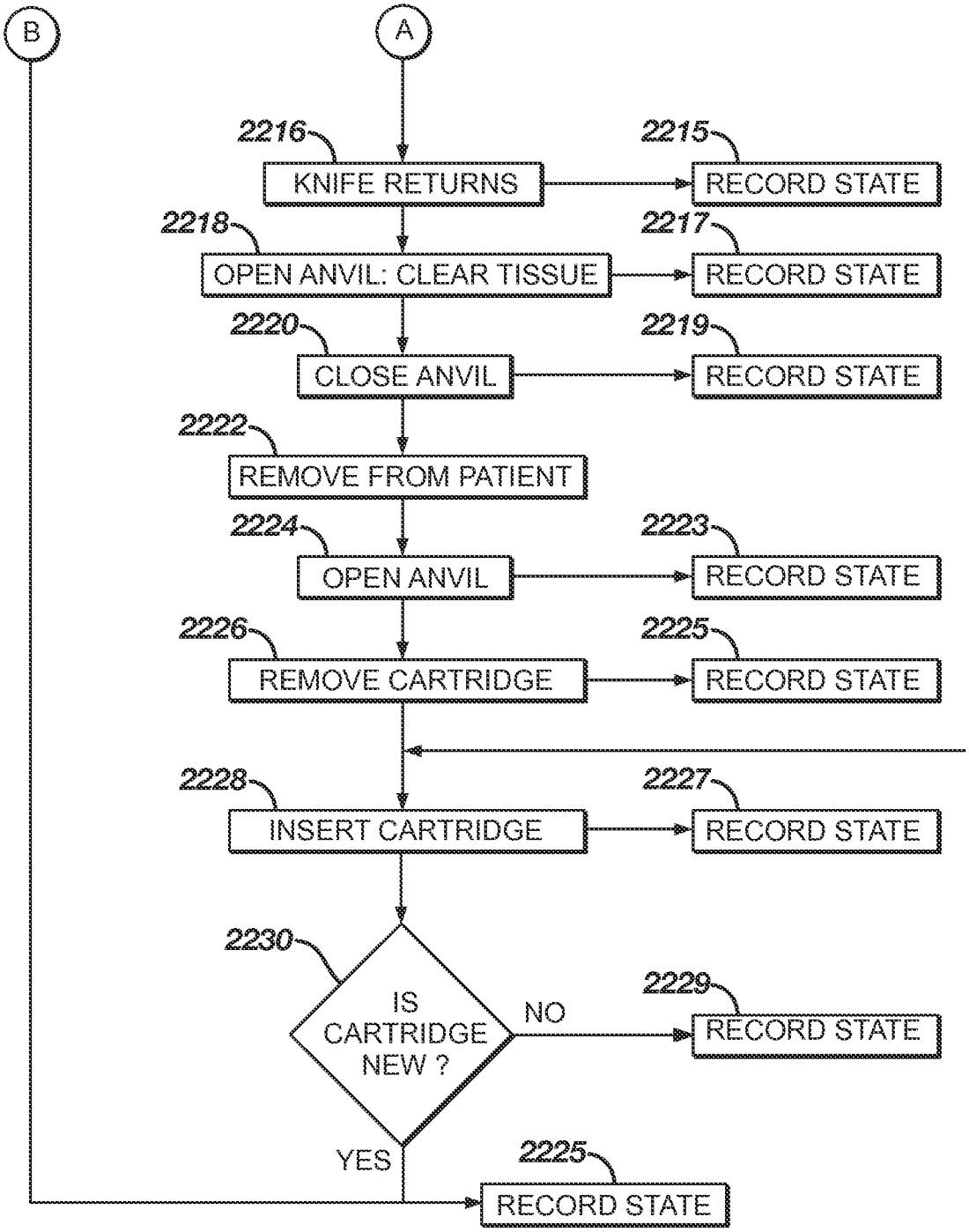

B
A
2216
KNIFE RETURNS
2215
RECORD STATE
2218
OPEN ANVIL: CLEAR TISSUE
2217
RECORD STATE
2220
CLOSE ANVIL
2219
RECORD STATE
2222
REMOVE FROM PATIENT
2224
OPEN ANVIL
2223
RECORD STATE
2226
REMOVE CARTRIDGE
2225
RECORD STATE
2228
INSERT CARTRIDGE
2227
RECORD STATE
2230
IS CARTRIDGE NEW ?
NO
2229
RECORD STATE
YES
2225
RECORD STATE

FIG. 52B

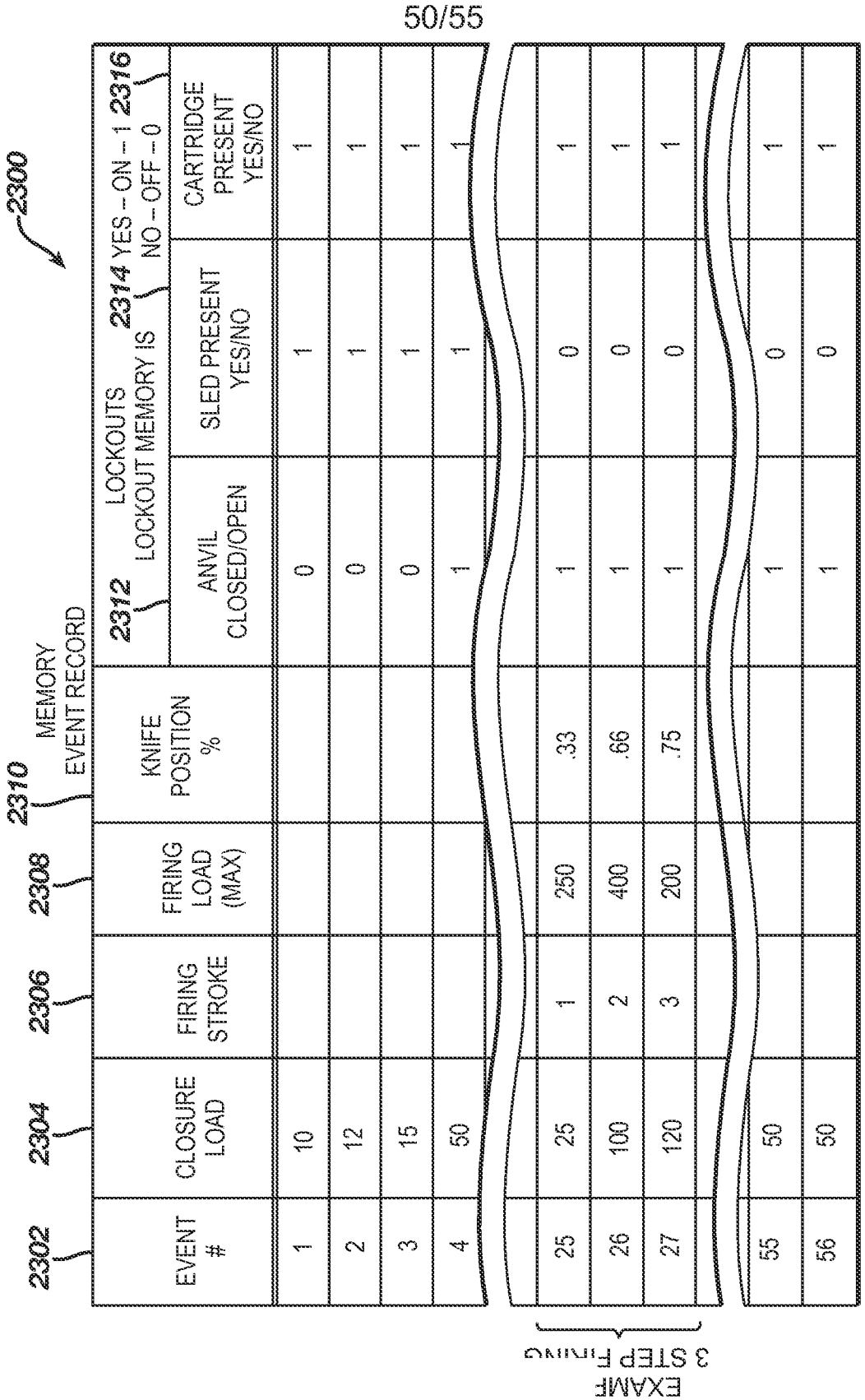

2300
2310 MEMORY EVENT RECORD
2312 LOCKOUTS LOCKOUT MEMORY IS
2314 YES – ON – 1 NO – OFF – 0
2316
2302 EVENT #
2304 CLOSURE LOAD
2306 FIRING STROKE
2308 FIRING LOAD (MAX)
KNIFE POSITION %
ANVIL CLOSED/OPEN
SLED PRESENT YES/NO
CARTRIDGE PRESENT YES/NO
1 10 0 1 1
2 12 0 1 1
3 15 0 1 1
4 50 1 1 1
25 25 1 250 .33 1 0 1
26 100 2 400 .66 1 0 1
27 120 3 200 .75 1 0 1
55 50 1 0 1
56 50 1 0 1
EXAMPLE 3 STEP FIRING

FIG. 53

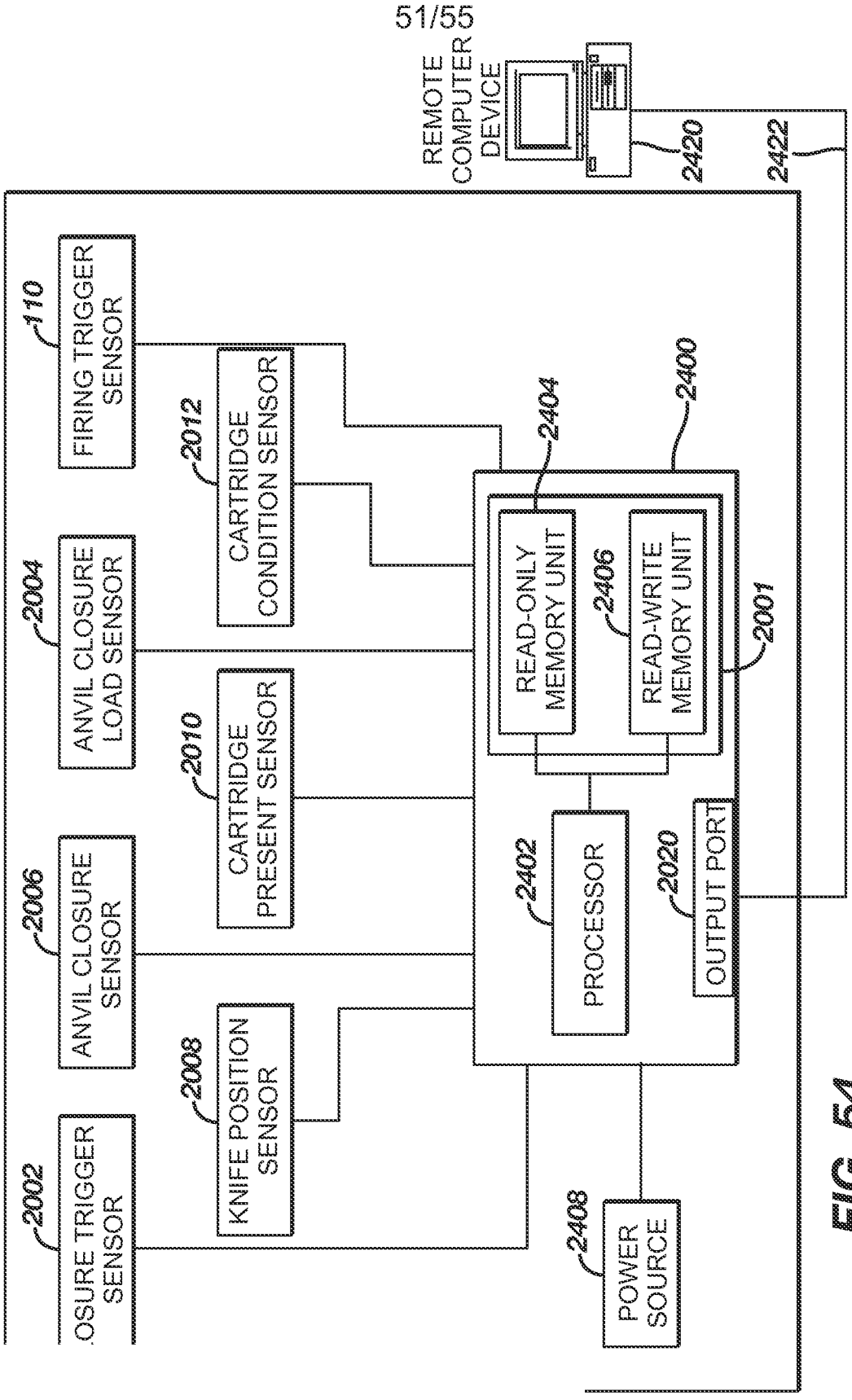

REMOTE COMPUTER DEVICE
2420
2422
2001
2400
2404
READ-ONLY MEMORY UNIT
2406
READ-WRITE MEMORY UNIT
2402
PROCESSOR
2020
OUTPUT PORT
2408
POWER SOURCE
2002
OSURE TRIGGER SENSOR
2006
ANVIL CLOSURE SENSOR
2008
KNIFE POSITION SENSOR
2010
CARTRIDGE PRESENT SENSOR
2004
ANVIL CLOSURE LOAD SENSOR
2012
CARTRIDGE CONDITION SENSOR
110
FIRING TRIGGER SENSOR

FIG. 54

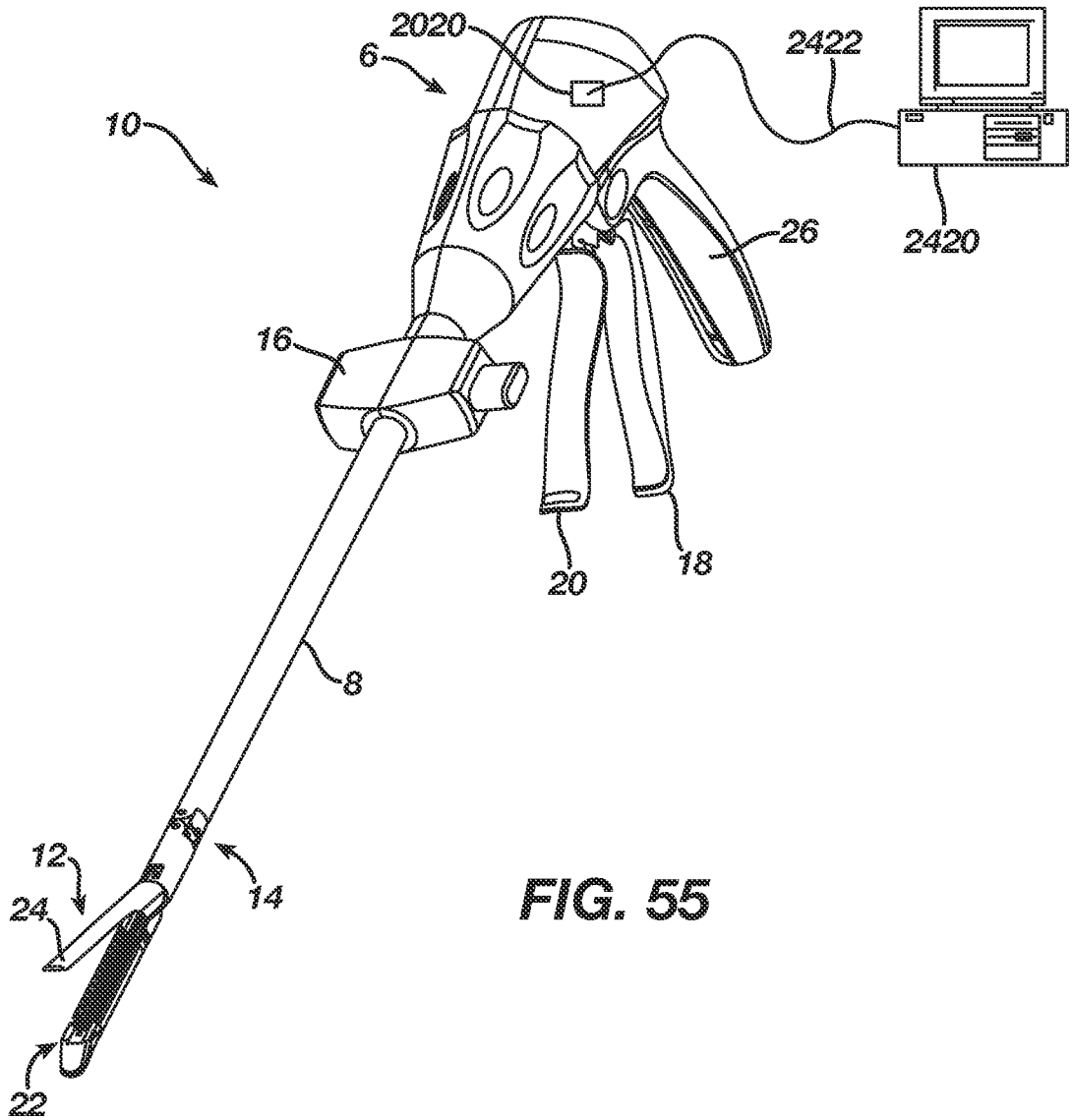


FIG. 55

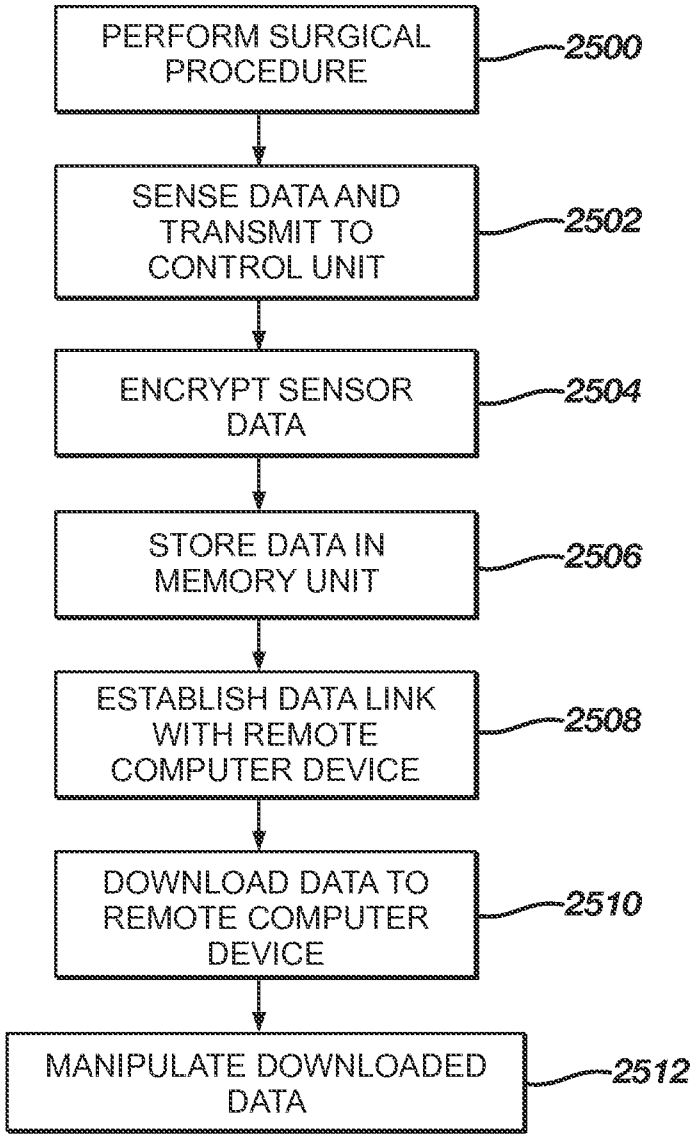

PERFORM SURGICAL PROCEDURE
2500
SENSE DATA AND TRANSMIT TO CONTROL UNIT
2502
ENCRYPT SENSOR DATA
2504
STORE DATA IN MEMORY UNIT
2506
ESTABLISH DATA LINK WITH REMOTE COMPUTER DEVICE
2508
DOWNLOAD DATA TO REMOTE COMPUTER DEVICE
2510
MANIPULATE DOWNLOADED DATA
2512

FIG. 56

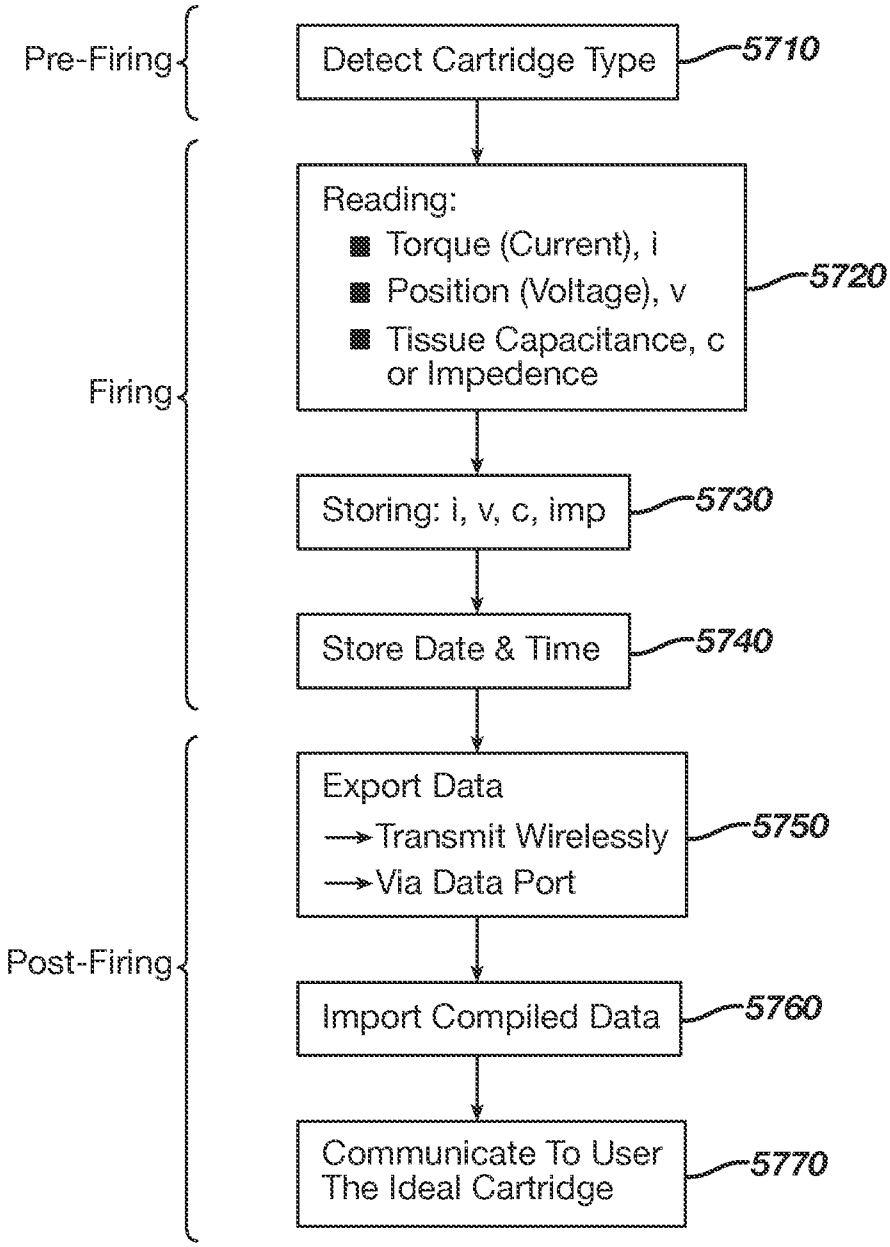

Pre-Firing
Firing
Post-Firing
Detect Cartridge Type
5710
Reading:
Torque (Current), i
Position (Voltage), v
Tissue Capacitance, c or Impedence
5720
Storing: i, v, c, imp
5730
Store Date & Time
5740
Export Data
Transmit Wirelessly
Via Data Port
5750
Import Compiled Data
5760
Communicate To User The Ideal Cartridge
5770

FIG. 57

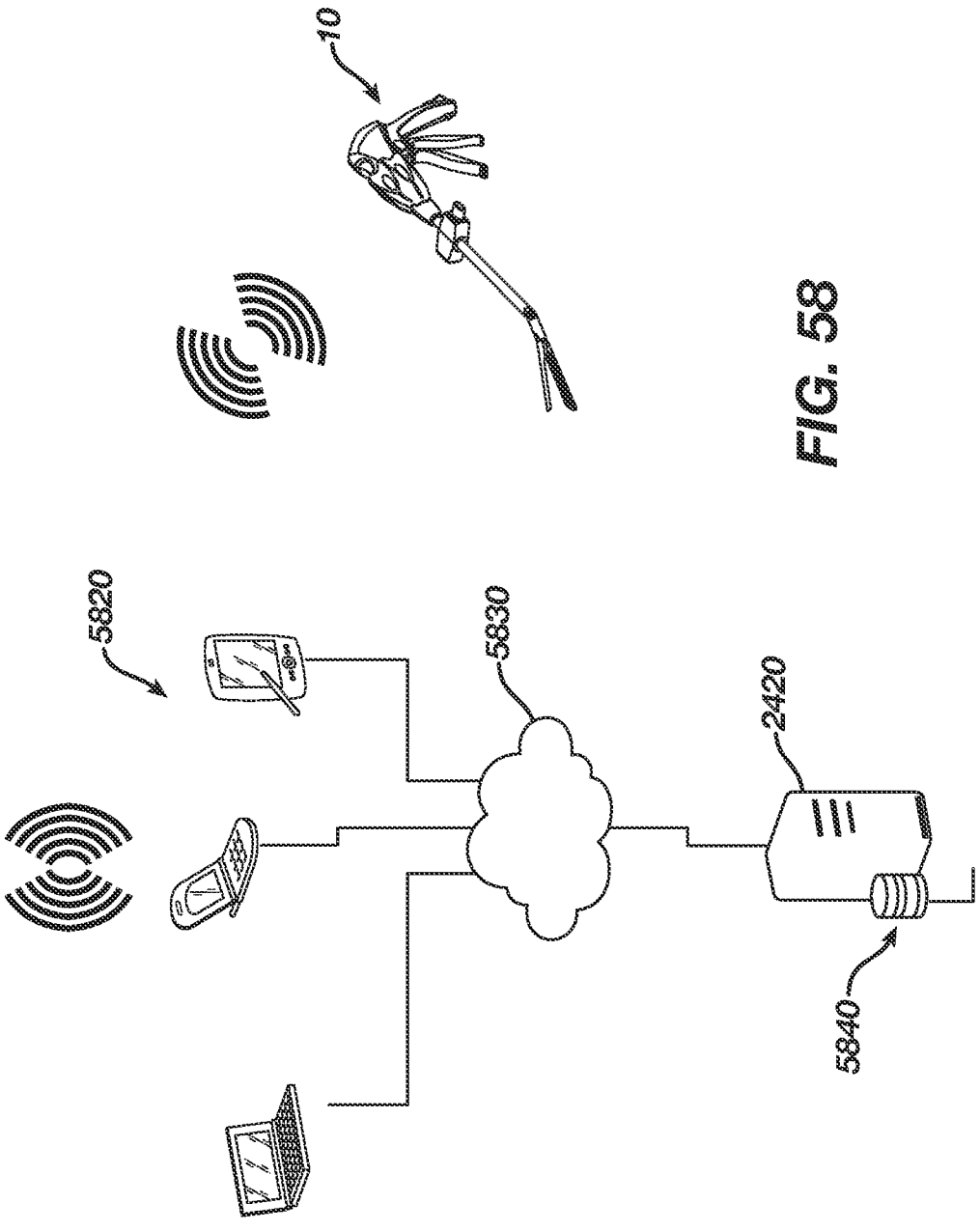


FIG. 58

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/055355

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/072 G08C17/02
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.
X	EP 2 044 890 A1 (TYCO HEALTHCARE [US]) 8 April 2009 (2009-04-08) paragraphs [0078] - [0084], [0102] - [0106], [0110] - [0112], [0127] - [0130], [0140] - [0152]; figures 1,3,4,13,20-23	1,2
X	US 2011/155781 A1 (SWENSGARD BRETT E [US] ET AL) 30 June 2011 (2011-06-30) paragraphs [0024], [0025], [0030] - [0040]; figures 1,8,9	1,2
A	US 2011/174862 A1 (SHELTON IV FREDERICK E [US] ET AL) 21 July 2011 (2011-07-21) paragraphs [0136], [0137], [0153] - [0160]; figures 54-56	1,2

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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	Date of mailing of the international search report
5 December 2014	15/12/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Maier, Christian

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/055355

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 2044890 A1	08-04-2009	AU 2008229719 A1	23-04-2009
		AU 2014210681 A1	28-08-2014
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		JP 2009090113 A	30-04-2009
		JP 2013208472 A	10-10-2013
		US 2009090763 A1	09-04-2009
US 2011155781 A1	30-06-2011	AU 2010333868 A1	31-05-2012
		CA 2784307 A1	30-06-2011
		CN 102665575 A	12-09-2012
		EP 2515769 A1	31-10-2012
		JP 2013515565 A	09-05-2013
		RU 2012131566 A	27-01-2014
		US 2011155781 A1	30-06-2011
		WO 2011078959 A1	30-06-2011
US 2011174862 A1	21-07-2011	AU 2012223474 A1	22-08-2013
		CA 2828466 A1	07-09-2012
		CN 103384501 A	06-11-2013
		EP 2680761 A1	08-01-2014
		JP 2014517706 A	24-07-2014
		US 2011174862 A1	21-07-2011
		US 2014299649 A1	09-10-2014
		WO 2012118838 A1	07-09-2012