



(22) Date de dépôt/Filing Date: 2007/01/30

(41) Mise à la disp. pub./Open to Public Insp.: 2007/07/31

(45) Date de délivrance/Issue Date: 2014/10/28

(30) Priorité/Priority: 2006/01/31 (US11/343,439)

(51) Cl.Int./Int.Cl. *A61B 17/068* (2006.01)

(72) Inventeurs/Inventors:

SHELTON, FREDERICK E., IV, US;
DOLL, KEVIN R., US;
SWAYZE, JEFFREY S., US;
TIMPERMAN, EUGENE L., US

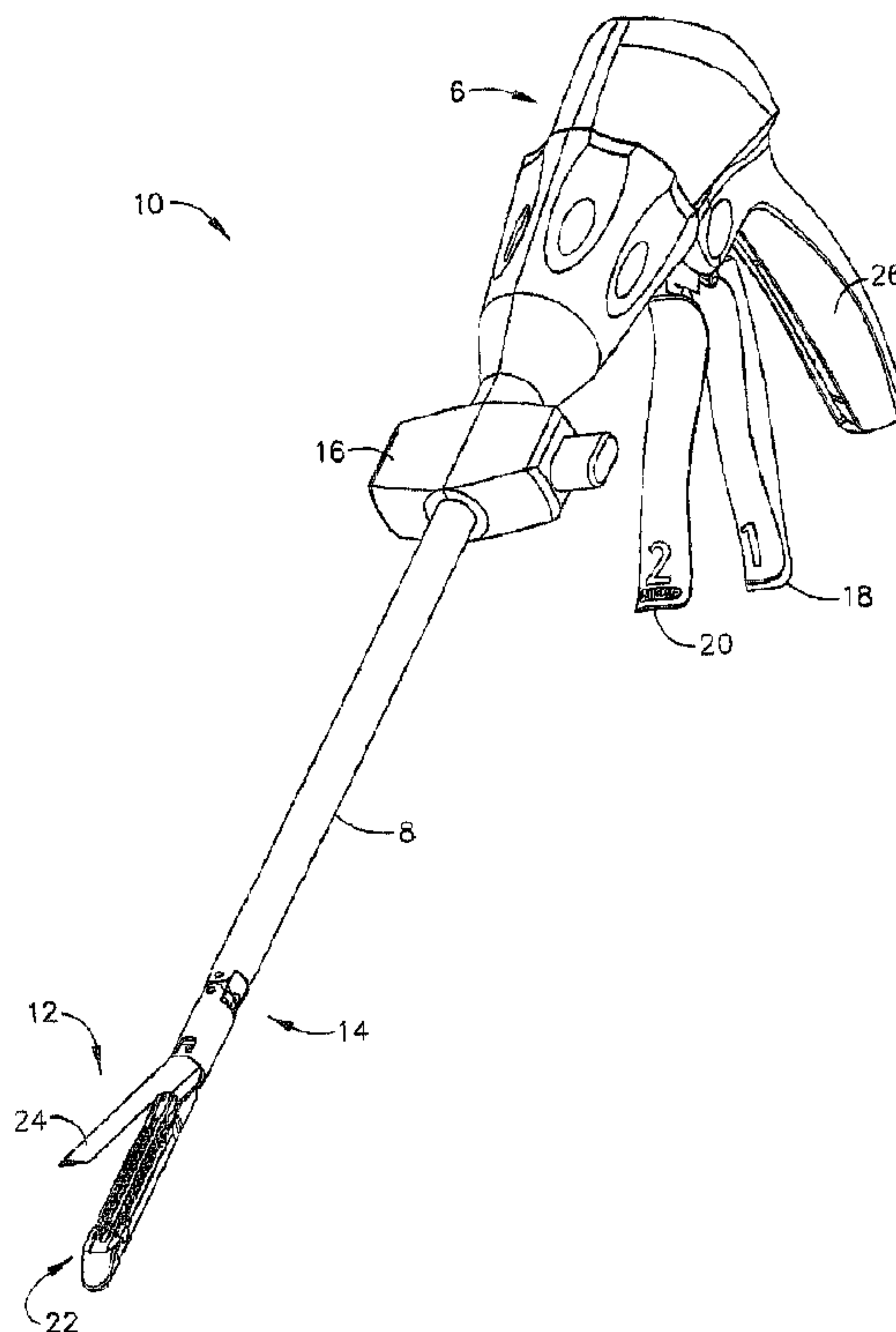
(73) Propriétaire/Owner:

ETHICON ENDO-SURGERY, INC., US

(74) Agent: NORTON ROSE FULBRIGHT CANADA
LLP/S.E.N.C.R.L., S.R.L.

(54) Titre : VERROUILLAGES ELECTRONIQUES ET INSTRUMENT CHIRURGICAL COMPORTANT DE TELS
VERROUILLAGES ELECTRONIQUES

(54) Title: ELECTRONIC LOCKOUTS AND SURGICAL INSTRUMENT INCLUDING SAME



(57) Abrégé/Abstract:

A surgical cutting and stapling instrument is disclosed. The instrument includes an end effector and a handle. The end effector includes a channel, an anvil pivotally attached to the channel, a moveable cutting instrument for cutting an object positioned between the anvil and the channel, and a staple cartridge configured for removable receipt by the channel. The staple cartridge includes a sled that is engaged by the cutting instrument during a cutting stroke. The handle includes a motor for actuating the cutting instrument via a main drive shaft assembly. The instrument further includes a first interlock circuit for enabling initiation of motor operation based upon a position of the staple cartridge.

ABSTRACT

A surgical cutting and stapling instrument is disclosed. The instrument includes an end effector and a handle. The end effector includes a channel, an anvil pivotally attached to the channel, a moveable cutting instrument for cutting an object positioned between the anvil and the channel, and a staple cartridge configured for removable receipt by the channel. The staple cartridge includes a sled that is engaged by the cutting instrument during a cutting stroke. The handle includes a motor for actuating the cutting instrument via a main drive shaft assembly. The instrument further includes a first interlock circuit for enabling initiation of motor operation based upon a position of the staple cartridge.

ELECTRONIC LOCKOUTS AND SURGICAL INSTRUMENT INCLUDING SAME

FIELD OF THE INVENTION

[0001] The disclosed invention relates generally and in various embodiments to surgical stapling and cutting instruments structured and configured for applying lines of staples from a reusable staple cartridge into tissue while cutting the tissue between the applied staple lines. More particularly the disclosed invention relates to electronic interlocks for use in motorized surgical stapling and cutting instruments that prevent cutting of the tissue when the staple cartridge is not installed, is improperly installed, or is spent, or when the surgical stapling and cutting instrument is not otherwise in a condition to perform a stapling and cutting operation in a safe and/or optimal manner. The disclosed invention further relates to electronic interlocks for disabling use of certain instrument features while a stapling and cutting operation is in progress.

BACKGROUND

[0002] Endoscopic surgical instruments are often preferred over traditional open surgical devices since 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.).

[0003] 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.

[0004] Advantageously, the design of the end effector may be such that it can be reused with the surgical stapler. For instance, one patient may need a series of severing and stapling operations. Replacing an entire end effector for each operation tends to be economically inefficient, especially if the end effector is built for strength and reliability over repeated operations. To that end, the staple cartridge is typically configured to be disposable and is fitted into the end effector prior to each operation of the surgical stapler.

[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. Thereby, a clinician 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 either 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] Because the actuating force (i.e., the “force-to-fire”, or FTF) necessary to close the jaws and simultaneously perform the cutting and stapling operation may be considerable, a manually-powered cutting and stapling instrument such as that described above may not be utilizable by otherwise qualified users who are unable to generate the required FTF. Accordingly, powered cutting and stapling instruments have been developed for decreasing the force-to-fire (FTF). Such instruments typically incorporate motors or other actuating mechanisms suitable for supplementing or replacing user-generated force for performing the cutting and stapling operation.

[0008] Although powered instruments provide numerous advantages, it is desirable to prevent inadvertent firing of the instrument under certain conditions. For example, firing the instrument without having a staple cartridge installed, or firing the instrument having an installed but spent staple cartridge, may result in cutting of tissue without simultaneous stapling to minimize bleeding. Additionally, firing of the instrument without proper closure of the jaw members may result in an unacceptable cutting and stapling operation and/or cause mechanical damage to the instrument. Similar consequences may result if the jaw members are inadvertently opened while a cutting and stapling operation is in progress. It is particularly desirable that interlock features for preventing such inadvertent firing and jaw manipulation be accomplished in a reliable way that is not subject to an intervening malfunction. Moreover, for ease of manufacturing and assembly, it is further desirable that the interlock features be accomplished with a minimum number of components.

[0009] Consequently, a significant need exists for electronic interlock features for use in powered cutting and stapling instruments that prevent inadvertent firing (i.e., cutting and stapling) and jaw manipulation during conditions such as those described above.

SUMMARY

[0010] The present invention discloses a surgical cutting and stapling instrument according to various embodiments. The instrument includes an end effector and a handle. The end effector includes a channel, an anvil pivotally attached to the channel, a moveable cutting instrument for cutting an object positioned between the anvil and the channel, and a staple cartridge configured for removable receipt by the channel. The staple cartridge includes a sled that is engaged by the cutting instrument during a cutting stroke. The handle includes a motor for actuating the cutting instrument via a main drive shaft assembly. The instrument further includes a first interlock circuit for enabling initiation of motor operation based upon a position of the staple cartridge.

[0010a] In one embodiment, there is provided a surgical cutting and stapling instrument comprising: an end effector and a handle. The end effector includes: a channel; an anvil pivotally attached to the channel; a moveable cutting instrument for cutting an object positioned between the anvil and the channel; and a staple cartridge configured for removable receipt by the channel, wherein the staple cartridge comprises a sled that is engaged by the cutting instrument during a cutting stroke. The handle includes: a pistol grip portion; a closure trigger comprising a first end and a second end opposite the first end, wherein the first end of the closure trigger is pivotally attached to the handle such that the closure trigger is retractable toward the pistol grip portion, and wherein retraction of the closure trigger toward the pistol grip portion causes the end effector to clamp the object positioned between the anvil and the channel; a firing trigger, separate from the closure trigger, wherein retraction of the firing trigger toward the pistol grip portion enables

operation of a motor for actuating the cutting instrument via a main drive shaft assembly; and a closure trigger locking assembly for releasably connecting the second end of the closure trigger to the pistol grip portion when the closure trigger is retracted. The instrument also comprises a first electronic circuit for enabling initiation of motor operation based upon a position of the staple cartridge; and a second electronic circuit for preventing the closure trigger locking assembly from disconnecting the second end of the closure trigger from the pistol grip portion until movement of the cutting instrument stops.

DRAWINGS

[0011] 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;

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 according to embodiments of the present invention;

Figures 41-42 illustrate a proportional sensor that may be used according to various embodiments of the present invention; and

Figures 43A-44C illustrate mounting arrangements and configurations of the lockout sensor switches of the interlock circuit according to various embodiments of the present invention.

DETAILED DESCRIPTION

[0012] 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 instrument 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 may be a non-endoscopic surgical cutting and fastening instrument, such as a laparoscopic instrument.

[0013] 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. 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.

[0014] 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 U.S. Pat. Application No. 11/329,020 entitled "SURGICAL INSTRUMENT HAVING AN ARTICULATING END EFFECTOR" to Hueil et al.

[0015] 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 towards which a closure trigger 18 is pivotally drawn by the clinician to cause clamping or closing of the anvil 24 toward 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.

[0016] 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.

[0017] 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, as a slide release button 160 shown in Figure 14, and/or button 172 shown in Figure 16.

[0018] 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 a pivot point 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 point 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. U.S. Pat. No. 6,978,921, entitled “SURGICAL STAPLING INSTRUMENT INCORPORATING AN E-BEAM FIRING MECHANISM” to Shelton, IV et al., provides more details about such two-stroke cutting and fastening instruments. The sled 33 may be an integral component of the cartridge 34, such that when the knife 32 retracts following the cutting operation, the sled 33 does not retract.

[0019] 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 “ELECTOSURGICAL HEMOSTATIC DEVICE WITH RECESSED AND/OR OFFSET ELECTRODES” to Yates et al., disclose cutting instruments that uses RF energy to fasten the severed tissue. U.S. Pat. Application No. 11/267,811 entitled “SURGICAL STAPLING INSTRUMENTS STRUCTURED FOR DELIVERY OF MEDICAL AGENTS” to Morgan et al., and U.S. Pat. Application No. 11/267,383 entitled “SURGICAL STAPLING INSTRUMENTS STRUCTURED FOR PUMP-ASSISTED DELIVERY OF MEDICAL AGENTS” to Shelton IV et al.,

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.

[0020] 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 links 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."

[0021] 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 proximally (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 34 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.

[0022] Because of the lack of user feedback for the cutting/stapling operation, there is a general lack of acceptance among physicians of motor-driven instruments 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 in the end effector.

[0023] Figures 7-10 illustrate an exemplary embodiment of a motor-driven endocutter, and in particular the handle 6 thereof, that provides user-feedback regarding the deployment and loading force of the cutting instrument in the end effector. 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). 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 a 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, 5000 RPM. 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.

[0024] The handle 6 may also include a run motor sensor 110 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.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] In addition, the handle 6 may include a reverse motor (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.

[0029] 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.

[0030] 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 at, for example, 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 is used.

[0031] 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.

[0032] 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 CCW 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 CCW. 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 CCW. Due to the backside shoulder 106 engaging the slotted arm 90, however, the middle handle piece 104 will only be able to rotate CCW 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 CCW due to the slotted arm 90.

[0033] Figure 41 and 42 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 (e.g., EAP) between the electrodes 282, 284. 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 42, 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 material 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.

[0034] 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 pin 251 that is 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 CCW. 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 proximal 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).

[0035] 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 6 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 point 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 proximally, which causes the distal closure tube 42 to slide proximally, which, by virtue of the tab 27 being inserted in the opening 45 of the distal closure tube 42, causes the anvil 24 to pivot about the pivot point 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 18 from the locked position.

[0036] 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 therethrough. 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, coil 134 of the relay 132 will not be energized, so the relay 132 will be in its de-energized state. The electrical circuit further includes lockout sensor switches 136a-d collectively defining an interlock circuit 137 through which current from the relay 132, when de-energized, must pass in order for electrical operation of the motor 65 to be initiated. Each lockout sensor switch 136a-d is configured to maintain an open (i.e., non-conductive) switch state or a closed (i.e., conductive) switch state responsive to the presence or absence, respectively, of a corresponding condition. Any of the corresponding conditions, if present when the instrument 10 is fired, may result in an unsatisfactory cutting and stapling operation and/or damage to the instrument 10. Conditions to which the lockout sensor switches 136a-d may respond include, for example, the absence of the staple cartridge 34 in the channel 22, the presence of a spent (e.g., previously fired) staple cartridge 34 in the channel 22, and an open (or otherwise insufficiently

closed) position of the anvil 24 with respect to the channel 22. Other conditions to which the lockout sensor switches 136a-d may respond, such as component wear, may be inferred based upon an accumulated number of firing operations produced by the instrument 10. Accordingly, if any of these conditions exists, the corresponding lockout sensor switches 136a-d maintain an open switch state, thus preventing passage of the current necessary to initiate operation of the motor 65. Passage of current by the lockout sensors 136a-d is allowed only after all of the conditions have been remedied. It will be appreciated that the above-described conditions are provided by way of example only, and that additional lockout sensor switches for responding to other conditions detrimental to operation of the instrument 10 may be provided. It will similarly be appreciated that for embodiments in which one or more of the above-described conditions may not exist or are of no concern, the number of lockout sensor switches may be fewer than that depicted.

[0037] As shown in Figure 11, the lockout sensor switch 136a may be implemented using a normally-open switch configuration such that a closed switch state is maintained when the staple cartridge 34 is in a position corresponding to its proper receipt by the channel 22. When the staple cartridge 34 is not installed in the channel 22, or is installed improperly (e.g., mis-aligned), the lockout sensor switch 136a maintains an open switch state.

[0038] Lockout sensor switch 136b may be implemented using a normally-open switch configuration such that a closed switch state is maintained only when an unspent staple cartridge 34 (i.e., a staple cartridge 34 having a sled 33 in the unfired position) is present in the channel 22. The presence of a spent staple cartridge 34 in the channel 22 causes the lockout sensor switch 136b to maintain an open switch state.

[0039] Lockout sensor switch 136c may be implemented using a normally-open switch configuration such that a closed switch state is maintained when the anvil 24 is in a closed position

with respect to the channel 22. As discussed in further detail below, the lockout sensor switch 136c may be controlled in accordance with a time delay feature wherein a closed switch state is maintained only after the anvil 24 is in the closed position for a pre-determined period of time.

[0040] Lockout sensor switch 136d may be implemented using a normally-closed switch configuration such that a closed switch state is maintained only when an accumulated number of firings produced by the instrument 10 is less than a pre-determined number. As discussed in further detail below, the lockout sensor switch 136d may be in communication with a counter 304 configured for maintaining a count representative of the accumulated number of firing operations performed by the instrument, comparing the count to the pre-determined number, and controlling the switch state of the lockout sensor switch 136d based upon the comparison.

[0041] According to various embodiments, the interlock circuit 137 may comprise one or more indicators visible to the user of the instrument 10 for displaying a status of at least one of the lockout sensor switches 136a-d. As shown in Figure 11, for example, each lockout sensor switch 136a-d may have a green LED 139a and a red LED 139b associated therewith. The interlock circuit 137 may be configured such that the LEDs 139a,b are energized when the corresponding lockout sensor switch 136a-d is maintained in the closed and open switch states, respectively. It will be appreciated that the lockout sensor switches 136a-d may comprise one or more auxiliary switch contacts (not shown) having a switch configuration suitable for operating the LEDs 139a,b in the manner described above.

[0042] Figures 43A-44C illustrate mounting arrangements and configurations of the lockout sensor switches 136a-d of the interlock circuit 137 according to various embodiments of the present invention. As shown in Figure 43A, the lockout sensor switch 136a may comprise a first switch contact 288a and a second switch contact 288b disposed upon an inner wall of the channel 22 and

electrically isolated therefrom. The respective positions of the first and second switch contacts 288a,b are such that when the staple cartridge 34 is in a position corresponding to its proper receipt by the channel 22, a conductive or semi-conductive portion 290 of the staple cartridge 34 (exemplified as a metal tray portion of the staple cartridge 34) contacts the first and second switch contacts 288a,b to establish a conductive path therebetween. As best seen in Figure 43B, each switch contact 288a,b may comprise a rounded profile for minimizing mechanical resistance to the staple cartridge 34 when received by the channel 22 and for enabling affirmative electrical contact with the conductive portion 290 thereof. The conductive portion 290 thus operates to maintain the lockout sensor switch 136a in a closed switch state. Although the switch contacts 288a,b are shown adjacently positioned on a sidewall portion of the channel 22, it will be appreciated that each switch contact 288a,b may generally be located at any location within the channel 22 where suitable electrical contact with the conductive member 290 is possible. It will further be appreciated that the lockout sensor switch 136a may alternatively be implemented using a conventional contact-actuated limit switch. According to such embodiments, the limit switch may be positioned such that staple cartridge 34, when received by the channel 22, mechanically actuates the limit switch such that a closed switch state is maintained. It will further be appreciated that the lockout sensor switch 136a may also be implemented using a conventional non-contact actuated limit switch, such as, for example, a magnetic reed limit switch or a Hall effect proximity switch. According to such embodiments, the staple cartridge 34 may comprise a magnet suitable for causing the lockout sensor switch 136a to maintain a closed switch state when the staple cartridge 34 is installed.

[0043] As best seen in Figure 43B, the lockout sensor switch 136b may be mounted on an interior bottom surface of the channel 22. According to various embodiments and as shown, the lockout sensor switch 136b may be implemented using a contact-actuated limit switch of a conventional

design that is suitable for detecting linear movement. Orientation of the lockout sensor switch 136b may be such that an actuated portion thereof extends upwardly from the bottom interior surface of the channel 22. The position of the lockout sensor switch 136b on the bottom surface of the channel 22 is such that when an unspent staple cartridge 34 is installed, a bottom portion of the sled 33 mechanically actuates the lockout sensor switch 136b and causes a closed switch state to be maintained thereby. Accordingly, the presence of an unspent staple cartridge 34 (i.e., a staple cartridge having a sled 33 in the unfired position) enables the passage of current through the lockout sensor switch 136b. It will be appreciated the lockout sensor switch 136b may instead be implemented using a non-contact actuated switch (e.g., a magnetic reed limit switch or a Hall effect proximity switch). For such implementations, the sled 33 may comprise a magnetized portion, for example, that actuates the lockout sensor switch 136b when the sled 33 is present in the un-fired position.

[0044] As shown in Figure 44A, the lockout sensor switch 136c is positioned adjacent a distal end of one of the pivot recesses 296 defined by the proximal end of the channel 22 for engaging a corresponding pivot point 25 of the anvil 24. According to various embodiments and as shown, the lockout sensor switch 136c may be implemented using a contact-actuated limit switch of a conventional design that is suitable for detecting linear movement. It will be appreciated, however, that a non-contact-actuated limit switch may be used instead. Orientation of the lockout sensor switch 136c may be such that an actuated portion thereof extends slightly over the distal end of the corresponding pivot recess 296. When the anvil 24 is in an open position with respect to the channel 22 (as shown in Figure 44A), the pivot point 25 is positioned at the proximal end of the pivot recess 296. Closure of the anvil 24 causes the pivot point 25 to move to the distal end of the pivot recess 296. The resulting contact of the pivot point 25 with the actuated portion of the lockout sensor

switch 136c causes the lockout sensor switch 136c to maintain a closed switch state, thus enabling the passage of current therethrough.

[0045] According to other embodiments and as shown in Figure 44B, the lockout sensor switch 136c may instead be configured to maintain a closed switch state responsive to an electrical signal. The electrical signal may be, for example, an analog signal generated by a force sensor 298 disposed on a bottom inner surface of the channel 22 that represents a magnitude of the clamping force applied by the anvil 24. The closed position of the anvil 24 may thus be inferred if the analog signal is sufficiently large in magnitude. Accordingly, the analog signal may be received by a comparator circuit 141 configured to determine if the magnitude exceeds a pre-determined threshold stored therein. If the threshold is exceeded, indicating closure of the anvil 24, the comparator circuit 141 causes the lockout sensor switch 136c to maintain a closed switch state, thus enabling the passage of current therethrough. If the magnitude of the analog signal is less than the pre-determined threshold, indicating that the anvil 24 is not sufficiently closed, the comparator circuit 141 causes the lockout sensor switch 136c to maintain an open switch state, thus preventing the passage of current therethrough. Although shown separately, it will be appreciated that the comparator circuit 141 may be integral with the lockout sensor switch 136c so as to form a common device. It will further be appreciated that the pre-defined threshold stored by the comparator circuit 141 may be adjusted as necessary to reflect the force indicative of closure of the anvil 24 for different cutting and stapling operations.

[0046] In certain instances, it may be necessary or otherwise desirable to delay commencement of a firing operation for a period of time subsequent to closure of the anvil 24. For example, the introduction of a delay between the clamping and firing operations may serve to improve the stabilization of clamped tissue. Accordingly, with reference to Figure 44C, embodiments of the

present invention may comprise a timer 300 having a pre-set time delay (e.g., 12 seconds) and configured for controlling the switch state of the lockout sensor switch 136c in accordance with a time-based position of the anvil 24. Although shown separately, it will be appreciated that the timer 300 may be integral with the lockout sensor switch 136c so as to form a common device (e.g., an on-delay timer). Preferably, the timer 300 is implemented as an electronic device, although it will be appreciated that a mechanical timer may be used instead. A normally-open limit switch 302 configured in a manner identical to that of Figure 44A may be connected to the timer 300 such that timing is initiated when the anvil 24 is in a closed position with respect to the channel 22. Upon expiration of the pre-set time delay, the timer 300 causes the lockout sensor switch 136c to maintain a closed switch state, thus enabling the passage of current therethrough. The timer 300 may be reset in response to the transition of the limit switch 302 to an open switch state (i.e., when the anvil 24 is in the open position). It will be appreciated that the pre-set time delay of the timer 300 may be selectively adjusted (e.g., using an integral potentiometer adjustment) as required.

[0047] Referring again to Figure 11, the electrical circuit may comprise a counter 304 configured to maintain a count representative of the accumulated number of firing operations performed by the instrument 10 and, based on the count, to control the switch state of the lockout sensor switch 136d. Although shown separately, it will be appreciated that counter 304 may be integral with the lockout sensor switch 136d so as to form a common device. Preferably, the counter 304 is implemented as an electronic device having an input for incrementing the maintained count based upon the transition of a discrete electrical signal provided thereto. It will be appreciated that a mechanical counter configured for maintaining the count based upon a mechanical input (e.g., retraction of the firing trigger 20) may be used instead. When implemented as an electronic device, any discrete signal present in the electrical circuit that transitions once for each firing operation may be utilized for the

counter 304 input. As shown in Figure 11, for example, the discrete electrical signal resulting from actuation of the end-of-stroke sensor 130 may be utilized. The counter 304 may control the switch state of lockout sensor switch 136d such that a closed switch state is maintained when the maintained count is less than a pre-determined number stored within the counter 304. When the maintained count is equal to the pre-determined number, the counter 304 causes the lockout sensor switch 136d to maintain an open switch state, thus preventing the passage of current therethrough. It will be appreciated that the pre-determined number stored by the counter 304 may be selectively adjusted as required. According to various embodiments, the counter 304 may be in communication with a display 305, such as an LCD display, integral to the instrument 10 for indicating to a user either the maintained count or the difference between the pre-determined number and the maintained count.

[0048] When the lockout sensor switches 136a-d collectively maintain a closed switch state, a single pole, single throw relay 138 is energized. When the relay 138 is energized, current flows through the relay 138, 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. Because the output of the relay 138, once energized, maintains the relay 138 in an energized state until relay 132 is energized, the interlock circuit 137 will not function to prevent operation of the motor 165 once initiated, even if one or more of the interlock sensor switches 136a-d subsequently maintains an open switch state. In other embodiments, however, it may be necessary or otherwise desirable to connect the interlock circuit 137 and the relay 138 such that one or more the lockout sensor switches 136a-d must maintain a closed switch state in order to sustain operation of the motor 165 once initiated.

[0049] Rotation of the motor in the forward direction causes the ring 84 to move distally and thereby de-actuate the stop motor sensor switch 142. Because the switch 142 is normally-closed, solenoid 306 is energized. The solenoid 306 may be a conventional push-type solenoid that, when energized, causes a plunger (not shown) to be axially extended. As discussed below in connection with Figures 14-22, extension of the plunger may operate to retain the closure trigger 18 in the retracted position, thus preventing the anvil 24 from opening while a firing operation is in progress (i.e., while the switch 142 is not actuated). Upon de-energization of the solenoid 306, the plunger is retracted such that manual release of the closure trigger 18 is possible.

[0050] 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 132. This causes the relay 132 to assume its energized state (not shown in Figure 11), which causes current to bypass the interlock circuit 137 and variable resistor 110, and instead causes current to flow to both the normally-closed double pole, double throw relay 140 and back to the motor 65, but in a manner, via the relay 140, that causes the motor 65 to reverse its rotational direction.

[0051] Because the stop motor sensor switch 142 is normally-closed, current will flow back to the relay 132 to keep it energized 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 and de-energizing the solenoid 306.

[0052] 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.

[0053] 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 90 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 116.

[0054] 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 CCW with the firing trigger 20 due to the forward motion stop 107 that engages the firing trigger 20. The CCW rotation of the middle piece 104 cause the arm 118 to rotate CCW 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 118 will contact and thereby trip the stop motor sensor 142. Such actions may reverse and stop the motor 65, respectively, as described above.

[0055] 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 CCW as the ring 84 advances due to the post 128 being disposed in the channel 126, as shown in Figure 13.

[0056] 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 CCW 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 CW in Figures 14-15) until the closure bar 154 completely passes the sloped portion 156 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 CW such that the closure bar 154 is released from the recessed notch 158. In order to prevent the anvil 24 from inadvertently being opened while a firing operation is in progress, the solenoid 306 may be positioned within the pistol grip 26 such that the plunger 308 of the solenoid 306, when energized, is received into a corresponding opening 163 of the slide button release 160. Accordingly, the slide button release 160 is locked in place such that manipulation of

the slide button release 160 is prevented until the plunger 308 is retracted from the opening 163 at the conclusion of the firing operation.

[0057] 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 CW) 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 CCW. Eventually the lower chamfered surface 166 fully passes the lower sidewall 168, removing the CCW 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.

[0058] 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 CCW and allowing the arrow-head portion 161 to slide out of the opening 164. In order to prevent the anvil 24 from inadvertently being opened while a firing operation is in progress, the solenoid 306 may be positioned within the pistol grip 26 such that the plunger 308 of the solenoid 306, when energized, is received into a corresponding opening 173 defined by the arrow-head portion 161. When received into the opening 173, the plunger 308 operates to prevent CCW rotation of the arrow-head portion 161. Accordingly, inadvertent manipulation of the button 172 by the user is prevented by the user until the plunger 308 is retracted from the opening 173 at the conclusion of the firing operation.

[0059] 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 CW) 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 CW force on the arm 176 is removed, and the pin 178 is rotated CCW 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.

[0060] 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. In order to prevent the anvil 24 from inadvertently being opened while a firing operation is in progress, the solenoid 306 may be positioned within the pistol grip 26 such that the plunger 308 of the solenoid 306, when energized, is received into the upper channel 192. When received into the upper channel 192, the plunger 308 operates to prevent passage of the pin 178 therethrough. Accordingly, unlocking the closure trigger 18 is prevented until the plunger 308 is retracted from the upper channel 192 at the conclusion of the firing operation.

[0061] 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 (180^0) orientation and Figure 23B shows the u-joint 195 at approximately a 150^0

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.

[0062] 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 25-31 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 25-31 is another power assist, motorized instrument 10 that provides feedback to the user regarding the loading force experienced by the cutting instrument 32.

[0063] 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 CCW 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.

[0064] 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.

[0065] 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 216 being coaxial with a fifth gear 218. The fifth gear 218 is a 90⁰ bevel gear that engages a mating 90⁰ bevel gear 220 (best shown in Fig. 31) that is connected to the pinion gear 124 that drives the main drive shaft 48.

[0066] 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.

[0067] Rotation of the motor 65 causes the bevel gears 66, 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.

[0068] 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 CCW when the motor 65 provides forward drive for the end effector 12 (and to rotate CCW 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 CW rotation force from the firing trigger 20 that is generally proportional to the reverse speed of the motor 65.

[0069] 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 CCW, 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.

[0070] 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 sled 33) and the end of retraction operation (full retraction of the knife 32). A circuit similar to that described above in connection with Figure 11 may be used to appropriately power the motor 65.

[0071] 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 CW 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 CW the lower portion 228 also rotates CW, and when the lower portion 228 rotates CCW the upper portion 230 also rotates CCW. Similarly, the lower portion 228 includes a rotational stop 238 that engages a lower shoulder of the upper portion 230. In that way, when the upper portion 230 is caused to rotate CCW the lower portion 228 also rotates CCW, and when the lower portion 228 rotates CW the upper portion 230 also rotates CW.

[0072] 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 a 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.

[0073] 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 U.S. Pat. No. 6,905,057 entitled "SURGICAL STAPLING INSTRUMENT INCORPORATING A FIRING MECHANISM HAVING A LINKED RACK TRANSMISSION" to Swayze et al., which is incorporated herein by reference) 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 230 is caused to rotate CCW, which causes the lower portion 228 to also rotate CCW.

[0074] 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 direction. This causes the main drive shaft assembly to reverse rotational direction to retract the knife 32. Reverse rotation of the main drive shaft assembly causes the gears 210-220 in the gear box assembly 200 to reverse direction, which causes the upper portion 230 of the firing trigger 20 to rotate CW, which causes the lower portion 228 of the firing trigger 20 to rotate CW until the front face 242 of the upper portion 230 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 CW rotation force from the firing trigger 20 that is generally proportional to the reverse speed of the motor 65.

[0075] 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 CCW, 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.

[0076] 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, gear drive train, and end effector) 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 12, but without having the firing trigger 20 geared into the gear drive train. Figures 37-40 illustrate a motorized surgical cutting and fastening instrument 10 with such a tactile position feedback system.

[0077] 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 10 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.

[0078] 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.

[0079] 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 18 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.

[0080] 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 CCW, which allows the lower portion 228 of the firing trigger to also rotate CCW. 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.

[0081] 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 CW, which causes the lower portion 228 to rotate CW. In that way, the operator may experience a CW 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.

[0082] 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.

[0083] The various embodiments of the present invention have been described above in connection with cutting-type surgical instruments. It should be noted, however, that in other embodiments, the inventive surgical instrument disclosed herein need not be a cutting-type surgical instrument. For example, it could be a non-cutting endoscopic instrument, a grasper, a stapler, a clip applier, an access device, a drug/gene therapy delivery device, an energy device using ultrasound, RF, laser, etc.

[0084] Although the present invention has been described herein in connection with certain disclosed embodiments, many modifications and variations to those embodiments may be implemented. For example, different types of end effectors may be employed. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modification and variations.

What is claimed is:

1. A surgical cutting and stapling instrument comprising:
 - an end effector comprising:
 - a channel;
 - an anvil pivotally attached to the channel;
 - a moveable cutting instrument for cutting an object positioned between the anvil and the channel; and
 - a staple cartridge configured for removable receipt by the channel, wherein the staple cartridge comprises a sled that is engaged by the cutting instrument during a cutting stroke;
 - a handle comprising:
 - a pistol grip portion;
 - a closure trigger comprising a first end and a second end opposite the first end, wherein the first end of the closure trigger is pivotally attached to the handle such that the closure trigger is retractable toward the pistol grip portion, and wherein retraction of the closure trigger toward the pistol grip portion causes the end effector to clamp the object positioned between the anvil and the channel;
 - a firing trigger, separate from the closure trigger, wherein retraction of the firing trigger toward the pistol grip portion enables operation of a motor for actuating the cutting instrument via a main drive shaft assembly; and
 - a closure trigger locking assembly for releasably connecting the second end of the closure trigger to the pistol grip portion when the closure trigger is retracted;
 - a first electronic circuit for enabling initiation of motor operation based upon a position of the staple cartridge; and
 - a second electronic circuit for preventing the closure trigger locking assembly from disconnecting the second end of the closure trigger from the pistol grip portion until movement of the cutting instrument stops.
2. The surgical instrument of claim 1, wherein the second electronic circuit comprises an

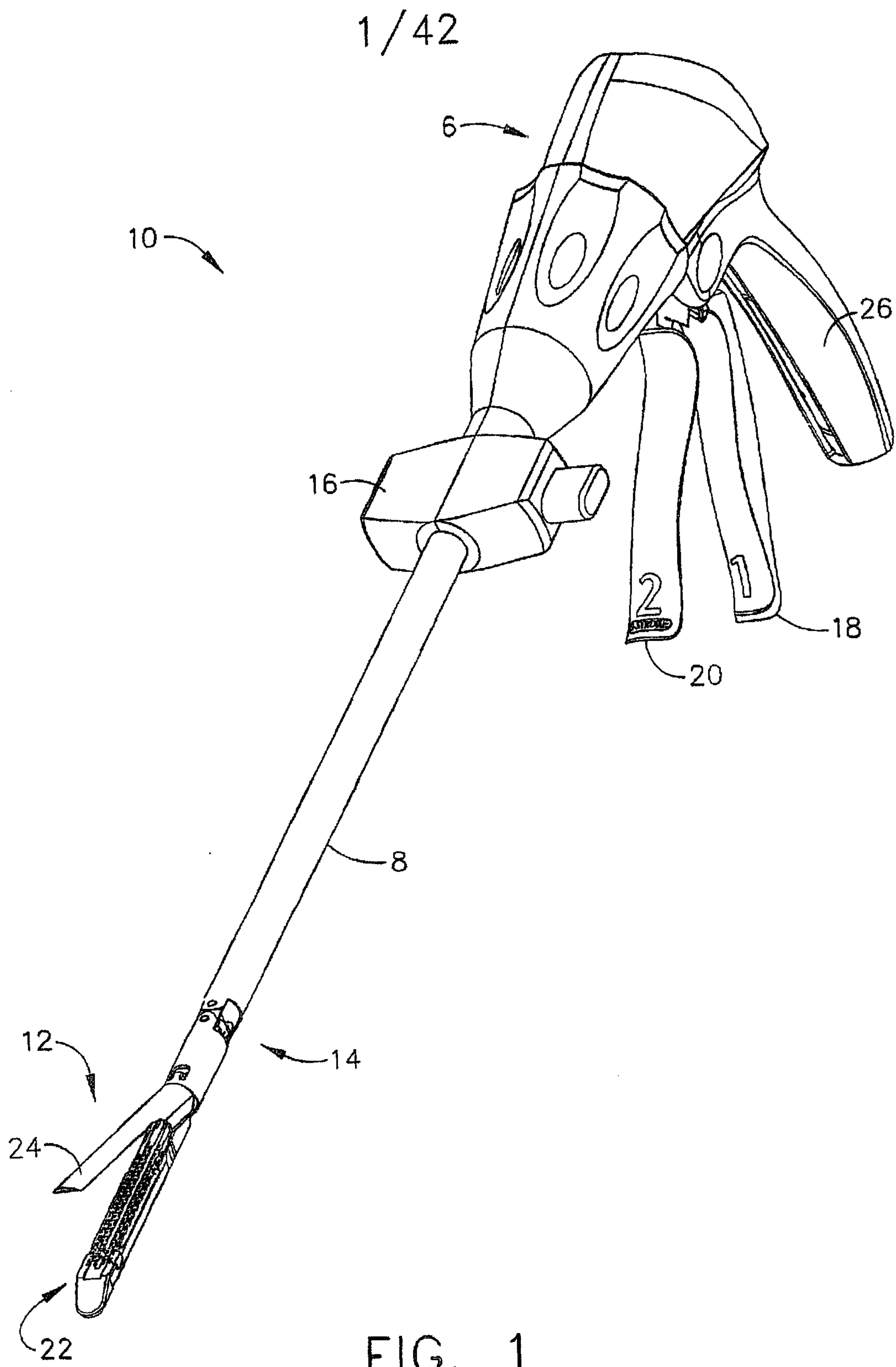
electromechanical actuator.

3. The surgical instrument of claim 1, wherein the first electronic circuit is further for enabling initiation of motor operation based upon at least one of a position of the anvil, a position of the sled within the staple cartridge, and an accumulated number of operations performed by the instrument.
4. The surgical instrument of claim 3, wherein the first electronic circuit comprises:
 - a first switch configured to maintain a first switch state when the staple cartridge is in a position corresponding to the receipt thereof by the channel;
 - a second switch configured to maintain a second switch state when the anvil is in a closed position with respect to the channel;
 - a third switch configured to maintain a third switch state when the sled is present in an unfired position within the staple cartridge; and
 - a fourth switch configured to maintain a fourth switch state when the accumulated number of operations is less than a pre-determined number;
 wherein the first, second, third, and fourth switches are connected such that the corresponding first, second, third, and fourth switch states, when collectively maintained, enable initiation of motor operation.
5. The surgical instrument of claim 4, wherein at least one of the first, second, third, and fourth switches is selected from:
 - a contact-actuated switch and a non-contact actuated switch.
6. The surgical instrument of claim 4, wherein the first switch comprises a first switch contact and a second switch contact disposed within the channel and electrically isolated therefrom, wherein the first and second switch contacts are positioned such that a portion of the staple cartridge, when in the position corresponding to the receipt thereof by the channel, establishes a conductive path between the first and second switch contacts.

7. The surgical instrument of claim 4, wherein the second switch is further configured to maintain the second switch state as a result of a mechanical force applied thereto when the anvil is in the closed position relative to the channel.
8. The surgical instrument of claim 4, wherein the second switch is further configured to maintain the second switch state responsive to an electrical signal, wherein the electrical signal is representative of a force exerted by the anvil when the anvil is in the closed position.
9. The surgical instrument of claim 4, wherein the second switch is further configured to maintain the second switch state after the anvil has been in the closed position with respect to the channel for a pre-determined period of time.
10. The surgical instrument of claim 4, wherein the third switch is further configured to maintain the third switch state as a result of a mechanical force applied thereto by the sled when present in the unfired position.
11. The surgical instrument of claim 4, further comprising a counter in communication with the fourth switch, wherein the counter is configured to maintain a count representative of the accumulated number of operations and to cause the fourth switch to maintain the fourth switch state when the count is less than the pre-determined number.
12. The surgical instrument of claim 11, wherein the counter is further configured to maintain the count based on one of a mechanical input and an electronic input received thereby.
13. The surgical instrument of claim 11, wherein the counter is in communication with a display for indicating one of the maintained count and a difference between the pre-determined number and the maintained count.
14. The surgical instrument of claim 4, further comprising at least one indicator displaying a

status of at least one of the first, second, third, and fourth switches.

15. The surgical instrument of claim 4, wherein each of the first, second, and third switches is characterized by a normally-open switch configuration, and wherein the fourth switch is characterized by a normally-closed switch configuration.
16. The surgical instrument of claim 15, wherein the first, second, third, and fourth switches are connected in series with one of the motor and a motor control circuit such that initiation of motor operation is prevented when any of the first, second, third, or fourth switch states is not maintained.



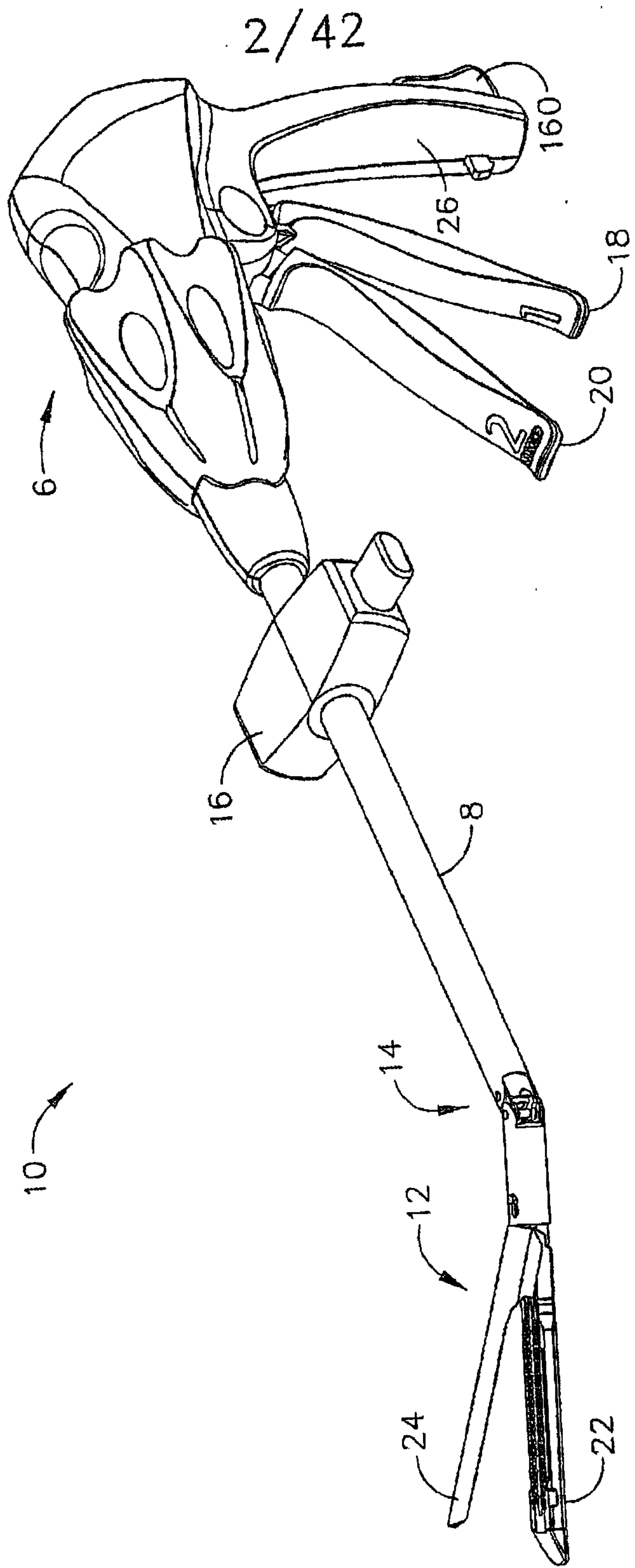


FIG. 2

3/42

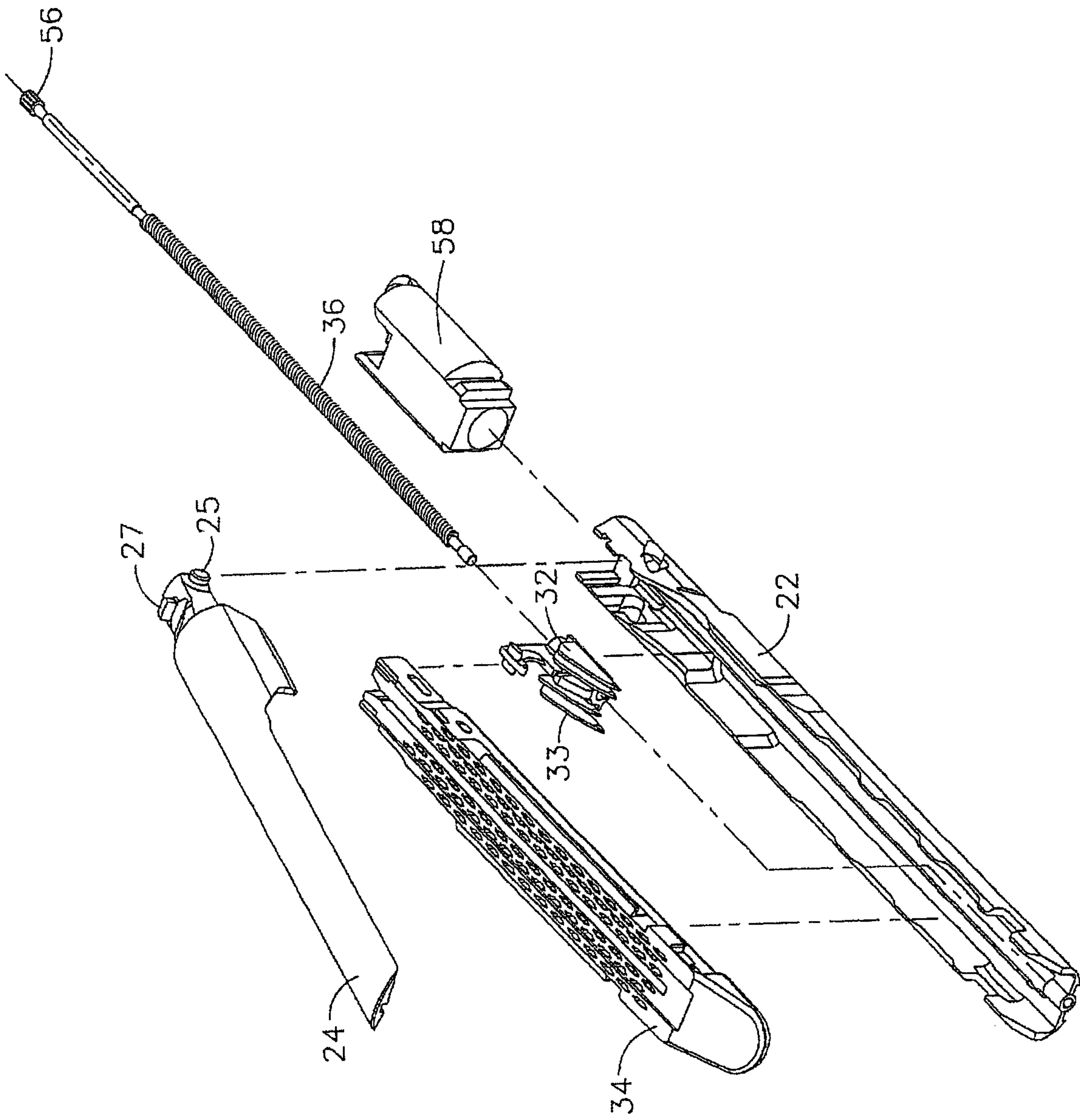
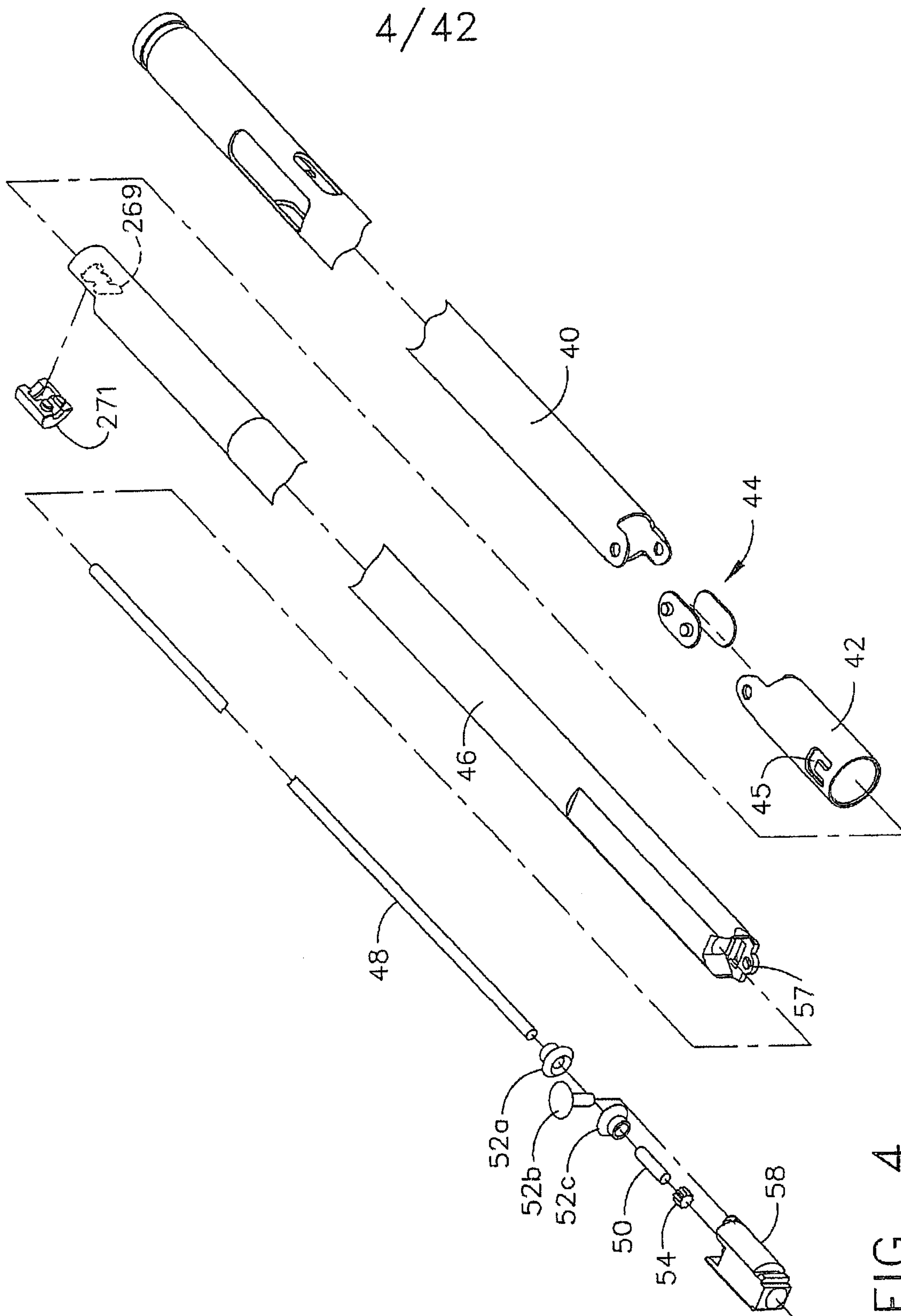


FIG. 3

4
G.
L.

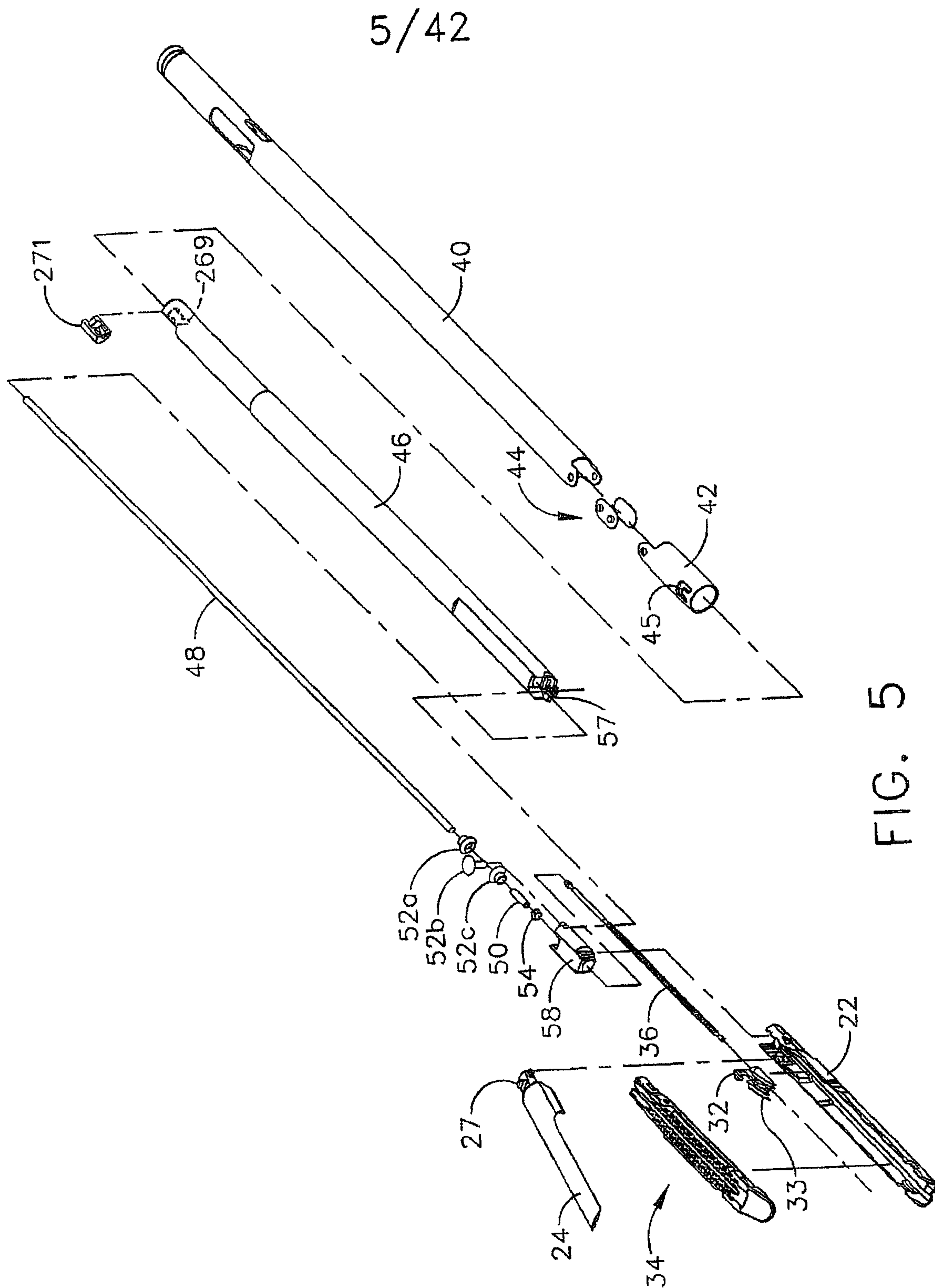


FIG. 5

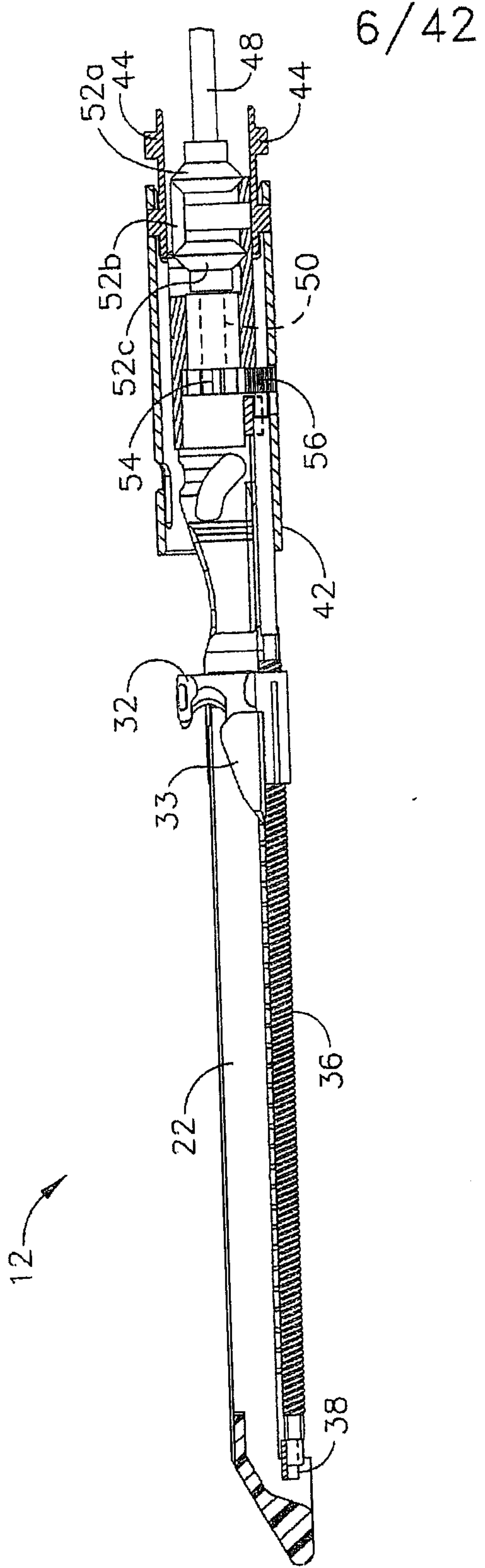
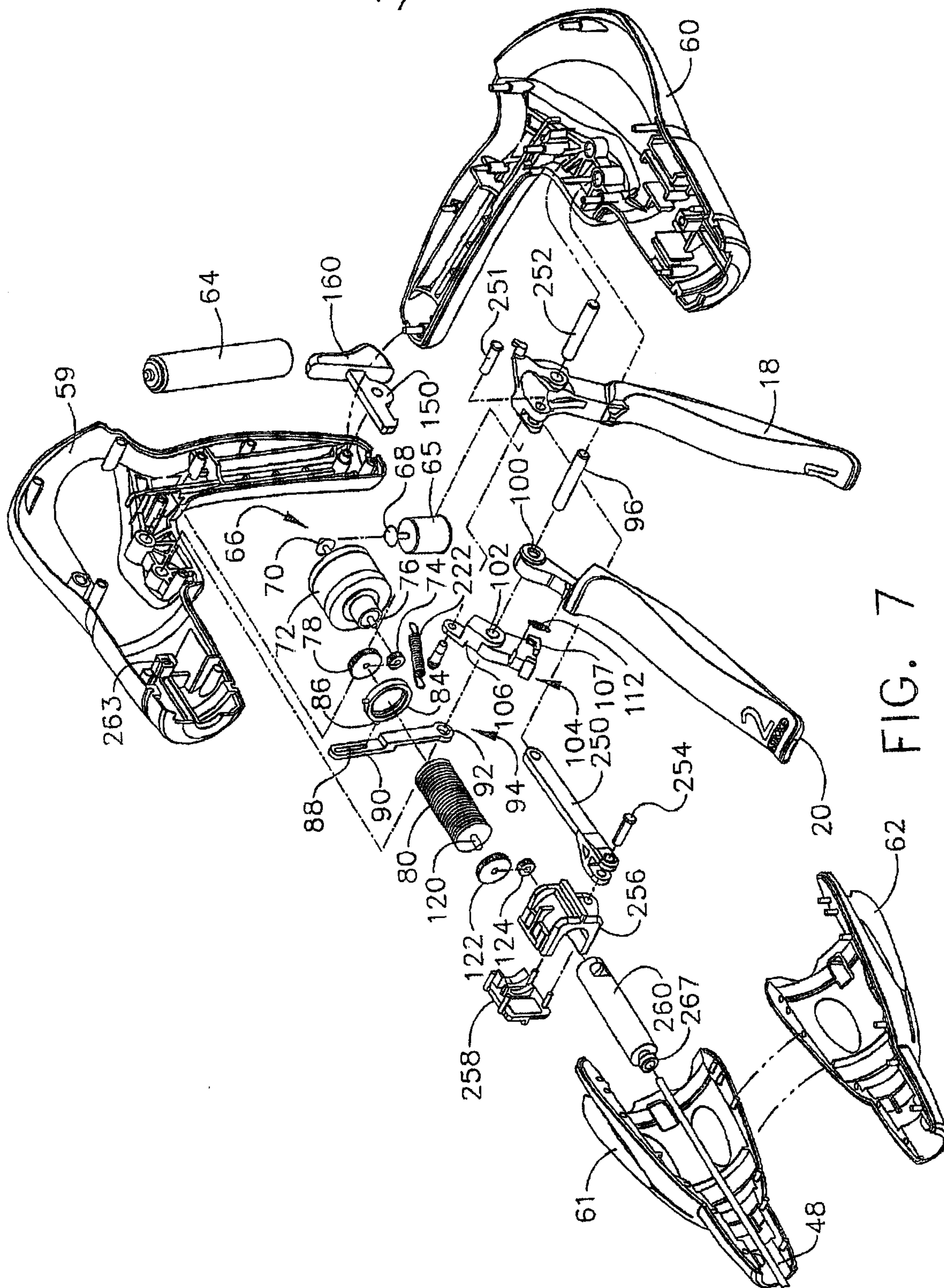


FIG. 6

7/42



8/42

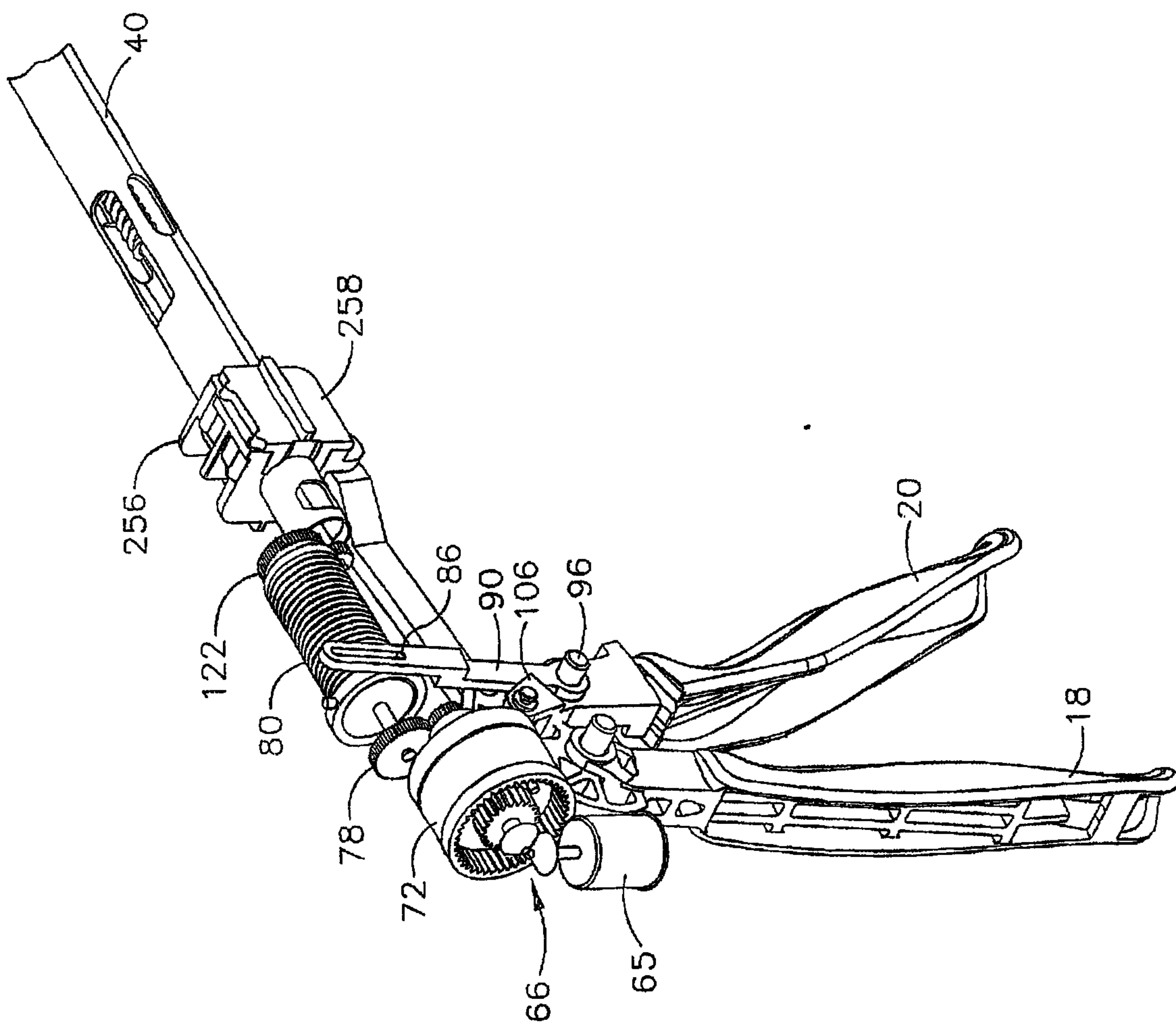


FIG. 8

9/42

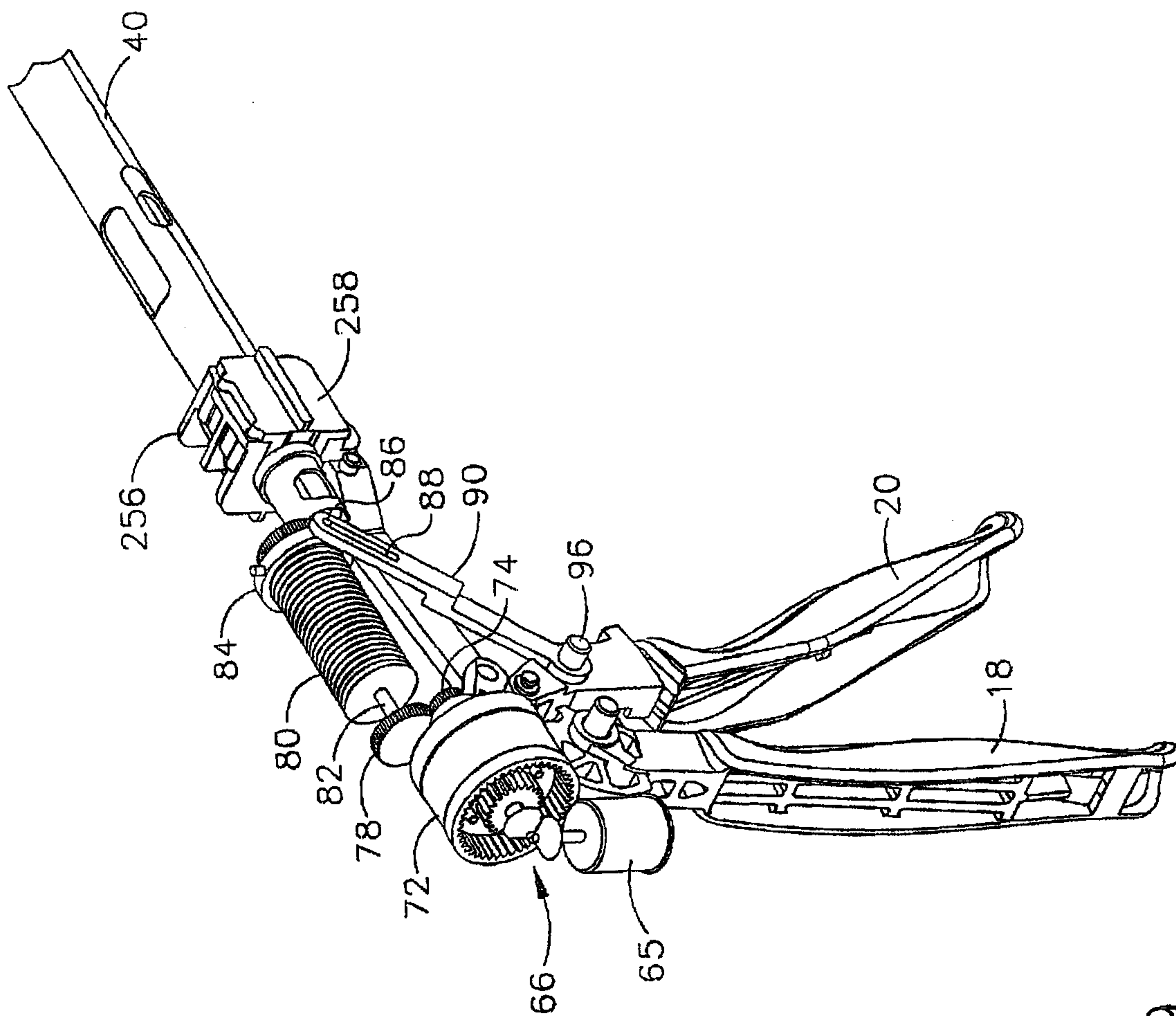


FIG. 9

10/42

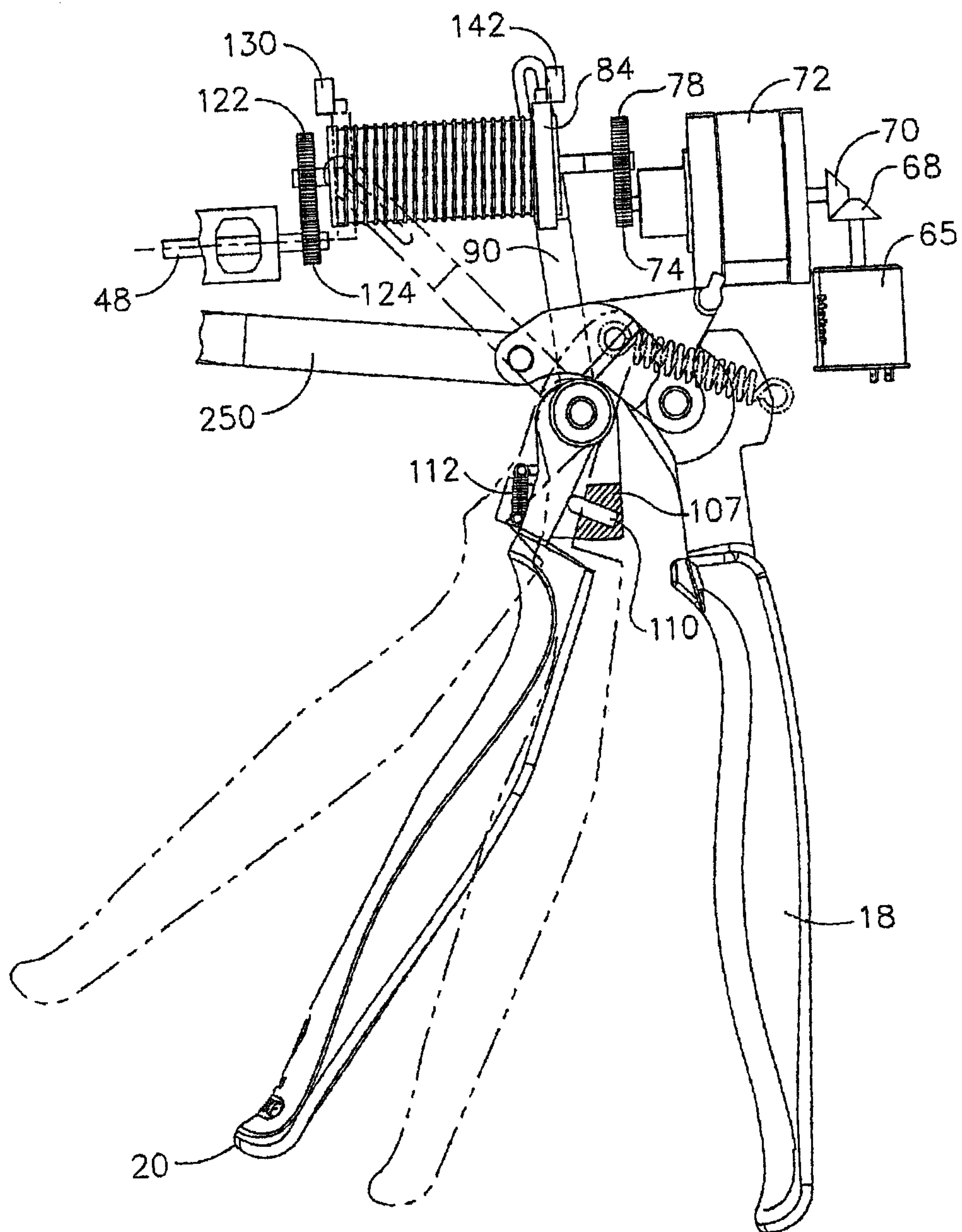


FIG. 10

11/42

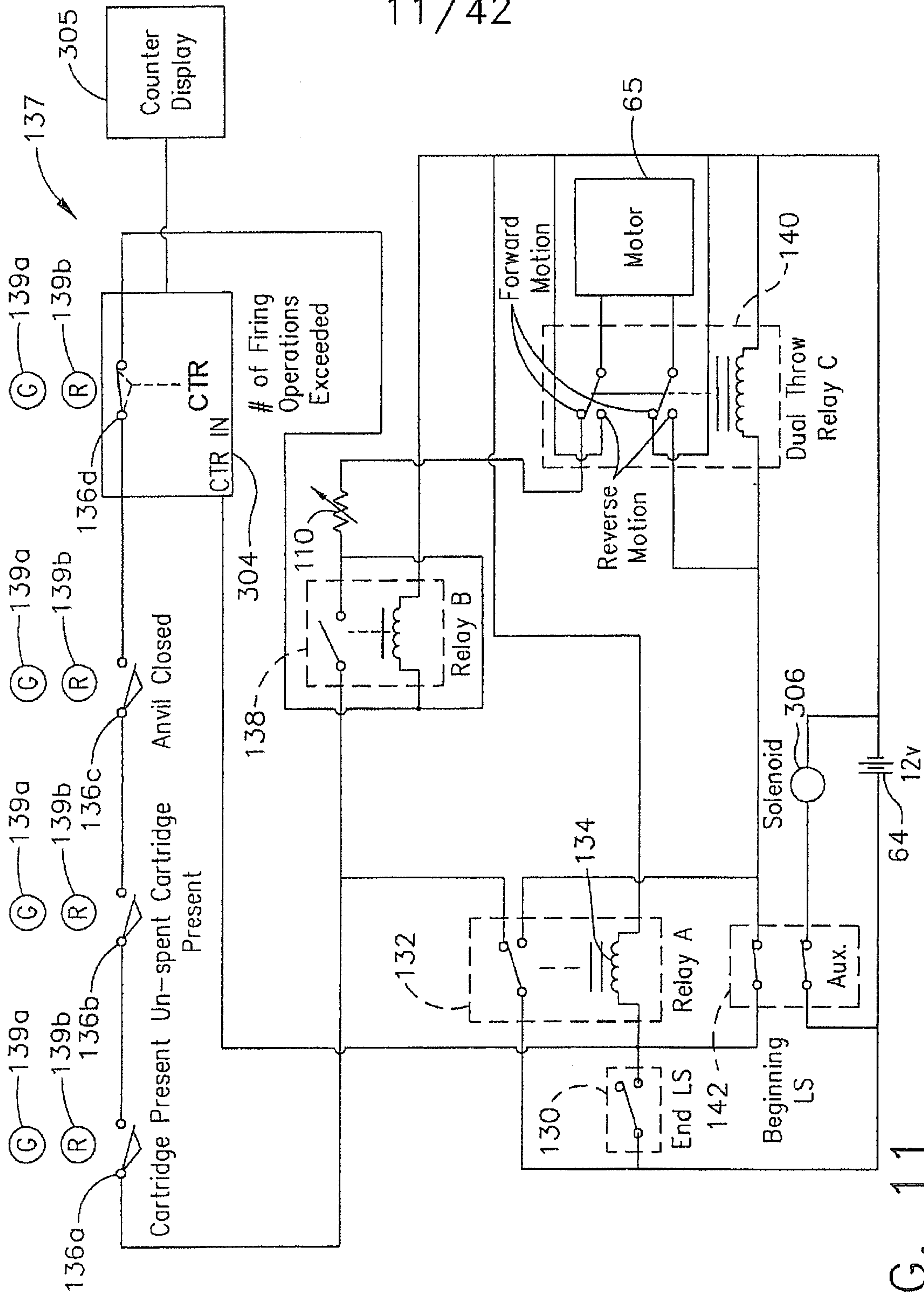


FIG. 11

12/42

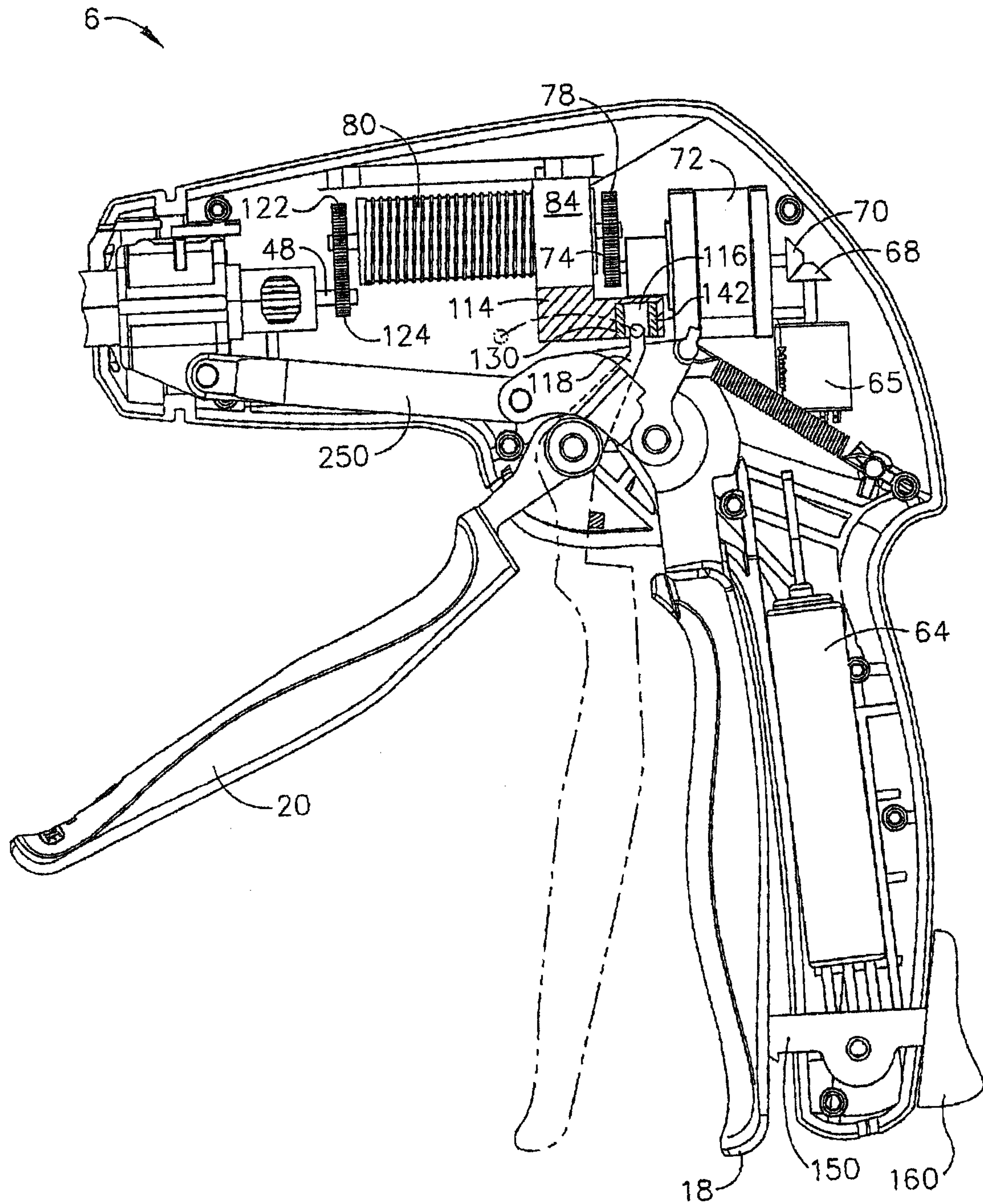
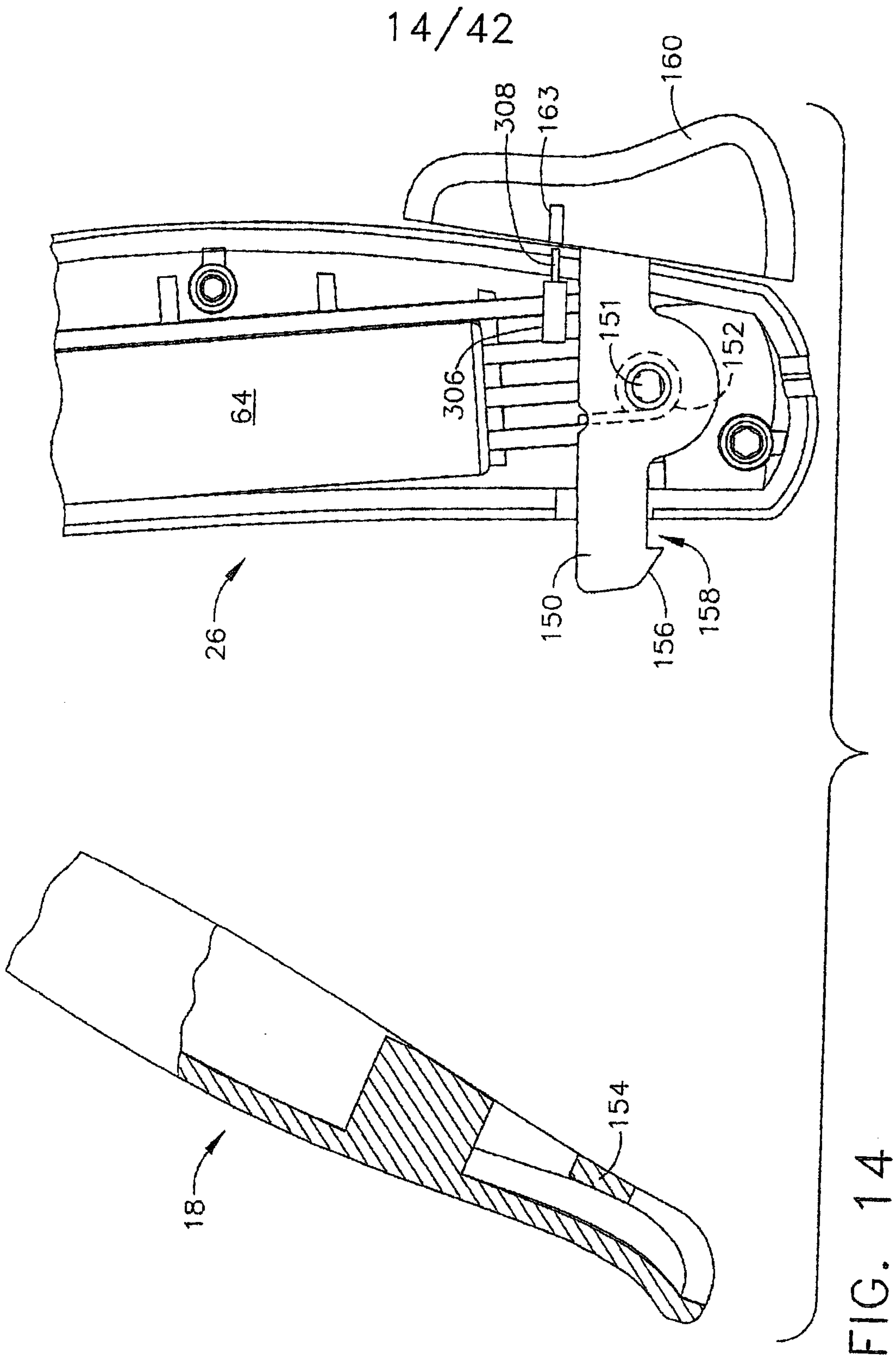


FIG. 12



15/42

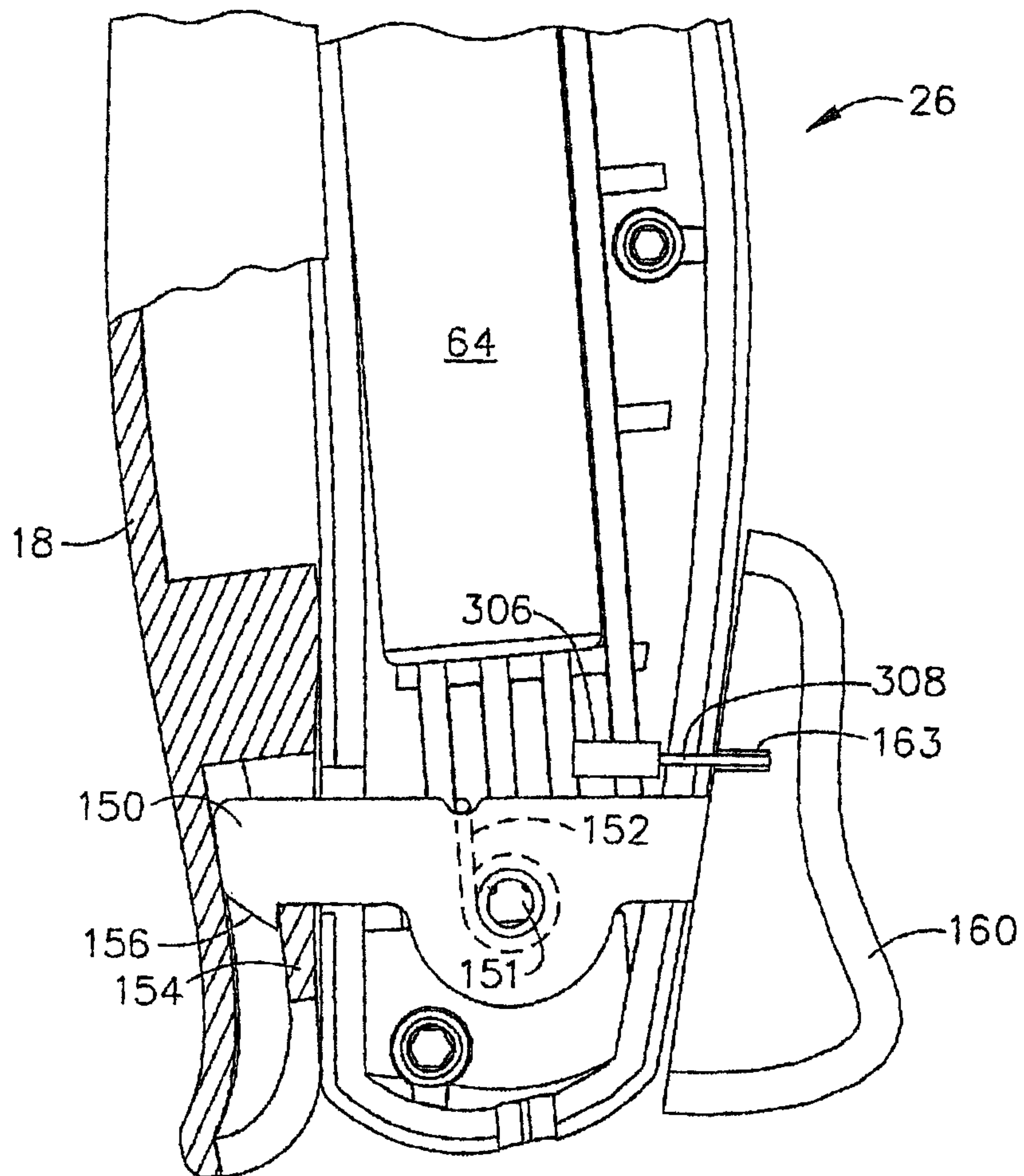


FIG. 15

16/42

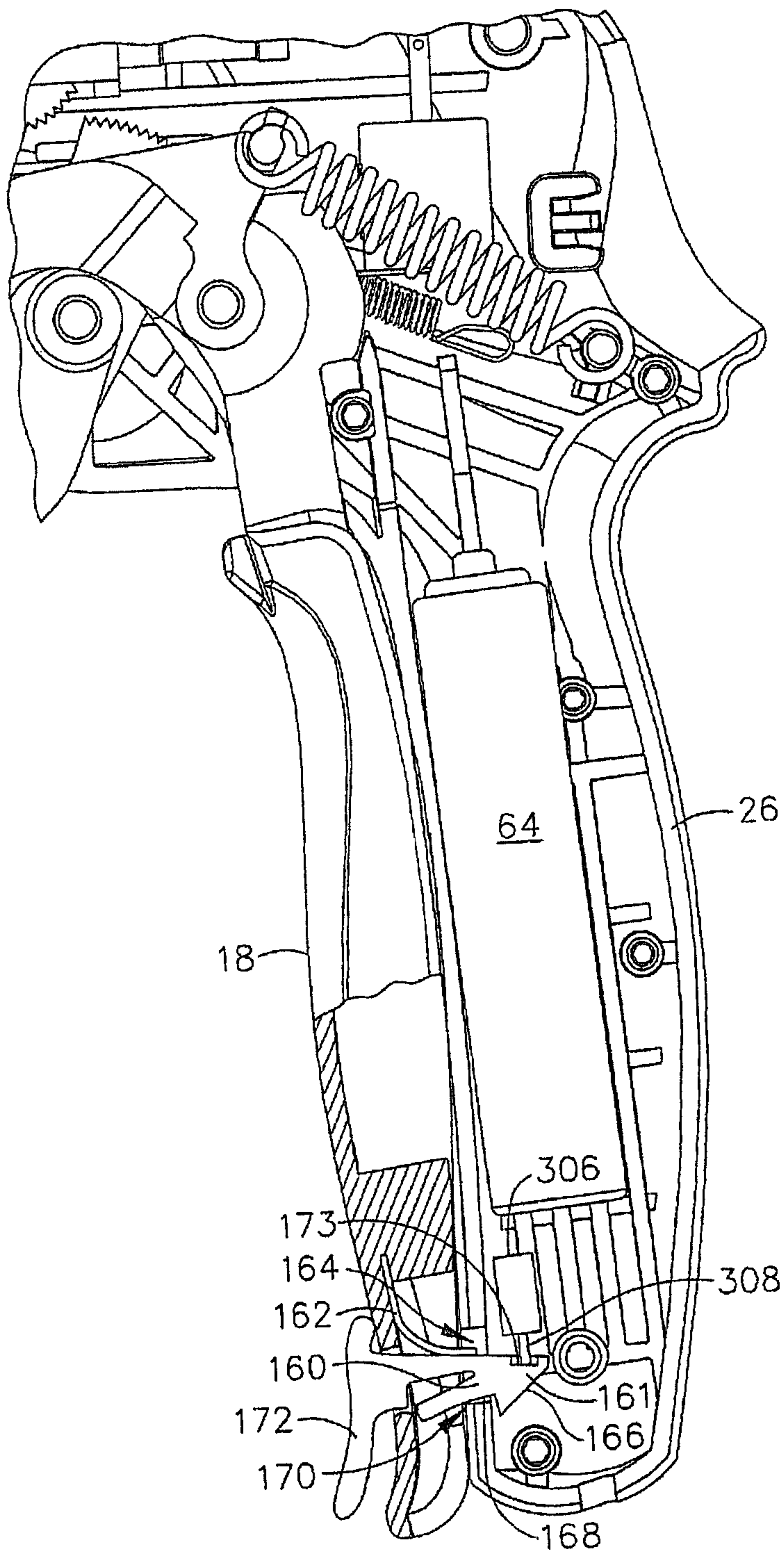


FIG. 16

17/42

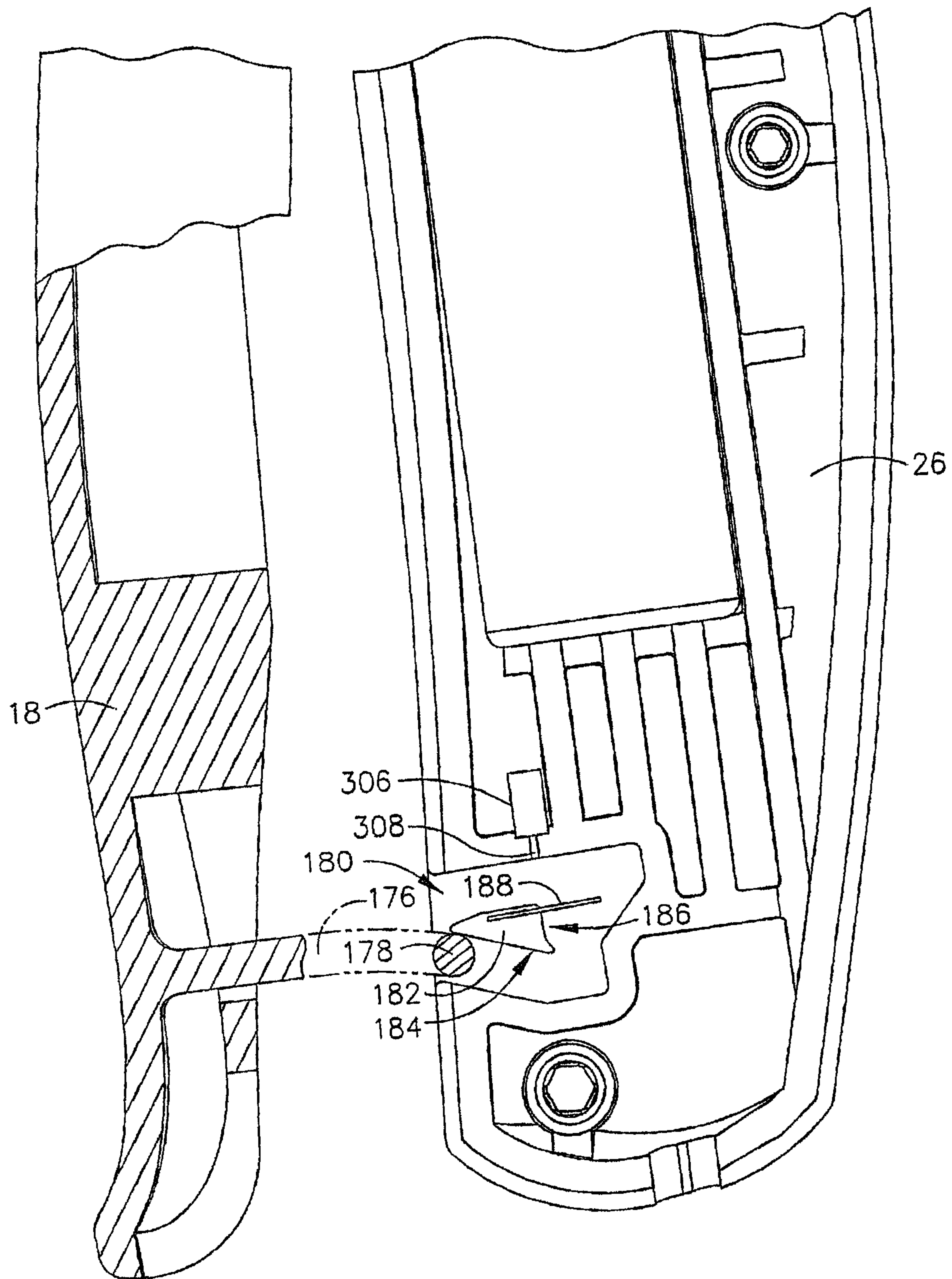


FIG. 17

19/42

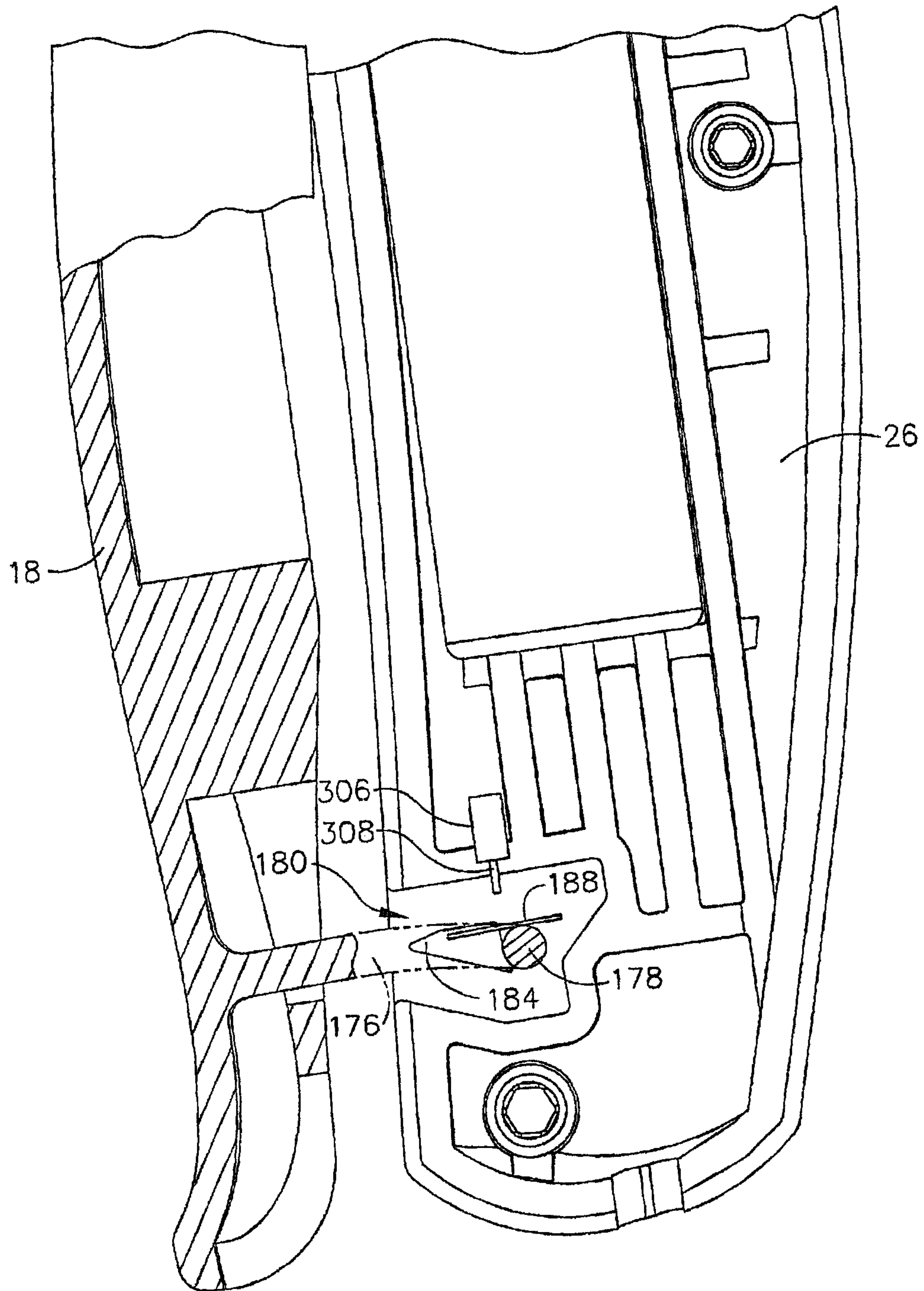


FIG. 19

20/42

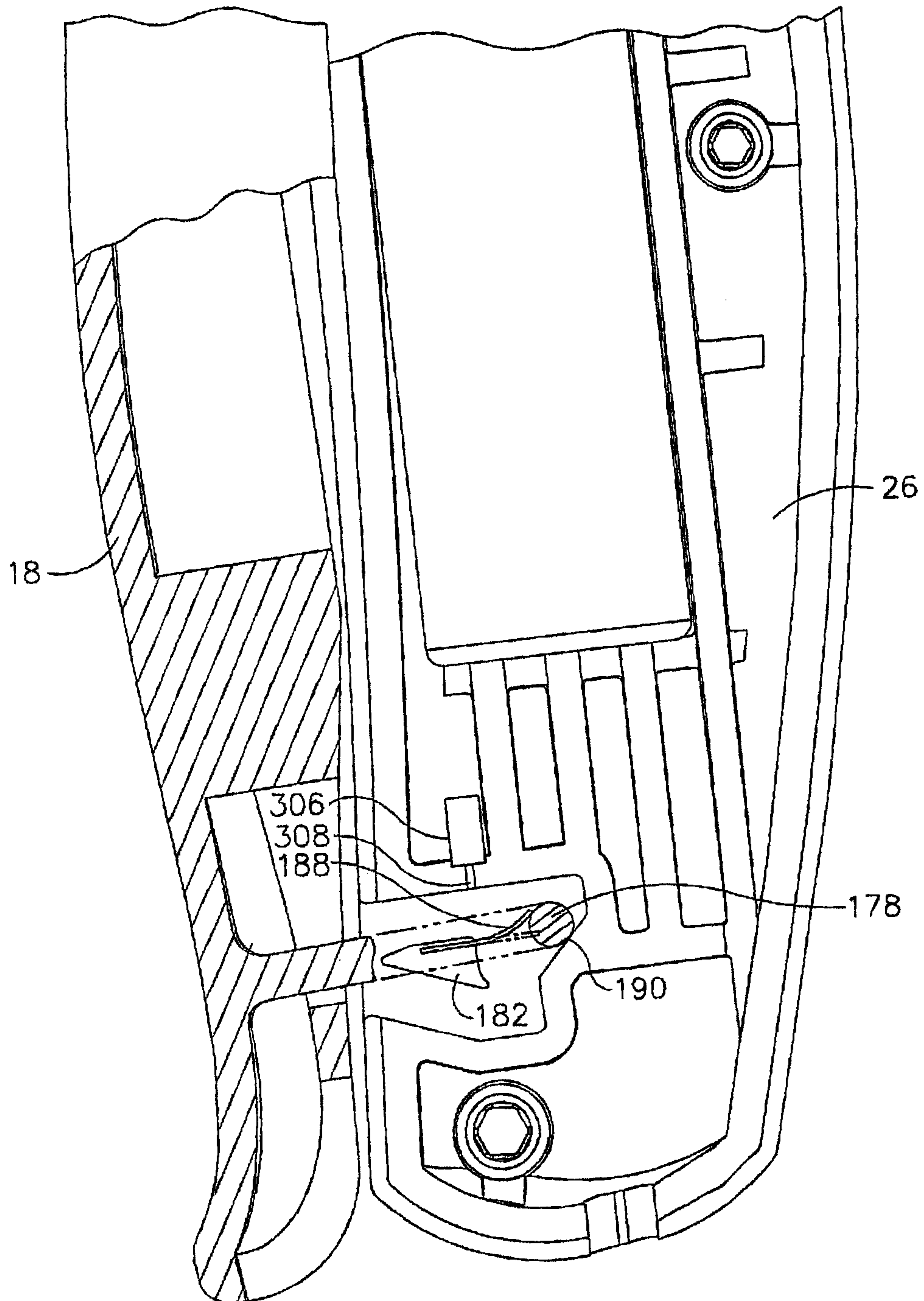


FIG. 20

21/42

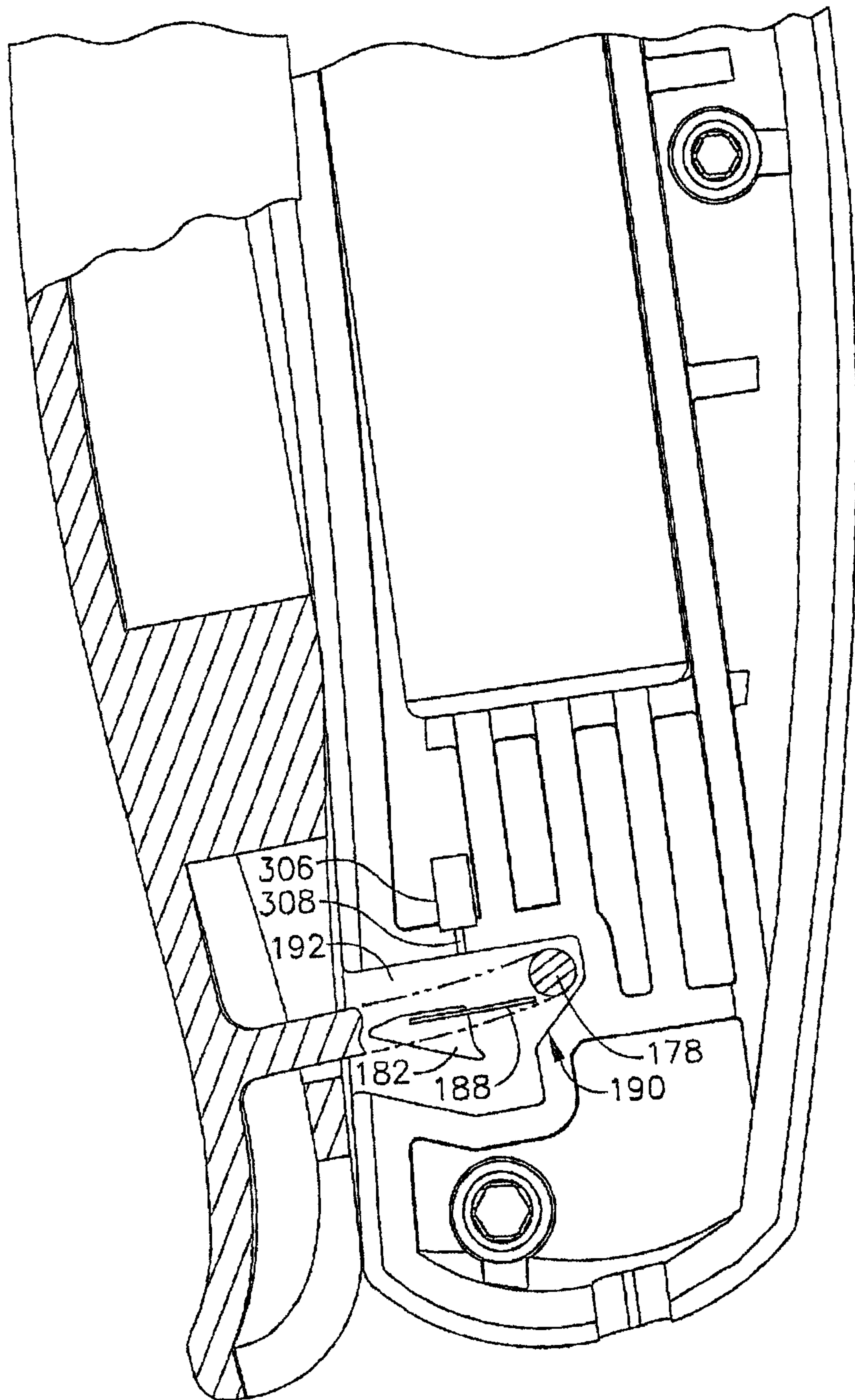


FIG. 21

22/42

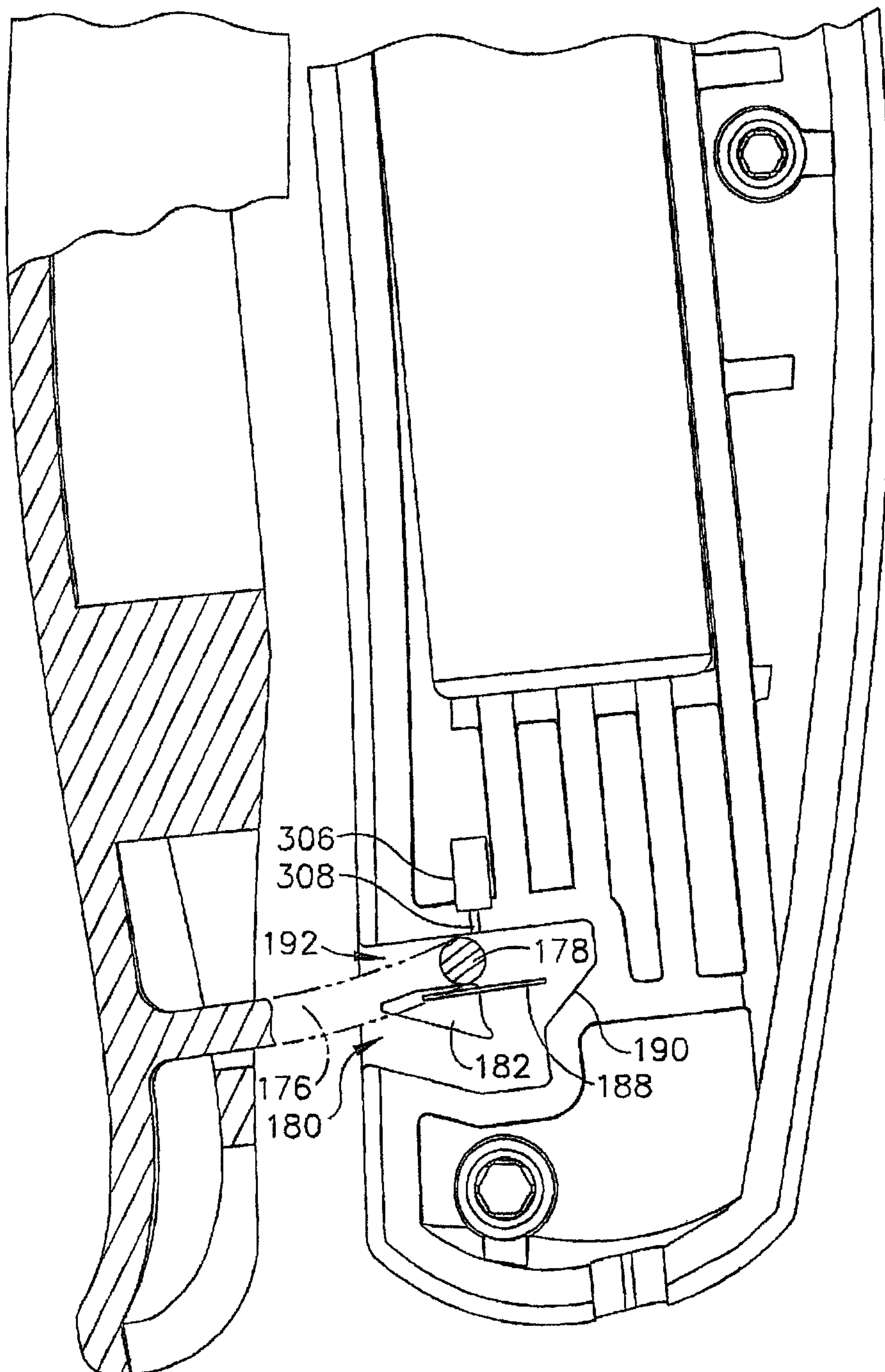


FIG. 22

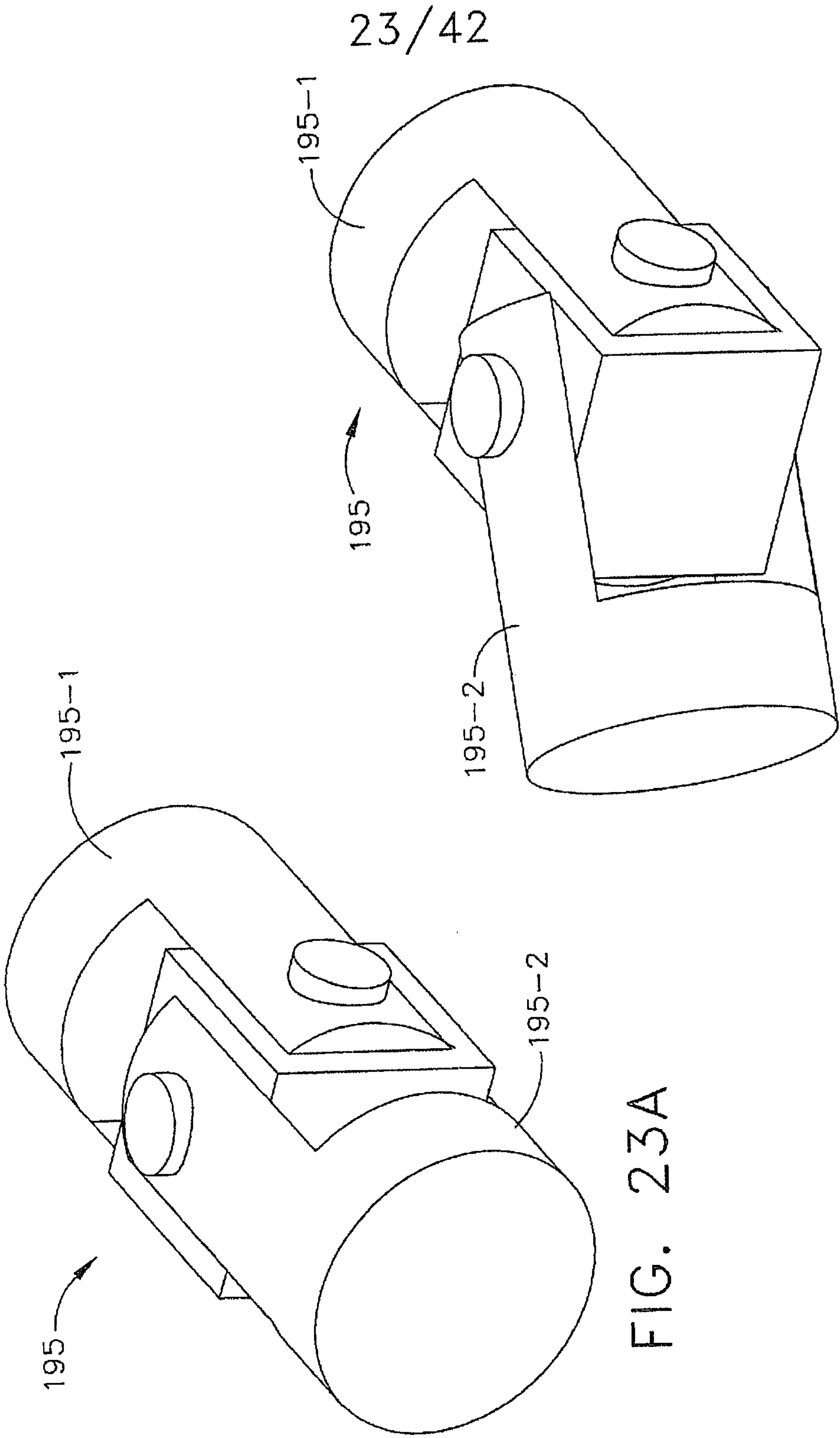


FIG. 23B

FIG. 23A

24/42

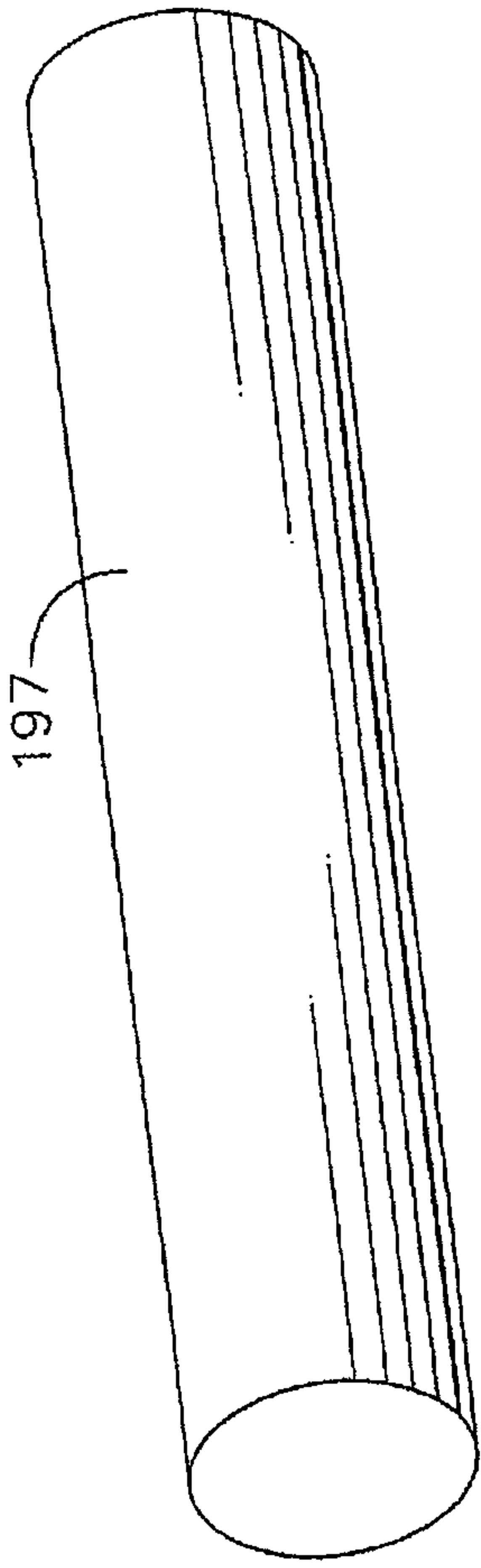


FIG. 24A

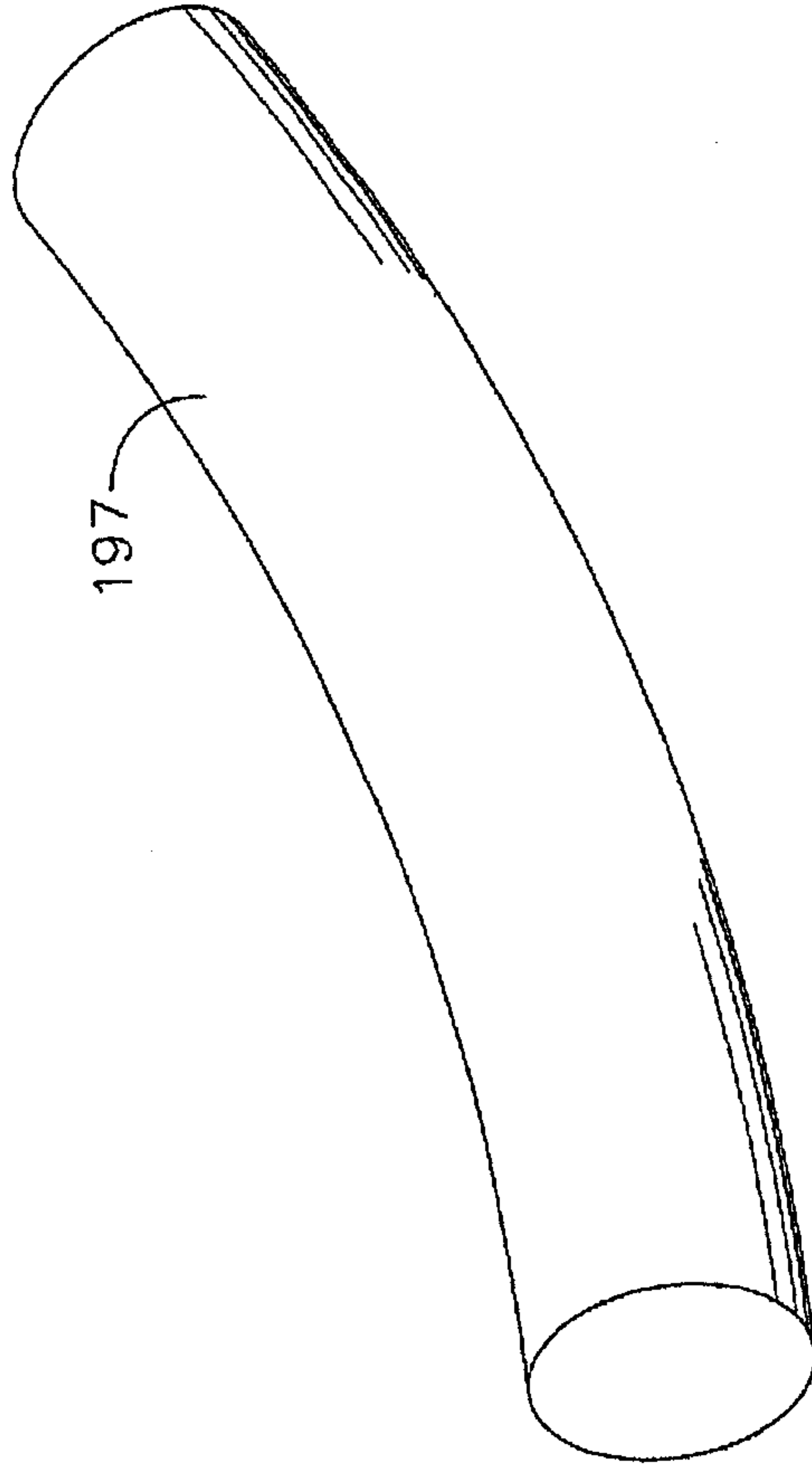


FIG. 24B

25/42

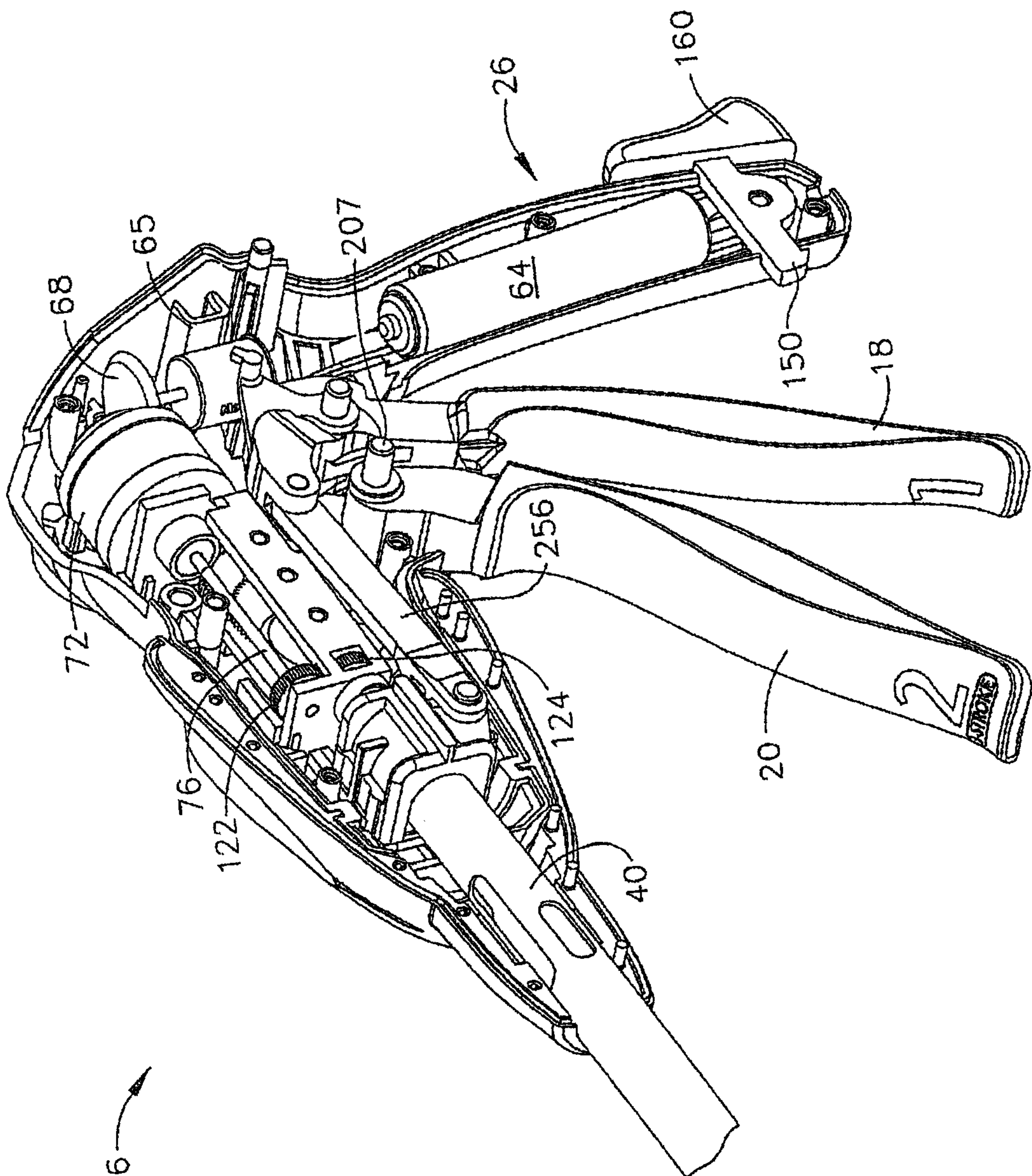


FIG. 25

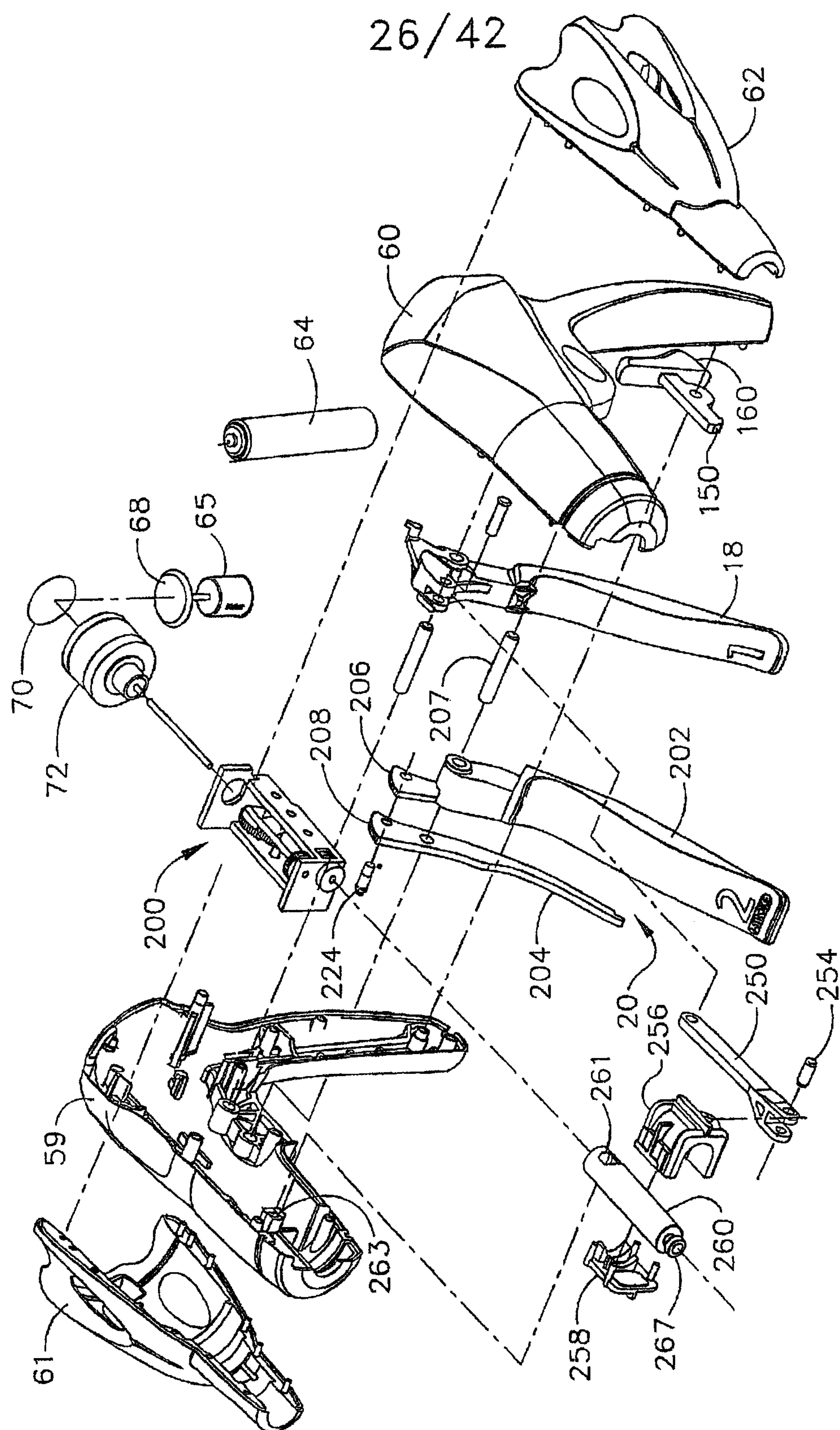


FIG. 26

27/42

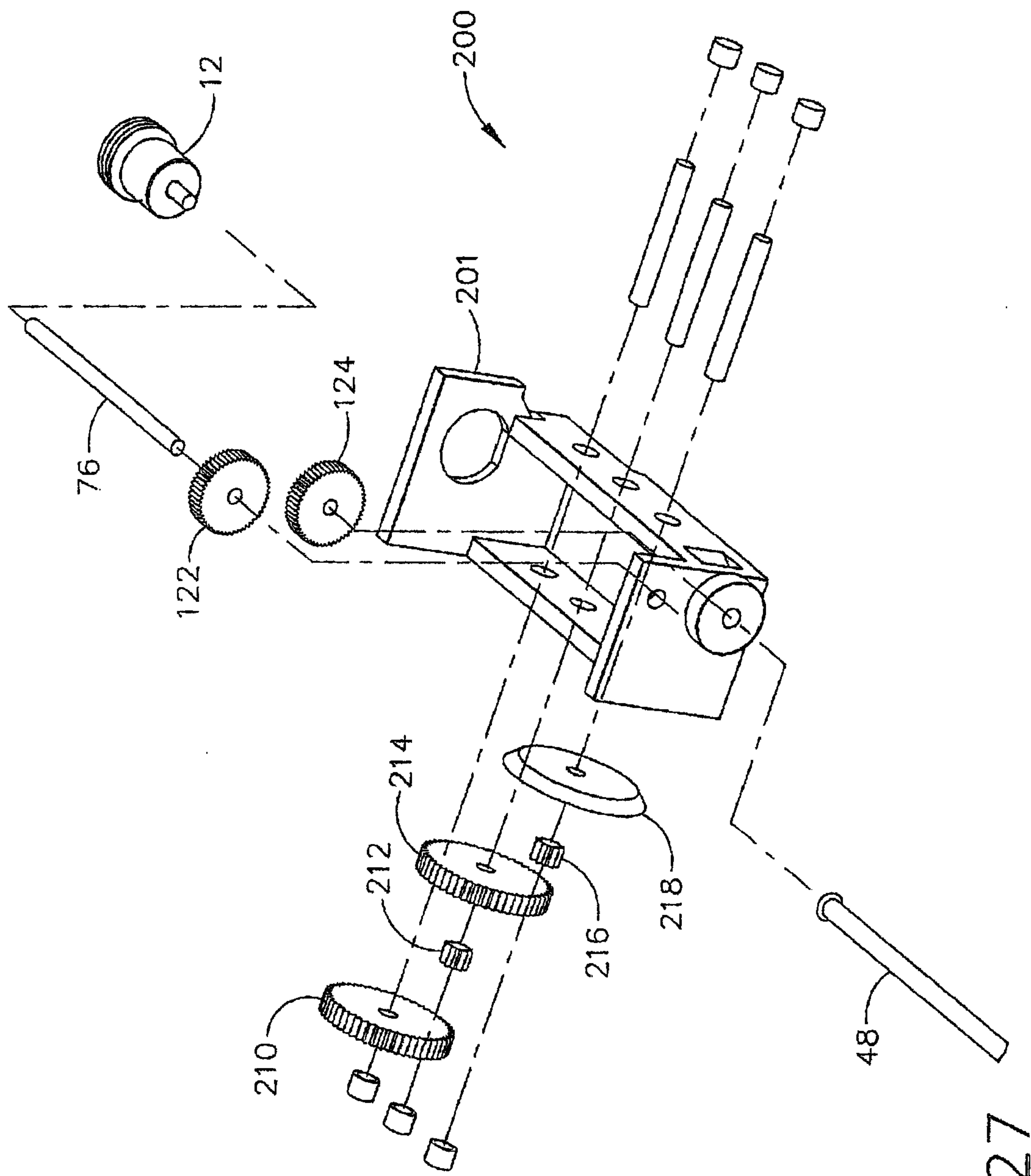


FIG. 27

28/42

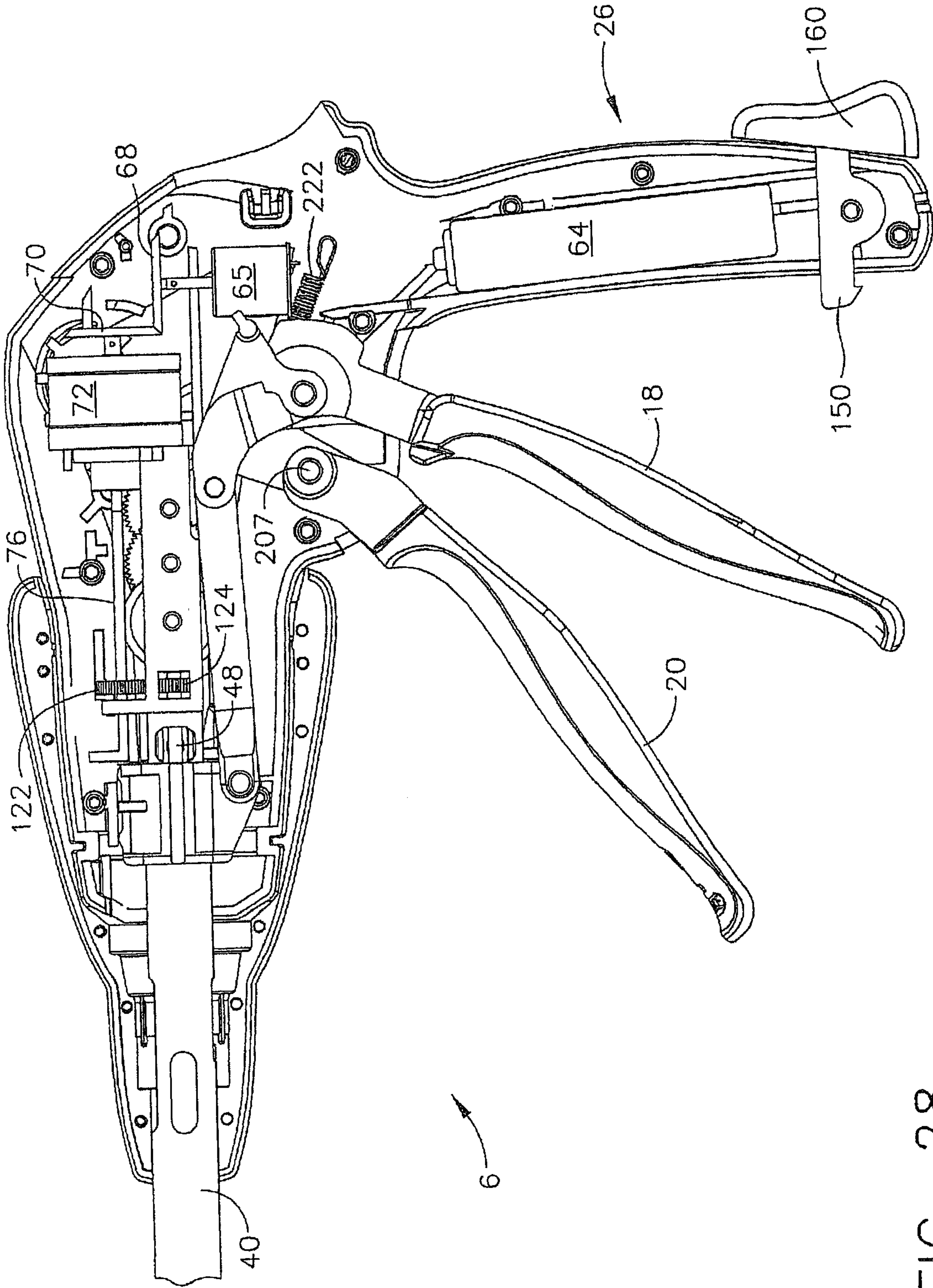


FIG. 28

29/42

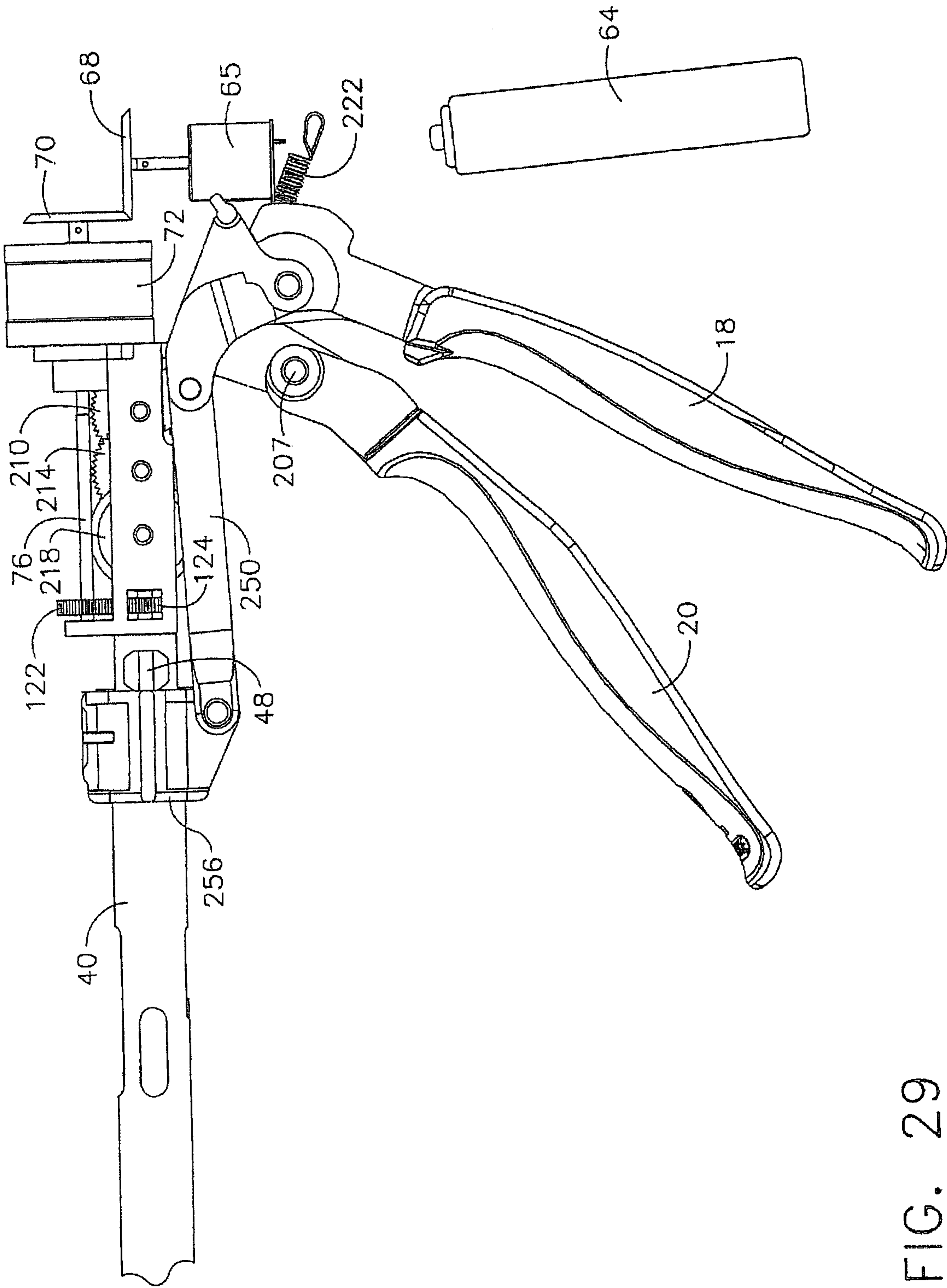


FIG. 29

30/42

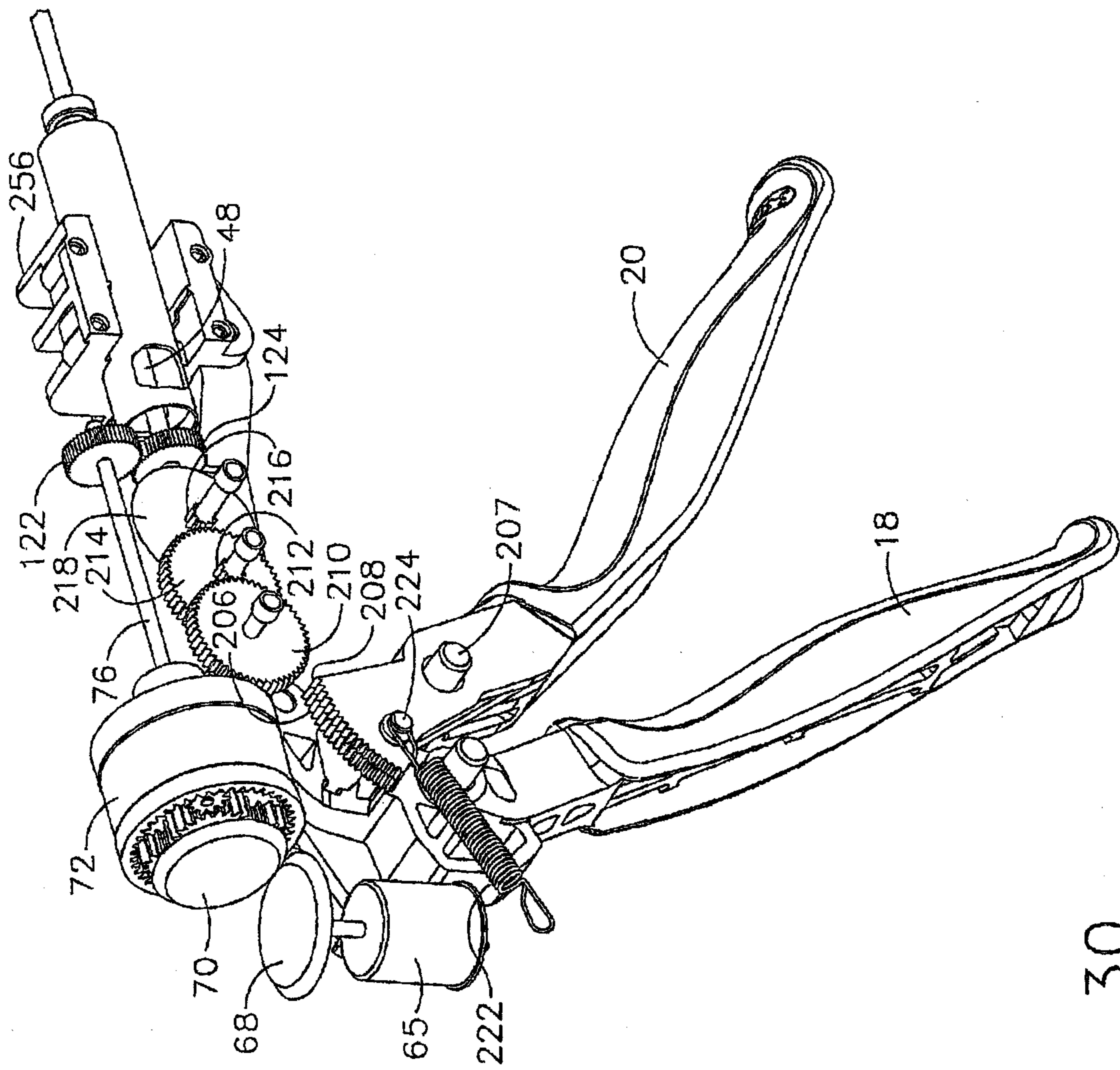


FIG. 30

31/42

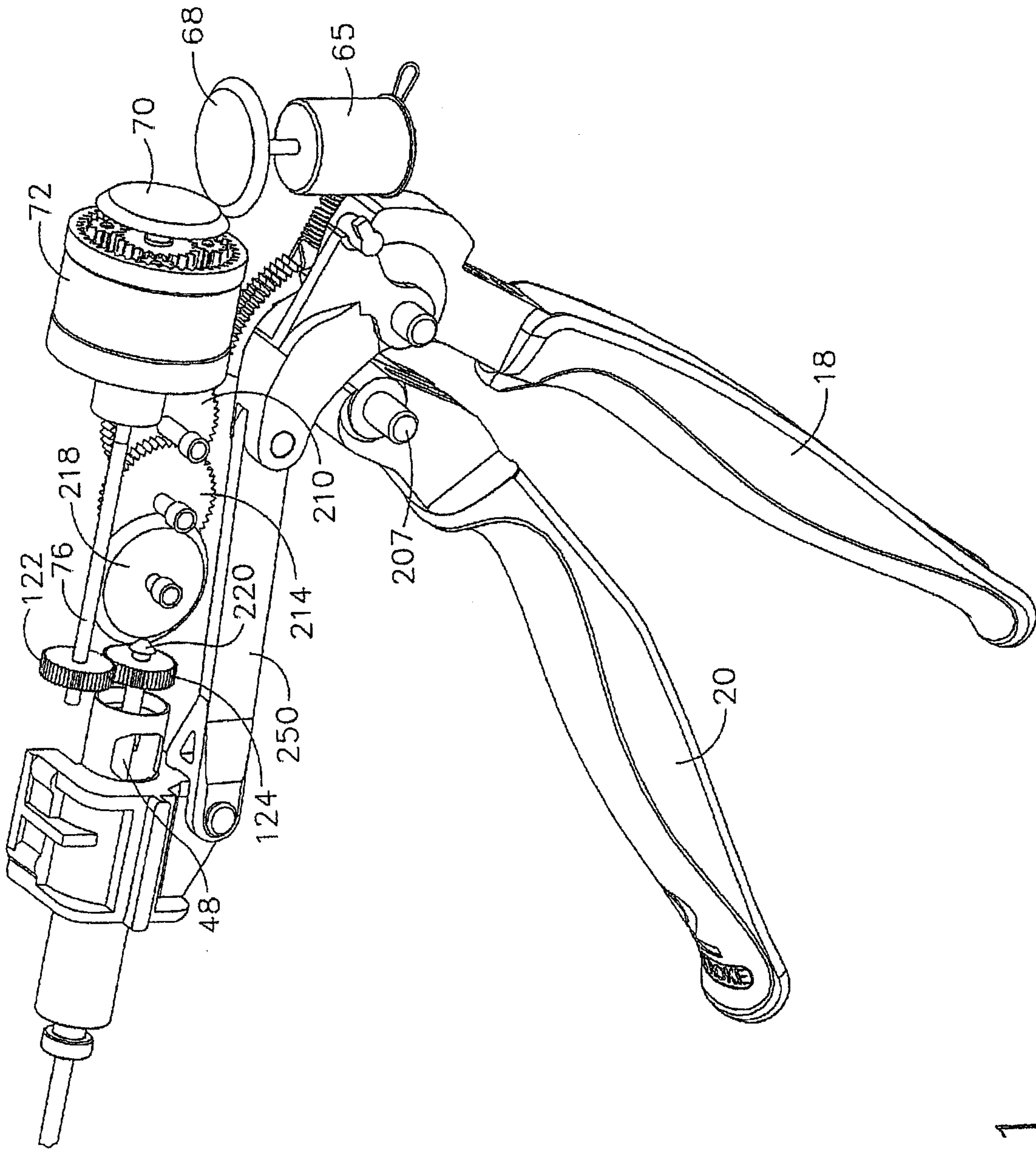


FIG. 31

32/42

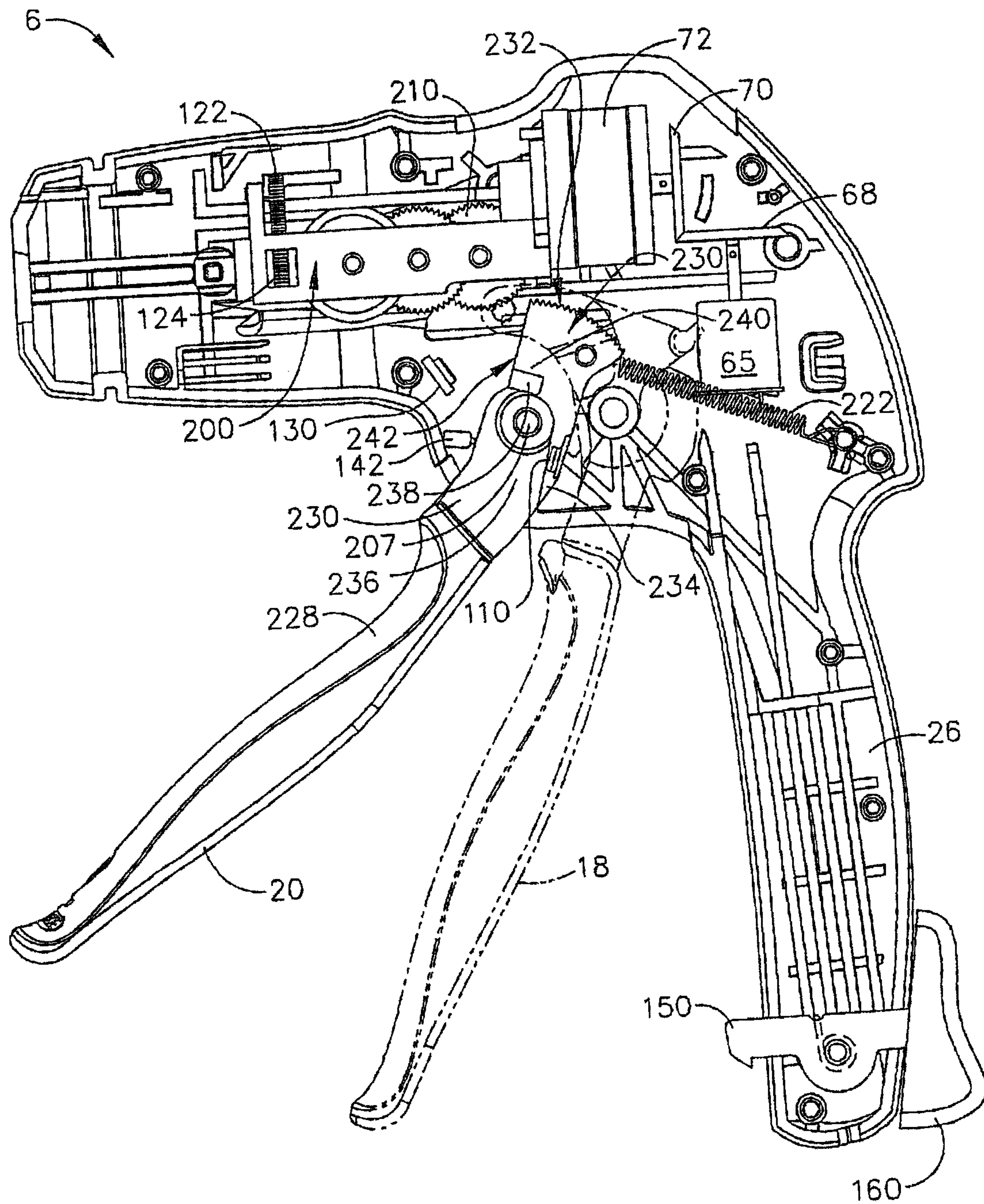


FIG. 32

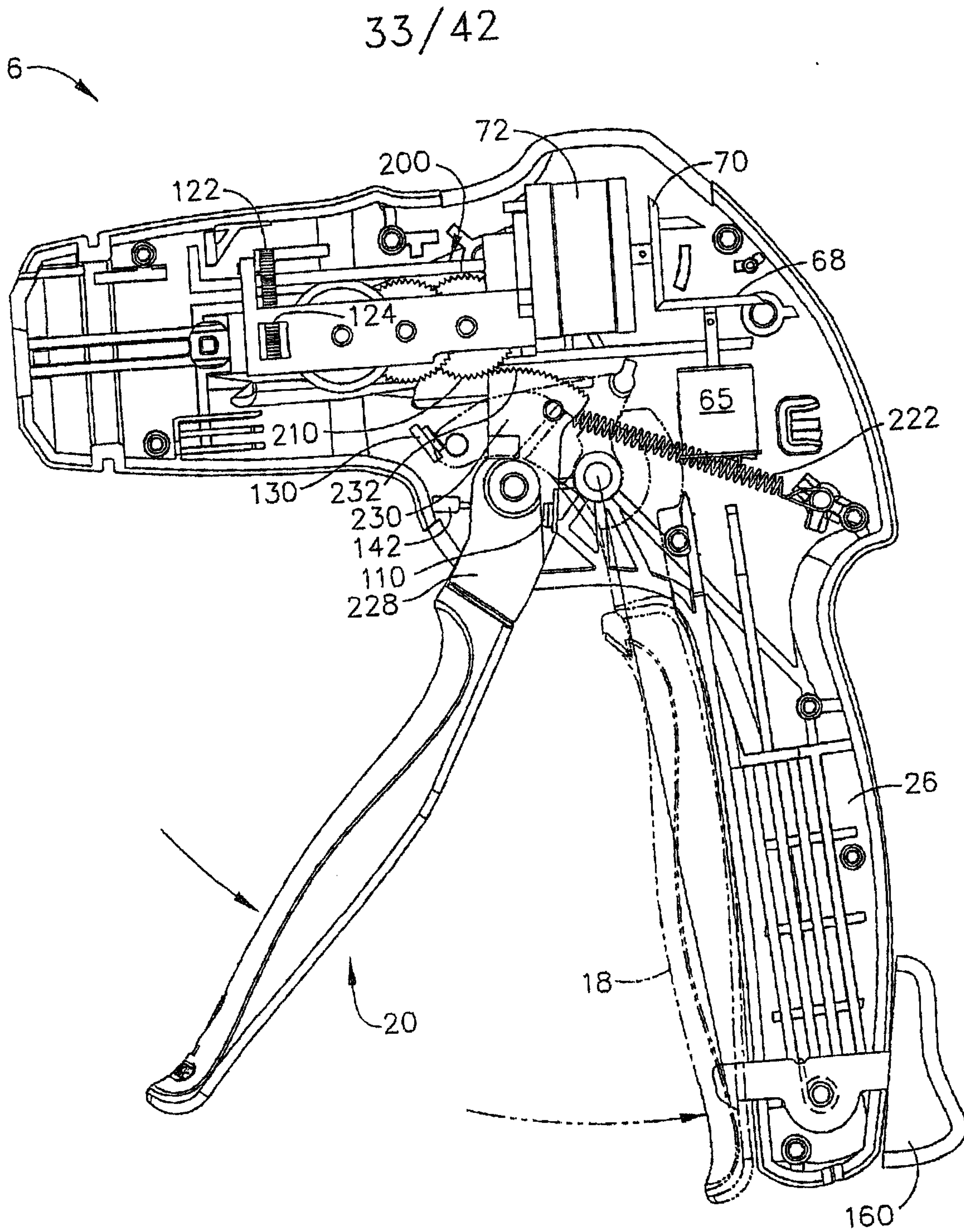


FIG. 33

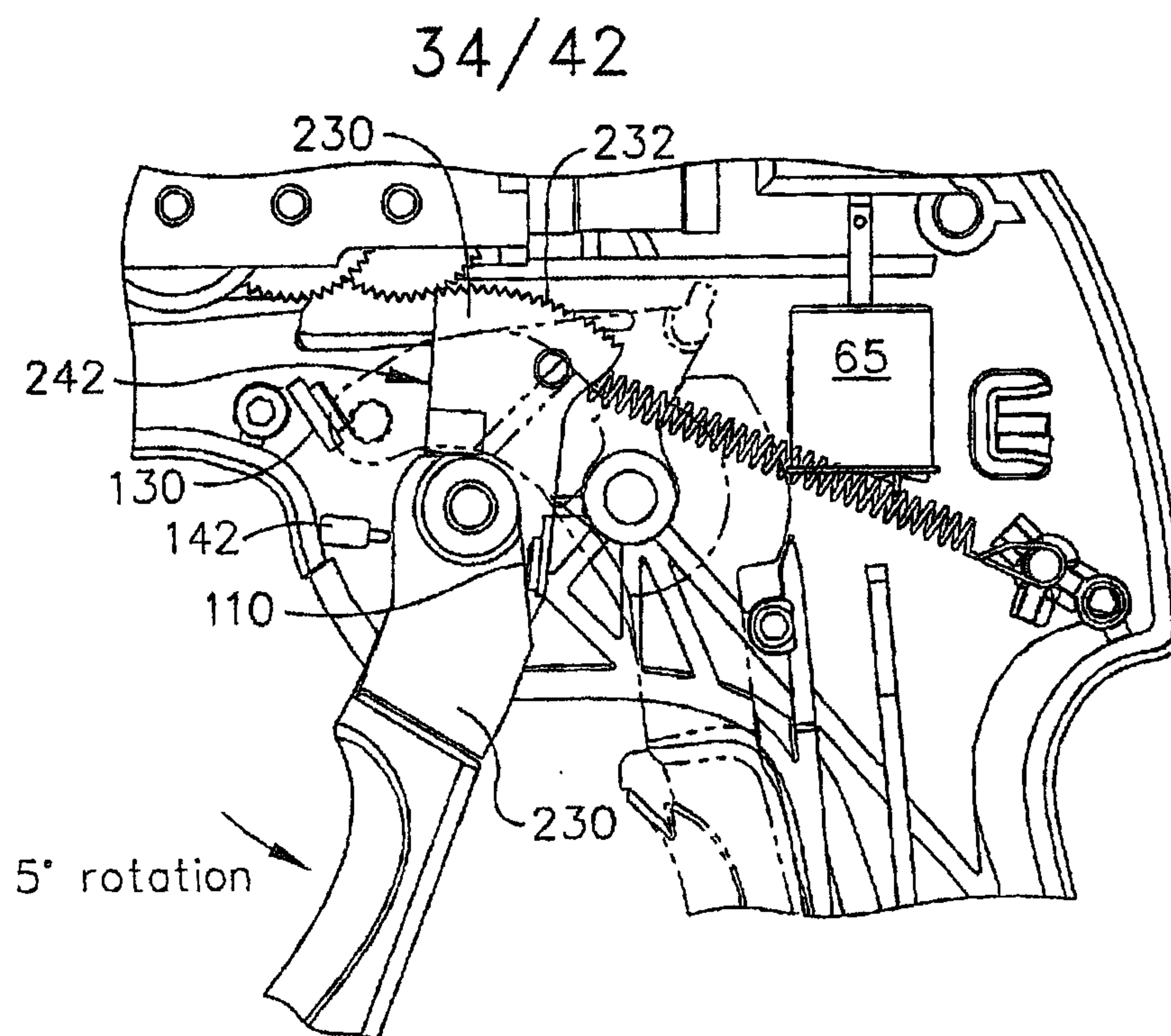


FIG. 34

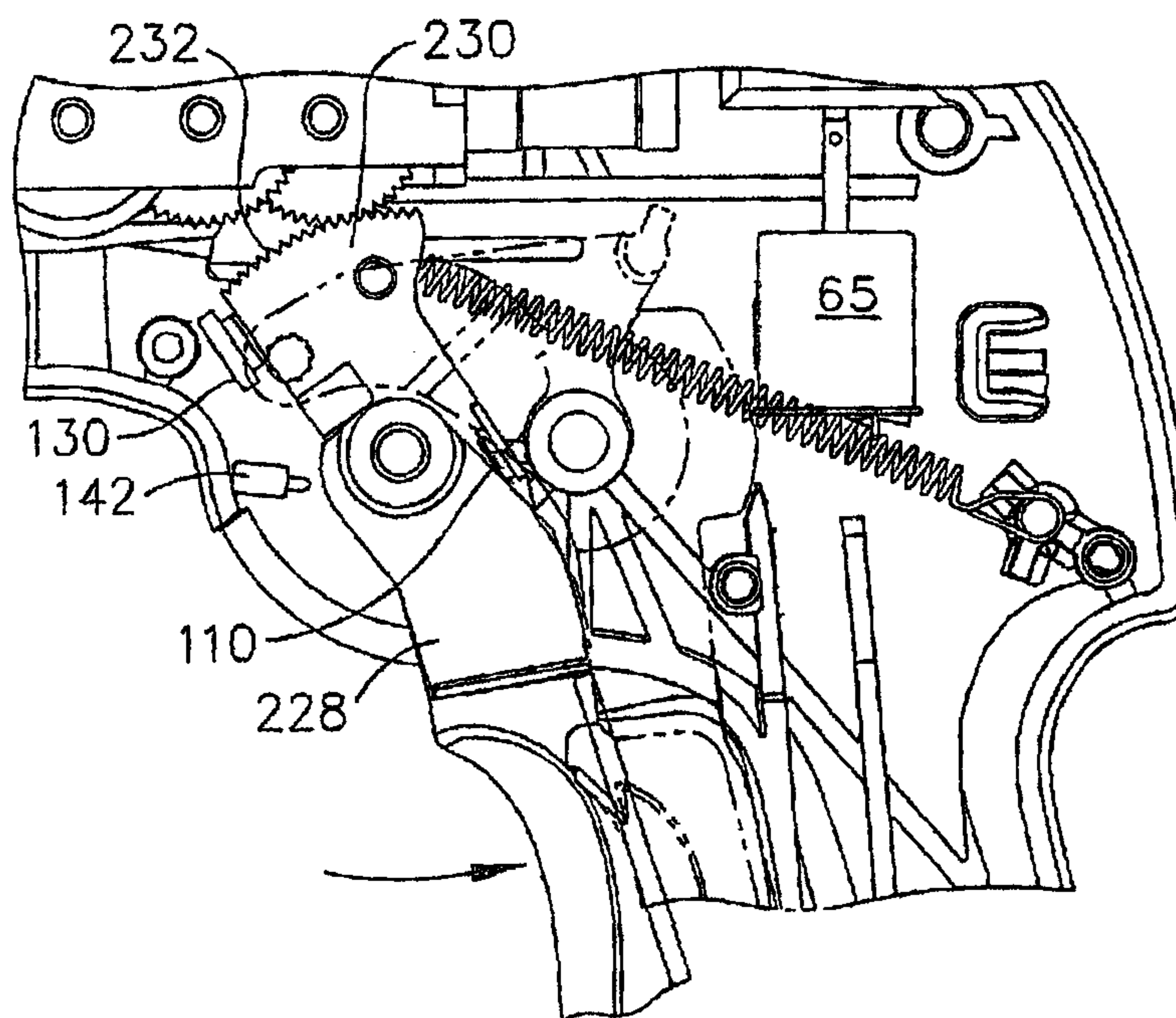


FIG. 35

35/42

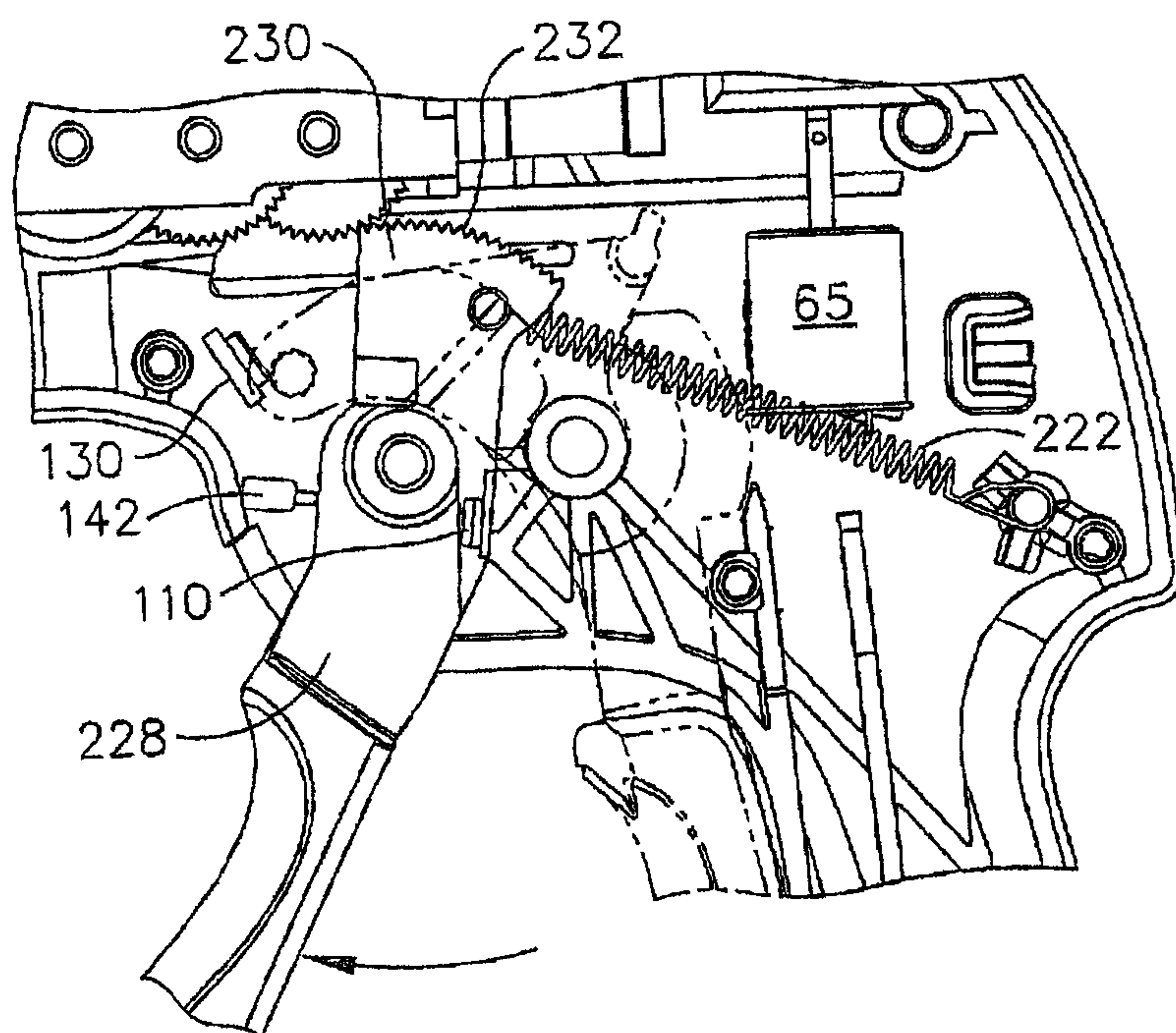


FIG. 36

36/42

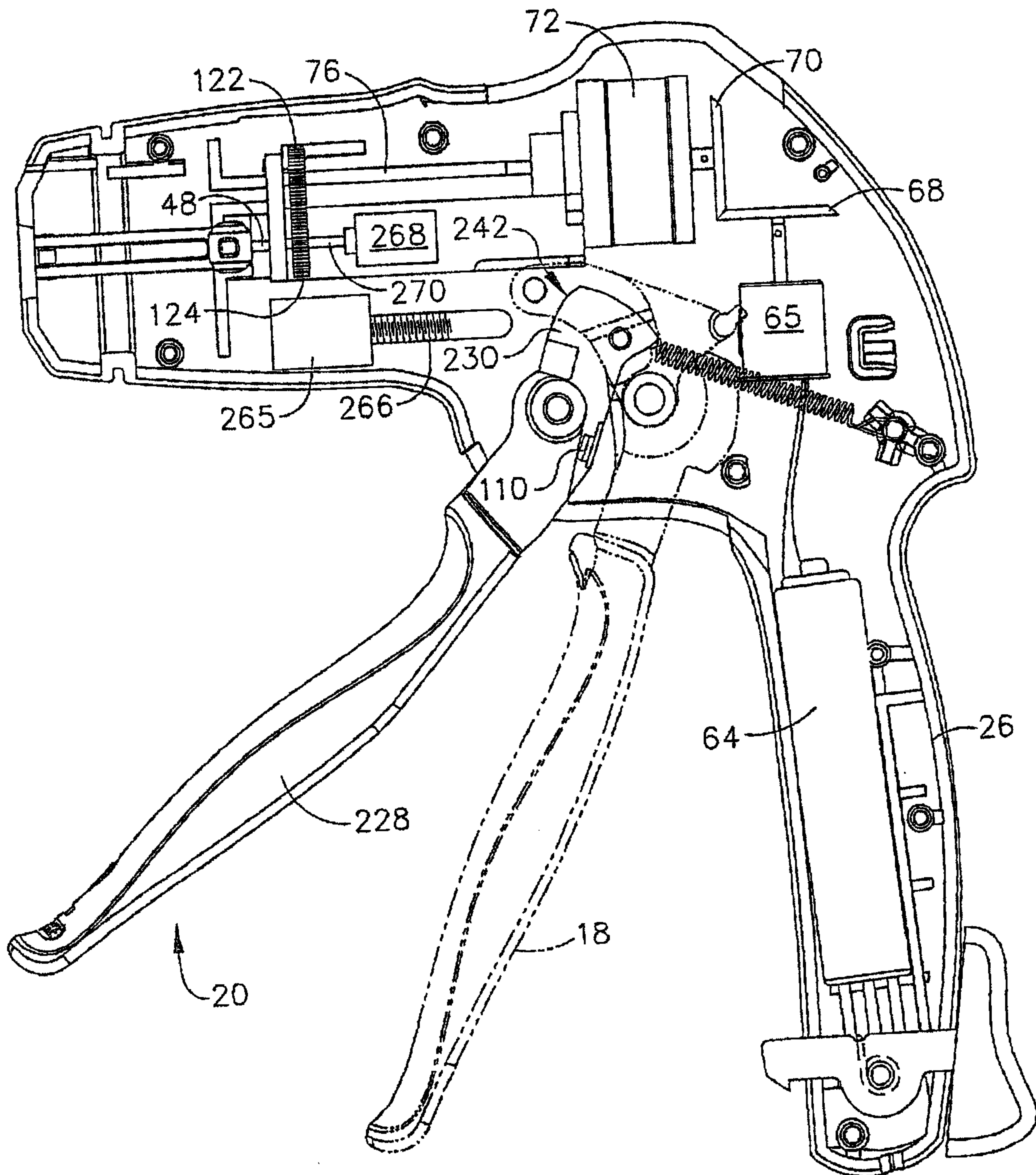


FIG. 37

37 / 42

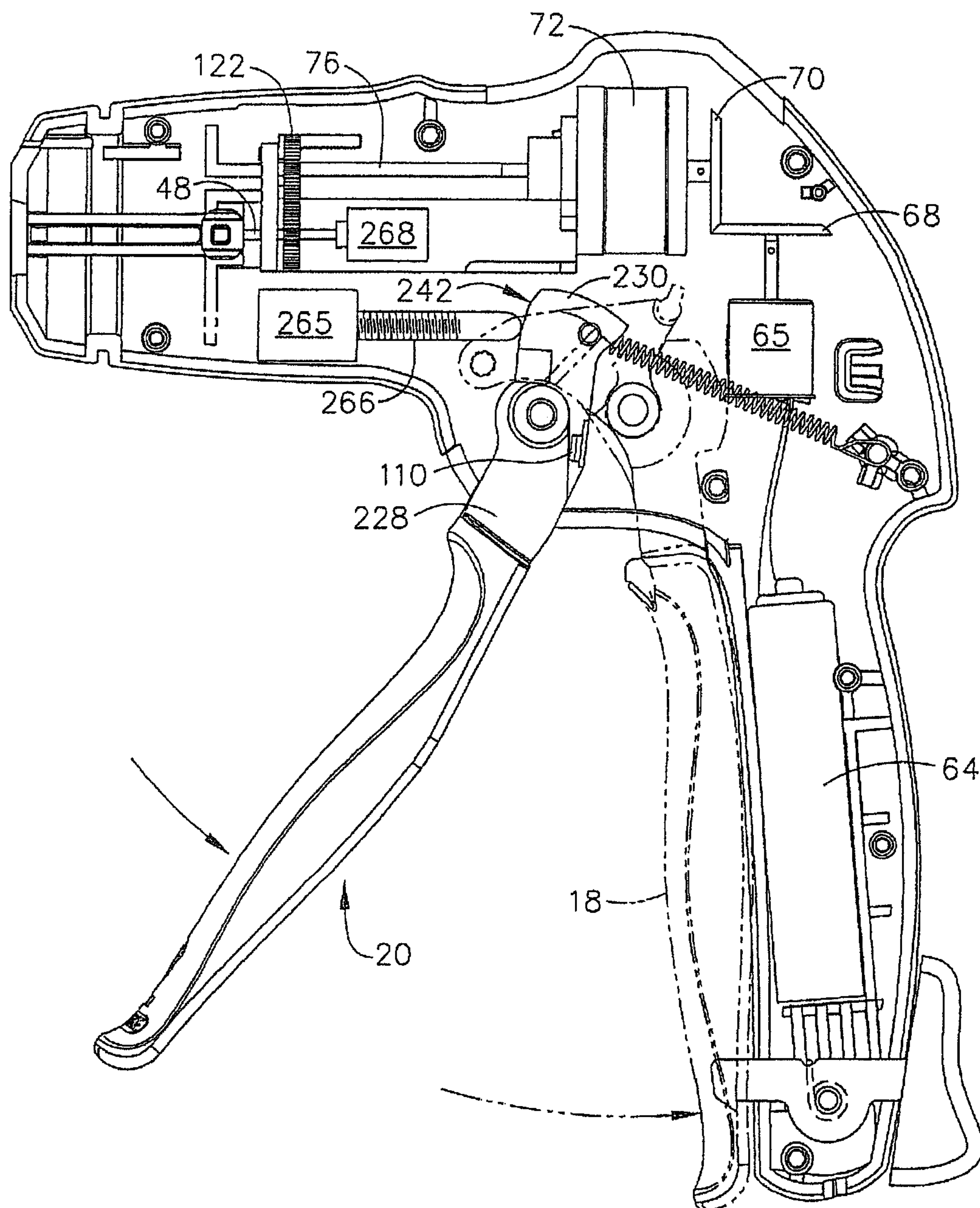


FIG. 38

38/42

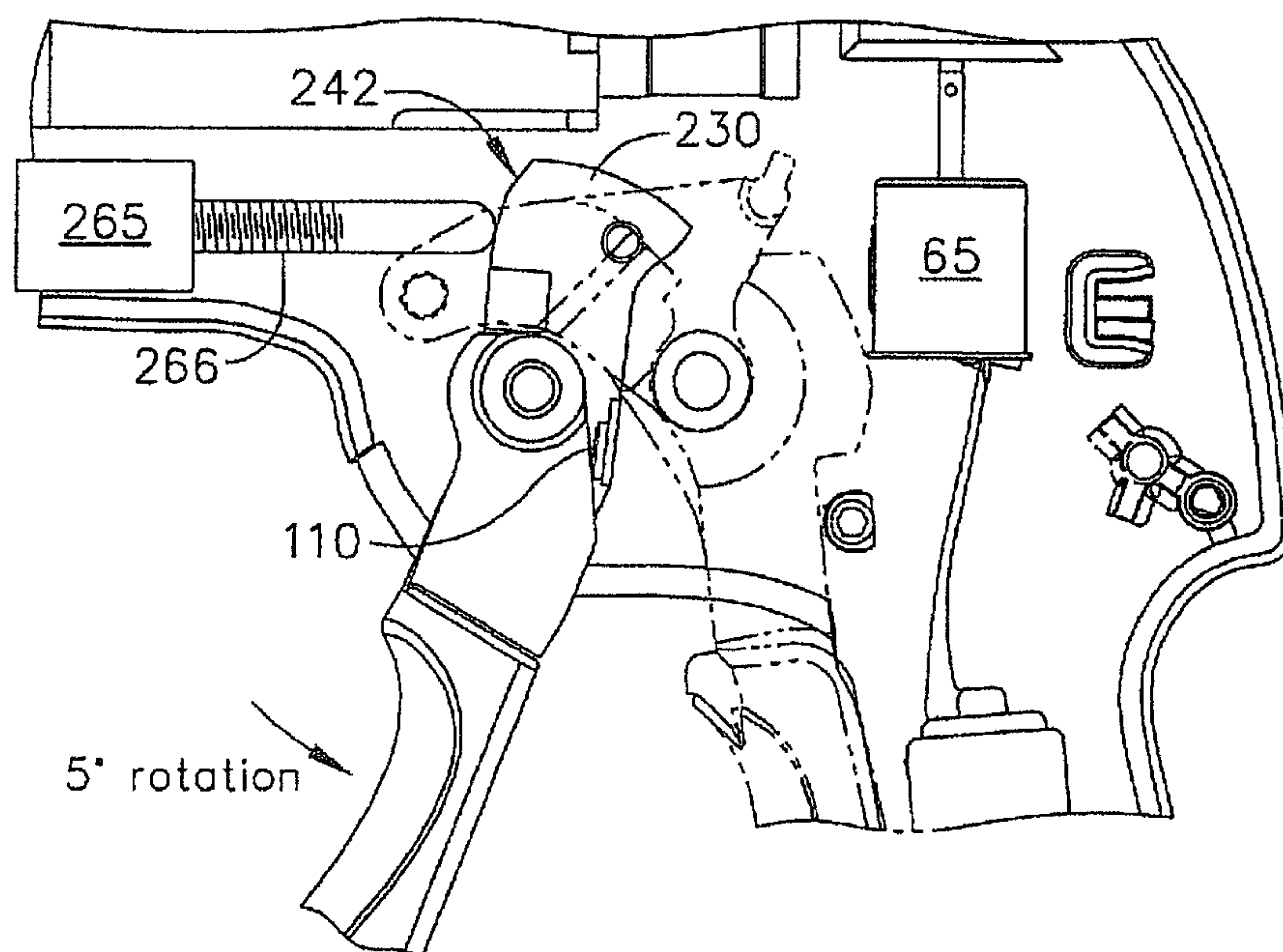


FIG. 39

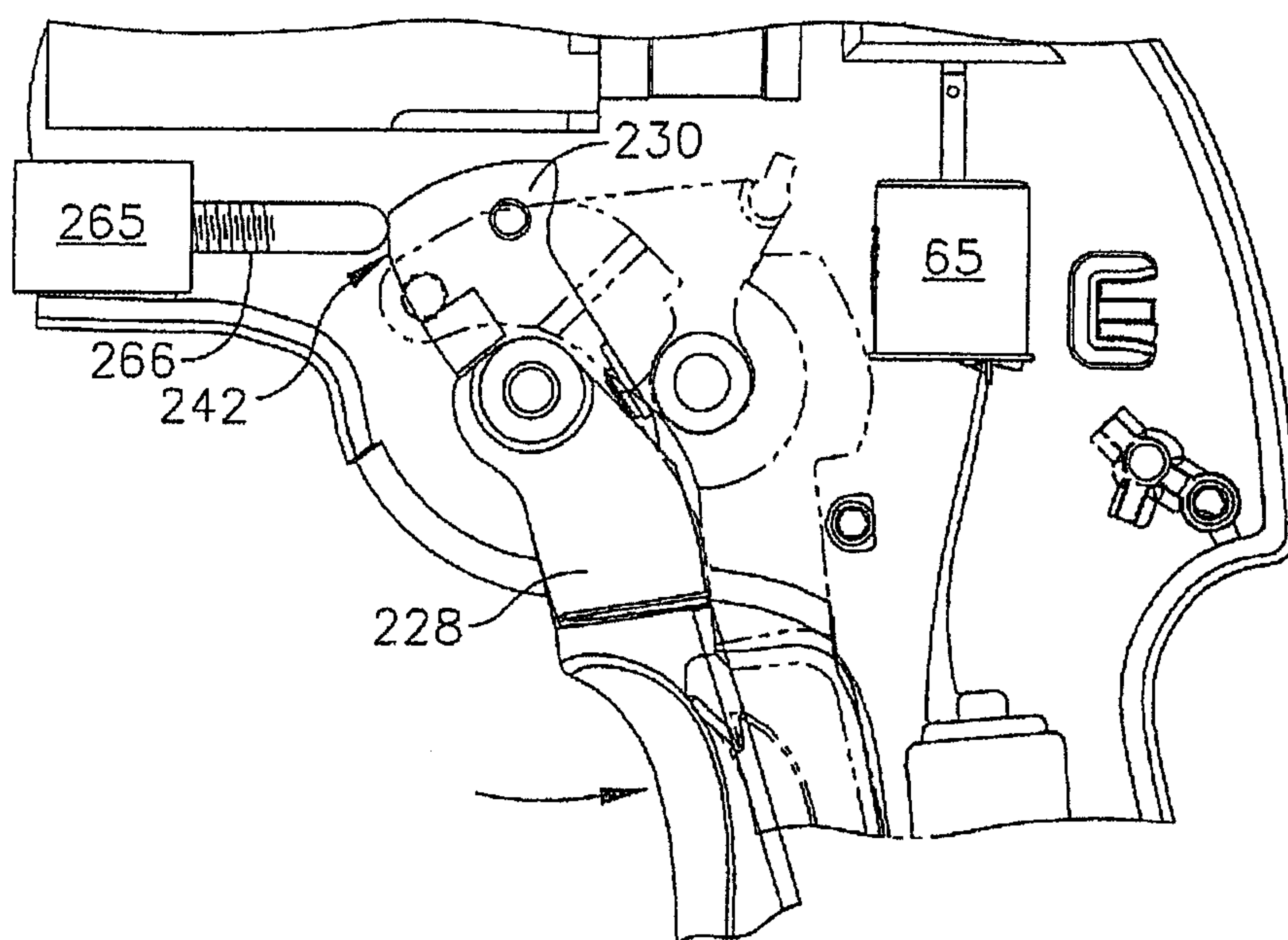


FIG. 40

39/42

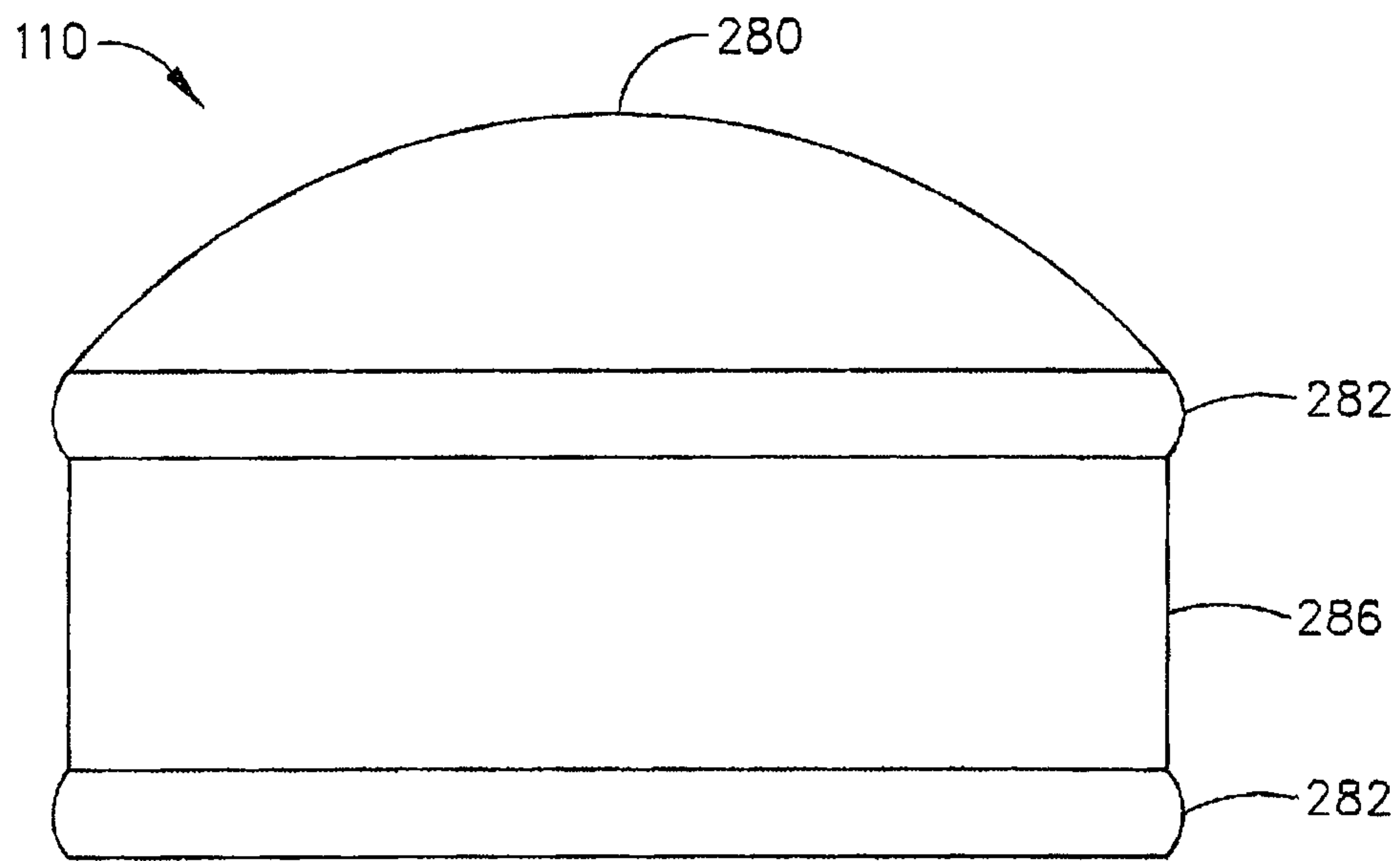


FIG. 41

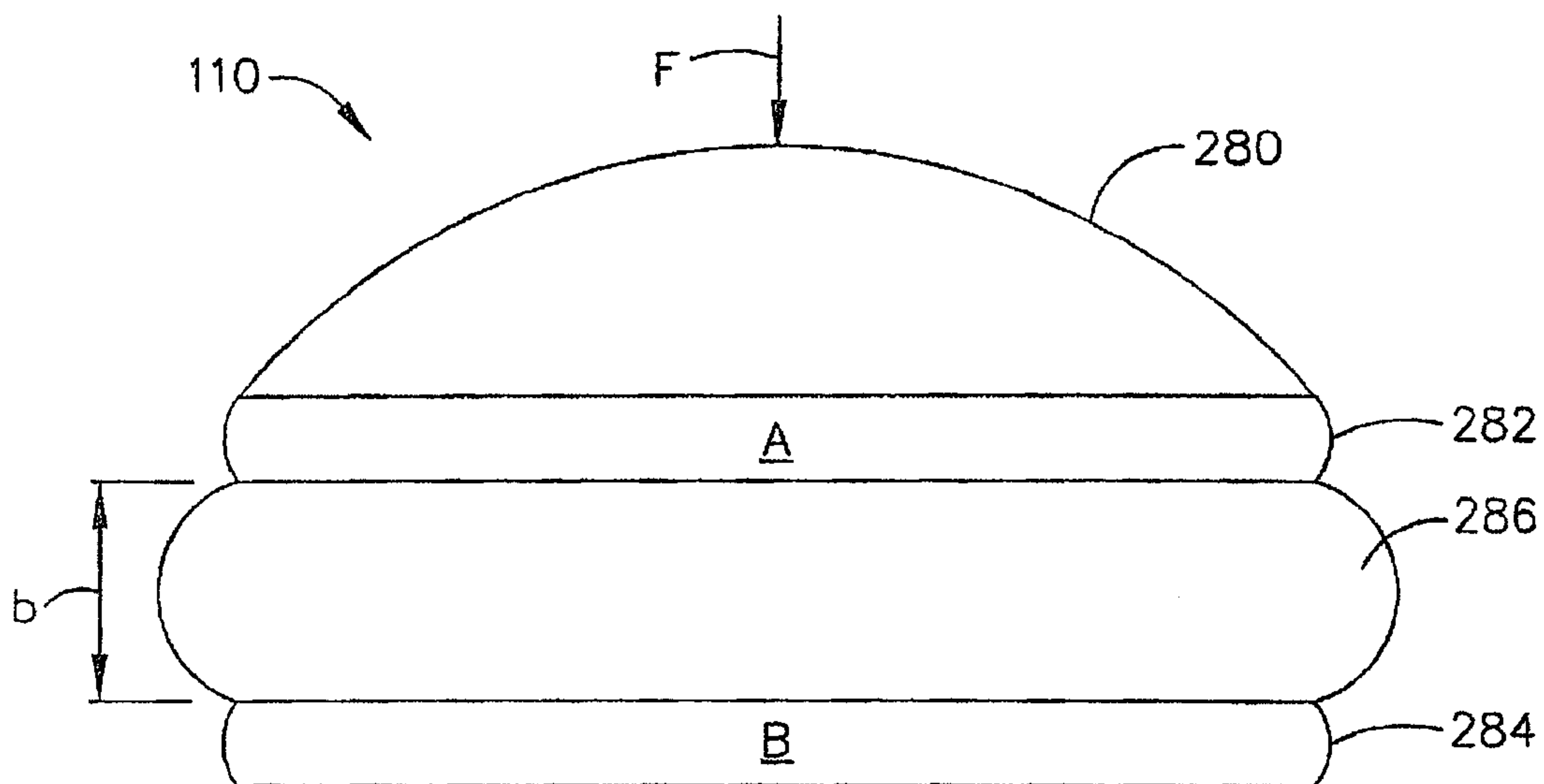
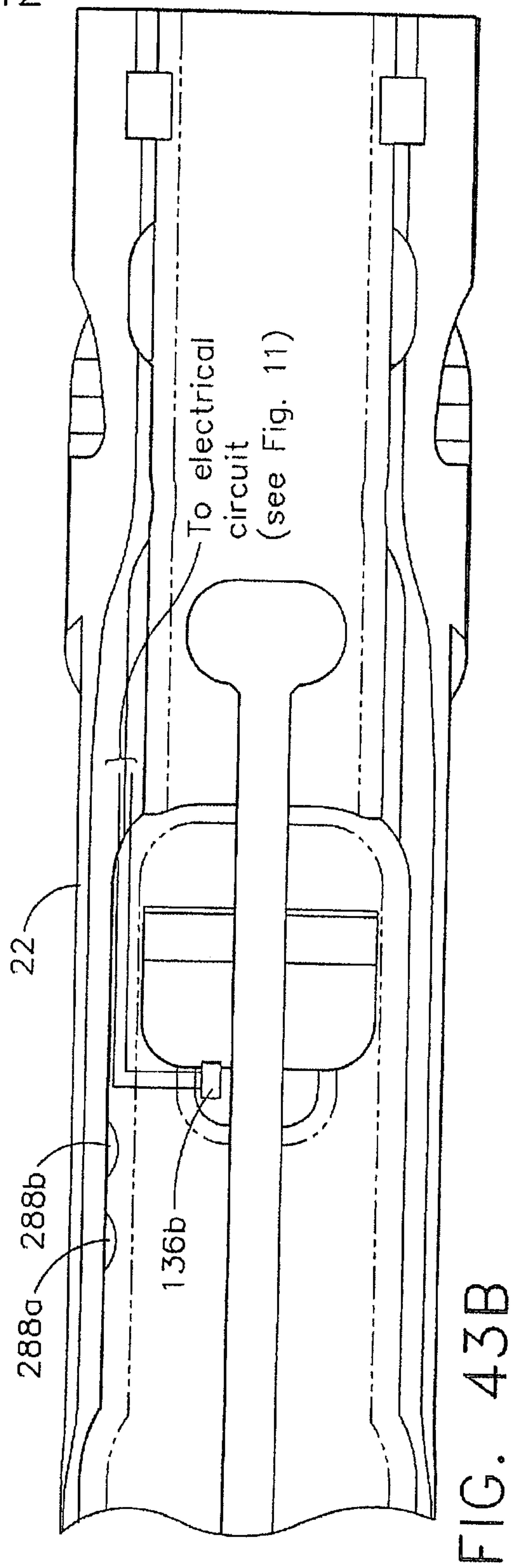
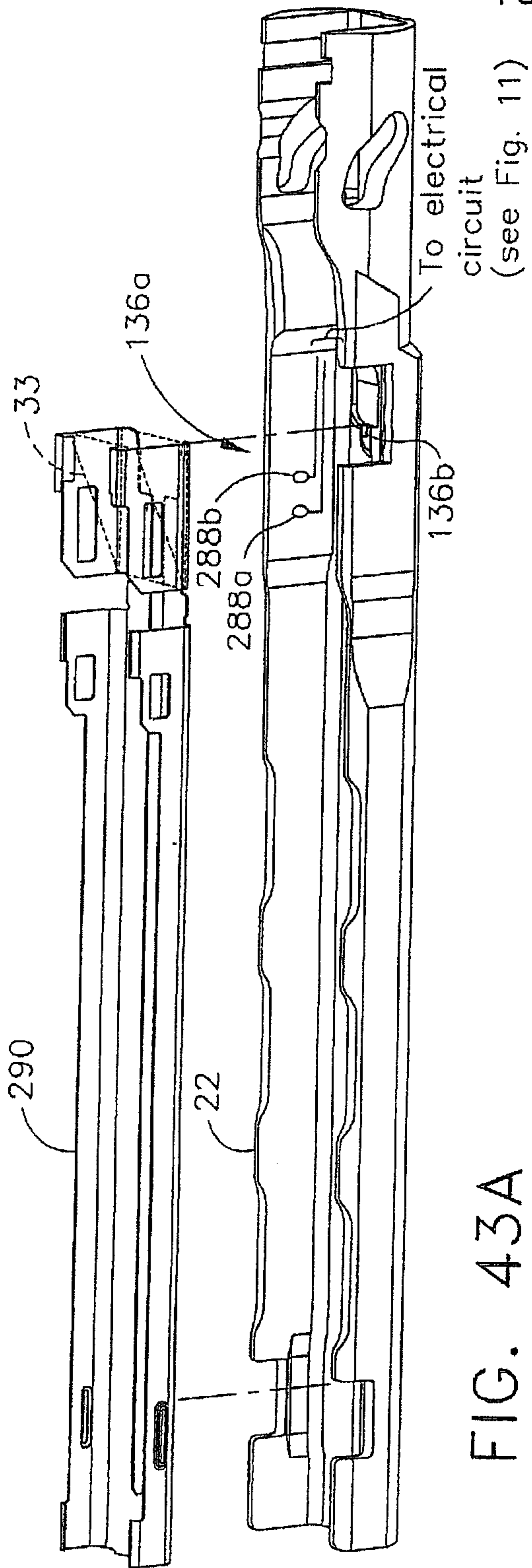
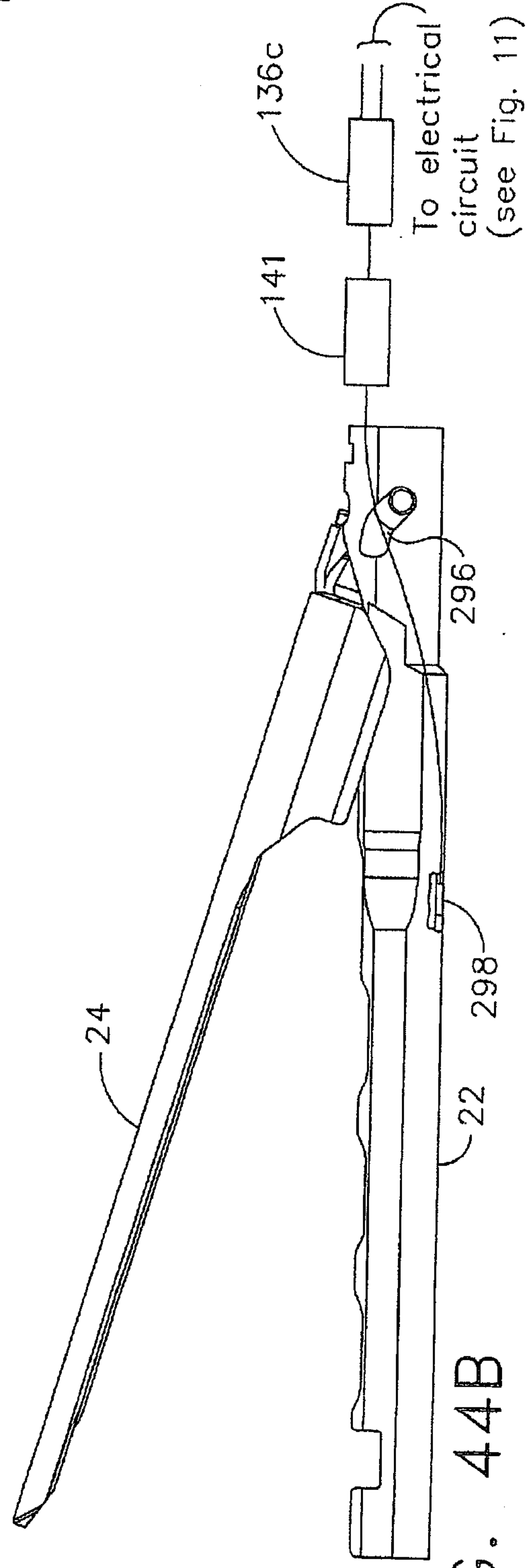
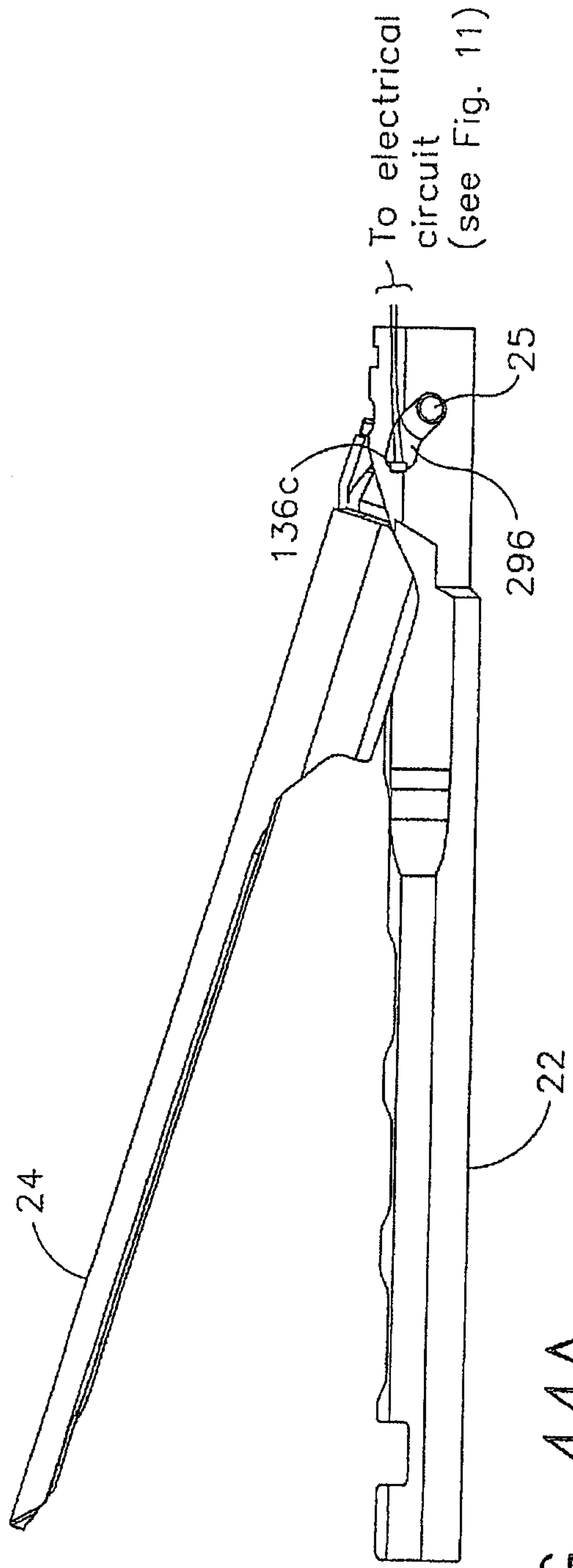


FIG. 42



41/42



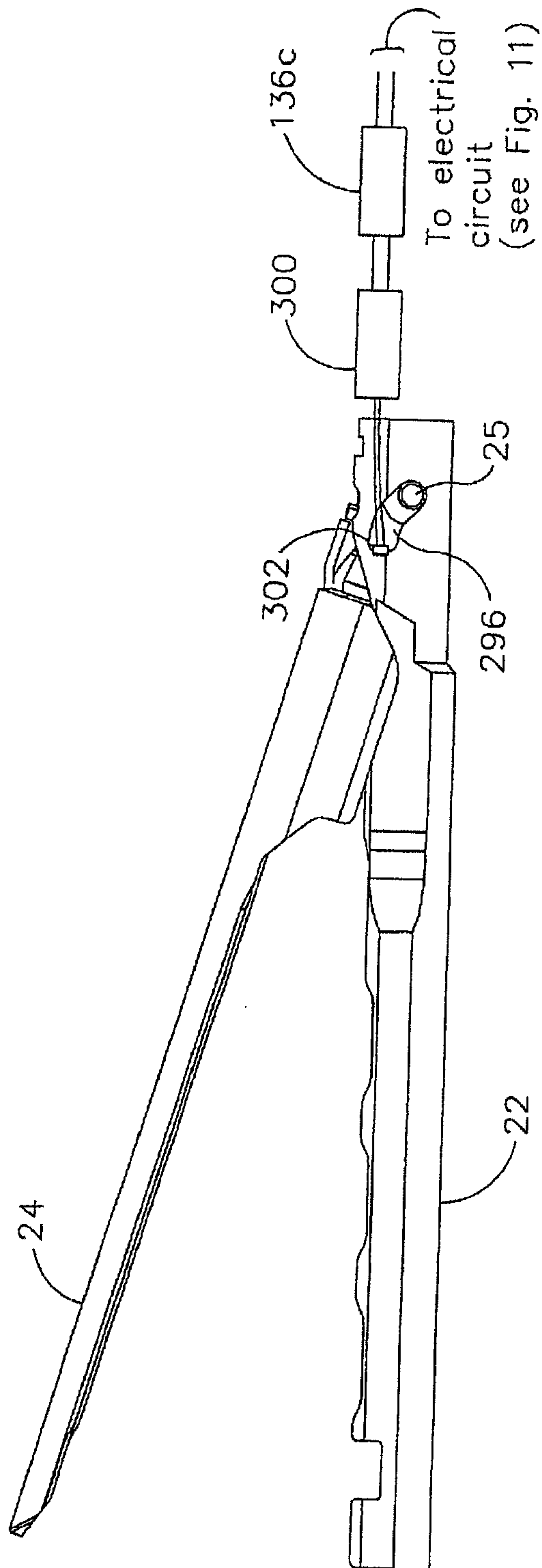


FIG. 44C

