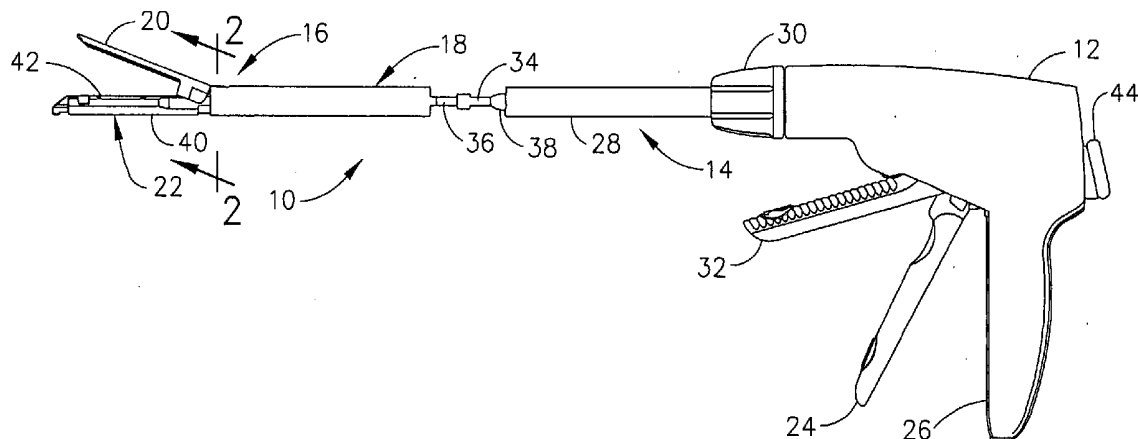




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Shelton, IV et al.(54) **SURGICAL STAPLING INSTRUMENTS
HAVING FLEXIBLE CHANNEL AND ANVIL
FEATURES FOR ADJUSTABLE STAPLE
HEIGHTS****Publication Classification**(51) **Int. Cl.**
A61B 17/10 (2006.01)
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Leslie M. Fugikawa, Cincinnati, OH
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Cincinnati, OH (US)(57) **ABSTRACT**

A surgical instrument for being endoscopically or laparoscopically inserted into a surgical site for simultaneous stapling and severing of tissue includes force adjusted spacing between an upper jaw (anvil) and a lower jaw (staple cartridge engaged to an elongate staple channel) so that the height of staple formation corresponds to the thickness of the tissue, yet does not exceed the height range that may be accommodated by the length of the staples. In particular, resilient structures may be formed into one or more of the elongate channel that supports the staple cartridge, the anvil that is pivotally attached to the elongate channel, and/or a firing member that includes a cutting surface (knife) that severs tissue between a top pin that engages the anvil and a lower foot that engage the elongate channel. The resilience responds to the force exerted by clamped tissue to vary the spacing between the anvil and the staple cartridge supported within the elongate channel.

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PITTSBURGH, PA 15222 (US)**(21) **Appl. No.:** **11/540,735**
(22) **Filed:** **Sep. 29, 2006****Related U.S. Application Data**(63) Continuation-in-part of application No. 11/231,456,
filed on Sep. 21, 2005.

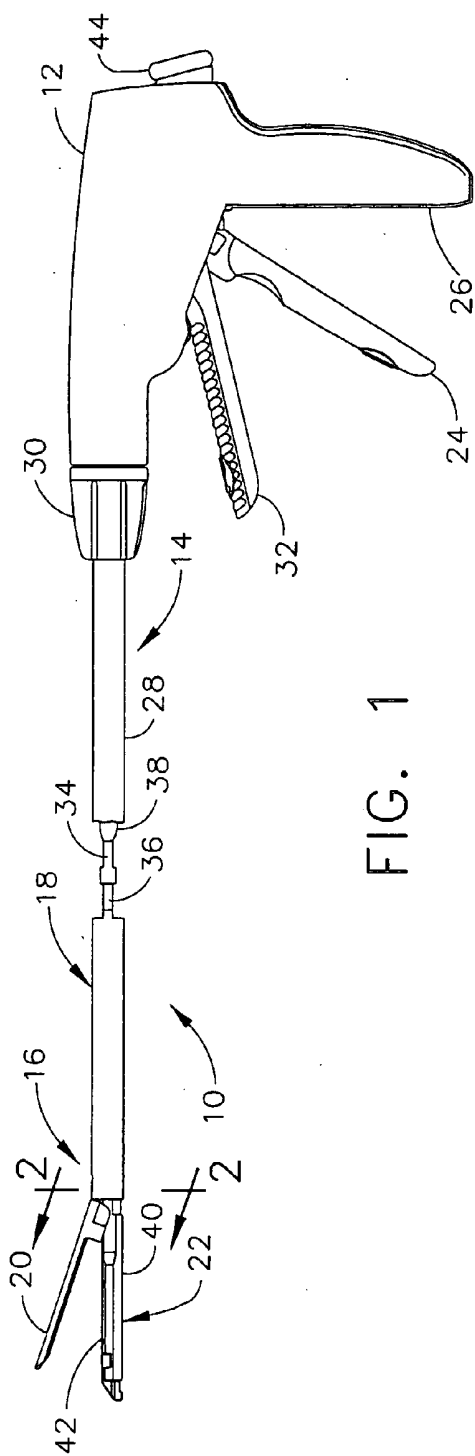


FIG. 1

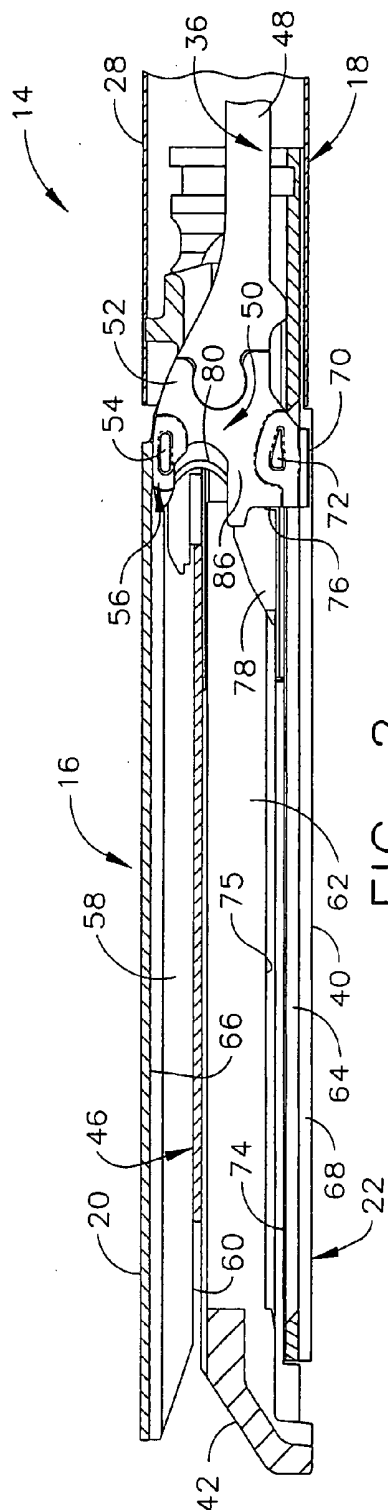


FIG. 2

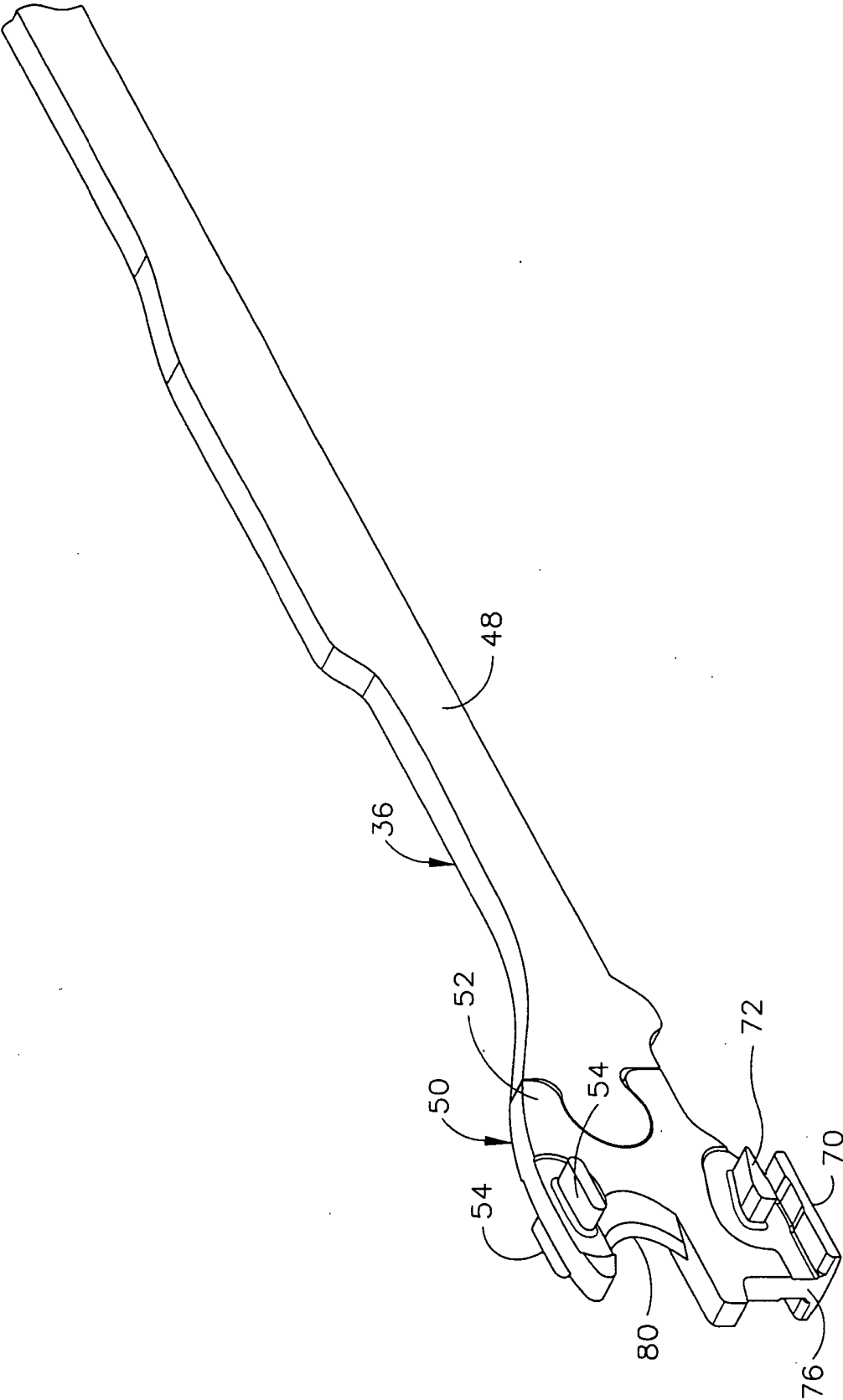
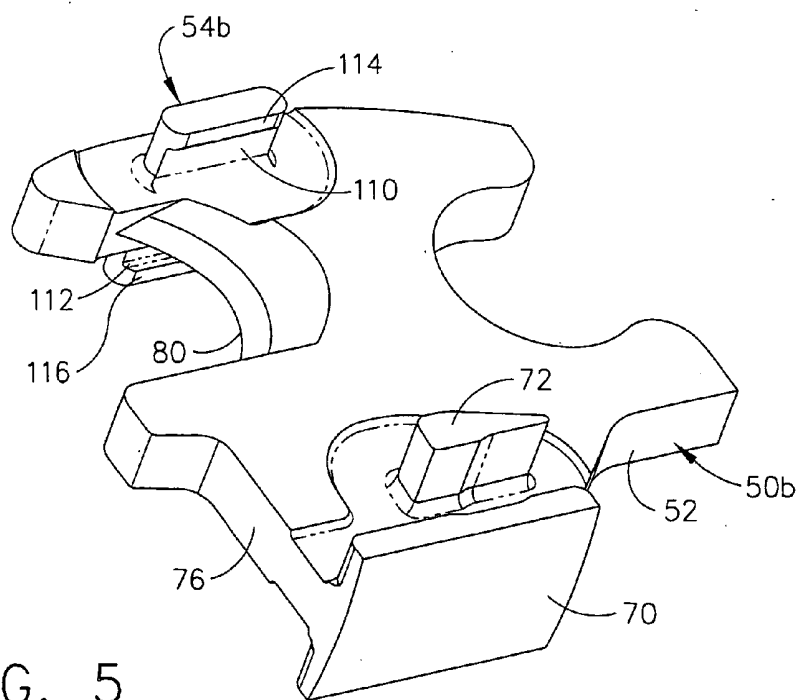
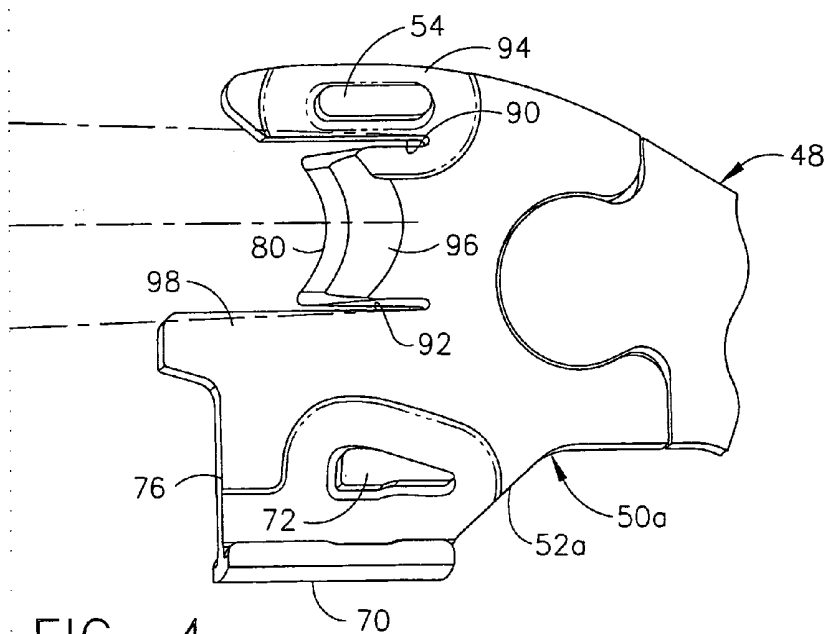


FIG. 3



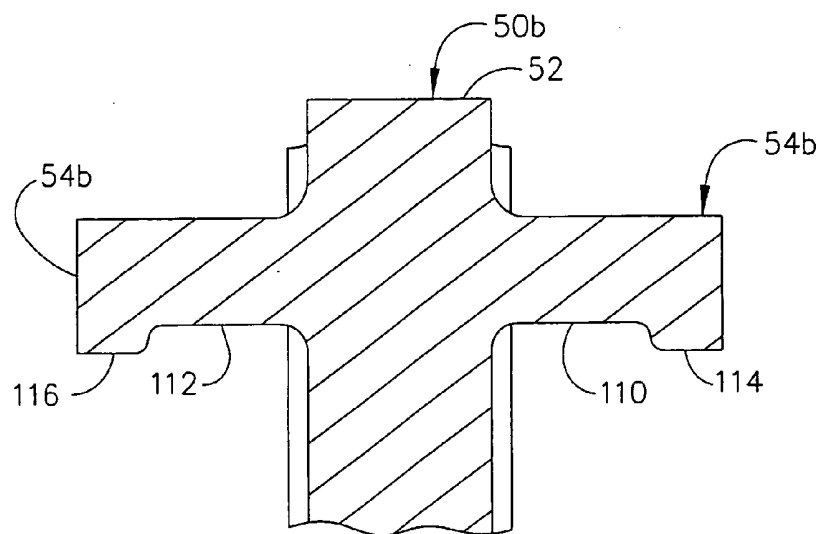


FIG. 6

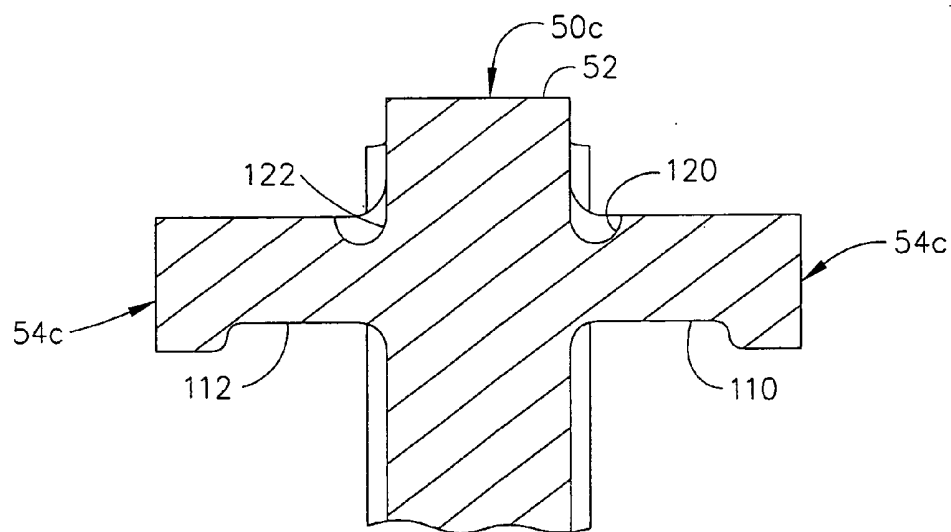


FIG. 7

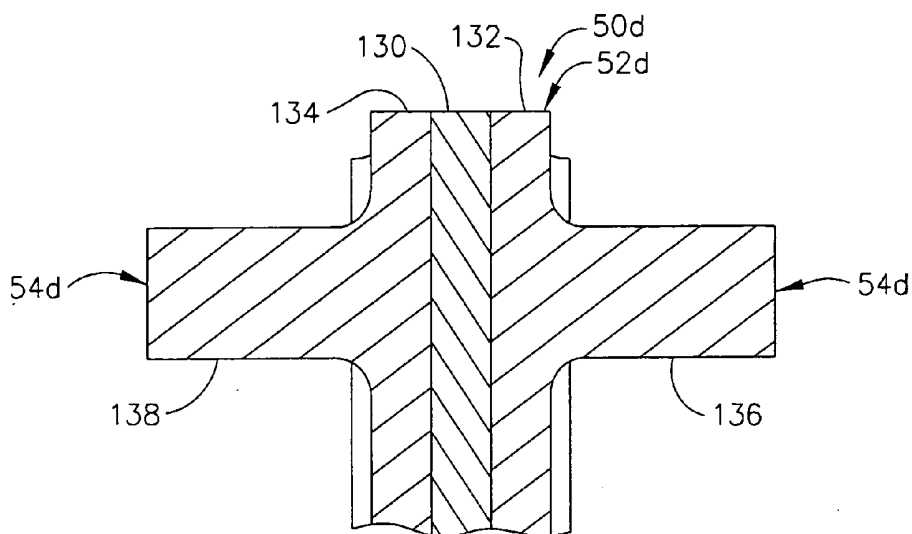


FIG. 8

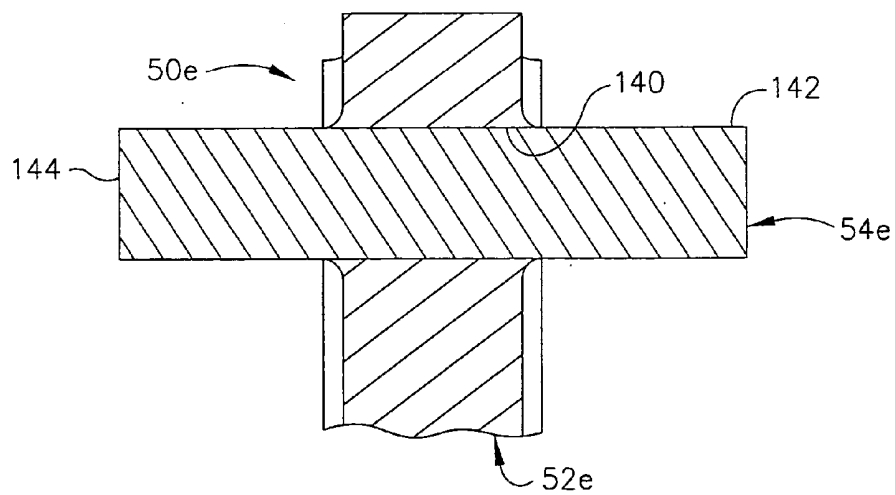


FIG. 9

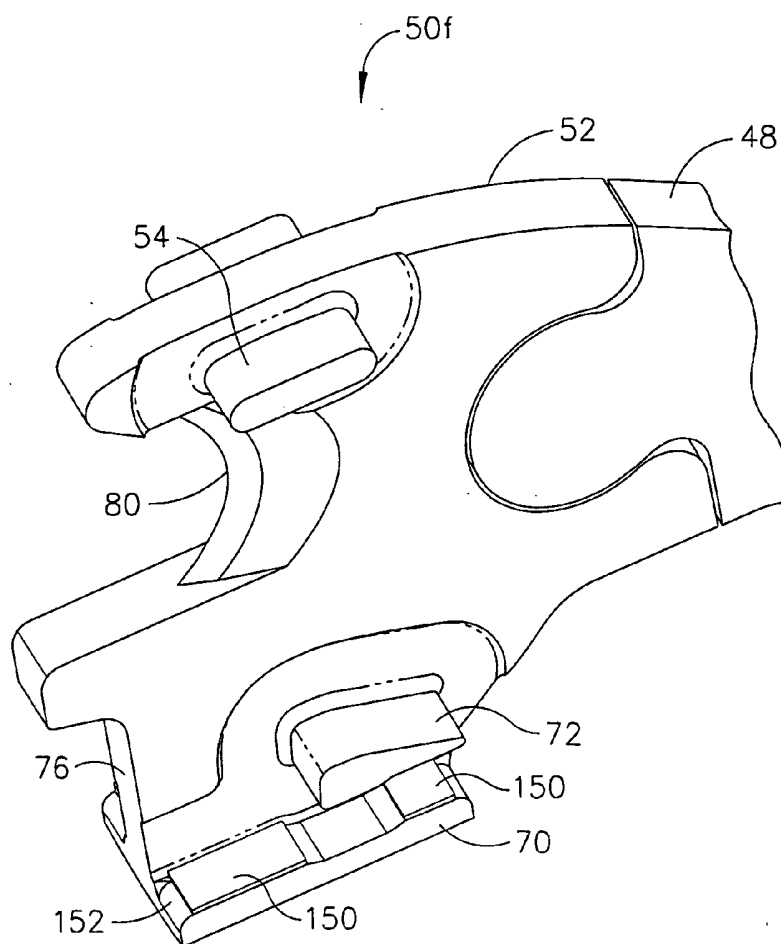


FIG. 10

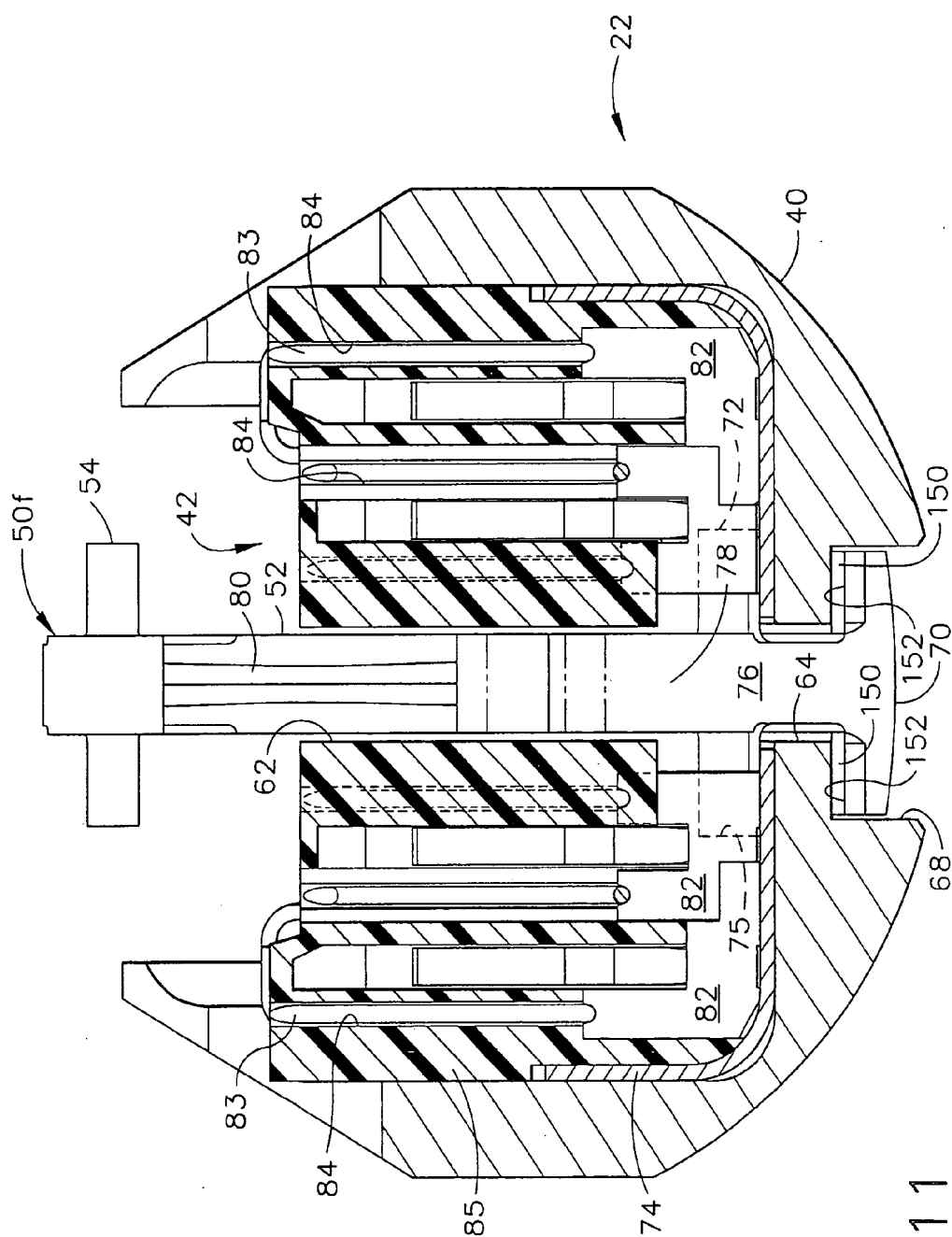


FIG. 11

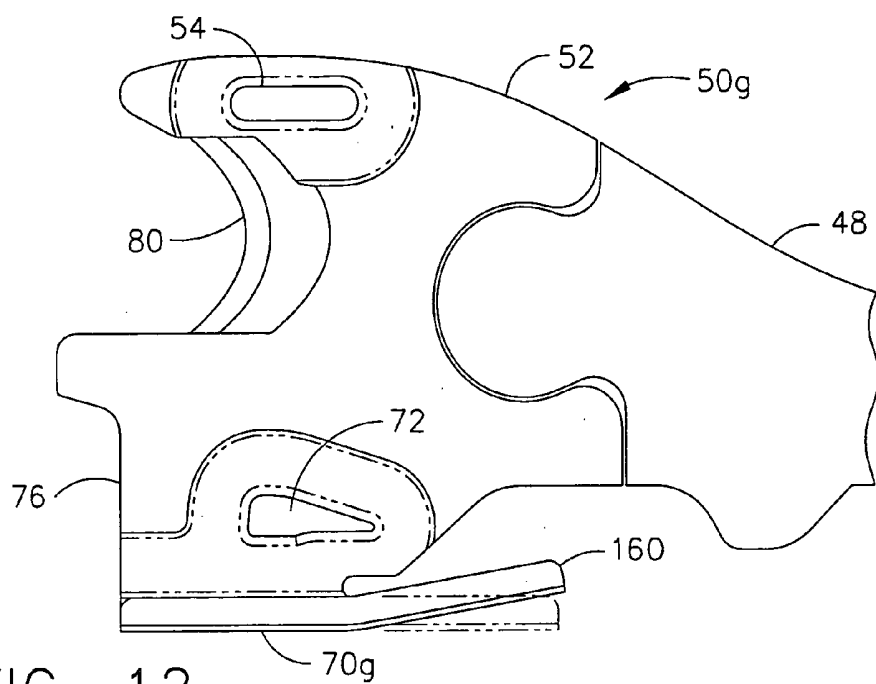


FIG. 12

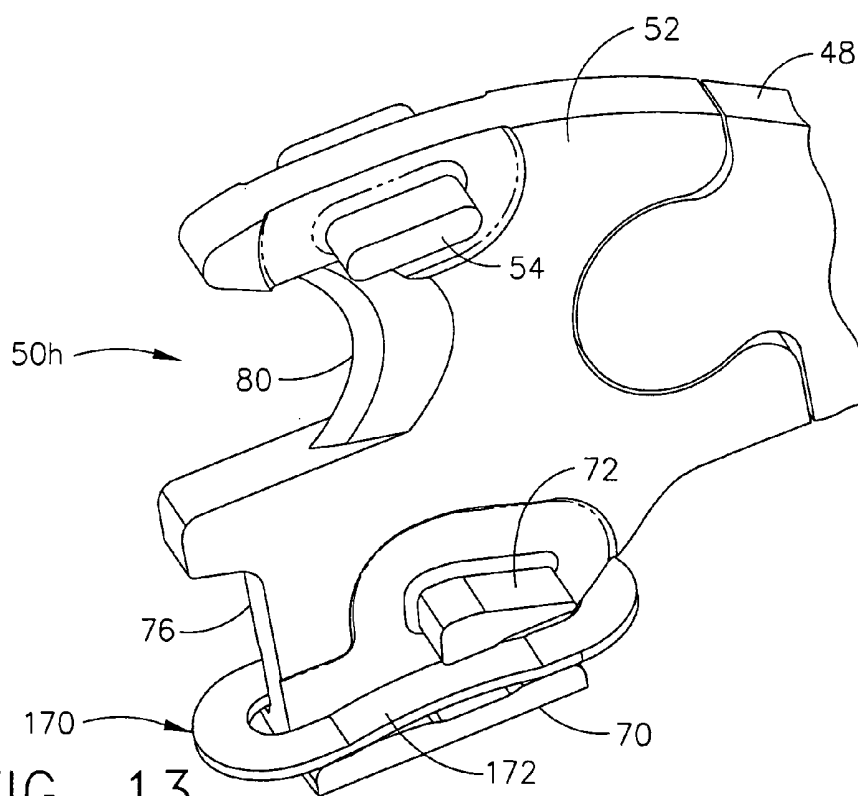


FIG. 13

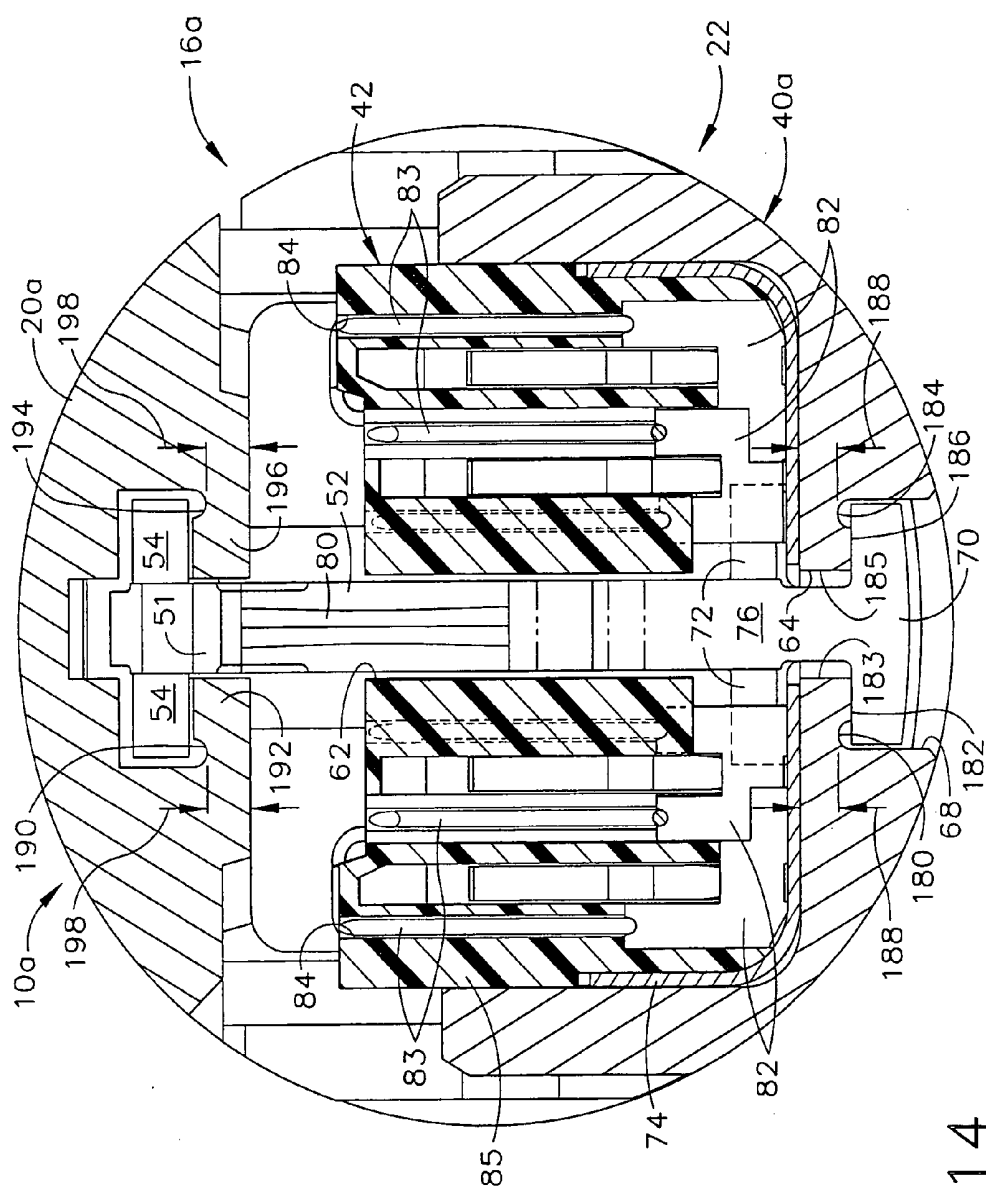


FIG. 14

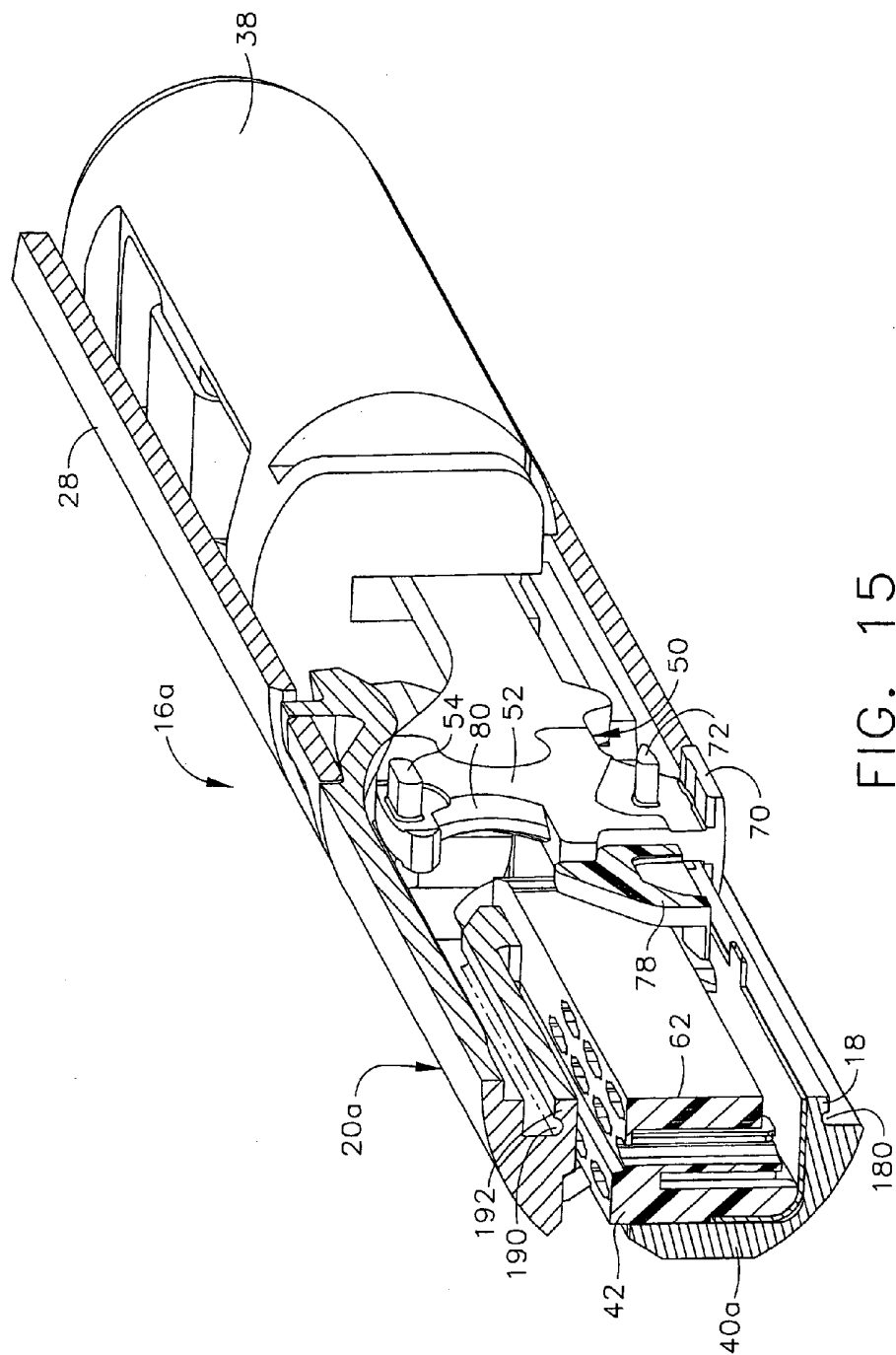
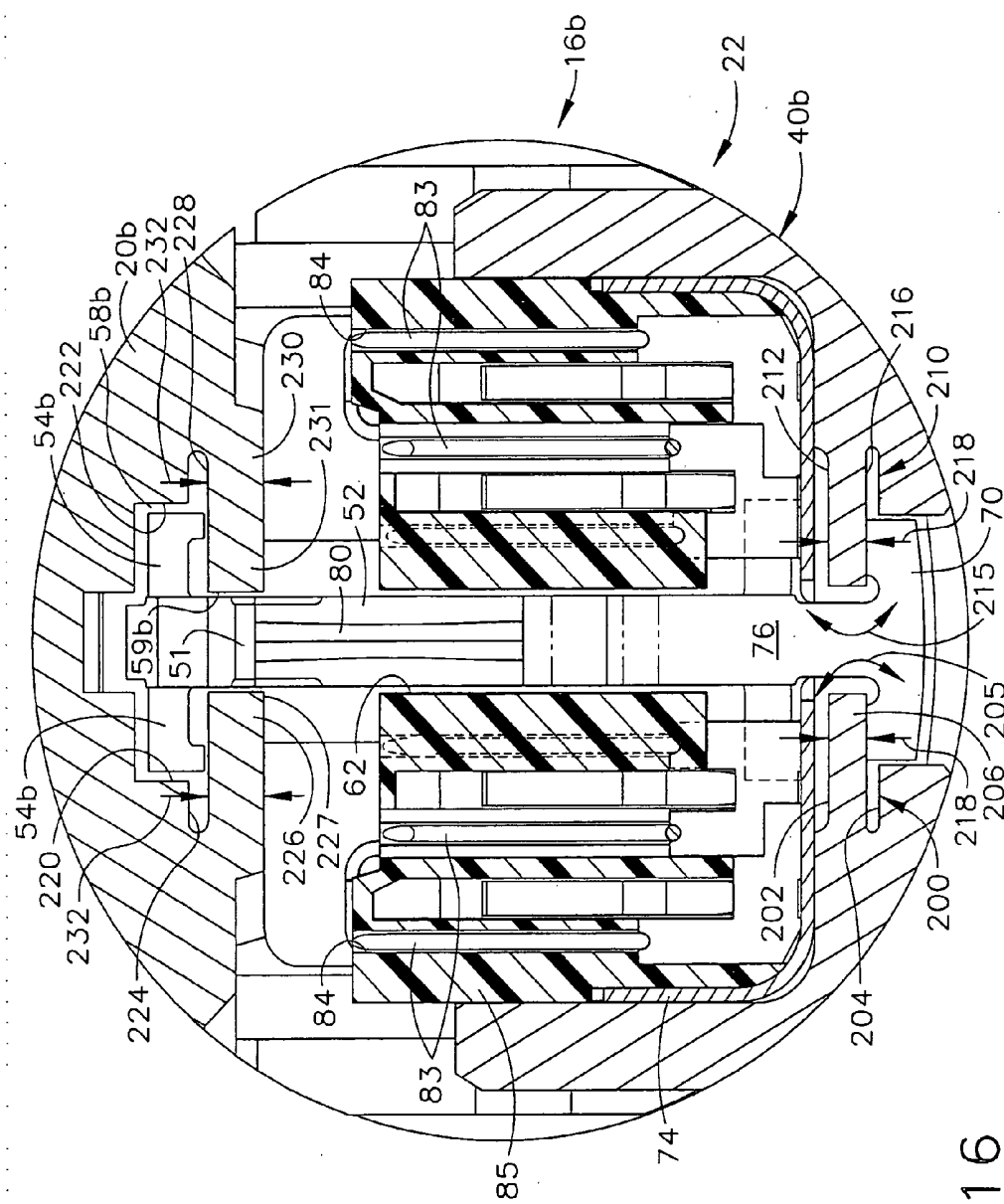
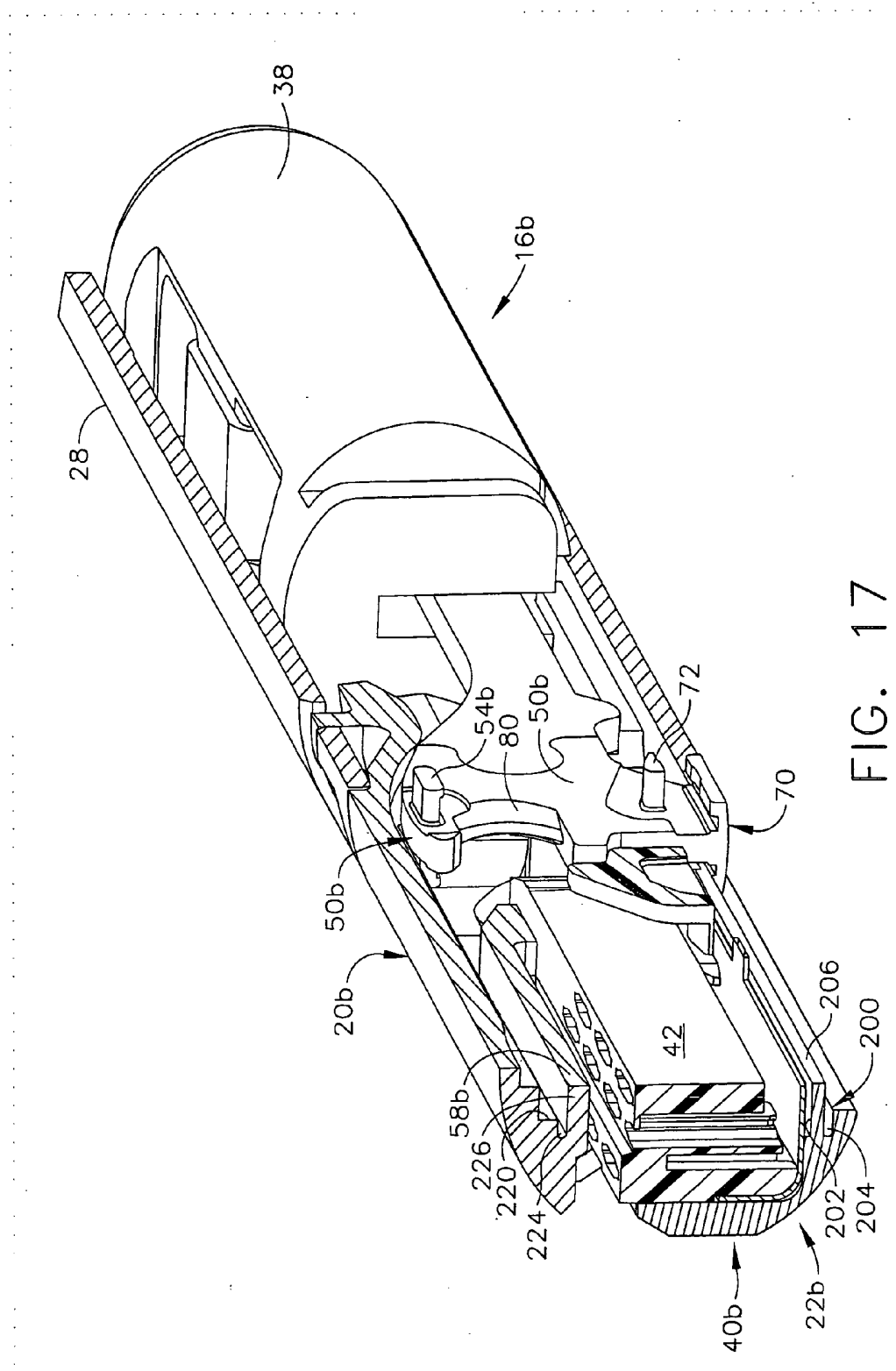
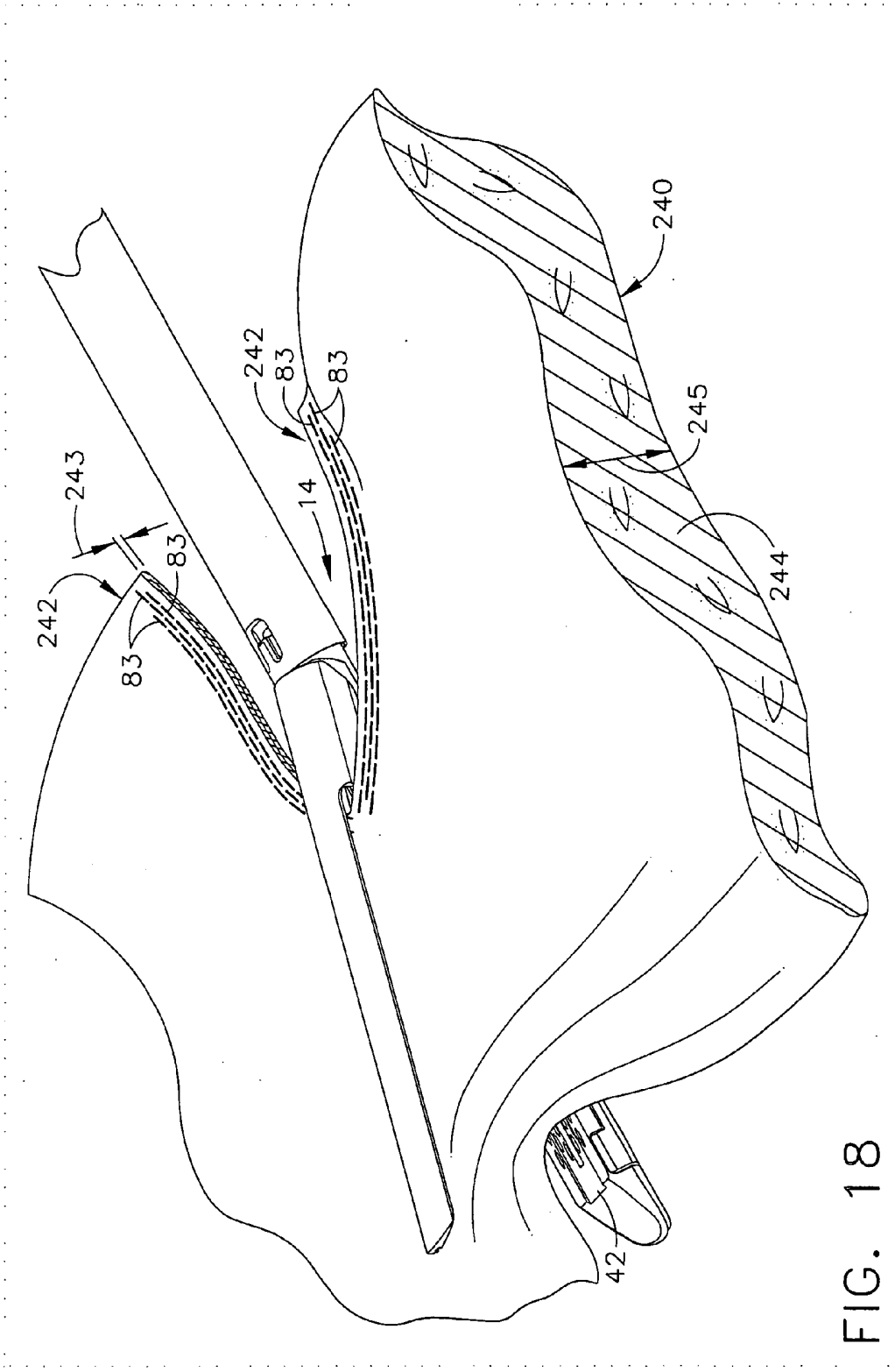


FIG. 15







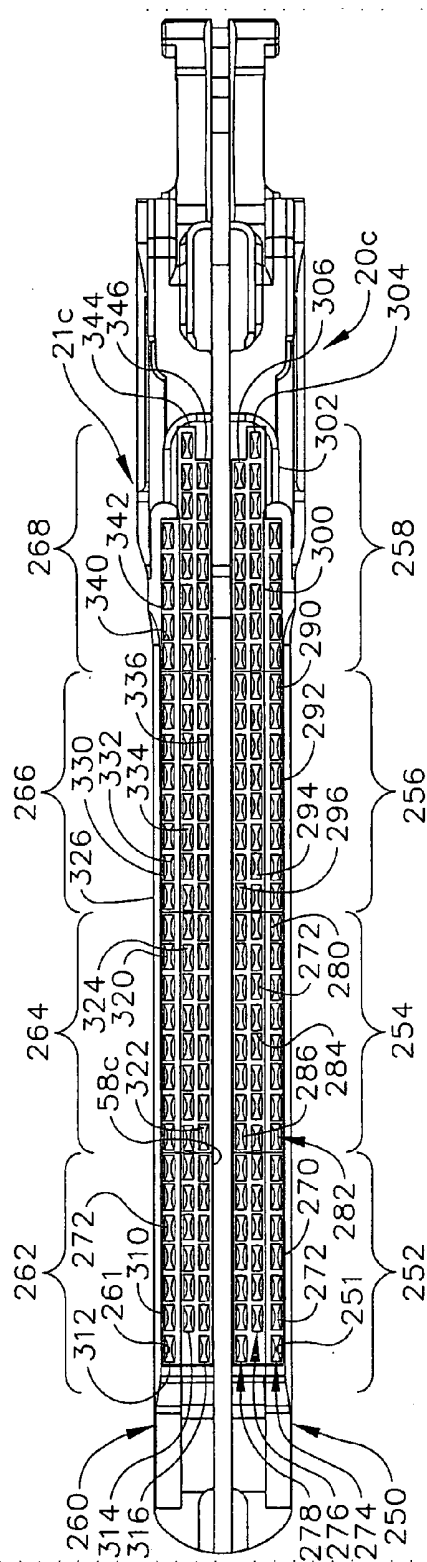
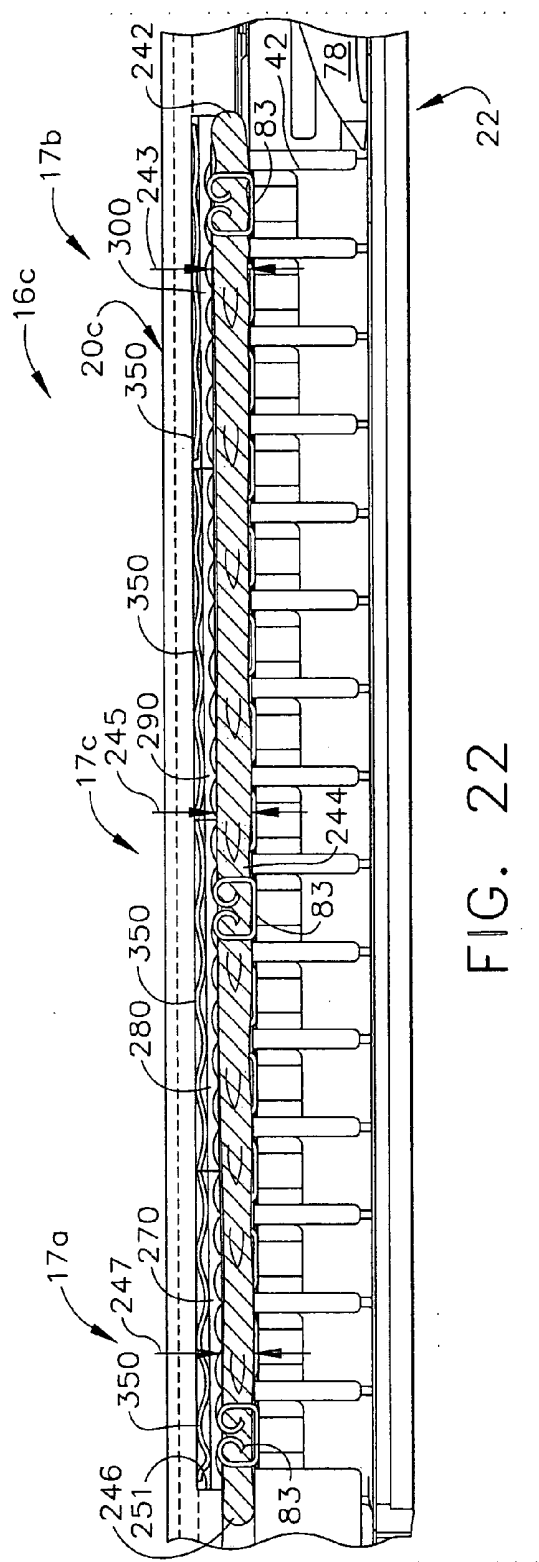
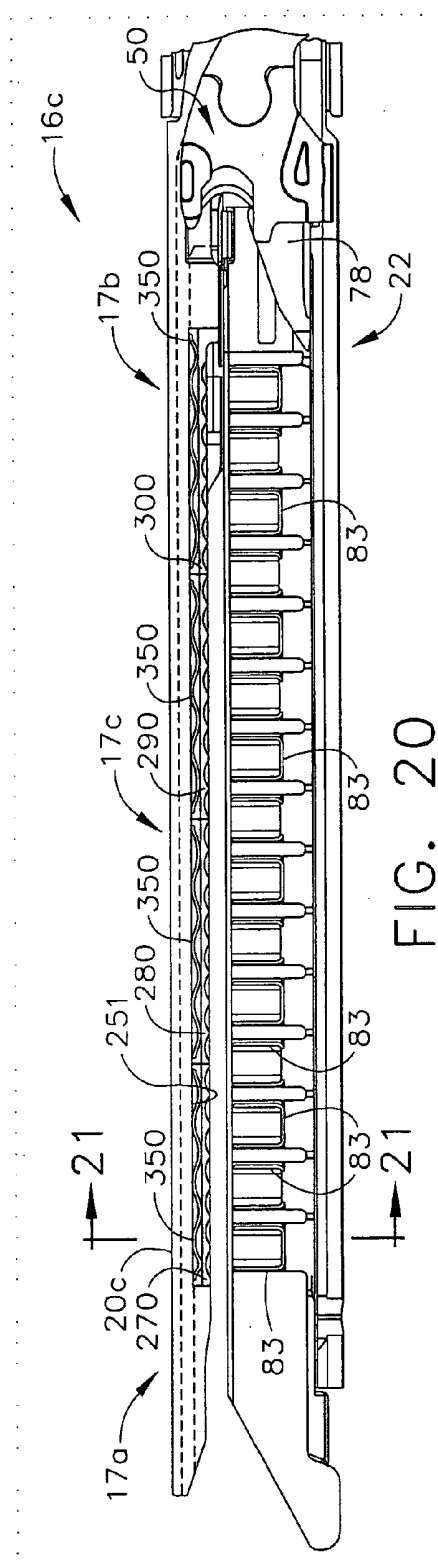


FIG. 19



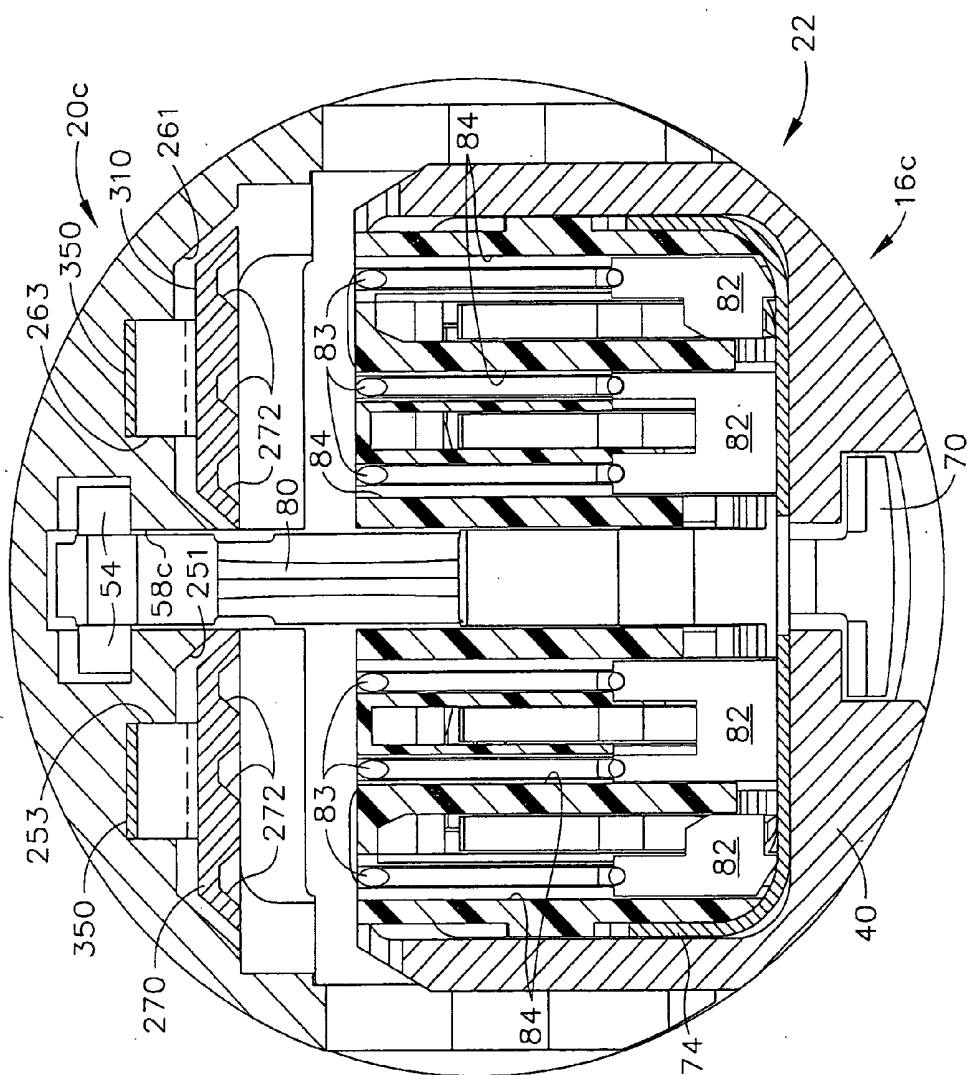


FIG. 21

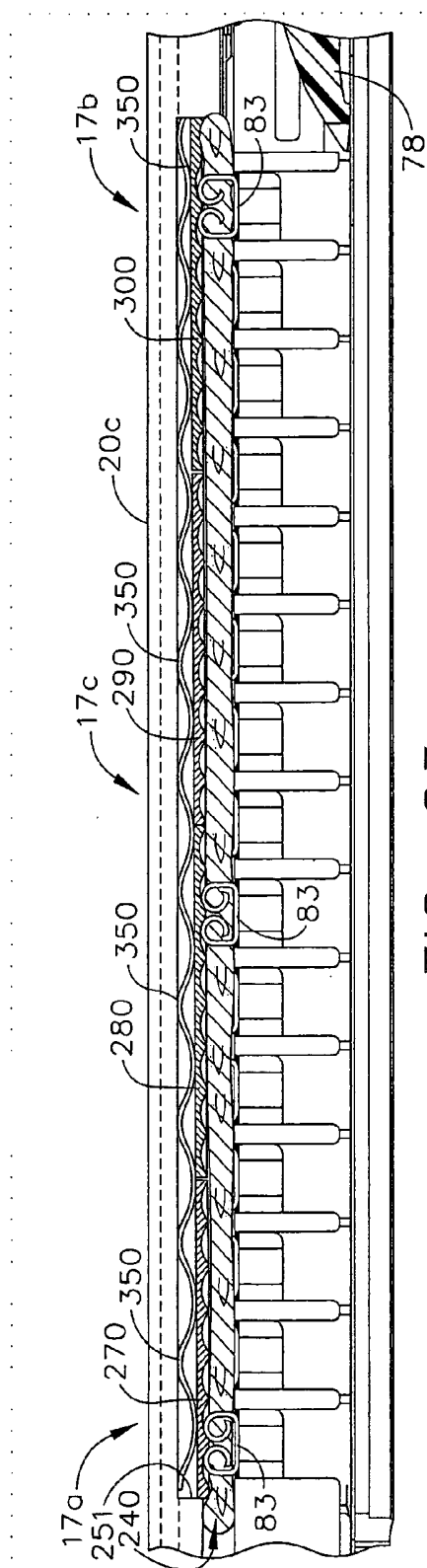


FIG. 23

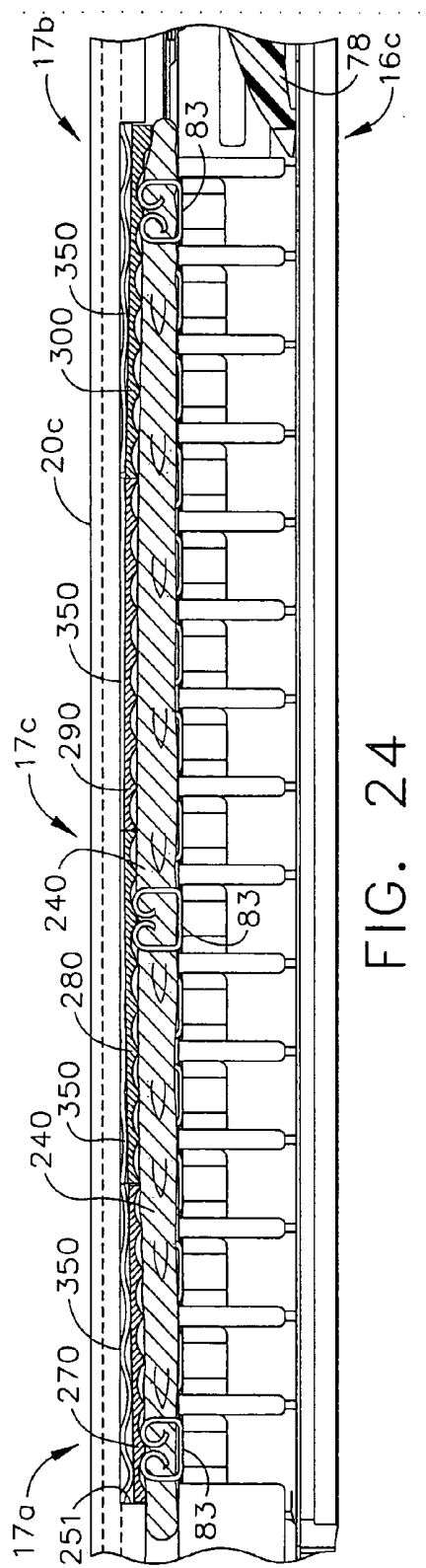


FIG. 24

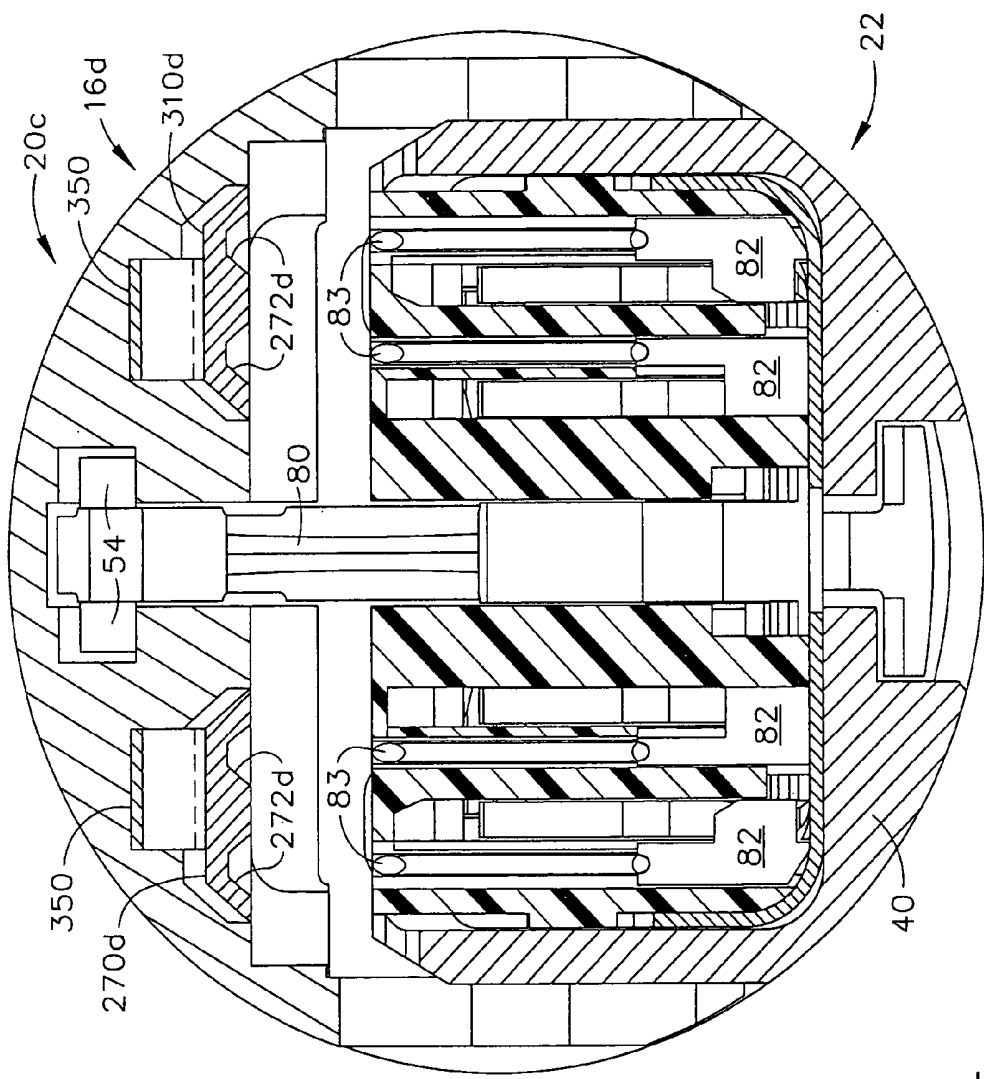


FIG. 25

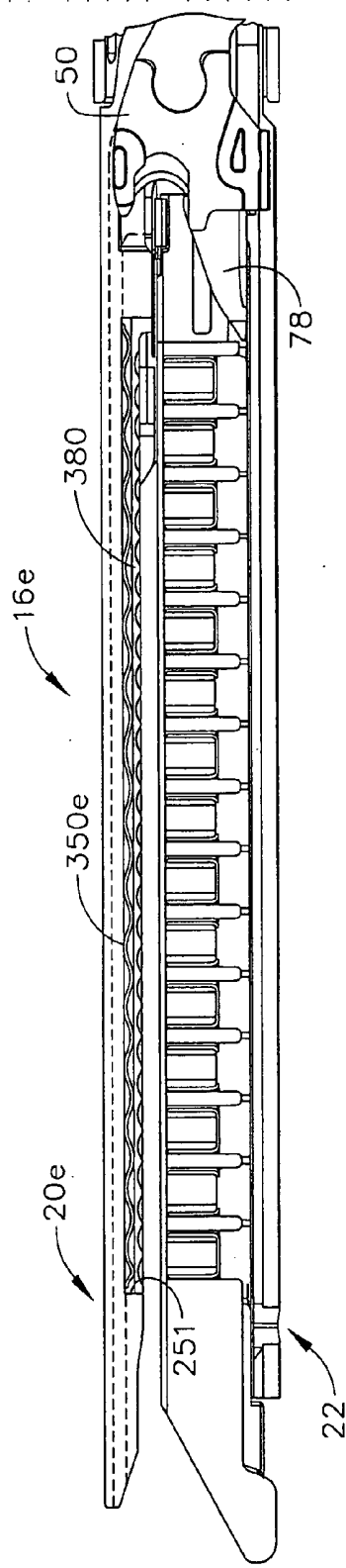
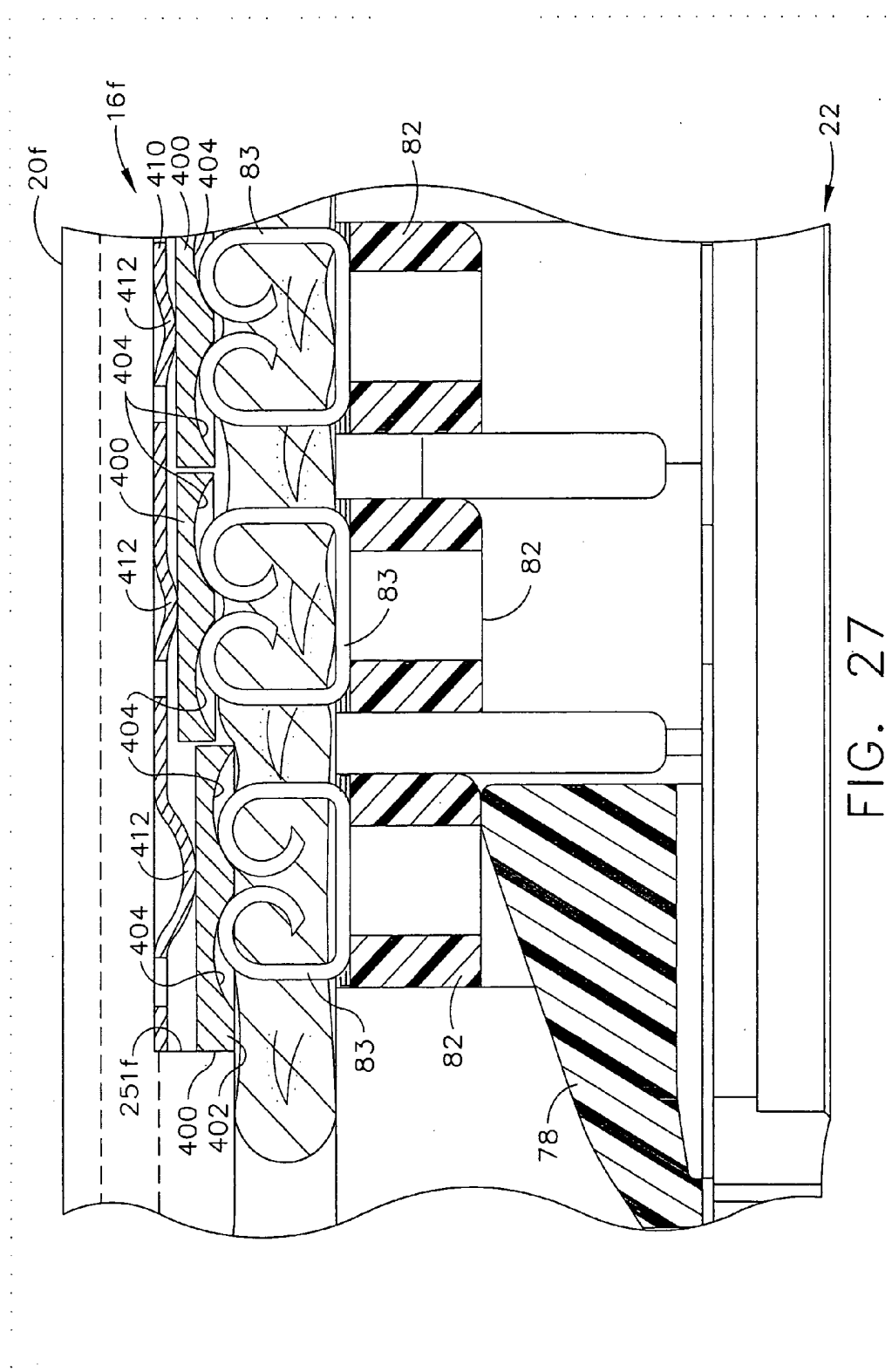


FIG. 26



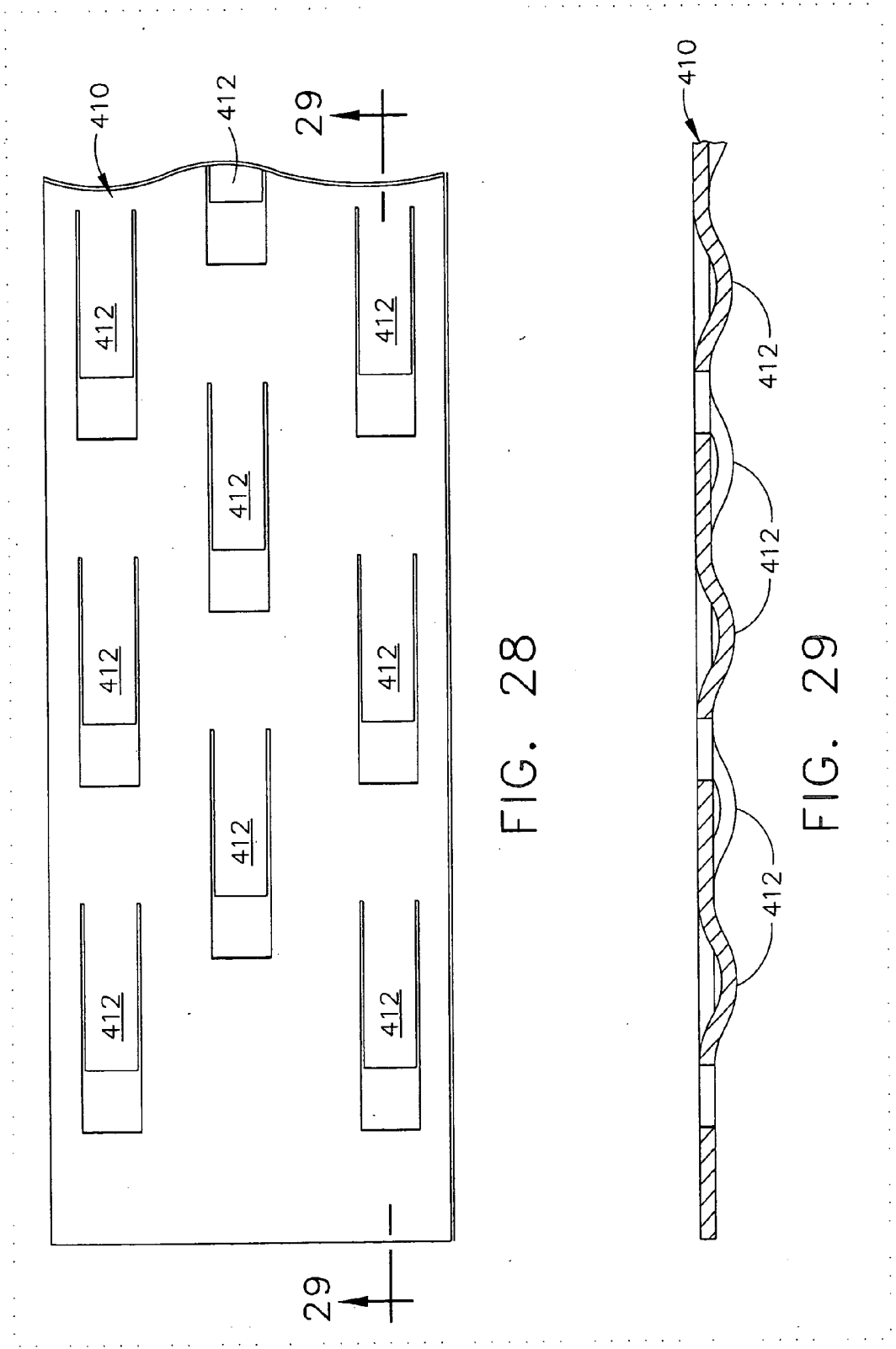


FIG. 28

FIG. 29

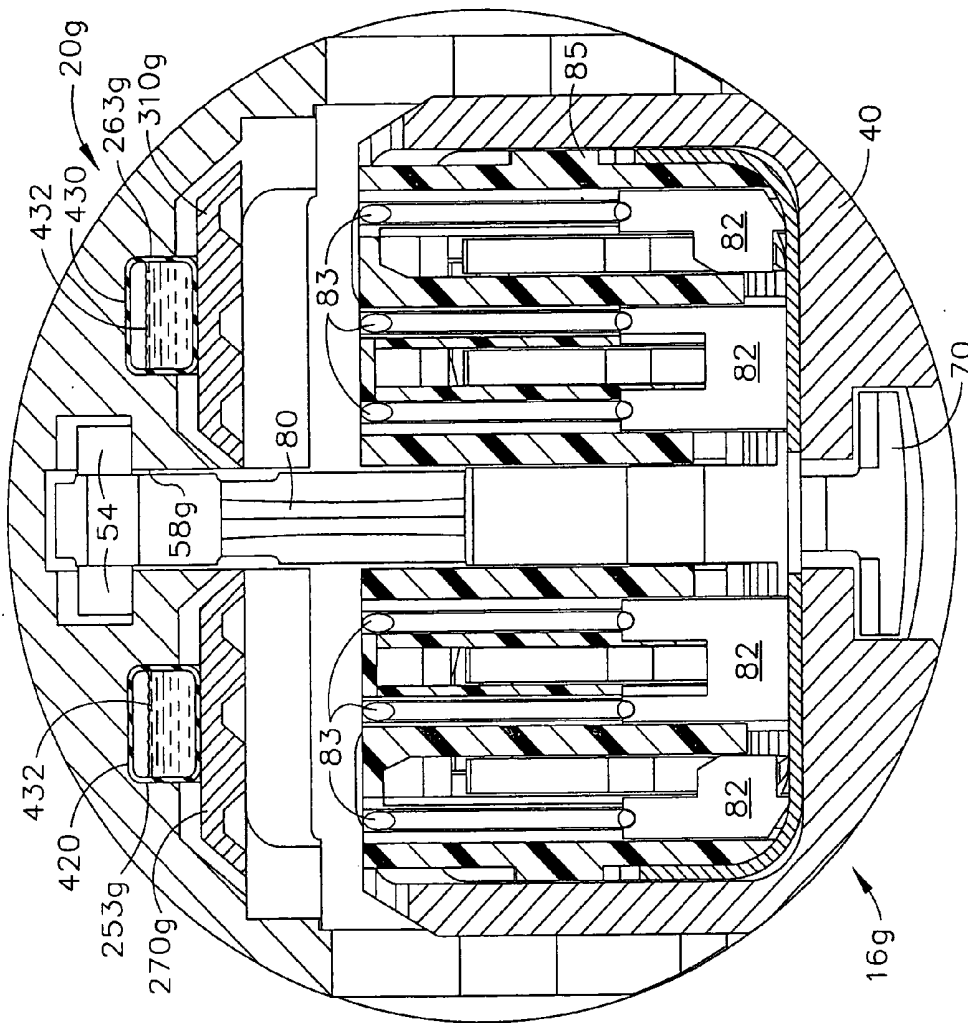


FIG. 30

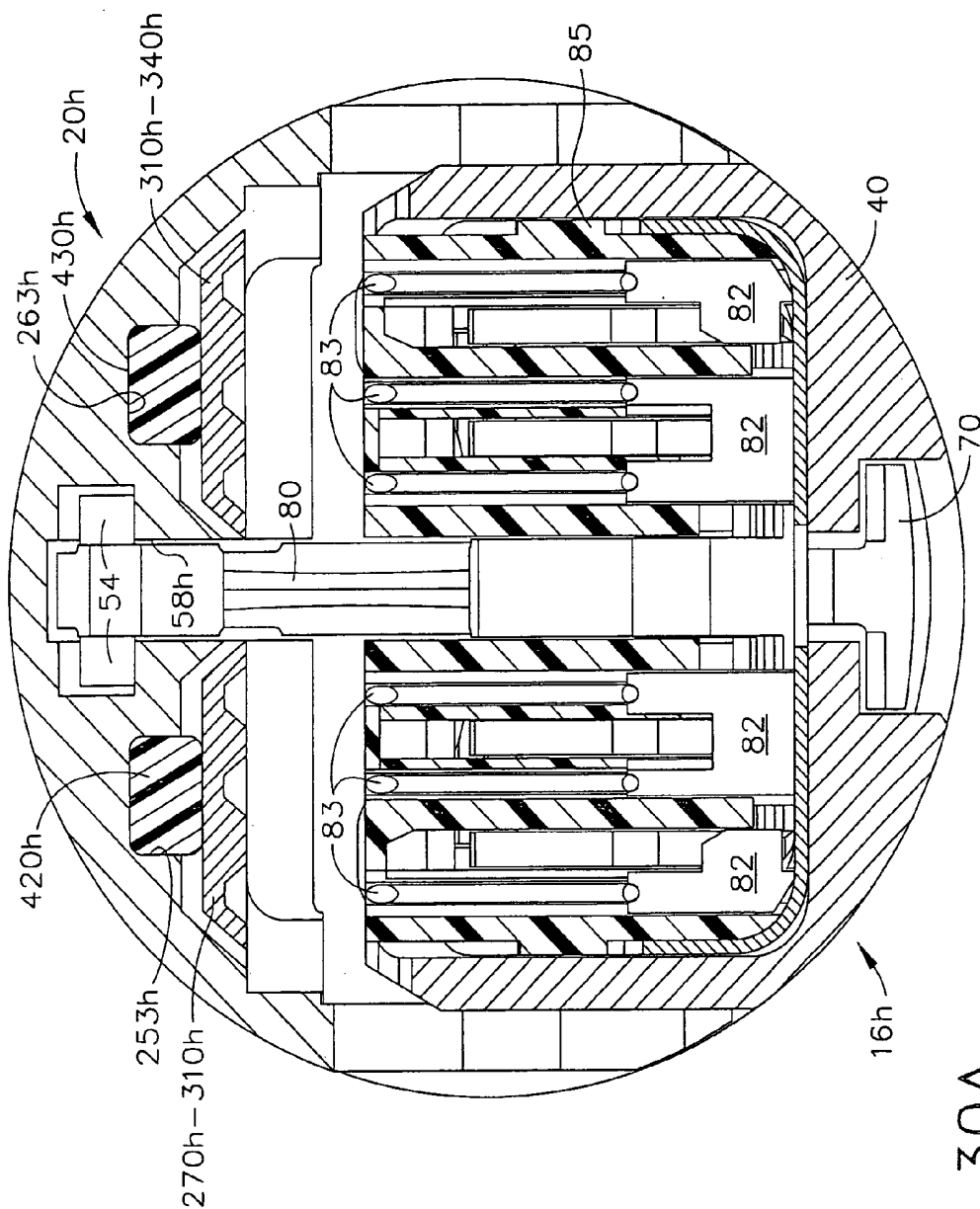
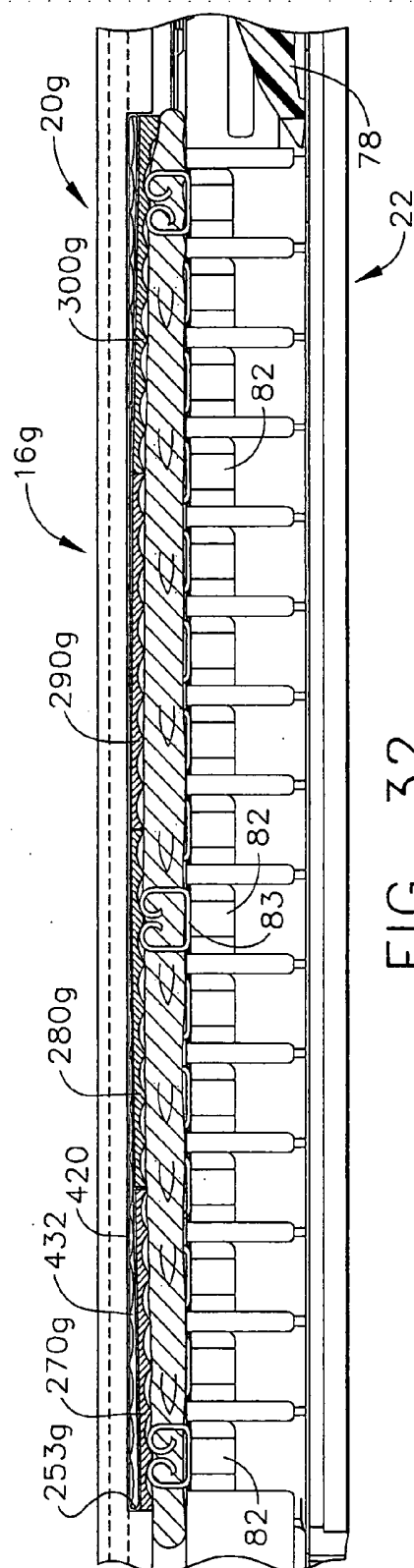
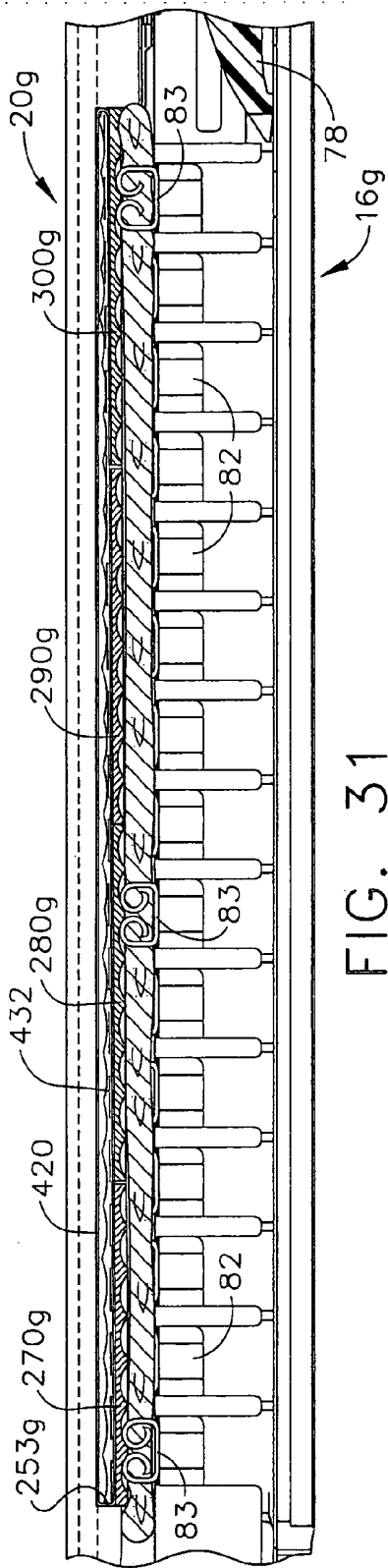


FIG. 30A



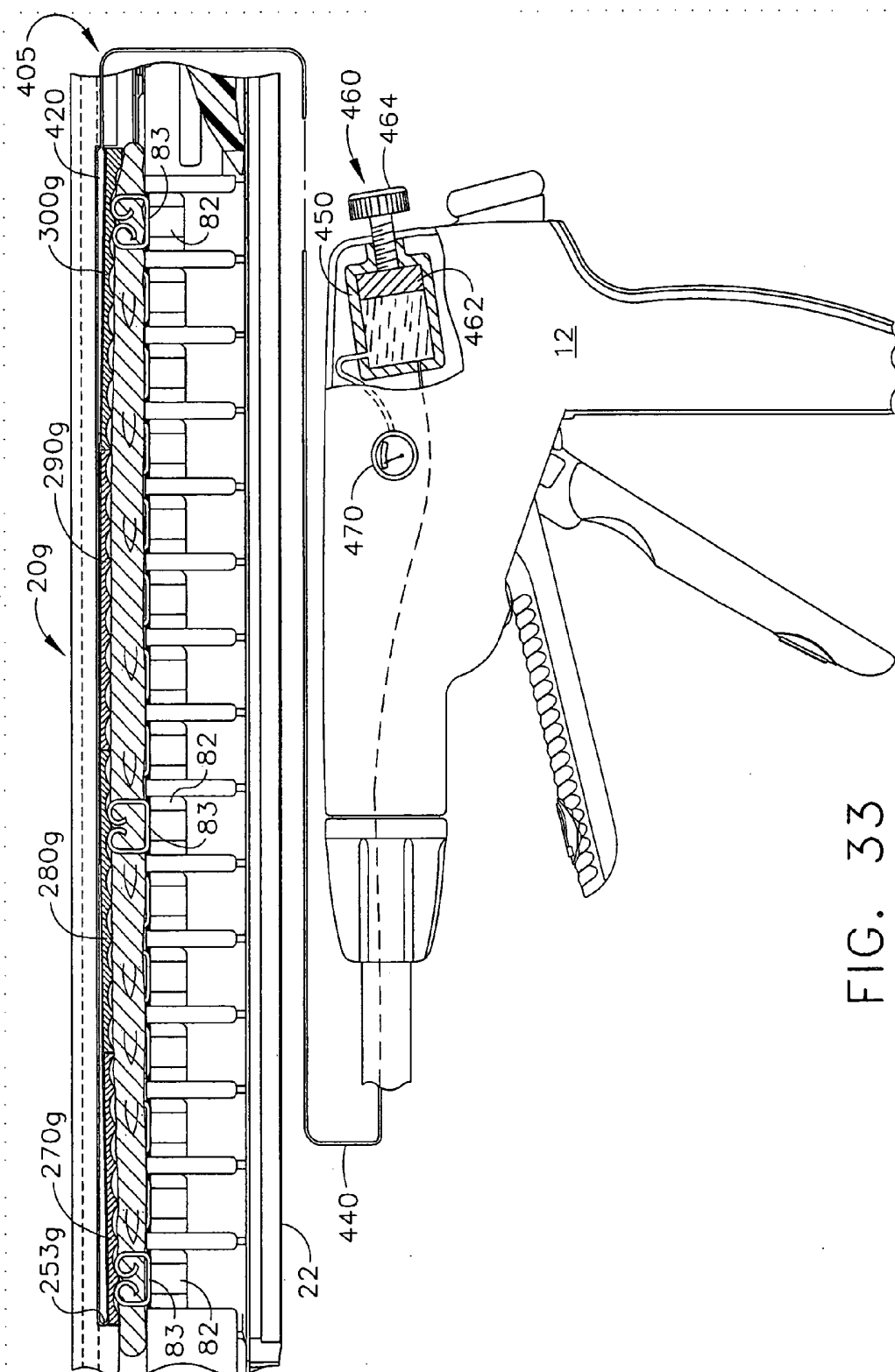
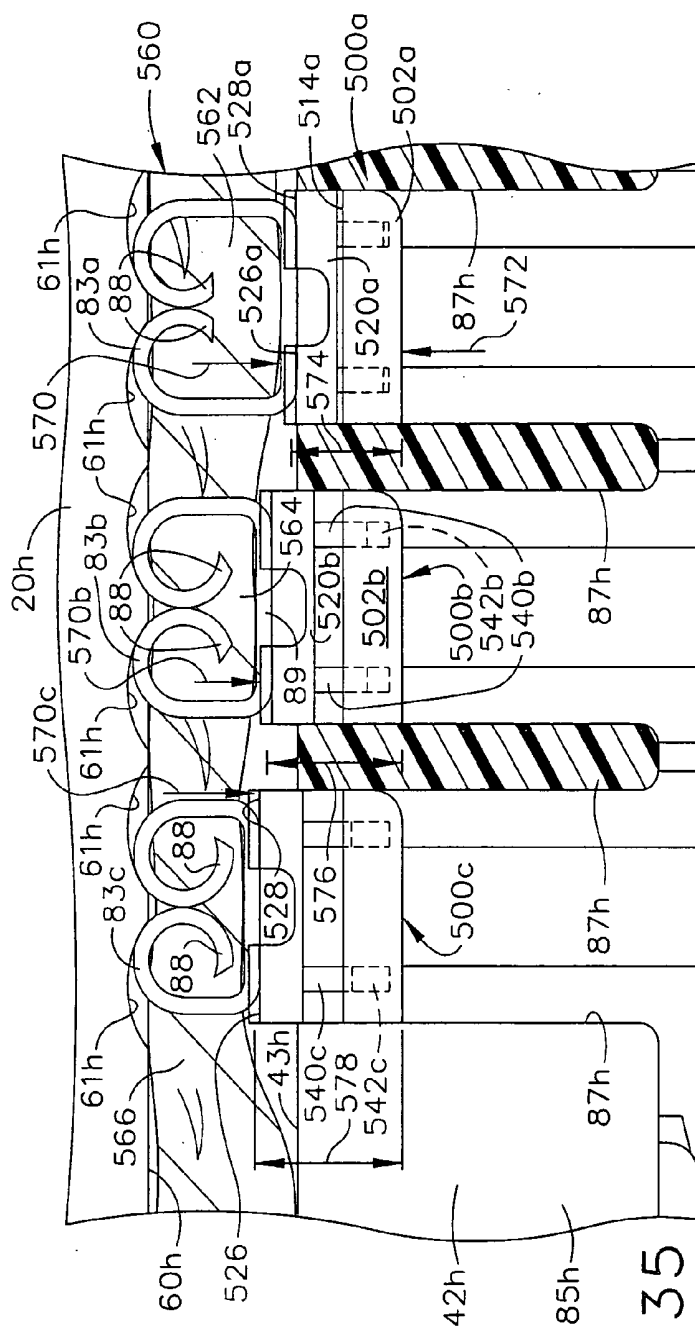
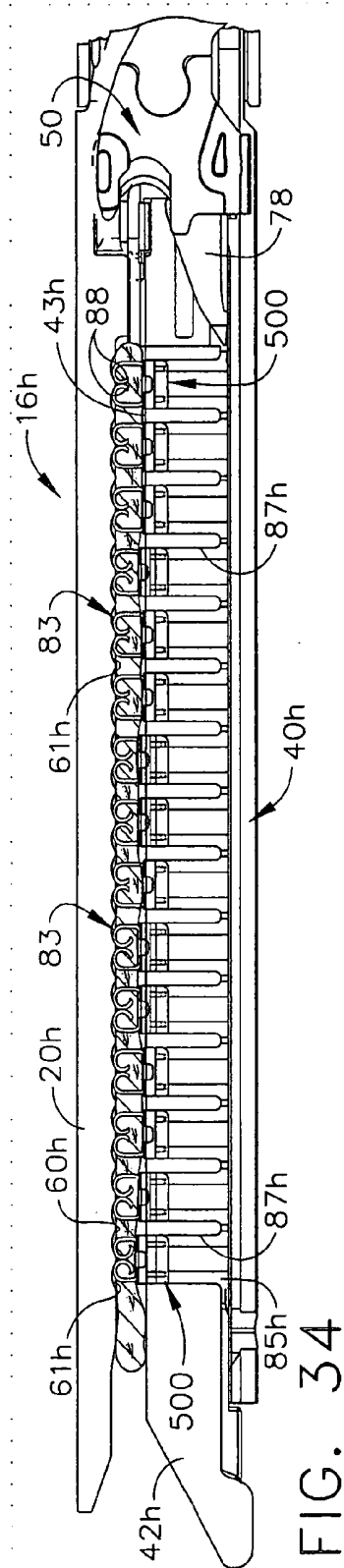
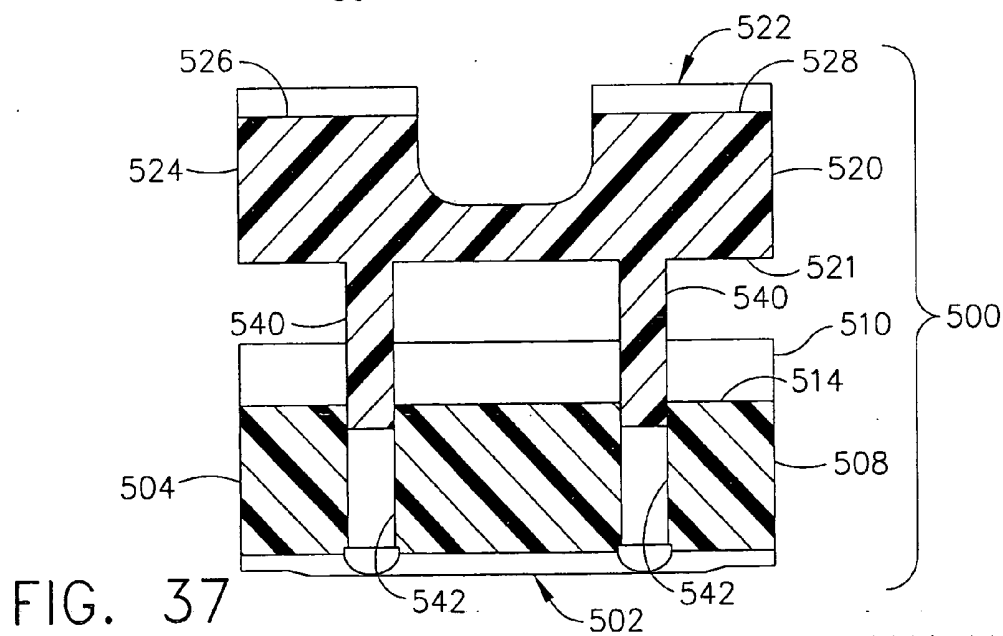
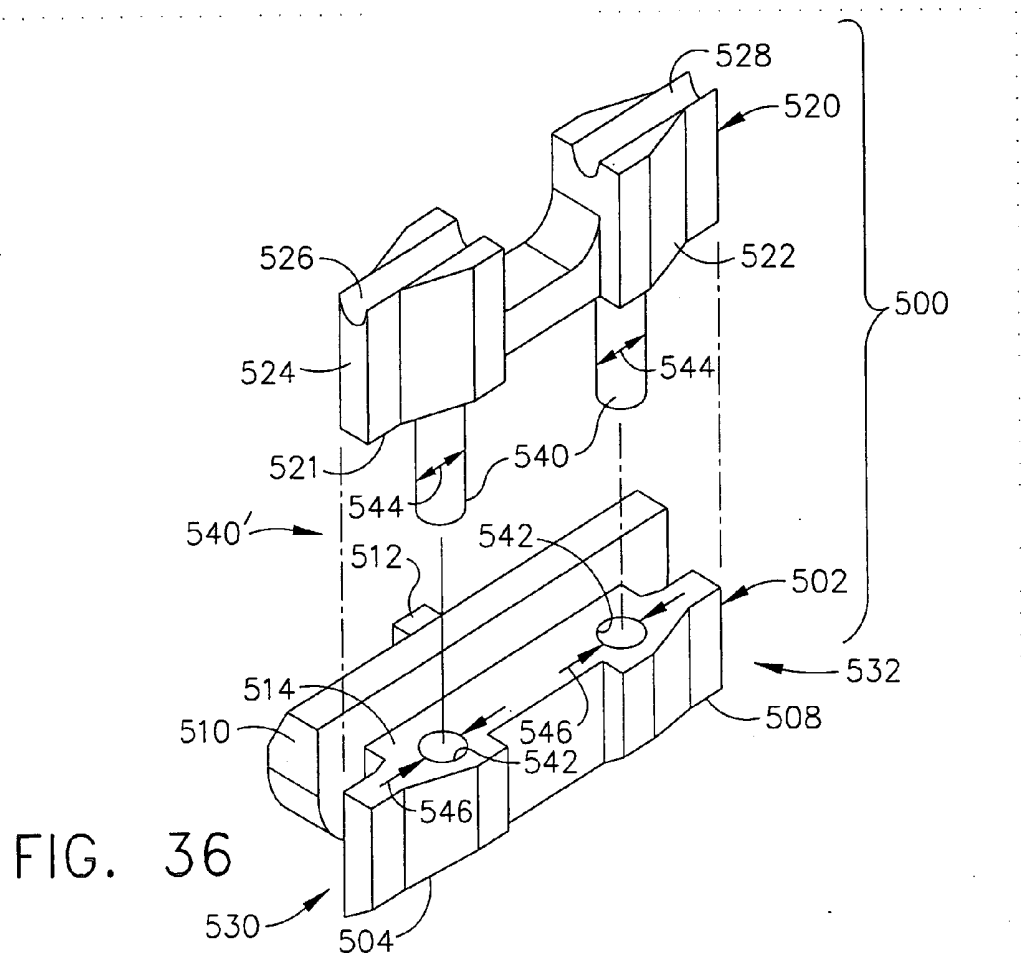
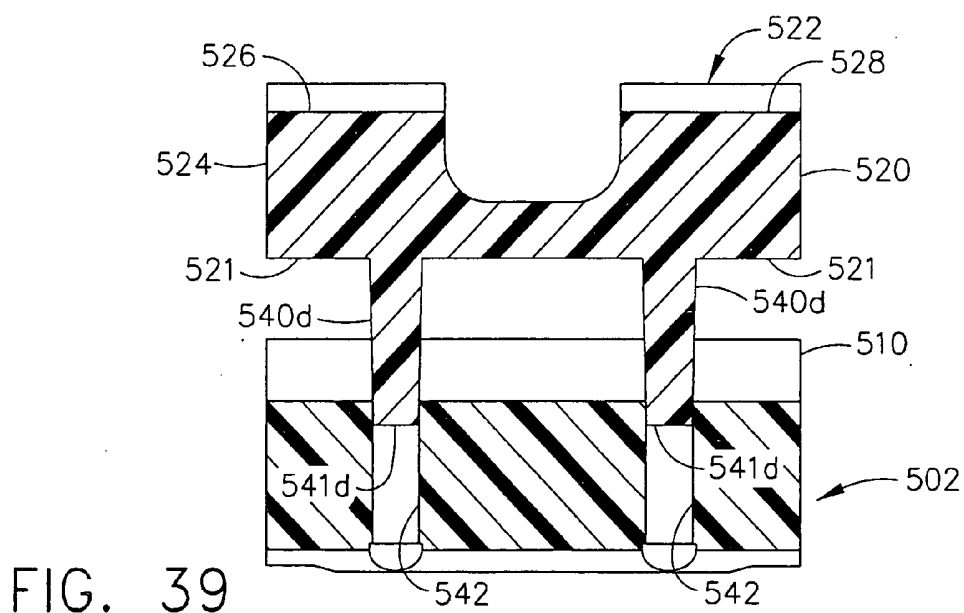
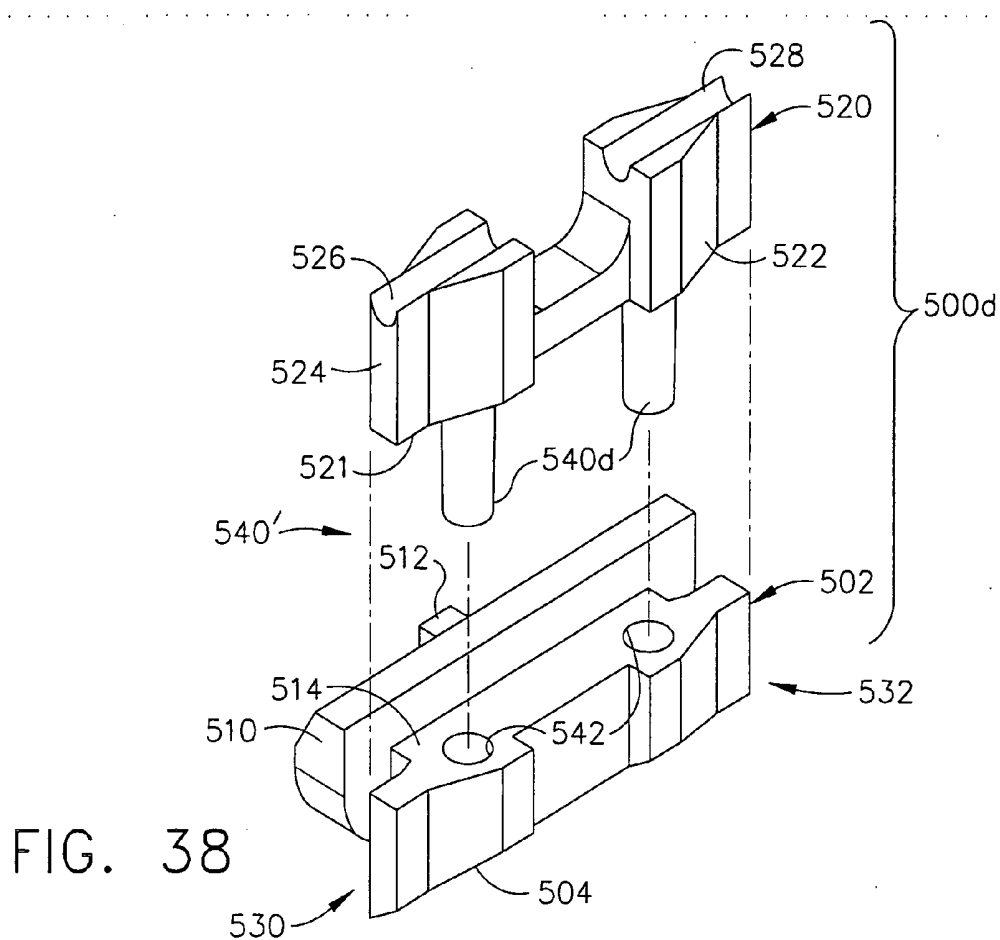
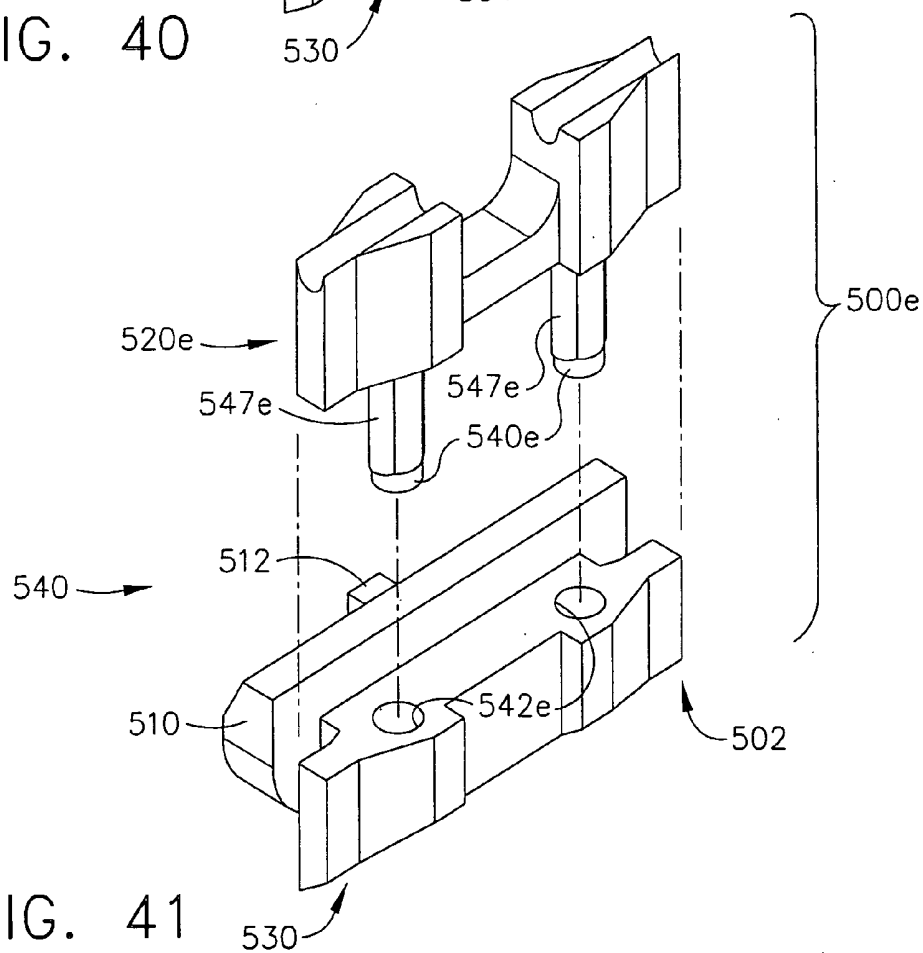
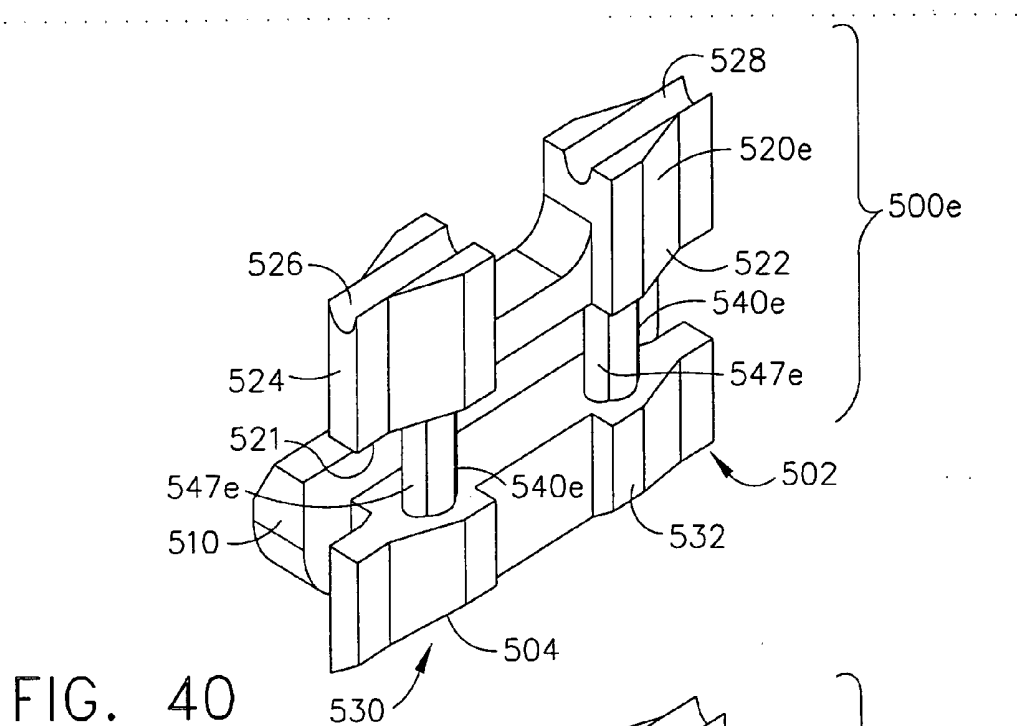


FIG. 33









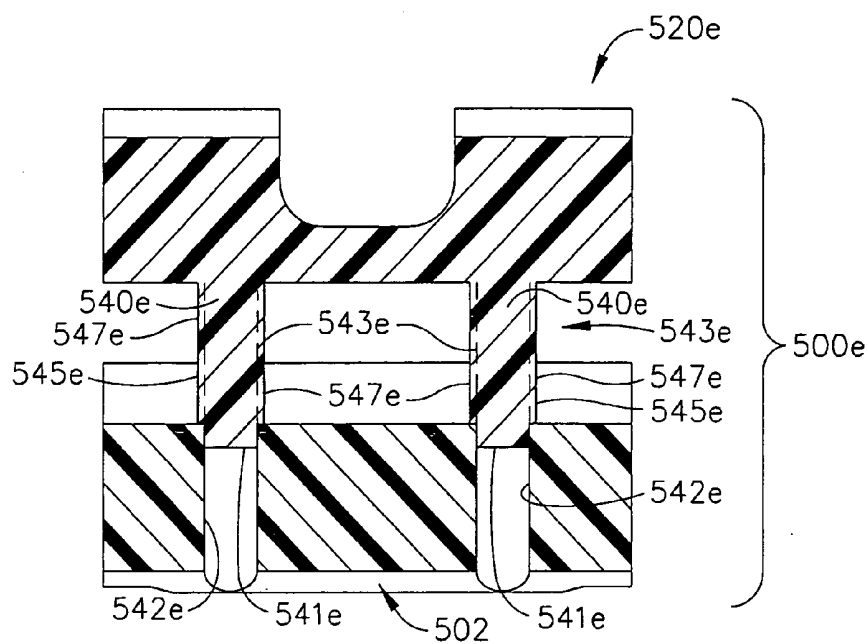


FIG. 42

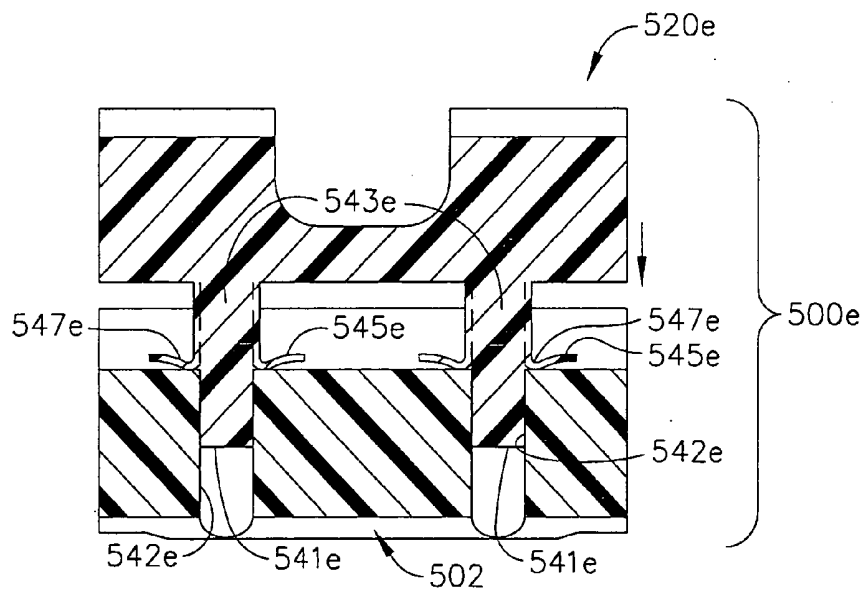


FIG. 43

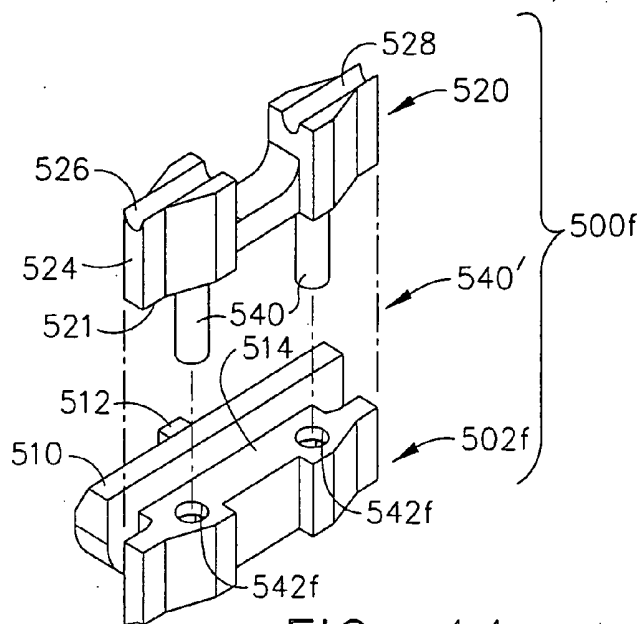


FIG. 44

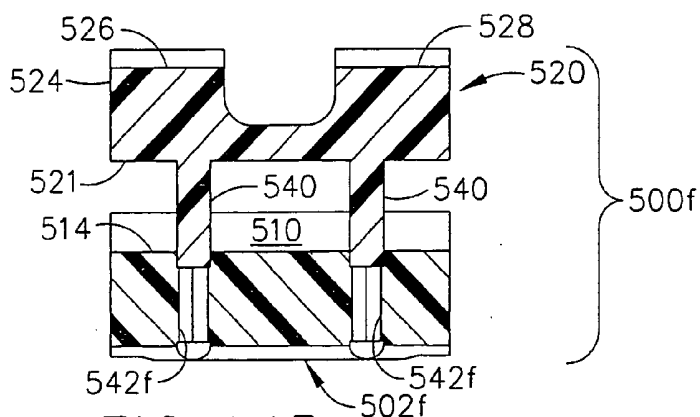


FIG. 45

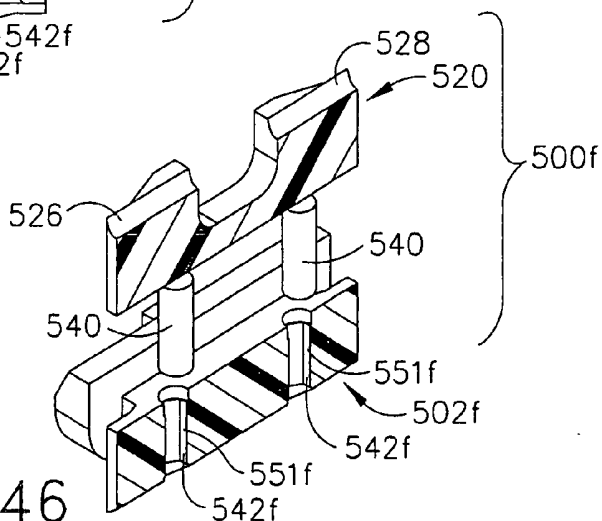


FIG. 46

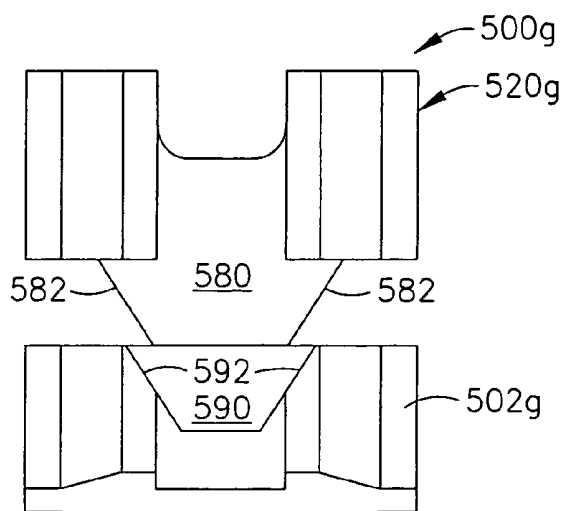


FIG. 47

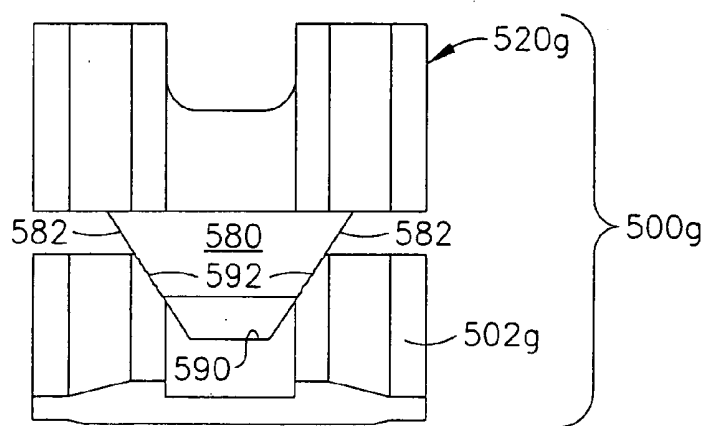


FIG. 48

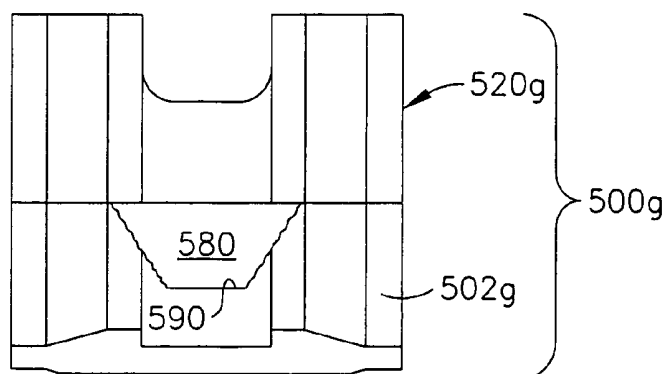
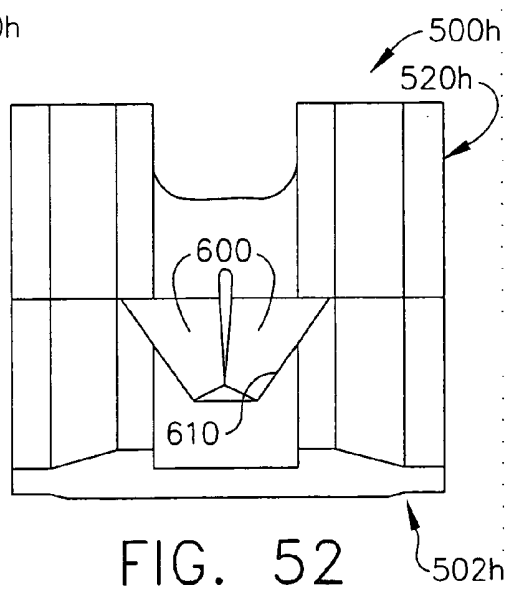
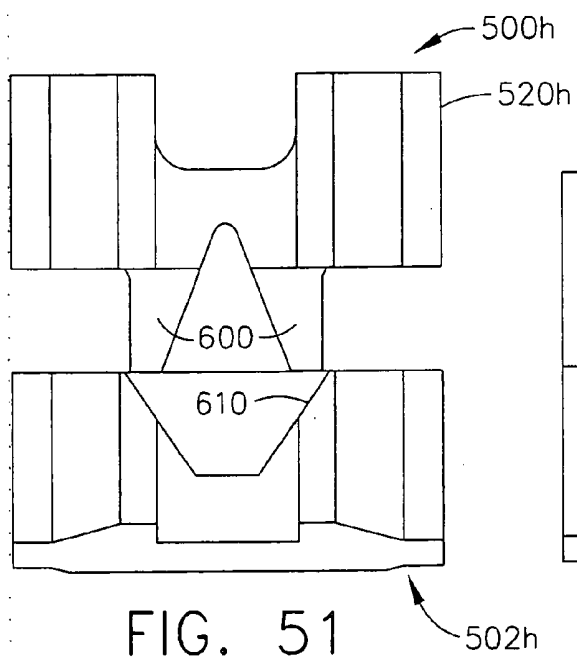
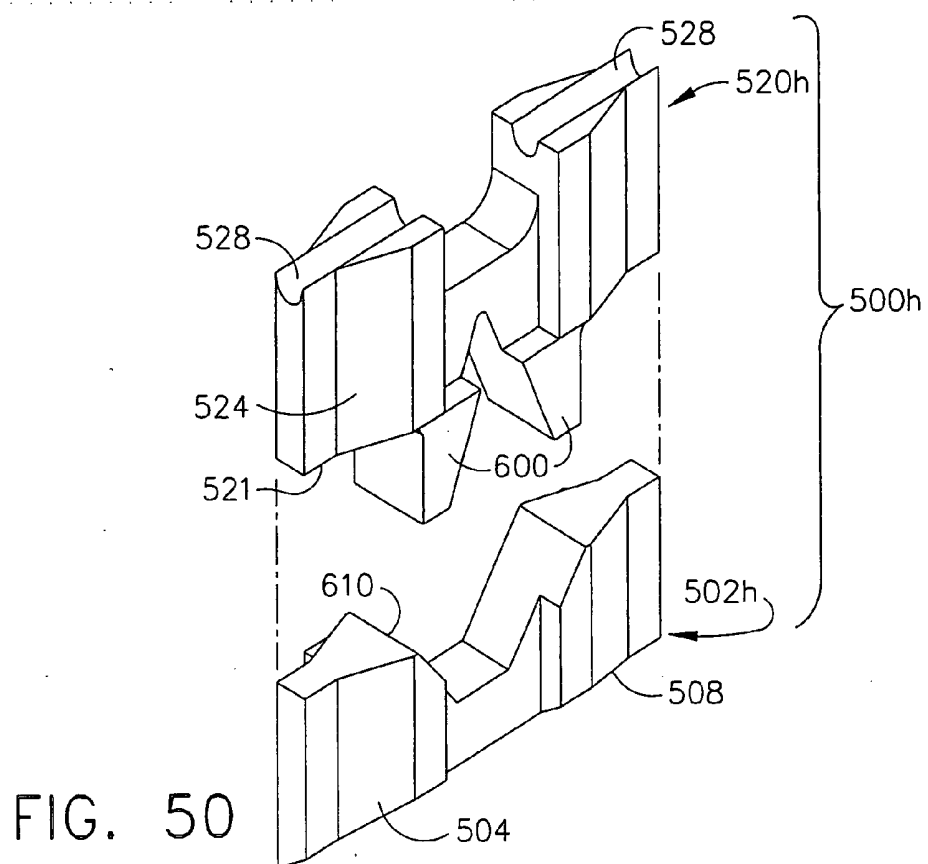
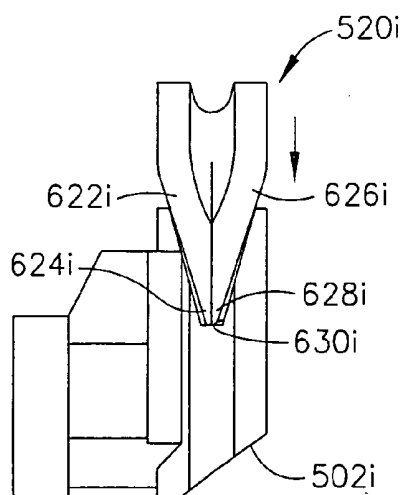
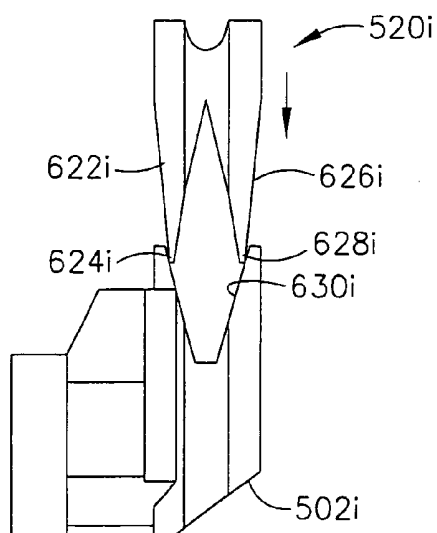
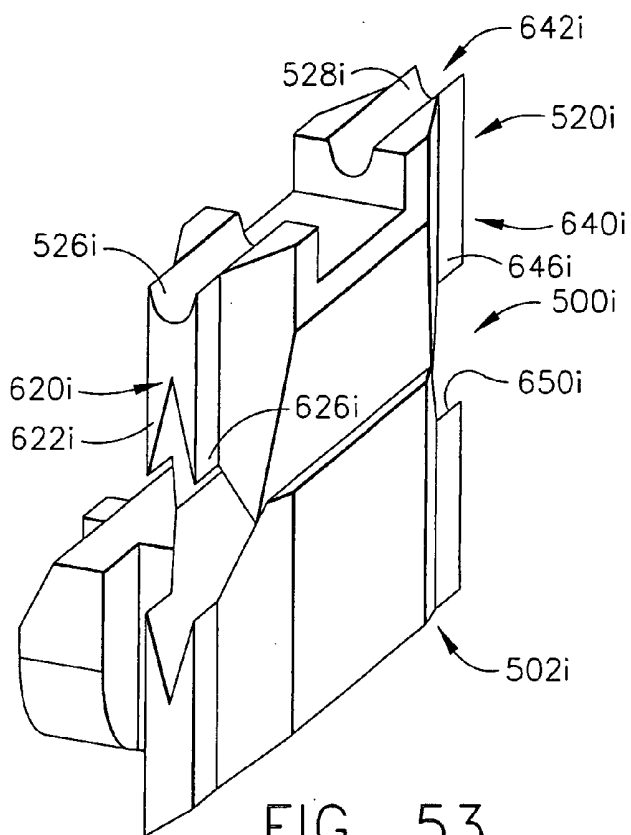


FIG. 49





SURGICAL STAPLING INSTRUMENTS HAVING FLEXIBLE CHANNEL AND ANVIL FEATURES FOR ADJUSTABLE STAPLE HEIGHTS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The subject application is a continuation-in-part application of U.S. patent application Ser. No. 11/231,456, filed Sep. 21, 2005 and entitled "Surgical Stapling Instrument Having Force Controlled Spacing End Effector", the disclosure of which is herein incorporated by reference in its entirety. This application is also related to the following U.S. patent application which is being concurrently filed herewith and which is herein incorporated by reference: Surgical Stapling Instruments With Collapsible Features For Controlling Staple Height, Inventors: Frederick E. Shelton, IV, Jeffery S. Swayze, Leslie M. Fugikawa, and Eugene L. Timperman (K&LNG Docket No. 060500CIP2/END5706USCIP2).

FIELD OF THE INVENTION

[0002] The present invention relates in general to surgical stapler instruments that are capable of applying lines of staples to tissue while cutting the tissue between those staple lines and, more particularly, to improvements relating to stapler instruments and improvements in processes for forming various components of such stapler instruments including adding bolstering material to the severed and stapled tissue.

BACKGROUND

[0003] Endoscopic and laparoscopic surgical instruments are often preferred over traditional open surgical devices since a smaller incision tends to reduce the post-operative recovery time and complications. The use of laparoscopic and endoscopic surgical procedures has been relatively popular and has provided additional incentive to develop the procedures further. In laparoscopic procedures, surgery is performed in the interior of the abdomen through a small incision. Similarly, in endoscopic procedures, surgery is performed in any hollow viscus of the body through narrow endoscopic tubes inserted through small entrance wounds in the skin.

[0004] Laparoscopic and endoscopic procedures generally require that the surgical region be insufflated. Accordingly, any instrumentation inserted into the body must be sealed to ensure that gases do not enter or exit the body through the incision. Moreover, laparoscopic and endoscopic procedures often require the surgeon to act on organs, tissues and/or vessels far removed from the incision. Thus, instruments used in such procedures are typically long and narrow while being functionally controllable from a proximal end of the instrument.

[0005] 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 applicator, access device, drug/gene therapy delivery device, and energy device using ultrasound, RF, laser, etc.).

[0006] 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.

[0007] Recently, an improved "E-beam" firing bar was described for a surgical stapling and severing instrument that advantageously included a top pin that slides within an internal slot formed in the upper jaw (anvil) and has a middle pin and bottom foot that slides on opposite sides of a lower jaw of an end effector, or more particularly a staple applying assembly. Distal to the middle pin, a contacting surface actuates a staple cartridge held within an elongate staple channel that forms the lower jaw. Between the contacting surface and the top pin, a cutting surface, or knife, severs tissue clamped between the anvil and the staple cartridge of the lower jaw. Since both jaws are thus engaged by the E-beam, the E-beam maintains a desired spacing between the jaws to ensure proper staple formation. Thus, if a lesser amount of tissue is clamped, the E-beam holds up the anvil to ensure sufficient spacing for the staples to properly form against an undersurface of the anvil. In addition, if a greater amount of tissue is clamped, the E-beam draws down the anvil to ensure that the spacing does not exceed the length of the staple such that ends of each staple are not sufficiently bent to achieve a desired degree of retention. Such an E-beam firing bar is described in U.S. patent application Ser. No. 10/443,617, entitled "Surgical Stapling Instrument Incorporating an E-Beam Firing Mechanism", filed on May 20, 2003, now U.S. Pat. No. 6,978,921, issued Dec. 27, 2005, the disclosure of which is hereby incorporated by reference in its entirety.

[0008] While an E-beam firing bar has many advantages for a surgical stapling and severing instrument, often it is desirable to sever and staple tissue of various thicknesses. A thin layer of tissue may result in staples that only form loosely, perhaps requiring the need for bolstering material. A thick layer of tissue may result in formed staples that exert a strong compressive force on the captured tissue, perhaps resulting in necrosis, bleeding or poor staple formation/retention. Rather than limiting the range of tissue thicknesses that are appropriate for a given surgical stapling and severing instrument, it would be desirable to accommodate a wider range of tissue thickness with the same surgical stapling and severing instrument.

[0009] Consequently, a significant need exists for an improved surgical stapling and severing instrument that incorporates a staple applying assembly (end effector) that adjusts to the amount of tissue that is clamped.

[0010] In addition, the staple drivers that are commonly employed in existing staple applying assemblies are traditionally made as stiff as possible to assure proper "B" form staple height. Because of this stiff construction, these drivers

do not provide any flexibility for adjusting the formed height of the staple to a particular thickness of tissue clamped within the assembly.

[0011] Thus, another significant need exists for staple drivers that are able to facilitate the adjustment of the formed height of the staples in response to variations in tissue thickness.

BRIEF SUMMARY

[0012] The invention overcomes the above-noted and other deficiencies of the prior art by providing a surgical instrument that incorporates a firing bar that translates through a staple applying assembly having a lower jaw and a pivotally attached upper jaw, engaging each to assist in maintaining the desired spacing between inner surfaces that compress tissue in between. Advantageously, the distance between the two jaws is allowed to flex apart slightly to allow for a larger thickness of compressed tissue, yet the firing bar prevents excessive flexure that would exceed the limits on the device to form staples through the compressed tissue. Thereby, enhanced clinical flexibility is achieved with the same surgical instrument being suitable for a larger range of surgical procedures or to accommodate variations in the patient population.

[0013] In one aspect of the invention, a surgical instrument has a lower jaw that includes an elongate staple channel having a longitudinal channel slot formed therein that receives a staple cartridge. Staples in the staple cartridge have a staple length sized for forming a closed staple between a range of tissue thicknesses. A firing bar has a vertical portion passing through a longitudinal anvil slot in an anvil pivotally attached to the elongate staple channel and passes through the longitudinal channel slot formed in the elongate staple channel. An upper lateral surface extending from the vertical portion exerts an inward compressive force on the anvil during firing translation and a lower lateral surface extending from the vertical portion exerts an inward compressive force on the elongate staple channel during firing translation. The firing bar advantageously accommodates the range of effective staple formation by including a resilient portion that varies in height between a staple forming undersurface of an anvil and an upper surface of the staple cartridge.

[0014] In another aspect of the invention, a surgical instrument has an anvil that is pivotally coupled to the elongate staple channel and includes an anvil channel that is internally formed. In particular, a vertical slot inwardly opens along a longitudinal axis of the anvil and has left and right rectangular prism-shaped recesses communicating with, bisected by, and transverse to the vertical slot, wherein said left and right rectangular prism-shaped recesses extend substantially along the longitudinal length of the vertical slot. A firing device that includes a distally presented cutting edge for severing tissue is longitudinally received between the elongate staple channel and the vertical slot of the anvil channel of the anvil. An upper member of the firing device has left and right lateral upper pins sized to slidably engage upper and lower inner surfaces of the left and right rectangular-shaped recesses of the anvil channel. A lower member of the firing device engages the channel slot in the elongate staple cartridge. A middle member of the firing device actuates the staple cartridge by distally translating a wedge

member of the staple cartridge. The firing device positively engages both the elongate staple channel and the anvil during longitudinal firing travel to provide spacing in between for staple formation. Engagement of the firing device during firing maintains vertical spacing between the elongate staple channel and the anvil resisting both pinching due to an inadequate clamped tissue and partial opening due to an excessive amount of clamped tissue. This affirmative spacing is advantageously varied within an effective range of the staple length of the staple cartridge by incorporating a resilient portion in the firing device to allow some flexure to accommodate an increased compression load due to a thicker layer of clamped tissue.

[0015] In yet another aspect of the invention, the surgical instrument advantageously operates through an elongate shaft with a closed end effector of upper and lower jaws suitably sized for insertion through a cannula of a trocar to an insufflated body cavity or body lumen.

[0016] In another aspect of the invention there is disclosed a surgical instrument that comprises an elongate channel that is configured to operably support a staple cartridge therein. An anvil is pivotally coupled to the elongate channel and is selectively pivotable between an open position and a closed position wherein a staple forming undersurface thereof is in confronting relationship to an upper surface of a staple cartridge supported within the elongate channel in response to a closing motion applied to the anvil and from a closed position to the open position in response to an opening motion applied to the anvil. A firing member is operably supported relative to the elongate channel and is selectively longitudinally translatable from an unfired position through the elongate channel in a staple firing motion in response to a firing force applied to the firing member and to retract to the unfired position in response to a retraction force applied to the firing member. In various embodiments, at least one of the elongate channel and the anvil has a resilient structure configured to flexibly interact with the firing member during the staple firing motion to allow a distance between the staple forming undersurface of the anvil and the upper surface of the staple cartridge to vary in relation to a thickness of tissue clamped between the staple forming undersurface of the anvil and the upper surface of the staple cartridge.

[0017] In another general aspect of the present invention there is disclosed a surgical instrument that comprises an elongate staple channel that has a first flexible portion and a second flexible portion that is spaced from the first flexible portion to define a longitudinal channel slot therebetween. A staple cartridge is operably supported within the elongate staple channel and an elongate shaft is operably coupled to the elongate staple channel. An anvil is pivotally attached to the elongate staple channel and is selectively pivotable between a closed position wherein a staple forming undersurface thereof is in confronting relationship to an upper surface of the staple cartridge and an open position wherein a distal end of the anvil is spaced from the upper surface of the staple cartridge. The anvil further has a longitudinal anvil slot therein. A control handle assembly is proximally operably coupled through the elongate shaft to selectively apply opening and closing motions to the anvil. A firing member is operably coupled to the control handle assembly through the elongate shaft for selective longitudinal reciprocating motion in the elongate staple channel such that one

portion of the firing member extends through the longitudinal anvil slot and another portion of the firing member extends through the longitudinal channel slot between the first and second flexible portions.

[0018] In yet another general aspect of the present invention there is disclosed a surgical instrument that comprises an elongate staple channel that has a longitudinal channel slot. A staple cartridge is operably supported within the elongate staple channel. An elongate shaft is operably coupled to the elongate staple channel. An anvil is pivotally attached to the elongate staple channel and is selectively pivotable between a closed position wherein a staple forming undersurface thereof is in confronting relationship to an upper surface of the staple cartridge and an open position wherein a distal end of the anvil is spaced from the upper surface of the staple cartridge. The anvil further has a first resilient anvil portion and a second resilient anvil portion that is spaced from the first resilient anvil portion to define a portion of an elongate anvil slot therebetween. A control handle assembly is proximally operably coupled through the elongate shaft to selectively apply opening and closing motions to the anvil. A firing member is operably coupled to the control handle assembly through the elongate shaft for selective longitudinal reciprocating motion in the elongate staple channel such that one portion of the firing member extends through the anvil slot between the first and second resilient anvil portions and another portion of the firing member extends through the longitudinal channel slot.

[0019] These and other objects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof.

BRIEF DESCRIPTION OF THE FIGURES

[0020] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

[0021] FIG. 1 is a left side view in elevation of a surgical stapling and severing instrument with an open end effector (staple applying assembly) with a shaft partially cut away to expose a firing member of a proximal firing rod and distal firing bar guided by a frame ground and encompassed by a closure sleeve.

[0022] FIG. 2 is a left side view of a closed end effector (staple applying assembly) with a retracted force adjusted height firing bar consistent with the present invention of the surgical stapling and severing instrument of FIG. 1 taken in longitudinal vertical cross section along lines 2-2.

[0023] FIG. 3 is a left isometric view of the force adjusted (compliant) height firing bar of FIG. 2.

[0024] FIG. 4 is a left side view of a distal portion ("E-beam") of a first version of the force adjusted height firing bar of FIG. 2 having horizontal slits formed respectively between the top pin and cutting surface and between the middle pin and the cutting surface to enhance vertical flexure.

[0025] FIG. 5 is a lower left isometric view of a distal portion ("E-beam") of a second version of the force adjusted

firing bar of FIG. 2 having a relieved lower area of an upper pin to enhance vertical flexure.

[0026] FIG. 6 is a front view in elevation of an upper portion of the E-beam of FIG. 5 taken in vertical and transverse cross section through the upper pin along lines 6-6.

[0027] FIG. 7 is a front view of an upper portion of a third version of the E-beam of FIG. 5 taken in vertical and transverse cross section along lines 6-6 but further including relieved upper root attachments of the top pin for enhanced vertical flexure.

[0028] FIG. 8 is a front view of an upper portion of a fourth version of the E-beam of FIG. 5 taken in vertical and transverse cross section along lines 6-6 but including a resilient inner vertical laminate layer instead of a relieved undersurface of the top pin for enhanced vertical flexure.

[0029] FIG. 9 is a front view of an upper portion of a fifth version of the E-beam of FIG. 5 taken in vertical and transverse cross section along lines 6-6 but including an upper pin formed of a resilient material instead of a relieved undersurface of the upper pin for enhanced vertical flexure.

[0030] FIG. 10 is an upper left isometric view of a distal portion ("E-beam") of a sixth version of the force adjusted firing bar of FIG. 2 having resilient material upon a bottom foot to enhance vertical flexure.

[0031] FIG. 11 is a front view in elevation taken in vertical and transverse cross section through the padded lower foot of the end effector (staple applying assembly) of the surgical stapling and severing instrument of FIG. 1.

[0032] FIG. 12 is a left view in elevation of a distal portion ("E-beam") of a seventh version of the force adjusted firing bar of FIG. 2 having a proximally and upwardly extended spring arm attached to a lower foot to enhance vertical flexure.

[0033] FIG. 13 is a left top isometric view of a distal portion ("E-beam") of an eighth version of the force adjusted firing bar of FIG. 2 having a spring washer encompassing a lower foot to enhance vertical flexure.

[0034] FIG. 14 is a cross-sectional end view of another staple applying assembly or end effector of the present invention in a clamped or closed position.

[0035] FIG. 15 is a partial perspective view of the staple applying assembly of FIG. 14 with some of the elements thereof shown in cross-section.

[0036] FIG. 16 is a cross-sectional end view of another staple applying assembly or end effector of the present invention in a clamped or closed position.

[0037] FIG. 17 is a partial perspective view of the staple applying assembly of FIG. 16 with some of the elements thereof shown in cross-section.

[0038] FIG. 18 is a partial perspective of a staple applying assembly of the present invention clamping a piece of tissue that has been partially cut and stapled.

[0039] FIG. 19 is a bottom view of an anvil embodiment of the present invention;

[0040] FIG. 20 is a longitudinal cross-sectional view of a staple applying assembly employing the anvil embodiment depicted in FIG. 19.

[0041] FIG. 21 is a cross-sectional end view of the staple applying assembly of FIG. 20 taken along line 21-21 in FIG. 20, with some elements shown in solid form for clarity.

[0042] FIG. 22 is another longitudinal cross-sectional view of the staple applying assembly of FIGS. 20 and 21 clamping a piece of tissue therein, wherein the tissue has varying cross-sectional thicknesses.

[0043] FIG. 23 is another partial longitudinal cross-sectional view of the staple applying assembly of FIGS. 20-22 clamping another piece of tissue therein.

[0044] FIG. 24 is another partial longitudinal cross-sectional of the staple applying assembly of FIGS. 20-23 clamping another piece of tissue therein.

[0045] FIG. 25 is an end cross-sectional view of another staple applying assembly of the present invention in a clamped position.

[0046] FIG. 26 is longitudinal cross-sectional view of another staple applying assembly of the present invention.

[0047] FIG. 27 is a cross-sectional view of a portion of another staple applying assembly of the present invention with a piece of tissue clamped and stapled therein.

[0048] FIG. 28 is a top view of a portion of a biasing plate embodiment of the present invention.

[0049] FIG. 29 is a cross-sectional view of a portion of the biasing plate of FIG. 28 taken along line 29-29 in FIG. 28.

[0050] FIG. 30 is an end cross-sectional view of another staple applying assembly of the present invention with some elements shown in solid form for clarity.

[0051] FIG. 30A is an end cross-sectional view of another staple applying assembly of the present invention with some elements shown in solid form for clarity.

[0052] FIG. 31 is a longitudinal cross-sectional view of the staple applying assembly of FIG. 30 with tissue clamped and stapled therein.

[0053] FIG. 32 is another longitudinal cross-sectional view of the staple applying assembly of FIG. 31 with another portion of tissue clamped and stapled therein.

[0054] FIG. 33 is another longitudinal cross-sectional view of the staple applying assembly of FIGS. 30-32 fluidically coupled to a fluid reservoir supported by a handle assembly of various embodiments of the present invention.

[0055] FIG. 34 is a longitudinal cross-sectional view of a staple applying assembly of other embodiments of the present invention wherein tissue of varying thickness is clamped therein.

[0056] FIG. 35 is an enlarged cross-sectional view of a portion of the staple applying assembly of FIG. 34.

[0057] FIG. 36 is an exploded perspective view of a collapsible staple driver embodiment of the present invention.

[0058] FIG. 37 is a cross-sectional view of the collapsible staple driver embodiment of FIG. 36 in a first (uncollapsed) position.

[0059] FIG. 38 is an exploded perspective view of another collapsible staple driver embodiment of the present invention.

[0060] FIG. 39 is a cross-sectional view of the collapsible staple driver embodiment of FIG. 38 in a first (uncollapsed) position.

[0061] FIG. 40 is a perspective view of another collapsible staple driver embodiment of the present invention in a first (uncollapsed) position.

[0062] FIG. 41 is an exploded perspective view of the collapsible staple driver embodiment of FIG. 40.

[0063] FIG. 42 is a cross-sectional view of the collapsible staple driver embodiment of FIGS. 40 and 41 in a first (uncollapsed) position.

[0064] FIG. 43 is another cross-sectional view of the collapsible staple driver embodiment of FIGS. 40-42 after compression forces have been applied thereto.

[0065] FIG. 44 is an exploded perspective view of another collapsible staple driver embodiment of the present invention.

[0066] FIG. 45 is a cross-sectional view of the collapsible staple driver embodiment of FIG. 44 in a first (uncollapsed) position.

[0067] FIG. 46 is an exploded perspective view of the collapsible staple driver embodiment of FIGS. 44 and 45 with some of the elements thereof shown in cross-section.

[0068] FIG. 47 is an exploded front view of another collapsible staple driver embodiment of the present invention.

[0069] FIG. 48 is another front view of the collapsible staple driver of FIG. 47 in a first (uncollapsed) position.

[0070] FIG. 49 is another front view of the staple driver of FIGS. 47 and 48 after it has been compressed to a fully collapsed position.

[0071] FIG. 50 is an exploded assembly view of another collapsible staple driver embodiment of the present invention.

[0072] FIG. 51 is an exploded front view of the collapsible staple driver embodiment of FIG. 50.

[0073] FIG. 52 is another front view of the collapsible staple driver embodiment of FIGS. 50 and 51 after being compressed into a fully collapsed position.

[0074] FIG. 53 is a perspective view of another collapsible staple driver embodiment of the present invention;

[0075] FIG. 54 is a side elevational view of the collapsible staple driver of FIG. 53 in a first (uncollapsed) position.

[0076] FIG. 55 is another side elevational view of the collapsible staple driver of FIGS. 53 and 54 after being compressed to a fully collapsed position.

DETAILED DESCRIPTION

[0077] Turning to the Drawings, wherein like numerals denote like components throughout the several views, in FIG. 1, a surgical stapling and severing instrument 10 includes a handle portion 12 that is manipulated to position an implement portion 14 including a fastening end effector, depicted as a staple applying assembly 16, distally attached to an elongate shaft 18. The implement portion 14 is sized for insertion through a cannula of a trocar (not shown) for an endoscopic or laparoscopic surgical procedure with an upper jaw (anvil) 20 and a lower jaw 22 of the staple applying assembly 16 closed by depression of a closure trigger 24 toward a pistol grip 26 of the handle portion 12, which advances an outer closure sleeve 28 of the elongate shaft 18 to pivot shut the anvil 20.

[0078] Once inserted into an insufflated body cavity or lumen, the surgeon may rotate the implement portion 14 about its longitudinal axis by twisting a shaft rotation knob 30 that engages across a distal end of the handle 12 and a proximal end of the elongate shaft 18. Thus positioned, the closure trigger 24 may be released, opening the anvil 20 so that tissue may be grasped and positioned. Once satisfied with the tissue held in the staple applying assembly 16, the surgeon depresses the closure trigger 24 until locked against the pistol grip 26, clamping tissue inside of the staple applying assembly 16.

[0079] Then a firing trigger 32 is depressed, drawn toward the closure trigger 24 and pistol grip 26, thereby applying a firing force or motion thereto to distally advance a firing member from an unfired position. The firing member is depicted as including a proximal firing rod 34 attached to a distal firing bar 36, that is supported within a frame ground 38 that connects the handle portion 12 to the staple applying assembly 16. During the staple firing motion, the firing bar 36 engages an elongate staple channel 40 and actuates a staple cartridge 42 contained therein, both forming the lower jaw 22. The firing bar 36 also engages the closed anvil 20. After releasing the firing trigger 32 to apply a retraction force or motion to the firing bar 36, depression of a closure release button 44 unclamps the closure trigger 24 so that the closure sleeve 28 may be retracted to pivot and open the anvil 20 to release the severed and stapled tissue from the staple applying assembly 16.

[0080] It should be appreciated that spatial terms such as vertical, horizontal, right, left etc., are given herein with reference to the figures assuming that the longitudinal axis of the surgical instrument 10 is co-axial to the central axis of the elongate shaft 18, with the triggers 24, 32 extending downwardly at an acute angle from the bottom of the handle assembly 12. In actual practice, however, the surgical instrument 10 may be oriented at various angles and, as such, these spatial terms are used relative to the surgical instrument 10 itself. Further, "proximal" is used to denote a perspective of a clinician who is behind the handle assembly 12 who places the implement portion 14 distal, or away from him or herself.

[0081] In FIG. 2, the staple applying assembly 16 is closed upon compressed tissue 46. In FIGS. 2-3, the firing bar 36 has a proximal portion 48 that is attached to a distal E-beam 50 that translates within the staple applying assembly 16. As depicted with the firing bar 36 retracted, a vertical portion 52 of the E-beam 50 resides essentially aft of the staple car-

tridge 42, as after a new staple cartridge 42 has been inserted into the elongate staple channel 40. An upper pin 54 that extends laterally from an upper portion of the vertical portion 52 of the E-beam 50 initially resides within an anvil pocket 56 recessed near a proximal pivoting end of the anvil 20. As the E-beam 50 is distally advanced during the staple firing motion, the vertical portion 52 passes through a narrow longitudinal anvil slot 58 (FIGS. 1, 11) formed in a staple forming undersurface 60 of the anvil 20, a proximally open vertical slot 62 formed in cartridge 42 and an underlying longitudinal channel slot 64 formed in the elongate staple channel 40.

[0082] In FIGS. 2, 11, the narrow longitudinal anvil slot 58 (FIG. 2) communicates upwardly to a laterally widened longitudinal anvil channel 66 sized to slidably receive the upper pin 54. The longitudinal channel slot 64 communicates downwardly to a laterally widened longitudinal channel track 68 that receives a lower foot 70, which is sized to slide therein and is attached at a bottom of the vertical portion 52 of the E-beam 50. A laterally widened middle pin 72 extending from the vertical portion 52 of the E-beam 50 is positioned to slide along a top surface of a bottom tray 74 of the staple cartridge 42, which in turn rests upon the elongate staple channel 40. A longitudinal firing recess 75 formed in the staple cartridge 42 above the bottom tray 74 is sized to allow the middle pin 72 to translate through the staple cartridge 42.

[0083] A distal driving surface 76 of the vertical portion 52 of the E-beam 50 is positioned to translate through the proximally open vertical slot 62 of the staple cartridge 42 and distally drive a wedge sled 78 proximally positioned in the staple cartridge 42. The vertical portion 52 of the E-beam 50 includes a cutting surface 80 along a distal edge above the distal driving surface 76 and below the upper pin 54 that severs the clamped tissue 46 simultaneously with this stapling.

[0084] With particular reference to FIG. 11, it should be appreciated that the wedge sled 78 drives upwardly staple drivers 82 that in turn drive upwardly staples 83 out of staple apertures 84 formed in a staple body 85 of the staple cartridge 42 to form against the undersurface 60 of the anvil 20 which is in confronting relationship relative to an upper surface 43 of staple cartridge 42 (FIG. 2).

[0085] In FIGS. 2, 11, advantageously, the illustrative spacing, denoted by arrow 86 (FIG. 2), between the upper pin 54 is compliantly biased toward a compressed state wherein 0.015 inches of compressed tissue 46 is contained in the staple applying assembly 16. However, a larger amount of compressed tissue 46 up to about 0.025 inches is allowed by an inherent flexure of the E-beam 50. Excessive flexure, of perhaps up to 0.030 inches, is avoided should the length of staples be insufficient to form with the additional height. It should be appreciated that these dimensions are illustrative for a staple height of 0.036 inches. The same would be true for each category of staple, however.

[0086] In FIG. 4, a first version of a compliant E-beam 50a includes top and bottom horizontal slits 90, 92 from a distal edge of the vertical portion 52a, perhaps formed by electro drilling machine (EDM). The vertical portion 52a thus contains a vertically compliant top distally projecting arm 94 containing the upper pin 54, a knife flange 96 containing the cutting surface 80, and a lower vertical portion 98 containing

the distal driving surface **76**, middle pin **72** and lower foot **70**. The horizontal slits **90**, **92** allow a compliant vertical spacing by allowing the top distally arm **94** to pivot upwardly to adjust to increased force from compressed tissue **46** (not shown).

[0087] In FIGS. **5-6**, a second version of a compliant E-beam **50b** includes left and right lower relieved areas **110**, **112** formed into an upper pin **54b** to each side of the vertical portion **52**, leaving left and right lower bearing points **114**, **116** respectively. The outboard position of the bearing points **114**, **116** provides a long moment arm to exert the force to flex. It should be appreciated given the benefit of the present disclosure that the dimensions of the relieved areas **110**, **112** and the choice of materials for the compliant E-beam **50b** may be selected for a desired degree of flexure, given the staple size and other considerations.

[0088] In FIG. **7**, a third version of a compliant E-beam **50c** is as described above in FIGS. **5-6** with further flexure provided by left and right upper narrow relieved areas **120**, **122** formed into opposite top root surfaces of an upper pin **54c** proximate to the vertical portion **52**.

[0089] In FIG. **8**, a fourth version of a compliant E-beam **50d** is as described for FIGS. **2-3** with an added feature of a composite/laminate vertical portion **52d** that includes a central resilient vertical layer **130** sandwiched between left and right vertical layers **132**, **134** that support respectively left and right portions **136**, **138** of an upper pin **54d**. As the left and right portions **136**, **138** are flexed either up or down, the resulting bowing of the left and right vertical layers **132**, **134** are accommodated by a corresponding compression or expansion of the central resilient vertical layer **130**.

[0090] In FIG. **9**, a fifth version of a compliant E-beam **50e** is as described for FIGS. **2-3** with an added feature of a discrete upper pin **54e** formed of a more flexible material that is inserted through a horizontal aperture **140** through a vertical portion **52e**. Thus, left and right outer ends **142**, **144** of the discrete upper pin **54e** flex in accordance with loading forces.

[0091] Alternatively or in addition to incorporating flexure into an upper pin **54**, in FIGS. **10-11**, a sixth version of a compliant E-beam **50f** as described for FIGS. **2-3** further includes resilient pads **150** that are attached to upper surfaces **152** of the bottom foot **70**. The resilient pads **150** adjust the spacing of the upper pin **54** in accordance to the compression force experienced at the bottom foot **70**.

[0092] In FIG. **12**, a seventh version of a compliant E-beam **50g** is as described above for FIGS. **2-3** with the added feature of a bottom foot (shoe) **70g** having an upwardly aft extended spring finger **160** that resiliently urges the E-beam **50g** downwardly to adjust vertical spacing in accordance with loading force.

[0093] In FIG. **13**, an eighth version of a compliant E-beam **50h** is as described above in FIGS. **2-3** with the added feature of an oval spring washer **170** resting upon the bottom foot **70** encircling the vertical portion **52** and having an upwardly bowed central portion **172** that resiliently urges the E-beam **50h** downwardly to adjust vertical spacing in accordance with loading force.

[0094] For another example, a compliant E-beam consistent with aspects of the present invention may include

engagement to an anvil similar to the engagement in the illustrative versions of two structures that slide against opposite sides of the elongate staple channel. Similarly, a compliant E-beam may engage a lower jaw by having a laterally widened portion that slides internally within a channel formed in a lower jaw structure.

[0095] As yet an additional example, in the illustrative version, the staple cartridge **42** is replaceable so that the other portions of the staple applying assembly **16** may be reused. It should be appreciated given the benefit of the present disclosure that applications consistent with the present invention may include a larger disposable portion, such as a distal portion of an elongate shaft and the upper and lower jaws with a staple cartridge permanently engaged as part of the lower jaw.

[0096] As yet another example, the illustrative E-beam advantageously affirmatively spaces the upper and lower jaws from each other. Thus, the E-beam has inwardly engaging surfaces that pull the jaws together during firing in instances where a larger amount of compressed tissue tends to spread the jaws. Thereby the E-beam prevents malformation of staples due to exceeding their effective length. In addition, the E-beam has outwardly engaging surfaces that push the jaws apart during firing in stances where a small amount of tissue or other structure attributes of the instrument tend to pinch the jaws together that may result in staple malformation. Either or both functions may be enhanced by applications consistent with aspects of the invention wherein inherent flexure in the E-beam adjusts to force to allow a degree of closing of the jaws or of opening of the jaws.

[0097] FIG. **14** is an end cross-sectional view of a surgical instrument **10a** that has a staple applying assembly **16a** of another embodiment of the present invention wherein like reference numerals are used to designate like elements and which employs an elongate channel **40a** for supporting a staple cartridge **42** therein. In various embodiments, the channel **40a** has resilient or flexible features configured to enable the staple applying assembly **40a** to effectively accommodate different thicknesses of tissue. FIG. **15** is a partial perspective view of the staple applying assembly **16a** with some components shown in cross-section for clarity. As can be seen in FIG. **14**, in this embodiment, a first longitudinally extending relief area **180** and a second longitudinally extending relief area **184** are provided in the longitudinal channel **40a**. The first longitudinally extending relief area **180** defines a first resilient or flexible channel ledge portion **182** and the second longitudinally extending relief area **184** defines a second resilient or flexible channel ledge portion **186**. The elongate channel slot **64** through which the upper end **51** of the vertical portion **52** of the firing member in the form of E-beam **50** extends is formed between the free ends **183**, **185** of the flexible ledges **182**, **186**, respectively. As can be further seen in FIG. **14**, such arrangement permits the lower foot **70** of the E-beam **50** to bear upon the flexible ledge portions **182**, **186** to accommodate differences in the thickness of the tissue clamped between the anvil **20** and the lower jaw **22** as the E-beam **50** transverses therethrough. It will be understood that the thickness **188** of the ledge portions **182**, **186** may be selected to provided the desired amount of flexure to those portions of the elongate channel **40a**. Also, the choice of materials for the elongate channel **40a** may be selected for a desired degree of flexure, in view of the staple size and other considerations.

[0098] The elongate channel **40a** as described above may be used in connection with a staple applying assembly that employs a conventional anvil **20**. That is, the longitudinally extending anvil slot **58** may essentially have a “T” shape that is sized to accommodate the upper pins **54** and an upper end **51** of the vertical portion **52** of the E-beam **50**. The embodiment depicted in FIGS. **14** and **15** employs anvil **20a** that has resilient or flexible features for further accommodating differences in tissue thicknesses clamped between the anvil **20a** and the lower jaw **22**. In particular, as can be seen in FIG. **14**, a third longitudinally extending relief area **190** and a fourth longitudinally extending relief area **194** may be provided in the anvil **20a** as shown. The third longitudinally extending relief area **190** defines a first anvil ledge portion **192** and the fourth longitudinally extending relief area **194** defines a second anvil ledge portion **196** upon which the upper pins **54** of the E-beam **50** may bear. Such arrangement provides a degree of flexure to the anvil **20a** to accommodate differences in tissue thickness clamped between the anvil **20a** and the lower jaw **22**. It will be understood that the thickness **198** of the ledge portions **192**, **196** may be selected to provide the desired amount of flexure to those portions of the anvil **20a**. Also, the choice of materials for the anvil **20a** may be selected for a desired degree of flexure, in view of the staple size and other considerations. Anvil **20a** may be used in connection with the above-described channel arrangement as shown in FIGS. **14** and **15** or it may be employed with conventional channel arrangements without departing from the spirit and scope of the present invention.

[0099] The person of ordinary skill in the art will also appreciate that the anvil **20a** and/or the channel **40a** may be successfully employed with a conventional E-beam arrangement or any of the E-beam arrangements depicted herein. The E-beams disclosed herein may be reciprocatingly driven by control arrangements housed within the handle assembly. Examples of such control arrangements are disclosed in U.S. Pat. No. 6,978,921, issued Dec. 27, 2005, which has been herein incorporated by reference. Other known firing member configurations and control arrangements for applying firing and retraction forces or motions thereto could conceivably be employed without departing from the spirit and scope of the present invention.

[0100] FIGS. **16** and **17** illustrate a staple applying assembly **16b** that employs another version of a channel **40b** and an anvil **20b** that each have resilient or flexible portions to accommodate differences in tissue thicknesses clamped between the anvil **20b** and the lower jaw **22b**. As can be seen in those Figures, a first pair **200** of upper and lower longitudinally extending relieved or undercut areas **202**, **204** are provided in the channel **40b** to define a first cantilever-type support ledge **206** and a second pair **210** of relieved or undercut areas **212**, **214** are provided in the channel **40b** to define a second cantilever-type support ledge **216**. The first pair relieved areas **202**, **204** provide a degree of flexure to the first support ledge **206** to enable it to flex as illustrated by arrow **205**. Likewise, the second pair **210** of relieved areas **212**, **214** provide a degree of flexure to the second support ledge **216** to enable it to flex as illustrated by arrow **215**. As with the above described embodiments, the thickness **208** of the support ledges **206** and **216** may be selected to provide the desired amount of flexure to those portions of the elongate channel **40b** to accommodate different thicknesses of tissue. Also, the choice of materials for the

elongate channel **40b** may be selected for a desired degree of flexure, in view of the staple size and other considerations.

[0101] FIGS. **16** and **17** further illustrate an anvil **20b** that has a T-shaped slot **58b** that defines a first lateral wall portion **220** and a second lateral wall portion **222**. In various embodiments, a first longitudinally extending undercut area **224** is provided in the first lateral wall portion **220** to define a resilient or flexible first ledge **226**. Similarly, in various embodiments, a second longitudinally extending undercut area **228** is provided in the second lateral wall portion **222** to define a resilient or flexible second ledge **230**. As can be seen in FIG. **16**, the ends **227**, **231** of the first and second ledges **226**, **230**, respectively serve to define a portion **59b** of anvil slot **58b** through which an upper end portion **51** of E-beam **50b** extends. Such arrangement permits the upper pins **54b** of the E-beam **50b** may bear upon the first resilient ledge **226** and the second resilient ledge **230** to provide a degree of flexure to the anvil **20ab** to accommodate differences in tissue thickness clamped between the anvil **20b** and the lower jaw **22b**. It will be understood that the thickness **232** of the ledges **226**, **230** may be selected to provide the anvil **20b** with a desired amount of flexure to accommodate different tissue thicknesses. Also, the choice of materials for the anvil **20b** may be selected for a desired degree of flexure, in view of the staple size and other considerations. Anvil **20b** may be used in connection with the above-described channel **40b** shown in FIGS. **16** and **17** or it may be employed with a conventional channel arrangement. The skilled artisan will also appreciate that the anvil **20a** and/or the channel **40bg** may be successfully employed with a conventional E-beam arrangement or any of the E-beams described herein.

[0102] FIG. **18** illustrates the cutting and stapling of tissue **240** with any one of the various surgical cutting and stapling instrument embodiments of the present invention. A portion **242** of the tissue **240** illustrated in FIG. **18** has already been cut and stapled. After the clinician has cut and stapled the first portion **242**, the instrument would be withdrawn to enable new staple cartridge **42** to be installed. FIG. **18** illustrates the position of the implement portion **14** prior to commencing the second cutting and stapling process. As can be seen in that Figure, the portion **242** of the tissue **240** that has been stapled has a thickness **243** that is less than the thickness **245** of other portions **244** of the tissue **240**.

[0103] FIG. **19** is a view of the underside of an anvil **20c** that may be employed with a staple applying assembly **16c** of various embodiments of the present invention. The anvil **20c** includes an anvil body **21c** that supports movable staple forming pockets that define different staple zones. In the embodiment depicted in FIG. **19**, four left staple zones **252**, **254**, **256**, **258** are provided on a left side **250** of the anvil slot **58c** and four right staple zones **262**, **264**, **266**, **268** are provided on a right side **260** of the anvil slot **58c** within the anvil body **21c**. The first left staple zone **252** is defined by a first left staple forming insert member **270** that has a series of staple forming pockets **272** therein. In this embodiment, three rows **274**, **276**, **278** of staple forming pockets **272** are provided in the insert **270**. As can be seen in FIG. **19**, the central row **276** of pockets **272** are slightly longitudinally offset from the outer two rows **274**, **278** of pockets **272** and correspond to the arrangement of the corresponding staple apertures **84** in corresponding staple cartridges **42**. Those of ordinary skill in the art will appreciate that such

arrangement serves to result in the application of the staples **83** in a staggered manner as illustrated in FIG. **18**.

[0104] Similarly, the second left staple zone **254** may be defined by a second left staple forming insert **280** that may have three rows **282, 284, 286** of staple forming pockets **272** therein. The third left staple zone **256** may be defined by a third left staple forming insert **290** that may have three rows **292, 294, 296** of staple forming pockets **272** therein. The fourth left staple zone **258** may be defined by a fourth left staple forming insert **300** that may have three rows **302, 304, 306** of staple forming pockets **272** therein. The first, second, third and fourth left staple forming inserts **270, 280, 290, 300** are longitudinally aligned in a left side cavity **251** provided in the anvil **20c** on the left side **250** of the anvil slot **58**.

[0105] The first right staple zone **262** may be defined by a first right staple forming insert member **310** that has a series of staple forming pockets **272** therein. In this embodiment, three rows **312, 314, 316** of staple forming pockets **272** are provided in the insert **310**. As can be seen in FIG. **19**, the central row **314** of staple forming pockets **272** are slightly longitudinally offset from the outer two rows **312, 316** and correspond to the arrangement of the corresponding staple apertures **84** in corresponding staple cartridges **42**. Such arrangement serves to result in the application of the staples **83** in a staggered manner on the right side of the tissue cut line. The second right staple zone **264** may be defined by a second right insert **320** that may have three rows **322, 324, 326** of staple forming pockets **272** therein. The third right staple zone **266** may be defined by a third right staple forming insert **330** that may have three rows **332, 334, 336** of staple forming pockets **272** therein. The fourth right staple zone **268** may be defined by a fourth right staple forming insert **340** that may have three rows **342, 344, 346** of staple forming pockets **272** therein. The first, second, third, and fourth right staple forming inserts **310, 320, 330, 340** are longitudinally aligned in a right side cavity **261** provided in the anvil **20c** on the right side **260** of the anvil slot **58**. In various embodiments, the staple forming inserts may be fabricated from stainless steel or other suitable materials that are harder than the material from which the staples are fabricated. For example, the inserts may be successfully fabricated from other materials such as cobalt chromium, aluminum, 17-4 stainless steel, 300 series stainless steel, 400 series stainless steel, other precipitant hardened stainless steels, etc.

[0106] At least one biasing member or compliant member in the form of a wave spring **350** or other suitable biasing or compliant medium or member corresponding to each of the staple forming inserts **270, 280, 290, 300, 310, 320, 330, 340** is provided between the respective left staple forming inserts **270, 280, 290, 300** and the bottom of the left side cavity **251** as shown in FIGS. **20-23**. Wave springs **350** or other suitable biasing or compliant medium or member is also provided between each of the right staple forming inserts **310, 320, 330, 340** and the bottom surface of the right side cavity **261**. The wave springs **350** on the left side of the anvil slot **58c** may be received in a corresponding spring cavity **253** and the wave springs **350** on the right side of the anvil cavity **58c** may be received in a corresponding spring cavity **263**. To biasingly retain each insert **270, 280, 290, 300, 310, 320, 330, 340** in the anvil **20c**, each insert **270, 280, 290, 300, 310, 320, 330, 340** may be attached to its corresponding

spring **350** or biasing member by, for example, adhesive or other fastener arrangements. In addition, each spring **350** may be attached to the anvil **20c** by, for example, adhesive or other mechanical fastener arrangements to retain a portion of the wave spring **350** within its respective spring cavity **253** or **263**. Such spring/biasing member arrangements serve to bias the inserts **270, 280, 290, 300, 310, 320, 330, 340** toward the tissue **240** and staples and essentially act as resilient "shock absorbers" to accommodate differences in tissue thicknesses. This advantage is illustrated in FIGS. **22-24**.

[0107] In particular, as can be seen in FIG. **22**, the portion **242** of the tissue **240** clamped in the proximal end **17b** of the staple applying assembly **16c** has a first thickness (arrow **243** that is thicker than the thickness (arrow **245**) of the portion **244** of tissue **240** clamped in the central portion **17c** of the staple applying assembly **16c**. The thickness **245** of tissue portion **244** is greater than the thickness (arrow **247**) of the portion **246** of tissue **240** that is clamped in the distal end **17a** of the staple applying assembly **16c**. Thus, the staples **83** formed in the distal portion **17a** of the staple applying assembly **16c** are more tightly formed than the staples **83** formed in the central portion **17c** of the staple applying assembly **16c** which are more tightly formed than those staples **83** formed in the proximal end **17b** of the staple applying assembly **16c** due to the differences in tissue thicknesses. FIG. **23** further illustrates the variations in staple formation heights based upon the variations in the thicknesses of the tissue clamped within the staple applying assembly **16c**. FIG. **24** illustrates a condition wherein the tissue **240** clamped in the central portion **17c** of the staple applying assembly **16c** is thicker than the portions of tissue clamped in the distal and proximal ends of the staple applying assembly **16c**. Thus, the formation heights of the staples in the central portion **17c** will be higher than the staple formation heights of the staples associated with the proximal end **17b** and distal end **17a** of the staple applying assembly **16c**.

[0108] Those of ordinary skill in the art will understand that the unique and novel features of the embodiments depicted in FIGS. **19-24** may also be employed in connection with a staple applying assembly that is essentially identical in construction and operation to staple applying assembly **16c** described above, except that the staple forming inserts **270, 280, 290, 300, 310, 320, 330, 340** may have just one row of staple formation pockets **272** therein or two rows of staple formation pockets **272** therein. For example, FIG. **25** illustrates an embodiment that only applies two rows of staples on each side of the tissue cut line. Shown in that Figure are staple forming inserts **270d** and **310d** that only have two rows of staple forming pockets **272d** each.

[0109] The skilled artisan will further understand that the number of staple forming inserts employed on each side of the anvil slot **58** may vary. For example a single longitudinally extending insert may be used on each side of the anvil slot **58**. FIG. **26** illustrates another staple applying assembly **16e** of the present invention that only employs one staple forming insert on each side of the anvil slot. FIG. **26** depicts a cross-sectional view of the left side of an anvil **20e** that supports a single left staple forming insert **380** that is attached to a single wave spring **350e**. Other biasing members or multiple wave springs or biasing members may also be employed. The biasing member or members **350e** are

supported in the left side cavity **251e** and attached to the anvil **20e** in one of the various manners described above. A similar right side insert (not shown) would be employed on the right side of the anvil slot **58**. Furthermore, although FIGS. **19-24** depict use of four staple forming inserts on each side of the anvil slot greater numbers of staple forming inserts may be employed.

[0110] FIGS. **27-29** illustrate another staple applying assembly **16f** of the present invention wherein a separate movable staple forming insert is provided for each staple **83**. In particular, as can be seen in FIG. **27**, a single staple forming insert **400** is provided for each staple **83**. Each staple forming insert **400** may have staple forming pockets **404** formed on its underside **402** thereof for forming the ends of the corresponding staple **83**. As with various embodiment described above, each insert **400** has a biasing member **412** associated therewith. In the example depicted in FIGS. **27-29**, the biasing members **412** comprise stamped portions of a biasing plate **410**. The biasing plate **410** may comprise a piece of metal or other suitable material wherein each biasing member **412** is stamped or otherwise cut and formed to correspond with a staple forming insert **400**. The biasing plate **410** may comprise a single plate that is supported within a cavity **251f** in the anvil **20f** or multiple plates **410** may be employed on each side of the anvil slot. It will be understood that a similar arrangement may be employed on the right side of the anvil slot. Each staple forming insert **400** may be attached to its corresponding biasing member **412** by adhesive or other suitable fastener arrangement. Thus, it will be appreciated that a variety of different numbers and arrangements of movable staple forming inserts may be employed without departing from the spirit and scope of the present invention. In particular, at least one movable staple forming insert may be employed on each side of the anvil slot.

[0111] FIGS. **30-32** illustrate another staple applying assembly **16g** of other embodiments of the present invention wherein the biasing or compliant medium between the staple forming inserts and the anvil comprises at least one fluid bladder. More specifically, as can be seen in FIG. **30**, a left bladder **420** is positioned within a left side cavity **253g** on the left side of the anvil slot **58g** in the anvil **20g**. Likewise, a right side bladder **430** is positioned with a right side cavity **263** in the anvil **20g**. The series of left side staple forming inserts **270g, 280g, 290g, 300g** may be attached to the left side bladder **430** by a suitable adhesive or other fastener arrangement. Likewise the right side staple forming inserts (not shown) may be attached to the right side bladder **430** by adhesive or other suitable fastener arrangements. In one embodiment, each bladder **420, 430** is sealed and partially filled with a liquid **432** such as, for example, glycerin oil or saline solution. Those of ordinary skill in the art will appreciate that such arrangement will permit the staple forming inserts to move to better accommodate variations in the thickness of the tissue clamped within the staple applying assembly **16g**. For example, for tissues that have a relatively constant thickness, the liquid **432** will be relatively evenly distributed within each of the bladders **420, 430** to provide a relatively even support arrangement for the staple forming inserts. See FIG. **31**. However, when a thicker portion of tissue is encountered, those staple forming inserts corresponding to the thicker tissue will be compressed into their respective anvil cavity thereby forcing the

liquid in that part of the bladder to the portions of the bladder corresponding to the thinner tissue portions. See FIG. **32**.

[0112] In some applications, it may be desirable for the clinician to be able to control the amount of pressure within the bladders **420, 430**. For example, less pressure may be desirable when cutting and stapling more delicate tissues such as lung tissue and the like. More pressure may be desirable when cutting and stapling thicker tissues such as, for example, stomach tissue, intestine tissue, kidney tissue, etc. To provide the clinician with this additional flexibility, the bladders **420, 430** may each be fluidically coupled by a supply line **440** or conduit to a fluid reservoir **450** supported by the handle portion **12** of the instrument. In the embodiment illustrated in FIG. **33**, the clinician can increase or decrease the amount of fluid within the bladders **420, 430** and resulting pressure therein by means of an adjustment mechanism **460** mounted to the fluid reservoir **450**. In various embodiments, the adjustment mechanism **460** may comprise a piston **462** that is attached to an adjustment screw **464**. By adjusting the adjustment screw **464** inward, the piston **462** forces fluid out of the reservoir **450** to the bladders **420, 430**. Conversely, by reversing the adjustment screw **464**, the piston **462** permits more fluid **432** to return or remain within the reservoir **450**. To assist the clinician in determining the amount of pressure within that hydraulic system, generally designated as **405**, a pressure gauge **470** may be employed as shown. Thus, for those tissues requiring a higher amount of pressure, the clinician can preset the pressure in the bladders **420, 430** to a pressure that is conducive to successfully clamp and staple that particular type of tissue. While a piston/screw arrangement has been described for controlling the pressure in the hydraulic system, the skilled artisan will understand that other control mechanisms could successfully be employed without departing from the spirit and scope of the present invention.

[0113] FIG. **30A** illustrates another staple applying assembly **16h** of other embodiments of the present invention wherein the biasing or compliant medium between the staple forming inserts and the anvil comprises at least one compressible polymer member. More specifically, as can be seen in FIG. **30A**, a left compressible polymer member **420h** is positioned within a left side cavity **253h** on the left side of the anvil slot **58h** in the anvil **20h**. Likewise, a right side compressible polymer member **430h** is positioned with a right side cavity **263h** in the anvil **20h**. The series of left side staple forming inserts **270h-300h** may be attached to the left compressible polymer member **420h** by a suitable adhesive or other fastener arrangement. Likewise the right side staple forming inserts **310h-340h** may be attached to the right side compressible polymer member **430h** by adhesive or other suitable fastener arrangements.

[0114] FIGS. **34-37** depict a unique and novel collapsible or compressible staple driver arrangement that enables the various staple drivers to accommodate different tissue thicknesses by collapsing or compressing in response to compression forces that the driver encounters during the firing process. As used herein, the term "firing process" refers to the process of driving the staple drivers towards the staple forming undersurface of the anvil. As was mentioned above, prior staple drivers were fabricated from stiff/rigid material designed to resist deflection and deformation when encountering compression forces during the firing process. A variety of such driver configurations are known. For example,

some staple drivers are configured to support a single staple and others are designed to support multiple staples. A discussion of single and double staple drivers and how they may be operably supported and fired within a staple cartridge is found in U.S. patent application Ser. No. 11/216,562, filed Sep. 9, 2005, entitled Staple Cartridges For Forming Staples Having Differing Formed Staple Heights to Frederick E. Shelton, IV, the disclosure of which is herein incorporated by reference.

[0115] FIG. 34 depicts a staple applying assembly 16*h* that includes an elongate channel 40*h* that has an anvil 20*h* pivotally coupled thereto in a known manner. The elongate channel 40*h* is configured to operably support a staple cartridge 42*h* therein. The anvil 20*h* has a staple forming undersurface 60*h* thereon that is adapted to confront the upper surface 43*h* of the staple cartridge 42*h* when the anvil 20*h* is pivoted to the closed position shown in FIG. 34. The staples 83 are each supported on a corresponding staple driver 500, the construction of which will be discussed in further detail below.

[0116] Each staple driver 500 may be movably supported within a corresponding staple channel 87*h* provided in the cartridge body 85*h* as shown in FIGS. 34 and 35. Also operably supported within the cartridge body 85*h* is a driving member or wedge sled 78 that is oriented for engagement by the E-beam firing member 50 during the firing process. See FIG. 34. As the E-beam firing member 50 and wedge sled 78 are driven distally through the elongate channel 40*h* and staple cartridge 42 in a known manner, the wedge sled 78 drives the staple drivers 500 upwardly within the cartridge body 85*h*. As the staple drivers 500 are driven upwardly toward the staple forming undersurface 60*h* of the anvil 20*h*, they carry with them their respective staple 83 or staples which are driven into forming engagement with the corresponding staple forming pockets 61*h* in the staple forming undersurface 60*h* of the anvil 20*h*. As the ends 88 of the staple 83 contact the forming pockets 61*h*, they are bent over thus providing the staple 83 with a shape that somewhat resembles a "B". While the various embodiments of the present invention have been described herein in connection with E-beam firing members, it is conceivable that these various embodiments may also be successfully employed with a variety of different firing member and driving member arrangements without departing from the spirit and scope of the present invention.

[0117] One collapsible staple driver embodiment of the present invention is depicted in FIGS. 36 and 37. As can be seen in those Figures, the collapsible or compressible staple driver 500 includes a base portion 502 and a staple supporting portion 520 that is movable from a first uncollapsed position relative to the base portion 502 in response to compression forces generated during the firing process. In various embodiments, the base portion 502 may have a forward support column segment 504 and a rearward support column segment 508 that is spaced from the forward support column segment 504 and is substantially integrally formed therewith. The base portion 502 may also have an upstanding side portion 510 that has a rib 512 protruding from a backside thereof. The upstanding side portion 510 serves to define a receiving ledge 514 in the base portion 502 for receiving the staple supporting portion 520 thereon. Those of ordinary skill in the art will understand that when

the staple supporting portion 520 is received on the ledge 514, the staple driver 500 is unable to collapse or compress any further.

[0118] The staple supporting portion 520 of the staple driver 500 may similarly include a forward support column segment 522 and rearward support column segment 524 that is spaced from the forward support column segment 522. When the staple supporting portion 520 is received on the base portion 502, the forward support column segments 504, 522 serve to form a forward column portion 530 and the rearward column segments 508, 524 form a rearward column portion 532. A forward staple receiving groove 526 is formed in the forward support column segment 522 and a rearward staple receiving groove 528 is formed in the rearward support column segment 524. The forward staple receiving groove 526 and the rearward staple receiving groove 528 serve to support a staple 83 therein as illustrated in FIG. 35. The rib 512 and the forward column 530 and rearward column 532 may cooperate with corresponding channels (not shown) in the staple cartridge body 85 to provide lateral support to the staple driver 500 while permitting the driver to be driven upward within the cartridge body 85 during the firing process.

[0119] In various embodiments, a resistive attachment structure, generally designated as 540' is provided to support the staple supporting portion 520 in a first uncompressed or uncollapsed orientation relative to the base portion (FIG. 37) prior to encountering any compressive forces during the firing operation and to permit the staple supporting portion 520 and the base portion to move towards each other (collapse or compress) in response to the magnitude of the compression forces applied to the staple supporting portion 520 and base portion 520 during the staple firing operation. As can be seen in FIGS. 36 and 37, the resistive attachment structure 540' in various embodiments may comprise a pair of attachment rods 540 that protrude from the bottom 521 of the staple supporting portion 520 and correspond to holes or apertures 542 in the base portion 502. The rods 540 are sized and shaped relative to the holes 542 to establish an interference fit or "light press fit" (i.e., an interference of approximately 0.001 inches) therebetween such that when the staple supporting portion 520 and base driver portion 502 are compressed together during the staple firing operation as will be discussed in further detail below, the staple supporting portion 520 and the base portion 502 can compress toward each other to reduce the overall height of the staple driver 500 in relation to the amount of compression force encountered during the firing process. In various embodiments, for example, the staple supporting portion 520 and base portion 502 may be fabricated from the same material such as, for example, ULTEM®. In other embodiments, the base portion 502 and the staple supporting portion 520 may be fabricated from different materials. For example, staple supporting portion 520 may be fabricated from ULTEM® and the base portion 502 may be fabricated from glass or mineral filled ULTEM®. However, other materials could also be employed. For example, the base portion 502 could be fabricated from Nylon 6/6 or Nylon 6/12.

[0120] In various embodiments, a frictional or an interference fit of approximately 0.001 inch may be established between the attachment rods 540 and their corresponding holes 542. However, other degrees of interference fit may be employed to attain the desired amount and rate of driver

compression in proportion to the magnitude of compression forces encountered when stapling a particular type/thickness of tissue. For example, in one embodiment, the degree of interference fit between the attachment rods **540** and their respective holes **542** may be approximately 0.002 to 0.005 inches for stapling tissues wherein it is anticipated that compression forces on the order of approximately 2-5 pounds may be generated during the firing operation.

[0121] FIG. 35 illustrates various ranges of travel and compression that the staple drivers **500** may experience when encountering tissues of varying thicknesses. More specifically, FIG. 35 illustrates a portion of tissue **560** clamped between the upper surface **43h** of the staple cartridge **42h** and the staple forming undersurface **60h** of the anvil **20h**. As illustrated in FIG. 35, the tissue **560** has three thicknesses. The thickest portion of tissue is designated as **562** and comprises the portion of tissue that is on the right side of the Figure. The next thickness portion of tissue is designated as **564** and the thinnest portion of tissue **560** is designated as **566** and is on the left side of the Figure. For the purposes of this explanation, the staple driver associated with tissue portion **562** is designated as staple driver **500a**. The staple driver associated with tissue portion **564** is designated as staple driver **500b** and the staple driver associated with tissue portion **566** is designated as **500c**. It will be understood that staple drivers **500a**, **500b**, **500c**, may be identical in construction to staple driver **500** as described above.

[0122] Turning to staple driver **500a** first, as the staple driver **500a** is driven upwardly towards the staple forming undersurface **60h** of the anvil **20h** by the wedge sled (not shown in FIG. 35), it encounters the thick tissue portion **562** which resists the upward movement of the staple driver **500a**. Such resistive force (represented by arrow **570**) opposes the drive force (represented by arrow **572**) generated by the wedge sled and serves to overcome the amount of interference established between the attachment rods **540** and their respective holes **542** and forces the rods **540** deeper into their respective holes **542** to thereby permit the staple supporting portion **520a** of the staple driver **500a** and base portion **502a** to move toward each other. This movement of the staple supporting portion **520a** and base portion **502a** towards each other under a compressive force generated during the staple firing operation is referred to herein as "collapsing" or "compressing". When in the completely compressed position wherein the staple supporting portion **520a** is received on the ledge **514a** of the base portion **502a**, the staple supporting ledges **526a**, **528a** on the staple supporting portion **520a** may preferably support the bottom cross member **89** of the staple **83** above the upper surface **43h** of the staple cartridge **42h** to avoid catching the staple **83** on the staple cartridge **42h** when the staple applying assembly **16h** is withdrawn. The compressed height of the staple driver **500a** is designated by arrow **574** in FIG. 35.

[0123] Turning next to staple driver **500b** which corresponds to tissue portion **564**, because the tissue portion **564** is not as thick as tissue portion **562**, the resistive force **570b** encountered by the staple driver **500b** during the firing operation is not as great as resistive force **570**. Therefore, the attachment pins **540b** of staple driver **500b** are not advanced into their respective holes **542b** as far as the pins **540** of staple driver **500a** were advanced into their respective holes **542**. Thus, the compressed height **576** of staple driver **500b**

is greater than the compressed height **574** of staple driver **500a**. As can also be seen in FIG. 35, the bottom portion **89** of the staple **83** supported in staple driver **500b** is supported above the upper surface **43h** of the staple cartridge **42h**.

[0124] Staple driver **500c** is associated with the thinnest tissue portion **566**. Thus, the resistive force **570c** encountered by the staple driver **500c** during the staple firing operation is less than the resistive force **570b** that was encountered by staple driver **500b**. Thus, the pins **540c** of staple driver **500c** are not advanced into their respective holes **542c** as far as the pins **540b** of staple driver **500b** were advanced into their respective holes **542b**. Thus, the compressed height **578** of staple driver **500c** is greater than the compressed height **576** of staple driver **500b**.

[0125] As can be further seen in FIG. 35, because the compressed height **578** of staple driver **500c** is greater than the compressed height **576** of staple driver **500b**, the staple **83c** supported by staple driver **500c** was compressed to a greater extent than the staple **83b** that was supported by staple driver **500b**. Thus, the formed height of staple **83c** is less than the formed height of staple **83b** which is less than the formed height of staple **83a** as illustrated in FIG. 35.

[0126] Those of ordinary skill in the art will appreciate that the number, shape, composition and size of the attachment rods and their respective holes can vary from embodiment to embodiment without departing from the spirit and scope of the present invention. Such interrelationship between the attachment rods and their respective holes serves to establish an amount of frictional interference therebetween which can be overcome in relation to various compression forces encountered when clamping/stapling different thicknesses of tissue. In an alternative version, the attachment to rods **540** may be formed on the base portion **502** and the holes provided in the staple supporting portion **520**.

[0127] FIGS. 38 and 39 illustrate another staple driver **500d** embodiment of the present invention that may be substantially identical in construction and operation to the staple drivers **500** described above, except that the attachment rods **540d** are somewhat tapered or frusto-conically shaped. In various embodiments, for example, the ends **541d** of the attachment rods **540d** may be sized relative to holes **542** such that a light press fit is established therebetween when in the first uncollapsed state depicted in FIG. 39. The degree of taper of the attachment rods **540d** may be tailored to attain the desired amount of staple driver compression in relation to the magnitude of compression forces encountered during the staple firing process. Thus, in these embodiments, the magnitude of the interference fit between the attachment rods **540d** and the holes **542** increases as the staple driver **500d** encounters greater compression forces which drive the attachment rods **540d** deeper into their respective holes **542d**. In alternative embodiments, the attachment rods **540** may have a round shape and the holes **542** may be tapered to attain the desired amount and rate of staple driver compression in proportion to the amount of anticipated compression forces applied thereto during the firing operation. In an alternative version, the attachment rods **540d** may be formed on the base portion **502** and the holes **542** be formed in the staple supporting portion **520**.

[0128] FIGS. 40-43 illustrate another staple driver **500e** embodiment of the present invention that may be substan-

tially identical in construction and operation to the staple drivers 500 described above, except that the attachment rods 540e are configured or shaped to include an additional amount of material oriented to be sheared off of the remaining portion of the rods as the staple driver 500e encounters compression forces during the firing operation. More specifically and with reference to FIG. 42, the attachment rods 540e have a tip portion 541e that is received within the corresponding hole 542e. The tip portion 541e may be sized relative to the hole 542e such that a sliding fit is achieved therebetween or, in other embodiments, a small interference fit may be established between those components when in the first uncollapsed position. The remaining portion 543e of each attachment rod 540e may be provided or formed with an additional amount of material 545e that is designed to be sheared therefrom as the staple driver 500e encounters the anticipated compression forces during the firing operation. See FIG. 43. The additional material 545e may extend completely around the circumference of the portion 543e of each attachment rod 540e or the material 543e may comprise one or more segments oriented around the circumference of the attachment rod 540e. For example, in the embodiment depicted in FIGS. 40-43, two segments 547e of material 543e are diametrically opposed on each attachment rod 540e as shown. In various embodiments, the diametric distance between the segments may be somewhat larger than the diameter of the holes 542e to cause the segments 547e to be sheared or removed from at least a portion of the rods 540e as the staple driver 500e encounters the anticipated compression forces during the firing operation.

[0129] The portions of additional material 543e may comprise an integral portion of the attachment rod 540e or the additional material 543e may comprise a second material applied to the attachment rod 540e and designed to shear off therefrom when the staple driver 500e encounters the anticipated compression forces. In various embodiments, the base portion 502 may be fabricated from a material that is more rigid than the material from which attachment rods 540e and/or the additional material 543e are fabricated such that the base portion 502 facilitates the shearing off of additional material 543e as the staple support portion 520e and base portion 502e are compressed together during the staple firing operation. In an alternative version, the attachment rods 540e may be formed on the base portion 502 and the holes 542e be provided in the staple supporting portion 520e.

[0130] FIGS. 44-46 illustrate another staple driver 500f of the present invention that may be substantially identical in construction and operation to the staple drivers 500 described above, except that the holes 542f in the base portion 502f may be hexagonally shaped or may have one or more surfaces therein designed to establish an interference fit with the attached rods 540 or to otherwise resist further entry of the attachment rods 540 into the holes 542f. For example, the holes 542f shown have a pair of flat surfaces 551f formed therein that serve to establish an interference fit or a degree of frictional resistance between the attachment rods 540f and the holes 542f which can be overcome by the various compression forces encountered when clamping/stapling different thicknesses of tissue. In the embodiment depicted in FIGS. 44-46, the attachment rods 540 have a substantially circular cross-sectional shape and the holes 542f have flat surfaces 551 formed therein. In alternative embodiments, however, the holes 542 may be round and the flat surfaces may be formed on the attachment rods 540. In

an alternative version, the attachment rods 540 may be provided on the base portion 502f and the holes 542f be provided in the staple supporting portion 520.

[0131] FIGS. 47-49 illustrate another staple driver 500g of the present invention that comprises a base portion 502g and a staple supporting portion 520g. The staple supporting portion 520g has staple supporting grooves (not shown) formed therein and a downwardly protruding tang 580 protruding from its undersurface 521g. The tang 580 has two tapered surfaces 582 and is shaped to be received in a corresponding cavity 590 formed in the base portion 502g. The cavity 590 is formed with tapered sides 572 and is sized to receive the tang 580 therein in the following manner. As the driver staple 500g encounters the compression forces generated during the firing operation, the tang 580 is forced into the cavity 590. FIG. 49 illustrates the staple driver 500g in a fully collapsed or compressed position. The staple supporting portion 520g and/or tang 580 may be fabricated from a material that is somewhat more compliant than the material from which the base portion 502g is formed so that the tang 580 can be forced into the cavity 590 in the base portion 502g without substantially distorting the base portion 502g to the extent that it would hamper the ability of the staple driver 500g to be fully driven to a final firing position. For example, the staple supporting portion and/or the tang 580 may be fabricated from ULTEM® and the base portion 502g may be fabricated from glass filled Nylon to achieve the desired amount of driver compression when encountering the anticipated compression forces during the firing operation. In an alternative version, the tang 580 may be provided on the base portion 502g and the hole 590 be provided in the staple supporting portion 520g.

[0132] FIGS. 50-52 illustrate another staple driver 500h embodiment of the present invention that may be substantially identical in construction and operation to the staple drivers 500 described above, except that, instead of attachment rods, the staple supporting portion 520h has two tapered tangs 600 protruding therefrom designed to be compressed into a V-shaped cavity 610 formed in the base portion 502h. Prior to commencement of the firing operation, the staple supporting portion 520h is supported on the base portion 502h within the staple cartridge. As the staple supporting portion 520h and the base portion 502h are compressed together during the firing operation, the tapered tangs 600 are forced inwardly as shown in FIG. 52. The degree to which the tangs 600 are compressed into the V-shaped cavity 610 is dependent upon the magnitude of the compression forces encountered during the firing operation.

[0133] The staple supporting portion 500h and/or tangs 600 may be fabricated from a material that is somewhat more compliant than the material from which the base portion 502h is formed so that the tangs 600 can be forced into the V-shaped cavity 610 in the base portion 502h without substantially distorting the base portion 502h to the extent that it would hamper the ability of the staple driver 500h to be fully driven to a final firing position. For example, the staple supporting portion and/or the tangs 600 may be fabricated from Nylon with no fill and the base portion 502h may be fabricated from ULTEM® with glass or mineral fill to achieve the desired amount of staple driver compression when encountering the anticipated compression forces during the firing operation. In an alternative

version, the tangs 600 may be provided on the base portion 502*h* and the cavity 610 may be provided in the staple supporting portion 520*h*.

[0134] FIGS. 53-55 illustrate yet another staple driver 500*i* embodiment of the present invention that includes a staple supporting portion 520*i* that has V-shaped staple supporting grooves 630*i*, 650*i* therein. In this embodiment, the staple supporting portion 520*i* has a first pair 620*i* of two tapered tangs 622*i*, 626*i* protruding therefrom oriented to be compressed into the first V-shaped groove or cavity 630*i* and a second pair 640*i* of two tapered tangs 642*i*, 646*i* oriented to be compressed into the second V-shaped groove or cavity 650*i*. More specifically and with reference to FIG. 54, the first tang 622*i* has an end 624*i* that is spaced from an end 628*i* of the second tang 626*i* prior to commencement of the staple firing operation. When in the position illustrated in FIG. 54, the ends 624*i*, 628*i* are biased outwardly into frictional contact with the upper side walls of the first V-shaped groove 630*i* to retain the staple supporting portion 520*i* in the uncollapsed position shown in FIG. 54. Although not shown, the second pair 640*i* of tangs 642*i*, 646*i* are also similarly configured as tangs 622*i*, 626*i* and serve to engage the second V-shaped groove 650*i* in the same manner.

[0135] As the staple supporting portion 520*i* and the base portion 502*i* are compressed together during the firing operation, the ends 624*i*, 628*i* of the first tangs 622*i*, 626*i* and the ends of the second tangs 642*i*, 646*i* are biased toward each other to permit the tangs to be driven deeper into their respective grooves 630*i*, 650*i*. FIG. 55 illustrates the first pair 620*i* of tangs 622*i*, 626*i* in their fully compressed state which also corresponds to the fully compressed state of the driver 500*i*. The degree to which the tangs are compressed into their respective V-shaped grooves is dependent upon the magnitude of the compression forces encountered during the firing operation.

[0136] The staple supporting portion 500*i* and/or tangs 622*i*, 626*i*, 642*i*, 646*i* may be fabricated from a material that is somewhat more compliant than the material from which the base portion 502*i* is formed so that the tangs 622*i*, 626*i*, 642*i*, 646*i* can be forced into their respective V-shaped grooves in the base portion 502*i* without substantially distorting the base portion 502*i* to the extent that it would hamper the ability of the driver 500*i* to be fully driven to a final firing position. For example, the staple supporting portion 520*i* and/or the tangs 622*i*, 626*i*, 642*i*, 646*i* may be fabricated from ULTEM® and the base portion 502*i* may be fabricated from Nylon with glass or mineral fill to achieve the desired amount of driver compression when encountering the anticipated compression forces during the firing operation. In an alternative version, the tangs 622*i*, 626*i*, 642*i*, 646*i* may be provided on the base portion 502*i* and the V-shaped grooves 630*i*, 650*i* may be provided in the staple supporting portion 520*i*.

[0137] The various embodiments of the present invention described above and their respective equivalent structures represent vast improvements over prior staple applying assemblies and end effectors. Various embodiments of the present invention provide anvils and/or channels with flexible portions that permit the overall staple height to increase as the compression within the assembly increases due to tissue thickness. Other embodiments employ anvil arrangements that have flexible forming pockets that can be com-

pressed away from the staple cartridge in response to variations in tissue thickness. In doing so, the inherent gap between the forming pocket and the cartridge increases which serves to increase the formed height of the staple. Such advantages can result in improved staple line consistency and provide better clinical outcomes.

[0138] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications may readily appear to those skilled in the art. For example, while various manually operated surgical instruments have been depicted for clarity, it should be appreciated that such devices may also be robotically manipulated. In addition, those skilled in the art will appreciate that the embodiments, features and improvements disclosed herein may be readily employed in connection with a variety of other known surgical cutter/staplers, staplers, etc. that may have application in open, laparoscopic, endoscopic and/or intraluminal surgical procedures. In particular, such unique and novel features may be practiced in connection with linear staplers, cutters, contour cutters, etc. Thus, the scope and protection afforded to the various embodiments disclosed herein should not be limited solely to endocutter-type surgical staplers.

[0139] While several embodiments of the invention have been described, it should be apparent, however, that various modifications, alterations and adaptations to those embodiments may occur to persons skilled in the art with the attainment of some or all of the advantages of the invention. For example, according to various embodiments, a single component may be replaced by multiple components, and multiple components may be replaced by a single component, to perform a given function or functions. This application is therefore intended to cover all such modifications, alterations and adaptations without departing from the scope and spirit of the disclosed invention as defined by the appended claims.

[0140] The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include a combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those of ordinary skill in the art will appreciate that the reconditioning of a device can utilize a variety of different techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[0141] Preferably, the invention described herein will be processed before surgery. First a new or used instrument is obtained and, if necessary, cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is

placed in a closed and sealed container, such as a plastic or TYVEK® bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or higher energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

[0142] As used herein, the term “fluidically coupled” means that the elements are coupled together with an appropriate line or other means to permit the passage of pressurized gas therebetween. As used herein, the term “line” as used in “supply line” or “return line” refers to an appropriate passage formed from rigid or flexible conduit, pipe, tubing, etc. for transporting fluid from one component to another.

[0143] Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

[0144] The invention which is intended to be protected is not to be construed as limited to the particular embodiments disclosed. The embodiments are therefore to be regarded as illustrative rather than restrictive. Variations and changes may be made by others without departing from the spirit of the present invention. Accordingly, it is expressly intended that all such equivalents, variations and changes which fall within the spirit and scope of the present invention as defined in the claims be embraced thereby.

What is claimed is:

1. A surgical instrument, comprising:

a cartridge supporting assembly configured to operably support a staple cartridge therein;

an anvil movably coupled to said cartridge supporting assembly and being selectively movable between an open position and a closed position in response to opening and closing motions respectively applied thereto; and

a firing member operably supported relative to said cartridge supporting assembly and being selectively translatable from an unfired position to a fired position in a staple firing motion in response to a firing force applied to said firing member and to retract to an unfired position in response to a retraction force applied to said firing member, and wherein at least one of said cartridge supporting assembly and said anvil has a resilient structure configured to flexibly interact with said firing member during said staple firing motion to allow a distance between a staple forming undersurface of said anvil and the upper surface of a staple cartridge sup-

ported within said cartridge supporting assembly to vary in relation to a thickness of tissue clamped therebetween.

2. The surgical instrument of claim 1 wherein said firing member has a vertical portion and a foot portion and wherein said cartridge supporting assembly comprises an elongate channel having a flexible structure comprising:

an elongate channel slot therethrough sized to receive said vertical portion of said firing bar;

a first flexible ledge substantially coextensive with a first side of said elongate channel slot and configured to flexibly coact with a first portion of said foot portion of said firing bar; and

a second flexible ledge substantially coextensive with a second side of said elongate channel slot and configured to flexibly coact with a second portion of said foot portion.

3. The surgical instrument of claim 1 wherein said firing member has a vertical portion and a pair of upper protrusions protruding therefrom and wherein said anvil has a flexible anvil structure comprising:

a first flexible anvil ledge formed therein; and

a second flexible anvil ledge formed therein and spaced from said first flexible anvil ledge to define an elongate anvil slot therebetween through which said vertical portion of said firing member may pass when said anvil is in said closed position such that one of said upper protrusions may flexibly coact with said first flexible ledge and the other of said upper protrusions may flexibly coact with said second anvil ledge.

4. The surgical instrument of claim 1 wherein at least portions of said staple forming undersurface of said anvil are movable relative to other portions of said anvil.

5. The surgical instrument of claim 4 wherein said anvil comprises:

an anvil body pivotally coupled to said cartridge supporting assembly and having an elongate anvil slot therein and wherein said staple forming undersurface comprises:

at least one right insert movably supported by said anvil body on a first side of said anvil slot and having a first staple forming undersurface thereon; and

at least one left insert movably supported by said anvil body on a left side of said anvil slot and having a second staple forming undersurface thereon.

6. The surgical instrument of claim 5 further comprising:

a right compliant member supported between each right insert and said anvil body; and

a left compliant member supported between each said left insert and said anvil body.

7. The surgical instrument of claim 6 wherein said right compliant member comprises at least one right bladder at least partially filled with a fluid medium and wherein said left compliant member comprises at least one left bladder at least partially filled with the fluid medium.

8. The surgical instrument of claim 7 wherein each of said right and left bladders are fluidically coupled to a fluid reservoir having a pressure adjustment mechanism operably

supported therein for selectively increasing or decreasing fluid pressure in said right and left bladders.

9. The surgical instrument of claim 5 wherein said at least one right insert comprises a plurality of right inserts that correspond in number to a number of right staples in a staple cartridge supported within said cartridge supporting assembly and wherein said at least one left insert comprises a plurality of left inserts that correspond in number to a number of left staples in the staple cartridge.

10. The surgical instrument of claim 9 further comprising:

at least one right biasing plate supported within said anvil body on a right side of said anvil slot and supporting a plurality of right biasing members wherein each said right biasing member corresponds to one of said right inserts; and

at least one left biasing plate supported within said anvil body on a left side of said anvil slot and supporting a plurality of left biasing members wherein each said left biasing member corresponds to one of said left inserts.

11. A method for processing an instrument for surgery, said method comprising:

obtaining said surgical instrument of claim 1;

sterilizing said surgical instrument; and

storing said instrument in a sterile container.

12. A surgical instrument, comprising:

an elongate staple channel having a first flexible portion and a second flexible portion spaced from said first flexible portion to define a longitudinal channel slot therebetween;

a staple cartridge operably supported within said elongate staple channel;

an elongate shaft operably coupled to said elongate staple channel;

an anvil pivotally attached to the elongate staple channel and being selectively pivotable between a closed position wherein a staple forming undersurface thereof is in confronting relationship to an upper surface of said staple cartridge supported within said elongate staple channel and an open position wherein a distal end of said anvil is spaced from said upper surface of said staple cartridge, said anvil having a longitudinal anvil slot therein;

a control handle assembly proximally operably coupled through the elongate shaft to selectively apply opening and closing motions to said anvil; and

a firing member operably coupled to the control handle assembly through said elongate shaft for selective longitudinal reciprocating motion in the elongate staple channel such that one portion of said firing member extends through said longitudinal anvil slot and another portion of said firing member extends through said longitudinal channel slot between said first and second flexible portions.

13. The surgical instrument of claim 12 wherein said firing member comprises:

a vertical portion wherein said one portion of said firing member comprises an upper end of said vertical portion

and wherein said another portion of said firing member comprises a lower end of said vertical portion;

an upper lateral surface extending from the upper end of said vertical portion positioned to exert an inward compressive force on the anvil during firing translation of said firing member therein; and

a foot portion extending from the lower end of the vertical portion positioned to exert an inward compressive force on the first and second flexible portions of said elongate staple channel during firing translation.

14. The surgical instrument of claim 13 wherein said foot portion has at least one resilient member thereon to bear upon a corresponding one of said first and second flexible portions of said elongate staple channel.

15. A surgical instrument comprising:

an elongate staple channel having a longitudinal channel slot;

a staple cartridge operably supported within said elongate staple channel;

an elongate shaft operably coupled to said elongate staple channel;

an anvil pivotally attached to the elongate staple channel and being selectively pivotable between a closed position wherein a staple forming undersurface thereof is in confronting relationship to an upper surface of said staple cartridge supported within said elongate staple channel and an open position wherein a distal end of said anvil is spaced from said upper surface of said staple cartridge, said anvil having a first resilient anvil portion and a second resilient anvil portion spaced from said first resilient anvil portion to define a portion of an elongate anvil slot therebetween;

a control handle assembly proximally operably coupled through the elongate shaft to selectively apply opening and closing motions to said anvil; and

a firing member operably coupled to the control handle assembly through said elongate shaft for selective longitudinal reciprocating motion in the elongate staple channel such that one portion of said firing member extends through said anvil slot between said first and second resilient anvil portions and another portion of said firing member extends through said longitudinal channel slot.

16. The surgical instrument of claim 15 wherein said firing member comprises:

a vertical portion wherein said one portion of said firing member comprises an upper end of said vertical portion and wherein said another portion of said firing member comprises a lower end of said vertical portion;

laterally extending pins protruding from the upper end of the vertical portion positioned to bear upon the first and second resilient portions of said anvil during firing translation of said firing member therein; and

a foot portion extending from the lower end of the vertical portion positioned to exert an inward compressive force on the elongate channel during firing translation.

17. The surgical instrument of claim 16 wherein said laterally extending pins are flexible relative to said upper end portion of said vertical portion of the firing member.

18. The surgical instrument of claim 15 wherein said first flexible portion of said anvil comprises at least one first staple insert movably supported within said anvil, said first staple insert having a first staple forming undersurface thereon and wherein said second flexible portion of said anvil comprises at least one second staple insert movably supported within said anvil and having a second staple forming undersurface thereon.

19. The surgical instrument of claim 18 further comprising:

at least one first compliant member corresponding to each said first staple insert and supported between said

corresponding first staple insert and a portion of said anvil; and

at least one second compliant member corresponding to each said second staple insert and supported between said corresponding second staple insert and another portion of said anvil.

20. The surgical instrument of claim 19 wherein each of said first and second compliant member is selected from the group of compliant members consisting of: springs, compressible polymer materials and fluid supporting bladders.

* * * * *

专利名称(译)	具有柔性通道和铁砧特征的外科缝合器械具有可调节的钉高度		
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摘要(译)

用于内窥镜或腹腔镜插入手术部位以同时缝合和切断组织的手术器械包括上颌（砧）和下颌（钉仓接合到细长钉通道）之间的力调节间隔，使得高度为钉的形成对应于组织的厚度，但是不超过钉的长度可以适应的高度范围。特别地，弹性结构可以形成支撑钉仓的细长通道中的一个或多个，可枢转地附接到细长通道的砧座，和/或包括切割组织的切割表面（刀）的击发构件在与砧座接合的顶销和与细长通道接合的下脚之间。弹性响应于被夹紧的组织施加的力，以改变砧座和支撑在细长通道内的钉仓之间的间隔。

