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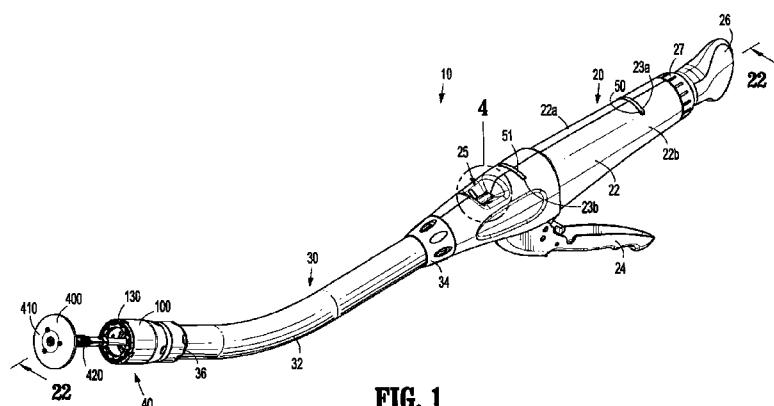
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(54) Title: SURGICAL STAPLING APPARATUS

**FIG. 1**

(57) **Abstract:** A surgical stapling apparatus (10) includes a tissue gap adjustment mechanism (260) having a stop member (250), an asymmetrical polygonal washer (264), and a set screw (262). The stop member (250) is supported on a drive screw (220), includes first and second flanges (255a, 255b), and defines a transverse slot (254) between the flanges (255a, 255b). The stop member (250) sets a minimum tissue gap. The washer (264) defines an eccentrically positioned aperture (268) and includes a plurality of pairs of opposed flat sides (269a-269h). The set screw (262) is configured to fix the stop member (250) relative to the drive screw (220). The washer (264) is selectively rotatable about the set screw (262) to position a selected pair of sides (269a-269h) between and in engagement with the flanges (255a, 255b) to set the position of the aperture (268) of the washer (264) relative to the transverse slot (254), thereby setting the stop member (250) relative to the drive screw (220) and defining the minimum tissue gap.

# SURGICAL STAPLING APPARATUS

## BACKGROUND

### *Technical Field*

**[0001]** The present disclosure relates generally to a surgical stapling apparatus for applying surgical staples to body tissue and, more particularly, to a surgical stapling apparatus for performing circular anastomosis of hollow tissue structures.

### *Background of Related Art*

**[0002]** Anastomosis refers to the surgical joining of separate hollow tissue sections. Typically, an anastomosis procedure follows surgery in which a diseased or defective section of a hollow tissue structure is removed, thus requiring the joining of the remaining sections of the tissue structure. Depending on the particular procedure being performed and/or other factors, the sections of the tissue may be joined by circular anastomosis, e.g., end-to-end anastomosis, end-to-side anastomosis, or side-to-side anastomosis.

**[0003]** In a circular anastomosis procedure, the two sections of a tubular organ are joined using a stapling apparatus that drives a circular array of staples through each of the sections to join the sections to one another in end-to-end, end-to-side, or side-to-side relation. Typically, any tissue within the newly joined hollow tissue structure is simultaneously cored to clear the passage defined by the hollow tissue structure.

**[0004]** A typical circular anastomosis apparatus includes an elongated shaft having a handle portion at a proximal end and a staple holding component at a

distal end. An anvil assembly including an anvil rod and an attached anvil head is mounted to the distal end of the elongated shaft adjacent the staple holding component. In use, the two sections of the tubular organ to be joined are clamped between the anvil head and the staple holding component. The clamped sections are then joined to one another by driving one or more staples from the staple holding component, through the tissue, and into the anvil head to form the staples about the tissue. Examples of such circular anastomosis apparatuses are described in U.S. Patent Nos. 7,857,187 to Milliman (“the Milliman ’187 patent”) and 6,945,444 to Gresham et al. (“the Gresham ’444 patent”), the entire contents of which are hereby incorporated by reference herein in their entireties.

**[0005]** Depending on the type, thickness, and/or other properties of the tissue structures to be joined, it may be desirable to provide a different “minimum tissue gap,” wherein the “minimum tissue gap” is defined as the distance between the anvil head and the staple holding component when the stapling apparatus is fully approximated. A need therefore exists for a tissue gap adjustment mechanism that facilitates adjustment of the minimum tissue gap between a plurality of tissue gap settings in a quick and efficient manner.

## SUMMARY

**[0006]** A surgical stapling apparatus provided in accordance with the present disclosure includes a handle portion, a body extending distally from the handle portion, a stapling assembly supported on a distal end of the body, an anvil assembly, a drive screw, and a tissue gap adjustment mechanism. The drive screw is supported within the handle portion and is operably coupled to the anvil assembly. The drive screw defines a transverse aperture and is movable relative to the stapling assembly to move the anvil assembly relative to the

stapling assembly between a spaced-apart position and an approximated position. The tissue gap adjustment mechanism is disposed within the handle portion and includes a stop member, an asymmetrical polygonal washer, and a set screw. The stop member is supported on the drive screw and includes first and second flanges which define a transverse slot. The stop member is configured to abut a stop surface within the handle portion to prevent further proximal movement of the drive screw within the handle portion and set a minimum tissue gap between the anvil assembly and the stapling assembly. The washer defines an eccentrically positioned aperture and includes a plurality of pairs of opposed flat sides. The washer is dimensioned to be positioned within the transverse slot such that each of the pairs of opposed flat sides can be selectively positioned between and in engagement with the first and second flanges. The set screw is configured for insertion through the aperture of the washer, the transverse slot, and the transverse aperture to fix the stop member relative to the drive screw. The washer is repositionable about the set screw to position a selected pair of the opposed flat sides between and in engagement with the first and second flanges. At least two of the pairs of opposed flat sides when engaged with the first and second flanges are spaced to position the aperture of the washer at different locations in relation to the transverse slot such that the position of the stop member in relation to the drive screw can be selectively varied by positioning a different pair of opposed flat sides in engagement with the first and second flanges to selectively change the minimum tissue gap.

- [0007] In embodiments, the washer defines an octagonal configuration.
- [0008] In embodiments, the washer is configured and dimensioned such that the minimum tissue gap is adjustable between about 4.55mm and about 5.45mm.
- [0009] In embodiments, the washer is configured and dimensioned such that

the minimum tissue gap is incrementally adjustable at a step size of about 0.15mm between about 4.55mm and about 5.45mm.

**[0010]** In embodiments, at least one indicator is disposed on the washer and an indicator is disposed on at least one of the flanges for indicating a selected setting of the tissue gap adjustment mechanism.

**[0011]** In embodiments, the set screw is configured to be loosened to facilitate rotation of the washer about the set screw and is configured to be tightened to fix the position of the washer and the stop member on the drive screw.

**[0012]** In embodiments, an approximation knob extends from the handle. The approximation knob is coupled to the drive screw and is selectively actuatable to move the anvil assembly between the spaced-apart position and the approximated position.

**[0013]** In embodiments, the drive screw defines a helical channel and the approximation knob is coupled to a ball disposed within the helical channel such that rotation of the approximation knob effects translation of the drive screw.

**[0014]** In embodiments, a firing assembly including a trigger coupled to the handle and a firing link coupled to the stapling assembly is provided. The firing link is configured for distal translation through the body in response to actuation of the trigger to eject a plurality of surgical staples from the stapling assembly.

**[0015]** In embodiments, the handle is formed from first and second handle sections that are releasably engagable with one another.

**[0016]** Another surgical stapling apparatus provided in accordance with the present disclosure includes a stapling assembly, an anvil assembly, a drive screw operably coupled to the anvil assembly, an approximation member, and a tissue gap adjustment mechanism. The approximation member is coupled to the drive

screw and is selectively actuatable to move the drive screw relative to the stapling assembly to move the anvil assembly relative to the stapling assembly between a spaced-apart position and an approximated position. The tissue gap adjustment mechanism includes a stop member supported on the drive screw. The stop member includes first and second flanges which define a transverse slot. The stop member is configured to limit movement of the drive screw relative to the stapling assembly to set a minimum tissue gap between the anvil assembly and the stapling assembly. An asymmetrical polygonal washer defining an eccentrically positioned aperture and including a plurality of pairs of opposed flat sides is dimensioned to be positioned within the transverse slot such that each of the pairs of opposed flat sides can be selectively positioned between and in engagement with the first and second flanges. A post is supported on the drive screw. The post is positioned to axially fix the stop member relative to the drive screw. The washer is repositionable about the post to position a selected pair of the opposed flat sides between and in engagement with the first and second flanges. At least two of the pairs of opposed flat sides when engaged with the first and second flanges are spaced to position the aperture of the washer at different locations within the transverse slot such that the position of the stop member in relation to the drive screw can be selectively varied by positioning a different pair of opposed flat sides in engagement with the first and second flanges to selectively change the minimum tissue gap between the anvil assembly and the stapling assembly.

- [0017] In embodiments, the washer defines an octagonal configuration.
- [0018] In embodiments, the washer is configured and dimensioned such that the minimum tissue gap is adjustable between about 4.55mm and about 5.45mm.
- [0019] In embodiments, the washer is configured and dimensioned such that

the minimum tissue gap is incrementally adjustable at a step size of about 0.15mm between about 4.55mm and about 5.45mm.

**[0020]** In embodiments, at least one indicator is disposed on the washer and an indicator is disposed on at least one of the flanges for indicating a selected setting of the tissue gap adjustment mechanism.

**[0021]** In embodiments, the surgical stapling apparatus further includes a handle portion defining a proximal end and a distal end. The drive screw is supported within the handle portion and the stop member is configured to abut a stop surface within the handle portion to limit movement of the drive screw relative to the stapling assembly to set the minimum tissue gap between the anvil assembly and the stapling assembly.

**[0022]** In embodiments, the surgical stapling apparatus further includes a body extending distally from the handle portion. The stapling assembly is supported on a distal end of the body.

**[0023]** A method of setting a minimum tissue gap tissue between an anvil assembly and a stapling assembly of a surgical stapling apparatus is also provided in accordance with the present disclosure. The surgical stapling apparatus includes a handle portion, a body extending from the handle portion and having the stapling assembly supported thereon, and a drive screw. The drive screw is supported within the handle portion and is operably coupled to the anvil assembly. The drive screw is movable relative to the stapling assembly to move the anvil assembly relative to the stapling assembly. The method includes positioning a stop member about the drive screw. The stop member includes first and second flanges which define a transverse slot. The stop member is configured to abut a stop surface within the handle portion to prevent further proximal movement of the drive screw within the handle portion and set a

minimum tissue gap between the anvil assembly and the stapling assembly. The method further includes positioning an asymmetrical polygonal washer defining an eccentrically positioned aperture and including a plurality of pairs of opposed flat sides between the first and second flanges such that a selected pair of the opposed flat sides are positioned between and in engagement with the first and second flanges to define a first minimum tissue gap. The method further includes securing the stop member to the drive screw with the washer positioned within the transverse slot and the selected pair of opposed flat sides positioned between the first and second flanges.

**[0024]** In embodiments, the method further includes un-securing the stop member from the drive screw, repositioning the washer to engage a different pair of the opposed flat sides between the first and second flanges to axially reposition the stop member relative to the drive screw to define a second minimum tissue gap, and re-securing the stop member to the drive screw to fix the position of the washer and the stop member on the drive screw.

**[0025]** In embodiments, the method further includes confirming a desired position of the washer by viewing indicators disposed on the washer and at least one of the flanges that indicate a selected position of the washer.

**[0026]** Another surgical stapling apparatus provided in accordance with the present disclosure includes a handle portion defining a proximal end and a distal end, a body extending distally from the handle portion, a stapling assembly supported on a distal end of the body, a firing assembly, and a trigger lock assembly. The firing assembly includes a firing trigger extending from the handle portion, a firing link coupling the firing trigger to the handle portion, and a pusher link coupled to the firing trigger and extending through the body. The pusher link is movably supported for distal translation through the body in

response to actuation of the firing trigger to eject the plurality of surgical staples from the stapling assembly. The trigger lock assembly includes a trigger lock member and a biasing member. The trigger lock member is pivotably coupled to the firing trigger and is movable relative to the firing trigger between a locked position, wherein the trigger lock abuts the firing link to inhibit actuation of the firing trigger, and an unlocked position, wherein the trigger lock is displaced from the firing link to permit actuation of the firing trigger. In the locked position of the trigger lock, the biasing member is positioned to bias the trigger lock towards the locked position. In the unlocked position of the trigger lock, the biasing member is positioned to bias the trigger lock towards the unlocked position.

**[0027]** In embodiments, the biasing member includes a coiled portion and a flat portion extending from the coiled portion. The flat portion is positioned to engage and bias the trigger lock towards the locked position when the trigger lock is disposed in the locked position and to engage and bias the trigger lock towards the unlocked position when the trigger lock is disposed in the unlocked position.

**[0028]** In embodiments, a first pivot member pivotably couples the firing link to the firing trigger. In such embodiments, the coiled portion of the biasing member may be disposed about the first pivot member.

**[0029]** In embodiments, the trigger lock includes an asymmetrical base member defining first and second contact surfaces on opposite sides of the base member. The biasing member is positioned to contact the first contact surface to bias the trigger lock towards the locked position and to contact the second contact surface to bias the trigger lock towards the unlocked position.

**[0030]** In embodiments, the base member of the trigger lock defines a

throughbore configured to receive a second pivot member for pivotably coupling the trigger lock to the firing trigger.

**[0031]** In embodiments, the surgical stapling apparatus further includes an anvil assembly configured to form the plurality of surgical staples ejected from the stapling assembly about tissue and a drive screw supported within the handle portion. The drive screw is operably coupled to the anvil assembly and is movable relative to the stapling assembly to move the anvil assembly relative to the stapling assembly between a spaced-apart position and an approximated position

**[0032]** In embodiments, the surgical stapling apparatus further includes an approximation knob extending from the handle portion. The approximation knob is coupled to the drive screw and is selectively actuatable to move the anvil assembly between the spaced-apart position and the approximated position.

**[0033]** In embodiments, the drive screw defines a helical channel and the approximation knob is coupled to a ball disposed within the helical channel such that rotation of the approximation knob effects translation of the drive screw.

**[0034]** In embodiments, the firing trigger includes a lockout member configured to interface with the drive screw to prevent actuation of the firing trigger when the anvil assembly is disposed in the spaced-apart position.

**[0035]** In embodiments, the drive screw defines a recess such that when the anvil assembly is disposed in the approximated position, the recess is aligned with the lockout member to permit actuation of the firing trigger.

**[0036]** In embodiments, the handle is formed from first and second handle sections, the first and second handle sections being releasably engagable with one another.

**[0037]** Another surgical stapling apparatus provided in accordance with the

present disclosure includes a handle portion defining a proximal end and a distal end, a body extending distally from the handle portion, a stapling assembly supported on a distal end of the body and including a plurality of surgical staples, a firing assembly, and a trigger lock assembly. The firing assembly includes a firing trigger coupled to and extending from the handle portion and a pusher link coupled to the firing trigger and extending through the body. The pusher link is movably supported for distal translation through the body in response to actuation of the firing trigger to eject the plurality of surgical staples from the stapling assembly. The trigger lock assembly includes a trigger lock member and a biasing member. The trigger lock member is pivotably coupled to the firing trigger and includes an asymmetrical base member defining first and second contact surfaces on opposite sides of the base member. The trigger lock is movable relative to the firing trigger between a locked position, wherein the trigger lock abuts the firing link to inhibit actuation of the firing trigger, and an unlocked position, wherein the trigger lock is displaced from the firing link to permit actuation of the firing trigger. In the locked position of the trigger lock, the biasing member is positioned to contact the first contact surface to bias the trigger lock towards the locked position and, in the unlocked position of the trigger lock, the biasing member is positioned to contact the second contact surface to bias the trigger lock towards the unlocked position.

**[0038]** In embodiments, the biasing member includes a coiled portion and a flat portion extending from the coiled portion. The flat portion is positioned to contact the first contact surface to bias the trigger lock towards the locked position when the trigger lock is disposed in the locked position and to contact the second contact surface to bias the trigger lock towards the unlocked position when the trigger lock is disposed in the unlocked position.

**[0039]** In embodiments, the firing assembly includes a firing link coupling the firing trigger to the handle portion.

**[0040]** In embodiments, a first pivot member pivotably couples the firing link to the firing trigger. The biasing member is at least partially disposed about the first pivot member.

**[0041]** In embodiments, the base member of the trigger lock defines a throughbore configured to receive a second pivot member for pivotably coupling the trigger lock to the firing trigger.

**[0042]** In embodiments, the surgical stapling apparatus further includes an anvil assembly configured to form the plurality of surgical staples ejected from the stapling assembly about tissue, and a drive screw supported within the handle portion. The drive screw is operably coupled to the anvil assembly and is movable relative to the stapling assembly to move the anvil assembly relative to the stapling assembly between a spaced-apart position and an approximated position

**[0043]** In embodiments, the surgical stapling apparatus further includes an approximation knob extending from the handle portion. The approximation knob is coupled to the drive screw and is selectively actuatable to effect linear movement of the drive screw and to move the anvil assembly between the spaced-apart position and the approximated position.

**[0044]** In embodiments, the firing trigger includes a lockout member configured to interface with the drive screw to prevent actuation of the firing trigger when the anvil assembly is disposed in the spaced-apart position.

**[0045]** In embodiments, the drive screw defines a recess. When the anvil assembly is disposed in the approximated position, the recess is aligned with the lockout member to permit actuation of the firing trigger.

**[0046]** Another surgical stapling apparatus provided in accordance with the present disclosure includes a handle portion defining a proximal end and a distal end. The handle portion includes at least one support member and first and second handle sections movably coupled to the at least one support member via a pin-slot engagement such that the first and second handle sections are translatable and rotatable relative to each other and the at least one support member from a closed position, wherein the first and second handle sections are in close alignment, and an open position, wherein the first and second handle sections are separated from each other to expose an interior of the handle portion. A body extends distally from the handle portion and a stapling assembly is supported on a distal end of the body. The stapling assembly includes a plurality of surgical staples.

**[0047]** In embodiments, the surgical stapling apparatus further includes a firing assembly including a firing trigger and a pusher link coupled to the firing trigger. The pusher link is configured for distal translation through the elongated body portion in response to actuation of the firing trigger to eject the plurality of surgical staples from the stapling assembly.

**[0048]** In embodiments, the firing trigger extends from the handle portion and the first and second handle sections define cut-outs that cooperate to define a slot when the handle sections are disposed in the closed position to permit extension of the firing trigger therethrough.

**[0049]** In embodiments, the firing assembly includes a firing link coupling the firing trigger to the handle portion. A pivot member may be provided for pivotably coupling the firing link to each of the first and second handle sections.

**[0050]** In embodiments, each of the first and second handle sections includes a threaded distal extension. A threaded bushing is disposed about the

body and is configured for engagement with the threaded distal extensions of the first and second handle sections to retain the first and second handle sections in the closed position and secure the body to the distal end of the handle portion.

**[0051]** In embodiments, the surgical stapling apparatus further includes an anvil assembly and an approximation assembly operably coupled to the anvil assembly. At least a portion of the approximation assembly is supported within the handle portion via the at least one support member. The approximation assembly is movable relative to the stapling assembly to move the anvil assembly relative to the stapling assembly between a spaced-apart position and an approximated position.

**[0052]** In embodiments, the at least one support member includes first and second support members. The first and second support members support the portion of the approximation assembly within the handle portion and are spaced-apart from one another.

**[0053]** In embodiments, the at least one support member is configured to abut a portion of the approximation assembly when the anvil assembly is disposed in the approximated position to prevent further axial movement of the anvil assembly in relation to the stapling assembly to set a minimum tissue gap between the anvil assembly and the stapling assembly.

**[0054]** In embodiments, the approximation assembly includes an approximation knob extending proximally from the handle portion. The approximation knob is selectively rotatable relative to the handle portion to move the anvil assembly relative to the stapling assembly. Each of the first and second handle sections includes a threaded proximal extension. A threaded collar disposed about the approximation knob is configured for engagement with the threaded proximal extensions of the first and second handle sections to retain

the first and second handle sections in the closed position and rotatably secure the approximation knob to the proximal end of the handle portion.

**[0055]** Another surgical stapling apparatus provided in accordance with the present disclosure includes a handle portion defining a proximal end and a distal end. The handle portion includes at least one support member and first and second handle sections movably coupled to the at least one support member such that the first and second handle sections are movable relative to each other and the at least one support member from a closed position, wherein the first and second handle sections are in close alignment, and an open position, wherein the first and second handle sections are separated from each other to expose an interior of the handle portion. The surgical stapling apparatus further includes a body extending distally from the handle portion, a stapling assembly supported on a distal end of the body and including a plurality of surgical staples, an anvil assembly, and an approximation assembly operably coupled to the anvil assembly. A portion of the approximation assembly is supported within the handle portion via the at least one support member. The approximation assembly is movable relative to the stapling assembly to move the anvil assembly relative to the stapling assembly between a spaced-apart position and an approximated position.

**[0056]** In embodiments, the first and second handle sections are movably coupled to the at least one support member via a pin-slot engagement such that the first and second handle sections are translatable and rotatable relative to each other and the at least one support member from the closed position to the open position.

**[0057]** In embodiments, each of the first and second handle sections includes a threaded distal extension. A threaded bushing disposed about the

body is configured for engagement with the threaded distal extensions of the first and second handle sections to retain the first and second handle sections in the closed position and secure the body to the distal end of the handle portion.

**[0058]** In embodiments, the surgical stapling apparatus further includes a firing assembly including a firing trigger and a pusher link coupled to the firing trigger. The pusher link is configured for distal translation through the elongated body portion in response to actuation of the firing trigger to eject the plurality of surgical staples from the stapling assembly.

**[0059]** In embodiments, the firing trigger extends from the handle portion and the first and second handle sections define cut-outs that cooperate to define a slot when the handle sections are disposed in the closed position to permit extension of the firing trigger therethrough.

**[0060]** In embodiments, the firing assembly includes a firing link coupling the firing trigger to the handle portion. A pivot member may be provided for pivotably coupling the firing link to each of the first and second handle sections.

**[0061]** In embodiments, the at least one support member includes first and second support members supporting the portion of the approximation assembly within the handle portion and being spaced-apart from one another.

**[0062]** In embodiments, the at least one support member is configured to abut a portion of the approximation assembly when the anvil assembly is disposed in the approximated position to prevent further movement of the anvil assembly in relation to the stapling assembly to set a minimum tissue gap between the anvil assembly and the stapling assembly.

**[0063]** In embodiments, the approximation assembly includes an approximation knob extending proximally from the handle portion. The approximation knob is selectively rotatable relative to the handle portion to

move the anvil assembly relative to the stapling assembly. Each of the first and second handle sections includes a threaded proximal extension. A threaded collar disposed about the approximation knob is configured for engagement with the threaded proximal extensions of the first and second handle sections to retain the first and second handle sections in the closed position and rotatably secure the approximation knob to the proximal end of the handle portion.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0064]** Various embodiments of the presently disclosed surgical stapling apparatus are described herein with reference to the drawings wherein:

**[0065]** FIG. 1 is a top, side, perspective view from the distal end of the presently disclosed surgical stapling apparatus;

**[0066]** FIG. 2 is a side, perspective view of the handle portion of the surgical stapling apparatus of FIG. 1 wherein one of the handle sections has been removed to show the internal components of the handle portion;

**[0067]** FIG. 3 is an exploded, perspective view of the surgical stapling apparatus of FIG. 1;

**[0068]** FIG. 3A is a top view of the proximal end of the surgical stapling apparatus of FIG. 1;

**[0069]** FIG. 3B is transverse, cross-sectional view taken along section line 3B-3B of FIG. 3A;

**[0070]** FIG. 3C is transverse, cross-sectional view taken along section line 3C-3C of FIG. 3A;

**[0071]** FIG. 3D is a side, perspective view of the proximal end of the surgical stapling apparatus of FIG. 1 illustrating disengagement of the bushing and the collar from the handle portion;

[0072] FIG. 3E is an enlarged, cross-sectional view of the proximal end of the surgical stapling apparatus of FIG. 1 illustrating the initial separation of the handle sections of the handle portion from a closed position towards an open position;

[0073] FIG. 3F is an enlarged, perspective view of the handle portion of the surgical stapling apparatus of FIG. 1 with the handle sections of the handle portion disposed in an open position;

[0074] FIG. 4 is an enlarged view of the area of detail indicated as “4” in FIG. 1;

[0075] FIG. 5 is an exploded, perspective view of the approximation assembly of the surgical stapling apparatus of FIG. 1;

[0076] FIG. 5A is a side perspective view of an embodiment of the set screw of the tissue gap adjustment mechanism;

[0077] FIG. 6 is a side, perspective view of the proximal end of the handle portion of the surgical stapling apparatus of FIG. 1 with the handle sections removed and the proximal portions of the firing assembly and approximation assembly illustrated;

[0078] FIG. 7 is an enlarged view of the area of detail indicated as “7” in FIG. 6;

[0079] FIG. 8 is a side, perspective view of the approximation assembly of the surgical stapling apparatus of FIG. 1;

[0080] FIG. 9 is an enlarged view if the area of detail indicated as “9” in FIG. 8;

[0081] FIG. 9A is an exploded, perspective view of the tissue gap adjustment mechanism of the surgical stapling apparatus of FIG. 1;

[0082] FIG. 9B is an enlarged, top view of the adjustment washer of the

tissue gap adjustment mechanism of FIG. 9A;

[0083] FIG. 10 is a perspective view of the staple pusher assembly of the surgical stapling apparatus of FIG. 1;

[0084] FIG. 11 is an exploded, perspective view of the staple pusher assembly of FIG. 10;

[0085] FIG. 11A is an enlarged, cross-sectional view of the proximal end of the firing assembly with the trigger lock disposed in a locked position;

[0086] FIG. 11B is an enlarged, cross-sectional view of the proximal end of the firing assembly with the trigger lock disposed in an unlocked position;

[0087] FIG. 12 is a side, perspective view from the distal end of the elongated body portion of the surgical stapling apparatus of FIG. 1;

[0088] FIG. 13 is an enlarged, perspective view of the proximal end of the elongated body portion of FIG. 12;

[0089] FIG. 14 is a perspective view from the distal end of the distal bushing of the elongated body portion of FIG. 12;

[0090] FIG. 15 is an exploded, perspective view of the elongated body portion of FIG. 12;

[0091] FIG. 16 is a perspective view from the proximal end of the proximal bushing of the elongated body portion of FIG. 12;

[0092] FIG. 17 is a perspective view of the distal end of the surgical stapling apparatus of FIG. 1 including a safety cap disposed about the distal end of the replaceable stapling assembly of the surgical stapling apparatus of FIG. 1;

[0093] FIG. 18 is a perspective of the distal end of the surgical stapling apparatus of FIG. 1 including the safety cap removed from the distal end of the replaceable stapling assembly;

[0094] FIG. 19 is a perspective view from the proximal end of the

replaceable stapling assembly of the surgical stapling apparatus of FIG. 1;

**[0095]** FIG. 20 is a perspective view from the distal end of the replaceable stapling assembly of the surgical stapling apparatus of FIG. 1;

**[0096]** FIG. 21 is an exploded, perspective view of the replaceable stapling assembly of FIGS. 19 and 20;

**[0097]** FIG. 22 is a longitudinal, cross-sectional view taken along section line 22-22 of FIG. 1;

**[0098]** FIG. 23 is an enlarged view of the area of detail indicated as "23" in FIG. 22; and

**[0099]** FIG. 24 is an enlarged view of the area of detail indicated as "24" in FIG. 22.

#### DETAILED DESCRIPTION OF EMBODIMENTS

**[00100]** Embodiments of the presently disclosed surgical stapling apparatus will now be described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. Throughout this description, the term "proximal" will refer to the portion of the apparatus closest to the user and the term "distal" will refer to the portion of the apparatus farthest from the user.

**[00101]** FIGS. 1-24 illustrate an embodiment of the presently disclosed surgical stapling apparatus designated generally by reference numeral 10. Surgical stapling apparatus 10 includes a proximal handle portion 20, an elongated central body portion 30, and a distal head portion 40. Alternatively, it may be desirable to have a substantially straight, shortened central body portion in some surgical procedures, e.g., the treatment of hemorrhoids. The length, shape and/or the diameter of any of the proximal handle portion 20, the central

body portion 30, and the distal head portion 40 may also be selected to suit a particular surgical purpose or procedure. Surgical stapling apparatus 10 further includes an anvil assembly 400 coupled at the distal end of distal head portion 40. Anvil assembly 400 includes an anvil head assembly 410 and an anvil center rod assembly 420. Although not described in detail herein, anvil assembly 400 may be configured to include any or all of the features of the anvil assemblies described in the Milliman '187 patent or the Gresham '444 patent, previously incorporated by reference herein in their entireties.

**[00102]** The various components of surgical stapling apparatus 10 described hereinbelow are configured to facilitate the assembly and disassembly of surgical stapling apparatus 10, thus facilitating the disposal and replacement of those components that are disposable and the sterilization and reassembly of those components that are reusable. The materials used to form the various components of surgical stapling apparatus 10 will depend upon the strength requirements of the particular component and the use requirements of the particular component, e.g., whether the component is reusable or disposable. The reusable components, for example, may generally be formed from thermoplastics including polycarbonates, and metals including stainless steel and aluminum, that are suited to withstand repeated sterilization procedures, e.g., autoclaving.

**[00103]** Referring to FIGS. 1-3, proximal handle portion 20 of surgical stapling apparatus 10 includes a stationary handle 22, a firing trigger 24, and a rotatable approximation knob 26. Stationary handle 22 is formed from first and second releasably engagable handle sections 22a, 22b (FIG. 3) that cooperate to house and support the internal components of handle portion 20, e.g., the proximal components of an approximation assembly 200 (FIG. 3) and a firing

assembly 300 (FIG. 3). Proximal handle portion 20 and the internal components thereof will be described in greater detail below.

**[00104]** As mentioned above, stationary handle 22 is formed from first and second handle sections 22a, 22b that cooperate to house and support the internal components of handle portion 20. Alternatively, stationary handle 22 may be unitarily formed or formed from multiple handle sections. Handle sections 22a, 22b can be configured as reusable, sterilizable components, or, alternatively, can be configured as disposable components.

**[00105]** Referring specifically to FIG. 3, each handle section 22a, 22b includes a threaded distal extension 22c, 22d. Distal extensions 22c, 22d cooperate to define a generally annular threaded member for releasably engaging proximal bushing 34 of central body portion 30. Engagement between distal extensions 22c, 22d and proximal bushing 34 releasably secures outer tube 32 and handle portion 20 to one another and also secures handle sections 22a, 22b to one another at the distal ends thereof. As an alternative to threaded engagement, proximal bushing 34 may be releasably engaged about distal extensions 22c, 22d of handle sections 22a, 22b via any other suitable mechanism including friction-fitting, snap-fitting, luer-locking, inter-fitting, etc. Handle sections 22a, 22b further include threaded proximal extensions 22e, 22f, respectively, that cooperate to define a generally annular threaded member for releasably engaging collar 27 of approximation knob 26. Similarly as above, engagement between proximal extensions 22e, 22f and collar 27 rotatably secures approximation knob 26 and handle portion 20 to one another and also secures handle sections 22a, 22b to one another at the proximal ends thereof. Collar 27 is rotatably secured to approximation knob 26. Alternatively, collar 27 can be formed separately from approximation knob 26.

**[00106]** Referring also to FIGS. 3A-3C, handle sections 22a, 22b are pivotably coupled to one another via a pair of support members, e.g., support discs 50, 51, and a plurality of pin-slots engagements. Support discs 50, 51 each define an upper engagement portion 52, 53 and a lower generally annular portion 54, 55 defining a respective aperture 54a, 55a. Upper engagement portions 52, 53 of support discs 50, 51 are disposed within respective slots 23a, 23b (FIG. 3A) defined by cooperating slot portions of handle sections 22a, 22b. A pair of pins 56a, 57a extend through respective apertures defined within handle sections 22a, 22b on opposite sides of each of slots 23a, 23b and through slots 56, 57 defined through upper engagement portions 52, 53 of support discs 50, 51 to pivotally secure handle sections 22a, 22b to support discs 50, 51 and to one another. Slots 56, 57 are dimensioned to permit lateral translation of pins 56a, 57a along slots 56, 57 and relative to one another as well as rotation of pins 56a, 57a within slots 56, 57. Apertures 54a, 55a defined by the lower portions 54, 55 of support discs 50, 51, respectively, are configured to receive rotatable sleeve 210 and indicator bar 270 of approximation assembly 200. The lower portions 54, 55 of support discs 50, 51 are configured to position and support approximation assembly 200 within stationary handle 22. As will be described in detail below with respect to the disassembly of stationary handle 22, the slot-pin engagement of handle sections 22a, 22b and support discs 50, 51 allows for translational and rotational movement of handle sections 22a, 22b relative to one another between a closed position (FIG. 3A), wherein stationary handle 22 encloses the proximal components of approximation assembly 200 and firing assembly 300, and an open position (FIG. 3F), wherein access to approximation assembly 200 and firing assembly 300 is provided to facilitate replacement of any or all of such components.

**[00107]** Referring to FIGS. 4 and 5, stationary handle 22 defines an indicator window 25 through which visual indicators 276, 278 disposed on indicator bar 270 may be viewed. Indicator window 25 may be formed via a hole or aperture defined by one or both of handle sections 22a, 22b. Alternatively, indicator window 25 may be formed from a transparent portion of one or both of handle sections 22a, 22b. Visual indicators 276, 278 are longitudinally-spaced along indicator bar 270 and, when visible through indicator window 25, indicate the position of anvil assembly 400 (FIG. 1) in relation to stapling assembly 100, e.g., whether the anvil assembly 400 (FIG. 1) is in a position spaced-apart from stapling assembly 100 (visual indicator 276) or an approximated position in juxtaposed alignment with stapling assembly 100 (visual indicator 278). Approximation assembly 200 is detailed below.

**[00108]** Referring to FIGS. 5-9, approximation assembly 200 of surgical stapling apparatus 10 (FIG. 1) includes an approximation knob 26, a collar 27, a rotatable sleeve 210, a drive screw 220, a screw extension 230, an anvil retainer 240, a screw stop 250, and a tissue gap adjustment mechanism 260.

**[00109]** Rotatable sleeve 210 includes a substantially cylindrical hollow body portion 211 and a distal housing 212 that cooperate to define a central bore 213. A clip 214 is received within an annular groove 214a formed about body portion 211. Support disc 50, as mentioned above, is configured to receive body portion 211 through aperture 54a thereof. Clip 214 and distal housing 212 abut support disc 50 on either side thereof to axially fix sleeve 210 and stationary handle 22 relative to one another while permitting rotation of sleeve 210 in relation to stationary handle 22.

**[00110]** With particular reference to FIG. 5, rotatable sleeve 210 further includes a ball detent assembly 215 having a plug 216 and a detent member. In

an embodiment, the detent member includes a ball 218. Ball 218 extends into central bore 213 of rotatable sleeve 210 from a recess 217 of distal housing 212 and is received in a helical channel 221 of drive screw 220. Plug 216 includes a body 216a configured for receipt within recess 217 and defines a semi-spherical concavity (not explicitly shown) for receiving a side of ball 218 opposite screw 220, and a head 216b configured for engagement with distal housing 212, e.g., via threaded-engagement, friction-fitting, etc. Once engaged with distal housing 212, plug 216 inhibits ball 218 from backing out of helical channel 221 of screw 220. In embodiments, the recess 217 can be defined only as a spherical recess (not shown) on an inner wall of the distal housing 212 which is configured to receive ball 218. In this embodiment, the plug 216 is not required.

**[00111]** A proximal end of body portion 211 of rotatable sleeve 210 extends through an opening 21 in a proximal end of stationary handle 22. Approximation knob 26 is affixed to the proximal end of body portion 211 of rotatable sleeve 210 such that rotation of knob 26 causes concurrent rotation of rotatable sleeve 210. Approximation knob 26 may be releasably or permanently affixed to rotatable sleeve 210, e.g., via snap-fitting, friction-fitting, an adhesive, welding, and/or mechanical fasteners. Approximation knob 26 and/or the proximal end of body portion 211 of rotatable sleeve 210 may include one or more complementary protrusions and/or slots (not explicitly shown) to rotatably fix approximation knob 26 relative to sleeve 210.

**[00112]** Referring again to FIGS. 5-9, a proximal portion 220a of screw 220 includes helical channel 221 and is dimensioned to be slidably positioned within central bore 213 (FIG. 5) of rotatable sleeve 210. As mentioned above, ball 218 (FIG. 5) of ball detent mechanism 215 extends into helical channel 221 of screw 220. Since sleeve 210 is axially fixed with respect to stationary handle 22,

rotation of sleeve 210 about screw 220 causes ball 218 (FIG. 5) to move along channel 221 of screw 220 to effect axial movement of screw 220 within stationary handle 22. Although shown having helical channel 221 configured to receive ball 218 (FIG. 5), it is envisioned that screw 220 may alternatively include a helical thread (not shown) on an outer surface thereof configured to be received within a channel or groove (not shown) formed on an inner surface of sleeve 210. Further, as an alternative to ball detent assembly 215, approximation assembly 200 may include a pin or other suitable mechanism for operably coupling rotatable sleeve 210 and screw 220 to one another.

**[00113]** Distal portion 220b of screw 220 defines a transverse slot 227a and a pair of throughbores 227b formed perpendicular to transverse slot 227a. Transverse slot 227a is configured to receive a proximal end of screw extension 230 and throughbores 227b are configured to receive pins 226 for securing screw extension 230 to screw 220.

**[00114]** Indicator bar 270 is positioned between proximal portion 220a and distal portion 220b of screw 220. Indicator bar 270 is seated within a longitudinal recess 272 defined along screw 220 and may be secured therein in any suitable manner, e.g., via snap-fitting, friction-fitting, an adhesive, welding, and/or mechanical fasteners. As detailed above, indicator bar 270 includes first and second indicators 276, 278 configured to be viewed through indicator window 25 (FIG. 4) to provide an indication that the anvil assembly 400 (FIG. 1) is in the spaced-apart position or the approximated position, respectively. Indicators 276, 278 may be of any suitable color(s), symbol(s) or may include any other suitable feature, e.g., reflective features, a light source (LED), etc., to facilitate the visualization of visual indicators 276, 278 through window 25 (FIG. 4). Other suitable indicator mechanisms are disclosed in the Milliman '187

patent and the Gresham '444 patent, previously incorporated by reference herein in their entirety.

**[00115]** With continued reference to FIGS. 5-9, screw extension 230 includes a flexible flat band having proximal and distal portions 232, 234. Although shown including only a single flexible flat band, it is envisioned that screw extension 230 may include more than one flexible flat band. Alternately, it is envisioned that screw extension 230 may have other than a flexible flat band configuration. For example, screw extension 230 may be semi-circular or circular in cross-section. The flexibility of screw extension 230 permits movement of screw extension 230 through curved elongated outer tube 32 (FIG. 3). Proximal portion 232 of screw extension 230 includes a pair of holes 233 dimensioned to receive pins 226 for securing proximal portion 232 of screw extension 230 within transverse slot 227a of screw 220. Alternatively, other fastening techniques may be used to secure screw extension 230 to screw 220, e.g., welding, crimping, etc. Distal portion 234 of screw extension 230 is configured to be received within a transverse slot 241a formed in a proximal end 242 of anvil retainer 240 to fasten anvil retainer 240 to distal end 234 of screw extension 230. In the illustrated embodiment, a pair of pins 244 extend through a pair of openings 241b defined in proximal end 242 of anvil retainer 240 and holes 235 in distal portion 234 of screw extension 230 to secure screw extension 230 to anvil retainer 240. Alternately, distal portion 234 of screw extension 230 may be secured within slot 241a using any other fastening technique, e.g., screws, crimping, brazing, welding or the like, suitable for securing distal portion 234 of screw extension 230 to anvil retainer 240.

**[00116]** Anvil retainer 240 includes a trocar portion 245a, a body portion 245b, and an attachment portion 245c. Trocar portion 245a includes a blunt

trocar tip 247, although other configurations are also contemplated. Body portion 245b is substantially cylindrical and has a diameter which is larger than the diameter of trocar portion 245a. An annular protrusion 248 is disposed about body portion 245b of anvil retainer 240 and is configured to engage anvil assembly 400 (FIG. 1) to retain anvil assembly 400 (FIG. 1) about anvil retainer 240. Alternatively, protrusion 248 need not be annular or may include different attachment structure, e.g., recesses, grooves, etc.

**[00117]** In use, when approximation knob 26 is manually rotated, rotatable sleeve 210 is likewise rotated about the proximal portion 220a of screw 220. Since sleeve 210 is axially fixed with respect to stationary handle 22, and with ball 218 (FIG. 5) disposed within helical channel 221 of screw 220, axial rotation of sleeve 210 about screw 220 causes ball 218 to move along channel 221 of screw 220 to thereby urge screw 220 to translate axially within stationary handle 22 and relative to sleeve 210. Upon axial translation of screw 220, screw extension 230, which is fastened to the distal end of screw 220, and anvil retainer 240, which is fastened to the distal end of screw extension 230, are moved axially through outer tube 32 of elongated body portion 30. Thus, referring particularly to FIG. 1, with anvil assembly 400 releasably engaged about the distal end of anvil retainer 240, knob 26 may be rotated to effect movement of anvil assembly 400 relative to stapling assembly 100 between an unapproximated position spaced-apart from stapling assembly 100 and an approximated position positioned adjacent to stapling assembly 100.

**[00118]** With additional reference to FIGS. 9A-9B, approximation assembly 200 further includes a screw stop 250 disposed about screw 220 and configured to function as a proximal stop for defining the minimum tissue gap between anvil assembly 400 and stapling assembly 100 (see FIG. 1). More specifically,

when stapling device 10 is in a fully approximated position, screw stop 250 abuts at stop surface formed at the distal end of distal housing 212 of rotatable sleeve 210, inhibiting further proximal translation of screw 220 within stationary handle 22, thereby defining the minimum tissue gap between anvil assembly 400 and stapling assembly 100 (see FIG. 1). Tissue gap adjustment mechanism 260 adjustably couples screw stop 250 to screw 200 to facilitate adjustment of the minimum tissue gap by adjusting the longitudinal position of screw stop 250 on screw 220. Tissue gap adjustment mechanism 260 is described in detail below.

**[00119]** Tissue gap adjustment mechanism 260, as mentioned above, is configured to selectively adjust the longitudinal position of screw stop 250 on screw 220, thereby enabling discrete adjustment of the minimum tissue gap between anvil assembly 400 and stapling assembly 100 (see FIG. 1). In particular, tissue gap adjustment mechanism 260 may be configured to permit adjustment of the minimum tissue gap through a plurality of pre-determined interval steps, e.g., a step size of about 0.15mm, between about 4.55mm and about 5.45mm, although a greater or lesser range and/or greater or lesser interval step sizes are also contemplated, depending on a particular surgical purpose. Any suitable number of intervals and/or varying step sizes may also be provided.

**[00120]** As best shown in FIG. 9A, tissue gap adjustment mechanism 260 includes a set screw 262 and an asymmetrical polygonal washer 264, e.g., an asymmetrical octagonal washer (although other configurations are also contemplated). Screw stop 250 includes a housing 252 that defines a central bore 253 configured to receive screw 220, and a transverse slot 254 configured to receive set screw 262. First and second spaced-apart flanges 255a, 255b extend transversely from housing 252 on either side of transverse slot 254 for retaining asymmetrical washer 264 therebetween. Screw 220 includes a

threaded aperture 228 (FIG. 5) configured to receive threaded shaft 265 of set screw 262 to retain screw stop 250 in a fixed position about screw 220. Head 266 of set screw 262 includes a slot 267 configured to receive a screw driver (not shown) or other suitable tool for driving set screw 262 into or out of threaded aperture 228. As opposed to a slot 267, other suitable tool-engaging features, e.g., recesses and/or protrusions, are also contemplated. For example, as shown in FIG. 5A, the set screw 262 includes a polygonal head, e.g., a pentagonal head, configured to be engaged by a ratchet or wrench. Further, as opposed to set screw 262 received within threaded aperture 228 (FIG. 5) of screw 220, screw 220 may include a post (not shown) or other suitable feature supported thereon for receipt within and longitudinal positioning relative to transverse slot 254 of stop member 250.

**[00121]** Referring to FIGS. 9A-9B, asymmetrical washer 264 defines an aperture 268 and includes a plurality of outer peripheral flats or sides 269a-269h, e.g., eight sides, although greater or fewer sides are also contemplated. Due to the asymmetrical configuration of washer 264, the position of set screw 262 within transverse slot 254 of screw stop 250 is varied depending on which opposed sides 269a-269h of washer 264 are positioned between flanges 255a, 255b. With threaded aperture 228 of screw 220 receiving threaded shaft 265 of set screw 262, varying the position of set screw 262 within transverse slot 254 likewise varies the longitudinal position of screw stop 250 relative to screw 220, thereby varying the size of the minimum tissue gap. For example, as the screw stop 250 is moved proximally on the screw 220, the minimum tissue gap is increased because the screw stop 250 will engage sooner. Sides 269a-269h may include indicators 256 and flange 255a may also include an indicator 258 to allow the user to readily ascertain the setting of tissue gap adjustment

mechanism 260. The minimum tissue gap corresponding to each setting of an exemplary configuration of asymmetrical washer 264 is provided in the following table, although other configurations are also contemplated.

<u>Setting</u>	<u>Minimum Tissue Gap (mm)</u>
1	4.55
2	4.70
3	4.85
4	5.00
5	5.00
6	5.15
7	5.30
8	5.45

**[00122]** With general reference to FIGS. 5-9B, in order to adjust the minimum tissue gap, stationary handle 22 (FIG. 1) is disassembled (or prior to assembly), set screw 262 is loosened, and asymmetrical washer 264 is rotated about set screw 262 and relative to screw stop 250 to the desired position. Once the desired position is achieved, set screw 262 may be re-tightened to maintain screw stop 250 in the desired position on screw 220, thus defining the desired minimum tissue gap. As an alternative to disassembling stationary handle 22 (FIG. 1), a hole or opening may be provided in stationary handle 22 (FIG. 1) to provide direct access to tissue gap adjustment mechanism 260 without the need to disassemble stationary handle 22 (FIG. 1). Alternatively, the tissue gap adjustment mechanism 260 can be preset to one of the predefined settings by the

manufacturer.

**[00123]** Firing assembly 300 will now be described with reference to FIGS. 10 and 11. Firing assembly 300 includes trigger 24, a firing link 310, and a pusher linkage 320. Pusher linkage 320 includes an elongated pusher tube 330, a pusher link 340, and a pusher end tube 350. Pusher linkage 320 is configured for transferring force from proximal handle portion 20 (FIG. 1) to distal head portion 40 (FIG. 1) to fire stapling assembly 100 (FIG. 1). Although shown as a three-part assembly, it is envisioned that pusher linkage 320 may include one or more additional sections. Optionally, firing assembly 300 includes a trigger lock 360, which will be described in further detail below.

**[00124]** Trigger 24 is configured for operable engagement by a user. Trigger 24 may support a cushioned gripping surface (not shown) formed of neoprene, rubber or the like. The cushioned gripping surface provides a non-slip cushioned surface to make actuation of stapling apparatus 10 (FIG. 1) more comfortable to a surgeon. Alternatively, trigger 24 may be formed of perforated stainless-steel or other metal to facilitate sterilization. The distal end of trigger 24 includes a pair of flanges 304a, 304b each defining an opening 305a, 305b, respectively. Flanges 304a, 304b are configured for pivotal connection with a pair of flanges 324 formed on proximal end 330a of elongated pusher tube 330 of pusher linkage 320 by a pivot member 308a. Alternatively, pusher linkage 320 may include a coupling member (not shown) integrally formed with or fixedly secured to proximal end 330a of pusher tube 330 for pivotally connecting trigger 24 with pusher linkage 320.

**[00125]** Trigger 24 further includes a lockout feature, e.g., protrusion 306, extending from a distal end of trigger 24 adjacent flanges 304a, 304b. Protrusion 306 is configured to engage the distal end of screw 220 (FIG. 5) of

approximation assembly 200 (FIG. 5) when approximation assembly 200 (FIG. 5) is in an unapproximated position to prevent accidental actuation of trigger 24 before the anvil assembly (FIG. 1) has been moved to the approximated position. When approximation assembly 200 (FIG. 5) is in the approximated position, recess 225 (FIG. 5) formed in the distal end of screw 220 (FIG. 5) is in alignment with protrusion 306, thereby permitting actuation of trigger 24, i.e., pivotal movement of trigger 24 about pivot member 308a towards stationary handle 22. A biasing member (not shown) may also be provided for biasing trigger 24 towards an unactuated position and for returning trigger 24 to the unactuated position after firing.

**[00126]** Referring still to FIGS. 10 and 11, trigger 24 further includes a first opening 301a, a second opening 301b, a notch 301c, and an indicator member 309. First opening 301a in trigger 24 is configured to receive a pin 308b for pivotally connecting trigger 24 with firing link 310. Second opening 301b in trigger 24 is configured to receive a pin 308c for pivotally connecting trigger 24 with trigger lock 360. Notch 301c is configured to releasably retain protrusion 362 of trigger lock 360 therein to retain trigger lock 360 in an unlocked position. Indicator member 309 is fixedly retained within a third opening 308d and is configured to engage an indicator member 318 of firing link 310 to provide an audible and/or tactile indication to a user as stapling apparatus 10 (FIG. 1) is fired.

**[00127]** Firing link 310 includes a distal end 312 pivotally secured to trigger 24 by a pivot member 308b received through opening 301a. A proximal end 314 of firing link 310 supports a pivot member 316 which is pivotally secured within a slot 31 (FIG. 3) formed on each internal wall of handle sections 22a, 22b (FIG. 3). Alternatively, the pivot member 316 can be formed integrally with the firing

link 310. Pivot member 316 is free to move vertically within slots 31 (FIG. 3). Although not shown, it is contemplated that a spring may be supported within handle sections 22a, 22b (FIG. 3) to urge pivot member 316 towards the bottom of slot 31 (FIG. 3), as provided in the Milliman '187 patent, the contents of which was previously incorporated by reference. Indicator member 318 is formed on distal end 312 of firing link 310 and is configured to engage indicator member 309 formed on trigger 24 during firing of stapling apparatus 10 (FIG. 1), as mentioned above.

**[00128]** As noted above, pusher linkage 320 includes an elongated pusher tube 330, a pusher link 340 and a pusher end tube 350. A spring 335 received about proximal end 330a of elongated pusher tube 330 is configured to bias pusher linkage 320 proximally to a retracted position. Spring 335 is retained about proximal end 330a of elongated pusher tube 330 via a ring member 332 and a clip 333, although other configurations for retaining spring 225 about proximal end 330a of elongated pusher tube 330 are also contemplated. Ring member 332 is positionable distally of spring 335 and includes a pair of opposed, inwardly-extending protrusions 332a configured for slidable receipt within elongated recesses 332b defined on opposed sides of pusher linkage 320. Clip 333 is configured for engagement about proximal end 330a of elongated pusher tube 330 proximally of spring 335. The ring member 332 abuts an inner wall of a distal end of stationary handle 22 (FIG. 2) such that spring 335 urges clip 333 and pushes linkage 320 proximally.

**[00129]** Distal end 330b of pusher tube 330 includes a pair of flanges 336a, 336b each defining an opening 337a, 337b, respectively. Each of openings 337a, 337b is configured to receive a pivot pin 338a, 338b, respectively, to pivotally secure a proximal end 340a of pusher link 340 with distal end 330b of elongated

pusher tube 330. Pusher link 340 includes an elongated member defining a channel 341 (FIG. 22) extending substantially the length thereof. As shown, pusher link 340 may be slightly curved along the length thereof. Channel 341 (FIG. 22) is configured to receive screw extension 230 of approximation assembly 200 therethrough (FIG. 5). Proximal end 340a of pusher link 340 includes a first pair of flanges 342a, 342b each defining an opening 343a, (not shown) sized to receive respective pivot pin 338a, 338b for pivotally connecting pusher link 340 and elongated pusher tube 330. A distal end 340b of pusher link 340 includes a second pair of flanges 344a, 344b, each defining an opening 345a, 345b sized to receive a pivot pin 348a, 348b, respectively, for pivotally connecting pusher link 340 and pusher end tube 350.

**[00130]** A proximal end 350a of pusher tube 350 includes a pair of flanges 352a, 352b each defining an opening 353a, 353b configured for receiving respective pivot pins 348a, 348b for pivotally connecting pusher tube 350 with pusher link 340. A distal end 350b of pusher end tube 350 is configured to selectively engage the stapling assembly 100 (FIG. 1), as will be detailed below.

**[00131]** With reference to FIGS. 11A and 11B, as noted above, firing assembly 300 may optionally include trigger lock 360. Trigger lock 360 includes a body 360a and a base 361 defining a throughbore for receiving a pin 308c. Pin 308c is received within the throughbore of base 361 to pivotably couple trigger lock 360 to trigger 24. Base 361 defines a radially asymmetric configuration, e.g., a tear-drop cross-sectional configuration, forming a pair of contact surfaces 361a, 361b on either side of the throughbore that receives pin 308c. Trigger lock 360 further includes a protrusion 362 extending from body 360a of trigger lock 360. Trigger lock 360 is rotatable relative to trigger 24 between an unlocked position, wherein protrusion 362 is received within notch

301c (FIG. 11) of trigger 24, and a locked position, wherein protrusion 362 is received within cut-out 363 (FIG. 11) of trigger 24 and free end 364 of body 360a of trigger lock 360 is disposed in close approximation or abutting relation with firing link 310 to inhibit actuation of trigger 24.

**[00132]** A biasing member 307, e.g., a torsion spring, is disposed about pivot member 308b, which, as mentioned above, is received through opening 301a of trigger 24 and distal end 312 of firing link 310 to pivotally secured firing link 310 to trigger 24. Biasing member 307 includes a coiled portion 307a and a flat portion 307b. Coiled portion 307a is disposed about pivot member 308b, while flat portion 307b extends proximally from coiled portion 307a along trigger 24. Coiled portion 307a biases flat portion 307b towards trigger 24. More specifically, in the locked position of trigger lock 360, as shown in FIG. 11A, flat portion 307b of biasing member 307 is biased into contact with contact surface 361a of base 361 of trigger lock 360 to urge trigger lock 360 in a counter-clockwise direction as viewed in FIG. 11A. In this position, biasing member 307 maintains trigger lock 360 in the locked position and inhibits accidental dislodgment of trigger lock 360 from the locked position. In the unlocked position of trigger lock 360, as shown in FIG. 11B, flat portion 307b of biasing member 307 is biased into contact with contact surface 361b of base 361 of trigger lock 360 to urge trigger lock 360 in a clockwise direction as viewed in FIG. 11B. In this position, biasing member 307 maintains trigger lock 360 in the unlocked position and inhibits accidental dislodgment of trigger lock 360 from the unlocked position. Thus, biasing member 307 establishes a bistable configuration of trigger lock 360, e.g., wherein trigger lock 360 is stable in both the locked position and the unlocked position.

**[00133]** Other suitable trigger locks are described in U.S. Patent 7,303,106 to

Milliman et al., hereby incorporated by reference here, and the Milliman '187 patent and the Gresham '444 patent, previously incorporated by reference herein. Firing assembly 300 may further include a feedback mechanism similar to that disclosed in the Milliman '187 patent, previously incorporated by reference herein.

**[00134]** With reference to FIGS. 12-16, elongated central body portion 30 of surgical stapling apparatus 10 (FIG. 1) includes a curved elongated outer tube 32, a proximal bushing 34 (FIG. 16), and a distal bushing 36 (FIG. 14). Outer tube 32 is configured to slidably receive components of approximation assembly 200 (FIG. 3) and firing assembly 300 (FIG. 3). Proximal bushing 34 is rotatably coupled about outer tube 32 via a ring 37 and is configured to enable releasable threaded engagement of the proximal end of outer tube 32 with stationary handle 22 of handle portion 20 (FIG. 6). Distal bushing 36, is engaged about the distal end of outer tube 32, e.g., via friction-fitting, snap-fitting, adhesion, or other suitable engagement, and is configured to enable releasable engagement of replaceable stapling assembly 100 (FIG. 3) with the distal end of outer tube 32.

**[00135]** Referring to FIGS. 17-21, distal head portion 40 of surgical stapling apparatus 10 (FIG. 1) includes anvil assembly 400 (FIG. 1), described above, that is releasably engagable with the distal end of approximation assembly 200 (FIG. 3), and a replaceable stapling assembly 100 that is releasably engagable with the distal end of elongated central body portion 30 (FIG. 3). A safety cap 500 (FIGS. 17-18) is also provided for engagement about the distal end of replaceable stapling assembly 100 when not in use, e.g., during shipping and storage. Replaceable stapling assembly 100 (or portions thereof) is configured as a disposable component that is to be replaced with a new replaceable stapling assembly 100 (or portions thereof) after each firing. The remaining components

of surgical stapling apparatus 10 (FIG. 1) are configured as reusable, sterilizable components, although one or more of these components may alternatively be configured as a disposable component. Other configurations are also contemplated. Distal head portion 40 will be described in greater detail below.

**[00136]** Replaceable stapling assembly 100 will now be described in detail with respect to FIGS. 17-21. Referring initially to FIGS. 17-18, and as mentioned above, a safety cap 500 is provided for engagement about the distal end of replaceable stapling assembly 100 when not in use, e.g., during shipping and storage. Safety cap 500 includes a disc member 510 configured for positioning about the distal end of stapling assembly 100, a pair of outer arms 520, 530 extending proximally from disc member 510, and a pair of inner posts 540, 550 extending proximally from disc member 510. Each outer arm 520, 530 includes an inwardly-extending protrusion 522, 532 disposed at its free end. Protrusions 522, 532 are configured for receipt within apertures 524 defined within outer housing portion 104 of shell assembly 102 of stapling assembly 100 to retain safety cap 500 about the distal end of stapling assembly 100. Arms 520, 530 may be formed from a resiliently flexible material so as to bias protrusions 522, 532 into apertures 524, although other engagement mechanisms for releasably retaining safety cap 500 about the distal end of stapling assembly 100 are also contemplated. Inner posts 540, 550 are configured for insertion into stapling assembly 100 to help retain safety cap 500 in position about the distal end of stapling assembly 100 and to inhibit distal movement of pusher back 110 (FIG. 21) as will be described below to prevent the inadvertent ejection of staples “S” (FIG. 21) from stapling assembly 100 during shipping or the like.

**[00137]** Referring to FIGS. 19-21, replaceable stapling assembly 100 includes a shell assembly 102, a pusher back 110, a cylindrical knife 120, and a

staple guide cap 130. Shell assembly 102 includes an outer housing portion 104 and an inner guide portion 106. Outer housing portion 104 defines a throughbore 105 and includes a distal cylindrical section 104a, a central conical section 104b, and a proximal cylindrical section 104c. Distal cylindrical section 104a includes a slot 105a and a plurality of recesses 105b. Slot 105a is configured to receive a protrusion 132 formed on staple guide cap 130 to properly align staple guide cap 130 with pusher back 110. Recesses 105b are configured for engagement with tabs 134 formed on staple guide 130 for securing staple guide cap 130 to staple back 110.

**[00138]** Proximal cylindrical section 104c of outer housing portion 104 of shell assembly 102 includes a pair of tabs 108 formed on inner surface thereof. Tabs 108 are configured to selectively engage threads 38 (FIGS. 15-16) formed on the inner surface of distal bushing 36 (FIGS. 15-16) to releasably theradably engage shell assembly 102 and outer tube 32 (FIG. 15) with one another. In this manner, shell assembly 102 of stapling assembly 100 may be removed from stapling apparatus 10 (FIG. 1) subsequent to use and stapling apparatus 10 (FIG. 1) may be reloaded with another stapling assembly 100 and reused.

**[00139]** Pusher back 110 includes a central throughbore 111 which is slidably positioned about inner guide portion 106 of shell 102. Pusher back 110 includes a distal cylindrical section 110a which is slidably positioned within distal cylindrical section 104c of outer housing portion 104, a central conical section 110b, and a proximal smaller diameter cylindrical section 110c. Pusher back 110 further includes a pair of proximally-extending arm members 125. Arm members 125 each include a finger 127 that is configured for insertion into and locking engagement within annular recess 128a of collar 128 disposed at distal end 350b of pusher end tube 350 of pusher link 320 (see FIG. 11). Thus,

with pusher link 320 (FIG. 11) engaged with pusher back 110, actuation of firing trigger 24 (FIG. 11) urges pusher back 110 distally through outer housing portion 104 to eject staples “S” from stapling assembly 100.

**[00140]** With particular reference to FIG. 21, distal cylindrical section 110a of pusher back 110 includes a plurality of distally extending fingers 114 dimensioned to be slidably received within slots 131 formed in staple guide cap 130 to eject staples “S” therefrom. Distal ends 114a of fingers 114 define a groove for engaging staples “S.” Cylindrical knife 120 is retained within central throughbore 111 of pusher back 110 by a pair of tabs 121. Alternately, knife 120 may be retained within pusher back 110 using adhesives, crimping, pins, etc. A distal end of knife 120 includes a circular cutting edge 122. A rigid bushing 140 is supported in the proximal end of inner guide portion 106 of shell 102. Bushing 140 defines a throughbore dimensioned to slidably receive anvil retainer 240 (FIG. 5) and center rod assembly 420 of anvil assembly 400 (FIG. 1).

**[00141]** In operation, when pusher linkage 320 (FIG. 10) is advanced distally in response to actuation of trigger 24 (FIG. 10), pusher back 110 is advanced distally within outer housing portion 104 of shell assembly 102. Advancement of pusher back 110 advances fingers 114 through slots 131 of staple guide cap 130 to advance staples “S” positioned within slots 131 and eject staples “S” from staple guide cap 130 into staple deforming pockets (not shown) formed on an opposed surface of anvil head assembly 410 of anvil assembly 400 (FIG. 1). Since knife 120 is secured to pusher back 110, knife 120 is also advanced distally to core tissue.

**[00142]** The use of surgical stapling apparatus 10, disassembly of surgical stapling apparatus 10 for sterilization of the reusable components and

replacement of the disposable components, and reassembly of surgical stapling apparatus 10 for subsequent use is now described. Adjustment of tissue gap adjustment mechanism 260 (FIG. 9A) is also described and may be effected during manufacturing, assembly, between uses, or at any other suitable point where setting and/or changing the minimum tissue gap is desired.

**[00143]** With general reference to FIGS. 1 and 22, in use, safety cap 500 (FIGS. 17-18) is initially removed from the distal end of stapling assembly 100. Next, distal head portion 40 of surgical stapling apparatus 10 inserted into an internal surgical site, before or after engagement of distal head portion 40 with the anvil assembly 400. Next, anvil assembly 400 and stapling assembly 100 are positioned adjacent tissue to be stapled. At this point, anvil assembly 400 is in an unapproximated position and screw 220 of approximation assembly 200 (FIGS. 5-9) is in its distal-most position. This position of anvil assembly 400 may be visually confirmed by viewing indicator 276 of indicator bar 270 (FIG. 3) through window 25 (FIG. 4) formed in stationary handle 22. As shown in FIG. 2, trigger lock 360 is disposed in the locked position at this point such that actuation of firing trigger 24 is inhibited. Trigger 24 is further prevented from being actuated by engagement of protrusion 306 (FIGS. 10-11) of trigger 24 with screw 220 (FIGS. 5-9), as detailed above.

**[00144]** Once distal head portion 40 of surgical stapling apparatus 10 is positioned as desired, anvil assembly 400 may be approximated relative to stapling assembly 100 to clamp tissue therebetween via manipulating approximation knob 26. Tissue can be secured between anvil assembly 400 and stapling assembly 100 using conventional techniques such as using purse-string sutures, resilient bands, or the like. Knob 26 may be rotated to approximate anvil assembly 400 relative to stapling assembly 100 to clamp tissue

therebetween until the minimum tissue gap between anvil assembly 400 and stapling assembly 100, which is set via tissue gap adjustment mechanism 260 (FIG. 9A), is achieved. Movement of the anvil assembly 400 to the approximated position can be visually confirmed once visual indicator 278 (FIG. 3) is viewable through window 25 (FIG. 4).

**[00145]** With anvil assembly 400 disposed in the approximated position and tissue clamped between anvil head 410 and staple guide cap 130 of stapling assembly 100, firing assembly 300 (FIGS. 10-11) may be actuated to staple and core the clamped tissue. In order to allow for firing, trigger lock 360 is rotated from the locked position to the unlocked position. In the approximated position of anvil assembly 400, recess 225 formed in screw 220 of approximation assembly 200 (see FIGS. 5-9) is aligned with protrusion 306 (FIGS. 10-11) formed on trigger 24 to permit actuation of trigger 24, provided trigger lock 260 is disposed in the unlocked position.

**[00146]** With trigger lock 360 and protrusion 306 (FIGS. 10-11) no longer inhibiting actuation of trigger 24, surgical stapling apparatus 10 may be actuated. In order to fire stapling apparatus 10, trigger 24 is compressed towards stationary handle 22, which urges pusher link assembly 320 (FIGS. 10-11) distally through outer tube 32 to urge pusher back 110 (FIG. 21). With additional reference to FIG. 21, distal translation of pusher back 110 relative to staple guide cap 130 urges pusher back 110 to engage and eject staples “S” from staple guide cap 130, through tissue, and into anvil head 410 of anvil assembly 400, which form staples “S” about tissue. Knife 120 is moved concurrently with pusher back 110 such that knife 120 is likewise advanced distally to core tissue.

**[00147]** Continuing with general reference to FIGS. 1 and 22, in one exemplary method of use, surgical stapling apparatus 10 is used to perform a

circular anastomosis. Typically, circular anastomoses are required during procedures for removing a portion of a diseased vessel such as the colon or the intestine. During such a procedure, the diseased portion of the vessel is removed and the end portions of the remaining first and second vessel sections are joined together using the surgical stapling apparatus 10.

**[00148]** During such a procedure using the surgical stapling apparatus 10, prior to removing the diseased vessel portion from the diseased vessel, anvil assembly 400 with a removable trocar (not shown) attached thereto is positioned in the first vessel section on a first side of the diseased portion. A removable trocar which is suitable for use with anvil assembly 400 is disclosed in the Gresham '444 patent, which, as discussed above, is incorporated herein by reference in its entirety. After the diseased vessel portion is removed and the open ends of the first and second vessel sections have been sutured, the distal end of apparatus 10 is positioned in the second vessel section on the other side of the diseased vessel portion which has been removed. At this time, the removable trocar is pushed through the suture line in the end of the first vessel section and removed from the anvil assembly. Next, trocar tip 247 of anvil retainer 240 is pushed through the suture line in the second vessel section and is joined to the center rod of the anvil assembly 400. The surgical stapling apparatus 10 can now be approximated and fired in the manner discussed above to join the ends of the first and second vessel sections and core out any tissue obstructing the vessel lumen.

**[00149]** At the completion of the stapling operation, surgical stapling apparatus 10 may be removed from the internal surgical site. More specifically, anvil assembly 400 may be configured to pivot to a low-profile configuration after firing and upon un-approximation of anvil assembly 400 relative to stapling

assembly 100 to facilitate removal of surgical stapling apparatus 10 from the internal surgical site. A suitable tilting mechanism is described in the Milliman '187 patent or the Gresham '444 patent, previously incorporated by reference herein in their entirety. Alternatively, anvil assembly 400 need not have a pivotal head and may be removed from the surgical site in the same orientation as it was advanced into the surgical site.

**[00150]** Upon removal from the internal surgical site at the completion of the surgical procedure (or prior to use), surgical stapling apparatus 10 may be disassembled to facilitate sterilization of the reusable components and replacement of the disposable components. Adjustment of tissue gap adjustment mechanism 260 (FIG. 9A) may also be effected at this time.

**[00151]** Referring still to FIGS. 1 and 22, to disassemble surgical stapling apparatus 10, anvil assembly 400 is first removed from anvil retainer 240 by moving anvil assembly 400 to the unapproximated position and separating anvil assembly 400 from anvil retainer 240 using sufficient force to disengage center rod assembly 420 from annular protrusion 248 (FIG. 5). Anvil assembly 400 is configured as a sterilizable, reusable component although it is also contemplated that anvil assembly be configured as a reusable component.

**[00152]** Once anvil assembly 400 has been removed, stapling assembly 100 may be disengaged from surgical stapling apparatus 10. More specifically, stapling assembly 100 is disengaged from the distal end of outer tube 32 by rotating shell assembly 102 relative to outer tube 32 to disengage tabs 108 (FIGS. 20-21) from threads 38 (FIG. 16) of distal bushing 36. Thereafter, shell assembly 102 is squeezed inwardly and translated distally to disengage fingers 127 (FIGS. 20-21) of arms 125 (FIGS. 20-21) from collar 128 of distal pusher end 350 (FIG. 11) to fully disengage stapling assembly 100 from outer tube 32.

Once disengaged, stapling assembly 100 may then be removed from positioning about anvil retainer 240 and may be disposed of, although it is also contemplated that one or more components of stapling assembly 100 be sterilizable for reuse.

**[00153]** Referring to FIGS. 3D-3F, in order to disassemble stationary handle 22 in preparation for sterilization, proximal bushing 34 is disengaged from the distal ends of handle sections 22a, 22b by rotating proximal bushing 34 relative to stationary handle 22, and collar 27 is disengaged from the proximal ends of handle sections 22a, 22b by rotating collar 27 relative to stationary handle 22. Once proximal bushing 34 and collar 27 have been disengaged from the proximal and distal ends of stationary handle 22, handle sections 22a, 22b may be moved relative to one another from the closed position (FIG. 3D) to the open position (FIG. 3F).

**[00154]** In order to move handle sections 22a, 22b from the closed position (FIG. 3D) to the open position (FIG. 3F), handle sections 22a, 22b are initially moved apart from one another and relative to discs 50, 51 (see FIG. 3E with respect to disc 50). In particular, handle sections 22a, 22b are translated apart from one another and relative to discs 50, 51 such that pins 56a, 57a are translated from the inner ends of slots 56, 57 (FIGS. 3B and 3C) to the outer ends of slots 56, 57, respectively. This outward translation of handle sections 22a, 22b provides clearance between handle sections 22a, 22b and the internal components retained within stationary handle 22. More specifically, the outward translation of handle sections 22a, 22b withdraws pivot member 316 from slots 31 (FIG. 2) and withdraws the wings of proximal end 330a of elongated pusher tube 330 from the channels defined within handle sections 22a, 22b (FIG. 3).

**[00155]** Once sufficient clearance has been achieved between handle sections

22a, 22b and the internal components of handle portion 20, the free sides of handle sections 22a, 22b, i.e., the sides of handle sections 22a, 22b opposite the pin-slot engagement of handle sections 22a, 22b and discs 50, 51, are rotated apart from one another about pins 56a, 57a relative to support discs 50, 51 to the open position. In the open position of handle sections 22a, 22b, the proximal components of approximation assembly 200 and firing assembly 300 are exposed, facilitating adjustment and/or removal of any or all of these components, as detailed below.

**[00156]** With momentary reference to FIG. 9A, at this point, if it is desired to change the minimum tissue gap setting, set screw 262 is loosened, and asymmetrical washer 264 is rotated about set screw 262 and relative to screw stop 250 to the desired position. Once the desired position is achieved, set screw 262 may be re-tightened to maintain screw stop 250 in the desired position on screw 220, thus defining the desired minimum tissue gap.

**[00157]** Referring to FIGS. 1, 2, and 22, once handle sections 22a, 22b have been pivoted to the open position (FIG. 3F), approximation assembly 200 and firing assembly 300 may be removed from stationary handle 22. Thus, with stationary handle 22 opened, and with approximation assembly 200 and firing assembly 300 removed from handle portion, sterilization of each of these components for reuse may be readily achieved. Alternatively, one or more of these components may be configured as a disposable component and, thus, may be replaced with a new component rather than being sterilized. Additionally or alternatively, sterilization may be effected with stationary handle 22 in the open position (FIG. 3F) but without the need to remove approximation assembly 200 and/or firing assembly 300.

**[00158]** Once the reusable components, e.g., handle sections 22a, 22b,

approximation assembly 200, and firing assembly 300, have been sterilized and the replaceable components, e.g., stapling assembly 100, replaced, surgical stapling apparatus 10 may be reassembled for subsequent use in reverse order of disassembly. As can be appreciated, the above-described cycle of use, disassembly, sterilization and replacement, adjustment, and reassembly, may be repeated for a plurality of usage cycles.

**[00159]** It will be understood that various modifications may be made to the embodiments of the surgical stapling apparatus disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

**WHAT IS CLAIMED IS:**

1. A surgical stapling apparatus, comprising:
  - a handle portion defining a proximal end and a distal end;
  - a body extending distally from the handle portion;
  - a stapling assembly supported on a distal end of the body;
  - an anvil assembly;
  - a drive screw supported within the handle portion and operably coupled to the anvil assembly, the drive screw defining a transverse aperture and being movable relative to the stapling assembly to move the anvil assembly relative to the stapling assembly between a spaced-apart position and an approximated position; and
  - a tissue gap adjustment mechanism disposed within the handle portion and including:
    - a stop member supported on the drive screw, the stop member including first and second flanges which define a transverse slot, the stop member configured to abut a stop surface within the handle portion to prevent further proximal movement of the drive screw within the handle portion and set a minimum tissue gap between the anvil assembly and the stapling assembly;
    - an asymmetrical polygonal washer defining an eccentrically positioned aperture and including a plurality of pairs of opposed flat sides, the washer being dimensioned to be positioned within the transverse slot such that each of the pairs of opposed flat sides can be selectively positioned between and in engagement with the first and second flanges; and
    - a set screw configured for insertion through the aperture of the washer, the transverse slot, and the transverse aperture to fix the stop member relative to the drive screw,

wherein the washer is repositionable about the set screw to position a selected pair of the opposed flat sides between and in engagement with the first and second flanges, at least two of the pairs of opposed flat sides when engaged with the first and second flanges being spaced to position the aperture of the washer at different locations within the transverse slot such that the position of the stop member in relation to the drive screw can be selectively varied by positioning a different pair of opposed flat sides in engagement with the first and second flanges to selectively change the minimum tissue gap.

2. The surgical stapling apparatus according to claim 1, wherein the washer defines an octagonal configuration.

3. The surgical stapling apparatus according to claim 1, wherein the washer is configured and dimensioned such that the minimum tissue gap is adjustable between 4.55mm and 5.45mm.

4. The surgical stapling apparatus according to claim 1, wherein the washer is configured and dimensioned such that the minimum tissue gap is incrementally adjustable at a step size of 0.15mm between 4.55mm and 5.45mm.

5. The surgical stapling apparatus according to claim 1, further comprising at least one indicator disposed on the washer and an indicator disposed on at least one of the flanges for indicating a selected setting of the tissue gap adjustment mechanism.

6. The surgical stapling apparatus according to claim 1, wherein the set screw

is configured to be loosened to facilitate repositioning of the washer about the set screw and is configured to be tightened to fix the position of the washer and the stop member on the drive screw.

7. The surgical stapling apparatus according to claim 1, further comprising an approximation knob extending from the handle portion, the approximation knob coupled to the drive screw and selectively actuatable to move the anvil assembly between the spaced-apart position and the approximated position.

8. The surgical stapling apparatus according to claim 7, wherein the drive screw defines a helical channel and the approximation knob is coupled to a ball disposed within the helical channel such that rotation of the approximation knob effects translation of the drive screw.

9. The surgical stapling apparatus according to claim 1, further comprising a firing assembly including a trigger coupled to the handle and a firing link coupled to the stapling assembly, the firing link configured for distal translation through the body in response to actuation of the trigger to eject a plurality of surgical staples from the stapling assembly.

10. The surgical stapling apparatus according to claim 1, wherein the handle is formed from first and second handle sections, the first and second handle sections being releasably engagable with one another.

11. A surgical stapling apparatus, comprising:
  - a handle portion defining a proximal end and a distal end;
  - a body extending distally from the handle portion;
  - a stapling assembly supported on a distal end of the body, the stapling assembly including a plurality of surgical staples;
  - a firing assembly including a firing trigger extending from the handle portion, a firing link coupling the firing trigger to the handle portion, and a pusher link coupled to the firing trigger and extending through the body, the pusher link being movably supported for distal translation through the body in response to actuation of the firing trigger to eject the plurality of surgical staples from the stapling assembly; and
  - a trigger lock assembly including a trigger lock member and a biasing member, the trigger lock member pivotably coupled to the firing trigger and being movable relative to the firing trigger between a locked position, wherein the trigger lock abuts the firing link to inhibit actuation of the firing trigger, and an unlocked position, wherein the trigger lock is displaced from the firing link to permit actuation of the firing trigger, wherein, in the locked position of the trigger lock, the biasing member is positioned to bias the trigger lock towards the locked position and, in the unlocked position of the trigger lock, the biasing member is positioned to bias the trigger lock towards the unlocked position.

12. The surgical stapling apparatus according to claim 11, wherein the biasing member includes a coiled portion and a flat portion extending from the coiled portion, the flat portion being positioned to engage and bias the trigger lock towards the locked position when the trigger lock is disposed in the locked position and to engage and bias the trigger lock towards the unlocked position

when the trigger lock is disposed in the unlocked position.

13. The surgical stapling apparatus according to claim 12, wherein a first pivot member pivotably couples the firing link to the firing trigger, and wherein the coiled portion of the biasing member is disposed about the first pivot member.

14. The surgical stapling apparatus according to claim 11, wherein the trigger lock includes an asymmetrical base member defining first and second contact surfaces on opposite sides of the base member, the biasing member being positioned to contact the first contact surface to bias the trigger lock towards the locked position and to contact the second contact surface to bias the trigger lock towards the unlocked position.

15. The surgical stapling apparatus according to claim 14, wherein the base member of the trigger lock defines a throughbore configured to receive a second pivot member for pivotably coupling the trigger lock to the firing trigger.

16. A surgical stapling apparatus, comprising:

a handle portion defining a proximal end and a distal end, the handle portion including at least one support member and first and second handle sections movably coupled to the at least one support member via a pin-slot engagement such that the first and second handle sections are translatable and rotatable relative to each other and the at least one support member from a closed position, wherein the first and second handle sections are in close alignment, and an open position, wherein the first and second handle sections are separated from each other to expose an interior of the handle portion;

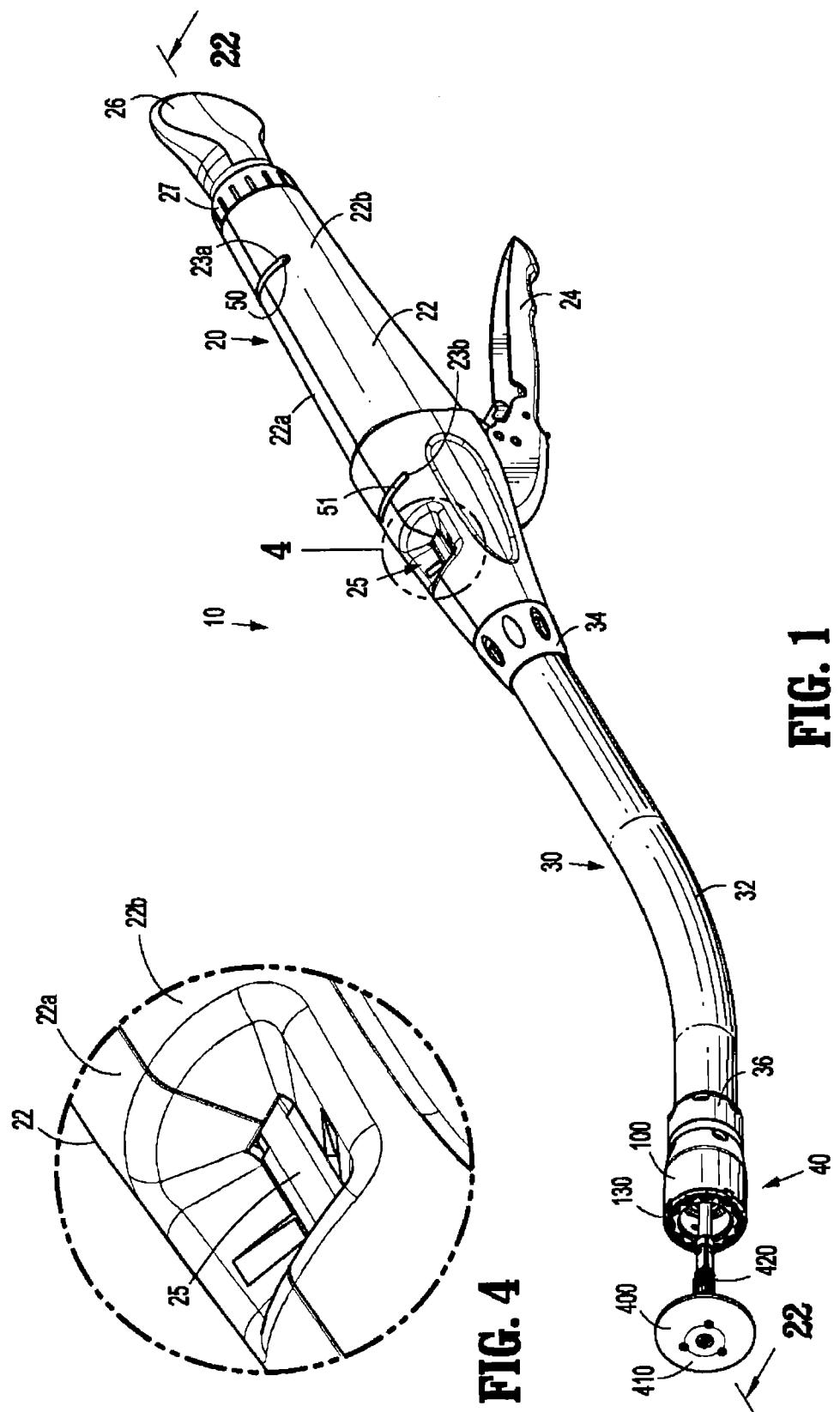
a body extending distally from the handle portion; and  
a stapling assembly supported on a distal end of the body, the stapling assembly including a plurality of surgical staples.

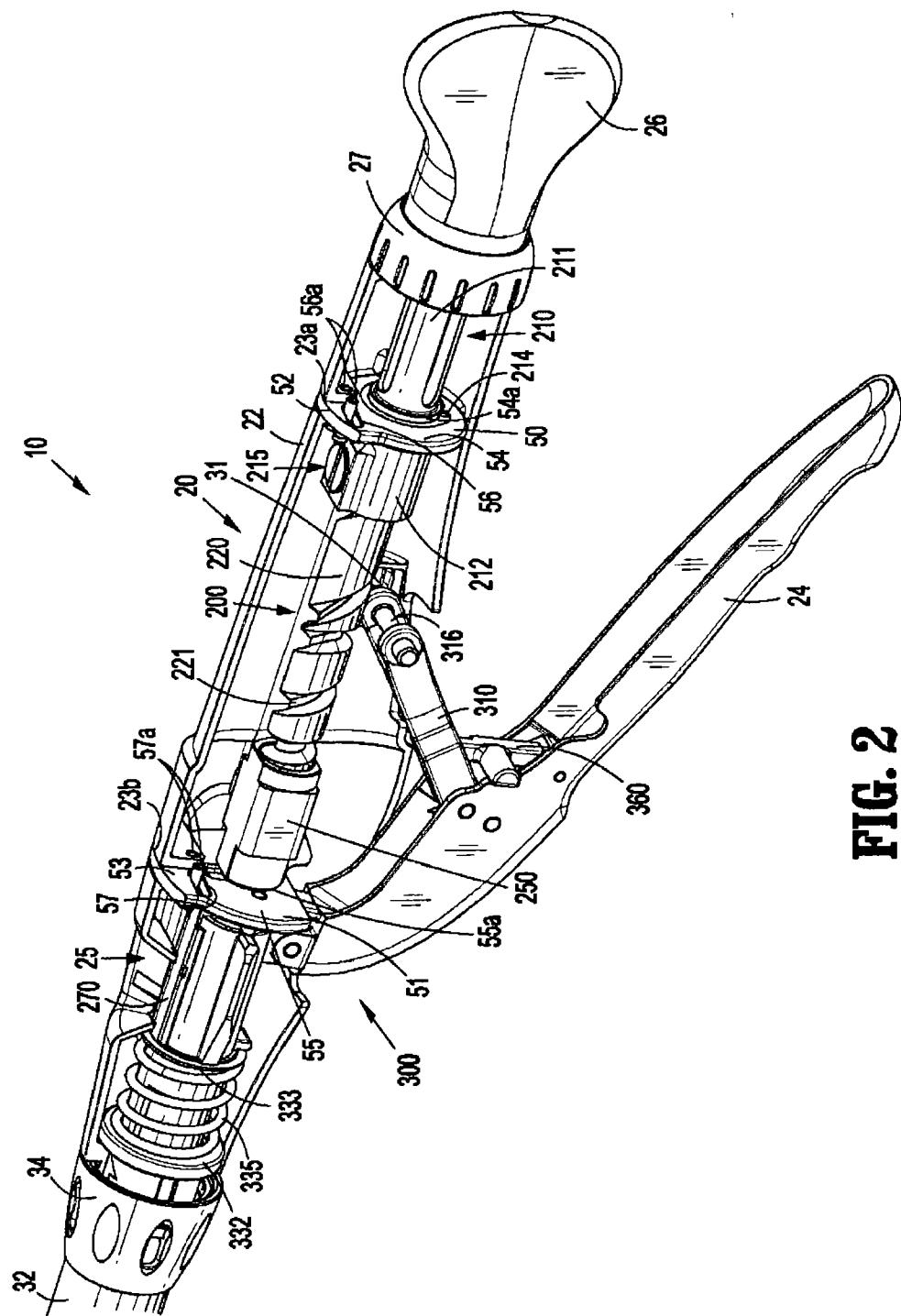
17. The surgical stapling apparatus according to claim 16, further comprising a firing assembly including a firing trigger and a pusher link coupled to the firing trigger, the pusher link configured for distal translation through the elongated body portion in response to actuation of the firing trigger to eject the plurality of surgical staples from the stapling assembly.

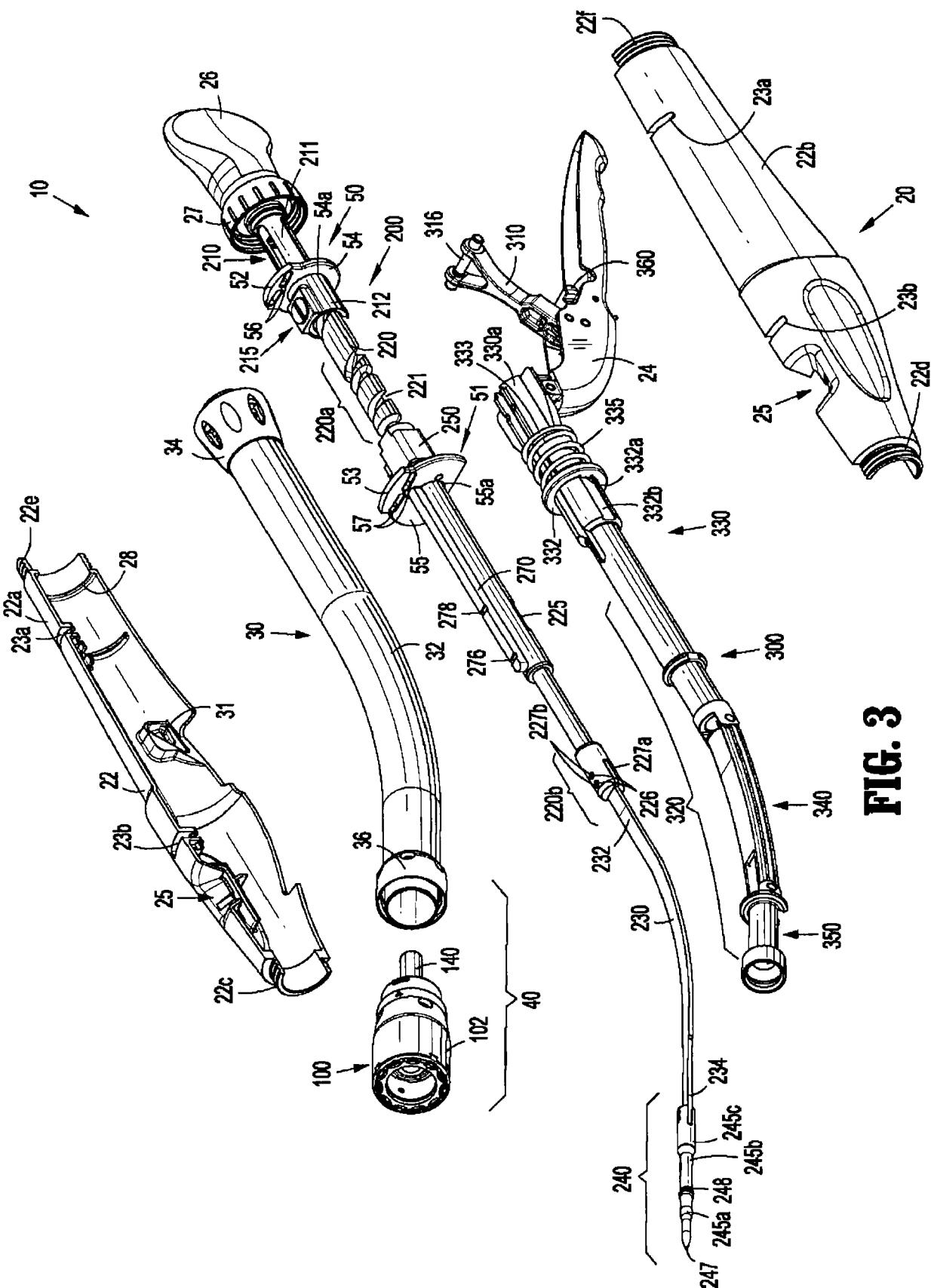
18. The surgical stapling apparatus according to claim 16, wherein each of the first and second handle sections includes a threaded distal extension and wherein a threaded bushing disposed about the body is configured for engagement with the threaded distal extensions of the first and second handle sections to retain the first and second handle sections in the closed position and secure the body to the distal end of the handle portion.

19. The surgical stapling apparatus according to claim 16, further comprising:  
an anvil assembly; and  
an approximation assembly operably coupled to the anvil assembly, at least a portion of the approximation assembly supported within the handle portion via the at least one support member, the approximation assembly being movable relative to the stapling assembly to move the anvil assembly relative to the stapling assembly between a spaced-apart position and an approximated position.

20. The surgical stapling apparatus according to claim 19, wherein the approximation assembly includes an approximation knob extending proximally from the handle portion, the approximation knob selectively rotatable relative to the handle portion to move the anvil assembly relative to the stapling assembly, wherein each of the first and second handle sections includes a threaded proximal extension, and wherein a threaded collar disposed about the approximation knob is configured for engagement with the threaded proximal extensions of the first and second handle sections to retain the first and second handle sections in the closed position and rotatably secure the approximation knob to the proximal end of the handle portion.



**FIG. 2**



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FIG.

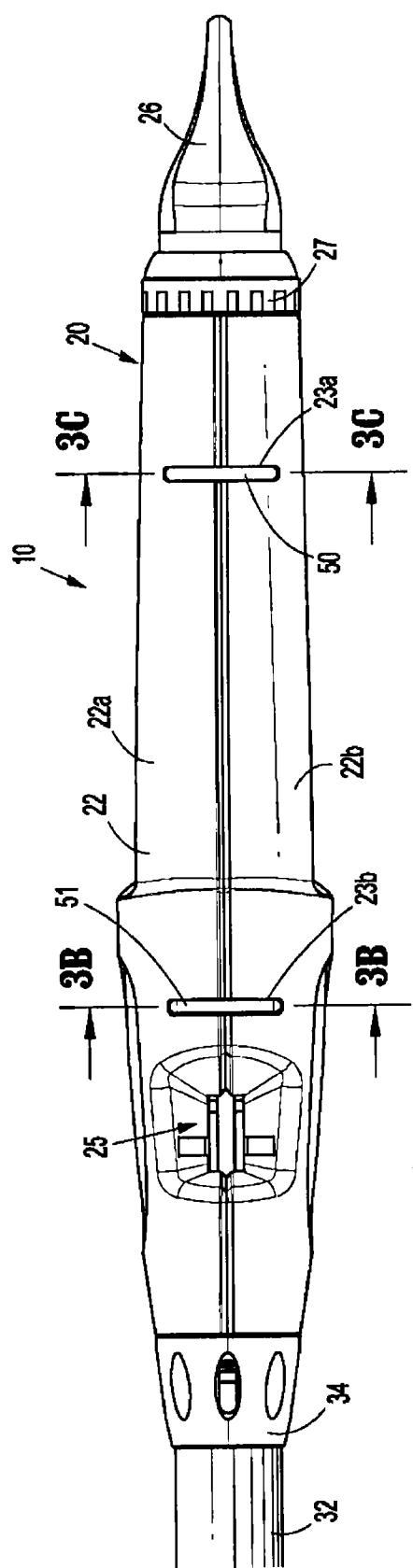


FIG. 3A

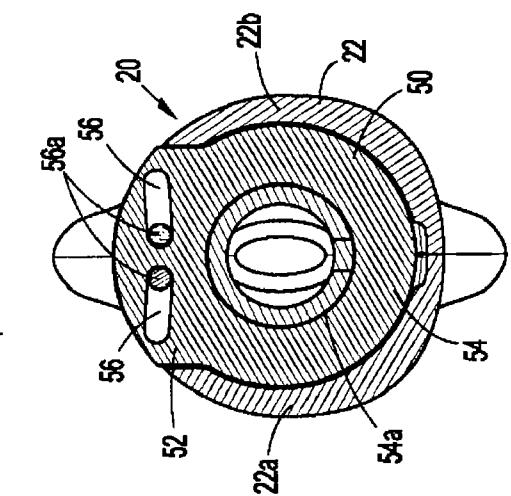
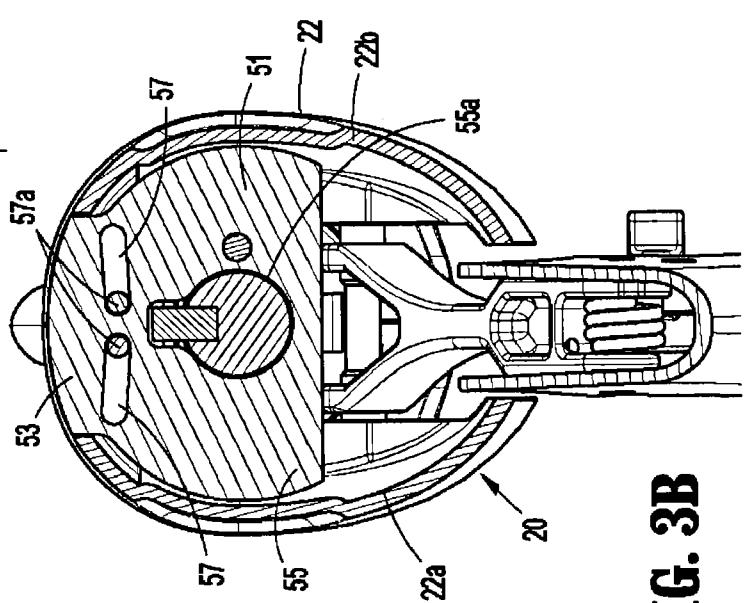
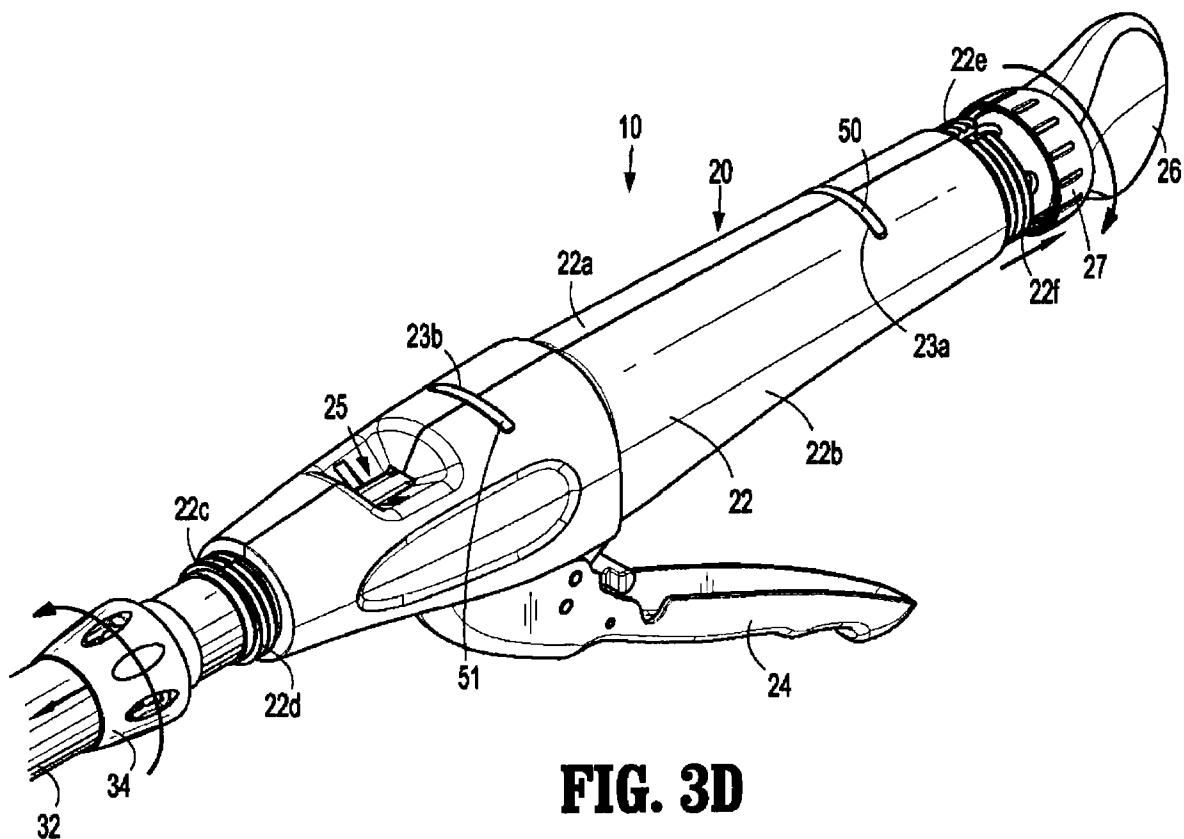
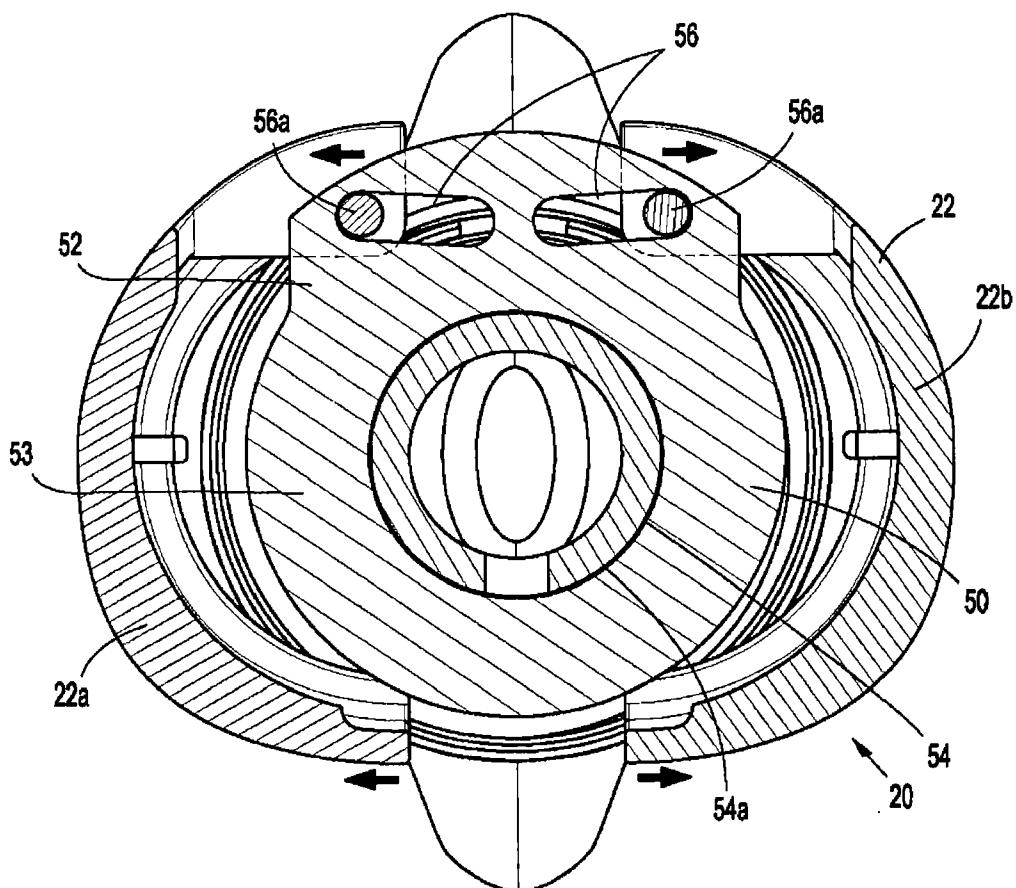


FIG. 3C



**FIG. 3B**

**FIG. 3D****FIG. 3E**

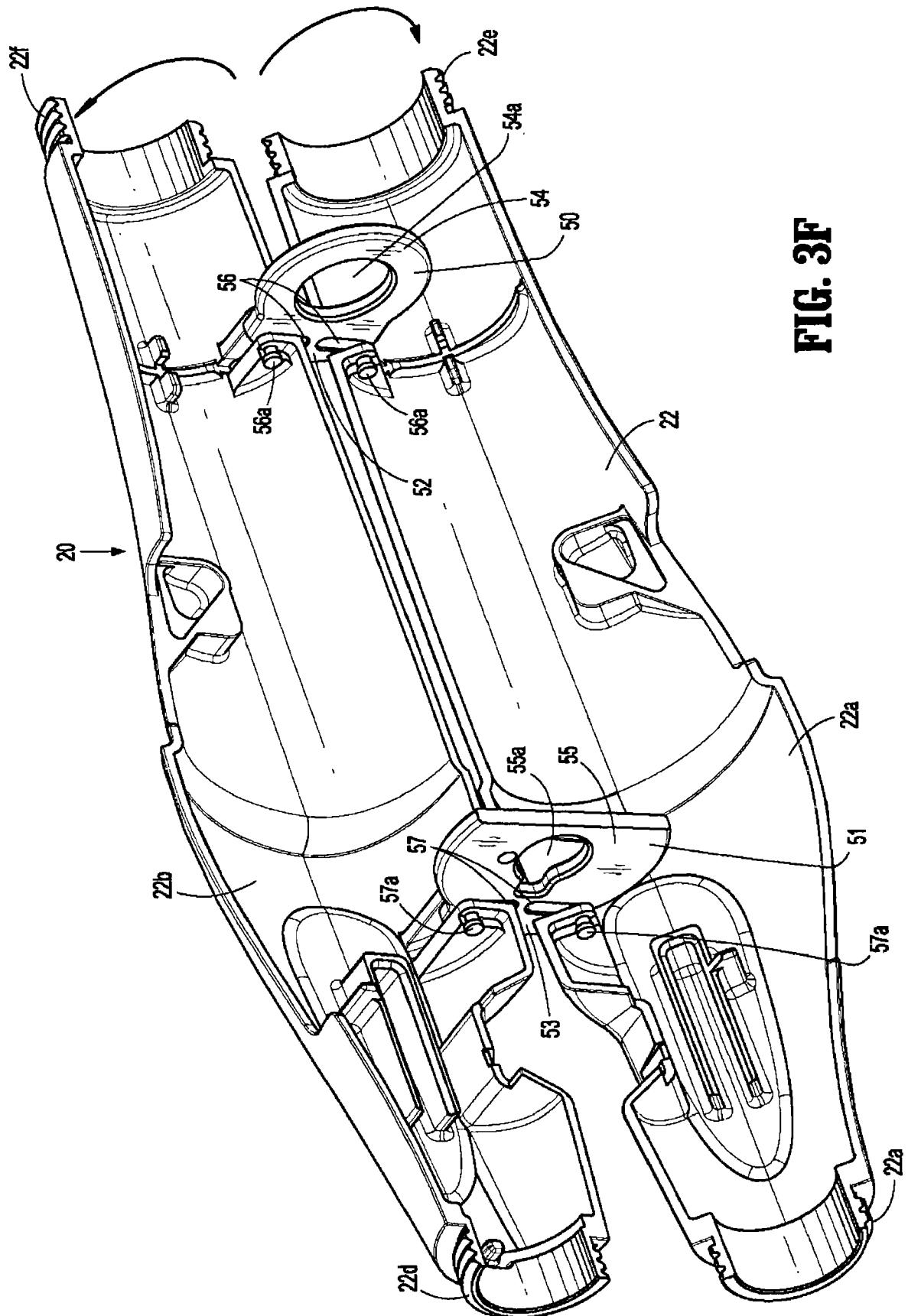
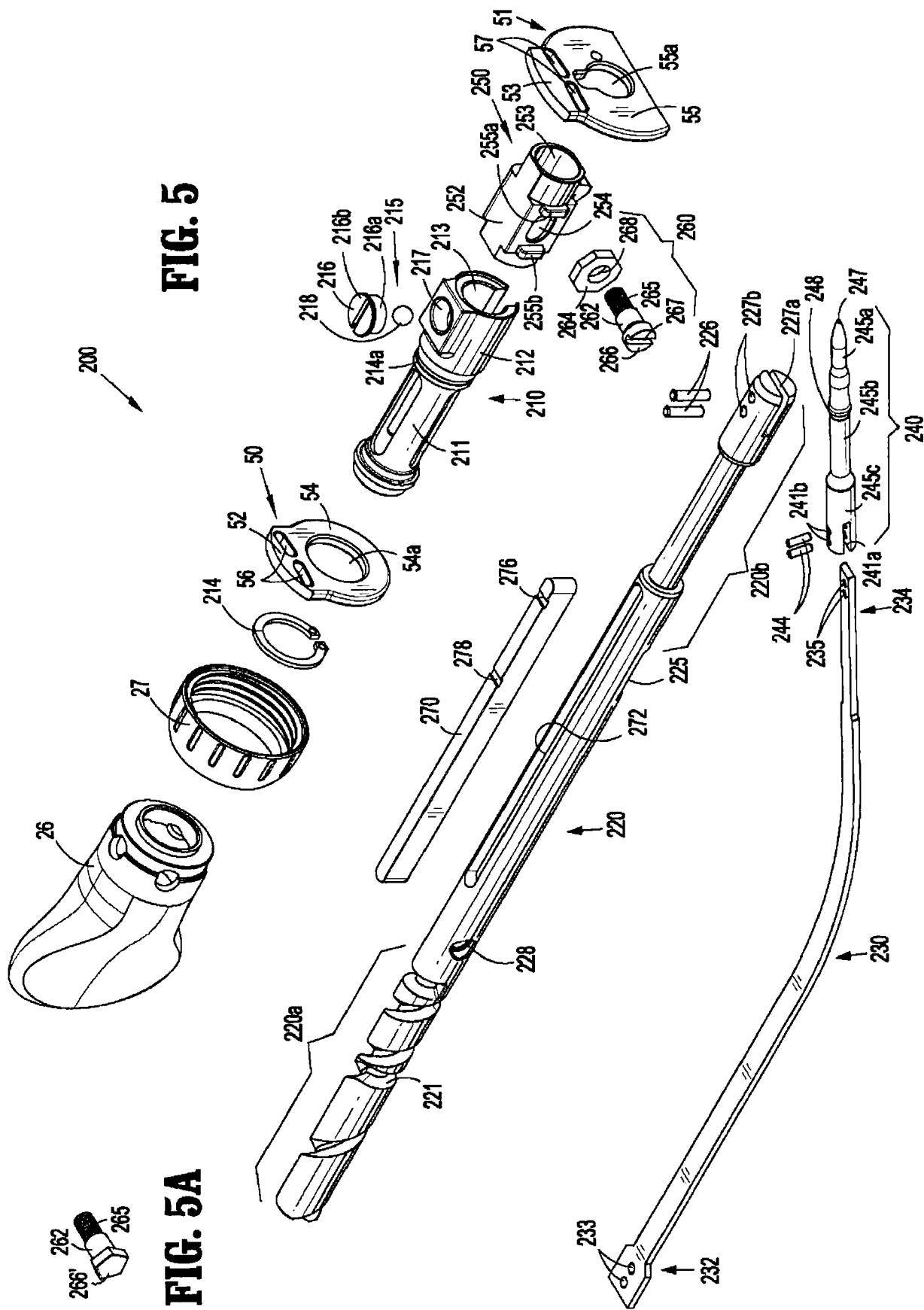
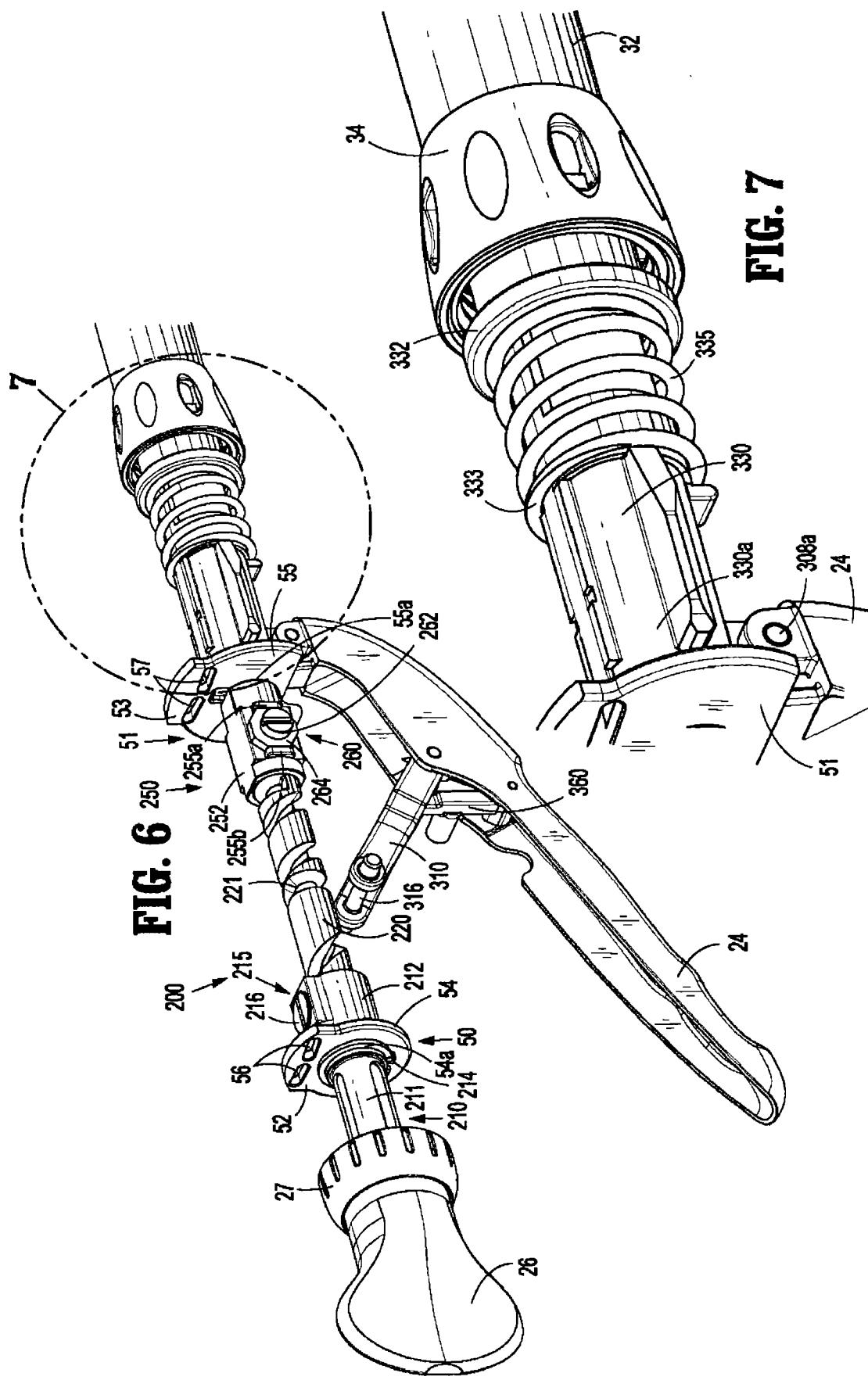
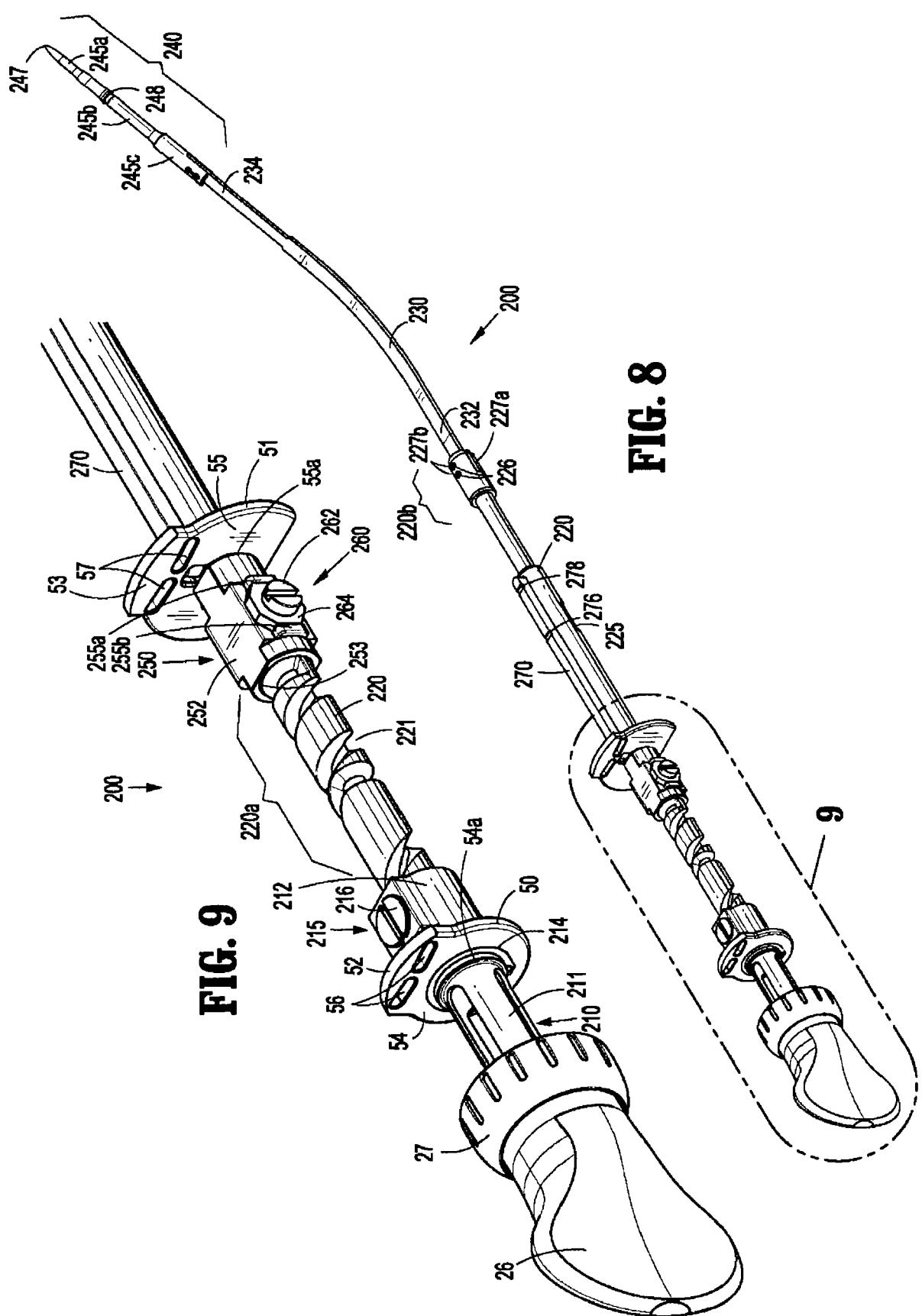
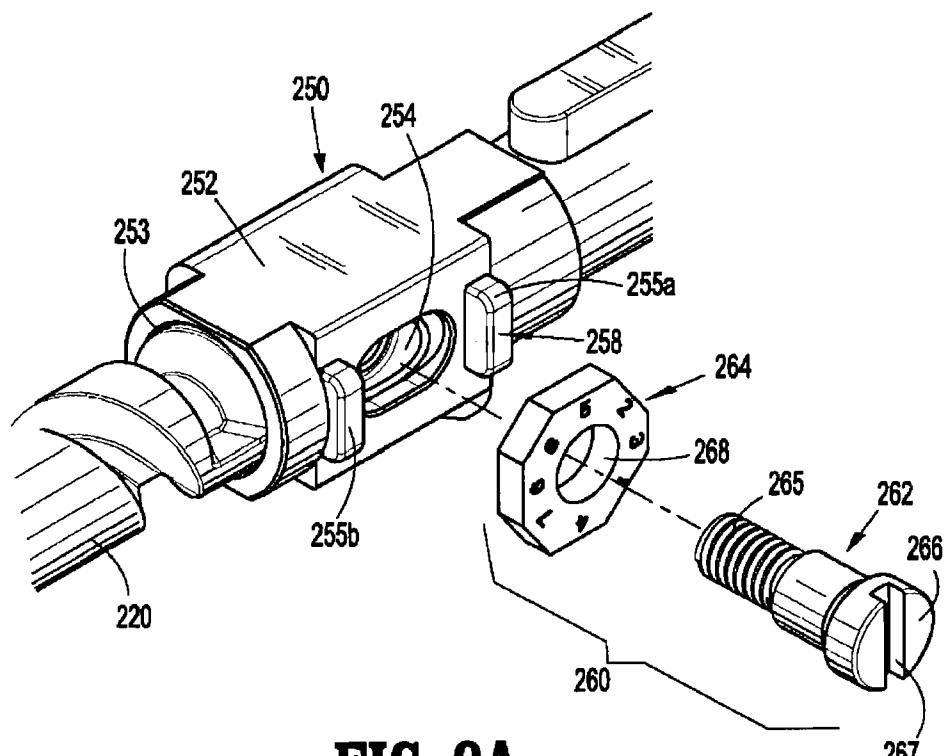
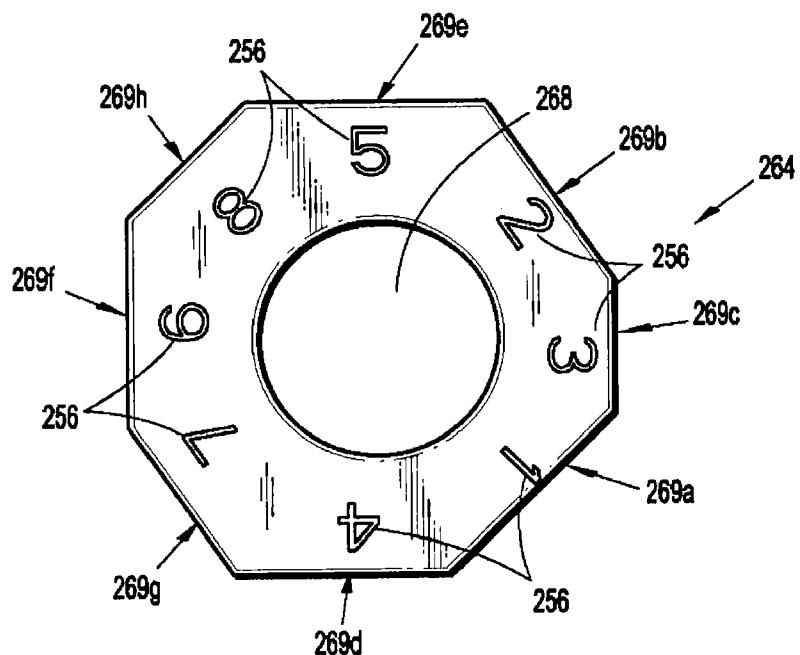


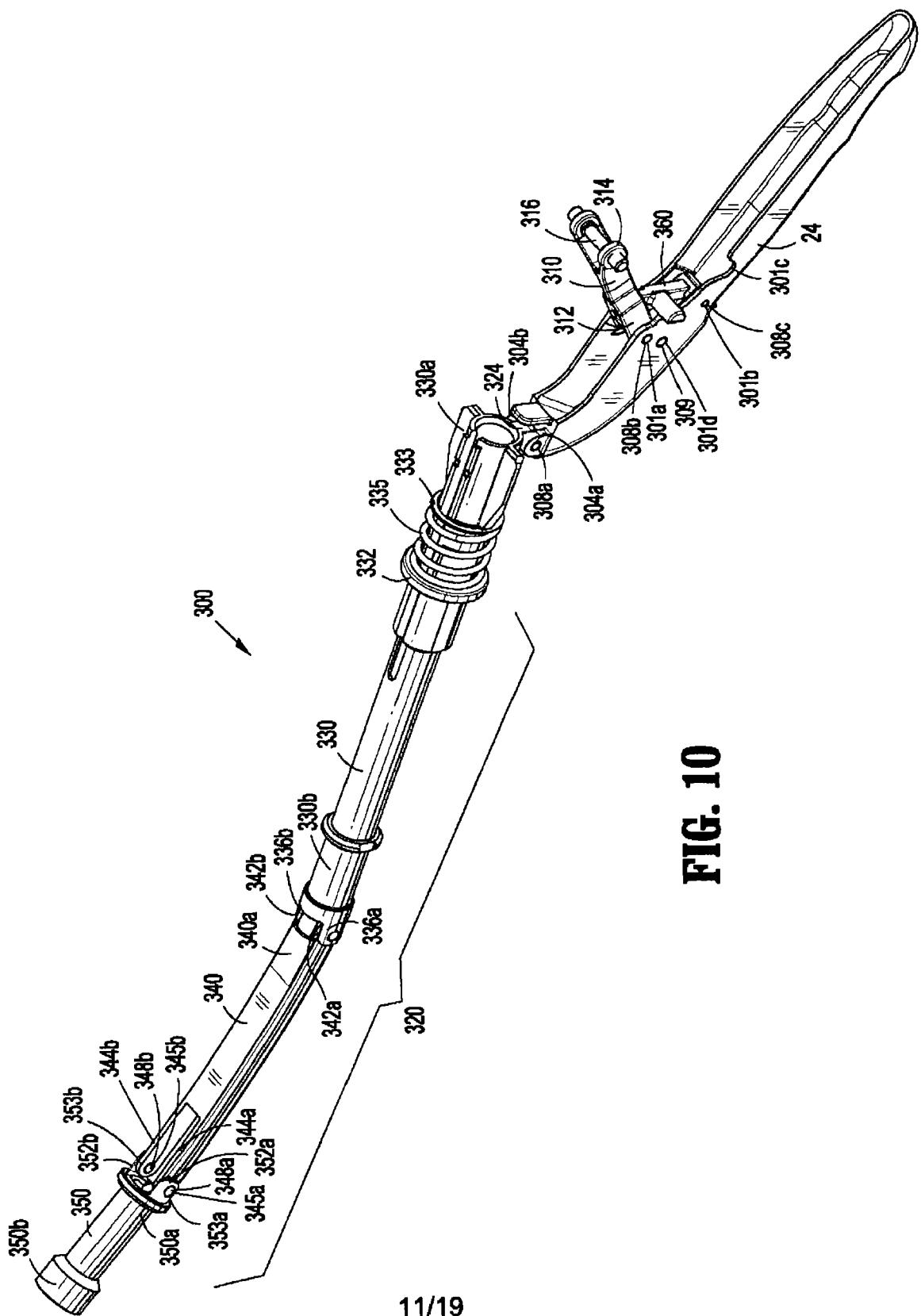
FIG. 5





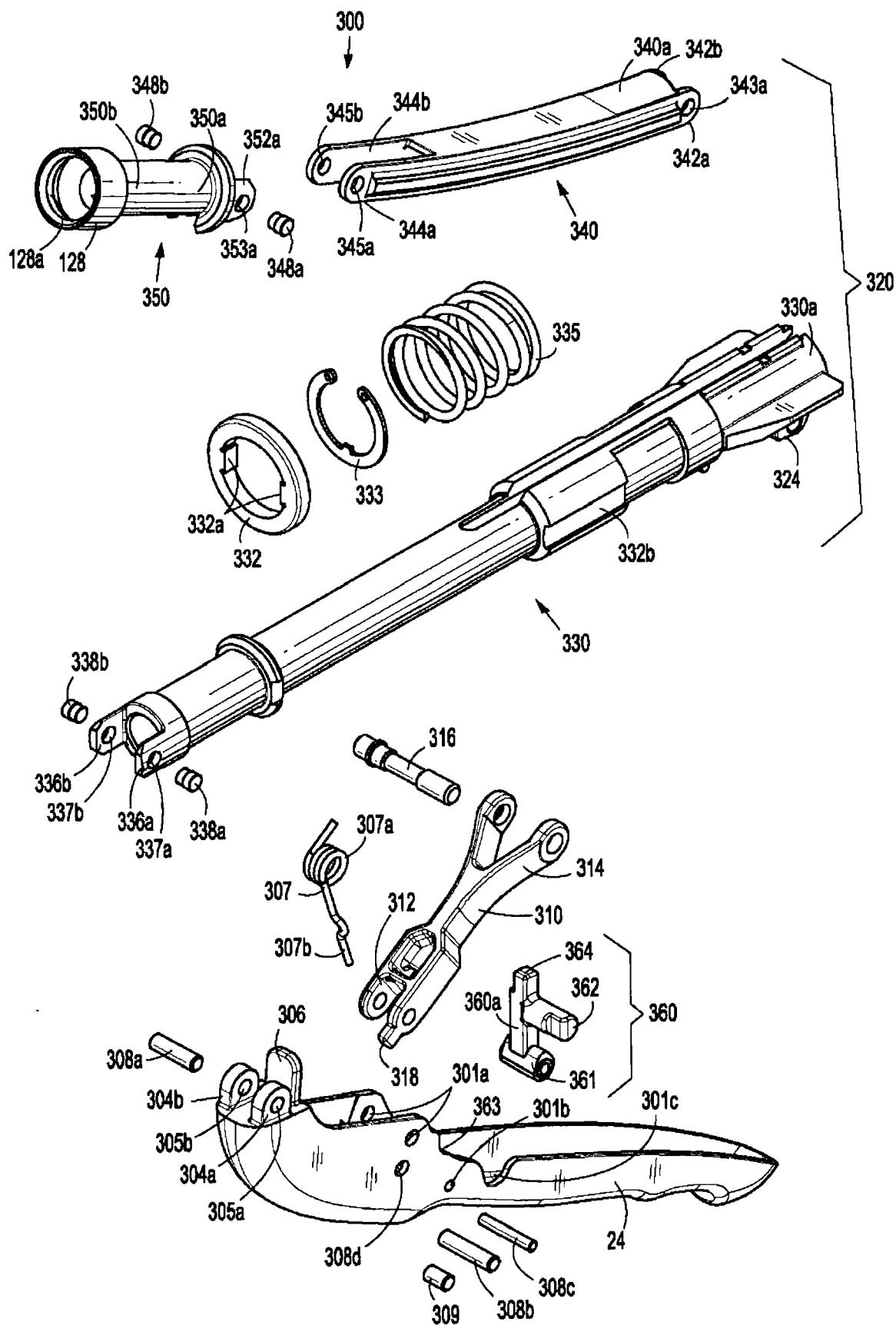


**FIG. 9A****FIG. 9B**

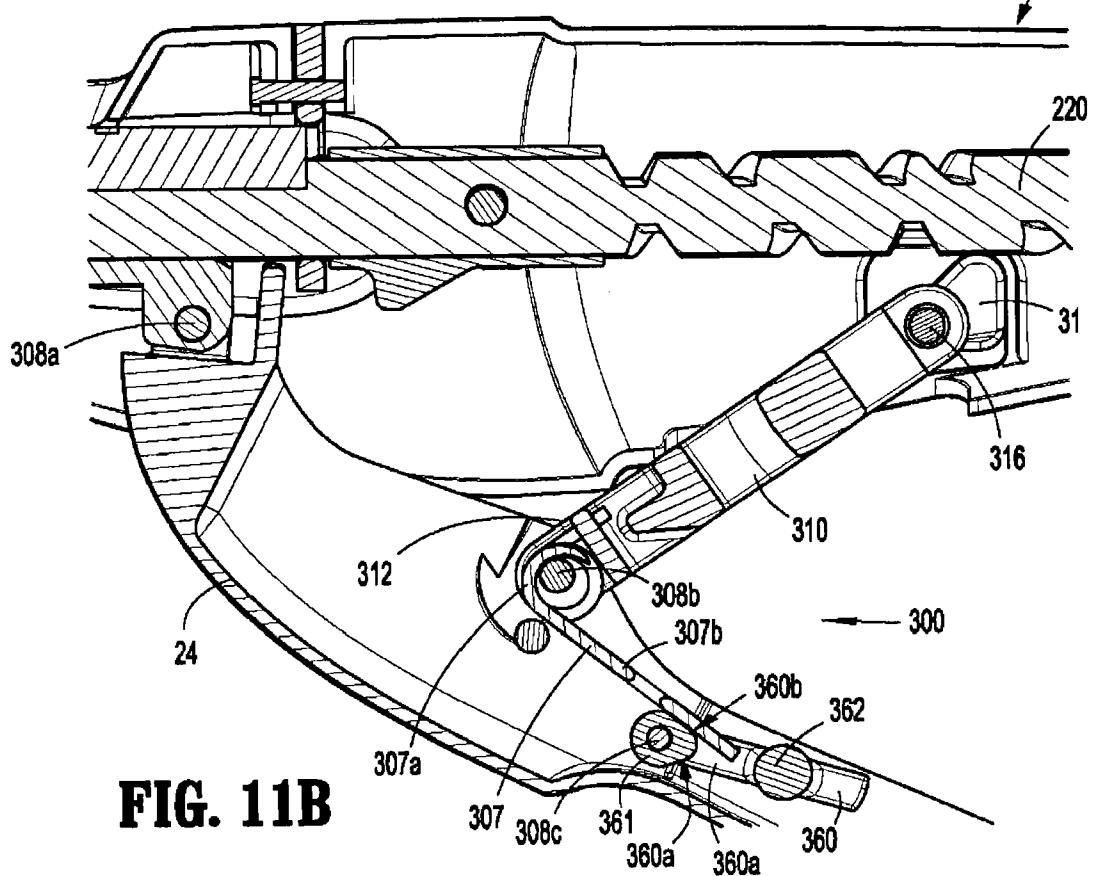
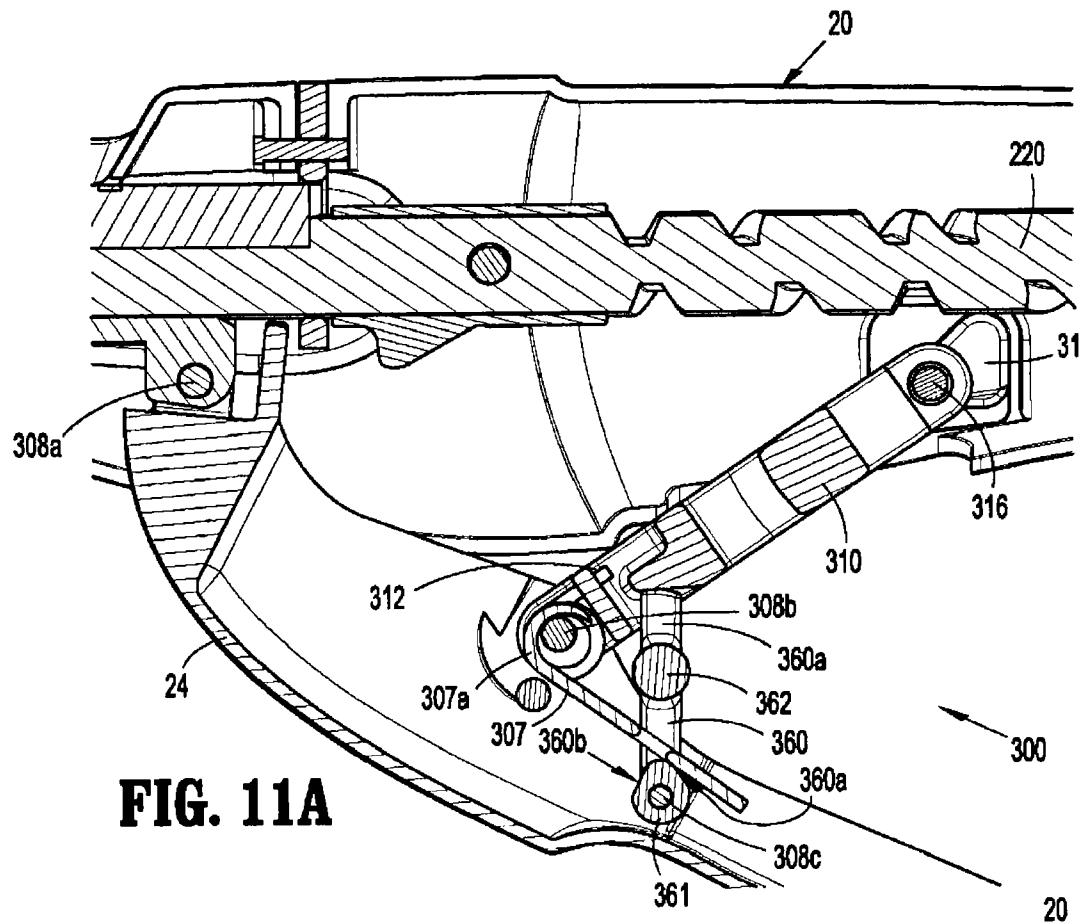


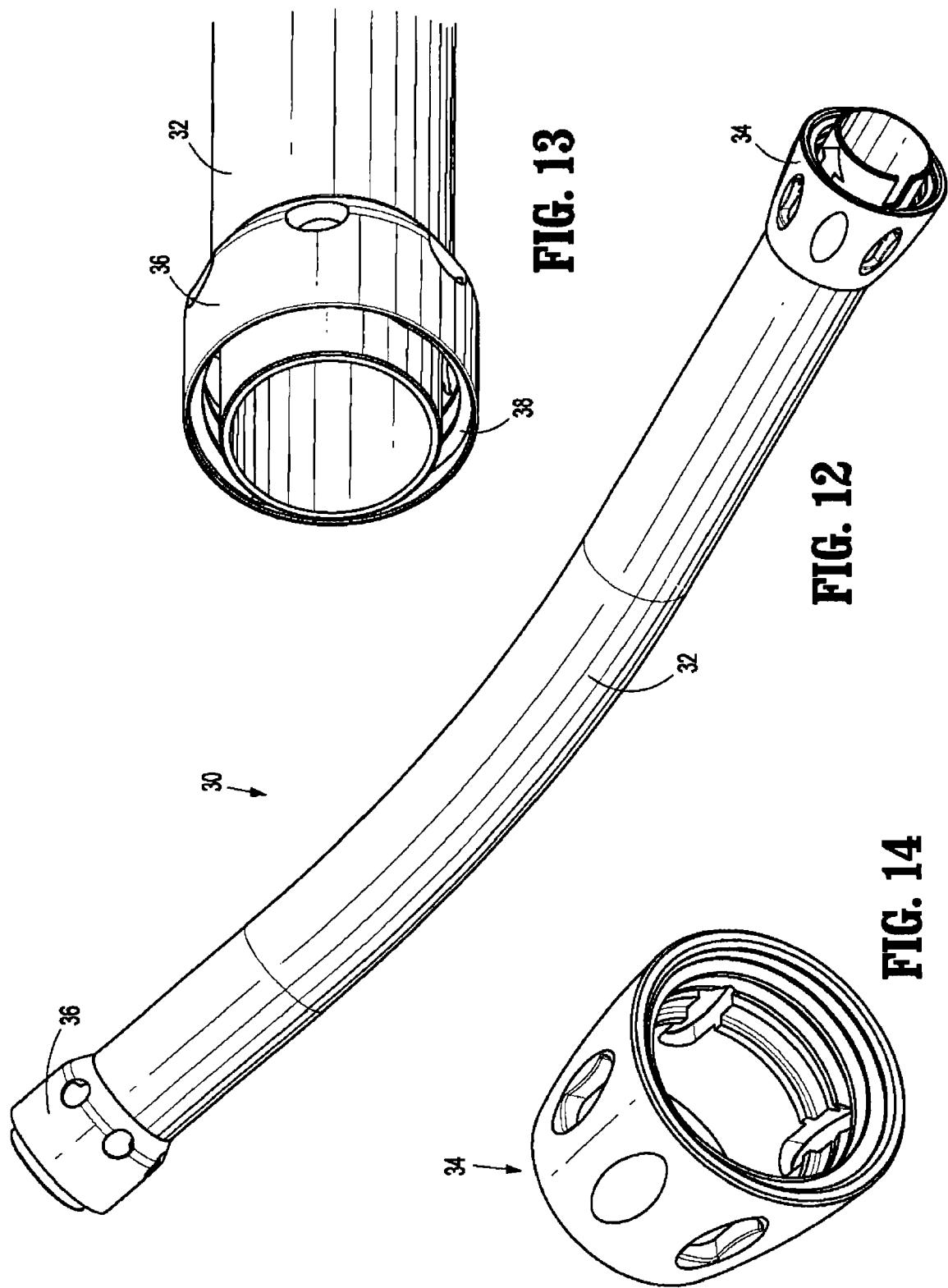
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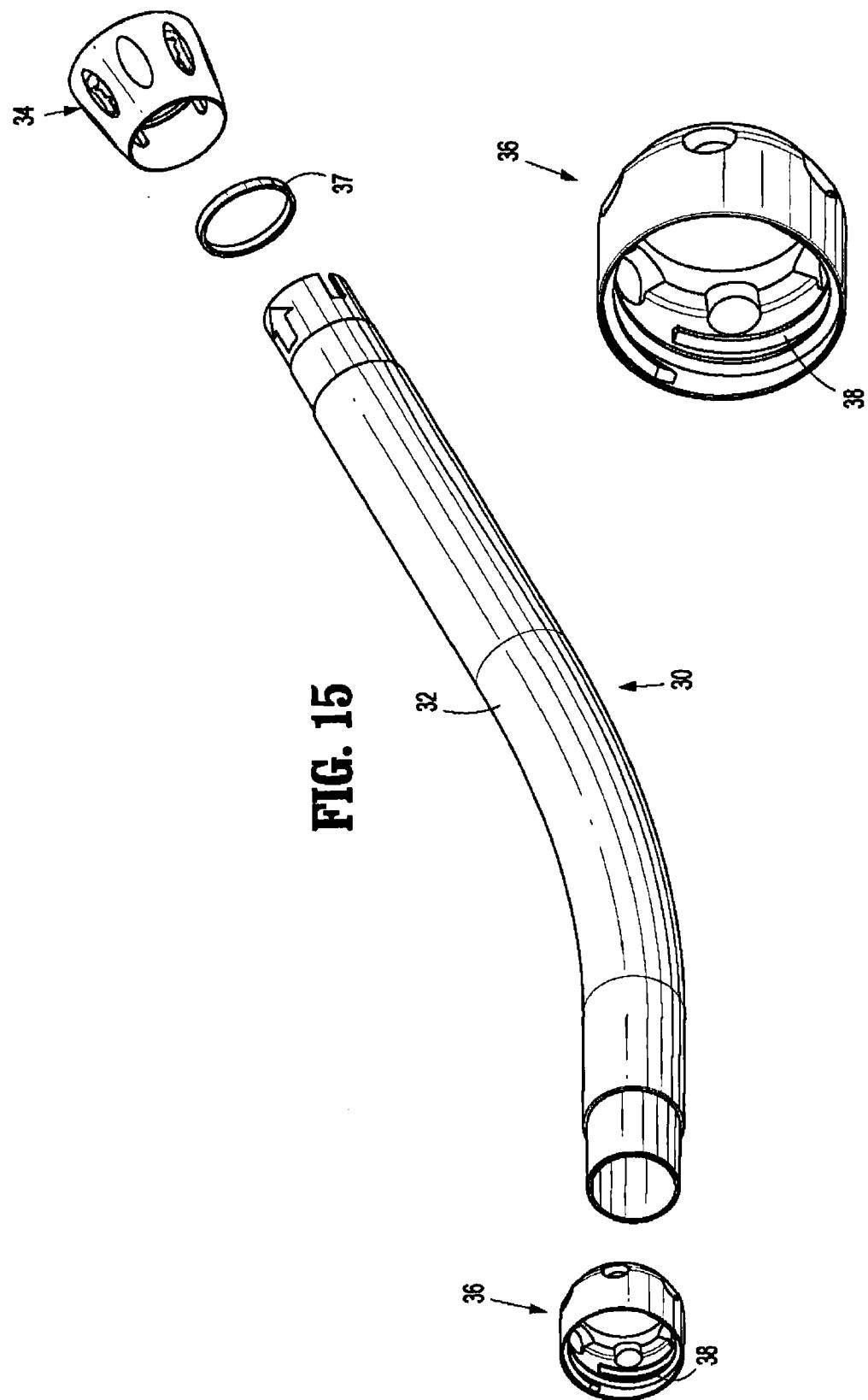
## **SUBSTITUTE SHEET (RULE 26)**

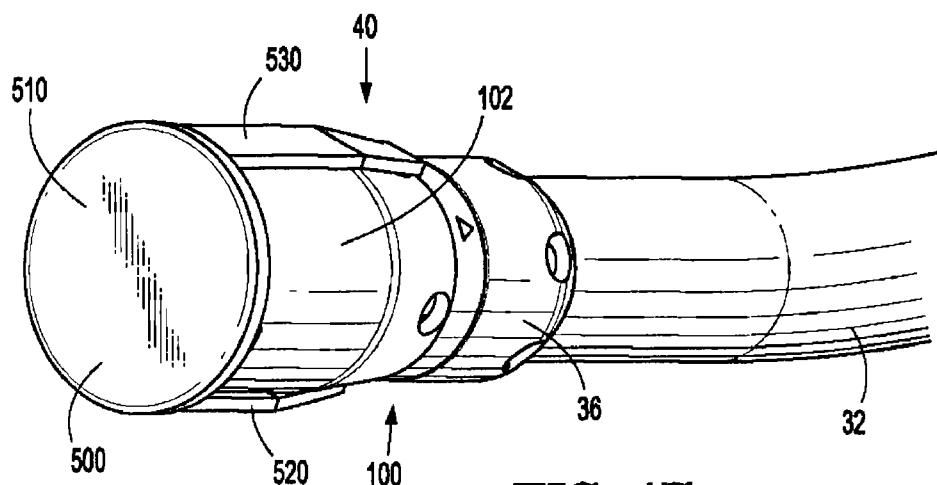
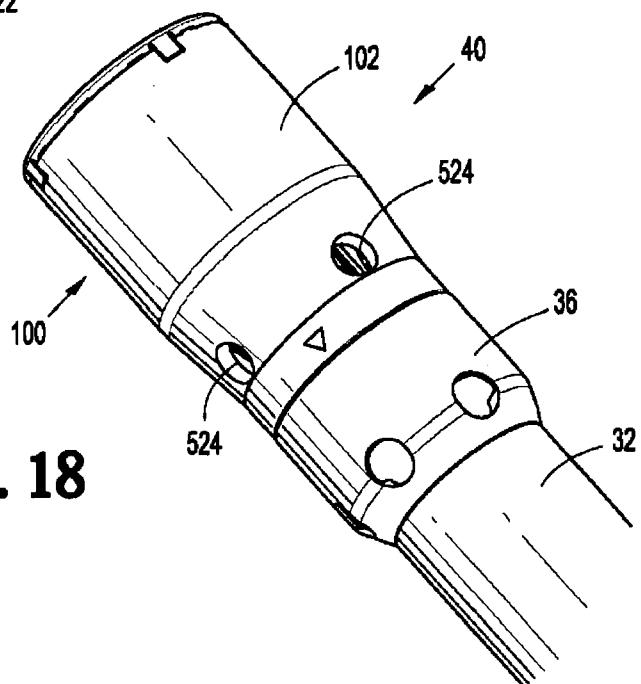
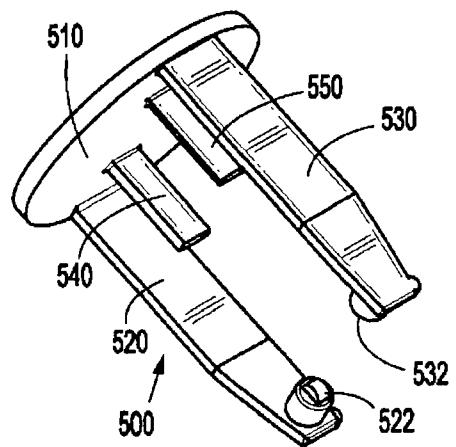
**FIG. 11**

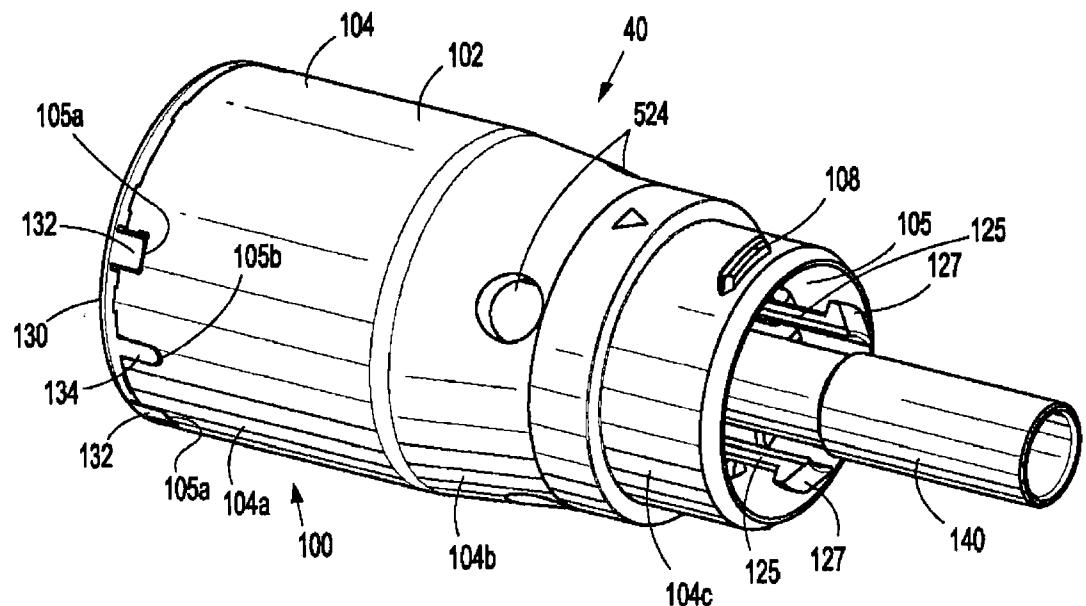
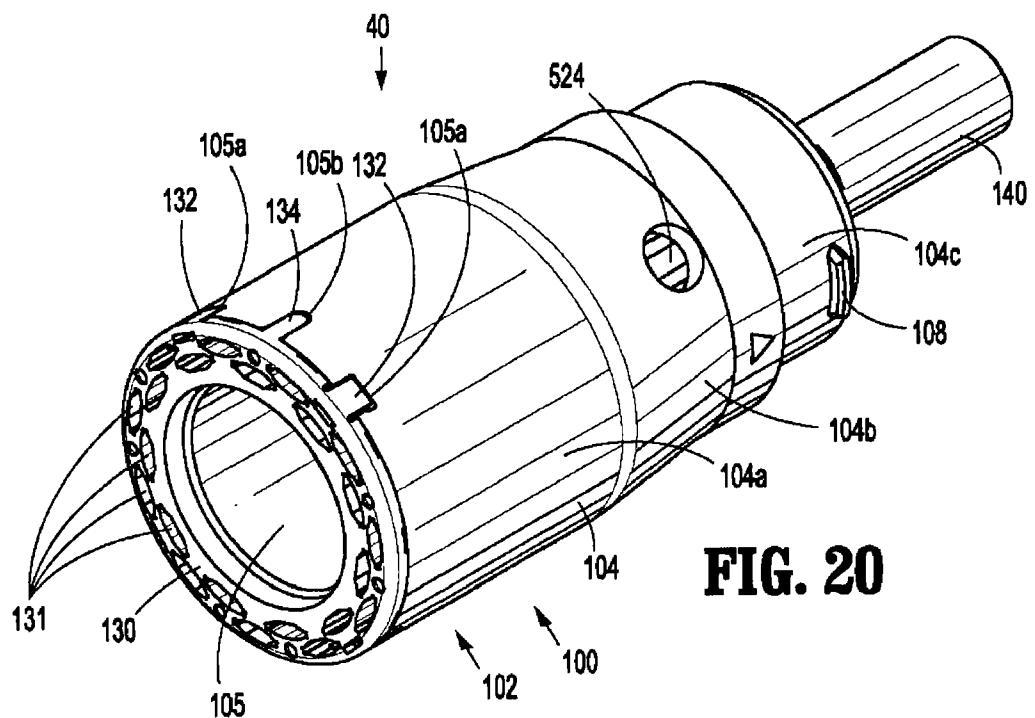
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**FIG. 15****FIG. 16**

**FIG. 17****FIG. 18**

**FIG. 19****FIG. 20**

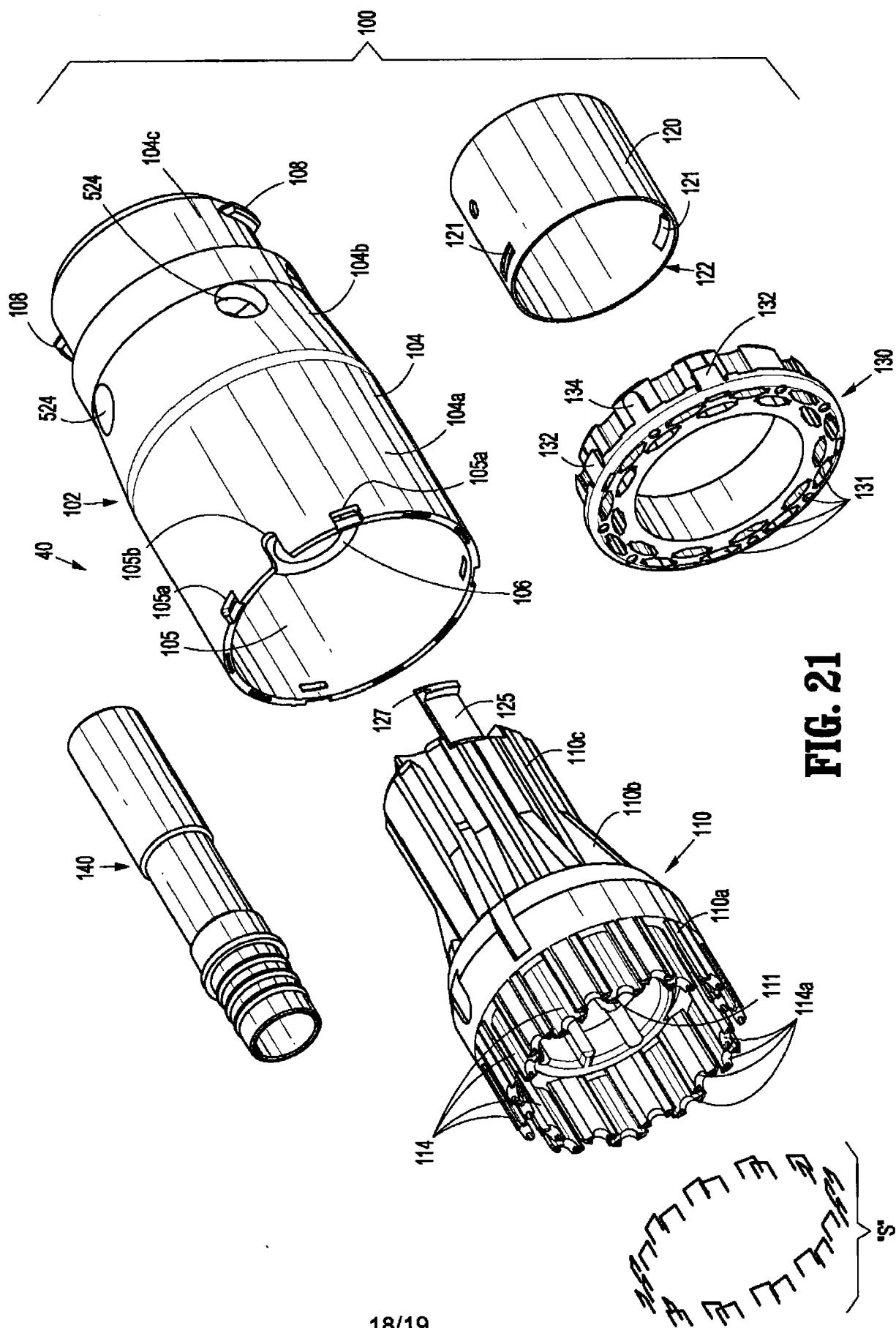


FIG. 21

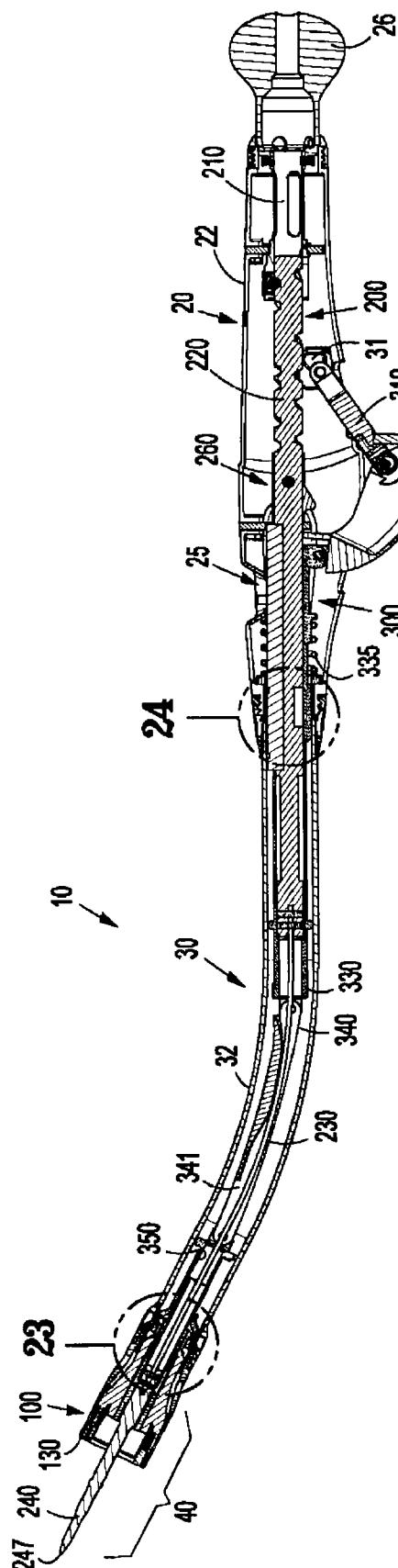


FIG. 22

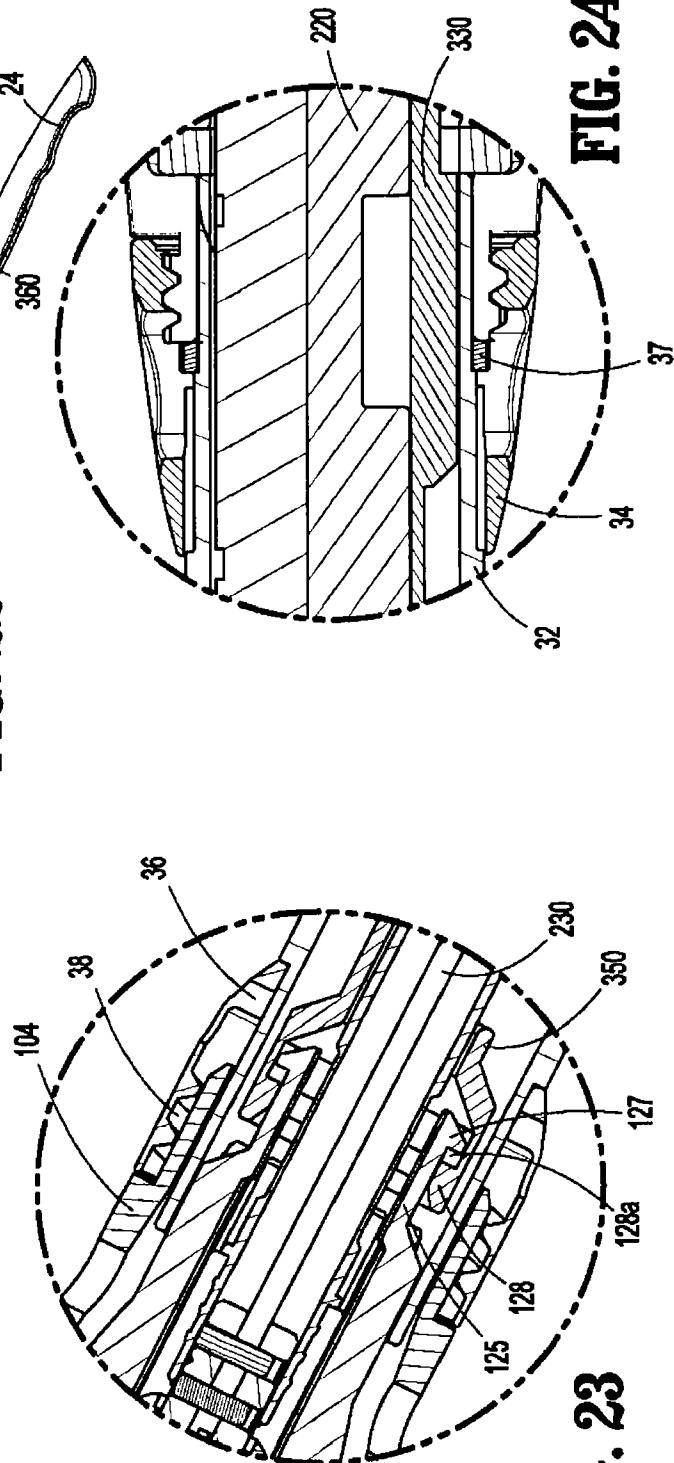


FIG. 24

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2014/074065

## A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/115(2006.01)i

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B17

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

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

CNABS, VEN: A61B17/115C, A61B17/115, clearance?, gap?, distance?, spac+, lock+

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 2100561 A2 (TYCO HEALTHCARE) 16 September 2009 (2009-09-16) the whole document	1-10
X	EP 2100561 A2 (TYCO HEALTHCARE) 16 September 2009 (2009-09-16) description, paragraphs 132-166, and figures 1-47	11-20
A	CN 102440816 A (TYCO HEALTHCARE) 09 May 2012 (2012-05-09) the whole document	1-20
A	CN 103371861 A (COVIDIEN LP) 30 October 2013 (2013-10-30) the whole document	1-20
A	CN 103096817 A (ETHICON ENDO SURGERY INC) 08 May 2013 (2013-05-08) the whole document	1-20
A	CN 102755180 A (TYCO HEALTHCARE) 31 October 2012 (2012-10-31) the whole document	1-20

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents:

- “A” document defining the general state of the art which is not considered to be of particular relevance
- “E” earlier application or patent but published on or after the international filing date
- “L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- “O” document referring to an oral disclosure, use, exhibition or other means
- “P” document published prior to the international filing date but later than the priority date claimed

- “T” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- “X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- “Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- “&” document member of the same patent family

Date of the actual completion of the international search  
**23 December 2014**

Date of mailing of the international search report  
**21 January 2015**

Name and mailing address of the ISA/CN  
**STATE INTELLECTUAL PROPERTY OFFICE OF THE  
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**INTERNATIONAL SEARCH REPORT**

International application No.

**PCT/CN2014/074065****Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

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

[1] Independent claims 1, 11, and 16 do not have the same or corresponding special technical features, thus lack of unity of invention and do not meet the requirements of Rule 13.1.

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

**Remark on Protest**

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

**INTERNATIONAL SEARCH REPORT**  
**Information on patent family members**

International application No.

**PCT/CN2014/074065**

Patent document cited in search report		Publication date (day/month/year)		Patent family member(s)			Publication date (day/month/year)
EP	2100561	A2	16 September 2009	CA	2657764	A1	12 September 2009
				US	2009230170	A1	17 September 2009
				JP	5461036	B2	02 April 2014
				AU	2009200965	B2	22 May 2014
				JP	2009213893	A	24 September 2009
				US	2014217144	A1	07 August 2014
				AU	2009200965	A1	01 October 2009
				US	8733611	B2	27 May 2014
CN	102440816	A	09 May 2012	AU	2011218605	A1	19 April 2012
				EP	2436318	A3	28 August 2013
				US	2012080492	A1	05 April 2012
				JP	2012075872	A	19 April 2012
				AU	2011218605	B2	31 July 2014
				CA	2749709	A1	01 April 2012
				EP	2436318	A2	04 April 2012
CN	103371861	A	30 October 2013	US	2013274771	A1	17 October 2013
				CA	2811955	A1	12 October 2013
				AU	2013201804	A1	31 October 2013
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				EP	2649950	A1	16 October 2013
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CN	103096817	A	08 May 2013	US	8360296	B2	29 January 2013
				JP	2013537066	A	30 September 2013
				CA	2810059	A1	15 March 2012
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				AU	2011299170	A1	21 February 2013
				EP	2613713	A1	17 July 2013
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				AU	2011299170	B2	21 August 2014
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				US	2012273545	A1	01 November 2012
				CA	2772423	A1	29 October 2012
				US	8490850	B2	23 July 2013
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				AU	2014202901	A1	19 June 2014
				AU	2012201688	B2	15 May 2014
				AU	2012201688	A1	15 November 2012
				EP	2517650	A2	31 October 2012
				US	2013299553	A1	14 November 2013