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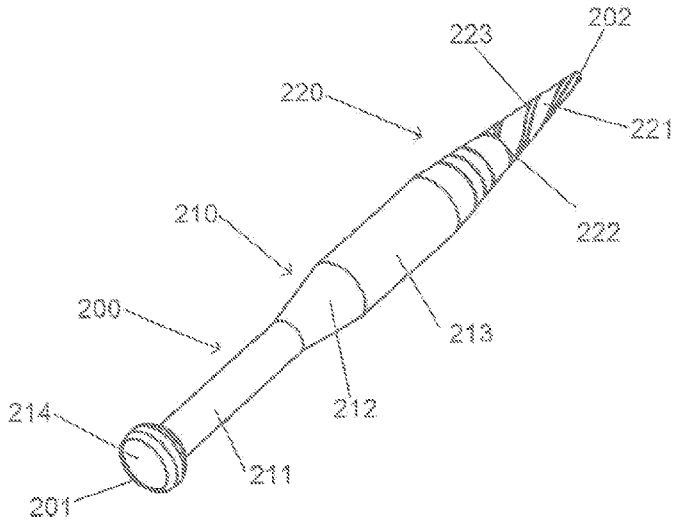

FIG. 1

(57) Abstract: A system for introducing a surgical instrument through a tissue lumen having: a surgical instrument; a sheath for preventing contamination of the tissue lumen; a dilator for dilating bodily tissue having an elongated body for positioning the dilator and a tapered section for facilitating dilation of the tissue lumen; and a cone having conical body that tapers from the proximal end to the distal end and facilitates insertion of the cone and the surgical instrument through the tissue lumen, an axial bore that extends longitudinally through the cone and receives an anvil retainer, a collar that engages the distal end of the surgical device and prevents lateral movement of the cone, grooves that engage the surface of the tapered section and reduce the friction between the cone and the tissue lumen, a securing device for securing the cone to the surgical instrument, and a retrieval device for retrieving the cone from a bodily cavity.

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Surgical Systems and Methods Thereof

Cross-Reference to Related Application

This application claims the benefit of priority to U.S. Provisional Application Number 61/438,958, filed on February 2, 2011, which is incorporated herein by reference in its entirety.

Background

In certain surgical procedures, surgeons insert instruments, for example, without limitation, surgical stapling devices, through an incision or lumen in the bodily tissue to a specific site or cavity to perform certain procedures. As the instrument is introduced or removed through the lumen to the surgical site, the distal end of the instrument can rip, tear, or cut the lumen leading to damage and trauma to the bodily tissues surrounding the lumen. This can promote contamination and /or infection of the surrounding tissues. The lumen and surrounding tissues can impede the passage of the instrument into the surgical site as well as disable or impair the functioning of the instrument. Recent advances such as rounding the end of a surgical device have failed to solve these problems. Specifically, tissue damage, trauma, infection or contamination and dysfunction of the device caused by or aggravated by the introduction or withdrawal of a surgical instrument through a lumen in the bodily tissue continues to be problematic.

Summary of the Invention

The present disclosure pertains to a system for introducing a surgical instrument through a tissue lumen. In one embodiment, the system has a cone for navigating a surgical instrument through a tissue lumen. In one embodiment, the surgical instrument is a surgical stapler device having a handle assembly, an elongated body, a cartridge assembly, and an anvil assembly. In one embodiment, the anvil assembly has an anvil retainer and an anvil. In one embodiment, the system has a shell for increasing the diameter of the elongated body. In one embodiment, the cone has a conical body having a proximal end and a distal end, wherein the conical body tapers from the proximal end to the distal end and facilitates insertion of the cone through the tissue lumen, an axial bore that extends longitudinally through the cone and receives an anvil retainer, and a collar that engages the distal end of the surgical device and prevents movement of the cone.

In one embodiment, the cone has cone grooves that engage the surface of the conical body and reduce the friction between the cone and the tissue lumen. In one embodiment, the cone has a securing device for securing the cone to the surgical instrument. In one embodiment, the securing device has a passage and a securing filament, wherein the passage traverses through the cone. In one embodiment, the cone has a retrieval device for retrieving the cone from a bodily cavity.

In one embodiment, the system has a dilator for dilating bodily tissue. In one embodiment, the dilator has an elongated body for positioning the dilator and a tapered section, having a proximal end and a

distal end wherein the tapered section tapers from the proximal end to the distal end and facilitates dilation of the tissue lumen. In one embodiment, the elongated body has a handle for positioning the dilator and a tapered portion for allowing the tissue lumen to be redilated upon retrieval of the dilator. In one embodiment, the elongated body has a non-tapered portion. In one embodiment, the tapered section has dilator grooves, wherein the dilator grooves are positioned on the surface of the tapered section and reduce the friction between the tapered section and the tissue lumen.

In one embodiment, the system has a protective sheath for preventing contamination of the tissue lumen wherein said sheath receives said surgical instrument. In one embodiment, the protective sheath has a rib for reducing the friction between the surgical instrument and the sheath. In one embodiment, the system has a sheath seal for reducing the amount of gas passing between the proximal end of the protective sheath and the surgical instrument. In one embodiment, the system has a separation mechanism for tearing the sheath seal.

In one embodiment, the present disclosure provides for a surgical device for dilating a tissue lumen having an elongated body for positioning said surgical device, and a tapered section, having a proximal end and a distal end, wherein said tapered section tapers from the proximal end to the distal end and facilitates dilation of said tissue lumen.

In one embodiment, the present disclosure provides for a surgical device for introducing a surgical instrument through a tissue lumen: having a conical body having a proximal end and a distal end, wherein the conical body tapers from the proximal end to the distal end and facilitates insertion of the cone through the tissue lumen; an axial bore, wherein the axial bore extends longitudinally through the cone and receives the anvil retainer; and a collar, wherein the collar engages the distal end of the surgical device and prevents lateral movement of the cone. In one embodiment, the surgical device has cone grooves, wherein the cone grooves are positioned on the surface of the tapered section and reduce the friction between the cone and the tissue lumen. In one embodiment, a surgical device has a securing device for securing the cone to the surgical instrument. In one embodiment, the securing device has a passage and a securing filament, wherein the passage extends transversely through the cone. In one embodiment, the surgical device has a retrieval device for retrieving the cone from a bodily cavity.

In one embodiment, the present disclosure provides for a surgical device for closing a wound having a guide and cone where the cone has a plurality of needle guidance bores for receiving a suture.

With those and other objects, advantages and features on the invention that may become hereinafter apparent, the nature of the invention may be more clearly understood by reference to the following detailed description of the invention, the appended claims, and the drawings attached hereto.

Brief Description of the Drawings

The accompanying drawings, which are incorporated herein and form part of the specification, illustrate various embodiments of the present invention and together with the description, further serve to

explain the principles of the invention and to enable a person skilled in the pertinent art to make and use the invention. In the drawings, like reference numbers indicate identical or functionally similar elements. A more complete appreciation of the invention and many of the attendant advantages thereof will be readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

FIG. 1 is a perspective view of a dilator according to an exemplary embodiment.

FIG. 2a is a perspective view of a surgical system according to an exemplary embodiment.

FIG. 2b is a perspective view of a surgical system according to an exemplary embodiment.

FIG. 2c is a perspective view of a surgical system according to an exemplary embodiment.

FIG. 3a is a side view of a protective sheath according to an exemplary embodiment.

FIG. 3b is a perspective view of a surgical system according to an exemplary embodiment.

FIG. 4a is a perspective view of a cone according to an exemplary embodiment.

FIG. 4b is a top plan view of a cone according to an exemplary embodiment.

FIG. 4c is a top plan view of a cone according to an exemplary embodiment.

FIG. 5 is a cross-sectional view of a cone according to an exemplary embodiment.

FIG. 6a is a cross sectional view of a closure device according to an exemplary embodiment.

FIG. 6b is a bottom plan view of a closure device according to an exemplary embodiment.

FIG. 6c is a cross sectional view of a closure device according to an exemplary embodiment.

FIG. 6d is a cross sectional view of a closure device according to an exemplary embodiment.

Detailed Description

To aid in understanding aspects of the invention described herein, some terms used in this description are defined below.

By "proximal" is meant the end of the surgical instrument of the present disclosure which is closer to the operator during use.

By "distal" is meant the end of the surgical instrument of the present disclosure which is further from the operator during use.

In the following detailed description, reference is made to the accompanying drawings which form a part hereof and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural or logical changes may be made without departing from the scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

The present disclosure pertains to a surgical system 100 having a plurality of surgical devices for providing minimally invasive access to a surgical site. In one embodiment, the surgical system 100 has a cone 300 a dilator 200, and a surgical instrument 400, a closure device 600, or any combination thereof.

Referring to FIG. 1, by way of example, without limitation, a dilator 200 for dilating bodily tissue or a colon is provided. Bodily tissue can be any tissue located in the body, for example, without limitation, skin, fascia, adipose tissue, muscle, ligaments, peritoneum, , or the like. The dilation of bodily tissue increases the diameter of a previously created tissue lumen passing from the exterior of a patient to a body cavity, for example, without limitation, the abdomen, thorax, viscera, joint, or the like. The dilator 200 has an elongated body 210, a tapered section 220, a proximal end 201, and a distal end 202.

The tapered section 220 is conical and tapers from the distal end of the elongated body 210 to the distal end 202 of the dilator 200, thereby providing for a dilator tip 221. The dilator tip 221 is rounded, or takes the shape of a semicircle, to avoid damage to bodily tissue and organs located in the body cavity. The dilator tip 221 facilitates insertion of the distal end 202 into a tissue lumen. In one embodiment, the tapered section 220 allows for a gradual dilation of the bodily tissue as the dilator 200 passes through the bodily tissue where the tapered section 220 circumferentially stretches or dilates the bodily tissue to a desired diameter, thereby increasing the diameter of the tissue lumen. The dilation of the tissue lumen allows for the passage of a surgical instrument 400 or a cone 300 engaged to a surgical instrument 400. In one embodiment, the tapered section 220 has a smooth surface.

The length of the tapered section 220 depends on the thickness of the bodily tissue. The length of the tapered section 220 is longer as the thickness of the bodily tissue increases. While any length of the tapered section 220 that allows for a suitable use is contemplated, the length of the tapered section 220 is preferably 1.00 inches to 6.50 inches. The diameter of the proximal end of the tapered section 220 depends on the width or diameter of the surgical instrument 400 and cone 300 to be inserted through the tissue lumen. While any diameter of the proximal end of the tapered section 220 that allows for a suitable use is contemplated, the diameter of the proximal end of the tapered section 220 is preferably 0.80 inches to 1.50 inches. For example, the proximal end of the tapered section 220 can have a diameter of 0.83 inches, 0.98 inches, 1.06 inches, 1.14 inches, 1.30 inches, or the like.

In one embodiment, the tapered section 220 has at least one marker 222. The marker 222 can indicate the diameter of the tissue lumen and /or the distance the dilator 200 has penetrated into the bodily tissue. The location of the marker 222 on the tapered section 220 can be varied and depends on the width or diameter of the surgical instrument 400 to be introduced through the tissue lumen. In one embodiment, the marker 222 is preferably a circumferential groove around the tapered section 220. The actual distance of the marker 222 from the distal end 202 depends on the desired diameter of the tissue lumen, the length of the tapered portion 220, the diameter of the nontapered portion 213, and/or the desired penetration distance into the bodily tissue. The preferred diameter at the marker 222 is greater than or equal to 0.60 inches. In one embodiment, the tapered section 220 has a plurality of markers 222 corresponding to a plurality of surgical instrument 400 diameters or cone 300 diameters. For example, the tapered section 220 has a

marker 222 corresponding to a diameter of 0.83 inches, a marker 222 corresponding to a diameter of 0.98 inches, a marker 222 corresponding to a diameter of 1.06 inches, a marker 222 corresponding to a diameter of 1.14 inches, and a marker 222 corresponding to a diameter of 1.30 inches.

In one embodiment, the dilator 200 has dilator grooves 223 to reduce surface area and thereby reduce friction between the dilator 200 and the tissue lumen created by the dilator penetrating the tissue lumen. The dilator grooves 223 are channels and can have any dimension that allow for the reduction of surface area friction of the dilator 200 and allow for the dilation of a tissue lumen. The width of the dilator grooves 223 affects the amount of friction between the dilator 200 and the tissue lumen where the increase in the width of the dilator groove 223 decreases the friction between the dilator 200 and the tissue lumen. In one embodiment, the dilator grooves 223 are positioned on the surface of the tapered section 220. In one embodiment, the dilator grooves 223 are positioned on the surface of the tapered section 220 and the non-tapered portion 213. The dilator grooves 223 extend from the proximal end of the tapered section 220 to the distal end of the tapered section 220 and can be straight, as shown in FIG. 1, or spiral. In one embodiment, the depth of the dilator grooves 223 at the distal end is shallower than the depth of the dilator grooves 223 at the proximal end.

In one embodiment, the elongated body 210 has a handle 211 and a tapered portion 212. The handle 211 is positioned on the proximal end 201 of the dilator 200. In one preferred embodiment, the elongated body 210 is configured to provide for and facilitate proper positioning of the handle 211 and indicates to a user the orientation of the handle 211 in relation to the tapered section 220. In one embodiment, the cross-section of handle 211 is polygonal in shape thereby allowing for stable gripping by the user. The tapered portion 212 is substantially fustoconical in shape. The tapered portion 212 allows for the tissue lumen to be redilated when the dilator 200 is retrieved by pulling the dilator 200 in the reverse direction through the tissue lumen. In one embodiment, the tapered portion 212 and the handle 211 allow for the dilator 200 to be lighter and more easily maneuverable. The proximal end of the tapered portion 212 engages the handle 211 and the distal end of the tapered portion 212 engages the proximal end of the tapered section 220.

In one embodiment, the elongated body 210 has a non-tapered portion 213 extending between the tapered section 220 and the tapered portion 212. Here, the proximal end of the tapered portion 212 engages the handle 211 and the distal end of the tapered portion 212 engages the non-tapered portion 213. The distal end of the non-tapered portion 213 engages the tapered section 220 and the proximal end of the non-tapered portion 213 engages the tapered portion 212 of the dilator 200. The non-tapered portion 213 maintains the dilation of the tissue bodily tissue.

In one embodiment, as shown in FIG. 1, the elongated body 210 has a knob 214 for preventing injury to the palm of the user's hand. The knob engages the proximal end of the elongated body 210. While the diameter of the knob 214 can be any dimension that allows for a suitable use, the diameter of the knob 214 is preferably the same diameter of the non-tapered portion 213.

In one embodiment, the knob 214 can have a marker 216 to indicate the diameter of a tissue lumen or colon, and /or the distance the knob 214 has penetrated into the bodily tissue or colon. The location of the marker 216 on the knob 214 can be varied and depends on the width or diameter of the surgical instrument 400 to be introduced through the tissue lumen or colon. In one embodiment, the marker 216 is preferably a circumferential groove around the knob 214. The actual distance of the marker 216 from the proximal end of the knob 214 depends on the desired diameter of the tissue lumen or colon, the length of the knob 214, and/or the desired penetration distance into the bodily tissue or colon. The preferred diameter at the marker 216 is greater than or equal to 0.60 inches. In one embodiment, the knob 214 has a plurality of markers 216 corresponding to a plurality of surgical instrument 400 diameters or cone 300 diameters. For example, the knob 214 has a marker 216 corresponding to a diameter of 0.83 inches, a marker 216 corresponding to a diameter of 0.98 inches, a marker 216 corresponding to a diameter of 1.06 inches, a marker 216 corresponding to a diameter of 1.14 inches, and a marker 216 corresponding to a diameter of 1.30 inches.

Although the dimensions of the dilator 200 depend on the desired diameter of the tissue lumen or colon, the thickness of the bodily tissue in which the tissue lumen passes, the cavity to be penetrated, or the type of surgical instrument 400 to pass through the tissue lumen, the length of the dilator 200 is any length that allows for a suitable use. For example, without limitation, the length of the dilator 200 is preferably 11.00 inches to 17.00 inches, the length of the elongated body 210 is preferably 5.00 inches to 11.00 inches, the length of the handle 211 is preferably 2.00 inches to 8.00 inches, the length of tapered section 220 is 1.00 inches to 6.50 inches, the length of the tapered portion 212 is preferably 1.00 inches to 3.00 inches, the length of the non-tapered portion 213 is preferably 1.00 inches to 5.00 inches, the length of the greatest diameter of the dilator tip 221 is preferably 0.12 inches to 0.38 inches, and the tapered angle of the tapered section 220 is preferably 4 degrees to 25 degrees.

In one embodiment, the dilator 200 has an external thread for engaging the wall of the tissue lumen thereby creating a force that pulls the dilator 200 through the tissue lumen upon the user screwing or twisting the dilator 200 into the tissue lumen. The thread spirally extends around the surface of the tapered section 220 from the proximal end of the tapered section 220 to the distal end 202 of the dilator 200. The thread can have any guide angle allowing for the dilator 200 to be pulled through the tissue lumen. In one embodiment, the dilator can have a plurality of discrete threads. The dilator 200 may be used in a corkscrew fashion to dilate the bodily tissue by rotating dilator 200 to penetrate and dilate the tissue lumen whereby the thread prevents the dilator 200 from plunging into the surgical site.

In one embodiment, the surgical instrument 400 can be any instrument that passes through bodily tissue, for example, without limitation, a surgical stapling device, a fan retractor, an articulating dissector, or the like. The surgical instrument 400 can be any size that allows for a suitable use. Referring to FIGS. 2a-3a, a surgical instrument 400 is provided, by way of example, without limitation, which is illustrated as a circular surgical stapling device having an approximation knob 410, a handle assembly 420, an elongated body 430, a cartridge assembly 440, and an anvil assembly 450.

Handle assembly 420 is connected to cartridge assembly 440 by the elongated body 430. Handle assembly 420 has a firing lever 422 for activating surgical stapling device that deploys a circular arrangement of staples and cuts and removes a circular shaped portion of tissue. Anvil assembly 450 has anvil retainer 451 and anvil 452. Approximation knob 410 is positioned on the proximal end 401 of the surgical instrument 400. Approximation knob 410 is operatively connected to an anvil retainer 451 in a known manner such that operation, e.g. rotation, of approximation knob 410 effects advancement or retraction of anvil retainer 451. Anvil 452 is releasably secured to anvil retainer 451 where in one position the anvil 452 is separated from the anvil retainer 451 and in another position the anvil 452 is intact with the anvil retainer 451. The anvil retainer 451 and thereby the anvil 452 is movable into approximation with cartridge assembly 440 by operating, for example, rotating approximation knob 410. Prior to firing the surgical stapling device a staple line enhancer, for example, without limitation, a peristrip is passed over the anvil retainer 451 and onto the distal end 402 of the surgical stapling device. Cartridge assembly 440 can have a plurality of diameter sizes.

Referring to FIGS. 2a-5, by way of example, without limitation, a cone 300 for introducing a surgical instrument 400 through bodily tissue or colon by dilating the surrounding bodily tissue or colon thereby minimizing the amount of trauma caused to the surrounding bodily tissue. In one embodiment, the cone 300 can minimize trauma by any suitable means, for example, without limitation, cone 300 allows a user to locate the orientation of a tissue lumen in the bodily tissue and navigate the surgical instrument 400 through the tissue lumen while causing minimal damage to the surrounding tissue. In one embodiment, when removed, the cone 300, having dilated the surrounding tissues instead of cutting them, allows the surrounding tissue and lumen to constrict somewhat and regain some of their its predilated form thereby reducing the risk of herniation and /or reducing the need for a greater number of sutures to close the tissue lumen. In one embodiment, the cone 300 allows a user to redilate a previously dilated tissue lumen that has constricted while causing minimal damage to the surrounding bodily tissue.

Referring to FIGS. 4a-4c and 5, cone 300 has a body 310, a cone tip 320, a longitudinally extending axial bore 330, and an exterior surface 303. The proximal end 301 of the cone 300 engages the distal end 402 of the surgical instrument 400.

The body 310 is conical and preferably tapers from the proximal end 301 to the distal end 302, thereby providing for a cone tip 320. The cone tip 320 is rounded, or takes the shape of a semicircle, to avoid damage to bodily tissue and organs located in the body cavity. In one embodiment, the cone tip 320 facilitates insertion of the distal end 302 into a previously created tissue lumen. The tissue lumen can be created by a trocar or like instrument. Here, the cone 300 allows for a gradual dilation of the bodily tissue as the cone 310 passes through the bodily tissue where the cone 300 circumferentially stretches or dilates the bodily tissue to a desired diameter, thereby increasing the diameter of the tissue lumen and allowing the instrument to enter more easily into a body or viscera cavity. In one embodiment, the tapered configuration facilitates insertion of the distal end 302 into a previously dilated tissue lumen. The tissue lumen can be previously dilated using, for example, without limitation, a dilator, a trocar, or the like. Here, the cone 300

allows for a gradual re-dilation of the bodily tissue as the cone 300 is passed through the bodily tissue. The cone 300 can allow the user to locate the orientation of the tissue lumen and navigate through the tissue lumen into the body or viscera cavity.

The longitudinally extending axial bore 330 co-axially receives the anvil retainer 451, thereby allowing the proximal end 301 of the cone 300 to engage the distal end 402 of the surgical instrument 400. In one embodiment, the axial bore 330 receives the anvil retainer 451, thereby preventing lateral movement or dislodgement of the cone 300. While any suitable dimensions of the axial bore 330 are contemplated, the dimensions preferably correspond to the dimensions of the anvil retainer 451 used with the cone 300. For example, without limitation, the tolerance between the anvil retainer 451 and the axial bore 330 is zero where the axial bore 330 is designed for mating to the anvil retainer 451 or greater than zero to allow the cone 300 to release from the anvil retainer 451. In one embodiment, the depth of the axial bore 330 is less than the length of the anvil retainer 451 thereby allowing for the anvil retainer to push the cone 300 off the surgical instrument 400 when the anvil retainer is in the extended position.

In one embodiment, the proximal end 301 of the cone 300 has a proximal cavity 340 and a cavity surface 341, where the outer edge of the cavity surface 341 engages the outer edge of the distal end 402 of the surgical instrument 400. The proximal cavity 340 prevents the peristrip from contacting the proximal end 301 of the cone 300 and in turn from sticking to the proximal end 301 of the cone 300 where the cone 300 disengages from the distal end 402 of the surgical instrument 400. In one embodiment, the proximal end 301 of the cone 300 has an annular shoulder 350 about the proximal cavity 340 where the shoulder 350 engages the outer edge of the distal end 402 of the surgical instrument 400. This prevents the peristrip from contacting the proximal end 301 of the cone 300 and in turn prevents the peristrip from sticking to the proximal end 301 of the cone 300 where the cone 300 disengages from the surgical instrument 400. The proximal cavity 340 can have a diameter that allows the proximal cavity 340 to receive the surgical instrument 400. The proximal cavity 340 can have a diameter that allows the proximal cavity 340 to receive the surgical instrument 400 and the protective sheath 500 where the surgical instrument 400 is received by the protective sheath 500.. The shoulder 350 can have any diameter that corresponds to the diameter of the surgical instrument 400. The shoulder 350 can have any diameter that corresponds to the diameter of the surgical instrument 400 and protective sheath 500 where the surgical instrument 400 is received by the protective sheath 500. In one embodiment, the diameter of the shoulder 350 allows for the shoulder 350 to avoid contact with the peristrips and allows the proper operation of the surgical instrument 400.

In one embodiment, where the anvil 452 is intact with the surgical stapler device and the surgical instrument 400 is in the closed position, the proximal cavity 340 is designed for mating to the distal end of the anvil 452. Here, the proximal cavity 340 and collar 360 allow for the cone 300 to be placed and held onto the distal end 402 of the surgical instrument 400 when the anvil 452 is in the attached closed position, thereby allowing for the anvil 452 to be engaged with the surgical instrument 400 when the surgical instrument 400 passes through the tissue lumen. In this embodiment, the proximal cavity 340 can have any

dimensions that correspond to the dimensions of the plurality of anvils 452 available for use with a surgical instrument 400 and yet still allow for easy release at the appropriate time.

In one embodiment, the cone 300 has a collar 360 for preventing lateral movement and /or dislodgement of the cone 300 when the cone 300 engages the proximal end 401 of the surgical instrument 400. The collar 360 provides for a collar cavity 370 that receives the distal end 402 of the surgical instrument 400. The collar 360 is designed for mating to the distal end 402 of the surgical instrument 400, thereby preventing lateral movement and /or dislodgement of the cone 300. In this embodiment, the annular shoulder 350 of the cone 300 engages the distal end 402 of the surgical instrument 400, thereby preventing the peristrip from sticking to the cone 300 when the cone 300 disengages from the surgical instrument 400. While any suitable dimensions of the collar 360 are contemplated, the collar 360 preferably has a height between 0.25 inches and 2.00 inches and a width extending from an exterior point on the collar 360 to an exterior point on the opposite side of the collar 360 between 0.60 inches and 1.50 inches, and a thickness between 0.03 inches and 0.16 inches. In one embodiment, the anvil retainer 451 is longer than the axial bore 330. Here, the collar 360 preferably has a height between 1/4 inches and 2 inches. In one embodiment, the collar 360 height is the length of the fully extended anvil retainer 451 minus the depth of the axial bore 330.

Although the dimensions of the cone 300 depend on the desired diameter of the tissue lumen, the thickness of the bodily tissue in which the tissue lumen passes, the cavity to be penetrated, and/or the type of surgical instrument 400 to pass through the tissue lumen, the length of the cone 300 is preferably approximately 1.00 inches to 6.50 inches, the depth of the proximal cavity 340 is preferably approximately 0.16 inches to 0.34 inches, the width of the shoulder 350 is preferably approximately 0.02 to 0.05 inches, and the height of the collar 360 is preferably approximately 0.25 to 2.00 inches.

The diameter of the proximal end of the cone 300 depends on the width or diameter of the surgical instrument 400 or the diameter of the surgical instrument 400 and protective sheath 500 where the surgical instrument 400 is received by the protective sheath 500. While any diameter of the proximal end of the cone 300 that allows for a suitable use is contemplated, the diameter of the proximal end of the cone is preferably 0.80 inches to 1.50 inches. For example, the proximal end of the cone 300 can have a diameter of 0.83 inches, 0.98 inches, 1.06 inches, 1.14 inches, 1.30 inches, or the like.

In one embodiment, the cone 300 has cone grooves 375 to reduce surface area and thereby reduce friction between the cone 300 and the tissue lumen. The cone grooves 375 are channels and can have any dimension that allow for the reduction of surface area friction of the cone 300 and allow for the dilation of a tissue lumen. The width of the cone grooves 375 affects the amount of friction between the cone 300 and the tissue lumen where the increase in the width of the cone groove 375 decreases the friction between the cone 300 and the tissue lumen. The dilator grooves 223 are positioned on the surface of the cone 300. The cone grooves 375 extend from the proximal end 301 to the distal end 302 of the cone 300 and can be straight or spiral as shown in FIGS. 4b and 4c. In one embodiment, the depth of the cone grooves 375 at the distal end is shallower than the depth of the cone grooves 375 at the proximal end. In one embodiment,

the width of the cone grooves 375 at the proximal end 301 is greater than the width of the cone grooves 375 as the distal end 302.

In one embodiment, as shown in FIG. 5, the cone 300 has securing device 380 for preventing longitudinal movement of the cone 300 in relation to the elongated body 430. While the securing device 380 preferably has a passage 381 and securing filament 382, all suitable securing devices 380 are contemplated. The passage 381 extends transversely through the cone 300 with a diameter that allows for a securing filament 382 to pass through the cone 300. Securing filament 382 has two ends 383, 384. With the cone 300 engaged to the distal end 402 of the surgical instrument 400 and the securing filaments 382 passed through the passage 381, the two ends 383, 384 of the securing filaments 382 are pulled toward the distal end 402 of the surgical instrument 400, thereby exerting a substantially longitudinal force on the cone 300 toward the distal end 402 of the surgical instrument 400 and securing the cone 300 to the surgical instrument 400. In one embodiment, the ends 383, 384 can be tied together to increase the ease of use of the securing filament and allow for a greater force vector to be applied to the cone 300. While the passage 381 preferably is located on the cone tip 320, all suitable locations of the passage 381 are contemplated, for example, without limitation, the passage 381 can be located on the proximal 301 end of the body 310. The securing filament 382 is preferably a suture.

In one embodiment, the securing device 380 is a clip incorporated into the axial bore 330. Here, the width of the axial bore 330 is slightly less than the width of the anvil retainer 451 causing the clip to engage the anvil retainer 451 when the anvil retainer 451 passes into the axial bore 330, thereby preventing longitudinal movement of the cone 300.

In the preferred embodiment, the system 100 has a protective sheath 500 for preventing contamination, seeding, infection, or the like, resulting from a surgical procedure. Referring to FIGS. 2a-3b, the protective sheath 500 has an elongated tubular body 510 defining an elongated lumen 520 and has a proximal end 501 and a distal end 502. The surgical instrument 400 passes through the lumen of the protective sheath 500, thereby preventing the surgical instrument 400 from contacting the bodily tissue upon entry and removal of the surgical instrument 400 through the tissue lumen. The dimensions of the protective sheath 500 can vary depending on the dimensions of the surgical instrument 400. The interior diameter of the protective sheath has a diameter greater than the exterior diameter of the surgical instrument 400 and is designed to allow the surgical instrument 400 to move smoothly through the lumen 520. The length of the protective sheath 500 is greater than the thickness of the bodily tissue in which the surgical instrument 400 will pass, thus isolating the surgical instrument 400 from bodily tissue contact, and therefore potential contamination of the tissues during placement and removal of the surgical instrument 400. In the preferred embodiment, the length of the protective sheath 500 is the distance between the distal end of the handle assembly 420 and one inch proximal to the distal end 402 of the surgical instrument 400. The protective sheath 500 can be molded from a plastic material such as polyethylene, polypropylene, nylon, latex, latex free material, or the like.

In one embodiment, as shown in FIG. 3a, the protective sheath 500 has at least one rib 530 that engages the interior surface of the protective sheath 500. The ribs 530 can reduce the friction between the surgical instrument and the interior surface of the protective sheath 500 created when the surgical instrument 400 is removed from the interior of the protective sheath 500. In one embodiment, the ribs 530 run the length of the protective sheath 500. In one embodiment, the ribs 530 run a portion of the length of the protective sheath 500. The ribs 530 provide for a gap 532 between the surgical instrument 400 and the interior surface of the protective sheath 500. Gas from the abdomen, for example, carbon dioxide, fills the gap 532 thereby reducing the amount of interior surface area of the protective sheath 500 that touches the surgical instrument 400, thereby reducing the amount of friction between the interior surface area of the protective sheath 500 and the surgical instrument 400.

In one embodiment, as shown in FIG. 3b, the system has a sheath seal 540 for reducing the amount of gas passing between the proximal end of the protective sheath and the surgical instrument 400, thereby ensuring the friction between the interior surface of the protective sheath 500 and the surgical instrument 400 is reduced and/or maintaining the size of the abdominal cavity required to perform a surgical procedure. In one embodiment, the sheath seal 540 has one surface with an adhesive substance allowing the sheath seal 540 to engage or be secured to the protective sheath 500 and/or the surgical instrument 400. As shown in FIG. 3b, the sheath seal 540 can simultaneously engage the proximal end of the protective sheath 500 and the surgical instrument 400, thereby preventing gas from passing between the proximal end of the protective sheath 500 and the surgical instrument 400. The sheath seal 540 wraps around the proximal end of the protective sheath 500 and the surgical instrument 400. In one embodiment, the gas can be abdominal gas, such as carbon dioxide.

In one embodiment, as shown in FIG. 3b, the system has a separation mechanism 550 for tearing the sheath seal 540 thereby detaching proximal end of the protective sheath 500 from the surgical instrument 400. While the separation mechanism 550 can be any means for separating or tearing the sheath seal 540, for example, a perforated line, the separation mechanism 550 is preferably a string, suture, or the like. As shown in FIG. 3b, the separation mechanism 550 wraps around the surgical instrument 400 juxtaposed to the proximal end of the protective sheath 500. A portion of the sheath seal 540 then wraps around and engages the proximal end of the protective sheath 500 and a portion of the sheath seal 540 wraps around and engages a portion of the surgical instrument 400 in which the separation mechanism 550 is positioned in a manner that allows a portion of the separation mechanism 550 to be exposed from the sheath seal 540. In one embodiment, the separation mechanism 550 is incorporated into the protective sheath 500. To allow the surgical instrument 400 to be removed from the interior of the protective sheath 500, the exposed portion of the separation mechanism 550 is pulled thereby tearing the sheath seal 540 into two portions and detaching the protective sheath 500 from the surgical instrument 400.

In one embodiment, the protective sheath 500 has a sheath securer for securing the protective sheath 500 to the surgical instrument 400, thereby preventing the protective sheath 500 from traveling down the surgical instrument 400. While the sheath securer can be any suitable means for securing the

protective sheath 500 to the surgical instrument 400, the sheath securer is preferably a reinforced section that engages with the anvil retainer 451, thereby securing the protective sheath 500 to the surgical instrument 400. The reinforced section can be any suitable means that allows the protective sheath 500 to be secured to the surgical instrument 400, for example, without limitation, a section with an increased thickness, a ring incorporated into the sheath securer and sized to receive a portion of the anvil retainer 451, or the like. In one embodiment, the sheath securer is a clip that engages the distal end of the surgical instrument 400. In one embodiment, the protective sheath 500 and cone 300 are prefabricated into a single device.

In one embodiment, where the diameter of the distal end 402 is greater than the diameter of other portions of the surgical instrument 400, for example, the cartridge assembly 440 and the elongated body 430, the system has a shell 460 for increasing the diameter of the surgical instrument 400 so that the diameter of the cartridge assembly 440 and/or the elongated body 430 is substantially similar to the diameter of the distal end 402. The increased diameter of the surgical instrument 400 by the shell 460 prevents abdominal gas from escaping from the body cavity between the protective sheath 500 and the tissue lumen when the cartridge assembly 440 and/or the elongated body 430 pass through the tissue lumen. The length of the shell 460 can be any length and is preferably substantially similar to the distance the surgical instrument 400 passes through the tissue lumen. The shell 460 can be made of any rigid material, for example, plastic, metal, or the like.

By way of example, the method of using the surgical system 100, where by way of example, without limitation, a surgical stapler device is the surgical instrument 400, will be described. An incision is made in the bodily tissue. A trocar or similar instrument is inserted into the incision and through the bodily tissue, thereby creating a tissue lumen. The trocar is removed from the tissue lumen and the dilator tip 221 is inserted into the tissue lumen, thereby dilating the tissue lumen. The dilator 200 penetrates to a desired depth within the bodily tissue indicated by the marker 222, thereby circumferentially stretching or dilating the bodily tissue to a certain diameter sufficient to receive the desired diameter of the surgical instrument 400 being used and increasing the diameter of the tissue lumen. The tissue lumen allows for the passage of a surgical stapler device. The elongated body 430 of the surgical stapler device traverses the lumen 520 of the protective sheath 500 until the distal end 502 of the protective sheath 500 lies substantially in the same plane with the distal end 402 of the surgical stapler device or slightly beyond the distal end 402.

A securing filament 382 is passed through the passage 381 of the cone 300. The cone 300 is engaged to the distal end 402 of a surgical stapler device whereby the collar cavity 370 receives the distal end 402 of the surgical stapler device and the distal end 502 of the protective sheath 500, and the circumferential edge of the surgical stapler device engages with the shoulder 350 of the cone 300. By receiving the protective sheath 500, the collar 360 secures the protective sheath 500 in place by juxtaposing the protective sheath 500 between the surgical stapler device and the cone 300. Alternatively, cone 300 may be pre-installed about the distal end 402 of the surgical stapling device. The two ends 383, 384 of the securing filaments 382 are pulled toward the distal end 402 of the surgical stapler device, thereby tethering

the cone 300 to the surgical stapler device. In one embodiment, the dimensions and shape of the tapered section 220 of the dilator 200 are substantially similar to the dimensions and shape of the cone 300. In one embodiment, the dimensions and shape of the tapered section 220 and cone 300 are dependent on the type of surgical instrument 400 to be introduced.

The tip of the cone 300 attached to the surgical stapler device is inserted into the tissue lumen. The cone tip 300 allows the user to find the orientation of the tissue lumen and navigates the cone 300, surgical stapler device, and sheath 500 through the tissue lumen dilating said tissue lumen. When the cone 300, sheath 500, and surgical stapler device reach a desired position in the body cavity, the force exerted on the two ends 383, 384 of the surgical filaments is removed and the anvil retainer 451 is withdrawn. The cone 300 falls away or is removed from the surgical stapler device and rests in the body cavity with the two securing filament ends 383, 384 remaining external to the patient. The protective sheath 500 remains around the surgical instrument 400 in the tissue lumen, thereby preventing the surgical stapler device from contacting and contaminating the tissue lumen.

In one embodiment, as shown in FIG. 5, the cone 300 has a retrieval device 390 for retrieving the cone 300 from a body cavity by pulling the cone 300 through the tissue lumen. In one embodiment, the retrieval device 390 is a retrieval filament where the retrieval filament is preferably the same filament as the securing filament 382. However, all suitable retrieval devices 390 are contemplated, for example, without limitation, a grasper, a needle, a clamp, or the like. The retrieval grasper can be a grasper with a peg positioned perpendicular to the longitudinal axis of the grasper. The peg passes through the passage 381 in the cone 300 and the cone 300 is pulled through the tissue lumen.

Upon completion of the use of the surgical stapler device, the surgical stapler device with the engaged anvil 452 is retrieved through the lumen 520 of the protective sheath 500, and thus exits the tissue lumen without contaminating or seeding for infection. The protective sheath 500 is then pulled through the tissue lumen and removed via another trocar site, thus diminishing and preventing contamination of the surrounding tissues. With the ends of the retrieval filaments protruding through the tissue lumen, the retrieval filaments are pulled causing the tip of the cone 300 to align and traverse back through the tissue lumen, thereby tracking through and dilating the tissue lumen and causing minimal damage to the surrounding tissue.

Referring to FIGS. 6a-6d, by way of example, without limitation, a closure device 600 for closing a wound. The closure device 600 has a guide 610 and cone 300 where the cone 300 has a plurality of needle guidance bores 621 for receiving a suture. The axial bore 330 receives the guide 610. In one embodiment, the horizontal cross-section of the axial bore 330 is polygonal shape and the guide 610 is a corresponding polygonal shape thereby allowing for the closure device 600 to be rotated about the vertical axis of the closure device 600. In one embodiment, the guide 610 allows for the positioning of the needle guidance bores 621. In one embodiment, the guide 610 allows for the closure device to be retrieved from the tissue lumen. The guide 610 has a handle 611, an elongated body 612, and a locking device 613. All suitable locking devices 613 are contemplated, for example, without limitation, a pressure friction device,

ball and plunger, or the like. Where the locking device 613 is a ball and plunger, the distal end 331 of the axial bore 330 has a slot 630 for receiving a ball 614 and thereby preventing the guide 610 from sliding out of the axial bore 330.

The number of needle guidance bores 621 will depend on the size of the cone 300. In the preferred embodiment, the cone 300 has four needle guidance bores 621a, 621b, 621c, and 621d. In one preferred embodiment, needle guidance bores 621a and 621c are substantially parallel to each other and needle guidance bores 621b and 621d are substantially parallel to each other. In one preferred embodiment, needle guidance bores 621 are positioned at substantially equal angles in relation to axial line 624. The needle guidance bore 621 has a proximal hole 622 and a distal hole 623 where the needle guidance bore 621 is positioned so that the proximal hole 622 is located on the surface of the proximal cavity 340 and the distal hole 623 is located on the exterior surface 303 of the cone 300. While all suitable angles of the needle guidance bores 621 are contemplated, the angle is preferably between 0 degrees and 60 degrees from axial line 624.

In one embodiment, the cone 300 has a closure device 600 for closing a wound. The number of needle guidance bores 621 will depend on the size of the cone 300. In the preferred embodiment, the cone 300 has four needle guidance bores 621a, 621b, 621c, and 621d. In one preferred embodiment, needle guidance bores 621a and 621c are substantially parallel to each other and needle guidance bores 621b and 621d are substantially parallel to each other. In one preferred embodiment, needle guidance bores 621 are positioned at substantially equal angles in relation to axial line 624. The needle guidance bore 621 has a proximal hole 622 and a distal hole 623 where the needle guidance bore 621 is positioned so that the proximal hole 622 is located on the surface of the proximal cavity 340 and the distal hole 623 is located on the exterior surface 303 of the cone 300. While all suitable angles of the needle guidance bores 621 are contemplated, the angle is preferably between 0 degrees and 60 degrees from axial line 624.

In one embodiment, end 641 of the suture passes through the proximal hole 622a of needle guidance bore 621a, passes through the needle guidance bore 621a, exits the distal hole 623a of needle guidance bore 621a, passes through the desired bodily tissue 660 to be closed, and into the body cavity. The end 641 is retrieved and pulled through the desired bodily tissue 660 to be closed, passes through the distal hole 623b of needle guidance bore 621b, passes through the needle guidance bore 621b, and exits through the proximal hole 622b of needle guidance bore 621b. The suture can pass through the needle guidance bore 621 and holes 622, 623 with the aid of a suture passing device, or the like. The cone 300 is then removed from the tissue lumen utilizing the guide 610 and closure is performed in traditional fashion.

In the preferred embodiment, as shown in FIGS. 6c-6d, while retaining one end 642 of an closing suture 640 external to the closing device 600 and the body cavity, the other end 641 of the closing suture 640 is passed with a suture passing device 650 through the proximal hole 622a of needle guidance bore 621a, through the needle guidance bore 621a, through the distal hole 623a of needle guidance bore 621a, through the desired bodily tissue 660 to be closed, and into the body cavity. The end 641 of the closing suture 640 is released and temporarily left in the body cavity. The suture passing device 650 without end

641 or end 642 is passed through the proximal hole 622b of needle guidance bore 621b, through the needle guidance bore 621b, through the distal hole 623b of needle guidance bore 621b, through the opposite side of the desired bodily tissue 660 to be closed, and into the body cavity. The end 641 is grasped by the suture passing device 650 and pulled through the bodily tissue 660, through the distal hole 623b of needle guidance bore 621b, through the needle guidance bore 621b, and through the proximal hole 622b. Both ends 641 and 642 are then secured and the cone 300 is removed from the tissue lumen utilizing the guide 610 and slid over the two ends 641 and 642 of the closing suture 640. The two ends 641 and 642 of the closing suture 640 are then tied to close the tissue lumen in traditional fashion. This can be repeated with additional closure sutures 640 through the plurality of needle guidance bores 621 or by using the retrieval guidance member 610 to redirect the orientation of needle guidance bores 621 and therefore the placement of the additional closure sutures 640.

The dilator 200, cone 300, closure device 600, and guide 610 may be constructed from any suitable material or combinations of materials including acceptable sterilizable medical grade material or combinations of materials. For example, without limitation, the dilator 200, cone 300, closure device 600, and guide 610 may be formed of stainless steel, surgical steel, titanium alloy, one or more moldable and/or thermoformable plastics, polymers, composites which is or are sufficiently rigidity for passage through or creation of a tissue lumen. The dilator 200, cone 300, closure device 600, and guide 610 can be manufactured by an injection molding process, a blow molding process with secondary slit, or other processes.

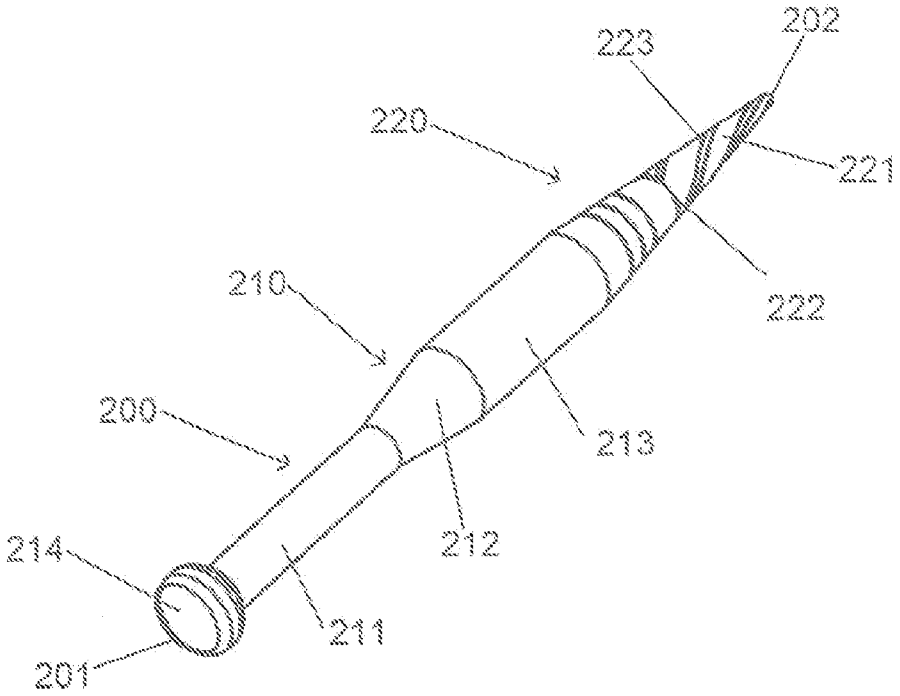
The foregoing has described the principles, embodiments, and modes of operation of the present invention. However, the invention should not be construed as being limited to the particular embodiments described above, as they should be regarded as being illustrative and not as restrictive. It should be appreciated that variations may be made in those embodiments by those skilled in the art without departing from the scope of the present invention.

Modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. A system for introducing a surgical instrument through a tissue lumen comprising:
a cone for navigating the surgical instrument through a tissue lumen,
wherein said cone engages the distal end of the surgical instrument.
2. A system of claim 1 wherein said surgical instrument is a surgical stapler device comprising a handle assembly, an elongated body, a cartridge assembly, and an anvil assembly.
3. A system of claim 2 wherein said anvil assembly comprises an anvil retainer and an anvil.
4. A system of claim 2 further comprising a shell for increasing the diameter of the elongated body.
5. A system of claim 1 wherein said cone comprises:
a conical body having a proximal end and a distal end, wherein said conical body tapers from the proximal end to the distal end and facilitates insertion of the cone through the tissue lumen,
an axial bore, wherein said axial bore extends longitudinally through said cone and receives an anvil retainer, and
a collar, wherein said collar engages the distal end of the surgical device and prevents movement of the cone.
6. A system of claim 5 wherein said cone comprises cone grooves, wherein said cone grooves are positioned on the surface of the conical body and reduce the friction between the cone and the tissue lumen.
7. A system of claim 1 wherein said cone comprises a securing device, wherein said securing device secures the cone to the surgical instrument.
8. A system of claim 7 wherein said securing device comprises a passage and a securing filament, wherein said passage extends transversely through said cone and said securing filament traverses said passage.
9. A system of claim 1 wherein said cone comprises a retrieval device for retrieving said cone from a bodily cavity.
10. The system of claim 1 further comprising a dilator for dilating bodily tissue.
11. The system of claim 10 wherein said dilator comprises:
an elongated body for positioning said dilator, and
a tapered section, having a proximal end and a distal end wherein said tapered section tapers from the proximal end to the distal end and facilitates dilation of said tissue lumen.
12. The system of claim 11 wherein said elongated body comprises:
a handle for positioning said dilator, and
a tapered portion, wherein said tapered portion allows for the tissue lumen to be redilated upon retrieval of the dilator.
13. The system of claim 11 wherein said elongated body comprises a non-tapered portion.

14. The system of claim 11 wherein said tapered section comprises dilator grooves, wherein said dilator grooves are positioned on the surface of the tapered section and reduce the friction between the tapered section and the tissue lumen.
15. The system of claim 1 further comprising a sheath for preventing contamination of the tissue lumen wherein said sheath receives said surgical instrument.
16. The system of claim 14 wherein said sheath comprises a rib for reducing the friction between the surgical instrument and the sheath.
17. The system of claim 1 further comprising a sheath seal for reducing the amount of gas passing between the proximal end of the protective sheath and the surgical instrument.
18. The system of claim 17 further comprising a separation mechanism for tearing the sheath seal.
19. A surgical device for dilating a tissue lumen comprising:
an elongated body for positioning said surgical device, and
a tapered section, having a proximal end and a distal end, wherein said tapered section tapers from the proximal end to the distal end and facilitates dilation of said tissue lumen.
20. A surgical device for introducing a surgical instrument through a tissue lumen comprising:
a conical body having a proximal end and a distal end, wherein said conical body tapers from the proximal end to the distal end and facilitates insertion of the surgical device through the tissue lumen,
an axial bore, wherein said axial bore extends longitudinally through said surgical device and receives an anvil retainer, and
a collar, wherein said collar engages the distal end of the surgical device and prevents movement of the surgical device.
21. A surgical device for closing a wound comprising a guide and cone whereby the cone has a plurality of needle guidance bores for receiving a suture.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201

FIG. 1

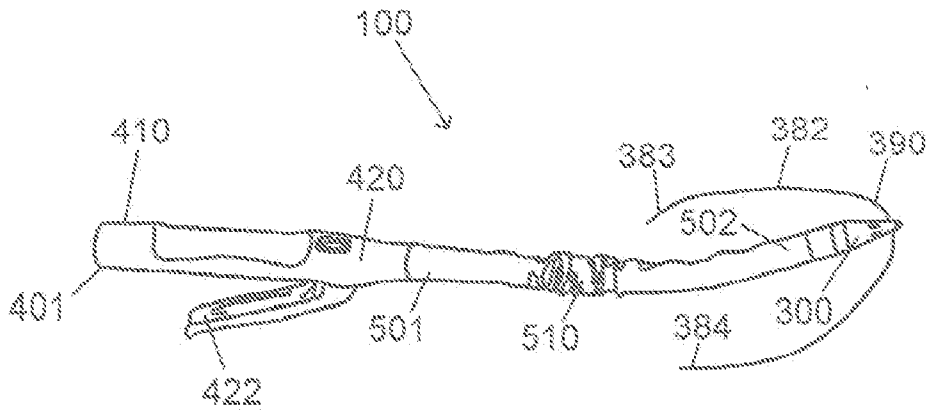
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FIG. 2a

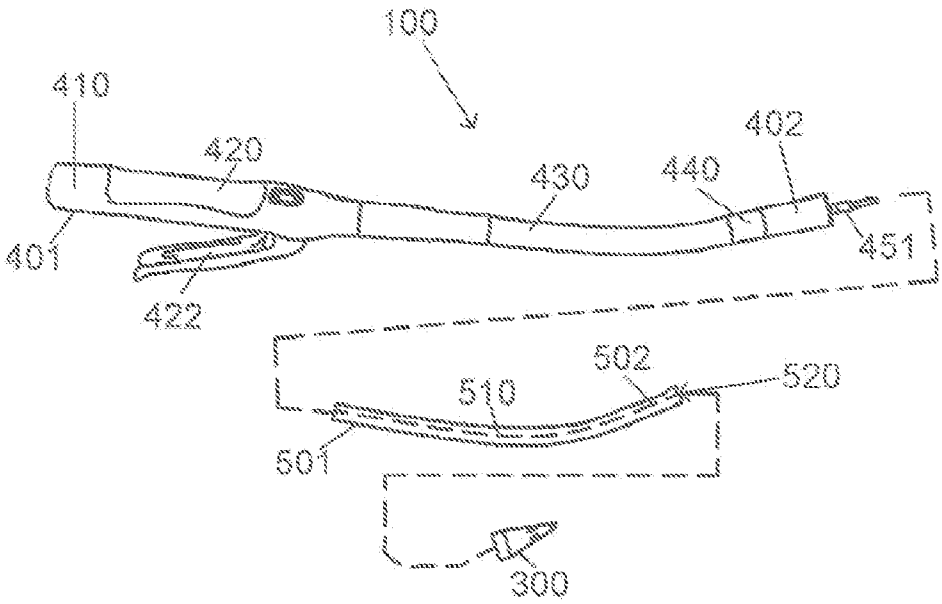
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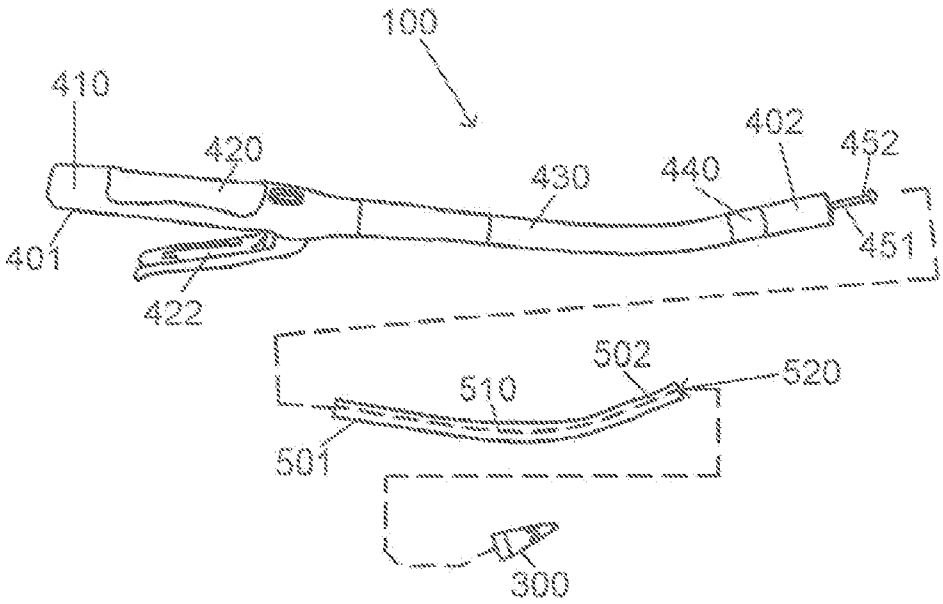
FIG. 2b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502
520
510
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300

FIG. 2c

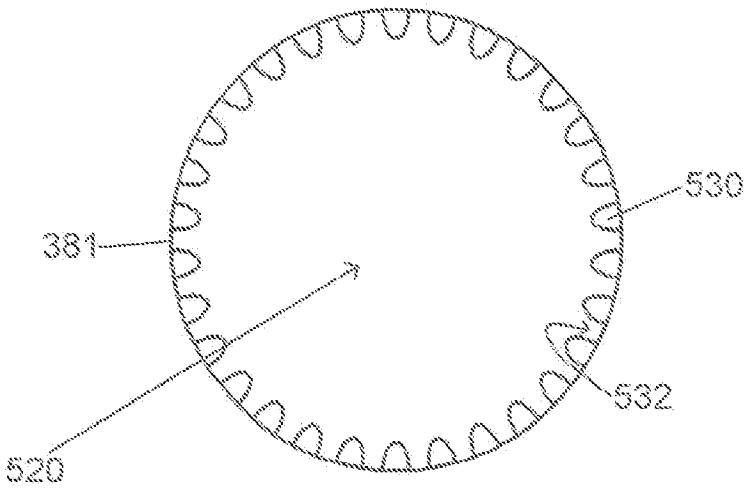
530
381
532
520

FIG. 3a

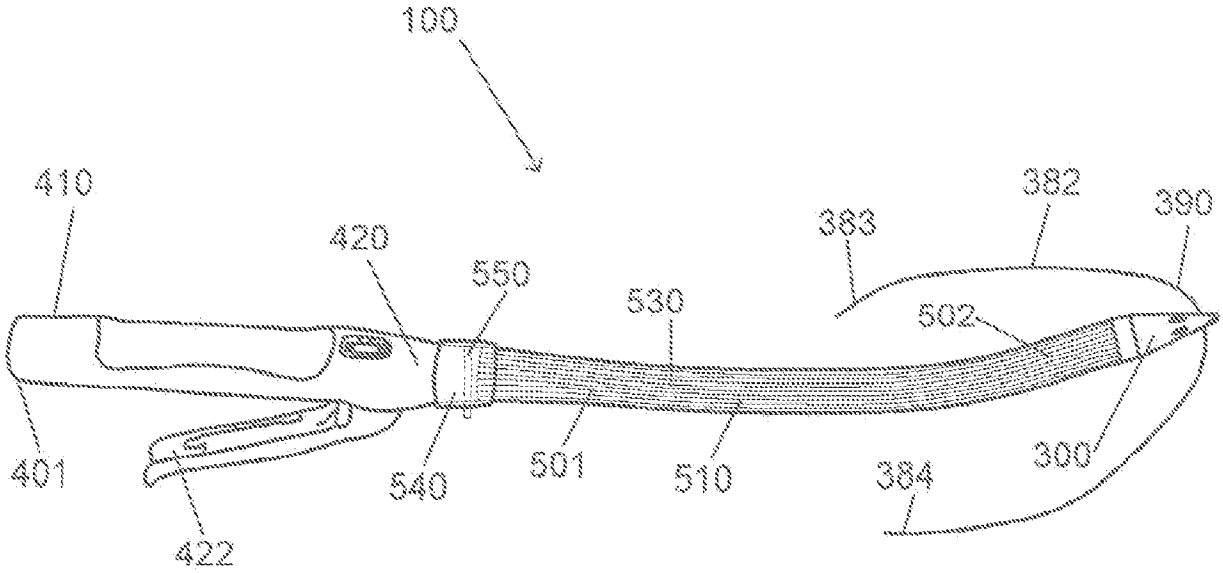
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FIG. 3b

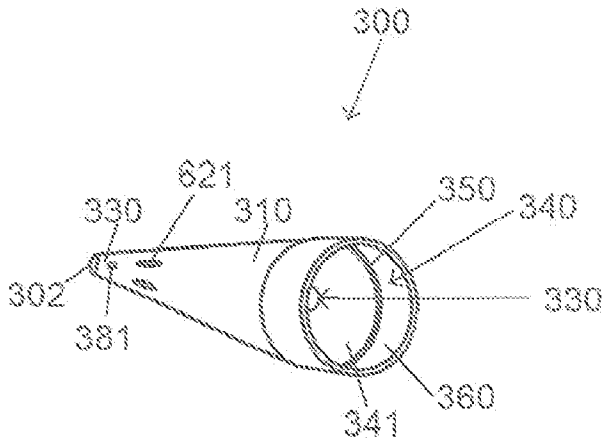


FIG. 4a

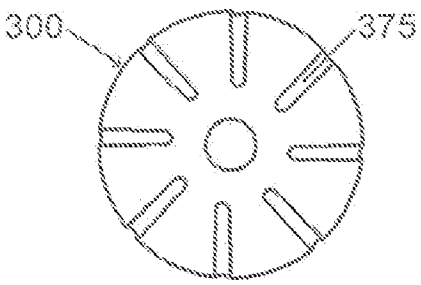


FIG. 4b

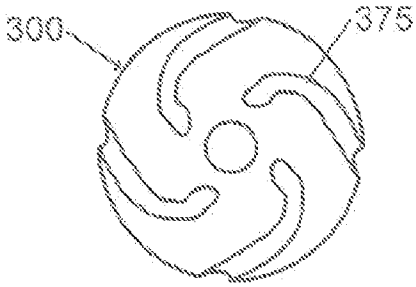


FIG. 4c

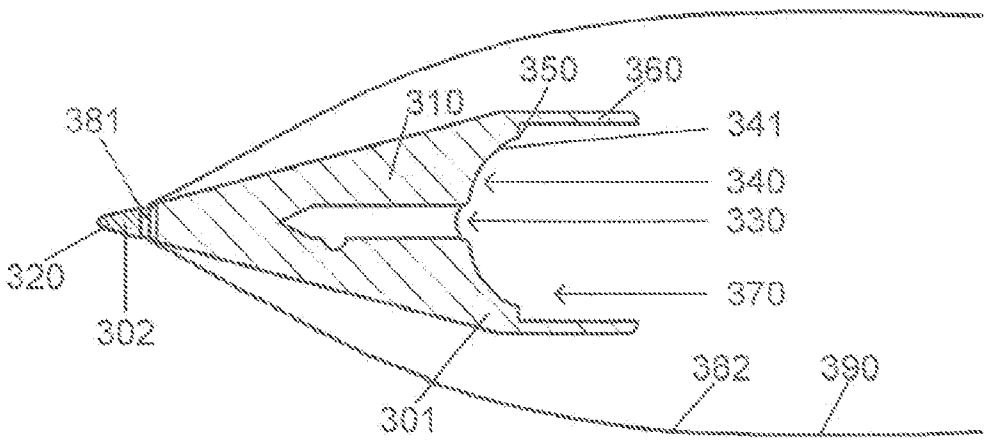
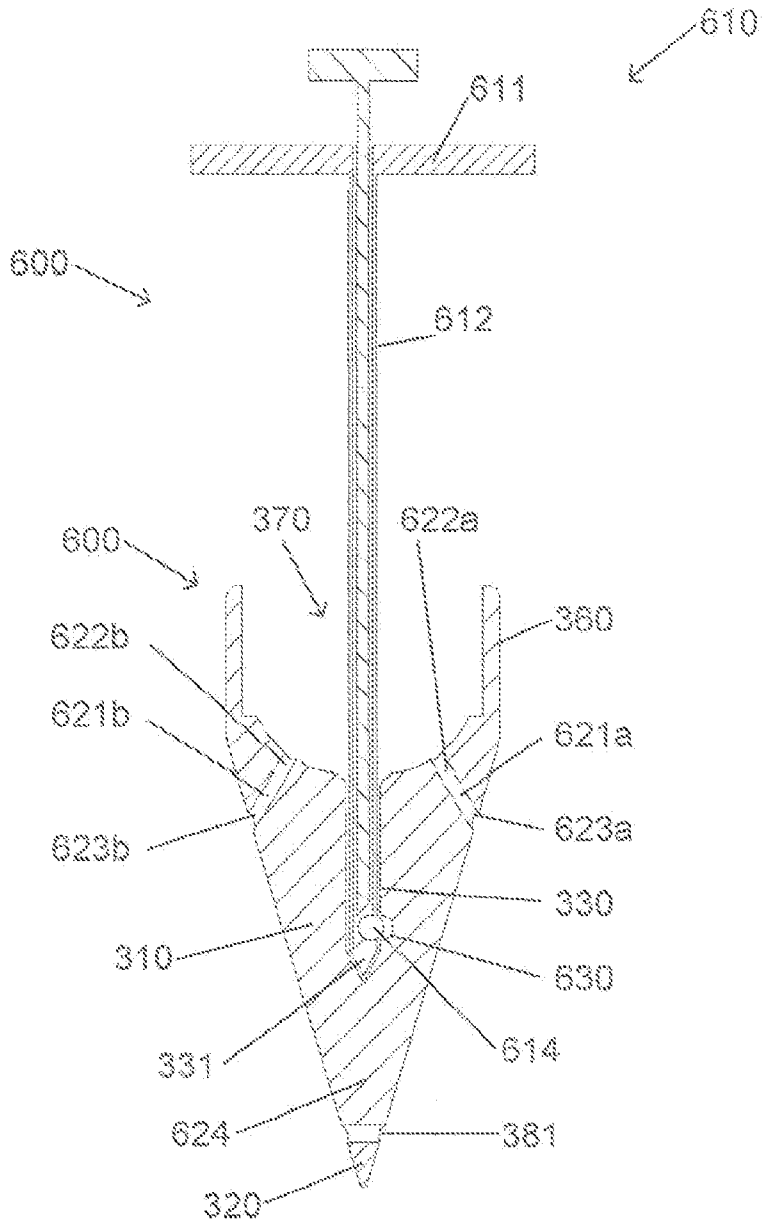


FIG. 5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612
600
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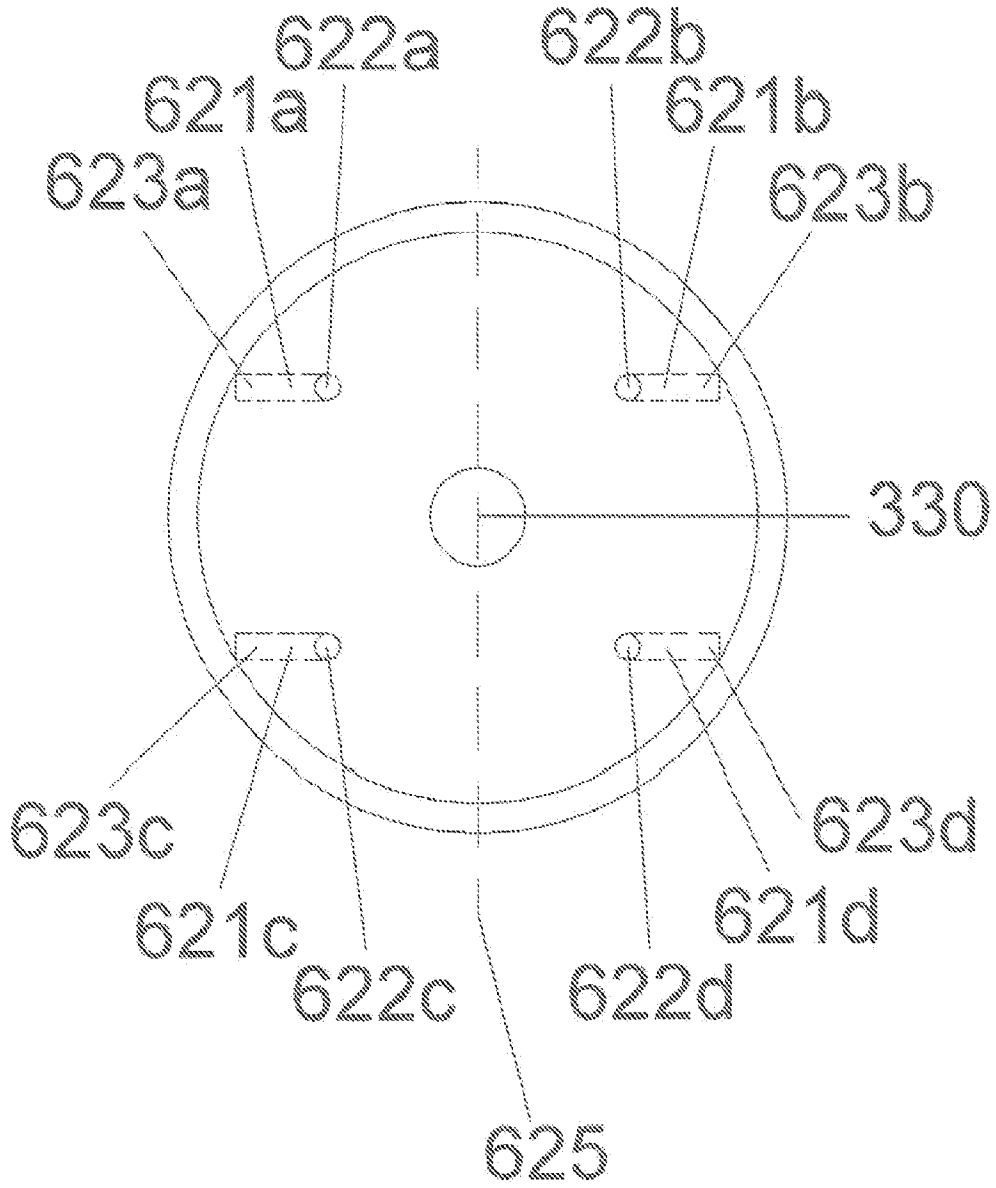
623a
330
310
630
614
331
624
381
320

FIG. 6a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621c
621d
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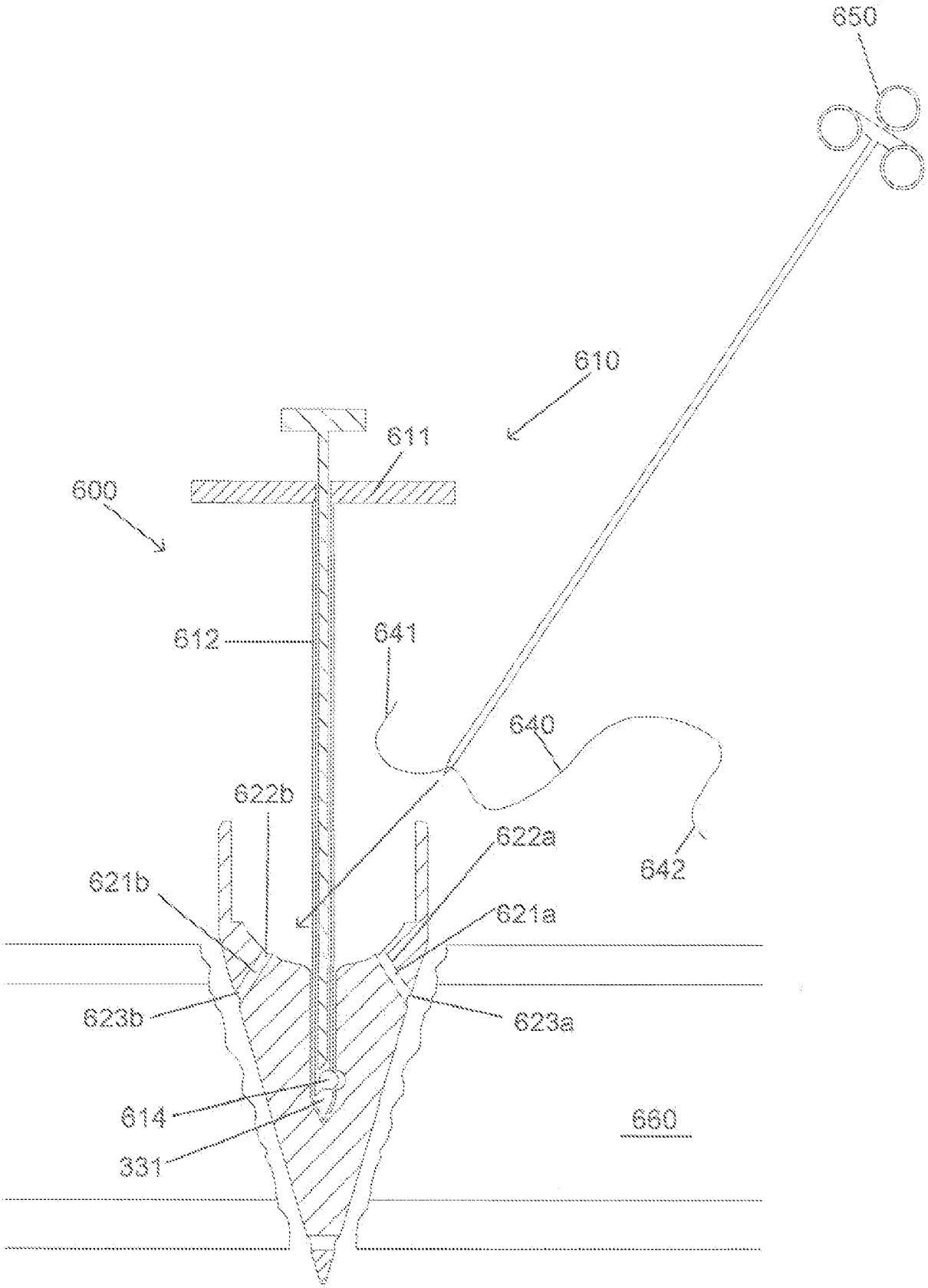
622d
625

FIG. 6b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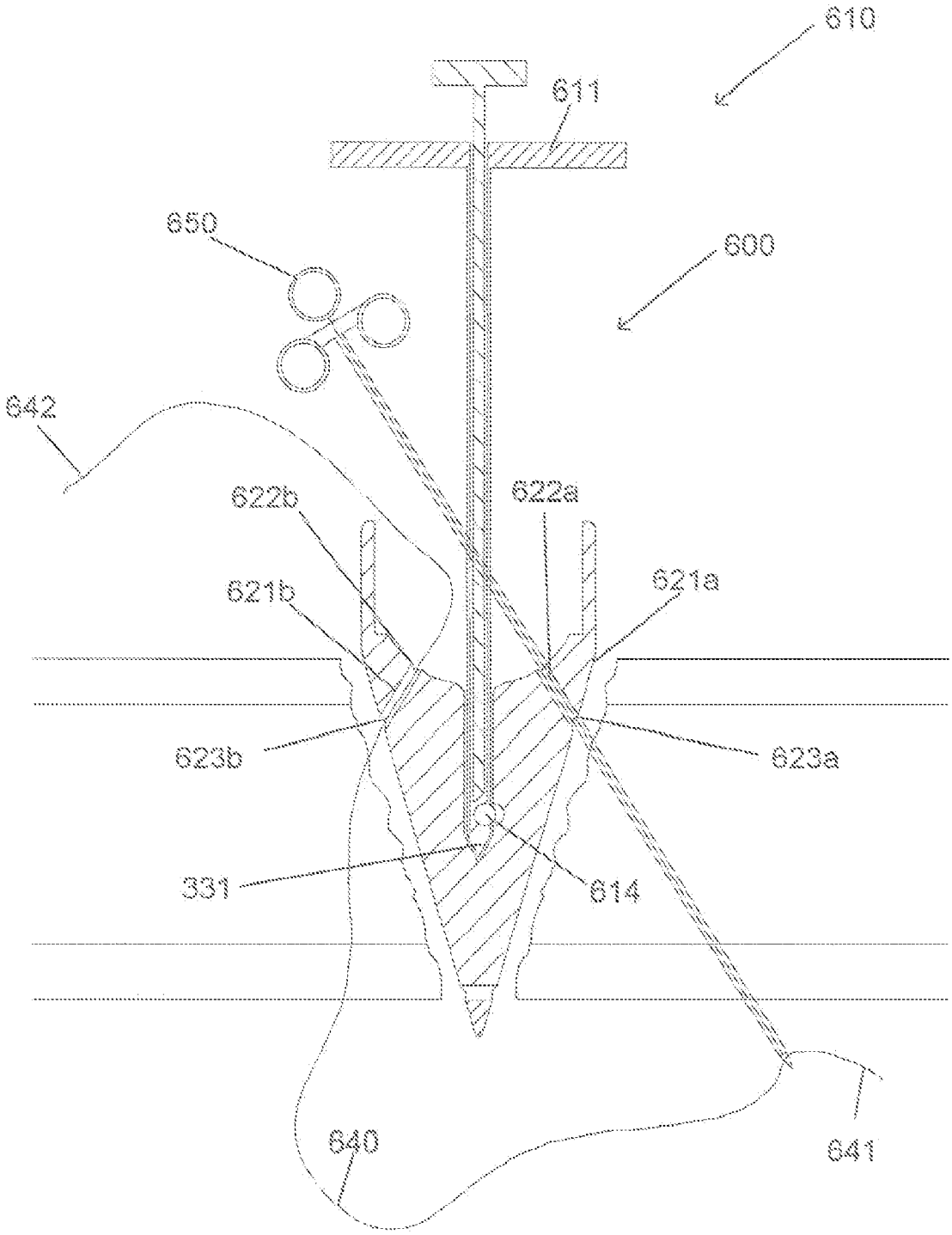
331

FIG. 6c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623b
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614
640
641

FIG. 6d