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— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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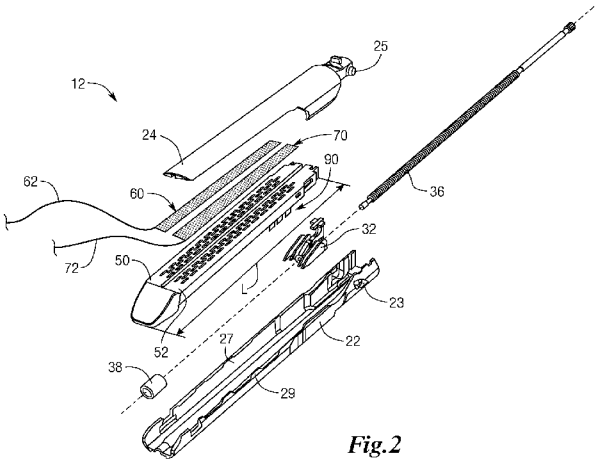


*Fig.2*

(57) Abstract: Surgical staple cartridges and methods for manipulating the severed ends of divided tissue. In various forms, the staple cartridge has at least one base material temporarily supported thereon that is oriented to be stapled to a corresponding end of the divided tissue. At least one elongated tether is non-removably affixed to each piece of base material. Once the base material is stapled to the corresponding piece of divided tissue, the clinician may manipulate that pieced of divided tissue by applying manipulation motions to the tether. Corresponding grooves or pockets may be provided on the cartridge body for temporarily supporting the tethers therein.

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# SURGICAL STAPLE CARTRIDGES WITH TISSUE TETHERS FOR MANIPULATING DIVIDED TISSUE AND METHODS OF USING SAME

## BACKGROUND

### Technical Field

**[0001]** The present invention relates to surgical instruments and, in various embodiments, to surgical cutting and stapling instruments and staple cartridges therefor that are designed to cut and staple tissue.

### Background

**[0002]** Surgical staplers have been used to simultaneously make a longitudinal incision in tissue and apply lines of staples on opposing sides of the incision. Such instruments commonly include a pair of cooperating jaw members that, if the instrument is intended for endoscopic or laparoscopic applications, are capable of passing through a cannula passageway. One of the jaw members receives a staple cartridge having at least two laterally spaced rows of staples. The other jaw member defines an anvil that has staple-forming pockets aligned with rows of unformed staples supported in the cartridge.

**[0003]** In use, a clinician is able to close the jaw members of the stapler upon tissue to position the tissue prior to firing. Once the clinician has determined that the jaw members are properly gripping tissue, the clinician can then fire the surgical stapler, thereby severing and stapling the tissue. The simultaneous severing and stapling avoids complications that may arise when performing such actions sequentially with different surgical tools that respectively only sever or staple.

**[0004]** A variety of surgical cutting and stapling instruments are known that may be employed laparoscopically and/or in connection with various "open" surgical procedures. Some surgical stapling and severing instruments are configured to support replaceable cartridges that support the unformed staples therein. Such devices commonly employ a retractable cutting member that remains with the stapling instrument and may be reused with several cartridges. After the staples are fired in one cartridge, the cutting member is retracted and the spent cartridge is removed to

enable a new cartridge to be installed if desired. As the cutting member is driven distally through the cartridge, the unformed staples are fired out of their respective pockets in the cartridge into forming contact with the underside of the anvil. Examples of such devices are disclosed in U.S. Patent No. 7,000,818, entitled "Surgical Stapling Instrument Having Separate Distinct Closing and Firing Systems", issued February 21, 2006, the disclosure of which is herein incorporated by reference in its entirety. Other surgical cutting and stapling instruments employ what is commonly referred to as a "disposable loading unit" or "DLU". Such devices support a staple cartridge and a fresh knife in the form of a "unit" that is configured to be operably attached to the surgical stapling instrument. The units are designed to be discarded after the staples have been fired. Examples of such instruments are disclosed in U.S. Patent No. 5,865,361 entitled "Surgical Stapling Apparatus", issued February 2, 1999, the entire disclosure of which is herein incorporated by reference.

**[0005]** In some circumstances, the layers of tissue can be relatively thin, can have a high fluid content, and/or can have a non-uniform thickness, which can cause the staples to be improperly formed within the tissue. To ameliorate this problem, a piece of "buttress" material has been utilized to support the tissue as the tissue is being clamped and stapled. Such piece of buttress material is commonly releasably attached to at least one of the first and second jaw members before they are inserted into a surgical site. The piece of buttress material serves to distribute the compressive force applied by the staples over the surface area of the tissue in order to create a more uniform pressure distribution within the tissue. U.S. Patent Publication No. US2009/0206143 A1, entitled "Surgical End Effector Having Buttress Retention Features", published August 20, 2009 discloses various buttresses and buttress retention arrangements and is herein incorporated by reference in its entirety.

**[0006]** In many surgical procedures and, in particular, in many vascular-related surgical procedures, once the tissue is divided by the cutting and stapling instrument, the two segments of tissue fall away from the end effector that supports the staple cartridge. In some procedures involving, for example, the bowel and/or stomach, may not be problematic. However, other tissue types such as vessels have a tendency to rapidly withdraw towards their origin after being severed. For example, in a procedure such as a lung lobectomy, wherein the vessels are generally located within a relatively confined thoracic cavity, once a vessel has pulled away, it

can be very difficult to reacquire should the need arise. For example, if the sealing or ligation is flawed and there is bleeding, it is imperative that the vessel be reacquired as quickly as possible to undertake repair of the leaking vessel.

**[0007]** Accordingly, there is a need for surgical staple cartridge arrangements that address many of the challenges discussed above.

**[0008]** The foregoing discussion is intended only to illustrate some of the shortcomings present in the field of the invention at the time, and should not be taken as a disavowal of claim scope.

## SUMMARY

**[0009]** In accordance with general aspects of at least one form, there is provided a surgical staple cartridge that has a cartridge body that operably supports a plurality of surgical staples therein. A base material is temporarily supported on a portion of the cartridge body and is configured to be stapled to tissue when the staples supported in the cartridge body are stapled into the tissue. The base material is configured to remain attached to the tissue when the cartridge body is withdrawn therefrom. At least one elongated tether is non-removably coupled to the base material.

**[0010]** In accordance with other general aspects of at least one form, there is provided a surgical end effector for use with a surgical instrument. In various embodiments, the surgical end effector comprises an elongated channel that is operably couplable to the surgical instrument. A staple cartridge that has a cartridge body is operably supported in the elongated channel. The cartridge body has a deck surface that is substantially split into a first deck portion and a second deck portion by a longitudinal slot that extends therebetween. The cartridge body operably supports a first plurality of unformed staples therein that correspond to the first deck portion. A second plurality of unformed staples correspond to the second deck portion. A tissue cutting member is operably supported in the cartridge body for axial advancement in the longitudinal slot upon application of a cutting actuation motion thereto by the surgical instrument. An anvil is supported for movable travel toward and away from the deck surface in response to opening and closing motions applied thereto by the surgical instrument. A first base material is removably supported on the first deck portion and at least one first tether is non-

removably attached thereto. A second base material is removably supported on the second deck portion and at least one second tether is non-removably attached thereto.

**[0011]** In accordance with still other general aspects of at least one form, there is provided a method for manipulating divided tissue. In various forms, the method comprises dividing a piece of tissue into two separate tissue segments wherein each tissue segment has a severed end. The method further comprises stapling the severed ends of the first and second tissue segments and affixing at least one tether to at least one of the severed ends of the first and second tissue segments during the stapling action. The method further comprises manipulating the severed end having the at least one tether affixed thereto by applying a manipulation motion to the tether.

## BRIEF DESCRIPTION OF DRAWINGS

**[0012]** The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

**[0013]** FIG. 1 is a side view of one form of a surgical cutting and stapling instrument with which various cartridges and end effector embodiments of the present invention may be used;

**[0014]** FIG. 2 is an exploded view of an end effector embodiment of the present invention;

**[0015]** FIG. 2A is an exploded view of another end effector embodiment of the present invention;

**[0016]** FIG. 2B is an exploded view of another end effector embodiment of the present invention;

**[0017]** FIG. 3 is an exploded assembly view of a portion of a staple cartridge embodiment of the present invention;

**[0018]** FIG. 4 is a perspective view of a portion of the staple cartridge of FIG. 3;

**[0019]** FIG. 5 is a partial plan view of an end effector embodiment clamping a vessel between the anvil and staple cartridge thereof;

**[0020]** FIG. 6 is a perspective view of the divided and stapled vessel depicted in FIG. 5;

**[0021]** FIG. 7 is a perspective view of a surgical cutting and stapling instrument that has a surgical staple cartridge embodiment of the present invention supported therein that has been inserted into a trocar cannula;

**[0022]** FIG. 8 is an exploded assembly view of a portion of another staple cartridge embodiment of the present invention;

**[0023]** FIG. 9 is a perspective view of a portion of the staple cartridge of FIG. 8;

**[0024]** FIG. 10 is an exploded assembly view of a portion of another staple cartridge embodiment of the present invention;

**[0025]** FIG. 11 is a perspective view of a portion of the staple cartridge of FIG. 10;

**[0026]** FIG. 12 is an exploded assembly view of a portion of another staple cartridge embodiment of the present invention;

**[0027]** FIG. 13 is a perspective view of a portion of the staple cartridge of FIG. 12;

**[0028]** FIG. 14 is an exploded assembly view of a portion of another staple cartridge embodiment of the present invention;

**[0029]** FIG. 15 is a perspective view of a portion of the staple cartridge of FIG. 14;

**[0030]** FIG. 16 is an exploded assembly view of a portion of another staple cartridge embodiment of the present invention; and

**[0031]** FIG. 17 is a perspective view of a portion of the staple cartridge of FIG. 16.

## DETAILED DESCRIPTION

**[0032]** The Applicant of the present application also owns U.S. Patent Application entitled "Surgical Fastener Instruments", Attorney Docket No. END6844USNP/100529, which was filed on even date herewith and which is herein incorporated by reference in its entirety.

**[0033]** Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the various embodiments of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

**[0034]** Reference throughout the specification to "various embodiments," "some embodiments," "one embodiment," or "an embodiment", or the like, means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases "in various embodiments," "in some embodiments," "in one embodiment", or "in an embodiment", or the like, in places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the features structures, or characteristics of one or more other embodiments without limitation. Such modifications and variations are intended to be included within the scope of the present invention.

**[0035]** The terms "proximal" and "distal" are used herein with reference to a clinician manipulating the handle portion of the surgical instrument. The term "proximal" referring to the portion closest to the clinician and the term "distal" referring to the portion located away from the clinician. It will be further appreciated that, for convenience and clarity, spatial terms such as "vertical", "horizontal", "up", and "down" may be used herein with respect to the drawings. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and/or absolute.

**[0036]** Various exemplary devices and methods are provided for performing laparoscopic and minimally invasive surgical procedures. However, the person of ordinary skill in the art will readily appreciate that the various methods and devices disclosed herein can be used in numerous surgical procedures and applications including, for example, in connection with "open" surgical procedures. As the present Detailed Description proceeds, those of ordinary skill in the art will further appreciate that the various instruments disclosed herein can be inserted into a body in any way, such as through a natural orifice, through an incision or puncture hole formed in tissue, etc. The working portions or end effector portions of the instruments can be inserted directly into a patient's body or can be inserted through an access device such as a trocar that has a working channel through which the end effector and elongated shaft of a surgical instrument can be advanced.

**[0037]** Turning to the Drawings wherein like numerals denote like components throughout the several views, FIG. 1 depict one embodiment of a surgical stapling and severing instrument 10 that is capable of practicing various unique benefits of the present invention. Various forms of the surgical instrument 10 are disclosed in U.S. Patent No. 7,753,904 entitled "Endoscopic Surgical Instrument With a Handle That Can Articulate With Respect to the Shaft", the entire disclosure of which is herein incorporated by reference. As such, the details concerning the construction and operation of that device not needed to understand the various embodiments and forms of the present invention will not be specifically repeated herein. The surgical instrument depicted in FIG. 1 is a motor driven or "powered instrument". As the present Detailed Description proceeds, the skilled artisan will appreciate that the unique and novel aspects of the present invention may also be effectively employed in connection with surgical stapling and severing instruments that employ mechanical (unpowered) systems for firing the staples and cutting tissue without departing from the spirit and scope of the present invention.

**[0038]** As can be seen in FIG. 1, one form of a surgical instrument 10 comprises a handle 6 that has an elongated tube assembly 30 that is operably attached thereto that is configured to transmit actuation motions to an end effector 12 that is attached to a distal end portion of the elongated tube assembly 30. The end effector 12 includes a channel 22 that is coupled to support various forms of staple cartridges of the present invention as will be discussed in greater detail below. An anvil 24 is movably supported relative to the channel 22 in response to opening and closing motions applied thereto by various portions of the elongated tube assembly 30.

**[0039]** The handle 6 includes a pistol grip 26 toward which a closure trigger 18 may be pivotally drawn by the clinician to cause clamping or closing of the anvil 24 toward the staple channel 22 of the end effector 12. A firing trigger 20 is farther outboard of the closure trigger 18. As shown in FIG. 2, the end effector 12 may include, in addition to the previously mentioned channel 22 and anvil 24, a knife and sled driving member 32, a staple cartridge 50 that supports a plurality of unformed staples 90 therein, a helical screw shaft 36 and a bearing 38 that is attached to the channel structure 22. The anvil 24 may be pivotably connected to the channel 22 at a proximate pivot point. In one embodiment, for example, the anvil 24 includes laterally projecting pivot pins 25 at its proximal end that pivotally engage pivot apertures 23 formed near the proximal end of the channel 22. When the closure trigger 18 is actuated, that is, drawn in by a user of the instrument 10, the trunnions 25 of the anvil 24 may pivot within the

pivot apertures 23 in the channel 22 about the pivot point into the clamped or closed position. If clamping of the end effector 12 is satisfactory, the operator may actuate the firing trigger 20, which activates a motor/transmission (not shown) in the handle 6 that applies rotary motion to the helical screw shaft 36 to cause the knife/sled driving member 32 to travel along the channel 22, thereby cutting tissue clamped within the end effector 12 and driving the unformed staples 90 into forming contact with the underside of the anvil 24. As used herein, the term "fire" with respect to the staples refers to the actions involved with driving the unformed staples 90 out of their respective staple pockets within the staple cartridge and into forming contact with a corresponding portion of the anvil. As the present Detailed Description proceeds, the reader will appreciate, however, that the unique and novel aspects of the present invention may be advantageously employed in connection with a variety of other surgical staplers and surgical stapler instruments including those surgical stapling units configured for use with so-called disposable loading units such, for example, those devices disclosed in U.S. Patent Application Publication No. 2006/0011699 A1, entitled "Surgical Stapler With Universal Articulation and Tissue Pre-Clamp", the disclosure of which is herein incorporated by reference in its entirety. Accordingly, the scope of protection afforded to the various embodiments of the present invention should not be limited to use with one particular type of surgical stapling instrument.

**[0040]** After the knife/sled driving member 32 has been driven to the distal end of the staple cartridge 50, the clinician releases the firing trigger 20 to enable the firing trigger 20 to return to an open position, which will result in the application of a retraction motion to the knife/sled driving member 32 to cause it to move proximally to a starting position. Once the knife/sled driving member 32 has been moved to a starting position out of the staple cartridge 50, the clinician may unlock the closure trigger 18 by means of a release button 30 on the handle to permit the closure trigger 18 to move to the open position and thereby cause the anvil 24 to pivot open and release the divided and stapled tissue.

**[0041]** In the embodiments depicted in FIGS. 3 and 4, the staple cartridge 50 includes a cartridge body 51 that supports a plurality of unformed staples 90 therein. The cartridge body 51 has a centrally disposed slot 55 therein that divides the cartridge deck into a first deck portion 53 and a second deck portion 54. The slot 55 accommodates the knife/sled driving member 32 as it is driven longitudinally within the cartridge body 51. Various embodiments of the present invention include a first base material 60 that is temporarily or removably supported on or

attached to the first deck portion 53. Similarly a second material 70 is temporarily or removably supported on or attached to the second deck portion 54. For example, the first and second base materials 60 and 70 may be removably attached to the respective first and second deck portions 53, 54 by adhesives (both natural and man-made), mechanically by deforming portions of the deck or by using biocompatible and/or absorbable fasteners. In various embodiments, the base materials 60 and 70 may be fabricated from a bioabsorbable mesh material. For example, the base materials 60 and 70 may be fabricated from Vicryl (or other absorbable) suture or a coallagen-based material. In other embodiments, the base materials 60 and 70 may be comprise a "buttress" material fabricated from, for example, bovine pericardium, GorTex® material, etc.

**[0042]** As can be seen in FIGS. 3 and 4, for example, various embodiments of the base materials 60 and 70 each have at least one elongated tether attached thereto. In particular, a first elongated tether 62 may extend completely around the first base material 60 and be attached thereto by, for example, adhesives (both natural and man-made), mechanically by deforming portions of the deck, or by using biocompatible and/or absorbably fasteners. In other embodiments, the first elongated tether 62 is attached to a single portion of the first base material (e.g., a corner, side, end, top or bottom surface) such that it extends therefrom. Likewise a second elongated tether 72 is attached to the second base material 70 by the same or similar materials and/or methods. In the embodiment depicted in FIGS. 3 and 4, the first and second elongated tethers 62, 72, respectively, may be provided in various lengths. In one embodiment, for example, the first and second tethers 62, 72 may each have a length that is approximately at least twice the length "L" of the cartridge 50. See FIG. 2. However, the first and second tethers 62, 72 may each have shorter lengths or longer lengths as will be discussed in further detail below. In still other embodiments, one of the elongated tethers 62 or 72 is shorter than the other elongated tether 62 or 72. Although FIG. 2, illustrates attachment of tethers 62 and 72 to the distal ends of the first and second base materials 60, 70, respectively, in other embodiments, the tethers 62, 72 may be attached to the proximal ends of the first and second base materials 60, 70, respectively or in other embodiments, one tether 62 or 72 may be attached to the distal end of its corresponding base material 60, 70 and the other tether 62 or 72 may be attached to the proximal end of its corresponding base material. See FIG. 2A, for example. In still other embodiments, tethers 62, 72 may be attached to both ends of their corresponding base material 60, 70 as shown

in FIG. 2B. In yet other embodiments, a tether 62, 72 may be attached to each corner of its respective base material 60, 70.

**[0043]** FIGS. 5 and 6 illustrate one use of the staple cartridge 50 for cutting and stapling a vessel 80. As can be seen in Fig. 5, the end effector 12 is positioned relative to the vessel 80 such that the portion of vessel 80 to be cut and stapled is received between the anvil 24 and the deck 52 of the staple cartridge 50. The anvil 24 is then closed (by pulling the closure trigger 18 and locking it in position). The firing trigger 20 may then be depressed to fire the staples 90 and cut the vessel into two vessel ends 82, 84. After firing, the first base material 60 is caught between the crowns of the staples 90 and the first vessel end 82. Likewise, the second base material 70 is caught between the crowns of the staples 90 and the second vessel end 84. See FIG. 6. After the cutting and stapling actions have been completed and the anvil 24 is moved to an open position to release the divided vessel ends 82, 84 from the end effector 12, the end effector 12 may be withdrawn from the site. In this embodiment, the tethers 62, 72 were not previously attached to the cartridge body 51 and remain hanging from their respective first and second base materials 60, 70. Thus, should the clinician need to retrieve or identify the divided vessel ends 82, 84, he or she can find the corresponding tethers 62, 72 and either use a separate instrument (e.g., a grasper, forceps, etc.) to bring the vessel end closer. Such arrangement represents a vast improvement over prior cutting and stapling devices and methods particularly when employed to cut tissue that may need to be further manipulated after stapling.

**[0044]** As shown in FIG. 7, the end effector 12 and the elongated shaft assembly 30 may be sized to be inserted through a trocar assembly 900 that has been inserted into the patient. Such trocar assemblies are known in the art and therefore, its construction and operation are not discussed in detail herein. For example, U.S. Pat. No. 6,017,356 to Frederick et al., entitled "Method For Using a Trocar For Penetration and Skin Incision", the disclosure of which is herein incorporated by reference in its entirety discloses various trocar assemblies. The reader will of course appreciate, however, that the various embodiments of the present invention may be effectively employed with a variety of different trocar, cannula, etc. arrangements without departing from the spirit and scope of the present invention. Therefore, the various embodiments of the present invention and their equivalent structures should not in any way be limited to use with the specific type of trocar described herein by way of example.

**[0045]** When used in connection with a trocar, cannula, etc. that provides an access passage into the surgical site within the patient, the first and second tethers 62, 72, respectively may be provided with a length that enables the tethers 62, 72 to extend outside of the trocar 900 to provide easy access thereto. In such arrangements, for example, if one staple line is attached to a portion of tissue destined for excision, the tether could be used to pull that tissue toward the trocar cannula 902 for exit therethrough. See FIG. 7. Such unique and novel arrangement may also be employed when the trocar has been removed, but the tether(s) extend out of the opening in the body cavity. Thus, the tether(s) may be used to manipulate the stapled tissue from outside of the body cavity even after the trocar has been removed.

**[0046]** FIGS. 8 and 9 illustrate another cartridge embodiment 150 that is substantially identical to cartridge 50 described above, except for the differences noted below. In this embodiment for example, the cartridge 150 has a cartridge deck 152 that is divided into a first deck portion 153 and a second deck portion 154 by a slot 155. The first base material 60 is temporarily attached to or removably supported on the first deck portion 153 and the second base material 70 is temporarily attached to or removably attached to or supported on the second deck portion 154 in the various manners described above. In this embodiment, however, a first groove or pocket 156 that is adapted to temporarily receive at least a portion of the first tether 62 therein is provided in the first deck portion 153. Similarly, a second groove or pocket 157 is formed in the second deck portion 154 for temporarily receiving at least a portion of the second tether 72 therein. See FIG. 9. The first groove or pocket 156 may be sized relative to the first tether 62 such that it may be pressed therein to retain it within the groove 156 while the end effector 12 is introduced to the surgical site and then is drawn out of the first groove 156 after the first base material 60 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. Likewise, the second groove 157 may be sized relative to the second tether 72 such that it may be pressed therein to retain it within the groove 157 while the end effector 12 is introduced to the surgical site and then is drawn out of the second groove 157 after the second base material 70 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. In other embodiments, the first tether 62 may be temporarily retained within the first groove 156 by biocompatible adhesive, gel, etc. and the second tether 72 may be temporarily retained within the second groove 157 by biocompatible adhesive, gel, etc.

**[0047]** FIGS. 10 and 11 illustrate another cartridge embodiment 250 that is substantially identical to cartridge 50 described above, except for the differences noted below. In this embodiment for example, the cartridge 250 has a cartridge deck 252 that is divided into a first deck portion 253 and a second deck portion 254 by an elongated slot 255. The first base material 60 is temporarily attached to or removably attached to or supported on the first deck portion 253. Likewise, the second base material 70 is temporarily attached to or removably attached to or supported on the second deck portion 254 in the various manners described above. In this embodiment, however, a first groove, pocket, zone or region 257 that is adapted to temporarily receive at least a portion of the first tether 62 therein is provided in the cartridge nose portion 256. Similarly, a second groove, pocket, zone or region 258 or pocket is formed in the cartridge nose portion 256 for temporarily receiving at least a portion of the second tether 72 therein. See FIG. 11. The first groove or pocket 257 may be sized relative to the first tether 62 such that it may be pressed therein to retain it within the groove 257 while the end effector 12 is introduced to the surgical site and then is drawn out of the first groove 257 after the first base material 60 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. Likewise, the second groove 258 may be sized relative to the second tether 72 such that it may be pressed therein to retain it within the groove 258 while the end effector 12 is introduced to the surgical site and then is drawn out of the second groove 258 after the second base material 70 has been affixed to the tissue and the end effector is withdrawn from the surgical site. In other embodiments, the first tether 62 may be temporarily retained within the first groove 257 by adhesive or friction and the second tether 72 may be temporarily retained within the second groove 258 by adhesive or friction.

**[0048]** FIGS. 12 and 13 illustrate another cartridge embodiment 350 that is substantially identical to cartridge 50 described above, except for the differences noted below. In this embodiment for example, the cartridge 350 has a cartridge body 351 that has a cartridge deck 352 that is divided into a first deck portion 353 and a second deck portion 354 by an elongated slot 355. The first base material 60 is temporarily attached to or removably attached to or supported on the first deck portion 353. Likewise, the second base material 70 is temporarily attached to or removably attached to or supported on the second deck portion 354 in the various manners described above. In this embodiment, however, a first groove, pocket, zone or region 358 that is adapted to temporarily receive at least a portion of the first tether 62 therein is

provided in the side 357 of the cartridge nose portion 356. Similarly, a second groove, pocket, zone or region 359 is formed in the side 357 of the cartridge nose portion 356 for temporarily receiving at least a portion of the second tether 72 therein. See FIG. 13. The first groove or pocket 358 may be sized relative to the first tether 62 such that it may be pressed therein to retain it within the groove 358 while the end effector 12 is introduced to the surgical site and then is drawn out of the first groove 358 after the first base material 60 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. Likewise, the second groove 359 may be sized relative to the second tether 72 such that it may be pressed therein to retain it within the second groove 359 while the end effector 12 is introduced to the surgical site and then is drawn out of the second groove 359 after the second base material 70 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. In other embodiments, the first tether 62 may be temporarily retained within the first groove 358 by adhesive or friction and the second tether 72 may be temporarily retained within the second groove 359 by adhesive or friction.

**[0049]** FIGS. 14 and 15 illustrate another cartridge embodiment 450 that is substantially identical to cartridge 50 described above, except for the differences noted below. In this embodiment for example, the cartridge 450 has a cartridge body 451 that has a cartridge deck 452 that is divided into a first deck portion 453 and a second deck portion 454 by an elongated slot 455. The first base material 60 is temporarily attached to or removably attached to or supported on the first deck portion 453. Likewise, the second base material 70 is temporarily attached to or removably attached to or supported on the second deck portion 454 in the various manners described above. In this embodiment, however, a first groove, pocket, zone or region 457 that is adapted to temporarily receive at least a portion of the first tether 62 therein is provided in the nose portion 456 of the cartridge 450. Similarly, a second groove, pocket, zone or region 458 is formed in the nose portion 456 for temporarily receiving at least a portion of the second tether 72 therein. See FIG. 15. The first groove or pocket 457 may be sized relative to the first tether 62 such that it may be pressed therein to retain it within the groove 457 while the end effector 12 is introduced to the surgical site and then is drawn out of the first groove 453 after the first base material 60 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. Likewise, the second groove 458 may be sized relative to the second tether 72 such that it may be pressed therein to retain it within the second groove 458 while the end effector 12 is introduced to the surgical site and then is drawn out of the second groove 458

after the second base material 70 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. In other embodiments, the first tether 62 may be temporarily retained within the first groove 457 by adhesive or friction and the second tether 72 may be temporarily retained within the second groove 458 by adhesive or friction.

**[0050]** FIGS. 16 and 17 illustrate another cartridge embodiment 550 that is substantially identical to cartridge 50 described above, except for the differences noted below. In this embodiment for example, the cartridge 550 has a cartridge body 551 that has a cartridge deck 552 that is divided into a first deck portion 553 and a second deck portion 554 by an elongated slot 555. The first base material 60 is temporarily attached to or removably attached to or supported on the first deck portion 553. Likewise, the second base material 70 is temporarily attached to or removably attached to or supported on the second deck portion 554 in the various manners described above. In this embodiment, however, a first groove, pocket, zone or region (not shown) that is adapted to temporarily receive at least a portion of the first tether 62 therein is provided in a first lateral side portion 556 of the cartridge 550. Similarly, a second groove, pocket, zone or region 558 is formed in a second lateral side portion 557 of the cartridge 550 for temporarily receiving at least a portion of the second tether 72 therein. See FIG. 17. The first groove or pocket may be sized relative to the first tether 62 such that it may be pressed therein to retain it within that groove while the end effector 12 is introduced to the surgical site and then is drawn out of the first groove after the first base material 60 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. Likewise, the second groove 558 may be sized relative to the second tether 72 such that it may be pressed therein to retain it within the second groove 558 while the end effector 12 is introduced to the surgical site and then is drawn out of the second groove 558 after the second base material 70 has been affixed to the tissue and the end effector 12 is withdrawn from the surgical site. In other embodiments, the first tether 62 may be temporarily retained within the first groove by adhesive or friction and the second tether 72 may be temporarily retained within the second groove 558 by adhesive or friction. In this embodiment, a sufficient amount of clearance is provided between the upstanding side walls 23, 25, of the channel (FIG. 2) and the first and second lateral side portions of the cartridge 550 to provide sufficient clearance for the first and second tethers to be pulled out of their respective grooves in the cartridge 550 or otherwise detached from the lateral sides of the cartridge 550

after the base materials 60, 70 have been stapled to the severed tissue portions and the end effector 12 is withdrawn from the surgical site.

**[0051]** The embodiments described above each employ first and second base materials 60 and 70. However, for those applications wherein the ability to manipulate only one portion of the divided/stapled tissue is desirable, only one base material may be employed. Thus, various embodiments of the present invention comprise at least one base material that is temporarily attached to or otherwise removably supported on the cartridge or other portion of the end effector 12 and which base material has at least one elongated tether attached thereto.

**[0052]** The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

**[0053]** Preferably, the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

**[0054]** Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set

forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

**[0055]** While this invention has been described as having exemplary designs, the present invention may be further modified within the spirit and scope of the disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains.

What is claimed is:

1. A method for manipulating divided tissue comprising:

dividing a piece of tissue into two separate tissue segments, each said tissue segment having a severed end;

stapling the severed ends of the first and second tissue segments;

affixing at least one tether to at least one of the severed ends of the first and second tissue segments during said stapling; and

manipulating the severed end having the at least one tether affixed thereto by applying a manipulation motion to the tether.

2. The method of claim 1 wherein said affixing comprises:

affixing a first base material having at least one said tether coupled thereto to one of the severed ends during said stapling; and

affixing a second base material having at least one other said tether coupled thereto to another one of said severed ends during said stapling.

3. The method of claim 1 wherein said dividing comprises:

inserting an end effector of a surgical cutting and stapling instrument into an opening in a patient, the end effector comprising:

a staple cartridge having a body portion supporting a plurality of unformed staples therein;

a tissue cutting member; and

an anvil supported for movable travel toward and away from a deck surface on the staple cartridge in response to opening and closing motions applied thereto by the surgical instrument; and

at least one base material temporarily supported on the deck surface and having at least one elongated tether non-removably coupled thereto and wherein said dividing further comprises:

clamping the tissue to be severed between the anvil and the staple cartridge; and

applying a driving motion to the tissue cutting member to divide the tissue.

4. The method of claim 3 wherein said affixing comprises stapling the at least one base material to one of the severed ends of the tissue.

5. The method of claim 3 wherein said inserting comprises inserting the end effector into opening in the patient such that a portion of at least one of the at least one tethers remains accessible outside of the patient and wherein said manipulating comprises applying a pulling motion to each portion of the at least one tether remaining outside of the patient.

6. The method of claim 2 wherein said first and second base materials and each said elongated tether are fabricated from bioabsorbable material.

7. The method of claim 2 wherein said first and second base materials comprise bioabsorbable buttress material.

8. The method of claim 3 wherein said base material is removably retained on said deck surface by bioabsorbable adhesive.

9. The method of claim 3 wherein said a least one elongated tether is removably supported on a corresponding portion of said cartridge body.

10. The method of claim 9 wherein each said elongated tether is removably supported within a corresponding groove provided in said cartridge body portion.

11. The method of claim 10 wherein said at least one said corresponding groove is provided in a lateral side portion of said cartridge body.

12. The method of claim 11 wherein said at least one corresponding groove is provided in a nose portion of said cartridge body portion.

13. A surgical staple cartridge comprising:

a cartridge body operably supporting a plurality of surgical staples therein, said cartridge body comprising:

a deck surface and first and second lateral sides; and

a slot centrally disposed therein dividing said deck surface into a first deck portion and a second deck portion;

a first base material segment removably retained on said first deck portion, said first base material having at least one first tether non-removably affixed thereto; and

a second base material segment removably retained on said second deck portion, said second base material having at least one second tether non-removably affixed thereto.

14. The surgical staple cartridge of claim 13 wherein said first base material and said second base material comprise a mesh material.

15. The surgical staple cartridge of claim 13 wherein said cartridge body has a body length and wherein at least one of said at least one elongated tethers has a tether length that is at least as long as said body length.

16. The surgical staple cartridge of claim 13 wherein said first tether is removably supported on a corresponding first portion of said cartridge body and wherein said second tether is removably supported on a corresponding second portion of said cartridge body.

17. The surgical staple cartridge of claim 16 wherein each said first tether is removably supported within a corresponding first groove provided in said first portion of said cartridge body portion and wherein said second tether is removably supported within a corresponding second groove provided in said second portion of said cartridge body.

18. The surgical staple cartridge of claim 17 wherein said first groove is provided in a first lateral side portion of said cartridge body and wherein said second groove is provided in a second lateral side portion of said cartridge body.

19. The surgical staple cartridge of claim 13 wherein portions of said first and second tethers are removably supported in at least one groove is in a nose portion of said cartridge body portion.

20. A surgical end effector for use with a surgical instrument, said surgical end effector comprising:

an elongated channel operably couplable to the surgical instrument;

a staple cartridge having a cartridge body operably supported in said elongated channel, said cartridge body having a deck surface substantially split into a first deck portion and a second deck portion by a longitudinal slot extending therebetween, said cartridge body operably supporting a first plurality of unformed staples therein corresponding to said first deck portion and a second plurality of unformed staples corresponding to said second deck portion;

a tissue cutting member operably supported in said cartridge body for axial advancement in said longitudinal slot upon application of a cutting actuation motion thereto by the surgical instrument;

an anvil supported for movable travel toward and away from said deck surface in response to opening and closing motions applied thereto by the surgical instrument;

a first base material removably supported on said first deck portion;

at least one first tether non-removably attached to said first base material;

a second base material removably supported on said second deck portion; and

at least one second tether non-removably attached to said second base material.

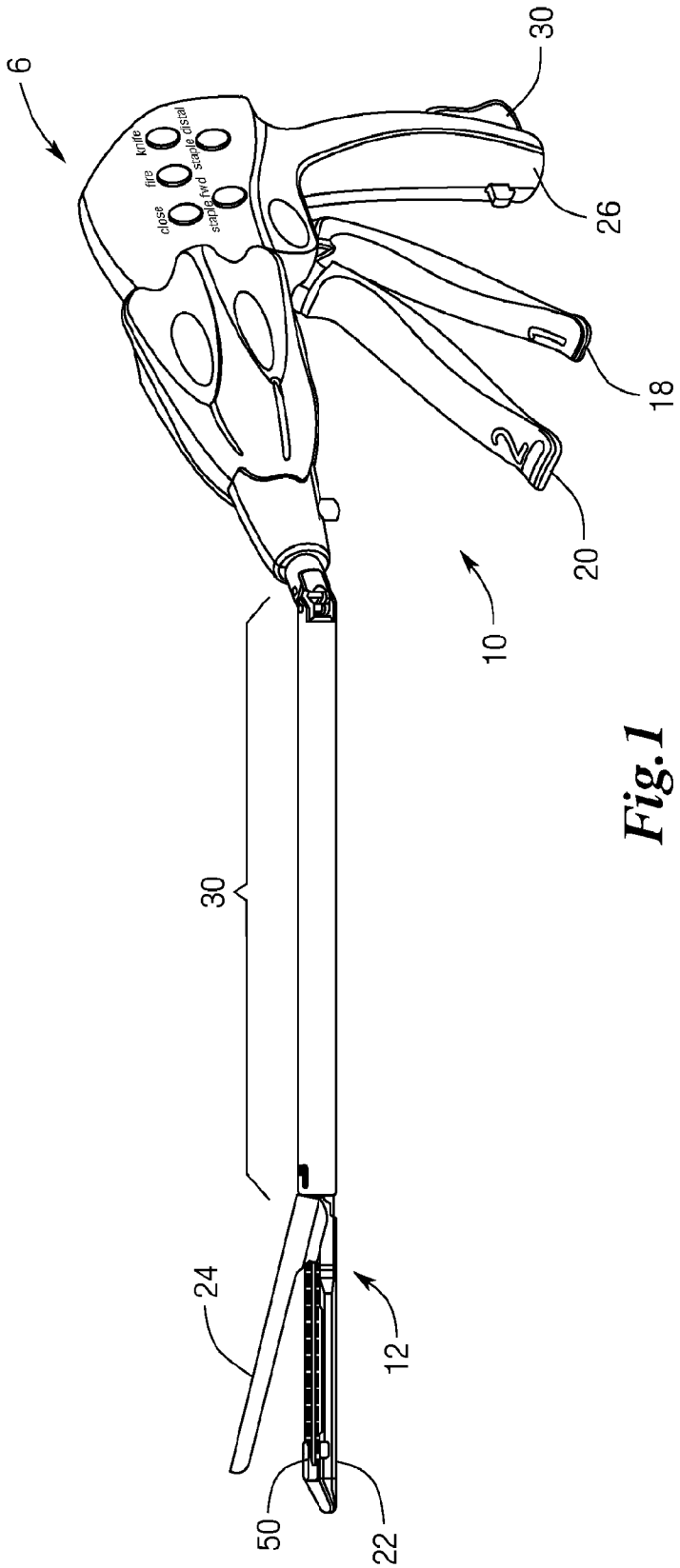
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*Fig.1*

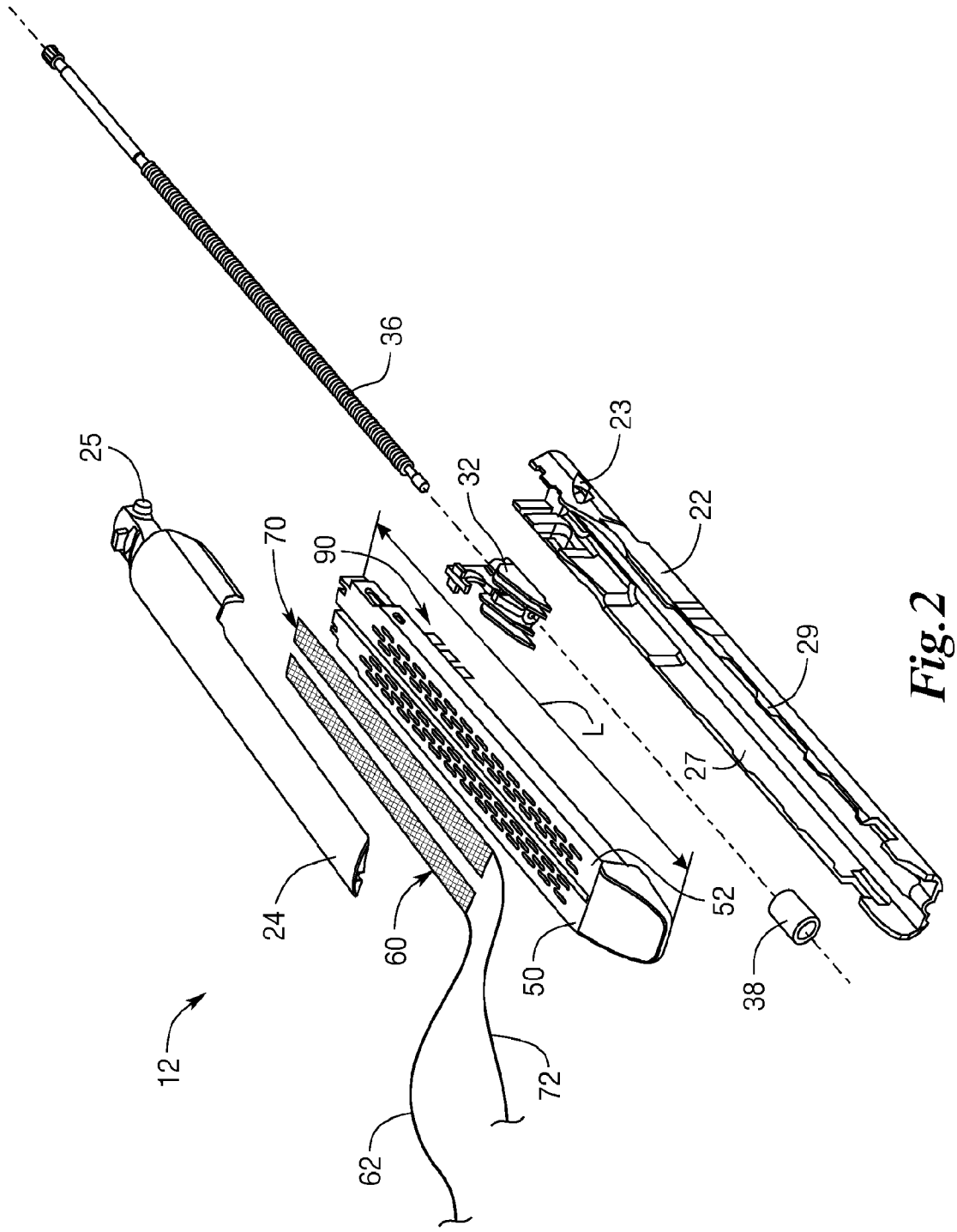


*Fig.2*

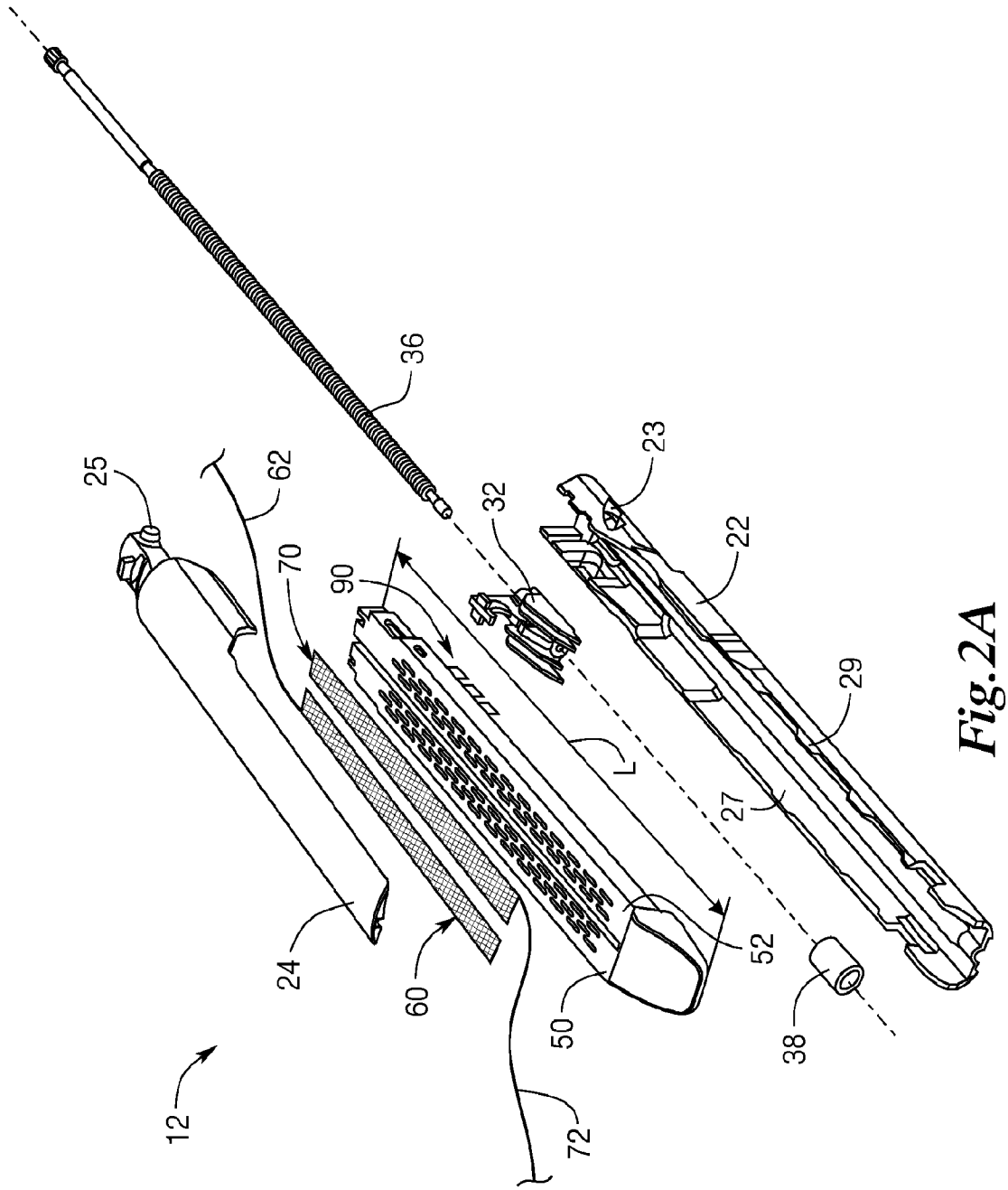


*Fig.2A*

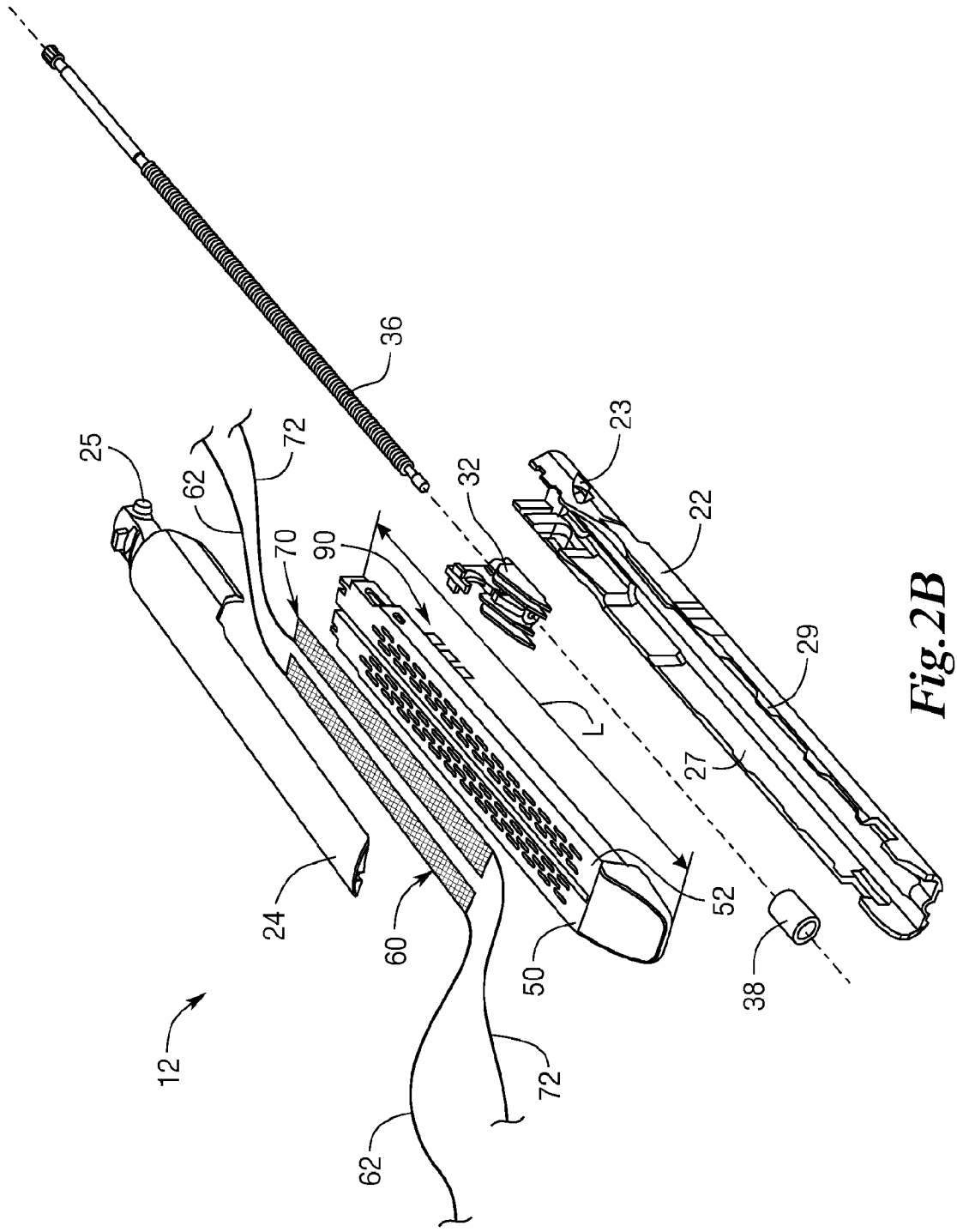


*Fig.2B*

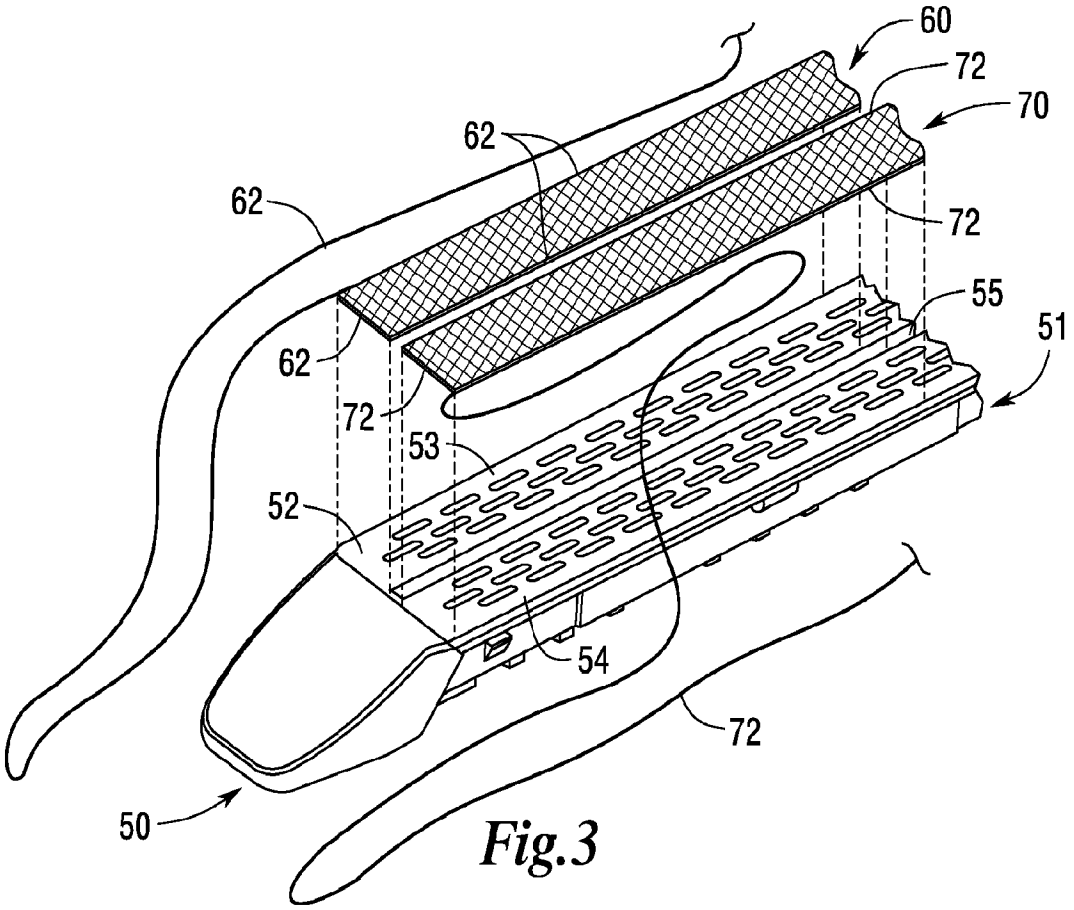
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*Fig.3*

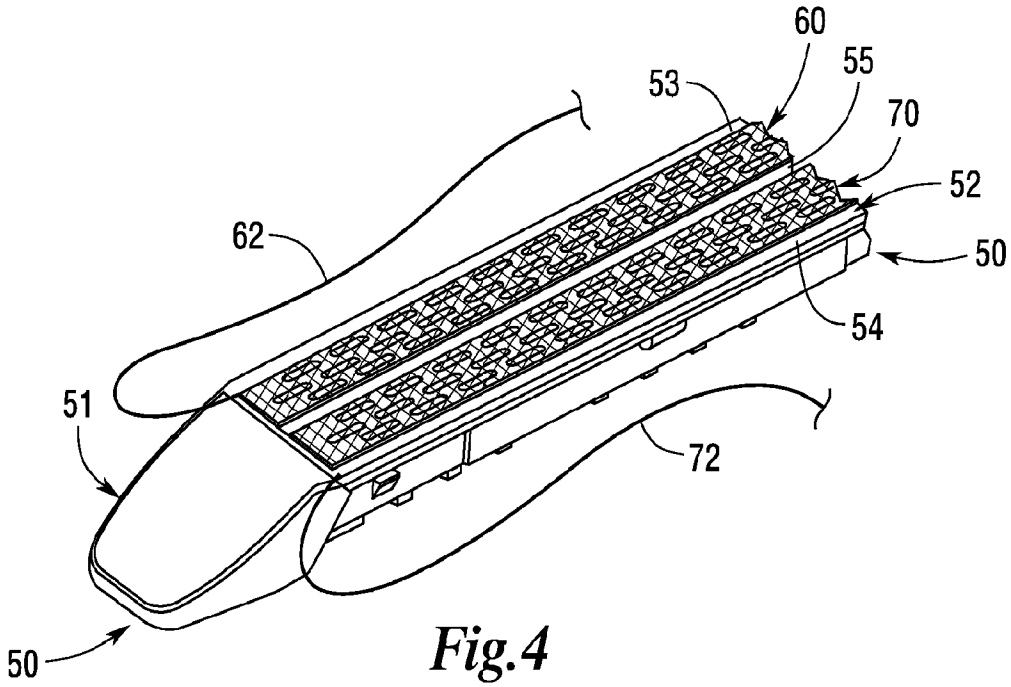
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*Fig.4*

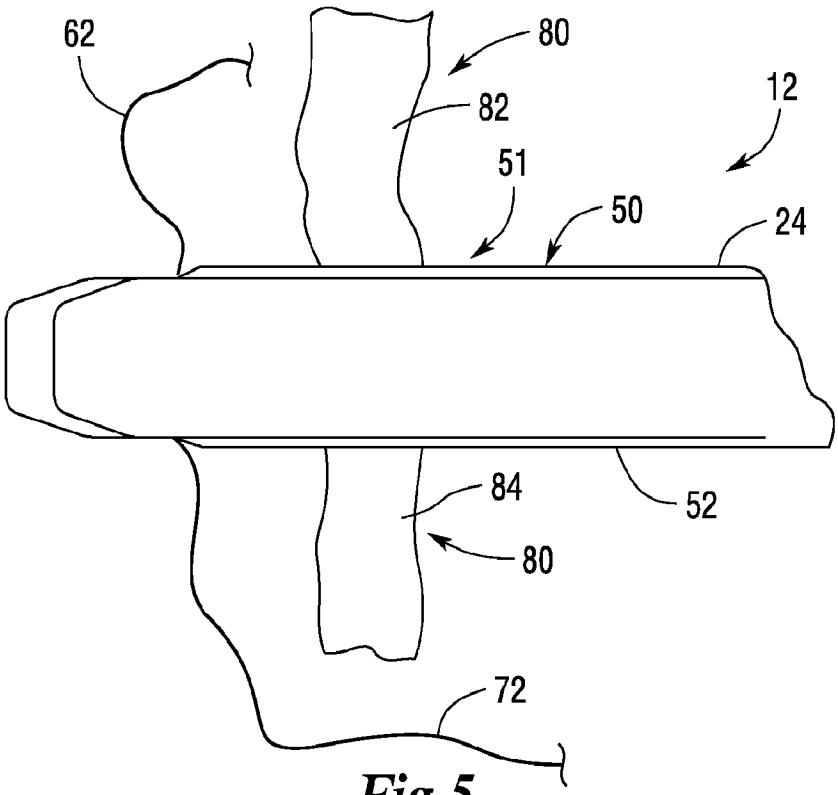


*Fig.5*

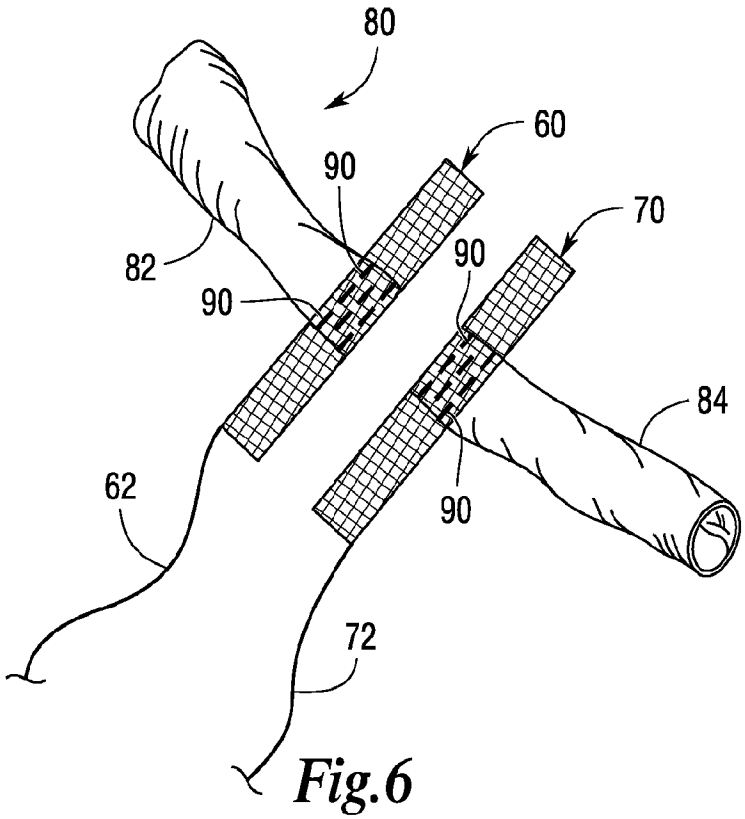


*Fig.6*

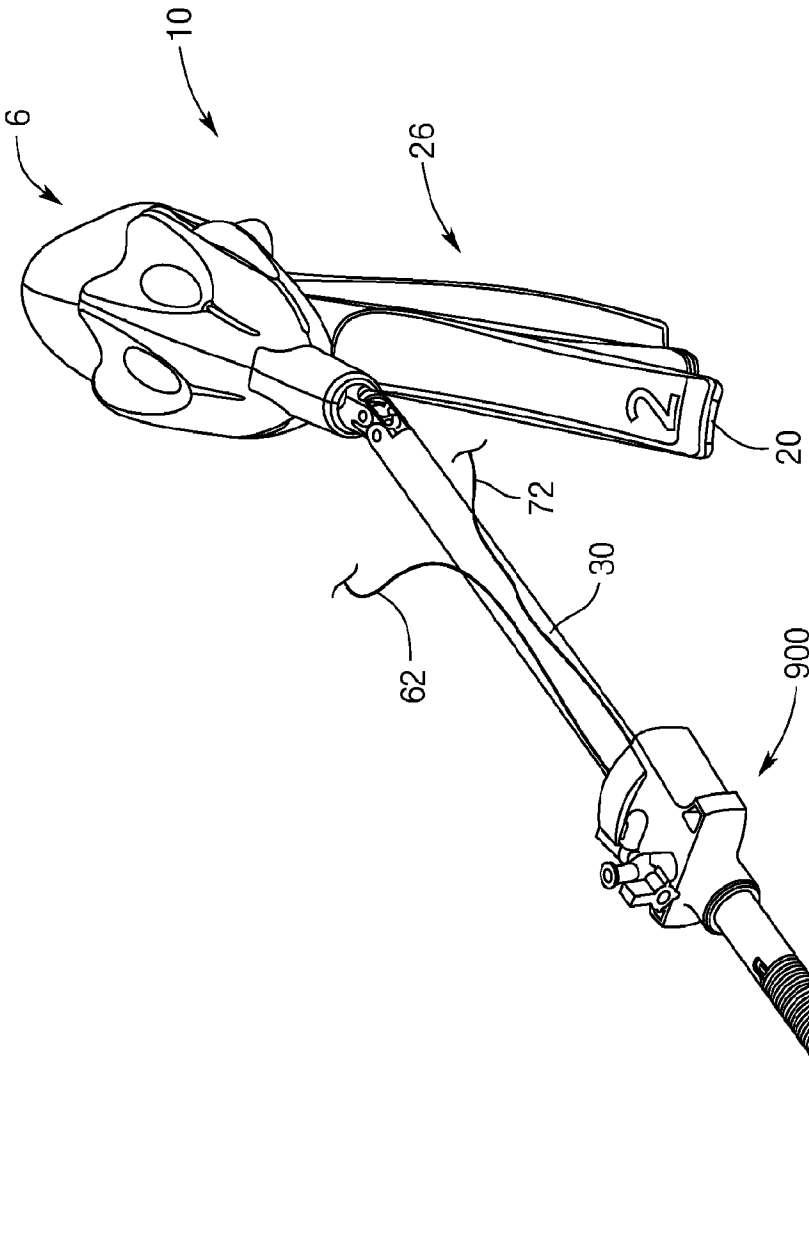


*Fig. 7*

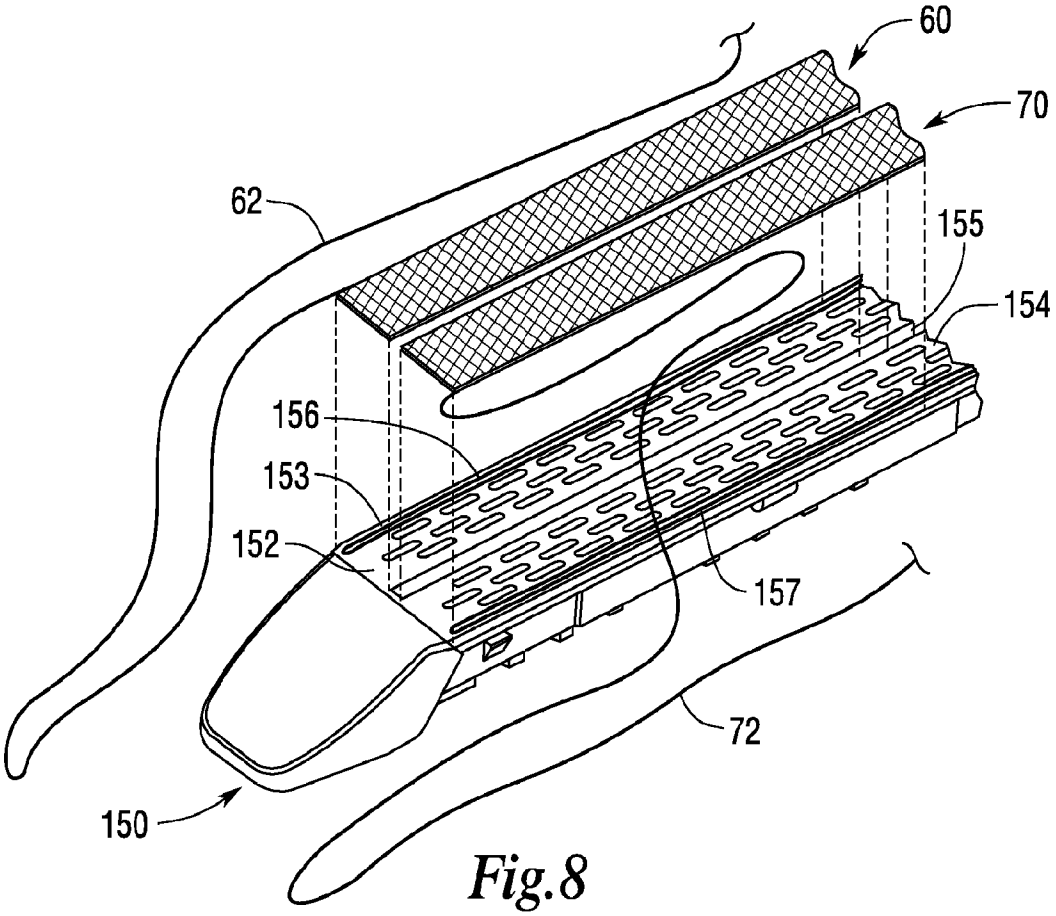
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*Fig.8*

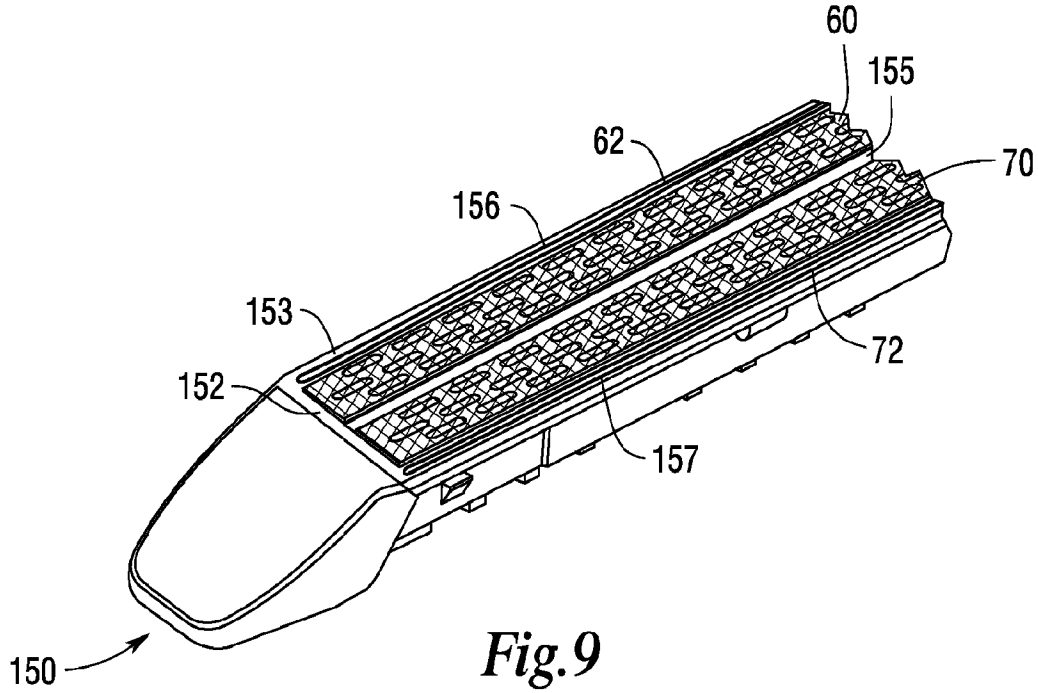
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*Fig.9*

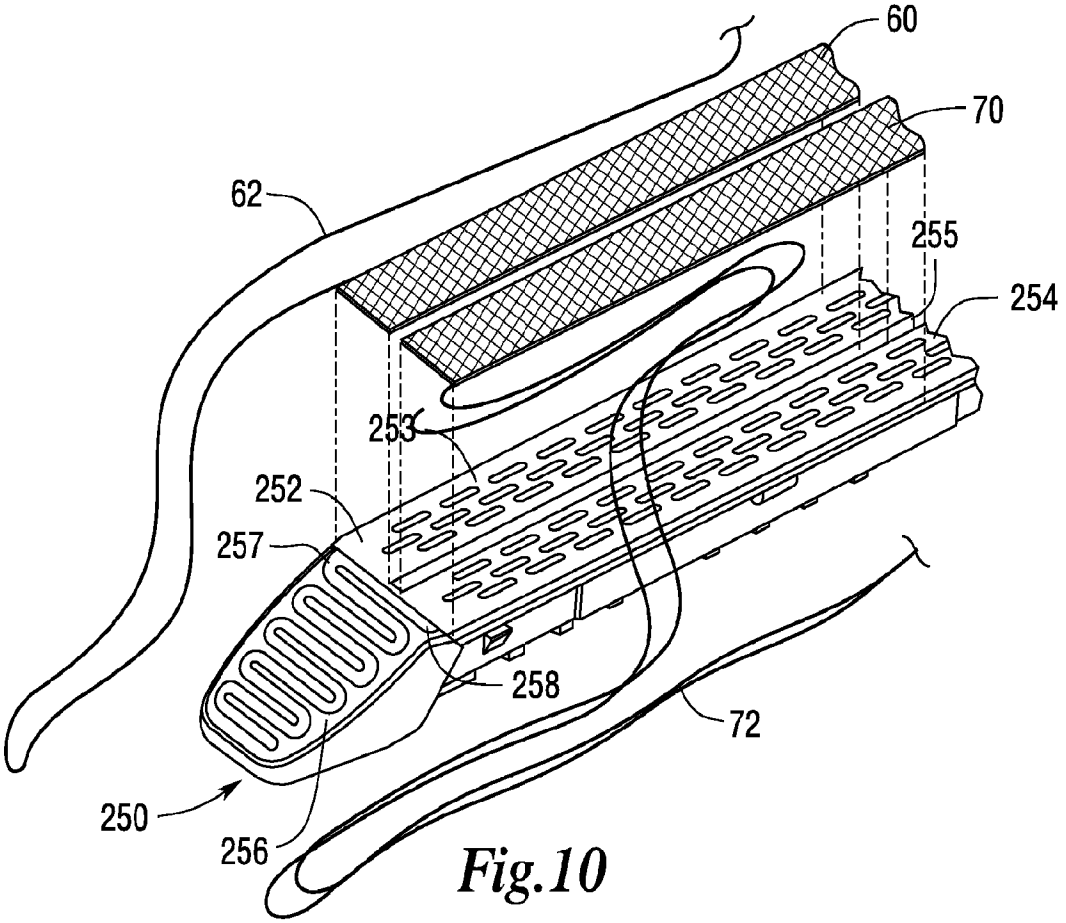
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*Fig.10*

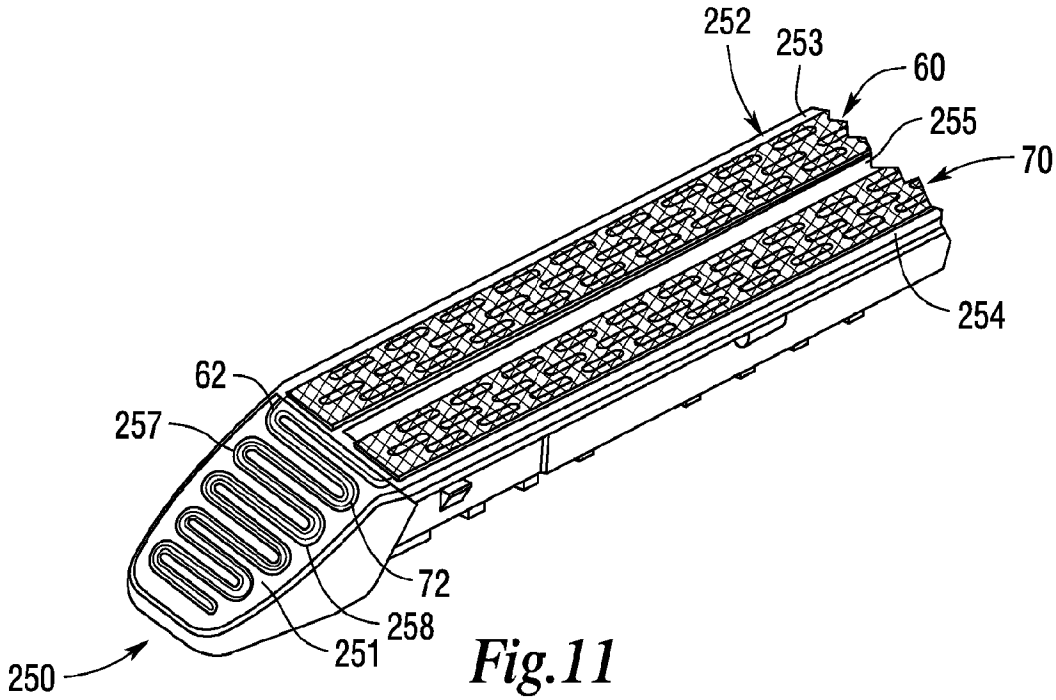
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*Fig.11*

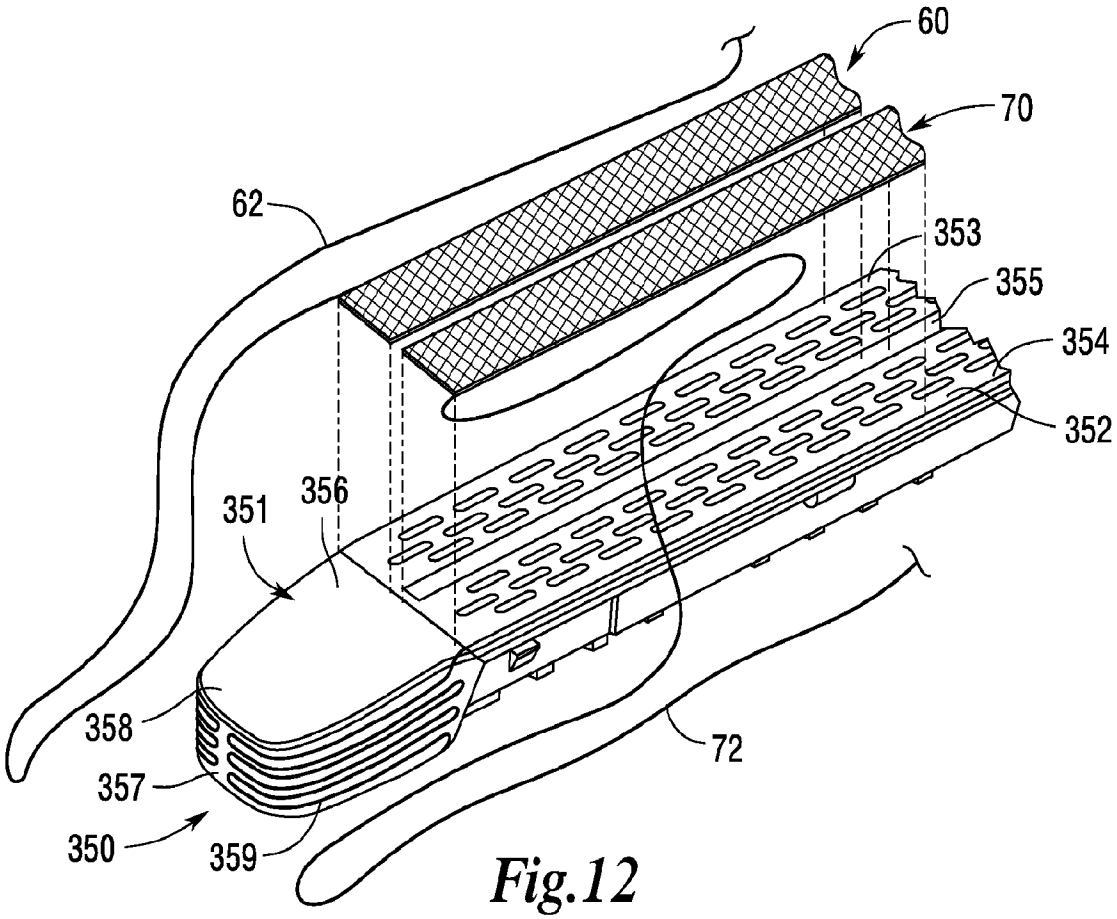
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*Fig.12*

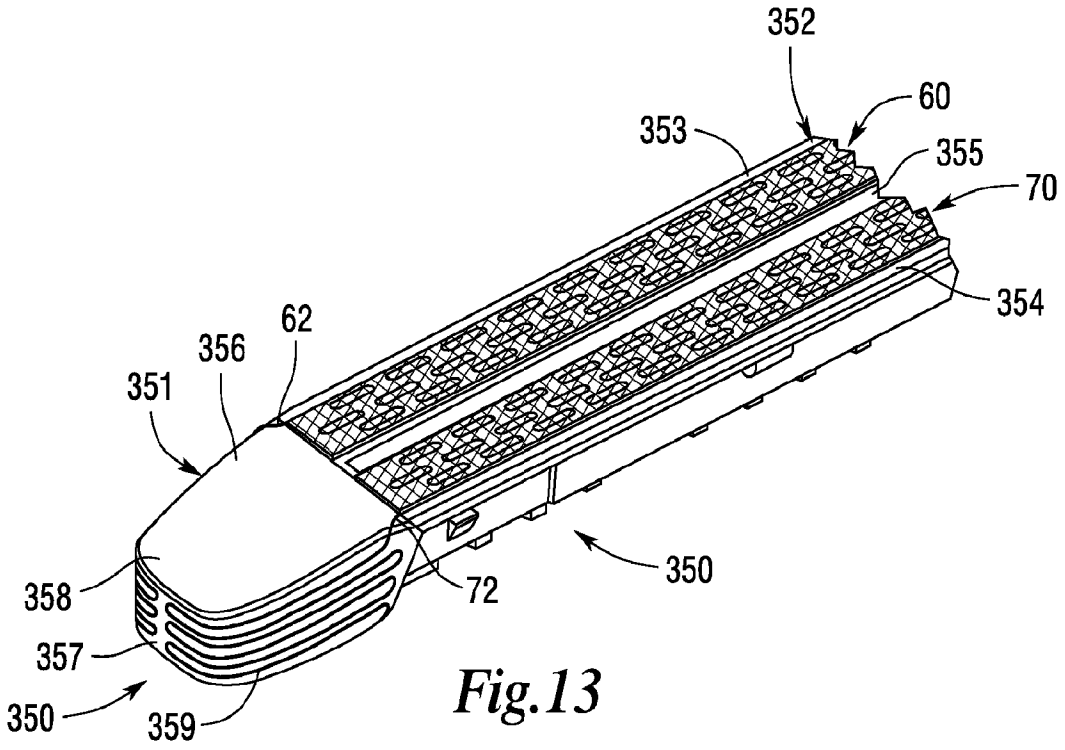
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*Fig.13*

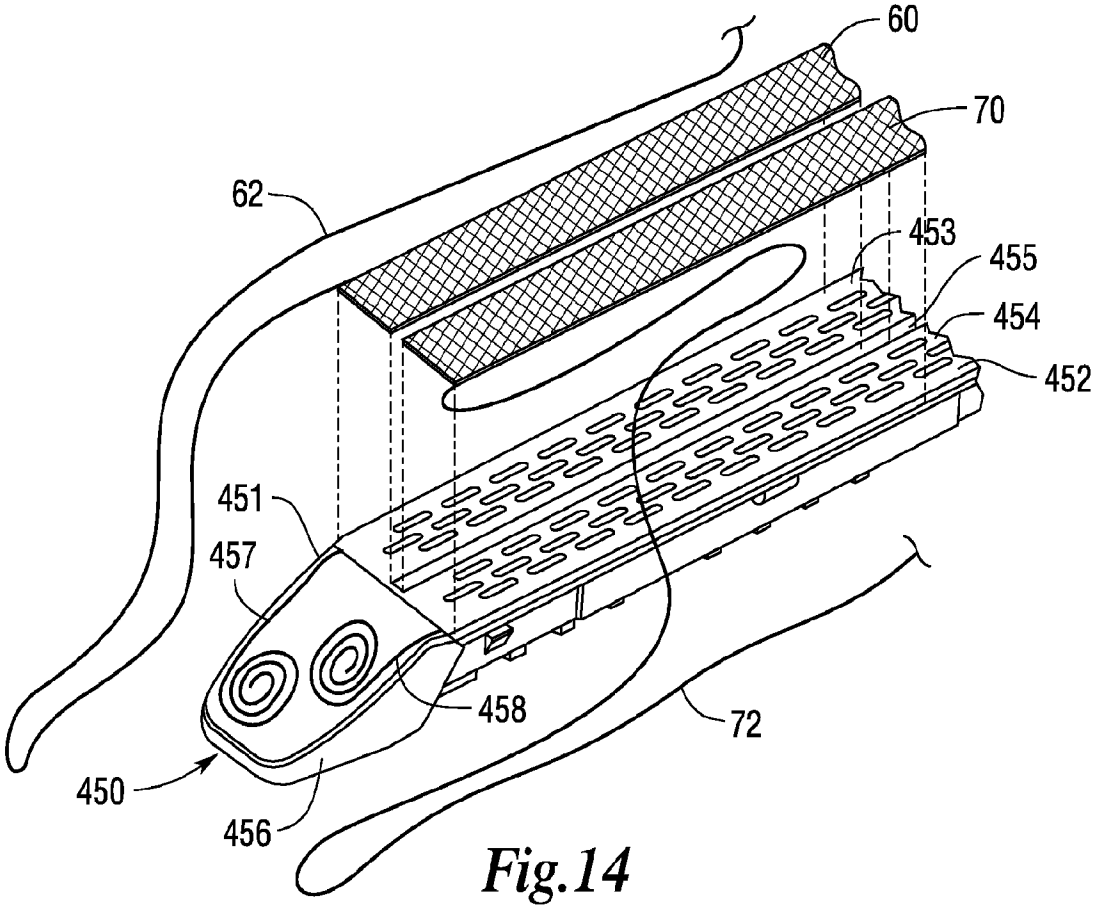
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*Fig.14*

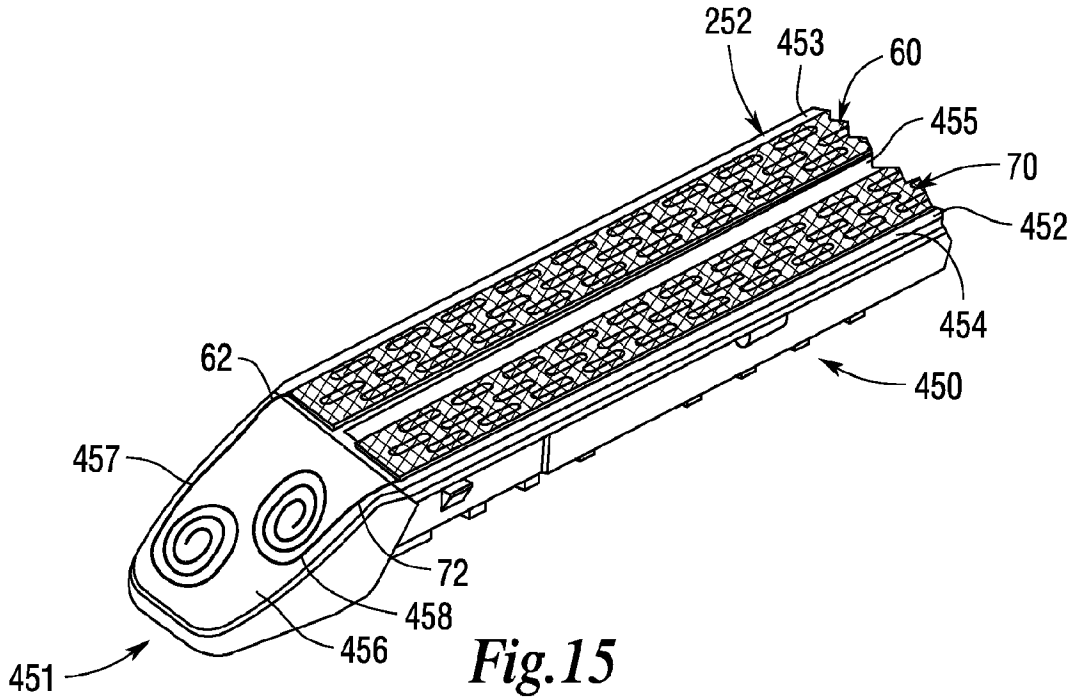
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*Fig.15*

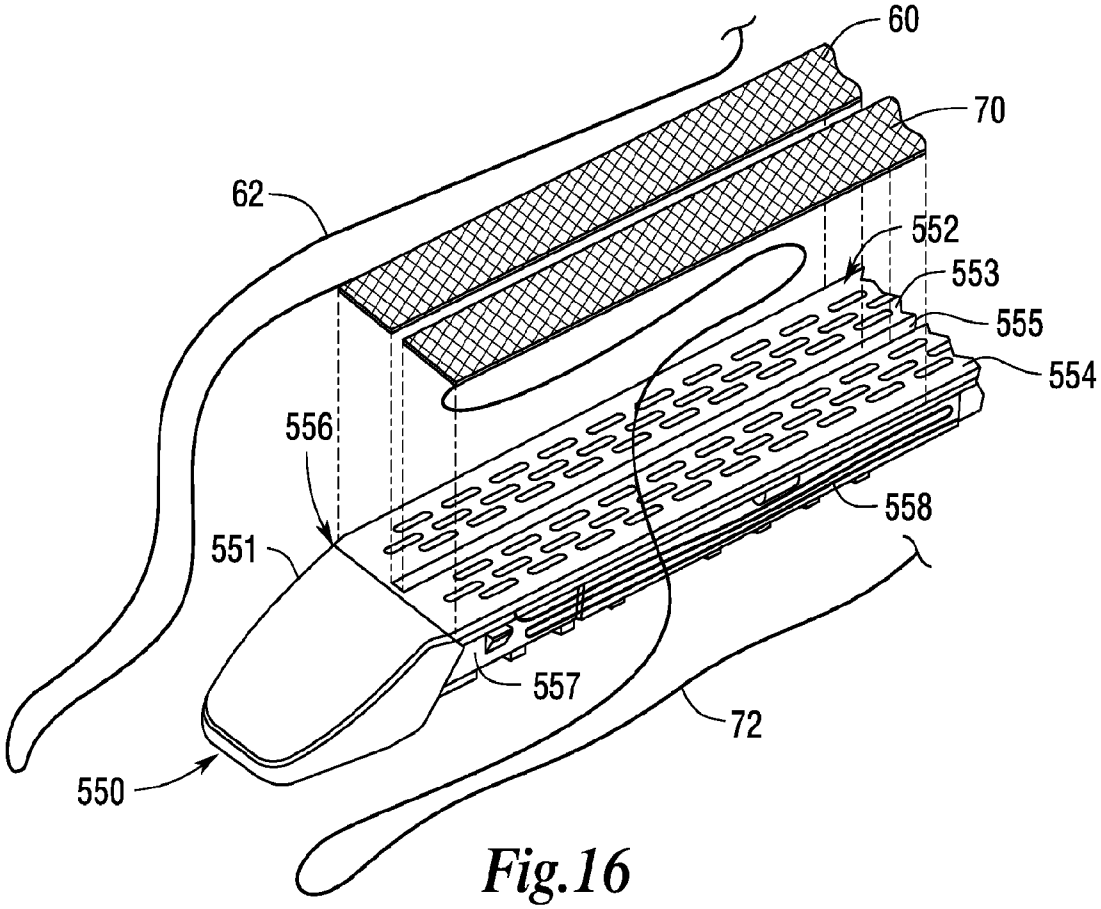
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*Fig.16*

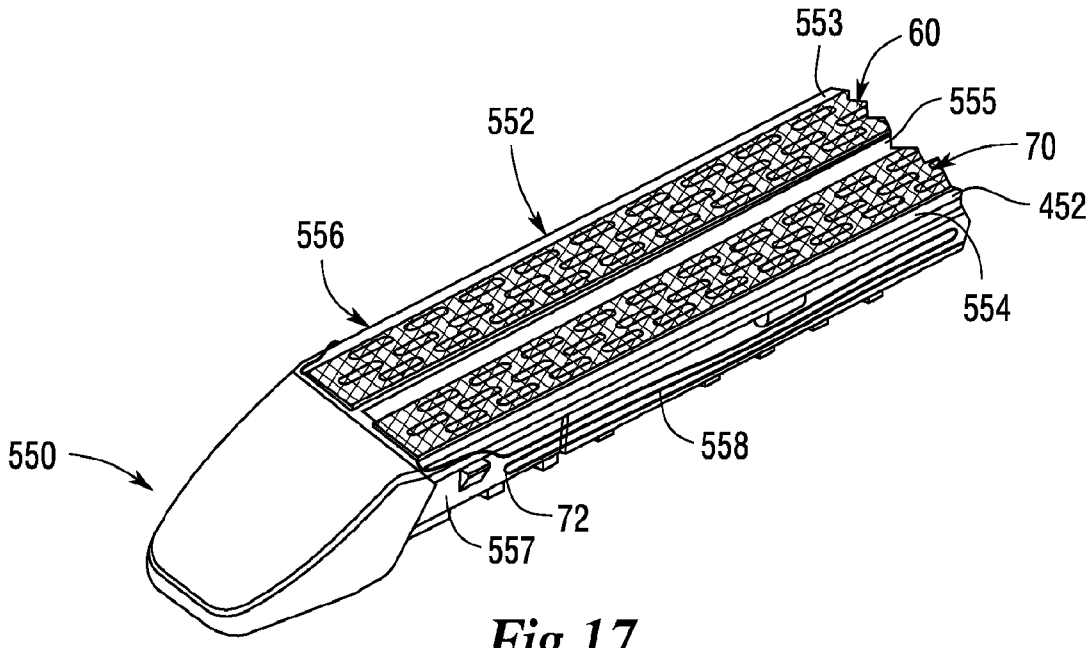
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*Fig.17*

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/028914

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/072
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 2009/206143 A1 (HUITEMA THOMAS W [US] ET AL) 20 August 2009 (2009-08-20) cited in the application figures 4,6 | 13-20 |
| A | US 5 843 096 A (IGAKI KEIJI [JP] ET AL) 1 December 1998 (1998-12-01) abstract; figure 7 | 13-20 |
| A | EP 1 647 286 A1 (GUNZE KK [JP]) 19 April 2006 (2006-04-19) abstract; figures 8,9,16 | 13-20 |
| A | WO 97/01989 A1 (FRATER DIRK A [US]; FRATER ROBERT W M [US]) 23 January 1997 (1997-01-23) figures 7,9,10 | 13-20 |

☐ 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 | Date of mailing of the international search report |
|---|---|
| 11 July 2012 | 20/07/2012 |

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

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/028914

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-12
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**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. [ ] 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 an 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/US2012/028914

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| | | DE 69625664 T2 | 16-10-2003 |
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