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(54) APPARATUS FOR DISSECTING AND COAGULATING TISSUE

(57) A surgical instrument (20) for cutting and coagulating tissue is provided that includes an elongate sheath (24) and an ultrasonic blade (22). In one embodiment, an ultrasonic blade (22) is positioned within a sheath (24) such that movement of the sheath (24) relative to the blade (22) results in the dissection and/or coagulation of tissue therebetween. In another embodiment, an ultrasonic blade (22) is positioned within a sheath (24) such that movement of the blade (22) relative to the sheath (24) results in the dissection and/or coagulation of tissue therebetween. The size and shape of distal ends of the blade (22) and sheath (24) determine the size and shape of the tissue being cut and/or removed from a body.

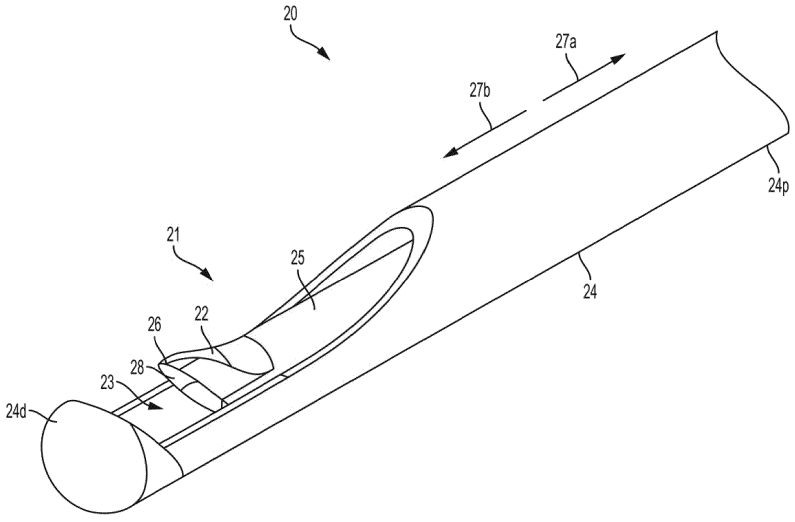

FIG. 4

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Description

INTRODUCTION

[0001] The present embodiments of the invention relate to surgical instruments and, in various circumstances, to surgical cutting instruments for dissecting and coagulating tissue.

[0002] The present disclosure is related generally to surgical instruments including ultrasonic instruments. Ultrasonic surgical instruments, such as ultrasonic scalpels, are used in many applications in surgical procedures by virtue of their unique performance characteristics. Ultrasonic surgical instruments can be configured for open surgical use, laparoscopic, or endoscopic surgical procedures including robotic-assisted procedures.

[0003] Various surgical instruments utilize energy to cut and seal tissue that is being removed from a body. Some of these instruments include various jaws or other shearing elements to grasp tissue therein. Energy can be applied to the tissue such that the tissue can be cut and coagulated.

[0004] It may be desirable to minimize the bleeding at the site of the tissue removal and to have the ability to control the size of the tissue being removed and the space left behind in the body by the removed tissue.

SUMMARY

[0005] In one embodiment, an apparatus for dissection and coagulation of tissue is provided. The apparatus comprises an ultrasonic blade configured to dissect and seal tissue and having a proximal end and distal end, the distal end of the ultrasonic blade comprising a surface proximal of the distal end to engage tissue; and an elongate sheath configured to extend over the ultrasonic blade and being movable relative to the ultrasonic blade between a first position in which the elongate sheath is positioned over a proximal portion of the ultrasonic blade and a second position in which the elongate sheath moves distally towards the surface of the distal end of the ultrasonic blade such that tissue can be dissected therebetween.

[0006] In another embodiment, a distal end of the elongate sheath is sized and shaped to correspond to the size and shape of the surface of the distal end of the ultrasonic blade.

[0007] In another embodiment, the shape of the distal end of the ultrasonic blade and the distal end of the elongate sheath define a cavity at the location of the dissected tissue.

[0008] In another embodiment, the proximal end of the ultrasonic blade communicates with an excitation mechanism to deliver mechanical energy at at least one ultrasonic frequency to the distal end of the ultrasonic blade.

[0009] In another embodiment, a proximal end of the elongate sheath is configured to couple to an actuator to move the sheath between the first and second positions.

[0010] In another embodiment, the apparatus comprises a suction mechanism in the form of an elongate hollow tube positioned within the sheath and extending to the distal end thereof such that a distal end of the suction mechanism is configured to remove tissue dissected by the ultrasonic blade and the sheath.

[0011] In another embodiment, the suction mechanism is configured to irrigate an area located substantially around the tissue being dissected and removed.

[0012] In another embodiment, the distal end of the suction mechanism is positioned between the distal end of the sheath and the distal end of the ultrasonic blade.

[0013] In one embodiment, an apparatus for dissection and coagulation of tissue is provided. The apparatus comprises an elongate sheath having a proximal end and distal end, the distal end of the elongate sheath comprises a substantially flat surface proximal of the distal end to form an anvil; and an ultrasonic blade configured to dissect and seal tissue and being positioned within the elongate sheath, the ultrasonic blade being movable relative to the elongate sheath between a first position in which the ultrasonic blade is positioned a distance from the distal end of the elongate sheath and a second position in which the sheath moves proximally towards the distal end of the ultrasonic blade such that tissue can be dissected therebetween.

[0014] In another embodiment, a distal end of the ultrasonic blade is sized and shaped to correspond to the size and shape of the surface of the distal end of the elongate sheath forming the anvil.

[0015] In another embodiment, the shape of the distal end of the ultrasonic blade and the distal end of the elongate sheath create a cavity at the location of the dissected tissue.

[0016] In another embodiment, a proximal end of the ultrasonic blade communicates with a excitation mechanism to deliver energy to the distal end of the ultrasonic blade.

[0017] In another embodiment, a proximal end of the ultrasonic blade is configured to couple to an actuator to move the blade between the first and second positions.

[0018] In another embodiment, a suction mechanism in the form of an elongate hollow tube positioned within the sheath and extending to the distal end thereof such that a distal end of the suction mechanism is configured to remove tissue dissected by the ultrasonic blade and the sheath.

[0019] In another embodiment, the suction mechanism is configured to irrigate an area located substantially around the tissue being dissected and removed.

[0020] In another embodiment, the distal end of the suction mechanism is positioned between the distal end of the sheath and the distal end of the ultrasonic blade.

[0021] In one embodiment, an apparatus for dissection and coagulation of tissue is provided. The apparatus comprises an ultrasonic blade; an elongate sheath defining an aperture, wherein the ultrasonic blade is positioned within the aperture, the elongate sheath being

movable distally relative to the ultrasonic blade between a first position defining a gap between a distal end of the sheath and the ultrasonic blade to receive target tissue in the gap, and a second position in which the elongate sheath is movable proximally towards the ultrasonic blade to grasp the target tissue therebetween; and a handle assembly mechanically coupled to the sheath to apply axial motion to the sheath.

[0022] In another embodiment, the ultrasonic blade comprises a curved surface for engaging the target tissue.

[0023] In another embodiment, a distal end of the ultrasonic blade extends distally beyond a distal end of the sheath.

[0024] In another embodiment, a distal end of the sheath extends distally beyond a distal end of the ultrasonic blade.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The features and advantages of the various embodiments of the invention, and the manner of attaining them, will become more apparent and the embodiment of the invention itself will be better understood by reference to the following description of embodiments of the embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

FIG. 1 is a perspective view of one embodiment of a surgical instrument having an ultrasonic blade positioned within a movable sheath, according to one embodiment;

FIG. 2 is a side view of the surgical instrument of FIG. 1 showing the movable sheath in a first position, according to one embodiment;

FIG. 3 is a side view of the surgical instrument of FIG. 1 showing the movable sheath in a second position, according to one embodiment;

FIG. 4 is a perspective view of another embodiment of a surgical instrument having a sheath that is movable relative to an ultrasonic blade, according to one embodiment;

FIG. 5 is a side view of the surgical instrument of FIG. 4 showing the movable sheath in a first position, according to one embodiment;

FIG. 6 is a cross-sectional side view of the surgical instrument of FIG. 5, according to one embodiment;

FIG. 7 is a side view of the surgical instrument of FIG. 4 showing the movable sheath in a second position, according to one embodiment;

FIG. 8 is a cross-sectional side view of the surgical instrument of FIG. 7, according tot one embodiment;

FIG. 9 is perspective view of the surgical instrument of FIGS. 1 or 4 coupled to a handle and a plug, according to one embodiment;

FIG. 10 is a side view of the surgical instrument of FIG. 9, according to one embodiment;

FIG. 11 is cross-sectional side view of the surgical instrument of FIG. 10, according to one embodiment;

FIG. 12 is a cross-sectional side view of the surgical instrument of FIG. 4 coupled to a handle with a movable sheath located in a first position where the sheath is movable relative to an ultrasonic blade, according to one embodiment;

FIG. 13 is a cross-sectional side view of the surgical instrument of FIG. 13 with a movable sheath located in a second position where the sheath is movable relative to an ultrasonic blade, according to one embodiment; and

FIG. 14 is a cross-sectional side view of a surgical instrument having an ultrasonic blade positioned within a movable sheath, a suction tube, and a pad positioned on a distal end of the movable sheath, according to one embodiment.

FIG. 15 is a side view of a surgical instrument comprising an opening defined between the blade/ultrasonic waveguide and the outer tube, where in one embodiment the opening is configured to couple to a suction source.

FIG. 16 is a sectional view taken along section line 16--16 of the distal end of the instrument shown in FIG. 15, according to one embodiment.

DESCRIPTION

[0026] Numerous specific details are set forth to provide a thorough understanding of the overall structure, function, manufacture, and use of the embodiments as described in the specification and illustrated in the accompanying drawings. It will be understood by those skilled in the art, however, that the embodiments may be practiced without such specific details. In other instances, well-known operations, components, and elements have not been described in detail so as not to obscure the embodiments described in the specification. Those of ordinary skill in the art will understand that the embodiments described and illustrated herein are non-limiting examples, and thus it can be appreciated that the specific structural and functional details disclosed herein may be representative and illustrative. Variations and changes thereto may be made without departing from the scope of the claims.

[0027] 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 em-

bodiment may be combined, in whole or in part, with the features structures, or characteristics of one or more other embodiments without limitation. Furthermore, it will be appreciated that for conciseness and clarity, spatial terms such as "vertical," "horizontal," "up," and "down", for example, may be used herein with respect to the illustrated embodiments. However, these terms are used to assist the reader and are not intended to be limiting and absolute.

[0028] In various embodiments, the present disclosure provides The device described herein is a surgical instrument with improved ultrasonic forceps. The ultrasonic blade stays stationary while the anvil moves axially toward the blade in order to appose tissue. In this specific embodiment the end effector contains an ultrasonic blade and an anvil which matches the distal end of the blade so as to effect tissue between the two components as they translate relative to on another in an axial motion. The ultrasonic blade will be activated once the target tissue is apposed in the end effecter. The activation of the ultrasonic blade will cauterize and cut through the target tissue. The device includes an ultrasonic transducer and an energy source if cordless, a cord if energy source is not in the device. The embodiments, however, are not limited in this context.

[0029] In another embodiment, a suction is applied to the target tissue to remove it after cutting is completed.

[0030] In another embodiment, monopolar and/or RF energy may be applied at the distal end for tissue effect.

[0031] Advantages of the disclosed embodiments include reduction in the amount of bleeding in surgical procedures such as, for example, otolaryngology (ENT) procedures. Specifically removing polyps or turbinate reduction. In current surgical procedures concerning the ear, nose and throat, when removing polyps or other tissues in that region of the body there is an excessive amount of bleeding that occurs, among other surgical procedures.

[0032] FIGS. 1-3 depict a surgical cutting and coagulating instrument 10 for dissecting and coagulating tissue according to one embodiment. In the illustrated embodiment, the instrument 10 includes an ultrasonic blade 12 positioned within an elongate sheath 14. The sheath 14 includes a distal end 14d and a proximal end 14p that is configured to couple to a handle that is configured to be grasped, manipulated and actuated by a clinician. The sheath 14 is movable relative to the ultrasonic blade 12 between a first proximal position in which the sheath 14 is positioned over a proximal portion of the blade 12 and a second position in which the sheath 14 moves distally in direction 17b such that tissue positioned in gap 13 between the blade 12 and the distal end 14d of the sheath 14 is dissected therebetween. Once the tissue is dissected, the sheath 14 is retracted proximally in direction 17a.

[0033] The elongate sheath 14 of the device can have a variety of configurations, and it can be flexible or rigid depending on the intended use. In one embodiment, the sheath 14 is relatively rigid. In other embodiments, at least portions of the sheath 14 can be semi-flexible or flexible to allow insertion therethrough. Thus, the instrument 10 can be adapted to be inserted in body cavities in endoscopic, laparascopic, or open surgical procedures. One skilled in the art will appreciate that the sheath 14 can be made from a variety of biocompatible materials that have properties sufficient to enable the sheath 14 to be inserted and moved within channels of a body. The sheath 14 can also have an elongate length to allow the distal end of the sheath 14 to be positioned within the body while the proximal end remains external to the body. The inner lumens of the sheath 14 can also be used to pass other instruments or fluids through the instrument 10 for use during a surgical procedure, as will be discussed in more detail below.

[0034] The proximal end 14p of the sheath 14 is configured to be coupled to an actuator operated by a handle assembly as discussed in connections with FIGS. 9-13 hereinbelow. The actuator can include various features, such as an actuating element for moving the sheath 14 between the first and second positions. The actuator can also include features to enable the delivery of energy from an energy source through the ultrasonic blade 12. By way of non-limiting example, the actuating element can be a button, a switch, a knob, or any other member configured to actuate delivery of energy from an energy source. In lieu of an actuating element disposed on the handle, one skilled in the art will appreciate that the actuating element can be located elsewhere, including on a foot pedal. The energy source can be an internal energy source, such as a battery disposed in the handle, or the handle can be adapted to be coupled to an external energy source. An ultrasonic waveguide 15 is disposed and isolated form the sheath 14. The ultrasonic blade 12 is disposed at the distal end of the ultrasonic waveguide 15. The proximal end of the ultrasonic waveguide 15 is acoustically coupled to the ultrasonic transducer. The blade 12 can be formed integrally with the waveguide 15 or may be attached thereto by welding, screw, or bolt mechanisms. The ultrasonic waveguide 15 is positioned within the proximal end 14p of the sheath 14 is configured to communicate with the ultrasonic transducer to deliver ultrasonic energy to the blade 12 at the distal end of the waveguide 15 such that tissue positioned between the blade 12 and the sheath 14 can be cut, coagulated, cauterized, evaluated, and the like. The ultrasonic energy delivered to the blade 12 can have various forms. For example, the energy can be of at least one ultrasonic frequency and be monopolar and/or RF energy sufficient to cut and coagulate tissue. In whatever for form, e.g., ultrasonic vibrations or RF, the energy delivered to the tissue positioned in the gap 13 can be therapeutic or sub-therapeutic.

[0035] The ultrasonic blade 12 and the ultrasonic waveguide 15 positioned within the sheath 14 can also have a variety of configurations. The waveguide 15 can have an elongate length to allow a distal end of the blade 12 to be positioned within the body at the location of a

tissue to be dissected such that the distal end of the blade 12 extends beyond the distal end of the sheath 14 while the proximal end remains external to the body. The ultrasonic blade 12 can have a diameter such that it can be positioned within the lumen of the sheath 14.

[0036] The size and shape of the distal end of the blade 12 determines the size and shape of the dissected tissue and the cavity created when the tissue is cut and removed. In one embodiment, the distal end of the blade 12 has a curved distal end with a substantially flat surface proximal of the curved distal end. For example, the distal end of the blade 12 can be in the form of an anvil and a pad. The distal end 14d of the sheath 14 is sized and shaped to correspond to the size and shape of the distal end of the blade 12 such that the movement of the sheath 14 distally towards the distal end of the blade 12 creates a scissor action therebetween to cut tissue. The distal end 14d of the sheath 14 includes an outer rim 16 that corresponds to the shape of the distal end of the blade 12. The outer rim 16 forms a cavity 18 in the distal end 14d of the sheath 14 such that, when tissue is dissected, a cavity that is substantially the size and shape of the cavity 18 of the distal end 14d of the sheath 14 is formed where tissue is cut and removed from the body.

[0037] In the configuration illustrated in FIG. 2, the sheath 14 has been retracted proximally in direction 17a to define a gap 13 for receiving target tissue therein. Once the target tissue is located in the gap 13, as shown in FIG. 3, the sheath is advanced distally in direction 17b to grasp the target tissue between the distal end of the ultrasonic blade 12 and the outer rim 16 defined by the distal end 14d of the sheath 14.

[0038] In other embodiments, rather than the sheath 14 being movable relative to the blade 12 as described above, the ultrasonic blade 22 can be configured to move relative to the sheath 24 such that tissue positioned between the ultrasonic blade 22 and the distal end 24d of the sheath 24 is dissected therebetween. A movable ultrasonic blade 22 would require a movable ultrasonic transducer assembly that maintains close mechanical acoustic coupling between the transducer and the blade 22 through an ultrasonic waveguide.

[0039] FIGS. 4-8 depict a surgical cutting and coagulating instrument 20 for dissecting and coagulating tissue. In the illustrated embodiment, the instrument 20 includes an ultrasonic blade 22 coupled or formed integrally with an ultrasonic waveguide 25 positioned within an elongate sheath 24. The sheath 24 includes a distal end 24d and a proximal end 24p that is configured to couple to a handle that is configured to be grasped, manipulated and actuated by a clinician. The sheath 24 defines an aperture 21 in which ultrasonic blade 22 is exposed allowing the sheath 24 to translate proximally in direction 27a and distally in direction 27b. The elongate sheath 24 is configured to be movable relative to the ultrasonic blade 22 between a first position in which the ultrasonic blade 22 is positioned a distance from the distal end 24d of the elongate sheath 24 to define a gap 23 and a second position in which the sheath 24 moves proximally in direction 27a towards the ultrasonic blade 22 to grasp the target tissue located in the gap 23 such that the target tissue can dissected, treated, or evaluated by the ultrasonic blade 22. Once the target tissue is dissected, treated, or evaluated, the sheath 24 can be advanced distally in direction 27b to prepare the gap 23 for receiving more target tissue.

[0040] The size and shape of the distal end 24d of the sheath 24 determines the size and shape of the target tissue and the cavity created when the tissue is cut and removed. In one embodiment, the distal end 24d of the sheath 24 has a curved distal end with a substantially flat surface proximal of the curved distal end. For example, the distal end 24d of the sheath 24 can be in the form of an anvil and a pad. The distal end of the ultrasonic blade 22 is sized and shaped to correspond to the size and shape of the distal end 24d of the sheath 24 such that the movement of the sheath 24 proximally in direction 27a towards the ultrasonic blade 22 creates a scissor or guillotine action therebetween to cut the target tissue. The distal end of the ultrasonic blade 22 defines an outer rim 26 that corresponds to the shape of the distal end 24d of the sheath 24, which defines a cavity. The outer rim 26 defines a surface 28 at the distal end of the ultrasonic blade 22 such that, when tissue is dissected, the cavity defined by the distal end 24d of the sheath 24 is substantially the size and shape of the surface 28 of the distal end of the ultrasonic blade 22 is formed where the target tissue is cut and removed from the body of the patient.

[0041] FIG. 5 is a side view of the surgical instrument 20 of FIG. 4 showing the movable sheath 24 in a first position. The sheath 24 is in the process of moving distally in direction 27b to define the gap 23 for receiving the target tissue therein.

[0042] FIG. 6 is a cross-sectional side view of the surgical instrument 20 of FIG. 5. As shown, the sheath 24 is acoustically isolated from the ultrasonic waveguide 25 by resilient members 27, which are positioned at nodes along the length of the waveguide 25. The resilient isolation members 27 are located at the nodes to minimize or eliminate any acoustic coupling or vibratory transfer of energy from the waveguide 25 to the outer sheath 24. It will be appreciated that mechanical displacement at the nodes is minimized whereas mechanical displacement at the antinodes is maximized.

[0043] FIG. 7 is a side view of the surgical instrument 20 of FIG. 4 showing the movable sheath 24 in a second position. Once the target tissue is located in the gap 23, the sheath 24 is retracted proximally in direction 27a to grasp the target tissue between the surface 28 (FIGS. 4-6) of the ultrasonic blade 22 and the distal end 24d of the sheath 24.

[0044] As explained above, other instruments can be passed through the device for use during a surgical procedure. In one embodiment, a suction and/or irrigation device can be used in combination with the instructions

shown in FIGS. 1-8 such that the tissue that is dissected using an ultrasonic blade can be removed without the need to remove cutting and coagulating instrument. For example, a suction device can be positioned within the lumen of the sheath such that suction can occur in the space between the sheath and the ultrasonic blade. In one exemplary embodiment, a suction mechanism can be in the form of an elongate hollow tube positioned within either sheath 14, 24 and extending to the distal end thereof such that a distal end of the suction mechanism is configured to remove tissue dissected by the ultrasonic blade and the sheath. The suction mechanism can also include additional features to effect the area of tissue dissection and removal. For example, the suction mechanism can also include features such that the suction mechanism can irrigate an area located substantially around the tissue being dissected and removed by the blade and the sheath.

[0045] As explained above, the instruments 10, 20 shown in connection with FIGS. 1-8 can be coupled to a handle assembly to move the sheath 14, 24 relative to the ultrasonic blade 12, 22. As previously discussed, the instruments 10, 20 shown in connection with FIGS. 1-8 can be adapted and configured to move the ultrasonic blade 12, 22 relative to the sheath 14, 24. This configuration would require the ultrasonic transducer and the acoustic assembly to be movable rather than the sheath 14, 24.

[0046] The description now turns to FIG. 9, where a perspective view of the surgical instrument of FIGS. 4-8 coupled to a handle, plug, and generator is illustrated. In the illustrated embodiment, the ultrasonic surgical instrument 110 may be employed in various surgical procedures including endoscopic or traditional open surgical procedures. In one example embodiment, the ultrasonic surgical instrument 110 comprises a handle assembly 112, an elongated shaft assembly 114, an ultrasonic transducer 116, and an ultrasonic waveguide 25 comprising an ultrasonic blade 22 at a distal end thereof. The handle assembly 112 comprises a trigger assembly 124, a distal rotation assembly 113, and a switch assembly 128. The elongated shaft assembly 114 comprises an end effector 126. The end effector 126 is formed of the distal end 24d of the sheath 24, which comprises an aperture 21 configured to receive a reciprocating ultrasonic blade 22 therein to dissect tissue or mutually grasp, cut, and coagulate vessels and/or tissue in cooperation with the ultrasonic blade 22. The sheath 24 is mechanically coupled to actuating elements in the handle assembly 112 to actuate the sheath 24, for example, to translate the sheath 24 proximally towards the ultrasonic blade 22 to grasp tissue within the aperture 21 defined by the sheath 24 or to reciprocate the sheath 24 distally away from the ultrasonic blade 22 prepare the aperture 21 for grasping tissue. When the sheath 24 extended distally in direction 170b, a gap 23 (FIGS. 11 and 12) is defined to receive target tissue therein for further therapeutic or sub-therapeutic treatment by the ultrasonic blade 22. When the sheath 24 is retracted proximally in direction 170a, the target tissue is grasped between the ultrasonic blade 22 and the distal end 24d of the sheath 24.

[0047] The handle assembly 112 is adapted to receive the ultrasonic transducer 116 at the proximal end. The ultrasonic transducer 116 can be mechanically engaged to the elongated shaft assembly 114 and portions of the end effector 126. The ultrasonic transducer 116 can be electrically coupled to a generator 120 via a cable 122 and plug 119. In certain instances, the generator can be integrated with the handle assembly 112, for example. Although the majority of the drawings depict a multiple end effector 126 for use in connection with laparoscopic surgical procedures, the ultrasonic surgical instrument 110 may be employed in more traditional open surgical procedures and in other embodiments, may be configured for use in endoscopic procedures. For the purposes herein, the ultrasonic surgical instrument 110 is described in terms of an endoscopic instrument; however, it is contemplated that an open and/or laparoscopic version of the ultrasonic surgical instrument 110 also may include the same or similar operating components and features as described herein. In one example embodiment, the handle assembly 112 is formed from two (2) housing portions or shrouds comprising a first portion 112a and a second portion 112b. The first and second portions 112a and 112b (as well as the other components described below) may be assembled together in any fashion known in the art. For example, alignment pins, snap-like interfaces, tongue and groove interfaces, locking tabs, adhesive ports, may all be utilized either alone or in combination for assembly purposes.

[0048] [0001]In various embodiments, the generator 120 comprises several functional elements, such as modules and/or blocks. Different functional elements or modules may be configured for driving different kinds of surgical devices. For example, an ultrasonic generator module 121 may drive an ultrasonic device, such as the ultrasonic surgical instrument 110. In some example embodiments, the generator 120 also comprises an electrosurgery/RF generator module 123 for driving an electrosurgical device (or an electrosurgical embodiment of the ultrasonic surgical instrument 110). In the example embodiment illustrated in FIG. 9, the generator 120 includes a control system 125 integral with the generator 120, and a foot switch 129 connected to the generator via a cable 127. The generator 120 may also comprise a triggering mechanism for activating a surgical instrument, such as the instrument 110. The triggering mechanism may include a power switch (not shown) as well as a foot switch 129. When activated by the foot switch 129, the generator 120 may provide energy to drive the acoustic assembly of the surgical instrument 110 and to drive the end effector 118 at a predetermined excursion level. The generator 120 drives or excites the acoustic assembly at any suitable resonant frequency of the acoustic assembly and/or derives the therapeutic/sub-therapeutic electromagnetic/RF energy.

[0049] In one embodiment, the electrosurgical/RF generator module 123 may be implemented as an electrosurgery unit (ESU) capable of supplying power sufficient to perform bipolar electrosurgery using radio frequency (RF) energy. In one embodiment, the ESU can be a bipolar ERBE ICC 350 sold by ERBE USA, Inc. of Marietta, Ga. In bipolar electrosurgery applications, as previously discussed, a surgical instrument having an active electrode and a return electrode can be utilized, wherein the active electrode and the return electrode can be positioned against, or adjacent to, the tissue to be treated such that current can flow from the active electrode to the return electrode through the tissue. Accordingly, the electrosurgical/RF module 123 generator may be configured for therapeutic purposes by applying electrical energy to the tissue T sufficient for treating the tissue (e.g., cauterization).

[0050] In one embodiment, the electrosurgical/RF generator module 123 may be configured to deliver a sub-therapeutic RF signal to implement a tissue impedance measurement module. In one embodiment, the electrosurgical/RF generator module 123 comprises a bipolar radio frequency generator as described in more detail below. In one embodiment, the electrosurgical/RF generator module 112 may be configured to monitor electrical impedance Z, of tissue T and to control the characteristics of time and power level based on the tissue T by way of a return electrode provided on a clamp member of the end effector 126. Accordingly, the electrosurgical/RF generator module 123 may be configured for sub-therapeutic purposes for measuring the impedance or other electrical characteristics of the tissue T. Techniques and circuit configurations for measuring the impedance or other electrical characteristics of tissue T are discussed in more detail in commonly assigned U.S. Patent Publication No. 2011/0015631, titled "Electrosurgical Generator for Ultrasonic Surgical Instrument," the disclosure of which is herein incorporated by reference in its entirety.

[0051] A suitable ultrasonic generator module 121 may be configured to functionally operate in a manner similar to the GEN300 sold by Ethicon Endo-Surgery, Inc. of Cincinnati, Ohio as is disclosed in one or more of the following U.S. patents, all of which are incorporated by reference herein in their entireties: U.S. Patent No. 6,480,796 (METHOD FOR IMPROVING THE START UP OF AN ULTRASONIC SYSTEM UNDER ZERO LOAD CONDITIONS); U.S. Patent No. 6,537,291 (METHOD FOR DETECTING BLADE BREAKAGE USING RATE AND/OR IMPEDANCE INFORMATION); U.S. Patent No. 6,662,127 (METHOD FOR DETECTING PRESENCE OF A BLADE IN AN ULTRASONIC SYSTEM); U.S. Patent No. 6,977,495 (DETECTION CIRCUITRY FOR SURGICAL HANDPIECE SYSTEM); U.S. Patent No. 7,077,853 (METHOD FOR CALCULATING TRANSDUCER CAPACITANCE TO DETERMINE TRANSDUCER TEMPERATURE); U.S. Patent No. 7,179,271 (METHOD FOR DRIVING AN ULTRASONIC SYSTEM TO IMPROVE ACQUISITION OF BLADE RESONANCE FREQUENCY AT STARTUP); and U.S. Patent No. 7,273,483 (APPARATUS AND METHOD FOR ALERTING GENERATOR FUNCTION IN AN ULTRASONIC SURGICAL SYSTEM). Furthermore, U.S. Patent Application Publication No. 2014/0005702 A1, entitled ULTRASONIC SURGICAL INSTRUMENTS WITH DISTALLY POSITIONED TRANSDUCERS, and filed on June 29, 2012, is incorporated by reference herein in its entirety.

[0052] It will be appreciated that in various embodiments, the generator 120 may be configured to operate in several modes. In one mode, the generator 120 may be configured such that the ultrasonic generator module 121 and the electrosurgical/RF generator module 123 may be operated independently.

[0053] For example, the ultrasonic generator module 121 may be activated to apply ultrasonic energy to the end effector 126 and subsequently, either therapeutic sub-therapeutic RF energy may be applied to the ultrasonic blade 22 of the end effector 126 by the electrosurgical/RF generator module 123. As previously discussed, the sub-therapeutic electrosurgical/RF energy may be applied to tissue clamped between claim elements of the end effector 126 to measure tissue impedance to control the activation, or modify the activation, of the ultrasonic generator module 121. Tissue impedance feedback from the application of the sub-therapeutic energy also may be employed to activate a therapeutic level of the electrosurgical/RF generator module 123 to seal the tissue (e.g., vessel) clamped between claim elements of the end effector 126.

[0054] In another embodiment, the ultrasonic generator module 121 and the electrosurgical/RF generator module 123 may be activated simultaneously. In one example, the ultrasonic generator module 121 is simultaneously activated with a sub-therapeutic RF energy level to measure tissue impedance simultaneously while an ultrasonic blade 22, for example, of the end effector 126 cuts and coagulates tissue (or vessel) clamped in the aperture 21 defined between the ultrasonic blade 22 and the distal end 24d of the sheath 24. Such feedback may be employed, for example, to modify the drive output of the ultrasonic generator module 121. In another example, the ultrasonic generator module 121 may be driven simultaneously with electrosurgical/RF generator module 123 such that the ultrasonic blade 22 of the end effector 126 is employed for cutting the damaged tissue while the electrosurgical/RF energy is applied to electrode portions of the end effector 126 for sealing the tissue (or vessel).

[0055] When the generator 120 is activated via the triggering mechanism, electrical energy is continuously applied by the generator 120 to a transducer stack or assembly of the acoustic assembly. In another embodiment, electrical energy is intermittently applied (e.g., pulsed) by the generator 120. A phase-locked loop in the control system of the generator 120 may monitor feedback from the acoustic assembly. The phase lock loop

adjusts the frequency of the electrical energy sent by the generator 120 to match the resonant frequency of the selected longitudinal mode of vibration of the acoustic assembly. In addition, a second feedback loop in the control system 125 maintains the electrical current supplied to the acoustic assembly at a pre-selected constant level in order to achieve substantially constant excursion at the end effector 118 of the acoustic assembly. In yet another embodiment, a third feedback loop in the control system 125 monitors impedance between electrodes located in the end effector 126.

[0056] In ultrasonic operation mode, the electrical signal supplied to the acoustic assembly may cause the distal end of the end effector 118, to vibrate longitudinally in the range of, for example, approximately 20 kHz to 250 kHz. According to various embodiments, the ultrasonic blade 166 may vibrate in the range of about 54 kHz to 56 kHz, for example, at about 55.5 kHz. In other embodiments, the ultrasonic blade 22 may vibrate at other frequencies including, for example, about 31 kHz or about 80 kHz. The excursion of the vibrations at the ultrasonic blade 22 can be controlled by, for example, controlling the amplitude of the electrical signal applied to the transducer assembly of the acoustic assembly by the generator 120. As noted above, the triggering mechanism of the generator 120 allows a user to activate the generator 120 so that electrical energy may be continuously or intermittently supplied to the acoustic assembly. The generator 120 also has a power line for insertion in an electrosurgical unit or conventional electrical outlet. It is contemplated that the generator 120 can also be powered by a direct current (DC) source, such as a battery. The generator 120 can comprise any suitable generator, such as Model No. GEN04, and/or Model No. GEN11 available from Ethicon Endo-Surgery, Inc.

[0057] In various instances, when the acoustic assembly is energized, a vibratory motion standing wave is generated through the acoustic assembly. The amplitude of the vibratory motion at any point along the acoustic assembly depends on the location along the acoustic assembly at which the vibratory motion is measured. A minimum or zero crossing in the vibratory motion standing wave is generally referred to as a node (i.e., where motion is usually minimal), and an absolute value maximum or peak in the standing wave is generally referred to as an anti-node.

[0058] FIG. 10 is a side view of the surgical instrument 110 of FIG. 9 showing the handle assembly 112, the distal rotation assembly 113, the elongated shaft assembly 114, and the end effector 126 showing the aperture 21 formed in the sheath 24, the ultrasonic waveguide 25, the ultrasonic blade 22, and the distal end 24d of the sheath 24. In the illustrated embodiment, the end effector 126 is located at a distal end of the elongated shaft assembly 114. A proximal end 150 of the elongated shaft assembly 114 mechanically engages the handle assembly 112 and the distal rotation assembly 113. The proximal end 150 of the elongated shaft assembly 114 is received within the handle assembly 112 and the distal rotation assembly 113.

[0059] In the illustrated embodiment, the trigger assembly 124 comprises a trigger 132 that operates in conjunction with a fixed handle 134. The fixed handle 134 and the trigger 132 are ergonomically formed and adapted to interface comfortably with the user. The fixed handle 134 is integrally associated with the handle assembly 112. The trigger 132 is pivotally movable relative to the fixed handle 134 as explained in more detail below with respect to the operation of the ultrasonic surgical instrument 110. The trigger 132 is pivotally movable in direction 133a toward the fixed handle 134 when the user applies a squeezing force against the trigger 132. A spring element 186 (FIGS. 11-13) may cause the trigger 132 to pivotally move in direction 133b when the user releases the squeezing force against the trigger 132.

[0060] In one example embodiment, the trigger 132 comprises an elongated trigger hook 136, which defines an aperture 138 between the elongated trigger hook 136 and the trigger 132. The aperture 138 is suitably sized to receive one or multiple fingers of the user therethrough. The trigger 132 also may comprise a resilient portion molded over the trigger substrate. The overmolded resilient portion 133a is formed to provide a more comfortable contact surface for control of the trigger 132 in outward direction 133b. In one example embodiment, the overmolded resilient portion may be provided over a portion of the elongated trigger hook 136. The proximal surface of the elongated trigger hook 136 remains uncoated or coated with a non-resilient substrate to enable the user to easily slide their fingers in and out of the aperture 138. In another embodiment, the geometry of the trigger 132 forms a loop which defines an aperture 138 suitably sized to receive one or multiple fingers of the user therethrough. A fully closed loop trigger also may comprise a resilient portion molded over the trigger substrate.

[0061] In one example embodiment, the fixed handle 134 comprises a proximal contact surface 140 and a grip anchor or saddle surface 142. The saddle surface 142 rests on the web where the thumb and the index finger are joined on the hand. The proximal contact surface 140 has a pistol grip contour that receives the palm of the hand in a normal pistol grip with no rings or apertures. The profile curve of the proximal contact surface 140 may be contoured to accommodate or receive the palm of the hand. A stabilization tail 144 is located towards a more proximal portion of the handle assembly 112. The stabilization tail 144 may be in contact with the uppermost web portion of the hand located between the thumb and the index finger to stabilize the handle assembly 112 and make the handle assembly 112 more controllable.

[0062] In one example embodiment, the switch assembly 128 may comprise a toggle switch 130. The toggle switch 130 may be implemented as a single component with a central pivot 131 (FIGS. 11-13) located within inside the handle assembly 112 to eliminate the possibility of simultaneous activation. In one example embodiment,

the toggle switch 130 comprises a first projecting knob 130a (top) and a second projecting knob 130b (bottom) to set the power setting of the ultrasonic transducer 116 between a minimum power level (e.g., MIN) and a maximum power level (e.g., MAX). In another embodiment, the rocker switch may pivot between a standard setting and a special setting. The special setting may allow one or more special programs to be implemented by the device. The toggle switch 130 rotates about the central pivot as the first projecting knob 130a and the second projecting knob 130b are actuated. The one or more projecting knobs 130a, 130b are coupled to one or more arms that move through a small arc and cause electrical contacts to close or open an electric circuit to electrically energize or deenergize the ultrasonic transducer 16 in accordance with the activation of the first or second projecting knob 130bs. The toggle switch 130 is coupled to the generator 120 (FIG. 9) to control the activation of the ultrasonic transducer 116. The toggle switch 130 comprises one or more electrical power setting switches to activate the ultrasonic transducer 116 to set one or more power settings for the ultrasonic transducer 116. The forces required to activate the toggle switch 130 are directed substantially toward the saddle point 142, thus avoiding any tendency of the instrument to rotate in the hand when the toggle switch 130 is activated.

[0063] In one example embodiment, the first and second projecting knobs 130a, 130b are located on the distal end of the handle assembly 112 such that they can be easily accessible by the user to activate the power with minimal, or substantially no, repositioning of the hand grip, making it suitable to maintain control and keep attention focused on the surgical site (e.g., a monitor in a laparoscopic procedure) while activating the toggle switch 130. The projecting knobs 130a, 130b may be configured to wrap around the side of the handle assembly 112 to some extent to be more easily accessible by variable finger lengths and to allow greater freedom of access to activation in awkward positions or for shorter fingers.

[0064] In the illustrated embodiment, the first projecting knob 130a comprises a plurality of tactile elements, e.g., textured projections or "bumps" in the illustrated embodiment, to allow the user to differentiate the first projecting knob 130a from the second projecting knob 130b. It will be appreciated by those skilled in the art that several ergonomic features may be incorporated into the handle assembly 112. Such ergonomic features are described in U.S. Pat. App. Pub. No. 2009/0105750 entitled "Ergonomic Surgical Instruments" which is incorporated by reference herein in its entirety.

[0065] In one example embodiment, the toggle switch 130 may be operated by the hand of the user. The user may easily access the first and second projecting knob 130bs at any point while also avoiding inadvertent or unintentional activation at any time. The toggle switch 130 may readily operated with a finger to control the power to the ultrasonic assembly 16 and/or to the ultrasonic assembly 116. For example, the index finger may be employed to activate the first contact portion to turn on the ultrasonic assembly 116 to a maximum (MAX) power level. The index finger may be employed to activate the second contact portion to turn on the ultrasonic assembly 116 to a minimum (MIN) power level. In another embodiment, the rocker switch may pivot the instrument 110 between a standard setting and a special setting. The special setting may allow one or more special programs to be implemented by the instrument 110. The toggle switch 130 may be operated without the user having to look at the first or second projecting knob 130a, 130b. For example, the first projecting knob 130a or the second projecting knob 130b may comprise a texture or projections to tactilely differentiate between the first and second projecting knobs 130a, 130b without looking.

[0066] In one example embodiment, the distal rotation assembly 113 is rotatable without limitation in either direction about a longitudinal axis "T." The distal rotation assembly 113 is mechanically engaged to the elongated shaft assembly 114. The distal rotation assembly 113 is located on a distal end of the handle assembly 112. The distal rotation assembly 113 comprises a cylindrical hub 146 and a rotation knob 148 formed over the hub 146. The hub 146 mechanically engages the elongated shaft assembly 114. The rotation knob 148 may comprise fluted polymeric features and may be engaged by a finger (e.g., an index finger) to rotate the elongated shaft assembly 114. The hub 146 may comprise a material molded over the primary structure to form the rotation knob 148. The rotation knob 148 may be overmolded over the hub 146. The hub 146 comprises an end cap portion that is exposed at the distal end. The end cap portion of the hub 146 may contact the surface of a trocar during laparoscopic procedures. The hub 146 may be formed of a hard durable plastic such as polycarbonate to alleviate any friction that may occur between the end cap portion and the trocar. The rotation knob 148 may comprise "scallops" or flutes formed of raised ribs and concave portions located between the ribs to provide a more precise rotational grip. In one example embodiment, the rotation knob 148 may comprise a plurality of flutes (e.g., three or more flutes). In other embodiments, any suitable number of flutes may be employed. The rotation knob 148 may be formed of a softer polymeric material overmolded onto the hard plastic material. For example, the rotation knob 148 may be formed of pliable, resilient, flexible polymeric materials including Versaflex® TPE alloys made by GLS Corporation, for example. This softer overmolded material may provide a greater grip and more precise control of the movement of the rotation knob 148. It will be appreciated that any materials that provide adequate resistance to sterilization, are biocompatible, and provide adequate frictional resistance to surgical gloves may be employed to form the rotation knob 148. The rotation knob 148 is coupled to the shaft assembly 114 and is able to rotate the shaft assembly clockwise or counterclockwise up to an including 360 degrees.

[0067] Referring to FIGS. 9-10, the elongated shaft assembly 114 comprises a proximal end 150 adapted to mechanically engage the handle assembly 112 and the distal rotation assembly 113, and a distal end 152 adapted to mechanically engage the end effector 126. The elongated shaft assembly 114 comprises an outer tubular sheath 24 which is mechanically coupled to the trigger 132 to reciprocate the outer tubular sheath 24. A proximal end of the ultrasonic blade 22 is acoustically coupled to an ultrasonic waveguide, which is acoustically coupled to the ultrasonic transducer 116. The outer sheath 24 is mechanically coupled to the trigger 132 of the handle assembly 112 through a yoke 170 (FIG. 11) and linkage (172 (FIG. 11) to move the sheath 24 in either direction 170a or 170b in response to the actuation and/or release of the trigger 132 in direction 133b or 133a, respectively. The pivotably moveable trigger 132 may generate reciprocating motion of the outer sheath 24 along the longitudinal axis "T." Such motion may be used, for example, to clamp, grip, or grasp tissue located within of the gap 23 defined between the distal end 24d of the sheath 24 and the distal end of the ultrasonic blade 22. A linkage 172 (FIG. 11) translates the pivotal rotation of the trigger 132 to axial movement of a yoke 170 (FIG. 11) coupled to an actuation mechanism, which controls the reciprocation of the outer sheath 24 relative to the ultrasonic blade 22 in the end effector 126.

[0068] In one example embodiment, the ultrasonically actuatable blade 22 is acoustically coupled to the ultrasonic transducer 116. The trigger 132 on the handle assembly 112 is ultimately connected to a drive assembly, which together, mechanically cooperate to effect movement of the outer sheath 24. Squeezing the trigger 132 in direction 133a moves the outer sheath 24 proximally in direction 170a from an open position to a closed position to grasp tissue located in the gap 23 between the distal end of the ultrasonic blade 22 and the distal end 24d of the sheath 24. Releasing the trigger 132 in direction 133b moves the outer sheath 24 distally in direction 170b from a closed position to an open position, wherein the ultrasonic blade 22 and the distal portion 24d are disposed in a spaced relation relative to one another.

[0069] The proximal portion of the handle assembly 112 comprises a proximal opening 168 to receive the distal end of the ultrasonic assembly 116. The ultrasonic assembly 116 is inserted in the proximal opening 168 and is mechanically engaged to the elongated shaft assembly 114.

[0070] FIG. 11 is cross-sectional side view of the surgical instrument 110 of FIG. 10. The trigger 132 pivotally moves about pivot 188 (FIG. 12) between the first and second portions 112a, 112b (FIG. 9) of the handle assembly 112. The trigger 132 is mechanically coupled to a linkage 172, which is coupled to a yoke 170 to convert pivotal motion of the trigger 132 to axial motion of the yoke 170. The yoke 170 is operably coupled to a drive member 190. The drive member 190 is connected to the outer sheath 24. As the trigger 132 is squeezed, the trigger 132 moves in direction 133a towards the fixed handle 134 portion and pivots about the pivot point 188 (FIGS. 12 and 13) and the linkage 172 drives the yoke 170 axially in a proximal direction 170a to retract the sheath 24 and close the gap 23 between the blade 22 and the distal end 24d of the sheath 24 to grasp target tissue therebetween. As the yoke 170 is driven proximally, the yoke 170 compresses a return spring 186. When the trigger 132 is released, the return spring 186 returns the trigger 132 to its initial position in direction 133b and drives the yoke 170 axially in a distal direction 170b to advance the sheath 24 distally and open the gap 23 between the blade 22 and the distal end 24d of the sheath 24 to receive target tissue therebetween.

[0071] In the embodiment illustrated in FIG. 11, a cross-sectional view of the ultrasonic transducer 116 is shown within a partial cutaway view of the handle assembly 112. One example embodiment of the ultrasonic surgical instrument 110 comprises the ultrasonic signal generator 120 (FIG. 9) coupled to the ultrasonic transducer 116, comprising a hand piece housing 112b, and an ultrasonically actuatable single or multiple element end effector 126. As previously discussed, the end effector 126 comprises an ultrasonically actuatable blade 22. The ultrasonic transducer 116, which is known as a "Langevin stack," generally includes a transduction portion, a first resonator portion or end-bell 178, and a second resonator portion or fore-bell 176, and ancillary components. The total construction of these components is a resonator. The ultrasonic transducer 116 is preferably an integral number of one-half system wavelengths ($n\lambda/2$; where "n" is any positive integer; *e.g.,* n = 1, 2, 3...) in length. An acoustic assembly includes the ultrasonic transducer 116, a nose cone, a velocity transformer, and a surface.

[0072] In one example embodiment, the distal end of the end-bell 178 is connected to the proximal end of the transduction portion, and the proximal end of the fore-bell 176 is connected to the distal end of the transduction portion. The fore-bell 176 and the end-bell 178 have a length determined by a number of variables, including the thickness of the transduction portion, the density and modulus of elasticity of the material used to manufacture the end-bell 178 and the fore-bell 176, and the resonant frequency of the ultrasonic transducer 116. The fore-bell 176 may be tapered inwardly from its proximal end to its distal end to amplify the ultrasonic vibration amplitude as the velocity transformer, or alternately may have no amplification. A suitable vibrational frequency range may be about 20Hz to 32kHz and a well-suited vibrational frequency range may be about 30-10kHz. A suitable operational vibrational frequency may be approximately 55.5kHz, for example.

[0073] In one example embodiment, the piezoelectric elements 174 may be fabricated from any suitable material, such as, for example, lead zirconate-titanate, lead meta-niobate, lead titanate, barium titanate, or other piezoelectric ceramic material. An electrical coupling 180

includes positive and negative electrodes electrically coupled to the piezoelectric elements 174. The piezoelectric elements include a bore extending through the center. The positive and negative electrodes are electrically coupled to wires coupled to the piezoelectric elements 174. The wires are encased within the cable 122 and electrically connectable to the ultrasonic signal generator 120 (FIG. 9).

[0074] The ultrasonic transducer 116 of the acoustic assembly converts the electrical signal from the ultrasonic signal generator 120 into mechanical energy that results in primarily a standing acoustic wave of longitudinal vibratory motion of the ultrasonic transducer 116 and the ultrasonic blade 22 portion of the end effector 126 at ultrasonic frequencies. In another embodiment, the vibratory motion of the ultrasonic transducer 116 may act in a different direction. For example, the vibratory motion may comprise a local longitudinal component of a more complicated motion of the tip of the elongated shaft assembly 114. A suitable generator is available as model number GEN11, from Ethicon Endo-Surgery, Inc., Cincinnati, Ohio. When the acoustic assembly 106 is energized, a vibratory motion standing wave is generated through the acoustic assembly. The ultrasonic surgical instrument 110 is designed to operate at a resonance such that an acoustic standing wave pattern of predetermined amplitude is produced. The amplitude of the vibratory motion at any point along the acoustic assembly 106 depends upon the location along the acoustic assembly at which the vibratory motion is measured. A minimum or zero crossing in the vibratory motion standing wave is generally referred to as a node (*i.e.,* where motion is minimal), and a local absolute value maximum or peak in the standing wave is generally referred to as an antinode (*e.g.*, where local motion is maximal). The distance between an anti-node and its nearest node is one-quarter wavelength ($\lambda/4$).

[0075] The wires transmit an electrical signal from the ultrasonic signal generator 120 (FIG. 9) to the positive and negative electrodes. The piezoelectric elements 174 are energized by the electrical signal supplied from the ultrasonic signal generator 120 in response to an actuator, such as a foot switch, for example, to produce an acoustic standing wave in the acoustic assembly. The electrical signal causes disturbances in the piezoelectric elements 174 in the form of repeated small displacements resulting in large alternating compression and tension forces within the material. The repeated small displacements cause the piezoelectric elements 174 to expand and contract in a continuous manner along the axis of the voltage gradient, producing longitudinal waves of ultrasonic energy. The ultrasonic energy is transmitted through the acoustic assembly to the ultrasonic blade 22 portion of the end effector 126 via a transmission component or an ultrasonic transmission waveguide 25 of the elongated shaft assembly 114.

[0076] In one example embodiment, in order for the acoustic assembly to deliver energy to the ultrasonic blade 22 portion of the end effector 126, all components of the acoustic assembly must be acoustically coupled to the blade 22. The distal end of the ultrasonic transducer 116 may be acoustically coupled at the surface to the proximal end of the ultrasonic transmission waveguide 25 by a threaded connection such as a stud 182 to the fore-bell 176.

[0077] In one example embodiment, the components of the acoustic assembly are preferably acoustically tuned such that the length of any assembly is an integral number of one-half wavelengths ($n\lambda/2$), where the wavelength λ is the wavelength of a pre-selected or operating longitudinal vibration drive frequency f_d of the acoustic assembly. It is also contemplated that the acoustic assembly may incorporate any suitable arrangement of acoustic elements.

[0078] In one example embodiment, the ultrasonic blade 22 may have a length substantially equal to an integral multiple of one-half system wavelengths ($n\lambda/2$). A distal end of the blade 22 may be disposed near an antinode in order to provide the maximum longitudinal excursion of the distal end. When the transducer assembly is energized, the distal end of the blade 22 may be configured to move in the range of, for example, approximately 10 to 500 microns peak-to-peak, and preferably in the range of about 30 to 64 microns at a predetermined vibrational frequency of 55kHz, for example.

[0079] In one example embodiment, the ultrasonic blade 22 may be coupled to the ultrasonic transmission waveguide 25. The blade 22 and the ultrasonic transmission waveguide 25 as illustrated are formed as a single unit construction from a material suitable for transmission of ultrasonic energy. Examples of such materials include Ti6A14V (an alloy of Titanium including Aluminum and Vanadium), Aluminum, Stainless Steel, or other suitable materials. Alternately, the blade 22 may be separable (and of differing composition) from the ultrasonic transmission waveguide 25, and coupled by, for example, a stud, weld, glue, quick connect, or other suitable known methods. The length of the ultrasonic transmission waveguide 25 may be substantially equal to an integral number of one-half wavelengths ($n\lambda/2$), for example. The ultrasonic transmission waveguide 25 may be preferably fabricated from a solid core shaft constructed out of material suitable to propagate ultrasonic energy efficiently, such as the titanium alloy discussed above (*i.e.,* Ti6A14V) or any suitable aluminum alloy, or other alloys, for example.

[0080] The switch assembly 128 comprises a toggle switch 130 that is pivotally movable about pivot 131. The toggle switch 130 may be implemented as a single component with a central pivot 131 located within inside the handle assembly 112 to eliminate the possibility of simultaneous activation. In one example embodiment, the toggle switch 130 comprises a first projecting knob 130a (top) and a second projecting knob 130b (bottom) to set the power setting of the ultrasonic transducer 116 between a minimum power level (e.g., MIN) and a maximum

power level (e.g., MAX). In another embodiment, the rocker switch may pivot about pivot 131 between a standard setting and a special setting.

[0081] FIG. 12 is a cross-sectional side view of the surgical instrument 110 of FIG. 11 coupled to a handle assembly 112 with a movable sheath 24 in a first position. As shown in FIG. 12, the trigger 132 is located in a first position such that the sheath 24 is in a distally extended position in direction 170b to define a gap 23 between the distal end 24d of the sheath 24 and the ultrasonic blade 22. In this configuration, target tissue can be positioned in the gap 23 for further therapeutic or sub-therapeutic treatment. Once the target tissue is positioned in the gap 23, the trigger 132 can be squeezed to clamp or grasp the target tissue between the distal end 24d of the sheath 24 and the distal end of the ultrasonic blade 22.

[0082] FIG. 13 is a cross-sectional side view of the surgical instrument 110 of FIG. 12 with a movable sheath 24 in a second position. As shown in FIG. 12, the trigger 132 is located in a second position such that the sheath 24 is in a proximally extended position in direction 170a to eliminate the gap 23 between the distal end 24d of the sheath 24 and the ultrasonic blade 22. In this configuration, target tissue positioned in the gap 23 is grasped for further therapeutic or sub-therapeutic treatment. Once the target tissue is positioned in the gap 23, the trigger 132 is squeezed to clamp or grasp the target tissue between the distal end 24d of the sheath 24 and the distal end of the ultrasonic blade 22.

[0083] FIG. 14 is a cross-sectional side view of a surgical instrument 200 having an ultrasonic blade 22 positioned within a movable sheath 24, a suction tube 206, and a pad 204 positioned on a distal end of the movable sheath 24, according to one embodiment. The suction tube 206 is fluidically coupled to a vacuum source and serves to suction target tissue 202 debris after the ultrasonic blade 22 cuts the target tissue 202. A pad 204 is positioned on a distal end 24d of the sheath 24 facing the surface 28 of the ultrasonic blade 22. The target tissue 202 is grasped between the pad 204 and the surface 28 of the ultrasonic blade 22. The pad 204 can be a non-stick polymeric pad made of Teflon, for example, and provides a surface upon which pressure can be applied while the ultrasonic blade 22 is activated to achieve better performance when cutting and coagulating the target tissue 202.

[0084] FIG. 15 is a side view of a surgical instrument 300 comprising an opening 306 defined between the blade 312/ultrasonic waveguide 315 and the outer tube 314, where in one embodiment the opening 306 is configured to couple to a suction and/or irrigation source at the handle end 304. FIG. 16 is a sectional view taken along section line 16--16 of the distal end of the instrument shown in FIG. 15, according to one embodiment. FIG. 16 illustrates a section portion of the ultrasonic waveguide 315 (or blade 312) located within the outer sheath 314 defining an opening 306 for the tissue 323 to travel through. FIGS. 15 and 16 show the blade 312/waveguide 315 with a linear longitudinal cavity 306 from a gap 313 for tissue 323 engagement distally to the proximally located suction/irrigation in order to remove the transected tissue 323. The illustrated embodiment comprises a "half moon" profile located above the blade 312/waveguide 315 at 12 o'clock and fluidically coupled to a suction and/or irrigation source at the handle end 304.

[0085] The illustration in FIG. 15 shows a distal end 302 and a proximal "handle" end of the 304 instrument 300. In the illustrated embodiment, the distal end 302 of the instrument 300 includes an ultrasonic blade 312 positioned within an elongate sheath 314. The sheath 314 includes a distal end 314d and a proximal end (not shown) that is configured to couple to a handle that is configured to be grasped, manipulated and actuated by a clinician. The sheath 314 is movable relative to the ultrasonic blade 312 between a first proximal position in which the sheath 314 is positioned over a proximal portion of the blade 312 and a second position in which the sheath 314 moves distally in direction 317b such that tissue 323 positioned in the gap 313 between the blade 312 and the distal end 314d of the sheath 314 is dissected therebetween. Once the tissue 313 is dissected, the sheath 314 is retracted proximally in direction 317a.

[0086] The opening 306 is defined between the blade 312/ultrasonic waveguide 315 and is configured to receive the tissue 323 after dissection. The blade 312 and the ultrasonic waveguide 315 are configured such that the opening 306 (e.g., "trough" or "channel") defined between the blade 312/waveguide 315 and the sheath 314 is configured for the tissue 323 to travel from the distal end 302 to the proximal end 304 of the instrument 300. The proximal end 304 comprises a first seal disposed at the handle to encompass the outer sheath 314 with an outer tube 324, and a second seal between the waveguide 315 and the outer sheath 314 such that the tissue 323 will travel through the opening 306 in the waveguide 315 and out of an opening 318 defined in the outer sheath 314.

[0087] The first seal comprises first and second mechanical gaskets 308, 310 and the second seal comprises a third mechanical gasket 316. The mechanical gaskets 308, 310, 316 may be resilient O-ring types of seals, also known as a packing, or a toric joint, and may be any mechanical gasket in the shape of a torus or loop of elastomer with a round cross-section, designed to be seated in a groove and compressed during assembly between two or more parts, creating a seal at the interface. A tube 322 is located between the first seal and is in fluid communication with the opening 318 defined in the outer sheath 314. Accordingly, the opening 306 is in fluid communication with the tube 322 such when a suction 320 is applied by a vacuum source, the dissected tissue 323 is sucked through the opening 306 and out of the tube 322 to the vacuum source.

[0088] The vacuum source is in fluid is provided in most modern hospitals and is available from wall outlets locat-

ed throughout the building. Other sources of vacuum may include electric pumps, gas-powered venturi suction units, and mechanical devices, such as hand pumps and wound drainage systems, for example. The major source of vacuum in hospitals is a pump in the basement of the building. By emptying a receiver or reservoir tank, the pump creates a vacuum that can be delivered through connecting pipes to wall outlets in patient care areas and hospital departments. When the vacuum pressure falls to a predetermined level, a switch engages the pump to restore vacuum pressure; when the vacuum builds back up, the switch disengages and no further vacuum is created. Generally the pump is set to begin operation when the vacuum level of the system drops to 19 inHg (483 mmHg) and ceases operation when the level reaches 25 inHg (635 mmHg). In most hospitals, a duplex pump system is used for safety; each pump is capable of maintaining minimum vacuum levels. A duplex system allows for periodic shut-down of each pump for service and repairs and also provides a backup source for negative pressure, should one of the pumps fail to operate properly.

[0089] Although the various embodiments of the devices have been described herein in connection with certain disclosed embodiments, many modifications and variations to those embodiments may be implemented. Also, where materials are disclosed for certain components, other materials may be used. Furthermore, according to various embodiments, a single component may be replaced by multiple components, and multiple components may be replaced by a single component, to perform a given function or functions. The foregoing description and following claims are intended to cover all such modification and variations.

[0090] 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.

[0091] 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.

[0092] 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.

[0093] 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.

[0094] Embodiments of the invention:

1. An apparatus for dissection and coagulation of tissue, comprising:

    an ultrasonic blade configured to dissect and seal tissue and having a proximal end and distal end, the distal end of the ultrasonic blade comprising a surface proximal of the distal end to engage tissue; and
    an elongate sheath configured to extend over the ultrasonic blade and being movable relative to the ultrasonic blade between a first position in which the elongate sheath is positioned over a proximal portion of the ultrasonic blade and a second position in which the elongate sheath moves distally towards the surface of the distal end of the ultrasonic blade such that tissue can be dissected therebetween.

2. The apparatus of embodiment 1, wherein a distal end of the elongate sheath is sized and shaped to correspond to the size and shape of the surface of the distal end of the ultrasonic blade.

3. The apparatus of embodiment 2, wherein the

shape of the distal end of the ultrasonic blade and the distal end of the elongate sheath define a cavity at the location of the dissected tissue.

4. The apparatus of embodiment 1, wherein the proximal end of the ultrasonic blade communicates with an excitation mechanism to deliver mechanical energy at at least one ultrasonic frequency to the distal end of the ultrasonic blade.

5. The apparatus of embodiment 1, wherein a proximal end of the elongate sheath is configured to couple to an actuator to move the sheath between the first and second positions.

6. The apparatus of embodiment 1, further comprising a suction mechanism in the form of an elongate hollow tube positioned within the sheath and extending to the distal end thereof such that a distal end of the suction mechanism is configured to remove tissue dissected by the ultrasonic blade and the sheath.

7. The apparatus of embodiment 6, wherein the suction mechanism is configured to irrigate an area located substantially around the tissue being dissected and removed.

8. The apparatus of embodiment 6, wherein the distal end of the suction mechanism is positioned between the distal end of the sheath and the distal end of the ultrasonic blade.

9. An apparatus for dissection and coagulation of tissue, comprising:

an elongate sheath having a proximal end and distal end, the distal end of the elongate sheath comprises a substantially flat surface proximal of the distal end to form an anvil; and
an ultrasonic blade configured to dissect and seal tissue and being positioned within the elongate sheath, the ultrasonic blade being movable relative to the elongate sheath between a first position in which the ultrasonic blade is positioned a distance from the distal end of the elongate sheath and a second position in which the sheath moves proximally towards the distal end of the ultrasonic blade such that tissue can be dissected therebetween.

10. The apparatus of embodiment 9, wherein a distal end of the ultrasonic blade is sized and shaped to correspond to the size and shape of the surface of the distal end of the elongate sheath forming the anvil.

11. The apparatus of embodiment 10, wherein the shape of the distal end of the ultrasonic blade and the distal end of the elongate sheath create a cavity at the location of the dissected tissue.

12. The apparatus of embodiment 9, wherein a proximal end of the ultrasonic blade communicates with a excitation mechanism to deliver energy to the distal end of the ultrasonic blade.

13. The apparatus of embodiment 9, wherein a proximal end of the ultrasonic blade is configured to couple to an actuator to move the blade between the first and second positions.

14. The apparatus of embodiment 9, further comprising a suction mechanism in the form of an elongate hollow tube positioned within the sheath and extending to the distal end thereof such that a distal end of the suction mechanism is configured to remove tissue dissected by the ultrasonic blade and the sheath.

15. The apparatus of embodiment 14, wherein the suction mechanism is configured to irrigate an area located substantially around the tissue being dissected and removed.

16. The apparatus of embodiment 14, wherein the distal end of the suction mechanism is positioned between the distal end of the sheath and the distal end of the ultrasonic blade.

17. An apparatus for dissection and coagulation of tissue, comprising:

an ultrasonic blade;
an elongate sheath defining an aperture, wherein the ultrasonic blade is positioned within the aperture, the elongate sheath being movable distally relative to the ultrasonic blade between a first position defining a gap between a distal end of the sheath and the ultrasonic blade to receive target tissue in the gap, and a second position in which the elongate sheath is movable proximally towards the ultrasonic blade to grasp the target tissue therebetween; and
a handle assembly mechanically coupled to the sheath to apply axial motion to the sheath.

18. The apparatus of emboidment 17, wherein the ultrasonic blade comprises a curved surface for engaging the target tissue.

19. The apparatus of embodiment 17, wherein a distal end of the ultrasonic blade extends distally beyond a distal end of the sheath.

20. The apparatus of embodiment 17, wherein a distal end of the sheath extends distally beyond a distal

end of the ultrasonic blade.

Claims

1. An apparatus for dissection and coagulation of tissue, comprising:

   an elongate sheath having a proximal end and distal end, the distal end of the elongate sheath comprises a substantially flat surface proximal of the distal end to form an anvil; and
   an ultrasonic blade configured to dissect and seal tissue and being positioned within the elongate sheath, the ultrasonic blade being movable relative to the elongate sheath between a first position in which the ultrasonic blade is positioned a distance from the distal end of the elongate sheath and a second position in which the sheath moves proximally towards the distal end of the ultrasonic blade such that tissue can be dissected therebetween.

2. The apparatus of claim 1, wherein a distal end of the ultrasonic blade is sized and shaped to correspond to the size and shape of the surface of the distal end of the elongate sheath forming the anvil.

3. The apparatus of claim 2, wherein the shape of the distal end of the ultrasonic blade and the distal end of the elongate sheath create a cavity at the location of the dissected tissue.

4. The apparatus of claim 1, wherein a proximal end of the ultrasonic blade communicates with a excitation mechanism to deliver energy to the distal end of the ultrasonic blade.

5. The apparatus of claim 1, wherein a proximal end of the ultrasonic blade is configured to couple to an actuator to move the blade between the first and second positions.

6. The apparatus of claim 1, further comprising a suction mechanism in the form of an elongate hollow tube positioned within the sheath and extending to the distal end thereof such that a distal end of the suction mechanism is configured to remove tissue dissected by the ultrasonic blade and the sheath.

7. The apparatus of claim 6, wherein the suction mechanism is configured to irrigate an area located substantially around the tissue being dissected and removed.

8. The apparatus of claim 6, wherein the distal end of the suction mechanism is positioned between the distal end of the sheath and the distal end of the ultrasonic blade.

9. An apparatus for dissection and coagulation of tissue, comprising:

   an ultrasonic blade;
   an elongate sheath defining an aperture, wherein the ultrasonic blade is positioned within the aperture, the elongate sheath being movable distally relative to the ultrasonic blade between a first position defining a gap between a distal end of the sheath and the ultrasonic blade to receive target tissue in the gap, and a second position in which the elongate sheath is movable proximally towards the ultrasonic blade to grasp the target tissue therebetween; and
   a handle assembly mechanically coupled to the sheath to apply axial motion to the sheath.

10. The apparatus of claim 9, wherein the ultrasonic blade comprises a curved surface for engaging the target tissue.

11. The apparatus of claim 9, wherein a distal end of the ultrasonic blade extends distally beyond a distal end of the sheath.

12. The apparatus of claim 9, wherein a distal end of the sheath extends distally beyond a distal end of the ultrasonic blade.

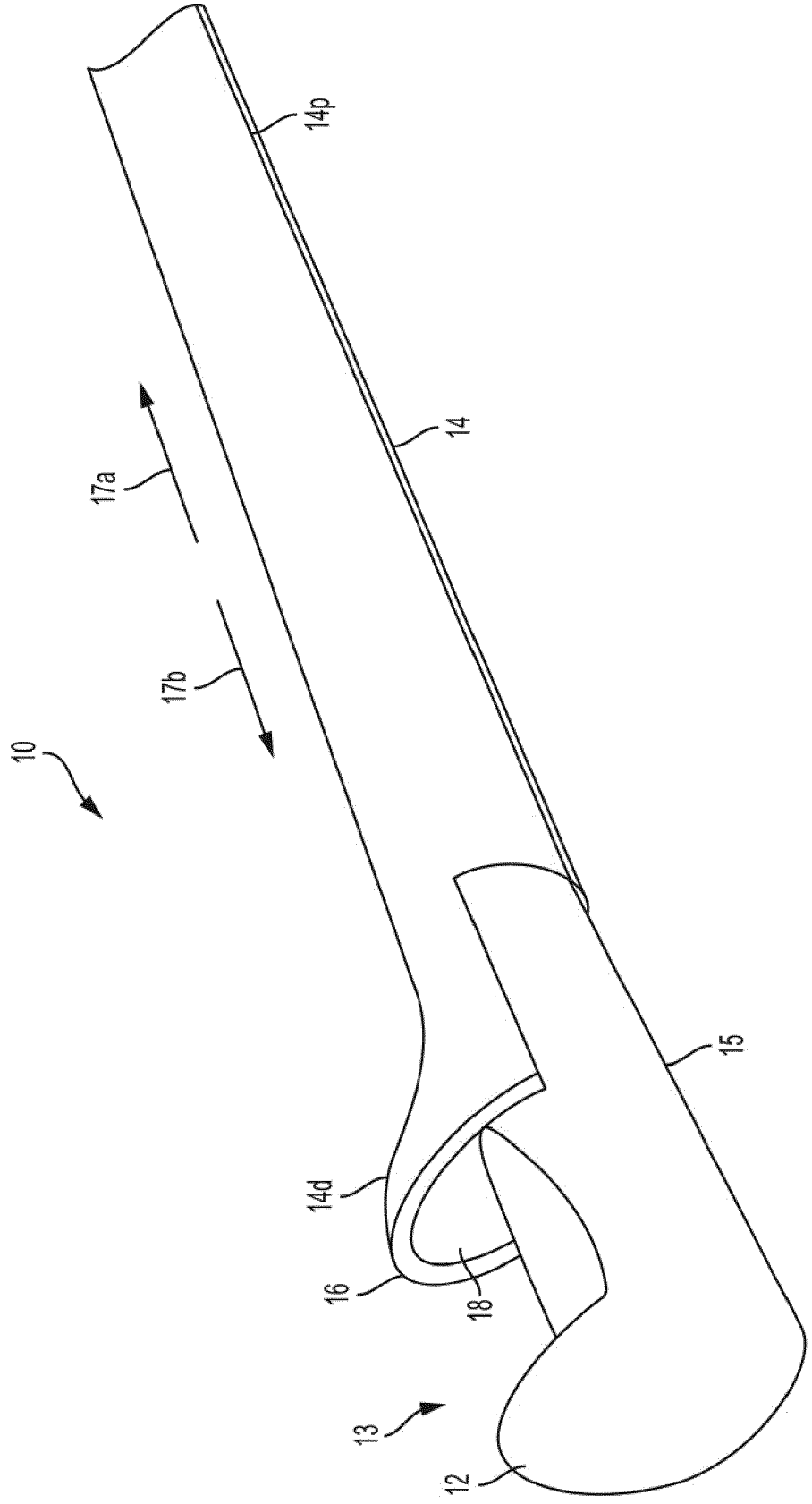
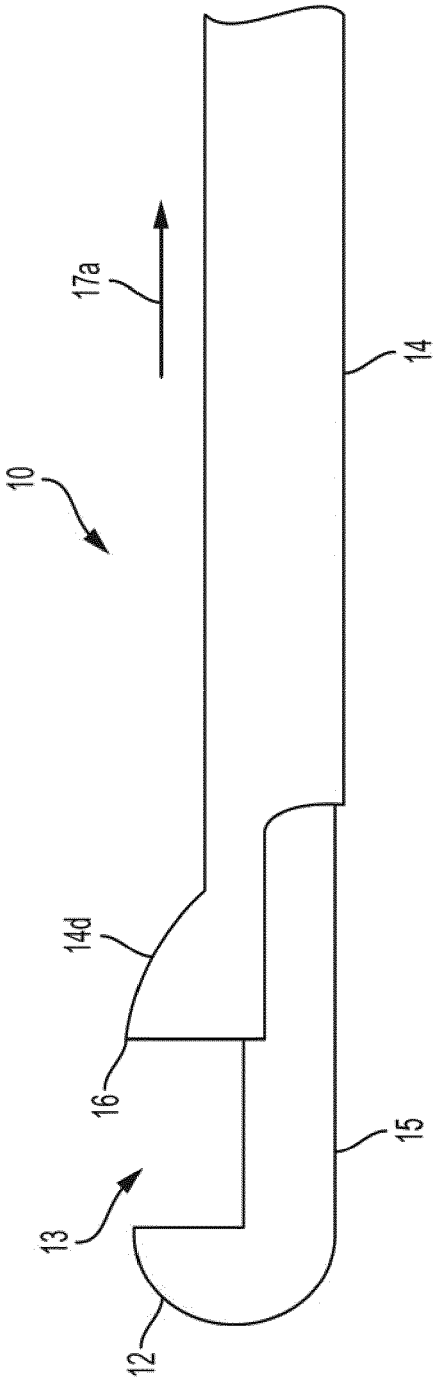


FIG. 1



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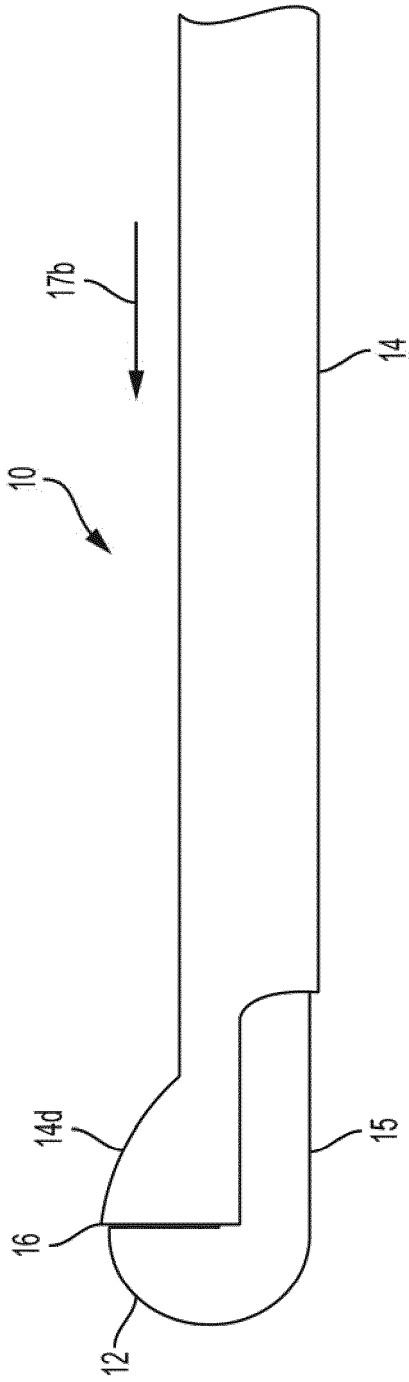

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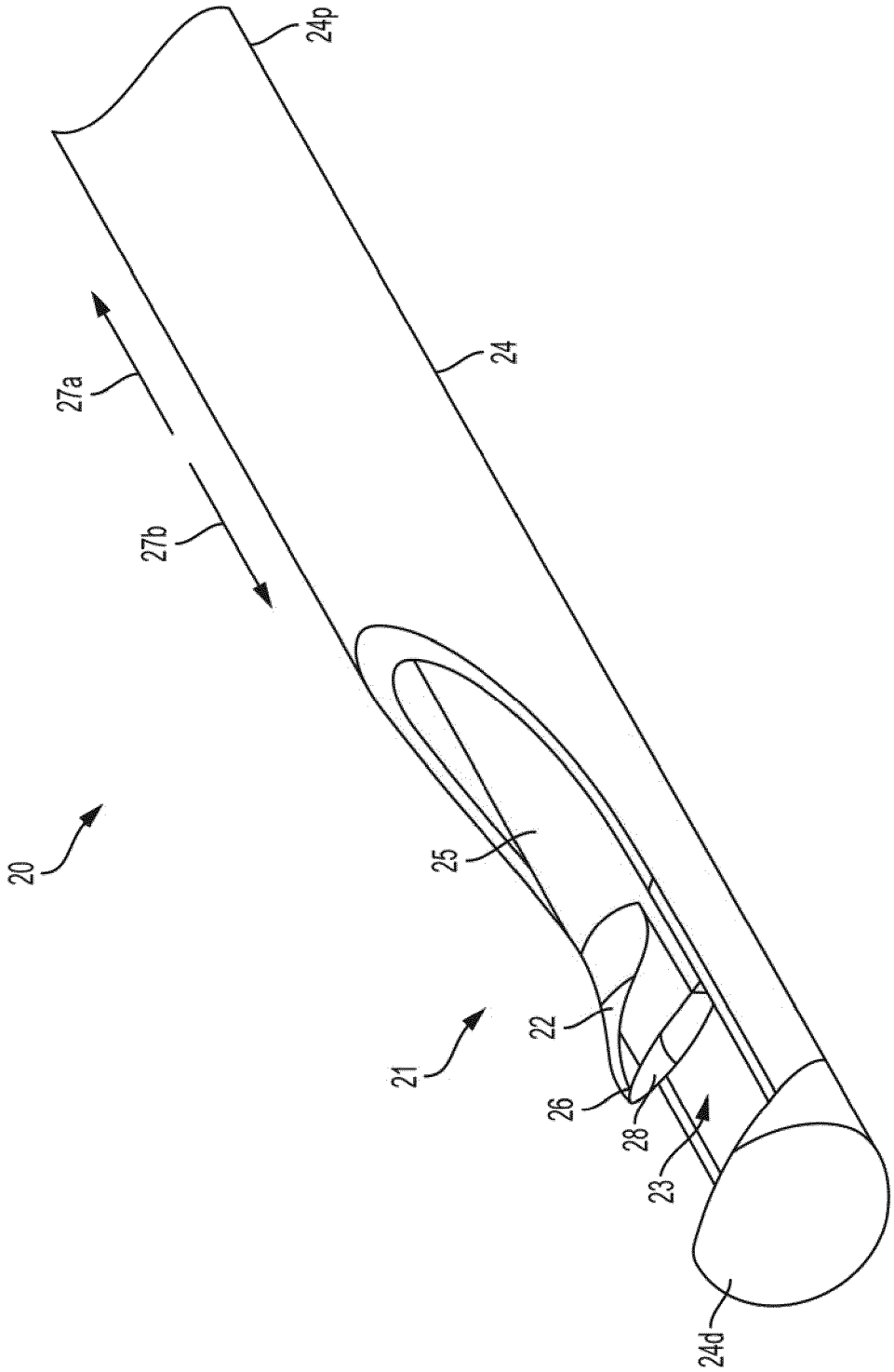


FIG. 4

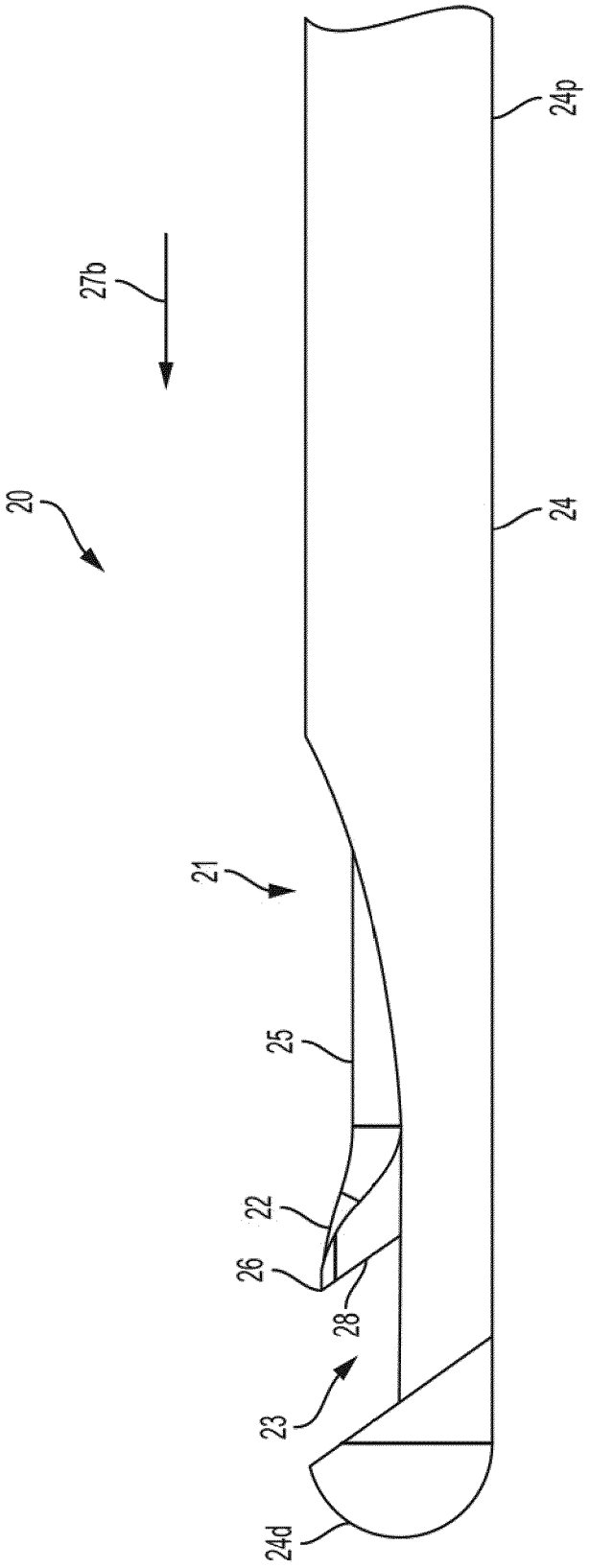


FIG. 5

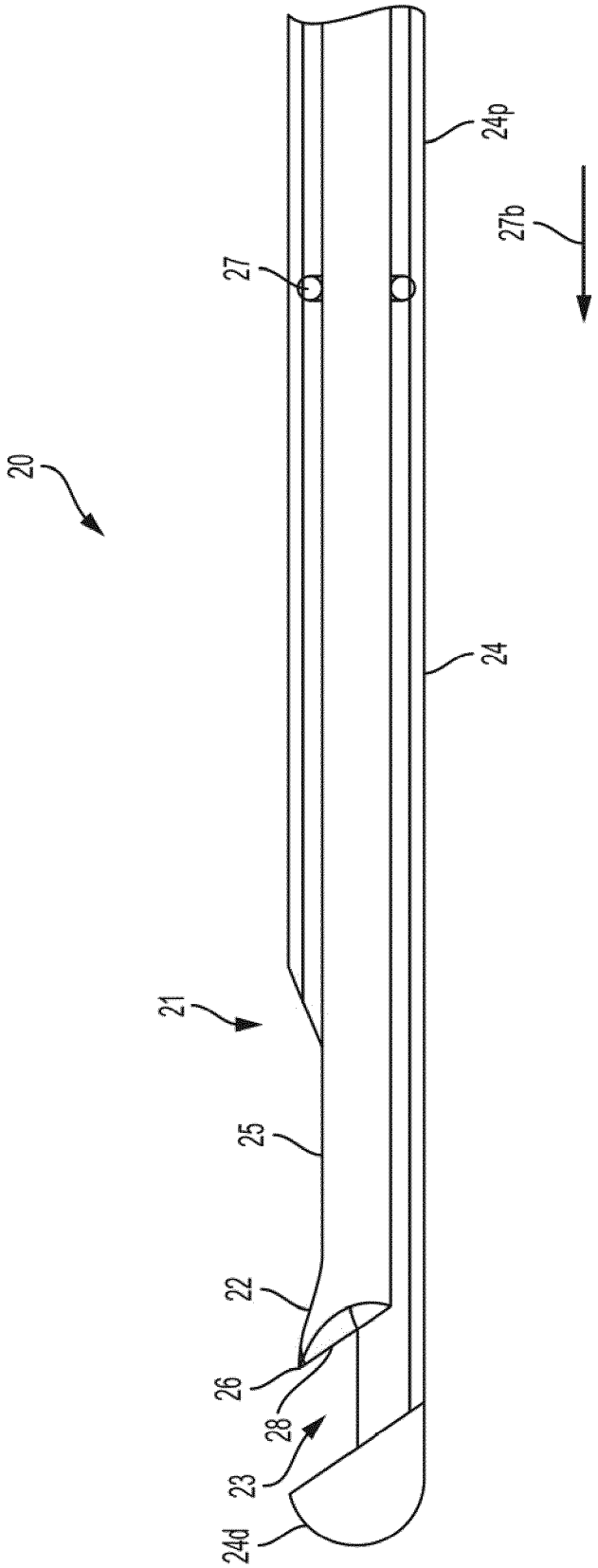


FIG. 6

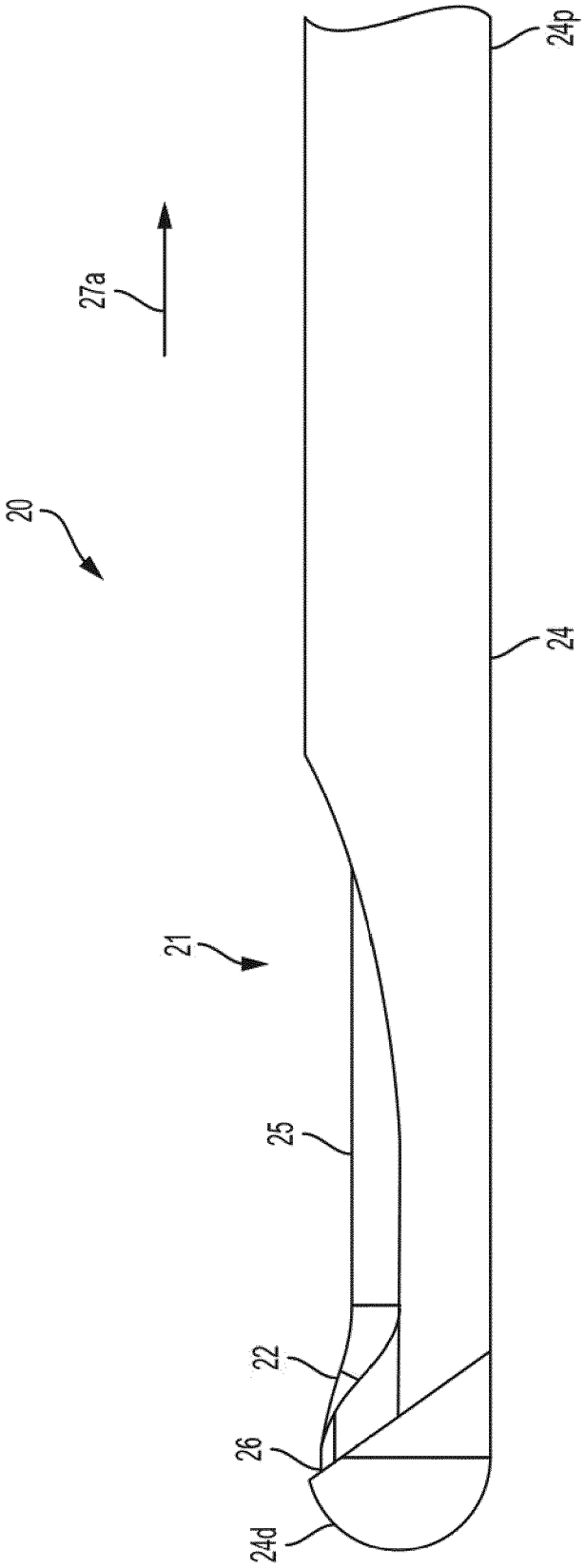
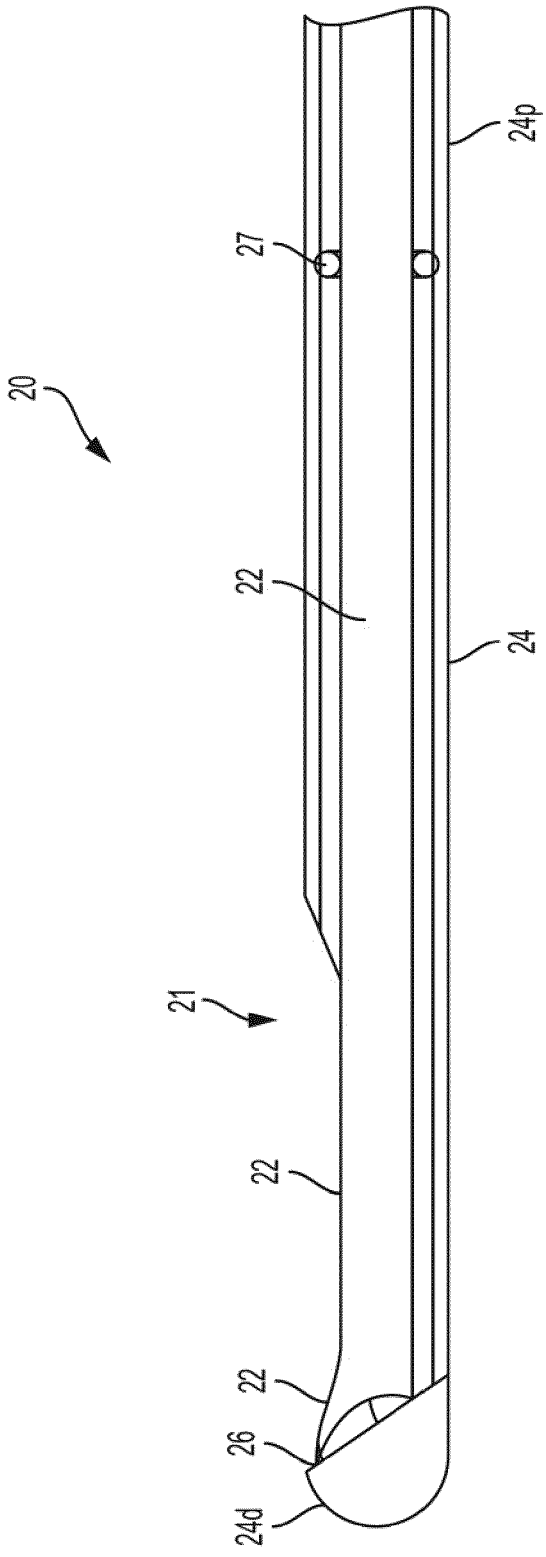


FIG. 7



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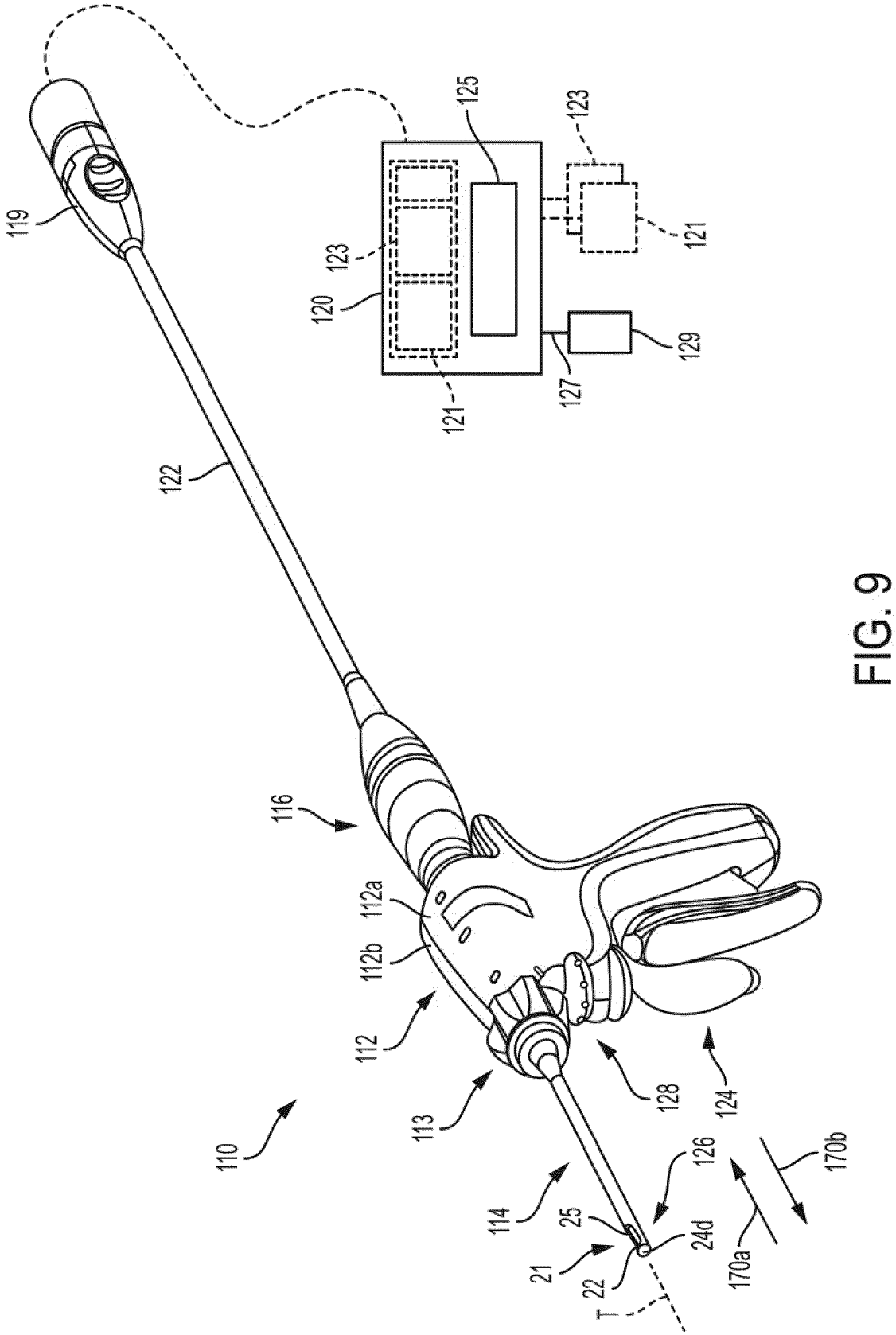
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FIG. 9

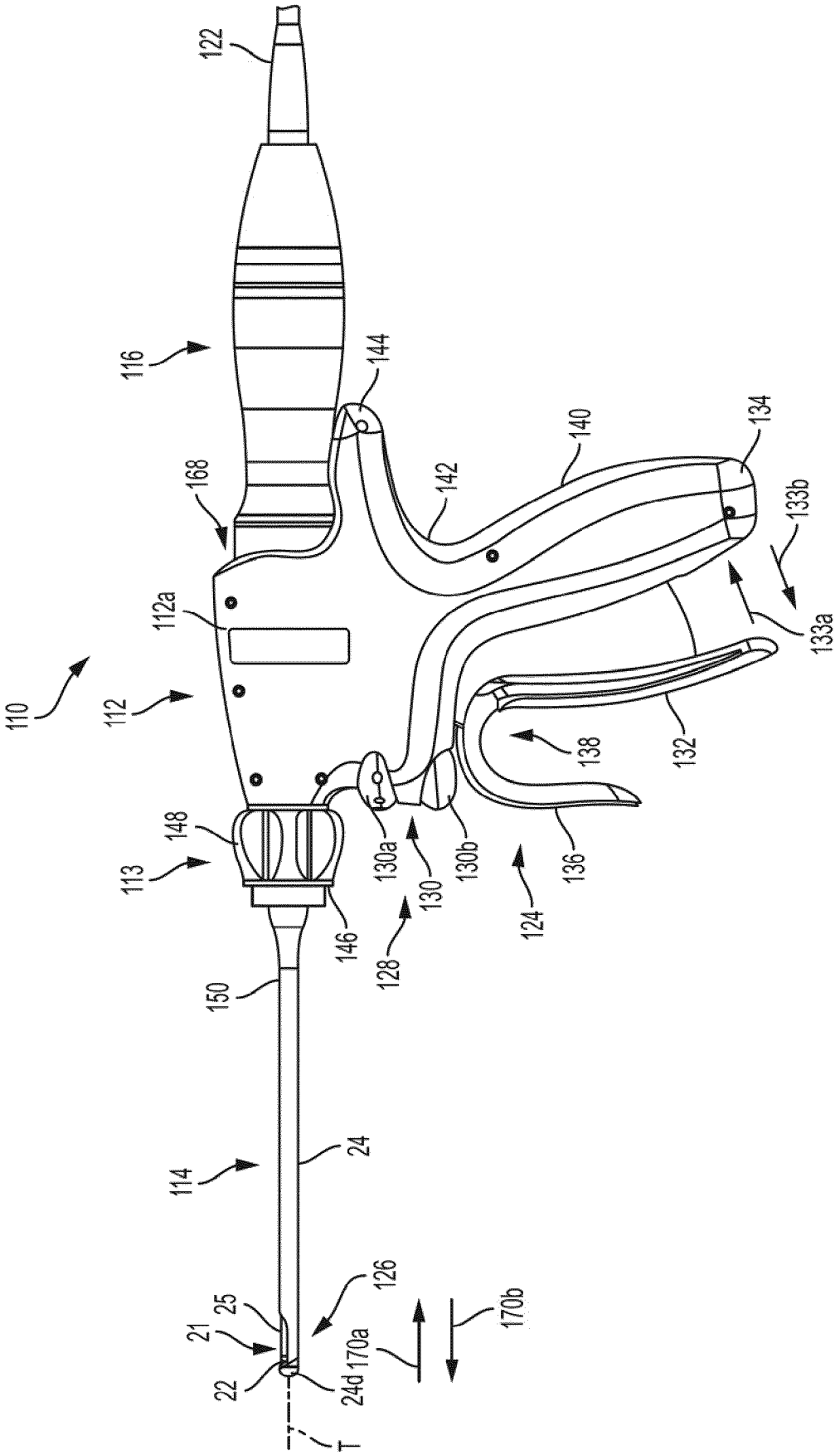
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FIG. 10

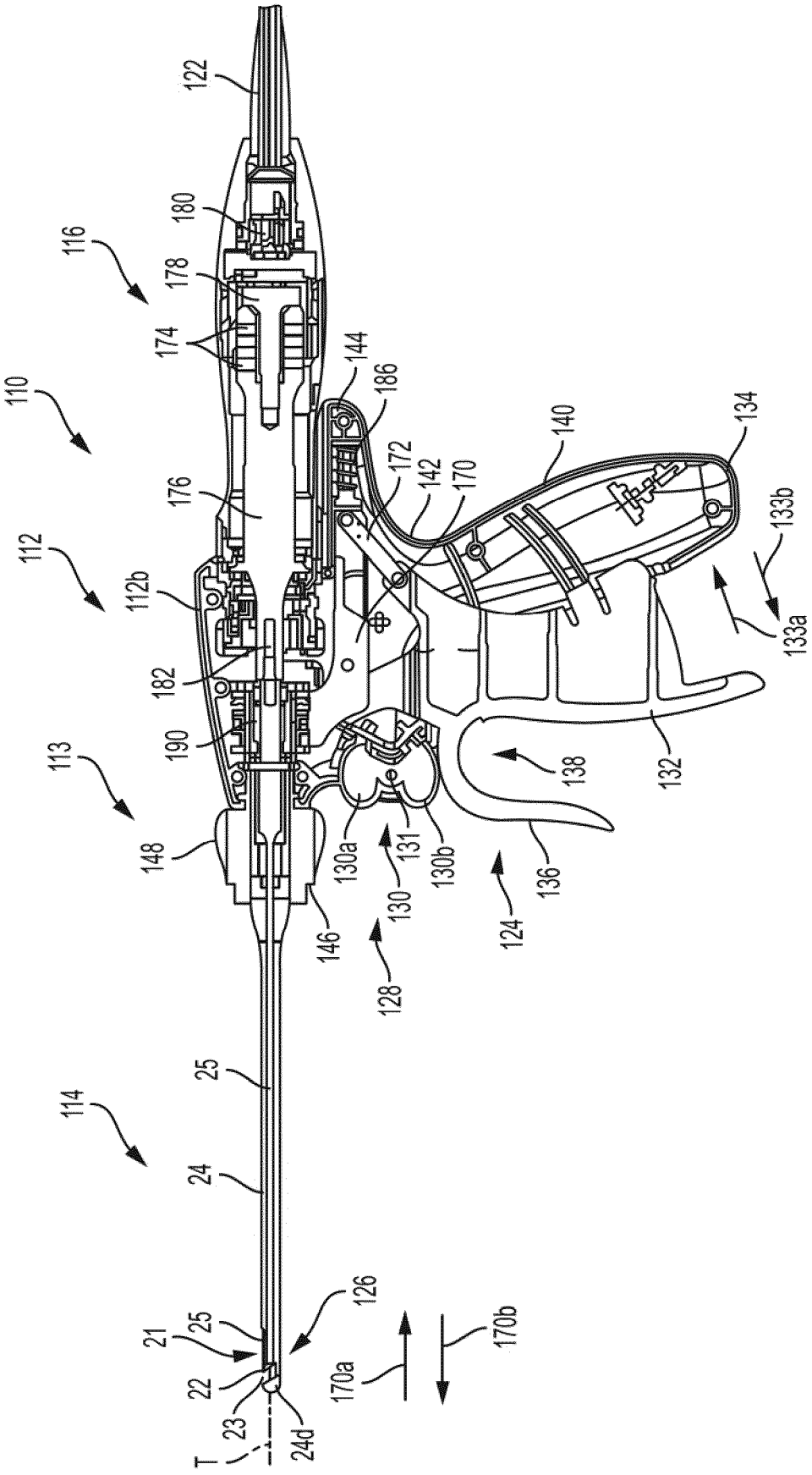
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FIG. 11

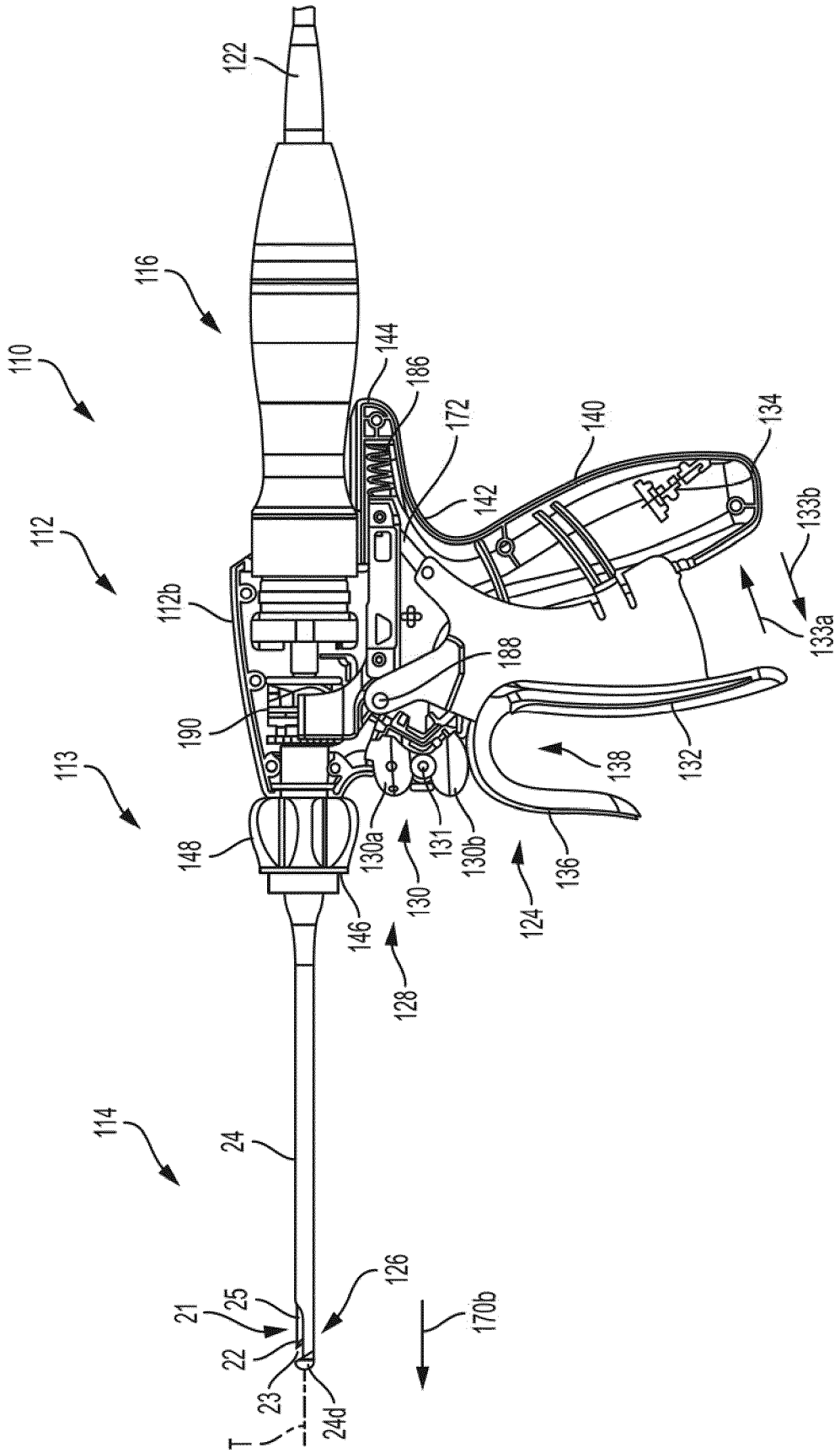
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FIG. 12

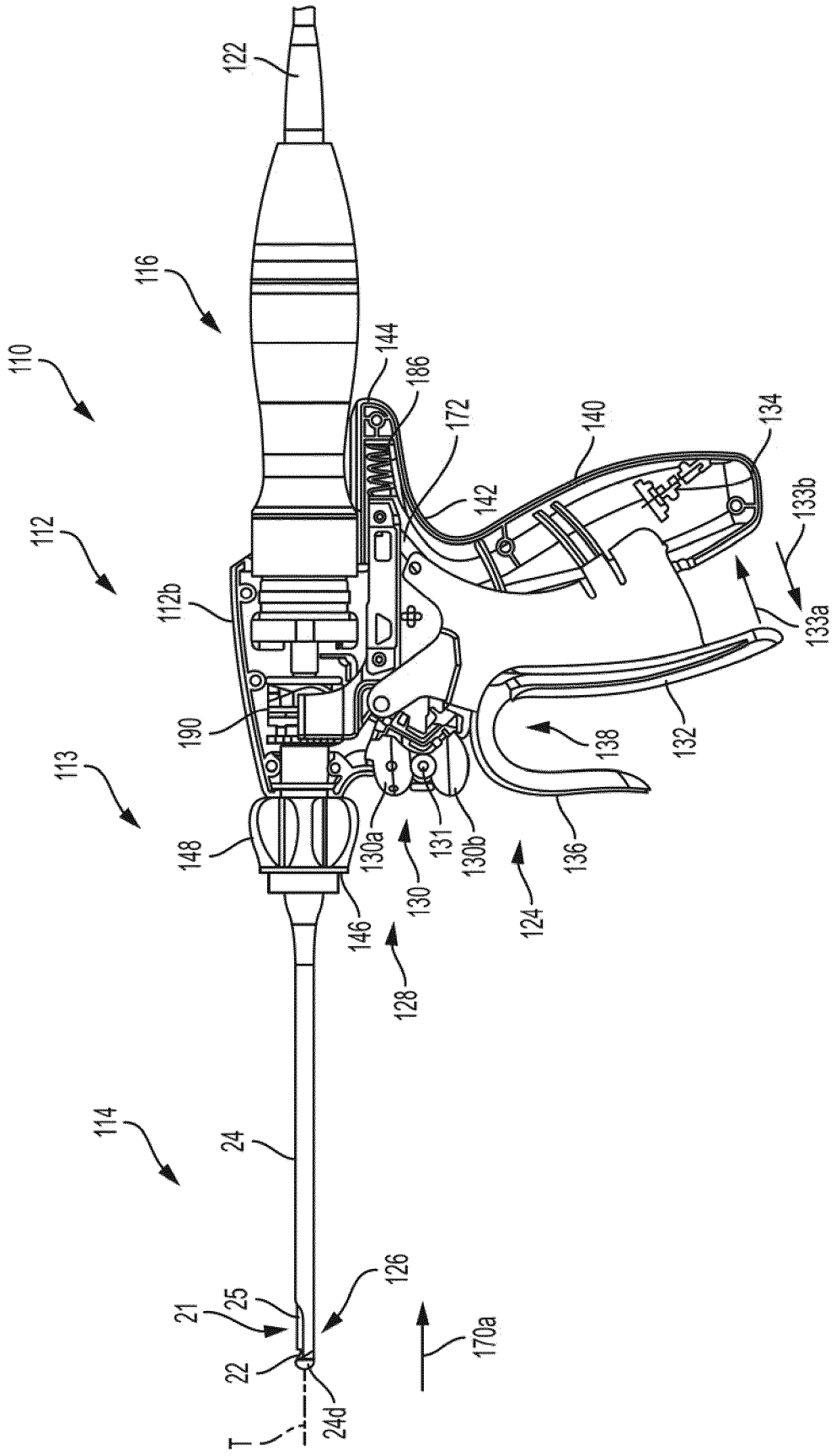
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FIG. 13

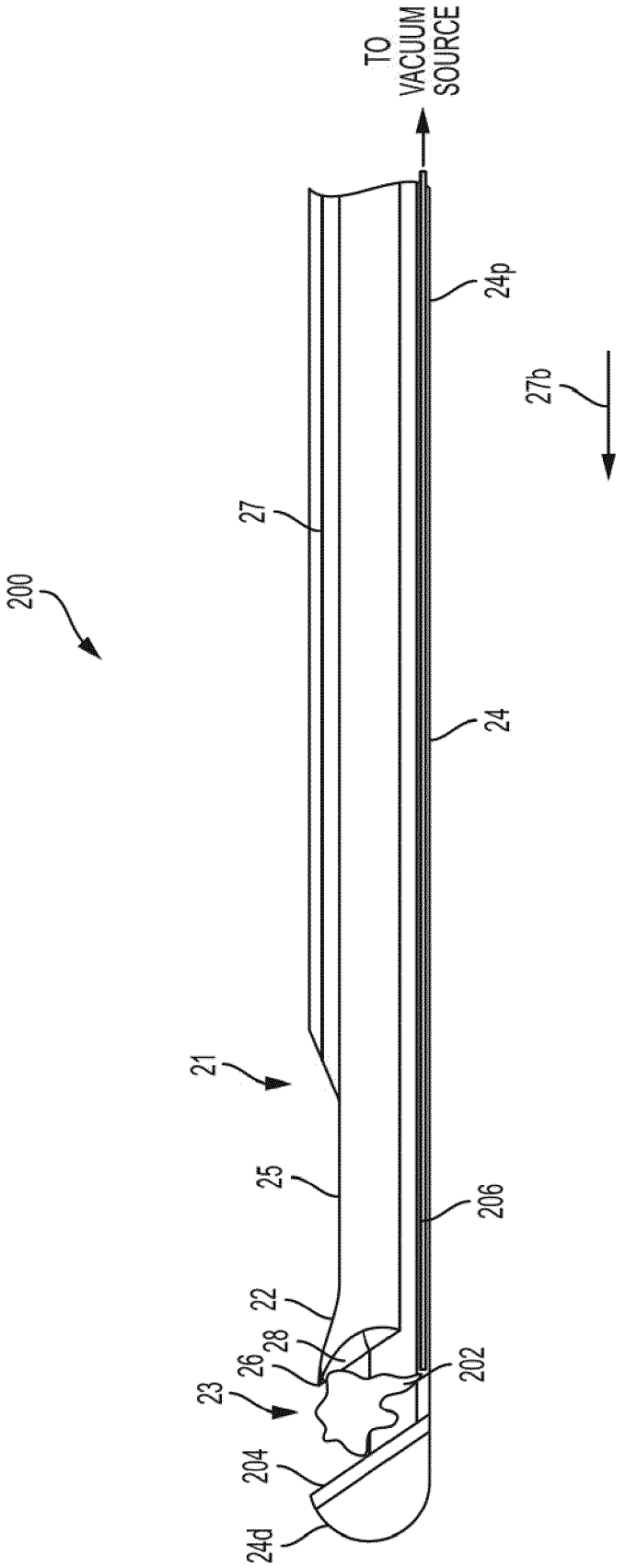
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FIG. 14

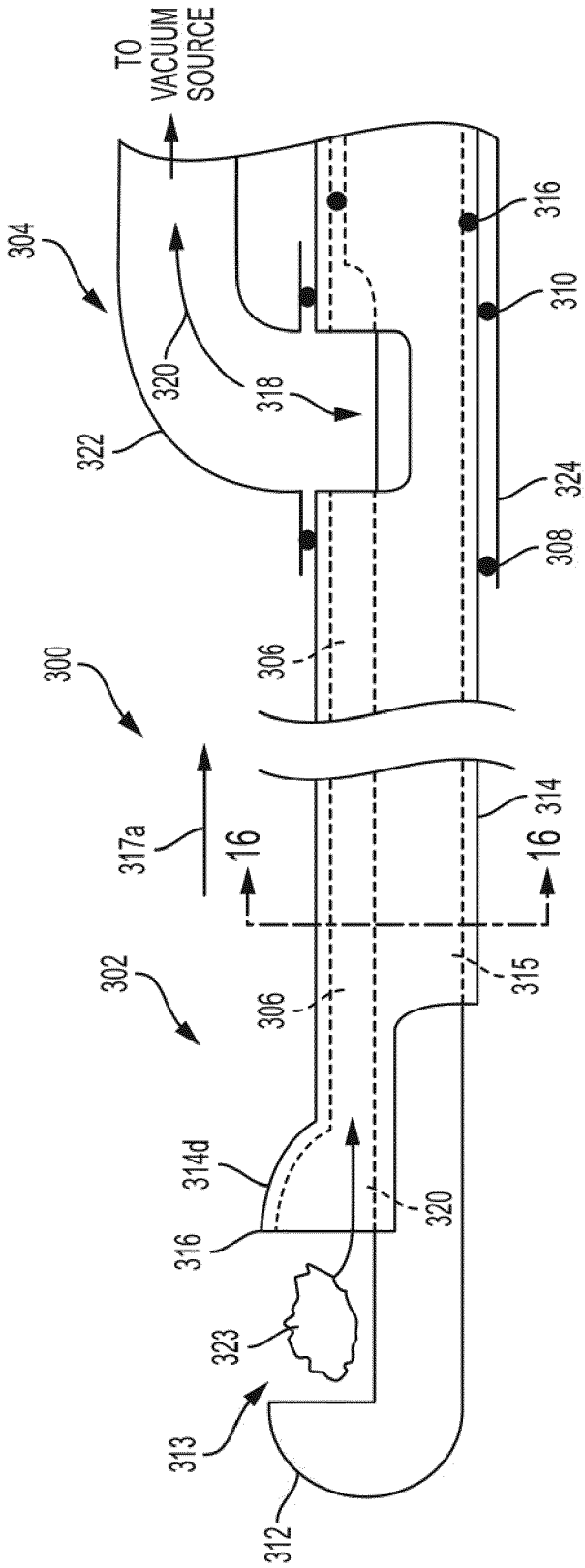
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FIG. 15

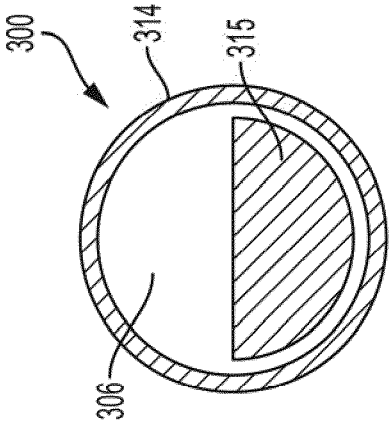
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FIG. 16

Europäisches Patentamt
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EUROPEAN SEARCH REPORT

Application Number
EP 19 19 1948

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 5 906 628 A (MIYAWAKI MAKOTO [JP] ET AL) 25 May 1999 (1999-05-25) * the whole document * -----	1-12	INV. A61B17/32 A61B18/14 A61B18/12
X	US 2011/196404 A1 (DIETZ TIMOTHY G [US] ET AL) 11 August 2011 (2011-08-11) * figures 1-6B * * paragraph [0084] - paragraph [0092] * -----	1-8	ADD. A61B17/24 A61B18/00
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A	US 2009/030437 A1 (HOUSER KEVIN L [US] ET AL) 29 January 2009 (2009-01-29) * figures 10-28C * * paragraph [0123] - paragraph [0134] * -----	1-12	

TECHNICAL FIELDS SEARCHED (IPC)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	15 October 2019	Emirdag, Eda

CATEGORY OF CITED DOCUMENTS

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L : document cited for other reasons

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EPO FORM 1503 03.82 (P04C01)

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15-10-2019

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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专利名称(译)	组织解剖和凝血装置		
公开(公告)号	EP3590449A1	公开(公告)日	2020-01-08
申请号	EP2019191948	申请日	2016-06-06
[标]申请(专利权)人(译)	ETHICON，LLC		
申请(专利权)人(译)	ETHICON LLC		
当前申请(专利权)人(译)	ETHICON LLC		
[标]发明人	WEISENBURGH II WILLIAM B JOHNSON GREGORY W KIMBALL CORY G		
发明人	WEISENBURGH II, WILLIAM B. JOHNSON, GREGORY W. KIMBALL, CORY G.		
IPC分类号	A61B17/32 A61B18/14 A61B18/12 A61B17/24 A61B18/00		
CPC分类号	A61B17/24 A61B17/320068 A61B17/320092 A61B2017/00477 A61B2017/00991 A61B2017/320084 A61B2018/00589 A61B2018/00607 A61B2018/00994 A61B2217/007 A61N7/00 A61B18/1206 A61B18/1482 A61B2017/320069 A61B2017/32007 A61B2017/320078 A61B2017/320089 A61B2017/320093 A61B2017/320094 A61B2017/320095 A61B2017/320071		
优先权	14/739792 2015-06-15 US PCT/US2016/035958 2016-06-06 WO		
外部链接	Espacenet		

摘要(译)

提供了一种用于切割和凝结组织的手术器械（20），该手术器械包括细长的护套（24）和超声刀（22）。 在一个实施例中，超声刀（22）被定位在护套（24）内，使得护套（24）相对于刀（22）的运动导致其间的组织的解剖和/或凝结。 在另一个实施例中，超声刀片（22）被定位在护套（24）内，使得刀片（22）相对于护套（24）的运动导致其间的组织的解剖和/或凝结。 刀片（22）和鞘（24）的远端的尺寸和形状确定了从身体切割和/或去除的组织的尺寸和形状。

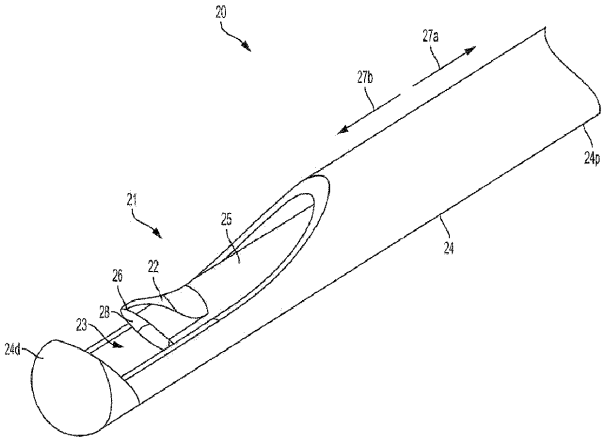

FIG. 4