



US010517578B2

(12) **United States Patent**
Truckai

(10) **Patent No.:** **US 10,517,578 B2**
(45) **Date of Patent:** **Dec. 31, 2019**

(54) **LAPAROSCOPIC DEVICE**

(71) Applicant: **Hermes Innovations, LLC**, Cupertino,
CA (US)

(72) Inventor: **Csaba Truckai**, Saratoga, CA (US)

(73) Assignee: **Hermes Innovations LLC**, Cupertino,
CA (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 162 days.

(21) Appl. No.: **15/488,270**

(22) Filed: **Apr. 14, 2017**

(65) **Prior Publication Data**

US 2017/0215912 A1 Aug. 3, 2017

Related U.S. Application Data

(63) Continuation of application No. 14/508,856, filed on
Oct. 7, 2014, now Pat. No. 9,649,125.
(Continued)

(51) **Int. Cl.**

A61B 17/22 (2006.01)

A61B 17/32 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC .. **A61B 17/00234** (2013.01); **A61B 17/32002**
(2013.01); **A61B 17/320068** (2013.01); **A61B**
17/3203 (2013.01); **A61B 2017/00022**
(2013.01); **A61B 2017/00026** (2013.01); **A61B**
2017/00039 (2013.01); **A61B 2017/00477**
(2013.01); **A61B 2017/00973** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC **A61B 17/32002**; **A61B 17/320068**; **A61B**
2017/320028; **A61B 2017/22027**; **A61B**
2017/22079

See application file for complete search history.

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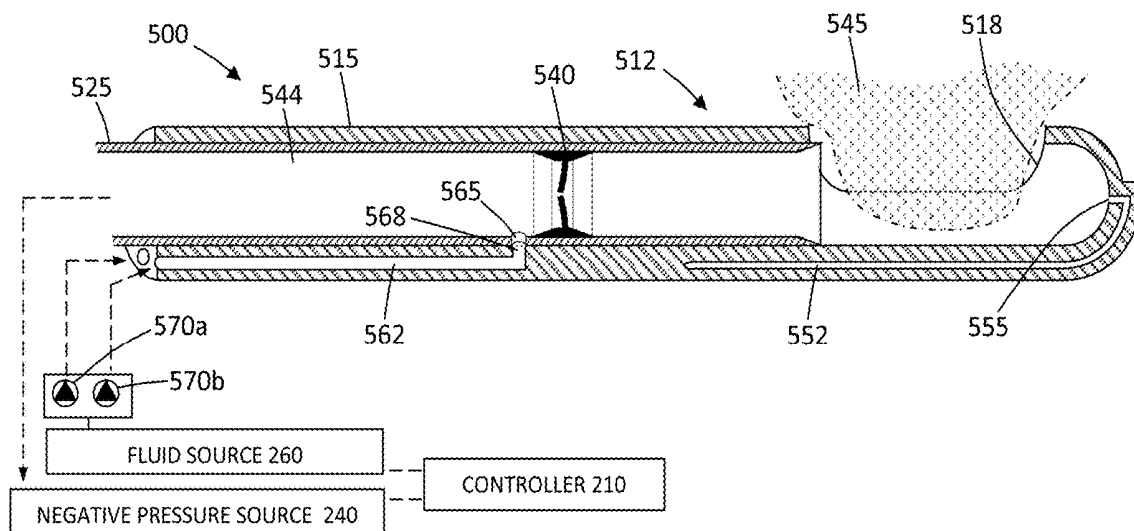
Primary Examiner — Julian W Woo

(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich
& Rosati

(57) **ABSTRACT**

A medical instrument includes a tubular cutter extending
along an axis and having a windowed outer sleeve and a
moveable inner cutting sleeve. An ultrasound transducer is
operatively coupled to the inner cutting sleeve in order to
induce motion in the inner cutting sleeve to enhance cutting
or resection of tissue by the inner cutting sleeve as it is
reciprocated or otherwise moved past the cutting window.
The instrument typically will include a motor drive config-
ured to reciprocate and/or rotate the inner cutting sleeve
relative to the windowed outer sleeve, usually at a recipro-
cation rate between 1 and 10 Hz.

28 Claims, 11 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 61/891,288, filed on Oct. 15, 2013.

(51) Int. Cl.

A61B 17/00 (2006.01)

A61B 17/3203 (2006.01)

A61B 90/00 (2016.01)

(52) U.S. Cl.

CPC *A61B 2017/22027* (2013.01); *A61B 2017/22079* (2013.01); *A61B 2017/32007* (2017.08); *A61B 2017/320028* (2013.01); *A61B 2090/065* (2016.02); *A61B 2217/005* (2013.01)

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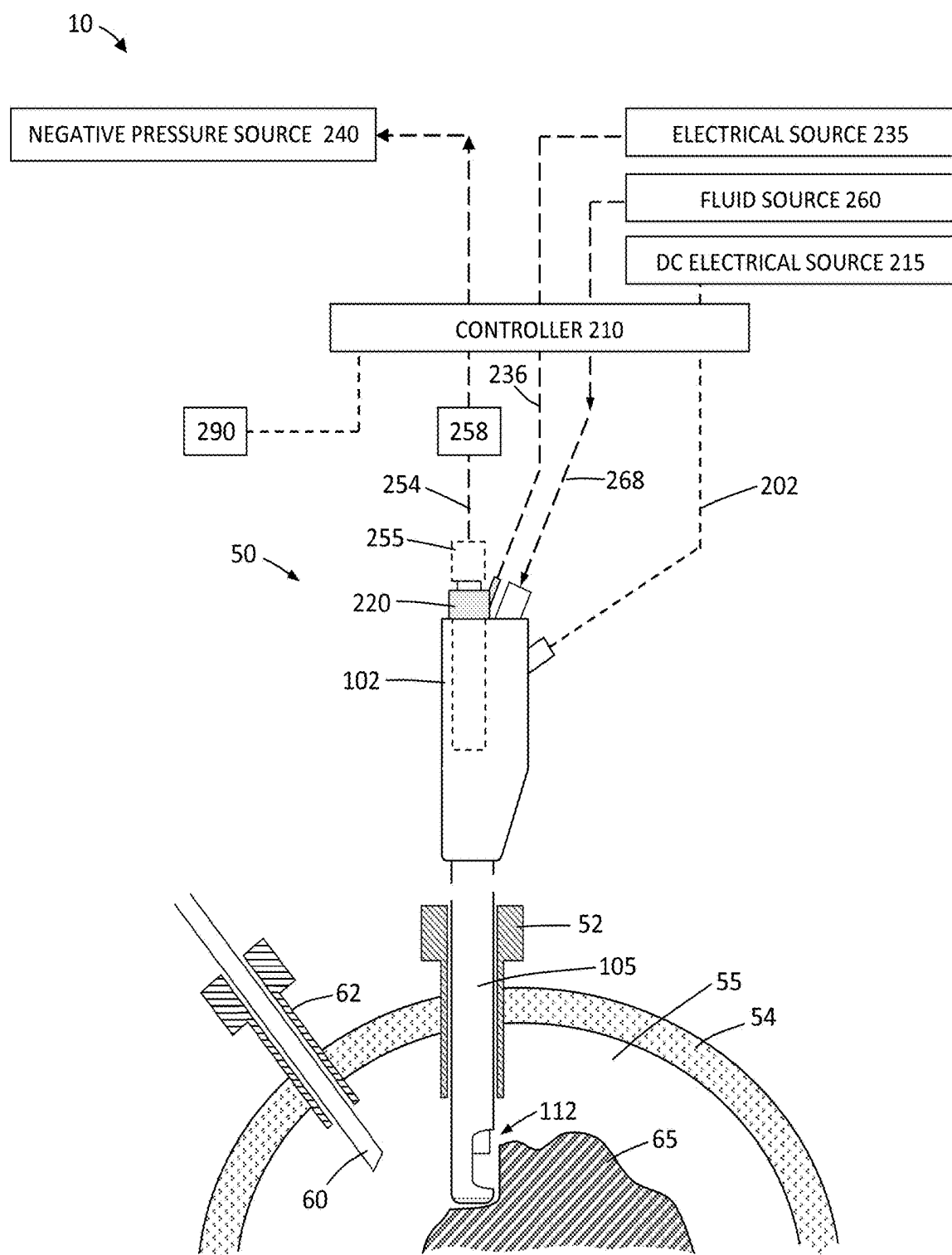


FIG. 1

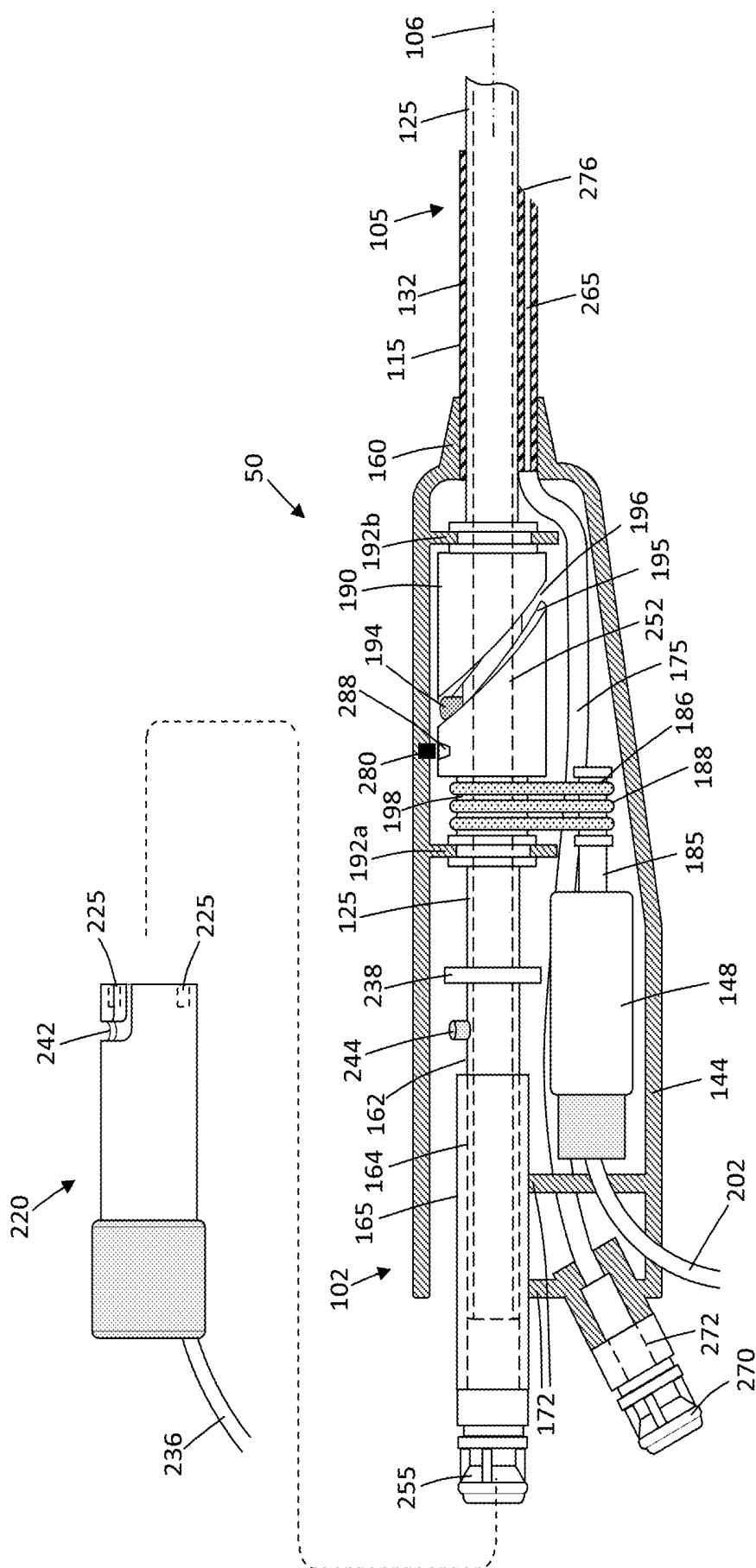


FIG. 2A

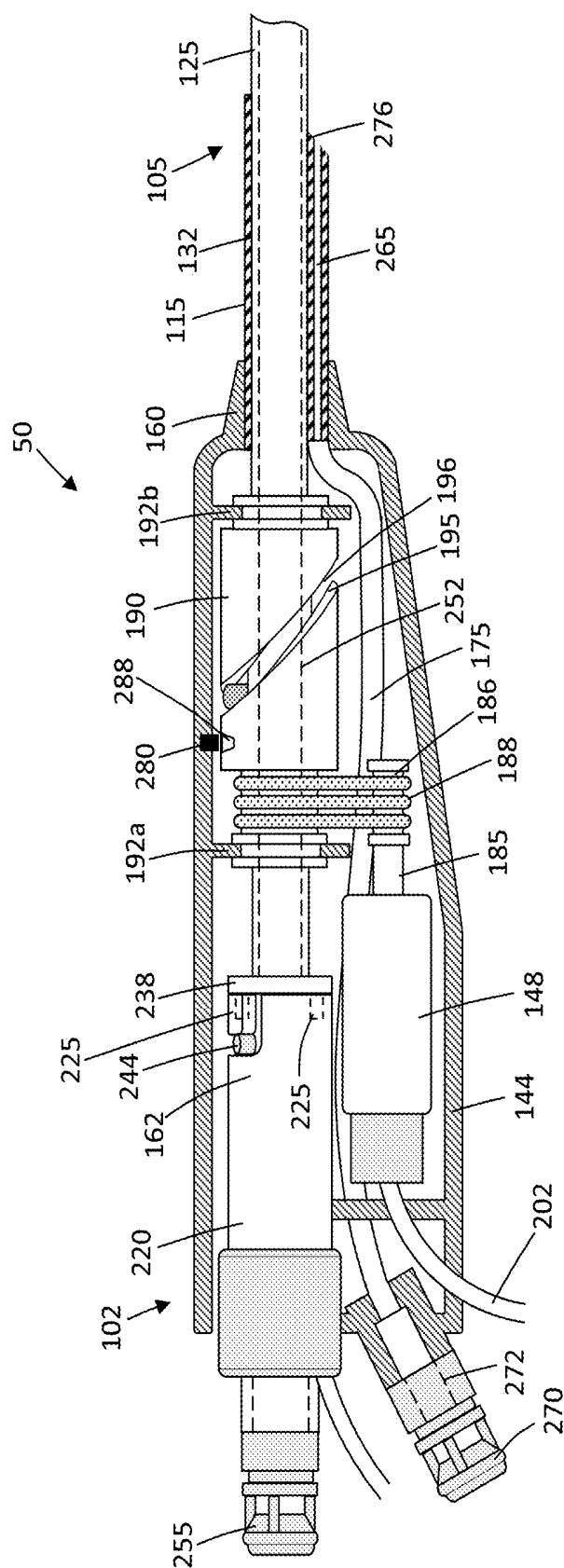


FIG. 2B

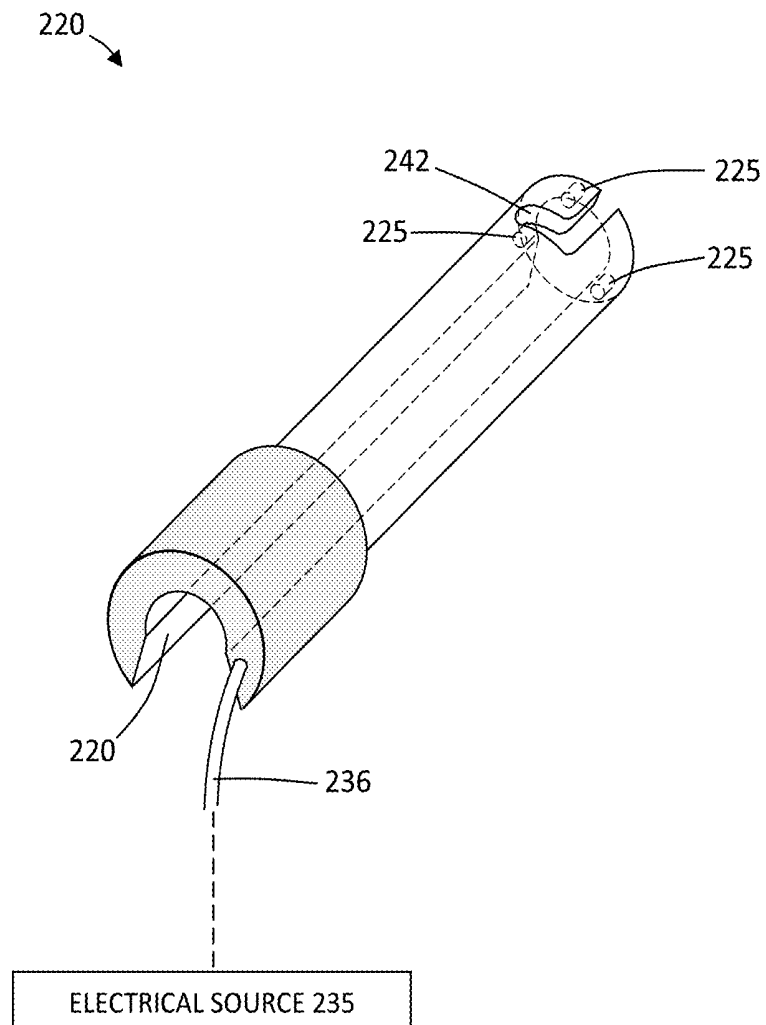


FIG. 3

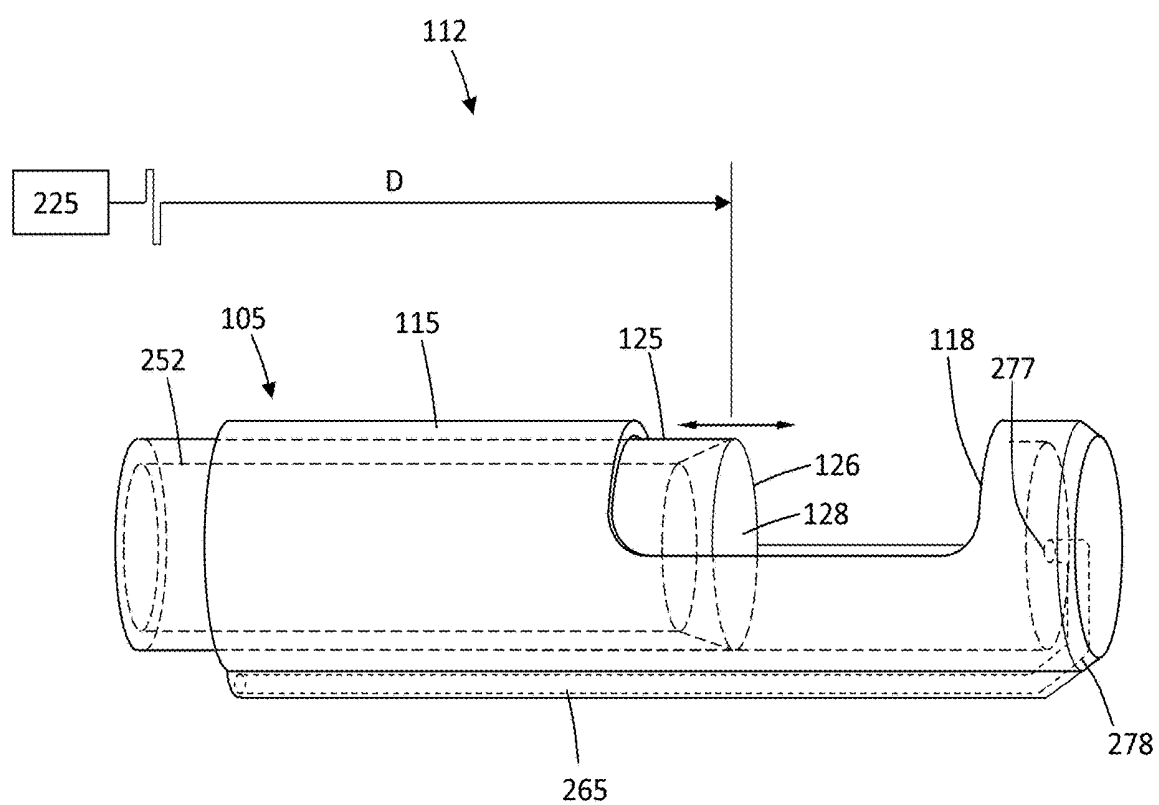


FIG. 4

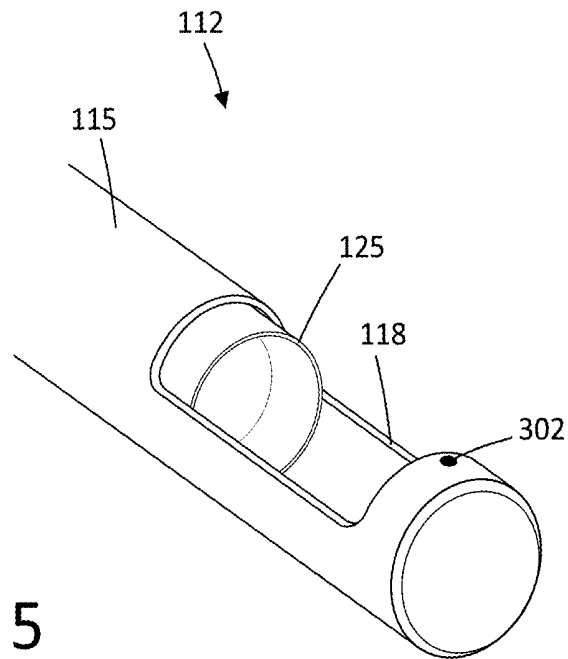


FIG. 5

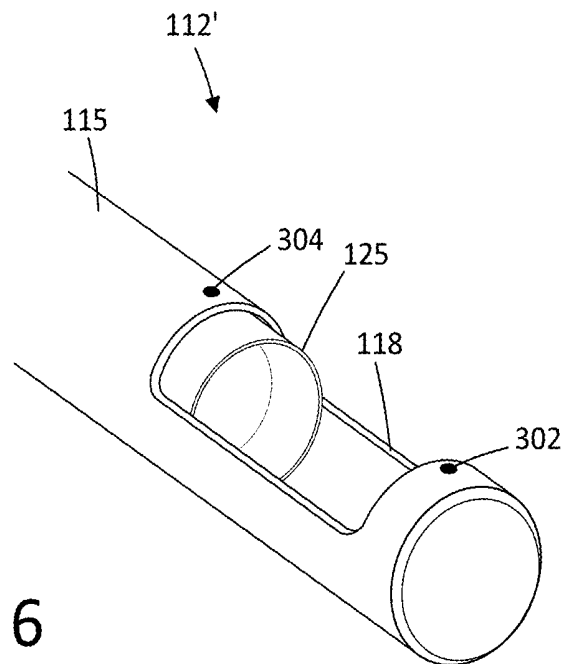


FIG. 6

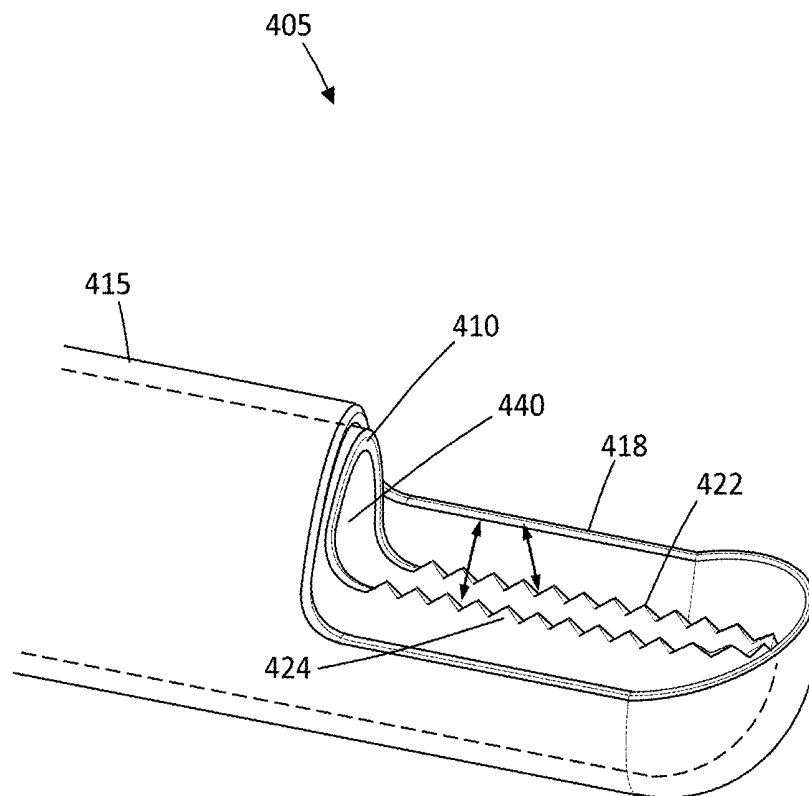


FIG. 7

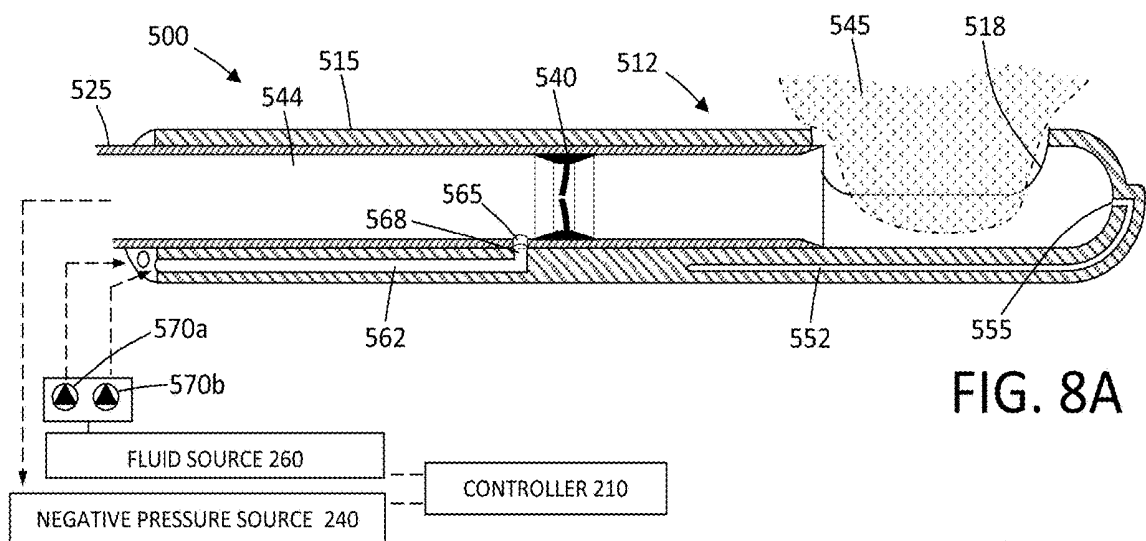


FIG. 8A

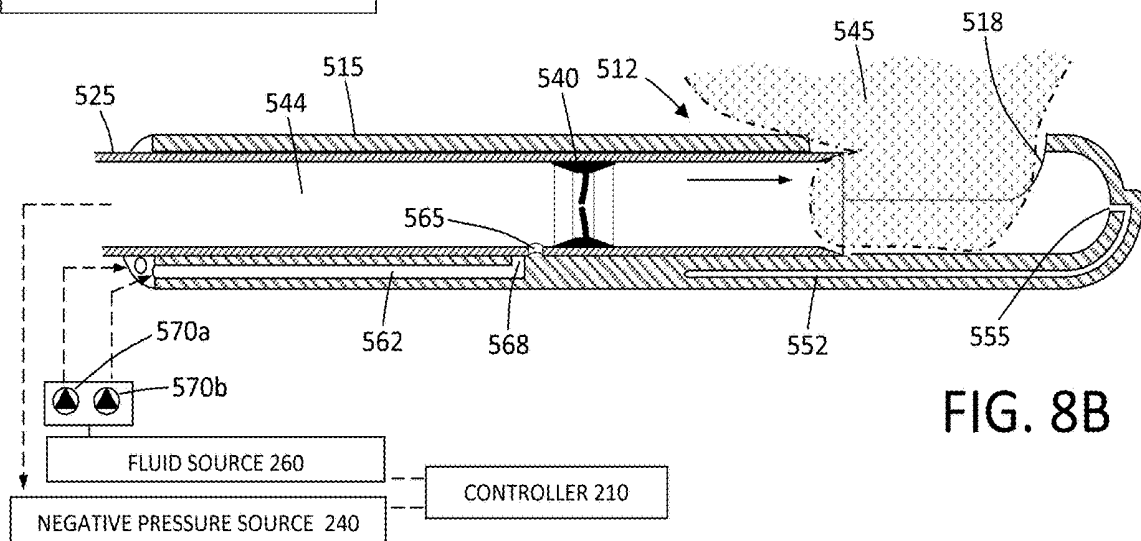


FIG. 8B

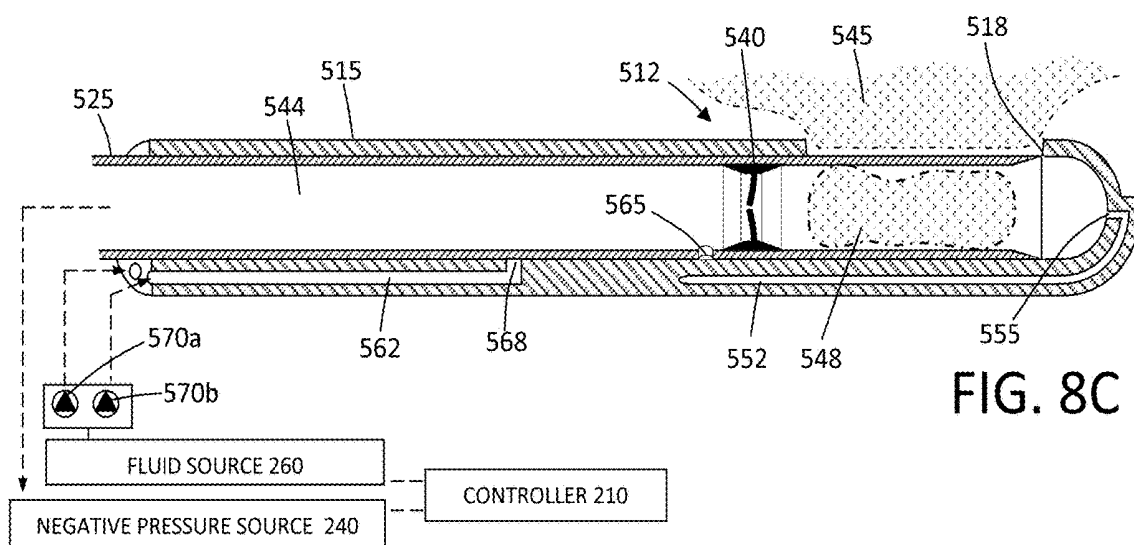


FIG. 8C

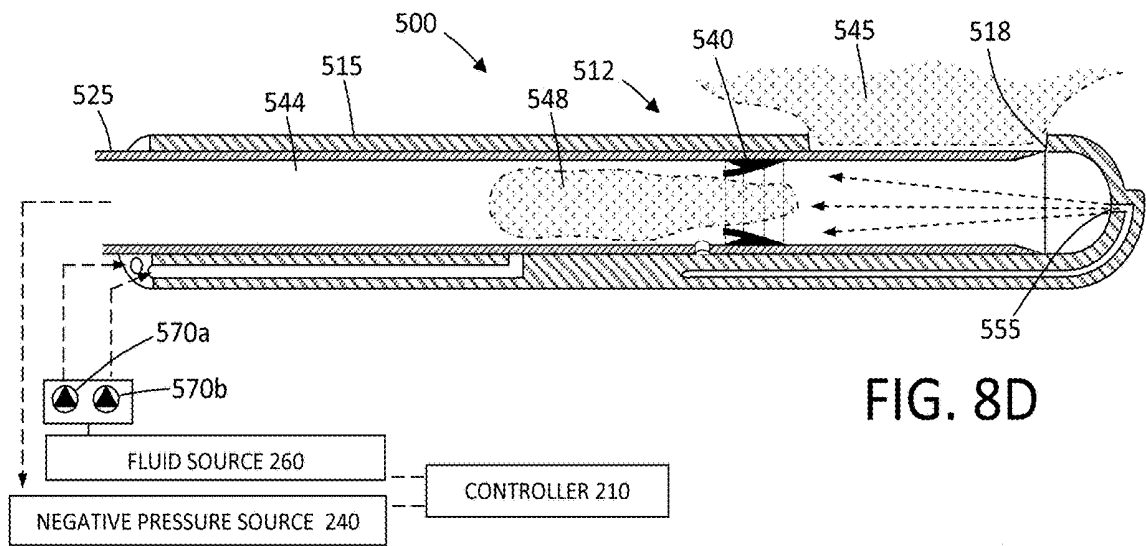


FIG. 8D

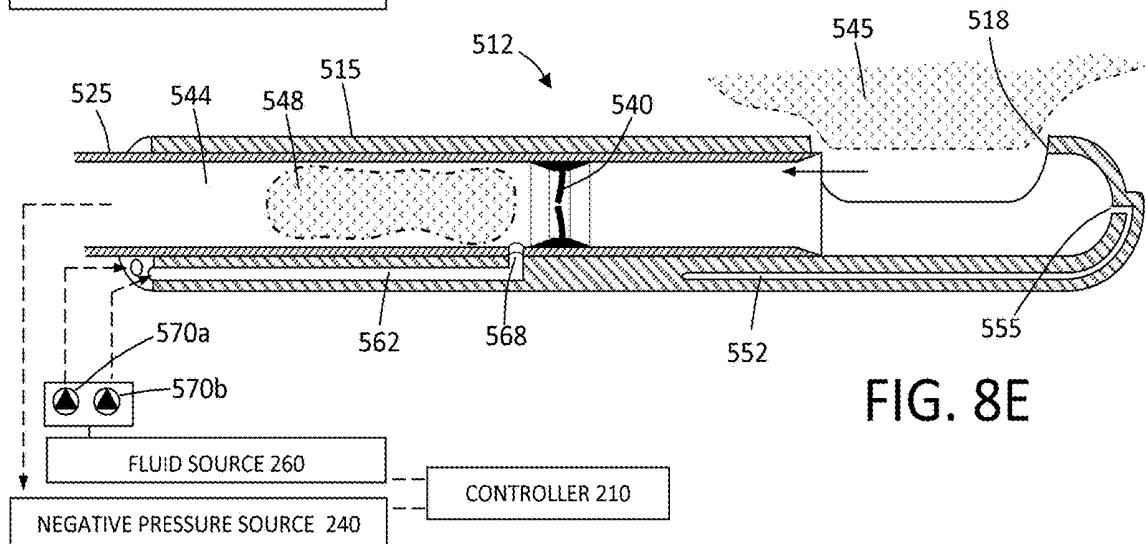


FIG. 8E

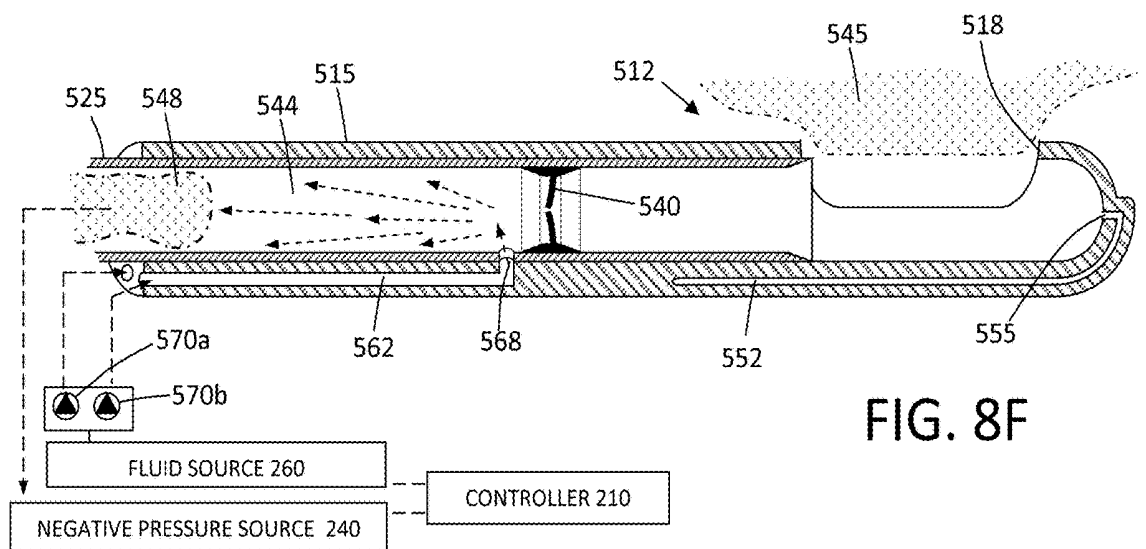


FIG. 8F

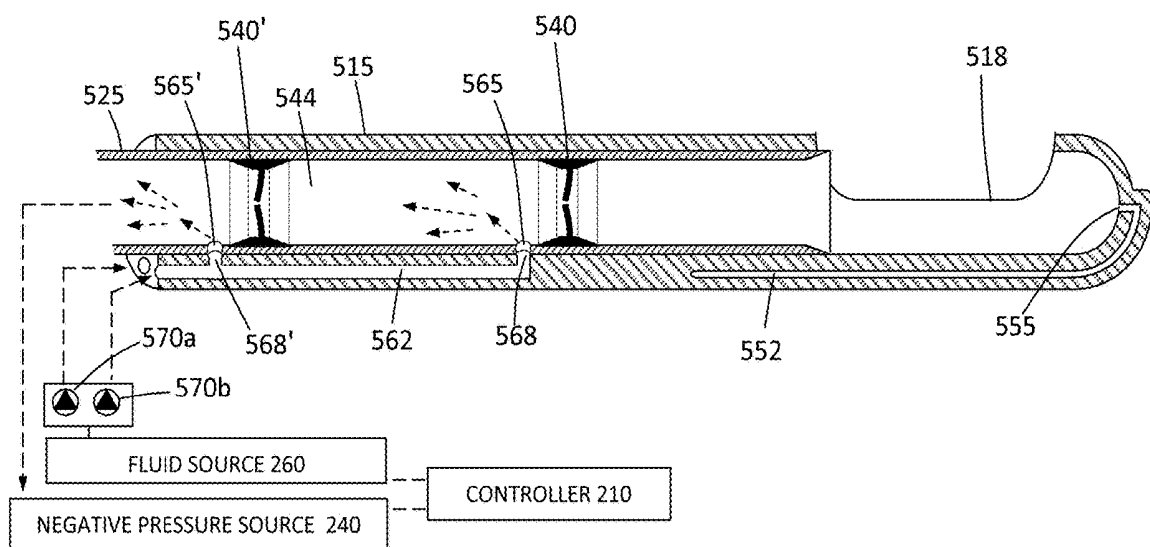


FIG. 9

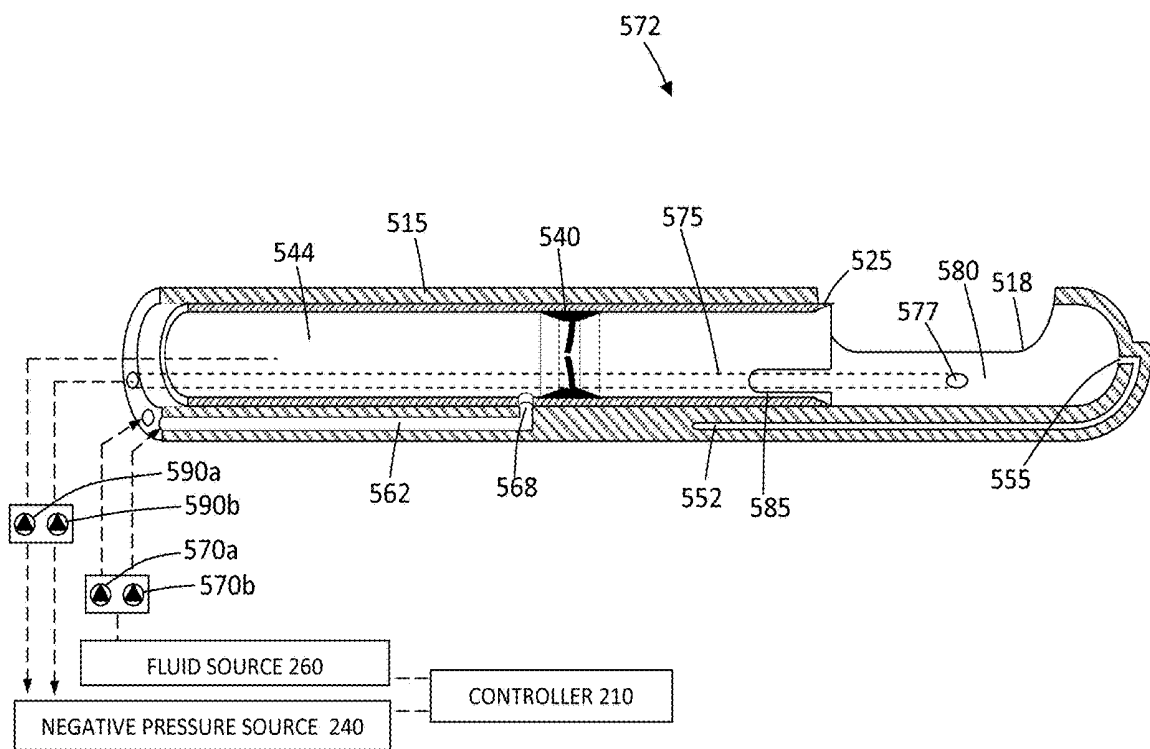


FIG. 10

LAPAROSCOPIC DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/508,856, filed Oct. 7, 2014, now U.S. Pat. No. 9,649,125, which claims the benefit of U.S. Provisional Application No. 61/891,288, filed Oct. 15, 2013, the entire content of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates devices and methods for cutting and removal of tissue from the interior of a patient's body, typically in a laparoscopic procedure.

Laparoscopic and other minimally invasive tissue cutters are known, some of which operate by advancing a tubular blade past an open window in an outer housing to resect or sever intruding tissue. Optionally the cutter may be rotated as it is axially advanced past the window to enhance cutting. Although quite effective, such cutters cannot always adequately cut difficult tissue structure, and it would therefore be advantageous to provide improved devices and methods for laparoscopic and other minimally invasive tissue resection.

2. Description of the Background Art

Reciprocating and rotational tissue cutters are described in U.S. Published Patent Applications 20130267937; 20130172870; and 20120330292. Atherectomy catheters having ultrasound imaging transducers on the cutting blades are described in U.S. Pat. No. 5,429,136.

SUMMARY OF THE INVENTION

In a first aspect, the present invention provides a medical instrument comprising a tubular cutter extending along an axis and having a windowed outer sleeve and a moveable inner cutting sleeve. An ultrasound transducer is operatively coupled to the inner cutting sleeve in order to induce motion in the inner cutting sleeve to enhance cutting or resection of tissue by the inner cutting sleeve as it is reciprocated or otherwise moved past the cutting window. The instrument typically will include a motor drive configured to reciprocate and/or rotate the inner cutting sleeve relative to the windowed outer sleeve, usually at a reciprocation rate between 1 and 10 Hz.

The ultrasound transducer is typically configured to cause at least one of axial motion and rotational motion in the distal end of the inner cutting sleeve. Usually, the inner cutting sleeve will have a cutting edge at its distal end so that the tissue may be effected by axially advancing the blade in a distal direction. Rotational and/or oscillatory motion may be superimposed on the axial reciprocation to enhance cutting with the ultrasonic motion being further superimposed to further enhance cutting. In other embodiments, the inner cutting sleeve may have an axially oriented cutting edge so that cutting is provided primarily by rotation of the sleeve about the axis. In that case, axial oscillation may be superimposed to enhance cutting together with the ultrasonic motion. In all cases, a dimension between the ultrasound transducer and the distal end of the inner sleeve may be selected to optimize at least one of axial motion and rotational motion in the distal end of the inner cutting sleeve.

In some embodiments, the instrument may further comprise at least a second ultrasound transducer, wherein first

and second ultrasound transducers are configured to cause axial and rotational motion in the distal end of the inner sleeve. The ultrasound transducer may be removably secured to a handle portion of the tubular cutter.

The instruments of the present invention may further comprise a negative pressure source coupled to a tissue extraction lumen in the tubular cutter. The instrument of the present invention may still further comprise a pressurized fluid source, either liquid, gas, or a mixed fluid, coupled to an inflow lumen in the cutter, and the inflow lumen may extend to an outlet in a distal portion of the cutter.

The instruments of the present invention may further comprise a controller coupled to the tubular cutter for controlling operating parameters of the ultrasound transducer, the motor drive, the negative pressure source, and/or the pressurized fluid source. In such cases, the instruments may still further comprise a sensor configured to send signals to the controller indicating the position of the inner sleeve relative to the window in the outer sleeve, and the controller may be adapted or configured to modulate activation of the ultrasound transducer in response to the sensor signals that indicate the position of the inner sleeve. The controller may activate the ultrasound transducer when the inner sleeve moves toward a window-closed position to cut tissue and de-activates the ultrasound transducer when the inner sleeve moves toward a window-open position. In particular, the controller may activate the pressurized fluid source when the inner sleeve is in a window-closed position and/or may de-activate the pressurized fluid source when the inner sleeve is in a window-open position.

In a second aspect, the present invention provides a medical instrument comprising a tubular assembly extending along an axis with a windowed outer sleeve and a moveable inner cutting sleeve. The inner cutting sleeve has a tissue-extraction passageway. A seal in the tissue-extraction passageway in the inner cutting sleeve has a first condition that closes the passageway and second condition that permits a tissue chip to pass through the seal. The tubular assembly typically has a flow channel terminating in a distal outlet in a region of the assembly that is distal to the seal, where the flow channel is in communication with a fluid source or a negative pressure source.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a schematic view of a tissue resecting device and block diagram of operating components corresponding to the invention in a laparoscopic resection procedure.

FIG. 2A is a cut-away view of a handle portion of a resecting device of the invention with a detachable ultrasound component de-coupled from the device.

FIG. 2B is a cut-away view of the resecting device handle as in FIG. 2A with the ultrasound component coupled to the resecting device to provide vibratory motion to the inner sleeve.

FIG. 3 is a perspective view of the ultrasound component de-coupled from the resecting device illustrating a plurality of piezoelectric elements carried therein.

FIG. 4 is a perspective view of the working end of a shaft portion of the resecting device showing the assembly of the outer and inner sleeves.

FIG. 5 is a perspective view of the working end of a resecting device showing a sensor for sensing tissue contact.

FIG. 6 is a perspective view of another working end of a resecting device showing a plurality of sensors for sensing tissue contact.

3

FIG. 7 is a perspective view of another working end of a resecting device showing a rotating inner sleeve that can be coupled to an ultrasound source.

FIG. 8A is a step of a method of cutting and extracting a tissue chip in a laparoscopic resection procedure using a tubular cutter as shown in FIGS. 1-4, with FIG. 8A being a sectional view of a resecting device working end illustrating the activation of a negative pressure source to suction tissue into a window of the cutter.

FIG. 8B is another step of the method following the step of FIG. 8A illustrating the activation of motor drive to reciprocate the inner cutting sleeve and actuating an ultrasound component to provide vibratory motion at the inner sleeve edge to resect tissue drawn into the window of the cutter.

FIG. 8C is another step following the step of FIG. 8B illustrating a resected tissue chip captured in an interior passageway of the cutting sleeve.

FIG. 8D is another step depicting actuation of a pressurized fluid flow through an inflow channel and outward from a flow outlet distal to an interior seal to eject the tissue chip through the seal in a proximal direction in the interior passageway of the inner sleeve.

FIG. 8E is a further step after the pressurized fluid flow of FIG. 8D pushes the tissue chip through the seal in the interior passageway.

FIG. 8F depicts a further step of the invention wherein another pressurized fluid flow outward from an outlet proximal of the seal to push the tissue chip further in the proximal direction in the interior passageway.

FIG. 9 is a perspective view of another working end of a resecting device showing a plurality of seals in the tissue extraction lumen and flow outlets for providing independent fluid flows distal of each seal to assist in expelling tissue through each seal.

FIG. 10 is a perspective view of another resecting device working end showing an independent fluid channel with a port proximate the window in the outer sleeve for suctioning tissue into the window.

DETAILED DESCRIPTION OF THE INVENTION

FIGS. 1, and 2A-2B illustrate a tissue resecting system 10 that includes a hand-held single-use tissue resection device 50. The device 50 has a handle portion 102 that is coupled to a shaft portion 105 having an outer diameter ranging from about 3 mm to 20 mm. The shaft portion 105 extends along axis 106 and can have a length suitable for introducing directly into a body space, for introducing through a trocar in a laparoscopic procedure or for introducing through a working channel of an endoscope. A hand-held device corresponding to the invention as depicted in FIGS. 1 and 2A-2B is adapted for laparoscopic resection procedures such as in a hysterectomy. FIG. 1 schematically illustrates the tissue resecting device 50 introduced through a trocar sleeve or port 52 in a body wall 54 to an insufflated working space 55, which, for example, can be an abdominal cavity. An endoscope 60 is introduced through a second port 62 to allow viewing of the tissue volume 65 targeted for resection and extraction. An additional port can be provided for a tissue grasping instrument (not shown) that may be used in the resection procedure. In another embodiment, a similar elongate resecting device can be configured for resecting tissue in other body tracts and spaces utilizing any type of endoscope to allow endoscopic viewing of the working space.

4

Referring to FIGS. 1, 2A-2B and 3, the resecting device 50 has a shaft portion 105 and working end 112 that comprises an assembly of a first or outer sleeve 115 extending along axis 106 to a distal end 116 having a window 118 therein for receiving tissue. A second or inner sleeve 125 with a distal blade edge 126 and distal opening 128 is dimensioned to reciprocate in bore 132 of outer sleeve 115. The outer and inner sleeves, 115 and 125, are typically fabricated of thin-wall stainless steel but any other suitable materials can be used. As can be understood from FIG. 4, reciprocation of the inner sleeve 125 will cut tissue captured in the window 118 of the outer sleeve. FIG. 4 shows the working end 112 or the assembly of outer sleeve 115 and inner sleeve 125 with the inner sleeve in a partially window-open position.

The resecting device 50 of FIGS. 1-2B includes subsystems operatively coupled to handle 102 and inner sleeve 125 to enhance the cutting and removal of tissue from a working space in the interior of a patient's body. FIG. 2A is a cut-away view of handle 102 of the resecting device showing outer sleeve 115 fixed to collar portion 160 of the handle. The handle 102 typically consists of a molded plastic two-part handle shell with a hollow interior. In one variation shown in FIGS. 1 and 2A, the reciprocable inner sleeve 125 extends partly through the interior of handle 102 and has a proximal sleeve end 162 that is received in bore 164 of cylindrical fixed member 165 that is fixed to support brackets 172 in shell 144 of handle 102. As will be described below, the inner sleeve 125 is reciprocated by DC electrical motor 148 in handle portion 102 (see FIGS. 2A-2B).

In one embodiment, the DC motor 148 is housed within the handle with motor shaft 185 having a pulley 186 that carries one or more flexible belts 188. The belts 188 can be fabricated of rubber, Viton® or a similar material and are adapted to rotate the cylindrical drive member 190 which in turn converts rotational motion to axial motion to thereby reciprocate the inner sleeve 125. A gear system instead of belts 188 also can be used to rotate the drive member 190. The drive member 190 is rotatable and secured in the handle 102 at rotation-permitting collars 192a and 192b at ends of the drive member. The inner sleeve 125 extends through the drive member 190 and has a projecting first pin 194 that engages the inner surfaces 195 of arcuate slot 196 in drive member 190. The DC motor is geared (together with pulleys 186 and 198) to rotate the drive member 190 at suitable speed to reciprocate the inner sleeve 125 within a range of 1 Hz to 10 Hz. The DC motor 148 has an electrical cable 202 extending to the controller 210 and a DC electrical source 215.

Referring to FIGS. 2A, 2B and 3, the resecting device 10 may be part of a system that includes a vibratory or ultrasound component 220 that is re-useable and removable from the resecting device 50. As can be seen in FIG. 3, the ultrasound component 220 has an elongate slot 222 therein that is configured to allow the component to slide axially over cylindrical fixed member 165 and the inner sleeve 125. Component 220 carries a vibrating mechanism such as at least one piezoelectric element 225 for applying vibratory motion to the inner sleeve 125 and more particularly to the distal blade edge 126 of the inner sleeve 125. In one variation shown in FIGS. 2A-3, three piezoelectric elements 225 are shown. An electrical source 235 is coupled to the piezoelectric elements 225 (see FIGS. 1 and 3) through electrical cable 236 and electrical leads (not shown) in the ultrasound component 220 to drive the piezoelectric elements. As can be seen in FIGS. 2A-3, the ultrasound component 220 has a J-lock 242 that engages second pin 244

of the inner sleeve 125 for securely locking the component 220 to the inner sleeve. The piezoelectric elements 225 are locked to inner sleeve 125 and are adapted to transmit energy to flange 238 of inner sleeve 125 and to its distal blade edge 126 (see FIGS. 2A-2B and 4). In one variation, the dimension between the piezoelectric element 225 and the distal blade edge 126 (see FIG. 4) of inner sleeve 125 is selected to optimize motion in the blade edge. The dimension D relates to the length of a standing wave caused by the piezoelectric element in the material of sleeve 125 as is known in that art of utilizing ultrasound to activate the working end of medical instruments. It should be appreciated that any suitable locking feature can be used to detachably couple the ultrasound component 220 to the inner sleeve 125 such as a threaded connector, a clamp, catches, magnets or the like. It should further be appreciated that independent electrical cable 236 that is directly coupled to the ultrasound component 220 can be eliminated. Instead, the electrical power for the ultrasound component 220 can be provided with electrical cable 202 and a slidable electrical contact (not shown) between handle 102 and the ultrasound component 220 can deliver current to the piezoelectric elements 225.

As can be seen in FIGS. 1, 2A-2B, and 4, the resecting device 10 may be part of a system that includes a negative pressure source 240 operatively coupled to a tissue extraction channel 252 in the device which is in part the passage-way in the inner sleeve 125. As can be understood from FIGS. 1 and 2A, a flexible outflow tube 254 can extend from the negative pressure source 240 to a quick-connect fitting 255 at the end of the fixed member 165. The tissue extraction channel 252 extends through inner sleeve 125 and handle 102 to the cylindrical fixed member 165 (FIG. 2A). In one variation, the negative pressure source 240 is a peristaltic pump but any other source such as hospital wall suction may be used. In another variation, the extraction channel 252 in the combination of inner sleeve 125 and fixed member 165 can transition from a smaller cross-section to a larger cross-section to facilitate the extraction of cut tissue chips. The controller 210 is adapted to control the negative pressure source 240 as indicated in FIG. 1. A tissue catch structure 258 is provided in outflow tube 254 to collect tissue chips.

In FIGS. 1, 2A-2B, and 4, it can be seen that the resecting device 10 may be part of a system that includes a fluid source 260 that includes positive pressure mechanism for providing a pressurized fluid flow through an inflow lumen 265 in the resecting device shaft 105 which is used to assist in applying pressure to expel captured tissue chips from the instrument's working end 112. In one variation, the fluid source 260 can comprise a reservoir containing saline solution and the pressurization mechanism can be a peristaltic pump. In another variation, the fluid source can be a hospital source of an insufflation gas such as CO₂. The fluid is delivered by tubing 268 to the quick-connect fitting 270 in handle 102. The flow pathway 272 in the quick-connect 270 extends through tubing 275 in the handle 102 to inflow lumen 265 in the shaft portion of the resecting device 50. As can be seen in FIG. 4, the inflow lumen 265 has a small cross section, e.g., a diameter from 0.05" to 0.25", and can be formed in the wall 276 of outer sleeve 115 or can be provided in a hypotube affixed to the outer sleeve 115. In one aspect of the invention, the inflow lumen 265 extends to an outlet 277 that is proximate to or distal to the window 118 to allow a fluid flow from the outlet in the window-closed position to apply proximally-directed fluid pressure on a tissue chip (not shown) captured in the extraction channel 252. In one

variation shown in FIG. 4, the inflow lumen 275 has a distal region 278 that includes a 180° turn to provide a flow from outlet 277 that is aligned with the axis 106 of the shaft 105.

Referring to FIGS. 2A-2B, the system further includes a sensor 285 in the handle that is adapted to determine the rotational position of drive member 190 and to send a signal to the controller 200 that indicates the drive member position. As can be easily understood from FIGS. 2A-2B and 4, the rotational position of drive member 190 determines the axial position of the inner sleeve and thus can indicate a fully window-open position, a window-closed position or any intermediate window-open position. In one embodiment, the sensor 285 is a Hall effect sensor that is actuated when a magnet 288 in the drive member 190 passes the sensor. In another variation, the sensor can be a mechanically-actuated switch that is actuated by an indent or projection carried by the drive member 190. In other embodiments, any sensor known in the art can be used and the sensor can be activated by either rotation of the drive member 190 or axial movement of the inner sleeve 125 in the handle 102.

Referring back to FIG. 1, the controller 210 of system 10 is adapted to receive signals from sensor 285 and in response can control operating parameters of the ultrasound transducer, the negative pressure source and the pressurized fluid source in relation to a window-open or window-closed position of the cutter. In one embodiment, a footswitch 290 is utilized to actuate the resecting device 50, but a finger-operated switch in the handle 102 also may be used (not shown). In one variation, the controller includes algorithms that activate the piezoelectric element 225 only when the inner sleeve 125 is moving forward or in distal direction from the fully window-open position to the window-closed position. In this variation, the piezoelectric element 225 is de-activated on the return or proximal stroke from the window-closed position to the window-open position. Thus, the ultrasonic or vibratory effect at the blade edge 126 of the inner sleeve 125 is only activated when tissue is being cut on the forward stroke of the inner sleeve.

Still referring to FIG. 1, the controller 210 can further control the pressurized fluid source 260 in response to signals from sensor 285 and the window-open or window-closed position of the inner sleeve 125. In one variation, the controller 210 has an algorithm that activates the fluid source 260 for a selected time interval only when the inner cutting sleeve 125 is in a fully window-closed position. Thus, at the moment the inner cutting sleeve 125 cuts and captures a tissue chip in the extraction channel 252, the controller 210 can provide a high pressure flow through the inflow lumen 275 and outlet 277 to push the tissue chip proximally in the extraction channel 252. In one embodiment, the controller 200 can have an algorithm that de-activates the motor 148 to thereby stop reciprocation of inner sleeve 125 in the window-closed position for a time interval to allow a longer pressurized flow from the fluid source 260 to push a captured tissue chip through the extraction lumen 252. For example, the inner sleeve 125 may be stopped for a time interval ranging from 0.1 second to 2 seconds.

Referring to FIG. 1, the controller 210 can include algorithms to modulate the negative pressure source 240 in response to signals from a sensor and the corresponding window-open or window-closed condition of the resecting device. In one variation of working end 112 shown in FIG. 5, the at least one sensor 302 is provided proximate the window 118 to sense tissue contact with the window. For example, the sensor 302 can be a capacitance sensor that is configured to send a signal to the controller when the sensor

contacts tissue. It can be easily understood that the capacitance reading from the sensor **302** when in contact with tissue would differ greatly from a capacitance reading in the absence of tissue contact. Any similar type sensor **302** could be used, such as an impedance sensor, pressure sensor and the like. As can be seen in FIG. 6, another variation of working end **212'** can have a plurality of sensors **302** and **304** and can be used to modulate the negative pressure source **240**. In one variation, the controller **210** can activate the negative pressure source **240** only when a sensor **302** and/or **304** (FIGS. 5 and 6) is in contact with tissue which then provides suction force to suction tissue into the window **118**. At other times, for example when the physician is repositioning the working end relative to tissue targeted for resection, the negative pressure source **240** would be deactivated to thus prevent insufflation gas from being withdrawn from the working space **55** (see FIG. 1).

In another aspect of the invention, the controller **210** can include an algorithm adapted to move the inner cutting sleeve **125** to a predetermined position relative to the window **118** each time the physician de-activates the device. In one variation, when the physician lifts his or foot from the footswitch, or lifts finger from a trigger, a "stop-reciprocation" signal is sent to controller **210** which in turn determines the location of the inner sleeve **125** relative to the window **118** by means of a timer and the next signal (or previous signal) from the position sensor **285** that determines the rotational position of drive member **190**. The controller **210** then can calculate the time interval needed to stop the drive member **190** and sleeve **125** at a predetermined location based on a library of known time intervals following de-activation of the motor **148** to allow the inner sleeve **125** to coast (overcome momentum) to the predetermined position. In one embodiment, the predetermined position can be a fully window-open condition, which would then allow the physician to position the open window **118** against the targeted tissue to commence resection. In one variation, the edge of window **118** and the tissue-contact sensor **302** would contact tissue which then cause the controller **210** to activate the negative pressure source **240** to suction tissue into the window and also actuate reciprocation and the piezoelectric elements **225**. It should be appreciated that the controller algorithm may be programmed to activate the negative pressure source **240** and reciprocation simultaneously or the reciprocation may be actuated in a sequence, for example 0.1 seconds to 2 seconds after the negative pressure. Alternatively, the device may be provided with a two stage trigger, with a first trigger actuation movement activating the negative pressure source and an additional second trigger movement activating the reciprocation and piezoelectric element **225**.

Referring back to FIGS. 3 and 4, it can be seen that the piezoelectric elements **225** are configured to cause axial motion in the distal end of the inner sleeve **125**. In another variation, the piezoelectric elements can be oriented to cause rotational motion in a keyed flange **138** (see FIGS. 2A-2B) to rotationally vibrate the blade edge **126** of the inner sleeve. In another variation, a plurality of piezoelectric elements can be provided to cause both axial and rotational motion in the distal end of the inner sleeve. Such motion can be sequential or contemporaneous. The blade edge **126** can have any suitable configuration such as being smooth or having teeth, etc.

FIG. 7 illustrates another variation of a working end **405** corresponding to the invention in which an inner sleeve **410** is configured to rotate relative to outer sleeve **415** rather than reciprocating as in the embodiment of FIGS. 1-5. It can be

easily understood that a handle similar to that of FIG. 2A can use an appropriately geared motor to rotate the inner sleeve **415** at a selected speed or rotate the sleeve **415** sequentially in clockwise and counter-clockwise directions. Contemporaneously, the at least one piezoelectric element can be used to vibrate the inner sleeve **415** in the manner described previously. As can be seen in FIG. 7, the window **418** of inner sleeve **415** has sharp teeth **422** at its edge **424**, and the combination of rotation and ultrasonic or vibratory movement of edge **424** will assist in cutting or sawing tougher tissues. In one variation, the controller can include an algorithm that will sequentially rotate the inner sleeve from a window-open start position in clockwise direction from 5° to 30°, then back past the start position and then 5° to 30°, in a counter-clockwise direction followed by one or more increased sequential angular rotation to cut a tissue chip. After successive cutting by such sequential rotations, the inner sleeve **415** can be rotated to the fully window closed position to capture the tissue in the extraction lumen **440** of the inner sleeve. In one variation, an inflow channel **265** as shown in FIG. 4 can be provided in the device of FIG. 7 to allow proximally directed fluid flow to push the tissue chip in the proximal direction in the extraction channel.

In general, the controller **210** can control all operating parameters of the ultrasound component, the motor drive that reciprocates or rotates the inner sleeve, the negative pressure source and the pressurized fluid source, as well as responding to signals from sensors to provide sequential actuation of different component as well as to provide interlocks between various operations and functions of the resecting devices and systems of the present invention.

FIGS. 8A-8F illustrate another resecting device **500** of the invention that has a working end **512** including an outer sleeve **515** with window **518** and a reciprocating, ultrasound-actuated inner cutting sleeve **525**. The resecting device **500** has at least one deformable seal **540** or valve in the tissue extraction channel **544** which allows a cut tissue chip to pass thru the seal **540**. The seal **540** is configured to close to its repose state to prevent the loss of insufflation gas after tissue passes through the seal. More in particular, FIGS. 8A-8F schematically illustrate one variation of resecting device **500** and a sequence of operating the pressurized fluid source **260** and the negative pressure source **240** to assist in cutting and extraction of tissue chips in a laparoscopic procedure.

In FIG. 8A, the working end **512** of the resecting device is positioned so that the window **518** is in contact with a targeted tissue volume **545**. As described above, the controller **210** has algorithms that stop the inner sleeve in a window-open position of FIG. 8A. At this point in time, none of the operational mechanisms (ultrasound component, motor drive, negative pressure source and pressurized fluid source) are activated, thus no insufflation gas is lost through the device. The insufflation pressure is maintained automatically by an independent insufflator system as is known in the art. In one variation, the physician then partially actuates a trigger switch **290** (see FIG. 1) which signals the controller **210** to activate the negative pressure source **240**. In FIG. 8A, the negative pressure source thus suctions a portion of the targeted tissue **545** into the window **518**. In FIG. 8B, the physician further actuates the trigger switch **290** which maintains activation of the negative pressure source **240** and activates the motor **148** (FIG. 2B) to cause reciprocation of the inner sleeve **525** and simultaneously activates the ultrasound component. As can be seen in FIG. 8B, the distal movement of the inner sleeve **525** begins to cut tissue. FIG. 8C illustrates the inner sleeve **525** at the distal end of its

stroke which captures a tissue chip 548 in the extraction channel 544 of the inner sleeve.

In FIG. 8D, the position of inner sleeve 525 at the distal end of its stroke can cause a controller algorithm to optionally terminate the ultrasound component and optionally halt reciprocation for a brief interval as described above. With the inner sleeve 525 in the window closed position in FIG. 8D, the controller 210 causes the fluid source 260 to provide a high pressure fluid flow through first inflow channel 552 and outward from outlet 555 to thus push the tissue chip 548 through the seal 540 in extraction channel 544 as depicted in FIG. 8E. The controller 210 can control the fluid volume, pressure and duration of the flow to optimize the expulsion of the tissue chip through the seal 540. An instant after the fluid flow has applied proximally-directed forces to the tissue chip, FIG. 8E shows the controller has activated the motor 148 to thereby move the inner sleeve 525 to the window open position.

FIG. 8F illustrates another step in the sequence of resecting tissue wherein the controller 210 causes the fluid source 260 to provide another high pressure fluid flow through a second inflow channel 562 and outward from outlet 565 to push tissue chip 548 further outward (proximally) through the extraction channel 544. It can be seen that the inflow channel 562 is within wall of outer sleeve 515 which has an outlet 568 that is aligned with port 565 in the inner sleeve 525 to thus permit a high pressure flow to reach the extraction channel 544 in the inner sleeve. In order to provide the fluid flows sequentially through the first inflow channel 552 and then the second inflow channel 562, the controller 210 can control solenoid valves 570a and 570b as shown schematically in FIGS. 8A-8F. Following the step of using the fluid flow to expel tissue as depicted in FIG. 8F, the sequence of steps 8A-8F can automatically be repeated to rapidly resect the targeted tissue volume. It should be appreciated that the inner sleeve 525 may reciprocate at a constant rate and the controller 210 can actuate the fluid source 260 at selected intervals to provide the sequential fluid flows through the first and second inflow channels 552 and 562. Further, the system can be configured to cause the pressurized fluid flow through the second inflow channel 562 with the inner sleeve 525 in any axial position relative to window 518.

In another variation, referring to FIG. 9, the inner sleeve 525 may be configured with a plurality of seals, for example seals 540 and 540' with inflow ports 565 and 565' (which can be elongated slots) to allow for a plurality of flow pulses in different axial locations to push and expel tissue chips through the extraction channel 544. The flow pulses can be contemporaneous or sequential through inflow ports 565 and 565' from a single inflow channel 562 and outlets 568 and 568' or can be sequenced through a plurality of independent inflow channels each in communication with an inflow ports 565 and 565'. In various embodiments, the number of seals 540 and corresponding inflow ports 565 can range from 1 to 10.

In any embodiment, the passageway seal 540 can be any type of flexible leaflet-type seal, hinged-door seal, duckbill-type seal or the like that is adapted to close the passageway in a repose condition.

FIG. 10 illustrates another resecting device 570 that is similar to that of FIGS. 8A-8F except that outer sleeve 515 carries an independent passageway 575 coupled to negative pressure source 240 that is controlled independently by controller 210 to provide suction forces in the interior of window 518. More in particular, the independent passage-

way 575 in outer sleeve 515 extends to a distal opening 577 in a distal region of the bore 580 of sleeve 515 proximate window 518. Thus, the controller 210 can actuates the negative pressure source 240 to suction tissue into the window independent of suction force provided through the tissue extraction channel 544 of the inner sleeve 525. Further, the controller 210 can use an algorithm to modulate suction pressure through passageway 575 and opening 577 during different portions of the stroke of the inner sleeve 515 to optimize suction for pulling tissue into the window and to minimize loss of insufflation gas. The controller 210 can operate solenoid valves 590a and 590b to control negative pressure in the channels 544 and 575. In one variation, the inner sleeve 515 can have a slot or notch 585 that is axially aligned with opening 577 so that the opening is not covered by the inner sleeve 515 during a distal region of the sleeve's reciprocation. Thus, suction forces can be applied to tissue throughout reciprocation of the inner sleeve 515.

In the various embodiments described above, the inflows from fluid source have been described as any suitable fluid or flow media. It should be appreciated the flow media can be a liquid (e.g., saline or sorbital) or a gas such as CO₂. Either a liquid or gas can be used to assist in expelling tissue, with each having its advantages. The use of an incompressible liquid could apply greater expelling forces to a captured tissue chip. The use of an insufflation gas can reduce the complexity of the system. In a variation, the system could use a gas media to expel a just-cut tissue chip from the region of the window through the seal 540 in the step shown in FIG. 8D and then use a liquid flow in the step depicted in FIG. 8F. In such a variation, pulse liquid flows can operate continuously or intermittently during operation of the device.

It should be appreciated that the features described in the system embodiments of FIGS. 8A-10 including seals 540 and independent suction passageway 570 can be provided in a "rotating" inner cutting sleeve as illustrated in FIG. 7.

In another variation, a plurality of piezoelectric element can each be coupled to a separate elongated member or component that is a part of an assembly that comprises the reciprocating or rotating cutting sleeve. Thus each piezoelectric element can drive a member that has a selected length to cooperate with a standing wave in the material caused by the piezoelectric element to optimize the tissue effect at the distal end of the cutting sleeve. Each elongated member can have an axial or spiral configuration.

Although particular embodiments of the present invention have been described above in detail, it will be understood that this description is merely for purposes of illustration and the above description of the invention is not exhaustive. Specific features of the invention are shown in some drawings and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. A number of variations and alternatives will be apparent to one having ordinary skills in the art. Such alternatives and variations are intended to be included within the scope of the claims. Particular features that are presented in dependent claims can be combined and fall within the scope of the invention. The invention also encompasses embodiments as if dependent claims were alternatively written in a multiple dependent claim format with reference to other independent claims.

11

What is claimed is:

1. A method for cutting tissue, said method comprising:
providing a cutting sleeve;
actuating a first ultrasound transducer operatively coupled
to the cutting sleeve to cause at least one of axial and
rotational oscillatory motion in a distal end of the
cutting sleeve;
advancing the distal end of the cutting sleeve through
tissue to cut said tissue; and
actuating a second ultrasound transducer operatively
coupled to the cutting sleeve to cause the other of axial
and rotational oscillatory motion in the distal end of the
cutting sleeve.
2. The method of claim 1 wherein advancing the cutter
sleeve comprises reciprocating said sleeve.
3. The method of claim 2 wherein advancing the cutter
sleeve further comprises rotating the cutter sleeve.
4. The method of claim 3 wherein the cutting sleeve is
reciprocated and rotated within an outer sleeve past a
window in the outer sleeve, wherein the tissue to be cut has
been drawn into the window by a negative pressure.
5. The method of claim 4 wherein the negative pressure
extracts tissue through a lumen in the cutting sleeve.
6. The method of claim 4 wherein the cutting sleeve is
reciprocated at a reciprocation rate between 1 and 10 Hz.
7. The method of claim 4 wherein reciprocating and/or
rotating the cutting sleeve comprises driving the sleeve with
a motor drive.
8. The method of claim 7 further comprising controlling
operating parameters of the ultrasound transducer(s), the
motor drive, the negative pressure source with a controller.
9. The method of claim 8 further comprising sending
signals from sensors to the controller indicating a position of
the cutting sleeve relative to the window in the outer sleeve.
10. The method of claim 9 wherein the controller modu-
lates activation of the ultrasound transducer(s) in response to
the sensor signals that indicate the position of the inner
sleeve.
11. The method of claim 10 wherein the controller acti-
vates the ultrasound transducer when the cutting sleeve
moves toward a window-closed position to cut tissue and
de-activates the ultrasound transducer when the cutting
sleeve moves toward a window-open position.
12. The method of claim 8 wherein the controller activates
a pressurized fluid source when the inner sleeve is in a
window-closed position.
13. The method of claim 12 wherein the controller de-
activates the pressurized fluid source when the inner sleeve
is in a window-open position.
14. The method of claim 12 wherein the pressurized fluid
source comprises a liquid source.
15. The method of claim 12 wherein the pressurized fluid
source comprises a gas source.

12

16. A method for cutting tissue, said method comprising:
providing a cutting sleeve;
actuating a first ultrasound transducer operatively coupled
to the cutting sleeve to cause at least one of axial and
rotational oscillatory motion in a distal end of the
cutting sleeve; and
advancing the distal end of the cutting sleeve through
tissue to cut said tissue;
wherein advancing the cutter sleeve comprises recipro-
cating and rotating said sleeve within an outer sleeve
past a window in the outer sleeve, wherein the tissue to
be cut has been drawn into the window by a negative
pressure.
17. The method of claim 16 further comprising actuating
a second ultrasound transducer operatively coupled to the
cutting sleeve to cause the other of axial and rotational
oscillatory motion in the distal end of the cutting sleeve.
18. The method of claim 16 wherein the negative pressure
extracts tissue through a lumen in the cutting sleeve.
19. The method of claim 16 wherein the cutting sleeve is
reciprocated at a reciprocation rate between 1 and 10 Hz.
20. The method of claim 16 wherein reciprocating and/or
rotating the cutting sleeve comprises driving the sleeve with
a motor drive.
21. The method of claim 20 further comprising control-
ling operating parameters of the ultrasound transducer(s),
the motor drive, the negative pressure source with a con-
troller.
22. The method of claim 21 further comprising sending
signals from sensors to the controller indicating a position of
the cutting sleeve relative to the window in the outer sleeve.
23. The method of claim 22 wherein the controller modu-
lates activation of the ultrasound transducer(s) in response to
the sensor signals that indicate the position of the inner
sleeve.
24. The method of claim 23 wherein the controller acti-
vates the ultrasound transducer when the cutting sleeve
moves toward a window-closed position to cut tissue and
de-activates the ultrasound transducer when the cutting
sleeve moves toward a window-open position.
25. The method of claim 21 wherein the controller acti-
vates a pressurized fluid source when the inner sleeve is in
a window-closed position.
26. The method of claim 25 wherein the controller de-
activates the pressurized fluid source when the inner sleeve
is in a window-open position.
27. The method of claim 25 wherein the pressurized fluid
source comprises a liquid source.
28. The method of claim 25 wherein the pressurized fluid
source comprises a gas source.

* * * * *

专利名称(译)	腹腔镜装置		
公开(公告)号	US10517578	公开(公告)日	2019-12-31
申请号	US15/488270	申请日	2017-04-14
申请(专利权)人(译)	HERMES的创新, LLC		
当前申请(专利权)人(译)	HERMES INNOVATIONS LLC		
[标]发明人	TRUCKAI CSABA		
发明人	TRUCKAI, CSABA		
IPC分类号	A61B17/22 A61B17/00 A61B17/32 A61B17/3203 A61B90/00		
CPC分类号	A61B17/32002 A61B17/00234 A61B17/320068 A61B2017/00022 A61B2017/00973 A61B2017/22027 A61B2017/00039 A61B2090/065 A61B2217/005 A61B17/3203 A61B2017/22079 A61B2017/32007 A61B2017/320028 A61B2017/00477 A61B2017/00026		
代理机构(译)	WILSON SONSINI盈丰 & ROSATI		
优先权	61/891288 2013-10-15 US		
其他公开文献	US20170215912A1		
外部链接	Espacenet		

摘要(译)

一种医疗器械，包括沿轴线延伸的管状切割器，该管状切割器具有开窗的外套筒和可移动的内切套。超声换能器可操作地耦合到内部切割套筒，以便在内部切割套筒中引起运动，以在内部切割套筒往复运动或以其他方式移动通过切割窗口时增强内部切割套筒对组织的切割或切除。器械通常将包括电动机驱动器，该电动机驱动器构造成通常以1Hz至10Hz之间的往复运动速率使内切割套筒相对于开窗的外部套筒往复运动和/或旋转。

