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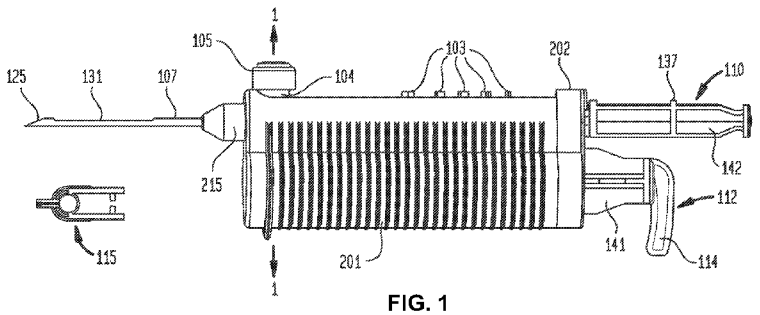


FIG. 1

(57) Abstract: A disposable biopsy device includes a vacuum generating assembly generating a vacuum. The disposable biopsy device also includes a tissue cutting assembly including a hollow outer needle having a longitudinal axis and an inner cutter needle positioned within the hollow outer needle. The tissue cutting assembly is pneumatically coupled to the vacuum assembly such that the vacuum drives a cutting motion of the inner cutter needle along the longitudinal axis of the hollow outer needle.

DISPOSABLE BIOPSY DEVICES AND METHODS OF OBTAINING TISSUE BIOPSY SAMPLES USING SAME

Cross-Reference to Related Applications

The present application is an international (PCT) application claiming priority to U.S. Patent Application Serial No. 14/558,273, entitled "DISPOSABLE BIOPSY DEVICES AND METHODS OF OBTAINING TISSUE BIOPSY SAMPLES USING SAME," filed December 2, 2014; to U.S. Provisional Application Serial No. 62/192,047, entitled "DISPOSABLE BIOPSY DEVICES AND METHODS OF OBTAINING TISSUE BIOPSY SAMPLES USING SAME," filed July 13, 2015; and to U.S. Patent Application Serial No. 14/590,214, entitled "DISPOSABLE BIOPSY DEVICES AND METHODS OF OBTAINING TISSUE BIOPSY SAMPLES USING SAME," filed January 6, 2015 (now U.S. Patent No. 9,078,640). The disclosures of the aforementioned patent applications and patent are incorporated herein by reference in their entireties.

Field of the Invention

The exemplary embodiments generally relate to biopsy devices and methods of obtaining a tissue biopsy with the biopsy devices.

Background of the Invention

A biopsy is a procedure to remove tissue from a patient for diagnostic examination that may involve taking a tissue sample and/or body fluid from a patient. Tests performed on the resulting tissue specimen can provide information for diagnosis of the patient's condition.

Biopsy samples have been obtained in a variety of ways in various medical procedures using a variety of devices. Biopsy devices may be used under stereotactic guidance, ultrasound guidance, magnetic resonance imaging (MRI) guidance, or otherwise. Exemplary biopsy devices include, without limitation, needle-based biopsy guns: for example, vacuum-assisted biopsy devices, fine needle aspiration biopsy devices (FNAB), and core needle biopsy devices; disposable and reusable biopsy needles; and biopsy forceps: general biopsy forceps and hot biopsy forceps, etc.

A biopsy may be obtained by an open or percutaneous technique. Open biopsy typically is an invasive surgical procedure which removes an entire mass or a part of the mass after an excision (denoting surgical removal of part or all of a structure) / incision (denoting surgical wound; a division of the soft parts usually made with a knife) is made. Percutaneous (denoting the passage of substances through unbroken skin and passage through the skin by needle puncture) biopsy is less invasive and usually is done with a needle-like instrument to collect a biopsy sample, for example, a fine needle aspiration (FNA) or a core biopsy. A FNA biopsy, which normally can be obtained for cytologic examination, generally includes individual cells or clusters of cells without preserving the histological architecture of the tissue cells. A core biopsy is a biopsy obtained for histologic examination in which a cylindrical sample of tissue is obtained using a hollow needle. The type of biopsy tools to be used depends on the circumstances. Typically, a core biopsy is used more frequently by the medical profession.

Methods and apparati for automated biopsy and collection of soft tissue are known. Many are cumbersome and not intended for disposable use. Methods that employ a vacuum chamber cannula to draw tissue into a receiving port where the

vacuum chamber defines at least one, usually multiple, communicating holes between the chamber and the outer cannula, for example, are problematic in that these small holes often become clogged with blood and bodily fluids, such that the fluids occlude the holes and prevent the aspiration from drawing the tissue into the receiving port. This ultimately prevents a core from being obtained, a condition called a “dry tap.” In addition, because many of the components of current biopsy devices are reusable, such as the driver portions, which control the outer and inner cutter needles, this can pose several disadvantages, for example, (1) the reusable portion must be cleaned and/or sterilized, which increases the time necessary to wrap up the procedure, which ultimately affects the cost of the procedure; (2) the required clean-up and/or sterilization of reusable parts increases the staffs’ potential exposure to body tissues and fluids; (3) the reusable handle is heavy, large and cumbersome for handheld use.

A variety of biopsy needles and guns have been described and used for obtaining tissue specimens. In biopsy needles and guns that employ a manual vacuum generation mechanism, the mechanism often is complex, cumbersome, potentially expensive, and not disposable.

Most currently available biopsy devices involve complex mechanism, and thus are not intended to be disposable. Some of them rely on electric power to drive the motors for cutting and to establish a vacuum. Although some of the automated or manually actuated biopsy guns contain a disposable needle (stylus or cannula), replacing the disposable stylus or cannula can be troublesome and can pose a potential danger because this action exposes persons handling the needles to danger of

infection. Also, in case the tissue touches other parts of the device, it could also expose the next patient or the medical professional to a potential health hazard.

In light of the foregoing disadvantages, a need exists for a disposable vacuum-assisted biopsy device which is simple, lightweight, portable, and cost effective to manufacture and dispose of.

Summary of the Invention

According to one aspect, the described invention provides a disposable biopsy device comprising: (A) a tissue cutting assembly comprising: an outer needle including a tissue receiving slot at a distal end of the outer needle; an elongated tube; an inner cutter needle including a tissue receiving port at a distal end of the inner cutter needle; a first plunger; and a first stopper; wherein (i) the outer needle is attached to a distal end of the tube; (ii) the inner cutter needle is attached to a distal end of the first plunger; (iii) the inner cutter needle and the first plunger are coaxially positioned within the tube and capable of rotating about and translating along the longitudinal axis of the tube; (iv) the inner cutter needle is coaxially positioned within the outer needle and capable of rotating about and translating along the longitudinal axis of the outer needle; (v) the first stopper is attached to or connected to a proximal end of the tube; and (B) a vacuum assembly comprising: an elongated cylinder; a second plunger; and a second stopper; wherein (i) the second plunger is coaxially disposed within the cylinder and capable of rotating about and translating along the longitudinal axis of the cylinder; and (ii) the second stopper is attached to or connected to a proximal end of the cylinder; wherein

the vacuum assembly and the cutting assembly are two separate compartments in fluid communication through one or more air holes in between.

According to one embodiment of the disposable biopsy device, the tube has one or more air path holes on the bottom surface, the cylinder has one or more air path holes on the top surface and the inner cutter needle has one or more holes near its proximal end such that the vacuum generated by pulling the second plunger creates a low pressure region near the tissue receiving slot. According to another embodiment, the tube has an air release hole on a top surface of the tube for releasing the vacuum. According to another embodiment, the first plunger and the first stopper are configured to mate, thereby controlling a length of tissue to be severed from a tissue mass; and the second plunger and the second stopper are configured to mate, thereby controlling vacuum levels. According to another embodiment, the tube has a cutting length indicator which has numerical indicia corresponding to the length of tissue to be separated from the tissue mass. According to another embodiment, the first plunger comprises a plunger rod, one or more ridges, and one or more notches on the plunger rod, the first plunger together with the first stopper controlling the length of tissue to be severed. According to another embodiment, the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, a plurality of ridges disposed at predetermined positions across adjacent raised edges, and a plurality of notches in front of or behind the ridges, the first plunger together with the first stopper controlling the length of tissue to be severed. According to another embodiment, the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined position across adjacent raised edges,

wherein the first stopper is configured to engage the ridge on the first plunger, thereby stopping the plunger from moving forward and controlling the length of tissue. According to another embodiment, the first plunger has a plurality of notches thereon which allow the first plunger to be rotated, which disengages the first stopper and allows the first plunger to move further backward or forward. According to another embodiment, the second plunger comprises a plunger rod, and one or more ridges, and one or more notches on the plunger rod, the second plunger together with the second stopper controlling the vacuum levels. According to another embodiment, the second plunger and the second stopper work together to control the vacuum levels, the second plunger comprising a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined position across adjacent raised edges, which when engaged, the second stopper stops the forward or backward movement of the plunger, and a plurality of notches in front of or behind the ridges, which allow the plunger to freely rotate, so that the second stopper is disengaged and the plunger is allowed to move forward or backward. According to another embodiment, the second plunger comprises a plunger rod, a plurality of raised edges projecting laterally therefrom, and a plurality of notches breaking the raised edges, and the second stopper is configured to interlock the raised edge of the plunger and restrict the plunger from rotating freely, while the notches allow the plunger to rotate and disengage the second stopper. According to another embodiment, the sample receiving slot has saw teeth thereon along its lateral sides, which hold the tissue tightly prior to and at the time that the inner cutter needle advances to cut the prolapsed tissue from the tissue mass. According to another embodiment, the disposable biopsy device further comprises a

sample collector, which grasps the severed tissue sample out of the inner cutter needle such that the tissue sample is securely handled. According to another embodiment, the disposable biopsy device further comprises a shell that closely encloses the tube and cylinder. According to another embodiment, the disposable biopsy device further comprises a silicone fitting on top of the air release hole that seals the air release hole when pressed and releases the vacuum inside the biopsy device when released. According to another embodiment, the distal end of the outer needle is open and sharp such that it is easy to insert into the tissue. According to another embodiment, the distal end of the inner cutter needle is open, beveled in shape, and contains a razor sharp edge that is effective to slice the tissue prolapsed into the tissue receiving slot and collect the severed tissue in its tissue receiving port. According to another embodiment, the first and second stoppers are continued as one unit or are two separate units.

According to another aspect, the described invention provides a method for obtaining a tissue sample for biopsy examination using a disposable hand held biopsy device, the method comprising: (a) providing a disposable biopsy device, the device comprising: (i) a tissue cutting assembly comprising: an outer needle comprising a tissue receiving slot at a distal end of the outer needle and saw teeth along lateral sides of the tissue receiving slot; an elongated tube comprising an air release hole and a cutting length indicator on a top surface of the tube; an inner cutter needle comprising a tissue receiving port at a distal end of the inner cutter needle; a first plunger; a first stopper; a silicone fitting on top of the air release hole; and a tissue sample collector; wherein (i) the outer needle is attached to a distal end of the tube (ii) the inner cutter needle is attached to a distal end of the first plunger (iii) the inner cutter needle and the

first plunger are coaxially positioned within the tube and capable of rotating about and translating along the longitudinal axis of the tube, (iv) the inner cutter needle is coaxially positioned within the outer needle and capable of rotating about and translating along the longitudinal axis of the outer needle, and (v) the first stopper is attached to or connected to a proximal end of the tube; and (ii) a vacuum assembly comprising: an elongated cylinder; a second plunger; and a second stopper; wherein (i) the second plunger is coaxially disposed within the cylinder and capable of rotating about and translating along the longitudinal axis of the cylinder; (ii) the second stopper is attached to or connected to a proximal end of the cylinder; wherein the vacuum assembly and the cutting assembly are two separate compartments in fluid communication through one or more air holes in between; and (b) placing the outer needle at a location of collecting sample tissue; (c) covering the air release hole; (d) withdrawing the second plunger, rotating the plunger, and locking the plunger in place; (e) pulling the first plunger backward such that its distal end is aligned with one of the numerical indicia on the cutting length indicator corresponding to a desired tissue length, exposing the tissue receiving slot on the outer needle so that the tissue prolapses into the sample receiving slot and is held tight by the vacuum and the saw teeth along the tissue receiving slot; (f) releasing the first plunger and the attached inner cutter needle, which are then propelled by a gradient pressure to advance into the tissue receiving slot and sever the tissue, which has prolapsed into the sample port, and stops when it hits the first stopper; (g) allowing the air flow into the biopsy device, releasing the vacuum; (h) pulling the biopsy device out from the body; and (i) once outside the body, (1) turning the first plunger clockwise until it stops; (2) pushing the first plunger all the way forwards; (3) grasping

the severed tissue sample using the sample collector; and (4) pulling the severed tissue out from the distal end of the inner cutter needle.

According to one embodiment of the method, in step (a), the tube has one or more air path holes on the bottom surface, the cylinder has one or more air path holes on the top surface and the inner cutter needle has one or more holes near its proximal end, such that the vacuum generated by pulling the second plunger creates the low pressure region near the tissue receiving slot. According to another embodiment, in step (a), the first plunger and the first stopper are configured to mate thereby controlling the length of the tissue to be severed from the tissue mass; and the second plunger and the second stopper are configured to mate thereby controlling the vacuum levels. According to another embodiment, in step (a), the first plunger comprises a plunger rod, one or more ridges, and one or more notches on the plunger rod, the first plunger together with the first stopper controlling the length of tissue to be severed. According to another embodiment, in step (a), the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, a plurality of ridges disposed at predetermined position across adjacent raised edges, and a plurality of notches in front of or behind the ridges, the first plunger together with the first stopper controlling the length of tissue to be severed. According to another embodiment, in step (a), the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined position across adjacent raised edges, wherein the first stopper is configured to engage the ridge on the first plunger, thereby stopping the plunger from moving forward whereby controlling the tissue length. According to another embodiment, in step (a), the first plunger comprises

a plurality notches thereon, which allow the first plunger to be rotated, thereby disengaging the first stopper and allowing the first plunger to move further backward or forward. According to another embodiment, in step (a), the second plunger comprises a plunger rod, one or more ridges, and one or more notches on the plunger rod, the second plunger together with the second stopper controlling the vacuum levels. According to another embodiment, in step (a), the second plunger and the second stopper work together to control the vacuum levels, the second plunger comprising a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined positions across adjacent raised edges, which when they engage the second stopper stops the forward or backward movement of the plunger, and a plurality of notches in front of or behind the ridges, which allow the plunger to freely rotate thereby disengaging the second stopper and allowing the plunger to move forward or backward. According to another embodiment, in step (a), the second plunger comprises a plunger rod, and a plurality of raised edges projecting laterally therefrom, wherein the second stopper is configured to interlock the raised edge of the plunger, restricting the plunger from rotating freely, and the plunger has a plurality of notches allowing the plunger to rotate and disengage the second stopper. According to another embodiment, in step (a), the disposable biopsy device further comprises a shell that closely encloses the tube and cylinder. According to another embodiment, in step (a), the distal end of the outer needle is open and sharp such that it is easy to insert into the tissue. According to another embodiment, in step (a), the distal end of the inner cutter needle is open, beveled in shape, and contains a razor sharp

edge, the distal end of the inner cutter needle slicing the tissue prolapsed into the tissue receiving slot and collecting the severed tissue in its tissue receiving port.

In an embodiment, a disposable biopsy device includes a vacuum generating assembly generating a vacuum. The disposable biopsy device also includes a tissue cutting assembly including a hollow outer needle having a longitudinal axis and an inner cutter needle positioned within the hollow outer needle. The tissue cutting assembly is pneumatically coupled to the vacuum assembly such that the vacuum drives a cutting motion of the inner cutter needle along the longitudinal axis of the hollow outer needle.

In an embodiment, the vacuum generating assembly includes a cylinder having a proximal end and a distal end opposite the proximal end. The vacuum generating assembly includes a plunger disposed within the cylinder such that motion of the plunger toward the proximal end of the cylinder generates a vacuum. In an embodiment, the hollow outer needle has a proximal end, a distal end opposite the proximal end, and a tissue receiving slot in the distal end. The inner cutter needle has a proximal end and a distal end opposite the proximal end and is capable of moving along the longitudinal axis. The cutting motion of the inner cutter needle is in a direction away from the proximal end of the outer needle and toward the distal end of the outer needle.

In an embodiment, the outer needle includes a tissue receiving slot adjacent the distal end of the outer needle. The longitudinal movement of the inner cutter needle selectively opens and selectively closes the tissue receiving slot. In an embodiment, the vacuum generating assembly is pneumatically coupled to the tissue cutting assembly such that, when the outer needle is placed at a location of a tissue sample and the tissue receiving slot is opened, the vacuum draws the tissue sample into the

tissue receiving slot. In an embodiment, the vacuum generating assembly further includes an air release hole for releasing the vacuum.

In an embodiment, the tissue cutting assembly includes a cutting tube having a longitudinal axis and a cutting plunger disposed within the cutting tube and movable along and about the longitudinal axis of the cutting tube. The cutting plunger has a proximal end and a distal end opposite the proximal end. The inner cutter needle is affixed to the distal end of the cutting plunger. The tissue cutting assembly also includes a shell defining said cutting tube and a trigger attached to the shell. The trigger is movable between an open position that allows movement of the cutting plunger along the longitudinal axis of the cutting tube to thereby allow the cutting motion of the inner cutter needle, and a closed position that prevents movement of the cutting plunger along the longitudinal axis of the cutting tube to thereby prevent the cutting motion of the inner cutter needle.

In an embodiment, the trigger includes a plurality of clips and the shell includes a plurality of slots formed therein. Each of said plurality of slots receives a corresponding one of the plurality of clips of the trigger, and further is sized, shaped and positioned so as to restrict movement of the trigger other than between the open position and the closed position. In an embodiment, the cutting plunger includes a plurality of tabs located between the proximal end and the distal end of the cutting plunger. The shell includes a plurality of protrusions. The trigger includes a plurality of protrusions sized, shaped, and positioned such that, when one of the plurality of tabs of the cutting plunger is aligned with the plurality of protrusions of said trigger, positioning of the trigger in the open position places the cutting plunger in a position such that the plurality of

protrusions of the shell do not restrict movement of said plurality of tabs and positioning of the trigger in the closed position places the cutting plunger in a position such that at least one of the plurality of protrusions of the shell restricts movement of the plurality of tabs. In an embodiment, the disposable biopsy device also includes an adapter constructed so as to be removably mounted on one of the plurality of tabs of the cutting plunger. The cutting plunger is movable between proximal and distal positions for creating the cutting motion of the inner cutter needle. The adapter is configured to define the proximal position of the cutting plunger.

In an embodiment, the trigger is rotatably mounted to the shell so as to move between the open position and the closed position. In an embodiment, the disposable biopsy device also includes a device removably mounted to the shell and having a pointed end for removing a tissue sample from the inner cutter needle. In an embodiment, the cylinder of the vacuum generating assembly includes a stopper proximate to the proximal end of the cylinder. The plunger of the vacuum generating assembly includes a plurality of ridges. The ridges selectively cooperate with the stopper to control an intensity of the vacuum.

In an embodiment, a method for obtaining a tissue sample includes providing a disposable biopsy device. The disposable biopsy device includes a vacuum generating assembly including a cylinder having a proximal end and a distal end opposite the proximal end. The vacuum generating assembly also includes a plunger disposed within the cylinder such that motion of the plunger toward the proximal end of the cylinder generates a vacuum. The disposable biopsy device also includes a tissue cutting assembly having a hollow outer needle including a proximal end, a distal end

opposite the proximal end, a longitudinal axis, and a tissue receiving slot at the distal end. The tissue cutting assembly also includes an inner cutter needle having a proximal end and a distal end opposite the proximal end. The inner cutter needle is coaxially positioned within the outer needle and is capable of moving along the longitudinal axis of said outer needle. The vacuum generating assembly is pneumatically coupled to the tissue cutting assembly such that the vacuum induces a cutting motion of the inner cutter needle in a direction away from the proximal end of the outer needle and toward the distal end of the outer needle.

In an embodiment, the vacuum generating assembly is pneumatically coupled to the tissue cutting assembly such that, when the inner cutter needle is placed at the cutting position, the vacuum draws the tissue sample into the tissue receiving slot of the outer needle.

In an embodiment, the tissue cutting assembly also includes a trigger adapted to be selectively positioned in an open position that allows movement of the inner cutter needle and adapted to be selectively positioned in a closed position that prevents movement of the inner cutter needle. The step of initiating the cutting motion of the inner cutter needle comprises moving the trigger from the closed position to the open position. In an embodiment, the tissue cutting assembly also includes a cutting plunger affixed to said proximal end of the inner cutter needle. The cutting plunger includes a plurality of tabs at a corresponding plurality of positions between the proximal end and the distal end.

In an embodiment, the disposable biopsy device also includes a shell enclosing at least a portion of the disposable biopsy device. The shell includes a plurality of

protrusions. In an embodiment, the trigger includes a plurality of protrusions sized, shaped, and positioned such that, when the trigger is positioned in the closed position, the plurality of protrusions of the trigger place one of the plurality of tabs of the cutting plunger in alignment with one of the plurality of protrusions of the shell such that the one of the plurality of protrusions of the shell prevents movement of the one of the plurality of tabs of the cutting plunger.

In an embodiment, a biopsy device includes a vacuum generating assembly generating a vacuum. The biopsy device also includes a cutting assembly having a hollow outer needle having a longitudinal axis. The cutting assembly also includes an inner cutter needle coaxially positioned within the hollow outer needle. The cutting assembly is pneumatically coupled to the vacuum assembly such that the vacuum drives a cutting motion of the inner cutter needle along the longitudinal axis of the hollow outer needle.

Brief Description of the Figures

FIG. 1 is a side view of an exemplary biopsy device including a cutting assembly on the top and a primary suction assembly on the bottom as well as a sample collector;

FIG. 2 is an exploded view of the biopsy device shown in FIG. 1;

FIG. 3 is a close up view of an outer needle having saw teeth along the tissue receiving slot near the open distal end thereon;

FIG. 4 is a close up view of an inner cutter needle having a tissue receiving port terminated by an inwardly beveled razor sharp edge at a distal end thereon;

FIG. 5 shows the dimensions of both the outer needle and inner cutting cannula;

FIG. 6 shows a close up view of the inner cutter needle having an air hole near the proximal end thereon;

FIG. 7 is a rear view of a mechanical stopper alone;

FIG. 8 is a cross sectional view of the biopsy device of FIG. 1 along line 1-1 showing an air path hole between the cutting needle tube and primary suction tube; and an air release hole on the top of the cutting needle tube;

FIG. 9 is a close up view of the distal end of the biopsy device of FIG. 1 showing the air passage when the silicone fitting on the air release hole is pressed and the primary suction plunger is pulled away from the distal end of the primary suction tube;

FIG. 10 is a close up view of the distal end of the biopsy device of FIG. 1 showing the air passage when the silicone fitting on the air release hole is released;

FIG. 11 shows the dimensions of the cutting plunger and the inner cutter needle attached thereto;

FIG. 12 shows the lengths of the cutting tube and the primary suction tube;

FIG. 13 shows the diameters of the cutting tube and the primary suction tube;

FIG. 14 shows the cutting length indicator and the diameter of a silicone fitting, which seals the air release hole on the top of cutting tube;

FIG. 15 shows a sample collector;

FIG. 16 shows the biopsy device at a ready to use position;

FIG. 17 illustrates a side view of the biopsy device being at a position where the silicone fitting on the air release hole is pressed and the primary suction plunger is pulled all the way back to generate a vacuum;

FIG. 18 illustrates a partial cross sectional view of the biopsy device in FIG. 17 along the line 17-17 where when the plunger raised edges 141 are aligned with the notches of the stopper, the plunger freely moves in or out;

FIG. 19A is an isometric view of the biopsy device showing that the raised edges of the plunger engage the board of the stopper thus locking the plunger in place after the plunger is turned;

FIG. 19B illustrates a partial cross sectional view of the biopsy device in FIG. 19A along the line 19A-19A where when the plunger raised edges 141 engage the board of the stopper, the plunger is locked in place;

FIG. 20A is a side view of the biopsy device being at a position where the cutting plunger is pulled all the way back with its distal end aligned with the last mark of the length indicator;

FIG. 20B illustrates a partial cross sectional view of the biopsy device in FIG. 20A along the line 20A-20A where when the grooves between the plunger raised edges 142 are aligned with the tab 203 of the stopper, the plunger freely moves in or out;

FIG. 21 is a close up view of the tissue receiving slot of the outer needle and the distal end of the inner cutter needle therein;

FIG. 22A is a side view of the biopsy device after the cutting plunger is withdrawn toward the distal end of the cutting tube by the suction force, advances into the tissue mass and slices the prolapsed tissue from the tissue mass;

FIG. 22B illustrates a partial cross sectional view of the biopsy device in FIG. 22A along the line 22A-22A where when the ridge 137 of the plunger is blocked by the tab 203 of the stopper, the plunger is locked in place;

FIG. 23 shows the user removes his/her thumb from the silicone fitting to release the vacuum inside the biopsy device;

FIG. 24 shows a side view of the biopsy device being in a position to collect sample tissue;

FIG. 25 illustrates a sample collector attached to the inner cutter needle at the distal end of the outer needle;

FIG. 26 illustrates that the collected sample tissue falls off by gravity when the inner cutter needle is pulled backward;

FIG. 27A illustrates a bottom plan view of a trigger that may control the release of a cutting plunger of a further embodiment of a biopsy device;

FIG. 27B illustrates a front plan view of the trigger of FIG. 27A;

FIG. 27C illustrates an isometric view of the trigger of FIG. 27A;

FIG. 28 illustrates a perspective view of a portion of a shell of a biopsy device engaging the trigger of FIG. 27A;

FIG. 29 illustrates a perspective view of a portion of a cutting plunger of a biopsy device engaging the trigger of FIG. 27A;

FIG. 30 illustrates a length adapter that may be used with the cutting plunger of FIG. 29 to control the length of a tissue sample by a disposable biopsy device;

FIG. 31A illustrates a perspective view of a portion of a biopsy device including the trigger of FIG. 27A, the shell of FIG. 28, and the cutting plunger of FIG. 29, showing the trigger and cutting plunger in a pre-use position;

FIG. 31B illustrates a further perspective view of the portion of the biopsy device of FIG. 31A, showing the trigger and cutting plunger in an in-use position;

FIG. 31C illustrates a further perspective view of the portion of the biopsy device of FIG. 31A, showing the trigger and cutting plunger in a locked position;

FIG. 31D illustrates a cutaway of the perspective view of FIG. 31C;

FIG. 31E illustrates a partial side cross-sectional view of the biopsy device as shown in FIG. 31B;

FIG. 31F illustrates a further perspective view of the portion of the biopsy device of FIG. 31A, showing the cutting plunger in a rotated position for withdrawal or sample removal;

FIG. 32 illustrates a tissue picker that may remove a tissue sample from a disposable biopsy device;

FIG. 33 illustrates a storage location within a disposable biopsy device for the tissue picker of FIG. 32; and

FIG. 34 illustrates the tissue picker of FIG. 32 as stored in the storage location of FIG. 33.

Detailed Description of the Invention

According to one aspect, the described invention provides a disposable biopsy device for obtaining a biopsy, the disposable biopsy device comprising a tissue cutting assembly, which has features to control the tissue length that will be severed by the cutting assembly. According to one embodiment, the tissue cutting assembly comprises a thin, elongated outer needle, a thin, elongated inner cutter needle, an elongated tube, and a first plunger. The outer needle is attached to the distal end of the elongated tube; the inner cutter needle is attached to the distal end of the first plunger (i.e. the cutting

plunger), both of which are coaxially positioned within the tube and capable of rotating about and translating along the longitudinal axis of the tube. According to one embodiment, the inner cutter needle is coaxially positioned within the outer needle and capable of rotating about and translating along the longitudinal axis of the outer needle. According to one embodiment, the elongated tube has a cutting length indicator, which has numerical indicia to indicate the length of the prolapsed tissue to be separated from the tissue mass. According to one embodiment, the cutting plunger has a plunger rod, notches and ridges on the plunger rod, which engage the stopper to control the length of the tissue to be severed as desired. According to one embodiment, the elongated tube has an air release hole on a top surface of the tube and at least one air path hole on a bottom surface of the tube. According to one embodiment, the inner cutter needle has at least one hole near its proximal end.

The disposable biopsy device further comprises a vacuum assembly, which has features to control a vacuum level. According to one embodiment, the vacuum assembly comprises an elongated cylinder and a second plunger (i.e. the suction plunger) which is coaxially disposed within the cylinder and is movable around and along the longitudinal axis of the cylinder. According to one embodiment, the plunger has a plunger rod, ridges, and notches on the plunger rod, which engage with the stopper attached to the proximal end of the cylinder to control the vacuum level to be generated.

According to one embodiment, the vacuum assembly is in fluid communication with the cutting assembly through one or more air hole(s) between them. According to one embodiment, the vacuum assembly and the cutting assembly are two separate

compartments, which are only connected through the air hole(s) in between. According to one embodiment, the vacuum assembly generates a vacuum based on the linear movement of a piston relative to a cylinder.

According to one embodiment, the cylinder has an air hole on a top surface of the cylinder which together with the air hole on the bottom surface of the tube forms an air path hole. The air hole in the inner cutter together with the air path hole allow the air to diffuse from the outer needle through the air hole in the inner cutter and through the air path hole between the tube and the cylinder to the cylinder when the suction plunger is pulled, thereby creating a low pressure region near the sample receiving slot in the outer needle. The suction force generated by the vacuum assembly pulls and traps the prolapsed tissue into a tissue sample receiving slot and holds the tissue tightly prior to and during cutting. The pressure gradient between the low pressure region and the outside ambient pressure propels the cutting plunger toward the low pressure area until it hits the stop position of the stopper, which is connected to the proximal end of the tube. Together with the cutting plunger, the attached inner cutter needle is propelled toward the tissue receiving slot and separates the prolapsed tissue from the tissue mass. According to another embodiment, the tissue sample receiving slot has saw teeth along its two lateral sides, which also hold the tissue tightly prior to and at the time that the inner cutter needle is advanced to separate the tissue from the tissue mass.

According to one embodiment, the biopsy device further comprises a sample collector which grasps the severed tissue sample out of the inner cutter needle such that the tissue sample is securely handled.

According to one embodiment, both the outer needle and inner cutter needle are formed of a surgical grade metal. According to one embodiment, the outer needle and inner cutter needle are formed of stainless steel. According to another embodiment, the outer needle and inner cutter needle are made of titanium or other materials. According to another embodiment, the outer needle and inner cutter needle are made of non-metallic material of appropriate strength and stiffness.

According to one embodiment, the mechanical stoppers for the suction plunger and cutting plunger are connected as one unit. According to another embodiment, the two mechanical stoppers are separate structures.

According to another aspect, the described invention also provides a method of obtaining a biopsy comprising: (1) providing a disposable biopsy device, the biopsy device including a tissue cutting assembly comprising means for controlling the length of tissue that will be severed by the cutting assembly; and a vacuum assembly comprising means for controlling how much vacuum is to be generated.

According to one embodiment, the tissue cutting assembly in step (1) comprises a thin, elongated outer needle, a thin, elongated inner cutter needle, an elongated tube, and a first plunger. The outer needle is attached to the distal end of the elongated tube; the inner cutter needle is attached to the distal end of the first plunger (i.e. the cutting plunger) both of which are coaxially positioned within the tube and capable of rotating about and translating along the longitudinal axis of the tube. According to one embodiment, the inner cutter needle is coaxially positioned within the outer needle and capable of rotating about and translating along the longitudinal axis of the outer needle. According to one embodiment, the elongated tube has a cutting length indicator, which

has numerical indicia to indicate the length of the prolapsed tissue to be separated from the tissue mass. According to one embodiment, the cutting plunger has a plunger rod, notches and ridges on the plunger rod, which engage the stopper to control the length of the tissue to be severed as desired. According to one embodiment, the elongated tube has an air release hole on the top surface and at least one air path hole on the bottom surface. According to one embodiment, the inner cutter needle has at least one hole near its proximal end.

According to one embodiment, the vacuum assembly of step (1) of the method comprises an elongated cylinder and a second plunger (i.e. the suction plunger) which is coaxially disposed within the cylinder and is movable around and along the longitudinal axis of the cylinder. According to one embodiment, the plunger has a plunger rod, ridges and notches on the plunger rod, which engage with the stopper attached to the proximal end of the cylinder to control vacuum level to be generated.

According to one embodiment, the vacuum assembly of step (1) of the method is in fluid communication with the cutting assembly through one or more air hole(s). According to one embodiment, the vacuum assembly and the cutting assembly of step (1) of the method are two separate compartments, which are only connected through the air hole(s) in between. According to one embodiment, the vacuum assembly of step (1) of the method generates a vacuum based on the linear movement of a piston relative to a cylinder.

According to one embodiment, the cylinder of step (1) of the method has an air hole on the top surface which together with the air hole on the bottom surface of the tube forms an air path hole. The air hole in the inner cutter together with the air path

hole allow the air to diffuse from the outer needle through the air hole in the inner cutter and through the air path hole between the tube and the cylinder to the cylinder when the suction plunger is pulled, thereby creating a low pressure region near the sample receiving slot in the outer needle. The suction force generated by the vacuum assembly pulls and traps the prolapsed tissue into the sample receiving slot and holds the tissue tightly prior to and during cutting. The pressure gradient between the low pressure region and the outside ambient pressure propels the cutting plunger toward the low pressure area until it hits the stop position of the stopper, which is connected to the proximal end of the tube. Together with the cutting plunger, the attached inner cutter is propelled toward the tissue receiving slot and separates the prolapsed tissue from the tissue mass. According to another embodiment, the sample receiving slot has saw teeth along its two lateral sides, which also hold the tissue tight prior to and at the time that the inner cutter is advanced to separate the tissue from the tissue mass.

According to one embodiment, the biopsy device of step (1) of the method further comprises a sample collector which grasps the severed tissue sample out of the inner cutter such that the tissue sample is securely handled.

In step (1) of the method, according to one embodiment, both the outer needle and inner cutter needle are formed of a surgical grade metal. According to one embodiment, the outer needle and inner cutter needle are formed of stainless steel. According to another embodiment, the outer needle and inner cutter needle may be made of titanium or other materials. According to another embodiment, the outer needle and inner cutter may be made of non-metallic material of appropriate strength and stiffness.

According to one embodiment, the mechanical stoppers of step (1) of the method for the suction plunger and cutting plunger are connected as one unit. According to another embodiment, the two mechanical stoppers are separate structures.

The method further comprises the steps (2) placing the outer needle at a location for collecting sample tissue in a patient's body; (3) covering the air release hole (e.g., with a thumb or a finger); (4) pulling out the suction plunger, turning (or rotating) the plunger and locking the plunger in place; (5) pulling the cutting plunger backward to generate a vacuum such that its distal end is aligned with one or more numerical indicia on the cutting length indicator that corresponds to a desired tissue length, thereby exposing the tissue receiving slot on the outer needle, where the tissue will prolapse into and be held tight by the suction force and the saw teeth; (6) releasing the cutting plunger, which, together with the inner cutter needle is propelled toward a low pressure region by a pressure gradient between the low pressure region and ambient pressure until it finally hits the first stopper and stops; the inner cutter advancing into the tissue receiving slot and severing the tissue which has prolapsed into the tissue receiving slot; (7) removing the means for covering the air release hole to allow air flow into the biopsy device and de-vacuum; (8) removing the biopsy device from the patient's body; (9) outside the body, turning the cutting plunger until it stops; (10) outside the body, pushing the first plunger all the way forwards; (11) and outside the body, grasping the severed tissue sample using the tissue collector, and pulling the severed tissue out from the sample receiving port of the inner cutter needle.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise,

between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges which may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, exemplary methods and materials have been described. All publications mentioned herein are incorporated herein by reference to disclose and described the methods and/or materials in connection with which the publications are cited.

It must be noted that as used herein and in the appended claims, the singular forms “a”, “and”, and “the” include plural references unless the context clearly dictates otherwise.

The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application and each is incorporated by reference in its entirety. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

EXAMPLES

The following examples are put forth so as to provide those of ordinary skill in the art with a complete disclosure and description of how to make and use the present invention, and are not intended to limit the scope of what the inventors regard as their invention nor are they intended to represent that the experiments below are all or the only experiments performed. Efforts have been made to ensure accuracy with respect to numbers used (e.g. amounts, temperature, etc.) but some experimental errors and deviations should be accounted for. Unless indicated otherwise, parts are parts by weight, molecular weight is weight average molecular weight, temperature is in degrees Centigrade, and pressure is at or near atmospheric.

Although the exemplified biopsy device is manually powered, the same inventive principles can apply to an automatic tissue biopsy device. Likewise, although the exemplified biopsy device is handheld, the same inventive principles can apply to a tissue biopsy device that is mounted on a support fixture.

FIGS. 1 and 2 show an exemplary tissue biopsy device 10 that is manually powered for both tissue sample cutting and vacuum generation. The tissue biopsy device 10 of the described invention is configured as a handheld device. However, the same inventive principles can be employed in a tissue biopsy device that is mounted on a support fixture. The biopsy device 10 comprises a cutting assembly for taking tissue samples and a vacuum assembly for generating a vacuum.

The cutting assembly includes a thin, long outer needle 107 attached to the distal end of the cutting tube 101. The outer needle 107 defines an outer lumen (FIG. 3) that is hollow along the entire length of the outer needle to provide for aspiration of the biopsy sample. The cutting assembly further includes an inner cutter needle 111 that fits

concentrically (or coaxially) within the outer needle 107. The thin elongated inner cutter needle 111 is attached to the distal end of a cutting plunger 110. The inner cutter needle 111 and cutting plunger 110 are configured to be able to move inside, about, and along the longitudinal axis (or length) of the close-fitting cutting tube 101. The inner cutter needle 111 is configured to be able to extend beyond the cutting tube 101 into the close-fitting hollow outer needle 107, and moves about and along the longitudinal axis of the outer needle 107. When the plunger 110 is pushed all the way in, the distal end of the inner cutter needle 111 can extend beyond the open distal end 125 of the outer needle 107.

The outer needle 107 has an open distant end 125 which is configured to penetrate tissue like a standard needle tip, a proximal end 126 attached to the distal end 121 of the cutting knife tube 101, and a tissue receiving slot 131 located proximal to the open distal end 125, which communicates with the outer lumen 127. The needle tip 125 is comparable to standard syringe needle tip, typically, for example, a standard bevel shape or short bevel shape.

The inner cutter needle 111 defines an inner lumen that is hollow along the entire length of the inner cutter needle to provide for aspiration of the biopsy sample. The inner cutter needle has a tissue receiving port 134, which communicates with the inner lumen and terminates in a razor sharp cutting edge 135, which is inwardly beveled at the distal end. The inwardly beveled edge helps eliminate the risk of catching the inwardly beveled edge on the tissue-sampling slot 131 of the outer needle. In addition, the beveled edge helps to avoid pinching the biopsy material between the inner and outer needles during a cutting stroke (FIG. 4). The inner cutter 111 further has an air

hole 109 located near the proximal end of the needle 111 (FIG. 6), which is a part of the suction air pathway and will be further discussed later. The suction air pathway provides a mechanism for trapping and holding the tissue in place to enhance the cutting efficiency.

Moreover, the outer needle 107 further includes saw teeth cutouts 108 (FIG. 3) along two lateral sides of the tissue receiving slot 131 for holding the tissue in place to enhance the cutting efficiency.

According to one embodiment, both the outer needle 107 and the inner cutter needle 111 are formed of a surgical grade metal. For example, the two needles are formed of stainless steel.

The extent of the translation of the inner cutter needle 111 within the outer needle 107 is controlled by the configuration of the cutting plunger 110 relative to the cutting plunger stopper 203. The cutting plunger 110 is configured such that it can be pulled out to several pre-determined distances relative to the cutting tube 101 corresponding to the desired tissue lengths. A variety of configurations are possible to control the translation of the inner cutter needle 111 within the outer needle 107.

One example is illustrated in FIGS. 1 and 2. According to one embodiment, the cutting plunger 110 comprises a plurality of ridges 137 disposed at pre-determined locations (FIGS. 1 and 2). Once one of the plunger's ridges 137 encounters the tab 203 of the mechanical stopper 202 (FIG. 7), the plunger is locked in place (meaning forward movement is prevented). The cutting plunger 110 also has a plurality of notches 139 in front of or behind the ridges 137, which allows the cutting plunger 110 to rotate and bypass the ridges 137 so that the plunger 110 can make further movement. The biopsy

device 10 further has a cutting length indicator 103 (as shown in FIG. 14) to enable a user to set a desired length of biopsy tissue. For example, if a tissue of one inch is desired, a user will align the distal end of the cutting plunger with the numerical indicia marked “one inch” on the indicator 103. This mechanism ensures that an accurate tissue length is sampled for further examination.

Similarly, the vacuum level is regulated by the configuration of the primary suction plunger 112 relative to the configuration of the stopper 202. A variety of configurations are possible. According to one embodiment as shown in FIGS. 1 and 2, the suction plunger 112 has a plurality of raised edges 141 along the plunger rod 140, and notches 113 breaking the raised edges (FIG. 2). The stopper 202 has notches 143 (FIG. 7) compatible with the raised edges on the plunger 112 such that the plunger can move backward and forward relative to the suction tube 102 as long as the raised edges 141 of the plunger engage the notches 143 of the stopper.

Once the plunger 112 is pushed / pulled to a desired position for a desired level of vacuum, the user turns / rotates the plunger such that the raised edges 141 of the plunger engages to another part 145 of the stopper, thereby locking the plunger 112 in place.

The primary suction tube 102 is closed at the distal end, and open at the primary end for receiving the primary suction plunger 112. The outer needle 107 is attached to the distal end of the cutting tube 101. The distal end of the cutting tube 101 may have a nozzle 122 for receiving the outer needle 107 and allowing the inner cutter needle to move in and out of the cutting tube. The suction plunger has a handle at the proximal end 114 to help manipulation.

The bottom surface of the cutting tube 101 is connected to the top surface of the primary suction tube 102, forming a shape with a cross sectional view of “8”. Although their exteriors are connected, their interior compartments are substantially separate from each other. The only connection between the two interior compartments is an air path hole 106 located near the distal end in the wall between the cutting tube 101 and the primary suction tube 102. FIG. 8 is a cross sectional view of the biopsy device where the air path hole 106 is shown.

The tissue receiving port 134, the air hole 109 of the inner cutter needle 111, and the air path hole 106 together form a suction air pathway when the primary suction plunger 112 is pulled. FIG. 9 illustrates such a suction air pathway which is indicated as a thick solid line.

The air hole 109 at the proximal end on the inner cutter needle 111 and the air path hole 106 at the wall between the cutting tube 101 and the primary suction tube 102 provide an air pathway between the hollow interior of the outer needle and the hollow interior of the primary suction tube. The low pressure region created by the vacuum near the tissue receiving slot facilitates the prolapse (meaning sinking down or dropping) of the tissue sample into the immediately adjacent tissue sample slot.

The cutting tube 101 further has an air release hole 104 on the top near the distal end. The air release hole 104 and the air path hole 106 form an outlet for releasing the vacuum. FIG. 10 illustrates such a vacuum release pathway, which is indicated as a thick solid line.

The biopsy device can have a variety of dimensions. For example, the outer needle is about 50 – 150 mm in length and 1.27 - 2.41 mm in outer diameter (O.D.),

which corresponds to a gauge 13 - 17 needle, and the sample receiving slot is about 5 - 25 mm in length. The inner cutter needle is about 80 - 180 mm long and 1.07 - 1.83 mm O.D., which corresponds to a gauge 15 - 19 needle, and the sample receiving port is about 32 mm long. The cutting plunger is about 90 mm long. The cutting tube is about 88 mm in length, 10 - 14 mm in inner diameter (I.D.) and 12.5 - 16.5 mm in O.D. The primary suction tube is about 80 mm long and 14 - 20 mm I.D. and 16.5 - 22.5 mm O.D. According to one embodiment, the cutting knife assembly further includes a silicone fitting 105 on top of the air release hole 104 to allow the air release hole to be closed by a finger or a thumb when necessary. The silicone fitting is of a size of about 6 - 8 mm I.D. and 8 - 10 mm O.D.

According to one particular device, the outer needle is about 100 mm in length and 1.83 mm in outer diameter (O.D.), which corresponds to a gauge 15 needle, and the sample receiving slot is about 25 mm in length. The inner cutter needle is about 137.5 mm long and 1.27 mm O.D., which corresponds to a gauge 18 needle, and the sample receiving port is about 32 mm long (FIG. 5 and FIG. 11). The cutting plunger is about 88 mm long (FIG. 11). The cutting tube is about 80 mm in length, 10 mm in inner diameter (I.D.) and 14 mm in O.D. The primary suction tube is about 80 mm long and 18 mm I.D. and 21 mm O.D. (FIGS. 12 and 13). The silicone fitting is of a size of about 5 mm I.D. and 8 mm O.D. (FIG. 11).

Both the cutting plunger and the primary suction plunger are tightly (closely) fit with the cutting tube and the primary suction cylinder, respectively. The distal end of both plungers can include, for example, silicone to ensure that the cutting and vacuum assemblies are air tight.

The cutting length indicator 103 has numerical indicia, for example, 0, ¼, ½, ¾, and 1 corresponding to 0, ¼, ½, ¾ and 1 inches. As shown in FIG. 14, according to one embodiment, the cutting length indicator 103 can be printed on the top surface of the cutting tube 101 to indicate the tissue length desired to be severed when the distal end of the plunger is aligned with that mark.

According to one embodiment, the biopsy device 10 further comprises a shell 201, which has an upper portion closely enclosing the cutting tube 101 and a lower portion closely enclosing the primary suction tube 102. The upper portion has a viewing window 211, which can be transparent or translucent, for viewing the tissue length indicator printed on the cutting tube 101. According to another embodiment, the window itself is a cutting length indicator showing the numerical indicia if the cutting length indicator is not printed on the cutting tube. The shell 201 further has a hole (not shown) open to the air release hole on the cutting knife tube 101. In the distal end of the upper portion, a protruding part 215 shaped to adapt to a nozzle 122 has an aperture 217 allowing the outer needle 107 to go through and inner cutter needle 111 to move in and out.

According to one embodiment, a stopper 202 is disposed at the proximal end of the cutting tube 101 and primary suction tube. According to another embodiment, the stopper 202 is disposed at (or attached to) the proximal end of a shell 201 as shown in FIGS. 1 and 2.

According to one embodiment, the biopsy device further comprises a sample collector 115 (FIG. 15). The sample collector has a clip 151 to grasp the tissue and the open space around the clip allows the clip to slide around the inner cutter's tissue

receiving port 134 and move the tissue sample forward out of the port 134. In this way, the sample tissue can be kept intact and undamaged for further examination. The handle 153 is for the user to hold the sample collector 115.

In operation, the user prepares the biopsy device in a ready to use position. Referring to FIG. 16 there is disclosed a ready to use biopsy device of the described invention, where the distal end of the cutting plunger 110 is aligned with the zero mark of the cutting length indicator 103 and the primary suction plunger 112 is fully pushed inside the suction tube 102.

The biopsy device 10 is handheld and the distal end 125 of the outer needle 107 is inserted into the precise location of the patient within the tissue 20 from which it is desired to obtain a tissue sample.

After the air release hole silicon fitting 105 is pressed (as demonstrated in FIG. 17), the primary suction plunger 112 is pulled towards the proximal end of the primary suction tube 102 to generate vacuum (FIG. 17). Then, the plunger is turned clockwise about 45 degrees to lock it in place as shown in FIG. 19 A. This action creates a vacuum in the biopsy device. FIGS. 18 and 19 B illustrate the locking mechanism. FIG. 18 is a cross sectional view of the biopsy device in FIG. 17 along the line 17-17, where when the plunger raised edges 141 are aligned with the notches 143 of the stopper 202, the plunger freely moves in or out. FIG. 19 A is an isometric view of the biopsy device showing the raised edges 141 of the plunger engage the board 145 of the stopper 202 after the plunger is turned, thus locking the plunger in place and securing the vacuum inside the tube. Thus, the user can manipulate the cutting plunger in the next step. If the user desires to move the suction plunger further distant, the user needs to rotate the

plunger such that the interlocking can be disengaged. FIG. 19 B illustrates a cross sectional view of the biopsy device in FIG. 19 A along the line 19A-19A, where when the plunger raised edges 141 engage the board 145 of the stopper, the plunger is locked in place. The vacuum level generated within the biopsy device depends on how far the plunger is pulled away from the distal end of the suction tube. For example, the biopsy device shown in FIG. 2 provides four (4) vacuum levels.

According to another embodiment, the second plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined position across adjacent raised edges, and a plurality of notches in front of or behind the ridges, which together with the second stopper, control the vacuum levels.

The air hole 109 at the proximal end on the inner cutter needle and the air path hole 106 at the wall between the cutting tube 101 and the primary suction tube 102 provides an air passageway between the hollow interior of the outer needle and the hollow interior of the primary suction tube. The low pressure created by the suction in the region near the tissue receiving slot can facilitate the prolapse of the tissue immediately adjacent the tissue receiving slot into the tissue receiving slot.

The distal end of the cutting plunger 110 is then aligned to the one of the numerical indicia on the cutting length indicator 103 that shows the desired tissue length to be severed. FIG. 20 shows that the biopsy device 10 is in a position which is ready to cut sample tissue where the cutting plunger 110 is pulled with the distal end aligning with the “one inch” mark on the sample length indicator 103. As shown in FIG. 21, when the cutting plunger 110 is pulled, the distal end of the inner cutter needle 111 is pulled

away from the distal end of the outer needle 107, thereby opening the tissue receiving slot 131. Due to the strong suction force created by the primary suction assembly, the tissue receiving slot 131 is filled with the solid and evenly distributed tissue sample. This prolapsed tissue sample will be tightly held during the process of biopsy (from beginning to end) by the suction force (vacuum) and by the saw teeth cut out 108.

FIG. 20 B illustrates a cross sectional view of the biopsy device in FIG. 20 A along the line 20 A-20 A where when the grooves between the plunger raised edges 142 are aligned with the tab 203 of the stopper, the plunger freely moves in or out.

After the cutting plunger 110 is released, the pressure gradient between the low pressure region and the outside ambient pressure propels the cutting plunger toward the low pressure area until it hits the stopping position 203 of the mechanic stopper 202. Together, the attached inner cutter 111 is propelled toward the tissue receiving slot and the beveled shaped razor edge 135 separates the prolapsed tissue 202 from the tissue mass 200. The cutting plunger is rested at a position such that its distal end is aligned with the zero mark of the tissue length indicator 103 as shown in FIG. 22 A. The tissue sample is collected into the tissue receiving port 134 of the inner cutter needle as it moves forward. During the process, the beveled shaped razor sharp knife 135 severs the prolapsed tissue sample, which then falls inside the tissue receiving port 134 on the inner cutter needle 111. The tissue sample is held in the inner cutter needle by friction with the inner walls of the inner cutter needle and by the suction created by the vacuum source, created by the pulling of the primary suction plunger and channeled through air path holes 106 and 109.

FIG. 22 A is a side view of the biopsy device after the cutting plunger is propelled by the gradient potential (or withdrawn by the suction force) toward the distal end of the cutting tube and advances into the tissue mass and slices the prolapsed tissue from the tissue mass.

FIG. 22 B illustrates a cross sectional view of the biopsy device in FIG. 22 A along the line 22A-22A where when the ridge 137 of the plunger hits the tab 203 of the stopper, it is blocked by the tab, the forward movement of the plunger is stopped and the plunger is locked in place.

The location of the ridges on the plunger determines the tissue length to be severed. Together with the cutting length indicator, this design provides a simple, accurate, precise and efficient mechanism for tissue length control.

Once the tissue is severed, the silicone fitting on the air release hole is released and the air flows back to the biopsy device through air release hole 104 and air path hole 106, thus de-vacuuming the entire biopsy device as shown in FIG. 23. The suction release pathway has been discussed earlier and is shown in FIG. 10.

The biopsy device 10 is pulled out from the patient's body and the cutting plunger 110 is rotated until it stops. The cutting plunger is then pushed all the way in as shown in FIG. 24. At the time, the sample slot 134 of the cutting knife inner cutter needle 111 is beyond the outer needle tip 125 and the tissue sample inside is ready for collection. A sample collector 115 is then attached to the outer needle 107 near the distal end as shown in FIG. 25.

Referring to FIG. 15 there is disclosed an embodiment of the sample collector 115. The sample collector has a clip 151 on one side and a handle 153 with a

compression spring 152 opposite to the clip 151. The clip 151 has a round tip of which the diameter is slightly smaller than the inner diameter of the inner cutter needle 111 so that the clip 151 can snugly fit in the tissue receiving port 134. After the user clips the sample collector 115 to the outer needle near the distal end as shown in FIG. 25, the user can pull the inner cutter needle 111 backward until the distal end of the cutting plunger 110 lines up with the mark "0" on the cutting length indicator 103. Consequently, the cylindrical sample tissue 22 is free from the device 10 and falls by gravity (FIG. 26) into a container (not shown). The sample collector 115 stays on the outer needle 107. In this way, the collected sample tissue 22 can be kept intact and undamaged for further examination. The handle 153 with the compression spring 152 is for the user to hold and operate the sample collector 115.

Referring now to FIGS. 27A-34, further exemplary embodiments of the present invention are shown therein. A biopsy device 300 in accordance with one embodiment (see, e.g., FIG. 31) may be substantially similar, in construction and operation, to the biopsy device 10 described above with reference to FIGS. 1-26, other than insofar as the description of the biopsy device 300 hereinafter differs from the description of the biopsy device 10 above.

Referring now to FIGS. 27A-27C, the biopsy device 300 includes a trigger 310. In an embodiment, the trigger 310 has a substantially ring-shaped main portion 312 with a similar size and shape to those of the upper portion of the biopsy device 300. The trigger 310 also includes tabs 314, 316 projecting from the main portion 312 for enabling a user of the biopsy device 300 to operate the trigger 310. The trigger 310 also includes clips 318, 320 that enable the trigger 310 to be attached to the biopsy device

300. The clips 318, 320 are sized and shaped to engage the biopsy device 300 and are further sized and shaped to provide a desired range of motion. The trigger 310 also includes projections 322, 324, 326, 328 that project inward from the main portion 312. The projections 322, 324 define a slot 323 therebetween, while the projections 326, 328 define a slot 327 therebetween. The trigger 310 may have a unitary construction, and may be formed of a suitable material such that the clips 318, 320 can be flexed to enable installation to the biopsy device 300, and may then return to an unflexed position retaining the trigger 310 in place.

Referring now to FIG. 28, the biopsy device 300 includes a shell 330 that is, other than in the features that will be described hereinafter, substantially similar to the shell 201 described above with reference to the biopsy device 10. FIG. 28 is a perspective view of a proximal upper end portion of the shell 330 including features that differ from those of shell 201. The shell 330 includes slots 332, 334 that are sized, shaped, and positioned to receive and retain the clips 318, 320 of the trigger 310. The slots 332, 334 are also sized and shaped to enable movement of the clips 318, 320 therein such that the trigger 310 may rotate with respect to the upper portion of the shell 330, but only to a desired extent. The shell 330 also includes brackets 336, 338 that cooperate with the slots 332, 334 to retain the trigger 310 and prevent movement thereof other than rotational movement allowed by the slots 332, 334 as described above.

The shell 330 also includes projections 340, 342, 344, 346. More particularly, the projections 340, 342 define a slot 341 therebetween, while the projections 344, 346 define a slot 345 therebetween. The projections 340, 342, 344, 346 are sized, shaped,

and positioned such that, when the trigger 310 is in an open position (see FIG. 31A), they substantially overlap (i.e., rotationally align with) the projections 322, 324, 326, 328, respectively, of the trigger 310. Correspondingly, in such position, the slot 323 rotationally aligns with the slot 341, while the slot 327 rotationally aligns with the slot 345. Conversely, the projections 340, 342, 344, 346 are sized, shaped, and positioned such that, when the trigger 310 is in a closed position (see FIG. 31C), the slot 323 overlaps and is closed off by the projection 342, and the slot 327 overlaps and is closed off by the projection 344.

Referring now to FIGS. 29 and 31A, the biopsy device 300 includes a cutting plunger 350 that is substantially similar to the cutting plunger 110 of the biopsy device 10, other than insofar as will be described hereinafter; for example, the cutting plunger 350 is configured to be able to move inside, about, and along the longitudinal axis of a close-fitting cutting tube. FIG. 29 is a perspective view of an intermediate portion of the cutting plunger 350 showing features that differ from those of the cutting plunger 110. In FIG. 29, a proximal end of the cutting plunger 350 is shown to the right and a distal end of the cutting plunger 350 is shown to the left.

Referring now to FIG. 29, the cutting plunger 350 includes insertion stops 352, 354 sized and shaped such that they cannot pass through the slots 323, 327 of the trigger 310 or through the slots 341, 345 of the shell 330. The sizing of the insertion stops 352, 354 thereby prevents insertion of the cutting plunger 350 into the biopsy device 300 past a desired point, as will be described hereinafter. The cutting plunger 350 also includes withdrawal stops 356, 358 sized and shaped such that they cannot pass through the slots 323, 327 of the trigger 310 or through the slots 341, 345 of the

shell 330. The sizing of the withdrawal stops 356, 358 thereby prevents withdrawal of the cutting plunger 350 from the biopsy device 300 past a desired point, as will be described hereinafter. Restriction of the movement of the cutting plunger 350 for retention within a desired range of motion may prevent inadvertent exposure of a cutting tip of an inner cutter needle affixed to the cutting plunger 350, thereby improving safety for a user of the biopsy device 300 and for patients and others.

Continuing to refer to FIG. 29, the cutting plunger 350 also includes tabs 360, 362 and tabs 364, 366, which are sized, shaped and positioned such that they are capable of passing through the slots 323 and 327, respectively of the trigger 310 and through the slots 341 and 345, respectively, of the shell 330. Such passage of the tabs 360, 362, 364, 366 allows longitudinal motion of the cutting plunger 350 within the range defined by the insertion stops 352, 354 and the withdrawal stops 356, 358, as described above. Referring now to FIG. 31A, the cutting plunger 350 includes an arrow 351 on a proximal end thereof. The arrow 351 points generally upward when the cutting plunger 350 is positioned for use, and is aligned with the tabs 360, 362, as shown in FIG. 31A.

Referring now to FIGS. 29 and 30, in an embodiment, the biopsy device 300 includes a cutting length adapter 370, which is in the form of a clip sized and shaped to be placed onto and retained by one of the tabs 360, 364 (see FIG. 29 illustrating, in phantom, the cutting length adapter 370 as placed onto the tab 360). The cutting length adapter 370 may increase the effective width of the tab 360, 364 onto which it is placed, causing the tab 360, 364 to function as an extension of the corresponding withdrawal stop 356, 358. This may have the effect of preventing the tab 360, 364 from passing through the slots 323, 327 of the trigger 310 or through the slots 341, 345 of the shell

330. The combination of the cutting length adapter 370 and the tab 360, 364 thereby prevents withdrawal of the cutting plunger 350 from the biopsy device 300 past a desired point, as will be described further hereinafter.

Referring now to FIGS. 32-34, in an embodiment, the biopsy device 300 includes a tissue picker 380. The tissue picker 380 includes a handle 382 that is sized and shaped to be held by a user of a biopsy device (e.g., the biopsy device 10 or the biopsy device 300). The tissue picker 380 also includes a tip 384 opposite the handle 382. With reference to FIG. 33, when not in use, the tissue picker 380 may be stored. FIG. 33 is a perspective view of a distal lower end portion of the shell 330 including features that differ from those of shell 201. A hole 386 may be formed in the shell 330. The hole 386 may be sized and shaped to receive the tip 384 of the tissue picker 380. The hole 386 may be surrounded by brackets 388, 390, 392, 394, which may be sized and shaped to engage and retain the handle 382 of the tissue picker 380 when the tip 384 is inserted into the hole 386. FIG. 34 shows a portion of the biopsy device 300 including the tissue picker 380, which is stored such that the brackets 388, 390, 392, 394 retain the handle 382. The opposing side brackets 388, 392 cooperate to produce a friction fit with the sides of the handle 382, while the opposing end brackets 390, 394 cooperate to produce a friction fit with the ends of the handle 382.

Referring now to FIGS. 31A-31F, use of the biopsy device 300 will now be described. To facilitate consideration and understanding, the following discussion will describe use of the biopsy device 300 in the absence of the cutting length adapter 370. FIG. 31A illustrates a pre-use position of the biopsy device 300. In FIG. 31A, the trigger 310 is in an open position, rotationally aligning the slot 323 of the trigger 310 with the

slot 341 of the shell 330 and rotationally aligning the slot 327 of the trigger 310 with the slot 345 of the shell 330 to enable longitudinal motion of the cutting plunger 350. The arrow 351 of the cutting plunger 350 points upward, which provides for a vertical orientation of the insertion stops 352, 354 of the cutting plunger 350 such that they abut the projections 322, 324 and the projections 326, 328, respectively, of the trigger 310, preventing further insertion of the cutting plunger 350 into the biopsy device 300 (i.e., movement toward a distal end of the shell 330 and the biopsy device 300). Such further insertion would expose a cutting tip of an inner cutter needle affixed to the cutting plunger 350, as shown in FIG. 24. The pre-use position shown in FIG. 31A may therefore be appropriate for packaging, storage, etc.

As described above with reference to the biopsy device 10, during use, the biopsy device 300, with the cutting plunger 350 positioned as shown in FIG. 31A, may be inserted into the body of a patient at a desired biopsy location. A user of the biopsy device 300 may then place a finger or thumb of a first hand over an air release hole (see, e.g., the air release hole 104 described above with reference to the biopsy device 10) located at a distal end of the biopsy device 300, and may withdraw a vacuum plunger 374 from the biopsy device 300 to a desired distance with a second hand, thereby generating a desired vacuum. As described above with reference to the biopsy device 10, the vacuum plunger 374 may be rotated for fixation at a desired position.

Referring now to FIG. 31B, once the user properly positions the vacuum plunger 374, he/she may use the second hand to withdraw the cutting plunger 350 from the device 300 until the withdrawal stops 356, 358 abut the projections 340, 342 and 344, 346, respectively, of the shell 330 (i.e., to a proximal position). More particularly, the

cutting plunger 350 is withdrawn from the biopsy device 300, with the tabs 360, 362 passing through the aligned slots 323, 341 and the tabs 364, 366 passing through the aligned slots 327, 345. Because the tubes containing the vacuum plunger 374 and the cutting plunger 350 are in pneumatic communication, the vacuum generated by the withdrawal of the vacuum plunger 374 urges the cutting plunger 350 forward (i.e., toward a distal end of the biopsy device 300), and withdrawal of the cutting plunger 350 is performed in opposition to the vacuum. Once the cutting plunger 350 has been withdrawn, the tab 360 is in longitudinal alignment (i.e., alignment in a direction along or parallel to a longitudinal axis of the biopsy device 300) with the projections 322, 324 of the trigger 310, and the tab 364 is in longitudinal alignment with the projections 326, 328 of the trigger 310 (i.e., the tabs 360, 364 are positioned in the slots 323, 327, respectively). FIG. 31B is a perspective view of a portion of the biopsy device 300, after the cutting plunger 350 has been withdrawn as described above. FIG. 31E is a section view of the biopsy device 300 as shown in FIG. 31B, showing the longitudinal alignment of the tabs 360, 364 with the projections 322, 324 and the projections 326, 328, respectively, of the trigger 310. In this position the tabs 360, 364 abut the projections 342, 344, respectively, of the shell 330. In addition, slots 361, 365 (see FIG. 29) formed between the tab 360 and the withdrawal stop 356 and between the tab 364 and the withdrawal stop 358, respectively, of the cutting plunger 350 are longitudinally aligned with the projections 340, 342 and the projections 344, 346, respectively, of the shell 330, so as to permit rotation of the cutting plunger 350.

Referring now to FIGS. 31C and 31D, after the cutting plunger 350 has been withdrawn, the user can rotate the cutting plunger 350 with the second hand. Because

the tabs 360, 364 of the cutting plunger 350 are longitudinally aligned with the projections 322, 324 and 326, 328, respectively, of the trigger 310, the trigger 310 rotates with the cutting plunger 350. Rotation of the trigger 310 and, thereby, of the cutting plunger 350 are constrained by the allowable travel of the clips 318, 320 of the trigger 310 within the slots 332, 334 (see also FIG. 28) of the shell 330. FIG. 31C shows the biopsy device 300 after the trigger 310 and the cutting plunger 350 have been rotated in this manner.

Continuing to refer to FIGS. 31C and 31D, the rotation of the trigger 310 and the cutting plunger 350 brings the tabs 360, 364 of the cutting plunger 350 into rotational or angular alignment (i.e., aligned rotationally or angularly about a longitudinal axis of the cutting plunger 350) with the projections 342, 344 of the shell 330. Therefore, despite the fact that the vacuum described above with reference to FIG. 31B continues to act on the cutting plunger 350, urging the cutting plunger 350 to move toward a distal end of the corresponding tube, the projections 342, 344 contact the tabs 360, 364, respectively, of the cutting plunger 350, and thereby exert a force opposing the vacuum and preventing the cutting plunger 350 from moving toward the distal end of the biopsy device 300. FIG. 31D is a cutaway perspective view of the biopsy device 300 as shown in FIG. 31C, showing the rotational alignment of the tab 360 with the projection 342, thereby preventing longitudinal motion of the cutting plunger 350 as described above.

As described above with reference to FIG. 21, withdrawal of the cutting plunger 350 moves an inner cutter needle affixed to the cutting plunger with respect to a coaxial outer needle of the biopsy device 300, thereby opening a desired portion of a slot formed within the outer needle. Because the interior of the coaxial outer needle is also

in pneumatic communication with the tube containing the cutting plunger 350, as described above with reference to the biopsy device 10, opening of the slot formed within the outer needle causes a portion of the tissue of the patient to be suctioned into the slot.

Once the trigger 310 and the cutting plunger 350 have been rotated, the user of the biopsy device 300 continues to hold the finger or thumb of the first hand over the air release hole to maintain the vacuum, but may remove the second hand, which is used to withdraw and rotate the cutting plunger 350, from the biopsy device 300. When the user of the biopsy device 300 is ready to sever the desired biopsy tissue, the user grasps the tabs 314, 316 of the trigger 310 with the second hand and rotates the trigger 310 from the closed position, as shown in FIG. 31C, back to the open position, as shown in FIG. 31B. Due to the longitudinal alignment of the projections 322, 324 of the trigger 310 with the tab 360 of the cutting plunger 350, rotation of the trigger 310 also rotates the cutting plunger 350, thereby returning tab 360 into rotational alignment with the slot 341 of the shell 330. Because the vacuum described above continues to act on the cutting plunger 350, the cutting plunger 350 is propelled toward the distal end of the biopsy device 300, with tabs 360, 362 and tabs 364, 366 of the cutting plunger 350 passing through the slots 341, 345, respectively, of the shell 330, until the insertion stops 352, 354 of the cutting plunger 350 contact the projections 322, 324 and the projections 326, 328, respectively, of the trigger 310, as shown in FIG. 31A (i.e., to a distal position). The inner cutter needle affixed to the cutting plunger 350 is propelled toward the distal end of the biopsy device 300 correspondingly, closing the slot in the outer needle that was opened by withdrawal of the cutting plunger 350 and severing

tissue that had been suctioned into the slot by the vacuum. The user may then release the finger or thumb of the first hand from the air release hole, causing the vacuum to abate and allowing the cutting plunger 350 to be freely movable as desired. The user may also then remove the biopsy device 310, with the severed sample contained therein, from the patient's body.

After the biopsy device 310, with severed sample contained therein, has been removed from the patient's body, the user may rotate the cutting plunger 350 to the rotational orientation shown in FIG. 31F. As shown, the arrow 351 of the cutting plunger 350 points sideways when the cutting plunger 350 is in this orientation. Such rotation aligns the tabs 396, 398 with the slots 323, 327 of the trigger 310 and with the slots 341, 345 of the shell 330, and aligns the insertion stops 352, 354 and the withdrawal stops 356, 358 with the larger side gaps between the projections 322 and 326, between the projections 324 and 328, between the projections 340 and 344, and between the projections 342 and 346. In such an alignment, the cutting plunger 350 may be fully inserted into the biopsy device 310 to expose a distal portion of an inner cutter needle affixed to the cutting plunger 350, as described above with reference to FIG. 24. Such insertion exposes the excised tissue for removal using the tissue picker 380 (e.g., by inserting the tip 384 into a sample slot of an inner cutter needle affixed to the cutting plunger 350).

As described above, in an embodiment, a cutting length adapter 370 may be placed onto one of the tabs 360, 364 of the cutting plunger 350. The tab 360 may be accessed for placement of the cutting length adapter 370 thereon by rotating the cutting plunger 350 (e.g., by approximately 90°), such that the arrow 351 points to the side, as

shown in FIG. 31F. Such rotation places the tabs 396, 398 in rotational alignment with the slots 341, 345 of the shell 330 and the slots 323, 327 of the trigger 310 and aligns the withdrawal stops 356, 358 with the larger side gaps between the projections 322 and 326, between the projections 324 and 328, between the projections 340 and 344, and between the projections 342 and 346. The user may then withdraw the cutting plunger 350 from the biopsy device 300 until the tab 360 is exposed (see, e.g., FIG. 31F). After placing the cutting length adapter 370 onto the tab 360, the cutting plunger 350 may be reinserted into the biopsy device 300, and may be rotated (e.g., by approximately 90°) back to the orientation shown in FIG. 31A.

The presence of the cutting length adapter 370 on the tab 360, 364, as shown in in phantom, changes the effective position of the withdrawal stop 356. The cutting length adapter 370 stops the withdrawal of the cutting plunger 350 (as described above with reference to FIG. 37B) when the cutting length adapter 370 abuts the projections 340, 342 of the shell 330, rather than when the withdrawal stops 356, 358 abut the projections 340, 342, 344, 346 of the shell 330 (i.e., to a proximal position that is withdrawn to a lesser extent than the proximal position described above with reference to use of the biopsy device 300 without the cutting length adapter 370). Withdrawal of the cutting plunger 350 to this reduced extent places the tab 362, rather than the tab 360, in longitudinal alignment with the projections 322, 324 of the trigger 310, and places slot 371 (see FIG. 29), rather than tab 361, in longitudinal alignment with the projections 340, 342 of the shell 330, so as to permit rotation of the cutting plunger 350.

The reduced withdrawal of the cutting plunger 350 (and, correspondingly, of an inner cutter needle affixed thereto) caused by the use of the cutting length adapter 370

results in a smaller slot being opened within the outer needle. As a result, a smaller portion of tissue is suctioned into the slot and excised from the body of the patient.

In an embodiment, portions of a disposable biopsy device (e.g., disposable biopsy device 10, disposable biopsy device 300) may be manufactured by any suitable manner, including three-dimensional printing. The size, shape and positioning of the trigger 310 and the tabs 360, 362, 364, 366 of the cutting plunger 350 enable the pre-cut position of the cutting plunger 350 to be controlled, enabling correspondingly precise control of the size of the tissue sample excised from the patient for biopsy. Further, because only a small movement of the trigger 310 is required to initiate a cut using the biopsy device 300, the cut may be triggered while maintaining the biopsy device 300 steadily in a constant position, ensuring that tissue is excised from the exact desired location and minimizing discomfort to the patient due to undesired movement of the biopsy device 300.

While the present invention has been described with reference to the specific embodiments thereof it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adopt a particular situation, material, composition of matter, process, process step or steps, to the objective spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

What is claimed is:

1. A disposable biopsy device, comprising:

a vacuum generating assembly generating a vacuum; and

a tissue cutting assembly including a hollow outer needle having a longitudinal axis, said tissue cutting assembly further including an inner cutter needle positioned within said hollow outer needle, said tissue cutting assembly being pneumatically coupled to said vacuum assembly such that said vacuum drives a cutting motion of said inner cutter needle along said longitudinal axis of said hollow outer needle.

2. The disposable biopsy device of Claim 1, wherein said vacuum generating assembly includes a cylinder having a proximal end and a distal end opposite said proximal end, said vacuum generating assembly including a plunger disposed within said cylinder such that motion of said plunger toward said proximal end of said cylinder generates a vacuum.

3. The disposable biopsy device of Claim 2,

wherein said hollow outer needle has a proximal end, a distal end opposite said proximal end, and a tissue receiving slot in said distal end,

wherein said inner cutter needle has a proximal end and a distal end opposite said proximal end, and wherein said inner cutter needle is capable of moving along said longitudinal axis, and

wherein said cutting motion of said inner cutter needle is in a direction away from said proximal end of said outer needle and toward said distal end of said outer needle.

4. The disposable biopsy device of Claim 3, wherein said outer needle includes a tissue receiving slot adjacent said distal end of said outer needle, and wherein said longitudinal movement of said inner cutter needle selectively opens and selectively closes said tissue receiving slot.

5. The disposable biopsy device of Claim 4, wherein said vacuum generating assembly is pneumatically coupled to said tissue cutting assembly such that, when said outer needle is placed at a location of a tissue sample and said tissue receiving slot is opened, said vacuum draws the tissue sample into said tissue receiving slot.

6. The disposable biopsy device of Claim 5, wherein said vacuum generating assembly further includes an air release hole for releasing said vacuum.

7. The disposable biopsy device of Claim 3, wherein said tissue cutting assembly includes:

a cutting tube having a longitudinal axis;

a cutting plunger disposed within said cutting tube and movable along and about said longitudinal axis of said cutting tube, said cutting plunger having a proximal end and a distal end opposite said proximal end, said inner cutter needle being affixed to said distal end of said cutting plunger;

a shell defining said cutting tube; and

a trigger attached to said shell, said trigger being movable between an open position that allows movement of said cutting plunger along said longitudinal axis of said cutting tube to thereby allow said cutting motion of said inner cutter needle, and a closed position that prevents movement of said cutting plunger along said longitudinal axis of said cutting tube to thereby prevent said cutting motion of said inner cutter needle.

8. The disposable biopsy device of Claim 7, wherein said trigger includes a plurality of clips, and wherein said shell includes a plurality of slots formed therein, each of said plurality of slots receiving a corresponding one of said plurality of clips of said trigger, and further being sized, shaped and positioned so as to restrict movement of said trigger other than between said open position and said closed position.

9. The disposable biopsy device of Claim 8, wherein said cutting plunger includes a plurality of tabs located between said proximal end and said distal end of said cutting plunger, wherein said shell includes a plurality of protrusions, and wherein said trigger includes a plurality of protrusions sized, shaped, and positioned such that, when one of said plurality of tabs of said cutting plunger is aligned with said plurality of protrusions of said trigger, positioning of said trigger in said open position places said cutting plunger in a position such that said plurality of protrusions of said shell do not restrict movement of said plurality of tabs and positioning of said trigger in said closed position places said

cutting plunger in a position such that at least one of said plurality of protrusions of said shell restricts movement of said plurality of tabs.

10. The disposable biopsy device of Claim 9, further comprising an adapter constructed so as to be removably mounted on one of said plurality of tabs of said cutting plunger, said cutting plunger being movable between proximal and distal positions for creating said cutting motion of said inner cutter needle, said adapter being configured to define said proximal position of said cutting plunger.

11. The disposable biopsy device of Claim 7, wherein said trigger is rotatably mounted to said shell so as to move between said open position and said closed position.

12. The disposable biopsy device of Claim 7, further comprising a device removably mounted to said shell and having a pointed end for removing a tissue sample from said inner cutter needle.

13. The disposable biopsy device of Claim 2, wherein said cylinder of said vacuum generating assembly includes a stopper proximate to said proximal end of said cylinder, wherein said plunger of said vacuum generating assembly includes a plurality of ridges, and wherein said ridges selectively cooperate with said stopper to control an intensity of said vacuum.

14. A method for obtaining a tissue sample, the method comprising the steps of:

providing a disposable biopsy device, the disposable biopsy device including:

a vacuum generating assembly including a cylinder and a plunger disposed within the cylinder such that motion of said plunger along said cylinder generates a vacuum; and

a tissue cutting assembly including:

a hollow outer needle including a proximal end, a distal end opposite said proximal end, a longitudinal axis, and a tissue receiving slot at said distal end; and

an inner cutter needle coaxially positioned within said outer needle and capable of moving along said longitudinal axis of said outer needle,

wherein said vacuum generating assembly is pneumatically coupled to said tissue cutting assembly such that said vacuum induces a cutting motion of said inner cutter needle in a direction away from said proximal end of said outer needle and toward said distal end of said outer needle;

placing the hollow outer needle at a location of the tissue sample;

withdrawing said plunger from said cylinder to generate said vacuum;

placing said inner cutter needle at a cutting position;

initiating said cutting motion of said inner cutter needle to sever said tissue sample.

15. The method of Claim 14, wherein said vacuum generating assembly is pneumatically coupled to said tissue cutting assembly such that, when said inner cutter

needle is placed at said cutting position, said vacuum draws the tissue sample into said tissue receiving slot of said outer needle.

16. The method of Claim 14, wherein said tissue cutting assembly further includes:

a trigger adapted to be selectively positioned in an open position that allows movement of said inner cutter needle and adapted to be selectively positioned in a closed position that prevents movement of said inner cutter needle,

wherein said step of initiating said cutting motion of said inner cutter needle comprises moving said trigger from said closed position to said open position.

17. The method of Claim 16, wherein said tissue cutting assembly further includes a cutting plunger affixed to said proximal end of said inner cutter needle, and wherein said cutting plunger includes a plurality of tabs at a corresponding plurality of positions between said proximal end and said distal end.

18. The method of Claim 17, wherein said disposable biopsy device further comprises a shell enclosing at least a portion of said disposable biopsy device, said shell including a plurality of protrusions.

19. The method of Claim 18, wherein said trigger includes a plurality of protrusions sized, shaped, and positioned such that, when said trigger is positioned in said closed position, said plurality of protrusions of said trigger place one of said plurality of tabs of said cutting plunger in alignment with one of said plurality of protrusions of said shell

such that said one of said plurality of protrusions of said shell prevents movement of said one of said plurality of tabs of the cutting plunger.

20. A disposable biopsy device comprising:

A. a tissue cutting assembly comprising:

an outer needle including a tissue receiving slot at a distal end of the outer needle; an elongated tube; an inner cutter needle including a tissue receiving port at a distal end of the inner cutter needle; a first plunger; and a first stopper;

wherein

(i) the outer needle is attached to a distal end of the tube;

(ii) the inner cutter needle is attached to a distal end of the first plunger;

(iii) the inner cutter needle and the first plunger are coaxially positioned within the tube and capable of rotating about and translating along the longitudinal axis of the tube;

(iv) the inner cutter needle is coaxially positioned within the outer needle and capable of rotating about and translating along the longitudinal axis of the outer needle; and

(v) the first stopper is attached to or connected to a proximal end of the tube; and

B. a vacuum assembly comprising:

an elongated cylinder; a second plunger; and a second stopper; wherein

(i) the second plunger is coaxially disposed within the cylinder and capable of rotating about and translating along the longitudinal axis of the cylinder; and

(ii) the second stopper is attached to or connected to a proximal end of the cylinder;

wherein the vacuum assembly and the cutting assembly are two separate compartments in fluid communication through one or more air holes in between.

21. The disposable biopsy device according to claim 20, wherein the tube has one or more air path holes on a bottom surface of the tube, the cylinder has one or more air path holes on the top surface of the cylinder, and the inner cutter needle has one or more holes near its proximal end such that the vacuum generated by pulling the second plunger creates a low pressure region near the tissue receiving slot.

22. The disposable biopsy device according to claim 21, wherein the tube has an air release hole on a top surface of the tube for releasing the vacuum.

23. The disposable biopsy device according to claim 20, wherein the first plunger and the first stopper are configured to mate thereby controlling a length of tissue to be severed from a tissue mass; and the second plunger and the second stopper are configured to mate thereby controlling vacuum levels.

24. The disposable biopsy device according to claim 20, wherein the tube has a cutting length indicator which has numerical indicia corresponding to the length of tissue to be separated from the tissue mass.

25. The disposable biopsy device according to claim 20, wherein the first plunger comprises a plunger rod, one or more ridges, and one or more notches on the plunger

rod, the first plunger together with the first stopper controlling the length of tissue to be severed.

26. The disposable biopsy device according to claim 20, wherein the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined position across adjacent raised edges, and a plurality of notches in front of or behind the ridges, the first plunger together with the first stopper controlling the length of tissue to be severed.

27. The disposable biopsy device according to claim 20, wherein the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined position across adjacent raised edges wherein the first stopper is configured to engage the ridge on the first plunger thereby stopping the plunger from moving forward and controlling the length of tissue.

28. The disposable biopsy device according to claim 27, wherein the first plunger has a plurality of notches thereon which allow the first plunger to be rotated, which disengages the first stopper and allows the first plunger to move further backward or forward.

29. The disposable biopsy device according to claim 20, wherein the second plunger comprises a plunger rod, and one or more ridges, and one or more notches on the

plunger rod, the second plunger together with the second stopper controlling the vacuum levels.

30. The disposable biopsy device according to claim 20, wherein the second plunger and the second stopper work together to control vacuum levels, the second plunger comprising a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined position across adjacent raised edges, which when engaged, the second stopper stops the forward or backward movement of the plunger, and a plurality of notches in front of or behind the ridges, which allow the plunger to freely rotate, so that the second stopper is disengaged and the plunger is allowed to move forward or backward.

31. The disposable hand held biopsy device according to claim 20, wherein the second plunger comprises a plunger rod, a plurality of raised edges projecting laterally therefrom, and a plurality of notches breaking the raised edges, and the second stopper is configured to interlock the raised edge of the plunger and restrict the plunger from rotating freely, while the notches allow the plunger to rotate and disengage the second stopper.

32. The disposable biopsy device according to claim 20, wherein the sample receiving slot has saw teeth thereon along its lateral sides, which hold the tissue tightly prior to and at the time that the inner cutter needle advances to cut the prolapsed tissue from the tissue mass.

33. The disposable biopsy device according to claim 20, further comprising the a sample collector, which grasps the severed tissue sample out of the inner cutter needle such that the tissue sample is securely handled.

34. The disposable biopsy device according to claim 20, further comprising a shell that closely encloses the tube and cylinder.

35. The disposable biopsy device according to claim 22, further comprising a silicone fitting on top of the air release hole that seals the air release hole when pressed and releases the vacuum inside the biopsy device when released.

36. The disposable biopsy device according to claim 20, wherein the distal end of the outer needle is open and sharp such that it is easy to insert into the tissue.

37. The disposable hand held biopsy device according to claim 20, wherein the distal end of the inner cutter needle is open, beveled in shape, and contains a razor sharp edge that is effective to slice the tissue prolapsed into the tissue receiving slot and collect the severed tissue in its tissue receiving port.

38. The disposable biopsy device according to claim 20, wherein the first and second stoppers are continued as one unit or are two separate units.

39. A method of obtaining a tissue sample for biopsy examination using a disposable hand held biopsy device, the method comprising:

(a) providing a disposable biopsy device, the device comprising:

(1) a tissue cutting assembly comprising:

an outer needle comprising a tissue receiving slot at a distal end of the outer needle and saw teeth along lateral sides of the tissue receiving slot; an elongated tube comprising an air release hole and a cutting length indicator on a top surface of the tube; an inner cutter needle comprising a tissue receiving port at a distal end of the inner cutter needle; a first plunger; a first stopper; a silicone fitting on top of the air release hole; and a tissue sample collector;

wherein

(i) the outer needle is attached to a distal end of the tube;

(ii) the inner cutter needle is attached to a distal end of the first plunger;

(iii) the inner cutter needle and the first plunger are coaxially positioned within the tube and capable of rotating about and translating along the longitudinal axis of the tube;

(iv) the inner cutter needle is coaxially positioned within the outer needle and capable of rotating about and translating along the longitudinal axis of the outer needle; and

(v) the first stopper is attached to or connected to a proximal end of the tube; and

(2) a vacuum assembly comprising:

an elongated cylinder; a second plunger; and a second stopper; wherein

(i) the second plunger is coaxially disposed within the cylinder and capable of rotating about and translating along the longitudinal axis of the cylinder; and

(ii) the second stopper is attached to or connected to a proximal end of the cylinder; wherein the vacuum assembly and the cutting assembly are two separate compartments in fluid communication through one or more air holes in between; and

(b) placing the outer needle at a location of collecting sample tissue;

(c) covering the air release hole;

(d) withdrawing the second plunger, rotating the plunger, and locking the plunger in place;

(e) pulling the first plunger backward such that its distal end is aligned with one of the numerical indicia on the cutting length indicator corresponding to a desired tissue length, exposing the tissue receiving slot on the outer needle so that the tissue prolapses into the sample receiving slot and is held tight by the vacuum and the saw teeth along the tissue receiving slot;

(f) releasing the first plunger and the attached inner cutter needle, which are then propelled by a gradient pressure to advance into the tissue receiving slot and sever the tissue, which has prolapsed into the sample port, and stops when it hits the first stopper;

(g) allowing air flow into the biopsy device, releasing the vacuum;

(h) pulling the biopsy device out from the body; and once outside the body,

(1) turning the first plunger clockwise until it stops;

(2) pushing the first plunger all the way forwards;

(3) grasping the outer needle near the distal end of the outer needle using the sample collector; and

(4) pulling the inner cutter needle backward to allow the severed tissue sample to fall out of the device by gravity.

40. The method according to claim 39, wherein the tube has one or more air path holes on the bottom surface, the cylinder has one or more air path holes on the top surface and the inner cutter needle has one or more holes near its proximal end, such that the vacuum generated by pulling the second plunger creates the low pressure region near the tissue receiving slot.

41. The method according to claim 39, wherein the first plunger and the first stopper are configured to mate thereby controlling the length of the tissue to be severed from the tissue mass; and the second plunger and the second stopper are configured to mate thereby controlling the vacuum levels.

42. The method according to claim 39, wherein the first plunger comprises a plunger rod, one or more ridges, and one or more notches on the plunger rod, the first plunger together with the first stopper controlling the length of tissue to be severed.

43. The method according to claim 39, wherein the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, a plurality of ridges disposed at predetermined position across adjacent raised edges, and a plurality of notches in front of or behind the ridges, the first plunger together with the first stopper controlling the length of tissue to be severed.

44. The method according to claim 39, wherein the first plunger comprises a plunger rod, a plurality of raised edges extending laterally therefrom, a plurality of ridges disposed at a predetermined position across adjacent raised edges, wherein the first stopper is configured to engage the ridge on the first plunger thereby stopping the plunger from moving forward whereby controlling the tissue length and a plurality notches thereon, which allow the first plunger to be rotated, thereby dis-engaging the first stopper and allowing the first plunger to move further backward or forward.

45. The method according to claim 39, wherein the second plunger comprises a plunger rod, one or more ridges, and one or more notches on the plunger rod, the second plunger together with the second stopper controlling the vacuum levels.

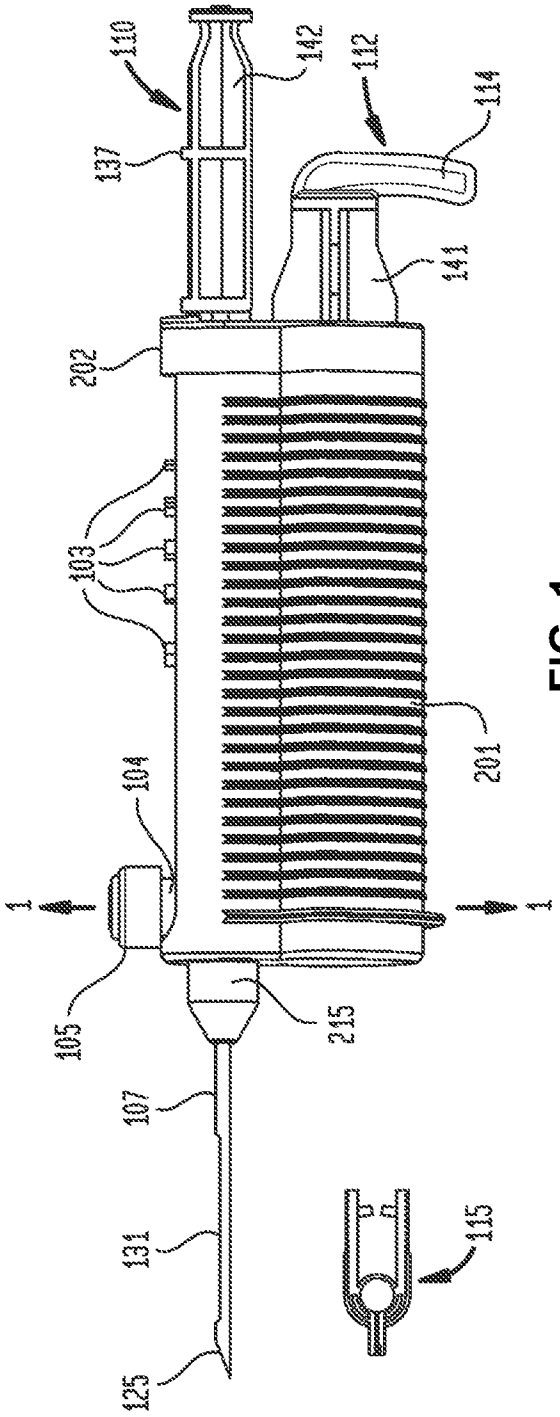
46. The method according to claim 39, wherein the second plunger and the second stopper work together to control the vacuum levels, the second plunger comprising a plunger rod, a plurality of raised edges extending laterally therefrom, and a plurality of ridges disposed at predetermined positions across adjacent raised edges, which when they engage the second stopper stops the forward or backward movement of the plunger, and a plurality of notches in front of or behind the ridges, which allow the plunger to freely rotate thereby disengaging the second stopper and allowing the plunger to move forward or backward.

47. The method according to claim 39, wherein the second plunger comprises a plunger rod, and a plurality of raised edges projecting laterally therefrom, wherein the

second stopper is configured to interlock the raised edge of the plunger, restricting the plunger from rotating freely, and the plunger has a plurality of notches allowing the plunger to rotate and disengage the second stopper.

48. The method according to claim 39, wherein the disposable biopsy device further comprising a shell that closely encloses the tube and cylinder.

49. The method according to claim 39, wherein the distal end of the outer needle is open and sharp such that it is easy to insert into the tissue and the distal end of the inner cutter needle is open, beveled in shape, and contains a razor sharp edge, the distal end of the inner cutter needle slicing the tissue prolapsed into the tissue receiving slot and collecting the severed tissue in its tissue receiving port.


110
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1
1
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131
125
115

FIG. 1

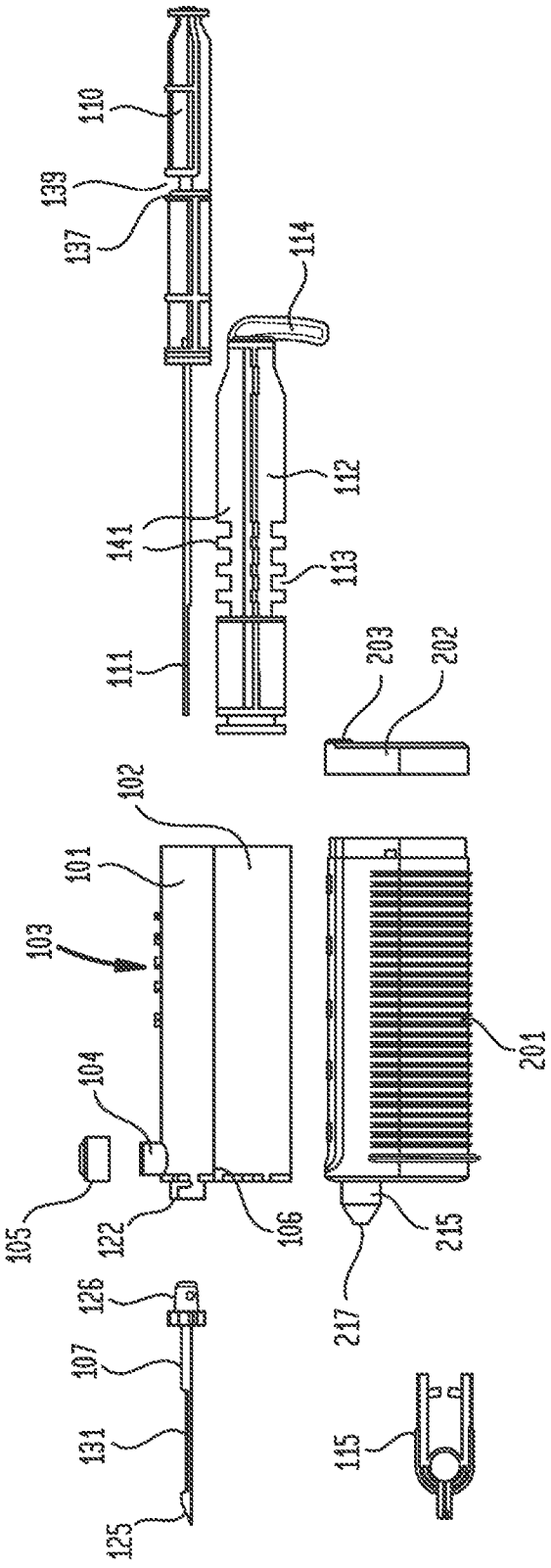
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FIG. 2

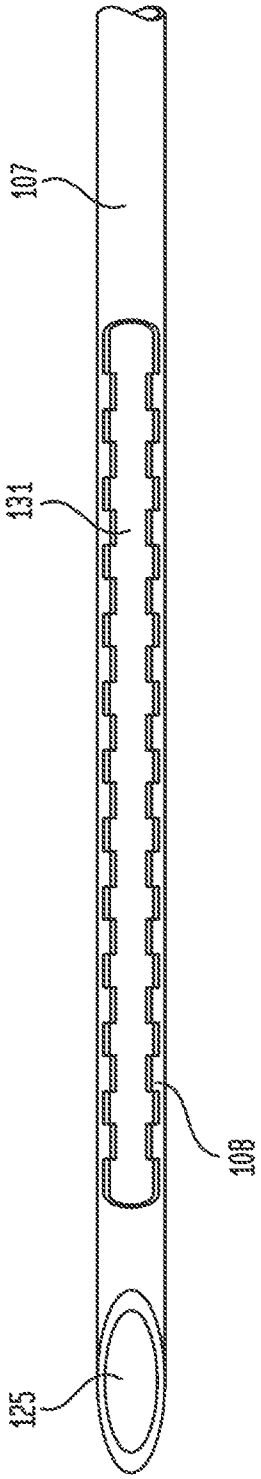

FIG. 3

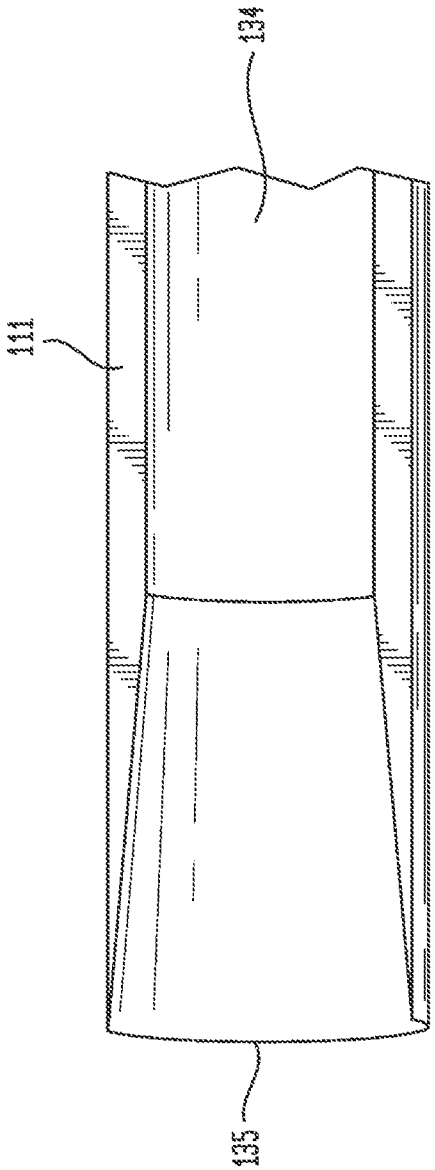

FIG. 4

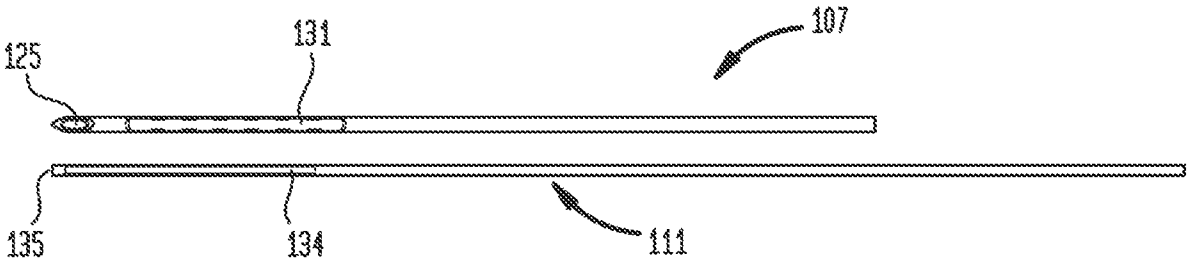

FIG. 5

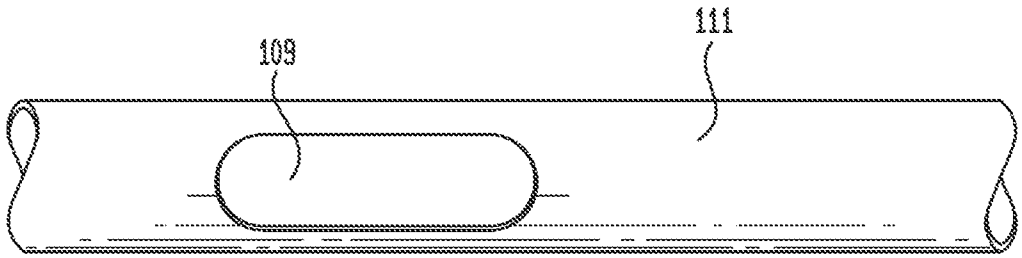

FIG. 6

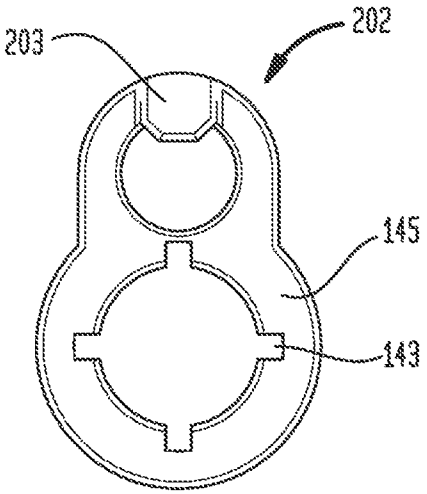

FIG. 7

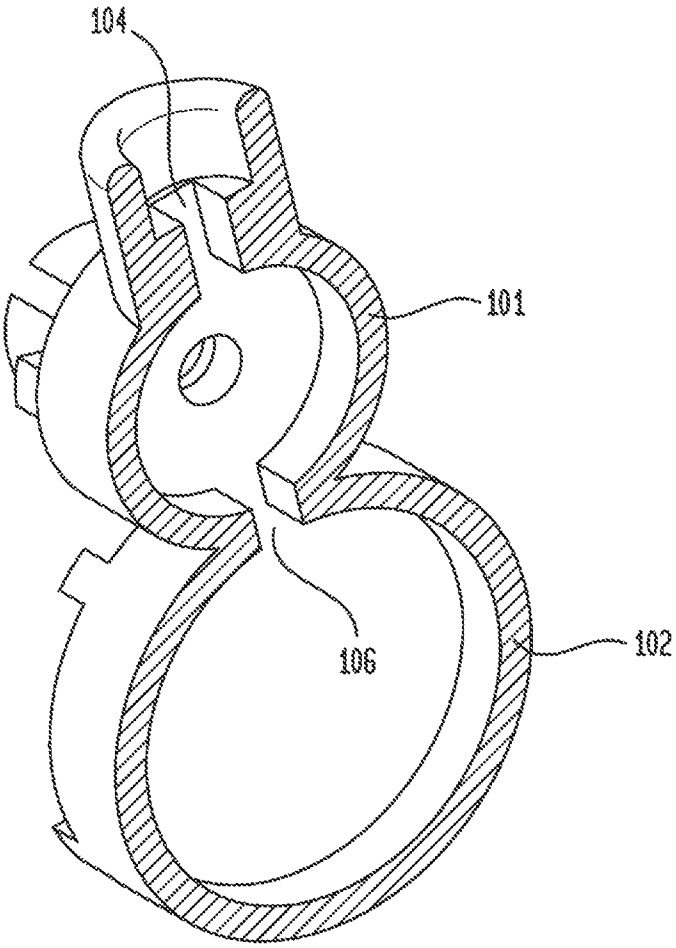

FIG. 8

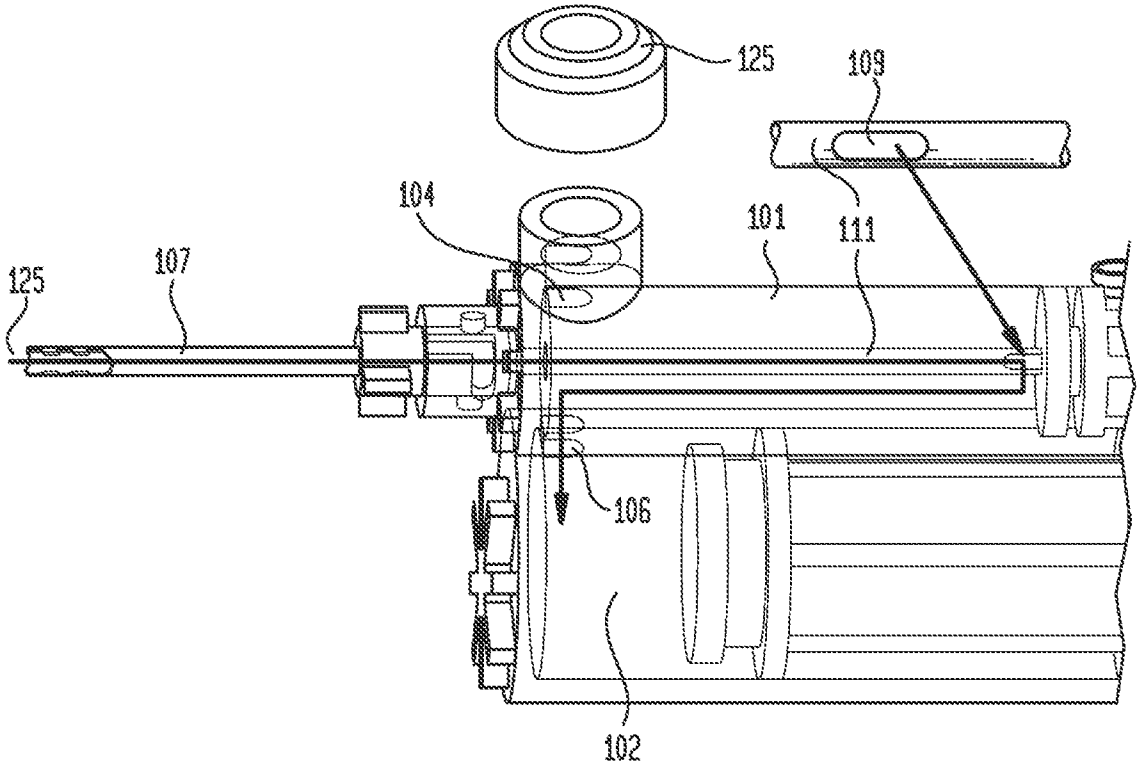

FIG. 9

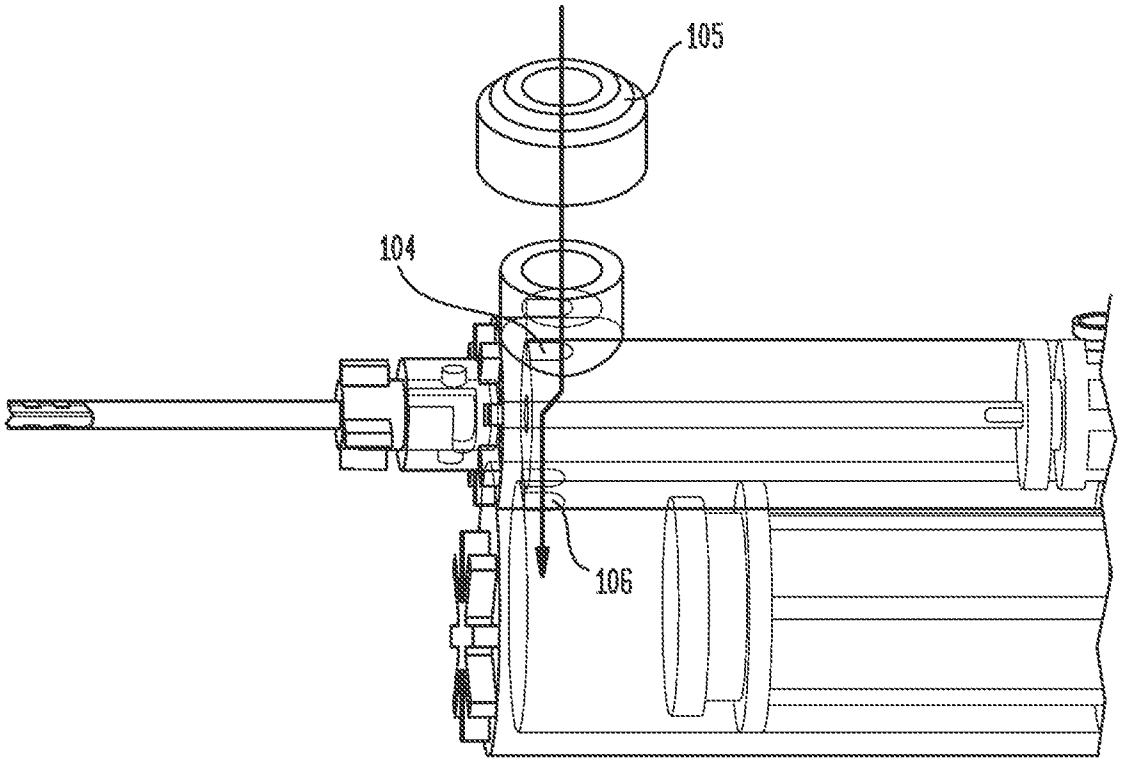

FIG. 10

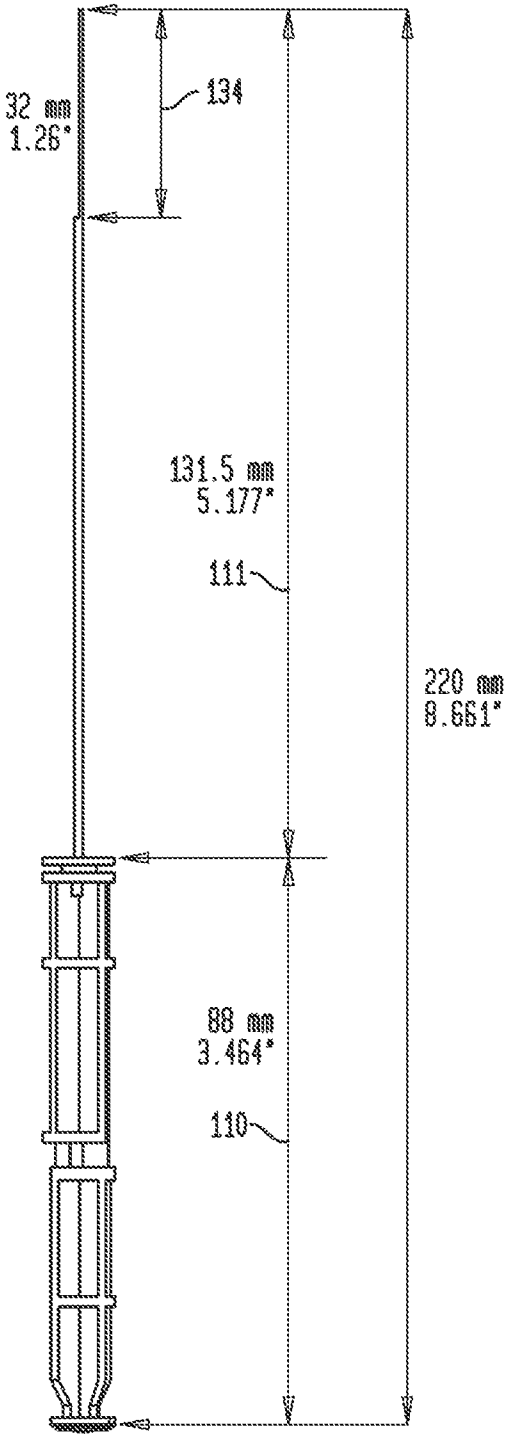

FIG. 11

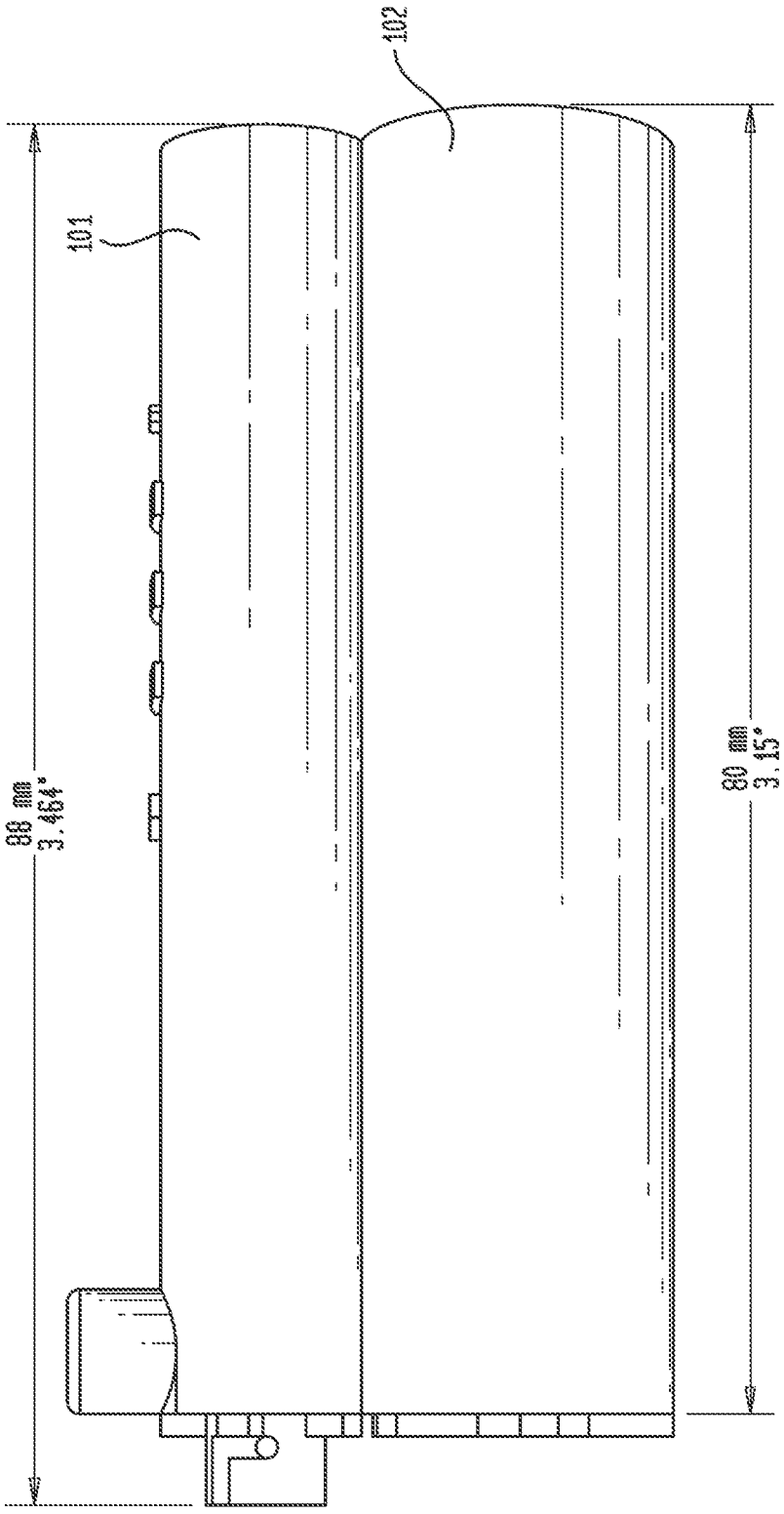

FIG. 12

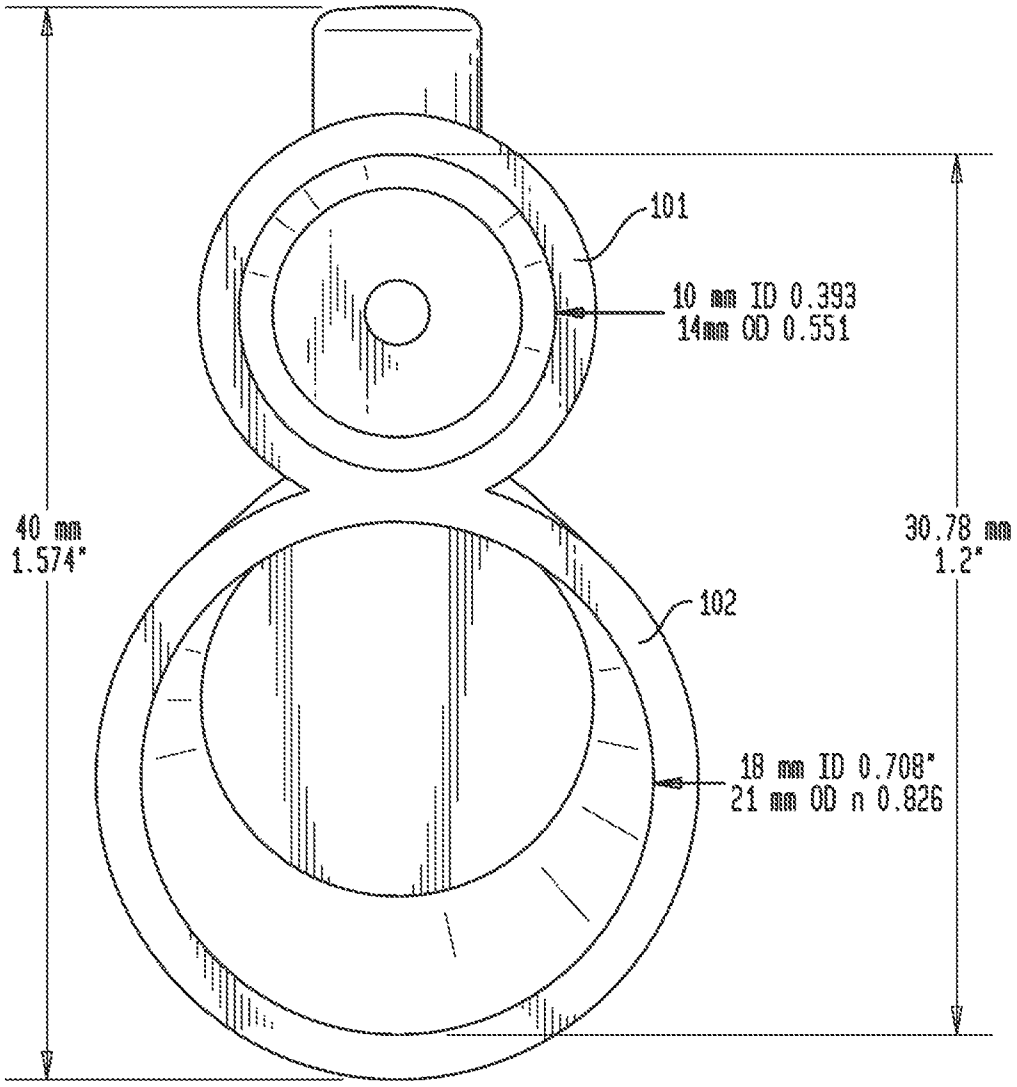
101
10 mm ID 0.393
14mm OD 0.551
40 mm
1.574"
30.78 mm
1.2"
102
18 mm ID 0.708"
21 mm OD n 0.826

FIG. 13

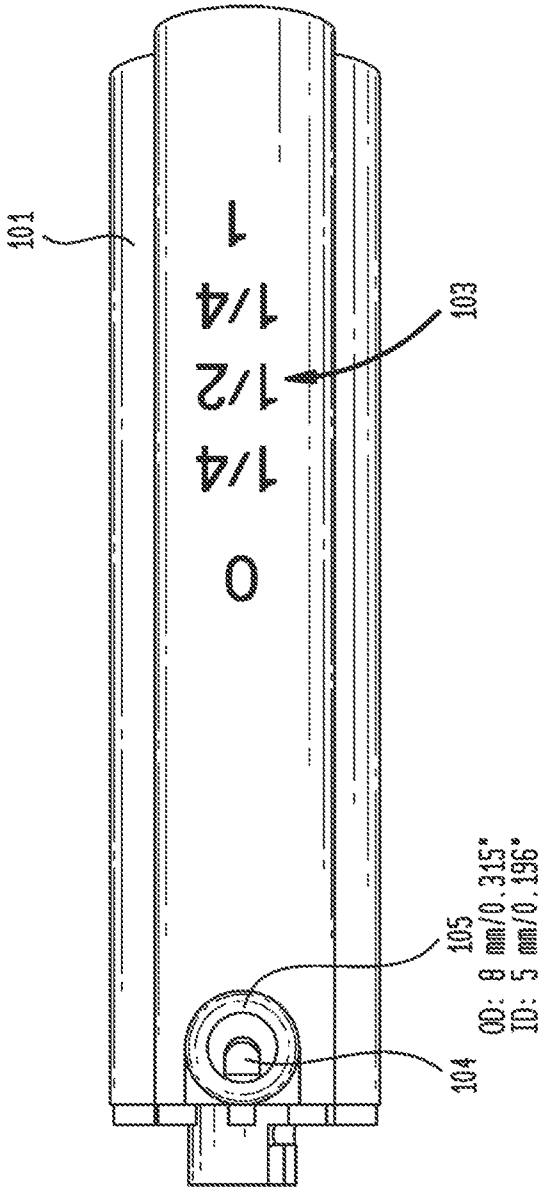

FIG. 14

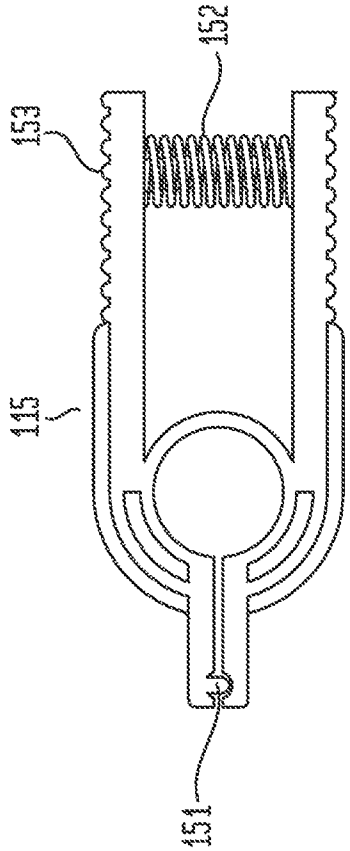

FIG. 15

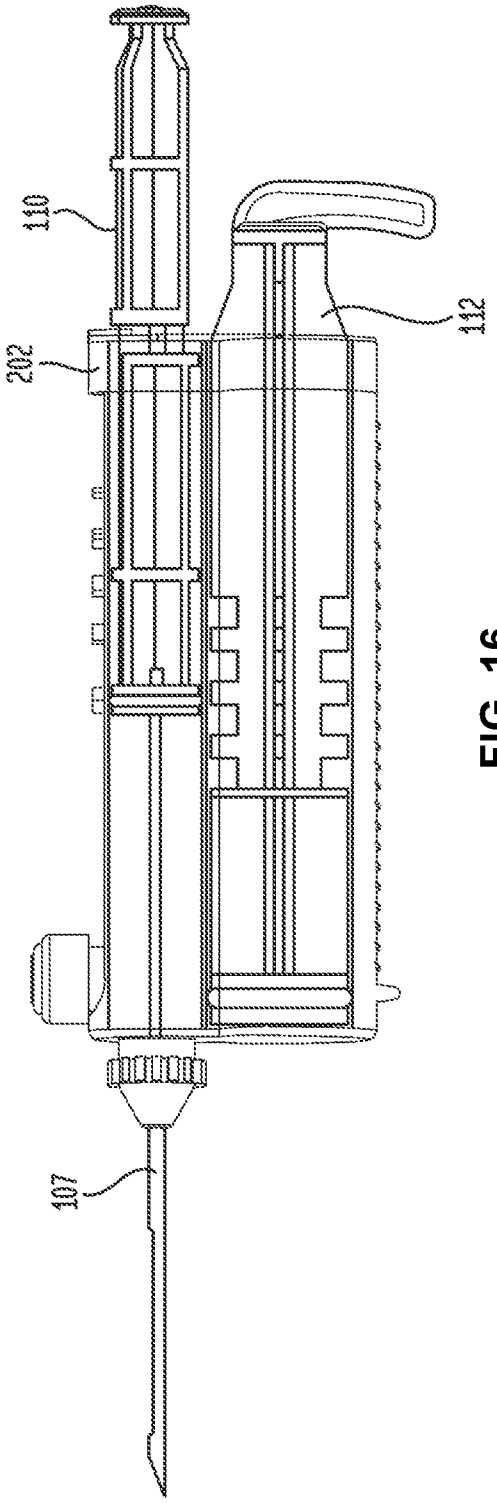

FIG. 16

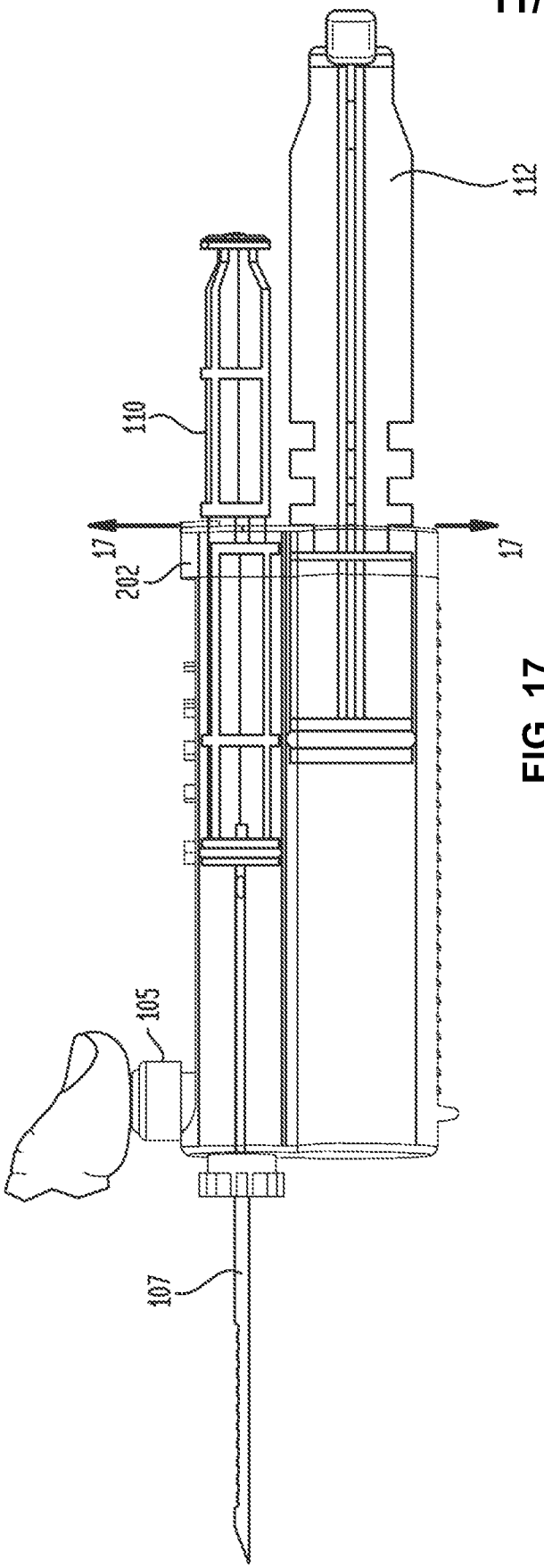

FIG. 17

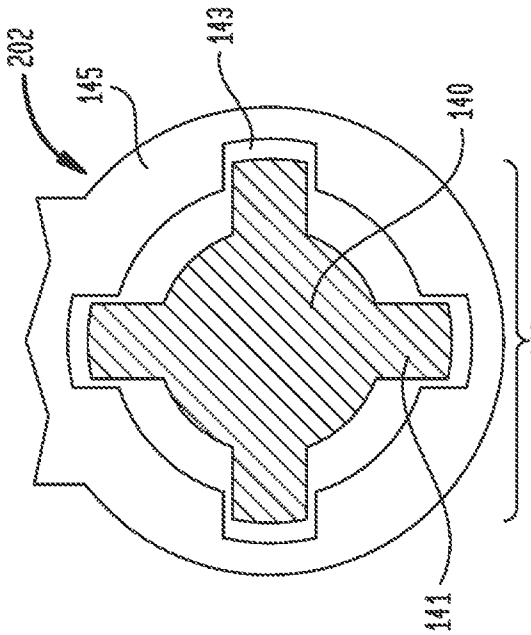

FIG. 18

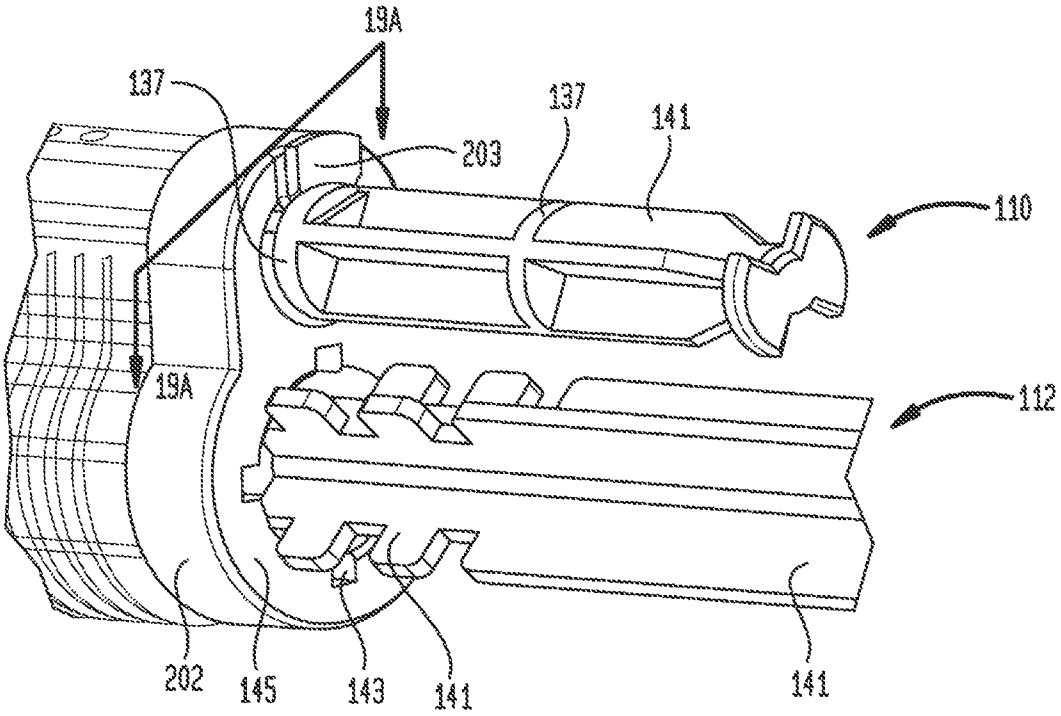

FIG. 19A

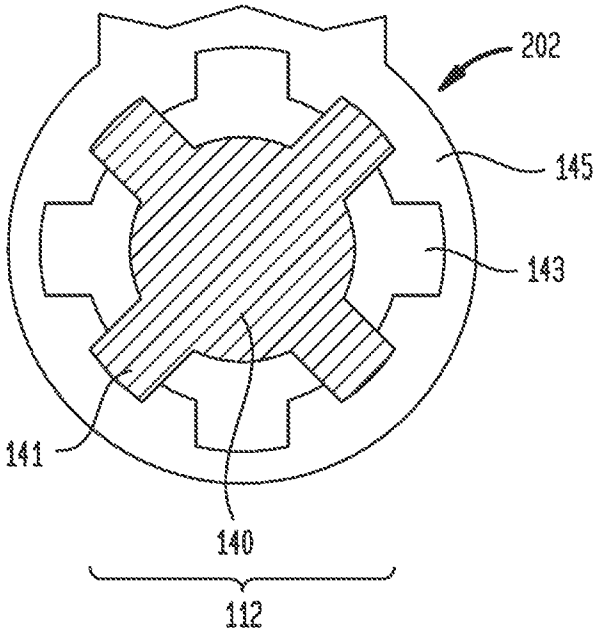

FIG. 19B

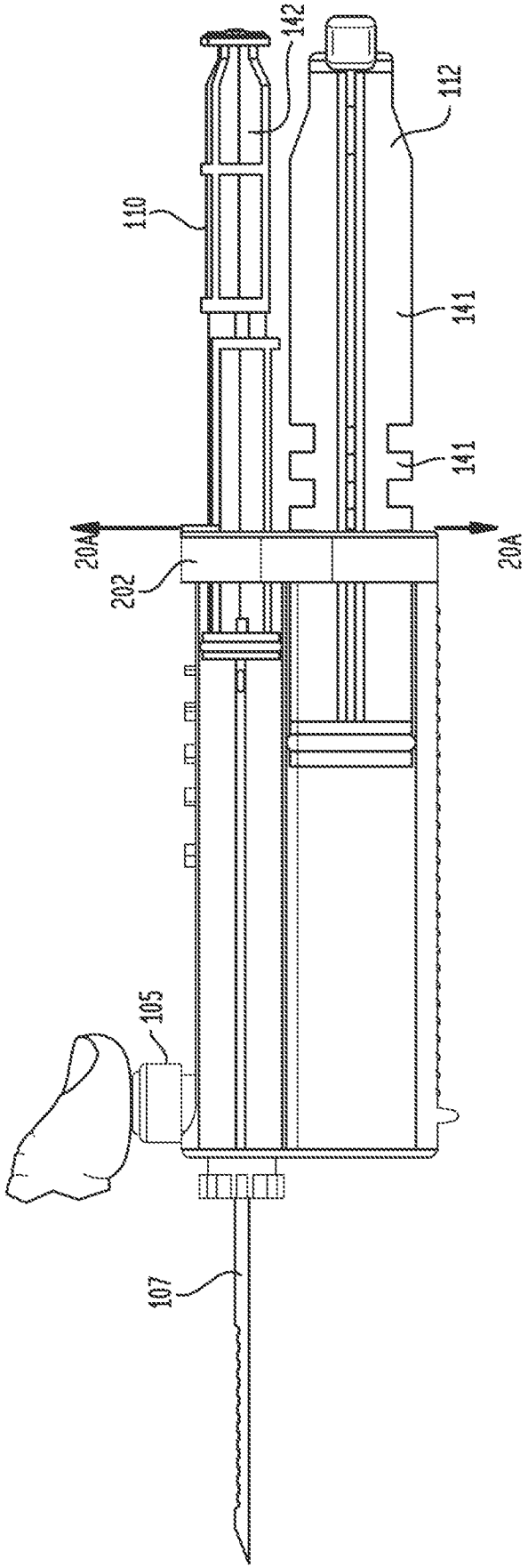

FIG. 20A

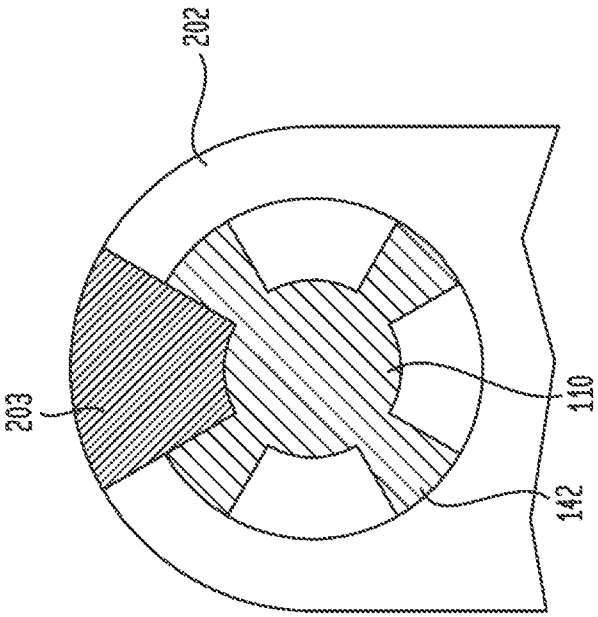

FIG. 20B

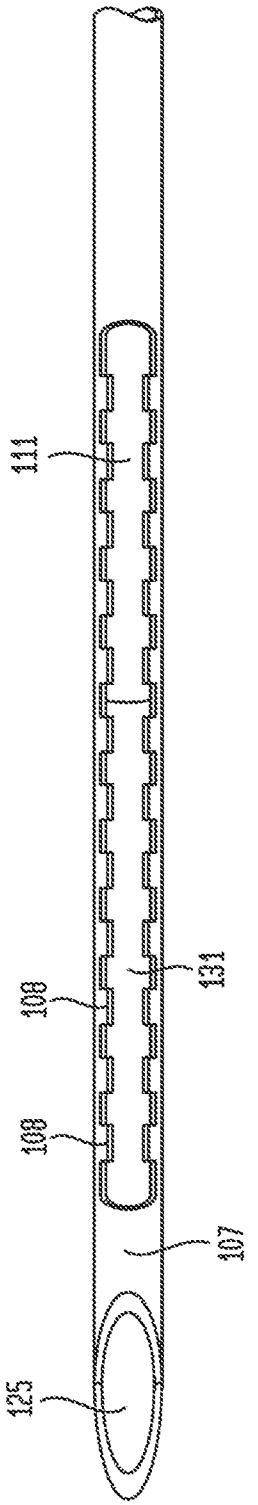

FIG. 21

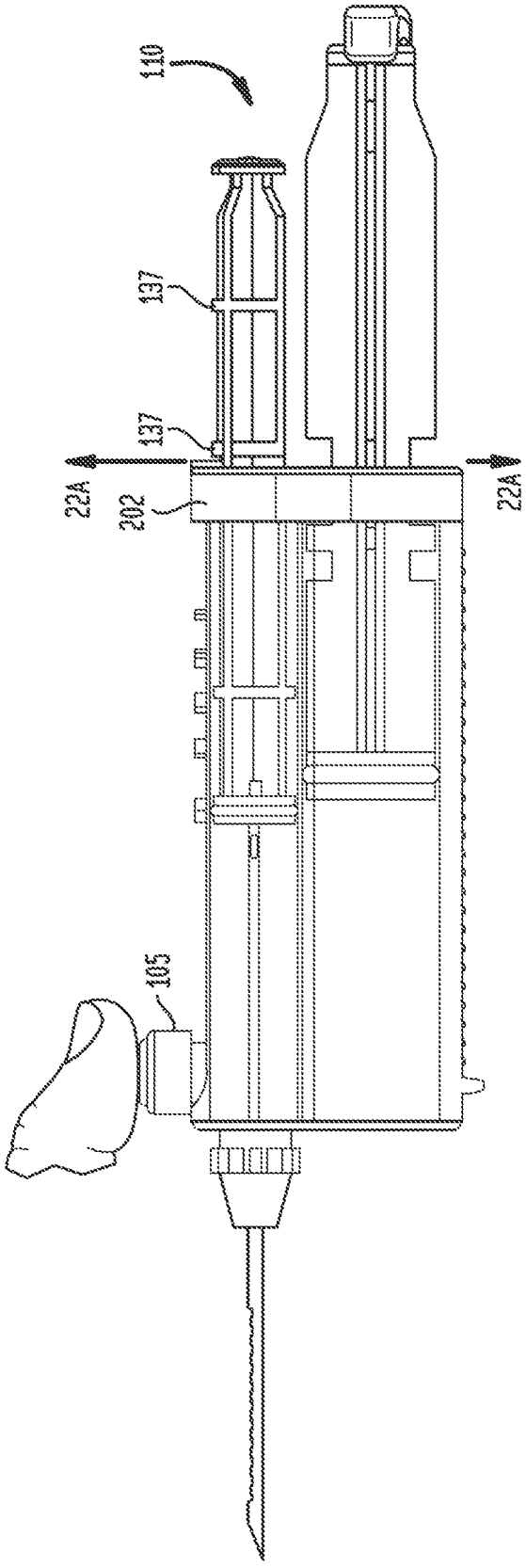

FIG. 22A

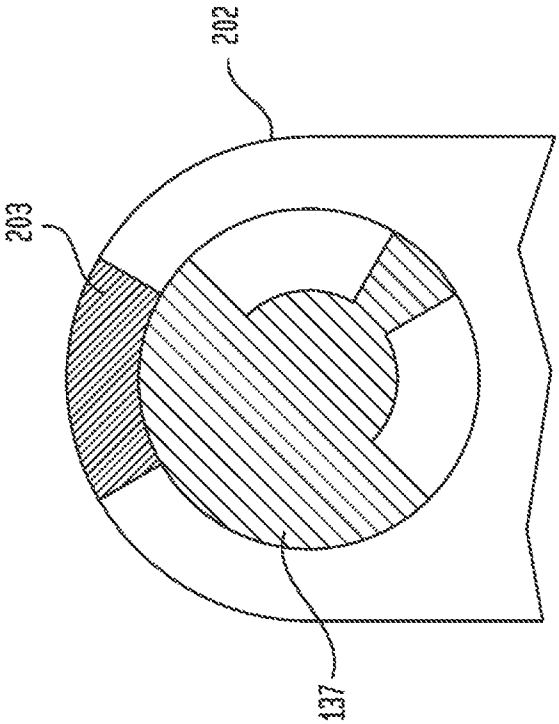

FIG. 22B

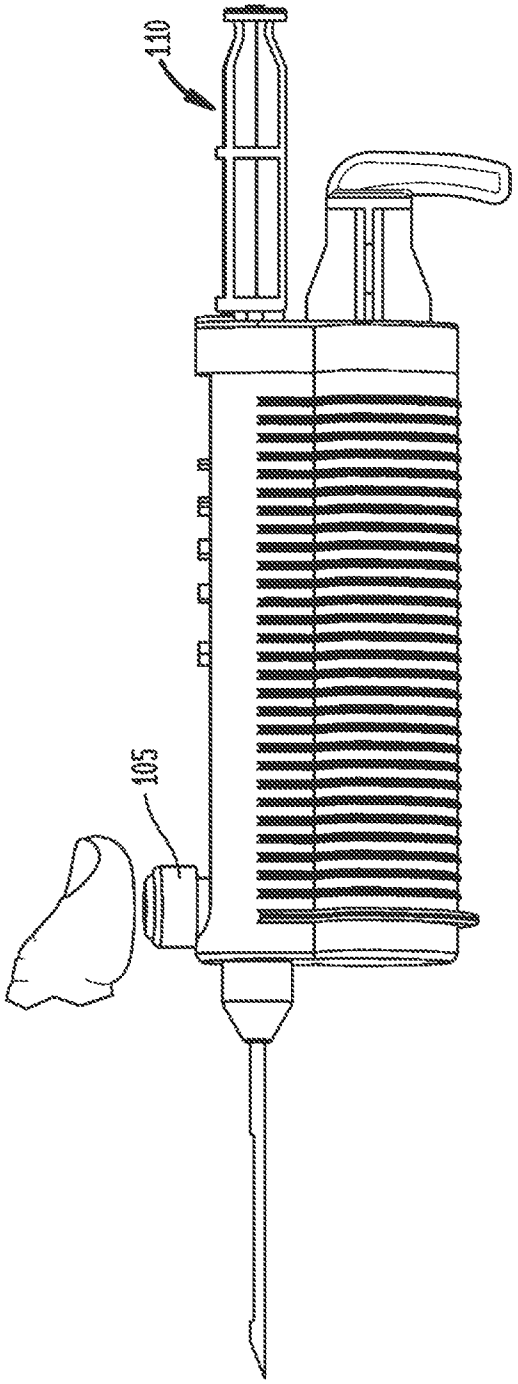

FIG. 23

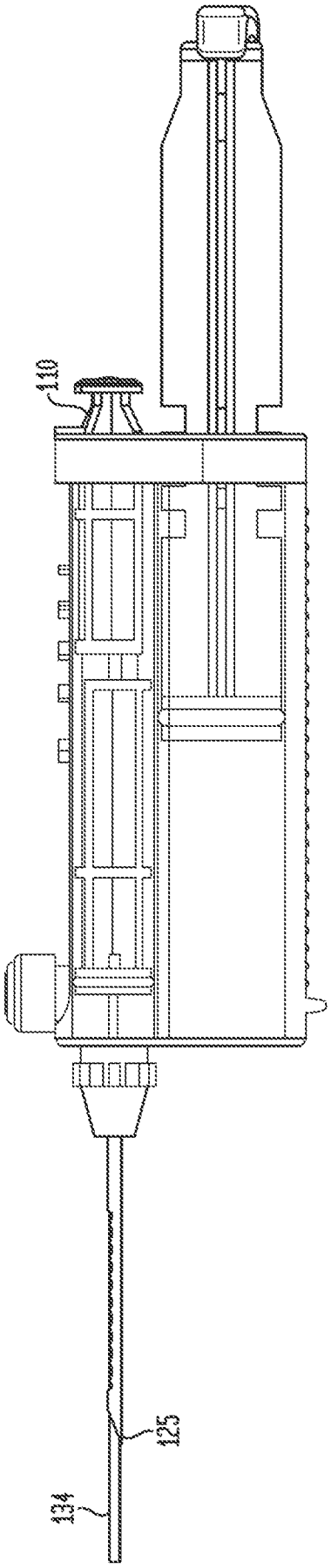

FIG. 24

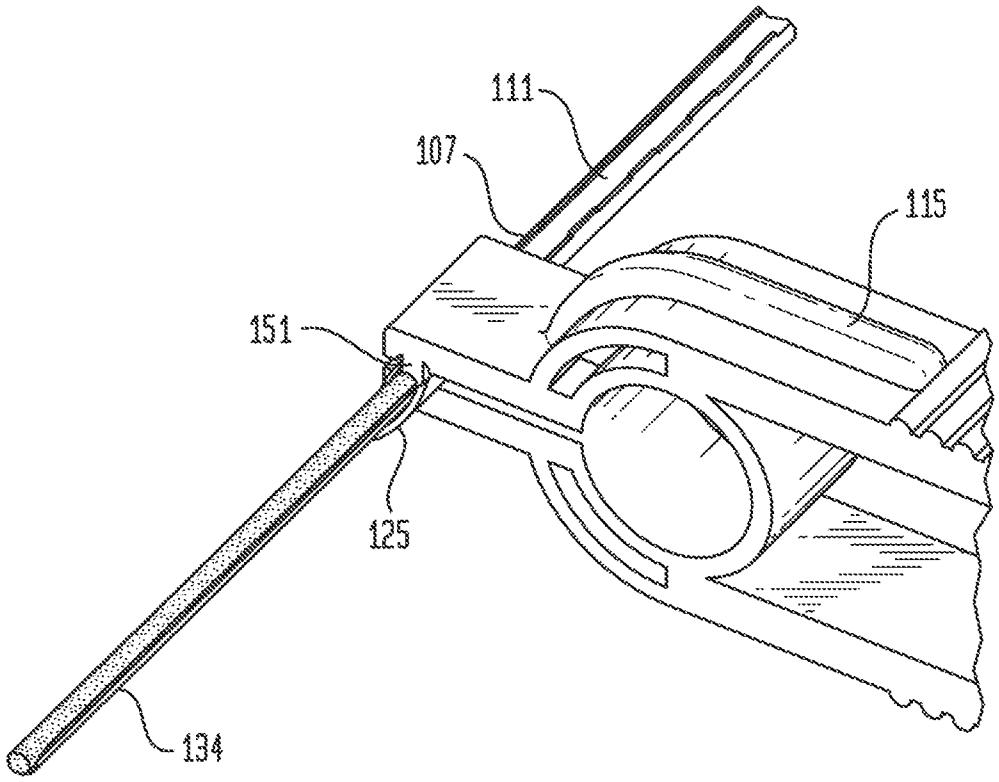

FIG. 25

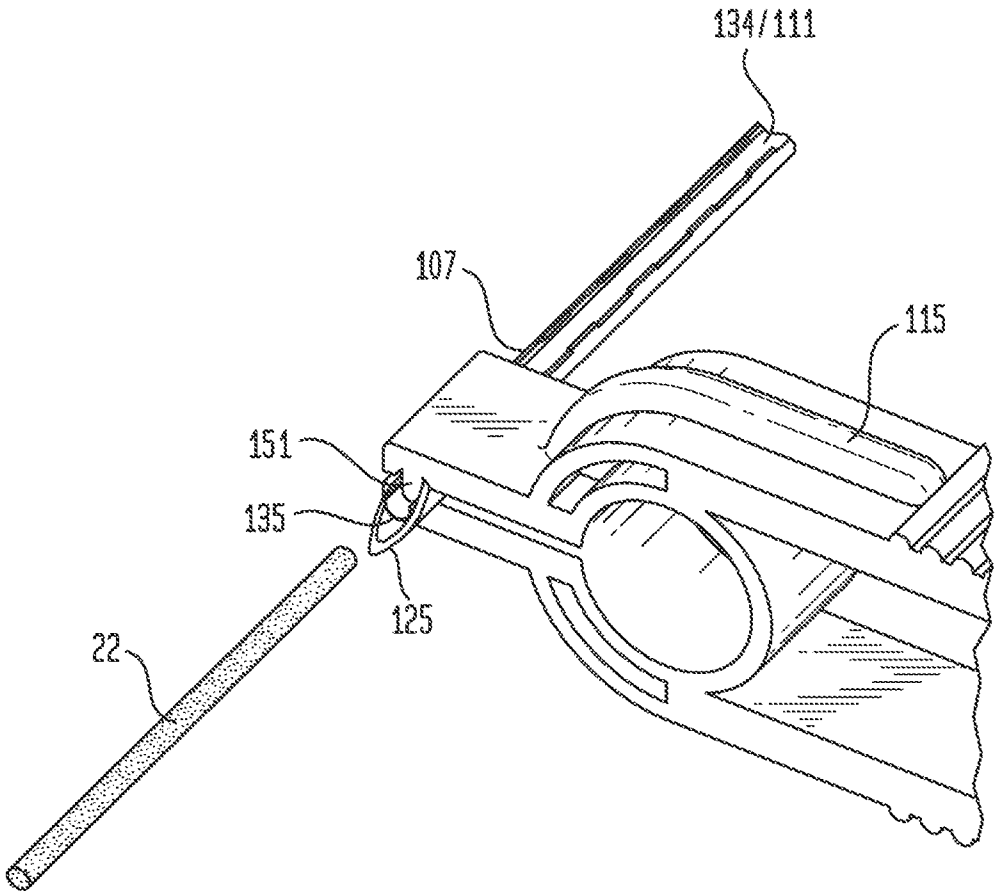

FIG. 26

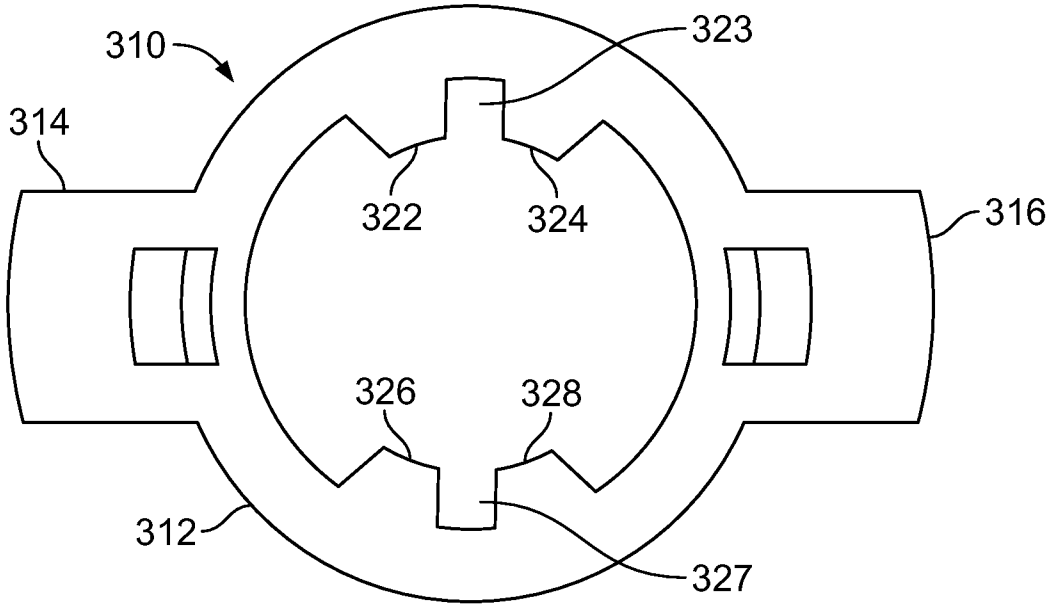

FIG. 27A

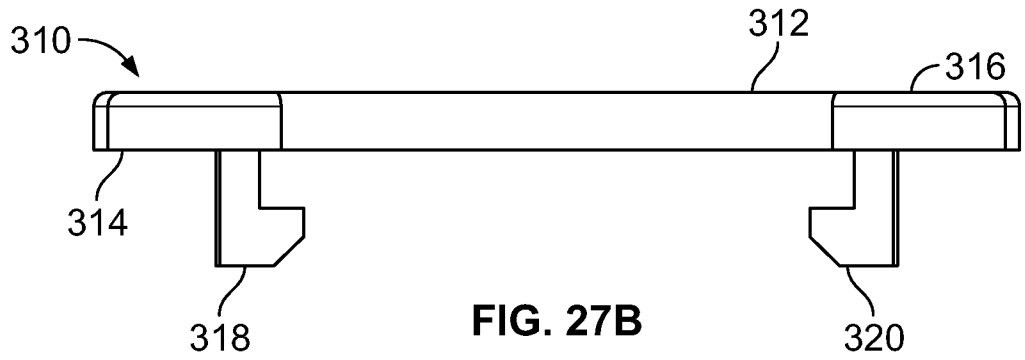

FIG. 27B

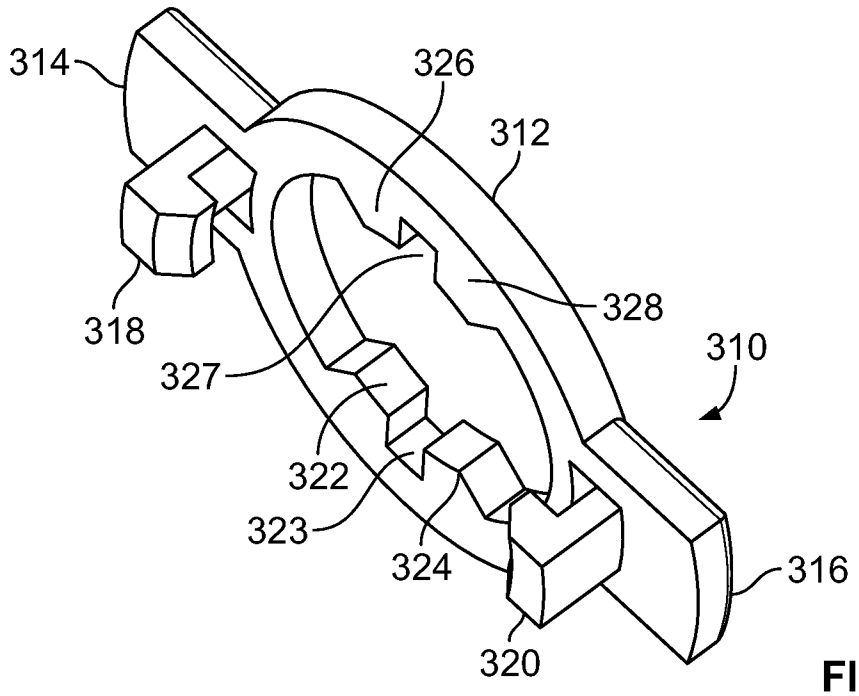

FIG. 27C

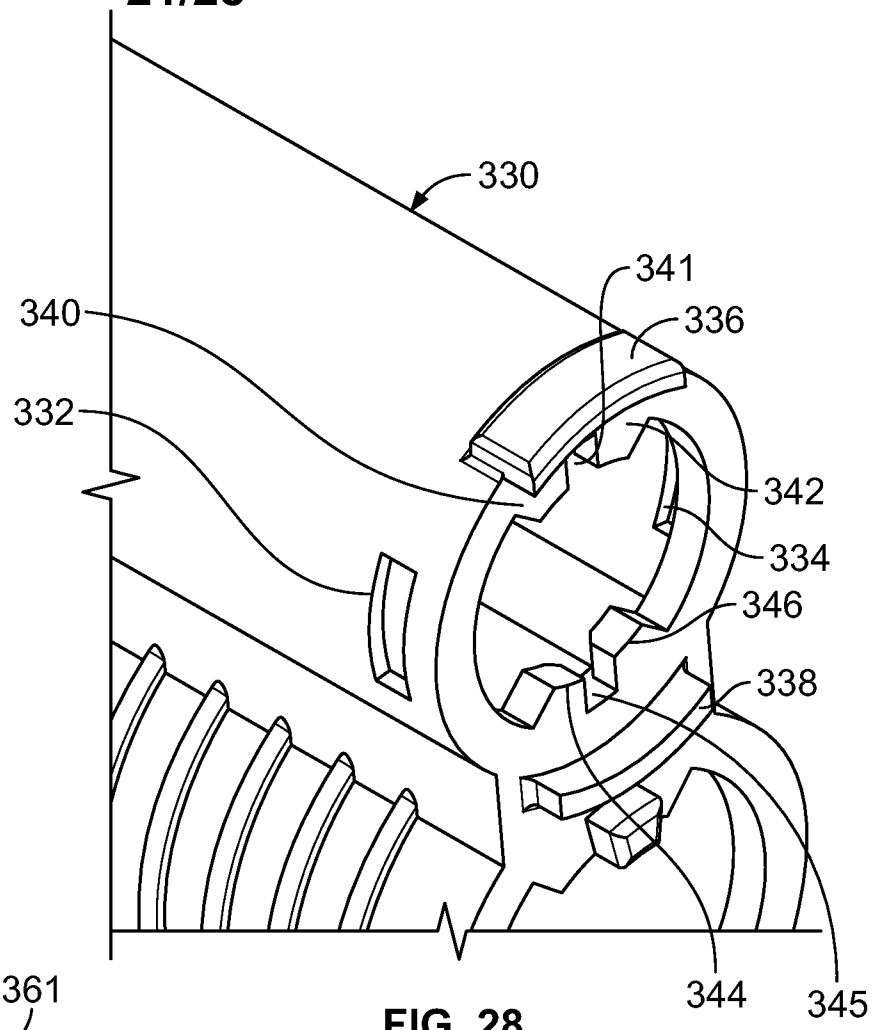

FIG. 28

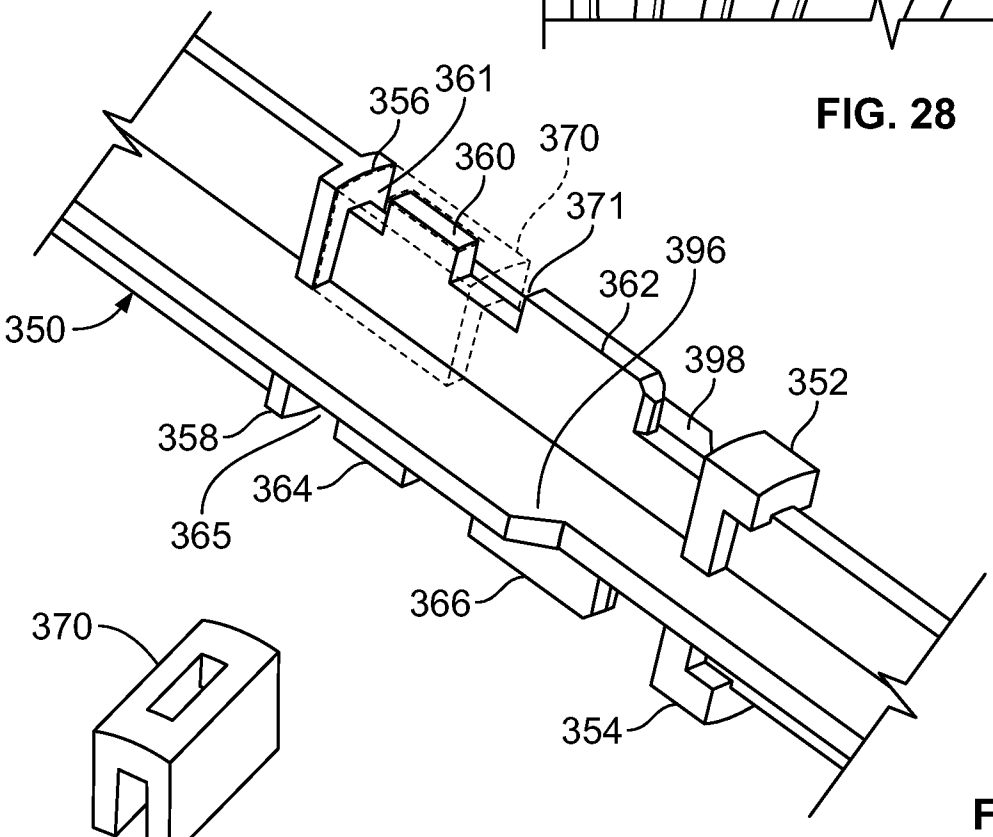

FIG. 29

FIG. 30

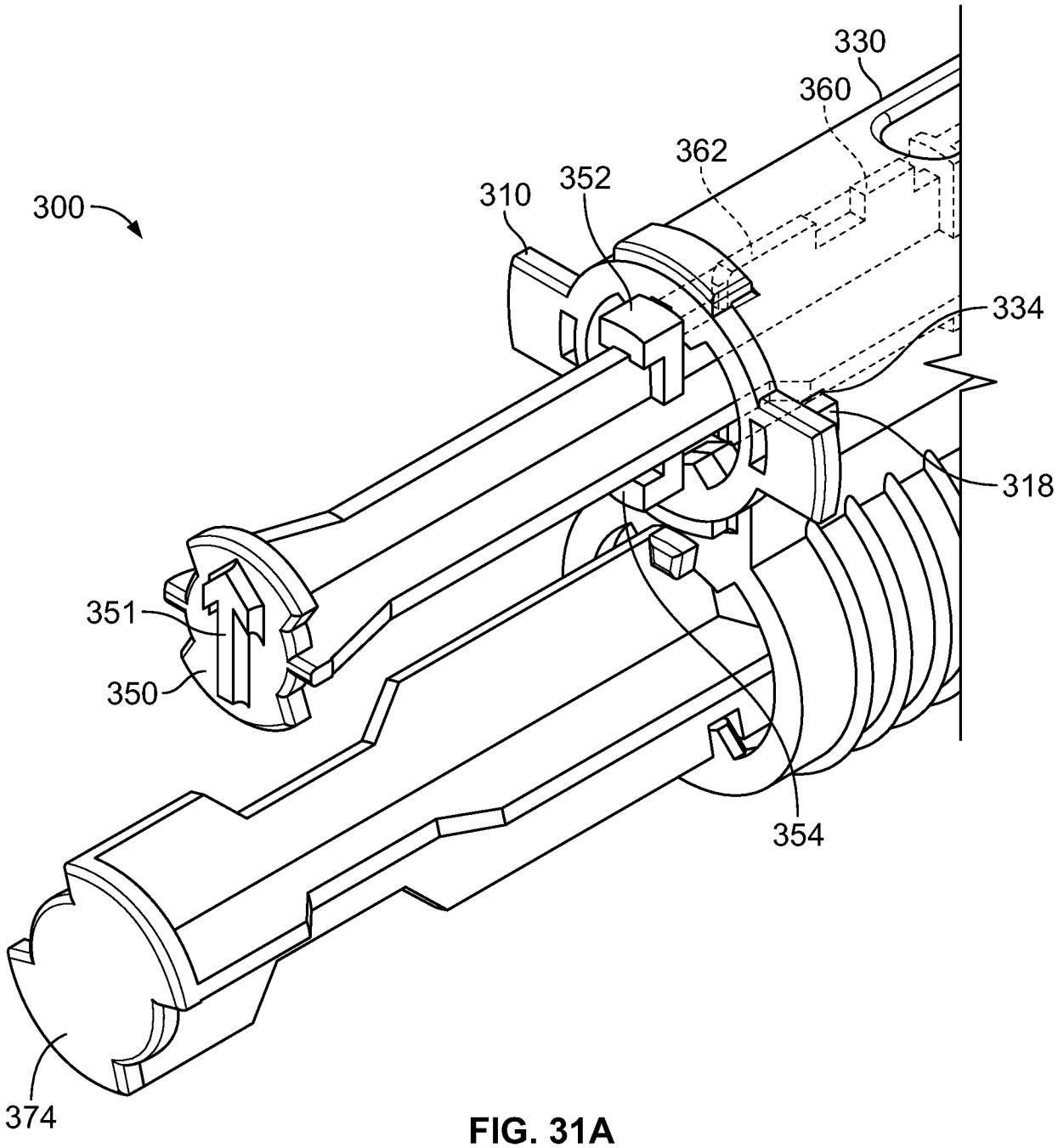

FIG. 31A

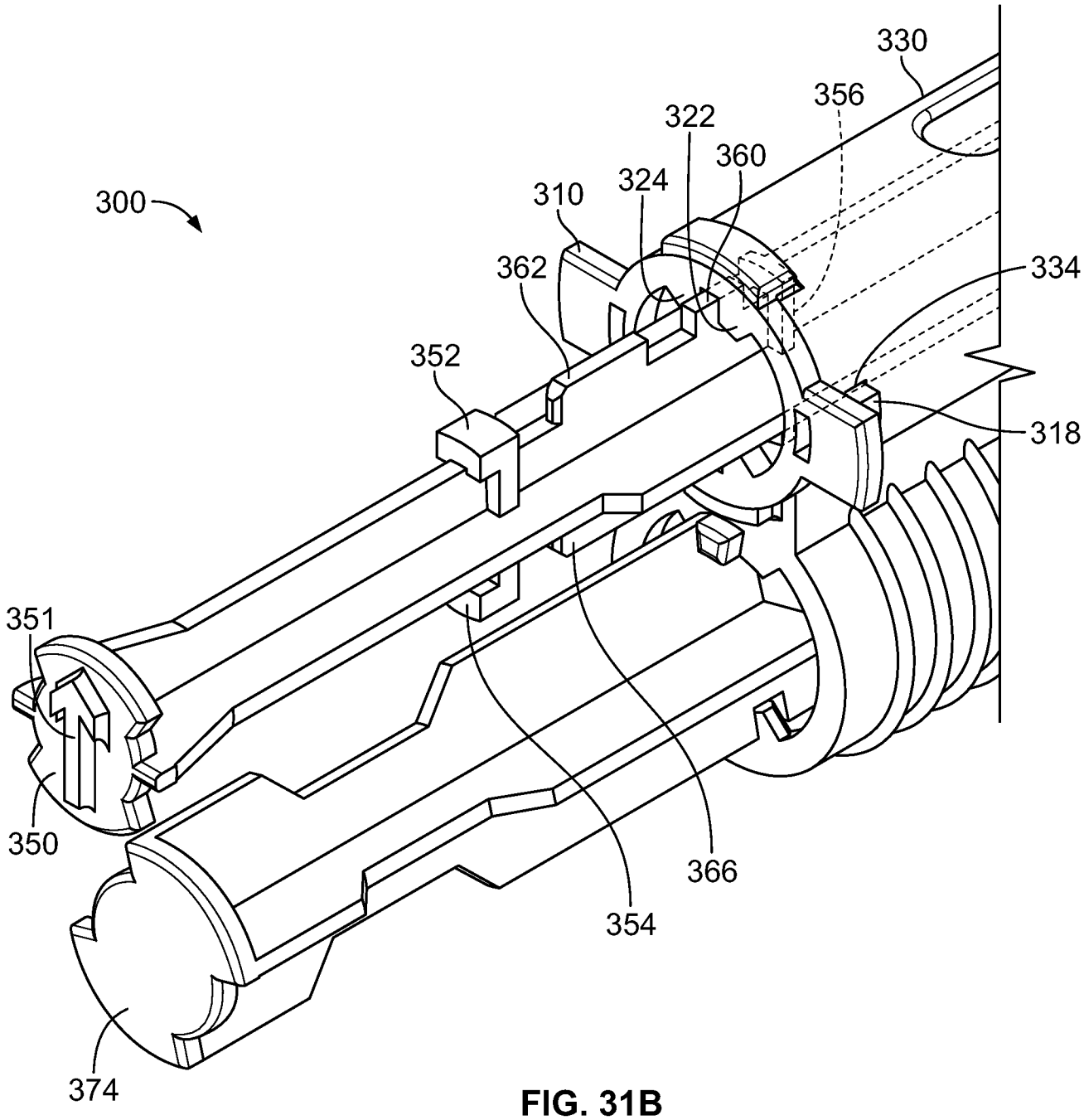

FIG. 31B

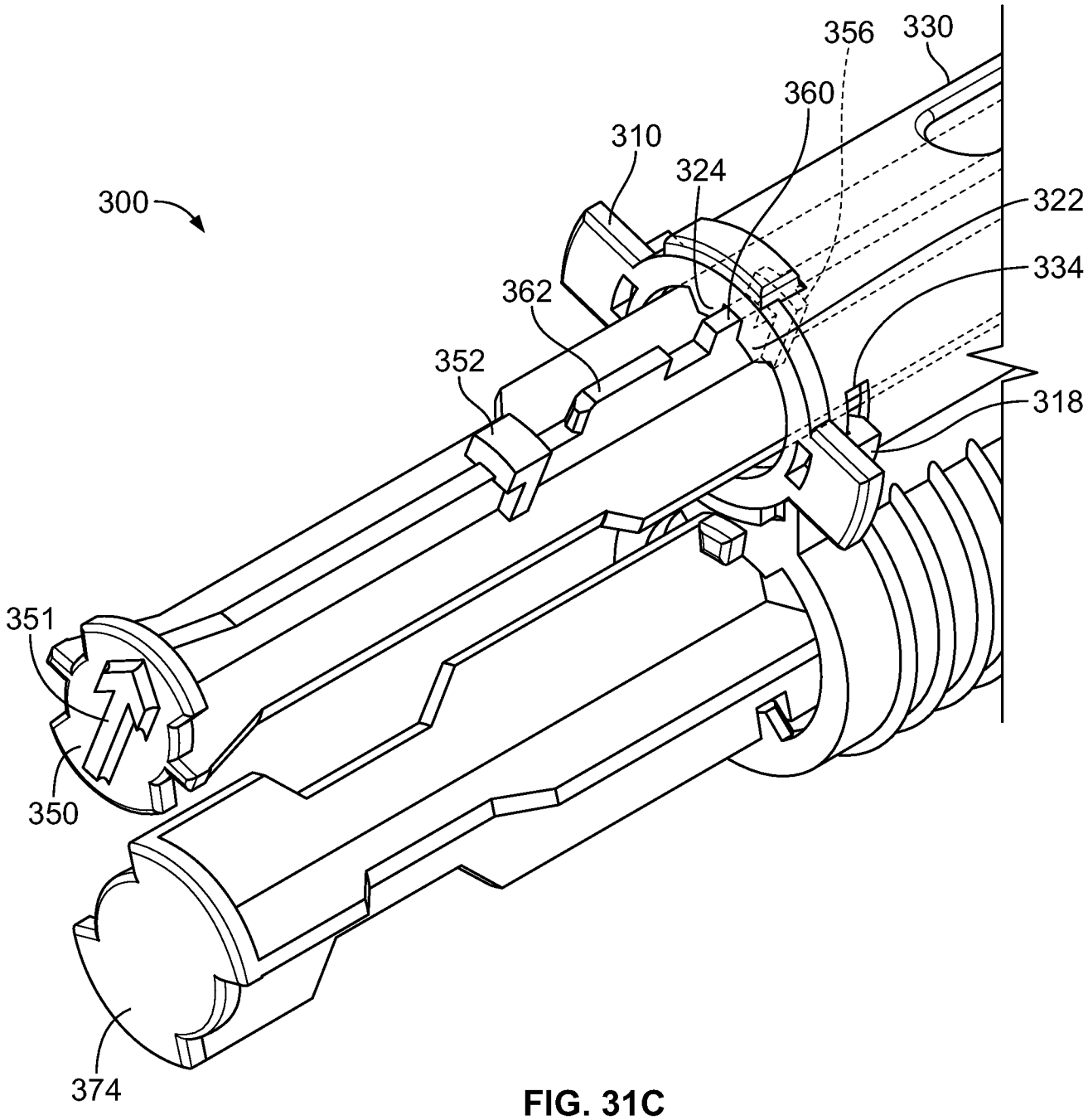

FIG. 31C

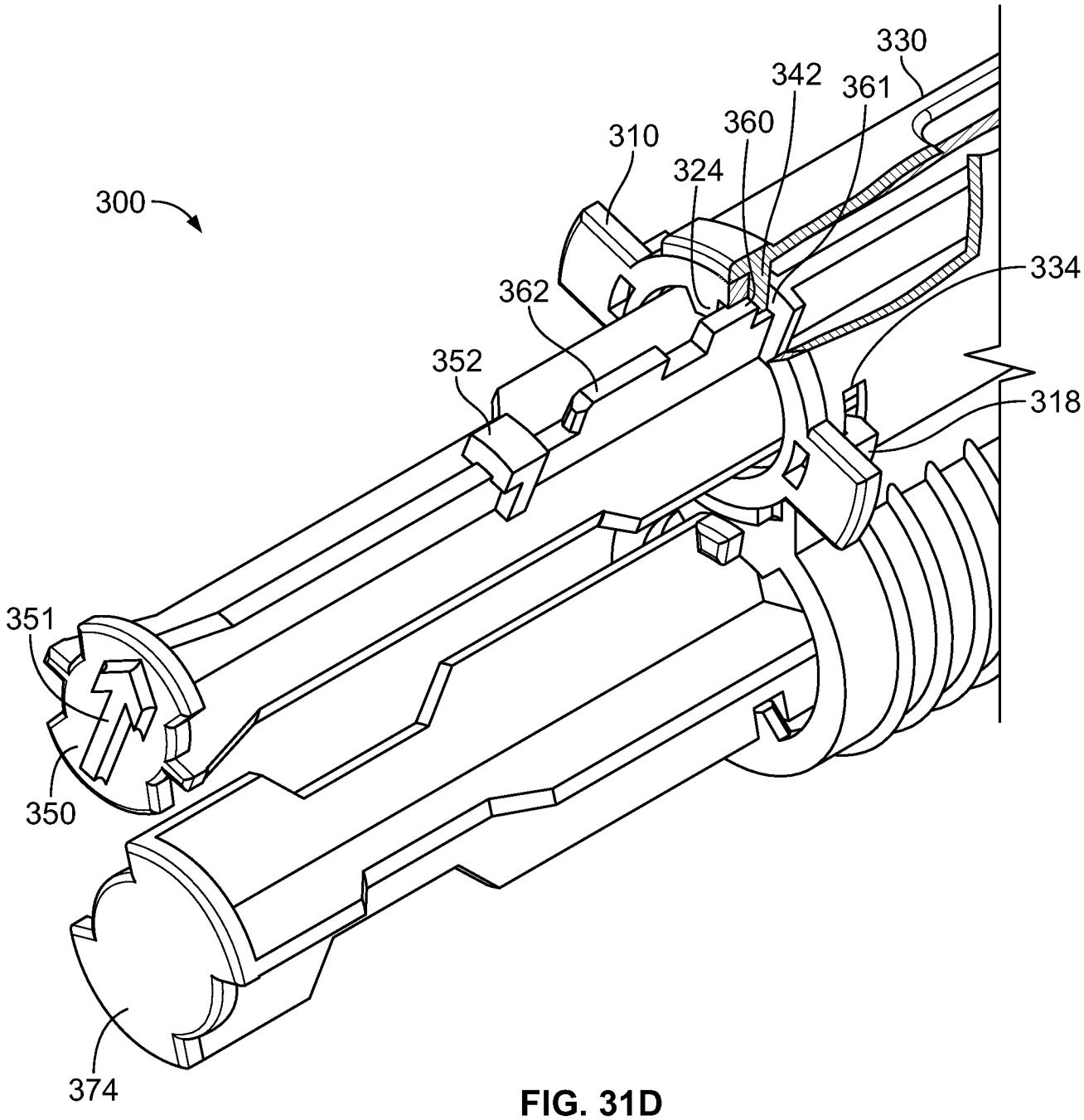

FIG. 31D

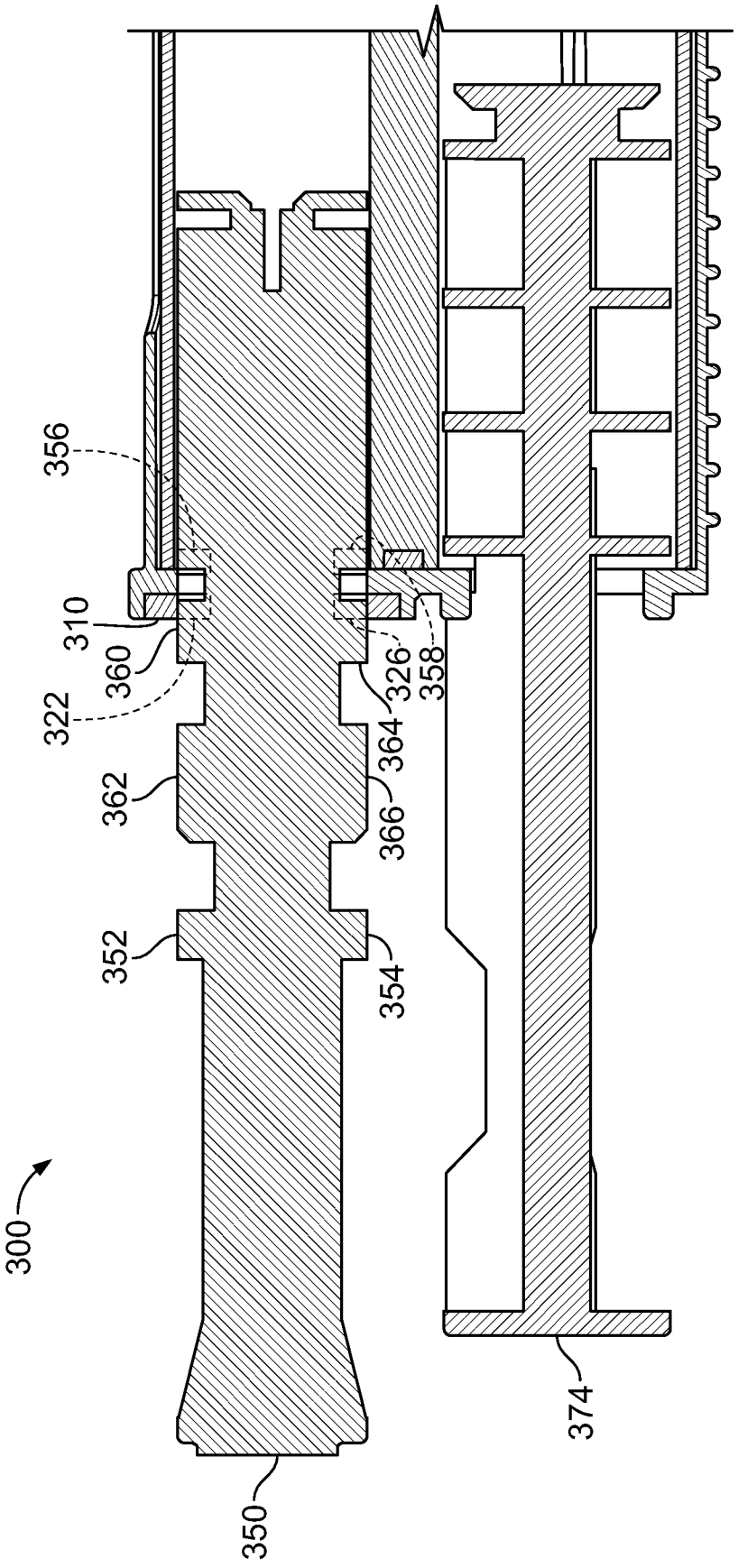

FIG. 31E

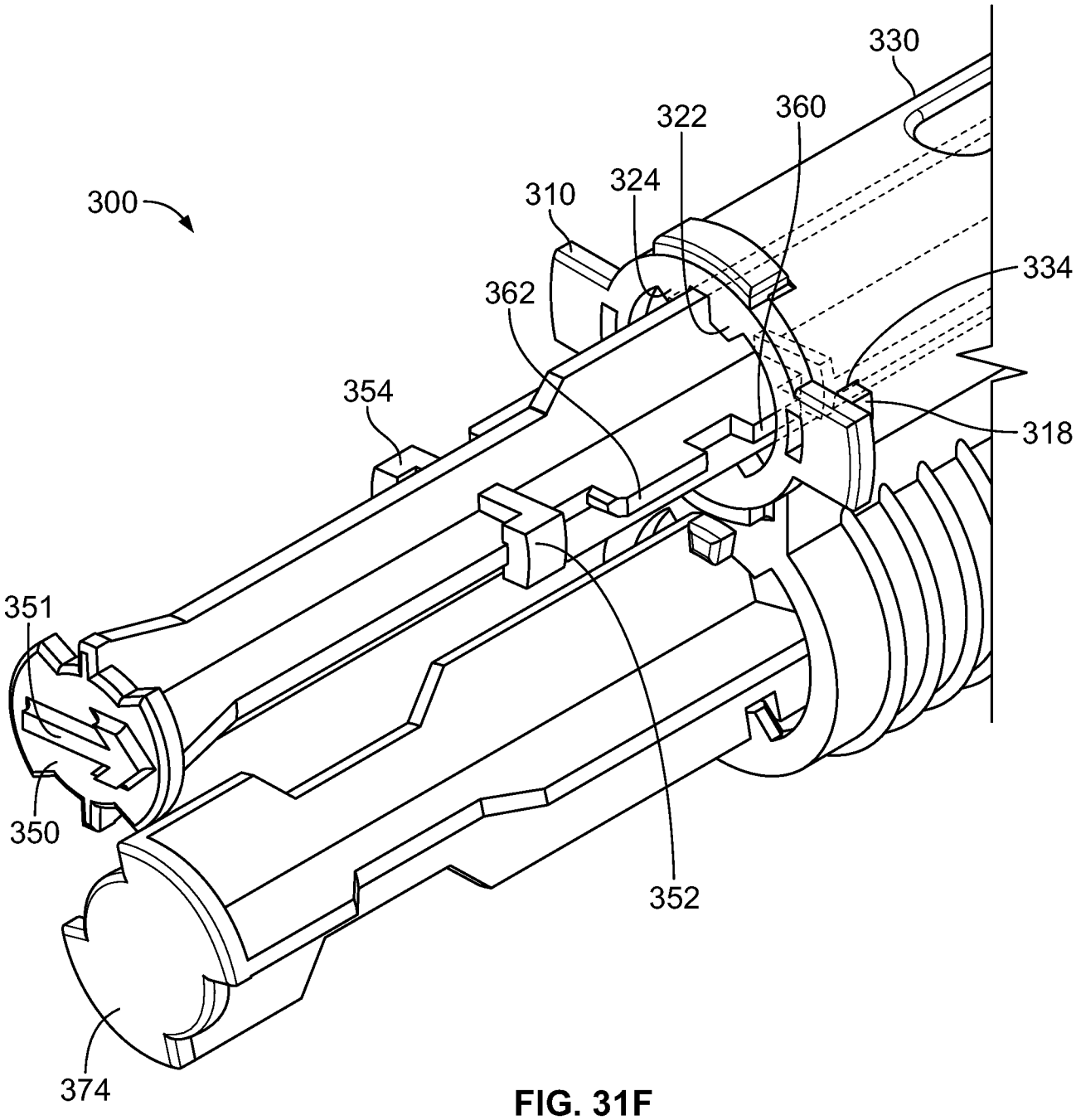

FIG. 31F

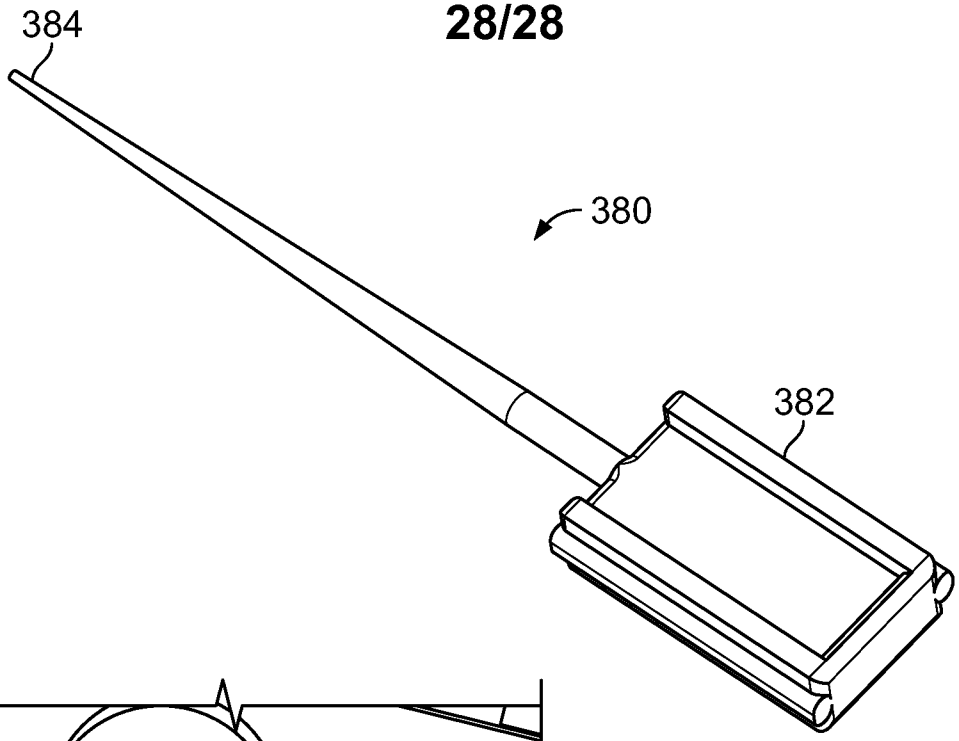

FIG. 32

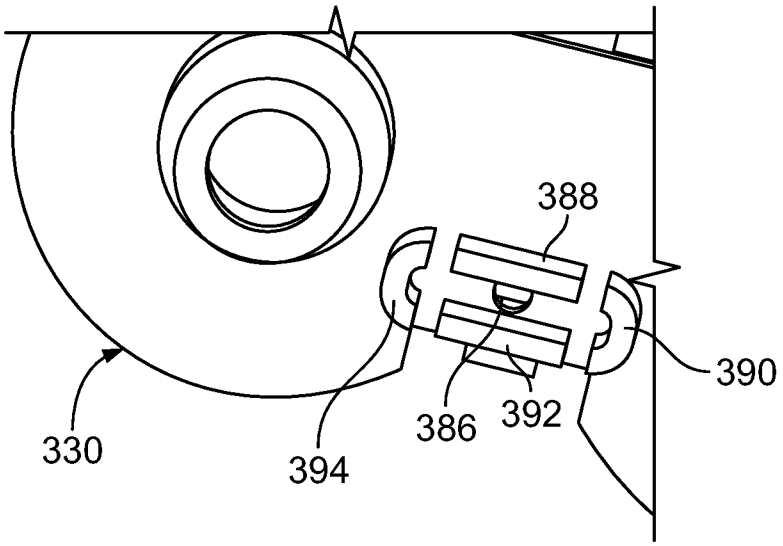

FIG. 33

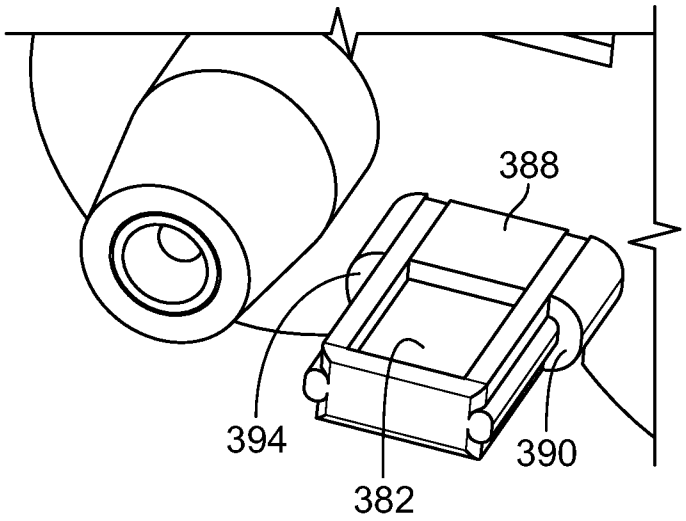

FIG. 34

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/063478

A. CLASSIFICATION OF SUBJECT MATTER

A61B 10/02(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 10/02; A61B 10/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: biopsy, plunger, vacuum, needle, pneumatic, fluid, communication, air, hole, attach, induce, drive

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 8052614 B2 (HESKE, N. et al.) 08 November 2011 See column 8, line 4 - column 22, line 49; claims 1-16; figures 1-19.	1-13,20-38
A	US 2012-0016262 A1 (HIBNER, J. A. et al.) 19 January 2012 See entire document.	1-13,20-38
A	EP 1889573 A1 (ETHICON ENDO-SURGERY, INC.) 20 February 2008 See entire document.	1-13,20-38
A	US 6022324 A (SKINNER, B. A. J.) 08 February 2000 See entire document.	1-13,20-38
A	US 6702760 B2 (KRAUSE, W. R. et al.) 09 March 2004 See entire document.	1-13,20-38

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 February 2016 (17.02.2016)	**15 March 2016 (15.03.2016)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
Han, Inho
Telephone No. +82-42-481-3362

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/063478

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

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

1. ☒ Claims Nos.: 14-19,39-49
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 14-19 and 39-49 pertains to a method for treatment of the human body by surgery and thus relate to a subject matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.

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

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2015/063478

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 8052614 B2	08/11/2011	AU 2003-218696 A1	29/09/2003
		AU 2003-223876 A1	29/09/2003
		CA 2479339 A1	25/09/2003
		CA 2479339 C	12/03/2013
		CA 2479349 A1	25/09/2003
		CA 2479349 C	03/07/2012
		CA 2771153 A1	25/09/2003
		CA 2771153 C	15/07/2014
		CA 2800959 A1	25/09/2003
		CA 2800959 C	05/05/2015
		CN 100515347 C	22/07/2009
		CN 1655724 A	17/08/2005
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		EP 1487346 A1	22/12/2004
		EP 1487346 B1	31/08/2005
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		EP 1524940 B1	24/08/2011
		JP 2005-527267 A	15/09/2005
		JP 2005-529632 A	06/10/2005
		JP 4260024 B2	30/04/2009
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