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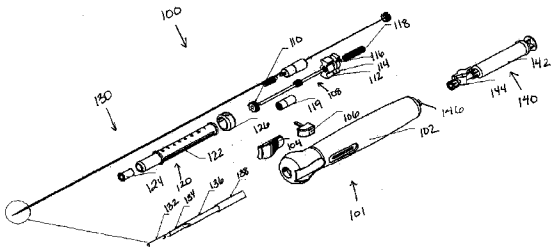


Fig. 1

(57) **Abstract:** Provided herein are biopsy devices each comprised of a tissue collection element having a distal end and a proximal end connected to a drive mechanism. In one embodiment, the tissue collection element can be formed from a material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle. In another embodiment, the tissue collection element can be formed from a material having a first constrained configuration when a stylet is inserted into the tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element. In a third embodiment, the tissue collection element comprises a helical cutting edge along at least a portion of the length of the tissue collection element, wherein the helical cutting edge is adaptable to cut a portion of tissue from the target location. The tissue collection element is translationally and rotationally moveable within a target location in response to actuation by the drive mechanism, thereby collecting tissue. The biopsy devices provided herein can further comprise provisions for echogenecity, a non-friction coating at the tip, and means for providing aspiration. Further provided herein are methods for using the devices described and a kit.

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DEVICES, METHODS, AND KITS FOR A BIOPSY DEVICE

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. **60/984,997**, filed November 2, 2007, which application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Fine needle aspiration (FNA) has been a well-accepted method for obtaining tissue samples for pathologic or histologic analysis in diagnosing tumors of the pancreas and other soft tissue organs. Endoscopic ultrasound (EUS) and EUS-guided fine needle aspiration (EUS-FNA) have become important tools in the evaluation of pancreatic masses.

[0003] Conventional surgical techniques for obtaining tissue samples accessible only through a flexible ultrasound-endoscope using a fine needle generally require numerous needle sticks. These procedures often result in obtaining a small number of cells with each aspiration, cells which may or may not be diagnostic. In addition, such procedures are often traumatic because of the multiple needle passes that it necessitates. This is especially true in the case of pancreatic biopsies. The pancreas secretes digestive enzymes. When injured, these enzymes are released, and may induce self digestion, and necrosis of the pancreas, and adjacent organs. The current technique used during Endoscopic Ultrasound Fine Needle Aspiration (EUS-FNA) of a pancreatic tumor entails the passage of a 19-25 gauge stainless steel needle. This needle is passed through the working channel of a linear echo endoscope under real-time guidance into the endo-sonographically visualized pancreatic mass. The needle is moved back and forth multiple times through the lesion with varying degrees of suction applied to it. The specimens obtained are then deposited onto a cytology slide for immediate fixation, staining and cytopathologic examination.

[0004] Aspirating a sample from a fluid medium through a needle is a simple procedure. Aspirating a sample from a solid mass is difficult. Most pancreatic EUS-FNA procedures take up to 30 needle passes to make a definitive cytological diagnosis of pancreatic carcinoma. Oftentimes, the only cells that are obtained are blood cells, or normal pancreatic tissue cells. Even when tumor cells are captured, these are often fragmented, and separated from each other. It is therefore almost impossible to differentiate a primary pancreatic tumor from a metastatic lesion.

[0005] Despite the time consuming and traumatic nature of the current FNA procedure, the consequence of a non-diagnostic aspirate is worse, because a missed diagnosis of pancreatic cancer is a sure death sentence. Therefore, if a pancreatic tumor is suspected but the FNA result is negative, the patient must then undergo a pancreatic biopsy through an abdominal incision. Although needles for taking core biopsies of internal organs exist, these needles are much thicker than the needles used during fine tissue aspiration. An example of such a needle is the Mangini needle, with which percutanous liver biopsies are used. In order to introduce this needle into the liver, an incision must be made in the skin with the sharp tip of a scalpel. The needle is then pushed into the incision, and under aspiration is quickly pushed in and out of the liver with a quick stabbing motion. The resulting core biopsy is almost always diagnostic, and ample to examine sheets of tissue cells representative of the pathology that is sought. The injury, however, is much greater than that inflicted with a fine needle.

[0006] The choices for obtaining diagnostic tissue from internal organs are three fold. The first choice is to obtain a biopsy though an open operative incision or a laparoscopic technique, which entails surgical intervention. The second option is to use a large diameter stiff stainless steel needle. This method may only be used for lesions that are near the exterior of the body, such as described above in relation to the Mangini needle. The third method is to obtain cells through a fine needle with ultrasound guidance. While this method is least traumatic with only one

needle in WO 2009/058436 duces a poor yield of diagnostic material. In the best case sce PCT/US2008/069034 iple needle sticks, several cells of the tumor are retrieved. Because the cells are obtained separate from one another, they are examined by the pathologist without their spatial relationship to the rest of the organ that they originated from. In the worst case, even these tumor cells are not obtained, only blood cells and normal tissue, necessitating one of the more invasive procedures. It is therefore most desirable to have an instrument of being passed through the flexible endoscope that is both delicate so as not to traumatize the area that is being biopsied, and at the same time be capable of obtaining a core tissue biopsy that will be diagnostic. It would be of great advantage if diagnostic certainty could be achieved with a minimal number of instrument passes, thus achieving excellent results with minimal trauma to the patient.

[0007] The fine needle aspiration technique is also widely used to obtain cells from suspected lesions in organs that are more superficial. These organs include breast, prostate, thyroid and parathyroid. Although these organs are more accessible to the needle than the pancreas, the trauma incurred by a thick core biopsy needle stick is great. Millions of people undergo fine needle aspirations for suspected cancer. Here too, 10-15 needle sticks are required to obtain what is deemed a sufficient number of cells for an adequate specimen. A device for obtaining a measurable tissue sample in one extraction would be highly beneficial for biopsy.

SUMMARY OF THE INVENTION

[0008] Provided herein is a biopsy device comprising: an outer needle having a distal end and a proximal end connected to a drive mechanism; and a tissue collection element having a distal end and a proximal end, the tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle, wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism. The distal end of the tissue collection element can deviate from the central axis of the outer needle from 0 degrees to 180 degrees and rotates around the central axis of the outer needle from 0 degrees to about 360 degrees. The distal end of the tissue collection element can deviate from a central axis of the outer needle along an angle, radius, helical path, or contour. The distal end of the tissue collection element can comprise an opening, wherein the opening obtains a portion of tissue having a cross-sectional diameter greater than the cross-sectional diameter of the outer needle. The tissue collection element can be translated from within the outer needle to a target location. In some embodiments, the distal end of the tissue collection element is rotationally actuated to produce a rotational motion. Furthermore, the rotational motion can be a motion selected from the group consisting of continuous, intermittent, reciprocating, and combinations thereof. In some embodiments, the tissue collection element is adaptable to be moved manually. Alternatively, the tissue collection element is adaptable to be moved automatically or semi-automatically. Additionally, the outer needle of the biopsy device can be adaptable to or adapted and configured to be moved manually. Alternatively, the outer needle can be adaptable to be moved automatically or semi-automatically. In some embodiments of the device, the tissue collection element comprises stainless steel. In some embodiments of the tissue collection element, a portion of the tissue collection element comprises a shape memory alloy. Additionally, at least a portion of the tissue collection element can be coated with a non-friction coating, such as Teflon®, poly(tetrafluoroethylene), perfluoroalkoxy polymer resin, fluorinated ethylene-propylene, fluoropolymers, and combinations thereof. The distal end of the outer needle can be coated with a non-friction coating. In some embodiments, the distal end of the tissue collection element comprises a beveled cutting edge. The tissue collection element can be disposable. The tissue collection element can also cut and receive tissue within

the tissue sample without further damaging the tissue. Additionally, the device can comprise a stylet, wherein the stylet is adaptable to be inserted into the tissue collection element. A negative pressure source adaptable to facilitate application of negative pressure to the distal end of the tissue collection element can also be used with the device. The negative pressure can be supplied by a syringe, such as a two-stage or multi-stage syringe. The outer needle can be echogenic. Alternatively, the tissue collection element can be echogenic. In some embodiments, both the outer needle and the tissue collection element can be echogenic. The echogenicity of the outer needle and the tissue collection element can be facilitated by rotational actuation applied to the outer needle or the tissue collection element. Alternatively, the echogenicity of the outer needle and the tissue collection element can be facilitated by vibrations induced at the distal tip of the outer needle. In some embodiments of the biopsy device, the biopsy device further comprises a cannula wherein the cannula is adaptable to contain the tissue collection element and outer needle and wherein the cannula is further translatable and rotatable relative to the tissue collection element and the outer needle. Additionally, the biopsy device can further comprise a depth gauge adaptable to assess the depth of penetration of the tissue collection element within a target location. A depth stop also can be included with the device, the depth stop adaptable to be set to limit the depth of penetration of the tissue collection element within a target location. The biopsy device described herein comprises a tissue collection element adaptable to capture a measurable target tissue sample from a collection region in at most three passes. One or more radiopaque markers on at least a portion of the length of the device can be included with the device. The device can be adaptable to be operated using single-hand operation. In some embodiments, the device can further comprise a quick excursion element adaptable to repeatedly extrude depth limited portions of target tissue. The outer needle can be a needle with a gauge between 18 and 27. The distal end of the tissue collection element can extract a portion of target tissue from a collection region having a diameter greater than 0.05 inches in diameter. Additionally, the device can further comprise an endoscope, wherein the position of the biopsy device can be adjusted to accommodate the working length of the endoscope.

[0009] Further provided herein is a biopsy device comprising: a stylet having a proximal end and a distal end wherein the stylet is adaptable to be inserted inside the tissue collection element; and a tissue collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element, wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism. The distal tip of the tissue collection element deviates from the axis of rotation of said tissue collection element from 0 degrees to 180 degrees and rotates around said axis of rotation from 0 degrees to about 360 degrees. Furthermore, the distal end of the tissue collection element deviates from the axis of rotation of said tissue collection element along an angle, radius, helical path, or contour. The distal end of the tissue collection element can comprise an opening wherein the opening obtains a portion of tissue having a cross-sectional diameter greater than the cross-sectional diameter of the tissue collection element in its constrained configuration. In some embodiments, the tissue collection element can be translated to a target location during tissue acquisition. The distal end of the tissue collection element can be rotationally actuated to produce a rotational motion. The rotational motion is a motion selected from the group consisting of continuous, intermittent, reciprocating, and combinations thereof. The tissue collection element can be adaptable to be moved manually. Alternatively, the tissue collection element can be adaptable to be moved automatically or semi-automatically. In some embodiments, the tissue collection element comprises stainless steel. In some embodiments, at least a portion of the tissue collection element comprises a shape memory alloy. The distal end of the tissue collection element can be coated with a non-friction coating. The distal end of the tissue collection element can comprise a beveled cutting edge. In some

tissue within the tissue collection element without further damaging the tissue. In some embodiments, the stylet can be adaptable to penetrate tissue as the tissue collection element is advanced toward the target location. Additionally, the stylet can be adaptable to preclude anomalous tissue acquisition as the tissue collection element is advanced toward the target location. The stylet can be adaptable to expel a biopsy tissue sample from the tissue collection element. In some embodiments, the device can further comprise a negative pressure source adaptable to facilitate application of negative pressure to the distal tip of the tissue collection element. The negative pressure can be supplied by a syringe, for example purposes only, a two-stage syringe or multi-stage syringe. In some embodiments, the tissue collection element is adaptable to be echogenic. The echogenecity of the tissue collection element can be facilitated by rotational actuation applied to the tissue collection element. Alternatively, the echogenecity of the tissue collection element can be facilitated by vibrations induced at the distal end of the tissue collection element. In some embodiments, the device can further comprise a cannula adaptable to contain the tissue collection element, the cannula further translatable and rotatable relative to the tissue collection element. In some embodiments, the device can further comprise a depth gauge adaptable to assess the depth of penetration of the tissue collection element within a target location. Additionally, the device can comprise a depth stop adaptable to set a limit for the depth of penetration of the tissue collection element within a target location. The tissue collection element can be adaptable to capture a measurable target tissue sample from a collection region in at most three passes. In some embodiments, the device can further comprise one or more radiopaque markers on at least a portion of the length of the device. The device can be adaptable to be operated using single-hand operation. In some embodiments, the device can further comprise a quick excursion element adaptable to repeatedly extrude depth-limited portions of target tissue. In some embodiments, the tissue collection element further comprises a shaft located between the proximal end and the distal end, the shaft having comprising a gauge of 18 to 27. The distal tip of the tissue collection element is adaptable to extract a portion of target tissue from a collection region having a diameter greater than 0.05 inches in diameter. Additionally, the device can further comprise an endoscope, wherein the position of the biopsy device can be adjusted to accommodate the working length of the endoscope.

[0010] Further provided herein is a biopsy device comprising: an outer needle having a proximal end and a distal end wherein the proximal end is connectable to a drive mechanism; and a tissue collection element comprising a proximal end, a distal end, and a helical cutting edge along at least a portion of the length of the tissue collection element, wherein the helical cutting edge is adaptable to cut a portion of tissue from a target tissue; and a non-friction coating adaptable to be applied to at least a portion of the distal end of the tissue collection element, wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism. Additionally, a non-friction coating can be applied to at least a portion of the outer needle. The helical cutting edge of the device can extend radially from a solid core. Alternatively, the helical cutting edge can be adaptable to encircle a hollow core. The tissue collection element is translated from within the outer needle to a target location. In some embodiments, the distal end of the tissue collection element is rotationally actuated to produce a rotational motion. The rotational motion can be a motion selected from the group consisting of continuous, intermittent, reciprocating, and combinations thereof. In some embodiments, the tissue collection element is adaptable to be moved manually. Alternatively, the tissue collection element can be adaptable to be moved automatically or semi-automatically. In some embodiments, the tissue collection element comprises stainless steel. Furthermore, at least a portion of the distal end of the tissue collection element comprises a beveled cutting edge. The tissue collection element can be disposable. The tissue collection element can cut and receive tissue within the outer needle without further

damaging some embodiments, the device further comprises a stylet adaptable to at least one of the outer needle and the tissue collection element. In some embodiments, the device can further comprise a negative pressure source adaptable to facilitate application of negative pressure to the distal end of at least one of the outer needle or the tissue collection element. The negative pressure can be supplied by a syringe, for example purposes only, a two-stage syringe or a multi-stage syringe. The outer needle can be echogenic. Alternatively, the tissue collection element can be echogenic. In some embodiments, both the outer needle and the tissue collection element can be echogenic. The echogenicity of the outer needle and the tissue collection element can be facilitated by rotational actuation applied to the outer needle or the tissue collection element. Alternatively, the echogenicity of the outer needle and the tissue collection element can be facilitated by vibrations induced at the distal tip of the outer needle. In some embodiments of the biopsy device, the biopsy device further comprises a cannula wherein the cannula is adaptable to contain the tissue collection element and outer needle and wherein the cannula is further translatable and rotatable relative to the tissue collection element and the outer needle. Additionally, the biopsy device can further comprise a depth gauge adaptable to assess the depth of penetration of the tissue collection element within a target location. A depth stop also can be included with the device, the depth stop adaptable to be set to limit the depth of penetration of the tissue collection element within a target location. The biopsy device described herein comprises a tissue collection element adaptable to capture a measurable target tissue sample from a collection region in at most three passes. Additionally, the device can further comprise an endoscope, wherein the position of the biopsy device can be adjusted to accommodate the working length of the endoscope.

[0011] Further provided herein is a biopsy device comprising an outer needle having a proximal end and a distal end wherein the proximal end is connected to a drive mechanism; a tissue collection element formed from material having a first constrained configuration when positioned within the cannula prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the cannula wherein the tissue collection element is translationally and rotationally moveable within the cannula and distally beyond the distal end of the cannula in response to actuation by the drive mechanism, wherein the distal end of said tissue collection element forms an opening adaptable to obtain a target tissue from a collection region, the opening having a cross-sectional diameter greater than the cross-sectional diameter of the outer needle.

[0012] Further provided herein is a biopsy device comprising a stylet having a proximal end and a distal end wherein the stylet is adaptable to be inserted inside the tissue collection element; and a tissue collection element having a proximal end and a distal end, the tissue collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism, wherein the distal end of said tissue collection element forms an opening adaptable to obtain a target tissue from a collection region, the opening having a cross-sectional diameter greater than the cross-sectional diameter of the outer cannula.

[0013] In some embodiments, provided herein, is a biopsy device comprising an outer needle having a proximal end and a distal end wherein the proximal end is connected to a drive mechanism; and a tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism; and a non-friction coating. The non-friction coating can be applied to the distal end of the outer needle. Additionally, the non-friction coating can be applied to the distal end of the tissue collection element.

[0014] herein is a biopsy device comprising a stylet having a proximal end wherein the stylet is insertable inside the tissue collection element; a tissue collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism; and a non-friction coating applied to some portion of the distal tip of the tissue collection element.

[0015] Also provided herein is a method for obtaining a measurable target tissue from a collection region comprising: inserting a biopsy device comprising an outer needle having a proximal end and a distal end wherein the proximal end is connected to a drive mechanism, and a tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism; advancing the tissue collection element into a patient toward a target tissue; excising a measurable amount of target tissue with the tissue collection element; and removing the excised target tissue from the patient. Additionally, the method can further comprise the step of transmitting a translational actuation force to at least one of the outer needle and the tissue collection element. In some embodiments, the method can further comprise the step of transmitting a rotational actuation force to the tissue collection element. The excising step can further comprises procuring a tissue sample by rotating the tissue collection element while translating the outer needle and tissue collection element. In some embodiments, the method can further comprise the step of step of inserting a stylet into the tissue collection element. Furthermore, the method can further comprising the step of applying negative pressure to the distal tip of at least one of the tissue collection element and cannula. The step of approaching the target location with the stylet inserted in the tissue collection element prior to sample acquisition.

[0016] In some embodiments, a method for obtaining a measurable target tissue from a collection region is provided herein, the method comprising: inserting a biopsy device comprising a stylet having a proximal end and a distal end wherein the stylet is insertable inside the tissue collection element; and a tissue collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism; advancing the tissue collection element into a patient toward a target tissue; excising a measurable amount of target tissue with the tissue collection element; and removing the excised target tissue from the patient. In some embodiments, the method can further comprise the step of transmitting a translational actuation force to the tissue collection element. Alternatively, the method can comprise the step of transmitting a rotational actuation force to the tissue collection element. In some embodiments of the method, the excising step further comprises procuring a tissue sample by rotating the tissue collection element while translating the tissue collection element. The excised tissue can further be removed from the biopsy device. The stylet can be used to remove the excised tissue. In some embodiments, the method can include the application of negative pressure to the distal tip of the tissue collection element. The stylet in the tissue collection element can also be used to approach the target location prior to sample acquisition.

[0017] Another method provided herein, is a method for obtaining a target tissue from a collection region comprising: inserting a biopsy device comprising a cannula having a proximal end and a distal end wherein the proximal end is connectable to a drive mechanism; and a tissue collection element having helical cutting features

along a path at the distal end thereof wherein the tissue collection element target tissue from a collection region and is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism; and a non-friction coating applied to some portion of the distal tip of the tissue collection element and/or the outer needle; advancing the tissue collection element into a patient toward a target tissue; excising a measurable amount of target tissue with the tissue collection element; and removing the target tissue from the patient. In some embodiments, the method can further comprise the step of transmitting a translational actuation force to the cannula and/or tissue collection element. Alternatively, the method can further comprise the step of transmitting a rotational actuation force to the tissue collection element. Furthermore, the excising step further comprises procuring a tissue sample by rotating the tissue collection element while translating the outer needle and tissue collection element. In some embodiments, the negative pressure can be applied to the distal end of at least one of the tissue collection element or outer needle prior to sample acquisition. The method can also provide for the step of approaching the target location with the stylet inserted in the outer needle or tissue collection element prior to sample acquisition.

[0018] Further provided herein is a kit for obtaining a measurable target tissue from a collection region comprising: a removable handle containing a drive mechanism; one or more cannula outer needles, each cannula outer needle having a proximal end and a distal end wherein the proximal end is adaptable to engages the drive mechanism; and one or more tissue collection elements, each tissue collection element having an adapted and configured form to receive a measurable target tissue from a collection region wherein the tissue collection element is translationally and rotationally moveable within the outer needle cannula distally beyond the distal end of the outer needle cannula in response to the drive mechanism.

INCORPORATION BY REFERENCE

[0019] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0021] **FIG. 1** is an exploded view of one embodiment of a biopsy device;

[0022] **FIG. 2** is an illustration of a lateral cross-section of one embodiment of an actuation module used with the device;

[0023] **FIG. 3** depicts one embodiment of a negative pressure module used with the device;

[0024] **FIG. 4** is an illustration of a lateral cross-section of a depth penetration module used with the device;

[0025] **FIG. 5** is an illustration of a device being assembled as viewed from the side;

[0026] **FIG. 6** is a perspective view of one embodiment of an assembled device;

[0027] **FIG. 7** is a static illustration of the device of **FIG. 6** in use;

[0028] **FIG. 8** is an exploded view on another embodiment of a biopsy device;

[0029] **FIG. 9A** is an illustration of an alternate embodiment of a actuation module; **FIG. 9B** is a perspective view of the actuation module; **FIG. 9C** is another perspective view of the actuation module; **FIG. 9D** is a cross-sectional view of the actuation module;

[0030] **FIG. 10A** is a cross-sectional view of one embodiment of a gear motor of a roller as viewed from the side; **FIG. 10B** is a view of the gear motor as viewed from the side;

[0031] **FIG. 11** depicts an isolated view of another embodiment of a negative pressure device;

[0032] **FIGS. 12A-12D** is an illustration of the steps to prepare the device for operation;

[0033] **FIG. 13A** is a lateral cross-sectional view of one embodiment of a catheter module; **FIG. 13B** is a cross-section of the catheter module of **FIG. 13A** along the line **B-B**; **FIG. 13C** is an isolated view of a tissue collection element in a first configuration; **FIG. 13D** is an isolated view of a tissue collection element in a second configuration; **FIG. 13E** is a side view of a catheter module; **FIG. 13F** is a cross-section of **FIG. 13E** along the line **F-F**; **FIG. 13G** is a cross-section of **FIG. 13E** along the line **G-G**.

[0034] **FIG. 14A** is a side view of a catheter module comprising a bent tube tissue collection element; **FIG. 14B** is a cross-sectional view of **FIG. 14A** along the line **B-B**; **FIG. 14C** is a cross-sectional view of **FIG. 14A** along the line **C-C**.

[0035] **FIG. 15A** depicts one embodiment of a drill-bit tissue collection element for use with a biopsy device; **FIG. 15B** is a lateral cross-sectional view of a catheter module comprising a drill-bit tissue collection element; **FIG. 15C** is a side view of a drill-bit catheter module; **FIG. 15D** is a cross-sectional view of **FIG. 15C** along the line **D-D**; **FIG. 15E** is a cross-sectional view of **FIG. 15C** along the line **D-D**;

[0036] **FIG. 16A** is another embodiment of a drill-bit tissue collection element; **FIG. 16B** is a lateral cross-sectional view of the catheter module comprising a drill-bit tissue collection element; **FIG. 16C** is a side view of a drill-bit catheter module; **FIG. 16D** is a cross-sectional view of **FIG. 16C** along the line **D-D**;

[0037] **FIG. 17A** is an embodiment of a bent tube tissue collection element with a low-friction coating; **FIG. 17B** is a view of the device of **FIG. 17A** as viewed from the end;

[0038] **FIGS. 18A-18D** illustrate a biopsy device in use; and

[0039] **FIG. 19** is an illustration of alternative embodiment of the biopsy device in use.

DETAILED DESCRIPTION OF THE INVENTION

[0040] The biopsy devices described herein can be designed to automate the procedure for the diagnosis of suspect areas of tissue. The device can be used with tumors and cysts, or any other suitable soft tissue from which a sample can be obtained. Various embodiments of the device are provided herein. In one embodiment, the device described herein can comprise an outer needle having a distal end, or end closer to the body, and a proximal end, or end closer to the exterior of the body, connected to a drive mechanism and a tissue collection element having a distal end and a proximal end. The distal end of the tissue collection element can be formed from a material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle, wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism. The outer needle can have a gauge of 18 to 27.

[0041] In some embodiments, the tissue collection element has a tube structure. The tissue collection element can be formed such that it has a first configuration that is constrained when positioned, for example, within an outer needle, and a second configuration when extended distally beyond the distal end of the outer needle. Once extended, and unconstrained, the tissue collection element biases away from a central axis such that the tubular structure of the tissue collection element bends, forming a bent tube. When introduced proximally to the tissue to be sampled, the tissue collection element can be housed within the outer needle. The outer needle holds the tissue collection element in a first configuration which follows the structure of the outer needle. When a tissue sample is

to be extended past the distal end of tissue collection element can be extended past the distal edle. Once the distal end of the tissue collection element extends past the distal end of the outer needle, the tissue collection element can change configuration to a second configuration. In the second configuration, the tissue collection element biases away from the central axis of the outer needle. In some embodiments, the tissue collection element deviates from the central axis from about 0 to about 180 degrees. This enlarges the cross-section of the opening in the distal end of the tissue collection element. The radial deviation of the distal end of the tissue collection element from the rotational axis is greater than the radius of the outer needle.. This enables a larger amount of tissue to be excised by the tissue collection element. The tissue collection element can be made of stainless steel. Alternatively, the tissue collection element, or solely a portion of the distal tip thereof, can be made of a shape memory material, for example, Nitinol. The tissue collection element can be made of any suitable material that can exist in at least two configurations. In some embodiments, the distal end of the tissue collection element comprises a beveled edge to facilitate the cutting of tissue. The enlarged opening of the tissue collection element, together with the rotational motion of the tissue collection element enables the tissue collection element to capture a larger amount of tissue in a single pass, as compared to conventional methods. A sufficient amount of sample can be obtained from the tissue of interest in approximately three passes. In some embodiments, a sufficient amount of sample can be obtained in a single pass.

[0042] The tissue collection element can transition between two configurations during use. As previously mentioned, the tissue collection element can exist in a first configuration before the sample is to be obtained. The tissue collection element is constrained in a first configuration by an external structure. When in use, the tissue collection element is no longer constrained by a constraining structure and transitions to a second configuration. In some embodiments, the constraining structure is an outer needle. The outer needle constrains the tissue collection element in a first configuration. In some embodiments, the constraining structure is a stylet located in tissue collection element. The stylet can constrain the tissue collection element in a first configuration. Once the stylet is retracted from the proximal end of the tissue collection element, the tissue collection element can transition to a second configuration.

[0043] In some embodiments, the stylet can be used to facilitate the penetration of the device to position the tissue collection element in proximity to the tissue of interest. The stylet additionally can preclude the capturing of anomalous tissue by the tissue collection element, as the tissue collection element is advanced toward the tissue to be sampled. Once the tissue collection element is in position, proximal to the tissue of interest, the stylet can be retracted and sample excised and collected by the tissue collection element. The stylet can further be used, in some embodiments, to remove the tissue collected in the tissue collection element.

[0044] In another embodiment, the tissue collection element comprises a rotatable cutting or boring tool having two or more helical cutting edges. The revolving tissue collection element can be adapted to provide flats or flutes for the capture and release of cut tissue. The rotatable cutting or boring tissue collection element has a drill-bit-like configuration. The drill-bit like structure comprises a helical cutting edge located on the exterior of the tissue collection element. In some embodiments, the helical cutting edge extends radially from a center core of the tissue collection element. In some embodiments, the helical cutting edge wraps around a center portion of the tissue collection element; the center portion of the tissue collection element remains hollow.

[0045] The distal end of the tissue collection element can then rotate around the central axis of the outer needle. The tissue collection element can rotate about the center axis from about 0 degrees to about 360 degrees. The distal end of the tissue collection element can be actuated to cause rotational motion of the distal tip of the tissue collection element. The motion can be any suitable rotational motion including, but not limited to, continuous motion,

intermittent reciprocating motion, and any combination thereof. In some embodiments, the rotation of the tissue collection element is controlled by the drive mechanism in the actuation module housing the drive mechanism. In addition to rotational actuation, the tissue collection element can be linearly translated. The rotational actuation and linear translation of the tissue rotation element can be affected by the user. In such an embodiment, the tissue collection element is said to be manually operated. Alternatively, the linear translation can be affected manually, while the rotational actuation can be affected by the drive mechanism. In such an embodiment, the tissue collection element is semi-automatically operated. In some embodiments, both the linear translation and the rotational motion of the tissue collection element are affected by the drive mechanism. In such an embodiment, the movement of the tissue collection element is considered to be automatic.

[0046] A feature of the invention provided herein is the ease of which the tissue collection element can be visualized during a procedure. The visualization of the tissue collection element can be done using the echogenicity of the tissue collection element. Small motion of the tissue collection element can enhance the echogenicity of the tissue collection element. The echogenicity of the tissue collection element can be enhanced or facilitated by rotation of the tissue collection element. The echogenicity of the tissue collection element can also be enhanced or facilitated by vibrations induced at the distal tip of the tissue collection element. The vibrations can be actuated by a piezoelectric element. The vibrations can be actuated by any suitable vibration source. In some embodiments, the outer needle has enhanced echogenicity. The echogenicity of the tissue collection element can be enhanced or facilitated by rotation of the tissue collection element. The echogenicity of the tissue collection element can also be enhanced or facilitated by vibrations induced at the distal tip of the outer needle. In some embodiments, both the tissue collection element and the outer needle have enhanced echogenicity. In some embodiments, the tissue collection element can be visualized by using radiopaque markers located along at least a portion of the tissue collection element. In some embodiments, radiopaque markers are located along at least a portion of the outer needle.

[0047] In some embodiments, the tissue collection element is disposable while the handle can be reusable. In some embodiments, the entire device is disposable. Alternatively, in some embodiments, the entire device can be reusable.

[0048] The device can be designed so that the device can be operated by single-handed operation. In some embodiments, the distal end of the tissue collection element can be coated with a non-friction coating. Current embodiments of biopsy devices are not coated with a non-friction coating. Current biopsy devices poke a sample in a single direction with a tissue collection element. These devices require friction to capture a tissue sample, since friction is used to capture the sample inside the tissue collection element. The invention disclosed herein does not require the use of friction due to the physical structure and rotation of the tissue collection element. The tissue collection element disclosed herein can be coated with a non-friction coating. In some embodiments, the entire distal end of the tissue collection element is coated. In some embodiments, the inside of the tissue collection element is coated with a non-friction coating. The non-friction coating can facilitate the translation and rotation of the tissue collection element through the tissue sample. Examples of non-friction coatings include, but are not limited to poly(tetrafluoroethylene), perfluoroalkoxy polymer resin, fluorinated ethylene-propylene, fluoropolymers, combinations thereof, or any other suitable non-friction coating.

I. DEVICES

[0049] FIG. 1 illustrates an exploded view of one embodiment of a biopsy device ***100***. The biopsy device ***100*** can be comprised of both reusable and disposable parts. As shown in FIG. 1 the device ***100*** comprises an actuation module ***101*** comprising a handle ***102*** which can comprise a motor control switch ***104*** and a quick excursion switch

106, and re barrel *108* inside the handle comprising at least one gear nal threaded slider *112*, a washer *114*, an o-ring *116*, and a spring *118*. The handle *102* of the device is in mechanical communication with a depth penetration module *120*. The depth penetration module *120* can further comprise a tissue collection element depth gauge *122* and a luer adaptor *124* for endoscopic assembly. The tissue element depth gauge *122* can additionally include a tissue collection element depth stop *126*. The device *100* further can further comprise a catheter module *130*. The catheter module *130* can comprise a tissue collection element *134* and an outer cannula *138*. In some embodiments, the catheter module *130* further comprises a stylet *132*, as shown in FIG. 1. Additionally, the catheter module *130* can comprise an outer needle *136*. FIG. 1 illustrates a catheter module *130* comprising a stylet *132* nested within a tissue collection element *134* which is nested within an outer needle *136*. The outer needle *136* can then be nested in the cannula *138*, as shown in FIG. 1. In some embodiments of the device *100*, an external negative pressure module *140* can be in communication with the actuation module *101*, as shown in FIG. 1. The negative pressure module *140* can comprise a syringe *142* and a luer adaptor *144*. The luer adaptor *144* on the negative pressure module *140* together with the luer adaptor *146* on the actuation module *101* provides communication between the negative pressure module *140* and the actuation module *101*. In some embodiments, the actuation module is powered by a battery *119*.

[0050] FIG. 2A is a lateral cross-sectional view of the actuation module *201*. The actuation module *201* comprises a handle *202*, a motor control switch *204*, and a quick excursion switch *206* on the exterior of the actuation module *201*. Additionally, the actuation module can comprise a luer adaptor *246*. The luer adaptor *246* can be used to connect a negative pressure module to the exterior of the of the actuation module *201*. In some embodiments of the biopsy device, a stylet can be connected to actuation module *201* through the luer adaptor *246*. Any suitable component can be connected to the exterior of the actuation module *201*. As shown in FIG. 2B, in the interior of the actuation module *201*, the proximal end of the tissue collection element *234* can be rigidly connected to the negative pressure barrel *208*. Negative pressure can be applied to the area from which tissue is being excised through the tissue collection element *234*.

[0051] The actuation module further comprises a drive mechanism *209*. The drive mechanism *209* comprises an assembly for actuating the tissue. In some embodiments, the drive mechanism causes rotational actuation of the tissue collection element. In some embodiments, the drive mechanism causes translational actuation of the tissue collection element. The drive mechanism can cause both rotational and translational actuation of the tissue collection element. The proximal end of the tissue collection element *234* is attached to a gear *210* in the actuation module *201*. The movement of the gear *210* can facilitate rotation of the tissue collection element *234*. The gear *210* attached to the tissue collection element is in communication with a second gear *211*. In some embodiments, the communication is mechanical communication. The second gear *211* is in communication with a gear motor *213*. In some embodiments, the communication between the second gear *211* and the gear motor *213* is mechanical communication. The gear of the actuation module can be driven by a motor, a spring, gear assembly, or any other suitable mechanism for rotating the gear. The rotation of the gears *210*, *211* causes the distal end of the tissue collection element *234* to rotate. The gear motor can be manually powered, for example, using a wind-up mechanism. Alternatively, the gear motor can be electrically powered. The gear motor can be powered by a battery *219*, as shown in FIG. 2A. The battery can be a rechargeable battery or can be a replaceable battery. In some embodiments, an external power source can be used to power the gear motor.

[0052] In some embodiments, the actuation module translates the tissue collection element linearly in addition to rotating the tissue collection element. The actuation module *201* can further comprise an internal threaded slider *215*. The slider *215* can facilitate linear translation of the tissue collection element *234*. Guides *217* are further

present t ler from rotating with the tissue collection element. A spring on with the slider *215* can facilitate translation of the slider *215*. FIG. 2C illustrates the negative pressure barrel *208* in communication with a luer adaptor *246*. At least one o-ring *216* can be used to facilitate forming a seal to create negative pressure inside the negative pressure barrel *208*.

[0053] In some embodiments, the actuation module comprises a quick excursion switch *206*, as shown in FIG. 2. The quick excursion switch *206* can be connected to the tissue connection element **234** and/or the negative pressure barrel **208**. In some embodiments, the quick excursion switch is rigidly connected to the tissue collection element **234** and/or the negative pressure barrel **208**.

[0054] FIG. 3 is a side view of one embodiment of a negative pressure module *340* that can be used with the biopsy device. In some embodiment, the negative pressure module is a syringe *342*. The negative pressure module *340* can comprise a barrel *343*, a plunger *348* able to reciprocate within the barrel *343*, and a valve *350*. The negative pressure module *340* can be used to create negative pressure. Negative pressure created can be applied through the tissue collection element to the area from which tissue is to be excised. The negative pressure module *340* can be connected to the actuation module through the luer adaptor *344*. The valve *350* of the negative pressure module *340* has an open position and a closed position. The valve can be in either the open or closed position when connected to the actuation module. Once the negative pressure module *340* has been connected to the device, the valve *350* is positioned in the closed position if not already in the closed position. The plunger *348* of the syringe *342* can then be drawn back to create negative pressure inside the barrel *343*. Once the tissue collection element has been actuated, the valve *344* can be turned to the open position so that the negative pressure inside the negative pressure module passes through to the negative pressure barrel inside the actuation module. The negative pressure in the negative pressure barrel creates negative pressure inside the tissue collection element, thereby facilitating drawing the tissue sample into the tissue collection element. As will be appreciated by those skilled in the art, any suitable method or force for drawing tissue into the collection element can be used.

[0055] FIG. 4 is a lateral cross-section through one embodiment of a depth penetration module *420*. The depth penetration module *420* is slidably connected to the distal end of the actuation module. The depth penetration module *420* can comprise a depth gauge *422*, with a depth stop *426*, and a luer adaptor *424*. The depth penetration module *420* can further comprise a translation guide *428* for automated translation of the tissue collection element in a distal and proximal direction. The tissue collection element *434* passes through the depth penetration module *420*. The outer needle *436* is connected to the tissue collection element to the depth penetration module *420* at the luer adaptor *424*. The depth gauge *422* controls the depth to which the tissue collection element can be inserted into the tissue sample. The depth can be set using the depth stop *426*. In some embodiments, the depth to which the tissue collection element passes into the tissue can be automatically controlled by the biopsy device. In some embodiments, the depth to which the tissue collection element passes into the tissue can be controlled manually, while using the depth gauge to determine the extent to which the tissue collection element has been inserted into the tissue.

[0056] FIG. 5 is a side view of a biopsy device *500* as the device is being assembled. The proximal end of the catheter module *530* is connected to the distal end of the depth penetration module *520*. The proximal end of the depth penetration module is slidably connected to the distal end of the actuation module *501*. In some embodiments, a negative pressure module *540* is connected to the proximal end of the actuation module, as is shown in FIG. 5.

[0057] FIG. 6 is an illustration of a perspective view of the device *600* as assembled. As shown in FIG. 6, the negative pressure module *640* is located on the distal end of the actuation module *601* and is in mechanical communication with the actuation module *601* through luer adaptors *644*, *646*. As further shown in FIG. 6, the

634. The motor control switch *604* activates the drive mechanism which can then actuate the tissue collection element *634* to cause the tissue collection element *634* to rotate, thereby excising tissue. In some embodiments, the tissue collection element *634* is translated through the tissue manually. Alternatively, the motor control switch *604* activates the drive mechanism to actuate the tissue collection element *634* to rotate and translate through the tissue. The quick excursion switch *606* on the handle *602* can further be used to excise small predefined volumes of tissue. The tissue collection element *634* is in communication with the distal end of the actuation module *601*. The tissue collection element *634* is connected to the actuation module *601* through a luer adaptor *624*. The amount of tissue excised can be controlled using the depth gauge *622*. The depth stop *626* together with the depth gauge *622* can be used to set the depth the tissue collection element can penetrate into the tissue to be sampled.

[0058] FIG. 7 is an illustration of the device *700* as assembled and ready for use. The motor control switch *704* can be activated once the tissue collection element *734* is positioned proximal to the tissue of interest *798*. The activation of the motor control switch *704* on the handle *702* causes the actuation module *701* to affect rotational actuation of the tissue collection element *734*, as indicated by the arrow in FIG. 7. The tissue collection element *734* can be translated manually to position the distal end of the tissue collection element *734* in proximity to the tissue of interest. The actuation module *701* can then be activated to cause rotational actuation of the tissue collection element *734* to excise and collect tissue. As the tissue collection element *734* rotates, the tissue collection element *734* can be manually advanced through the tissue to a desired depth. Alternatively, once the device *701* has been manually positioned proximal to the tissue of interest, the activation of the actuation module *701* can cause linear actuation of the tissue collection element *734* as well as rotational actuation of the tissue collection element *734*. In some embodiments, the device *700* can further comprise an endoscope *790* to visualize the placement of the tissue collection element *734*, as shown in FIG. 7. The biopsy device can be adjusted so that the position of the biopsy device relative to the associated endoscope can accommodate the working length of the endoscope. Additionally, in some embodiments, an external negative pressure module *740* can be connected to the distal end of the actuation module *701*. The negative pressure module *740* can create constant negative pressure at the site of the tissue excision by activating the negative pressure module *740*. In FIG. 7, the negative pressure module *740* is activated by pulling back on the plunger *748*. The negative pressure module *740* can facilitate drawing the excised tissue up the tissue collection element *734* thereby containing the excised tissue within the tissue collection element *734*.

[0059] FIG. 8 illustrates an exploded view of another embodiment of the device, in which the actuation module comprises a negative pressure module. The device *800* comprises a handle *802* comprising translational and rotational actuation elements, a disposable syringe *842*, a disposable catheter module *830* consisting of a rotating tissue collection element *834*, a cannula *838*, flexible tubing *862* connecting the cannula *838* to the syringe *842*, a luer-lock or other suitable connector *860* that interfaces the cannula *838* and rotating tissue collection element *834* with the handle *802*. The handle *802* can comprise a rotational module *870* and translational actuation module *880*. The reusable rotational actuation module *870* inside the handle *802* can transmit translational actuation to the catheter module *830*. The sample is procured by the combined effect of rotating the tissue collection element *834*, translating the cannula *838* and the tissue collection element *834*, and actuating the syringe *842* to provide aspiration. The handle can be designed so that the user can perform all functions during the biopsy with one hand leaving the other hand free to operate the endoscope. The catheter module *830* can snap onto the bottom of the handle and can be easily removed and discarded after the procedure. In some embodiments, the catheter module comprises a bent tube tissue collection element. In some embodiments, the catheter module comprises a drill-bit

syringe can be a 5 mL or a 15 mL syringe. The syringe can be any suitable sized syringe.

[0060] **FIG. 9A** illustrates a cross-section view of the actuation module ***901*** comprising a negative pressure module ***940*** as assembled. The handle ***902*** comprises a syringe ***942***, and the rotational actuation module ***970*** and the translational actuation module ***980***. **FIG. 9B** illustrates a perspective view of the actuation module ***901***. The device can be designed for one handed use. The actuation module ***901*** comprises a handle lever ***964*** for manually translating the cannula and tissue collection element. Additionally, the handle can comprise a ratchet slider switch ***966*** for releasing the ratchet mechanism that interfaces with the motor module. The actuation module can further comprise a home position slider switch ***967*** for actuating the tissue collection element and setting the home position for the motor module can also be included. The actuation module ***901*** can further comprise an aspiration slider switch ***968*** for partially releasing a compressed spring, thereby actuating a syringe that provides aspiration through the cannula and the rotating tube. During operation, the cannula and rotating tissue collection element can be translated from within the sheath of the endoscope to the desired location near the solid tumor. This is achieved by repeatedly squeezing the hand-activated handle lever. Sample collection will be iterated from this point, so the set position can be designated as the home position. Also, the motor is actuated and the rotating tissue collection element emerges from the cannula. These three actions can be completed simultaneously by sliding the home position switch to the locked position. Once the device is prepared for sample collection, the syringe can be actuated using the aspiration slider switch ***968***. Sample can then be collected by repeatedly squeezing the handle. After one pass of collecting the sample, the ratchet slider switch ***966*** is used to return the cannula and the tissue collection element to the home position. Sample collection is iterated until enough sample has been collected. Once sample collection has been completed, the cannula and the tissue collection element can be retracted into the sheath of the endoscope by unlocking the home position switch ***967***. The sample is subsequently obtained from the cannula by exerting positive pressure with the syringe and locking the home position switch to actuate the tissue collection element. **FIG. 9C** is a perspective view of the handle of **FIG. 9A** as viewed from the bottom. **FIG. 9D** is a cross-sectional view of the handle.

[0061] **FIG. 10A** is a lateral cross-section of the rotational actuation module ***1070*** and the translational actuation module ***1080***. **FIG. 10B** is an isolated view of the rotational actuation module ***1070*** as viewed from the side.

[0062] **FIG. 11** depicts an exploded view of another embodiment of the syringe ***1142***. The syringe ***1142*** comprises a syringe barrel ***1143*** and a plunger ***1148***. The syringe ***1142*** further comprises an aspiration slider switch ***1168***, a spring ***1141***, and a negative pressure gauge ***1147***. The aspiration switch ***1168*** is in communication with the plunger ***1148***. The aspiration switch ***1168*** is drawn up through the groove ***1149*** on the negative pressure gauge ***1147***. The movement of the aspiration switch ***1168*** creates negative pressure in the syringe barrel ***1143***. The negative pressure in the syringe barrel ***1143*** can be transferred to the tissue collection element and to the portion of tissue to be excised.

[0063] **FIGS. 12A-D** illustrates the steps for preparing the device for operation. **FIG. 12A** illustrates how the handle ***1202*** of the actuation module ***1201*** can be fit with a y-tube connector ***1262***. A close-up view of **FIG. 12B** illustrates how the y-tube connector ***1262*** from the actuation module is inserted into a magnetic coupler ***1261*** and secured to the module by twisting a luer-lock ***1263***. Once these connections have been made, a negative pressure module can be inserted into the actuation module. The negative pressure module ***1240*** can then be armed and attached to flexible tubing **1264**, which in turn is attached to the y-tube connector ***1262***, as illustrated in **FIG. 12C**. The connector ***1260*** with attached catheter module ***1230*** can then be connected to the handle to complete the device

1200, as WO 2009/058436 D. In some embodiments, the connector *1260* is snap-fit to t PCT/US2008/069034 ome embodiments, the connector *1260* is screwed to the handle *1202*.

[0064] Further provided herein are alternate embodiments of the tissue collection element and the catheter module. **FIG. 13A** is one embodiment of the catheter module *1330* of a biopsy device described herein. **FIG. 13A** illustrates a lateral cross-sectional view of the catheter module *1330*. The catheter module *1330* comprises a stylet *1332*, tissue collection element *1334*, and outer needle *1336* nested in a cannula *1338*. **FIG. 13B** illustrates a cross-sectional view of **FIG. 13A** along the line **B-B**. **FIG. 13C** illustrates an isolated tissue collection element *1334*. The tissue collection element *1334* comprises a shaft *1385* and a distal end *1386*. The distal end *1386* of the tissue collection comprises an opening *1387*. The opening *1387* is created such that a larger area of tissue can be cut. When the tissue collection element is introduced proximal to the tissue to be sampled, the tissue collection element can be housed in an outer needle. When housed in an outer needle, the tissue collection element conforms to the shape of the outer needle. Once the outer needle is positioned adjacent to the tissue, the tissue collection element is extended past the distal end of the outer needle. Once the distal end of the tissue collection extend past the distal end of the outer needle, the tissue collection element assumes a secondary configuration where the distal end of the tissue collection element biases away from the center axis of the tissue collection element, as shown in **FIG. 13D**. In some embodiments, the tissue collection element is held in a first configuration by an outer needle. The tissue collection element can be held in a first configuration by a stylet extending through the tissue collection element. Once the stylet is removed from distal end of the tissue collection element, the tissue collection element can change configuration to a second configuration.

[0065] In **FIG. 13E**, the stylet *1332* is nested in the tissue collection element *1334*. The tissue collection element *1334* is nested at least partially in the outer needle *1336*. The stylet *1332*, tissue collection element *1334*, and outer needle *1336* extend past the distal end of the cannula *1338*. The components of the catheter module *1330* are nested when the device is introduced to the patient and into the stomach. **FIG. 13F** is a cross-section of the **FIG. 13E** along the line **F-F**, illustrating the nesting of the stylet *1332*, the tissue collection element *1334*, the outer needle *1336* and the cannula *1338*. **FIG. 13G** is a cross-sectional view of **FIG. 13E** along the line **G-G** illustrating the nesting of the stylet *1332*, tissue collection element *1334*, and outer needle *1336*.

[0066] In some embodiments of a biopsy device comprising a bent tube tissue collection element, the catheter module *1430* does not comprise an outer needle, as shown in **FIG. 14A**. **FIG. 14A** is a side view of the catheter module *1430* in which the tissue collection element *1434* and stylet *1432* extend past the distal end of the cannula *1438*. **FIG. 14B** is a cross-sectional view of the **FIG. 14A** along the line **B-B**. As shown in **FIG. 14B**, the stylet *1432* is encompassed by the tissue collection element *1434*, and both the stylet *1432* and the tissue collection element *1434* are encompassed by the cannula *1438*. **FIG. 14C** is a cross-sectional view of **FIG. 14A** along the line **C-C** illustrating the tissue collection element *1434* encompassing the stylet *1432*.

[0067] Other embodiments of the tissue collection element are also considered. In some embodiments, the tissue collection element *1534* comprises a twisted configuration. The twisting of the tissue collection element *1534* is similar to a drill-bit. **FIG. 15A** illustrates a drill-bit tissue collection element *1534*. The drill-bit has a structure that is twisted about a center axis. When the drill-bit tissue collection element *1534* is activated the drill-bit rotates about the center axis. When placed in contact with the tissue to be excised, the cutting edges *1552* of the drill-bit cut the tissue, and the tissue is drawn up the grooves *1554* of the drill-bit tissue collection element *1534*. As shown in **FIG. 15B**, the drill-bit tissue collection element *1534* can be encompassed by an outer needle *1536* and a cannula *1538*. **FIG. 15B** is a lateral cross-section of the drill-bit tissue collection element *1534* and catheter module *1530* illustrating the tissue collection element *1534* nested in an outer needle *1536*, nesting in a cannula *1538*. **FIG. 15C** is

a side view module *1530* with a tissue collection element *1534* and outer needle *1536* extending past the distal end of the cannula *1538*. **FIG. 15D** is a cross-sectional view of **FIG. 15C** along the line **D-D**, illustrating the cannula *1538* encompassing the outer needle *1536* which further encompasses the tissue collection element *1534*. **FIG. 15E** is a lateral cross of the catheter module *1530* of **FIG. 15C** with outer needle *1536* encompassing a drill-bit tissue collection element *1534* along the line **E-E**.

[0068] Another embodiment of the biopsy device comprises a drill-bit tissue collection element in the shape of a helical coil with a hollow center. **FIG. 16A** is an alternative drill-bit tissue collection element *1634* as viewed from the side. The cutting edges *1652* of the drill-bit tissue collection element *1634* rotate when actuated by the drive mechanism of the actuation module. As the drill-bit tissue collection element *1634* is translated through the tissue, a segment of tissue is excised and drawn up the grooves *1654* of the tissue collection element *1634*. Alternatively, tissue can be drawn up the center *1672* of the drill bit tissue collection element *1634*. **FIG. 16B** is a lateral cross-sectional view of the catheter module *1630* illustrating the tissue collection element *1634* nested in an outer needle *1636* encompassed by a cannula *1638*. **FIG. 16C** is a side-view of the catheter module *1630* where the outer needle *1636* and the tissue collection element *1634* extend past the distal end of the cannula *1638*. **FIG. 16D** is a cross-sectional view of **FIG. 16C** along the line **D-D**, illustrating the nesting of the tissue collection element *1634*, the outer needle *1636*, and the cannula *1638*, and further illustrating the hollow center *1672* of the tissue collection element *1634*.

[0069] In some embodiments of the invention described herein, the tissue collection element can be coated with a low-friction coating, such as an amorphous fluoropolymer (Teflon® available from Dupont), poly(tetrafluoroethylene), perfluoroalkoxy polymer resin, fluorinated ethylene-propylene, fluoropolymers, and combinations thereof. For example, **FIG. 17A** illustrates one embodiment of a catheter module *1730* in which the tissue collection element *1734* has been coated with a low-friction coating *1774*. **FIG. 17A** is a side view of a bent tube tissue collection element *1734*. The outer needle *1736* and tissue collection element *1734* are shown extending past the distal end of the cannula *1738*. The tissue collection element *1734* is also shown extending past the distal end of the outer needle *1736*. The tissue collection element *1734* can be coated with a low-friction coating *1774*. In some embodiments, the entire tip of the tissue collection element *1734* can be coated with a low friction coating *1774*. Alternatively, the inside of the tissue collection element *1734* can be coated with a low-friction coating *1774*, as shown in **FIG. 17A**. Additionally, a low-friction coating can be applied to a drill-bit embodiment of the device. The entire tissue collection element can be coated in a low-friction coating. Alternatively, the low friction coating can be applied to the grooves of the tissue collection element. **FIG. 17B** is frontal view of the catheter module of **FIG. 17A**.

[0070] **FIGS. 18A-D** illustrate one embodiment of a biopsy device in operation. **FIG. 18A** illustrates the device penetrating the stomach wall. In the embodiment of device shown in **FIG. 18A**, the catheter module *1830* comprises a cannula *1838*, an outer needle *1836*, and a tissue collection element *1834*. In some embodiments, the device can further comprise a stylet *1832*. The stylet *1832* can be used to establish and puncture through the point of penetration of the stomach wall *1897*. The outer needle *1836*, tissue collection element *1834*, and stylet *1832* extend from the distal end of the cannula 1*838*. The outer needle *1836* facilitates the penetration of the stomach wall *1897* to position the tissue collection element *1834* proximal to the tissue of interest *1898*. In **FIG. 18A**, the catheter module *1830* is positioned proximal to a lesion *1899* in the pancreas *1898*. **FIG. 18B** illustrates how the tissue collection element *1834* is then extended past the distal end of the outer needle *1836*. The stylet *1832* is retracted from the tissue collection element *1834* so that tissue can be collected by the tissue collection element *1834*. The actuation module can then be activated, thereby causing the tissue collection element *1834* to rotate. In some

collection element further extends from the distal end of the outer needle. In some embodiments, negative pressure can be applied through the tissue collection element to draw the excised tissue into the tissue collection element. Alternatively, magnetic forces can be used to draw the excised tissue into the tissue collection element. Any suitable force can be used for drawing excised tissue into the tissue collection element.

[0071] **FIG. 18C** illustrates the device and tissue collection element ***1834*** in use. Once the tissue collection element ***1834*** is proximal to the tissue ***1899*** to be sampled, the tissue collection element ***1834*** is actuated by the actuation module. The tissue collection element ***1834*** thereby rotates to excise a portion of tissue ***1899***, as indicated by the arrow in **FIG. 18C**. The tissue collection element ***1834*** can further be translated through the tissue ***1899*** to collect more tissue. The enlarged opening ***1887*** of the tissue collection element ***1834***, together with the rotation of the tissue collection element ***1834***, enables the biopsy device to excise a larger portion of tissue. Traditional biopsy devices capture a volume of tissue equal to the area of the opening of the tissue collection element times the depth to which the element is inserted into the tissue. In other words, the volume (V) of tissue excised by traditional tissue collection element is the area (A) of the opening multiplied by the depth or length (L) or $V = A \cdot L$. Making the opening of the tissue collection element elongated and rotating the tissue collection element, instead of moving it along a straight path, can thereby increase the volume (V) of the sample collected while using a tissue collection element of the same diameter as used in the typical case. For example purposes only, the volume of the tissue excised can be described as follows. As compared to current embodiments of biopsy devices, the area of the opening – as perceived from a line of sight tangent to the cutting path – of a device described herein can be described by kA, where A is the area of the catheter multiplied by a constant, k. The device is then actuated so that the opening rotates a desired number of turns through the tissue. The distance that the device travels can be described as $L \cdot \sqrt{1 + (2\pi Rn)^2}$, where L is the depth to which the device is inserted, R is the radius of rotation – measured as the radial separation between the rotational axis and the centroid of the area kA – through the sample, and 1/n is the distance between each rotation. Therefore, using an embodiment of a device described herein allows you to excise a portion of sample having a volume (V), where $V = kA \cdot L \cdot \sqrt{1 + (2\pi Rn)^2}$, assuming the helical cavity created by the tissue collection element is not self-overlapping.

[0072] Once it is decided that a desired amount of tissue has been collected from the lesion or tissue sample, the actuation module is deactivated. The tissue collection element can be retracted into the outer needle and the entire catheter module removed from the patient. In some embodiments, the tissue collection element can be retracted into the cannula and the entire catheter module is removed from the patient. In some embodiments, the catheter module is removed from the patient without retracting the tissue collection element into the outer needle. Once the catheter module is outside the patient, the excised tissue sample can be tested. In some embodiments, the tissue sample is removed from the biopsy device. **FIG. 18D** illustrates one embodiment of how the tissue sample collected by the tissue collection element ***1834*** can be removed from the catheter module ***1830*** of the biopsy device and collected in a suitable container ***1896***, such as a Petri dish. One way a sample can be removed from the catheter module includes removing the negative pressure and retracting the tissue collection element ***1834*** into the outer needle ***1836***. In some embodiments, the negative pressure can be reduced instead of removed. The stylet ***1832*** can be advanced through the tissue collection element ***1834*** to expel the excised tissue ***1899***, by pushing the excised tissue ***1899*** out of the distal end of the tissue collection element ***1834***. Alternatively, the tissue collection element ***1834*** can be retracted to expel the excised tissue. As the tissue collection element ***1834*** is retracted the tissue is retracted with the tissue collection element ***1834*** until the tissue contacts the stylet ***1832*** in the tissue collection element ***1834***. As the

tissue collection element *834* continues to be withdrawn, the stylet *1832* holds the tissue collection element *1834* no longer encompasses the tissue. In some embodiments, positive pressure can be applied through the tissue collection element *1834* to expel the excised portion of tissue. In some embodiments, another device can be used to remove the excised portion of tissue. The excised portion of tissue can be tested by removing the excised tissue from the tissue collection element. Alternatively, the tissue can be tested without removing the excised portion of tissue from the tissue collection element. In some embodiments, a testing device is directly connected to the catheter module. Alternatively, a testing element is connected to the entire biopsy device. In some embodiments, the actuation module further comprises a testing element for testing the excised portion of tissue.

[0073] **FIG. 19** illustrates another embodiment of the tissue collection element *1934* in use. Once the cannula *1938*, outer needle *1936*, and tissue collection element *1934* are proximal to the tissue *1999* to be sampled, the tissue collection element *1934* is actuated by the drive mechanism. The tissue collection element thereby rotates (as indicated by the arrow) to excise a portion of tissue. The tissue collection element can further be translated through the tissue to collect more tissue. As the tissue collection element is translated through the tissue sample a spiral shaped segment of tissue can be carved from the sample. As the tissue is cut by the tissue collection element, the tissue moves along the grooves of the tissue collection element and into the cannula. In some embodiments, the excised tissue moves into the cannula through the center of the drill-bit. Alternatively, the excised tissue is drawn into the cannula by following the grooves of drill-bit tissue collection element and through the center of the drill-bit tissue collection element. The tissue can be removed from the cannula module by any suitable means for removing the sample by, for example purposes only, pushing the sample out of the outer needle using the tissue collection element.

II. METHODS

[0074] Also provided herein are methods for obtaining biopsy samples. In some embodiments, the method provides for obtaining a measurable target tissue from a collection region comprising: inserting a biopsy device comprising an outer needle having a proximal end and a distal end wherein the proximal end is connected to a drive mechanism, and a tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism; advancing the tissue collection element into a patient toward a target tissue; excising a measurable amount of target tissue with the tissue collection element; and removing the excised target tissue from the patient. Additionally, the method can further comprise the step of transmitting a translational actuation force to at least one of the outer needle and the tissue collection element. In some embodiments, the method can further comprise the step of transmitting a rotational actuation force to the tissue collection element. The excising step can further comprises procuring a tissue sample by rotating the tissue collection element while translating the outer needle and tissue collection element. In some embodiments, the method can further comprise the step of step of inserting a stylet into the tissue collection element. Furthermore, the method can further comprise the step of applying negative pressure to the distal tip of at least one of the tissue collection element and cannula. Also, the method can further comprise the step of approaching the target location with the stylet inserted in the tissue collection element prior to sample acquisition.

[0075] In some embodiments, a method for obtaining a measurable target tissue from a collection region is provided herein, the method comprising: inserting a biopsy device comprising a stylet having a proximal end and a distal end wherein the stylet is insertable inside the tissue collection element; and a tissue collection element formed

from ma[illegible]t constrained configuration when the stylet is inserted inside[illegible]t element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism; advancing the tissue collection element into a patient toward a target tissue; excising a measurable amount of target tissue with the tissue collection element; and removing the excised target tissue from the patient. In some embodiments, the method can further comprise the step of transmitting a translational actuation force to the tissue collection element. Alternatively, the method can comprise the step of transmitting a rotational actuation force to the tissue collection element. In some embodiments of the method, the excising step further comprises procuring a tissue sample by rotating the tissue collection element while translating the tissue collection element. The excised tissue can further be removed from the biopsy device. The stylet can be used to remove the excised tissue. In some embodiments, the method can include the application of negative pressure to the distal tip of the tissue collection element. The stylet in the tissue collection element can also be used to approach the target location prior to sample acquisition.

[0076] Another method provided herein, is a method for obtaining a target tissue from a collection region comprising: inserting a biopsy device comprising a cannula having a proximal end and a distal end wherein the proximal end is connectable to a drive mechanism; and a tissue collection element having helical cutting features along a portion of its length at the distal end thereof wherein the tissue collection element is adapted to cut target tissue from a collection region and is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism; and a non-friction coating applied to some portion of the distal tip of the tissue collection element and/or the outer needle; advancing the tissue collection element into a patient toward a target tissue; excising a measurable amount of target tissue with the tissue collection element; and removing the target tissue from the patient. In some embodiments, the method can further comprise the step of transmitting a translational actuation force to the cannula and/or tissue collection element. Alternatively, the method can further comprise the step of transmitting a rotational actuation force to the tissue collection element. Furthermore, the excising step further comprises procuring a tissue sample by rotating the tissue collection element while translating the outer needle and tissue collection element. In some embodiments, the negative pressure can be applied to the distal end of at least one of the tissue collection element or outer needle prior to sample acquisition. The method can also provide for the step of approaching the target location with the stylet inserted in the outer needle or tissue collection element prior to sample acquisition.

III. KITS

[0077] Further provided herein is a kit for obtaining a measurable target tissue from a collection region comprising: a removable handle containing a drive mechanism; one or more outer needles, each outer needle having a proximal end and a distal end wherein the proximal end is adaptable to engaging the drive mechanism; and one or more tissue collection elements, each tissue collection element having an adapted and configured form to receive a measurable target tissue from a collection region wherein the tissue collection element is translationally and rotationally moveable within the outer needle distally beyond the distal end of the outer needle in response to the drive mechanism.

[0078] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be

employe invention. It is intended that the following claims define thon and that methods and structures within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A biopsy device comprising:

an outer needle having a distal end and a proximal end connected to a drive mechanism; and

a tissue collection element having a distal end and a proximal end, the tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle,

wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism.

2. The biopsy device of claim 1 wherein the distal end of the tissue collection element deviates from the central axis of the outer needle from about 0 degrees to about 180 degrees and rotates around the central axis of the outer needle from about 0 degrees to about 360 degrees.

3. The biopsy device of claim 1 wherein the distal end of the tissue collection element deviates from a central axis of the outer needle along an angle, radius, helical path, or contour.

4. The biopsy device of claim 1 wherein the distal end of the tissue collection element comprises an opening, wherein the opening obtains a portion of tissue having a cross-sectional diameter greater than the cross-sectional diameter of the outer needle.

5. The biopsy device of claim 1 wherein the tissue collection element is translated from within the outer needle to a target location.

6. The biopsy device of claim 1 wherein the distal end of the tissue collection element is rotationally actuated to produce a rotational motion.

7. The biopsy device of claim 6 wherein the rotational motion is a motion selected from the group consisting of continuous, intermittent, reciprocating, and combinations thereof.

8. The biopsy device of claim 1 wherein the tissue collection element is adaptable to be moved manually.

9. The biopsy device of claim 1 wherein the tissue collection element is adaptable to be moved automatically or semi-automatically.

10. The biopsy device of claim 1 wherein the outer needle is adaptable to be moved manually.

11. The biopsy device of claim 1 wherein the outer needle is adaptable to be moved automatically or semi-automatically.

12. The biopsy device of claim 1 wherein the tissue collection element comprises stainless steel.

13. The biopsy device of claim 1 wherein at least a portion of the tissue collection element comprises a shape memory alloy.

14. The biopsy device of claim 1 wherein at least a portion of the tissue collection element is coated with a non-friction coating.

15. The biopsy device of claim 1 wherein at least a portion of the distal end of the outer needle is coated with a non-friction coating.

16. The biopsy device of claim 1 wherein the distal end of the tissue collection element comprises a beveled cutting edge.

17. The biopsy device of claim 1 wherein the tissue collection element is disposable.

18. The biopsy device of claim 1 wherein the tissue collection element cuts and receives tissue within the tissue collection element without further damaging the tissue.

19. The biopsy device of claim 1 wherein the device further comprises a stylet inserted into the tissue collection element.

20. The biopsy device of claim 1 further comprising a negative pressure source adaptable to facilitate application of negative pressure to the distal end of the tissue collection element.

21. The biopsy device of claim 20 wherein the negative pressure is supplied by a syringe.

22. The biopsy device of claim 21 wherein the syringe is a two-stage or a multi-stage syringe.

23. The biopsy device of claim 1 wherein the outer needle is adaptable to be echogenic.

24. The biopsy device of claim 23 wherein the echogenecity is facilitated by rotational actuation applied to the outer needle.

25. The biopsy device of claim 23 wherein echogenecity is facilitated by vibrations induced at the distal tip of the outer needle.

26. The biopsy device of claim 1 wherein the tissue collection element is adaptable to be echogenic.

27. The biopsy device of claim 26 wherein the echogenecity is facilitated by rotational actuation applied to the tissue collection element.

28. The biopsy device of claim 26 wherein the echogenecity is facilitated by vibrations induced at the distal end of the tissue collection element.

29. The biopsy device of claim 1 further comprising a cannula wherein the cannula is adaptable to contain the tissue collection element and outer needle and wherein the tissue collection element and outer needle are translatable and rotatable relative to the cannula.

30. The biopsy device of claim 1 further comprising a depth gauge adaptable to assess the depth of penetration of the tissue collection element within a target location.

31. The biopsy device of claim 1 further comprising a depth stop adaptable to be set to limit the depth of penetration of the tissue collection element within a target location.

32. The biopsy device of claim 1 wherein the tissue collection element is adaptable to capture a measurable target tissue sample from a collection region in at least three passes.

33. The biopsy device of claim 1 further comprising one or more radiopaque markers on at least a portion of the length of the device.

34. The biopsy device of claim 1 wherein the device is adaptable to be operated using single-hand operation.

35. The device of claim 1 further comprising a quick excursion element adaptable to repeatedly extrude depth limited portions of target tissue.

36. The biopsy device of claim 1 wherein the outer needle has a gauge of 18 to 27.

37. The biopsy device of claim 1 wherein the distal end of the tissue collection element extracts a portion of target tissue from a collection region having a diameter greater than 0.05 inches in diameter.

38. The biopsy device of claim 1 further comprising an endoscope having a working length.

39. The biopsy device of claim 38 wherein the biopsy device is adaptable to accommodate the working length of the endoscope.

40. A biopsy device comprising

a stylet having a proximal end and a distal end wherein the stylet is adaptable to be inserted inside the tissue collection element; and

collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element,

wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism.

41. The biopsy device of claim 40 wherein the distal tip of the tissue collection element deviates from the axis of rotation of said tissue collection element from 0 degrees to 180 degrees and rotates around said axis of rotation from 0 degrees to about 360 degrees.

42. The biopsy device of claim 40 wherein the distal end of the tissue collection element deviates from the axis of rotation of said tissue collection element along an angle, radius, helical path, or contour.

43. The biopsy device of claim 40 wherein the distal end of the tissue collection element comprises an opening wherein the opening obtains a portion of tissue having a cross-sectional diameter greater than the cross-sectional diameter of the tissue collection element in its constrained configuration.

44. The biopsy device of claim 40 wherein the tissue collection element is translated to a target location during tissue acquisition.

45. The biopsy device of claim 40 wherein the distal end of the tissue collection element is rotationally actuated to produce a rotational motion.

46. The biopsy device of claim 45 wherein the rotational motion is a motion selected from the group consisting of continuous, intermittent, reciprocating, and combinations thereof.

47. The biopsy device of claim 40 wherein the tissue collection element is adaptable to be moved manually.

48. The biopsy device of claim 40 wherein the tissue collection element is adaptable to be moved automatically or semi-automatically.

49. The biopsy device of claim 40 wherein the tissue collection element comprises stainless steel.

50. The biopsy device of claim 40 wherein at least a portion of the tissue collection element comprises a shape memory alloy.

51. The biopsy device of claim 40 wherein at least a portion of the distal end of the tissue collection element is coated with a non-friction coating.

52. The biopsy device of claim 40 wherein the distal end of the tissue collection element comprises a beveled cutting edge.

53. The biopsy device of claim 40 wherein the tissue collection element is disposable.

54. The biopsy device of claim 40 wherein the tissue collection element cuts and receives tissue within the tissue collection element without further damaging the tissue.

55. The biopsy device of claim 40 wherein the stylet is adaptable to penetrate tissue as the tissue collection element is advanced toward the target location.

56. The biopsy device of claim 40 wherein the stylet is adaptable to preclude anomalous tissue acquisition as the tissue collection element is advanced toward the target location.

57. The biopsy device of claim 40 wherein the stylet is adaptable to expel a biopsy tissue sample from the tissue collection element.

58. The biopsy device of claim 40 further comprising a negative pressure source adaptable to facilitate application of negative pressure to the distal tip of the tissue collection element.

59. The biopsy device of claim 58 wherein the negative pressure source is a syringe.

60. The biopsy device of claim 59 wherein the syringe is selected from a two-stage or a multi-stage syringe.

61. The biopsy device of claim 40 wherein the tissue collection element is adaptable to be replaced.

62. The biopsy device of claim 40 wherein the echogenecity is facilitated by rotational actuation applied to the tissue collection element.

63. The biopsy device of claim 40 wherein the echogenecity is facilitated by vibrations induced at the distal end of the tissue collection element.

64. The biopsy device of claim 40 further comprising a cannula adaptable to contain the tissue collection element, the cannula further translatable and rotatable relative to the tissue collection element.

65. The biopsy device of claim 40 further comprising a depth gauge adaptable to assess the depth of penetration of the tissue collection element within a target location.

66. The biopsy device of claim 40 further comprising a depth stop or similar means for setting a limit for the depth of penetration of the tissue collection element within a target location.

67. The biopsy device of claim 40 wherein the tissue collection element is adaptable to capture a measurable target tissue sample from a collection region in at most three passes.

68. The biopsy device of claim 40 further comprising one or more radiopaque markers on at least a portion of the length of the device.

69. The biopsy device of claim 40 wherein the device is adaptable to be operated using single-hand operation.

70. The biopsy device of claim 40 further comprising a quick excursion element adaptable to repeatedly extrude depth limited-portions of target tissue.

71. The biopsy device of claim 40 wherein the tissue collection element comprises a hollow shaft having a gauge of 18 to 27.

72. The biopsy device of claim 40 wherein the distal end of the tissue collection element is adaptable to extract a portion of target tissue from a collection region having a diameter greater than 0.05 inches in diameter.

73. The biopsy device of claim 40 further comprising an endoscope having a working length.

74. The biopsy device of claim 73 wherein the biopsy device is adaptable to accommodate the working length of the endoscope.

75. A biopsy device comprising:

an outer needle having a proximal end and a distal end wherein the proximal end is connectable to a drive mechanism; and

a tissue collection element comprising a proximal end, a distal end, and a helical cutting edge along at least a portion of the length of the tissue collection element, wherein the helical cutting edge is adaptable to cut a portion of tissue from a target location; and

a non-friction coating adaptable to be applied to at least a portion of the distal end of the tissue collection element,

wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism.

76. The biopsy device of claim 75 further comprising a non-friction coating adaptable to be applied to at least a portion of the outer needle.

77. The biopsy device of claim 75 wherein the helical cutting edge extends radially from a solid core.

78. The biopsy device of claim 75 wherein the helical cutting edge is adaptable to encircle a hollow core.

79. The biopsy device of claim 75 wherein the tissue collection element is translated from within the outer needle to a target location.

80. The biopsy device of claim 75 wherein the distal end of the tissue collection element is adaptable to be actuated to produce a rotational motion.

81. The biopsy device of claim 80 wherein the rotational motion is a motion selected from the group consisting of continuous, intermittent, reciprocating, and combinations thereof.

82. The biopsy device of claim 75 wherein the tissue collection element is adaptable to be moved manually.

83. The biopsy device of claim 75 wherein the tissue collection element is adaptable to be moved automatically or semi-automatically.

84. The biopsy device of claim 75 wherein the tissue collection element comprises stainless steel.

85. The biopsy device of claim 75 wherein at least a portion of the distal end of the tissue collection element comprises a beveled cutting edge.

86. The biopsy device of claim 75 wherein the tissue collection element is disposable.

87. The biopsy device of claim 75 wherein the tissue collection element cuts and receives tissue within the outer needle without further damaging the tissue.

88. The biopsy device of claim 75 wherein the device further comprises a stylet adaptable to be inserted in at least one of the outer needle and the tissue collection element.

89. The biopsy device of claim 75 further comprising a negative pressure source adaptable to facilitate application of negative pressure to the distal end of at least one of the outer needle or the tissue collection element.

90. The biopsy device of claim 89 wherein the negative pressure source is a syringe.

91. The biopsy device of claim 90 wherein the syringe is a two-stage syringe or a multi-stage syringe.

92. The biopsy device of claim 75 wherein the outer needle is adaptable to be echogenic.

93. The biopsy device of claim 92 wherein the echogenecity is facilitated by rotational actuation applied to the outer needle.

94. The biopsy device of claim 92 wherein enhanced echogenecity is facilitated by vibrations induced at the distal tip of the outer needle.

95. The biopsy device of claim 75 wherein the tissue collection element is adaptable to be echogenic.

96. The biopsy device of claim 95 wherein the echogenecity is facilitated by rotational actuation applied to the tissue collection element.

97. The biopsy device of claim 95 wherein the echogenecity is facilitated by vibrations induced at the distal tip of the tissue collection element.

98. The biopsy device of claim 75 further comprising a cannula wherein the cannula is adaptable to contain the tissue collection element and outer needle and wherein the tissue collection element and outer needle are translatable and rotatable relative to the cannula.

99. The biopsy device of claim 75 further comprising a depth gauge adaptable to assess the depth of penetration of the tissue collection element within a target location.

100. The biopsy device of claim 75 further comprising a depth stop adaptable to be set to limit the depth of penetration of the tissue collection element within a target location.

101. The biopsy device of claim 75 wherein the tissue collection element captures a measurable target tissue sample from a collection region in at least three passes.

102. The biopsy device of claim 75 further comprising an endoscope having a working length.

103. The biopsy device of claim 102 wherein the biopsy device is adaptable to accommodate the working length of the endoscope.

an outer needle having a proximal end and a distal end wherein the proximal end is connected to a drive mechanism; and

a tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism,

wherein the distal end of said tissue collection element forms an opening adaptable to obtain a target tissue from a collection region, the opening having a cross-sectional diameter greater than the cross-sectional diameter of the outer needle.

105. A biopsy device comprising

a stylet having a proximal end and a distal end wherein the stylet is adaptable to be inserted inside the tissue collection element; and

a tissue collection element having a proximal end and a distal end, the tissue collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism,

wherein the distal end of said tissue collection element forms an opening adaptable to obtain a target tissue from a collection region, the opening having a cross-sectional diameter greater than the cross-sectional diameter of the outer needle.

106. A biopsy device comprising

an outer needle having a proximal end and a distal end wherein the proximal end is connected to a drive mechanism;

a tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism; and

a non-friction coating.

107. The biopsy device of claim 106 wherein the non-friction coating is adaptable to be applied to the distal end of the tissue collection element.

108. The biopsy device of claim 106 wherein the non-friction coating is adaptable to be applied to the distal end of the outer needle.

109. A biopsy device comprising

a stylet having a proximal end and a distal end wherein the stylet is insertable inside the tissue collection element; and

a tissue collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism; and

ction coating applied to some portion of the distal tip of the ient.

110. A kit for obtaining a measurable target tissue from a collection region comprising:

a removable handle containing a drive mechanism;

one or more outer needles, each outer needle having a proximal end and a distal end wherein the proximal end is adaptable to engage the drive mechanism; and

one or more tissue collection elements, each tissue collection element having an adapted and configured form to receive a measurable target tissue from a collection region wherein the tissue collection element is translationally and rotationally moveable within the outer needle distally beyond the distal end of the outer needle in response to the drive mechanism.

111. A method for obtaining a measurable target tissue from a collection region comprising:

inserting a biopsy device comprising an outer needle having a proximal end and a distal end wherein the proximal end is connected to a drive mechanism, and a tissue collection element formed from material having a first constrained configuration when positioned within the outer needle prior to deployment and a second unconstrained configuration when extended distally beyond the distal end of the outer needle wherein the tissue collection element is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism;

advancing the tissue collection element into a patient toward a target location;

excising a measurable amount of target tissue with the tissue collection element; and

removing the excised target tissue from the patient.

112. The method of claim 111 further comprising the step of transmitting a translational actuation force to at least one of the outer needle and the tissue collection element.

113. The method of claim 111 further comprising the step of transmitting a rotational actuation force to the tissue collection element.

114. The method of claim 111 wherein the excising step further comprises procuring a tissue sample by rotating the tissue collection element while translating the outer needle and tissue collection element.

115. The method of claim 111 further comprising the step of inserting a stylet into the tissue collection element.

116. The method of claim 111 further comprising the step of applying negative pressure to the distal end of at least one of the tissue collection element and outer needle.

117. The method of claim 111 further comprising the step of approaching the target location with the stylet inserted in the tissue collection element prior to sample acquisition.

118. A method for obtaining a measurable target tissue from a collection region comprising:

inserting a biopsy device comprising a stylet having a proximal end and a distal end wherein the stylet is insertable inside the tissue collection element; and a tissue collection element formed from material having a first constrained configuration when the stylet is inserted inside said tissue collection element and a second unconstrained configuration when the stylet is retracted from within the tissue collection element wherein the tissue collection element is translationally and rotationally moveable in response to actuation by the drive mechanism;

advancing the tissue collection element into a patient toward a target location;

excising a measurable amount of target tissue with the tissue collection element; and

removing the excised target tissue from the patient.

120. The method of claim118 further comprising the step of transmitting a rotational actuation force to the tissue collection element.

121. The method of claim 118 wherein the excising step further comprises procuring a tissue sample by rotating the tissue collection element while translating the tissue collection element.

122. The method of claim 118 further comprising the step of removing the excised tissue from the biopsy device.

123. The method of claim 122 wherein the stylet is adapted to remove the excised tissue.

124. The method of claim 118 further comprising the step of applying negative pressure to the distal tip of the tissue collection element.

125. The method of claim 118 further comprising the step of approaching the target location with the stylet inserted in the tissue collection element prior to sample acquisition.

126. A method for obtaining a target tissue from a collection region comprising:

inserting a biopsy device comprising a outer needle having a proximal end and a distal end wherein the proximal end is connectable to a drive mechanism; and a tissue collection element having helical cutting features along a portion of its length at the distal end thereof wherein the tissue collection element is adapted to cut target tissue from a collection region and is translationally and rotationally moveable within the outer needle and distally beyond the distal end of the outer needle in response to actuation by the drive mechanism; and a non-friction coating applied to some portion of the distal tip of the tissue collection element and/or the outer needle;

advancing the tissue collection element into a patient toward a target location;

excising a measurable amount of target tissue with the tissue collection element; and

removing the target tissue from the patient.

127. The method of claim 126 further comprising the step of transmitting a translational actuation force to the outer needle and/or tissue collection element.

128. The method of claim 126 further comprising the step of transmitting a rotational actuation force to the tissue collection element.

129. The method of claim 126 wherein the excising step further comprises procuring a tissue sample by rotating the tissue collection element while translating the outer needle and tissue collection element.

130. The method of claim 126 further comprising the step of applying negative pressure to the distal tip of the tissue collection element and/or outer needle prior to sample acquisition.

131. The method of claim 126 further comprising the step of approaching the target location with the stylet inserted in the outer needle or tissue collection element prior to sample acquisition.

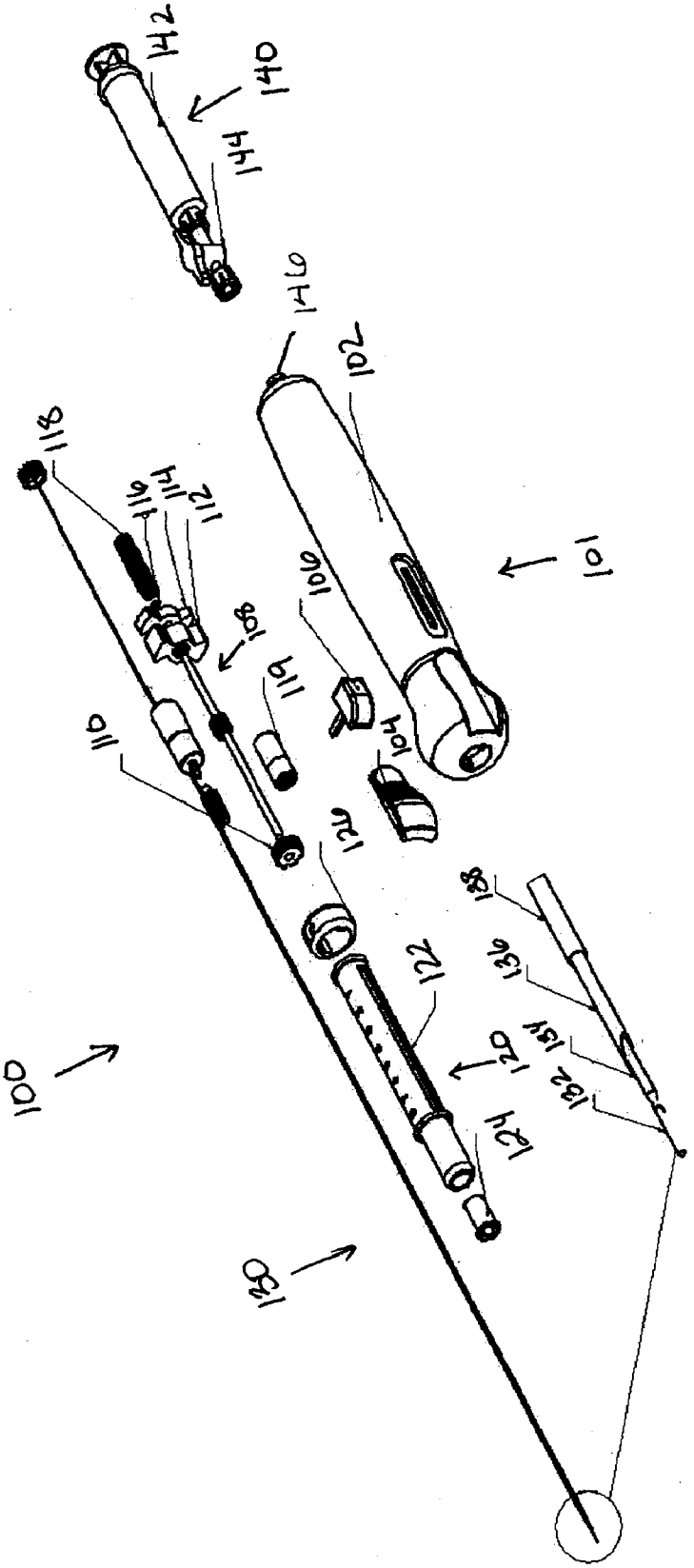

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Fig. 1

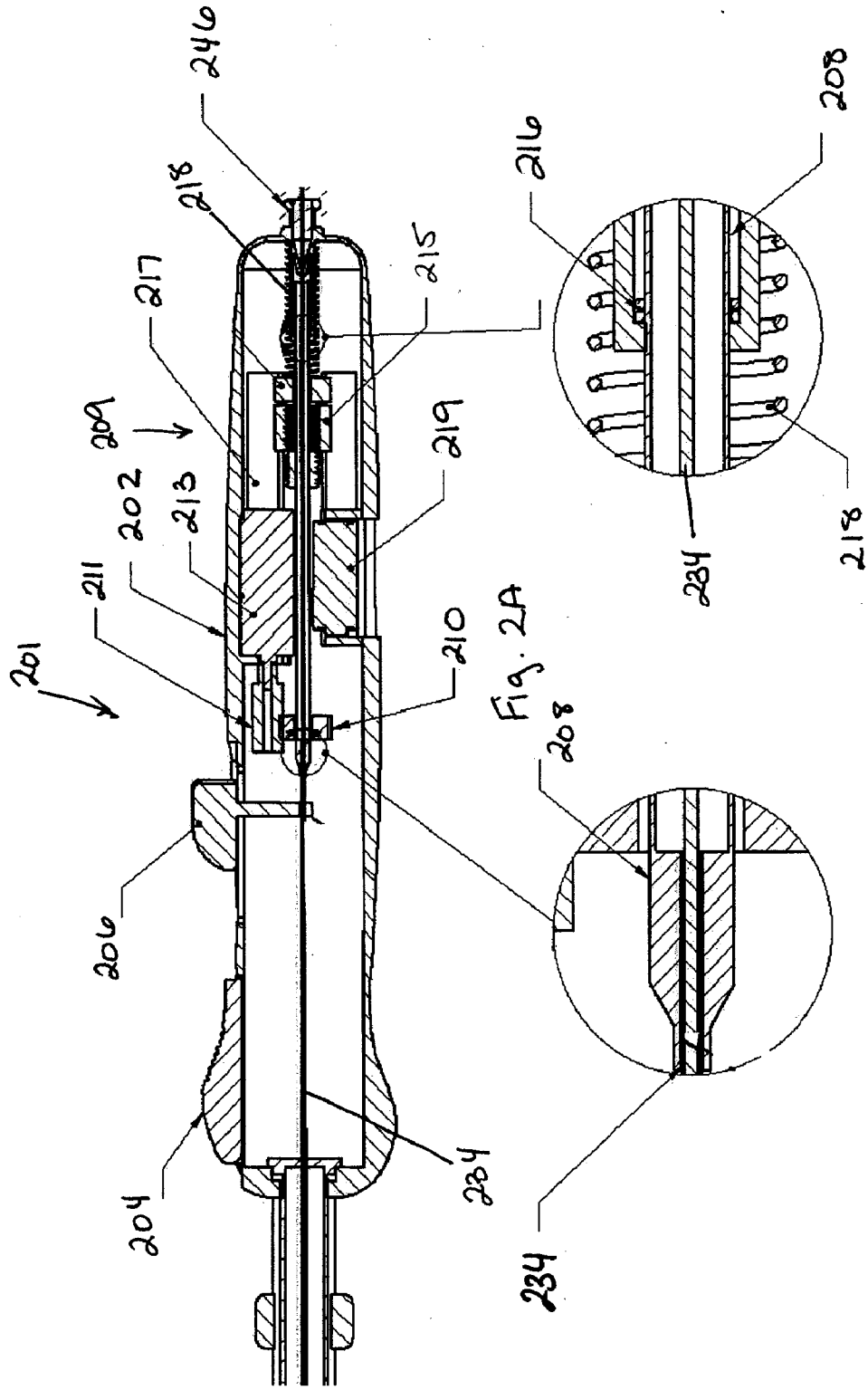

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Fig. 2A
Fig. 2B
Fig. 2C

Fig. 2

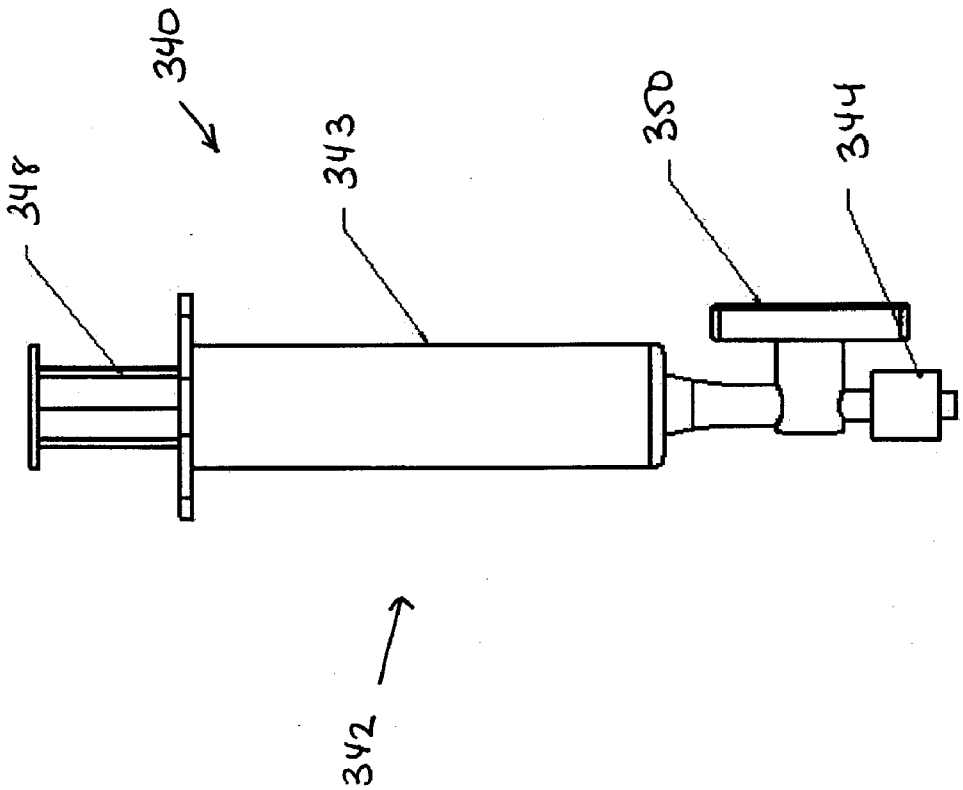


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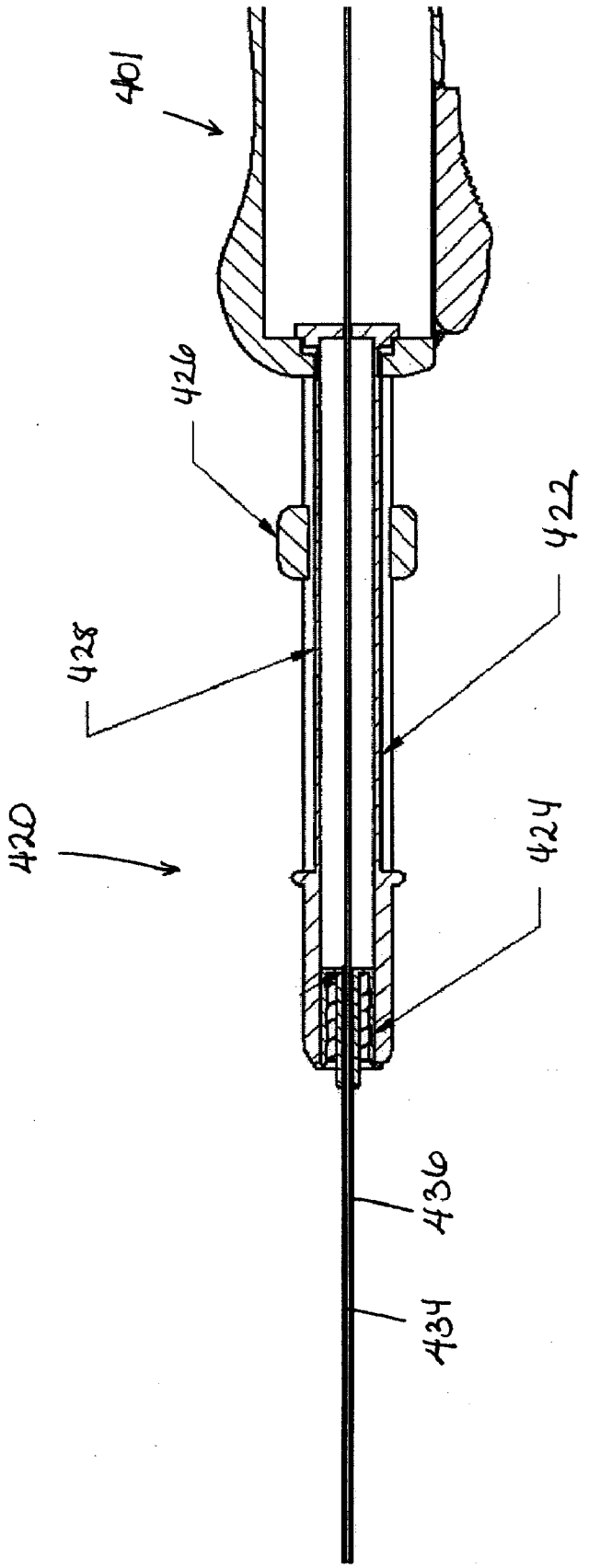


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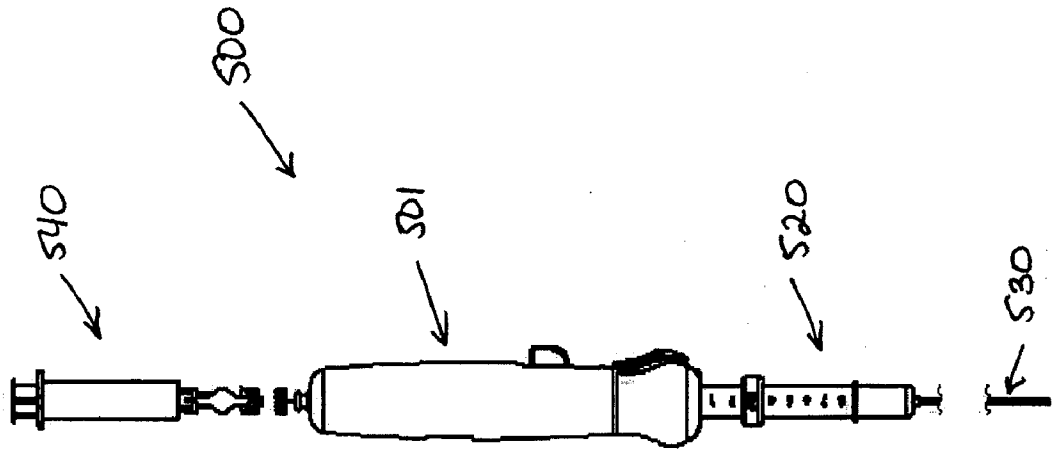


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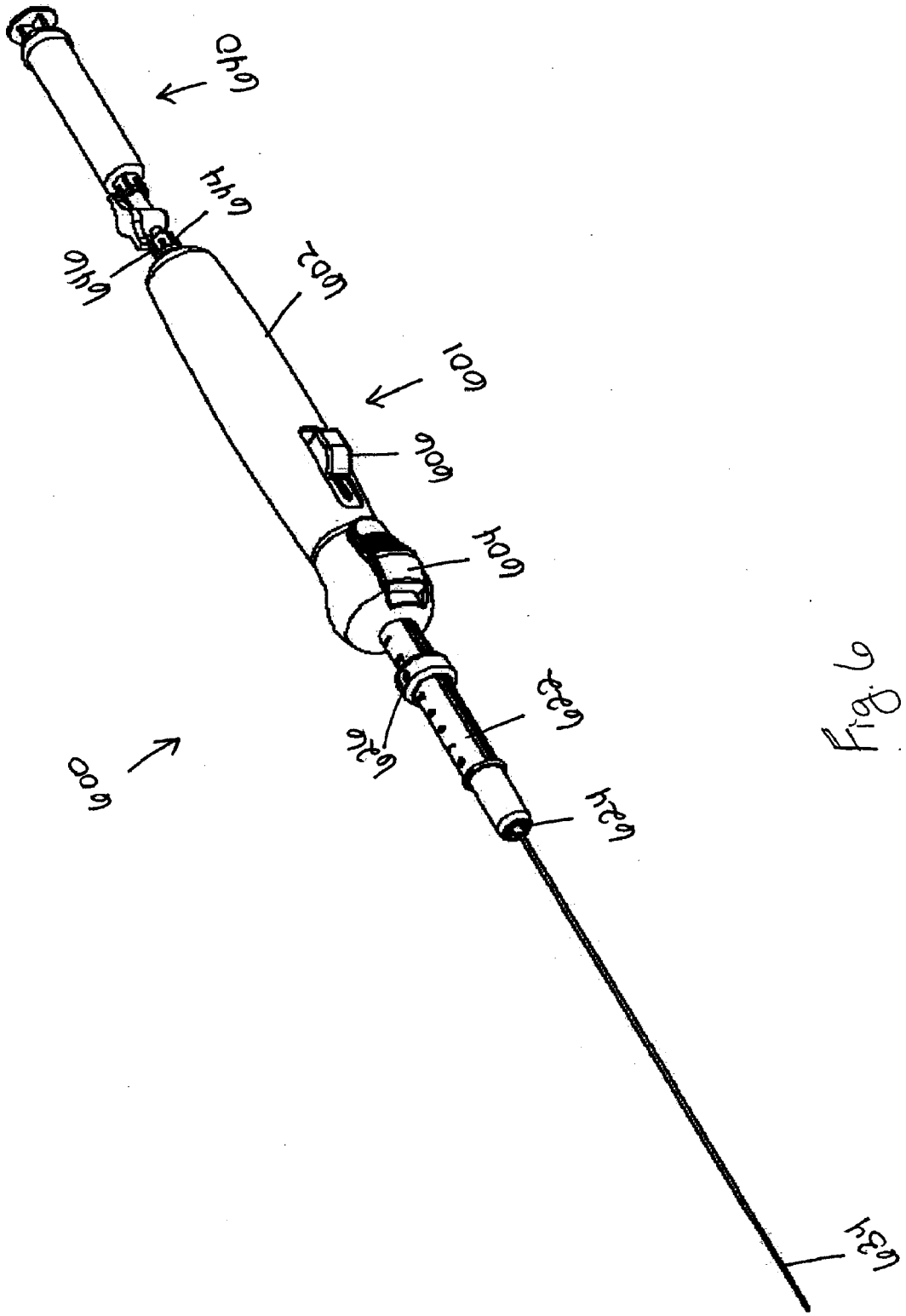


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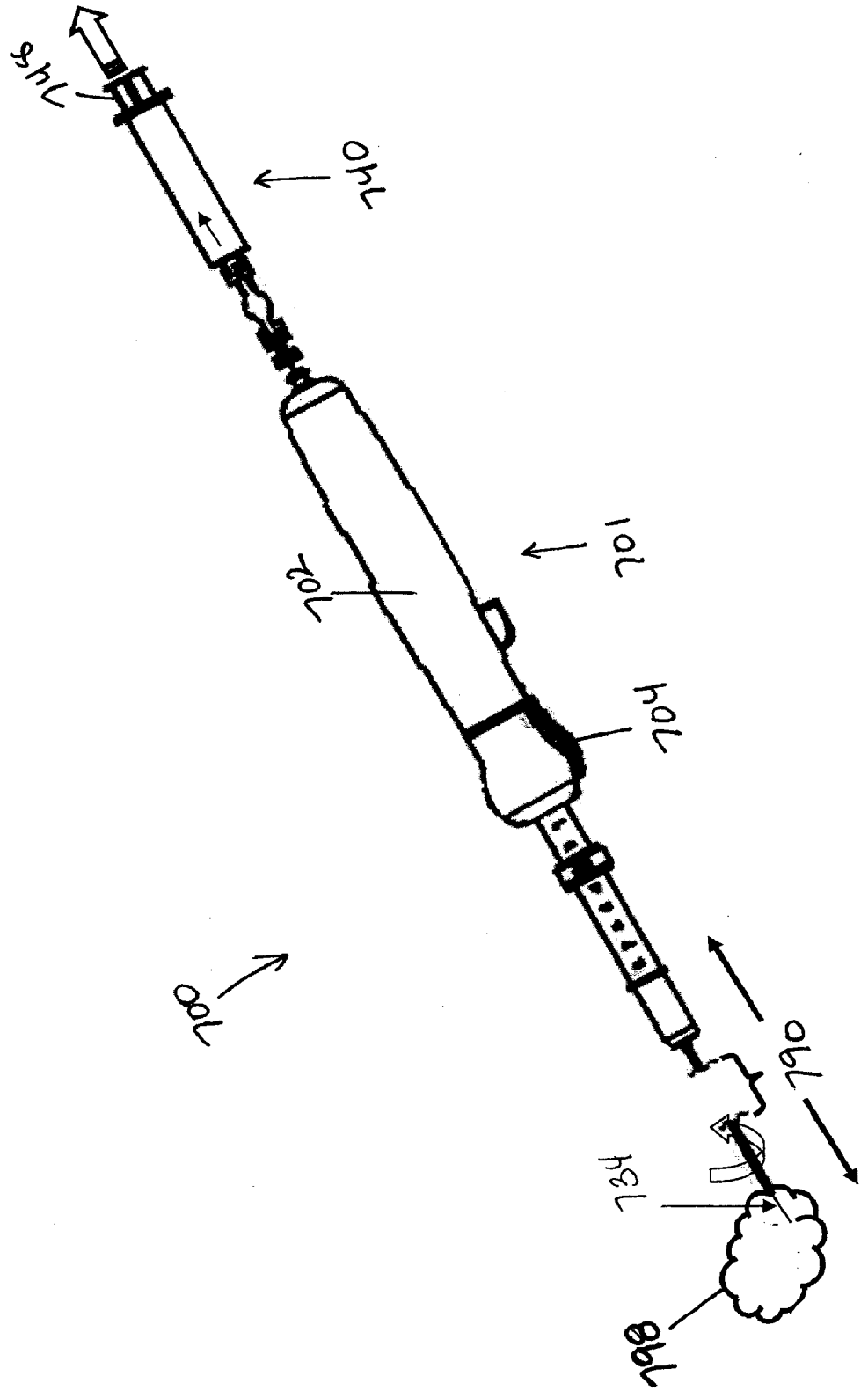


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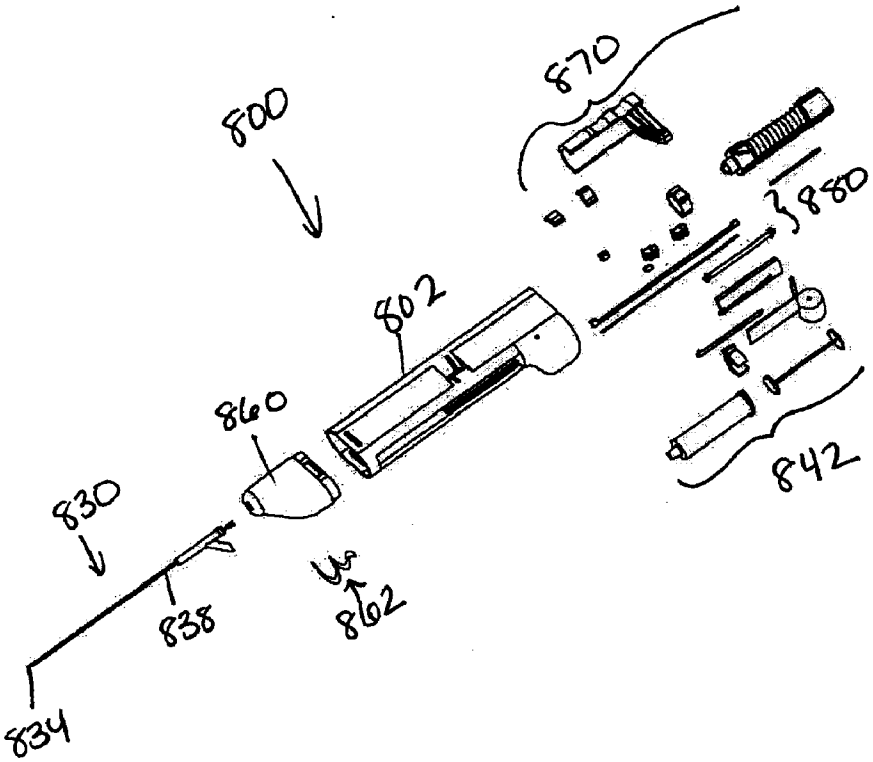


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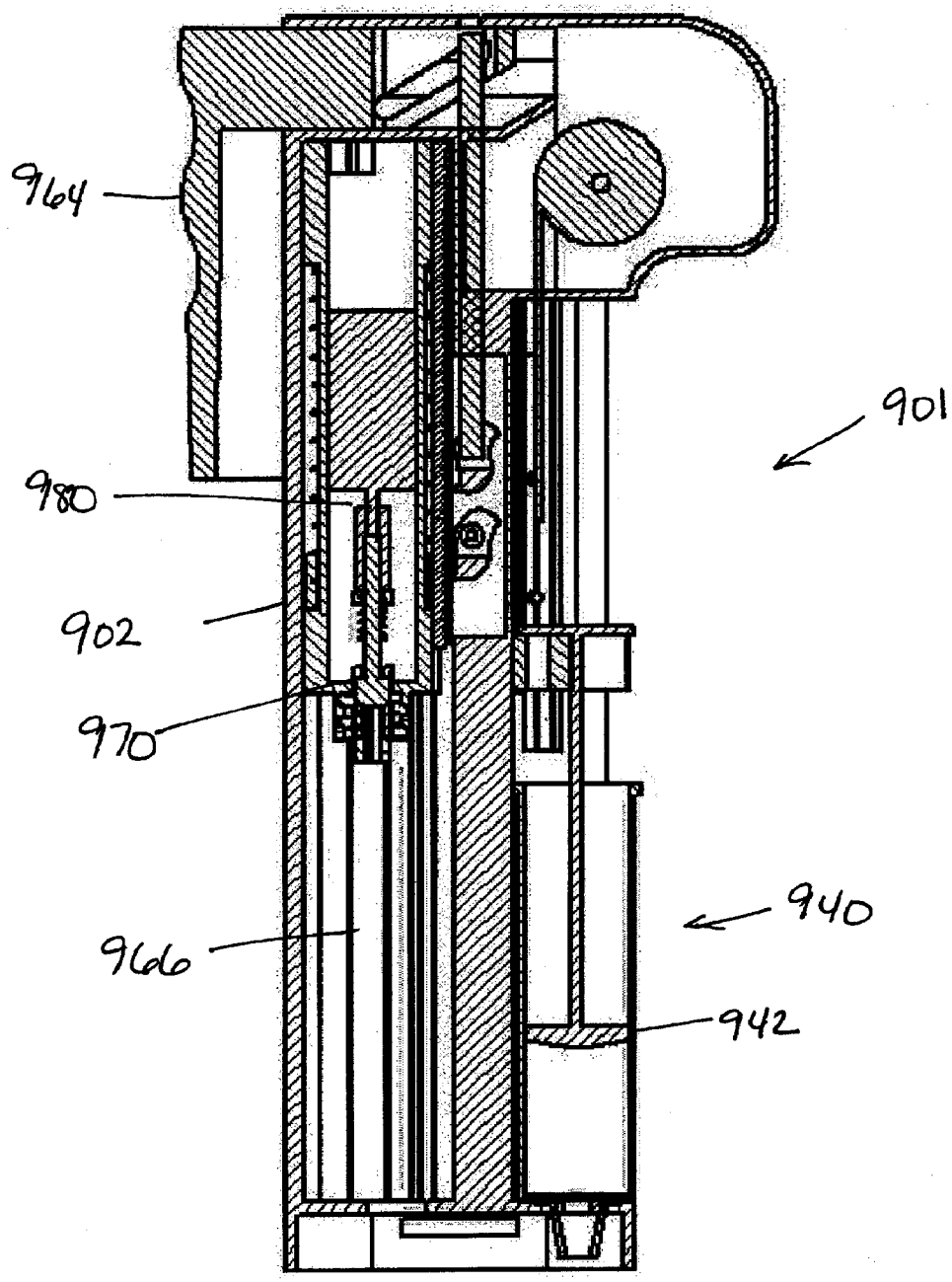


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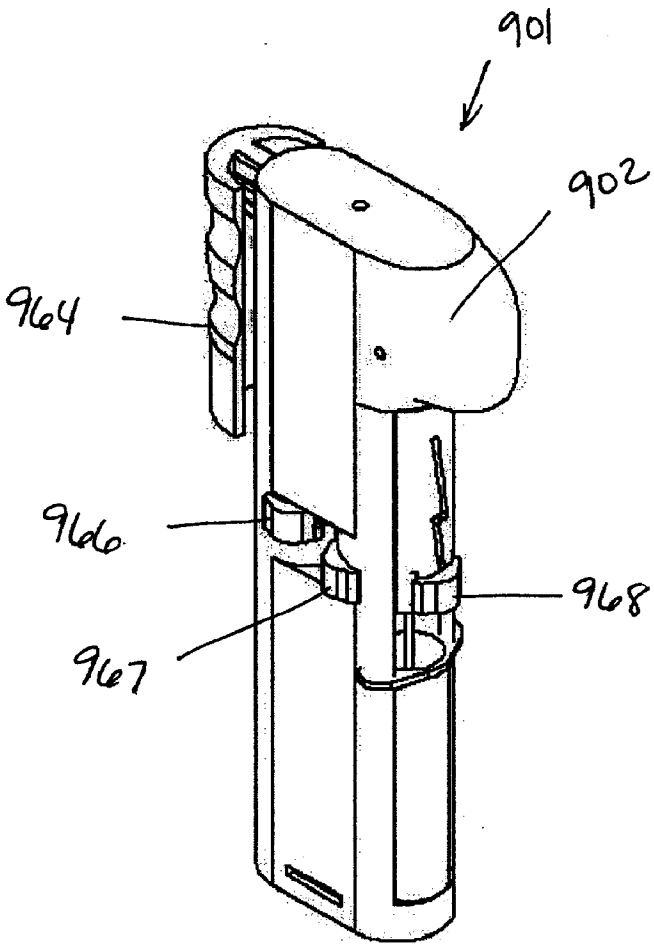


Fig. 9B

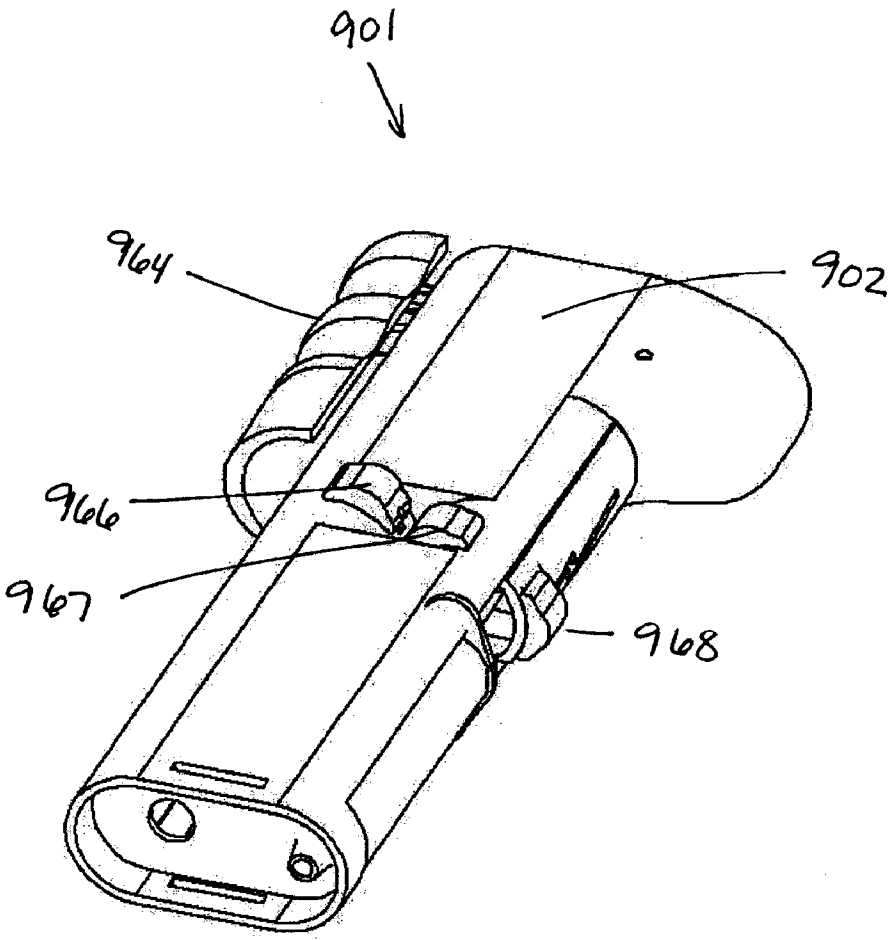


Fig. 9C

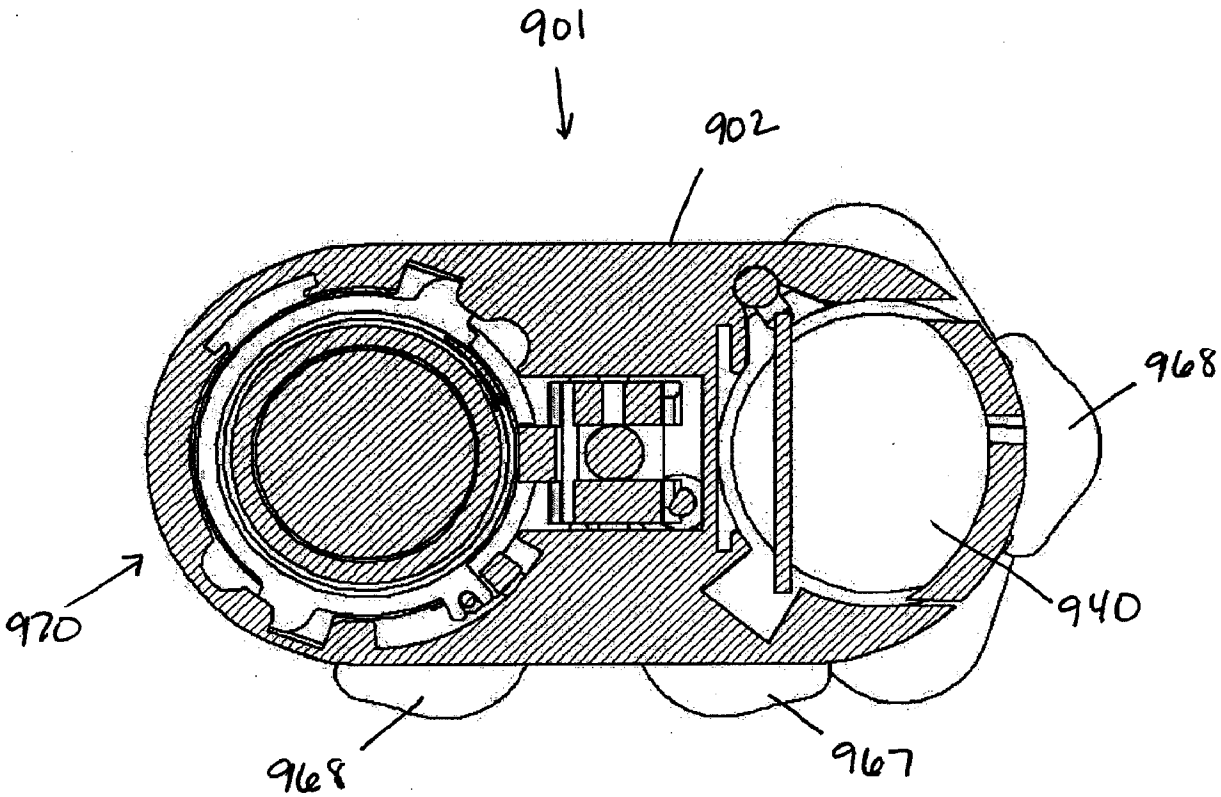


Fig. 9D

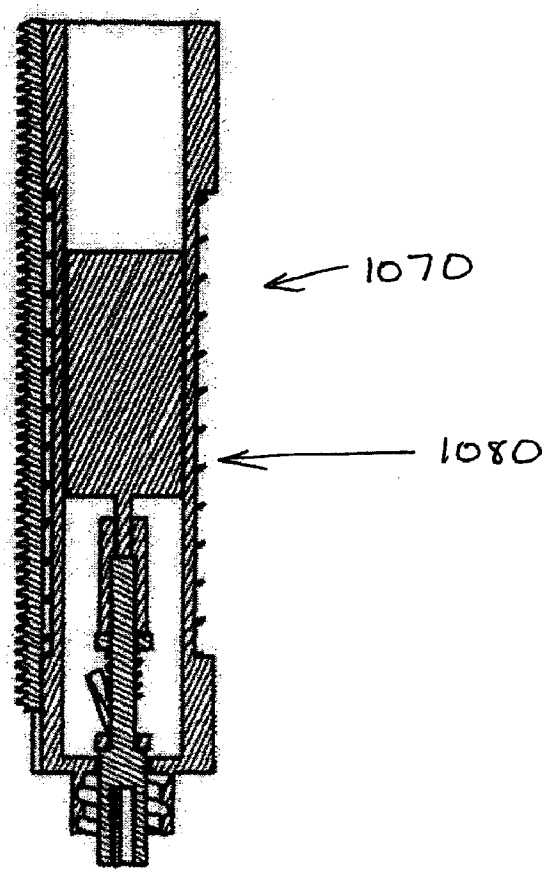


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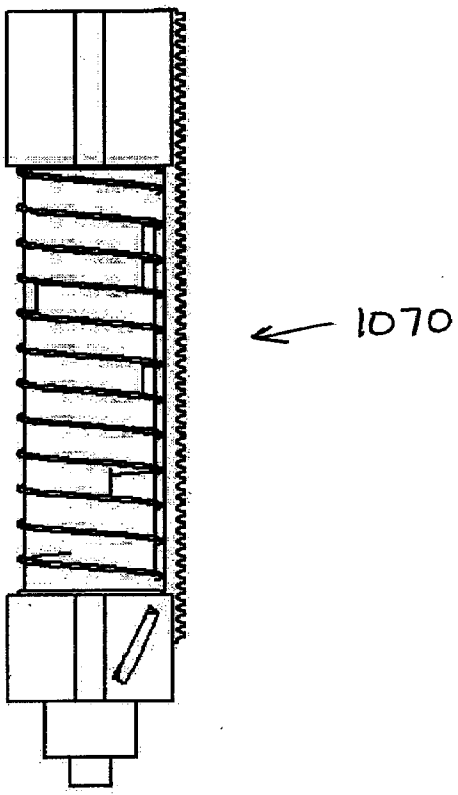


Fig. 10B

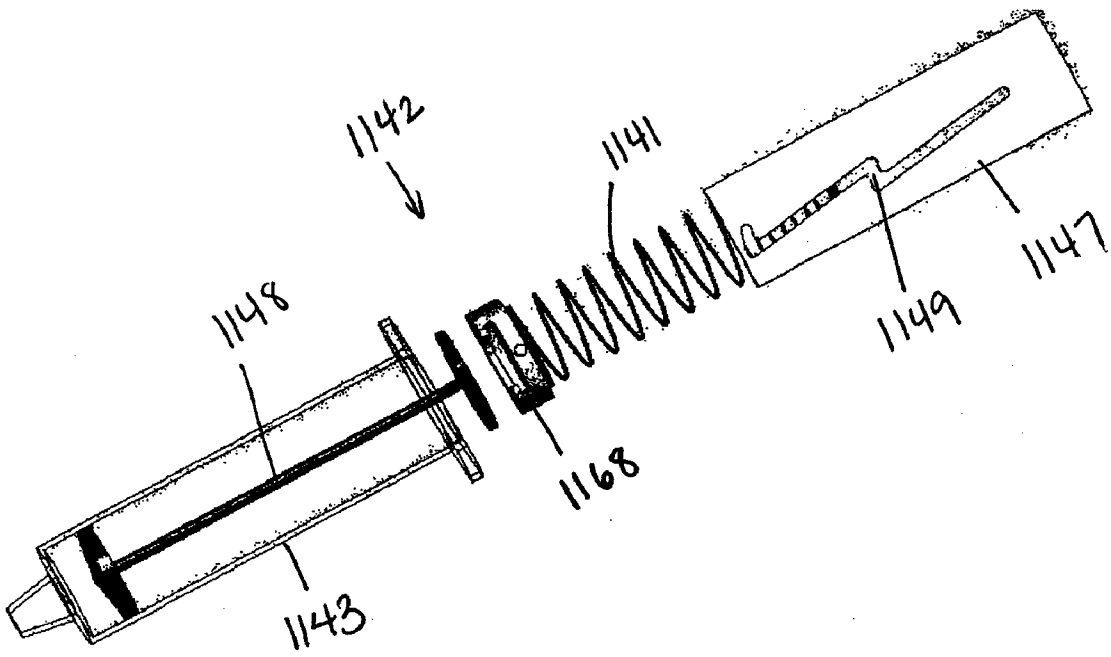


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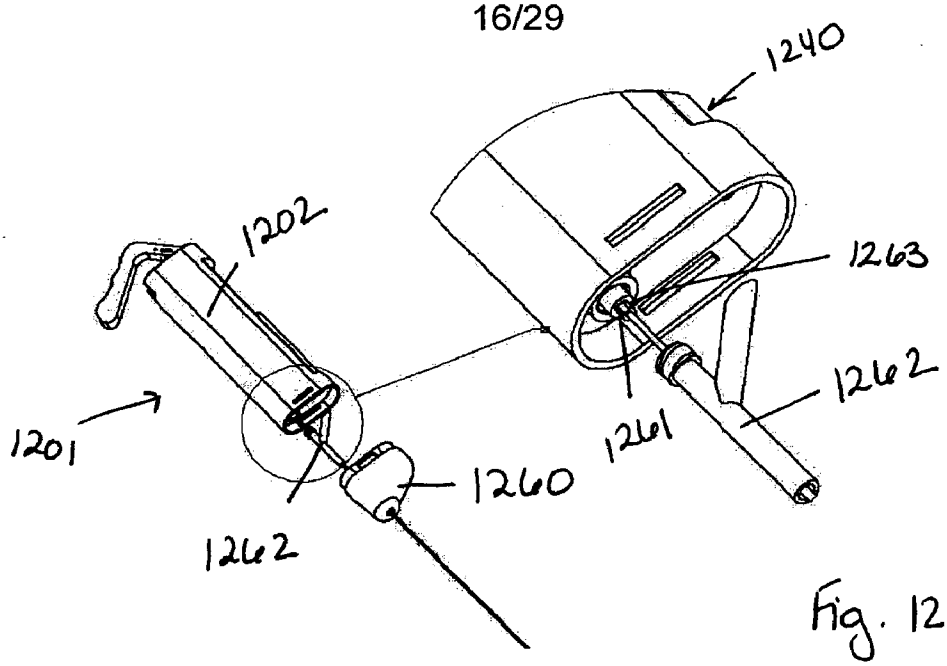


Fig. 12B

Fig. 12A

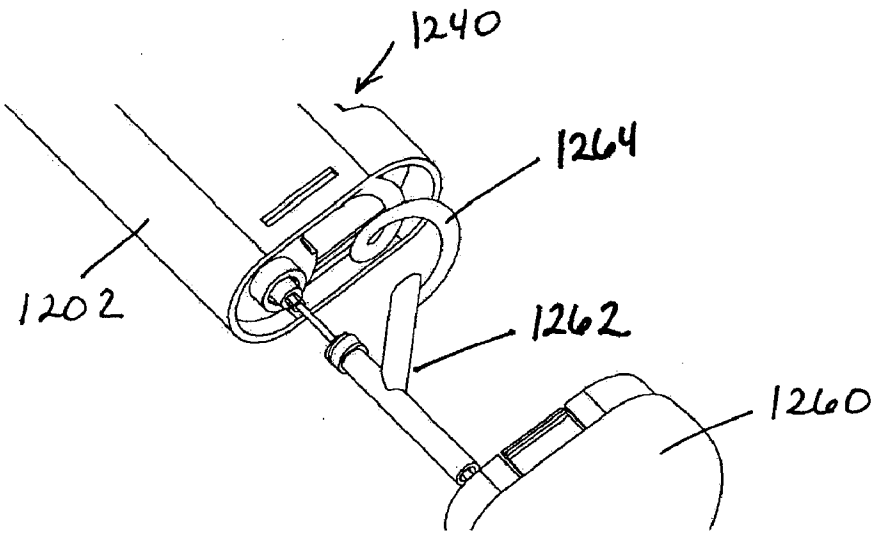


Fig. 12C

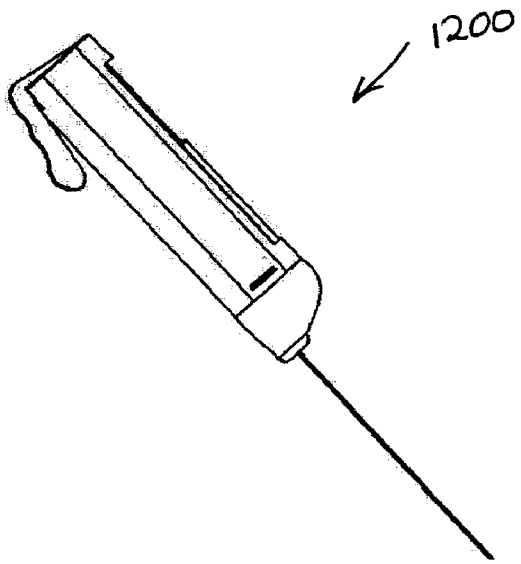


Fig. 12D

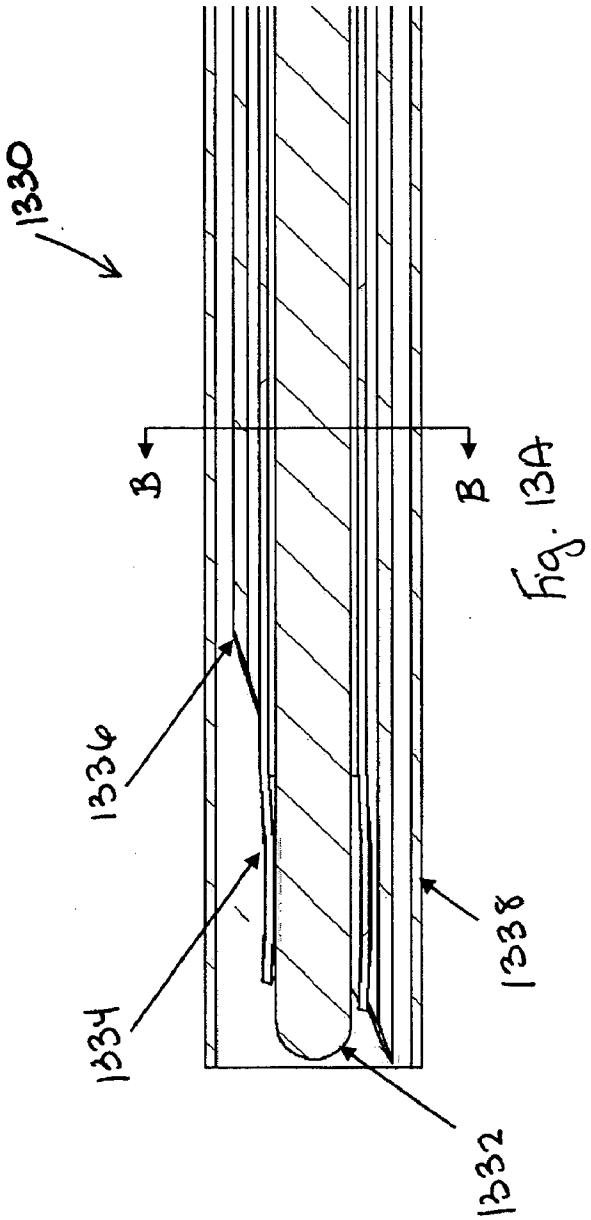


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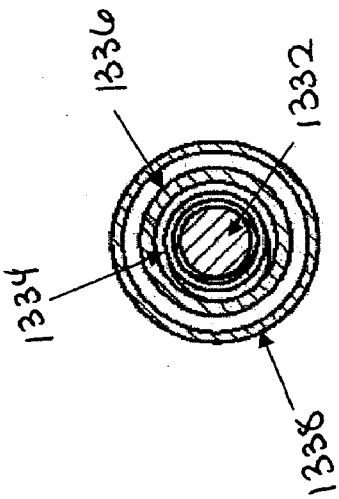


Fig. 13B

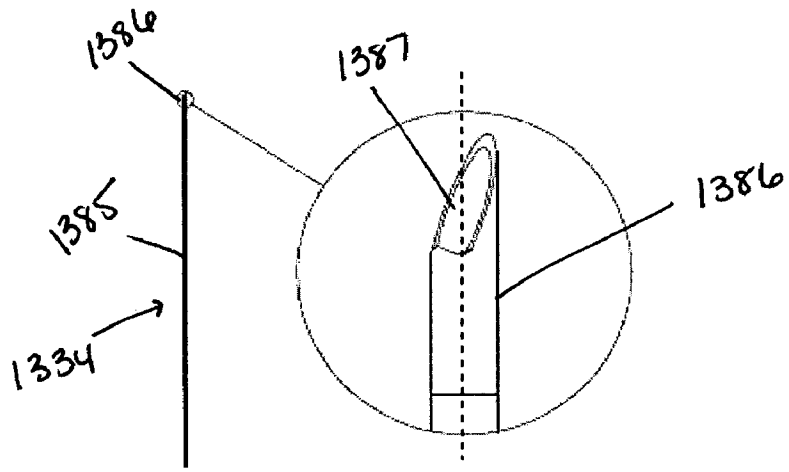


Fig. 13C

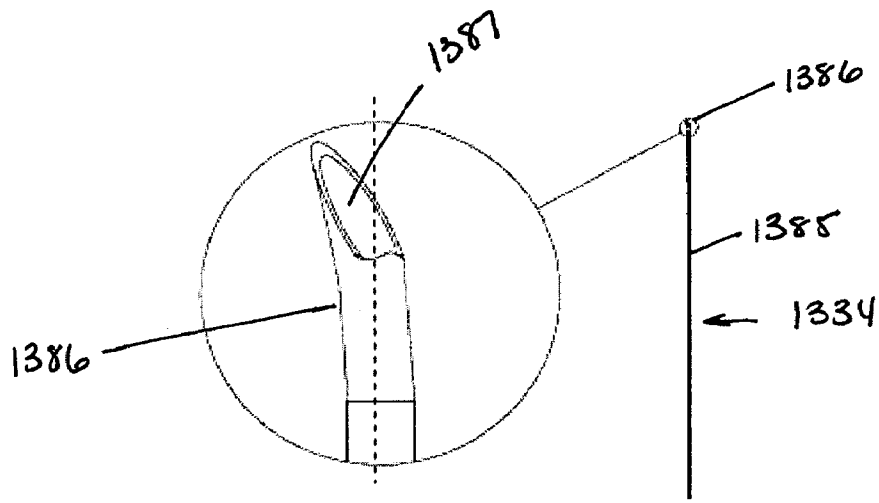


Fig. 13D

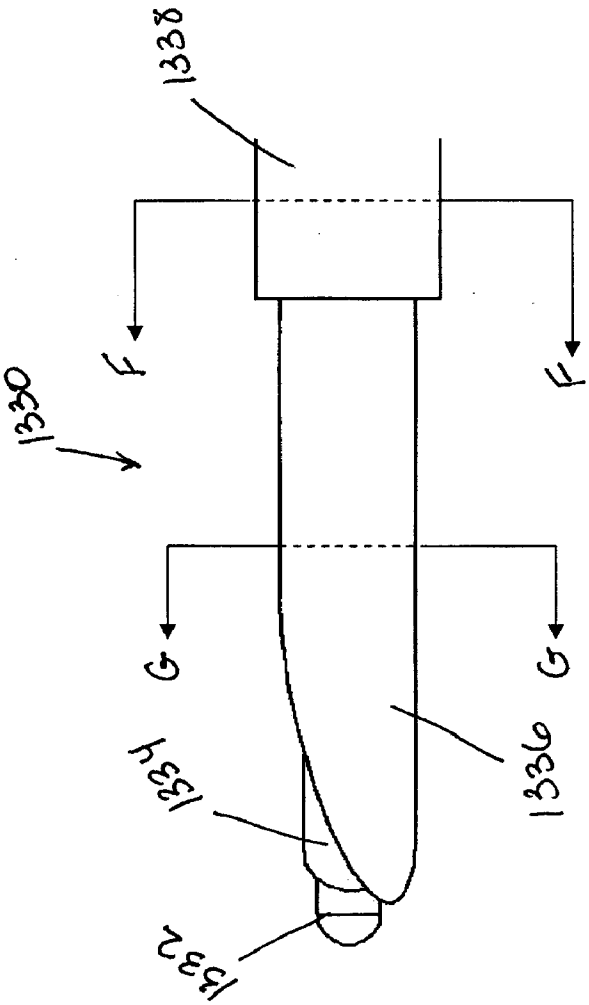


Fig. 13E

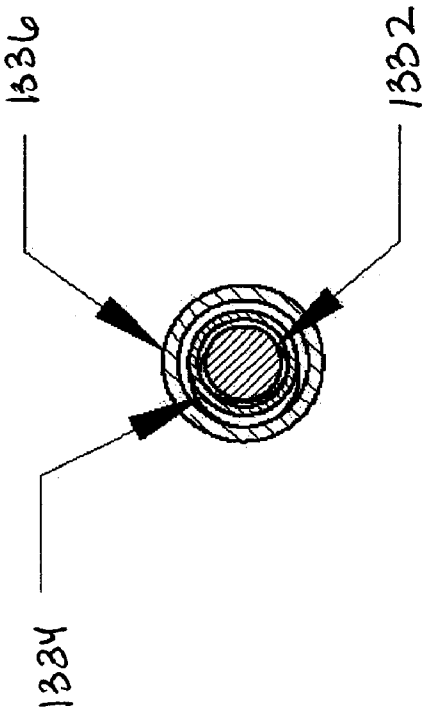


Fig. 13G

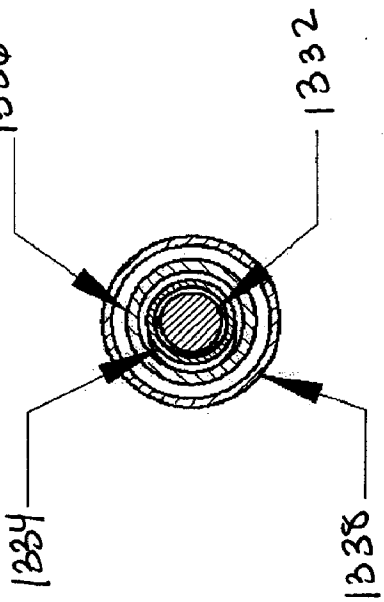


Fig. 13F

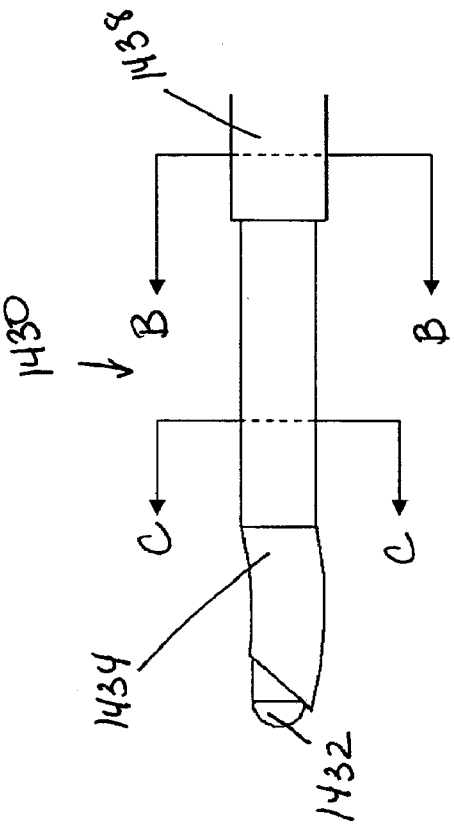


Fig. 14A

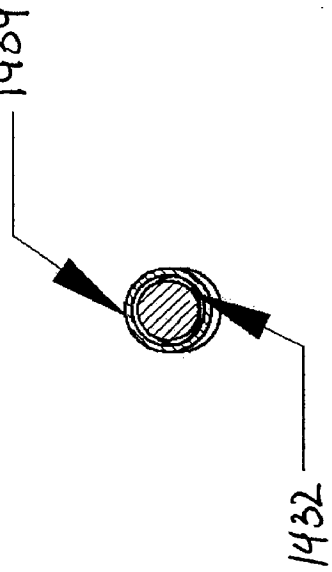


Fig. 14C

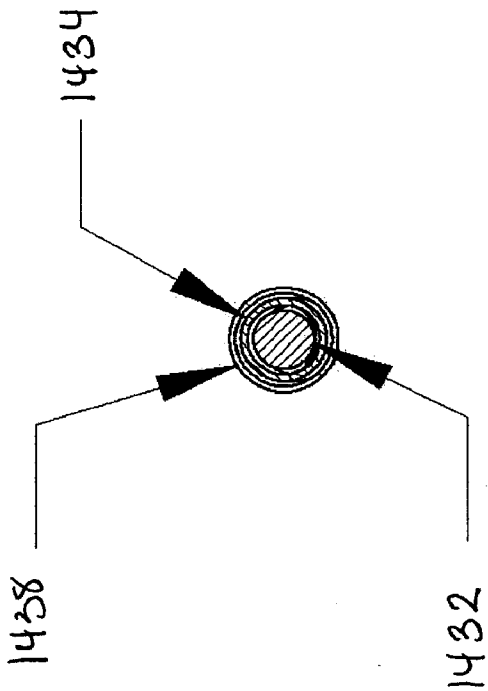


Fig. 14B

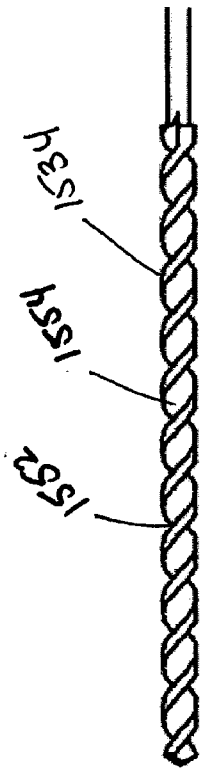


Fig. 15A

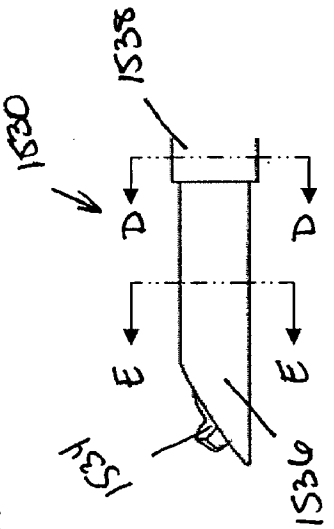


Fig. 15C

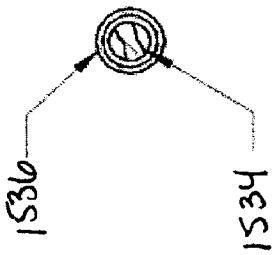


Fig. 15E

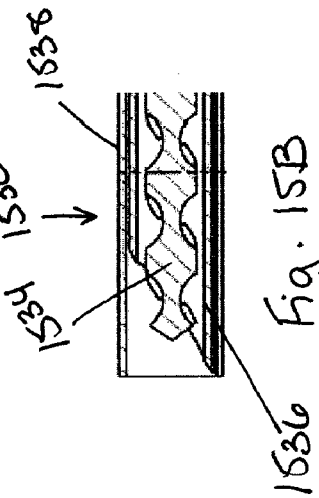


Fig. 15B

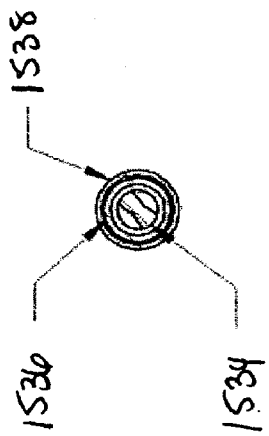


Fig. 15D

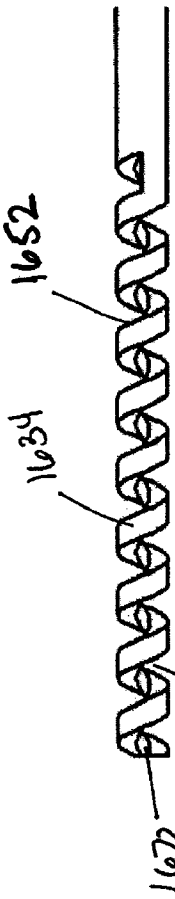


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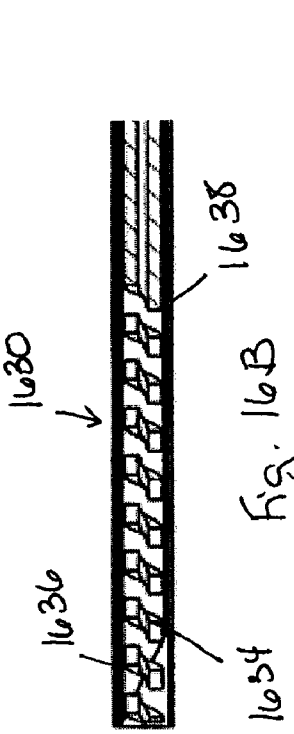


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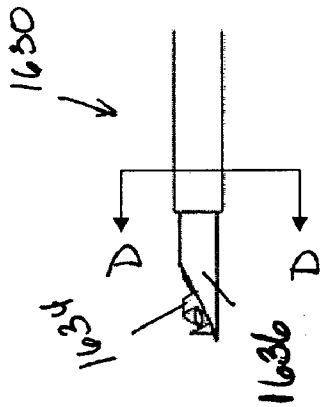


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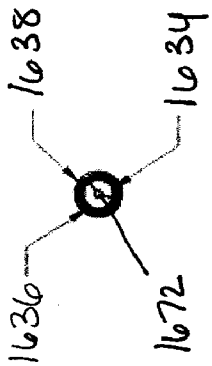


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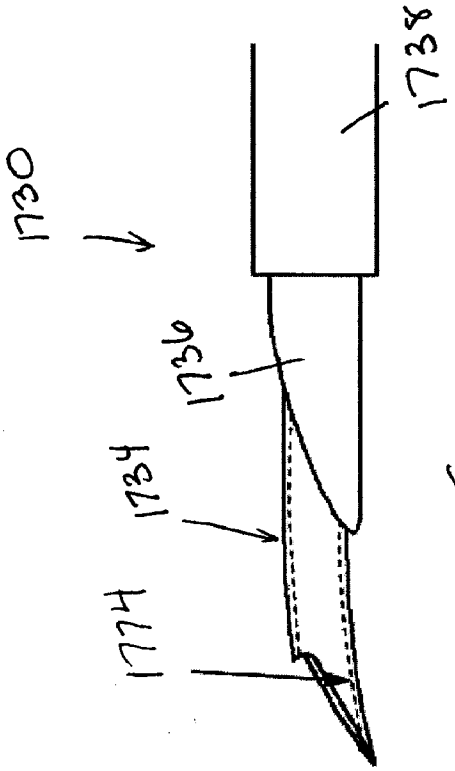


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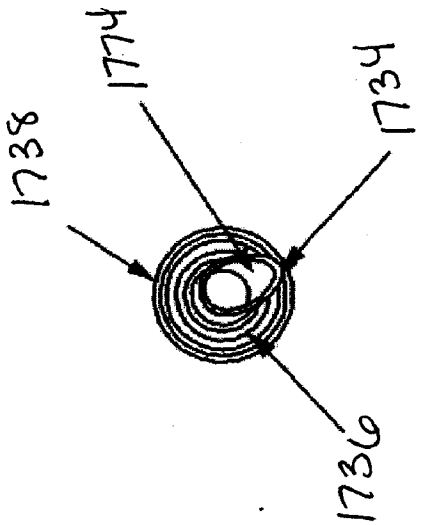


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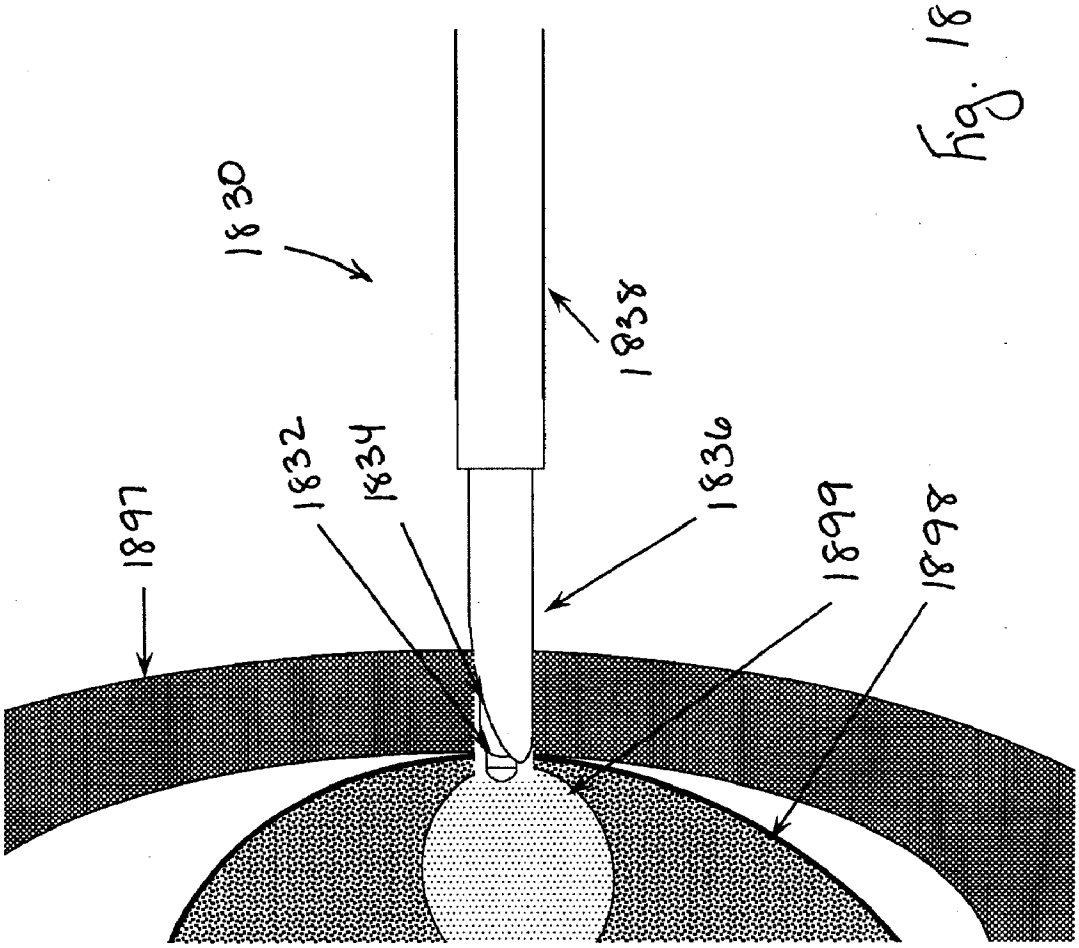


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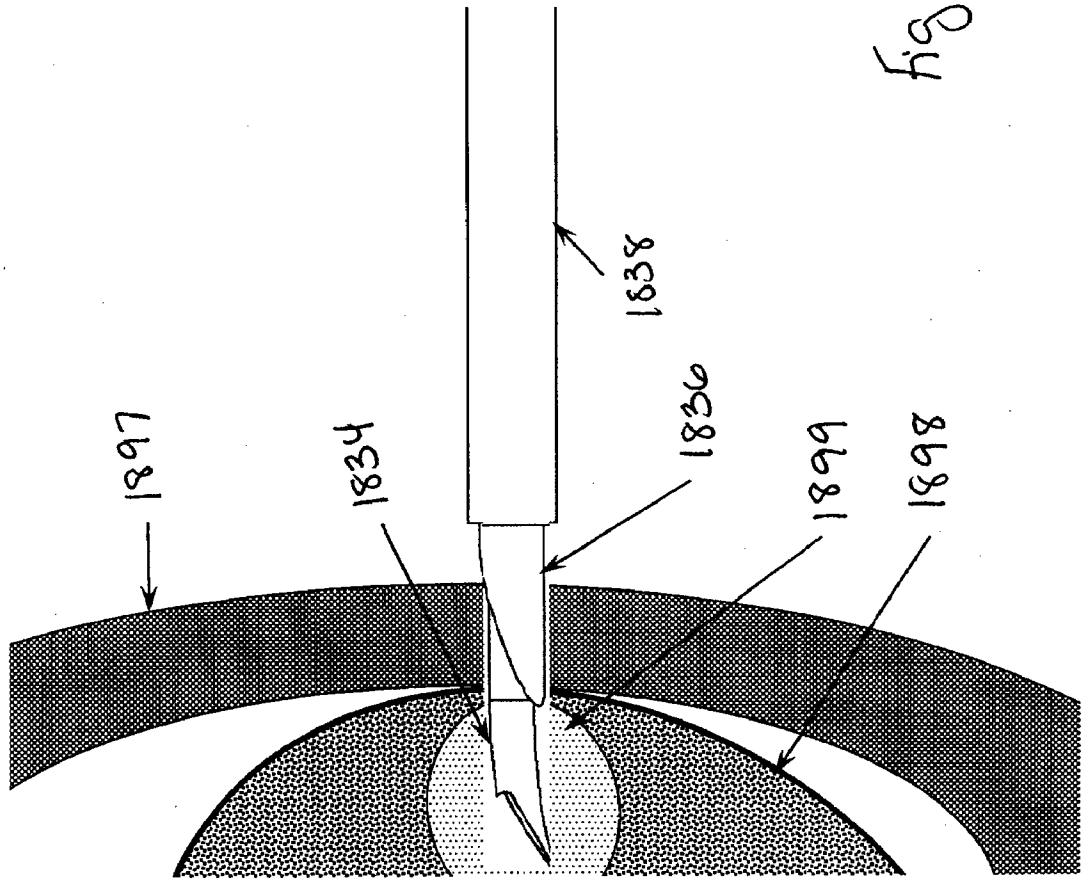


fig. 18B

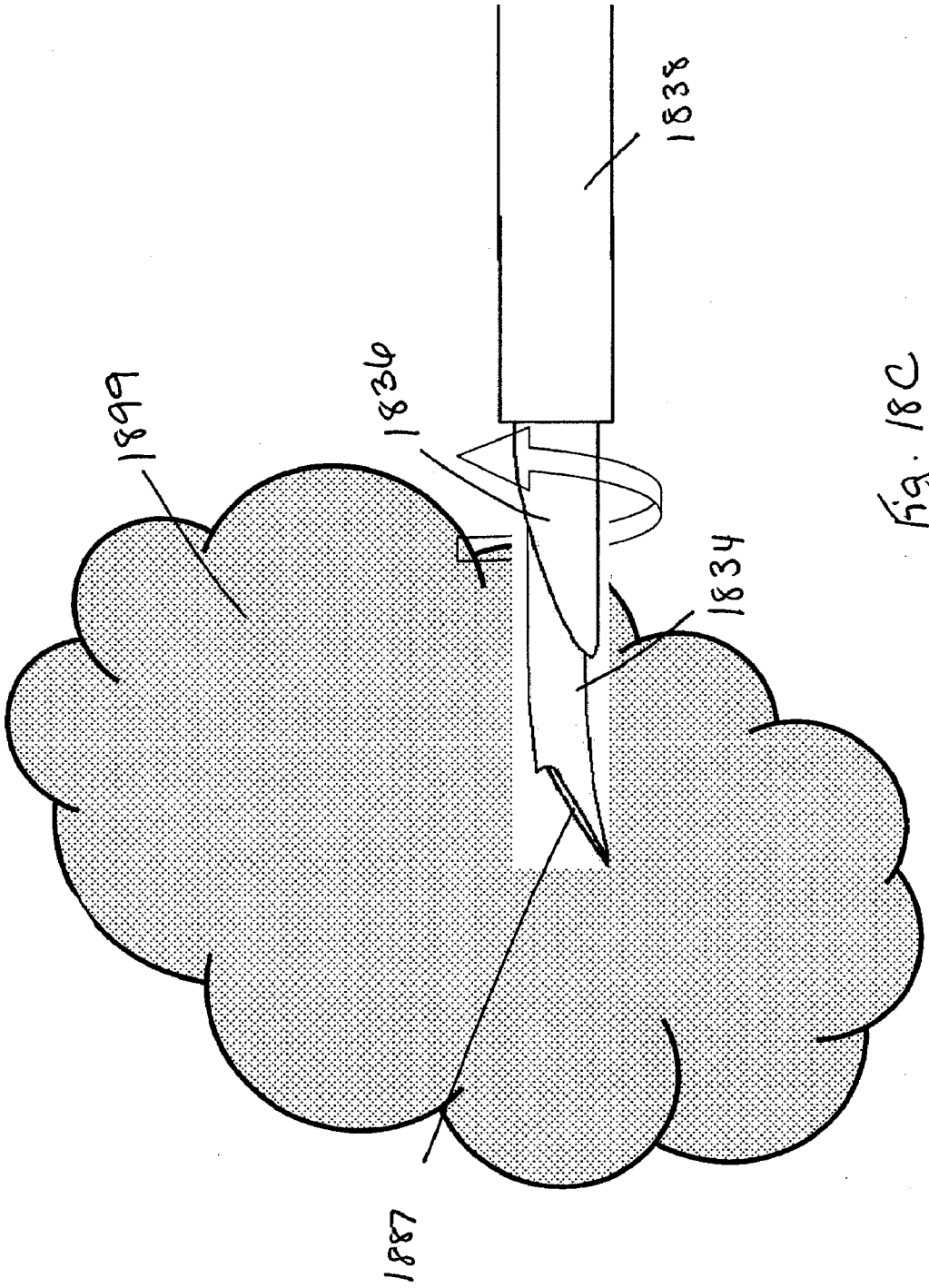


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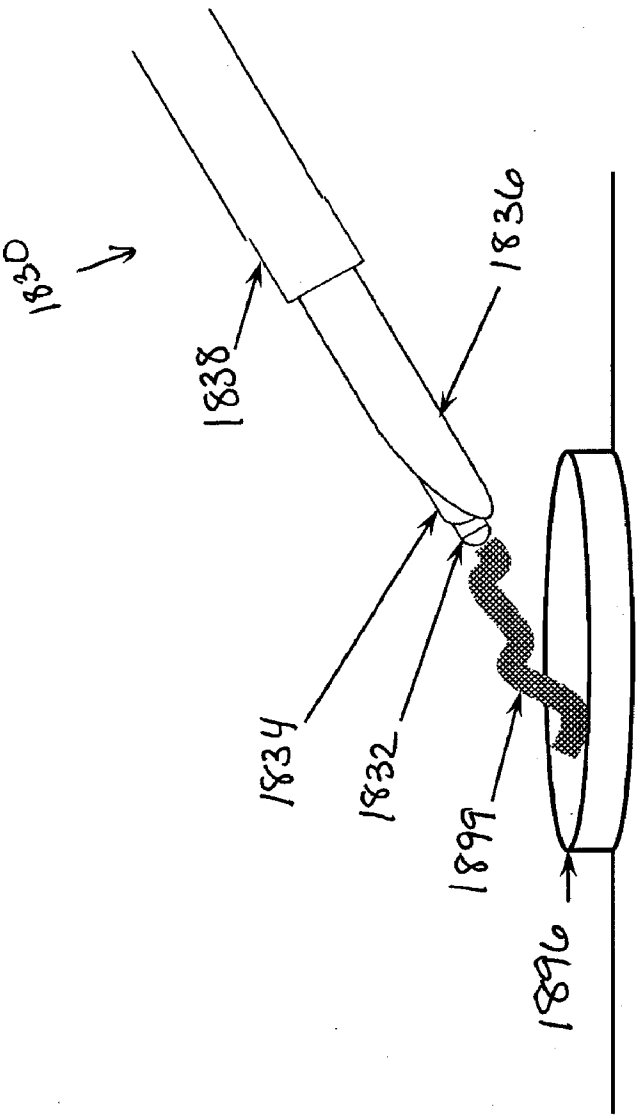


Fig. 18D

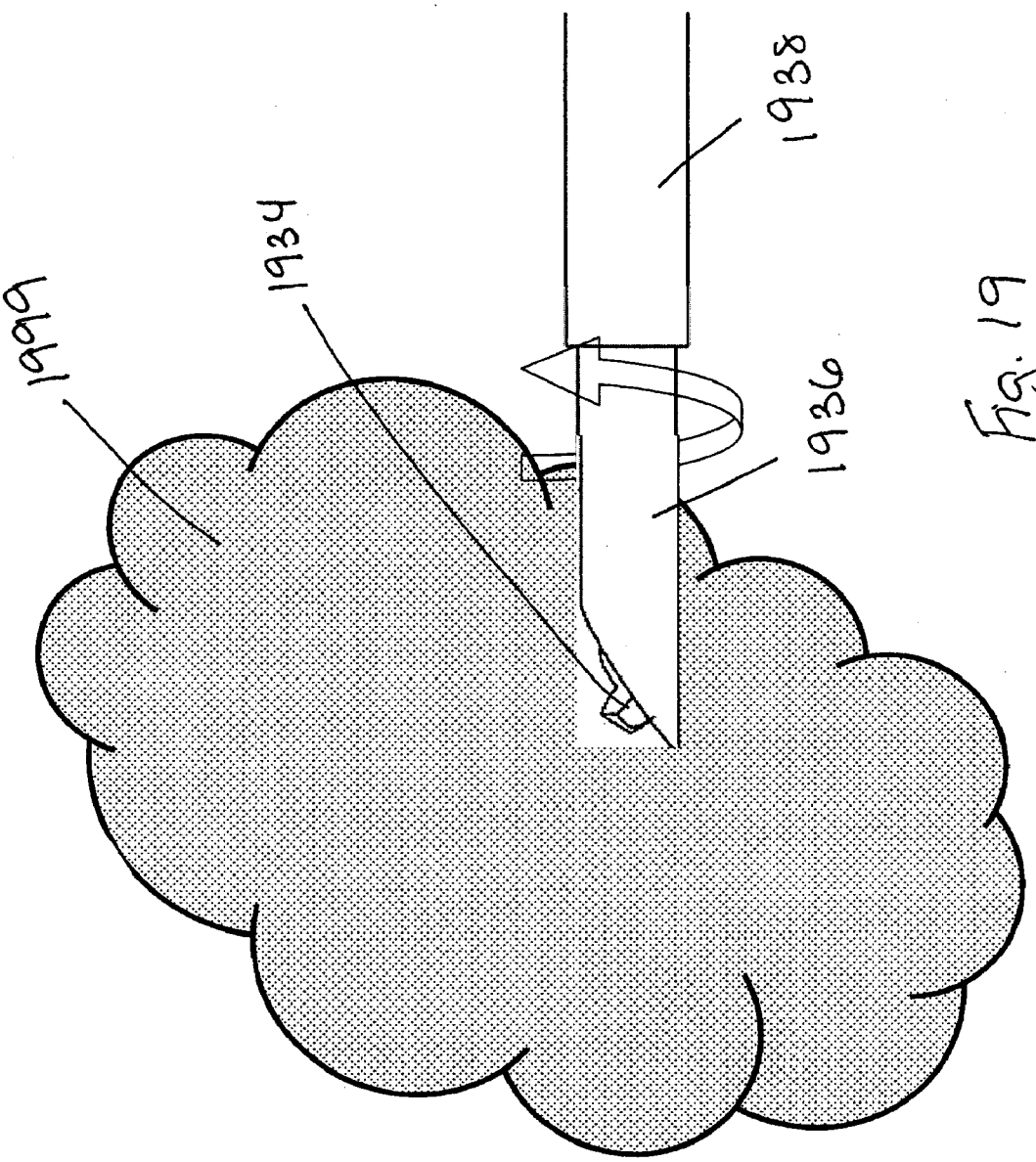


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/069034

A. CLASSIFICATION OF SUBJECT MATTER

A61B 10/00(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)

IPC : 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 since 1975
- Japanese Utility models and applications for Utility models since 1975

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

eKIPASS(KIPO internal) & keywords : "biopsy", "tissue", "rotate", and "needle"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5928164 A (BURBANK, FRED H. et al.) 27 Jul. 1999 The whole documents.	1 - 131
A	US 2007-0016099 A1 (YEM CHIN et al.) 18 Jan. 2007 The whole documents.	1 - 131
A	US 2005-0054948 A1 (ALEC, S. GOLDENBERG) 10 Mar. 2005 The whole documents.	1 - 131

☐ 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 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
30 JANUARY 2009 (30.01.2009)	**30 JANUARY 2009 (30.01.2009)**

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

YANG, Seong Ji

Telephone No. 82-42-481-5624

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/069034

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