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[Continued on next page]

(54) Title: BIOPSY CUTTER AND METHODS OF USE THEREFOR

(57) Abstract: The present invention provides embodiments of a device for taking a skin biopsy and methods for use the same that minimize the duration of and pain and scarring caused by the procedure.

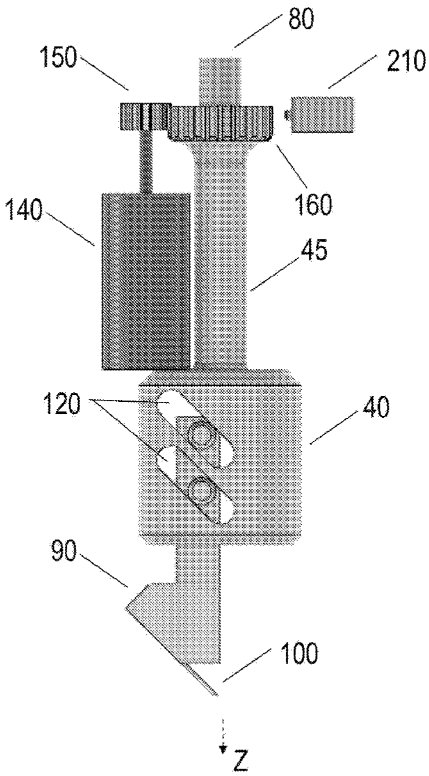

FIG. 3

WO 2017/180761 A1

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BIOPSY CUTTER AND METHODS OF USE THEREFOR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application Serial No. 62/321,608, filed 12 April 2016, the content of which is herein incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to novel methods and products to construct and use a motorized biopsy device to collect standardized and conical skin samples.

DESCRIPTION OF RELATED ART

[0003] There are five million new cases of skin cancer per year in the United States. To properly diagnose skin cancer and other skin diseases, doctors need to obtain a skin sample to help tailor medical treatment. For example, a skin biopsy can help to differentiate between a cancerous lesion and a benign, non-cancerous lesion.

[0004] One method to perform a biopsy is by using a punch device. When manually pushed into and withdrawn from the skin, the punch removes a cylindrical sample. However, the manual pressure necessary makes it difficult for the doctor to cut appropriately deep skin samples of uniform size and shape. This may result in skin sample damage or deterioration, which could render the sample useless for diagnostic or experimental analysis. Non-uniform pressure may also result in avoidable pain, bleeding, and damage at the wound site and cause avoidable injury to the patient.

[0005] One current solution to this problem is the use of a mechanical, motorized biopsy punch that would deliver standardized pressure every time a sample is taken. The motorized biopsy punch removes the skin sample via an oscillating motion. It results in faster, standardized skin samples. However, there are many major limitations to this approach. One limitation, like the manual biopsy punch, is that this punch still removes a cylindrical sample of the skin, which means that more tissue is removed than necessary.

[0006] Some skin biopsies are taken from the skin surface down to subcutaneous adipose tissue. This type of biopsy wound ordinarily results in bleeding, pain, and scarring from the volume of tissue obtained. If a patient has chronic medical conditions or some other issue that affects the healing ability of the skin, such as smoking or the tendency to form keloids, then they may face healing problems. Therefore, it is important to remove only as much tissue as is necessary. Indeed, a non-adjustable, cylindrical biopsy punch results in unnecessary tissue extraction, causing the patient to experience avoidable bleeding, pain and scarring from the biopsy wound site. Another limitation in the punch biopsy's un-adjustable approach is that it can only go as deep as the length of the cylinder. Therefore, unless the doctor has multiple cylinder lengths, it is difficult to tailor the patient's treatment to their individual needs.

[0007] Additionally, both prior art manual and motorized biopsy punches utilize imprecise and excess force to detach the skin sample from the body. Currently, to detach the sample from the patient, the doctor must rock the punch tool around the incision site to forcibly and imprecisely undercut the sample to detach it from the patient. Alternatively, the doctor must use forceps to pull up the sample, stretching the incision site further, and only then undercut the sample free with scissors or a scalpel. This is a major limitation in the current approach that exacerbates bleeding, pain, and scarring from the biopsy wound site.

[0008] Yet another limitation is that the entire punch biopsy instrument must either be constantly replaced or frequently sharpened. Disposable punch biopsy cutters are expensive to constantly replace in the long term. Reusable cutters dull easily and require frequent sharpening. Constant sharpening requires the purchase of a sharpening tool and excess time and effort. It is desirable to manufacture a product and devise a method that can improve the speed, efficiency, and quality of obtaining a skin sample while removing a little as tissue as possible from the patient to minimize bleeding, pain, and scarring.

[0009] The present invention is a device and method of use thereof that minimizes the size of the sample by extracting a conically-shaped biopsy. Geometrically, this allows for less tissue to be removed, while still allowing for a viable skin surface sample. In addition, the conical shape of the tissue reduces the amount of force necessary when detaching the skin sample from the patient. Because the present method is motorized and automatic, it provides standardized, fast, and efficient results. The present invention solves this problem of non-personalized medical treatment by using adjustable rotational, angled blades that can be moved rotationally about the number of degrees necessary to obtain the desired volume of skin sample. The present invention also uses replaceable blades and/or a replaceable cutting mechanism. In this manner, the entire tool does not need to be thrown away and repurchased. Nor does a doctor need to waste precious time and resources to re-sharpen the punch cutter frequently. Using the present invention, the doctor merely replaces the blades when necessary. Thus, the present invention provides a cost- and time-efficient, as well as safer, solution to both the patient and the healthcare provider.

[0010] The present invention discloses a faster and more efficient method and device for obtaining a standardized, minimized skin sample. The device utilizes at least one rotational angled blade that automatically and precisely cuts, removes, and dispenses a sample of human skin and up to subcutaneous adipose tissue.

[0011] While certain novel features of this invention shown and described below are pointed out in the annexed claims, the invention is not intended to be limited to the details specified, since a person of ordinary skill in the relevant art will understand that various omissions, modifications, substitutions and changes in the forms and details of the invention illustrated and in its operation may be made without departing in any way from the spirit of the present invention. No feature of the invention is critical or essential unless it is expressly stated as being “critical” or “essential.”

BRIEF SUMMARY OF THE INVENTION

[0012] The present invention provides novel methods to more rapidly and more efficiently obtain tissue samples.

[0013] The present invention also provides a novel device to obtain tissue samples.

[0014] In accordance with this discovery, it is an additional objective of the present invention to provide an automated, motorized, and adjustable device for obtaining precise skin tissue sample sizes and minimizing the duration of and the pain and scarring caused by the procedure.

[0015] A first object of the present disclosure relates to a biopsy cutter comprising: a) a proximal end, a distal end, and a longitudinal axis therebetween; b) at least one blade at the distal end, wherein the at least one blade is positioned at an angle with respect to the longitudinal axis and the distal end of the at least one blade is closer to the longitudinal axis than the proximal end of the at least one blade; c) a first means for imparting to the at least one blade diagonal motion relative to the longitudinal axis, whereby the first means drives the at least one blade diagonally toward the longitudinal axis; and d) a second means for imparting to the at least one blade rotational motion about the longitudinal axis.

[0016] A second object of the present disclosure relates to the biopsy cutter of the first object, wherein the first means comprises, in proximal-to-distal order, a plunger device, a rotational blade holder, and a blade holder.

[0017] A third object of the present disclosure relates to the biopsy cutter of the first object, wherein the second means comprises a motor, and a motor geared linkage.

[0018] A fourth object of the present disclosure relates to the biopsy cutter of the first object, wherein the at least one blade is attached to the blade holder at an angle of between 20 and 70 degrees from the longitudinal axis.

[0019] A fifth object of the present disclosure relates to a method for obtaining a sample using the biopsy cutter of the first object, comprising: a) positioning the at least one blade adjacent to the location where the sample is to be obtained; b) activating the first means, thereby driving the at least one blade distally, then activating the second means, thereby rotating the blades about the longitudinal axis.

[0020] A sixth object of the present disclosure relates to a biopsy cutter comprising a cylindrical carrier having a proximal end and a distal end, a first helical groove and a second helical groove disposed opposite to each other in an outer surface of the carrier, a tube-shaped bearing guide having a channel for receiving the carrier, a first bearing and a second bearing disposed opposite to each other in an inside surface of the tube-shaped bearing guide, wherein the first bearing and the second bearing are movably disposed in the first and the second helical grooves respectively, a plurality of blades disposed at the distal end of the carrier, wherein each of the plurality of blades is positioned at an angle with respect to the longitudinal axis and the distal end of each of the plurality of blades is closer to the longitudinal axis than the proximal end of each of the plurality of blades, and an actuator disposed at the proximal end of the carrier and operably connected with the tube-shaped bearing guide such that, when the actuator is triggered, the tube-shaped bearing guide slides in a proximal-to-distal direction of the carrier through the first and the second helical grooves to rotate the plurality of blades about the longitudinal axis such that the distal ends of the plurality of blades meet at a point at the longitudinal axis.

[0021] A seventh object of the present disclosure relates to the biopsy cutter of the sixth object, wherein the plurality of blades is disposed at an angle of between 20 and 70 degrees from the longitudinal axis.

[0022] An eighth object of the present disclosure relates to the biopsy cutter of the sixth object, wherein the plurality of blades comprises at least three blades.

[0023] A ninth object of the present disclosure relates to the biopsy cutter of the sixth object, wherein the plurality of blades comprises at least four blades.

[0024] A tenth object of the present disclosure relates to the biopsy cutter of the sixth object, further comprises a rejection mechanism for releasing the plurality of blades.

[0025] An eleventh object of the present disclosure relates to a method for obtaining a sample using the biopsy cutter of the sixth object, comprising: a) positioning the plurality of blades adjacent to the location where the sample is to be obtained; and b) triggering the actuator, thereby rotating the plurality of blades about the longitudinal axis such that the distal ends of the plurality of blades cut into the sample and meet at a point at the longitudinal axis, thereby collecting the sample.

[0026] Other objects and advantages of this invention will become readily apparent from the ensuing description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 shows an embodiment of the device (10) without the outer casing (20). The device (10) comprises a plunger mechanism (60), linked to an axial shaft (80). A motor (140) is linked to the axial shaft (80) via gears (150), through which the motor (140) rotates the axial shaft (80), rotational blade holder (40), and blade holder (90), to which at least one blade (100) is attached (*e.g.*, via a friction fit), to cut out a sample. The standoff (220) is not shown here.

[0028] FIG. 2 shows a cross-section of an embodiment of the device (10), including the outer casing (20) and standoff (220). The first needle bearings (bushing) (30) for the rotational blade holder (40) maintain the alignment of the rotational blade holder (40), blade holder (90), and at least one blade (100).

[0029] FIG. 3 shows a magnified view of the lower part of an embodiment of the device (10) and the geared linkage (150) between the motor (140) and rotational blade holder (40).

[0030] FIG. 4 shows an embodiment of the device (10), including the standoff (220) with the at least one blade (100) and blade holder (90) in a retracted position.

[0031] FIG. 5 shows the rotational blade holder (40) and the blade holder (90).

[0032] FIG. 6 shows the outer casing (20) and standoff (220) with the at least one blade (100) and blade holder (90) in a retracted position.

[0033] FIG. 7 shows the spring (250).

[0034] FIG. 8 shows an exploded view of the device (10).

[0035] FIG. 9 shows an embodiment of the device (500) in cross section, in a retracted position.

[0036] FIG. 10 shows an embodiment of the device (500) in cross section, in an extended position.

[0037] FIG. 11 shows the outer casing (570) of an embodiment of the device (500).

[0038] FIG. 12 shows an embodiment of the device (500) with the outer casing (570) removed to show the relationships between the button (510), bearing guide (520), ball bearings (540), central carrier (550), outer guide (580), bottom guide plate (600), tapered end (620), and outer cone (640).

[0039] FIG. 13 shows an embodiment of the device (500) with the outer casing (570) and outer cone (640) removed to show the relationships between the button (510), bearing guide (520), ball bearings (540), central carrier (550), outer guide (580), bottom guide plate (600), tapered end (620), blade holder (650), flexible membrane (660), and blades (670).

[0040] FIG. 14 shows the relationships between the central carrier (550), the upper toothed interface (590), the lower toothed interface (630), blade holder (650), flexible membrane (660), and blades (670), in an embodiment of the device (500).

[0041] FIG. 15 shows an exploded view of an embodiment of the device (500).

[0042] FIG. 16 shows an exploded view of the button (510), bearing guide (520), bearings (540), central carrier (550), pegs (560), and upper toothed interface (590) of an embodiment of the device (500).

[0043] FIG. 17 shows an exploded view of the outer guide (580), bottom guide plate (600), and tapered end (620) of an embodiment of the device (500).

[0044] FIG. 18 shows an exploded view of the tapered end (620), lower toothed interface (630), flexible membrane (660), blade holder (650), blades (670), and outer cone (640) of an embodiment of the device (500).

[0045] FIG. 19 shows a cross-sectional view of the outer guide (580), with channels (585).

[0046] FIG. 20 shows the ejector mechanism (700).

DETAILED DESCRIPTION OF THE INVENTION

[0047] Detailed descriptions of one or more preferred embodiments are provided herein. It is to be understood, however, that the present invention may be embodied in various forms. Therefore, specific details disclosed herein are not to be interpreted as limiting, but rather as a basis for the claims and as a representative basis for teaching one skilled in the art to employ the present invention in any appropriate manner.

[0048] Wherever any of the phrases “for example,” “such as,” “including” and the like are used herein, the phrase “and without limitation” is understood to follow unless explicitly stated otherwise. Similarly “an example,” “exemplary” and the like are understood to be non-limiting.

[0049] The term “substantially” allows for deviations from the descriptor that do not negatively impact the intended purpose. Descriptive terms are understood to be modified by the term “substantially” even if the word “substantially” is not explicitly recited. Therefore, for example, the phrase “wherein the lever extends vertically” means “wherein the lever extends substantially vertically” so long as a precise vertical arrangement is not necessary for the lever to perform its function.

[0050] The terms “comprising” and “including” and “having” and “involving” (and similarly “comprises”, “includes,” “has,” and “involves”) and the like are used interchangeably and have the same meaning. Specifically, each of the terms is defined consistent with the common United States patent law definition of “comprising” and is therefore interpreted to be an open term meaning “at least the following,” and is also interpreted not to exclude additional features, limitations, aspects, etc. Thus, for example, “a process involving steps a, b, and c” means that the process includes at least steps a, b and c. Wherever the terms “a” or “an” are used, “one or more” is understood, unless such interpretation is nonsensical in context.

[0051] In one embodiment of the device (10), the outer casing (20) is made of plastic, metal, or another suitable material, and houses the internal components. The internal components comprise a first needle bearing (30) at the distal end of the device (10) connected to rotational blade holder (40); a second needle bearing (or bushing) (50) at the proximal end of the device (10) at the plunger mechanism (60), a plunger device (70) at the proximal end to actuate the axial shaft (80) that comes in contact with the rotational blade holder (40), which is activated by user-applied physical pressure; the blade holder (90) to which disposable surgical cutting blades (100) are attached at an angle between 20 and 70 degrees (optimally between 30 and 60 degrees); a guide mechanism of angled slots (120) equal to the angle of the blades (100), wherein the guides (130) connected to the blade holder (90) ride in the rotational blade housing slots (120); one or more replaceable surgical stainless steel blades (100); a DC geared motor (140) to actuate the rotational blade holder (90); a geared linkage (150) between the motor (140) and the rotational blade holder (90); a momentary switch or sensor (210) that activates protrusions (170) from the rotational blade holder (90) to measure the angle of rotation; a microcontroller (180); a disposable or rechargeable battery (190); a user-activated switch (200) to actuate the motor (140); a sensor (210) to measure the rotation of the blade (100) via the gear (150); a standoff (220) to stabilize device on patient and separate blade (100) and patient before desired contact; and a retaining ring (230) as an integral part of the inner surface of the outer casing (20) to keep the first needle bearing (30) inside the outer casing (20). In some embodiments, the standoff (220) has two or more legs (240). At full depression the legs (240) are positioned such that the blade (100) is at desired depth. In some embodiments the retaining ring (230) is physically incorporated into the outer casing (20). In some embodiments the outer casing (20) is surrounded by an ergonomic rubber sleeve.

[0052] In some embodiments of the device (10), the plunger mechanism (60) on the most proximal part of the device is physically connected to the axial shaft (80) that runs through the device (10) through a small hole (not shown) in the proximal cross section of the outer casing (20). The axial shaft (80) of the plunger device (70) runs distally until it reaches the rotational blade holder (40), where it enters the hollow shaft of the rotational blade holder (45). The rotational blade holder (40) comprises a rotational blade holder geared linkage (160), and is connected to the DC geared motor (140) via a motor geared linkage (150).

The rotational blade holder (40) has angled slots (120) with guides (130) slidably connected to the blade holder (40). The guides (130) are attached to the blade holder (90), and the guides (130) slide through the slots (120) with user activated physical pressure, pushing the surgical blade (100) into the skin of the patient. At the point at which the guides (130) cannot slide further in the slots (120), the at least one blade (100) is at its maximum distance, distally. At this point, the user activates the motor (140) via a switch (200) to rotate the at least one blade (100) by a chosen number degrees, and angle of rotation may be measured using a momentary switch or sensor (210) to prevent accidental unwanted rotation. The momentary switch or sensor (210) could be a standard mechanical switch or a hall effect sensor. Either could be actuated by a protrusion from the rotational blade holder (40) or by the gear teeth present of the rotational blade holder geared linkage (160). The hall effect sensor would need the teeth or protrusion to be made of metal, or for there to be an embedded piece of metal or small magnet within the shaft. Either would be functionally identical for the overall operation.

[0053] The rotation of the at least one blade (100) is about the longitudinal axis (X). The amount of rotation is sufficient to cut a complete circle with the at least one blade (100), thereby excising the sample from the patient's skin. For example, if a number *n* of blades (100) is provided, then the amount of rotation could be ($360° \div n$), and optionally additional degrees of rotation (or fractions thereof) of the blades (100) about the longitudinal axis (X) that may be necessary to cut a complete circle or to detach the sample from the patient's skin. The device (10) is stabilized by a standoff mechanism (220) attached to the outer casing (20).

[0054] The device (10) comprises two bearings: a first bearing (30) at the distal end and a second bearing (50) at the proximal end. The motor (140) may be friction fitted into a slot (not shown) on the inside surface of the outer casing (20) along with the user operated switch (200), or the motor (140) and switch (200) may be affixed by other means known in the art. The battery (190) and microcontroller (180) may be affixed with adhesive to the outer casing (20). A voltage sensor LED (210) may be attached to the outside of the casing (20). A spring (250) placed between the rotational blade holder (40) and the blade holder (90) forces the blade holder (40) to return to the retracted position.

[0055] In some embodiments the device (10) may be manually set to a variety of depths by altering the shaft (80) position and rotational blade holder (40) angle. In some embodiments the device (10) is motorless and operated only by user-applied pressure to the plunger mechanism (60) to actuate linear and rotational motion. In some embodiments the device (10) collects statistics on the number of procedures it has performed via a manual counter, sensor, or microcontroller. In some embodiments the device (10) has a motorized shaft and requires little to no user-applied pressure against the patient's skin. In some embodiments the outer casing has an ergonomic design for ease of use or has an ergonomic sleeve surrounding it. In some embodiments the device (10) accommodates straight blades (100). In other embodiments the device (10) accommodates curved blades (100). In still other embodiments the device (10) accommodates both straight and curved blades (100). In some embodiments the device (10) uses more than one blade (100) to extract the sample using purely user applied pressure to grab the sample.

[0056] In use, a user depresses the plunger mechanism (60) of the device (10) in a proximal-to-distal direction along the longitudinal axis (Z). This motion drives the axial shaft (80) distally into the hollow shaft (45) of the rotational blade holder (40), which is slidably connected to the blade holder guides (130) via angled slots (120). Thus, the proximal-to-distal motion of the plunger mechanism (60) is translated to diagonal motion of the blade holder (90) and the attached at least one blade (100). Consequently, the at least one blade (100) is driven diagonally and distally toward the longitudinal axis (Z) and ultimately meets or crosses the longitudinal axis (Z). Opposing the diagonal and distal motion of the blade holder (90) and the attached at least one blade (100) toward the longitudinal axis (Z) is a spring (250) situated between the blade holder (90) and the rotational blade holder (40). The spring (250) acts to push the blade holder (90) and the attached at least one blade (100) diagonally away from the longitudinal axis (Z), and proximally.

[0057] Once the at least one blade (100) has achieved the desired position (*e.g.*, once it meets or crosses the longitudinal axis (Z)), the user may initiate rotation of the blade (100) about the longitudinal axis (Z) via a user-activated switch (200). In this way, the at least one blade (100) cuts a conical biopsy.

[0058] The at least one blade (100) may be similar to a #15 scalpel blade, with an edge length of between about 3 and about 20 mm. Preferably, the at least one blade (100) is between about 0.3 mm and 1.0 mm thick, preferably about 0.4 mm thick.

[0059] In an embodiment, the device (500) comprises a button (510). The button (510) is the most proximal portion of the device (500), and through the button (510) a user may actuate the blade mechanism (690) at the distal end of the device (500) by pressing the button (510) in a proximal-to-distal motion along the longitudinal axis (Z).

[0060] The device (500) further comprises a tube-shaped bearing guide (520) that slidably connects the ball bearings (540) to the button (510) via bearing guide holes (530) in the bearing guide (520), allowing the proximal-to-distal force of the button press (the stroke) along the longitudinal axis (Z) to be applied to the ball bearings (540). The ball bearings (540) are held by the bearing guide holes (530) in the helical grooves (555) of the central carrier (550). When the button (510) is pressed, force from the button press is transmitted to the ball bearings (540), which follow the helical grooves (555) in the central carrier (550) distally, and ultimately transmit force from the button press to the blade mechanism (690), providing helical motion to the blades (670).

[0061] The central carrier (550) is substantially cylindrical, proximally, and at its distal end if comprises at least one peg (560), preferably two pegs. As described above, two opposing helical grooves (555) are present on the outer surface of the central carrier (550), proximal to the at least one peg (560), in which the ball bearings (540) may travel. The tube-shaped bearing guide (520) is slidably connected to the substantially cylindrical portion of the central carrier (550) via the ball bearings (540). The central carrier (550) interfaces with the bearings (540) to provide and transmit helical motion (*i.e.*, transverse rotational motion spiraling about the longitudinal axis (Z)) to the blade mechanism (690). The central carrier (550) also interfaces with the outer guide (580) through at least one peg (560) on the distal end of the central carrier (550). The at least one peg (560) of the central carrier (550) restricts the motion of the central carrier to strictly linear motion, parallel to the longitudinal axis (Z), until such time that the at least one peg (560) is freed by traveling beyond the distal end of the outer guide (580) and leaving the channels (585), and enters an area encapsulated by the bottom guide plate (600), at which point the central carrier (550) is no longer free to move linearly, but may rotate about the longitudinal axis (Z). It is at this point, where the at least one peg (560) of the central carrier (550) enters the open space encapsulated by the bottom guide plate (600), that the blades (670) cease moving distally and begin rotating about the longitudinal axis (Z). The central carrier (550) is fixed to the upper toothed interface (590), which transmits linear and rotational movement to the entirety of the blade mechanism (690) through its connection with the lower toothed interface (630).

[0062] The chassis (570) houses and shields internal mechanisms from debris and contamination, provides an ergonomic grip for the user, and further provides support for internal mechanisms to hold them in a proper orientation with respect to one another.

[0063] The outer guide (580) is a hollow cylinder with at least one channel (585), running parallel to the longitudinal axis (Z), cut into its inner surface (and if more than one channel, they are preferably cut into opposing sides of the inner surface or distributed evenly between one another on the inner surface). The at least one channel (585) accommodates and guide the at least one peg (560) of the central carrier (550) distally and/or proximally along the longitudinal axis (Z). The inner surface of the outer guide (580) also prevents the bearings (540) from falling out of the bearing guide (520).

[0064] The upper toothed interface (590) is a cylinder or annulus with teeth (*e.g.*, serrations) arranged on the distal-facing circular surface, and projecting substantially distally. The teeth of the upper toothed interface (590) engage with teeth of the lower toothed interface (630), which project substantially proximally. The upper toothed interface (590) is used to press down on the accompanying lower toothed interface (630) and to transmit the proximal-to-distal component of the stroke to the blade mechanism (690). The teeth of upper and lower toothed interfaces (590,630) serve further to transmit the rotational component of the stroke to the blade mechanism (690) once the vertical stroke is complete.

[0065] The bottom guide plate (600) provides a surface for the central carrier (550) to rotate upon during the last stage of motion, and contains stops (610) to prevent over-rotation.

[0066] The lower toothed interface (630) is a cylinder or annulus with teeth (*e.g.*, serrations) arranged on the proximal-facing circular surface. The lower toothed interface (630) is connected to the blade holder (650) and provides an interface to the blade mechanism (690).

[0067] The outer cone (640) provides a housing or cover for the replaceable blade mechanism (690). The outer cone (640) both protects the user from the blades (670) until they are deployed, and provides an angled internal surface that guides the blades (670) to move in the proper orientation, at the appropriate angle, and/or in the proper direction for insertion into the skin of a patient.

[0068] The blade holder (650) is connected to the proximal end of each blade (670) and is connected to the outer cone (640) via the flexible membrane (660). The flexible membrane (660) may be made from a suitably material such as polyurethane or latex, preferably polyurethane. The modulus of elasticity of the flexible membrane should be in the range of about 0.05 to about 1 Gigapascals (GPa). The blade holder (650) moves proximally and/or distally along the longitudinal axis (Z) and rotates about the longitudinal axis (Z) to drive the blades (670) through the entirety of the cutting stroke.

[0069] The flexible membrane (660) keeps the blade holder (650) attached to the outer cone (640) while allowing free movement linearly and rotationally, along and about the longitudinal axis (Z), respectively. This attachment remains even after the blade mechanism (690) is ejected or otherwise detached from the device (500) via the ejector mechanism (700). The ejector mechanism (700) works in the same fashion as a micro-pipette tip ejector. Essentially, a side mounted rod is depressed by the user which engages on the blade mechanism (690) and forces it off the body of the device (500). The engagement mechanism is usually a small piece of plastic that snaps into place on a groove or cutaway in the surface of the tip so that it can be installed by hand.

[0070] The blades (670) are flexible, and they are sized and arranged in the device (500) so that their distal tips will meet at the chosen depth of cut and, after they are rotated the desired number of degrees around the longitudinal axis (Z), form a cone-shaped biopsy. The ends of the blades (670) are angled so that they may slide on the angled inner surface of the outer cone (640) and enter the patient's skin to a depth chosen by the user. The inner surface of the outer cone (640) is angled in a manner that forces the blades (670) to adopt an appropriate angle of entry into a patient's skin. The blades (670) may be between about 1/32 inches and about 0.5 inches wide, and between about 0.5 inches and 3.0 inches long. Preferably, the blades (670) are between about 0.3 mm and 1.0 mm thick, preferably about 0.4 mm thick.

[0071] The standoff (680) attaches to the outer casing (570) and holds the blade mechanism (690) at the correct distance relative to the patient so that the blades (670) enter to the depth chose by the user.

[0072] The blade mechanism (690) comprises the lower toothed interface (630), the outer cone (640), the blade holder (650), the flexible membrane (660), and the blades (670). The blade mechanism (690) is detachable from the rest of the device (500) and can be replaced with another blade mechanism (690). The blade mechanism (690) may also be used to enclose and/or transport a biopsy.

[0073] In use, a user depresses the button (510) of the device (500) in a proximal-to-distal direction along the longitudinal axis (Z). Depressing the button (510) in turn pushes the bearing guide (520) distally. The bearing guide (520) is slidably connected to the helical grooves (555) of the central carrier (550) via bearings (540) and bearing guide holes (530). Thus, proximal-to-distal motion of the button (510) is translated into proximal-to-distal motion of the central carrier (550) as well. The central carrier (550) comprises at least one peg (560), preferably two, which fit into corresponding channels (585) of the outer guide (580). As long as the pegs (560) are accommodated by the channels (585), the central carrier (550) cannot rotate about the longitudinal axis (Z) but it may travel proximally or distally in connection with the action of the button (510).

[0074] After the pegs (560) travel beyond the distal end of the outer guide (580), they are no longer constrained by the channels (585). At this point in the proximal-to-distal motion of the central carrier (550), the central carrier (550) is free to rotate about the longitudinal axis (Z), but it may proceed no further distally. The helical grooves (555) of the central carrier (550) guide this rotational motion of the central carrier (550). The rotational motion of the central carrier (550) is limited by stops (610) on the inner proximal-facing surface of the bottom guide plate (600). The stops (610) are positioned to contact the pegs (560) after a predetermined amount of rotation of the central carrier (550) is achieved, thus limiting rotational motion of the central carrier (550).

[0075] The upper toothed interface (590) is connected to the central carrier (550), and meshes with the lower toothed interface (630) to transmit rotational motion of the central carrier (550) to the blade holder (650) and blades (670). Thus, by depressing the button (510), a user forces the blades (670) against the angled inner surface of the outer cone (640), which forces the blades to an angle conforming with the angled inner surface of the outer cone (640). Ultimately, the distal-most ends of the blades (670) are pushed to a point at the longitudinal axis (Z) or each blade just crossing the longitudinal axis (Z). Further depression of the button (510) pushes the pegs (560) beyond the channels (585), and the helical grooves (555) and open area bounded by the bottom guide plate (600) now permit rotational motion of the central carrier (550) and the blades (670) until the pegs (560) are stopped by the stops (610).

[0076] The angle of the inner surface of the outer cone (640) should be equal to the desired angle of the blades (670) once in their fully deployed position. This value can vary by roughly 5% from the desired angle if the manufacturer wishes to change where the blades (670) engage this inner surface for ease of manufacturing.

[0077] The angle at which the at least one blade (100,670) may enter the patient's skin may be about 3°, about 5°, about 10°, about 15°, about 20°, about 25°, about 30°, about 35°, about 40°, about 45°, about 50°, about 55°, about 60°, about 65°, between about 5° to about 60°, between about 10° and about 50°, between about 15° and about 45°, between about 20° and about 40°, preferably between about 30° and about 35°, and preferably about 30° from the patient's skin surface (*e.g.*, with 90° being perpendicular to the patient's skin surface).

[0078] Thus, with reference to the longitudinal axis (Z), the angle of the at least one blade (100,670) when rotating about the longitudinal axis (Z) to excise a biopsy may be about 87°, about 85°, about 80°, about 75°, about 70°, about 65°, about 60°, about 55°, about

50°, about 45°, about 40°, about 35°, about 30°, about 25°, between about 85° to about 30°, between about 80° and about 40°, between about 75° and about 45°, between about 70° and about 50°, preferably between about 60° and about 55°, and preferably about 30° from the longitudinal axis (Z) (*e.g.*, with 0° being parallel to the longitudinal axis).

[0079] The components of the device (10,500) may be made from materials that are known to those of skill in the art. Preferred materials are those that may be easily and reliably sterilized by means that are known to those of skill in the art (*e.g.*, ethylene oxide, autoclaving, irradiation, etc.), and include but are not limited to metal, plastic, resin, and polyurethane.

[0080] In one embodiment, the present invention provides a method of using the device to obtain a tissue sample comprising: setting the blade and rotational blade holder angles; bringing the standoff into contact with the patient's skin; fully depressing the plunger; pressing and holding the switch until the blade travels the desired circumferential distance; and pulling the device away from the patient with the tissue sample held between the blade and the blade holder.

[0081] In another embodiment, the present disclosure provides a method of using the device to obtain a tissue sample comprising bringing the standoff into contact with the patient's skin and depressing the button, whereby depressing the button first drives the blades into the patient's skin and then drives the blades about the longitudinal axis to excise the biopsy.

Table of Components

Number	Part
10	device
20	outer casing
30	first needle bearing
40	rotational blade holder
45	hollow shaft of rotational blade holder
50	second needle bearing
60	plunger mechanism

70	plunger device
80	axial shaft
90	blade holder
100	blade(s)
120	angled slots
130	blade holder guides
140	motor
150	motor geared linkage
160	rotational blade holder geared linkage
170	protrusions
180	microcontroller
190	battery
200	user-activated switch
210	sensor
220	standoff
230	retaining ring
240	standoff legs
250	spring
500	device
510	button
520	bearing guide
530	bearing guide holes
540	bearings
550	central carrier
555	helical grooves
560	pegs
570	outer casing
580	outer guide
585	channel
590	upper toothed interface
600	bottom guide plate
610	stops
620	tapered end

630	lower toothed interface
640	outer cone
650	blade holder
660	flexible membrane
670	blade(s)
680	standoff
690	blade mechanism
700	ejector

CLAIMS

What is claimed is:

1. A biopsy cutter comprising:
   a) a proximal end, a distal end, and a longitudinal axis therebetween;
   b) at least one blade at the distal end, wherein the at least one blade is positioned at an angle with respect to the longitudinal axis and the distal end of the at least one blade is closer to the longitudinal axis than the proximal end of the at least one blade;
   c) a first means for imparting to the at least one blade diagonal motion relative to the longitudinal axis, whereby the first means drives the at least one blade diagonally toward the longitudinal axis; and
   d) a second means for imparting to the at least one blade rotational motion about the longitudinal axis.

2. The biopsy cutter of claim 1, wherein the first means comprises, in proximal-to-distal order, a plunger device, a rotational blade holder, and a blade holder.

3. The biopsy cutter of claim 1, wherein the second means comprises a motor, and a motor geared linkage.

4. The biopsy cutter of claim 1, wherein the at least one blade is attached to the blade holder at an angle of between 20 and 70 degrees from the longitudinal axis.

5. A method for obtaining a sample using the biopsy cutter of claim 1, comprising:
   a) positioning the at least one blade adjacent to the location where the sample is to be obtained;
   b) activating the first means, thereby driving the at least one blade distally, then activating the second means, thereby rotating the blades about the longitudinal axis.

6. A biopsy cutter comprising

a cylindrical carrier having a proximal end and a distal end,

a first helical groove and a second helical groove disposed opposite to each other in an outer surface of the carrier,

a tube-shaped bearing guide having a channel for receiving the carrier,

a first bearing and a second bearing disposed opposite to each other in an inside surface of the tube-shaped bearing guide, wherein the first bearing and the second bearing are movably disposed in the first and the second helical grooves respectively,

a plurality of blades disposed at the distal end of the carrier, wherein each of the plurality of blades is positioned at an angle with respect to the longitudinal axis and the distal end of each of the plurality of blades is closer to the longitudinal axis than the proximal end of each of the plurality of blades, and

an actuator disposed at the proximal end of the carrier and operably connected with the tube-shaped bearing guide such that, when the actuator is triggered, the tube-shaped bearing guide slides in a proximal-to-distal direction of the carrier through the first and the second helical grooves to rotate the plurality of blades about the longitudinal axis such that the distal ends of the plurality of blades meet at a point at the longitudinal axis.

7. The biopsy cutter of claim 6, wherein the plurality of blades is disposed at an angle of between 20 and 70 degrees from the longitudinal axis.

8. The biopsy cutter of claim 6, wherein the plurality of blades comprises at least three blades.

9. The biopsy cutter of claim 6, wherein the plurality of blades comprises at least four blades.

10. The biopsy cutter of claim 6, further comprises a rejection mechanism for releasing the plurality of blades.

11. A method for obtaining a sample using the biopsy cutter of claim 6, comprising:
    a) positioning the plurality of blades adjacent to the location where the sample is to be obtained; and
    b) triggering the actuator, thereby rotating the plurality of blades about the longitudinal axis such that the distal ends of the plurality of blades cut into the sample and meet at a point at the longitudinal axis, thereby collecting the sample.

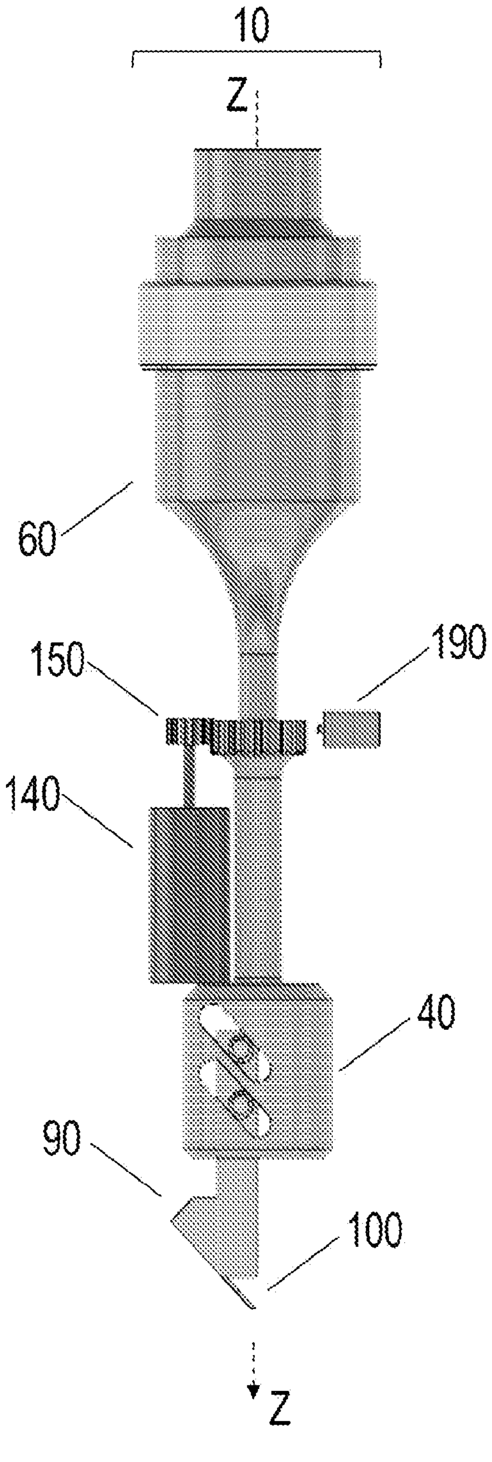

FIG. 1

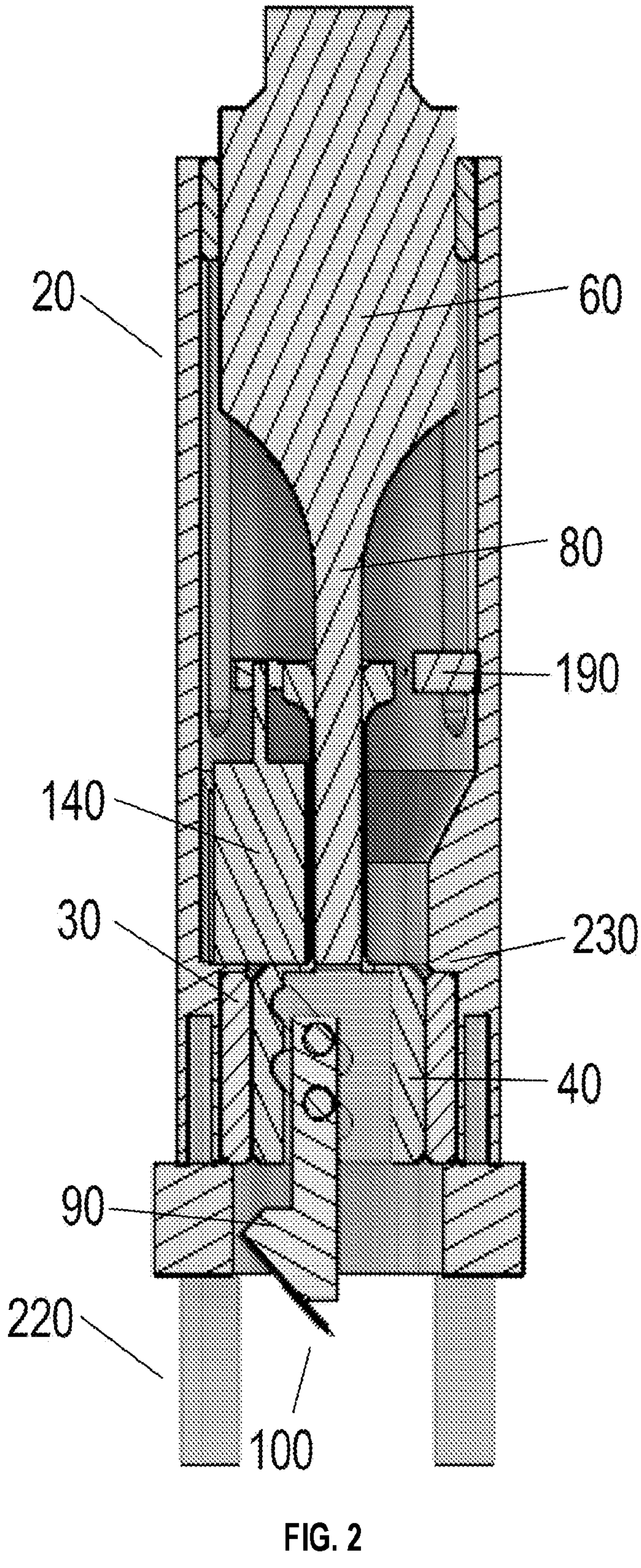

FIG. 2

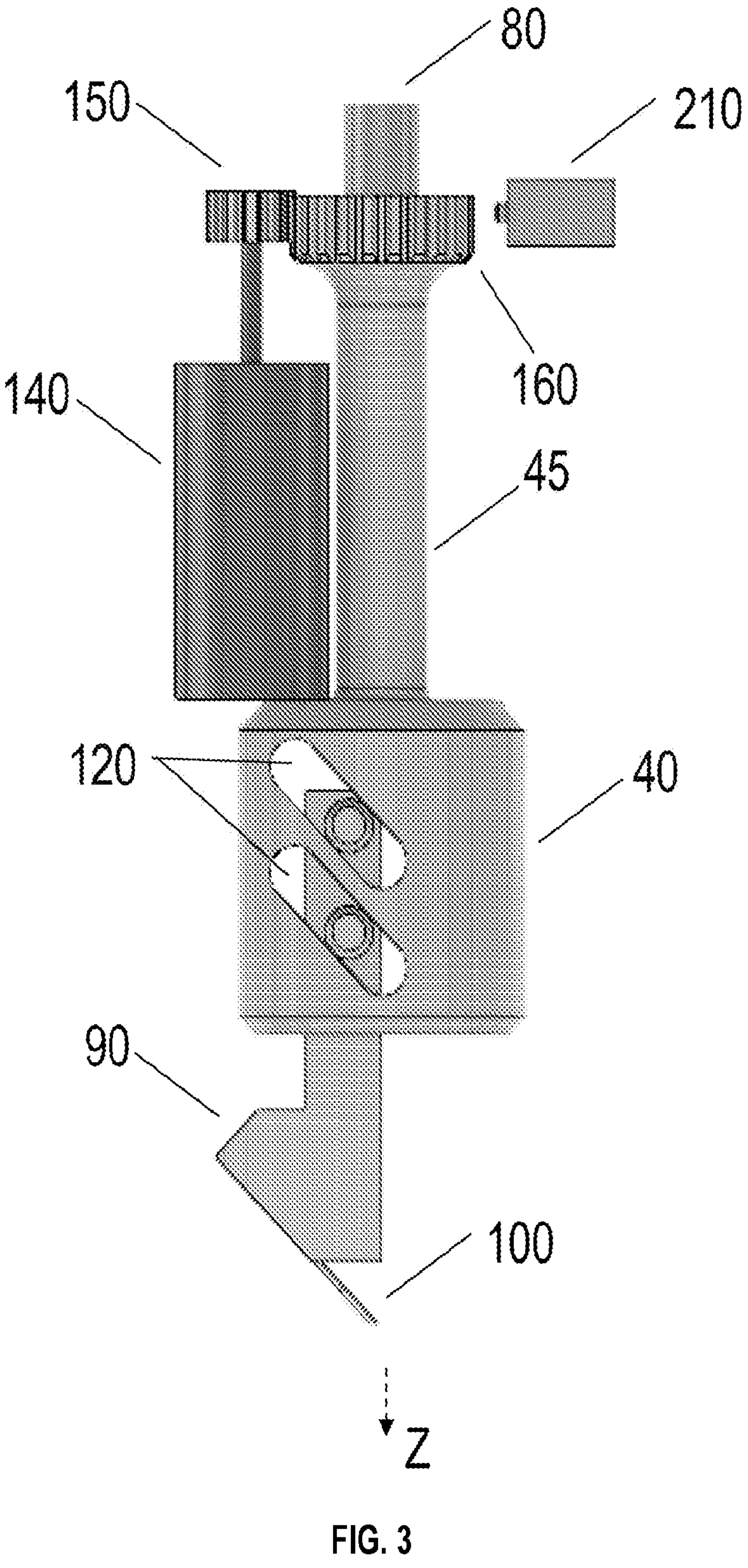

FIG. 3

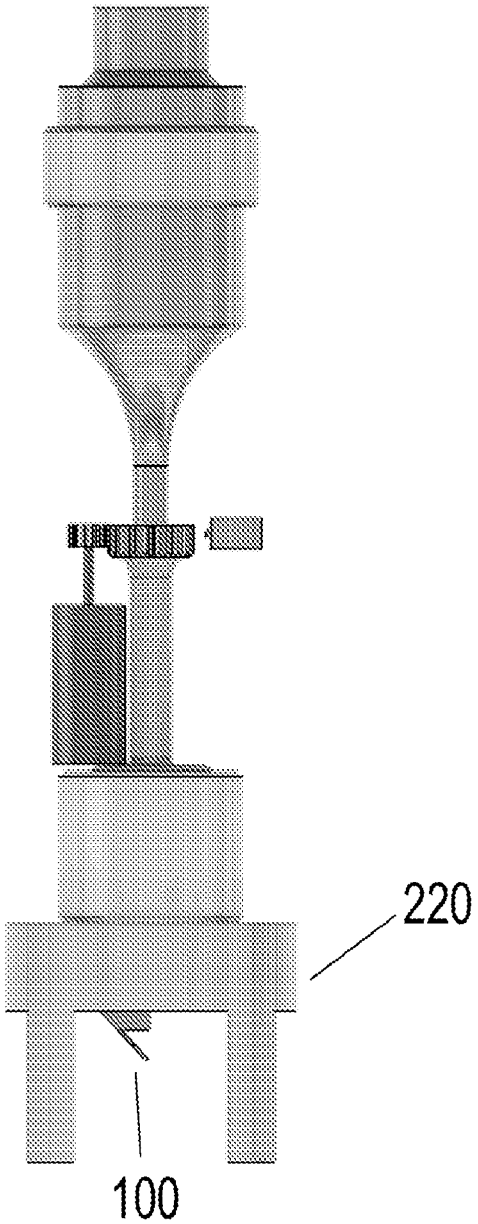

FIG. 4

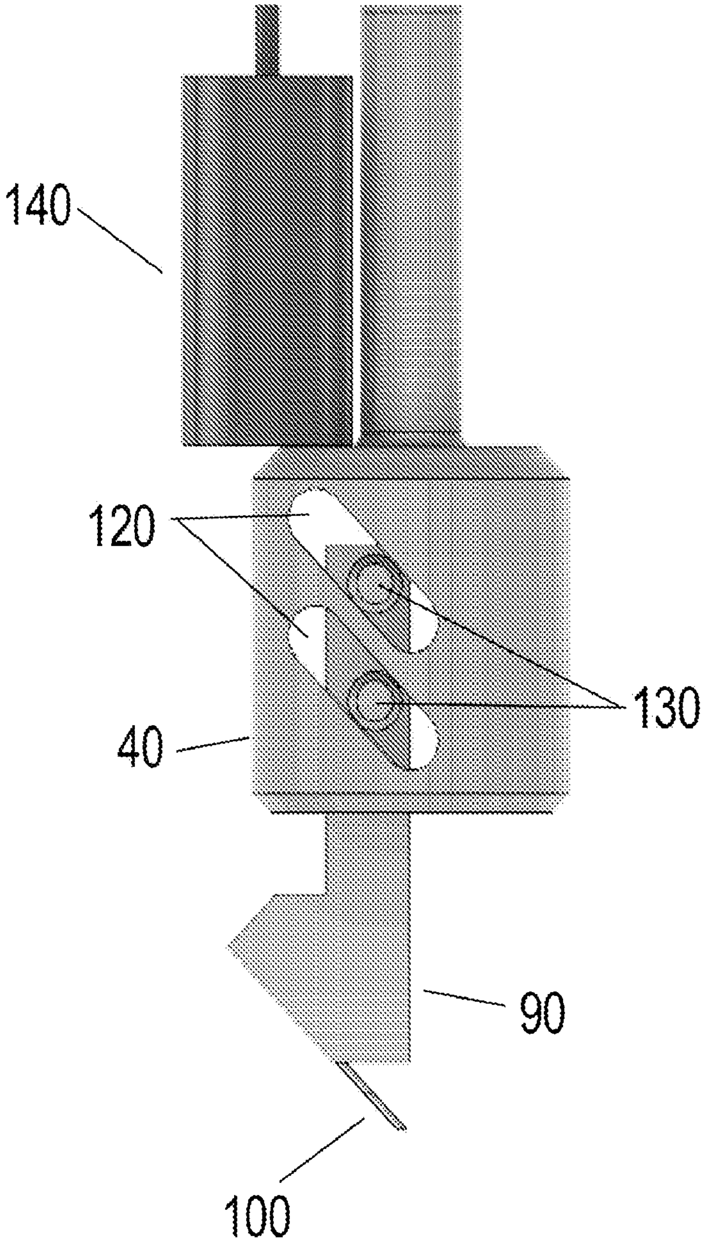

FIG. 5

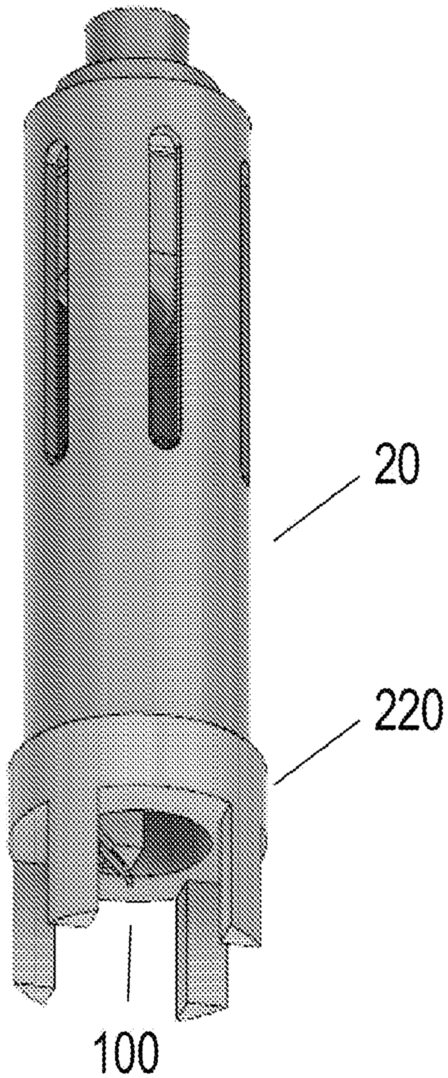

FIG. 6

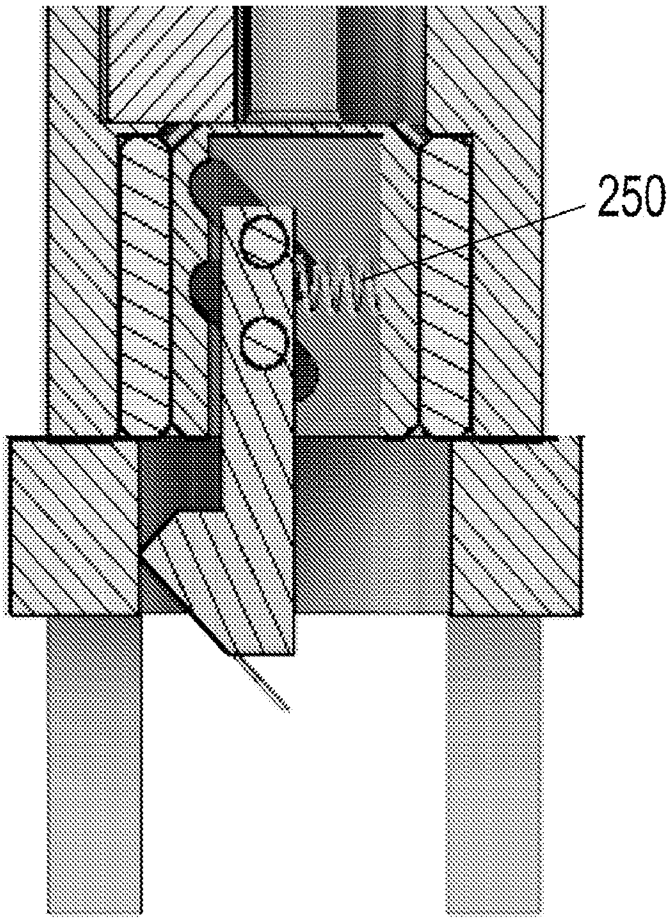

FIG. 7

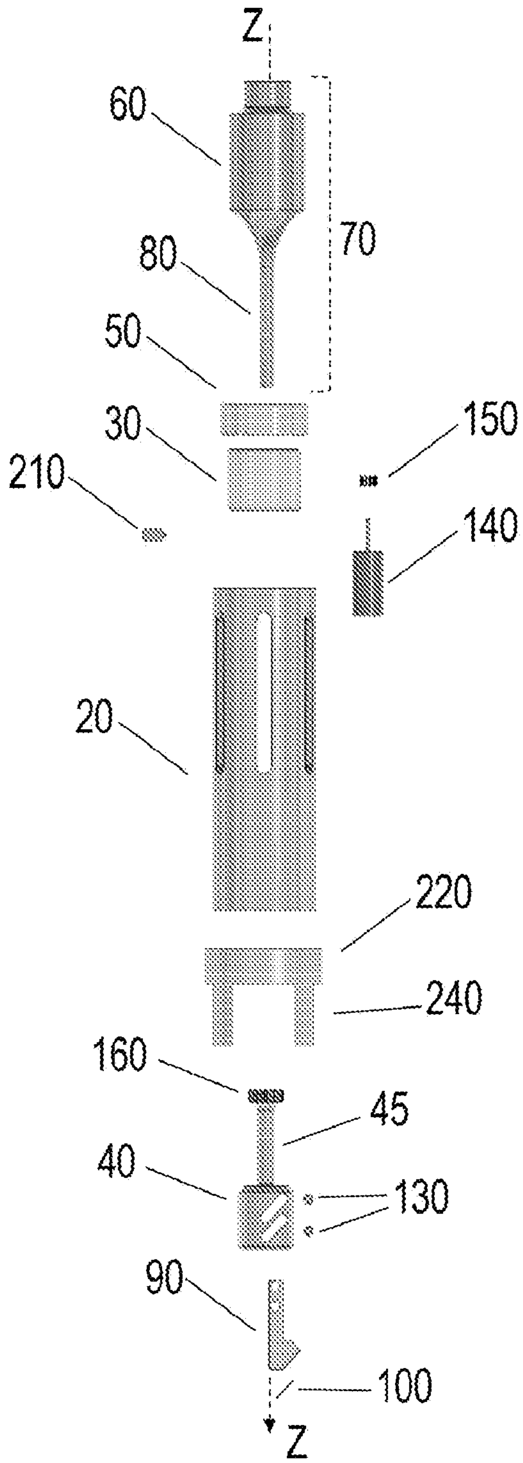

FIG. 8

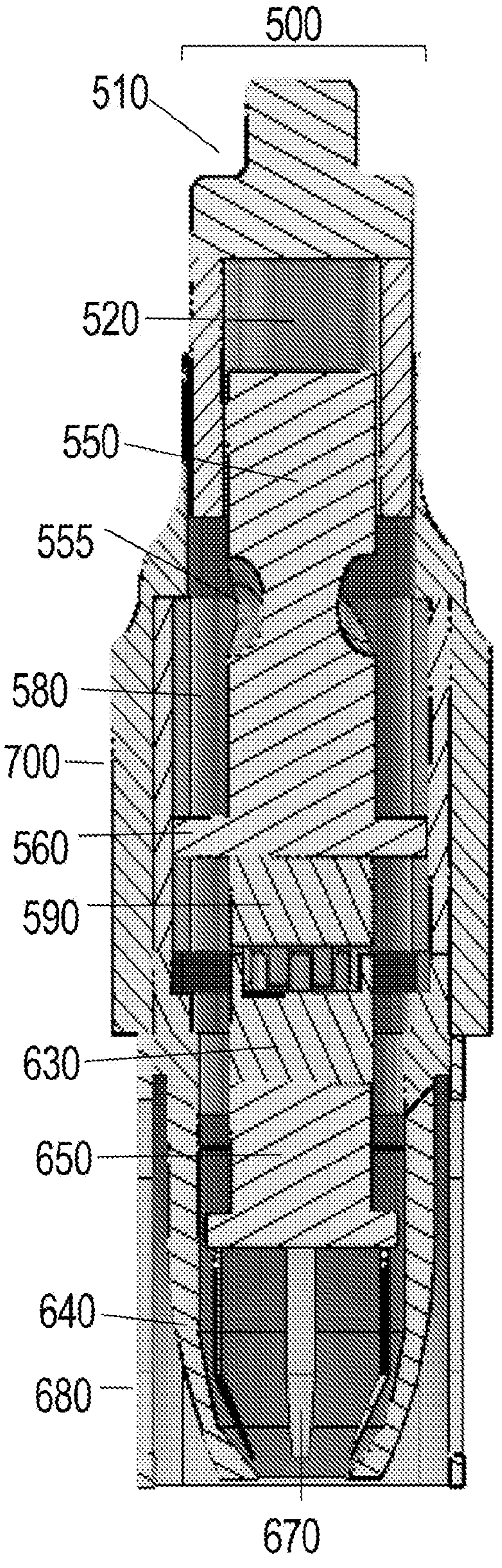

FIG. 9

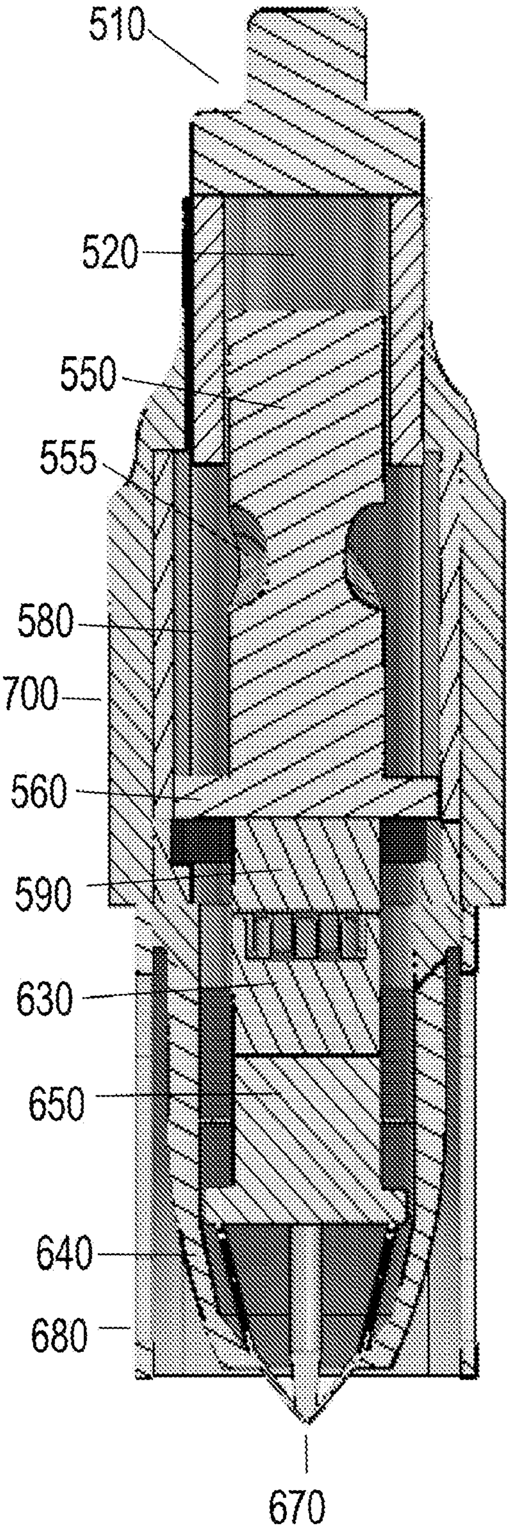

FIG. 10

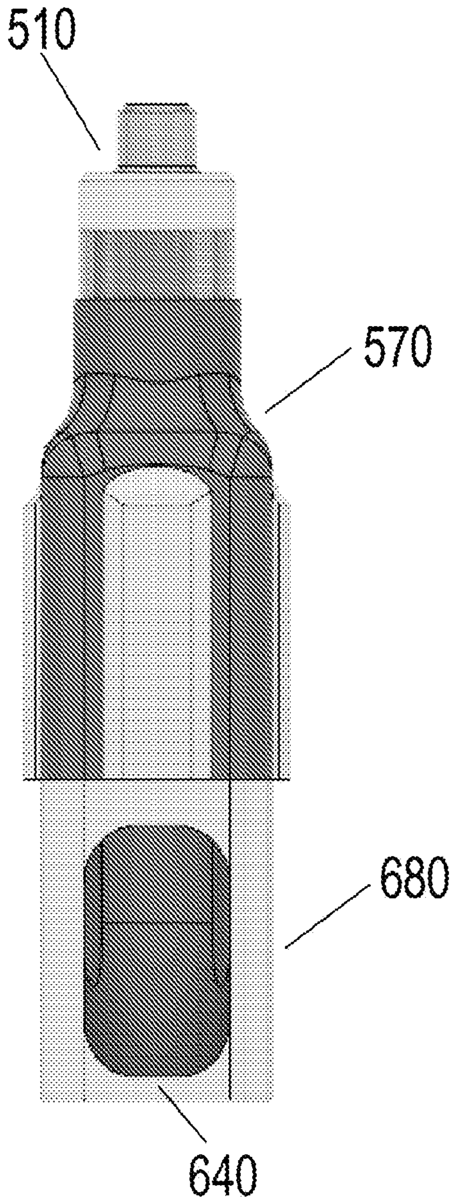

FIG. 11

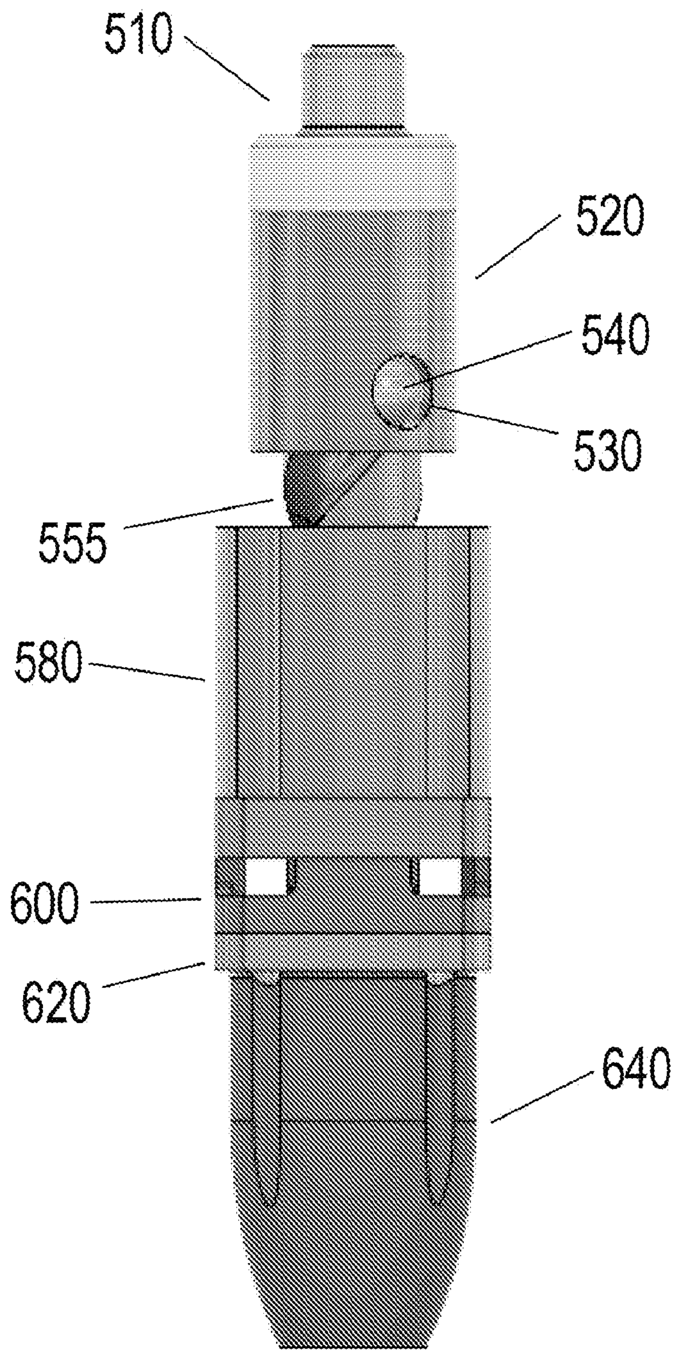

FIG. 12

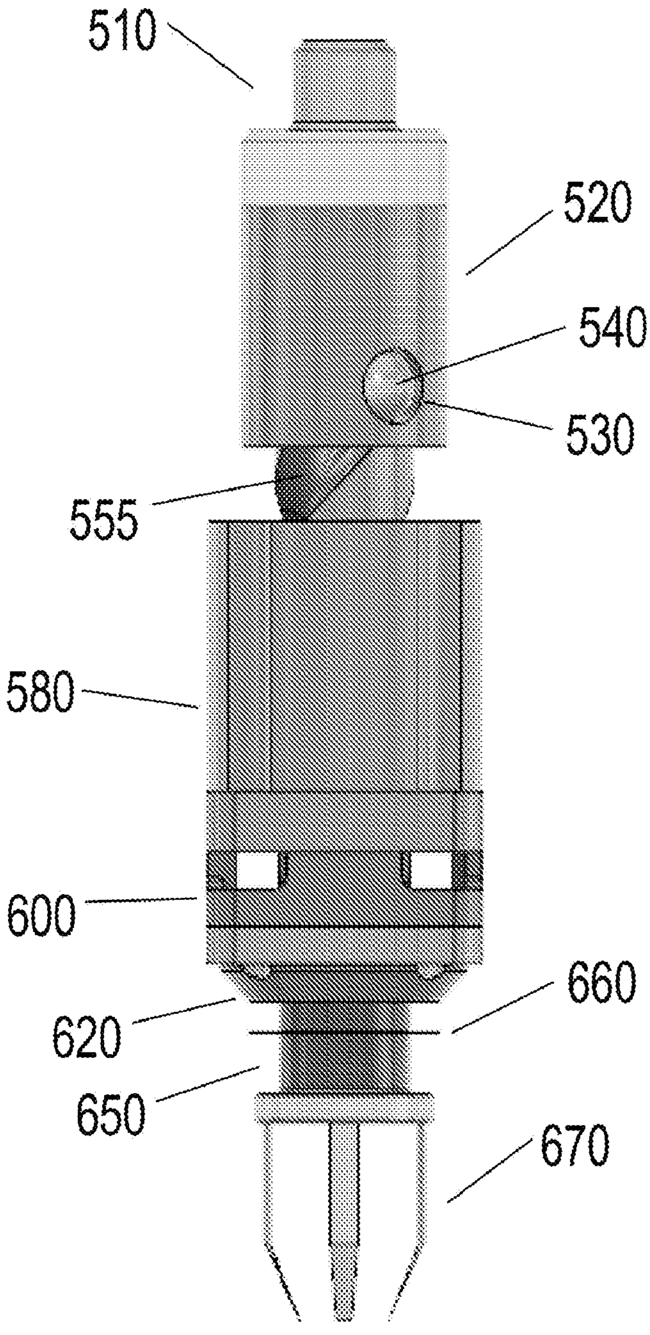

FIG. 13

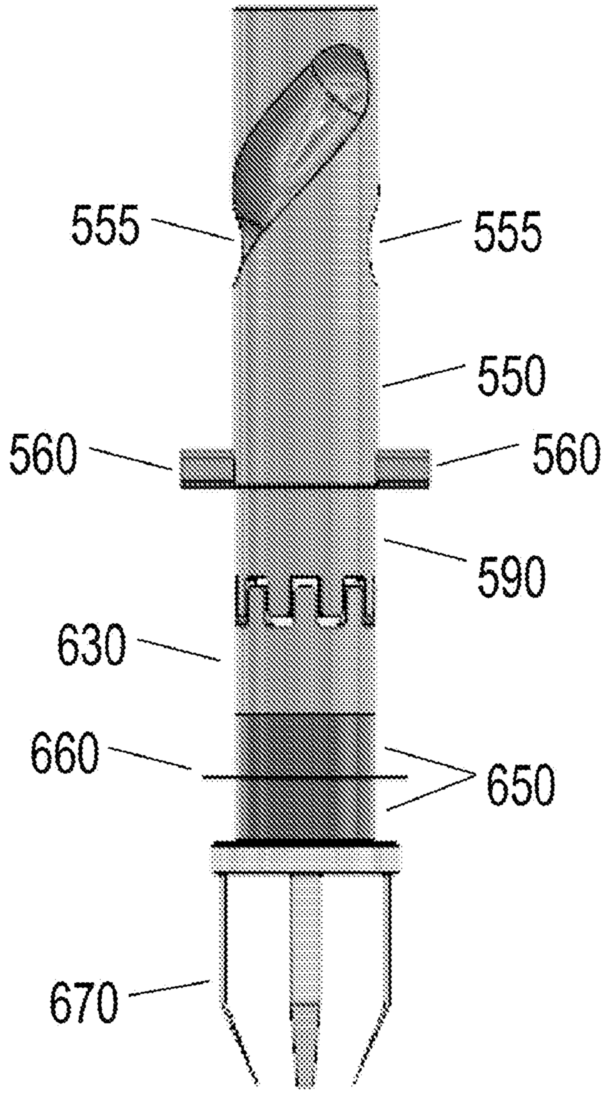

FIG. 14

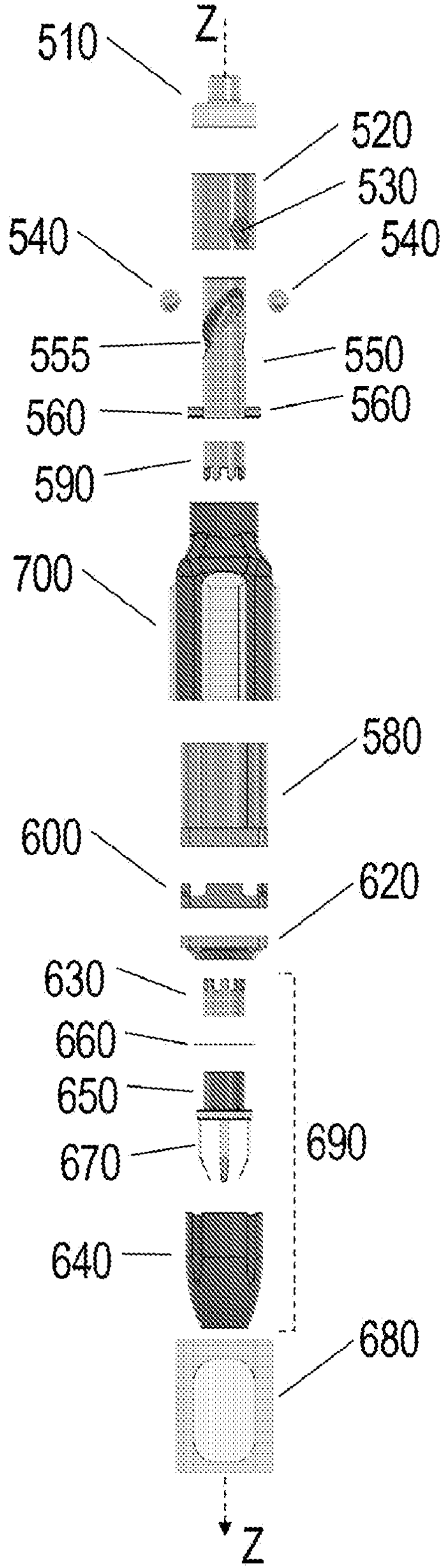
Z
510
520
530
540
540
555
550
560
560
590
700
580
600
620
630
660
650
670
690
640
680
Z

FIG. 15

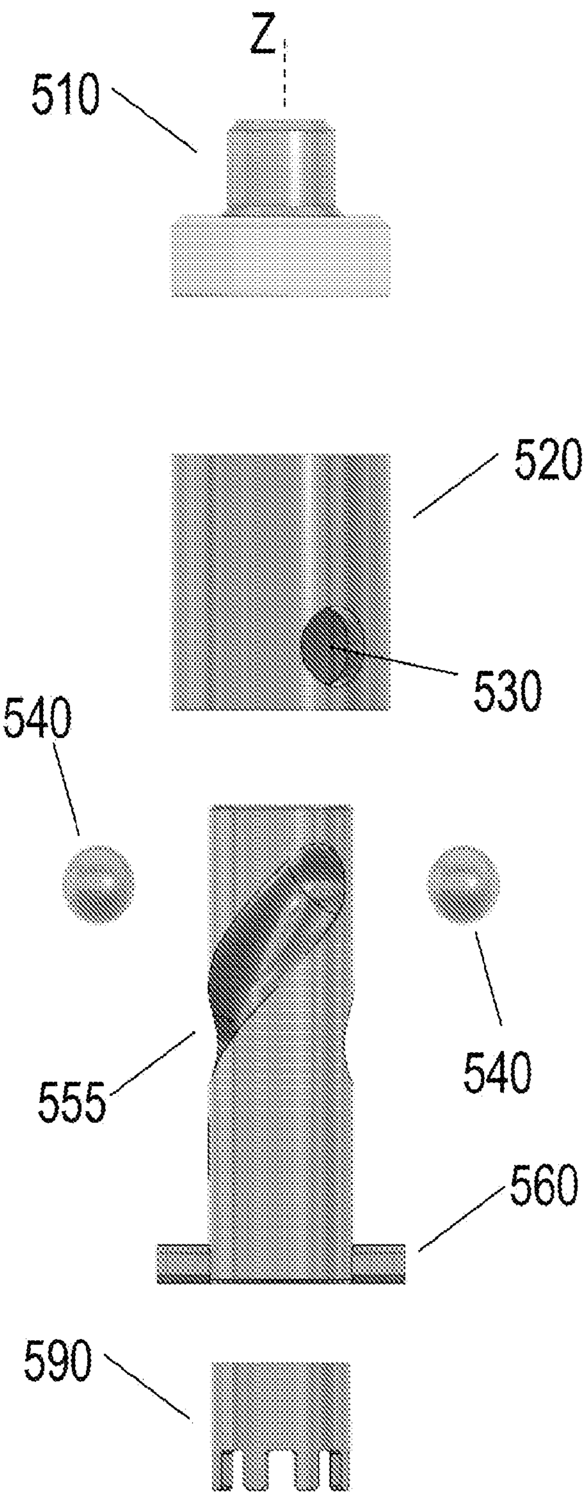

FIG. 16

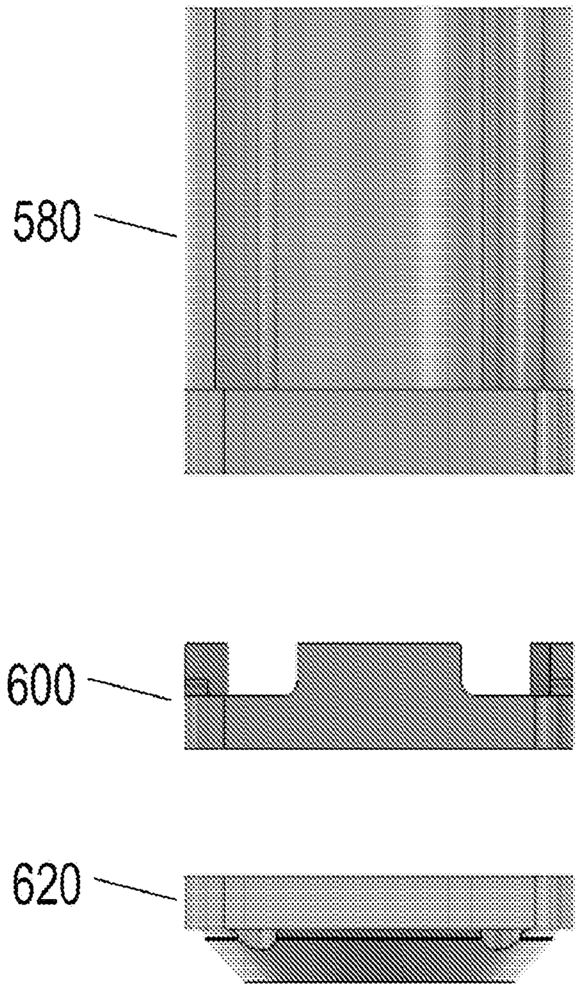

FIG. 17

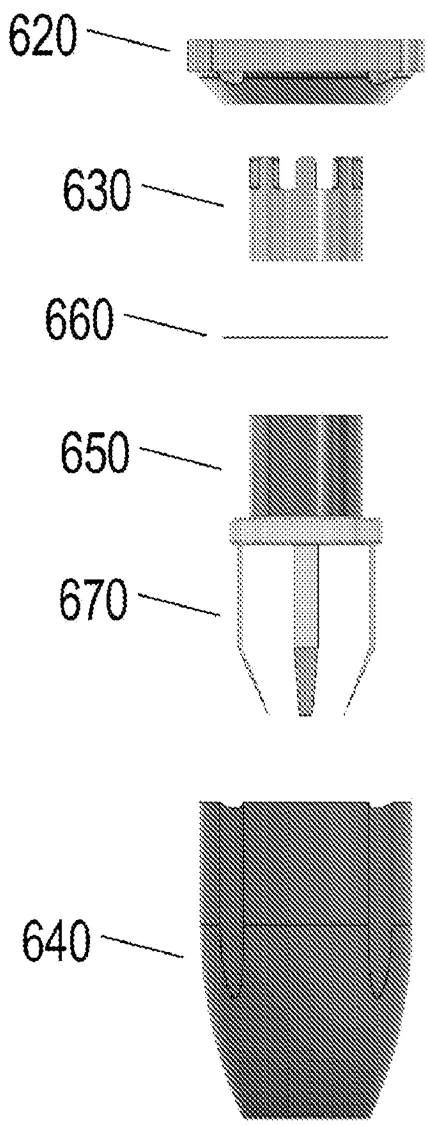

FIG. 18

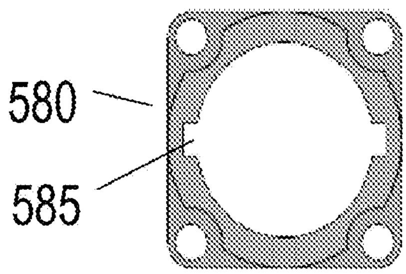

FIG. 19

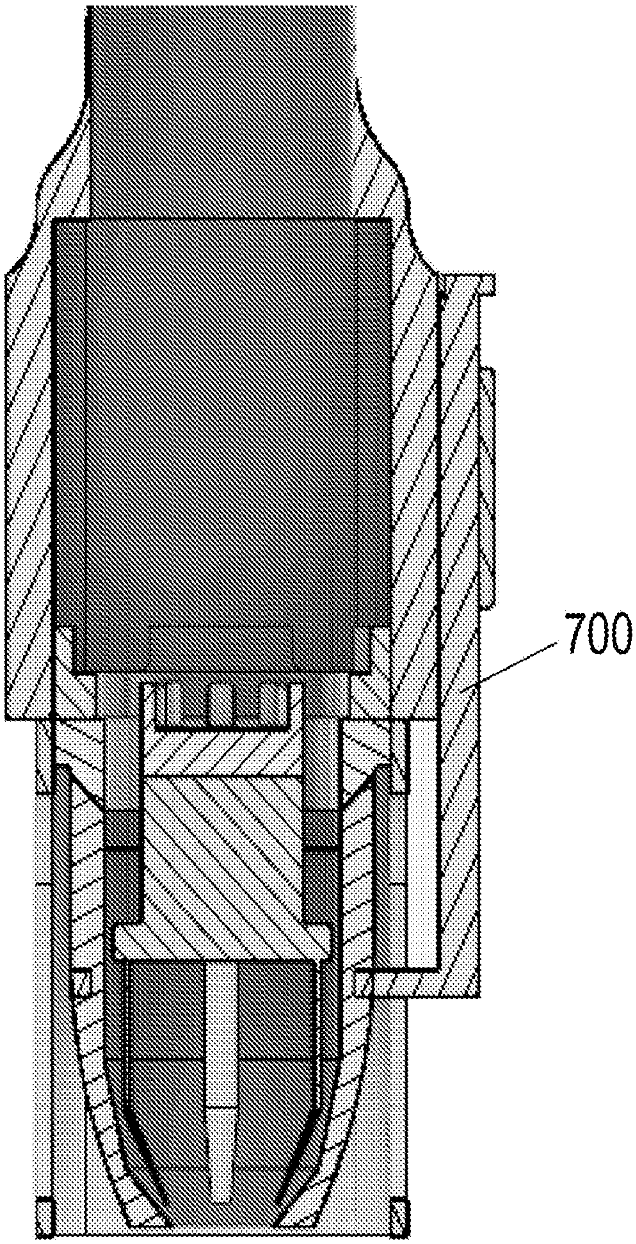

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/27236

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 10/02 (2017.01)
CPC - A61B 1/02, A61B 10/0266, A61B 10/0233, A61B 2010/0208

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)
See Search History Document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ------------- A	US 2,710,000 A (CROMER et al) 07 June 1955 (07.06.1955) fig 1, 6, col 2, ln 23-32, col 4, ln 31 -37, col 5, ln 3-16, col 6, ln 54-73	1-5 ------------- 6-11
A	US 2005/0054947 A1 (GOLDENBERG) 10 March 2005 (10.03.2005) fig 2, 3, par a[0074]	6-11
A	US 5,746,760 A (HUMPHREY JR) 05 May 1998 (05.05.1998) fig 2, 3, col 6, ln 46-60	6-11
A	US 2016/0058431 A1 (HOLZER) 03 March 2016 (03.03.2016) entire document, especially para [0049], [0052]	1-11
A	US 3,628,522 A (KATO) 21 December 1971 (21.12.1971) entire document	1-11
A	US 2011/0245727 A1 (FLATLAND et al) 06 October 2001 (06.10.2011) entire document	1-11
A	US 6,083,237 A (HUITEMA et al) 04 July 2000 (04.07.2000) entire document	1-11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
22 June 2017	14 JUL 2017

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774