

TISSUE BIOPSY INSTRUMENT AND METHOD OF FORMING THE SAME**TECHNICAL FIELD**

[0001] Various embodiments of this disclosure may relate to a tissue biopsy instrument. Various embodiments of this disclosure may relate to a method of forming a tissue biopsy instrument.

BACKGROUND

[0002] A tissue biopsy involves extraction of sample tissue from a patient to determine the presence or extent of a disease, e.g. cancer. Often, a core of tissue is extracted to facilitate histological diagnosis. In order to obtain the core of tissue, two things would need to be obtained: (1) a core of tissue would need to be excised from the patient; and (2) the end of the core of tissue would need to be cut and the core extracted.

[0003] Currently, the most common technique used is the “core-cut”. In core-cut needle biopsy, a long, hollow tube with a stylet within the hollow tube is used to obtain the sample tissue. The stylet has a trough at the side of the stylet near the tip. A spring loaded mechanism is used to actuate a two-steps operation. This mechanism may be disposable or reusable (e.g. Magnum Reusable Core Biopsy Instrument). During operation, when the operator presses the actuation button, there is a two-steps action (commonly referred to as “throw”). Firstly, the stylet extends beyond the distal end of the hollow tube into the tissue or tumor of interest so that the trough is exposed. Next, the hollow tube moves distally to excise the tissue and encase the excised tissue between the trough and the hollow tube. Such a procedure may be difficult to control, and may often be uncomfortable and/or painful for the patient. Further, it may injure adjacent critical structures. Also, the operation may be noisy due to the spring mechanism required to effect the throw. In addition, the sample collected may be limited by the length of the trough. Also, obtaining samples from dense tumors may be inconsistent.

[0004] The other existing technology to obtain core biopsies is the vacuum-assisted core biopsy. Hence, vacuum is used to hold the tissue within a trough of a needle. The rotary cutter situated in the needle itself is then used to cut and extract the biopsy sample. Vacuum-assisted core biopsy has been in the market since 1995, and is introduced in Singapore since 1999 for applications such as breast biopsy. However, instruments using vacuum-assisted core biopsy are often bulky.

SUMMARY

[0005] Various embodiments may relate to a tissue biopsy instrument. The tissue biopsy instrument may include a hollow tube having a distal end portion and a proximal end portion. The tissue biopsy instrument may further include a cutting device held or fixed within a distal end portion of the hollow tube.

[0006] Various embodiments may relate to a method of forming a tissue biopsy instrument. The method may include providing or forming a hollow tube having a distal end portion and a proximal end portion. The method may also include forming or attaching to the hollow tube a cutting device such that the cutting device is held or fixed within a distal end portion of the hollow tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] In the drawings, like reference characters generally refer to the same parts throughout the different views. The drawings are not necessarily drawn to scale, emphasis instead generally being placed upon illustrating the principles of various embodiments. In the following description, various embodiments of the invention are described with reference to the following drawings.

[0008] FIG. 1 is a schematic of a portion of a tissue biopsy instrument according to various embodiments.

[0009] FIG. 2A is a schematic of a portion of a tissue biopsy instrument with a stylet according to various embodiments.

[0010] FIG. 2B is a cross-sectional schematic of the tissue biopsy instrument shown in FIG. 2A with a handle according to various embodiments.

[0011] FIG. 2C shows a schematic in which the handle is removed from the hollow tube and an external vacuum source/pump is fitted into the proximal end portion of the hollow tube for creating suction force or vacuum for retrieving the tissue sample within the hollow tube according to various other embodiments.

[0012] FIG. 2D shows a schematic of the tissue biopsy instrument according to various embodiments being used for breast biopsy.

[0013] FIG. 2E shows a schematic of the tissue biopsy instrument according to various embodiments being rotated to make a cut of the distal end of the core of tissue.

[0014] FIG. 3A shows a traverse cross-sectional view of a tissue biopsy instrument according to various embodiments.

[0015] FIG. 3B shows a traverse cross-sectional view of another tissue biopsy instrument according to various embodiments.

[0016] FIG. 4A is a cross-sectional schematic of a portion of a hollow tube with a pointed tip according to various embodiments.

[0017] FIG. 4B is a cross-sectional schematic of a portion of another hollow tube with two pointed tips such that the two pointed tips form a “V” shape according to various embodiments.

[0018] FIG. 4C is a cross-sectional schematic of a portion of yet another hollow tube with a first pointed tip and a second pointed tip having a height greater than a height of the first pointed tip according to various embodiments.

[0019] FIG. 4D is a cross-sectional schematic of a portion of yet another hollow tube with a flat cutting edge at the distal end of the hollow tube according to various embodiments.

[0020] FIG. 5A is a cross-sectional schematic of a portion of a stylet with a pointed tip portion at one side of the distal end of the stylet according to various embodiments.

[0021] FIG. 5B is a cross-sectional schematic of a portion of another stylet with a pointed tip portion at the center of the distal end of the stylet according to various embodiments.

[0022] FIG. 5C is a cross-sectional schematic of a portion of the tissue biopsy instrument according to various embodiments when the stylet as shown in FIG. 5A is fully inserted into a hollow tube similar to the hollow tube as shown in FIG. 4A.

[0023] FIG. 5D is a cross-sectional schematic of a portion of the tissue biopsy instrument according to various embodiments when the stylet as shown in FIG. 5B is fully inserted into a hollow tube similar to the hollow tube as shown in FIG. 4B.

[0024] FIG. 6 is a cross-sectional schematic of the tissue biopsy instrument according to various embodiments.

[0025] FIG. 7 is a cross-sectional schematic of another tissue biopsy instrument according to various embodiments.

[0026] FIG. 8 shows a schematic illustrating a method of forming a tissue biopsy instrument according to various embodiments.

DESCRIPTION

[0027] The following detailed description refers to the accompanying drawings that show, by way of illustration, specific details and embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention. Other embodiments may be utilized and structural, logical, and electrical changes may be made without departing from the scope of the invention. The various embodiments are not necessarily mutually exclusive, as some embodiments can be combined with one or more other embodiments to form new embodiments.

[0028] Features that are described in the context of an embodiment may correspondingly be applicable to the same or similar features in the other embodiments. Features that are described in the context of an embodiment may correspondingly be applicable to the other embodiments, even if not explicitly described in these other embodiments. Furthermore, additions and/or combinations and/or alternatives as described for a feature in the context of an embodiment may correspondingly be applicable to the same or similar feature in the other embodiments.

[0029] In the context of various embodiments, the articles “a”, “an” and “the” as used with regard to a feature or element include a reference to one or more of the features or elements.

[0030] In the context of various embodiments, the term “about” or “approximately” as applied to a numeric value encompasses the exact value and a reasonable variance, e.g. within 10% of the specified value.

[0031] As used herein, the term “and/or” includes any and all combinations of one or more of the associated listed items.

[0032] By “comprising” it is meant including, but not limited to, whatever follows the word “comprising”. Thus, use of the term “comprising” indicates that the listed elements are required or mandatory, but that other elements are optional and may or may not be present.

[0033] By “consisting of” is meant including, and limited to, whatever follows the phrase “consisting of”. Thus, the phrase “consisting of” indicates that the listed elements are required or mandatory, and that no other elements may be present.

[0034] Embodiments described in the context of one of the instruments are analogously valid for the other instruments. Similarly, embodiments described in the context of a method are analogously valid for an instrument, and vice versa.

[0035] Various embodiments may address one of more issues facing conventional tissue biopsy devices.

[0036] FIG. 1 is a schematic of a portion of a tissue biopsy instrument according to various embodiments. The tissue biopsy instrument may include a hollow tube 102 (alternatively referred to as sleeve) having a distal end portion and a proximal end portion. The tissue biopsy instrument may further include a cutting device 104 fixed, held or suspended within a distal end portion of the hollow tube 102.

[0037] In other words, the tissue biopsy instrument may be a hollow tube 102 with one end portion having a cutting device 104.

[0038] For avoidance of doubt, FIG. 1 is intended to illustrate features of the tissue biopsy instrument according to various embodiments, and is not intended to limit, for instance, the dimensions, shape, orientation etc. of the various components. For instance, while FIG. 1 shows the cutting device 104 extending horizontally, various other embodiments may relate to cutting device in any other direction or any other angle, e.g. vertically. The curved line in FIG. 1 indicates that FIG. 1 shows only a portion of the tissue biopsy instrument and the tissue biopsy instrument extends beyond the curved line.

[0039] In various embodiments, the tissue biopsy instrument may be a tissue biopsy device or part of a tissue biopsy device that is able to perform the steps of core, cut and extract.

[0040] During operation, an operator (e.g. a surgeon, a radiologist or any other suitable person) may “twist” or rotate the hollow tube 102, i.e. around a central axis (as shown in FIG. 1) parallel to a longitudinal length of the hollow tube 102. By rotating the hollow tube 102, the cutting device 104 may be able to cut or excise a tissue sample (“twist cut” technique). Accordingly, various embodiments may not require the spring mechanism present in a conventional core needle biopsy surgical instrument to remove the tissue sample. Various embodiments may allow the operator to use the “twist cut” technique as described above, which is easier to control compared to the conventional core-cut needle biopsy surgical instrument. Also, as various embodiments do not involve the release of the spring mechanism to effect the throw, the operation may be carried out more quietly, and in a more controlled manner. Additionally, various embodiments may involve the smoother insertion into, and retrieval of tissue samples from a patient’s body. Various embodiments may reduce trauma and/or pain to the patient. The patient may be a human. Alternatively, the patient may be an animal, e.g. a dog. The trough of the stylet in the conventional core-cut needle biopsy surgical instrument may typically be 1.9 cm long, thereby limiting the volume of the sample that can be retrieved. Various embodiments may not be limited to such a dimension, and may potentially be capable

of collecting a greater volume of the sample by using the entire length of the hollow tube 102. There may be no or smaller dead space length as compared to the conventional core needle biopsy surgical instrument and vacuum-assisted core biopsy surgical instrument. The hollow tube 102 may include openings at both ends of the tube 102 with a space extending between the openings at both ends. The hollow tube 102 may be devoid of any other opening or trough, e.g. at the sides of the tube 102.

[0041] In various embodiments, the cutting device 104 may be a wire. The wire, may, for instance, have a thickness selected from a range from about 0.01 mm to about 0.2 mm, e.g. about 0.1 mm. In various other embodiments, the cutting device 104 may be a blade. The blade may have a sharp edge (i.e. the cutting edge) facing away from the proximal end portion of the tissue biopsy instrument. In various embodiments, the blade may have a single cutting edge extending along a length of the blade. The cutting device 104 (e.g. the wire or the blade) may be required to be robust (i.e. withstand insertion, advancement, and cutting of tissue without deforming or breaking). The cutting device 104 may be fixed to the hollow tube 102, and may not be movable relative to the hollow tube.

[0042] In various embodiments, the cutting device 104 may include any suitable material. For instance, the cutting device 104 may include a material selected from a group consisting of hardened steel, tempered steel, stainless steel, carbon steel, titanium, ceramic, platinum, and obsidian.

[0043] In various embodiments, the hollow tube 102 may include any suitable material. For instance, the hollow tube may include a material selected from a group consisting of hardened steel, tempered steel, stainless steel, carbon steel and titanium.

[0044] In various embodiments, the hollow tube 102 may be of any value selected from a range from Gauge 8 to Gauge 20. The hollow tube may have an inner diameter selected from a range from about 0.603 mm (Gauge 20) to about 3.429 mm (Gauge 8). The hollow tube may have an outer diameter selected from a range from 0.9081 mm (Gauge 20) to about 4.191 mm (Gauge 8). The hollow tube 102 may have a longitudinal length selected from a range from about 8 cm to about 20 cm, e.g. from about 10 cm to about 15 cm.

[0045] In various embodiments, the cutting device 104 may extend or be suspended from a first portion of an inner wall of the hollow tube 102 to a second portion of the inner wall of the hollow tube 102. The cutting device 104 may extend across the inner space of the tube 102. The cutting device 104 may extend along a diameter (i.e. an inner diameter defined by the inner

wall) of the hollow tube 102. In various other embodiments, the cutting device 104 may extend from a portion of an inner wall, the cutting device 104 having a free end protruding into a space defined by the hollow tube 102. In other words, the cutting device 104 may be held only at one end and may have a free end extending into the space enclosed by the hollow tube. For instance, the cutting device may extend to 50% or 75% along the inner diameter of the hollow tube 102. The cutting device 104 may be fixed to the hollow tube 102, and may not be moved relative to the hollow tube 102. When the cutting device 104 extends from a first portion of an inner wall of the hollow tube 102 to a second portion of the inner wall of the hollow tube 102, the hollow tube 102 may be required to rotate 180 degrees or more to make a cut of the distal end of the core of tissue. In contrast, when the cutting device 104 is held or is fixed only at one end, a rotation of 360 degrees or more of the hollow tube 102 may be required to make the cut.

[0046] While FIG. 1 shows that the inner wall of the tube 102 defines a circular inner space (across a traverse cross-section of the tube 102), it may be envisioned that, in various other embodiments, the inner wall of the tube 102 may define an inner space of any other suitable shape. The first portion of the inner wall and the second portion of the inner wall may be opposing portions of the inner wall. In various embodiments, the cutting device 104 may be welded, attached or joined via any suitable secure means to the hollow tube 102. In various embodiments, the cutting device 104 and the hollow tube 102 may form a monolithic structure, with the cutting device 104 extending from the first portion of the inner wall of the hollow tube 102 to the second portion of the inner wall of the hollow tube 102, or from only one portion of the inner wall into the space defined by the hollow tube 102.

[0047] As mentioned above, a cutting device 104 may be held within a distal end portion of the hollow tube 102. In various embodiments, the distal end portion may refer to the most distal portion of the hollow tube 102, which may, for instance, be the most distal 5%, 10%, 20% or 30% of the hollow tube 102.

[0048] In various embodiments, the distal end portion of the hollow tube 102 may include a pointed tip. The pointed tip may be used to pierce into the patient during surgery. In various other embodiments, the distal end portion of the hollow tube 102 may have two pointed tips such that the two tips form a “V” shape. In yet various other embodiments, the distal end portion of the hollow tube 102 may be flat, but with a cutting end.

[0049] In various embodiments, the tissue biopsy instrument may include a stylet within the hollow tube 102. The stylet may be slidably movable along the longitudinal length of the

hollow tube 102. The stylet may have a longitudinal length selected from a range from about 8 cm to about 20 cm, e.g. from about 10 cm to about 15 cm. The stylet may include a material selected from a group consisting of hardened steel, tempered steel, stainless steel, carbon steel and titanium. The stylet may have one or more grooves. The one or more grooves may extend from a distal end of the stylet (partially towards an opposing proximal end of the stylet) parallel to or along a longitudinal length of the stylet. The one or more grooves may serve to accommodate the cutting device 104.

[0050] In various embodiments, the tissue biopsy instrument may further include a handle holding or configured to hold the proximal end portion of the hollow tube. In various embodiments, the handle together with the hollow tube 102 and the cutting device 104 may be disposed after each surgical operation.

[0051] In various other embodiments, the handle may be reusable, while the hollow tube 104 with the cutting device 104 may form the disposable portion. The handle may include a covering made of any suitable material, e.g. a suitable polymer or a metal such as stainless steel. The tissue biopsy instrument or the handle may include a coupling mechanism, e.g. a connector, configured to hold the hollow tube 102. The connector may be disposable. The connector may include a transparent or translucent material, e.g. a plastic material. By having the transparent or translucent material, the operator may be able to see whether the hollow tube 102 is being filled with the excised tissue sample, thereby facilitating the operator to make a judgement on whether to withdraw the tissue biopsy instrument. Before the surgical operation or during the surgical operation (i.e. after a new or unused sterile hollow tube 102 with the cutting device 104 is used to pierce into the patient's body), the distal end portion of the hollow tube 104 may be inserted or be attached to the handle via the coupling mechanism or the connector. The coupling mechanism or the connector may already be inserted or attached to the handle when the hollow tube 102 is being inserted or attached to the coupling mechanism or the connector. After the surgical operation, the hollow tube 104 with the cutting device 104 may be detached or removed from the coupling mechanism/connector and be disposed, while the handle may be reused for future surgical operations. The coupling mechanism or connector may also be disposed. The coupling mechanism may, for instance, be a clamping mechanism to clamp the needle, a bolt and joint mechanism (e.g. in which the outer surface of the proximal end portion of the hollow tube 102 has treads for engagement with grooves of a mating surface

of the handle), a magnetic coupling mechanism in which the hollow tube 102 is coupled to the handle via a magnetic or electromagnetic field, or any other suitable coupling means.

[0052] In various embodiments, the tissue biopsy instrument may be configured to be manually operated. During operation, an operator may manually “twist” or rotate the hollow tube 102, i.e. around the central axis, such that the cutting device 104 may be able to cut or excise a tissue sample. In various other embodiments, the tissue biopsy instrument may be electrically powered or battery operated. In various embodiments, the handle may include a rotary mechanism configured to (upon supply of electrical energy) rotate the hollow tube 102 around the central axis passing through the hollow tube 102. In one implementation, the handle may further include a compartment configured to hold an electrical energy source, e.g. a battery, for driving the rotary mechanism. In another implementation, the handle may include a power cord to be plugged into an external power source (e.g. a wall socket), which may supply the electrical energy required for driving the rotary mechanism.

[0053] In various embodiments, the tissue biopsy instrument may not be required to be vacuum-assisted. In various embodiments, the cutting device 104 may trap the tissue sample within the hollow tube 102. The hollow tube 102 with the trapped tissue sample may then be withdrawn from the patient’s body to retrieve the tissue sample. The tissue biopsy instrument may not include a vacuum pump or source. After the hollow tube 102 with the trapped tissue sample is withdrawn, the tissue sample may be retrieved by using an external device, such as a wire to push the tissue sample out from the hollow tube 102 (“wire push”). Alternatively, an external device including a vacuum pump or source may be attached to the hollow tube 102 to retrieve the tissue sample. In various other embodiments, the tissue biopsy instrument may be a vacuum-assisted device. The handle may include a vacuum pump or source connected to the hollow tube 102. In the current context, the vacuum pump or source may refer to a component or device that generates full or partial vacuum, or suction force. The vacuum or suction force generated may cause the retrieval of the tissue sample. In various embodiments, the rotary mechanism may be configured to generate vacuum or suction force. In other words, in various embodiments, the rotary mechanism may also act as the vacuum source (in addition to its function of rotating the hollow tube 102), and a single mechanism or device may cause the rotary movement of the hollow tube 102 and provide suction power. In various other embodiments, the rotary mechanism and the vacuum pump or source may be separate/independent of each other. The vacuum pump or source may be powered by the

electrical energy source, or by the external power source via the power cord. The vacuum pump or source may be configured to (upon supply of electrical energy) generate a vacuum or partial vacuum to “suck” (i.e. move via suction force) the excised tissue sample along the hollow tube. The battery or the external power source may provide the electrical energy for driving the vacuum pump or source. In various embodiments, the tissue biopsy instrument or the handle may include a tissue collector to collect the excised tissue.

[0054] FIG. 2A is a schematic of a portion of a tissue biopsy instrument with a stylet according to various embodiments. The curved line in FIG. 2A indicates that FIG. 2A shows only a portion of the tissue biopsy instrument and the tissue biopsy instrument extends beyond the curved line. The tissue biopsy instrument may include a hollow tube 202 with a cutting device 204. The tissue biopsy instrument may include a stylet 206 within the hollow tube 202. As indicated by the hatched lines, the stylet 206 may be solid with a groove 207 extending from a distal end parallel to or along the longitudinal length of the stylet 206. In various embodiments, the stylet 206 may be used to prevent tissues from getting into the hollow tube 202 when the hollow tube 202 is advanced into the human or animal body e.g. when the hollow tube 202 is inserted or introduced into the patient and during insertion to reach a tumour. The groove 207 may serve to accommodate the cutting device 204 when stylet 206 is fully inserted into the hollow tube 202 during advancement of the hollow tube 202 into the human or animal body. The groove 207 may extend along an entire diameter of the stylet 206. In embodiments in which the cutting device 204 extends only partially from the inner wall of the hollow tube 202 (i.e. the cutting device 204 has a free end protruding into the space within the hollow tube 202), the groove 207 may only also extend partially along the diameter of the stylet 206 to accommodate the cutting device 204.

[0055] FIG. 2B is a cross-sectional schematic of the tissue biopsy instrument shown in FIG. 2A with a handle 208 according to various embodiments. The stylet 206 may be removed from the hollow tube 202 prior to the handle 208 being attached to the hollow tube 202.

[0056] In various embodiments, there may be a coupling mechanism or connector 212 as described earlier. The coupling mechanism or connector 212 may be used to attach or fix the hollow needle 202 to the handle 208. In various embodiments, the handle 208 may include a rotary mechanism 214 and/or a vacuum pump/source 216. As mentioned earlier, the rotary mechanism 214 may be configured to rotate the hollow tube 202 around the central axis passing through the hollow tube 202, while the vacuum pump/source 216 may be configured to

generate a vacuum or partial vacuum to “suck” the excised tissue sample along the hollow tube. In various embodiments, as mentioned earlier, the rotary mechanism 214 and the vacuum pump/source 216 may be combined instead of being separate as shown in FIG. 2B. In other words, the rotary mechanism 214 may act as the vacuum pump/source 216. The handle 208 may further include an electrical energy source 218, e.g. a battery, to provide electrical energy to the rotary mechanism 214 and/or the vacuum pump/source 216. In various embodiments, the handle 208 may be devoid of the rotary mechanism 214 and/or the vacuum pump/source 216. For instance, the “twist-cut” may be performed manually, retrieval may be carried out using “wire push”, and/or an external vacuum source/pump may be used as mentioned earlier. FIG. 2C shows a schematic in which the handle is removed from the hollow tube 202 and an external vacuum source/pump is fitted into the proximal end portion of the hollow tube 202 for creating suction force or vacuum for retrieving the tissue sample within the hollow tube 202 according to various other embodiments. After withdrawal of the tissue biopsy instrument from the patient’s body, the tissue sample trapped within the hollow tube 202 may be retrieved by attaching the external vacuum source/pump to the proximal end portion of the hollow tube 202 and using the external vacuum source/pump to suck or move the tissue sample from the hollow tube 202.

[0057] FIG. 2D shows a schematic of the tissue biopsy instrument according to various embodiments being used for breast biopsy. First, an ultrasound probe may be used to locate the tumor, and a puncture is made. The operator may then use the hollow tube 202 (with the stylet 206 fully inserted into the hollow tube 202) to insert into the puncture of the skin, and advance the hollow tube through the soft fat layer and firm breast layer to reach the tumor. The stylet 206 may prevent cells or tissues from entering into the hollow tube 202 when the hollow tube 202 is advanced through the soft fat layer and firm breast layer. After advancing through the soft fat layer and firm breast layer, the stylet 206 is removed from the hollow tube 202 (as shown in FIG. 2D), before the handle 208 is attached to the hollow tube 202 via the disposable, sterile connector 212 (as shown in FIG. 2B).

[0058] FIG. 2E shows a schematic of the tissue biopsy instrument according to various embodiments being rotated to make a cut of the distal end of the core of tissue. The cutting device 204 may cut off the distal end of the core of tissue when the hollow tube 202 is rotated. The core of tissue may then be trapped in the hollow tube 202 by the cutting device 204. The

hollow tube 202 together with the trapped tissue sample of the core of tissue may then be removed from the patient's body.

[0059] For avoidance of doubt, FIGS. 2A-E are intended to illustrate features of the tissue biopsy instrument according to various embodiments, and are not intended to limit, for instance, the dimensions, shape, orientation etc. of the various components.

[0060] FIG. 3A shows a traverse cross-sectional view of a tissue biopsy instrument according to various embodiments, while FIG. 3B shows a traverse cross-sectional view of another tissue biopsy instrument according to various embodiments. The tissue biopsy instrument shown in FIG. 3A has a hollow tube 302a and a cutting device 304a extending along the inner diameter of the hollow tube 302a from one portion of the inner wall of the hollow tube 302 to an opposing portion of the inner wall of the hollow tube 302a. The tissue biopsy instrument as shown in FIG. 3B has a hollow tube 302b and a cutting device 304b extending only partially along the inner diameter of the hollow tube 302b from one portion of the inner wall of the hollow tube 302b. As shown in FIG. 3B, one end of the cutting device 304b may be joined, fixed or attached to the hollow tube 302b, while the opposing end of the cutting device 304b may be free, i.e. not attached to the hollow tube 302b. As mentioned above, while FIGS. 3A-B show the cutting devices 304a, 304b extending horizontally across the traverse cross-section of the hollow tubes 302a, 302b, various embodiments may relate to an instrument with a cutting device extending at any suitable angle or direction.

[0061] FIG. 4A is a cross-sectional schematic of a portion of a hollow tube 402a with a pointed tip according to various embodiments. The hollow tube 402a may have a cutting edge at the distal end of the hollow tube 402a extending from the pointed tip. FIG. 4B is a cross-sectional schematic of a portion of another hollow tube 402b with two pointed tips such that the two pointed tips form a "V" shape according to various embodiments. The hollow tube 402b may have two cutting edges at the distal end of the hollow tube 402b extending from the pointed tips. FIG. 4C is a cross-sectional schematic of a portion of yet another hollow tube 402c with a first pointed tip and a second pointed tip having a height greater than a height of the first pointed tip according to various embodiments. The hollow tube 402c may have two cutting edges at the distal end of the hollow tube 402c extending from the pointed tips. The two pointed tips may form an asymmetrical "V" shape. FIG. 4D is a cross-sectional schematic of a portion of yet another hollow tube 402d with a flat cutting edge at the distal end of the hollow tube 402d according to various embodiments. The curved lines shown in FIGS. 4A-D indicate

that FIGS. 4A-D show only portions of the respective tissue biopsy instrument. The cutting devices are not shown in FIGS. 4A-D.

[0062] FIG. 5A is a cross-sectional schematic of a portion of a stylet 506a with a pointed tip portion at one side of the distal end of the stylet 506a according to various embodiments. The stylet 506a may have one or more grooves 507a extending along a longitudinal length of the stylet 506a from a distal end of the stylet 506a. The stylet 506a may also include cutting edges at the distal end of the stylet 506a as shown in FIG. 5A. FIG. 5B is a cross-sectional schematic of a portion of another stylet 506b with a pointed tip portion at the center of the distal end of the stylet 506b according to various embodiments. The stylet 506b may have one or more grooves 507b extending along a longitudinal length of the stylet 506b from a distal end (and from the pointed tip portion) of the stylet 506b. The stylet 506b may also include cutting edges at the distal end of the stylet 506b as shown in FIG. 5B.

[0063] FIG. 5C is a cross-sectional schematic of a portion of the tissue biopsy instrument according to various embodiments when the stylet 506a as shown in FIG. 5A is fully inserted into a hollow tube 502a similar to the hollow tube 402a as shown in FIG. 4A. As shown in FIG. 5C, the cutting device 504a may fit into the one or more grooves 507a of the stylet 506a. The distal end of the stylet 506a may not extend beyond the distal end of the hollow tube 502a. As such, the cutting edge of the hollow tube 502a is used to cut the subcutaneous tissue when the stylet 506a is fully inserted into the hollow tube 502a during advancing the tissue biopsy instrument through the subcutaneous tissue. FIG. 5D is a cross-sectional schematic of a portion of the tissue biopsy instrument according to various embodiments when the stylet 506b as shown in FIG. 5B is fully inserted into a hollow tube 502b similar to the hollow tube 402b as shown in FIG. 4B. As shown in FIG. 5D, the cutting device 504b may fit into the one or more grooves 507b of the stylet 506b. The distal end of the stylet 506b may extend beyond the distal end of the hollow tube 502b. As such, the cutting edges of the stylet 506b is used to cut the subcutaneous tissue when the stylet 506b is fully inserted into the hollow tube 502b during advancing the tissue biopsy instrument through the subcutaneous tissue. When reaching the tumor, the stylet 506b may be withdrawn from the hollow tube 502b, and the cutting edges of the hollow tube 502b may be used to penetrate into the tumor, before the cutting device 506b is used to cut the distal end of the core of tissue of the tumor. The curved lines shown in FIGS. 5A-D indicate that FIGS. 5A-D show only portions of the respective stylet.

[0064] FIG. 6 is a cross-sectional schematic of the tissue biopsy instrument according to various embodiments. The entire tissue biopsy instrument including the hollow tube 602, the cutting device 604 and the handle 608 may be disposable. The tissue biopsy instrument shown in FIG. 6 may not require a connector. In various embodiments, the hollow tube 602 and the handle 608 may form a single monolithic device. In various other embodiments, the hollow tube 602 may be directly attached to the handle 608. In various embodiments, the handle 608 may include a channel 609 extending from a back from the handle 608 such that the stylet may be inserted into the hollow tube 602 through the channel 609 of the handle 608.

[0065] FIG. 7 is a cross-sectional schematic of another tissue biopsy instrument according to various embodiments. The hollow tube 702 with the cutting device 704 may be disposable, while the handle 708 may be reusable. A disposable connector 712 may be used to attach or connect the hollow tube 702 to the handle 708. The disposable connector 712 may include a transparent or translucent material, e.g. a plastic material. Prior to the operation, the connector 712 may be attached to the handle 708. The hollow tube 702 (with an inserted stylet) may be advanced through tissue layers underlying the skin to reach the tumor. The stylet may then be withdrawn from the hollow tube 702, and the handle 708 may be coupled or attached to the hollow tube 702 via the (sterile) connector 712. If reinsertion is required, the hollow tube 702 may be decoupled or detached from the (sterile) connector 712. The same (sterile) stylet may be reinserted into the same (sterile) hollow tube 702, and the (sterile) hollow tube 702 (with the reinserted (sterile) stylet) may then be advanced through tissue layers underlying the skin, and the same handle 708 may be coupled or attached to the hollow tube 702 via the same (sterile) connector 712.

[0066] Various embodiments may be used for endoscopy biopsy. In various embodiments, the tissue biopsy device may be attached to the distal end portion of a wire/cable extending along the length of the endoscope device.

[0067] FIG. 8 shows a schematic illustrating a method of forming a tissue biopsy instrument according to various embodiments. The method may include, in 802, providing or forming a hollow tube having a distal end portion and a proximal end portion. The method may also include, in 804, forming or attaching to the hollow tube a cutting device such that the cutting device is fixed, held or suspended within a distal end portion of the hollow tube. The cutting device may be a wire or a blade.

[0068] In various embodiments, the method may include forming or providing a handle holding or configured to hold the proximal end portion of the hollow tube. As mentioned above, the handle may include a rotary mechanism, a compartment configured to hold an electrical energy source, a coupling mechanism, and/or a vacuum source/pump. The method may include forming or providing the rotary mechanism, the compartment configured to hold the electrical energy source, the coupling mechanism, and/or the vacuum source/pump.

[0069] In various embodiments, the method may include providing or forming a stylet within the hollow tube.

[0070] Various embodiments may include a method of operating a tissue biopsy instrument as described herein. The method may include inserting a hollow tube with a cutting device fixed or held within a distal end portion of the hollow tube into a patient. The method may further include twisting or rotating the hollow tube to excise or remove a tissue sample from the patient's body (e.g. from a tumor within the patient's body).

Claims

1. A tissue biopsy instrument comprising:
a hollow tube having a distal end portion and a proximal end portion; and
a cutting device fixed within a distal end portion of the hollow tube.
2. The tissue biopsy instrument according to claim 1
wherein the cutting device is a wire.
3. The tissue biopsy instrument according to claim 1,
wherein the cutting device is a blade.
4. The tissue biopsy instrument according to any one of claims 1 to 3,
wherein the cutting device comprises a material selected from a group
consisting of hardened steel, tempered steel, stainless steel, carbon steel,
titanium, ceramic, and obsidian.
5. The tissue biopsy instrument according to any one of claims 1 to 4,
wherein the cutting device extends from a first portion of an inner wall of the
hollow tube to a second portion of the inner wall of the hollow tube.
6. The tissue biopsy instrument according to any one of claims 1 to 4,
wherein the cutting device extends from a portion of an inner wall, the cutting
device having a free end protruding into a space defined by the hollow tube.
7. The tissue biopsy instrument according to any one of claims 1 to 6, further
comprising:
a handle holding the proximal end portion of the hollow tube.
8. The tissue biopsy instrument according to claim 7,

wherein the handle comprises a rotary mechanism configured to, upon supply of electrical energy, rotate the hollow tube around a central axis passing through the hollow tube.

9. The tissue biopsy instrument according to claim 8,
wherein the handle further comprises a compartment configured to hold an electrical energy source for driving the rotary mechanism.
10. The tissue biopsy instrument according to any one of claims 7 to 9,
wherein the handle comprises a coupling mechanism configured to hold the hollow tube.
11. The tissue biopsy instrument according to any one of claims 7 to 10,
wherein the handle comprises a vacuum pump connected to the hollow tube.
12. The tissue biopsy instrument according to any one of claims 1 to 11, further comprising:
a stylet within the hollow tube.
13. The tissue biopsy instrument according to claim 12,
wherein the stylet has one or more grooves extending from a distal end of the stylet parallel to a longitudinal length of the stylet.
14. A method of forming a tissue biopsy instrument, the method comprising:
providing a hollow tube having a distal end portion and a proximal end portion; and
forming or attaching to the hollow tube a cutting device such that the cutting device is fixed within a distal end portion of the hollow tube.