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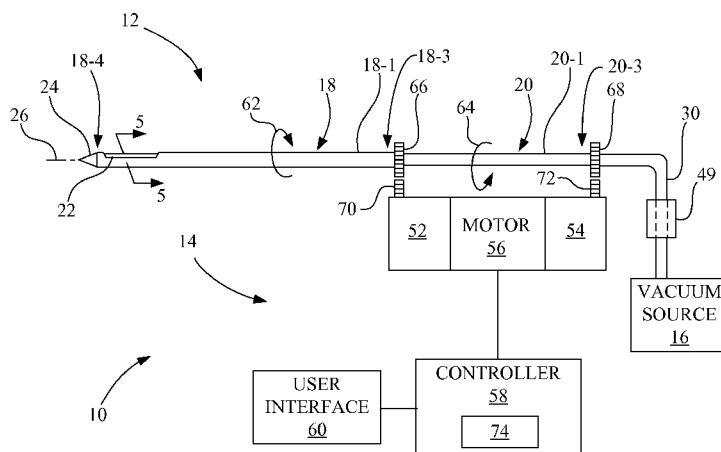


Fig. 1

(57) **Abstract:** A biopsy device includes a probe assembly and a driver unit. The probe assembly includes a first cannula having a first aperture extending to a lumen proximal to a first distal end of the first cannula. A second cannula has a second aperture extending to a lumen proximal to the second distal end of the second cannula. The second cannula is disposed co-axially with the first cannula. A least one of the first aperture and the second aperture has a cutting edge. The driver unit is configured for releasably mounting the probe assembly. The driver unit is operatively configured to simultaneously rotate the first cannula and the second cannula at different rotational velocities so that the first aperture and the second aperture periodically come into alignment to form a virtual tissue sample aperture.

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BIOPSY DEVICE HAVING ROTATIONAL CUTTING

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to medical devices, and, more particularly, to a biopsy device having rotational cutting.

2. Description of the Related Art

[0002] A typical biopsy device includes a probe assembly having a cannula configured with a sample notch and a tissue sampling chamber and associated tissue cutting mechanism. During a biopsy procedure, vacuum assistance may be used to help draw tissue through the sample notch and into the sampling chamber and maximize the amount of tissue obtained with each sample. Some biopsy devices, commonly referred to as single insertion, multiple samples, or SIMS devices, utilize sample acquisition and delivery mechanisms that allow multiple samples to be acquired from a given lesion without removing and reinserting the needle after each sample. One type of cutting mechanism used in a vacuum assisted SIMS biopsy device uses rotational and linear motion of a cutter with respect to the sample notch to sever the tissue drawn through the sample notch into the tissue sampling chamber. Vacuum is applied to transport the tissue from the sampling chamber to a sample collection basket. This process may be repeated until the desired amount of tissue has been obtained.

[0003] In one common SIMS biopsy device, it is necessary for an operator to manually rotate the probe assembly to different orientations after each sample in order to obtain tissue samples at different radial orientations within the target site. However, in some situations, such manual rotation may be inconvenient.

SUMMARY OF THE INVENTION

[0004] The present invention provides a biopsy device and method for obtaining biopsy samples, wherein the biopsy device is configured to periodically form a virtual tissue sample aperture at a plurality of angular radial positions.

[0005] In the description of the invention that follows, the terms “first” and “second” preceding an element name are used for identification purposes to distinguish between similar or related elements, results or concepts, and are not intended to necessarily imply order, nor

are the terms “first” and “second” intended to preclude the inclusion of additional similar or related elements, results or concepts, unless otherwise indicated.

[0006] The invention, in one form thereof, is directed to a biopsy device including a probe assembly and a driver unit. The probe assembly includes a first cannula having a first side wall defining a first lumen. The first cannula has a first proximal end and a first distal end. The first cannula has a first aperture extending through the first side wall to the first lumen proximal to the first distal end. The first cannula has a longitudinal axis. A second cannula has a second side wall defining a second lumen. The second cannula has a second proximal end and a second distal end. The second cannula has a second aperture extending through the second side wall to the second lumen proximal to the second distal end. The second cannula is disposed co-axially with the first cannula. A least one of the first aperture and the second aperture has a cutting edge. The driver unit is configured for releasably mounting the probe assembly. The driver unit is operatively configured to simultaneously rotate the first cannula and the second cannula in opposite rotational directions at different rotational velocities so that the first aperture and the second aperture periodically come into alignment to form a virtual tissue sample aperture.

[0007] The invention, in another form thereof, is directed to a biopsy device including a probe assembly and a driver unit. The probe assembly includes a first cannula having a first side wall defining a first lumen. The first cannula has a first proximal end and a first distal end. The first cannula has a first aperture extending through the first side wall to the first lumen proximal to the first distal end. The first cannula has a longitudinal axis. A second cannula has a second side wall defining a second lumen. The second cannula has a second proximal end and a second distal end. The second cannula has a second aperture extending through the second side wall to the second lumen proximal to the second distal end. The second cannula is disposed co-axially with the first cannula. At least one of the first aperture and the second aperture has a cutting edge. The driver unit is configured for releasably mounting the probe assembly. The driver unit is operatively configured to rotate the first cannula in accordance with a first velocity profile and the second cannula in accordance with a second velocity profile to periodically align the first aperture and the second aperture to form a virtual tissue sample aperture at a plurality of angular radial positions relative to the longitudinal axis during a biopsy procedure by continuous simultaneous rotation of both of the first cannula and the second cannula.

[0008] The invention, in another form thereof, is directed to a method for controlling a biopsy device during a biopsy procedure, the biopsy device having a probe assembly with an outer cannula having a distal needle tip and an inner cannula arranged coaxial with the outer cannula with respect to a longitudinal axis, the outer cannula having a first side aperture and the inner cannula having a second side aperture with at least one of the first side aperture and the second side aperture having a cutting edge, and a vacuum source connected in fluid communication with a lumen of the inner cannula and with a tissue sample receptacle. The method includes positioning each of the outer cannula and the inner cannula at a respective initial rotational position; inserting the probe assembly in a region of a patient to be biopsied; establishing continuous simultaneous rotation of the outer cannula in accordance with a first velocity profile and the inner cannula in accordance with a second velocity profile to periodically align the first side aperture and the second side aperture to form a virtual tissue sample aperture at a plurality of angular radial positions relative to the longitudinal axis; establishing a supply of negative pressure in the lumen of the inner cannula, such that each time the virtual tissue sample aperture is formed tissue is pulled through the virtual tissue sample aperture into the lumen of the inner cannula, and thereafter the first side aperture and the second side aperture cooperate to sever the tissue that is pulled into the inner cannula as the virtual tissue sample aperture is closed by the continuous simultaneous rotation of the outer cannula and the inner cannula, each tissue sample so severed being transported through the lumen of the inner cannula by the negative pressure to a tissue sample receptacle; and ceasing the continuous simultaneous rotation of the outer cannula and the inner cannula after all desired tissue samples have been harvested.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0010] Fig. 1 is a pictorial illustration of a biopsy device including a probe assembly and driver unit, configured in accordance with an embodiment of the present invention.

[0011] Fig. 2A is an exploded view of the probe assembly of Fig. 1.

[0012] Fig. 2B is a cross-section view of the outer cannula of Fig. 2A taken along line 2B-2B.

[0013] Fig. 2C is a cross-section view of the inner cannula of Fig. 2A taken along line 2C-2C.

[0014] Fig. 3 is an assembled view of the probe assembly of Fig. 2A having the respective apertures of the outer cannula and inner cannula in alignment.

[0015] Fig. 4 is a cross-section view of the probe assembly of Fig. 3 taken along line 4-4, showing tissue being drawn through a virtual tissue sample aperture.

[0016] Fig. 5 is a cross-section view of the probe assembly of Fig. 1 taken along line 5-5.

[0017] Fig. 6A is an exploded view of another embodiment for a probe assembly suitable for use in the biopsy device of Fig. 1.

[0018] Fig. 6B is a cross-section view of the outer cannula of Fig. 6A taken along line 6B-6B.

[0019] Fig. 6C is a cross-section view of the inner cannula of Fig. 6A taken along line 6C-6C.

[0020] Fig. 7 is an assembled view of the probe assembly of Fig. 6A having the respective apertures of the outer cannula and inner cannula in alignment.

[0021] Fig. 8 is a graphical representation of exemplary velocity profiles for the outer cannula and the inner cannula of Fig. 1.

[0022] Fig. 9 is a graphical representation of the formation of a virtual tissue sample aperture at each of a plurality of angular radial positions.

[0023] Fig. 10 is a pictorial illustration of another embodiment of a biopsy device including a probe assembly and driver unit, configured in accordance with an embodiment of the present invention.

[0024] Fig. 11 is a graphical representation of exemplary velocity profiles for the outer cannula and the inner cannula in the embodiment of Fig. 10.

[0025] Fig. 12 is a flowchart of a method for controlling a biopsy device, such as the biopsy device of Fig. 1.

[0026] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate embodiments of the invention, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DETAILED DESCRIPTION OF THE INVENTION

[0027] Referring now to the drawings and particularly to Fig. 1, there is shown a biopsy device 10 configured in accordance with an embodiment of the present invention. Biopsy device 10 includes a probe assembly 12, a driver unit 14, and a vacuum source 16.

[0028] Referring also to Figs. 2A-2C, 3, 4, and 5, probe assembly 12 includes an outer cannula 18 and an inner cannula 20.

[0029] Outer cannula 18 has a first side wall 18-1 defining a first lumen 18-2. Outer cannula 18 has a first proximal end 18-3, a first distal end 18-4, and a first aperture 22 extending through first side wall 18-1 to the first lumen 18-2 at a location proximal to first distal end 18-4. A needle tip 24 is located at first distal end 18-4 of outer cannula 18. A longitudinal axis 26 of probe assembly 12 passes centrally through first lumen 18-2 of outer cannula 18 parallel to a longitudinal extent 18-5 of outer cannula 18.

[0030] Inner cannula 20 is disposed co-axially with outer cannula 18 with respect to longitudinal axis 26. Inner cannula 20 has a second side wall 20-1 defining a second lumen 20-2. Inner cannula 20 has a second proximal end 20-3, a second distal end 20-4, and a second aperture 28 extending through second side wall 20-1 to second lumen 20-2 at a location proximal to second distal end 20-4. Longitudinal axis 26 of probe assembly 12 passes centrally through second lumen 20-2 of inner cannula 20 parallel to a longitudinal extent 20-5 of inner cannula 20.

[0031] Vacuum source 16 is in fluid communication with inner cannula 20 via a fluid conduit 30, and may establish a continuous or intermittent negative pressure in second lumen 20-2 of inner cannula 20.

[0032] In the present embodiment as shown in Figs. 1 and 2, first aperture 22 has a longitudinal edge 22-1 spaced apart from a longitudinal edge 22-2, with a longitudinal extent 22-3 of first aperture 22 being parallel to longitudinal axis 26. Second aperture 28 has a longitudinal edge 28-1 spaced apart from a longitudinal edge 28-2, with a longitudinal extent 28-3 of second aperture 28 being parallel to longitudinal axis 26. At least one of first aperture 22 of outer cannula 18 and second aperture 28 of inner cannula 20 has a cutting edge 32 that is sharpened to razor sharpness. For example, cutting edge 32 may be formed on one or more of longitudinal edges 22-1, 22-2, 28-1 and 28-2. Also, for example, the one or more of longitudinal edges 22-1, 22-2, 28-1 and 28-2 having cutting edge 32 may have an elliptical shape so that cutting edge 32 is correspondingly elliptical to aid in severing tissue.

[0033] Figs. 6A-6C and 7 show another exemplary embodiment for a probe assembly 34 that may be substituted for probe assembly 12. Probe assembly 34 has an outer cannula 36 and an inner cannula 38.

[0034] Outer cannula 36 has a first side wall 36-1 defining a first lumen 36-2. Outer cannula 36 has a first proximal end 36-3, a first distal end 36-4, and a first aperture 40 extending through first side wall 36-1 to the first lumen 36-2 at a location proximal to first distal end 36-4. Needle tip 24 is located at first distal end 36-4 of outer cannula 36. Longitudinal axis 26 of probe assembly 34 passes centrally through first lumen 36-2 of outer cannula 36.

[0035] Inner cannula 38 is disposed co-axially with outer cannula 36 with respect to longitudinal axis 26. Inner cannula 38 has a second side wall 38-1 defining a second lumen 38-2. Inner cannula 38 has a second proximal end 38-3, a second distal end 38-4, and a second aperture 42 extending through second side wall 38-1 to second lumen 38-2 at a location proximal to second distal end 38-4. Longitudinal axis 26 of probe assembly 34 passes centrally through second lumen 38-2 of inner cannula 38.

[0036] Probe assembly 34 differs from probe assembly 12 only in the shape of apertures 40 and 42 relative to apertures 22, 28. Aperture 40 of outer cannula 36 has a longitudinal edge 40-1 spaced apart from a longitudinal edge 40-2, with a longitudinal extent 40-3 of aperture 40 being non-parallel, i.e., angled, with respect to longitudinal axis 26 at a first direction 40-4. Aperture 42 of inner cannula 38 has a longitudinal edge 42-1 spaced apart from a longitudinal edge 42-2, with a longitudinal extent 42-3 of aperture 42 being non-parallel, i.e., angled, with respect to longitudinal axis 26 in a second direction 42-4 that intersects first direction 40-4 of aperture 40.

[0037] At least one of first aperture 40 of outer cannula 36 and second aperture 42 of inner cannula 38 has a cutting edge 44 that is sharpened to razor sharpness. For example, cutting edge 44 may be formed on one or more of longitudinal edges 40-1, 40-2, 42-1 and 42-2. The angled extent of the one or more of longitudinal edges 40-1, 40-2, 42-1 and 42-2 having cutting edge 44 aids in severing tissue.

[0038] Referring again to Figs. 1, 2A and 6A, driver unit 14 is configured for releasably mounting probe assembly 12 or probe assembly 34. For brevity, unless otherwise indicated, the discussions that follow will describe the invention with reference to the components of probe assembly 12. However, it is to be understood that the discussion as applied to probe

assembly 12 may be easily applied to the use of probe assembly 34 as a substitute for probe assembly 12, and thus for brevity will not be repeated.

[0039] Referring to Figs. 1-5, driver unit 14 is operatively configured to simultaneously rotate outer cannula 18 and inner cannula 20, which in one exemplary implementation are rotated in opposite rotational directions at different rotational velocities so that first aperture 22 and second aperture 28 periodically come into alignment to form a virtual tissue sample aperture 46, as illustrated in Figs. 3 and 4. As more fully described below, virtual tissue sample aperture 46 may be formed at a plurality of angular radial positions relative to longitudinal axis 26 during a biopsy procedure by continuous simultaneous rotation of both of outer cannula 18 and inner cannula 20.

[0040] In the present embodiment, as shown in Figs. 3 and 4, a maximum opening size of virtual tissue sample aperture 46 is equal to the smaller of a respective opening size for each of first aperture 22 of outer cannula 18 and second aperture 28 of inner cannula 20. In some implementations, it may be desirable for first aperture 22 and second aperture 28 to be of substantially the same size.

[0041] Each time a virtual tissue sample aperture 46 is formed, negative pressure established in second lumen 20-2 of inner cannula 20 by vacuum source 16 pulls surrounding tissue 48 that is adjacent to virtual tissue sample aperture 46 into inner cannula 20. Grooves or channels (not shown) may be placed in inner cannula 20 to allow vacuum to reach both sides of the tissue collection area in second lumen 20-2. Thereafter, the first aperture 22 of outer cannula 18 and second aperture 28 of inner cannula 20 cooperate to sever tissue 48 that is pulled into inner cannula 20 as virtual tissue sample aperture 46 is closed by the continued simultaneous rotation of outer cannula 18 and inner cannula 20. Each tissue sample so severed is transported through the second lumen 20-2 of inner cannula 20 by the negative pressure to a tissue sample receptacle 49.

[0042] In the embodiment shown in Figs. 6A-6C, with further reference to Fig. 7, probe assembly 34 including outer cannula 36 and inner cannula 38 may be installed on driver unit 14, and in a one implementation outer cannula 36 and inner cannula 38 may be rotated in opposite rotational directions at different rotational velocities so aperture 40 and aperture 42 periodically come into alignment to form a virtual tissue sample aperture 50, as illustrated in Fig. 7. In this embodiment as shown in Figs. 6A-7, however, a maximum opening size of virtual tissue sample aperture 50 is less than an opening size of either of aperture 40 of outer cannula 36 and aperture 42 of inner cannula 38.

[0043] It is contemplated that other shapes may be used for the respective apertures, such as polygonal, circles, ellipses or combinations thereof.

[0044] Referring again to Figs. 1-5, driver unit 14 includes a first drive mechanism 52, a second drive mechanism 54, a motor 56, a controller 58 and a user interface 60. First drive mechanism 52 is configured for drivable engagement with outer cannula 18 to rotate outer cannula 18 of probe assembly 12 at a first rotational velocity in a first rotational direction 62. Second drive mechanism 54 is configured for drivable engagement with the inner cannula 20 of probe assembly 12 to rotate inner cannula 20 at a second rotational velocity different from the first rotational velocity in a second rotational direction 64, opposite to the first rotational direction 62, simultaneously with the rotation of outer cannula 18.

[0045] More particularly, in the present embodiment as shown in Figs. 1-3, a first gear 66 is fixedly attached to outer cannula 18 for rotation about longitudinal axis 26. A second gear 68 is fixedly attached to inner cannula 20 for rotation about longitudinal axis 26. First drive mechanism 52 may be in the form of a first gear drive mechanism 70 engaged first gear 66. Second drive mechanism 54 may be in the form of a second gear drive mechanism 72 engaged with second gear 68. Motor 56, such as a D.C. motor, is drivably coupled to each of first drive mechanism 52 (and in turn first gear drive mechanism 70) and second drive mechanism 54 (and in turn second gear drive mechanism 72).

[0046] In the present embodiment having a single motor 56 common to first drive mechanism 52 and second drive mechanism 54, the rotational velocity differences and rotational directions associated with outer cannula 18 and inner cannula 20, and in turn the angular radial positions of the formation of virtual tissue sample aperture 46 for harvesting the tissue samples, are predefined by the gearing in the gear drive mechanisms 70, 72 respectively of first drive mechanism 52 and second drive mechanism 54.

[0047] Controller 58 is communicatively coupled to user interface 60, such as a keypad, touch screen, foot-pedal, etc., and may be used to receive user input, such as the desired number of tissue samples to be taken, and to display status. Also, controller 58 is communicatively coupled to motor 56 and controls the speed of motor 56 in accordance with a motor velocity profile 74. As such, referring now also to Fig. 8, controller 58 is configured to control motor 56 to effect rotation of outer cannula 18 in accordance with a first velocity profile 76 and to effect rotation of inner cannula 20 in accordance with a second velocity profile 78.

[0048] In the present example, as illustrated in Fig. 8, the velocity magnitude of inner cannula 20 subject to velocity profile 78 is three times the velocity magnitude of outer cannula 18 subject to velocity profile 76, with outer cannula 18 and inner cannula 20 rotating in opposite directions. Accordingly, as illustrated in Fig. 9, a complete continuous rotation of outer cannula 18 as illustrated by waveform 79 from an initial position 80 (see also Fig. 5) to a final position 82 (see also Fig. 5), and a simultaneous counter rotation of inner cannula 20 at three times the velocity of that of outer cannula 18 as illustrated by waveform 83 from initial position 80 to a final position 82, results in the formation of a plurality of virtual tissue sample apertures 46 (see Figs. 3 and 4), which in the present example virtual tissue sample apertures 46-1, 46-2, 46-3 and 46-4 are formed at angular radial positions relative to longitudinal axis 26 offset from one another at 90 degrees of rotation of outer cannula 18, resulting in four samples being harvested within one rotation of outer cannula 18. More particularly, in the example shown in Fig. 9, a virtual tissue sample aperture 46-1 is formed at 0 degrees, a virtual tissue sample aperture 46-2 is formed at 90 degrees, a virtual tissue sample aperture 46-3 is formed at 180 degrees and a virtual tissue sample aperture 46-4 is formed at 270 degrees.

[0049] Referring again to Fig. 8, first velocity profile 76 and second velocity profile 78 include an acceleration 84 of outer cannula 18 and an acceleration 86 of inner cannula 20, in their respective directions of rotation 62, 64, to facilitate an increase in rotational velocity during the onset of tissue cutting, e.g., immediately following the formation of each respective virtual tissue sample aperture 46, to enhance the start of tissue cutting.

[0050] Thus, controller 58 may be configured to execute a velocity profile, e.g., motor velocity profile 74, first velocity profile 76 and/or second velocity profile 78, that provides a variable rotational velocity for at least one of outer cannula 18 and inner cannula 20 during continuous simultaneous rotation of outer cannula 18 and inner cannula 20. The velocity profile provides an increase in velocity of at least one of outer cannula 18 and inner cannula 20 as virtual tissue sample aperture 46 begins to close to sever the tissue.

[0051] Fig. 10 shows an alternative embodiment for the driver unit 14 of Fig. 1, and is referenced as driver unit 88. Driver unit 88 differs from driver unit 14 in that first drive mechanism 52 is driven by a first motor 90-1 and second drive mechanism 54 is driven by a second motor 90-2. Each motor 90-1 and 90-2 is separately coupled to controller 58 for independent control thereof, thus facilitating more design options with respect to the velocity profiles used in controlling the rotation of outer cannula 18 and inner cannula 20.

[0052] For example, referring also to Fig. 11, controller 58 is configured to control motor 90-1 to effect rotation of outer cannula 18 in accordance with a first velocity profile 92 and is configured to control motor 90-2 to effect rotation of inner cannula 20 in accordance with a second velocity profile 94. On average, as shown in Fig. 11, the velocity magnitude of inner cannula 20 subject to velocity profile 94 is three times the velocity magnitude of outer cannula 18 subject to velocity profile 92, with outer cannula 18 and inner cannula 20 rotating in opposite directions.

[0053] In the present example, however, first velocity profile 92 provides for the rotation of outer cannula 18 at a constant velocity. Second velocity profile 94 provides for both acceleration 96, and offsetting deceleration 98, to maintain on average the velocity magnitude of inner cannula 20 at three times the velocity magnitude of outer cannula 18. Accordingly, as illustrated in Figs. 10 and 11, with further reference to Fig. 8, a complete continuous rotation of outer cannula 18 from initial position 80 to final position 82, and a simultaneous counter rotation of inner cannula at an average of three times the velocity of that of outer cannula 18 from initial position 80 to a final position 82, results in the formation of a plurality of virtual tissue sample apertures 46, which in the present example virtual tissue sample apertures 46-1, 46-2, 46-3 and 46-4 are formed at angular radial positions relative to longitudinal axis 26 offset from one another at 90 degrees of rotation of outer cannula 18, resulting in four samples being harvested within one rotation of outer cannula 18. Thus, in the present example a virtual tissue sample aperture 46-1 is formed at 0 degrees, a virtual tissue sample aperture 46-2 is formed at 90 degrees, a virtual tissue sample aperture 46-3 is formed at 180 degrees and a virtual tissue sample aperture 46-4 is formed at 270 degrees.

[0054] Since each motor 90-1 and 90-2 is separately coupled to controller 58 for independent control thereof, and in turn providing independent control of outer cannula 18 and inner cannula 20, the flexibility exists such that the respective velocity profiles for outer cannula 18 and inner cannula 20 may be modified to provide an equal magnitude of velocity for outer cannula 18 and inner cannula 20 as virtual tissue sample aperture 46 begins to close to sever the tissue, if desired.

[0055] Also, the flexibility exists such that the respective velocity profiles for outer cannula 18 and inner cannula 20 may be modified to provide a change in rotational velocity of at least one of outer cannula 18 and inner cannula 20 to define a next angular radial position of a next formation of virtual tissue sample aperture 46. For example, changes to the rotational velocities of outer cannula 18 and inner cannula 20 during the absence of a virtual tissue

sample aperture, i.e., while the virtual tissue sample aperture is closed, can orient outer cannula 18 and inner cannula 20 to effect a new desired angular radial position of the virtual tissue sample aperture.

[0056] Accordingly, in view of the above, those skilled in the art will recognize that by varying the rotational velocity differences between the rotational velocity of outer cannula 18 and the rotational velocity of inner cannula 20, more or less samples may be taken than in the example above. Further, while the example above provides for multiple samples within one revolution of outer cannula 18, velocity profiles may be generated to provide for the harvesting of samples over multiple rotations of outer cannula 18. Also, while in the examples discussed above outer cannula 18 rotates at a slower velocity than inner cannula 20, it is possible to harvest samples using the opposite approach, i.e., with the outer cannula 18 having the higher rotational velocity than inner cannula 20. Still further, while the examples provided above provide for sequential sampling, it is contemplated that more complex velocity profiles may be generated to facilitate non-sequential sampling during one or more rotations of the cannula that has the slower rotational velocity.

[0057] Fig. 12 is a flowchart of a method for controlling a biopsy device, such as biopsy device 10, during a biopsy procedure, with reference to the embodiment of Figs. 1-5.

[0058] At act S100, each of outer cannula 18 and inner cannula 20 is positioned at a respective initial rotational position 80 (see Figs. 5 and 9). The respective initial rotational position of outer cannula 18 and inner cannula 20 is selected such that first aperture 22 and second aperture 28 are not in alignment such that the virtual tissue sample aperture is not formed prior to insertion of said probe assembly into the patient.

[0059] At act S102, probe assembly 12, e.g., the distal ends of outer cannula 18 and inner cannula 20, is inserted in a region of a patient to be biopsied. The region may be, for example, breast tissue.

[0060] At act S104, continuous simultaneous rotation of outer cannula 18 in accordance with a first velocity profile and inner cannula 20 in accordance with a second velocity profile is established to periodically align first side aperture 22 and second side aperture 28 to form a virtual tissue sample aperture 46 at a plurality of angular radial positions relative to longitudinal axis 26 (see Figs. 4 and 9). In the present embodiment, for example, outer cannula 18 and inner cannula 20 are rotated in opposite rotational directions 62, 64.

[0061] At act S106, a supply of negative pressure is established in lumen 20-2 of inner cannula 20, such that each time the virtual tissue sample aperture 46 is formed, tissue 48 is

pulled through virtual tissue sample aperture 46 into lumen 20-2 of inner cannula 20, as illustrated in Fig. 4, and thereafter first side aperture 22 and second side aperture 28 cooperate to sever tissue 48 that is pulled into inner cannula 20 as virtual tissue sample aperture 46 is closed by the continuous simultaneous rotation of the outer cannula 18 and inner cannula 20 (see, e.g., Fig. 5 depicting a closed orientation). The supply of negative pressure may be continuous or intermittent. Thus, advantageously, biopsy device 10 severs the tissue sample during the tissue sample acquisition process. Each tissue sample so severed is transported through lumen 20-2 of inner cannula 20 by the negative pressure provided by vacuum source 16 to tissue sample receptacle 49.

[0062] At act S108, the continuous simultaneous rotation of outer cannula 18 and inner cannula 20 is ceased after all desired tissue samples have been harvested. The end of the continuous simultaneous rotation of outer cannula 18 and inner cannula 20 is selected to coincide with a final position 82 (see Figs. 5 and 9) wherein first side aperture 22 and second side aperture 28 are not in alignment, such that prior to removal of probe assembly 12 from the patient the virtual tissue sample aperture 46 is not again formed.

[0063] While this invention has been described with respect to embodiments of the invention, the present invention may be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

CLAIMS

What is claimed is:

1. A biopsy device, comprising:

a probe assembly including:

a first cannula having a first side wall defining a first lumen, said first cannula having a first proximal end and a first distal end, said first cannula having a first aperture extending through said first side wall to said first lumen proximal to said first distal end, said first cannula having a longitudinal axis, and

a second cannula having a second side wall defining a second lumen, said second cannula having a second proximal end and a second distal end, said second cannula having a second aperture extending through said second side wall to said second lumen proximal to said second distal end, said second cannula being disposed co-axially with said first cannula,

at least one of said first aperture and said second aperture having a cutting edge; and

a driver unit configured for releasably mounting said probe assembly, said driver unit being operatively configured to simultaneously rotate said first cannula and said second cannula in opposite rotational directions at different rotational velocities so that said first aperture and said second aperture periodically come into alignment to form a virtual tissue sample aperture.

2. The biopsy device of claim 1 or claim 2, said first cannula being an outer cannula having a needle tip located at said first distal end, and said second cannula being an inner cannula positioned in said first lumen of said outer cannula, said biopsy device further comprising a vacuum source in fluid communication with the inner cannula to pull tissue by negative pressure into said inner cannula each time said virtual tissue sample aperture is formed, said first aperture and said second aperture cooperating to sever said tissue that is pulled into said inner cannula as said virtual tissue sample aperture is closed by continued rotation of said outer cannula and said inner cannula.

3. The biopsy device of claim 1 or claim 2, wherein said virtual tissue sample aperture is formed at a plurality of angular radial positions relative to said longitudinal axis

during a biopsy procedure by continuous simultaneous rotation of both of said first cannula and said second cannula.

4. The biopsy device of claim 3, wherein said second cannula is positioned in said first lumen of said first cannula, said biopsy device further comprising a vacuum source in fluid communication with the second cannula to provide a supply of negative pressure in said second lumen of said second cannula, and wherein during a biopsy procedure each time said virtual tissue sample aperture is formed tissue is pulled into said second lumen of said second cannula, and thereafter said first aperture and said second aperture cooperating to sever said tissue that is pulled into said inner cannula as said virtual tissue sample aperture is closed by said continuous simultaneous rotation of said first cannula and said second cannula, each tissue sample so severed being transported through said second lumen of said second cannula by said negative pressure to a tissue sample receptacle.

5. The biopsy device of claim 4, said driver unit including a controller configured to execute a velocity profile that provides a variable rotational velocity for at least one of said first cannula and said second cannula during said continuous simultaneous rotation of said first cannula and said second cannula.

6. The biopsy device of claim 5, wherein said velocity profile provides an increase in velocity of at least one of said first cannula and said second cannula as said virtual tissue sample aperture begins to close to sever said tissue.

7. The biopsy device of claim 5, wherein said velocity profile provides an equal magnitude of velocity for said first cannula and said second cannula as said virtual tissue sample aperture begins to close to sever said tissue.

8. The biopsy device of claim 5, wherein said velocity profile provides a change in rotational velocity of at least one of said first cannula and said second cannula to define a next angular radial position of a next formation of said virtual tissue sample aperture.

9. The biopsy device of any preceding claim, said driver unit including a controller configured to execute a velocity profile that provides a variable rotational velocity for at least

one of said first cannula and said second cannula during continuous simultaneous rotation of said first cannula and said second cannula.

10. The biopsy device of claim 9, wherein said velocity profile provides an increase in rotational velocity of at least one of said first cannula and said second cannula as said virtual tissue sample aperture begins to close.

11. The biopsy device of claim 9, wherein said velocity profile provides an equal magnitude of velocity for said first cannula and said second cannula as said virtual tissue sample aperture begins to close.

12. The biopsy device of claim 9, wherein said velocity profile provides a change in rotational velocity of at least one of said first cannula and said second cannula to define a next angular radial position of a next formation of said virtual tissue sample aperture.

13. The biopsy device of any preceding claim, said driver unit including:
a first drive mechanism configured for drivable engagement with the first cannula to rotate said first cannula at a first rotational velocity in a first rotational direction; and
a second drive mechanism configured for drivable engagement with the second cannula, said second drive mechanism being configured to rotate said second cannula at a second rotational velocity different from said first rotational velocity in a second rotational direction, opposite to said first rotational direction, simultaneously with the rotation of said first cannula.

14. The biopsy device of claim 13, wherein said first drive mechanism and said second drive mechanism has a motor associated therewith, said driver unit further including a controller communicatively coupled to said motor, said controller being configured to control said motor to effect rotation of said first cannula in accordance with a first velocity profile and to effect rotation of said second cannula in accordance with a second velocity profile.

15. The biopsy device of claim 13, wherein said first driving mechanism has a first motor and said second driving mechanism has a second motor, said driver unit further including a controller communicatively coupled to said first motor and said second motor,

said controller being configured to control said first motor to effect rotation of said first cannula in accordance with a first velocity profile and to control said second motor to effect rotation of said second cannula in accordance with a second velocity profile.

16. The biopsy device of claim 1 or claim 2, comprising:

a first gear fixedly attached to said first cannula for rotation about said longitudinal axis;

a second gear fixedly attached to said second cannula for rotation about said longitudinal axis; and

said drive unit including:

a first gear drive mechanism engaged said first gear;

a second gear drive mechanism engaged with said second gear;

a motor drivably coupled to each of said first gear drive mechanism and said second gear drive mechanism; and

a controller communicatively coupled to said motor, said controller being configured to control said motor to effect rotation of said first cannula in accordance with a first velocity profile and to effect rotation of said second cannula in accordance with a second velocity profile.

17. The biopsy device of any preceding claim, wherein a longitudinal extent of said first aperture is parallel to said longitudinal axis, and a longitudinal extent of said second aperture is parallel to said longitudinal axis, such that a maximum opening size of said virtual tissue sample aperture is equally to the smaller of a respective opening size for each of said first aperture and said second aperture.

18. The biopsy device of claim 17, wherein at least said first aperture is elliptical and said cutting edge is formed along said longitudinal extent of said first aperture.

19. The biopsy device of any one of claims 1 to 16, wherein a longitudinal extent of said first aperture is angled in a first direction relative to said longitudinal axis, and a longitudinal extent of said second aperture is angled in a second direction relative to said longitudinal axis that intersects said first direction, such that a maximum opening size of said

virtual tissue sample aperture is less than an opening size or either of said first aperture and said second aperture.

20. The biopsy device of claim 19, wherein said cutting edge is formed along said longitudinal extent of said first aperture.

21. A biopsy device, comprising:

a probe assembly including:

a first cannula having a first side wall defining a first lumen, said first cannula having a first proximal end and a first distal end, said first cannula having a first aperture extending through said first side wall to said first lumen proximal to said first distal end, said first cannula having a longitudinal axis, and

a second cannula having a second side wall defining a second lumen, said second cannula having a second proximal end and a second distal end, said second cannula having a second aperture extending through said second side wall to said second lumen proximal to said second distal end, said second cannula being disposed co-axially with said first cannula,

at least one of said first aperture and said second aperture having a cutting edge; and

a driver unit configured for releasably mounting said probe assembly, said driver unit being operatively configured to rotate said first cannula in accordance with a first velocity profile and said second cannula in accordance with a second velocity profile to periodically align said first aperture and said second aperture to form a virtual tissue sample aperture at a plurality of angular radial positions relative to said longitudinal axis during a biopsy procedure by continuous simultaneous rotation of both of said first cannula and said second cannula.

22. The biopsy device of claim 21, wherein said first cannula and said second cannula are rotated in opposite rotational directions.

23. The biopsy device of claim 21, wherein said second cannula is positioned in said first lumen of said first cannula, said biopsy device further comprising a vacuum source in fluid communication with the second cannula to provide a source of negative pressure in said

second lumen of said second cannula, and wherein during said biopsy procedure each time said virtual tissue sample aperture is formed tissue is pulled into said second lumen of said second cannula, and thereafter said first aperture and said second aperture cooperating to sever said tissue that is pulled into said inner cannula as said virtual tissue sample aperture is closed by said continuous simultaneous rotation of said first cannula and said second cannula, each tissue sample so severed being transported through said second lumen of said second cannula by said negative pressure to a tissue sample receptacle.

24. A method for controlling a biopsy device during a biopsy procedure, said biopsy device having a probe assembly with an outer cannula having a distal needle tip and an inner cannula arranged coaxial with said outer cannula with respect to a longitudinal axis, said outer cannula having a first side aperture and said inner cannula having a second side aperture with at least one of said first side aperture and said second side aperture having a cutting edge, and a vacuum source connected in fluid communication with a lumen of said inner cannula and with a tissue sample receptacle, comprising:

positioning each of said outer cannula and said inner cannula at a respective initial rotational position;

inserting said probe assembly in a region of a patient to be biopsied;

establishing continuous simultaneous rotation of said outer cannula in accordance with a first velocity profile and said inner cannula in accordance with a second velocity profile to periodically align said first side aperture and said second side aperture to form a virtual tissue sample aperture at a plurality of angular radial positions relative to said longitudinal axis;

establishing a supply of negative pressure in said lumen of said inner cannula, such that each time said virtual tissue sample aperture is formed tissue is pulled through said virtual tissue sample aperture into said lumen of said inner cannula, thereafter said first side aperture and said second side aperture cooperate to sever said tissue that is pulled into said inner cannula as said virtual tissue sample aperture is closed by said continuous simultaneous rotation of said outer cannula and said inner cannula, each tissue sample so severed being transported through said lumen of said inner cannula by said negative pressure to a tissue sample receptacle; and

ceasing said continuous simultaneous rotation of said outer cannula and said inner cannula after all desired tissue samples have been harvested.

25. The method of claim 24, wherein said outer cannula and said inner cannula are rotated in opposite rotational directions.

26. The method of claim 24, wherein said respective initial rotational position of said outer cannula and said inner cannula is selected such that said first side aperture and said second side aperture are not in alignment such that said virtual tissue sample aperture is not formed prior to insertion of said probe assembly into said patient.

27. The method of claim 24, wherein said continuous simultaneous rotation said outer cannula and said inner cannula is selected to coincide with a final position wherein said first side aperture and said second side aperture are not in alignment, such that said virtual tissue sample aperture is not again formed prior to removal of said probe assembly from said patient.

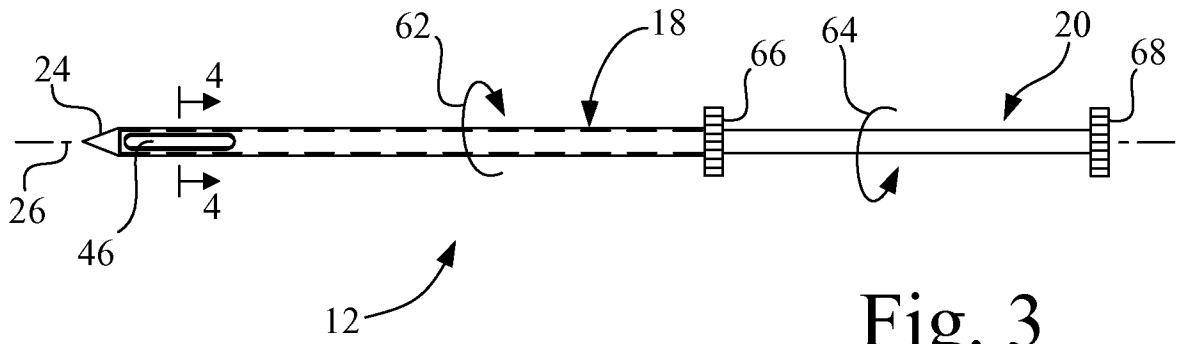


Fig. 3

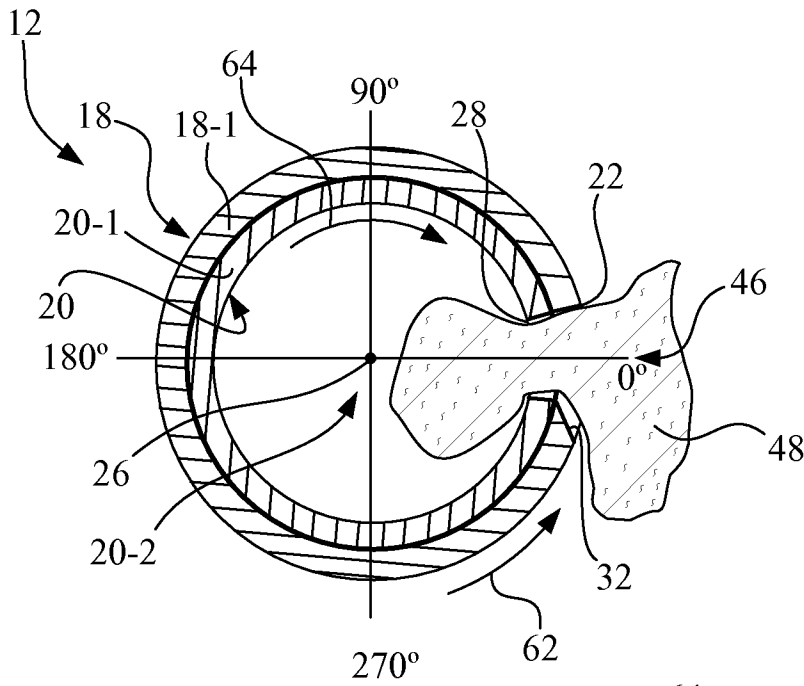


Fig. 4

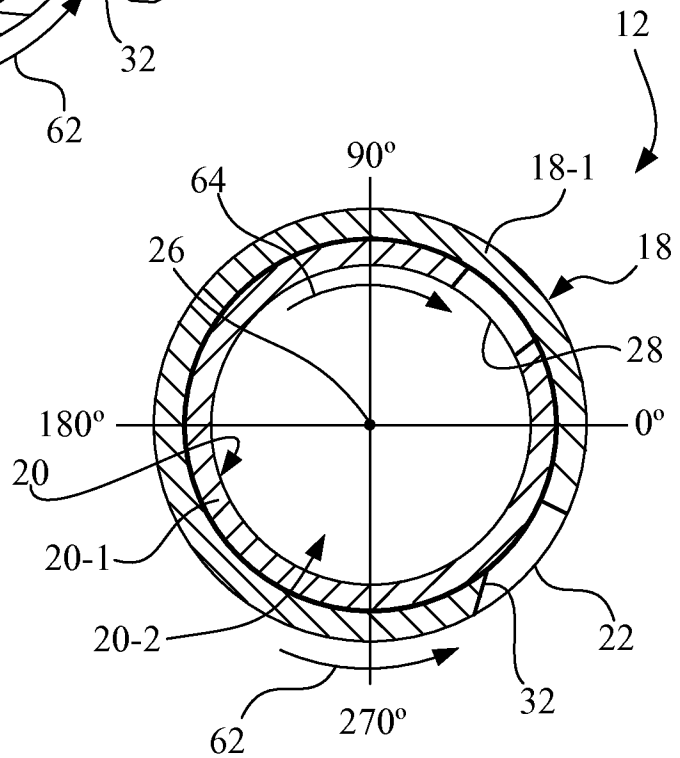


Fig. 5

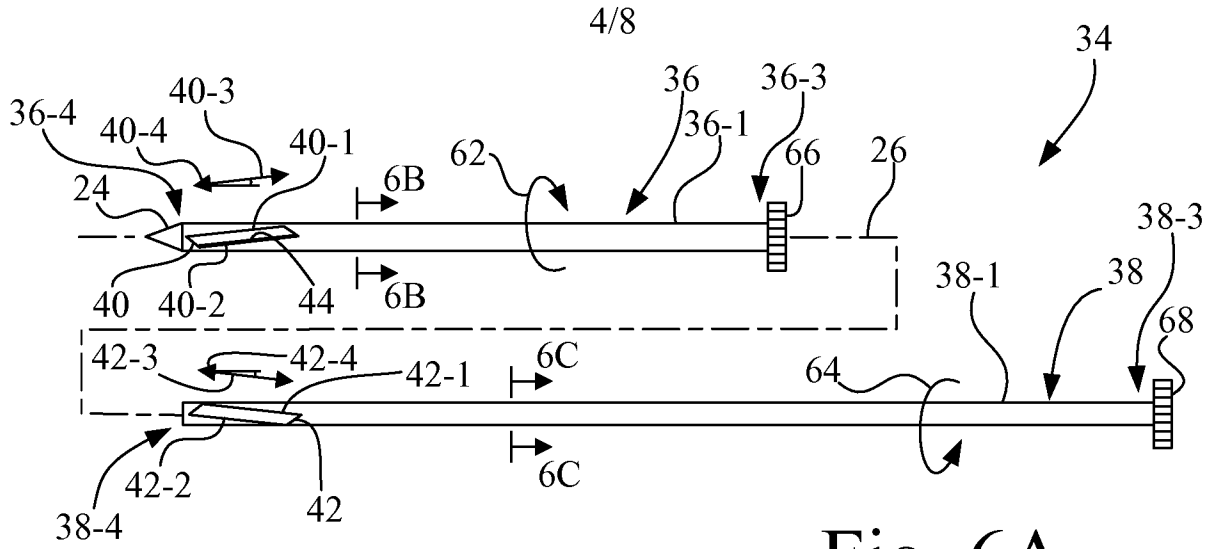


Fig. 6A

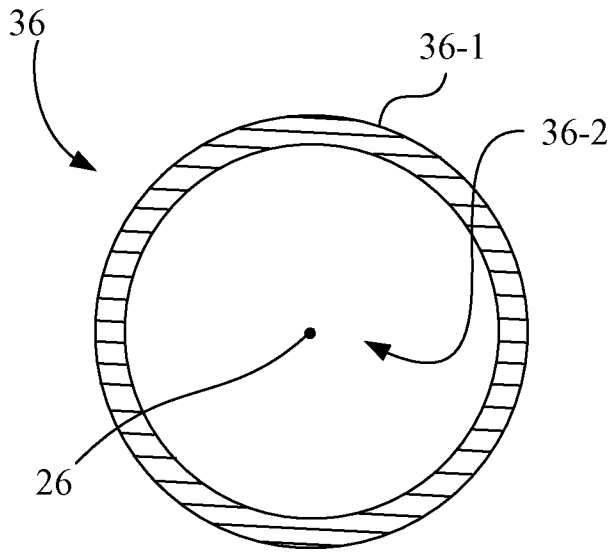


Fig. 6B

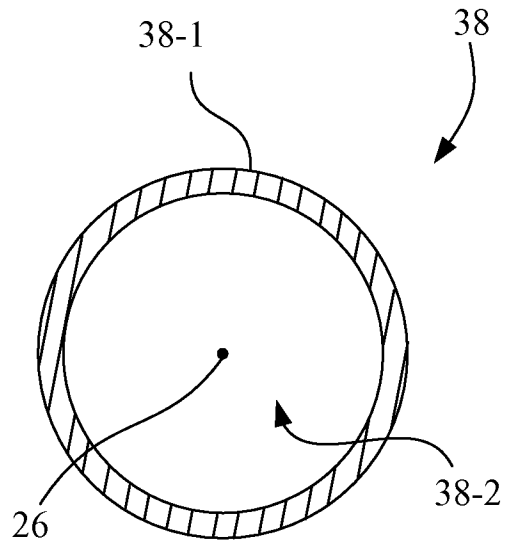


Fig. 6C

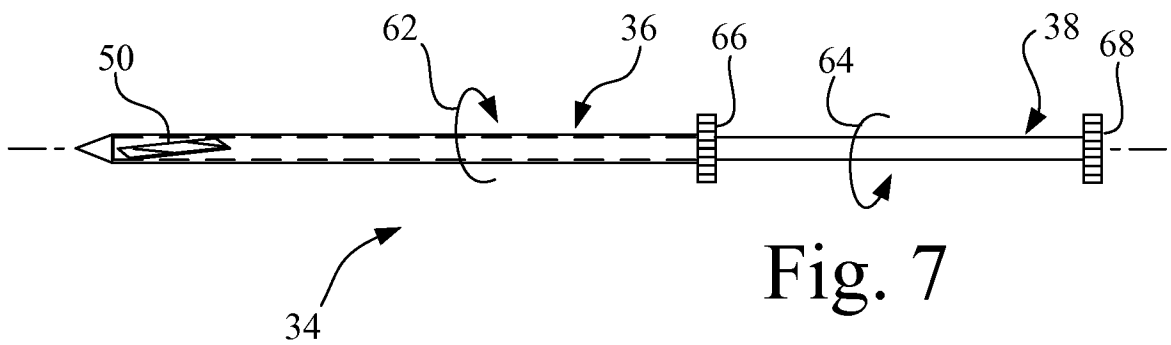


Fig. 7

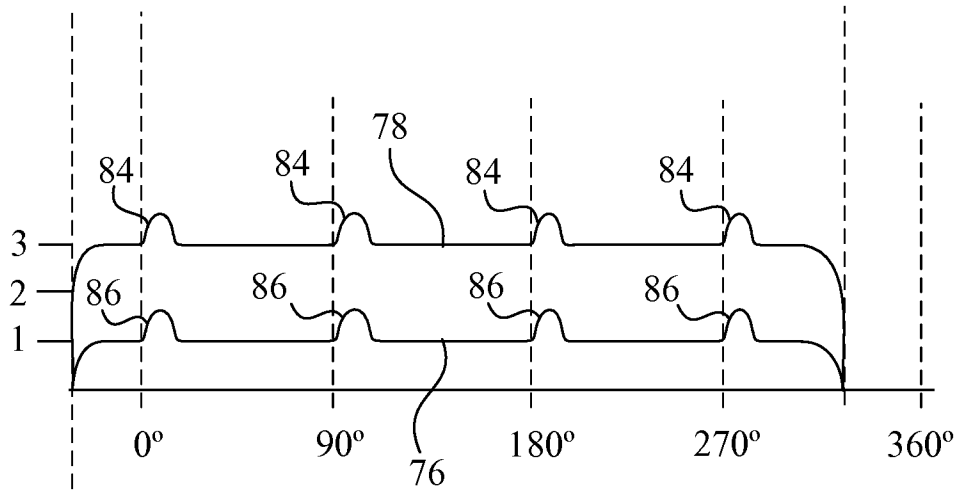


Fig. 8

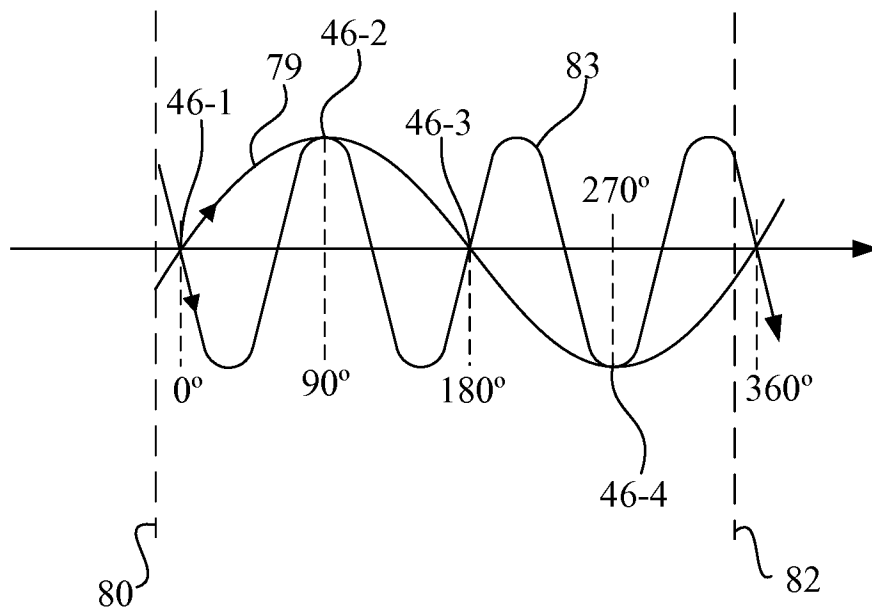


Fig. 9

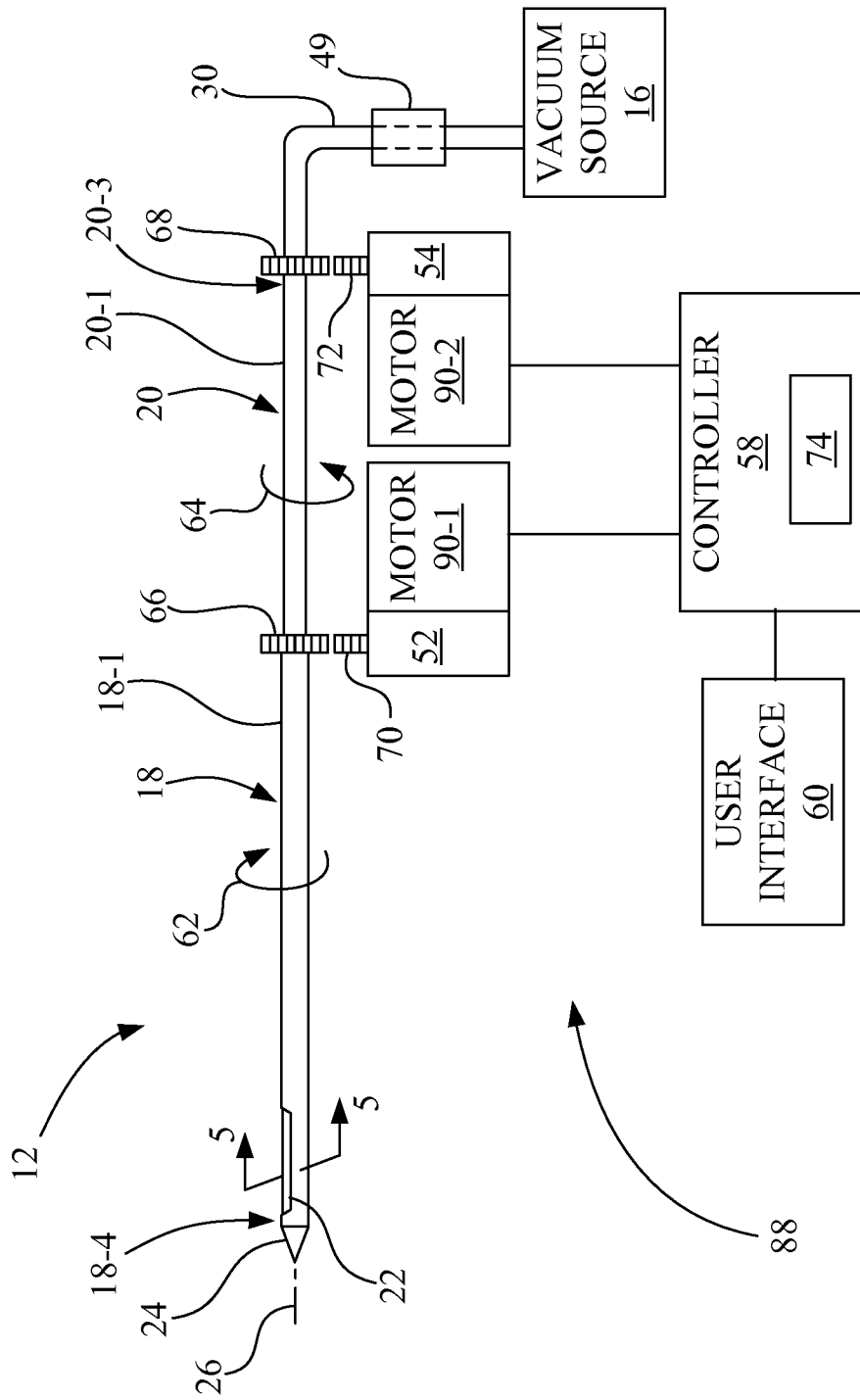


Fig. 10

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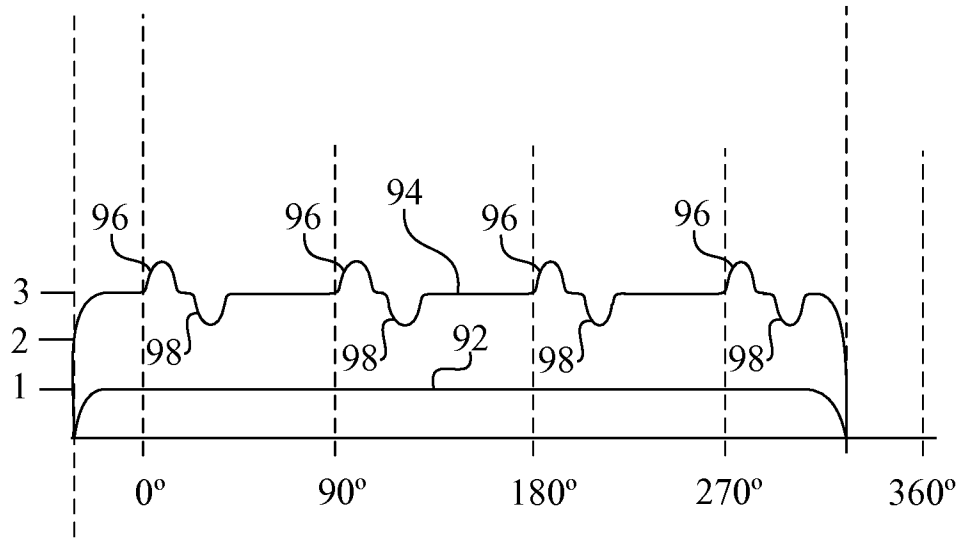


Fig. 11

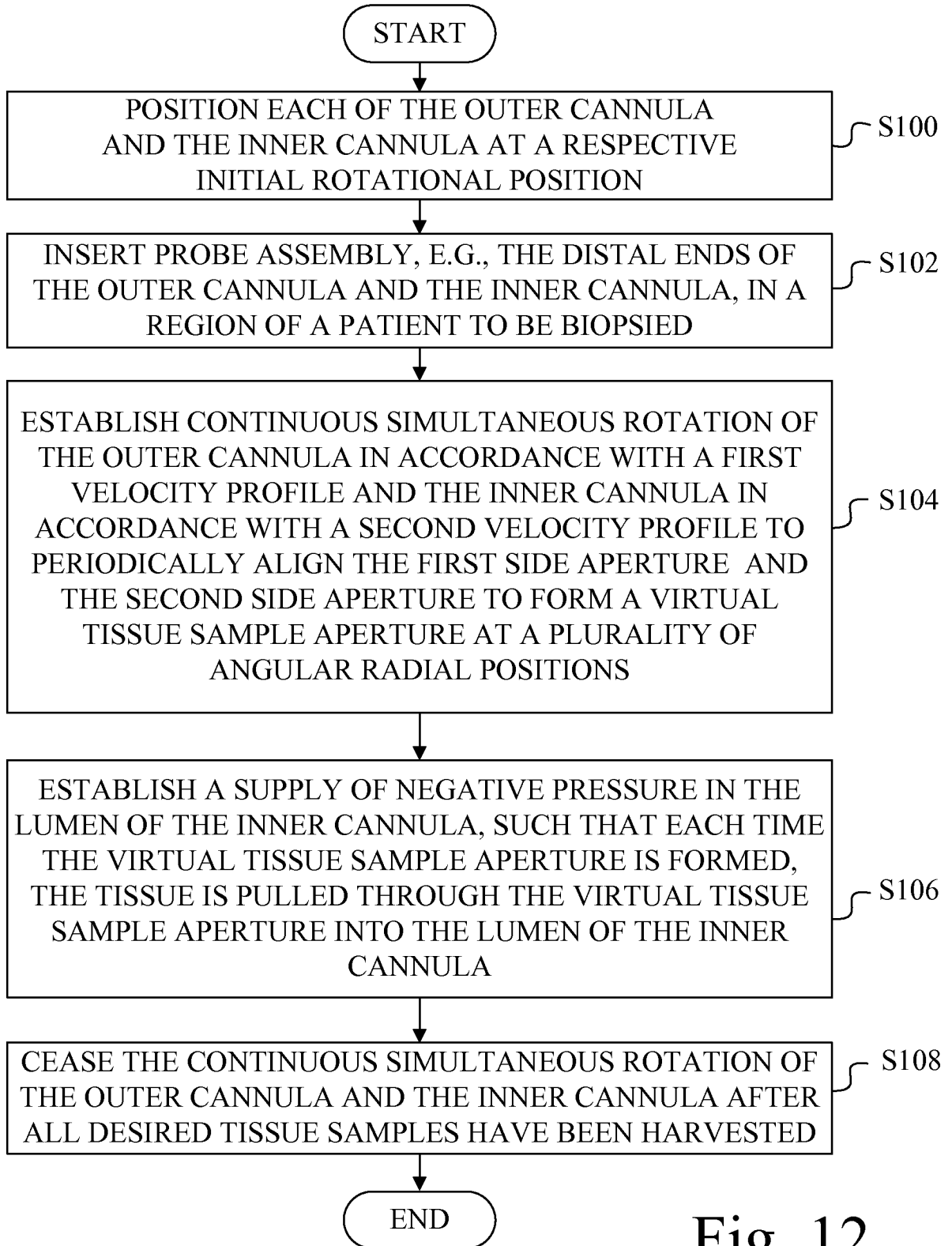


Fig. 12

A. CLASSIFICATION OF SUBJECT MATTER*A61B 10/02(2006.01)i, A61B 17/34(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 10/02, A61B 17/34

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)

eKOMPASS(KIPO internal) & keywords: biopsy, cutting, cannula, aperture, and vacuum

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 05602449 A (KENNETH W. KRAUSE et al.) 11 FEBRUARY 1997 See column 5, line 28 - column 7, line 38; Figures. 6-8.	1,2,21-23
A	US 05769086 A (MARK A. RICHART et al.) 23 JUNE 1998 See column 5, line 3 - column 8, line 31; Figures. 1-12.	1,2,21-23
A	US 06432064 B1 (JOHN A. HIBNER et al.) 13 AUGUST 2002 See column 4, line 26 - column 6, line 67; Figures. 3-14.	1,2,21-23
A	US 05775333 A (FRED H. BURBANK et al.) 7 JULY 1998 See column 13, line 64 - column 19, line 38; Figures. 6A-16.	1,2,21-23

 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

14 DECEMBER 2009 (14.12.2009)

Date of mailing of the international search report

17 DECEMBER 2009 (17.12.2009)

Name and mailing address of the ISA/KR

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

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

1. Claims Nos.: 24-27
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 24-27 pertain to methods for treatment of the human body by surgery, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. Claims Nos.: 4-8, 10-12, 14, 15, 18, 20
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 4-8, 10-12, 14, 15, 18 and 20 are not to make meaningful search, because the claims refer multiple dependent claim.
3. Claims Nos.: 3, 9, 13, 16, 17, 19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2009/037289

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