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# DESCRIPTION

## CROSS-REFERENCE TO RELATED APPLICATION

**[0001]** This application claims the benefit of U.S. Provisional Patent Application No. 61/974,826, titled "METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES", filed April 3, 2014.

## FIELD

**[0002]** The disclosure relates to biopsy procedures and systems. In particular, the disclosure relates to methods, systems, and apparatus useful for planning and performing guided and free-handed transperineal prostate biopsies. The presently claimed invention relates to a system for performing guided and free-handed transperineal prostate biopsies.

## BACKGROUND

**[0003]** A biopsy is a medical procedure that involves sampling and removing tissues or cells from a living body for further examination and analysis. A prostate biopsy may be performed by a care provider for diagnosis and treatment of a patient's prostate. For example, the vast majority of patients with an abnormal prostate specific antigen (PSA) or suspicious results from a digital rectal examination (DRE) undergo biopsy. Typical biopsy procedures include transrectal ultrasound-guided (TRUS) biopsies and transperineal ultrasound-guided (TPUS) biopsies.

**[0004]** TRUS involves obtaining tissue or cell specimens by passing a biopsy needle or other biopsy instruments through the rectal wall and into the prostate at various locations using a sagittal imaging plane. The biopsy needle or other biopsy instruments may be guided by ultrasound in a sagittal plane. There are disadvantages associated with TRUS. In particular, the patient may be required to take antibiotics prior to the procedure to reduce the risk of infections.

Also, TRUS requires the patient to perform bowel preparation, which is a procedure usually undertaken before the biopsy, for cleansing the intestines of fecal matter and secretions. Further, the passage of the biopsy needle through the rectal wall may introduce bacteria from the rectum into the prostate, such as coliform bacteria that may lead to an infection or other complications. Additionally, many clinically significant prostate cancers are found in locations of the prostate that are often too difficult to access when using the transrectal approach.

**[0005]** TPUS includes obtaining tissue or cells specimens by passing one or more biopsy needles through the perineum and into the prostate. TRUS has been favored over TPUS.

Unlike TRUS, TPUS does not require a patient to take antibiotics prior to the procedure or to undergo the bowel preparation for lowering the risk of bacterial issues. Further, TPUS uses a more effective route to access the prostate and is capable of accessing target locations that may be difficult to access utilizing the transrectal approach in comparison with TRUS. In addition, the needle does not pass through the rectal wall which eliminates the risk associated with TRUS of coliform bacteria entering the prostate or the bloodstream.

**[0006]** Systems configured for TPUS include a biopsy grid that may be fixed to, for example, a floor, platform, or table on which the patient receiving the biopsy lies. The biopsy grid may provide multiple apertures through which a biopsy needle or other biopsy instruments may be inserted. An ultrasound probe is fixed directly to the apparatus and is used to axially guide the biopsy needle or other instruments, for example other biopsy instruments. Thus, TPUS systems require imaging in an axial plane of the ultrasound or a transverse transducer for positioning the biopsy needle. US5494039A discloses a biopsy needle insertion guide and method of use with an ultrasound probe in medical procedures to accurately position biopsy needles in internal tissues.

#### **SOME EXAMPLE EMBODIMENTS**

**[0007]** Related art systems and prostate biopsy TPUS methods do not allow free-hand movement of the ultrasound probe, and heavily rely on the axial ultrasound plane to confirm positioning of the biopsy needle or other instruments. Moreover, such systems and methods include extracting prostate tissue specimens by delivering separate punctures into the transperineal tissue. Also, a care provider executing TPUS procedure using related art systems may experience substantial difficulty in freely handling and positioning a biopsy needle at a desired target location of the prostate relying on the sagittal plane in using the TRUS methods.

**[0008]** An apparatus in accordance with an embodiment may include an upper mount and a lower mount. The lower mount may be configured to connect with the upper mount to secure a transrectal probe therebetween. The upper mount may be configured to support an access needle, the access needle configured for perforation of subcutaneous tissue of a perineum at an access site of a target area of a patient. The upper mount may be configured to guide the access needle whereby movement of the access needle is fixed relative to movement of the transrectal probe.

**[0009]** A system in accordance with the presently claimed invention comprises at least the features of claim 1. The system includes a biopsy guide and a transrectal transducer fixed to the biopsy guide. The system also includes an access needle configured to perforate an access site in subcutaneous tissue of a perineum, the access needle being supported by the biopsy guide. The biopsy guide is configured to guide the access needle to perforate an access site in subcutaneous tissue of a perineum, whereby movement of the access needle is fixed relative to a movement of the transrectal transducer. The system also includes a biopsy instrument configured to remove tissue or cells from a prostate, the biopsy instrument

configured to pass through the access needle.

**[0010]** A method of performing a prostate biopsy in accordance with an embodiment may include imaging a prostate in an axial plane and a sagittal plane with a transducer providing a real-time image, locating a target area of the prostate, and positioning an access needle and an access site in subcutaneous tissue of a perineum wherein the access site is at a midpoint between a lateral edge of the prostate and a urethra along a first axis and a midpoint between an anterior capsule and a posterior capsule along a second axis. The method may include guiding a biopsy instrument along a sagittal plane to the target using the real-time image, and obtaining one or more specimens of the prostate through the access needle with a biopsy instrument.

**[0011]** Accordingly, there is a demand for transperineal biopsy methods, systems, and apparatus that enables a biopsy that is less burdensome for the patient and for the practitioner performing the biopsy, increased guidance of needle or other biopsy instruments, and with a higher rate of efficacy and lower rate of health risk than related art TPUS and TRUS systems and methods. Apparatus, systems, and methods disclosed herein satisfy these demands.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0012]** Various exemplary embodiments are illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings in which like reference numerals refer to similar elements and in which:

FIG. 1 shows a side view of a guide secured to a probe in accordance with an embodiment;

FIG. 2A shows an internal view of a guide fastener in accordance with an embodiment;

FIG. 2B shows a sheath-based guide fastener in accordance with an embodiment;

FIG. 2C shows a zip-tie-based guide fastener in accordance with an embodiment;

FIG. 3 shows a top view of a guide secured to a probe in accordance with an embodiment;

FIG. 4 shows a cross-sectional view of the back of a guide secured to a probe in accordance with an embodiment.

FIG. 5 shows a magnified view of a guide secured to a probe in accordance with an embodiment;

FIG. 6 is a magnified top view of a guide fastener in accordance with an embodiment;

FIG. 7 is a magnified view of a guide in accordance with an embodiment;

FIG. 8 is a side view of a biopsy instrument that has penetrated the prostate in accordance with an embodiment;

FIG. 9 is a front view of a designated area of the prostate where a biopsy instrument will penetrate in accordance with an embodiment;

FIG. 10 is a side view of a biopsy instrument penetrating the prostate in accordance with an embodiment;

FIG. 11 is a front view of a designated area of the prostate where a biopsy instrument will penetrate with areas in which the cell or tissue specimen has already been extracted in accordance with an embodiment;

FIG. 12 is a top view of a biopsy instrument that has penetrated the prostate in accordance with an embodiment;

FIG. 13 is a side view of a prostate and the path of the biopsy instrument;

FIG. 14 is a front view of a guide positioned at a designated area of the prostate in accordance with an embodiment;

FIG. 15 is a side view of a guide positioned at a designated area of the prostate in accordance with an embodiment;

FIG. 16 is a front view of a guide positioned at another designated area of the prostate in accordance with an embodiment;

FIG. 17 is a side view of a guide positioned at another designated area of the prostate;

FIG. 18 is a front view of a guide positioned at a higher designated area of the prostate, according to one embodiment;

FIG. 19 is a right side view of a guide positioned at a higher designated area of the prostate in comparison with that shown in FIGS. 14-17 in accordance with an embodiment;

FIG. 20 is a side view of a guide and a biopsy instrument firmly penetrating a fat plane and perineum skin of a patient in accordance with an embodiment;

FIG. 21 is a view of an access needle positioned at the access site in accordance with an embodiment;

FIG. 22 is a magnified view of the right side of a prostate and a biopsy instrument in accordance with an embodiment;

FIG. 23 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas in accordance with an embodiment;

FIG. 24 shows a method for performing a prostate biopsy in accordance with an embodiment;

FIG. 25 is an ultrasound image showing a transducer, access needle path extending from an access point at a perineal site to a prostate, and a prostate; and

FIGs. 26A-26C show side views of a guide configured with a pivoting mount in accordance with an embodiment.

## DESCRIPTION OF SOME EMBODIMENTS

**[0013]** The apparatus, systems, and methods provided herein enable real-time visualization, free-handed, guided, and multi-sample transperineal methods for performing a biopsy. The methods, systems, and apparatus provided herein also enable a complete biopsy of the prostate with only one perforation, or with minimal perforations of a patient's skin by way of an initial access site, such that the access needle is freely moveable. The biopsy guide may be placed on or fitted to an assortment of ultrasound probes of different sizes and shapes due to an adjustable mounting system. The guide may be configured to fit to the probe using any suitably configured fastening system. For example, the guide may be configured as a sleeve that is formed to slide over an end of a probe and into an operable position. Alternatively, the guide may be configured to fit to a probe using screws, flanges, zip ties, or other temporary, permanent, or semi-permanent fastening systems.

**[0014]** In one embodiment, the guide allows biopsies of one or more tissue or cell samples to be obtained through an initial access needle, while providing direct, real-time ultrasound visualization by, for instance, fixing a position of the access needle relative to an ultrasound probe to provide. For example, the guide is fixed to an ultrasound probe that is not fixed and may be freely moveable in operation. Stabilization bars that are built into the guide facilitate the positioning and holding of the perineal skin and subcutaneous tissue to allow positioning of the access needle. The position of the access needle is facilitated by locking the access needle into the subcutaneous tissue of the perineum using a sliding platform that allows a user, such as a medical practitioner or patient caregiver, to place the access needle along a sagittal transducer plane at optimal positions for obtaining prostate biopsies. In some embodiments, upon placement of the access needle into a locked position, for example, in the pelvic floor, a user may then pass a biopsy needle through the access needle to a desired location of the prostate. In yet further embodiments, the passing of the biopsy needle through the access needle and to the prostate may be facilitated by direct sagittal plane visualization based on the alignment of the access needle.

**[0015]** Methods and systems provided herein do not require a patient to take antibiotics at any point prior to the biopsy procedure, nor do they require a patient to undergo bowel preparation in advance of the procedure. Methods, systems, and apparatus can reduce or eliminate multiple skin perforations by using a single access location or access site, while allowing multiple extractions of tissue or cell specimens from the prostate. Methods, systems, and apparatus in accordance with embodiments allow for real-time visualization during a free-handed, guided, transperineal approach, while also facilitating a complete assessment of the prostate with, for example, only one perforation of the patient's skin wherein the access needle

is freely moveable in each plane.

**[0016]** Methods, systems, and apparatus of embodiments may include and facilitate treatment that uses a cryoablation probe for focal therapy of prostate cancer, a radiofrequency instrument, a thermotherapy instrument, any instrument for treatment of the cancerous area, or a combination of any of these instruments.

**[0017]** Methods, systems, and apparatus of embodiments enable planning and performing the free-hand transperineal prostate biopsies under the guidance of a device and of a real-time transducer in the sagittal imaging plane.

**[0018]** The biopsy is performed using a system that includes a biopsy guide, a transducer, an access needle, and a biopsy instrument. The access needle may allow the anesthesia to be injected into the patient, and the tissue or cell specimens of the prostate to be extracted. If anesthesia is used, a syringe may be included in the system. The transducer may be an ultrasound probe or any other type of device that is capable of causing a visualization of the prostate in a display device. In embodiments, the biopsy guide may be disposable. In embodiments, the biopsy guide may be formed of materials intended for a single use. In other embodiments, the biopsy guide is reusable. In some embodiments, the biopsy guide may be formed of materials intended for multiple uses.

**[0019]** The guide may include a sliding platform, stabilization bars, one or more upper and lower mounts, and a fastener. The upper and lower mounts may be curvilinear in shape. The upper and lower mounts may be positioned proximally or distally along an ultrasound probe, such as a transrectal ultrasound probe. The configuration and positioning of the upper and lower mounts are adjustable based on the shape of the ultrasound probe and the patient's body habitus.

**[0020]** The guide may be made of any material such as a plastic or metallic material. The guide may be disposable and made of a biodegradable plastic material. In other embodiments, the guide may be reusable and made of stainless steel. The dimensions, for example, the length, width, height, depth, and breadth of the sliding platform, stabilization bars, upper and lower mounts, and the fastener may vary and may be adjustable. The variable and adjustable dimensions, for example, of the stabilization bars, provide a user with flexibility in achieving and maintaining the guide in an appropriate ultrasound plane while performing biopsy procedures, while the user's patients may vary in size and levels of perineal subcutaneous tissue and fat. In a patient with an excessive amount of perineal subcutaneous tissue and fat, a larger stabilization bar will assist in locking the guide in the proper ultrasound plane.

**[0021]** The adjustable stabilization bars and mounts may be curvilinear in shape, allowing the guide to be placed proximally or distally along any cylindrical instrument, such as the transrectal ultrasound probe, which is determined by the surgeon based on the shape of the probe and the patient's body habitus. This allows the guide to be mounted to any assortment of ultrasound probes. Similarly, the platform may, for example, have various thicknesses.

**[0022]** The stabilization bars may be fixed to a top portion of the upper curvilinear mounts of the guide, and may extend beyond the front edge of the upper mounts. The stabilization bars may extend beyond the front edge of the upper curvilinear mount by approximately 8 mm. The guide may be approximately 60 mm wide, or the guide may be approximately 50 mm long, for example. The stabilization bars may have grooves for accommodating a sliding platform that is shorter in length than the stabilization bars. The grooves being configured to allow the platform to slide forward and backward along the stabilization bars.

**[0023]** An inner portion of the stabilization bars may have built-in grooves. The grooves accommodate a sliding platform which is shorter in length than the stabilization bars. This allows the sliding platform to slide from the back to the front of the stabilization bars. The stabilization bars may include a resistance as to prevent the sliding bar to freely move back and forth on the stabilization bar. This resistance may be introduced by the sliding platform or both the stabilization bar and the sliding platform. The resistance may be provided by a strip of rubber or any other material capable of providing friction or other. The strip may be curvilinear. The resistance may be generated by a mechanical system, such as a spring mechanism.

**[0024]** The sliding platform may have a hole through the platform. In some embodiments, the hole is drilled in the center of the platform. The hole can accommodate various types of needles, including access needles having various diameters, for example, spinal needles having a gauge in the range of 14-18. The hole can also accommodate needles having various lengths. The lengths of the needle may depend, in part, on the body habitus. The needle may be a reusable needle, such as a reusable spinal needle. The needle may be a disposable needle, such as a disposable spinal needle.

**[0025]** A flange of the guide secures the placement of the access needle to the guide. The flange may be configured to snap into the guide to secure the needle. The flange may be secured to the guide by other securing mechanisms. The flange can be of various shapes and configurations. For example, the flange may be u-shaped. As another example, the flange may have a thin or slim configuration. The guide assists in providing the appropriate angle of penetration and direction of the access needle, or other instruments that may be used in combination with the guide.

**[0026]** The hole in the guide is placed so that once the guide is mounted to the ultrasound probe, the drilled hole will be parallel to the sagittal transducer. The drilled hole may also accommodate the tip of a biopsy gun, or any other biopsy instrument. The sliding platform may be interchangeable and may be removed to allow placement of another sliding platform with a different sized to permit different sizes of needles and other instruments. The hole may be configured to accommodate a cryoablation instrument, a radiofrequency instrument, thermotherapy instrument, or any other instrument for diagnosis and treatment of a bodily tissue, including a cancerous area of a prostate.

**[0027]** The platform may have or define a predrilled hole in the center of the platform that can

accommodate various sizes of needles and instruments. For example, the hole may be configured to accommodate a needle having a range of 14-18 gauges, such as a reusable 14 gauge spinal needle. Central hole placement on the platform provides enables alignment of the hole with a sagittal transducer when the guide is mounted to an ultrasound probe. The platform may have multiple holes to accommodate various applications and body habitus. Further, the platform may be of various thicknesses.

**[0028]** Once the one or more upper curvilinear mounts are placed at the desired location on the transrectal ultrasound probe, the access hole for a needle, such as a 14 gauge reusable spinal needle, will remain a fixed distance from the ultrasound probe. In embodiments, having one or more lower curvilinear mounts, the mounts may be positioned to cradle an upper aspect of the ultrasound probe.

**[0029]** At least two lower mounts are provided and may be individually positioned to accommodate various types of probes, which may have variable diameters along their shafts. In embodiments, a probe, such as a transrectal ultrasound probe, may have one or more diameters along the probe's shaft. In yet further embodiments, one end of the guide may be fixed at a location of the probe having a different diameter than the location where the other end of the guide is fixed. The separate lower mounts allow for the fixation of the guide, even with varying probe diameters.

**[0030]** The lower mount of the guide may include a lower right mount and a lower left mount connected by an adjustable mid-joint or fastener. The adjustable mid joint or fastener allows the guide to be secured to the probe even if the diameter of the shaft of the probe is longer than the width of the lower mount. The mid-joint or fastener may be flexible to allow the right lower mount to form an acute angle with the left lower mount. This also allows for fixation of the guide to a probe shaft that is not circular in shape.

**[0031]** The lateral edges on both ends of the lower mounts may contain a notched post. Corresponding locations of the upper mounts contain holes, such as square shaped holes, to accommodate the notched post of a corresponding lower mount. An upper aspect of each hole includes a flange for locking the notched post in a fixed position. This configuration allows the lower mounts and the upper mounts to be secured to each other and to the probe.

**[0032]** Methods may include locating a suspicious area, positioning an access needle, and obtaining one or more tissue or cell specimens from an accurate point in the prostate. The method allows for multiple tissue or cell specimens to be obtained from a bodily organ, such as the prostate, and permits access to the prostate from different angles through a single initial access needle. The method may include calculating the volume of the prostate by positioning the access needle at a mid point in the x axis from the lateral edge of the prostate to the urethra.

**[0033]** Methods may be performed using no anesthesia. Alternatively, an anesthetic may be used. For example, the anesthetic may be lidocaine, or any type of local anesthetic. The

lidocaine may include 1 or 2% of a lidocaine solution.

**[0034]** The suspicious area or bodily organ may be located by using a transducer. The transducer may be any type of probe for accessing and viewing a targeted site or object, such as an ultrasound probe, or any type of transducer capable of providing visualization of the prostate and/or instruments and devices for diagnosis and treatment of the tissue. The biopsy may be performed using a biopsy gun, a suction device, or any type of instrument that is small enough to be introduced through the access needle and capable of extracting the tissue or cell specimen. The biopsy may be performed while the patient is in a dorsal lobothy position, prone position, or any position that allows for access to the perineal area.

**[0035]** Methods may include applying an antiseptic solution to the perineal area. The antiseptic solution may include betadine, or any other substance that reduces the possibility of infection, sepsis, or putrefaction. Methods may include applying bacitracin to the skin at the puncture site or any other type of topical preparation for preventing the possibility of infection.

**[0036]** Methods may include attaching a needle to a luer lock syringe, which may contain an anesthetic, or any other type of device capable of retaining its contents and dispensing its contents through the needle. A biopsy gun or any other instrument that may be attached to the needle and used for inserting or extracting any substance thru the lumen of the access needle.

**[0037]** Methods may include releasing the syringe from the needle after the anesthetic is injected. Methods may include dividing the prostate in three different regions and designating lateral, mid, apical prostate, and may include labeling the tissue or cell specimen containers, which will identify the tissue or cell specimens.

**[0038]** Methods may include securing the guide to the probe. This will permit the practitioner to take the biopsy gun as many times as necessary using his/her other hand, and, consequently, extract multiple tissue or cell specimens. It is contemplated that this can be done without assistance of any other person, and that the biopsy gun may also be attached to the guide in order to permit the surgeon to, for example, label the container with the tissue or cell specimen while performing the biopsy. Methods may also include monitoring all the actions in the prostate by way of a display device that provides images captured by the probe.

**[0039]** Methods may include moving the needle in x, y, and z planes. By being able to move the needle in x, y, and z planes, the surgeon is capable of extracting tissue or cell specimens from several different areas of the prostate without having to retrieve the needle and preventing other perforation of the patient's skin. In embodiments, movement of the needle within the patient's body is facilitated by using a display device.

**[0040]** Methods may include removing the access needle from the perineal area. This may be done while the biopsy gun is secured to the access needle or after the biopsy gun has been detached from the access needle.

**[0041]** Methods may include realigning the needle in the desired prostate region. If the surgeon wishes to start at the right lateral prostate region and notices that the needle tip is not directed at the lateral region, the surgeon rolls the ultrasound probe slightly and to note that the needle tip is directed to the desired region, then the surgeon may realign the needle to obtain tissue or cell specimen. The surgeon may realign the needle using one hand while having the needle attached to the biopsy gun, which may be attached to the probe through the guide.

**[0042]** Methods may include identifying the areas in which biopsy have already been performed. After each extraction of tissue or cell specimen during the biopsy, a hyperechoic streak remains visible on ultrasound display. This allows the surgeon to identify the area of the prostate and that an extraction has been made, as to allow the surgeon to prevent overlap of extractions.

**[0043]** In another embodiment, the method includes identifying the path of the urethra. This allows the surgeon from preventing passing the biopsy needle thru or into this path.

**[0044]** FIG. 1 is a side view of a guide 100 secured to a probe including a stabilization bar 101, fasteners 102, probe 103, lower mounts 104, and an upper mount 105. The stabilization bar 101 is an extension of the upper mount 105, as further discussed in FIG. 4. In embodiments, the distance between the fasteners 102 and the upper mount 105 may be adjustable to accommodate various applications and body habitus.

**[0045]** FIG. 2A is an internal view of a guide's fastener, including an aperture 201, teeth 202, and a flange 203. The flange 203 may be an extension of the aperture 201, which is part of the upper mount 105. Aperture 201 will allow the teeth 202 to be inserted into the upper mount 105, and the flange 203 will lock the teeth 202, which is connected to lower mount 104, to the upper mount 105. The aperture 201 with flange 203 and teeth 202 allows for adjusting the height of the guide 100.

**[0046]** In one embodiment, the fastener (e.g., via the aperture 201, flange 203, and/or the teeth 202) can be configured to fasten the guide 100 to the probe 103 with, e.g., varying levels of tension to provide for adjustments of the relative positions of the guide 100 and the probe 103 even after the guide 100 has been mounted to the probe 103. For example, the fastener 102 can provide a first level of tension sufficient to hold the position of an access needle (e.g., introduced through a hole or other needle mount of the guide 100) rotationally fixed to the probe 103 while still allowing for a forward or reverse sliding of the probe 103 with respect to the guide 100. By way of example, the forward or reverse sliding adjustment can be performed to adjust the penetration depth of the probe 103 with respect to the patient depending on a size of the patient. Once the final adjustment is made, the fastener can be actuated to final position or tension that will then lock further adjustments of the positioning of the guide 101 relative to the probe 103.

**[0047]** It is noted that the guide's fastener as described above is one example embodiment

among other possible example fasteners that are applicable to various embodiments of the guide 100. Accordingly, it is contemplated that various embodiments of the guide 100 may use any now known or later developed fastening system that can secure the guide 100 to the probe 103.

**[0048]** By way illustration and not limitation, examples of two fasteners are discussed with respect to FIGs. 2B and 2C. FIG. 2B shows a sheath-based fastener whereby the fasteners 102 are attached to a sheath 211 that is configured to slide over an end of a probe 103 and into an operable position. Although the sheath 211 is shown as a closed sheath, in another embodiment, the sheath 211 can be configured as a sleeve that is open-ended to slide over the probe 103. By way of example, the sheath 211 can be made of a flexible material (e.g., rubber) to provide for stretching and tension on probe 103.

**[0049]** In another embodiment, as shown in FIG. 2C, the guide 100 can be configured with a zip-tie style fastener in place of a lower mount mechanism to secure the guide 100 to the probe 100. In other embodiments (now shown), the guide 100 may be configured to fit to the probe 100 using screws, flanges, or other temporary, permanent, or semi-permanent fastening systems. In addition, although the fasteners 102 of the guide 100 may be configured as generic and adjustable fasteners that can support probes of a variety of sizes and shapes, it is also contemplated that the fasteners can be fit to specific models of probes for customized applications.

**[0050]** FIG. 3 is a top view of a guide secured to a probe. This figure includes a sliding platform 301, a drilled hole 302, stabilization bars 101, fasteners 102, an upper mount 105, and a probe 103. As previously described, in one embodiment, the drilled hole 102 can accommodate or support various sizes and/or configurations of needles (e.g., straight needles, curved needles, etc.) and instruments for performing a biopsy so that the needle can be aligned relative to the probe 103, thereby, also providing an alignment between the needle and an image produced by the ultrasound probe 103. In one embodiment, the drilled hole 102 can support an access needle through which a biopsy needle or other instrument can be introduced at a known alignment with respect to the probe 103. In addition, although the hole 102 to support, e.g., an access needle or other instrument is shown in a central midline position, the location of the hole can be configured at any position of the guide 100.

**[0051]** FIG. 4 is a cross-section view of the back of a guide secured to a probe including a sliding platform 301, drilled hole 302, stabilization bars 101, lower mount 104, upper mount 105, fasteners 102, and probe 103.

**[0052]** FIG. 5 is a magnified view of FIG. 1. FIG. 5 demonstrates minimum dimensions of preferred embodiments, which includes stabilization bars 101 and upper mount 105 from 30mm to 50mm long; the upper mount 105 with a height ranging from 10mm to 15mm; the stabilization bars 101 with a height that is about 1/3 of the height of the upper mount 105; fasteners 102 with a height of about 25mm and 10mm wide; a lower mount 104 10mm wide. Additionally, the offset 501 from the distal point of the stabilization bar 105 to the fasteners 102

may be 5mm. It is contemplated that any of these dimensions may vary, including the stabilization bar 101, which may be longer than the upper mount 105.

**[0053]** FIG. 6 is a magnified internal view of the guide fastener shown in FIG. 2. FIG. 6 demonstrates minimum dimensions of preferred embodiments. The fasteners 102 may have an aperture 201 to accommodate teeth 202, wherein the fastener 102 is 5mm to 10mm wide. Additionally, the sliding platform 301, which may be from 12mm to 25mm wide, is slightly shorter than the distance between the two stabilization bars 101 as to accommodate the sliding platform while also securing it to the guide 100.

**[0054]** FIG. 7 is a magnified view of the guide depicted FIG. 3, without the probe 103. FIG. 7 also demonstrates minimum dimensions of preferred embodiments, wherein the height of the upper mount 105 ranges from 5mm to 10mm; and the teeth 202 is from 5mm to 8mm wide.

**[0055]** FIG. 8 is a side view of a biopsy instrument that is about to penetrate the prostate, including a prostate 801, a probe 103, a biopsy instrument 802, a perineum skin 803, an anus 804, and a perforation point 805. The probe 103 is inserted into the anus 804 to provide real-time images of the biopsy, including images of the biopsy instrument 802 and the prostate 801. It is contemplated that the biopsy instrument 802 includes a needle and any other instrument capable of performing a biopsy.

**[0056]** FIG. 9 is a front view of a targeted area 902 of the prostate 801. FIG. 10 is a side view of a biopsy instrument penetrating the prostate 801, including a targeted area 902 of the prostate 801. The targeted area 902 is reached by biopsy instrument 802 after perforating perineum skin 803.

**[0057]** FIG. 11 is a front view of a targeted area of the prostate where a biopsy instrument will penetrate with areas in which the cell or tissue specimen has already been extracted. FIG. 11 depicts both an extracted area 1101 and a targeted area 902. The possibility of viewing the area in which the cell or tissue specimen has already been extracted permits the practitioner to avoid placing the access needle in an area that cell or tissue specimen has already been extracted. This allows the biopsy to be more efficient and more accurate.

**[0058]** FIG. 12 is a top view of FIG. 8, depicting a prostate 801, perineum skin 803, a probe 103, and a biopsy instrument 802. FIG. 13 is a right side view of a prostate and the path of the biopsy instrument including the path of the biopsy instrument 1301 and the perforation point 805. FIG. 13 illustrates that only one initial perforation to the skin of the patient is necessary in order to extract one or more cell or tissue specimens.

**[0059]** FIG. 14 is a front view of a guide determining a lower targeted or suspicious area 1401 of the prostate in which to penetrate the biopsy instrument, a prostate, and a probe. FIG. 16 is a front view of a guide determining a mid target or suspicious area 1601 of the prostate in which to penetrate the biopsy instrument, a prostate, and a probe. FIG. 18 is a front view of a guide determining a higher targeted or suspicious area 1801 of the prostate in which to

penetrate the biopsy instrument, a prostate, a probe. FIGS. 14, 16, and 18 demonstrates the variety of angles and positions in which a guide may be positioned in order to reach several regions of the prostate, such as the lateral region, mid region, and apical region. In order to be able to reach these areas, FIGS. 14, 16, and 18 demonstrate how the upper mount 105, the stabilization bars 101, or a combination of thereof can adjust in order to reach a lower targeted or suspicious area 1401, a mid targeted or suspicious area 1601, or a higher targeted or suspicious area 1801 of the prostate.

**[0060]** FIGS. 15, 17, and 19 demonstrate a side view of FIGS. 14, 16, and 18 and the paths of the biopsy instrument 1301 taken by a biopsy instrument to reach lower targeted or suspicious area 1401, a mid targeted or suspicious area 1601, or a higher targeted or suspicious area 1801 of the prostate.

**[0061]** FIG. 20 is a right side view of a guide, and a biopsy instrument firmly penetrating a fat plane of perineum skin, including offset 501 of a stabilization bar 101. This allows for stabilization in a patient with an excessive amount of perineal subcutaneous tissue, fat, or a combination thereof. A larger stabilization bar 101 will assist in locking the guide in the proper ultrasound plane. Accordingly, the offset 501 may longer than 5mm for these purposes.

**[0062]** FIG. 21 is a front view of a prostate, a probe, a targeted or suspicious area, wherein the biopsy instrument may reach any area of the prostate. FIG. 21 demonstrates that the biopsy instrument can reach the entire prostate while using only one perforation point 805. After obtaining one cell or tissue specimen, the biopsy instrument 802 may be partially retrieved from the perineum area at a point in which the distal point of the biopsy instrument 802 is redirected to another targeted or suspicious area. Then, the biopsy instrument (usually the needle of the biopsy instrument) is inserted to the second targeted or suspicious area for obtaining a cell or tissue specimen of another area of the prostate.

**[0063]** FIG. 22 is a magnified view of the right side of a prostate and a biopsy instrument. FIG. 22 depicts the location of the biopsy instrument inside the prostate and the other paths in which the biopsy instrument may take utilize for additional samples or retrieval. In embodiments, the biopsy needle or other instruments do not reach the initial part of the penis, which is in a different plane from the prostate.

**[0064]** FIG. 23 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas. FIG. 23 shows a procedure being applied to the apical region of the prostate.

**[0065]** The urethra should be avoided in any part of the procedure, but it is mostly important when extracting cell or tissue specimens from the apical region of the prostate, when the chances of perforation is greater. After several extractions, the practitioner is able to see the blood streak from where the cell or tissue specimen was taken so as to avoid overlapping.

**[0066]** After this procedure, the patient may be put with restriction for no more than 1 day. If

the patient is put on restriction for 1 day, after the one-day-restriction, no restriction is made.

**[0067]** In an embodiment, the biopsy system performs the processes 2400 of FIG. 24. At 2401, a patient is prepared for the biopsy procedure by having the patient get into a lithotomic position, prone position, or any position that allows for access to the perineal area. The biopsy procedure may be a prostate biopsy. In some embodiments, the patient's scrotum is elevated using, for example, two strips of plastic tape. The perineum is prepared with an antiseptic solution to the perineal area, for example, the antiseptic solution may include betadine.

**[0068]** At 2402, a target area or object, such as the prostate, is imaged. Imaging may be performed with a transducer, such as an ultrasound probe. Imaging of a target area may be in a sagittal and/or axial plane and may be performed in real-time with direct visualization. Utilizing the real-time image, a user can identify areas of interest, e.g. suspicious areas or the target area or object at 2403.

**[0069]** The user may determine an access site for positioning an access needle. At 2404, an access needle is positioned at an access site in subcutaneous tissue of the perineum. The access site may be at a midpoint between a lateral edge of the prostate and the urethra along an x axis, and a midpoint between an anterior capsule and a posterior capsule along a y axis. The access needle is guided and positioned at the access site by using the guide.

**[0070]** At 2405, a biopsy instrument is guided to the target or suspicious areas or object. The biopsy instrument may include a biopsy needle. The guiding of the biopsy instrument can be facilitated by using the real-time visualization provided by the transducer. Real-time visualization also facilitates obtaining tissue or cell specimens from an accurate point in the prostate, for example. The method allows for one or more tissue or cell specimens to be obtained from a bodily organ, such as the prostate at 2406, and permits access to the prostate from different angles through a single initial access needle.

**[0071]** At 2407, the biopsy instrument may be retrieved and removed from the patient. The method may include calculating the volume of the prostate by positioning the access needle at a mid point in x axis from the lateral edge of the prostate to the urethra.

**[0072]** FIG. 25 shows an ultrasound 2501 showing a transrectal probe 2503 and an access needle guide line 2505. The needle guide line enables the practitioner to observe a needle path whereby the access needle has contacted the prostate 2507, thereby enabling the practitioner to avoid overlapping sampling, and to avoid perforating the prostate.

**[0073]** FIGs. 26A-26C show side views of an alternative embodiment of a guide 2600 secured to a probe including a stabilization bar 101, fasteners 102, probe 103, lower mount 104, and an upper mount 105. The stabilization bar 101 is an extension of the upper mount 105, as further discussed in FIG. 4. In embodiments, the distance between the fasteners 102 and the upper mount 105 may be adjustable to accommodate various applications and body habitus.

**[0074]** The guide 2600 includes a sliding platform 301. The guide is fitted to the probe 103 by a sleeve 2607. The sleeve 2607 is formed by the lower mount 104 and the upper mount 105. The sleeve 2607 may be configured to slide over an end of the probe 103 into an operable position as shown in FIGS. 26A-26C. The sleeve 2607 is a partial sleeve that has an opening at both ends of the sleeve 2607 to enable slidable mounting to and removal from the probe 103.

**[0075]** The sliding platform 301 of the guide 2600 may be pivotably mounted to enable movement in a direction perpendicular to a longitudinal axis of the probe 103, as shown in FIGS. 26A-26C. In particular FIGS. 26A-26C show that the sliding platform 103 is fixed to the guide at a pivot point 2608. The sliding platform 103 is configured to pivot at pivot point 2608 to enable, for example, normal or vertical adjustment of an access needle (not shown) in directions perpendicular to a longitudinal axis of the probe 103 while ensuring that a longitudinal axis of the access needle (not shown) remains parallel to the longitudinal axis of the probe 103.

**[0076]** For example, FIG. 26A shows a sliding platform 301 in a first position at which a lateral planar surface of the platform 301 extends in a direction parallel to the longitudinal axis of the probe 103. FIG. 26B shows the sliding platform 301 pivoted to a second position wherein a front end the platform 301 is disposed a distance from the probe 103 that is greater than a distance between an opposite rear portion of the platform 301 and the probe 103. FIG. 26C shows the sliding platform 301 pivoted to a third position wherein the rear end of the platform 301 is disposed a distance from the probe 103 that is greater than a distance between the opposite front end of the platform 301 and the probe 103.

**[0077]** In another embodiment, the method may be performed without the patient taking antibiotics or undergoing bowel preparation before having the procedure. During the procedure, the practitioner may administer an anesthetic to the patient, for example, lidocaine, or any type of local, anesthetic. The lidocaine may be included in a solution having 1% of lidocaine.

**[0078]** In an embodiment, the suspicious area is located by using a transducer. The transducer may be any type of transrectal robe for prostate cancer, such as an ultrasound probe, or any type of transducer capable of imaging the prostate and the extraction device. The biopsy may be performed using a biopsy gun, a suction-mechanism, or any type of instrument that is small enough to be introduced through the access needle and capable of extracting the tissue or cell specimen. The biopsy may be performed while the patient is in a lithotomy position, prone position, or any position that allows for access to the perineal area.

**[0079]** In another embodiment, methods may include applying an antiseptic solution to the perineal area such as betadine, or any other substance that reduces the possibility of infection, sepsis, or putrefaction.

**[0080]** In another embodiment, the ultrasound probe may be a B&K 8848 transrectal

ultrasound probe, or any other ultrasound capable of causing visualization of the prostate and the extraction device. The frequency range may be 5 -12 MHZ, and the focal range may be 3-60 mm. The ultrasound probe may be able to cause the visualization of the prostate and extraction devices at least in the axial plane, sagittal plane, or a combination thereof.

**[0081]** In another embodiment, methods may include attaching a needle to a luer lock syringe, which may contain an anesthetic, or any other type of device capable of retaining its contents and to dispense its contents through the needle. A biopsy gun or any other instrument may be attached to the needle for inserting or extracting any substance through the lumen of the access needle.

**[0082]** In another embodiment, the method includes releasing the syringe from the needle after the anesthetic is injected. The method may include dividing the prostate in three different regions and designating lateral, mid, apical prostate, and may include labeling the tissue or cell specimen containers, which will identify the tissue or cell specimens.

**[0083]** In another embodiment, a biopsy gun may be an 18 gauge biopsy gun, or any other size that is capable of being coaxially inserted thru the lumen of the access needle.

**[0084]** In another embodiment, methods may include securing the guide to the probe. This will permit the practitioner to take the biopsy gun as many times as necessary using his or her other hand, and, consequently, extract multiple tissue or cell specimens. It is contemplated that this can be done without assistance of any other person, and that the biopsy gun may also be attached to the guide in order to permit the surgeon to e.g. label the container with the tissue or cell specimen while performing the biopsy. The method may also include monitoring all the actions in the prostate thru a display device, which will transmit images captured by the probe.

**[0085]** In another embodiment, methods may include moving the needle in x, y, and z planes. By being able to move the need in x, y, and z planes, the surgeon is capable of extracting tissue or cell specimens from several different areas of the prostate without having to retrieve the needle and preventing other perforation of the patient's skin.

**[0086]** Methods may further include removing the access needle from the perennial area. Removal of the access needle may be performed while the biopsy gun is secured to the access needle or after the biopsy gun has been detached from the access needle.

**[0087]** Methods may include realigning the needle in the desired prostate region. If the surgeon wishes to start at the right lateral prostate region and notices that the needle tip is not directed at the lateral region, the surgeon rolls the ultrasound probe slightly and to note that the needle tip is directed to the desired region, then the surgeon may realign the needle to obtain tissue or cell specimen. The surgeon may realign the needle using one hand while having the needle attached to the biopsy gun, which may be attached to the probe through the guide.

**[0088]** Methods may include identifying the area in which a biopsy has already been performed. After each extraction of tissue or cell specimen during the biopsy, a hyperechoic streak remains visible on ultrasound display. This allows the surgeon to identify the area of the prostate and that an extraction has been made, as to allow the surgeon to prevent overlap of extractions.

**[0089]** In another embodiment, methods may include identifying the path of the urethra. This allows the surgeon from preventing passing the biopsy needle thru or into this path. In another embodiment, the method includes pressuring the perineum. In yet another embodiment, the method includes applying bacitracin to the skin at the puncture site or any other type of topical preparation for preventing the possibility of infection. In another embodiment, positioning the access needle is performed without the need of a biopsy grip, wherein the guide provides the precise point for the biopsy.

**[0090]** An apparatus and system in accordance with embodiments discussed above is used to carry out these methods. In an alternative embodiment of apparatus and systems, a guide may not include a lower mount, and may include an access needle. The guide includes a stabilization bar, sliding platform, a hole located in approximately the center of the platform, an upper mount, teeth, aperture, arms, and a connector. The access needle includes a hub and is secured to the guide. The teeth may be part of, or may be attached to, a lower mount. The teeth may be inserted into the aperture in order to secure the guide to a probe, for example. It is contemplated that the combination of the aperture and the teeth may form a fastener mechanism. In embodiments, connector is part of, or may be attached to, an access needle, and may be secured to the upper mount in order to provide stabilization of the access needle and to allow the practitioner to move the access needle by merely moving, for example, a probe that may be secured to the guide.

**[0091]** A connector and a hub permit the use of various other instruments such as, for example, a non-biopsy instrument, to be secured. A biopsy instrument may be inserted into the access needle in order to reach a targeted area. The upper mount may include arms. In embodiments, the arms may be shorter, longer, or may not exist, in which case the aperture is disposed directly in the upper mount. When the aperture is directly in the upper mount, upper mount may be longer, thicker, or a combination thereof.

**[0092]** In some embodiments, the guide may include lower mounts that have teeth. Arms may extend from the upper mount to allow the height of the guide to be adjusted and to be placed farther from or closer to the probe. The arms permit the access needle to be maintained at a certain distance from a probe. In embodiments, the material of the guide may be a plastic or any other material, including other plastic materials, or any other material that is cost effective. In embodiments, the guide may be reusable and may be formed with a stainless steel. The lower mount may be curvilinear and flexible to allow the lower mount to bend if necessary to secure the guide to the probe.

**[0093]** While the invention has been described in connection with a number of embodiments

and implementations, the invention is not so limited but covers various obvious modifications and equivalent arrangements, which fall within the purview of the appended claims.

## REFERENCES CITED IN THE DESCRIPTION

Cited references

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

**Patent documents cited in the description**

- US61974826 [0001]
- US5494039A [0006]

**Patentkrav**

1. Et system omfattende:  
en biopsiføring (100);

5

en adgangsnål konfigureret til at perforere et adgangsområde i subkutant væv i et perineum (803), adgangsnålen er understøttet af biopsiføringen (100);

10

en transrektal transducer (103), transduceren (103) er fastgjort til biopsiføringen (100), biopsiføringen (100) er konfigureret til at føre adgangsnålen til at perforere et adgangsområde i subkutant væv i et perineum (803), hvorved bevægelsen af adgangsnålen er fastgjort i forhold til en bevægelse af den transrektale transducer (103); og

15

et biopsi instrument (802), der er konfigureret til at fjerne væv eller celler fra en prostata (801), biopsi instrumentet (802) er konfigureret til at passere gennem adgangsnålen.

2. Systemet ifølge krav 1, yderligere omfattende: en sprøjte konfigureret til at passere gennem adgangsnålen.

20

3. Systemet ifølge ethvert af de foregående krav, transduceren (103) omfatter yderligere en ultralydsprobe.

4. Systemet ifølge ethvert af de foregående krav, biopsiføringen (100) yderligere omfattende: en flerhed af stabiliseringselementer (101), der strækker sig i en retning parallelt med en længde af adgangsnålen.

25

5. Systemet ifølge krav 4, hvori flerheden af stabiliseringselementer (101) er kurve-linære og definerer en eller flere riller konfigureret til at rumme en glidende platform (301).

30

6. Systemet ifølge ethvert af de foregående krav, biopsiføringen (100) omfatter yderligere en glidende platform (301), den glidende platform (301) definerer et eller flere huller.

35

7. Systemet ifølge ethvert af de foregående krav, biopsiføringen omfatter yderligere: en øvre montering (105) og en nedre montering (104).

8. Systemet ifølge ethvert af de foregående krav, hvori biopsiføringen (100) yderligere omfatter:

- 5 en øvre montering (105) omfattende en længdeakse;  
en første stabiliseringsstang (101) og en anden stabiliseringsstang (101), der strækker sig fra den øvre montering (105) langs længdeaksen af den øvre montering (105); og
- 10 en nedre montering (104), den nedre montering (104) er konfigureret til at forbinde med den øvre montering (105) for at fastgøre den transrektale transducer (103) mellem dem, den transrektale transducer (103) er ikke fastgjort og er frit bevægelig i drift, den øvre montering (105) er konfigureret til at understøtte adgangsnålen, adgangsnålen er konfigureret til perforering af subkutant væv i perineum (803) på adgangsområdet af et målområde hos en
- 15 patient under en styret og frihåndet transperineal prostatabiopsi, den øvre montering (105) er konfigureret til at føre adgangsnålen, hvorved adgangsnålens bevægelse er fastgjort i forhold til bevægelsen af den transrektale transducer (103);
- hvor den øvre montering (105) yderligere omfatter en glidende platform (301) konfigureret til glidende at modtage adgangsnålen; og
- 20 hvor den glidende platform (301) er konfigureret til at glide fra en bagside til en forside af den første og den anden stabiliseringsstang (101).

# DRAWINGS

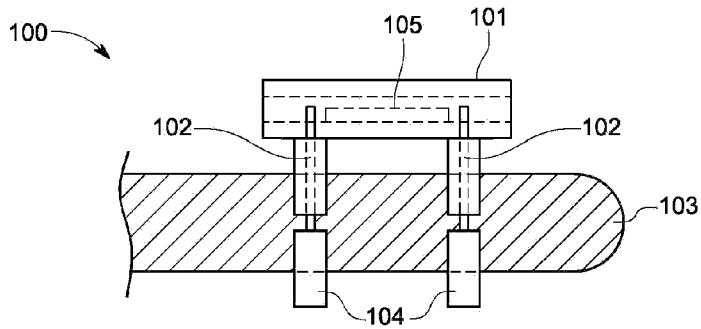


FIG. 1

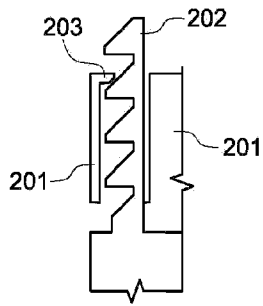


FIG. 2A

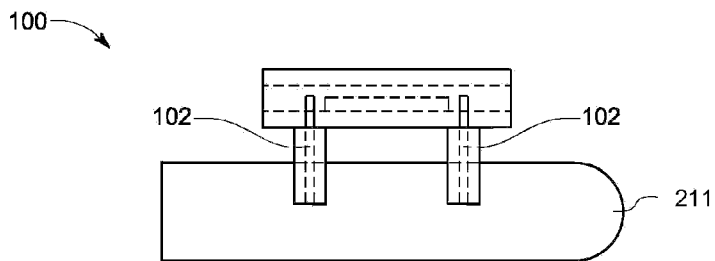


FIG. 2B

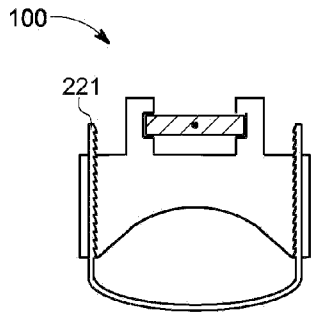


FIG. 2C

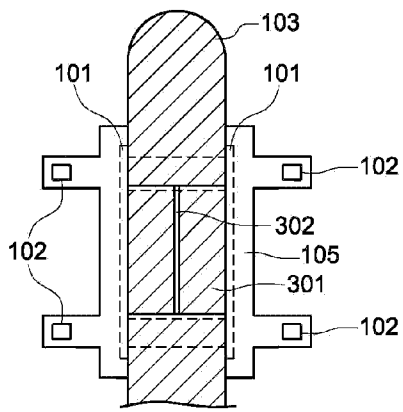


FIG. 3

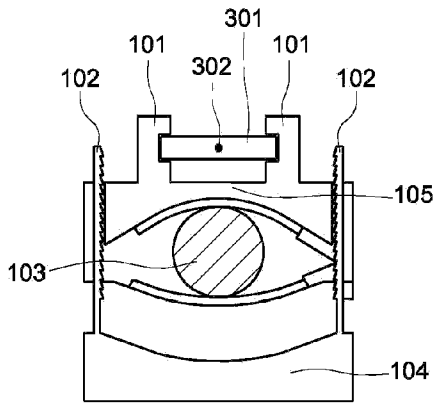


FIG. 4

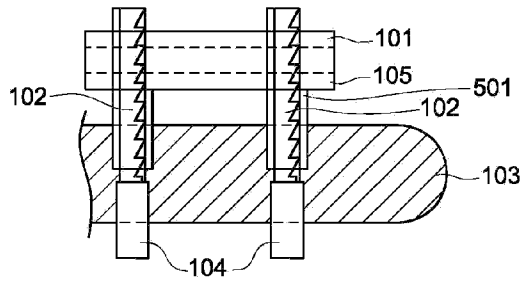


FIG. 5

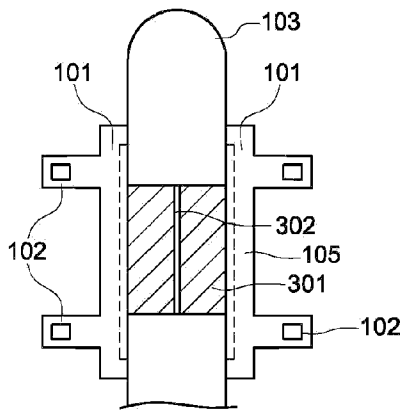


FIG. 6

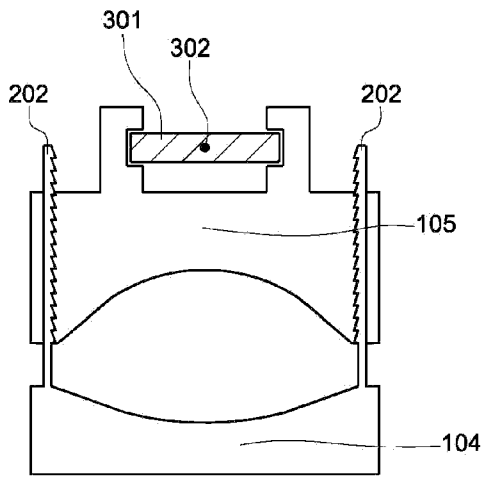


FIG. 7

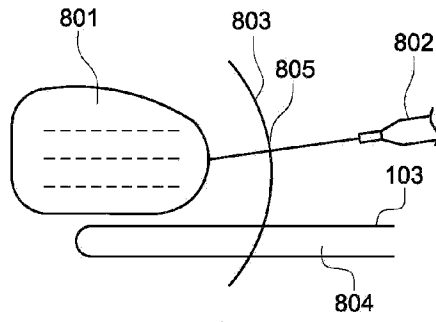


FIG. 8

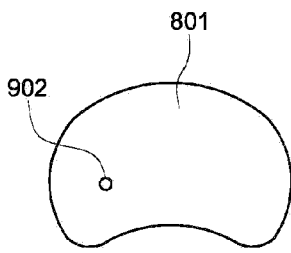


FIG. 9

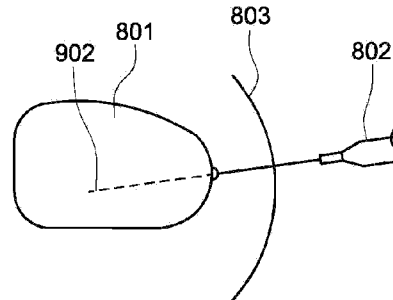


FIG. 10

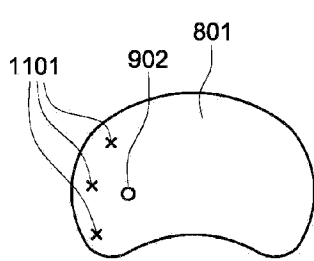


FIG. 11

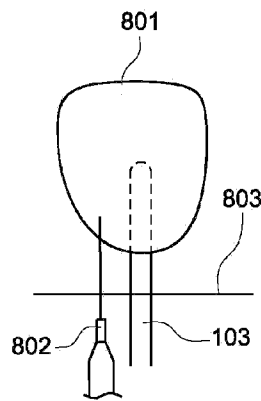


FIG. 12

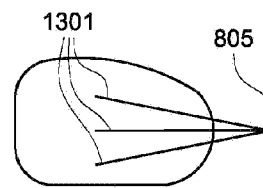


FIG. 13

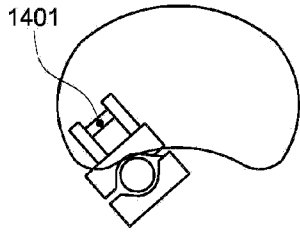


FIG. 14

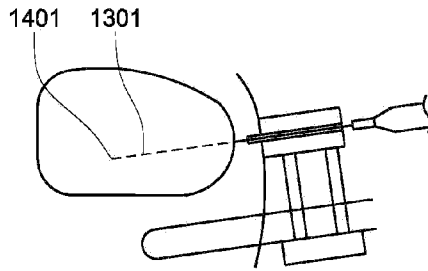


FIG. 15

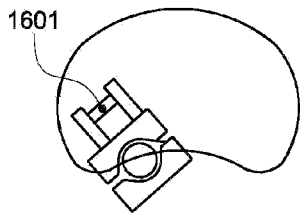


FIG. 16

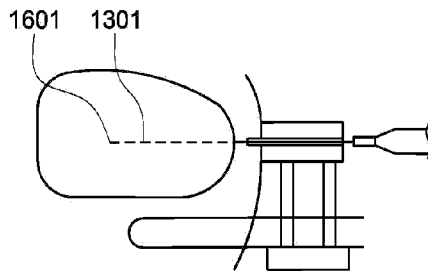


FIG. 17

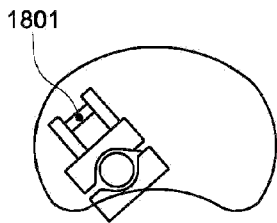


FIG. 18

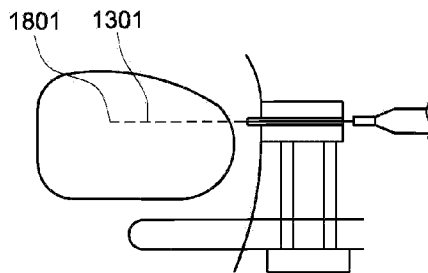


FIG. 19

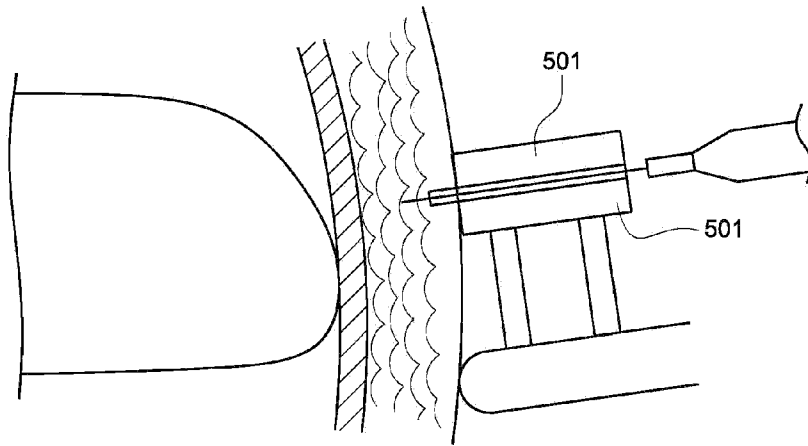


FIG. 20

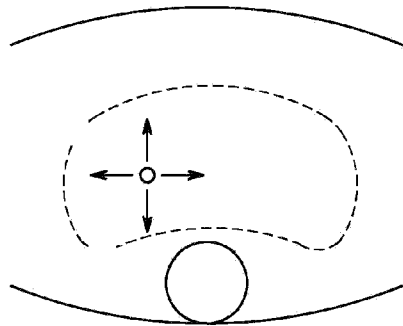


FIG. 21

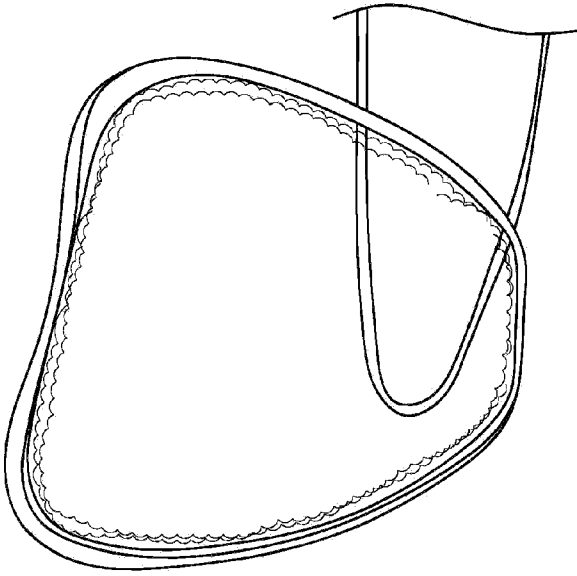


FIG. 22

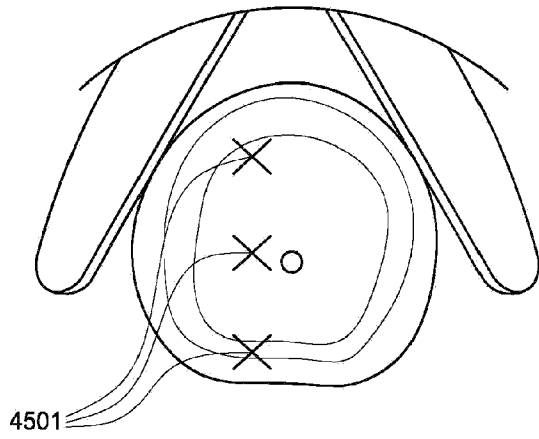
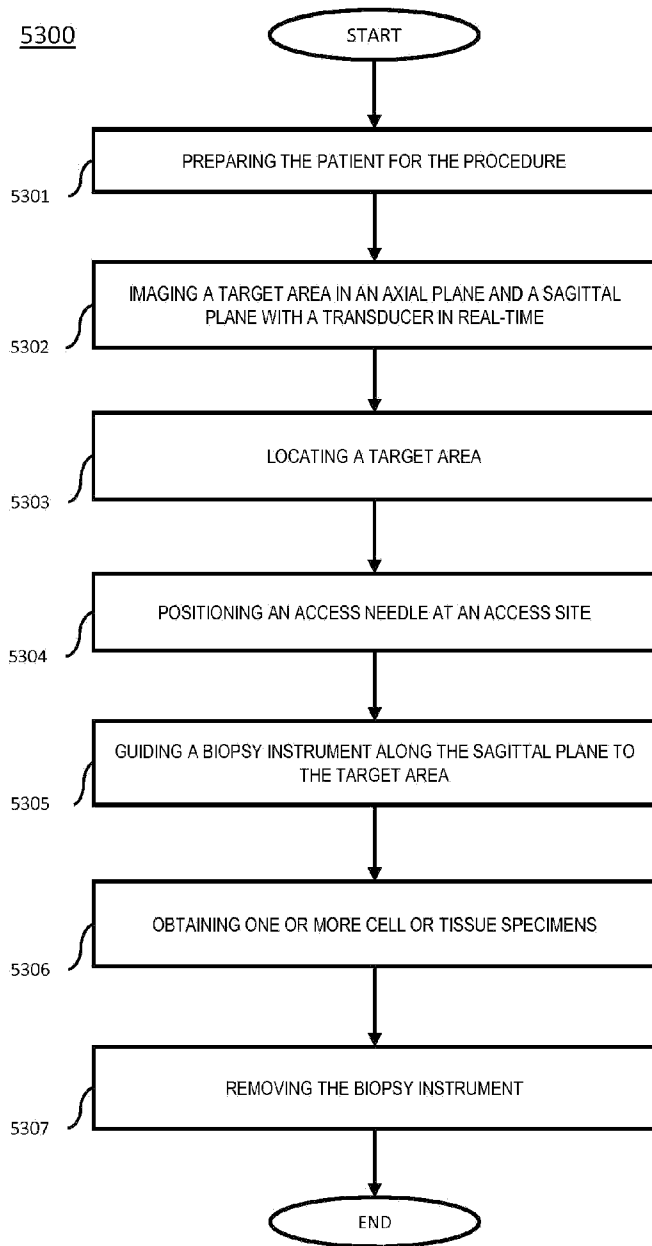


FIG. 23

FIG. 24



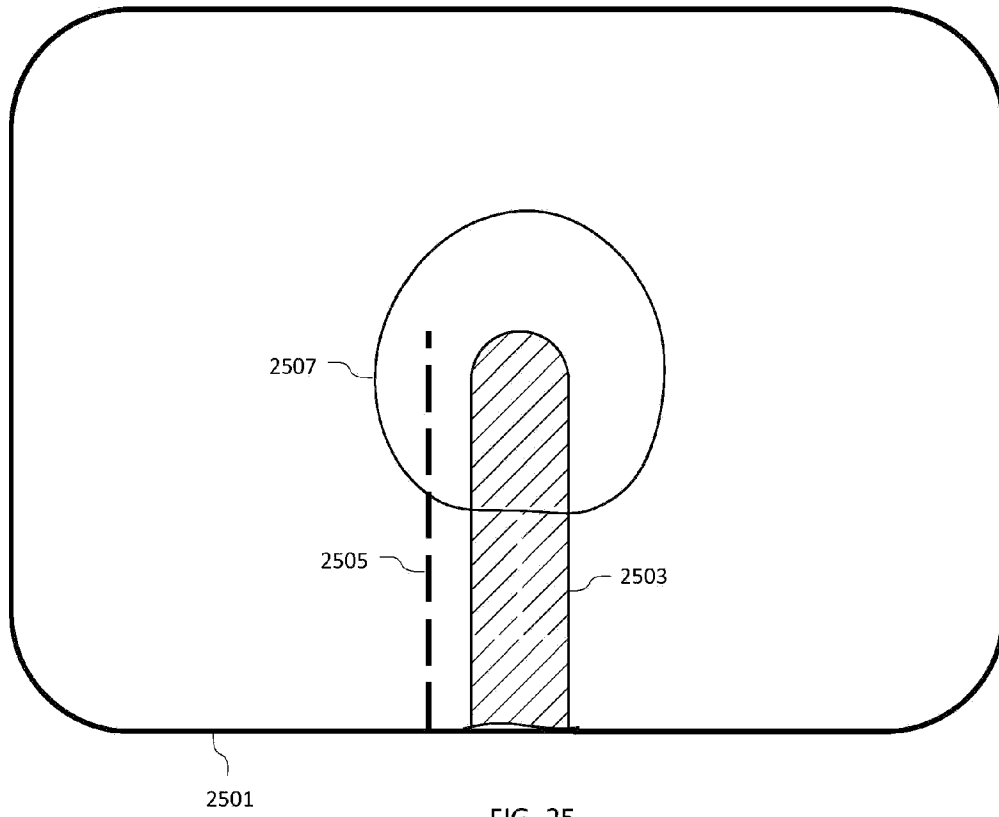


FIG. 25

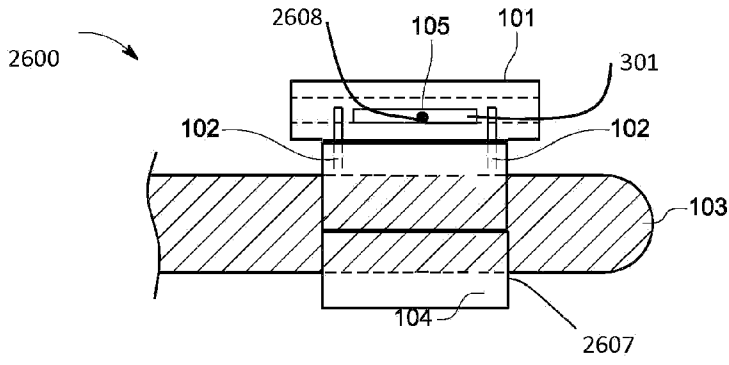


FIG. 26A

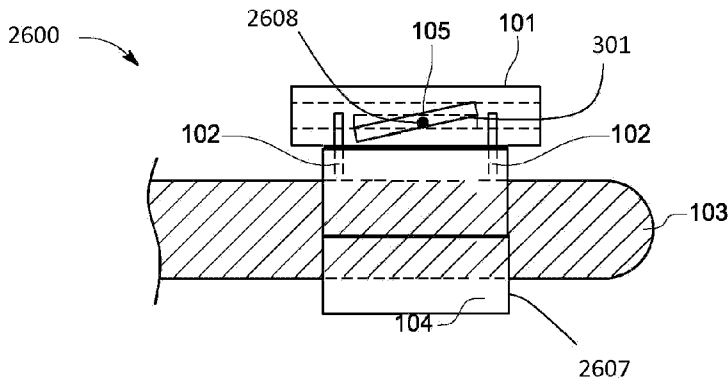


FIG. 26B

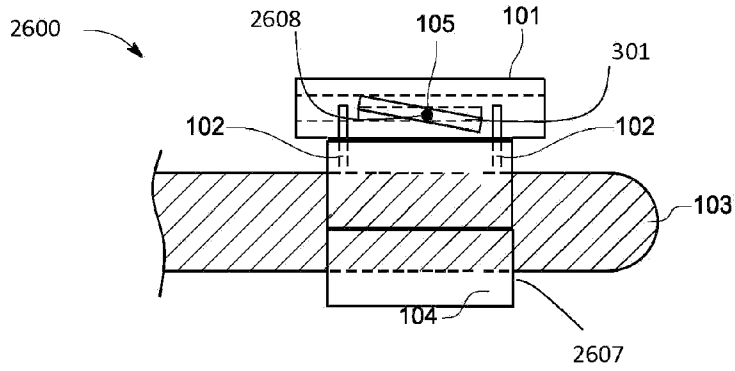


FIG. 26C