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TRANSPERINEAL PROSTATE BIOPSY DEVICE, SYSTEMS, AND METHODS OF USE

Abstract

A transperineal biopsy guide for use with an access needle and a transrectal imaging probe. The transperineal biopsy guide includes a mount, a guide member, and an access needle support structure. The mount is attachable to the probe. The guide member includes: a first side comprising a first distal member and a first surface extending proximally from the first distal member; a second side comprising a second distal member and a second surface extending proximally from the second distal member; and a gap between the first distal member and the second distal member. The access needle support structure is securable to the guide member in a distal position that inhibits vertical and distal displacement of the access needle support structure relative to the guide member while permitting disengagement from the distal position via proximal movement of the access needle support structure relative to the guide member.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] The present application is a continuation of U.S. application Ser. No. 18/094,534 filed Jan. 9, 2023, which is a continuation of U.S. application Ser. No. 17/698,641 filed Mar. 18, 2022, now U.S. Pat. No. 11,547,436, which is a continuation of U.S. application Ser. No. 17/494,962 filed Oct. 6, 2021, now U.S. Pat. No. 11,446,056, which is a continuation-in-part of U.S. application Ser. No. 17/314,845 filed May 7, 2021, now U.S. Pat. No. 11,246,677, which is a continuation of U.S. application Ser. No. 16/115,180 filed Aug. 28, 2018, now U.S. Pat. No. 11,096,762, which is a continuation of U.S. application Ser. No. 14/677,286 filed Apr. 2, 2015, now U.S. Pat. No. 10,064,681, which claims priority under 35 U.S.C. § 119 to U.S. Provisional Patent Application No. 61/974,826 filed Apr. 3, 2014. [0002] Application Ser. No. 17/494,962 is also a continuation-in-part of U.S. application Ser. No. 16/991,150 filed Aug. 12, 2020, now U.S. Pat. No. 11,583,310, which is a continuation of U.S. application Ser. No. 14/874,104 filed Oct. 2, 2015, now U.S. Pat. No. 10,743,909, which is a continuation-in-part of U.S. patent application Ser. No. 14/677,286 filed Apr. 2, 2015, now U.S. Pat. No. 10,064,681, which claims priority under 35 U.S.C. § 119 to U.S. Provisional Patent Application No. 61/974,826 filed Apr. 3, 2014. [0003] All the above-referenced applications are hereby incorporated by reference in their entireties.

TECHNICAL FIELD

[0004] Aspects of the present 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.

BACKGROUND

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] It is with these observations in mind, among others, that various aspects of the present disclosure were conceived and developed.

SUMMARY

[0010] Aspects of the present disclosure include a transperineal biopsy guide configured for use with an access needle and a transrectal imaging probe adjacent a patient's perineum. The access needle includes a proximal end hub, a distal sharp end opposite the proximal end hub and a longitudinal axis extending between the proximal end hub and the distal sharp end. The access needle is sized to receive a biopsy instrument therethrough. The transrectal imaging probe includes a proximal end, a distal end, and a longitudinal axis extending between the proximal end and the distal end. The transrectal imaging probe is configured to provide imaging in an imaging plane of the transrectal ultrasound probe. The transperineal biopsy guide includes a mount, a guide member, and an access needle support structure. The mount is attachable to the transrectal imaging probe between the proximal and distal ends of the transrectal imaging probe. The guide member extends from the mount and includes: a first side comprising a first distal member and a first surface extending proximally from the first distal member; a second side comprising a second distal member and a second surface extending proximally from the second distal member; and a gap between the first distal member and the second distal member. The access needle support structure is securable to the guide member in a distal position that inhibits vertical displacement and distal displacement of the access needle support structure relative to the guide member while permitting disengagement from the distal position via proximal movement of the access needle support structure relative to the guide member. The access needle support structure is configured to support the access needle at a plurality of heights relative to the mount with the access needle being at least partially located in the gap when the access needle support structure is secured to the guide member in the distal position. The access needle support structure includes first and second members extending laterally therefrom. The first and second members are on opposite sides of the access needle support structure.

[0011] In certain embodiments, in the distal position, the first member of the access needle support structure abuts the first distal member and the first surface, and the second member of the access needle support structure abuts the second distal member and the second surface.

[0012] In certain embodiments, the vertical displacement of the access needle support structure relative to the guide member is inhibited by interaction of the first member with the first surface, and by interaction of the second member with the second distal member and the second surface.

[0013] In certain embodiments, the vertical displacement and the distal displacement of the access needle support structure relative to the guide member is inhibited by interaction of the first member with the first distal member and the first surface, and by interaction of the second member with the second distal member and the second surface.

[0014] In certain embodiments, the access needle support structure further includes an opening configured to receive the access needle.

[0015] In certain embodiments, the access needle support structure further includes a plurality of openings, the opening being one of the plurality of openings.

[0016] In certain embodiments, the access needle and the access needle support structure are securable together when access needle is received in the opening.

[0017] In certain embodiments, the proximal end hub of the access needle and a proximal end of the opening include corresponding surfaces that inhibit rotation therebetween when the proximal end hub is received in the proximal end of the opening.

[0018] In certain embodiments, when the access needle support structure is secured to the guide member, the opening of the access needle support structure is centrally positioned relative to the first side and the second side of the guide member.

[0019] In certain embodiments, the gap is vertically between a top side of the first and second distal members and a bottom side of the first and second distal members.

[0020] In certain embodiments, the first surface includes a first ramp and the second surface includes a second ramp, and wherein, in in the distal position, the first member is positioned intermediate of the first distal member and the first ramp, and the second member is positioned intermediate of the second distal member and the second ramp.

[0021] In certain embodiments, the first and second members are generally parallel with each other.

[0022] In certain embodiments, when the mount is attached to the transrectal imaging probe, movement of the transrectal imaging probe causes corresponding movement to the guide member.

[0023] In certain embodiments, guide further includes the access needle.

[0024] In certain embodiments, the transrectal imaging probe provides ultrasound imaging.

[0025] Aspects of the present disclosure include a method of performing a transperineal biopsy procedure. The method includes: providing the transperineal biopsy guide as described herein; attaching the mount of the transperineal biopsy guide to the transrectal imaging probe; supporting the access needle to the access needle support structure; securing the access needle support

structure to the guide member in the distal position; inserting the access needle into the patient's perineum along a first trajectory; and inserting at least part of the biopsy instrument through the access needle and into the prostate and taking a first biopsy of the prostate along the first trajectory.
[0026] In certain embodiments, the method further includes: without removing the access needle from the patient's perineum, moving the transrectal imaging probe thereby moving the access needle to a second trajectory; and inserting at least part of the biopsy instrument through the access needle and into the prostate and taking a second biopsy of the prostate along the second trajectory. The first trajectory and the second trajectory are different from each other.
[0027] In certain embodiments, supporting the access needle to the access needle support structure includes securing the access needle to the access needle support structure.
[0028] In certain embodiments, in being secured to the access needle support structure, rotation of the access needle relative to the access needle support structure is inhibited.
[0029] In certain embodiments, the access needle support structure further includes an opening, and supporting the access needle to the access needle support structure comprises inserting the access needle into the opening.
[0030] In certain embodiments, inserting the access needle into the opening causes the proximal end hub of the access needle to at least partially be positioned within a proximal end of the opening thereby inhibiting rotation of the access needle relative to the access needle support structure.
[0031] 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.
[0032] 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.
[0033] A system in accordance with an embodiment may include a biopsy guide and a transrectal transducer fixed to the biopsy guide. The biopsy guide may be configured to guide an 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.
[0034] 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.
[0035] 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.
[0036] Other implementations are also described and recited herein. Further, while multiple implementations are disclosed, still other implementations of the presently disclosed technology

will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative implementations of the presently disclosed technology. As will be realized, the presently disclosed technology is capable of modifications in various aspects, all without departing from the spirit and scope of the presently disclosed technology. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not limiting.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] FIG. **1** shows a side view of a guide secured to a probe in accordance with an embodiment;

[0038] FIG. **2**A shows an internal view of a guide fastener in accordance with an embodiment;

[0039] FIG. **2**B shows a sheath-based guide fastener in accordance with an embodiment;

[0040] FIG. **2**C shows a zip-tie-based guide fastener in accordance with an embodiment;

[0041] FIG. **3** shows a top view of a guide secured to a probe in accordance with an embodiment;

[0042] FIG. **4** shows a cross-sectional view of the back of a guide secured to a probe in accordance with an embodiment.

[0043] FIG. **5** shows a magnified view of a guide secured to a probe in accordance with an embodiment;

[0044] FIG. **6** is a magnified top view of a guide fastener in accordance with an embodiment;

[0045] FIG. **7** is a magnified view of a guide in accordance with an embodiment;

[0046] FIG. **8** is a side view of a biopsy instrument that has penetrated the prostate in accordance with an embodiment;

[0047] FIG. **9** is a front view of a designated area of the prostate where a biopsy instrument will penetrate in accordance with an embodiment;

[0048] FIG. **10** is a side view of a biopsy instrument penetrating the prostate in accordance with an embodiment;

[0049] 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;

[0050] FIG. **12** is a top view of a biopsy instrument that has penetrated the prostate in accordance with an embodiment;

[0051] FIG. **13** is a side view of a prostate and the path of the biopsy instrument;

[0052] FIG. **14** is a front view of a guide positioned at a designated area of the prostate in accordance with an embodiment;

[0053] FIG. **15** is a side view of a guide positioned at a designated area of the prostate in accordance with an embodiment;

[0054] FIG. **16** is a front view of a guide positioned at another designated area of the prostate in accordance with an embodiment;

[0055] FIG. **17** is a side view of a guide positioned at another designated area of the prostate;

[0056] FIG. **18** is a front view of a guide positioned at a higher designated area of the prostate, according to one embodiment;

[0057] 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;

[0058] 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;

[0059] FIG. **21** is a view of an access needle positioned at the access site in accordance with an embodiment;

[0060] FIG. **22** is a magnified view of the right side of a prostate and a biopsy instrument in accordance with an embodiment;

[0061] 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;
[0062] FIG. **24** shows a method for performing a prostate biopsy in accordance with an embodiment;
[0063] 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;
[0064] FIGS. **26**A-**26**C show side views of a guide configured with a pivoting mount in accordance with an embodiment;
[0065] FIG. **27** is an isometric front view of another embodiment of a biopsy guide;
[0066] FIG. **28** is a front view of the biopsy guide of FIG. **27**;
[0067] FIG. **29** is a side view of the biopsy guide of FIG. **27**;
[0068] FIG. **30** is an isometric front exploded view of the biopsy guide of FIG. **27**;
[0069] FIG. **31**A is a front isometric view of the upper mount of the biopsy guide;
[0070] FIG. **31**B is a front view of the upper mount of the biopsy guide;
[0071] FIG. **31**C is a back view of the upper mount of the biopsy guide;
[0072] FIG. **31**D is a side view of the upper mount of the biopsy guide;
[0073] FIG. **31**E is a bottom view of the upper mount of the biopsy guide;
[0074] FIG. **31**F is a top view of the upper mount of the biopsy guide;
[0075] FIG. **32**A is a front isometric view of the displacement member of the biopsy guide;
[0076] FIG. **32**B is a front view of the displacement member;
[0077] FIG. **32**C is a back view of the displacement member;
[0078] FIG. **33**A is an isometric front view of the lower mount of the biopsy guide;
[0079] FIG. **33**B is a front view of the lower mount;
[0080] FIG. **34** is front isometric view of an access needle;
[0081] FIG. **35**A is a front isometric view of the lower mount;
[0082] FIG. **35**B is a front isometric view of the lower mount coupled with the upper mount;
[0083] FIG. **35**C is a front isometric view of the lower mount coupled with the upper mount and the sliding platform engaging with the rails of the upper mount;
[0084] FIG. **35**D is a front isometric view of the assembly of FIG. **35**C with an access needle supported by the sliding platform;
[0085] FIG. **36** is a front view of another embodiment of the displacement member;
[0086] FIG. **37**A is an isometric front view of another embodiment of the biopsy guide;
[0087] FIG. **37**B is an isometric front exploded view of the upper mount of the biopsy guide of FIG. **37**A;
[0088] FIG. **37**C is an isometric back exploded view of the upper mount of the biopsy guide of FIG. **37**A;
[0089] FIG. **37**D is a front view of the upper mount of the biopsy guide; FIG. **37**E is a front isometric view of the displacement member of the biopsy guide;
[0090] FIG. **37**F is a front view of the displacement member;
[0091] FIG. **37**G is a side view of another embodiment of the displacement member with the access needle partially positioned within the top needle receiving port of the vertically extending member;
[0092] FIG. **37**H is a front isometric view of another embodiment of the a biopsy guide;
[0093] FIG. **37**I is a side view of the biopsy guide of FIG. **37**H showing the platform member in various positions relative to the probe;
[0094] FIG. **37**J is a front isometric view of another embodiment of an upper mount;
[0095] FIG. **37**K is a front view of another embodiment of a biopsy guide;
[0096] FIG. **37**L is a side view of the biopsy guide of FIG. **37**K;
[0097] FIG. **37**M is a front isometric view of another embodiment of a biopsy guide;
[0098] FIG. **37**N is a front view of the biopsy guide of FIG. **37**M;
[0099] FIG. **37**O is a front isometric view of a cinch strap;

[0100] FIG. **37**P is a front isometric view of a V-block insert;
[0101] FIG. **37**Q is a front view of the biopsy guide of FIG. **37**M with a V-block insert of FIG. **37**P;
[0102] FIG. **37**R is a front isometric view of another embodiment of a biopsy guide;
[0103] FIG. **37**S is a front view of the biopsy guide of FIG. **37**R;
[0104] FIG. **37**T is a front isometric view of another embodiment of a biopsy guide;
[0105] FIG. **37**U is a front view of the biopsy guide of FIG. **37**T;
[0106] FIG. **37**V is a front view of another embodiment of a lower mount;
[0107] FIG. **37**W is an isometric front view of another embodiment of a lower mount;
[0108] FIG. **37**X is a front view of another embodiment of a lower mount;
[0109] FIG. **38**A is a transverse plane or slice view of a prostate depicting the urethra and an access site for penetration of the access needle;
[0110] FIG. **38**B is a sagittal plane or slice view of the prostate depicting the urethra and an access site for penetration of the access needle;
[0111] FIG. **38**C is the same transverse plane or slice view as FIG. **38**A, but including a marking device positioned within the urethra for biopsy navigation; and
[0112] FIG. **38**D is the same sagittal plane or slice view as FIG. **38**B, but including a marking device positioned within the urethra for biopsy navigation.

DETAILED DESCRIPTION

[0113] 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.

[0114] 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.

[0115] 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 freehanded, guided, transperincal 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.

[0116] 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.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] 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.

[0123] 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.

[0124] 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.

[0125] 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.

[0126] 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.

[0127] 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 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.

[0128] 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.

[0129] 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.

[0130] 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.

[0131] 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.
[0132] 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.
[0133] 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.
[0134] 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.
[0135] 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.
[0136] 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.
[0137] 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.
[0138] 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.
[0139] 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.
[0140] 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.
[0141] 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.

[0142] 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.

[0143] 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.

[0144] 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.

[0145] FIG. **2**A 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**.

[0146] 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**.

[0147] 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**.

[0148] By way illustration and not limitation, examples of two fasteners are discussed with respect to FIGS. **2**B and **2**C. FIG. **2**B 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**.

[0149] In another embodiment, as shown in FIG. **2**C, 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 sizes and shapes, it is also contemplated that the fasteners can be fit to specific models of probes for customized applications.

[0150] 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 showed in a central midline position, the location of the hole can be configured at any position of the guide **100**.
[0151] 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**.
[0152] 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 30 mm to 50 mm long; the upper mount **105** with a height ranging from 10 mm to 15 mm; the stabilization bars **101** with a height that is about ⅓ of the height of the upper mount **105**; fasteners **102** with a height of about 25 mm and 10 mm wide; a lower mount **104** 10 mm wide. Additionally, the offset **501** from the distal point of the stabilization bar **105** to the fasteners **102** may be 5 mm. It is contemplated that any of these dimensions may vary, including the stabilization bar **101**, which may be longer than the upper mount **105**.
[0153] 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 5 mm to 10 mm wide. Additionally, the sliding platform **301**, which may be from 12 mm to 25 mm 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**.
[0154] 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 5 mm to 10 mm; and the teeth **202** is from 5 mm to 8 mm wide.
[0155] 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.
[0156] 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**.
[0157] 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.
[0158] 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.
[0159] 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 the 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.

[0160] 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.

[0161] 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 5 mm for these purposes.

[0162] 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.

[0163] 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.

[0164] 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.

[0165] 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.

[0166] 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.

[0167] 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.

[0168] 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**.

[0169] 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.

[0170] 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.

[0171] 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.

[0172] 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.

[0173] FIGS. **26**A-**26**C 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.

[0174] 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. **26**A-**26**C. 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**.

[0175] 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. **26**A-**26**C. In particular FIGS. **26**A-**26**C 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**.

[0176] For example, FIG. **26**A 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. **26**B 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. **26**C 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**.

[0177] 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.

[0178] 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.

[0179] 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.

[0180] 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.

[0181] 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.

[0182] 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.

[0183] 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.

[0184] 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.

[0185] 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.

[0186] 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.

[0187] 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.

[0188] 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.

[0189] 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.

[0190] 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.

[0191] 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 exists, 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.

[0192] 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.

[0193] Reference is made to FIGS. **27-35**D, which depict various views of another embodiment of a transperineal biopsy guide **2700**. As with the previously described embodiments, the biopsy guide **2700** may couple with a transrectal probe and may be used in guiding an access needle in a transperineal prostate biopsy procedure. While reference will be made to the embodiment in FIGS. **27-35**D, aspects of the previously described embodiments may be incorporated into the present embodiment without limitation. And, aspects of the present embodiment may be similarly incorporated into the previously described embodiments without limitation.

[0194] To begin, reference is made to FIGS. **27-30**, which depict, respectively, a front isometric view, a front view, a side view, and a front isometric exploded view of the transperineal biopsy guide **2700**. As seen in the figures, the biopsy guide **2700** includes an upper mount **2702** and a lower mount **2704**. The lower mount **2704** includes a probe coupling or fastening mechanism **2706** to couple the lower mount **2704** with a transrectal probe (not shown in FIGS. **27-28**, but shown in FIGS. **1**, **2**B, and **3-6**, for example). The lower mount **2704** additionally includes an upper mount coupling mechanism **2714** to couple the lower mount **2704** with the upper mount **2702**. While FIGS. **27-30** depict a single coupling mechanism **2706**, it is foreseen that the biopsy guide **2700** may include more than one coupling mechanism **2706**, as shown and described in previous embodiments.

[0195] The upper mount **2702** may couple with the lower mount **2704** and may include a guide member **2708** and a displacement member (also referred to as a translating member, access needle support structure, or sliding platform) **2710**. The displacement member **2710** may couple with an access needle **2712** and be supported by the guide member **2708**. More particularly, the displacement member **2710** may slidingly couple with the guide member **2708** such that the displacement member **2710** and the access needle **2712** are guided along a trajectory that is fixed relative to the guide member **2708** and the transrectal probe. The trajectory of the access needle **2712** may be generally parallel with a longitudinal axis of the transrectal probe when the biopsy guide **2700** is coupled with the probe.

[0196] Reference is made to FIGS. **31**A-**31**F, which depict various views of the guide member **2708** of the upper mount **2702** of the biopsy guide **2700**. FIG. **31**A is a front isometric view of the guide member **2708**; FIG. **31**B is a front view of the guide member **2708**; FIG. **31**C Is a back view of the guide member **2708**; FIG. **31**D is a side view of the guide member **2708**; FIG. **31**E is a bottom view of the guide member **2708**; and, FIG. **31**F is a top view of the guide member **2708**.

[0197] As seen in the figures, the guide member **2708** includes a distal end **2716**, a proximal end **2718** opposite the distal end **2716**, and a longitudinal axis **2720** extending through the distal and proximal ends **2716**, **2718**. As described herein locational orientations of distal and proximal are relative to the patient or, more particularly, the perineum of the patient. As such, distal generally refers to towards the patient and proximal refers to away from the patient.

[0198] Referring back to the figures, the guide member **2708** further includes a base platform **2722** extending substantially perpendicularly between a pair of vertical extension members **2724**. Atop each of the vertical extension members **2724** is a guide rail or stabilization bar **2726** that is adapted to slidingly engage with and allow the displacement member **2710** to translate along a trajectory that is parallel with the longitudinal axis **2720** of the guide member **2708**.

[0199] As best seen in FIGS. **31**A and **31**C, each of the guide rails **2726** includes a generally rectangular member **2728** that is perpendicularly oriented to the vertical extension members **2724**. The rectangular member **2728** extends from the proximal end **2718** to the distal end **2716** of the guide member **2708**. The vertical extension members **2724** couples with a bottom surface **2730** of the rectangular member **2728**. An outer lateral edge of the rectangular member is coupled with a side member **2732** that extends from the proximal end **2718** to the distal end **2716** of the guide member **2708**. A distal member or flange **2734** extends inwardly from the rectangular member **2728** a distance that is equal to the width of the rectangular member **2728**. More particularly, the distal member **2734** includes a rounded inner edge **2736** that is coplanar, at its apex, with an inner edge **2738** of the rectangular member **2728**. The distal member **2734** may include a planar distal face or surface **2740** with an opening **2742** formed therein. The opening **2742** may facilitate an access point for injection molding. As with previously described embodiments, the guide rails **2726** and, more particularly, the distal face **2740** of the guide rails **2726** may facilitate the positioning and holding of the perineal skin and subcutaneous tissue to allow positioning of the access needle **2712**.

[0200] As seen in FIGS. **31**A, **31**C, and **31**F, a top surface **2744** of the rectangular member **2728** includes a stop feature **2746** to secure or lock the displacement member **2710** in a distal or deployed condition or position. The stop feature **2746** is a ramp that distally slopes upward until the apex of the ramp at which point the ramp distally slopes downward. In the distal position, the displacement member **2710** is at a distal-most position and abuts or is adjacent a proximal face **2748** of the distal member **2734**. The distal member **2734**, thus, prevents further distal movement of the displacement member **2710** and the stop feature **2746** restrains proximal movement a certain amount. In certain embodiments, as seen in the figures, the proximal end **2718** of the rectangular member **2728** is open such that the displacement member **2710** can be slidingly engaged and disengaged with the rectangular member **2728**. As seen in the figures, in the distal position, vertical displacement of the displacement member **2710** relative to the guide member **2708** is inhibited since the upper members **2784** and the lower tab members **2780** sandwich the rectangular members **2728**.

[0201] As seen in FIGS. **31**A and **31**D-**31**F, the base platform **2722** extends about one half of the overall longitudinal distance of the guide rails **2726**. In this way, the guide rails **2726** extend beyond both the base platform **2722** and the vertical extension members **2724** such that the guide rails **2726** may contact the perineal skin and subcutaneous tissue of the patient but not a distal edge **2750** of the base platform **2722** or a distal edge **2752** of the vertical extension members **2724**. And since a distal portion of the lower mount **2704** lies generally flush with the distal edge **2750** of the base platform **2722**, the lower mount **2704** also may be spaced apart from the skin of the patient during the biopsy procedure. In this way, in certain embodiments, the guide rails **2726** may contact the skin of the patient while the other portions of the guide **2700** remain spaced apart from the patient's skin.

[0202] As seen in FIG. **31**D, the distal edge **2752** of the vertical extension member **2724** is arcuate and a proximal edge **2754** of the vertical extension member **2724** includes a semi-circular path about halfway between the base platform **2722** and the guide rails **2726**. As seen in FIGS. **31**E-**31**F, the base platform **2722** includes a pair of channels **2756** extending parallel to each other and extending longitudinally. These channels **2756** may coaxially align with snap features **2758** in the upper mount coupling mechanism **2714** of the lower mount **2704** to facilitate the upper mount **2702** being coupled with the lower mount **2704**. Once the channels **2756** and the snap features **2758** are aligned, the upper and lower mounts **2702**, **2704** may be snapped together such that the snap feature **2758** extends through the channels **2756** to securely couple the mounts together. While the figures show channels **2756** and snap features **2758**, other mechanisms are possible to couple the upper and lower mounts **2702**, **2704**. For example, the base platform **2722** and the upper mount coupling mechanism **2714** may each include through holes that coaxially align. And, screws or nuts/bolts may be used to secure the mounts **2702**, **2704** together.

[0203] As seen in FIGS. **31**B-**31**C and **31**E, the bottom surface **2762** of the base platform **2722** includes a rectangular rail or protrusion **2764** extending longitudinally. The top surface of the base platform **2722** includes a longitudinally extending groove, which may be used to align the guide member **2708** with the sagittal plane of the ultrasound probe. As seen in FIG. **31**E, the channels **2756** extend through the rail **2764**. As will be described subsequently, the rail **2764** may engage with a platform **2766** of the upper mount coupling mechanism **2714** of the lower mount **2704** so as to align the upper and lower mounts **2702**, **2704** upon coupling together.

[0204] Reference is made to FIGS. **32**A-**32**C, which depict, respectively, a front isometric view, a front view, and a back view of the displacement member **2710**. As described previously, the translating or displacement member **2710** may be coupled with the guide rails **2726** of the guide member **2708** so as to be displaceable or slidable between the proximal end **2718** of the guide member **2708** to the distal end **2716**. Thus, when the access needle **2712** is coupled with the displacement member **2710**, the access needle **2712** is also displaceable between the proximal end **2718** of the guide member **2708** to the distal end **2716**.

[0205] As seen in the figures, the displacement member **2710** includes a central vertically extending member **2760** having five needle receiving ports **2768** formed therein. Each needle receiving port **2768** includes an opening **2770** extending from a distal end **2772** to a proximal end **2774** of the displacement member **2710**. Each of the openings **2770** of the needle receiving ports **2768** are generally vertically aligned with each other and each includes a trajectory axis **2776** defining a trajectory of the access needle **2712** when positioned within the opening **2770**. The trajectory axis **2776** is generally parallel to the longitudinal axis **2720** of the guide member **2708** when the displacement member **2710** is coupled with the guide member **2708**. The trajectory axis is also generally parallel with a longitudinal axis of the probe when the biopsy guide **2700** is coupled with the probe. Thus, the trajectory axis **2776** of the access needle **2712** may be generally fixed or constant, in a generally parallel orientation to the previously described axes, as the displacement member **2710** displaces distal-proximal relative to the guide member **2708**.

[0206] A particular needle receiving port **2768** may be chosen based on a desired distance from the probe. Thus, if a physician desires that the access needle **2712** should be positioned nearer the probe, a particular needle receiving port **2768** may be chosen that is at the bottom of the displacement member **2710**. In certain embodiments, the openings **2770** of the needle receiving ports **2768** may be vertically spaced apart about 5 mm. In certain embodiments, the openings **2770** of the needle receiving ports **2768** may be vertically spaced apart about 3 mm. In certain embodiments, the openings **2770** of the needle receiving ports **2768** may be vertically spaced apart about 4 mm. In certain embodiments, the openings **2770** of the needle receiving ports **2768** may be vertically spaced apart at any interval between about 2 mm to about 6 mm, among other distances.

[0207] While the vertically extending member **2760** includes five needle receiving ports **2768**, it is foreseen that more or less ports may be included in the displacement member **2710** without limitation.

[0208] The displacement member **2710** further includes a coupling mechanism **2778** to displaceably couple the displacement member **2710** and the guide rails **2726**. The coupling mechanism **2778** includes a pair of lower tab members **2780** extending laterally out and away from the vertically extending member **2760**. When coupled with the guide rails **2726**, the lower tab members **2780** may abut or be positioned adjacent the bottom surface **2730** of the rectangular member **2728**. The tab members **2780** include a planar top surface **2782** that may provide sliding contact with the bottom surface **2730** of the rectangular member **2728**. The planar contact between the surfaces may contribute to stability of the displacement member **2710** relative to the guide rails **2726** by reducing vertical tilt of the displacement member **2710**.

[0209] The coupling mechanism **2778** further include an upper member **2784** positioned above the lower tab members **2780**. A bottom surface **2786** of the upper members **2784** may abut or be positioned adjacent the top surface **2744** of the rectangular member **2728** when the displacement member **2710** is coupled with the guide rails **2726**. The bottom surface **2786** of the upper members **2784** is planar and, thus, the planar contact between the surfaces may contribute to stability of the displacement member **2710** relative to the guide rails **2726** by reducing vertical tilt of the displacement member **2710**. The upper members **2784** and the lower tab members **2780** operate to sandwich the rectangular members **2728** of the guide rails **2726** when the displacement member **2710** is coupled with the guide member **2708**.

[0210] The coupling mechanism **2778** further includes a lateral brace mechanism **2788** at lateral ends of the upper members **2784**. The lateral brace mechanism **2788** includes an upside-down U-shaped member **2790** having three inner surfaces **2792** that define a longitudinal extending channel **2794** therein. The channel **2794** may receive the side members **2732** therein when the displacement member **2710** couples with the guide rails **2726**. In this way, the lateral brace mechanism **2788** may contribute to stability of the displacement member **2710** relative to the guide rails **2726** by reducing lateral tilt of the displacement member **2710**. It is foreseen that the displacement member **2710** may not include the lateral brace mechanism **2792** and may instead only include the upper member **2784** and the lower tab members **2780**. Alternatively, it is foreseen that the displacement member **2710** may not include the upper member **2784** and the lower tab members **2780**, but may only include the lateral brace mechanism **2792**. Additionally and alternatively, other mechanisms are possible to facilitate the displacement member **2710** displacing between the proximal and distal ends **2718**, **2716** of the guide member **2708**. For example, the guide member **2708** could include longitudinally extending rods (not shown) and the displacement member **2710** may include a sleeve that engages and is guided by the rods. In such an embodiment, the rods may be adapted to slide within the openings **2770** of the needle receiving ports **2768** with or without modification to the displacement member **2708**.

[0211] Still referring to FIGS. **32**A-**32**C, flanges **2796** extend laterally from the upside-down U-shaped members **2790**, which may act as grasping points for the physician. The flanges **2796** extend inwardly and are coplanar with a back wall member **2798** that spans between the upside-down U-shaped members **2790**, the vertically extending member **2760**, and the upper members **2784**. The back wall member **2798** may function to provide rigidity between the various components of the displacement member **2710**. As seen in FIG. **32**C, a proximal side **2800** of the needle receiving ports **2768** includes keyed features to lockingly engage the access needle **2712** such that it does not rotate once it is coupled with the port **2768**.

[0212] Reference is made to FIGS. **33**A and **33**B, which depict, respectively, a front isometric view and a front view of the lower mount **2704** of the biopsy guide **2700**. As previously described, the upper mount coupling mechanism **2714** includes the snap features **2758** to couple with the channel **2756** in the base platform **2722**. Each of the snap features **2758** may be vertical flanges **2802** with a lip **2804** at its vertical termination. As the inner surfaces defining the channels **2756** contact the vertical flanges **2802**, the inner surfaces compress the lips **2804** together relative to each other until the flanges **2802** “snap” or expand outwardly relative to each other such that the lips **2804** are on a top surface of the base platform **2722**. The vertical flanges **2802** extend from the platform **2766** of the upper mount coupling mechanism **2714**. The platform **2766** is coupled with the probe coupling mechanism **2706**, which, as seen in the figures, may be a snap-grip or snap-clip type of hose or tube clamp. The mechanism **2706** may include a first and a second arm member **2804**, **2806** extending from opposite sides **2808** of the platform **2766**. The arm members **2804**, **2806** are flexible and designed to wrap around a portion of the probe fitted within the opening formed by the first and second arms **2804**, **2806**. The first arm member **2804** includes a first clamping structure **2810** including an upper row of teeth **2812** and a lower smooth sliding surface **2814**. The second arm member **2806** includes a second clamping structure **2816** including an upper smooth sliding surface **2818** and a lower row of teeth **2820**. The first and second clamping structures **2810**, **2816** work together to provide a clamping or gripping function to securely support the transrectal probe to the lower mount **2704** and, thus, the upper mount **2702**.

[0213] In operation, a transrectal probe is positioned within the opening between the first and second clamping structures **2810**, **2816**. The physician may determine a desired position on the probe based on the patient's anatomy, the particular transrectal probe, or the particular procedure to be performed, among other possible criteria. Once a position for the lower mount **2704** is chosen, the physician may cause the first and second arm members **2804**, **2806** to be contracted relative to each other by pushing on the outer ends **2822** of the clamping structures **2810**, **2816**, respectively. As the clamping structures **2810**, **2816** converge relative to each other, the lower row of teeth **2820** on the second clamping structure **2806** is received within an opening **2824** formed between the upper row of teeth **2812** and the lower smooth surface **2814**. The upper row of teeth **2812** are caused to engage with the lower row of teeth **2820**. Additionally, the upper smooth surface **2818** is caused to slide on an inner smooth surface **2826** of the first arm member. And, the lower smooth sliding surface **2814** is caused to slide on a lowest smooth surface **2828** on the second clamping structure **2816**. The teeth of the upper and lower row **2812**, **2820** are arranged in a saw tooth like manner such that when they are increasingly engaged with each other the teeth grip each other and resist moving in the opposite direction. Once engaged, the teeth may be disengaged by pulling on a tab **2830** on a bottom portion of the first clamping structure **2810**. Pulling on the tab **2830** allows the teeth **2812**, **2820** to disengage with each other and the flexible nature of the first and second arms **2804**, **2806** are caused to spring back into the shape shown in FIG. **33**B. As seen in FIGS. **33**B-**33**B, an inner surface **2834** of the first and second arms **2804**, **2806** includes a gasket **2832** that may be flexible and deformable to provide for a gripping surface between the probe and the lower mount **2704**.

[0214] Reference is made to FIG. **34**, which depicts a front isometric view of an access needle **2712**. As seen in the figure, the needle **2712** includes a distal end **2836** and a proximal end **2838** opposite the distal end **2836**. At the distal end **2836** is the bevel **2840** extending distally from a shaft **2842**. Within the shaft **2842** is a lumen **2844** for communication of fluids or, in the case of the access needle **2712**, a shaft of a smaller gage biopsy needle. The proximal end **2838** of the needle **2712** includes a hub **2846** with ridges **2848** extending longitudinally around a circumference of the hub **2846**. The ridges **2848** may engage with corresponding and negatively shaped features on the proximal side **2800** of the needle receiving ports **2768**.

[0215] The following discussion will focus on use of the biopsy guide **2700** and will refer to FIGS.

35A-**35**D, which depict, respectively: a front isometric view of the lower mount **2704**; a front isometric view of the lower mount **2704** coupled with the upper mount **2702**; a front isometric view of the lower mount **2704** coupled with the upper mount **2702** and the displacement member **2710** positioned at a proximal end of the guide member **2708**; and, a front isometric view of the lower mount **2704** coupled with the upper mount **2702** and the displacement member **2710** positioned at a proximal end of the guide member **2708** with the access needle **2712** positioned within one of the needle receiving ports **2768**.

[0216] As seen in FIG. **35**A, the lower mount **2704** is positioned with the first and second clamping structures **2810**, **2816** of the first and second arm members **2804**, **2806** uncoupled such that a transrectal probe may positioned between the arm members **2804**, **2806**. While it is not depicted in the figures, the first and second clamping structures **2810**, **2816** may be engaged with each other or coupled as described previously to grasp the probe between the arm members **2804**, **2806** and against the gasket **2832**.

[0217] As seen in FIG. **35**B, the upper mount **2702** may be coupled with the lower mount **2704**. More particularly, the vertical flanges **2802** on the platform **2766** of the upper mount coupling mechanism **2714** may be engaged with or snapped together with the channels **2756** on the base platform **2722** of the guide member **2708**.

[0218] As seen in FIG. **35**C, the displacement member **2710** may be engaged with the guide member **2708**. More particularly, the distal end **2772** of the displacement member **2710** is longitudinally aligned with the proximal end **2718** of the guide member **2708** such that the proximal ends of the guide rails **2726** are positioned to extend into the corresponding features of the displacement member **2710**. That is, the rectangular member **2728** is aligned with the opening between the upper members **2784** and the lower tab members **2780**, and the vertically extending side members **2732** are aligned with the channels **2794** between the inner surfaces **2792** of the upside-down U-shaped member **2790** of the displacement member **2710**. Once aligned, the displacement member **2710** is displaced, moved, or translated into engagement with the guide member **2708**, as seen in FIG. **35**C, which depicts the displacement member **2710** in a proximal-most position.

[0219] As seen in FIG. **35**D, the access needle **2712** is coupled with the displacement member **2710**. More particularly, the bevel **2840** and shaft **2842** of the access needle **2712** are extended through the proximal side **2800** of a particular opening **2770** of a needle receiving port **2768** until the hub **2846** of the access needle **2712** engages with the proximal side **2800** of the port **2768**. The ridges **2848** of the access needle **2712** may engaged with corresponding features within the opening **2770** of the port **2768** such that the access needle **2712** remains coupled with the displacement member **2710**. The access needle **2712** may be restrained from rotating by the ridges **2848**. In certain embodiments, the access needle **2712** may be secured to the displacement member **2710** by, for example, a threaded features on the hub **2846** and openings **2770** of the ports **2768** such that the needle **2712** and the displacement member **2710** may be threadably engaged and disengaged with each other.

[0220] In the orientation shown in FIG. **35**D, the displacement member **2710** and the access needle **2712** are in a proximal-most position or condition. As seen in the figure, in this particular embodiment, the bevel **2840** of the access needle **2712** lies about flush with the planar distal face **2740** of the distal member **2734**. In other embodiments or with a different sized needle **2712**, the bevel **2840** of the access needle **2712** may extend beyond the distal face **2740** of the distal member **2734** when the displacement member **2710** is in the proximal-most position, or the bevel **2840** of the access needle **2712** may be positioned proximal of the distal face **2740** of the distal member **2734** when the displacement member **2710** is in the proximal-most position.

[0221] In certain embodiments where the bevel **2840** of the access needle **2712** does not extend past the distal face **2740** of the distal member **2734**, the physician may use the distal member **2734** to manipulate the perineal skin and subcutaneous tissue of the patient while having the displacement member **2710** coupled to the guide member **2708**, but while not having the bevel **2840** of the access needle **2712** contact the patient's skin.

[0222] While FIG. **35**D depicts the access needle **2712** coupling with the displacement member **2710** when the displacement member **2710** is in the proximal-most position, the access needle **2712** may be engaged with the displacement member **2710** when the displacement member is at the distal-most position or at any position between the distal-most position and the proximal-most position. When the access needle **2712** is in the proximal-most position, as shown in FIG. **35**D, the physician may manipulate the probe and the distal member **2734** of the upper mount **2702** to manipulate the perineal skin and subcutaneous tissue of the patient. When the trajectory of the access needle **2712** is appropriately positioned relative to the patient's perineal skin and subcutaneous tissue, the physician may distally displace the access needle **2712** by pushing on one or more of the back wall member **2798** or flanges **2796** of the displacement member **2710**, or the hub **2846** of the access needle **2712**. In certain embodiments, the displacement member **2710** may be biased or spring-loaded such that the physician may actuate a mechanism that distally advances the displacement member **2710** and the access needle **2712** without a need for manual advancement by the physician. As the access needle **2712** and the displacement member distally advance or displace, the displacement member **2712** will lock or be secured into the distal-most position via the ramps of the stop feature **2746** positioned on the top surface **2744** of the rectangular member **2728**. In the distal-most position, as seen in FIG. **27**, the displacement member **2710** is prevented from further distal displacement via the distal member **2734**. In particular, a front edge or surface **2850** of the distal end **2772** of the displacement member **2710** abuts or is adjacent a proximal surface **2748** of the distal member **2734** when the displacement member **2710** is in the distal-most position. In certain embodiments, as seen in FIG. **27**, the back surface **2748** may abut or be adjacent the front edge or surface **2850** of the upper members **2784**, the lower tab members **2780** (not seen in FIG. **27**) and/or part of the upside-down U-shaped member **2790**.

[0223] As further seen in FIG. **27**, the distal members **2734** extend inward towards the needle receiving ports **2768** but may define an opening or gap between the rounded inner edges **2736** for the access needle **2712** to extend therethrough. The displacement member **2710** can support the access needle **2712** at a various heights relative to the mount **2704** (and the probe) with the access needle **2712** being at least partially located in the gap when the displacement member **2710** is secured to the guide member **2708** in the distal position, as seen in FIG. **27**.

[0224] Once the access needle **2712** is in position in the patient's skin and subcutaneous tissue, the biopsy procedure may continue, as described previously, with the physician extending a biopsy needle through the lumen **2844** of the access needle **2712** and into the patient's prostate. Once the procedure is complete, the physician may remove the access needle **2712** from the patient's body by proximally displacing the displacement member **2710** and the access needle **2712** by pulling or pushing on the displacement member **2710** or access needle. Alternatively, the access needle **2712** may be disengaged with the displacement member **2710** while the displacement member **2710** is in the distal-most position.

[0225] The discussion will now focus on additional and alternative embodiments of the biopsy guide. As seen in FIG. **36**, the displacement member **2710** may include the upper members **2784** and the lower tab members **2780** for engaging with and sliding or displacing relative to the rectangular members **2728** of the guide rails **2726**. The displacement member **2710** of FIG. **36**, however, does not include an upside-down U-shaped member for engaging with the side members **2732** of the guide rails **2726** and, further, does not include the back wall member **2798** and the flanges **2796**. Features of both embodiments of the displacement member **2710** may be combined as needed and without limitation.

[0226] The lower mount **2704**, as described herein, may take many forms without departing from the scope of the present disclosure. Other mechanisms to couple the upper mount **2702** to the probe are possible and contemplated herein. For example, the upper mount **2702** may couple with or be integrally formed with a thin sheath or sleeve of latex, polyurethane, or other materials, such as a male condom. The sheath may be fitted over the probe in a tight fitting manner such that the upper mount **2702** is secured in position relative to the probe.

[0227] Additional or alternative embodiments of the lower mount **2704** may include rubber or rubber-type cinch straps that are coupled with or integral with the upper mount **2702**.

[0228] The upper mount **2702**, as described herein, may take many forms without departing from the scope of the present disclosure. Other mechanisms to guide the access needle **2712** are possible and contemplated herein. For example, the displacement member **2710** supporting the access needle **2712** may be coupled to a platform on a coupler side of a four-bar linkage (e.g., parallelogram linkage) where the fixed portion of the linkage may be coupled with the base platform **2722** of the guide member **2710**. The platform may be displaceable distal-proximal by urging the platform distally or proximally, while displacing in an arcuate path. In the case of a parallelogram linkage, the trajectory of the access needle **2712** may remain parallel to the longitudinal axes of the probe and guide member **2710** while vertically displacing. In this way, such a linkage may be used for distal-proximal displacement as well as vertical displacement or adjustment, as needed for a particular biopsy procedure. This type of displacement member **2710** may be used with the guide member **2708** as described herein with or without modification.

[0229] As another example, the displacement member **2710** supporting the access needle **2712** may be coupled to a carriage or lead screw nut that is displaced relative to the guide member **2708** (and probe) via rotation of a lead screw. The lead screw may be positioned parallel to the longitudinal axis of the guide member **2708** and the probe such that displacement of the lead screw nut and, thus, the displacement member **2710** and access needle **2712** displace or translate distal-proximal while maintaining a trajectory of the access needle **2712** that may be fixed. A bottom side of the lead screw nut may include a feature or protrusion that extends into a channel formed in the base platform **2722** of the guide member **2708** such that the lead screw nut does not rotate, but, rather, displaces or translates linearly distal-proximal in response to rotation of the lead screw. The lead screw may be rotatable by hand via, for example, a handle at the proximal end of the lead screw.

[0230] Reference is now made to FIGS. **37**A-**37**F, which depict various views of another embodiment of the biopsy guide **3700**. As seen in FIG. **37**A, which is a front isometric view of the biopsy guide **3700**, the guide **3700** is similar to previously described embodiments of the guide in that it includes an upper mount **3702** and a lower mount **3704**. The lower mount **3704** is adapted to secure the guide **3700** to a transrectal probe and includes the same features as the previously described embodiment. The upper mount **3702** may releasably couple with the lower mount **3704**. As seen in FIGS. **37**B and **37**C, which are, respectively, front and back isometric exploded views of the upper mount **3702**, the biopsy guide **3700** further includes a guide member **3710** and a displacement, sliding, or translating member **3706** that is adapted to couple with an access needle **3708**.

[0231] As seen in FIGS. **37**B-**37**C and **37**E-**37**F, the displacement member **3706** includes a vertically extending member **3712** having five needle receiving ports **3714** formed within the member **3712**. The ports **3714** may receive the access needle **3708** within any of the ports **3714**, as previously described, to vary the height of the access needle **3708** relative to the probe (not shown). The access needle **3708** may couple with the needle receiving ports **3714** such that they may be displaced together relative to the guide member **3710**.

[0232] As seen in the figures, a bottom end **3716** of the vertically extending member **3712** is coupled to a distal end **3718** of a rail member **3720** that may slidingly engage with the guide member **3710**. The rail member **3720** includes a flange member **3722** and a web member **3724** arranged in a T-beam shape. That is, the flange member **3722** is wider than the web member **3724**, which projects upward and substantially perpendicularly from a central portion of the flange member **3722**. From the distal end **3718**, the rail member **3720** extends proximally to a proximal end **3726**. At the proximal end **3726** is an end plate member **3728**, which prevents distal displacement of the displacement member **3706** past a certain point.

[0233] As seen in FIGS. **37**C and **37**D, the guide member **3710** includes a rail receiving slot or channel **3730** having a proximal opening **3732**, a distal opening **3734** (seen in FIG. **37**B), and a top opening **3736**. The rail receiving slot **3730** is generally a negative shape of the rail member **3720** and may receive the rail member **3720** therein and permit the rail member **3720** and, thus, the displacement member **3706** and access needle **3708** to displace relative to the guide member **3710**. When the rail member **3720** is positioned within the rail receiving slot **3730**, inner surfaces **3738** of the slot **3730** may contact the flange and web members **3722**, **3724** and restrain the displacement member **3706** from lateral displacement and vertical tilting while allowing distal-proximal displacement or translation of the displacement member **3706**. Thus, the displacement member **3706** may be displaced or translated distally and proximally while maintaining alignment of a trajectory of the access needle **3708** substantially parallel with a longitudinal axis of the probe when the biopsy guide **3700** is coupled with the probe.

[0234] As seen in FIG. **37**A, the displacement member **3706** is in a distal-most position with the distal end **3718** of the rail member **3720** and a distal end **3740** of the vertically extending member **3712** being about coplanar with a distal face **3742** of a distal member **3744** of the guide rail members **3746**, which may be similar to as previously described in relation to previous embodiments. In the distal-most position, the rail member **3720** extends past the distal opening **3734** of the rail receiving slot **3730**, and the end plate member **3728** of the rail member **3720** abuts or is adjacent the proximal opening **3732** of the rail receiving slot **3730**. To proximally displace the displacement member **3706** from the distal-most position, the physician may pull or push on the end plate member **3728**, the vertically extending member **3712**, or the access needle **3708**.

[0235] It is noted that the guide rail members **3746** and, more particularly, the distal members **3744** may be used by the physician to manipulate the perineal skin and subcutaneous tissue of the patient, as described previously. And while the embodiment of the biopsy guide **3700** in FIGS. **37**A-**37**F describe a rail and slot type of arrangement between the displacement member **3706** and the guide member **3710**, other mechanisms are possible to displace the displacement member **3706** relative to the guide member **3710**. Additionally or alternatively, features and elements from other embodiments of the biopsy guide may be incorporated into the present embodiment without limitation. Similarly, features and elements from the present embodiment of the biopsy guide may be incorporated into any of the other embodiments of the biopsy guide without limitation.

[0236] As seen in FIG. **37**G, which is a side view of another embodiment of the displacement member **3706** with the access needle **3708** partially positioned within the top needle receiving port **3714** of the vertically extending member **3712**, the rail member **3720** may be replaced by a lead screw **3748** and the bottom end **3716** of the vertically extending member **3712** may include a lead screw nut **3750** that rotationally engages with the lead screw **3748** to cause the displacement member **3706** and the access needle **3708** to displace or linearly translate relative to the probe and the guide member **3710** (not shown). The lead screw **3748** may be rotationally coupled with bearings **3752** at opposite ends which allow the lead screw **3748** to rotate thereon. The lead screw nut **3750** may be prevented from rotating by a guide rail **3754** that extends between the bearings **3752** and also extends through a passageway in the lead screw nut **3750**. In this way, as the lead screw **3748** rotates, the lead screw nut **3750**, as well as the vertically extending member **3712** and the access needle **3708**, are caused to displace or translate distal-proximal because the lead screw nut **3750** is prevented from rotating by the guide rail **3754**. The lead screw **3748** may include a handle **3756** for rotating the lead screw **3748**. The displacement member **3706** shown in FIG. **37**G may be coupled with the guide member **3710** shown in the previous figures such that the lead screw **3748** is generally parallel with the longitudinal axis of the guide member **3710** and the probe. The displacement member **3706** may, for example, couple with the base platform of the guide member **3710** at the bearings **3752**, or at other parts of the member **3706**.

[0237] As seen in FIGS. **37**H-**37**I, which are, respectively, an isometric front view and a side view of another embodiment of the biopsy guide **3900**, it includes a probe coupling mechanism **3902** in the form of collars that may be adjustably secured to the probe **3904**. Four arm members **3906** are pivotally coupled at bottom ends **3908** to the probe coupling mechanism **3902** and pivotally coupled at top ends **3910** to a platform member **3912**. The arm members **3906** may be of equal length such that the platform member **3912** is capable of displacing distal-proximal while maintaining a parallel orientation relative to the probe **3904**. More particularly, as seen in FIG. **37**I, the platform member **3912** may include a longitudinal axis that is generally parallel to a longitudinal axis of the probe **3904** in all distal-proximal orientations of the platform member **3912** relative to the probe **3904**. The platform member **3912** may include a longitudinally extending channel **3914** for receiving and guiding a displacement member **3916** having a needle receiving port **3918**. The displacement member **3916** may include a flanged lower body portion **3920** that matches a shape of the channel **3914** such that the displacement member **3916** may slide within the channel **3914** or displace relative to the platform member **3912** while maintaining an orientation of a needle positioned within the needle receiving port **3918** that is generally parallel to the longitudinal axis of the probe **3904**.

[0238] As seen in FIG. **37**I, the biopsy guide **3900** may function as a four bar parallel or parallelogram linkage during displacement of the platform member **3912**. In particular, FIG. **37**I shows three positions of the platform member **3912** as it displaces. A first position **3922** shows the platform member **3912** at a highest position relative to the probe **3904** where the arm members **3906** are vertically extended to their maximum. A second position **3924** shows the platform member **3912** as it distally displaces while rotating clockwise and lowering the platform member **3912** relative to the probe. A third position **3926** shows the platform member **3912** as it further distally displaces while rotating clockwise and lowering the platform member **3912** relative to the probe. As seen in all positions **3922**, **3924**, **3926**, a longitudinal axis of the platform member **3912** may remain generally parallel with a longitudinal axis of the probe **3904**.

[0239] Reference is now made to FIG. **37**J, which is a front isometric view of another embodiment of an upper mount **4000**. As seen in the figure, the upper mount **4000** includes a guide member **4002** that is similar to previously described embodiments in that it includes a pair of guide rails **4004** that extend longitudinally and are spaced apart from each other. This embodiment of the upper mount **4000**, however, does not include a displacement member. Rather, the guide mount **4002** of the upper mount **4000** of FIG. **37**J includes a vertically oriented member **4008** including needle receiving ports **4006** that are also vertically aligned. The member **4008** may not be displaceable relative to the guide member **4002** in this particular embodiment.

[0240] That is, the needle receiving ports **4006** may align a trajectory of an access needle in any of the ports **4006** such that a trajectory of the access needle may be generally parallel to a longitudinal axis of the probe. The needle receiving ports **4006** may be integrally formed with the guide member **4002**. Or, the vertical member **4008** including the needle receiving ports **4006** may be releasably coupled to the guide member. In a releasable arrangement, the vertical member **4008** may be coupled with the guide member via any coupling mechanism described herein or known in the art. As seen in the figure, the needle receiving ports **4006** are cylindrical and extend generally from a proximal end **4010** to a distal end **4012** of the guide member **4002**. The distal tip **4014** of the needle receiving ports **4006** may be about coplanar with a distal face **4016** of the distal members **4018** of the guide rails **4004**.

[0241] Reference is made to FIGS. **37**K-**37**L, which are, respectively, front and side views of another embodiment of a biopsy guide **4100**. As seen in the figures, the biopsy guide **4100** includes displacement member **4102** including a vertically oriented body **4104** having five vertically aligned needle receiving ports **4106** for receiving, supporting, and orienting an access needle. At a bottom end **4108** of the vertical body **4104** is a probe coupling mechanism **4110** including a collar **4112** having a guide rail or protrusion **4114** extending from an inner surface **4116** of the collar **4112**. The guide rail **4114** extends longitudinally in the collar **4112** and may be received by a correspondingly shaped channel or slot **4120** in a transrectal probe **4118**. In this way, the displacement member **4102** may slide, displace, or translate relative to the probe **4118** while being restrained from certain movements by the interaction between the guide rail **4114** and the channel **4120**. As such, the access needle supported by the needle receiving port **4106** may displace or translate distal-proximal relative to the probe **4118** while maintaining a trajectory that is generally parallel with a longitudinal axis of the probe **4118**.

[0242] The inner surface **4116** may include roller bearings or similar structures to permit the collar **4112** to roll, translate, or displace relative to the probe **4118**. While the channel **4120** is described as being formed in the probe **4118**, the channel **4120** may be formed in a separate member that is coupled to the probe **4118**. In this case, a specialized probe having a channel may not be needed; rather, any off-the-shelf ultrasound probe may be used with the separate member having the channel **4120** to utilize the biopsy guide **4100** of the present embodiment.

[0243] Reference is made to FIGS. **37**M-**37**U, which depict various views of alternative embodiments of the lower mount. To begin, reference is made to FIGS. **37**M-**37**Q. FIG. **37**M is a front isometric view of a biopsy guide **4200**. FIG. **37**N is a front view of the biopsy guide **4200**. FIG. **37**O is a front isometric view of a cinch strap **4202**. FIG. **37**P is a front isometric view of a V-block insert **4204**. FIG. **37**Q is a front view of the biopsy guide **4200** of FIG. **37**M with an insert **4204** of FIG. **37**P.

[0244] As seen in FIG. **37**M, the biopsy guide **4200** includes an upper mount **4206** and a lower mount **4208**. The upper mount **4206** may include a base platform **4210** and a pair of guide rails **4212** extending longitudinally from the base platform **4210**. The guide rails **4212** may guide a displacement member (not shown), which may support an access needle (not shown), as described in previous embodiments. The lower mount **4208** may include a cinch strap **4202**, as shown in FIG. **37**), which may include a flange **4214** at one end **4216** and a series of transversely extending ridges **4218**. The cinch strap **4202** may be fitted or positioned within a slot **4220** in the base platform **4210** such that the flange **4214** abuts the surfaces of the slot **4220** and is prevented from extending through the slot **4220**. The cinch strap **4202** may be fitted around the transrectal probe **4222** and positioned within a locking opening **4224** opposite the slot **4220** in the base platform **4210**. The cinch strap **4202**, which may be rubber or otherwise made of a flexible material, may be pulled tightly at the free end **4226** such that the ridges **4218** are progressively locked by the locking opening **4224**. Once appropriately tightened, the upper mount **4206** is now secured to the probe **4222**.

[0245] As seen in FIGS. **37**P-**37**Q, the lower mount **4208** of the biopsy guide **4200** may include a V-block insert **4204** positioned between the probe **4222** and the cinch strap **4202**. The V-block insert **4204** may include a pair of slots **4228** on opposite sides of the insert **4204** that may be sized to receive the cinch strap **4202** therethrough to secure the V-block insert **4204** into position relative to the cinch strap **4202**. The V-block insert **4204** ensures at least three points of contact between the probe and the biopsy guide **4200**: one point of contact between the probe **4222** and an underside of the base platform **4210**; and, two points of contact between the probe **4222** and the V-block insert **4204**.

[0246] Reference is made to FIGS. **37**R-**37**S, which depict, respectively, a front isometric view and a front view of another embodiment of a biopsy guide **4300**. Similar to the previously described embodiments, the biopsy guide **4300** includes an upper mount **4302** and a lower mount **4304**. The upper mount **4302** may include a base platform **4306** and a pair of guide rails **4308** extending longitudinally and spaced apart from each other. The guide rails **4308** may guide a displacement member (not shown), which may support an access needle (not shown), as described in previous embodiments. The lower mount **4304** may include a curvilinear shaped inner surface **4310** opposite the base platform **4306** and pair of opposing arms **4312** extending downward. The arms **4312** may converge on a bottom side **4314** of the lower mount **4304**. A V-block insert **4316** may be positioned an opening **4318** of the lower mount **4304**. The opening **4318** may be sized and shaped to receive the transrectal probe **4322** therein. The V-block insert **4316** may be vertically adjustable within the opening **4318** via a thumb-screw **4320**. When actuated or rotated, the thumb-screw **4320** may push the V-block insert **4316** vertically to exert a force on the probe **4322**, which, in turn, exerts a force on the inner surface **4310** of the base platform **4306** of the lower mount **4304**.

[0247] Reference is made to FIGS. **37**T-**37**U, which depict, respectively, a front isometric view and a front view of another embodiment of a biopsy guide **4400**. As seen in the figures, the device **4400** includes an upper mount **4402** and a lower mount **4404**. The upper mount **4402** may include a base platform **4406** and a pair of guide rails **4408** extending longitudinally and spaced apart from each other. The guide rails **4408** may guide a displacement member (not shown), which may support an access needle (not shown), as described in previous embodiments. The lower mount **4404** couples the upper mount **4402** to the probe **4410** and may include a strap **4412** that is affixed at one side **4414** via a pair of fasteners (e.g., screws, bolts) **4416**. The strap **4412** may wrap around the probe **4410** and be secured in place via a worm gear mount **4418**. The worm gear mount **4418** may include a thumb-knob **4420** that is rotatable and extending to a threaded feature (e.g., ACME threads) **4422** that threadably engage with slots **4424** on the second end **4426** of the strap **4412**. As the thumb-knob **4420** is tightened, the thread feature **4422** advances on the slots **4424** and pulls the strap **4412** tighter on the probe **4410** (similar to a hose clamp). This embodiment may include a V-block insert (not shown). As seen in the figures, an underside **4426** of the base platform **4406** may be curvilinear to match the shape of the probe **4410**. These features among features from other embodiments may be combined as needed to modify any of the features of any of the biopsy guides described herein.

[0248] Reference is made to FIGS. **37**V-**37**X, which depict additional and alternative embodiments of a lower mount **4502** of a biopsy guide **4500**. As seen in FIG. **37**V, which is a front view of a lower mount **4502**, the upper mount **4504** may be similar to previously describe embodiments in that it includes a base platform **4506** and a pair of guide rails **4508**. The lower mount may include a pair of semi-circular arm members, clamps, or collars **4510** that are pivotally coupled together at a joint **4512** (e.g., pin). The pair of semi-circular arm members **4510** may open and close about the joint **4512** in a clam-shell type manner. Opposite the joint **4512**, the arm members **4510** are adjustably secured together via a thumb-screw **4514** that extends between a pair of flanges **4516**. Thus, turning the thumb-screw **4514** in a first direction may cause the pair of arm members **4510** to constrict against a probe (not shown) positioned within the opening **4518** between the arm members **4510**. And, turning the thumb-screw **4514** in a second direction may cause the pair of arm members **4510** to loosen against the probe positioned within the opening **4518**.

[0249] FIG. **37**W depicts a front isometric view of the lower mount **4504** including a flexible spring band or biasing collar **4520** extending circumferentially and terminating in a pair of flanges or tabs **4522** that may be compressed together, relative to each other, to selectively enlarge the opening **4518**. The probe (not shown) may be positioned within the opening **4518** and the spring band **4520** may compress against the probe and cause a constant force to be exerted on the probe, allowing it to be used on probes of multiple diameters. The flat spring band **4520** may be replaced by a wire spring band (i.e., dumbbell clamp) without departing from the scope of the disclosure.

[0250] FIG. **37**X depicts a front view of a lower mount **4504** having a pair of semi-circular arm members, clamps, or collars **4510** that are pivotally coupled together at a joint **4512** (e.g., pin). The pair of semi-circular arm members **4510** may open and close about the joint **4512** in a clam-shell type manner. Opposite the joint **4512**, the arm members **4510** are adjustably secured together via a snap-clip, ratchet, or clamp assembly **4524** including a lever arm handle **4526** a wire arm or loop **4528**. The lever arm handle **4526** is attached to one free end **4534** of the arm members **4510** and the wire arm **4528** is attached to the lever arm handle **4526**. The other free end **4530** of the other arm member **4510** includes a lip **4532** such that the wire arm **4528** may be fitted around the lip **4532** with the lever arm handle **4526** in an opened position. Once the wire arm **4528** is positioned within the lip **4532**, the lever arm handle **4526** may be pivoted towards the arm member **4510**, which pulls the free ends **4534**, **4530** together to secure the arm members **4510** against the probe (not shown). To remove the probe from the lower mount **4504**, the lever arm handle **4526** may be pivoted outward away from the arm member **4510** of the free end **4534** and the arm members **4510** will expand relative to each other and release the probe.

[0251] As with many of the embodiments of the biopsy guide described herein, there may be a particular type of mechanical arrangement between the guide member and the displacement member that at least facilitates the displacement of the access needle along at least a portion of the length of the guide member. As discussed in relation to each of the embodiments, the mechanical arrangement may include at least one of a sliding arrangement, a lead screw, or a parallel bar linkage. And, as described with reference to the various embodiments of the biopsy guide, the guide member may operably couple with the transrectal probe via at least one of a sheath arrangement, a ratchet arrangement, a biased collar arrangement, a flexible strap arrangement, a clamping arrangement, or a clamshell collar arrangement.

[0252] Reference is now made to FIGS. **38**A-**38**D, which depict, respectively, a transverse plane or slice image of a prostate **3800** and a urethra **3804**, a sagittal plane or slice image of a prostate **3800** and a urethra **3804**, a transverse plane or slice image of a prostate **3800** and a urethra **3804** with a marking device **3824** positioned within the urethra **3804**, and a sagittal plane or slice image of a prostate **3800** and a urethra **3804** with a marking device **3824** positioned within the urethra **3804**. As mentioned previously, during a prostate biopsy procedure it may important for the physician to identify the path of the urethra so that he or she can avoid puncturing the urethra with the access needle and the biopsy needle. The biopsy guides described herein may be used with various systems to locate the urethra via the transrectal probe in sagittal and axial planes.

[0253] As described previously, the probe or transducer provides imaging in axial and sagittal planes so as to provide real-time images of the prostate. As seen in FIG. **38**A, which is a transverse plane showing the prostate **3800** and the probe **3802**, the urethra **3804** is shown, as well as a path **3806** of the urethra **3804**, as would be seen in a sagittal plane. As seen in FIG. **38**B, which is a sagittal plane showing the prostate **3800** and the probe **3802**, the urethra **3804** is shown extending over the prostate **3800** and connecting with the bladder **3808**.

[0254] When the prostate is viewed, as seen in FIGS. **38**A and **38**B, the physician may then position the access needle **2712** in an access site **3810** in the subcutaneous tissue **3812** of the perineum **3814**, where the access site **3810** is at a midpoint between a lateral edge of the prostate **3816** and the urethral path **3806** along a first axis and a midpoint between an anterior capsule **3818** and a posterior capsule **3820** along a second axis. The physician may guide the probe **3802** and the biopsy guide (not shown) along a sagittal plane to the target using the real-time image from the probe **3802**, and the physician may obtain one or more specimens **3822** of the prostate **3800** through the access needle **2712** being guided by the biopsy guide.

[0255] Identifying the urethra may be accomplished via a number of methods. First, as seen in FIGS. **38**C-**38**D, a marking device **3824** such as, for example, a balloon catheter can be inserted into the urethra **3804** and used by the physician to locate the urethra **3804**. As seen in FIG. **38**C-**38**D, the marking device **3824** may include a catheter **3826** and a balloon **3828**. The balloon **3828** may be expanded in the bladder **3808** and the catheter **3826** may extend through the urethra **3804** and out of the patient's body. The balloon **3828** and/or catheter **3826** may be visible in certain planes during the biopsy procedure and may aid in identifying the urethra **3804**.

[0256] Additionally or alternatively, the marking device **3824** may include markers **3830** such as physical or chemical markers that are visible in an ultrasound environment (e.g., pellets of polylactic and polyglycolic acids containing carbon dioxide, polyglycolic acid pads) along the length of the catheter **3826** so that the physician can view the path of the urethra **3804** as viewed in transverse or sagittal planes. Thus, the physician may be able to position a trajectory of the access needle **2712** to be adjacent and not intersecting with the path of the urethra as indicated by the markers **3830** on the catheter **3826**. The markers **3830** may be positioned on the catheter at certain

intervals so as to provide a way to estimate the size or volume of the prostate **3800**. Additionally or alternatively, the catheter **3826** may include a contrast medium (e.g., dye) for visualization purposes and may otherwise function similarly to markers **3830** positioned on the catheter **3826**.
[0257] The biopsy guides and devices described herein may additionally include markers or sensors positioned on the biopsy guide or access needle such that movement of the guide or needle, or any device/material placed through the access needle, may be visualized via the markers/sensors by ultrasound equipment (e.g., probe) or other equipment using different imaging modalities (e.g., MRI, CT). In this way, for example, a marker positioned at a distal end of the access needle may provide visual guidance as to the location of the tip of the access needle relative to the boundaries of the prostate.
[0258] Although various representative implementations have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of the inventive subject matter set forth in the specification. All directional references (e.g., distal, proximal, front, back, side, top, bottom, fore, aft, right, left, etc.) are only used for identification purposes to aid the reader's understanding of the implementations, and do not create limitations, particularly as to the position, orientation, or use of the embodiments described herein unless specifically set forth in the claims. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other.
[0259] It is believed that the present disclosure and many of its attendant advantages will be understood by the foregoing description, and it will be apparent that various changes may be made in the form, construction and arrangement of the components without departing from the disclosed subject matter or without sacrificing all of its material advantages. The form described is merely explanatory, and it is the intention of the following claims to encompass and include such changes.
[0260] While the present disclosure has been described with reference to various embodiments, it will be understood that these embodiments are illustrative and that the scope of the disclosure is not limited to them. Many variations, modifications, additions, and improvements are possible. More generally, embodiments in accordance with the present disclosure have been described in the context of particular implementations. Functionality may be separated or combined in blocks differently in various embodiments of the disclosure or described with different terminology. These and other variations, modifications, additions, and improvements may fall within the scope of the disclosure as defined in the claims that follow.

Claims

1. A transperineal biopsy guide configured for use with an access needle and a transrectal imaging probe adjacent a patient's perineum, the access needle including a proximal end hub, a distal sharp end opposite the proximal end hub and a longitudinal axis extending between the proximal end hub and the distal sharp end, the access needle sized to receive a biopsy instrument therethrough, the transrectal imaging probe including a proximal end, a distal end and a longitudinal axis extending between the proximal end and the distal end, the transrectal imaging probe configured to provide imaging in an imaging plane of the transrectal imaging probe, the transperineal biopsy guide comprising: a mount attachable to the transrectal imaging probe between the proximal and distal ends of the transrectal imaging probe; a guide member extending from the mount and including: a first side comprising a first distal member and a first surface extending proximally from the first distal member; a second side comprising a second distal member and a second surface extending proximally from the second distal member; and a gap between the first distal member and the second distal member; and an access needle support structure securable to the guide member in a

distal position that inhibits vertical displacement and distal displacement of the access needle support structure relative to the guide member while permitting disengagement from the distal position via proximal movement of the access needle support structure relative to the guide member, the access needle support structure configured to support the access needle at a plurality of heights relative to the mount with the access needle being at least partially located in the gap when the access needle support structure is secured to the guide member in the distal position, the access needle support structure comprising first and second members extending laterally therefrom, the first and second members being on opposite sides of the access needle support structure.
2. The transperineal biopsy guide of claim 1, wherein, in the distal position, the first member of the access needle support structure abuts the first distal member and the first surface, and the second member of the access needle support structure abuts the second distal member and the second surface.
3. The transperineal biopsy guide of claim 2, wherein the vertical displacement of the access needle support structure relative to the guide member is inhibited by interaction of the first member with the first surface, and by interaction of the second member with the second distal member and the second surface.
4. The transperineal biopsy guide of claim 3, wherein the vertical displacement and the distal displacement of the access needle support structure relative to the guide member is inhibited by interaction of the first member with the first distal member and the first surface, and by interaction of the second member with the second distal member and the second surface.
5. The transperineal biopsy guide of claim 1, wherein the access needle support structure further comprising an opening configured to receive the access needle.
6. The transperineal biopsy guide of claim 5, wherein the access needle support structure further comprising a plurality of openings, the opening being one of the plurality of openings.
7. The transperineal biopsy guide of claim 5, wherein the access needle and the access needle support structure are securable together when access needle is received in the opening.
8. The transperineal biopsy guide of claim 7, wherein the proximal end hub of the access needle and a proximal end of the opening include corresponding surfaces that inhibit rotation therebetween when the proximal end hub is received in the proximal end of the opening.
9. The transperineal biopsy guide of claim 5, wherein, when the access needle support structure is secured to the guide member, the opening of the access needle support structure is centrally positioned relative to the first side and the second side of the guide member.
10. The transperineal biopsy guide of claim 1, wherein the gap is vertically between a top side of the first and second distal members and a bottom side of the first and second distal members.
11. The transperineal biopsy guide of claim 1, wherein the first surface includes a first ramp and the second surface includes a second ramp, and wherein, in in the distal position, the first member is positioned intermediate of the first distal member and the first ramp, and the second member is positioned intermediate of the second distal member and the second ramp.
12. The transperineal biopsy guide of claim 1, wherein the first and second members are generally parallel with each other.
13. The transperineal biopsy guide of claim 1, wherein, when the mount is attached to the transrectal imaging probe, movement of the transrectal imaging probe causes corresponding movement to the guide member.
14. The transperineal biopsy guide of claim 1, further comprising the access needle.
15. The transperineal biopsy guide of claim 1, wherein the transrectal imaging probe provides ultrasound imaging.
16. A method of performing a transperineal biopsy procedure, the method comprising: providing the transperineal biopsy guide of claim 1; attaching the mount of the transperineal biopsy guide to the transrectal imaging probe; supporting the access needle to the access needle support structure; securing the access needle support structure to the guide member in the distal position; inserting the

access needle into the patient's perineum along a first trajectory; and inserting at least part of the biopsy instrument through the access needle and into the prostate and taking a first biopsy of the prostate along the first trajectory.

17. The method of claim 16, further comprising: without removing the access needle from the patient's perineum, moving the transrectal imaging probe thereby moving the access needle to a second trajectory; and inserting at least part of the biopsy instrument through the access needle and into the prostate and taking a second biopsy of the prostate along the second trajectory, the first trajectory and the second trajectory being different from each other.

18. The method of claim 16, wherein supporting the access needle to the access needle support structure comprises securing the access needle to the access needle support structure.

19. The method of claim 18, wherein, in being secured to the access needle support structure, rotation of the access needle relative to the access needle support structure is inhibited.

20. The method of claim 16, wherein the access needle support structure further comprising an opening, and supporting the access needle to the access needle support structure comprises inserting the access needle into the opening.

21. The method of claim 20, wherein inserting the access needle into the opening causes the proximal end hub of the access needle to at least partially be positioned within a proximal end of the opening thereby inhibiting rotation of the access needle relative to the access needle support structure.