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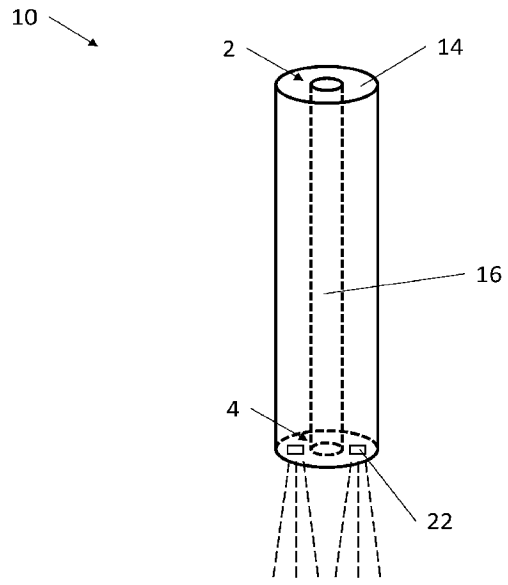

Figure 1

(57) Abstract: The present invention provides fixation devices, locking assemblies, and methods for using the same. The fixation devices of the invention are capable of accurate insertion of medical devices by providing detection means of a patient's internal anatomy and localizing a desired target. The devices are capable of locking into position to maintain accuracy.

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TITLE

INTEGRATED FIXATION DEVICE COMPRISING AN EMISSION AND RECOVERY SOURCE WITH THE PURPOSE OF TARGET LOCALIZATION AND LOCKING RELATIVE TO THE FIXATION POINT IN ORDER TO FACILITATE INTERVENTION TO SAID TARGET

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application No. 62/206,636 filed August 18, 2015 and U.S. Provisional Patent Application No. 62/266,077 filed December 11, 2015, the contents of which are incorporated by reference herein in their entirety.

BACKGROUND OF THE INVENTION

Stereotactic surgical procedures generally employ navigation equipment that utilizes optical and/or electromagnetic technologies. These technologies rely on previously obtained and processed images calibrated to patient landmarks. The systems are large, expensive, and have several parts that require a stable, unencumbered platform for use. In addition, practitioners have no navigational devices for use in unstable patients in the ICU who require precise placement of devices, such as external ventricular drains (EVD) to prevent ischemia or herniation. For example, EVDs are typically placed by neurosurgeons using anatomical landmarks to guide their passage. This technique relies heavily on the practitioner's skill level and may require multiple passes through normal, undamaged brain.

Some devices in the art employ features that attempt to improve device targeting and placement. These devices use a pivoting housing to stably hold a device for insertion. However, the housings generally do not have inherent imaging capabilities. As a result, the devices require the use of a separate imaging device, such as an ultrasound probe, to be used for the selection of a desired direction of insertion. The ultrasound probe must then be removed before the device can be inserted, and the operator is unable to visualize the device insertion without using another imaging device.

There is a need in the art for better devices and methods for accurate localization and intervention of targets within a patient. The present invention meets this need.

SUMMARY OF THE INVENTION

The present invention provides fixation devices, locking assemblies, and methods for using the same. The fixation devices of the invention are capable of accurate insertion of medical devices by providing detection means of a patient's internal anatomy and localizing a desired target. The devices are capable of at least partially locking into position to maintain accuracy.

In one aspect, the invention relates to a fixation device comprising: an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; at least one emission means at a distal end region of the elongate body; and at least one receiving means for receiving at least some emissions from said emission means.

In one embodiment, the elongate body lumen is sized suitably for an instrument, tool, implant, or biological material to pass therethrough. In one embodiment, the elongate body lumen is sized suitably for an inserted instrument, tool, implant, or biological material to rotate. In one embodiment, the elongate body lumen has a cross-section that is circular, elliptical, polygonal, or keyed. In one embodiment, the elongate body lumen may be centered or off-center in the elongate body.

In one embodiment, the emission means are selected from the group consisting of: ultrasonic transducers, optical sensors, thermal sensors, electromagnetic sensors, photoelectric transducers, laser diodes, radio transducers, Doppler, x-ray, particle sensors, chemical sensors, and piezoelectric sensors. In one embodiment, the ultrasonic transducers are either piezoelectric ultrasonic transducers or capacitive ultrasonic transducers. In one embodiment, the distal end region of the elongate body is composed of a material which is at least partially transmissive to said emission.

In one embodiment, the device further comprises: a grommet having a proximal end opening, a distal end opening, and a lumen connecting the proximal and

distal end openings; and at least one locking member; wherein the grommet lumen is sized such that the elongate body of the fixation device can pass through the grommet lumen and be at least partially locked into place by the at least one locking member.

In one embodiment, the grommet comprises one or more materials selected from the group consisting of: metals, ceramics, and polymers. In one embodiment, the grommet comprises one or more materials selected from the group consisting of: stainless steel, cobalt, titanium, aluminum oxide, zirconia, calcium phosphate, silicon, polyethylene, polyvinyl chloride, polyurethane, and polylactide.

In one embodiment, the device further comprises: a cup having a base member and perimeter sidewalls forming an open top, wherein the base member includes at least one opening, and at least one locking member; wherein the cup is sized such that the distal end region of the elongate body of the fixation device can be at least partially locked into place within the cup by the at least one locking member.

In one embodiment, the cup comprises one or more materials selected from the group consisting of: metals, ceramics, and polymers. In one embodiment, wherein the cup comprises one or more materials selected from the group consisting of: stainless steel, cobalt, titanium, aluminum oxide, zirconia, calcium phosphate, silicon, polyethylene, polyvinyl chloride, polyurethane, and polylactide. In one embodiment, the at least one locking member is selected from the group consisting of: a screw, a bolt, a pin, an adhesive, and a clamp. In one embodiment, the at least one locking member is engaged mechanically, electro-mechanically, magnetically, or adhesively.

In one embodiment, the device further comprises an anchoring patch comprising: a flexible substrate having a first and a second surface; and a rigid housing positioned within the flexible substrate; wherein the housing is dimensioned to engage the devices of the present invention.

In one embodiment, the flexible substrate comprises a material selected from the group consisting of plastics, polymers, metals, and gels. In one embodiment, the device further comprises an adhesive material on at least a portion of the first surface of the flexible substrate.

In one embodiment, the device further comprises a first angled shim housing having a space at its center and a cranial burr anchor, wherein the first angled shim housing is attached to the cranial burr anchor, wherein the fixation device fits within and is rotatable within the space of the first angled shim housing, and the first angled shim housing is rotatable about the cranial burr anchor.

In one embodiment, the device further comprises a second angled shim housing, wherein the second angled shim housing is attached between the first angled shim housing and the cranial burr anchor, and wherein the second angled shim housing is rotatable about the first angled shim housing and the cranial burr anchor.

In one embodiment, the device further comprises a lever attachment having a lumen attached to and continuous with the lumen of the fixation device, wherein the lumen of the lever attachment is sized to accept a medical instrument.

In one embodiment, the device further comprises a rotatable housing, a cranial burr anchor, and a lever attachment having a lumen connected to the proximal end opening of the fixation device, wherein the rotatable housing is attached to the cranial burr anchor, wherein the fixation device is encased and rotatable within the rotatable housing, wherein the rotatable housing is rotatable about the cranial burr anchor, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

In one embodiment, the device further comprises a cranial interface component having at least two angular rails, an anterior-posterior angle control component having at least two angular rails, a lateral angle control component having a space at its center, and a lever attachment having a lumen connected to the proximal opening of the fixation device, wherein the anterior-posterior angle control component is movable along the at least two angular rails of the cranial interface component, wherein the lateral angle control component is movable along the at least two angular rails of the anterior-posterior angle control component, wherein the fixation device fits within and is rotatable within the space of the lateral angle control component, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

In one embodiment, the device further comprises a hemispherical cap having a first track and a hemispherical cranial burr anchor having a second track,

wherein the first track spans the diameter of the hemispherical cap, wherein the second track spans the diameter of the hemispherical cranial burr anchor, wherein the hemispherical cap is movable along the second track, wherein the fixation device is movable along the first track, and wherein the first track and the second track are perpendicular to each other.

In another aspect, the present invention relates to a method of localizing and interacting with a target site within a patient's anatomy, comprising the steps of: attaching the device of the present invention to the patient's body near the target site; generating emissions using the attached device; receiving the emissions from the attached device; adjusting the orientation of the attached device to aim the attached device at the target site; at least partially locking the attached device; determining a target site first boundary having a minimum depth and a target site second boundary having a maximum depth; and inserting medical devices through the lumen of the attached device to interact with the target site such that the medical devices pass the minimum depth but do not exceed the maximum depth.

In another aspect, the present invention relates to a method for accurate insertion of an external ventricular drain (EVD), comprising the steps of: inserting the device of the present invention into a burr hole in a patient's skull; imaging a region within the patient's brain using the attached device; aligning the lumen of the attached device with a desired site of drainage; at least partially locking the attached device in place; determining a desired site of drainage first boundary having a minimum depth and a desired site of drainage second boundary having a maximum depth; and guiding an EVD through the lumen of the attached device into the desired site of drainage for draining such that the EVD passes the minimum depth but does not exceed the maximum depth. In one embodiment, an ultrasonic reflective strip is attached to the EVD.

In another aspect, the present invention relates to a method for accurate insertion of a medical device to a target site, comprising the steps of: affixing an anchoring patch having a flexible substrate and a rigid housing onto a patient at a desired site of insertion of a medical device; engaging the device of claims 9 or 12 to the rigid housing of the anchoring patch; aligning the lumen of the attached device with the target

site; at least partially locking the attached device in place; determining a target site first boundary having a minimum depth and a target site second boundary having a maximum depth; and guiding the medical device through the lumen of the attached device to the target site such that the medical device passes the minimum depth but does not exceed the maximum depth.

In one embodiment, the medical device is selected from the group consisting of: catheters, microforceps, microscalpels, biopsy needles, radiofrequency ablation probes, cryoablation probes, suturing instruments, and syringes. In one embodiment, an ultrasonic reflective strip is attached to the medical device.

In another aspect, the present invention relates to a method of stereotactic mapping; comprising the steps of: attaching at least two devices of the present invention to a patient's body; generating emissions using at least one of the attached devices; and receiving the emissions using at least one of the attached devices.

In another aspect, the present invention relates to a method of using a fixation device to insert a ventricular catheter into a subject's brain, comprising the steps of: marking the skin at Kocher's point above a subject's skull; making an incision at the marked skin; perforating the skull; inserting a fixation device having ultrasonic transducers; aligning the ultrasonic transducers to capture a cross-sectional ultrasound image of the brain and the positional, angular, and rotational orientation of the ultrasonic transducers; actuating the ultrasonic transducers; acquiring a series of ultrasonic images of the brain and associated positional, angular, and rotational orientation of the ultrasonic transducers during actuation; assembling the ultrasonic images into a 3D reconstruction of the brain ventricles using the associated positional, angular, and rotational orientation of the ultrasonic transducers; performing an automatic segmentation of the 3D reconstruction to isolate an anatomy of interest; acquiring the positional, angular, and rotational orientation of the anatomy of interest; aligning the fixation device to target the anatomy of interest; fixing the alignment of the fixation device relative to the skull; inserting a catheter and ventricular drain through the fixation device into the anatomy of interest; and removing the fixation device over the catheter and ventricular drain..

In another aspect, the present invention relates to a fixation device comprising: an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; a first angled shim housing having a space at its center; and a cranial burr anchor; wherein the first angled shim housing is attached to the cranial burr anchor, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, and wherein the first angled shim housing is rotatable about the cranial burr anchor.

In another aspect, the present invention relates to a fixation device comprising: an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; a first angled shim housing having a space at its center; a second angled shim housing; and a cranial burr anchor; wherein the first angled shim housing is attached to the second angled shim housing, wherein the second angled shim housing is attached to the cranial burr anchor, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, wherein the first angled shim housing is rotatable about the second angled shim housing, and wherein the second angled shim housing is rotatable about the cranial burr anchor.

In another aspect, the present invention relates to a fixation device comprising: an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; a first angled shim housing having a space at its center; a lever attachment having a lumen; and a cranial burr anchor; wherein the lever attachment is attached to the first angled shim housing, wherein the first angled shim housing is attached to the cranial burr anchor, wherein the lumen of the elongate body is attached to and continuous with the lumen of the lever attachment, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, and wherein the first angled shim housing is rotatable about the cranial burr anchor.

In another aspect, the present invention relates to a fixation device comprising: an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; a rotatable housing; a cranial

burr anchor; and a lever attachment having a lumen attached to and continuous with the lumen of the elongate body; wherein the rotatable housing is attached to the cranial burr anchor, wherein the elongate body is encased and rotatable within the rotatable housing, wherein the rotatable housing is rotatable about the cranial burr anchor, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

In another aspect, the present invention relates to a fixation device comprising: an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; a cranial interface component having at least two angular rails; an anterior-posterior angle control component having at least two angular rails; a lateral angle control component having a space at its center; and a lever attachment having a lumen attached to and continuous with the lumen of the elongate body; wherein the anterior-posterior angle control component is movable along the at least two angular rails of the cranial interface component, wherein the lateral angle control component is movable along the at least two angular rails of the anterior-posterior angle control component, wherein the elongate body fits within and is rotatable within the space of the lateral angle control component, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

In another aspect, the present invention relates to a fixation device comprising: an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; a hemispherical cap having a first track; and a hemispherical cranial burr anchor having a second track; wherein the first track spans the diameter of the hemispherical cap, wherein the second track spans the diameter of the hemispherical cranial burr anchor, wherein the hemispherical cap is movable along the second track, wherein the elongate body is movable along the first track, and wherein the first track and the second track are perpendicular to each other.

In another aspect, the present invention relates to a kit comprising: the device of the present invention; a hair clipper; a tape measure; a surgical marking implement; skin preparation material; a scalpel; and a drilling instrument.

In one embodiment, the kit further comprises display equipment. In one embodiment, the kit further comprises a portable power source.

In another aspect, the present invention relates to a kit comprising: a devices of any of claims 34-39; a power source; a hair clipper; a tape measure; a surgical marking implement; skin preparation material; a scalpel; and a drilling instrument.

In one embodiment, the kit further comprises at least one emission means and at least one receiving means for receiving at least some emissions from said emission means. In one embodiment, the kit further comprises display equipment. In one embodiment, the kit further comprises a portable power source.

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description of preferred embodiments of the invention will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the invention, there are shown in the drawings embodiments which are presently preferred. It should be understood, however, that the invention is not limited to the precise arrangements, geometry, and instrumentalities of the embodiments shown in the drawings.

Figure 1 depicts one embodiment of an exemplary fixation device.

Figure 2A and Figure 2B depict an exemplary fixation device coupled with a grommet locking assembly.

Figure 3 depicts an exemplary fixation device coupled with a cup locking assembly.

Figure 4A and Figure 4B depict an exemplary single shim 3 Degrees of Freedom (DoF) device.

Figure 5 depicts an exemplary double shim 3 DoF device.

Figure 6 depicts an exemplary single shim 4 DoF device.

Figure 7A through Figure 7C depict an exemplary levered 3 DoF device.

Figure 8A and Figure 8B depict an exemplary 5 DoF device.

Figure 9A through Figure 9D depict an exemplary compact 4 DoF device.

Figure 10A and Figure 10B depict (Figure 10A) an exemplary fixation device coupled with a cup locking assembly and an anchoring patch and (Figure 10B) a

schematic depicting a cross sectional view of the entire assembly adhered to a patient's calf.

Figure 11 is a flowchart for an exemplary method of using a fixation device.

Figure 12A and Figure 12B depict an exemplary method of using a fixation device for accurate depth determination.

Figure 13 depicts a top-down view of a skull with a fixation device inserted at Kocher's point.

Figure 14A and Figure 14B depict the malplacement of a shunt in a three dimensional model of the ventricles of a brain. Wherein the goal of a ventriculostomy is to deliver the shunt (solid line) to the anterior ipsilateral horn of the ventricle by transiting the burr location on the cranium known as Kocher's point, the traditional free-hand technique via a trajectory normal to the cranium surface (dashed line) is prone to malplacement of the shunt into the contralateral ventricle or other, less desirous or contrary locations.

Figure 15A through Figure 15F depict a method of stepwise rotation of an ultrasound transducer to generate the three dimensional model of the ventricles depicted in Figure 14A and Figure 14B. Figure 15A: initial position; Figure 15B: 15 degree rotation from initial; Figure 15C: 30 degree rotation from initial; Figure 15D: 45 degree rotation from initial; Figure 15E: 60 degree rotation from initial: Figure 15F: 75 degree rotation from initial.

Figure 16 is a flowchart for an exemplary method of using a fixation device to insert a ventricular drain.

Figure 17 depicts an exemplary method of marking the skin by locating the point between the pupils (nasion), drawing a line 10 cm from the nasion along the skull heading posterior to the occiput, and measuring 3 cm laterally.

Figure 18 depicts an exemplary method of making an incision at the skin marked in Figure 17.

Figure 19 depicts an exemplary method of perforating the skull at the incision made in Figure 18.

Figure 20 depicts an exemplary skull perforation dimensioned to fit a device of the present invention.

Figure 21 depicts the insertion of a device of the present invention into a skull perforation.

Figure 22 depicts a device of the present invention inserted into a skull perforation.

Figure 23 depicts an exemplary alignment of a device of the present invention to capture a cross-sectional ultrasound image of the ventricles of the brain.

Figure 24 depicts a device of the present invention actuated slightly from Figure 23 to capture a second cross-sectional ultrasound image of the ventricles of the brain.

Figure 25 depicts a device of the present invention actuated slightly from Figure 23 to capture a third cross-sectional ultrasound image of the ventricles of the brain.

Figure 26 depicts a device of the present invention actuated slightly from Figure 23 to capture a fourth and a fifth cross-sectional ultrasound image of the ventricles of the brain.

Figure 27 depicts a device of the present invention actuated slightly from Figure 23 to capture a sixth cross-sectional ultrasound image of the ventricles of the brain.

Figure 28 depicts an exemplary 3D reconstruction of the ventricles of the brain using the ultrasound images captured in Figure 23 through Figure 27.

Figure 29 depicts an exemplary method of determining an ideal angle of entry from the skull perforation performed in Figure 20 into the ventricles of the brain.

Figure 30 depicts an exemplary method of targeting a location in the ventricles of the brain using the exemplary 3D reconstruction of the ventricles of the brain in Figure 28, wherein the targeted location is indicated by the outlined circle, the crosshairs are aimed at the targeted location, and the ultrasound images are supplemented with angle, rotation, and tilt data.

Figure 31 depicts the alignment of a device of the present invention to match the ideal angle of entry determined in Figure 29.

Figure 32 depicts an exemplary method of accurate insertion of a medical device through a device of the present invention, wherein the location of the medical device is monitored using out-of-plane ultrasound imaging.

Figure 33 depicts the result of accurately inserting an external ventricular drain using a device of the present invention.

Figure 34 depicts the removal of a device of the present invention over an inserted medical device, leaving the medical device behind.

DETAILED DESCRIPTION

The present invention provides fixation devices, locking assemblies, and methods for using the same. The fixation devices of the invention are capable of accurate insertion of medical devices by providing detection means of a patient's internal anatomy to localize a desired target. The devices are capable of at least partially locking into position to maintain accuracy.

Definitions

It is to be understood that the figures and descriptions of the present invention have been simplified to illustrate elements that are relevant for a clear understanding of the present invention, while eliminating, for the purpose of clarity, many other elements found in typical medical devices. Those of ordinary skill in the art may recognize that other elements and/or steps are desirable and/or required in implementing the present invention. However, because such elements and steps are well known in the art, and because they do not facilitate a better understanding of the present invention, a discussion of such elements and steps is not provided herein. The disclosure herein is directed to all such variations and modifications to such elements and methods known to those skilled in the art.

Unless defined elsewhere, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are described.

As used herein, each of the following terms has the meaning associated with it in this section.

The articles "a" and "an" are used herein to refer to one or to more than one (i.e., to at least one) of the grammatical object of the article. By way of example, "an element" means one element or more than one element.

"About" as used herein when referring to a measurable value such as an amount, a temporal duration, and the like, is meant to encompass variations of ±20%, ±10%, ±5%, ±1%, and ±0.1% from the specified value, as such variations are appropriate.

As used herein, "imaging" may include ultrasonic imaging, be it one dimensional, two dimensional, three dimensional, or real-time three dimensional imaging (4D). Two dimensional images may be generated by one dimensional transducer arrays (e.g., linear arrays or arrays having a single row of elements). Three dimensional images may be produced by two dimensional arrays (e.g., those arrays with elements arranged in an n by n planar configuration) or by mechanically reciprocated, one dimensional transducer arrays. The term "imaging" also includes optical imaging, tomography, including optical coherence tomography (OCT), radiographic imaging, photoacoustic imaging, and thermography.

The terms "patient," "subject," "individual," and the like are used interchangeably herein, and refer to any animal, or cells thereof whether in vitro or in situ, amenable to the methods described herein. In certain non-limiting embodiments, the patient, subject or individual is a human.

As used herein, "sonolucent" is defined as a property wherein a material is capable of transmitting ultrasound pulses without introducing significant interference,

such that an acceptable acoustic response can be obtained from the body structure(s) of interest.

Throughout this disclosure, various aspects of the invention can be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6, etc., as well as individual numbers within that range, for example, 1, 2, 2.7, 3, 4, 5, 5.3, 6, and any whole and partial increments there between. This applies regardless of the breadth of the range.

Locking Fixation Device

The present invention provides fixation devices, locking assemblies, and methods for using the same. The fixation devices of the invention are capable of accurate insertion of medical devices by providing detection means of a patient's internal anatomy and localizing a desired target. The devices are capable of at least partially locking into position to maintain accuracy.

Referring now to Figure 1, an exemplary fixation device 10 is depicted. Fixation device 10 comprises elongate body 14, lumen 16, proximal end opening 2, distal end opening 4, and a plurality of transducers 22. Elongate body 14 can have any suitable shape. In one embodiment, elongate body 14 is cylindrical. There are no limitations to the particular sizes and dimensions elongate body 14 may have. Elongate body 14 can be made from any suitable material. For example, elongate body 14 can comprise silicones, plastics, polymers, metals, and the like. In one embodiment, elongate body 14 comprises a sonolucent material throughout. In one embodiment, elongate body 14 comprises a sonolucent material only at its distal end.

Elongate body 14 comprises lumen 16 and transducers 22. Lumen 16 extends through the entire length of elongate body 14 and connects proximal opening 2

and distal opening 4. Lumen 16 can have any suitable diameter. In one embodiment, lumen 16 has a diameter of at least 0.1 mm. In one embodiment, lumen 16 has a diameter of 1.2 mm. In various embodiments, lumen 16 has a diameter between 0.5 mm and 10 mm. In one embodiment, lumen 16 is dimensioned to fit a catheter.

Transducers 22 can be any suitable device capable of emitting energy, receiving energy, or both energy emission and reception. In various embodiments, elongate body 14 comprises one, two, three, four, or more transducers 22. Elongate body 14 may also comprise combinations of different transducers 22. For example, elongate body 14 may comprise a combination of emitting transducers and receiving transducers, or a combination of transducers that respond to different types of energy. Non-limiting examples of types of transducers suitable for use with the present invention include: ultrasonic transducers, optical sensors, thermal sensors, electromagnetic sensors, photoelectric transducers, laser diodes, radio transducers, Doppler, x-ray, particle sensors, chemical sensors, piezoelectric sensors, and the like.

Lumen 16 can have any suitable cross-section, such as a cross-section that is circular, elliptical, polygonal, or keyed. Lumen 16 may be centered or off-center in fixation device 10. Lumen 16 of fixation device 10 is amenable to guiding any various types of medical devices. For example, lumen 16 may accommodate additional probes or instruments appropriate for any given medical procedure. Non-limiting examples of additional components include catheters, microforceps, microscalpels, biopsy needles, radiofrequency ablation probes, cryoablation probes, suturing instruments, syringes, and the like. In some embodiments, lumen 16 comprises a circular cross-section and is sized and dimensioned to permit an inserted instrument to rotate.

Referring now to Figure 2A, a top-down view of an exemplary grommet locking assembly 11 is depicted. Grommet locking assembly 11 comprises grommet 12, fixation device 10, fulcrum 18, and locking member 20. Referring now to Figure 2B, an isometric view of an exemplary grommet locking assembly 11 is depicted. Grommet 12 fits within an opening on a patient to provide access to the interior of a patient's anatomy.

In various embodiments, the exterior surface of grommet 12 can comprise features to enhance the fit of grommet 12 within a patient, such as ridges, flanges,

threads, barbs, and the like. Grommet 12 can be made from any suitable biocompatible material, such as stainless steel, cobalt, titanium, aluminum oxide, zirconia, calcium phosphate, silicon, polyethylene, polyvinyl chloride, polyurethane, polylactide, and the like. In one embodiment, grommet 12 comprises a sonolucent material throughout. In one embodiment, grommet 12 comprises a sonolucent material only at its distal end.

Grommet 12 can have any suitable shape. Non-limiting examples of grommet 12 shapes include cylinders, cubes, cuboids, and the like. There are no limitations to the particular sizes and dimensions grommet 12 may have.

Grommet 12 comprises a lumen that extends through the entire length of grommet 12. Within the lumen, grommet 12 comprises a plurality of fulcrums 18. For example, in one exemplary embodiment, grommet 12 comprises at least two fulcrums 18. Fulcrums 18 attach to the lumen of grommet 12 and to the exterior surface of fixation device 10. Fulcrums 18 may be made from any suitable material. In one embodiment, fulcrums 18 are made from a pliable material, such as a biocompatible rubber, polymer, or gel. Fulcrums 18 secure fixation device 10 to grommet 12 while providing fixation device 10 with the ability to move independently from grommet 12. For example, pliable fulcrums 18 are deformable to allow fixation device 10 to be oriented within grommet 12. Fixation device 10 can be oriented by angling to any degree. In one embodiment, fixation device 10 can be oriented by angling up to 20 degrees from vertical. In another embodiment, fixation device 10 can be oriented by angling by up to 45 degrees from vertical. In one embodiment, instead of fulcrums 18, fixation device 10 is attached to grommet 12 by a pliable membrane.

Grommet 12 further comprises at least one locking member 20. Locking member 20 can be any suitable locking member, including but not limited to: a screw, a bolt, a pin, an adhesive, and a clamp. For example, in one exemplary embodiment, a grommet locking assembly 11 may comprise locking members 20 that are screws that pass through grommet 12 to contact fixation device 10. The screws may be screwed in or out of grommet 12 to vary and lock the orientation of fixation device 10. In other embodiments, the locking member 20 may be mechanical, electro-mechanical, magnetic, or adhesive.

Referring now to Figure 3, a side view cross section of an exemplary cup locking assembly 30 is depicted. Cup locking assembly 30 comprises fixation device 10 and cup 32. Fixation device 10 further comprises ball adapter 36. Cup 32 fits within an opening on a patient to provide access to the interior of a patient's anatomy.

In various embodiments, the exterior surface of cup 32 can comprise features to enhance the fit of cup 32 within a patient, such as ridges, flanges, threads, barbs, and the like. Cup 32 can be made from any suitable biocompatible material, such as stainless steel, cobalt, titanium, aluminum oxide, zirconia, calcium phosphate, silicon, polyethylene, polyvinyl chloride, polyurethane, polylactide, and the like. In one embodiment, cup 32 comprises a sonolucent material throughout. In one embodiment, cup 32 comprises a sonolucent material only at its distal end.

Cup 32 comprises a base member and perimeter sidewalls forming an open top. The base member comprises at least one opening 34. Cup 32 can have any suitable shape. In some embodiments, cup 32 has the shape of a conical frustum with wide diameter facing away from the patient and a narrow diameter facing towards the patient. Cup 32 can have any suitable dimensions. For example, cup 32 can have a height of 5 to 50 mm, and a diameter of 5 to 50 mm.

The interior of cup 32 is dimensioned to fit ball adapter 36 of fixation device 10. Ball adapter 36 is able to rotate freely within cup 32, like a ball joint, to provide fixation device 10 with an orientation. Fixation device 10 can be oriented by angling to any degree. In one embodiment, fixation device 10 can be oriented by angling up to 20 degrees from vertical. In another embodiment, fixation device 10 can be oriented by angling up to 45 degrees from vertical.

Cup 32 further comprises locking member 20. Locking member 20 can be any suitable locking member, including but not limited to: a screw, a bolt, a pin, an adhesive, and a clamp. For example, in one embodiment, locking member 20 is a screw. The screw may be screwed in or out of cup 32 such that when the screw contacts ball adapter 36, the screw arrests the movement of ball adapter 36, thereby locking the orientation of fixation device 10. In other embodiments, the locking member 20 may be mechanical, electro-mechanical, magnetic, or adhesive.

In various embodiments, the present invention relates to fixation devices having fixed degrees of freedom for precise movement. Referring now to Figure 4A and Figure 4B, an exemplary single shim 3 Degrees of Freedom (DoF) fixation device 110 is depicted. Device 110 comprises anchor 112, rotating shim 114, and rotating transducer housing 116. Anchor 112 is secured within a burr hole, such as that of a skull depicted in Figure 4A and Figure 4B. Rotating shim 114 fits within anchor 112. In various embodiments, rotating shim 114 comprises an angle, wherein the angle can be any suitable angle between 1 and 10 degrees. Rotating shim 114 comprises a space at its center for accepting rotating transducer housing 116. Transducer housing 116 comprises at least one ultrasonic transducer and at least one aperture for accepting a medical instrument 38. The first DoF of device 110 is the vertical travel of medical instrument 38. The second DoF is the rotation of transducer housing 116. The third DoF is the rotation of shim 114.

Referring now to Figure 5, an exemplary double shim 3 DoF fixation device 120 is depicted. Device 120 comprises anchor 122, a first rotating shim 124, a second rotating shim 126, and a rotating transducer housing 128. Similarly to the components of device 110, anchor 122 secures within a burr hole, wherein anchor 122 holds a first rotating shim 124. The second rotating shim 126 fits on top of the first rotating shim 124, and the second rotating shim 126 comprises a space at its center for accepting rotating transducer housing 128. In various embodiments, transducer housing 128 comprises at least one ultrasonic transducer and at least one aperture for accepting a medical instrument 38. The first rotating shim 124 and the second rotating shim 126 each comprise an angle, wherein the angle can be any suitable angle between 1 and 10 degrees. In various embodiments, the first rotating shim 124 can have the same angle or a different angle than the second rotating shim 126. The first DoF of device 120 is the vertical travel of medical instrument 38. The second DoF of device 120 is the rotation of transducer housing 128. The third DoF of device 120 is the rotation of first shim 124, second shim 126, or both.

Referring now to Figure 6, an exemplary single shim 4 DoF fixation device 130 is depicted. Device 130 comprises anchor 132, rotating shim 134, transducer

housing 136, and lever 138. As described elsewhere herein, anchor 132 secures within a burr hole. Rotating shim 134 fits within anchor 132. In various embodiments, rotating shim 134 comprises an angle, wherein the angle can be any suitable angle between 1 and 10 degrees. Rotating shim 134 comprises a space at its center for accepting transducer housing 136. Transducer housing 136 comprises at least one ultrasonic transducer and a lever housing, whereupon lever 138 actuates. The lever housing may comprise regularly spaced markings to indicate the relative position of lever 138. In various embodiments, lever 138 may be angled between 5 and 15 degrees from vertical. Lever 138 comprises at least one aperture for accepting a medical instrument 38. The first DoF of device 130 is the vertical travel of medical instrument 38. The second DoF of device 130 is the angulation of lever 138. The third DoF of device 130 is the rotation of transducer housing 136. The fourth DoF of device 130 is the rotation of shim 134.

Referring now to Figure 7A through Figure 7B, an exemplary levered 3 DoF fixation device 140 is depicted. Device 140 comprises anchor 142, rotatable housing 144, transducer housing 146, and lever 148. As described elsewhere herein, anchor 142 secures within a burr hole, and articulating component 144 fits within anchor 142. Rotatable housing 144 comprises a space at its center for accepting transducer housing 146. Transducer housing 146 comprises at least one ultrasonic transducer and a lever housing, whereupon lever 148 actuates. The lever housing may comprise regularly spaced markings to indicate the relative position of lever 148. In various embodiments, lever 148 may be angled between 5 and 15 degrees from vertical. Lever 148 comprises at least one aperture for accepting a medical instrument 38. The first DoF of device 140 is the vertical travel of medical instrument 38. The second DoF of device 140 is the angulation of lever 148. The third DoF of device 140 is the rotation of transducer housing 146.

Referring now to Figure 8A and Figure 8B, an exemplary 5 DoF fixation device 150 is depicted. Device 150 comprises cranial interface component 152, anterior-posterior angle control 154, lateral angle control 156, transducer housing 158, and lever 159. Cranial interface component 152 is at least partially secured into a burr hole. Cranial interface component 152 features a frame and at least two angular rails for

guiding the movement of anterior-posterior angle control 154. Anterior-posterior angle control 154 in turn comprises at least two angular rails for guiding the movement of lateral angle control 156. Lateral angle control 156 comprises a space at its center for accepting transducer housing 158. Transducer housing 158 comprises at least one ultrasonic transducer located within a conical region that fits within cranial interface component 152, wherein the conical region serves as a pivot point while the orientation of transducer housing 158 is adjusted. Transducer housing 158 comprises a lever housing, whereupon lever 159 actuates. The lever housing may comprise regularly spaced markings to indicate the relative position of lever 159. In various embodiments, lever 159 may be angled between 5 and 15 degrees from vertical. Lever 159 comprises at least one aperture for accepting a medical instrument 38. The first DoF of device 150 is the vertical travel of medical instrument 38. The second DoF of device 150 is the angulation of lever 159. The third DoF of device 150 is the rotation of transducer housing 158. The fourth DoF of device 150 is the angulation of lateral angle control 156. The fifth DoF of device 150 is the angulation of anterior-posterior angle control 154.

Referring now to Figure 9A through Figure 9D, an exemplary compact 4 DoF fixation device 160 is depicted. Device 160 comprises anchor 162, hemispheric cap 164, and transducer housing 166. Anchor 162 is at least partially secured into a burr hole and comprises a hemispheric top with track 168 on its surface, track 168 spanning the diameter of anchor 162. Hemispheric cap 164 sits on top of anchor 162 and moves along track 168. Hemispheric cap 164 comprises track 169 on its surface, track 169 being perpendicular to track 168 and spanning the diameter of hemispheric cap 164. Both anchor 162 and hemispheric cap 164 comprise an open space at their centers to fit transducer housing 166. Transducer housing 166 sits on top of hemispheric cap 164 and moves along track 169. Transducer housing 166 comprises at least one ultrasonic transducer and at least one aperture for accepting a medical instrument 38.

In various embodiments, the fixation devices of the present invention may be sterilized or autoclaved. In certain embodiments, the fixation devices of the present devices may be partially disposable. For example, certain components enclosing transducers 22 and any associated circuitry and electronics may be detachable and

cleaned between uses, while other components may be discarded and replaced between uses.

The fixation devices of the present invention can be combined with additional components to facilitate their use in various applications. The additional components may include features that help automate the use of the fixation devices, such as actuators for mechanical movement and adjustment of the fixation device. The actuators may comprise position sensors to record positional orientations of the fixation device. For example, the fixation devices of the present invention may further include encoders, multi-degree of freedom mems devices (e.g., Bosch BNO055 9 degrees of freedom absolute orientation sensor), or any other suitable device for sensing, communicating, and recording data relating to the position, angle, and rotation of the transducer. In some embodiments, the position, angle, and rotation data may be mapped to a specific image set to correspond to the orientation of the fixation device when the image set was taken. The position, angle, and rotation data may be used to generate a 3D map from a series of image sets, to calculate volume rendering, to determine orientation parameters for a particular angle of entry, and the like. In certain embodiments, the sensing, communicating, and recording may be activated and deactivated by a remote switch, such that a user may choose when to begin and when to terminate the collection of location data. The remote switch enables a user to capture data in an efficient manner. The positional data may, for example, be later conveyed to the actuators such that a fixation device may quickly reacquire the positional orientation needed to find a target site, with subsequent emissions from the transducers to confirm accurate targeting.

In one embodiment, the additional component is an anchoring patch. For example, as depicted in Figure 10A, cup locking assembly 30 may be adhered to anchoring patch 52 to form fixation device patch 50. Fixation device patch 50 is useful in applications where guided accurate insertion of medical instruments is required but the surrounding tissue is too soft to secure a cup locking assembly 30. As shown in Figure 10B, anchoring patch 52 provides cup locking assembly 30 with a stable substrate to anchor into. Cup locking assembly 30 is then able to image, for example, the interior of

the calf between the tibia and the fibula and accurately insert medical instrument 38 as depicted in Figure 10B.

Anchoring patch 52 may be made from any suitable material, including plastics, polymers, metals, gels, and the like. In one embodiment, anchoring patch 52 may be flexible. In another embodiment, anchoring patch 52 may be rigid. Anchoring patch 52 may comprise an adhesive on the surface that contacts a patient. Cup locking assembly 30 may be adhered to anchoring patch 52 in any suitable way, such as by an adhesive or by friction. In one embodiment, anchoring patch 52 may comprise a rigid housing having features such as screw threads, clips, latches, and the like to connect to cup locking assembly 30.

In some embodiments, the devices of the present invention may operate in conjunction with a computer platform system, such as a local or remote executable software platform, or as a hosted internet or network program or portal. In certain embodiments, portions of the system may be computer operated, or in other embodiments, the entire system may be computer operated. As contemplated herein, any computing device as would be understood by those skilled in the art may be used with the system, including desktop or mobile devices, laptops, desktops, tablets, smartphones or other wireless digital/cellular phones, televisions or other thin client devices as would be understood by those skilled in the art.

The computer platform is fully capable of sending and interpreting device emissions signals as described herein throughout. For example, the computer platform can be configured to control emissions parameters such as frequency, intensity, amplitude, period, wavelength, pulsing, and the like, depending on the emissions type. The computer platform can also be configured to control the actuation of the device, such as angulation and partial locking. The computer platform can be configured to record received emissions signals, and subsequently interpret the emissions. For example, the computer platform may be configured to interpret the emissions as images and subsequently transmit the images to a digital display. The computer platform may further perform automated calculations based on the received emissions to output data such as density, distance, temperature, composition, imaging, and the like, depending on the type

of emissions received. The computer platform may further provide a means to communicate the received emissions and data outputs, such as by projecting one or more static and moving images on a screen, emitting one or more auditory signals, presenting one or more digital readouts, providing one or more light indicators, providing one or more tactile responses (such as vibrations), and the like. In some embodiments, the computer platform communicates received emissions signals and data outputs in real time, such that an operator may adjust the use of the device in response to the real time communication. For example, in response to a stronger received emission, the computer platform may output a more intense light indicator, a louder auditory signal, or a more vigorous tactile response to an operator, such that the operator may adjust the device to receive a stronger signal or the operator may partially lock the device in a position that registers the strongest signal. In a further example, the computer platform may display image overlays to represent an inserted medical device in relation to a displayed ultrasound image or volume rendering (3D reconstruction) on screen.

In some embodiments, the computer platform is integrated into the devices of the present invention. For example, in some embodiments, at least one component of the computer platform described elsewhere herein is incorporated into a fixation device of the present invention, such as emissions parameter controlling means, emissions recording and interpretation means, communication means for the received emissions and data outputs, and one or more features for displaying the received emissions, data, and images. Fixation devices having at least one integrated computer platform component may be operable as a self-contained unit, such that additional computer platform components apart from the device itself are not necessary. Self-contained units provide a convenient means of using the devices of the present invention by performing a plurality of functions related to the devices. Self-contained units may be swappable and disposable, improving portability and decreasing the risk of contamination.

The computer operable component(s) may reside entirely on a single computing device, or may reside on a central server and run on any number of end-user devices via a communications network. The computing devices may include at least one processor, standard input and output devices, as well as all hardware and software

typically found on computing devices for storing data and running programs, and for sending and receiving data over a network, if needed. If a central server is used, it may be one server or, more preferably, a combination of scalable servers, providing functionality as a network mainframe server, a web server, a mail server and central database server, all maintained and managed by an administrator or operator of the system. The computing device(s) may also be connected directly or via a network to remote databases, such as for additional storage backup, and to allow for the communication of files, email, software, and any other data formats between two or more computing devices. There are no limitations to the number, type or connectivity of the databases utilized by the system of the present invention. The communications network can be a wide area network and may be any suitable networked system understood by those having ordinary skill in the art, such as, for example, an open, wide area network (e.g., the internet), an electronic network, an optical network, a wireless network, a physically secure network or virtual private network, and any combinations thereof. The communications network may also include any intermediate nodes, such as gateways, routers, bridges, internet service provider networks, public-switched telephone networks, proxy servers, firewalls, and the like, such that the communications network may be suitable for the transmission of information items and other data throughout the system.

The software may also include standard reporting mechanisms, such as generating a printable results report, or an electronic results report that can be transmitted to any communicatively connected computing device, such as a generated email message or file attachment. Likewise, particular results of the aforementioned system can trigger an alert signal, such as the generation of an alert email, text or phone call, to alert a manager, expert, researcher, or other professional of the particular results. Further embodiments of such mechanisms are described elsewhere herein or may standard systems understood by those skilled in the art.

Methods of Use

The invention provides methods for using the fixation device and locking assemblies of the present invention. The methods of using the fixation device and

locking assemblies provide accurate insertion of various medical devices by providing detection means of a patient's internal anatomy and at least partially locking the orientation and position of the fixation device.

In one embodiment, a single fixation device with transducers having energy emission means and energy reception means is used to provide detection means of a patient's internal anatomy for the accurate insertion of medical devices. Referring now to Figure 11, an exemplary method 100 begins with step 110 of attaching a single fixation device to the patient's body near a target site within the patient's anatomy. In step 120, the single fixation device generates emissions, and in step 130, at least some emissions are received by the single fixation device to determine the location of the target site within the patient's anatomy. In step 140, the orientation of the single fixation device is adjusted such that the lumen of the fixation device is pointed at the target site, and in step 150, the single fixation device is at least partially locked. In step 160, a target site first boundary having a minimum depth is determined, and a target site second boundary having a maximum depth is determined. Finally, in step 170, medical devices may then be accurately inserted through the single fixation device lumen to interact with the target site as needed, wherein the medical devices pass the minimum depth but do not exceed the maximum depth.

Referring now to Figure 12A and Figure 12B, the method step of determining a target site first boundary and a target site second boundary is depicted. In Figure 12A, a plurality of emissions 60 are emitted from fixation device 30 in the direction of target site 62. In Figure 12B, at least a portion of the plurality of emissions 60 are reflected back and received by fixation device 30. For example, reflected emission 64 indicates the depth of a fat-muscle boundary interface. Reflected emission 66 indicates the depth of the target site first boundary having a minimum depth, which is the location of the target site that is closest to fixation device 30. Reflected emission 68 indicates the depth of the target site second boundary having a maximum depth, which is the location of the target site that is furthest from fixation device 30. Medical device 38 may then be inserted into target site 62 with accuracy by passing the minimum depth and not exceeding the maximum depth.

In some embodiments, depth of insertion may be determined by measuring the length of medical device 38 as it passes through fixation device 30. Medical device 38 will have reached the correct depth once the measured length is between the minimum depth and the maximum depth. In other embodiments, depth of insertion may be determined using a medical device having an ultrasonic reflective material. For example, a medical device having an ultrasonic reflective material at its distal end can have its distance from fixation device 30 continually monitored such that the medical device will have reached the correct depth once fixation device 30 detects that the ultrasonic reflective material is located between the minimum depth and the maximum depth.

In one embodiment, one or more fixation devices are used to provide detection means of a patient's internal anatomy for the accurate insertion of medical devices. For example, one or more fixation devices are attached to the exterior of a patient's body near a target site within the patient's anatomy. In one embodiment, the transducers of the one or more fixation devices may comprise both energy emission means and energy reception means. In another embodiment, at least one fixation device comprises transducers with emission means while the remaining fixation devices comprise transducers with reception means. In another embodiment, at least one fixation device comprises transducers with reception means while the remaining fixation devices comprise transducers with emission means.

In one embodiment, one or more fixation devices are used to map the internal anatomy of a patient in three dimensions. The fixation devices are useful in stereotactic mapping and stereotactic surgery. For example, one or more fixation devices are attached to the exterior of a patient's body, whereupon energy emission and reception determines the internal anatomy of the patient and maps it in three dimensions. The mapping data can be interpreted using a coordinate system, and surgery may be performed upon precise coordinates using the devices and methods of the present invention.

In one embodiment, the invention provides methods for inserting an external ventricular drain (EVD) into a patient using a fixation device and a grommet locking assembly. The grommet locking assembly may be inserted into a burr hole in the

skull, preferably at Kocher's point (Figure 13), approximately 10 cm along the sagittal axis as measured from the nasion and 3 cm laterally towards the right or left ear. The grommet locking assembly spans the thickness 24 of the skull (Figure 2B). Ultrasound imaging is performed using the ultrasonic transducers located in the fixation device to determine the brain's anatomy, including location and depth. An operator may vary the orientation of the fixation device such that the fixation device is aimed at the right lateral ventricle, preferably the frontal horn of the right lateral ventricle. The operator may then at least partially lock the fixation device in place by actuating the at least one locking member so that the grommet locking assembly maintains the aim of the fixation device at the frontal horn of the right lateral ventricle. An operator may then determine a first boundary of the right lateral ventricle closest to the fixation device having a minimum depth and a second boundary of the right lateral ventricle furthest from the fixation device having a maximum depth. The operator may then insert a drainage catheter into the frontal horn of the right lateral ventricle by guiding the catheter into the lumen of the at least partially locked fixation device such that the drainage catheter passes the minimum depth but does not exceed the maximum depth. In one embodiment, the drainage catheter may be fitted with an ultrasonic reflective strip for enhanced visualization of the catheter.

In another embodiment, the invention provides methods for inserting an EVD into a patient using a fixation device and a cup locking assembly. For example, a cup may be first inserted into a burr hole in the skull, preferably at Kocher's point (Figure 13), approximately 10 cm along the sagittal axis as measured from the nasion and 3 cm laterally towards the right or left ear. The cup spans the thickness 24 of the skull (Figure 4). The fixation device with ball adapter is then inserted into the cup, and ultrasound imaging is performed using the ultrasonic transducers located in the fixation device to determine the brain's anatomy, including location and depth. An operator may vary the orientation of the fixation device such that the fixation device is aimed at the right lateral ventricle, preferably the frontal horn of the right lateral ventricle. The operator may then at least partially lock the fixation device in place by actuating the at least one locking member so that the cup locking assembly maintains the aim of the fixation device at the

frontal horn of the right lateral ventricle. An operator may then determine a first boundary of the right lateral ventricle closest to the fixation device having a minimum depth and a second boundary of the right lateral ventricle furthest from the fixation device having a maximum depth. The operator may then insert a drainage catheter into the frontal horn of the right lateral ventricle by guiding the catheter into the lumen of the at least partially locked fixation device such that the drainage catheter passes the minimum depth but does not exceed the maximum depth. In one embodiment, the drainage catheter may be fitted with an ultrasonic reflective strip for enhanced visualization of the catheter.

In certain embodiments, the present invention provides methods of using the fixation devices of the present invention in conjunction with imaging software, wherein the imaging software acquires ultrasound images of the body to form real-time three dimensional display models from the reconstruction of gathered image data sets (Figure 14A, Figure 14B). The ultrasound transducer portion of a fixation device is controllably moved to image the anatomy of the body (Figure 15A through Figure 15F). While the fixation device is moved, position, angle, and rotation data relative to the fixation device are collected for each image (such as via a mems sensor) to generate a three-dimensional model. The combination of the 3D data and the position, angle, and rotation data allows a physician to determine the ideal trajectory and stopping point of an inserted medical instrument into the body. Upon selection of target coordinates, the computer, attached by either wired or wireless means to the fixation device, will calculate the correct orientation of the individual components of the fixation device, assuring precise and efficient placement of the medical instrument. In some embodiments, the fixation device further comprises one or more motors, such that the computer may further automatically adjust the orientation of the fixation device to match the selected target coordinates.

In some embodiments, the methods of using the fixation devices in conjunction with imaging software are suitable for placing ventricular catheters. As described elsewhere herein, the fixation devices incorporate at least one ultrasound transducer component capable of selectively moving its sonic energy wave front. In

some embodiments, the sonic energy wave front can be moved in a pivoting manner such that the axis of rotation is parallel to the face of the transmission surface. The sonic energy wave front is moved along, and normal to, a given plane face such as the sagittal or coronal planes of the brain, wherein "normal" is referred to in the geometric sense as perpendicular to a line tangential to the skull. The sonic energy wave front can also be rotated about a fixed axis that is generally oriented in an axial direction, normal to the ultrasound transducer transmission face; rotating in this manner causes the sonic energy wave front to cross the sagittal plane, the coronal plane, or both. As the transducer is either pivoted or spun about an axis of rotation, encoders mounted in the fixation devices are capable of providing real-time positional (rotational and angular information) of the transducer's position. The positional information of the transducer face angle, referenced from a starting zero position, is combined with the associated image pixel data acquired at that specific point of data collection in space and time. In some embodiments, the fixation devices also provide real-time positional data of the inserted medical instruments.

It should be appreciated that movement of the transducers to capture imaging and positional data is not limited to a single rotation. For example, the transducers may be actuated in a single sweeping direction. The transducers may also be actuated in more than once rotation, or more than one sweeping direction. The transducers may also be actuated in a combination of one or more rotations and one or more sweeping directions. Using a sweeping actuation, volumetric image formation can be obtained by sequential anterior to posterior translation of a transducer relative to a subject. In the context of imaging a brain, a sweep of the transducer may be performed in the sagittal plane to render a three dimensional image of a desired structure. If, for instance, an object of interest is not represented in the sagittal sweep, the transducer can be translated along the coronal plane and a repeated anterior to posterior sweep of the transducer can be made to obtain the volumetric image of the desired structure.

Referring now to Figure 16, an exemplary method 200 of using a fixation device of the present invention to insert a ventricular catheter is depicted. Method 200 begins with step 202, wherein the skin is marked at Kocher's point above a subject's

skull. Typically, Kocher's point is located with reference to the point between the subject's pupils, known as the nasion. A 10 cm line is drawn from the nasion along the skull in a posterior direction to the occiput. At the endpoint of the 10 cm line, a 3 cm line is drawn laterally towards the left or right ear. The endpoint of the 3 cm line is roughly Kocher's point. In step 204, an incision is made at the marked skin. The incision is preferable large enough to accommodate a fixation device of the present invention. Hemostasis should be established. To provide easier access to the skull, the skin may be spread with a retraction device. In step 206, the skull is perforated. The skull may be perforated using any suitable drill bit. In some embodiments, it is recommended not to exceed 800 RPM when drilling. In step 208, a fixation device of the present invention having ultrasonic transducers is inserted into the skull perforation. In step 210, the ultrasonic transducers are aligned to capture a cross-sectional ultrasound image of the brain with the positional, angular, and rotational orientation of the ultrasonic transducers. In step 212, the ultrasonic transducers are actuated. In step 214, a series of ultrasonic images of the brain and associated positional, angular, and rotational orientation of the ultrasonic transducers are acquired during actuation. Typically, anechoic regions visible in the ultrasonic images represent the brain ventricles. In step 216, the ultrasonic images are assembled to form a 3D reconstruction of the brain ventricles using the associated positional, angular, and rotational orientation of the ultrasonic transducers. In step 218, an automatic segmentation of the 3D reconstruction is performed to isolate an anatomy of interest. The 3D reconstruction and segmentation views can be displayed from multiple angles, such as from a sagittal, coronal, and axial plane view, as well as a 3D view. Any suitable software can be used to generate the views, such as Osirix, ITK-Snap, 3D-Slicer, and Mimics. In step 220, the positional, angular, and rotational orientation of the anatomy of interest are acquired. The location can be confirmed on the 3D reconstruction and segmentation views. In step 222, the fixation device is aligned to target the anatomy of interest. In step 224, the alignment of the fixation device is fixed relative to the skull. In step 226, a catheter and ventricular drain are inserted through the fixation device into the anatomy of interest. In some embodiments, the ultrasonic transducers may be activated to monitor the entry of the catheter and ventricular drain.

For example, out-of-plane imaging using the ultrasonic transducers can verify accurate catheter and ventricular drain insertion. In step 228, the fixation device is removed over the catheter and ventricular drain.

In one embodiment, the invention provides improved methods for accurate biopsies. For example, a fixation device patch may be adhered to the soft tissue near the desired sample site. Emissions from the fixation device transducers determine the patient's internal anatomy, including structure depth. An operator may vary the orientation of the fixation device such that the fixation device is aimed at the desired sample site. The operator may then at least partially lock the fixation device in place by actuating the at least one locking member so that the fixation device maintains its aim at the desired sample site. The operator may then accurately direct a biopsy needle into the sample site by guiding the biopsy needle into the lumen of the locked fixation device. In one embodiment, the biopsy needle may be fitted with an ultrasonic reflective strip for enhanced visualization of the catheter.

In various embodiments, the invention provides improved methods for accurate insertion of any medical apparatus into the internal anatomy of a patient. The partial locking feature of the invention enables medical apparatuses to be freely interchanged while maintaining positional accuracy to a target site. Examples of procedures that the present invention may be applied to and improve include, but are not limited to: brachytherapy, tracheotomy, localized drug delivery, microsurgery, and the like.

Kits of the Invention

The invention also includes a kit comprising components useful within the methods of the invention and instructional material that describes, for instance, the method of using the fixation devices and locking assemblies as described elsewhere herein. The kit may comprise components and materials useful for performing the methods of the invention. For instance, the kit may comprise a fixation device, a grommet locking assembly, a cup locking assembly, and catheters. In other embodiments, the kit may include separately the transducer components and the locking

assemblies, such that the transducer components may be sterilized and reusable, while the locking assemblies may be sterilized and reusable or discarded and replaced. In other embodiments, the kit may further comprise software and electronic equipment to convert received waves into images. The software and electronic equipment may be presented in a compact form for portable use.

In certain embodiments, the kit comprises instructional material. Instructional material may include a publication, a recording, a diagram, or any other medium of expression which can be used to communicate the usefulness of the device described herein. The instructional material of the kit of the invention may, for example, be affixed to a package which contains one or more instruments which may be necessary for the desired procedure. Alternatively, the instructional material may be shipped separately from the package, or may be accessible electronically via a communications network, such as the Internet.

In one embodiment, the invention includes a kit for portable use. To facilitate portable use, a kit of the present invention may further include a razor or clipper for removing hair from a subject, a ruler or tape measure for measuring the location of a site for incision, a surgical marker or other implement for marking the site of incision, skin preparation material (i.e., antiseptic, alcohol pads) to clean the site of incision, a scalpel to perform the incision, a drilling instrument to perforate any bone, and any additional surgical and medical elements that may be useful for such an operation, such as surgical tape, gauze, bandages, surgical thread and needle, and the like.

The disclosures of each and every patent, patent application, and publication cited herein are hereby incorporated herein by reference in their entirety. While this invention has been disclosed with reference to specific embodiments, it is apparent that other embodiments and variations of this invention may be devised by others skilled in the art without departing from the true spirit and scope of the invention. The appended claims are intended to be construed to include all such embodiments and equivalent variations.

CLAIMS

What is claimed is:

1. A fixation device comprising:

an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings;

at least one emission means at a distal end region of the elongate body; and

at least one receiving means for receiving at least some emissions from said emission means.

2. The device of claim 1, wherein the elongate body lumen is sized suitably for an instrument, tool, implant, or biological material to pass therethrough.

3. The device of claim 2, wherein the elongate body lumen is sized suitably for an inserted instrument, tool, implant, or biological material to rotate.

4. The device of claim 1, wherein the elongate body lumen has a cross-section that is circular, elliptical, polygonal, or keyed.

5. The device of claim 1, wherein the elongate body lumen may be centered or off-center in the elongate body.

6. The device of claim 1, wherein the emission means are selected from the group consisting of: ultrasonic transducers, optical sensors, thermal sensors, electromagnetic sensors, photoelectric transducers, laser diodes, radio transducers, Doppler, x-ray, particle sensors, chemical sensors, and piezoelectric sensors.

7. The device of claim 6, wherein the ultrasonic transducers are either piezoelectric ultrasonic transducers or capacitive ultrasonic transducers.

8. The device of claim 1, wherein the distal end region of the elongate body is composed of a material which is at least partially transmissive to said emission.

9. The device of claim 1, further comprising:

a grommet having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings; and

at least one locking member;

wherein the grommet lumen is sized such that the elongate body of the fixation device can pass through the grommet lumen and be at least partially locked into place by the at least one locking member.

10. The device of claim 9, wherein the grommet comprises one or more materials selected from the group consisting of: metals, ceramics, and polymers.

11. The device of claim 10, wherein the grommet comprises one or more materials selected from the group consisting of: stainless steel, cobalt, titanium, aluminum oxide, zirconia, calcium phosphate, silicon, polyethylene, polyvinyl chloride, polyurethane, and polylactide.

12. The device of claim 1, further comprising:

a cup having a base member and perimeter sidewalls forming an open top, wherein the base member includes at least one opening, and

at least one locking member;

wherein the cup is sized such that the distal end region of the elongate body of the fixation device can be at least partially locked into place within the cup by the at least one locking member.

13. The device of claim 12, wherein the cup comprises one or more materials selected from the group consisting of: metals, ceramics, and polymers.

14. The device of claim 13, wherein the cup comprises one or more materials selected from the group consisting of: stainless steel, cobalt, titanium, aluminum oxide, zirconia, calcium phosphate, silicon, polyethylene, polyvinyl chloride, polyurethane, and polylactide.

15. The device of claims 9 or 12, wherein the at least one locking member is selected from the group consisting of: a screw, a bolt, a pin, an adhesive, and a clamp.

16. The device of claims 9 or 12, wherein the at least one locking member is engaged mechanically, electro-mechanically, magnetically, or adhesively.

17. The device of claim 1, further comprising an anchoring patch comprising:

a flexible substrate having a first and a second surface; and

a rigid housing positioned within the flexible substrate;

wherein the housing is dimensioned to engage the device of claims 9 or 12.

18. The device of claim 17, wherein the flexible substrate comprises a material selected from the group consisting of plastics, polymers, metals, and gels.

19. The device of claim 17, further comprising an adhesive material on at least a portion of the first surface of the flexible substrate.

20. The device of claim 1, further comprising a first angled shim housing having a space at its center and a cranial burr anchor, wherein the first angled shim housing is attached to the cranial burr anchor, wherein the fixation device fits within and is rotatable within the space of the first angled shim housing, and the first angled shim housing is rotatable about the cranial burr anchor.

21. The device of claim 20, further comprising a second angled shim housing, wherein the second angled shim housing is attached between the first angled

shim housing and the cranial burr anchor, and wherein the second angled shim housing is rotatable about the first angled shim housing and the cranial burr anchor.

22. The device of claim 20, further comprising a lever attachment having a lumen attached to and continuous with the lumen of the fixation device, wherein the lumen of the lever attachment is sized to accept a medical instrument.

23. The device of claim 1, further comprising a rotatable housing, a cranial burr anchor, and a lever attachment having a lumen connected to the proximal end opening of the fixation device, wherein the rotatable housing is attached to the cranial burr anchor, wherein the fixation device is encased and rotatable within the rotatable housing, wherein the rotatable housing is rotatable about the cranial burr anchor, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

24. The device of claim 1, further comprising a cranial interface component having at least two angular rails, an anterior-posterior angle control component having at least two angular rails, a lateral angle control component having a space at its center, and a lever attachment having a lumen connected to the proximal opening of the fixation device, wherein the anterior-posterior angle control component is movable along the at least two angular rails of the cranial interface component, wherein the lateral angle control component is movable along the at least two angular rails of the anterior-posterior angle control component, wherein the fixation device fits within and is rotatable within the space of the lateral angle control component, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

25. The device of claim 1, further comprising a hemispherical cap having a first track and a hemispherical cranial burr anchor having a second track, wherein the first track spans the diameter of the hemispherical cap, wherein the second track spans the diameter of the hemispherical cranial burr anchor, wherein the hemispherical cap is movable along the second track, wherein the fixation device is movable along the first track, and wherein the first track and the second track are perpendicular to each other.

26. A method of localizing and interacting with a target site within a patient's anatomy, comprising the steps of:

attaching the device of claims 9 or 12 to the patient's body near the target site;

generating emissions using the attached device;

receiving the emissions from the attached device;

adjusting the orientation of the attached device to aim the attached device at the target site;

at least partially locking the attached device;

determining a target site first boundary having a minimum depth and a target site second boundary having a maximum depth; and

inserting medical devices through the lumen of the attached device to interact with the target site such that the medical devices pass the minimum depth but do not exceed the maximum depth.

27. A method for accurate insertion of an external ventricular drain (EVD), comprising the steps of:

inserting the device of claims 9 or 12 into a burr hole in a patient's skull;

imaging a region within the patient's brain using the attached device;

aligning the lumen of the attached device with a desired site of drainage;

at least partially locking the attached device in place;

determining a desired site of drainage first boundary having a minimum depth and a desired site of drainage second boundary having a maximum depth; and

guiding an EVD through the lumen of the attached device into the desired site of drainage for draining such that the EVD passes the minimum depth but does not exceed the maximum depth.

28. The method of claim 27, wherein an ultrasonic reflective strip is attached to the EVD.

29. A method for accurate insertion of a medical device to a target site, comprising the steps of:

affixing an anchoring patch having a flexible substrate and a rigid housing onto a patient at a desired site of insertion of a medical device;

engaging the device of claims 9 or 12 to the rigid housing of the anchoring patch;

aligning the lumen of the attached device with the target site;

at least partially locking the attached device in place;

determining a target site first boundary having a minimum depth and a target site second boundary having a maximum depth; and

guiding the medical device through the lumen of the attached device to the target site such that the medical device passes the minimum depth but does not exceed the maximum depth.

30. The method of claim 29, wherein the medical device is selected from the group consisting of: catheters, microforceps, microscalpels, biopsy needles, radiofrequency ablation probes, cryoablation probes, suturing instruments, and syringes.

31. The method of claim 29, wherein an ultrasonic reflective strip is attached to the medical device.

32. A method of stereotactic mapping; comprising the steps of:

attaching at least two devices of claims 9 or 12 to a patient's body;

generating emissions using at least one of the attached devices; and

receiving the emissions using at least one of the attached devices.

33. A method of using a fixation device to insert a ventricular catheter into a subject's brain, comprising the steps of:

marking the skin at Kocher's point above a subject's skull;

making an incision at the marked skin;

perforating the skull;

inserting a fixation device having ultrasonic transducers;

aligning the ultrasonic transducers to capture a cross-sectional ultrasound image of the brain and the positional, angular, and rotational orientation of the ultrasonic transducers;

actuating the ultrasonic transducers;

acquiring a series of ultrasonic images of the brain and associated positional, angular, and rotational orientation of the ultrasonic transducers during actuation;

assembling the ultrasonic images into a 3D reconstruction of the brain ventricles using the associated positional, angular, and rotational orientation of the ultrasonic transducers;

performing an automatic segmentation of the 3D reconstruction to isolate an anatomy of interest;

acquiring the positional, angular, and rotational orientation of the anatomy of interest;

aligning the fixation device to target the anatomy of interest;

fixing the alignment of the fixation device relative to the skull;

inserting a catheter and ventricular drain through the fixation device into the anatomy of interest; and

removing the fixation device over the catheter and ventricular drain.

34. A fixation device comprising:

an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings;

a first angled shim housing having a space at its center; and

a cranial burr anchor;

wherein the first angled shim housing is attached to the cranial burr

anchor, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, and wherein the first angled shim housing is rotatable about the cranial burr anchor.

35. A fixation device comprising:

an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings;

a first angled shim housing having a space at its center;

a second angled shim housing;

and a cranial burr anchor;

wherein the first angled shim housing is attached to the second angled shim housing, wherein the second angled shim housing is attached to the cranial burr anchor, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, wherein the first angled shim housing is rotatable about the second angled shim housing, and wherein the second angled shim housing is rotatable about the cranial burr anchor.

36. A fixation device comprising:

an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings;

a first angled shim housing having a space at its center;

a lever attachment having a lumen; and

a cranial burr anchor;

wherein the lever attachment is attached to the first angled shim housing, wherein the first angled shim housing is attached to the cranial burr anchor, wherein the lumen of the elongate body is attached to and continuous with the lumen of the lever attachment, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, and wherein the first angled shim housing is rotatable about the cranial burr anchor.

37. A fixation device comprising:

an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings;

a rotatable housing;

a cranial burr anchor; and

a lever attachment having a lumen attached to and continuous with the lumen of the elongate body;

wherein the rotatable housing is attached to the cranial burr anchor, wherein the elongate body is encased and rotatable within the rotatable housing, wherein the rotatable housing is rotatable about the cranial burr anchor, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

38. A fixation device comprising:

an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings;

a cranial interface component having at least two angular rails;

an anterior-posterior angle control component having at least two angular rails;

a lateral angle control component having a space at its center; and

a lever attachment having a lumen attached to and continuous with the lumen of the elongate body;

wherein the anterior-posterior angle control component is movable along the at least two angular rails of the cranial interface component, wherein the lateral angle control component is movable along the at least two angular rails of the anterior-posterior angle control component, wherein the elongate body fits within and is rotatable within the space of the lateral angle control component, and wherein the lumen of the lever attachment is sized to accept a medical instrument.

39. A fixation device comprising:

an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings;

a hemispherical cap having a first track; and

a hemispherical cranial burr anchor having a second track;

wherein the first track spans the diameter of the hemispherical cap, wherein the second track spans the diameter of the hemispherical cranial burr anchor, wherein the hemispherical cap is movable along the second track, wherein the elongate body is movable along the first track, and wherein the first track and the second track are perpendicular to each other.

40. A kit comprising:

the device of claim 1;

a hair clipper;

a tape measure;

a surgical marking implement;

skin preparation material;

a scalpel; and

a drilling instrument.

41. The kit of claim 40, further comprising display equipment.

42. The kit of claim 40, further comprising a portable power source.

43. A kit comprising:

a devices of any of claims 34-39;

a power source;

a hair clipper;

a tape measure;

a surgical marking implement;

skin preparation material;

a scalpel; and

a drilling instrument.

44. The kit of claim 43, further comprising at least one emission means and at least one receiving means for receiving at least some emissions from said emission means.

45. The kit of claim 43, further comprising display equipment.

46. The kit of claim 43, further comprising a portable power source.

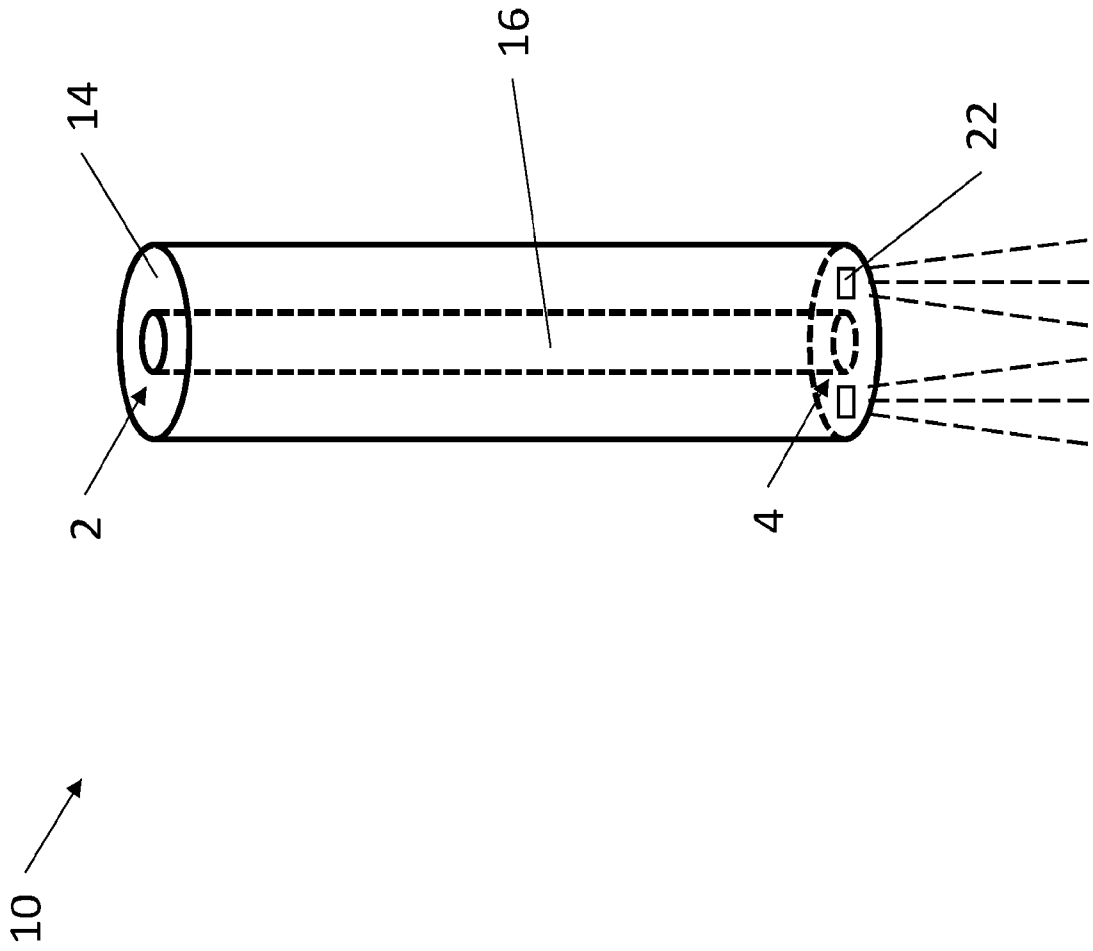

Figure 1

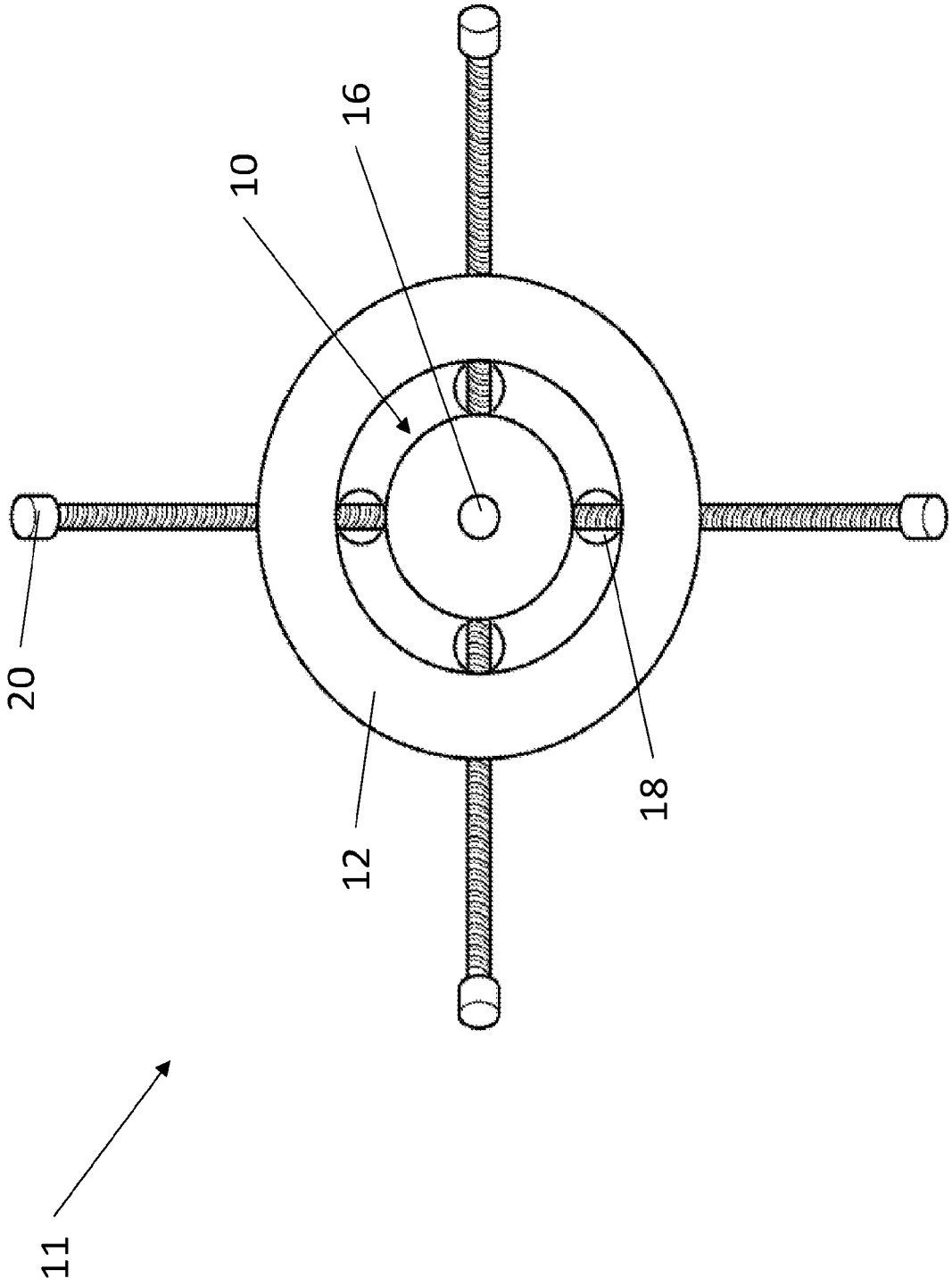

Figure 2A

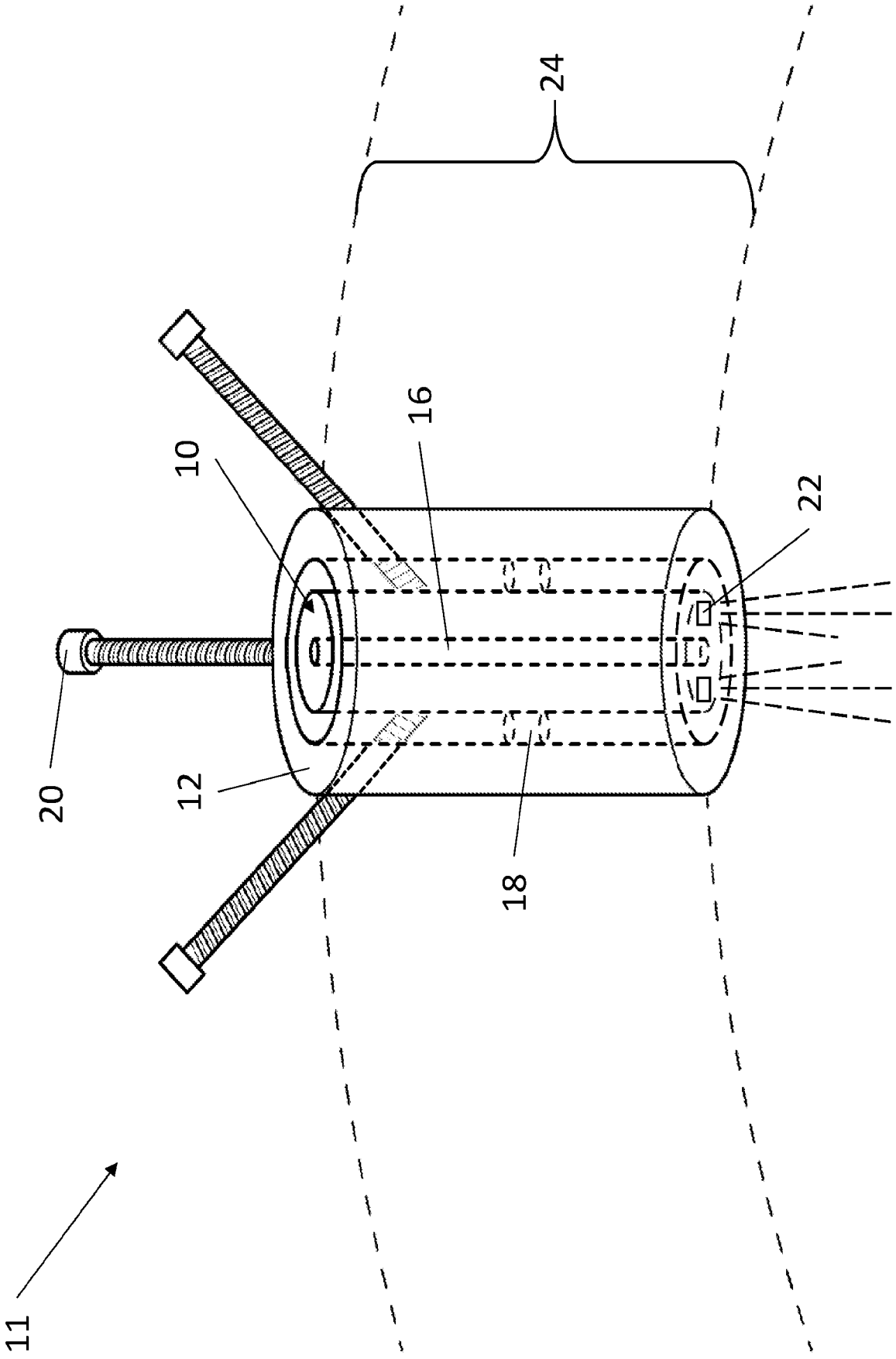

Figure 2B

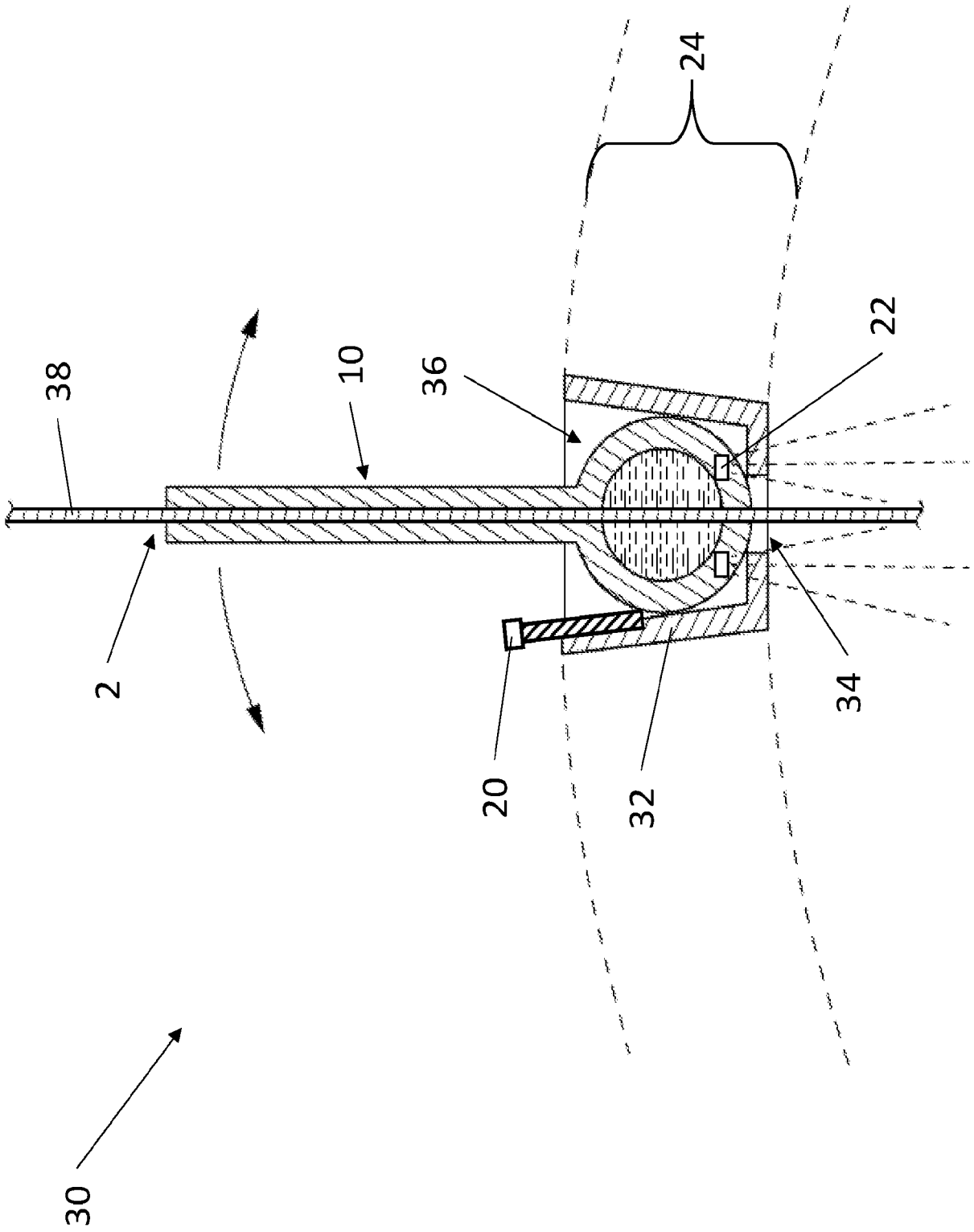

Figure 3

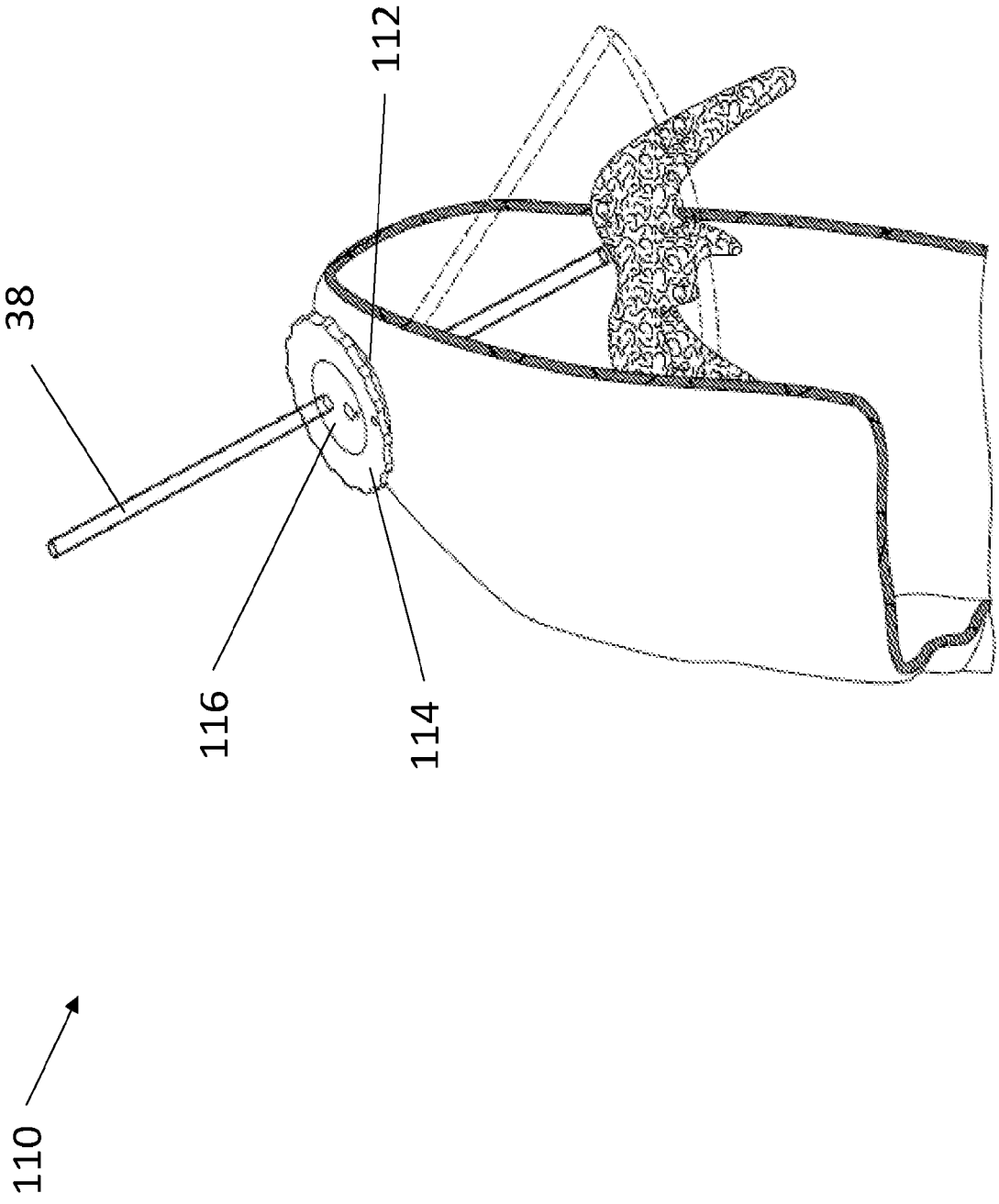

Figure 4A

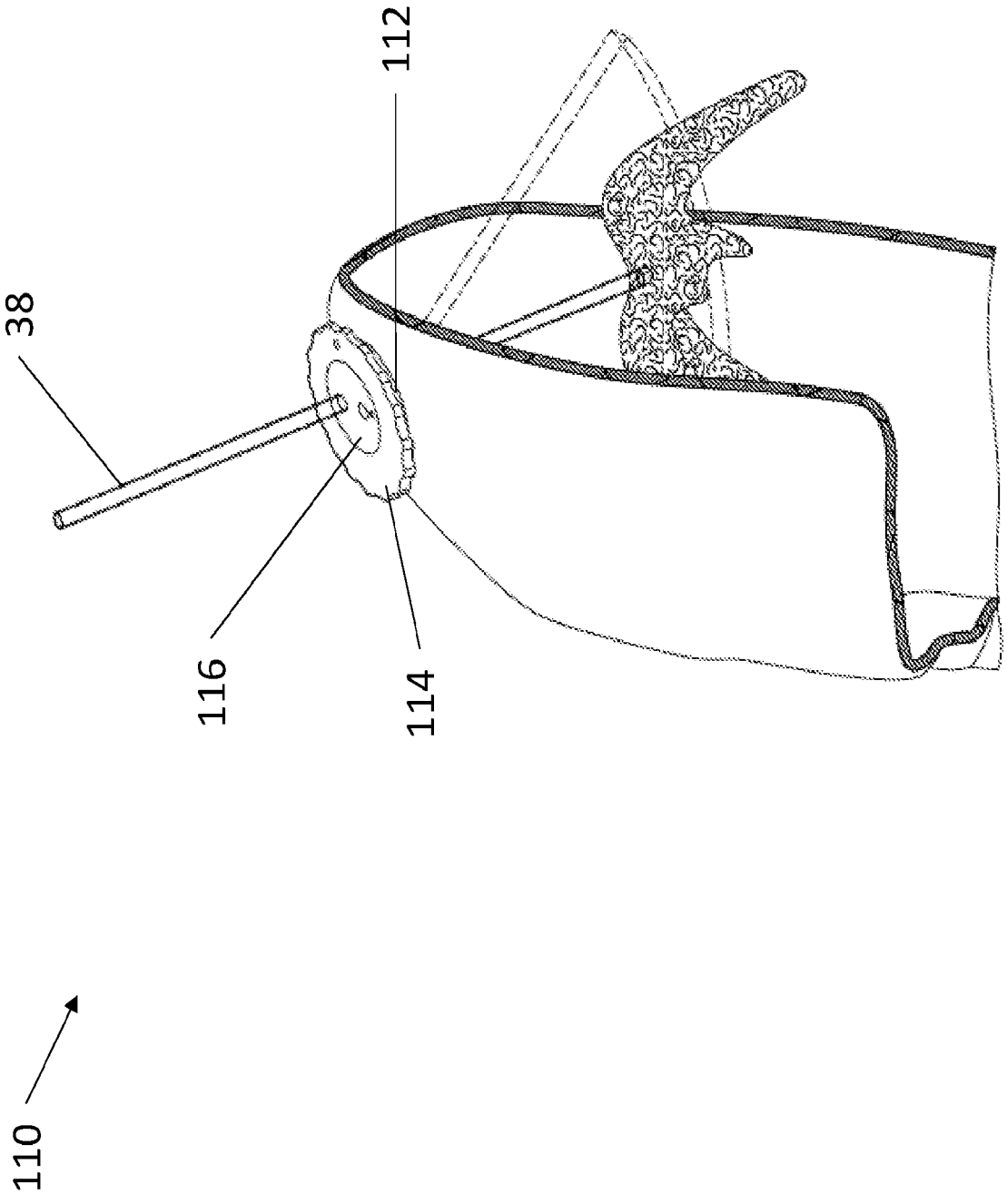

Figure 4B

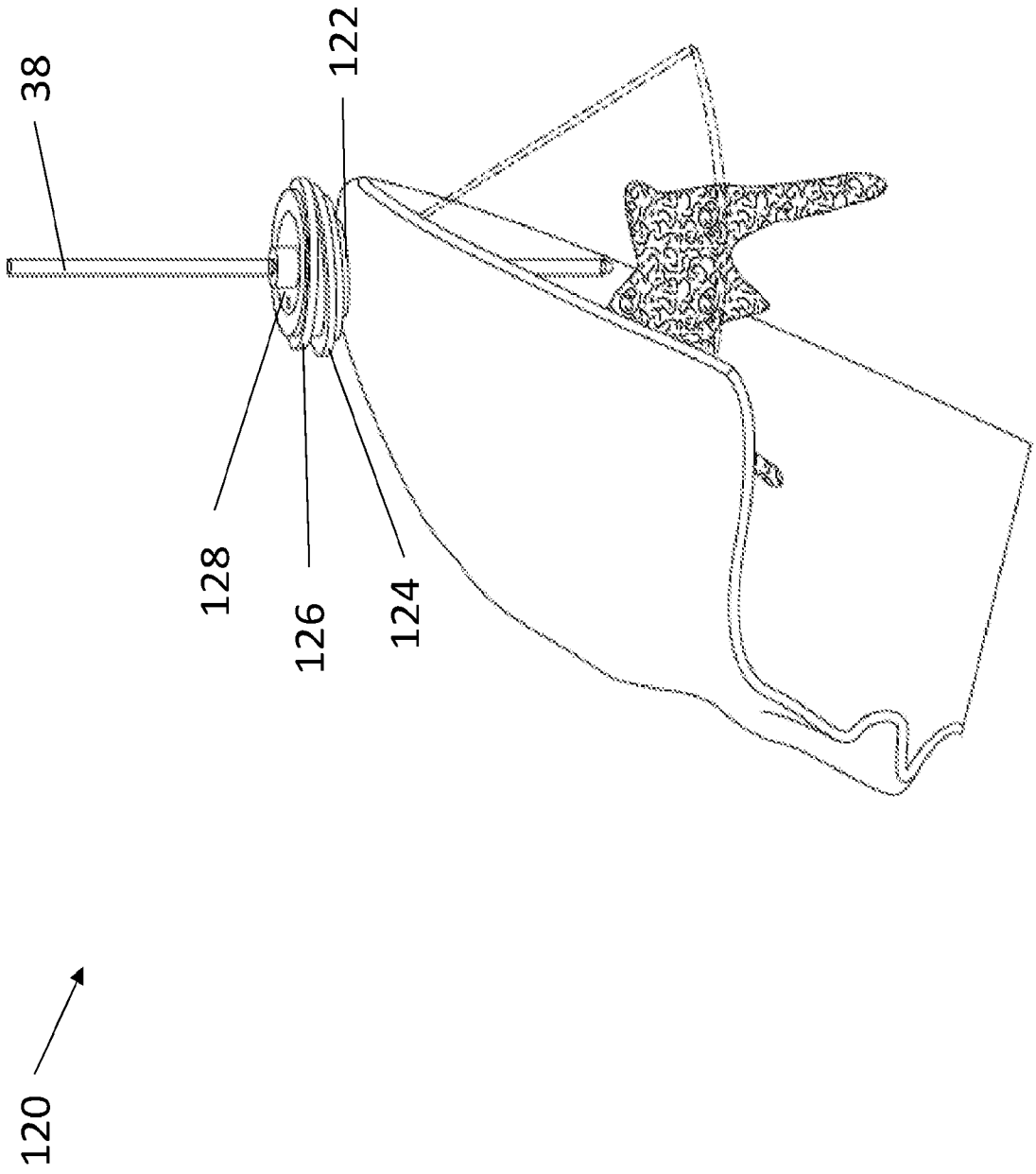

Figure 5

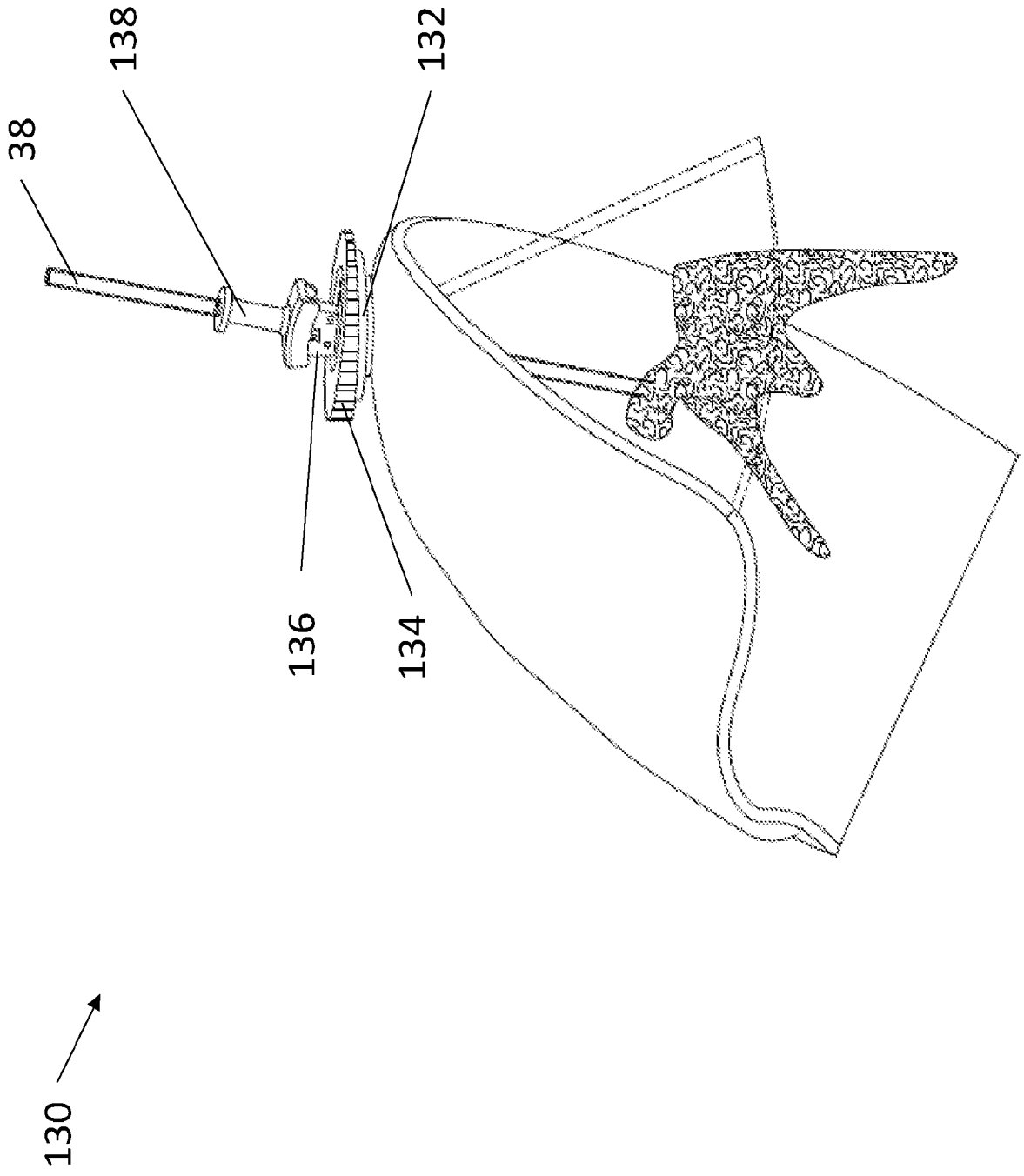

Figure 6

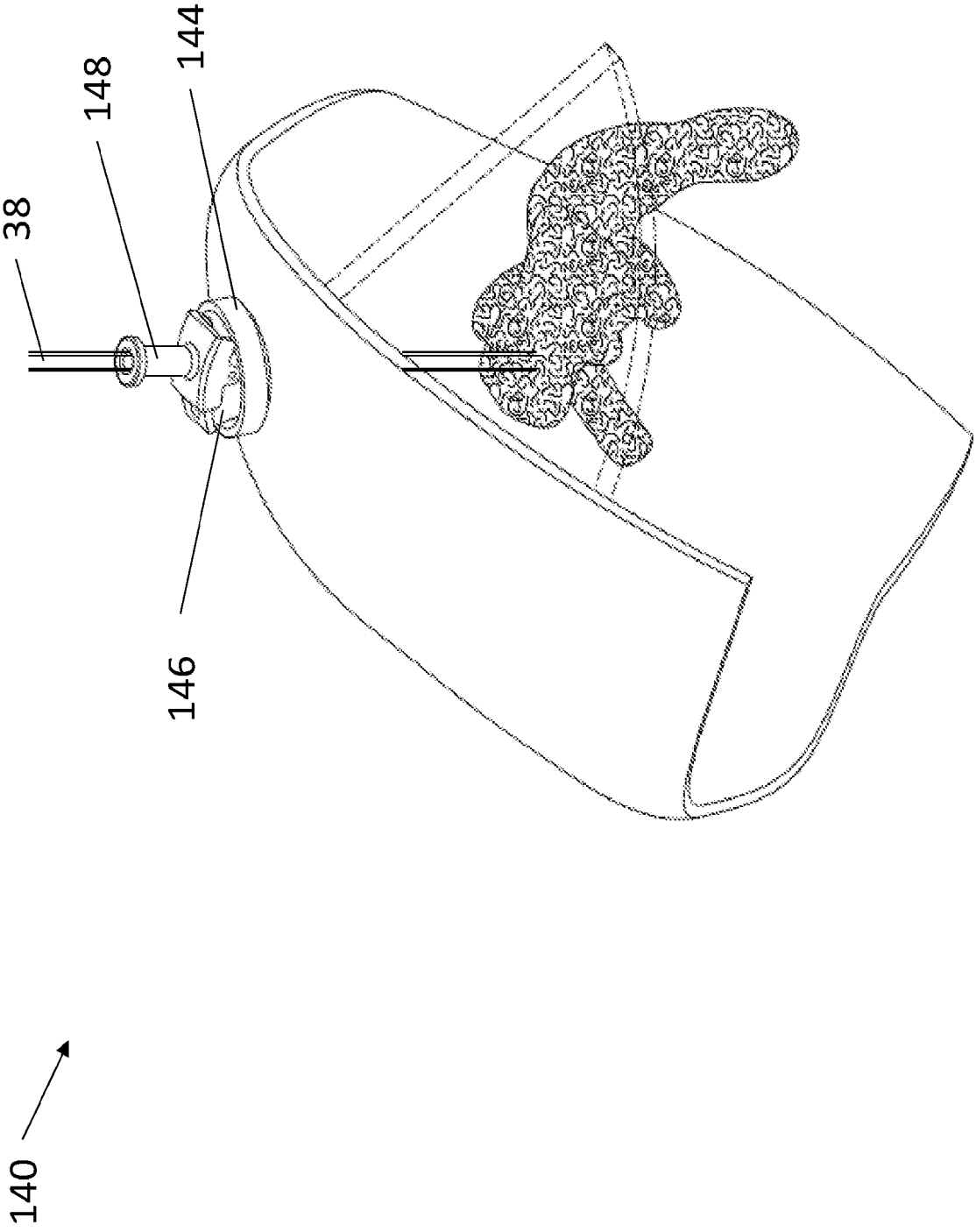

Figure 7A

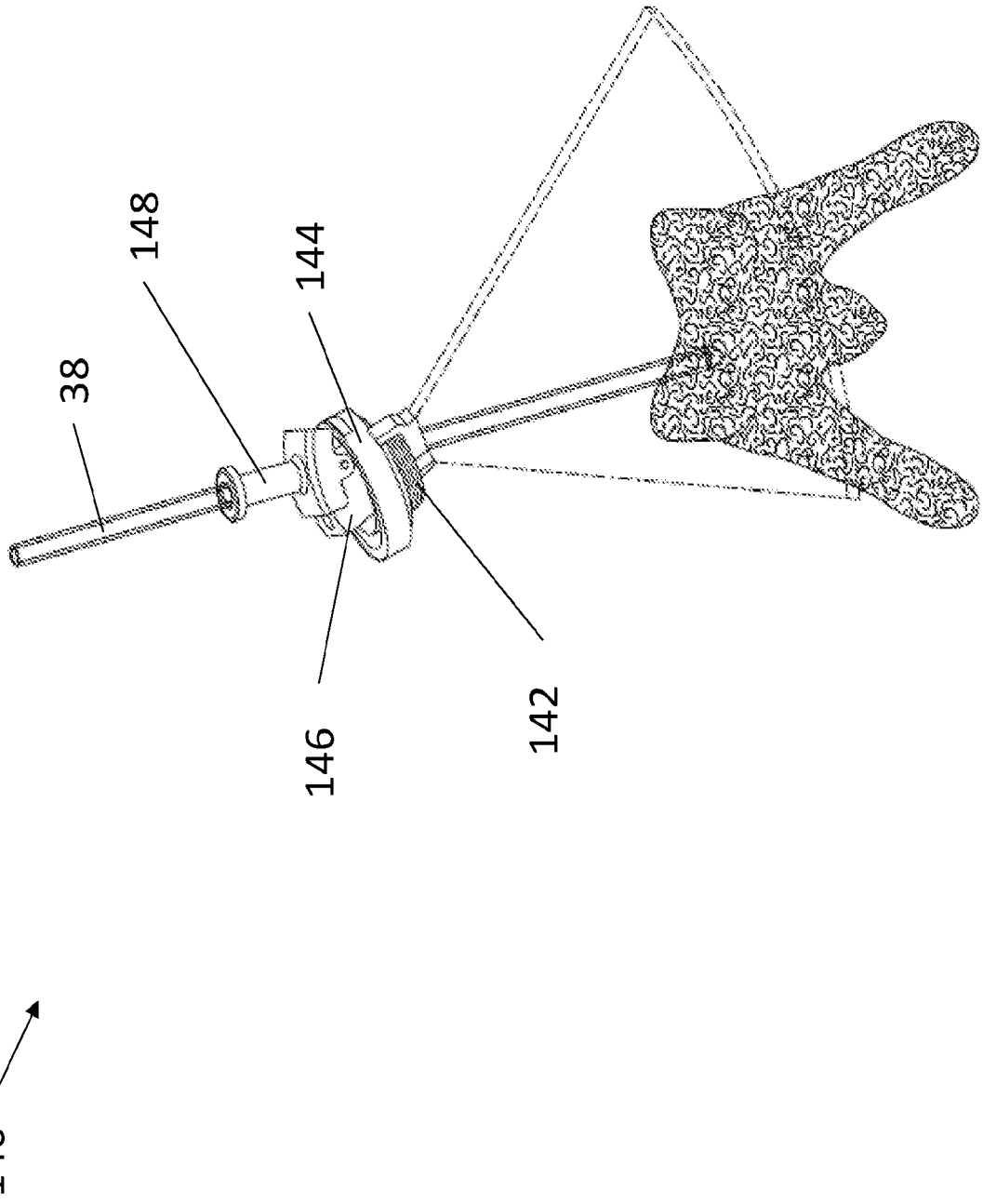

Figure 7B

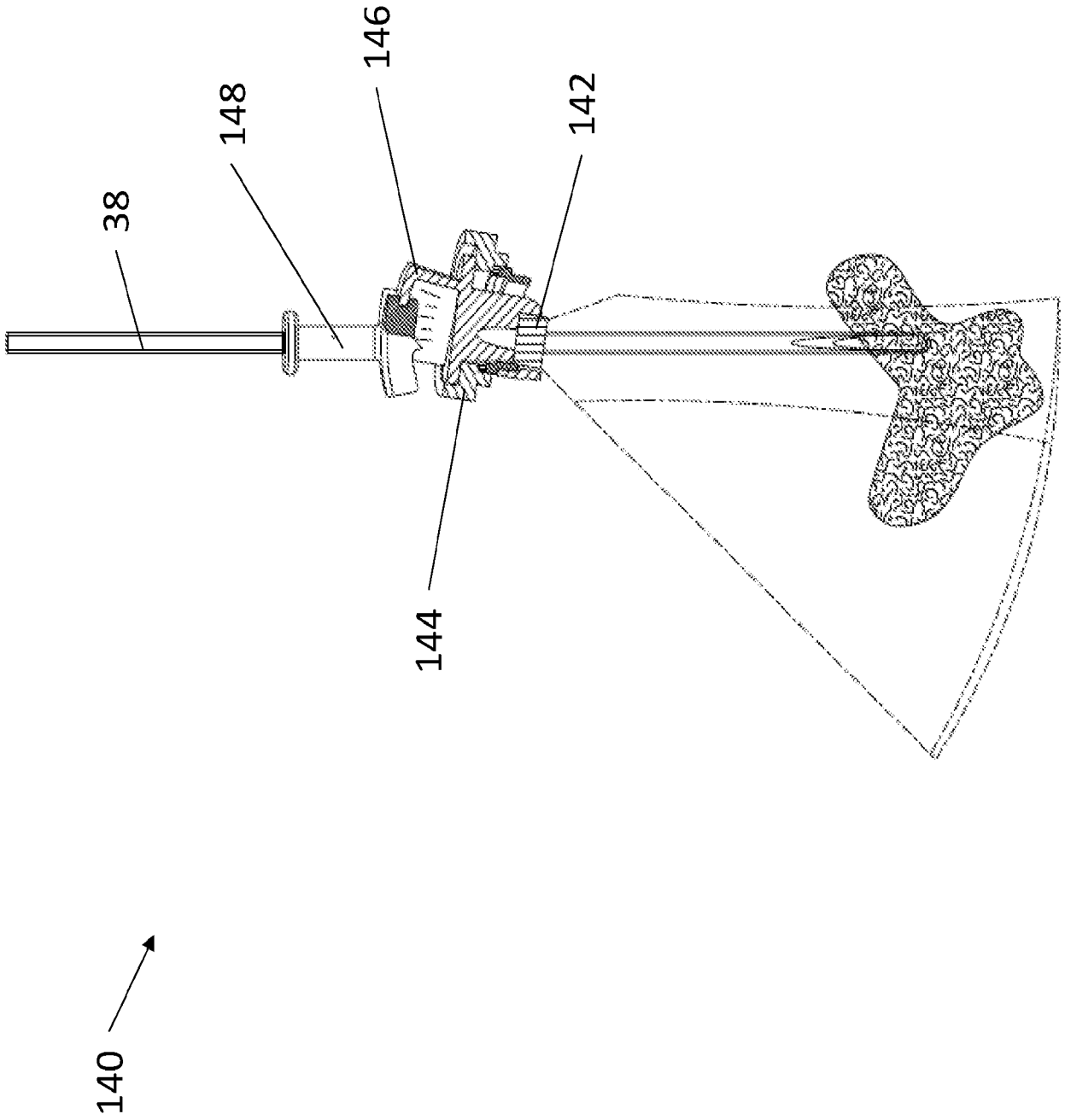

Figure 7C

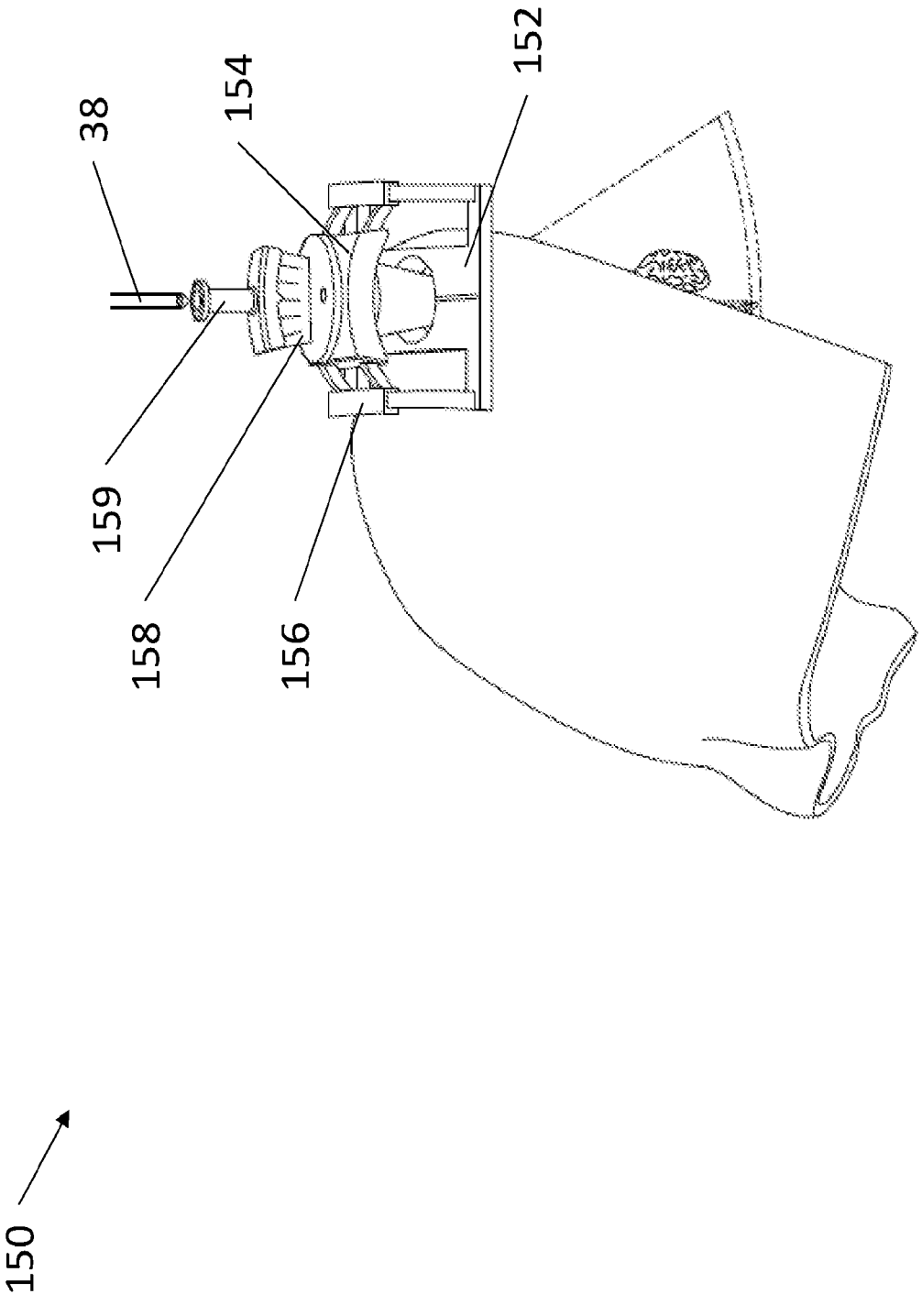

Figure 8A

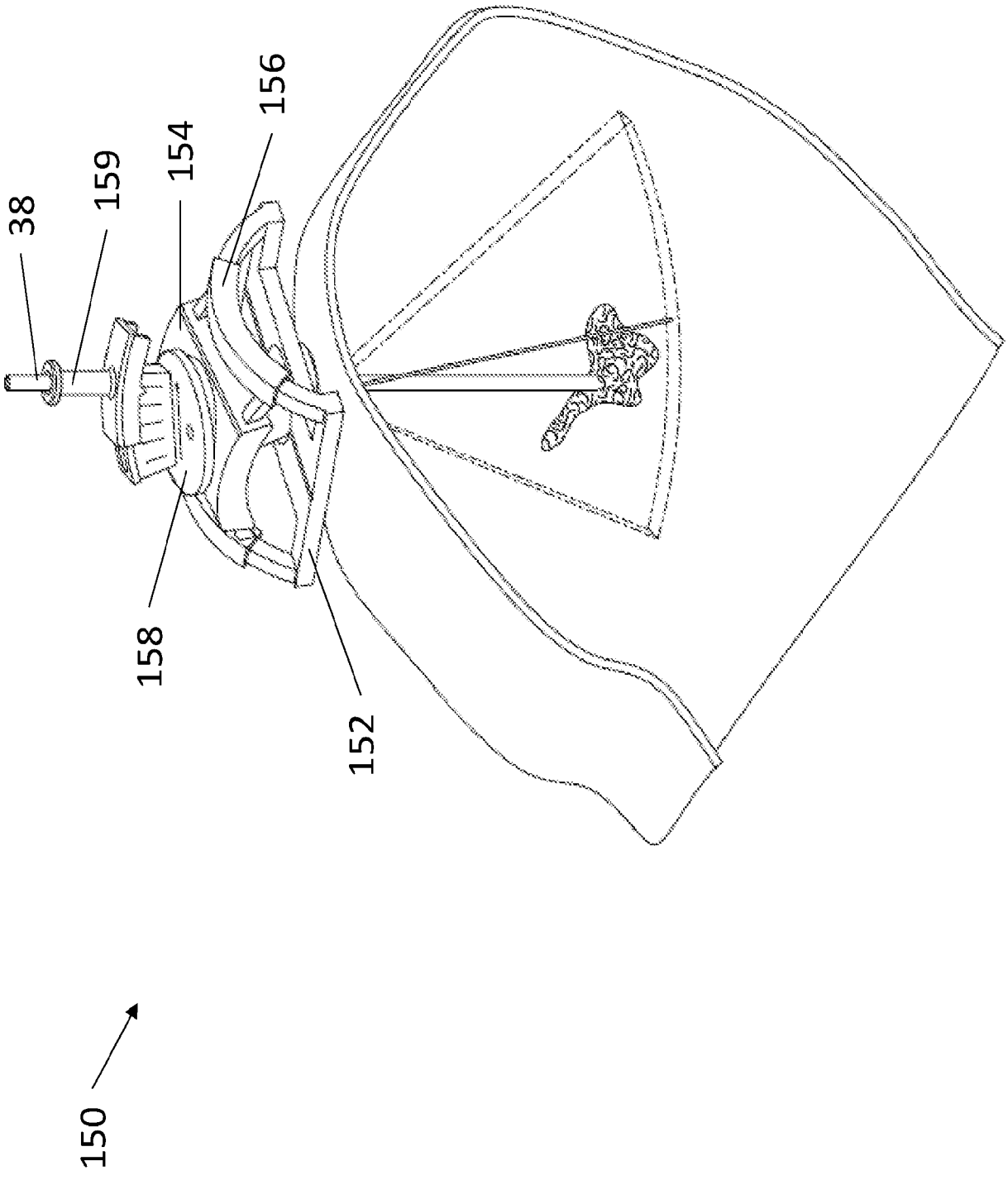

Figure 8B

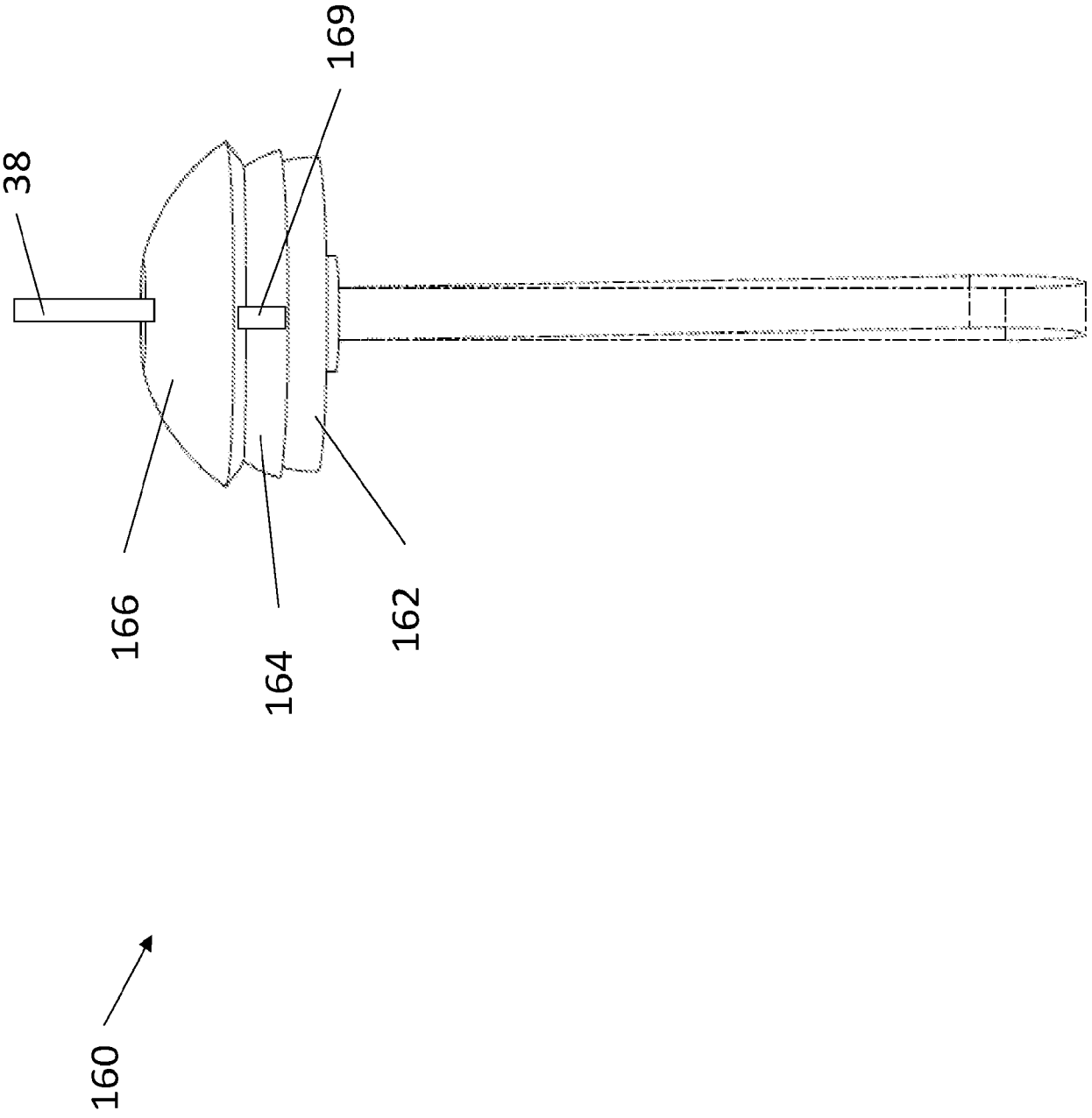

Figure 9A

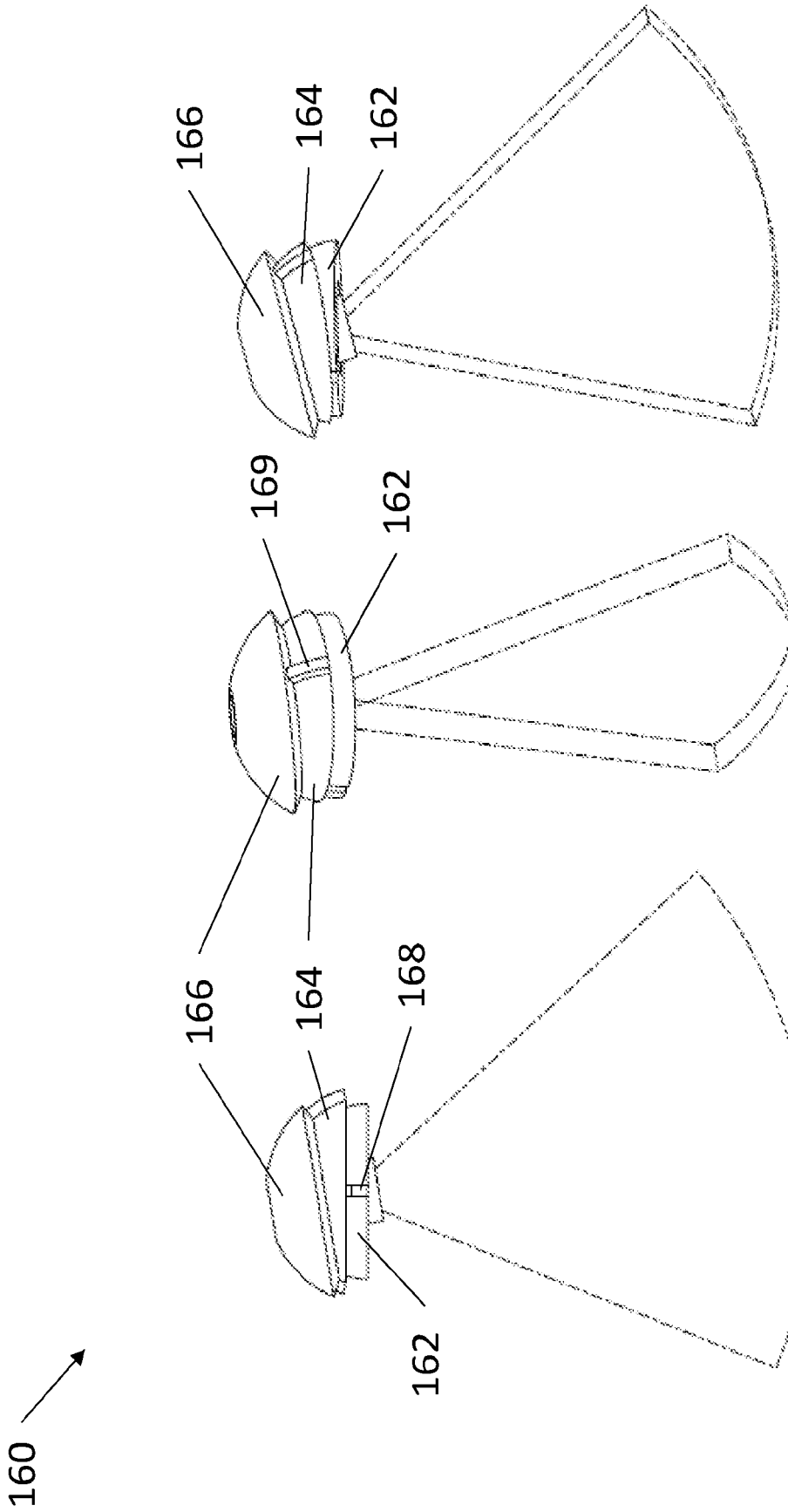

Figure 9B

Figure 9C

Figure 9D

Figure 9B – 9D

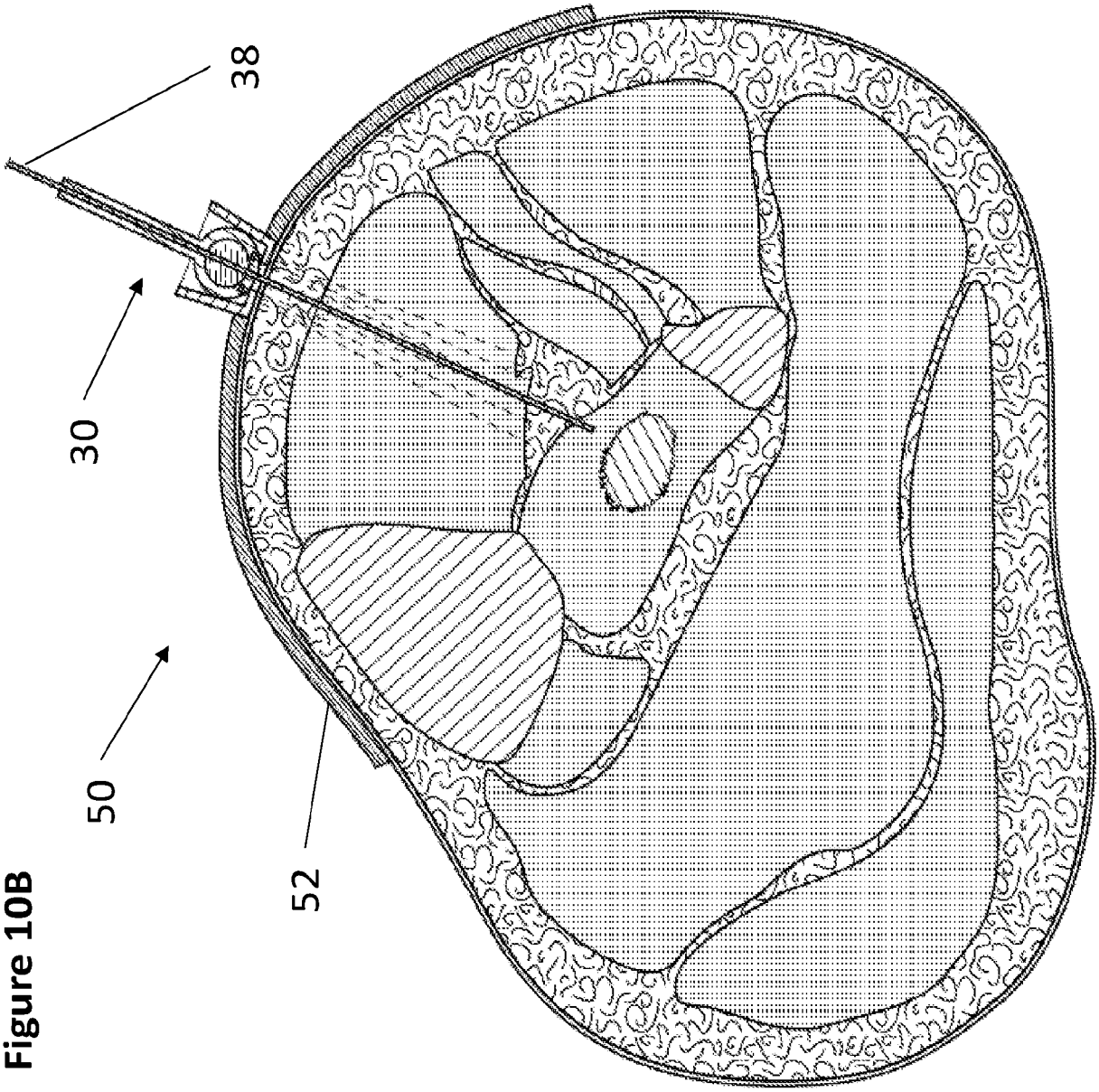

Figure 10B

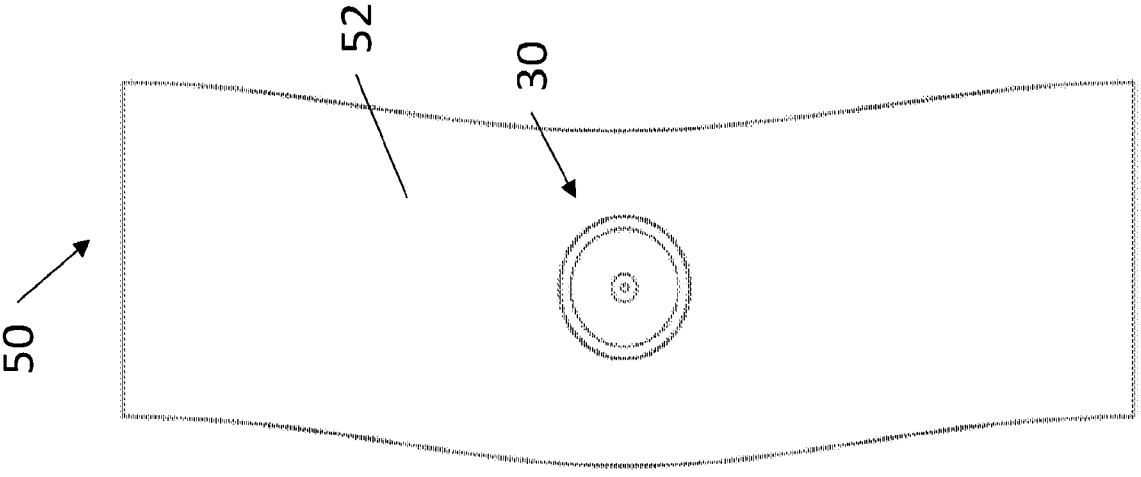

Figure 10A

Figure 10A – Figure 10B

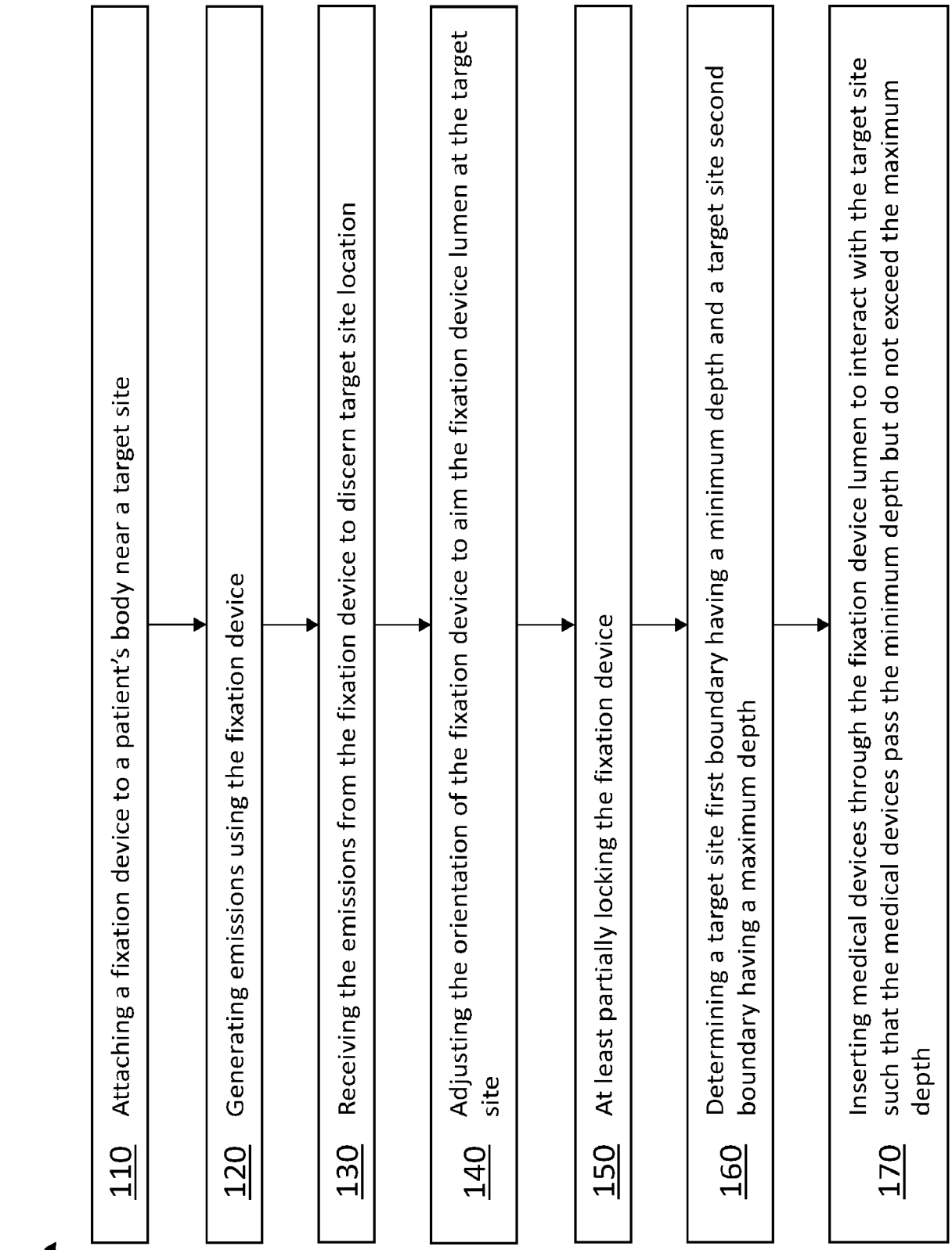
100
110 Attaching a fixation device to a patient's body near a target site
120 Generating emissions using the fixation device
130 Receiving the emissions from the fixation device to discern target site location
140 Adjusting the orientation of the fixation device to aim the fixation device lumen at the target site
150 At least partially locking the fixation device
160 Determining a target site first boundary having a minimum depth and a target site second boundary having a maximum depth
170 Inserting medical devices through the fixation device lumen to interact with the target site such that the medical devices pass the minimum depth but do not exceed the maximum depth

Figure 11

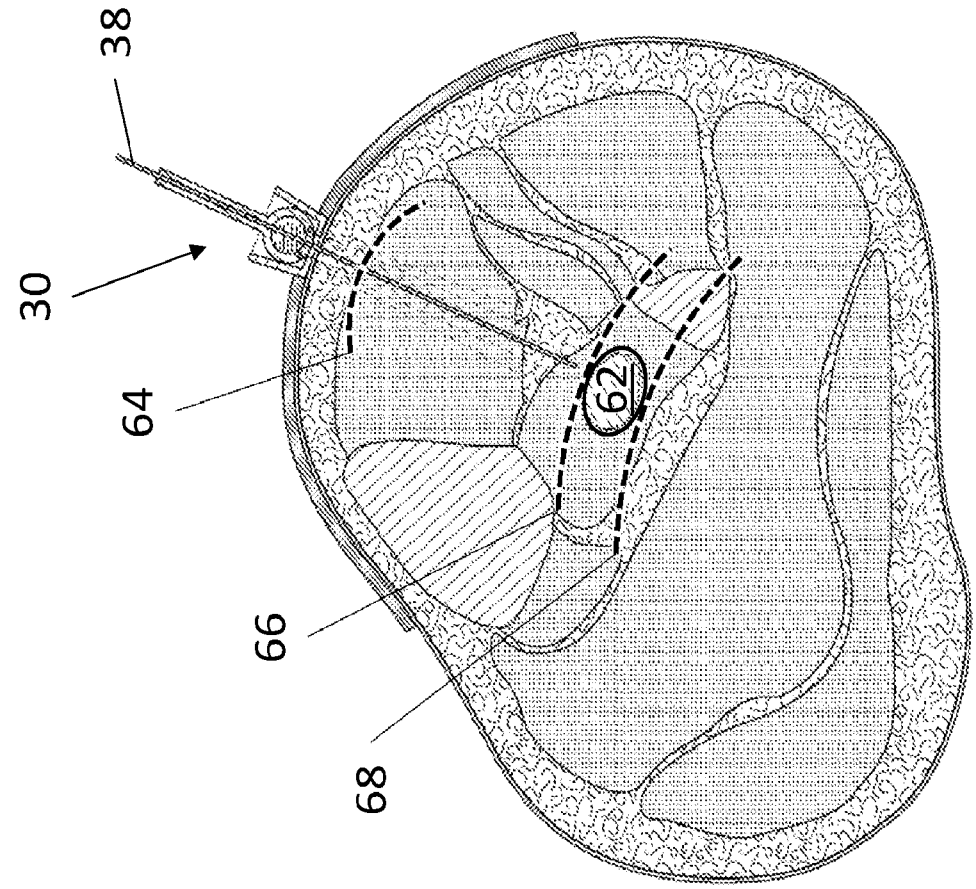

Figure 12B

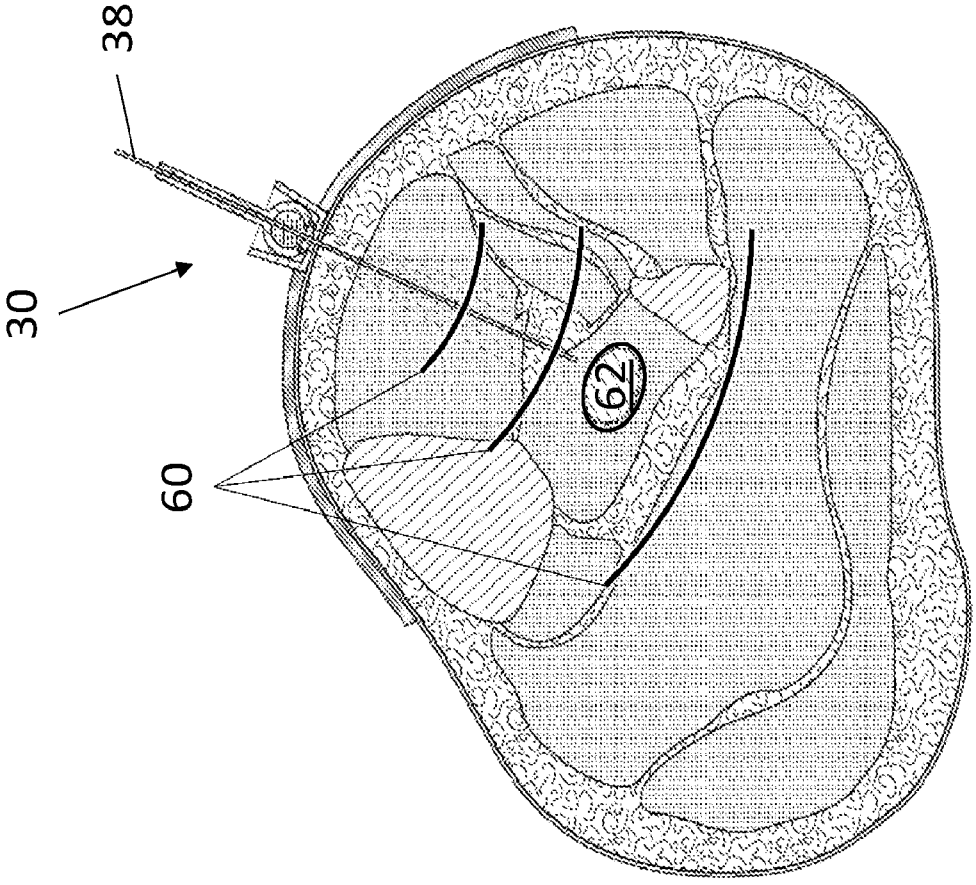

Figure 12A

Figure 12A – Figure 12B

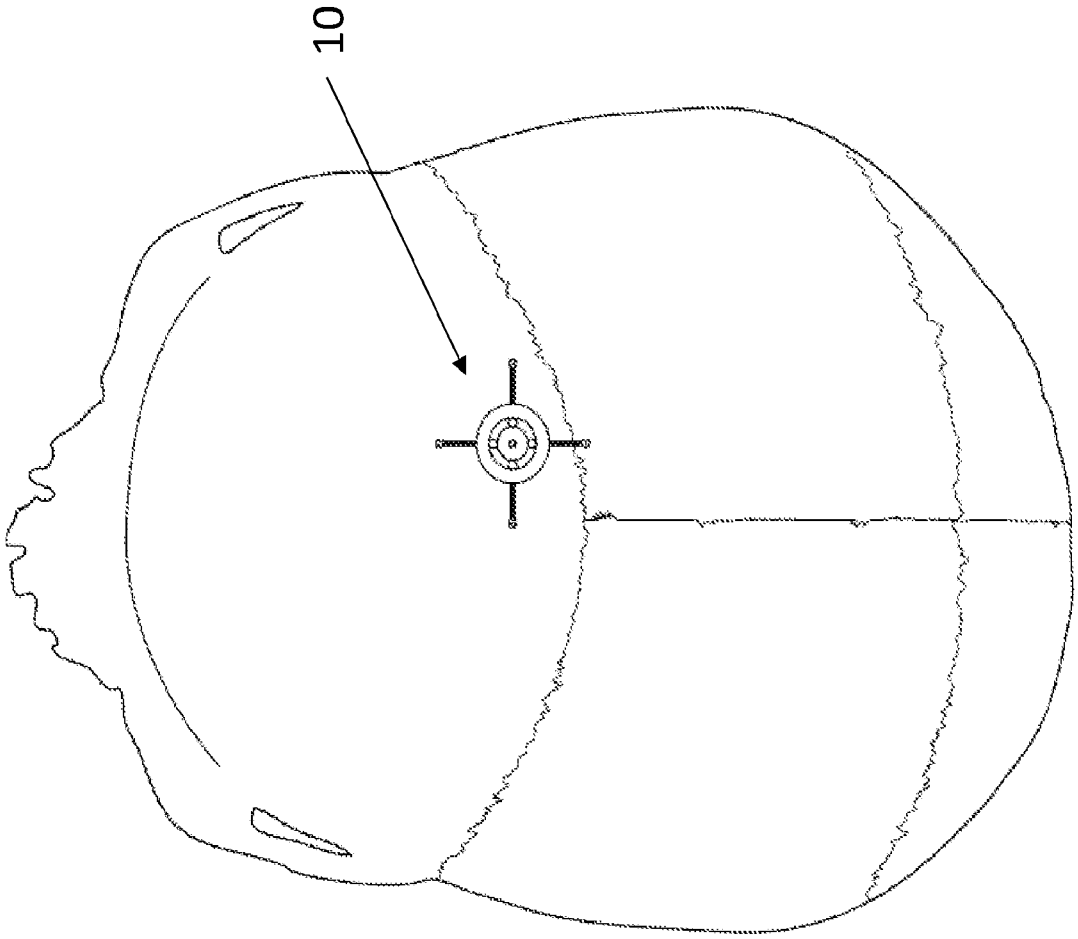

Figure 13

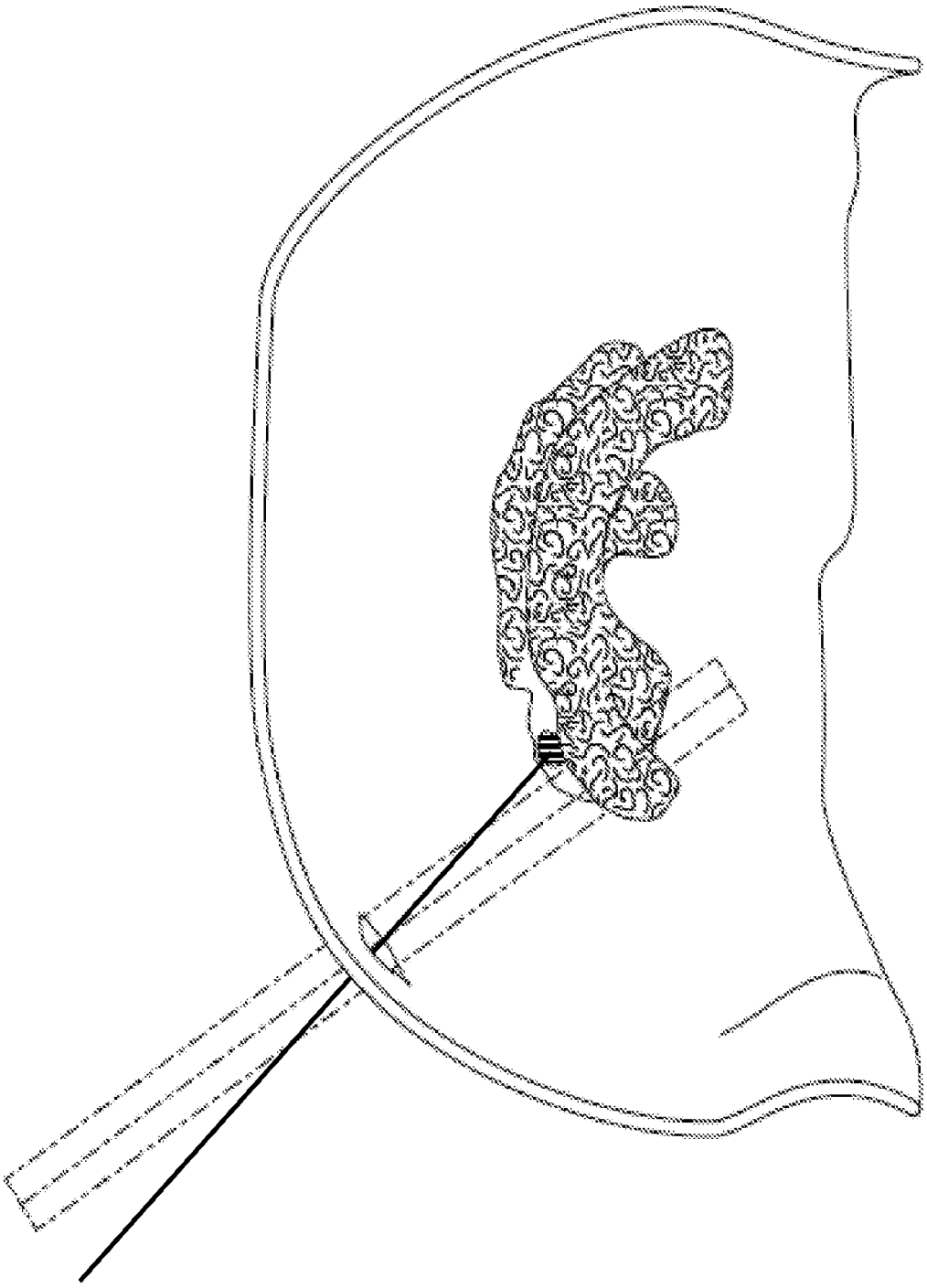

Figure 14A

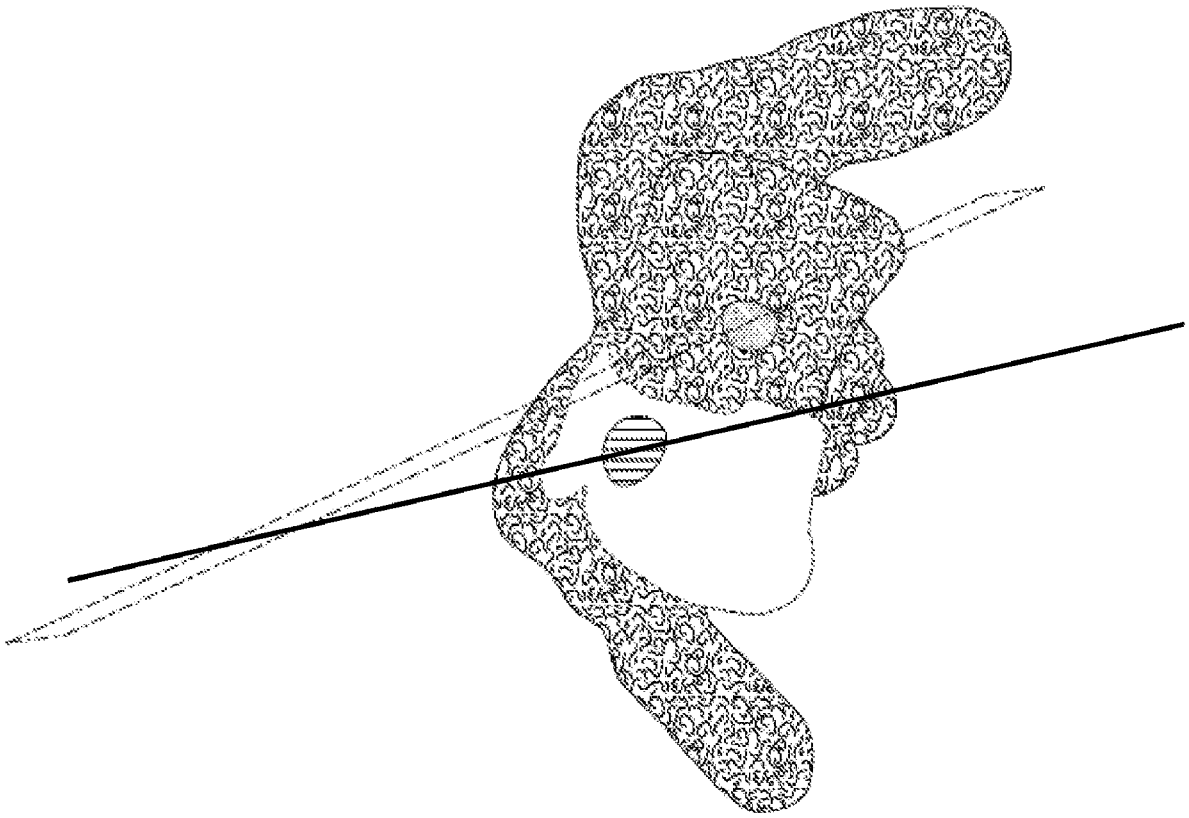

Figure 14B

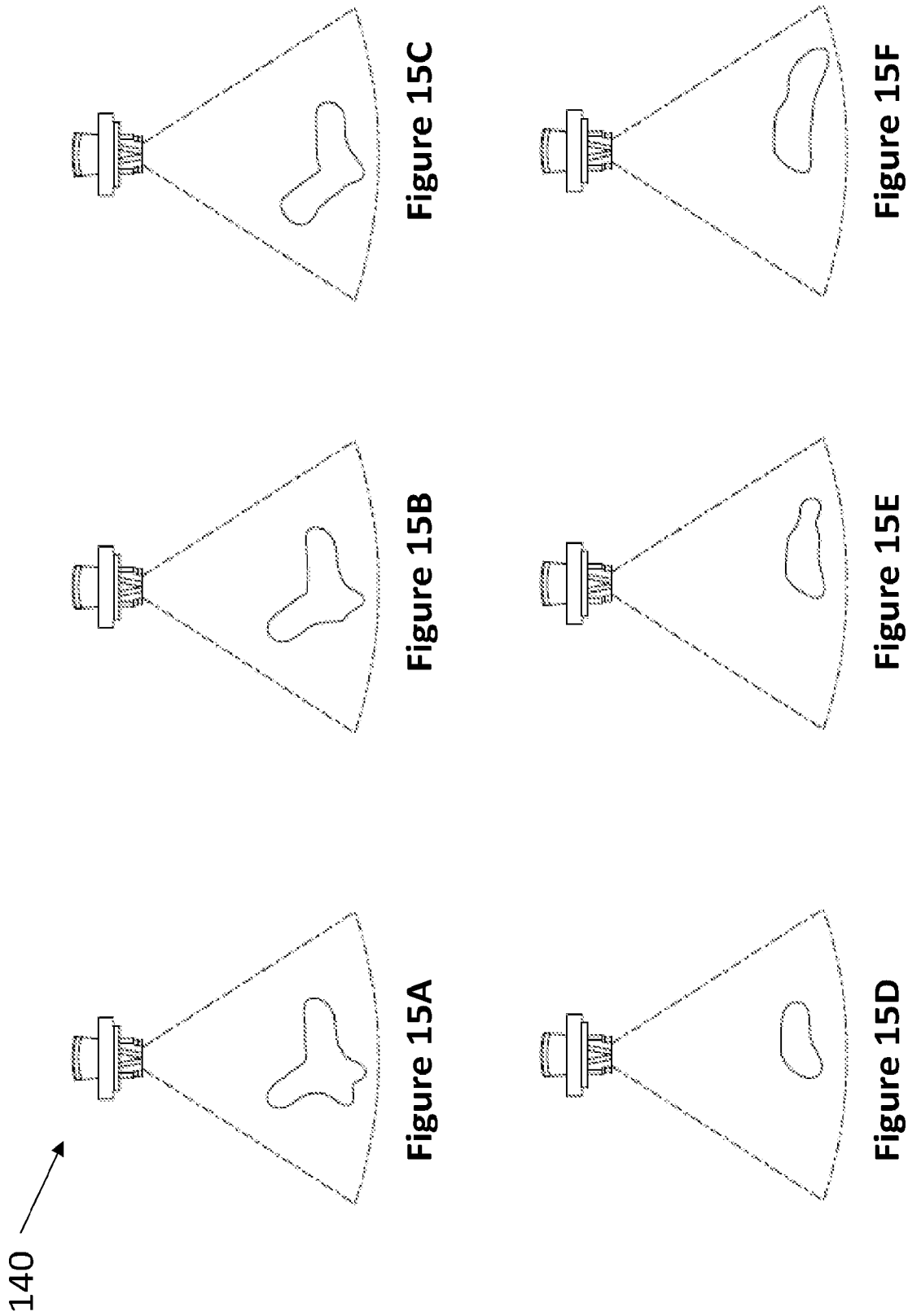

Figure 15A – Figure 15F

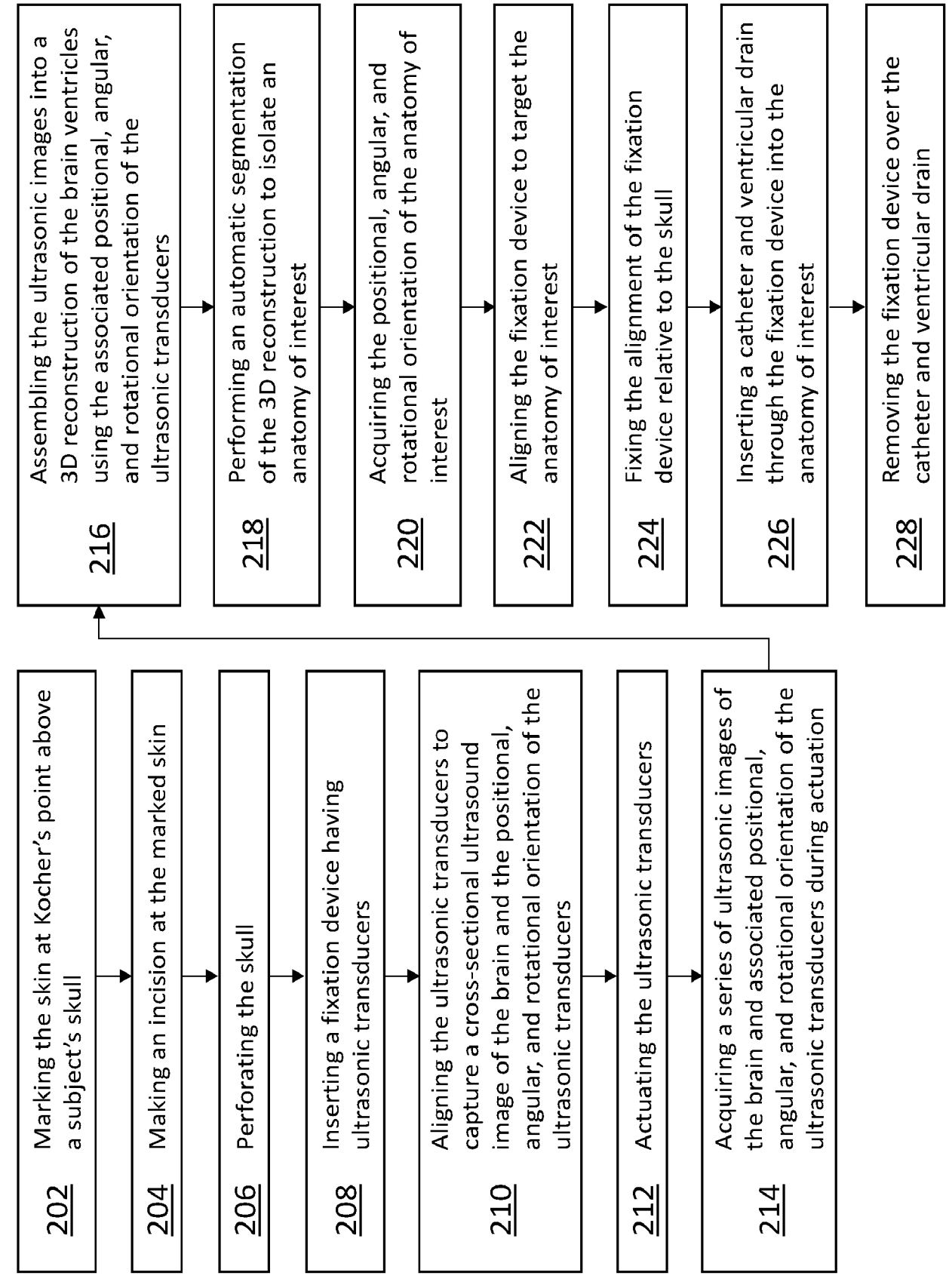
200
202 Marking the skin at Kocher's point above a subject's skull
204 Making an incision at the marked skin
206 Perforating the skull
208 Inserting a fixation device having ultrasonic transducers
210 Aligning the ultrasonic transducers to capture a cross-sectional ultrasound image of the brain and the positional, angular, and rotational orientation of the ultrasonic transducers
212 Actuating the ultrasonic transducers
214 Acquiring a series of ultrasonic images of the brain and associated positional, angular, and rotational orientation of the ultrasonic transducers during actuation
216 Assembling the ultrasonic images into a 3D reconstruction of the brain ventricles using the associated positional, angular, and rotational orientation of the ultrasonic transducers
218 Performing an automatic segmentation of the 3D reconstruction to isolate an anatomy of interest
220 Acquiring the positional, angular, and rotational orientation of the anatomy of interest
222 Aligning the fixation device to target the anatomy of interest
224 Fixing the alignment of the fixation device relative to the skull
226 Inserting a catheter and ventricular drain through the fixation device into the anatomy of interest
228 Removing the fixation device over the catheter and ventricular drain

Figure 16

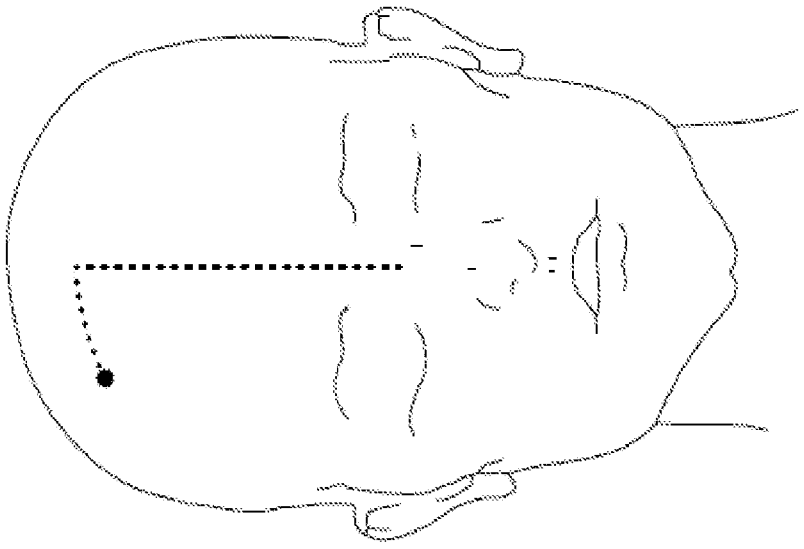

Figure 17

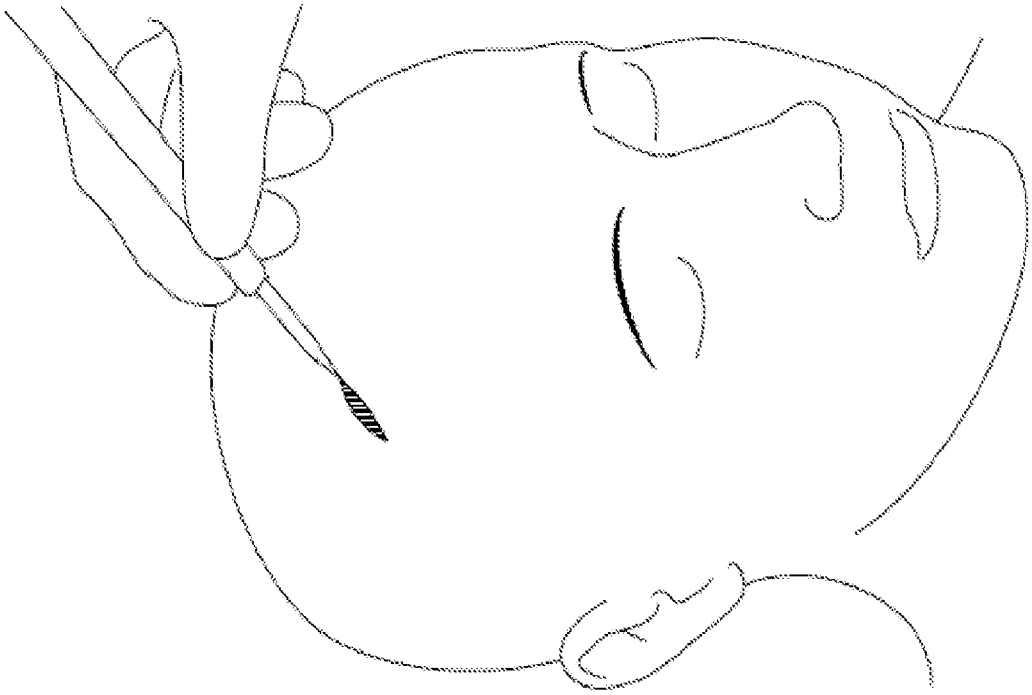

Figure 18

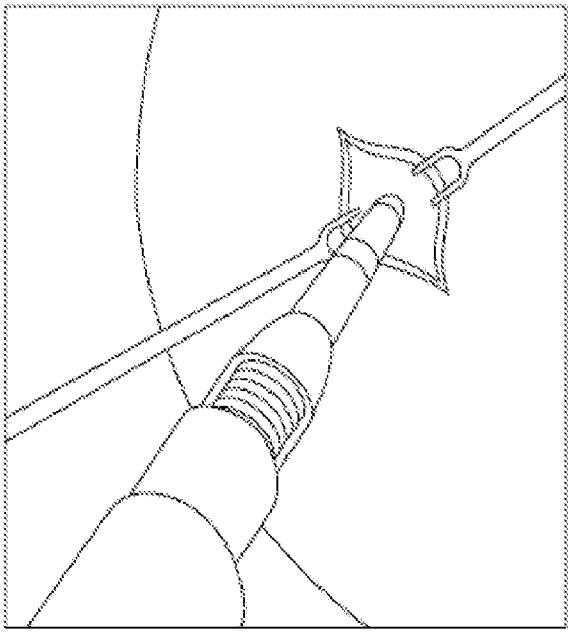

Figure 19

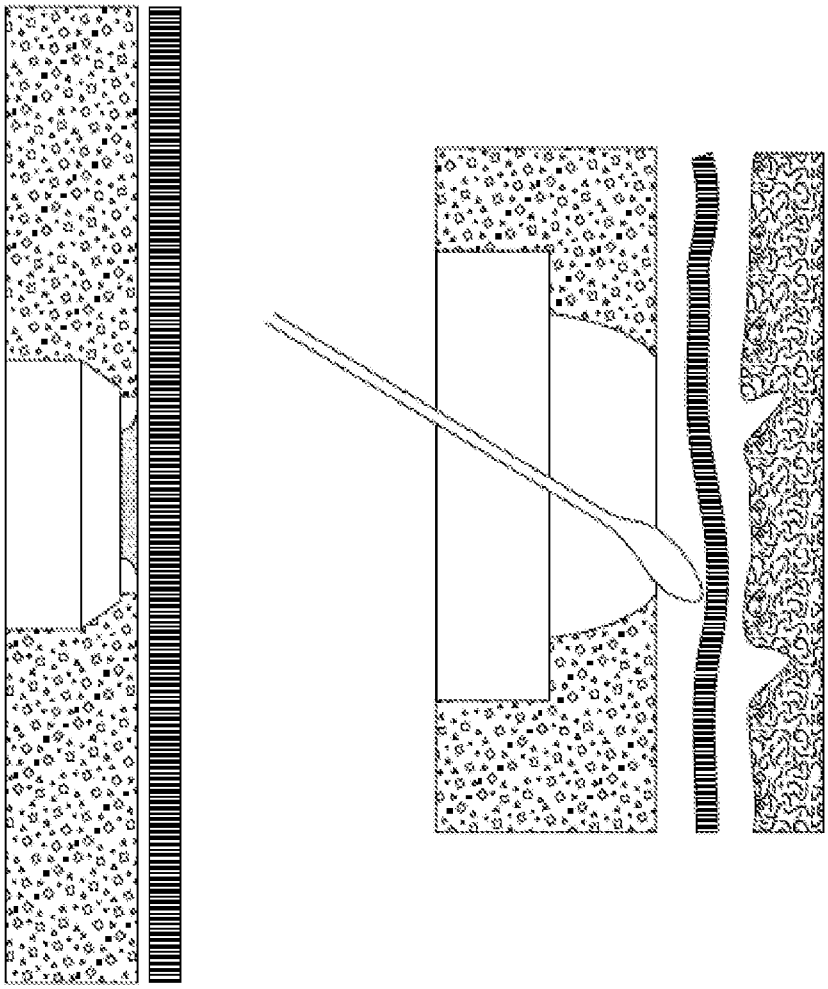

Figure 20

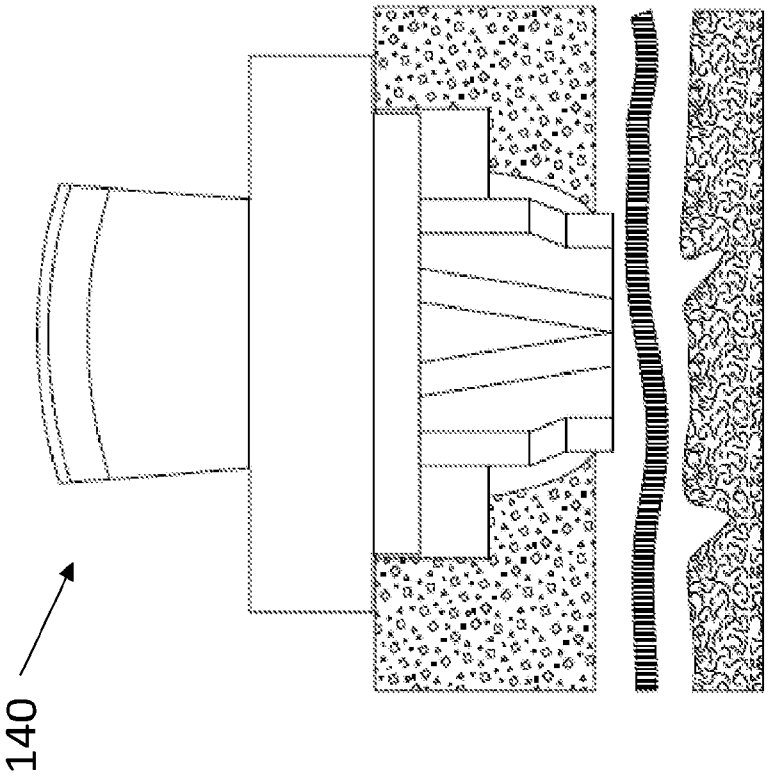

Figure 21

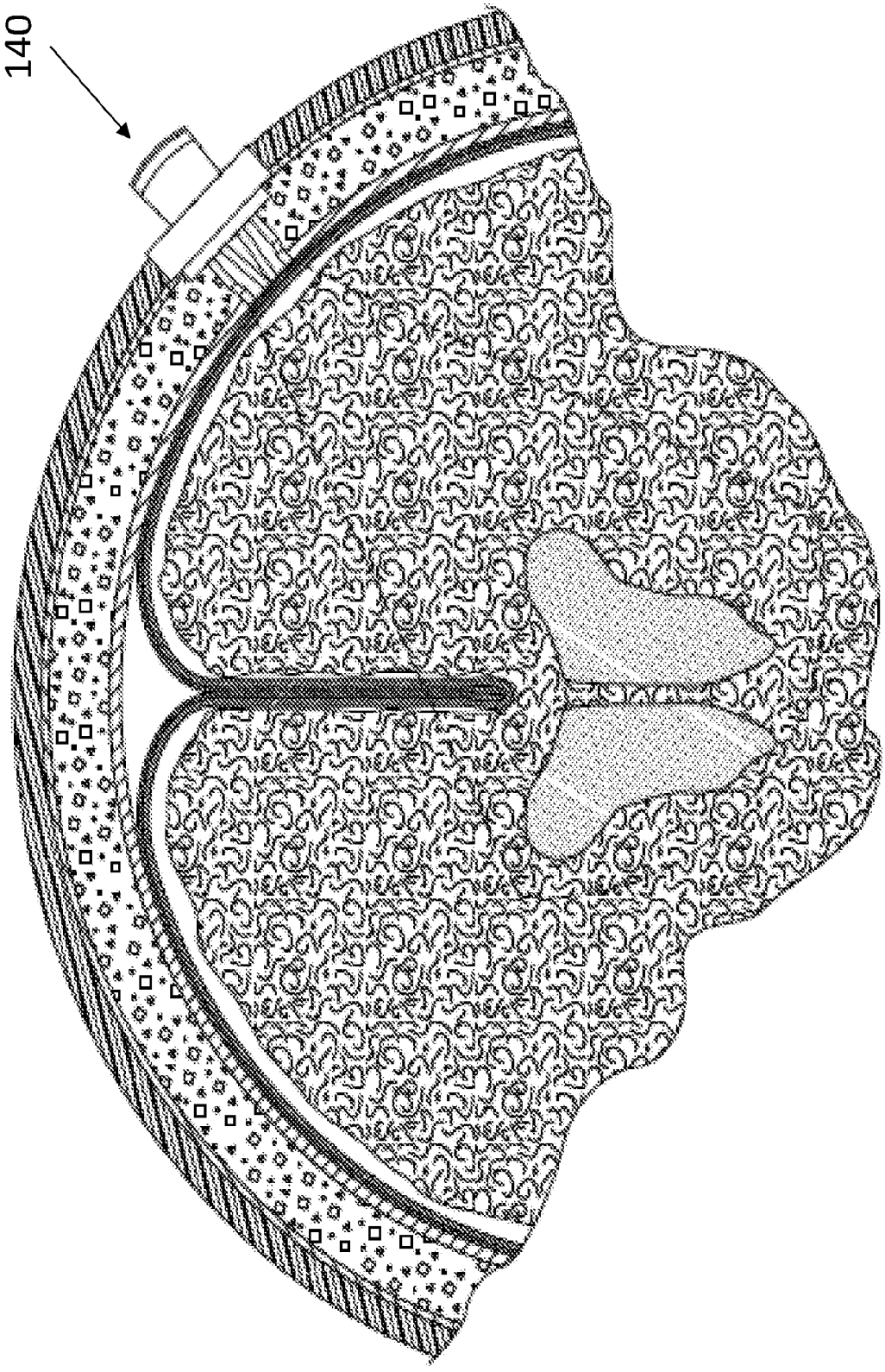

Figure 22

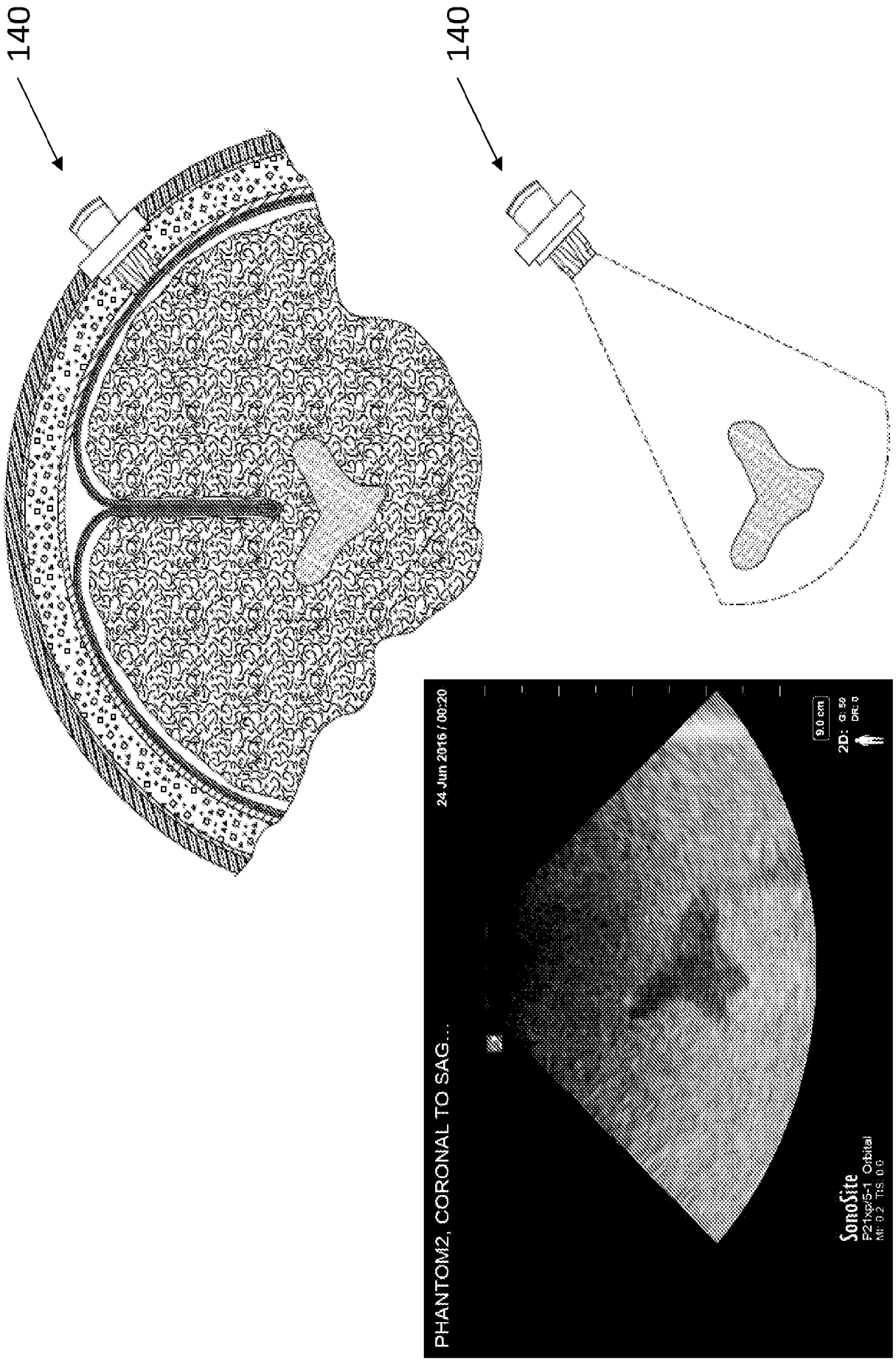
140
140
PHANTOM2, CORONAL TO SAG...
24 Jun 2016 / 00:20
9.0 cm
2D: G: 59
DR: 0
SonoSite
P21xp/5-1 Orbital
MI: 0.2 TIS: 0.0

Figure 23

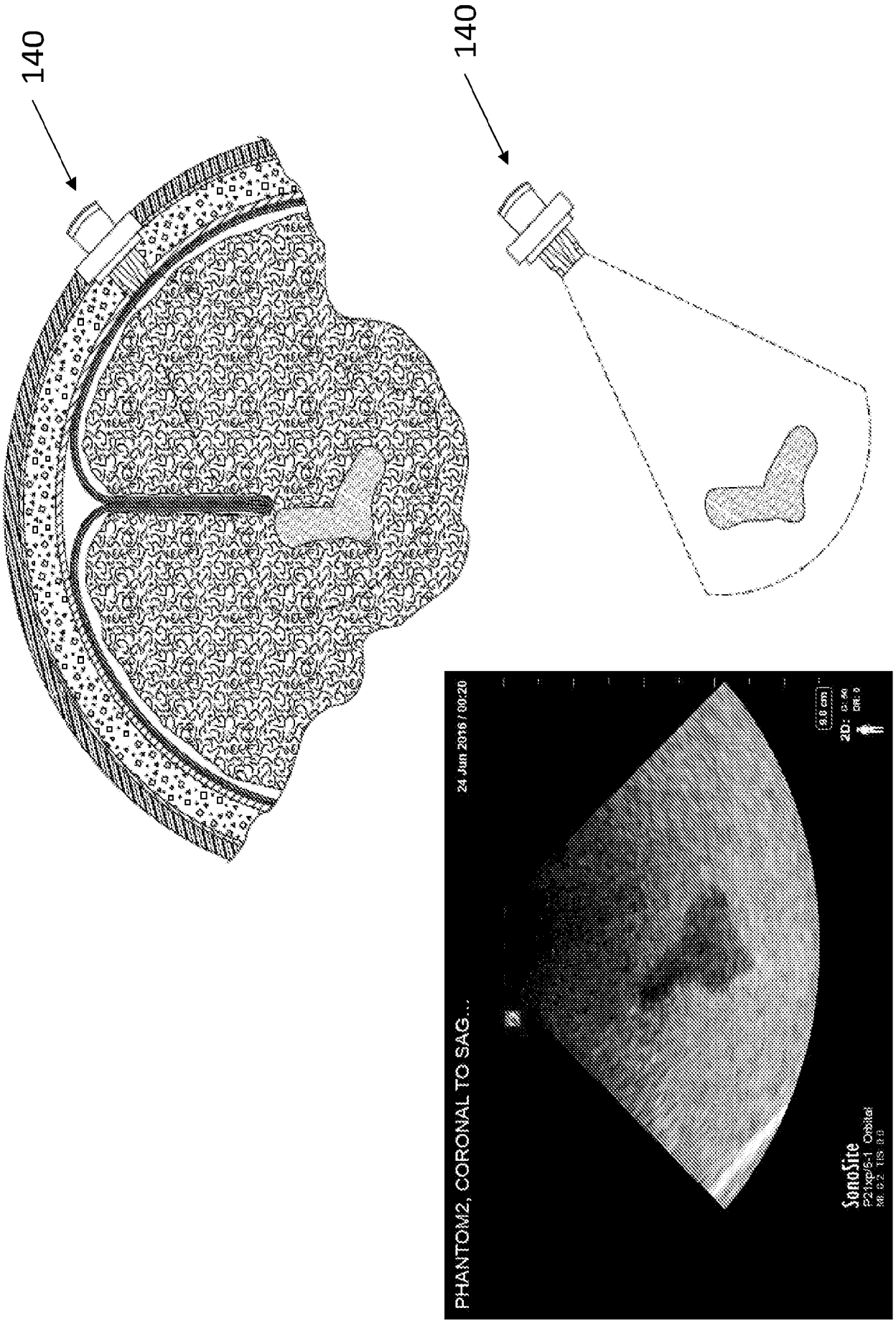
140
140
PHANTOM2, CORONAL TO SAG...
24 Jun 2016 / 09:20
9.0 cm
SonoSite
P21xp/6-1 Orbital

Figure 24

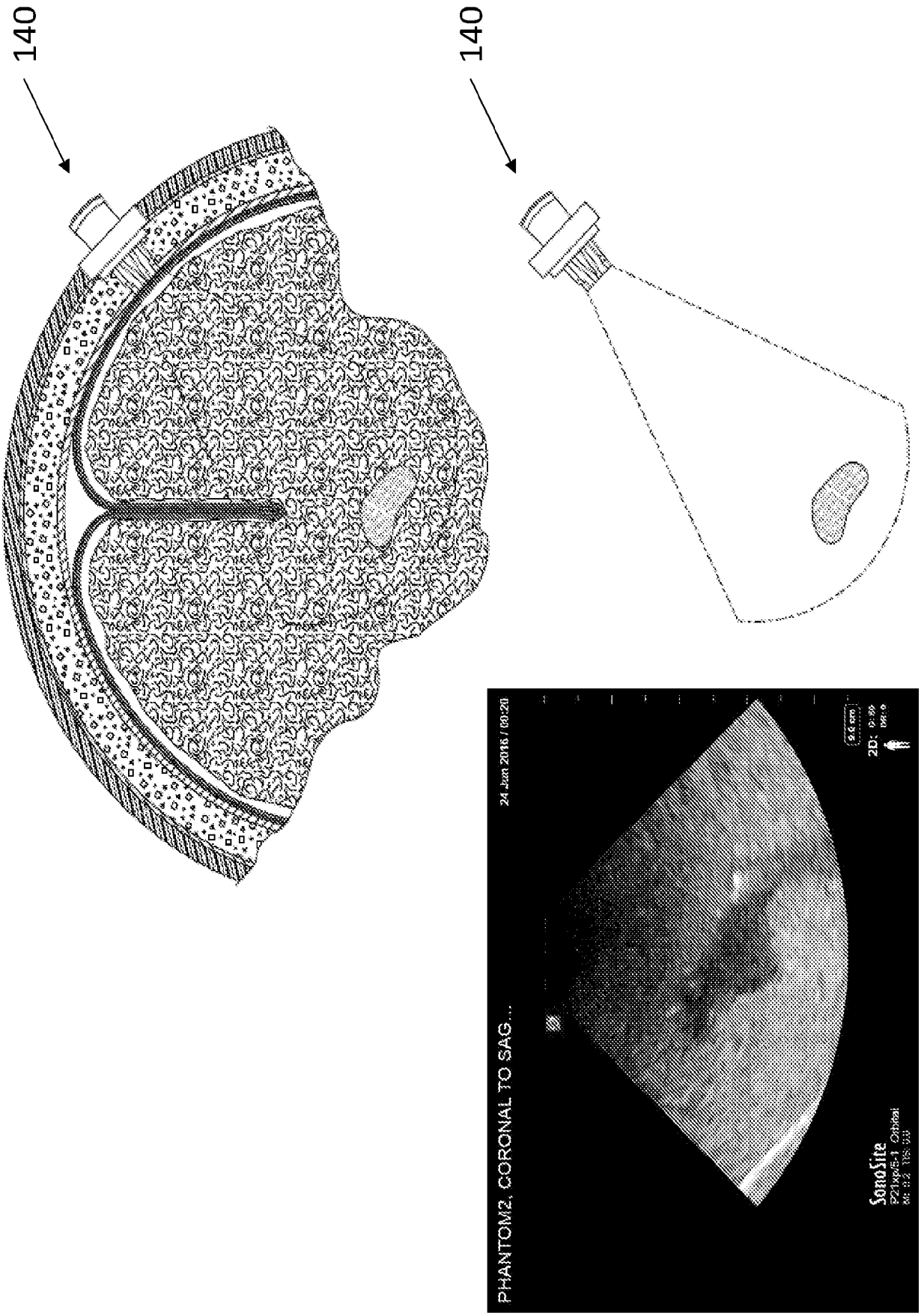

Figure 25

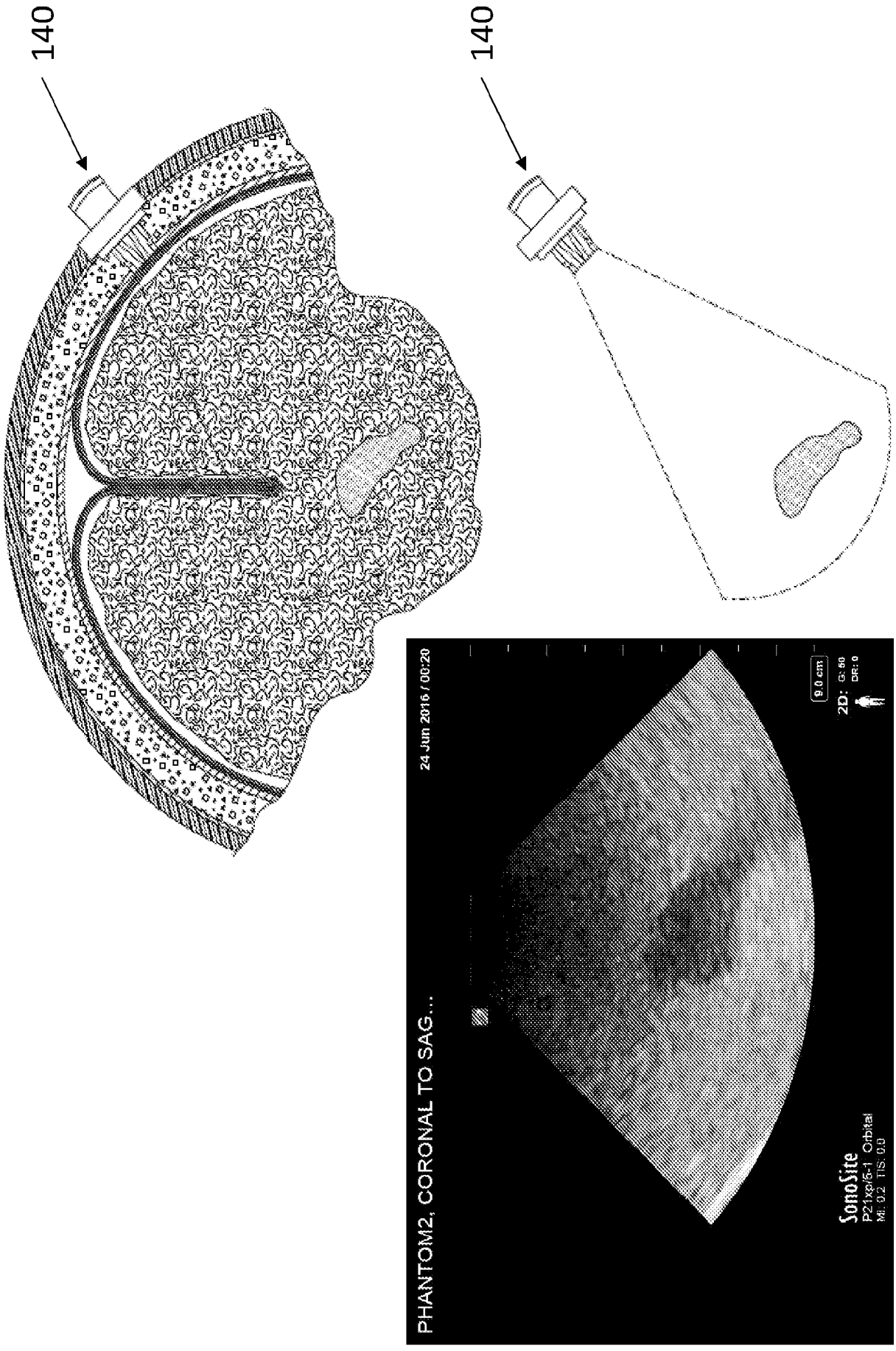
140
140
PHANTOM2, CORONAL TO SAG...
24 Jun 2016 / 00:20
9.0 cm
2D: G: 60
DR: 0
SonoSite
P21xp/5-1 Orbital
MI: 0.2 TIS: 0.0

Figure 26

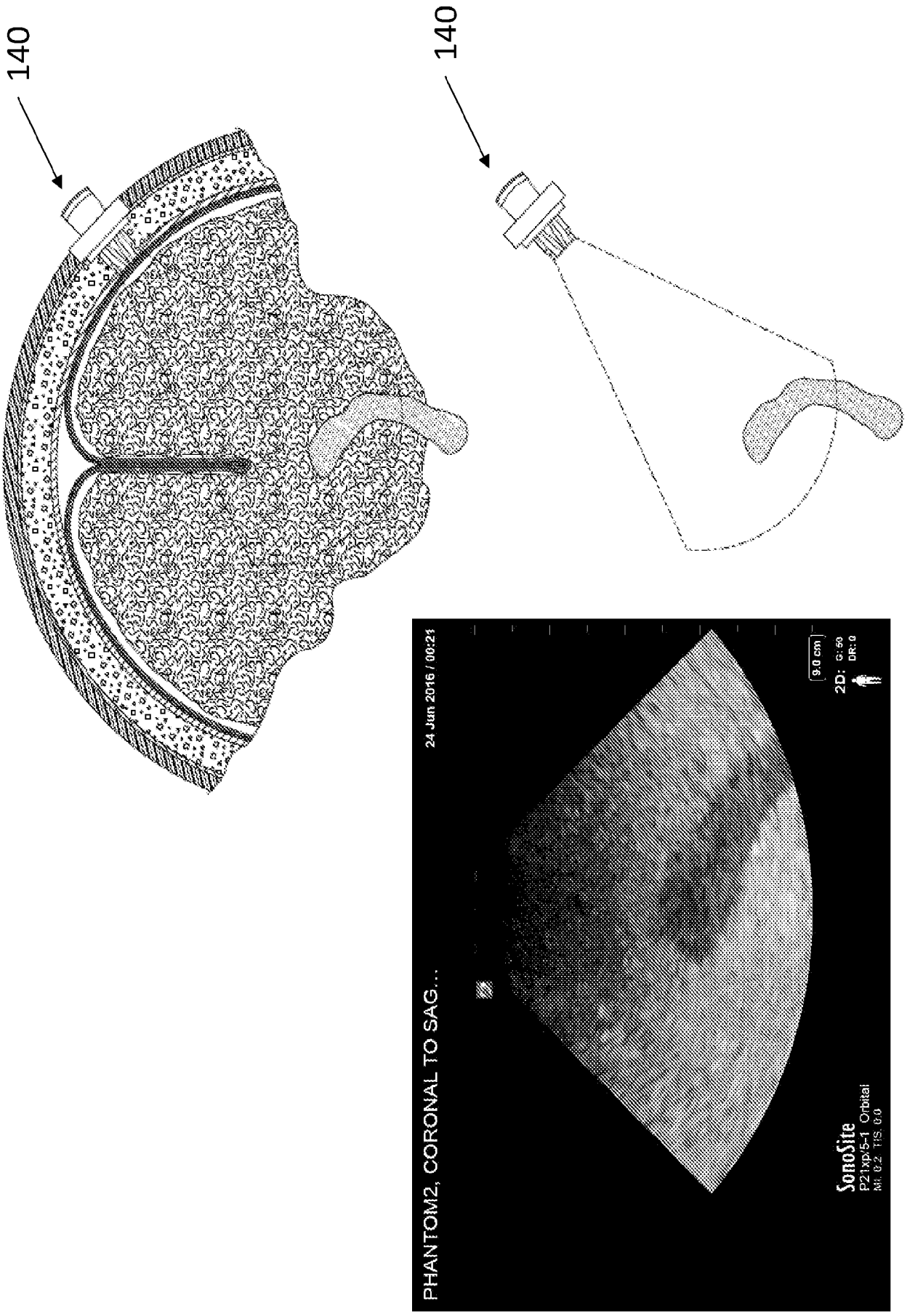
140
140
PHANTOM2, CORONAL TO SAG...
24 Jun 2016 / 09:21
9.0 cm
2D: G: 50
DR: 0
SonoSite
P21xp/5-1 Orbital
MI: 0.2 TIS: 0.0

Figure 27

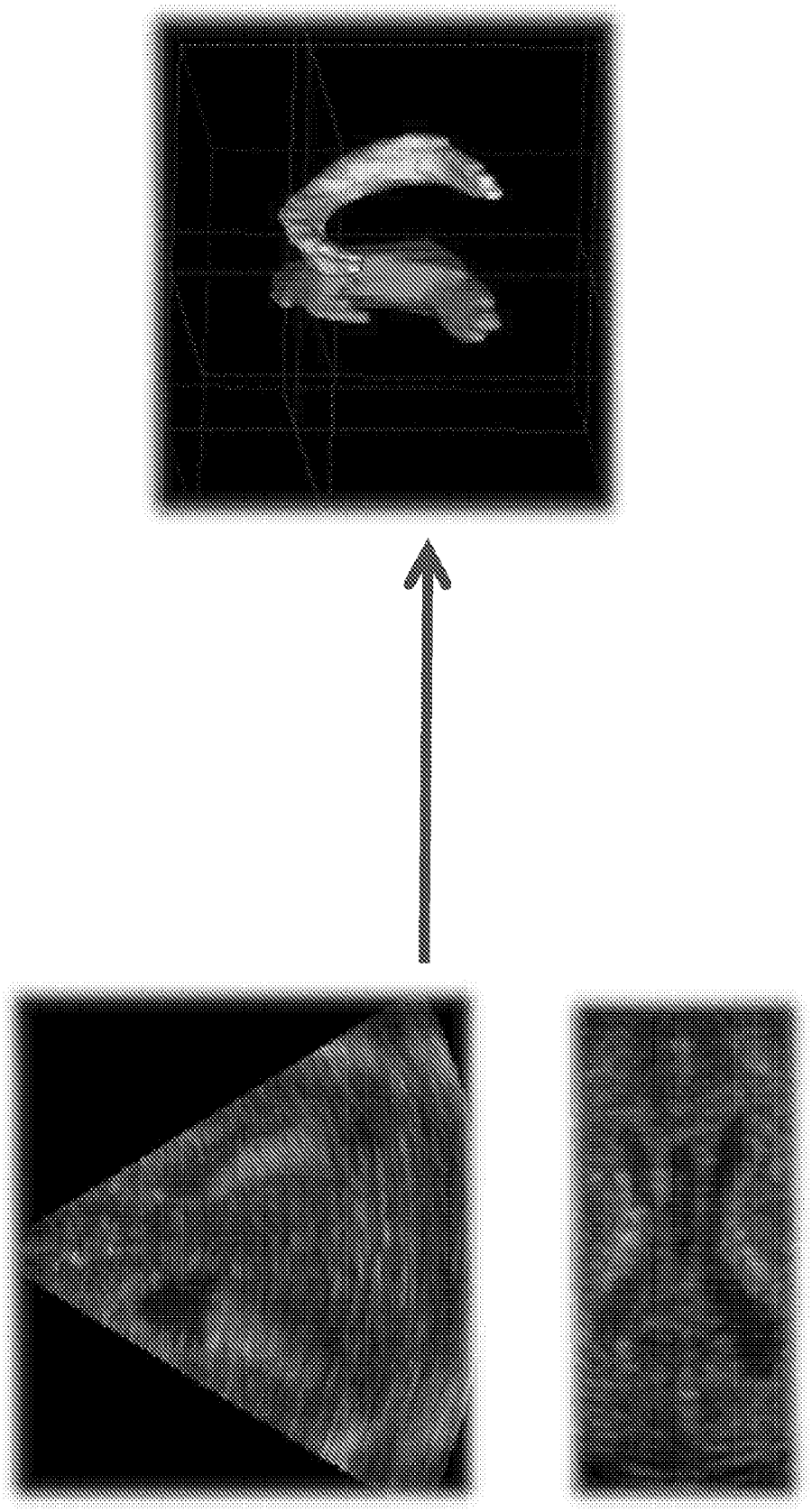

Figure 28

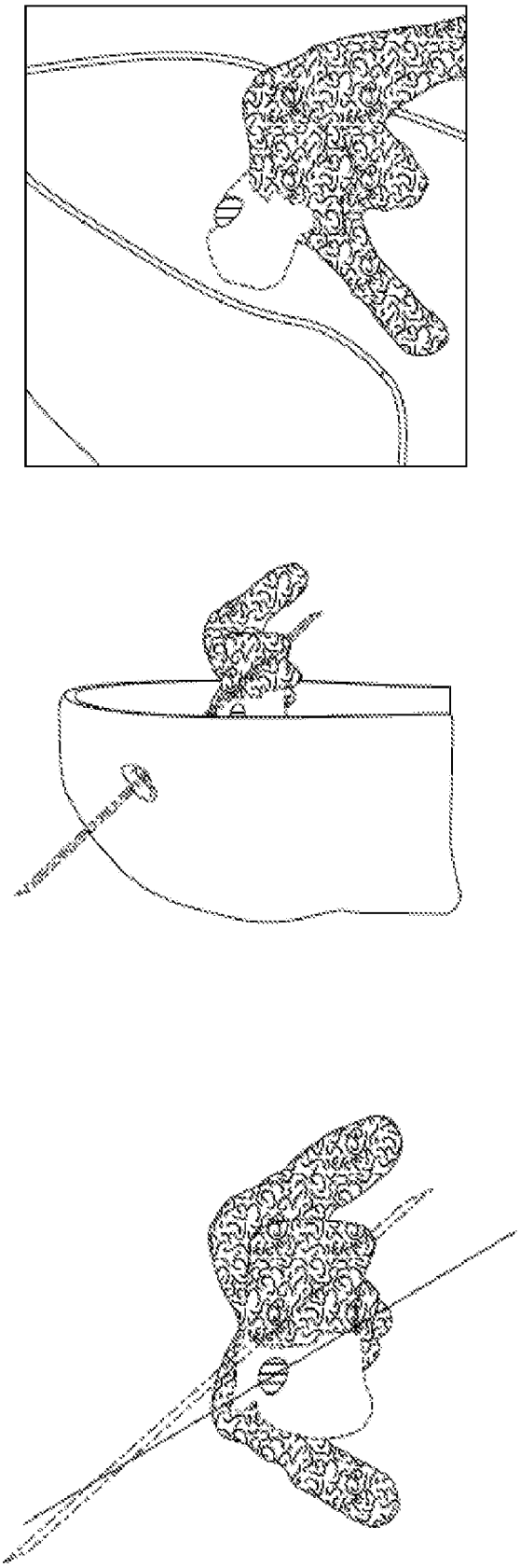

Figure 29

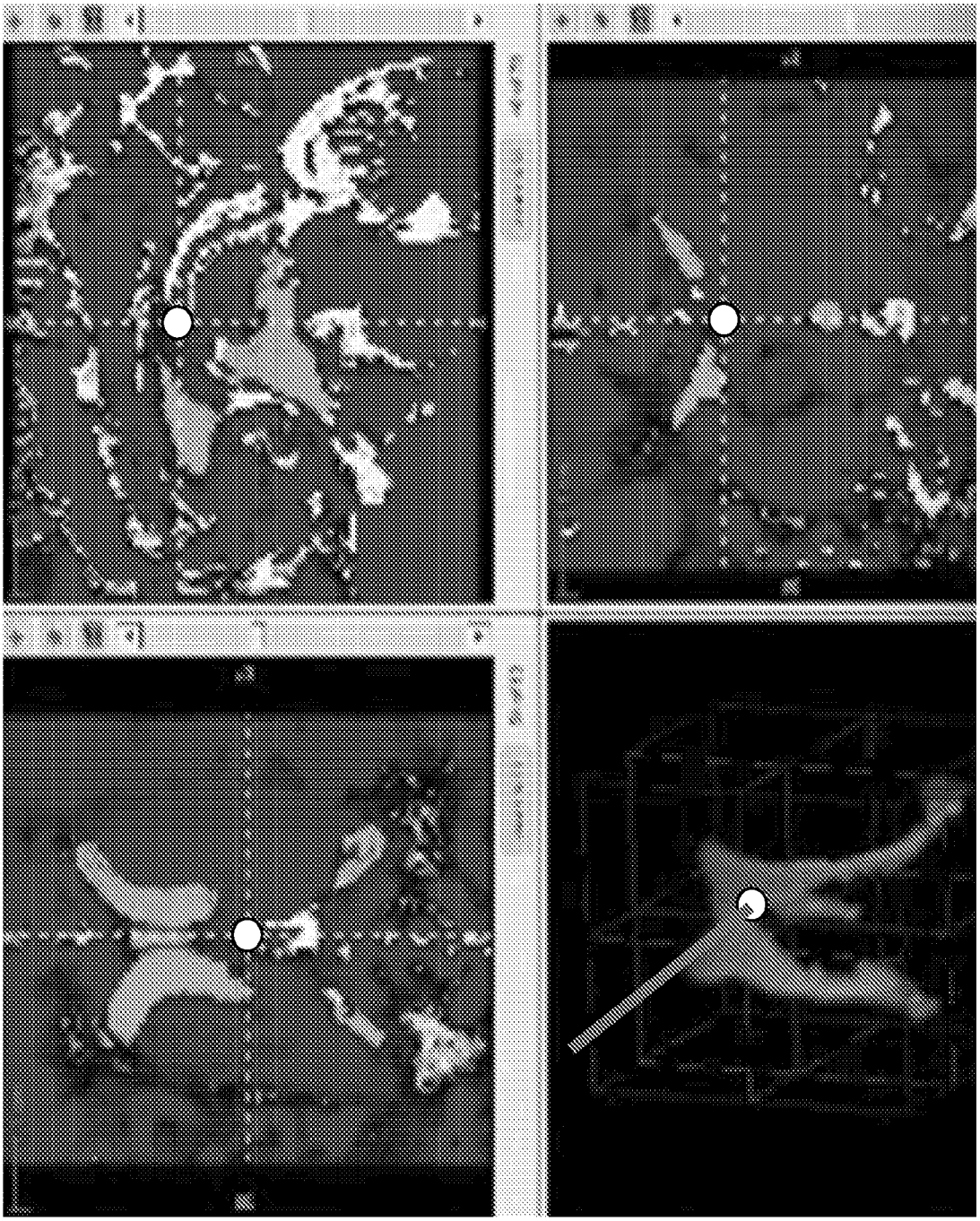

Figure 30

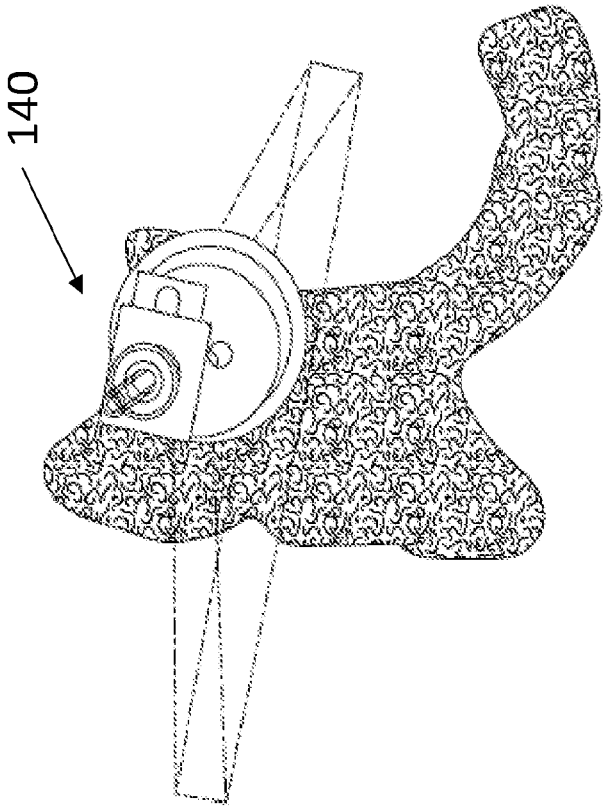

Figure 31

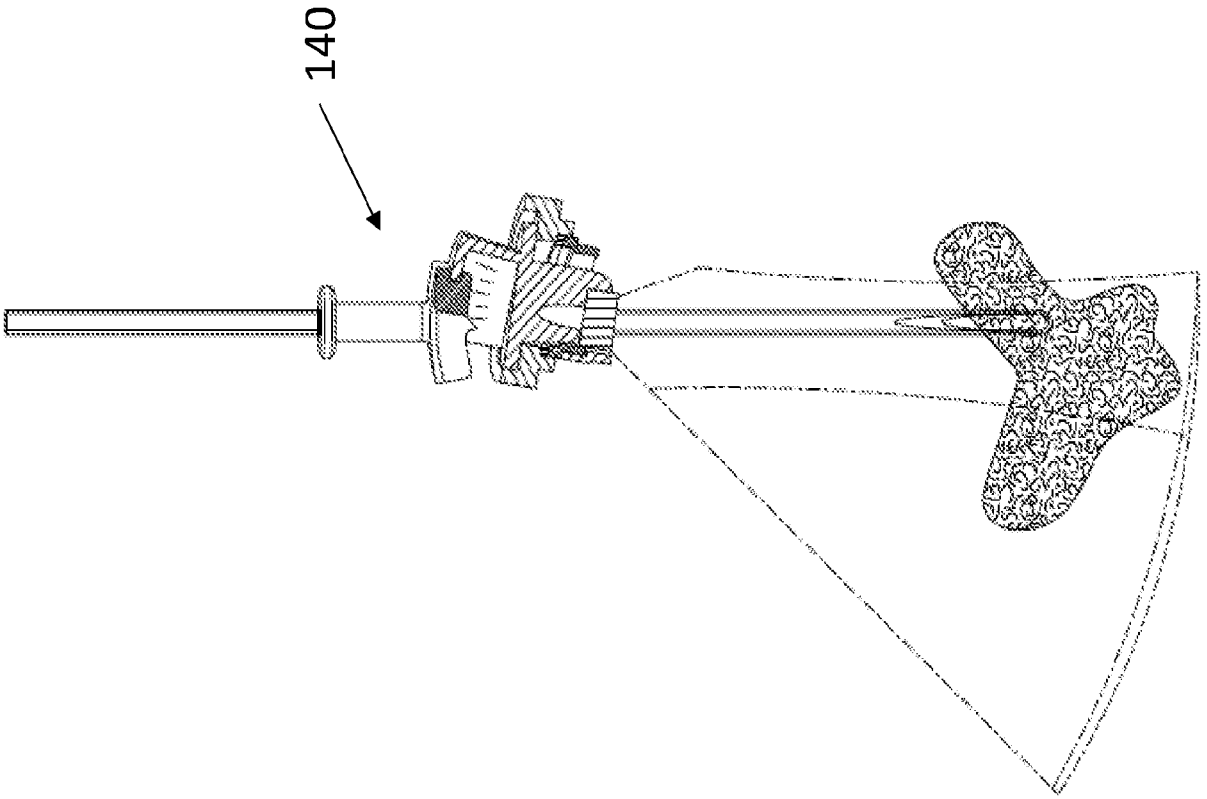

Figure 32

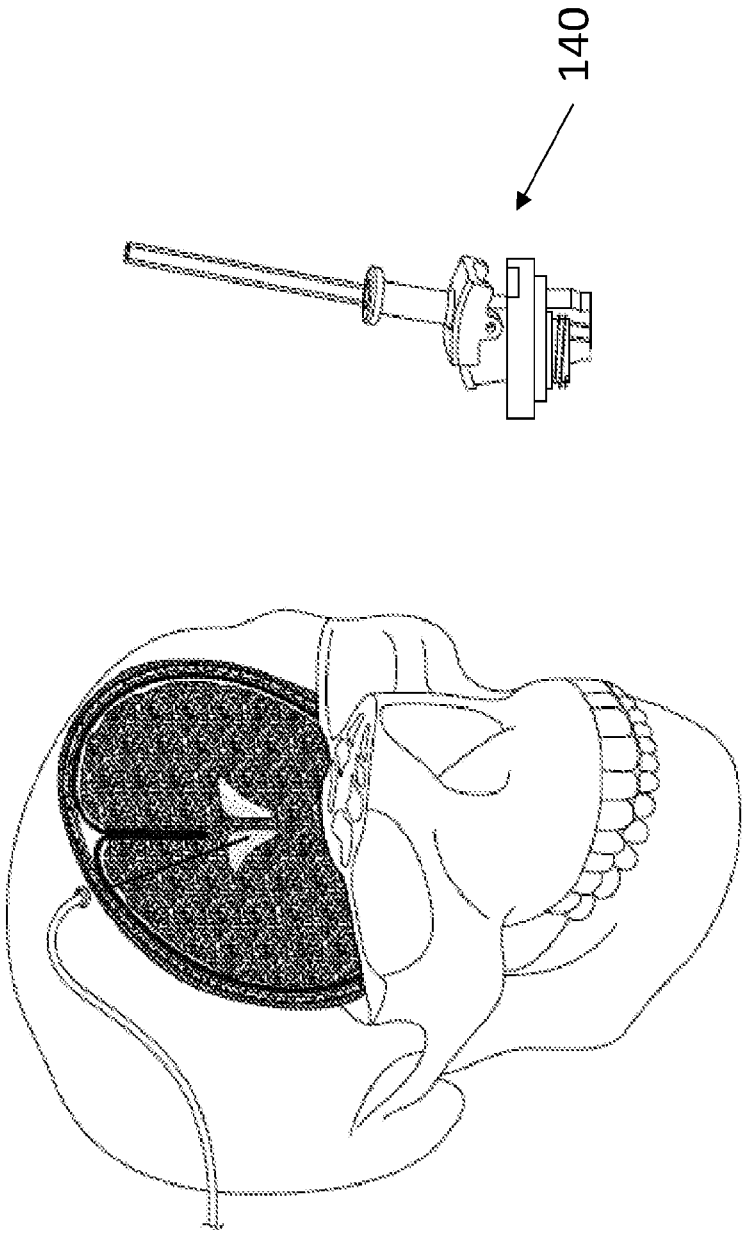

Figure 33

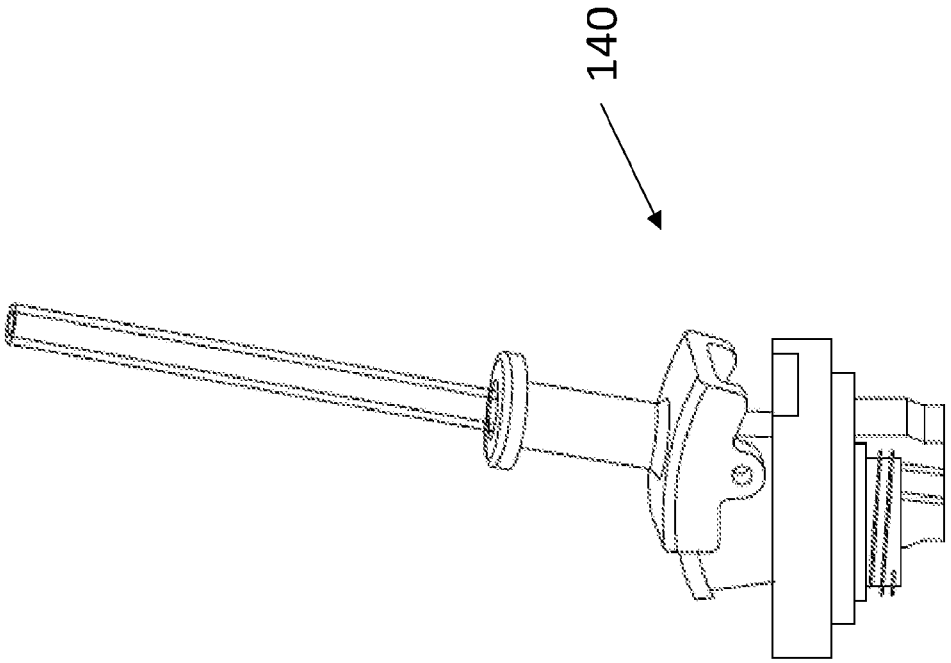

Figure 34

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/047593

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/00; A61B 5/03; A61B 17/00; A61B 17/34; A61B 19/00; A61N 1/05 (2016.01)

CPC - A61B 5/6864; A61B 5/6865; A61B 5/6868; A61B 8/0808; A61B 8/4209; A61B 17/3403 (2016.08)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC - A61B 5/00; A61B 5/03; A61B 17/00; A61B 17/34; A61B 19/00; A61N 1/05

CPC - A61B 5/6864; A61B 5/6865; A61B 5/6868; A61B 8/0808; A61B 8/4209; A61B 17/3403; A61B 17/3423; A61B 34/20 A61B 90/10; A61B 90/11; A61B 90/37; A61B 2090/103; A61M 27/006

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

USPC - 600/417; 600/424; 600/429; 604/175; 606/96; 606/129; 606/130 (keyword delimited)

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

PatBase, Google Patents, Google Scholar

Search terms used: cranial, burr hole, integrated, ultrasound, access port

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2015/0164548 A1 (MEDTRONIC NAVIGATION INC) 18 June 2015 (18.06.2015) entire document	1-6, 8 --- 7, 9-16, 20-27, 40
X --- Y	US 2015/0202011 A1 (MEDTRONIC NAVIGATION INC) 23 July 2015 (23.07.2015) entire document	34, 36, 37 --- 20-23
X --- Y	US 2003/0187351 A1 (FRANCK et al) 02 October 2003 (02.10.2003) entire document	38 --- 24
X --- Y	US 2009/0306501 A1 (FLINT) 10 December 2009 (10.12.2009) entire document	39 --- 12-14, 16, 25-27, 43-45
Y	US 2013/0204316 A1 (CARPENTIER et al) 08 August 2013 (08.08.2013) entire document	7
Y	US 2010/0268308 A1 (ROSSBY) 21 October 2010 (21.10.2010) entire document	9-11, 15
Y	US 7,694,821 B1 (ASFORA) 13 April 2010 (13.04.2010) entire document	40, 43-45
A	US 2014/0074202 A1 (BOSTON SCIENTIFIC NEUROMODULATION CORPORATION) 13 March 2014 (13.03.2014) entire document	1-16, 20-46
A	WO 2015/066280 A1 (BRIGHAM AND WOMENS HOSPITAL INC et al) 07 May 2015 (07.05.2015) entire document	1-16, 20-46

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

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 November 2016	20 DEC 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/047593

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/0019641 A1 (TRUWIT) 14 February 2002 (14.02.2002) entire document	1-16, 20-46

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/047593

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 17-19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/047593

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees need to be paid.

Group I, claims 1-33, 40-42 are drawn to a fixation device including emission and receiving means.
Group II, claims 34-39, 43-46 are drawn to a fixation device including a cranial fixation component.

The inventions listed in Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, at least one emission means at a distal end region of the elongate body; and at least one receiving means for receiving at least some emissions from said emission means, marking the skin at Kocher's point above a subject's skull; making an incision at the marked skin; perforating the skull; inserting a fixation device having ultrasonic transducers; aligning the ultrasonic transducers to capture a cross-sectional ultrasound image of the brain and the positional, angular, and rotational orientation of the ultrasonic transducers; actuating the ultrasonic transducers; acquiring a series of ultrasonic images of the brain and associated positional, angular, and rotational orientation of the ultrasonic transducers during actuation; assembling the ultrasonic images into a 3D reconstruction of the brain ventricles using the associated positional, angular, and rotational orientation of the ultrasonic transducers; performing an automatic segmentation of the 3D reconstruction to isolate an anatomy of interest; acquiring the positional, angular, and rotational orientation of the anatomy of interest; aligning the fixation device to target the anatomy of interest; fixing the alignment of the fixation device relative to the skull; inserting a catheter and ventricular drain through the fixation device into the anatomy of interest; and removing the fixation device over the catheter and ventricular drain, are not present in Groups I or III; and the special technical features of Group II, a first angled shim housing having a space at its center; and a cranial burr anchor; wherein the first angled shim housing is attached to the cranial burr anchor, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, and wherein the first angled shim housing is rotatable about the cranial burr anchor, a second angled shim housing, wherein the first angled shim housing is attached to the second angled shim housing, wherein the second angled shim housing is attached to the cranial burr anchor, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, wherein the first angled shim housing is rotatable about the second angled shim housing, and wherein the second angled shim housing is rotatable about the cranial burr anchor, a lever attachment having a lumen, wherein the lever attachment is attached to the first angled shim housing, wherein the first angled shim housing is attached to the cranial burr anchor, wherein the lumen of the elongate body is attached to and continuous with the lumen of the lever attachment, wherein the elongate body fits within and is rotatable within the space of the first angled shim housing, and wherein the first angled shim housing is rotatable about the cranial burr anchor, a cranial interface component having at least two angular rails; an anterior-posterior angle control component having at least two angular rails; a lateral angle control component having a space at its center; and a lever attachment having a lumen attached to and continuous with the lumen of the elongate body; wherein the anterior-posterior angle control component is movable along the at least two angular rails of the cranial interface component, wherein the lateral angle control component is movable along the at least two angular rails of the anteriorposterior angle control component, wherein the elongate body fits within and is rotatable within the space of the lateral angle control component, and wherein the lumen of the lever attachment is sized to accept a medical instrument, a hemispherical cap having a first track, are not present in Group I.

Groups I and II share the technical features of a fixation device comprising an elongate body having a proximal end opening, a distal end opening, and a lumen connecting the proximal and distal end openings. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 2009/0306501 A1 to Flint teaches of a fixation device (Fig. 7D, access port 40, para. [0058] & [0060]) comprising an elongate body having a proximal end opening (Fig. 7D-8B, access port 40 has a proximal opening to thereby allow an ultrasound probe 80, para. [0076]), a distal end opening (Fig. 7D-8B, wherein the access port 40 has a distal opening opposite the proximal opening, para. [0060]), and a lumen connecting the proximal and distal end openings (Fig. 7D-8B, the access port including a lumen 19 therethrough, para. [0067]).

Since none of the special technical features of the Group I and II inventions are found in more than one of the inventions, unity is lacking.

专利名称(译)	包括发射和恢复源的集成固定装置，其目的是相对于固定点进行目标定位和锁定，以便于干预所述目标		
公开(公告)号	EP3337389A4	公开(公告)日	2019-04-10
申请号	EP2016837852	申请日	2016-08-18
[标]申请(专利权)人(译)	宾州研究基金会		
申请(专利权)人(译)	宾州州立大学研究基金会		
当前申请(专利权)人(译)	宾州州立研究基金会		
[标]发明人	HAZARD SPRAGUE W III FELL BARRY HALUCK RANDY ROHATGI PRATIK DILLON PETER		
发明人	HAZARD, SPRAGUE, W., III. FELL, BARRY HALUCK, RANDY ROHATGI, PRATIK DILLON, PETER		
IPC分类号	A61B5/00 A61B5/03 A61B17/00 A61B17/34		
CPC分类号	A61B90/10 A61B5/065 A61B5/1076 A61B5/6852 A61B5/6865 A61B17/34 A61B34/20 A61B90/11 A61B2034/2063 A61B2090/103 A61B2505/05 A61N1/05		
代理机构(译)	LEONARD，THOMAS CHARLES		
优先权	62/266077 2015-12-11 US 62/206636 2015-08-18 US		
其他公开文献	EP3337389A1		
外部链接	Espacenet		

摘要(译)

本发明提供固定装置，锁定组件及其使用方法。本发明的固定装置能够通过提供患者内部解剖结构的检测装置并定位所需目标来精确插入医疗装置。这些设备能够锁定到位以保持准确性。