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- (54) **IMAGE-GUIDED THERAPY OF A TISSUE**
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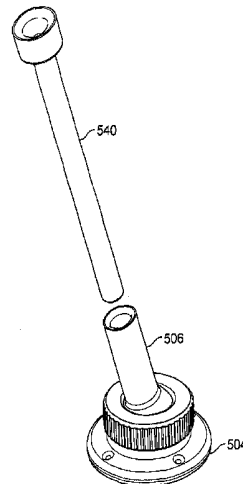
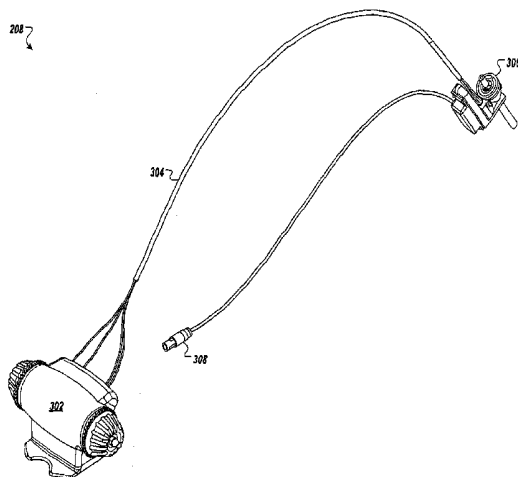
- (57) **ABSTRACT**  
Image-guided therapy of a tissue can utilize magnetic resonance imaging (MRI) or another medical imaging device to guide an instrument within the tissue. A workstation can actuate movement of the instrument, and can actuate energy emission and/or cooling of the instrument to effect treatment to the tissue. The workstation and/or an user of the workstation can be located outside a vicinity of an MRI device or other medical imaging device, and drive means for positioning the instrument can be located within the vicinity of the MRI device or the other medical imaging device. The instrument can be an MRI compatible laser or high-intensity focused ultrasound probe that provides thermal therapy to, e.g., a tissue in a brain of a patient.

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*A61B 2019/208*; *A61B 2019/461*; *A61B 2019/5265*; *A61B 2019/5236*; *A61B 5/702*; *A61B 5/4839*; *A61B 5/0555*; *A61B 5/055*; *A61B 5/01*; *A61B 5/0042*; *A61B 5/0035*; *A61B 5/015*; *A61B 5/748*; *A61B 5/742*; *A61B 2576/026*; *A61B 2017/00973*; *A61B 2562/0271*; *A61B 2562/226*; *A61B 90/11*; *A61B 90/13*; *A61B 90/14*; *A61B 90/36*; *A61B 90/361*; *A61B 90/37*; *A61B 2090/3612*; *A61B 2090/3614*; *A61B 2090/363*; *A61B 2090/364*; *A61B 2090/374*; *A61B 2090/103*; *A61B 18/04*; *A61B 18/1492*; *A61B 18/22*; *A61B 34/20*; *A61B 2018/00791*; *A61B 2018/00011*; *A61B 2018/00446*; *A61B 2018/0293*; *A61B 2018/1869*; *A61B 2034/2065*; *A61N 7/022*; *A61N 2007/003*; *A61N 5/062*; *A61F 7/12*; *A61F 2007/0095*; *A61F 2007/0002*

See application file for complete search history.

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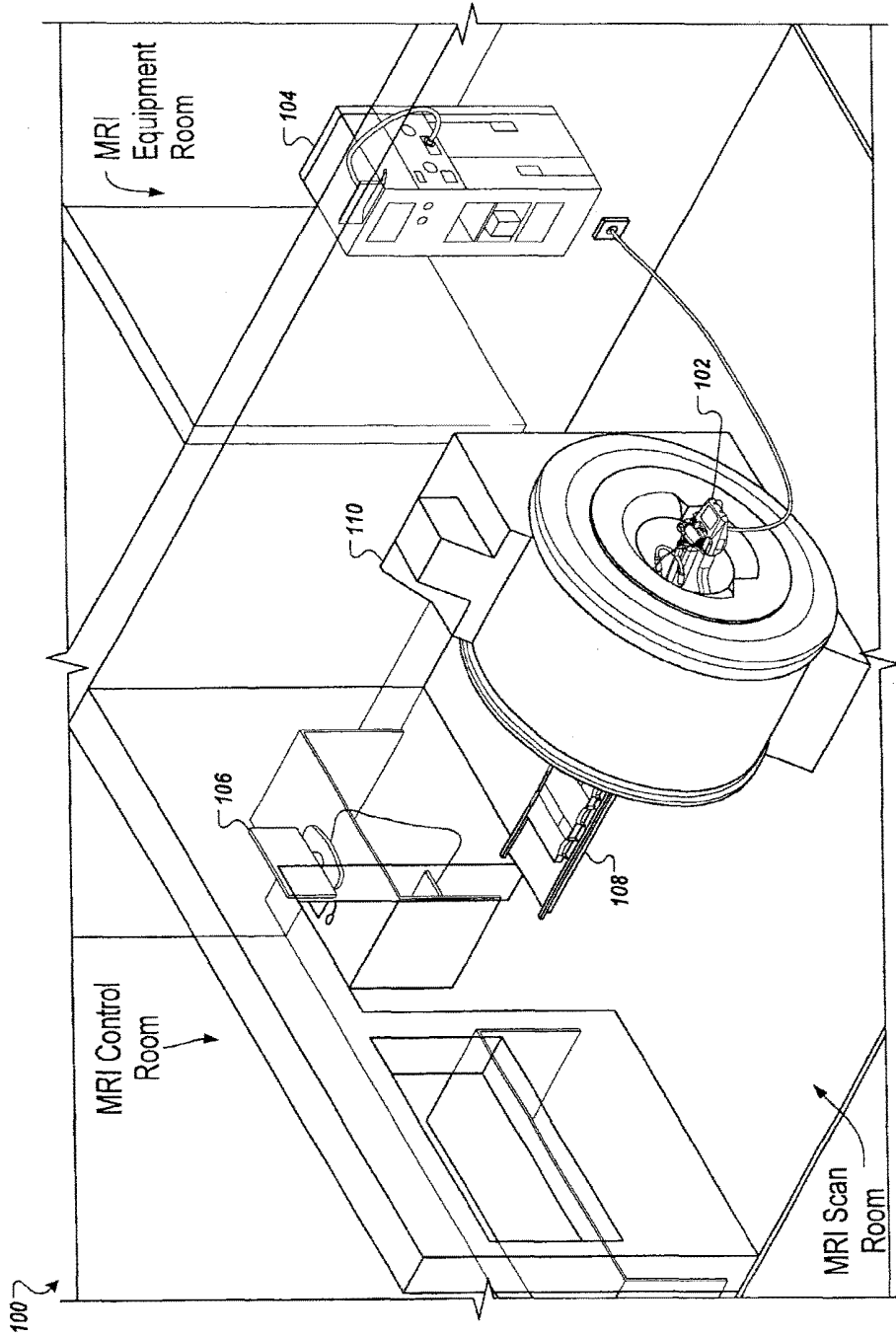


FIG. 1

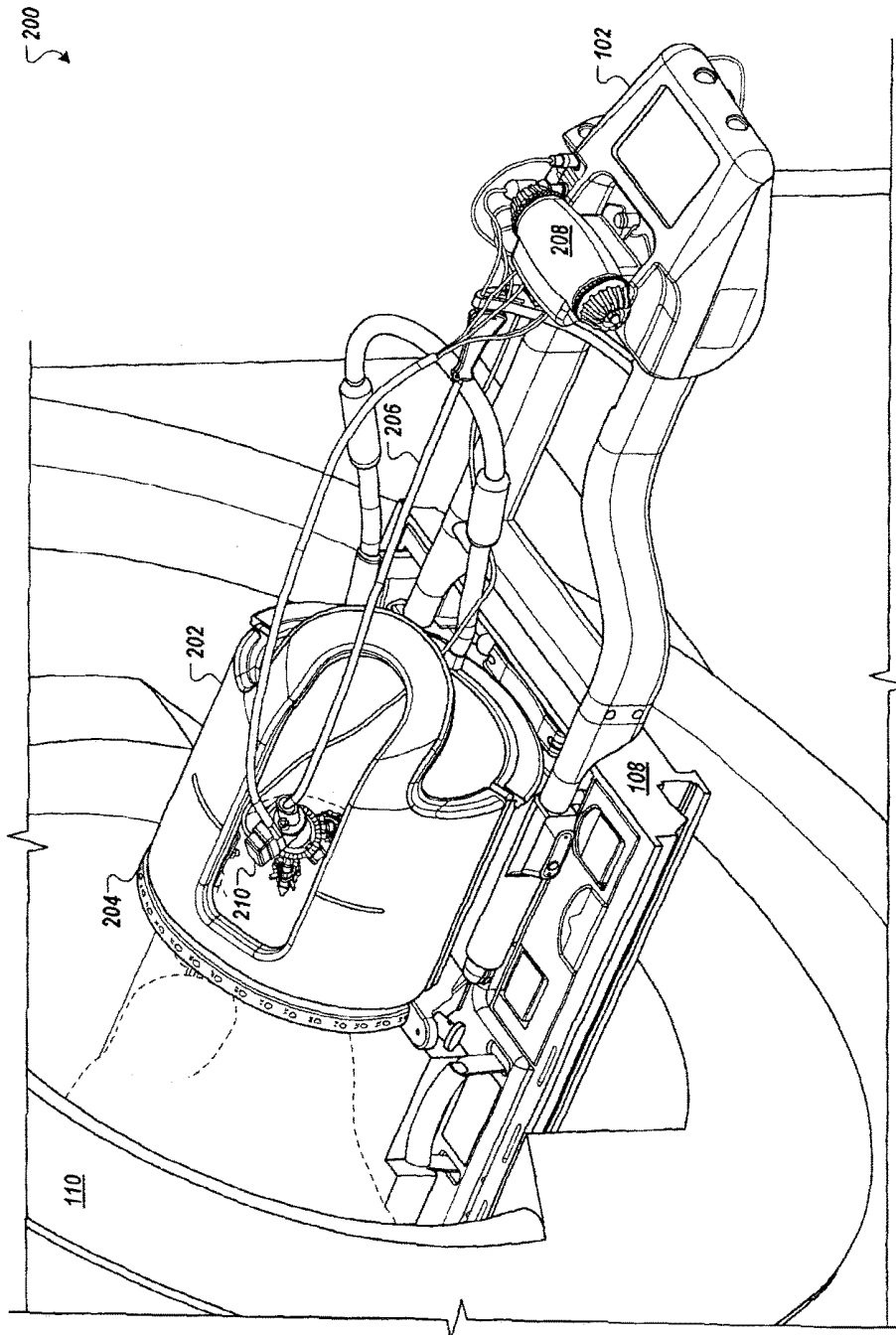


FIG. 2

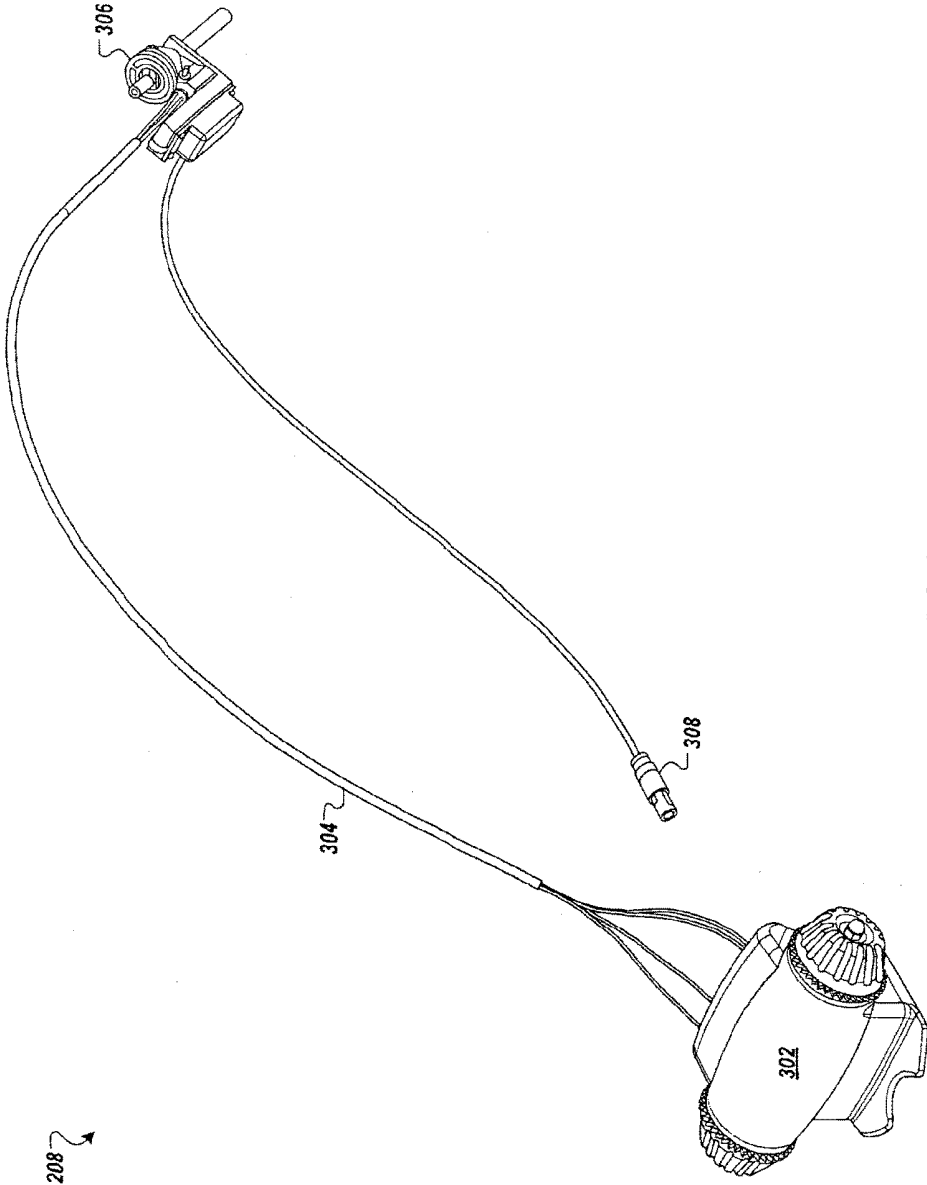


FIG. 3

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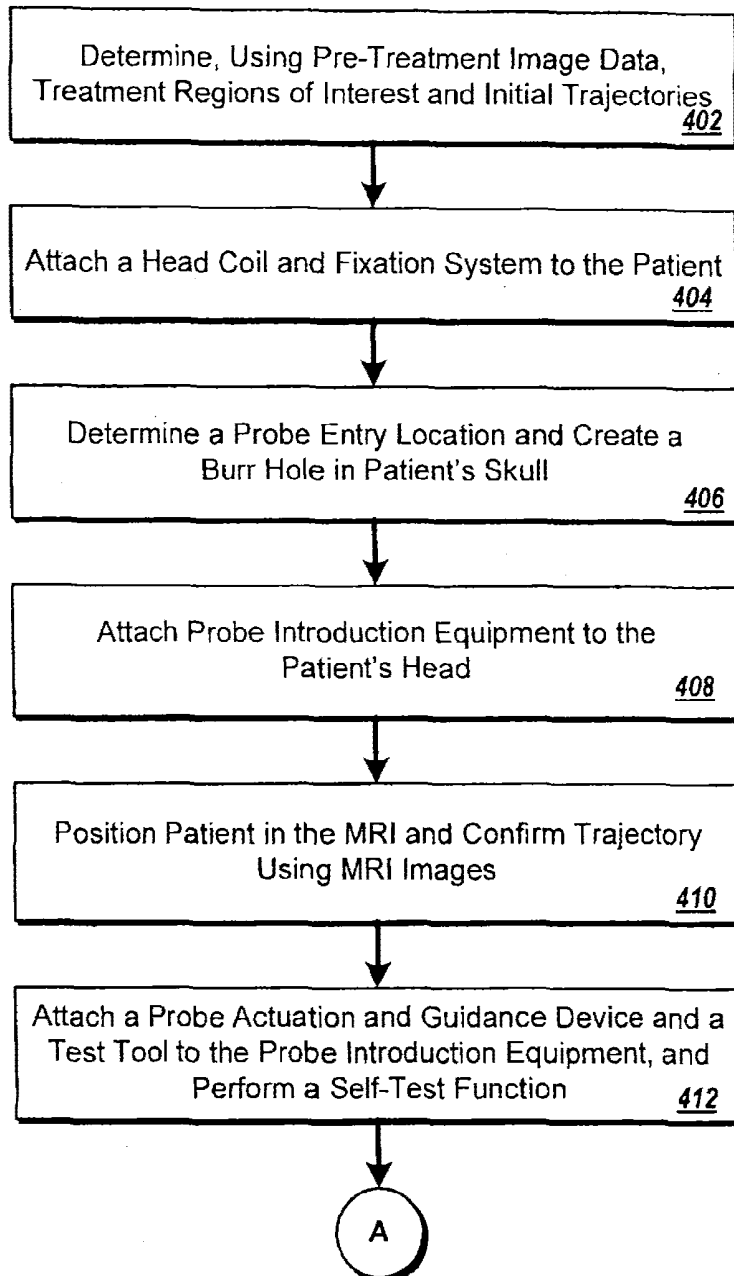


FIG. 4A

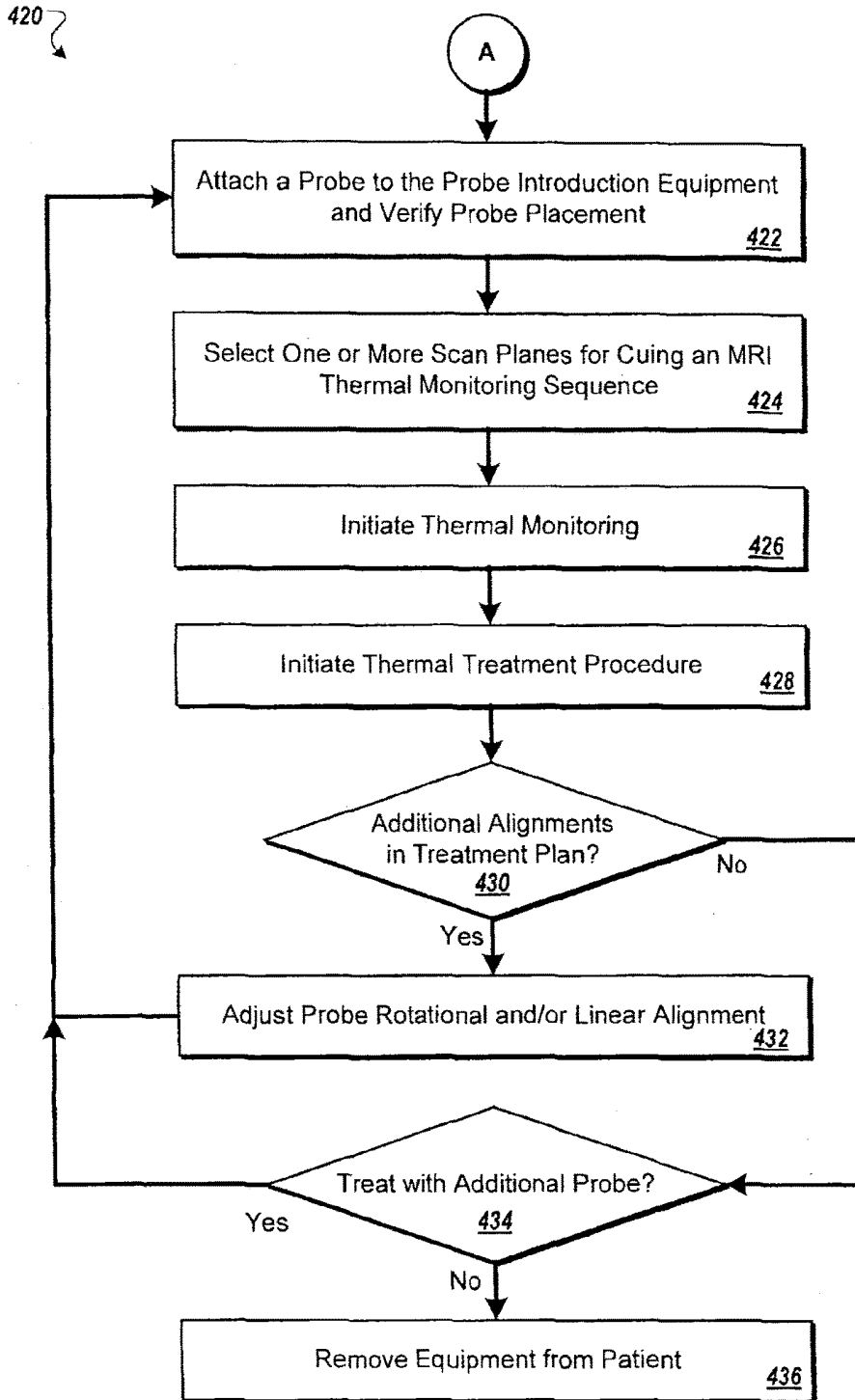
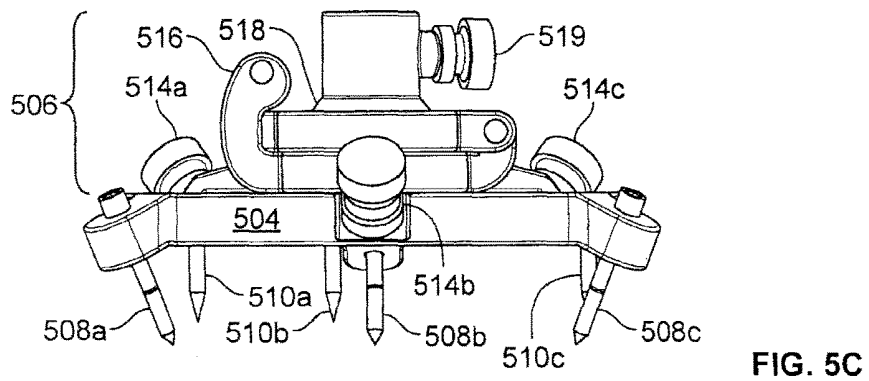
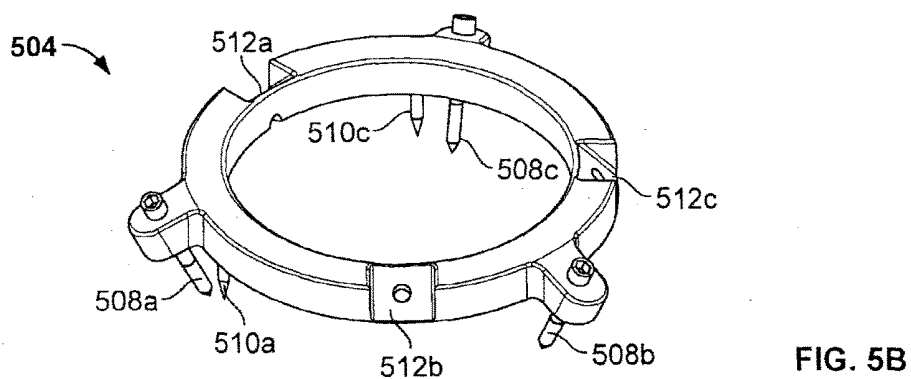
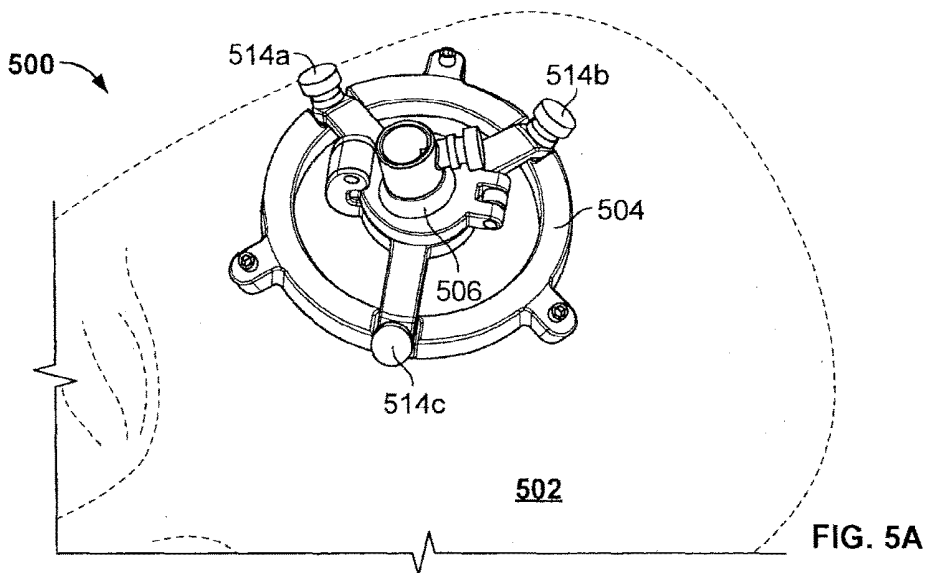


FIG. 4B



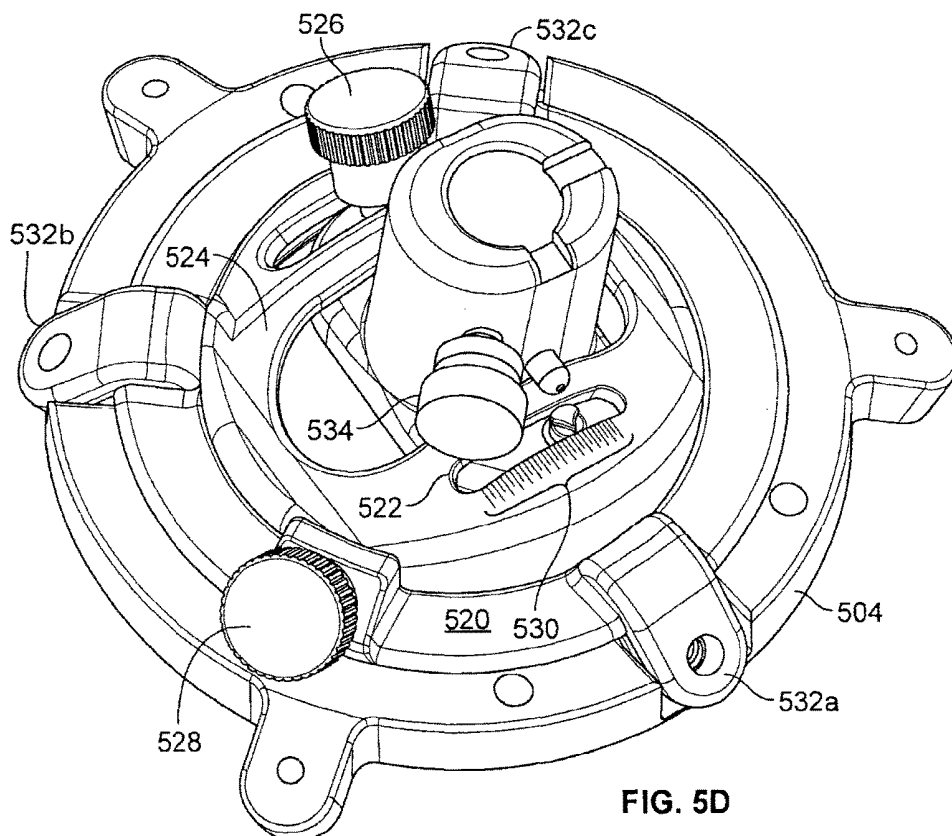


FIG. 5D

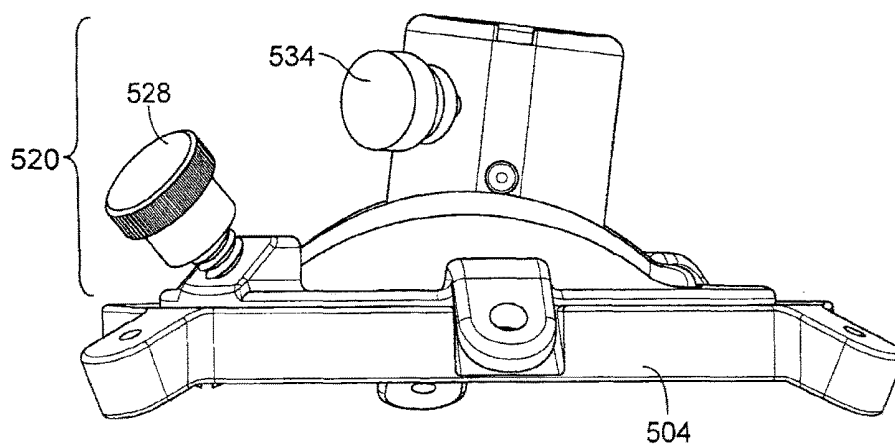


FIG. 5E

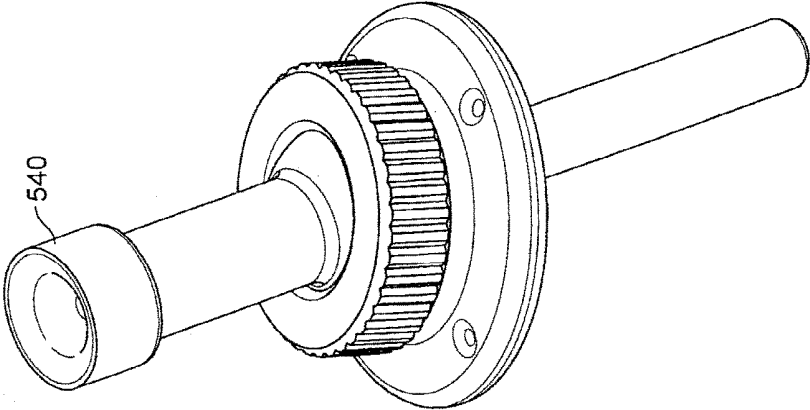


FIG. 5G

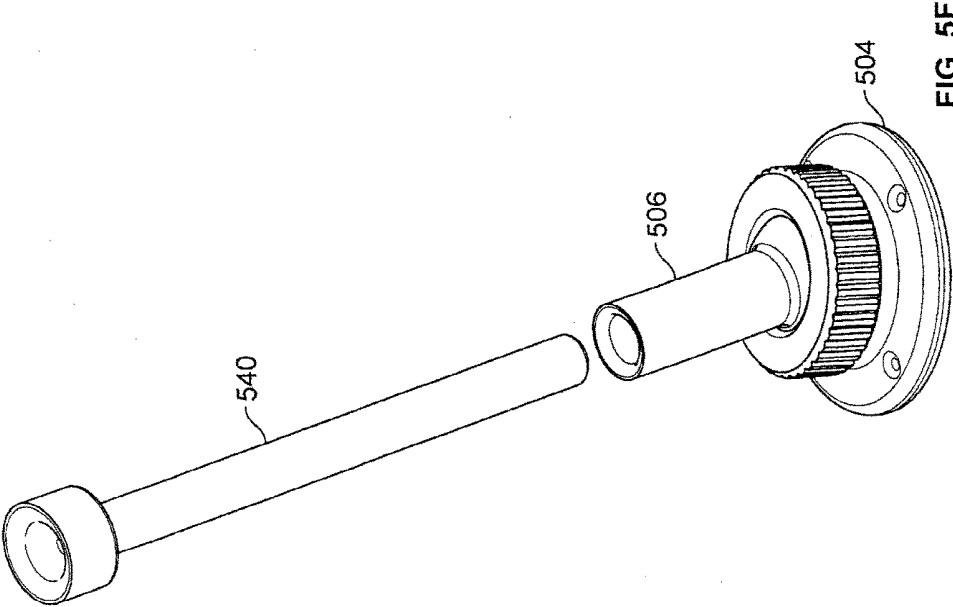


FIG. 5F

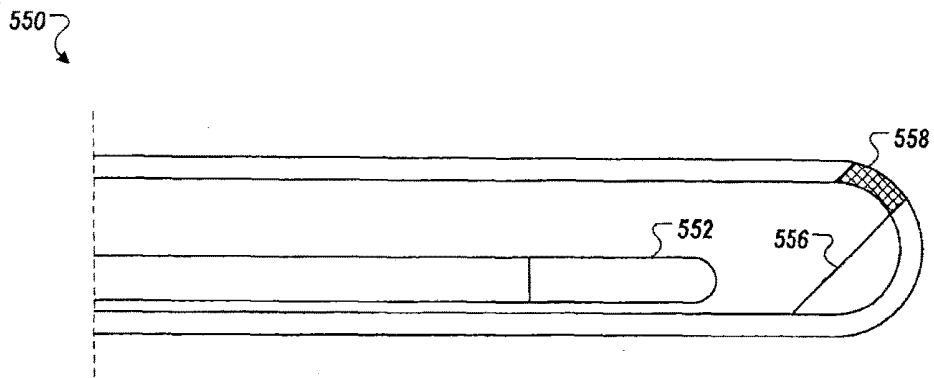


FIG. 5H

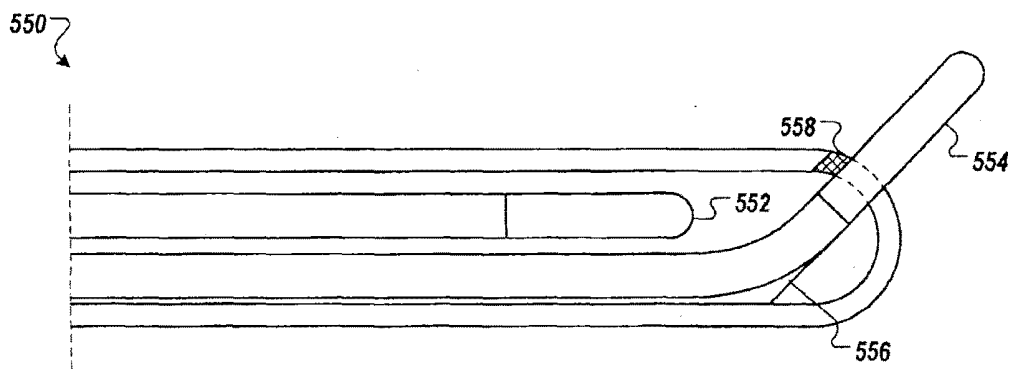


FIG. 5I

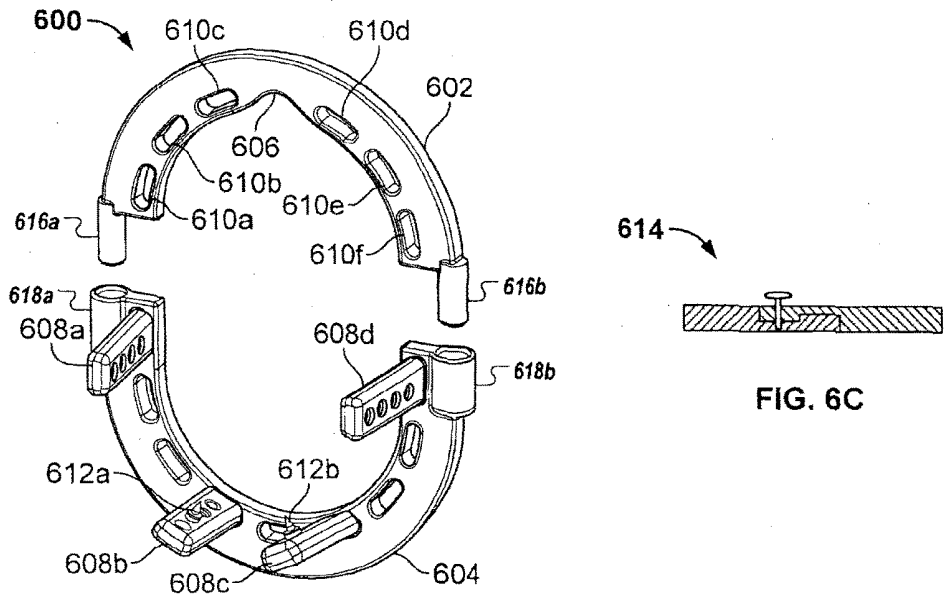


FIG. 6A

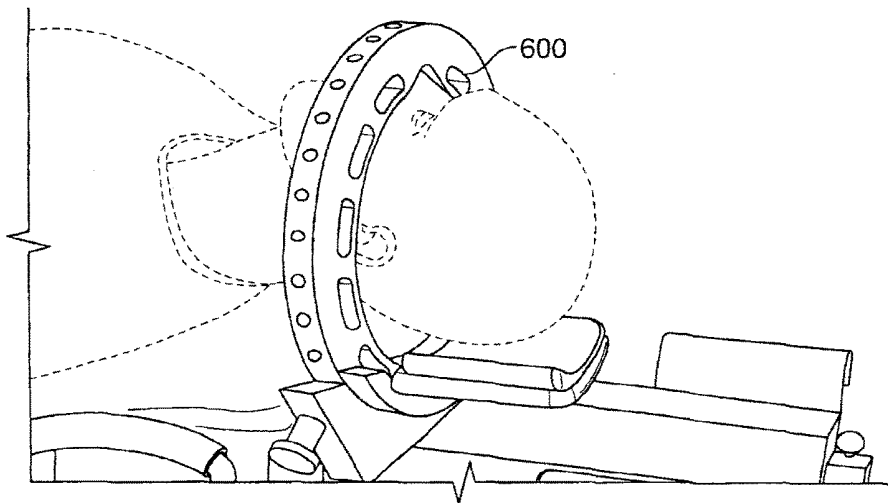


FIG. 6B

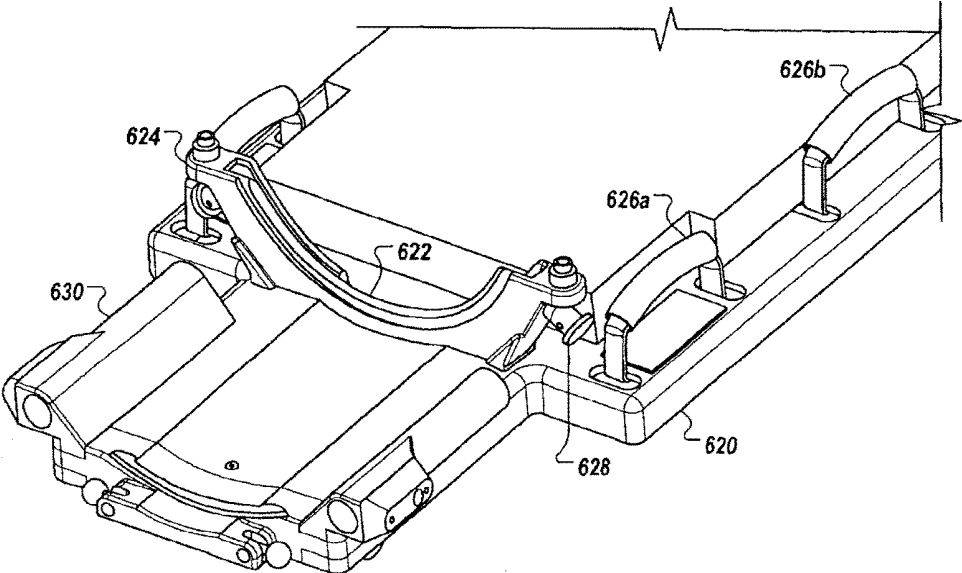


FIG. 6D

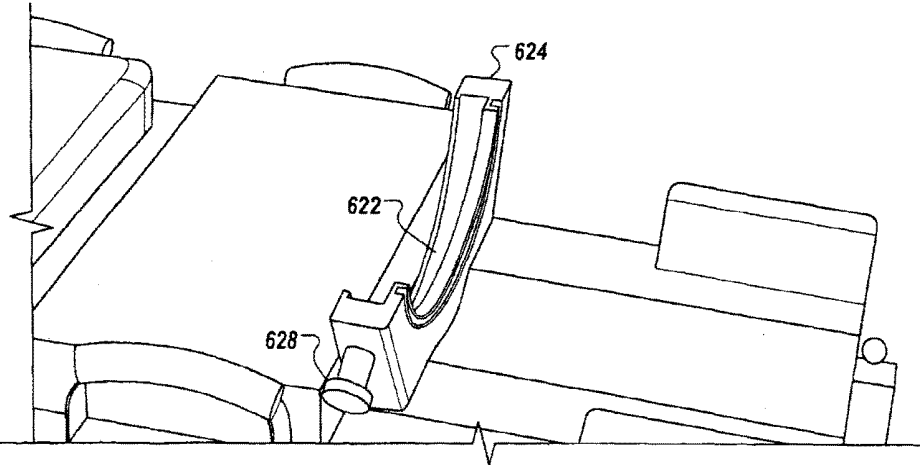


FIG. 6E

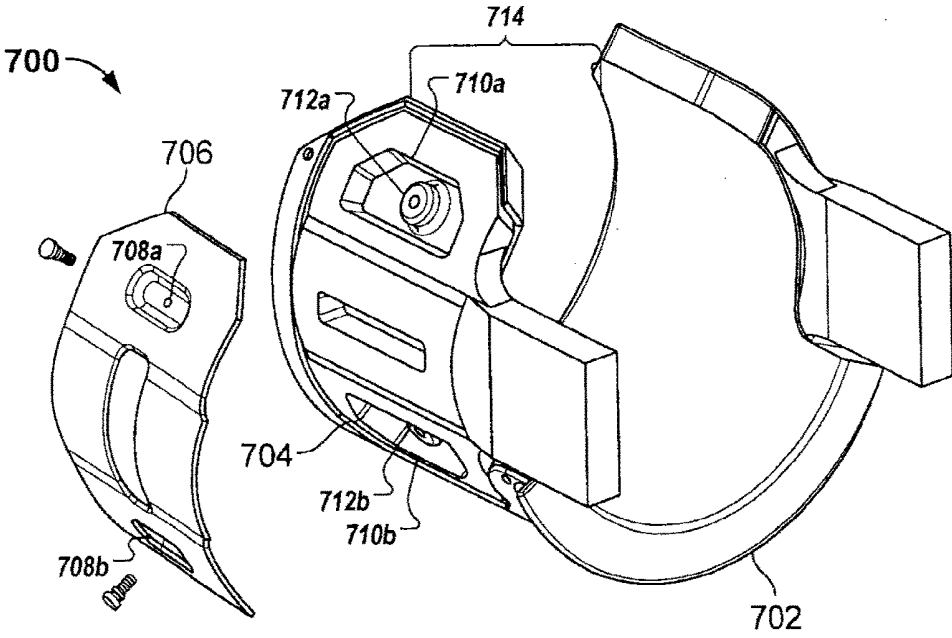


FIG. 7

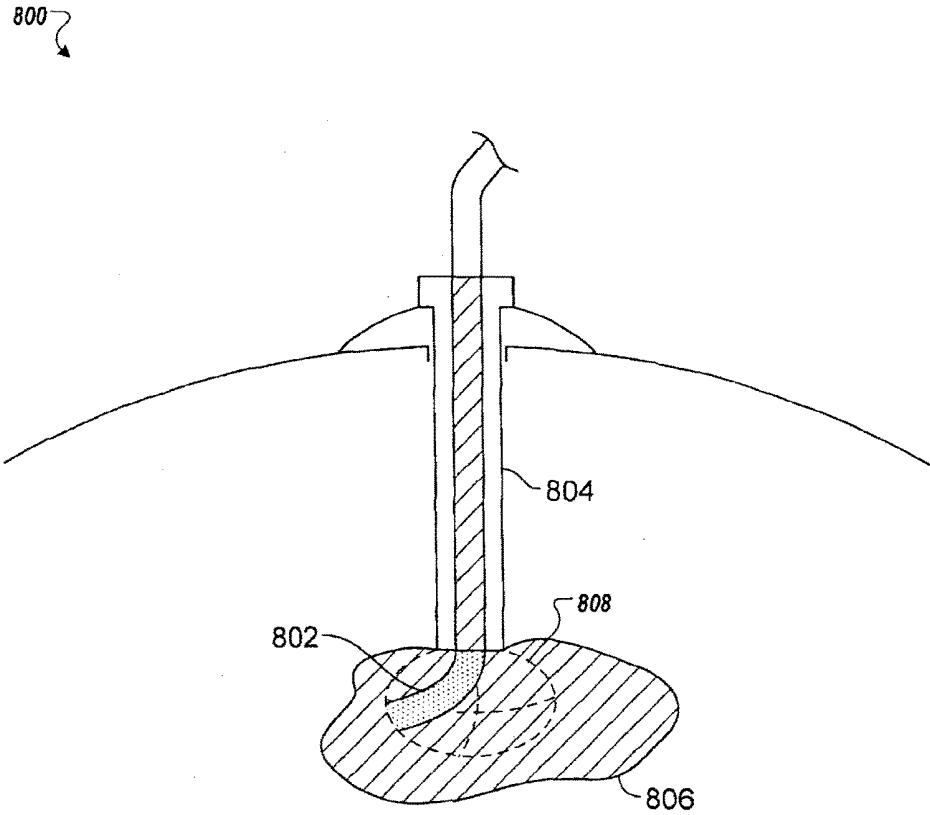


FIG. 8

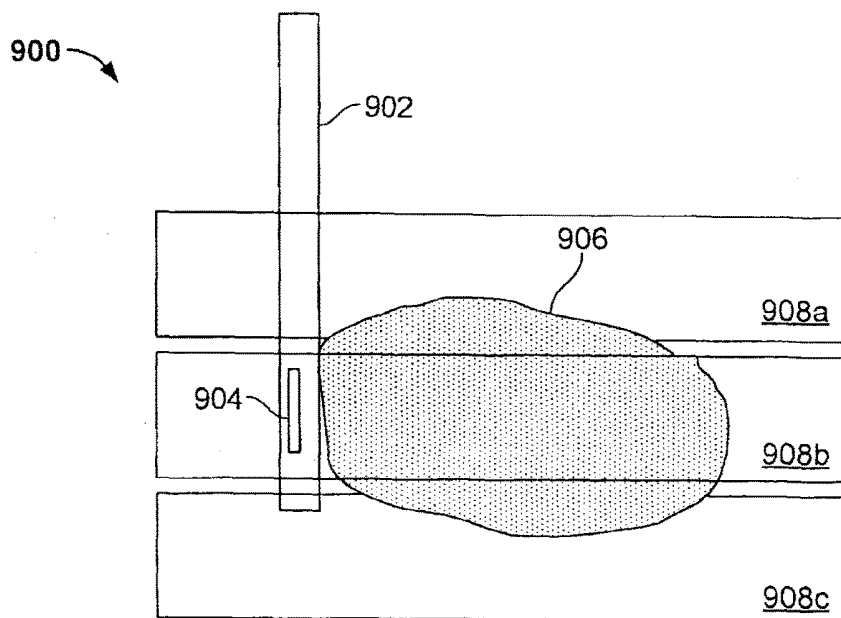


FIG. 9A

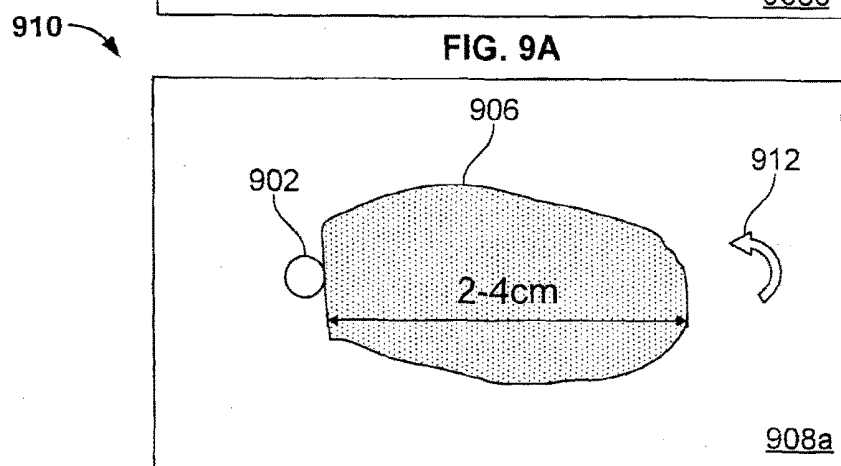


FIG. 9B

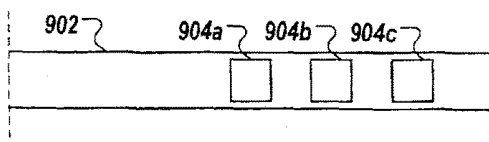


FIG. 9C

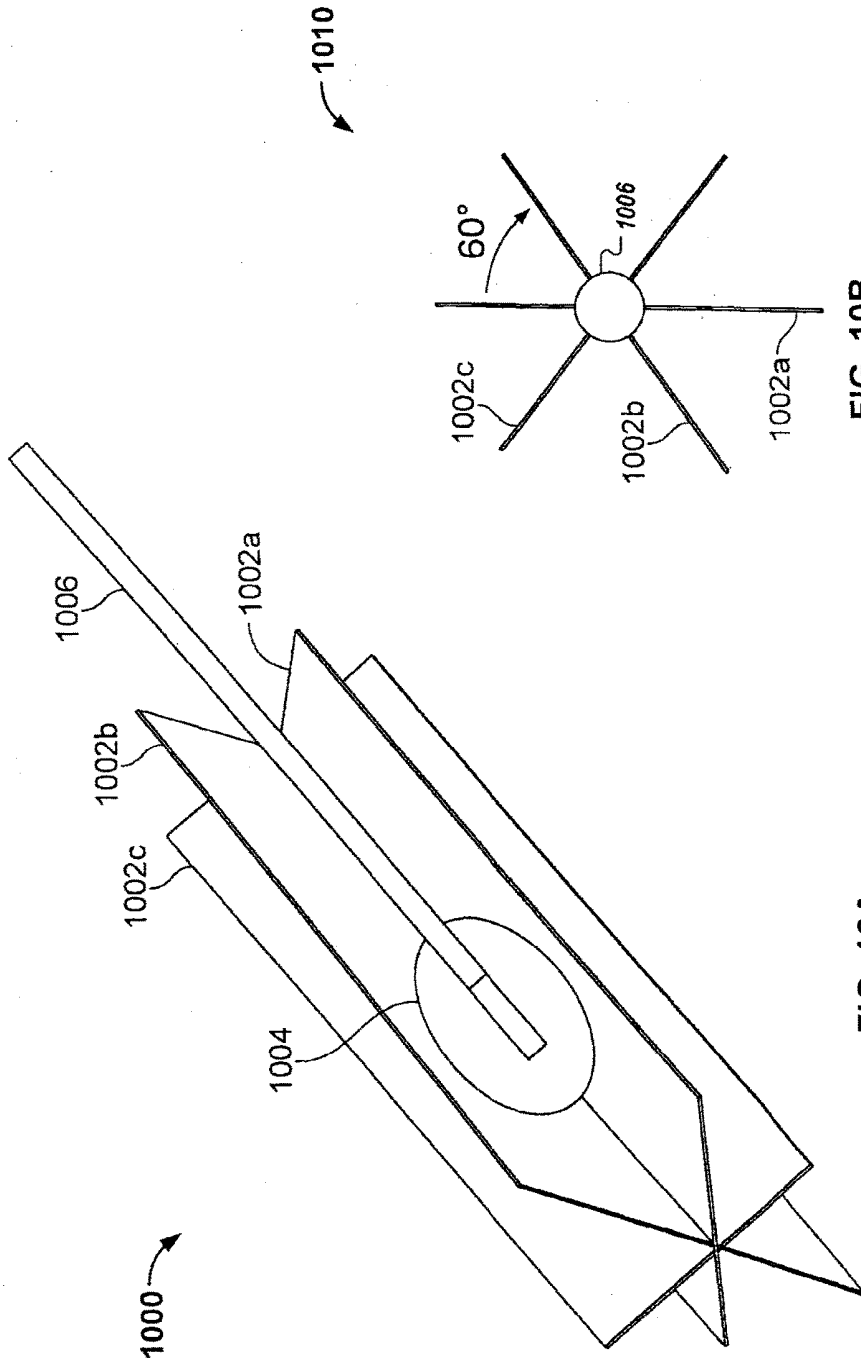


FIG. 10B

FIG. 10A

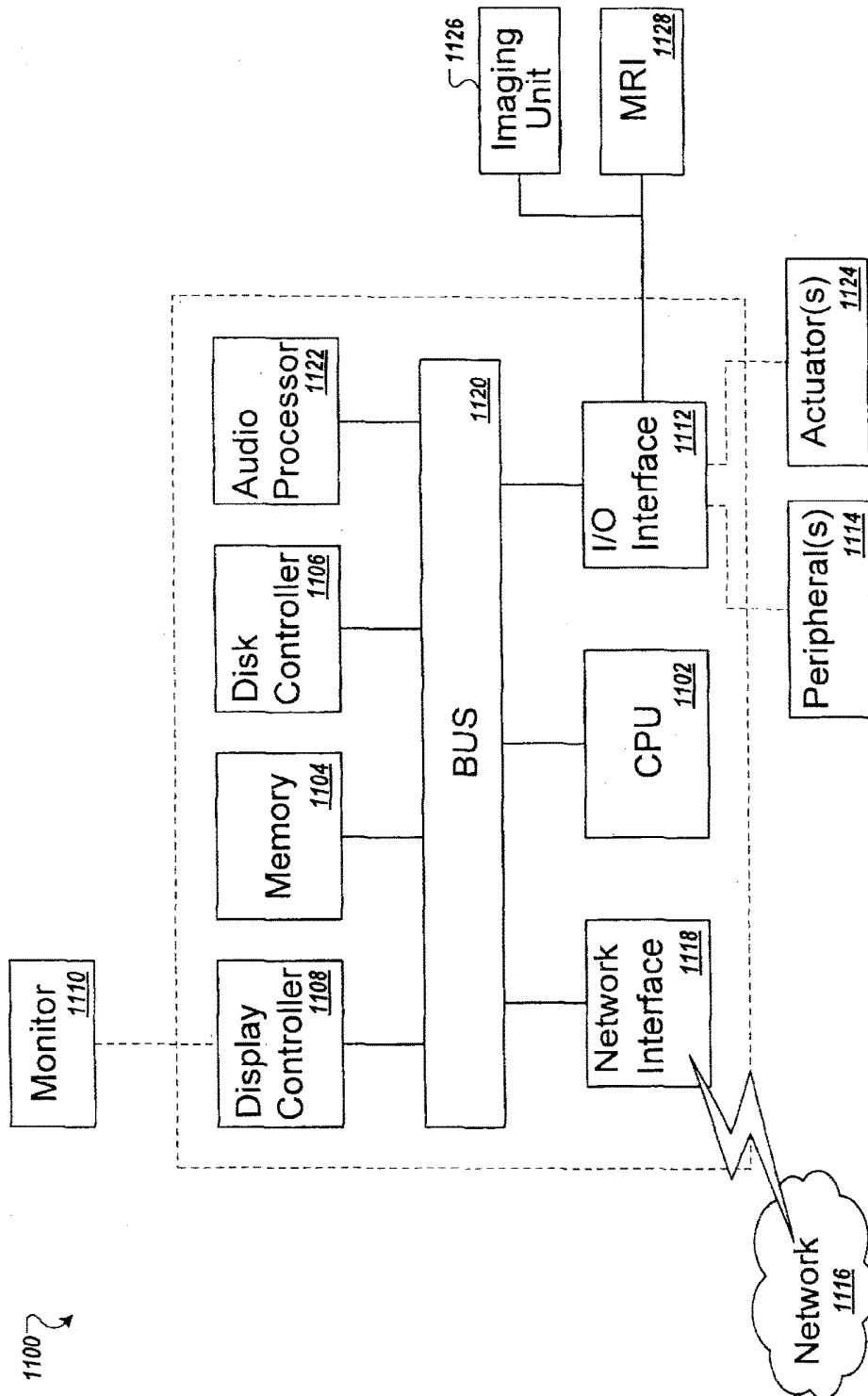


FIG. 11

**IMAGE-GUIDED THERAPY OF A TISSUE**

## RELATED APPLICATIONS

The present application is a divisional of U.S. patent application Ser. No. 14/661,212 filed Mar. 18, 2015, which is related to and claims the benefit of U.S. Provisional Patent Application 61/955,124 entitled "Image-Guided Therapy of a Tissue" and filed Mar. 18, 2014. The present disclosure is also related to U.S. Provisional Patent Application 61/955,121 entitled "Image-Guided Therapy of a Tissue" and filed Mar. 18, 2014. The contents of each of the above listed applications are hereby incorporated by reference in their entireties.

## BACKGROUND

Cancerous brain tumors can be "primary" tumors, meaning that the tumors originate in the brain. Primary tumors include brain tissue with mutated DNA that grows (sometimes aggressively) and displaces or replaces healthy brain tissue. Gliomas are one type of primary tumor that indicate cancer of the glial cells of the brain. While primary tumors can appear as single masses, they can often be quite large, irregularly-shaped, multi-lobed and/or infiltrated into surrounding brain tissue.

Primary tumors may not be diagnosed until the patient experiences symptoms, including those such as headaches, altered behavior, and sensory impairment. However, by the time the symptoms develop, the tumor may already be large and aggressive.

One treatment for cancerous brain tumors is surgery. Surgery involves a craniotomy (i.e., removal of a portion of the skull), dissection, and total or partial tumor resection. The objectives of surgery may include removing or lessening of the number of active malignant cells within the brain, or reducing a patient's pain or functional impairment due to the effect of the tumor on adjacent brain structures. Not only can surgery be invasive and accompanied by risks, for some tumors, surgery is often only partially effective. In other tumors, surgery may not be feasible. Surgery may risk impairment to the patient, may not be well-tolerated by the patient, and/or may involve significant costs, recovery time, and recovery efforts.

Another treatment for cancerous brain tumors is stereotactic radiosurgery (SRS). SRS is a treatment method by which multiple intersecting beams of radiation are directed at the tumor such that, at the point of intersection of the beams, a lethal dose of radiation is delivered, while tissue in the path of any single beam remains unharmed. However, confirmation that the tumor has been killed is often not possible for several months post-treatment. Furthermore, in situations where high doses of radiation may be required to kill a tumor, such as in the case of multiple or recurring tumors, it is common for the patient to reach a toxic threshold for radiation dose, prior to killing all of the tumors. Reaching this toxic threshold renders further radiation inadvisable.

## SUMMARY

In one aspect, the present disclosure relates to an apparatus including a low profile skull anchor device configured to attach to an area of a skull of a patient, the low profile skull anchor device including a central opening for access to an entry formed in the skull of the patient, where the low profile skull anchor device, upon attachment to the area of

the skull, protrudes from the area of the skull at a height no greater than forty millimeters. The apparatus may further include a removable guide stem configured to detachably connect to the low profile skull anchor device, the removable guide stem including a cylindrical opening, where upon connection of the removable guide stem to the low profile skull anchor device, the cylindrical opening is positioned substantially above the entry formed in the skull of the patient, and the removable guide stem is configured to adjust a trajectory of the cylindrical opening in at least one of a tilt direction and a rotation direction.

In some implementations, the low profile skull anchor device includes at least three fastener positions for attaching the low profile skull anchor device to bone anchors set in the skull of the patient using screws. The low profile skull anchor device may include at least three skull pins for maintaining a gap between the low profile skull anchor device and a surface of the skull of the patient, thereby avoiding skin compression. The central opening of the low profile skull anchor device may be at least sixty millimeters in diameter.

In some implementations, the low profile skull anchor device includes at least two fastener openings for connecting the removable guide stem to the low profile skull anchor device. The removable guide stem may include a ball joint for adjusting the trajectory of the cylindrical opening in both the tilt direction and the rotation direction. The removable guide stem may include a tilt adjustment mechanism for adjusting the trajectory of the cylindrical opening in a tilt direction and a separate rotation adjustment mechanism for adjusting the trajectory of the cylindrical opening in a rotation direction. At least one of the removable guide stem and the low profile skull anchor device may include a number of guide lines for aid in setting the trajectory of the cylindrical opening.

In some implementations, the apparatus includes a guide sheath, where the guide sheath is configured for insertion within the cylindrical opening of the removable guide stem, and the guide sheath includes at least one hollow lumen extending between a proximal end of the guide sheath and a distal end of the guide sheath, where the at least one hollow lumen is configured for introduction of a neurosurgical instrument. The removable guide stem may include a lock mechanism for locking the guide sheath to the removable guide stem at a selected linear depth of insertion within the cylindrical opening of a number of linear depths of insertion available for selection. The distal end of the guide sheath may include two or more openings for deployment of the neurosurgical instrument.

In one aspect, the present disclosure relates to a head fixation system including an upper ring portion including a nose indent for positioning the nose of a patient when a head of the patient is encircled by the head fixation system, and a lower ring portion including a number of support posts, where the number of support posts are configured to support the head of the patient laid upon the lower ring portion, and the lower ring portion is configured to lock to the upper ring portion after positioning the head of the patient upon the number of support posts.

In some implementations, the support posts are adjustably connected to the lower ring portion via a number of slots, where the head fixation system includes more slots than support posts. Each support post of the number of support posts may include at least one connection point for connecting a fastener. The at least one connection point may be configured for connection of a skull pin. Each support post of the number of support posts may include at least three

connection points for connecting a fastener, where a positioning of a fastener upon a first support post of the number of support posts is user selectable. Upon positioning the head of the patient between the lower ring portion and the upper ring portion and locking the lower ring portion to the upper ring portion, a user may tighten the fasteners to fix a position of the head of the patient.

In some implementations, the head fixation system includes one or more additional upper ring portions, where the upper ring portion is selected based upon a size of the head of the patient. The lower ring portion may be curved to provide at least forty degrees of angular head adjustment upon placing the head fixation system within a fixation ring channel of a patient table.

In one aspect, the present disclosure relates to a probe for use in effecting intracranial high intensity focused ultrasound (HIFU) treatment, including at least one ultrasonic transducer, an acoustic coupling medium contacting the at least one ultrasonic transducer, and a rigid external shaft for interstitial positioning of the at least one ultrasonic transducer, where the rigid shaft is up to 3.5 millimeters in diameter, and the at least one ultrasonic transducer is mounted within the rigid external shaft. The probe may be configured to drive ultrasonic energy at least three centimeters into tissue for effecting thermal treatment of the tissue.

In some implementations, the at least one ultrasonic transducer is mounted in a side-firing position within the rigid external shaft. The at least one ultrasonic transducer may include a linear array of three or more ultrasonic transducers. The at least one ultrasonic transducer may be a planar transducer. The thermal treatment may include one of coagulation and cavitation.

The foregoing general description of the illustrative implementations and the following detailed description thereof are merely example aspects of the teachings of this disclosure, and are not restrictive.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of an exemplary layout of an MRI Control Room, an MRI Scan Room, and an MRI Equipment Room;

FIG. 2 is an illustration of a perspective view of a patient inserted into an MRI, with a head fixation and stabilization system installed;

FIG. 3 illustrates a probe driver;

FIGS. 4A and 4B are flow charts illustrating an exemplary procedure for treating a patient;

FIGS. 5A through 5E illustrate a low profile skull anchoring device and example guide stems;

FIGS. 5F and 5G illustrate a guide stem and sheath configured to interconnect with the low profile skull anchoring device;

FIGS. 5H and 5I illustrate example internal configurations of a guide sheath;

FIGS. 6A and 6B illustrate a head fixation system;

FIG. 6C illustrates a locking mechanism;

FIGS. 6D and 6E illustrate a mounting location on an MRI platform for the head fixation system of FIGS. 6A and 6B;

FIG. 7 is an illustration of an MRI coil holder;

FIG. 8 is an illustration of a pre-shaped probe deployed from a rigid sheath;

FIGS. 9A through 9C illustrate a high intensity focused ultrasound probe;

FIGS. 10A and 10B illustrate a method for MR thermal monitoring using offset thermal imaging planes; and

FIG. 11 illustrates exemplary hardware of a workstation.

#### DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

In the drawings, like reference numerals designate identical or corresponding parts throughout the several views.

As used herein, the words “a,” “an” and the like generally carry a meaning of “one or more,” unless stated otherwise. The term “plurality”, as used herein, is defined as two or more than two. The term “another”, as used herein, is defined as at least a second or more. The terms “including” and/or “having”, as used herein, are defined as comprising (i.e., open language). The term “program” or “computer program” or similar terms, as used herein, is defined as a sequence of instructions designed for execution on a computer system. A “program”, or “computer program”, may include a subroutine, a program module, a script, a function, a procedure, an object method, an object implementation, in an executable application, an applet, a servlet, a source code, an object code, a shared library/dynamic load library and/or other sequence of instructions designed for execution on a computer system.

Reference throughout this document to “one embodiment”, “certain embodiments”, “an embodiment”, “an implementation”, “an example” or similar terms means that a particular feature, structure, or characteristic described in connection with the example is included in at least one example of the present disclosure. Thus, the appearances of such phrases or in various places throughout this specification are not necessarily all referring to the same example. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more examples without limitation.

The term “or” as used herein is to be interpreted as an inclusive or meaning any one or any combination. Therefore, “A, B or C” means “any of the following: A; B; C; A and B; A and C; B and C; A, B and C”. An exception to this definition will occur only when a combination of elements, functions, steps or acts are in some way inherently mutually exclusive.

Further, in individual drawings figures, some components/features shown are drawn to scale to exemplify a particular implementation. For some drawings, components/features are drawn to scale across separate drawing figures. However, for other drawings, components/features are shown magnified with respect to one or more other drawings. Measurements and ranges described herein relate to example embodiments and identify a value or values within a range of 1%, 2%, 3%, 4%, 5%, or, preferably, 1.5% of the specified value(s) in various implementations.

The system or method may include one or more processors and circuits that embody aspects of various functions by executing corresponding code, instructions and/or software stored on tangible memories or other storage products. A display may include various flat-panel displays, including liquid crystal displays.

The treatment of tumors by heat is referred to as hyperthermia or thermal therapy. Above approximately 57° C., heat energy needs only to be applied for a short period of time since living tissue is almost immediately and irreparably damaged and killed, for example through a process called coagulation, necrosis, or ablation. Malignant tumors, because of their high vascularization and altered DNA, are more susceptible to heat-induced damage than healthy tis-

sue. In other procedures, heat energy is applied to produce reversible cell damage. Temporary damage to cellular structures may cause the cells to be more conducive to certain therapies including, in some examples, radiation therapy and chemotherapy. Different types of energy sources, for example, laser, microwave, radiofrequency, electric, and ultrasound sources may be selected for heat treatment based on factors including: the type of tissue that is being treated, the region of the body in which the tissue to be treated is located, whether cellular death or reversible cellular damage is desired, the nature of energy application parameters for each source, and variability of the energy application parameters. Depending on these factors, the energy source may be extracorporeal (i.e., outside the body), extrastitial (i.e., outside the tumor), or interstitial (i.e., inside the tumor).

In interstitial thermal therapy (ITT), a tumor is heated and destroyed from within the tumor itself, energy may be applied directly to the tumor instead of requiring an indirect route through surrounding healthy tissue. In ITT, energy deposition can be extended throughout the entire tumor. The energy can be applied to heat tissue in the treatment area to a temperature within a range of about 45° to 60° C.

An exemplary ITT process begins by inserting an ultrasound applicator including one or more transducers into the tumor. The ultrasonic energy from the applicator may therefore extend into the tissue surrounding the end or tip including the one or more transducers to effect heating within the tumor. In some implementations, the transducer(s) is/are aligned with an edge of the applicator and the applicator is rotatable so as to rotate the ultrasonic energy beam around the axis of the applicator to effect heating of different parts of the tumor at positions around the applicator. In other implementations or for other applications, the transducer(s) are presented on a tip of the applicator or otherwise surrounding an inserted portion of the applicator. Depending upon the distribution of transducers, the applicator may be moved longitudinally and/or rotated to effect heating of the tumor over a full volume of the targeted region.

In yet other implementations, the ultrasonic applicator is controlled and manipulated by a surgeon with little or no guidance apart from the surgeon's memory of the anatomy of the patient and the location of the tumor. In still other implementations, images may be used during the ITT process to provide guidance for treatment. For example, locations of tumors and other lesions to be excised can be determined using a magnetic resonance imaging (MRI) system or computer tomography (CT) imaging system. During the ITT process, for example, MRI imaging can be used in real time to control or aid in guidance accuracy in an automated or semi-automated fashion.

In some implementations, thermography (e.g., MR thermography, ultrasonic thermography, etc.) provides contemporaneous temperature feedback regarding one or both of the targeted region and the surrounding tissue during the ITT process. The temperature information, for example, can be used to monitor necrosis of tumor tissue while ensuring that surrounding (healthy) tissue suffers minimal to no damage. The temperature feedback, in some implementations, is used to perform either or both of: automating engagement of the ultrasonic energy and cooling functionality of the ultrasonic applicator. In this manner, it is possible to control a temperature distribution or thermal dose in and around the tumor.

Effecting treatment to a tissue, in some implementations, includes an automated drive mechanism with a holder to hold a treatment device (e.g., medical probe, ultrasonic

applicator, laser fiber, etc.). In some implementations, the drive mechanism is motorless and consists of thermal imaging compatible components. The drive mechanism, for example, can be configured without an electric motor. The drive mechanism, in some examples, is included in an MRI or MRI head coil. The drive mechanism can be coupled to one or more wires or umbilicals such that a translation of the one or more wires or umbilicals affects one or more of a longitudinal displacement of the holder and a rotation of the holder. A controller, in some implementations, processes position control signals for setting and/or monitoring a position of the holder (e.g., via an input interface to the wires or umbilicals), and issues subsequent position control signals to manipulate positioning of the holder (e.g., via an output interface to the wires or umbilicals).

The system or method, in some implementations, includes a guide mechanism that is attachable to a surface of a patient. The guide mechanism, for example, can include a base structure configured to remain stationary relative to the patient when the guide mechanism is attached to the surface of the patient in a locked state. The guide mechanism can further include a tilt portion that is coupled to the base structure and provides an adjustable tilt between a trajectory of the drive mechanism and the base structure. The guide mechanism can further include a rotation portion that provides an adjustable rotation of the tilt portion relative to the base structure.

The controller, in some implementations, is configured to process a sequence of the position control signals to direct the guide mechanism to move the holder during treatment. For example, the controller can be programmed to move the holder to a first position for effecting the treatment to the tissue at a first portion of the tissue that coincides with the first position and then move the holder to a second position for effecting the treatment to the tissue at a second portion of the tissue that coincides with the second position.

During treatment, in some implementations, a workstation transmits the position control signals to the controller and displays feedback images (e.g., MRI images and/or thermometry images) of the tissue to a user of the workstation. The workstation, for example, can continuously display the thermometry images of the tissue during the treatment to the tissue at the first and second portions of the tissue, and while the holder moves between the first and second positions.

In some implementations, an imaging system receives images of the tissue and the treatment device and analyzes the images to monitor control of positioning and/or therapeutic energy delivery within the tissue. For example, the imaging system may process, in real time, the images of the tissue and the treatment device, as well as the thermometry images of the tissue to forecast errors or interruptions in the treatment to the tissue. Responsive to the analysis, the imaging system may display, via the workstation, an appropriate warning. Position control signals may be updated and transmitted by the workstation to the controller based on one or more of the images, as the images are received by the workstation in real time.

In some implementations, treatment is delivered via an energy emission probe, such as an ultrasonic applicator or laser probe. The energy emission probe, in some examples, may include one or more emitters, such as a radiofrequency emitter, HIFU emitter, a microwave emitter, a cryogenic cooling device, and a photodynamic therapy light emitter. The energy emission probe may include multiple emitters, where the emitters are longitudinally spaced with respect to a longitudinal axis of the energy emission probe.

In some implementations, the energy emission of the probe can be controlled to generate a number of different energy output patterns. The different patterns, for example, can include energy delivered via two or more ultrasonic transducers and/or two or more laser fibers. For example, a laser probe may include a first laser fiber for outputting a symmetrical output pattern with respect to a longitudinal axis of the first laser fiber and a second laser fiber for outputting an asymmetrical output pattern with respect to a longitudinal axis of the second laser fiber. In another example, an ultrasonic applicator may include a first ultrasonic transducer for outputting a first ultrasonic frequency and a second ultrasonic transducer for outputting a second ultrasonic frequency.

The energy output pattern, in some implementations, includes a pulsed output pattern. For example, a higher power density may be achieved without causing tissue scorching or carbonization by pulsing a high power laser treatment for x seconds with y seconds break between so that tissue in the immediate vicinity of the treatment area has an opportunity to dissipate. In a particular example, the laser pattern may be active for two seconds and inactive for one second.

In some implementations, the treatment pattern includes effecting treatment while simultaneously moving the probe (e.g., linearly and/or rotationally). For example, an ultrasonic probe may be rotated while an emission pattern is simultaneously adjusted to effect treatment at a desired depth based upon a particular geometry of a region of interest (ROI) including a targeted tissue area. In one embodiment, the ROT includes multiple targeted tissue areas, which are treated either concurrently, consecutively, or in succession. In this manner, for example, while the ultrasonic treatment beam is focused upon a radial portion of the tumor having a depth of 1.5 centimeters, the power density of the HIFU probe may be tuned for this first treatment depth. Upon rotation to a second radial portion of the tumor may have a depth of 2 centimeters, the power density of the HIFU probe may be increased accordingly to tune for this second treatment depth of 2 centimeters.

An energy source generates energy for the probe. In some implementations, the workstation transmits energy control signals to the energy source. The workstation, for example, may be configured to process a sequence of the energy control signals to first effect a symmetrical treatment area with respect to the tissue, via the probe, and subsequently effect an asymmetrical treatment area with respect to the tissue, via the probe, after the symmetrical treatment. In a particular example, the workstation may be configured to process a sequence of position and laser control signals to move the holder to a first position for effecting the treatment to the tissue at a first portion of the tissue that coincides with the first position, effect a symmetrical treatment to the first portion of the tissue with the first laser fiber, move the holder to a second position for effecting the treatment to the tissue at a second portion of the tissue that coincides with the second position, and effect an asymmetrical treatment to the second portion of the tissue with the second laser fiber. During treatment, the workstation may be configured to display thermometry images of the tissue continuously and concurrently with processing control signals specifying the position and energy associated with the symmetrical and asymmetrical treatments.

In some implementations, the system or method includes a guide sheath configured to accept two or more probes associated with different energy modalities as the treatment device. The modalities may include, for example, laser,

radiofrequency, HIFU, microwave, cryogenic, photodynamic therapy, chemical release and drug release. The guide sheath may include one or more off-axis lumens for positioning an emitting point of one or more of the number of probes at an off-axis angle.

A system in accordance with this disclosure incorporates, in an embodiment, MRI-compatible energy emission probes and/or other treatment devices and accessories for controlled delivery of thermal therapy to a number of locations and tumor sizes within a brain. The system, however, is not limited to MRI-guided thermal therapy, as other therapies such as computer tomography (CT) are utilized in other embodiments. Further, this disclosure refers to an MRI scanner as an exemplary medical imaging machine, which may be referred to herein as an MRI.

#### I. Overview

Turning to FIG. 1, in certain embodiments, an environment **100** for intracranial therapy includes an interface platform **102** (herein an interface platform or interface console), a system electronics rack **104** and components (herein rack), and a control workstation **106** (herein workstation). The interface platform **102** may be used to manipulate and monitor therapy equipment related to one or more energy sources, such as probe introduction equipment including, in an embodiment, a probe driver, a probe, and/or a probe holding and alignment device. The probe introduction equipment, in some examples, can include the low profile anchoring system described in FIGS. 5A-5G below or the stereotactic miniframe described in U.S. patent application Ser. No. 13/838,310 to Tyc, filed Mar. 14, 2013 and titled "Image-Guided Therapy of a Tissue," incorporated herein by reference in its entirety. In certain embodiments, the workstation **106** is configured to control the interface platform **102** for control of the energy emission therapy equipment.

The interface platform **102** is secured to a patient table **108** of an MRI system **110**. The MRI system **110** may include a head coil and stabilization system (herein stabilization system), an instrument adaptor, and an MRI trajectory wand. Exemplary MRI systems that can be utilized together with the features discussed herein include those manufactured by Siemens AG, Munich, Germany (including the MAGNETOM AVANTO, TRIO, ESPREE, VERIO MRI Systems, which are trademarks and/or trade names of Siemens AG). Further, example MRI systems include those manufactured by General Electric Company, Fairfield, Conn. (including the SIGNA, OPTIMA and DISCOVERY MRI systems, which are trademarks and/or trade names of General Electric Company).

In certain embodiments, all of the above components of the interface platform **102** and the energy emission therapy equipment are MRI compatible, which refers to a capability or limited capability of a component to be used in an MRI environment. For example, an MRI compatible component operates and does not significantly interfere with the accuracy of temperature feedback provided by the MRI system operating with exemplary flux densities including: magnetic flux densities of 1.5 T or 3.0 T, where no hazards are known for a specified environment (e.g., 1.5 T or 3.0 T). Compatibility can also be defined with respect to one or more other magnetic flux densities, including at least 0.5 T, 0.75 T, 1.0 T, 2 T, and 5 T.

In certain embodiments, the system electronics rack **104** includes cables, penetration panels and hardware that effectuate mechanical, electrical, and electronic operation of the energy emission therapy equipment and the MRI system

**110.** The system electronics rack **104** may further be used to power and route control signals and/or communications for the control workstation **106**.

The workstation **106** includes a display that displays a user interface, e.g., a graphical user interface (GUI) and/or a command line interface that enables a user to plan a treatment procedure and interactively monitor the procedure, the interface platform **102**, and the entire MRI system **110**. In certain embodiments, the user interface also provides the user, e.g., a medical professional, the ability to directly control the energy emission therapy equipment including an energy source associated therewith, and therefore, enables directly control of the application of the therapy to the patient.

Turning to FIG. 2, an exemplary position of a patient on the patient table **108** of the MRI system **110** is illustrated. The interface platform **102** is secured to the patient table **108** together with a head coil **202** and stabilization system, which is a head fixation device that immobilizes a patient's head. The stabilization system includes a head fixation ring **204**. A probe **206** and probe driver **208** are coupled to probe introduction equipment **210**, and to the interface platform **102** via umbilicals. A cable, for example, can be used to provide data, laser, fluid, etc. connections between the probe **206**, probe driver **208**, and interface platform **102** and the electronics rack **104** in the MRI equipment room (as illustrated in FIG. 1).

The probe introduction equipment **210**, in certain embodiments, includes at least a portion that is detectable by the MRI system (e.g., included in temperature data that is displayed by an imaging portion of the MRI system) and is used for trajectory determination, alignment, and guidance of the probe **206**. An MRI trajectory wand (e.g., an MRI detectable, fluid-filled tube) may be placed into the probe introduction equipment **210**, for example, to confirm a trajectory, associated with an intended alignment, to a targeted tissue region, via MRI. After confirmation, the probe **206** may be introduced into the probe introduction equipment **210** to effect surgery or therapy.

The probe **206** may be composed of MRI compatible materials that permit concurrent energy emission and thermal imaging, and can be provided in multiple lengths, cross-sectional areas, and dimensions. Types of probes that can be utilized with the components and procedures discussed herein include RF, HIFU, microwave, cryogenic, and chemical release probes; the chemical release probes may include photodynamic therapy (PDT), and drug releasing probes. Treatments in accordance with the descriptions provided in this disclosure include treatments that ablate (i.e., "treat") a tissue to destroy, inhibit, and/or stop one or more or all biological functions of the tissue, or otherwise cause cell damage or cell death that is indicated by a structural change in cells of the targeted tissue area. Ablation can be effected by laser, RF, HIFU, microwave, cryogenic, PDT and drug or chemical release. A corresponding probe and/or other instrument, such as a needle, fiber or intravenous line can be utilized to deliver one or more of these ablation agents intracorporeally or percutaneously and proximate to, in the vicinity of, abutting, or adjacent to a targeted tissue area so as to effect treatment. The probe **206** can be a gas-cooled probe so as to control delivery of the energy to the targeted tissue area. The length and diameter of the probe **206** is preselectable based on the targeted tissue area and/or the ROI. The probe **206**, in some particular examples, can be a laser delivery probe that is used to deliver laser interstitial thermal therapy or a HIFU applicator that is used to deliver HIFU interstitial thermal therapy.

The probe driver **208** controls positioning, stabilization and manipulation of the probe **206** within a specified degree of precision or granularity. Turning to FIG. 3, the components of the probe driver **208** generally include a commander **302**, umbilicals **304**, a follower **306**, and a position feedback plug **308** that receives position feedback signals from, for example, potentiometers within the follower **306**. The probe **206** (illustrated in FIG. 2) can be inserted into the follower **306**, and the follower **306** can control a rotational and longitudinal alignment and/or movement of the probe **206**. The probe driver **208** can further include a rotary test tool (not illustrated) that can be used during a self-test procedure to simulate attaching a probe to the follower **306**. An exemplary probe driver that can be utilized in accordance with the various aspects presented in this disclosure is described in U.S. Pat. No. 8,728,092 to Qureshi, entitled "Stereotactic Drive System" and filed Aug. 13, 2009, the entirety of which is incorporated herein by reference.

The probe driver **208** (illustrated in FIG. 2) is mounted to the interface platform **102**. The position feedback plug **308** (illustrated in FIG. 3) connects to the interface platform **102** in order to communicate the position of the probe **206** to the user and/or the workstation **106** (illustrated in FIG. 1). The probe driver **208** is used to rotate or translate, e.g., by extending or retracting the probe **206**. The probe driver **208**, in a particular example, can provide, at a minimum, a translation of 20-80 mm, 30-70 mm, 40-60 mm or 40 mm, with a maximum translation of 60 mm, 80 mm, 100 mm, 120 mm or 60-150 mm. The probe driver **208**, further to the example, can also provide, at a minimum, a rotation of 300°-340°, with a maximum rotation of 350°, 359°, 360°, 540°, 720° or angles therebetween.

Returning to FIG. 1, in certain embodiments, the workstation **106** outputs signals to the MRI system **110** to initiate certain imaging tasks. In other implementations, the workstation **106** outputs signals to an intermediary system or device that causes the MRI system **110** to initiate the imaging tasks. In certain embodiments, the workstation **106** additionally outputs signals to the electronics rack **104**. The electronics rack **104** includes various actuators and controllers that control the thermal therapy devices, such as, in some examples, a cooling fluid pressure and/or a flow rate of the cooling fluid, and a power source that powers a thermal therapy device. In one example of a thermal therapy device, the power source is a laser source that outputs laser light via an optical fiber. As illustrated in FIG. 1, the electronics rack **104** is located in an MRI Equipment Room and includes storage tanks to hold the cooling fluid, one or more interfaces that receive the signals from the control workstation **106** and/or a separate MRI workstation, an energy emission source (e.g. laser), and an output interface. One or more of the interfaces are connected with or include physical wiring or cabling that receives the signals and transmits other signals, as well as physical wiring or cabling that transmit energy to corresponding components in the MRI Scan Room through a portal that routes the signals and/or energy in a manner that minimizes any interface with or by the MRI system **110**. The wiring or cabling are connected at or by the interface platform **102** to corresponding components to effect and actuate control of a thermal therapy device and/or an associated thermal therapy session. Controlling the thermal therapy device, for example, by a user in the MRI control room prevents the introduction of noise to the MRI system, which includes the MRI cabin. The remotely controlled procedure enhances thermal therapy efficiency and accuracy by preventing heating loss due to stopping and restarting energy application.

In certain embodiments, the system is indicated for use to ablate, necrotize, carbonize, and/or coagulate the targeted tissue area (e.g., an area of soft tissue) through interstitial irradiation or thermal therapy, in accordance with neurosurgical principles, with a HIFU thermal therapy device. The HIFU thermal therapy device or probe includes ultrasonic transducers for directing ultrasonic energy at the targeted tissue area, causing the tissue to heat. The ultrasonic beam of the HIFU probe can be geometrically focused (e.g., using a curved ultrasonic transducer or lens) or electronically focused (e.g., through adjustment of relative phases of the individual elements within an array of ultrasonic transducers). In an ultrasonic transducer array, the focused beam can be directed at particular locations, allowing treatment of multiple locations of an ROI without mechanical manipulation of the probe. The depth of treatment can be controlled by adjusting the power and/or frequency of the one or more transducers of the HIFU probe.

In certain embodiments, either additionally or alternatively to HIFU thermal therapy, a laser-based thermal therapy is utilized in the MRI system. Laser probes of a variety of outputs can be utilized, including, in some examples, laser probes emitting laser light having wavelengths of 0.1 nm to 1 mm, and laser probes emitting laser light in one or more of the ultraviolet, visible, near-infrared, mid-infrared, and far-infrared spectrums. Types of lasers used with respect the laser probe include, for example, gas lasers, chemical lasers, dye lasers, metal-vapor lasers, solid-state lasers, semiconductor lasers, and free electron lasers. In a particular example, one or more wavelengths of the laser light emitted by the laser probe are within the visible spectrum, and one or more wavelengths of the laser probe are within the near-infrared spectrum.

In certain embodiments, the environment 100 can be utilized for planning and monitoring thermal therapies effected via MRI-imaging, and can provide MRI-based trajectory planning for the stereotactic placement of an MRI compatible (conditional) probe. The environment 100, in certain embodiments provides real-time thermographic analysis of selected MRI images and thus, temperature feedback information and/or thermal dose profiles for the targeted tissue area. For example, thermographic analysis of the MRI images can provide real-time verification of cellular damage in a targeted tissue area that corresponds to necrosis, carbonization, ablation, and/or coagulation. In another example, thermographic analysis can be used to monitor tissue surrounding a periphery of an ROI to ensure minimal if any damage to healthy tissues. Components of the environment 100 may assist in guiding, planning, adjusting, performing and confirming a thermal therapy session and trajectories associated therewith.

A procedure includes, generally, identifying an ROI and/or associated targeted tissue areas in a patient that should be treated, planning one or more trajectories for treating the tissue, preparing the patient and components for the treatment, and performing the treatment. Aspects of the various parts of the treatment are described throughout this disclosure, and an exemplary sequence of treatment steps is illustrated in FIGS. 4A and 4B.

Turning to FIG. 4A, a process flow diagram illustrates an exemplary method 400 for pre-planning a treatment of a patient. In pre-planning the thermal therapy session, in certain embodiments, pre-treatment Digital Imaging and Communications in Medicine (DICOM) image data is loaded and co-registered, for example, via the workstation 106 (illustrated in FIG. 1). Using the DICOM image data,

one or more ROIs and/or targeted tissue areas and one or more initial trajectories can be determined and set (402).

In preparation for treatment, in certain embodiments, a head coil and fixation system is attached to the patient (404), for example by positioning the head coil and stabilization system on the surgical table. The patient can be immobilized using a head fixation ring. To ensure stable imaging, for example, the patient's head can be secured with the head fixation ring and remain fixed for the entire imaging portion of the flow chart in FIG. 4A. An example head fixation system is described below in relation to FIGS. 6A through 6E.

Prior to applying thermal energy to an ROI, a probe entry location into the skull is identified. In certain embodiments, a burr hole is drilled in the skull (406). The burr hole may be drilled prior to attachment of probe introduction equipment (e.g., a miniframe, anchoring device, guide stem, instrument sheath, etc.). A twist-drill hole, in certain embodiments, can be created following a trajectory alignment of the probe introduction equipment. The twist-drill hole can have a size of 1-5 mm, 2 mm, 3 mm, 4 mm or 4.5 mm.

The probe introduction equipment, such as a stereotactic miniframe or low profile anchoring device, in certain embodiments, is attached to the patient's head (408). Probe aligning equipment, such as the miniframe or guide stem, can then be aligned along the intended trajectory, for example using image-guided navigation. After attaching the probe introduction equipment, the head coil can be attached. An exemplary head coil system is described below in relation to FIG. 7. Depending on a process flow that is specific to a surgical center, the interface platform may be attached prior to or after MRI trajectory confirmation. The order of steps in a site-specific process may be determined based on members of MRI or surgical support team and may be determined during on-site training with respect to the MRI system. The interface platform (IP) is attached to the head end of the head coil and stabilization system. Then, the IP power and motor plugs are connected.

In certain embodiments, the patient is positioned in the MRI cabin, and MRI imaging is performed to confirm a trajectory (410) associated with a thermal therapy device and/or probe introduction equipment. For example, an MRI trajectory wand may be inserted into the probe introduction equipment for use in confirming its trajectory. The trajectory of the probe introduction equipment, for example, can be evaluated using MRI imaging prior to inserting a probe into the brain. Volumetric imaging or volumetric visualization may be captured to include the entire head and full extent of the probe introduction equipment. Along with trajectory confirmation, in some examples, beam fiducial marker detection may also be performed. For example, the captured images may also display a position of a beam fiducial marker located in a portion of the probe introduction equipment. This marker can be detected and identified by the MRI imaging system and method to store an orientation of the physical direction of the probe. The captured images, in implementations where pre-treatment image data is not available, can be used for planning a thermal therapy session.

In certain embodiments, a probe actuation and guidance device (e.g., a follower) and a test tool are attached to the probe introduction equipment, to provide positional feedback for a self-test function (412). The self-test function, for example, may be used to confirm that inputs to the probe actuation and guidance device, (e.g., from the workstation), accurately and/or precisely drive the probe. Upon complet-

ing the self-test function, the rotary test tool may be removed. Upon completing the procedure described in relation to FIG. 4A, the procedure equipment may be introduced and the procedure initiated.

Turning to FIG. 4B, a process flow diagram illustrates an exemplary method 420 for a treatment procedure. In certain embodiments, a probe is attached and inserted into the probe introduction equipment and/or the patient's skull (e.g., secured for manipulation via the probe actuation and guidance device) (422). Exemplary implementations of neurosurgical probes are discussed in below under the section entitled "Probes." It is noted that different types of probes can be used in conjunction different types of thermal therapy, for example, when an ROI is not in the brain. An MRI scan can then be conducted to ensure probe alignment is correct and confirm movement and delivery of the probe along the intended trajectory. In one example, the acquired image data can be displayed, along with pre-planning image data by the workstation 106. Using a graphical user interface (GUI), a user can adjust the probe displayed by the GUI by interacting with, for example, the GUI to match the probe artifact on the acquired image to ensure that the alignment and arrangement of the probe as physically placed in the probe introduction equipment and inserted into the patient coincides with the rendered probe at the workstation. The probe's trajectory, for example, can be adjusted to a desired position for delivering thermal energy, via interaction with the GUI. Further, the probe's rotational position can also be adjusted to a desired direction or angle for thermal delivery, via interaction with the GUI. Once the probe rendering presented by the GUI matches the probe artifact on the display, the user may confirm the trajectory via the GUI.

In certain embodiments, one or more scan planes are selected for cuing a thermal monitoring sequence via the MRI system's sequence protocol list (424). In another embodiment, a 3D volume is selected and in yet another embodiment, a linear contour is selected. Parameters associated with scan plane, in some examples, can be entered by a user via a workstation connected with the MRI system or directly into the thermal monitoring sequences protocol's geometry parameters of the MRI.

In certain embodiments, temperature feedback information and/or thermal dose profiles are initialized and monitored (426). For example, under a noise masking heading of the workstation interface, at least three reference points (e.g., six, twelve, twenty, etc.) can be selected by the user at the periphery of the ROI. The ROI, for example, may include an overlaid, orange noise mask in one or more image monitoring view panes to illustrate the intended thermal delivery area. The noise masking may be used to improve accuracy of temperature monitoring during tissue treatment.

In certain embodiments, energy delivery via the probe is actuated to begin the thermal therapy session (428). For example, once "Ready" indicator or the like is displayed under a laser status heading of the GUI at the workstation, the user may depress a foot pedal operatively connected to the workstation to deliver thermal energy to the ROI or a targeted tissue area within the ROT. Thermal energy can then be either continuously or intermittently delivered while monitoring thermal dose profiles, which can be presented as contours that are overlaid onto one or more (e.g., three) thermal monitoring view panes rendered by the GUI of the work station. Thermal delivery may be halted as desired or as necessary by releasing the foot pedal. The view panes, for example, may display an energy dose profile or thermal dose profile supplied by the probe, with respect to a specified time period and/or a specified targeted tissue area or ROI; the

thermal dose or energy dose profile can be displayed as a succession of temperature gradients. The thermal dose profiles and/or the temperature gradients permit the determination of an extent of cellular damage in the targeted tissue area and/or other effects upon the targeted tissue area occurring as a result of the thermal therapy.

Once a thermal dose for a particular alignment and positioning of the probe is completed, if further probe alignments are desired within the treatment plan (430), a rotational and/or linear alignment of the probe may be adjusted (432) by translating or rotating the probe. For example, an energy output of the probe may be terminated and then the probe may be subjected to linear translation and/or rotational movement, which can be controlled, for example, by a probe driver (a particular implementation of which is illustrated in FIG. 3). After adjusting the probe alignment, in certain embodiments, the process returns to step 422 to verify a current placement of the probe. In certain embodiments, a second thermal treatment procedure is not initiated (e.g., when repeating step 428) until one or more targeted tissue areas within the ROI returns to a baseline body temperature. The thermal dose associated with the one or more targeted tissue areas in the ROI, as described in relation to steps 422 through 432, may continue at various probe rotational and/or linear alignments until the entire ROI has been treated.

Upon determining that the thermal therapy is complete (430), should treatment with an additional probe be needed or desired (434), the procedure can be repeated by attaching the new probe to the probe introduction equipment and verifying probe placement (422). If, instead, the second probe was initially included within the probe introduction equipment (e.g., via a separate lumen in a guide sheath in relation to the first probe), the user may initiate positioning of the second probe, for example, via the GUI, and verify placement of the second probe (422). A multi-probe configuration is described in greater detail in relation to FIG. 5I.

If the second probe is being deployed to treat the same ROT or the same targeted tissue area at the same linear and rotational alignment(s) associated with the first probe, in certain embodiments, step 424 involving selection of scan planes for the cuing the thermal monitoring sequence may be skipped. If, instead, a second probe is deployed at a different linear position or a different trajectory, step 422 may be performed to confirm the trajectory and alignment of the second probe.

When the thermal therapy is complete (434), in certain embodiments, the patient is removed from the MRI bore and the probe, probe actuation and guidance device, and probe introduction equipment are detached from the patient. The bore hole may be closed, for example, at this time.

## II. Low Profile Probe Introduction Equipment

### A. Low Profile Skull Anchoring Device

In certain embodiments, when preparing for an intracranial neurosurgical procedure, a patient 502 is fitted with a low profile skull anchoring device 504, as illustrated in an exemplary mounting illustration 500 of FIG. 5A. The low profile skull anchoring device 504 may be releasably attached to the head of the patient 502, for example, using three or more bone anchors mounted to the skull of the patient 502. Turning to FIG. 5B, the low profile skull anchoring device 504 includes three bone screws 508 for connecting to bone anchors within the skull of the patient 502, as well as pins 510 for further securing the low profile skull anchoring device 504 to the head of the patient 502 and for ensuring that the low profile skull anchoring device 504 mounts above the surface of the head of the patient 502. In

this way, there will be minimal or no compression of the patient's scalp, and frameless, on-trajectory access is provide, as discussed in further detail below. In one embodiment, the low profile skull anchoring device 504 has an oval or an oblong shape.

In one embodiment, the screws 508 and pins 510 are composed of, for example, titanium. It should be noted that the screws 508 and the pins 510 are not necessarily limited to three pins; the number of screws 508 and pins 510 is the number which is necessary to provide sufficient rigidity. The screws 508 and pins 510 may be evenly spaced around the circumference of the low profile skull anchoring device 504 (e.g., positioned approximately every 120 degrees). In another embodiment, the screws 508 and pins 510 are positioned at unequal distances apart, for example, based on an irregular skull curvature. In yet another embodiment, the screws 508 and the pins 510 are movable with respect to the low profile skull anchoring device 504. In still another embodiment, the screws 508 are replaced with a sufficiently rigid adhesive or a staple, each of which provide sufficient rigidity to allow for the drilling of a burr hole in the skull.

Due to the low height of the low profile skull anchoring device 504, the medical team is provided with greater access for lateral trajectories of biopsy, probes, and other apparatus to be inserted intracranially into the patient 502 via the low profile skull anchoring device 504. This may be especially useful when working within the confines of an MRI bore, for example during MRI-guided thermal therapy treatments. As such, the low profile skull anchoring device 504 may be composed of MRI compatible materials and, optionally, include MRI visible markers for aligning a desired trajectory or defining a particular direction relative to the low profile skull anchoring device 504. In another example, the low profile skull anchoring device 504 may allow easier access to back-of-the-head entry trajectories, such as trajectories used in performing epilepsy treatments. A mounting height of the low profile skull anchoring device 504, for example, may be thirty millimeters or less from the surface of the skull of the patient 502.

In some implementations, the low profile skull anchoring device 504 includes one or more fiducial markers for reference within an MRI scan. For example, the low profile skull anchoring device 504 may include at least three fiducial markers used, in an MRI scan, to identify a position and orientation of the low profile skull anchoring device 504 as attached to the surface of the skull of the patient 502. In a particular example, three fiducial markers, at least one of which having a unique length, width, and/or shape in comparison to the others, may be positioned upon the low profile skull anchoring device 504 to allow for visual display and confirmation of a position and orientation of the low profile skull anchoring device 504 as attached to the skull of the patient 502. The fiducial marker(s) may be held in place via any suitable connector including, but not limited to, an adhesive or the like.

#### B. Removable Guide Stem

Turning to FIG. 5A, the low profile skull anchoring device 504 includes a removable guide stem 506. The removable guide stem 506, in some examples, may lock to the low profile skull anchoring device 504 using a screw mechanism, keyed locking mechanism, or other connector configured to firmly connect the removable guide stem 502 to the low profile skull anchoring device 504 with relative ease of removal.

Turning to FIG. 5B, the exemplary the low profile skull anchoring device 504 includes three connection points 512 for securing the removable guide stem 506 to the low profile

skull anchoring device 504. The removable guide stem 506, for example, may include a series of guide stem connectors 514 (e.g., screws or locking pins) which mate with the connection points 512 of the low profile skull anchoring device 504, as shown in FIGS. 5A and 5C. In one embodiment, the alignment of the guide stem connectors 514 and the connection points 512 differs based on a skull curvature of the patient.

A central cylindrical portion of the removable guide stem 506 is configured to receive various adapters and/or instruments such as, in some examples, drill bits, biopsy needles, and treatment probes. The central cylindrical portion of the removable guide stem 506, in certain embodiments, is rotatably adjustable, allowing an orientation of central cylindrical portion of the removable guide stem 506 to be manipulated to align the probe in accordance with a desired trajectory. Upon alignment, in certain embodiments, a locking mechanism 516 may be actuated to lock the central cylindrical portion of removable guide stem 506 into place at the set alignment.

Turning to FIG. 5C, the removable guide stem 506 may include, for example, a ball joint 518 for establishing an adjustable trajectory for passing instruments to the skull of the patient 502 via the central cylindrical portion of removable guide stem 506. In certain embodiments, the central portion has another geometric or polygonal shape that corresponds to a cross-section of the probe. In certain embodiments, interior portions of the central cylindrical portion of the removable guide stem 506 are deformable so as to cover an outer surface of the probe. In still other embodiments, the interior portions of the central cylindrical guide stem are comprised of shape memory alloys that have a transition temperature that exceeds a maximum temperature associated with a specified thermal therapy.

The ball joint 518 can achieve a number of trajectories that is based on the granularity with which the ball joint 518 is manipulated. Upon setting the trajectory of the central cylindrical portion of removable guide stem 506, for example, the ball joint 518 may be clamped into position using the locking mechanism 516. In one embodiment, the locking mechanism 516 is a cam lock. In another embodiment, the locking mechanism 516 is a ring clamp. In still another embodiment, the locking mechanism 516 has a screw engagement.

Turning to FIGS. 5D and 5E, illustrative examples of a removable guide stem 520 including both a tilt adjustment 522 and a rotation adjustment 524 are shown. The separate tilt adjustment 522 and rotation adjustment 524, for example, may be used to more precisely adjust a trajectory of the central cylindrical portion of removable guide stem 520. Upon adjusting the tilt adjustment 522, for example, a tilt lock mechanism 526 (e.g., screw, pin and slot, etc.) may be activated to hold the central cylindrical portion of removable guide stem 520 at the tilt position. In another example, upon adjusting the rotation of the central cylindrical portion of removable guide stem 520, for example by turning the rotation adjustment 524, a rotation lock mechanism 528 (e.g., screw, pin and slot, etc.) may be activated to hold the removable guide stem 520 at the selected rotation. In an embodiment, either or both of the tilt lock mechanism 526 and the rotation lock mechanism 528 are actuated by a motor. In another embodiment, the motor is wirelessly controlled via a remotely located controller. The removable guide stem 520 is removable during a thermal therapy session, prior to completion of the treatment, and independent of removing the low profile skull anchoring device 504.

In certain embodiments, guide lines such as a set of guide lines **530** are marked on the removable guide stem **520** (or the removable guide stem **506** illustrated in FIG. **5A**) to provide a user with an indication of the selected trajectory. For example, an angle of tilt in relation to the low profile skull anchor **504** may be selected via the guide lines **530** (e.g., within a one, two, or five degree angle of adjustment). The guide lines **530**, in certain embodiments, are MR indicators, such that an MR image captured of the removable guide stem **520** will allow a software package to register an initial trajectory in relation to the head of the patient (e.g., patient **502** of FIG. **5A**).

In certain embodiments, in addition to a tilt and rotation adjustment, either the first removable guide stem **506** or the second removable guide stem **520** may be modified to include an x,y degree of freedom adjustment mechanism (not illustrated). In this manner, a position of the central cylindrical portion of guide stem **506** in relation to a burr hole opening beneath the low profile skull anchor **504** may be adjusted by the user, thus providing on-trajectory access. Rather than the central cylindrical portion of guide stem **506** or **520** being centered within the low profile skull anchor **504**, for example, an x,y adjustment mechanism may allow an offset of the central cylindrical portion of removable guide stem **506** or **520**. In a particular example, should the burr hole fail to be centered between bone anchors planted within the skull of the patient **502**, the central cylindrical portion of guide stem **506** or **520** may be adjusted by up to at least ten to twenty millimeters to be centered above the burr hole using an x,y adjustment mechanism.

In some implementations, the removable guide stem **506** or **520** includes at least one fiducial marker for identifying, via an MRI scan, at least an angle of trajectory of the removable guide stem **506** or **520**. If the removable guide stem **506** or **520** additionally includes an adjustment mechanism, fiducial marker(s) may be used to identify the x,y offset of the removable guide stem **506** or **520** relative to the low profile anchoring device **504**.

Turning to FIG. **5B**, upon removal of the removable guide stem **506** or **520**, the skull entry location becomes accessible, for example to allow for formation of a burr hole or to otherwise prepare the skull entry location. After preparation of the entrance, the removable guide stem **506** or **520** may be locked to the low profile skull anchor **504**. For example, as illustrated in FIG. **5D**, the removable guide stem **520** may be locked to the low profile skull anchor device **504** by attaching screws at three connection locations **532**. At any point in a procedure, should access to the entrance be desired, the guide stem **520** may be removed. Removal of the guide stem **520**, for example, allows a medical professional quick access to react to bleeding or to adjust the burr hole opening for trajectory correction.

When performing a medical procedure via the low profile skull anchoring device **504**, in certain embodiments, the low profile skull anchoring device **504** may first be aligned with screw anchors mounted upon the patient's skull and then screwed to the head of the patient **502**, as illustrated in FIG. **5A**. The skull entry location may be prepared for treatment during the thermal therapy while the removable guide stem **506** or **520** has been separated from the low profile skull anchoring device **504**. Following preparation of the skull entry location, the removable guide stem **506** or **520** may be replaced and its trajectory aligned.

To align the removable guide stem **506**, **520** with a desired treatment trajectory, in certain embodiments, the removable guide stem **506**, **520** is manipulated via an image guided system (e.g., MRI-imaging system) or manipulated via a

trajectory planning module of an MRI-imaging method. The manipulations of the removable guide stem **506**, **520**, for example, may be performed by a probe actuation and guidance device. In a particular example, as described in relation to the method **400** of FIG. **4A**, a test tool may be inserted into the removable guide stem **506**, **520**, and the test tool may be aligned with pre-treatment image data to determine an initial trajectory. In other implementations, a user manually adjusts the trajectory of the removable guide stem **506**, **520**. Alignment of the trajectory of the removable guide stem **506**, **520**, in certain embodiments, is aided by one or more guide lines or fiducial markers upon the surface of the low profile skull anchoring device **504** and/or upon the surface of the removable guide stem **506**, **520**, such as the guide lines **530** illustrated in FIG. **5D**.

Upon positioning the trajectory of the removable guide stem **506**, **520**, in certain embodiments, the trajectory is locked via a locking mechanism, such as the locking mechanism **516** of FIG. **5C** or the locking mechanisms **526** and **528** of FIG. **5D**.

After the removable guide stem **502** has been locked into its initial trajectory, in certain embodiments, instruments may be guided into the skull via the removable guide stem **506** or **520**. For example, biopsy tools, a thermal treatment probe, medicament delivery probe, or other neurosurgical device may be delivered to a ROI of the brain of the patient via the removable guide stem **506** or **520**.

#### C. Guide Sheath

Turning to FIGS. **5F** and **5G**, in certain embodiments, rather than inserting instruments directly into the removable guide stem **506** or **520**, a guide sheath **540** is inserted into the removable guide stem (e.g., removable guide stem **506**). The guide sheath **540** may include, for example, one or more distal openings and one or more proximal openings to introduce at least one neurosurgical instrument to the ROI in the patient's brain.

In certain embodiments, instead of using the guide sheath **540** configured for receipt of neurosurgical devices, a hollow trocar may be introduced via the removable guide stem **506** or **520** to prepare an initial entry into a region of the brain. For example, when entering a particularly fibrous area, rather than pushing in directly with a neurosurgical instrument and risking damage to the neurosurgical instrument, a trocar and stylette, for example with a bullet shaped nose and sharp distal opening, may be used to cut a path for the neurosurgical instrument. In other implementations, a stylette or trocar may be introduced to the ROI via the guide sheath **540**. In one embodiment, the guide sheath **540** has a shape of a 3D almond. In another embodiment, a ball joint portion of the guide sheath **540** rotates around a track. In yet another embodiment, the probe holder is attached at a non-zero angle to the longitudinal access of at least a portion of the probe.

In certain embodiments, the guide sheath **540** locks to the removable guide stem **506**. The guide sheath **540**, for example, may be configured to lock to the removable guide stem **506** at a variable linear height depending upon a distance between the skull opening and a ROI. In this manner, the guide sheath **540** may be deployed in proximity to, in the vicinity of, or adjacent to an ROI without abutting or entering the ROI. As such, upon removal of one or more neurosurgical instruments via the guide sheath **540**, cells from the ROI will not be able to contaminate other regions of the patient's brain.

Turning back to FIG. **5C**, in certain embodiments, a guide stem locking mechanism **519** may be used to clamp the guide sheath **540** at a particular linear depth. The guide

sheath 540, in a particular example, may have spaced indentations or other connection points for interfacing with the guide stem locking mechanism 519 (e.g., set screw or spring-loaded plunger). The indentations (or, alternatively, ratcheting teeth) may be positioned at precise measurements (e.g., 1 mm apart) to aid in linear position adjustment. In other examples, the guide sheath 540 and guide stem locking mechanism 519 may be configured to provide positive feedback to a medical professional during adjustment. For example, a linear actuator system such as a rack and pinion may be used to provide precise linear position adjustment (e.g., one “click” per millimeter). Upon adjustment, to lock the guide sheath 540 at the selected linear position, in certain embodiments a cam lock mechanism may be used to engage teeth or depressions within the guide sheath 540. For example, a cam lock mechanism such as the locking mechanism 516 illustrated in FIG. 5C may be used to lock the guide sheath 540 at a selected linear depth.

Turning back to FIG. 5D, the removable guide stem 520 similarly includes a guide stem locking mechanism 534. In other implementations, the guide sheath 540 may directly connect to the low profile skull anchoring device 504 or to another receiving port connected to the low profile skull anchoring device 504 (not illustrated).

The guide sheath 540, upon interlocking with the guide stem 506, 520 and/or the low profile skull anchoring device 504 and receiving one or more neurosurgical tools, may create an air-tight seal during a neurosurgical operation. For example, the proximal and/or distal end of the guide sheath 540 may include a receiving port adaptable to the surgical instrument being introduced. In certain embodiments, various guide sheaths can be used interchangeably with the guide stem 506, 520, such that a guide sheath corresponding to the surgical instrument diameter may be selected. In other implementations, one or more guide sleeves (not illustrated) may be secured inside the guide sheath 540, each of the one or more guide sleeves having a different distal end diameter. A divided (e.g., bifurcated) guide sleeve, in certain embodiments, may be used to introduce two or more instruments simultaneously or concurrently, each with a particular instrument diameter.

In certain embodiments, the guide sheath 540 is intracranially delivered using an introducer and guide wire. An image guidance system, such as the MRI imaging system, may be used instead of or in addition to the introducer and guide wire during placement of the guide sheath 540. The guide sheath 540 may be composed of MRI compatible materials.

The materials of the guide sheath 540, in certain embodiments, are selected to provide rigid or inflexible support during introduction of one or more neurosurgical tools within the guide sheath 540. For example, the guide sheath 540 may be composed of one or more of Kevlar, carbon fiber, ceramic, polymer-based materials, or other MRI-compatible materials. The geometry of the guide sheath 540, in certain embodiments, further enhances the strength and rigidity of the guide sheath 540.

In certain embodiments, the guide sheath 540 (or guide sleeve, as described above) includes two or more lumens for introduction of various neurosurgical instruments. By introducing two or more neurosurgical instruments via the guide sheath 540, a series of treatments may be performed without interruption of the meninges layer between treatments. For example, FIG. 5I illustrates two neurosurgical instruments 552 and 554 that are simultaneously inserted into a guide sheath 550 and can be used to carry out treatment of a tissue consecutively, concurrently, or simultaneously.

Neurosurgical instruments deployed via the guide sheath 540 may exit a same distal opening or different distal openings. In certain embodiments, the guide sheath 540 may include at least one off-axis distal opening. For example, as illustrated in FIG. 5H, exemplary guide sheath 550 includes a contact surface 556 having a predefined angle. Upon encountering the contact surface 556, the trajectory of a surgical instrument 552 presented through the guide sheath 550 may be deflected to exit the proximal end via an off-axis delivery hole 558, as illustrated in FIG. 5I. The angles shown in FIGS. 5H and 5I can be considered as drawn to scale in one implementation. However, the alignment of the contact surface 556 and the delivery hole 558 can be varied by adjusting their respective axial angles. By adjusting these angles, a number of possible positions of the surgical instrument 554 are provided. Further, multiple off-axis delivery holes and multiple contact surfaces can be provided, which are displaced from each other in a direction of the longitudinal axis of the guide sheath.

Upon introducing a neurosurgical instrument such as a probe, in certain embodiments, the guide sheath 510 enables coupling between the probe and a probe actuation and guidance device. For example, commands for linear and/or rotational control of the probe may be issued to the probe via an interface within the guide sheath 540.

### III. Probes

A number of different probes can be utilized in accordance with the various aspects presented in this disclosure. Example probes are described in: U.S. Pat. No. 8,256,430 to Torchia, entitled “Hyperthermia Treatment and Probe Therefor” and filed Dec. 17, 2007; U.S. Pat. No. 7,691,100 to Torchia, entitled “Hyperthermia Treatment and Probe Therefor” and filed Aug. 25, 2006; U.S. Pat. No. 7,344,529 to Torchia, entitled “Hyperthermia Treatment and Probe Therefor” and filed Nov. 5, 2003; U.S. Pat. No. 7,167,741 to Torchia, entitled “Hyperthermia Treatment and Probe Therefor” and filed Dec. 14, 2001; PCT/CA01/00905, entitled “MRI Guided Hyperthermia Surgery” and filed Jun. 15, 2001, published as WO 2001/095821; and U.S. patent application Ser. No. 13/838,310, entitled “Image-Guided Therapy of a Tissue” and filed Mar. 15, 2013. These documents are incorporated herein by reference in their entireties.

A number of probe lengths are provided in any of the probe examples described herein based on a degree of longitudinal travel allowed by a follower and a depth of the tissue to be treated. An appropriate probe length can be determined by the interface platform and/or the workstation during a planning stage, or determined during a trajectory planning stage.

Exemplary probe lengths can be indicated on the probes with reference to a probe shaft color, in which white can indicate “extra short” having a ruler reading of 113 mm, yellow can indicate “short” having a ruler reading of 134 mm, green can indicate “medium” having a ruler reading of 155 mm, blue can indicate “long” having a ruler reading of 176 mm, and dark gray can indicate “extra long” having a ruler reading of 197 mm. Different model numberings can also be utilized on the probes to indicate different lengths.

An energy output pattern of a probe, such as a laser probe or HIFU probe, in certain embodiments, includes a pulsed output pattern. For example, a higher power density may be achieved without causing tissue scorching by pulsing a high power laser treatment for x seconds with y seconds break between (e.g., allowing for tissue in the immediate vicinity to cool down). In a particular example, the energy output pattern of a probe may include a ten Watt output for two seconds followed by a one second period of inactivity. In

certain embodiments, a particular energy output pattern may be developed based upon the type of probe (e.g., laser, HIFU, etc.), an emission style of the probe tip (e.g., side-firing, diffuse tip, etc.), and/or the depth of the ROI or the targeted tissue area (e.g., based in part on the shape of a tumor region, etc.).

In certain embodiments, a treatment pattern includes effecting treatment while concurrently or simultaneously moving the probe (e.g., linearly and/or rotationally). For example, a HIFU probe may be automatically rotated (e.g., using a commander and follower as described in FIG. 3, etc.) while an emission pattern is simultaneously or concurrently adjusted to effect treatment to a desired depth based upon a particular geometry of the ROI. In this manner, for example, while the ultrasonic probe's beam is focused on a radial portion of the tumor having a depth of 1.5 centimeters, the power density of the HIFU probe may be tuned for the first treatment depth. Upon rotation, a second radial portion of the tumor may have a depth of 2 centimeters, and the power density of the HIFU probe may be increased accordingly to tune for the treatment depth of 2 centimeters.

#### A. Side-Fire HIFU Probe

Turning to FIG. 9A, a view 900 of an exemplary treatment scenario involving a HIFU probe 902 deployed to treat an ROI 906 is illustrated. HIFU technology advantageously provides directional control and greater depth penetration as compared with laser-based thermal therapy. For example, in comparison to laser therapy, ultrasonic therapy may achieve at least three to four times greater depth penetration. For example, estimated depths of thermal treatment using HIFU technology include three to five centimeters or greater than six centimeters. By completing treatment via an initial trajectory, the treatment may be performed faster and less invasively than it may have been performed using a laser probe. As such, a HIFU probe may be used to treat a larger ROI without the need to adjust a probe trajectory or introduce the probe into multiple locations within the brain. Although treatment may be provided at a greater depth, it also may be provided using a narrow focal beam, containing a width of the treated tissue. Furthermore, although HIFU-based thermal therapy can advantageously achieve a greater penetration depth than laser-based thermal therapy, the ultrasonic treatment has greater uniformity over temperature gradients than laser-based thermal therapy, which heats a portion of the targeted tissue area close to the probe much more rapidly than portions of the targeted tissue area further away from the probe. In selecting thermal therapy via a HIFU probe, scorching or carbonization of the targeted tissue area close to the probe may be avoided and/or the HIFU probe may be operated independently of external cooling to protect immediately surrounding tissue.

In performing thermal therapy using a HIFU probe, constructive and destructive interference can be utilized by selecting a number of different longitudinal spaced emission points to fine tune a position and depth of energy applied to a targeted tissue area and/or an ROI. As such, the depth of energy, as such, may be tuned to conform with a non-uniform, irregular, and/or non-polygonal shape of the ROI which, for example, corresponds to a tumor. Preparing trajectories, determining linear translational adjustments and/or rotational movements, and/or energy output patterns may be selected and/or optimized to prevent heating of the skull and/or bouncing energy off of the surfaces of the skull. HIFU treatment, in some examples, can be used for opening a blood-brain barrier, coagulation of tissue, or cavitation of tissue.

The HIFU probe 902 includes one or more side-firing transducers 904 for effecting treatment to the ROI 906. The ultrasonic transducer(s) 904 may be flat or rounded. The HIFU probe, in some examples, can include a shaft composed of plastic, brass, titanium, ceramic, polymer-based materials, or other MRI-compatible materials in which one or more ultrasonic transducer(s) 904 have been mounted. The ultrasonic transducer(s) 904 may be mounted upon an interior surface of the shaft of the HIFU probe 902. The ultrasonic transducer(s) 904 may include a linear array of individually controllable transducers, such that a frequency or power output of each transducer 904 may be individually tuned to control a treatment beam of the HIFU probe 902. For example, as illustrated in FIG. 9C, the tip of the probe 902 can include a linear array of three transducers 904. The longitudinally spaced apart transducers 904 can be spaced equally apart. However, in other implementations, the spacing between the transducers 904 can be unequal.

In certain embodiments, the HIFU probe 902 includes a cooling mechanism for cooling the ultrasonic transducers 904. For example, a cooling fluid or gas may be delivered to the tip of the HIFU probe 902 to control a temperature of the ultrasonic transducer(s) 904. Additionally, the ultrasonic transducer(s) 904 may be surrounded by an acoustic medium, such as an acoustic coupling fluid (e.g., water) to enable ultrasonic frequency tuning of the ultrasonic transducer(s) 904.

As illustrated in FIG. 9A, the HIFU probe 902 is embedded within an ROI 906 spanning multiple MR thermal monitoring planes 908. During treatment, thermal effects within each MR thermal monitoring plane 908 may be monitored in order to monitor thermal coagulation of the ROI 906. Information derived from the thermal monitoring, for example, may be fed back into control algorithms of the HIFU probe 902, for example, to adjust a power intensity and/or frequency of the HIFU probe to tune a depth of treatment of the ultrasonic beam or to adjust a rotational and/or linear positioning of the HIFU probe 902 upon determining that ablation is achieved at a current rotational and linear position.

To increase the monitoring region, additional MR thermal monitoring planes 908 may be monitored (e.g., between four and eight planes, up to twelve planes, etc.). Alternatively, in certain embodiments, the three thermal monitoring planes 908 may be spread out over the y-axis such that a first gap exists between plane 908a and plane 908b and a second gap exists between plane 908b and plane 908c. The thermal monitoring algorithm, in this circumstance, can interpolate data between the MR thermal monitoring planes 908.

In other implementations, rather than obtaining parallel images of MR thermal monitoring planes, at least three thermal monitoring planes, each at a distinct imaging angle bisecting an axis defined by a neurosurgical instrument such as a thermal ablation probe, may be interpolated to obtain thermal data regarding a three-dimensional region.

Turning to FIG. 10A, an aspect illustration 1000 demonstrates three MR thermal monitoring planes 1002 for monitoring ablation of an ROI 1004 by a probe 1006. The angles between the thermal monitoring planes, in some examples, may be based upon an anatomy of the region of the skull of the patient or a shape of the ROI. The angles, in some examples, may differ by at least ten degrees.

Turning to FIG. 10B, an end view 1010 of the probe 1006 provides an illustrative example of MR thermal monitoring planes 1002 that are each offset by sixty degrees. In comparison to using parallel MR thermal monitoring planes, the thermal monitoring planes 1002 provide a more realistic

three-dimensional space. Thus, volumetric visualization is provided. In certain embodiments, volumetric visualization that independent of ablation is provided. Temperature gradients and/or thermal dose profiles between the thermal monitoring planes **1002** can be interpolated. Similar to increasing a number of parallel MR thermal monitoring planes, in other implementations, four or more thermal monitoring planes may be captured and combined, for example, to increase thermal monitoring accuracy.

As a result of the side-firing capability of the HIFU probe **902**, a number of rotationally different portions of the ROI can be treated with the ultrasonic energy by rotating the HIFU probe **902**. For example, as illustrated in an x-axis sectional view **910**, the HIFU probe **902** may be rotated as illustrated in an arrow **912** to effect treatment throughout the ROI **906**. Additionally, the HIFU probe **902** can be longitudinally translated, for example automatically by a follower of a probe driver, to change a longitudinal position at which ultrasonic energy is applied within the ROI **906**.

Rotation, power intensity, duty cycle, longitudinal positioning, and cooling, in certain embodiments, are controlled by the electronics rack **104** and the workstation **106**, such as the electronics rack **104** and workstation **106** described in relation to FIG. 1. A sequence, such as an algorithm or software encoding, can be executed to cause a probe tip or a number of probe tips to execute a particular energy output pattern effect a predefined thermal therapy to a targeted tissue area. The energy output pattern can be based on rotational and/or longitudinal movements of the probe.

#### B. Pre-Shaped Probe

Turning to FIG. 8, in certain embodiments, a probe delivery apparatus **800** includes a pre-shaped probe **802** (e.g., laser probe) that accesses an ROI **806** along a curved path. The pre-shaped probe **802** can be provided proximate to the ROI **806** through a rigid sheath **804** or guide cannula. Although the rigid sheath **804** is straight, the pre-shaped probe **802** is flexible such that it exits the rigid sheath **804** in a predetermined arc. The curvature of the pre-shaped probe **802**, for example, can be configured to deploy towards a known radial position, for example in a quarter arc of a circle. In exiting the rigid sheath **804**, the pre-shaped probe **802** follows a clean arc along a path into the ROI **806**. In this manner, the pre-shaped probe **802** avoids tearing tissue, for example due to pushing a distal end of the probe against the targeted tissue area and/or an ROI.

In certain embodiments, the pre-shaped probe **802** includes a wire and/or polymer encasement for a laser fiber. The materials of the pre-shaped probe **802**, for example, may prevent the laser probe (and optical fiber corresponding thereto) from straightening, which is its natural inclination. The pre-shaped probe **802**, in certain embodiments, is composed of MRI-compatible materials to enable use in MRI-guided neurosurgery. In one example, the pre-shaped probe may include a polymer tubing with a pre-curved band to the probe tip, surrounding a laser fiber. In certain embodiments, a tip region of the pre-shaped probe **802** includes at least one fiducial marker to aid in validating an angle of deployment from the rigid sheath **804**.

During thermal therapy, the pre-shaped probe **802**, in certain embodiments, may be deployed into the ROI **806** at a first location, then withdrawn into the rigid sheath **804**, rotated, and deployed into the ROI **806** at a different radial location. A range outline **808** demonstrates a rotational range of the pre-shaped probe **802** at a current linear position. Rotational adjustment of the pre-shaped probe **802** may be repeated a number of times, for example to effect treatment spanning substantially a full rotational range **808**. Addition-

ally, upon withdrawal, the rigid sheath **804** may be made linearly adjusted (e.g., manually or automatically using a probe driver) and the pre-shaped probe **802** deployed in a different linear region at the same or a different rotational projection.

In some examples, a length of the rigid sheath **804** can be approximately twelve to fifteen centimeters, and a diameter of the rigid sheath **804** can be approximately three-tenths of a centimeter to one centimeter. A diameter of the pre-shaped probe **802** can be one-tenth of a millimeter to three millimeters. A curved extension of the pre-shaped probe, for example, may be about one to two centimeters. The pre-shaped probe **802** can include one or more energy delivery elements. For example, the pre-shaped probe may include a diffuse laser emission tip. In certain embodiments, the pre-shaped probe **802** includes a cooling element. Examples of energy element and cooling element configurations of laser probes are illustrated, for example, in U.S. patent application Ser. No. 13/838,310 to Tyc, filed Mar. 14, 2013 and titled "Image-Guided Therapy of a Tissue," incorporated herein by reference in its entirety.

In certain embodiments, additional neurosurgical instruments may be provided to the ROI **806** via the rigid sheath **804** along with the pre-shaped probe **802**. For example, the pre-shaped probe **802** may be positioned within the rigid sheath **804** along with other probes to be used consecutively, contemporaneously, simultaneously or concurrently with the pre-shaped probe **802**.

#### IV. Head Coil and Stabilization

Prior to positioning in an MRI bore, a head fixation ring is attached to the patient's head to ensure a fixed position during the thermal therapy. A standard fixation ring can be problematic, both in fitting various sizes of patients and in the difficulty of positioning the patient within the ring. For example, patients with spinal deformation or unusually large heads (e.g., due to steroid treatments) may be difficult to position within the standard fixation ring, which is pre-formed.

Turning to FIG. 6A, rather than using a standard size fixation ring for fixating a patient's head, a head fixation system **600** includes an upper ring portion **602** and a lower ring portion **604**. A patient's head may be laid upon the lower ring portion **604**, and the upper ring portion **602** may be lowered and connected to the lower ring portion **604** such that the patient's nose is aligned with an indent **606** of the upper ring portion **602**.

In certain embodiments, the upper ring portion **602** connects with the lower ring portion **604** in an adjustable fashion, providing for a secure and close fit for a variety of head sizes. In other embodiments, various sizes of upper ring portions **602** may be provided, such that, rather than connecting to form a circular ring, each upper ring portion extends to form an ovoid shape of the head fixation system **600** to a different length.

As illustrated in FIG. 6A, the lower ring portion **604** includes a number of support posts **608** for aiding in fixation of the head. The support posts **608**, in certain embodiments, are selectively positioned in a number of support post mounting slots **610** arranged radially along both the upper ring portion **602** and the lower ring portion **604**. As illustrated, there are six support post mounting slots **610** arranged on the upper ring **602** and seven support post mounting slots **610** arranged on the lower ring **604**. In other implementations (not illustrated), the support posts **608** are mounted in fixed positions upon one or both of the upper ring portion **602** and the lower ring portion **604**. The number of support post mounting slots **610** may vary. Additionally,

in another embodiment, the support posts **608** may selectively mount by two or more pegs or posts connected to each support post **608** rather than by a single connection point (e.g., support post mounting slot **610**).

The support posts **608** can be used to introduce a number of fasteners, such as a set of skull pins **612a** and **612b**, for affixing the ring portions **602**, **604** to the head of the patient. As illustrated, each support post **608** includes a series of four pin mounts for mounting a skull pin **612**. In another example, each support post **608** may include a number of offset pin mounts (not illustrated), such that the pin mounts will not necessarily be centered upon the support post. In this manner, the medical professional may adjust both radial pinning locations via the support post mounting slots **610** and linear pinning locations via the pin mounts of each support post **608** to adaptably secure a patient within the head fixation system **600**. In other implementations, rather than using pins, a passive fixation system can provide conforming abutments, such as formable pads, for closely securing the head of the patient within the head fixation system **600** without the use of pins **612**. The conforming abutments, in one embodiment, are fixedly mounted to each support post **608**. In other embodiments, the conforming abutments may be releasably connected in a manner similar to the fixation pins **612**.

A patient's head can be positioned into the lower ring portion **604** and onto skull pins **612**. The lower ring portion **604**, for example, may be mounted within a channel **622** of a ring mount **624** of a platform **620**, as illustrated in FIGS. **6D** and **6E**. The upper ring portion **602** may then be lowered into place, connecting with the lower ring portion **604** (e.g., at mating points **616** and **618**). The mating points **616** and **618**, in certain embodiments, include spaced indentations or openings for interfacing with a locking mechanism such as a set screw or spring-loaded plunger. In other implementations, the head fixation system **600** may have spaced ratcheting teeth on one of the ring portions **602**, **604** for interfacing with a ball plunger or toggle release mounted on the other ring portion **602**, **604**. In further implementations, a linear actuator system such as a rack and pinion may be used to provide position adjustment (e.g., one "click" per linear setting), lockable, for example, using a cam lock.

Positions of the support posts **608** and/or skull pins of the upper ring portion **602** may be adjusted. When a desired positioning has been achieved, the upper ring portion **602** may be locked to the lower ring portion **604**, as illustrated in FIG. **6B**.

Turning to FIG. **6C**, in a particular example, a locking mechanism **614** demonstrates that the upper ring portion **602** may lock to the lower ring portion **604** using keyed shapes secured with a fastener, such as a thumb screw. After locking the upper ring portion **602** to the lower ring portion **604**, the skull pins can be tightened to achieve appropriate fixation. At this point, in certain embodiments, the patient can be wheeled upon the platform **620** to an MRI room, where users can utilize the handles **626** to move the fixated patient from, e.g., a wheeled operating table to an MRI table. In other implementations, the platform is part of the MRI table, for example as illustrated in FIG. **2**. The fixation system **600** may be locked to the ring mount **624** via knobs **628**.

In certain embodiments, upon positioning the head fixation system **600** into the ring mount **624**, an angle of the head of the patient can be adjusted. For example, turning to FIG. **6D**, the head fixation system **600** (not illustrated) may be rotated within the channel **622** (e.g., up to fifty degrees to either the left or the right) prior to locking the head fixation system **600** into the ring mount **624** via the knobs **628**.

The head fixation system **600**, in certain embodiments, includes one or more fiducial markers used, for example, to identify a position or type of head fixation ring. For example, if the upper ring portion **602** is one of a set of various radiuses of upper ring portions, one or more fiducial markers may identify the particular upper ring portion **602** selected. In another example, one or more fiducial markers can be used to identify an angle of rotation of the head fixation system **600** from a central position (e.g., nose indent **606** pointing upwards). The fiducial markers, in a particular example, may be arranged radially upon an exterior of at least one of the upper ring portion **602** and the lower ring portion **604**) for aiding in registration of an MR image. Furthermore, the fiducial markers may be used by a software tool to provide modeling for the head fixation system **600** in relation to an instrument introduction apparatus, neurosurgical instruments, and/or other medical equipment used during the neurosurgical procedure. The fiducial markers, for example, may provide the software with an indication of angle of rotation of the head of the patient.

After attaching the head fixation system **600** to the patient, a head coil can be fixed to the head fixation system **600** and/or a head coil support **630**. For example, turning to FIG. **2**, a patient is arranged on a patient table **108** in a bore of the MRI system **110**. The patient's head **210** is fixed to a head fixation ring **204** by fixation pins. The head fixation ring **204** is received in a ring mount of the patient table **108**, for example the ring mount **624** illustrated in FIG. **6E**. The patient table **108** extends, in a direction away from the bore of the MRI system **110**, providing a head coil support.

Turning to FIG. **7**, a head coil system **700** including a coil holder **702** that accommodates various off-the-shelf MRI coils, such as an MRI coil **704** is illustrated. The coil holder **702**, for example, can include adjustable attachment points for attaching the MRI coil **704** to the coil holder **702**. The adjustable attachment points, for example, can include mated fastener openings **708**, **710** between a cover **706** and the coil **704**. The cover **706**, for example, may align over the MRI coil **704** such that fastener openings **708** in the cover **706** align with fastener openings **710** within the coil **704** to hold the coil **704** in place against the coil holder **702**. The MRI coil **704** may be aligned with openings in the MRI coil **704** positioned to expose one or more fastener attachment points **712**. The user may then secure the MRI coil **704** to the coil holder **702** by attaching fasteners through the fastener openings **708**, **710** of the cover **706** to fastener attachment points **712** upon the coil holder **702**. Any number of fastener openings **708**, **710** and fastener attachment points **712** can be included the head coil system **700** to accommodate a variety of off-the-shelf MRI coils, such that the coil holder **702** and cover **706** provide a "universal" attachment system for a number of styles and/or brands of off-the-shelf MRI coils. In other implementations, rather than including fastener openings **708**, **710** in the cover **706** and fastener attachment points **712** upon the coil holder **702**, the cover **706** may mateably engage with the coil holder **702**. For example, upon positioning the MRI coil **704** within the coil holder **702**, the cover **706** may be slid into mating grooves and snapped into place, securing the MRI coil **704**. In another example, latches or clips formed into one of the coil holder **702** and the cover **706** may mate to opposing connection points on the other of the coil holder **702** and the cover **706**. Rather than the cover **706**, in certain embodiments, two or more attachment bands or sections may releasably attach to the coil holder **702** (e.g., in a manner described above in relation to the cover **706**), securing the MRI coil **704** in place.

The head coil system **700**, in certain embodiments, includes openings that provide access for neurosurgical instruments, such as an opening **714**. A user can adjust the openings to align the openings with a desired trajectory. Due to the open structure of the head coil system **700**, while a patient is positioned within the head coil system **700**, a surgical team has access to a wide variety of trajectories for performing neurosurgical operations, such as a trajectory at or near a side to forehead region of the patient's head, a trajectory at a side of the patient's head, or a trajectory at the top of the patient's head. The components of the head coil system **700** are easily released to incorporate different MRI coils.

After the user has achieved a desired alignment and positioned the patient within the MRI bore with the head coil system **700**, the user can connect the head coil system **700** to a cable to energize the MRI coil **704**. Further, the user can drape the patient and attach probe introduction equipment, such as a miniframe or low profile skull anchor and guide. Due to a smooth inner surface of the head coil system **700**, surgical draping of the patient is simplified.

The procedures and routines described herein can be embodied as a system, method or computer program product, and can be executed via one or more dedicated circuits or programmed processors. Accordingly, the descriptions provided herein may take the form of exclusively hardware, exclusively software executed on hardware (including firmware, resident software, micro-code, etc.), or through a combination of dedicated hardware components and general processors that are configured by specific algorithms and process codes. Hardware components are referred to as a "circuit," "module," "unit," "device," or "system." Executable code that is executed by hardware is embodied on a tangible memory device, such as a computer program product. Examples include CDs, DVDs, flash drives, hard disk units, ROMs, RAMs and other memory devices.

FIG. **11** illustrates an exemplary processing system **1100**, and illustrates example hardware found in a controller or computing system (such as a personal computer, i.e., a laptop or desktop computer, which can embody a workstation according to this disclosure) for implementing and/or executing the processes, algorithms and/or methods described in this disclosure. The processing system **1100** in accordance with this disclosure can be implemented in one or more the components shown in FIG. **1**. One or more processing systems can be provided to collectively and/or cooperatively implement the processes and algorithms discussed herein.

As shown in FIG. **11**, the processing system **1100** in accordance with this disclosure can be implemented using a microprocessor **1102** or its equivalent, such as a central processing unit (CPU) and/or at least one application specific processor ASP (not shown). The microprocessor **1102** is a circuit that utilizes a computer readable storage medium **1104**, such as a memory circuit (e.g., ROM, EPROM, EEPROM, flash memory, static memory, DRAM, SDRAM, and their equivalents), configured to control the microprocessor **1102** to perform and/or control the processes and systems of this disclosure. Other storage mediums can be controlled via a controller, such as a disk controller **1106**, which can controls a hard disk drive or optical disk drive.

The microprocessor **1102** or aspects thereof, in alternate implementations, can include or exclusively include a logic device for augmenting or fully implementing this disclosure. Such a logic device includes, but is not limited to, an application-specific integrated circuit (ASIC), a field programmable gate array (FPGA), a generic-array of logic

(GAL), and their equivalents. The microprocessor **1102** can be a separate device or a single processing mechanism. Further, this disclosure can benefit from parallel processing capabilities of a multi-cored CPU.

In another aspect, results of processing in accordance with this disclosure can be displayed via a display controller **1108** to a display device (e.g., monitor) **1110**. The display controller **1108** preferably includes at least one graphic processing unit, which can be provided by a number of graphics processing cores, for improved computational efficiency. Additionally, an I/O (input/output) interface **1112** is provided for inputting signals and/or data from microphones, speakers, cameras, a mouse, a keyboard, a touch-based display or pad interface, etc., which can be connected to the I/O interface as a peripheral **1114**. For example, a keyboard or a pointing device for controlling parameters of the various processes and algorithms of this disclosure can be connected to the I/O interface **1112** to provide additional functionality and configuration options, or control display characteristics. An audio processor **1122** may be used to process signals obtained from I/O devices such as a microphone, or to generate signals to I/O devices such as a speaker. Moreover, the display device **1110** can be provided with a touch-sensitive interface for providing a command/instruction interface.

The above-noted components can be coupled to a network **1116**, such as the Internet or a local intranet, via a network interface **1118** for the transmission or reception of data, including controllable parameters. A central BUS **1120** is provided to connect the above hardware components together and provides at least one path for digital communication there between.

The workstation shown in FIG. **1** can be implemented using one or more processing systems in accordance with that shown in FIG. **11**. For example, the workstation can provide control signals to peripheral devices attached to the I/O interface **1112**, such as actuators **1124** to drive probe positioning and actuation equipment. The workstation, in certain embodiments, can communicate with additional computing systems, such as an imaging unit **1126** and/or an MRI unit **1128**, via the I/O interface **1112**.

One or more processors can be utilized to implement any functions and/or algorithms described herein, unless explicitly stated otherwise. Also, the equipment rack and the interface platform each include hardware similar to that shown in FIG. **11**, with appropriate changes to control specific hardware thereof.

Reference has been made to flowchart illustrations and block diagrams of methods, systems and computer program products according to implementations of this disclosure. Aspects thereof are implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

These computer program instructions may also be stored in a computer-readable medium that can direct a computer or other programmable data processing apparatus to function in a particular manner, such that the instructions stored in the computer-readable medium produce an article of manufacture including instruction means which implement the function/act specified in the flowchart and/or block diagram block or blocks.

The computer program instructions may also be loaded onto a computer or other programmable data processing apparatus to cause a series of operational steps to be performed on the computer or other programmable apparatus to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of this disclosure. For example, preferable results may be achieved if the steps of the disclosed techniques were performed in a different sequence, if components in the disclosed systems were combined in a different manner, or if the components were replaced or supplemented by other components. The functions, processes and algorithms described herein may be performed in hardware or software executed by hardware, including computer processors and/or programmable circuits configured to execute program code and/or computer instructions to execute the functions, processes and algorithms described herein. Additionally, certain embodiments may be performed on modules or hardware not identical to those described. Accordingly, other implementations are within the scope that may be claimed.

The invention claimed is:

1. A system for introducing neurosurgical instruments into a skull of a patient, comprising:

a low profile skull anchor device comprising attachment means to attach to an area of a skull of a patient, wherein

the low profile skull anchor device comprises a central opening for providing access to an entry formed in the skull of the patient, and

the attachment means provides a mounting height of the low profile skull anchor device of 30 millimeters or less from a surface of the skull of the patient;

a removable guide stem comprising a locking means for detachably connecting the guide stem to the low profile skull anchor device;

a guide sheath for inserting a neurosurgical instrument, wherein the guide sheath comprises a proximal opening and at least one distal opening and is configured to extend beyond the low profile skull anchor device and into the entry formed in the skull of the patient; and

a pre-shaped probe for delivery of thermal therapy to a three-dimensional region of tissue in the skull of the patient, the pre-shaped probe having a pre-determined angle of curvature such that the pre-shaped probe is configured to exit the at least one distal opening of the guide sheath following a predetermined curved trajectory path.

2. The system of claim 1, further comprising: a height locking means for locking a height of the guide sheath.

3. The system of claim 2, wherein the guide sheath comprises a plurality of connection points for mating with the height locking means.

4. The system of claim 3, wherein each consecutive pair of connection points of the plurality of connection points is separated by a precise distance to enable selection of a particular height of a plurality of heights.

5. The system of claim 2, further comprising a second guide sheath for introduction of another neurosurgical instrument, wherein a diameter of the distal opening of the second guide sheath is smaller than the diameter of the distal opening of the guide sheath.

6. The system of claim 5, wherein the second guide sheath is configured for insertion within the guide sheath.

7. The system of claim 1, further comprising a second guide sheath having a smaller diameter opening than the guide sheath, wherein the guide sheath and the second guide sheath are configured to be interchangeably connected to the low profile skull anchor device.

8. The system of claim 7, wherein a shape of the opening of the second guide sheath is different from a shape of an opening of the guide sheath.

9. The system of claim 1, wherein the pre-shaped probe is a laser probe having a diameter of between one-tenth of a millimeter to three millimeters.

10. The system of claim 1, wherein a portion of the pre-shaped probe having the predetermined angle of curvature is between one millimeter to two centimeters in length.

11. The system of claim 1, wherein the pre-determined angle of curvature is maintained by a flexible encasement.

12. The system of claim 11, wherein the flexible encasement comprises a polymer tubing surrounding a laser fiber.

13. The system of claim 1, wherein the guide sheath comprises at least two lumens, wherein the pre-shaped probe is configured for introduction via a first lumen of the at least two lumens, and an additional instrument is configured for contemporaneous introduction via a second lumen of the at least two lumens.

14. The system of claim 1, wherein the pre-shaped probe comprises at least one fiducial marker for validating an angle of deployment during image-guided therapy.

15. The system of claim 1, wherein at least a portion of an interior portion of a central cylindrical portion of the removable guide stem is deformable so as to cover an outer surface of the probe.

16. The system of claim 15, wherein at least a portion of the interior portion of the central cylindrical guide stem is comprised of a shape memory alloy material having a transition temperature that exceeds a maximum temperature associated with a specified thermal therapy.

\* \* \* \* \*

专利名称(译)	组织的图像引导治疗		
公开(公告)号	<a href="#">US10092367</a>	公开(公告)日	2018-10-09
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[标]申请(专利权)人(译)	曼特瑞斯醫藥有限責任公司		
申请(专利权)人(译)	MONTERIS医疗法人		
当前申请(专利权)人(译)	MONTERIS医疗法人		
[标]发明人	ANDREWS ERIC GRANT MARK REN BROOKE TYC RICHARD		
发明人	ANDREWS, ERIC GRANT, MARK REN, BROOKE TYC, RICHARD		
IPC分类号	A61B90/14 A61B6/04 A61B17/17 A61B5/01 A61B17/34 A61B17/00 A61B18/14 A61B34/20 A61B90/50 A61B90/11 A61B34/10 A61B90/00 A61B6/03 A61B18/22 A61N5/06 A61F5/37 A61B5/055 A61B5/00 A61B18/04 A61B18/00 A61B90/10 A61N7/00 A61N5/10 A61B18/02 A61B18/18 A61N7/02		
CPC分类号	A61B90/14 A61B5/015 A61B5/0555 A61B5/4839 A61B5/702 A61B5/742 A61B5/748 A61B6/032 A61B6 /04 A61B6/0421 A61B6/0492 A61B17/00234 A61B17/1703 A61B17/1739 A61B17/3403 A61B18/04 A61B18/1477 A61B18/1492 A61B18/22 A61B34/10 A61B34/20 A61B90/11 A61B90/37 A61B90/50 A61F5/37 A61F5/3707 A61N5/062 A61N7/02 A61N7/022 A61B5/0042 A61N2007/025 A61B5/0035 A61B5/01 A61B5/055 A61B2018/00011 A61B2018/00321 A61B2018/00446 A61B2018/00791 A61B2018/0293 A61B2018/1869 A61B2034/107 A61B2034/2051 A61B2034/2065 A61B2090/103 A61B2090/374 A61B2090/3954 A61B2576/026 A61N5/1048 A61N2005/1051 A61N2005/1055 A61N2005/1097 A61N2007/003 A61N2007/0047 A61B2018/20361 G16H30/40		
优先权	61/955124 2014-03-18 US		
其他公开文献	US20160354175A1		
外部链接	<a href="#">Espacenet</a>		

摘要(译)

组织的图像引导治疗可以利用磁共振成像 (MRI) 或其他医学成像设备来引导组织内的器械。工作站可以致动器械的运动，并且可以致动器械的能量发射和/或冷却以实现组织的治疗。工作站和/或工作站的用户可以位于MRI设备或其他医学成像设备附近之外，并且用于定位器械的驱动装置可以位于MRI设备或其他医学成像设备的附近。该器械可以是MRI兼容激光器或高强度聚焦超声探头，其为例如患者脑中的组织提供治疗。

