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(54) **Title:** 3D PRINTED, CUSTOMIZED ANTENNA NAVIGATION FOR ABLATING TISSUE

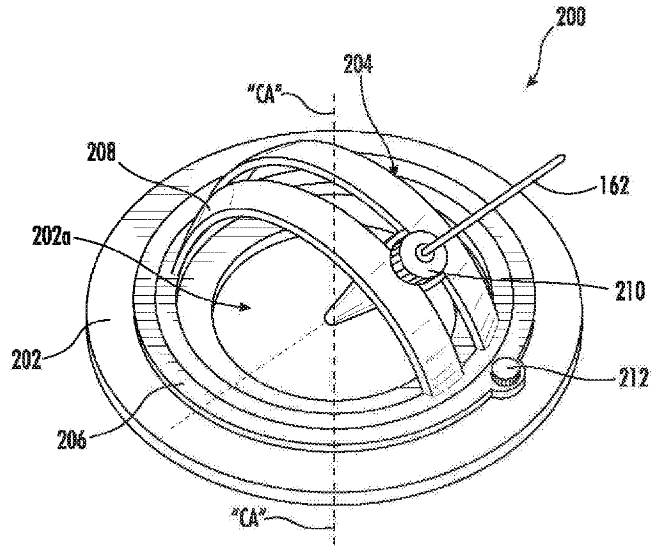

FIG. 4

(57) **Abstract:** An ablation system includes an ablation antenna, a generator coupled to the ablation antenna, and a customized navigation system. The customized navigation system includes a 3D printed base and an antenna support assembly. The 3D printed base is customized to a patient's body and configured to mount to the patient's body. The antenna support assembly is configured to mount to the 3D printed base. The antenna support assembly includes a fixer that is selectively movable relative to the 3D printed base and is configured to receive the ablation antenna therethrough.

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3D PRINTED, CUSTOMIZED ANTENNA NAVIGATION FOR ABLATING TISSUE

TECHNICAL FIELD

[0001] The present disclosure relates to ablation, and more particularly, to methods and devices for navigating ablation devices.

BACKGROUND

[0002] Treatment of certain diseases requires the destruction of malignant tissue growths, e.g., tumors. In this regard, electrosurgical devices utilizing electromagnetic radiation have been developed to heat and destroy tumor cells. For example, apparatus for use in ablation procedures include a power generation source, e.g., a microwave or radio frequency (RF) electrosurgical generator that functions as an energy source, and a surgical instrument (e.g., ablation probe having an antenna assembly) for directing energy to the target tissue. A cable assembly having a plurality of conductors operatively couple and transmit energy from the generator to the instrument. The cable assembly also communicates control, feedback and identification signals between the instrument and the generator.

[0003] During treatment, the antenna assembly may be inserted into tissues where cancerous cells have been identified so that energy can be applied to the cancerous cells for denaturing them. Due to variations in patient body size and body movement resulting from ventilation, for example, during a liver cancer ablation procedure, the challenge of achieving physician proficiency during such ablation procedures remains critical. Thus, there is a need to develop advanced ablation planning and navigation tools that can improve specificity and accuracy of ablative procedures as well as physician proficiency.

SUMMARY

[0004] According to an aspect of the present disclosure, an ablation system includes an ablation antenna, a generator coupled to the ablation antenna, and a customized navigation system. The customized navigation system includes a 3D printed base and an antenna support assembly. The 3D printed base is customized to a patient's body and configured to mount to the patient's body. The antenna support assembly is configured to mount to the 3D printed base. The antenna support assembly includes a fixer that is selectively movable relative to the 3D printed base and is configured to receive the ablation antenna therethrough.

[0005] In some embodiments, the 3D printed base may have a top surface and a bottom surface. The bottom surface may support an adhesive material.

[0006] In embodiments, the antenna support assembly may include a mounting ring that secures to the 3D printed base. The antenna support assembly may include a rotatable frame rotatably coupled to the mounting ring. The rotatable frame may include an annulus and one or more arches that extend from the annulus. The one or more arches may be configured to support the fixer. The one or more arches may include a first arch and a second arch disposed in spaced-apart relation to define an arcuate channel that receives the fixer therein. The first and second arches may be disposed in parallel relation with one another. The fixer may be selectively slidably movable through the arcuate channel.

[0007] In certain embodiments, the antenna support assembly may further include a frame. The fixer may include a rotatable knob that is movable relative to the frame to selectively lock the fixer to the frame.

[0008] In accordance with another aspect of the present disclosure, a method for navigating an ablation antenna is provided. The method includes determining patient-specific information, inputting patient-specific information into a 3D printing device, printing a base with the 3D printing

device, the base being customized to the patient, mounting the base and an antenna support assembly to the patient, and advancing an antenna through a fixer of the antenna support assembly, along the base, and into the patient.

[0009] The method may further involve selectively moving the fixer of the antenna support assembly relative to the base.

[0010] Advantageously, through patient-specific customization, the presently disclosed systems and methods enable clinicians to increase procedure proficiency and accuracy. In particular, the presently disclosed systems and methods provide increased stability and precision to enhance efficiencies.

[0011] Other aspects, features, and advantages will be apparent from the description, the drawings, and the claims that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the presently disclosed ablation system and, together with a general description of the disclosure given above, and the detailed description of the embodiment(s) given below, serve to explain the principles of the disclosure.

[0013] FIG. 1 is a side view of an ablation system provided in accordance with the present disclosure;

[0014] FIG. 2 is a side, cross-sectional view of an electronic image illustrating a portion of a patient's body with a portion of the ablation system supported thereon;

[0015] FIGS. 3A and 3B are side and top views, respectively, of a customized 3D printed base of the ablation system of FIG. 1;

[0016] FIG. 4 is a perspective view of a customized navigation system including the customized 3D printed base of FIGS. 3A and 3B;

[0017] FIG. 5A is a perspective view of an antenna support assembly of the customized navigation system of FIG. 4;

[0018] FIG. 5B is cross-sectional view of FIG. 5A taken along section line 5B-5B illustrated in FIG. 5;

[0019] FIG. 6A is a side view of a fixer of the antenna support assembly of FIG. 5A, the fixer shown with a knob thereof removed for clarity;

[0020] FIG. 6B is a top, perspective view of FIG. 6A;

[0021] FIG. 7 is a perspective view of the customized navigation system of FIG. 4 mounted to a patient's body;

[0022] FIG. 8 is a perspective view of another embodiment of an antenna support assembly;

[0023] FIG. 9A is a top view of a lock of the antenna support assembly of FIG. 8; and

[0024] FIGS. 9B-9D are progressive views illustrating the lock of FIG. 9 moving between different positions.

DETAILED DESCRIPTION

[0025] Embodiments of the present disclosure are described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views. As used herein, the term "distal" refers to that portion of structure farther from the user, while the term "proximal" refers to that portion of structure, closer to the user. Further, as used herein, the term "clinician" refers to a doctor, nurse, or other care provider and may include support personnel.

[0026] In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

[0027] An ablation system is described herein that improves specificity and accuracy of ablative procedures.

[0028] The embodiments disclosed herein are not limited to application of any particular tissue or organ for treatment, such as the liver or kidney. For example, the systems and methods of the present disclosure may be used to treat pancreatic tissue, gastrointestinal tissue, interstitial masses, and/or other portions of the body that may be treatable via ablation.

[0029] Further, although various methods described hereinbelow are targeted toward microwave ablation and the complete destruction of target tissue, it is to be understood that methods for directing electromagnetic radiation may be used with other therapies in which the target tissue is partially destroyed or damaged, such as, for example, to prevent the conduction of electrical impulses within heart tissue. In addition, the teachings of the present disclosure may apply to a monopole, dipole, helical, or other suitable type of microwave antenna or RF electrode.

[0030] Electromagnetic energy is generally classified by increasing energy or decreasing wavelength into radio waves, microwaves, infrared, visible light, ultraviolet, X-rays and gamma-rays. As it is used in this description, “microwave” generally refers to electromagnetic waves in the frequency range of 300 megahertz (MHz) (3 x 108 cycles/second) to 300 gigahertz (GHz) (3 x 1011 cycles/second). Further, “ablation procedure,” as used herein, generally refers to any ablation procedure, such as, for example, microwave ablation, radiofrequency (RF) ablation, or microwave or RF ablation-assisted resection.

[0031] Referring now to FIG. 1, an ablation system 10 of the present disclosure is depicted. Ablation system 10 includes a computing device 100 storing one or more ablation planning and electromagnetic tracking applications, a touch display computer 110, an ablation generator 115, an operating table 120, including an electromagnetic (EM) field generator 121, a second display 130, an imaging sensor 140, an imaging workstation 150, an ablation antenna assembly 160, and a base unit 170 configured to support computing device 100, ablation generator 115, and touch display computer 110.

[0032] Computing devices of ablation system 10 may be, for example, any suitable laptop computer, desktop computer, tablet computer, or other similar device, and may include one or more of any suitable electrical or computer components such as a memory, a processor, a display, a network interface, an input device, an output module, and the like, or combinations thereof.

[0033] For instance, memory may include any non-transitory computer-readable storage media for storing data and/or software that is executable by the processor and which controls the operation of computing device 100 and/or touch display computer 110. In embodiments, memory may store an application that may, when executed by the processor, cause the display (e.g., display 130) to present a user interface. Memory may include one or more solid-state storage devices such as flash memory chips. Alternatively, or in addition to the one or more solid-state storage devices, memory may include one or more mass storage devices connected to the processor through any suitable mass storage controller (not shown) and a communications bus (not shown). Although the description of computer-readable media contained herein refers to a solid-state storage, it should be appreciated by those skilled in the art that computer-readable storage media can be any available media that can be accessed by the processor. That is, computer readable storage media includes non-transitory, volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules or other data. For example, computer-readable storage media includes RAM, ROM, EPROM, EEPROM, flash memory or other solid state memory technology, CD-ROM, DVD, Blu-Ray or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium that can be used to store the desired information and which can be accessed by workstation 150.

[0034] The network interface (not shown) may be configured to connect to a network such as a local area network (LAN) consisting of a wired network and/or a wireless network, a wide area network (WAN), a wireless mobile network, a Bluetooth network, and/or the internet. The input device (not shown) may be any device by means of which a user may interact with computing device 100 and/or touch display computer 110, such as, a touch screen of touch display computer 110, or may include another device coupled thereto, for example, a mouse, keyboard, foot pedal, and/or voice interface. The output module (not shown) may include any connectivity port or bus, such as, for example, parallel ports, serial ports, universal serial busses (USB), or any other similar connectivity port.

[0035] Touch display computer 110 of ablation system 10 is configured to control generator 115, ablation antenna assembly 160, and other accessories and peripheral devices relating to, or forming part of, ablation system 10. Touch display computer 110 is configured to present a user interface, for example, on a display such as display 130, enabling a clinician to input instructions and settings for ablation generator 115, display images, and/or messages relating to the performance of ablation generator 115, the progress of a procedure, and issue alarms or alerts related to the same.

[0036] Operating table 120 of ablation system 10 may be any table suitable for use during a surgical procedure, which, in certain embodiments, includes or is associated with an EM field generator 121. EM field generator 121 is used to generate an EM field during the ablation procedure and forms part of an EM tracking system, which is used to track the positions of surgical instruments, e.g., ablation antenna assembly 160 and imaging sensor 140, within the EM field around and within the body of a patient. Display 130, in association with computing device 100, may be used for displaying imaging (e.g., ultrasound) and providing visualization of tissue to be treated as well as navigation of ablation antenna assembly 160. However, it is envisioned that touch display computer 110 and computing device 100 may also be used for imaging and navigation purposes in addition to its ablation generator 115 control functions discussed above.

[0037] Ablation antenna assembly 160 of ablation system 10 includes an antenna 162 that is used to ablate tissue, e.g., a target site, by using energy (e.g., microwave) to heat tissue in order to denature or kill cancerous cells. Further, although an exemplary ablation antenna assembly 160 is disclosed herein, it is contemplated that other suitable ablation antennas may be utilized in accordance with the present disclosure. For example, the ablation antennas and systems described in U.S. Patent Application Publication No. 2016/0058507, entitled MICROWAVE ABLATION SYSTEM, filed on August 18, 2015 by Dickhans, International Application No. PCT/US15/46729, entitled MICROWAVE ABLATION SYSTEM, filed on August 25, 2015 by Dickhans, U.S. Patent No. 9,247,992, entitled MICROWAVE ABLATION CATHETER AND METHOD OF UTILIZING THE SAME, issued on February 2, 2016 to Ladtkow et al., and U.S. Patent No. 9,119,650, entitled MICROWAVE ENERGY-DELIVERY DEVICE AND SYSTEM, issued on September 1, 2015 to Brannan et al., the entire contents of each of which are incorporated herein by reference, may be used in conjunction with the aspects and features of the present disclosure.

[0038] Ablation antenna assembly 160 of ablation system 10 is coupled to ablation generator 115 of ablation system 10 via a flexible coaxial cable 116. Ablation generator 115 is configured to provide energy (e.g., microwave) to antenna 162 at an operational frequency from about 915MHz to about 2.45GHz, although other suitable frequencies are also contemplated.

[0039] Antenna 162 of ablation antenna assembly 160 may be visualized by using imaging workstation 150 of ablation system 10. Imaging sensor 140 of ablation system 10, which may be, e.g., an ultrasound wand, may be used to image the patient's body "B" during the ablation procedure to visualize a location of antenna 162 inside the patient's body "B." Imaging sensor 140 may have an EM tracking sensor embedded within or attached thereto, for example, a clip-on sensor or a sticker sensor. Imaging sensor 140 may be positioned in relation to antenna 162 of ablation antenna assembly 160 such that antenna 162 is at an angle to an image plane, thereby enabling the clinician to visualize a spatial relationship of antenna 162 with the image plane and with objects being imaged. Further, the EM tracking system may also track a location of imaging sensor 140. This spatial depiction of imaging sensor 140 and antenna 162 is described in greater detail in U.S. Patent Application Publication No. 2016/0317224, entitled METHODS FOR MICROWAVE ABLATION PLANNING AND PROCEDURE, filed on April 15, 2016 by Girotto, which is incorporated herein by reference. During surgery, one or more imaging sensors 140 may be placed on or inside the patient's body "B." EM tracking system may then track the location of such imaging sensors 140 and antenna 162 as they are moved relative to each other. It is also envisioned that imaging workstation 150 and its related components may be interchanged with other imaging devices such as real time fluoroscopy, MRI or CT imaging stations.

[0040] Ablation system 10 further includes a 3D printing device 180, and a customized navigation system 200 that is mountable to the patient "P."

[0041] With body size, tumor size, and tumor position being patient-specific characteristics that vary widely from patient to patient, the clinician must carefully plan appropriate instrumentation positioning (e.g., ablation antenna points of insertion, angles, depth, etc.) for performing an ablation procedure. And since every patient is different, ablation procedures are difficult for clinicians to effectuate proficiently in light of the specificity and accuracy required. In order to improve such clinician proficiency, a clinician can collect patient specific information such as via imaging with imaging device 150 and/or via an assessment (e.g., from a physical exam, patient history, etc.). Such information may be compared with other patient data and/or collected from one or more databases of patient information, which may include from the same or different patients.

[0042] With reference also to FIGS. 2, 3A, 3B, and 4, after analyzing such information and determining an optimal position "O" along the patient's body "B" to effectively access the tumor "T" for effectuating tumor ablation, 3D printing device 180 can be utilized to create a customized 3D printed base 202 of customized navigation system 200 (FIG. 1) that is configured to conform to the patient's body surface contour "C" adjacent to the optimal position "O" along the patient's body "B." This customization or bespoke profile is determined, for instance, based on computer modeling of patient's body surface contour "C." Such computer modeling can be generated via any suitable application, software, etc. (e.g., CAD) or the like that may be directly or indirectly coupled to, or a part of, 3D printing device 180. This customization may be generated utilizing analog or electronic information established, for instance, with the imaging device 150, the computing device

100 or connected networks and/or databases thereof, and/or a physical examination of the patient "P." 3D printing device 180 is configured to make (e.g., print) the customized 3D printed base 202. For a more detailed description of a 3D printing device, reference may be made to U.S. Patent Publication No. 2012/0201960, for example, the entire contents of which are incorporated herein by reference.

[0043] Customized 3D printed base 202 functions to mount an antenna support assembly 204 of customized navigation system 200 to the patient's body "B" so that antenna support assembly 204 can movably and/or fixedly position and/or support ablation antenna assembly 160 (e.g., for mounting on the patient "P," inserting antenna 162 of antenna support assembly 204 into the patient "P," and/or advancing antenna 162 through the patient "P" toward the tumor "T") at the optimal position "O" along the patient's body "B." With customized 3D printed base 202 being bespoke, customized 3D printed base 202 can have any suitable shape and/or dimension including, for example, any suitable polygonal, linear, circular, non-circular, curvilinear configurations, etc., or combinations thereof. Customized 3D printed base 202 can include a central opening 202a defined therethrough for directly accessing the patient's body. In some embodiments, customized 3D printed base 202 may include multiple openings defined therethrough, and positioned at one or more suitable locations threrealong for accessing the patient's body "B." In certain embodiments, customized 3D printed base 202 may be devoid of openings, but may be formed of any suitable material or combinations of materials configured to enable access through customized 3D printed base 202. In some embodiments, customized 3D printed base 202 may include perforations, frangible portions, etc., or combinations thereof.

[0044] As seen in FIG. 3A, a bottom surface of customized 3D printed base 202 can include adhesive 202x or the like, which may be layered and/or coated thereon, to facilitate securement of customized 3D printed base 202 to the patient's body "B." Indeed, customized 3D printed base 202 can be secured to the patient's body "B" using any suitable securement technique such as fastening, suturing, adhesive, etc., or combinations thereof.

[0045] Referring now to FIGS. 4-7, customized navigation system 200 of ablation system 10 includes customized 3D printed base 202 and antenna support assembly 204 that mounts to customized 3D printed base 202. Antenna support assembly 204 of customized navigation system 200 includes a mounting ring 206 that rotatably supports a rotatable frame 208. Antenna support assembly 204 further includes a fixer 210 movably mounted to rotatable frame 208 and selectively fixable thereto. Mounting ring 206 of antenna support assembly 204 may include adhesive material (not shown) supported on a bottom surface thereof to facilitate securement to a top surface of customized 3D printed base 202. In some embodiments, the adhesive material may be layered and/or coated on the bottom surface of mounting ring 206. Additionally or alternatively, mounting ring 206 can be secured to the top surface of customized 3D printed base 202 via any suitable securement technique such as fastening, friction-fit, snap-fit, etc., or combinations thereof. The top surface of customized 3D printed base 202 and/or the bottom surface of mounting ring 206 may include mounting structure (e.g., recesses, tabs, pins, protrusions, openings, etc., or combinations thereof) to facilitate such securement.

[0046] Rotatable frame 208 of antenna support assembly 204 is rotatably mounted to mounting ring 206, as indicated by arrows "Z," and is selectively lockable relative to mounting ring 206 with a lock 212 including a lock screw 212a. Lock screw 212 is positioned to threadably rotate into or out of a threaded opening 206b defined in mounting ring 206, as indicated by arrows "L1" and "L2" (FIG. 7). Rotatable frame 208 includes an annulus 208a that is rotatably supported in an inner channel 206a of mounting ring 206 via a flange 208d (e.g., tongue and groove type configuration). Inner channel 206a is annular. Flange 208d extends radially outward from an outer surface of annulus 208a and is positioned to frictionally engage lock screw 212a such that lock screw 212a prevents rotatable frame 208 from rotating relative to mounting ring 206 when lock screw 212a and flange 208d are frictionally engaged (see FIG. 5B). Lock screw 212a can be tightened against or loosed from a top surface of flange 208d as desired to selectively rotationally fix rotatable frame 208 (or limit rotational movement thereof, depending on how much lock screw 212a is tightened or loosened). When flange 208d and lock screw 212a are disengaged, rotatable frame 208 is freely rotatable about central longitudinal axis "CA-CA" (FIG. 4) of rotatable frame 208.

[0047] Rotatable frame 208 further includes first and second arches 208b, 208c that extend from annulus 208a. First and second arches 208b, 208c are disposed in spaced-apart and parallel relation relative to one another to define an arcuate channel 208d between respective inner surfaces of first and second arches 208b, 208c. Arcuate channel 208 is positioned to slidably receive fixer 210 therealong, as indicated by arrows "Y."

[0048] Fixer 210 of antenna support assembly 204 includes a rotatable knob 210a on a proximal end thereof that is threadably coupled to a protuberance 210b that extends proximally from a guide 210f supported on a platform 210c of antenna support assembly 204. Rotatable knob 210a of fixer 210 rotates about protuberance 210b to axially translate rotatable knob 210a relative to guide 210f or platform 210c to selectively secure fixer 210 to first and second arches 208b, 208c. Rotatable knob 210a extends radially outward over top surfaces of first and second arches 208b, 208c to selectively frictionally engage the top surfaces of first and second arches 208b, 208c with a bottom surface of rotatable knob 210a. In particular, when rotatable knob 210a is rotated in a first direction (e.g., clockwise or counterclockwise), as indicated by "X1," and axially translated towards guide 210f of platform 210c, for example, in an approximating direction, first and second arches 208b, 208c are captured between a top surface of platform 210c and the bottom surface of rotatable knob 210a. And when rotatable knob 210a is rotated in a second direction (e.g., clockwise or counterclockwise), as indicated by "X2" and which may be opposite the first direction, and axially translated away from platform 210c (e.g., unapproximation), the bottom surface of rotatable knob 210a disengages from the top surfaces of first and second arches 208b, 208c while the top surface of the platform 210c disengages from bottom surfaces of first and second arches 208b, 208c. Once fixer 210 is disengaged from rotatable frame 208, for example, not frictionally engaged therewith, but loosely coupled thereto, fixer 210 can slide along first and second arches 208b, 208c for adjusting a position of fixer 210 relative to rotatable frame 208. In particular, guide 210f of fixer 210 includes planar side surfaces 210g, 210f (FIG. 6B) that support fixer 210 between inner side surfaces of first and second arches 208b, 208c to facilitate slidable movement therealong. Fixer 210 can be re-secured to rotatable frame 208, for instance, frictionally engaged therewith via approximating rotation of rotatable knob 210a, as desired. Readjustment can be repeated as desired.

[0049] Fixer 210 of antenna support assembly 204 further includes an elongated tube 210d that extends distally from platform 210b. Fixer 210 also includes a central passage 210e defined therein that extends centrally through elongated tube 210d, platform 210c, guide 210f, and rotatable knob 210a. Central passage 210e of fixer 210 is configured to receive antenna 162 of ablation antenna assembly 160 so that fixer 210 can guide antenna 162 toward the tumor "T" within the patient's body "B."

[0050] In use, with reference to FIGS. 1-6, once customized navigation system 200 is secured to the patient's body "B," and a desired path for advancing antenna 162 of ablation antenna assembly 160 into the patient's body "B" is identified, rotatable frame 208 of antenna support assembly 204 can be rotated relative to mounting ring 206 of antenna support assembly 204 and selectively secured thereto via lock 212. Additionally or alternatively, fixer 210 of antenna support assembly 204 can be selectively slid along rotatable frame 208 and selectively secured thereto via rotatable knob 210a, as desired. Once rotatable frame 208 and fixer 210 are positioned as desired (e.g., to enable antenna 162 of ablation antenna assembly 160 to advance through fixer 210 along the desired path), antenna 162 can be advanced through central passage 210e of fixer 210 and along the desired path to access the tumor "T" for ablating the tumor "T" upon selective activation of antenna 162. Fixer 210 and/or rotatable frame 208 can be adjusted and selectively fixed in various positions as desired to enable different antenna approach angles for accessing the tumor “T.” Once ablation is completed, antenna 162 and customized navigation system 200 are then removed so that wound closure can be effectuated.

[0051] With reference to FIGS. 8-9D, another embodiment of an antenna support assembly is generally referred to as antenna support assembly 300. Antenna support assembly 300 is substantially similar to antenna support assembly 300 but includes a lock 312. Lock 312 includes a lock switch 312a pivotally supported on mounting ring 206 via a pin 312b. Lock switch 312a includes a lock surface 312c that is positioned to selectively engage an outer surface 208x of annulus 208a of rotatable frame 208 to selectively lock rotatable frame 208 in position. Lock surface 312c may be defined by one or more radii and/or diameters, which may be the same or different. For example, lock surface 212c may include a first radius “r1,” a second radius “r2,” a third radius “r3,” and a fourth radius “r4,” each of which may be the same or different from one another. For instance, “r2” may be greater than “r3,” which is greater than “r4,” and all of which are greater than “r1.”

[0052] As seen in FIG. 9B, when lock switch 312a is in a first position, lock surface 312c is spaced from outer surface 208x so that rotatable frame 208 is freely rotatable relative to mounting ring 206, as indicated by arrow “R1.” With reference to FIG. 9C, when lock switch 312 is in a second position, outer surface 208x and lock surface 312c are in slight frictionally contact with one another so as to tighten or limit rotatable movement of rotatable frame 208 relative to mounting ring 206 and lock switch 312, as indicated by arrow “R2,” while enabling some rotatable movement of rotatable frame 208 relative to mounting ring 206. As seen in FIG. 9D, when lock switch 312 is in a third position, outer surface 208x and lock surface 312c are in frictionally locked together so that rotatable frame 208 is rotatably fixed in position relative to mounting ring 206 as indicated by the “X.”

[0053] Securement of any of the components of the presently described devices to any of the other components of the presently described devices can be effectuated using known securement techniques such welding (e.g., ultrasonic), crimping, gluing, fastening, interference-fit, snap-fit, etc., or combinations thereof.

[0054] Persons skilled in the art will understand that the structures and methods specifically described herein and shown in the accompanying figures are non-limiting exemplary embodiments, and that the description, disclosure, and figures should be construed merely as exemplary of particular embodiments. It is to be understood, therefore, that the present disclosure is not limited to the precise embodiments described, and that various other changes and modifications may be effected by one skilled in the art without departing from the scope or spirit of the disclosure. Additionally, the elements and features shown or described in connection with certain embodiments may be combined with the elements and features of certain other embodiments without departing from the scope of the present disclosure, and that such modifications and variations are also included within the scope of the present disclosure. Accordingly, the subject matter of the present disclosure is not limited by what has been particularly shown and described.

WHAT IS CLAIMED IS

1. An ablation system, comprising:

an ablation antenna;

a generator coupled to the ablation antenna; and

a customized navigation system including:

a 3D printed base customized to a patient's body and configured to mount to the patient's body; and

an antenna support assembly configured to mount to the 3D printed base, the antenna support assembly including a fixer that is selectively movable relative to the 3D printed base and configured to receive the ablation antenna therethrough.

2. The ablation system of claim 1, wherein the 3D printed base has a top surface and a bottom surface, the bottom surface supporting an adhesive material.

3. The ablation system of claim 1, wherein the antenna support assembly includes a mounting ring that secures to the 3D printed base.

4. The ablation system of claim 3, wherein the antenna support assembly includes a rotatable frame rotatably coupled to the mounting ring.

5. The ablation system of claim 4, wherein the rotatable frame includes an annulus and at least one arch that extends from the annulus, the at least one arch configured to support the fixer.

6. The ablation system of claim 5, wherein the at least one arch includes a first arch and a second arch disposed in spaced-apart relation to define an arcuate channel that receives the fixer therein.

7. The ablation system of claim 6, wherein the first and second arches are disposed in parallel relation with one another.

8. The ablation system of claim 6, wherein the fixer is selectively slidably movable through the arcuate channel.

9. The ablation system of claim 1, wherein the antenna support assembly further includes a frame, and wherein the fixer includes a rotatable knob that is movable relative to the frame to selectively lock the fixer to the frame.

10. A customized navigation system comprising:

a 3D printed base customized to a patient’s body and configured to mount to the patient’s body; and

an antenna support assembly configured to mount to the 3D printed base, the antenna support assembly including a fixer that is selectively movable relative to the 3D printed base and configured to receive an ablation antenna therethrough.

11. The customized navigation system of claim 10, wherein the 3D printed base has a top surface and a bottom surface, the bottom surface supporting an adhesive material.

12. The customized navigation system of claim 10, wherein the antenna support assembly includes a mounting ring that secures to the 3D printed base.

13. The customized navigation system of claim 12, wherein the antenna support assembly includes a rotatable frame rotatably coupled to the mounting ring.

14. The customized navigation system of claim 13, wherein the rotatable frame includes an annulus and at least one arch that extends from the annulus, the at least one arch configured to support the fixer.

15. The customized navigation system of claim 14, wherein the at least one arch includes a first arch and a second arch disposed in spaced-apart relation to define an arcuate channel that receives the fixer therein.

16. The customized navigation system of claim 15, wherein the first and second arches are disposed in parallel relation with one another.

17. The customized navigation system of claim 15, wherein the fixer is selectively slidably movable through the arcuate channel.

18. The customized navigation system of claim 10, wherein the antenna support assembly further includes a frame, and wherein the fixer includes a rotatable knob that is movable relative to the frame to selectively lock the fixer to the frame.

19. A method for navigating an ablation antenna, the method comprising:

determining patient-specific information;

inputting patient specific information into a 3D printing device;

printing a base with the 3D printing device, the base being customized to the patient;

mounting the base and an antenna support assembly to the patient; and

advancing an antenna through a fixer of the antenna support assembly, along the base, and into the patient.

20. The method of claim 19, further comprising selectively moving the fixer of the antenna support assembly relative to the base.

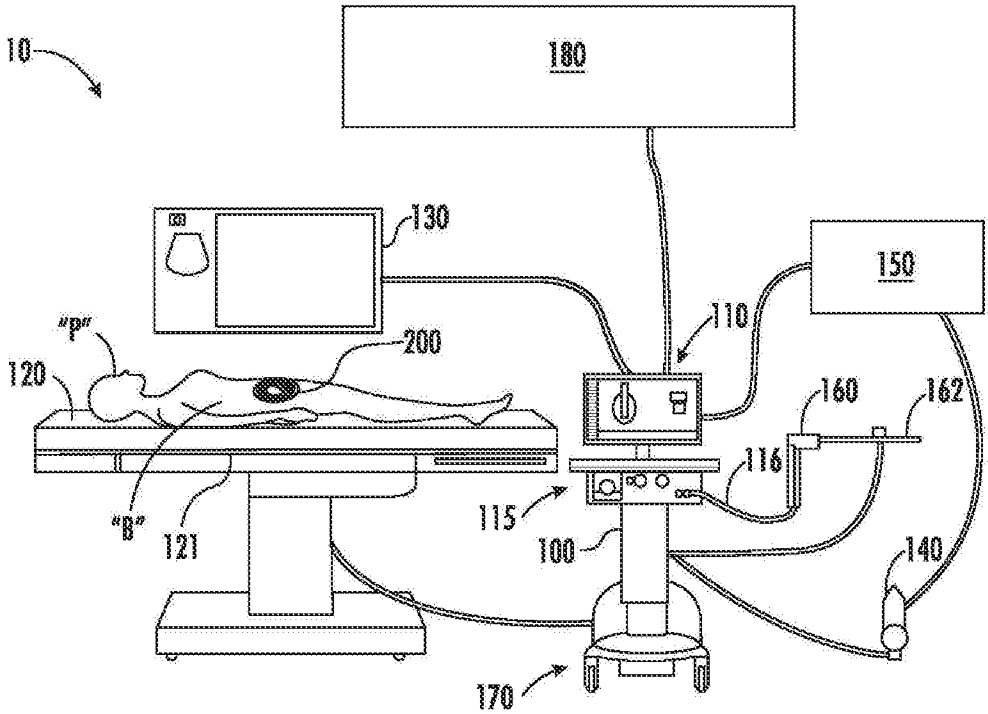

FIG. 1

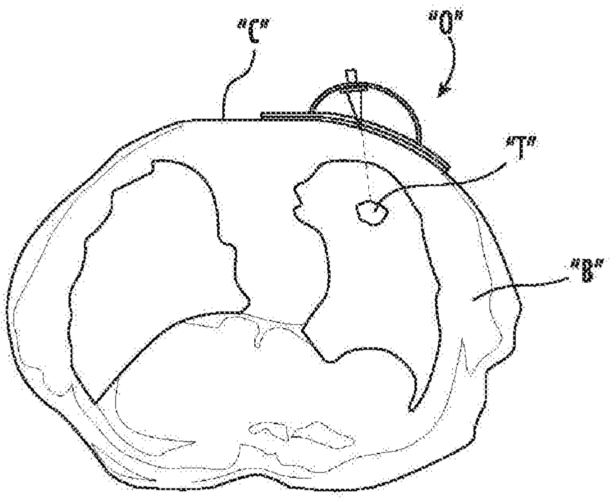

FIG. 2

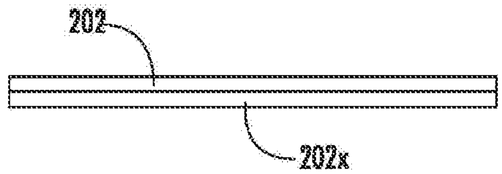

FIG. 3A

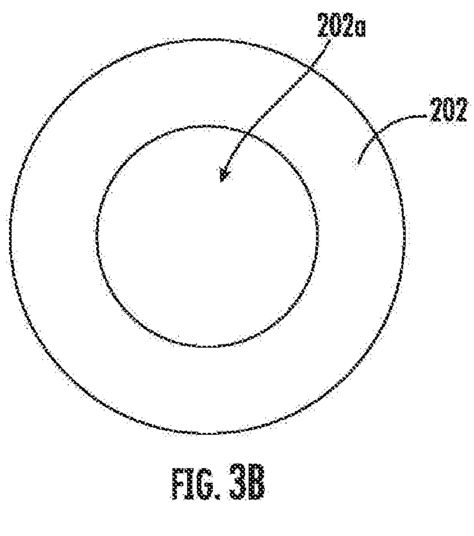

FIG. 3B

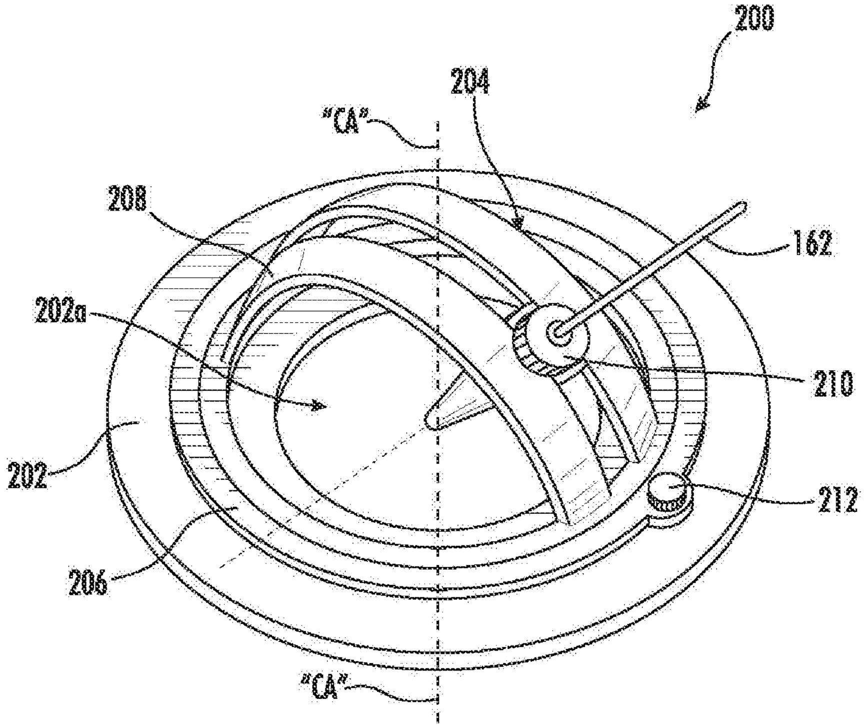
200
204
"CA"
208
162
202a
210
202
212
206
"CA"

FIG. 4

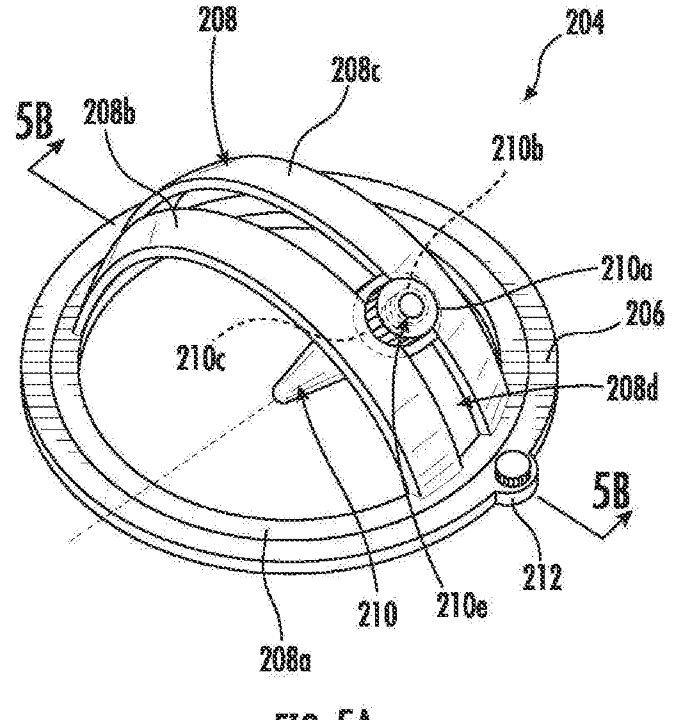
208
204
208c
5B
208b
210b
210a
206
210c
208d
5B
212
210
210e
208a

FIG. 5A

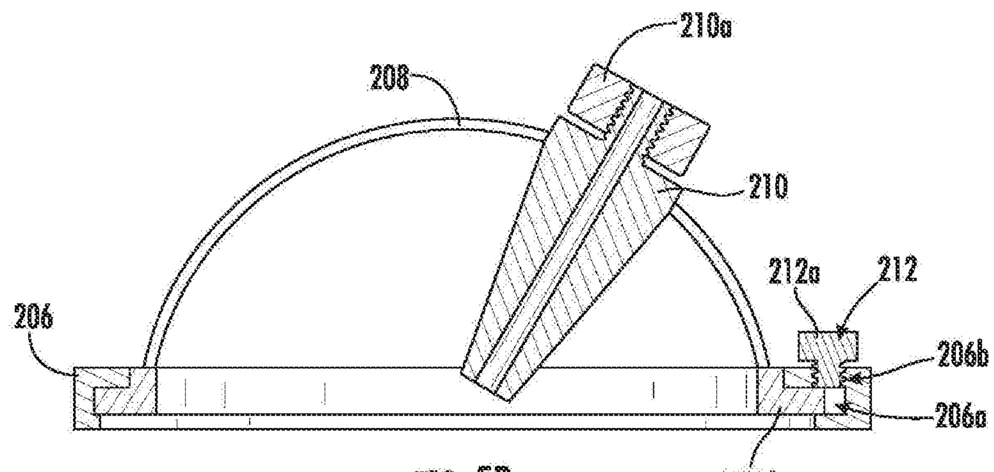

FIG. 5B

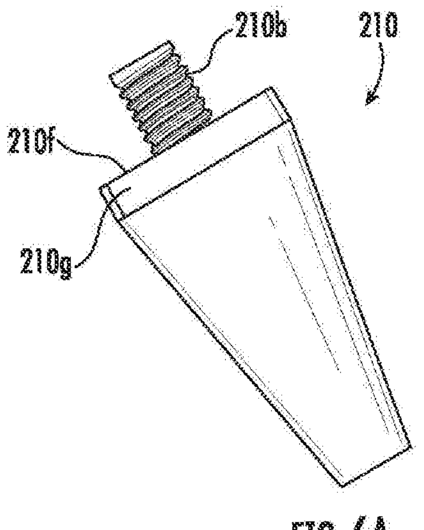

FIG. 6A

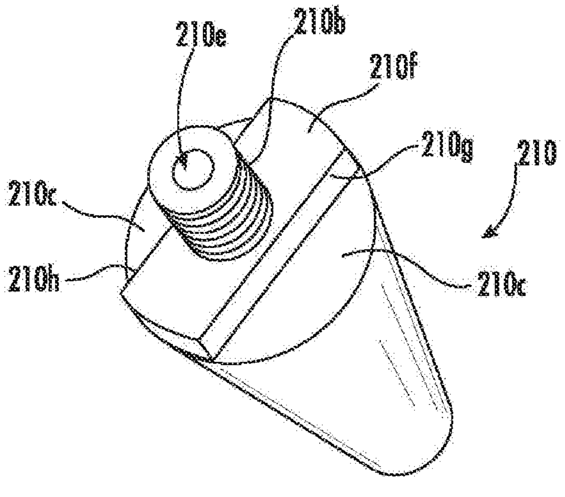

FIG. 6B

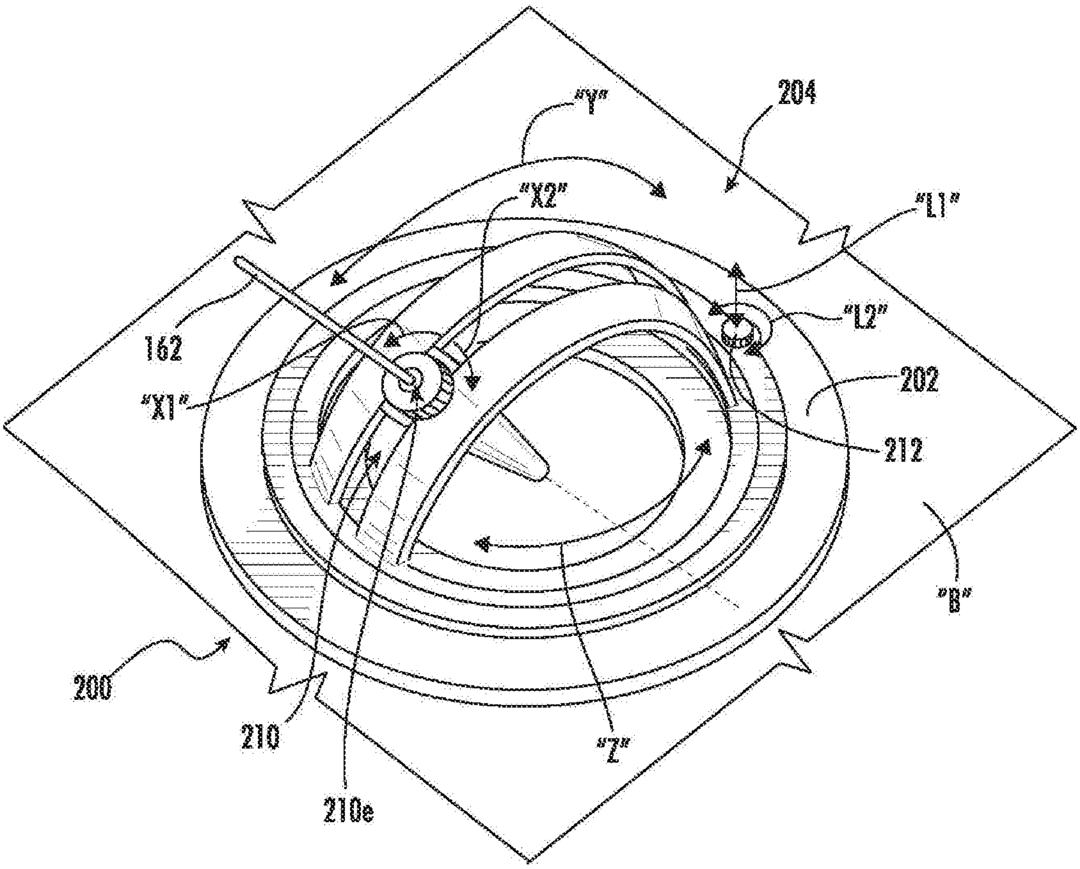

FIG. 7

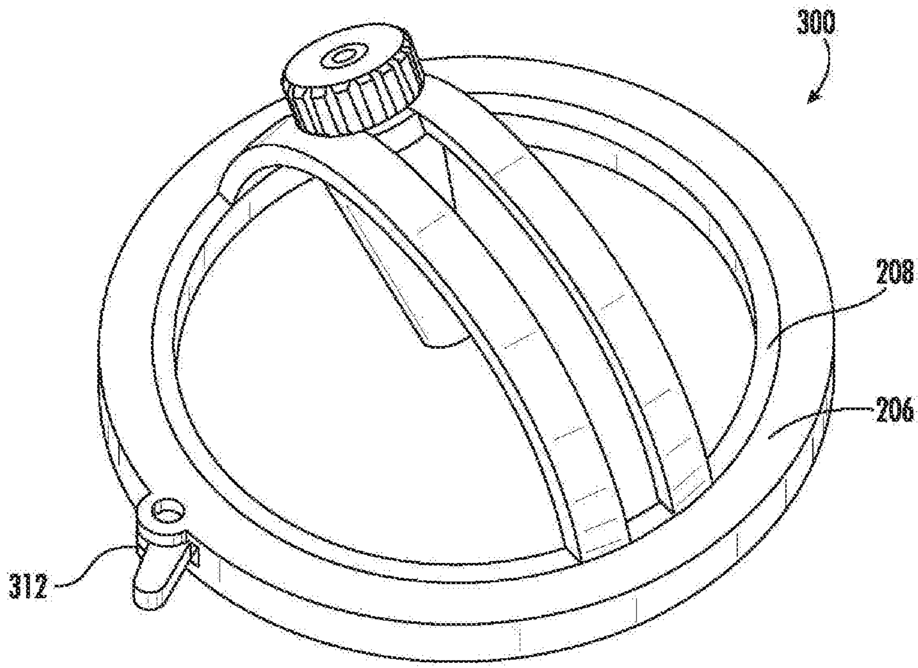
300
208
206
312

FIG. 8

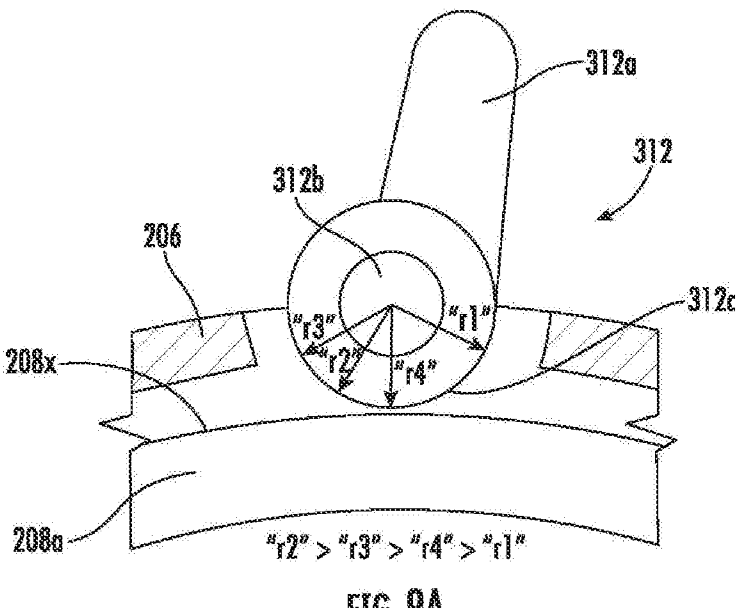
312a
312
312b
206
312c
"r3"
"r1"
208x
"r2"
"r4"
208a
"r2" > "r3" > "r4" > "r1"

FIG. 9A

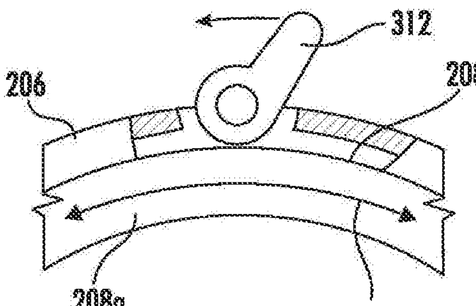

FIG. 9B

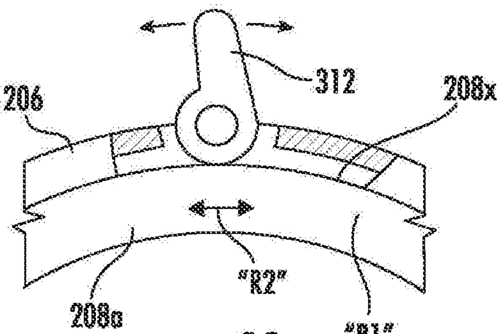

FIG. 9C

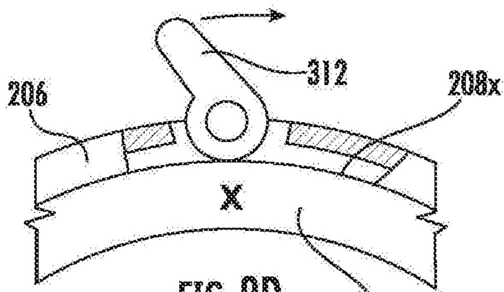

FIG. 9D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2018/094063

A. CLASSIFICATION OF SUBJECT MATTER

A61B 18/18(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

CNPAT,CNKI,WPI,EPODOC: ablation, ablative, 3D, three w dimensional, print+, base, navigat+, patient, antenna, catheter, probe.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2016038252 A1 (THE TRUSTEES OF DARTMOUTH COLLEGE) 11 February 2016 (2016-02-11) description, paragraphs [0195]-[0211], figures 22-28	1-20
A	CN 106687060 A (COVIDIEN LP) 17 May 2017 (2017-05-17) the whole document	1-20
A	CN 107530059 A (COVIDIEN LP) 02 January 2018 (2018-01-02) the whole document	1-20
A	CN 205598006 U (GUANGZHOU YUEBEI BIOTECHNOLOGY CO., LTD.) 28 September 2016 (2016-09-28) the whole document	1-20
A	US 2005208168 A1 (HICKERSON, KEVIN P. ET AL.) 22 September 2005 (2005-09-22) the whole document	1-20

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

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 March 2019	**02 April 2019**

Name and mailing address of the ISA/CN	Authorized officer
National Intellectual Property Administration, PRC **6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088** **China**	**LI,Hui**
Facsimile No. **(86-10)62019451**	Telephone No. **86-10-53961720**

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2018/094063

Patent document cited in search report			Publication date (day/month/year)	Patent family member(s)			Publication date (day/month/year)
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				CN	107949337	A	20 April 2018
				CA	2989342	A1	15 December 2016
				WO	2016201341	A1	15 December 2016
CN	106687060	A	17 May 2017	JP	2017529145	A	05 October 2017
				AU	2015306746	A1	02 March 2017
				US	2016058507	A1	03 March 2016
				CA	2959337	A1	03 March 2016
				EP	3185804	A1	05 July 2017
				WO	2016033066	A1	03 March 2016
CN	107530059	A	02 January 2018	CA	2982263	A1	03 November 2016
				US	2016317231	A1	03 November 2016
				US	2016317230	A1	03 November 2016
				US	2016317225	A1	03 November 2016
				AU	2016254139	A1	26 October 2017
				EP	3291736	A1	14 March 2018
				US	2016317224	A1	03 November 2016
				WO	2016176549	A1	03 November 2016
				JP	2018524031	A	30 August 2018
				US	2016317229	A1	03 November 2016
CN	205598006	U	28 September 2016	None			
US	2005208168	A1	22 September 2005	WO	2005089463	A2	29 September 2005
				JP	2007529349	A	25 October 2007
				EP	1735133	A2	27 December 2006
				US	2010244333	A1	30 September 2010
				US	2008036117	A1	14 February 2008
				AT	516128	T	15 July 2011