

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau



(10) International Publication Number

WO 2017/139278 A1

(43) International Publication Date

17 August 2017 (17.08.2017)

WIPO | PCT

(51) International Patent Classification:

A61B 18/18 (2006.01) *A61B 18/00* (2006.01)
A61L 31/06 (2006.01) *A61M 25/09* (2006.01)
A61L 31/14 (2006.01)

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(21) International Application Number:

PCT/US2017/016855

(22) International Filing Date:

7 February 2017 (07.02.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/293,965 11 February 2016 (11.02.2016) US
15/425,762 6 February 2017 (06.02.2017) US

(71) Applicant: **COVIDIEN LP** [US/US]; 15 Hampshire Street, Mansfield, MA 02048 (US).

(72) Inventor: **DICKHANS, William, J.**; 2845 Hartwick Circle, Longmont, CO 80503 (US).

(74) Agent: **BELENCHIA, Giordana, M.**; Medtronic, Attn: IP Legal, 5920 Longbow Drive, Boulder, CO 80301 (US).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: SYSTEMS AND METHODS FOR DETERMINING THE STATUS OF A FLUID-COOLED MICROWAVE ABLATION SYSTEM

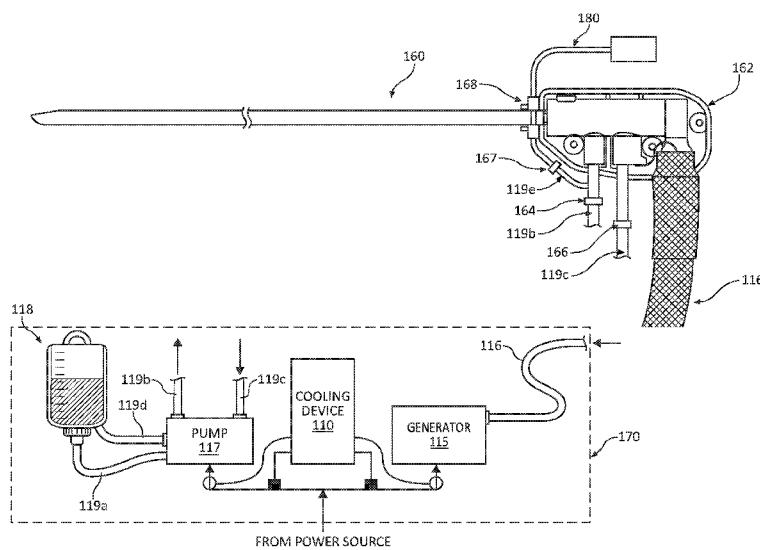


FIG. 2

(57) Abstract: Provided in accordance with aspects of the present disclosure is a microwave ablation system including an introducer having a lumen therethrough, a stylus configured for slidable engagement within the lumen of the introducer, and a microwave ablation antenna configured to deliver energy to a target during an ablation procedure, wherein the microwave ablation antenna is configured for slidable engagement within the lumen of the introducer.

WO 2017/139278 A1

SYSTEMS AND METHODS FOR DETERMINING THE STATUS OF A FLUID-COOLED MICROWAVE ABLATION SYSTEM

BACKGROUND

1. Technical Field

[0001] The present disclosure relates to microwave ablation and, more particularly, to systems and methods for percutaneous microwave ablation.

2. Discussion of Related Art

[0002] Treatment of certain diseases requires the destruction of malignant tissue growths, e.g., tumors. Electromagnetic (“EM”) radiation can be used to heat and destroy tumor cells. Microwave ablation for treatment of tumors is often preferred over other treatments because it is minimally invasive and achievable through small incisions made into the skin (e.g., percutaneous, laparoscopic, etc.). Treatment may involve inserting ablation antennas into or adjacent to tissues where cancerous tumors have been identified. Once the antennas are positioned, electromagnetic energy is passed through the antenna into surrounding tissue to treat, e.g., heat, ablate and/or coagulate tissue.

[0003] Often, tumors are located subcutaneously and/or surrounded by critical tissue structures, making navigation of the ablation antenna to the tumor site difficult or impossible. In such situations, addressing the tumor often requires open surgery or other invasive procedures.

SUMMARY

[0004] Provided in accordance with aspects of the present disclosure is a microwave ablation system including an introducer having a lumen therethrough, a stylus configured for slidable engagement within the lumen of the introducer, and a microwave ablation antenna configured to deliver energy to a target during an ablation procedure, wherein the microwave ablation antenna is configured for slidable engagement within the lumen of the introducer.

[0005] In an aspect of the present disclosure, an electromagnetic navigation system is provided to facilitate navigation of at least the introducer, the stylus, and the microwave ablation antenna to the target.

[0006] In another aspect of the present disclosure, the introducer is formed from a non-conductive material that allows the microwave ablation antenna to radiate microwave energy throughout an entire length of the introducer.

[0007] In yet another aspect of the present disclosure, the introducer is formed from a material selected from the group consisting of Polyether ether ketone and fiberglass.

[0008] In still another aspect of the present disclosure, the introducer has a first end, a second end, and a shaft disposed therebetween, wherein the first end has a first aperture and a fitting configured for engagement with the microwave ablation antenna and the stylus, the second end has a second aperture, and the shaft has a length, an outside diameter, and an inside diameter defined by a lumen.

[0009] In still yet another aspect of the present disclosure, the stylus is configured to articulate and adopt at least one curved configuration to navigate to the target.

[0010] In another aspect of the present disclosure, the introducer is formed from a shape-memory material and configured to adopt and maintain the at least one curved configuration of the stylus.

[0011] In yet another aspect of the present disclosure, the introducer maintains the at least one curved configuration defined by the stylus after the stylus has been removed from the introducer.

[0012] In still another aspect of the present disclosure, a fluid can be introduced into the lumen of the introducer.

[0013] In still yet another aspect of the present disclosure, the fluid is disposed between an outer surface of the microwave ablation antenna and the lumen of the introducer.

[0014] In another aspect of the present disclosure, therapeutic agents can be introduced into the lumen of the introducer.

[0015] In yet another aspect of the present disclosure, the therapeutic agents are thermo-sensitive and configured to react with the energy radiated from the microwave ablation antenna.

[0016] In still yet another aspect of the present disclosure, the electromagnetic navigation system is used in conjunction with real time ultrasound, fluoroscopy, CT, or MRI imaging.

[0017] Provided in accordance with another aspect of the present disclosure is a method of performing a microwave ablation procedure, including inserting a combination introducer and stylus into a patient at a desired location, navigating the combination introducer and stylus to a target, inserting the combination introducer and stylus into the target, removing the stylus from the introducer while leaving the introducer in the target, inserting a microwave ablation antenna into a lumen of the introducer, advancing the microwave ablation antenna through the lumen of the introducer until a radiating (portion or section of) the microwave ablation antenna is proximate the target, and radiating energy from the microwave ablation antenna through at least a portion of the introducer into the target.

[0018] In another aspect of the present disclosure, a first introducer is placed at a first target site, and a second introducer is placed at a second target site.

[0019] In yet another aspect of the present disclosure, an electromagnetic navigation system is provided to facilitate navigation of the introducer, the stylus, and the microwave ablation antenna to the targets.

[0020] In still another aspect of the present disclosure, the introducer is formed from a non-conductive material that allows the microwave ablation antenna to radiate microwave energy throughout an entire length of the introducer.

[0021] In still yet another aspect of the present disclosure, fluid is introduced into the lumen of the introducer between an outer surface of the microwave ablation antenna and an inner surface of the lumen of the introducer.

[0022] Provided in accordance with another aspect of present disclosure is at least one introducer having a lumen therethrough, a stylus configured for slidable engagement within the lumen of the at least one introducer, and a microwave ablation antenna configured to deliver energy to a target during an ablation procedure, wherein the microwave ablation antenna is configured for slidable engagement within the lumen of the at least one introducer.

[0023] In another aspect of the present disclosure, the at least one introducer is formed from a non-conductive material that allows the microwave ablation antenna to radiate microwave energy throughout an entire length of the at least one introducer.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Objects and features of the present disclosure will become apparent to those of ordinary skill in the art when descriptions of various embodiments thereof are read with reference to the accompanying drawings, of which:

[0025] FIG. 1 is a side view of a fluid cooled microwave ablation system provided in accordance with the present disclosure;

[0026] FIG. 2 is a side, partial cross-sectional view of a fluid cooled microwave ablation antenna assembly and base unit of the system of FIG. 1;

[0027] FIG. 3 is a cross-sectional view of a distal end of the antenna assembly of FIG. 3;

[0028] FIG. 4 is a side view of a stylus;

[0029] FIG. 5 is a side view of an introducer;

[0030] FIG. 6 is a schematic diagram of a cross-sectional view of an access assembly placed into tissue;

[0031] FIG. 7 is a schematic diagram of a cross-sectional view of a treatment assembly placed into tissue;

[0032] FIG. 7A is a partial exploded cross-sectional view of the schematic diagram of FIG. 7; and

[0033] FIG. 8 is an illustration of a user interface presenting a view during a microwave ablation treatment.

DETAILED DESCRIPTION OF THE DRAWINGS

[0034] The present disclosure is directed to a flexible microwave ablation antenna in combination with a stylus and an introducer. This combination can be useful in treating tumors that have limited accessibility. Specifically, the stylus, introducer, and flexible microwave ablation antenna may be customized to reach any depth and/or traverse any path within a patient's body to gain access to a tumor. The microwave ablation antenna may radiate energy through the introducer, further enhancing the versatility of the described device. These and other aspects and features of the present disclosure are detailed herein below.

[0035] Referring now to FIG. 1, an exemplary microwave ablation system 10 of the present disclosure is depicted. The microwave ablation system 10 includes a

computing device 100 storing one or more ablation planning and electromagnetic tracking applications, a touch display computer 110, microwave ablation generator 115, an operating table 120, including an electromagnetic (EM) field generator 121, a second display 130, an ultrasound imaging sensor 140, an ultrasound workstation 150, a microwave ablation antenna assembly 160, and a base unit 170 configured to support computing device 100, the microwave ablation generator 115, and the touch display computer 110. Computing devices described herein may be, for example, a laptop computer, desktop computer, tablet computer, or other similar device. Touch display computer 110 is configured to control microwave generator 115, pump 117, microwave ablation antenna assembly 160, and other accessories and peripheral devices relating to, or forming part of, microwave ablation system 10. Touch display computer 110 is configured to present a user interface enabling a clinician to input instructions and setting for the microwave ablation generator 115, display images, and/or messages relating to the performance of the microwave ablation generator 115, the progress of a procedure, and issue alarms or alerts related to the same.

[0036] Operating table 120 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 microwave ablation procedure and forms part of an EM tracking system, which is used to track the positions of surgical instruments, e.g., microwave ablation antenna assembly 160 and ultrasound sensor 140, within the EM field around and within the body of a patient. Second display 130 (FIG. 1), in association with computing device 100, may be used for displaying ultrasound imaging and providing visualization of tissue to be treated as well as navigation of the fluid cooled microwave ablation antenna assembly 160. However, it is envisioned that touch display computer 110 and computing device 100 may also be used

for ultrasound imaging and navigation purposes in addition to its microwave ablation generator 115 control functions discussed above.

[0037] As will be described in more detail below (FIG. 2 and FIG. 3) microwave ablation antenna assembly 160 is used to ablate tissue, e.g., a lesion or tumor (hereinafter referred to as a “target”), by using microwave energy to heat tissue in order to denature or kill cancerous cells. Further, although an exemplary microwave ablation antenna assembly 160 is detailed herein, it is contemplated that other suitable microwave ablation antennas may be utilized in accordance with the present disclosure. For example, the ablation antennas and systems described in U.S. Patent Application No. 14/828,682 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 Application No. 13/836,203 entitled MICROWAVE ABLATION CATHETER AND METHOD OF UTILIZING THE SAME, filed on March 15, 2013 by Ladtkow et al., U.S. Patent Application No. 13/834,581 entitled MICROWAVE ENERGY-DELIVERY DEVICE AND SYSTEM, filed on March 15, 2013 by 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] In addition to the EM tracking system, the surgical instruments, e.g., microwave ablation antenna assembly 160, may also be visualized by using ultrasound imaging work station 150. Ultrasound sensor 140, such as an ultrasound wand, may be used to image the patient’s body during the microwave ablation procedure to visualize the location of microwave ablation antenna assembly 160 inside the patient’s body. Ultrasound sensor 140 may have an EM tracking sensor embedded within or attached to the ultrasound wand, for example, a clip-on sensor or a sticker sensor. Ultrasound sensor

140 may be positioned in relation to microwave ablation antenna assembly 160 such that microwave ablation antenna assembly 160 is at an angle to the ultrasound image plane, thereby enabling the clinician to visualize the spatial relationship of microwave ablation antenna assembly 160 with the ultrasound image plane and with objects being imaged. Further, the EM tracking system may also track the location of ultrasound sensor 140. This spatial depiction of the ultrasound sensor 140 and the microwave ablation antenna assembly 160 is described in greater detail in U.S. Patent Application No. 62/154,924 entitled METHODS FOR MICROWAVE ABLATION PLANNING AND PROCEDURE, filed on April 30, 2015 by Girotto, which is incorporated herein by reference. During surgery, one or more ultrasound sensors 140 may be placed on or inside the body of the patient. EM tracking system may then track the location of such ultrasound sensors 140 and microwave ablation antenna assembly 160 as they are moved relative to each other. It is also envisioned that ultrasound workstation 150 and its related components may be interchanged with real time fluoroscopy, MRI or CT imaging stations.

[0039] Referring now to FIG. 3, microwave ablation antenna assembly 160, microwave ablation generator 115, touch display computer 110, and peristaltic pump 117 are depicted schematically as housed on base unit 170 of system 10 (FIG. 1). Microwave ablation antenna assembly 160 is coupled to a microwave generator 115 via a flexible coaxial cable 116. Microwave generator 115 is configured to provide microwave energy at an operational frequency from about 915MHz to about 2.45GHz, although other suitable frequencies are also contemplated. Microwave ablation antenna assembly 160 may include a connection hub 162 for connection of coaxial cable 116, as well as the connection of a fluid inlet port 164 and a fluid outlet port 166. Fluid inlet port 164 permits the ingress of fluid into the microwave ablation antenna assembly 160 for cooling of components housed therein and control of the energy dissipation of microwave energy.

Fluid outlet port 166 permits the egress of the fluid following circulation of the fluid through the microwave ablation antenna assembly 160.

[0040] The ports 164 and 166 are also coupled to a pump 117 that is, in turn, coupled to a supply tank 118 via a connection line 119a. Supply tank 118 may be a fluid filled bag (e.g., saline), as depicted in FIG. 3, or any other type of storage unit for any type of fluid. Pump 117 may be a positive displacement pump, such as a peristaltic pump. The supply tank 118 stores the fluid and may maintain the fluid at a predetermined temperature. The supply tank 118 may include a coolant unit (not explicitly shown) that cools returning liquid from the microwave ablation antenna assembly 160. In another embodiment, the fluid may be a gas and/or a mixture of liquid and gas. Pump 117 forces fluid from supply tank 118 through a supply line 119b into microwave ablation antenna assembly 160, such that heat is drawn away from the microwave ablation antenna assembly 160, which may enhance the overall ablation pattern, prevent damage to microwave ablation antenna assembly 160, and prevent harm to the clinician or patient. The fluid is returned to pump 117 and, ultimately, supply tank 118, via return line 119c and pump return line 119d. Connected to and branching from supply line 119b is an irrigation line 119e, which includes a valve 167 and an outlet nozzle 168. As will be described in more detail below (FIG. 7), during use, irrigation line 119e permits the egress of cooling fluid (e.g., saline) through outlet nozzle 168 into introducer 500 such that the space between the outer surface of microwave ablation antenna assembly 160 and introducer 500 is filled with cooling fluid. Additionally or alternatively, fluid may be ejected from the free end 503 of introducer 500 into a target site.

[0041] FIG. 3 illustrates the distal portion 200 of the microwave ablation antenna assembly 160. Distal portion 200 of microwave ablation antenna assembly includes a proximal radiating portion 212 having a length “L1,” and a distal radiating portion 214

having a length “L2,” including an electrically-conductive radiator 205 and a feed point 207 disposed between the proximal and distal radiating portions 212 and 214. A feedline 204 is formed of a coaxial cable having an inner conductor 206, and outer conductor 208, and a dielectric 210 separating the two. The feedline 204 is connected at its proximal end to flexible cable 116 (Fig. 3). The distal radiating portion 214 and the proximal radiating portion 212 may be either balanced (e.g., of equal lengths) or unbalanced (e.g., of unequal lengths). The proximal radiating portion 212 may be formed of a portion of the feedline 204, and particularly the outer conductor 208 extending between a balun 220 and the feedgap 216.

[0042] Referring still to FIG. 3, microwave ablation antenna assembly 160 also includes a balun (e.g., a choke) 220 disposed around the feedline 204. The balun 220 may be a quarter-wavelength balun formed of at least a dielectric layer 221 and a conductive layer 223. The conductive layer 223 may be shorted to the feedline 204 at the proximal end of the balun 220 by soldering or other suitable methods, or may be in electrical contact with a balun short 225 which itself is in electrical contact with the outer conductor 208 of the feedline 204. Microwave ablation antenna assembly 160 also includes a tip 215 having a tapered end 217 that terminates, in one embodiment, at a pointed end 219 to allow for insertion into tissue with minimal resistance. In cases where the microwave ablation assembly 160 is inserted into a pre-existing opening, tip 215 may be rounded or flat. The tip 215 may be formed from a variety of heat-resistant materials suitable for penetrating tissue, such as metals (e.g., stainless steel) and various thermoplastic materials, such as polyetherimide, and polyamide thermoplastic resins.

[0043] The microwave ablation antenna assembly 160 includes fluid channels 227 and 229. Fluid channel 227 is spaced between the feedline 204 (including its electrically connected components balun 220 and proximal and distal radiating portions 212 and 214)

and an inner tube 231. Fluid channel 229 is formed between the inner tube 231 and an outer cannula 233 of the microwave ablation antenna assembly 160. Fluid channel 227 connects to fluid inlet port 164 and fluid channel 229 connects to fluid outlet port 166, thereby completing a fluid circuit from the fluid tank 118, through the pump 117 and through the microwave ablation antenna assembly 160.

[0044] Referring now to FIG. 4, an example of a stylus 400 is generally depicted, including a cap 401, a shaft 402, and a tip 403. With reference to FIG. 5, an introducer 500 is generally depicted and includes a fitting 501, a shaft 502, and a free end 503. Stylus 400 (FIG. 4) is fabricated such that it may be disposed within introducer 500 (FIG. 5) in coaxial arrangement. In use, stylus 400 and introducer 500 are inserted into a patient's body together (FIG. 6, access assembly 600), with the tip 403 of stylus 400 projecting slightly beyond the free end 503 of introducer 500 for piercing the skin. After stylus 400 and introducer 500 have reached their target destination (e.g., the tumor site), stylus 400 is removed. Microwave ablation antenna assembly 160 is then inserted and advanced down shaft 502 of introducer 500 (FIG. 7, as treatment assembly 700) such that treatment of the target site can be initiated.

[0045] Referring back to FIG. 4, stylus 400 may be formed of a metallic or non-metallic (e.g., ceramic MRI compatible) rigid or semi-rigid material having the ability to traverse tissue. Preferably, stylus 400 is formed of a material that is visible in real time ultrasound, CT, MRI, or other imaging systems. Cap 401 of stylus 400 may have a lumen (not shown) for ejection of fluids (e.g., blood), or so that other devices (e.g., guide wires) may be inserted into the lumen through shaft 402 of stylus 400. Cap 401 may also have a lock fitting for attachment to other devices, such as fitting 501 of introducer 500, microwave ablation antenna assembly 160, guide wires, extending working channels, or the like. Shaft 402 of stylus 400 may be any length (e.g., 10cm, 15cm, 20cm, etc.) and

may have a substantially straight or, alternatively, a curved profile. Stylus 400 may also be articulable and/or steerable to accommodate a specific surgical procedure, a specific luminal structure, specific target tissue, a clinician's preference, etc. For example, a user may manipulate shaft 402 of stylus 400 to adopt a curved profile such that stylus 400 may traverse critical tissue structures or narrow pathways to reach a target site. Tip 403 of stylus 400 may be a sharp edge for penetrating skin, such as a single bevel, dual bevel, or the like.

[0046] With reference to FIG. 5, introducer 500 may be formed from Polyether ether ketone (PEEK), fiberglass, or any other plastic, polymer, or the like. Preferably, introducer 500 is formed of a material visible in real time ultrasound, CT, or MRI imaging. Depth markers may be placed on shaft 502 of stylus 500 for indicating distance (e.g., in real time ultrasound, CT, or MRI imaging). Introducer 500 may be rigid, semi-rigid, or flexible and may be formed of a shape-memory material, such that it can adopt and maintain the profile (e.g., curved) of steerable stylus 400 (FIG. 6, described in more detail below). Fitting 501 of introducer 500 may have a lumen (not shown) for connection and/or insertion of other devices (e.g., guide wires, extended working channels, microwave ablation antenna assembly 160, stylus 400, etc.). Shaft 502 of introducer 500 may be fabricated of any length suitable to reach a target site. Likewise, shaft 502 of introducer 500 may have any suitable outer diameter for passage into and through tissues, vessels, or other luminal networks, or any suitable inner diameter (e.g., a lumen) for the insertion of other devices 502 (e.g., microwave ablation antenna assembly 160, stylus 400, etc.) through the inside of shaft 503.

[0047] Referring now to FIG. 6, an access assembly 600 is depicted, which includes stylus 400 and introducer 500, as shown inside a body cavity. During use, stylus 400 and introducer 500 are inserted together as access assembly 600, with stylus 400

inserted into introducer 500 and aligned coaxially therewith. Tip 403 of stylus 400 protrudes from free end 503 of introducer 500 for puncturing skin and advancing access assembly 600 to a desired target site. Stylus 400 is manipulated, articulated, and/or steered to avoid critical tissue structures and to reach the desired target site. For example, as shown in FIG. 6, stylus 400 may include an articulation joint 410, which may be articulated by using a dial or other attachment (not shown) that is separate from or integral to cap 401. Advantageously, access assembly 600 assists in eliminating stresses applied to microwave ablation antenna assembly 160 during insertion because all of the tissue separation is done by access assembly 600 and not microwave ablation antenna assembly 160.

[0048] With continued reference to FIG. 6, introducer 500 dynamically adopts and maintains the path of stylus 400 even after formed stylus 400 is removed. Although stylus 400 and introducer 500 are shown as having a single curved configuration, it should be appreciated that stylus 400 and introducer 500 of access assembly 600 may adopt a trajectory having any configuration (e.g., straight, a plurality of curves, etc.) for reaching challenging targets. After the desired target site has been reached, stylus 400 may be withdrawn from introducer 500, with introducer 500 maintaining the trajectory that formed stylus 400 had prior to its removal from introducer 500. After removal of stylus 400, introducer 500 may be kept in place by the body's natural pressures. In other words, removal of the stylus 400 leaves behind the flexible introducer 500, which can be compressed and held in place by the tissue in which it is inserted. As such, introducer 500 maintains access to the target site and is ready for insertion of microwave ablation antenna assembly 160 for treatment of the target site.

[0049] If multiple tumors are identified at several remote locations within the same patient, the same procedure described above can be repeated. For example, multiple

introducers 500 may be placed and left at several target sites within the body. After a surgeon finishes ablating one target site and removes microwave ablation antenna assembly 160 from a first introducer 500, the surgeon may move on to the second introducer 500, insert microwave ablation antenna assembly 160, and begin ablation at a second target site, and so on and so forth. Thus, advantageously, a surgeon may reuse a single microwave ablation antenna assembly 160 to sequentially ablate all required target sites. The aforementioned procedure reduces the cost of procedures which require the placement of multiple antennas. Further, introducer 500 and stylus 400 are less likely to move after placement as compared to microwave ablation antenna assemblies which require separate cooling fluid lines, energy feed lines, and the like, all of which exert force on the microwave ablation antenna assembly and can cause it to move after placement. Having none of these encumbrances, introducer 500 and stylus 400 are less prone to movement after placement in a target site.

[0050] Referring now to FIG. 7, a treatment assembly 700 is shown, including microwave ablation antenna assembly 160 and introducer 500. After the removal of stylus 400 from introducer 500, microwave ablation antenna assembly 160 is inserted into introducer 500 and aligned coaxially therewith. Advantageously, introducer 500 is formed from a non-conductive (e.g., non-metallic) material allowing microwave ablation antenna assembly 160 to radiate through introducer 500. Specifically, proximal radiating portion 212 and distal radiating portion 214 of distal portion 200 of microwave ablation antenna assembly 160 can radiate energy and generate an ablation field “F” (FIG. 7) through any portion of introducer 500, which allows treatment of target sites (e.g., “T1,” “T2,” and “T3”) beyond just the free end 503 of introducer 500, as shown in FIG. 7. As such, microwave ablation antenna assembly 160 can be retracted or advanced through introducer 500, so that target sites anywhere along the trajectory of introducer 500 can receive the

optimal amount of radiation from the radiating portions 212, 214 of microwave antenna assembly 160. As shown in FIG. 7, after target sites T1 and T2 have been treated, microwave ablation antenna assembly 160 may be retracted within introducer 500 until it is proximal to target T3. After microwave ablation antenna assembly 160 is in place, an ablation field “F” is generated for treatment of target T3.

[0051] Moreover, radiating through introducer 500 helps prevent the charring of tissue and/or the sticking of microwave ablation antenna assembly 160 to tissue during ablation. Thus, by preventing charring and sticking, wavelength elongation and/or reduction of the dielectric constant is also prevented. In order to further enhance the overall ablation field, fluid is allowed to flow between the outer surface of microwave ablation antenna assembly 160 and introducer 500 via irrigation line 119e and outlet nozzle 168 of microwave ablation antenna assembly 160 (FIG. 2). The cooling fluid (e.g. saline) has an unchanging dielectric constant versus air or other fluids. As such, cooling and/or surrounding the external surface of microwave ablation antenna assembly 160 with fluid maintains the dielectric constant, reduces or eliminates wavelength elongation, enables larger and more uniform ablation zones, and enhances impedance matching over internal cooling of microwave ablation antenna assembly 160 alone.

[0052] Free end 503 of introducer 500 may have an airtight or watertight seal (e.g., a gasket and/or through an interference fit with microwave ablation antenna assembly 160) to prevent the ejection of fluid into a target site. Alternatively, free end 503 of introducer 500 may allow for the passage of fluid into a target site. The expulsion of fluid from the free end 503 of introducer 500 may be used to hydro-defect or move tissue structures out of the path of treatment assembly 700, or to positively affect the dielectric constant of the area proximate to the target site. Referring back to FIG. 1, a supply line 180 may be connected to a source of therapeutic (e.g., chemotherapeutic) agents, which

may then be delivered into and/or out of introducer 500. The therapeutic agents may be, for example, thermo-sensitive or activated upon the radiation from microwave ablation antenna assembly 160.

[0053] Referring now to FIG. 8, an example screen 800 is shown, which may be displayed on touch display computer 110 or display 130 during a microwave ablation procedure. Screen 800 includes a view 801 of the live 2D ultrasound (or real time CT, MRI, fluoroscopy) images captured during the procedure. Screen 800 may aid a user in the positioning and/or the resulting location of access assembly(s) 600, treatment assembly(s) 700, stylus(s) 400, introducer(s) 500, microwave ablation antenna assembly(s) 160, or any other devices used in the procedure. Ultrasound sensor 140 may be positioned in relation to the aforementioned devices such that they are at an angle to the ultrasound image plane, thereby enabling the clinician to visualize their spatial relationship with the ultrasound image plane and with objects being imaged. As can be appreciated, other imaging techniques such as fluoroscopy, CT and MRI may be used with and/or separately from ultrasound workstation 150 to e.g., visualize and confirm placement of stylus 400, introducer 500, and microwave ablation antenna assembly 160 into a target.

[0054] Although embodiments have been described in detail with reference to the accompanying drawings for the purpose of illustration and description, it is to be understood that the inventive processes and apparatus are not to be construed as limited thereby. It will be apparent to those of ordinary skill in the art that various modifications to the foregoing embodiments may be made without departing from the scope of the disclosure.

WHAT IS CLAIMED IS:

1. A microwave ablation system comprising:
 - an introducer having a lumen therethrough;
 - a stylus configured for slidable engagement within the lumen of the introducer; and
 - a microwave ablation antenna configured to deliver energy to a target during an ablation procedure, wherein the microwave ablation antenna is configured for slidable engagement within the lumen of the introducer.
2. The microwave ablation system of claim 1, further comprising an electromagnetic navigation system to facilitate navigation of at least the introducer, the stylus, and the microwave ablation antenna to the target.
3. The microwave ablation system of claim 1, wherein the introducer is formed from a non-conductive material that allows the microwave ablation antenna to radiate microwave energy throughout an entire length of the introducer.
4. The microwave ablation system of claim 1, wherein the introducer is formed from a material selected from the group consisting of Polyether ether ketone and fiberglass.
5. The microwave ablation system of claim 1, wherein the introducer has a first end, a second end, and a shaft disposed therebetween, wherein:
 - the first end has a first aperture and a fitting configured for engagement with the microwave ablation antenna and the stylus;

the second end has a second aperture; and
the shaft has a length, an outside diameter, and an inside diameter defined
by a lumen.

6. The microwave ablation system of claim 1, wherein the stylus is configured to articulate and adopt at least one curved configuration to navigate to the target.
7. The microwave ablation system of claim 6, wherein the introducer is formed from a shape-memory material and configured to adopt and maintain the at least one curved configuration of the stylus.
8. The microwave ablation system of claim 7, wherein the introducer maintains the at least one curved configuration defined by the stylus after the stylus has been removed from the introducer.
9. The microwave ablation system of claim 1, wherein a fluid can be introduced into the lumen of the introducer.
10. The microwave ablation system of claim 9, wherein the fluid is disposed between an outer surface of the microwave ablation antenna and the lumen of the introducer.
11. The microwave ablation system of claim 1, wherein therapeutic agents can be introduced into the lumen of the introducer.

12. The microwave ablation system of claim 11, wherein the therapeutic agents are thermo-sensitive and configured to react with the energy radiated from the microwave ablation antenna.

13. The microwave ablation system of claim 2, wherein the electromagnetic navigation system is used in conjunction with real time ultrasound, fluoroscopy, CT, or MRI imaging.

14. A method of performing a microwave ablation procedure, comprising:

- inserting a combination introducer and stylus into a patient at a desired location;
- navigating the combination introducer and stylus to a target;
- inserting the combination introducer and stylus into the target;
- removing the stylus from the introducer while leaving the introducer in the target;
- inserting a microwave ablation antenna into a lumen of the introducer;
- advancing the microwave ablation antenna through the lumen of the introducer until a radiating (portion or section of) the microwave ablation antenna is proximate the target; and
- radiating energy from the microwave ablation antenna through at least a portion of the introducer into the target.

15. The method of claim 14, further comprising:

- placing a first introducer at a first target; and
- placing a second introducer at a second target.

16. The method of claim 14, further comprising:
providing an electromagnetic navigation system to facilitate navigation of the introducer, the stylus, and the microwave ablation antenna to the targets.
17. The method of claim 14, wherein the introducer is formed from a non-conductive material that allows the microwave ablation antenna to radiate microwave energy throughout an entire length of the introducer.
18. The method of claim 14, further comprising:
introducing fluid into the lumen of the introducer between an outer surface of the microwave ablation antenna and an inner surface of the lumen of the introducer.
19. A kit for use with a microwave ablation system, comprising:
at least one introducer having a lumen therethrough;
a stylus configured for slidable engagement within the lumen of the at least one introducer; and
a microwave ablation antenna configured to deliver energy to a target during an ablation procedure, wherein the microwave ablation antenna is configured for slidable engagement within the lumen of the at least one introducer.
20. The kit of claim 19, wherein the at least one introducer is formed from a non-conductive material that allows the microwave ablation antenna to radiate microwave energy throughout an entire length of the at least one introducer.

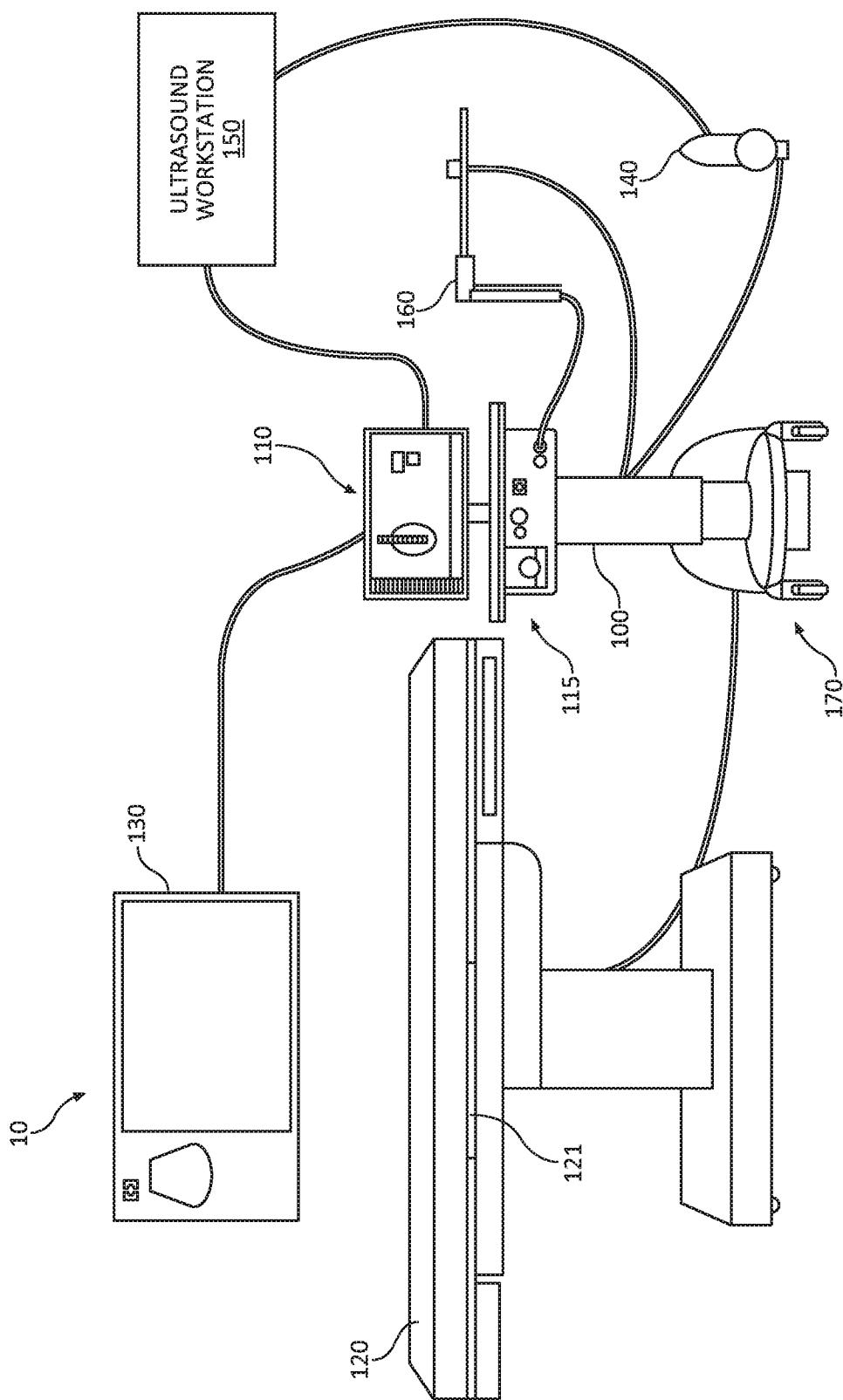
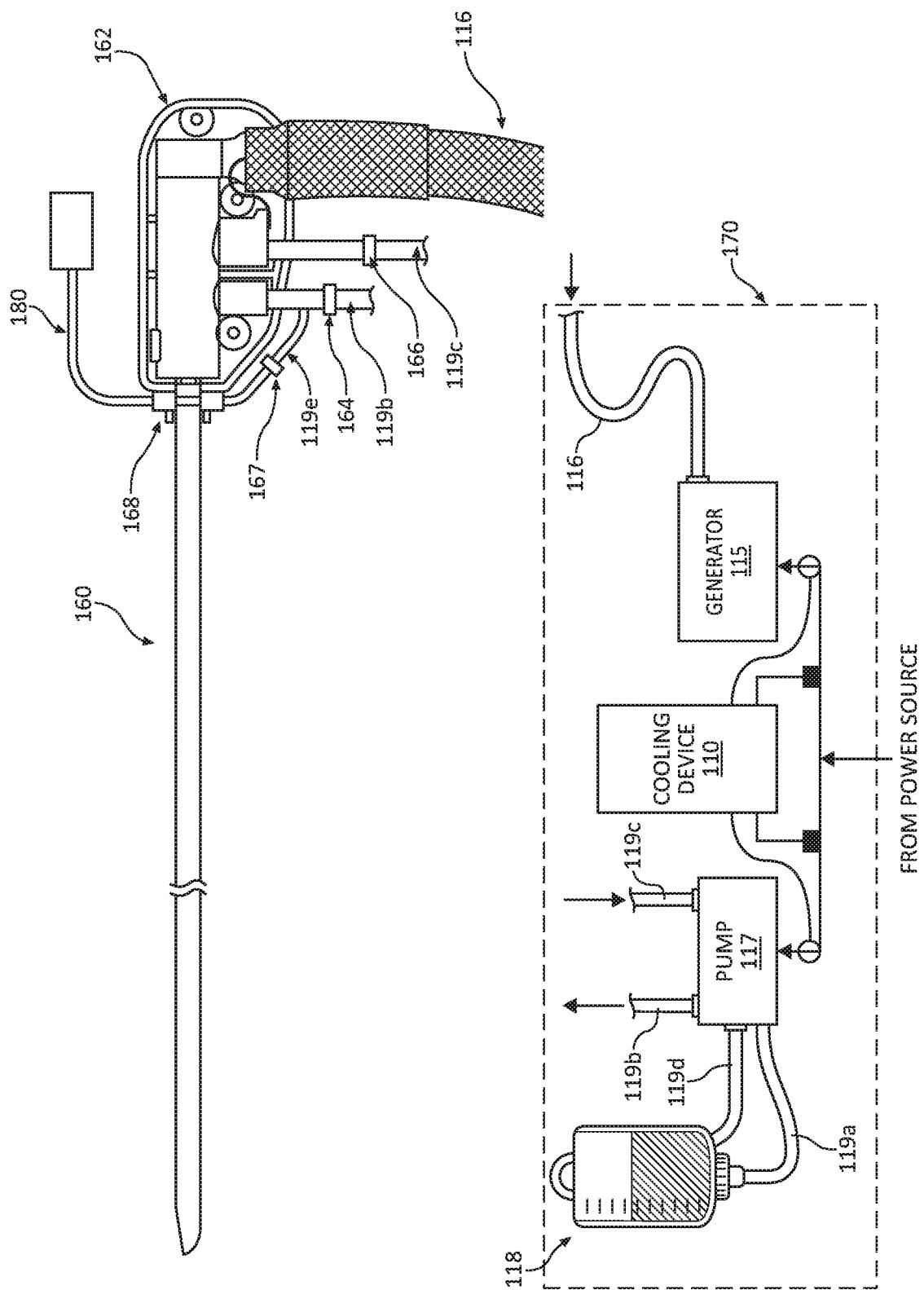
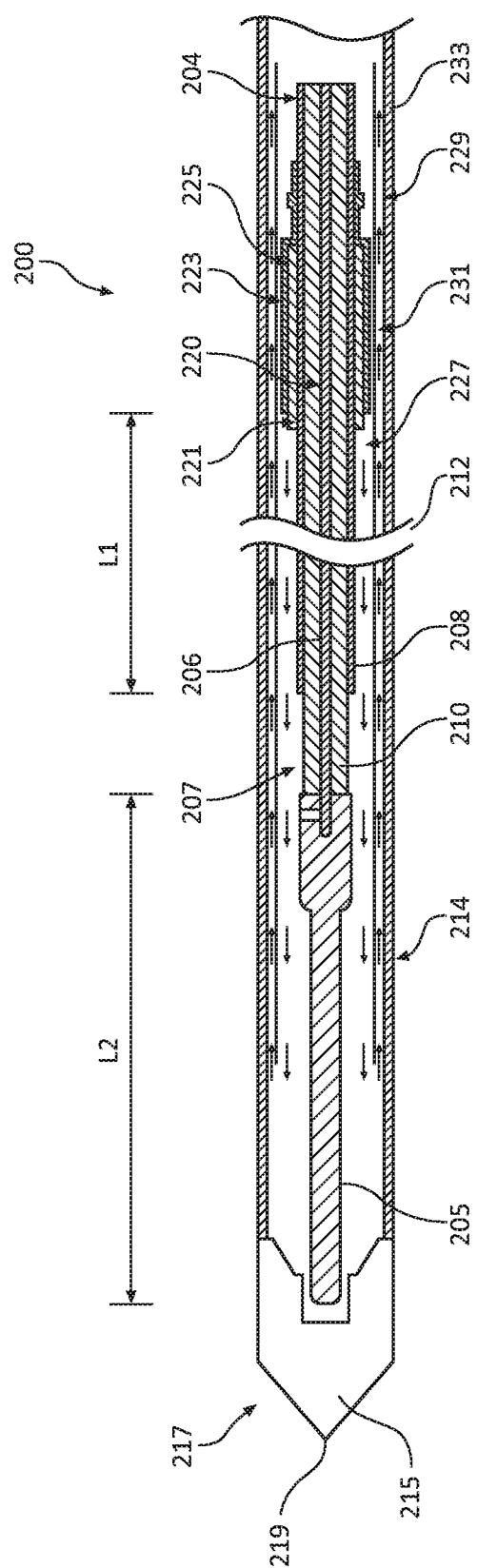
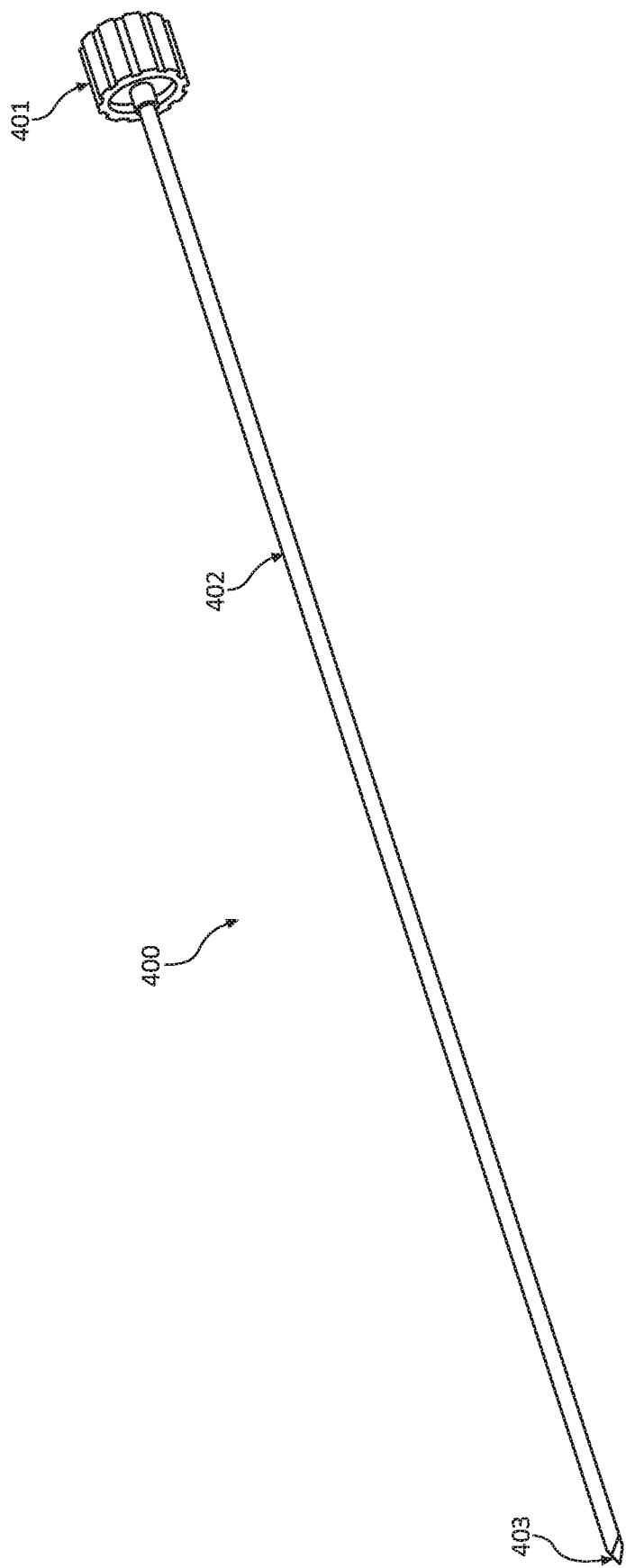


FIG. 1

**FIG. 2**

**FIG. 3**

**FIG. 4**

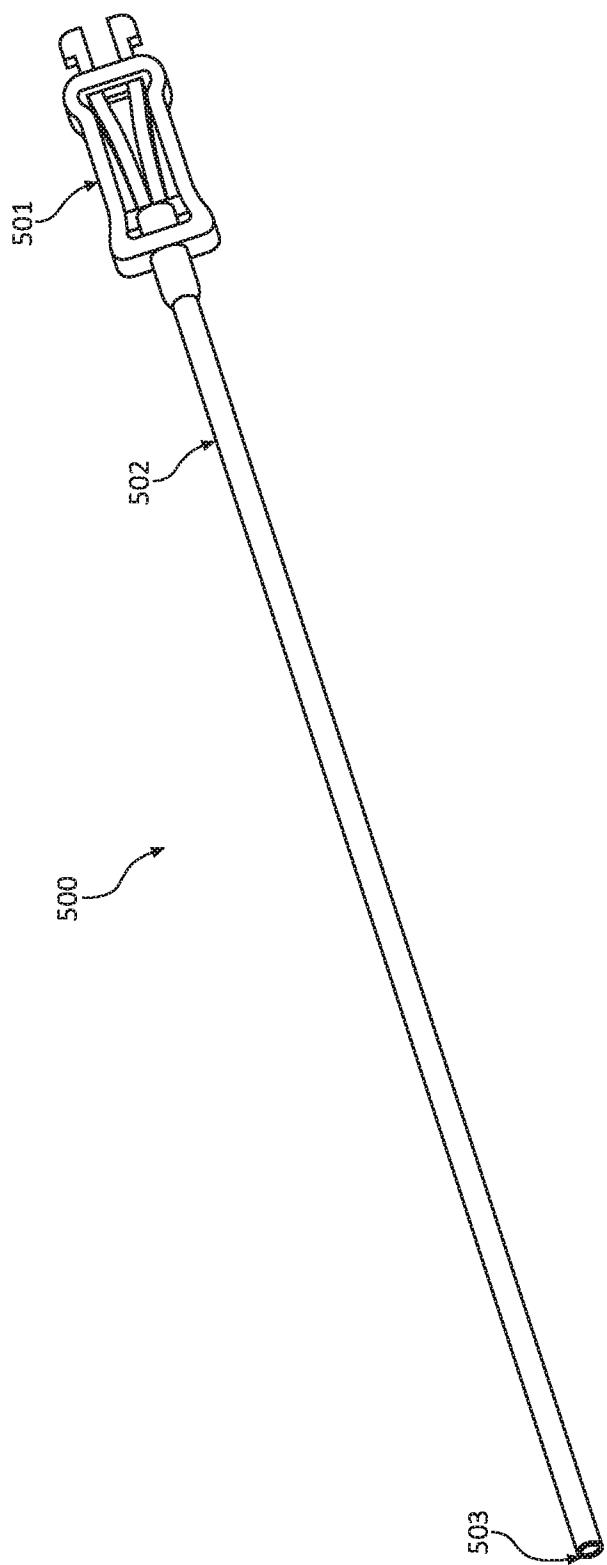


FIG. 5

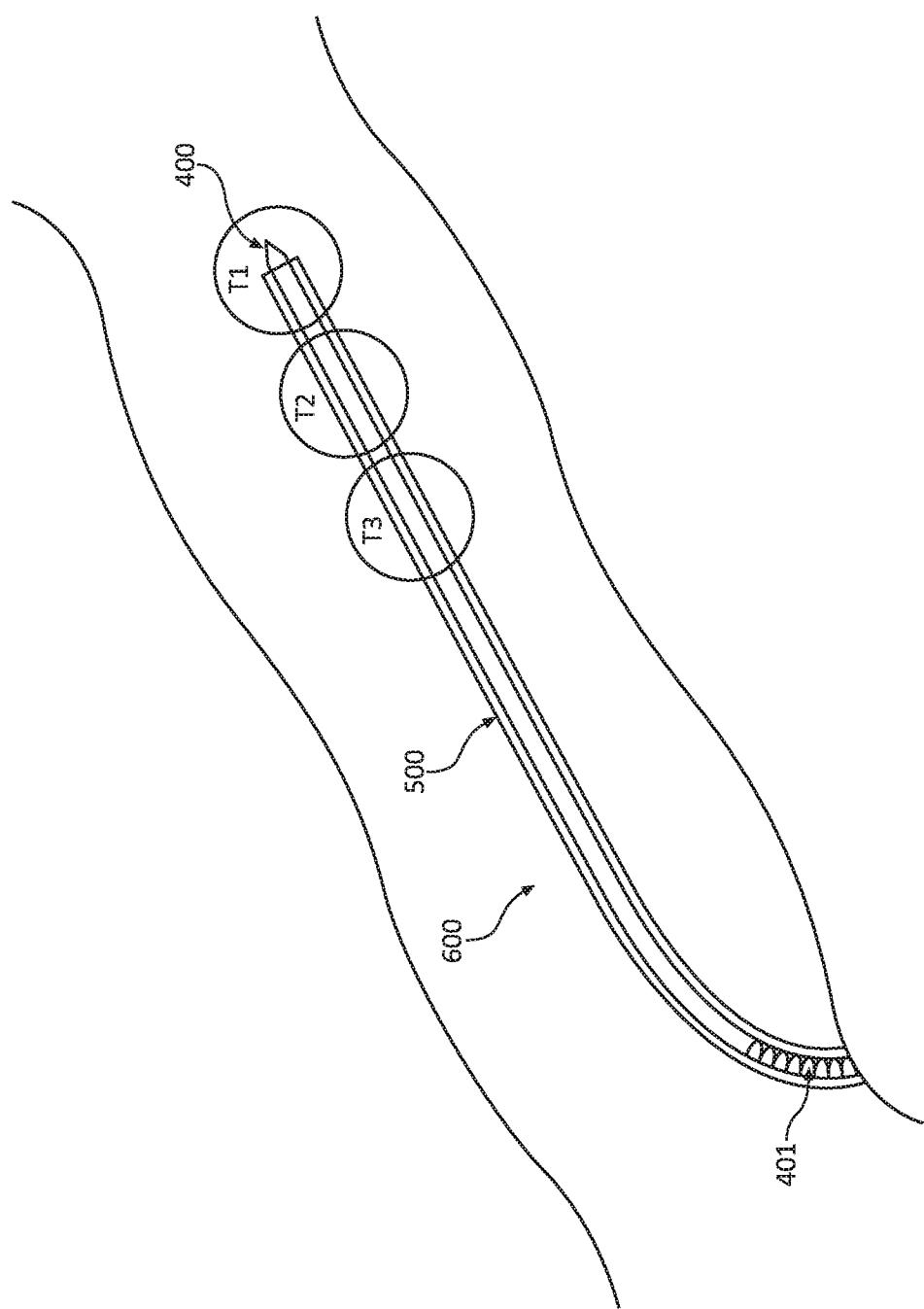


FIG. 6

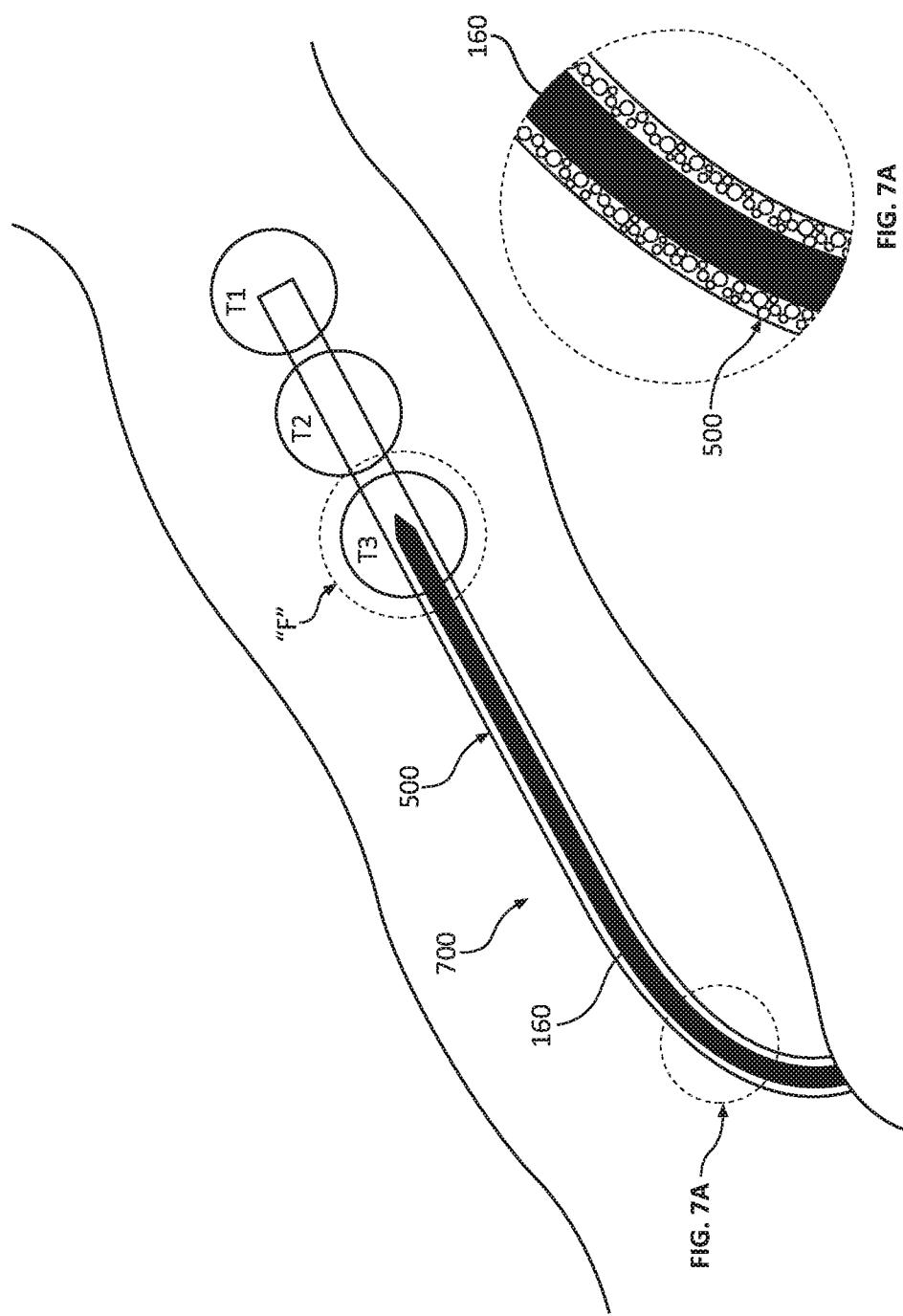
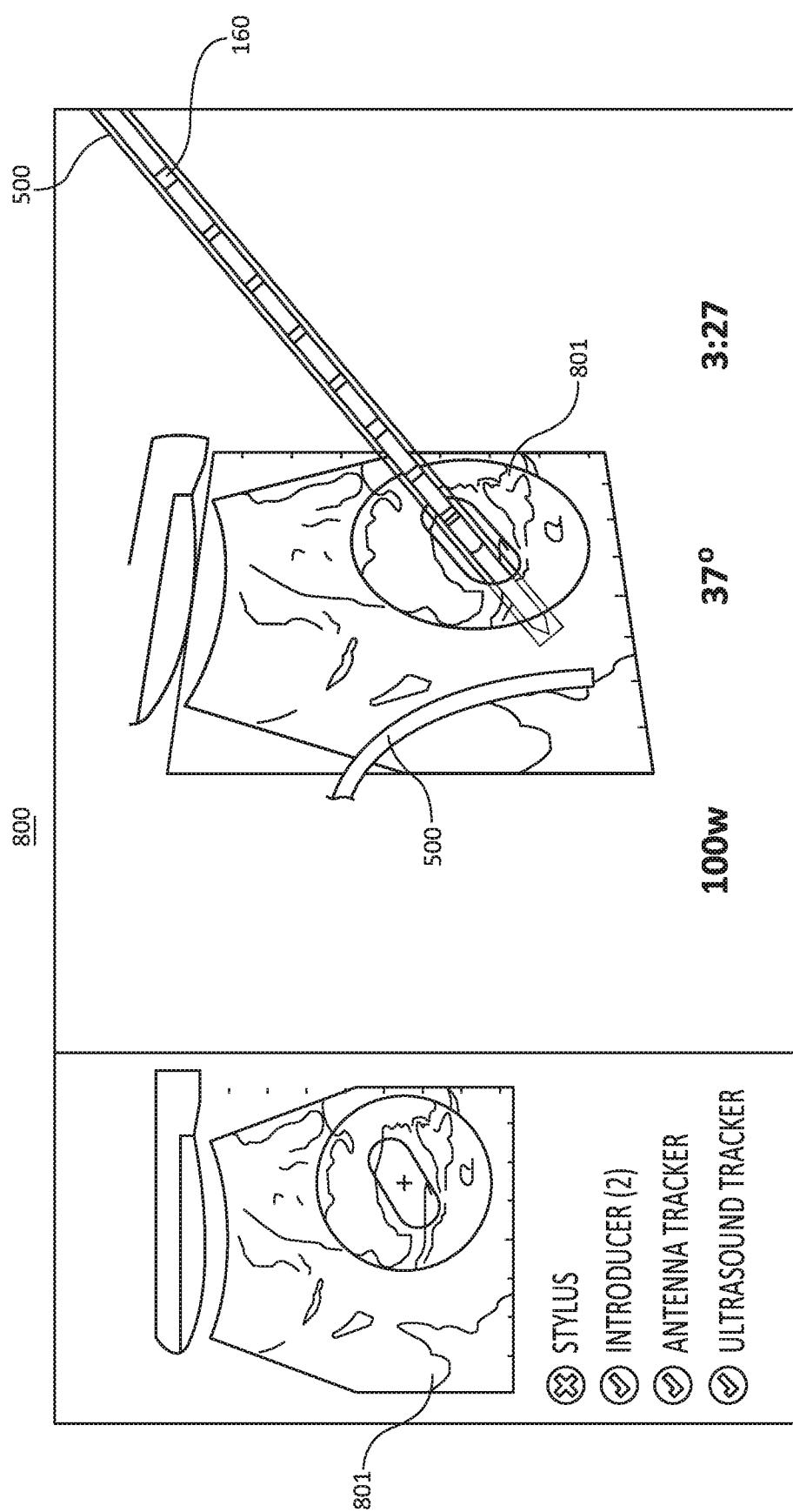


FIG. 7

**FIG. 8**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/016855

A. CLASSIFICATION OF SUBJECT MATTER

A61B 18/18(2006.01)i, A61L 31/06(2006.01)i, A61L 31/14(2006.01)i, A61B 18/00(2006.01)i, A61M 25/09(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 18/18; A61B 18/14; A61M 25/00; A61K 33/00; A61L 31/06; A61L 31/14; A61B 18/00; A61M 25/09

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility modelsElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: introducer, stylus, microwave ablation antenna, electromagnetic navigation system

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013-0226172 A1 (COVIDIEN LP) 29 August 2013 See paragraphs [0028]–[0030], [0032]–[0034], [0039], [0045], [0048], [0053]; and figures 1A–3B, 5B.	1, 2, 5, 6, 9, 10, 13, 19
Y		3, 4, 7, 8, 11, 12, 20
Y	US 2011-0004205 A1 (CHU, C. Y. et al.) 06 January 2011 See abstract; paragraphs [0060], [0063]; and figure 2A.	3, 4, 20
Y	US 2006-0241564 A1 (CORCORAN, N. et al.) 26 October 2006 See paragraphs [0053], [0058]; claims 1, 11; and figures 1, 3.	7, 8
Y	US 8476242 B2 (MON, J.) 02 July 2013 See column 14, line 43 – column 15, line 12; column 16, lines 5–39; and figures 1A–1 – 1A–3, 6A–6C.	11, 12
A	US 2015-0366615 A1 (COVIDIEN LP) 24 December 2015 See the whole document.	1–13, 19, 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	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 22 May 2017 (22.05.2017)	Date of mailing of the international search report 22 May 2017 (22.05.2017)
Name and mailing address of the ISA/KR International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea Facsimile No. +82-42-481-8578	Authorized officer CHO, Ki Yun Telephone No. +82-42-481-5655

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/016855

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

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

1. Claims Nos.: 14-18
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 14-18 pertain to a method for treatment of the human body by surgery and thus relate to a subject-matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

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

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2017/016855

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013-0226172 A1	29/08/2013	EP 2786720 A1 EP 2786720 B1 US 2011-0054459 A1	08/10/2014 04/01/2017 03/03/2011
US 2011-0004205 A1	06/01/2011	CN 102245119 A CN 102256560 A CN 102256560 B CN 104487854 A EP 2349045 A1 EP 2349045 A4 EP 2349045 B1 EP 2349452 A1 EP 2349452 A4 EP 2349452 B1 EP 2355738 A1 EP 2355738 A4 EP 2355738 B1 EP 2813192 A2 EP 2813192 A3 EP 2831604 A1 EP 2831604 A4 JP 2012-508062 A JP 2015-037587 A JP 5406933 B2 JP 6083928 B2 US 2010-0121319 A1 US 2010-0125269 A1 US 2010-0137857 A1 US 2013-0256302 A1 US 2014-0190960 A9 US 2014-0358140 A1 US 2015-0313670 A1 US 8808281 B2 US 8968287 B2 US 9462642 B2 WO 2010-048334 A1 WO 2010-048335 A1 WO 2010-053700 A1 WO 2012-003232 A1 WO 2013-149245 A1	16/11/2011 23/11/2011 09/07/2014 01/04/2015 03/08/2011 11/04/2012 16/07/2014 03/08/2011 05/09/2012 11/05/2016 17/08/2011 09/05/2012 19/08/2015 17/12/2014 15/04/2015 04/02/2015 30/03/2016 05/04/2012 26/02/2015 05/02/2014 22/02/2017 13/05/2010 20/05/2010 03/06/2010 03/10/2013 10/07/2014 04/12/2014 05/11/2015 19/08/2014 03/03/2015 04/10/2016 29/04/2010 29/04/2010 14/05/2010 05/01/2012 03/10/2013
US 2006-0241564 A1	26/10/2006	AT 452676 T EP 1709987 A1 EP 1709987 B1	15/01/2010 11/10/2006 23/12/2009
US 8476242 B2	02/07/2013	CA 2602065 A1 CA 2602065 C EP 1877089 A2 EP 1877089 B1	28/09/2006 12/08/2014 16/01/2008 20/11/2013

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2017/016855

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2006-0216275 A1	28/09/2006
		US 2007-0077230 A1	05/04/2007
		US 8765116 B2	01/07/2014
		WO 2006-102471 A2	28/09/2006
		WO 2006-102471 A3	23/08/2007
US 2015-0366615 A1	24/12/2015	AU 2014-201394 A1	02/10/2014
		CA 2845864 A1	15/09/2014
		CN 104042337 A	17/09/2014
		CN 104042341 A	17/09/2014
		CN 203873877 U	15/10/2014
		CN 203943736 U	19/11/2014
		EP 2796106 A1	29/10/2014
		EP 2796106 B1	25/05/2016
		EP 3067004 A1	14/09/2016
		JP 2014-180547 A	29/09/2014
		JP 2014-180582 A	29/09/2014
		US 2014-0276739 A1	18/09/2014
		US 2017-0056109 A1	02/03/2017
		US 9119650 B2	01/09/2015
		US 9498286 B2	22/11/2016