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(54) **Title**: SELECTIVELY DEFORMABLE ABLATION DEVICE

(57) **Abstract**: In accordance with at least one aspect of this disclosure, an ablation apparatus includes a proximal body portion, a shaft extending distally from the proximal body portion, the shaft being selectively deformable utilizing at least one deformation system between a first position wherein the shaft is straight an a second position wherein the shaft is bent, the at least one deformation system configured to retain the shaft in each of the first and second positions, and at least one electrode disposed at least partially within the shaft, the electrode movable with the shaft upon movement of the shaft between the first and second positions.

SELECTIVELY DEFORMABLE ABLATION DEVICE

BACKGROUND

1. Technical Field

[0001] The present disclosure relates to medical instruments. More particularly, the present disclosure is directed to selectively deformable medical devices for use in a surgical procedure.

2. Background of the Related Art

[0002] The use of radio-frequency (RF) and other forms of energy to create therapeutic lesions in living bodies to facilitate healing has been around for many decades. Ablation electrodes, for example, are configured to be inserted into a living body and to apply energy to surrounding tissue to form these tissue lesions. A typical ablation electrode incorporates an insulated sheath from which an exposed (uninsulated) tip extends that emits energy to surrounding tissue to create a tissue lesion.

[0003] Generally, the ablation electrode is coupled between a grounded RF power source, e.g., an electrosurgical generator, and a reference ground or indifferent electrode, e.g., return electrode pad, that is in contact with and dimensioned to engage a large surface of the body. When an RF voltage is provided between the ablation electrode and the reference ground, RF current flows from the ablation electrode through the body and back to the energy source via the return electrode pad. Typically, the current density is very high near the tip of the ablation electrode, which heats and destroys the adjacent tissue.

[0004] Many surgical instruments incorporate deformable or bendable shafts that allow the instrument to be better positioned within an internal surgical site. For example, U.S. Patent 6,911,029 to Platt, the entire disclosure of which is hereby incorporated by reference herein, discloses an electrosurgical coagulator including an articulatable member. With respect to ablation devices, providing a deformation system that allows for bending or deformation would facilitate the insertion and/or placement of the electrode within a living body adjacent the target tissue to be treated.

SUMMARY

[0005] As shown in the drawings and described throughout the following description, as is traditional when referring to relative positioning on a surgical instrument, the term "proximal" refers to the end of the apparatus that is closer to the user and the term "distal" refers to the end of the apparatus that is farther away from the user. The term "clinician" refers to any medical professional (e.g., doctor, surgeon, nurse, or the like) performing a medical procedure involving the use of embodiments described herein.

[0006] In accordance with at least one aspect of this disclosure, an ablation apparatus includes a proximal body portion, a shaft extending distally from the proximal body portion, the shaft being selectively deformable utilizing at least one deformation system between a first position wherein the shaft is straight an a second position wherein the shaft is bent, the at least one deformation system configured to retain the shaft in each of the first and second positions, and at least one electrode disposed at least partially within the shaft, the electrode movable with the shaft upon movement of the shaft between the first and second positions.

[0007] In accordance with another aspect of this disclosure the deformation system comprises a goose-neck type shaft having at least two links operably coupled to each other.

[0008] In accordance with yet another aspect of this disclosure, the goose-neck type shaft includes a flexible layer disposed thereon to cover one or more separations between the at least two links.

[0009] In accordance with still yet another aspect of this disclosure, the shaft is made of a flexible material, and the deformation system comprises a line pull system, the line pull system comprising at least one anchor fixedly attached to the shaft, and at least one line connected to the at least one anchor and configured to be pulled to bend the shaft.

[0010] In accordance with still yet another aspect of this disclosure, the at least one line pull system comprises a first anchor connected to a first line, a second anchor connected to a second line and a third anchor connected to a third line, each anchor being spaced about equal distances circumferentially around the shaft such that the shaft is bendable in any desired direction.

[0011] In accordance with still yet another aspect of this disclosure, the shaft further comprises a flexible material and the deformation system comprises at least one of a material selected from the group consisting of a magnet and a ferromagnetic material, the material allowing the shaft to be moved by a magnetic field in the direction of the magnetic field.

[0012] In accordance with still yet another aspect of this disclosure, the deformation system further includes the material disposed within the flexible material at the distal end of the shaft.

[0013] In accordance with still yet another aspect of this disclosure wherein the deformation system comprises a weave having a rigid state and a deformable state.

[0014] In accordance with still yet another aspect of this disclosure, the rigid state is an elongated state and the deformable state is a neutral state.

[0015] In accordance with still yet another aspect of this disclosure, the deformable state is an elongated state and the rigid state is a neutral state.

[0016] In accordance with still yet another aspect of this disclosure, the deformation system comprises at least one semi-rigid rod configured to bend and hold the bent position.

[0017] In accordance with still yet another aspect of this disclosure, the semi-rigid rod is made of at least one metal.

[0018] In accordance with still yet another aspect of this disclosure, the deformation system includes at least one reservoir disposed within the shaft and at least one fluid supply connected to the reservoir to act as a pressure source, wherein the shaft is bendable when the reservoir is depressurized and rigid when the reservoir is pressurized.

[0019] In accordance with still yet another aspect of this disclosure, the deformation system comprises an electro-rheological material selectively connected to an electrical supply, the electro-rheological material having a rigid state and a deformable state.

[0020] In accordance with still yet another aspect of this disclosure, the electro-rheological material is in the deformable state when subjected to an electrical current.

[0021] In accordance with still yet another aspect of this disclosure, the electro-rheological material is in the rigid state when subjected to an electrical current.

[0022] In accordance with still yet another aspect of this disclosure, the deformation system comprises a magneto-rheological material selectively subjected to a magnetic field, the magneto-rheological material having a rigid state and a deformable state.

[0023] In accordance with still yet another aspect of this disclosure, wherein the magneto-rheological material is in the rigid state when subjected to a magnetic field.

[0024] In accordance with still yet another aspect of this disclosure, the deformation system comprises a spring winding disposed on said shaft, wherein the spring winding is connected to a tightener such that spring winding may be tightened to become substantially rigid and loosened to become deformable.

[0025] In accordance with still yet another aspect of this disclosure, a method for ablating a target site comprises providing an ablation apparatus including a proximal body portion, a shaft extending distally from the proximal body portion, the shaft being selectively deformable utilizing at least one deformation system between a first position wherein the shaft is straight an a second position wherein the shaft is bent, the at least one deformation system configured to retain the shaft in each of the first and second positions, and at least one electrode disposed at least partially within the shaft and extending from a distal end of the shaft, the electrode movable with the shaft upon movement of the shaft between the first and second positions, inserting the shaft into an incision, bending the shaft to position the at least one electrode at a target location and retaining the shaft in the bent position, and ablating the target location.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] The above and other aspects, features, and advantages of the present disclosure are described in detail with reference to the accompanying drawings, wherein like reference numerals may refer to similar or identical elements:

[0027] Fig. 1 is a schematic, side, cross-sectional view of an ablation apparatus provided in accordance with the present disclosure;

[0028] Fig. 2A is a side view of an ablation apparatus provided in accordance with the present disclosure in a straight position;

[0029] Fig. 2B is a side view of the ablation apparatus of Fig. 2A in a bent or deformed position;

[0030] Fig. 3A is a side view of another ablation apparatus provided in accordance with the present disclosure including a series of links disposed in a straight position;

[0031] Fig. 3B is a side view of the ablation apparatus of Fig. 3A in a bent position;

[0032] Fig. 4A is a top, perspective view of a representative link of the ablation apparatus of Figs. 3A and 3B;

[0033] Fig. 4B is a front view of the link of Fig. 4A;

[0034] Fig. 4C is a side, cross-sectional view of the link of Fig. 4B taken along section line 4C-4C;

[0035] Fig. 5A is an internal, side view of the ablation apparatus of Figs. 3A and 3B oriented in a straight position;

[0036] Fig. 5B is an internal, side view of the ablation apparatus of Figs. 3A and 3B oriented in a bent position;

[0037] Fig. 6A is a schematic illustration of another ablation apparatus provided in accordance with the present disclosure in a straight position;

[0038] Fig. 6B is a schematic illustration of the ablation apparatus of Fig. 6A in a bent position;

[0039] Fig. 6C is a perspective view of another ablation apparatus provided in accordance with the present disclosure in a straight position;

[0040] Fig. 7A is a schematic illustration of another ablation apparatus provided in accordance with the present disclosure in a straight position;

[0041] Fig. 7B is a schematic illustration of the ablation apparatus of Fig. 7A in a bent position;

[0042] Fig. 7C is an illustration of a magnet emitting a magnetic field;

[0043] Fig. 8A is a side view of another ablation apparatus provided in accordance with the present disclosure in a straight but flexible position;

[0044] Fig. 8B is a side view of the ablation apparatus of Fig. 8A in a bent position;

[0045] Fig. 8C is a side view of another ablation apparatus provided in accordance with the present disclosure in a straight and rigid position;

[0046] Fig. 9A is a side cross-sectional view of another ablation apparatus provided in accordance with the present disclosure in a straight position;

[0047] Fig. 9B is a side cross-sectional view of the ablation apparatus of Fig. 9A in a bent position;

[0048] Fig. 10A is a side, cross-sectional view of yet another ablation apparatus provided in accordance with the present disclosure in a straight position;

[0049] Fig. 10B is a side, cross-sectional view of the ablation apparatus of Fig. 10A in a bent position;

[0050] Fig. 10C is a side, cross-sectional view of the ablation apparatus of Fig. 10A in a bent but pressurized rigid position;

[0051] Fig. 11A is a side, cross-sectional view of another ablation apparatus provided in accordance with the present disclosure in a straight, switch-open position;

[0052] Fig. 11B is a side, cross-sectional view of the ablation apparatus of Fig. 11A in a bent, switch closed position;

[0053] Fig. 12A is a side view of yet another ablation apparatus provided in accordance with the present disclosure in a straight but flexible position;

[0054] Fig. 12B is a side view of the ablation apparatus of Fig. 12A in a bent but flaccid position; and

[0055] Fig. 12C is a side view of the ablation apparatus of Fig. 12A in bent but tightly-wound rigid position.

DETAILED DESCRIPTION

[0056] Particular embodiments of the present disclosure are described hereinbelow with reference to the accompanying drawings; however, the disclosed embodiments are merely examples of the disclosure and may be embodied in various forms. Well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

[0057] Referring to Figs. 1, 2A and 2B, an embodiment of an ablation device, e.g., radiofrequency ablation apparatus 100, is shown including an elongated electrode 105 configured for insertion into tissue, either percutaneously or intraoperatively, e.g., into an open wound site. The electrode 105 includes a closed, pointed tip 122 that facilitates penetration through tissue, although other configurations are also contemplated.

[0058] The electrode 105 is at least partially disposed within shaft 103, which includes one or more insulative coatings or sleeves extending over at least a portion of the electrode 105. A distal end 113 of the electrode 105 extends distally from the shaft 103 such that the distal end 113 including the pointed tip 122 is exposed. The exposed distal end 113, when in contact with target tissue within the body and when energized with a high frequency current functions to heat tissue in the surrounding volume near the exposed distal end 113. Although the electrode 105 is shown and described herein as an RF electrode for radio frequency ablation, electrode 105 may alternatively be configured as a microwave antenna for microwave ablation, or any other suitable energy delivery device.

[0059] The electrode 105 is formed at least partially from a flexible material and/or includes flexible couplings, e.g., flexible conductive joints or linkages, such that, as will be described in greater detail below with respect to the various deformation systems provided herein, electrode 105 may be shaped to a desired configuration upon selective deformation of shaft 103. Alternatively, the deformation system may be coupled to or incorporated in electrode 105. In such embodiments, shaft 103 may be formed from a flexible material and/or may include flexible couplings such that shaft 103 is shaped in accordance with the selective deformation of electrode 105.

[0060] The ablation apparatus 100 further includes a proximal body portion 101 that includes respective inlet and outlet tubes 107 and 108. Coolant fluid is injected or urged under pressure into inlet tube 107 and through internal tube 140 so as to emanate from lumen 141 of internal tube 140 in proximity to the exposed distal end 113 of the electrode 105. The coolant fluid then circulates back through the electrode 105, as indicated by arrow "A," ultimately exiting electrode 105 via the outlet tube 108 in the proximal body portion 101, although it is also contemplated that the direction of fluid flow be reversed. In either configuration, a so-called "cooled tip" electrode system is provided to maintain the distal end 113 of the electrode 105 in a relatively cooled state during use. Other coolant systems may also be employed with the ablation apparatus 100.

[0061] Continuing with reference to Figs. 1, 2A and 2B, the proximal body portion 101 includes a luer-type female connector 109, although other connectors are contemplated. A high frequency or thermo-sensing probe 130 is inserted and sealed within the female connector 109 via a corresponding male luer connector 111. The probe 130 includes a probe shaft 114 which extends distally through the electrode 105. A distal end 104 of probe 130 includes a thermal sensor (not shown) configured to sense the temperature of the coolant fluid at the exposed distal end 113 of the electrode 105. Since the exposed distal end 113 is contiguous and in contact with the target tissue within the patient's body, the thermal sensor (not shown) at distal end 104 of thermo probe 130 provides an indication of the temperature of tissue immediately outside of the exposed distal end 113. Thermo probe 130 may be electrically coupled to generator 120 and/or a thermal-sensing circuit 112. The generator 120, as mentioned above, is the source of high frequency voltage which produces the high frequency current that emanates from the electrode 105. The thermal-sensing circuit 112 may be a thermocouple type, and the thermal probe 130 may be a bi-metal junction thermocouple such as copper constantan, although any other suitable probe 130 and thermal-sensing circuit 112 may be provided.

[0062] The shaft 103 of ablation device 100 is selectively deformable utilizing one or more of the deformation systems described hereinbelow to allow the shaft 103 and electrode 105 to bend as shown in the figures that follow. More specifically, shaft 103 may be bent from a first configuration, e.g., a straight configuration (see Fig. 2A), to a second configuration, e.g., a bent configuration (see Fig. 2B) to likewise bend electrode 105 to position distal end 113 of electrode 105 adjacent target tissue to be treated. Various deformation systems and the like configured for use with ablation apparatus 100 are described below.

[0063] Referring to Figs. 3A-5B, deformation system 300 includes a goose-neck type shaft 305 having two or more links 310 operably coupled to each other. Each link 310 includes a flange 320 with a socket 325 defined therein for receiving a hinge portion 330 of an adjacent link 310. The links 310 cooperate to define an elongated opening 340 that is configured to receive an electrode 302 (similar to the electrode 105) therethrough. The flange 320 may be of any desired operable shape for accepting the hinge portion 330 and allowing the hinge portion 330 to operably move. For example, as shown in Figs. 3A-5B, the socket 325 is substantially spherical-shaped to accept a substantially spherical-shaped hinge portion 330. The goose-neck type shaft 305 further includes an outer flexible layer 330 disposed thereabout to cover the separations between the links 310 (see Fig. 3B). The outer flexible layer 330 may be disposed on the outer periphery of shaft 305 or may fully encase links 310 of shaft 305.

[0064] The electrode 302 extends through the opening 340 defined by links 310. More specifically, similarly as mentioned above with respect to electrode 105 (Fig. 1), electrode 302 may be formed at least partially from a flexible material or may include flexible couplings, e.g., flexible conductive joints, such that, as the shaft 305 is articulated or bent to a desired orientation, the electrode 302 bends in a similar manner. The electrode 302 may further be configured to slide relative to and within the shaft 305 upon movement of shaft 305 to one or more orientations.

[0065] Referring more specifically to Figs. 5A and 5B, shaft 305 is shown in a first straight position (Fig. 5A) and a second bent position (Fig. 5B), respectively. While the degree of directional change between adjacent links 310 is limited by the inherent design of each link 310, a successive series of links 310 will allow any desired degree of bending as each individual link 310 compounds the overall flexation of the shaft 305.

[0066] The goose-neck type shaft 305 may also include a locking feature such that after the goose-neck type shaft 305 is bent and positioned as desired, a locking mechanism may be set to prevent further bending. In one embodiment, the locking mechanism includes a system of wires 350 that are positionable to compress and lock each link 310 against a subsequent link creating a resulting force that holds a desired shaft shape. For example, if each wire 350 is fixed to an anchor link 310a and extends through each of the other links 310, the wires 350 may be pulled such that each link 310 becomes forcibly immobile against an adjacent link 310 as a result of the compressive force applied therethrough. Further, the compression may allow the links 310 to collapse into each other reducing gaps between the flange portions 320, thus not allowing any relative motion to occur between the links 310.

[0067] Referring to Figs. 6A-6C, another embodiment of a deformation system is shown including a shaft 605 made of a flexible material, and having a line pull system 650. Line pull system 650 includes at least one line 604 connected to at least one anchor 603 attached at the distal end of the shaft 605. The line pull system 650 is pulled manually to bend the shaft 605 to a desired orientation. The flexible material forming shaft 605 may include any suitable plastic, foam, rubber, polymer, weave, malleable metal, or any combination thereof as desired. The flexible material may also be biocompatible. The line pull system 650 may include additional lines 604 connected to a second anchor 603. The line pull system 650 may further include a slider 607 that the one or more lines 604 moveably pass through such that the at least one line 604 may be kept to the contour of the shaft 605 as it bends under tension of the at least one line 604.

[0068] As shown in Fig. 6C, the line pull system 650 may further include a first anchor 603a connected to a first line 604a, a second anchor 603b connected to a second line 604b and a third anchor 603c connected to a third line 604c, each anchor being spaced about equal distances circumferentially around the shaft 605 such that a bend in any direction may be effected. More specifically, at least one line 604 of the line pull system 650 may be pulled to effectuate a bend in a desired direction. By pulling multiple lines 604, a bend in any desired direction may be effected due to the resulting forces applied by the pulled lines 604 to each respective anchor 603 on the shaft 605. This ability to bend the shaft 605 in multiple directions not only facilitates positioning of the instrument, but also allows the clinician to treat a plurality of target sites without having to rotate the entire instrument.

[0069] Referring to Figs. 7A-7C, another embodiment of a shaft 705 is formed at least partially from a flexible material, similar to the flexible materials described above, and includes deformation system having at least one ferromagnetic material 703 disposed on or within the shaft 705 that allows the shaft 705 to be pulled or pushed by a magnetic field 709 created by a magnet 707. The magnet 707, as shown in Fig. 7C, may be a permanent magnet or an electro-magnet, and may be separate from the shaft 705, or may be disposed anywhere along or within the shaft 705 or proximal body portion 701. The at least one ferromagnetic material 703 may be incorporated into the shaft 705 itself, or may otherwise be coupled to the shaft 705 in any suitable fashion. In particular, the ferromagnetic material 703 may be disposed towards the distal end of the shaft 705 to facilitate accurate placement of the electrode 302.

[0070] The deformation system, as shown in Figs. 7A and 7B, allows a clinician to bend the shaft 705 to a desired position by applying a magnetic field in the vicinity of the ferromagnetic material 703. The bend may be controlled as a function of field intensity and distance to the source of the magnetic field. Thus, the more powerful the magnetic field and/or the closer the shaft 705 is to the source of the magnetic field, the more the shaft 705 bends.

[0071] Referring to Figs. 8A-8C, another embodiment of a deformation system includes a weave 801 disposed on or within the shaft 805 having a rigid state and a deformable state. For example, the rigid state may be an elongated state and the deformable state is a neutral or compressed state, such that when the weave 801 is pulled or extended, the weave 801 locks up and prevents bending of the shaft 805. In other embodiments, the deformable state is an elongated state and the rigid state is a neutral or compressed state such that compressing the weave 801 locks up the weave 801 and prevents bending of the shaft 805.

[0072] By using such a deformation system, as shown in Figs. 8A-8C, a clinician may bend the shaft 805 to a desired position when the weave 801 is deformable. For example, the clinician may compress the weave 801 (see Figs. 8A and 8B) and proceed to bend or deform the shaft 805. When the clinician is satisfied with the shape, the clinician may then pull the weave 801 to make it rigid (see Fig. 8C).

[0073] Referring to Figs. 9A and 9B, deformation system includes at least one semi-rigid rod 903 disposed on or within the at least one shaft 905. The shaft 905 is formed at least partially from a flexible material, similarly as described above. The semi-rigid rod 903 is configured to bend and hold its bent position. The at least one semi-rigid rod 903 may be made at least partially of metal or another suitable material. The at least one semi-rigid rod 903 allows the shaft 905 to be bent and to hold the bent shape because the bent semi-rigid rod 903 will not allow the flexible material 901 to bend back under its normal restoring force. As such, a clinician may mechanically deform the shaft 905 to a desired position and it will hold shape due to the semi-rigid rod 903 having a larger resistance to restoration than the restoring force of the flexible material 901 and any other static forces.

[0074] Referring to Figs. 10A-10C, deformation system includes at least one reservoir 1003 disposed within the shaft 1005 and at least one fluid supply (not shown) connected to the reservoir 1003 to act as a pressure source. The shaft 1005 is formed at least partially from a flexible material, similarly as describe above. The shaft 1005 is permitted to be bent when the reservoir 1003 is depressurized, and is inhibited from bending when the reservoir 1003 is pressurized as a result of the pressure within reservoir 1003. Thus, a clinician may bend the shaft 1005 to a desired position when the shaft 1005 is depressurized, and thereafter retain the bent shape of the shaft 1005 by pressurizing the reservoir 1003 while shaft 1005 is bent. Alternatively, the shaft 1005 may be configured to define a pre-determined depressurized shape, e.g., a straight configuration, and a pre-determined pressurized shape, e.g., a bent configuration, such that, upon pressurizing, the shaft 1005 is transitioned from the depressurized shape to the pressurized shape.

[0075] Referring to Fig. 11A and 11B, another embodiment of a deformation system is shown including a shaft 1105 formed at least partially from or including at least one smart material 1101 that has a first physical state when in a first condition and a second physical state when in a second condition.

[0076] The first condition may be a neutral condition wherein the at least one smart material 1101 is not subjected to a magnetic or electrical field, or other activator. When shaft 1105 is disposed in the first physical state, corresponding to the neutral first condition, the shaft 1105 may be in a fluidic, viscous, malleable, and/or otherwise deformable state. The first physical state may also be of a substantially rigid state.

[0077] The second condition may an activated condition wherein the at least one smart material 1101 is subjected to an activator, e.g., one or more of a magnetic field, electric field, electrical current, or activating chemical. The second physical state caused by the second condition may be a substantially rigid state such that the smart material 1101 resists bending or any other deformation. Where the first physical state is a substantially rigid state, the second physical state is at least one of a fluidic, viscous, malleable, and otherwise deformable state. That is, either the first or second physical state may be the deformable state, with the other being the substantially rigid state.

[0078] The at least one smart material 1101 may react to at least one magnetic field such that the magnetic field causes the at least one smart material 1101 to transition from the first physical state to the second physical state. For example, an initially malleable or fluidic smart material 1101 may become substantially rigid when subjected to a magnetic field. In such embodiments, the smart material 1101 may include any ferromagnetic or magneto-rheological composition that is malleable or fluidic when not exposed to a magnetic field. The at least one smart material 1101 may alternatively include a ferrous nano-suspension such as a ferro-fluid that takes a shape when subjected to a magnetic field, or may include a magneto-rheological fluid that increases in apparent viscosity in the presence of a magnetic field. Such fluids may be stored in a reservoir, e.g., a reservoir similar to reservoir 1003 (Fig. 10A). With such magneto-reactive compositions, the at least one smart material 1101 may be subjected to one or more magnetic fields to transition the smart material 1101 from a substantially fluid state to a substantially rigid state.

[0079] The at least one smart material 1101 may react to at least one electrical influence (an electrical field and/or electrical current) such that the electrical influence causes the at least one smart material 1101 to transition from a substantially rigid/malleable first physical state to a substantially malleable/rigid second physical state respectively. For example, a smart material 1101 may include a metallic state switching material which includes at least one metal and at least one conductive fluid disposed in pores of the at least one metal. The first physical state of the metallic switching material is a substantially rigid state, and the second physical state is a more malleable state when an electrical influence is applied. The smart material 1101 may include an electro-rheological fluid which is fluidic in the first physical state and transitions to a more viscous or substantially rigid state when an electrical influence is applied thereto, depending on the composition of the electro-rheological fluid and the intensity of the electrical influence. The smart fluid may additionally or alternatively include any suitable shape memory material that can be bent in a first physical state and then returned to a predetermined shaped under the influence of an electrical or thermal influence.

[0080] The smart material 1101 may include a chemical mixture that undergoes a hardening cycle at a predetermined time. For example the smart material 1101 may be a liquid in the first physical state that hardens when another chemical is selectively introduced to create a rigid material in the second physical state. The fluid may be stored in a reservoir, e.g., a reservoir similar to reservoir 1003 (Fig. 10A). A non-limiting example of such a chemical mixture is a resin and hardener combination that has a liquid resin in the first physical state that converts to a solid after selective introduction of the hardener into the resin. The hardener may be stored in a separate enclosed cavity in the body such that a clinician may choose when to allow the hardener to mix with the resin, for example, through puncturing the separate enclosed cavity, or through the use of a mechanical floodgate.

[0081] In embodiments where the first physical state of the smart material 1101 is a fluidic or malleable state, the clinician may deform the ablation apparatus 100 to be of any desirable state while in the first condition. For example, the clinician may deform the ablation apparatus 100 to fit into a surgical incision more easily, and then deform it again to another desired shape after insertion.

[0082] The clinician may then transition the smart material 1101 from the fluidic or malleable first physical state to a substantially rigid second physical state using one or more of the above described systems in order to prevent further deformation of the ablation apparatus 100.

[0083] In embodiments where the first physical state of the smart material 1101 is a rigid or substantially rigid state, the clinician may apply any of the above described systems to transition the smart material 1101 from the rigid first physical state to a fluidic or malleable second physical state to deform the ablation apparatus 100 to be of any desirable state while in the second condition. For example, the clinician may deform the ablation apparatus 100 to fit into a surgical incision more easily in the second physical state, and then deform it again to another desired shape after insertion.

[0084] The clinician may then transition the smart material 1101 from the fluidic or malleable second physical state back to substantially rigid first physical state by transitioning back to the above described first condition in order to prevent further deformation of the ablation apparatus 100, the at least one port, the first opening, and/or the second opening.

[0085] With continued reference to Figs. 11A and 11B, deformation system, as mentioned above, includes a smart material 1101 formed with, incorporated into, or disposed on or within the shaft 1105. Smart material 1101 is described hereinbelow as being an electro-rheological material 1101 having a rigid state and a deformable state although, as discussed above, various other smart materials 1101 may additionally or alternatively be provided. The smart material 1101 is selectively coupled by at least one switch 1107 to an electrical supply 1103. The electro-rheological material 1101 may be in the deformable state when subjected to an electrical current, e.g. when switch 1107 is closed although the electro-rheological material 1101 may alternatively be in the rigid state when subjected to an electrical current, e.g. when the switch 1107 is closed.

[0086] Referring to Figs. 12A-12C, deformation system includes a spring winding 1201 disposed on a shaft 1205. Spring winding 1201 is connected to a tightener 1203 such that the spring winding 1203 may be tightened to become substantially rigid and loosened to become deformable. Spring winding 1201 may be fixed at both ends, one end on the shaft 1205 and the other end to the tightener 1203. For example, the shaft 1205 may be bent while the spring winding 1201 is loose as in Fig. 12B. The spring winding 1201 may be tightened after bending to hold shape as shown in Fig. 12C.

[0087] A method for ablating a target site is further disclosed and includes providing an ablation apparatus including a proximal body portion, a shaft extending distally from the proximal body portion, the shaft being selectively deformable utilizing at least one deformation system as described above to allow the shaft to be bent, and at least one electrode disposed at least partially within the shaft and extending from a distal end of the shaft. The method may further include inserting the shaft into an incision and bending the shaft to position the at least one electrode at a target location, and ablating the target location.

[0088] It should be understood that the foregoing description is only illustrative of the present disclosure. Various alternatives and modifications can be devised by those skilled in the art without departing from the disclosure. Accordingly, the present disclosure is intended to embrace all such alternatives, modifications, and variances. The embodiments described with reference to the attached drawing figs. are presented only to demonstrate certain examples of the disclosure. Other elements, steps, methods, and techniques that are insubstantially different from those described above and/or in the appended claims are also intended to be within the scope of the disclosure.

WHAT IS CLAIMED IS:

1. An ablation apparatus, comprising:

a proximal body portion;

a shaft extending distally from the proximal body portion, the shaft being selectively deformable utilizing at least one deformation system between a first position wherein the shaft is substantially straight and a second position wherein the shaft is bent, the at least one deformation system configured to retain the shaft in each of the first and second positions; and

at least one electrode disposed at least partially within the shaft, the at least one electrode movable with the shaft upon movement of the shaft between the first and second positions.

2. The ablation apparatus of claim 1, wherein the deformation system comprises a goose-neck type shaft having at least two links operably coupled to each other.

3. The ablation apparatus of claim 2, wherein the goose-neck type shaft includes a flexible layer disposed thereon to cover one or more separations between the at least two links.

4. The ablation apparatus of claim 1, wherein the shaft is made of a flexible material, and the deformation system comprises a line pull system, the line pull system comprising:

at least one anchor fixedly attached to the shaft; and

at least one line connected to the at least one anchor and configured to be pulled to bend the shaft.

5. The ablation apparatus of claim 4, wherein the at least one line pull system comprises a first anchor connected to a first line, a second anchor connected to a second line and a third anchor connected to a third line, each anchor being spaced about equal

distances circumferentially around the shaft such that the shaft is bendable in any desired direction.

6. The ablation apparatus of claim 1, wherein the shaft further comprises a flexible material and the deformation system comprises at least one of a material selected from the group consisting of a magnet and a ferromagnetic material, the material allowing the shaft to be moved by a magnetic field in the direction of the magnetic field.

7. The ablation apparatus of claim 6, wherein the deformation system further includes the material disposed within the flexible material at the distal end of the shaft.

8. The ablation apparatus of claim 1, wherein the deformation system comprises a weave having a rigid state and a deformable state.

9. The ablation apparatus of claim 8, wherein the rigid state is an elongated state and the deformable state is a neutral state.

10. The ablation apparatus of claim 8, wherein the deformable state is an elongated state and the rigid state is a neutral state.

11. The ablation apparatus of claim 1, wherein the deformation system comprises at least one semi-rigid rod configured to bend and hold the bent position.

12. The ablation apparatus of claim 11, wherein the semi-rigid rod is made of at least one metal.

13. The ablation apparatus of claim 1, wherein the deformation system comprises:

at least one reservoir disposed within the shaft; and

at least one fluid supply connected to the reservoir to act as a pressure source, wherein the shaft is bendable when the reservoir is depressurized and rigid when the reservoir is pressurized.

14. The ablation apparatus of claim 1, wherein the deformation system comprises an electro-rheological material selectively connected to an electrical supply, the electro-rheological material having a rigid state and a deformable state.

15. The ablation apparatus of claim 14, wherein the electro-rheological material is in the deformable state when subjected to an electrical current.

16. The ablation apparatus of claim 14, wherein the electro-rheological material is in the rigid state when subjected to an electrical current.

17. The ablation apparatus of claim 1, wherein the deformation system comprises a magneto-rheological material selectively subjected to a magnetic field, the magneto-rheological material having a rigid state and a deformable state.

18. The ablation apparatus of claim 17, wherein the magneto-rheological material is in the rigid state when subjected to a magnetic field.

19. The ablation apparatus of claim 1, wherein the deformation system comprises a spring winding disposed on said shaft, wherein the spring winding is connected to a tightener such that spring winding may be tightened to become substantially rigid and loosened to become deformable.

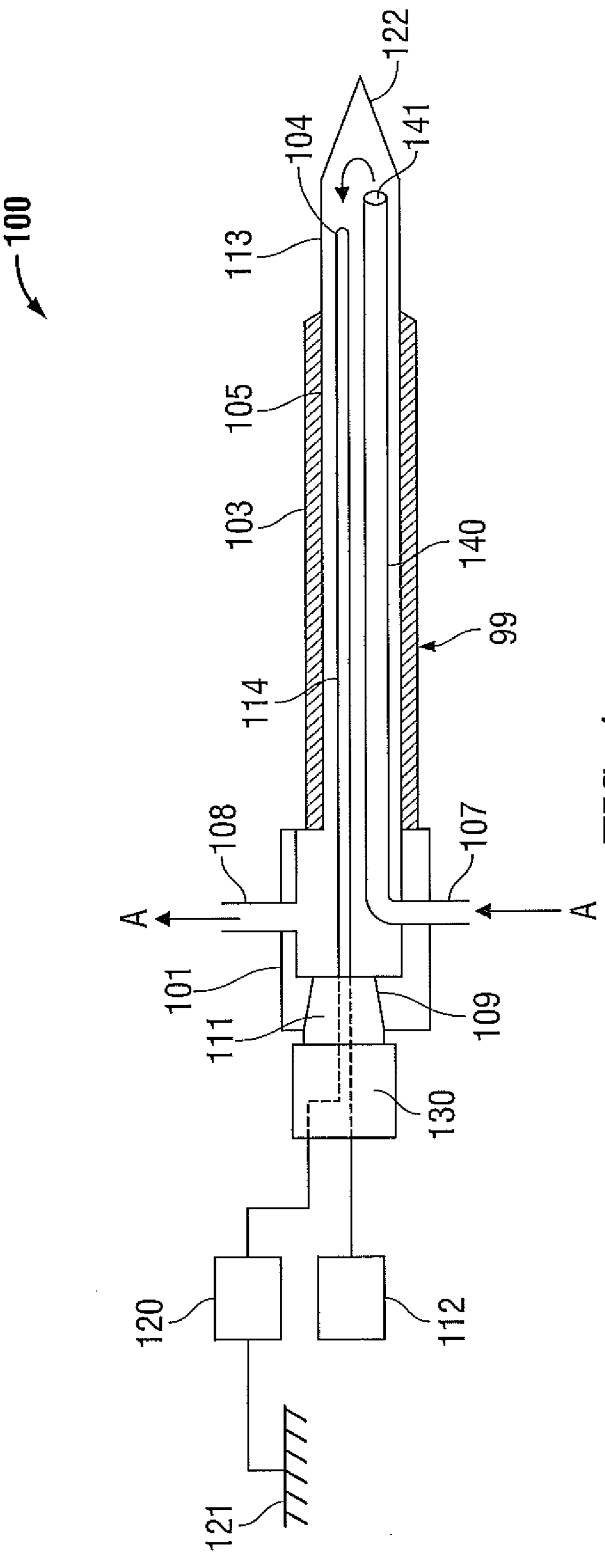
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FIG. 1

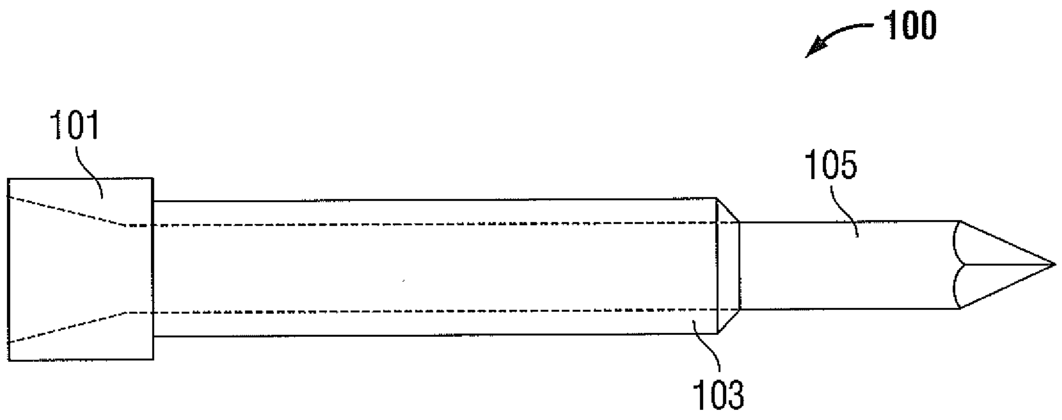

FIG. 2A

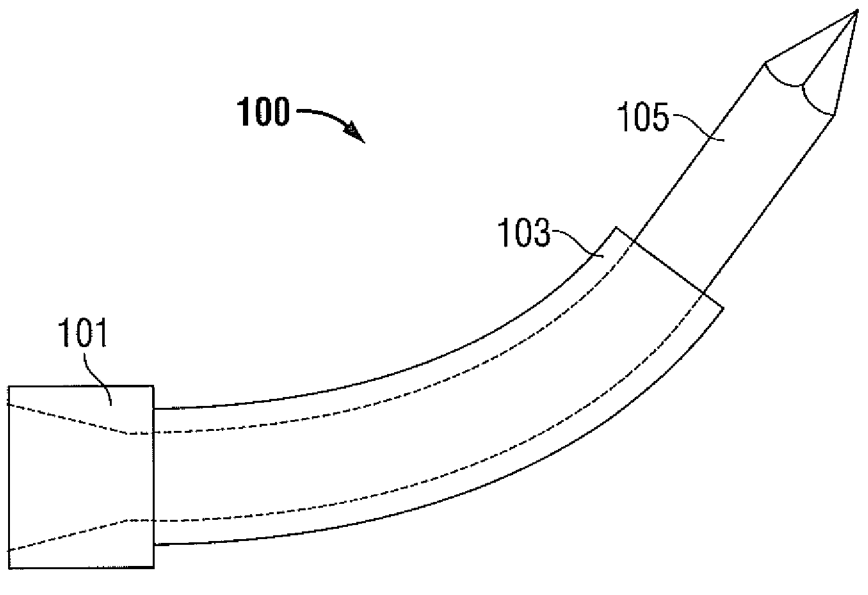

FIG. 2B

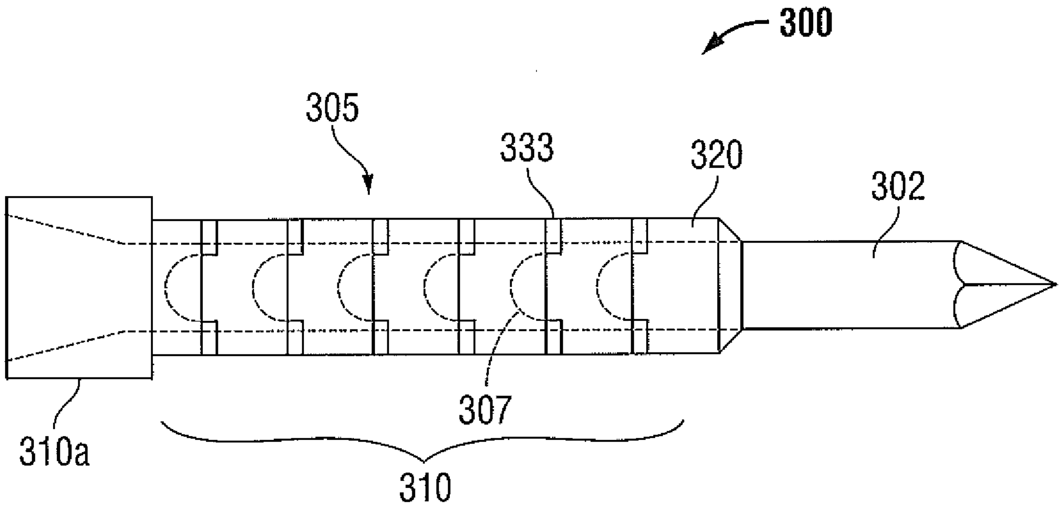

FIG. 3A

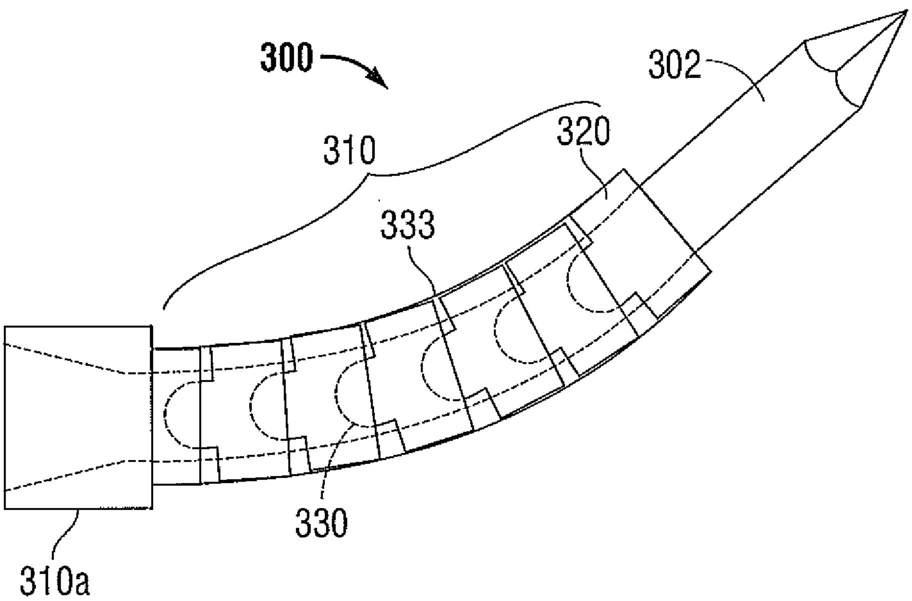

FIG. 3B

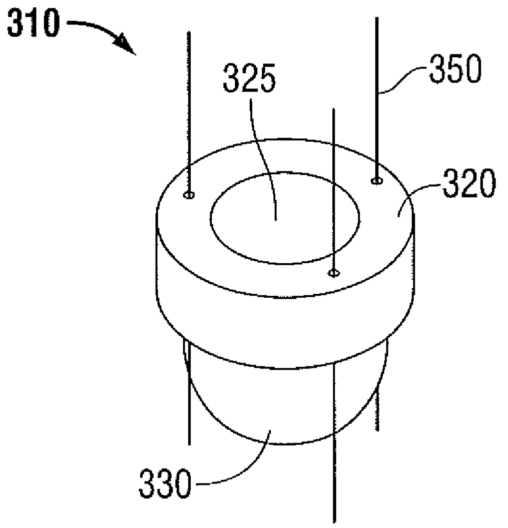

FIG. 4A

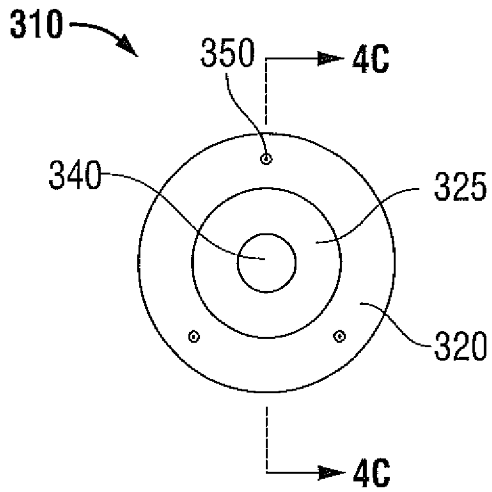

FIG. 4B

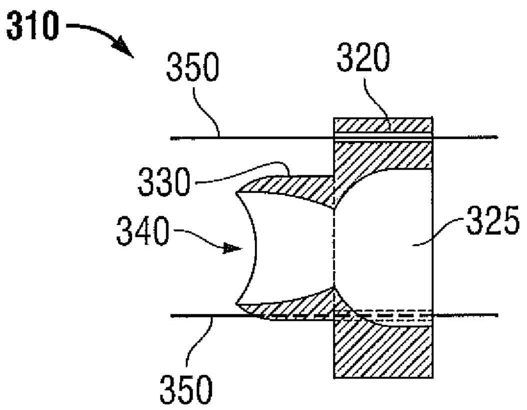

FIG. 4C

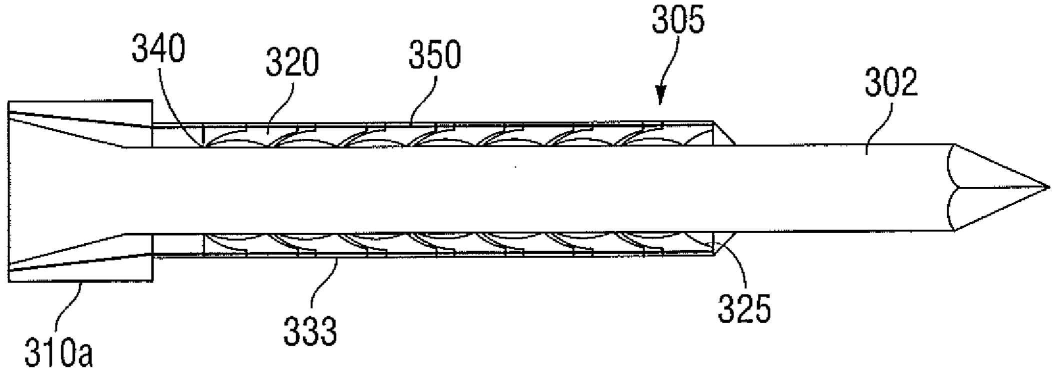
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FIG. 5A

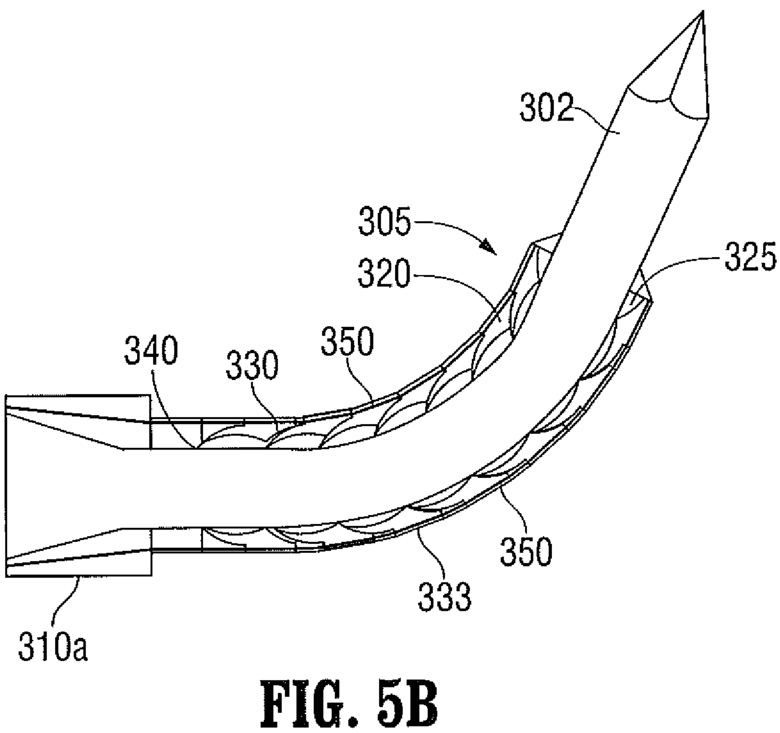
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FIG. 5B

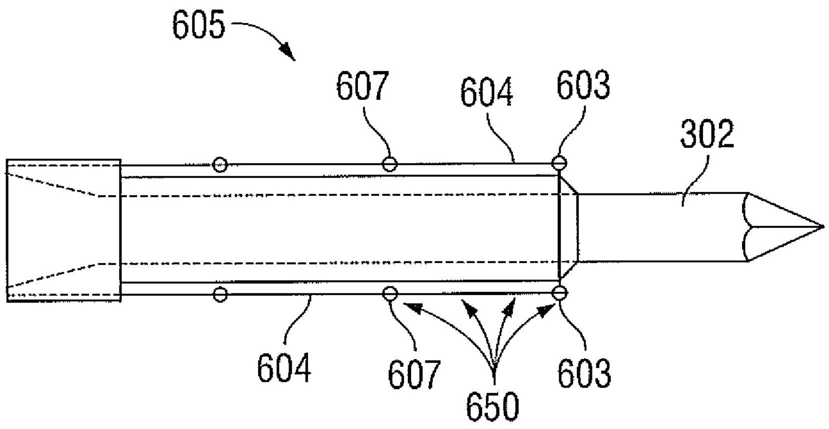

FIG. 6A

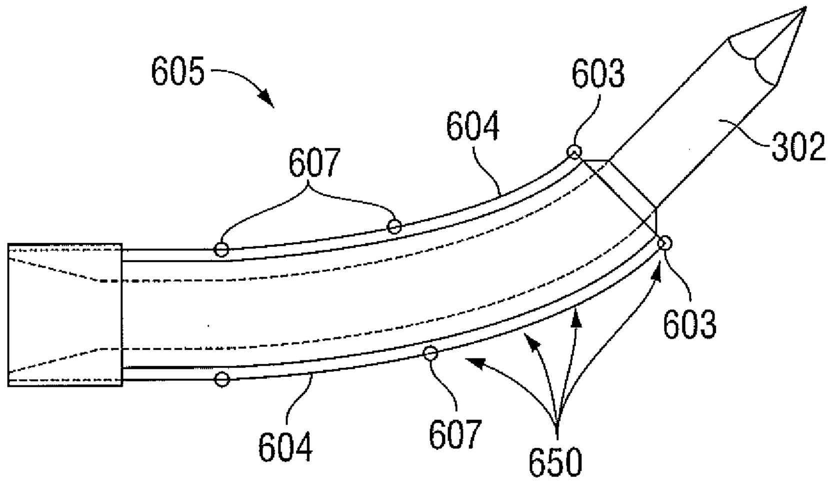

FIG. 6B

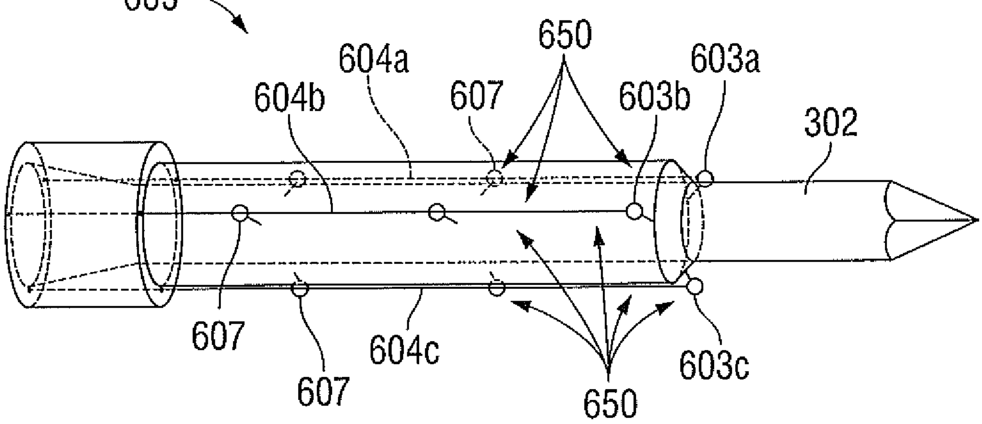

FIG. 6C

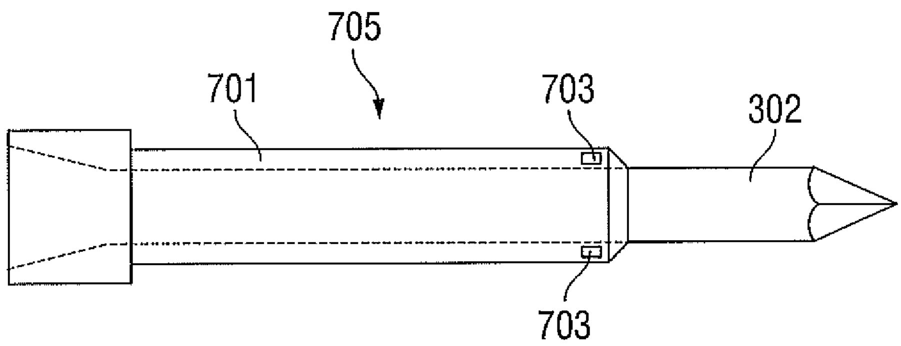

FIG. 7A

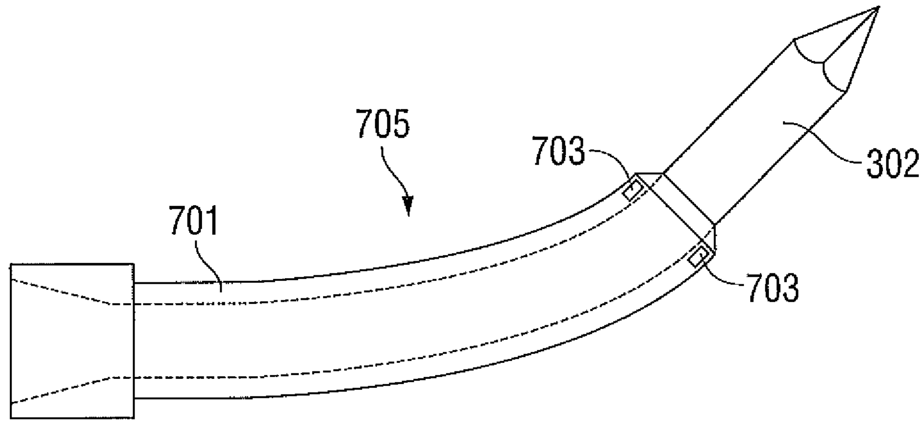

FIG. 7B

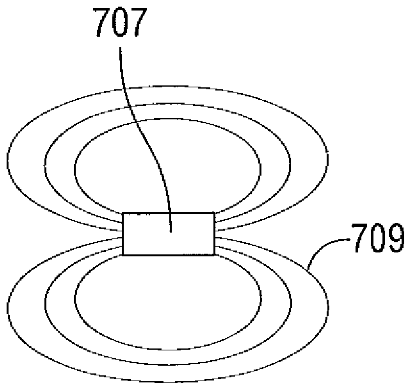

FIG. 7C

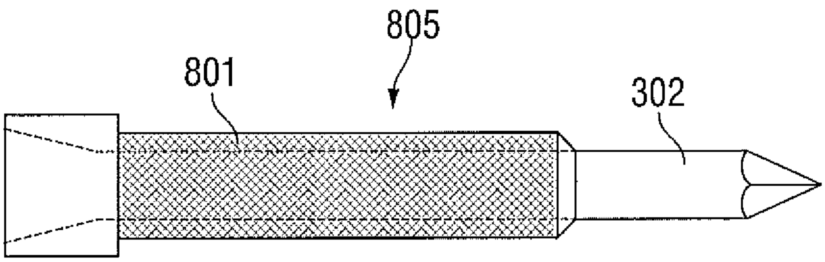

FIG. 8A

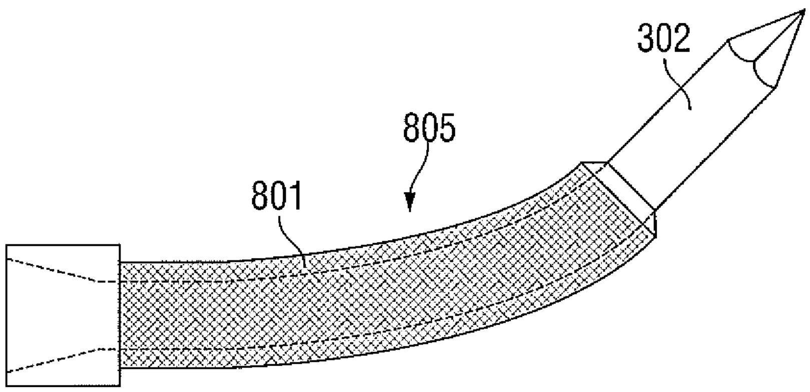

FIG. 8B

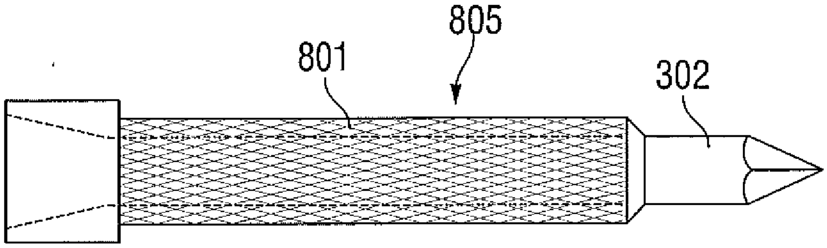

FIG. 8C

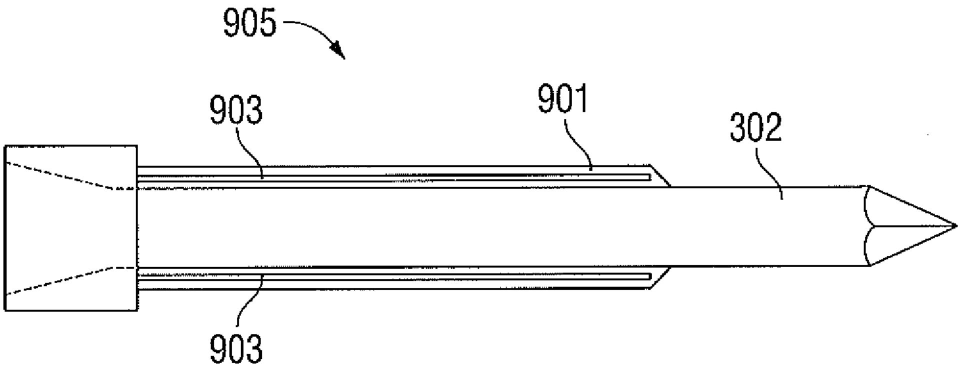

FIG. 9A

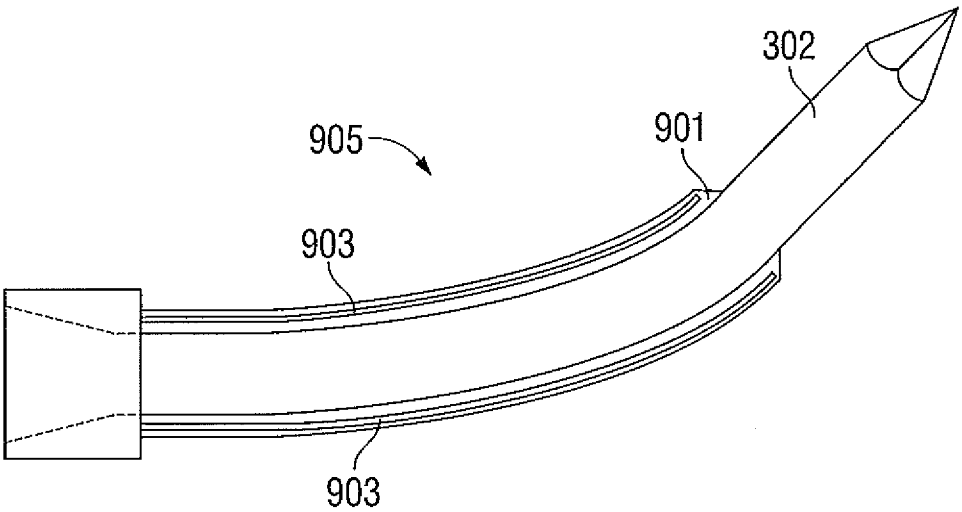

FIG. 9B

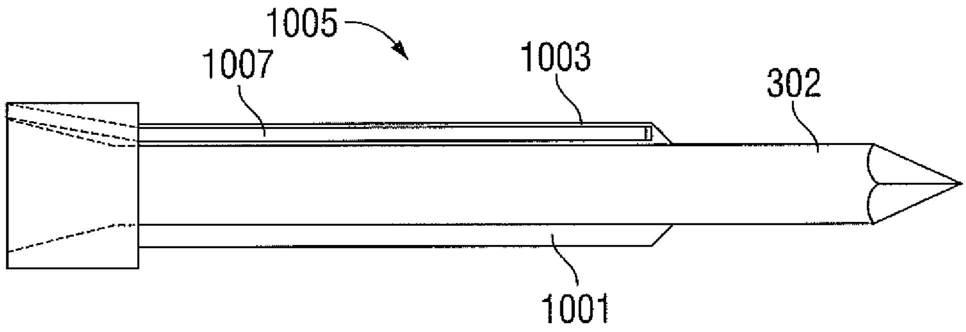

FIG. 10A

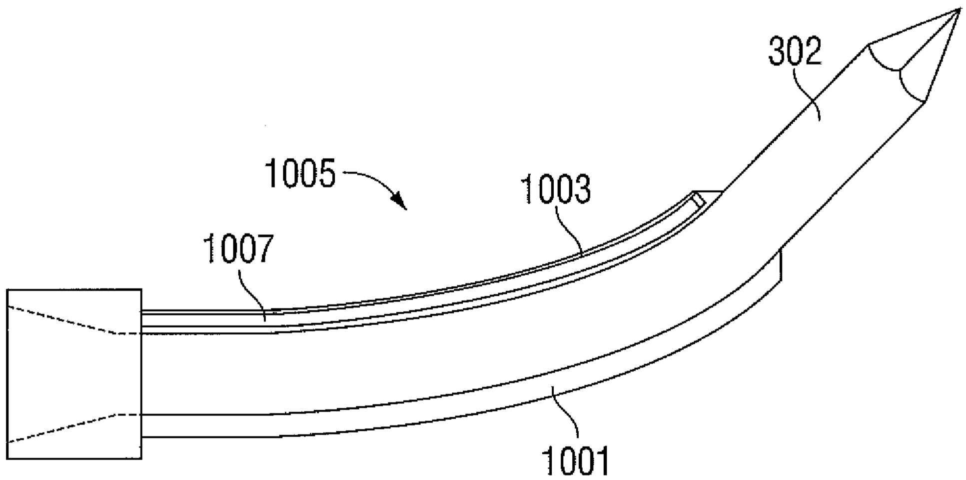

FIG. 10B

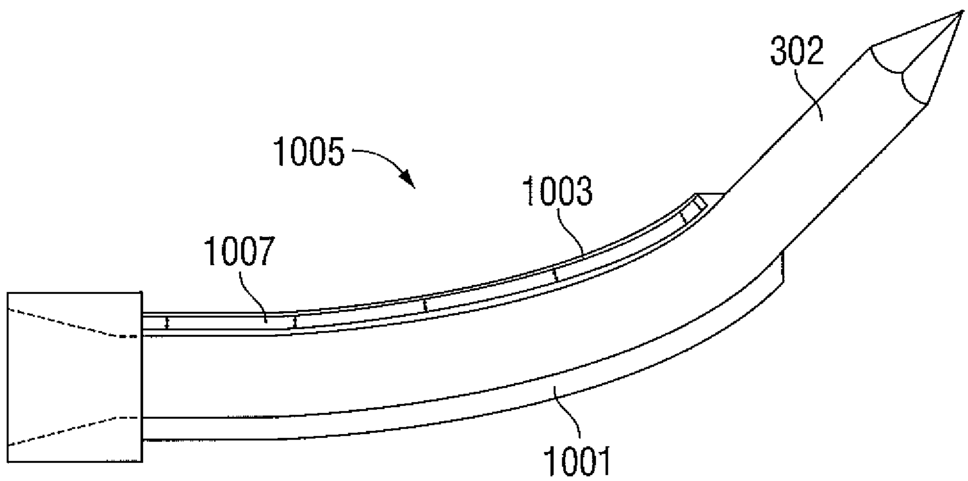

FIG. 10C

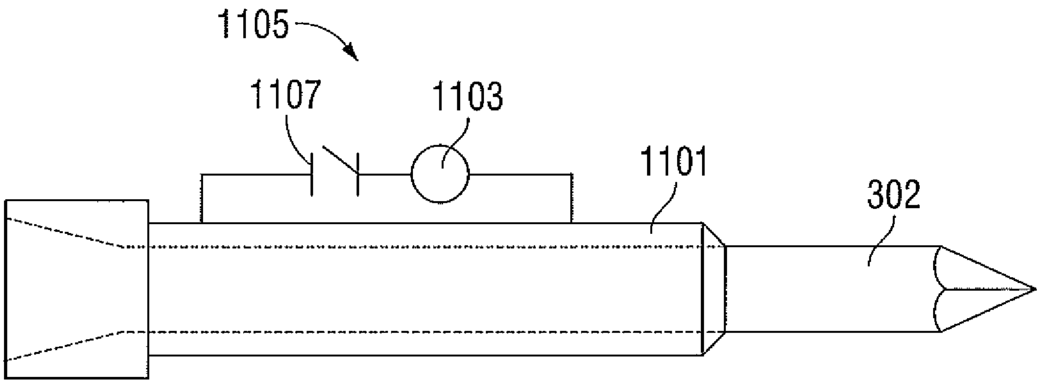

FIG. 11A

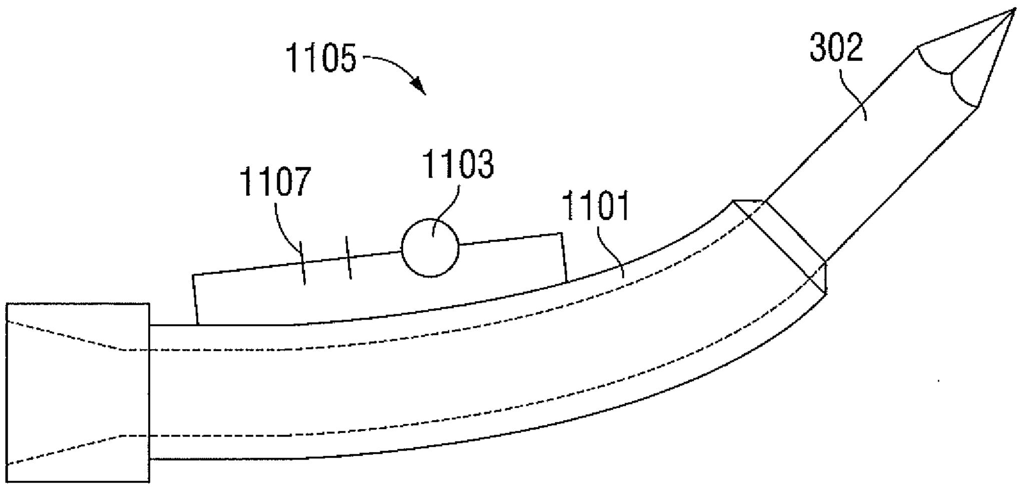

FIG. 11B

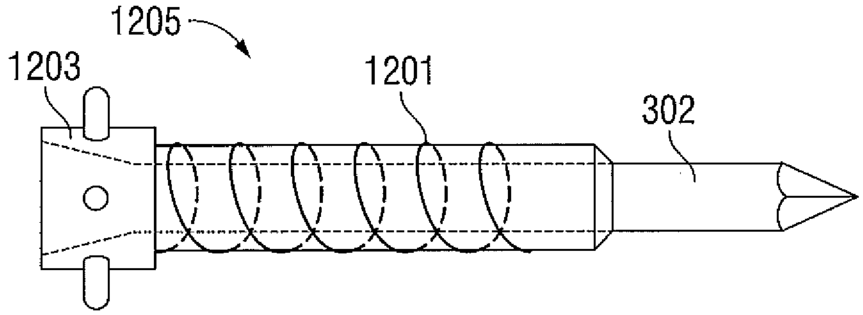

FIG. 12A

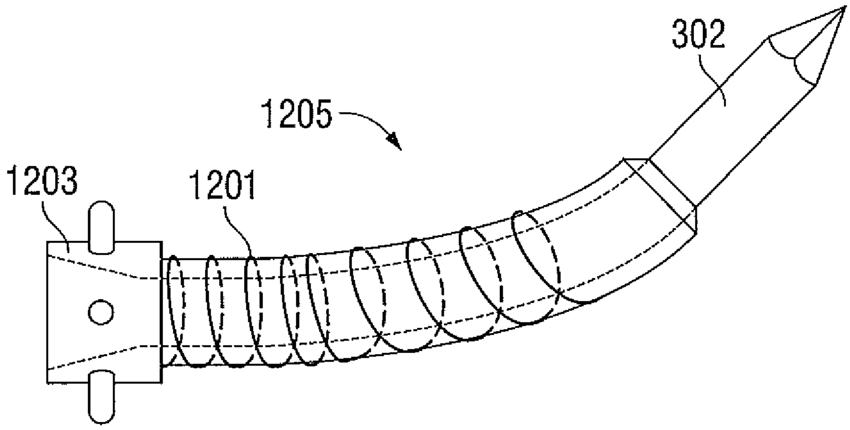

FIG. 12B

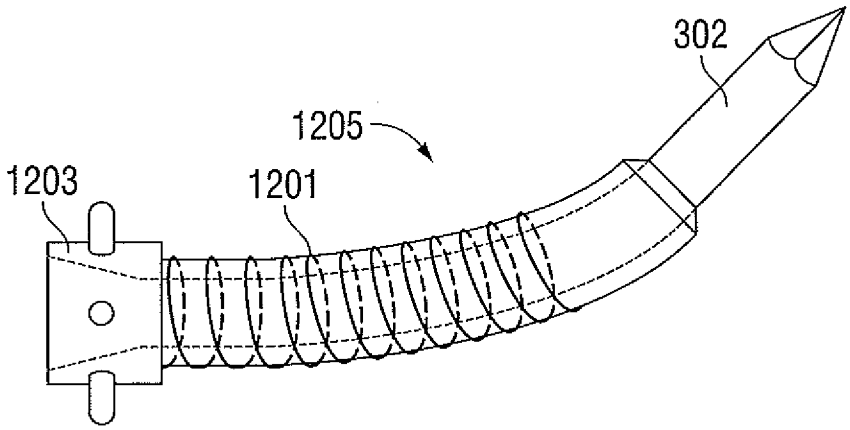

FIG. 12B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/061612

A. CLASSIFICATION OF SUBJECT MATTER

A61B 18/12(2006.01)i, A61M 25/092(2006.01)i, A61L 29/14(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 18/12; A61M 25/01; A61M 5/32; A61N 1/05; A61M 25/00; A61B 18/18; A61F 2/84; A61B 5/00; A61M 25/092; A61L 29/14

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 models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: ablation apparatus, proximal body portion, shaft, electrode

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0009858 A1 (ORMSBY, T. C. et al.) 13 January 2011 See claim 1; figures 1A-6B; paragraphs [0051], [0054].	1,13
Y		2-12,14-19
Y	US 2007-0100424 A1 (CHEW, S. et al.) 03 May 2007 See claims 1, 15-17, 19; figures 5C-5D; paragraphs [0060]-[0062].	2-3
Y	US 2012-0053569 A1 (HONEBRINK, B. et al.) 01 March 2012 See claims 1, 6; figure 2; paragraphs [0050]-[0051].	4-5
Y	US 2010-0004632 A1 (WU, K. K. et al.) 07 January 2010 See claims 1, 15; figures 7-8; paragraph [0052].	6-7
Y	US 2004-0153049 A1 (HEWITT, T. J. et al.) 05 August 2004 See claims 1-2; figures 1-2; paragraph [0039].	8-10
Y	US 2003-0088212 A1 (TAL, M.) 08 May 2003 See claims 1, 5; figure 2; paragraphs [0022]-[0023].	11-12
Y	US 2003-0065373 A1 (LOVETT, E. G. et al.) 03 April 2003 See abstract; paragraphs [0006], [0010]-[0012], [0060]-[0061], [0070]-[0081]; figures 11-21.	14-18

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

* Special categories of cited documents:
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"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
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"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
17 January 2014 (17.01.2014)	**20 January 2014 (20.01.2014)**

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Authorized officer
Han, Inho
Telephone No. +82-42-481-3362

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5431168 A (WEBSTER, JR., W. W.) 11 July 1995 See claim 1; figures 1, 3; column 3 lines 63-68, column 4 lines 1-9.	19

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011-0009858 A1	13/01/2011	AU 2003-365882 A1	17/06/2003
		CA 2468531 A1	12/06/2003
		CN 1625371 A	08/06/2005
		EP 1460954 A1	29/09/2004
		EP 1460954 A4	14/12/2005
		EP 1460954 B1	10/10/2007
		HK 1073239 A1	16/04/2010
		JP 2005-511135 A	28/04/2005
		US 2003-0114844 A1	19/06/2003
		US 2006-0142752 A1	29/06/2006
		US 7004938 B2	28/02/2006
		US 7815637 B2	19/10/2010
		US 8152799 B2	10/04/2012
		WO 03-047448 A1	12/06/2003
US 2007-0100424 A1	03/05/2007	AU 2003-357073 A1	17/06/2003
		AU 357073 B2	13/03/2008
		CA 2469127 A1	12/06/2003
		EP 1460975 A2	29/09/2004
		EP 1460975 A4	24/01/2007
		JP 2005-511149 A	28/04/2005
		US 2003-0135266 A1	17/07/2003
		US 2007-0088422 A1	19/04/2007
		US 2007-0156226 A1	05/07/2007
		US 2008-0234798 A1	25/09/2008
		US 2010-0004729 A1	07/01/2010
		US 7905913 B2	15/03/2011
		US 8016871 B2	13/09/2011
		WO 03-047651 A2	12/06/2003
		WO 03-047651 A3	30/10/2003
US 2012-0053569 A1	01/03/2012	CA 2610586 A1	21/12/2006
		EP 1896108 A1	12/03/2008
		US 2007-0005008 A1	04/01/2007
		US 2009-0235511 A1	24/09/2009
		US 7553305 B2	30/06/2009
		US 8056207 B2	15/11/2011
		WO 2006-135774 A1	21/12/2006
US 2010-0004632 A1	07/01/2010	None	
US 2004-0153049 A1	05/08/2004	AU 2004-277361 A1	04/05/2004
		CA 2501147 A1	22/04/2004
		EP 1551489 A1	13/07/2005
		EP 1551489 B1	09/12/2009
		JP 2006-501969 A	19/01/2006
		JP 2011-019983 A	03/02/2011
		US 7507229 B2	24/03/2009
		WO 2004-033015 A1	22/04/2004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003-0088212 A1	08/05/2003	CA 2454375 A1	30/01/2003
		EP 1438093 A1	21/07/2004
		EP 1438093 A4	03/11/2004
		US 6994693 B2	07/02/2006
		WO 03-008020 A1	30/01/2003
US 2003-0065373 A1	03/04/2003	None	
US 5431168 A	11/07/1995	CA 2170274 A1	02/03/1995
		EP 0715530 A1	12/06/1996
		EP 0715530 A4	04/06/1997
		EP 0715530 B1	27/02/2002
		JP 09-501851 A	25/02/1997
		JP 2006-192293 A	27/07/2006
		JP 2010-284537 A	24/12/2010
		WO 95-05771 A1	02/03/1995