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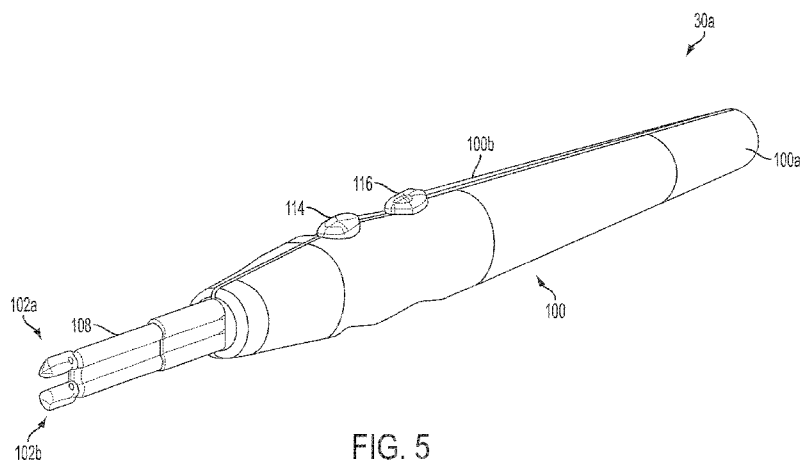


FIG. 5

(57) Abstract: The invention provides an electrosurgical device and methods of use thereof. The device comprises a first elec-  
trode, a second electrode and at least one fluid outlet. In one embodiment, the first electrode has a distal portion with an electrical-  
ly conductive spherical surface, the second electrode has a distal portion with an electrically conductive spherical surface, and at  
least one of the first electrode and the second electrode have a blade portion.

**FLUID-ASSISTED ELECTROSURGICAL DEVICE**  
**AND METHODS OF USE THEREOF**

**Cross Reference To Related Applications**

5           This application claims priority to U.S. provisional application serial no. 61/154,623, filed February 23, 2009, which is incorporated by reference herein to the extent it is consistent.

**Field**

10           This invention relates generally to the field of medical devices, systems and methods for use upon a human body during surgery. More particularly, the invention relates to surgical devices, systems and methods that provide cutting of tissue as well as coagulation, hemostasis and sealing of tissue to inhibit blood and other fluid loss during surgery such as abdominal, orthopedic, spine and thoracic surgery as well as general surgery of the body.

**Background**

15           Fluid-assisted electrosurgical devices have been developed which, when used in conjunction with an electrically conductive fluid such as saline, may be moved along a tissue surface, without cutting the tissue, to seal tissue to inhibit blood and other fluid loss during  
20           surgery. However, to cut tissue the surgeon must utilize a second device, which necessitates delays associated when switching between devices. What is still needed is an electrosurgical device which is capable of cutting of tissue as well as providing fluid-assisted sealing of tissue to inhibit blood and other fluid loss during surgery, as well as inhibit undesirable effects of tissue desiccation, tissue sticking to the electrode, tissue perforation, char formation  
25           and smoke generation.

**Summary of the Invention**

30           The invention, in one embodiment, may provide an electrosurgical device to treat tissue in a presence of a fluid from a fluid source and radio-frequency power from a radio-frequency power source, particularly providing a bipolar power output and a monopolar power output. The device may comprise a distal portion comprising a first electrode tip, a second electrode tip and at least one fluid outlet. The first and second electrode tips may be

configured as bipolar electrodes, to receive the bipolar power output from the radio-frequency power source, and at least one of the electrode tips may be configured as a monopolar electrode, to receive the monopolar power output from the radio-frequency power source.

5           In certain embodiments, the at least one electrode tip configured as a monopolar electrode may provide an electrosurgical cutting edge, which may be configured to cut tissue by moving along a tissue surface in a presence of monopolar power output provided from the distal portion.

10           In certain embodiments, the at least one electrode tip configured as a monopolar electrode may comprise a blade portion. The blade portion may comprise opposing sides and an electrosurgical cutting edge. The electrosurgical cutting edge may extend from a proximal portion of the electrode tip to a distal portion of the electrode tip. The blade portion may narrow as the opposing sides approach the cutting edge.

15           In certain embodiments, at least one of the opposing sides may comprise a planar surface, concave surface or convex surface. Furthermore, the opposing sides may comprise opposing planer surfaces, concave surfaces or convex surfaces.

          In certain embodiments, the first electrode tip and the second electrode tip may be configured to treat tissue by moving along a tissue surface in a presence of a bipolar power output and a fluid provided simultaneously from the distal portion.

20           In certain embodiments, the at least one fluid outlet may further comprise at least one fluid outlet in fluid communication with the first electrode tip, and at least one fluid outlet in fluid communication to the second electrode tip. The at least one fluid outlet in fluid communication with the first electrode tip may be proximal to a distal end of the first electrode tip, and the at least one fluid outlet in fluid communication with the second electrode tip may be proximal to a distal end of the second electrode tip. The at least one fluid outlet in fluid communication with the first electrode tip may be at least partially defined by the first electrode tip, and the at least one fluid outlet in fluid communication with the second electrode tip may be at least partially defined by the second electrode tip. The at least one fluid outlet in fluid communication with the first electrode tip may comprise a plurality of fluid outlets at least partially defined by the first electrode tip and the at least one fluid outlet in fluid communication with the second electrode tip may comprise a plurality of fluid outlets at least partially defined by the second electrode tip.

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In certain embodiments, the first electrode tip may be laterally spaced from the second electrode tip. The first electrode tip may have a blunt distal end, and the second electrode tip may have a blunt distal end. The first electrode tip may also have a rounded distal end, and the second electrode tip may also have a rounded distal end. The first electrode tip and  
5 second electrode tip may be at a distal end of a shaft assembly.

In certain embodiments, an electrosurgical device to treat tissue in a presence of radio frequency energy and a fluid provided from the device may be provided, with the device comprising a distal portion comprising a first electrode tip, a second electrode tip and at least one fluid outlet. The first electrode tip may comprise a first electrode having a distal portion  
10 with an electrically conductive spherical surface, and the second electrode tip may comprise a second electrode having a distal portion with an electrically conductive spherical surface. At least one of the first electrode and the second electrode may have a blade portion.

In certain embodiments, the first electrode and the second electrode may be configured to be electrically coupled to a bipolar power output, and the at least one electrode  
15 having the blade portion may be configured to be electrically coupled to a monopolar power output. The blade portion may extend longitudinally along the electrode, from a proximal portion to the distal portion of the electrode. The blade portion may have a cutting edge, and more particularly have an electrosurgical cutting edge. The blade portion may have opposing sides, and narrow as the opposing sides approach the cutting edge. At least one of the  
20 opposing sides may comprise a planar surface, a concave surface or a convex surface.

In certain embodiments, the at least one fluid outlet may further comprise at least one fluid outlet in fluid communication with the first electrode and at least one fluid outlet in fluid communication with the second electrode. The at least one fluid outlet in fluid communication with the first electrode may be proximal to a distal end of the first electrode  
25 and at least partially defined by the first electrode, and the at least one fluid outlet in fluid communication with the second electrode may be proximal to a distal end of the second electrode and at least partially defined by the second electrode.

In certain embodiments, the first electrode may be laterally spaced from the second electrode. The first electrode may be carried by a first tubing segment at a distal end thereof,  
30 and the second electrode may be carried by a second tubing segment at a distal end thereof. The first electrode may be connected at a distal end of a first tubing segment, particularly mechanically joined to the first tubing segment, and the second electrode may be connected

at a distal end of the second tubing segment, particularly mechanically joined to the second tubing segment. The first electrode also may be welded to the first tubing segment, and the second electrode may be welded to the second tubing segment.

In certain embodiments, the first tubing segment may be electrically conductive and  
5 in electrical contact with the first electrode, and the second tubing segment may be electrically conductive and in electrical contact with the second electrode.

In certain embodiments, an electrosurgical device having a distal portion comprising a first electrode tip, a second electrode tip and at least one fluid outlet may be provided, with the first electrode tip comprising a first electrode having a blade portion and the second  
10 electrode tip comprising a second electrode having a blade portion. The first and second electrodes may be configured to be electrically coupled to a bipolar energy source and at least one of the electrodes may be configured to be electrically coupled to a monopolar energy source. The first and second electrodes may be electrically coupled to the bipolar energy source by first and second bipolar electrical connectors in electrical communication with the  
15 first and second electrodes, respectively, and at least one of the electrodes may be electrically coupled to the monopolar energy source by a monopolar electrical connector in electrical communication with at least one of the electrodes.

### **Brief Description Of The Drawings**

20 FIG. 1 is a front view of one embodiment of a system of the present invention having an electrosurgical unit in combination with a fluid source and handheld electrosurgical device;

FIG. 2 a front perspective view of the electrosurgical unit of FIG. 1;

FIG. 3 is a graph of the bipolar RF power output versus impedance for the  
25 electrosurgical unit of FIG. 1;

FIG. 4 is graph showing a relationship of fluid flow rate  $Q$  in units of cubic centimetres per minute (cc/min) on the Y-axis, and the RF power setting  $P_s$  in units of watts on the X-axis;

FIG. 5 is a perspective view of an electrosurgical device according to the present  
30 invention;

FIG. 6A is a plan view showing the various electrical connections and conductors of the device of FIG. 5 with the electrosurgical unit of FIG. 1;

FIG. 6B is a plan view showing the various fluid connections and passages of the device of FIG. 5 with the electrosurgical unit and fluid source of FIG. 1;

FIG. 7 is a close-up view of the shaft assembly of the device of FIG. 5;

FIG. 8 is a close-up cross-sectional view of the electrodes of the device of FIG. 5  
5 taken along line 8-8 of FIG. 7;

FIG. 9 is a close-up view of the shape of the electrodes of another embodiment of the device of FIG. 5 taken along line 8-8 of FIG. 7;

FIG. 10 is a close-up view of the shape of the electrodes of another embodiment of the device of FIG. 5 taken along line 8-8 of FIG. 7;

FIG. 11 is a close-up cross-sectional view of a distal end portion of the device of FIG. 5  
10 taken perpendicular to line 8-8 of FIG. 7;

FIG. 12 is a close-up view of a distal end portion of the device of FIG. 5 with an exemplary fluid coupling to a tissue surface of tissue; and

FIG. 13 is a perspective view of the device of FIG. 5 cutting tissue.

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### **Detailed Description**

Throughout the description, like reference numerals and letters indicate corresponding structure throughout the several views. Also, any particular feature(s) of a particular exemplary embodiment may be equally applied to any other exemplary embodiment(s) of this  
20 specification as suitable. In other words, features between the various exemplary embodiments described herein are interchangeable as suitable, and not exclusive. From the specification, it should be clear that any use of the terms “distal” and “proximal” are made in reference from the user of the device, and not the patient.

The invention provides devices, systems and methods for controlling tissue  
25 temperature at a tissue treatment site during an electrosurgical procedure, as well as shrinking, coagulating, cutting and sealing tissue against blood loss, for example, by shrinking lumens of blood vessels (e.g., arteries, veins).

The invention will now be discussed with reference to the figures, with FIG. 1 showing a front view of one embodiment of a system of the present invention having an  
30 exemplary electrosurgical unit 10 in combination with a fluid source 20 and a handheld electrosurgical device 30. FIG. 1 shows a movable cart 2 having a support member 4

comprising a hollow cylindrical post which carries a platform 6 comprising a pedestal table to provide a flat, stable surface for location of the electrosurgical unit 10.

As shown, cart 2 further comprises a fluid source carrying pole 8 having a height which may be adjusted by sliding the carrying pole 8 up and down within the support member 4 and thereafter secured in position with a set screw. On the top of the fluid source carrying pole 8 is a cross support provided with loops at the ends thereof to provide a hook for carrying fluid source 20.

As shown in FIG. 1, fluid source 20 comprises a bag of fluid from which the fluid 12 flows through a drip chamber 14 after the bag is penetrated with a spike located at the end of the drip chamber 14. Thereafter, fluid 12 flows through flexible delivery tubing 16 to handheld electrosurgical device 30. Preferably the fluid delivery tubing 16 is made from a polymer material.

As shown in FIG. 1, the fluid delivery tubing 16 passes through pump 22. As shown pump 22 comprises a peristaltic pump and, more specifically, a rotary peristaltic pump. With a rotary peristaltic pump, a portion of the delivery tubing 16 is loaded into the pump head by raising and lower the pump head in a known manner. Fluid 12 is then conveyed within the delivery tubing 16 by waves of contraction placed externally on the tubing 16 which are produced mechanically, typically by rotating pinch rollers which rotate on a drive shaft and intermittently compress the tubing 16 against an anvil support. Peristaltic pumps are generally preferred, as the electro-mechanical force mechanism, here rollers driven by electric motor, does not make contact the fluid 12, thus reducing the likelihood of inadvertent contamination.

In the present embodiment the fluid 12 comprises saline solution, and even more specifically, normal (physiologic) saline. Although the description herein may make reference to saline as the fluid 12, other electrically conductive fluids can be used in accordance with the invention.

While an electrically conductive fluid having an electrically conductivity similar to normal saline is preferred, as will become more apparent with further reading of this specification, fluid 12 may also comprise an electrically non-conductive fluid. The use of a non-conductive fluid, while not providing all the advantage of an electrically conductive fluid, still provides certain advantages over the use of a dry electrode including, for example, reduced occurrence of tissue sticking to the electrode of device 30 and cooling of the

electrode and/or tissue. Therefore, it is also within the scope of the invention to include the use of a non-conducting fluid, such as, for example, deionized water.

Electrosurgical unit 10 is configured to provide both monopolar and bipolar power output. However, electrosurgical unit 10 includes a lock out feature which prevents both  
5 monopolar and bipolar output from being activated simultaneously. Alternatively, rather than use a single electrosurgical unit 10, device may be simultaneously connected to two separate electrosurgical units. For example, device 30 may be connected to a first electrosurgical unit to provide monopolar power output and a second electrosurgical unit to provide bipolar power output.

10 During monopolar operation, a first electrode, often referred to as the active electrode, is provided with the monopolar electrosurgical device while a second electrode, often referred to as the indifferent or neutral electrode, is provided in the form of a ground pad dispersive electrode located on the patient (also known as a patient return electrode), typically on the back or other suitable anatomical location. An electrical circuit is formed between the  
15 active electrode and ground pad dispersive electrode with electrical current flowing from the active electrode through the patient to ground pad dispersive electrode in a manner known in the art. During bipolar operation, the ground pad electrode located on the patient is not required, and a second electrode providing an electrical pole is provided as part of the device. An alternating current electrical circuit is then created between the first and second electrical  
20 poles of the device. Consequently, alternating current no longer flows through the patient's body to the ground pad electrode, but rather through a localized portion of tissue between the poles of the bipolar device. Monopolar and bipolar power may be provided from electrosurgical unit 10 as known in the art, or from separate electrosurgical units.

As shown in FIG. 1, electrosurgical device 30 is connected to electrosurgical unit 10  
25 via electrical cables 24 and 26. Cable 24 has a plug 34 which connects to bipolar mode output receptacle 38 of electrosurgical unit 10. Cable 26 has a plug 42 which connects to the monopolar mode output receptacle 46 of electrosurgical unit 10. As shown in FIG. 6A, when electrosurgical 10 is used in monopolar mode, an additional cable 28 is utilized to connect a ground pad dispersive electrode 48 to the ground pad receptacle 56 of the electrosurgical unit  
30 10.

FIG. 2 shows the front panel of the exemplary electrosurgical unit 10. A power switch 58 may be used to turn the electrosurgical unit 10 on and off. After turning the



electrosurgical unit 10 on, an RF power setting display 60 may be used to display the RF power setting numerically in watts. The power setting display 60 may further comprise a liquid crystal display (LCD).

Electrosurgical unit 10 may further comprise an RF power selector 62 comprising RF power setting switches 62a, 62b which may be used to select the RF power setting. Pushing the switch 62a may increase the RF power setting, while pushing the switch 62b may decrease the RF power setting. RF power output may be set in 5 watt increments in the range of 20 to 100 watts, and 10 watt increments in the range of 100 to 200 watts. Additionally, electrosurgical unit 10 may include an RF power activation display 64 comprising an indicator light which may illuminate when RF power is activated, either via a handswitch on device 30 or a footswitch. Switches 62a, 62b may comprise membrane switches. It should be understood that while only one RF power selector 62 is shown, electrosurgical unit 10 will have two such RF power selectors with one each for monopolar and bipolar power selection.

In addition to having a RF power setting display 60, electrosurgical unit 10 may further include a fluid flow rate setting display 66. Flow rate setting display 66 may comprise three indicator lights 66a, 66b and 66c with first light 66a corresponding to a fluid flow rate setting of low, second light 66b corresponding to a fluid flow rate setting of medium (intermediate) and third light 66c corresponding to a flow rate setting of high. One of these three indicator lights will illuminate when a fluid flow rate setting is selected.

Electrosurgical unit 10 may further include a fluid flow selector 68 comprising flow rate setting switches 68a, 68b and 68c used to select or switch the flow rate setting. Three push switches may be provided with first switch 68a corresponding to the fluid flow rate setting of low, second switch 68b corresponding to a fluid flow rate setting of medium (intermediate) and third switch 68c corresponding to a flow rate setting of high. Pushing one of these three switches may select the corresponding flow rate setting of either low, medium (intermediate) or high. The medium, or intermediate, flow rate setting may be automatically selected as the default setting if no setting is manually selected. Switches 68a, 68b and 68c may comprise membrane switches.

Before starting a surgical procedure, it may be desirable to prime device 30 with fluid 12. Priming may be desirable to inhibit RF power activation without the presence of fluid 12.

A priming switch 70 may be used to initiate priming of device 30 with fluid 12. Pushing switch 70 once may initiate operation of pump 22 for a predetermined time period to prime device 30. After the time period is complete, the pump 22 may shut off automatically. When priming of device 30 is initiated, a priming display 72 comprising an indicator light may illuminate during the priming cycle.

An exemplary bipolar RF power output curve of electrosurgical unit 10 is shown in FIG. 3. Impedance  $Z$ , shown in units of ohms on the X-axis and output power  $P_O$  is shown in units of watts on the Y-axis. In the illustrated embodiment, the bipolar electrosurgical power (RF) is set to 200 watts. As shown in the figure, for an RF power setting  $P_S$  of 200 watts, the output power  $P_O$  will remain constant with the set RF power  $P_S$  as long as the impedance  $Z$  stays between the low impedance cut-off of 30 ohms and the high impedance cut-off of 120 ohms. Below an impedance  $Z$  of 30 ohms, the output power  $P_O$  will decrease as shown by the low impedance ramp. Above an impedance  $Z$  of 120 ohms, the output power  $P_O$  will also decrease as shown by the high impedance ramp. With respect to monopolar power output, an exemplary monopolar RF power output curve would include that of the Valleylab Force FX, hereby incorporated by reference.

Electrosurgical unit 10 may be configured such that the speed of pump 22, and therefore the throughput of fluid 12 expelled by the pump 22, is predetermined based on two input variables, the RF power setting and the fluid flow rate setting. In FIG. 4 there is shown an exemplary functional relationship of fluid flow rate  $Q$  in units of cubic centimetres per minute (cc/min) on the Y-axis, and the RF power setting  $P_S$  in units of watts on the X-axis. The relationship may be engineered to inhibit undesirable effects such as tissue desiccation, electrode sticking, smoke production and char formation, while at the same time not providing a fluid flow rate  $Q$  at a corresponding RF power setting  $P_S$  which is so great as to provide too much electrical dispersion and cooling at the electrode/tissue interface. While not being bound to a particular theory, a more detailed discussion on how the fluid flow rate interacts with the radio frequency power, modes of heat transfer away from the tissue, fractional boiling of the fluid and various control strategies may be found in U.S. Publication No. 2001/0032002, published October 18, 2001, assigned to the assignee of the present invention and hereby incorporated by reference in its entirety to the extent it is consistent.

As shown in FIG. 4, electrosurgical unit 10 has been configured to increase the fluid flow rate  $Q$  linearly with an increasing RF power setting  $P_S$  for each of three fluid flow rate

settings of low, medium and high corresponding to  $Q_L$ ,  $Q_M$  and  $Q_H$ , respectively. Conversely, electrosurgical unit 10 has been configured to decrease the fluid flow rate  $Q$  linearly with a decrease RF power setting  $P_S$  for each of three fluid flow rate settings of low, medium and high corresponding to  $Q_L$ ,  $Q_M$  and  $Q_H$ , respectively.

5 An electrosurgical unit similar to exemplary electrosurgical unit 10 and having detailed schematic drawings, albeit without monopolar output, may be found in U.S. Publication No. 2006/0149225, published July 6, 2006, assigned to the assignee of the present invention and hereby incorporated by reference in its entirety to the extent it is consistent.

10 While electrosurgical unit 10 as shown above includes an attached pump 22, in other embodiments pump 22 may not be integrated with electrosurgical unit 10, but rather be separate from electrosurgical unit 10.

In still other embodiments, pump 22 may be eliminated and there may be no preset functional relationship of fluid flow rate  $Q$  versus RF power setting  $P_S$  stored in the electrosurgical unit 10. In such an instance, rather than the fluid flow rate  $Q$  being automatically controlled by the electrosurgical unit 10 based on the RF power setting  $P_S$ , the fluid flow rate  $Q$  may be manually controlled, such as by the user of device 10 or another member of the surgical team, with a roller (pinch) clamp or other clamp provided with device 10 and configured to act upon and compress the tubing 16 and control flow in a manner known in the art. Exemplary fluid flow control mechanisms may be found in U.S. Publication No. 2005/0090816, published April 28, 2005, assigned to the assignee of the present invention and hereby incorporated by reference in its entirety to the extent it is consistent. An example of an electrosurgical unit which does not include a pump, but may be used in conjunction with a manually operated fluid flow control mechanism on device 10, includes an electrosurgical unit such as the Valleylab Force FX.

25 An exemplary bipolar and/or monopolar electrosurgical device of the present invention which may be used in conjunction with electrosurgical unit 10 of the present invention is shown at reference character 30a in FIG. 5. While various electrosurgical devices of the present invention are described herein with reference to use with electrosurgical unit 10, it should be understood that the description of the combination is for purposes of illustrating the system of the invention. Consequently, it should be understood that while the electrosurgical devices disclosed herein may be disclosed for use with

electrosurgical unit 10, it may be plausible to use other electrosurgical devices with electrosurgical unit 10, or it may be plausible to use the electrosurgical devices disclosed herein with another electrosurgical unit.

As shown in FIG. 5, exemplary device 30a comprises an elongated handle 100 comprising mating handle portions 100a, 100b. Handle 100 is slender, along with the rest of device 30a, to enable a user of device 30a to hold and manipulate device 30a between the thumb and index finger like a pen-type device. Handle 100 may comprise a sterilizable, rigid, non-conductive material, such as a polymer (e.g., polycarbonate).

As best shown in FIG. 6A, device 30a also comprises cables 24 and 26 which are connectable to electrosurgical unit 10 to provide device 30a with bipolar and monopolar power output, respectively, from electrosurgical unit 10. As shown, cable 24 of device 30a comprises three insulated wire conductors 32a, 32b, 32c connectable to bipolar power output receptacles 38a, 38b, 38c of electrosurgical unit 10 via three banana (male) plug connectors 36a, 36b, 36c. The banana plug connectors 36a, 36b, 36c are each assembled with insulated wire conductors 32a, 32b, 32c within the housing of plug 34 in a known manner. On device 30a, insulated wire conductor 32a is connected to a bipolar hand switch assembly 104, and insulated wire conductors 32b and 32c are connected to semi-circular barrel crimp terminals which snap connect to a proximal portion of shafts 106a, 106b of shaft assembly 108.

Cable 26 of device 30a comprises two insulated wire conductors 40a, 40b connectable to monopolar power output receptacles 46a, 46b of electrosurgical unit 10 via two banana (male) plug connectors 44a, 44b. The banana plug connectors 44a, 44b are each assembled with insulated wire conductors 40a, 40b within the housing of plug 42 in a known manner. On device 30a, insulated wire conductor 40a is connected to a monopolar hand switch assembly 110, and insulated wire conductor 40b is connected to a semi-circular barrel crimp terminal which snap connects to a proximal portion of shaft 106b of shaft assembly 108. When device 30a is used in monopolar mode, an additional cable 28 is utilized to connect a ground pad dispersive electrode 48 which is attached to the patient to the electrosurgical unit 10 comprising wire conductor 50 and plug 52 at the end thereof having plug connector 54 which connects to the ground pad receptacle 56. As shown wire conductors 32b and 40b merge inside handle 100 and share the same attachment location to shaft 106b.

Hand switch assemblies 104 and 110 may comprise push buttons 114 and 116, respectively, (best shown in FIG. 5) which overlie domed switches on a platform comprising

a printed circuit board, with the construction and wiring of the hand switch assemblies 104 and 110 known in the art. Upon depression of push buttons 114 or 116, a domed switch beneath the push button forms a closed circuit which is sensed by electrosurgical unit 10, which then provides bipolar or monopolar power, respectively. Exemplary hand switches  
5 may be found in U.S. Publication No. 2006/0149225, published July 6, 2006, and U.S. Publication No. 2005/0090816, published April 28, 2005, which are assigned to the assignee of the present invention and are hereby incorporated by reference in their entirety to the extent they are consistent.

As shown FIG. 6B, during use of device 30a, fluid 12 from fluid source 20 is  
10 communicated through a tubular fluid passage which is provided by various structures. In the present embodiment, fluid 12 from the fluid source 20 is first communicated through lumen 18 of delivery tubing 16. Fluid 12 may also flow through lumen 120 of a special pump tubing segment 118 designed to operate specifically with the peristaltic pump 22, which may be spliced in between portions of delivery tubing 16 and connected thereto using barbed fluid  
15 line connectors 122 at each end thereof.

Within handle 100 of device 30a, fluid delivery tubing 16 is connected to the inlet branch of a Y-splitter 124, which thereafter provides two outlet branches which are connected to the proximal ends of polymer delivery tubing segments 128a, 128b. The distal ends of delivery tubing segments 128a, 128b are thereafter connected to the proximal ends of shafts  
20 106a, 106b. To connect delivery tubing 128a, 128b to shafts 106a, 106b, the lumens 130a, 130b are preferably interference fit over the outside diameter of shafts 106a, 106b to provide an interference fit seal there between. Fluid 12 then may flow through the lumens 134a, 134b of shafts 106a, 106b.

Once the semi-circular barrel crimp terminals and delivery tubing segments 128a,  
25 128b are connected to shafts 106a, 106b, a polymer shrink wrap tubing may then be heat shrink wrapped around the connections to better electrically insulate the shafts 106a, 106b and better secure the connections.

As best shown in FIG. 7, shaft assembly 108 of the present embodiment comprises two parallel, self-supporting, electrically conductive hollow shafts 106a, 106b, which  
30 comprise metal tubing segments, such as stainless steel tubing segments. Carried by and connected to the distal ends of shafts 106a, 106b are two laterally and spatially separated (by empty space) contact elements in the form of electrode tips comprising electrodes 102a, 102b

which may be configured as mirror images in size and shape, and have a blunt distal end with a surface devoid of edges (to provide a uniform current density) to treat tissue. In the present embodiment electrodes 102a, 102b comprise an electrically conductive material, particularly metal, such as stainless steel. Other suitable materials may include titanium, gold, silver and platinum.

In certain embodiments, the tubing segments of one or both shafts 106a, 106b may be made of electrically non-conducting material except for the portion at the distal end that comes in physical and electrical contact with electrodes 102a, 102b. In these embodiment, an insulated wire conductor would extend and be joined to the electrically conducting portion of shaft 106a, 106b. In still other embodiments, shafts 106a, 106b may completely comprise electrically non-conducting material, in which case an insulated wire conductor would extend and be joined directly to electrodes 102a, 102b.

As shown in FIG. 7, each electrode 102a, 102b comprises an elongated portion 138a, 138b. With respect to length, in the present embodiment elongated portion 138a, 138b has a length in the range between and including about 2 mm to 6 mm, and more specifically have a length of about 3 mm to 5 mm. With respect to spacing, in the present embodiment the spatial gap separation GS between electrodes 102a, 102b in the range between and including about 0.1 mm to about 4 mm, and more specifically about 1 mm to 2.5 mm, and more specifically about 1.5 mm to 2.3 mm.

As best shown in FIG. 8, opposing sides 140a/142a of elongated portion 138a, and opposing sides 140b/142b of elongated portion 138b converge laterally to provide a wedge shaped blade portion 144a, 144b which terminates in a lateral cutting edge 146a, 146b which extends longitudinally along a length of each electrode 102a, 102b. As shown in FIG. 8, lateral cutting edge 146a, 146b extends from a proximal to distal portion of each electrode 102a, 102b, as well as transitions onto the distal end of each electrode 102a, 102b and forms a portion of the distal end of each electrode 102a, 102b.

Lateral cutting edge 146a, 146b is preferably configured to cut tissue electrosurgically in the presence of monopolar radio frequency energy from electrosurgical unit 10 as to provide an electrosurgical cutting edge, but without any fluid 12 being provided from fluid source 20. However, in other embodiments, lateral cutting edge 146a, 146b may be configured to cut tissue with fluid 12 being provided simultaneously from device 30a, or be configured to cut tissue mechanically without electrosurgical energy. Furthermore, while two

cutting edges 146a, 146b are shown, only one of the edges 146a or 146b needs to be configured to cut tissue electrosurgically or mechanically. In such instance, the blade portion of the electrode may be eliminated and the elongated portion may be completely cylindrical.

As shown in FIG. 8, blade portion 144a, 144b narrows as the opposing sides 140a/142a and 140b/142b approach cutting edge 146a, 146b. More particularly, as shown in FIG. 8, the sides 140a/142a and 140b/142b of blade portion 144a, 144b are concave. However, in other embodiments, sides 140a/142a and 140b/142b may be planar or convex as shown in FIGS. 9 and 10, respectively. Also, in other embodiments, only one of sides 140a/142a and 140b/142b may be concave, planar or convex.

Returning to FIG. 7, electrodes 102a, 102b and elongated portions 138a, 138b terminate in distal end portion 148a, 148b. The distal end portion 148a, 148b of electrodes 102a, 102b are configured to slide across a tissue surface in the presence of bipolar radio frequency energy from electrosurgical unit 10 and fluid 12 from the fluid source 20. As shown, the distal end portion 148a, 148b of each electrode 102a, 102b has a blunt, rounded shape which provides a smooth contour surface which is devoid of points or edges. More specifically, as shown, distal end portion 148a, 148b of each electrode 102a, 102b has a spherical surface provided by spherical portion 150a, 150b. In the present embodiment, spherical portion 150a, 150b has a radius in the range between and including about 0.5 mm to 1.5 mm, and more specifically about 0.75 mm to 1.15 mm.

As best shown in FIGS. 8 and 11, within a cylindrical portion 152a, 152b of each electrode 102a, 102b proximal to distal end portion 148a, 148b, each electrode 102a, 102b includes a longitudinally oriented linear blind bore 158a, 158b and counter bore 160a, 160b. As shown in FIG. 11, the outside diameter of a distal end portion of each shaft 106a, 106b is configured to extend into counter bore 160a, 160b of electrodes 102a, 102b and fit with the diameter of counter bore 160a, 160b, with the distal end of each shaft 106a, 106b in contact with the bottom of the counter bore. The electrodes 102a, 102b and shafts 106a, 106b may then be welded together to connect the two components. In alternative embodiments, the outside diameter of shafts 106a, 106b may be configured to fit with the diameter of counter bore 160a, 160b and mechanically join in the form of a press (interference) fit to provide a secure connection. In other alternative embodiments, electrodes 102a, 102b may be assembled to shafts 106a, 106b by threaded engagement. In still other embodiments,

electrodes 102a, 102b may be detachably assembled to shafts 106a, 106b such that they may be removed from the shafts 106a, 106b, preferably manually by human hand.

In addition to blind bore 158a, 158b and counterbore 160a, 160b, as shown in FIG. 8, electrodes 102a, 102b also include a through bores 162a/164a and 162b/164b which  
 5 perpendicularly intersects bore 158a, 158b and perpendicularly intersect one another to provide outlets 166a/168a/170a/172a and 166b/168b/170b/172b (for fluid 12) which are in fluid communication with electrodes 102a, 102b. Thus, after fluid 12 flows through the lumens 134a, 134b of shafts 106a, 106b, fluid 12 then flows through into the tubular passage provided by blind bore 158a, 158b and then into the tubular passage provided by through  
 10 bores 162a/164a and 162b/164b where it thereafter exits device 30a from fluid outlets 166a/168a/170a/172a and 166b/168b/170b/172b, which are all proximal to distal end portion 148a, 148b of electrodes 102a, 102b. As shown in FIG. 8, fluid outlets 166a/170a and 166b/170b are at least partially defined by the cylindrical portion 152a, 152b of electrodes 102a, 102b, while fluid outlets 168a/172a and 168b/172b are at least partially defined by  
 15 sides of 140a/142a and 140b/142b of blade portion 144a, 144b and adjacent cutting edge 146a, 146b. More particularly, as shown in FIG. 8, fluid outlets 166a/170a and 166b/170b are fully defined by the cylindrical portion 152a, 152b of electrodes 102a, 102b, while fluid outlets 168a/172a and 168b/172b are fully defined by sides of 140a/142a and 140b/142b of blade portion 144a, 144b and adjacent cutting edge 146a, 146b. In certain embodiments, each electrode 102a, 102b may have only one fluid outlet in fluid communication therewith, such as outlets 168a, 168b. In still other embodiments, only a single one fluid outlet may be present.

The relationship between the material for electrodes 102a, 102b and their surfaces, and fluid 12 throughout the various embodiments should be such that the fluid 12 wets the  
 25 surface of the electrodes 102a, 102b. Contact angle,  $\theta$ , is a quantitative measure of the wetting of a solid by a liquid. It is defined geometrically as the angle formed by a liquid at the three phase boundary where a liquid, gas and solid intersect. In terms of the thermodynamics of the materials involved, contact angle  $\theta$  involves the interfacial free energies between the three phases given by the equation

$$\gamma_{LV} \cos \theta = \gamma_{SV} - \gamma_{SL}$$



where  $\gamma_{LV}$ ,  $\gamma_{SV}$  and  $\gamma_{SL}$  refer to the interfacial energies of the liquid/vapor, solid/vapor and solid/liquid interfaces, respectively. If the contact angle  $\theta$  is less than 90 degrees the liquid is said to wet the solid. If the contact angle is greater than 90 degrees the liquid is non-wetting. A zero contact angle  $\theta$  represents complete wetting. Thus, preferably the contact angle is less than 90 degrees.

As best shown in FIGS. 7 and 11, a portion of the lengths of shafts 106a, 106b are surrounded by and encapsulated in a common outer member 184, which may comprises a flexible polymer. Outer member 184 electrically insulates the exposed length of shafts 106a, 106b.

Outer member 184 may be formed by injection molding. During the injection molding process, a sub-assembly comprising electrodes 102a, 102b and shafts 106a, 106b is placed in the injection mold prior to the introduction of polymer. Thereafter, the mold is closed and a thermoplastic polymer may be injected into the unoccupied portions of the mold cavity to overmold and mold-in place portions of the sub-assembly as shown in FIG. 7. During the injection molding process, retainer clips (not shown) may provide the benefit of retaining shafts 106a, 106b in position relative to each other to better ensure that the shafts 106a, 106b are centrally located within the polymer molding.

To be hand shapeable by surgeons and other users of device 30a, so that the device 30a may be used in a greater multitude of angles and locations, at least a portion of shafts 106a, 106b of device 30a may be malleable to provide a malleable shaft assembly 108. Also, in this manner, a distal portion of shafts 106a, 106b may be bendable at an angle relative to the longitudinal axis of the proximal portion of shafts 106a, 106b during manufacturing of device 30a so they may be provided to users of device 30a at various angles. For example, angle may range from about 5 degrees to 90 degrees, and more preferably, about 15 degrees to 45 degrees, and even more preferably about 30 degrees. As used herein, malleable means able to be shaped, particularly by bending (without a mechanical mechanism, such as a hinge or joint). It should be understood that shaft assembly 108 is to independently maintain the shape associated with the selected bent shape, and does not require additional components (e.g., pull wires, etc.) to maintain the selected bent shape. Furthermore, shaft assembly 108 is to maintain the selected shape such that when device 30a is used to treat tissue, and will not overtly deflect from the selected shape. Furthermore, shaft assembly 108 is constructed such

that a user can readily re-shape the shafts back to a straight state and/or other desired bent configurations.

Outer member 184, in addition to electrically insulating shafts 106a, 106b from one another, has been found to be particularly useful in facilitating the hand shaping of shafts 106a, 106b of shaft assembly 108 simultaneously and with a similar contour without cracking. In this manner, surgeons and other users of device 30a need not bend the shafts 106a, 106b individually, and the relative spacing and position of the electrodes 102a, 102b may be maintained constant.

To provide malleability, shafts 106a, 106b preferably have an outer wall diameter of about 0.063 inches and an inner wall diameter of about 0.032 inches. Shafts 106a, 106b also preferably are made from 304 stainless steel with a temper from about  $\frac{1}{2}$  to  $\frac{3}{4}$  hard, 130,000 to 150,000 psi. (pounds per square inch) tensile strength) and an elongation at break of about 40%. Shafts 106a, 106b with the foregoing properties provide sufficient stiffness as not to be too pliable during normal use of device 30a, while at the same time inhibiting the shafts 106a, 106b from kinking or breaking when shaped for application. When the wall thickness is too thin, shafts 106a, 106b may kink, and when the wall thickness is too thick, the shafts 106a, 106b may be too stiff. Furthermore, a shaft 106a, 106b with a larger diameter may also kink more than a shaft of smaller diameter. Shafts 106a, 106b may also be malleable for a portion of the length or full length depending on application. For example, the shafts 106a, 106b can be made with variable stiffness along the length and be malleable only for a distal portion thereof. Preferably this is performed by controlled annealing of the shafts 106a, 106b only in the area where malleability is desired.

As shown in FIG. 12, one way in which device 30a may be used is with the longitudinal axis of electrodes 102a, 102b vertically orientated, and the distal end portion 148a, 148b of electrodes 102a, 102b laterally spaced adjacent tissue surface 202 of tissue 200. When device 30a is used in this manner, electrodes 102a, 102b are connected to electrosurgical unit 10 and receive bipolar radio frequency energy which forms an alternating current electrical field in tissue 200 located between electrodes 102a, 102b. In the presence of alternating current, the electrodes 102a, 102b alternate polarity between positive and negative charges with current flow from the positive to negative charge. Without being bound to a particular theory, heating of the tissue is performed by electrical resistance heating.

Fluid 12, in addition to providing an electrical coupling between the device 30a and tissue 200, lubricates surface 202 of tissue 200 and facilitates the movement of electrodes 102a, 102b across surface 202 of tissue 200. During movement of electrodes 102a, 102b, electrodes 102a, 102b typically slide across the surface 202 of tissue 200. Typically the user of device 30a slides electrodes 102a, 102b across surface 202 of tissue 200 back and forth with a painting motion while using fluid 12 as, among other things, a lubricating coating. Preferably the thickness of the fluid 12 between the distal end portions 148a, 148b of electrodes 102a, 102b and surface 202 of tissue 200 at the outer edge of couplings 204a, 204b is in the range between and including about 0.05 mm to 1.5 mm. Also, in certain embodiments, the distal end portion 148a, 148b of electrodes 102a, 102b may contact surface 202 of tissue 200 without any fluid 12 in between.

As shown in FIG. 12, fluid 12 expelled from fluid outlets may form into droplets 208a, 208b which flow distally on electrodes 102a, 102b. As shown in FIG. 12, droplets 208a, 208b may form at varying times from fluid 12 expelled from any one of the fluid outlets. Also, fluid 12 may be expelled in varying quantity from each of the fluid outlets, depending on, for example, device orientation, pressure, flow rate and varying fluid outlet sizes. With use of device 30a, the size of droplets 208a, 208b may also vary due to changes in the surface finish of the electrodes 102a, 102b, for example, as a result of being contaminated by blood and tissue.

As shown in FIG. 12, fluid couplings 204a, 204b comprise discrete, localized webs and more specifically comprise triangular shaped webs or bead portions providing a film of fluid 12 between surface 202 of tissue 200 and electrodes 102a, 102b. When the user of electrosurgical device 30a places electrodes 102a, 102b at a tissue treatment site and moves electrodes 102a, 102b across the surface 202 of the tissue 200, fluid 12 is expelled from fluid outlets 166a/168a/170a/172a and 166b/168b/170b/172b around the surfaces of electrodes 102a, 102b and onto the surface 202 of the tissue 200 via couplings 204a, 204b. At the same time, RF electrical energy, shown by electrical field lines 206, is provided to tissue 200 at tissue surface 202 and below tissue surface 202 into tissue 200 through fluid couplings 204a, 204b. As shown in FIG. 13, device 30a may be used to cut tissue by applying either cutting edge 146a or 146b to tissue 200, depending which electrode 102a, 102b is utilized, and repeatedly moving the electrode 102a or 102b along a desired incision or resection line in the tissue to form the depicted crevice.

Device 30a may be used to perform a solid organ resection such as a liver resection. Edge 146a or 146b may be first used to score the outer capsule of the liver along the planned line of resection. Thereafter, the distal end portions 148a, 148b of electrodes 102a, 102b may be moved back and forth along the line, with radio frequency power and the flow of fluid on, resulting in coagulation of the liver parenchyma beneath the scored capsule. As the tissue is coagulated under and around the electrode surfaces, the electrodes 102a, 102b may be used to separate and blunt dissect the coagulated parenchyma and enter the resulting crevice. As the distal end portions 148a, 148b of electrodes 102a, 102b treat the parenchyma, the treated parenchyma loses integrity and becomes easier to separate, either alone or in conjunction with separation force applied by electrodes 102a, 102b from the user of the device.

Blunt dissection of the coagulated parenchyma is performed by continuous abrading or splitting apart of the parenchyma with substantially the same back and forth motion as coagulation and with the device 30a being held substantially in the same orientation as for coagulation of the liver parenchyma. However, with blunt dissection, the surgeon typically applies more force to the tissue. In various embodiments, once the liver parenchyma is coagulated, blunt dissection may be performed with or without the radio frequency power (i.e., on or off) and/or with or without the presence of fluid from device 30a. Additionally or alternatively, the tissue on opposing sides of the line of resection may be placed into tension perpendicular to the line of resection to facilitate resection. Furthermore, resection may also be accomplished by sharp dissection with edge 146a or 146b of electrodes 102a, 102b. Thus, with device 30a, a surgeon may perform a resection procedure in a number of different ways.

As the parenchyma is resected, blood vessels within the parenchyma may be uncovered which extend across or transverse the line of resection. Device 30a may be used to shrink and seal these vessels by heating and shrinking the collagen contained in the walls of the vessels thus decreasing the diameter of the lumen of these vessels. For vessels with a diameter too large to completely occlude the lumen, the vessels may be tied with suture on each side of the line of resection and thereafter severed therebetween. If such vessels are not first uncovered by removing the surrounding parenchyma tissue and without being severed, they may bleed profusely and require much more time to stop the bleeding. Consequently, it may be desirable to avoid separation by sharp dissection in situations where large vessels are not first uncovered and exposed.

This technique can also be used on other parenchymal organs such as the pancreas, the kidney, and the lung. In addition, it may also be useful on muscle tissue and subcutaneous fat. Its use can also extend to tumors, cysts or other tissue masses found in the urological or gynecological areas. It would also enable the removal of highly vascularized tumors such as hemangiomas.

The devices disclosed herein are particularly useful as non-coaptive devices that provide cutting of tissue, as well as coagulation, hemostasis and sealing of tissue to inhibit blood and other fluid loss during surgery. In other words, grasping of the tissue is not necessary to shrink, coagulate, cut and seal tissue against blood loss, for example, by shrinking collagen and associated lumens of blood vessels (e.g., arteries, veins) to provided the desired hemostasis of the tissue. Furthermore, the control system of the electrosurgical unit 10 is not necessarily dependent on tissue feedback such as temperature or impedance to operate. Thus, the control system of electrosurgical unit 10 may be open loop with respect to the tissue which simplifies use.

Device 30a disclosed herein may be particularly useful to surgeons to achieve hemostasis after cutting through soft tissue, as part of hip or knee arthroplasty. The distal end portions 148a, 148b can be painted over the raw, oozing surface 202 of tissue 200 to seal the tissue 200 against bleeding, or focused on individual larger bleeding vessels to stop vessel bleeding. As part of the same or different procedure, device 30a is also useful to stop bleeding from the surface of cut bone, or osseous, tissue as part of any orthopaedic procedure that requires bone to be cut. Device 30a may be particularly useful for use during orthopedic knee, hip, shoulder and spine procedures. Additional discussion concerning such procedures may be found in U.S. Publication No. 2006/0149225, published July 6, 2006, and U.S. Publication No. 2005/0090816, published April 28, 2005, which are assigned to the assignee of the present invention and are hereby incorporated by reference in there entirety to the extent they are consistent.

As established above, device 30a of the present invention inhibit such undesirable effects of tissue desiccation, electrode sticking, char formation and smoke generation, and thus do not suffer from the same drawbacks as prior art dry tip electrosurgical devices. The use of the disclosed devices can result in significantly lower blood loss during surgical procedures. Such a reduction in blood loss can reduce or eliminate the need for blood

transfusions, and thus the cost and negative clinical consequences associated with blood transfusions, such as prolonged hospitalization.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications can be made therein without departing from the spirit of the invention and the scope of the appended claims. The scope of the invention should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the appended claims along with their full scope of equivalents. Furthermore, it should be understood that the appended claims do not necessarily comprise the broadest scope of the invention which the Applicant is entitled to claim, or the only manner(s) in which the invention may be claimed, or that all recited features are necessary.

All publications and patent documents cited in this application are incorporated by reference in their entirety for all purposes to the extent they are consistent.

What is claimed:

1. An electrosurgical device to treat tissue in a presence of radio frequency energy and a fluid provided from the device, the device comprising:
  - 5 a distal portion comprising a first electrode tip, a second electrode tip and at least one fluid outlet;  
the first electrode tip comprising a first electrode having a distal portion with an electrically conductive spherical surface;  
the second electrode tip comprising a second electrode having a distal portion with an  
10 electrically conductive spherical surface; and  
at least one of the first electrode and the second electrode having a blade portion.
2. The device of claim 1 wherein:  
the first electrode and the second electrode are configured to be electrically coupled to  
15 a bipolar power output; and  
the at least one electrode having the blade portion is configured to be electrically coupled to a monopolar power output.
3. The device of claim 1 or 2 wherein:  
20 the blade portion extends longitudinally along the electrode.
4. The device of any preceding claim wherein:  
the blade portion extends from a proximal portion to the distal portion of the  
electrode.  
25
5. The device of any preceding claim wherein:  
the blade portion has a cutting edge.
6. The device of any preceding claim wherein:  
30 the cutting edge is an electrosurgical cutting edge.

7. The device of any preceding claim wherein:  
the blade portion has opposing sides;  
the blade portion narrows as the opposing sides approach the cutting edge.

5 8. The device of claim 7 wherein:  
at least one of the opposing sides comprises a planar surface.

9. The device of claim 7 wherein:  
at least one of the opposing sides comprises a concave surface.

10

10. The device of claim 7 wherein:  
at least one of the opposing sides comprises a convex surface.

11. The device of any preceding claim wherein:

15 the at least one fluid outlet further comprises at least one fluid outlet in fluid  
communication with the first electrode and at least one fluid outlet in fluid communication  
with the second electrode.

12. The device of claim 11 wherein:

20 the at least one fluid outlet in fluid communication with the first electrode is proximal  
to a distal end of the first electrode; and

the at least one fluid outlet in fluid communication with the second electrode is  
proximal to a distal end of the second electrode.

13. The device of claim 11 wherein:

25 the at least one fluid outlet in fluid communication with the first electrode is at least  
partially defined by the first electrode; and

the at least one fluid outlet in fluid communication with the second electrode is at  
least partially defined by the second electrode.

30

14. The device of any preceding claim wherein:

the first electrode is laterally spaced from the second electrode.



15. The device of any preceding claim wherein:  
the first electrode is carried by a first tubing segment; and  
the second electrode is carried by a second tubing segment.
- 5 16. The device of claim 15 wherein:  
the first tubing segment is electrically conductive; and  
the second tubing segment is electrically conductive.
17. The device of claim 16 wherein:  
10 the electrically conductive first tubing segment is in electrical contact with the first  
electrode; and  
the electrically conductive second tubing segment is in electrical contact with the  
second electrode.
- 15 18. The device of any preceding claim wherein:  
the first electrode is connected at a distal end of a first tubing segment; and  
the second electrode is connected at a distal end of a second tubing segment.
19. The device of claim 18 wherein:  
20 the first electrode is mechanically joined to the first tubing segment; and  
the second electrode is mechanically joined to the second tubing segment.
20. The device of claim 18 wherein:  
the first electrode is welded to the first tubing segment; and  
25 the second electrode is welded to the second tubing segment.
21. An electrosurgical device comprising:  
a distal portion comprising a first electrode tip, a second electrode tip and at least one  
fluid outlet;  
30 the first electrode tip comprising a first electrode having a blade portion;  
the second electrode tip comprising a second electrode having a blade portion;

each of the first and second electrodes configured to be electrically coupled to a bipolar energy source by first and second bipolar electrical connectors in electrical communication with the first and second electrodes, respectively; and

- 5       at least one of the electrodes configured to be electrically coupled to a monopolar energy source by a monopolar electrical connector in electrical communication with at least one of the electrodes.

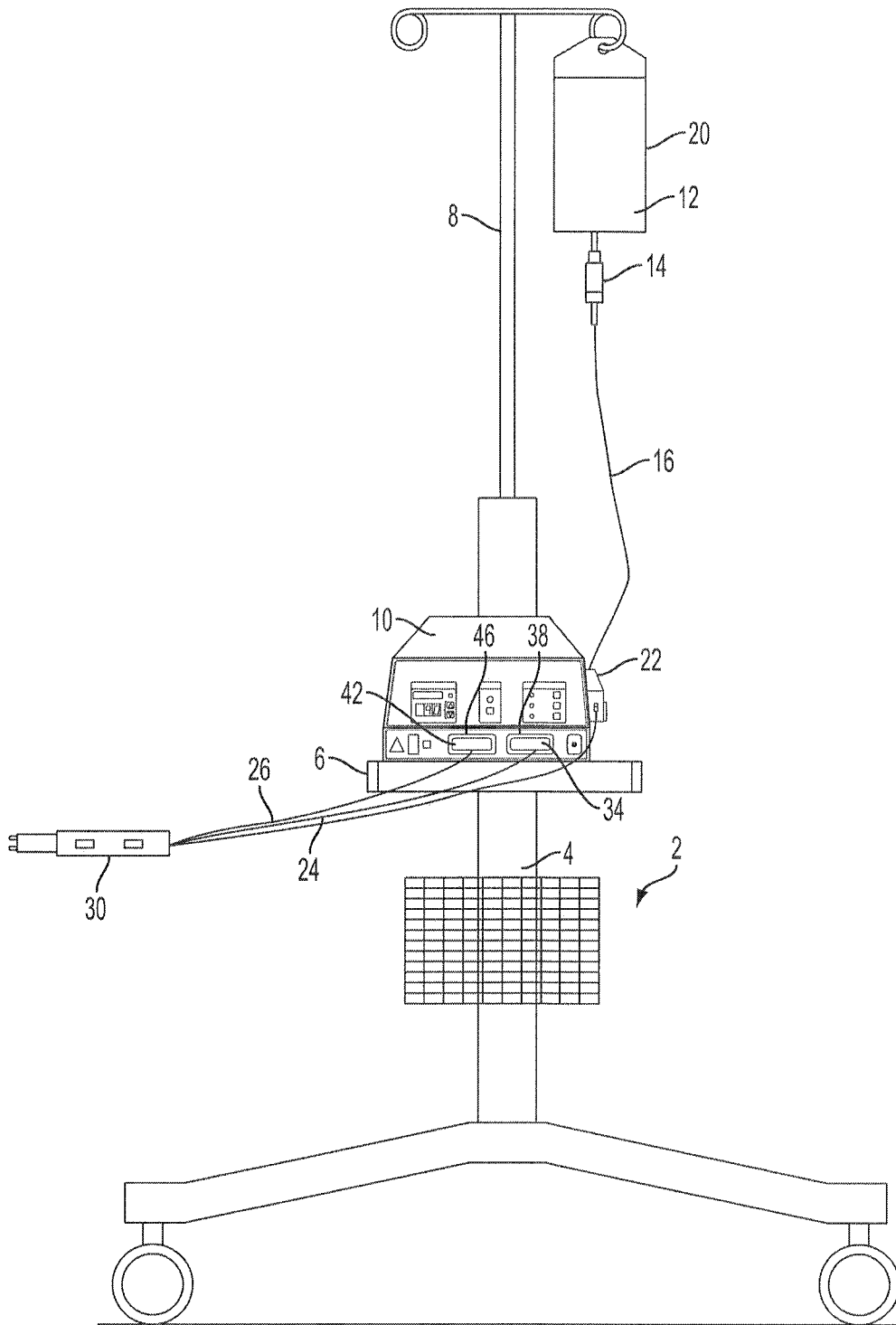


FIG. 1

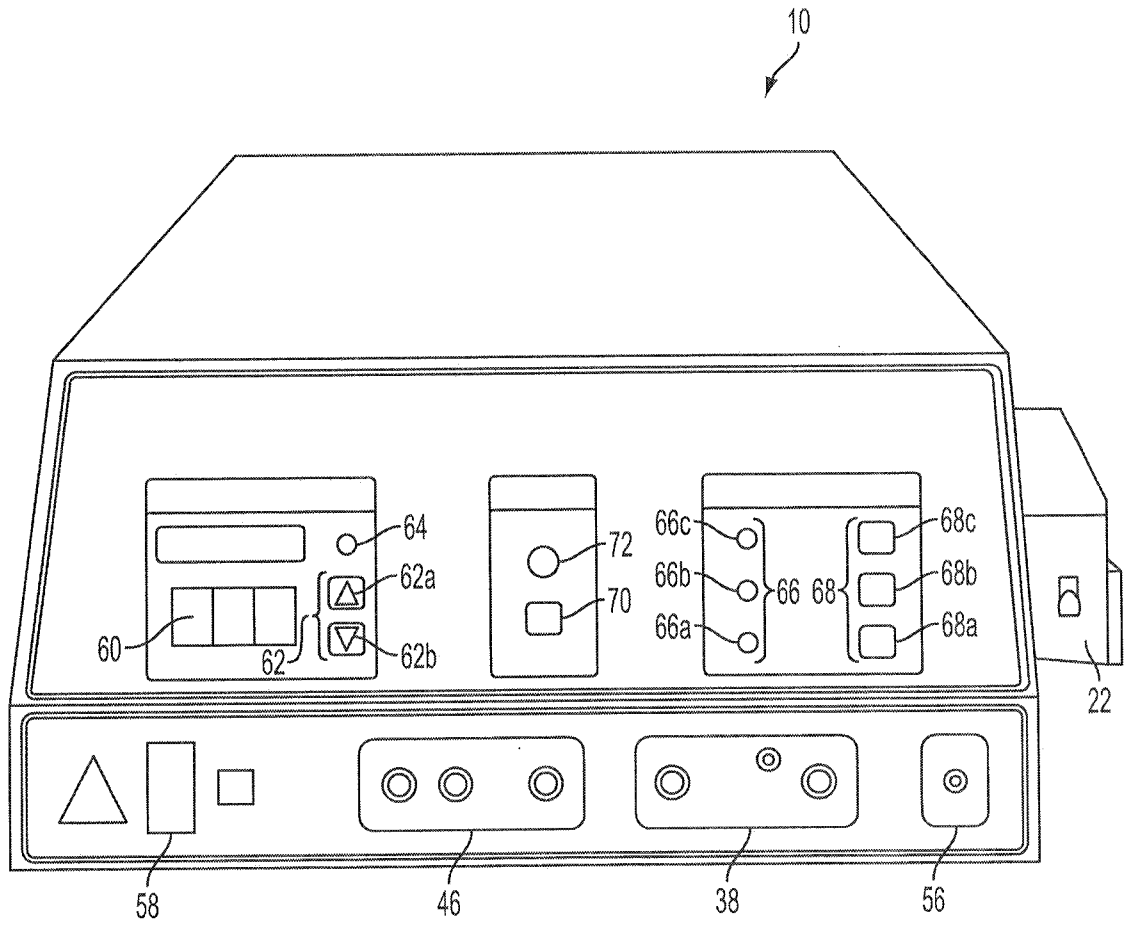


FIG. 2

3/12

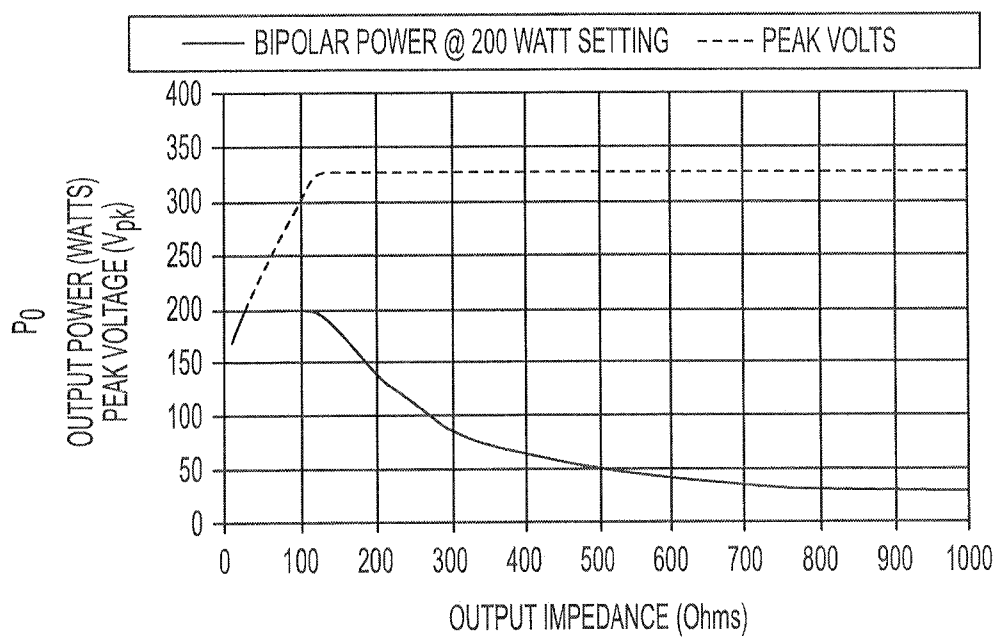


FIG. 3

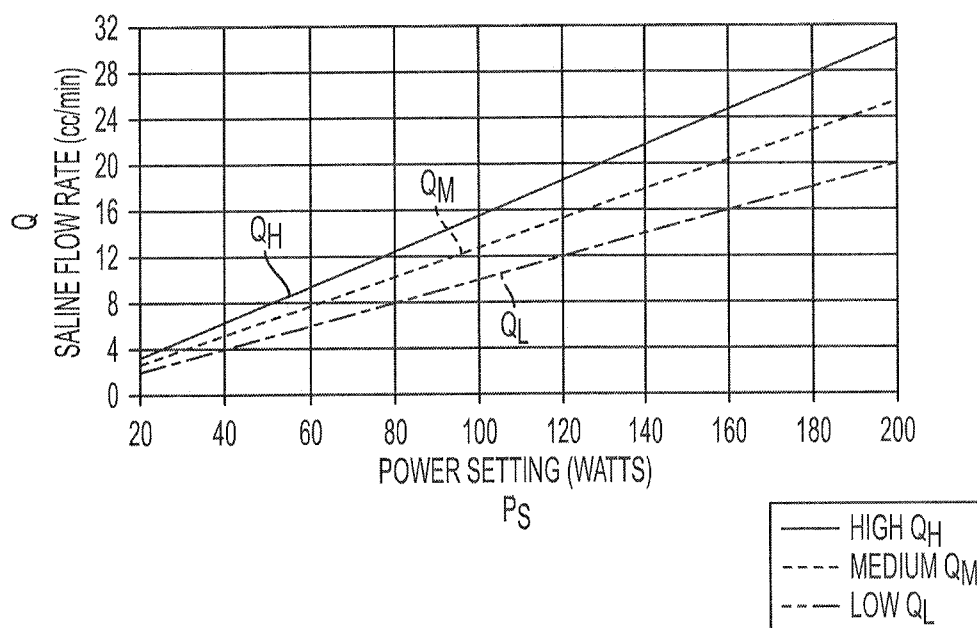
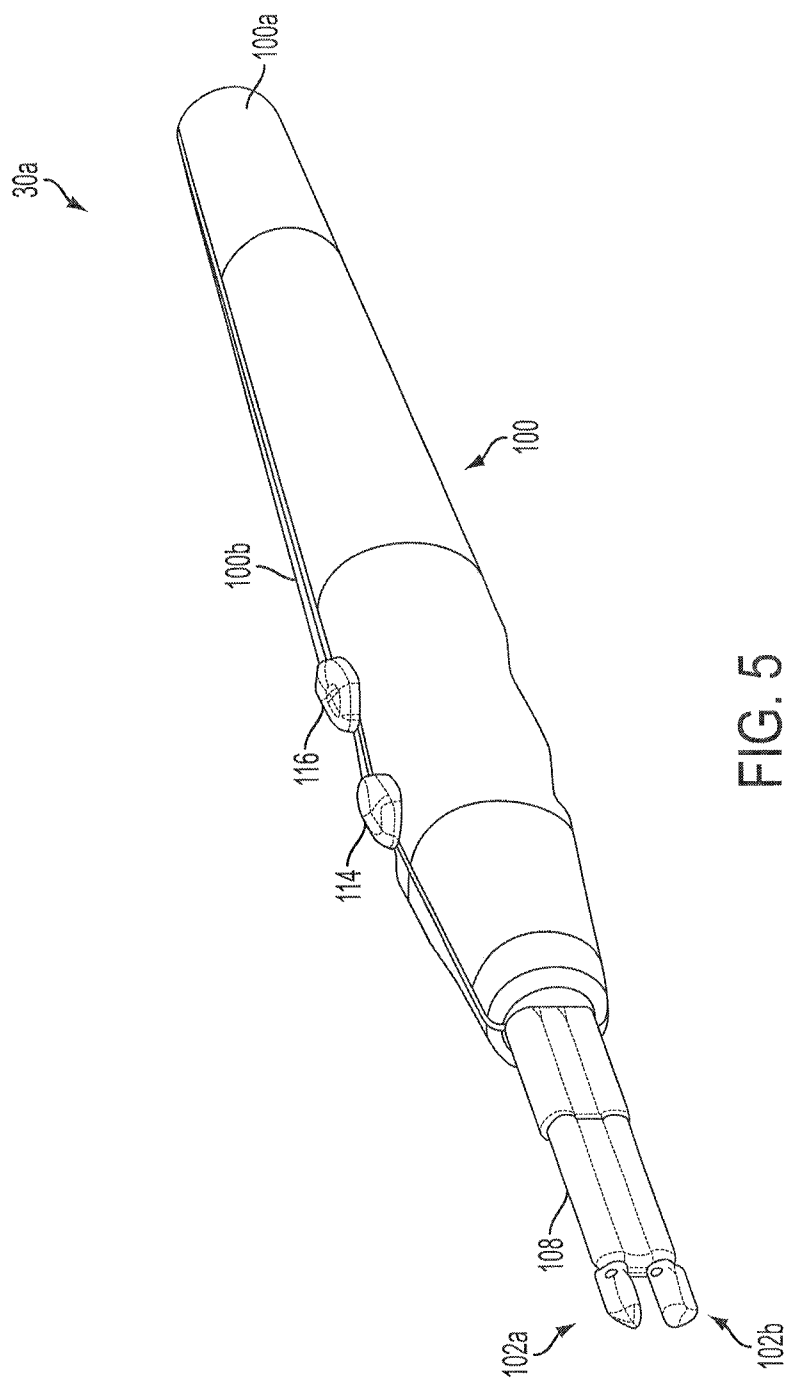


FIG. 4



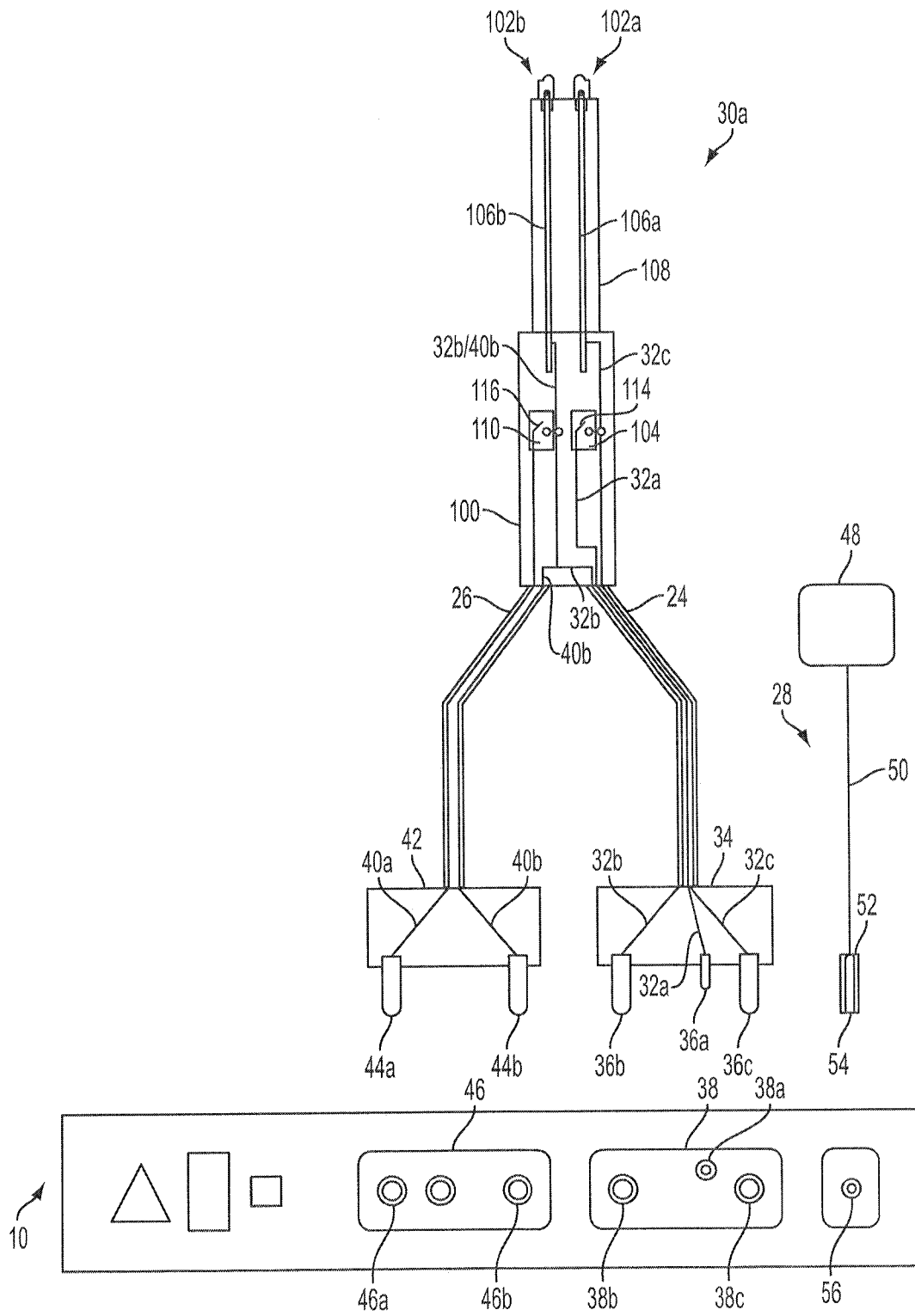


FIG. 6A

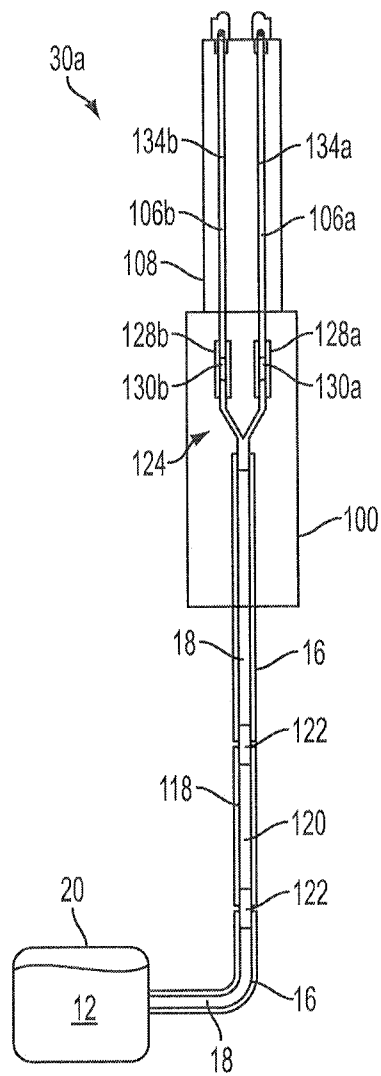


FIG. 6B



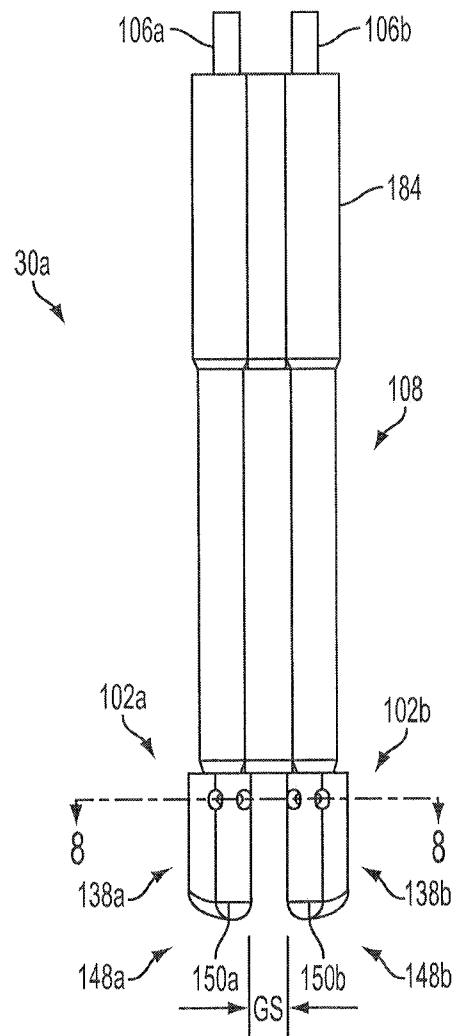


FIG. 7

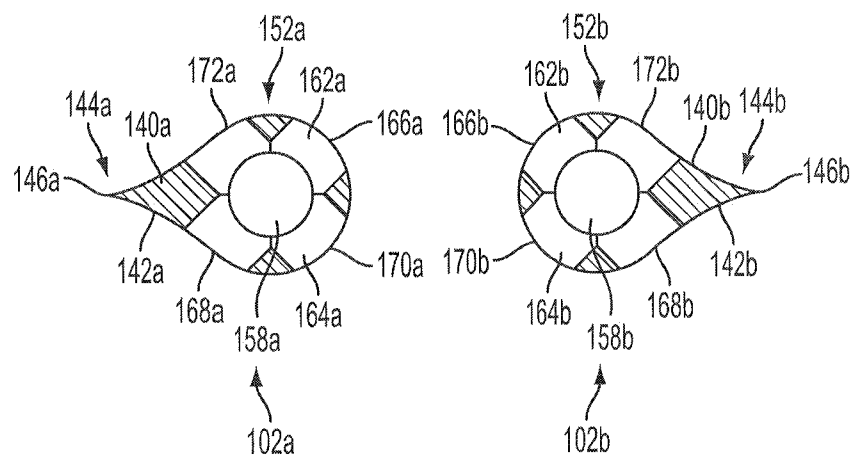


FIG. 8

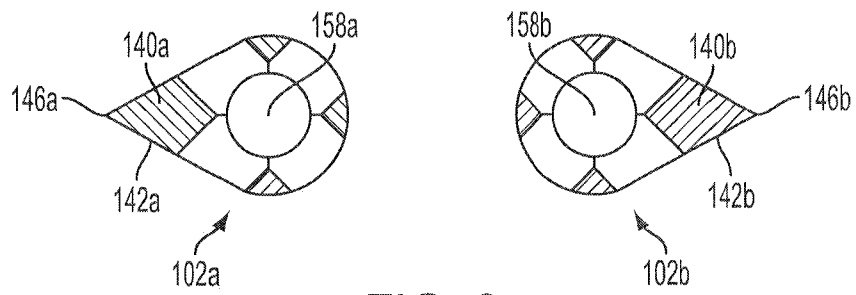


FIG. 9

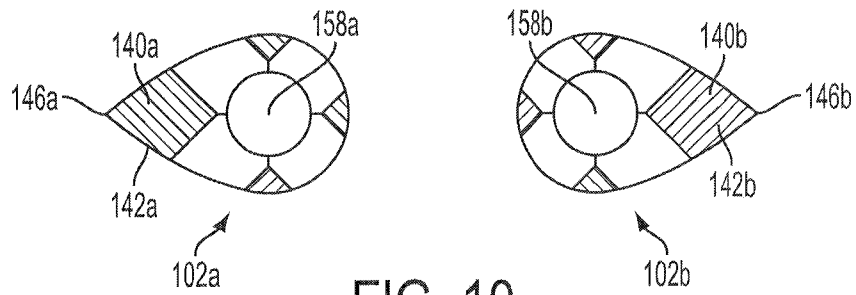


FIG. 10

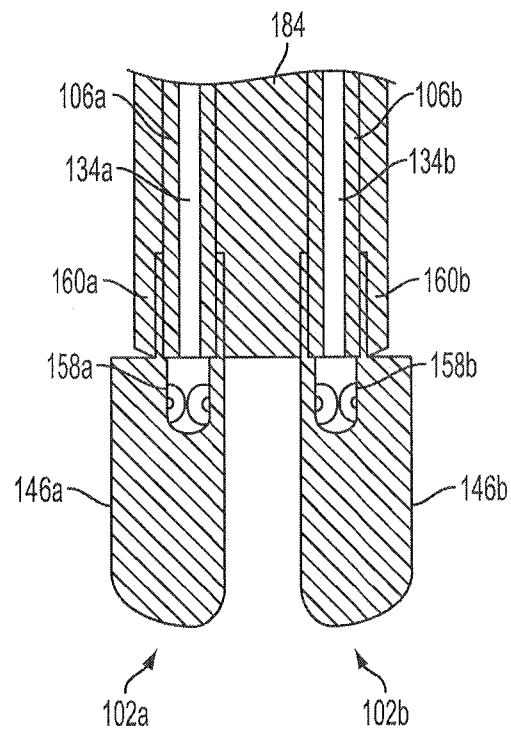


FIG. 11

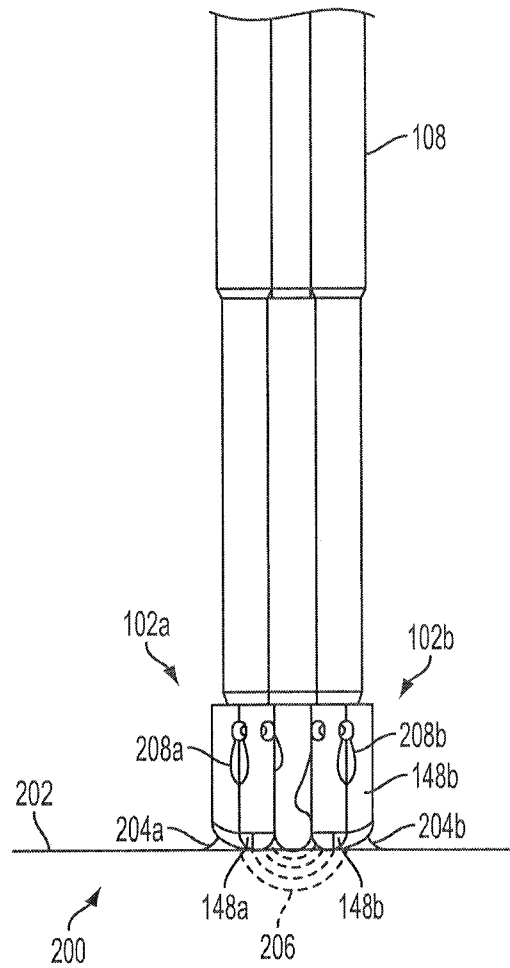


FIG. 12

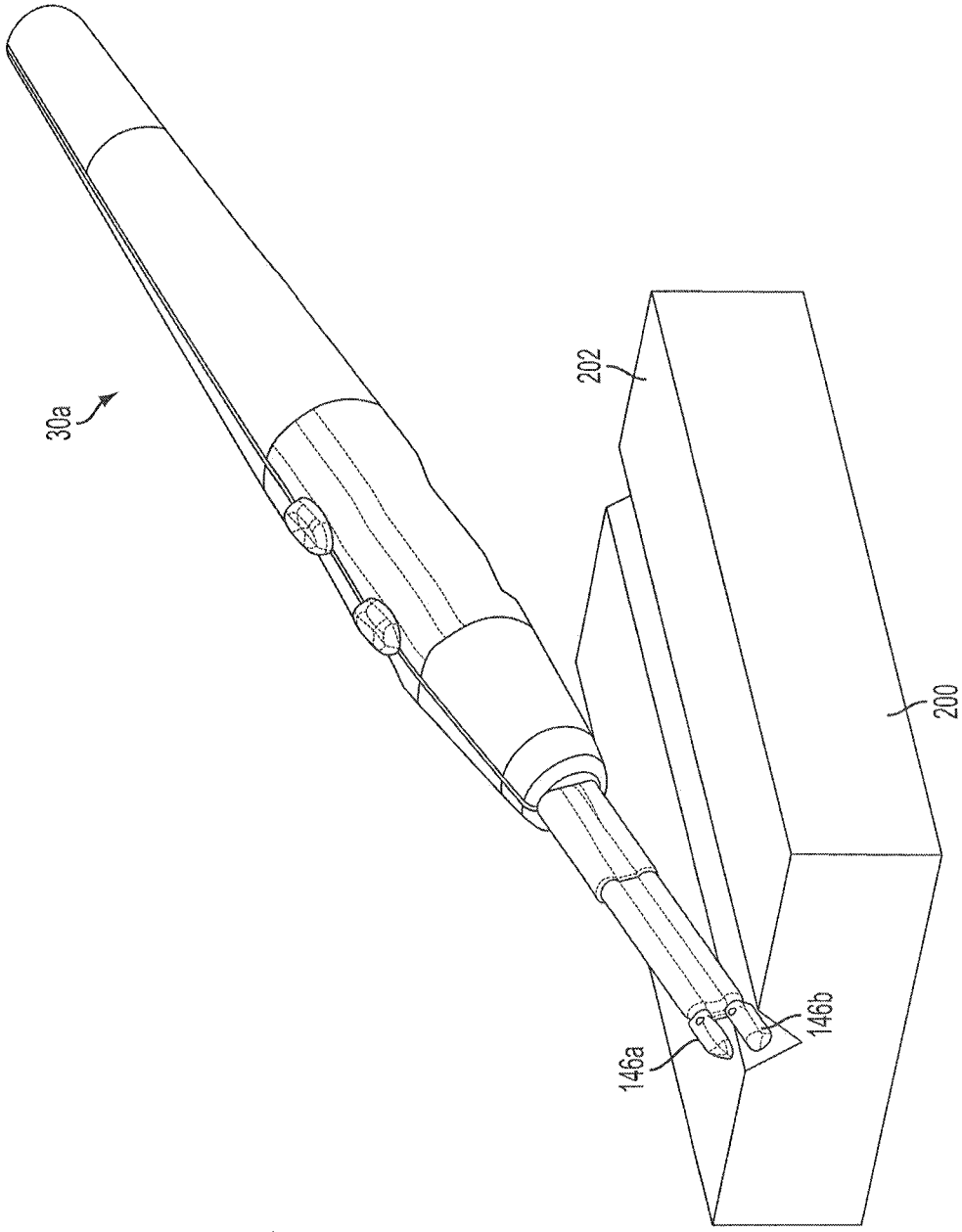


FIG. 13

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/025058

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 18/14(2010.01)

USPC - 606/41

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 18/14(2010.01)

USPC - 606/41

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

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

PatBase

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0071266 A1 (RIOUX et al) 20 March 2008 (20.03.2008) entire document	1-3, 21
Y	US 2005/0015085 A1 (MCCLURKEN et al) 20 January 2005 (20.01.2005) entire document	1-3
Y	US 5,562,720 A (STERN et al) 08 October 1996 (08.10.1996) entire document	21
A	US 2004/0199226 A1 (SHADDUCK) 07 October 2004 (07.10.2004) entire document	1-3 and 21
A	US 5,919,191 A (LENNOX et al) 06 July 1999 (06.07.1999) entire document	1-3 and 21

☐ Further documents are listed in the continuation of Box C.

## \* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

07 April 2010

Date of mailing of the international search report

21 APR 2010

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Authorized officer:

Blaine R. Copenheaver

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PCT OSP: 571-272-7774

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/025058

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

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

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 4-20  
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 additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.