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(71) Applicant *(for all designated States except US)*: **ELECTROMEDICAL ASSOCIATES, LLC** [US/US]; 6006 Massachusetts Avenue, Bethesda, MD 20816 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **VAN WYK, Robert, A.** [US/US]; 10801 Starkey Road, #104-16, Largo, FL 33777 (US). **CARMEL, Yuval** [US/US]; 6006 Massachusetts Avenue, Bethesda, MD 20816 (US). **SHKVARUNETS, Anatoly** [RU/US]; 618 Ivy League Lane, Rockville, MD 20850 (US).

(74) Agents: **COLE, Troy, J.** et al.; Woodard, Emhardt, Moriarty, Mcnett & Henry LLP, 111 Monument Circle, Suite 3700, Indianapolis, IN 46204 (US).

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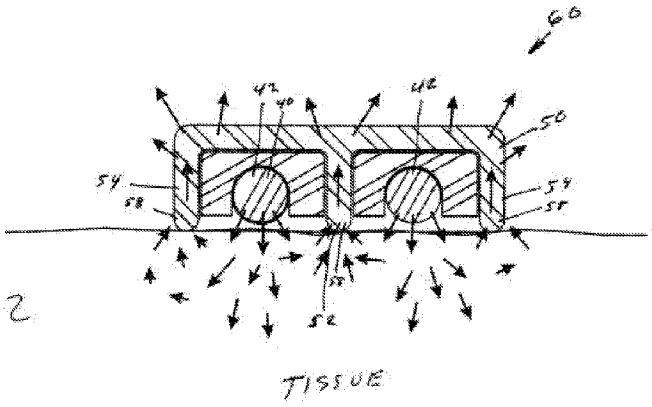

FIG 22

(57) Abstract: Disclosed herein are high efficiency surgical devices and methods of using same using radio frequency (RF) electrical power and/or electrically heated filaments to destroy tumors, form lesions, denaturize, desiccate, coagulate and ablate soft tissues, as well as to drill, cut, resect and vaporize soft tissues. According to the principles of this invention, the electrosurgical instruments can be used with externally supplied conductive or non-conductive liquids, as well as without externally supplied liquids, a mode of operation often referred to as "dry field" environment.

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INSTRUMENTS AND METHODS FOR THERMAL TISSUE TREATMENT

Priority

This application claims the benefit of U.S. Provisional Application No. 60/902,548 filed February 21, 2007, the entire contents of which are incorporated by reference herein.

Field of the invention

The present invention relates generally to the field of thermal tissue treatment, and more particularly, to high efficiency surgical instruments and methods which use radio frequency (RF) electrical power and/or electrically heated filaments to destroy tumors, form lesions, denaturize, desiccate, coagulate and ablate soft tissues, as well as to drill, cut, resect and vaporize soft tissues. According to the principles of this invention, the electrosurgical instruments of the present invention can be used to thermally treat target tissues of interest, either at the tissue surface, below the tissue surface or at a site remote therefrom, using externally supplied conductive or non-conductive fluids, as well as without externally supplied liquids, a mode of operation often referred to as "dry field" environment.

Background of the invention

Electrosurgical procedures are advantageous since they generally reduce patient bleeding and trauma. The devices used are electrically energized, typically using an RF generator operating at a frequency that ranges between 100 kHz to over 4 MHz. Due to their ability to provide beneficial outcomes with reduced patient pain and recuperation time, electrosurgical devices have recently gained significant popularity recently. In common terminology and as used herein, the term "electrode" can refer to one or more components of an electrosurgical device (such as an "active electrode" or a "return electrode") or to the entire device, as in an "ablator electrode" or "cutting electrode". Electrosurgical devices may also be referred to as electrosurgical "probes" or "instruments".

Many types of electrosurgical instruments are currently in use, and can be divided into two general categories: monopolar devices and bipolar devices. In the context of monopolar electrosurgical devices, the RF current generally flows from

an exposed active electrode, through the patient's body, to a passive, return current electrode that is externally attached to a suitable location on the patient body. In this manner, the patient's body becomes part of the return current circuit. In the context of bipolar electrosurgical devices, both the active and the return current electrodes are exposed, and are typically positioned in close proximity to each other, more frequently mounted on the same instrument. The RF current flows from the active electrode to the return electrode through the nearby tissue and conductive fluids.

The need to effectively yet minimally invasively treat tumor tissue from a patient's body arises in the context of many medical practice areas, including, but not limited to, oncology, ear nose and throat (ENT), urology, gynecology, laparoscopy and general surgery. More specifically, there is often a need to denaturize, desiccate or coagulate tissue and destroy tumors in the liver, kidney, breast, lung, bone, lymph nodes, nerve ganglia and other organs. Such procedures are collectively referred to as tissue ablation or lesion formation, and are often used to destroy tumors without radical surgery. In such cases, an effective treatment is one in which the tumor itself, and perhaps a small margin of tissue around the tumor, is affected. The affected tumor tissue is not immediately removed. Over time, the dead tissue will naturally shrink, dissolve and, in some cases, be gradually replaced by scar tissue.

Although the benefits of these procedures are well recognized by those of skill in the art, current electrosurgical instruments and procedures suffer from very significant deficiencies. Quite often existing instruments are composed of one or more needles which are electrically energized by radiofrequency. As a result, the energy deposition in the tissue is concentrated close to where the needle is positioned, leading to overheating in the immediate region and under-heating in areas farther away . The result is a highly non-homogeneous energy deposition and highly non-homogeneous lesion. It is inherently impossible to accurately control the shape and size of the lesion formed with existing instruments because the energy deposition and heating occurs from the inside out. However, in order to destroy a tumor, it is often necessary, yet undesirable, to also destroy a large margin of healthy tissue around the tumor. As a result the current processes are inefficient, require high power levels and therefore can lead to unnecessary complications and

undesired side effects. In some cases, additional return electrodes (also called grounding pads or patient electrodes) are needed in order to safely handle the high energy and high current required to perform the procedure. One such system marketed by Boston Scientific (Natick, MA) for lever ablation uses four patient electrodes simultaneously.

In view of these and other deficiencies, there is a need in the art for improved electrosurgical instruments that are capable of creating uniform lesions of a desired size and shape, capable of treating tissue and tumors from the outside in rather than from the inside out, and capable of treating large and non uniform tumors and leaving healthy tissue unharmed. There is also a need in the art for a high efficiency electrosurgical instrument capable of destroying the tumor at relatively low power, thereby increasing patient safety and efficacy and reducing undesired side effects.

Summary of the Invention

It is accordingly an object of the present invention to provide a highly efficient, minimally invasive surgical instrument capable of overcoming the deficiencies discussed above. More particularly, in view of the ever-present need in the art for improvements in electrode design, it is an object of the present invention to provide a highly efficient and efficacious electrosurgical instrument suitable for the thermal treatment of tumors, more particularly a radiofrequency electrosurgical device adapted for enhanced lesion formation.

Electrosurgical instruments of the present invention may be designed to be inserted directly, to penetrate the patient tissue at the desired location, or alternatively to be introduced into the patient body through a cannula, a resectoscope, an endoscope or an opening in the body.

In certain embodiments, the electrosurgical instruments of the present invention may optionally be provided with means for externally supplying irrigation liquid, either electrically conductive or non-conductive, to the surgical site. In other embodiments, the electrosurgical instrument of the present invention may be designed to function in the absence of an external source of fluids, relying instead on the tissue properties or endogenous bodily fluids. As noted above, this mode of operation is sometimes referred to as "dry field".

In further embodiments, the electrosurgical instrument of the present invention may optionally be equipped with irrigation, aspiration or both, as well as oscillatory or imitational motion.

The electrosurgical instrument of the present invention may be either monopolar or bipolar electrodes and may optionally be equipped with one or more floating elements. "Floating" electrodes for electrosurgery are described in co-pending U.S. Patent Application Nos. 10/911,309 (published as US 2005-0065510) and 11/136,514 (published as US 2005-023446), the contents of which are incorporated by reference herein in their entirety.

In yet further embodiments, the electrosurgical instrument of the present invention may include an advanced active electrode designed to operate at high temperatures for improved efficiency.

In yet further embodiments, the electrosurgical instrument of the present invention may be provided with one or more high-powered sources of non-coherent radiation to affect tissue surfaces.

In yet further embodiments, the electrosurgical instrument of the present invention may be designed to operate without contact between the electrode and the tissue surface.

It will be understood by those skilled in the art that one or more aspects of this invention can meet certain objectives, while one or more other aspects can meet certain other objectives. Each objective may not apply equally, in all its respects, to every aspect of this invention. As such, the following objects should be viewed in the alternative with respect to any one aspect of this invention:

Thus, it is an object of the present invention to provide an electrosurgical instrument for thermal tissue treatment composed of:

(a) an elongate shaft having a proximal end configured for connection to a power source and a distal end having an electrode assembly mounted thereto;

(b) an electrode assembly comprising an active electrode, a floating electrode, and an insulator separating the active and floating electrodes and defining a cavity therebetween;

(c) a means for supplying an irrigant to the cavity;

wherein the insulator is formed from a nonconductive dielectric material while said active and floating electrodes are formed from an electrically conductive material;

wherein the active and floating electrodes are positioned in close proximity to each other;

wherein the active electrode is connected via cabling disposed within said shaft to said power source while the floating electrode is not connected to a power source such that powering of the active electrode results in flow of current from the active electrode to said floating electrode via the irrigant, thereby resulting in the heating of the irrigant and the generation of steam;

wherein the heated irrigant and steam contacts target tissue so as to thermally treat the target tissue of interest.

It is a further object of the present invention to provide an electrosurgical instrument for sub-surface thermal treatment of target tissue composed of:

(a) an elongate shaft having a proximal end configured for connection to a power source and a distal end having an electrode assembly mounted thereto;

(b) an electrode assembly including (i) an insulating tubular member, (ii) an active electrode disposed at the distal tip of the insulating tubular member and connected via cabling disposed within the shaft to said power source, and (iii) a tubular conductive member concentrically disposed about the insulating tubular member; and

(c) a switching means for alternately connecting and disconnecting the conductive member to a power source;

wherein the insulating tubular member is formed from a nonconductive dielectric material while the active electrode and said conductive member are formed from an electrically conductive material;

wherein the active and floating electrodes are positioned in close proximity to each other but are prevented by the insulator from directly contacting each other; and

wherein the active electrode takes the form of a tapered conical member that is sufficiently sharp to permit insertion of the electrode assembly into the target tissue.

It is yet a further object of the present invention to provide a method for thermally treating a target tissue in the body of a patient including the steps of:

(a) introducing an electrosurgical instrument the present invention into the patient such that the electrode assembly is in close contact with the target tissue;

(b) supplying an irrigant to the cavity defined between the active and floating electrodes; and

(c) applying a high-frequency voltage to the active electrode;

wherein the high frequency voltage results not only in the flow of current among active electrode, floating electrode and target tissue but further results in the boiling of irrigant, such that expanding steam and heated irrigant flow from the cavity to the target tissue site, thereby thermally treating the target tissue.

The present invention relates generally to the field of thermal tissue treatment, and more particularly, to high efficiency surgical instruments and methods which use radio frequency (RF) electrical power and/or electrically heated filaments to destroy tumors, form lesions, denaturize, desiccate, coagulate and ablate soft tissues, as well as to drill, cut, resect and vaporize soft tissues. According to the principles of this invention, the surgical instruments of the present invention can be used with externally supplied conductive or non-conductive liquids, as well as without externally supplied liquids, a mode of operation often referred to as "dry field" environment.

In one embodiment, the present invention provides a high efficiency electrosurgical instrument particularly suited to surface treatment of tissues, such a tumor tissues, the instrument including an active end having radiused corners and composed of a unique combination of active electrode, insulator, floating electrode and return electrode that limit sparking and tissue vaporization. Illustrative examples of this object are set forth in Figures 1-22.

In another embodiment, the present invention provides a high efficiency electrosurgical instrument wherein the active electrode and floating electrode interact to boil an exogenous irrigant therebetween such that lesion formation is accomplished primarily by steam and heated fluid which contact the tissue. Illustrative examples of this object are set forth in Figures 23-29.

In yet another embodiment, the present invention provides a high efficiency electrosurgical instrument particularly suited to sub-surface tissue treatment, the instrument including a switching means that allows a circumferential electrode to function as a floating electrode when drilling into the tissue, and subsequently as an active electrode to thermally treat tissue when in close proximity to a target site. Illustrative examples of this object are set forth in Figures 30-32.

In a further embodiment, the present invention provides a high efficiency electrosurgical instrument particularly suited to sub-surface tissue treatment, wherein the instrument uses heated irrigant and steam generated within the probe to thermally treat tissue in close proximity. In one embodiment, the heating occurs within the instrument tip, between an active tip electrode and a floating electrode in

contact with the tissue. Illustrative examples of this object are set forth in Figures 33-36.

In yet a further embodiment, the present invention provides a high efficiency electrosurgical instrument particularly suited to sub-surface tissue treatment, the instrument including an active electrode is inserted into the tissue and a return electrode positioned on the surface of the organ in close proximity to the active electrode so as to focus the current flow in the desired region. Illustrative examples of this object are set forth in Figures 37-38.

In yet a further embodiment, the present invention provides a high efficiency electrosurgical instrument particularly suited to thermal tissue treatment, the instrument composed of a monopolar probe with low-flow irrigation to prevent tissue charring. Illustrative examples of this object are set forth in Figures 39-41.

In yet a further embodiment, the present invention provides a high efficiency electrosurgical instrument particularly suited to thermal tissue treatment, wherein the instrument includes a heated filament to generate plasma channels between the filament and the surface. Illustrative examples of this object are set forth in Figures 42-60.

In yet a further embodiment, the present invention provides a minimally invasive instrument particularly suited to thermal tissue treatment, wherein the instrument includes a heated filament emitting electromagnetic radiation in the form of a non-coherent infra-red, ultraviolet and/or visible spectrum to achieve thermal surface treatment and lesion formation. Illustrative examples of this object are set forth in Figures 61-62.

These and other objects and features of the invention will become more fully apparent when the following detailed description is read in conjunction with the accompanying figures and/or examples. However, it is to be understood that both the foregoing summary of the invention and the following detailed description are of a preferred embodiment and not restrictive of the invention or other alternate embodiments of the invention. In particular, while the invention is described herein with reference to a number of specific embodiments, it will be appreciated that the description is illustrative of the invention and is not constructed as limiting of the invention. Various modifications and applications may occur to those who are

skilled in the art, without departing from the spirit and the scope of the invention, as described by the appended claims. Likewise, other objects, features, benefits and advantages of the present invention will be apparent from this summary and certain embodiments described below, and will be readily apparent to those skilled in the art having knowledge of electrode design. Such objects, features, benefits and advantages will be apparent from the above in conjunction with the accompanying examples, data, figures and all reasonable inferences to be drawn there-from, alone or with consideration of the references incorporated herein.

Brief description of the drawings

Various aspects and applications of the present invention will become apparent to the skilled artisan upon consideration of the brief description of the figures and the detailed description of the present invention and its preferred embodiments which follows:

Figure 1 is a plan view of an insulator for a lesion forming electrosurgical instrument formed in accordance with the principles of this invention.

Figure 2 is a side elevational view of the objects of Figure 1.

Figure 3 is a bottom side plan view of the objects of Figure 1.

Figure 4 is a perspective view of the objects of Figure 1.

Figure 5 is an axial sectional view of the objects of Figure 1 at location A – A of Figure 1.

Figure 6 is a side elevational sectional view of the objects of Figure 1 at location B – B of Figure 1.

Figure 7 is a plan view of an active electrode for a lesion forming electrosurgical instrument formed in accordance with the principles of this invention.

Figure 8 is a side elevational view of the objects of Figure 7.

Figure 9 is a perspective view of the objects of Figure 7.

Figure 10 is a distal axial view of the objects of Figure 7.

Figure 11 is a plan view of a floating electrode for a lesion forming electrosurgical instrument formed in accordance with the principles of this invention.

Figure 12 is a side elevational view of the objects of Figure 11.

Figure 13 is a bottom side plan view of the objects of Figure 11.

Figure 14 is a perspective view of the objects of Figure 11.

Figure 15 is an axial view of the objects of Figure 11.

Figure 16 is a plan view of a distal portion of a lesion forming electrosurgical instrument formed in accordance with the principles of this invention.

Figure 17 is a side elevational view of the objects of Figure 16.

Figure 18 is a bottom side plan view of the objects of Figure 16.

Figure 19 is a perspective view of the objects of Figure 16.

Figure 20 is an axial sectional view of the objects of Figure 16 at location C – C of Figure 17.

Figure 21 is a side elevational sectional view of the objects of Figure 16 at location D – D of Figure 16.

Figure 22 is an axial sectional view of the objects of Figure 16 during use showing current flow.

Figure 23 is a plan view of a distal portion of an alternate embodiment electrosurgical instrument adapted for thermal tissue treatment near a tissue surface.

Figure 24 is a side elevational view of the objects of Figure 23.

Figure 25 is a bottom side plan view of the objects of Figure 23.

Figure 26 is a side elevational sectional view of the objects of Figure 23 at location B – B of Figure 23.

Figure 27 is an axial sectional view of the objects of Figure 23 at location E – E of Figure 24.

Figure 28 is an axial sectional view of the objects of Figure 23 in use in a dry field environment.

Figure 29 is an axial sectional view of the objects of Figure 23 in use in a conductive fluid environment.

Figure 30 is a perspective view of a distal portion of an alternate embodiment RF electrosurgical instrument adapted for thermal tissue treatment from a location remote from the tissue surface (e.g., sub-surface).

Figure 31 is a plan view of the objects of Figure 30.

Figure 32 is a side elevational sectional view of the objects of Figure 30 at location A – A of Figure 31.

Figure 33 is a perspective view of a distal portion of an alternate embodiment RF electrosurgical instrument adapted for thermal tissue treatment from a location remote from the tissue surface (e.g., sub-surface).

Figure 34 is a plan view of the objects of Figure 33.

Figure 35 is a side elevational sectional view of the objects of Figure 34 at location A – A of Figure 34.

Figure 36 is a sectional view of the objects of Figure 33 during use.

Figure 37 is a side elevational view of the distal portion of an alternate embodiment.

Figure 38 is a side elevational view of the distal portion of an alternate embodiment.

Figure 39 is a perspective view of the distal portion of an alternate embodiment.

Figure 40 is a plan view of the objects of Figure 38.

Figure 41 is a side elevational sectional view of the objects of Figure 38 at location A – A of Figure 39 during use.

Figure 42 is a perspective view of an alternate embodiment probe.

Figure 43 is a plan view of the objects of Figure 42.

Figure 44 is a side elevational view of the objects of Figure 42.

Figure 45 is an expanded view of the distal portion of the instrument of Figure 42.

Figure 46 is a side elevational sectional view of the objects of Figure 44 at location A – A of Figure 45.

Figure 47 is a side elevational sectional view of the objects of Figure 44 at location B – B of Figure 45.

Figure 48 is an axial sectional view of the objects of Figure 44 at location C – C of Figure 45.

Figure 49 is a perspective view of the objects of Figure 45.

Figure 50 is a side elevational sectional view of the distal portion of the instrument of Figures 42 in use.

Figure 51 is a schematic representation of the probe of Figure 42 in use.

Figure 52(a) is a schematic representation of the distal end portion of the instrument of Figure 42. Figure 52(b) is an axial sectional view of the objects of Figure 51(a) at location A – A of Figure 51(a). Figure 52(c) is an axial sectional view of an alternate embodiment at location A – A of Figure 51(a).

Figure 53 is a schematic representation of a distal portion of an alternate embodiment having a coil filament.

Figure 54 is a schematic representation of a distal portion of an alternate embodiment having a filament integral with the conductive members.

Figure 55 is a schematic representation of a distal portion of an alternate embodiment which uses micro-sparking between the conductive members rather than a filament.

Figure 56 is a schematic representation of a distal portion of an alternate embodiment which uses a UV lamp as a heat source.

Figure 57 is a schematic representation of a distal portion of an alternate embodiment which has no filament for micro-sparking.

Figure 58 is a schematic representation of a distal portion of an alternate embodiment which uses dielectric breakdown to produce micro-sparking.

Figure 59 is a schematic representation of a distal portion of an alternate embodiment which does not use an external power source for micro-sparking or heating a filament.

Figure 60(a) is a schematic representation of a distal portion of an alternate embodiment which is configured for gas flow outward from the instrument tip. Figure 60(b) is a schematic representation of a distal portion of an alternate embodiment which is configured for gas flow inward from the instrument tip.

Figure 61 is a schematic representation of an alternate embodiment for treating a cavity in a body using a miniature electromagnetic energy source.

Figure 62 is a schematic representation of an alternate embodiment for treating a surface using a miniature electromagnetic energy source.

Description of the Preferred Embodiments

This present invention constitutes a marked improvement in the field of electrosurgery, more particularly, to high efficiency electrosurgical surgical instruments and methods which use radio frequency (RF) electrical power and/or electrically heated filaments to destroy tumors, form lesions, denaturize, desiccate, coagulate and ablate soft tissues, as well as to drill, cut, resect and vaporize soft tissues.

Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the present invention, the preferred methods, devices, and materials are now described. However, before the present materials and methods are described, it is to be understood that this invention is not limited to the particular compositions, methodologies or protocols herein described, as these may vary in accordance with routine experimentation and optimization. It is also to be understood that the terminology used in the description is for the purpose of describing the particular versions or embodiments only, and is not intended to limit the scope of the present invention which will be limited only by the appended claims.

Elements of the Present Invention:

In the context of the present invention, the following definitions apply:

The words "a", "an", and "the" as used herein mean "at least one" unless otherwise specifically indicated.

In common terminology and as used herein, the term “electrode” may refer to one or more components of an electrosurgical device (such as an active electrode or a return electrode) or to the entire device, as in an “ablator electrode” or “cutting electrode”. Such electrosurgical devices are often interchangeably referred to herein as electrosurgical “probes” or “instruments”.

The present invention makes reference to an “active electrode” or “active element”. As used herein, the term “active electrode” refers to one or more conductive elements formed from any suitable metallic material, such as stainless

steel, nickel, titanium, tungsten, and the like, connected, for example via cabling disposed within the elongated proximal portion of the instrument, to a power supply, for example, an externally disposed electrosurgical generator, and capable of generating an electric field.

The present invention makes reference to a "floating electrode" or "floating element". As used herein, the term "floating electrode" refers to one or more conductive elements formed from any suitable metallic material, such as stainless steel, nickel, titanium, tungsten, and the like, that, while disconnected from any power supply, is nevertheless but capable of intensifying the electric field in proximity to the active electrode and aid in bubble retention when the instrument is used to vaporize tissue.

The present invention makes reference to a "filament'. As used herein, the term filament refers to one or more electrically powered conductive elements resistively heated to high temperatures.

The present invention makes reference to a "return electrode". As used herein, the term "return electrode" refers to one or more powered conductive elements formed from any suitable metallic material, such as stainless steel, nickel, titanium, tungsten, and the like, to which current flows after passing from the active electrode(s)and through the plasma field.

The term "proximal" refers to that end or portion which is situated closest to the user; in other words, the proximal end of an electrosurgical instrument of the instant invention will typically include the handle portion.

The term "distal" refers to that end or portion situated farthest away from the user; in other words, the distal end of an electrosurgical instrument of the instant invention will typically include the active electrode portion.

The present invention makes reference to the thermal treatment of tissue, more preferably soft tissue, even more preferably tumor tissue. As used herein, the term "tissue" refers to biological tissues, generally defined as a collection of interconnected cells that perform a similar function within an organism. Four basic types of tissue are found in the bodies of all animals, including the human body and lower multicellular organisms such as insects, including epithelium, connective tissue, muscle tissue, and nervous tissue. These tissues make up all the organs,

structures and other body contents. The present invention is not limited in terms of the tissue to be treated but rather has broad application to the thermal treatment of any target tissue with particular applicability to the ablation, removal and/or destruction of benign and cancerous tumors.

The instant invention has both human medical and veterinary applications. Accordingly, the terms "subject" and "patient" are used interchangeably herein to refer to the person or animal being treated or examined. Exemplary animals include house pets, farm animals, and zoo animals. In a preferred embodiment, the subject is a mammal.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. In case of conflict, the present specification, including definitions, will control.

Utilities of the Present Invention:

As noted above, the present invention is directed to high efficiency monopolar or bipolar electrosurgical instruments and methods which utilize radio frequency (RF) energy, electrically energized filaments, and/or non-coherent radiation emitted by heated filaments to destroy tumors, form lesions, denaturize, desiccate, coagulate and ablate soft tissues, as well as to drill, cut, resect and vaporize soft tissues, with or without externally supplied liquids, having particular utility in the context of oncology, ear nose and throat (ENT), urology, gynecology, and laparoscopy, as well as general surgery.

Certain embodiments of the electrosurgical instrument of the present invention find particular utility in the treatment of tissue surfaces. Others are configured for sub-surface tissue treatment. Similarly, while some embodiments utilize the endogenous fluid of a "wet field" environment to transmit current to target sites, others require an exogenous irrigant. In certain embodiments, the irrigant is heated to the boiling point, whereby thermal tissue treatment arises through direct contact with either the boiling liquid itself or steam associated therewith.

As described in further detail below, in one aspect, the present invention expands on the floating electrode concept. For example, the present invention relates to the design and deployment of novel "floating electrode" electrosurgical instruments that use steam/ hot fluid to thermally treat target tissue, both at the surface and below the surface.

A further aspect of the present invention involves the construction and use of hybrid monopolar/bipolar electrosurgical instruments that combine features of monopolar and bipolar instruments to concentrate the energy in the desired region of the tissue to be treated. More particularly, the present invention relates to the discovery of a new type of electrosurgical device, a hybrid between monopolar and bipolar instruments, that results in a novel electrosurgical therapeutic approach for the thermal treatment of tissue. Unlike a bipolar instrument, wherein the return electrode is mounted on the same shaft as the active electrode, according to the principles of this invention, the return electrode is not mounted on the same shaft. Unlike monopolar instruments, wherein the return electrode is mounted on the patient body far away from the surgical site, according to the principles of this invention, the return electrode may be mounted on the patient body close to the surgical site.

Such devices, according to the principles of the present invention, constitute hybrid instruments in the sense that the return electrode size, shape and location is playing a critically important, and beneficial role in distributing and focusing the RF current in the desired area. For illustration purposes of this concept, consider a case of treating a breast tumor. The return electrode may be externally attached to the skin of the patient breast being treated, and the instrument itself is inserted into the breast tissue/tumor, in close proximity to the return electrode. When energized, the RF energy is concentrated in the desired tissue/tumor region depending on the medical needs. More specifically, a specially designed return electrode (size, shape and position) and a specially designed active electrode(s) are used to optimize the energy distribution in the tissue over the desired area.

Usually the return (ground) electrode plays a "passive" role in electrosurgery in the sense that it does not effect the electrical energy distribution in the vicinity of the "active" electrode – the area where the tissue is being treated. This is a

consequence of the return electrode being positioned too far away from the area being treated. In contrast, if the main active electrode is in close proximity of the surface of the body (skin), then positioning of a specially designed return electrode on the skin near area being treated can substantially and favorably effect the electrical energy distribution in the tissue. Moreover, the shape and position of return electrode can be changed during procedure for the purpose of optimizing the clinical effects. The devices may be used in conjunction with various fluids, bodily fluids or dry fields. This unexpected discovery provides a new modality, or a new method of electrosurgical therapeutic approach for the thermal treatment of tissue.

In a further aspect, the present invention relates to electrosurgical instruments that use hot filaments to generate plasma which may then be used to deliver energy for the thermal treatment of tissue. More particularly, the present invention relates to the discovery of a new type of plasma-based electrosurgical device that utilizes a hot filament (300-900^{0}C) to enhance plasma generation efficiency, ionization, arcing/sparking and effectiveness. In prior art plasma-based electrosurgical devices, like the argon beam coagulators mentioned above, a sufficiently high electrical voltage must be applied to the electrode, the voltage exceeding the breakdown threshold (electrical strength) of the gaseous gap, at which point an electrical breakdown (ionization) takes place forming plasma channels between the electrode and the tissue. The present invention utilizes a much more efficient approach to achieve gas ionization (plasma formation). In particular, the present invention uses schemes to substantially and permanently reduce the electrical breakdown threshold of the gaseous media between the electrode and the surface of the tissue. In this manner, the plasma can be generated efficiently at lower voltages (0.5-3kV) than otherwise possible. According to the principles of this invention, this can be achieved, for example, by using a hot filament (electrode) to substantially reduce the electrical breakdown threshold of the gaseous gap between the electrode and the surface of the tissue. This result arises from the substantial enhancement of the probability of electron emission from the heated filament. The filament also enhances the intensity of the RF field in its vicinity, making it easier to maintain the plasma discharge. The heated filament also heats at

least part of the discharge volume up to a high temperature and also seeds the discharge channel with ionized particles making it easier to support the discharge.

The instruments according to the principles of this invention may operate without gas flow, with a gas flow and with a reversed gas flow (gas suction). The instruments can operate in various fluids like liquid, gas or air or a combination of all the above at various pressures, including atmospheric pressure. The instruments according to the principles of this invention may operate in electrically conductive, such as saline, or non conductive fluids. Various embodiments are illustrated, as examples, in Figs 42 to 60, the details of which are discussed in further detail below. In all embodiments, a portion of the tissue surface can be coated with a thin layer of material with low potential of ionization. This material can be continuously evaporated to seed the discharge channel with neutral particles having low potential of ionization, again lowering the threshold for generating and maintaining the plasma channel. In this manner, the present invention provides a novel electrosurgical therapeutic approach for the thermal treatment of tissue, an approach that may be used in conjunction with various irrigants, fluids, and bodily fluids or, alternatively, in a dry environment.

In yet a further aspect, the present invention relates to the delivery of energy generated by an electrically heated filament to thermally treat target tissue. More particularly, the present invention relates to the discovery of a new type of minimally invasive instrument, based on miniature, intense sources of electromagnetic radiation in the form of non-coherent infra-red, visible and/or ultraviolet generated by an electrically heated filament mounted inside a disposable instrument. The instruments based on the principles of this invention can treat either large or small tissue areas, depending on the designs.

Specifically, in order to create a lesion close to an outer or an inner surface of tissue, the tissue has to be heated. The heating takes place if the tissue surface absorbs energy. The energy according to the principles of this invention is a non-coherent electromagnetic energy, such as infrared (IR), visible (V) and ultraviolet (UV) radiation, radiated by a filament heated to temperatures of approximately 500-2200^{0}C. This radiation is absorbed by the surface of the tissue, heats the surface and adjacent layer of the tissue creating layer of surface lesion. The surface temperature

rises as a function of time, tissue properties, area of absorption, radiation power, and distance between the filament and the tissue. By controlling the power of the source and distance to the surface of tissue, one can control the temperature of the layer of the tissue as well as the thickness of the lesion layer. Illustrative embodiments of such a device, using the above principles, are described in further detail below. In all embodiments, the source of radiation is an electrically heated open or encapsulated filament, heated to temperatures of approximately 500-2200 ^{0}C, producing non-coherent IR, visible and UV radiation of enough power. The media between source and surface can be gaseous or liquid (conductive or non conductive), bodily fluids, solid or combination of above. Gas ventilation and liquid circulation, aspiration and irrigation may be used for cooling and/or removing byproducts and/or debris.

As an example, two embodiments are illustrated in Figs 61 & 62, discussed in greater detail below. The embodiment shown in Fig 61 includes an inflated transparent flexible bag with the heated filament source of non-coherent radiation inside, and also gas ventilation/circulation for cooling. The embodiment shown in Fig 62 includes a directed movable energy source configured like a headlight (projector), with or without ventilation. However, many other embodiments may utilize the same principles of this invention. For example: (a) elongated miniature linear versions (b), encapsulated or non-encapsulated heated filament for insertion directly into tissue; (c) Filament/heater coated with an insulator; (d) an external filament/energy source coupled via a fiber optic to bring the energy into the desired area to be treated; (e) same of the above with channels in insulators for additional driving of RF current, monopolar and/or bipolar; (f) various geometries of the above instrument, like cylindrical, linear, spherical, curvilinear, polygonal and or combinations of the above; (g) embodiments can include a flexible bag with controlled transparency and gas ventilation for cooling; (h) miniature versions and combinations of the above. Thus, the present invention provides a new therapeutic approach for thermal tissue treatment, a method that may be used in conjunction with various fluids, bodily fluids or dry fields.

The tissue treatment instruments of the present invention may be used in conjunction with existing diagnostic and imaging technologies, for example imaging systems including, but not limited to, MRI, CT, PET, x-ray, fluoroscopic, and

ultrasound. Such imaging technology may be used to monitor the introduction and operation of the instruments of the present invention. For example, existing imaging systems may be used to determine location of target tissue, to confirm accuracy of instrument positioning, to assess the degree of thermal tissue treatment (e.g., sufficiency of tissue removal), to determine if subsequent procedures are required, and to assist in the atraumatic removal of the instrument.

As noted above, the instruments of the present invention find utility in thermal tissue treatment, more particularly in thermal treatment of tumor tissue, both benign and cancerous, to destroy tumors, form lesions, denaturize, desiccate, coagulate and/or ablate tumor tissues, as well as to drill, cut, resect and vaporize tumor tissues, with or without externally supplied liquids. Though the present invention is not particularly limited to the treatment of any one specific disease or the removal of any one specific type of tumor, the instruments of the present invention nevertheless find particular utility in the treatment and removal of liver, breast, bladder and spinal tumors, uterine fibroids, ovarian cysts, and colon polyps as well as the treatment of noncancerous conditions such as endometriosis.

Illustrative Embodiments of the Present Invention:

Hereinafter, the present invention is described in more detail by reference to the exemplary embodiments. However, the following examples only illustrate aspects of the invention and in no way are intended to limit the scope of the present invention. As such, embodiments similar or equivalent to those described herein can be used in the practice or testing of the present invention.

Referring to Figures 1 through 6, which depict an insulator of an electrosurgical instrument of the present invention that is particularly suited to thermally treating patient tissue, insulator **20** has a distal end portion **22**, a proximal end portion **24** and mid-portions **26**. Distal end portion **22** has formed in its proximal face cylindrical recesses **28**. Proximal end portion **24** has axial cylindrical openings **30** axially aligned with recesses **28**. Mid-portions **26** have formed in lower surface **32** channels **34**. Insulator **20** is made from a suitable dielectric material, examples of which include, but are not limited to, alumina, zirconia, and high-temperature polymers.

Referring to Figures 7 through 10, which depict an active electrode of an electrosurgical instrument of the present invention that is particularly suited to thermally treating patient tissue, active electrode **40** has a distal portion forming parallel cylindrical portions **42** connected by flange **44** to proximal conductor **46**. Electrode **40** may be formed from any suitable metallic material, examples of which include, but are not limited to, stainless steel, nickel, titanium, tungsten, and the like.

Figures 11 through 15 depict a floating electrode for an electrosurgical instrument of the present invention that is particularly suited to thermally treating patient tissue. As shown herein, the floating electrode **50** forms adjacent channels having a common flange **52**, and lateral flanges **54** and wall **56**. Flanges **52** and **54** have ends **58** formed to a radius. However, the present invention is not limited to the depicted design and includes alternate floating electrode embodiments, such as those described in co-pending U.S. Patent Application Nos. 10/911,309 (published as US 2005-0065510) and 11/136,514 (published as US 2005-023446) cited above, the contents of which are incorporated by reference herein in their entirety. Referring now to Figures 16 to 21, which depict a distal portion of an electrosurgical instrument of the present invention formed from the components of Figures 1 through 15, the distal portion of probe **60** is an assembly in which distal portions **42** of active electrode **40** are positioned within channel portions **34** of insulator **30**. Floating electrode **50** is positioned between distal portion **22** and proximal portion **24** of insulator **20**. Dielectric coating **62** covers flange **44** and conductor **46** of active electrode **40**. Conductor **40** is connected by means within the probe **60** and electrical cable to a suitable electrosurgical generator.

Figure 22 depicts probe **60** in use, fully or partially submerged in irrigant (either endogenous to site or exogenously supplied). Flanges **52** and **54** of floating electrode **50** contact the tissue. Distal portions **42** of active electrode **40** may contact the tissue, or may contact the fluid in a gap between the electrode **40** and the tissue. Fluid surrounding the distal end of probe **60** is conductive. It may be supplied to the site as a conductive liquid such as standard saline, or may be supplied to the site as a non-conductive irrigant such as water, the fluid becoming conductive by contamination by body fluids such as blood, or by ablation by-products.

During use, current (indicated by arrows) flows from active electrode **40** to a return electrode (not shown), either at a remote site or mounted on the instrument **60**. Current flows from distal portions **42** of active electrode **40** through tissue in contact with or in close proximity to portions **42**. Some current flows through the tissue to the return electrode. A portion of the current flows through the tissue to radiused portions **58** of flanges **52** and **54** of floating electrode **50** in contact with the tissue to portions of floating electrode **50** in lower potential portions of the electric field. This current then flows from floating electrode **50** to conductive fluid in contact therewith, and then through the fluid to the return electrode. The efficiency of probe **60** for thermally treating tissue is enhanced by the elimination of regions of high current density. Such regions of high current density cause boiling of irrigant in close proximity, and arcing through the steam bubbles formed so as to vaporize tissue. The absence of these regions allows the device to be used at higher power levels for more rapid tissue treatment without creating these undesirable vaporizing sparks. Specifically, portions of flanges **52** and **54** which contact tissue are radiused so as to eliminate sharp corners which create regions of high current density. In addition, portions **42** of active electrode **40** are also rounded to eliminate sharp edges which create regions of high current density.

Figures 23 through 27 depict the distal portion of another thermal treatment electrosurgical instrument of the present invention. Probe **70** has a planar active electrode **72** suspended by distal dielectric end piece **74** and proximal dielectric end piece **76** in an inverted channel formed by floating electrode **78**. Lateral edges **80** of active electrode **72**, and edges **82** of floating electrode **78** are radiused. Lower surface **86** of active electrode **72** is recessed distance **88** from the plane of edges **82** of floating electrode **78**. Conductor means **90** within probe **70** and cabling connect active electrode **72** to a suitable electrosurgical generator. Tubular member **92** is connected by means within probe **70** to an external conductive irrigant source.

Although the active electrode assembly is depicted as a having a square/rectangular profile and/or cross-section, the invention is not limited to the depicted configuration. So long as a particular configuration provides the requisite confined space, more particularly the presence of a fluid-fillable cavity defined between the active and floating electrodes, other geometries may be contemplated

including, but not limited to, electrode assemblies having rounded, circular, elliptical, and polygonal profiles.

Referring now to Figure 28, which depicts probe **70** in use in a "dry field", conductive irrigant **96** may be supplied by tubular member **92** to the interior of the distal portion of probe **70,** between the upper surface of active electrode **72** and the interior surface of floating electrode **78**. Current (indicated by arrows) flows from active electrode **72** to a return electrode, either remotely located or on probe **70**. A portion of the current flows through conductive liquid surrounding active electrode **72** to floating electrode **78** and therethrough to tissue in contact with or close proximity to edges **82**. Current flowing from the floating electrode **78** to the tissue in this manner is conducted through direct contact or through conductive fluid in close proximity. A second portion of the current flows from the active electrode **72** to the tissue through conductive fluid between active electrode **72** and the tissue. Current flowing through conductive irrigant **96** heats irrigant **96** primarily in the regions in which active electrode **72** and floating electrode **78** are in close proximity. If the current flow is sufficiently high related to the flow rate of conductive irrigant **96**, boiling of irrigant **96** occurs. Expanding steam and irrigant flow from tubular member **92** causes heated liquid and steam to flow into the region between active electrode **72** and the tissue. Thermal treatment of the tissue is accomplished through contact with heated liquid and steam, and through flow of current. The relative proportion of the two depends on the power supplied and the flow rate of conductive irrigant **96**.

Figure 29 depicts probe **70** in use in a conductive liquid environment. Conductive irrigant **96** is supplied by tubular member **92** to the interior of the distal portion of probe **70**, between the upper surface of active electrode **72** and the interior surface of floating electrode **78**. Current flows from active electrode **72** to a return electrode, either remotely located or on probe **70**. A portion of the current flows through conductive liquid surrounding active electrode **72** to floating electrode **78** and therethrough to conductive liquid in contact with the exterior surfaces of floating electrode **78**. A second portion of the current flows from the active electrode **72** to the tissue through conductive fluid between active electrode **72** and the tissue. Current flowing through conductive irrigant **96** heats irrigant **96**

primarily in the regions in which active electrode **72** and floating electrode **78** are in close proximity. If the current flow is sufficiently high related to the flow rate of conductive irrigant **96**, boiling of irrigant **96** occurs. Expanding steam and irrigant flow from tubular member **92** causes heated liquid and steam to flow into the region between active electrode **72** and the target tissue. Thermal treatment of the tissue is accomplished through contact with heated liquid and steam, and through flow of current. The relative proportion of the two depends on the power supplied and the flow rate of conductive irrigant **96**. As with the instrument **60** previously herein described, probe **70** is designed to minimize or eliminate regions of high current density which cause arcing and tissue vaporization. Particularly, edges **82** of floating electrode **78** which contact target tissue are rounded to eliminate regions of high current density and arcing which may result therefrom. Also, lateral edges **80** of active electrode **72** are radiused to prevent arcing between active electrode **72** and the tissue or between electrode **72** and floating electrode **78**. Lower surface **86** of active electrode **72** does not have features such as grooves, protuberances, recesses which increase current density, but is smooth. These features, individually and/or in combination, allow probe **70** to be used at higher power levels for more rapid tissue treatment without arcing and the resulting undesirable tissue vaporization.

Figures 30 through 32 depict the distal portion of an electrosurgical instrument of the present invention that is particularly suited to the thermal treatment of tissue, more particularly sub-surface tissue treatment. While the previous embodiments are designed for surface treatment, electrosurgical instrument **100** thermally treats tissue into which it is inserted. Probe **100** is formed from a dielectric tube **102** having a sharpened, tapered or conical distal end **104** that facilitates atraumatic insertion into the target tissue. To distal end **104** is mounted active electrode **106** connected by conductor **108** insulated by dielectric coating **109** and means within probe **100** and cabling to a suitable electrosurgical generator. Tubular conductive member **110** is assembled to dielectric tube **102** near its distal end, and connected by conductor **112** insulated with dielectric coating **114** to a control element in the handle portion of probe **100**. The control element has a first position in which conductor **112** is not connected to the electrosurgical generator, and a second position in which the conductor **112** is connected to the generator

output such that when the generator is activated RF voltage is applied to member **110**.

During use, probe **100**, while energized, is first inserted into the tissue, tubular member **110** functioning as a floating electrode, the switching means being in its first position. When probe **100** is inserted to the desired depth, switching means is put in its second position and RF energy is supplied to conductive member **110** so as to treat tissue in close proximity.

Figures 33 through 35 depict another embodiment of an electrosurgical instrument of the present invention that is particularly suited to thermal treatment of tissue into which it is inserted. Probe **120**, the distal portion of which is shown has a first conductive tubular member **122** having a distal end **124** in which is mounted dielectric member **126**. Member **122** has a plurality of ports or perforations **128**. Second tubular member **130** is coaxially positioned within member **122**, and has a distal end **132** positioned within a recess in dielectric member **126**. Second tubular member **130** with lumen **133** has a plurality of perforations **134**. Proximal end **136** of member **122** is mounted to tubular member **138**, the distal end of first tubular member **138** and proximal portion of member **122** are covered by dielectric coating **140**. Second tubular member **130** is connected by means within probe **120** and cabling to a suitable electrosurgical generator. Region **142** is defined by the interior surface of first tubular member **122** and the exterior surface of second tubular member **130**. Second tubular member **130** is connected by means within probe **120** and tubing to an external source for conductive irrigant.

Referring now to Figure 36 depicting a portion of probe **120** during use, probe **120** is inserted into tissue to be thermally treated. Conductive irrigant **150** is supplied to lumen **133** of second tubular member **130**. Lumen **133**, perforations **134**, region **142**, and perforations **128** together form a flow path for irrigant **150** from lumen **133** of second tubular member **130** to region **144** between the external surface of probe **120** and the tissue into which it is inserted. Current flows from second tubular member **132** which acts as an active electrode, through conductive irrigant **150** to first tubular member **122**, and therethrough to adjacent tissue via conductive irrigant in the gap between probe **120** and the tissue, and finally to a return electrode (not shown), either remotely located or on probe **120**. First tubular

member **122** is not connected to the electrosurgical unit, but has a floating potential between that of the active electrode (second tubular member **130**) and the tissue. Current flowing through irrigant **150** in region **142** heats the irrigant causing it to boil. Irrigant **150** flowing from region **142** through perforations **128** is a two-phase mixture of steam and liquid which heats tissue with which it is in contact.. The relative portions of steam and liquid are determined by the flow rate of irrigant **150**, and by the applied power level. Decreasing the power or increasing the flow rate will cause the liquid phase to increase. Tissue thermally treated by probe **120** is heated by the irrigant and by resistive heating caused by current flow. The RF energy supplied to probe **120** has characteristics selected to minimize arcing within bubbles in the irrigant, and between member **122** and adjacent tissue.

Figure 37 is an illustrative example of the above-described hybrid electrosurgical instrument of the present invention. In particular, the instrument of Figure 37 includes an active electrode **400** which is embedded in the tumor **406** and a return electrode **402** on the instrument which contacts a free surface of the tissue near the tumor so as to concentrate the current flow **404** between the active and return electrodes, through the tumor.

An alternate embodiment of the above-described hybrid electrosurgical instrument of the present invention is depicted in Figure 38. The instrument of Figure 38 includes an active electrode **410** which is embedded in the tumor **416** and a return electrode **412** not on the instrument which contacts a free surface of the tissue near the tumor so as to concentrate the current flow **414** between the active **410** and return electrodes **412** , through the tumor.

Figures 39 through 41 depict the distal portion **500** of an alternate embodiment designed to be embedded in a tumor **512** to go undergo treatment, the probe having a tubular active electrode **502** covered by dielectric coating **508** except for uninsulated portion **510** with perforations **504** such that irrigant **506** supplied to the active electrode flows from the electrode through perforations **504** so as to prevent desiccation and burning of tissue in contact with the electrode. In an alternate embodiment also designed to be embedded in a tumor to go undergo treatment, the probe distal portion construction is identical to that of distal portion **500**, with the exception that uninsulated portion **510** of active electrode **502** is

formed from a porous metallic material and perforations **504** are eliminated. Irrigant supplied to the active electrode flows from the electrode **502** through the porous material so as to prevent desiccation and burning of tissue in contact with the electrode. In yet another embodiment, perforations **504** are eliminated, and irrigant is supplied to the site by an annular passage between active electrode **502** and dielectric coating **508**. As with the previous embodiments, irrigant so supplied prevents desiccation and burning of tissue in contact with the electrode.

Most widely used electro surgical electrodes – ablators, coagulators, evaporators, cutters, electrodes for lesion forming and electrodes for treatment of tumors (often referred to as tumor ablation) need to be very close to or in direct contact with the tissue being treated in order to be effective. Electrosurgical instruments like the Argon Beam Coagulator (Conmed Corporation, Utica, NY) and other similar devices operate without direct contact with the tissue. These instruments employ a gaseous gap between the instrument's electrode and the tissue. The electrode is insulated, and high voltage is applied to the gaseous gap between electrode and the surface of the tissue. If sufficiently high voltage is applied to the electrode, the electric field exceeds the breakdown threshold (electrical strength) of the gaseous gap, and electrical breakdown takes place forming a plasma channel between the electrode and the tissue. This electrically conductive plasma channel acts as a non-contact extension of the electrode, allowing treatment at a "stand-off" distance. Instruments based on this scheme, sometimes referred to as plasma torches, generally require very high voltages (up to 10– 20 kV), which are beyond the capability of standard, general purpose, commonly available electrosurgical radio-frequency (RF) generators. In addition, plasma torches require specially shaped electrodes, a flow of gas (usually a noble gas jet), a specially designed nozzle to control the gas flow, and high voltage circuitry to bring high voltage to the proximity of the surgical field.

Advanced, non-contact, plasma-based electrosurgical instruments constructed in accordance with the principles of this invention may be operated in the plasma torch regime yet are compatible with "standard" electrosurgical RF generators. The electrosurgical instruments of the present invention (which may be single-use disposables) can operate without a gas flow, with a gas flow and with a

reversed gas flow (gas suction). The electrosurgical instruments of the present invention substantially and permanently reduce the electrical breakdown threshold of the gaseous gap between the electrode and the surface of the tissue. In addition, the plasma can be generated efficiently at low voltages (0.5-2kV), thereby allowing for the use of general purpose, standard electrosurgical RF generators. Among the factors employed to achieve this goal are increasing the probability of electron emission from electrode; heating at least part of the discharge volume; seeding the discharge channel with ionized particles; filling the discharge channel with gas having a low rate of attraction of electrons; and seeding the discharge channel with neutral particles with low potential of ionization.

Referring now to Figures 42 through 44 which depict an embodiment of an electrosurgical instrument of the present invention that utilizes a hot filament to generate plasma channel particularly suited to the thermal treatment of surfaces, probe **200** has a proximal portion **202** forming a handle having a proximal end **204** from which passes electrical cable **206** which is connected to a suitable electrosurgical generator, and a distal end **208** from which protrudes elongated instrument distal portion **210**. Portion **210** has a proximal end **212** mounted to handle portion **202**, and a distal end **220**. Activation button **216** controls the electrosurgical generator to which probe **200** is connected by cable **206**. Handle portion **202** contains batteries **218**.

Referring now to Figures 45 through 49 depicting the active distal end of **220** of distal portion **210** of probe **200**, elongated tubular member **222** with lumen **223** has mounted to its distal end closed-end tubular member **224** to which is mounted insulator **226**. Insulator **226** has a first recess **228** formed coaxial with insulator **226**, recess **228** having a planar surface **230**. Surface **230** has formed therein second recess **232**. Insulator **226** has formed therein passages **234** between second recess **232** and surface **234** of insulator **226**. Filament wire **236** is connected by tubular members **238** to wires **240** in lumen **223** of tubular member **222**, wires **240** being connected by circuitry within handle portion **202** to batteries **218**, and by cable **206** to the electrosurgical generator such that depressing activation button **216** causes batteries **218** to supply the battery voltage to filament **236**, and the electrosurgical generator to supply RF voltage to filament **236**. Insulation **242** covers wires **240**.

Insulation **244** covers the proximal portion of tubular members **238** , and the distal portion of wires **240**.

Figure 50 depicts probe **200** in use thermally treating a tissue surface. Direct current power supplied by batteries **218** heats filament wire **236** which also heats air and other gasses in proximity to filament wire **236**. RF power from the electrosurgical generator is also applied to filament wire **236**. The high temperature of filament **236** increases the ease with which electrons may be ejected from filament **236**. Heating of the air and other gases in proximity to filament **236** decreases the resistance of the air and gases to electrical breakdown. These two effects together allow the formation of plasma channels through the air and gases in the gap between filament wire **236** and tissue in close proximity. Power transmitted through these channels interacts with the surface of the tissue thermally treating the tissue and desiccating tissue near the surface. Movement **250** of probe **200** relative to the tissue creates a linear region of treatment, depth **252** of the thermal effect being determined by the applied power and the rate of movement **250**.

Referring now to Figure 51 depicting a schematic representation of probe **200** in use, electrosurgical generator **260** is connected by wire **262** to return electrode pad **264**, and by wire **265** to first wire **241** of wires **240** connected to batteries **218** and filament **236** in distal end assembly **220**. Heating of filament **236** by power from batteries **218** and RF power from generator **260** together produce arcs **266** between filament **236** and tissue in close proximity. Desiccation by heat from arcs **266** creates local layer **268** of dry insulating tissue. Secondary arcing **270** may occur beneath layer **268**. Current **272** flows from the region near arcs **266** through the tissue to return electrode **264**.

Figure 52 schematically depicts distal end assembly **220** of probe **200**. Batteries **218** via wires **240** and conductive members **238** to filament **236**. Wire **265** conducts power from the RF generator to first wire **241** and therefrom via conductive member **238** to filament **236**. Power from batteries **218** heats the filament. Power from the RF generator causes arcing **266** and produces the desired clinical effect. Figures 52 (B) and (C) show that insulator **226** may have a variety of cross-sections. However, those shown are merely illustrative and not intended to limit the scope of the invention.

Figure 53 depicts an alternate embodiment of distal end assembly **220** of probe **200**. Filament **236** has a coil for enhanced heating of the region surrounding filament **236** for increased probe efficiency.

Figure 54 depicts an alternate embodiment of distal end assembly **220** of probe **200** in which filament **236** is integral with conductive members **238**, the filament portion being of a reduced cross-section.

Figure 55 depicts an alternate embodiment of distal end assembly **220** of probe **200** in which the filament has been deleted. Conductive members **238** have distal ends which are in sufficiently close proximity to produce micro-arcing **276** therebetween when voltage from power supply **218** is applied.

Figure 56 depicts an alternate embodiment of distal end assembly **220** of probe **200** in which heating at the distal region of the probe is accomplished by a UV lamp **278** connected to power supply **276**, rather than by a filament.

Figure 57 depicts an alternate embodiment of distal end assembly **220** of probe **200** in which the conductive member **238** has a sharpened distal end having a low included angle so that the distal portion is heated to an elevated temperature by arcs **266**. Heating of the distal portion is enhanced by insulator **226** which closely conforms to member **238** so as to prevent radiant or convective heat loss from member **238**.

Figure 58 depicts an alternate embodiment of distal end assembly **220** of probe **200** in which conductive member **238** has a sharpened distal end which is in contact with a portion of insulator **226** such that dielectric breakdown produces micro-sparking which heats the region causing arcs **266** to occur.

Figure 59 depicts an alternate embodiment of distal end assembly **220** of probe **200** in which conductive member **280**, connected via resistor **282** to wire **262** of the return electrode circuit, is positioned in close proximity to member **238** such that micro-arcing occurs between members **280** and **238**, the micro-arcing producing sufficient heat to allow arcing **266**. Resistor **282** limits current through member **280**.

As noted above, the embodiment depicted in Figure 60 corresponds to a new type of minimally invasive instrument, based on miniature, intense sources of infra-red, visible and ultra violet generated by an electrically heated filament mounted inside a disposable instrument. More particularly, Figure 60 depicts an alternate

embodiment of distal end assembly **220** of probe **200** configured for gas flow through the distal portion of probe **200**. In Figure 60(a) gas **292** supplied to nozzle **290** floods the area around filament **236** and arcs **266**. In Figure 60(b) air and gases **294** surrounding arcs **266** and filament **236** are evacuated through nozzle **290**.

As noted above, Figure 61 depicts an alternate embodiment **600** for treating a surface in a body cavity in which a source of electromagnetic energy, which, in this case is a miniature high-intensity infrared lamp **602** is positioned within a transparent inflatable bag **606**. The assembly is positioned within a body cavity to be thermally treated. Gas **604** is injected into the bag causing it to inflate and conform to the tissue surface. The IR lamp **602** is energized causing heating of the tissue in contact with the bag **604**. Gas flow into and out of the bag is maintained during treatment.

Figure 62 depicts an alternate embodiment for treating a surface using a probe having at its distal tip **700** a miniature infrared lamp **702**, a lens **704** and a reflector **706** for directing heat **708** from the lamp to the tissue surface. The profiles of reflector **706** and lens **704** together determine the energy distribution. In a preferred embodiment the profiles of reflector **706** and lens **704** together produce a uniform distribution across the distal opening of tip **700**. In other embodiments, the profiles can cooperate to form distributions such as a concentrated spot, line, annulus, or other predetermined desired profile.

Industrial Applicability:

The minimally invasive monopolar and bipolar electrosurgical instruments of the present invention find utility in the area of remote tissue ablation and lesion formation, to destroy tumors, form lesions, denaturize, desiccate, coagulate and ablate soft tissues, as well as to drill, cut, resect and vaporize soft tissues, with or without externally supplied conductive or non-conductive liquids (i.e., in the context of both wet and dry field electrosurgery). More particularly, the electrosurgical instruments of the present invention are designed to heat tissue from the outside in, to provide homogeneous energy deposition using less power, which in turn yields a highly homogeneous lesion.

In this manner, the electrosurgical instruments of the present invention allow one to effectively and efficiently control of the shape and size of the lesion formed, to thereby avoid unnecessary complications and undesired side effects. Such instruments are particularly useful in the context of oncological, ENT, urological, gynecological, and laparascopic procedures, as well as in the context of general surgery.

All patents and publications mentioned herein are incorporated by reference in their entirety. Nothing herein is to be construed as an admission that the invention is not entitled to antedate such disclosure by virtue of prior invention.

While the invention has been described in detail and with reference to specific embodiments thereof, it is to be understood that the foregoing description is exemplary and explanatory in nature and is intended to illustrate the invention and its preferred embodiments. Through routine experimentation, one skilled in the art will readily recognize that various changes and modifications can be made therein without departing from the spirit and scope of the invention.

Other advantages and features will become apparent from the claims filed hereafter, with the scope of such claims to be determined by their reasonable equivalents, as would be understood by those skilled in the art. Thus, the invention is intended to be defined not by the above description, but by the following claims and their equivalents.

What is claimed:

1. An electrosurgical instrument for thermal tissue treatment comprising:
    a. an elongate shaft having a proximal end configured for connection to a power source and a distal end having an electrode assembly mounted thereto;
    b. an electrode assembly comprising an active electrode, a floating electrode, and an insulator separating said active and floating electrodes and defining a cavity therebetween;
    c. a means for supplying an irrigant to said cavity;

    wherein said insulator is formed from a nonconductive dielectric material while said active and floating electrodes are formed from an electrically conductive material;

    wherein said active and floating electrodes are positioned in close proximity to each other;

    wherein said active electrode is connected via cabling disposed within said shaft to said power source while said floating electrode is not connected to a power source such that powering of said active electrode results in flow of current from said active electrode to said floating electrode via said irrigant, thereby resulting in the heating of said irrigant and the generation of steam;

    wherein said heated irrigant and steam contacts target tissue so as to thermally treat said tissue.
2. The electrosurgical instrument of claim 1, wherein said tissue comprises tumor tissue.
3. The electrosurgical instrument of claim 2, wherein said thermal treatment results in tumor destruction, lesion formation, or the denaturization, dessication, coagulation or ablation of tumor tissue.
4. The electrosurgical instrument of claim 1, further comprising a return electrode.
5. The electrosurgical instrument of claim 1, wherein said electrode assembly comprises an open structure, wherein:

said floating electrode, comprising a flat base having upper and lower flanges normal to said base, defines a top and two sides of said electrode assembly;

wherein said insulator comprises a pair of planar end pieces that define the remaining sides of said electrode assembly;

wherein said floating electrode and said insulator coordinate to define an inverted open channel in which said planar active electrode is suspended;

further wherein said means for supplying irrigant to the cavity defined by said active and floating electrodes includes a tubular member receiving port disposed in the middle of the flat base of said floating electrode.

6. The electrosurgical instrument of claim 1, wherein said active electrode and said floating electrode comprise concentric tubes that define an annular cavity therebetween, wherein said floating electrode comprises a single-lumened tube having a first set of perforations for delivering said irrigant to said cavity and said active electrode comprises a single-lumened tube having a second set of perforation for delivering said heated irrigant to said target tissue.

7. The electrosurgical instrument of claim 6, wherein said first and second set of perforations are offset.

8. The electrosurgical instrument of claim 6, wherein said insulator comprises a conical tip disposed at the distal end of said electrode assembly, said conical tip being sufficiently sharp to permit insertion of said electrode assembly into said target tissue.

9. An electrosurgical instrument for sub-surface thermal treatment of target tissue comprising:

   a. an elongate shaft having a proximal end configured for connection to a power source and a distal end having an electrode assembly mounted thereto;

   b. an electrode assembly comprising (i) an insulating tubular member, (ii) an active electrode disposed at the distal tip of said insulating tubular member and connected via cabling disposed within said shaft

to said power source, and (iii) a tubular conductive member concentrically disposed about said insulating tubular member; and

c. a switching means for alternately connecting and disconnecting said conductive member to a power source;

wherein said insulating tubular member is formed from a nonconductive dielectric material while said active electrode and said conductive member are formed from an electrically conductive material;

wherein said active and floating electrodes are positioned in close proximity to each other but are prevented by said insulator from directly contacting each other; and

wherein said active electrode comprises a tapered conical member that is sufficiently sharp to permit insertion of said electrode assembly into said target tissue.

10. A method for thermally treating a target tissue in the body of a patient comprising the step of:

a. introducing the electrosurgical instrument of claim 1 into the patient such that the electrode assembly is in close contact with the target tissue;

b. supplying an irrigant to the cavity defined between said active and floating electrodes; and

c. applying a high-frequency voltage to said active electrode;

wherein said high frequency voltage results not only in the flow of current among active electrode, floating electrode and target tissue but further results in the boiling of irrigant, such that expanding steam and heated irrigant flow from the cavity to the target tissue site, thereby thermally treating said target tissue.

11. The method of claim 10, wherein said instrument further comprises a return electrode disposed thereon.

12. The method of claim 10, wherein said target tissue is a tumor.

13. The method of claim 12, wherein the electrode assembly is placed in direct contact with the surface of the tumor.

14. The method of claim 12, wherein the electrode assembly embedded in the tumor tissue.

15. The method of claim 14, wherein the electrode assembly is provided with a means to facilitate atraumatic insertion into said tumor.

16. The method of claim 15, wherein said means comprises a sharp, tapered conical tip provided at the distal end of said electrode assembly.

17. The method of claim 16, further comprising the step of applying a return electrode to a free surface of tissue near the tumor so as to concentrate current flow between the active and return electrodes, through the tumor.

18. The method of claim 10, wherein said high-frequency voltage comprises RF energy.

19. The method of claim 10, wherein said introduction step (a) is monitored with the use of an external imaging system.

20. The method of claim 19, wherein said imaging system is selected from the group consisting of MRI, CT, PET, ultrasound, x-ray, and fluoroscope.

21. The method of claim 10, wherein the sufficiency of the thermal treatment of said target tissue is determined by means of an external imaging system.

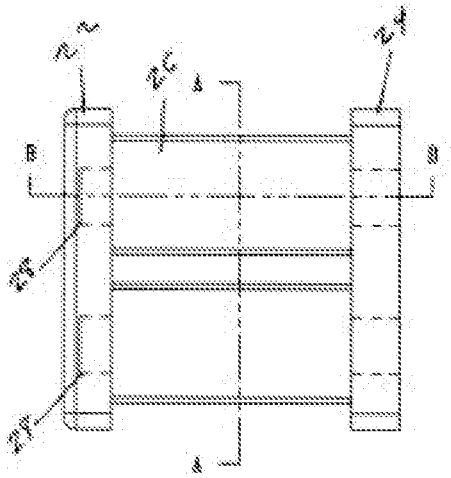


FIG. 1

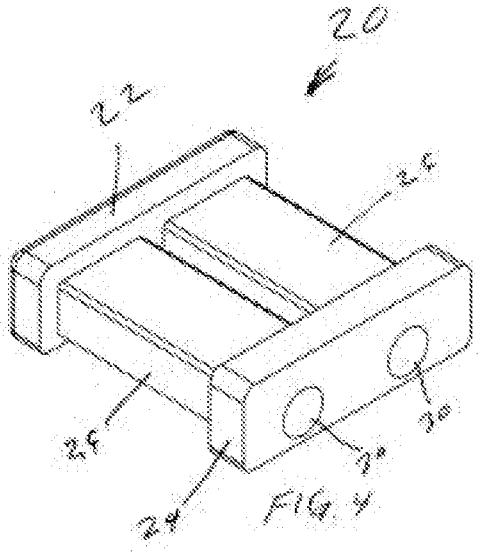


FIG. 4

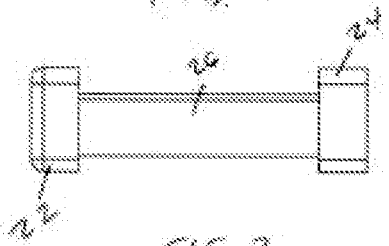


FIG. 2

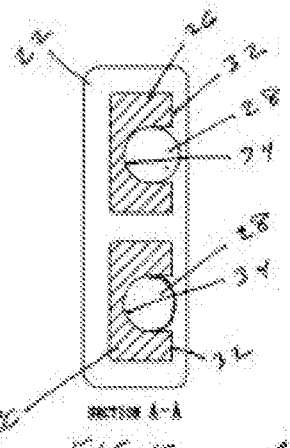


FIG. 5

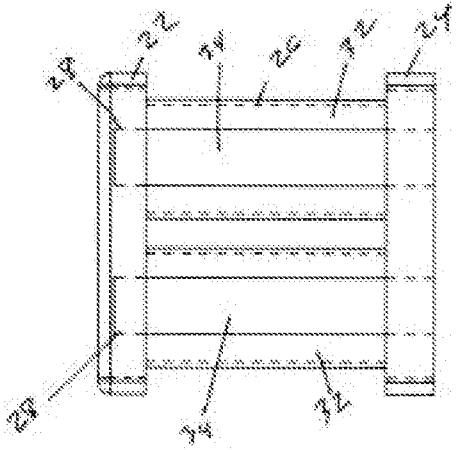


FIG. 3

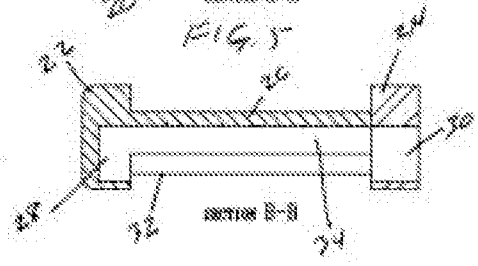


FIG. 6

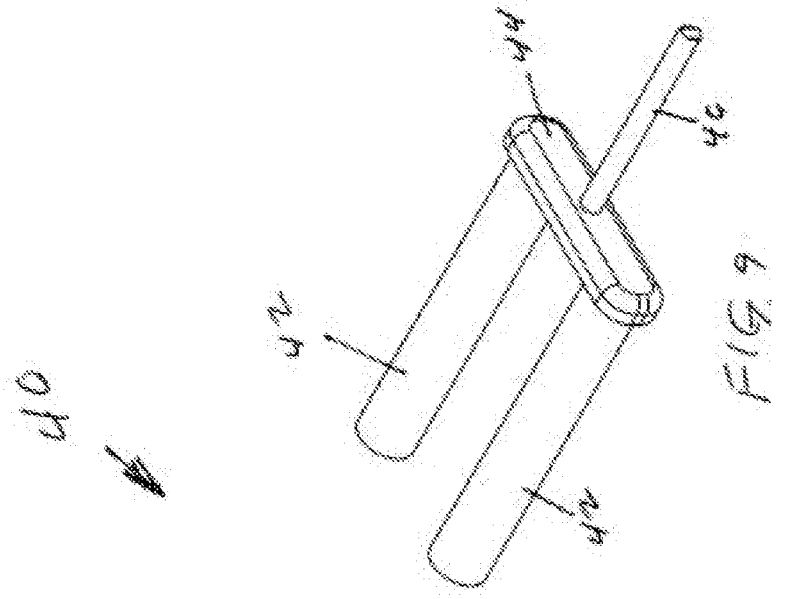


FIG. 9

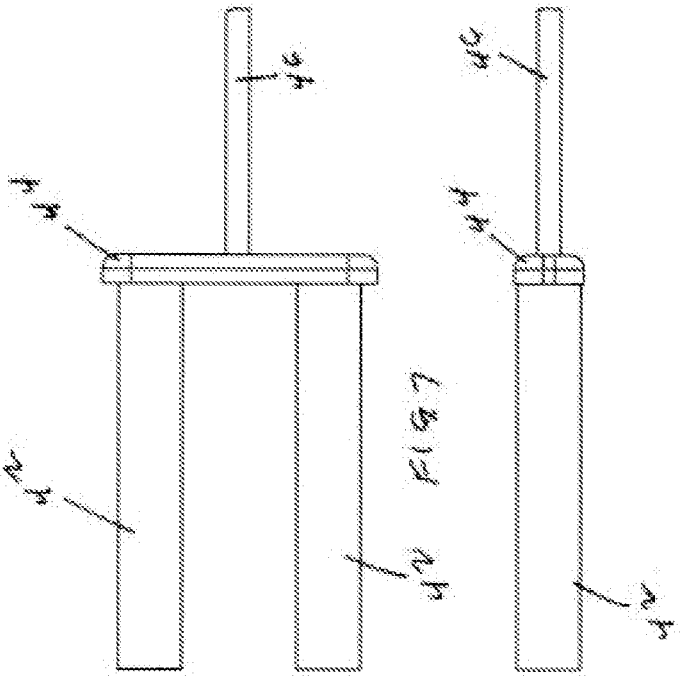


FIG. 7

FIG. 8

FIG. 10

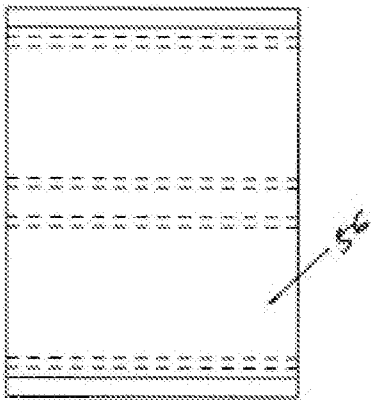


FIG. 11

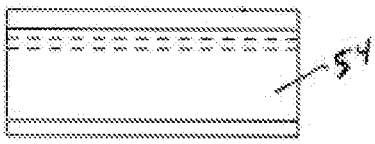


FIG. 12

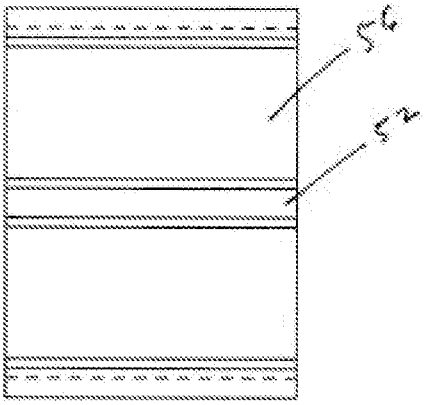


FIG. 13

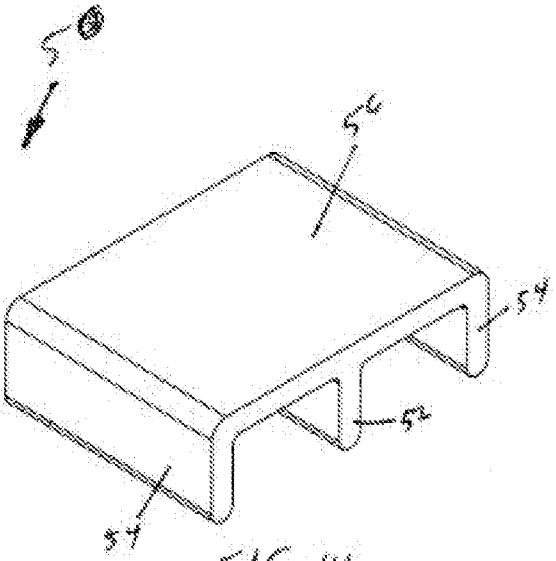


FIG. 14

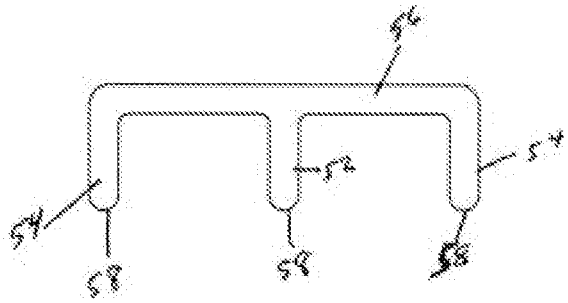
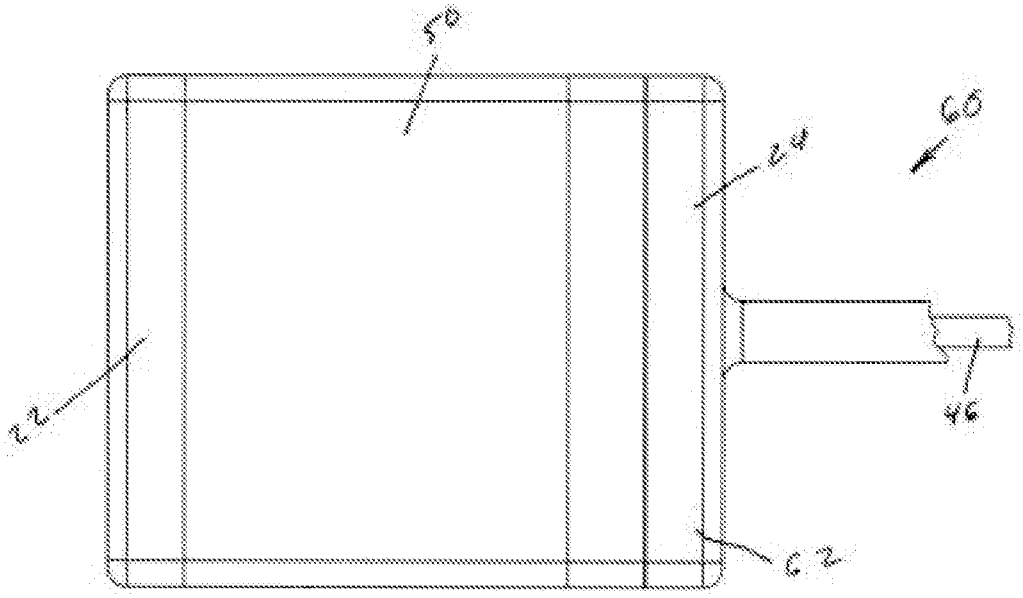


FIG. 15



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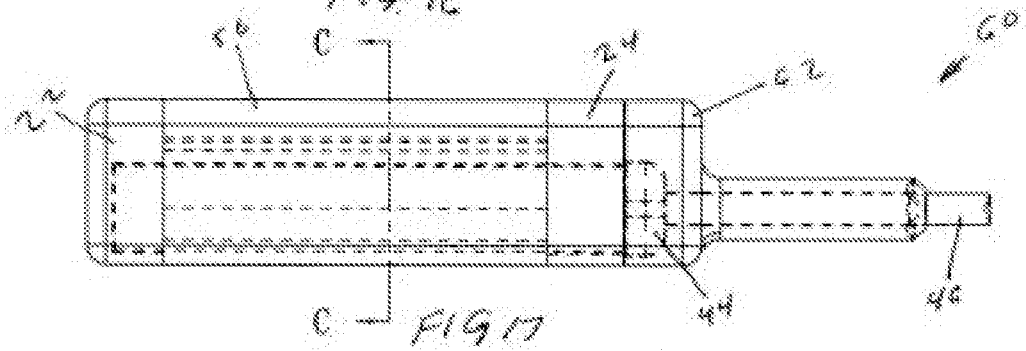


FIG 17

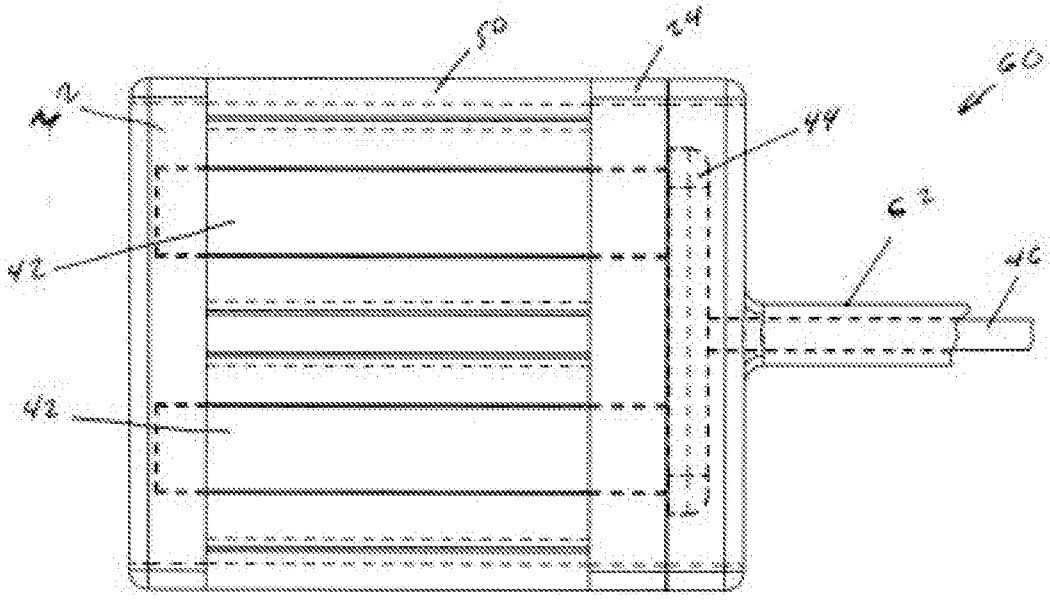


FIG. 18

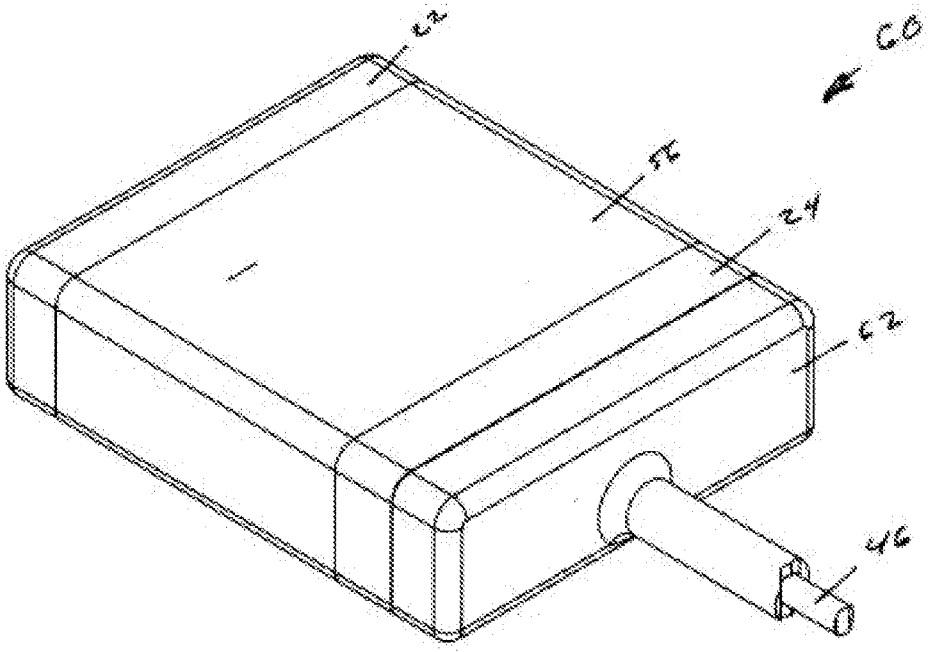


FIG. 19

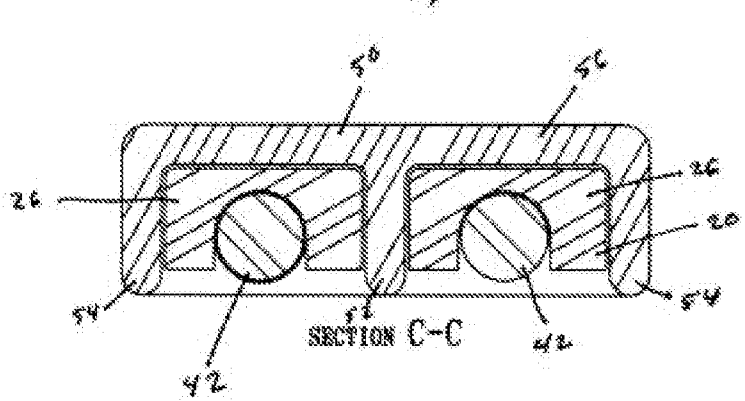


FIG. 20

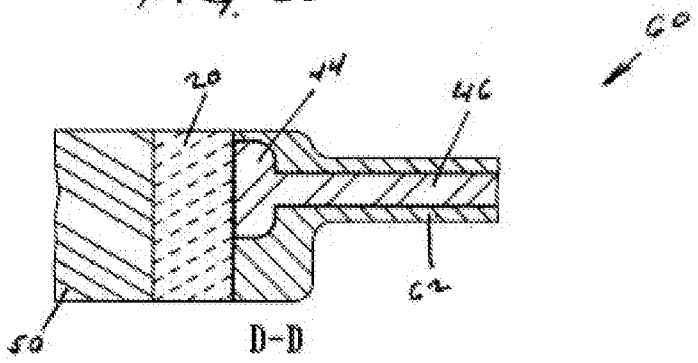


FIG. 21

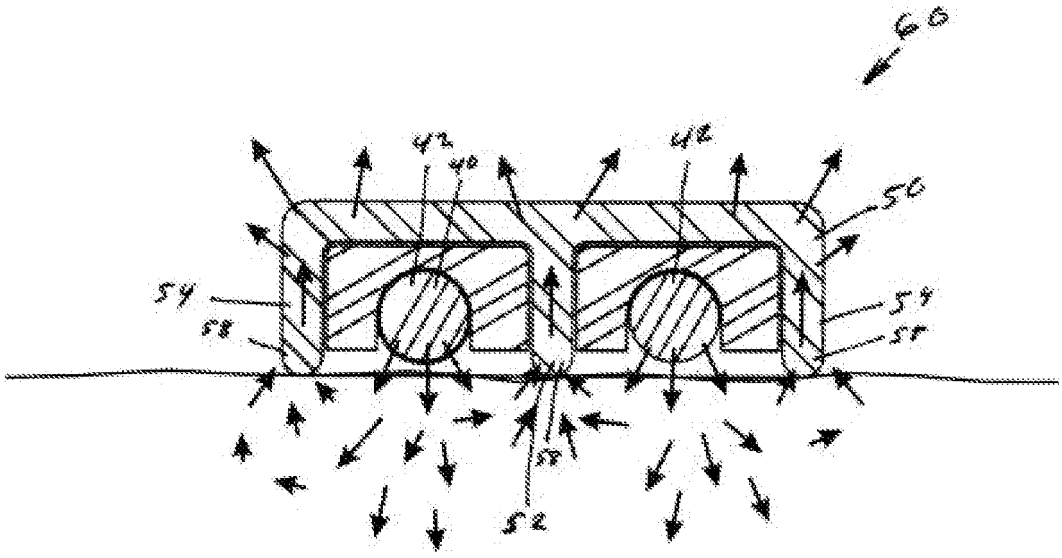


FIG 22

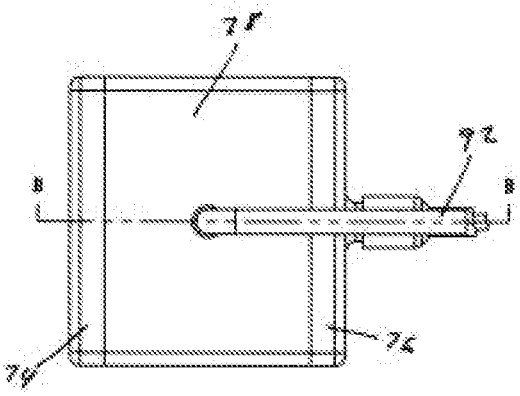


FIG. 23

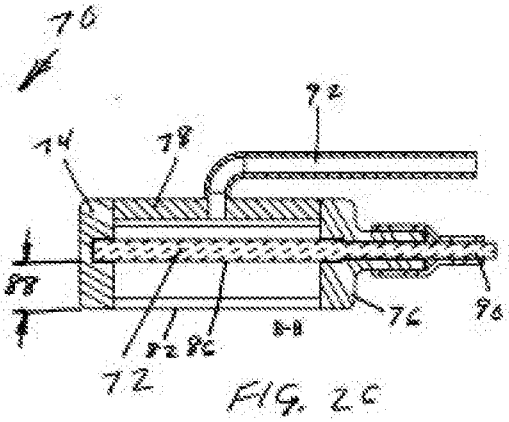


FIG. 2C

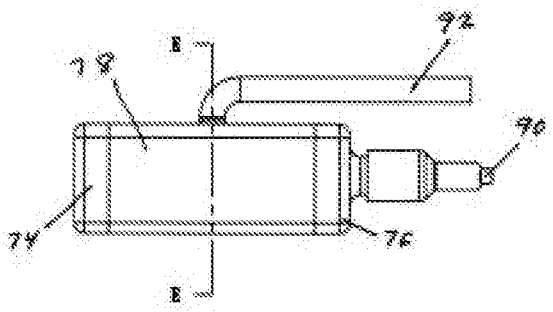


FIG. 24

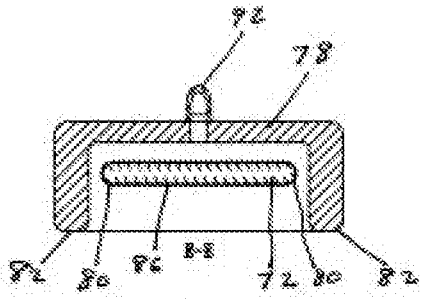


FIG. 27

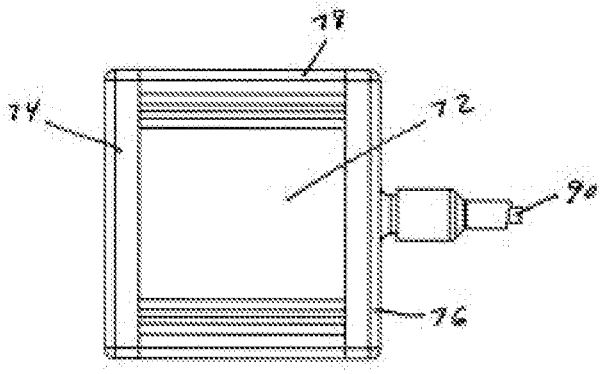


FIG. 25

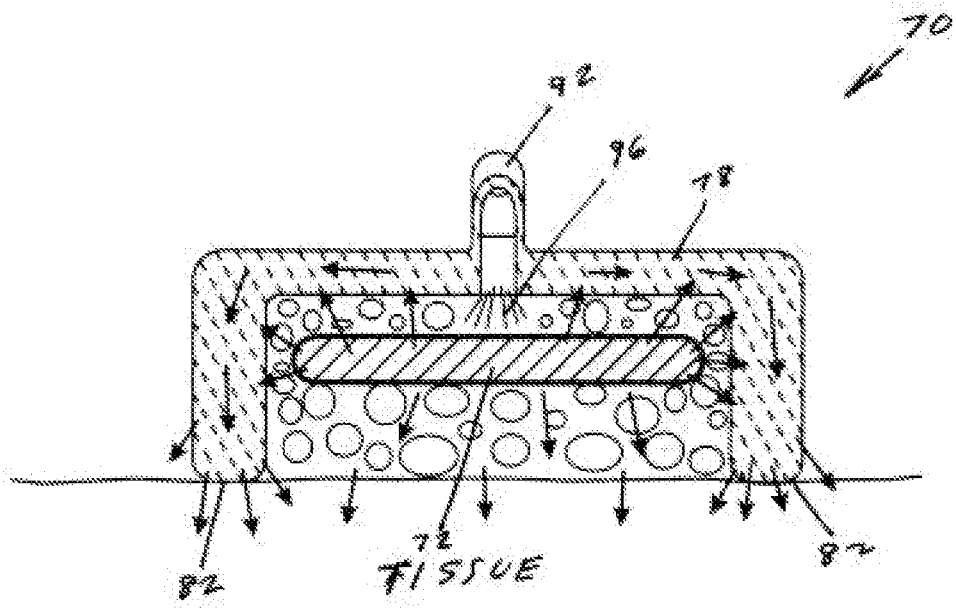
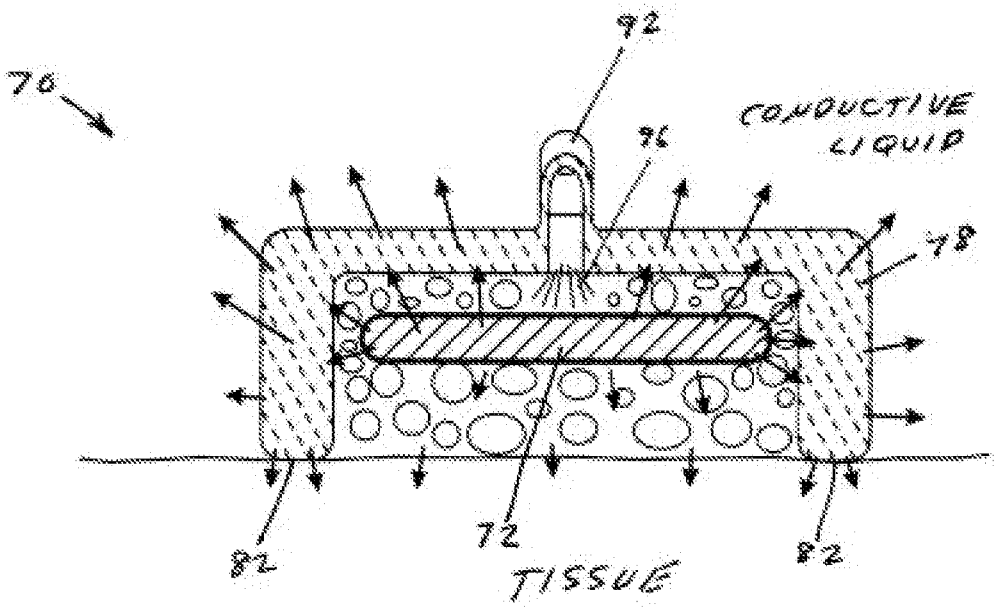

70
92
96
78
72
82
82
TISSUE

FIG. 28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CONDUCTIVE LIQUID
96
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72
82
82
TISSUE

FIG. 29

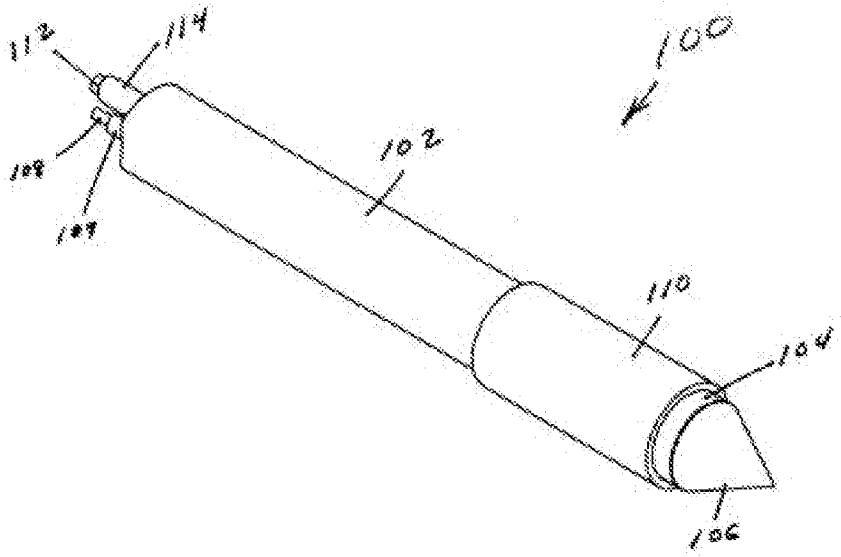


FIG. 30

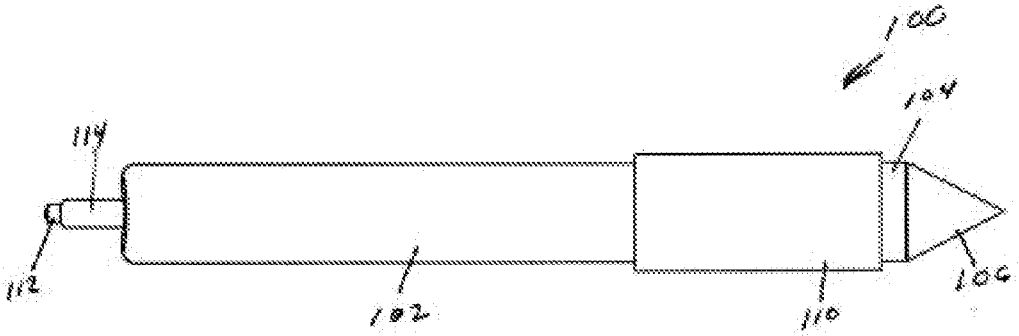


FIG. 31

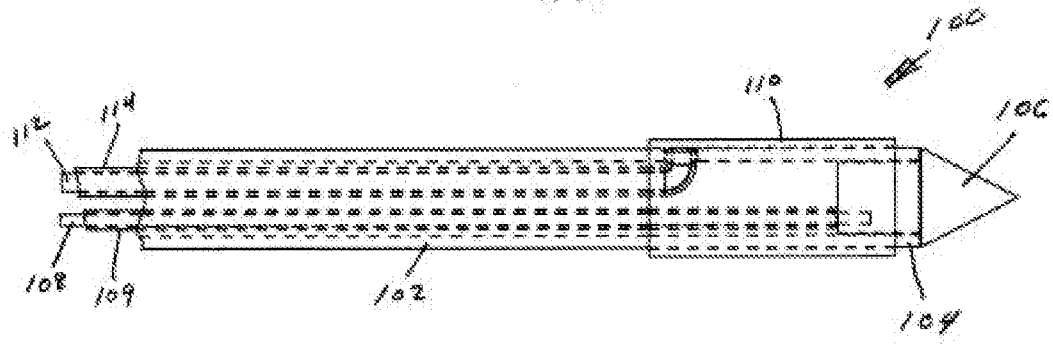


FIG. 32

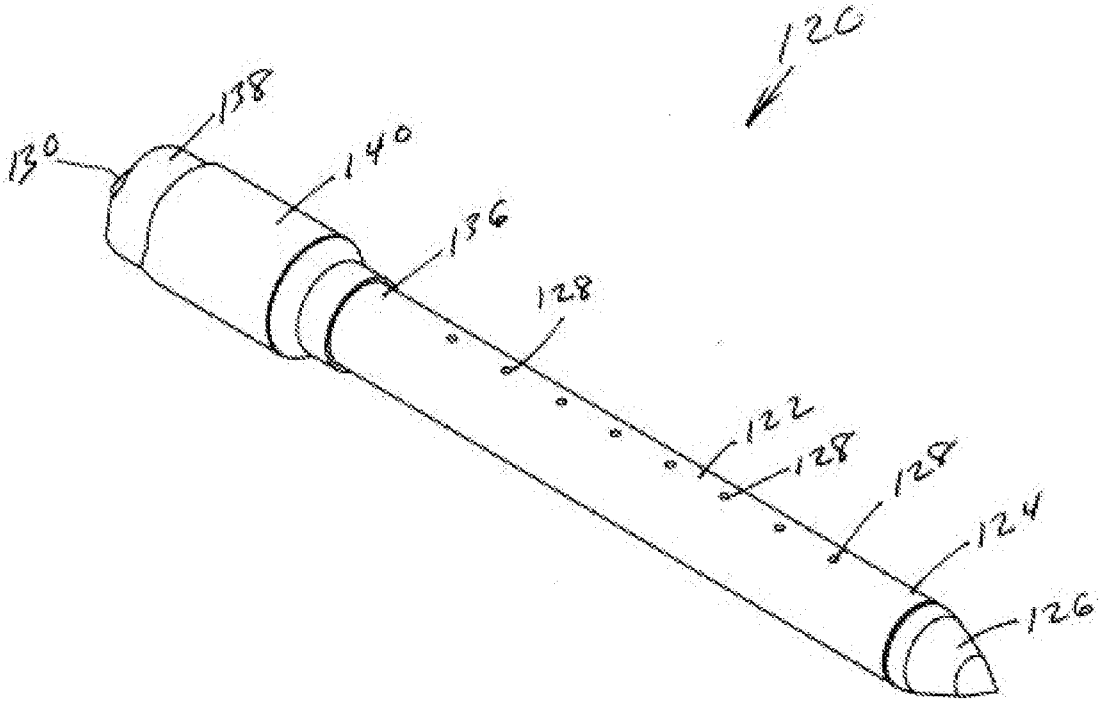
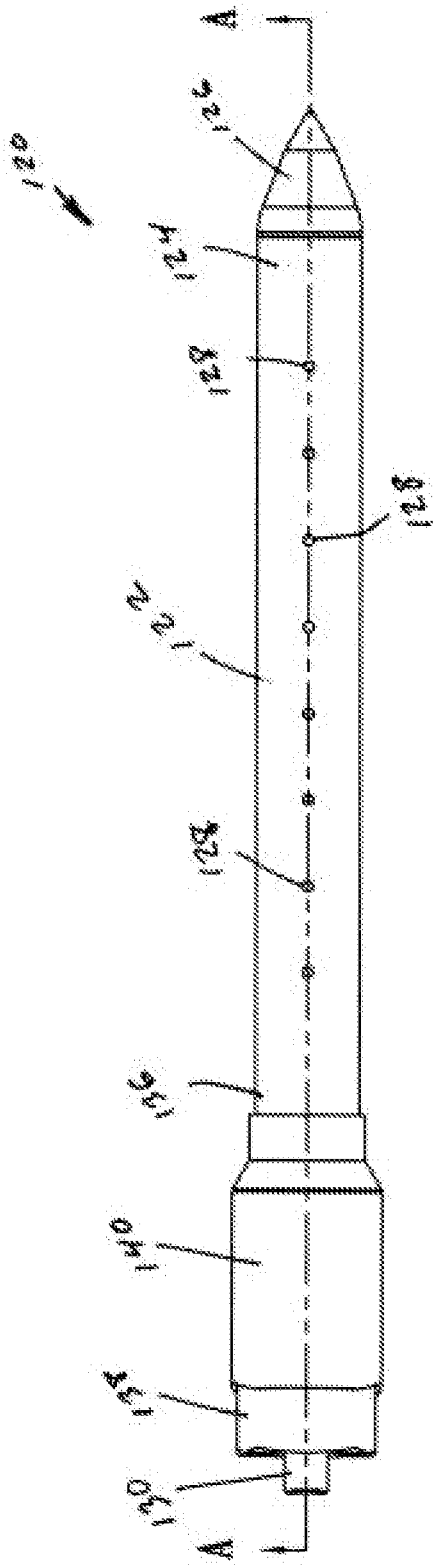


FIG. 3J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221
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96
140
142
120
A
A

FIG. 34

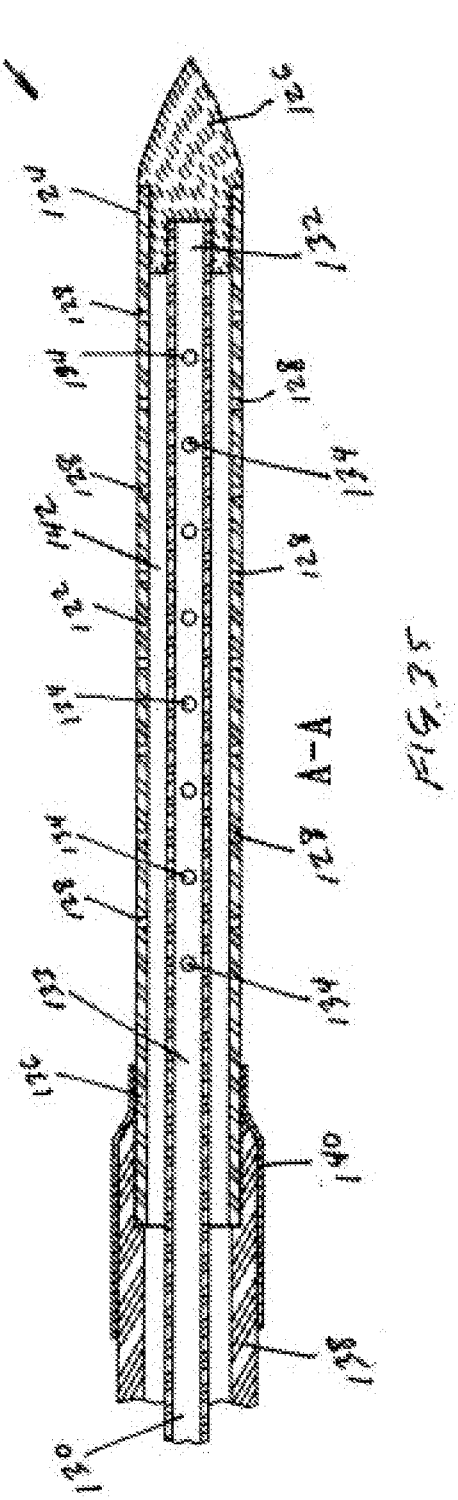
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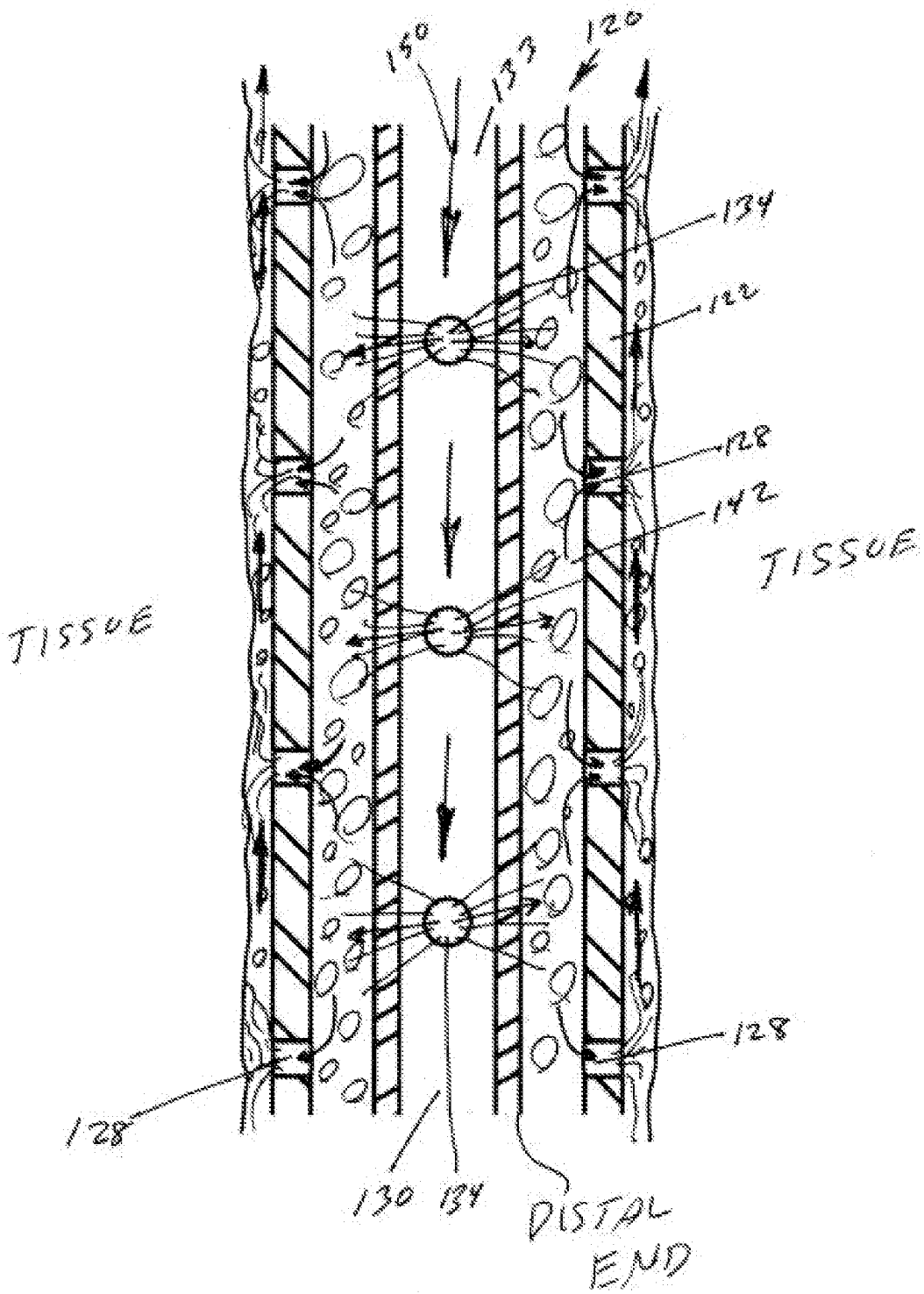
FIG. 35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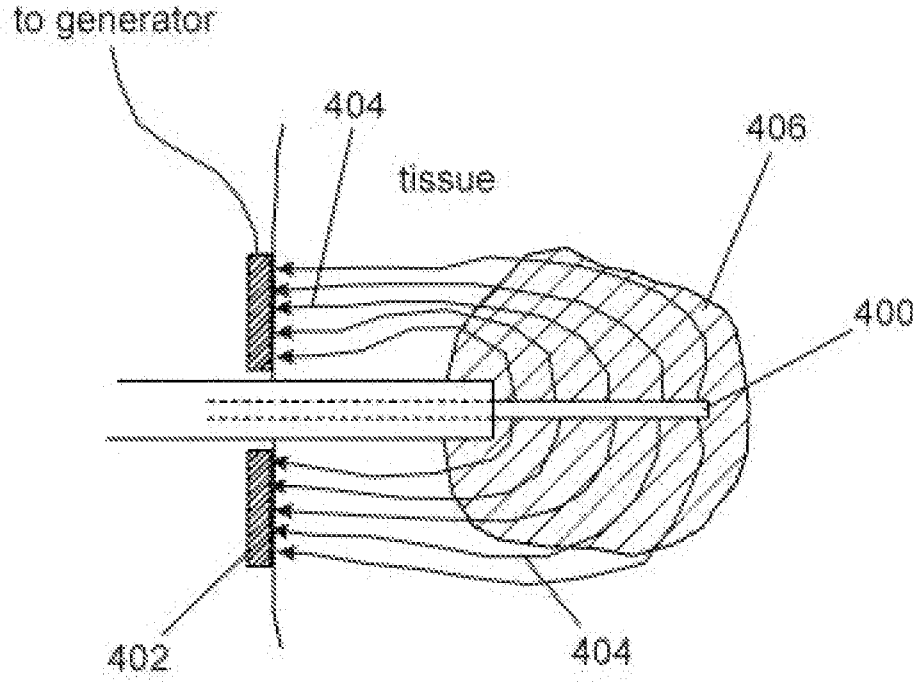
142
TISSUE
TISSUE
128
128
130
134
DISTAL END

FIG. 36


to generator
404
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tissue
400
402
404

Fig. 37

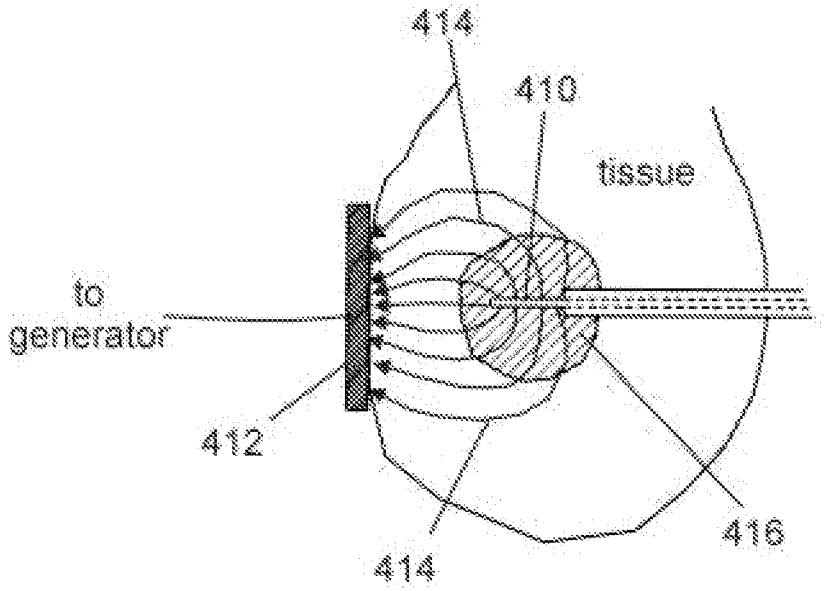

414
410
tissue
to
generator
412
414
416

Fig. 38

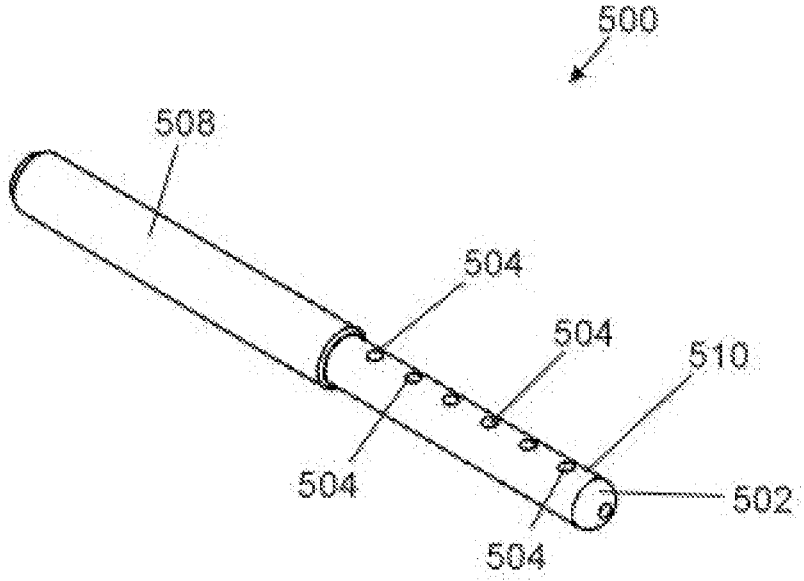


Fig. 39

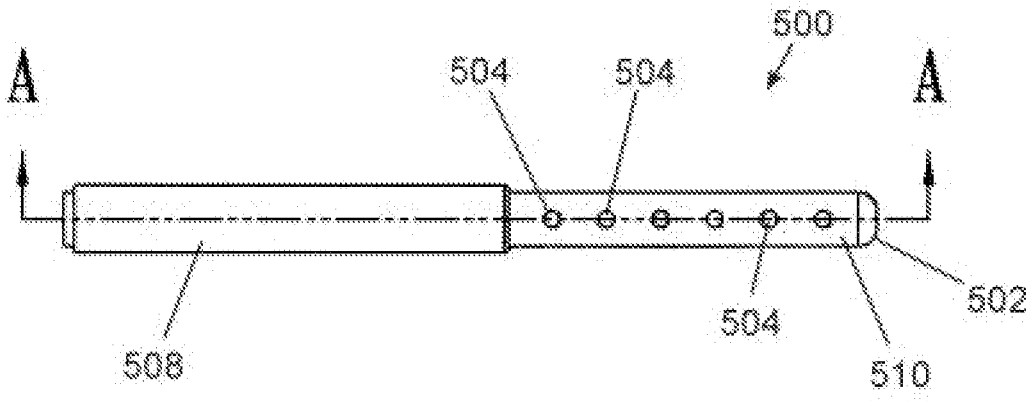


Fig. 40

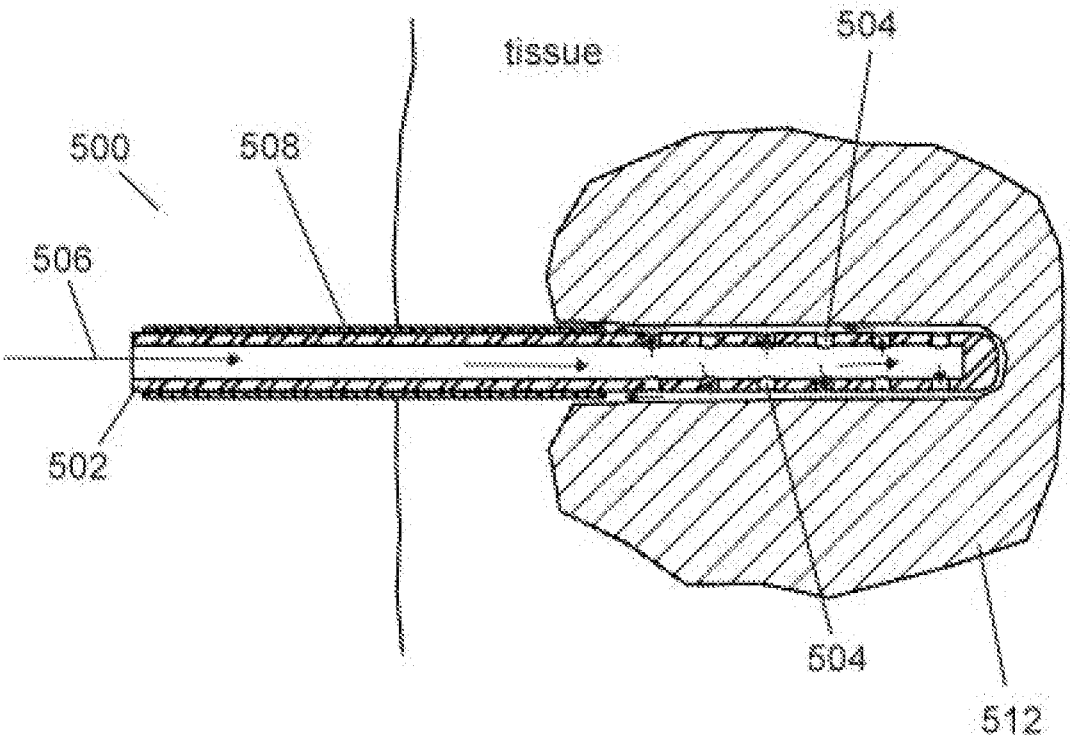


Fig. 41

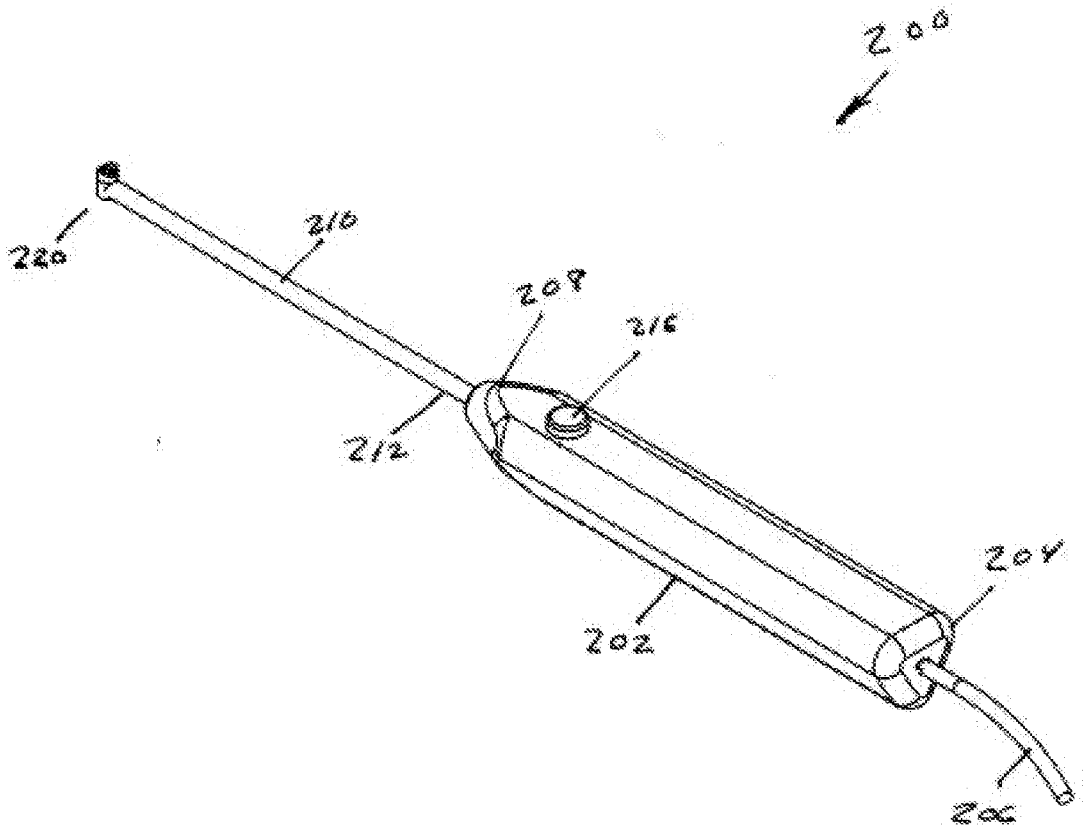
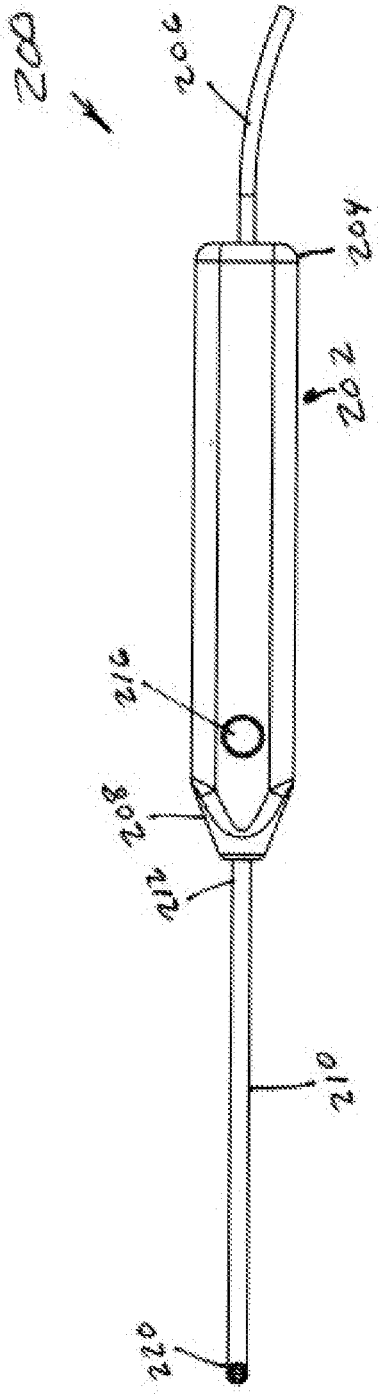


FIG. 42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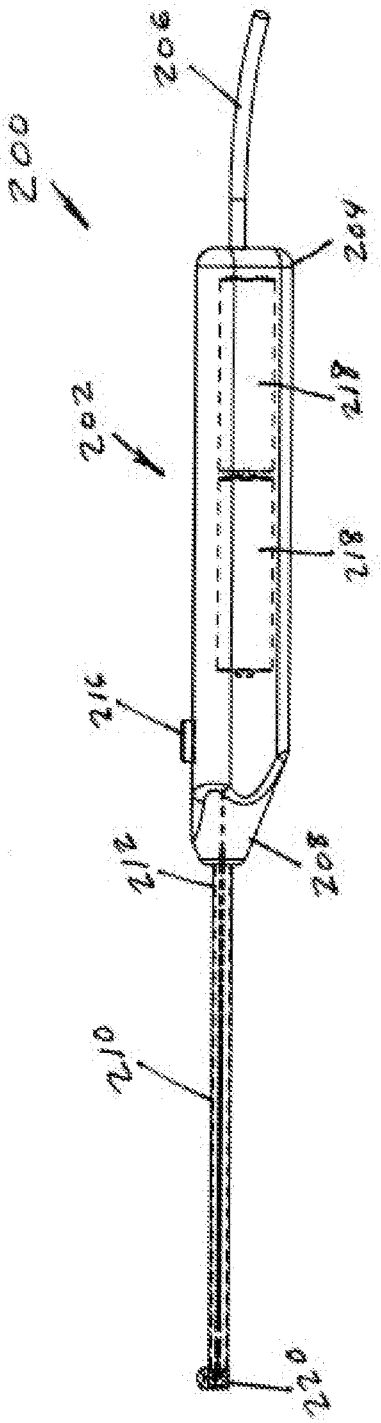
220

FIG. 4B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220

FIG. 4A

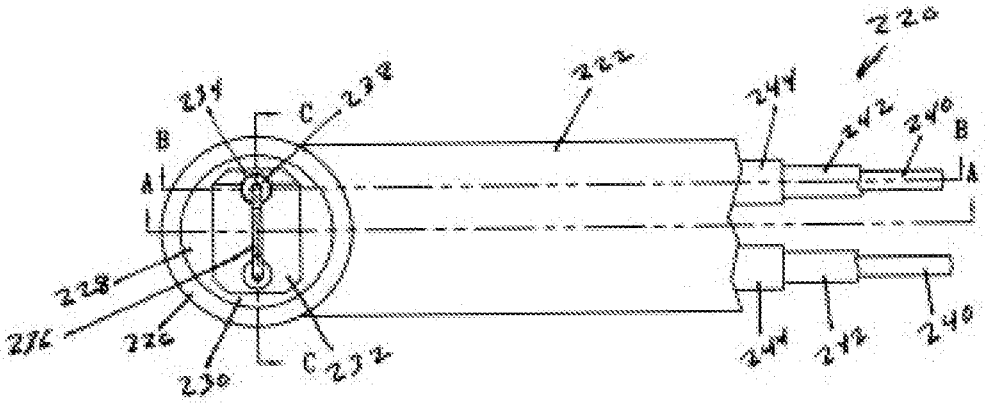


FIG. 4B

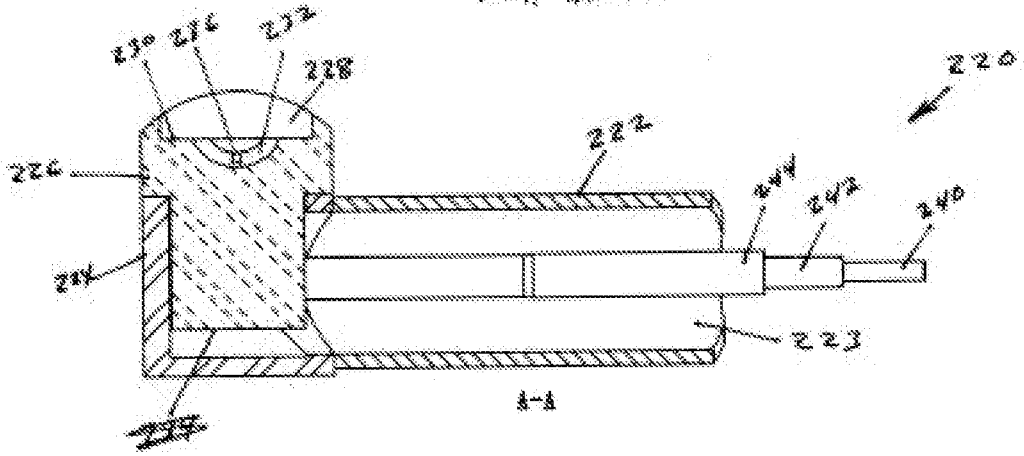


FIG. 4C

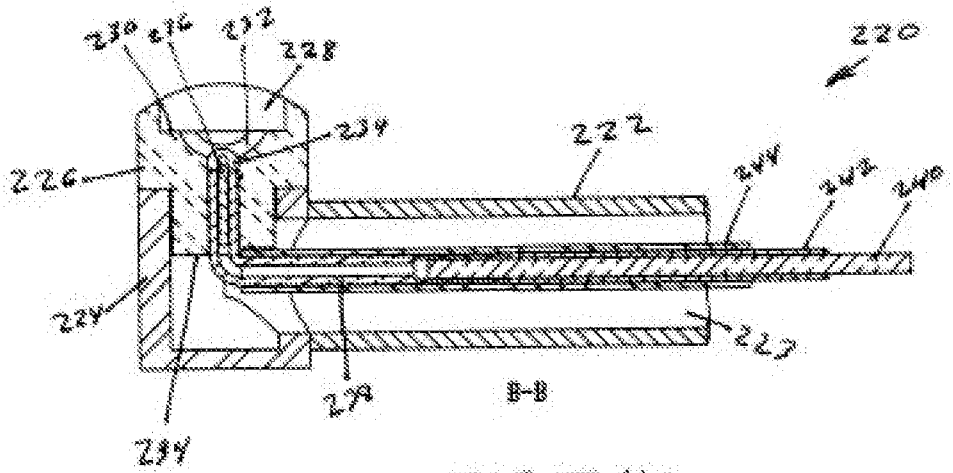


FIG. 4D

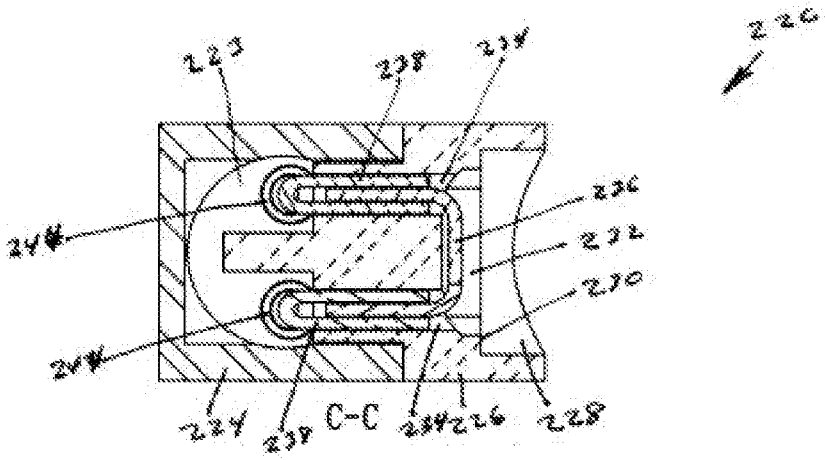
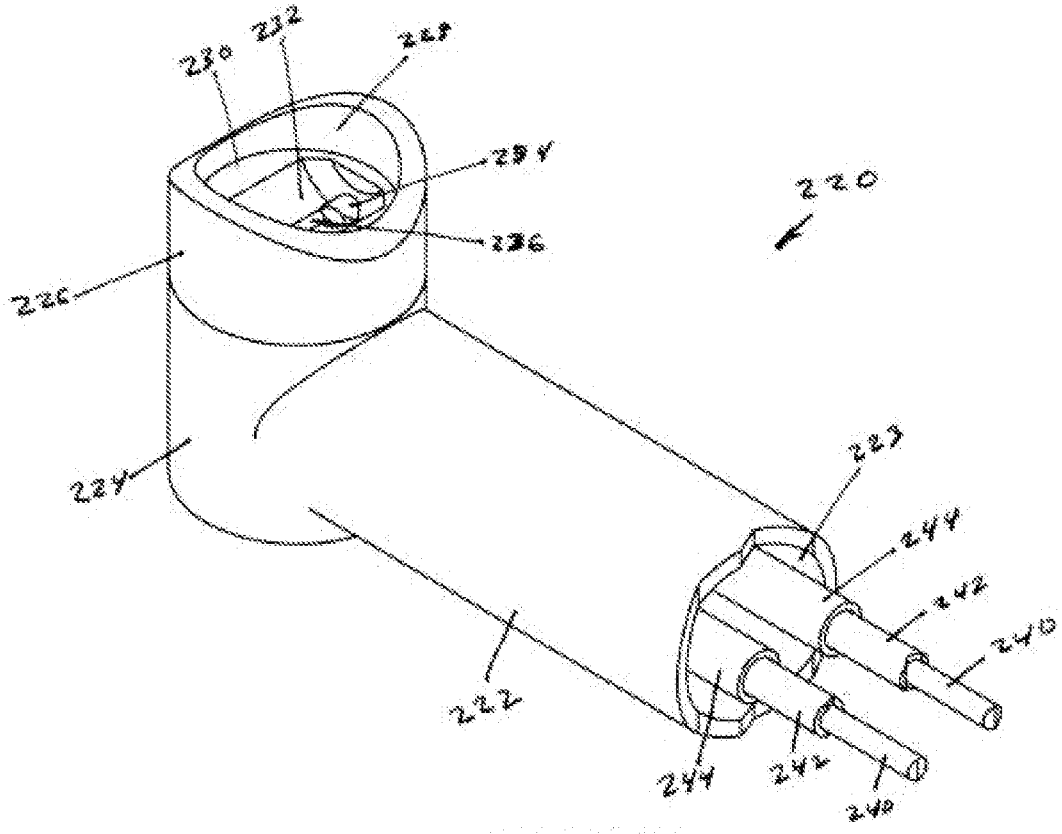

220
223
238
234
236
232
230
244
224
239
C-C
234
226
228

FIG. 48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240

FIG. 49

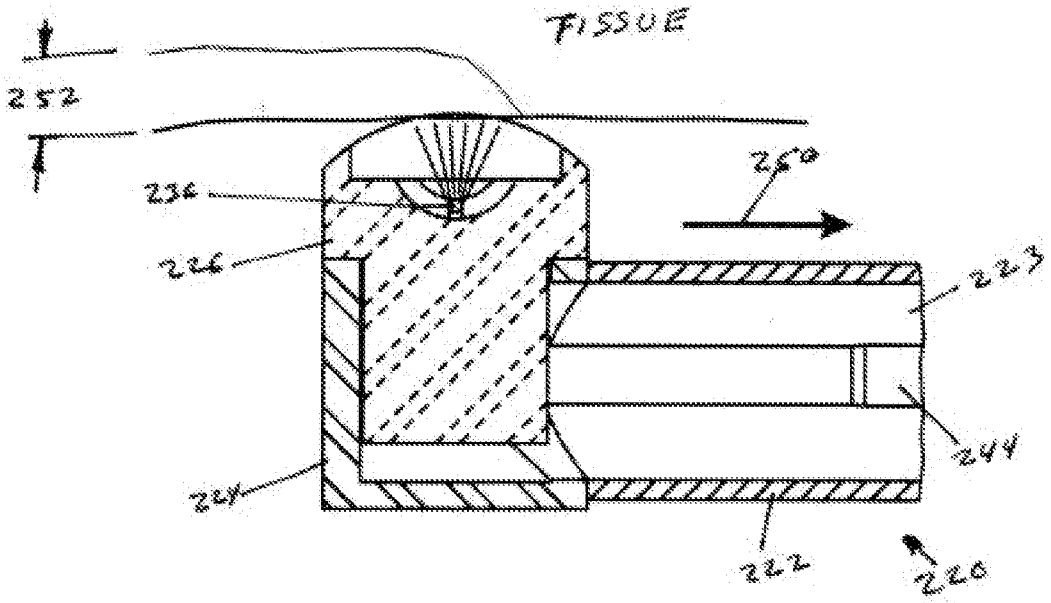
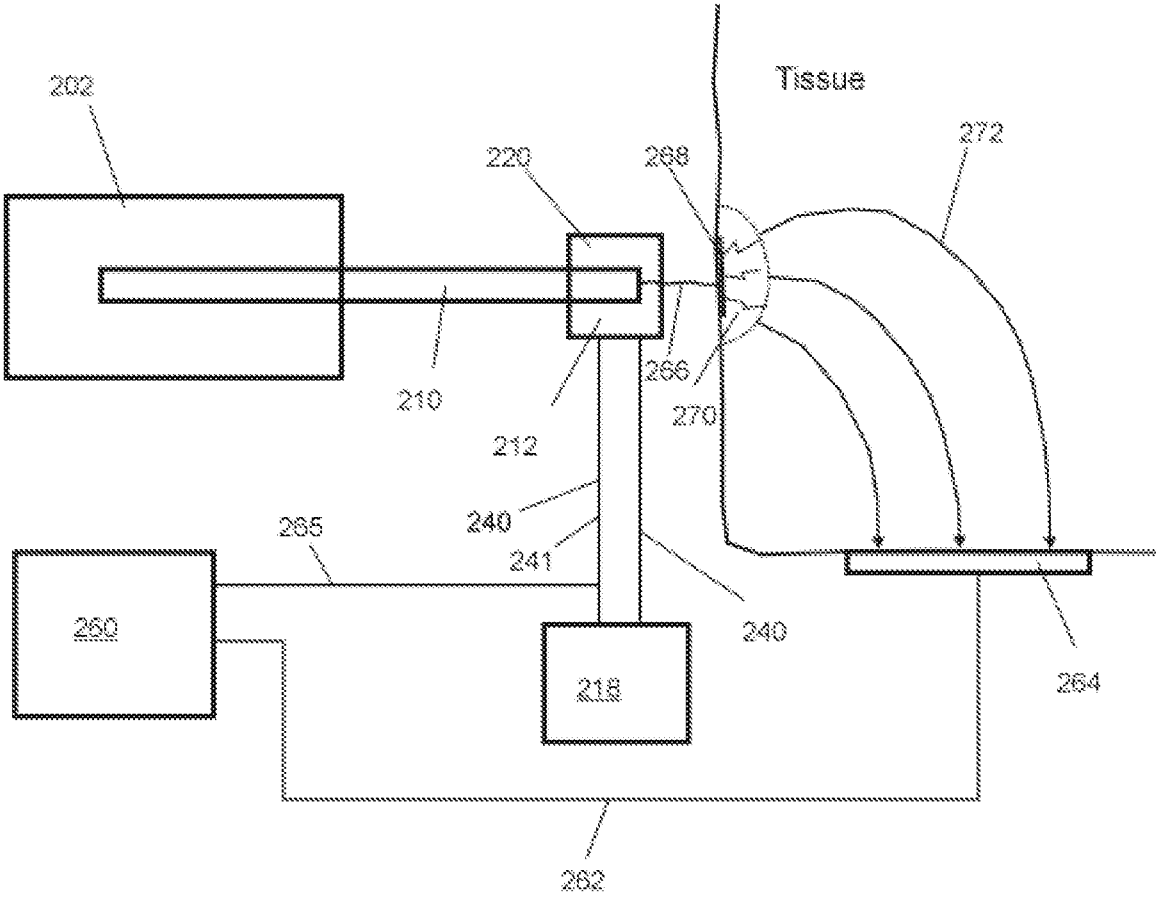


FIG. 50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Tissue
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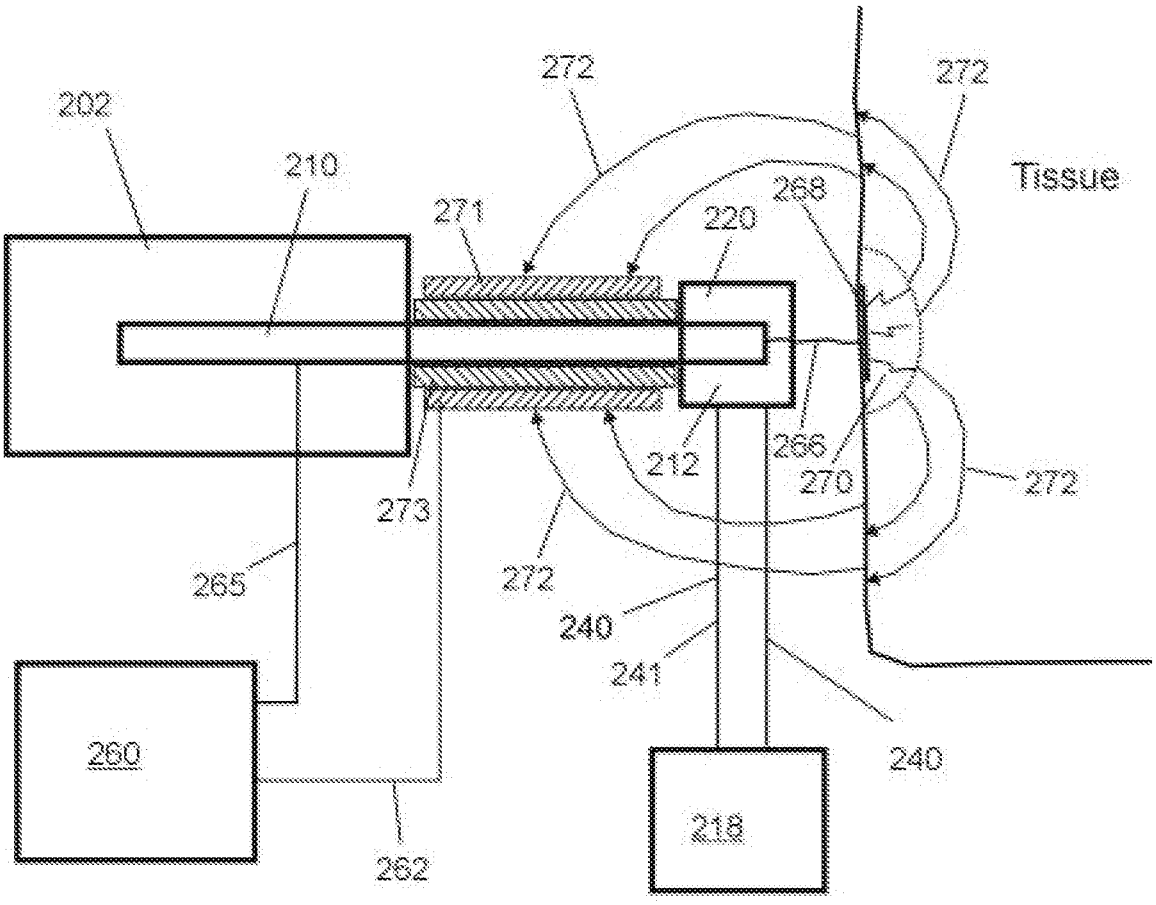
268
210
266
270
212
240
241
265
260
240
218
264
262

Fig. 51(a)


202
210
271
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272
Tissue
268
220
266
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272
212
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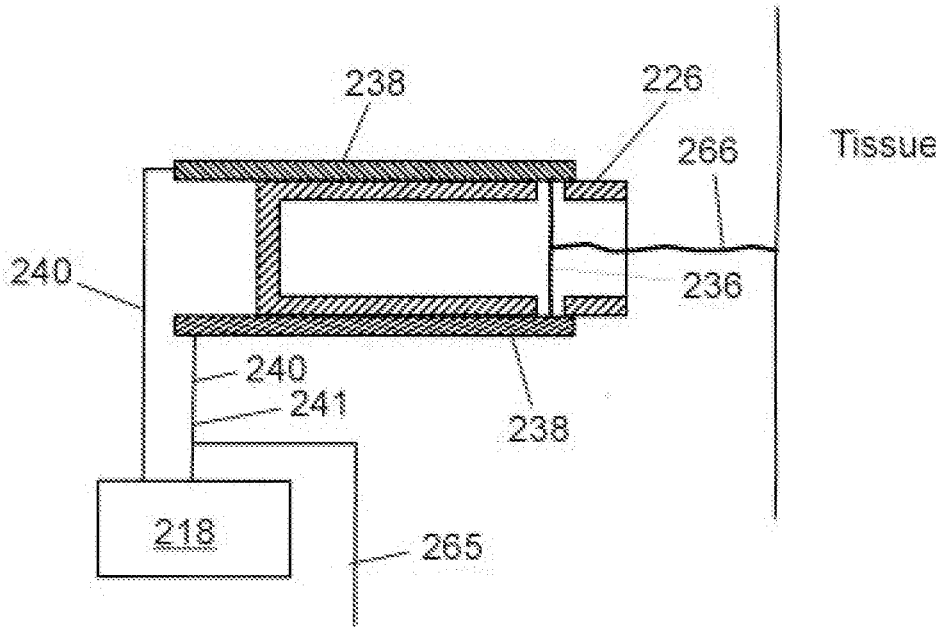
240
260
218
262

Fig. 51(b)


238
226
266
Tissue
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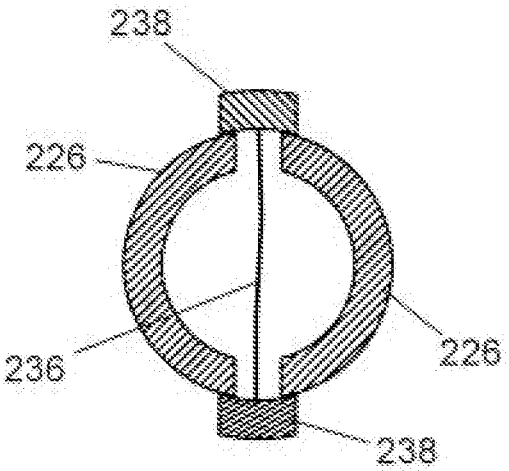
236
240
241
238
218
265

(A)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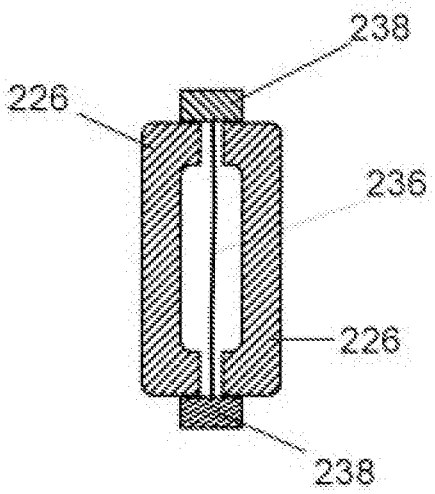
236
226
238

(B)


238
226
236
226
238

(C)

Fig. 52

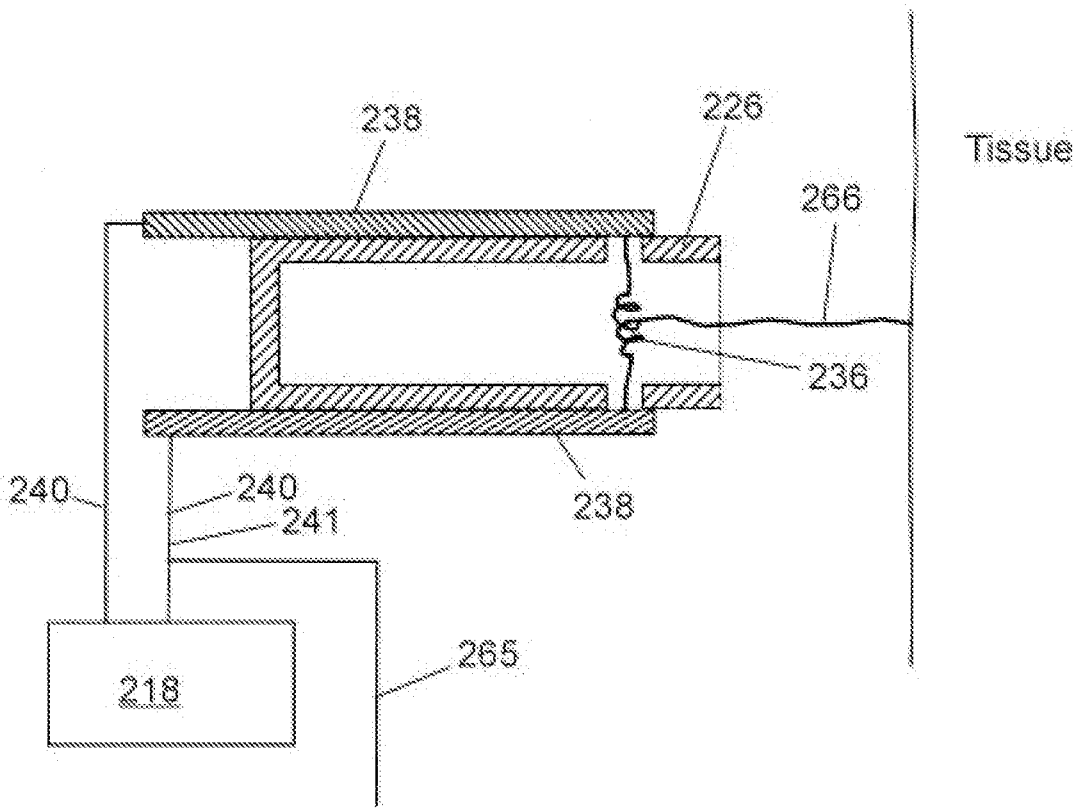

238
226
Tissue
266
236
240
240
241
238
218
265

Fig. 53

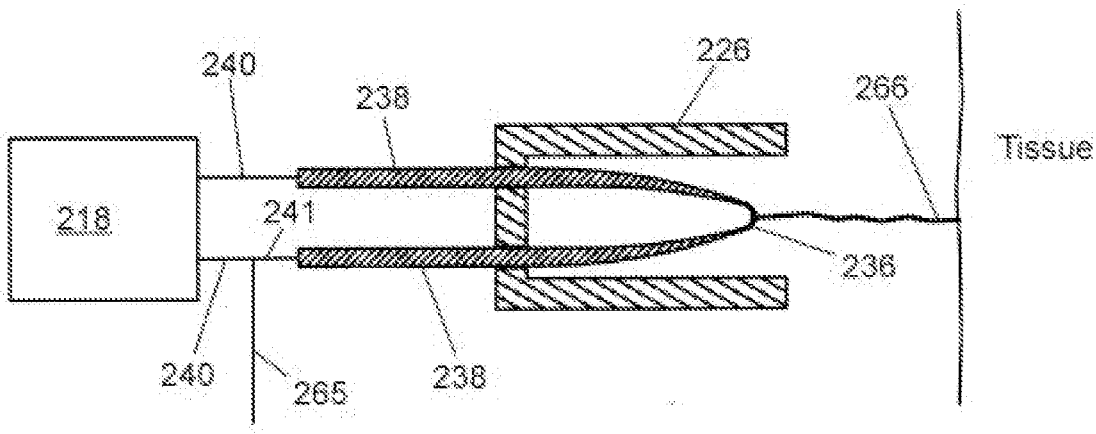

240
238
226
266
Tissue
218
241
236
240
265
238

Fig. 54

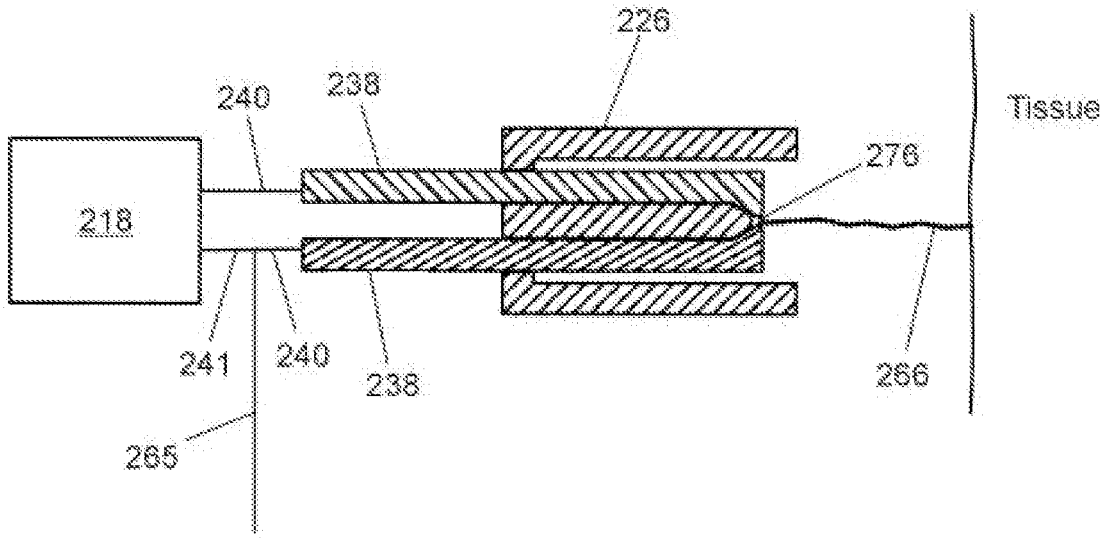

226
240
238
Tissue
276
218
241
240
238
266
265

Fig. 55

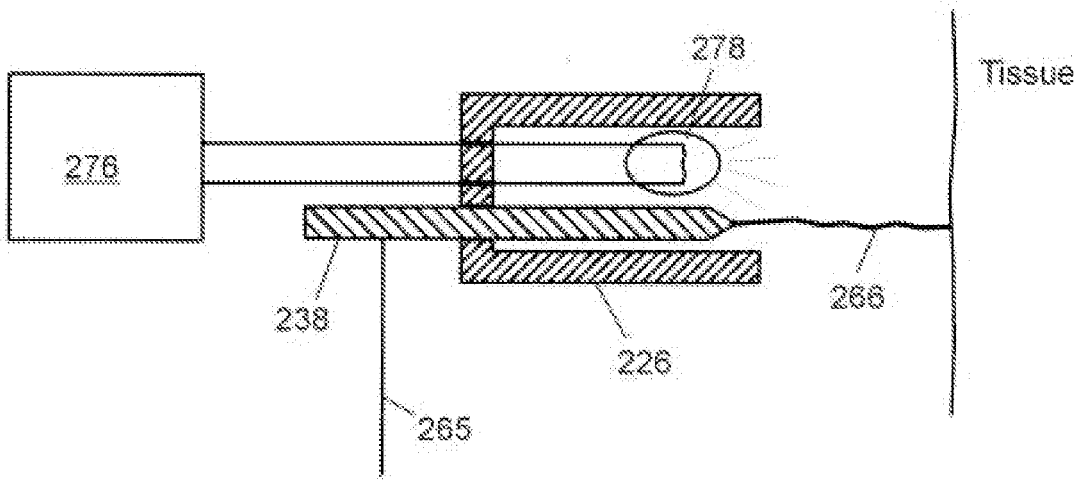

278
Tissue
276
238
266
226
265

Fig. 56

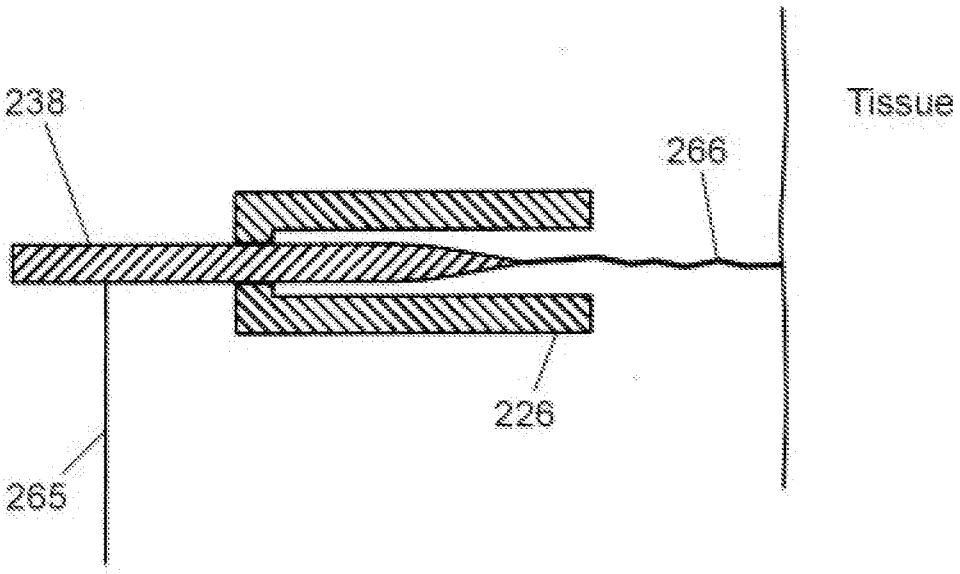


Fig. 57

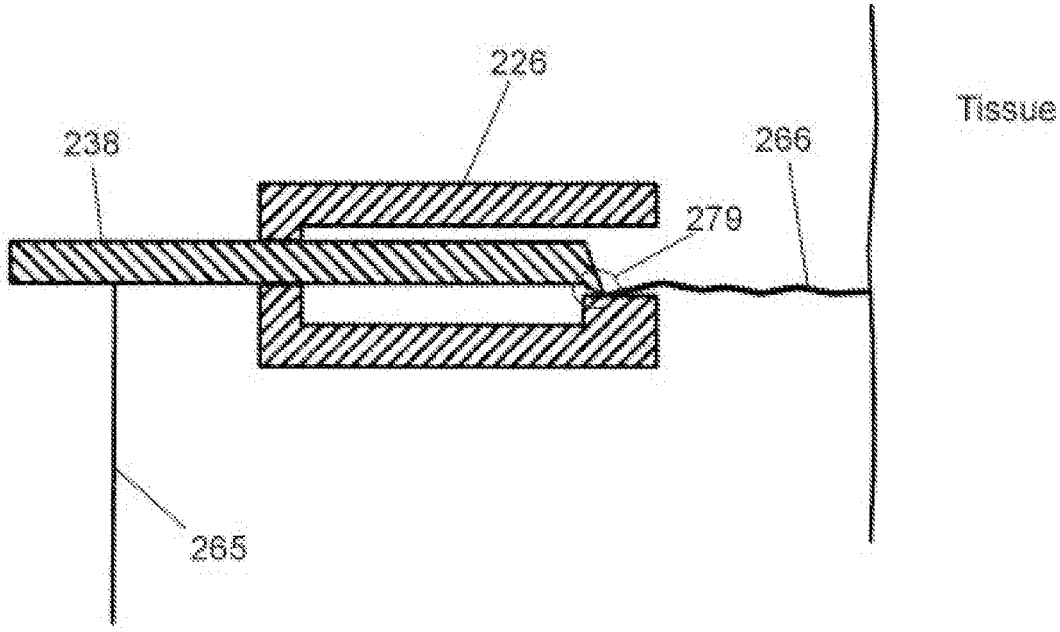


Fig. 58

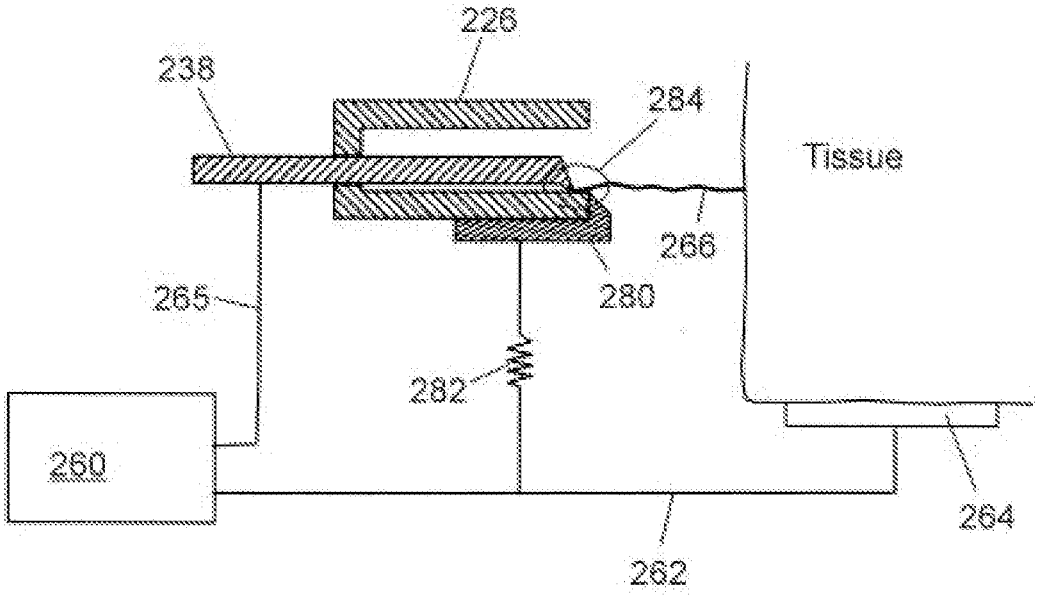
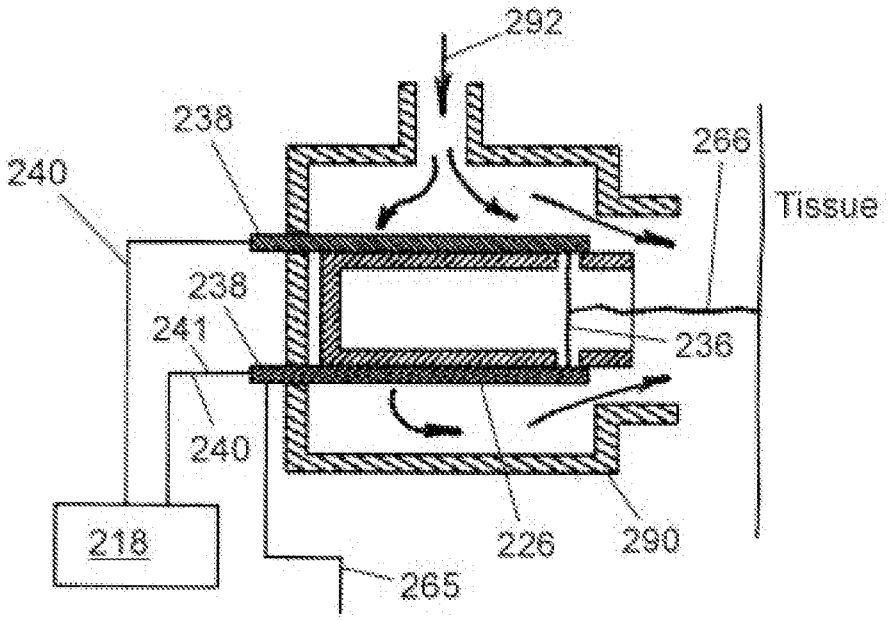


Fig. 59


292
238
240
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Tissue
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241
236
240
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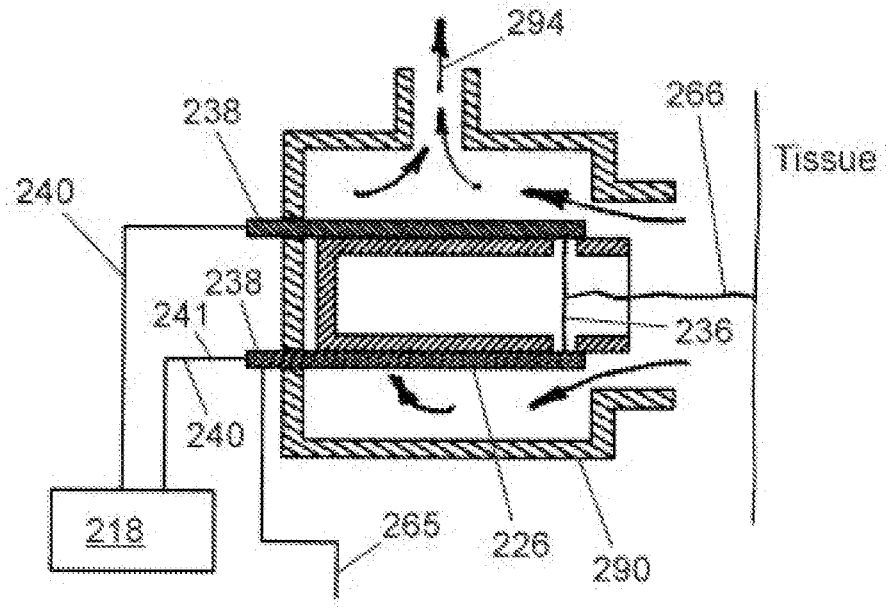
226
290
265

(A)


294
238
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Tissue
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290

(B)

Fig. 60

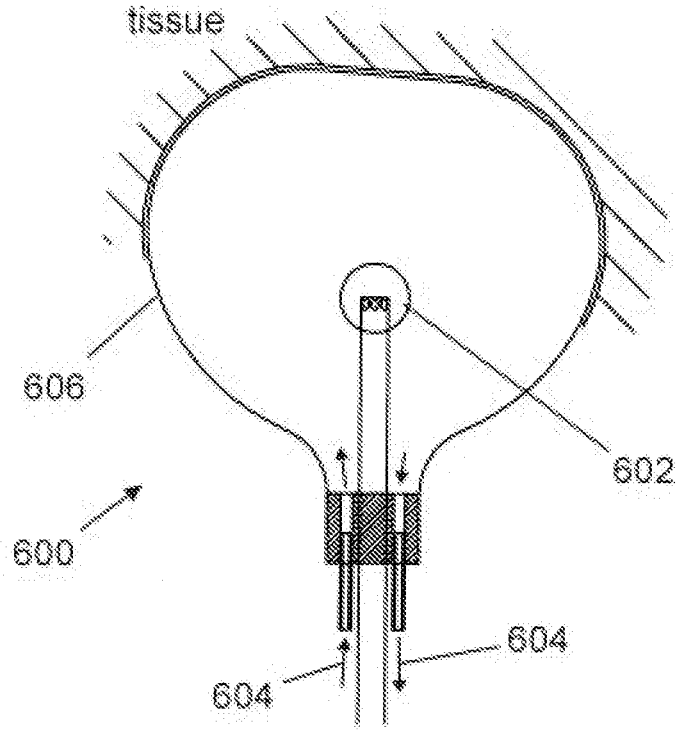

Fig. 61

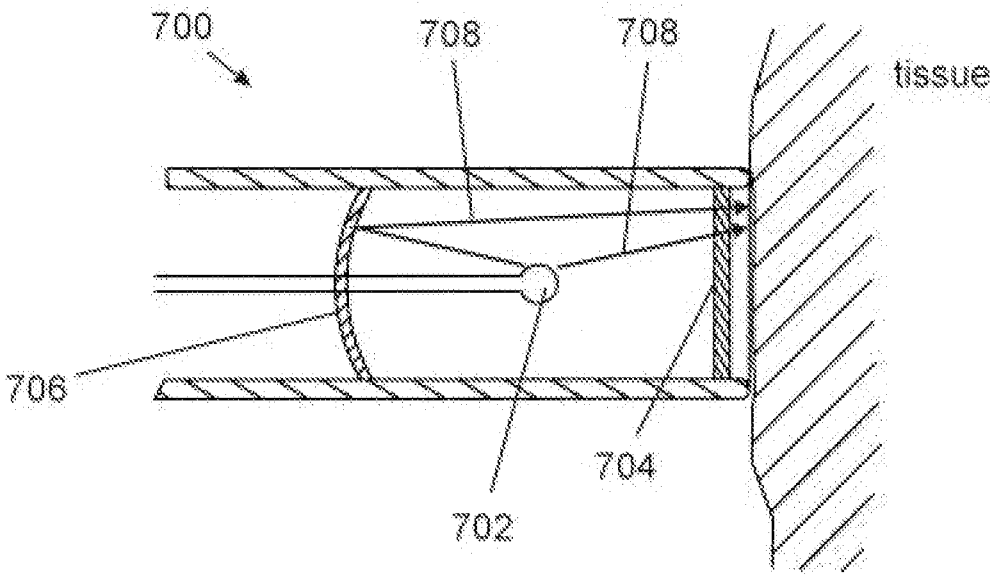

Fig. 62

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/054500

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/04
ADD. A61B18/00 A61F7/12

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/234446 A1 (VAN WYK ROBERT A [US] ET AL) 20 October 2005 (2005-10-20) cited in the application paragraphs [0002], [0018] - [0031] paragraph [0066] paragraphs [0083] - [0089]; figures 5,10 paragraphs [0098] - [0101]; figures 22-25,29	1-4
X	US 2005/065510 A1 (CARMEL YUVAL [US] ET AL) 24 March 2005 (2005-03-24) cited in the application paragraphs [0011], [0017] paragraphs [0123] - [0134]; figures 5,18,41,47 paragraph [0144]; figure 61	1-4

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 July 2008	06/08/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Loveniers, Kris

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/054500

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/224154 A1 (SHADDUCK JOHN H [US] ET AL) 5 October 2006 (2006-10-05) paragraphs [0051] - [0055]; figure 3	1-8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/054500

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. [X] Claims Nos.: 9-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [X] Claims Nos.: 9
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:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an 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 reportcovers 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 9-21

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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Continuation of Box II.2

Claims Nos.: 9

Claim 9 specifies the location of a "floating electrode" which however was not introduced in this claim. It is therefore not clear (Article 6 PCT) to what feature the term "floating electrode" refers and this renders claim 9 as a whole unclear to an extent that a meaningful search is not possible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/054500

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005234446 A1	20-10-2005	NONE	
US 2005065510 A1	24-03-2005	NONE	
US 2006224154 A1	05-10-2006	NONE	

专利名称(译)	用于热组织治疗的仪器和方法		
公开(公告)号	EP2124792A1	公开(公告)日	2009-12-02
申请号	EP2008730326	申请日	2008-02-21
[标]申请(专利权)人(译)	电子医疗ASSOCS		
申请(专利权)人(译)	电子医疗ASSOCIATES，LLC		
当前申请(专利权)人(译)	电子医疗ASSOCIATES，LLC		
[标]发明人	VAN WYK ROBERT A CARMEL YUVAL SHKVARUNETS ANATOLY		
发明人	VAN WYK, ROBERT, A. CARMEL, YUVAL SHKVARUNETS, ANATOLY		
IPC分类号	A61B18/04 A61B18/00 A61F7/12 A61B18/14		
CPC分类号	A61B18/082 A61B18/04 A61B18/042 A61B18/1477 A61B18/18 A61B2018/00029 A61B2018/00083 A61B2018/044 A61B2018/046 A61B2018/048 A61B2018/1472 A61B2218/002		
优先权	60/902548 2007-02-21 US 12/033987 2008-02-20 US		
其他公开文献	EP2124792B1		
外部链接	Espacenet		

摘要(译)

本文公开了高效手术装置及使用其的方法，其使用射频（RF）电功率和/或电加热细丝来破坏肿瘤，形成病变，变性，干燥，凝固和消融软组织，以及钻孔，切割，切除并蒸发软组织。根据本发明的原理，电外科器械可以与外部供应的导电或非导电液体一起使用，也可以不使用外部供应的液体，通常称为“干场”环境。