ROBERT E. FREITAS (SBN 80948)
rfreitas@ftklaw.com
QUDUS B. OLANIRAN (SBN 267838)
qolaniran@ftklaw.com
FREITAS TSENG & KAUFMAN LLP
100 Marine Parkway, Suite 200
Redwood Shores, California 94065
Telephone: (650) 593-6300
Facsimile: (650) 593-6301

Attorneys for Plaintiff
Perfect Surgical Techniques, Inc.

DMR

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PERFECT SURGICAL TECHNIQUES, INC.,

Plaintiff,

v.

OLYMPUS SURGICAL & INDUSTRIAL AMERICA INC.,

Defendant.

Case No. C 12 5967

COMPLAINT FOR PATENT INFRINGEMENT

DEMAND FOR JURY TRIAL

FILE VIA FAX

Plaintiff Perfect Surgical Techniques, Inc. ("PST") hereby brings this action against Olympus Surgical & Industrial America Inc. ("Olympus") for infringement of United States Patent No. 6,030,384 ("the '384 patent") and United States Patent No. 6,682,527 ("the '527 patent"), and alleges as follows:

NATURE OF THE ACTION AND PARTIES

1. This is an action for patent infringement arising under the patent laws of the United States.

2. PST is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Palo Alto, California.

3. Olympus is a corporation organized and existing under the laws of New Jersey with its principal place of business in New York, New York.

JURISDICTION

4. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), as this is an action arising under the Patent Act, 35 U.S.C. § 1 *et seq.*

VENUE

5. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1391 (d), and 1400(b).

INTRADISTRICT ASSIGNMENT

6. Pursuant to Local Rule 3-2(c), Intellectual Property Actions are assigned on a district-wide basis.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,030,384

7. PST realleges and incorporates by reference the allegations of paragraphs 1-6.

8. The '384 patent is entitled "BIPOLAR SURGICAL INSTRUMENTS HAVING FOCUSED ELECTRICAL FIELDS." The application that resulted in the '384 patent was filed on May 1, 1998, and the United States Patent and Trademark Office duly and legally issued the '384 patent on February 29, 2000. A true and correct copy of the '384 patent is attached hereto as Exhibit A.

9. PST owns all right, title and interest in the '384 patent, and has owned all right, title, and interest throughout the period of the infringement complained of herein.

10. Olympus uses, offers to sell, sells, distributes, supplies, provides and/or imports into the United States bipolar surgical instruments, including but not limited to PKS Cutting Forceps, that directly infringe at least claim 1 of the '384 patent either literally or under the doctrine of equivalents.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 6,682,527

11. PST realleges and incorporates by reference the allegations of paragraphs 1-10.

12. The '527 patent is entitled "METHOD AND SYSTEM FOR HEATING TISSUE WITH A BIPOLAR INSTRUMENT." The application that resulted in the '527 patent was filed on March 13, 2001, and the United States Patent and Trademark Office duly and legally issued

///

the '527 patent on January 27, 2004. A true and correct copy of the '527 patent is attached hereto as Exhibit B.

13. PST owns all right, title and interest in the '527 patent, and has owned all right, title, and interest throughout the period of the infringement complained of herein.

14. Olympus uses, offers to sell, sells, distributes, supplies, provides and/or imports into the United States electrosurgical generators, including but not limited to Gyrus ACMI G400 Workstation, that directly infringe at least claim 15 of the '527 patent either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

PST prays for relief as follows:

1. Judgment that Olympus has infringed the '384 and '527 patents as alleged herein;

2. Compensatory damages in an amount according to proof, and in no event less than a reasonable royalty;

3. Prejudgment interest on the compensatory damages awarded to PST;

4. Post-judgment interest on all sums awarded to PST from the date of judgment;

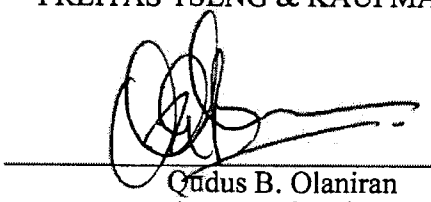
5. A preliminary and permanent injunction forbidding Olympus and its officers, agents, servants, employees, and attorneys, and all those in active concert or participation with them, from further infringing the '384 and '527 patents;

6. Costs of suit incurred herein; and

7. Any and all other relief that the Court deems just and equitable.

Dated: November 21, 2012

FREITAS TSENG & KAUFMAN LLP



Qudus B. Olaniran
Attorney for Plaintiff,
Perfect Surgical Techniques, Inc.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, PST demands a jury trial for all issues so triable.

Dated: November 21, 2012

FREITAS TSENG & KAUFMAN LLP

Qudus B. Olaniran
Attorney for Plaintiff,
Perfect Surgical Techniques, Inc.

EXHIBIT A

US006030384A

United States Patent [19]

Nezhat

[11] Patent Number: 6,030,384

[45] Date of Patent: Feb. 29, 2000

[54] **BIPOLAR SURGICAL INSTRUMENTS HAVING FOCUSED ELECTRICAL FIELDS**

[76] Inventor: **Camran Nezhat**, 240 Mountain Wood La., Woodside, Calif. 94062

[21] Appl. No.: **09/071,689**

[22] Filed: **May 1, 1998**

[51] **Int. Cl.**[7] **A61B 17/39**

[52] **U.S. Cl.** **606/48**; 606/51

[58] **Field of Search** 606/48, 50–52, 606/45, 49

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,920,021	11/1975	Hiltebrandt .	
4,016,886	4/1977	Doss et al.	128/422
4,041,952	8/1977	Morrison, Jr. et al. .	
4,043,342	8/1977	Morrison, Jr. .	
4,671,274	6/1987	Sorochenko .	
5,098,431	3/1992	Rydell .	
5,151,102	9/1992	Kamiyama et al. .	
5,207,691	5/1993	Nardella .	
5,217,030	6/1993	Yoon .	
5,217,460	6/1993	Knoepfler	606/52
5,267,998	12/1993	Hagen .	
5,269,780	12/1993	Roos .	
5,269,782	12/1993	Sutter .	
5,281,216	1/1994	Klicek .	
5,282,799	2/1994	Rydell .	
5,290,287	3/1994	Boebel et al. .	
5,295,990	3/1994	Levin .	
5,300,087	4/1994	Knoepfler .	
5,324,289	6/1994	Eggers .	
5,330,471	7/1994	Eggers .	
5,336,229	8/1994	Noda .	
5,342,381	8/1994	Tidemand .	
5,352,223	10/1994	McBrayer et al. .	

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

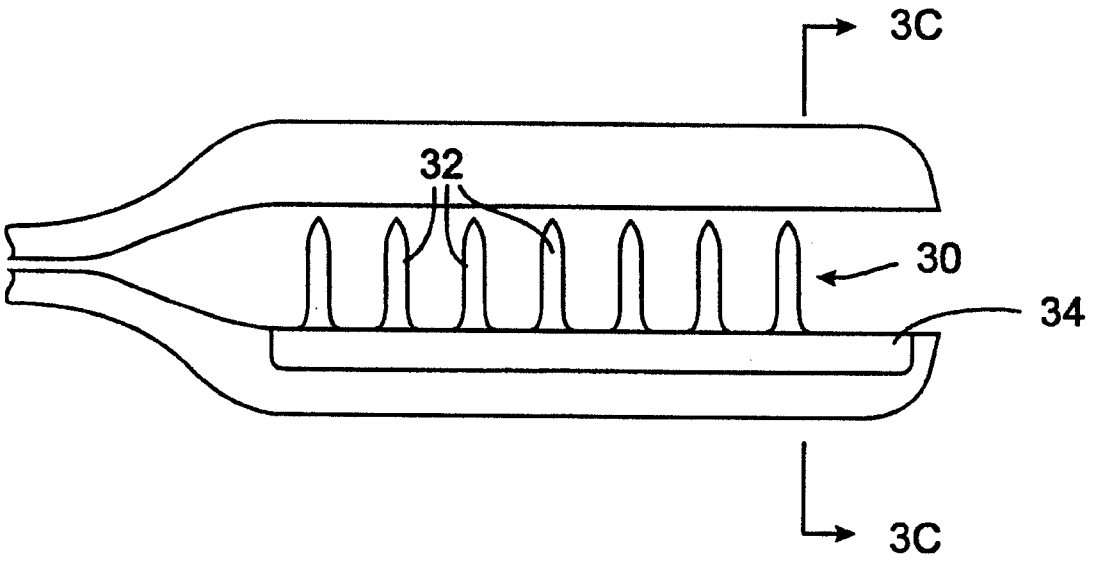
598149	7/1925	France .
197711	11/1977	Russian Federation .

Primary Examiner—Linda C. M. Dvorak
Assistant Examiner—Roy Gibson
Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

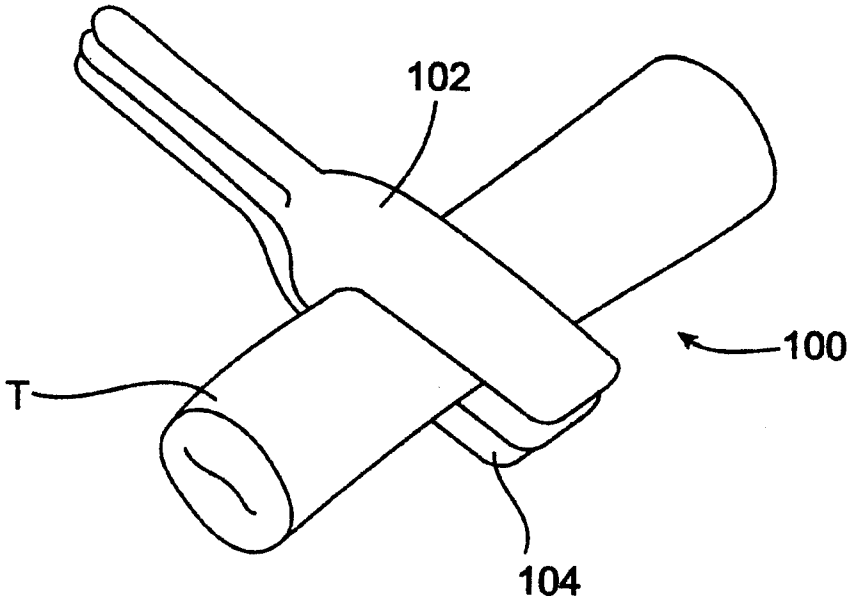
A bipolar surgical device includes a pair of actuable jaws. A first electrode member which usually includes a line of electrically coupled tissue penetrating elements is formed on one of the jaws, and a second electrode member which usually includes a line of electrically coupled tissue penetrating elements is formed on the same or the other jaw. The electrode members are laterally spaced-apart and arranged in a parallel, usually linear manner so that the lateral distance therebetween remains generally constant. In operation, tissue may be grasped between the jaws so that the electrode members contact and/or the tissue penetrating elements enter into the tissue. By energizing the electrode members at opposite polarities using a high frequency energy source, tissue between the jaws will be heated, coagulated, and/or necrosed, while heating of tissue outside of the lines will be minimized.

49 Claims, 6 Drawing Sheets

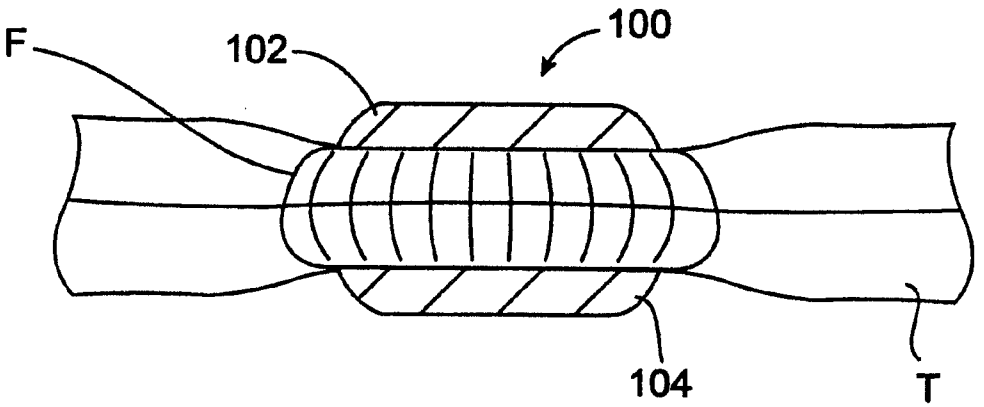


U.S. PATENT DOCUMENTS

5,352,235	10/1994	Koros et al. .	
5,356,408	10/1994	Rydell .	
5,383,876	1/1995	Nardella .	
5,391,166	2/1995	Eggers .	
5,395,369	3/1995	McBrayer et al. .	
5,396,900	3/1995	Slater et al. .	
5,403,312	4/1995	Yates et al. .	
5,417,687	5/1995	Nardella et al. .	
5,423,814	6/1995	Zhu et al. .	
5,443,463	8/1995	Stern et al. .	
5,445,638	8/1995	Rydell et al. .	
5,456,684	10/1995	Schmidt et al. .	
5,458,598	10/1995	Feinberg et al. .	
5,462,546	10/1995	Rydell .	
5,469,312	11/1995	Klicek .	
5,482,054	1/1996	Slater et al. .	
5,484,435	1/1996	Fleenor et al. .	
5,484,436	1/1996	Eggers et al. .	
5,496,317	3/1996	Goble et al. .	
5,514,134	5/1996	Rydell et al. .	
5,527,313	6/1996	Scott et al.	606/51
5,531,744	7/1996	Nardella et al. .	
5,540,684	7/1996	Hassler, Jr. .	
5,540,685	7/1996	Parins et al. .	
5,542,945	8/1996	Fritzsch .	
5,549,606	8/1996	McBrayer et al. .	
5,558,100	9/1996	Cox .	
5,558,671	9/1996	Yates .	
5,569,243	10/1996	Kortenbach et al. .	
5,573,535	11/1996	Viklund .	
5,578,052	11/1996	Koros et al. .	
5,599,350	2/1997	Schulze et al. .	
5,603,711	2/1997	Parins et al. .	
5,624,452	4/1997	Yates .	
5,626,578	5/1997	Tihon .	
5,637,110	6/1997	Pennybacker et al. .	
5,637,111	6/1997	Sutcu et al. .	
5,658,281	8/1997	Heard .	
5,662,680	9/1997	Desai .	
5,665,085	9/1997	Nardella .	
5,665,100	9/1997	Yoon .	
5,667,526	9/1997	Levin .	
5,669,907	9/1997	Platt, Jr. et al. .	
5,674,184	10/1997	Hassler, Jr. .	
5,674,220	10/1997	Fox et al. .	
5,681,282	10/1997	Eggers et al. .	
5,683,385	11/1997	Kortenbach et al. .	
5,683,388	11/1997	Slater .	
5,688,270	11/1997	Yates et al. .	
5,693,051	12/1997	Schulze et al. .	
5,697,949	12/1997	Giurtino et al. .	
5,700,261	12/1997	Brinkerhoff .	
5,702,390	12/1997	Austin et al. .	
5,707,369	1/1998	Vaitekunas et al. .	
5,709,680	1/1998	Yates et al. .	
5,713,896	2/1998	Nardella .	
5,718,703	2/1998	Chin .	
5,733,283	3/1998	Malis et al. .	
5,735,848	4/1998	Yates et al. .	
5,735,849	4/1998	Baden et al. .	
5,741,285	4/1998	McBrayer et al. .	
5,743,906	4/1998	Parins et al. .	
5,755,717	5/1998	Yates et al. .	
5,891,142	4/1999	Eggers et al.	606/51



(PRIOR ART)
FIG. 1A



(PRIOR ART)
FIG. 1B

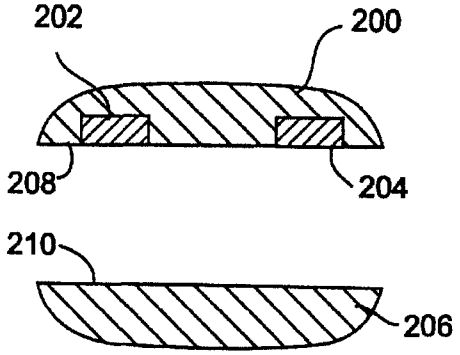


FIG. 2A

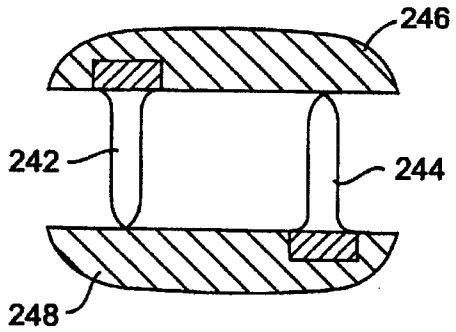


FIG. 2D

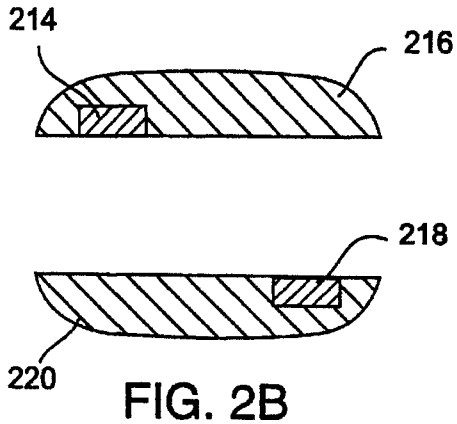


FIG. 2B

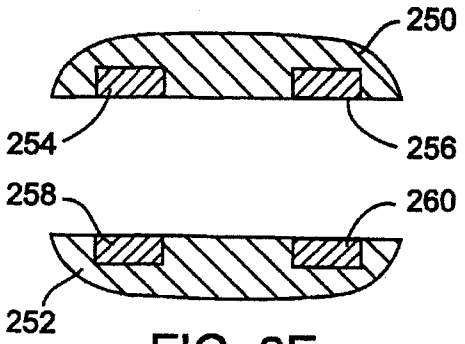


FIG. 2E

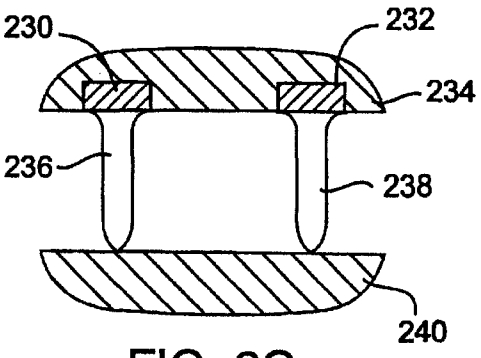


FIG. 2C

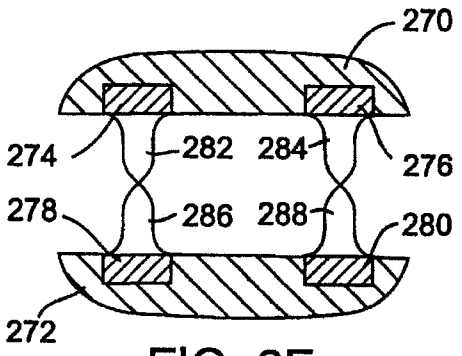


FIG. 2F

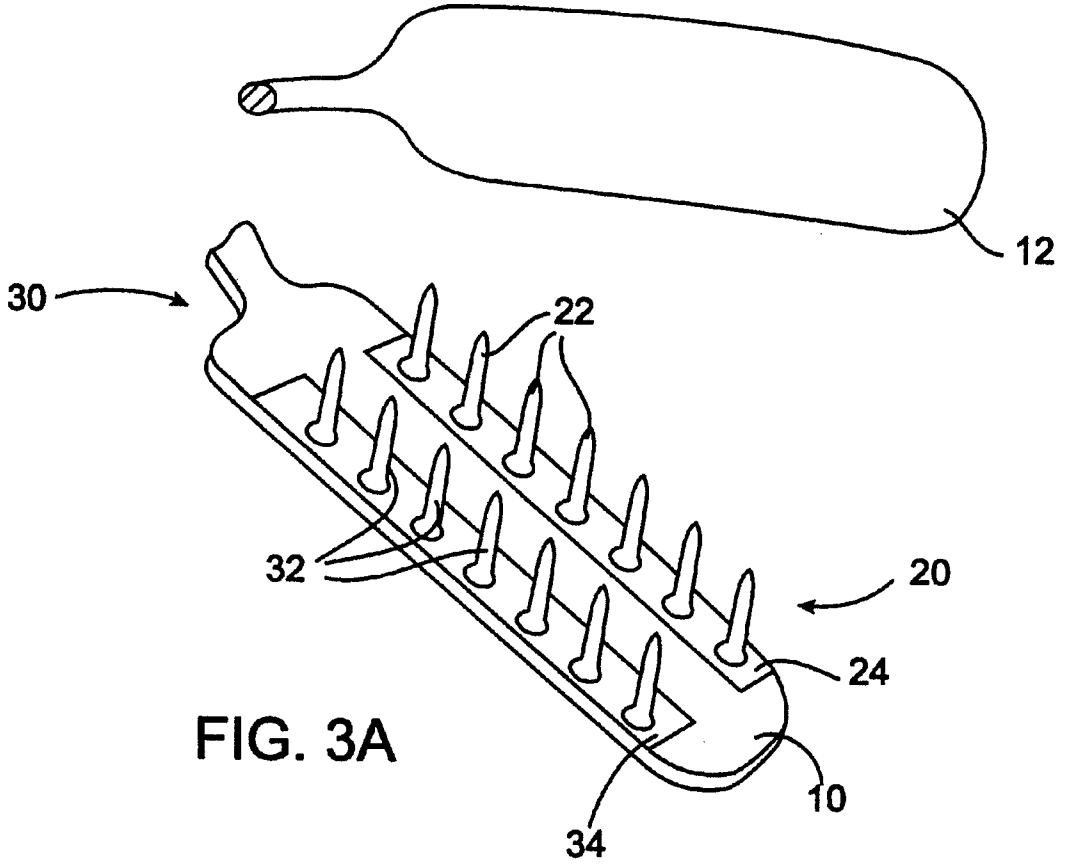


FIG. 3A

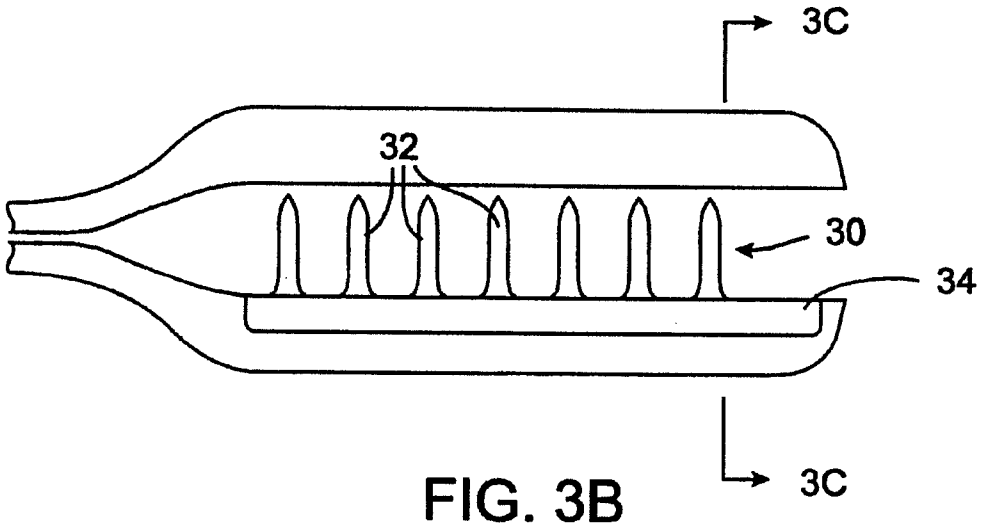


FIG. 3B

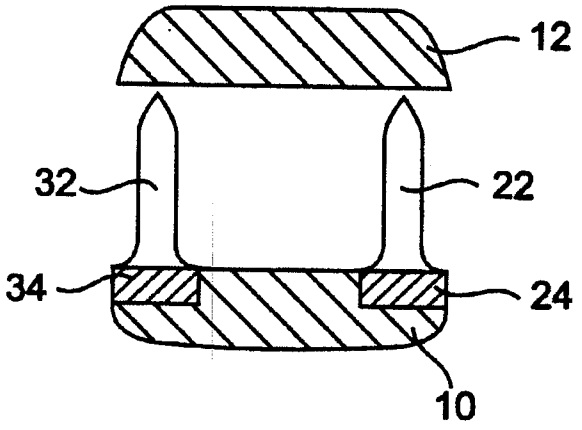


FIG. 3C

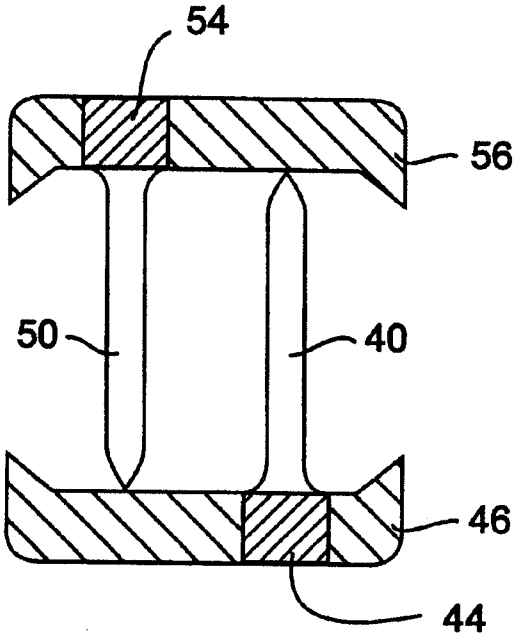


FIG. 4

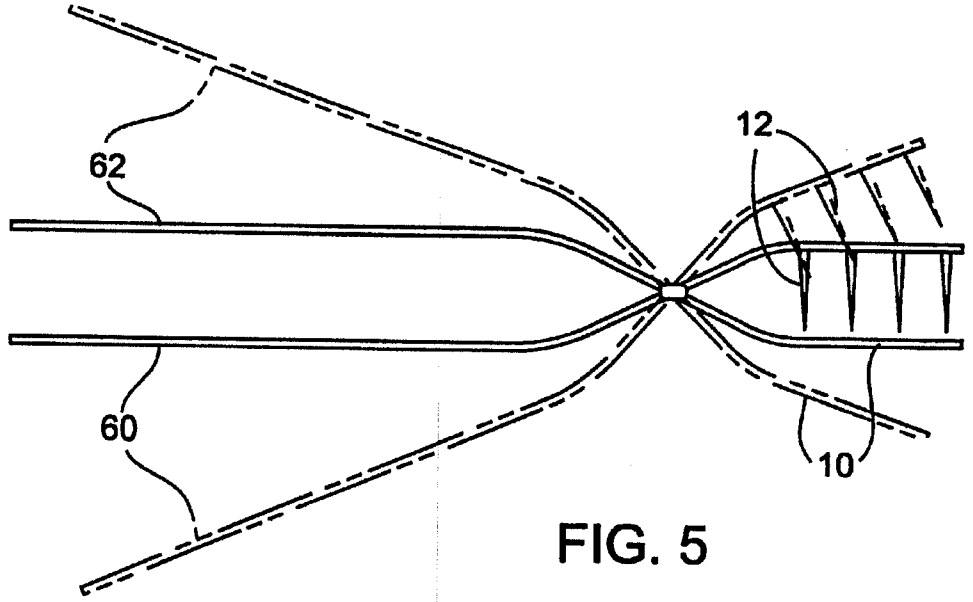


FIG. 5

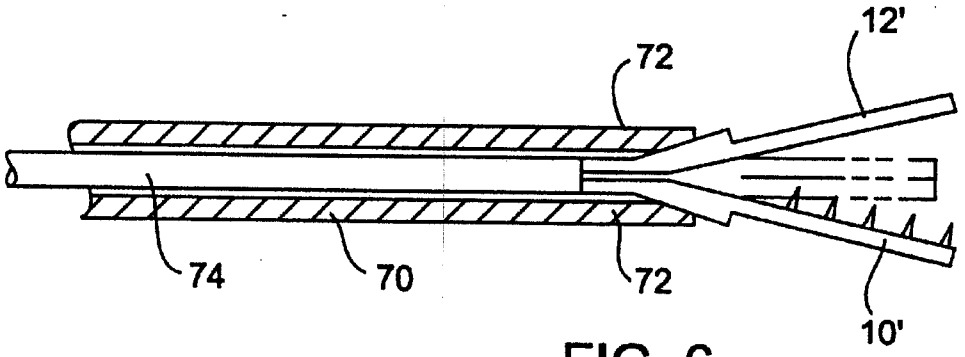


FIG. 6

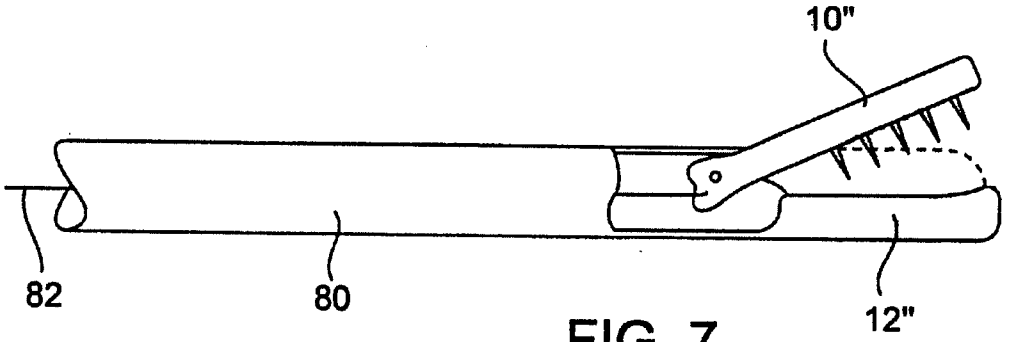


FIG. 7

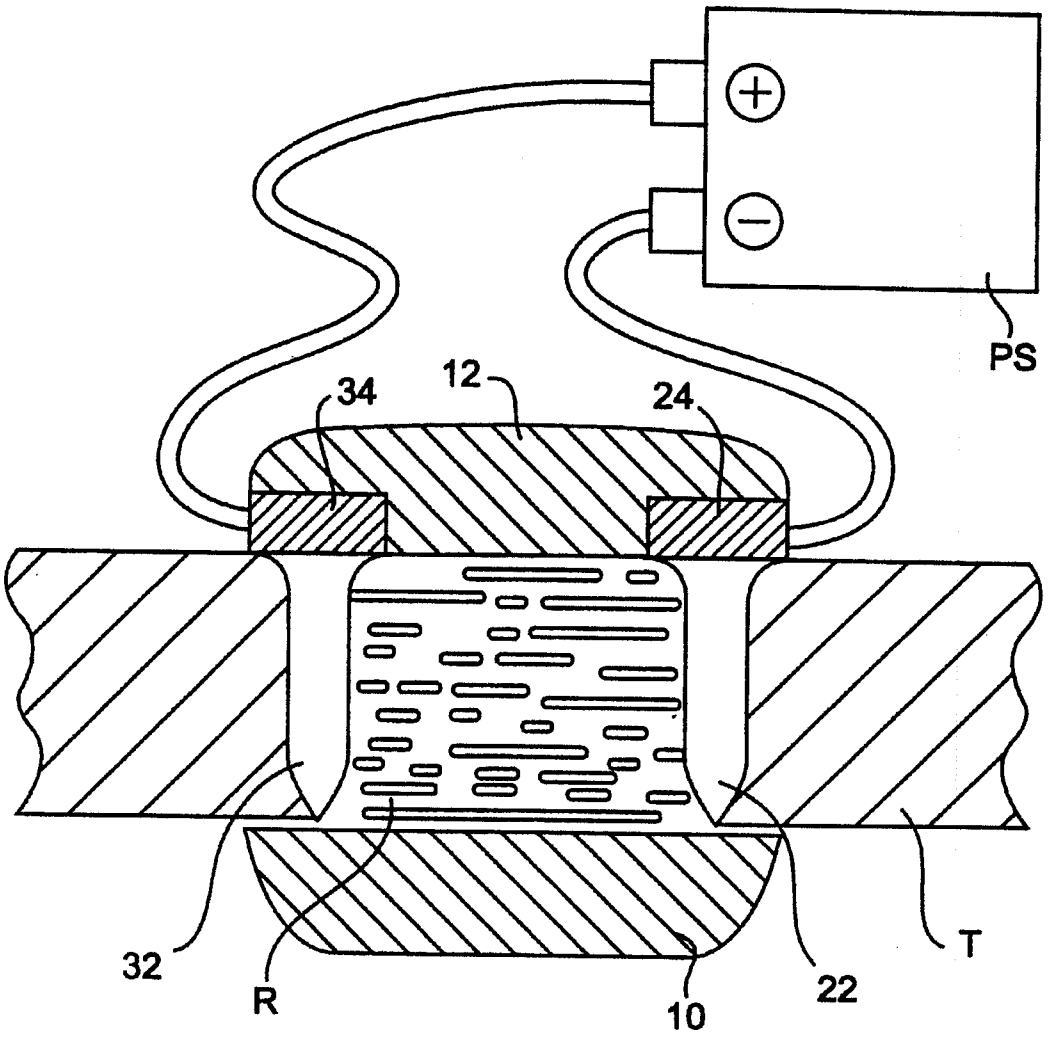


FIG. 8

BIPOLAR SURGICAL INSTRUMENTS HAVING FOCUSED ELECTRICAL FIELDS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical devices and methods. More particularly, the present invention relates to the structure and use of bipolar forceps and other instruments for coagulating, cutting, and necrosing tissue.

Electrosurgery refers broadly to a class of medical procedures which rely on the application of high frequency electrical energy, usually radio frequency energy, to patient tissue to achieve a number of possible effects, such as cutting, coagulation, hyperthermia, necrosis, and the like. Of particular interest to the present invention, bipolar electrosurgical devices rely on contacting electrodes of different polarity in close proximity to each other against or into tissue. For example, bipolar forceps **100** (FIGS. **1** and **2**) have been used for cutting and coagulating tissue, where the opposed jaws **102** and **104** of the forceps are connected to different poles of an electrosurgical power supply. The high frequency electrical current thus flows from one jaw to the other through the tissue present therebetween. Use of such bipolar forceps is effective for a number of purposes and advantageous in that its effect is generally limited to the tissue held between the jaws. Heating, however, is not totally limited to such intermediate tissue, and in some instances heating of adjacent tissues can be problematic. Such heating occurs because the current flows not only between the jaws but also laterally outward, as shown by flux lines F in FIG. 1B.

Various improvements to bipolar forceps have been proposed. For example, the placement of pins or other tissue-penetrating elements onto the tissue-engaging surface(s) of either or both jaws has been suggested for a variety of purposes. Regardless of the intended purpose, the placement of tissue-penetrating elements on the jaw(s) can marginally focus the current density and somewhat lessen heating of adjacent tissues. Such prior designs employing tissue-penetrating elements, however, still cause unwanted heating of adjacent tissues in at least certain circumstances.

A second problem with conventional bipolar forceps is limited power delivery. With conventional forceps, jaws having a length of about 20 mm and a width of about 5 mm can usually deliver only 25 W of current without causing charring of the tissue. Charring greatly increases electrical resistance through the tissue and can result in premature termination of the treatment. With such a low power level, the time to fully coagulate the tissue can be excessive.

It would therefore be desirable to provide still further improved bipolar forceps and other electrosurgical device designs. In particular, it would be desirable to provide bipolar forceps which provide a very high degree of focused heating, i.e., provide heating of tissue between the jaws with minimized heating of tissue adjacent to the jaws. It would be further desirable to provide bipolar forceps which can deliver higher current flows and densities to the tissue being treated without charring the tissue and terminating the current flow. Such device designs should be relatively simple and easy to fabricate. The devices and methods should be compatible with conventional electrosurgical power supplies and usable in a wide variety of procedures, including cutting, coagulation, and necrosis, where the localized and specific heating of patient tissues is desired. At least some of these objectives will be met by the invention described hereinafter.

2. Description of the Background Art

Bipolar forceps having penetrating elements on opposed jaws thereof are described in U.S. Pat. Nos. 5,527,313 and 5,217,460; Soviet Union Patent Publication SU197711; and French Patent No. 598,149. A radio frequency tumor heating device comprising parallel electrode arrays of opposite polarity is described in U.S. Pat. No. 4,016,886.

SUMMARY OF THE INVENTION

The present invention provides improved bipolar surgical instruments, such as forceps, graspers, or the like, which comprise a pair of opposed jaws at the distal end of a shaft. The present invention is directed at a unique electrode configuration on either or both of the jaws which will provide improved current focussing characteristics and lessened heating of adjacent tissues. In particular, electrode members on either or both of the jaws will be laterally spaced apart from each other when the jaws are closed so that current will flow from one electrode to the other with minimum current flow outside of the region defined between the electrodes. optionally, a pair of electrodes can be provided on each jaw with a positive and negative electrode on one jaw and a positive and negative electrode on the other jaw, with the two positive electrodes and the two negative electrodes being aligned with each other when the jaws are closed to defined the desired focussed current flow.

Preferably, at least one of the electrode members will include tissue penetrating elements. Usually a first line of electrically coupled tissue penetrating elements will be provided on a first electrode member, and a second line of electrically coupled tissue penetrating elements will be provided on a second electrode member. Third and fourth lines of electrically coupled tissue penetrating elements will preferably be provided when third and fourth electrode members are provided on the instrument. The first and second lines (and optionally third and fourth lines) of tissue penetrating elements will be electrically isolated from each other to permit energization in a bipolar manner, i.e., each line of electrically coupled tissue penetrating elements may be separately connected to the opposite pole of a conventional electrosurgical power supply. The shaft includes or comprises an actuating mechanism for moving the jaws between opened and closed configurations, where the lines of tissue penetrating elements lie parallel to and spaced-apart from each other when the jaws are closed. In this way, the jaws can be closed on a target tissue structure, such as a fallopian tube, artery, vein, and the like, in order to penetrate the lines of elements into the tissue. By then applying high frequency electrical energy to the lines in a bipolar manner, current flux will be focused to within that portion of the tissue which lies between the adjacent lines, with minimum heating of tissue outside of the parallel lines. Usually, but not necessarily, the lines will both be straight. Alternatively, the lines could be nonlinear, e.g., curved, serpentine, zig-zag, or the like, so long as the patterns are similar and the lateral spacing between adjacent points on the lines remains substantially constant. Preferably, the spacing between the adjacent lines of tissue penetrating elements will be in the range from 0.5 mm to 10 mm, more preferably from 2 mm to 5 mm.

The lines of tissue penetrating elements may be on the same jaw or on different jaws. When the lines are on the same jaw, it is necessary to provide insulation so that each line is electrically isolated from the other, while the plurality of tissue penetrating elements in an individual line remain electrically coupled. Electrical conductors will be provided

within the shaft in order to permit attachment of each line to opposite polarity connections on an electrosurgical power supply. When present on different jaws, the lines of tissue penetrating elements may be isolated from each other by maintaining appropriate electrical isolation between the jaws and/or at either or both ends of the tissue penetrating elements.

The tissue penetrating elements may have a wide variety of different configurations. Most commonly, they will be in the form of a pin or other rod-like tissue-penetrating electrode, usually having a sharpened distal end to facilitate penetration into tissue. Alternatively, an appropriate cutting current could be applied to the electrodes in order to facilitate tissue penetration while the jaws are being closed. Each line of tissue penetrating elements may contain from 2 to 50 individual elements, usually from 6 to 10. The elements may extend over a length on the jaw(s) in the range from 1 mm to 10 mm, usually from 2 mm to 5 mm, with spacing between individual elements being in the range from 0.5 mm to 3 mm, usually from 0.5 mm to 2 mm. The height of the tissue penetrating elements (corresponding to the depth of tissue penetration) will usually be in the range from 1 mm to 10 mm, preferably from 2 mm to 5 mm, while the diameter of the elements will typically from 0.1 mm to 10 mm, usually from 0.5 mm to 0.5 mm.

Optionally, either or both of the jaws may be perforated or otherwise provided with passages in order to permit the release of steam which is a byproduct of tissue heating. A mechanism will be provided on the shaft for actuating the jaws, i.e., opening and closing the jaws so that they may grasp tissue therebetween. Exemplary actuating mechanisms include scissors, camming mechanisms, linear/pivot actuators, and the like.

Methods according to the present invention rely on grasping tissue between a first jaw and a second jaw. A high frequency energy is then applied between a first line of tissue penetrating elements on one of the jaws and a second line of tissue penetrating elements on the same or a different jaw. The tissue penetrating element lines are parallel and spaced-apart from each other, generally as described above. The high frequency energy will preferably be applied to the tissue at a level and for a time sufficient to necrose substantially all tissue between the lines without causing substantial damage to other tissue, i.e., tissue outside of the lines. Typically, the high frequency energy will be applied at a frequency in the range from 100 kHz to 1 MHz, preferably from 400 kHz to 500 kHz. The energy will be applied at a power from 25 W to 200 W, preferably from 50 W to 100 W, and for a time in the range from 5 seconds to 5 minutes, usually from 10 seconds to 40 minutes.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1A** and **1B** illustrate use of conventional bipolar forceps for coagulating a tubular structure in the body.

FIGS. **2A–2F** illustrate a plurality of alternative electrode configurations according to the method of the present invention.

FIG. **3A** is a perspective view of a pair of actuable jaws carrying two lines of electrically coupled tissue penetrating elements in accordance with the principles of the present invention.

FIG. **3B** is a side, elevational view of the jaws of FIG. **1**, shown with the jaws closed.

FIG. **3C** is a cross-sectional view taken along line **3—3** of FIG. **2**.

FIG. **4** is an alternative cross-sectional view of a pair of jaws constructed in accordance with the principles of the present invention.

FIG. **5** illustrates a scissors-type actuating mechanism that can be used with the jaws of FIG. **1**.

FIG. **6** illustrates a pair of resiliently-mounted jaws that can be opened and closed with a cam surface, where the jaws incorporate tissue-penetrating elements according to the principles of the present invention.

FIG. **7** illustrates an alternative jaw actuating mechanism which may be utilized in the devices of the present invention.

FIG. **8** illustrates use of the jaws of FIG. **1** in treating tissue according to the method of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

According to the present invention, bipolar surgical instruments will include at least two and up to four or more laterally spaced-apart electrode members disposed on a pair of actuable jaws. By properly positioning the electrode members relative to each other, radio frequency energy applied to tissue disposed between the jaws can be focused within a well-defined region between the electrode members. In contrast to prior art devices and methods, where electrodes of opposite polarity are generally engaged against directly opposed tissue surfaces, the present invention will position at least one positive electrode and at least one negative electrode on and/or into laterally spaced-apart sites on opposed tissue surfaces.

The electrode members may be configured in a wide variety of patterns and designs, some of which are illustrated in FIGS. **2A–2E**. Most simply, one jaw **200** may carry a first electrode member **202** which is laterally spaced-apart from a second electrode member **204**, where the electrode members are connectable to opposite poles of a power supply. An opposed jaw **206** may be free from electrodes of any sort. The jaws **200** and **206** will be actuable, as described in more detail hereinafter, so the tissue may be grasped between two opposed tissue-engaging surfaces **208** and **210**. When tissue is grabbed between the jaws **200** and **206**, current flow will be generally limited to between the electrode members **202** and **204**.

While the electrode member configuration of FIG. **2A** is functional, the current flow pattern between the electrodes can be improved by having a first electrode member **214** on a first jaw **216** and a second electrode member **218** on a second jaw **220** as illustrated in FIG. **2B**. As with the configuration of FIG. **2A**, the electrode members **214** and **218** of FIG. **2B** will generally limit current flow so that it does not extend significantly to tissue outside the lateral boundaries of the jaws **216** and **220**. By placing the electrode members **214** and **218** on opposed jaws, enhanced current flow through the tissue may be achieved.

A further alternative improved configuration of the electrode members according to the present invention is illustrated in FIG. **2C**. First electrode member **230** and second electrode member **232** are each carried on a first jaw **234**, in a manner similar to the embodiment of FIG. **2A**. The electrode members **230** and **232**, however, each include a line of tissue-penetrating elements thereon. The electrode members **202** and **204** in FIG. **2A** are generally linear electrodes having a width and length within the ranges set forth above. Such electrodes will form a flat contact or interface with the tissue which is engaged between the jaws **200** and **206**. By providing tissue-penetrating elements **236** and **238**, as illustrated in FIG. **2C**, two advantages are achieved. First, the total electrode area in contact with the tissue can be greatly enhanced, typically from two-fold to

10-fold, or greater. Moreover, by extending the electrode "boundaries" into the tissue, the ability to achieve uniform current flux within the tissue is improved and the containment of that current flux within the target region is also enhanced. The embodiment of FIG. **2C** will include an opposed jaw **240** which is free from electrodes.

A slightly modified configuration for tissue penetrating elements **242** and **244** is illustrated in FIG. **2D**. Instead of carrying both lines of tissue penetrating elements **242** and **244** on a single jaw, the first line **242** is carried on an upper jaw **246** and the second line **244** is carried on a lower jaw **248**. The advantages regarding increased electrode area and current flux containment, however, are generally comparable to those achieved with the embodiment of FIG. **2C**.

Yet another alternative for the electrode member configuration is illustrated in FIG. **2E**. Jaws **250** and **252** each carry pairs of laterally spaced-apart members **254, 256, 258** and **260**. The electrode members can be adapted for connection to a power supply so that laterally spaced-apart pairs of electrodes will have opposite polarity when the instrument is powered. For example, electrodes **254** and **258** may have a first polarity while electrodes **256** and **260** may have a second polarity. Alternatively, but less preferably, electrodes **254** and **260** may have a first polarity while electrodes **258** and **256** may have a second polarity. The latter configuration will be generally less effective at containing current flow than the former configuration since pairs of oppositely energized electrodes will directly oppose each other when the instrument is engaged against tissue.

Yet another electrode configuration is illustrated in FIG. **2F**. There, each jaw **270** and **272** carries a pair of electrode members **274, 276, 278, 280**. Each of the electrode members, in turn, carries a line of tissue-penetrating elements **282, 284, 286, 288**. The tissue-penetrating elements are arranged so that their distal tips will engage each other when the jaws **270** and **272** are closed together. Opposed pairs of electrode members **274/278** and **276/280** will have the same polarity, i.e. the laterally spaced-apart pairs will be of opposite polarity. In many ways, the operation of the embodiment of FIG. **2F** will be the same as that of both FIG. **2C** and FIG. **2D**. The embodiment of FIG. **2F** may also be modified by axially spacing apart the opposed penetrating elements **282/286** and **284/288** so that the elements penetrate fully to the opposed jaw **270** or **272**. A variety of other electrode modifications will also be possible within the scope and spirit of the present invention.

Referring now to FIGS. **3A–3C**, a first exemplary pair of jaws **10** and **12** which may be utilized for grasping tissue and applying high frequency energy according to the methods of the present invention will be described. The jaws **10** and **12** will be actuable or reciprocatable in a manner conventional for forceps, graspers, and other similar types of medical devices. Specific shaft designs which provide for such actuation will be described hereinafter in connection with FIGS. **5–7**.

A first line **20** comprising seven tissue penetrating pins **22** is disposed on one side of the lower jaw **10** and a second line **30** of tissue penetrating pins **32** is disposed on the other side of the lower jaw. The first line **20** of pins **22** is electrically coupled by an electrically conductive strip **24** into which the pins are attached. Similarly, a second electrically conductive strip **34** is disposed on the other side of the jaw and electrically couples the second line **30** of pins **32**. Each of the electrically conductive strips **24** and **32** will be attached to conductors (not shown) which extend proximally down the shaft of the device and which provide for electrical attachment of the lines **20** and **30** to a conventional electrosurgical power supply.

The electrically conductive strips **24** and **34** will be electrically isolated from each other. For example, the strips **24** and **34** may be imbedded in an insulating material, such as a ceramic, plastic, or the like. Alternatively, an insulating layer may be formed around the strips **24** so that they are electrically isolated from the lower jaw **10**. The upper jaw **12** may also be formed from a ceramic or other electrically insulating material to assure that the pins **22** and **32** are not shorted by contact with the upper jaw. The pins **22** and **32** and strips **24** and **34** will be formed from an electrically conductive material, typically a metal such as stainless steel, gold, silver, or the like. The dimensions, number, spacing, and other characteristics of the pins **22** and **32** will be within the ranges set forth above. While shown in a straight line, the pins **22** and **32** could also be arranged in the other patterns set forth above.

The embodiment of FIGS. **3A–3C** shows both lines **20** and **30** of tissue penetrating elements **22** and **32** being connected to the same jaw. The present invention would also cover embodiments where the lines of tissue penetrating elements are connected to opposite jaws, as shown in FIG. **4**. There, a first line of pins **40** are mounted within a conductive strip **44** in a lower jaw **46**, while a second line of tissue penetrating elements **50** are mounted in an electrically conductive strip **54** in an upper jaw **56**. The individual tissue penetrating elements **40** and **50** are thus coupled to each other within each line, but the two lines are electrically isolated, so that the result is a pair of electrically isolated lines of tissue penetrating elements, as with the first embodiment.

Referring now to FIGS. **5–7**, the present invention can rely on virtually any jaw-actuating mechanism of a type utilized in medical devices. For example, the mechanism can be a simple scissors mechanism, as shown in FIG. **5**, where the jaws **10** and **12** are pivotally connected to actuating levers **60** and **62**. Opening and closing of the levers **60** and **62** will open and close the jaws in a conventional manner.

Jaws **10'** and **12'** can also be mounted within a hollow tube **70** having cam surfaces **72** formed at its distal end. The jaws **10'** and **12'** are resiliently mounted on a rod **74** so that the jaws may be axially translated relative to the cam surfaces **72** to open the jaws (as shown in full line) and close the jaws (as shown in broken line) in FIG. **6**.

As a third common alternative, jaws **10"** and **12"** may be formed at the distal end of a tubular actuator **80**. The jaw **10"** which is free from tissue penetrating elements is integrally formed at the end of the tube **80**. The moveable jaw **10"** having the tissue penetrating elements is pivotally attached and is actuated by a rod **74** or cable **82** extending to a proximal end of the device (not shown).

The assemblies of FIGS. **6** and **7** may be manually operated by conventional proximal assemblies (not shown), such as three-ring actuators, pistol grips, or any other actuator which permits linear movement of the rod **74** or cable **82**. The devices of FIGS. **6** and **7** would be particularly useful for laparoscopic, thoracoscopic, arthroscopic, or other procedures where they are to be introduced through narrow diameter cannulas, typically having shaft diameters below 12 mm, more typically below 10 mm, and sometimes 5 mm or smaller.

Referring now to FIG. **8**, use of the jaws **10** and **12** of FIGS. **1–3** for treating tissue T is illustrated. The jaws **10** and **12** are actuated to grasp a tissue structure, such as an artery, vein, fallopian tube, ligament, or other tubular or elongate structure therebetween. The tissue penetrating elements **22** and **32** pierce and penetrate into the tissue T to create a

region R therebetween. The electrically conductive strips **24** and **34** are attached to an external power supply PS so that they may be energized with opposite polarities. Suitable power supplies are available from commercial suppliers, such as Valleylab, Aspen, and Bovie. The power supplies may operate with conventional sinusoidal or non-sinusoidal wave forms and may operate at fixed or controlled power levels, where voltage, current, or both may be selected. When energized at the power levels, frequencies, and durations described above, the tissue region R between the lines of penetrating elements **22** and **32** will receive a high flux of energy, causing heating, coagulation, and optionally necrosis of the tissue. Heating of the adjacent tissues outside of this region R is minimal.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A bipolar surgical instrument comprising:

a shaft having a proximal end and a distal end;

a pair of opposed jaws at the distal end of the shaft;

a first electrode member on one of the jaws;

a second electrode member on one of the jaws, wherein the first and second electrode members are electrically isolated from each other; and

an actuating mechanism for moving the jaws between an opened and closed configuration, wherein electrode members lie parallel to and laterally spaced-apart from each other when the jaws are closed, wherein at least one of the electrode members comprises a plurality of tissue penetrating elements which project toward the opposed jaw.

2. A bipolar surgical instrument as in claim **1**, wherein the electrode members are laterally spaced-apart by a distance in the range from 0.5 mm to 10 mm.

3. A bipolar surgical instrument as in claim **1**, wherein the electrode members have a length in the range from 5 mm to 30 mm and a width from 0.5 mm to 5 mm.

4. A bipolar surgical instrument as in claim **1**, wherein electrode members are on the same jaw.

5. A bipolar surgical instrument as in claim **1**, wherein the first electrode member is on one jaw and the second electrode member is on the other jaw.

6. A bipolar surgical instrument as in claim **1**, wherein both electrode members comprise a plurality of tissue penetrating elements which project toward the opposed jaw.

7. A bipolar surgical instrument as in claim **1**, wherein the tissue penetrating elements have a length in the range from 1 mm to 6 mm and a diameter in the range from 0.1 mm to 1 mm.

8. A bipolar surgical instrument as in claim **6**, wherein the first and second electrode members each comprise from 5 to 20 tissue penetrating elements.

9. A bipolar surgical instrument as in claim **8**, wherein the tissue-penetrating elements are arranged in two straight lines which are parallel to each other when the jaws are closed over tissue.

10. A bipolar surgical instrument as in claim **1**, further comprising a third electrode member aligned with the first electrode member but disposed on the other jaw and a fourth electrode member aligned with the second electrode member but disposed on the other jaw.

11. A bipolar surgical instrument as in claim **1**, wherein at least one of the jaws is perforated to permit the release of steam during use.

12. A bipolar surgical instrument as in claim **1**, wherein the actuating mechanism comprises scissors, a camming mechanism, or a linear/pivot actuator.

13. A method for applying high frequency electrical energy to tissue, said method comprising:

grasping tissue between first jaw and a second jaw;

applying high frequency energy between a first electrode member comprising a first line of tissue-penetrating elements on one of said jaws and a second electrode member comprising a second line of tissue-penetrating elements on one of said jaws, wherein said lines of tissue penetrating elements are parallel to and laterally spaced-apart from each other when grasping the tissue.

14. A method as in claim **13**, wherein the high frequency energy is applied at a level and for a time sufficient to necrose substantially all tissue between said electrode members without causing substantial damage to other tissue.

15. A method as in claim **14**, wherein the high frequency energy has a frequency from 100 kHz to 1 MHz, a power level from 25 W to 200 W, and is applied for a time from 5 seconds to 5 minutes.

16. A method as in claim **13**, wherein the electrode members are laterally spaced-apart by a distance in the range from 0.5 mm to 10 mm.

17. A method as in claim **13**, wherein the electrode members have a length in the range from 5 mm to 30 mm and a width from 0.5 mm to 5 mm.

18. A method as in claim **13**, wherein both electrode members are on the same jaw.

19. A method as in claim **13**, wherein the first electrode member is on one jaw and the second electrode member is on the other jaw.

20. A method as in claim **13**, wherein at least one of the electrode members comprises a plurality of tissue penetrating elements which project toward the opposed jaw.

21. A method as in claim **19**, wherein the tissue penetrating elements have a length from 1 mm to 6 mm and a diameter in the range from 0.1 mm to 1 mm.

22. A method as in claims **21**, wherein the first and second electrode members each comprise from 5 to 20 tissue-penetrating elements.

23. A method as in claims **20**, wherein the tissue penetrating elements are arranged in two straight lines which are parallel to each other when the jaws are closed over the tissue.

24. A methods as in claim **20**, wherein the energy is further applied between a third electrode member aligned with the first electrode member but disposed on the other jaw and a fourth electrode member aligned with the second electrode member but disposed on the other jaw.

25. A method as in claim **13**, wherein at least one of the jaws is perforated to permit the release of steam during use.

26. A bipolar surgical instrument comprising:

a shaft having a proximal end and a distal end;

a pair of opposed jaws at the distal end of the shaft;

a first electrode member on one of the jaws;

a second electrode member on one of the jaws, wherein the first and second electrode members are electrically isolated from each other;

a third electrode member aligned with the first electrode member but disposed on the other jaw and a fourth electrode member aligned with the second electrode member but disposed on the other jaw; and

an actuating mechanism for moving the jaws between an opened and closed configuration, wherein electrode members lie parallel to and laterally spaced-apart from each other when the jaws are closed.

27. A bipolar surgical instrument as in claim 26, wherein the electrode members are laterally spaced-apart by a distance in the range from 0.5 mm to 10 mm.

28. A bipolar surgical instrument as in claim 26, wherein the electrode members have a length in the range from 5 mm to 30 mm and a width from 0.5 mm to 5 mm.

29. A bipolar surgical instrument as in claim 26, wherein electrode members are on the same jaw.

30. A bipolar surgical instrument as in claim 26, wherein the first electrode member is on one jaw and the second electrode member is on the other jaw.

31. A bipolar surgical instrument as in claim 26, wherein at least one of the electrode members comprises a plurality of tissue penetrating elements which project toward the opposed jaw.

32. A bipolar surgical instrument as in claim 26, wherein both electrode members comprise a plurality of tissue penetrating elements which project toward the opposed jaw.

33. A bipolar surgical instrument as in claim 31, wherein the tissue penetrating elements have a length in the range from 1 mm to 6 mm and a diameter in the range from 0.1 mm to 1 mm.

34. A bipolar surgical instrument as in claim 32, wherein the first and second electrode members each comprise from 5 to 20 tissue-penetrating elements.

35. A bipolar surgical instrument as in claim 34, wherein the tissue-penetrating elements are arranged in two straight lines which are parallel to each other when the jaws are closed over tissue.

36. A bipolar surgical instrument as in claim 26, wherein at least one of the jaws is perforated to permit the release of steam during use.

37. A bipolar surgical instrument as in claim 26, wherein the actuating mechanism comprises scissors, a camming mechanism, or a linear/pivot actuator.

38. A bipolar surgical instrument comprising:

a shaft having a proximal end and a distal end;

a pair of opposed jaws at the distal end of the shaft;

a first electrode member on one of the jaws;

a second electrode member on one of the jaws, wherein the first and second electrode members are electrically isolated from each other;

wherein at least one of the jaws is perforated to permit the release of steam during use; and

an actuating mechanism for moving the jaws between an opened and closed configuration, wherein electrode members lie parallel to and laterally spaced-apart from each other when the jaws are closed.

39. A bipolar surgical instrument as in claim 38, wherein the electrode members are laterally spaced-apart by a distance in the range from 0.5 mm to 10 mm.

40. A bipolar surgical instrument as in claim 38, wherein the electrode members have a length in the range from 5 mm to 30 mm and a width from 0.5 mm to 5 mm.

41. A bipolar surgical instrument as in claim 38, wherein electrode members are on the same jaw.

42. A bipolar surgical instrument as in claim 38, wherein the first electrode member is on one jaw and the second electrode member is on the other jaw.

43. A bipolar surgical instrument as in claim 38, wherein at least one of the electrode members comprises a plurality of tissue penetrating elements which project toward the opposed jaw.

44. A bipolar surgical instrument as in claim 38, wherein both electrode members comprise a plurality of tissue penetrating elements which project toward the opposed jaw.

45. A bipolar surgical instrument as in claim 43, wherein the tissue penetrating elements have a length in the range from 1 mm to 6 mm and a diameter in the range from 0.1 mm to 1 mm.

46. A bipolar surgical instrument as in claim 44, wherein the first and second electrode members each comprise from 5 to 20 tissue-penetrating elements.

47. A bipolar surgical instrument as in claim 46, wherein the tissue-penetrating elements are arranged in two straight lines which are parallel to each other when the jaws are closed over tissue.

48. A bipolar surgical instrument as in claim 38, further comprising a third electrode member aligned with the first electrode member but disposed on the other jaw and a fourth electrode member aligned with the second electrode member but disposed on the other jaw.

49. A bipolar surgical instrument as in claim 38, wherein the actuating mechanism comprises scissors, a camming mechanism, or a linear/pivot actuator.

* * * * *

EXHIBIT B

US006682527B2

(12) **United States Patent**
Strul

(10) **Patent No.: US 6,682,527 B2**
(45) **Date of Patent: Jan. 27, 2004**

(54) **METHOD AND SYSTEM FOR HEATING TISSUE WITH A BIPOLAR INSTRUMENT**

(75) Inventor: **Bruno Strul**, Portola Valley, CA (US)

(73) Assignee: **Perfect Surgical Techniques, Inc.**, Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 506 days.

(21) Appl. No.: **09/808,096**

(22) Filed: **Mar. 13, 2001**

(65) **Prior Publication Data**

US 2002/0133152 A1 Sep. 19, 2002

(51) **Int. Cl.**[7] **A61B 18/18**

(52) **U.S. Cl.** **606/51**; 606/52; 606/34; 606/38

(58) **Field of Search** 606/51, 33, 45, 606/52, 34, 41, 48, 49, 50, 37, 38

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,016,886	A	4/1977	Doss et al.
4,043,342	A	8/1977	Morrison, Jr.
5,098,431	A	3/1992	Rydell
5,151,102	A	9/1992	Kamiyama et al.
5,217,460	A	6/1993	Knoepfler
5,370,645	A	12/1994	Klicek et al.
5,383,876	A	1/1995	Nardella
5,403,312	A	4/1995	Yates et al.
5,437,664	A	8/1995	Cohen et al.
5,441,499	A	8/1995	Fritzsch
5,445,638	A	8/1995	Rydell et al.
5,496,312	A	3/1996	Klicek
5,514,129	A	5/1996	Smith
5,527,313	A	6/1996	Scott et al.
5,556,396	A	9/1996	Cohen et al.
5,558,671	A	9/1996	Yates
5,582,611	A	12/1996	Tsuruta et al.
5,599,344	A	2/1997	Paterson
5,655,085	A	8/1997	Ryan et al.
5,662,680	A	9/1997	Desai
5,688,270	A	11/1997	Yates et al.
5,693,051	A	12/1997	Schulze et al.
5,695,494	A	12/1997	Becker
5,702,390	A	12/1997	Austin et al.
5,772,659	A	6/1998	Becker et al.
5,776,130	A	7/1998	Buysse et al.
5,797,941	A	8/1998	Schulze et al.
5,827,271	A	10/1998	Buysse et al.
5,833,690	A	11/1998	Yates et al.
5,954,717	A	9/1999	Behl et al.

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

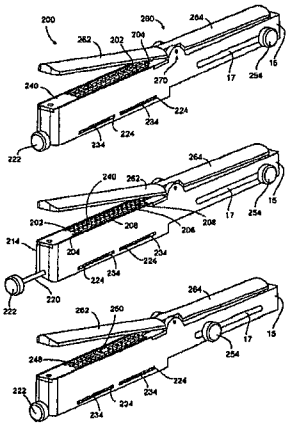
FR	598149	5/1925
SU	197711	8/1967
WO	WO 93/08757	5/1993
WO	WO 95/09577	4/1995
WO	WO 95/20360	8/1995

Primary Examiner—Sang Y. Paik
Assistant Examiner—Fadi H. Dahbour
(74) *Attorney, Agent, or Firm*—Townsend and Townsend and Crew LLP

(57) **ABSTRACT**

Methods for heating tissue completely, thoroughly, and uniformly comprise delivering radio frequency energy through a bipolar surgical instrument having first and second jaws with first and second electrode members within the treatment region. Tissue is grasped between the first and second jaws of the bipolar instrument. The electrode members are energized at a power level to deliver electrical energy to and heat tissue between the first and second electrode members. The power level is increased at a predetermined rate from an initial level. The initial level and predetermined rate are selected to avoid creating a vapor layer and to permit an impedance increase to occur as a result of complete tissue desiccation. A tissue impedance may also be measured and compared to a preset impedance limit for terminating the power delivery when the measured impedance exceeds the impedance limit.

30 Claims, 6 Drawing Sheets



U.S. PATENT DOCUMENTS

6,030,384	A	*	2/2000	Nezhat	606/48
6,033,399	A		3/2000	Gines	
6,123,701	A	*	9/2000	Nezhat	606/33
6,132,429	A		10/2000	Baker	
6,162,220	A		12/2000	Nezhat	
6,478,794	B1	*	11/2002	Trapp et al.	606/45
6,482,205	B1	*	11/2002	Bonnet	606/51
6,514,252	B2	*	2/2003	Nezhat et al.	606/48
6,520,960	B2	*	2/2003	Blocher et al.	606/51
6,524,309	B1	*	2/2003	Watrelot et al.	606/51
6,585,735	B1	*	7/2003	Frazier et al.	606/51
6,616,662	B2	*	9/2003	Scholer et al.	606/51

* cited by examiner

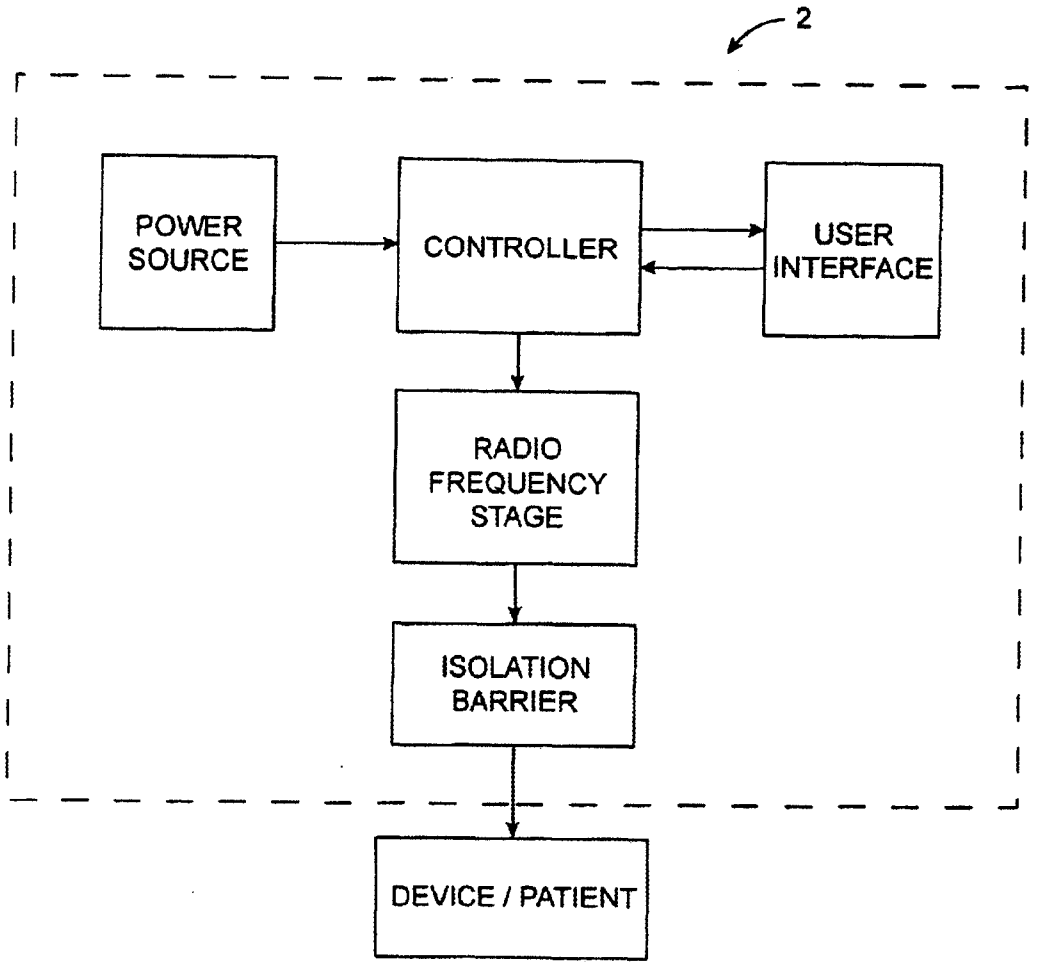

2
POWER SOURCE
CONTROLLER
USER INTERFACE
RADIO FREQUENCY STAGE
ISOLATION BARRIER
DEVICE / PATIENT

FIG. 1

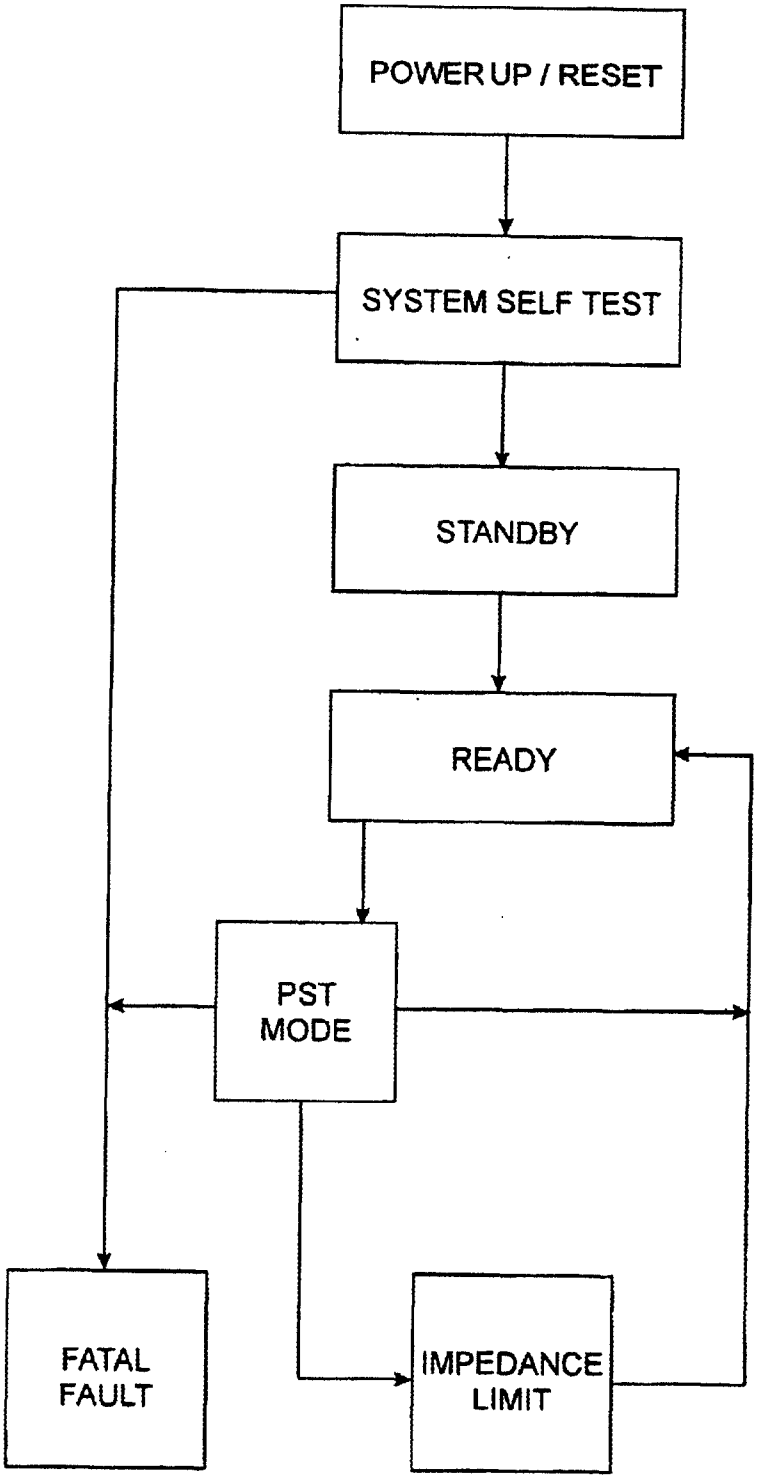

POWER UP / RESET
SYSTEM SELF TEST
STANDBY
READY
PST MODE
FATAL FAULT
IMPEDANCE LIMIT

FIG. 2

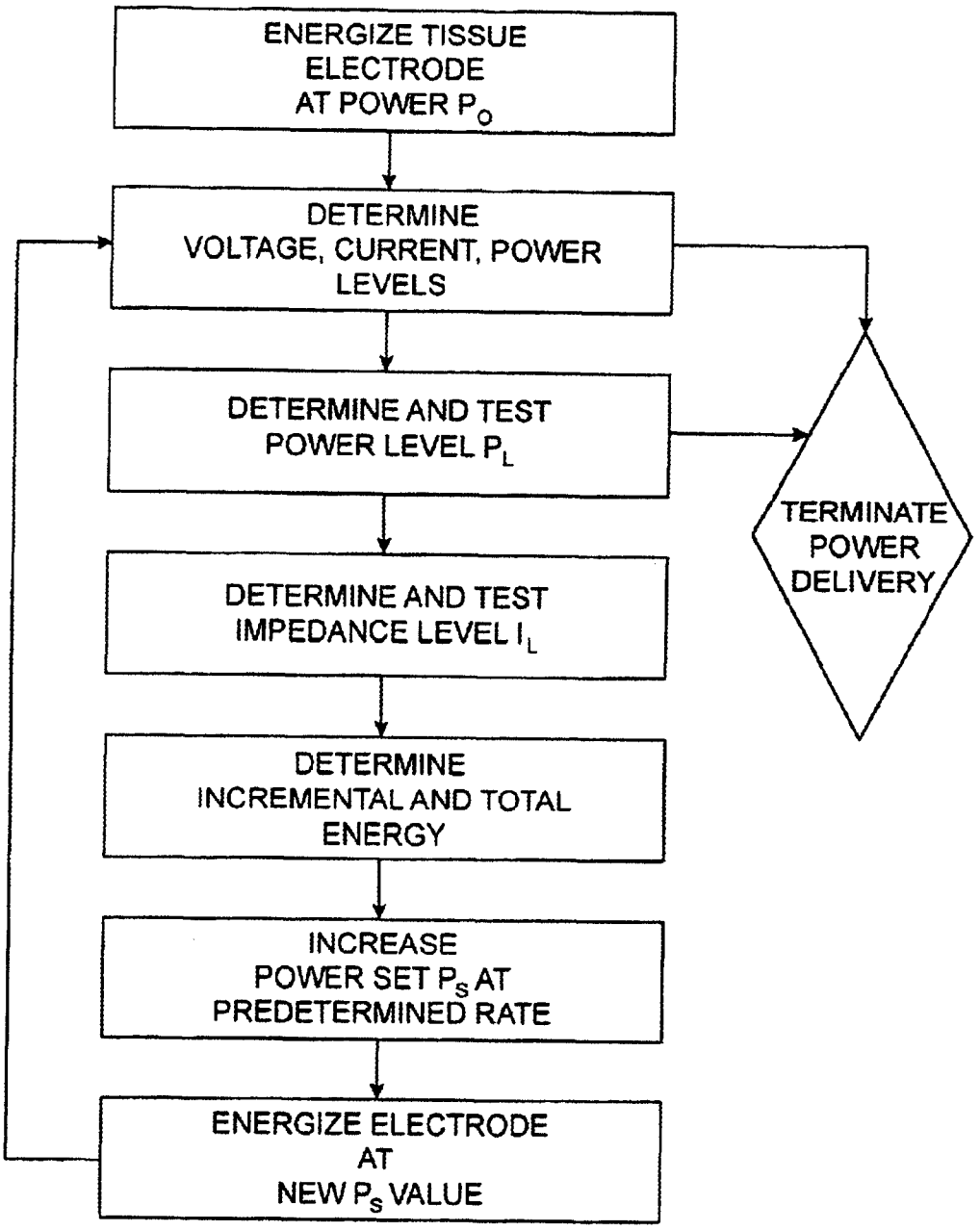

ENERGIZE TISSUE ELECTRODE AT POWER P_O
DETERMINE VOLTAGE, CURRENT, POWER LEVELS
DETERMINE AND TEST POWER LEVEL P_L
DETERMINE AND TEST IMPEDANCE LEVEL I_L
DETERMINE INCREMENTAL AND TOTAL ENERGY
INCREASE POWER SET P_S AT PREDETERMINED RATE
ENERGIZE ELECTRODE AT NEW P_S VALUE
TERMINATE POWER DELIVERY

FIG. 3

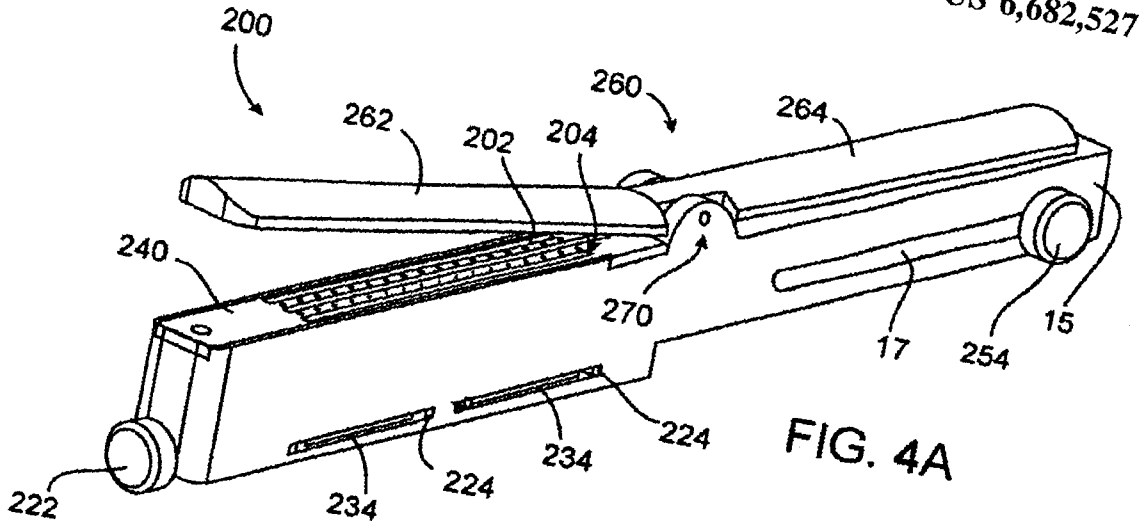


FIG. 4A

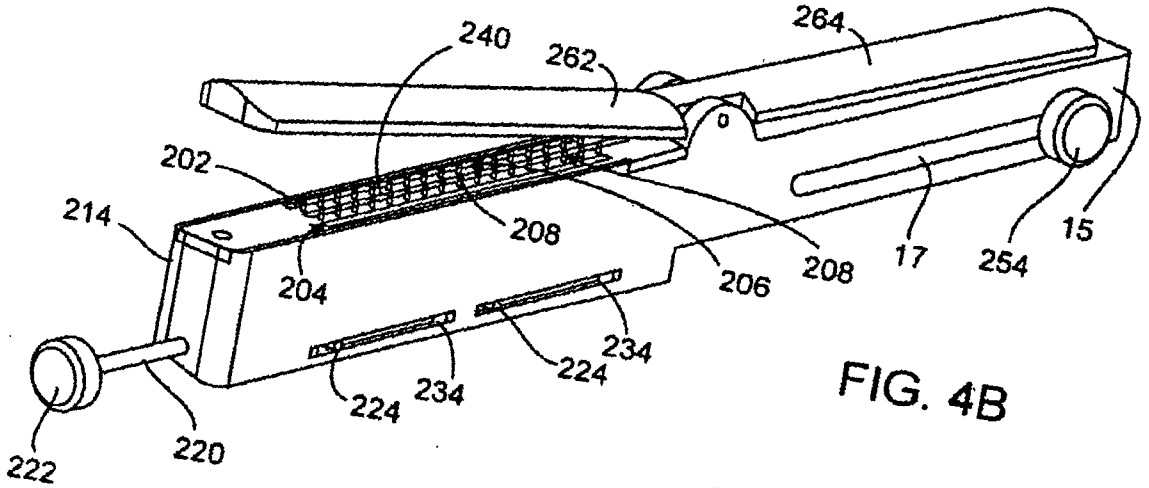


FIG. 4B

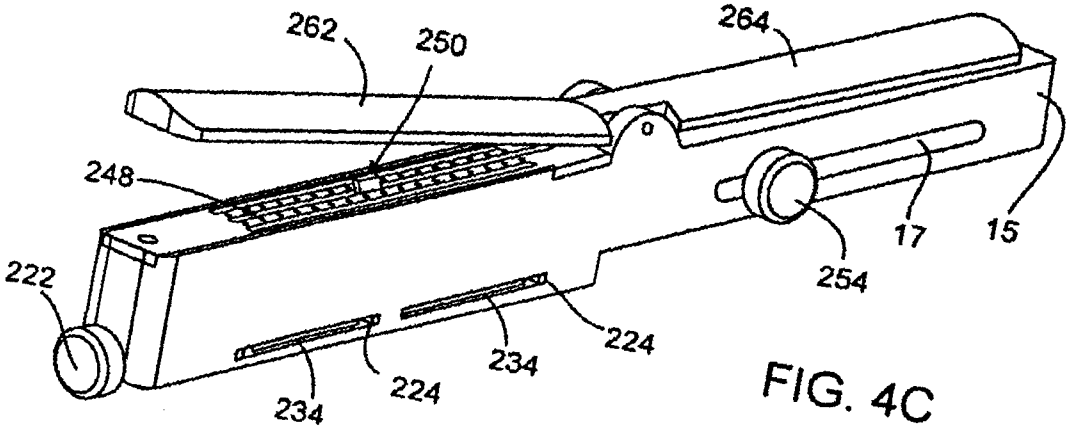


FIG. 4C

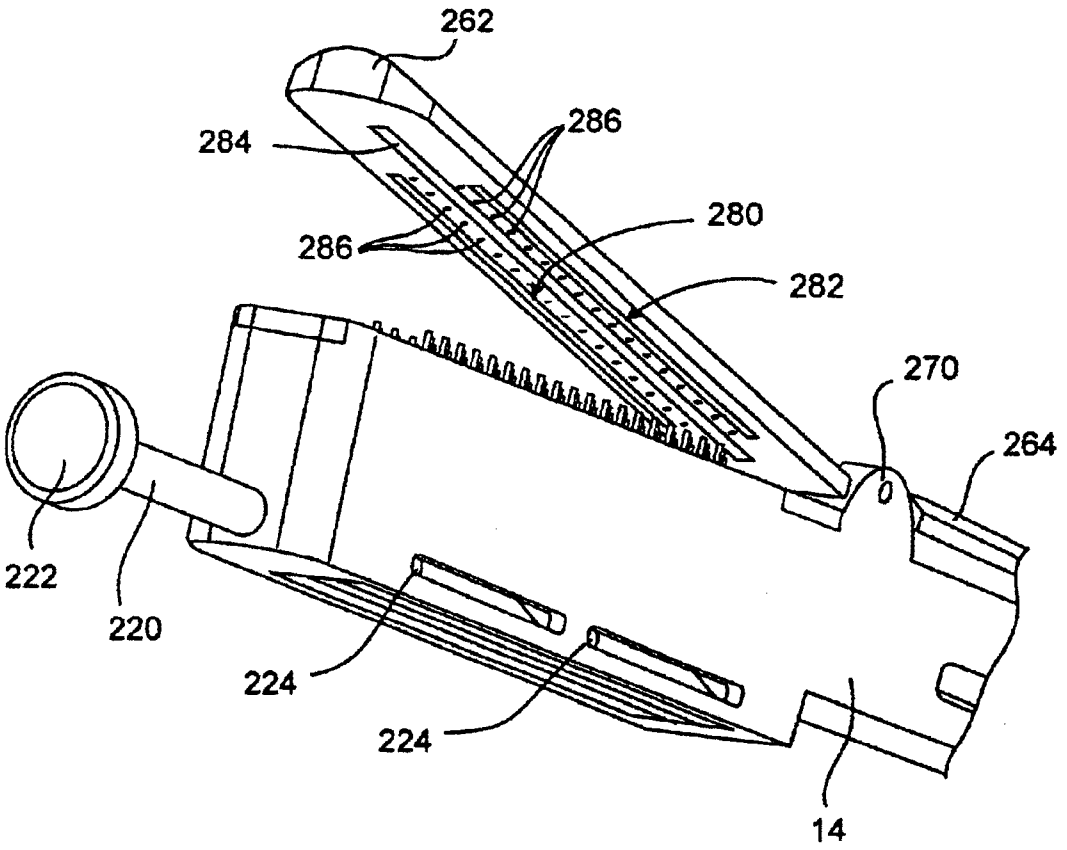


FIG. 5

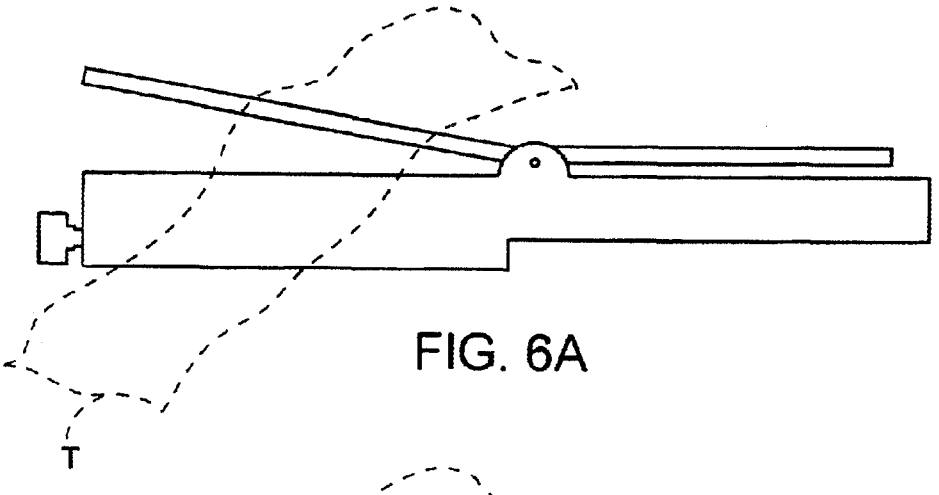


FIG. 6A

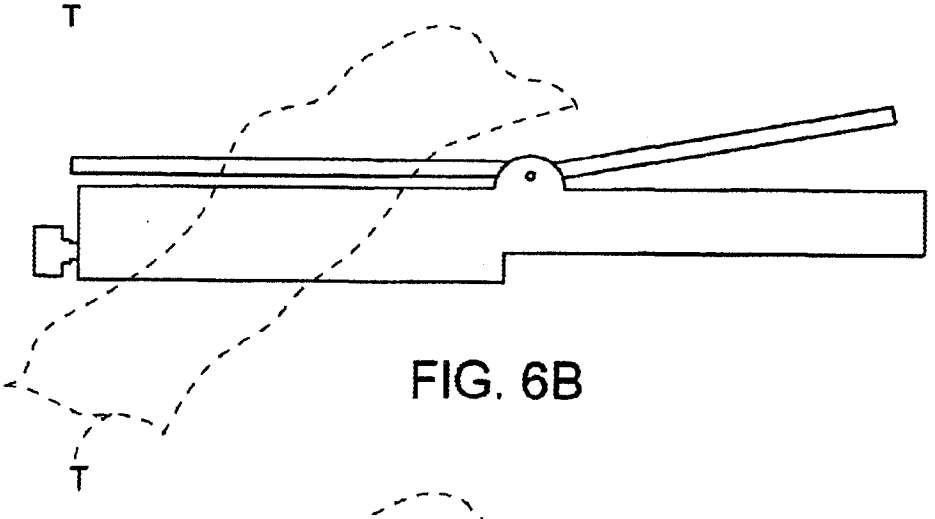


FIG. 6B

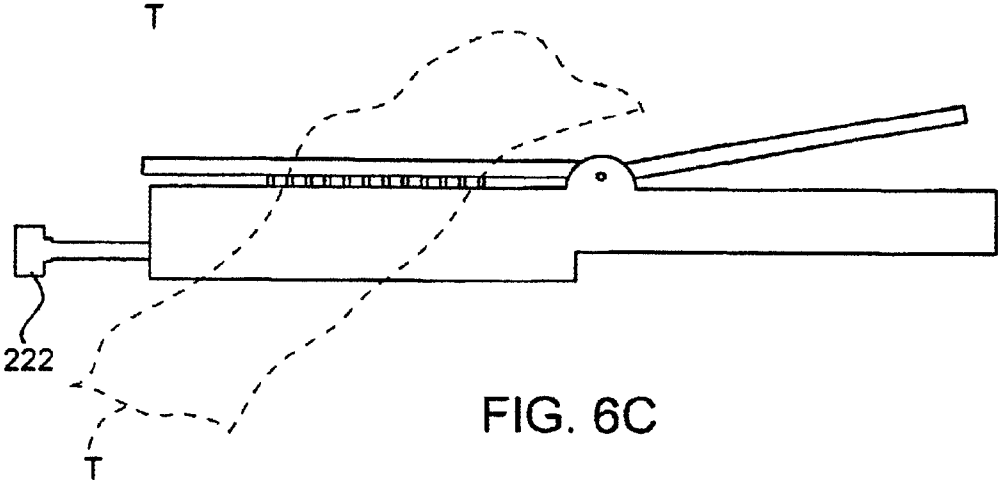


FIG. 6C

METHOD AND SYSTEM FOR HEATING TISSUE WITH A BIPOLAR INSTRUMENT

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the use of radio frequency energy for heating and desiccating tissue. More particularly, the present invention relates to a control method, system, and apparatus for delivering radio frequency current to the tissue through electrodes disposed on bipolar surgical instruments.

The delivery of bipolar radio frequency energy to target regions within tissue is known for a variety of purposes. Of particular interest to the present invention, radio frequency energy may be delivered by bipolar surgical instruments to regions in target tissue for the purpose of heating and/or desiccation, referred to generally as hyperthermia. Bipolar electrosurgical devices rely on contacting electrodes of different polarity in close proximity to each other against or into tissue. For example, bipolar forceps have been used for coagulating, cutting, and desiccating tissue, where opposed jaws of the forceps are connected to different poles of an electrosurgical power supply. The radio frequency current thus flows from one jaw to the other through the tissue present therebetween. Use of such bipolar forceps is effective for a number of purposes and advantageous in that its effect is generally limited to the tissue held between the jaws without unwanted heating of adjacent tissues.

A primary goal for the delivery of bipolar radio frequency energy for hyperthermic treatments is the complete, thorough, and uniform heating of the treatment tissue without causing charring of the treatment tissue. Charring greatly increases electrical resistance through the tissue prematurely and can result in termination of the treatment before the tissue is uniformly heated. Uniform heating of the target tissue, however, can be difficult to achieve, particularly in highly vascularized tissues where the variability in local blood flow can have a significant effect on the heating characteristics of the tissue. For example, creation of a lesion in some highly perfused tissue locations may require twice as much power as an identically-sized lesion in less highly perfused locations. While a variety of approaches for achieving such complete, thorough, and uniform heating of tissue have been proposed, most such approaches are somewhat complex. In general, many approaches for achieving uniform tissue heating have relied on slow, low power level, gradual heating of the tissue to avoid the formation of charred or otherwise desiccated, high radio frequency impedance regions within the target tissue. Such approaches, however, are complex, can result in undesirable prolongation of the treatment, and are not always successful.

For these reasons, it would be desirable to provide improved treatment methods, systems, and apparatus which allow for effective and efficient delivery of radio frequency energy to target tissue using electrodes disposed on bipolar devices. In particular, it would be desirable to provide such methods, systems, and apparatus which are useful with many or all bipolar surgical instruments which are now available or which might become available in the future. The methods, systems, and apparatus should be simple to implement and use, and should preferably reduce the complexity, cost, and treatment time required to achieve complete, thorough, and uniform heating and/or desiccation of the target tissue without charring the target tissue. At least some of these objectives will be met by the invention described hereinafter.

DESCRIPTION OF THE BACKGROUND ART

The heating of tissue with radio frequency current using the preferred bipolar surgical systems of the present invention is described in co-pending application Ser. Nos. 09/071,689 filed May 1, 1998 and 09/303,007 filed Apr. 30, 1999, the full disclosures of which are incorporated herein by reference. Radio frequency power apparatus and methods are described in U.S. Pat. Nos. 5,954,717, 5,556,396; 5,514,129; 5,496,312; 5,437,664; and 5,370,645; WO 95/20360, WO 95/09577, and WO 93/08757. Bipolar electrosurgical devices are described in U.S. Pat. Nos. 5,833,690; 5,797,941; 5,702,390; 5,688,270; 5,655,085; 5,662,680; 5,582,611; 5,527,313; 5,445,638; 5,441,499; 5,403,312; 5,383,876; 5,217,460; 5,151,102; 5,098,431; 4,043,342; and 4,016,886; Soviet Union Patent Publication SU 197711; and French Patent No. 598,149.

SUMMARY OF THE INVENTION

The present invention provides improved methods, systems, and apparatus for effective and efficient delivery of radio frequency (RF) energy to electrodes of bipolar surgical instruments disposed in treatment tissue for inducing hyperthermia and other purposes. The treatment region resulting from bipolar radio frequency treatment may be located anywhere in the body where hyperthermic exposure may be beneficial. The treatment region may comprise and/or be located in tissue of or surrounding the liver, kidney, lung, bowel, stomach, pancreas, breast, uterus, prostate, muscle, membrane, appendix, other abdominal or thoracic organs, and the like.

Treatments according the present invention will usually be effected by passing a radio frequency current through the treatment tissue region in a bipolar manner where paired treatment electrodes are employed to both form a complete circuit and to uniformly and thoroughly heat tissue therebetween. The paired electrodes will have similar or identical surface areas in contact with tissue and geometries so that current flux is not concentrated preferentially at either electrode (or electrode component such as a tissue-penetrating needle) relative to the other electrode(s). Such bipolar current delivery is to be contrasted with "monopolar" delivery where one electrode has a much smaller surface area and one or more "counter" or "dispersive" electrodes are placed on the patient's back or thighs to provide the necessary current return path. In the latter case, the smaller or active electrode will be the only one to effect tissue as a result of the current flux which is concentrated thereabout.

It has been found that the delivery of bipolar radio frequency power to electrodes disposed in tissue can, if the power is delivered for a sufficient time and/or at a sufficient power delivery level or flux, result in an increase in the electrical impedance between the electrodes and tissue. While such an increase in impedance is the natural consequence of tissue desiccation, it can be undesirable if it occurs prematurely since it results in an immediate fall-off of energy delivery (for a voltage limited radio frequency power source). Accordingly, the present invention relies on unique methods of radio frequency power delivery to uniformly and thoroughly heat the target tissue without charring the target tissue.

It is presently believed that the premature increase in electrode-tissue interface impedance may result from the formation of a thin gaseous or vapor layer over the electrode surfaces, apparently resulting from vaporization of water within the tissue as the temperature approaches the local boiling point. The thin gaseous layer appears to spread from

an initial nucleation site to cover most or all of the electrode surfaces in a very short time period, resulting in the premature increase in electrode-tissue interface impedance which is very large when compared to the total system impedance prior to formation of the gaseous layer. The methods, systems, and apparatus of the present invention have been found to be useful and effective regardless of the actual mechanism which is responsible for the premature increase in impedance.

In a first particular aspect of the present invention, a method for heating a treatment region of tissue comprises introducing a bipolar surgical instrument, such as forceps, graspers, or the like, having first and second jaws with first and second electrode members within the treatment region. Tissue is grasped between the first and second jaws of the bipolar instrument. The electrode members are energized at a power level to deliver electrical energy to and heat tissue between the first and second electrode members. The power level is increased at a predetermined rate from an initial level. The initial level and predetermined rate are selected to avoid creating a vapor layer and to permit an impedance increase to occur as a result of complete tissue desiccation. The predetermined rate of power increase may be preselected by a user depending on the electrode sizes, the target tissue type, the degree of tissue perfusion, and the initial power level. Typically, the predetermined rate of power increase will be linear and increase at a rate in the range from 1 W/sec to 100 W/sec, preferably from 1 W/sec to 10 W/sec. Thus, the initial power level and predetermined rate of power increase allow for controlled delivery of bipolar radio frequency energy without premature impedance resulting from the formation of the thin gaseous layer. Furthermore, the increase in the power level at a predetermined rate from an initial level permits a natural impedance increase to occur as a result of complete tissue desiccation.

It may be further desirable to measure tissue impedance. The measured impedance may be compared to an impedance limit, wherein the impedance limit will be preselected by the user to indicate the impedance increase due to complete tissue desiccation, typically in the range from 50 ohms to 1000 ohms, preferably from 250 ohms to 750 ohms. If the measured impedance exceeds the impedance limit, the power delivery is automatically terminated. Additionally, the energizing of the electrode members and increasing the power level at a predetermined rate may be repeated at least once after termination until all the tissue between the electrode members is completely desiccated without charring the target tissue. Thus, complete heating and desiccation of tissue can be further optimized by monitoring tissue impedance and terminating the power delivery at a maximum impedance limit. As an added safety feature, the power delivery may also be automatically terminated after a preset amount of time, typically after period of 5 minutes, regardless of measured impedance so as to avoid overheating of the target tissue or unwanted heating of adjacent tissue. Alternatively, the power delivery may be manually terminated with the use of a radio frequency off switch that will immediately terminate power delivery.

In general, electrode members are energized with radio frequency energy supplied as a radio frequency current using a controlled voltage supply. The use of such radio frequency power sources is preferred because the limited voltage available decreases the likelihood of arcing or sparking from the electrode members into the tissue. Usually, the power supply will be operated at a level which depends on the electrode sizes, the target tissue type, and the degree of tissue perfusion. Typically, the power supply will

provide power in the range from 5 W to 150 W, preferably from 10 W to 80 W, and a frequency in the range from 100 kHz to 2 MHz, preferably from 400 kHz to 500 kHz, during all phases of the above-described methods. The electrode members are energized typically for a time less than 5 minutes, preferably for a time in a range from 10 seconds to 1 minute. Additionally, at least one of the electrode members may comprise a plurality of tissue penetrating elements, the tissue penetrating elements engaging the tissue before the electrode members are energized.

In further aspects of the present invention, systems are provided which comprise an electrosurgical power supply, typically a radio frequency generator, in combination with written, electronic, or other instructions setting forth any of the methods set forth above.

In still another aspect of the present invention, computer programs embodied in a tangible medium, such as a floppy disk, compact disk, tape, flash memory, hard disk memory, read only memory (ROM), internet/modem instructions, and the like, may set forth any of the methods described above, in computer-readable code. Such computer programs are useful with digital controllers which may be built into a radio frequency generator or other electrosurgical power supply according to the present invention. Alternatively, such programs may be useful with general purpose computers, which can be interfaced with conventional electrosurgical power supplies for the control thereof according to any of the methods of the present invention.

In a still further aspect of the present invention, radio frequency generators are provided which comprise a radio frequency power source having both a controlled voltage output and a standard bipolar connection for bipolar forceps or the like. The radio frequency generator will further comprise means for automatically increasing power delivered to the bipolar connection. The increasing means increases the power at a predetermined rate from an initial level. The initial level and predetermined rate avoid formation of a vapor layer while permitting an impedance increase to occur as a result of complete tissue desiccation. The predetermined rate of power increase will be preselected by a user depending on the electrode sizes as well as the initial power level, typically being linear and increasing at a rate in the range from 1 W/sec to 100 W/sec, preferably from 1 W/sec to 10 W/sec.

The increasing means may initiate a cycle where it measures an impedance of tissue, compares the measured impedance to an impedance limit, and increases the power level based on the predetermined rate of power increase if the measured impedance does not exceed the impedance limit. The impedance limit is selected to indicate the impedance increase due to complete tissue desiccation, typically in the range from 50 ohms to 1000 ohms, preferably from 250 ohms to 750 ohms. Furthermore, the increasing means repeats the cycle and need only be activated once for continual cycling. The increasing means may comprise a programmable digital controller, a control program embodied in a tangible medium, or other means for automatically increasing power delivered by the generator. In particular, the digital controller or other increasing means can be programmed to implement any of the methods described above independent of operator intervention.

The radio frequency generator may further comprise a user interface for inputting the rate of power increase, the initial power level, and an impedance limit. The user interface may further comprise a front panel display that displays at least one of the following: a real-time impedance, total

energy delivered, and/or instantaneous power delivered. Optionally, the user interface may comprise an audible alarm which indicates the current delivery of power in addition to appropriate generator status signals.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a functional flow diagram illustrating an overview of the bipolar radio frequency power apparatus of the present invention.

FIG. **2** is a flow chart illustrating method steps of the present invention which are implemented automatically by the digital controller of FIG. **1**.

FIG. **3** is a flow chart illustrating method steps of the present invention which are implemented automatically in the PST mode of FIG. **2**.

FIGS. **4**A–**4**C illustrate an exemplary bipolar surgical instrument which may be employed in the methods and systems of the present invention.

FIG. **5** is an alternative view of the instrument of FIGS. **4**A–**4**C.

FIGS. **6**A–**6**C illustrate use of the of the bipolar instrument of FIGS. **4**A–**4**C in treating a target tissue region according the methods of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Methods, systems, and apparatus according to the present invention will rely on the controlled delivery of radio frequency power to electrode members of a bipolar surgical instrument placed at or within a treatment tissue region of a patient for heating and/or desiccating the treatment tissue. FIG. **1** illustrates a functional flow diagram of an overview of the bipolar radio frequency power apparatus of the present invention. The radio frequency power apparatus or generator **2** comprises a radio frequency power source having a controlled voltage output and a bipolar connection for bipolar forceps or the like. The desired radio frequency power may be supplied by a conventional general purpose electrosurgical power source operating at a frequency between 100 kHz to 2 MHz, preferably from 400 kHz to 500 kHz, with a conventional sinusoidal or non-sinusoidal wave form. Preferred power sources will operate at relatively low fixed voltages, typically from 100 V to 240 V. In all cases, current will be selected based on electrode sizes, target tissue type, and the degree of tissue perfusion, to provide an operating power in the range from 5 W to 150 W, preferably from 10 W to 80 W, for a time less than 5 minutes, preferably for a time in a range from 10 seconds to 1 minute.

Preferably, the radio frequency generator **2** will further incorporate means for automatically increasing power delivered to the bipolar connection. Such increasing means may comprise a programmable digital controller, such as a computer microprocessor, a control program embodied in a tangible medium, or other means for automatically increasing power delivered by the generator. Advantageously, the digital controller or other increasing means can be programmed to implement any of the methods described herein independent of operator intervention. The increasing means or controller will increase the power at a predetermined rate from an initial level, the initial level and predetermined rate avoiding formation of a vapor layer while permitting an impedance increase to occur as a result of complete tissue desiccation. Usually, the rate of increase is in the range from 1 W/sec to 100 W/sec, preferably from 1 W/sec to 10 W/sec.

The increasing means or controller may also initiate a cycle where it measures an impedance of tissue, compares the measured impedance to an impedance limit, and increases the power level based on the predetermined rate of power increase if the measured impedance does not exceed the impedance limit. The impedance limit is selected to indicate the impedance increase due to complete tissue desiccation, typically in the range from 50 ohms to 1000 ohms, preferably from 250 ohms to 750 ohms. Furthermore, the increasing means repeats the cycle and need only be activated once for continual cycling.

The generator **2** may further comprise a user interface for inputting the rate of power increase, the initial power level, and an impedance limit. The interface may also comprise a front panel display that displays at least one of a real time impedance, total energy delivered, and maximum power delivered. These display values are typically updated at 300 millisecond intervals. Additionally, the user interface may comprise an audible alarm for notifying the user that power is currently being delivered. The alarm usually beeps for short periods at 3 second intervals. Optionally, the user interface may have a radio frequency off switch that will immediately shut off delivery of radio frequency energy to the electrode members. This off switch serves as a back-up method to the impedance limit method to terminate power delivery.

The power source as controlled by the controller and/or user interface then connects to a radio frequency stage for delivery of energy to the patient via electrodes of the bipolar device. As an added safety feature, an isolation barrier is placed between the radio frequency delivery stage and the patient to minimize electrocution hazards. The radio frequency generator **2** is interfaced with the bipolar device/patient using a conventional cable. An exemplary radio frequency generator **2**, as described above, having the capabilities suitable for the present invention is the PST Model 2150, which runs on a MOTOROLA® 68HC11 microprocessor with "C" programming language software, available from Perfect Surgical Techniques, Inc., Palo Alto, Calif., assignee of the present invention.

Referring now to FIG. **2**, method steps of the present invention which are implemented automatically by the programmable digital controller of the radio frequency generator of FIG. **1** will be generally described. After power up/reset of the generator system, the system enters a self-test state to verify that system hardware and software are functioning normally. Failure of any self-test causes the system to enter a fatal fault state, where it remains until the system is re-powered. After successful completion of all self-tests, the system automatically enters the standby state. The standby state is a non-finctional state and no radio frequency energy can be delivered in this state. The system remains in the standby state until the user requests a change to an operational mode by pressing the ready switch. While in the ready state, the system can be commanded to deliver controlled bipolar radio frequency power via a PST mode, which is described in more detail below, or a standard bipolar mode.

FIG. **3** is a flow chart illustrating method steps of the present invention which are implemented automatically in the PST Mode. Initially, a method for heating a treatment region of tissue comprises introducing a bipolar surgical instrument having first and second jaws with first and second electrode members within the treatment region (FIG. **6**A). Tissue is grasped between the first and second jaws of the bipolar instrument (FIG. **6**C). The electrode members are then energized at an initial power level P_o in the PST mode to deliver electrical energy to and heat tissue between the first and second electrode members.

As seen in FIG. **3**, voltage, current, and power levels are determined and the power level is tested at 20 millisecond intervals. If the power level read is more than 5 watts greater than a power set value, the system automatically terminates power delivery and enters the fault state, where it remains until the system is re-powered. At this same interval, tissue impedance is measured and tested by comparing the measured impedance to an impedance limit, the impedance limit typically being in the range from 50 ohms to 1000 ohms. If the measured impedance exceeds the impedance limit, the power delivery is automatically terminated and the system returns to ready state. Incremental and total energy levels are also calculated during this 20 millisecond interval. If the impedance limit is not exceeded, the power set level is increased at a predetermined rate from the initial level, wherein the initial level and predetermined rate are selected to avoid creating a vapor layer and to permit an impedance increase to occur as a result of complete tissue desiccation. Typically, the predetermined rate is from 1 W/sec to 100 W/sec, and the electrode members are energized at this increased power set value at 100 millisecond intervals.

The above described sequence of steps are automatically repeated until all the tissue between the first and second electrode members is completely desiccated with minimal charring to the treatment tissue. The electrodes are energized with bipolar radio frequency current supplied with a controlled voltage power supply, as described in FIG. **1**. In some instances, at least one of the electrode members may comprise a plurality of tissue penetrating elements, the tissue penetrating elements engaging the tissue before the electrode members are energized (FIG. **6**C). Furthermore, energizing of the electrode members and increasing the power level steps may be repeated at least once after power delivery termination. As an added safety feature, the system will also terminate power delivery in the PST mode after a preset amount of time, typically after a period of 5 minutes, at which time it will return to the ready state, to ensure that the treatment tissue is not overheated.

Referring now to FIGS. **4**A–4C and **5**, a preferred bipolar surgical instrument with electrode members for use with the methods and apparatus of the present invention will be described. A bipolar surgical instrument **200** having an arrangement of surface electrodes **202** and **204** and rows **206** and **208** of tissue-penetrating electrodes, is illustrated. The rows **206** and **208** of tissue-penetrating electrodes are mounted in an electrically conductive insert which in turn is mounted in a cavity in instrument housing **214**. The insert is free to reciprocate within the cavity and is mounted on a rod **220** having a knob **222** and a pair of pins **224**. The rod **220** is received in a channel in the bottom of the insert, and the pins **224** extend outwardly through a pair of inclined slots in the insert and then through slots **234** in the side of the housing **214**. In this way, axial movement of the rod **220** (caused by pulling or pushing on the knob **222**) can cause the insert to rise or lower within the cavity. In turn, this causes the tissue-penetrating electrodes **206** and **208** to reciprocate between a lowered configuration (FIG. **4**A) and a raised configuration (FIG. **4**B).

The outer electrodes **202** and **204** are received in a plate **240** which is mounted over the cavity in housing **214**. The plate **240** has a pair of slots for receiving the electrodes **202** and **204**, respectively. Additionally, plate **240** has a plurality of holes along lines spaced inwardly from the slots. Additionally, a channel **248** is formed along the center line of the plate **240** to receive a cutting blade **250**, as best seen in FIG. **4**C.

The housing **214** forms a lower jaw structure and a hinged lever assembly **260** forms the upper jaw structure. The lever **260** includes a cover section **262** and a lever arm section **264**. A center or fulcrum section is secured between brackets **270** formed on the top of housing **214**. In this way, the cover section **262** can be moved between an open configuration (FIG. **4**A) and a closed configuration (FIGS. **6**B and **6**C) by lifting and lowering the lever arm section **264**. The bottom of the cover section **262** is best illustrated in FIG. **5**. The bottom includes a pair of top surface electrodes **280** and **282**, a relief channel **284** for receiving the cutting blade **250**, and relief holes **286** for receiving the upper tips of the tissue-penetrating electrodes when they are raised.

The cutting blade **250** is formed at a forward end of an elongate blade structure having a pair of knobs **254** at its opposite or proximal end. The body portion of the blade is received in a slot in a handle portion **15** of the housing **214**. The knobs extend on a connecting shaft out through a slot **17** in the handle **15**. Thus, the blade can be advanced and retracted axially by moving the knob **254** from a retracted configuration (FIGS. **4**A and **4**B) to an advanced configuration (FIG. **4**C). The knob is disposed in the channel **248** so that it will pass and cut through tissue which has been previously desiccated by applying radio frequency energy through the electrode structures of instrument **200**, as described below.

Referring now to FIGS. **6**B–6C, a treatment region of tissue T may be located anywhere in the body where hyperthermic exposure may be beneficial. The treatment region may comprise and/or be located in tissue of or surrounding the liver, kidney, lung, bowel, stomach, pancreas, breast, uterus, prostate, muscle, membrane, appendix, other abdominal or thoracic organs, and the like. Initially, the cover **262** will be open and the tissue-penetrating electrodes **206** and **208** will be retracted into the housing **14** (FIGS. **6**A and **4**B). After introducing a bipolar surgical instrument **200** into a patient and positioning a target tissue structure between the open cover **262** and plate **240** of the housing **14**, as shown in FIG. **6**A, the cover can be closed grasping the tissue (as shown in FIG. **6**B). The tissue-penetrating electrodes are then raised by pulling knob **222** (FIG. **6**C), causing the electrodes **206** and **208** to engage the tissue before energizing the electrodes. Surface electrodes **202**, **204**, **280**, and **282** in contrast, will compress on opposite sides of the tissue, but will not penetrate into the tissue.

Radio frequency current will then be applied to the tissue according to the PST mode protocols as described above, with the surface electrodes being attached to one pole of radio frequency generator **2** and the tissue-penetrating electrodes being attached to the other pole. The electrical field will thus be concentrated between an outermost pair of surface electrodes (**202**/**280** or **204**/**282**) and the adjacent tissue-penetrating electrodes (**206** or **208**). Alternatively, the pole attachments of the radio frequency generator may be configured to provide an electrical field that is concentrated between the surface electrodes (**202** and **204**) or between the rows of tissue penetrating electrodes (**206** and **208**). The tissue may be completely desiccated with all the advantages of the use of a tissue-penetrating electrode energized by a bipolar radio frequency generator as described above. After complete desiccation is achieved, the blade **250** can be advanced to cut through the parallel segments of desiccated tissue which have been formed.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for heating a treatment region of tissue, said method comprising:

introducing a bipolar surgical instrument having first and second jaws with first and second electrode members within the treatment region;

grasping tissue between the first and second jaws;

energizing the electrode members at a power level to deliver electrical energy to and heat tissue between the first and second electrode members; and

increasing the power level at a predetermined rate from an initial level, wherein the initial level and predetermined rate are selected to avoid creating a vapor layer and to permit an impedance increase to occur as a result of complete tissue desiccation.

2. A method as in claim 1, further comprising measuring tissue impedance.

3. A method as in claim 2, further comprising comparing the measured impedance to an impedance limit, and automatically terminating power delivery if the measured impedance exceeds the impedance limit.

4. A method as in claim 3, wherein the impedance limit is selected to indicate the impedance increase due to complete tissue desiccation.

5. A method as in claim 3, wherein the impedance limit is in the range from 50 ohms to 1000 ohms.

6. A method as in claim 3, further comprising repeating the energizing and increasing steps at least once after termination until all the tissue between the first and second electrodes is completely desiccated without charring the treatment tissue.

7. A method as in claim 1, further comprising terminating power delivery automatically after a preset amount of time.

8. A method as in claim 1, wherein the electrode members are energized with radio frequency current.

9. A method as in claim 8, wherein the radio frequency current is supplied with a controlled voltage power supply.

10. A method as in claim 1, wherein at least one of the electrode members comprises a plurality of tissue penetrating elements, the tissue penetrating elements engaging the tissue before the electrode members are energized.

11. A method as in claim 1, wherein the power level is in a range from 5 W to 150 W.

12. A method as in claim 1, wherein the predetermined rate of power increase is in the range from 1 W/sec to 100 W/sec.

13. A method as in claim 1, wherein the electrode members are energized for a time less than 5 minutes.

14. A method as in claim 1, wherein the tissue comprises tissue of or surrounding the liver, kidney, lung, bowel, stomach, pancreas, breast, uterus, prostate, muscle, membrane, appendix, other abdominal organs, or other thoracic organs.

15. A system comprising:

a radio frequency generator; and

instructions setting forth the method of claim 1.

16. A computer program embodied in a tangible medium, wherein the program sets forth a method according to claim 1.

17. A radio frequency generator comprising:

a radio frequency power source having a controlled voltage output and a bipolar connection for bipolar forceps having first and second jaws with first and second electrode members; and

means for automatically increasing power delivered to the bipolar forceps;

wherein the increasing means increases the power at a predetermined rate from an initial level, the initial level and predetermined rate avoiding formation of a vapor layer while permitting an impedance increase to occur as a result of complete tissue dessication.

18. A radio frequency generator as in claim 17, wherein the increasing means initiates a cycle where it measures an impedance of tissue, compares the measured impedance to an impedance limit, and increases the power level based on the predetermined rate if the measured impedance does not exceed the impedance limit.

19. A radio frequency generator as in claim 18, wherein the impedance limit is selected to indicate the impedance increase due to complete tissue desiccation.

20. A radio frequency generator as in claim 18, wherein the impedance limit is in the range from 50 ohms to 1000 ohms.

21. A radio frequency generator as in claim 18, wherein the increasing means repeats the cycle.

22. A radio frequency generator as in claim 18, wherein the increasing means is activated only once for continual cycling.

23. A radio frequency generator as in claim 17, further comprising a user interface for inputting the rate of power increase, the initial power level, and an impedance limit.

24. A radio frequency generator as in claim 23, wherein the user interface further comprises a front panel display that displays at least one of real-time impedance, total energy delivered, and instantaneous power delivered.

25. A radio frequency generator as in claim 23, wherein the user interface further comprises an audible alarm which indicates the delivery of power.

26. A radio frequency generator as in claim 17, wherein the predetermined rate of power increase is in the range from 1 W/sec to 100 W/sec.

27. A radio frequency generator as in claim 17, wherein a time of power delivery is less than 5 minutes.

28. A radio frequency generator as in claim 17, wherein the power source operates at a frequency in the range from 100 kHz to 2 MHz and a power level in the range from 5 W to 150 W.

29. A radio frequency generator as in claim 17, wherein the increasing means comprises a programmable digital controller.

30. A radio frequency generator as in claim 17, wherein the increasing means comprises a control program embodied in a tangible medium.

* * * * *