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PATENTS ACT 1990

NOTICE OF ENTITLEMENT

We, HEMOSTATIX CORPORATION of 2330 Marinship Way, Suite 301, Sausalito, California 94965-2853, UNITED STATES OF AMERICA formerly of 351 California Street, 13th Floor, San Francisco, California 94104-2142, U.S.A. being the applicant and nominated person in respect of Application No. 21999/92, state the following:-

The person nominated for the grant of the patent has entitlement from the actual inventor PHILIP E. EGGERS by virtue of the following:

The said inventor assigned an equal right in the invention to HEMOSTATIC SURGERY CORPORATION who in turned assigned that right in the invention to HEMOSTATIX CORPORATION. The inventor then assigned his remaining right in the invention to HEMOSTATIX CORPORATION

The person nominated for the grant of the patent has entitlement from the applicants of the application listed in the declaration under Article 8 of the PCT by virtue of the following:

The said inventor assigned a joint right to claim priority in respect of the invention to HEMOSTATIC SURGERY CORPORATION who in turn assigned that right to HEMOSTATIX CORPORATION. The inventor subsequently assigned all his remaining right in the invention to HEMOSTATIX CORPORATION

The basic application listed in the declaration made under Article 8 of the PCT is the first application made in a Convention country in respect of the invention

HEMOSTATIX CORPORATION
By their Patent Attorneys

CULLEN & CO.


RON HALIDAY

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HEMOSTATIC BI-POLAR ELECTROSURGICAL CUTTING APPARATUS AND METHOD
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- (56) Prior Art Documents
US 4940466
US 4271838
US 3651311
- (57) Claim

1. Apparatus for hemostatically cutting tissue, the apparatus comprising a first support member having a first shearing member, a first shearing surface and a first cutting edge; a second support member having a second shearing member having a second shearing surface and a second cutting edge; and connection means for pivotally joining the first and second shearing members together so that the first and second shearing surfaces face one another and the first cutting edge contacts the second cutting edge as the first shearing member pivots relative to the second shearing member in a scissors-like motion, the connection means comprising an electrically insulative material that electrically isolates the first shearing member from the second shearing member at the connection means wherein the first shearing member comprises a composite of an electrically conductive material and a layer of electrically insulative material disposed substantially for the entire length of the first

shearing member to electrically isolate the first and second shearing members from one another along their respective lengths when the first and second cutting edges contact each other.

18. Apparatus according to any one of claims 1 to 17, for cutting and coagulating tissue, wherein

the first shearing member comprises a first blade member having a portion defining the first shearing surface, the first cutting edge having a length, and a first electrode extending substantially for the length of the first cutting edge; and the second shearing member comprises a second blade member having a portion defining the second shearing surface, the second cutting edge having a length, and a second electrode extending substantially for the length of the second cutting edge;

the electrically conductive material of the composite of the first blade member forms the first electrode; and

the second blade member comprises an electrically conductive material; and

wherein the layer of electrically insulative material of the first blade member electrically isolates the first electrode from the second electrode when the first and second cutting edges contact each other.

19. Apparatus for cutting and coagulating tissue, the apparatus comprising a first blade member having a portion defining a first shearing surface, a first cutting edge having a length, a first exterior surface,

and a first electrode extending substantially for the length of the first cutting edge; a second blade member having a portion defining a second shearing surface, a second cutting edge having a length, a second exterior surface and a second electrode extending substantially for the length of the second cutting edge; connection means for pivotally joining the first and second blade members together so that the first and second shearing

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faces face one another and the first cutting edge contacts the second cutting edge as the first blade member pivots relative to the second blade member in a scissors-like motion; wherein

the first blade member comprises an electrically insulative material and the first electrode comprises first layer of electrically conductive material disposed on the first exterior surface; and

the second blade member comprises an electrically insulative material and the second electrode comprises a second layer of electrically conductive material disposed on the second exterior surface;

wherein the electrically insulative material of the first blade member and the electrically insulative material of the second blade member electrically isolate the first electrode from the second electrode when the first and second cutting edges contact each other.



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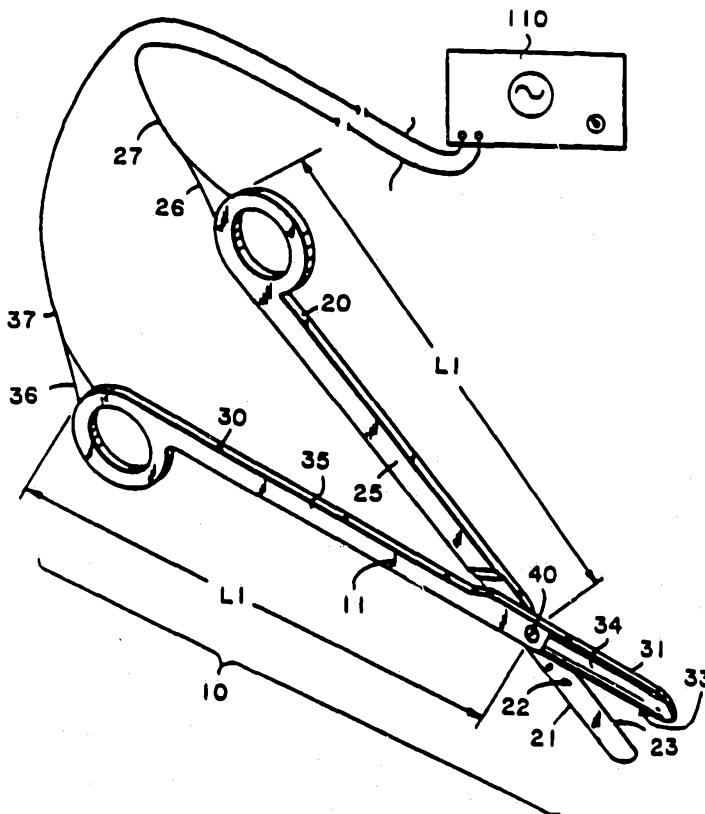
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(54) Title: HEMOSTATIC BI-POLAR ELECTROSURGICAL CUTTING APPARATUS AND METHOD

(57) Abstract

A surgical instrument (10) is described that incorporates bipolar electrodes on opposing shearing members (20, 30) for passing a high frequency current through the tissue for causing hemostasis of the tissue and for cutting the tissue. An electrically insulating material is interposed between the shearing members so that the electrodes are spaced apart from 0.002 to 0.050 inches and the current passes between the opposing electrodes through the tissue and not between the opposing shearing surfaces (21, 31). The insulating material has a higher hardness than the opposing members to reduce wear of the insulation and provide a self-sharpening feature. Methods of simultaneously causing tissue and severing tissue are also provided. The use of a constant voltage high frequency power supply (110) to deliver current to the tissue to cause hemostasis is described in conjunction with those methods.



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HEMOSTATIC BI-POLAR ELECTROSURGICAL CUTTING APPARATUS AND METHOD

This invention relates to improved hemostatic
electrosurgical instruments, and particularly to
5 improved bi-polar electrosurgical instruments for
severing and causing hemostasis of tissue.

Background of the Invention

The control of bleeding during surgery
accounts for a major portion of the time involved in an
10 operation. In particular, bleeding that occurs when
tissue is incised or severed can obscure the surgeon's
vision, prolong the operation, and adversely effect the
precision of cutting. Blood loss from surgical cutting
may require blood infusion, thereby increasing the risk
15 of harm to the patient.

Hemostatic surgical techniques are known for
reducing the bleeding from incised tissue prior to,
during, and subsequent to incision. One such technique
uses a heating element to transfer heat to the severed
20 tissue to thermally reform collagen. Heat transferred
from the instrument to the issue produces a thin
collagenous film which seals over the severed blood
vessels and capillaries, thus reducing bleeding.
Localized application of heat reduces tissue necrosis
25 or damage that may retard healing.

Electrosurgical techniques that pass a high
frequency or radio frequency current through the

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patient's tissue between two electrodes for both cutting and causing hemostasis tissue also are known. The current passing through the tissue causes joulean (ohmic) heating of the tissue as a function of the current density and the resistance of the tissue through which the current passes. Such heating denatures the tissue proteins to form a coagulum that seals the bleeding sites.

Monopolar electrosurgical devices employ a small electrode at the end of a handle in the surgeon's hand and a large electrode plate beneath and in contact with the patient. Only one of the two electrodes required to complete the electrical circuit is manipulated by the surgeon and placed on or near the tissue being operated on. The other electrode is the large plate beneath the patient. The electrosurgery power supply impresses high frequency voltage spikes of thousands of volts between these two electrodes, sufficient to cause an electric arcing from the small operating electrode the surgeon holds to the most proximate tissues, then through the patient to the large electrode plate beneath the patient. In the patient, the electrical current becomes converted to heat; hottest in the tissues immediately below the small hand-held electrode where the currents are most concentrated.

A principal disadvantage of monopolar electrocautery is that current flows completely through the patient. These high voltage electrical currents may arc from the small electrode to nearby non-targeted vital structures, or follow erratic paths as they flow through the patient's body, thus causing damage to tissues both near and at some distance from the electrode.

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Another drawback of monopolar electrosurgical devices is the excessive tissue damage caused by the high voltage arc, including carbonization of the tissue, which compromises wound healing. Furthermore, 5 monopolar devices typically create vision obscuring smoke, which must be evacuated from the surgical site.

In bipolar electrosurgical devices, two electrodes are closely spaced together and have the same surface area in contact with the tissue. The 10 current flow is thus locally confined to the tissue that is disposed between and electrically connects the electrodes.

One difficulty encountered with prior art electrosurgical devices is that of controlling the 15 current flow through the patient's tissue to obtain hemostasis in localized areas, without also heating and causing undesirable trauma to adjacent tissue. Although the introduction of bipolar electrosurgical devices has helped to localize current flow, previously 20 known bipolar electrosurgical devices present difficulties in selectively applying the current flow.

For example, Hildebrandt et al. U.S. Patent 3,651,811 and Soviet Union Patent Certificate 575,103 describe bipolar electrosurgical scissors having 25 opposing cutting blades forming active electrodes. These devices enable a surgeon to sequentially coagulate the blood vessels contained in the tissue and then mechanically sever the tissue with the scissor blades. However, these devices apparently require the 30 surgeon to cycle the power supplied to the electrodes during separate steps of obtaining hemostasis in the tissue and then cutting the tissue. In particular, these previously known devices require the surgeon to first energize the electrodes and grasp the tissue to 35 cause hemostasis. Once the blood vessels contained

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within the tissue are coagulated, the electrodes are deenergized so that the scissor blades may be closed completely to sever the tissue mechanically. The scissors are then repositioned for another cut, and the power supply to the scissors cycled on and off again to congeal the tissue. Neither of these devices appear to permit the surgeon to maintain the electrodes in a continuously energized state, because the power supply would be shorted out or damaged if the blades were permitted to contact each other while energized.

Accordingly, a major drawback of previously known hemostatic bipolar electrosurgical cutting devices is that they have neither recognized the existence of, nor resolved the problem of, selectively delivering a current to obtain hemostasis at one location in the tissue, while simultaneously allowing already hemostatically heated tissue to be severed. It would therefore be desirable to provide a bipolar electrosurgical instrument that automatically and continuously adjusts the current delivery location so that it precedes the cutting point, without shorting the electrodes and interrupting the current providing hemostasis of the tissue.

Another drawback of previously known bipolar electrosurgical devices is the tendency for coagulum to build up on the electrode surfaces. Such buildup may impede the cutting ability of the device, cause sticking of the tissue to the device, and interfere with the surgeon's ability to manipulate the device at the surgical site.

Another related drawback is the tendency in previously known bipolar electrosurgical devices to experience some current leakage near the electrodes, which may result in coagulum buildup on the non-active surfaces of the electrosurgical instrument as well.

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It would therefore be desirable to provide an electrosurgical instrument wherein coagulum buildup on the surfaces of the instrument is reduced, thereby improving maneuverability of the instrument at the surgical site and reducing trauma to adjacent tissue.

Heretofore, no bipolar electrosurgical instrument for cutting and causing hemostasis of planar tissue areas has recognized or overcome the aforementioned problems. A continuing need for improved hemostatic electrosurgical scissors-like devices for simultaneously causing hemostasis in tissue and severing that tissue therefore exists.

Summary of the Invention

In view of the foregoing, it is an object of the present invention to provide a bipolar electrosurgical scissors-like cutting instrument which simultaneously causes hemostasis of tissue and mechanically severs tissue in a continuous manner at a cutting point that advances along the cutting edges of the scissor members.

It is another object of the present invention to provide an electrosurgical scissors-like cutting instrument that eliminates the need for the surgeon to energize and deenergize the electrodes of the scissor members during the steps of causing hemostasis of the tissue and mechanically severing the tissue. The instrument constructed in accordance with the principles of this invention therefore reduces the likelihood that the electrodes may short circuit during cutting, thus permitting the instrument to be used for continuously hemostatically cutting tissue. The result is an instrument providing a smoother and more precise surgical cut than previously known devices, which

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permit hemostasis and cutting of discrete tissue sections in an intermittent, non-continuous, manner.

It is yet another object of the present invention to provide improved hemostatic
5 electrosurgical scissors that reduce coagulum buildup and adherence of tissue to the working and non-working surfaces of the instrument.

It is still a further object of the present invention to provide methods for hemostatically
10 severing tissue with an electrosurgical instrument, thereby reducing the number of steps required of the surgeon to employ the electrosurgical instrument in a continuous manner.

It is another object of the present invention
15 to provide methods of using electrosurgical instruments that reduces coagulum buildup and sticking of tissue to the surfaces of the instrument.

These and other objects are accomplished in accordance with the principles of the present invention
20 by providing a bipolar electrosurgical scissors-like instrument wherein each scissor member comprises an electrode for causing hemostasis of tissue and a shearing surface for mechanically severing the tissue. A layer of insulating material is disposed on at least
25 one shearing surface of the scissors so that the electrically active portions of the scissor members do not contact each other at any point during operation of the instrument. Thus, current flows through tissue between the scissor members, but short circuits --
30 which would terminate hemostasis -- do not occur. With this arrangement, hemostasis and cutting occurs in a continuous manner along tissue disposed between the scissor blades.

In particular, an electrosurgical instrument
35 constructed in accordance with the present invention

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comprises a scissors-like instrument including first and second scissor members. Each scissor member comprises a blade-like portion or shearing member having a shearing surface, a cutting edge and an exterior surface. The first and second scissor members are connected by connecting means so that the respective shearing surfaces move through a range of motion in a conventional scissors-like cutting action. That cutting action defines a cutting point that moves along the cutting edges of the respective shearing members through the range of motion, as is known. The instrument of the present invention further includes an electrode on each shearing member which is connected to a power supply that provides a high frequency current. An electrically insulating material is interposed between the electrodes so that the electrodes on the respective shearing members do not contact each other in the range of motion. The insulating material is disposed so that current passes between the electrodes of the respective shearing members distal to the cutting point, but not between the shearing surfaces.

In a first family of embodiments of the present invention, the first and second shearing members are made of an electrically conducting material so that they comprise, respectively, first and second electrodes. A first layer of electrically insulating material is disposed on at least one of the shearing surfaces, thereby forming the cutting edge and shearing surface of that shearing member. In these embodiments, the connecting means includes an electrically insulating material so that the shearing members are electrically isolated at the connecting means. The first layer of insulating material, whether disposed on one or both shearing surfaces, has a total thickness in

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the range of 0.050 mm to 1.270 mm (0.002 to 0.050 inches), and preferably in the range of 0.076 to 0.178 mm (0.003 to 0.007 inches).

To further achieve the advantages of the present invention, individual instruments of the first family of embodiments may include one or more of the following: a layer of material having a high electrical and thermal conductivity on one or both of the exterior surfaces of the shearing members; a second layer of insulating material disposed on the exterior surfaces of the shearing members, except for regions proximate the cutting edges; and a layer of adherent material disposed on the outermost tissue contacting portions of the instrument. These layers reduce coagulum buildup on the non-working surfaces of scissors, thereby reducing sticking and trauma to adjacent tissue. They also improve maneuverability of the instrument and enhance the surgeon's view of field, thereby enabling more precise surgical cutting.

A self-sharpening feature can be attained by employing a first layer of a first hardness on one of the shearing surfaces and a second layer of a second different hardness on the other shearing surface. Advantageously, the use of a harder material as one of the shearing surfaces provides for obtaining excellently mated cutting edges after a few cycles of operation and keeps the cutting edges sharp during repeated use.

In a second family of embodiments of the present invention, the first and second shearing members are made of a non-electrically conducting material, and the electrodes comprise a layer of electrically conducting material disposed on the exterior surfaces of each shearing member. In this arrangement, the electrically insulating material is



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comprised of the shearing members. The electrically
conductive layers of the respective shearing members
are spaced apart, at the cutting point, a distance in
the range of from 0.050 mm to 1.270 mm (0.002 to 0.050
5 inches), preferably 0.076 to 0.178 mm (0.003 to 0.007
inches), as the cutting point moves through the range
of motion. The layer of electrically conducting
material on each shearing member may be comprised of an
inner layer of a high electrical and thermal
10 conductivity material and an outer layer of an
oxidation resistant, high electrical and thermal
conductivity material, the outer layer being
superimposed in electrical contact over the inner
layer.

15 Individual variations on instruments within
the second family of embodiments may include an
adherent layer covering the electrically conductive
layer and a layer of electrically insulating material
covering all of the electrically conductive layer
20 except for a region of each shearing member proximate
the cutting edge.

The present invention also includes methods
of using bipolar electrosurgical instruments to
simultaneously cause hemostasis in tissue while
25 mechanically severing that tissue in a continuous
manner, and without significant coagulum buildup or
sticking. The methods include the steps of

(a) providing first and second shearing
members, each shearing member having a shearing
30 surface, a cutting edge and an electrode, the shearing
members connected together so that the shearing
surfaces move in opposition through a range of motion
in a scissors-like action that defines a cutting point
moving along the cutting edges through the range of
35 motion;



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(b) connecting the electrodes to a power supply;

(c) selecting and maintaining a substantially constant voltage level output across the power supply, the voltage level output independent of the impedance of the load connected across the power supply;

(d) providing an electrically insulating material between the first and second electrodes so that the electrodes do not contact each other in the range of motion;

(e) placing the electrodes in electrical contact with tissue to be cut so that high frequency current passes between the electrodes and through the tissue distal to the cutting point, but not between the shearing surfaces; and

(f) moving the first and second shearing members through the range of motion, thereby passing current through the tissue in a region distal to the cutting point, simultaneously causing hemostasis of the tissue and cutting the tissue at the cutting point.

The methods of the present invention include selecting suitable voltage and current ranges for employing the present invention. The methods further include the use of alternating current voltage waveforms having a crest factor -- ratio of peak voltage to root-mean-square (RMS) voltage -- near unity.

30 Brief Description of the Drawings

The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which



like reference numerals refer to like parts throughout, and in which:

FIG. 1 is an elevation perspective view of a scissors constructed in accordance with a typical one
5 of a family of embodiments of the present invention;

FIG. 2 is a side view of the scissors of FIG. 1, showing tissue disposed between the shearing members;

FIG. 3 is a cross-sectional view taken along
10 line 3-3 of FIG. 2;

FIGS. 4-8 are cross-sectional views similar to that of FIG. 2 for various alternative embodiments of the present invention.

Detailed Description of the Invention

15 Referring to FIGS. 1-3, bipolar electrosurgical scissors 10 for simultaneously causing hemostasis in and shearing a patient's tissue 100 is described. Scissors 10 includes first scissor half 20 and second scissor half 30 pivotally connected by
20 fastener 40. In a first family of embodiments constructed in accordance with present invention, scissor half 20 is made of an electrically conducting material and has at one end a first shearing member 21. Shearing member 21 forms a first electrode comprising
25 shearing surface 22, cutting edge 23 and exterior surface 24. Scissor half 20 has, at the other end, support member 25, preferably configured with a thumb or finger hole for manipulating scissors half 20, and electrical connection 26 which connects the electrode
30 to a conventional constant voltage power supply 10 via cable 27. Scissor half 30 is likewise made of an electrically conducting material and has at one end shearing member 31. Shearing member 31 forms a second electrode comprising shearing surface 32, cutting



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edge 33 and exterior surface 34. Scissors half 30 also has, at the other end, support member 35, preferably configured with a thumb or finger hole for manipulating scissors half 30, and electrical connection 36 which
5 connects to power supply 110 via cable 37.

Power supply 110 may be a high frequency voltage source having a substantially constant voltage at selectable output levels. Such devices are described, for example, in U.S. Patent Nos. 4,092,986
10 and 4,969,885. The power supply used in conjunction with the present invention preferably provides an output voltage level that is substantially constant at the user selected level, and independent of the electrical resistance encountered by the electrodes.

15 To reduce coagulum buildup on the working surfaces of the scissors, applicant has developed power supplies providing substantially constant voltage output that is independent of the load impedance, low source impedance and a alternating-current voltage
20 waveform having a crest factor -- the ratio of peak voltage to RMS voltage -- near unity. The present invention, when powered by such power supplies, has been observed to provide highly satisfactory hemostasis without arcing or charring of the tissue, and little
25 coagulum buildup.

Scissor halves 20 and 30 are preferably made of a rigid, structural material capable of sustaining sharp scissors-like cutting edges 23 and 33, such as stainless steel or martensitic stainless steel.
30 Alternatively, materials of high electrical and thermal conductivity, and structurally strong enough for shearing tissue, such as copper or copper alloys, may be used. Halves 20 and 30 are pivotally connected by
35 fastener 40 in opposition so that shearing surfaces 22 and 32 and cutting edges 23 and 33 of the shearing



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members move in scissors-like opposition through a range of motion to sever tissue 100 placed therebetween.

Fastener 40 may be, for example, a screw or a rivet that electrically insulates scissor halves 20 and 30 at the pivot point. The fastener may be made of an insulating material, for example, polyamide or nylon. Alternatively, fastener 40 may comprise a combination of non-insulating and insulating materials, such as a stainless steel screw insulated from one or both scissor halves 20 and 30 by nylon bushings.

Scissor support members 25 and 35 have insulating coating 11 in regions L_1 to electrically insulate the support members from each other and from the surgeon using scissors 10. Insulating coating 11, which may comprise polyvinyl chloride, nylon, or other plastic insulating material, also may be applied to those areas of scissors 10 not used for cutting tissue.

As illustrated in FIG. 3, exterior surfaces 24 and 34 of the shearing members may have a coating 12 of a high electrical and thermal conductivity material, e.g., silver or copper, other than on their respective shearing surfaces 22 and 32. Coating 12 facilitates good electrical contact between exterior surfaces 24 and 34 and the tissue that comes into contact with those surfaces as shearing members 21 and 31 are moved relative to one another.

Coating 12 reduces localized heating of the exterior surfaces 24 and 34 of shearing members 21 and 31 by dissipating the heat throughout the thermally conducting surface area of the coating. Coating 12 also reduces the likelihood that joulean heating of shearing members 21 and 31 will occur, because any localized current flow is re-distributed over the entire coating 12. Consequently, coating 12 reduces



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thermal decomposition and sticking of blood and tissue to exterior surfaces 24 and 34 of scissors 10 during use.

A thin coating 13 of an electrically
5 insulating material is disposed on each of shearing surfaces 22 and 32 to cover at least as much of those shearing surfaces as could contact each other within the full range of motion of scissor halves 20 and 30. Insulating coating 13 covers cutting edges 23 and 33 so
10 that the cutting edges are electrically inactive and non-conducting.

As shown in FIG. 4, an alternative embodiment provides insulating coating 13 only on shearing surface 32 of shearing member 31. The other shearing surface
15 21 and cutting edge 23 remain electrically active, i.e., conductive. In this embodiment, electrical isolation between scissor halves 20 and 30 is achieved by the single layer of insulating material.

Insulating coating 13 allows the scissor
20 halves forming the bipolar electrodes to move relative to each other so that current flows between exterior surface 24 of shearing member 21 and exterior surface 34 of shearing member 31, while ensuring that scissor halves 20 and 30 do not electrically contact each
25 other. This configuration enables the cutting edges to contact each other to sever tissue while preventing short circuiting, which would impede simultaneous coagulation of the blood vessels extending through the tissue. Coating 13 substantially prevents current flow
30 directly between opposing shearing surfaces 22 and 32 when the scissor halves are closed together. Rather, the current flows through the path of least resistance between the electrodes, i.e., through the tissue in direct contact with regions 28 and 38, respectively, of
35 exterior surfaces 24 and 34 of the shearing members.



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This current flow is represented schematically by flux lines 99 shown in FIGS. 3 and 4.

The arrangement of the present invention confines current flow between regions 28 and 38 of exterior surfaces 24 and 34 to region 101 (see FIG. 2), from where cutting edges 23 and 33 contact each other to a point distal to the cutting point. That distal point is where either the tissue no longer forms an electrical connection between the electrode surfaces (region 102 of FIG. 2) or the spacing between halves 20 and 30 is sufficiently large that the current density is too low to cause significant joulean heating of the tissue (region 103 of FIG. 2).

It is therefore apparent that as scissors 10 is gradually closed, the cutting point moves along cutting edges 23 and 33 of shearing members 21 and 31 distally of fastener 40 and is preceded by region 101 in which a current flows from one scissor halve to the other to achieve hemostasis of the tissue. Thus, hemostasis occurs at a location just in advance of the cutting point while cutting edges 23 and 33 simultaneously sever the hemostatically heated tissue.

The embodiment of FIG. 4 permits an asymmetrical current flow between scissor halves 20 and 30 compared to the embodiment of FIG. 3. Specifically, proximal to the cutting point, some current may flow from the uninsulated shearing surface to tissue in contact with that surface, through the tissue, and to an uninsulated portion of the other shearing member. The applicant has determined that this asymmetry has no significant effect on the hemostatic cutting operation or the ability of the device to deliver current to the tissue relative to the embodiment of FIG. 3.

Electrically insulating layer 13 is preferably made of a material having a hardness that is

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greater or substantially greater than the steel or other electrically conducting material used to manufacture conventional scissors-like devices. For example, referring to the embodiment illustrated in FIG. 4, shearing members 21 and 31 may be made of a martensitic stainless steel, e.g., AISI 420. Insulating layer 13 comprises an inorganic electrically insulating material such as a glass, ceramic, nitride, boride or synthetic diamond. Depending upon the material selected, insulating layer 13 may be deposited on shearing surface 32 by conventional techniques, for example, plasma or flame-sprayed deposition. Applicant has obtained good results using ceramic materials such as alumina or zirconia.

The applied coating forms a non-conductive cutting edge for that shearing member and has a greater hardness than the steel substrate and the steel of opposing shearing member 21. Consequently, as coating 13 rubs against the cutting edge 23 or shearing surface 22 of shearing member 21, steel shearing surface 22 and cutting edge 23 are mechanically ground or polished by the harder insulating material 13. Scissors 10 are therefore self-sharpening and remain sharp during continued use. Furthermore, the relatively lower hardness of steel cutting edge 23 will not wear or degrade the insulating characteristics or structure of the harder electrically insulating coating 13, thus providing a durable instrument.

The self-sharpening feature provided by the relatively greater hardness of insulating coating 13 also permits the use of less expensive materials for shearing members 21 and 31. For example, scissors 10 may be made of a material that may not retain a sharp cutting edge during repeated use absent the self-sharpening characteristic of the applied harder

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coating. This feature is particularly advantageous for constructing scissors 10 to be disposable, or in having disposable shearing members 21 and 31 that detach from their respective support members 25 and 35 (not shown).

5 Insulating coating 13 is deposited in a layer having a thickness in the range of 0.050 mm to about 1.270 mm (0.002 inches to about 0.050 inches), more preferably 0.076 to 0.178 mm (0.003 to .007 inches). The applicant has determined that at thicknesses of
10 0.025 mm (0.001 inch) or less, the thickness of the insulating layer 13 is insufficient to prevent shorting of the electrodes. Insulating layer thicknesses above 0.050 mm (0.002 inches) and below 1.270 mm (0.050 inches) provide adequate hemostasis. It has been
15 observed, however, that the greater the minimum distance between the proximate current conducting portions of the opposing electrodes in the region of current flow through the tissue, the longer the current path through the tissue and the more difficult it
20 becomes to obtain the desired degree of hemostasis. For the ceramic insulating materials described, insulating layer thicknesses above 1.270 mm (0.050 inches) are believed to be too large for most practical applications.

25 Referring now to FIG. 5, another embodiment of the scissors of FIG. 1 is described. The scissors, constructed as described hereinbefore with respect to FIG. 3, have a coating 14 of an adherent material disposed on coating 12. The adherent material
30 constituting coating 14 is capable of conducting high frequency current through its thickness and further reduces the sticking and accumulation of blood and tissue to exterior surfaces 24 and 34 of the shearing members. Suitable adherent materials for coating 14
35 include fluorocarbon material, conductor-filled



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fluorocarbon coatings or thin fluorocarbon coatings less than about 0.0051 mm (0.0002 inches) thick (which may otherwise be electrically insulating), e.g., Vyolex 10002, available from Du Pont.

5 FIG. 6 shows yet another embodiment of the bipolar electrosurgical instrument of the present invention. This embodiment is similar to that of FIG. 4, except that exterior surfaces 24 and 34 of shearing members 21 and 31 are provided only with
10 coating 14 of an adherent material and electrically conducting coating 12 is not applied.

Referring now to FIG. 7, another alternative embodiment of the present invention is described. This embodiment is substantially the same as that
15 described hereinbefore with respect to FIG. 4. This embodiment differs, however, in that instead of the electrically conductive coating 12 of the embodiment of FIG. 4, an electrically insulating layer 15 is disposed on exterior surfaces 24 and 34 of shearing members 21
20 and 31. Layer 15 is omitted from regions 28 and 38 immediately adjacent to cutting edges 23 and 33, respectively. Insulating layer 15 inhibits current flow to the tissue other than through regions 28 and 38 adjacent to cutting edges 23 and 33. Accordingly,
25 heating of the tissue is localized to the region in and preceding the shearing region, thereby reducing joulean heating of tissue proximate to the portions of the exterior surfaces of shearing members 21 and 31 covered by insulating layer 15. Materials suitable for use in
30 insulating layer 15 include aluminum oxide, fluorocarbons, polyamide and silicone based coatings.

Referring to FIG. 8, an embodiment representative of a second family of embodiments constructed in accordance with the present invention is
35 described, with similar components indicated by like-



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primed members. In this embodiment, which outwardly resembles the scissors of FIG. 1, opposing shearing members 21' and 31' are made of an electrically insulating material, e.g., a ceramic material such as zirconium oxide or aluminum oxide-based ceramics. The exterior surfaces of members 21' and 31', i.e., those portions other than the shearing surfaces 22' and 32' and cutting edges 23' and 33', have a coating 16 comprising a material of high electrical and thermal conductivity, e.g., copper, silver or nickel. Coating 16 thereby provides opposing electrodes for conduction of high frequency current through tissue between coatings 16 on exterior surfaces 24' and 34' of shearing members 21' and 31'. In this embodiment, coating 16 covers most of the exterior surface of shearing members 21' and 31' such that the current carrying sections closest to cutting edges 23' and 33' are no closer than 0.050 mm to 1.270 mm (0.002 to 0.050 inches), and more preferably 0.076 to 0.178 mm (0.003 to 0.007 inches). With the configuration of the embodiment of FIG. 8, shearing members 21' and 31' provide the desired insulating material between the electrodes.

EXAMPLES

Scissors in accordance with the embodiments illustrated in FIGS. 1-3 and 4 have been constructed of a martensitic stainless steel material (Grade AISI 420). Scissor halves 20 and 30 were nominally 177.8 mm (seven inches) in length with shearing members 21 and 31 extending 38.1 mm (one and one-half inches) beyond fastener 40. Shearing members 21 and 31 were 2.5 to 7.6 mm (0.1 to 0.3 inches) wide and 1.78 to 2.54 mm (0.07 to 0.10 inches) thick, the smaller dimensions being distal to the pivot. An insulating coating 13



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was deposited on shearing surface 32 of shearing member 31 by plasma spraying alumina to a thickness in the range of 0.076 to 0.178 mm (0.003 to 0.007 inches).

Coating 13 was applied along the length of member 31 that contacts opposing member 21 in the full range of motion. Using conventional electroplating techniques, exterior surfaces 24 and 34 were provided with a coating 12 of a material having a high electrical and thermal conductivity comprising three layers:

10 a first layer of copper, 0.050 to 0.076 mm (0.002 to 0.003 inches) thick, was deposited on all surfaces except the shearing surfaces;

a second layer of nickel, 0.254 to 1.016 mm (0.010 to 0.040 inches) thick, was then
15 deposited on the copper layer and;

a third layer of gold, 0.508 to 1.016 mm (0.020 to .040 inches) thick, was deposited on the nickel layer.

The nickel and gold layers provide an oxidation
20 resistant protective outer layer for the thermally and electrically conductive sublayer of copper. Support members 25 and 35 included a coating 11 of an insulating material about 0.127 mm (0.005 inches) thick.

25 Experiments were performed on biological tissue and raw beefsteak using the above-described scissors in conjunction with an experimental power supply. The experimental power supply was operated at various selected constant frequencies in the range of
30 400 to 800 kHz and at selected levels providing a substantially constant voltage output level at the electrodes of the scissors in the range of 10 to 120 volts (RMS). This power supply had a low source impedance, and provided an alternating-current voltage
35 waveform having a crest factor near one. The voltage



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waveform was maintained at a substantially constant level in the sense that the output voltage did not drop significantly at high loading.

The preferred operating range for the above-described embodiment was found to provide a voltage at the electrodes of the instrument of 10-120 volts, more preferably 30-90 volts (RMS). The instrument operated satisfactorily throughout the above range of operating conditions, causing hemostasis of tissue and cutting tissue with minimal bleeding of that tissue. Accumulation of coagulated blood and tissue on the scissors was slight.

Frequencies below 100 kHz are known to affect the neuro-muscular systems of the patients, and may cause undesired stimulation. Applicant observed that frequencies above 800 kHz provided no advantage in operation and added cost to the power supply. While applicant believes that it would be possible to use higher frequencies, up to 2 MHz, the line losses in the cable connecting the electrosurgical instrument to the power supply would make use of such frequencies impractical.

Applicant observed that voltages (at the electrodes) below 10 volts (RMS) did not produce adequate joulean heating in the tissue to cause hemostasis. While prior art bipolar electrosurgical hemostatic teachings indicated that voltages above 120 volts (RMS) would be most desirable for achieving hemostasis of tissue, applicant observed that voltages above 120 volts (RMS) caused localized overheating of the electrodes and excessive accumulation of coagulum. Above 120 volts (RMS), rapid coagulum buildup necessitated frequent cleaning of the scissors, for example, every one to three cuts.



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Applicant observed that the device according to FIG. 4, which has coating 13 on only one shearing surface, provides the same level of performance as devices having insulating layers on both shearing surfaces (when operated under the same conditions). For both embodiments, the amount of heating and depth of hemostasis on both sides of the cut tissue are substantially uniform. It will of course be understood by one skilled in the art that use of a voltage level greater than the above specified ranges may be suitable for causing hemostasis in tissue having higher impedance.

* * *

The scissors of the present invention also can be used for blunt dissection, for example, by spreading the scissors as they are advanced into tissue during the raising of a skin flap. For such an embodiment, the blunt tips of the scissors are configured to cause hemostasis during the blunt dissection procedure. In such a procedure, the scissors are closed when inserted and then gradually opened, causing current flow outward of the cutting point, i.e., so that the dissected tissue hemostatically severed.

The various embodiments described herein are presented for purposes of illustration and not limitation, as the present invention can be practiced with surgical scissors-like instruments of any type or size having two cutting or shearing members movable with respect to one another. Thus, instruments constructed in accordance with the present invention may be adapted for use in cutting surface tissue, deep tissue and internal tissue, vessels, capillaries or organs, as may be required, for example, in



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microsurgery, macrosurgery, laparoscopy and other surgical procedures.

The present invention includes the method steps of employing an apparatus having shearing members
5 that include electrodes, wherein operation of the apparatus simultaneously causes hemostasis of tissue and severs that tissue. As noted in the EXAMPLES provided above, applicant has observed that use of a
10 scissors-like apparatus employing electrodes isolated by an intervening layer of insulating material at frequencies in the range of 400 to 800 kHz and 10 to 120 volts (RMS) provides satisfactory results.

The method of the present invention, suitable for use in a great variety of surgical procedures,
15 comprises the steps of:

(a) providing first and second shearing members, each shearing member having a shearing surface, a cutting edge and an electrode, the shearing members connected together so that the shearing
20 surfaces move in opposition through a range of motion in a scissors-like action that defines a cutting point moving along the cutting edges through the range of motion;

(b) connecting the electrodes to a
25 power supply;

(c) selecting and maintaining a substantially constant voltage level output across the power supply, the voltage level output independent of the impedance of the load connected across the power
30 supply;

(d) providing an electrically insulating material between the first and second electrodes so that the electrodes do not contact each other in the range of motion;



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(e) placing the electrodes in electrical contact with tissue to be cut so that high frequency current passes between the electrodes and through the tissue distal to the cutting point, but not
5 between the shearing surfaces; and

(f) moving the first and second shearing members through the range of motion, thereby passing current through the tissue in a region distal to the cutting point, simultaneously causing hemostasis
10 of the tissue and cutting the tissue at the cutting point.

Of course, it will be apparent to one skilled in the art that steps (a) and (d) described above can be combined by simply providing an apparatus as
15 hereinbefore described. Operation of the apparatus in the range 30 to 90 volts (RMS) will be desirable in many cases, depending upon the impedance of the tissue encountered during the surgical procedure.

The use of a power supply having a selectable
20 substantially constant voltage level output that is independent of load impedance provides sufficient power to cause effective hemostasis. Use of constant voltage output levels lower than those generally used in previously known electrosurgical instruments reduces
25 the power delivered to the electrodes when they are not in contact with tissue, i.e., open-circuited, and reduces the likelihood of generating a current arc when the electrodes are brought into contact with the tissue.

30 Use of a constant voltage level output that is independent of the load impedance inhibits excessive current flow through the tissue, as the tissue resistance increases during desiccation. Consequently, the depth of hemostasis obtained in the tissue can be
35 more precisely controlled, and localized overheating of



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the electrodes better avoided. Reduced localized heating of the electrodes also inhibits coagulum buildup, which can both interfere with efficient hemostasis and impede maneuverability of the
5 instrument.

One skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, and that the present invention is limited only by the claims which follow.



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. Apparatus for hemostatically cutting tissue, the apparatus comprising a first support member having a first shearing member, a first shearing surface and a first cutting edge; a second support member having a second shearing member having a second shearing surface and a second cutting edge; and connection means for pivotally joining the first and second shearing members together so that the first and second shearing surfaces face one another and the first cutting edge contacts the second cutting edge as the first shearing member pivots relative to the second shearing member in a scissors-like motion, the connection means comprising an electrically insulative material that electrically isolates the first shearing member from the second shearing member at the connection means wherein the first shearing member comprises a composite of an electrically conductive material and a layer of electrically insulative material disposed substantially for the entire length of the first shearing member to electrically isolate the first and second shearing members from one another along their respective lengths when the first and second cutting edges contact each other.

25

2. The apparatus according to claim 1 wherein the layer of electrically insulative material of the first shearing member forms substantially the entire first cutting edge and first shearing surface.

30

3. The apparatus according to claim 2 and wherein the layer of electrically insulative material has a hardness that is greater than the hardness of the second cutting edge and the second shearing surface.

35

4. The apparatus according to claim 1 or 2 wherein the layer of electrically insulative material of the first shearing member has a thickness in a range of 0.050



to 1.270 mm (0.002 to 0.050 inches).

5. The apparatus according to claim 4 wherein the layer of electrically insulative material of the first shearing member has a thickness in a range of 0.076 to 0.178 mm (0.003 to 0.007 inches).

6. The apparatus according to any one of claims 1 to 5 wherein the layer of the first shearing member has a first thickness and wherein the second shearing member comprises a layer of electrically insulating material having a second thickness and the sum of the first and second thicknesses is selected in a range of from 0.050 to 1.270 mm (0.002 to 0.050 inches).

7. Apparatus according to claim 1 wherein the first shearing member has a portion defining a first electrode extending substantially for the length of the first cutting edge and wherein the second shearing member comprises a composite of an electrically conductive material and a layer of electrically insulative material, the second shearing member having a portion defining a second electrode extending substantially for the length of the second cutting edge; the layer of the first shearing member and the layer of the second shearing member electrically isolating the first electrode from the second electrode when the first and second cutting edges contact each other.

8. The apparatus according to claim 7 wherein the layer of the first shearing member has a thickness selected in the range of from 0.050 to 1.270 mm (0.002 to 0.050 inches).

9. The apparatus according to claim 7 wherein the layer of the first shearing member has a first thickness and the layer of the second shearing member has a second thickness and the sum of the first and second thicknesses



is selected in a range of from 0.050 to 1.270mm (0.002 to 0.050 inches).

10. The apparatus according to any one of claims 6
5 to 9 and wherein the layer of the first shearing member has a first hardness and the layer of the second shearing member has a second hardness different than the first hardness.

10 11. The apparatus according to any one of claims 1 to 10 and further comprising a layer of material having a high electrical and thermal conductivity disposed on at least one of the first and second shearing members.

15 12. The apparatus according to any one of claims 1 to 11 and further comprising a layer of electrically conductive adherent material disposed on at least one of the first and second shearing members.

20 13. The apparatus according to any one of claims 1 to 12 wherein the first shearing member further comprises a first support member and the second shearing member further comprises a second support member, the first and second support members cooperating with the connection
25 means, the first and second support members having a layer of electrically insulating material disposed thereon.

30 14. The apparatus according to any one of claims 1 to 13 in combination with a power supply that provides a high frequency alternating-current waveform, the power supply having a selectable substantially constant voltage level output that is independent of the load impedance, and means for electrically connecting the power supply to
35 the first and second electrodes.

15. The apparatus according to claim 14 wherein the substantially constant voltage level output of the power



supply is selectable to provide a voltage across the first and second electrodes from the range of 10 to 120 volts (RMS).

5 16. The apparatus according to claim 14 or 15 wherein the power supply provides a voltage waveform having a crest factor near unity.

10 17. The apparatus of any of claims 14 to 16 wherein the power supply provides an alternating-currently voltage waveform having a high frequency selected from the range of 100 kHz to 2 MHz.

15 18. Apparatus according to any one of claims 1 to 17, for cutting and coagulating tissue, wherein

the first shearing member comprises a first blade member having a portion defining the first shearing surface, the first cutting edge having a length, and a first electrode extending substantially for the length of the first cutting edge; and the second shearing member comprises a second blade member having a portion defining the second shearing surface, the second cutting edge having a length, and a second electrode extending substantially for the length of the second cutting edge;

20 25 the electrically conductive material of the composite of the first blade member forms the first electrode; and

the second blade member comprises an electrically conductive material; and

30 wherein the layer of electrically insulative material of the first blade member electrically isolates the first electrode from the second electrode when the first and second cutting edges contact each other.

35 19. Apparatus for cutting and coagulating tissue, the apparatus comprising a first blade member having a portion defining a first shearing surface, a first cutting edge having a length, a first exterior surface,



and a first electrode extending substantially for the length of the first cutting edge; a second blade member having a portion defining a second shearing surface, a second cutting edge having a length, a second exterior surface and a second electrode extending substantially for the length of the second cutting edge; connection means for pivotally joining the first and second blade members together so that the first and second shearing faces face one another and the first cutting edge contacts the second cutting edge as the first blade member pivots relative to the second blade member in a scissors-like motion; wherein

the first blade member comprises an electrically insulative material and the first electrode comprises first layer of electrically conductive material disposed on the first exterior surface; and

the second blade member comprises an electrically insulative material and the second electrode comprises a second layer of electrically conductive material disposed on the second exterior surface;

wherein the electrically insulative material of the first blade member and the electrically insulative material of the second blade member electrically isolate the first electrode from the second electrode when the first and second cutting edges contact each other.

20. The apparatus according to claim 19 further comprising a layer of an electrically insulative material disposed on each of the first and second layers of electrically conductive material, except for a first region proximate to the first cutting edge and a second region proximate to the second cutting edge.

21. The apparatus according to claim 19 or 20 further comprising a layer of an electrically conductive adherent material disposed in superposition on the first and second layers of electrically conductive material.



22. The apparatus according to any one of claims 19
to 21 wherein the first electrode and the second
electrode are spaced apart, when the first cutting edge
contacts the second cutting edge, a distance in a range
5 of from 0.050 to 1.270 mm (0.002 to 0.050 inches).

23. The apparatus according to any one of claims 19
to 22 in combination with a power supply that provides a
high frequency alternating-current waveform, the power
10 supply having a selectable substantially constant voltage
level output that is independent of the load impedance,
and means for electrically connecting the power supply to
the first and second electrodes.

15 24. The apparatus of claim 23 wherein the
substantially constant voltage level output of the power
supply is selectable to provide a voltage across the
first and second electrodes in a range of from 10 to 120
volts (RMS).

20 25. The apparatus of claim 23 or 24 wherein the
power supply provides an alternating-current voltage
waveform having a frequency selected in a range of from
100 kHz to 2 MHz.

25

DATED this 15th day of August 1996

HEMOSTATIX CORPORATION

By their Patent Attorneys

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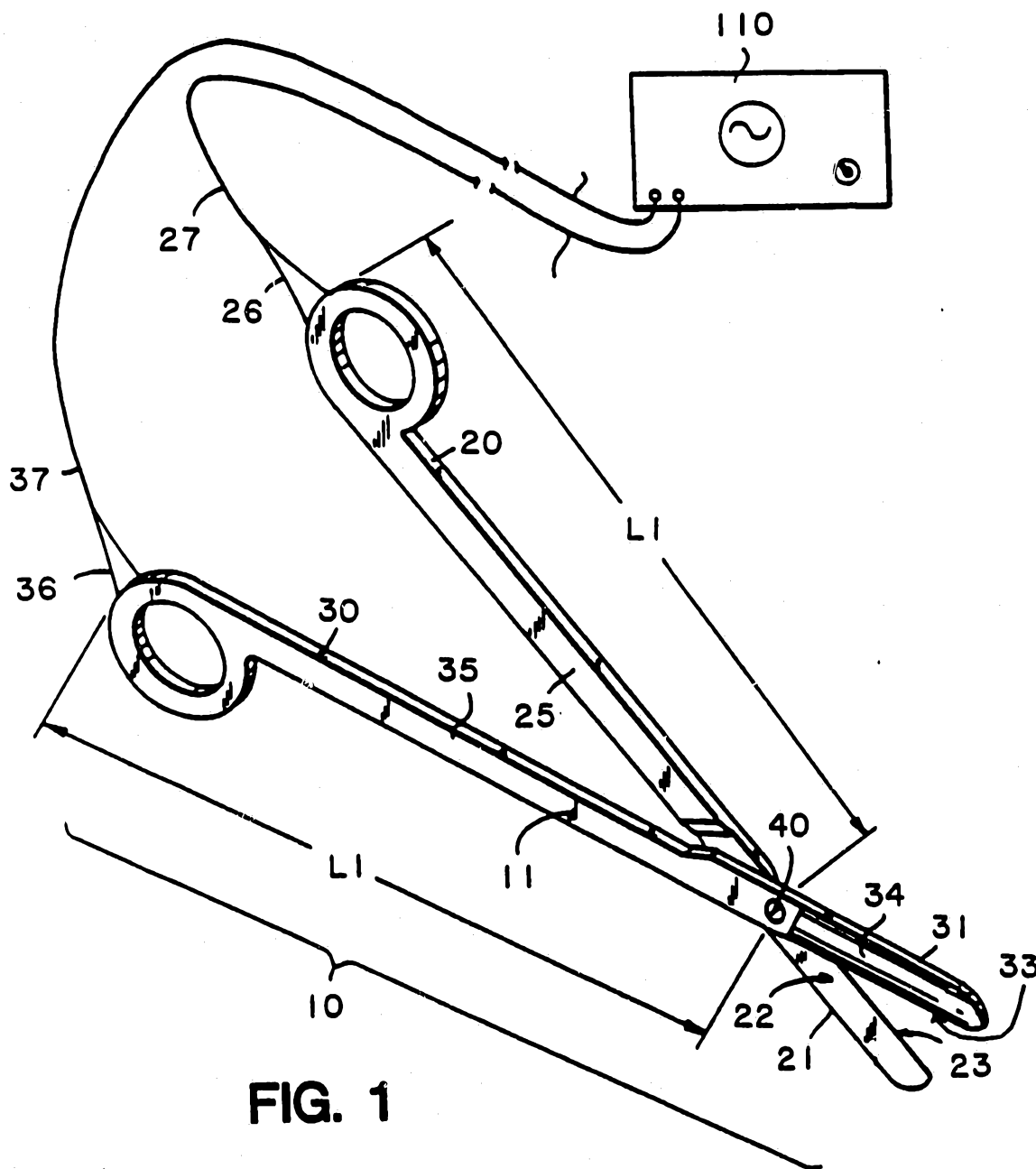


FIG. 1

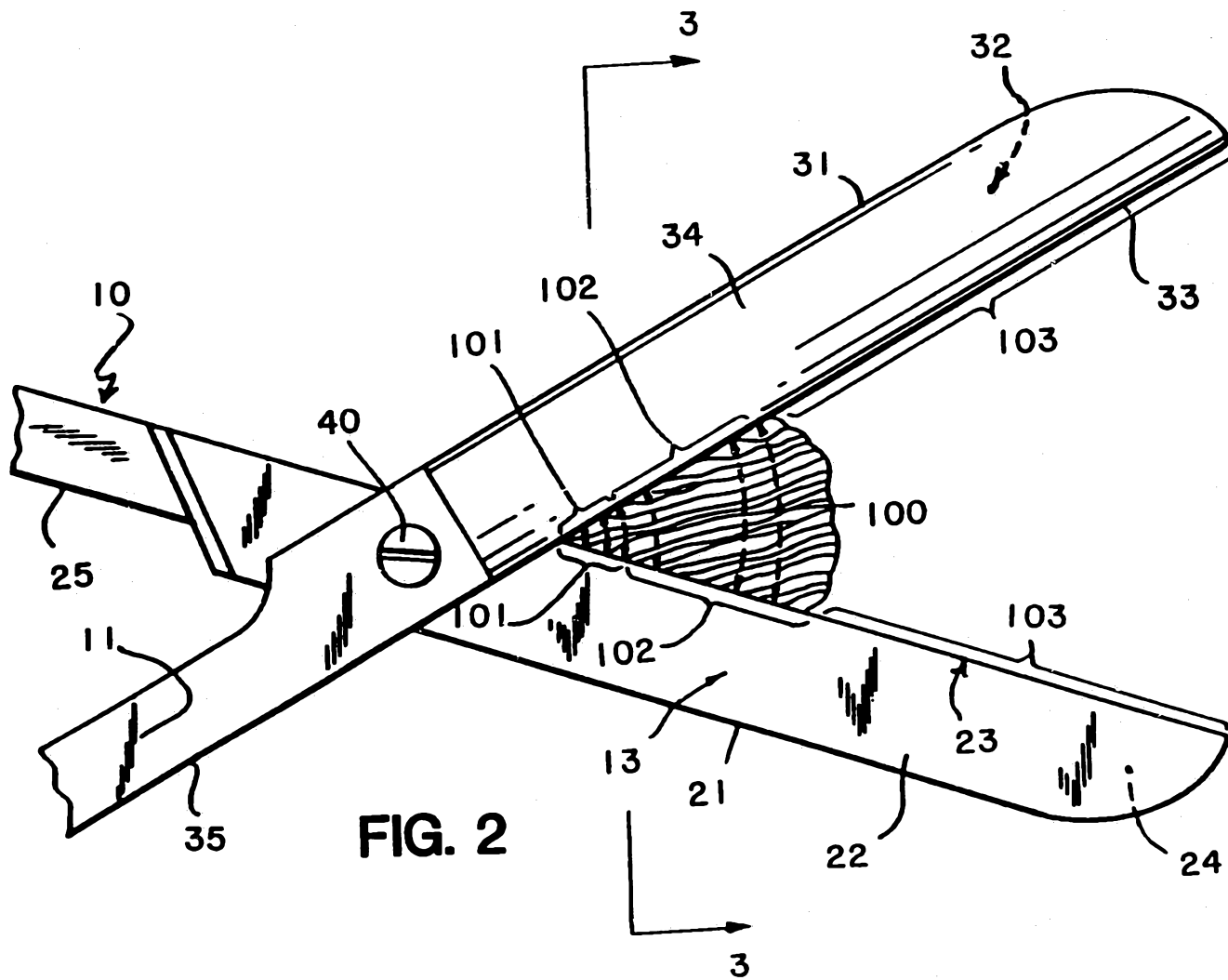
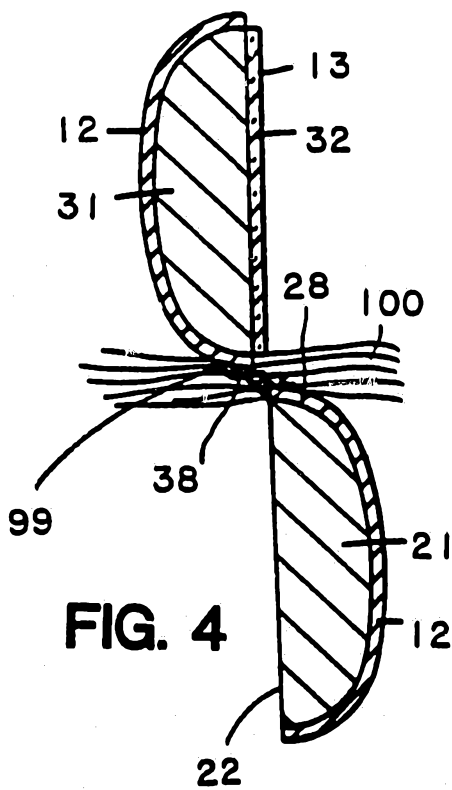
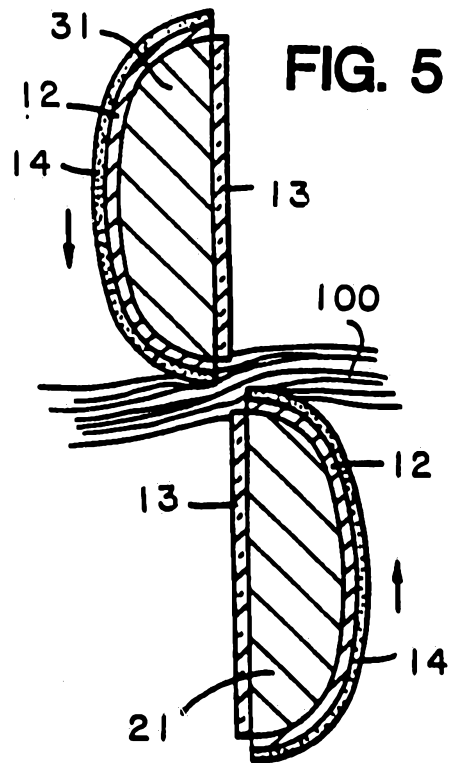
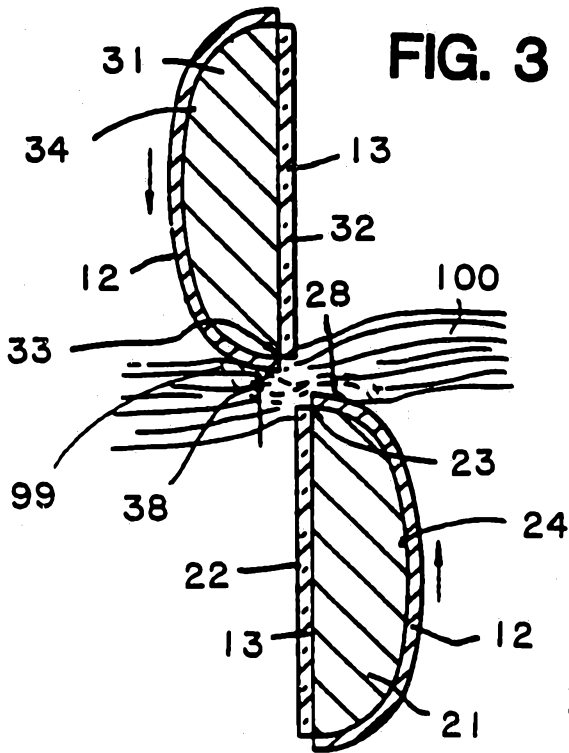
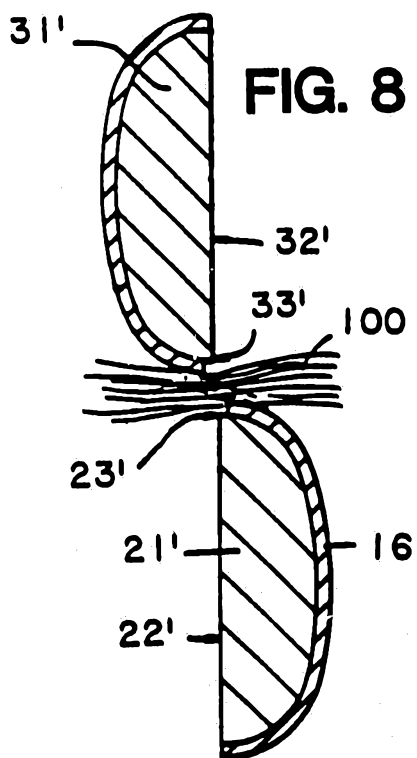
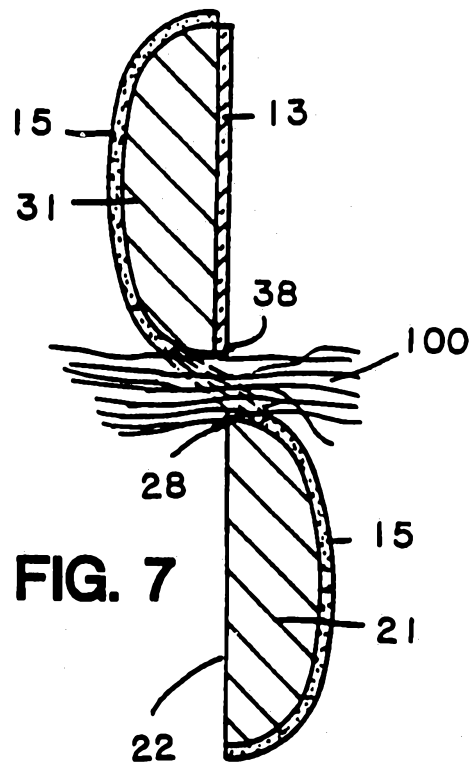
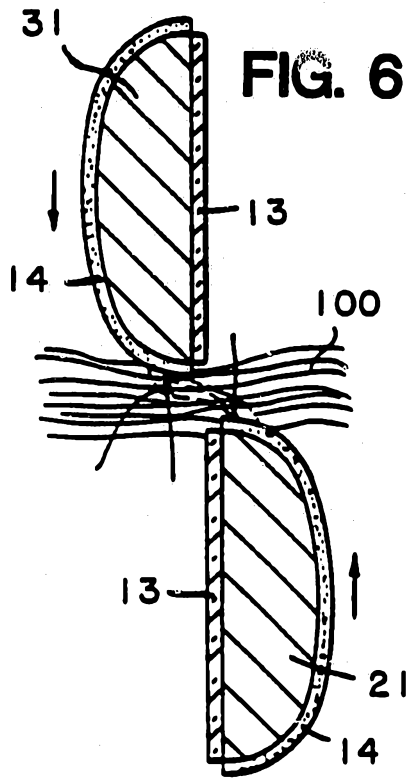


FIG. 2





INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/04664

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/39
US CL :606/48

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)

U.S. : 30/35-36,233,51/246,76/82,82.2, 128/399,402,606/32,34,37,39-40,45,49-52,167,174

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Automated Patent System Search terms on attachment.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A, 3,651,811 (HILDEBRANDT ET AL), 28 March 1972, see whole document.	<u>1</u> 31-34
Y	US,A, 4,271,838 (LASNER ET AL.), 09 JUNE 1981, See column 4 and figures 1 and 4.	36
Y	US,A, 4,940,468 (PETILLO), 10 JULY 1990, See lines 30-36 of column 3.	36
Y	The Cavitron Bipolar Coagulator, 1979, Cavitron Surgical Systems, See front and back of brochure.	31-34

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

* Special categories of cited documents:	*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
A document defining the general state of the art which is not considered to be part of particular relevance	*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
E earlier document published on or after the international filing date	*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
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P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 07 SEPTEMBER 1992	Date of mailing of the international search report OCT 1992
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