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Haemmerich et al.

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(54) ELECTRODE ARRAY FOR TISSUE ABLATION

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 463 days.

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(51) **Int. Cl.**
A61B 18/18 (2006.01)

(52) **U.S. Cl.** **606/41**; 128/898

(58) **Field of Classification Search** 606/27-52; 128/898

See application file for complete search history.

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(57) ABSTRACT

An electrode array allows for rapid ablation of a strip of tissue in an organ providing a barrier to blood loss during resection operations.

9 Claims, 6 Drawing Sheets

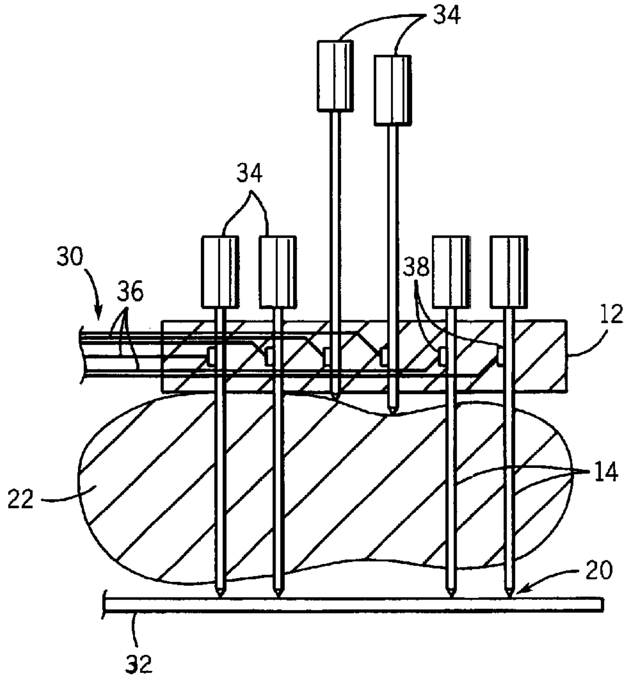


FIG. 1

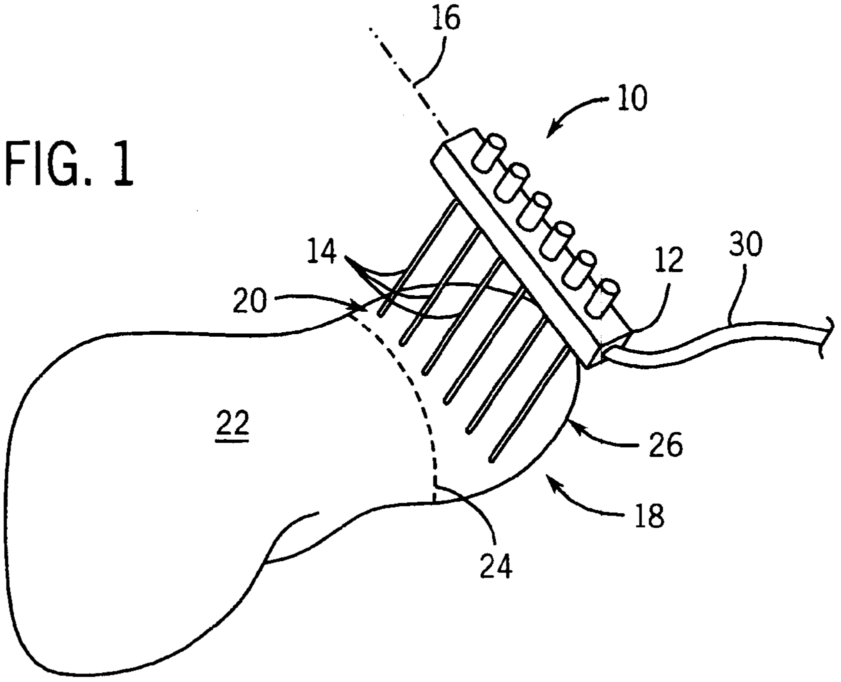
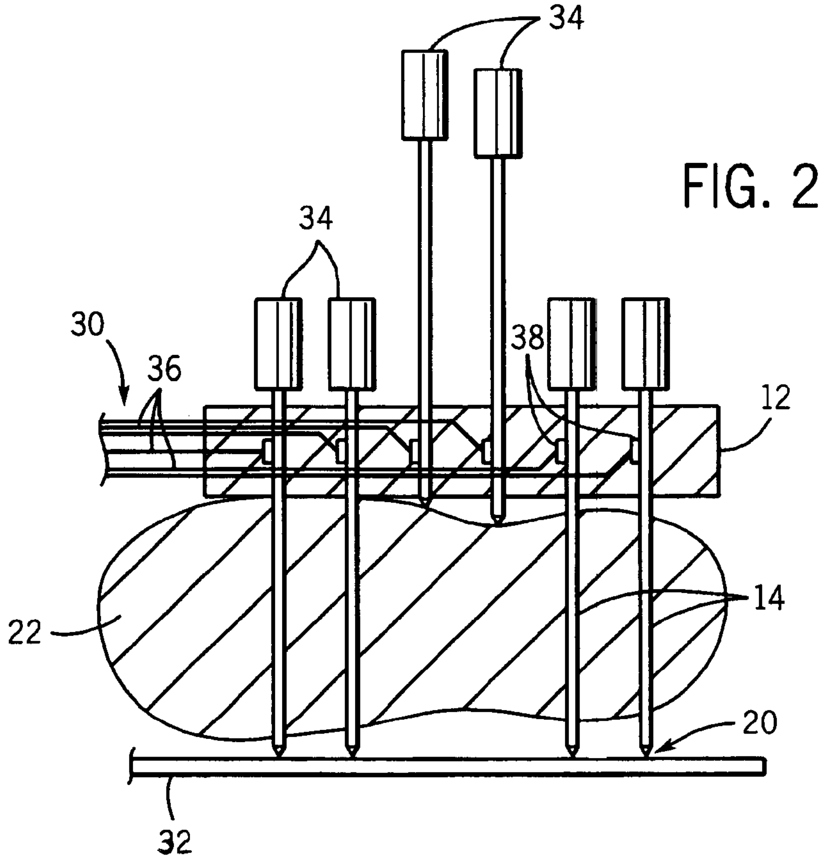


FIG. 2



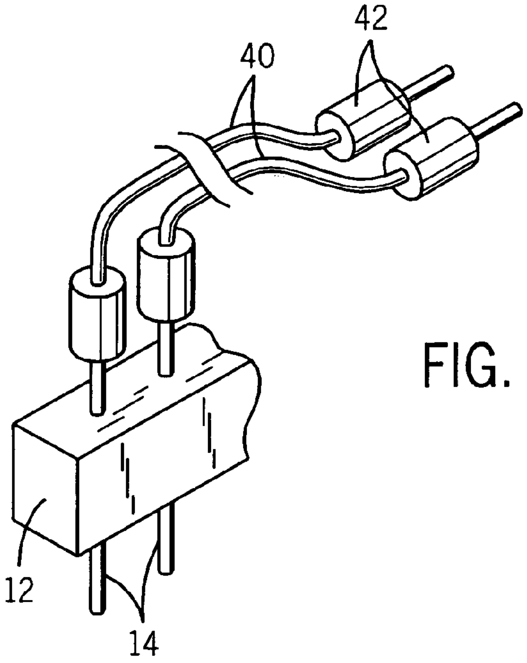


FIG. 3

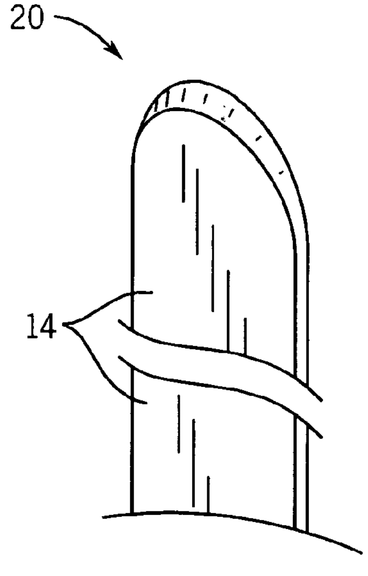


FIG. 4

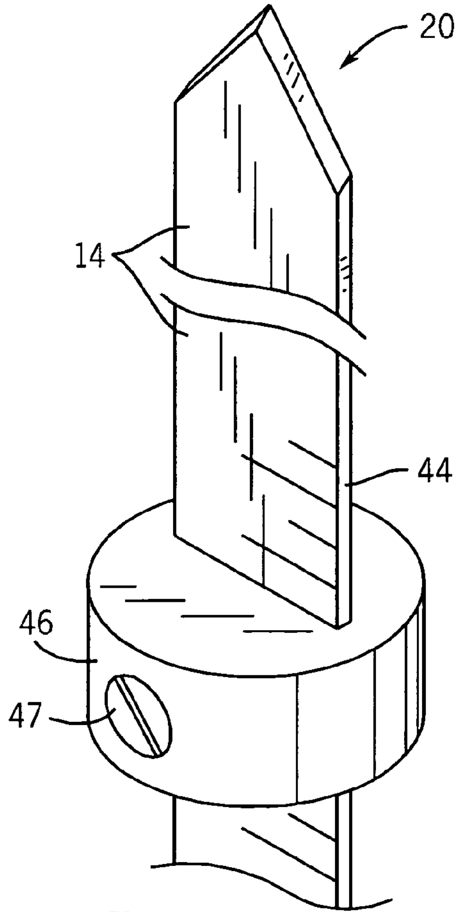


FIG. 5

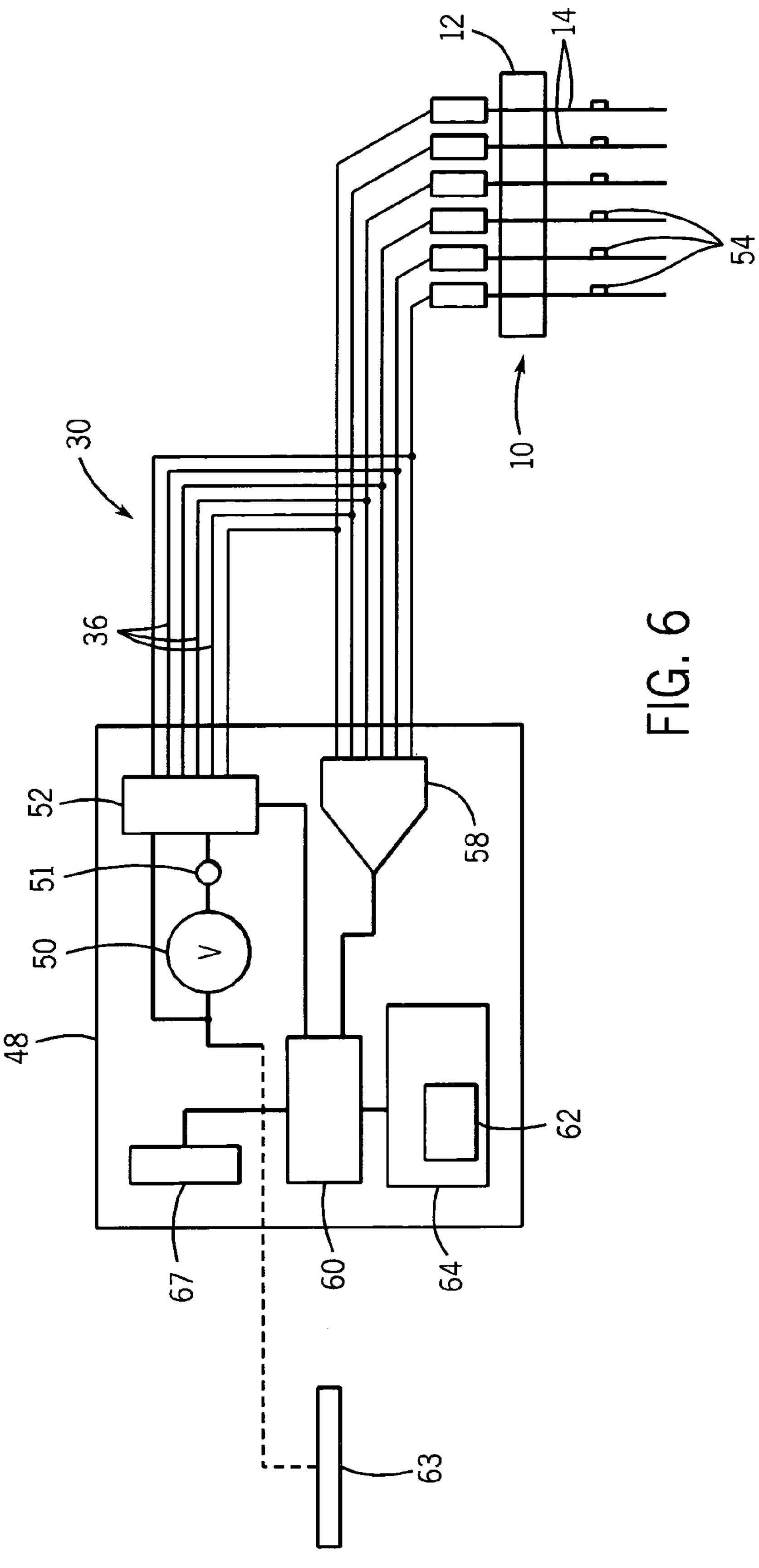


FIG. 6

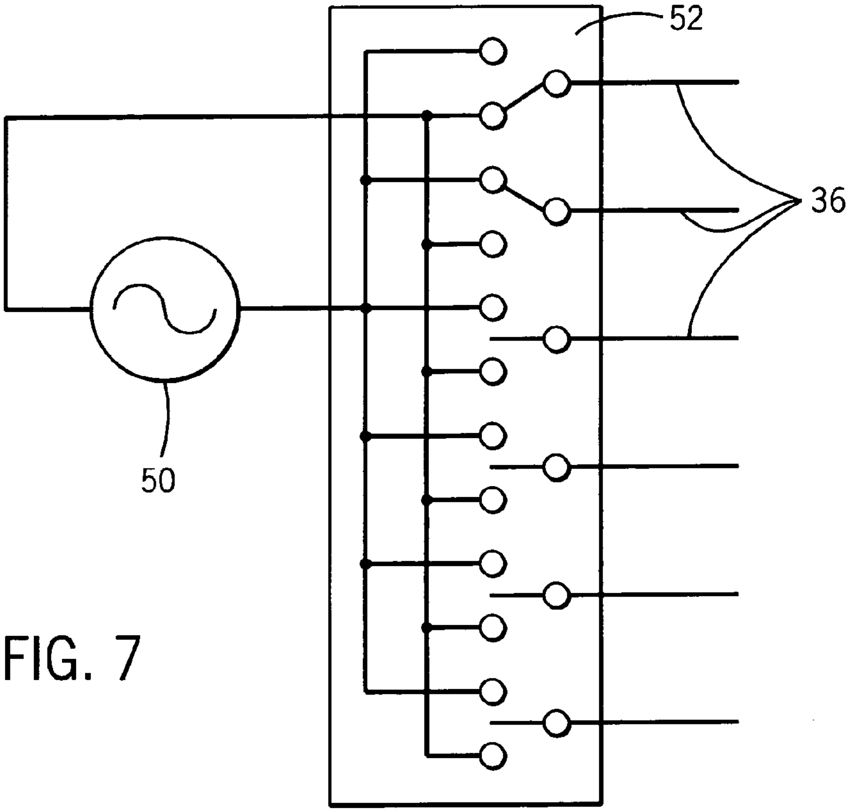


FIG. 7

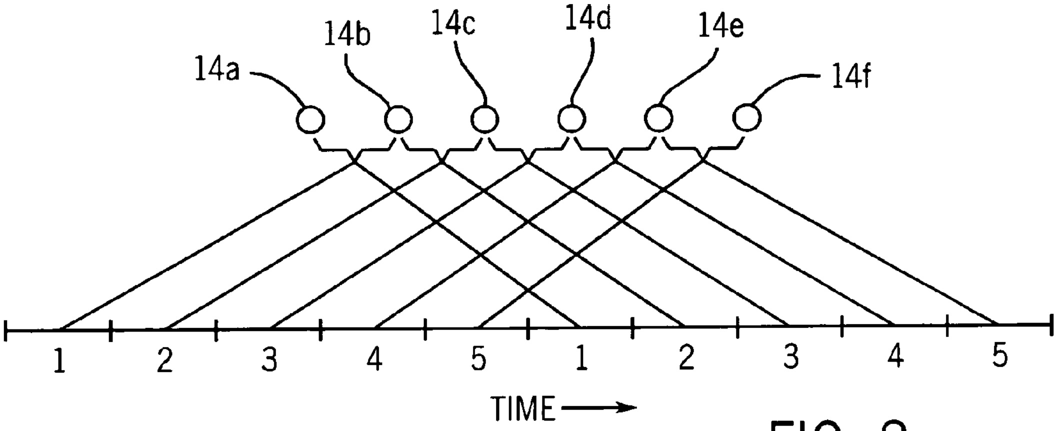


FIG. 8

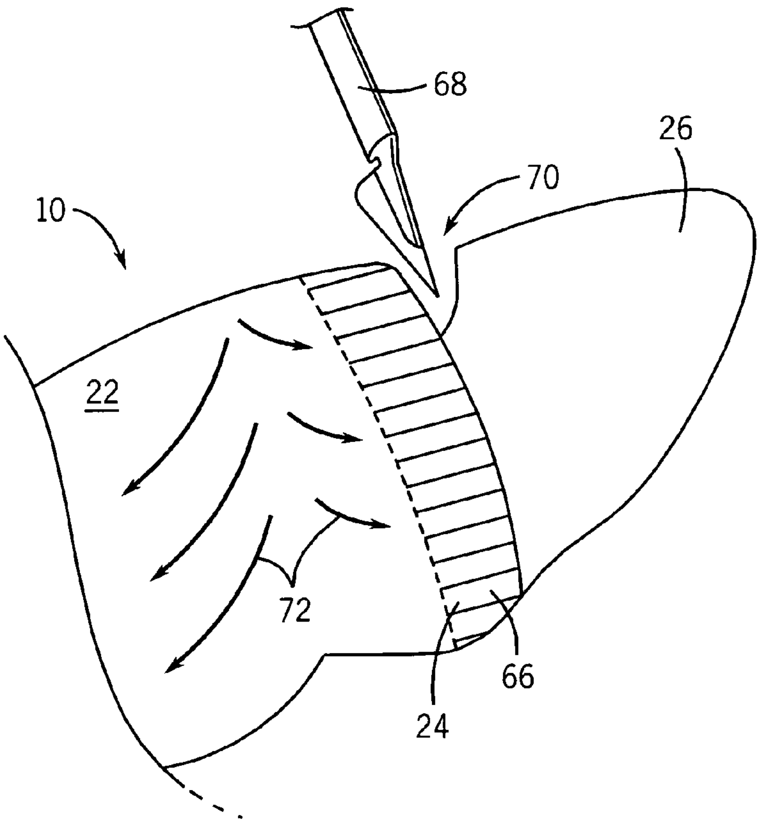


FIG. 9

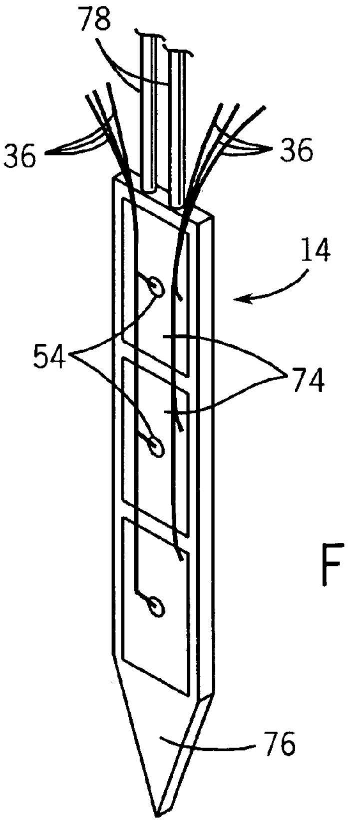


FIG. 10

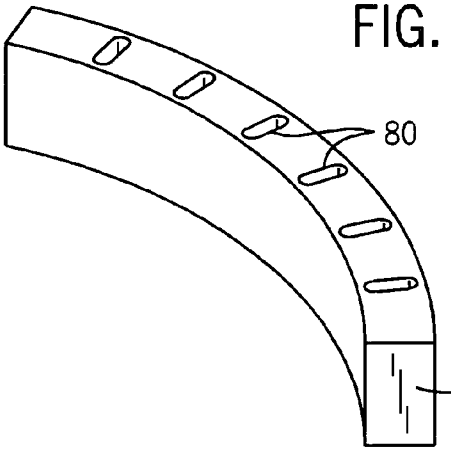


FIG. 11

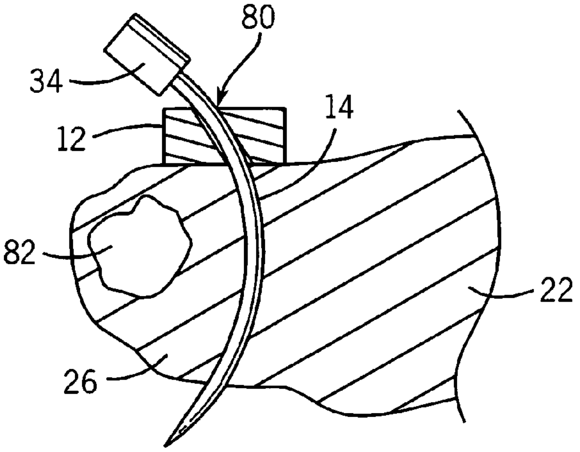


FIG. 12

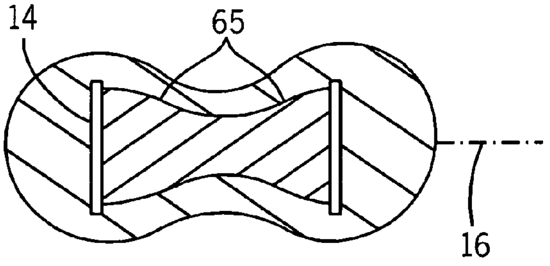


FIG. 13

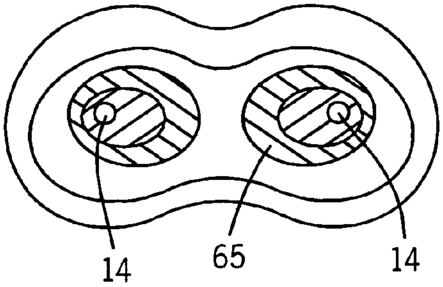


FIG. 14

ELECTRODE ARRAY FOR TISSUE ABLATION

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

This invention was made with United States Government Support awarded by the following agencies: Grant NIH 5 RO1 DK58839-02. The United States has certain rights in this invention.

CROSS REFERENCE TO RELATED APPLICATIONS

BACKGROUND OF THE INVENTION

The present invention relates to radio frequency (RF) ablation of tissue and in particular to an apparatus using ablation to control bleeding during the resection of a portion of an organ.

The liver is a common site for both primary and metastatic cancer. Surgical resection (hepatectomy) is currently the preferred treatment for liver cancer. During resection, the surgeon typically removes a lobe of the liver, a time consuming procedure where the surgeon must cut through tissue while avoiding or closing large blood vessels. Blood loss during this procedure can adversely affect patient survival, increase hospital stay, and increase complication rates.

Some studies have investigated the use of radio RF ablation or microwave (MW) ablation to coagulate tissue before resection. Henceforth, both RF and MW ablation will be referred to collectively as RF ablation.

In RF ablation, an electrode is inserted into the tissue and current passing from the electrode through the patient to a large area ground pad on the patient's skin coagulates the tissue near the electrode through resistive heating, sealing it against blood flow. In order to ablate the necessary area of tissue, the electrode is removed and reapplied at a series of locations along the tissue slice. The time required for this procedure is generally too long for clinic practice.

BRIEF SUMMARY OF THE INVENTION

The present invention provides an electrode array which may more rapidly ablate an area of tissue to staunch blood flow during resection. The shape of the individual electrodes of the array and their separation is adjusted to reduce insertion force while providing a sufficient area for partitioning. A switching of electricity between the electrodes provides rapid ablation of a tissue slice.

Specifically, the present invention provides an electrode array for RF ablation having a set of elongate electrodes for insertion through tissue of an organ. A holder or guide positions the electrodes with respect to each other to define a surface partitioning the organ.

It is thus one object of at least one embodiment of the invention to provide an electrode assembly that allows for rapid ablation of a slice through an organ to reduce blood loss during resection of a portion of the organ.

It is another object of at least one embodiment of the invention to provide a method for rapidly positioning electrodes for this purpose that may be practical in clinical application.

It is yet another object of at least one embodiment of the invention to enforce an optimized separation and orientation of the electrodes during this procedure.

The electrodes may be flat blades having their flat surfaces parallel.

It is an object of at least one embodiment of the invention to provide an electrode shape which preferentially creates a thin slice of ablated tissue by providing increased surface area facing other electrodes thereby concentrating the heating between electrodes

It is another object of at least one embodiment of the invention to provide an electrode shape which reduces insertion forces on the electrodes for a given electrode cross-sectional area.

The elongate electrodes may be separately inserted, sliding along their length through the holder.

It is thus another object of at least one embodiment of the invention to provide a system in which the electrodes may be individually inserted into the organ thus reducing the instantaneous force placed on the organ.

The elongate electrodes may be fixed within the holder.

Thus, it is another object of an alternative embodiment of the invention to allow the electrodes to be simply and rapidly inserted in unison.

The elongate electrodes may be substantially straight and the holder may separate the elongate electrodes along a line so that the elongate electrodes define a plane surface within the organ. Alternatively, the electrode holder may separate the electrodes along a curve so that the elongate electrodes define a curved cylindrical surface within the organ. Alternatively or in addition, the elongate electrodes may be curved so that the elongate electrodes define a curved spherical surface within the organ.

Thus, it is another object of at least one embodiment of the invention to provide an electrode system that may accurately define an ablation region having a variety of shapes.

Each elongate electrode may be affixed to a flexible conductor conducting RF power independently to the elongate electrode.

Thus, it is another object of at least one embodiment of the invention to provide an electrode that allows for sophisticated control of electrode energy to produce a uniform ablation region.

The elongate electrodes may be removable from the holder and the holder may incorporate connectors joining flexible conductors to the elongate electrodes when they are inserted in the holder.

Thus, it is another object of at least one embodiment of the invention to eliminate the need for the surgeon to manage multiple connectors when using the present invention.

The elongate electrodes may slide within the holder and the holder may incorporate slide contact connectors joining the flexible conductors to the elongate electrodes.

Thus, it is another object of at least one embodiment of the invention to provide an electrical connection system that accommodates insertion of the electrodes into the organ at different distances.

The electrode may include thermal sensors for detecting a temperature of tissue around the elongate electrodes. Each of the elongate electrodes may alternatively or in addition include at least two electrically independent zones along their length allowing independent application of electrical power to the zones. Each of these zones may provide a separate thermal sensor.

Thus, it is another object of at least one embodiment of the invention to provide for sophisticated feedback control and sophisticated localized application of power to provide a uniform ablation region in the presence of different tissue characteristics.

Each of the elongate electrodes may include graduations indicating a length along the elongate electrode.

Thus, it is another object of at least one embodiment of the invention to provide electrodes that may be accurately inserted to predetermined depths.

The electrodes may include stops that may be preset to particular depths or a backer sheet that will stop further travel of the electrodes once it has passed through the organ and confronted the backer sheet placed beneath the organ.

Thus, it is another object of at least one embodiment of the invention to provide a method of allowing complete insertion of the electrodes through the organ with minimal risk to underlying tissue.

The RF power may be applied between the electrodes in bipolar fashion.

Thus, it is another object of at least one embodiment of the invention to provide improved slice ablation by confining the electrical flow largely to the plane of the electrodes.

The RF power may be applied to one pair of electrodes at a time.

It is thus another object of at least one embodiment of the invention to provide an ablation system that does not over tax the current output of a conventional RF ablation device.

The particular pair of electrodes between which power flows may be changed on a periodic basis.

Thus, it is another object of at least one embodiment of the invention to provide control of ablation throughout the slice defined by the electrodes.

These particular objects and advantages may apply to only some embodiments falling within the claims and thus do not define the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a liver showing positioning of the electrode array of the present invention for insertion into the liver for creating an ablated partition in a first embodiment having fixed electrodes;

FIG. **2** is a cross-sectional view through the liver after insertion of the electrodes against a stopper plate in a second embodiment having sliding electrodes and electrode connectors;

FIG. **3** is a fragmentary view of the holder of the electrodes of FIG. **2** showing an alternative electrical connection method using individual cables attached to each electrode;

FIG. **4** is a fragmentary detailed perspective view of a sharpened end of one electrode of FIG. **2** showing a blade configuration with a rounded end;

FIG. **5** is a figure similar to that of FIG. **4** showing an alternative embodiment of the blade of FIG. **4** showing a blade configuration with a pointed end and further showing graduation marks on the length of the electrode together with an electrode stop used for controlling insertion depth;

FIG. **6** is a simplified block diagram of a RF power supply suitable for use with the present invention as connected to the electrodes;

FIG. **7** is a block diagram with a switching circuit used with the power supply of FIG. **6**;

FIG. **8** is a timing diagram showing a sequencing of operation of the switching circuit of FIG. **7** to connect pairs of the electrodes together for bipolar operation;

FIG. **9** is a fragmentary perspective view of the liver showing resection of a portion of the tumor after ablation by cutting on an outside edge of the ablation region;

FIG. **10** is an alternative embodiment of the electrode of FIG. **5** having multiple isolated conductive zones and thermal sensors on each zone for independent control of ablation along the length of the electrode;

FIG. **11** is an alternative embodiment of the holder of FIG. **1** for providing a curved surface for the ablation region;

FIG. **12** is a cross-sectional view through a liver showing the use of a curved electrode such as may be used with the curved holder FIG. **11** to realize a hemispherical ablation surface or with the straight holder of FIG. **1** to realize a cylindrical ablation surface;

FIG. **13** is a simplified representation of the spacing between two blade electrodes showing the improved ablation zones obtained by the parallel blade structure and bipolar operation; and

FIG. **14** is a view similar to FIG. **13** showing needle electrodes such as provide asymmetrical ablation regions through the use of bipolar stimulation but which may require closer electrode spacing.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. **1**, an electrode array assembly **10** of the present invention includes a holder **12** supporting a number of elongate electrodes **14** spaced along an axis **16** to define a generally planar surface **18** among them. The surface **18**, for example, may be 8 cm long and 10 cm wide.

Sharpened tips **20** of the elongate electrodes **14** may be inserted into the liver **22** at an insertion line **24** to isolate one lobe **26** of the liver **22** for resection. The elongate electrodes **14** may, for example, be constructed of a biocompatible stainless steel.

The holder **12** may be, for example, an insulating plastic block having holes cut in the holder **12** to receive metallic shafts of the elongate electrodes **14** at regular intervals. In a preferred embodiment, the separation of the electrodes is approximately 1.5 cm. The elongate electrodes **14** may be fixed to the holder **12** so as to be moved in unison for rapid insertion. Each elongate electrode **14** may be independently attached to a separate conductor **23** (not shown in FIG. **2**) of a cable **30** providing independently controllable RF power to each of the elongate electrodes **14** as will be described below.

Referring now to FIG. **2** in an alternative embodiment, each elongate electrode **14** may be separately slidable within the holder **12** as gripped by handles **34** on ends of the elongate electrodes opposite the sharpened tips **20**. Separate conductors **36** of the cable **30** may pass to sliding contacts **38** allowing electrical connection to the elongate electrodes **14** throughout their range of travel through the holder **12**. In this embodiment, the holder **12** is placed against the liver **22** along insertion line **24** (as shown in FIG. **1**) and the individual elongate electrodes **14** are inserted one at a time providing a reduced instantaneous force to be applied to the liver **22**. The sliding contacts **38** allow the depth of insertion of the elongate electrodes **14** to be varied freely. A flexible plastic backer sheet **32** may be placed under the liver **22**. Insertion of the elongate electrodes **14** through the liver **22** may be stopped by the backer sheet **32** ensuring their full extent through the liver **22** without significant incursion into underlying tissue. In this case, the elongate electrodes **14** may be removable from the holder **12** or may be held in slidable configuration but captive within the holder **12** to prevent the components from being separated.

The backer sheet **32** may also be used with the embodiment of FIG. **1**.

Referring now to FIG. **3**, the sliding contacts **38** of FIG. **2** may be eliminated in favor of separate cables **40** attached to each elongate electrode **14** and terminating in connectors **42** such as may be connected directly to a source of RF power or to a connector block on the holder **12** (not shown) which may in turn communicate through a cable **30** with the source of RF power. Separate cables **40** may also be used with the embodiment of FIG. **1**.

Referring now to FIG. **4**, while conventional needle electrodes having a cylindrical cross-section may be used for the elongate electrodes **14** in a preferred embodiment, the elongate electrodes **14** are flattened blades. The tips **20** of the blade elongate electrodes **14** may have a rounded profile with a sharpened peripheral edge to reduce the force of insertion into the liver **22**. Alternatively, referring to FIG. **5**, the tips **20** of the blade elongate electrodes **14** may have a chisel point leading to a sharpened apex, again with a sharpened peripheral edge. RF power may be applied during insertion of the electrode, to reduce required insertion force and limit bleeding during the insertion.

The side of the elongate electrode **14** may include graduations **44** allowing visible control of the depth of the elongate electrode **14**. These graduation marks may be used alone or to set a stop **46** using a set screw **47** or the like that attaches to the elongate electrode **14** at any of a range of locations along the side of the elongate electrode **14** so that the depth of the elongate electrode **14** may be reached accurately and quickly.

The handles **34** may be numbered or colored so as to provide for a particular ordering of insertion into the holder **12**, in the case when depth has been preset by stops **46**, so that the correct elongate electrodes **14** may be inserted appropriately in the holder **12**.

Referring now to FIG. **6**, the electrode array assembly **10** may be used in conjunction with a power unit **48** providing an RF power source **50**. The power unit **48** provides power to the elongate electrodes **14** via an electronically controllable switching circuit **52** communicating with the multiple conductors **36** of cable **30** (or cables **40**) passing to the elongate electrodes **14**. RF power sources **50** suitable for multiple electrodes are described in U.S. application Ser. No. 10/796,239 filed Mar. 9, 2004 and entitled Multipolar Electrode System for Volumetric Radio Frequency Ablation and U.S. application Ser. No. 10/11,681 filed Jun. 10, 2002 and entitled: Radio-Frequency Ablation System Using Multiple Electrodes, both hereby incorporated by reference.

The power unit **48** may also receive signals from each of the elongate electrodes **14** from an optional thermal sensor **54**, such as a thermocouple or solid-state temperature sensor, attached to the surface of the elongate electrodes **14** or within the electrodes. Signals from these thermal sensors **54** may be received by the power unit at input circuit **58** which digitizes and samples the temperature signals and provides them to a microprocessor **60**.

The microprocessor **60** executes a stored program **62** held in a memory **64** and also communicates with a front panel control set **67** to provide data to a user and accept user input commands.

While the present invention contemplates that power will be applied to the elongate electrodes **14** in a bipolar mode as will be described, power unit **48** may alternatively communicate with a ground pad **63** to allow monopolar operation.

Referring now to FIG. **7**, the switching circuit **52** provides solid-state switches that allow each conductor **36** attached to an elongate electrode **14** to be switched to either terminal of the RF power source **50** so that the elongate electrode **14** provides either a return or source of RF power. Switching circuit **52** may also be used to disconnect particular ones of the conductors **36** so as to isolate the associated elongate electrode **14** and to allow a duty cycle modulated control of the power going to each elongate electrode **14**. Thus, while the power source **50** may optionally run at a constant rate control of the power may be obtained through the switching circuit **52**. The switching circuit **52** is connected to the microprocessor **60** to be controlled thereby.

Referring now to FIG. **8**, the microprocessor **60** in a preferred embodiment executes the program **62** in memory **64** to sequentially control the switches of the switching circuit **52** to connect one pair of elongate electrodes **14** to the power source **50** at each time. Accordingly, at a time period **1**, a pair of elongate electrodes **14***a* and **14***b* will be connected across power source **50** for current to flow therebetween. At this time, all other elongate electrodes **14** are disconnected from the power source **50**. At a second time period **2**, elongate electrodes **14***b* and **14***c* will be connected across the power source **50** for power to flow therebetween and elongate electrode **14***a* is disconnected from the power source **50**.

This process repeats itself for the remaining elongate electrodes **14** until each electrode has been pair-wise connected to the power source **50**. After this, the cycle is reinitiated with elongate electrodes **14***a* and **14***b* being connected.

In an alternative embodiment, each of the elongate electrodes **14** other than the pair being connected to the power source **50** is connected to a return path so as to provide an effective virtual ground plane for return of current.

In yet another alternative embodiment, the sequential switching of pairs of elongate electrodes **14** does not proceed continuously from left to right but rather every other sequential pairing is skipped to allow cooling of the tissue near each energized electrode before the next adjacent pair is energized. Accordingly, elongate electrodes **14***a* and **14***b* may be connected across the power source **50** and then elongate electrodes **14***c* and **14***d*, and then elongate electrodes **14***e* and **14***f*, and then elongate electrodes **14***b* and **14***c*, and then elongate electrodes **14***d* and **14***e* and so forth.

As well as limiting the overheating of tissue, the switching of the elongate electrodes **14** provides other benefits. The large number of elongate electrodes **14** may create a very low impedance device which may be beyond the current capability of standard power sources **50**. Accordingly, the switched operation also allows that power to be allocated among pairs of the elongate electrodes **14**. With standard power sources **50**, the ablation region will typically be 1 to 2 cm wide and can be obtained in five to ten minutes. The switching among elongate electrodes **14** may also eliminate shielding effects among electrodes providing a more uniform ablation region.

The amount of power deposited at the tissue surrounding each elongate electrode **14** may be changed by varying the length of the duration of the time periods **1** to **5** as shown in FIG. **8**. Alternatively, a high-frequency duty cycle modulation may be imposed on the power applied during the periods **1** to **5** by power source **50** according to well-known techniques.

The control of power deposited at the tissue near each electrode **14** may be controlled by these techniques according to the temperature measured at each elongate electrode **14**, for example, to reduce power when the temperature rises above a pre-determined threshold either according to a simple thresholding technique or a more complex feedback loop using proportional, integral, and derivative terms.

As an alternative to temperature control, the impedance of the tissue between each pair of electrodes **14** may be determined by monitoring the current flow into the tissue and the particular voltage of the power source **50** (using an in-line current sensor **51**), and this impedance can be used to control power by decreasing, or shutting down power for a certain time period as impedance rises, the latter indicating a heating of the tissue.

Impedance measurements can also be used to gauge the thickness of the tissue being ablated. Referring also to FIG. **2**, the tissue may have different thickness in the slice where the electrode array assembly **10** is inserted. By measuring impedance (with low power application of RF current) between adjacent electrodes **14**, the slice thickness along the electrodes **14** can be estimated before ablating the slice. Power applied between each electrode pair can then be applied according to tissue thickness (e.g. tissue twice as thick requires twice the power). In one embodiment, this can be achieved by applying a constant voltage bipolar between each electrode pair. If tissue is twice as thick, impedance is about half as great, and as a result the applied power is twice as high with that constant voltage.

Monitoring current and voltage with the microprocessor **60** may also be used to detect excess or low currents to any particular elongate electrode **14**. In the former case, power limiting may be imposed. The latter case may indicate a disconnection of one or more elongate electrodes **14** and an indication of this may be provided on the front panel control set **67** to the user.

It will be apparent to those of ordinary skill in the art that a number of other control feedback techniques may be used including those which control current flow or voltage or power (the latter being the product of current and voltage) according to each of these terms.

Referring now to FIG. **13**, the flat shape of the elongate electrodes **14** provides an asymmetrical ablation region **65** that preferentially ablates tissue along axis **16** allowing increased spacing of elongate electrodes **14** (and thus fewer electrodes and less insertion force) as well as a relative uniform but thin ablation region. In contrast, the use of needle elongate electrodes **14** as shown in FIG. **14** may require closer spacing to obtain a continuous ablation region **65**.

Referring now to FIG. **9**, once the liver **22** is ablated along an ablation region **66** intersecting insertion line **24**, a scalpel **68** may be used to resect a lobe **26** of the liver **22** by making a cut **70** on the outside of the ablation region **66** with respect to a general path **72** of blood flow through the liver **22**. The ablation region **66** thus reduces blood loss during the resection process.

Referring now to FIG. **10** in an alternative embodiment, elongate electrode **14** may include a number of independently conductive zones **74** separated on an insulating substrate **76**. Each conductive zone **74** communicates with a separate conductor **36** so as to allow independent control of current flow into the tissue not simply among elongate electrodes but along the length of each elongate electrode **14**. A thermal sensor **54** may be associated with each region further providing independent feedback control of each region.

Referring still to FIG. **10**, active cooling of the elongate electrodes **14** may also be accomplished through the use of small pipes **78** through which cooled fluid such as air or liquid may be passed.

Referring now to FIG. **11** in an alternative embodiment, the holder **12** is not planar, but may have an arcuate shape with holes **80**, through which the elongate electrodes **14** are inserted, being arranged along a radius so that the elongate electrodes **14** as positioned by the holder **12** describe a hemi cylindrical surface conforming to an outline, for example, of a tumor in the lobe **26** to be resected.

Referring to FIG. **12**, alternatively or in addition, each elongate electrode **14** may be curved so as to fit through an arcuate hole **80** in the holder **12**, the holder **12** which may be straight or curved. In the former case, the elongate electrodes provide a hemicylindrical ablation surface having an axis parallel to axis **16** along which the elongate electrodes are separated. In the latter case, the elongate electrodes provide a curved surface in two dimensions approximating a hemispherical surface to conform to a possible tumor region **82** within the lobe **26**.

The present invention is not limited to use with the liver **22**, but may be used generally in any medical procedure where a barrier needs to be created prior to a cutting of tissue and in particular for surgery in other organs. The switching schedule through which power deposition is controlled may be regular or varied.

It is specifically intended that the present invention not be limited to the embodiments and illustrations contained herein, but include modified forms of those embodiments including portions of the embodiments and combinations of elements of different embodiments as come within the scope of the following claims. For example, the range of RF frequencies used in the present invention may extend from the kilohertz range to microwave frequencies using appropriate electrode structures.

We claim:

1. A method of resecting a portion of an organ comprising the steps of:

(a) inserting an electrode array into the organ, the electrode array providing a set of elongate electrodes positioned by a holder to a surface along a resection cut line;

(b) switching radio frequency power to the electrodes to cyclically apply power between different pairs of the electrodes to create a partition of ablated tissue across the cut line; and

(c) cutting the tissue of the organ at the ablated tissue to reduce blood loss during resection of a portion of the organ;

wherein the elongate electrodes slide within the holder and include graduation marks and including the steps of:

(1) positioning the holder against the organ; and

(2) individually inserting the electrodes into the holder and sliding them different distances guided by the graduation marks so that the electrodes penetrate the organ to different predetermined depths matching thicknesses of the organ.

2. The method of claim **1** wherein the cut positions at least a portion of the ablated tissue between the cut and a region of blood flow into the organ.

3. The method of claim **1** further including placing an electrode stop beneath the organ with respect to the electrode array to stop further travel of the electrodes of the electrode array after the electrodes have passed through the organ.

4. The method of claim **1** wherein the radio frequency is duty cycle modulated to control the application of power to the organ.

5. The method of claim **1** including the step of controlling an average current flow at the electrodes according to at least one parameter selected from the group consisting of: local temperature of the tissue, local impedance of the tissue, a predetermined current limit, and a predetermined power limit.

6. A method of resecting a portion of an organ comprising the steps of:

(a) inserting an electrode array into the organ, the electrode array providing a set of elongate electrodes positioned by a holder to a surface along a resection cut line;

(b) switching radio frequency power to the electrodes to cyclically apply power between different pairs of the electrodes to create a partition of ablated tissue across the cut line; and

(c) cutting the tissue of the organ at the ablated tissue to reduce blood loss during resection of a portion of the organ;

wherein the elongate electrodes slide within the holder and including the steps of:

(1) based on determined thicknesses of the organ, moving and affixing stops to different locations on the electrodes to control the insertion of the electrodes to different depths to match the thicknesses of the organ;

(2) positioning the holder against the organ; and

(3) individually inserting the electrodes into the holder and sliding them through the holder against the stops.

7. The method of claim **6** wherein the cut positions at least a portion of the ablated tissue between the cut and a region of blood flow into the organ.

8. The method of claim **6** wherein the radio frequency is duty cycle modulated to control the application of power to the organ.

9. The method of claim **6** including the step of controlling an average current flow at the electrodes according to at least one parameter selected from the group consisting of: local temperature of the tissue, local impedance of the tissue, a predetermined current limit, and a predetermined power limit.

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