



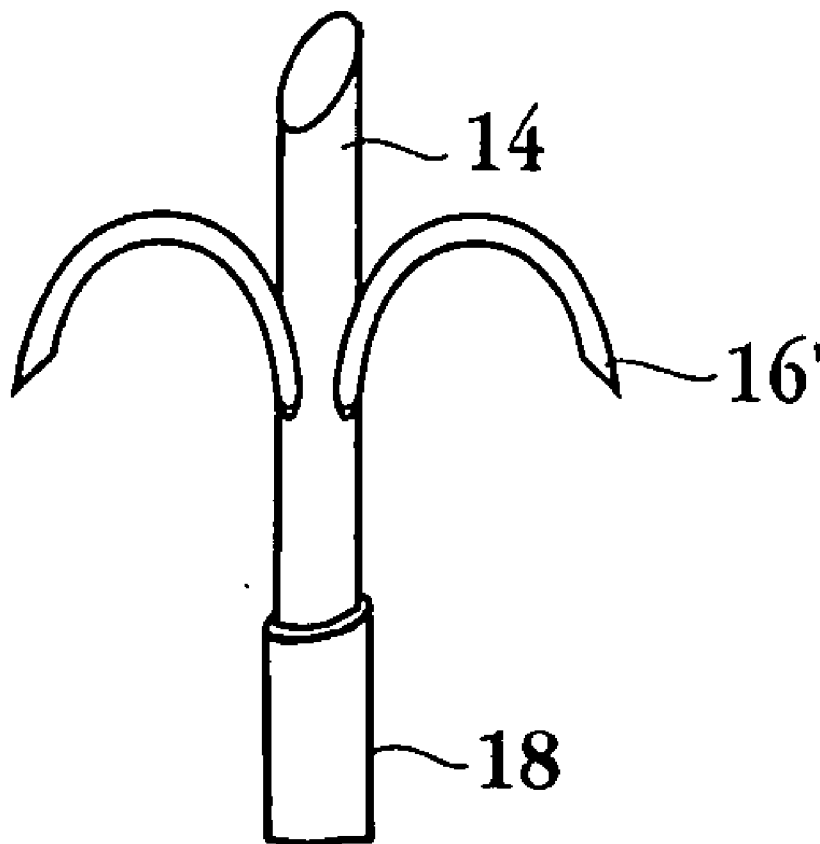
US 20040260282A1

(19) **United States**(12) **Patent Application Publication**
Gough et al.(10) **Pub. No.: US 2004/0260282 A1**(43) **Pub. Date: Dec. 23, 2004**(54) **MULTIPLE ANTENNA ABLATION
APPARATUS AND METHOD WITH
MULTIPLE SENSOR FEEDBACK**continuation-in-part of application No. 08/515,379,
filed on Aug. 15, 1995, now Pat. No. 5,683,384.**Publication Classification**(75) Inventors: **Edward J. Gough**, Menlo Park, CA
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(US)(51) **Int. Cl.⁷** **A61B 18/14**(52) **U.S. Cl.** **606/41**

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PERKINS COIE LLP**P.O. BOX 2168****MENLO PARK, CA 94026 (US)**(57) **ABSTRACT**(73) Assignee: **RITA Medical Systems, Inc.**(21) Appl. No.: **10/775,747**(22) Filed: **Feb. 9, 2004****Related U.S. Application Data**(63) Continuation of application No. 08/577,208, filed on
Dec. 22, 1995, now Pat. No. 6,689,127, which is a

An ablation apparatus includes an ablation energy source producing an electromagnetic energy output. A monopolar multiple antenna device is included and has a primary antenna with a longitudinal axis, a central lumen and a distal end, and a secondary antenna with a distal end. The secondary antenna is deployed from the primary antenna central lumen in a lateral direction relative to the longitudinal axis. The primary antenna and secondary antennas are each electromagnetically coupled to the electromagnetic energy source.



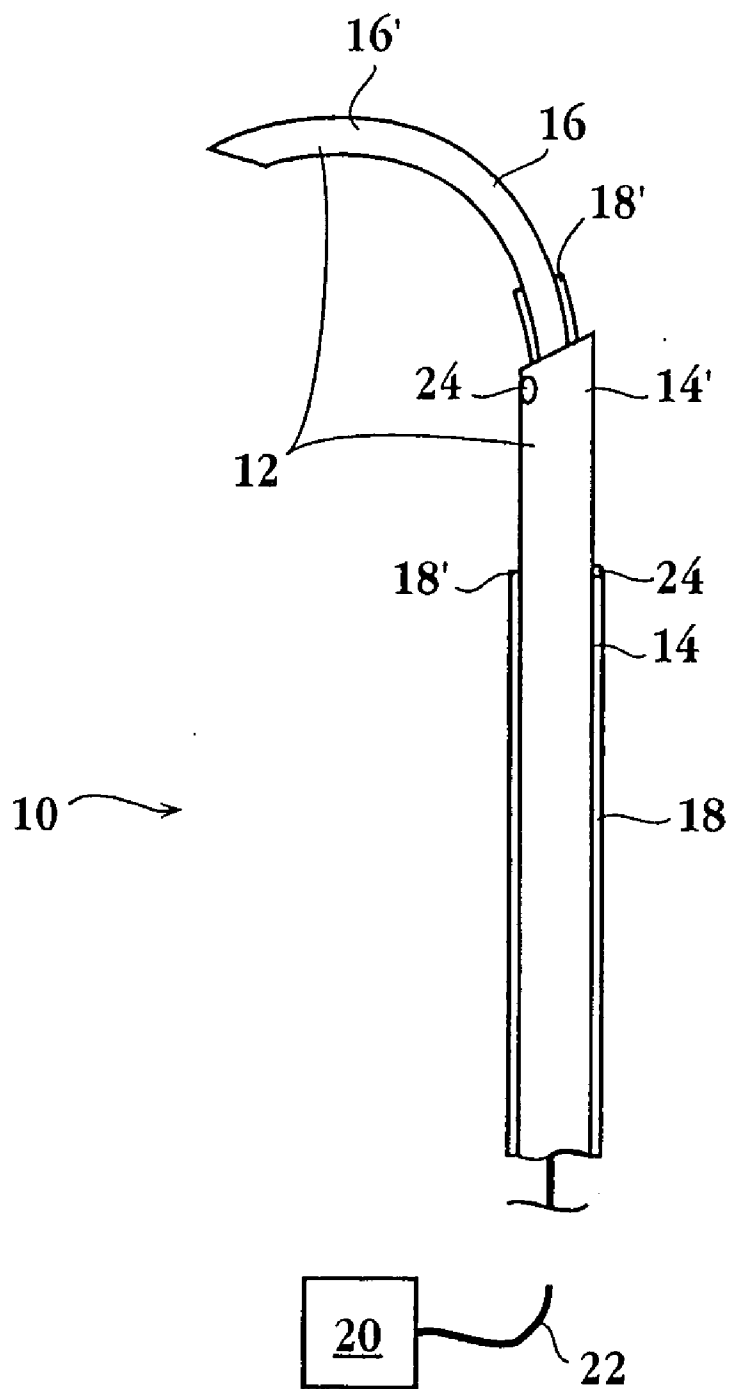


Fig. 1

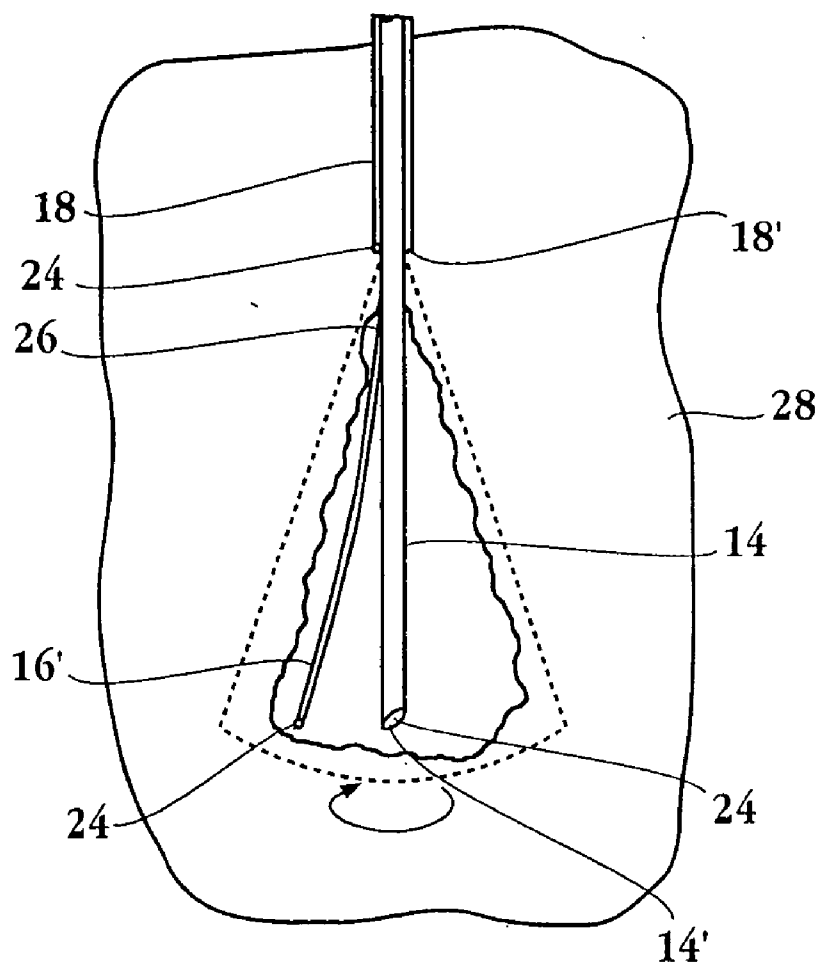


Fig. 2

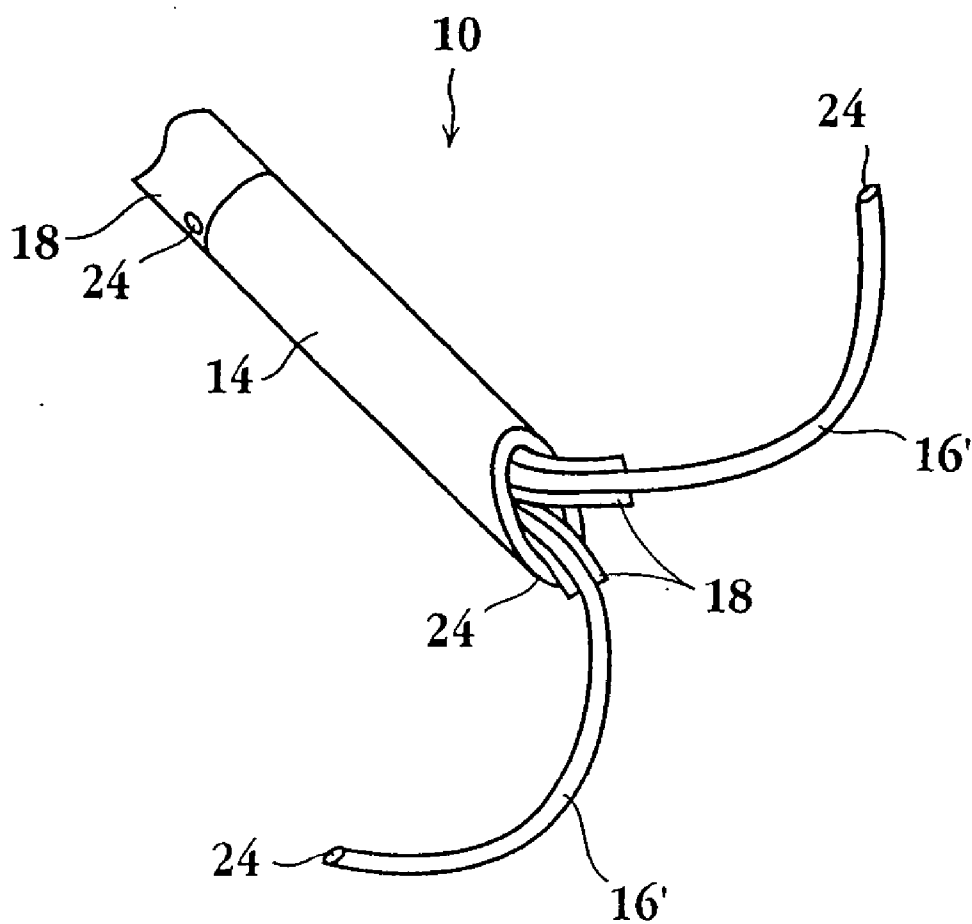


Fig. 3

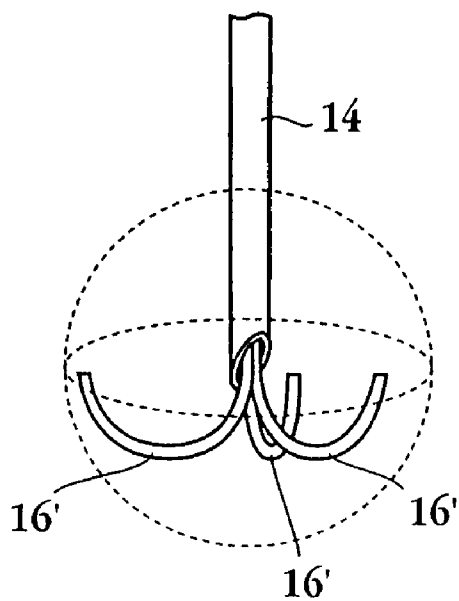


Fig. 4

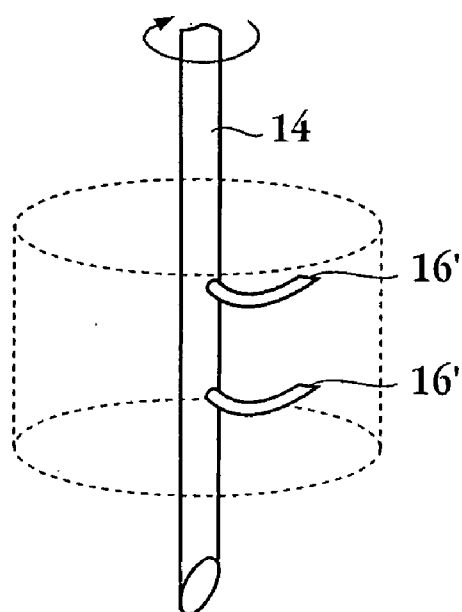


Fig. 5

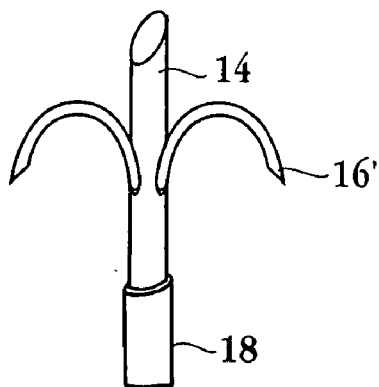


Fig. 6A

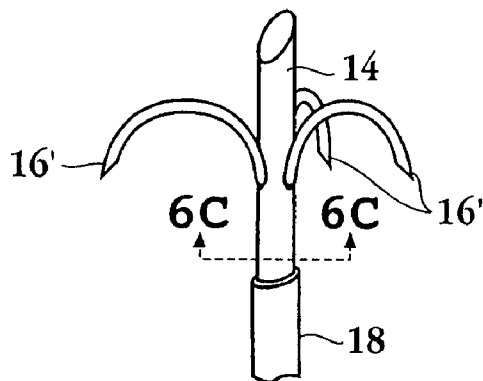


Fig. 6A

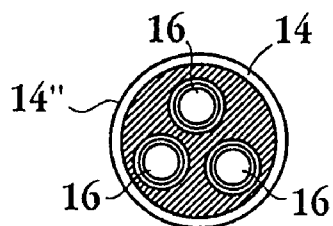


Fig. 6C

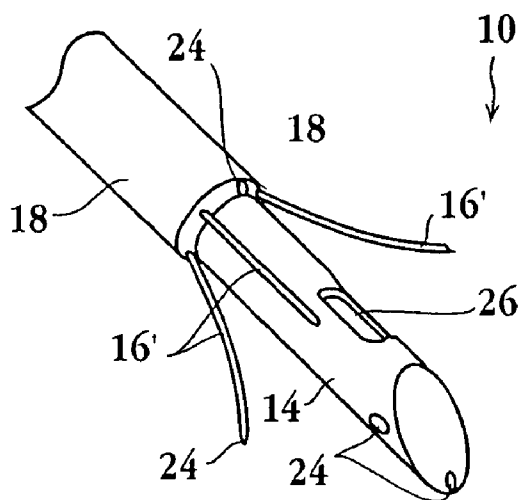


Fig. 7

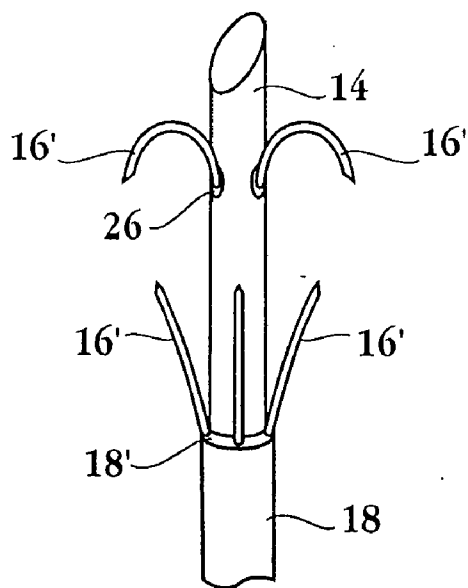


Fig. 8

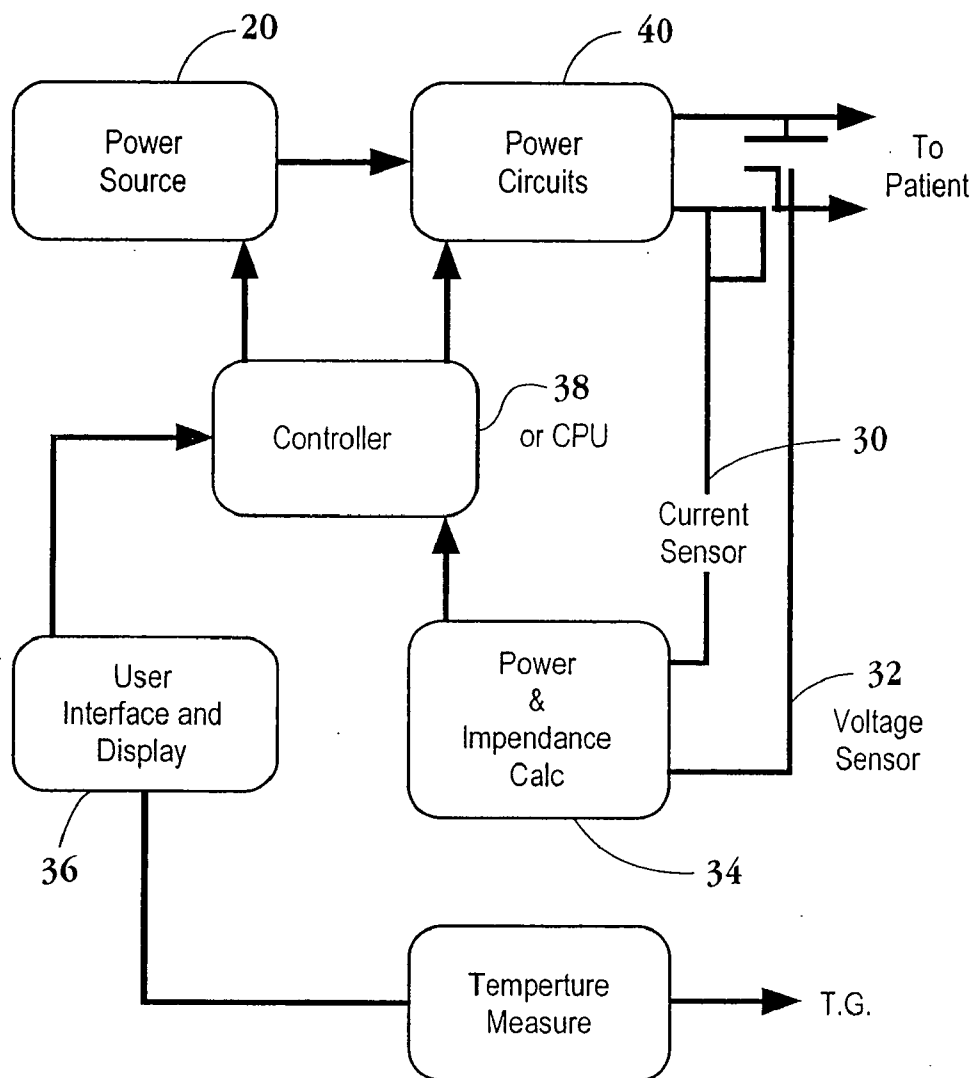


Fig. 9

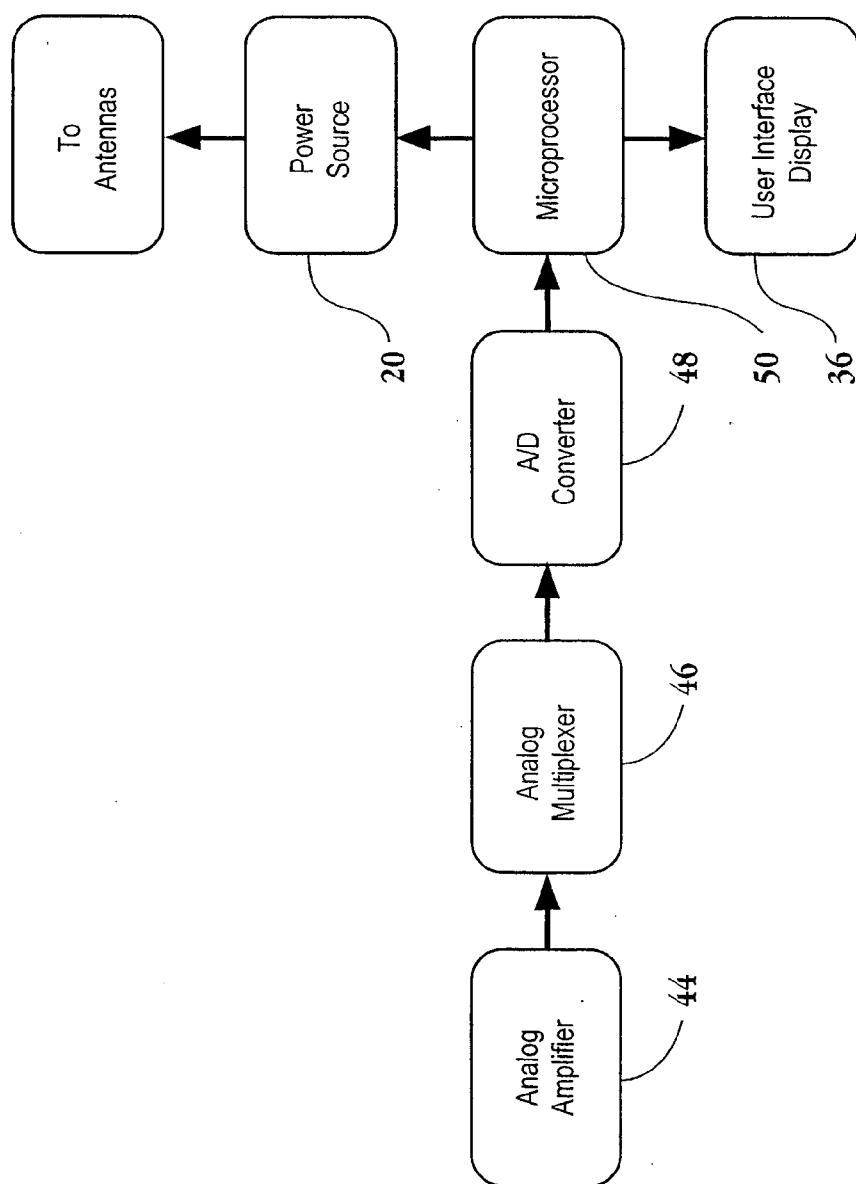


Fig. 10

MULTIPLE ANTENNA ABLATION APPARATUS AND METHOD WITH MULTIPLE SENSOR FEEDBACK

REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 08/515,379, filed Aug. 15, 1995, entitled "Multiple Antenna Ablation Apparatus", incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates generally to a treatment and ablation apparatus that includes a primary antenna inserted into or adjacent to a selected body mass, such as a tumor, with one or more side deployed secondary antennas which are actively coupled to the primary antenna, and more particularly to a multiple antenna RF treatment and ablation apparatus with one or more secondary antennas actively coupled to the primary antenna, with the primary antenna coupled to a feedback control device and energy source.

[0004] 2. Description of the Related Art

[0005] Current open procedures for treatment of tumors are extremely disruptive and cause a great deal of damage to healthy tissue. During the surgical procedure, the physician must exercise care in not cutting the tumor in a manner that creates seeding of the tumor, resulting in metastasis. In recent years, development of products has been directed with an emphasis on minimizing the traumatic nature of traditional surgical procedures.

[0006] There has been a relatively significant amount of activity in the area of hyperthermia as a tool for treatment of tumors. It is known that elevating the temperature of tumors is helpful in the treatment and management of cancerous tissues. The mechanisms of selective treatment are not completely understood. However, four cellular effects of hyperthermia on cancerous tissue have been proposed, (i) changes in cell or nuclear membrane permeability or fluidity, (ii) cytoplasmic lysosomal disintegration, causing release of digestive enzymes, (iii) protein thermal damage affecting cell respiration and the synthesis of DNA or RNA and (iv) potential excitation of immunologic systems. Treatment methods for applying heat to tumors include the use of direct contact radio-frequency (RF) applicators, microwave radiation, inductively coupled RF fields, ultrasound, and a variety of simple thermal conduction techniques.

[0007] Among the problems associated with all of these procedures is the requirement that highly localized heat be produced at depths of several centimeters beneath the surface of the skin. RF applications may be used at depth during surgery. However, the extent of localization is generally poor, with the result that healthy tissue may be harmed.

[0008] With RF lesion making, a high frequency alternating current flows from the electrode into the tissue. Ionic agitation is produced in the region of tissue about the electrode tip as the ions attempt to follow the directional variations of the alternating current. This agitation results in frictional heating so that the tissue about the electrode, rather than the electrode itself, is the primary source of heat. Tissue heat generated is produced by the flow of current through the

electrical resistance offered by the tissue. The greater this resistance, the greater the heat generated.

[0009] Lesion size ultimately is governed by tissue temperature. Some idea of tissue temperature can be obtained by monitoring the temperature at an electrode or probe tip, usually with a thermistor. RF lesion heat is generated within the tissue, the temperature monitored will be the resultant heating of the electrode by the lesion. RF lesion heat is generated within the tissue, the temperature monitored is the resultant heating of the probe by the lesion. A temperature gradient extends from the lesion to the probe tip, so that the probe tip is slightly cooler than the tissue immediately surrounding it, but substantially hotter than the periphery of the lesion because of the rapid attenuation of heating effect with distance.

[0010] Current spreads out radially from the electrode tip, so that current density is greatest next to the tip, and decreases progressively at distances from it. The frictional heat produced from ionic agitation is proportional to current, i.e., ionic density. Therefore, the heating effect is greatest next to the electrode and decreases with distance from it. One consequence of this is that lesions can inadvertently be made smaller than anticipated for a given electrode size if the RF current level is too high. There must be time for equilibrium heating of tissue to be reached, especially at the center of the desired lesion volume. If the current density is too high, the tissue temperature next to the electrode rapidly exceeds desired levels and carbonization and boiling occurs in a thin tissue shell surrounding the electrode tip.

[0011] A need exists for an ablation apparatus with an electromagnetic energy source and a monopolar multiple antenna device. There is a further need for a monopolar multiple antenna device with a primary antenna, and one or more secondary antennas that are positioned in a lumen of the primary antenna, laterally deployable from the primary antenna into a selected tissue mass, with both antennas electromagnetically coupled to an electromagnetic energy source. It would be desirable to provide a monopolar method to ablate a selected tissue mass by introducing the primary antenna into the selected mass, deploying a distal end of the secondary antenna into the selected mass, and applying electromagnetic energy to the primary and secondary antennas.

SUMMARY OF THE INVENTION

[0012] Accordingly, it is an object of the invention to provide an ablation device which includes a monopolar multiple antenna.

[0013] Another object of the invention is to provide an ablation apparatus with a monopolar multiple antenna device including a primary antenna that pierces and advances through tissue, a secondary electrode positioned in a primary antenna lumen that is laterally deployable from the primary antenna into a selected tissue mass.

[0014] Yet another object of the invention is to provide an ablation apparatus with a monopolar multiple antenna device, including primary and secondary antennas that are each electromagnetically coupled to an electromagnetic energy source.

[0015] A further object of the invention is to provide a method for ablating a selected tissue mass utilizing a monopolar multiple antenna device.

[0016] These and other objectives are achieved in an ablation treatment apparatus. The apparatus includes an ablation energy source producing an electromagnetic energy output. A monopolar multiple antenna device is included and has a primary antenna with a longitudinal axis, a central lumen and a distal end, and a secondary antenna with a distal end. The secondary antenna is deployed from the primary antenna central lumen in a lateral direction relative to the longitudinal axis. The primary antenna and secondary antennas are each electromagnetically coupled to the electromagnetic energy source.

[0017] In another embodiment, a method of ablating a selected tissue mass is provided utilizing a monopolar multiple antenna device.

[0018] The monopolar multiple antenna device can be an RF antenna, a microwave antenna, a short wave antenna and the like. At least two secondary antennas can be included and laterally deployed from the primary antenna. The secondary antenna is retractable into the primary antenna, permitting repositioning of the primary antenna. When the multiple antenna is an RF antenna, it can be operated in monopolar or bipolar modes, and is capable of switching between the two.

[0019] One or more sensors may be positioned at an interior or exterior of the primary or secondary antennas to detect impedance or temperature. A feedback control system is coupled to each of the sensors, the electromagnetic energy source and the primary and secondary antennas.

[0020] An insulation sleeve can be positioned around the primary and secondary antennas. Another sensor is positioned at the distal end of the insulation sleeve surrounding the primary antenna.

[0021] The feedback control device can detect impedance or temperature at a sensor. In some embodiments, the feedback control system can include a multiplexer. Further, the feedback control system can provide an ablation energy output for a selected length of time, adjust ablation energy output and reduce or cut off the delivery of the ablation energy output to the antennas. The feedback control system can include a temperature detection circuit which provides a control signal representative of temperature or impedance detected at any of the sensors. The feedback control system can also include a microprocessor connected to the temperature detection circuit. Initially, temperature, ablation duration and energy level are selected and manually input into the feedback control system. As process parameters change, the initial manually input values are then automatically modified by the feedback control system to achieve the desired level of ablation without impeding out, and minimize the ablation of non-targeted tissue.

[0022] Further, the multiple antenna device can be a multi-modality apparatus. One or all of the antennas can be hollow to receive an infusion medium from an infusion source and introduce the infusion medium into the targeted tissue mass.

BRIEF DESCRIPTION OF THE FIGURES

[0023] FIG. 1 is a perspective view of the multiple antenna ablation apparatus of the present invention illustrating a primary antenna and a single laterally deployed secondary antenna.

[0024] FIG. 2 is a perspective view of a conic geometric ablation achieved with the apparatus of FIG. 1.

[0025] FIG. 3 is a perspective view of the multiple antenna ablation apparatus of the present invention with two secondary antennas.

[0026] FIG. 4 is a perspective view illustrating the adjacent positioning of the multiple antenna ablation apparatus next to a selected tissue mass.

[0027] FIG. 5 is a perspective view illustrating the positioning of the multiple antenna ablation apparatus in the center of a selected tissue mass, and the creation of a cylindrical ablation.

[0028] FIG. 6(a) is a perspective view of the multiple antenna ablation of the present invention illustrating two secondary antennas which provide a retaining and gripping function.

[0029] FIG. 6(b) is a perspective view of the multiple antenna ablation of the present invention illustrating three secondary antennas which provide a retaining and gripping function.

[0030] FIG. 6(c) is a cross-sectional view of the apparatus of FIG. 6(b) taken along the lines 6(c)-6(c).

[0031] FIG. 7 is a perspective view of the multiple antenna ablation of the present invention illustrating the deployment of three secondary antennas from a distal end of the insulation sleeve surrounding the primary antenna.

[0032] FIG. 8 is a perspective view of the multiple antenna ablation of the present invention illustrating the deployment of two secondary antennas from the primary antenna, and the deployment of three secondary antennas from the distal end of the insulation sleeve surrounding the primary antenna.

[0033] FIG. 9 is a block diagram illustrating the inclusion of a controller, energy source and other electronic components of the present invention.

[0034] FIG. 10 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with the present invention.

DETAILED DESCRIPTION

[0035] The present invention provides an ablation treatment apparatus which includes an ablation energy source producing an electromagnetic energy output. A monopolar multiple antenna device is included and has a primary antenna with a longitudinal axis, a central lumen and a distal end, and a secondary antenna with a distal end. The secondary antenna is deployed from the primary antenna central lumen in a lateral direction relative to the longitudinal axis. The primary antenna and secondary antennas are each electromagnetically coupled to the electromagnetic energy source.

[0036] As shown in FIG. 1, an ablation treatment apparatus 10 includes a monopolar multiple antenna device 12. Monopolar multiple antenna device 12 includes a primary antenna 14, and one or more secondary antennas 16, which are typically electrodes. Secondary antennas 16 are initially positioned in a primary antenna lumen when primary antenna 14 is advanced through tissue. When primary

antenna **14** reaches a selected tissue ablation site in a selected tissue mass, including but not limited to a solid lesion, secondary antennas **16** are laterally deployed from the primary antenna lumen and into the selected tissue mass. Ablation proceeds from the interior of the selected tissue mass in a direction towards a periphery of the selected tissue mass.

[0037] Each primary and secondary antenna **14** and **16** has an exterior ablation surface which delivers electromagnetic energy to the selected tissue mass. The length and size of each ablation surface can be variable. The length of primary antenna ablation surface relative to secondary antenna ablation surface can be 20% or greater, 33 and $\frac{1}{3}$ % or greater, 50% or greater, 75% or greater, about the same length, or greater than the length of secondary electrode ablation surface. Lengths of primary and secondary antennas **14** and **16** can be adjustable. Primary antenna **14** can be moved up and down, rotated about its longitudinal axis, and moved back and forth, in order to define, along with sensors, the periphery or boundary of the selected tissue mass, including but not limited to a tumor. This provides a variety of different geometries, not always symmetrical, that can be ablated. The ablation can be between the ablation surfaces of primary and secondary antennas **14** and **16** when operated in a mono-polar mode with a ground pad.

[0038] Primary antenna **14** is constructed so that it can be introduced percutaneously or laparoscopically through tissue without an introducer. Primary antenna **14** combines the function of an introducer and an electrode.

[0039] In one embodiment, primary antenna **14** can have a sharpened distal end **14'** to assist introduction through tissue. Each secondary antenna **16** has a distal end **16'** that is constructed to be less structurally rigid than primary antenna **14**. Distal end **16'** is that section of secondary antenna **16** that is advanced from the lumen antenna **14** and into the selected tissue mass. Distal end is typically less structurally rigid than primary antenna **14**. However, even though sections of secondary antenna **16** which are not advanced through the selected tissue mass may be less structurally rigid than primary antenna **14**.

[0040] Structural rigidity is determined by, (i) choosing different materials for antenna **14** and distal end **16'** or some greater length of secondary antenna **16**, (ii) using the same material but having less of it for secondary antenna **16** or distal end **16'**, e.g., secondary antenna **16** or distal end **16'** is not as thick as primary electrode **14**, or (iii) including another material in one of the antennas **14** or **16** to vary their structural rigidity. For purposes of this disclosure, structural rigidity is defined as the amount of deflection that an antenna has relative to its longitudinal axis. It will be appreciated that a given antenna will have different levels of rigidity depending on its length.

[0041] Primary and secondary antennas **14** and **16** can be made of a variety of conductive materials, both metallic and non-metallic. One suitable material is type 304 stainless steel of hypodermic quality. In some applications, all or a portion of secondary electrode **16** can be made of a shaped memory metal, such as NiTi, commercially available from Raychem Corporation, Menlo Park, Calif.

[0042] Each of primary or secondary antennas **14** or **16** can have different lengths. The lengths can be determined by

the actual physical length of an antenna, the amount of an antenna that has an ablation delivery surface, and the length of an antenna that is not covered by an insulator. Suitable lengths include but are not limited to 17.5 cm, 25.0 cm, and 30.0 cm. The actual length of an antenna depends on the location of the selected tissue mass to be ablated, its distance from the skin, its accessibility as well as whether or not the physician chooses a laproscopic, percutaneous or other procedure. Further, ablation treatment apparatus **10**, and more particularly multiple antenna device **12**, can be introduced through a guide to the desired tissue mass site.

[0043] An insulation sleeve **18** may be positioned around an exterior of one or both of the primary and secondary antennas **14** and **16** respectively. Preferably, each insulation sleeve **18** is adjustably positioned so that the length of an antenna ablation surface can be varied. Each insulation sleeve **18** surrounding a primary antenna **14** can include one or more apertures. This permits the introduction of a secondary antenna **16** through primary antenna **14** and insulation sleeve **18**.

[0044] In one embodiment, insulation sleeve **18** can comprise a polyamide material. A sensor **24** may be positioned on top of polyimide insulation sleeve **18**. The polyamide insulation sleeve **18** is semi-rigid. Sensor **24** can lay down substantially along the entire length of polyamide insulation sleeve **18**. Primary antenna **14** is made of a stainless-steel hypodermic tubing with 2 cm of exposed ablation surface. Secondary antennas **16** have distal ends **16'** that are made of

[0045] NiTi hypodermic tubing. A handle is included with markings to show the varying distance of secondary antennas **16** from primary antenna **14**. Fluid infusion is delivered through a Luer port at a side of the handle. Type-T thermocouples are positioned at distal ends **16'**.

[0046] An energy source **20** is connected to multiple antenna device **12** with one or more cables **22**. Energy source **20** can be an RF source, microwave source, short wave source, laser source and the like. Multiple antenna device **12** can be comprised of primary and secondary antennas **14** and **16** that are RF electrodes, microwave antennas, as well as combinations thereof. Energy source **20** may be a combination RF/microwave box. Further a laser optical fiber, coupled to a laser source **20** can be introduced through one or both of primary or secondary antennas **14** and **16**. One or more of the primary or secondary antennas **14** and **16** can be an arm for the purposes of introducing the optical fiber.

[0047] Antennas **14** and **16** are each electromagnetically coupled to energy source **20**. The coupling can be direct from energy source **20** to each antenna **14** and **16**, or indirect by using a collet, sleeve and the like which couples antennas **14** and **16** to energy source **20**.

[0048] One or more sensors **24** may be positioned on at least a portion of interior or exterior surfaces of primary antenna **14**, secondary antenna **16** or insulation sleeve **18**. Preferably sensors **24** are positioned at primary antenna distal end **14'**, secondary antenna distal end **16'** and insulation sleeve distal end **18'**. Sensors **24** permit accurate measurement of temperature at a tissue site in order to determine, (i) the extent of ablation, (ii) the amount of ablation, (iii) **25** whether or not further ablation is needed and (iv) the boundary or periphery of the ablated mass. Further, sensors **24** prevent non-targeted tissue from being destroyed or ablated.

[0049] Sensors 24 are of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. Suitable thermal sensors 24 include a T type thermocouple with copper constantine, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. It will be appreciated that sensors 24 need not be thermal sensors.

[0050] Sensors 24 measure temperature and/or impedance to permit monitoring and a desired level of ablation to be achieved without destroying too much tissue. This reduces damage to tissue surrounding the targeted mass to be ablated. By monitoring the temperature at various points within the interior of the selected tissue mass, a determination of the selected tissue mass periphery can be made, as well as a determination of when ablation is complete. If at any time sensor 24 determines that a desired ablation temperature is exceeded, then an appropriate feedback signal is received at energy source 20 which then regulates the amount of energy delivered to primary and/or secondary antennas 14 and 16.

[0051] Thus the geometry of the ablated mass is selectable and controllable. Any number of different ablation geometries can be achieved. This is a result of having variable lengths for primary antenna 14 and secondary antenna 16 ablation surfaces as well as the inclusion of sensors. 24.

[0052] Preferably, distal end 16' is laterally deployed relative to a longitudinal axis of primary antenna 14 out of an aperture 26 formed in primary antenna 14. Aperture 26 is at distal end 14' or formed in a side of an exterior of antenna 14.

[0053] In one embodiment, a method for creating an ablation volume in a selected tissue mass includes; providing a monopolar ablation device with a primary antenna, a secondary antenna with a distal end, and an energy source electromagnetically coupled to both antennas. A ground pad electrode is also included. The primary antenna is inserted into the selected tissue mass with the secondary antenna distal end positioned in the primary antenna lumen. The secondary antenna distal end is advanced out of the primary antenna lumen into the selected tissue mass in a lateral direction relative to a longitudinal axis of the primary antenna. Electromagnetic energy is delivered from one of a primary antenna ablation surface, a secondary antenna ablation surface or both to the selected tissue mass. This creates an ablation volume in the selected tissue mass.

[0054] There is wide variation in the amount of deflection of secondary antenna 16. For example, secondary antenna 16 can be deflected a few degrees from the longitudinal axis of primary antenna 14, or secondary antenna can be deflected in any number of geometric configurations, including but not limited to a "J" hook. Further, secondary antenna 16 is capable of being introduced from primary antenna 14 a few millimeters from primary antenna, or a much larger distance. Ablation by secondary antenna 16 can begin a few millimeters away from primary antenna 14, or secondary electrode 16 can be advanced a greater distance from primary antenna 14 and at that point the initial ablation by secondary antenna 16 begins.

[0055] A number of parameters permit ablation of selected tissue masses, including but not limited to tumors, of different size and shapes including, a series of ablations having

primary and secondary antennas 14 and 16 with variable length ablation surfaces, the use of sensors 24 and the use of the feedback control system.

[0056] As illustrated in FIG. 2, primary antenna 14 has been introduced into a selected tissue mass 28. One or more secondary antennas are positioned within a primary antenna lumen as primary antenna 14 is introduced into and through the selected tissue mass. Subsequently, secondary antenna distal end 16' is advanced out of aperture 26 and into selected tissue mass 28. Insulation sleeves 18 are adjusted for primary and secondary antennas 14 and 16 respectively. RF, microwave, short wave and the like energy is delivery to antenna 16 in a monopolar mode (RF), or alternatively, multiple antenna device 12 can be operated in a bipolar mode (RF). Multi antenna device 12 can be switched between monopolar and bipolar operation and has multiplexing capability between antennas 14 and 16. Secondary antenna distal end 16' is retracted back into primary antenna 14, and primary antenna is then rotated. Secondary antenna distal end 16' is then introduced into selected tissue mass 28. Secondary antenna may be introduced a short distance into selected tissue mass 28 to ablate a small area. It can then be advanced further into any number of times to create more ablation zones. Again, secondary antenna distal end 16' is retracted back into primary antenna 14, and primary antenna 14 can be, (i) rotated again, (ii) moved along a longitudinal axis of selected tissue mass 28 to begin another series of ablations with secondary antenna distal end 16' being introduced and retracted in and out of primary antenna 14, or (iii) removed from selected tissue mass 28. A number of parameters permit ablation of selected tissue masses 28 of different sign and shapes including a series of ablations having primary and secondary antennas 14 and 16 with variable length ablation surfaces and the use of sensor 24.

[0057] In FIG. 3, two secondary antennas 16 are each deployed out of distal end 14' and introduced into selected tissue mass 28. Secondary antennas 16 form a plane and the area of ablation extends between the ablation surfaces of primary and secondary antennas 14 and 16. Primary antenna 14 can be introduced in an adjacent relationship to selected tissue mass 28. This particular deployment is particularly useful for small selected tissue masses 28, or where piercing selected tissue mass 28 is not desirable. Primary antenna 14 can be rotated, with secondary antennas 16 retracted into a central lumen of primary antenna 14, and another ablation volume defined between the two secondary antennas 16 is created. Further, primary electrode 14 can be withdrawn from its initial position adjacent to selected tissue mass 28, repositioned to another position adjacent to selected tissue mass 28, and secondary antennas 16 deployed to begin another ablation cycle. Any variety of different positionings may be utilized to create a desired ablation geometry for selected tissue mass of different geometries and sizes.

[0058] In FIG. 4, three secondary antennas 16 are introduced into selected tissue mass 28. The effect is the creation of an ablation volume without leaving non-ablated areas between antenna ablation surfaces. The ablation is complete.

[0059] Referring now to FIG. 5, a center of selected tissue mass 28 is pierced by primary antenna 14, secondary antennas 16 are laterally deployed and retracted, primary antenna 14 is rotated, secondary antennas 16 are deployed and retracted, and so on until a cylindrical ablation volume is

achieved. Multiple antenna device 12 can be operated in the bipolar mode between the two secondary antennas 16, or between a secondary antenna 16 and primary antenna 14. Alternatively, multiple antenna device 12 can be operated in a monopolar mode.

[0060] Secondary antennas 16 can serve the additional function of anchoring multiple antenna device 12 in a selected mass, as illustrated in FIGS. 6(a) and 6(b). In FIG. 6(a) one or both secondary antennas 16 are used to anchor and position primary antenna 14. Further, one or both secondary antennas 16 are also used to ablate tissue. In FIG. 6(b), three secondary antennas are deployed and anchor primary antenna 14.

[0061] FIG. 6(c) illustrates the infusion capability of multiple antenna device 12. Three secondary antennas 16 are positioned in a central lumen 14" of primary antenna 14. One or more of the secondary antennas 16 can also include a central lumen coupled to an infusion source. Central lumen 14" is coupled to an infusion source and delivers a variety of infusion mediums to selected places both within and outside of the targeted ablation mass. Suitable infusion mediums include but are not limited to, therapeutic agents, conductivity enhancement mediums, contrast agents or dyes, and the like. An example of a therapeutic agent is a chemotherapeutic agent.

[0062] As shown in FIG. 7 insulation sleeve 18 can include one or more lumens for receiving secondary antennas 16 which are deployed out of an insulation sleeve distal end 18'. FIG. 8 illustrates two secondary antennas 16

[0063] being introduced out of insulation sleeve distal end 18', and two secondary antennas 16 introduced through apertures 26 formed in primary antenna 14. As illustrated, the secondary electrodes introduced through apertures 26 provide an anchoring function. It will be appreciated that FIG. 8 illustrates how secondary antennas 16 can have a variety of different geometric configurations in multiple antenna device 12.

[0064] A feedback control system 29 is connected to energy source 20, sensors 24 and antennas 14 and 16. Feedback control system 29 receives temperature or impedance data from sensors 24 and the amount of electromagnetic energy received by antennas 14 and 16 is modified from an initial setting of ablation energy output, ablation time, temperature, and current density (the "Four Parameters"). Feedback control system 29 can automatically change any of the Four Parameters. Feedback control system 29 can detect impedance or temperature and change any of the Four Parameters. Feedback control system can include a multiplexer to multiplex different antennas, a temperature detection circuit that provides a control signal representative of temperature or impedance detected at one or more sensors 24. A microprocessor can be connected to the temperature control circuit.

[0065] The following discussion pertains particularly to the use of an RF energy source and RF multiple antenna device 12. It will be appreciated that devices similar to those associated with RF multiple antenna device 12 can be utilized with laser optical fibers, microwave devices and the like.

[0066] Referring now to FIG. 9, all or portions of feedback control system 29 are illustrated. Current delivered

through primary and secondary antennas 14 and 16 is measured by current sensor 30. Voltage is measured by voltage sensor 32. Impedance and power are then calculated at power and impedance calculation device 34. These values can then be displayed at user interface and display 36. Signals representative of power and impedance values are received by controller 38. A control signal is generated by controller 38 that is proportional to the difference between an actual measured value, and a desired value. The control signal is used by power circuits 40 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at the respective primary and/or secondary antennas 14 and 16.

[0067] In a similar manner, temperatures detected at sensors 24 provide feedback for maintaining a selected power. The actual temperatures are measured at temperature measurement device 42, and the temperatures are displayed at user interface and display 36. A control signal is generated by controller 38 that is proportional to the difference between an actual measured temperature, and a desired temperature. The control signal is used by power circuits 40 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the respective sensor 24. A multiplexer can be included to measure current, voltage and temperature, at the numerous sensors 24, and energy is delivered between primary antenna 14 and secondary antennas 16.

[0068] Controller 38 can be a digital or analog controller, or a computer with software. When controller 38 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus are a program memory and a data memory.

[0069] User interface and display 36 includes operator controls and a display. Controller 38 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

[0070] The output of current sensor 30 and voltage sensor 32 is used by controller 38 to maintain a selected power level at primary and secondary antennas 14 and 16. The amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 38, and a preset amount of energy to be delivered can also be profiled.

[0071] Circuitry, software and feedback to controller 38 result in process control, and the maintenance of the selected power, and are used to change, (i) the selected power, including RF, microwave, laser and the like, (ii) the duty cycle (on-off and wattage), (iii) bipolar or monopolar energy delivery and (iv) infusion medium delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensors 24.

[0072] Referring now to FIG. 10, current sensor 30 and voltage sensor 32 are connected to the input of an analog amplifier 44. Analog amplifier 44 can be a conventional differential amplifier circuit for use with sensors 24. The

output of analog amplifier 44 is sequentially connected by an analog multiplexer 46 to the input of A/D converter 48. The output of analog amplifier 44 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 48 to a microprocessor 50. Microprocessor 50 may be Model No. 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

[0073] Microprocessor 50 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 50 corresponds to different temperatures and impedances.

[0074] Calculated power and impedance values can be indicated on user interface and display 36. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 50 with power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 36, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 50 can modify the power level supplied by energy source 20.

[0075] The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

1. An ablation treatment apparatus, comprising:

an introducer having a distal portion and a proximal portion; and at least one antenna positioned in the introducer as the introducer is introduced through tissue and exhibiting a changing direction of travel when deployed from the introducer at a selected tissue mass, said at least one antenna being operatively coupled to a microwave energy source; and

at least one thermal sensor coupled to at least one of (i) the introducer, or (ii) at least one of the at least one antennas.

2. The apparatus of claim 1, wherein at least a portion of a distal end of the at least one antenna is constructed to be structurally less rigid than the introducer, and the introducer is constructed to be rigid enough to be introduced through tissue.

3. The apparatus of claim 1, further comprising:

a feedback control system operatively coupled to the at least one sensor and the microwave energy source.

4-6. (canceled)

7. The apparatus of claim 1, wherein said at least one antenna comprises at least two antennas, each of the antennas having an energy delivery surface to create an ablation volume between the energy delivery surfaces.

8. The apparatus of claim 1, wherein each antenna includes at least one thermal sensor to measure temperature.

9. The apparatus of claim 1, wherein said at least one antenna comprises at least three antennas, each of the antennas having an energy delivery surface to create an ablation volume between the energy delivery surfaces.

10. (canceled)

11. The apparatus of claim 1, further comprising:

an insulation sleeve positioned in a surrounding relationship around at least a portion of at least one of (i) the introducer, or (ii) the at least one antenna.

12. The apparatus of claim 11, wherein the insulation sleeve is adjustably moveable along an exterior of the introducer or the at least one antenna.

13-14. (canceled)

15. The apparatus of claim 1, further including a ground pad electrode.

16-17. (canceled)

18. The apparatus of claim 1, wherein the introducer is hollow and coupled to an infusion medium source to receive an infusion medium.

19. The apparatus of claim 1, further comprising: a cooling element coupled to the introducer.

20. A method for creating an ablation volume in a selected tissue mass, comprising:

providing an ablation device with an introducer at least one antenna with a distal end and being operatively coupled to a microwave energy source, and at least one thermal sensor coupled to at least one of (i) the introducer, or (ii) at least one of the at least one antennas;

inserting the introducer into the selected tissue mass with the at least one antenna distal end positioned in the introducer lumen;

advancing the at least one antenna distal end out of the introducer lumen and into the selected tissue mass;

delivering electromagnetic energy from the microwave energy source to the at least one antenna; and

creating an ablation volume in the selected tissue mass.

21. The method of claim 20, wherein said at least one antenna comprises at least two antennas, each having an energy delivery surface, are advanced from the primary antenna, and an ablation volume is created between the two antennas energy delivery surfaces.

23. The method of claim 21, wherein the at least two antennas are advanced out of a distal end of the introducer

24. The method of claim 21, wherein the at least two antennas are advanced out of separate ports formed in the introducer.

25-29. (canceled)

30. The method of claim 20, wherein the introducer is operatively coupled to an energy source and has an energy delivery surface.

31. The apparatus of claim 3, wherein the feedback control adjusts at least one of (i) a power level, (ii) a duty cycle, and (iii) an energy delivery in response to the temperature measured at the at least one sensor.

32. The apparatus of claim 1, further comprising:

a display for displaying temperature values measured at the at least one sensor.

33. The apparatus of claim 1, wherein said introducer is an antenna operatively coupled to an energy source.

34. The apparatus of claim 33, wherein said introducer is coupled to a RF energy source.

35. The apparatus of claim 1, wherein the introducer includes a tissue piercing distal end.

36. The apparatus of claim 3, further comprising:

a controller coupled to the energy source and at least one of (i) the at least one thermal sensor and (ii) the feedback control to adjust the energy supplied to the

antennas in response to the temperature measured at the at least one sensor.

37. The apparatus of claim 20, further comprising:

adjusting the energy supplied to the at least one antenna in response to a temperature measured at the at least one sensor.

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