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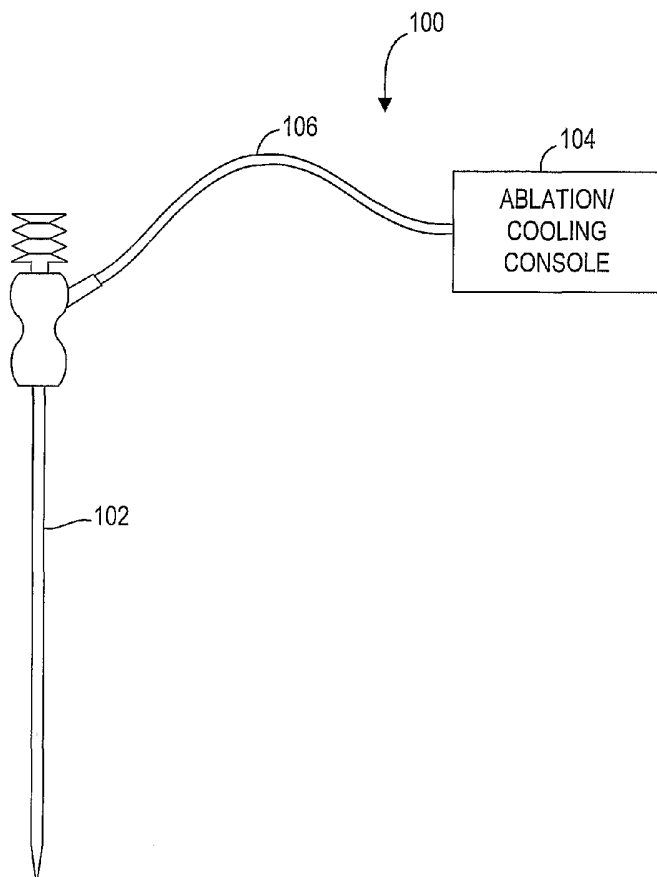
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(54) Title: ABLATION PROBE WITH PELTIER EFFECT THERMAL CONTROL



(57) Abstract: A tissue ablation system comprising an elongated member, an ablative element mounted on the distal end of the elongated member, and at least one thermoelectric device mounted to the member in thermal communication with the ablative element. The system may include the ablation probe, thermal control circuitry for controlling the thermal effect of the thermoelectric device, and an ablation source for supplying ablation energy to the ablative element. A plurality of circumferentially distributed thermoelectric devices can be provided, so that radial tissue sectors can be selectively affected by independently controlling the thermal effect of the thermoelectric devices.



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ABLATION PROBE WITH PELTIER EFFECT THERMAL CONTROL

TECHNICAL FIELD

This invention relates generally to medical devices for performing thermal
5 energy ablation procedures.

BACKGROUND OF THE INVENTION

Tissue may be destroyed, ablated, or otherwise treated using thermal energy during various therapeutic procedures. Many forms of thermal energy may be imparted to tissue, such as radio frequency (RF) electrical energy, microwave
10 electromagnetic energy, laser energy, acoustic energy, or thermal conduction. In one particular application, RF energy may be delivered to diseased regions (e.g., tumors) for the purpose of ablating predictable volumes of tissue with minimal patient trauma.

One approach uses a single needle electrode, which when attached to a RF
15 generator, emits RF energy from an exposed, uninsulated portion of the electrode. This energy translates into ion agitation, which is converted into heat and induces cellular death via coagulation necrosis. By varying the power output and the type of electrical waveform, it is theoretically possible to control the extent of heating, and thus, uniformly sculpt the volume of necrosis to match the extent of the tumor. The
20 diameter of tissue coagulation from a single electrode, however, is limited by heat dispersion. As a result, multiple probe insertions are required to treat all but the smallest tumors.

Another approach utilizes multiple needle electrodes, which have been designed for the treatment and necrosis of tumors in the liver and other solid tissues.
25 U.S. Patent No. 6,379,353 discloses such a probe, which is commercially available as the LeVeen Needle Electrode. This probe comprises a cannula having a needle

electrode array, which is reciprocatably mounted within the cannula to alternately deploy the electrode array from the cannula and retract electrode array within the cannula. The individual electrodes within the array have spring memory, so that they assume a radially outward, arcuate configuration as they are deployed from the
5 cannula. In general, a multiple electrode array creates a larger lesion than that created by a single needle electrode.

Whichever approach is utilized, increasing generator output has been unsuccessful for increasing lesion diameter, because an increased wattage is associated with a local increase of temperature to more than 100°C, which induces
10 tissue vaporization and charring. This then increases local tissue impedance, limiting RF deposition, and therefore heat diffusion and associated coagulation necrosis. To reduce the local temperature, thereby minimizing tissue vaporization and charring, the needle electrode or electrodes can be cooled. With regard to the single needle technology, two coaxial lumens may currently be provided in the
15 needle electrode, one of which is used to deliver a cooled saline (e.g., room temperature or cooler) to the tip of the electrode, and the other of which is used to return the saline to a collection unit outside of the body. See, e.g., Goldberg et al., Radiofrequency Tissue Ablation: Increased Lesion Diameter with a Perfusion Electrode, Acad Radiol, August 1996, pp. 636-644.

20 Although the circulation of a cooled fluid through the needle electrode provides for a more efficient means for creating a lesion, it requires additional equipment in the form of a pump and collection reservoir. In addition, uniform lesions are not always created even when the needle electrodes are cooled, because the vascular heating sinking effect often pulls heat away from adjacent
25 tissue that is being ablated.

SUMMARY OF THE INVENTION

In one embodiment of the invention, an ablation probe comprises an elongated member, which is preferably rigid or semi-rigid, so that it can be introduced through solid tissue. The ablation probe, however, can be flexible without straying from the principles taught by this invention. The ablation probe further comprises an ablative element. In one embodiment, the ablative element is a tissue-penetrating electrode, such that the ablation probe can be more easily introduced through solid tissue. In another embodiment, a plurality of tissue-penetrating needle electrodes can be provided. In this case, the needle electrodes can be deployable from, e.g., a cannula.

The ablation probe further comprises at least one thermoelectric device mounted to the elongated member in thermal communication with the ablative element. The thermoelectric device(s) may be in direct contact with the ablative element, but need not be as long as there is thermal communication. The thermoelectric device(s) can be conveniently operated merely by transmitting signals, e.g., applying a direct current (DC), to the thermoelectric device(s).

The thermoelectric device(s) can be configured in a variety of manners, depending on the nature of the ablative element and whether tissue is to be hyperthermically or hypothermically ablated. For example, if the ablative element is a heat ablative element having an independent heating means, such as a radio frequency (RF) electrode, the thermoelectric device(s) can be used to cool the heat ablative element during the ablation process, thereby providing for a more efficient ablation. The thermoelectric device(s) can optionally be used to pre-heat the heat ablative element. This cooling and pre-heating functionality can be combined into a single ablation probe merely by switching the polarity of signals transmitted to the

thermoelectric devices. The thermal nature of the ablative element can also be dictated by the thermoelectric device(s). For example, the thermoelectric device(s) can be configured for cryogenically cooling the ablative element, so that the ablative element can hypothermically ablate tissue. Or the thermoelectric device(s) can be
5 configured for heating the ablative element, so that the ablative element can hyperthermically ablate tissue. This cryogenic cooling and heating functionality can be combined into a single ablation probe merely by switching the polarity of signals transmitted to the thermoelectric devices.

If the thermoelectric device(s) are designed to cool the ablative element,
10 whether to provide a more efficient hyperthermic ablation process, or to cryogenically cool the ablative element, the ablation probe may optionally comprise a heat sink thermally coupled to the thermoelectric device. In this case, the thermoelectric device(s) comprises a cold side in thermal communication with the ablative element and a hot side in thermal communication with the heat sink. Preferably, the heat sink
15 comprises a heat sink rod that extends through the elongated member and cooling fins formed at a proximal end of the heat sink rod. Rather than using a separate heat sink, the thermoelectric device may take the form of an elongated tube that extends through the elongated member.

The ablation probe can be used in an ablation system that comprises thermal
20 control circuitry electrically coupled to the thermoelectric device, and an ablation source (e.g., an RF ablation source) coupled to the ablative element. The control circuitry is configured for transmitting signals to the thermoelectric device(s), whereby the thermoelectric device(s) either cool or heat the ablative element, whichever the case may be. Optionally, the ablation system comprises a console
25 that conveniently contains the thermal control circuitry and ablation source.

In another embodiment of the invention, an ablation probe comprises a delivery cannula, which is preferably rigid or semi-rigid, but may be flexible. The ablation probe further comprises an inner probe member slidably disposed within a lumen of the cannula. The inner probe member may be removable from the

5 cannula, such that the cannula lumen can be used to deliver therapeutic agents prior or subsequent to the ablation process. The ablation probe further comprises a first tissue ablation electrode mounted to the distal end of the cannula, and a second tissue ablation electrode mounted to a distal end of the probe member, wherein the first and second electrodes are configured to be placed into a bipolar configuration.

10 In one embodiment, the second ablation electrode is a tissue-penetrating electrode, such that the ablation probe can be more easily introduced through solid tissue. In another embodiment, the first and second ablation electrodes may be RF electrodes. The ablation probe further comprises a thermoelectric cooling device mounted either to the delivery cannula in thermal communication with the first electrode or to the

15 inner probe member in thermal communication with the second electrode. The thermoelectric cooling device may be in direct contact with the respective electrode, but need not be as long as there is thermal communication.

In yet another embodiment of the invention, an ablation probe comprises an elongated member and a heat ablative element mounted to the distal end of the

20 elongated member. The structure of the elongated member and heat ablative element can be the same as previously described. The ablation probe further comprises a plurality of circumferentially distributed cooling devices in thermal communication with the ablative element. In one embodiment, the cooling devices are thermoelectric cooling devices, but may take the form of other types of cooling

25 devices also. The ablative element may optionally comprise a cylindrical portion, in

which case, the cooling devices may be circumferentially distributed around the inner surface of the cylindrical portion. The ablation probe may optionally comprise a heat sink, which may have the same structure and association with the thermoelectric devices as previously described above.

5 The ablation probe can be used in an ablation system that comprises thermal control circuitry and an ablation source (e.g., an RF ablation source) coupled to the ablative element. The control circuitry is configured for independently controlling the respective cooling devices, whereby the cooling devices cool the ablative element. Optionally, the ablation system comprises a console that conveniently contains the
10 thermal control circuitry and ablation source.

 In still another embodiment of the invention, an ablation system comprises an elongated member and a heat ablative element mounted to the distal end of the elongated member. The structure of the elongated member and heat ablative element can be the same as previously described. The ablation system further
15 comprises a plurality of thermoelectric cooling devices mounted to the elongated member in thermal communication with the ablative element, and thermal control circuitry electrically coupled to the thermoelectric device. The ablation system can have an ablation source (e.g., an RF ablation source) coupled to the ablative element. Optionally, the ablation system comprises a console that conveniently
20 contains the thermal control circuitry and ablation source.

 The control circuitry is configured for independently transmitting signals to the respective thermoelectric devices, whereby the thermoelectric devices heat the ablative element. For example, the thermal control circuitry may be configured to selectively turn certain thermoelectric devices off, so that they do not provide a
25 cooling effect. This can be accomplished based on predetermined criteria (e.g., the

tissue adjacent the thermoelectric device is already being cooled by a blood vessel), or based on a feedback signal, e.g., a tissue temperature or impedance signal.

Alternatively, the thermal control circuitry is configured for cycling each thermoelectric device with a uniform duty cycle, e.g., to moderate the cooling effect

5 of the thermoelectric devices. In this case, the thermal control circuitry can be configured for independently varying the uniform duty cycles of the thermoelectric devices, so that some provide a greater cooling effect than others. Or, the thermal control circuitry can be configured for independently transmitting signals with different amplitudes to the thermoelectric devices, so that some thermoelectric
10 devices (e.g., those to which higher amplitude signals are supplied) provide a greater cooling effect than others.

In still another embodiment of the invention, a tissue ablation console comprises a tissue ablation source (e.g., an RF source) and thermal control circuitry configured for transmitting electrical signals to a thermoelectric device. If a plurality
15 of thermoelectric devices are to be controlled, the thermal control circuitry may be configured for independently transmitting electrical signals to the thermoelectric devices. The thermal control circuitry may be configured to independently control the thermoelectric devices in the same manner described above.

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BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate the design and utility of embodiments of the invention, in which similar elements are referred to by common reference numerals, and in which:

Fig. 1 is a plan view of an ablation system constructed in accordance with an
25 embodiment of the invention;

Fig. 2 is a partially cutaway side view of an ablation probe used in the ablation system of **Fig. 1**;

Fig. 3 is a cross-sectional view of the ablation probe of **Fig. 2**, taken along the line 3-3;

5 **Fig. 4** is an electrical schematic of a type of thermoelectric cooling device that can be used in the ablation probe of **Fig. 2**;

Fig. 5 is a partially cutaway top view of a thermoelectric cooling module that can be adapted to be used in the ablation probe of **Fig. 2**;

10 **Fig. 6** is a perspective view of another ablation probe that can be used in the ablation system of **Fig. 1**, particularly showing a retracted electrode array;

Fig. 7 is a perspective view of the ablation probe of **Fig. 6**, particularly showing the electrode array deployed;

Fig. 8 is a partially cutaway side view of the distal end of the ablation probe of **Fig. 6**;

15 **Fig. 9** is a cross-sectional view of the distal end of the ablation probe of **Fig. 8**, taken along the line 9-9; and

Fig. 10 is a cutaway side view of an ablation probe of **Fig. 2** slidably disposed within a cannula to form a bipolar electrode arrangement.

20 DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Referring to **Fig. 1**, a tissue ablation system 100 constructed in accordance with one embodiment of the invention, will now be described. The tissue ablation system 100 generally comprises an ablation probe 102 configured for introduction into the body of a patient for ablative treatment of target tissue, an ablation/cooling console 104 configured for supplying both RF energy and cooling signals to the

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ablation probe 102 in a controlled manner, and a cable 106 electrically connecting the ablation probe 102 to the ablation/cooling console 104.

Referring now to **Fig. 2**, the ablation probe 102 will be described in further detail. The ablation probe 102 comprises an elongated shaft 108 having a proximal end 110, a distal end 112, and an internal axial lumen 114. The probe shaft 108 is preferably composed of a rigid or semi-rigid material, such that the probe shaft 108 can be introduced through solid tissue to a target tissue site. The distal end 112 of the probe shaft 108 comprises a tissue-penetrating tip 116, which allows the probe shaft 108 to be more easily introduced through tissue, while minimizing tissue trauma. Alternatively, the probe shaft 108 may be introduced through the tissue with the aid of a cannula and trocar assembly, in which case, the probe shaft 108 may be composed of a flexible material, and the distal end 112 may be blunted. The distal end 112 of the probe shaft 108 preferably carries a visualization marker 118 to allow the physician to identify the orientation of the ablation probe 102. The visualization marker 118 may be an ultrasound, MRI, RF signal reflector, or other visualization marker known to those of skill in the art.

In the illustrated embodiment, the probe shaft 108 is composed of an electrically conductive material, such as stainless steel. In this case, the exterior surface of the probe shaft 108, with the exception of the distal tip 116, is preferably composed of an electrically insulative material (not shown). Alternatively, the probe shaft 108 may be composed of an electrically insulative material, such as a medical grade plastic, in which case, a separate insulative coating is not needed. The probe shaft 108 has a suitable length, typically in the range from 5 cm to 30 cm, preferably from 10 cm to 25 cm, and an outer diameter consistent with its intended use, typically being from 0.7 mm to 5 mm, usually from 1 mm to 4 mm.

The ablation probe 102 further comprises a handle 120 mounted to the proximal end 110 of the probe shaft 108. The handle 120 is preferably composed of a durable and rigid material, such as medical grade plastic, and is ergonomically molded to allow a physician to more easily manipulate the ablation probe 102. The handle 120 comprises an electrical connector 122 with which the cable 106 (shown in **Fig. 1**) mates.

The ablation probe 102 further comprises an RF ablation electrode 124 carried by the distal end 112 of the probe shaft 108. In the illustrated embodiment, the electrode 124 is formed by the exposed portion of the shaft distal tip 116.

Alternatively, if the probe shaft 108 is composed of an electrically insulative material, the distal tip 116 can be coated with an electrically conductive material to form the electrode thereon, or a discrete ring electrode can be interference fit at the base of the distal tip 116. In this alternative case, a separate RF wire (not shown) will need to be routed from the electrode back through the shaft lumen 114. As best shown in **Fig. 3**, the ablation electrode 124 comprises a cylindrical hollow portion 126, the function of which will be described in further detail below.

The ablation probe 102 further comprises a heat sink 128 composed of a thermally conductive material, such as aluminum. The distal end of the heat sink 128 is disposed within the hollow portion 126 of the electrode 124. The ablation probe 102 further comprises a number of thermoelectric devices 130 (in this case, five) circumferentially arranged and mounted to the external distal surface of the heat sink 128. The heat sink 128 serves to dissipate unwanted heat absorbed by the thermoelectric devices 130 from the hollow portion 126 of the electrode 124. In particular, the heat sink 128 comprises a rod 132 that extends through the lumen 114 of the elongated shaft 108 and out from the handle 120, and cooling fins 134

formed at the proximal end of the heat sink rod 132 and exposed to the ambient air.

The heat sink rod 132 has a pentagonal cross-sectional shape to provide mounting surfaces for the five respective thermoelectric devices 130. Of course, the cross-sectional shape of the heat sink rod will differ, depending on the number of

5 thermoelectric devices 130 that are to be installed within the ablation probe 102.

With the exception of the portion of the heat sink rod 132 on which the thermoelectric devices 130 are mounted, the exterior surface of the heat sink rod 132 comprises an electrically insulative coating (not shown) to provide electrical isolation from the RF energy conducting probe shaft 108. Alternatively, if a heat sink with cooling fins is

10 not desirable, a thermoelectric device in the form of a tube can be disposed through the lumen 114 of the probe shaft 108. Although the heat sink 128 is illustrated as being outside of the handle 120, it should be noted that the heat sink 128 is preferably contained within the handle 120, with the fins 134 extending partially or totally along the heat sink rod 132.

15 Each thermoelectric device 130 comprises a cold side 136, which is in thermal communication with the hollow portion 126 of the electrode 124, and a hot side 138, which is in thermal communication with the heat sink 128. Two signal wires (a positive wire and a negative wire, both not shown) are connected to each of the thermoelectric devices 130 and proximally extend through the lumen 114 of the

20 probe shaft 108 to the electrical connector 122 on the handle 120. When the positive wire is coupled to a positive pole, and the negative wire is coupled to a negative pole, the cold and hot sides 136 and 138 of the thermoelectric devices 130 become cold and hot, respectively. As a result, thermal energy from the electrode 124 is absorbed by the cold sides 136 of the thermoelectric devices 130, which is

25 then conducted to the hot sides 138 of the thermoelectric devices 130. The thermal

energy emitted from the hot sides 138 of the thermoelectric devices 130 is then conducted through the heat sink rod 132 to the heat sink fins 134, where it dissipates into the ambient air.

As illustrated in **Figs. 4** and **5**, an example of a thermoelectric module is formed by a series of P- and N-doped pellets coupled together via electrical connectors 140, e.g, copper tabs. The exemplary thermoelectric module further comprises a pair of thin ceramic wafers 142 between which the P- and N-doped pellets are sandwiched. The ceramic wafers 142 add rigidity and are necessary for electrical insulation. The N-type pellets have an excess of electrons, while the P-type pellets has a deficit of electrons. The doped materials are preferably composed of bismuth-telluride semiconductor material.

The free (bottom) end of the P-type pellet is connected to a positive voltage potential (e.g., the positive signal wire) and the free (bottom) end of the N-type pellet is connected to ground (e.g., the negative signal wire). The positive charge carriers (i.e., the holes) in the P-type pellets are repelled by the positive voltage potential and attracted by the negative pole, whereas the negative charge carriers (electrons) in the N-type pellets are repelled by the negative potential and attracted by the positive pole. As the electrons move from a P-type pellet to an N-type pellet through an electrical connector 122, the electrons jump to a higher energy state, thereby absorbing thermal energy (cold side). Continuing through the lattice of material, the electrons flow from an N-type pellet to a P-type pellet through an electrical connector 122, dropping to a lower energy state and releasing energy as heat. The most common thermoelectric devices connect two hundred fifty-four alternating P- and N-type pellets, which can run from a 12 to 16 Volt DC supply and draw from 4 to 5 amps.

It should be noted that the thermoelectric module illustrated in **Figs. 4 and 5** is only an example and its detailed structure will vary depending on the geometry and size of the electrode in which it is to be mounted.

Referring back to **Fig. 1**, the ablation/cooling console is electrically connected
5 via the cable 106 to the connector 122 on the handle 120. The electrical connector 122 comprises ablation/cooling connections that allows the ablation functionality of the ablation/cooling console 104 to be indirectly electrically coupled to the electrode 124 through the probe shaft 108, and the cooling functionality of the ablation/cooled console 104 to be indirectly coupled to the thermoelectric devices 130 via the
10 insulated signal wires extending through the lumen 114 of the probe shaft 108.

The ablation/cooling console 104 may be similar to a conventional RF power supply (with the exception of the added cooling functionality described below) that operates at a frequency in the range from 200 KHz to 1.25 MHz, with a conventional sinusoidal or non-sinusoidal wave form. Such power supplies are available from
15 many commercial suppliers, such as Valleylab, Aspen, and Bovie. Most general purpose electrosurgical power supplies, however, operate at higher voltages and powers than would normally be necessary or suitable for vessel occlusion. Thus, such power supplies would usually be operated at the lower ends of their voltage and power capabilities. More suitable power supplies will be capable of supplying an
20 ablation current at a relatively low voltage, typically below 150V (peak-to-peak), usually being from 50V to 100V. The power will usually be from 20W to 200W, usually having a sine wave form, although other wave forms would also be acceptable. Power supplies capable of operating within these ranges are available from commercial vendors, such as Boston Scientific Corporation of San Jose,

California, who markets these power supplies under the trademarks RF2000™ (100W) and RF3000™ (200W).

RF current is preferably delivered from the ablation/cooling console 104 to the electrode 124 in a monopolar fashion, which means that current will pass from the electrode 124, which is configured to concentrate the energy flux in order to have an injurious effect on the adjacent tissue, and a dispersive electrode (not shown), which is located remotely from the electrode 124 and has a sufficiently large area (typically 130 cm² for an adult), so that the current density is low and non-injurious to surrounding tissue. In the illustrated embodiment, the dispersive electrode may be attached externally to the patient, e.g., using a contact pad placed on the patient's flank.

Alternatively, RF current may be delivered from the ablation/cooling console 104 in a bipolar arrangement. For example, **Fig. 10** illustrates the use of the ablation probe 102 within a bipolar assembly. In particular, the ablation probe 102 is reciprocatably disposed within a cannula 150 having a distally mounted electrode 152. A bipolar relationship between the electrode 124 on the ablation probe 102, and the electrode 152 on the cannula 150, can be formed by electrically coupling the respective poles of the ablation/cooling console 104 to the electrodes 124 and 152. The distance between the electrodes 124 and 152 can be adjusted by distally or proximally sliding the ablation probe 102 within the cannula 150, thereby providing a means for adjusting the ablation results. Optionally, the ablation probe 102 may be removable from the cannula 150 in order to provide a means for delivering therapeutic agents to the treated region before or after the ablation process. In an alternative embodiment, thermoelectric devices 130 can be located on the cannula

150 adjacent the electrode 152, in addition to, or rather than, placing the thermoelectric devices 130 on the ablation probe 102 adjacent the electrode 124.

The ablation/cooling console 104 additionally includes controlled cooling capability, and in particular, supplies DC voltage to the thermoelectric devices 130, which in turn, cool the electrode 124, and thus, the tissue in contact with the electrode 124. The ablation/cooling console 104 optionally has control circuitry (not shown) that turns the thermoelectric devices 130 off using temperature or impedance feedback, e.g., to maintain the treated tissue in a specific temperature range. As will be described in further detail below, the control circuitry is also capable of independently controlling the individual thermoelectric devices 130 in order to shape the resulting tissue ablation. The visualization marker 118 on the distal end 112 of the probe shaft 108 can be used by the physician to select which thermoelectric devices 130 are to be turned off or on.

Although the ablative and cooling control functionality has been described as being combined into a single console, i.e., the RF generator, these functionalities could be incorporated into two separate respective consoles, which would require separate pieces of equipment.

Thus, it can be appreciated that the use of the thermoelectric devices 130 provides a convenient means of cooling the tissue in contact with the electrode 124, thereby eliminating or minimizing tissue charring close to the electrode and maximizing energy dispersion distant from the electrode. The use of the thermoelectric devices 130 also allows the physician to selectively cool a portion of the tissue, since the thermoelectric devices 130 can be selectively and independently turned on and off. The selective cooling allows the physician to sculpt the shape of the lesion.

Referring now to **Figs. 6 and 7**, another embodiment of an ablation probe 202 will be described. The ablation probe 202 generally comprises an elongated delivery cannula 204 and an inner probe 206 slidably disposed within the cannula 204. The cannula 204 has a proximal end 208, a distal end 210 with a sharpened distal tip 214, and a central lumen 212 (shown in **Fig. 8**) extending through the cannula 204. The cannula 204 may be rigid, semi-rigid, or flexible depending upon the designed means for introducing the cannula 204 to the target tissue. The cannula 204 is composed of a suitable material, such as plastic, metal or the like, and has a suitable length, typically in the range from 5 cm to 30 cm, preferably from 10 cm to 25 cm. If composed of an electrically conductive material, the cannula 204 is preferably covered with an insulative material. The cannula 204 has an outside diameter consistent with its intended use, typically being from 1 mm to 5 mm, usually from 1.3 mm to 4 mm. The cannula 204 has an inner diameter in the range from 0.7 mm to 4 mm, preferably from 1 mm to 3.5 mm. The cannula 204 is provided with a handle 216 to allow a physician to more easily grasp the proximal end of the ablation probe 202 when inserting the distal end into solid tissue, e.g., through the abdominal wall and liver tissue of a patient.

Referring further to **Fig. 8**, the inner probe 206 comprises a reciprocating deployment member 218, a distally mounted hollow cylindrical member 220, and an array 222 of tissue penetrating needle electrodes 224 circumferentially mounted within the cylindrical member 220. Like the cannula 204, the deployment member 218 and cylindrical member 220 are composed of a suitable material, such as plastic, metal or the like. A proximal plunger 226 is mounted to the deployment member 218, such that movement of the plunger 226 relative to the handle 216 provides for deployment of the electrode array 222 out of the distal end 210 of the

cannula 204 (**Fig. 7**), and retraction of the electrode array 222 into the distal end 210 of the cannula 204 (**Fig. 6**). The plunger 226 comprises an electrical connector (not shown) with which the cable 106 from the ablation/cooling console 104 (shown in **Fig. 1**) mates. The electrical connector is indirectly electrically coupled to the electrode array 222 through the deployment member 218. The ablation/cooling console 104 may deliver RF ablation energy in a monopolar fashion, as previously described above.

Each of the individual needle electrodes 224 is in the form of a small diameter metal element, which can penetrate into tissue as it is advanced from a target site within the target region. When deployed from the cannula 204 (**Fig. 7**), the electrode array 222 is placed in a three-dimensional configuration that usually defines a generally ellipsoidal or spherical volume having a periphery with a maximum radius in the range from 0.5 to 4 cm. The needle electrodes 224 are resilient and pre-shaped to assume a desired configuration when advanced into tissue. In the illustrated embodiment, the needle electrodes 224 diverge radially outwardly from the cannula 204 in a uniform pattern, i.e., with the spacing between adjacent needle electrodes 224 diverging in a substantially uniform and/or symmetric pattern. In the illustrated embodiment, the needle electrodes 224 also evert proximally, so that they face partially or fully in the proximal direction when fully deployed.

More comprehensive details describing the general structure and operation of the ablation probes with deployable needle electrode arrays are disclosed in U.S. Patent No. 6,575,967.

In addition to the standard RF ablation capability, the ablation probe 202 has cooling functionality. To this end, and as best shown in **Fig. 9**, the inner probe 206 further comprises the previously described heat sink 128 and thermoelectric devices

130. The cold side 136 of each thermoelectric device 130 is in thermal communication with the cylindrical member 220, which, is in turn, in thermal communication with the needle electrodes 224. As a result, thermal energy from the electrode array 222 is absorbed by the cold sides 136 of the thermoelectric devices 130 via the cylindrical member 220, which is then conducted to the hot sides 138 of the thermoelectric devices 130. The thermal energy emitted from the hot sides 138 of the thermoelectric devices 130 are then conducted through the heat sink rod 132 to the heat sink fins 134, where it dissipates into the ambient air. The ablation/cooling console 104 (shown in **Fig. 1**) is electrically coupled to the electrical connector 122 on the plunger 226, which is in turn, electrically coupled to the signal wires (not shown) connected to the thermoelectric devices 130.

Alternatively, rather than locating the thermoelectric devices 130 within the cylindrical member 220, they can be mounted on the proximal ends of the needle electrodes 224. Or the needle electrodes 224, themselves, can be thermoelectric devices 130.

CLAIMS

1. An ablation probe, comprising:
an elongated member;
a heat ablative element mounted to a distal end of the elongated member;
a thermoelectric cooling device mounted to the elongated member in thermal communication with the ablative element.
2. The ablation probe of claim 1, further comprising a plurality of thermoelectric cooling devices mounted to the elongated member in thermal communication with the ablative element.
3. The ablation probe of claim 1, wherein the thermoelectric device is formed as an elongated tube that extends through the elongated member.
4. The ablation probe of any of claims 1 - 3, wherein the thermoelectric device is in direct contact with the ablative element.
5. The ablation probe of any of claims 1 - 4, wherein the ablative element comprises a plurality of tissue penetrating needle electrodes.
6. The ablation probe of any of claims 1 - 5, further comprising a heat sink thermally coupled to the thermoelectric device.
7. The ablation probe of claim 6, wherein the heat sink comprises a heat sink rod that extends through the elongated member, and a plurality of cooling fins formed at a proximal end of the heat sink rod.
8. The ablation probe of claim 6, wherein the thermoelectric device comprises a cold side in thermal communication with the ablative element and a hot side in thermal communication with the heat sink.

9. An ablation system including the ablation probe of claim 1, further comprising:

thermal control circuitry electrically coupled to the thermoelectric device, the control circuitry configured for transmitting a signal to the thermoelectric device, whereby the thermoelectric device cools the ablative element.

10. The ablation system of claim 9, further comprising an ablation source coupled to the ablative element.

11. The ablation system of claim 10, further comprising a console containing the thermal control circuitry and ablation source.

12. The ablation probe of any of claims 1 - 11, wherein the ablative element is a heat/cryogenic ablative element.

13. The ablation probe of any of claims 1 - 11, wherein the ablative element is a radio frequency (RF) electrode.

14. An ablation probe, comprising:

an elongated member;
a heat ablative element mounted to a distal end of the elongated member, the ablative element having a hollow cylindrical portion; and
a plurality of discrete cooling devices circumferentially distributed around an inner surface of the cylindrical portion.

15. The ablation probe of claim 14, wherein the cooling devices are thermoelectric cooling devices.

16. The ablation probe of either of claims 14 or 15, wherein the ablative element is a radio frequency (RF) electrode.

17. The ablation probe of any of claims 14 - 16, further comprising a heat sink thermally coupled to the cooling devices.

18. The ablation probe of claim 17, wherein the heat sink comprises a heat sink rod that extends through the elongated member, and a plurality of cooling fins formed at a proximal end of the heat sink rod.

19. An ablation system including the ablation probe of claim 14, further comprising:

thermal control circuitry configured for independently controlling the respective cooling devices, whereby the cooling devices cool the ablative element.

20. The ablation system of claim 19, further comprising an ablation source coupled to the ablative element.

21. The ablation system of claim 20, further comprising a console containing the thermal control circuitry and ablation source.

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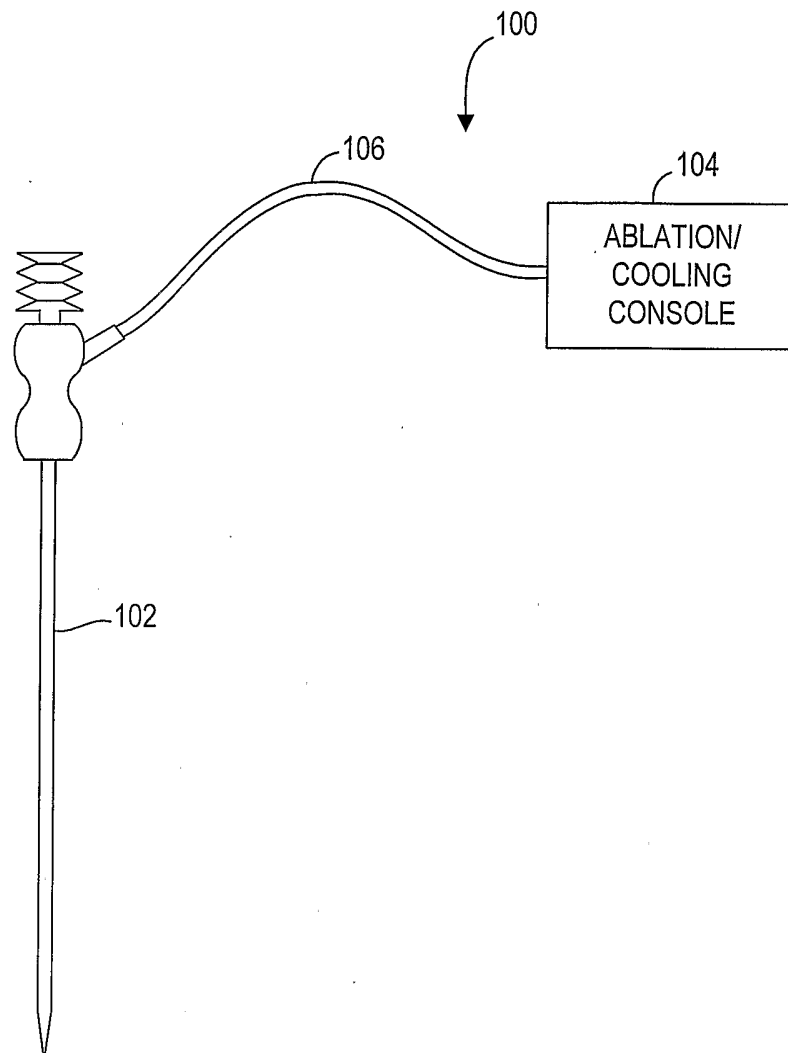


Fig. 1

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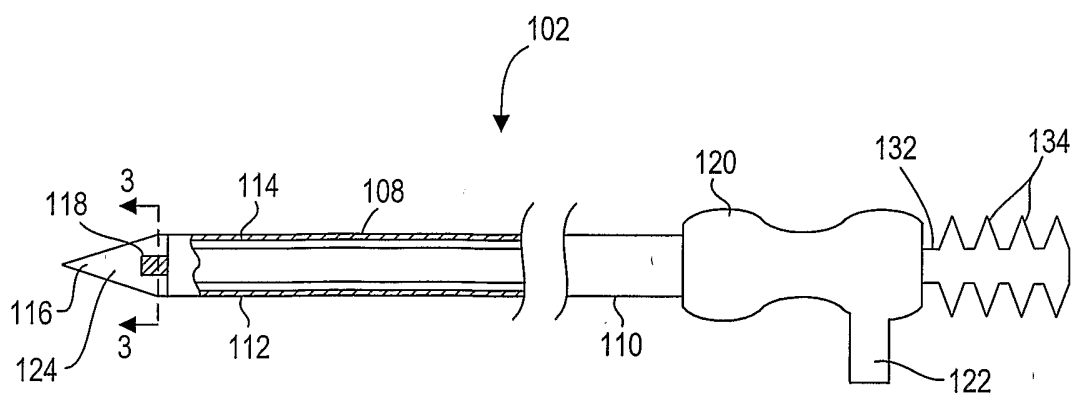


Fig. 2

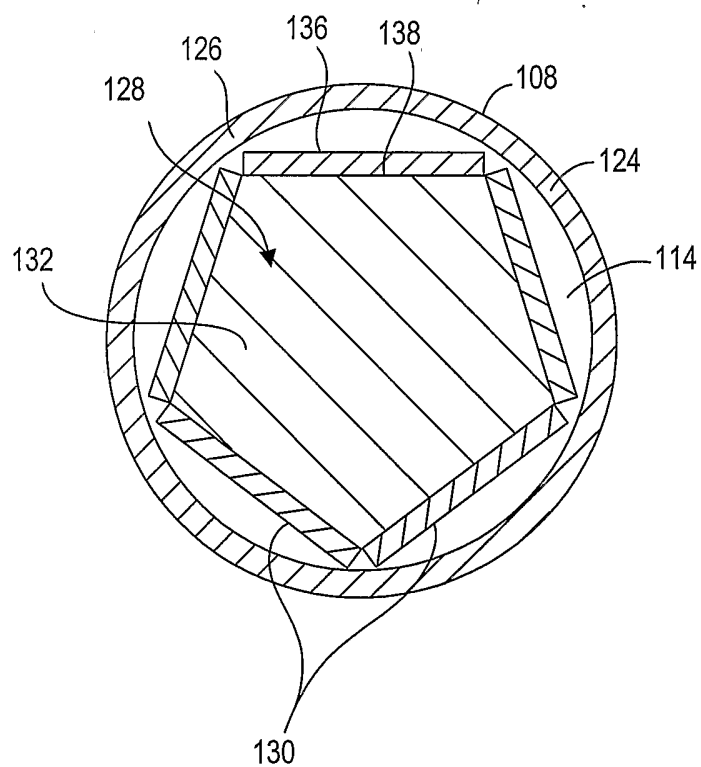


Fig. 3

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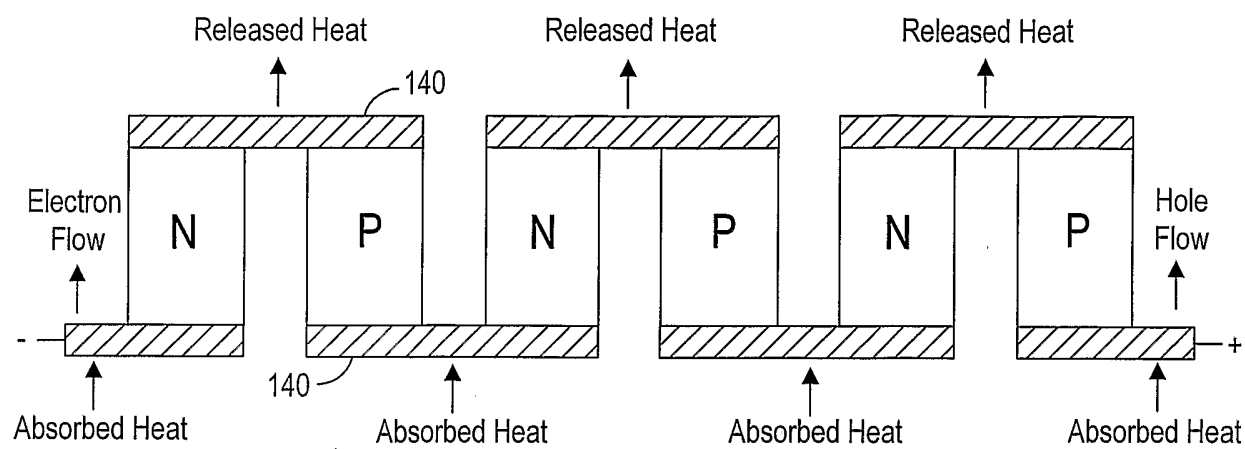


Fig. 4

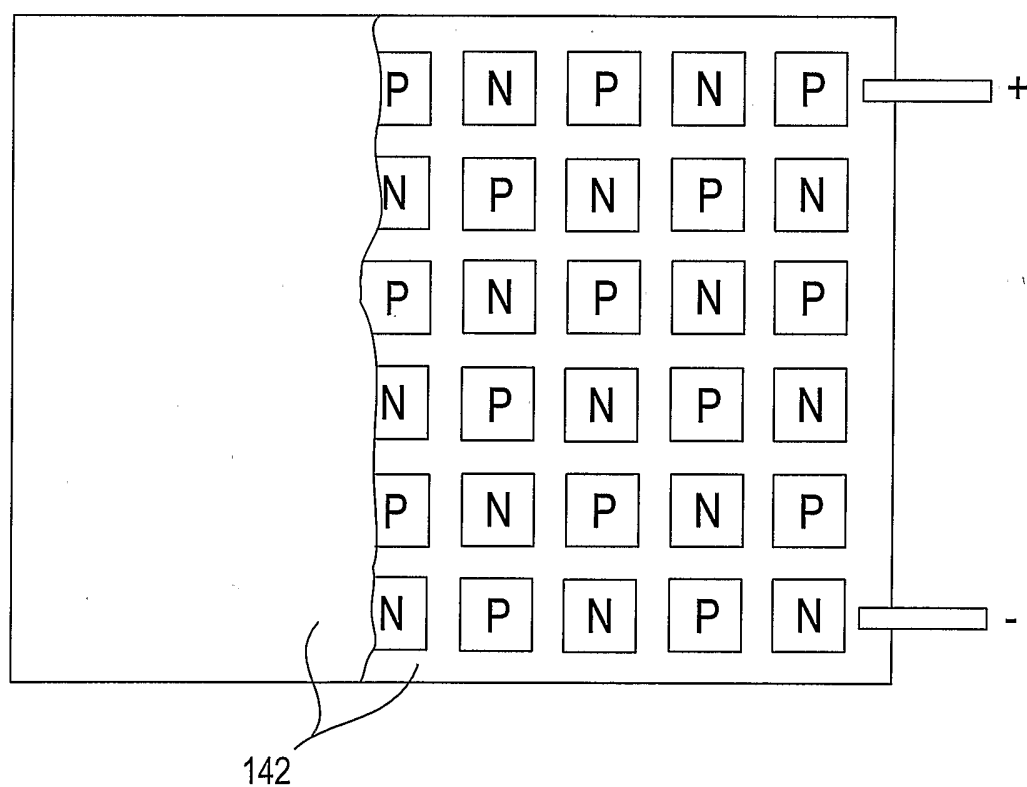


Fig. 5

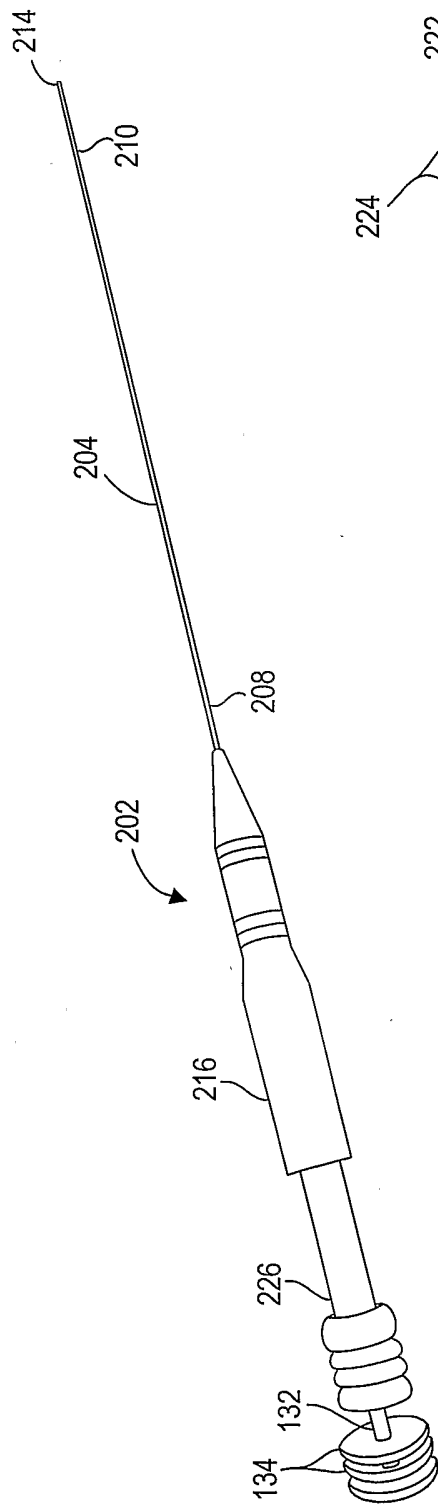


Fig. 6

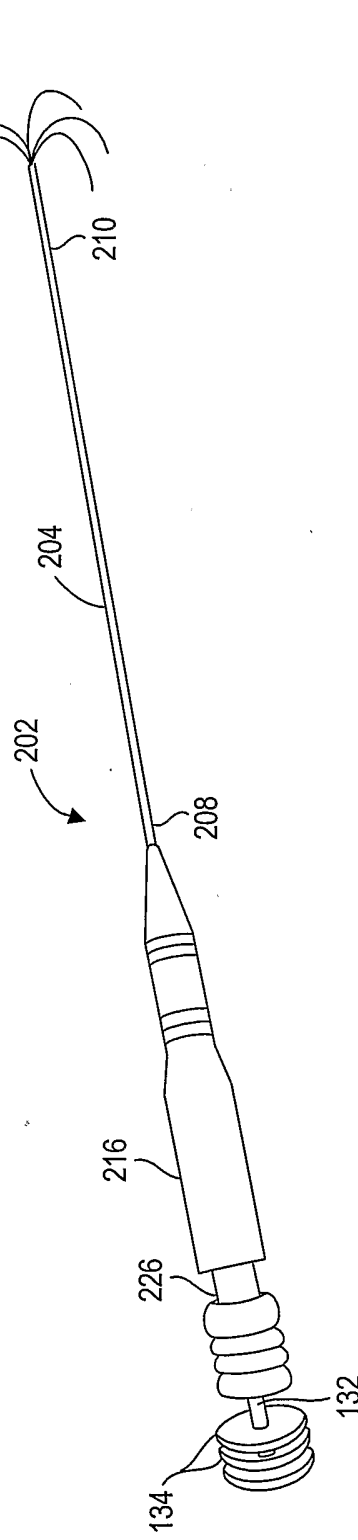


Fig. 7

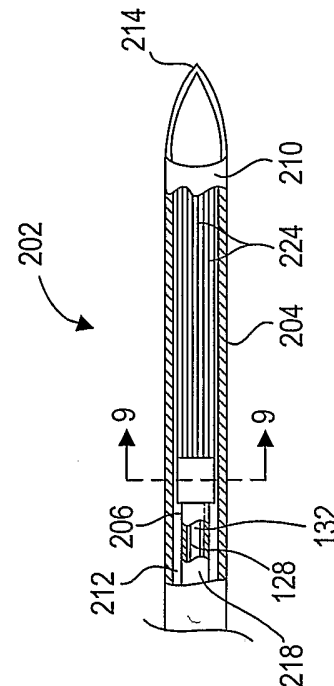


Fig. 8

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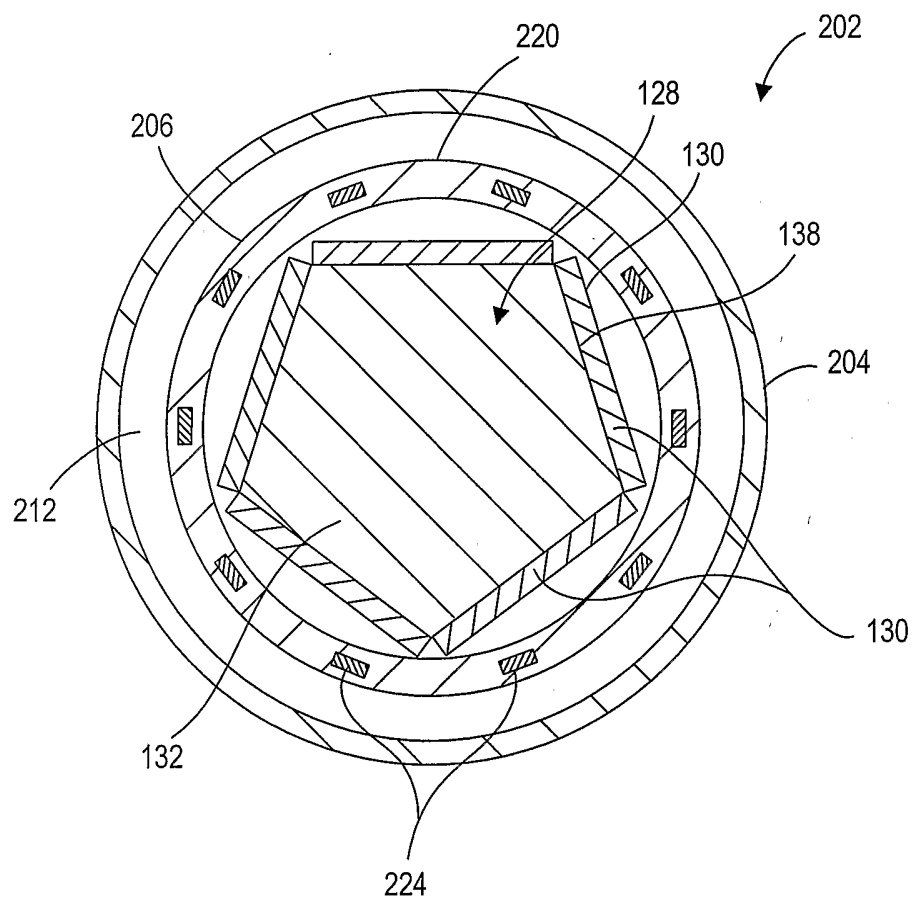


Fig. 9

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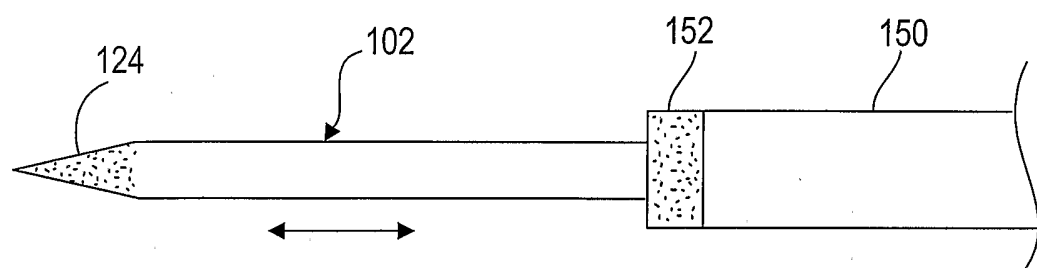


Fig. 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/003588

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

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)
IPC 7 A61B

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

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 735 846 A (PANESCU ET AL) 7 April 1998 (1998-04-07) column 1, line 41 - column 2, line 12 column 7, line 59 - column 8, line 21 figure 7	1-13 14
X Y	US 2003/014098 A1 (QUIJANO RODOLFO C ET AL) 16 January 2003 (2003-01-16) paragraph '0001! paragraph '0010! - paragraph '0015! paragraph '0032! - paragraph '0038!	1-13 15-21
X	FR 2 768 931 A (TECHNOMED MEDICAL SYSTEMS) 2 April 1999 (1999-04-02) page 9, line 23 - page 10, line 9 figure 4	1,2

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

18 April 2005

Date of mailing of the international search report

28/04/2005

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/003588

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 427 089 B1 (KNOWLTON EDWARD W) 30 July 2002 (2002-07-30)	1
A	column 4, line 42 - column 5, line 24 column 13, line 66 - column 14, line 3 -----	14
X	US 5 951 546 A (LORENTZEN ET AL) 14 September 1999 (1999-09-14)	14
Y	column 3, line 38 - column 5, line 12 column 10, line 10 - line 14 column 10, line 22 - line 26 figures 2b,2d -----	15-21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/003588

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13

An ablation probe comprising a heat ablative element and a thermoelectric cooling device

2. claims: 14-21

An ablation probe comprising a heat ablative element having a hollow cylindrical portion and a plurality of cooling devices circumferentially distributed around an inner surface of the cylindrical portion

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US2005/003588

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