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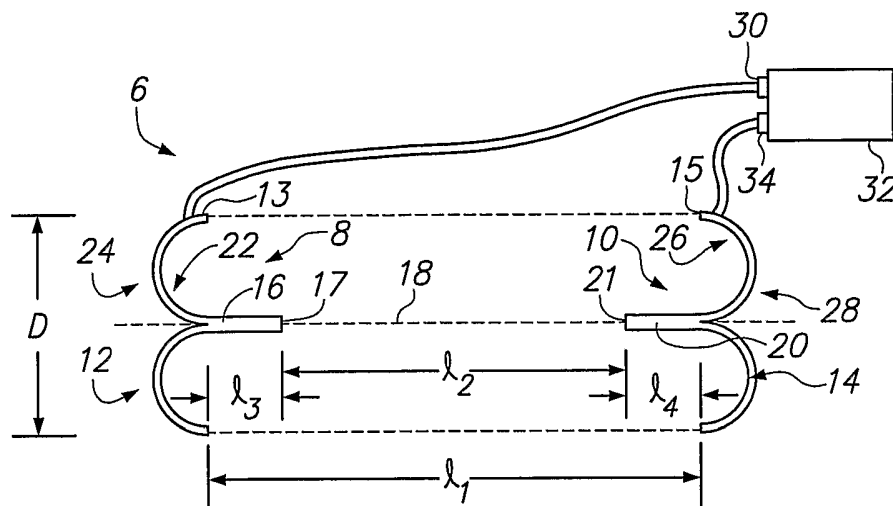
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(54) Title: APPARATUS FOR FOCUSED BIPOLAR TISSUE ABLATION USING AN INSULATED SHAFT



(57) Abstract: A tissue ablation probe is provided. The probe comprises a proximal electrode element, which includes a proximal electrode stem and a deployable proximal electrode array, and a distal electrode element, which includes a distal electrode stem and a deployable distal electrode array. The probe is configured, such that a majority of electrical energy conveyed between the proximal and distal electrode elements is conveyed between distal termini of the electrode arrays, whereas a relatively small amount of the electrical energy is conveyed between the electrode stems. One or more of the electrodes on the arrays may be optionally insulated to further enhance the electrical characteristics of the arrays.

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APPARATUS FOR FOCUSED BIPOLAR TISSUE ABLATION USING AN INSULATED SHAFT

FIELD OF THE INVENTION

The invention relates generally to the structure and use of
5 radiofrequency electrosurgical apparatus for the treatment of tissue.

BACKGROUND

The delivery of radiofrequency energy to treatment regions within
tissue is known for a variety of purposes. Of particular interest to the
invention, radiofrequency energy may be delivered to diseased regions in
10 target tissue for the purpose of causing tissue necrosis. For example, the
liver is a common depository for metastases of many primary cancers, such
as cancers of the stomach, bowel, pancreas, kidney, and lung.
Electrosurgical probes for deploying multiple electrodes have been designed
for the treatment and necrosis of tumors in the liver and other solid tissues.
15 See, for example, the LeVeen™ Needle Electrode available from Boston
Scientific Corporation, which is constructed generally in accordance with
published PCT application WO 98/52480.

The probes described in WO 98/52480 comprise a number of
independent wire electrodes, which are extended into tissue from the distal
20 end of a cannula. The wire electrodes may then be energized in a monopolar
or bipolar fashion to heat and necrose tissue within a defined generally
spherical volumetric region of target tissue. In order to assure that the target
tissue is adequately treated and to limit damage to adjacent healthy tissues, it

is desirable that the array formed by the wire electrodes within the tissue be precisely and uniformly defined.

Despite the significant success that has accompanied use of wire electrode arrays in treating solid tissue tumors, the ability to treat particular types of tumors has been somewhat limited. For example, the ability to produce very large tissue lesions, for example lesions having volumes greater than 30-35 cm³, has been problematic. In addition, such larger tumors tend to be less spheroidal in shape than smaller tumors. Additionally, the ability to treat highly vascularized tissues and/or tissue near a large blood vessel has also been limited, since heat introduced by the electrode can be rapidly carried away by circulating blood. The ability to provide uniform heating and the creation of homogenous tissue lesions is particularly difficult with bipolar devices, since the respective electrodes may be placed in regions with substantially different perfusion characteristics. That is, one electrode pole may be located adjacent to a large blood vessel, while the other electrode pole may be located adjacent to tissue, which is less perfused, and will heat much more rapidly. In such circumstances, the less perfused tissue may be preferentially heated and necrosed, while the tissue surrounding the other pole will neither be heated nor necrosed sufficiently.

Fig. 1 depicts a prior art bipolar dual electrode array probe 1 having an elongated shaft 2 from which distal and proximal electrode arrays 3 and 4 are deployed. These electrode arrays 3 and 4 may be operated in a bipolar mode, such that electrical energy is transmitted between the distal electrode

array 3 and proximal electrode array 4 via electrical energy paths (shown as arrows) in order to ablate tissue therebetween. The shaft 2 is electrically conductive and comprises a non-conductive gap 5 in order to electrically isolate the arrays 3 and 4 from each other. As can be seen from Fig. 1, the electrical energy paths follow the path of least resistance through the electrically conductive shaft 2. In particular, electrical energy is transmitted from the distal portion of the shaft 2 adjacent the distal electrode array 3 to the tips of the proximal electrode array 4, and electrical energy is transmitted from the tips of the distal electrode array 3 to the proximal portion of the shaft 2 adjacent the proximal electrode array 4. It has been discovered, however, that tissue located radially outward from the center region of the shaft 2 may not be ablated, resulting in the hour-glass shaped ablation region illustrated in Fig. 2.

SUMMARY OF THE INVENTION

In one embodiment of the invention, a tissue ablation probe comprises proximal and distal electrode arrays, each of which has a retracted configuration and a deployed configuration. The probe further comprises a shaft for carrying the electrode arrays. In one embodiment, the electrode arrays are electrically isolated from each other and have respective concave faces that oppose each other when in the deployed configuration, thereby enhancing the bipolar nature of the probe. In forming a concave face, an electrode array may comprise a plurality of individual electrodes that initially move axially and then evert as they are deployed. In another embodiment, the shaft comprises a proximal conductive tube from which the proximal

electrode array is deployed, and a distal conductive tube from which the distal electrode array is deployed. The conductive tubes may, e.g., be coaxial relative to each other or may be in a side-by-side relationship.

In another embodiment of the invention, the electrode arrays have
5 distal termini, and the shaft has an electrically insulative portion that separates the electrode arrays. In one embodiment, the insulative portion is continuous, but may also have gaps. The shaft portion can be insulated in any one of a variety of ways, but in one embodiment, the insulative shaft portion comprises an electrically conductive wall on which electrically insulative material is
10 disposed. The electrode arrays are separated from each other by a first length when deployed, and the insulative shaft portion spans a second length greater than seventy-five percent of the first length. By way of non-limiting example, the insulative shaft portion may allow most of the electrical current to flow between the electrode arrays, rather than along the normally
15 conductive shaft, thereby enhancing the shape of the resulting tissue ablation. The second length may be further increased relative to the first length (e.g., equal to or greater than) to allow even more electrical current to flow between the electrode arrays.

In yet another embodiment of the invention, the shaft has an
20 intervening portion between the electrode arrays. The intervening portion has an electrically conductive proximal region, an electrically conductive distal region, and a non-conductive gap therebetween. The probe further comprises an electrically insulative material covering at least portions of the proximal and

distal shaft regions. Optionally, the insulative material may also cover the non-conductive gap. By way of non-limiting example, the application of the insulative material on the conductive shaft provides a convenient means of modifying the amount of current that flows between the electrode arrays. In one embodiment, the insulative material is closer to one of the electrode arrays than the other. In this manner, the flow of electrical current adjacent one array can be modified relative to the other array.

In still another embodiment of the invention, the probe comprises proximal and distal electrically conductive tubes that are electrically isolated from each other. The proximal electrode array is proximally deployable from and electrically coupled to the proximal tube, and the distal electrode array distally deployable from and electrically coupled to the distal tube. The probe further comprises an electrically insulative material covering at least portions of the proximal and distal tubes. In one embodiment, the insulative material continuously extends from the proximal tube to the distal tube, and, depending on the desired proportion of electrical current conveyed between the electrode arrays, may cover the entirety of the proximal and distal tubes.

In yet a further embodiment of the invention, another tissue ablation probe comprises a proximal electrode element that includes a proximal electrode stem and a deployable proximal electrode array, which has distal termini and is electrically coupled to a proximal end of the proximal electrode stem when deployed. The probe further comprises a distal electrode element including a distal electrode stem and a deployable distal electrode array,

which has distal termini and is electrically coupled to a distal end of the distal electrode stem when deployed. The electrode arrays may have the same features as the electrode array previously described above. The probe is configured, such that a majority of electrical energy conveyed between the proximal and distal electrode elements is conveyed between distal termini of the electrode arrays. In some embodiments, substantially all of the electrical energy conveyed between the proximal and distal electrode elements is conveyed between distal termini of the electrode arrays. In one embodiment, the proximal electrode stem comprises a proximal conductive tube from which the proximal electrode array is deployed, and the distal electrode stem comprises a distal conductive tube from which the distal electrode array is deployed.

In accordance with another embodiment of the invention, a tissue ablation probe comprises an array of needle electrodes having a retracted configuration and a deployed configuration, and a shaft carrying the electrode array. The probe further comprises an electrically insulative material partially disposed on at least one needle electrode of each array, whereby a tip of the needle electrode(s) is left exposed. For example, the insulative material can be disposed on the needle electrode(s) at a point on the shaft from which the needle electrodes deploy to somewhere along the length of the needle electrode(s). In one embodiment, the insulative material may be partially disposed on all the needle electrodes of each array, whereby tips of the needle electrodes are left exposed. By way of non-limiting example, the electrical insulation of portions of the needle electrode(s) allows the electrical

current to be more focused at the tips of the electrode array, thereby providing for a greater tissue ablation. In one embodiment, the probe comprises proximal and distal electrode arrays on which the electrically insulative material is applied. In this case, the shaft and electrode arrays can optionally
5 have the same features as the electrode arrays previously described above to further enhance bipolar ablation between the arrays.

BRIEF DESCRIPTION OF DRAWINGS

The drawings illustrate the design and utility of embodiment(s) of the
10 invention, in which similar elements are referred to by common reference numerals, and in which:

FIG. 1 is a plan view of a prior art bipolar probe;

FIG. 2 is a plan view of an ablation lesion resulting from the probe of
FIG. 1;

15 FIG. 3 is schematic illustration of one set of bipolar electrode arrays arranged in accordance with the invention;

FIG. 4 is schematic illustration of another set of bipolar electrode arrays arranged in accordance with the invention;

FIG. 5 is schematic illustration of still another set of bipolar electrode
20 arrays arranged in accordance with the invention;

FIGS. 6A-6B are schematic illustrations of the progression of tissue ablation achieved with the bipolar electrode arrays of FIG. 3 are electrically activated;

FIGS. 7A-7B are schematic illustrations of the progression of tissue ablation achieved with the bipolar electrode arrays of FIG. 4 are electrically activated;

FIGS. 8A-8B are schematic illustrations of the progression of tissue ablation achieved with the bipolar electrode arrays of FIG. 5 are electrically activated;

FIG. 9 is a perspective view of one embodiment of a bipolar electrode array probe constructed in accordance with the invention, wherein the electrode arrays are particularly shown deployed;

FIG. 10 is a perspective view of the distal end of the probe of FIG. 9;

FIG. 11 is a perspective view of the probe of FIG. 9, wherein the electrode arrays are particularly shown retracted;

FIG. 12 is a perspective view of the distal end of the probe of FIG. 11;

FIG. 13 is a perspective view of the distal end of the probe of FIG. 12, particularly showing a layer of insulation for enhancing the electrical characteristics of the probe;

FIG. 14 is a perspective view of another embodiment of a bipolar electrode array probe constructed in accordance with the invention, wherein the electrode arrays are particularly shown deployed;

FIG. 15 is a perspective view of the distal end of the probe of FIG. 14;

5 FIG. 16 is a perspective view of the distal end of the probe of FIG. 15, particularly showing a layer of insulation for enhancing the electrical characteristics of the probe;

FIG. 17 is a perspective view of still another embodiment of a bipolar electrode array probe constructed in accordance with the invention, wherein
10 the electrode arrays are particularly shown deployed; and

FIG. 18 is a close-up perspective view of the distal electrode array of the probe of FIG. 17, particularly showing a layer of insulation for enhancing the electrical characteristics of the probe.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

15 Generally, embodiments of the invention are directed to the use of RF electrode arrays, particularly bipolar electrode arrays, for the ablation of treatment regions within solid tissue of a patient. The treatment regions may be located anywhere in the body where hyperthermic exposure may be beneficial. Most commonly, the treatment region will comprise a solid tumor
20 within an organ of the body, such as the liver, lung, kidney, pancreas, breast, prostate (not accessed via the urethra), uterus, and the like. The volume to be treated will depend on the size of the tumor or other lesion, but

embodiments of the invention are particularly suitable for treating relatively large tissue regions. The peripheral dimensions of a particular treatment region may be regular, e.g., spherical or ellipsoidal, but will more usually be somewhat irregular. The lesion created to enclose the target tissue region

5 utilizing embodiments of this invention will usually be cylindrical or a truncated conical volume, as described in more detail below. The treatment region may be identified using conventional imaging techniques capable of elucidating a target tissue, e.g., tumor tissue, such as ultrasonic scanning, magnetic resonance imaging (MRI), computer-assisted tomography (CAT), fluoroscopy,

10 nuclear scanning (using radiolabeled tumor-specific probes), and the like. Preferred is the use of high-resolution ultrasound, which can be employed to monitor the size and location of the tumor or other target tissue, being treated, either intraoperatively or externally.

Apparatus according to embodiments of the invention will usually

15 comprise at least one probe having a distal end adapted to be positioned beneath a tissue surface at or near the treatment region or regions. A first array of electrodes comprising a plurality of tissue-penetrating electrodes, typically in the form of sharpened, small cross-section metal elements are reciprocatably attached to the probe so that they penetrate into tissue as they

20 are advanced from a first specific site (referred to hereinafter as the first target site) at or adjacent to a peripheral boundary of the treatment region, as described in more detail hereinafter. The primary requirement of such electrode elements is that they can be deployed in an array, preferably a three-dimensional array, emanating from the first treatment site within the

treatment region of the tissue. Usually, the first electrode array will be deployed from a first target site on a "distal" side of the treatment region, i.e., the side that is most remote from the organ or tissue entry point. In the exemplary embodiments, the electrode elements are first introduced to the treatment region in a radially collapsed or other constrained configuration, and thereafter advanced into the tissue from a delivery cannula or other element in a divergent pattern to achieve the desired three-dimensional array. The electrode elements will diverge radially outwardly from the delivery cannula (located at the first target site) in a uniform pattern, i.e., with the spacing between adjacent electrodes diverging in a substantially uniform and/or symmetric pattern. Preferably, adjacent electrodes will be spaced-apart from each other in similar or identical, repeated patterns and will usually be symmetrically positioned about an axis of the delivery element. The electrode elements may extend or project along generally straight lines from the probe, but will more usually be shaped to curve radially outwardly and to evert proximally so that they face partially or fully in the proximal direction when fully deployed. It will be appreciated that a wide variety of particular patterns can be provided to uniformly cover the region to be treated.

Apparatus according to embodiments of the invention will also comprise at least a second array of electrodes comprising a plurality of tissue-penetrating electrodes typically in the form of sharpened, small cross-section metal wires or elements. The second electrode array will usually be attached to the same probe as is the first electrode array. In some instances, however, the use of such embodiments may utilize first and second electrode arrays,

which are deployed from separate probes and operated in a bipolar manner, as, described in more detail below. The electrode wires or elements of the second array will be deployed from a second target site within the treatment region, usually on a "proximal" side thereof, i.e., the side which is closest to the organ or tissue entry point. The electrodes of the second array will be introduced similarly to those of the first array, i.e., in a collapsed configuration, and subsequently deployed radially outwardly. In the exemplary embodiments, both the first and the second electrode arrays include everting electrode elements, which form arrays having generally concave and convex surfaces. By facing the concave surfaces and electrode tips of the two electrode arrays toward each other so that they are generally aligned along a common axis, usually defined by a shaft of the probe, radiofrequency and other high frequency currents may be applied to tissue in a manner which creates a uniform lesion, i.e., a lesion which is continuous and without significant portions of viable tissue, even when the region has portions which have different perfusion and different cooling characteristics.

Referring to FIGS. 3-5, a system 6 comprising a first electrode element 8 and a second electrode element 10 is schematically show. The first and second electrode elements 8 and 10 include respective first and second electrode arrays 12 and 14 that are shown as fully everting arrays, where individual electrode wires extend first in an axial direction, diverge radially outwardly, and turn back upon themselves until they face in an opposite direction from which they began. The first electrode element 8 further includes a first axial electrode stem 16, which extends along an axis line 18

toward a second axial electrode stem 20, which is part of the second electrode element 10.

The first electrode array 12 has a concave surface 22 and a convex surface 24, and the second electrode array 14 also has a concave surface 26 and a convex surface 28. In the illustrated embodiment, the concave surfaces at 22 and 26 of the electrode arrays 12 and 14 face each other along the axis line 18, so that a distance ℓ_1 is defined between distal termini 13 and 15 (i.e., the tips of the electrode wires) of the electrode arrays 12 and 14. The axial electrode stems 16 and 20 also face each other and extend toward each other, leaving a distance ℓ_2 between the inner termini 17 and 21 (i.e., the tips) of the electrode stems 16 and 20. FIGS. 3 and 5 show the distance ℓ_2 as being less than the distance ℓ_1 , whereas FIG. 4 shows the distance ℓ_2 as being greater than the distance ℓ_1 . As will be described in further detail below, the radial shape of an ablation lesion created by the system 6 about the axis 18 can be modified via selection of the distances ℓ_1 and ℓ_2 relative to each other.

As shown in FIG. 2, due mainly to the greater distance ℓ_1 relative to distance ℓ_2 , the inner terminal 17 of the first electrode stem 16 extends axially inwardly beyond the distal terminal 13 of the first electrode array 12, thereby defining a distance ℓ_3 therebetween, and the inner terminal 21 of the second electrode stem 20 extends axially inwardly beyond the distal terminal 15 of the second electrode array 14, thereby defining a distance ℓ_4 therebetween. In

contrast, as shown in FIG. 4, due mainly to the greater distance ℓ_2 relative to distance ℓ_1 , the distal terminal 13 of the first electrode array 12 extends axially inwardly from the inner terminal 17 of the first electrode stem 16, thereby defining a distance ℓ_3 therebetween, and the distal terminal 15 of the second electrode array 14 extends axially inwardly beyond the inner terminal 21 of the second electrode stem 20, thereby defining a distance ℓ_4 therebetween.

As shown in FIGS. 3 and 4, the distances ℓ_3 and ℓ_4 are equal to each other, so that an ablation lesion created by the system 6 will be somewhat symmetrical along the axis 18, as will be described in further detail below. In contrast, as shown in FIG. 5, the distances ℓ_3 and ℓ_4 are not equal to each other, so that an ablation lesion created by the system 6 will be somewhat asymmetrical along the axis 18, or a symmetrical ablation lesion can be created by the system 6 within a treatment region with asymmetrical tissue properties, as will be described in further detail below.

In exemplary procedures using embodiments of the invention, the electrode arrays 12 and 14 will be disposed within tissue on opposite sides of a treatment region. The arrays will be disposed generally as shown in FIGS. 3-5, preferably with the axial electrode stems 16 and 20 aligned along the axis 18, most preferably being positioned on a single probe shaft, as will be described in more detail hereinafter. The first electrode element 8 is connected to a first pole 30 of a radiofrequency power supply 32. The second electrode element 10 is connected to the other pole 34 of the power supply

32. In this way, the electrode elements 8 and 10 will be powered in bipolar manner in order to effect radiofrequency current flow through the tissue volume between the arrays. Tissue destruction by the current will define the treatment region.

5 The RF power supply 32 may be a conventional general purpose electrosurgical power supply operating at a frequency in the range from 300 kHz to 1.2 MHz, with a conventional sinusoidal or non-sinusoidal wave form. Such power supplies are available from many commercial suppliers, such as Valleylab, Aspen, and Bovie. Most general purpose electrosurgical power
10 supplies, however, are constant current, variable voltage devices and operate at higher voltages and powers than would normally be necessary or suitable. Thus, such power supplies will usually be operated initially at the lower ends of their voltage and power capabilities, with voltage then being increased as necessary to maintain current flow. More suitable power supplies will be
15 capable of supplying an ablation current at a relatively low fixed voltage, typically below 200 V (peak-to-peak). Such low voltage operation permits use of a power supply that will significantly and passively reduce output in response to impedance changes in the target tissue. The output will usually be from 50 W to 300 W, usually having a sinusoidal wave form, but other
20 wave forms would also be acceptable. Power supplies capable of operating within these ranges are available from commercial vendors, such as Boston Scientific Therapeutics Corporation. Preferred power supplies are model RF-2000 and RF-3000, available from Boston Scientific Corporation.

The geometry and volume of the treatment region within the tissue can be determined by controlling various dimensions of the apparatus. For example, the arrays 12 and 14 will usually have outer circular diameters D in the range from 1 cm to 6 cm, usually from 2 cm to 4 cm. When the diameters of each array are the same, the geometry of the lesion created will be generally cylindrical. When the diameters are different, the lesion geometry could generally be a truncated cone. The distance ℓ_1 between the inner termini 13 and 15 of the electrode arrays 12 and 14 will usually be in the range from 2 cm to 10 cm, more usually in the range from 3 cm to 7 cm, and preferably in the range from 4 cm to 6 cm. The axial electrode stems 16 and 20 will typically have a length in the range from 0.0 cm (i.e., non-existent) to 2 cm.

Based on the distance ℓ_1 , the desired shape of the resulting ablation lesion, and the desired ablation time, the distance ℓ_2 between the inner termini 17 and 21 of the axial stems 16 and 20 is selected to control the proportion of current flowing between the distal termini 13 and 15 of the electrode arrays 12 and 14 relative to the current flowing between the inner termini 17 and 21 of the electrode stems 16 and 20.

It has been discovered that, in general, the greater the proportion of current flowing between the distal termini 13 and 15 of the electrode arrays 12 and 14, as opposed to current flowing between the inner termini 17 and 21 of the electrode stems 16 and 20, the more uniform the resulting ablation lesion will be along the periphery of the tissue treatment region (e.g., so that the ablation lesion is more cylindrical, rather than hour-glass shaped), but the

greater the time needed to ablate the tissue core along the axis 18. In contrast, the greater the proportion of current flowing between inner termini 17 and 21 of the electrode stems 16 and 20, the less uniform the resulting ablation lesion will be along the periphery of the tissue treatment region, but
5 the lesser the time needed to ablate the tissue core along the axis 18.

With this phenomenon in mind, the distance ℓ_2 is preferably selected relative to the distance ℓ_1 , such that a majority of the current, and preferably substantially all of the electrical current, will essentially flow between distal termini 13 and 15 of the electrode arrays 12 and 14, while a small or minimal
10 amount of current flows between the inner termini 17 and 21 of the electrode stems 16 and 20. It has been discovered that the preferred distance ℓ_2 should be greater than fifty percent of the distance ℓ_1 in order to ensure that the majority of the electrical current flows between the distal termini 13 and 15 of the respective electrode arrays 12 and 14. Optimally, the distance ℓ_2 should
15 be greater than seventy-five percent of the distance ℓ_1 in order to ensure that substantially all of the electrical current flows between the distal termini 13 and 15 of the respective electrode arrays 12 and 14. In some cases, the distance ℓ_2 may be greater than the distance ℓ_1 , as illustrated in FIG. 4, although, in other cases, it may be desirable that the distance ℓ_2 be less than
20 the distance ℓ_1 , so that some electrical current flows between the electrodes stems 16 and 20 to aid in ablating tissue along the axis 18, thereby reducing the tissue ablation time.

Thus, it will be appreciated that by increasing the proportion of current flowing between the distal termini 13 and 15 of the electrode arrays 12 and 14 and increasing the ablation time, the treatment region will be heated and necrosed from the outer regions inward towards the center region, thus enhancing the ability to completely and uniformly necrose the entire tissue volume of the treatment region defined by the outward perimeters of the arrays 12 and 14.

It has been discovered that the axial symmetry of a resulting ablation lesion can be modified by selecting the distances ℓ_3 and ℓ_4 relative to each other. In particular, as the distance ℓ_4 decreases relative to the distance ℓ_3 (assuming the arrangement in FIGS. 3 and 5) or increases relative to the distance ℓ_3 (assuming the arrangement in FIG. 4), more electrical current will be focused in the peripheral tissue region adjacent the electrode array 14. In contrast, as the distance ℓ_4 increases relative to the distance ℓ_3 (assuming the arrangement in FIGS. 3 and 5) or increases relative to the distance ℓ_3 (assuming the arrangement in FIG. 4), more electrical current will be focused in the peripheral tissue region adjacent the electrode array 12. Thus, it can be appreciated that the electrode array with the higher peripheral concentration of electrical current can be located in a portion of the treatment region requiring an increased ablation power (e.g., if such tissue portion is radially larger than the remaining portion of the treatment region, or if such tissue portion is adjacent a blood vessel that conducts heat away from it).

Referring to FIGS. 6A-6B, the ideal propagation of the tissue necrosis region achieved by the embodiment of FIG. 3 will now be described. Initially, the current flux is concentrated between the distal termini 13 and 15 of the electrode arrays 12 and 14, resulting in a generally hollow cylindrical necrosis region at the periphery of the treatment region, as shown in FIG. 6A. As the tissue become necrosed, its impedance increases, causing the current flux to move inwardly between the inner termini 17 and 21 of the electrodes stems 16 and 20 to ablate the tissue core along the axis 18, resulting in a solid cylindrical necrosis region, as shown in FIG. 6B. Usually, the region of necrosis will extend slightly beyond the arrays themselves due to heat conduction from the tissue, which is being directly heated by the electrical current flow. In addition to the impedance increase, the reduction of blood flow through the central portions of the treatment region as that tissue becomes necrosed will also contribute to the uniformity of heating and subsequent necrosis of the larger volume. That is, as the blood flow through the treatment region is decreased, the ability to uniformly heat the tissue via the passage of current is enhanced.

Referring to FIGS. 7A-7B, the ideal propagation of the tissue necrosis region achieved by the embodiment of FIG. 4 will now be described. As with the embodiment of FIG. 3, the current flux will be concentrated between the distal termini 13 and 15 of the electrode arrays 12 and 14, resulting in a generally hollow cylindrical necrosis region at the periphery of the treatment region, as shown in FIG. 7A. In this case, however, because a small or minimal amount of current will flow between the inner termini 17 and 21 of the

electrode stems 16 and 20, the necrosis region is uniform along the axis 18.

Preferably, because the electrode arrays 12 and 14 are solely used to ablate the core tissue region, the magnitude of the current is reduced, so that the tissue impedance does not rise too sharply. As a result, given enough time,
5 the tissue core along the axis 18 will necrose via heat conduction, thereby resulting in a solid cylindrical necrosis region, as shown in FIG. 7B.

Referring to FIGS. 8A-8B, the ideal propagation of the tissue necrosis region achieved by the embodiment of FIG. 5 will now be described. As with the embodiments of FIG. 3, the current flux will be concentrated between the
10 distal termini 13 and 15 of the electrode arrays 12 and 14. However, the current flux will be more concentrated at the peripheral of the treatment region nearest the electrode array 14. If the treatment region has uniform tissue characteristics, a generally hollow vase-shaped necrosis region will result, as shown in FIG. 8A. If the tissue adjacent the electrode array 12 has either an
15 increased impedance or heat loss, a generally hollow cylindrical necrosis region may result, as previously shown in FIGS. 6A and 7A. As the tissue become necrosed, its impedance increases, causing the current flux to move inwardly between the inner termini 17 and 21 of the electrodes stems 16 and 20 to ablate the tissue core along the axis 18, resulting in a solid vase-like
20 necrosis region, as shown in FIG. 8B, or in the case of a tissue region with asymmetrical tissue characteristics, a solid cylindrical necrosis region, as previously shown in FIGS. 6B and 7B.

The previously described electrode elements 8 and 10 will typically be integrated within a probe for deployment within a patient's body. The probe will usually comprise an elongate shaft, typically a rigid or semi-rigid, metal or plastic cannula. In some cases, the cannula will have a sharpened tip, e.g.,
5 be in the form of a needle, to facilitate introduction to the tissue treatment region. In such cases, it is desirable that the cannula or needle be sufficiently rigid, i.e., have sufficient column strength, so that it can be accurately advanced through tissue. In other cases, the cannula may be introduced using an internal stylet, which is subsequently exchanged for one or more of
10 the electrode arrays. In the latter case, the cannula can be relatively flexible since the initial column strength will be provided by the stylet. The cannula serves to constrain the individual electrode elements of the electrode arrays in a radially collapsed configuration to facilitate their introduction to the tissue treatment region. The first electrode array can then be deployed to its desired
15 configuration, usually a three-dimensional configuration, by extending distal ends of the electrode elements from the distal end of the cannula into the tissue. In the case of the tubular cannula, this can be accomplished simply by advancing the distal ends of the electrode elements of the first electrode array distally from the tube so that they emerge and deflect (usually as a result of
20 their own spring or shape memory) in a radially outward pattern. The electrode arrays of the second electrode array may then be proximally advanced from the tube so that they emerge and deflect (again, usually as a result of their own spring or shape memory) in a radially outward pattern, which is a mirror image of the pattern formed by the first electrode array.

Particular devices employing a single probe or elongate member for deploying such spaced-apart arrays will be described in more detail below.

Referring now to FIGS. 9-13, one exemplary electrode probe 50 will be described. The probe 50 has a coaxial design with a distal electrode array 52 and a proximal electrode array 54. The proximal electrode array 54 is
5 attached to a proximal conductor 62 (shown in Figs. 9 and 10), which in turn, is attached to a proximal yoke 64. The proximal yoke 64 also has a threaded end 66 in a handle 68 of the probe 50. The distal electrode array 52 is deployed by a distal conductor 56 (shown in FIG. 11), which is attached to a
10 slider 58 having a threaded end 60. The distal conductor 56 axially extends within a distal tube 86 mounted within the handle 68. The distal tube 86, with the distal conductor 56, axially extends through the proximal conductor 62 to the distal tip of the probe. To prevent shorting, the portion of the distal tube 86 that extends through the proximal conductor 62 is electrically insulated.

15 The handle 68, in turn, includes a stationary portion 70 and a rotatable portion 72. The rotatable portion 72 has a first threaded channel 74, which receives the threaded end 60 of the distal array slider 58. A second threaded channel 76 receives the threaded end 66 of the proximal yoke 64. In this way, rotation of the rotatable part 72 of handle 68 will simultaneously advance the
20 distal slider 58 to deploy the distal electrode array 52 and retract the proximal yoke 64 which will deploy the proximal array 54, as best illustrated in FIG. 3.

The proximal conductor 62 extends distally through an insulated outer sheath 80 and past a gap 82 (FIG. 10) between the sheath 80 and a proximal

conductive tube 84. When the proximal array 54 is distally advanced, as shown in FIGS. 11 and 12, the proximal array 54 will be contained within a central lumen of the proximal conductive tube 84. As the array 54 is proximally advanced, by rotation of handle portion 72, the individual electrode
5 times advance radially outwardly through the gap 82 and eventually extend to their fully everted configuration, as shown in FIGS. 9 and 10.

While the proximal array 54 is being proximally deployed, the distal array 52 is simultaneously being deployed by advancing distally outwardly from the distal conductive tube 86 at the distal end of the probe 50. When
10 fully deployed, as shown in FIGS. 9 and 10, the distal electrode array 52 is in electrical contact with the distal conductive tube 86, and the proximal electrode array 54 is in electrical contact with the proximal conductive tube 84. The proximal portion of the distal conductive tube 86, and in particular, the portion extending from the handle 72 to just distal to the proximal conductive
15 tube 84 is electrically insulated, thereby forming a non-conductive gap 88 between the conductive tubes 86 and 84. Alternatively, the proximal and distal arrays 52 and 54 can be separately deployed using deployment mechanisms described in U.S. Patent Application Ser. No. 09/663,048.

It can be appreciated that the proximal conductive tube 84 effectively
20 forms a proximal electrode stem, such as the stem 20 illustrated in FIGS. 3-5, and the distal conductive tube 86 effectively forms a distal electrode stem similar to the stem 16 illustrated in FIGS. 3-5. As shown in FIG. 13, a layer of electrically insulative material 92 is applied over the proximal conductive tube

84, distal conductive tube 86, and the non-conductive gap 88 in order to shorten the effective electrode stems, thus increasing the distance $\square 2$ between the stems. The insulative material 92 may, e.g., be plastic, such as fluorinated ethylene propylene (FEP), rubber, a polymer coating or any other
5 medical grade material suitable for insulating against radio frequency energy.

The insulative material 92 may be applied to the probe 50 equidistantly between the electrode arrays 52 and 54 to form the electrode configuration illustrated in FIGS. 3 and 4 (equal distances $\square 3$ and $\square 4$), or can be shifted towards one of the electrode arrays 52 and 54 to form the electrode
10 configuration illustrated in FIG. 5 (non-equal distances $\square 3$ and $\square 4$). Although shown as partially covering the conductive tubes 84 and 86, the insulative material 92 can cover all of the conductive tubes 84 and 86 to minimize or eliminate the stems. Although the application of a separate insulative material 92 provides a convenient means for shaping the resulting tissue ablation
15 lesion given an existing bipolar ablation probe, it should be noted that the distances $\square 2$, $\square 3$, and $\square 4$ can be selected by adjusting the lengths of the conductive tubes 84 and 84 or by forming portions of the conductive tubes 84 and 86 out of an electrically insulative material. It should also be noted that the insulative material 92 is shown as continuously extending along the probe
20 50. Alternatively, there may be cylindrical gaps within the insulative material 92. For example, the insulative material 92 may not cover the non-conductive gap 88.

Referring now to FIGS. 14 and 15, a second exemplary probe 100 constructed in accordance with another embodiment of the invention will be described. The probe 100 includes a distal array 102 and a proximal array 104, each of which comprise a plurality of individual everting electrodes which may be similar in construction to those described in connection with probe 50. The distal array 102 is connected through a conductor 106 to a first rack 108. The proximal array 104 is connected to a conductor 110, which is connected to a second rack 112. A pinion gear 114 couples the racks 108 and 112 so that pulling on a knob 116 in a proximal direction (arrow 118) causes the first rack 108 to move proximally and the second rack 112 to move distally. This way, the distal array 102, which is connected to rack 108, will be retracted proximally within the probe while the proximal array 104 will be retracted distally within the probe.

Unlike probe 50, however, the distal array 102 and proximal array 104 are disposed in different, parallel tubular structures. As best shown in FIG. 15, the distal array 102 is disposed in a distal conductive tube 120, and the proximal array 104 is disposed in a proximal conductive tube 122. The distal conductive tube 120 and proximal conductive tube 122 are both electrically conductive so they act as axial conductors in conjunction with their respective arrays. Moreover, an insulated gap 124 exists between the electrically conductive tubes 120 and 122 to provide a gap between them, as generally described previously. Additionally, the distal tip 126 of at least the distal conductive tube 120 will be sharpened to facilitate tissue insertion. Optionally, the insulated gap region 124 at the distal end of the proximal conductive tube

122 may also be tapered or beveled in order to facilitate insertion. As best seen in FIG. 15, the proximal conductor 110 and distal conductor 106 will both extend through parallel tubes, which are covered by an insulating material 130. Thus, the probe 100 may be used in generally the same manner as
5 described for prior probe 50.

It can be appreciated that the proximal conductive tube 122 effectively forms a proximal electrode stem, such as the stem 20 illustrated in FIGS. 3-5, and the distal conductive tube 120 effectively forms a distal electrode stem similar to the stem 16 illustrated in FIGS. 3-5. As shown in FIG. 16, a layer of
10 electrically insulative material 132 is applied over the proximal conductive tube 122, distal conductive tube 120, and the non-conductive gap 124 in order to shorten the electrode stems, thus increasing the distance ℓ_2 between the stems in the same manner previously described with respect to the probe 50. The insulative material 132 cover only portions of the conductive tubes 120
15 and 122, as illustrated in FIG. 16, can alternatively cover all of the conductive tubes 120. The insulative material 132 can equidistantly separate the electrode arrays 102 and 104, as illustrated in FIG. 16, so that the distances ℓ_3 and ℓ_4 are equal, or can be shifted towards one of the electrode arrays 102 and 104 so that the distances ℓ_3 and ℓ_4 are unequal. The insulative material
20 132 may be continuous, as illustrated in FIG. 16, or can have gaps.

In addition to the provision of insulation on the shafts of the previously described probes 50 and 100, electrical insulation can be also be provided on the needles of the electrode arrays. For example, FIGS. 17 and 18 illustrate a

probe 150 with partially insulated electrode arrays 150 and 152. In particular, a length of each needle is partially coated with an insulating material 154, leaving exposed distal needle portions 156. The insulating material may be plastic, such as fluorinated ethylene propylene (FEP), rubber, a polymer
5 coating or any other medical grade material suitable for insulating against radio frequency energy.

As shown, the needles are substantially insulated from a point of deployment 158 to a peak of an arch 160 formed by each needle. In this manner, the electrical current conveyed between the electrode arrays 150 and
10 152 will be concentrated at the tips 156, thereby maximizing the radius of the resulting ablation lesion. The needles may be insulated along any portion between the point of deployment 158 and any designated point along the needle. Although all of the needles are shown to be partially insulated, less than all of the needles may be insulated, depending on the desired shaped of
15 the ablation.

CLAIMS

1. A tissue ablation probe, comprising:
a proximal electrode array having a retracted configuration and a
5 deployed configuration;
a distal electrode array electrically isolated from the proximal array and
having a retracted configuration and a deployed configuration, wherein
proximal and distal electrode arrays have distal terminals that are separated
from each other by a first length when deployed; and
10 a shaft carrying the proximal and distal electrode arrays, wherein the
shaft has an electrically insulative portion that separates the proximal and
distal electrode arrays, the insulative shaft portion spanning a second length
greater than about seventy-five percent of the first length.
2. The probe of claim 1, wherein the electrically insulative portion
15 of the shaft is continuous.
3. The probe of claims 1 or 2, wherein the shaft comprises a
proximal conductive tube from which the proximal electrode array is deployed,
and a distal conductive tube from which the distal electrode array is deployed.
4. The probe of any of claims 1 - 3, wherein the insulative shaft
20 portion comprises an electrically conductive wall and an electrically insulative
material disposed on the exterior of the conductive wall.
5. The probe of any of claims 1 - 4, wherein the proximal and distal
electrode arrays have respective concave faces that oppose each other when
in the deployed configuration.

6. The probe of any of claims 1 - 5, wherein the respective proximal and distal electrode arrays each comprise a plurality of individual electrodes that initially move axially and then evert as they are deployed.
7. The probe of any of claims 1 - 6, wherein the second length is
5 equal to or greater than the first length.
8. A tissue ablation probe, comprising:
a proximal electrode array having a retracted configuration and a deployed configuration;
a distal electrode array having a retracted configuration and a deployed
10 configuration;
a shaft carrying the proximal and distal electrode arrays, the shaft having an intervening portion between the proximal and distal electrode arrays, the intervening portion having an electrically conductive proximal region, an electrically conductive distal region, and a non-conductive gap
15 therebetween; and
a separate electrically insulative material covering at least portions of the proximal and distal shaft regions.
9. The probe of claim 8, wherein the insulative material covers the non-conductive gap.
- 20 10. The probe of claims 8 or 9, wherein the shaft comprises a proximal conductive tube from which the proximal electrode array is deployed, and a distal conductive tube from which the distal electrode array is deployed, and wherein the proximal and distal electrode arrays have respective concave faces that oppose each other when in the deployed configuration.

11. The probe of any of claims 8 - 10, wherein the insulative material covers the entirety of the intervening shaft portion.

12. The probe of any of claims 8 - 11, wherein the proximal and distal electrode arrays have distal terminals that are separated from each other by a first length when deployed, and the insulative material spans a second length greater than about fifty percent of the first length.

13. The probe of claim 12, wherein the insulative material spans a second length equal to or greater than the first length.

14. The probe of claim 8, wherein the insulative material is positioned closer to one of the proximal and distal electrode arrays than the other.

15. A tissue ablation probe, comprising:
a proximal array of needle electrodes having a retracted configuration and a deployed configuration;
a distal array of needle electrodes having a retracted configuration and a deployed configuration;
a shaft carrying the proximal and distal electrode arrays; and
an electrically insulative material partially disposed on at least one needle electrode of each array, whereby a tip of the at least one needle electrode is left exposed.

16. The probe of claim 15, wherein the electrically insulative material is partially disposed on all the needle electrodes of each array, whereby tips of all of the needle electrodes are left exposed.

17. The probe of claim 15, wherein the shaft has location from which the proximal and distal electrode arrays deploy, and the insulative material is disposed on the at least one needle electrode of each array at the respective location of deployment.

5 18. The probe of any of claims 15 - 17, wherein the shaft comprises a proximal conductive tube from which the proximal electrode array is deployed, and a distal conductive tube from which the distal electrode array is deployed.

10 19. The probe of any of claims 15 - 18, wherein the proximal and distal electrode arrays have respective concave faces that oppose each other when deployed.

20. The probe of any of claims 15 - 19, wherein the needle electrodes of the move axially and then evert as they are deployed.

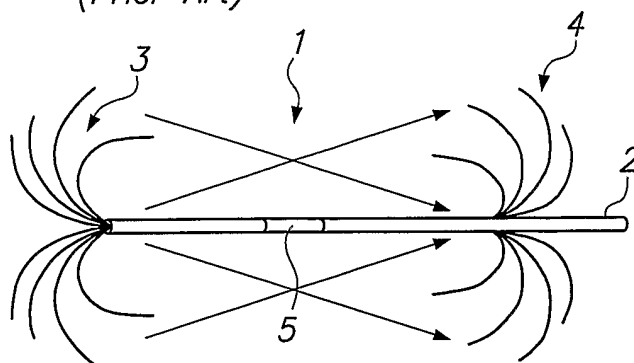
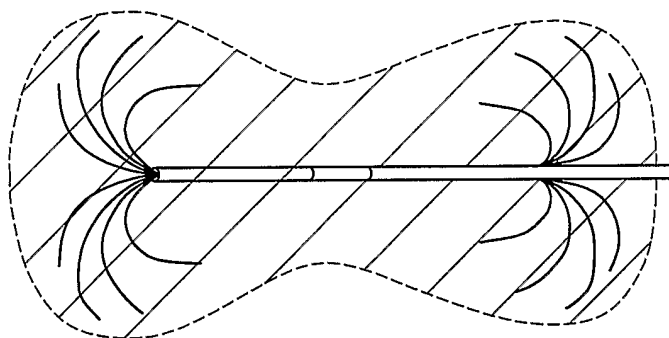
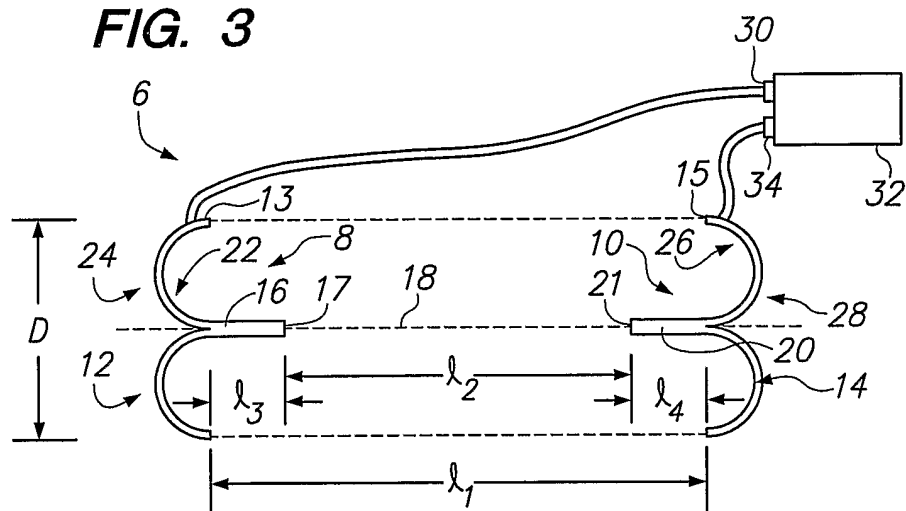
15 21. The probe of claim 20, wherein the needle electrodes form an arc when deployed, and the insulative material is disposed on the arc of the at least one needle electrode.

22. The probe of claim 15, wherein a portion of the shaft is electrically insulated.

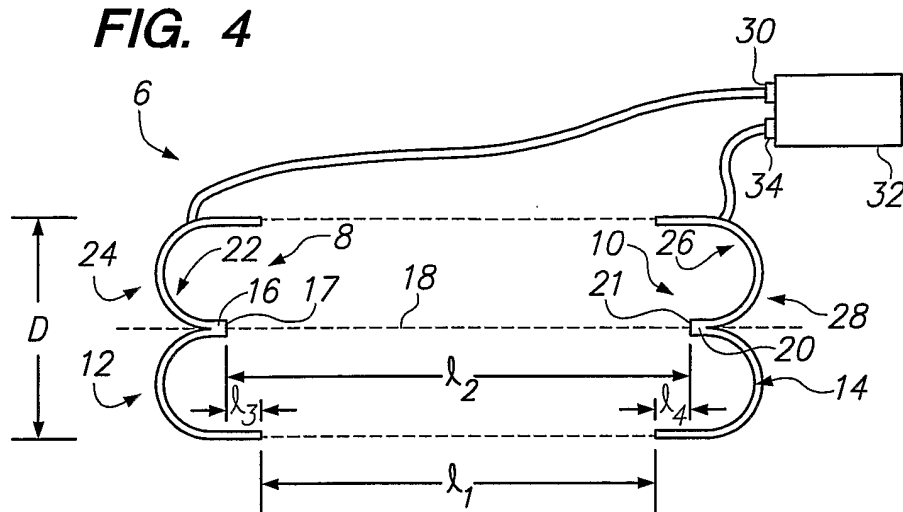
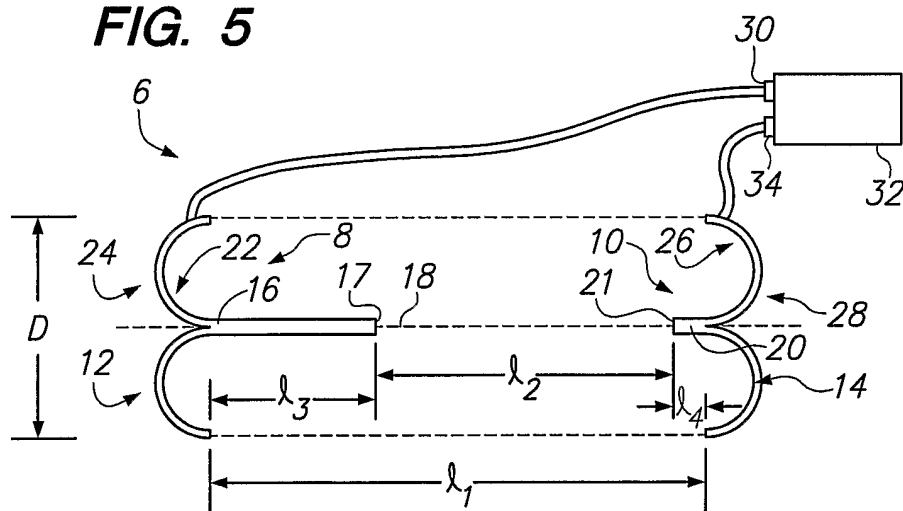
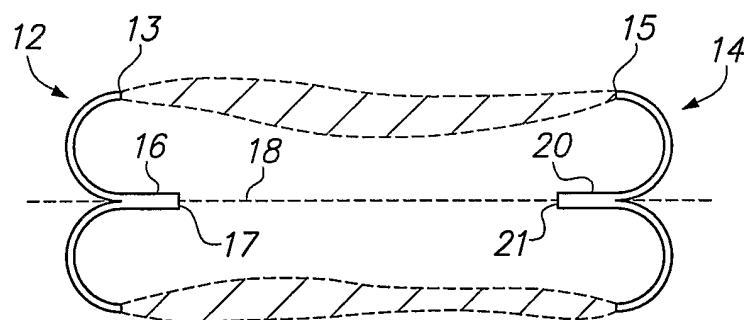
20 23. The probe of claim 22, wherein the proximal and distal electrode arrays have distal terminals that are separated from each other by a first length when deployed, and the insulated portion of the shaft spans a second length greater than fifty percent of the first length.

24. The probe of claim 23, wherein the second length is greater than seventy-five percent of the first length.

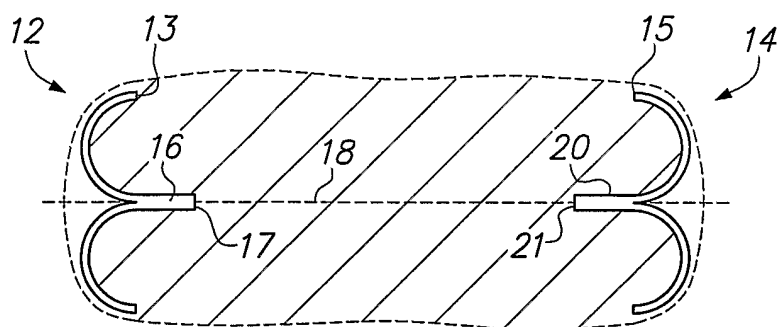
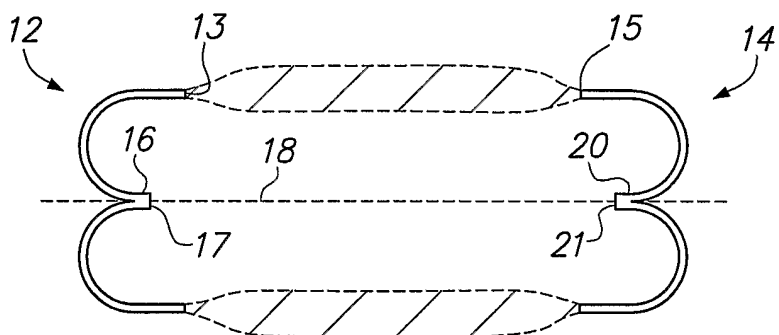
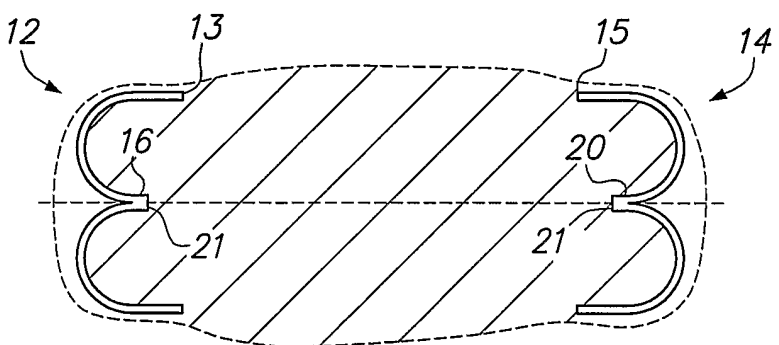
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FIG. 1*(Prior Art)***FIG. 2***(Prior Art)***FIG. 3**

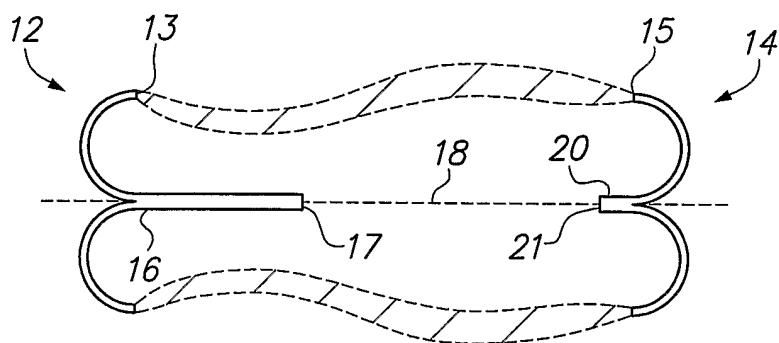
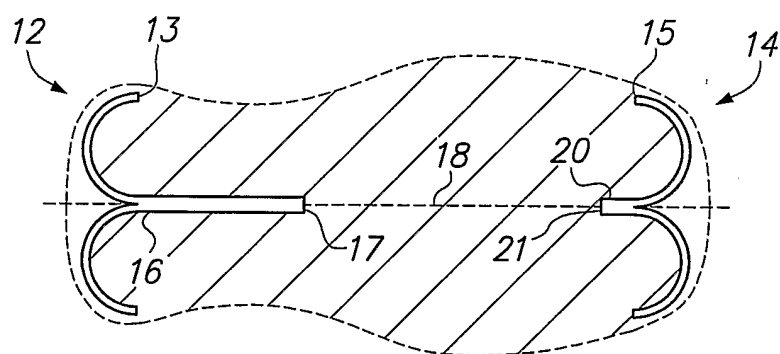
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FIG. 4**FIG. 5****FIG. 6A**

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FIG. 6B**FIG. 7A****FIG. 7B**

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FIG. 8A**FIG. 8B**

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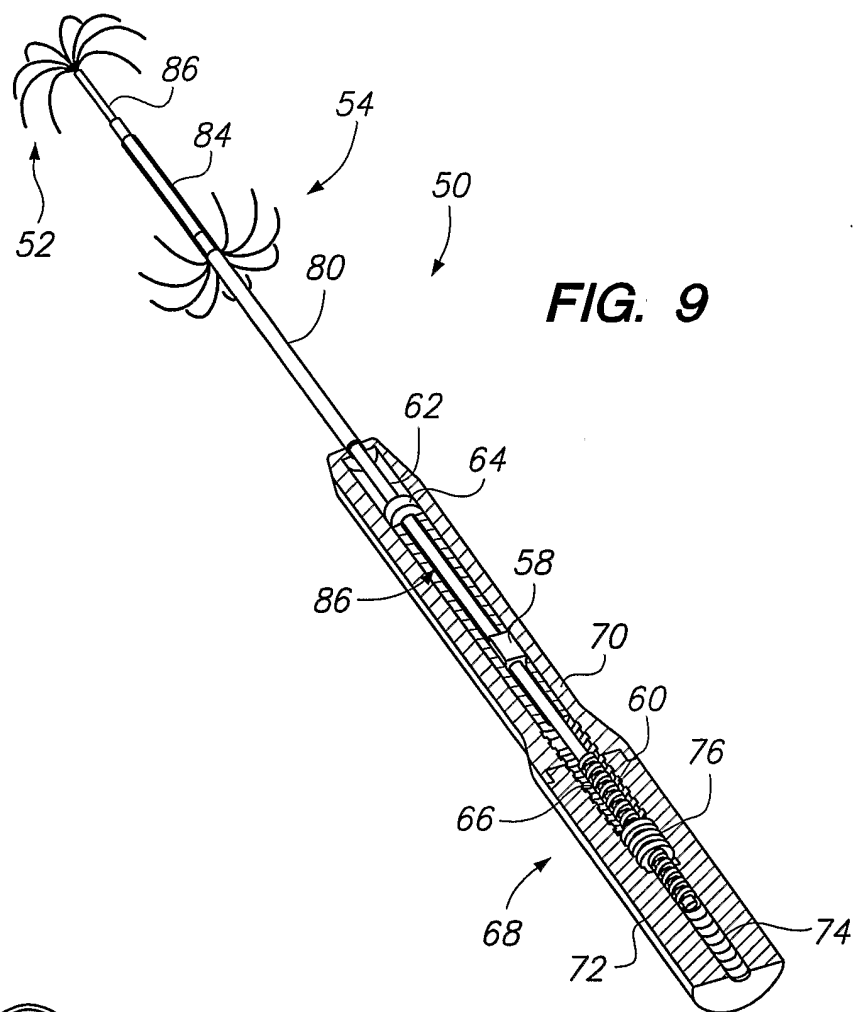


FIG. 9

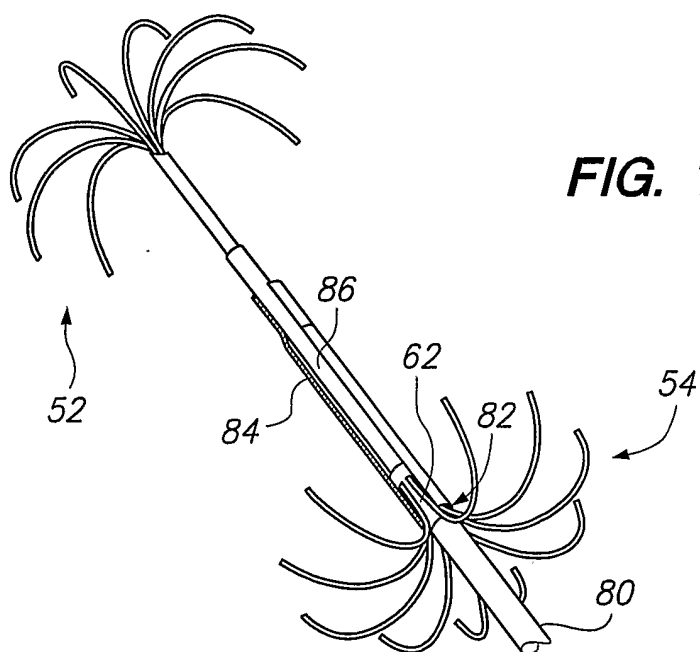


FIG. 10

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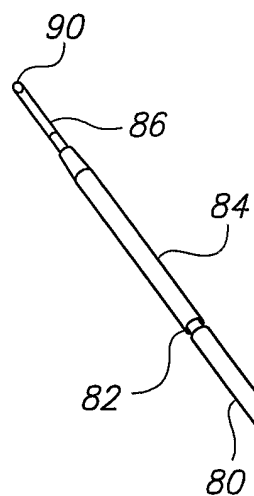


FIG. 11

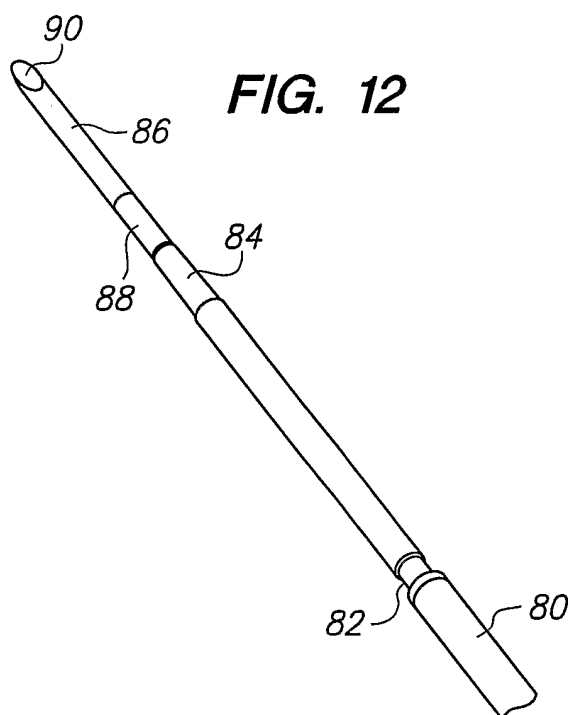
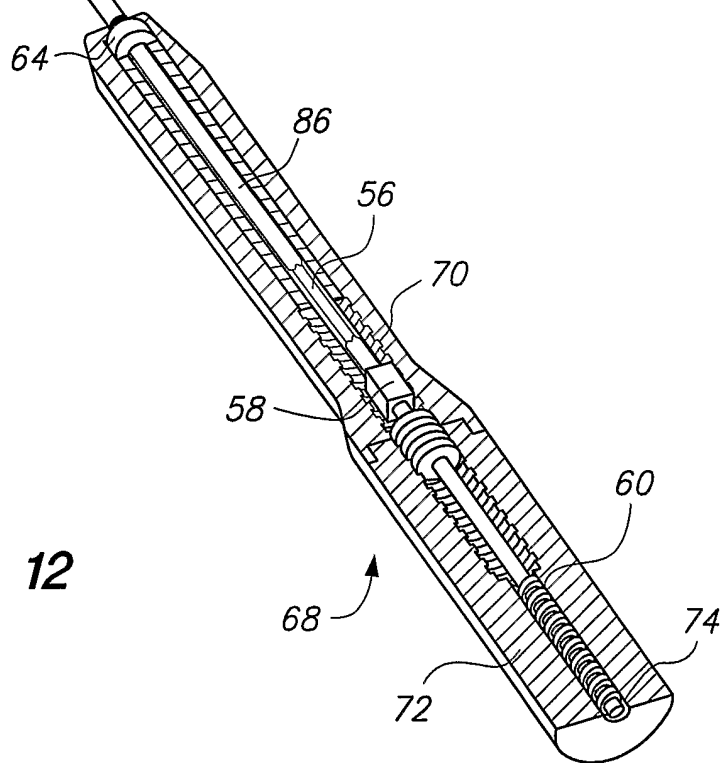
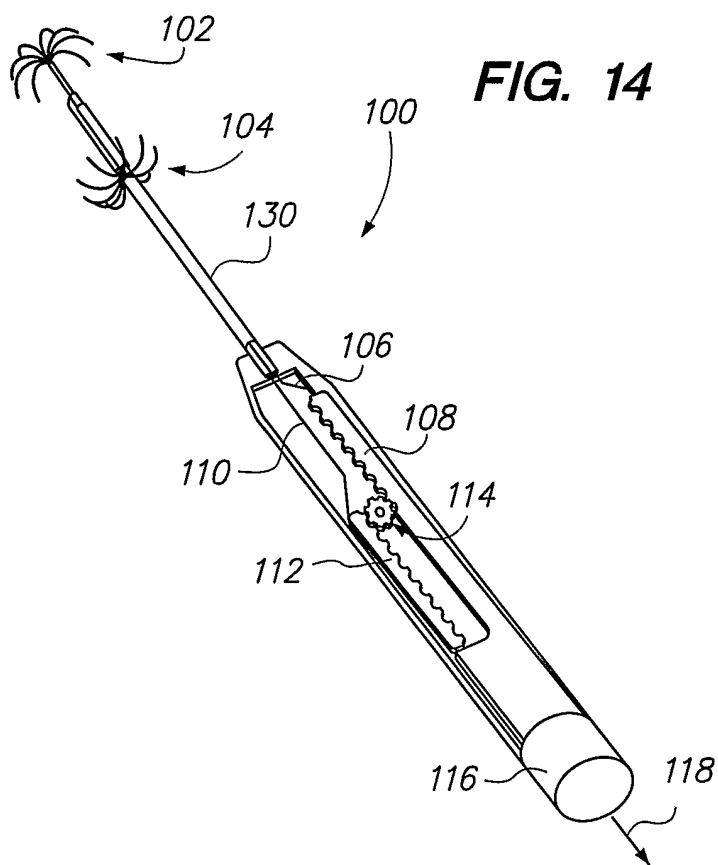
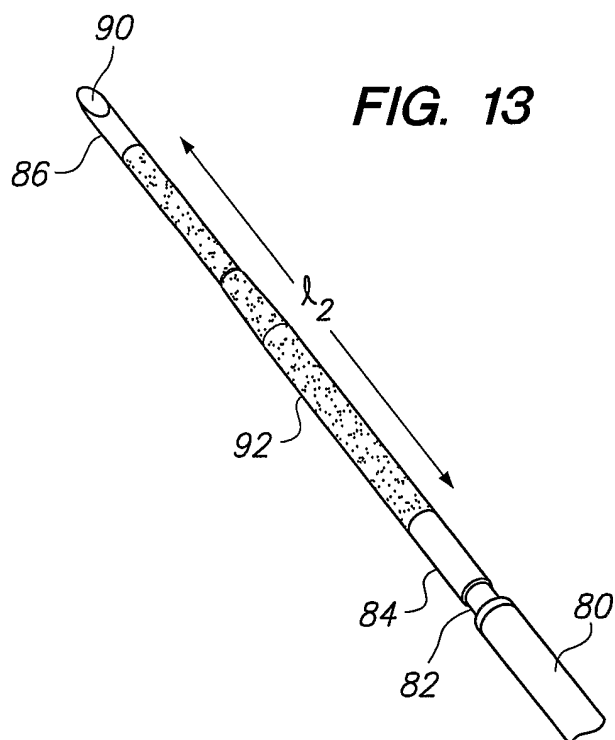
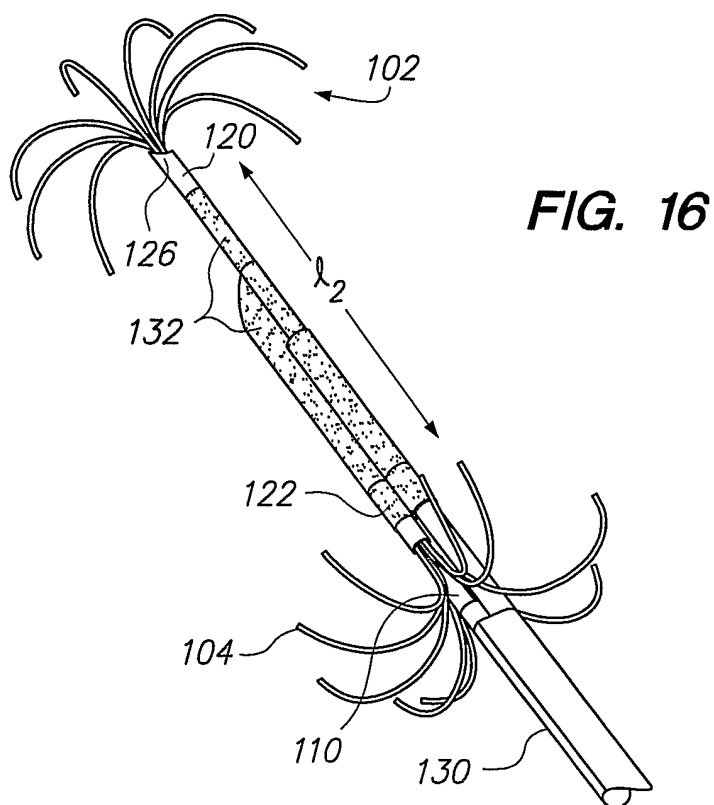
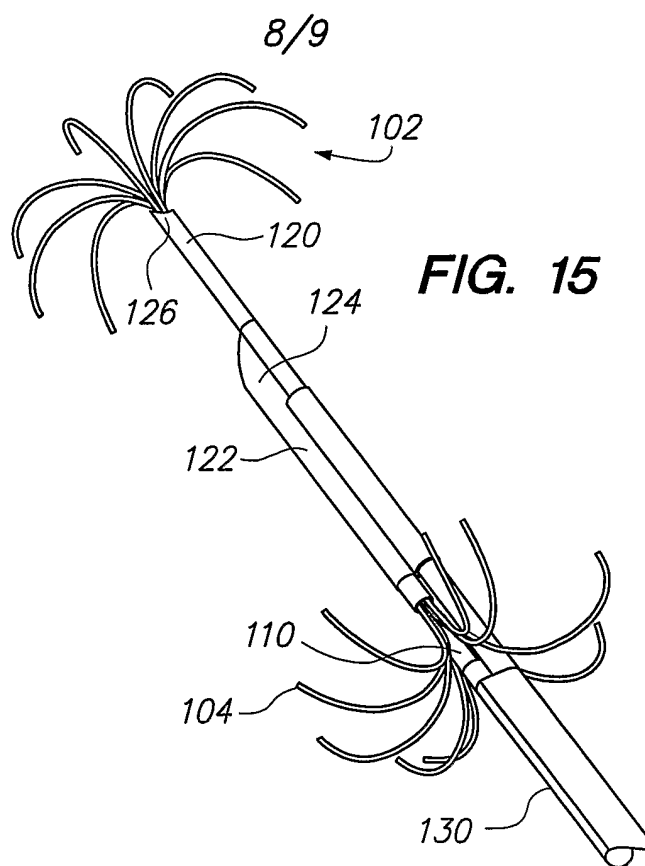


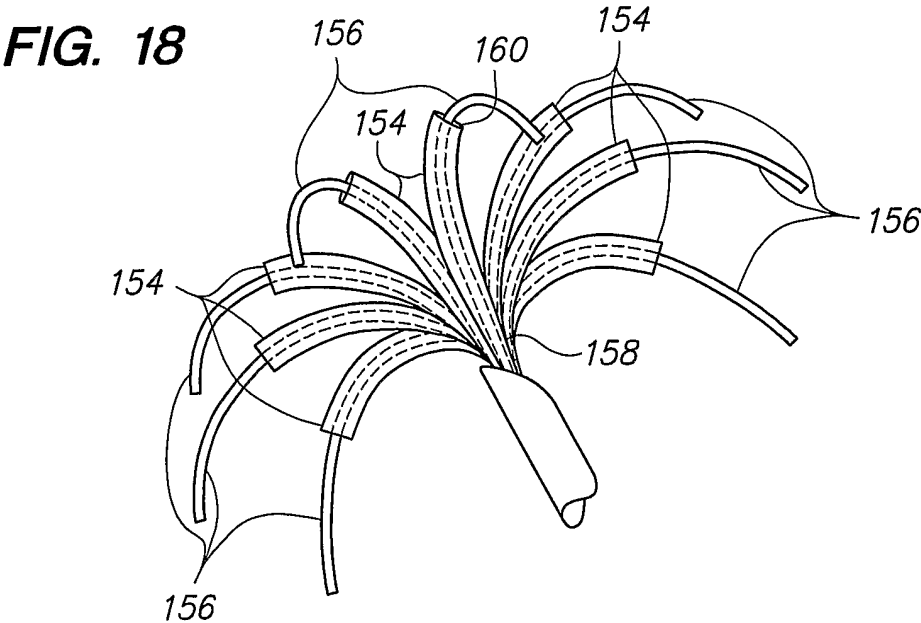
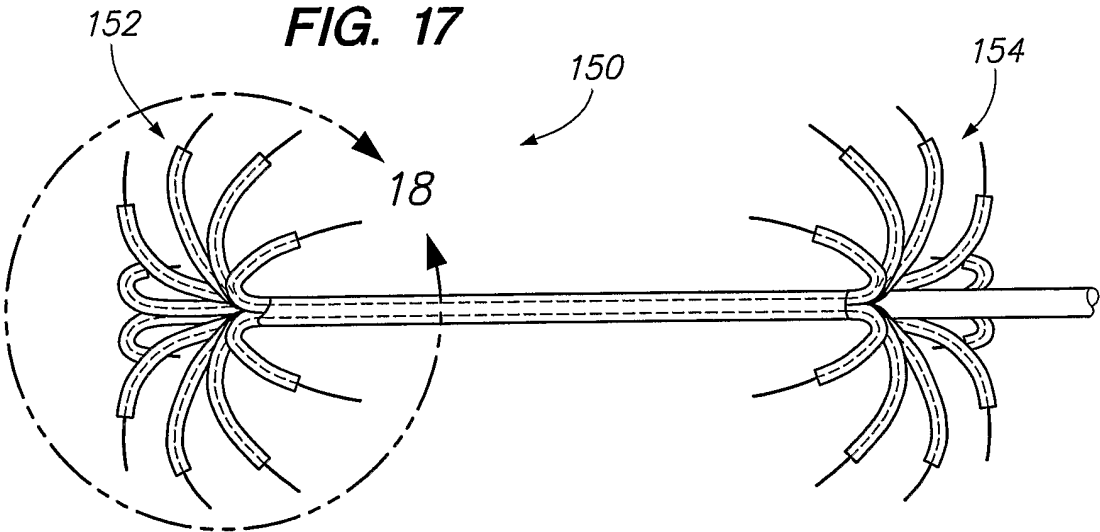
FIG. 12



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INTERNATIONAL SEARCH REPORT

national application No
T/US2005/037640

A. CLASSIFICATION OF SUBJECT MATTER 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) 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	US 2002/022864 A1 (MAHVI DAVID M ET AL) 21 February 2002 (2002-02-21)	1-4,6,7
Y	paragraph '0048!; figures 1,3	5,11,13, 19,23,24

X	US 6 575 967 B1 (LEVEEN ROBERT F ET AL) 10 June 2003 (2003-06-10)	15-18, 20-22
Y	column 6, line 22 - line 25 column 8, line 49 - line 67 column 9, line 42 - line 51; figures 5,7	19,23,24

X	DE 21 24 684 A1 (STADELMANN W) 30 November 1972 (1972-11-30)	1-3,6,7
A	claim 10; figure 3	8,15

X	US 2004/158239 A1 (BEHL ROBERT S ET AL) 12 August 2004 (2004-08-12)	8-10,12
Y	paragraphs '0060! - '0063!; figures 7,8	5,11,13

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☒ Further documents are listed in the continuation of Box C. ☒ See patent family 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 *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *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 *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *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	Date of mailing of the international search report	
10 February 2006	17/02/2006	
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Mayer-Martenson, E	

INTERNATIONAL SEARCH REPORT

International application No
T/US2005/037640

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 2005/048862 A (SCIMED LIFE SYSTEMS, INC; OSTROVSKY, ISAAC; MCINTYRE, JON, T) 2 June 2005 (2005-06-02) paragraphs '0050!, '0051!; figure 16 -----	1-4,6,7, 15-18, 20-24
X,P	WO 2005/037119 A (SCIMED LIFE SYSTEMS, INC; YOUNG, KIMBOLT; ANDERSON, STEVE) 28 April 2005 (2005-04-28) page 12, line 24 - page 13, line 13; figures 7,17 -----	1-7

INTERNATIONAL SEARCH REPORT

International application No
T/US2005/037640

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2002022864	A1	21-02-2002	US 2005010209 A1	13-01-2005
US 6575967	B1	10-06-2003	US 6454765 B1	24-09-2002
			US 6468273 B1	22-10-2002
			US 5827276 A	27-10-1998
DE 2124684	A1	30-11-1972	NONE	
US 2004158239	A1	12-08-2004	AU 9265501 A	26-03-2002
			CA 2421795 A1	21-03-2002
			EP 1328206 A1	23-07-2003
			JP 2004508131 T	18-03-2004
			WO 0222032 A1	21-03-2002
WO 2005048862	A	02-06-2005	NONE	
WO 2005037119	A	28-04-2005	US 2005080409 A1	14-04-2005