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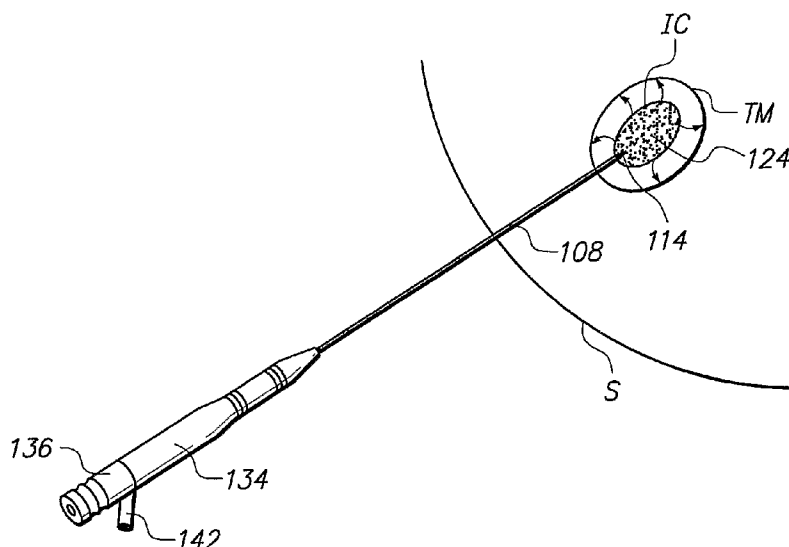
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(54) Title: COMPRESSIBLE/EXPANDABLE HYDROPHILIC ABLATION ELECTRODE



(57) Abstract: A probe assembly is provided for treating tissue margins surrounding interstitial spaces created via the removal of tumors. The interstitial space may be in any tissue, e.g., breast tissue, and the interstitial space may be created by removing abnormal tissue. A hydrophilic electrode is compressed and introduced (e.g., percutaneously) into the interstitial cavity. An electrically conductive liquid (e.g., saline) is applied to the electrode, such that the electrode absorbs the electrically conductive liquid. The electrode is expanded into contact with the tissue margin, and electrical energy (e.g., radio frequency (RF) energy) is conveyed to the electrode, thereby ablating the tissue margin.

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COMPRESSIBLE/EXPANDABLE HYDROPHILIC ABLATION ELECTRODE

FIELD OF THE INVENTION

The field of the invention relates generally to the structure and use of radio frequency (RF) electrosurgical devices for the treatment of tissue, and in particular, to the RF ablative treatment of tissue margins surrounding excised interstitial spaces.

BACKGROUND

Tumors and other abnormal tissues can be treated in any one of a variety of manners. A tumor can be removed from the afflicted patient by retrieving the tumor from the surrounding tissue. For example, breast cancer, if not in an advanced stage that would otherwise require a radical mastectomy (i.e., complete removal of the breast), can be treated using a breast conserving surgical procedure, such as lumpectomy, tumorectomy, segmental mastectomy, or local excision, which involves removal of the suspect tissue and a margin of healthy tissue surrounding the suspect tissue through an open or keyhole incision. In some cases, breast tumors may be removed during a biopsy procedure, e.g., using a tissue retrieval device, such as that described in U.S. Patent No. 6,471,659.

In any case, the excised interstitial space, which is left behind after removal of the tissue, is typically treated under the theory that a thin finite layer of cells contained within the tissue margin surrounding the interstitial space may be

diseased, yet undetectable under the current range of technology, and that even a single malignant cell left in the margins of an excised interstitial space can multiply into a new tumor. Treatment of the margins of the interstitial space is key in reducing the recurrence rate of the disease.

5

SUMMARY OF THE INVENTION

In accordance with one embodiment of the invention, a probe assembly comprises a probe configured for being percutaneously introduced through tissue. A compressible/expandable tissue ablation electrode is carried on the distal end of the probe, and an electrical connector carried by the proximal end of the probe. In one embodiment, the probe comprises a cannula having a lumen and an inner probe shaft disposed within the cannula lumen. In this case, the electrode is mounted on the inner probe shaft, such that the electrode can be alternately retracted within the cannula lumen and deployed from the cannula lumen. The ablation electrode is configured for absorbing fluid, and the connector is in electrical communication with the electrode. The electrode may be composed of any compressible/expandable material that has the capability absorbing a sufficient amount of liquid (e.g., an amount equal to at least the weight of the electrode), such that the electrode is sufficiently electrically conductive enough to act as an ablation electrode when electrical energy is applied to it.

In one embodiment, the electrode is composed of an electrically insulative material, in which case, the fluid, if electrically conductive, solely provides an

electrical path through the electrode. The expanded electrode can have any shape, e.g., spherical, but preferably assumes a shape that allows the expanded electrode to easily conform to an interstitial cavity in which it is intended to treat.

In one embodiment, the electrode is self-expanding, such that the electrode

5 instantaneously expands upon the release of a compressive force. In an optional embodiment, the electrode is impregnated with a chemotherapeutic agent.

BRIEF DESCRIPTION OF DRAWINGS

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

10 numerals and in which:

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

Fig. 2 is a perspective view of a tissue ablation assembly used in the tissue ablation system of Fig. 1, particularly illustrating a retracted ablation
15 electrode;

Fig. 3 is a perspective view of the tissue ablation assembly of Fig. 2, particularly illustrating a deployed ablation electrode;

Fig. 4 is a magnified view of the distal end of the tissue ablation assembly illustrated in Fig. 2;

20 Fig. 5 is a magnified view of the distal end of the tissue ablation assembly illustrated in Fig. 3;

Fig. 6 is a cross-sectional view of the ablation electrode illustrated in Fig. 3;

Figs. 7A-7G are side views illustrating the use of embodiments of the invention, for purposes of better understanding the invention.

5

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Fig. 1 illustrates a tissue ablation system 100 constructed in accordance with one embodiment of the invention. The tissue ablation system 100 generally comprises a probe assembly 102 configured for introduction into the body of a patient for ablative treatment of a targeted margin of tissue surrounding an interstitial cavity (illustrated in Figs. 7A-7G), an ablation energy source, and in particular a radio frequency (RF) generator 104, configured for supplying RF energy to the probe assembly 102 in a controlled manner, and an electrically conductive fluid source, and in particular a syringe 106 configured for supplying saline to the probe assembly 102 to provide an electrically conductive path for the RF energy from the probe assembly 102 to the targeted tissue margin.

Referring specifically now to Figs. 2 and 3, the probe assembly 102 generally comprises an elongated cannula 108 and an inner probe 110 (shown in Fig. 4) slidably disposed within the cannula 108. As will be described in further detail below, the cannula 108 serves to deliver the active portion of the inner probe 110 to the target tissue. The cannula 108 has a proximal end 112, a distal end 114, and a central lumen 116 extending through the cannula 108 between

the proximal end 112 and the distal end 114. As will be described in further detail below, the cannula 108 may be rigid, semi-rigid, or flexible depending upon the designed means for introducing the cannula 108 to the target tissue. The cannula 108 has a sharpened distal tip to facilitate percutaneous introduction directly through the patient's skin. The cannula 108 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 20 cm. If composed of an electrically conductive material, the cannula 108 is preferably covered with an insulative material (not shown). The cannula 108 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 108 has an inner diameter in the range from 0.7 mm to 4 mm, preferably from 1 mm to 3.5 mm.

Referring further to Fig. 4, the inner probe 110 comprises a reciprocating shaft 118 having a proximal end (not shown) and a distal end 122, a tissue ablation electrode 124 mounted to the distal end 114 of the shaft 118, and a fluid delivery lumen 128 extending through shaft 118 in fluid communication the electrode 124 via lateral ports 130 extending through the wall of the shaft 118. Like the cannula 108, the shaft 118 is composed of a suitable material, such as plastic, metal or the like. It can be appreciated that longitudinal translation of the shaft 118 relative to the cannula 108 in a proximal direction retracts the electrode 126 into the distal end 114 of the cannula 108 (Figs. 2 and 4), while longitudinal translation of the shaft 118 relative to the cannula 108 in a distal direction

deploys the electrode 126 from the distal end 114 of the cannula 108 (Figs. 3 and 5).

The electrode 124 is composed of biocompatible compressible/expandable material that allows the electrode 124 to be alternately compressed (as illustrated in Figs. 2 and 4), so that it can be housed within the relatively small profile cannula lumen 116, and expanded (as illustrated in Figs. 3 and 5), so that it can substantially fill the interstitial cavity when deployed from the cannula lumen 116. In the illustrated embodiment, the electrode 124 is self-expanding in that the electrode 124 automatically expands from its compressed state immediately upon the release of a compressive force.

To this end, as illustrated in Fig. 6, the compressible/expandable material comprises a skeletal structure 125 formed of elements 127 that collapse within spaces 129 between the elements 127 upon the application of a compressive force and expand upon the release of the compressive force. Preferably, the elements 127 are as thin as possible to maximize the expandability/compressibility ratio of the electrode 124, i.e., the volume of the electrode 124 in its expanded form divided by the volume of the electrode 124 in its compressed form. In this manner, the size of the cannula lumen 116, and thus the cannula 108, can be minimized as much as possible, while ensuring that the electrode 124 fills the interstitial cavity when expanded. In one embodiment, the electrode 124 preferably has an expandability/compressibility ratio of more than one, preferably more than two, and most preferably more than five. The electrode 124 may also be composed of a material that expands the electrode

124 in additional volume in response absorption of the fluid. In this manner, the effective expandability/compressibility ratio of the electrode 124 is further increased.

The electrode 124 may be sized and shaped in accordance with the
5 interstitial cavity. In the illustrated embodiment, the expanded electrode 124 is spherically-shaped. Other shapes, such as ellipsoidal, can be used, depending on the shape of the interstitial cavity. However, since the electrode 124 is preferably composed of a material that has a relatively high compliancy (i.e., it is highly compressible), any one electrode will naturally assume the shape of any
10 variety of differently shaped interstitial cavities when expanded. Suitable expanded sizes may fall in the range of 0.5-8.0 cm, and preferably within the range of 2.0-5 cm.

The electrode 124 is hydrophilic in that it is capable of absorbing a substantial amount of fluid. It is preferred that the material used in the electrode
15 124 be capable of absorbing an amount of liquid at least equal to its weight, preferably an amount at least equal to at least two times its weight, and more preferably an amount at least equal to at least four times its weight. In general, the more liquid absorbed per unit weight of the electrode 124, the more electrically conductive the electrode 124 will be. To this end, the ratio between
20 the volume of the spaces 129 and the volume of the elements 127 is maximized.

Suitable materials that can be used to construct the electrode 124 include open-cell foam (such as polyethylene foam, polyurethane foam, polyvinylchloride foam) and medical-grade sponges. In the illustrated embodiment, a foam

composed of Hypol 3000 base polymer marketed by W.R. Grace & Co, an L-62 Surfactant marketed by BASF Corporation, and water is used. It has been found that the open-cell polyurethane foam marketed by Avitar, Inc. as Hydrosorb™ is especially suitable, and has been found to have an expandability/compressibility ratio of 10:1, and be capable of absorbing an amount of liquid twenty times its weight. In addition, it has been found that the use of Hydrosorb™ allows the electrode 124 to expand to 125-130% of its original uncompressed size, thereby facilitating conformance of the electrode 124 within the interstitial cavity, and thus, uniform firm contact between the electrode 124 and the tissue margin.

Polyvinyl acetal sponges, such as Merocel™, marketed by Medtronic, Inc., and cellulose sponges, such as Weckcel™ are also suitable. It should be appreciated that material, other than foam or sponges may be used for the electrode 124 as long as it is capable of absorbing a sufficient amount of liquid and expands to a size necessary to fill the interstitial cavity to be treated. For example, spun-laced polyester, cotton, gauze, cellulose fiber, or the like can be used. It can be appreciated that although suitable materials used in the electrode 124 will typically be electrically insulative, the electrode 124 will become electrically conductive upon absorption of electrically conductive fluid.

For the purpose of delaying absorption of bodily fluids, the electrode 124 may optionally have a bioabsorption coating (not shown) applied to its outer surface, which controls the rate and amount of fluid that enters into the absorbent material of the electrode 124. That is, the bioabsorption coating gradually dissolves upon exposure to bodily fluid at a known rate. In this manner, the

electrode 124 will not fully expand until it is desired, i.e., when the electrically conductive fluid is perfused into the electrode 124. In another optional embodiment, the electrode 124 may be impregnated with a chemotherapeutic agent (not shown). In this manner, the tissue margin, in addition to being therapeutically ablated, will be treated with the chemotherapeutic agent.

Referring back to Figs. 2 and 3, the probe assembly 102 further comprises a handle assembly 132 composed of any suitable rigid material, such as, e.g., metal, plastic, or the like. The handle assembly 132 includes a handle sleeve 134 mounted to the proximal end 112 of the cannula 108, and a handle member 136 slidably engaged with the sleeve 134 and mounted to the proximal end (not shown) of the shaft 118. The handle member 136 further carries a perfusion port 142, which is in fluid communication with the fluid delivery lumen 128, which is further in fluid communication with the electrode 124 via the lateral ports 130.

The handle member 136 carries an electrical connector 144 that is electrically coupled to the electrode 124 via the shaft 118 of the inner probe 110. In this case, the core of the shaft 118 is composed of an electrically conductive material, such as stainless steel, and the exterior of the shaft 118 is coated with an electrically insulative material. Alternatively, the electrical connector 144 may be electrically coupled to the electrode 124 via wires (not shown) extending through the shaft 118 and terminating within the electrode 124 or in the shaft distal end 122 (which will be electrically conductive in this case) on which the electrode 124 is directly mounted.

Referring back to Fig. 1, the RF generator 104 is electrically connected to the electrical connector 144 on the probe assembly 102 via a cable 105. The RF generator 104 may be a conventional RF power supply that operates at a frequency in the range from 200 KHz to 5 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 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 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).

In the illustrated embodiment, RF current is delivered from the RF generator 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 surrounding 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.

The syringe 106 is connected to the perfusion port 142 on the probe assembly 102 via tubing 107. As briefly discussed above, the syringe 106 contains an electrically conductive fluid, such as saline. The syringe 106 is conventional and is of a suitable size, e.g., 200 ml. In the illustrated embodiment, the electrically conductive fluid is 0.9% saline. Thus, it can be appreciated the syringe 106 can be operated to convey the saline through the tubing 107, into the perfusion port 142, through the fluid delivery lumen 128 extending through the inner probe shaft 118, and into contact with the electrode 124 via the lateral ports 130. The normally electrically insulative material of the electrode 124, in turn, absorbs the saline, thereby creating an electrical path through the insulative material and transforming the electrode 124 into an electrically conductive element.

In an alternative embodiment, the probe assembly 104 and a tissue removal device are combined into a single assembly in a manner similar to co-access biopsy/ablation assemblies described in U.S. Patent Application Publication. Nos. 2005-0234443 and 2006-0149226. In these assemblies, the cannula used to introduce the inner ablation probe and the cannula used to introduce an inner tissue removal device are one in the same. That is, a single cannula is used to provide access to a treatment region for an inner tissue removal device, in addition to the inner ablation probe. In these arrangements,

the cannula can be used to interchangeably introduce the inner tissue removal device and inner probe, so that a treatment region within the patient need only be accessed once. That is, an access cannula need only be percutaneously advanced through intervening tissue to the treatment region one time, since it will be used to provide access to both the tissue removal device and the inner probe.

Having described the structure of the tissue ablation system 100, its operation, along with a conventional percutaneous tissue removal device 200 (such as the En-bloc tumor removal assembly marketed by Neothermia or the MiniTome Potential marketed by Artemis), in treating targeted tissue will now be described. Although the tissue ablation system 100 and associated tissue removal device 200 lend themselves well to the treatment of tumors within breast tissue, the tissue ablation system 100 and associated tissue removal device 200 may be used to treat targeted tissue located anywhere in the body where hyperthermic exposure may be beneficial, e.g., within an organ of the body, such as the liver, kidney, pancreas, prostate (not accessed via the urethra), and the like. The volume to be treated will depend on the size of the tumor or other lesion, typically having a total volume from 1 cm³ to 150 cm³, and often from 2 cm³ to 35 cm³. The peripheral dimensions of the treatment region may be regular, e.g., spherical or ellipsoidal, but will more usually be irregular. 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, nuclear scanning (using radiolabeled tumor-specific probes),

and the like. Preferred is the use of high resolution ultrasound of the tumor or other lesion being treated, either intraoperatively or externally.

Referring now to Figs. 7A-7G, the operation of the tissue removal device and tissue ablation system 100 is described in treating a tumor T located beneath the skin or an organ surface S of a patient (Fig. 7A). First, the tissue removal device 200 is percutaneously introduced within the tumor T (Fig. 7B), and then operated in a conventional manner to remove the tumor T from the patient, thereby creating an interstitial cavity IC surrounding by a tissue margin TM (Fig. 7C).

Next, the probe assembly 102, while the electrode 124 is retracted and placed in its compressed state within the cannula 108, is introduced within the tissue, so that the distal end 114 of the cannula 108 is located within the interstitial cavity IC (Fig. 7D). Introduction of the probe assembly 102 can be performed transoperatively, i.e., soon after the tumor T is removed, or post-operatively, i.e., a significant amount of time (perhaps days) after the tumor T has been removed. In the latter case, a drainage tube is typically placed within the tissue to drain any fluid from the interstitial cavity IC, thereby maintaining a convenient path through which the probe assembly 104 can be later introduced.

This can be accomplished using any one of a variety of techniques. In some cases, the probe assembly 102 may be introduced to the target site TS percutaneously directly through the patient's skin or through an open surgical incision. In this case, the cannula 108 may have a sharpened tip, e.g., in the form of a needle, to facilitate introduction to the treatment region TR. In such

cases, it is desirable that the cannula 108 be sufficiently rigid, i.e., have a sufficient column strength, so that it can be accurately advanced through tissue. Of course, if the cannula 108 is introduced through the same path initially created by the tissue removal device 200, access through the patient's skin will have
5 already been provided.

Alternatively, the cannula 108 may be introduced using an internal stylet that is subsequently exchanged for the inner probe 110. In this latter case, the cannula 108 can be relatively flexible, since the initial column strength will be provided by the stylet. More alternatively, a component or element may be
10 provided for introducing the cannula 108 to the interstitial cavity IC. For example, a conventional sheath and sharpened obturator (stylet) assembly can be used to access the interstitial cavity IC. The assembly can be positioned under ultrasonic or other conventional imaging, with the obturator/stylet then removed to leave an access lumen through the sheath. The probe assembly 104 can then be
15 introduced through the sheath lumen, so that the distal end 114 of the cannula 108 advances from the sheath into the interstitial cavity IC. In the case of the co-access assembly described above, the same cannula used to introduce the tissue removal device 200 will be used to introduce the inner probe 110, thereby obviating the need to subsequently reintroduce another cannula through the
20 tissue.

In any event, after the cannula 108 is properly placed, the shaft 118 is distally advanced relative to the cannula 108 in a stable position to deploy the electrode 124 out from the distal end 114 of the cannula 108 (Fig. 7E). This can

be accomplished either by holding the cannula 108 via the handle sleeve 134 and distally advancing the shaft 118, or by holding shaft 118 via the handle member 136 and proximally advancing the cannula 108 via the handle sleeve 134. Depending upon the architecture and composition of the electrode 124, the electrode 124 may partially or completely self-expand upon its deployment from the cannula 108, or may remain in its compressed state. The electrode 124 is shown partially expanded, so that it only partially fills the entire interstitial cavity IC.

Next, the syringe 106 and associated tubing 107 (shown in Fig. 1) are connected to the perfusion port 142 on the handle member 136, and the syringe 106 operated, such that the saline is conveyed under positive pressure, through the tubing 107, and into the perfusion port 142 on the handle member 136. The saline then travels through the lumen 128 in the inner probe shaft 118, through the lateral ports 130 (shown in Fig. 4), and into contact with the ablation electrode 124, where it is absorbed by the electrode 124. As a result, the ablation electrode 124 becomes electrically conductive, and if not completely expanded already, will expand into firm and uniform contact with the tissue margin TM (Fig. 7F). Notably, even if the shape of the expanded electrode 124 does not match the shape of the interstitial cavity IC, the pliability of the electrode 124 allows it to easily conform to the tissue margin TM.

Next, the RF generator 104 and associated cable 105 (shown in Fig. 1) are connected to the connector 144 on the handle member 136, and then operated to ablate the tissue margin TM (Fig. 7G). If the electrode 124 is

impregnated with a chemotherapeutic agent, any gaseous substances created as a result of the thermal ablation process will escape from the interstitial cavity IC outward through the tissue margin TM, thereby carrying the chemotherapeutic agent with it into the tissue margin TM where chemotherapy is needed. Thus, any pathological agents not otherwise killed by the ablation process will be killed by the chemotherapy. It should also be noted that the heat created by the thermal ablation process increases the metabolic process of the tissue margin TM, thereby facilitating uptake of the chemotherapeutic agent within the tissue. The probe assembly 104 is then removed from the patient.

It should be noted that although use of a compressible/expandable hydrophilic electrode has been described in terms of percutaneous delivery systems, such electrodes can be introduced through open surgical incisions if desired. For example, an open incision can be made through the skin S of the patient, so that the tumor T can be removed via conventional surgical means.

The electrode can then be placed within the resulting interstitial cavity IC (either with or without the aid of a probe), and RF energy applied to the electrode to ablate the targeted tissue margin TM. If a probe is not used, insulated RF wires can be connected directly to the electrode, and an electrically conductive fluid can be directly applied to the electrode simply by directly perfusing the electrode with, e.g., a syringe. Depending upon the size of the surgical opening and the size of the fully expanded electrode, the electrode may not need to be compressed prior to its introduction within the interstitial cavity IC.

CLAIMS

1. A probe assembly, comprising:

a probe having a proximal end and a distal end;

an compressible/expandable tissue ablation electrode carried by the distal

5 probe end, the electrode configured for absorbing fluid; and

an electrical connector carried by the proximal probe end, the connector in electrical communication with the electrode.

2. The probe assembly of claim 1, wherein the probe is configured for being percutaneously introduced through tissue.

10 3. The probe assembly of claims 1 or 2, wherein the probe comprises a cannula having a lumen and an inner probe shaft disposed within the cannula lumen, and wherein the electrode is mounted on the inner probe shaft, such the electrode can be alternately retracted within the cannula lumen and deployed from the cannula lumen.

15 4. The probe assembly of any of claims 1 - 3, wherein the electrode is composed of an electrically insulative material.

5. The probe assembly of any of claims 1 - 4, wherein the electrode is self-expanding.

20 6. The probe assembly of any of claims 1 - 5, wherein the electrode comprises a network of spaces configured to fill with the fluid.

7. The probe assembly of any of claims 1 - 6, wherein the electrode is configured for absorbing an amount of the fluid equal to at least the weight of the electrode.

8. The probe assembly any of claims 1 - 7, further comprising an electrical energy source electrically coupled to the electrical connector.

9. The probe assembly any of claims 1 - 8, further comprising a perfusion port carried by the proximal shaft end, the perfusion port in fluid
5 communication with the electrode.

10. The probe assembly of any of claims 1 - 3, further comprising a chemotherapeutic agent impregnated in the electrode.

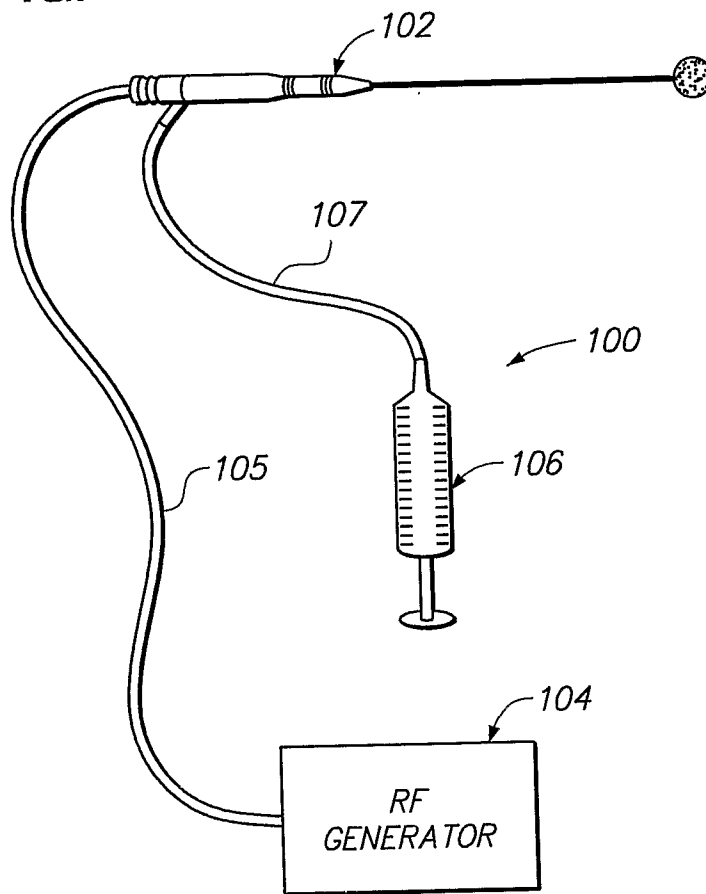
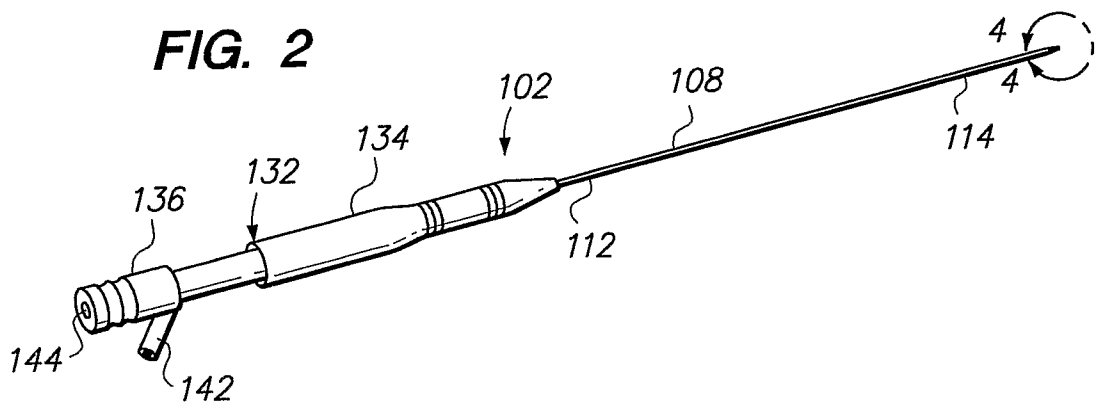
FIG. 1**FIG. 2**

FIG. 3

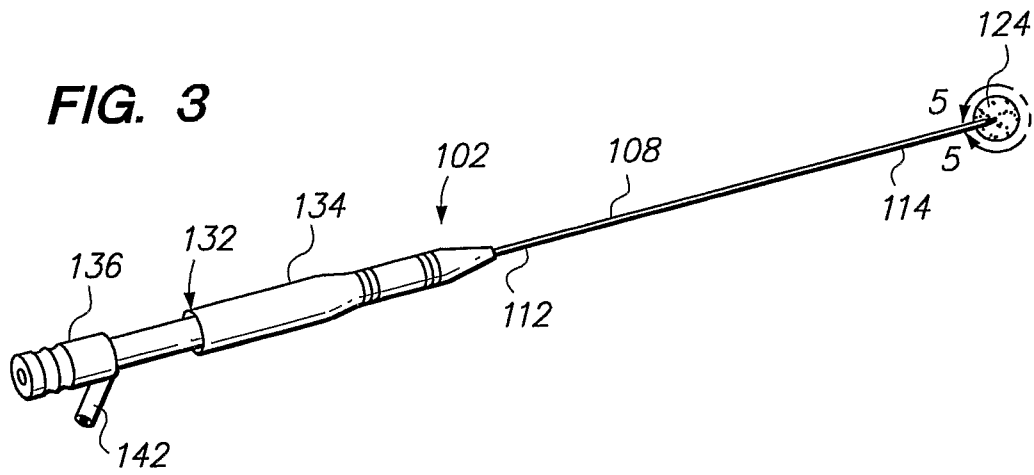


FIG. 4

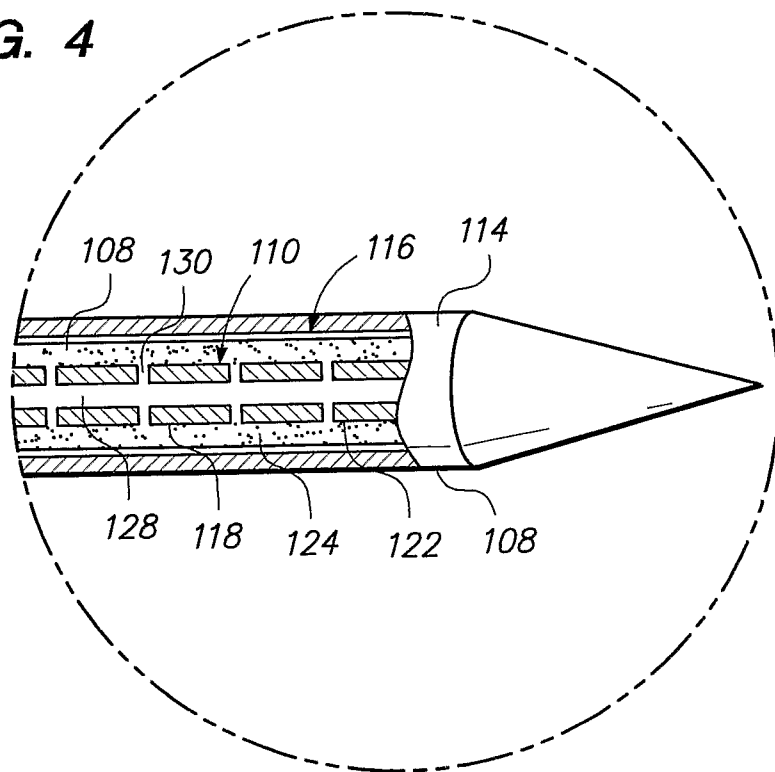


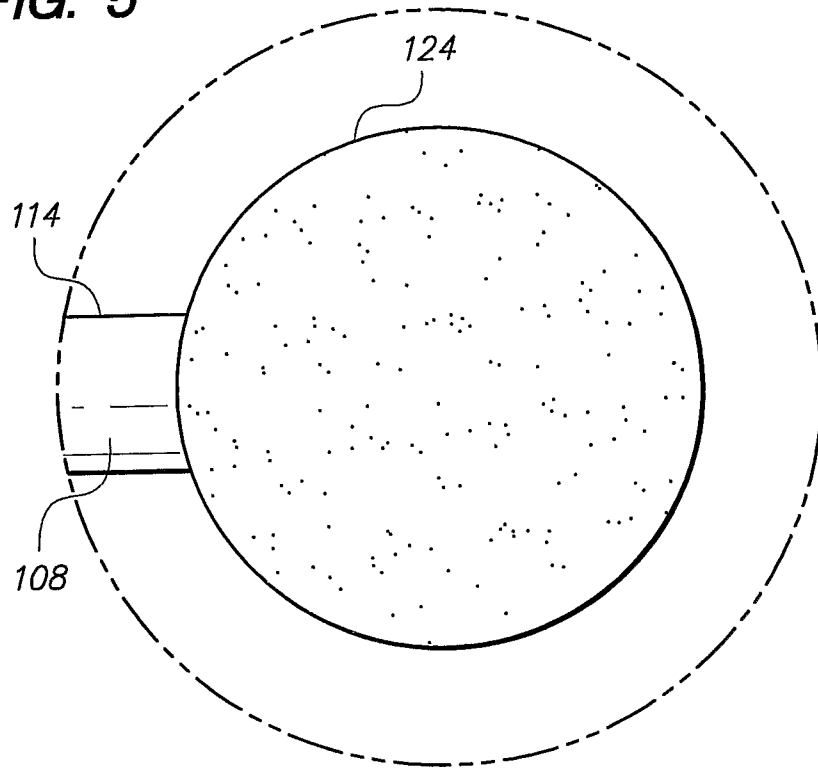
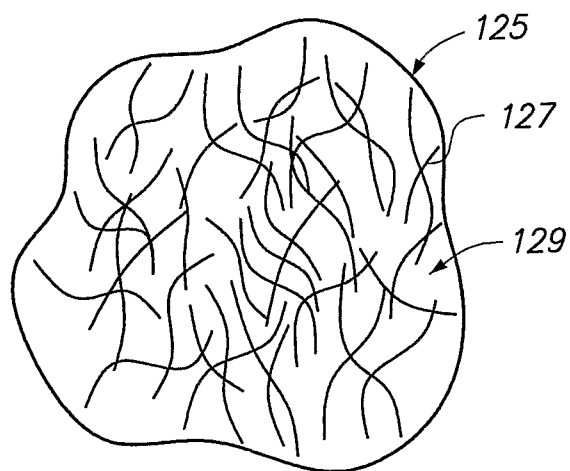
FIG. 5**FIG. 6**

FIG. 7A

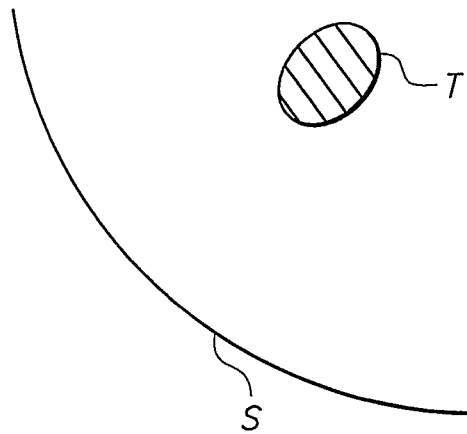


FIG. 7B

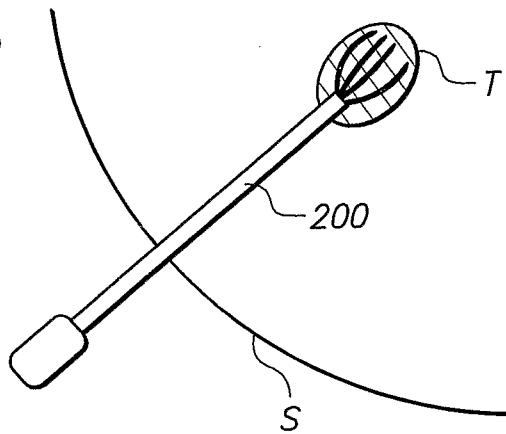


FIG. 7C

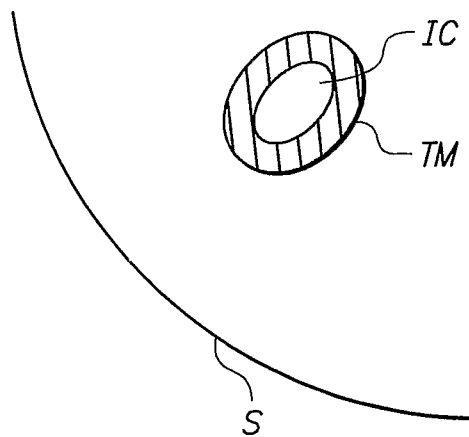


FIG. 7D

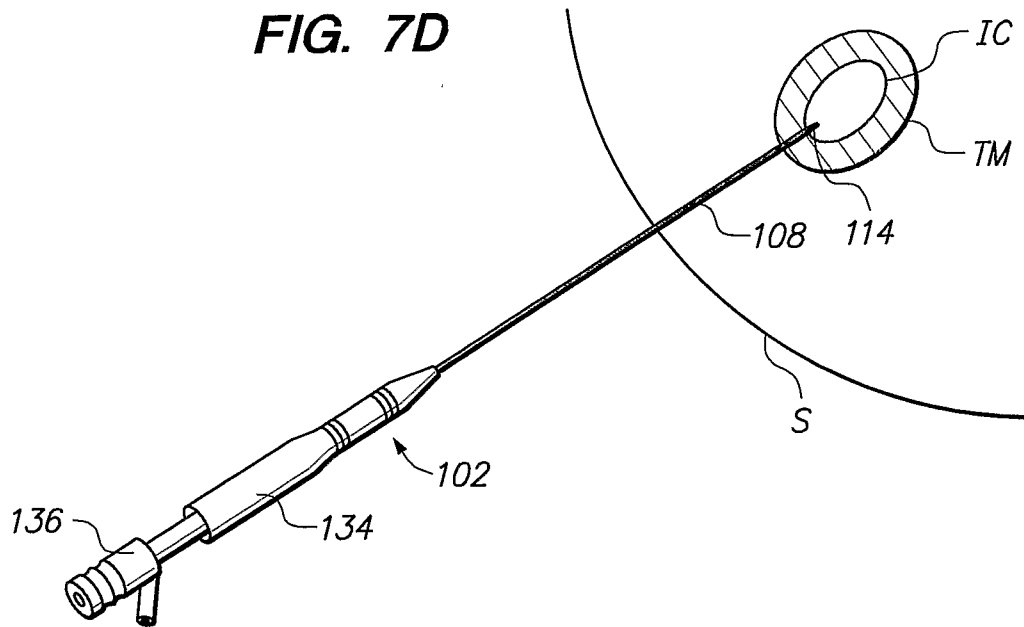


FIG. 7E

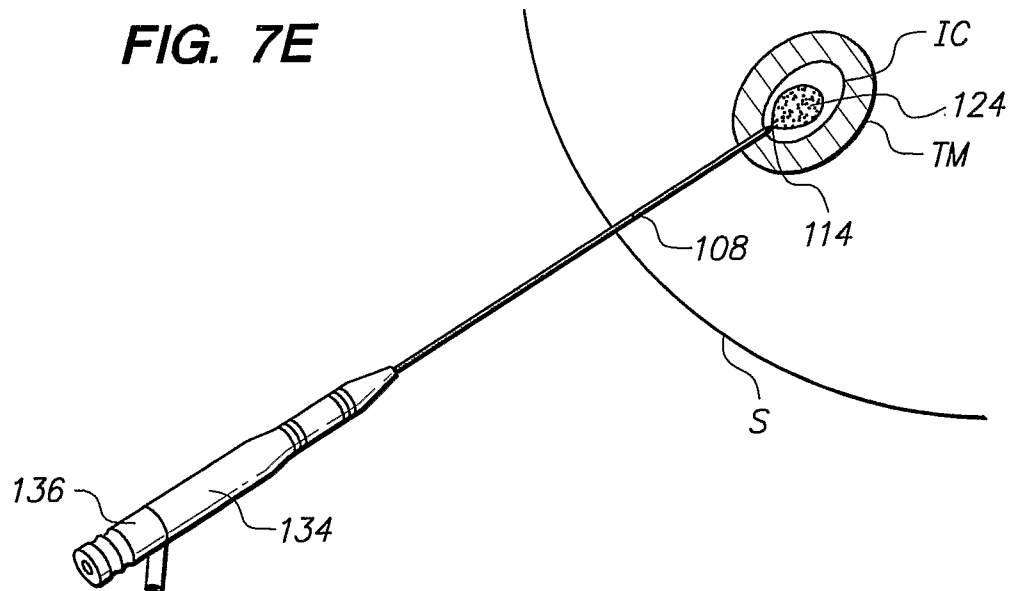


FIG. 7F

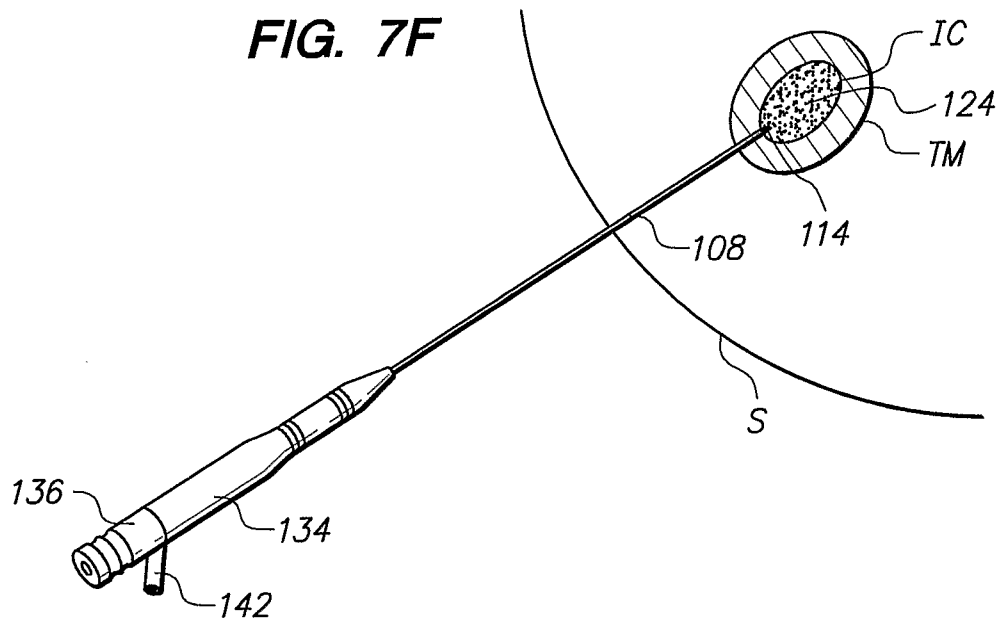
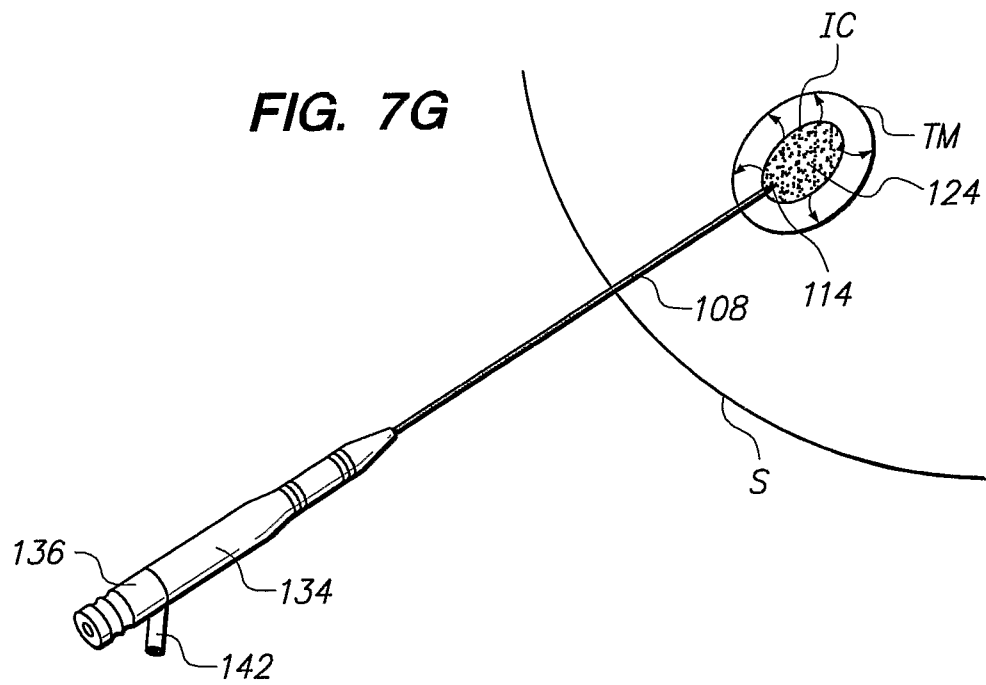


FIG. 7G



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/027079

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/00041 A (EDWARDS STUART D [US]; SHARKEY HUGH R [US]) 4 January 1996 (1996-01-04) page 1, lines 21-24 page 2, lines 1-10 page 6, line 20 - page 10, line 10 page 15, line 28 - page 19, line 23 page 24, lines 16-23 page 26, lines 24-30 page 29, lines 13-16 page 30, lines 1-5 page 34, lines 14-29 claim 33	1-4, 6-10
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/027079

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