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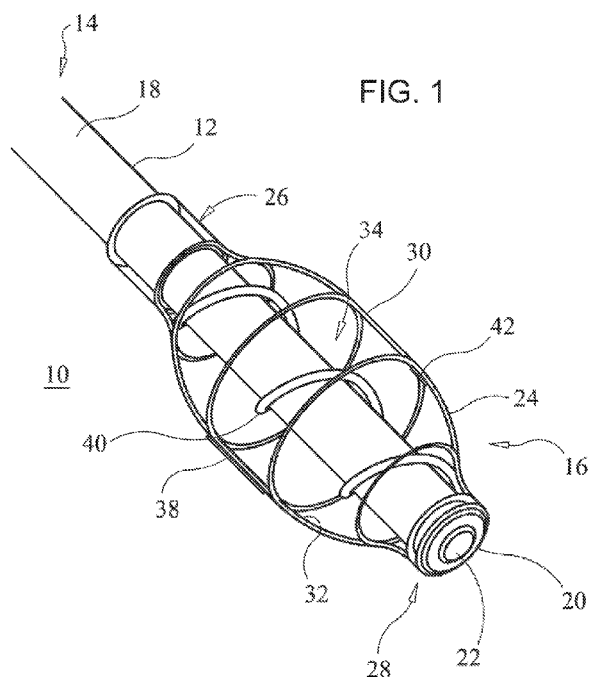
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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

[Continued on next page]

(54) Title: RF ENABLED INFLATABLE BONE TAMP



(57) Abstract: A device for performing a surgical procedure includes an elongated shaft extending between a proximal end and a distal end. The shaft includes an outer surface and an inner surface. An expandable member is disposed at the distal end of the shaft. The expandable member is configured to receive inflation material. At least one electrode is disposed with the inflatable member. Methods of use are disclosed.



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RF ENABLED INFLATABLE BONE TAMP

TECHNICAL FIELD

The present disclosure generally relates to medical devices for the treatment of cancers, and more particularly to a surgical system and method employing an
5 inflatable bone tamp to correct vertebral deformities, ablate tumors and stabilize fractures in cancer patients.

BACKGROUND

Radio frequency ablation (RFA) is a medical procedure in which tumors or other
10 dysfunctional tissue is ablated using the heat generated from high frequency alternating current. An important advantage of radio frequency (RF) current (over previously used low frequency AC or pulses of DC) is that RF current does not directly stimulate nerves or muscles and can therefore often be used without the need for general anesthetic. RFA has become increasingly accepted in the last 15 years with promising results. RFA procedures are
15 performed under image guidance (such as X-ray screening, CT scan or ultrasound) by an interventional pain specialist (such as an anesthesiologist), interventional radiologist, a gastrointestinal or surgical endoscopist, or a cardiac electrophysiologist, a subspecialty of cardiologists.

RFA is performed to treat tumors in the lungs, liver, kidneys, bones and other organs.
20 Once the diagnosis of tumor is confirmed, a needle-like RFA probe is placed inside the tumor. RF waves are passed through a probe to increase the temperature within tumor tissue to destroy the tumor. Generally, RFA is used to treat patients with small tumors that started within a specific organ (primary tumors) or that spread to the organ (metastases). The suitability of a patient to receive RFA is typically decided by doctors based on multiple factors.
25 RFA can usually be administered as an out-patient procedure, but may at times require a brief hospital stay. RFA may be combined with locally-delivered chemotherapy to treat hepatocellular carcinoma (primary liver cancer). The low-level heat (hyperthermia) created by the RFA probe causes heat-sensitive liposomes to release concentrated levels of chemotherapy in margins around ablated tissue, which is a method commonly used to treat Hepatocellular
30 carcinoma (HCC). RFA is also used in pancreatic cancer and bile duct cancer.

SUMMARY

In one embodiment, in accordance with the principles of the present disclosure, a device for performing a surgical procedure is provided comprising a cannula extending between a proximal end and a distal end. The cannula includes an outer surface and an inner surface. A balloon is disposed at the distal end of the cannula. The balloon is configured to receive inflation material and includes an inner surface defining a cavity. At least one electrode disposed with the balloon.

In one embodiment, in accordance with the principles of the present disclosure, a device for destroying pathological tissue is provided comprising a cannula extending between a proximal end and a distal end. The cannula includes an outer surface and an inner surface. A balloon is disposed at the distal end of the cannula. The balloon is configured to receive inflation material and includes an inner surface defining a cavity. At least one RF electrode is disposed with the balloon. A temperature feedback system is configured to monitor tissue desiccation.

In one embodiment, in accordance with the principles of the present disclosure, a method for destroying pathological tissue at a surgical site is provided. The method comprises providing a device comprising: a cannula extending between a proximal end and a distal end, the cannula including an outer surface and an inner surface; a balloon disposed at the distal end the cannula configured to receive inflation material, the balloon including an inner surface defining a cavity; at least one electrode disposed with the balloon and configured for emitting RF signals; and a temperature feedback system configured to monitor the extent of tissue desiccation; creating an access path to the surgical site; inserting the balloon into the surgical site and inflating the balloon; manipulating the balloon to move bone and create a void; emitting RF signals through the electrodes to thermally ablate and destroy pathological tissue; and monitoring the extent of tissue desiccation to determine if application of RF energy should be continued.

BRIEF DESCRIPTION OF THE DRAWINGS

The present disclosure will become more readily apparent from the specific description accompanied by the following drawings, in which:

FIG. 1 is a perspective view of one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. 2 is a perspective view of the system shown in FIG. 1 disposed in tissue;
and

FIG. 3 is a perspective view of one embodiment of a surgical system in
accordance with the principles of the present disclosure.

5 Like reference numerals indicate similar parts throughout the figures.

DETAILED DESCRIPTION

The exemplary embodiments of the surgical system and related methods of use
disclosed are discussed in terms of medical devices for the treatment of
10 musculoskeletal disorders and more particularly, in terms of a surgical system 10 and
method for nerve destruction.

In one embodiment, an RF enable inflatable bone tamp is manipulated to move
bone and create a void. RF energy is delivered to thermally ablate and destroy
pathological tissue. The void is then filled according to the particular surgical
15 procedure. The RF electrodes can be energized with either monopolar or bipolar RF.
Because of the small temperature difference between the temperature required for
denaturing malignant cells and the temperature normally injurious to healthy cells, a
known heating pattern and precise temperature control is needed to lead to more
predictable temperature distribution to eradicate the tumor cells while minimizing the
20 damage to surrounding normal tissue. Excessive temperatures can cause adverse
tissue effects. During the course of heating, tissue in an overly-heated area may
become desiccated and charred. As tissue temperature increases to 100° C, tissue will
lose water content due to evaporation or by the diffusion of liquid water from treated
cells, and the tissue becomes desiccated. Desiccation of the tissue changes the
25 electrical and other material properties of the tissue, and may impede treatment. For
example, as the tissue is desiccated, the electrical resistance of the tissue increases,
making it increasingly more difficult to supply power to the tissue. Desiccated tissue
may also adhere to the device, hindering delivery of power. At tissue temperatures in
excess of 100° C, the solid contents of the tissue begin to char. Like desiccated tissue,
30 charred tissue is relatively high in resistance to current and may impede treatment. In
one embodiment, a temperature or impedance-based feedback system enables the
system to accurately monitor the extent of tissue desiccation and permit continued
delivery of the RF energy.

The RF enabled inflatable bone tamp includes one or a plurality of RF electrodes. The electrodes can be straight, helical or curved. The electrodes can be positioned inside, outside or within the wall of the RF enabled inflatable bone tamp. In one embodiment, a liquid pumping system may be connected to the RF enabled inflatable bone tamp to inflate and cool down inflation liquid used to inflate the RF enabled inflatable bone tamp dynamically (active cooling) or the RF enabled inflatable bone tamp may be inflated with a cooled liquid (passive cooling).

It is contemplated that one or all of the components of the surgical system may be disposable, peel-pack, pre-packed sterile devices. One or all of the components of the surgical system may be reusable. The surgical system may be configured as a kit with multiple sized and configured components, such as, for example, inflatable members (balloons) that are preformed to have different sizes and shapes.

It is envisioned that the present disclosure may be employed to treat bones, and in particular arm bones such as a distal radius. It should be understood that the present principles are applicable to any bone structures, including but not limited to bones of the spine, legs, feet, arms, etc. It is contemplated that the present disclosure may be employed with other osteal and bone related applications, including those associated with diagnostics and therapeutics. It is further contemplated that the disclosed surgical system and methods may alternatively be employed in a surgical treatment with a patient in a prone or supine position, and/or employ various surgical approaches, including anterior, posterior, posterior mid-line, direct lateral, postero-lateral, antero-lateral, etc. approaches in the calcaneus, spine or other body regions. The present disclosure may also be alternatively employed with procedures for treating the muscles, ligaments, tendons or any other body part. The system and methods of the present disclosure may also be used on animals, bone models and other non-living substrates, such as, for example, in training, testing and demonstration.

The present disclosure may be understood more readily by reference to the following detailed description of the disclosure taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this disclosure is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed disclosure. Also, as used in the

specification and including the appended claims, the singular forms “a,” “an,” and “the” include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from “about” or “approximately” one particular value and/or to 5 “about” or “approximately” another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent “about,” it will be understood that the particular value forms another embodiment. It is also understood that all spatial references, such as, for example, 10 horizontal, vertical, top, upper, lower, bottom, left and right, are for illustrative purposes only and can be varied within the scope of the disclosure. For example, the references “upper” and “lower” are relative and used only in the context to the other, and are not necessarily “superior” and “inferior”.

Further, as used in the specification and including the appended claims, 15 “treating” or “treatment” of a disease or condition refers to performing a procedure that may include administering one or more drugs to a patient (human, normal or otherwise or other mammal), in an effort to alleviate signs or symptoms of the disease or condition. Alleviation can occur prior to signs or symptoms of the disease or condition appearing, as well as after their appearance. Thus, treating or treatment 20 includes preventing or prevention of disease or undesirable condition (e.g., preventing the disease from occurring in a patient, who may be predisposed to the disease but has not yet been diagnosed as having it). In addition, treating or treatment does not require complete alleviation of signs or symptoms, does not require a cure, and specifically includes procedures that have only a marginal effect on the patient. Treatment can 25 include inhibiting the disease, e.g., arresting its development, or relieving the disease, e.g., causing regression of the disease. For example, treatment can include reducing acute or chronic inflammation; alleviating pain and mitigating and inducing re-growth of new ligament, bone and other tissues; as an adjunct in surgery; and/or any repair procedure. Also, as used in the specification and including the appended claims, the 30 term “tissue” includes soft tissue, ligaments, tendons, cartilage and/or bone unless specifically referred to otherwise.

The components of system 10 can be fabricated from biologically acceptable materials suitable for medical applications, including metals, synthetic polymers,

ceramics and bone material and/or their composites, depending on the particular application and/or preference of a medical practitioner. For example, the components of system 10, individually or collectively, can be fabricated from materials such as stainless steel alloys, commercially pure titanium, titanium alloys, Grade 5 titanium, super-elastic titanium alloys, cobalt-chrome alloys, stainless steel alloys, superelastic metallic alloys (e.g., Nitinol, super elasto-plastic metals, such as GUM METAL[®] manufactured by Toyota Material Incorporated of Japan), ceramics and composites thereof such as calcium phosphate (e.g., SKELITE[™] manufactured by Biologix Inc.), thermoplastics such as polyaryletherketone (PAEK) including polyetheretherketone (PEEK), polyetherketoneketone (PEKK) and polyetherketone (PEK), carbon-PEEK composites, PEEK-BaSO₄ polymeric rubbers, polyethylene terephthalate (PET), fabric, silicone, polyurethane, silicone-polyurethane copolymers, polymeric rubbers, polyolefin rubbers, hydrogels, semi-rigid and rigid materials, elastomers, rubbers, thermoplastic elastomers, thermoset elastomers, elastomeric composites, rigid polymers including polyphenylene, polyamide, polyimide, polyetherimide, polyethylene, epoxy, bone material including autograft, allograft, xenograft or transgenic cortical and/or corticocancellous bone, and tissue growth or differentiation factors, partially resorbable materials, such as, for example, composites of metals and calcium-based ceramics, composites of PEEK and calcium based ceramics, composites of PEEK with resorbable polymers, totally resorbable materials, such as, for example, calcium based ceramics such as calcium phosphate, tri-calcium phosphate (TCP), hydroxyapatite (HA)-TCP, calcium sulfate, or other resorbable polymers such as polyactide, polyglycolide, polytyrosine carbonate, polycaprolactone and their combinations. Various components of system 10 may have material composites, including the above materials, to achieve various desired characteristics such as strength, rigidity, elasticity, compliance, biomechanical performance, durability and radiolucency or imaging preference.

The components of system 10, individually or collectively, may also be fabricated from a heterogeneous material such as a combination of two or more of the above-described materials. The components of system 10 may be monolithically formed, integrally connected or include fastening elements and/or instruments, as described herein.

The following discussion includes a description of a system for performing a surgical procedure and related methods of employing the system in accordance with the principles of the present disclosure. Alternate embodiments are also disclosed. Reference will now be made in detail to the exemplary embodiments of the present disclosure, which are illustrated in the accompanying figures. Turning now to FIGS. 1-3, there are illustrated components of system 10 in accordance with the principles of the present disclosure.

As shown in FIGS. 1 and 2, system 10 includes an elongated shaft 12. Shaft 12 extends between a proximal end 14 and a distal end 16. Shaft 12 includes an outer surface 18 and an inner surface 20 defining a passageway 22. Passageway 22 extends the entire length of shaft 12 and has a cylindrical cross sectional configuration having a uniform diameter along the length of passageway 22. In some embodiments, passageway 22 may have alternate cross section configurations, such as, for example, oval, oblong, triangular, square, hexagonal, polygonal, irregular, uniform, non-uniform and/or tapered.

An inflatable member, such as, for example, a balloon 24 is disposed with distal end 16 of shaft 12. Balloon 24 has a proximal end 26 and a distal end 28. Balloon 24 includes an outer surface 30 and an inner surface 32. Surface 32 defines a cavity 34 extending the entire length of balloon 24. Balloon 24 includes a wall 36 extending between surfaces 30 and 32 and defines a thickness t . Shaft 12 may be attached to a fill tube (not shown) such that a material, such as, for example, saline, a contrast solution or compressed air may be delivered from the tube, through passageway 22 and into cavity 34. As the material fills cavity 34, balloon moves from an unexpanded configuration, to an expanded configuration. It is envisioned that the shapes and sizes of balloon 24 when in the expanded configuration can be selected to provide a desired result during a procedure. For example, balloon 24 may include shapes such as spheres, cylinders, etc. and have different dimensions to make balloon 24 narrower or wider in a longitudinal direction, or extend further in a radial direction. Balloon 24 comprises a compliant material, such as, for example, polyurethane, pellethane, polyethylene, silicone, cronoprene or non-compliant material such as Nylon.

It is envisioned that balloon 24 can be a single or multi-layered balloon where each balloon layer has the same diameter and/or wall thickness, is comprised of the same material or materials having substantially identical mechanical properties, and

has the same degree of molecular orientation in the body portion of the balloon. It will be apparent that in some situations it will be desirable to have some balloon layers having different thicknesses, materials, and/or degree of molecular orientations upon deflation, while at the same time having equivalent size, mechanical properties, and/or orientation upon inflation or expansion. For other applications, it will be apparent that one can vary size, material, and/or orientation to at least some degree, depending upon the requirements of a particular application.

It is contemplated that balloon 24 may include an impenetrable structural layer having low friction surfaces so as to facilitate deployment through a delivery tube, such as, for example, through shaft 12 and prevent rupture of balloon 24 as it is inflated or expanded *in situ*. Further variations are contemplated involving different combinations of lubricating layers and structural layers. In some embodiments, structural layers of balloon 24 can contain polyamides, polyesters, polyethylenes, polyurethanes, their co-polymers and combinations thereof.

At least one electrode 38 is disposed with balloon 24. Electrode 38 is configured to emit an RF frequency for cutting and/or destroying tissue or nerves. In one embodiment, shown in FIG. 1, electrode 38 is disposed on outer surface 30. In one embodiment, electrode 38 is disposed on inner surface 32. In one embodiment, electrode 38 is disposed within wall 26. This configuration will accommodate different anatomies as well as different control methods. Electrode 38 can be of any shape such as, for example, straight, helical or curved. If more than one electrode 38 is provided, they can be positioned symmetrically or directionally along balloon 24. The RF signal is configured to temporarily interrupt or destroy nerves to reduce pain in the patient.

In one embodiment, a temperature or impedance-based feedback system is provided. A sensor 42 of the feedback system is disposed on balloon 24 and is configured to monitor the temperature of tissue effected by the RF signal to determine the extent of desiccation and thereby determine if RF energy needs to be continued.

In one embodiment, a cooling mechanism is provided and is configured to cool inflation material used to move balloon 24 from the unexpanded configuration to the expanded configuration. In one embodiment, shown in FIG. 1, active cooling is provided by the cooling mechanism by including a cooling tube 40 disposed in within cavity 34. Cooling tube 40 extends through shaft 12 and is connected to a liquid

pumping system (not shown). In one embodiment, cooling tube 40 is disposed within wall 36 of balloon 24. As shown in FIG. 1, cooling tube 40 can spiral around shaft 12 such that cooling of the inflation material is uniform. In one embodiment, passive cooling is providing by having the cooling mechanism cool the inflation material prior to filling balloon 24.

In some embodiments, shaft 12 and/or balloon 24 includes one or a plurality of marker bands (not shown) comprising a radiopaque material. In one embodiment, the polymeric material is polyether block amide. In some embodiments, the highly radiopaque material incorporated into the polymeric material is barium sulfate, bismuth subcarbonate, tungsten, or a combination thereof.

In assembly, operation and use, system 10 is employed with a surgical procedure, such as, for a treatment of a cancerous tumor. It is contemplated that one or all of the components of system 10 can be delivered or implanted as a pre-assembled device or can be assembled *in situ*. System 10 may be completely or partially revised, removed or replaced. It is envisioned that system 10 may also be used to treat other affected portions of the patient, such as, for example, a calcaneus bone, bones of the feet or hands, bones of the spine, bones of the arms and legs, etc.

In use, to treat cancer, the medical practitioner obtains access to a surgical site including in any appropriate manner, such as through the skin, or through an incision and retraction of tissues. In one embodiment, a drill is employed to remove bone tissue to provide access to a repair site. It is envisioned that system 10 can be used in any existing surgical method or technique including open surgery, mini-open surgery, minimally invasive surgery and percutaneous surgical implantation, whereby the fractured or injured bone is accessed through a mini-incision or sleeve that provides a protected passageway to the area. Once access to the surgical site is obtained, the particular surgical procedure can be performed for treating the injury or disorder. The configuration and dimension of system 10 is determined according to the configuration, dimension and location of a selected section of nerves and the requirements of a particular application.

An incision is made in the body of a patient and a cutting instrument (not shown) creates a surgical pathway for implantation of components of system 10. This may include the use of a cannula or other device. A preparation instrument (not shown) can be employed to prepare tissue surfaces, as well as for aspiration and

irrigation of a surgical region according to the requirements of a particular surgical application.

An instrument, such as, for example, a cannula may be inserted through the incision such that a distal end of the cannula is positioned adjacent the surgical site.

5 Balloon 24 is then inserted through the cannula such that distal end 16 of balloon 24 is positioned adjacent the surgical site. A material, such as, for example, saline, a contrast solution or compressed air may be delivered through shaft 12 and passageway 22 and into cavity 34. The material may be delivered into cavity 34 until balloon 24 assumes the desired profile. Balloon 24 can be manipulated to move bone and create a void at the desired location by viewing balloon 24 with use of markers. As shown in FIG. 2, once balloon 24 is properly positioned within an organ or bone, electrode(s) 38 can be activated to emit the desired RF signal to heat the cancerous tissue T. Sensor 42 monitors the temperature of tissue T to determine the extent of desiccation and thereby determine if RF energy needs to be continued to further remove cancerous tissue.

15 As RF signals are emitted, temperature of balloon 24 increases. The cooling mechanism may be utilized to decrease the temperature of balloon 24 so that the procedure can be repeated at various locations. Removal of the material from cavity 34 causes balloon 24 to move from the expanded configuration to the unexpanded configuration for removal from the patient. That is, after balloon 24 is moved from the expanded configuration to the unexpanded configuration, balloon 24 may be retracted into the cannula and removed.

20

As shown in FIG. 3, a balloon system 110 is provided in accordance with the principles of the present disclosure. System 110 includes an elongated shaft 112. Shaft 112 extends between a proximal end 114 and a distal end 116. Shaft 112 includes an outer surface 118 and an inner surface 120. Surface 120 defines a passageway 122. A balloon 124 is provided at distal end 116 of shaft 112. Balloon 124 has a proximal end 126 and a distal end 128. Balloon 124 includes an outer surface 130 and an inner surface 132. Surface 132 defines a cavity 134 extending the entire length of balloon 124. Cavity 134 is configured to receive an inflation material.

25

30 An expandable cage 150 is disposed around balloon 124. Cage 150 provides a certain amount of stiffness to balloon 124 and protects balloon 124 from bone material that may puncture balloon 124. In one embodiment, an electrode 138 similar to electrode 38 and a sensor 142 similar to sensor 42 are disposed with cage 150. Some

advantages of using cage 150 includes ease of manufacturing and robustness of the device. In addition cage 150 also contributes to more accurate control in both temperature and impedance control modes. Cage 150 is configured to expand with balloon 124 as surface 130 of balloon 124 applies force to cage 150. As discussed
5 above, a cooling mechanism, such as, for example, a cooling tube 140 is provided and is configured to cool inflation material used to move balloon 124 from an unexpanded configuration to an expanded configuration.

In one embodiment, a distal end 152 of the expandable cage 150 is attached to a ring-shaped member 154 having an inner surface defining an opening. Distal end
10 152 of cage 150 is positioned within the opening of ring shaped member 154. A proximal end of cage 150 is engaged with a collar 156 so that when balloon 124 expands, cage 150 expands. Similarly, when balloon 124 is deflated cage 150 contracts to give a slimmer profile.

It will be understood that various modifications may be made to the
15 embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto. The balloon can be modified or extended to accommodate particular formulations of balloon construction materials or fabrication
20 techniques. Different balloon materials and surface coatings, or outer layers of different materials or surface coatings may also be applied to the balloon to facilitate a smaller balloon profile, biocompatibility, lubrication as well as other properties. The embodiments above can also be modified so that some features of one embodiment are used with the features of another embodiment. One skilled in the art may find
25 variations of these preferred embodiments, which, nevertheless, fall within the spirit of the present invention, whose scope is defined by the claims set forth below.

WHAT IS CLAIMED IS:

1. A device for performing a surgical procedure comprising:
an elongated shaft extending between a proximal end and a distal end, the shaft
5 including an outer surface and an inner surface;
an expandable member disposed at the distal end of the shaft configured to
receive inflation material; and
at least one electrode disposed with the expandable member.
- 10 2. A device as recited in Claim 1, wherein the expandable member
includes a wall defining a thickness and the at least one electrode is disposed within
the thickness of the wall.
- 15 3. A device as recited in Claim 1, wherein the expandable member
includes an outer surface and the at least one electrode is disposed on the outer surface
of the expandable member.
- 20 4. A device as recited in Claim 1, wherein the expandable member
includes an inner surface and the at least one electrode is disposed on the inner surface
of the expandable member.
- 25 5. A device as recited in Claim 1, further including a cooling mechanism
comprising a liquid pumping system configured for disposal within a cavity defined by
an inner surface of the expandable member.
6. A device as recited in Claim 1, wherein the at least one electrode is
configured to emit a radio frequency (RF) signal to ablate cancerous tissue.

7. A device as recited in Claim 6, wherein the at least one electrode is configured to be energized by monopolar RF.

8. A device as recited in Claim 6, wherein the at least one electrode is
5 configured to be energized by bipolar RF.

9. A device as recited in Claim 1, wherein the expandable member is a balloon.

10. A device as recited in Claim 1, wherein comprising an expandable cage
10 disposed around the expandable member.

11. A device as recited in Claim 10, wherein the at least one electrode is disposed on an outer surface of the cage.

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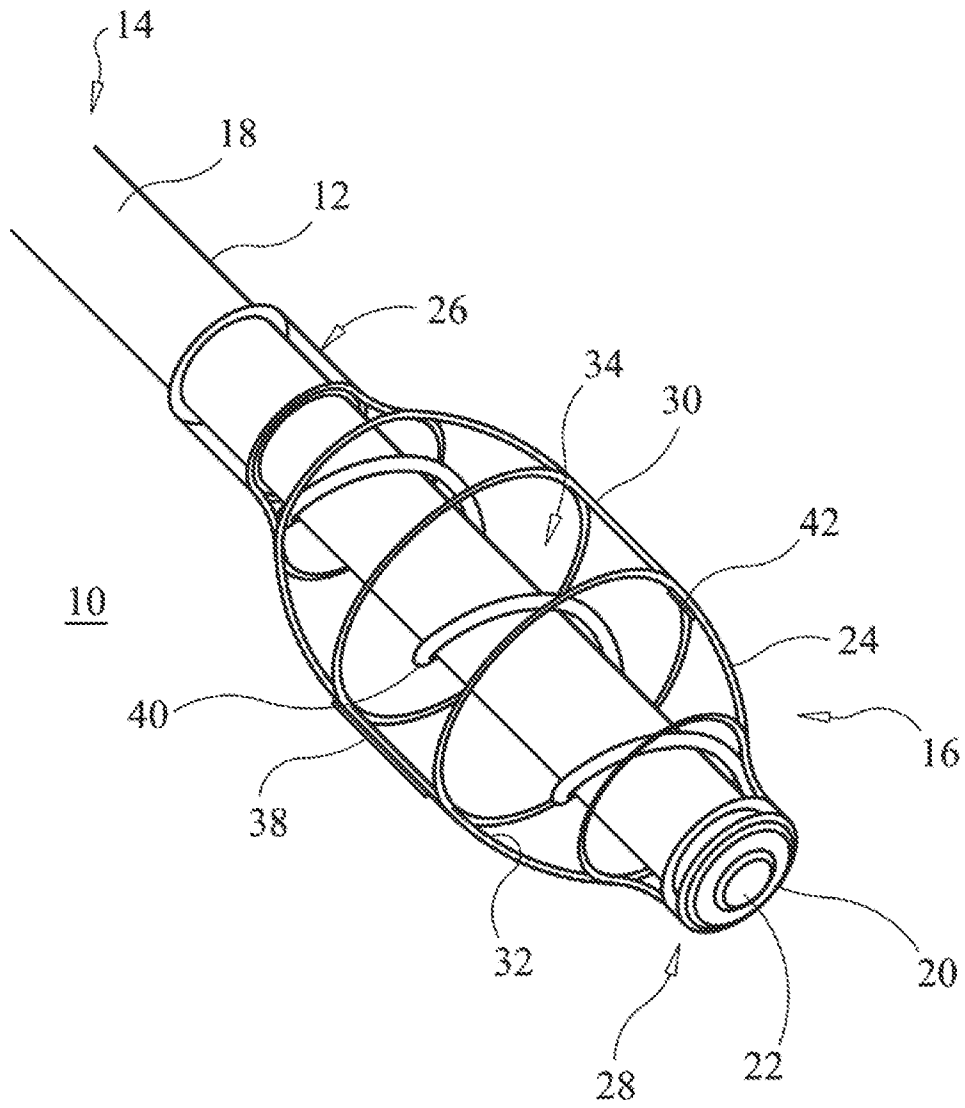


FIG. 1

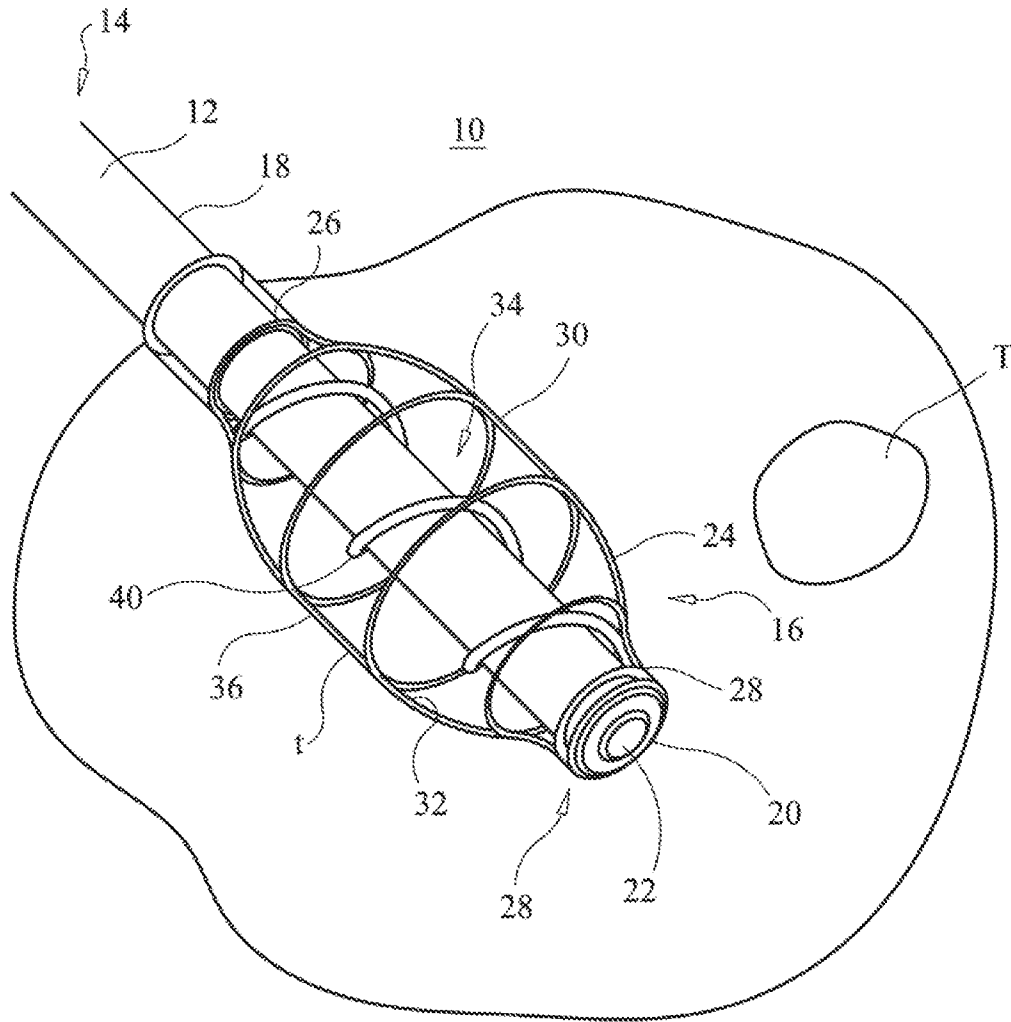


FIG. 2

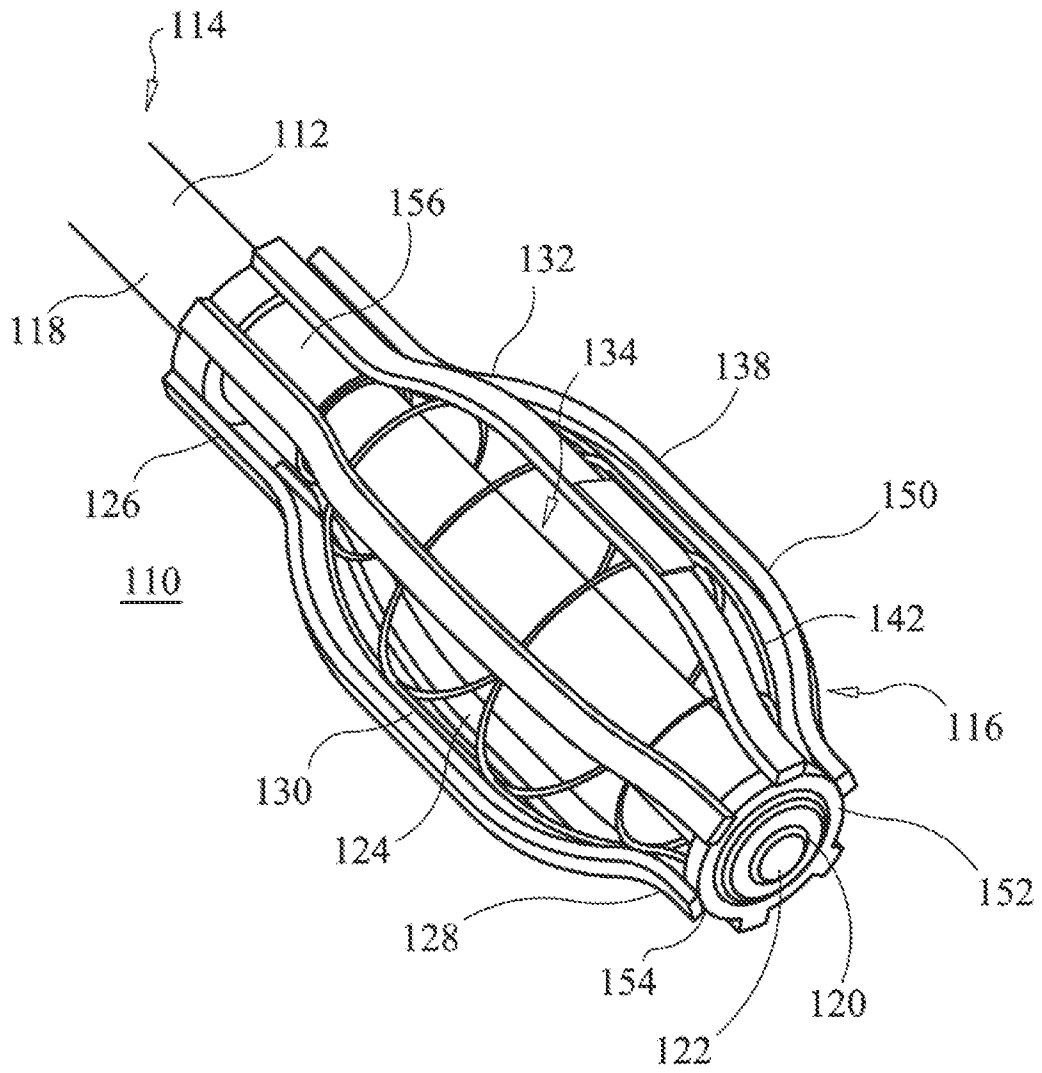


FIG. 3

A. CLASSIFICATION OF SUBJECT MATTER**A61B 18/12(2006.01)i, A61M 25/10(2006.01)i, A61B 18/14(2006.01)i, A61M 29/00(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
A61B 18/12; A61B 5/04; A61B 18/14; A61B 18/18; A61B 8/00; A61M 25/10; A61M 29/00Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility modelsElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: shaft, expandable member, electrode, radio frequency, cooling mechanism, expandable cage**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012-122157 A1 (TIDAL WAVE TECHNOLOGY, INC.) 13 September 2012 See paragraphs [0042]-[0047], [0050]-[0053], [0056]-[0059]; and figures 1-2.	1-11
A	US 2001-0034518 A1 (EDWARDS et al.) 25 October 2001 See abstract; paragraphs [0050]-[0052], [0057]-[0058]; and figures 2a, 2d.	1-11
A	US 6004269 A (CROWLEY et al.) 21 December 1999 See abstract; column 20, lines 14-32; column 24, lines 24-33, 50-66; and figures 14, 20.	1-11
A	US 2003-0236455 A1 (SWANSON et al.) 25 December 2003 See abstract; paragraphs [0057], [0059], [0104], [0118]-[0119]; and figures 1, 9, 12.	1-11
A	US 2005-0096647 A1 (STEINKE et al.) 5 May 2005 See abstract; paragraphs [0075]-[0076], [0080]-[0082], [0084], [0098], [0105]; and figures 2-3, 17A.	1-11

 Further documents are listed in the continuation of Box C. See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

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