ABLECTION DEVICE WITH DRUG DELIVERY COMPONENT AND BIOPSY TISSUE-SAMPLING COMPONENT

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Ablation device includes a handle assembly, an ablation electrode extending from the handle assembly, and one or more delivery needles extending from the handle assembly. The ablation electrode includes an ablation needle. The ablation needle includes a distal end portion including a drug delivery port defined therethrough. The ablation device also includes and a biopsy tool extending from the handle assembly.
FIG. 30

Cutting Effect

Hemostasis Effect

Ablation Effect

Spot Size

295μ

349μ

404μ

458μ

839μ

1111μ

5mm

1mm
ABLATION DEVICE WITH DRUG DELIVERY COMPONENT AND BIOPSY TISSUE-SAMPLING COMPONENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to, and the benefit of, U.S. Provisional Application Ser. No. 61/653,804, filed on May 31, 2012, and U.S. Provisional Application Ser. No. 61/688,577, filed on June 12, 2012, the disclosures of which are herein incorporated by reference in their entireties.

BACKGROUND

[0002] 1. Technical Field

[0003] The present disclosure relates to electrosurgical systems and devices for performing medical procedures. The present disclosure relates to the administration of beneficial agents in general, which include any physiologically, pharmacologically active and/or psychotropic substance(s). The present disclosure relates to biopsy devices. More particularly, the present disclosure relates to ablation devices with drug delivery (and/or contrast agent) components and biopsy tissue-sampling components, and electrosurgical systems including the same.

[0004] 2. Discussion of Related Art

[0005] Clinicians obtain biopsy specimens for various purposes such as diagnosing, staging and grading disease states. A biopsy procedure may be performed using needles, bronchoscopes, and/or surgery to obtain tissue or fluid samples. The appropriate method of biopsy for a patient depends upon a variety of factors, including the size, location, appearance and characteristics of the abnormality, and the patient’s medical history. The clinician performing the biopsy may use specialized imaging equipment to guide the biopsy tool to the desired site. Some biopsies may be performed under image guidance using ultrasound, computed tomography (CT) scan, or magnetic resonance imaging (MRI). For example, CT imaging may be used to guide lung biopsies.

[0006] A variety of biopsy techniques may be applied, e.g., fine-needle aspiration (FNA), core needle, and surgical biopsies. FNA biopsy is a percutaneous procedure that uses a fine gauge needle. Core needle biopsy is typically performed by inserting a small hollow needle through the skin and into the organ or abnormality to be investigated. After the biopsy specimen is obtained, the specimen is examined to determine if abnormal or cancerous cells are present.

[0007] Treatment of certain diseases requires the destruction of malignant tissue growths, e.g., tumors. Electromagnetic radiation can be used to heat and destroy tumor cells. Treatment may involve inserting ablation probes into tissues where cancerous tumors have been identified. Once the probes are positioned, electromagnetic energy is passed through the probes into surrounding tissue.

[0008] In the treatment of diseases such as cancer, certain types of tumor cells have been found to denature at elevated temperatures that are slightly lower than temperatures normally injurious to healthy cells. Known treatment methods, such as hyperthermia therapy, heat-doused cells to temperatures above 41°C while maintaining adjacent healthy cells below the temperature at which irreversible cell destruction occurs. These methods involve applying various forms of energy (e.g., electromagnetic, ultrasonic, etc.) to heat, ablate and/or coagulate tissue. Microwave or radio-frequency energy is sometimes utilized to perform these methods. Radio-frequency (RF) and microwave (MW) energy are electromagnetic radiation in the frequency ranges of 3 kilohertz (kHz) to 300 Megahertz (MHz), and 300 MHz to 300 gigahertz (GHz), respectively. Other procedures utilizing electromagnetic radiation to heat tissue also include coagulation, cutting and/or ablation of tissue.

[0009] Electrosurgical devices utilizing electromagnetic radiation have been developed for a variety of uses and applications. A number of devices are available that can be used to provide high bursts of energy for short periods of time to achieve cutting and coagulative effects on various tissues. There are a number of different types of apparatus that can be used to perform ablation procedures. Typically, microwave apparatus for use in ablation procedures include a microwave generator that functions as an energy source, and a microwave surgical instrument (e.g., microwave ablation probe) having an antenna assembly for directing the energy to the target tissue. The microwave generator and surgical instrument are typically operatively coupled by a cable assembly having a plurality of conductors for transmitting microwave energy from the generator to the instrument, and for communicating control, feedback and identification signals between the instrument and the generator.

[0010] The basic purpose of both monopolar and bipolar electrosurgery is to produce heat to achieve the desired tissue clinical effect. In monopolar electrosurgery, devices use an instrument with a single, active electrode to deliver energy from an electrosurgical generator to tissue, and a patient return electrode (usually a plate positioned on the patient’s thigh or back) as the means to complete the electrical circuit between the electrosurgical generator and the patient. In bipolar electrosurgery, the electrosurgical device includes two electrodes that are located in proximity to one another for the application of current between their surfaces. Bipolar electrosurgical current travels from one electrode, through the intervening tissue to the other electrode to complete the electrical circuit.

[0011] The benefits provided by controlled delivery of active agents for the treatment of injury or disease are well recognized in the art and various approaches have been taken to realize the goal of delivering active agents at desired rates over predetermined periods of time. Various different implantable controlled-delivery formulations are in use in the art, and various different mechanisms have been employed for delivering active agent from implantable formulations at a controlled rate over time.

[0012] Medical imaging has become a significant component in the clinical setting and in basic physiology and biology research, e.g., due to enhanced spatial resolution, accuracy and contrast mechanisms that have been made widely available. Medical imaging now incorporates a wide variety of modalities, e.g., computed tomography (CT) and magnetic resonance imaging (MRI), that noninvasively capture the structure and/or function of the human body. Such images are acquired and used in many different ways including medical images for diagnosis, staging and therapeutic management of malignant disease.

[0013] Medical image processing, analysis and visualization may play an increasingly useful role in disease diagnosis and monitoring as well as, among other things, surgical planning and monitoring of therapeutic procedures. A contrast agent may be used for enhancement of the contrast of structures or fluids within the body (or region of interest) in medical imag-
ing to allow visualization and evaluation of lesions seen minimally, if at all, with imaging alone.

[0014] Despite advancements in the use of electrosurgical devices for treating biological tissue, there are still concerns for tumor reoccurrence. There is a continuing need for biopsy devices.

SUMMARY

[0015] There is a need for ablation devices capable of collecting tissue samples, e.g., to eliminate the need for a separate, biopsy tissue-sampling device. There is a need for ablation devices capable of dispensing a controlled delivery formulation of a desired active agent. There is a need for devices capable of dispensing a contrast agent to enhance the visualization of the region of interest during a medical procedure. The combination of ablation (e.g., RF ablation and/or microwave ablation) and drug delivery may help to reduce or eliminate tumor reoccurrence. There is a need for an ablation device that is configured to dispense an active agent in a controlled delivery formulation and/or non-active agent (e.g., contrast agent) before, during and/or after ablation, e.g., without the need for further manipulation of the device. A need exists for ablation needles with a drug delivery component. A need exists for ablation needles with absorbent surfaces and/or materials, e.g., to provide tissue retrieving capabilities.

[0016] Electromagnetic energy is generally classified by increasing energy or decreasing wavelength into radio waves, microwaves, infrared, visible light, ultraviolet, X-rays and gamma-rays. As it is used in this description, “ablation procedure” generally refers to any ablation procedure, such as microwave ablation, radio frequency (RF) ablation or microwave ablation-assisted resection.

[0017] As it is used in this description, “energy-delivery device” generally refers to any device that can be used to transfer energy from a power generating source, such as a microwave or RF electrosurgical generator, to tissue. For the purposes herein, the term “ablation device” is interchangeable with the term “energy-delivery device.” As it is used in this description, “transmission line” generally refers to any transmission medium that can be used for the propagation of signals from one point to another. A transmission line may be, for example, a wire, a two-wire line, a coaxial wire, and/or a waveguide.

[0018] For the purposes of this description, the terms “drug,” “drug agent,” “implantable drug agent,” “active agent,” “beneficial agent,” “therapeutic agent,” “therapeutic molecule,” and the like are used interchangeably herein, and may include, for example, small molecules, proteins, enzymes, hormones, nucleosides, nucleotide-like, polysaccharides, glycoproteins, lipoproteins, polypeptides, steroids, analgesics, local anesthetics, antibiotic agents, anti-inflammatory corticosteroids, ocular drugs and synthetic analogs of these species. Some examples of drug agents that may be delivered by devices according to embodiments of the present disclosure are provided later in this description.

[0019] A variety of absorbent materials may be utilized by devices according to embodiments of the present disclosure. The absorbent materials used along with the biopsy component according to embodiments of the present disclosure may be materials that can absorb and retain large amounts of body fluid relative to their own mass. Polymeric absorbents, derived from synthetic or natural polymers, may be particularly useful. In some embodiments, the absorbent materials utilized by devices according to the present disclosure may be water-absorbing polymers known as crosslinked hydrogels. The absorbent polymers which may be suitable for use by devices according to the present disclosure may be broadly categorized into two types: based on charge (e.g., nonionic and ionic), and based on affinity towards water (e.g., hydrophobic and hydrophilic). Ionic polymeric absorbents may be further classified into ionic and anionic. These types of polymers are characterized by their water absorption capacity, swelling rate, swollen gel strength, wicking capacity, sol fraction, residual monomer, ionic sensitivity, and adhesion to the biopsy component of the device. Natural polymers can also be modified to exhibit absorbent properties. For example, graft copolymerization of vinyl monomers onto natural polymers is an efficient approach to achieve these materials. Some examples of natural polymers include starches from different resources and polysaccharides like cellulose, hydroxyethyl cellulose, agar, sodium alginate, and guar gums. These natural polymers may be grafted copolymerized to achieve water absorbing polymers, such as Polyacrylonitrile (PAN), polyacrylamide, and poly (acrylic acid).

[0020] According to an aspect of the present disclosure, an ablation device is provided. The ablation device includes a handle assembly, an ablation electrode extending from the handle assembly, and one or more delivery needles extending from the handle assembly. The ablation electrode includes an ablation needle. The ablation needle includes a distal end portion including a drug delivery port defined therethrough. The ablation device also includes a biopsy tool extending from the handle assembly.

[0021] According to another aspect of the present disclosure, an ablation device is provided. The ablation device includes a handle assembly, an ablation electrode extending from the handle assembly, and one or more delivery needles extending from the handle assembly. The ablation electrode includes an ablation needle. The ablation needle includes a recess defined therein. An absorbent material disposed at least in part within the recess. The ablation device also includes a biopsy tool extending from the handle assembly.

[0022] According to another aspect of the present disclosure, an ablation device is provided. The ablation device includes a handle assembly, an array of ablation electrodes operably associated with the handle assembly, and a biopsy tool including an end-effector assembly operably associated with the handle assembly. One or more ablation electrodes of the array of ablation electrodes include a recess defined therein. An absorbent material is disposed at least in part within the recess.

[0023] According to another aspect of the present disclosure, an ablation system is provided. The ablation system includes a source of electrosurgical energy, a source of coolant fluid, and an ablation device. The ablation device includes a handle assembly and an electrode assembly including an ablation needle extending from the handle assembly. The electrode assembly is operatively connected to the source of electrosurgical energy and fluidly-coupled to the source of coolant fluid. The ablation device also includes one or more delivery needles extending from the handle assembly. The one or more delivery needles are selectively moveable from a first position, wherein the distal end of the delivery needle is disposed proximal to the distal end portion of the ablation needle, to at least a second position, wherein at least the distal end of the delivery needle is disposed distally beyond the
distal end portion of the ablation needle. The ablation device also includes a biopsy tool extending from the handle assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Objects and features of the presently-disclosed ablation devices with drug delivery (and/or contrast agent) components and/or biopsy tissue-sampling components, and electrosurgical systems including the same, will become apparent to those of ordinary skill in the art when descriptions of various embodiments thereof are read with reference to the accompanying drawings, of which:

[0025] FIG. 1A is a diagrammatic illustration of an electrosurgical system including an enlarged, perspective view of an ablation device that includes an array of ablation electrodes, a tissue-sampling needle, and a delivery needle in accordance with an embodiment of the present disclosure;

[0026] FIG. 1B is an enlarged, perspective view of the indicated area of detail of FIG. 1A in accordance with an embodiment of the present disclosure;

[0027] FIG. 2 is an enlarged, perspective view of an ablation system including an electrode array in accordance with an embodiment of the present disclosure;

[0028] FIG. 3 is an enlarged, perspective view of an ablation system including an electrode array in accordance with another embodiment of the present disclosure;

[0029] FIG. 4 is an enlarged, perspective view of an ablation system including an electrode array in accordance with yet another embodiment of the present disclosure;

[0030] FIG. 5 is an enlarged, perspective view of an ablation system including an electrode array in accordance with still another embodiment of the present disclosure;

[0031] FIG. 6 is a diagrammatic illustration of an electrosurgical system including an enlarged, perspective view of an ablation device that includes an array of ablation electrodes, a tissue-sampling device including an end-effector, and a delivery needle in accordance with an embodiment of the present disclosure;

[0032] FIG. 7 is an enlarged, perspective view of the indicated area of detail of FIG. 6 in accordance with an embodiment of the present disclosure;

[0033] FIG. 8 is an enlarged, perspective view of a portion of an ablation device, similar to the ablation device shown in FIGS. 6 and 7, shown with one ablation needle that includes an absorbent surface area, and another ablation needle that includes a drug delivery component and an absorbent surface area, in accordance with an embodiment of the present disclosure;

[0034] FIG. 9 is a diagrammatic illustration of an electrosurgical system including an enlarged, perspective view of an ablation device that includes an array of ablation electrodes, a delivery needle, and a tissue-sampling device including a biopsy forceps in accordance with an embodiment of the present disclosure;

[0035] FIG. 10A is a diagrammatic illustration of an electrosurgical system including an enlarged, perspective view of an ablation device that includes a delivery needle and an array of ablation electrodes, shown with one ablation electrode including an axially-movable, tissue-sampling needle, in accordance with an embodiment of the present disclosure;

[0036] FIG. 10B is an enlarged view of the indicated area of detail of FIG. 10A showing a distal portion of the tissue-sampling needle disposed in a first configuration in accordance with an embodiment of the present disclosure;

[0037] FIG. 10C is an enlarged view of the indicated area of detail of FIG. 10A showing a distal portion of the tissue-sampling needle disposed in a second configuration in accordance with an embodiment of the present disclosure;

[0038] FIG. 11A is an enlarged, perspective view of a portion of an elongated body including an opening defined therein and an absorbent material operably disposed in association with a shaft configured to be selectively, rotatably moveable to position the absorbent material within the opening, shown with the shaft disposed in a first configuration, in accordance with an embodiment of the present disclosure;

[0039] FIG. 11B is an enlarged, perspective view of the portion of the elongated body shown in FIG. 11A, shown with the shaft disposed in a second configuration, in accordance with an embodiment of the present disclosure;

[0040] FIG. 12A is a perspective view of a portion of an ablation device that includes a tip portion in accordance with an embodiment of the present disclosure;

[0041] FIG. 12B is an enlarged, perspective view of the indicated area of detail of FIG. 12A showing the tip portion disposed in a first configuration in accordance with an embodiment of the present disclosure;

[0042] FIG. 12C is an enlarged, perspective view of the tip portion shown in FIG. 12A showing the tip portion disposed in a second configuration in accordance with an embodiment of the present disclosure;

[0043] FIG. 13 is an enlarged, perspective view of a portion of an ablation device including an opening defined therein and an absorbent material operably disposed in association with a shaft, the shaft configured to be selectively, rotatably moveable to position the absorbent material within the opening, in accordance with an embodiment of the present disclosure;

[0044] FIG. 14 is an enlarged, perspective view of a portion of an ablation device including an opening defined therein and a biopsy tool operably disposed in association with a rotatable member configured to be selectively, rotatably moveable to position one or more cutting members of the biopsy tool within the opening in accordance with an embodiment of the present disclosure;

[0045] FIG. 15 is an enlarged, perspective view of a portion of an ablation device that includes a biopsy tool including an absorbent material in accordance with an embodiment of the present disclosure;

[0046] FIG. 16 is a diagrammatic illustration of an absorbent material in accordance with an embodiment of the present disclosure;

[0047] FIG. 17 is an enlarged, perspective view of a portion of a Chiba type biopsy needle;

[0048] FIG. 18 is an enlarged, perspective view of a portion of a Green type biopsy needle;

[0049] FIG. 19 is an enlarged, perspective view of a portion of a Turner type biopsy needle;

[0050] FIG. 20 is an enlarged, perspective view of a portion of a Westcott type biopsy needle;

[0051] FIG. 21 is an enlarged, perspective view of a portion of a Madyatag type biopsy needle;

[0052] FIG. 22 is an enlarged, perspective view of a portion of a Franseen type biopsy needle;

[0053] FIG. 23 is an enlarged, perspective view of a portion of an ablation electrode including a ribbon blade disposed in association with a portion of an ablation needle in accordance with an embodiment of the present disclosure;
FIG. 24 is an enlarged, cross-sectional view of a portion of an ablation device including a barrel portion configured to contain absorbent filaments deployable therefrom and a moveable tip portion in accordance with an embodiment of the present disclosure;

FIG. 25 is an enlarged, perspective view of the indicated area of detail of FIG. 9 in accordance with an embodiment of the present disclosure;

FIG. 26 is an enlarged, perspective view a portion of an ablation device, similar to the ablation device shown in FIGS. 9 and 25, shown with one ablation needle that includes an absorbent surface area, another ablation needle that includes a drug delivery component and an absorbent surface area, and a tissue-sampling device including a configuration of micro-nozzles in accordance with an embodiment of the present disclosure;

FIG. 27 is an enlarged, perspective view of a portion of the tissue-sampling device shown in FIG. 26 including a plurality of drug reservoir divots associated therewith in accordance with an embodiment of the present disclosure;

FIG. 28 is an enlarged, perspective view of a portion of an ablation needle that includes an interchangeable sleeve member including a plurality of drug reservoir divots associated therewith in accordance with an embodiment of the present disclosure;

FIG. 29A is a diagrammatic illustration of an electrosurgical system including a medical laser device with a tissue-sampling component in accordance with an embodiment of the present disclosure;

FIG. 29B is an enlarged, perspective view of the indicated area of detail of FIG. 29A in accordance with an embodiment of the present disclosure; and

FIG. 30 is a diagrammatic illustration showing the relation of fiber tip distance from tissue for cutting effect, hemostasis effect, and ablation effect in accordance with an embodiment of the present disclosure.

DETAILED DESCRIPTION

Hereinafter, embodiments of the presently disclosed ablation devices with drug delivery (and/or contrast agent) components and/or biopsy tissue-sampling components, and electrosurgical systems including the same, are described with reference to the accompanying drawings. Like reference numerals may refer to similar or identical elements throughout the description of the figures. As shown in the drawings and as used in this description, and as is traditional when referring to relative positioning on an object, the term “proximal” refers to that portion of the device, or component thereof, closer to the user and the term “distal” refers to that portion of the device, or component thereof, farther from the user.

This description may use the phrases “in an embodiment,” “in embodiments,” “in some embodiments,” or “in other embodiments,” which may each refer to one or more of the same or different embodiments in accordance with the present disclosure.

Various embodiments of the present disclosure provide an energy-delivery device with a fluid-cooled ablation electrode assembly. Various embodiments of the present disclosure provide energy-delivery devices including ablation needles with drug delivery and/or contrast agent components. Various embodiments of the present disclosure provide biopsy tools, e.g., end-effectors, micro-forceps, micro-nozzles, and absorbent materials. Various embodiments of the present disclosure provide an energy-delivery device with tissue-sampling components and one or more fluid-cooled ablation electrodes. Embodiments may be suitable for use with Cool-tip™ RF ablation devices. Embodiments may be suitable for utilization in open surgical applications. Embodiments may be suitable for utilization with endoscopic and laparoscopic surgical procedures. Embodiments may be implemented using electromagnetic radiation at microwave frequencies, RF frequencies or at other frequencies.

Various embodiments of the present disclosure provide an electrosurgical system including an energy-delivery device provided with one or more biopsy tools and/or ablation needles with drug delivery (and/or contrast agent) components. Various embodiments of the presently disclosed electrosurgical systems may be suitable for microwave ablation and for use to pre-coagulate tissue for microwave ablation assisted surgical resection. Various embodiments of the presently disclosed electrosurgical systems including an ablation device may include any feature or combination of features of the ablation device embodiments disclosed herein.

Various energy-delivery device embodiments include absorbent materials, such as materials that can absorb and retain large amounts of body fluid relative to their own mass. Some examples of suitable absorbent materials include polymeric absorbers, e.g., derived from synthetic or natural polymers. In general, absorbent materials are water-absorbing polymers known as crosslinked hydrogels, which are not water soluble but absorb aqueous solutions through hydrogen bonding with water molecules. The total absorbency and swelling capacity of a cross-linked hydrogel polymer may depend upon the type and degree of cross-linkers used to make the gel. Materials with a low density of cross-linkers in the polymer network generally exhibit a higher absorbent and swelling capacity. These types of gels commonly have a softer and stickier gel formation. High cross-link density polymers exhibit lower absorbent capacity and swell, but the gel strength is firmer and can maintain particle shape even under modest pressure. The polymer chains in the hydrogels are crosslinked by covalent bonding. However, the polymer chains can be cross-linked by noncovalent bonding as well, and such polymer networks are called physical gels.

Absorbent polymers that may be suitable for use in accordance with embodiments of the present disclosure may be categorized into two types: e.g., nonionic and ionic; and based on the material’s affinity towards water, e.g., hydrophobic and hydrophilic. Ionic polymeric absorbents may be further classified into cationic and anionic. These types of polymers may be characterized by their water absorption capacity, swelling rate, swollen gel strength, wicking capacity, sol fraction, residual monomer, ionic sensitivity, and adhesion to the biopsy component of the device.

Natural polymers can also be modified to exhibit absorbent properties. For example, graft copolymerization of vinyl monomers onto natural polymers is an efficient approach to achieve these materials. Examples of natural polymers are starches from different resources and polysaccharides like cellulose, hydroxyethyl cellulose, agar, sodium alginate, and guar gums. These polymers can be graft copolymerized to achieve water absorbing polymers. Polyacrylonitrile (PAN), polyacrylamide, and poly(acrylic acid) have been frequently grafted, mostly onto starch.

Drug agents which may be delivered by devices according to embodiments of the present disclosure include drugs which act on the peripheral nerves, adrenergic recep-
tors, cholinergic receptors, the skeletal muscles, the cardiovascular system, smooth muscles, the blood circulatory system, synaptic sites, neuroeffector junctional sites, endocrine and hormone systems, the immunological system, the reproductive system, the skeletal system, autocrine systems, the alimentary and excretory systems, the histamine system and the central nervous system. Some examples of implantable drug agents which may be delivered by devices according to embodiments of the present disclosure are provided later in this description.

[0070] In accordance with various embodiments, the combination of tissue ablation and drug delivery may help to reduce and/or eliminate tumor recurrence. In accordance with various embodiments, the combination of biopsy tools and ablation devices with drug delivery and/or contrast agent components may help to reduce procedure times and/or eliminate the need for a separate, biopsy tissue-sampling device.

[0071] FIG. 1A shows an electrosurgical system (shown generally as 100) in accordance with an embodiment of the present disclosure that includes an ablation device 10 including a delivery needle 101 and a tissue-sampling needle 111 for use with various surgical procedures. Ablation device 10 generally includes a handle assembly 150 and an array of ablation electrodes 110. Ablation electrodes 110 are operatively connected to an electrosurgical power generating source 28, e.g., a microwave or radio frequency (RF) electrosurgical generator. An embodiment of the ablation electrode assembly 110 of the ablation device 10 shown in FIG. 1A is described in more detail later in this description with reference to FIG. 2. Ablation device 10 may include additional, fewer, or different components than shown in FIG. 1A, depending upon a particular purpose or to achieve a desired result. In some embodiments, as shown in FIGS. 1A and 1B, the tissue-sampling needle 111 includes a micro-needle 132 configured to be slidely movable within the tissue-sampling needle 111.

[0072] In some embodiments, electrosurgical system 100 (also referred to herein as ablation system 100) may include a controller 26 for controlling and/or monitoring the operating parameters of the ablation system 100. In some embodiments, as shown in FIG. 1A, the controller 26 is communicatively-coupled to the electrosurgical power generating source 28. Controller 26 may additionally, or alternatively, be communicatively-coupled to a fluid source (e.g., coolant source 48 shown in FIG. 2). In some embodiments, electrosurgical system 100 includes an imaging system (not shown) capable of generating image data, and the controller 26 may be communicatively-coupled to the imaging system. Controller 26 may include any type of computing device, computational circuit, or any type of processor or processing circuit capable of executing a series of instructions that are stored in a memory (not shown) associated with the controller 26.

[0073] Ablation electrode assembly 110 includes an elongated ablation needle 112. In some embodiments, coolant fluid (and/or drug agent) may circulate to a tip portion for cooling of the ablation needle 112. One or more sensors may be utilized to measure temperatures at various locations in the proximity of the tip portion. One or more sensor devices, or components thereof, may be disposed outside the distal end portion 118 of the ablation needle 112. The sensed temperature may be utilized to control the flow of energy and/or the flow of coolant to attain the desired ablation while maintaining the maximum temperature substantially below a predetermined temperature, e.g., 100°C.

[0074] Ablation device 10 is adapted to allow the user to selectively position the delivery needle 101 in tissue. Ablation device 10 may additionally, or alternatively, be adapted to allow the user to selectively position the tissue-sampling needle 111 in tissue. For ease of explanation and understanding, the delivery needle 101 and the tissue-sampling needle (also referred to herein as a biopsy needle) 111 are described below as selectively positionable with respect to fixed structures, or portions thereof, of the ablation device 10, e.g., in relation to the distal end portion 118 of the ablation needles 112 and/or in relation to the distal end 117 of the handle assembly 150.

[0075] In some embodiments, ablation device 10 is adapted to allow the user to selectively position the delivery needle 101 from one or more first configurations, wherein the distal end 123 of the delivery needle 101 is positioned proximal to the distal end portion 118 of the ablation needles 112, to one or more second configurations, wherein at least the distal end 123 of the delivery needle 101 is positioned distally beyond the distal end portion 118 of the ablation needles 112. Ablation device 10 may additionally, or alternatively, be adapted to allow the user to selectively position the biopsy needle 111 from one or more first configurations, wherein the distal end 133 of the biopsy needle 111 is positioned proximal to the distal end portion 118 of the ablation needles 112, to one or more second configurations, wherein at least the distal end 133 of the biopsy needle 111 is positioned distally beyond the distal end portion 118 of the ablation needles 112.

[0076] Handle assembly 150 generally includes a handle body 151 configured to support the ablation electrodes 110, the delivery needle 101, and the biopsy needle 111 at the distal end 117 of the handle body 151. Handle assembly 150 includes a slideably moveable member 160 adapted to allow the user to selectively move the delivery needle 101 and/or the biopsy needle 111. Slideably moveable member 160 may include one or more buttons having a desired ergonomic form operably associated with the handle body 151. In some embodiments, as shown in FIG. 1A, slideably moveable member 160 includes a first member 161, e.g., adapted to allow the user to selectively move the delivery needle 101, and a second member 162, e.g., adapted to allow the user to selectively move the biopsy needle 111, wherein the first member 161 and the second members 162 are independently, slideably moveable. In some embodiments, slideably moveable member 160 may additionally, or alternatively, be configured to allow the user to selectively initiate/activate the delivery of drug and/or contrast agent from the supply line 14 to the delivery needle 101. Handle assembly 150 may additionally, or alternatively, include a slidesly moveable member 190, e.g., thumb-slide actuator, adapted to allow the user to selectively position a micro-needle 132 from one or more first configurations, wherein the micro-needle 132 is positioned within the biopsy needle 111, to one or more second configurations, wherein the micro-needle 132, or portion thereof, is positioned distally beyond the distal end portion 133 of the biopsy needle 111.

[0077] Handle assembly 150 may have various configurations. In some embodiments, the handle body 151 defines therein a handle-body chamber 176 having an interior space configured to accommodate one or more components of the ablation device 10, e.g., a hub (e.g., hub 230 shown in FIG. 2). Handle body 151 may include one or more internal walls (not
shown) configured to partition the handle-body chamber 176 into one or more compartments. Handle assembly 150 may be formed of any suitable material or combination of materials by any suitable process. In some embodiments, the ablation device 10 may be adapted to be a reusable device. Autoclavable materials may be used to form the housing 151, and/or other components of the ablation device 10, to provide for a sterilizable device.

[0078] Handle assembly 150 or portions thereof, may be formed from two housing halves (not shown). Each half of the housing may include a series of mechanical interfacing components (not shown) configured to matingly engage with a corresponding series of mechanical interfaces (not shown) to align the two housing halves about the inner components and assemblies of the ablation device 10. It is contemplated that the housing halves (as well as other components described herein) may be assembled together with the aid of alignment pins, snap-like interfaces, tongue and groove interfaces, locking tabs, adhesive ports, etc., utilized either alone or in combination for assembly purposes.

[0079] Ablation electrodes 110 are operatively connected to an electrosurgical power generating source 28, and may be disposed in fluid communication with a coolant source (e.g., coolant source 48 shown in FIG. 2). A transmission line 15 may be provided to electrically-couple the ablation device 10 to the electrosurgical power generating source 28. Power generating source 28 may be any generator suitable for use with electrosurgical devices and may be configured to provide various frequencies of energy. Examples of electrosurgical generators that may be suitable for use as a source of electrosurgical energy include generators sold by Covidien Surgical Solutions of Boulder, Colo., e.g., FORCE EZ™ electrosurgical generator, FORCE FX™ electrosurgical generator, and FORCE TRIAD™ electrosurgical generator FORCE ICM™ generator, FORCE 2™ generator, Surgistat™ II, or other generators which may perform different or enhanced functions.

[0080] In some embodiments, transmission line 15 may provide a conduit (not shown) configured to provide coolant from a coolant source, e.g., deionized water, or other suitable cooling medium, for cooling one or more components of the ablation device 10, such as the ablation electrodes 110. Transmission line 15 may additionally, or alternatively, provide a conduit (not shown) configured to provide drugs and/or contrast agent to the handle assembly 150 and/or the delivery needle 101.

[0081] A drug and/or contrast agent supply line 14 may be provided to fluidly-couple the ablation device 10 to a source of the drug and/or contrast agent delivery supply for supplying drugs and/or contrast agent to the handle assembly 150 and/or the delivery needle 101. Handle assembly 150 may include one or more fluid conduits (not shown) associated with the handle body 151 configured to provide fluid communication between the supply line 14 and the delivery needle 101.

[0082] In some embodiments, handle-body chamber 176 may include an interior space configured to accommodate a housing (not shown) containing a reservoir of drugs. In such case, handle body 151 may be provided with an opening covered by a removable cover plate, e.g., to allow removal of the housing containing a reservoir of the drug delivery supply. In some embodiments, a coolant supply line 18 leads from the handle assembly 150 to a coolant source (e.g., coolant source 48 shown in FIG. 2).

[0083] Ablation device embodiments, e.g., ablation device 10 shown in FIG. 1A and/or ablation device 60 shown in FIG. 6, may include a user interface, e.g., configured to provide user-input capabilities and/or capabilities for simplification use and/or programming of the ablation device 10 and/or the electrosurgical power generating source 28. Some examples of operating parameters associated with the power generating source 28 that may be adjusted include: temperature, impedance, power, current, voltage, mode of operation, and duration of application of electromagnetic energy. The user interface may be adapted to enable a user to selectively configure one or more operating parameters of the ablation device 10, or component thereof, e.g., depending upon a particular purpose and/or to achieve a desired surgical outcome.

[0084] During ablation, e.g., using the electrosurgical system 10, the ablation electrodes 110 are inserted into or placed into the body of a patient, e.g., percutaneously or intraoperatively. Ultrasound or computed tomography (CT) guidance may be used to accurately guide the ablation electrodes 110 into the area of tissue to be treated. Electrosurgical power generating source 28 may be the source of high-frequency voltage which produces the high-frequency current that emanates from the distal end portion 118 of ablation needles 112. Following treatment or ablation of the target tissue, ablation electrodes 110 may be withdrawn from the target site and introduced into another target site, into the same target site from a different angle or approach, or in substantially the same location.

[0085] FIG. 2 shows an ablation system 200 in accordance with an embodiment of the present disclosure that includes an electrode array 20. Electrode array 20 may include one or more ablation electrodes 110. Electrode array 50 may include any feature or combination of features disclosed herein. In some embodiments, as shown in FIG. 2, electrode array 20 includes three ablation electrodes 110 supported on and/or operatively connected to a hub 230, which carries electrical and coolant connections. Electrode array 20 is operatively connected to an electrosurgical power generating source 28, e.g., a microwave or radio frequency (RF) electrosurgical generator. Ablation electrodes 110 of the electrode array 20 are disposed in fluid communication with a coolant source 48 via the hub 230.

[0086] Hub 230 is adapted to provide fluid to the electrodes 110, and may have a variety of suitable shapes, e.g., cylindrical, rectangular, etc. Hub 230 generally includes a hub body 345 defining a chamber 332 therein. In some embodiments, hub body 345 defines an outlet fluid port (not shown) and an inlet fluid port (not shown) disposed in fluid communication with the chamber 332. In some embodiments, coolant chamber 332 may include baffles, multiple lumens, flow restricting devices, or other structures that may redirect, concentrate, or disperse flow depending on their shape. Examples of coolant chamber embodiments are disclosed in commonly assigned U.S. patent application Ser. No. 12/350,292 filed on Jan. 8, 2009, entitled “CHOKED DIELECTRIC LOADED TIP DIPOLE MICROWAVE ANTENNA,” commonly assigned to the inventors and commonly assigned U.S. patent application Ser. No. 12/401,268 filed on Mar. 10, 2009, entitled “COOLED DIELECTRICALLY BUFFERED MICROWAVE DIPOLE ANTENNA,” and U.S. Pat. No. 7,311,703, entitled “DEVICES AND METHODS FOR COOLED MICROWAVE ANTENNAS,” the disclosures of which are incorporated herein by reference in their entirety.

[0087] As seen in FIGS. 1A and 2, ablation electrode assembly 110 includes an elongated ablation needle 112.
Ablation needle 112 includes a distal end portion 118 including a tapered portion, which may terminate in a sharp tip to allow for insertion into tissue with minimal resistance. Ablation needle 112 generally includes a proximal end portion configured for connection to a hub (e.g., hub 230 shown in FIG. 2). Ablation needle 112 is fabricated from an electrically-conductive material, e.g., stainless steel, titanium, etc. In accordance herewith, temperatures at, or near the tip 118 may be controlled by controlling the flow of coolant fluid through the ablation needle 112. In this manner, the temperature of the surface area of the distal end portion 118 in contact with tissue is controllable. The shape and size of the ablation needle 112 may be varied from the configuration depicted in FIGS. 1A and 2.

Ablation electrode assembly 110 includes an insulative coating 122 over at least a portion of the length of the ablation needle 112. In some embodiments, the insulative coating 122 is disposed over substantially the length of the ablation needle 112. In some embodiments, the insulative coating 122 extends from the hub 230 to the distal end portion 118 of the ablation needle 112, such that the distal end portion 118 of the ablation needle 112 is exposed or non-insulated. Insulative coating 122 is used to prevent the flow of electrical current from the shaft portion 114 of the ablation needle 112 into surrounding tissue. Insulative coating 122 shields the intervening tissue from RF current, so that such tissue is not substantially heated along the length of shaft portion 114 except by the heating effect from the distal end portion 118 which is exposed. The shape, size and number of ablation electrodes 110 of the electrode array 20 may be varied from the configuration depicted in FIG. 2.

During operation, cooling the ablation electrodes 110 may enhance the overall heating pattern of the ablation electrodes, prevent damage to the ablation electrodes, and/or prevent harm to the clinician or patient. Coolant source 48 may be any suitable housing containing a reservoir of coolant fluid "F", and may maintain coolant fluid "F" at a predetermined temperature. For example, the coolant source 48 may include a cooling unit (not shown) that cools the returning coolant fluid "F" from the ablation electrode assembly 110. Ablation system 100 may include a coolant supply system (not shown) adapted to provide the coolant fluid "F", e.g., from the coolant source 48, to the hub 230. In some embodiments, one or more components of a coolant supply system may be integrated fully or partially into the electrosurgical power generating source 28.

Coolant fluid "F" may be any suitable fluid that can be used for cooling or buffering the electrodes 110, e.g., deionized water, or other suitable cooling medium. Coolant fluid "F" may have dielectric properties and may provide dielectric impedance buffering for the ablation needle 112. Coolant fluid "F" composition may vary depending upon desired cooling rates and the desired tissue impedance matching properties. Various fluids may be used, e.g., liquids including, but not limited to, water, saline, perfluorocarbon, such as the commercially available Fluorinert® perfluorocarbon liquid offered by Minnesota Mining and Manufacturing Company (3M), liquid chlorodifluoromethane, etc. In other variations, gases (such as nitrous oxide, nitrogen, carbon dioxide, etc.) may also be utilized as the cooling fluid. In yet another variation, a combination of liquids and/or gases, including, for example, those mentioned above, may be utilized as the coolant fluid "F".

In alternative embodiments (not shown), the ablation electrode assembly 110 may include an inflatable balloon member which may be connected to walls of the electrode assembly 110 using any fastening technique, e.g., adhesive, sonic welding, or by any other suitable process. The inflatable balloon member (not shown) may be operable in conjunction with the delivery of a drug agent. The walls of the electrode assembly 110 may be provided with an opening or port disposed and configured to place an inflation lumen in fluid communication with the inflatable balloon member, e.g., to allow drug-delivery flow supplied via the inflation lumen to be used to operate the inflatable balloon member, e.g., drug-eluting balloon. In some embodiments, the electrode assembly 110 may be adapted to allow user control of operational characteristics of the drug-eluting balloon, e.g., rate of inflation, inflation volume, and pressure exerted by the inflatable balloon member on the tissue surrounding the inflatable balloon member.

FIG. 3 shows an ablation system 300 in accordance with an embodiment of the present disclosure that includes an electrode array 30. Electrode array 30 includes three ablation electrodes 310 supported on and/or operatively connected to the hub 230 shown in FIG. 2. Electrode array 30 is operatively connected to an electrosurgical power generating source 28, e.g., a microwave or radio frequency (RF) electrosurgical generator, and may be disposed in fluid communication with a drug reservoir 448. The shape, size, position and number of the ablation electrodes 310 may be varied from the configuration depicted in FIG. 3. Ablation electrodes 310 are similar to the ablation electrodes 110 shown in FIG. 2, except for the distal end portions 318 of the ablation needles 112, and further description with respect to the same elements is omitted herein for brevity.

As seen in FIG. 3, the ablation needle 112 includes a distal end portion 318 including a tapered portion, which may terminate in a sharp tip to allow for insertion into tissue with minimal resistance. The distal end portion 318 of the ablation needle 112 of the electrode electrode 310 includes one or more drug delivery ports 330. The shape and size of the distal end portion 318 of the ablation needle 112 may be varied from the configuration depicted in FIG. 3.

FIG. 4 shows an ablation system 400 in accordance with an embodiment of the present disclosure that includes an electrode array 40. Electrode array 40 includes two ablation electrodes 410, and may include one or more ablation electrodes 110, which are supported on and/or operatively connected to the hub 230. Ablation electrodes 410 are similar to the ablation electrode 110, except for the ablation needles 412, and further description with respect to the same elements is omitted herein for brevity. Electrode array 40 may include additional, fewer, or different ablation electrodes than shown in FIG. 4, depending upon a particular purpose or to achieve a desired result.

Ablation needles 412 define a recess 439 therein. The recess 439 may be formed in any suitable shape, and may define one or more receptacles of any suitable volume to contain one or more materials 340 capable of absorbing tissue and/or fluid. Absorbent material 340 may include one or more absorbent layers, e.g., adapted to absorb tissue and/or fluid. In some embodiments, the absorbent material 340 includes polymeric absorbents, e.g., derived from synthetic or natural polymers.

Recess 439 may have any suitable depth less than a through-penetration depth. In some embodiments, the pres-
ently-disclosed ablation needle (e.g., ablation needle 1112 shown in FIGS. 11A and 11B) includes an opening defined therethrough, and may be configured to allow an absorbent material to be selectively positionable within the opening, e.g., to absorb tissue and/or fluid for biopsy.

FIG. 5 shows an ablation system 500 in accordance with an embodiment of the present disclosure that includes an electrode array 50. Electrode array 50 may include any feature or combination of features disclosed herein. Electrode array 50 includes two ablation electrodes 310 (also shown in FIG. 3) and an ablation electrode 510, which are supported on and/or operatively connected to the hub 230. Ablation electrode 510 is similar to the ablation electrodes 310 shown in FIG. 2, except for the ablation needle 512, and further description with respect to the same elements is omitted herein for brevity.

As seen in FIG. 5, the ablation needle 512 includes a recess 439 defined therein. An absorbent material 440 is disposed in association with the recess 439. In some embodiments, the absorbent material 440 includes polymeric absorbents, e.g., derived from synthetic or natural polymers.

Ablation needle 512 includes a distal tip portion 318 including a drug delivery port 330. Electrode array 50 may include additional, fewer, or different ablation electrodes than shown in FIG. 5, depending upon a particular purpose or to achieve a desired result.

FIG. 6 shows an embodiment of an electrosurgical system (shown generally as 600) for use with various surgical procedures that includes an ablation device 60 including a delivery needle 101 and a tissue-sampling device 680. Ablation device 60 generally includes a handle assembly 650 and an array of ablation electrodes 110. Handle assembly 650 may have various configurations. Ablation device 60 may include additional, fewer, or different components than shown in FIG. 6, depending upon a particular purpose or to achieve a desired result. Ablation device 60 may include any feature or combination of features of the ablation device embodiments disclosed herein.

In some embodiments, the handle body 151 defines therein a handle-body chamber 676 having an interior space configured to accommodate one or more components of the ablation device 60. Handle body 451 may include one or more internal walls (not shown) configured to partition the handle-body chamber 676 into one or more compartments. Handle assembly 650 may be formed of any suitable material or combination of materials by any suitable process. In some embodiments, the ablation device 60 may be adapted to be a reusable device. Autoclavable materials may be used to form the handle body 651, and/or other components of the ablation device 60, to provide for a sterilizable device.

Ablation electrodes 110 are operatively connected to an electrosurgical power generating source 28, e.g., a microwave or radio frequency (RF) electrosurgical generator, and may be disposed in fluid communication with a drug reservoir (e.g., reservoir 448 shown in FIG. 3). A transmission line 15 may be provided to electrically-couple the ablation device 60 to the electrosurgical power generating source 28. Transmission line 15 may additionally provide a conduit (not shown) configured to provide coolant from a coolant source, e.g., deionized water, or other suitable cooling medium, for cooling one or more components of the ablation device 60, such as the ablation electrodes 110.

In some embodiments, handle-body chamber 676 may include an interior space configured to accommodate a housing (not shown) containing a reservoir of drugs. In such case, handle assembly 650 may be provided with an opening covered by a removable cover plate, e.g., to allow removal and/or replacement of the housing containing a reservoir of the drug delivery system. In some embodiments, a coolant supply line 18 leads from the handle assembly 650 to a coolant source (e.g., coolant source 48 shown in FIG. 2).

In some embodiments, electrosurgical system 600 (also referred to herein as ablation system 100) may include a controller (e.g., controller 26 shown in FIG. 1A) for controlling and/or monitoring the operating parameters of the ablation system 600. The controller may include logic, circuitry and/or code adapted to control the electrosurgical power generating source 28 and/or a coolant source (e.g., coolant source 48 shown in FIG. 2) responsive to one or more electrical signals received from one or more sensors and/or one or more user-input devices.

Delivery needle 101 is selectively moveable from one or more first configurations, wherein the distal end 123 of the delivery needle 101 is positioned proximal to the distal end portion 118 of the ablation needle 110 to one or more second configurations, wherein at least the distal end 123 of the delivery needle 101 is positioned distally beyond the distal end portion 118 of the ablation needle 110. In some embodiments, the delivery needle 101 may be advanced and retracted by way of a slideably moveable member 460, e.g., a thumb-slide actuator, or the like, which may be adapted to keep the delivery needle retracted during the ablation portion of the procedure, then extended post ablation to administer the drug and/or contrast agents to the target site. Slideably moveable member 460 may include a button 461 having a desired ergonomic form operably associated with the handle body 651. The button 461 may be configured to allow the user to selectively initiate/activate the delivery of drug and/or contrast agent from the supply line 14 to the delivery needle 101.

Tissue-sampling device 680 includes an end-effector 683. As seen in FIG. 7, the end-effector assembly 683 generally includes two jaw members 681 and 683 disposed in opposing relation relative to one another. One or more components of the ablation device 60, e.g., the handle assembly 650, the slideably moveable member 690, and/or the end-effector assembly 683, may be adapted to mutually cooperate to grasp and/or divide tissue.

FIG. 8 shows a portion of an ablation device 80 in accordance with an embodiment of the present disclosure that includes the delivery needle 101 and the tissue-sampling device 680 of the ablation device 60 shown in FIGS. 6 and 7. Ablation device 80 may include one or more of the above-described ablation electrodes of the presently-disclosed ablation devices. In some embodiments, as shown FIG. 8, the ablation device 80 includes an ablation electrode 110, an ablative electrode 510, and an ablative electrode 410. Ablation device 80 may include any feature or combination of features of the ablation device embodiments disclosed herein.

FIG. 9 shows an embodiment of an electrosurgical system (shown generally as 900) for use with various surgical procedures that includes an ablation device 90 including an array of ablation electrodes 110, a delivery needle 101, and a tissue-sampling device 980 including a biopsy forceps 983. Electrosurgical system 900 is similar to the electrosurgical system 600 shown in FIG. 6, except for the tissue-sampling device 980, and further description with respect to the same elements is omitted herein for brevity. Ablation device 90 may include additional, fewer, or different components than
shown in FIG. 9, depending upon a particular purpose or to achieve a desired result. Ablation device 90 may include any feature or combination of features of the ablation device embodiments disclosed herein.

[0109] Tissue-sampling device 980 is configured to allow the biopsy forceps 983 to be selectively moveable distally from the distal end 981 of the tissue-sampling device 980. As best seen in FIG. 25, the biopsy forceps 983 is coupled to an elongated shaft 984 and generally includes two jaw members 981 and 983 disposed in opposing relation relative to one another. In some embodiments, the shaft 984 is coupled to the slideably moveable member 690 (FIG. 9), e.g., to allow the biopsy forceps 983 to be selectively positionable and/or to move at least one jaw member relative to the other jaw member to grasp tissue therebetween. In some embodiments, as shown in FIG. 25, the tissue-sampling device 980 includes a port 987 defined in the distal end 981. Port 987 may be configured to allow suction and/or irrigation.

[0110] In some embodiments, electrosurgical system 900 may include a controller (e.g., controller 26 shown in FIG. 1A) for controlling and/or monitoring the operating parameters of the ablation system 900. The controller may include logic, circuitry and/or code adapted to control the electrosurgical power generating source 28 and/or a coolant source (e.g., coolant source 48 shown in FIG. 2) responsive to one or more electrical signals received from one or more sensors and/or one or more user-input devices.

[0111] In some embodiments, as shown in FIG. 25, the tissue-sampling device 980 includes a camera device 985. Camera device 985 may include a micro-lens and a CCD chip.

[0112] FIG. 10A shows an embodiment of an electrosurgical system (shown generally as 1000) for use with various surgical procedures that includes an ablation device 1010 including an array of ablation electrodes 110 and the delivery needle 101 of the ablation device 10 shown in FIG. 1. Ablation device 1010 includes an ablation electrode 1011. As shown in FIGS. 10A through 10C, the ablation electrode 1011 includes a tissue-sampling needle 1023 configured to be slideably moveable within the elongated ablation needle 1014. Electrosurgical system 1000 is similar to the electrosurgical system 100 shown in FIG. 1, except for the ablation electrode 1011, and further description with respect to the same elements is omitted herein for brevity.

[0113] Ablation device 1010 may include additional, fewer, or different components than shown in FIG. 10A, depending upon a particular purpose or to achieve a desired result. Ablation device 1010 may include any feature or combination of features of the ablation device embodiments disclosed herein.

[0114] FIG. 10B shows a distal portion of the ablation electrode 1011 with the tissue-sampling needle 1023 shown disposed in a first configuration. FIG. 10C shows a distal portion of the ablation electrode 1011 with the tissue-sampling needle 1023 shown disposed in a second configuration.

[0115] FIGS. 11A and 11B show a portion of a sleeve 1112 and an absorbent material 1190 operably disposed in association with a shaft 1103. Sleeve 1112 includes an opening 1114 defined therethrough. Shaft 1103 is disposed at least in part within the sleeve 1112 and configured to be selectively, rotatably moveable to position the absorbent material 1190 within the opening 1114.

[0116] FIGS. 12A through 12C show an ablation device (shown generally as 1200 in FIG. 12A) in accordance with an embodiment of the present disclosure. As seen in FIG. 12A, the ablation device 1200 includes a sleeve 1212, e.g., an ablation needle, including a tip portion 1223. Tip portion 1223 includes a chamber 1214, which may have a variety of suitable shapes, e.g., cylindrical, rectangular, etc. In some embodiments, as shown in FIGS. 12B and 12C, chamber 1214 has a slot-like shape. An absorbent material 1290 is disposed within the chamber 1214. Absorbent material 1290 may include any suitable material configured for uptake of cellular material and biological fluids. In some embodiments, the absorbent material 1290 includes polymers, e.g., absorbents, e.g., derived from synthetic or natural polymers.

[0117] As cooperatively shown in FIGS. 12B and 12C, ablation device 1200 is adapted to allow the user to selectively expose the chamber 1214 containing the absorbent material 1290. In some embodiments, sleeve 1212 is rotated 90 degrees to expose the chamber 1214 containing the absorbent material 1290.

[0118] FIG. 13 shows a portion of an ablation device 1300 and an absorbent material 1390 operably disposed in association with a shaft 1303 configured to be selectively, rotatably moveable to position the absorbent material 1390 within an opening 1314 formed in the ablation needle 1312 in accordance with an embodiment of the present disclosure.

[0119] FIG. 14 shows a portion of an ablation device 1400 in accordance with an embodiment of the present disclosure that includes an aperture or opening 1450 defined in a distal portion 1410 of the ablation device 1400. Ablation device 1400 includes a cutting mechanism 1461 configured to be selectively, rotatably moveable within the distal portion 1410.

[0120] FIG. 15 shows a portion of an ablation device 1500 including a biopsy tool in accordance with an embodiment of the present disclosure. Ablation device 1500 includes an ablation needle 1512 including an opening 1514 defined therethrough. As seen in FIG. 15, an absorbent material 1590 is provided to fill the opening 1514.

[0121] FIG. 16 is a diagrammatic illustration of an absorbent material 1600 in accordance with an embodiment of the present disclosure. Absorbent material 1600 may be any biomaterial which can be introduced in the body and having the potential to absorb body fluids and/or tissue samples for the purpose of biopsy upon withdrawal. Some examples of materials that may be suitable for the absorbent material 1600 include hydrogels, textile-based biomaterials, composite materials (e.g., wherein high absorbance has been engineered using a combination of materials), and naturally derived materials (e.g., those from cellulose, shellfish, etc.). Absorbent material 1600 may include any material having desirable absorbency, texture, shape, size, physical, mechanical and other properties. Absorbent material 1600 may include any material having desirable properties such as high surface-area-to-volume ratio, film thinness, porosity, and light weight. In some embodiments, the absorbent material 1600 may include nanofibres. Absorbent material 1600 may be a composite absorbent material including one or more layers bonded together, and may include one or more reinforcing layers.

[0122] In some embodiments, the absorbent material 1660 includes water-absorbing polymers known as crosslinked hydrogels. Hydrogels, which are not water soluble, absorb aqueous solutions through hydrogen bonding with water molecules. The total absorbency and swelling capacity of a crosslinked hydrogel polymer may be controlled by the type and degree of cross-linkers used to make the gel. Low density of cross-linkers in the polymer network generally exhibits a
higher absorbent and swelling capacity. These types of gels typically have a softer and stickier gel formation. High cross-link density polymers exhibit lower absorbent capacity and swell, but the gel strength is firmer and can maintain particle shape even under modest pressure. The polymer chains in the hydrogels are crosslinked by covalent bonding; however, the polymer chains may be cross-linked by noncovalent bonding as well, such networks are called physical gels.

[0123] FIG. 17 shows a portion of a Chiba type biopsy needle 1700. Chiba type biopsy needle 1700 includes a tip portion 1724 configured with a beveled tip. In some embodiments, the bevel of the tip portion 1724 may be 25 degrees.

[0124] FIG. 18, a portion of a Green type biopsy needle 1800 is shown. Green type biopsy needle 1800 includes a tip portion 1824 configured with a beveled tip. In some embodiments, the bevel of the tip portion 1824 may be 90 degrees.

[0125] FIG. 19 shows a portion of a Turner type biopsy needle 1900. Turner type biopsy needle 1900 includes a tip portion 1924 configured with a beveled tip. In some embodiments, the bevel of the tip portion 1924 may be 45 degrees.

[0126] FIG. 20 shows a portion of a Westcott type biopsy needle 2000. Westcott type biopsy needle 2000 includes a tip portion 2024 configured with a slotted type tip.

[0127] FIG. 21, a portion of a Madaya type biopsy needle 2100 is shown. Madaya type biopsy needle 2100 includes a tip portion 2124 configured with a beveled tip. In some embodiments, the bevel of the tip portion 2124 may be 90 degrees.

[0128] FIG. 22 shows a portion of a Fransen type biopsy needle 2200. Fransen type biopsy needle 2200 includes a tip portion 2224 configured with a trephine type tip.

[0129] FIG. 23 shows a portion of an ablation electrode 2300 including an ablation needle 2312. Ablation electrode 2300 includes a ribbon blade 2301 disposed in association with an inner surface of the ablation needle 2312. Ablation needle 2312 may include a shape edge 2305, e.g., to facilitate coring. During a procedure, when the ablation electrode 2300 is inserted into tissue, the ablation needle 2312 can be rotated to core tissue with the shape edge 2305. Upon rotation of the ablation needle 2312, the resulting rotation of the ribbon blade 2301 slices tissue free, and the sample may be compressed as the ablation needle 2312 is rotated before being withdrawn.

[0130] FIG. 24 shows a portion of an ablation device 2400 including a barrel portion 2414 configured to contain absorbent filaments 2491, which are selectively deployable therefrom deployable therefrom, and a moveable tip portion 2423 in accordance with an embodiment of the present disclosure.

[0131] In the deployed configuration shown in FIG. 24, the tip portion 2423 is spaced apart from the barrel portion 2414 to allow the absorbent filaments 2491 to deploy from the chamber defined by the barrel 2414. In some embodiments, the absorbent filaments 2491 include polymeric absorbents, e.g., derived from synthetic or natural polymers.

[0132] FIG. 26 shows a portion of an ablation device 260 in accordance with an embodiment of the present disclosure that includes the tissue-sampling device 980 of the ablation device 60 shown in FIGS. 9 and 25. In some embodiments, the ablation device 260 may additionally include the ablation electrode 110, the ablation electrode 510, and/or the ablation electrode 410 of the ablation device 80 shown in FIG. 8. Ablation device 260 may include any feature or combination of features of the ablation device embodiments disclosed herein.

[0133] Ablation device 260 includes a tissue-sampling needle 2601 including a tissue-collection member 2690 adapted to be slideably moveable with the tissue-sampling needle 2601. The tissue-sampling needle 2601 may additionally include a plurality of drug reservoir divots 931 associated with an outer surface of the needle 2601. Tissue-sampling device 2601 includes a configuration of micro-nozzles 2691. Micro-nozzles 2691 may be oriented in any suitable manner.

[0134] FIG. 27 shows a portion of the tissue-sampling needle 2601 of FIG. 26 that includes a plurality of drug reservoir divots 931 associated therewith. Any suitable number of the same or different drug reservoir divots 931 may be utilized. Ablation needle 900 includes a substantially cylindrically-shaped body or shaft portion 914 defining a plurality of recesses 930 therein.

[0135] The recesses 930 are provided with one or more drugs 834 therein, such as without limitation, microspheres, chemotherapeutic agents, and/or a thermo-sensitive binding agent, e.g., wax. The shape, size, position and number of the recesses 930 may be varied from the configuration depicted in FIG. 27.

[0136] FIG. 28 shows a portion of an ablation needle assembly (shown generally as 2800) in accordance with an embodiment of the present disclosure that includes an interchangeable sleeve member 870 including a plurality of drug reservoir divots 831 associated therewith. Ablation needle assembly 800 includes a generally tubular-shaped sleeve body 817 defining a plurality of recesses 830 therein. The recesses 830 may be formed in any suitable shape, and may define receptacles of any suitable volume to contain one or more drugs. The recesses 830 may have any suitable depth less than a through-penetration depth. Sleeve member 870 may be configured to be disposed coaxially around the body or shaft portion 814, or portion thereof. Sleeve member 870 may be either disposable or reusable.

[0137] The recesses 830 are provided with one or more drugs, which may be temperature-sensitive, therein. In some embodiments, the recesses 830 are provided with microspheres, e.g., API or CTA microspheres and/or microparticles, and may be provided with a thermo-sensitive binding agent, e.g., wax. In some embodiments, the recesses 830 are provided with one or more chemotherapeutic agents, and may be provided with a thermo-sensitive binding agent. A thermo-sensitive binding agent may be combined with the microspheres, API, or CTA disposed in the recesses 830. A thermo-sensitive binding agent may additionally, or alternatively, be formed as layered coating to protect and/or postpone delivery of the microspheres, API, or CTA.

[0138] In some embodiments, as shown in FIG. 8, a first drug 834 is disposed within one or more of the recesses 830, and a second drug 836 may be disposed within one or more of the recesses 830. Any suitable number of the same or different drug reservoir divots 831 may be utilized, e.g., depending upon a particular purpose and/or to achieve a desired surgical outcome. In some embodiments, one or more drug reservoir divots 831, e.g., containing the first drug 834, may be configured to be released at a first temperature (or first temperature range), and one or more drug reservoir divots 831, e.g., containing the second drug 836, may be configured to be released at a second temperature (or second temperature range). The shape, size, position and number of the recesses 830 may be varied from the configuration depicted in FIG. 8.
Fig. 29A is a diagrammatic illustration of an electrosurgical system (shown generally as 2900) including a medical laser device 2901 suitable for use with a tissue-sampling component in accordance with an embodiment of the present disclosure. Medical laser device 2901 includes a light source connection 2940, a processor connection 2930, a working channel 2920, and an energy-based device fiber 2915 operably coupled to the working channel 2920. Working channel 2920 includes a suction port 2910. The medical laser device may include a light source selected from among gas [e.g., CO₂, Halogenum, Argo, etc.] and/or chemical [e.g., fluoride and iodine-based] lasers, or other type.

Electrosurgical system 2900 may be suitable for use for performing a wide range of procedures, e.g., bone marrow biopsies, needle-based biopsies (e.g., fine, core, vacuum, image guided, etc.), endoscopic-based biopsies (e.g., cystoscopy, colonoscopy, conization, bronchoscopy, etc.). In bronchoscopy and conization, for example, procedures may involve endoscopically entering an area through flexible scope 2925 and introducing an energy-based device through the flexible scope 2925. Some examples of energy-based devices include electrocautery, energy ablation scalpels, medical lasers, etc. In the case of bronchoscopy, a CO₂ laser may be introduced via a flexible scope 2925.

The tissue-sampling component in accordance with embodiments of the present disclosure may include micro brushes, needles or forceps. One or more tissue-sampling component could be introduced in the flexible scope 2925, sequentially or simultaneously depending on the multi-lumen configuration of the flexible scope 2925. In some embodiments, the tissue-sampling component may be a needle collection device known as a Boston Scientific Trans bronchial aspiration needle. In various embodiments, a micro needle that works in conjunction with slight vacuum and may be used to collect lung biopsies and/or other biopsies, including delicate and difficult biopsies to collect given the anatomy, collection difficulty, tissue size and procedure complexity. In some embodiments, as shown in Fig. 29B, the distal end 2928 of the flexible scope 2925 includes a camera device 2985. Camera device 2985 may include a micro-lens and a CCD chip.

Fig. 30 is diagrammatic illustration showing the relation of fiber tip distance from tissue for cutting effect, homostasis effect, and ablation effect in accordance with an embodiment of the present disclosure. In some embodiments, energy-based device fiber may be inserted down the working channel 2920 of the flexible scope 2925 (Fig. 29A). As shown in Fig. 30, fiber tip may have various configurations and their distance to the target anatomy may create different effects based on desired procedure.

Controlled delivery of a drug agent from an implantable formulation over periods of time (e.g., periods of time measured in days or weeks) may help to assure patient compliance, as implantable formulations are not easily tampered with by the patient and can be designed to provide therapeutic doses of beneficial agent over periods of days or weeks without patient input. In accordance with embodiments of the present disclosure wherein an implantable formulation may be placed during an ablation procedure, possible concerns over intrusive access may be markedly mitigated. Other potential benefits of the use of implantable formulation placed during an ablation procedure according to embodiments of the present disclosure include non-permanent functional life obviating extraction, reduced site irritation, fewer occupational hazards for patients and practitioners, reduced waste disposal hazards, decreased costs, and increased efficacy as compared to other parenteral administration techniques, such as injections, which may require multiple administrations over relatively short time intervals.

A variety of drug agents may be delivered by devices according to embodiments of the present disclosure. Some examples of drug agents which may be delivered by devices according to embodiments of the present disclosure include chemotherapeutic agents such as without limitation cisplatin, paclitaxel, doxorubicin, fluorouracil, as well as other compounds such as without limitation prochlorperazine edisylate, ferrous sulfate, aminocaproic acid, mecamylamine hydrochloride, procainamide hydrochloride, amphetamine sulfate, mepiphametaine hydrochloride, benzamethamide hydrochloride, isoperteronol sulfate, phenemzetrane hydrochloride, bethanecol chloride, methacholine chloride, pilocarpine hydrochloride, atropine sulfate, scopolamine bromide, isopropamide iodide, trisihexlyethyl chloride, phenformin hydrochloride, methylphenidate hydrochloride, theophylline chlorinate, cephalexin hydrochloride, diphenyl, meclizine hydrochloride, prochlorperazine maleate, phe-noxybenzamine, thiethylperazine maleate, anisidone, diphenadione erythritol tetranitrate, digoxin, isofluropine, acetazolamide, methazolamide, bendroflumethiazide, chlorpropamide, tolazamide, chloromadin acidate, phenylglycodol, alfopurinol, aluminum aspartin, methotrexate, acetyl sulfisoxazole, erythromycin, hydrocortisone, hydrocortisone acetate, cortisone acetate, dexamethasone and its derivatives such as betamethasone, trimacanolone, methyltestosterone, 17-S-estradiol, ethinyl estradiol, ethinyl estradiol 3-methyl ether, prednisolone, 17-oc-hydroxyprogesterone acetate, 19-nor-progesterone, norgestrel, norethindrone, norethisterone, norethindron, norethindrone, progesterone, norgestone, norethynodrel, aspartin, indomethacin, naproxen, fenoprofen, sulindac, indoprofen, nitroglycerin, isosorbide dinitrate, propranolol, timolol, atenolol, aprotenol, cimetidine, clomidone, imipramine, levodopa, chlorpromazine, methyl dop, dihydroxyphenylalanine, theophylline, calcium gluconate, ketoprofen, ibuprofen, cephalixin, erythromycin, haloperidol, zomepirac, ferrous lactate, vincamine, diazepam, phenoxym-benazine, diliazem, nitrinin, capropril, mandol, quan-benz, hydrochloorthizide, ranitidine, flurbiprofen, fenitoin, fluprofen, tolmetin, ochlofenac, mafenamic, flufenamic, diflunisal, nimesulide, nortriapridine, nisoldipine, nicardipine, felodipine, lidoflazin, tiapamil, gallopampl, amiodipine, moftlazin, lisinoipril, enalapril, enalaprilat, captopril, ramipril, fomotidine, nitazidate, sucrafate, etitidine, tretinol, minoxidil, chlorzadepoxide, diazepam, amitryptiline, and imipramine; opioids such as morphine, hydrocodeine, oxycodone, and semi-synthetic opioids such as oxymorphone, hydromorphone, opiates such as asopanine and codeine, opioid antagonists such as without limitation naltrixone, nalbuphine, nalorexone as well as opioid agonist/antagonist compounds such as buprenorphine, and synthetic analogues such as methadone, tramadol, fentanyl and sufentanil.

Some other examples of drug agents which may be delivered by devices according to embodiments of the present disclosure include vitamin and supplements such as vitamins B-12 (cyanocobalamin) and D2, anti-virals such as without limitation acyclovir and zidovudine; proteins and peptides such as without limitation insulin, colechicine, glucagon, thyroid stimulating hormone, parathyroid and pituitary hormones, calcium, renin prolectin, corticotrophin, thyrotro-
pic hormone, follicle stimulating hormone, chorionic gonadotropin, gonadotropin releasing hormone, bovine somatotropin, porcine somatotropin, oxytocin, vasopressin, GRE, prolactin, somatostatin, lyprosin, pancreozymin, luteinizing hormone, LH, LHRH agonists and antagonists, leuprolide, interferons, interleukins, growth hormones such as human growth hormone, bovine growth hormone and porcine growth hormone, fertility inhibitors such as the prosta
glandins, fertility promoters, growth factors, coagulation factors, human pancreas hormone releasing factor, analogs and derivatives of these compounds, and pharmaceutically acceptable salts of these compounds, or their analogs or derivatives. On the molecular level, the various forms of the
beneficial agent may include uncharged molecules, molecular complexes, and pharmaceutically acceptable acid addition and base addition salts such as hydrochlorides, hydrobromides, acetate, sulfate, laurylate, olate, and salicylate. Examples of acidic compounds which may be delivered by
devices according to embodiments of the present disclosure include salts of metals, amines or organic amines. Derivatives such as esters, ethers and amides may also be used.

[0146] A drug agent for delivery by devices according to embodiments of the present disclosure may be used alone or mixed with other agents. A drug agent for delivery by the presently-disclosed devices may include pharmaceutically acceptable excipients, polymeric carriers and/or additional ingredients, such as antioxidants, stabilizing agents, permeation enhancers, polysaccharides, proteins, nucleotides like aptamers, and fatty acids, etc., and fabricated into different forms such as solution, suspension, gel, colloidal dispersion like liposome, or micro- and nano-particles for controlled delivery of the drug agent. A drug agent for delivery by the presently-disclosed devices may include a thermo-sensitive metal deposit or any such compound that increases the sensitivity of the target tissue, e.g., tumor, to ablation.

[0147] A drug agent for delivery by the presently-disclosed devices may include a cryoablation agent, e.g., liquid nitrogen, and may prove complementary to thermal ablation that uses electrosurgical energy at RF or microwave frequencies.

[0148] The above-described systems and ablation devices may offer improved anti-cancer efficacy with RF ablation (or microwave ablation), localized drug delivery capabilities, and tissue-sampling components integrated into a single medical device. In accordance with the above-described systems and ablation devices, an approach is taken to deliver drug formulation(s) locally when the anatomical access has already been obtained for the purpose of RF or microwave ablation, which, in turn, presents the prospect of reduced side-effects associated with systemic administration of the same drug molecule(s).

[0149] The above-described ablation devices capable of collecting tissue samples may eliminate the need for a separate, biopsy tissue-sampling device.

[0150] Although embodiments have been described in detail with reference to the accompanying drawings for the purpose of illustration and description, it is to be understood that the inventive processes and apparatus are not to be construed as limited thereby. It will be apparent to those of ordinary skill in the art that various modifications to the foregoing embodiments may be made without departing from the scope of the disclosure.

What is claimed is:

1. An ablation device, comprising:
a handle assembly;
an ablation electrode extending from the handle assembly, the ablation electrode including an ablation needle, wherein the ablation needle includes a distal end portion including a drug delivery port defined therethrough;
at least one delivery needle extending from the handle assembly; and
a biopsy tool extending from the handle assembly.

2. The ablation device of claim 1, wherein the biopsy tool is a tissue-sampling needle.

3. The ablation device of claim 2, wherein the handle assembly is adapted to allow the user to selectively position the tissue-sampling needle in tissue.

4. The ablation device of claim 3, wherein the tissue-sampling needle is selectively moveable from a first position, wherein a distal end of the tissue-sampling needle is disposed proximal to a distal end portion of the ablation needle, to at least a second position, wherein at least the distal end of the tissue-sampling needle is disposed distally beyond the distal end portion of the ablation needle.

5. The ablation device of claim 1, wherein the biopsy tool is a tissue-sampling device including an end-effector.

6. An ablation device, comprising:
a handle assembly;
an ablation electrode extending from the handle assembly, the ablation electrode including an ablation needle, wherein the ablation needle includes a recess defined therein;
an absorbent material disposed at least in part within the recess;
at least one delivery needle extending from the handle assembly; and
a biopsy tool extending from the handle assembly.

7. The ablation device of claim 6, wherein the handle assembly is adapted to allow the user to selectively position the at least one delivery needle in tissue.

8. The ablation device of claim 7, wherein the delivery needle is selectively moveable from a first position, wherein a distal end of the delivery needle is disposed proximal to a distal end portion of the ablation needle, to at least a second position, wherein at least the distal end of the delivery needle is disposed distally beyond the distal end portion of the ablation needle.

9. The ablation device of claim 1, wherein the biopsy tool includes a micro-forceps.

10. An ablation device, comprising:
a handle assembly;
an array of ablation electrodes operably associated with the handle assembly, wherein at least one ablation electrode of the array of ablation electrodes includes a recess defined therein, and wherein an absorbent material is disposed at least in part within the recess; and
a biopsy tool including an end-effector assembly operably associated with the handle assembly.

11. The ablation device of claim 10, wherein at least one ablation electrode of the array of ablation electrodes includes a distal end portion including a drug delivery port defined therethrough.

12. The ablation device of claim 10, further comprising a delivery needle extending from the handle assembly.
13. An ablation system, comprising:
a source of electrosurgical energy;
a source of coolant fluid; and
an ablation device, including:
a handle assembly;
an ablation electrode operatively connected to the source
of electrosurgical energy and fluidly-coupled to the
source of coolant fluid, the ablation electrode includ-
ing an ablation needle extending from the handle
assembly;
at least one delivery needle extending from the handle
assembly, wherein the at least one delivery needle is
selectively moveable from a first position, wherein a
distal end of the at least one delivery needle is dis-
posed proximal to a distal end portion of the ablation
needle, to at least a second position, wherein at least
the distal end of the at least one delivery needle is
disposed distally beyond the distal end portion of the
ablation needle; and
a biopsy tool extending from the handle assembly.

14. The ablation system of claim 13, wherein the biopsy
tool includes a tissue-sampling needle.

15. The ablation device of claim 13, wherein the tissue-
sampling needle includes a micro-needle configured to be
slideably moveable within the tissue-sampling needle.

16. The ablation system of claim 13, wherein the biopsy
tool is a tissue-sampling device including an end-effector.

17. The ablation system of claim 13, further comprising a
drug reservoir.

18. The ablation system of claim 17, wherein the at least
one delivery needle is disposed in fluid communication with
the drug reservoir.

19. The ablation device of claim 13, wherein the biopsy
tool includes a micro-forceps.

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