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Ibrahim et al.

(54) **TRANSMURALITY CLAMP SYSTEMS AND METHODS**

(75) Inventors: **Tamer Ibrahim**, Pleasant Hill, CA (US); **David K. Swanson**, Campbell, CA (US)

Correspondence Address:
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER, EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834 (US)

(73) Assignee: **ESTECH, Inc. (Endoscopic Technologies, Inc.)**, San Ramon, CA (US)

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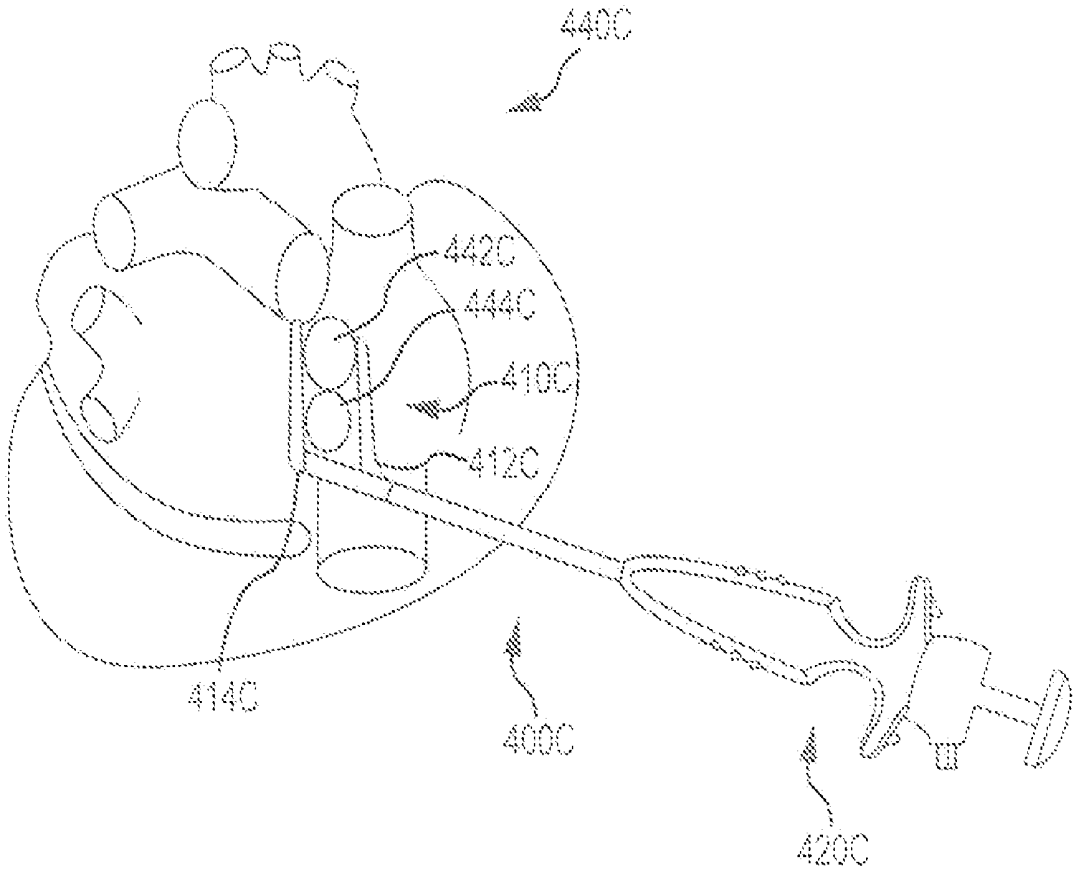
(57) **ABSTRACT**

Tissue clamp systems and methods assess the transmurality of a lesion created by ablation. Exemplary clamp systems for ablating tissue include a first jaw, an ablation element mounted on the first jaw, a second jaw, and a sensing element mounted on the second jaw. The sensing element can be configured to assess transmurality of a lesion created by the ablation element. Systems may also include a connection mechanism that connects the ablation element and the sensing element to a connector for connecting the ablation element and the sensing element to an ablation system.



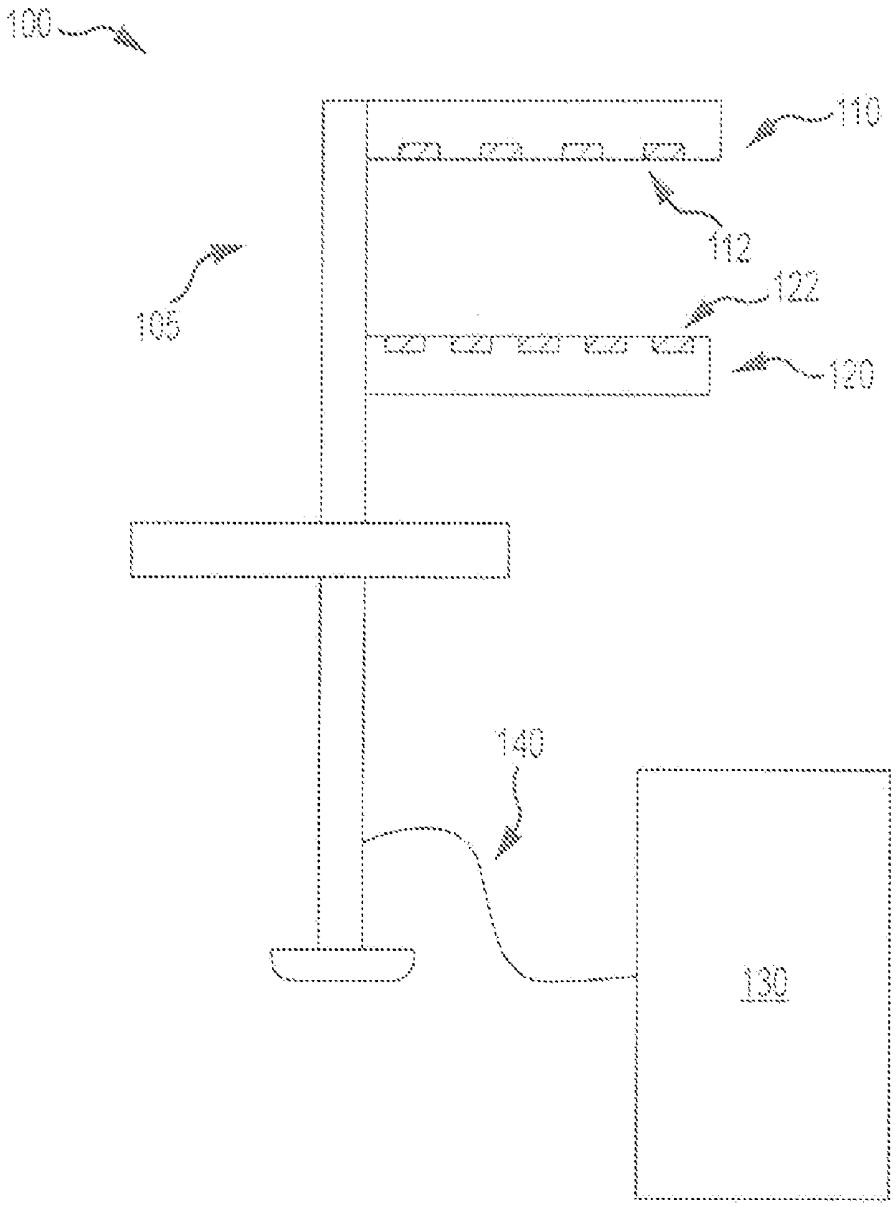


FIG. 1

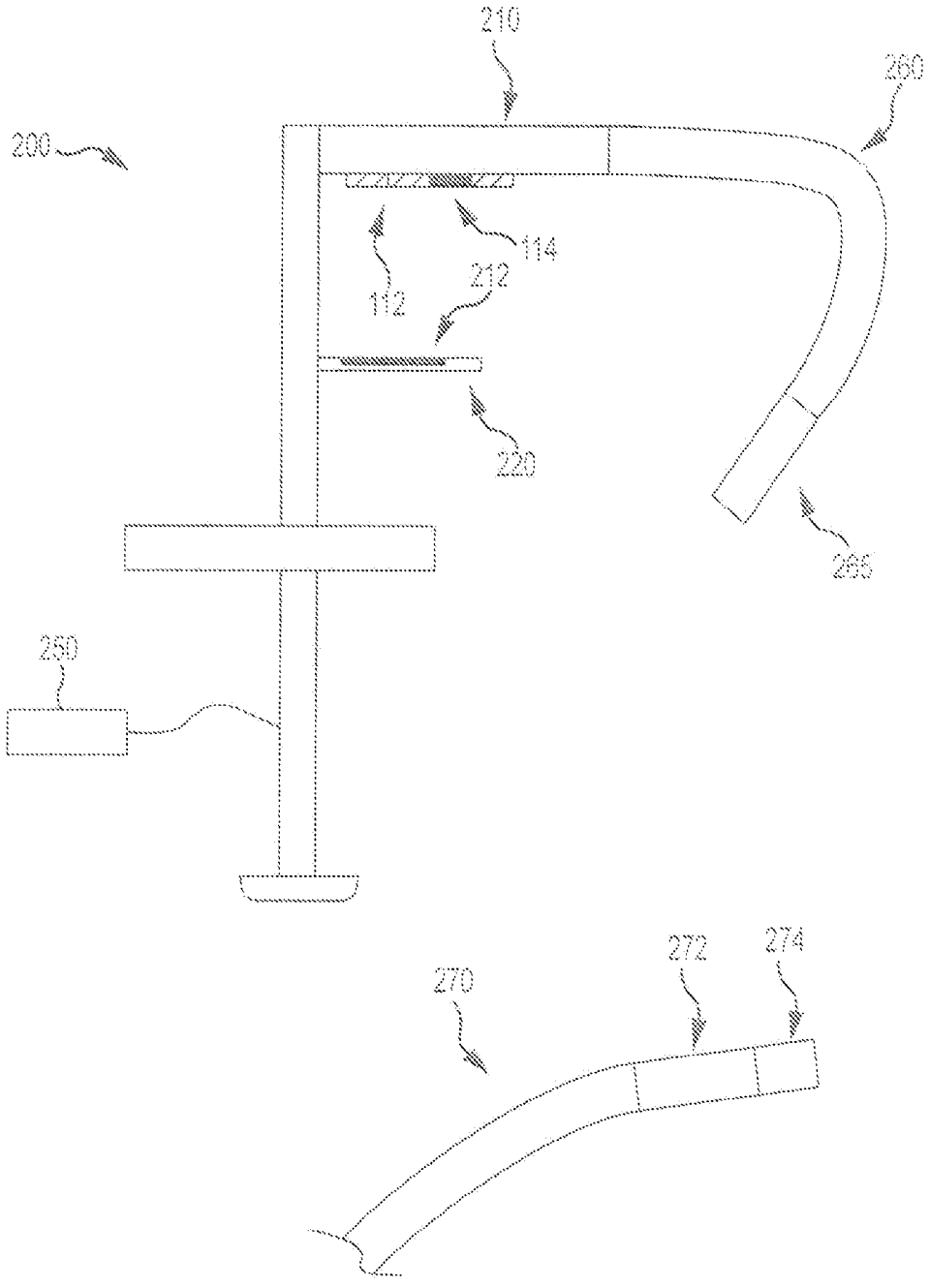


FIG.2

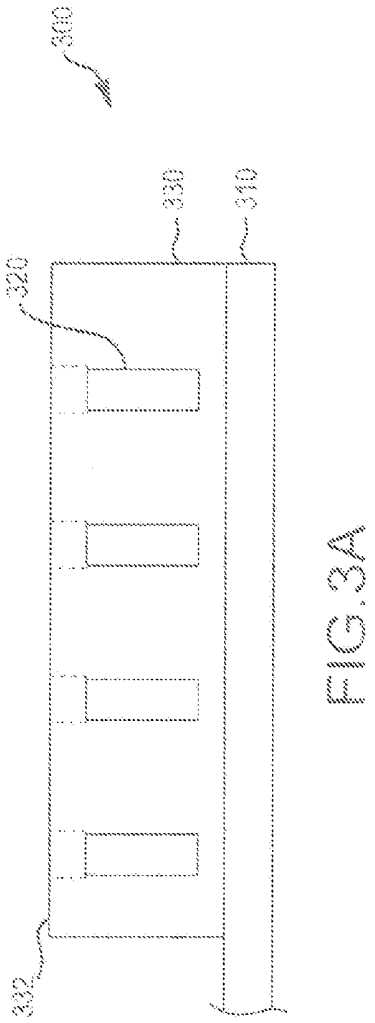


FIG. 3A

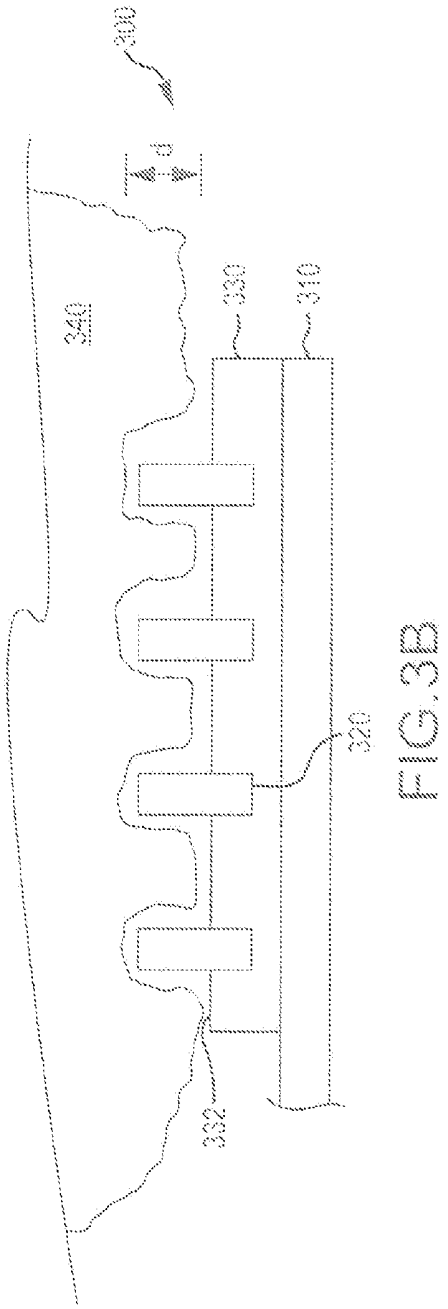


FIG. 3B

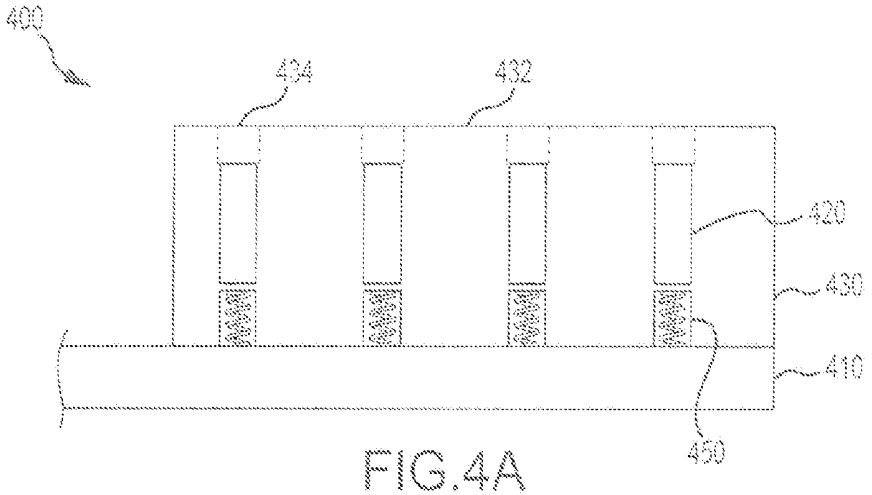


FIG.4A

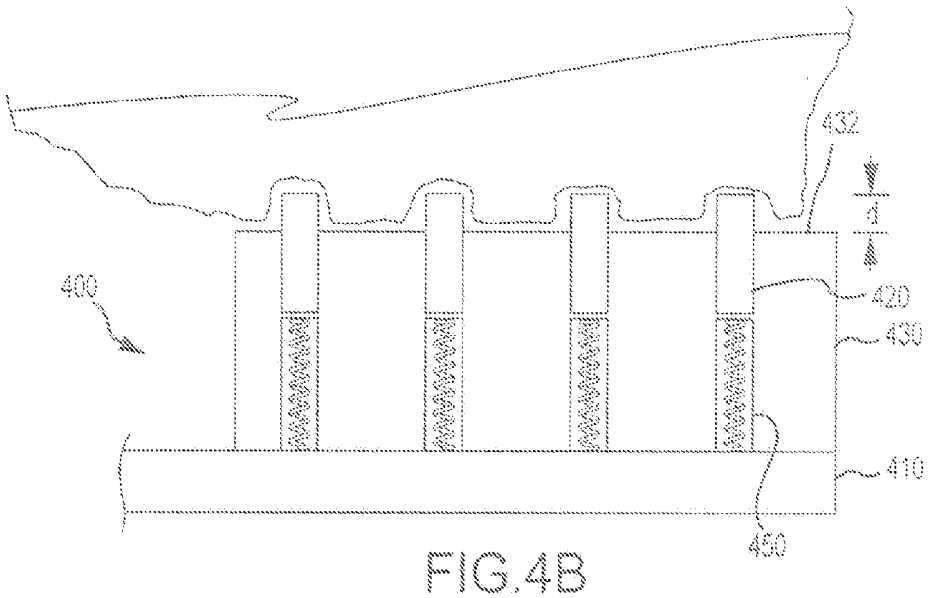


FIG.4B

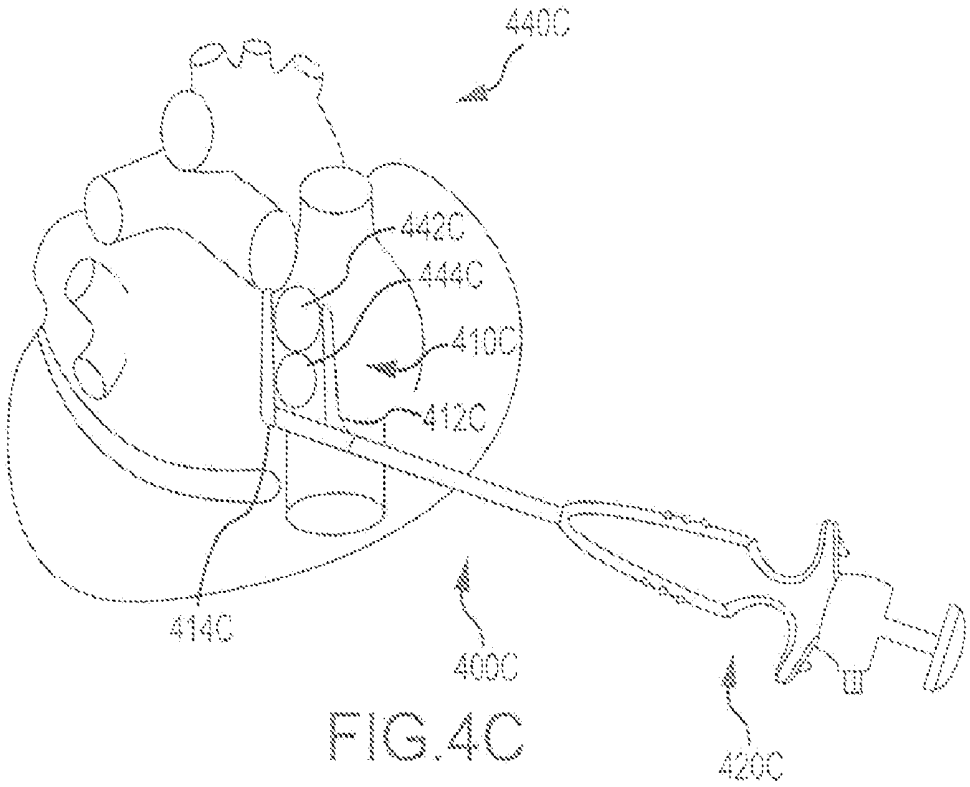


FIG.4C

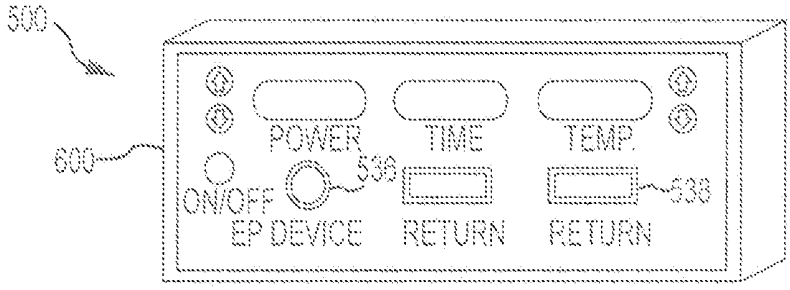

500
600
POWER
TIME
TEMP.
ON/OFF
538
538
EP DEVICE
RETURN
RETURN

FIG.5

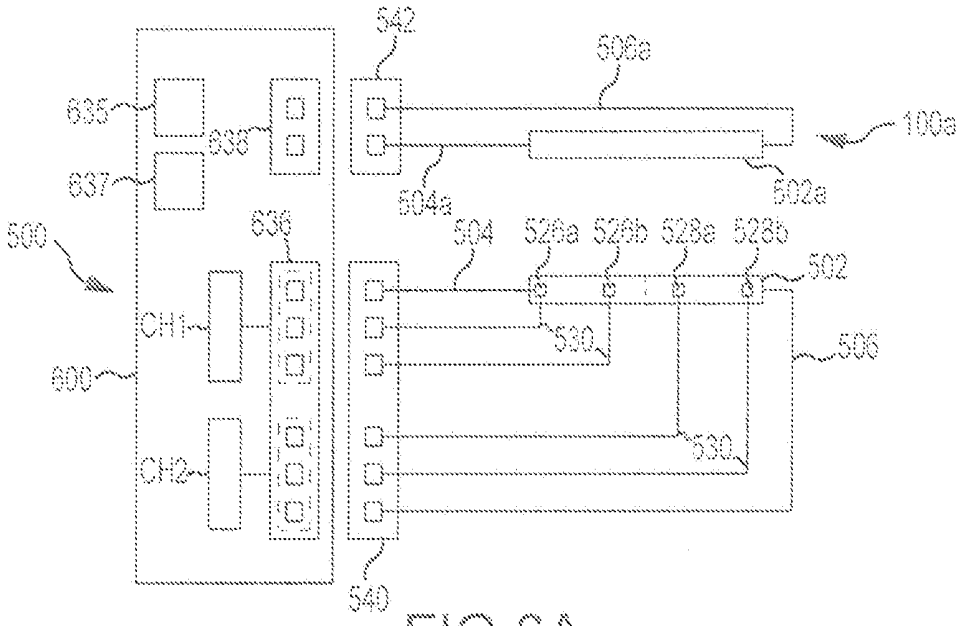

542
506a
635
638
637
100a
504a
502a
500
636
504
526a
526b
528a
528b
502
CH1
530
506
600
530
CH2
540

FIG.6A

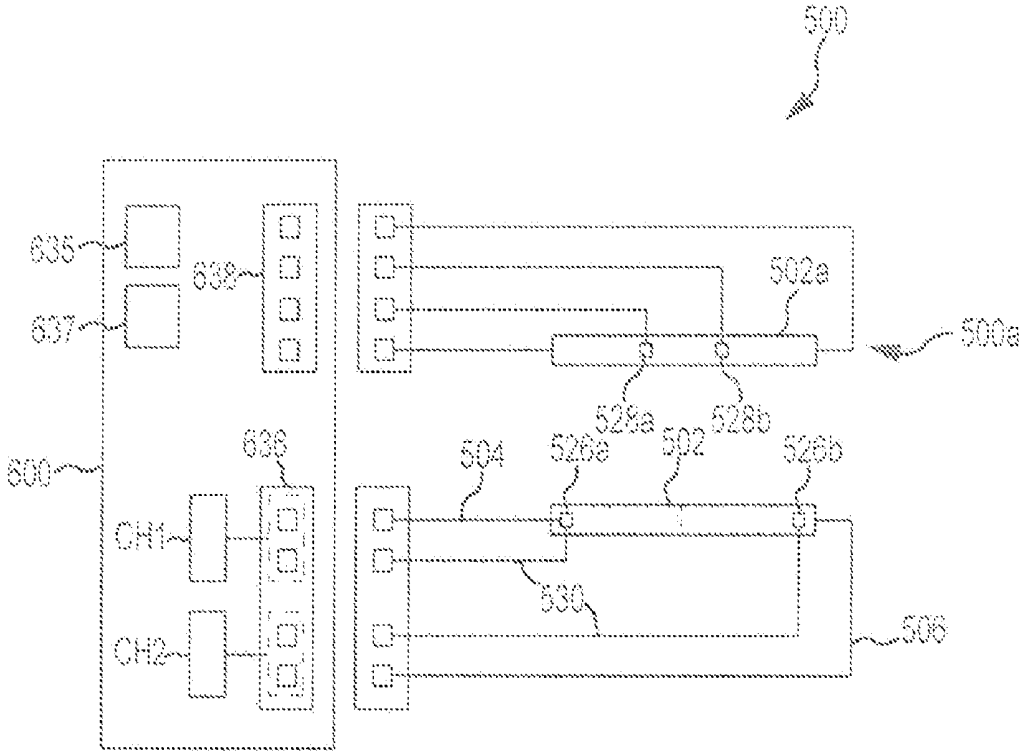

500
635
637
638
600
638
CH1
CH2
502a
500a
528a
528b
504
526a
502
526b
530
506

FIG.6B

TRANSMURALITY CLAMP SYSTEMS AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a nonprovisional of, and claims the benefit of the filing date of U.S. Provisional Patent Application No. 61/220,414 filed Jun. 25, 2009, entitled "Transmurality Clamp Systems and Methods," the entire disclosure of which is incorporated herein by reference for all purposes.

BACKGROUND OF THE INVENTION

[0002] Embodiments of the present invention relate in general to tissue ablation systems and methods. Particular embodiments related to clamp systems and methods for assessing the transmurality of a lesion created by ablation.

[0003] There are many instances where it is beneficial to perform a therapeutic intervention in a patient, using a system that is inserted within the patient's body. One exemplary therapeutic intervention involves the formation of therapeutic lesions in the patient's heart tissue to treat cardiac conditions such as atrial fibrillation, atrial flutter, and arrhythmia. Therapeutic lesions may also be used to treat conditions in other regions of the body including, but not limited to, the prostate, liver, brain, gall bladder, uterus, and other solid organs. Typically, the lesions are formed by ablating tissue with one or more electrodes. Electromagnetic radio frequency ("RF") energy applied by the electrode heats and eventually kills or ablates the tissue to form a lesion. During the ablation of soft tissue (e.g. tissue other than blood, bone and connective tissue), tissue coagulation occurs, which leads to tissue death. Thus, references to the ablation of soft tissue are typically references to soft tissue coagulation. "Tissue coagulation" can refer to the process of cross linking proteins in tissue to cause the tissue to jell. In soft tissue, it is the fluid within the tissue cell membranes that jells to kill the cells, thereby killing the tissue. Depending on the procedure, a variety of different electrophysiology devices may be used to position one or more electrodes at the target location. Electrodes can be connected to power supply lines and, in some instances, the power to the electrodes can be controlled on an electrode-by-electrode basis. Examples of electrophysiology devices include catheters, surgical probes, and clamps.

[0004] Currently known surgical probes which can be used to create lesions often include a handle, a relatively short shaft that is from 4 inches to 18 inches in length and either rigid or relatively stiff, and a distal section that is from 1 inch to 10 inches in length and either malleable or somewhat flexible. One or more electrodes are carried by the distal section. Surgical probes are used in epicardial and endocardial procedures, including open heart procedures and minimally invasive procedures where access to the heart is obtained via a thoracotomy, thoracostomy or median sternotomy. Exemplary surgical probes are disclosed in U.S. Pat. No. 6,142,994, the content of which is incorporated herein by reference.

[0005] Clamps, which have a pair of opposable clamp members that may be used to hold a bodily structure or a portion thereof, are used in many types surgical procedures. Lesion creating electrodes have also been secured to certain types of clamps. Examples of clamps which carry lesion creating electrodes are discussed in U.S. Pat. No. 6,142,994, and U.S. Patent Publication Nos. 2003/0158549, 2004/0059325, and 2004/024175, the contents of which are incorporated herein by reference. Such clamps can be useful when the physician intends to position electrodes on opposite sides of a body structure in a bipolar arrangement.

[0006] Although these and other proposed treatment devices and methods may provide real benefits to patients in need thereof, still further advances would be desirable. For example, there continues to be a need for improved ablation systems and methods that can be used by surgeons to treat patient tissue or anatomical features having various sizes, shapes, densities, and the like. Embodiments of the present invention provide solutions that address the problems which may be associated with known techniques, and hence provide answers to at least some of these outstanding needs.

BRIEF SUMMARY OF THE INVENTION

[0007] Systems for ablating tissue can be used with any preferred surgical access technique, including without limitation sternotomy and thoracotomy procedures. Exemplary tissue ablation systems may include a clamp structure for clamping single or double wall thickness tissue. According to some embodiments, an ablation system may include a unipolar ablation clamp. For example, a first jaw of the clamp can have include an active energy delivery mechanism which may incorporate any of a variety of energy sources, including radiofrequency (RF), ultrasound, cryothermy, microwave, laser, and the like. Relatedly, the energy delivery mechanism may incorporate any of a variety of transmission mechanisms, such as electrodes, transducers, antennas, and the like.

[0008] A tissue ablation system can include a clamp having a first jaw and a second jaw. The first jaw may have an active energy delivery mechanism that includes a temperature sensor as a means of controlling energy delivery to ensure target tissue reaches target temperature. A second, opposing jaw can have either a continuous element or series of one or more discrete temperature sensing elements for same purpose. Temperature sensors can provide feedback to a energy delivery source that delivers energy until sensors on an inactive jaw register that the target temperature has been reached or a predefined timepoint, in the event the temperature endpoint is not reached within that timeframe. Temperature sensing elements may be complimented by pacing and sensing elements to determine lag in conduction time across lesion. Clamp may include visualization and delivery system including scopes with protective lenses and introducers with stylets, sheaths, and or magnets.

[0009] In one aspect, embodiments of the present invention encompass clamp assembly systems and methods for ablating tissue of a human patient. An exemplary clamp assembly for ablating tissue may include a first jaw, an ablation element mounted on the first jaw, a second jaw, and a sensing element mounted on the second jaw. The sensing element can be configured to assess transmurality of a lesion created by the ablation element. The clamp assembly may also include a connection mechanism that connects the ablation element and the sensing element to a connector for connecting the ablation element and the sensing element to an ablation system. In some cases, the connection mechanism includes one or more wires. In some cases, the sensing element includes a temperature sensor. Optionally, the sensing element may include a pacing electrode. Relatedly, the sensing element may include an optical sensor. In some cases, the optical sensor detects tissue color change that occurs as tissues are heated to above 60° C. In some cases, the optical sensor detects changes to near-field microwave that occur as tissues

temperatures rise or fall. In some cases, a sensing element penetrates a tissue surface of a tissue as the tissue is clamped between the first and second jaws of the clamp assembly. Optionally, the sensing element may include a temperature sensor. In some instances, the sensing element can include a pacing electrode. According to certain embodiments of the present invention, the sensing element includes an electrode that senses tissue impedance. Optionally, the ablation element can be configured to heat tissue using radiofrequency energy. In some instances, the ablation element heats tissue using microwave energy. In some instances, the ablation element heats tissue using ultrasonic energy. According to some embodiments, the ablation element freezes tissue to achieve ablation. A clamp assembly may also include one or more ablation elements coupled with the second jaw.

[0010] In another aspect, embodiments of the present invention encompass systems for ablating tissue which include, for example, an ablation clamp having a first jaw, a second jaw, one or more ablation elements mounted on the first jaw, and a sensing element mounted on the second jaw that assesses transmurality of a lesion created by the ablation element. Tissue ablating systems may also include an ablation control system for controlling an ablation process provided by the ablation clamp, and means, such as wires, for connecting the ablating element and the sensing element with the ablation control system. In some cases, the ablation control system can stop the ablation process when the sensing element carried by the second jaw indicates that a transmural lesion has been created. In some cases, the ablation control system can stop the ablation process if a predetermined maximum time limit has been reached.

[0011] In a further aspect, embodiments of the present invention encompass a clamp assembly for ablating tissue that includes a first jaw, an ablation element mounted on the first jaw, a second jaw, and a sensing element mounted on the second jaw. The sensing element can include a temperature sensor, a pacing element, or an optical sensor, and can be configured to penetrate a tissue surface of a tissue as the tissue is clamped between the first and second jaws of the clamp assembly. In some cases, the sensing element can be configured to assess transmurality of a lesion created by the ablation element. A clamp assembly may also include a connection mechanism that connects the ablation element and the sensing element to a connector for connecting the ablation element and the sensing element to an ablation system.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. **1** shows aspects of a tissue treatment system according to embodiments of the present invention.

[0013] FIG. **2** shows aspects of a tissue treatment system according to embodiments of the present invention.

[0014] FIGS. **3**A and **3**B show aspects of a tissue treatment system according to embodiments of the present invention.

[0015] FIGS. **4**A, **4**B, and **4**C show aspects of a tissue treatment system according to embodiments of the present invention.

[0016] FIG. **5** shows aspects of a tissue treatment system according to embodiments of the present invention.

[0017] FIGS. **6**A and **6**B show aspects of a tissue treatment system according to embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Turning now to the drawings, FIG. **1** shows a system **100** for ablating tissue, according to embodiments of the present invention. System **100** may have a clamp assembly **105** that includes a first jaw **110** and one or more ablation elements **112** mounted on or coupled with first jaw **110**. In some cases, ablation elements **112** can be configured to heat tissue using radiofrequency energy. For example, the ablation elements can include active radiofrequency (RF) ablation mechanisms. In some cases, ablation elements **112** may heat tissue using microwave energy. Optionally, ablation elements **112** may heat tissue using ultrasonic energy. Embodiments also provide ablation elements **112** that freeze tissue to achieve ablation.

[0019] Clamp assembly **105** may also include a second jaw **120** and one or more sensing elements **122** mounted on or coupled with second jaw **120**. Sensing elements **122** can be configured to assess the transmurality of a lesion created by ablation elements **112**. Clamp assembly **100** may also include wires connecting the ablation elements **112** and the sensing elements **122** to a connector for connecting the ablation elements **112** and the sensing elements **122** to an ablation system. Sensing elements **122** may in some cases include temperature sensors. Optionally, sensing elements **122** may include pacing electrodes. According to some embodiments, sensing elements **122** include optical sensors. For example, sensing elements **122** may include optical sensors that detect tissue color changes that occur as tissues are heated to above 60° C. Relatedly, sensing elements **122** may include optical sensors that detect changes to near-field microwave that occurs as tissues temperatures rise or fall. In some instances, sensing elements **122** may include electrodes that sense tissue impedance. Sensing elements **122** may be configured to penetrate the tissue surface as the tissue is clamped between the first jaw **110** and the second jaw **120** of clamp assembly **100**.

[0020] As shown in FIG. **1**, system **100** may include an ablation control system for controlling the ablation process provided by the ablation clamp **105**. System **100** may further include a means for connecting ablating elements **112** and sensing elements **122** carried by ablation clamp **105** to an ablation control system **130**. For example, system **100** may include a connection mechanism **140** that connects ablating elements **112** and sensing elements **122** with ablation control system **130**.

[0021] FIG. **2** depicts a system **200** for delivering a tissue ablation treatment to a patient. System **200** includes a clamp assembly **205** having a first jaw **210** and a second, opposing jaw **220**. First jaw **210** may have an active energy delivery mechanism **212** that includes a temperature sensor **214** as a means of controlling energy delivery to ensure target tissue reaches target temperature. Second jaw **220** can have either a continuous element **212** or series of one or more discrete temperature sensing elements for same purpose. Temperature sensors can provide feedback to a energy delivery source **250** that delivers energy until sensors on an inactive jaw register that the target temperature has been reached or a predefined timepoint, in the event the temperature endpoint is not reached within that timeframe. Temperature sensing elements may be complimented by pacing and sensing elements to determine lag in conduction time across lesion. Clamp system **200** may incorporate visualization and delivery system elements including scopes with protective lenses and introducers with stylets, sheaths, and or magnets. For example, as shown in FIG. **2**, system **200** includes an introducer **260** having a magnet **265**, and a scope **270** having a scope lens **272** and a magnet **274**.

[0022] FIGS. **3**A and **3**B illustrate aspects of a transmurality clamp system according to embodiments of the present invention. As depicted in FIG. **3**A, a system can have a clamp jaw **300** which includes a base member **310**, one or more penetrating sensors or electrodes **320**, and a resilient or compressible structure **330**. Clamp jaw **300** may present any number of sensors **320**. For example, in some cases, a clamp jaw may present two sensors. In other instances, a clamp jaw may present four sensors. Sensors **320** may include impedance sensors, temperature sensors, and the like. Resilient structure **330** may be constructed of or include a compressible material such as an open cell foam, a closed cell foam, a low durometer silicon rubber, or the like. As shown here, sensors **320** are disposed slightly below or recessed from a contact surface **332** of resilient member **330**, when the resilient member is in an uncompressed configuration, such as when little or no pressure is being applied to the resilient member. In contrast, FIG. **3**B illustrates a configuration of resilient member **330** when a pressure is applied to contact surface **332**, for example when clamp jaw **300** is pressed against a patient tissue **340**. Penetrating sensors **320** now protrude into patient tissue **340** to a depth d. In some cases, depth d may vary depending on the compressibility of resilient member **330**. Hence, when pressure is applied, contact surface **332** of resilient member **330** retracts so as to expose sensors **320**. In some instances, resilient member **330** and sensors **320** are configured so that sensors **320** can extend or penetrate into a patient tissue to a depth d of about 2 mm. Hence, impedance, temperature, or other parameters may be sensed at locations below the tissue surface. In some cases, subsurface sensing can provide a more accurate assessment of a tissue condition, when compared to surface sensing.

[0023] FIGS. **4**A and **4**B illustrate aspects of a transmurality clamp system according to embodiments of the present invention. As depicted in FIG. **4**A, a system can have a clamp jaw **400** which includes a base member **410**, one or more penetrating sensors or electrodes **420**, a housing element **430**, and one or more actuating mechanisms **450**. Clamp jaw **400** may present any number of sensors **420**. For example, in some cases, a clamp jaw may present two sensors. In other instances, a clamp jaw may present four sensors. Sensors **420** may include impedance sensors, temperature sensors, and the like. Housing element **430** can include channels **434** within which sensors **420** may translate. As shown here, sensors **420** are disposed slightly below or recessed from a contact surface **432** of housing element **430**, when the actuating mechanisms are in a retracted configuration. In contrast, FIG. **4**B illustrates an extended configuration of actuating mechanisms **450**, such that an actuating mechanism **450** is expanded so as to push or expel a penetrating sensor **420** outward from channel **434**, and into a patient tissue **440**. In some cases, an actuating mechanism **450** may include a spring mechanism. Penetrating sensors **420** now protrude into patient tissue **440** to a depth d. In some cases, depth d may vary depending on the extent to which actuating mechanism **450** is expanded. In some instances, actuating mechanism **450** and sensor **420** are configured so that sensor **420** can extend or penetrate into a patient tissue to a depth d of about 2 mm. Hence, impedance, temperature, or other parameters may be sensed at locations below the tissue surface. In some cases, subsurface sensing can provide a more accurate assessment of a tissue condition, when compared to surface sensing.

[0024] FIG. **4**C shows a treatment system **400***c* in a position for performing an ablation or treatment procedure on epicardial tissue of heart **440***c*. Treatment system **400***c* includes a clamp assembly **410***c* having first and second jaw mechanisms **412***c*, **414***c*, and can be configured to ablate in a pattern approximating two lines adjacent the right pulmonary veins **442***c*, **444***c*. Jaw mechanisms **412***c*, **414***c* can be positioned as desired to provide a variety of ablation configurations. Additionally, treatment system **400***c* may be moved to a variety of positions to ablate multiple patterns in multiple locations on the epicardial tissue.

[0025] Treatment system **400***c* includes a handle or actuator assembly **420***c* disposed toward a proximal portion of the system. As shown here, first and second jaw mechanisms **412***c*, **414***c*, which may include two bipolar ablation clamps, are disposed toward a distal portion of the system. The jaw mechanisms **412***c*, **414***c* can be curved or shaped. In some cases, jaw mechanisms **412***c*, **414***c* are curved and adjustable. In some cases, a jaw mechanism can be in connectivity with an ablation and monitoring assembly or ESU. During use, the tissue treatment system can be used to contact the cardiac tissue, which can be effectively accomplished for example by the curvature orientation. The curved or contoured shape of the jaw mechanisms can allow the treatment system to be placed on the heart without impinging upon the pulmonary veins. Hence, there is an increased likelihood of ablating tissue of the atrium, as opposed to ablating tissue of the pulmonary veins themselves. Treatment system **400***c* is well suited for use in surgical methods where access ports are not employed. For example, the treatment system can be inserted into a patient via a 3-4 inch thoracotomy. In use, the jaw mechanisms are placed at or near the ostia, and actuated until the opposing jaw members are approximately 2-5 millimeters apart. This action serves to collapse the atrium near the pulmonary veins. An ablation is performed, and the clamping pressure is released thus allowing the atrium to return to the uncompressed state.

[0026] Electrosurgical Unit Operation

[0027] According to some embodiments, a treatment system may include or be coupled in operative association with an electrosurgical unit (ESU) that can supply and control power to an ablation assembly of the treatment system. FIGS. **5**, **6**A, and **6**B illustrate aspects of a treatment system **500** that includes or is coupled with an ESU **600** that supplies and controls power, such RF power, during a treatment procedure. As shown here, ESU **600** includes a controller **635**, a source of RF power **637** that is controlled by the controller, and a plurality of displays and buttons that are used to set the level of power supplied to one or more electrodes and the temperature at various locations on an electrode. The exemplary ESU **600** illustrated is operable in a bipolar mode, where tissue coagulation energy emitted by an electrode **502** is returned through a return electrode **502***a*, and a unipolar mode, where the tissue coagulation energy emitted by the electrode is returned through one or more indifferent electrodes (not shown) that are externally attached to the skin of the patient with a patch or one or more electrodes (not shown) that are positioned in the blood pool. The return electrode **502***a*, which in a bipolar configuration can be identical to the electrode **502**, may be connected to the ESU **600** by a pair of power return lines **504***a* and **506***a*. The return electrode **502***a* and power return lines **504***a* and **506***a* together define a return electrode assembly **500***a*.

[0028] In some embodiments, return electrode **502***a* can be an indifferent electrode. In a bipolar configuration, an active electrode and an indifferent electrode can cooperate to help

form a complete circuit of RF energy, for example when the two electrodes are placed across an anatomical feature such as the atria or other patient tissue. Energy can travel from the active electrode through the tissue to the indifferent electrode. An active electrode can be temperature controlled, and can be coupled with one or more RF wires and one or more thermocouples. An indifferent electrode can provide a return path, optionally as a single wire, operating as a ground. In use, energy passing through the electrodes can raise the temperature of the intervening tissue, for example tissue which is secured between two clamp mechanisms. In turn, the heated tissue can raise the temperature of the electrodes. In some cases, active electrodes, indifferent electrodes, or both, can be cooled with internal cooling mechanisms.

[0029] In some instances, a treatment system may include multiple active electrodes along a length of a clamp. Each active electrode can be coupled with an RF wire that supplied energy to the electrode, and two thermocouple pairs. A thermocouple pair can include two wires joined by a thermocouple, and the thermocouple can be attached to the electrode, for example at an end portion of the electrode. The thermocouple pair can be used to monitor the temperature of the electrode, or a portion of the electrode. In some embodiments, an electrode is coupled with two thermocouple pairs, and the highest of the two temperatures sensed by the thermocouple pairs can be used to control RF energy delivery to the electrode.

[0030] ESU **600** can be provided with a power output connector **636** and a pair of return connectors **638**. The electrode **502** is connected to the power output connector **636** by way of the power supply lines **504** and **506** and a power connector **540**, while the return electrode **502***a* is connected to one of the return connectors **638** by way of the power return lines **504***a* and **506***a* and a return connector **542**. In some cases, the ESU output and return connectors **636** and **638** have different shapes to avoid confusion and the power and return connectors **540** and **542** are correspondingly shaped. For example, power connector **540** may have a circular shape corresponding to an ESU power output connector **636** having a circular shape, and return connector **542** may have a rectangular shape corresponding to an ESU return connector **638** having a rectangular shape. Signals from the temperature sensors **526***a*/**526***b* and **528***a*/**528***b* can transmitted to the ESU **600** by way of the signal lines **530** and the power connector **540**.

[0031] ESU **600** can be configured to individually power and control a plurality of electrodes. In some cases, the electrodes may be about 10 mm in length. Optionally, a bipolar clamp configuration may include two 32 mm active electrodes and one 70 mm electrode. Such individually powered or controlled configurations may be referred to as providing "multi-channel control." In some cases, ESU **600** can include up to 8 channels, or more. ESU **600** can also be configured to individually power and control two or more portions of a single electrode as well as two or more portions of each of a plurality of electrodes during a lesion formation procedure. Electrode **502** as shown here can be divided into two portions for power control purposes. The electrode portion connected to the power supply line **504** on one side of the dash line in FIG. **6**A and the electrode portion connected to the power supply line **506** on the other side of the dash line. According to some embodiments, the dash line does not represent a physical division and the electrode **502** is a continuous, unitary structure. Electrode **502** can be placed adjacent to tissue and power to one portion can be controlled by control channel CH**1** and power to the other portion is controlled by control channel CH**2**. The power can be, although not necessarily, supplied to both portions simultaneously.

[0032] According to some embodiments, the level of power supplied to the electrode **502** by way of the power supply line **504** may be controlled based on the temperatures sensed by the temperature sensors **526***a*/**526***b*, while the level of power supplied to the electrode **502** by way of the power supply line **506** may be controlled based on the temperatures sensed by the temperature sensors **528***a*/**528***b*. In one exemplary control scheme, the level of power supplied to the electrode **502** by way of the power supply line **504** can be controlled based on the highest of the two temperatures sensed by the temperature sensors **526***a*/**526***b*, while the level of power supplied to the electrode **502** by way of the power supply line **506** can be controlled based on the highest of the two temperatures sensed by the temperature sensors **528***a*/**528***b*.

[0033] The amount of power required to coagulate tissue typically ranges from 5 to 150 w. Aspects of suitable temperature sensors and power control schemes that are based on sensed temperatures are disclosed in U.S. Pat. Nos. 5,456,682, 5,582,609 and 5,755,715, the contents of which are incorporated herein by reference.

[0034] The actual number and location of the temperature sensors may be varied in order to suit particular applications. As illustrated for example in FIG. **6**B, the temperature sensors **528***a* and **528***b* may be located on the return electrode **502***a* in certain bipolar implementations. Optionally, the power control scheme can be the same in that the level of power supplied to the electrode **502** by way of the power supply line **504** can be controlled based on the temperatures sensed by the temperature sensors **526***a*/**526***b*, while the level of power supplied to the electrode **502** by way of the power supply line **506** can be controlled based on the temperatures sensed the temperature sensors **528***a*/**528***b*.

[0035] According to some embodiments, a plurality of spaced electrodes can be provided that operate in a unipolar mode. Each of the electrodes can be connected to a respective pair of power supply lines and include its own set of temperature sensors. Each of the electrodes on a surgical probe can be divided into portions for power control purposes, and the level of power supplied to some electrode portions by way of power supply lines can be controlled based on the temperatures sensed by certain temperature sensors, while the level of power supplied to other electrode portions by way of power supply lines can be controlled based on the temperatures sensed by certain other temperature sensors.

[0036] As used herein, the term "clamp" or "jaw" includes, but is not limited to, clamps, jaws, clips, forceps, hemostats, and any other surgical device that includes a pair of opposable clamp members that hold tissue, at least one of which is movable relative to the other. In some instances, the clamp members are connected to a scissors-like arrangement including a pair of handle supporting arms that are pivotably connected to one another. The clamp members can be secured to one end of the arms and the handles can be secured to the other end. The clamp members can come together as the handles move toward one another. Certain clamps that are particularly useful in minimally invasive procedures also include a pair of handles and a pair of clamp members. In some cases, the clamp members and handles are not mounted on the opposite ends of the same arm. Instead, the handles can be carried by one end of an elongate housing and the clamp members are carried by the other. A suitable mechanical linkage located

within the housing can cause the clamp members to move relative to one another in response to movement of the handles.

[0037] According to some embodiments, the treatment systems and methods described herein may be used in conjunction or combined with aspects of other medical systems and methods such as those described in U.S. Patent Application Nos. 60/337,070 filed Dec. 4, 2001; 10/272,446 filed Oct. 15, 2002; 10/310,675 filed Dec. 4, 2002; 10/410,618 filed Apr. 8, 2003; 11/148,611 filed Jun. 8, 2005; 60/939,201 filed May 21, 2007; 61/015,472 filed Dec. 20, 2007; 61/051,975, filed May 9, 2008; 12/124,743 filed May 21, 2008; 12/124,766 filed May 21, 2008; 12/255,076 filed Oct. 21, 2008; 12/273,938 filed Nov. 19, 2008; 12/339,331 filed Dec. 19, 2008; 12/463,760 filed May 11, 2009; 61/179,564 filed May 19, 2009; 61/231,613 filed Aug. 5, 2009; and 61/241,297 filed Sep. 10, 2009. The entire content of each of these filings is incorporated herein by reference for all purposes.

[0038] Relatedly, in some instances, the treatment systems and methods described herein may include elements or aspects of the medical systems and methods discussed in U.S. Patent Application Nos. 60/337,070 filed Dec. 4, 2001; 10/080,374 filed Feb. 19, 2002; 10/255,025 filed Sep. 24, 2002; 10/272,446 filed Oct. 15, 2002; 10/310,675 filed Dec. 4, 2002; 10/410,618 filed Apr. 8, 2003; 11/067,535 filed Feb. 25, 2005; 11/148,611 filed Jun. 8, 2005; 60/939,201 filed May 21, 2007; 61/015,472 filed Dec. 20, 2007; 61/051,975, filed May 9, 2008; 12/124,743 filed May 21, 2008; 12/124,766 filed May 21, 2008; 12/255,076 filed Oct. 21, 2008; 12/273,938 filed Nov. 19, 2008; 12/339,331 filed Dec. 19, 2008; 12/463,760 filed May 11, 2009; 61/179,564 filed May 19, 2009; 61/231,613 filed Aug. 5, 2009; and 61/241,297 filed Sep. 10, 2009. The entire content of each of these filings is incorporated herein by reference for all purposes.

[0039] Further, according to some embodiments, the treatment systems and methods described herein may be used in conjunction or combined with aspects of other medical systems and methods such as those described in U.S. patent application Ser. No. 09/268,556 filed Mar. 15, 1999; 10/272,541 filed Oct. 15, 2002; 60/431,628 filed Dec. 6, 2002; 10/727,144 filed Dec. 2, 2003; 10/731,683 filed Dec. 8, 2003; 11/186,149 filed Jul. 20, 2005; 11/753,720 filed May 25, 2007; 60/939,201 filed May 21, 2007; 61/015,472 filed Dec. 20, 2007; 12/576,607 filed Oct. 15, 2009; 61/288,031 filed Dec. 18, 2009; 12/688,618 filed Jan. 15, 2010; and 12/781,077 filed May 17, 2010. The entire content of each of these filings is incorporated herein by reference for all purposes.

[0040] While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modification, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the claims.

What is claimed is:

1. A clamp assembly for ablating tissue, comprising:

a first jaw;

an ablation element mounted on the first jaw;

a second jaw;

a sensing element mounted on the second jaw, wherein the sensing element is configured to assess transmurality of a lesion created by the ablation element; and

a connection mechanism that connects the ablation element and the sensing element to a connector for connecting the ablation element and the sensing element to an ablation system.

2. A clamp assembly as in claim **1**, wherein the connection mechanism comprises one or more wires.

3. A clamp assembly as in claim **1**, wherein the sensing element comprises a temperature sensor.

4. A clamp assembly as in claim **1**, wherein the sensing element comprises a pacing electrode.

5. A clamp assembly as in claim **1**, wherein the sensing element comprises an optical sensor.

6. A clamp assembly as in claim **5**, wherein the optical sensor detects tissue color change that occurs as tissues are heated to above 60° C.

7. A clamp assembly as in claim **5**, wherein the optical sensor detects changes to near-field microwave that occur as tissues temperatures rise or fall.

8. A clamp assembly as in claim **1**, wherein the sensing element penetrates a tissue surface of a tissue as the tissue is clamped between the first and second jaws of the clamp assembly.

9. A clamp assembly as in claim **8**, wherein the sensing element comprises a temperature sensor.

10. A clamp assembly as in claim **8**, wherein the sensing element comprises a pacing electrode.

11. A clamp assembly as in claim **8**, wherein the sensing element comprises an electrode that senses tissue impedance.

12. A clamp assembly as in claim **1**, wherein the ablation element heats tissue using radiofrequency energy.

13. A clamp assembly as in claim **1**, wherein the ablation element heats tissue using microwave energy.

14. A clamp assembly as in claim **1**, wherein the ablation element heats tissue using ultrasonic energy.

15. A clamp assembly as in claim **1**, wherein the ablation element freezes tissue to achieve ablation.

16. A clamp assembly as in claim **8**, further comprising one or more ablation elements coupled with the second jaw.

17. A system for ablating tissue, comprising:

an ablation clamp comprising a first jaw, a second jaw, one or more ablation elements mounted on the first jaw, and a sensing element mounted on the second jaw that assesses transmurality of a lesion created by the ablation element;

an ablation control system for controlling an ablation process provided by the ablation clamp; and

means for connecting the ablating element and the sensing element with the ablation control system.

18. A system as in claim **17**, wherein the ablation control system stops the ablation process when the sensing element carried by the second jaw indicates that a transmural lesion has been created.

19. A system as in claim **17**, wherein the ablation control system stops the ablation process if a predetermined maximum time limit has been reached.

20. A clamp assembly for ablating tissue, comprising:

a first jaw;

an ablation element mounted on the first jaw;

a second jaw;

a sensing element mounted on the second jaw, wherein the sensing element comprises a temperature sensor, a pac-

ing element, or an optical sensor, wherein the sensing element penetrates a tissue surface of a tissue as the tissue is clamped between the first and second jaws of the clamp assembly, and wherein the sensing element is configured to assess transmurality of a lesion created by the ablation element; and

a connection mechanism that connects the ablation element and the sensing element to a connector for connecting the ablation element and the sensing element to an ablation system.

* * * * *

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申请(专利权)人(译)	ESTECH，INC.（内镜TECHNOLOGIES，INC.）		
当前申请(专利权)人(译)	ESTECH，INC.（内镜TECHNOLOGIES，INC.）		
[标]发明人	IBRAHIM TAMER SWANSON DAVID K		
发明人	IBRAHIM, TAMER SWANSON, DAVID K.		
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摘要(译)

组织夹持系统和方法评估通过消融产生的损伤的透壁性。用于消融组织的示例性夹持系统包括第一钳口，安装在第一钳口上的消融元件，第二钳口和安装在第二钳口上的传感元件。传感元件可以配置成评估由消融元件产生的损伤的透壁性。系统还可以包括连接机构，该连接机构将消融元件和传感元件连接到连接器，用于将消融元件和传感元件连接到消融系统。