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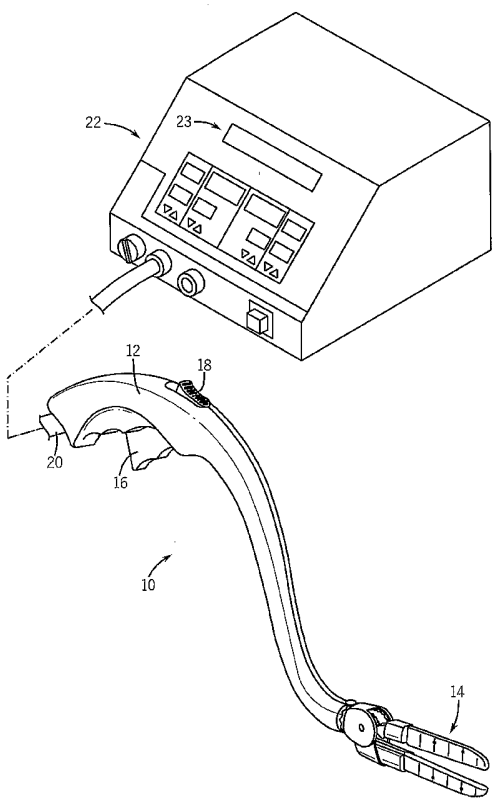
(54) Title: DEVICE AND METHOD FOR DETERMINING TISSUE THICKNESS AND CREATING CARDIAC ABLATION LESIONS



(57) Abstract: A tissue ablation device (10) has a handle (12) and an ablation head (14) coupled to the handle. The ablation head has a first jaw (24), a second jaw, and an ablative element (28) coupled to at least one of the first and second jaws. A thickness measurement device (40) may be coupled to the ablation device to indicate the distance separating the first and second jaws. Further, a force measurement device (50) may be coupled to the ablation device to measure the force being applied by the first and second jaws to a piece of tissue. Further, a strain measurement device (60) may be coupled to the ablation device to indicate the strain resulting in a piece of tissue disposed between the first and second jaws when a stress is applied to the tissue.

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DEVICE AND METHOD FOR DETERMINING TISSUE THICKNESS AND CREATING CARDIAC ABLATION LESIONS

FIELD OF THE INVENTION

The present invention relates to tissue ablation devices generally, and more particularly to devices adapted to ablate lines of tissue, for example for use in conjunction with an electrosurgical version of the Maze procedure. More particularly, the invention relates to an ablation device that aids in the measurement of tissue thickness and monitoring the transmurality of lesions.

BACKGROUND OF THE INVENTION

Various types of electrophysiology devices are used for ablating tissue. Typically, such devices include a conductive tip or blade which serves as one electrode in an electrical circuit which is completed via a grounding electrode coupled to the patient. With sufficiently high levels of electrical energy between the two electrodes, heat is generated which is sufficient to denature proteins within

It is well known that by controlling the energy level, the amount of heat generated and degree of tissue damage can also be controlled. High levels of voltage can cut and remove tissue (i.e. electrosurgery), while lower levels will simply create sufficient heat to cause cell damage, but leave the structure intact and block electrical pathways within the tissue. Irrigation of the electrodes with saline or other conductive fluid can decrease the interface impedance, cool the tissue, and allow for a greater lesion depth. It is also know that a bipolar system (where the grounding electrode is in close proximity to the conductive tip) can create narrower and deeper lesions. At the limit, the grounding electrode is in the same dimension as the conductive tip, and both electrodes are used to create the lesion.

A bipolar ablation design may be created by integrating the electrode into the jaws of a hemostat (or forceps) like device. Mounting two electrodes onto the

jaws of a forceps results in a tool that can clamp and ablate the tissue between the jaws.

[A wide variety of surgical procedures involve ablation of selected tissue. One such procedure is the Maze procedure, which is a surgical operation for patients with atrial fibrillation that is resistant to medical treatment. In the conventional version of this procedure, incisions are created in the right and left atria to produce an orderly passage of the electrical impulse from the sino-atrial node (SA node) to the atrial-ventricular node (AV node). Blind passageways are also created to suppress reentry cycles. Ablation of cardiac conduction pathways in the region of tissue where electrical signals are malfunctioning is now being used to replace surgical incisions in the Maze procedure. Ablation is also used therapeutically with other organ tissues, such as the lungs, liver, prostate, and uterus. Ablation may also be used in treatment of disorders, such as tumors, cancers, or undesirable growths. There are various types of ablation devices that are in use and in development that are intended for use in the Maze procedure.

Sometimes ablation is necessary only at discrete positions along the tissue. At other times, ablation is desired along a line, called linear ablation. This is the case for atrial fibrillation, where the aim is to reduce the total mass of contiguous (electrically connected) atrial tissue below a threshold believed to be critical for sustaining multiple reentrant wavelets. Linear lesions are created between electrically non-conductive anatomic landmarks to reduce the contiguous atrial mass. One way of accomplishing linear ablation is to use a pair of bipolar electrosurgical forceps having jaws with an elongated electrode or series of electrodes used to apply energy to tissue for ablation purposes. One embodiment of this approach is described in U.S. Patent Publication No. 2003/0171745, published September 11, 2003, and titled "Ablation System and Method of Use," which is incorporated herein by reference in its entirety.

In conjunction with the use of electrosurgical ablation devices, various control mechanisms have been developed to control delivery of ablation energy to achieve the desired result of ablation (killing of cells at the ablation site while leaving the basic structure of the organ to be ablated intact). Additionally, there

has been substantial work done toward assuring that the ablation procedure is complete, i.e. that the ablation extends through the thickness of the tissue to be ablated, before terminating application of ablation energy. This desired result is referred to as "transmural" ablation. Non-transmural lesions may be capable of propagating a depolarization wave form, or action potential and may not be effective in treating an arrhythmia. One embodiment of a system for assessing the transmurality of an ablation lesion is described in U.S. Patent Publication No. 2003/0195384, published October 16, 2003, and titled "System and Method for Assessing Transmurality of Ablation Lesions," which is incorporated herein by reference in its entirety.

One challenge associated with ablation procedures relates to determining the proper energy to apply to the tissue and duration of application of that energy in order to achieve the desired transmurality. One approach is to estimate tissue thickness and then to consult a look-up table to determine an experimentally determined energy and duration associated with that thickness. However, such an approach requires an accurate assessment of tissue thickness, which may also present a challenge. Further, depending on the type of device used to apply ablation energy to the tissue, further variables may be introduced. For example, when using a hemostat type device, the pressure between the jaws is a function of the force applied to the handles any may vary depending on the person holding the device. Such variability impacts the most effective treatment time and energy.

The design challenge with any ablation device, and in particular with a hemostat type device, is to create a lesion having consistent quality, in particular a continuous linear lesion when engaging in the Maze procedure. Further, it is desirable to create a lesion that is not too wide and that may be created in the least amount of time. Further, a challenge in the creation of such a device is to reduce the variability based upon the user such that a device may be used by various users with consistent results.

Accordingly, there is a need for an ablation device that is configured to permit a consistent application of appropriate force at the tissue site when in use. Further, there is a need for a device configured to permit real time assessment of

lesion transmurality while in use. Further still, there is a need for an ablation device having the ability to aid in the determination of ablation parameters, such as degree of applied force, time of treatment, and treatment energy.

It would be desirable to provide a system and/or method that provides one or more of these or other advantageous features. Other features and advantages will be made apparent from the present specification. The teachings disclosed herein extend to those embodiments that fall within the scope of the appended claims, regardless of whether they accomplish one or more of the aforementioned needs.

SUMMARY OF THE INVENTION

The invention relates to a tissue ablation system having a handle and an ablation head coupled to the handle. The ablation head has a first jaw and a second jaw and an ablative element coupled to at least one of the first and second jaws. A thickness measurement device is coupled to the ablation head. The thickness measurement device indicates a distance separating the first and second jaws.

The invention further relates to a tissue ablation system having a handle and an ablation head coupled to the handle. The ablation head has a first jaw and a second jaw and an ablative element coupled to at least one of the first and second jaws. A force measurement device is coupled to the ablation head. The force measurement device indicates the force being applied by the first and second jaws on a piece of tissue disposed between the first and second jaws.

The invention further relates to a tissue ablation system having a handle and an ablation head coupled to the handle. The ablation head has a first jaw and a second jaw and an ablative element coupled to at least one of the first and second jaws. A strain measurement device is coupled to the ablation head. The strain measurement device indicates the strain resulting in a piece of tissue disposed between the first and second jaws when a stress is applied to the tissue.

The invention further relates to a method of assessing the transmurality of an ablation lesion in a piece of tissue during the performance of a surgical ablation procedure. The method includes the steps of applying a stress to the piece of tissue

and calculating a strain in the tissue resulting from the application of the stress. The method further includes the step of determining the degree of transmurality of the ablation lesion based upon the strain and the stress.

The invention further relates to a method of ablating tissue. The method includes the steps of providing a bipolar ablation device having a pair of jaws, the jaws having one or more ablation electrodes, inserting the tissue between the jaws, and closing the jaws until the jaws engage the tissue. The method further includes the steps of measuring a thickness of the tissue by determining the distance between the jaws, selecting a jaw force, selecting an electrode energy, and selecting a time of energy application. The method further includes the steps of applying the selected jaw force to the tissue, energizing the one or more ablation electrodes to apply the selected electrode energy, and deenergizing the one or more ablation electrodes after the selected time has elapsed.

The invention is capable of other embodiments and of being practiced or carried out in various ways. Alternative exemplary embodiments relate to other features and combinations of features as may be generally recited in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will become more fully understood from the following detailed description, taken in conjunction with the accompanying drawings, wherein like reference numerals refer to like elements, in which:

FIG. 1 is a schematic perspective view of a tissue ablation system;

FIG. 2 is a perspective view of the head of a bipolar tissue ablation device having a thickness gauge;

FIG. 3 is a perspective view of the head of a bipolar tissue ablation device having a force meter;

FIG. 4 is a perspective view of the head of a bipolar ablation device having a strain gauge integrated therein;

FIG. 5 is an elevation view of the head of a bipolar ablation device engaging a piece of tissue; and

FIG. 6 is a chart showing exemplary stress versus strain curves for tissues in various states of ablation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, a tissue ablation device, shown as a bipolar ablation device 10 has a handle 12 and an ablation head 14. A trigger 16 may be used by a surgeon to control certain functions of the ablation head 14. A switch, shown as locking mechanism 18, may be utilized to lock the ablation head 14 into position during a surgical procedure.

Further referring to FIG. 1, in an exemplary embodiment of a tissue ablation system, bipolar ablation device 10 may be partially controlled by and may provide feedback to a control device, such as generator 22. A cord 20 serves as a conduit for various smaller cords and tubes between generator 22 and ablation device 10. For example, cord 20 may house a power line for ablation head 14, saline irrigation lines to and from ablation head 14, and various other wires and cords sending signals to and receiving signals from ablation head 14. An exemplary bipolar ablation device having many of the features described with respect to FIG. 1 is the CARDIOBLATE BP™ brand ablation system, available from Medtronic, Inc.

Referring to FIG. 2, in an exemplary embodiment, ablation head 14 has a pair of jaws 24, 26. One or both of the jaws 24, 26 may have an ablative element for ablating tissue. The ablative element is typically an energy transfer device. In the embodiment shown in FIG. 2, ablative elements are shown as linear electrodes 28, that are used to impart RF energy to tissue for ablation purposes. There are many types of ablative elements and electrodes that may be used for ablation purposes, some of which are described in U.S. Patent Publication No. 2003/0171745.

Further referring to FIG. 2, one jaw 24 may be pivotally coupled to the other jaw 26 via a pivot point 32 so that the jaws 24, 26 may be opened and closed via a mechanical or electromechanical mechanism known in the art. Further, jaw 26 is shown as being rotatably coupled to a base 34 via a pivot point 30, allowing

jaws 24, 26 to be rotated together with respect to base 34. Base 34 is coupled to handle 12 and may have a mechanism allowing for quick removal from handle 12. In an exemplary embodiment, jaws 24, 26 are approximately seven centimeters in length and the electrodes 28 are each approximately five centimeters in length. Jaws 24, 26 may have length markings 36 to aid in their performance of surgical procedures. Further, jaws 24, 26 may be malleable such that a surgeon may curve the jaws to conform to a desired ablation lesion shape.

Further referring to FIG. 2, a thickness measurement device shown as thickness gauge 40 may be coupled to ablation head 14 in an exemplary embodiment. The thickness gauge 40 is used to determine the thickness of material placed between jaws 24, 26. One such way of determining the thickness of material between jaws 24, 26 is for thickness gauge 40 to be a potentiometer or rheostat coupled to the ablation head 14 at pivot point 32. Such a potentiometer may provide an electronic output signal representative of the distance between jaws 24, 26, the signal changing as upper jaw 24 is rotated with respect to lower jaw 26. In an exemplary embodiment, the signal provided by the potentiometer may be converted by the generator 22 (see FIG. 1) into a reading representative of the distance between jaws 24, 26, indicating the thickness of a piece of tissue between jaws 24, 26. The reading may be shown on a display 23 (see FIG. 1).

Although thickness gauge 40 is shown as a potentiometer or rheostat in FIG. 2, other thickness measurement devices may also be used, such as an ultrasonic thickness gauge or markings on the head 14 providing a visual indication of the distance between jaws 24, 26. Alternatively, receiver/transmitter pairs may be inserted into the jaws that electronically measure the distance between the electrodes and therefore the thickness of tissue between the jaws. In the embodiment depicted in FIG. 2, the jaws are pivotally coupled to one another so the distance between the jaws may be related to the angle between the jaws. However, in other systems where the jaws are adjusted in a linear fashion, thus maintaining the electrodes parallel with one another, the measured distance may be in units of length. Even when the measurement is made in degrees, the number of

degrees may be converted to a reading in units of length, such as to provide the distance between the midpoints of each of the jaws 24, 26.

Referring to FIG. 3, in an exemplary embodiment, a force measurement device, shown as force meter 50 is incorporated into ablation head 14. The force meter 50 provides a measurement of the force being applied between jaws 24, 26 on material, such as tissue placed between jaws 24, 26. Various types of force meters used to provide an indication of the force between a pair of jaws are known in the mechanical arts.

The force meter 50 may provide a direct indication of the force being applied between the electrodes 28 or may alternatively provide an electronic signal representative of the force to another instrument, such as generator 22, which may then convert the electronic signal into a reading representative of the force being applied. In one embodiment, the jaws 24, 26 are closed by depressing trigger 16 (see FIG. 1). In such a case, a user may apply a certain amount of force to trigger 16 resulting in an appropriate force between jaws 24, 26 as indicated by force meter 50. The user may then lock the jaws 24, 26 into place with locking mechanism 18 prior to energizing linear electrodes 28. Alternatively, a user may program an appropriate jaw force into generator 22, for example, which may automatically close jaws 24, 26 over a desired piece of tissue and apply the desired amount of force, without the user having to depress trigger 16. While the force meter 50 is shown as being attached to base 34, it is to be understood that a force measurement device providing the desired functionality of force meter 50 may be placed in several different locations on bipolar ablation device, depending on the method by which the force between jaws 24, 26 is measured.

Referring to FIG. 4, in an exemplary embodiment, a strain measurement device, shown as strain gauge 60, may be incorporated into bipolar ablation device 10. The strain gauge 60 may be used to determine the amount of strain resulting in a material between jaws 24, 26 due to an applied stress. Various types of strain gauges are known in the art. The strain in the material between jaws 24, 26 may be calculated by any of a number of methods, such as by calculating the ratio of the distance of compaction of the material between jaws 24, 26 and the original

thickness of the material between jaws 24, 26. The strain gauge 60 may automatically calculate the strain, or the strain may be calculated by an external instrument, such as generator 22, utilizing inputs provided by the strain gage 60 or other devices in the head 14, such as the thickness gauge 40. The output from strain gauge 60 may be utilized in other calculations as discussed below.

Referring to FIG. 5, in the performance of certain surgical procedures, such as a Maze procedure, the bipolar ablation device is used to create ablation lesions in tissue, such as heart tissue. In the performance of such a procedure utilizing bipolar ablation device, jaws 24, 26 are placed over a selected portion of tissue 70. An electrode energy is then selected along with a desired degree of force to be applied to tissue 70 between jaws 24, 26. Further, an ablation time may be selected that corresponds to the thickness of tissue 70 and the force being applied between jaws 24, 26.

In order to access the tissue to be ablated, a surgeon must first open an aperture into a patient's body. In the performance of a Maze procedure, access to the patient's heart may be provided via an open chest, such as utilizing a median sternotomy. Alternatively, access to the heart may be provided via a minimally invasive approach, such as with endoscopic tools on a "closed" chest, using one or more small incisions or ports. The Maze procedure may be performed on a beating heart, or on a stopped heart, requiring the use of a heart lung machine to place the patient on cardiopulmonary bypass. The locations of the lesions made in the performance of a Maze procedure, as well as methods of accessing the heart, are known in the art.

In order to create a lesion, the surgeon inserts a selected portion of tissue 70 between jaws 24, 26 and closes the jaws on the tissue 70 using an appropriate amount of force. The jaws may be closed utilizing the trigger 16 (see FIG. 1) or may be done automatically from signals sent from generator 22 or other control device.

Prior to selecting the ablation parameters such as RF energy, force, and time, the surgeon may wish to know the tissue thickness. The thickness gauge 40 may be utilized to provide the thickness parameter by closing the jaws 24, 26 over

the selected portion of tissue 70 and providing a visual indication of or signal representative of the thickness of tissue 70.

After determining the thickness of tissue 70, the surgeon may apply an appropriate amount of force using jaws 24, 26 prior to engaging electrodes 28. In order to provide accuracy in the amount of force applied, the force meter 50 of the present invention may be utilized to measure the force being applied. The amount of force may be visually read by the surgeon or may be provided in an electronic signal representative of the force to a control unit such as generator 22.

After closing the jaws 24, 26 on tissue 70 at the appropriate degree of force, the surgeon may lock the jaws into place at that degree of force utilizing locking mechanism 18. Alternatively, robotic control of the jaws may be provided by a control device, such as generator 22, rather than a manual locking mechanism 18. At this point, the surgeon may engage linear electrodes 28 to begin the creation of an ablation lesion in tissue 70. During the application of RF energy to create the ablation lesion, saline may be applied to the ablation area between electrodes 28 to cool the tissue 70. Saline may be provided to jaws 24, 26 via a saline irrigation line connected to a saline source.

Once an RF energy and force of application have been selected and the tissue thickness has been determined, a surgeon may determine the time of energy application necessary to accomplish the goal of a transmural lesion. The time may be selected from experimental results for a particular type of tissue. Particularly when performing a Maze procedure, it is desirable to select the proper amount of time to ensure lesion transmurality, as a non-transmural ablation may not accomplish the goal of the procedure, and applying energy for too much time may damage the tissue more than necessary. Once the time of energy application has been determined, the surgeon may activate the electrodes 28 to ablate the tissue 70 between jaws 24, 26. After a transmural lesion has been created, the surgeon opens the jaws 24, 26 and repositions the bipolar ablation device to another region of tissue or removes the device from the patient's body and completes the procedure.

Although a precise tissue thickness measurement and application of force aids in accurately determining the amount of time necessary to create a transmural lesion, it may be beneficial to provide an indicator of lesion transmurality to ensure success of the procedure. Visual assessment of the tissue to determine transmurality may be inconvenient or impossible depending on the location of the tissue being ablated and the type of ablation device. Methods of assessing the transmurality of ablation lesions have been disclosed, such as the temperature assessment method disclosed in U.S. Patent Publication No. 2003/0195384.

According to one embodiment of the invention, the bipolar ablation device 10 provides a method of assessing lesion transmurality. The method may be utilized while the electrodes are energized to provide a real time assessment of lesion transmurality or may be utilized after electrodes have been utilized to create a lesion, to ensure the proper depth of ablation. It is known that ablated tissue exhibits a different strain for a given amount of stress than does non-ablated tissue. Referring to FIG. 6, hypothetical stress versus strain curves are shown to indicate the difference in strain for a given application of stress for ablated and non-ablated tissues. For example, curve 72 may correspond to fully ablated tissue in which complete transmurality has been achieved, curve 74 may correspond to partially ablated tissue, and curve 76 may correspond to non-ablated tissue.

As described above, certain embodiments of the present invention are described as having a strain measurement device, such as strain gauge 60, and a force measurement device such as force meter 50. These elements may be combined to provide the information necessary to utilize stress versus strain data to determine lesion transmurality. A given amount of stress may be applied to the tissue utilizing force meter 50 as an indicator of the force being applied over the area of the jaws. Alternatively, the selected amount of stress may be applied automatically using a control device such as generator 22. The resultant strain may be directly measured using strain gauge 60, but may also be calculated using thickness gauge 40 to calculate the change in thickness resultant from the applied stress versus the original thickness of the tissue.

The strain measurement may be quickly performed during a procedure while the electrodes are activated if desired. If this is the case, a control device, such as generator 22, may be programmed to perform real time assessments of lesion transmurality and automatically cease the application of RF energy through electrodes 28 when lesion transmurality has been accomplished. Further, stress versus strain curves for a number of degrees of lesion transmurality may be generated and programmed into generator 22 such that the user may be provided a real time indication of depth of ablation as a procedure is being performed.

While the concepts of measuring tissue thickness, force application, and tissue strain are described with respect to a bipolar ablation device, such concepts may be useful when applied to other types of ablation devices such as an electrocautery device, an electrosurgical device, an ablation paddle, and an ablation wire, among other types of devices. A set up similar to that shown in FIGS. 1-5 may be utilized, for example by replacing the ablation head 14 with a different type of ablation device. Further, ablation may be accomplished using ultrasonic energy, microwave energy, or a cryogenic approach, instead of or in addition to the RF energy described herein.

The bipolar ablation device and system may be used in procedures requiring tissue ablation in the heart as described herein. However, the ablation device and system may also be used on other tissues (e.g. lungs, liver, prostate, etc.) and in other types of surgical procedures that require tissue ablation.

The generator depicted in FIG. 1 may be used to provide power to bipolar ablation device 10 and to control the various parts that are subject to automatic control, such as the opening, closing, and positioning of ablation head 14 and jaws 24, 26. The generator may have various visual displays, such as the force being applied, the thickness of a selected piece of tissue, and the degree of lesion transmurality (such as percentage complete). The generator may also incorporate other functions associated with surgical procedures, such as functioning as a cardiac monitor.

While the detailed drawings and specific examples given herein describe various exemplary embodiments, they serve the purpose of illustration only. It is

to be understood that the invention is not limited in its application to the details of construction and the arrangements of components set forth in the preceding description or illustrated in the drawings. For example, in various embodiments described in this application, a force measurement device, a thickness measurement device, and a strain measurement device are described. These may be used separately on devices, or in various combinations as desired. Furthermore, other substitutions, modifications, changes, and omissions may be made in the design, operating conditions, and arrangements of the exemplary embodiments without departing from the scope of the invention as expressed in the appended claims.

WHAT IS CLAIMED IS:

1. A tissue ablation system, comprising:
a handle;
an ablation head coupled to the handle, the ablation head having a first jaw and a second jaw;
an ablative element coupled to at least one of the first and second jaws; and
a thickness measurement device coupled to the ablation head, wherein the thickness measurement device indicates a distance separating the first and second jaws.

2. The tissue ablation system of claim 1, wherein the thickness measurement device is a thickness gauge.

3. The tissue ablation system of claim 2, wherein the thickness gauge is a potentiometer.

4. The tissue ablation system of claim 1, further comprising a generator electrically coupled to the ablation head, the generator having a display and wherein the distance separating the first and second jaws is shown on the display.

5. The tissue ablation system of claim 1, further comprising a force measurement device, wherein the force measurement device indicates the force being applied by the first and second jaws on a piece of tissue disposed between the first and second jaws.

6. The tissue ablation system of claim 1, further comprising a strain measurement device, wherein the strain measurement device indicates the strain resulting in a piece of tissue disposed between the first and second jaws when a stress is applied to the tissue.

7. The tissue ablation system of claim 6, further comprising a force measurement device, wherein the force measurement device indicates the stress applied to the tissue.

8. A tissue ablation system, comprising:

a handle;

an ablation head coupled to the handle, the ablation head having a first jaw and a second jaw;

an ablative element coupled to at least one of the first and second jaws; and

a force measurement device, wherein the force measurement device indicates the force being applied by the first and second jaws on a piece of tissue disposed between the first and second jaws.

9. The tissue ablation system of claim 8, wherein the force measurement device is a force meter.

10. The tissue ablation system of claim 8, further comprising a generator coupled to the ablation head, the generator having a display and wherein the force being applied by the first and second jaws is shown on the display.

11. The tissue ablation system of claim 10, wherein the generator controls the amount of force being applied by the first and second jaws.

12. The tissue ablation system of claim 8, further comprising a strain measurement device, wherein the strain measurement device indicates the strain resulting in the tissue when the force is applied.

13. A tissue ablation system, comprising:

a handle;

an ablation head coupled to the handle, the ablation head having a first jaw and a second jaw;

an ablative element coupled to at least one of the first and second jaws; and

a strain measurement device coupled to the ablation head, wherein the strain measurement device indicates the strain resulting in a piece of tissue disposed between the first and second jaws when a stress is applied to the tissue.

14. The tissue ablation system of claim 13, wherein the strain measurement device is a strain gauge.

The tissue ablation system of claim 13, further comprising a generator having a display, and wherein the strain is shown on the display.

15. A method of assessing the transmurality of an ablation lesion in a piece of tissue during the performance of a surgical ablation procedure, comprising:

applying a stress to the piece of tissue;

calculating a strain in the tissue resulting from the application of the stress; and

determining the degree of transmurality of the ablation lesion based upon the strain and the stress.

16. The method of claim 16, wherein the determination of the degree of transmurality of the ablation lesion is performed by consulting a set of experimentally determined stress versus strain curves for the type of tissue being ablated.

17. The method of claim 16, wherein the strain is calculated by a strain gauge.

18. The method of claim 16, wherein an ablation head having a pair of jaws with ablation electrodes implanted therein is utilized for applying ablation energy to the piece of tissue.

19. The method of claim 19, wherein the stress is applied to the piece of tissue by the pair of jaws.

20. The method of claim 20, further comprising providing a force meter coupled to the pair of jaws and wherein the force meter calculates the stress applied to the piece of tissue.

21. The method of claim 21, wherein the transmurality assessment is performed while applying ablation energy to the piece of tissue.

22. A method of ablating tissue, comprising:
providing a bipolar ablation device having a pair of jaws, the jaws having one or more ablation electrodes;
inserting tissue between the jaws;
closing the jaws until the jaws engage the tissue;
measuring a thickness of the tissue by determining the distance between the jaws;
selecting a jaw force;
selecting an electrode energy;
selecting a time of energy application;
applying the selected jaw force to the tissue;
energizing the one or more ablation electrodes to apply the selected electrode energy;
deenergizing the one or more ablation electrodes after the selected time has elapsed; and
opening the jaws to release the tissue.

23. The method of claim 23, further comprising a generator coupled to the ablation device and wherein the generator controls the application of the selected jaw force.

24. The method of claim 24, further comprising programming the selected time into the generator and wherein the generator automatically deenergizes the one or more ablation electrodes after the selected time has elapsed.

25. The method of claim 23, further comprising determining the degree of tissue ablation.

26. The method of claim 26, wherein the degree of tissue ablation is determined by analyzing the strain in the tissue resulting from an applied stress.

27. The method of claim 27, further comprising a force meter coupled to the pair of jaws and wherein the force meter is used to determine the applied stress.

28. The method of claim 27, further comprising consulting a set of experimentally determined stress versus strain curves for the type of tissue being ablated to determine the degree of tissue ablation.

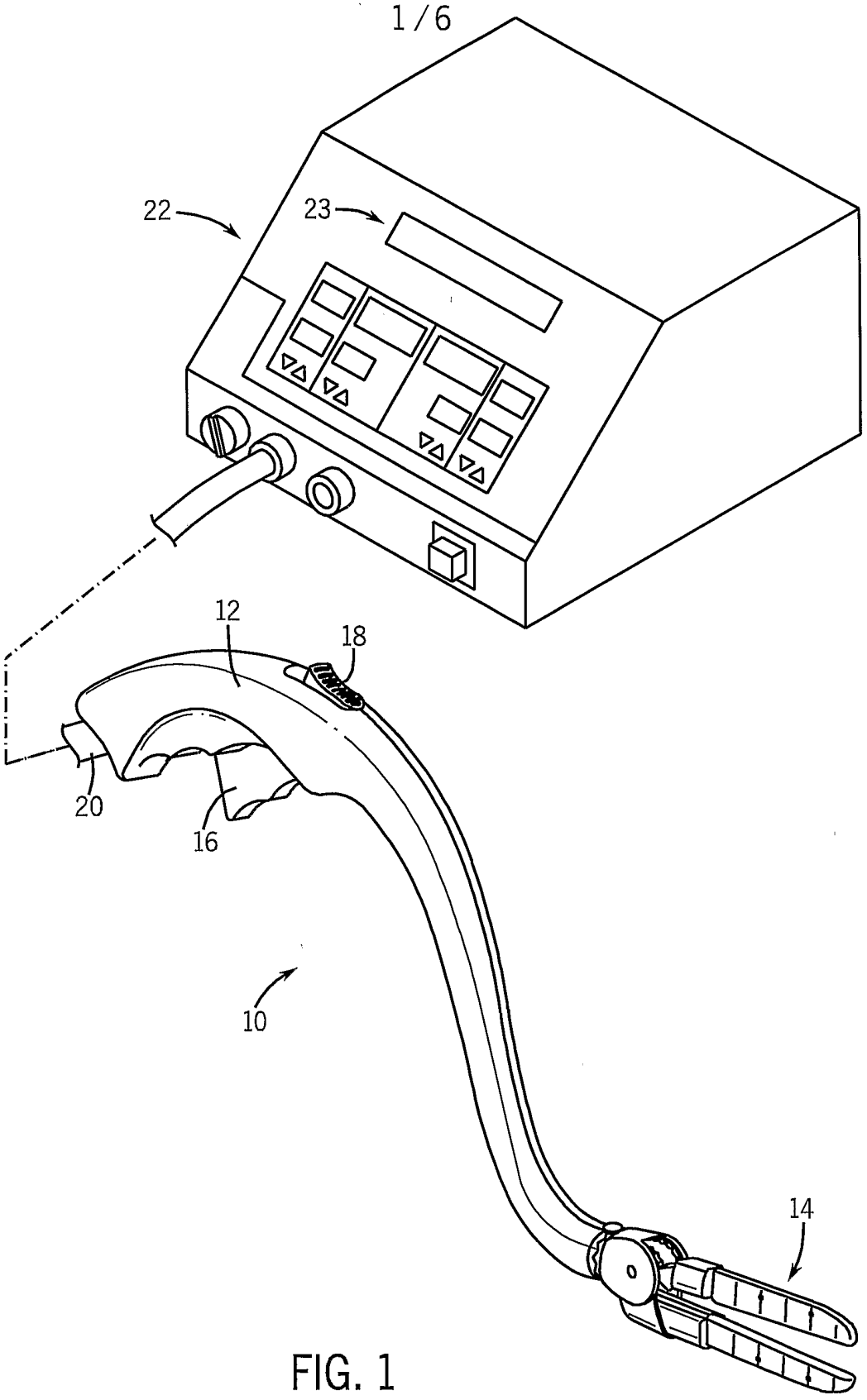

FIG. 1

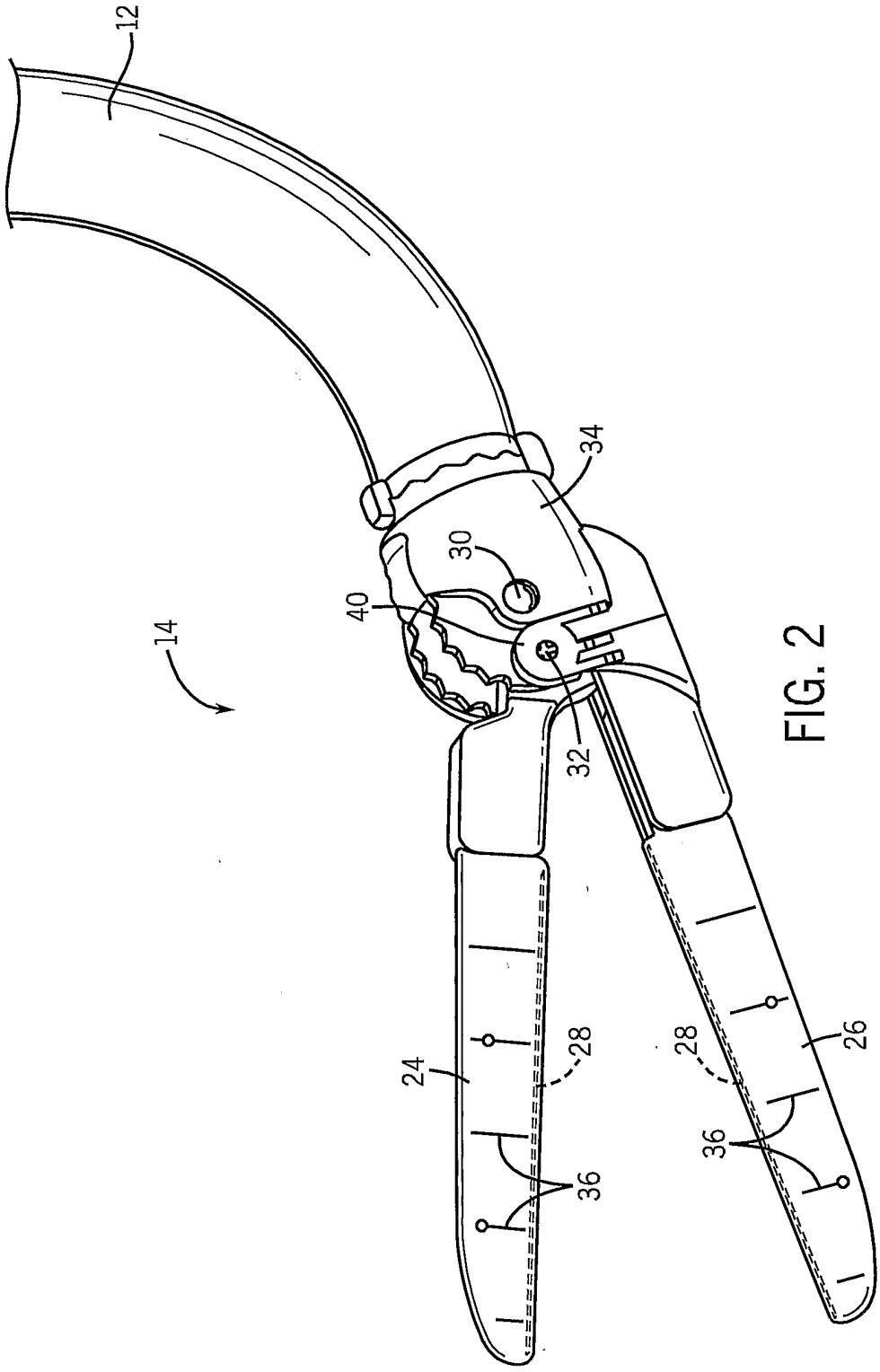

FIG. 2

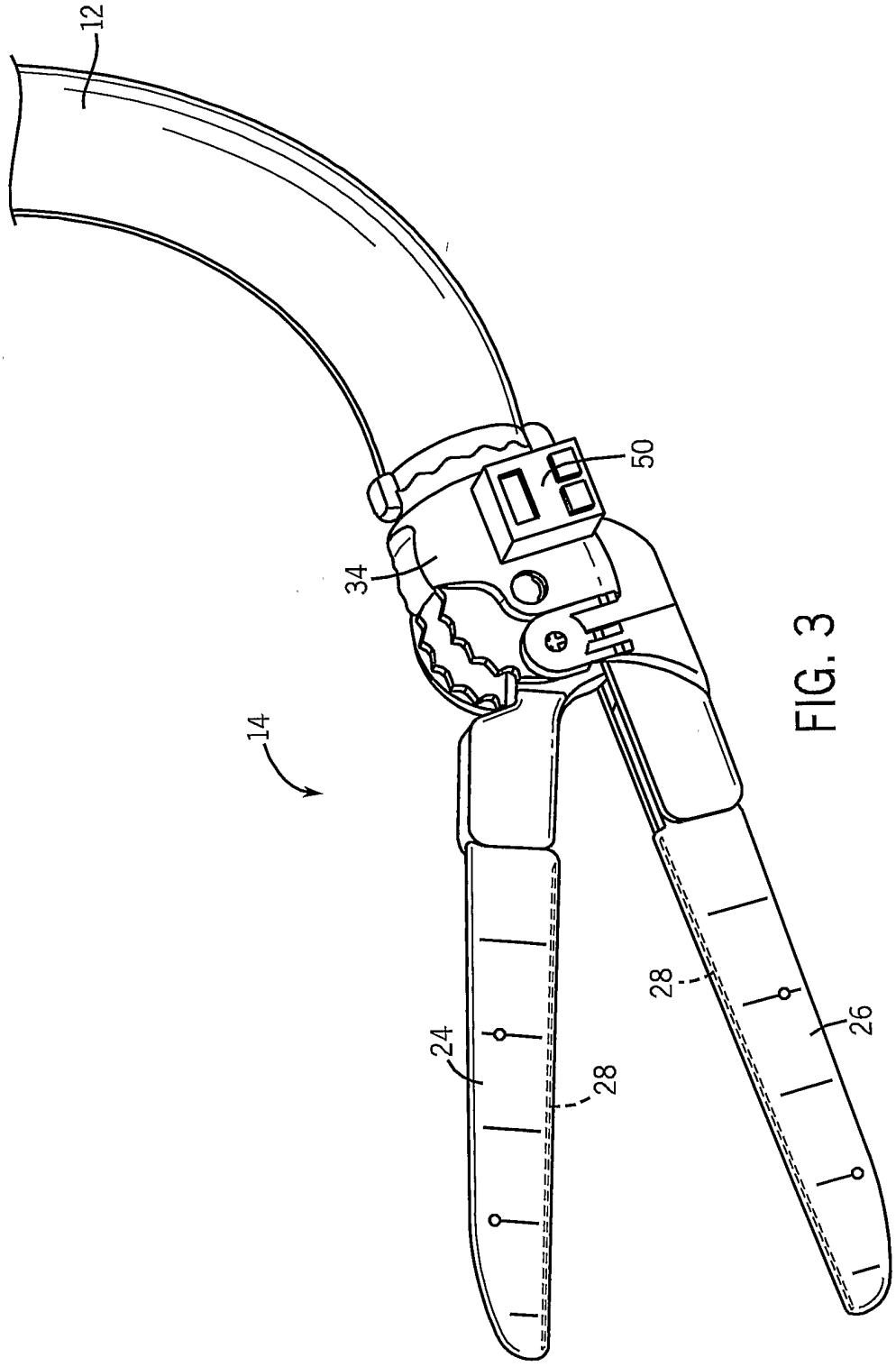

FIG. 3

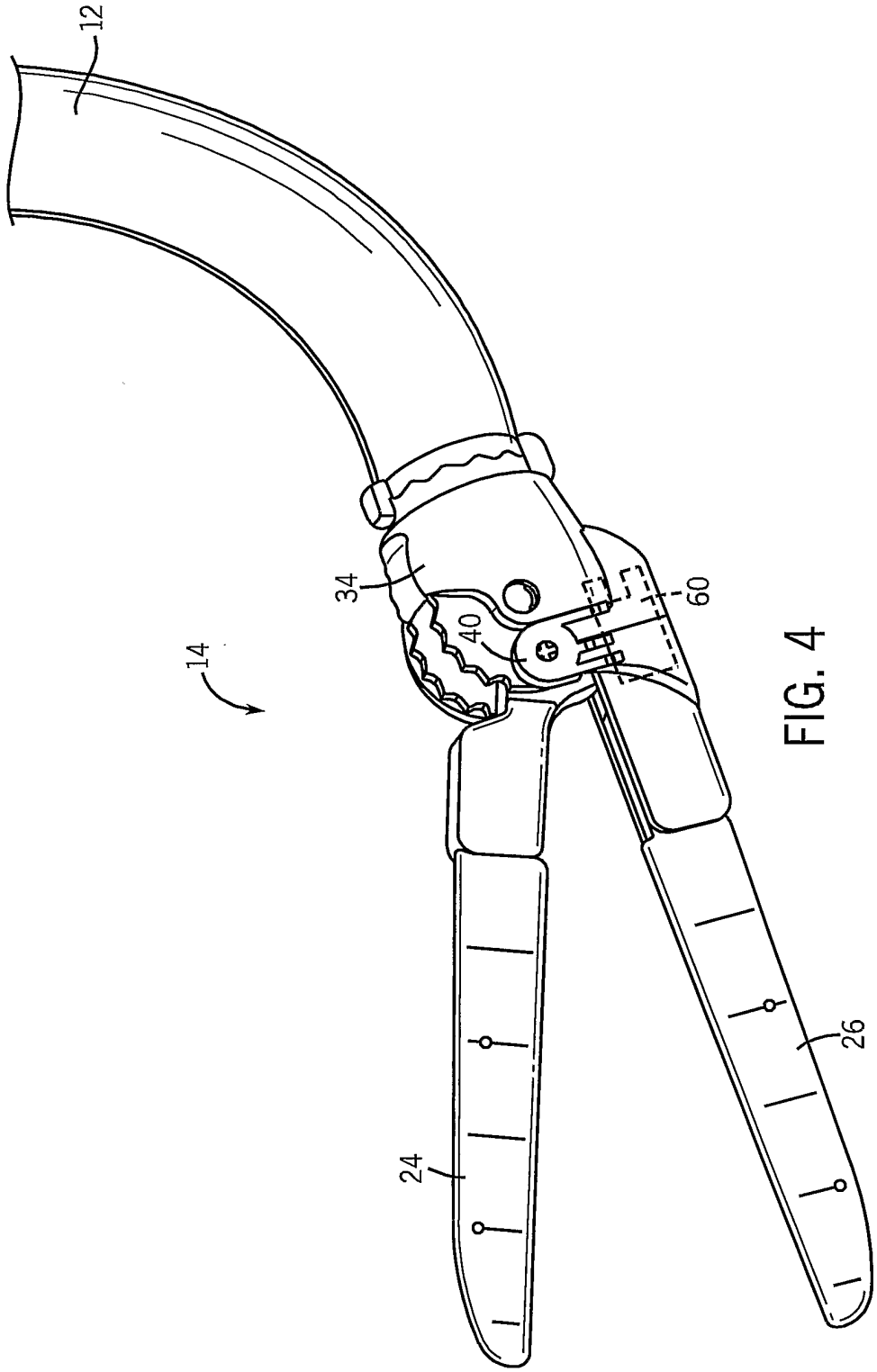

FIG. 4

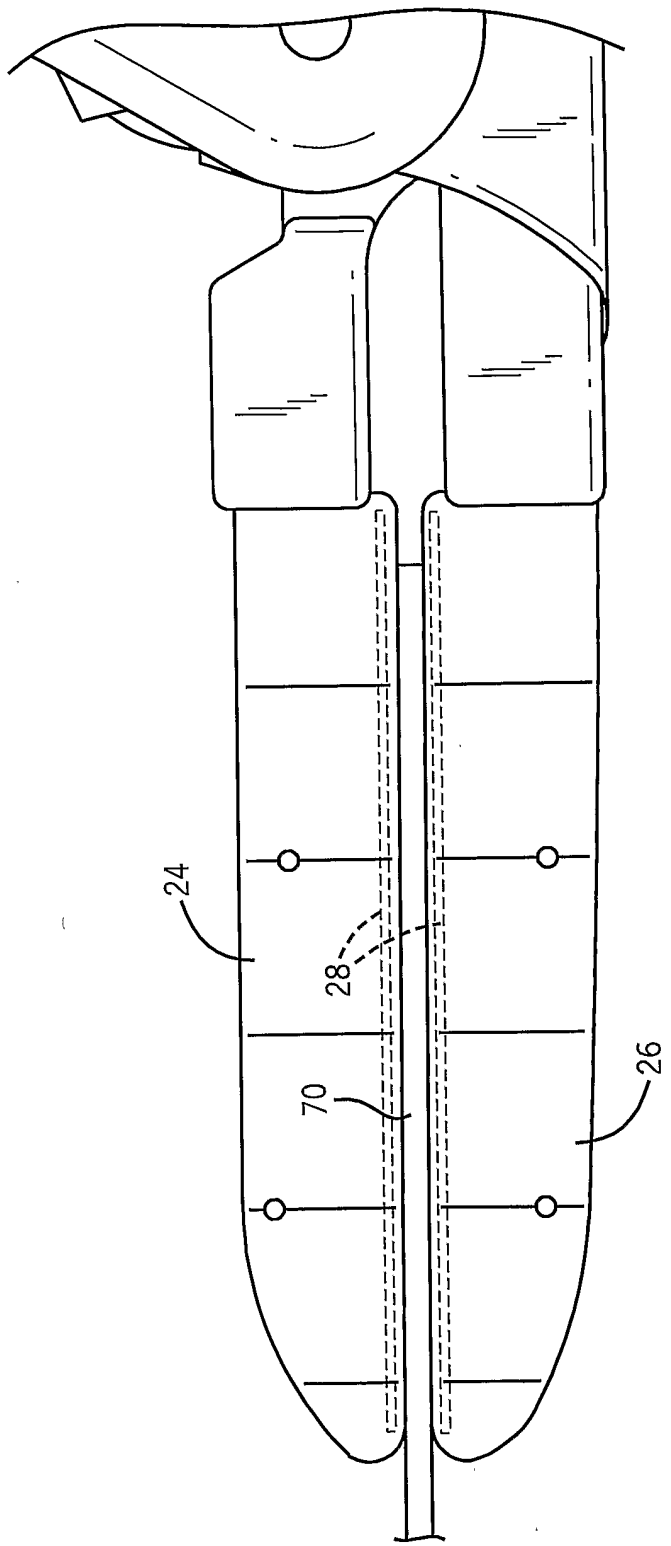

FIG. 5

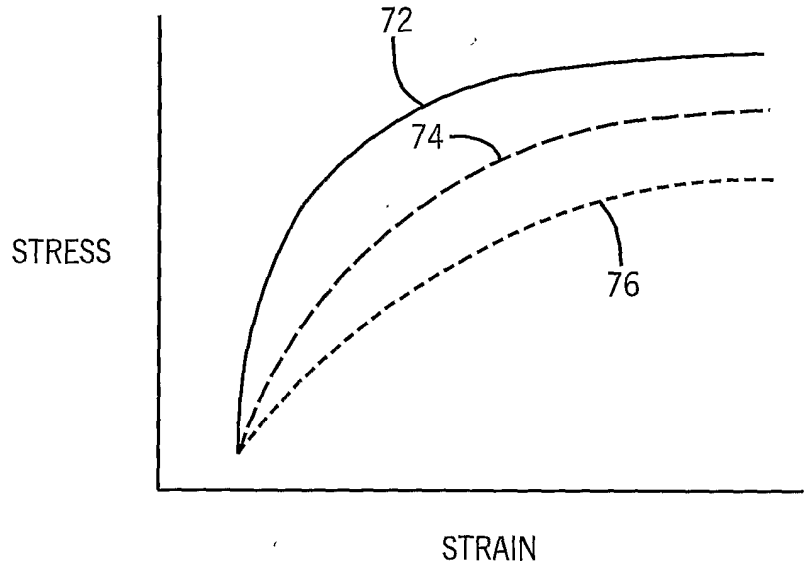

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/015614

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/090630 A (TYCO HEALTHCARE GROUP, LP; HEINRICH, RUSSELL; CUNY, DOUGLAS, J) 6 November 2003 (2003-11-06)	1-14
Y	page 19, line 24 - page 23, line 25; figures 6-8,10	1-14
Y	US 5 431 645 A (SMITH ET AL) 11 July 1995 (1995-07-11) column 2, line 33 - column 6, line 44; figures 1,15,16a,18e column 13, line 1 - column 15, line 23	1-14
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-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2005	04/08/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Fischer, O

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US2005/015614

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 582 451 B1 (MARUCCI DAMIAN DELIO ET AL) 24 June 2003 (2003-06-24) column 1, lines 5-43 column 10, lines 4-32 column 11, lines 14-31 column 16, lines 1-31; figures 1a-g,6	1,2,6, 13,14
Y	US 5 395 033 A (BYRNE ET AL) 7 March 1995 (1995-03-07) column 1, line 37 - column 4, line 3; figures 1-7	1,2,4
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/015614

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-28
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery: the method of claim 15 requires a surgical step and claim 22 concerns a surgical method of ablating tissue.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

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Intern[illegible]al Application No
PCT/US2005/015614

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Information on patent family members

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PCT/US2005/015614

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