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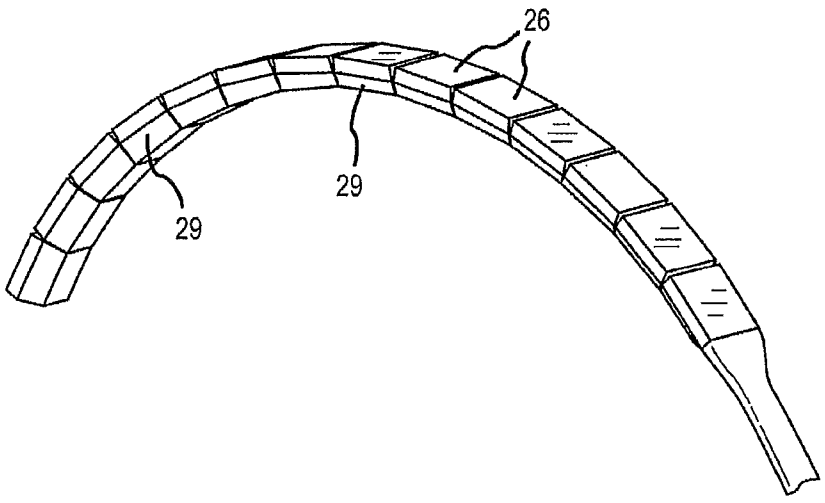

(57) **Abstract:** A device for ablating cardiac tissue includes a plurality of ablation elements substantially aligned along a common axis and adjustable between first and second predetermined positions. In the first predetermined position, the plurality of ablation elements form a curved contact surface. In the second predetermined position, the plurality of ablation elements form a substantially straight insertion configuration. At least one hinge (27) may connect adjacent ones of the plurality of ablation elements (26). Each of the plurality of ablation elements may be located within a housing (29), which may have at least a portion of a hinge integrally formed therewith to connect adjacent ablation elements. Alternatively, a strand of superelastic material (38), such as a Nitinol wire, may interconnect ablation elements. The superelastic material may bias the plurality of ablation elements into at least one of the first and second predetermined positions.

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APPARATUS AND METHOD FOR ABLATING TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to United States provisional application no. 60/815,852, filed 23 June 2006 (the '852 application). This application also claims priority to United States nonprovisional patent application no. 11/646,526, filed 28 December 2006 (the '526 application), now pending. The `852 application and the `526 application are both hereby incorporated by reference as though fully set forth herein.

[0002] This application is related to United States provisional application no. 60/815,853, United States provisional application no. 60/815,880, United States provisional application no. 60/815,881, and United States provisional application no. 60/815,882, all filed 23 June 2006. All of the foregoing applications are hereby incorporated by reference as though fully set forth herein.

[0003] This application is also related to United States application nos. 11/401,345, and 11/401,357, both filed 11 April 2006, which are continuations of United States application no. 10/255,134, filed 24 September 2002, now United States patent no. 7,052,493, which is a continuation-in-part of United States application no. 10/077,470, filed 15 February 2002, now United States patent no. 6,840,936, which is a continuation-in-part of United States application no. 09/884,435, filed 19 June 2001, now United States patent no. 6,719,755, which is a continuation-in-part of United States application no. 09/614,991, filed 12 July 2000, now United States patent no. 6,805,128, which is a continuation-in-part of United States application no. 09/507,336 filed 18 February 2000, which is a continuation-in-part of United States application no. 09/356,476, filed 19 July 1999, now United States patent no. 6,311,692, which is a continuation-in-part of United States application no. 09/157,824, filed 21 September 1998, now United States patent no. 6,237,605, which is a continuation-in-part of United States application no. 08/943,683, filed 15 October 1997, now United States patent no. 6,161,543, which is a continuation-in-part of United States application no. 08/735,036, filed 22 October 1996, now abandoned. All of the foregoing are hereby expressly incorporated by reference as though fully set forth herein.

BACKGROUND OF THE INVENTION

a. Field of the Invention

[0004] The instant invention generally relates to devices and methods for treating electrophysiological diseases of the heart. In particular, the instant invention relates to devices and methods for epicardial ablation for the treatment of atrial fibrillation.

b. Background Art

[0005] It is well known that atrial fibrillation results from disorganized electrical activity in the heart muscle (the myocardium). The surgical maze procedure has been developed for treating atrial fibrillation, and involves the creation of a series of surgical incisions through the atrial myocardium in a preselected pattern so as to create conductive corridors of viable tissue bounded by scar tissue.

[0006] As an alternative to the surgical incisions of the maze procedure, transmural ablations of the heart may be used. Such ablations may be performed either from within the chambers of the heart (endocardial ablation), using endovascular devices (e.g., catheters) introduced through arteries or veins, or from outside the heart (epicardial ablation) using devices introduced into the patient's chest. Various ablation techniques may be used, including, but not limited to, cryogenic ablation, radio frequency (RF) ablation, laser ablation, ultrasonic ablation, and microwave ablation. The ablation devices are used to create elongated transmural lesions—that is, lesions extending through a sufficient thickness of the myocardium to block electrical conduction—forming the boundaries of the conductive corridors in the atrial myocardium. Perhaps most advantageous about the use of transmural ablation rather than surgical incision is the ability to perform ablation procedures without first establishing cardiopulmonary bypass (CPB).

[0007] In performing the maze procedure and its variants, whether using ablation or surgical incisions, it is generally considered most efficacious to include a transmural incision or lesion isolating the pulmonary veins from the surrounding myocardium. The pulmonary veins connect the lungs to the left atrium of the heart, joining the left atrial wall on the posterior side of the heart. Such procedures have been found to offer 57% to 70% success without antiarrhythmic drugs. However, they are also associated with a 20% to 60% recurrence rate as the result of lesion recovery, non-pulmonary vein foci of the arrhythmia, or the need for further tissue modifications.

[0008] This location creates significant difficulties for endocardial ablation devices for several reasons. First, while many of the other lesions created in the maze procedure may be created from within the right atrium, the pulmonary venous lesions must be created in the left atrium, requiring either a separate arterial access point or a transseptal puncture from the right atrium. Second, typical elongated and flexible endovascular ablation devices are difficult to manipulate into the complex geometries required to form the pulmonary venous lesions and to maintain in such positions against the wall of the beating heart. The process is therefore very time consuming and may result in lesions that do not completely encircle the pulmonary veins or that contain gaps or discontinuities. Third, because elongated ablation devices are often pre-shaped to maintain a minimum curvature, a surgeon must create an incision in the patient's body sufficiently large to accommodate not only the width of the ablation device, but also its curvature.

BRIEF SUMMARY OF THE INVENTION

[0009] It is therefore desirable to be able to provide an ablation device for forming pulmonary vein isolation lesions that can be introduced through a relatively small incision.

[0010] It is further desirable to provide an ablation device for facilitating formation of a substantially continuous lesion about the pulmonary veins.

[0011] It is also desirable to provide an ablation device that may be used epicardially in order to avoid the need for access into the left chambers of the heart and to minimize the risk of producing thrombi.

[0012] According to a first embodiment of the invention, a device for ablating cardiac tissue includes: a plurality of ablation elements substantially aligned along a common axis, wherein the plurality of ablation elements is adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset position being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration. Optionally, the device further includes at least one hinge connecting adjacent ones of the plurality of ablation elements. Each of the plurality of ablation elements may be located within a housing, and the housing may have at least a portion of a hinge integrally formed therewith connecting adjacent ones of the plurality of ablation elements. Alternatively, a strand of superelastic material, such as a Nitinol wire, may interconnect at least two of, and optionally each of, the plurality of ablation elements.

The superelastic material may bias the plurality of ablation elements into at least one of the first and second preset positions. Optionally, the device further includes a track to which at least one ablation element is coupled such that the at least one ablation element may be positioned at a plurality of locations along the track. The track may be made of superelastic material, and may also be a medium along which control signals propagate to control operation of the at least one ablation element coupled to the track. In other embodiments of the invention, a plurality of springs bias the plurality of ablation elements into at least one of the first and second preset positions. Optionally, each of a plurality of housings accommodates at least one ablation element. The housings have first and second surfaces. When the device is adjusted in the first preset position, the plurality of housings are aligned to contact each other on their respective first surfaces. When the device is adjusted in the second preset position, the plurality of housings are aligned to contact each other on their respective second surfaces. A strand of superelastic material may interconnect at least two adjacent housings. Alternatively, a plurality of springs operate upon the plurality of housings to form at least one of the first and second preset positions.

[0013] According to another aspect of the invention, a method of ablating cardiac tissue from an epicardial location includes the steps of: providing an ablation device having a plurality of ablation elements substantially aligned along a common axis, wherein the ablation device is adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset position being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration; creating an incision in a patient; adjusting the ablation device to the second preset position; introducing the ablation device into the patient through the incision; adjusting the ablation device to the first preset position; manipulating the ablation device about an epicardial surface such that the plurality of ablation elements are positioned over tissue to be ablated; and ablating tissue by activating the plurality of ablation elements. Optionally, the ablation device further includes a track, and the method also includes the steps of adjusting at least one ablation element along the track and ablating tissue by activating the at least one ablation element adjusted along the track.

[0014] In yet another embodiment of the invention, a device for ablating cardiac tissue includes: a plurality of ablation elements substantially aligned along a common axis,

wherein the plurality of ablation elements are adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset configuration being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration; and at least one strand of a superelastic material interconnecting at least two ablation elements. Optionally, the device includes at least one hinge connecting each of the plurality of ablation elements to at least one adjacent ablation element.

[0015] According to still another embodiment, a device for ablating cardiac tissue includes: a plurality of ablation elements substantially aligned along a common axis, wherein the plurality of ablation elements are adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset configuration being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration; and at least one track to which the plurality of ablation elements is coupled, wherein one or more of the plurality of ablation elements may be repositioned at a different location along the at least one track. Optionally, the track is a superelastic material such as Nitinol. The track may also include a medium that conducts control signals used to control operation of the ablation elements coupled thereto.

[0016] According to a further embodiment of the invention, a device for ablating cardiac tissue includes: a plurality of ablation elements substantially aligned along a common axis, wherein the plurality of ablation elements are adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset configuration being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration; and a plurality of springs operating upon the plurality of ablation elements to form at least one of the first and second preset positions.

[0017] In still another embodiment of the invention, a device for ablating cardiac tissue includes: a plurality of ablation elements substantially aligned along a common axis, wherein the plurality of ablation elements are adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the

plurality of ablation elements form a curved contact surface, and the second preset configuration being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration; and a plurality of housings each accommodating at least one ablation element and having a first surface and a second surface, wherein, when the device is adjusted in the first preset position, the plurality of housings are aligned to contact each other on their respective first surfaces. Optionally, the device includes at least one strand of a superelastic material interconnecting at least two adjacent housings.

[0018] In another aspect of the invention, a method of ablating cardiac tissue from an epicardial location includes the steps of: providing an ablation device having a plurality of ablation elements substantially aligned along a track, wherein at least one of the plurality of ablation elements may be repositioned at a different location along the track; manipulating the ablation device about an epicardial surface; ablating tissue by activating the plurality of ablation elements; adjusting at least one ablation element to a different position along the track; and ablating tissue by activating the at least one ablation element that has been repositioned along the track. Optionally, the ablation device includes a plurality of ablation elements substantially aligned along a common axis, wherein the plurality of ablation elements are adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset configuration being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration, and the method further includes the steps of: creating an incision in a patient; adjusting the ablation device into the second preset position; inserting the ablation device through the incision; and adjusting the ablation device into the first preset position.

[0019] In yet a further embodiment of the invention, a device for ablating cardiac tissue includes: a plurality of ablation elements substantially aligned along a common axis, wherein the plurality of ablation elements are biased into a first preset position in which the plurality of ablation elements form a curved contact surface, and wherein the plurality of ablation elements may be elastically deformed into a second preset position in which the plurality of ablation elements form a substantially straight insertion configuration. Optionally, a hinge wire of superelastic or memory material permits the plurality of

ablation elements to be elastically deformed into the second preset position. Alternatively, a plurality of springs may permit the plurality of ablation elements to be elastically deformed into the second preset position. The plurality of ablation elements may be inserted into a sheath in order to deform the plurality of ablation elements into the second preset position. Alternatively, the plurality of ablation elements may be deformed via the use of a stylet that passes through guide holes in the plurality of ablation elements.

[0020] The device of the present invention enables creation of a uniform, continuous, linear lesion during cardiac ablation. The device can be placed securely around the patient's atrium and/or pulmonary veins while transducers apply ablation energy (for example, high intensity ultrasonic energy) safely and precisely through the targeted tissue. The present invention contemplates that the ablation device is offered in multiple sizes to accommodate varying patient anatomies.

[0021] An advantage of the present invention is that smaller incisions may be used by a surgeon during ablation treatment, which speeds the recovery process for the patient.

[0022] In another aspect of the invention, the ablating device is able to utilize a reduced number of ablation elements because a smaller number of elements may be repositioned along a track to permit ablation of tissue not initially ablated. This advantageously results in a cost savings in the manufacturing process because ablation elements are often expensive.

[0023] The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Fig. 1 schematically illustrates an ablation system according to an embodiment of the present invention.

[0025] Fig. 2 shows an introducer.

[0026] Fig. 3 is a side view of the introducer illustrated in Fig. 2.

[0027] Fig. 4 illustrates an ablation device for creating PV isolation ablations.

[0028] Fig. 5 illustrates the ablation device of Fig. 4 in an open position.

[0029] Fig. 6 shows the ablation device of Fig. 4 forming a closed loop.

[0030] Fig. 7 illustrates the introducer of Fig. 2 being advanced around the pulmonary veins.

[0031] Fig. 8 depicts the introducer extending around the pulmonary veins in order to size an ablation device.

[0032] Fig. 9 shows the ablation device being connected to the introducer.

[0033] Fig. 10 illustrates the ablation device coupled to the introducer and being advanced around the pulmonary veins via manipulation of the introducer.

[0034] Fig. 11 illustrates the same thing as Fig. 10 at a later stage of the process.

[0035] Fig. 12 shows the introducer being decoupled from the ablation device.

[0036] Fig. 13 is an expanded view of the connection between the introducer and the ablation device.

[0037] Fig. 14 depicts the ablation device forming a closed loop about the pulmonary veins.

[0038] Fig. 15 depicts the ablation device forming a closed loop about the pulmonary veins and secured in this configuration using sutures.

[0039] Fig. 16 is a magnified view of one segment of the ablation device of Fig. 4 illustrating the ablation elements interconnected via hinges.

[0040] Fig. 17 illustrates an ablation device according to an embodiment of the invention in a flat configuration.

[0041] Fig. 18 illustrates an ablation device according to an embodiment of the invention in a generally curved configuration.

[0042] Fig. 19 is a magnified view of one segment of the ablation device of Fig. 4 illustrating the ablation elements interconnected via a hinge wire.

[0043] Fig. 20 is a magnified view of one segment of the ablation device of Fig. 4 illustrating the ablation elements interconnected via springs.

[0044] Fig. 21 illustrates use of a sheath to deform the ablation device into a flat configuration.

[0045] Fig. 22 illustrates use of a pair of stylets to deform the ablation device into a flat configuration.

[0046] Fig. 23 illustrates an ablation device incorporating a track along which one or more ablation elements may be moved.

DETAILED DESCRIPTION OF THE INVENTION

[0047] Referring now to Fig. 1, an ablation system 10 according to one embodiment of the present invention is shown. Ablation system 10 includes a controller 12, which preferably operates to deliver focused ultrasound energy. Ablation system 10 may be used to wrap an ablation device 14 around the pulmonary veins at an epicardial location in order to create a pulmonary vein (PV) isolation ablation lesion. Ablation system 10 may further include a source 16 of a flowable material, which may be a bag of saline that provides a gravity feed to ablation device 14 via a standard luer connection 18.

[0048] The system further includes an introducer 20, illustrated in Figs. 2 and 3, which is advanced around the pulmonary veins as shown in Figs. 7 and 8 and described below. As shown in Fig. 2, introducer 20 preferably forms a substantially closed loop in an unbiased configuration, with a small offset near its distal tip 22 as shown in Fig. 3.

[0049] Introducer 20 may be used as a sizing device for sizing ablation device 14. For example, as shown in Fig. 2, introducer 20 may have size indicators 24 usable to determine the appropriate size of ablation device 14. For ablation device 14 shown in Figs. 4 through 6 and described in detail herein, the size of ablation device 14 is effectively determined by the number of ablation elements. It is also contemplated, however, that other methodologies for sizing ablation device 14 may be used without departing from the spirit and scope of the present invention.

[0050] In use, and as illustrated in Figs. 7 and 8, introducer 20 is inserted into the patient and passed through an incision in the pericardial reflection adjacent the right superior pulmonary vein adjacent the transverse pericardial sinus. Introducer 20 is then advanced through the transverse pericardial sinus, around the left superior and inferior pulmonary veins, and out through another incision in the pericardial reflection near the right inferior pulmonary vein. The appropriate size of ablation device 14 may then be read using indicators 24 imprinted on introducer 20. For example, in Fig. 8, size indicators 24 of introducer 20 read "12," indicating that an ablation device 14 having 12 ablation elements will substantially encircle the pulmonary veins.

[0051] With reference to Figs. 4-6 and 16-18, ablation device 14 includes a plurality of ablation elements 26 substantially aligned along a common axis and coupled together, preferably through integrally formed hinges 27 (as seen in Fig. 16) in ablation device 14. By "substantially aligned along a common axis," it is meant that there is little or no

staggering between ablation elements 26 along the direction in which they are coupled together. It should be understood that ablation elements 26 may alternatively be coupled together with mechanical connections, rather than integrally formed hinges 27, without departing from the scope of the invention. Ablation device 14 preferably has from about 5 to about 30 ablation elements 26, more preferably from about 10 to about 25 ablation elements 26, and most preferably less than about 15 ablation elements 26. It should be understood, however, that any number of ablation elements 26 may be used depending upon the specific application for ablation device 14. For example, ablation device 14 may be used to extend around only a single vessel, such as the aorta, a pulmonary vein, the superior vena cava, or inferior vena cava, in which case ablation device 14 preferably includes about 4 to about 12 ablation elements 26, and more preferably includes about 8 ablation elements 26. Each ablation element 26 is preferably a discrete, autonomously controlled cell.

[0052] A body 28 of ablation device 14 is preferably made of a polymeric material such as polycarbonate, polyetherimide (e.g., Ultem®), silicone, or urethane, and is preferably formed by injection molding. One of ordinary skill will appreciate, however, that any suitable materials and methods may be used to form ablation device 14 without departing from the spirit and scope of the present invention. Preferably, an outer surface of body 28 is smooth in order to limit the risk of catching ablation device 14 on patient tissue or otherwise causing trauma during insertion of ablation device 14.

[0053] Ablation device 14 is configured to have a predetermined curvature that facilitates encircling an area of the heart while simultaneously permitting ablation device 14 to be straightened or flattened to minimize the overall width thereof. The latter (i.e., flattened) configuration facilitates insertion of ablation device 14 through a relatively smaller incision in the patient in order to reach the heart tissue, and thus is referred to herein as an "insertion configuration." In other words, ablation device 14 is configured to permit at least two distinct configurations: a predetermined curvature (e.g., Fig. 5) to facilitate manipulation around the heart and a substantially straight, generally flattened shape (having little or no curvature, e.g., Fig. 17) to facilitate insertion into the patient's body. By using the flattened configuration during insertion, the surgeon may use a smaller incision, which reduces the patient's recovery time. By using the curved configuration to manipulate ablation device 14 around the patient's heart, the surgeon is able to more easily

maneuver ablation device 14 into position for treatment. Ablation device 14 may also be deformed into a third configuration, which is a generally closed loop as seen in Figs. 6, 14, and 15. This third configuration will be described in further detail below.

[0054] The phrase "predetermined curvature" is intended to convey that ablation device 14 is designed to assume a curved shape and maintain that general shape during certain intended manipulations. For example, while ablation device 14 may be maintained in a substantially straightened position for insertion, ablation device 14 is intended to resume and maintain a curved shape during manipulation about the heart. Additional forces may be applied on ablation device 14 in order to increase or decrease the degree of curvature, for example into the substantially closed loop third configuration illustrated in Fig. 6. The use of "predetermined" is intended to convey that ablation device 14 maintains a generally curved shape while being positioned around a portion of the heart (that is, the "relaxed" state of ablation device 14, with no external forces applied thereto, is a generally curved configuration).

[0055] In one preferred embodiment of ablation device 14, ablation elements 26 are connected using a superelastic material, including, by way of example only, a memory metal such as Nitinol. As one of ordinary skill in the art will understand, a "superelastic material" is a type of shape memory alloy that does not require a temperature change in order to regain its original, undeformed shape. The superelastic properties allow ablation device 14 to be substantially deformed to become substantially coplanar (Fig. 17) and then to return to the predetermined curvature (Fig. 18). For example, all ablation elements 26 may be interconnected using one or more strands of Nitinol, or another superelastic material, such that ablation device 14 may be substantially straightened for insertion into the patient through a relatively small incision, and thereafter manipulated into position about the heart in a generally curved configuration. The Nitinol or other superelastic material may take the form of a hinge wire 38 (Fig. 19) that connects a plurality of ablation elements 26 to maintain the predetermined curvature.

[0056] In one embodiment, each ablation element 26 is contained in a housing 29, the edges 30 of which may be angled to permit adjacent ablation elements 26 to have at least two relationships to one another: one in which they are substantially coplanar, resulting in a substantially flat configuration (e.g., Fig. 17), and another in which they are at an angle, resulting in a generally curved configuration (e.g., Fig. 18). Preferably, the angle between

the faces of adjacent ablation elements 26 when ablation device 14 is in its relaxed state (i.e., the generally curved configuration) may be adjusted based on the number of ablation elements 26, and may typically be between about 10 degrees and about 30 degrees. The hinges may be integrated wholly or partially into housings 29.

[0057] It is also contemplated that the adjustable configurations of ablation elements 26 may be implemented utilizing a spring system, such as a combination of mechanical hinges and/or springs, for example the spring-biased hinges seen in Fig. 20. The mechanical hinges and/or springs may be used in conjunction with ablation elements 26 having angled edges 30 as described above. In addition, a standard guidewire structure (not shown), which generally includes a tightly coiled wire and, optionally, a core wire running therethrough, may be utilized to interconnect ablation elements 26 without departing from the spirit and scope of the present invention.

[0058] Optionally, as shown to good advantage in Fig. 21, ablation device 14 may be deformed temporarily during insertion of ablation device 14 into the patient with the assistance of a sheath 32. Sheath 32 applies a deforming force to ablation device 14 and assists in maintaining ablation elements 26 in a substantially straight insertion configuration. Preferably, sheath 32 is a straight cylinder that is sized to accommodate ablation device 14 in the substantially straight insertion configuration. Thus, sheath 32 may be used to introduce ablation device 14 through an incision into the patient. Once ablation device 14 has been introduced through the incision, sheath 32 may be removed, and the tension caused by the superelastic wire or spring system will cause ablation device 14 to resume its predetermined curvature.

[0059] Alternatively, one or more stylets 34 may be used to deform ablation device 14 into the generally straight insertion configuration. Each ablation element 26 may include one or more guide tubes 35 shaped to receive stylets 34 therethrough. Guide tubes 35 may be internal to each ablation element 26 or, as shown in Fig. 22, mounted to the exterior of ablation device 14. As stylets 34 pass through guide tubes 35, they apply a deforming force to ablation device 14 and assist in maintaining ablation elements 26 in a substantially straight configuration to facilitate insertion of ablation device 14 through an incision into the patient. Once ablation device 14 has been introduced, stylets 34 may be withdrawn, at which time the restorative force caused by the superelastic wire or spring system will cause ablation device 14 to resume its predetermined curvature.

[0060] It is also contemplated that a sheath, stylet, or other suitable straightening device may be used to straighten introducer 20 for insertion into the patient.

[0061] Ablation elements 26 may be any element for directing and delivering ablating energy to the cardiac tissue, including, but not limited to, focused ultrasound elements, radio frequency (RF) elements, laser elements, and microwave elements. Ablation elements 26 preferably have a width of about 1 mm to about 15 mm, and more preferably of about 10 mm, and a length of about 2 mm to about 25 mm, and more preferably of about 12 mm.

[0062] Ablation elements 26 are coupled to controller 12 via wires. The wires may be collectively incorporated into a plug 36 usable to couple ablation device 14 to controller 12 as shown in Fig. 1. Controller 12 controls ablation, for example in the manner described herein. A source of ablation energy (e.g., a signal generator) may be part of controller 12 or separate therefrom. One or more temperature sensors, preferably thermocouples or thermistors, are positioned within recesses in the inner and outer lips of ablation device 14 in order to measure temperature. The temperature sensors are also coupled to controller 12, for example via plug 36, for monitoring purposes and to provide temperature feedback for controlling the ablation process as described herein.

[0063] Each ablation element 26 may also have a membrane 40 that contains the flowable material within a fluid chamber to provide a conformable interface with the tissue to be ablated as seen in Fig. 16. Membrane 40 may include openings 42 through which the flowable material may leak or weep, and each membrane 40 may be fed by an individual inlet leading thereto.

[0064] The flowable material is preferably supplied at an average flow rate of at least about 0.24 cc/sec, more preferably at least about 0.50 cc/sec, and most preferably at least about 1.0 cc/sec to each ablation element 26, although lower or higher flow rates may be used. The flowable material is preferably delivered to the inlet of ablation device 14 at a set pressure that results in the desired average flow rate through ablation elements 26. The flowable material may be heated or cooled as desired or required by passing it through a heat exchanger 44 prior to delivery to the inlet of ablation device 14 (e.g., luer connection 18 as seen in Fig. 1). The flowable material is preferably delivered at a temperature of no more than about 40 degrees C, and more preferably at a temperature of no more than about 25 degrees C, to cool the tissue and/or ablation elements 26. A fluid permeable, porous

structure, such as gauze, may be also positioned to hold the flowable material within the fluid chamber and prevent direct contact between ablation elements 26 and the tissue being ablated.

[0065] After the appropriate size of ablation device 14 is identified, for example by using introducer 20 as described above, ablation device 14 may be coupled to the proximal end of introducer 20 with any suitable connection, such as mating snap fit connectors 46 as shown in Figs. 9 and 13. It should be understood that the appropriate size of ablation device 14 may also be determined using a device or method independent of introducer 20. As described above, ablation device 14 is preferably introduced into the patient while straightened, optionally through the use of a sheath. Introducer 20 is then pulled further, as shown in Figs. 10 and 11, in order to manipulate ablation device 14 and wrap ablation device 14 about the pulmonary veins. As described above, once ablation device 14 has been introduced through the incision, the sheath may be removed in order to permit ablation device 14 to resume its predetermined curvature for manipulation about the pulmonary veins.

[0066] As shown in Fig. 12, once ablation device 14 is wrapped about the pulmonary veins, introducer 20 may be detached from ablation device 14 by detaching a releasable assembly 48 from ablation device 14. In some embodiments of the invention, releasable assembly 48 is detached by simply cutting one or more sutures 50 (Fig. 13) that hold releasable assembly 48 to the device 14. It is also contemplated that snap fit connection 46 between introducer 20 and ablation device 14 may be releasable to permit decoupling introducer 20 at the same place introducer 20 is initially coupled to ablation device 24 without the need to cut one or more sutures 50.

[0067] Ablation device 14 may then be locked to itself in a third, substantially closed-loop configuration to encircle all or part of the pulmonary veins. Device 14 has elongate elements, such as sutures 52, at both ends, which can be tensioned and cinched together to lock the ends of device 14 to each other using tourniquets 54 and suture snares 56 as shown in Figs. 6, 14, and 15.

[0068] Preferably, ablation device 14 has two opposing pairs of sutures 52, though other numbers and configurations of sutures 52 are regarded as within the scope of the invention. Sutures 52 are tensioned using tourniquets 54 to approximate the ends of ablation device 14, such that tensioning sutures 52 forces the ends of ablation device 14

together. The sizing of ablation device 14 (which may be determined using introducer 20, as described above) provides a snug fit around all or part of the pulmonary veins such that tensioning sutures 52 forces ablation device 14 into contact with the epicardial surface. Hemostats 58 or other suitable devices may be used to pinch or crimp tourniquets 54 in order to secure ablation device 14 in place about the pulmonary veins as seen in Fig. 15. Alternatively, ablation device 14 may utilize a locking mechanism, such as a buckle or other releasable locking mechanism, to be locked to itself and thereby secured in place about the pulmonary veins.

[0069] Ablation device 14 may also contain a suction well to assist device 14 in adhering to the tissue to be ablated. The suction well may take any form, and is preferably formed between the inner and outer lips of body 28 of ablation device 14. The suction well may have a suction port coupled to a vacuum source through a lumen. The vacuum source may be activated to cause the suction well to hold ablation element 26 against the tissue to be ablated. The suction port preferably has a cross-sectional size that is no more than about 10% of the cross-sectional size of the lumen. Thus, if suction is lost at one ablation element 26, suction can be maintained at other ablation elements 26, since the relatively small suction port produces low flow. Of course, another part of the vacuum flow path, other than the suction port, may be sized small to reduce losses through ablation elements 26 not adhered to the tissue.

[0070] Controller 12 preferably activates ablation elements 26 in a predetermined manner. The phrase "predetermined manner" is intended to refer to a non-random sequence. In one mode of operation, ablation is carried out at adjacent ablation elements 26. Ablation may also be carried out at a number of pairs of adjacent ablation elements 26, such as the first and second ablation elements 26 and the fifth and sixth ablation elements 26. After ablation is carried out at these adjacent ablation elements 26, another pair or pairs of adjacent ablation elements 26 are activated, such as the third and fourth and seventh and eighth ablation elements 26. The continuity of the ablation between adjacent ablation elements 26 may be confirmed in any suitable manner. In other modes of operation, controller 12 may energize every other ablation element 26, every third ablation element 26, or a limited number of ablation elements 26, such as no more than four. Controller 12 may also activate less than about 50%, and even less than about 30%, of the

total ablation area at one time (for ablation device 14, a percentage of the total ablation area is effectively a percentage of the total number of ablation elements 26).

[0071] Preferably, ablation device 14 is designed to achieve and maintain particular near surface (NS) temperatures during an ablation procedure. For example, ablation device 14 may be designed to maintain a near surface (NS) temperature of about 0 degree C to about 80 degrees C, more preferably about 20 degrees C to about 80 degrees C, and most preferably about 40 degrees C to about 80 degrees C. The temperature can be adjusted by changing the flow rate of the flowable material, the temperature of the flowable material, and/or the power delivered to ablation elements 26.

[0072] In some embodiments, ablation is controlled based on temperature measured by the temperature sensors. For example, controller 12 may incorporate a multiplexer that delivers ablating energy only to those ablation elements 26 having a temperature below a threshold temperature. Alternatively, the multiplexer may deliver ablating energy only to the coldest ablation elements 26 or only to those ablation elements registering the coolest temperatures.

[0073] After measuring the temperature change over time, the temperature response may be analyzed to determine the appropriate ablation technique. The analysis may be a comparison of the temperature response to temperature response curves of known tissue types. The temperature response curves may be developed empirically or may be calculated. The temperature response may also consider other variables input by the user, including, but not limited to, blood temperature, blood flow rate, and the presence and amount of fat. When assessing the temperature response during heating with ablation elements 26, the amount of energy delivered to the tissue may also be taken into account in characterizing the tissue.

[0074] Using the results of the temperature response assessment, controller 12 preferably determines the appropriate ablation technique to produce the desired far surface (FS) temperature. In one mode of operation, controller 12 determines the amount of time required to reach a desired FS temperature when the NS is maintained at a temperature of less than about 60 degrees C. Controller 12 preferably maintains an adequate flow rate and temperature of the flowable material to maintain the desired NS temperature. Controller 12 monitors the temperature of the NS with the temperature sensors. After the calculated amount of time has elapsed, controller 12 automatically stops delivering ablating energy to

ablation elements 26. Alternatively, the ablation may take place until the NS reaches a target temperature as sensed by the temperature sensors. The continuity of the ablation may then be checked in any manner described herein.

[0075] Ablation device 14 preferably delivers ultrasound energy focused in at least one dimension. In particular, ablation device 14 preferably delivers focused ultrasound having a focal length of about 2 mm to about 20 mm, more preferably of about 2 mm to about 12 mm, and most preferably of about 8 mm. Stated another way, a focus is spaced apart from a bottom (or contact) surface of ablation device 14 along a focal axis (FA) within the stated ranges. The focused ultrasound also forms an angle of about 10 degrees to about 170 degrees, more preferably of about 30 degrees to about 90 degrees, and most preferably of about 60 degrees relative to the FA. Preferably, a piezoelectric transducer is utilized as an ultrasonic ablation element 26. The transducer is preferably mounted within a housing having an enclosure and a top that fits over the enclosure. The enclosure may have curved lips on both sides of the enclosure that generally conform to the curvature of the transducer. The transducer preferably has a length of about 0.43 inch, a width of about 0.35 inch, and a thickness of about 0.017 inch. The transducer has a radius of curvature (R) consistent with the preferred focal lengths described above. The transducer forms an angle (A) with the focus (F) within the preferred angle ranges described above.

[0076] An advantage of using focused ultrasonic energy is that the energy can be concentrated within the tissue. Another advantage of using focused ultrasound is that the energy diverges after reaching the focus, thereby reducing the possibility of damaging tissue beyond the target tissue as compared to collimated ultrasonic energy. When ablating epicardial tissue with collimated ultrasound, the collimated ultrasound energy not absorbed by the target tissue travels through the heart chamber and remains concentrated on a relatively small area when it reaches the endocardial surface on the other side of the chamber. The present invention reduces the likelihood of damage to other structures since the ultrasonic energy diverges beyond the focus and is spread over a larger area.

[0077] Although the focused ultrasonic energy is preferably produced with a curved transducer, the focused ultrasonic energy may be produced with any suitable structure. For example, acoustic lensing may be used to provide focused ultrasound. The acoustic lens can be used with a flat piezoelectric element and matching layer. Furthermore, although the ultrasound energy is preferably emitted directly toward the tissue, the ultrasound

energy may also be reflected off a surface and directed toward the tissue without departing from the scope of the invention.

[0078] The energy may also be produced by a number of small transducers oriented to focus or concentrate ultrasonic energy, such as at least about 90% of the energy, within the preferred angle ranges and radius of curvature described herein when viewed along a longitudinal axis or along the FA. For example, a multi-element acoustic phased array may be used to provide an acoustic beam-steering capability from one or more cells. One skilled in the art can also appreciate the use of multiple matching layers, focusing acoustic lenses, and non-focusing acoustic windows and the like. Thus, the focused energy may be produced in a number of different ways, including other ways not mentioned here, without departing from the scope of the invention.

[0079] In another aspect of the invention, ablation device 14 is operated during two different time periods while varying at least one characteristic of ablation device 14, such as the frequency of the ablating energy, the power of the ablating energy, the position of the focus relative to the tissue, and/or the ablating time. For example, ablation device 14 may be operated at varying frequencies over time to ablate tissue in a controlled manner. Specifically, ablation device 14 is preferably operated to create a transmural lesion by controlling the delivery of energy to the tissue. Although it is preferred to vary the frequency when ablating the tissue, ablation device 14 may, of course, be operated at a single frequency without departing from the spirit and scope of the invention.

[0080] In a first treatment method of the present invention, the transducer is activated at a frequency of about 2 MHz to about 7 MHz, and preferably of about 3.5 MHz, and a power of about 80 watts to about 150 watts, and preferably of about 130 watts, in short bursts. For example, the transducer may be activated for about 0.01 second to about 2.0 seconds, and preferably for about 1.2 seconds. The transducer is inactive for about 2 seconds to about 90 seconds, more preferably about 5 seconds to about 80 seconds, and most preferably about 45 seconds between activations. In this manner, a controlled amount of accumulated energy can be delivered to the tissue in short bursts to heat tissue at and near the focus while minimizing the impact of blood cooling at the FS. Ablation at this frequency may continue until a controlled amount of energy is delivered, such as about 0.5 kilojoule to about 3 kilojoules. Treatment at this frequency in relatively short bursts produces localized heating at the focus. At the first frequency, energy is not absorbed as

quickly in the tissue as it is at higher frequencies, so that heating at the focus is not significantly affected by absorption of ultrasound energy in tissue before reaching the focus.

[0081] Following treatment at the first frequency, the transducer is operated for longer periods of time, preferably about 1 second to about 4 seconds, and more preferably about 2 seconds, to ablate tissue between the focus and the transducer. The frequency during this treatment is also preferably about 2 MHz to about 14 MHz, more preferably about 3 MHz to about 7 MHz, and most preferably about 6 MHz. The transducer is operated for about 0.7 second to about 4 seconds at a power of about 20 watts to about 80 watts, and preferably about 60 watts. The transducer is inactive for between about 3 seconds and about 60 seconds, and preferably for about 40 seconds, between each activation. In this manner, a controlled amount of energy can be delivered to heat tissue between the focus and the transducer. The treatment at this frequency may continue until a controlled amount of total energy is delivered, such as about 750 joules.

[0082] As a final treatment, the ultrasonic transducer is activated at a higher frequency to heat and ablate the NS. The transducer is preferably operated at a frequency of between about 3 MHz and about 16 MHz, and preferably at about 6 MHz. The transducer is operated at lower power than the treatment methods above since the ultrasonic energy is rapidly absorbed by the tissue at these frequencies, so that the NS is heated quickly. In a preferred method, the transducer is operated at about 2 watts to about 20 watts, and more preferably about 15 watts. The transducer is preferably operated for a sufficient duration to ablate tissue, such as about 20 seconds to about 80 seconds, and preferably about 40 seconds. Often, the NS temperature will reach about 70 degrees C to about 85 degrees C.

[0083] Each of the treatments described above may be used by itself or in combination with other treatments. Furthermore, the combination of transducer size, power, frequency, activation time, and focal length may all be varied to produce the desired delivery of ultrasound energy to the tissue. As such, it is understood that the preferred embodiment may be adjusted by adjusting one or more of the characteristics and, thus, these parameters may be changed without departing from the spirit and scope of the invention. The treatment sequence described above generally delivers energy closer to the NS during the second treatment and even closer to the NS for the third treatment (that is, it ablates tissue from the FS towards the NS in successive treatments).

[0084] The focus of the ultrasound energy may also be moved relative to the tissue to deliver energy to different depths in the tissue. Ablation device 14 can be moved closer to and farther away from the target tissue, with membrane 40 conforming to the required shape to fill the gap between the transducer and the tissue. Membrane 40 is preferably inflated, for example utilizing a fluid such as saline, and deflated to move the focus. However, ablation device 14 may also be moved with any other suitable mechanism, such as a threaded foot.

[0085] The focus may be moved while ablation elements 26 are activated or may be moved between activations of ablation elements 26. Moving the focus of the ultrasound energy may be sufficient to create a transmural lesion without changing frequencies, or may be used in conjunction with a change in frequencies as described above. The focus may also be moved in any other manner such as with a phased array or variable acoustic lensing.

[0086] After ablation elements 26 have been activated to ablate tissue, it may be necessary to ablate tissue in gaps between ablations from each ablation element 26. In one method of ablating these gaps, the entire ablation device 14 is shifted so that at least some ablation elements 26 are positioned to ablate tissue within one or more gaps. Thus, after first ablating tissue with all of the ablation elements 26, ablation device 14 is shifted and at least some, and preferably all, ablation elements 26 are activated again to create a substantially continuous lesion.

[0087] Another method to ablate tissue within gaps is to tilt ablation elements 26 to ablate tissue within gaps. In this method, ablation device 14 does not need to be moved. Rather, membrane 40 may be inflated to tilt the transducer, which directs the ultrasound energy toward tissue within gaps between transducers.

[0088] In another embodiment, ablation elements 26 may be located along a track 60, as seen in Fig. 23, such that one or more ablation elements 26 may be adjusted or moved (for example, by sliding) along track 60 so that any gaps in the ablation may be filled in by an activation of ablation elements 26 after they have been resituated over any such gaps. The use of sliding elements 26 may also be used to reduce the number of overall ablation elements 26 that are needed for an ablation procedure. For example, if sizing measurements (e.g., with introducer 20) reveal that an appropriately sized ablation device 14 would require 20 ablation elements 26, an ablation device 14 having 10 or fewer

ablation elements 26 could be used, provided the 10 ablation elements 26 are adjustable along track 60 in order to complete the ablation annulus. Preferably, track 60 could be made using a superelastic material, including for example, a memory metal such as Nitinol. For example, all of the ablation elements 26 may be interconnected using one or more tracks 60 of Nitinol or another superelastic material, such that ablation device 14 may be straightened for insertion into a patient and thereafter manipulated into a predetermined curvature to facilitate manipulations around the heart.

[0089] When track 60 is formed of superelastic material, track 60 not only permits ablation elements 26 to move therealong, it also permits ablation device 14 to achieve two different configurations. As described above, the superelastic properties allow ablation device 14 to be deformed such that ablation elements 26 are substantially coplanar, thereby allowing ablation device 14 to be straightened for insertion and guiding through a small incision, and then returning to the predetermined curvature when manipulated about the heart.

[0090] Track 60 itself, or an isolated channel in track 60, may also permit transmission of control signals from controller 12 that are used to control the operation of ablation elements 26 positioned along track 60. These control signals may be used to reposition ablation elements 26 along track 60 or otherwise alter the ablating energy being delivered to the tissue.

[0091] Controller 12 may be designed to automatically ablate in any manner described herein. For example, controller 12 can change the frequency, power, focal length, and/or operating time to provide the desired ablating technique. The change in frequency and power may be completely automatic or may require some user input such as visual indications of fat and/or tissue thickness. For example, controller 12 may be designed to automatically sequence through two or more different ablating techniques such as those described above. Other techniques, of course, may be used depending on the tissue characteristics and the type and characteristics of the one or more ultrasound transducers. Controller 12 may also utilize feedback, such as temperature feedback or electrical impedance, to actively control the ablations.

[0092] Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this

invention. For example, although the ablation device has been described in connection with creating a substantially continuous lesion around all pulmonary veins, it should be understood that the methods disclosed herein are equally applicable to ablating only partially around the pulmonary veins. Furthermore, other lesions may be beneficial in treating electrophysiological conditions, and the devices and methods described herein may be useful in creating such lesions on other parts of the heart and in other areas of the body. It should also be understood that a wand-type device may be used in conjunction with invention disclosed herein during an ablation procedure, for example to create a mitral isthmus ablation lesion contiguous with the PV isolation lesion or to fill in any gaps in the PV isolation lesion created by ablation device 14.

[0093] All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other.

[0094] It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the spirit of the invention as defined in the appended claims.

CLAIMS

What is claimed is:

1. A device for ablating cardiac tissue, comprising:

a plurality of ablation elements substantially aligned along a common axis;

wherein said plurality of ablation elements is adjustable between a first preset position and a second preset position, said first preset position being a configuration in which said plurality of ablation elements form a curved contact surface, and said second preset position being a configuration in which said plurality of ablation elements form a substantially straight insertion configuration.

2. The device according to claim 1, further comprising at least one hinge connecting adjacent ones of said plurality of ablation elements.

3. The device according to claim 2, wherein each of said plurality of ablation elements is located within a housing, wherein said housing has at least a portion of a hinge integrally formed with said housing, and wherein said integrally formed hinge connects adjacent ones of said plurality of ablation elements.

4. The device according to claim 3, further comprising a strand of a superelastic material interconnecting at least two adjacent ablation elements.

5. The device according to claim 3, further comprising a strand of a superelastic material interconnecting each of said plurality of ablation elements.

6. A method of ablating cardiac tissue from an epicardial location, comprising:

providing an ablation device having a plurality of ablation elements substantially aligned along a common axis, wherein the ablation device is adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset position being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration;

creating an incision in a patient;

adjusting the ablation device to the second preset position;

introducing the ablation device into the patient through the incision;

adjusting the ablation device to the first preset position;

manipulating the ablation device about an epicardial surface to position the plurality of ablation elements over tissue to be ablated; and

ablating tissue by activating the plurality of ablation elements.

7. The method according to claim 6, wherein the ablation device further comprises a track, and wherein the method further comprises the steps of:

adjusting at least one ablation element along the track; and

ablating tissue by activating the at least one ablation element adjusted along the track.

8. A device for ablating cardiac tissue, comprising:

a plurality of ablation elements substantially aligned along a common axis;

wherein said plurality of ablation elements is adjustable between a first preset position and a second preset position, said first preset position being a configuration in which said plurality of ablation elements form a curved contact surface, and said second preset position being a configuration in which said plurality of ablation elements form a substantially straight insertion configuration; and

at least one strand of a superelastic material interconnecting at least two ablation elements.

9. The device according to claim 8, wherein said strand of a superelastic material comprises a Nitinol wire.

10. The device according to claim 8, wherein said strand of a superelastic material interconnects each of said plurality of ablation elements.

11. The device according to claim 10, wherein said strand of a superelastic material biases said plurality of ablation elements into at least one of said first and second preset positions.

12. The device according to claim 8, further comprising at least one hinge connecting each of said plurality of ablation elements to at least one adjacent ablation element.

13. A device for ablating cardiac tissue, comprising:

a plurality of ablation elements substantially aligned along a common axis;

wherein said plurality of ablation elements is adjustable between a first preset position and a second preset position, said first preset position being a configuration in which said plurality of ablation elements form a curved contact surface, and said second

preset position being a configuration in which said plurality of ablation elements form a substantially straight insertion configuration; and

at least one track to which said plurality of ablation elements is coupled, wherein one or more of said plurality of ablation elements may be repositioned at a different location along said at least one track.

14. The device according to claim 13, wherein said at least one track comprises a superelastic material.

15. The device according to claim14, wherein said superelastic material is Nitinol.

16. The device according to claim 13, wherein said at least one track includes a medium that conducts control signals used to control operation of said ablation elements coupled to said track.

17. A device for ablating cardiac tissue, comprising:

a plurality of ablation elements substantially aligned along a common axis;

wherein said plurality of ablation elements is adjustable between a first preset position and a second preset position, said first preset position being a configuration in which said plurality of ablation elements form a curved contact surface, and said second preset position being a configuration in which said plurality of ablation elements form a substantially straight insertion configuration; and

a plurality of springs operating upon said plurality of ablation elements to form at least one of said first and second preset positions.

18. A device for ablating cardiac tissue, comprising:

a plurality of ablation elements substantially aligned along a common axis;

wherein said plurality of ablation elements is adjustable between a first preset position and a second preset position, said first preset position being a configuration in which said plurality of ablation elements form a curved contact surface, and said second preset position being a configuration in which said plurality of ablation elements form a substantially straight insertion configuration; and

a plurality of housings each accommodating at least one ablation element and having a first surface and a second surface, wherein, when said device is adjusted in said first preset position, said plurality of housings are aligned to contact each other on their respective first surfaces.

19. The device according to claim 18, further comprising a plurality of springs operating upon said plurality of housings to form at least one of said first and second preset positions.

20. The device according to claim 18, wherein, when said device is adjusted in said second preset position, said plurality of housings are aligned to contact each other on their respective second surfaces.

21. The device according to claim 18, further comprising at least one strand of a superelastic material interconnecting at least two adjacent housings.

22. A method of ablating cardiac tissue from an epicardial location, comprising:

providing an ablation device having a plurality of ablation elements substantially aligned along a track, wherein at least one of the plurality of ablation elements may be repositioned at a different location along the track;

manipulating the ablation device about an epicardial surface;

ablating tissue by activating the plurality of ablation elements;

adjusting at least one ablation element to a different position along the track; and

ablating tissue by activating the at least one ablation element that has been repositioned along the track.

23. The method according to claim 22, wherein the ablation device includes a plurality of ablation elements substantially aligned along a common axis, wherein the plurality of ablation elements is adjustable between a first preset position and a second preset position, the first preset position being a configuration in which the plurality of ablation elements form a curved contact surface, and the second preset position being a configuration in which the plurality of ablation elements form a substantially straight insertion configuration, said method further comprising:

creating an incision in a patient;

adjusting the ablation device into the second preset position;

inserting the ablation device through the incision; and

adjusting the ablation device into the first preset position.

24. A device for ablating cardiac tissue, comprising:

a plurality of ablation elements substantially aligned along a common axis;

wherein said plurality of ablation elements are biased into a first preset position in which said plurality of ablation elements form a curved contact surface; and

wherein said plurality of ablation elements may be elastically deformed into a second preset position in which said plurality of ablation elements form a substantially straight insertion configuration.

25. The device according to claim 24, further comprising a hinge wire made of a superelastic material permitting said plurality of ablation elements to be elastically deformed into said second preset position.

26. The device according to claim 24, further comprising a plurality of springs permitting said plurality of ablation elements to be elastically deformed into said second preset position.

27. The device according to claim 24, further comprising a hinge wire made of a memory metal permitting said plurality of ablation elements to be elastically deformed into said second preset position.

28. The device according to claim 24, further comprising a sheath in which said plurality of ablation elements may be inserted in order to deform said plurality of ablation elements into said second preset position.

29. The device according to claim 24, further comprising a stylet, and wherein:

each of said plurality of ablation elements includes a guide tube,

such that, when said stylet is inserted into said guide tubes, said plurality of ablation elements is deformed into said second preset configuration, and

when said stylet is removed from said guide tubes, said plurality of ablation elements returns to said first preset configuration.

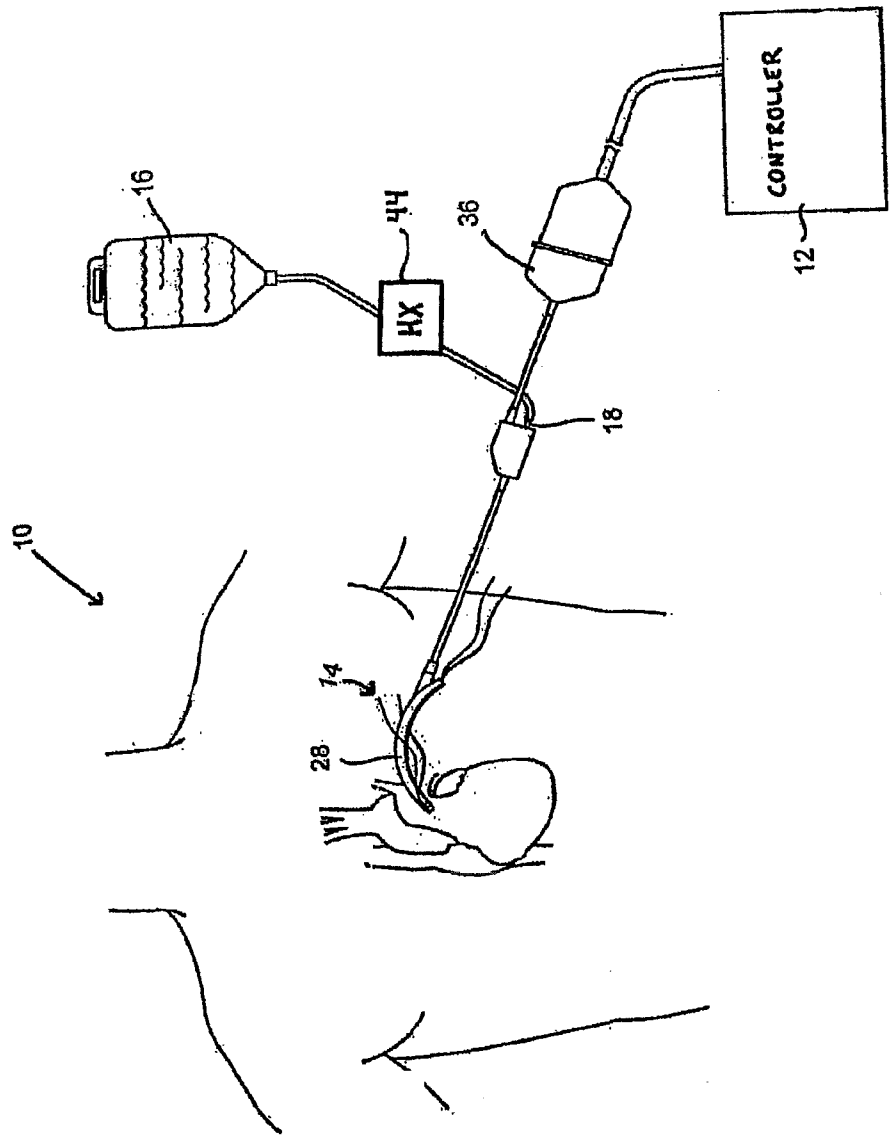

FIG. 1

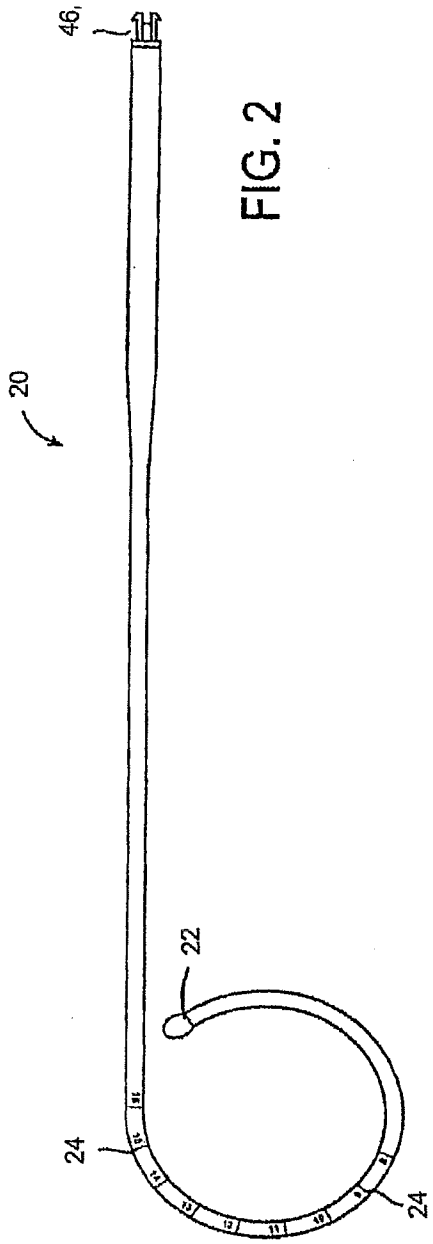

FIG. 2

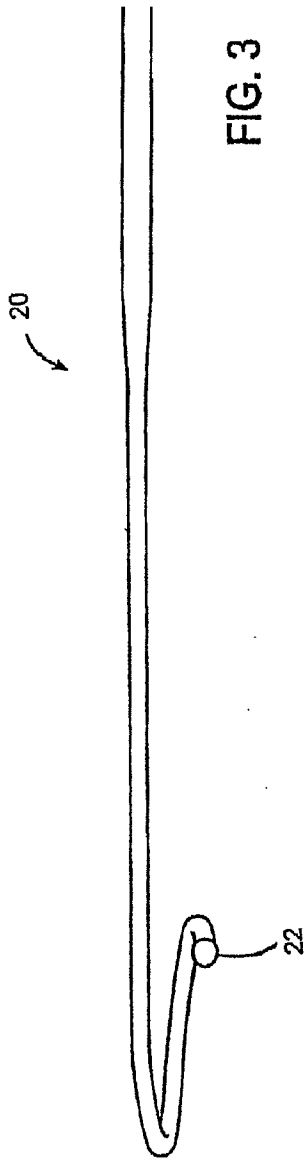

FIG. 3

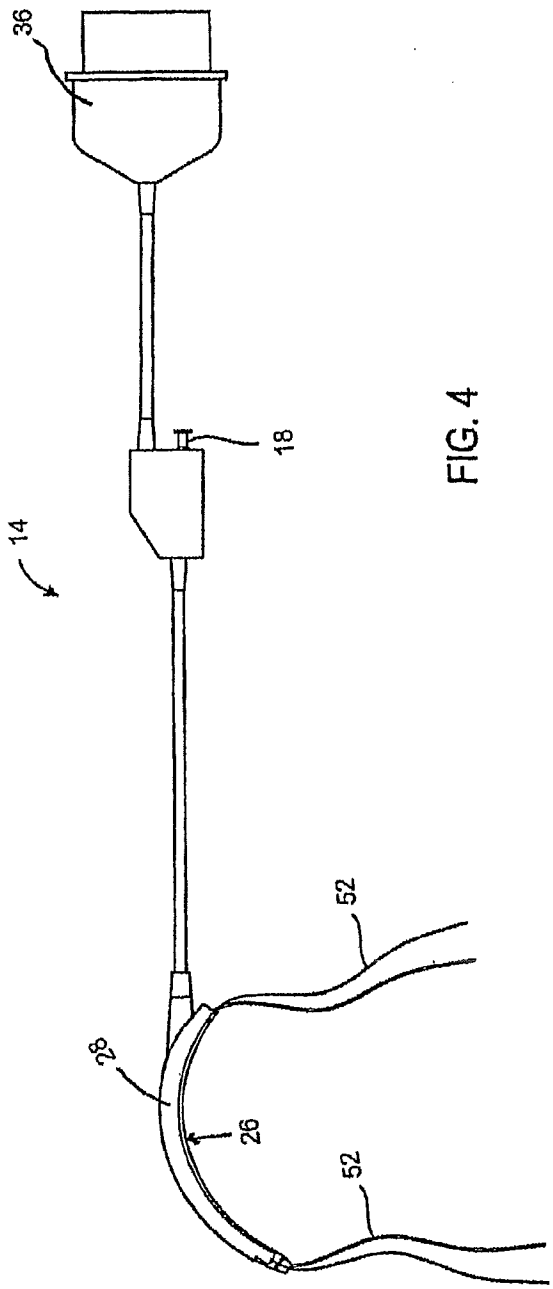

FIG. 4

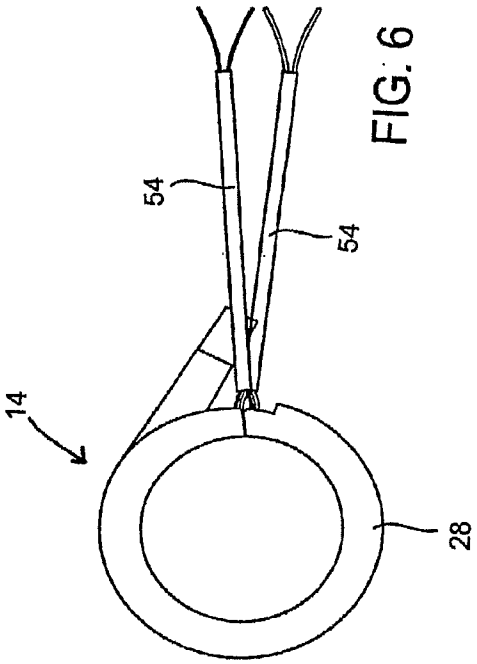

FIG. 6

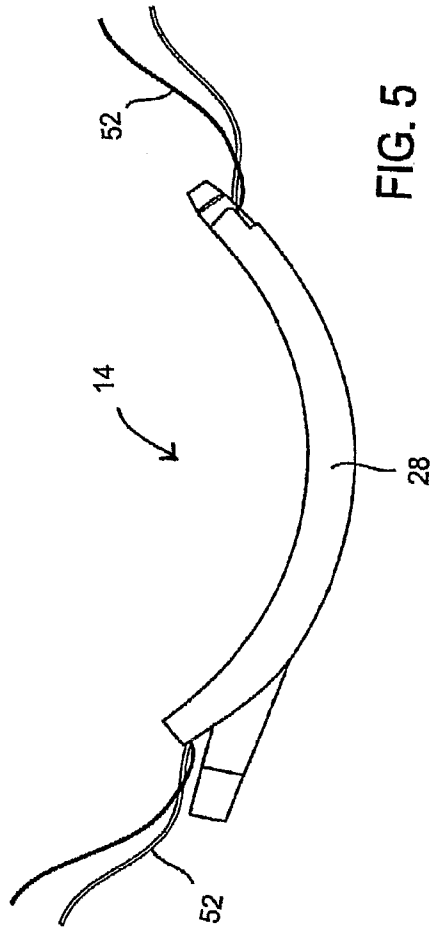

FIG. 5

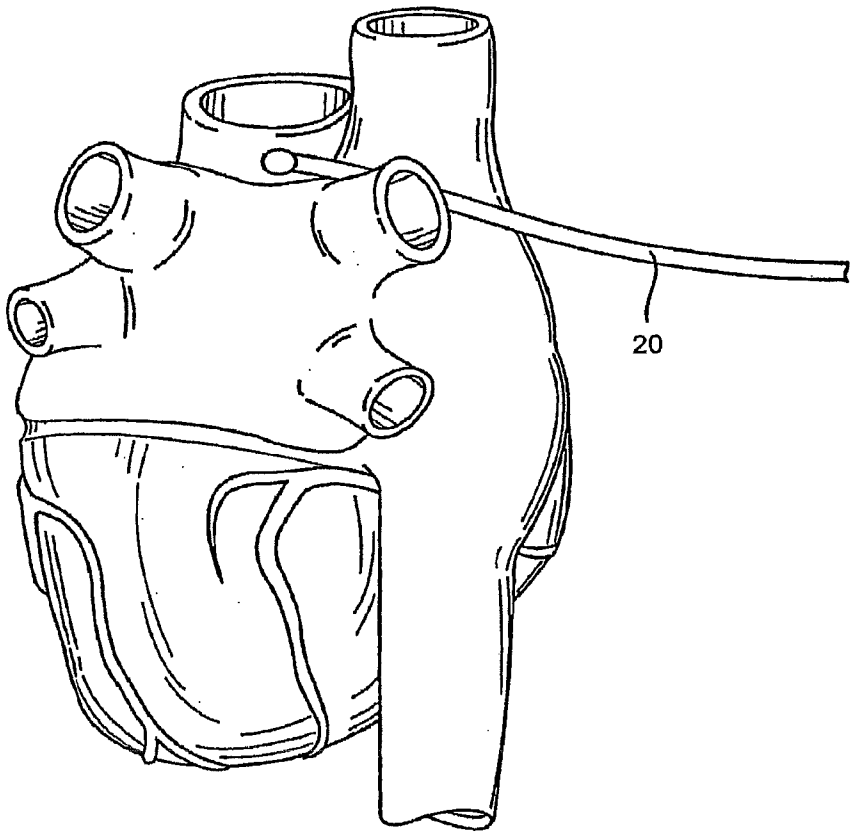

FIG. 7

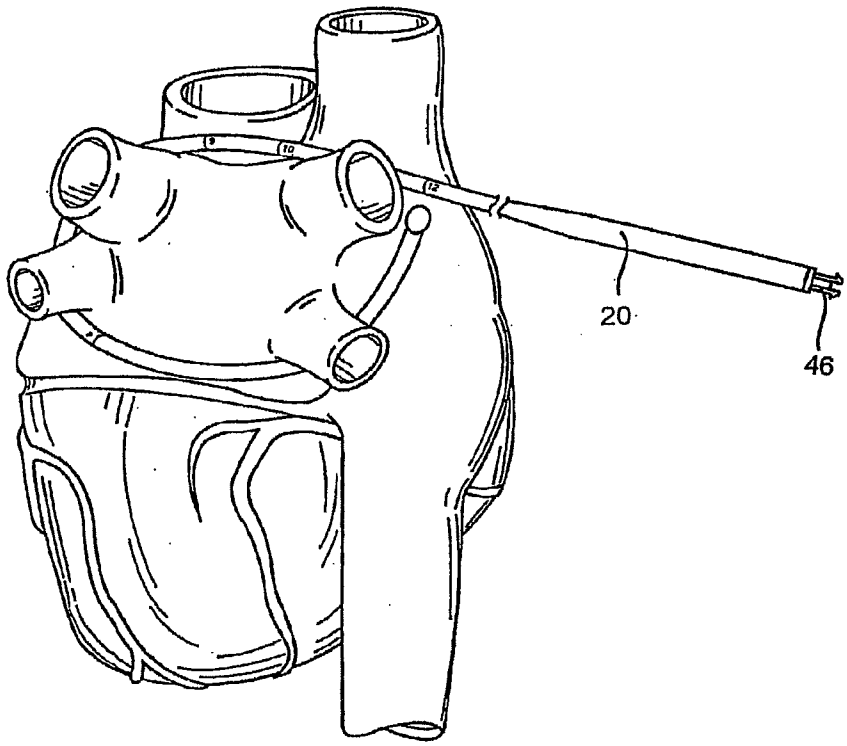

FIG. 8

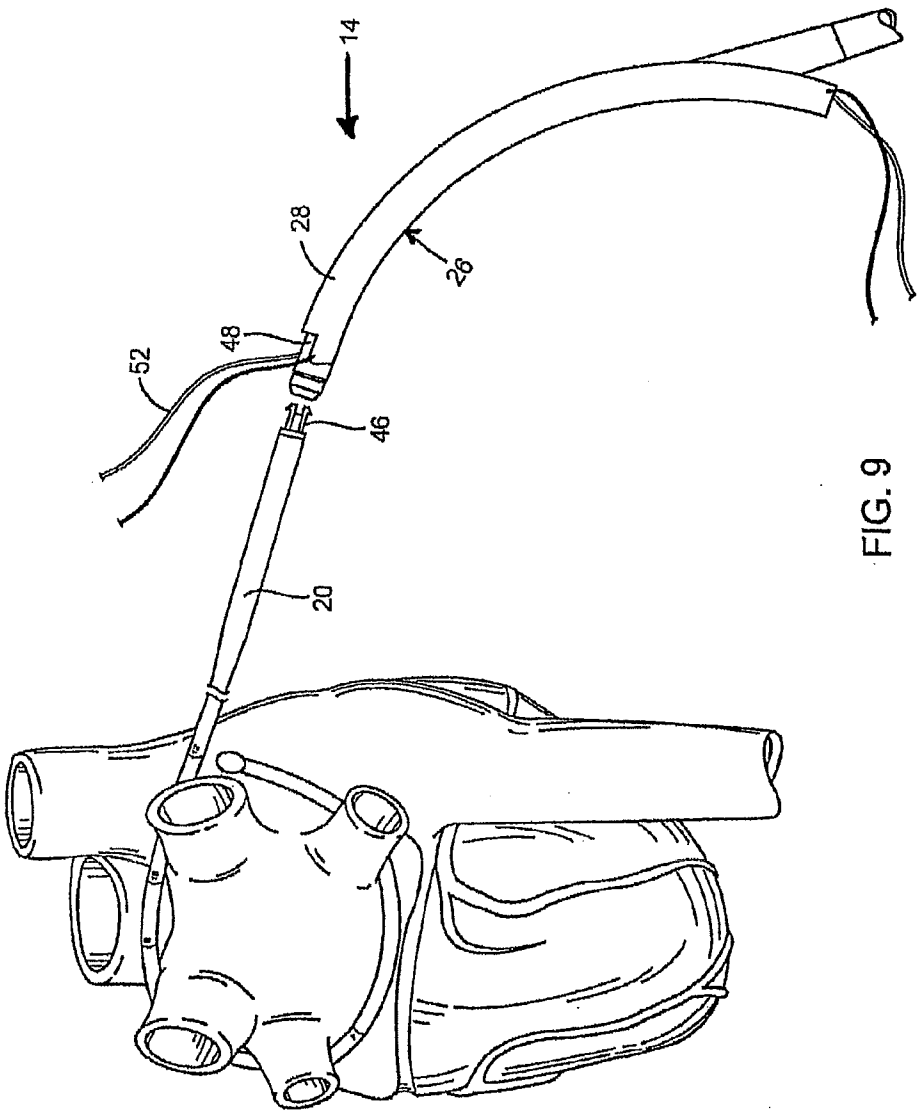

FIG. 9

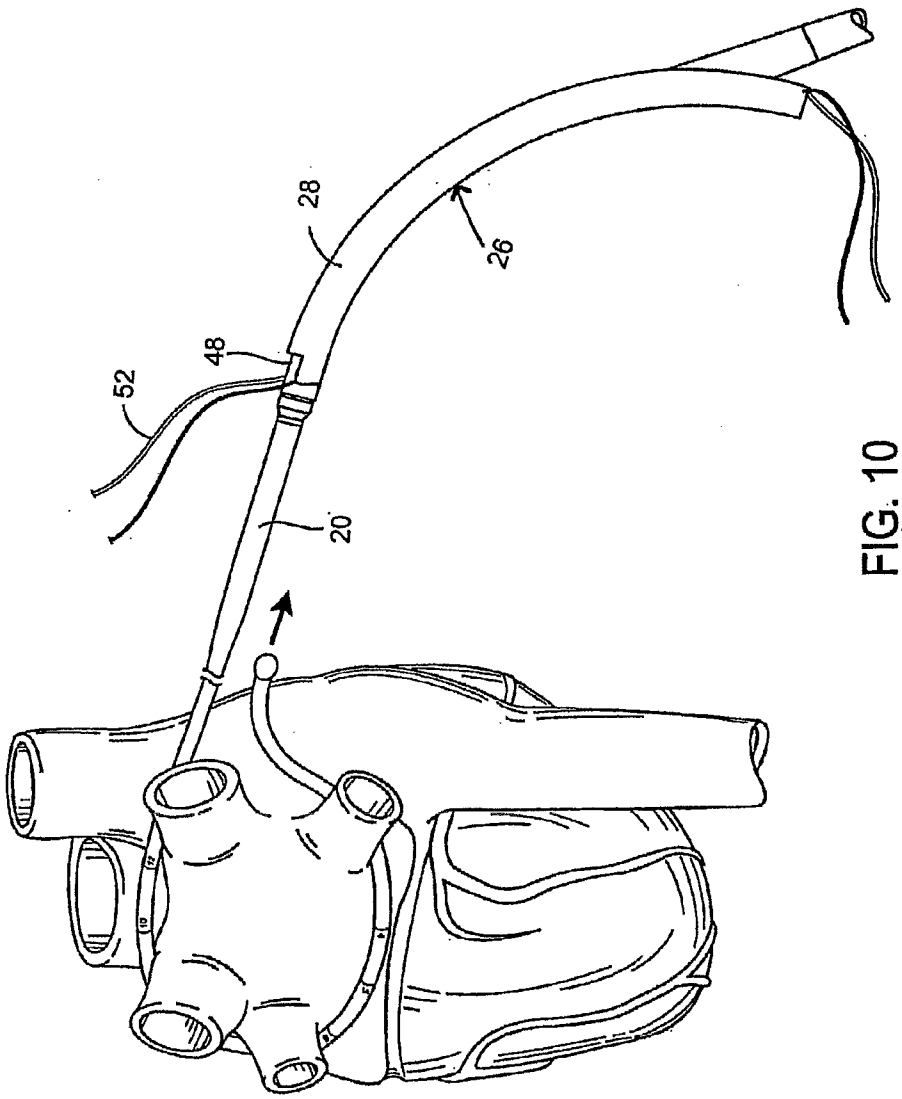

FIG. 10

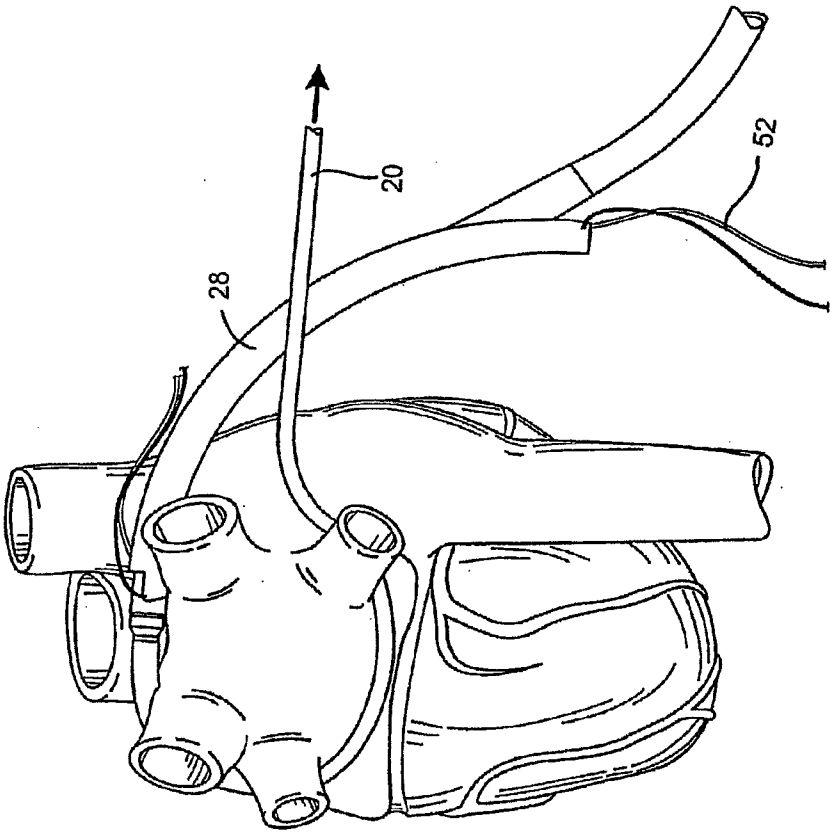

FIG. 11

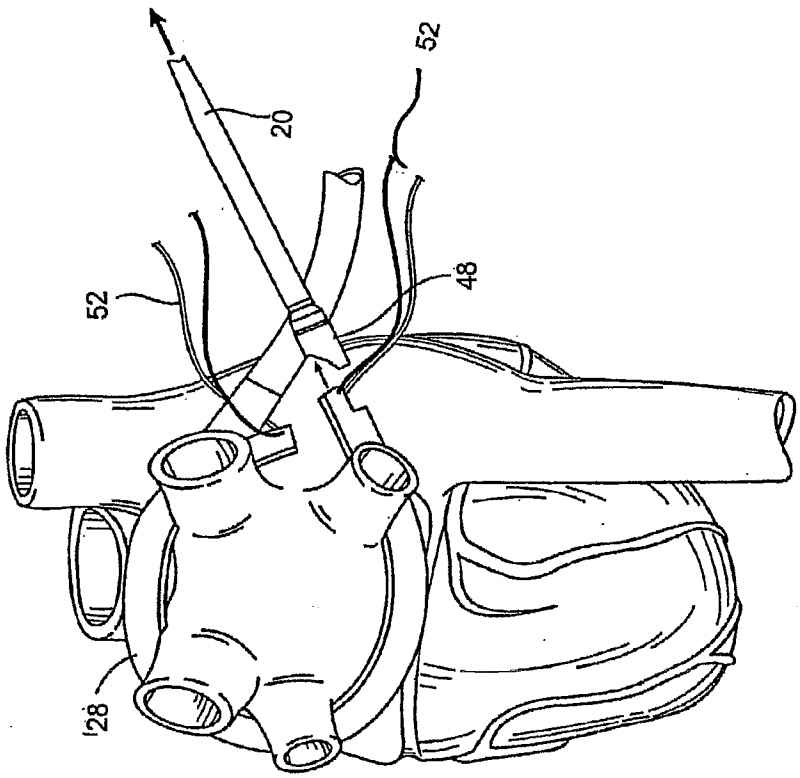

FIG. 12

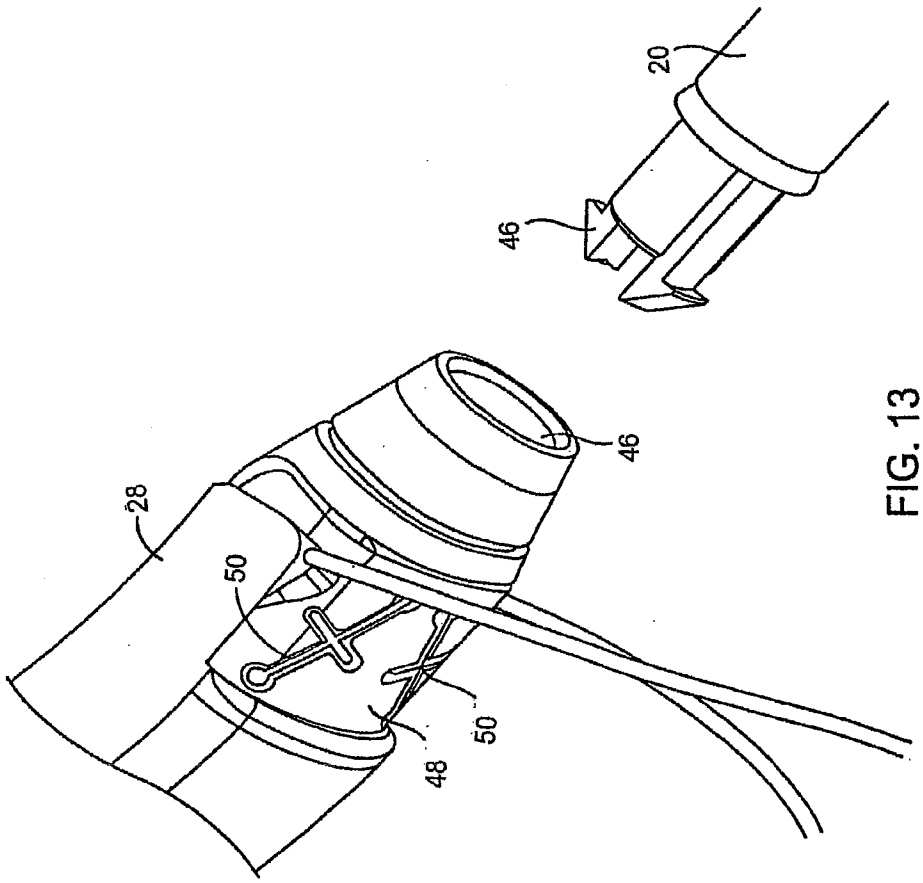

FIG. 13

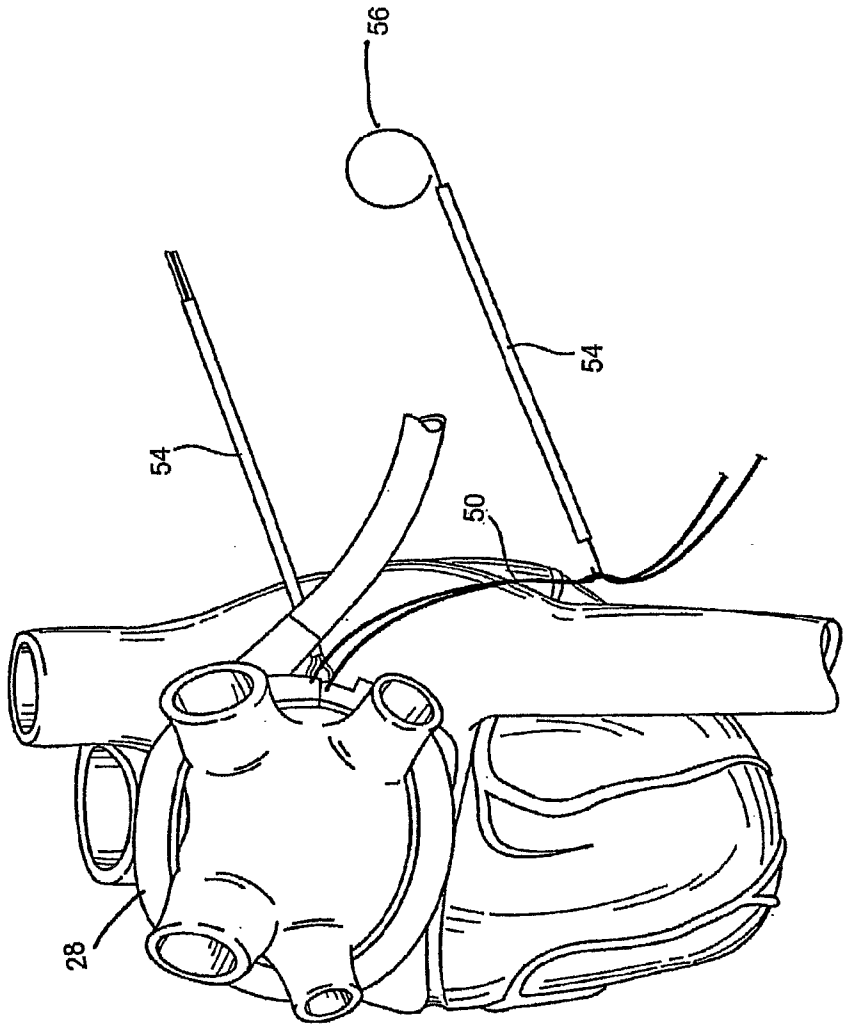

FIG. 14

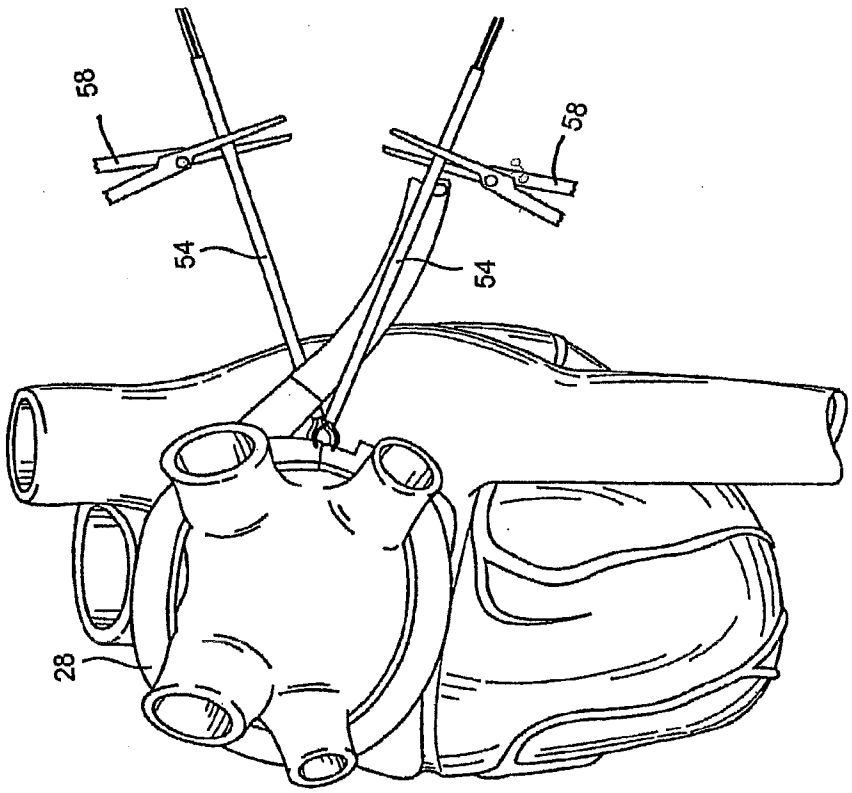

FIG. 15

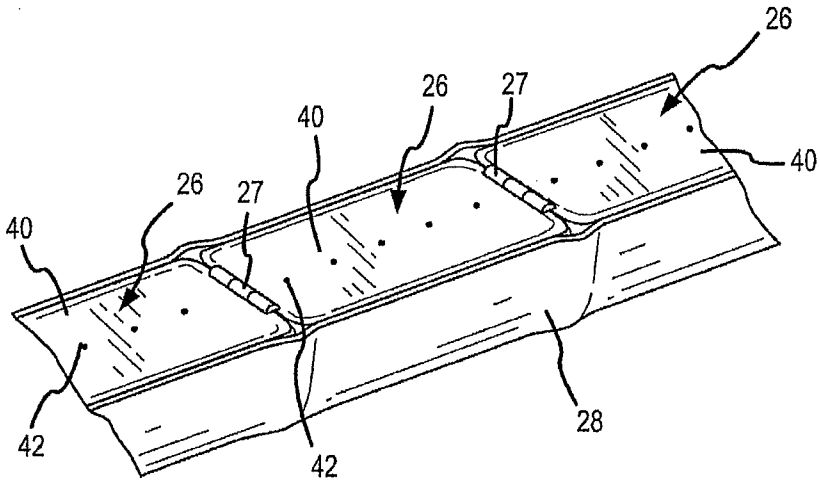

FIG.16

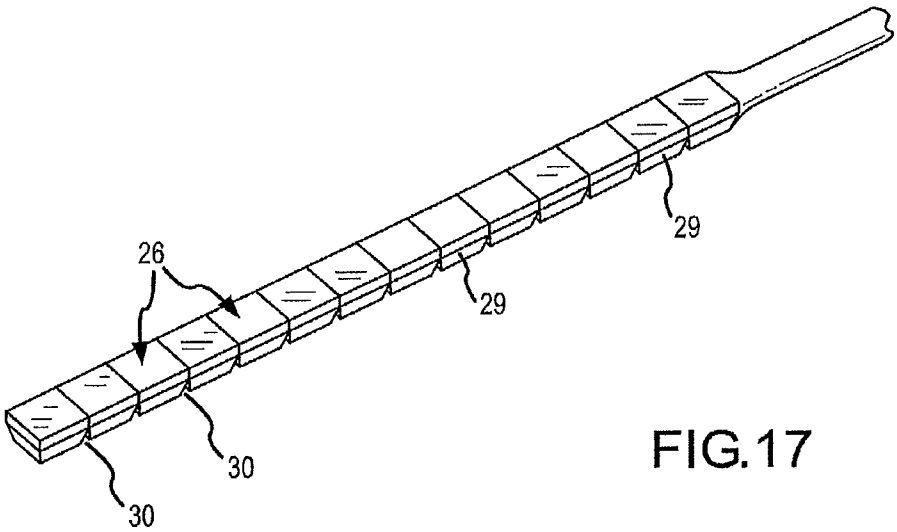

FIG.17

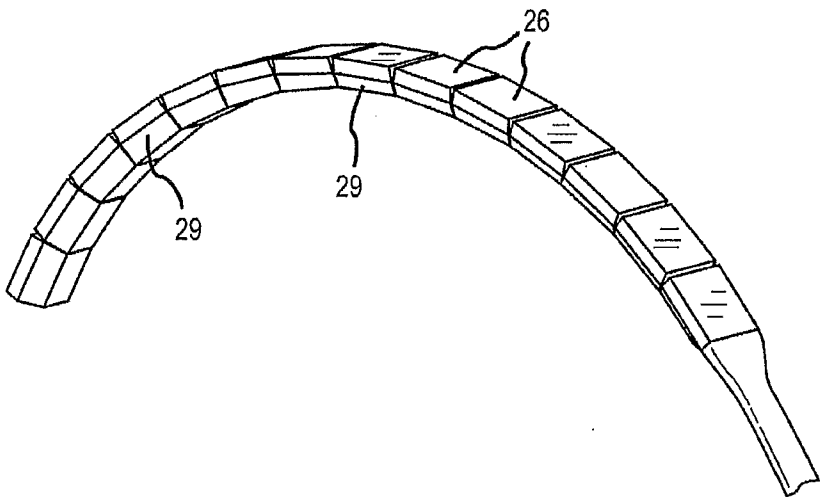

FIG.18

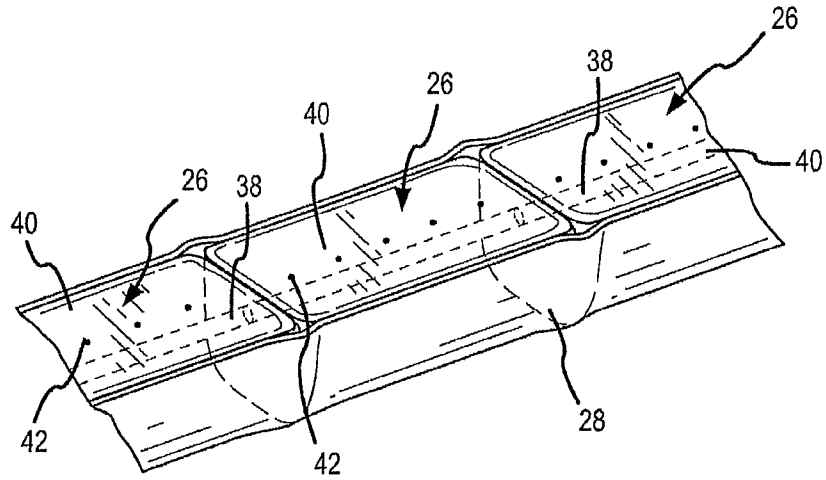

FIG.19

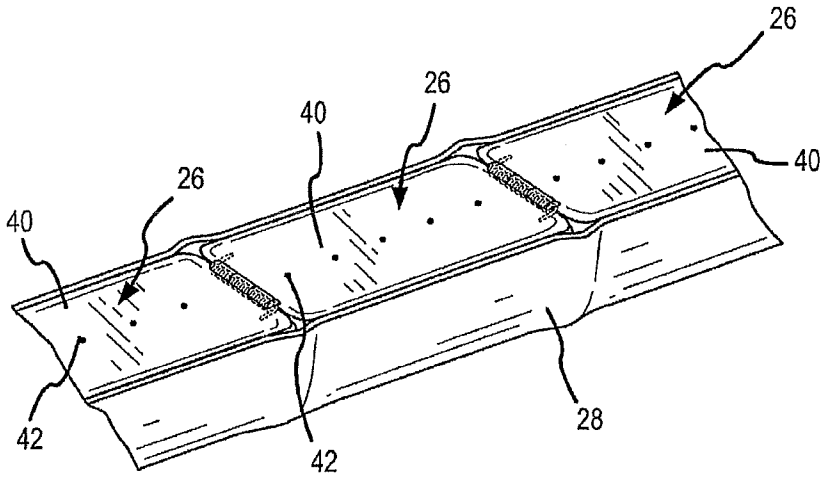

FIG.20

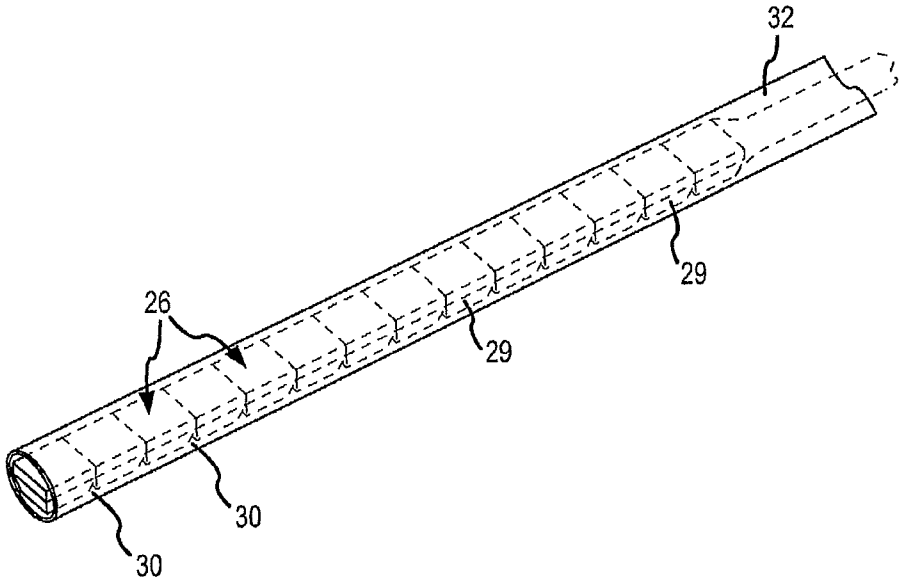

FIG.21

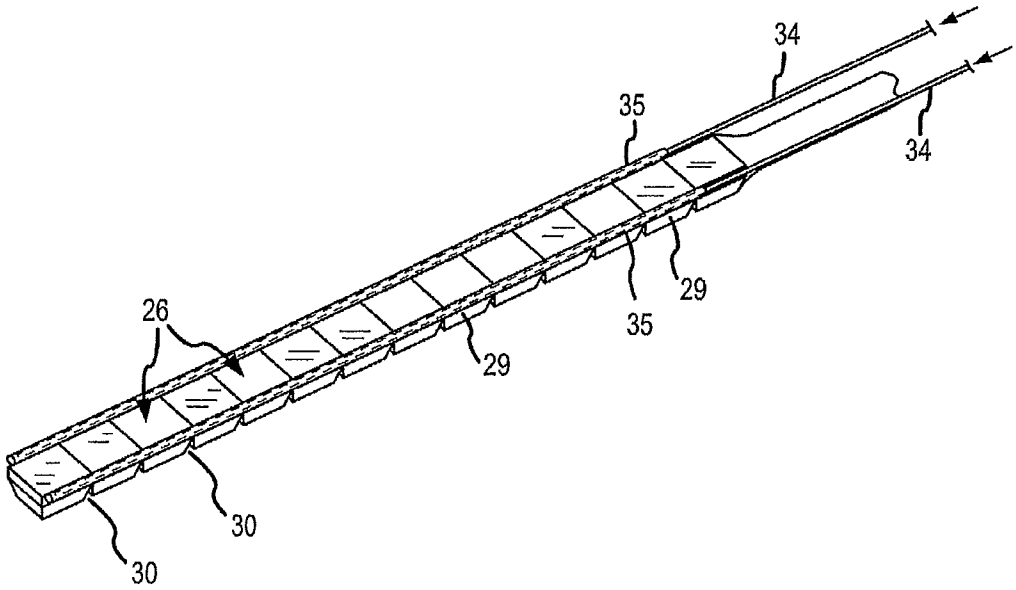

FIG.22

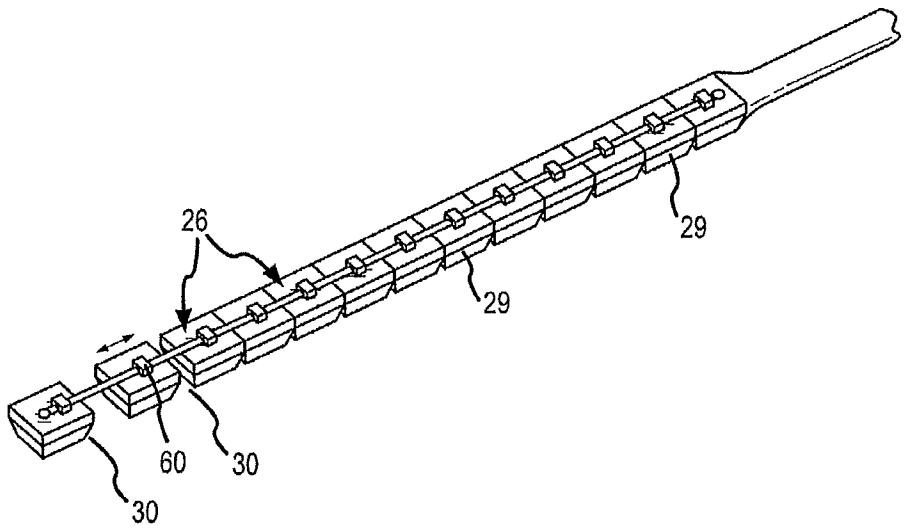

FIG.23