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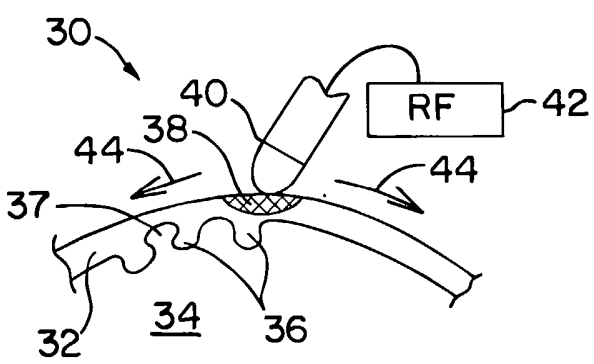
(54) Title: ENDOCARDIAL DISPERSIVE ELECTRODE FOR USE WITH A MONOPOLAR RF ABLATION PEN



(57) Abstract: Methods and devices for forming a lesion in a target tissue having a cavity within. A first RF electrode and a second RF electrode can be coupled to opposite poles of an RF current source. The second electrode can be inserted into the tissue cavity and expanded to contact the target tissue from within. The first electrode can be externally disposed against the target tissue while applying RF current between the first and second electrodes to ablate the target tissue. Some methods are directed to ablating tribiculated atrial wall tissue to treat atrial fibrillation. The second electrode can contact the tribiculated tissue directly from within to provide a direct path between the two electrodes. In some methods, the second electrode is inserted through an incision made to remove an atrial appendage. The methods can provide deeper, narrower lesions relative to those made using remote, indifferent electrodes. Atrial fibrillation ablation procedures can be performed using the invention, requiring fewer incisions than conventional methods.

WO 2004/096070 A1

ENDOCARDIAL DISPERSIVE ELECTRODE FOR USE WITH A MONOPOLAR RF ABLATION PEN

FIELD OF THE INVENTION

The present invention relates generally to devices for cardiac surgery, and more specifically to devices for ablation of cardiac tissue.

BACKGROUND OF THE INVENTION

The present invention is directed toward treatment of tachyarrhythmias, which are heart rhythms in which one or more chambers of the heart exhibit an excessively fast rhythm. In particular, the present invention is directed toward treatment of tachycardias, which are due to the presence of ectopic foci within the cardiac tissue or due to the presence of aberrant condition pathways within the cardiac tissue.

There are many medical treatments that involve instances of cutting, ablating, coagulating, destroying, or otherwise changing the physiological properties of tissue. These techniques can be used beneficially to change the electrophysiological properties of tissue. For example, ablation of cardiac tissue can be used to cure various cardiac conditions. Normal sinus rhythm of the heart begins with the sinoatrial node (or "SA node") generating a depolarization wave front. The impulse causes adjacent myocardial tissue cells in the atria to depolarize, which in turn causes adjacent myocardial tissue cells to depolarize. The depolarization propagates across the atria, causing the atria to contract and empty blood from the atria into the ventricles. The impulse is next delivered via the atrioventricular node (or "AV node") and the bundle of HIS (or "HIS bundle") to myocardial tissue cells of the ventricles. The depolarization of these cells propagates across the ventricles, causing the ventricles to contract. This conduction system results in the described, organized sequence of myocardial contraction leading to a normal heartbeat.

Sometimes aberrant conductive pathways develop in heart tissue, which disrupt the normal path of depolarization events. For example, anatomical obstacles in the atria or ventricles can disrupt the normal propagation of electrical impulses. These anatomical obstacles (called "conduction blocks") can cause the electrical impulse to degenerate into

several circular wavelets that circulate about the obstacles. These wavelets, called "reentry circuits," disrupt the normal activation of the atria or ventricles.

The aberrant conductive pathways create abnormal, irregular, and sometimes life-threatening heart rhythms, called arrhythmias. An arrhythmia can take place in the atria, for example, as in atrial tachycardia, atrial fibrillation or atrial flutter. The arrhythmia can also take place in the ventricle, for example, as in ventricular tachycardia.

The lesions used to treat atrial fibrillation, are typically long and thin and are carefully placed to interrupt the conduction routes of the most common reentry circuits. More specifically, the long thin lesions are used to create a maze pattern that creates a convoluted path for electrical propagation within the left and right atria. The lesions direct the electrical impulse from the SA node along a specified route through all regions of both atria, causing uniform contraction required for normal atrial transport function. The lesions finally direct the impulse to the AV node to activate the ventricles, restoring normal atrioventricular synchrony. Several surgical approaches have been developed with the intention of treating atrial fibrillation. One particular example is known as the "maze procedure," as is disclosed by Cox, JL et al. in "The surgical treatment of atrial fibrillation. I. Summary" Thoracic and Cardiovascular Surgery 101(3), pp. 402-405 (1991); and also by Cox, JL in "The surgical treatment of atrial fibrillation. IV. Surgical Technique", Thoracic and Cardiovascular Surgery 101(4), pp. 584-592 (1991), both of which are incorporated by reference herein in their entireties. In general, the "maze" procedure is designed to relieve atrial arrhythmia by restoring effective atrial systole and sinus node control through a prescribed pattern of incisions about the tissue wall. In the early clinical experiences reported, the "maze" procedure included surgical incisions in both the right and the left atrial chambers. However, more recent reports predict that the surgical "maze" procedure may be substantially efficacious when performed only in the left atrium, such as is disclosed in Sueda et al., "Simple Left Atrial Procedure for Chronic Atrial Fibrillation Associated With Mitral Valve Disease" (1996), which is incorporated herein by reference in its entirety.

When modifying the electrophysiological properties of cardiac tissue by ablation, or by other means of destroying tissue to create lesions, physicians must carefully place the lesions. Otherwise, tissue will be unnecessarily destroyed. In addition, the heart is in

close proximity to nerves and other nervous tissue and the destruction of this tissue will result in severe harm to the patient. Anatomical methods are used to locate the areas to be ablated or otherwise modified. In other words, the physician locates key structures such as the mitral valve annulus and the pulmonary veins. Lesions are typically formed that block propagations near these structures. Additional lesions are then formed which connect these lesions and complete the so-called "maze pattern." However, the exact lesion pattern, and number of lesions created, can vary from patient to patient.

The surgical "maze procedure" as performed in the left atrium generally includes forming vertical incisions from the two superior pulmonary veins and terminating in the region of the mitral valve annulus, traversing the inferior pulmonary veins en route. An additional horizontal line also connects the superior ends of the two vertical incisions. Thus, the atrial wall region bordered by the pulmonary vein ostia is isolated from the other atrial tissue. In this process, the mechanical sectioning of atrial tissue eliminates the precipitating conduction to the atrial arrhythmia by creating conduction blocks within the aberrant electrical conduction pathways.

Injection of alcohol into heart tissue has also been employed to ablate cardiac tissue. Alcohol may be delivered to blood vessels supplying the tissue to be ablated, as described in "Transcoronary Chemical Ablation of Arrhythmias", by Nellens et al, Pace Vol. 15, pages 1368-1373, September 1992. Alternatively, alcohol can be delivered directly to the tissue to be ablated by means of a needle inserted through a catheter, as described in "Chemical Ablation by Subendocardial Injection of Ethanol via Catheter--Preliminary Results in the Pig Heart", by Weismuller et al, European Heart Journal, Volume 12, pages 1234-1239, 1991.

Although successful at treating AF, the surgical maze procedure is quite complex and is currently performed by only a few skilled cardiac surgeons in conjunction with other open-heart procedures. Tools that could reliably duplicate the Maze incisions by other means (e.g. radio frequency, laser, microwave, ultrasound energy) will reduce the time and invasiveness required for the maze procedure and make it more accessible to more surgeons. Problems faced by these methods, however, include (a) the creation of continuous, linear lesions in the atria for the prevention of atrial fibrillation, (b) minimization of clotting and thromboembolism, (c) the effect of heat loss due to

circulating blood, (d) minimization of lesion width and minimization of atrial debulking, (e) conforming to an irregular myocardial thickness, (f) adaptability to a variety of lesion geometries and (g) usefulness from either the endocardial surface of an open heart, or the epicardial surface of a beating heart.

One particular procedure, the monopolar RF ablation of cardiac atrial tissue to treat atrial fibrillation, causes wide, shallow lesions, due to current dispersion through the tissue. In heavily tribiculated tissue, monopolar ablation is only feasible endocardially. An epicardial approach using conventional methods will not efficiently transfer energy into the deep tissue folds, due to that tissue being out of the conductive path between the external epicardial electrode and the remote indifferent electrode. Bipolar hemostats have been used to concentrate the current through a direct tissue path between closely spaced electrodes to provide improved ablation through smooth or heavily tribiculated tissue. However, the bipolar hemostats require significant tissue cutting to provide complete access to necessary lesion sites.

Some tissue cutting is required in a Maze procedure. In particular, the atrial appendages are typically removed. Monopolar RF cardiac ablation requires significant additional tissue cutting in order to position the electrode in the proper positions to perform endocardial ablations.

What would be desirable are methods that would reduce tissue cutting and improve the efficacy of epicardial ablation. What would be advantageous are devices that direct RF current along the desired transmural path, creating narrower and deeper lesions.

SUMMARY OF THE INVENTION

The present invention includes devices and methods for ablation of cardiac tissue in which a hand-held, monopolar RF ablation device is used to ablate cardiac tissue in conjunction with an expandable endocardial electrode inserted into a heart chamber and urged against the chamber wall. The endocardial electrode can be expandable or inflatable and have a conductive surface. The endocardial electrode may be inserted through a small incision made in the heart chamber wall and/or through the opening made by the removal

of the atrial appendage. The electrode can then be expanded or inflated, urging the conductive surface against the endocardium.

A monopolar RF ablation device can then be drawn along the desired lesion line on the epicardium. A current path is thus formed between the epicardial RF device and the expanded surface electrode disposed against the endocardium. The direct path between the external monopolar RF electrode and the endocardial surface internal electrode can provide a narrower, deeper lesion relative to the lesion created using a current path between the RF electrode and an external, indifferent electrode. The incision required to insert the expandable or inflatable electrode can be significantly smaller than that required to insert and successfully maneuver the monopolar RF electrode endocardially.

The monopolar electrode tissue-contacting surface can be connected to one pole of a radio frequency generator while the other pole of the generator is connected to a large surface, endocardial electrode. In one embodiment of the invention, the epicardial monopolar electrode is a conventional radio frequency ablation device such as the Cardioblate ® pen available Medtronic, Inc.

The present invention includes methods for forming a lesion in a target tissue having a cavity within. The methods can include providing a first RF electrode coupled to a RF current source and a second RF electrode electrically coupled to form a ground path for the first RF electrode, wherein the second RF electrode is electrically conductive and expandable, wherein the second electrode has a first, unexpanded configuration and a second, expanded configuration. The second electrode can be inserted into the tissue cavity and expanded to the second configuration to contact the target tissue from within the cavity. The first electrode can be disposed against the target tissue while applying RF current between the first and second electrodes to ablate the target tissue.

The present invention includes methods for treating atrial fibrillation that do not require making any incisions in the right or left atria other than those to remove the left and/or right atrial appendages. The methods can include making lesion paths of the Maze, Maze 3 or Modified Maze 3 procedures, while performing only the incisions to remove the atrial appendages. The methods can include making lesions along the paths described in the: Cox, JL et al.; Cox, JL; and Sueda et al. publications, previously incorporated by reference in the present application.

In one method, an incision is made to remove the right atrial appendage and the method does not include making any other incisions in the right atrium. One such method does not include making an incision from the right atrial appendage incision toward the inferior vena caval orifice. Another such method does not include making a posterior longitudinal incision starting caudal to the superior caval cannulation site at the dorsal aspect of the right atrium.

In another method, an incision is made to remove the left atrial appendage, and the method does not include making any other incisions in the left atrium. One such method does not include making a standard atriotomy in the inter-atrial groove between the left and right atria.

One device includes a shaft and an electrode including an envelope having an interior and an electrically conductive flexible surface disposed near the shaft distal region. The second electrode surface can have a first configuration having a first interior volume within the conductive surface and a second, expanded configuration having a second interior volume within the conductive surface, with the second volume being greater than the first volume.

In some devices, the electrically conductive surface includes an outer metallic layer disposed over a polymeric layer. Some electrodes include an outer metallic mesh disposed over a polymeric layer. The polymeric layer can be substantially resistant to fluid permeation, such that the polymeric layer is inflatable. The envelope can be formed of an electrically conductive polymer. Some envelopes according to the present invention are porous, and the electrically conductive surface can be the outer surface an electrically conductive porous mesh. Some meshes are metallic meshes.

Some device embodiments have a fluid lumen extending through the shaft, which can be used to inflate the envelope. Other embodiments have envelopes biased to expand when unconstrained. Still other embodiment envelopes include shape memory materials that expand when heated to body temperature.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a prior art, fragmentary, cross-sectional view of a heart chamber wall having tribiculated tissue, the wall being partially ablated using an external RF electrode and a remote, indifferent electrode;

Figure 2 is a fragmentary, cross-sectional view of the tribiculated heart chamber wall of Figure 1, being ablated using the RF electrode of Figure 1 and an internal, expandable surface electrode contacting the tribiculated tissue;

Figure 3 is a diagrammatic, longitudinal cross-sectional view of one device having an expandable surface electrode, shown in an un-expanded configuration;

Figure 4 is a diagrammatic, longitudinal cross-sectional view of another device having an expandable surface electrode, shown in an un-expanded configuration;

Figure 5 is a diagrammatic, longitudinal cross-sectional view of yet another device having an expandable surface electrode, shown in an un-expanded configuration within a retractable delivery sheath;

Figure 6 is a diagrammatic, longitudinal cross-sectional view of still another device having an expandable surface electrode, shown in an un-expanded configuration within a retractable delivery sheath;

Figure 7 is a diagrammatic, longitudinal cross-sectional view of a device having an expandable surface electrode, shown in an expanded configuration;

Figure 8 is a fragmentary, cross-sectional view of an envelope formed of an electrically conductive material;

Figure 9 is a fragmentary, cross-sectional view of an envelope formed of an electrically conductive material layer formed over another, more interior material;

Figure 10 is a fragmentary, cross-sectional view of an envelope formed of an electrically conductive mesh formed over another, more interior material; and

Figure 11 is a fragmentary, side view of an envelope formed of an electrically conductive porous mesh.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 illustrates a prior art method for ablating cardiac tissue in the atria. In particular, a tribiculated region of the atria is illustrated. An atrial region 30 is illustrated, having an atrial wall 32, an interior 34, and tribiculated tissue 36 is illustrated, having gaps or cavities 37 disposed between the tribiculated tissue regions. A monopolar electrode 40 is illustrated, coupled to an RF energy source 42. A lesion area 38 formed from the ablation is also illustrated. In Figure 1, a remote, indifferent electrode (not illustrated in Figure 1) provides the return path for the RF energy supplied by monopolar electrode 40. As may be seen from inspection of Figure 1, lesion area 38 is fairly wide, and does not penetrate into tribiculated tissue regions 36. The shallow and insufficiently deep lesions are formed due to the RF current dispersion, indicated at 44, as RF energy takes a path to the indifferent electrode that does not include penetrating directly into atrial wall 32. As maybe seen from inspection of Figure 1, monopolar ablation of some tissue regions may not be feasible using a monopolar electrode, due to the shallow penetration. In such cases, endocardial ablation, using electrode 40, may be required.

Figure 2 illustrates atrial region 30 of Figure 1, using devices and methods according to the present invention. Tribiculated tissue regions 36 may be seen, as discussed with respect to Figure 1. In Figure 2 however, a second electrode 46 may be seen, having an envelope surface 48 contacting the tissue of atrial wall 32 and tribiculated tissue regions 36. Second electrode 46 may be described as an envelope or membrane, in various embodiments. Second electrode 46 may be seen to contact tribiculated tissue 36 and other endocardial tissue directly, providing a short, direct current path, indicated at 50, between second electrode 46 and a monopolar electrode 40. As a result of the more direct current path, a deeper and narrower lesion 52 may be formed between monopolar electrode 40 and second electrode 46. As illustrated in Figure 2, the present invention can provide a lesion formed entirely through the heart chamber wall, using an external electrode and the second, internal electrode.

Figure 3 illustrates a device 70 that can be used to facilitate ablating cardiac tissue. Device 70 includes a device shaft 72 having an interior 84, a proximal region

74, and a distal region 76. An expandable envelope 78 may be seen affixed to shaft distal region 76. Envelope 78 is shown in a first, unexpanded configuration, having folds 80 and an internal volume, indicated at 82. Envelope 78 further includes a proximal mouth 77, secured to shaft distal region 77. As used herein, "expandable" refers to the envelope having an unexpanded and an expanded configuration, wherein the expanded configuration has a larger internal volume than the first configuration. The term "expandable" does not require that the envelope be elastic or stretchable in any way.

While some embodiments include a proximal shaft, other embodiments have no shaft. Some embodiments utilize the proximal mouth of the envelope or balloon to expand or inflate the envelope or balloon. In such embodiments, the balloon or envelope can be inserted into the heart chamber through an opening and inflated through a fluid supplied to the balloon proximal mouth.

Shaft 72 may be solid in some embodiments and hollow in other embodiments, carrying an inflation lumen within. In some embodiments, shaft 72 has a length of between about 12 and 18 inches. Some embodiments have a shaft length less than 12 inches, while other embodiments have a shaft length less than 6 inches. Some shafts have an outer diameter of between about 20 Fr. and 30 Fr. Shaft 72, and other shafts according to the present invention may be of shaft or tube materials well known to those skilled in the biomedical arts. Exemplary shaft materials include silicone, PEBAX, polyurethane, and PVC.

Figure 4 illustrates another device 90 that can be used according to the present invention. Device 90 includes a shaft 92 having a proximal region 94 and a distal region 96. Shaft 92 further includes a lumen 100 within, carrying a proximal push rod 102 having a distal flange 104 attached to the push rod. An envelope 98 may be seen, in an unexpanded configuration within shaft lumen 100. In use, push rod 102 can be used to force envelope 98 out of shaft 92, allowing envelope 98 to expand. Envelope 98 may be self-expanding in some embodiments, and require fluid inflation, in other embodiments.

Figure 5 illustrates still another device 120 having a shaft 128 having an envelope 132 secured to a shaft distal region 129. Envelope 132 may be seen to be in

an unexpanded configuration. Envelope 132 may be seen to be in a compressed, folded state. Device 120 further includes an outer delivery sheath or sleeve 134 having a distal region 124 and a proximal region 126. Sleeve 134 can be proximally retracted from shaft 128 bearing envelope 132, or shaft 128 and envelope 132 can be distally urged out of delivery sleeve 134. In some embodiments, envelope 132 is self-expanding. In other embodiments, envelope 132 is inflated with fluid supplied through a lumen extending through shaft 128.

Figure 6 illustrates still another device 140 having a delivery sheath 142 having distal region 144 and proximal region 146. An expandable envelope 150 may be seen, secured to a shaft 148. Shaft 148 and envelope 150 are both disposed within delivery sheath 142. In some embodiments, envelope 150 is biased to expand radially outward to form a spherical or bulbous shape, when unconstrained by outer sheath 142. In some embodiments, the envelope, for example, envelope 150, may be urged distally from a constraining tube, for example, sheath 142. After being distally urged from the outer tube, the envelope may be radially expanded and the outer tube used as a catheter to guide the now expanded envelope to the target site.

Figure 7 illustrates device 70 of Figure 3, in a second, expanded configuration. Device 70 may be seen to have a much larger envelope internal volume 82. Envelope 78 may be seen to be in a significantly expanded configuration relative to that seen in Figure 3. In some embodiments, envelope 78 is self-expanding. In other embodiments, envelope 78 is inflated with fluid provided through a lumen provided through shaft 72, within shaft interior 84. In some methods, saline is used as the inflation fluid.

Figure 8 illustrates a section of envelope material 160, wherein the entire thickness of the envelope material is electrically conductive. One such envelope material includes a conductive polymer.

Figure 9 illustrates another envelope 162. Envelope 162 includes an inner layer 164 and an outer layer 166. In some embodiments, inner layer 164 is a polymeric, substantially nonconductive material. Outer layer 166 can be an electrically conductive material, for example, a metallic film. In some embodiments,

envelope 162 is formed of Mylar, having a metallic film disposed over a polymeric layer.

Figure 10 illustrates yet another envelope section 168 having an inner, substantially contiguous layer 170 and an outer mesh 172. In some embodiments, inner layer 170 is a polymeric layer that is substantially impervious to fluid flow, enabling the envelope to be fluid expanded. In some envelopes, mesh 172 is an electrically conductive, metallic mesh. Mesh 172 can be formed of Nitinol in some embodiments and stainless steel in other embodiments. In still other embodiments, electrically conductive mesh 172 is formed of an electrically conductive polymer. In some envelopes, mesh 172 is formed of a material biased to expand outwardly when unconstrained. In other embodiments, mesh 172 is formed of a shape memory material, set to expand outwardly when heated toward body temperature from room temperature. For the purposes of the present invention, room temperature may be defined as about 70 degrees Fahrenheit.

Figure 11 illustrates still another envelope section 174, having a porous mesh including braids or strands 176 having pores 178 disposed therebetween. In embodiments having a porous mesh, the mesh itself may be self-expandable or may be expanded through an inflation envelope disposed within the mesh.

In one method according to the present invention, a first RF electrode is provided, coupled to a RF current source. A second RF electrode is also provided and coupled to form a ground path for the first RF electrode. The second electrode can include an electrically conductive envelope surface defining an interior volume within. The envelope can have a first, unexpanded configuration and a second, expanded configuration. The second configuration can have an interior volume greater than the first, unexpanded configuration. An incision can be made in a heart chamber wall. A preferred use of the present invention is to ablate atrial wall tissue. One such incision is an incision made to remove an atrial appendage. Such incisions are typically made as part of a maze procedure.

After the incision is made, the second electrode can be inserted through the incision and into the heart chamber interior. The second electrode can then be expanded to urge the second electrode conductive surface to contact a target region of

the heart chamber endocardium. The first electrode can be disposed against the target region epicardium while applying RF current through the first electrode.

A short, direct current path is thus formed between the first electrode on the epicardium and the expanded surface electrode bearing against the endocardium. The second electrode can be urged against tribiculated tissue to provide direct contact with the second electrode and therefore provide a short and direct current path directed through the tribiculated tissue. A lesion resulting from the current path formed between the first electrode and the second, interior electrode, can thus be both deeper and narrower than lesions formed using the external electrode and a remote indifferent electrode.

In some methods, the second electrode is biased to expand when unconstrained, and is freed from constraint after being inserted into the heart chamber through the incision. In some such methods, a sleeve or delivery tube is retracted from about the constrained second electrode. While some electrodes are simply biased to expand outward when unconstrained, other internal electrodes are formed of a shape memory material that expands when heated toward body temperature.

Some methods include providing a fluid expandable or inflatable envelope. In such methods, a fluid, for example, saline, can be injected into the envelope interior to expand the envelope to its fully expanded shape.

Applicant believes that the present invention provides novel methods for forming lesions entirely through the atrial wall using a first, external electrode on the epicardium and a second, expanded surface internal electrode on the endocardium, simultaneously. This may be contrasted with using an electrode drawn over the endocardial surface, for example, a pen electrode. While forming a lesion using an inserted pen electrode may be efficacious, a large incision must be made through the heart chamber wall in order to properly direct the drawing of the pen electrode across the endocardium. Using the present invention, an incision only large enough to insert the expandable or inflatable envelope need be made.

Applicant believes that target sites in the entire right and left atrial free wall regions may be ablated using RF ablation, and entirely through the atrial wall, where ablating these sites does not require making an incision in the right atrium from the

excised atrial appendage parallel to the right atrioventricular groove toward the inferior vena cava (IVC), an incision from about 1 cm, above the IVC cannulation site to the top of the atrioventricular groove, or in the left atrium in the interatrial groove.

In general, the present invention provides methods for forming lesions in target tissue having a cavity within. In the general case of the invention, a first electrode is coupled to a RF current source and a second RF electrode is electrically coupled to form a ground path for the first RF electrode. The second electrode can be inserted into the tissue cavity and expanded to contact the target tissue from within the cavity. The first electrode can then be disposed against the target tissue from the outside, while applying RF current through the first electrode to ablate the target tissue.

It will be appreciated by those skilled in the art that while the invention has been described above in connection with particular embodiments and examples, the invention is not necessarily so limited, and that numerous other embodiments, examples, uses, modifications and departures from the embodiments, examples and uses are intended to be encompassed by the claims attached hereto. The entire disclosure of each patent and publication cited herein is incorporated by reference, as if each such patent or publication were individually incorporated by reference herein.

CLAIMS

1. A device for facilitating cardiac tissue ablation, the device comprising:

a shaft having a proximal region and a distal region;

an electrode including an envelope, the envelope having an interior and an electrically conductive surface disposed near the shaft distal region, wherein the surface has a first configuration having a first interior volume within the conductive surface and a second, expanded configuration having a second interior volume within the conductive surface, wherein the second volume is greater than the first volume.

2. A device as in claim 1, wherein the electrically conductive surface includes an outer metallic layer disposed over a polymeric layer.

3. A device as in claim 1, wherein the electrically conductive surface includes an outer metallic mesh disposed over a polymeric layer.

4. A device as in claim 3, wherein the polymeric layer is substantially resistant to fluid permeation, and wherein the polymeric layer is inflatable.

5. A device as in claim 1, wherein the electrically conductive surface is the outer surface of an electrically conductive polymeric layer.

6. A device as in claim 1, wherein the envelope is porous and the electrically conductive surface is the outer surface an electrically conductive porous mesh.

7. A device as in claim 1, wherein the device shaft includes a lumen extending along the shaft length and in fluid communication with the envelope interior for inflating the electrode surface.

8. A device as in claim 7, wherein the lumen is disposed within the shaft.

9. A device as in claim 1, wherein the device shaft includes a lumen within, wherein the lumen is in fluid communication with the envelope interior for inflating the surface electrode.

10. A device as in claim 1, wherein the device has a length of less than about 12 inches when expanded.

11. A device as in claim 1, wherein the device has a length of less than about 6 inches when expanded.

12. A device as in claim 1, wherein the envelope is biased to expand outwardly when unconstrained.

13. A device as in claim 12, wherein the envelope includes a metallic mesh that is biased to expand outwardly when unconstrained.

14. A device as in claim 1, wherein the envelope includes an electrically conductive shape memory metallic mesh that expands outwardly when heated to body temperature from room temperature.

15. A method for forming a lesion in cardiac tissue, the method comprising:

providing a first RF electrode coupled to a RF current source;

providing a second RF electrode electrically coupled to form a current path for the first RF electrode, wherein the second RF electrode includes an electrically conductive envelope surface defining an interior volume within, wherein the envelope has a first, unexpanded configuration and a second, expanded configuration, wherein the second configuration has an interior volume greater that the first configuration interior volume;

making an incision in a heart chamber wall;

inserting the second electrode through the incision and into the heart chamber interior;

expanding the second electrode conductive surface to the second configuration to contact a target region of the heart chamber endocardium; and

disposing the first electrode against the target region epicardium while applying RF current between the first and second electrodes.

16. A method as in claim 15, wherein the second electrode is biased to expand when unconstrained, and wherein the expanding step includes allowing the second electrode to expand inside the heart chamber.

17. A method as in claim 15, wherein the second electrode includes a shape memory material that expands when heated to body temperature, and wherein the expanding step includes allowing the second electrode to expand inside the heart chamber.

18. A method as in claim 15, further comprising providing a sheath over the envelope in the first, unexpanded envelope configuration, and retracting the sheath relative to the envelope.

19. A method as in claim 15, wherein the second electrode is fluid inflatable, and wherein the expanding step includes injecting fluid into the second electrode interior to expand the second electrode inside the heart chamber.

20. A method as in claim 15, wherein the making incision includes making an incision to remove an atrial appendage.

21. A method as in claim 15, wherein making the incision includes amputating the right atrial appendage.

22. A method as in claim 21, wherein inserting the second electrode through the incision includes inserting the second electrode through the incision amputating the right atrial appendage.

23. A method as in claim 22, wherein the target region includes a region disposed between the middle of the anterolateral aspect of the incision amputating the right atrial appendage and the inferior vena caval orifice.

24. A method as in claim 22, wherein the lesion is formed using the first and second electrodes, from the middle of the anterolateral aspect of the incision amputating the right atrial appendage towards the inferior vena caval orifice.

25. A method as in claim 23, further comprising making a second lesion that is slightly curved and extends along the border of the inter-atrial septum and ends at the atrioventricular groove, where the second lesion is formed by applying RF current between the first and second electrodes, where the second electrode has been inserted through the incision amputating the right atrial appendage.

26. A method as in claim 15, wherein making the incision includes amputating the left atrial appendage.

27. A method as in claim 26, wherein inserting the second electrode through the incision includes inserting the second electrode through the incision amputating the left atrial appendage.

28. A method as in claim 27, wherein the target region includes a region disposed within the inter-atrial groove between the left and right atria.

29. A method as in claim 28, wherein the lesion is formed by applying RF current between the first and second electrodes.

30. A method for forming a lesion in a target tissue having a cavity within, the method comprising:

providing a first RF electrode coupled to one pole of an RF current source;

providing a second RF electrode electrically coupled to the other pole of the RF current source, wherein the second RF electrode has an electrically conductive expandable surface;

inserting the second electrode into the tissue cavity;

expanding the second electrode to contact the target tissue from within the cavity; and

disposing the first electrode against the target tissue while applying RF current between the first and second electrodes to ablate the target tissue.

31. A method as in claim 30, wherein the target tissue in atrial tissue and the cavity is the atria, wherein the expanding includes expanding the second electrode by inflating the electrode within the atria.

32. A method for performing a maze procedure to treat atrial fibrillation by ablating atrial tissue to form at least one lesion in the atrial tissue, the method comprising:

providing a first RF electrode coupled to one pole of an RF current source;

providing a second RF electrode electrically coupled to the other pole of the RF current source;

inserting the second electrode into the atrial chamber; and

disposing the first electrode against the target tissue and drawing paths with the first electrode to form the maze lesions while applying RF current between the first and second electrodes to ablate the target tissue in a maze pattern,

wherein the inserting is done through an incision made at the atrial appendage.

33. A method as in claim 32, wherein the incision is made to remove the right atrial appendage and the method does not include making any other incisions in the right atrium.

34. A method as in claim 32, wherein the incision is made to remove the right atrial appendage and wherein the method does not include making an incision from the right atrial appendage incision toward the inferior vena caval orifice.

35. A method as in claim 32, wherein the incision is made to remove the right atrial appendage, and wherein the method does not include making a posterior longitudinal incision starting caudal to the superior caval cannulation site at the dorsal aspect of the right atrium.

36. A method as in claim 32, wherein the incision is made to remove the left atrial appendage, and wherein the method does not include making any other incisions in the left atrium.

37. A method as in claim 32, wherein the incision is made to remove the left atrial appendage, wherein the method does not include making an atriotomy in the inter-atrial groove between the left and right atria.

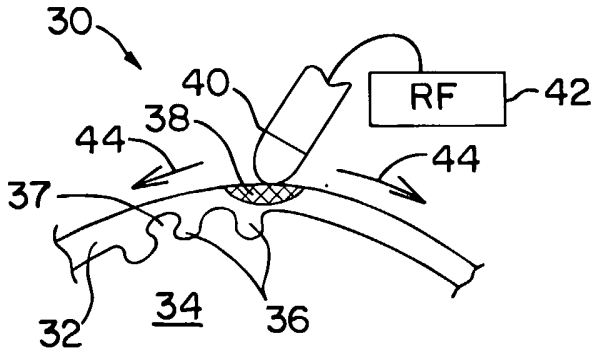


FIG. 1
PRIOR ART

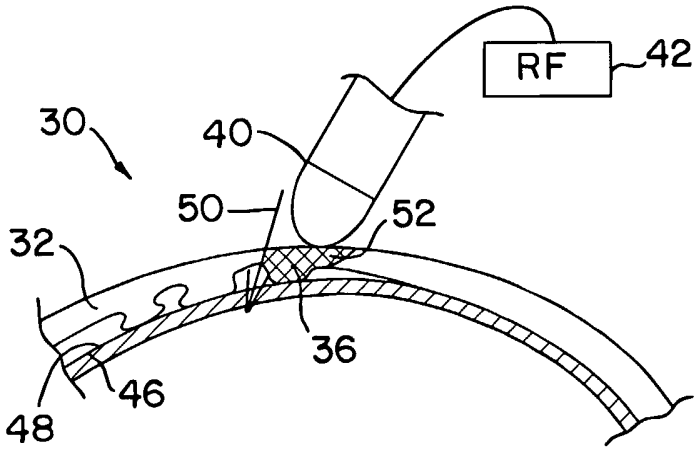


FIG. 2
PRIOR ART

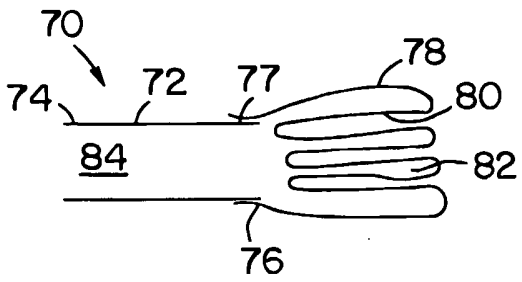
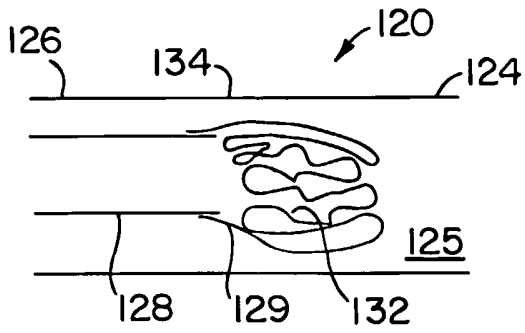


FIG. 3



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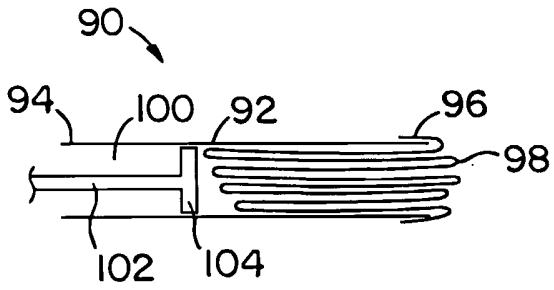

FIG. 4

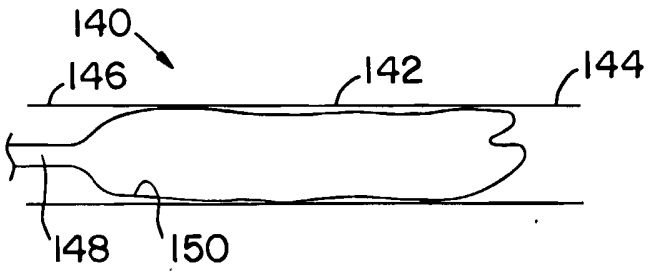

FIG. 6

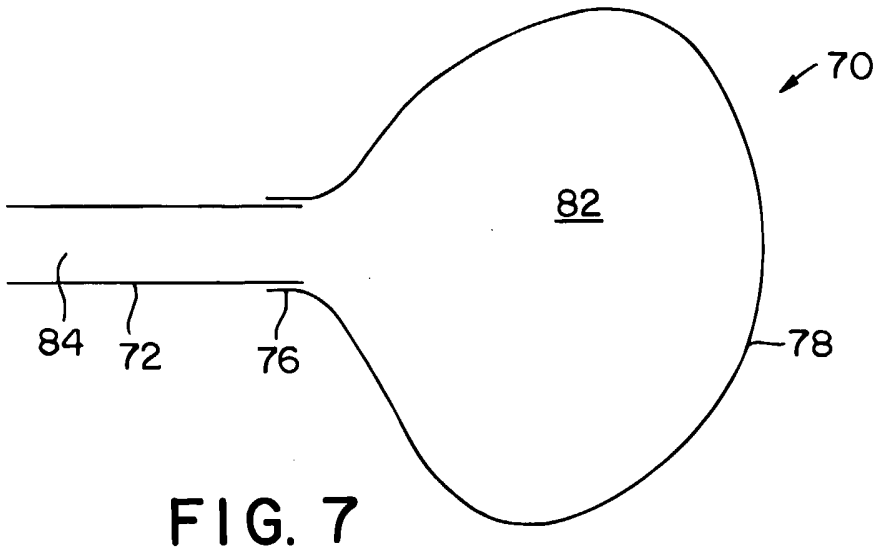

FIG. 7

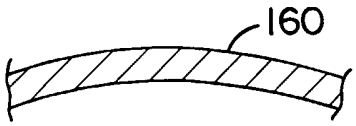

FIG. 8

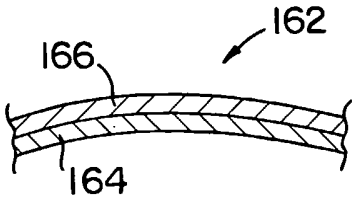

FIG. 9

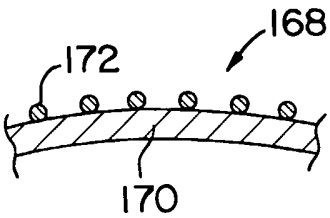

FIG. 10

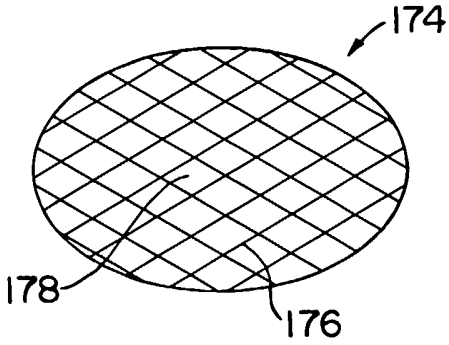

FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/012270

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, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 254 598 B1 (GAISER JOHN W ET AL) 3 July 2001 (2001-07-03) column 5, line 13,26-29 column 6, line 18-26 column 7, line 33-38 column 8, line 7-16; figure 2A column 10, line 58 ---	1,2,5, 7-13
X	WO 01/87169 A (ATRIONIX INC) 22 November 2001 (2001-11-22) column 5, line 6 column 9, line 4 column 10, line 31-33 column 38, line 6-18 column 41, line 31-33 column 48, line 12-16; figure 16B --- -/--	1-4,7,8, 10,11

[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
30 August 2004	07/09/2004

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	Aronsson, F

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/012270

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 989 284 A (LAUFER MICHAEL D) 23 November 1999 (1999-11-23) column 3, line 4,5 column 6, line 43,60-64 column 10, line 62 -column 11, line 5	1,2,7, 10-14
X	WO 02/087456 A (HE DING SHENG ;MACADAM DAVID (US); BARD INC C R (US)) 7 November 2002 (2002-11-07) column 6, line 9-24 column 9, line 4-16	1,2,6, 10,11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/012270

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.: 15-37
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 and therapy

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

Information on patent family members

International Application No
PCT/US2004/012270

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