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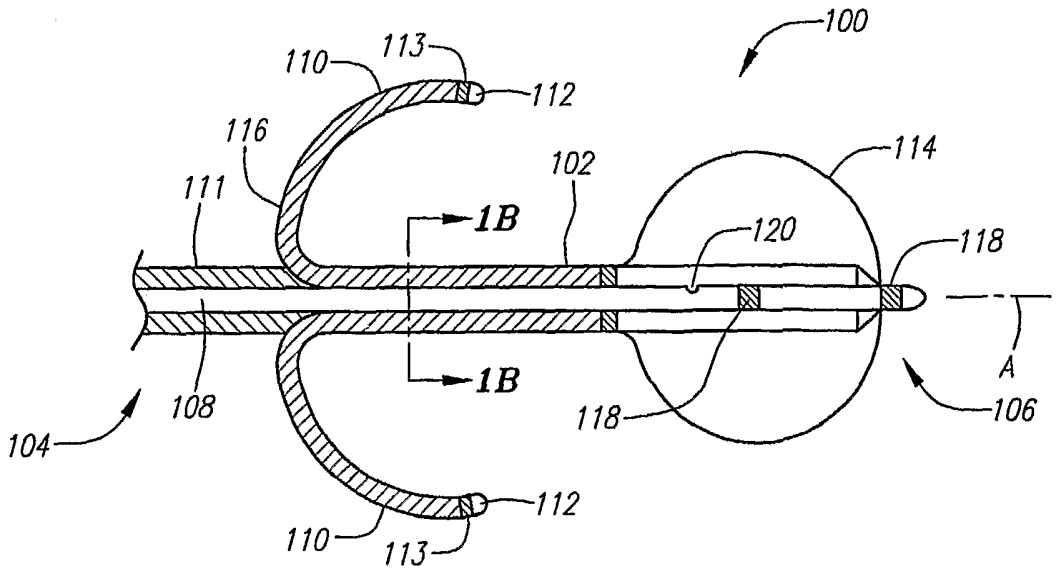
(54) Title: BALLOON CENTERED RADIALLY EXPANDING ABLATION DEVICE



(57) Abstract: A device and associated method for performing ablation procedures on anatomical structures accessible from within the chambers of the heart to form lesions that electrically isolate the tissue. The device including an ablation device having a catheter body concentrically formed with an outer sheath. The device also including a balloon used to perform a centering and anchoring function at an orifice within the cardiac myocardium. At least one ablation element can be positioned proximal to the balloon which can be radially deployed with respect to the central axis of the apparatus for creating a lesion at a lesion creation site in the heart wall.

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Balloon Centered Radially Expanding Ablation Device

BACKGROUND

[0100] This application claims the benefit and priority of United States Provisional Patent Application Serial No. 60/473,774, filed May 27, 2003, which is herein incorporated by reference for all purposes.

1. Field of the Invention

[0101] The invention generally relates to the treatment of electrophysiological disease, and more particularly to devices and method for ablating tissue in treating atrial fibrillation.

2. Related Art

[0102] A procedure known as the surgical maze procedure has been developed for treating atrial fibrillation, a condition which results from, disorganized electrical activity in the heart muscle or myocardium. The surgical maze procedure involves the creation of a series of surgical incisions in a preselected pattern so as to create conductive corridors of viable tissue bounded by scar tissue.

[0103] Ablative procedures have been used as an alternative to the surgical incisions used in the maze procedure. Typically, the ablative techniques include endocardial or epicardial ablation, which create lesions extending through a sufficient thickness of the myocardium to block electrical conduction.

[0104] Unfortunately, the maze procedure, whether using surgical or ablative techniques, is often very time-consuming and can result in lesions which do not completely encircle the pulmonary veins or which contain gaps and discontinuities. Most procedures do not include means for visualization of endocardial anatomy and most endovascular devices are often inadequate in relaying the precise position of such devices in the heart. This may result in misplaced lesions.

SUMMARY

[0105] The present invention provides a device and associated method for performing ablation procedures on anatomical structures accessible from within the chambers of the heart to form lesions that electrically isolate the tissue.

[0106] The method includes placing at least one ablation device through the major vein or artery usually in the neck or groin area, and guided into the heart chambers; deploying an inflatable balloon at an orifice within the cardiac myocardium in which the balloon can be anchored; radially deploying at least one ablation element; and ablating the heart wall with at least one ablation element to create at least one lesion.

[0107] In another aspect of the invention, an apparatus for forming a lesion in the heart wall includes an ablation device including a catheter body concentrically formed with an outer sheath having a distal end and a proximal end; a balloon coupled at the distal end to perform a centering and anchoring function at an orifice within the cardiac myocardium; at least one ablation element positioned proximal to the balloon which can be radially deployed with respect to the central axis of the apparatus for creating a lesion in the heart wall. The apparatus may also include a control device at the proximal end for manipulating the ablation device.

[0108] The ablation element may be a radiofrequency electrode, microwave transmitter, cryogenic element, laser, ultrasonic transducer or any of the other known types of ablation devices suitable for forming lesions. The apparatus includes a plurality of such ablation devices arranged along the working end in a linear pattern suitable for forming a continuous, uninterrupted lesion around the orifice of heart vasculature or around the ostium of the pulmonary veins.

[0109] These and other features and advantages of the present invention will be more readily apparent from the detailed description of the preferred embodiments set forth below taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

[0110] FIG. 1A is a simplified side view of an ablation device in accordance with an embodiment of the present invention;

[0111] FIG. 1B is a simplified sectional view as indicated of a cross section of the embodiment of FIG. 1A;

[0112] FIG. 1C is a simplified side view of an ablation device shown with alternate ablating member within the sheath in accordance with an embodiment of the present invention.

[0113] FIG. 2 is a side cross sectional view of yet another embodiment of the present invention;

[0114] FIGS. 3A and 3B are simplified illustrations of a deployed ablation device in accordance with an embodiment of the present invention;

[0115] FIG. 4 is a simplified cross sectional view of a balloon in accordance with an embodiment of the present invention;

[0116] FIG. 5 is a simplified view of an ablation element including protective sheath in accordance with an embodiment of the present invention;

[0117] FIG. 6 is a simplified view of a deployed ablation device in accordance with an embodiment of the present invention;

[0118] FIG. 7 is a simplified illustration of a display coupleable to the ablation device for showing the radially deployed ablation elements in accordance with an embodiment of the present invention;

[0119] FIG. 8 is a simplified illustration of an embodiment of the present invention.

[0120] FIGS. 9A and 9B are a simplified illustration of an embodiment of the present invention.

DETAILED DESCRIPTION

[0121] FIG. 1A and FIG. 1C are simplified side cross-sectional views of an embodiment of ablation device 100 in accordance with the present invention. In this embodiment, ablation device 100 includes a catheter body 102 having a proximal end 104 and a distal end 106 with a balloon 114 formed at distal end 106. Catheter body 102 includes an inflation/deflation lumen 108 surrounded by an outer sheath 111 formed concentric with lumen 108. In one embodiment, outer sheath 108 can be made to translate over lumen 108 in a telescopic arrangement.

[0122] Catheter body 102 and balloon 114 of ablation device 100 are configured for insertion into a main vein or artery through a small percutaneous incision. The extreme proximal end of ablation device 100 is operably coupled to a control device (not shown) used for manipulating ablation device 100 from outside the vein or artery. In one embodiment, ablation device 100 is made to enter the left heart chamber and advanced to the pulmonary veins. Ablation device 100 is made flexible enough to allow advancement to the heart chambers and can be made to any suitable dimension to reach the desired location within the heart chamber. Ablation device 100 can be made of a flexible biocompatible polymer or polymer matrix with metal wire braids and can include radiopaque markers 118 or radiopaque filler such as bismuth or barium sulfate.

[0123] FIG. 1B is a sectional view as indicated of a cross section of catheter body 102 of FIG. 1A. As shown in FIG. 1B, outer sheath 108 can include one to a plurality of smaller element housing lumen 116 configured to receive an ablation element 110. The one to a plurality of ablation elements 110 are used to form lesions isolating the pulmonary veins from the surrounding myocardium.

[0124] In one embodiment, each ablation probe 110 disposed in lumens 116 includes a pre-shaped wire. In one embodiment, ablation elements 110 may include an energy tip 112 formed at the most distal end of the element. As described in detail below, energy tip 110 may include, for example, an RF electrode or other type of energy source capable of performing ablation of tissue. Thermocouples 113 can also be positioned proximate to energy tip 112, or may be welded or bonded to the energy tips themselves, to monitor the amount of heat generated at the ablation site and to facilitate temperature measurement of the target tissue during ablation and thus, prevent overheating. Thermocouples 113 can be coupled to wires which extend to proximal end 104 of ablation device 100 and ultimately to temperature monitoring equipment or electrical monitoring equipment as to facilitate mapping of electrical activity at the target sites.

[0125] As shown in FIG. 2, the pre-shaped wire can be received within lumens 116 and aligned parallel to a central axis A of catheter body 102. Openings 202 are formed along outer sheath 111 to allow ablation elements 110 to exit from lumen 116. In one embodiment, ablation elements 110 exit lumens 116 in a direction toward proximal end 104 through openings 202 while in one embodiment, ablation elements 110 can be made to exit lumens 116 in direction toward distal end 106 as shown in FIG. 1C.As the ablation elements 110 exit lumens 116 the pre-shaped wires radially expand away from central axis A, while at the same time the pre-shaped wire begins to regain its arcuate shape causing energy tip 112 to translate toward distal 106 (FIG. 1A). Generally, as described in greater detail below, the bend in arcuate shaped ablation element 110 causes energy tip 112 to advance toward the ablation site.

[0126] Ablation elements 110 include electrodes 112 formed at the distal end of ablation elements 110 for delivering current to the myocardium so as to create lesions of sufficient depth to block electrical conduction. Electrodes 112 may be solid metal rings or cylinders, foil strips, wire coils or other suitable construction for producing elongated lesions. It is understood that the term electrodes 112 as used herein may refer to any suitable ablating element 112, such as microwave transmitters, cryogenic elements, lasers,

heated elements, ultrasound, hot fluid or other types of ablation devices suitable for forming lesions.

[0127] Referring again to FIG. 1B, ablation elements 110 are disposed in outer sheath 111 spaced apart a distance d about the circumference of sheath 111. The number of ablation elements 110 disposed in outer sheath 111 is variable and depends on the desired procedure. In one embodiment, each ablation element 110 is positioned a distance r from the central axis A. In one embodiment, ablation elements 110 are positioned so as to facilitate lesion formation on the three-dimensional topography of the myocardium. Ablation elements 110 can be made of any flexibly resilient material that possess a spring quality and can be pre-shaped, such as Nitinol and other memory shape metals, stainless steel, and steel alloys, and the like.

[0128] Proximal end 104 of ablation device 100 further includes a control handle (not shown) which locates distal end 106 at one of the pulmonary veins. The control end can includes a handle and one to a plurality of slidable actuators, which are used to extend each ablation element 110 from lumens 116. An electrical connector suitable for connection to an energy source can be mounted to the handle.

[0129] As shown in FIG. 2, electrical wires, disposed in electric conduits 204, can be used to electrically couple the energy source to ablation elements 110 and ultimately electrodes 112. Each electrode 112 can be coupled to a separate wire to allow any electrode 112 or combination of electrodes to be selectively activated. The thermocouples mounted near the electrodes can be coupled to temperature or electrical monitoring equipment to control temperature of selected electrode 112 and monitor electrical activity at the target site. Also mounted to the handle can be a connector for connection to a source of inflation fluid or suction, used for the inflation/deflation of balloon 114.

[0130] In one embodiment, the actuators in the handle are coupled to the proximal end of each ablation element 110, and may be advanced forward to deploy each ablation element 110 from a non-deployed or retracted orientation, as shown in FIG. 2 to a deployed or radially expanded orientation, as shown in FIG. 1A.

[0131] The ablating element captured within the outer sheath 111 is free to transverse and rotate relative to the inner sheath 108. This allows the positioning of the radially expanded ablating element and its electrode112 to vary in distance relative to the location of the anchoring balloon 114 and rotate along the central axis of the anchored balloon 114. Alternatively, outer sheath 111 and inner lumen 108 are coupled in a slidable

relationship while the ablating element is captured in between the outer sheath 111 and inner sheath lumen 108 and not part of the outer sheath 111. In this alternative embodiment, outer sheath 111 can be pulled back relative to inner lumen 108 which causes ablation elements to become exposed, which allows ablation elements to radially expand due to their shaped memory and be directed to the tissues to be ablated.

[0132] Referring again to FIGS. 1A and 2, balloon 114 is positioned at the distal end 106 of ablation device 100 just distal to ablation elements 110. Balloon 114 is used to position and manipulate ablation elements 110. In operation, inner lumen 108 is configured to carry a gas or fluid through opening 120, to or away from balloon 114, to cause the balloon to inflate or deflate as desired. As shown in FIGS. 3A and 3B, the size of the inflated balloon 114 controls the range of the ablation site along the axis of the vasculature. For example, balloon 114 can be used to anchor ablation device 100 at the opening of the vasculature (FIG. 3A). Alternatively, ablation device 100 can be allowed to enter into the vasculature and expanded to anchor ablation device 100 upstream of the vascular opening. In any embodiment, the inflated balloon is used to position and manipulate the ablation element 110.

[0133] FIG. 1C is a simplified illustration of an alternative embodiment of ablation device 100. In this alternative embodiment, ablation elements 110 are deployed forward toward distal end 106. Upon exiting outer sheath 111, ablation elements 110 take a pre-shaped form which causes them to bend around balloon 114 and avoid contact therewith.

[0134] As shown in FIG. 4, in one embodiment, balloon 402 is formed of multi-chambers in a shape other than a sphere. Inner lumen 108 can include multiple openings 120, to feed gas or liquid into each chamber of balloon 402. For example, balloon 402 can be made with a clove-like shape. The clover like shaped balloon can anchor ablation device 100 within an orifice at the highest points of the clover-like shape, while allowing blood to flow between the recessed spaces formed between the multi-chamber sections.

[0135] In situations where the ostium is not normal to the axis of the vascular opening, ablation element 110 can be manipulated to contact the high and low points of the ostium by the use of balloon 114 having multi-chambers and independently controlled inflation chambers. For example, filling one of the chambers more or less against the other chambers can be used to bias ablation elements 110 to only contact specific quadrants of the circumferential pattern. Alternatively, the biasing of the elements to specific areas can

be accomplished using a single chamber balloon and independent and selectively deploying the abating element. This may be controlled by the user at the handle.

[0136] The radially expanding ablation elements 110 can be made flexible enough to account for the varying topography of the opening.

[0137] FIG. 5 is a simplified illustration of ablation element 110 including a protective sheath 502 which provides a more efficient energy delivery. Protective sheath 502 can be a non-conductive compliant polymer. The differential stiffness between the ablation element 110 and the protective sheath 502 pushes back the sheath relative to the tip of the ablation element to form an expanded lip portion or petal 504. Petal 504 provides increased impedance and provides minimal heating of blood surrounding electrode 112.

[0138] Protective sheath 502 can be made to seal against the tissue wall before electrode 112 is energized to minimize the contact with blood and to maximize the contact with the tissue. A soft suction within the sheath 502 can be used to cause the sheath 502 to seal against the soft tissue.

[0139] As shown in FIG. 6, petal 504 at the end of sheath 502 can also provide a self-aligning footing for the un-even contours of the tissue wall by directing electrode 112 of ablation element 110 to contact the tissue perpendicular to the surface of the tissue. The flexible ablation element 110 can adjust to align the petal 504 perpendicular to the contact surface, since petal 504 will naturally try to bias ablation element 110 into such an orientation.

[0140] Ablation elements 110 can accomplish focal, segmented, or circumferential ablation concentric to balloon 114, which is deployed in an orifice of the vasculature, such as the pulmonary vein near its ostium.

[0141] In one embodiment, outer sheath 111 which houses ablation elements 110 is free to rotate with respect to inner lumen 108. Where a circumferential pattern is desired, the radially expanding ablation elements 110 can be indexed while the inner lumen 108 coupled to balloon 114 is anchored and remains stationary to complete the ablation concentric with a central axis of balloon 114.

[0142] FIGS. 9A and 9B show that outer sheath 111 can be made to traverse along the central axis A to provide flexible positioning of ablation elements 110. The traversed position as well as the amount of radial deployment of ablation element 110 determines the size of the circumferential pattern and the precise location of the segmented focal lesion site (FIG. 8). For example, outer sheath 111 can be positioned such that ablation

elements 110 deploy to form a circumferential pattern C_1 or positioned closer to balloon 114 to form circumferential pattern C_2.

[0143] FIG. 7 is a simplified illustration of a display feature 702 to show when contact has been made between ablation element 110 and the tissue. A visual display can be used with energy delivery equipment to show when optimum contact has been achieved (impedance). Display 702 shows a location of each radially deployed ablation element 110 that has made good contact with the target tissue.

[0144] In one embodiment, the LEDs 704 light up a pattern that corresponds to the contact points of the ablation elements 110 on the target tissue based on an impedance measurement at each electrode 112. Sensitivity setting can be adjusted to show whether the contact made is optimal or not or how close to optimal the contact has become.

[0145] Having thus described embodiments of the present invention, persons skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. Thus the invention is limited only by the following claims.

WHAT IS CLAIMED IS:

1. A method comprising:

positioning at least one ablation device into the heart chambers;

deploying an inflatable balloon at an orifice within the cardiac myocardium in which the balloon can be anchored;

radially deploying at least one ablation element; and

ablating the heart wall with at least one ablation element to create at least one lesion.

2. An apparatus for forming a lesion in the heart wall comprising:

an ablation device including a catheter body concentrically formed with an outer sheath having a distal end and a proximal end;

a balloon coupled at the distal end to perform a centering and anchoring function at an orifice within the cardiac myocardium; and

at least one ablation element positioned proximal to the balloon which can be radially deployed with respect to the central axis of the apparatus for creating a lesion at a lesion creation site in the heart wall.

3. The apparatus of Claim 2, further comprising an insulative sheath formed around the ablation element to seal an electrode from contact with surrounding blood at the lesion creation site, said insulative sheath being flared at the tip to orient the electrode normal to the tissue surface to be ablated for maximum delivery of energy.

4. The apparatus of Claim 2, wherein said outer sheath is configured to translate over the catheter body in telescopic arrangement to radially deploy at least one ablation element with respect to the central axis of the catheter body.

5. The apparatus of Claim 2, wherein said outer sheath can include one to plurality of smaller housing lumens configured to receive one to plurality of ablation elements.

6. The apparatus of Claim 2, wherein said catheter body is coupled to said at least one ablation element and is configured to translate over an inner lumen in telescopic arrangement where the inner lumen is coupled to said balloon at its distal end.

7. The apparatus of Claim 2, wherein said at least one ablation element comprises a radiofrequency electrode, microwave transmitter, cyrogenic element, laser, ultrasonic transducer or any of the other known type of ablation element suitable for forming lesions.

8. The apparatus of Claim 2, wherein said at least one ablation element comprises a pre-shaped wire capable of delivering RF energy at said lesion creation site.

9. The apparatus of Claim 8, further comprising at least one thermocouple positioned proximate to said at least one ablation element to monitor the amount of heat generated at the lesion creation site and to facilitate temperature measurement of target tissue at the lesion creation site.

10. The apparatus of Claim 8, further comprising conductive leads coupled to said pre-shaped wire, said conductive leads configured to connect to mapping equipment to facilitate mapping of the electrical activity at said lesion creation site.

11. The apparatus of Claim 8, wherein said pre-shaped wire comprises a flexibly resilient material that possess a spring quality.

12. The apparatus of Claim 11, wherein said flexibly resilient material that possess a spring quality consists of materials taken from the group of Nitinol, other memory shape metals, stainless steel, and steel alloys.

13. The apparatus of Claim 8, wherein said pre-shaped wire comprises a shape taken form the group of solid metal rings or cylinders, foil strips, wire coils and other suitable construction for producing elongated lesions.

14. The apparatus of Claim 2, wherein said at least one ablation element comprises microwave transmitters, cryogenic elements, lasers, heated elements, ultrasound, hot fluids and other types of ablation elements suitable for forming lesions.

15. The apparatus of Claim 2, wherein said at least one ablation element comprises a plurality of spaced apart ablation elements positioned about the circumference of the catheter body and outer sheath.

16. The apparatus of Claim 2, said at least one ablation element comprises a plurality of ablation elements positioned to facilitate lesion formation on the three-dimensional topography of the pulmonary vein ostium.

17. The apparatus of Claim 2, wherein said at least one ablation element is received within the outer sheath aligned parallel to a central axis of the catheter body, said at least one ablation element radially expanded away from the central axis of the catheter body to allow said at least one ablation element to regain a preformed arcuate shape.

18. The apparatus of Claim 2, further comprising a handle which controls the distal end of the catheter body to position said distal end ,said handle including a slidable actuator which controls the amount of transverse movement of the outer sheath relative to catheter body containing said at least one ablation element to control the amount of said at least one ablation element that can be radially deployed.

19. The apparatus of Claim 2, further comprising a handle including a slidable actuator which can control the radial extension of said at least one ablation element.

20. The apparatus of Claim 19, wherein said slidable actuator is configured to selectively deploy said at least one ablation element.

21. The apparatus of Claim 2, wherein said at least one ablation element comprises a plurality of ablation elements, wherein leads couple an energy source to each of said ablation elements, wherein each ablation element is wired to allow selective activation of said ablation elements separately or in combination .

22. The apparatus of Claim 2, wherein said outer sheath transverses and rotates relative to said central axis to allow the initial positioning of the at least one ablation element to vary in distance relative to the location of the balloon and to rotate along the central axis.

23. The apparatus of Claim 2, wherein said balloon is used to position and manipulate the at least one ablation element.

24. The apparatus of Claim 2, wherein said balloon is configured to inflate to variable sizes to control where the balloon is located within the orifice which varies the positioning of the at least one ablation element.

25. The apparatus of Claim 2, wherein said balloon comprises multi-chambers in a shape other than a circular cross-section, wherein the inflation of said multiple chambers is independently controlled to allow for biasing the at least one ablation element to a specific lesion creation site.

26. The apparatus of Claim 25, wherein said multi-chamber balloon comprises a clover-like shape wherein the most outer point of the multi-chamber balloon positions the ablation device while allowing blood to flow between recessed spaces formed between the multi-chamber sections and the heart wall.

27. The apparatus of Claim 2, further comprising a visual display feature integrated with energy source equipment configured to indicate evidence of contact made between the at lest one ablation elements and the lesion creation site.

28. The apparatus of Claim 27, wherein said visual display feature comprises an LED pattern corresponding to a contact point between the at least one ablation element and the lesion creation site.

29. The apparatus of Claim 27, wherein said visual display feature comprises an adjustable sensitivity setting to indicate a level of contact between the at least one ablation element and the lesion creation site.

30. An apparatus for forming a lesion in the heart wall comprising:

an ablation device including a catheter body concentrically formed with an outer sheath and inner lumen having a distal end and a proximal end;

a balloon coupled at the distal end of the inner lumen to position the catheter; and

at least one ablation element positioned proximal to the balloon which can be radially deployed with respect to central axis of the apparatus and can be indexed while inner lumen remains stationary and can traverse along the central axis.

31. The apparatus of Claim 30, wherein said outer sheath is configured to translate over the catheter body in telescopic arrangement to radially deploy at least one ablation element with respect to the central axis of the catheter body.

32. The apparatus of Claim 30, wherein said outer sheath can include one to plurality of smaller housing lumens configured to receive one to plurality of ablation elements.

33. The apparatus of Claim 30, wherein said catheter body is coupled to said at least one ablation element and is configured to translate over an inner lumen in telescopic arrangement where the inner lumen is coupled to said balloon at its distal end.

34. The apparatus of Claim 30, wherein said at least one ablation element comprises a radiofrequency electrode, microwave transmitter, cryogenic element, laser, ultrasonic transducer or any of the other known type of ablation element suitable for forming lesions.

35. The apparatus of Claim 30, wherein said at least one ablation element comprises a pre-shaped wire capable of delivering RF energy at said lesion creation site.

36. The apparatus of Claim 35, further comprising at least one thermocouple positioned proximate to said at least one ablation element to monitor the amount of heat generated at the lesion creation site and to facilitate temperature measurement of target tissue at the lesion creation site.

37. The apparatus of Claim 35, further comprising conductive leads coupled to said pre-shaped wire, said conductive leads configured to connect to mapping equipment to facilitate mapping of the electrical activity at said lesion creation site.

38. The apparatus of Claim 35, wherein said pre-shaped wire comprises a flexibly resilient material that possess a spring quality.

39. The apparatus of Claim 38, wherein said flexibly resilient material that possess a spring quality consists of materials taken from the group of Nitinol, other memory shape metals, stainless steel, and steel alloys.

40. The apparatus of Claim 35, wherein said pre-shaped wire comprises a shape taken form the group of solid metal rings or cylinders, foil strips, wire coils and other suitable construction for producing elongated lesions.

41. The apparatus of Claim 30, wherein said at least one ablation element comprises microwave transmitters, cryogenic elements, lasers, heated elements, ultrasound, hot fluids and other types of ablation elements suitable for forming lesions.

42. The apparatus of Claim 30, wherein said at least one ablation element comprises a plurality of spaced apart ablation elements positioned about the circumference of the catheter body and outer sheath.

43. The apparatus of Claim 30, said at least one ablation element comprises a plurality of ablation elements positioned to facilitate lesion formation on the three-dimensional topography of the pulmonary vein ostium.

44. The apparatus of Claim 30, wherein said at least one ablation element is received within the outer sheath aligned parallel to a central axis of the catheter body, said at least one ablation element radially expanded away from the central axis of the catheter body to allow said at least one ablation element to regain a preformed arcuate shape.

45. The apparatus of Claim 30, further comprising a handle which controls the distal end of the catheter body to position said distal end ,said handle including a slidable actuator which controls the amount of transverse movement of the outer sheath relative to catheter body containing said at least one ablation element to control the amount of said at least one ablation element that can be radially deployed.

46. The apparatus of Claim 30, further comprising a handle including a slidable actuator which can control the radial extension of said at least one ablation element.

47. The apparatus of Claim 46, wherein said slidable actuator is configured to selectively deploy said at least one ablation element.

48. The apparatus of Claim 30, wherein said at least one ablation element comprises a plurality of ablation elements, wherein leads couple an energy source to each of said ablation elements, wherein each ablation element is wired to allow selective activation of said ablation elements separately or in combination .

49. The apparatus of Claim 30, wherein said outer sheath transverses and rotates relative to said central axis to allow the initial positioning of the at least one ablation element to vary in distance relative to the location of the balloon and to rotate along the central axis.

50. The apparatus of Claim 30, wherein said balloon is used to position and manipulate the at least one ablation element.

51. The apparatus of Claim 30, wherein said balloon is configured to inflate to variable sizes to control where the balloon is located within the orifice which varies the positioning of the at least one ablation element.

52. The apparatus of Claim 30, wherein said balloon comprises multi-chambers in a shape other than a circular cross-section, wherein the inflation of said

multiple chambers is independently controlled to allow for biasing the at least one ablation element to a specific lesion creation site.

53. The apparatus of Claim 52, wherein said multi-chamber balloon comprises a clover-like shape wherein the most outer point of the multi-chamber balloon positions the ablation device while allowing blood to flow between recessed spaces formed between the multi-chamber sections and the heart wall.

54. The apparatus of Claim 30, further comprising a visual display feature integrated with energy source equipment configured to indicate evidence of contact made between the at lest one ablation elements and the lesion creation site.

55. The apparatus of Claim 54, wherein said visual display feature comprises an LED pattern corresponding to a contact point between the at least one ablation element and the lesion creation site.

56. The apparatus of Claim 54, wherein said visual display feature comprises an adjustable sensitivity setting to indicate a level of contact between the at least one ablation element and the lesion creation site.

57. A method for creating a lesion in the heart wall to create an ablation pattern to electrically isolate the vasculature from the chamber and to create a segmental electrical isolation for treatment of cardiac arrhythmia, the method comprising:

positioning at least one ablation catheter having proximal and distal portion into the heart chamber near a vasculature ostium;

deploying an inflatable balloon to position at least one expandable ablation element proximal to the balloon,

traversing the outer sheath along the catheter body to expose the at least one ablation element in a radial direction relative to a central axis of the ablation catheter;

advancing the exposed ablation element along an inner lumen of the catheter to cause said at least one ablation element to contact a chamber wall about the vasculature ostium; and

ablating a lesion pattern on said chamber wall to electrically isolate the vasculature ostium.

58. The method of claim 57, wherein said ablating a lesion pattern on said chamber wall comprises performing focal, segmented, or circumferential ablation.

59. The method of claim 57, wherein said ablating a lesion pattern on said chamber wall comprises forming a circumferential lesion pattern around the vasculature ostium by repeatedly rotating the at least one ablation element about the central axis and traversing in and out to contact the chamber wall while activating the ablative energy upon contact.

60. The method of claim 57, wherein said deploying said inflatable balloon comprises positioning the inflatable balloon inside the vasculature ostium.

61. The method of Claim 57, wherein said vasculature ostium comprises a pulmonary vein, wherein said pulmonary vein can be a single distinct circular ostium, two distinct circular ostia sharing a vascular wall, and one elliptical-shape common ostium that bifurcate or trifurcate to separate pulmonary veins.

62. The method of Claim 61, which can be ablated using the multi-chamber balloon which can bias the ablating member to selectively ablate specific quadrants of circumferential ablation pattern.

63. The method of Claim 57, wherein said advancing the exposed ablation element comprises controlling the lesion pattern shape and size by allowing only a predetermined portion of the at least one ablation element to be exposed and to regain a preselected shape.

64. The method of Claim 57, further comprising visually displaying points of contact made between the at least one ablation element and targeted tissue using a feature made of an LED pattern corresponding to said contact points of the ablation element on the target tissue, wherein the visual display has an adjustable sensitivity setting to show the levels of contact.

65. The method of Claim 64, wherein deploying said inflatable balloon comprises deploying a multi-chamber balloon, wherein said each chamber of said multi-

chamber balloon is configured to be independently controlled to increase or decrease the electrical contact made between target tissue and the at least one ablation element.

66. A method for mapping the electrical signals inside the vasculature and around the ostium on the chamber side of the heart, the method comprising:

positioning a catheter having a catheter body and an outer sheath inside the vasculature or outside the vasculature around the ostium on the chamber side; and

radially expanding a predetermined amount of pre-shaped ablating elements to allow each pre-shaped ablating elements to regain a preselected shape by controlling the amount of transverse movement of the outer sheath relative to the catheter body which contains the pre-shaped the ablating elements.

67. A method of claim 66, wherein said pre-shaped ablating elements are coupled with mapping electrodes which contact tissue and provide mapping signals to a mapping device connected to a proximal end of the catheter.

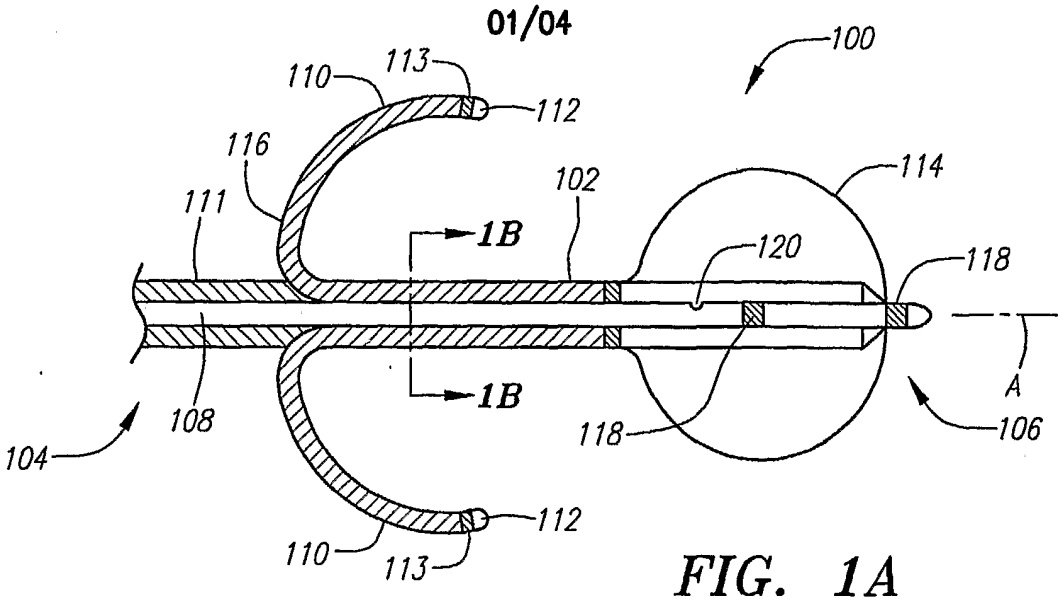

FIG. 1A

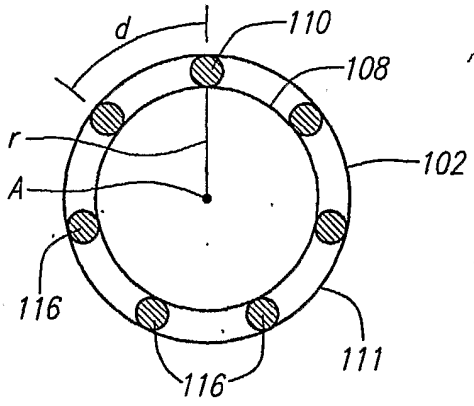

FIG. 1B

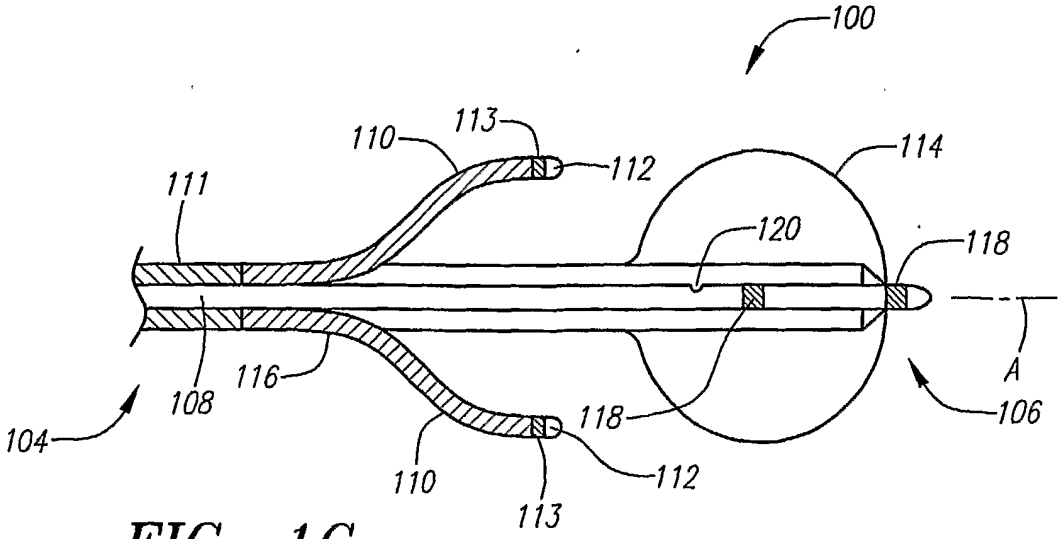

FIG. 1C

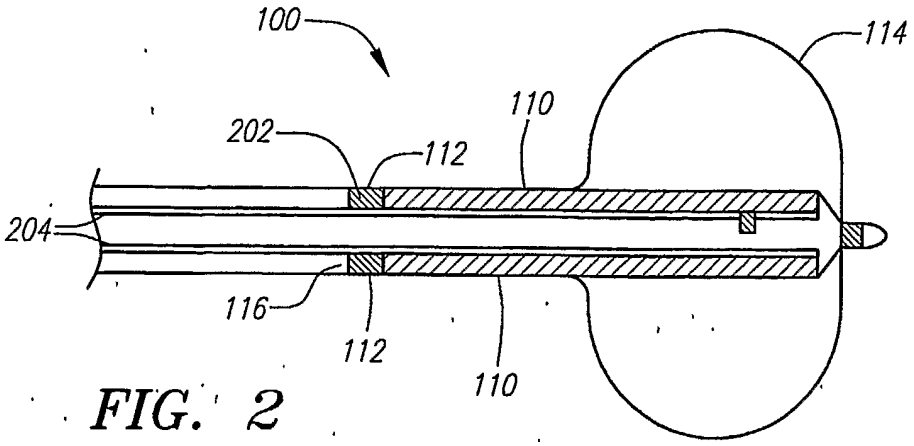

FIG. 2

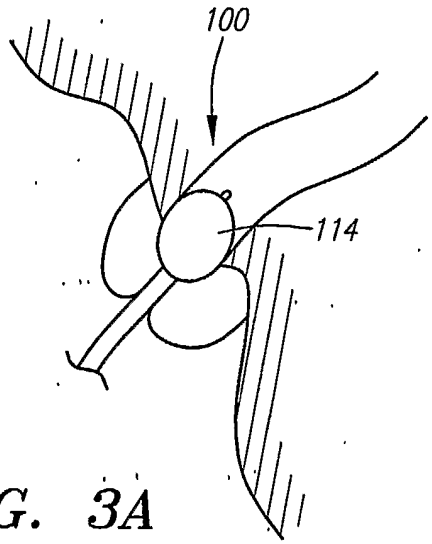

FIG. 3A

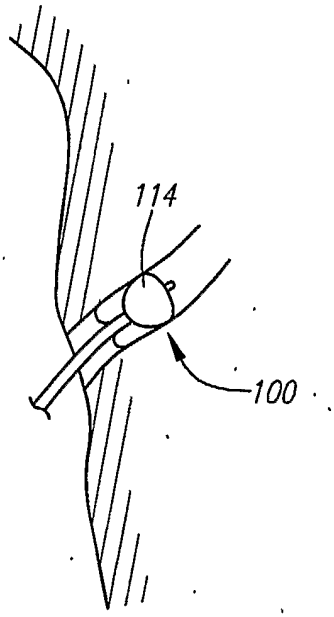

FIG. 3B

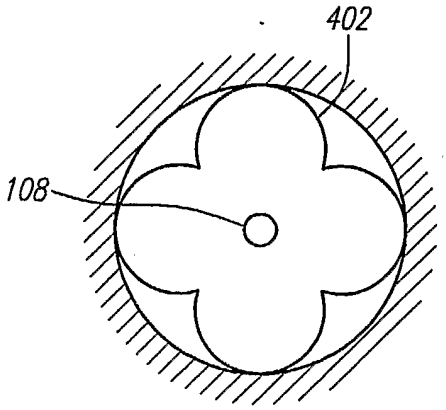

FIG. 4

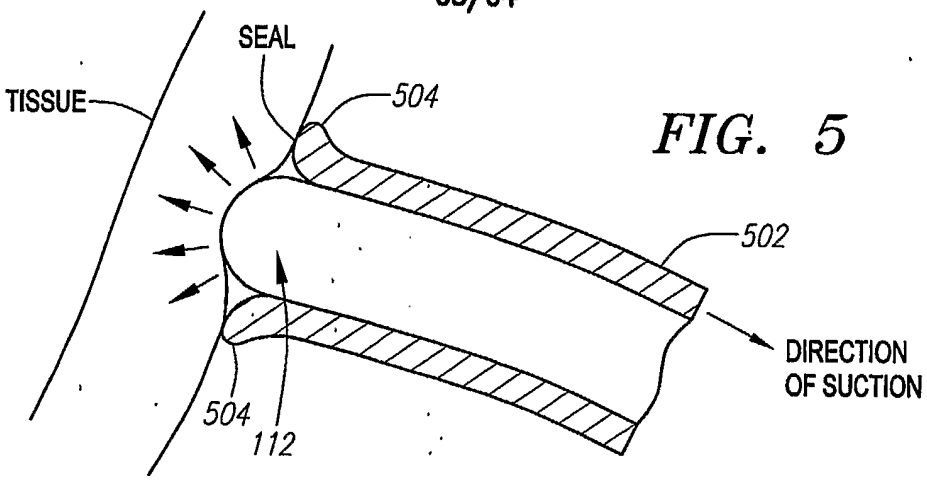

FIG. 5

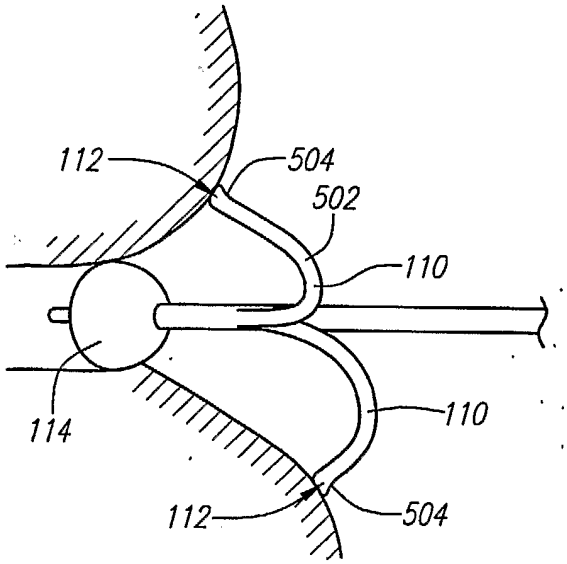

FIG. 6

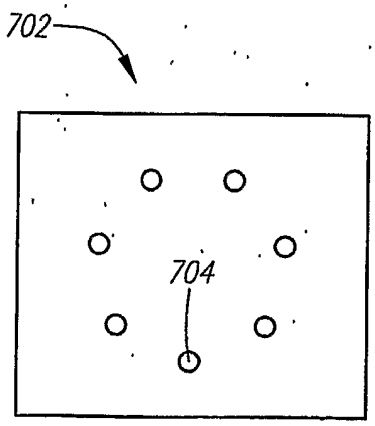

FIG. 7

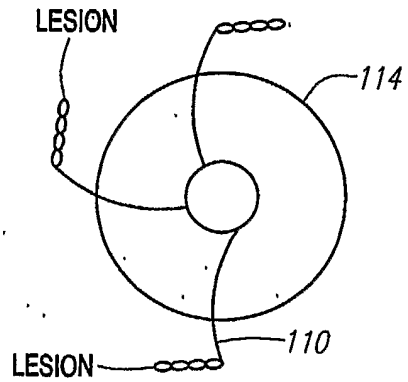

FIG. 8

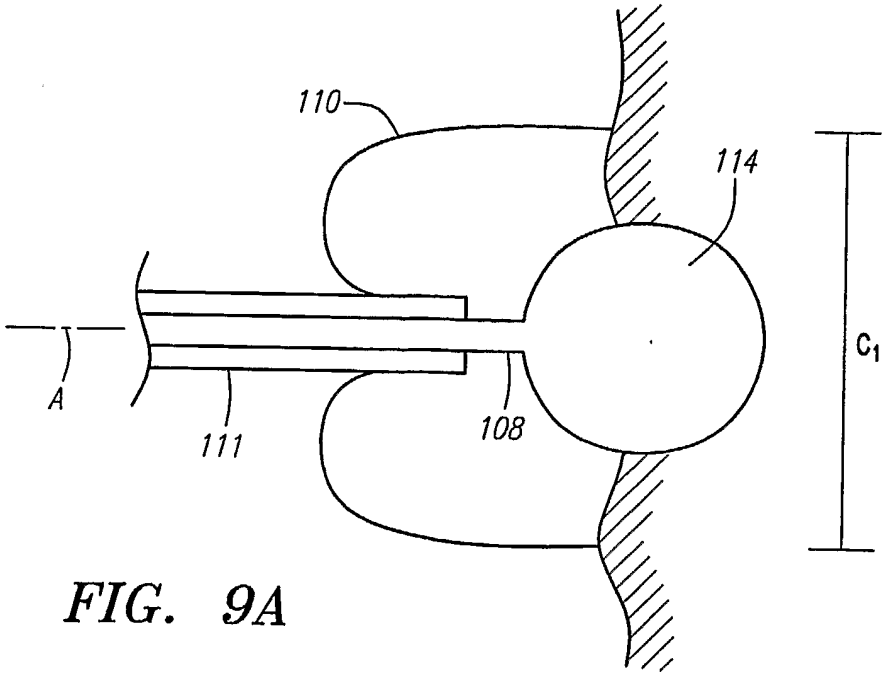

FIG. 9A

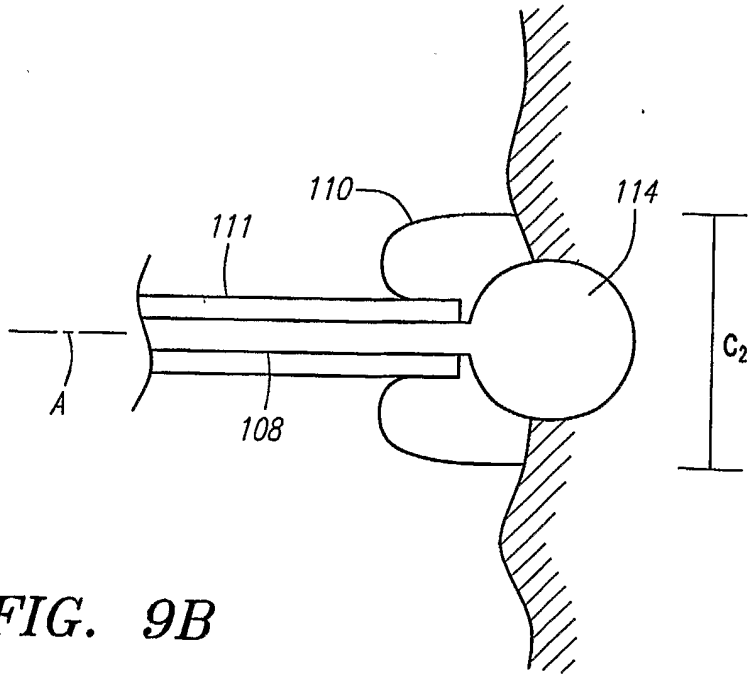

FIG. 9B