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(54) **HELICALLY SHAPED ELECTROPHYSIOLOGY CATHETER**

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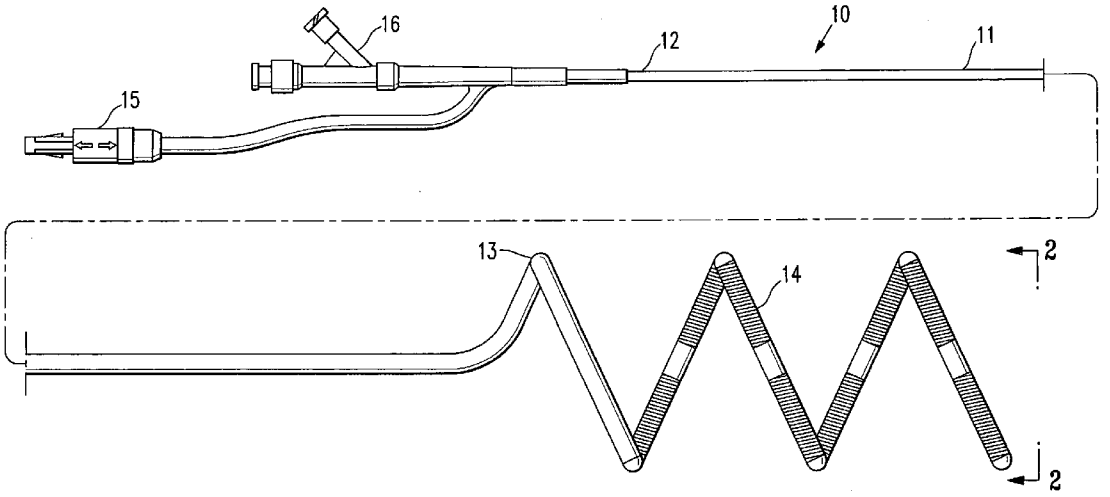
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(57) **ABSTRACT**

An electrophysiology (EP) device suitable for ablating tissue within a patient's body lumen. The EP device of the invention generally comprises an elongated shaft having a distal shaft section with a helical shape and at least one electrode on an exterior portion thereof. One aspect of the invention comprises a method of performing a medical procedure, such as treating a patient for atrial arrhythmia, by forming a lesion using an EP device embodying features of the invention.



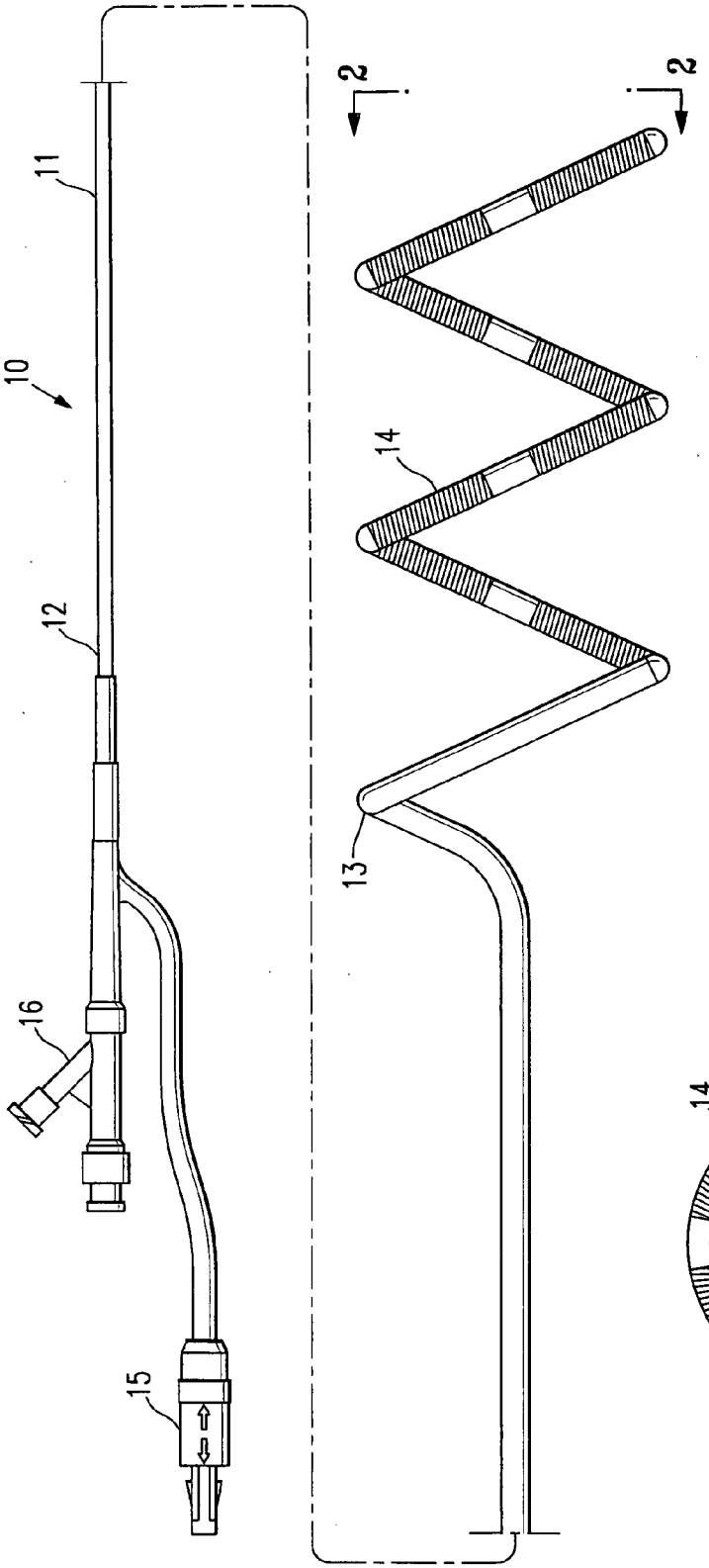


FIG. 1

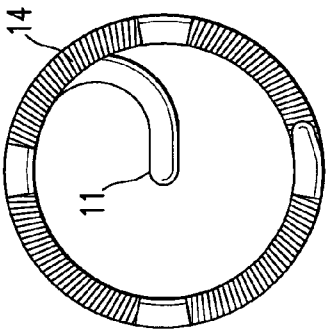


FIG. 2

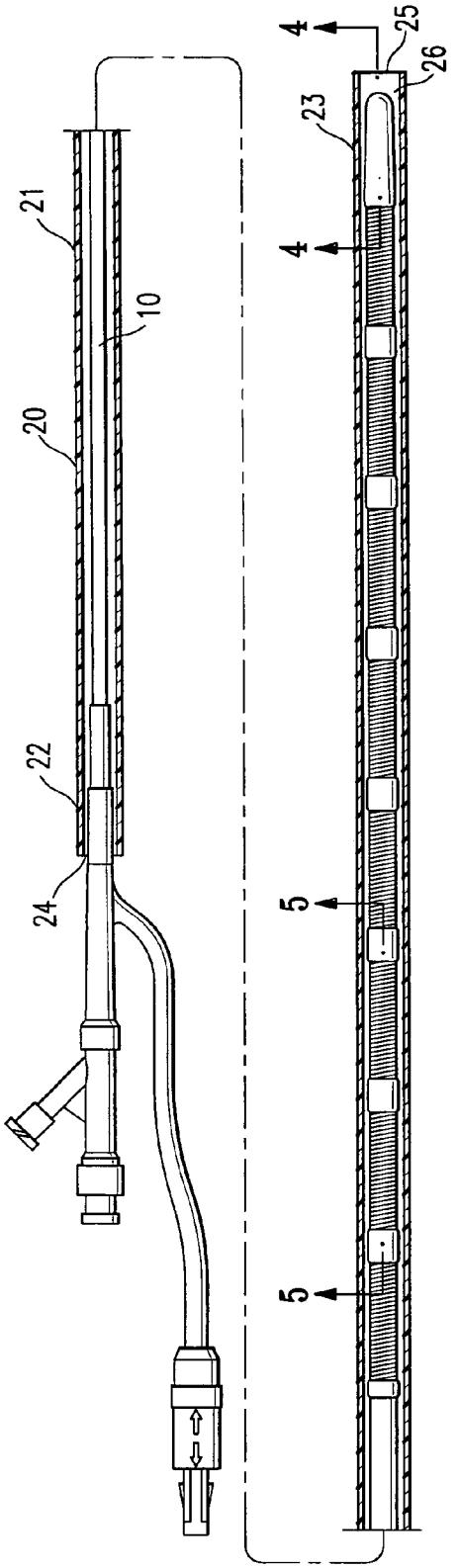


FIG. 3

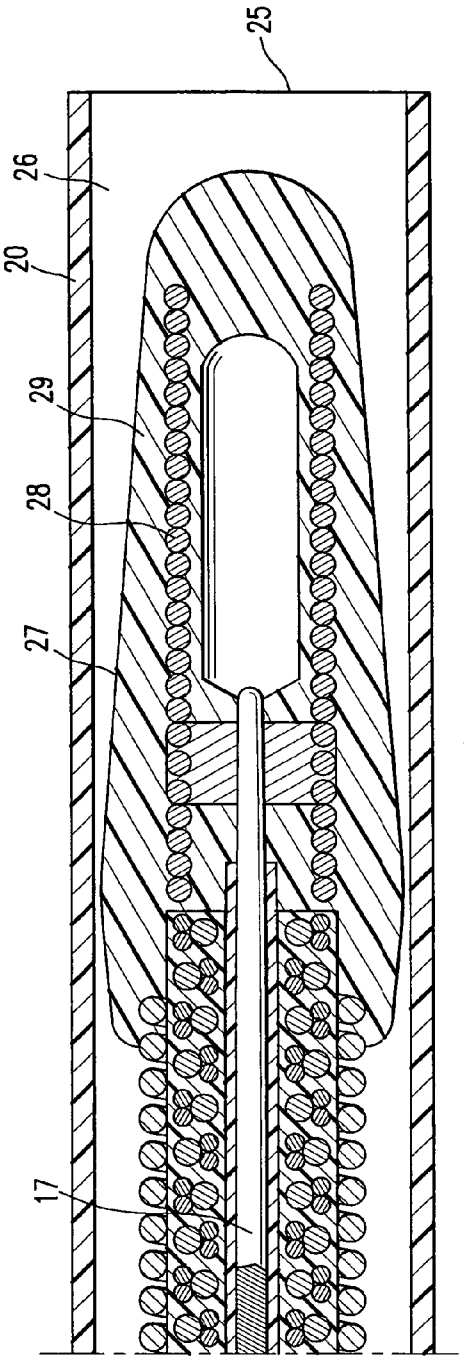


FIG. 4

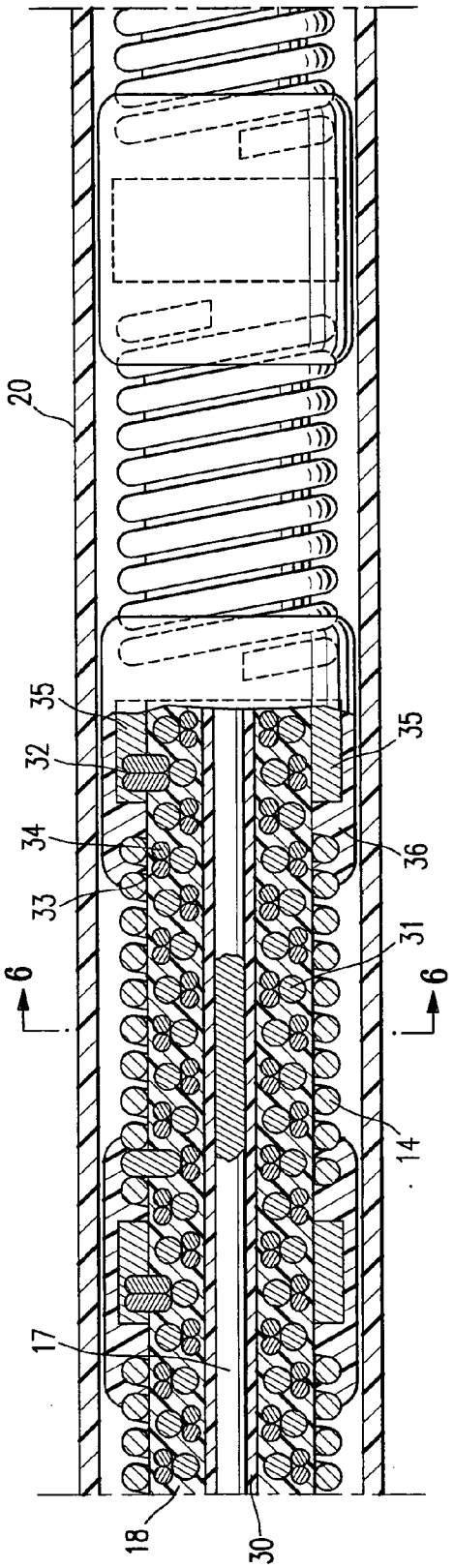


FIG. 5

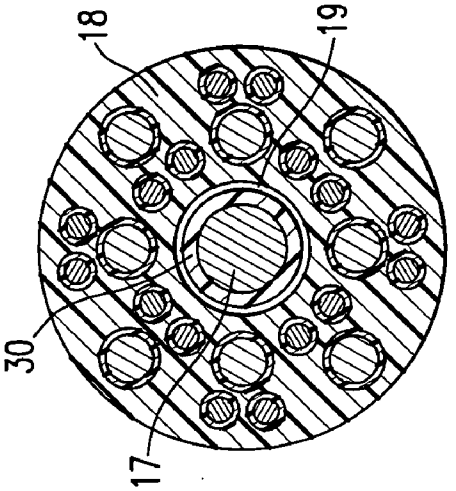


FIG. 7

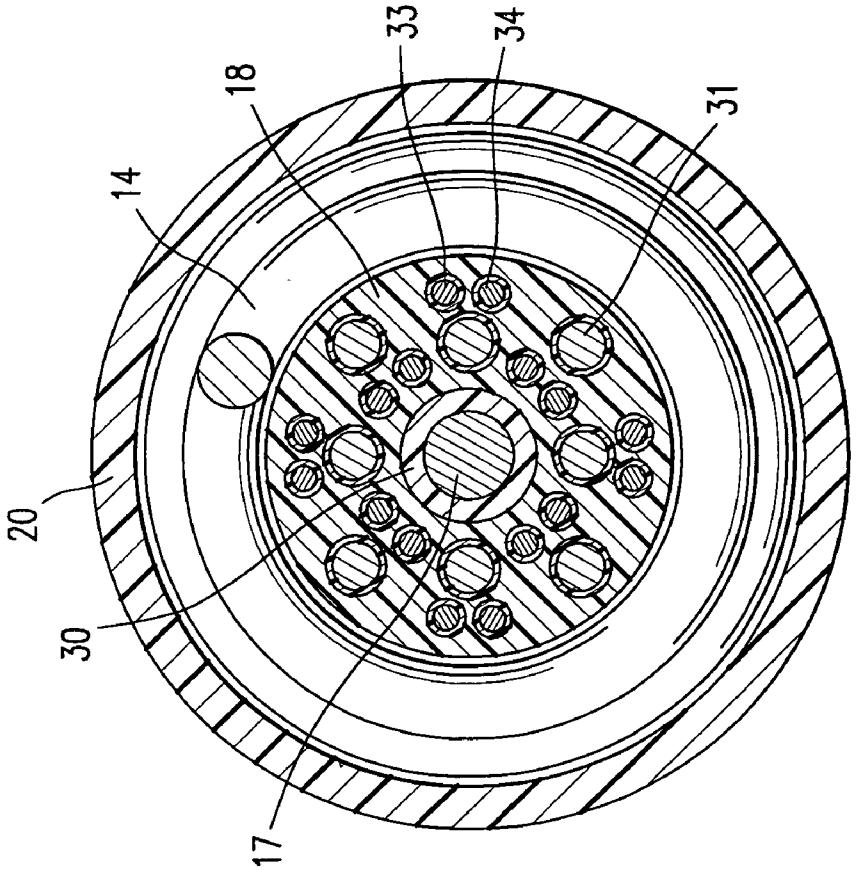


FIG. 6

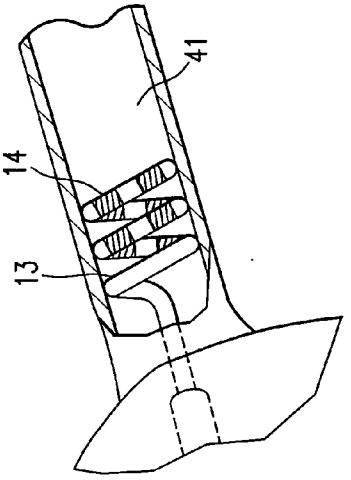
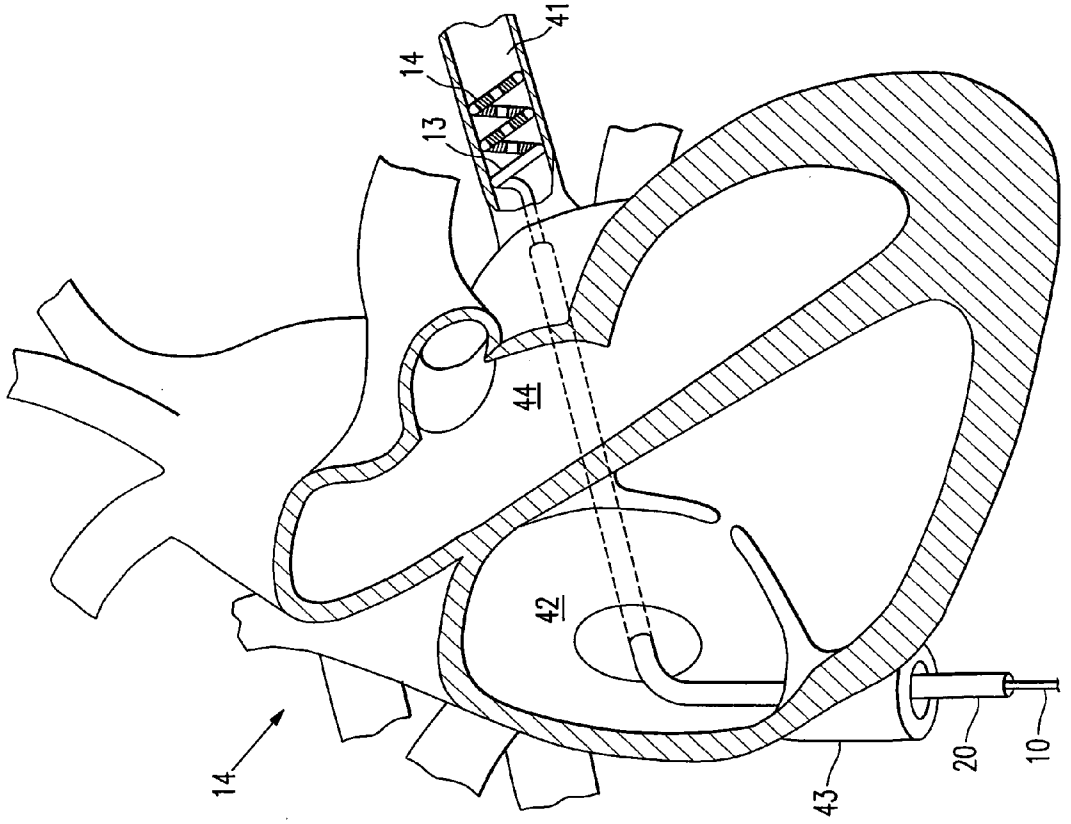


FIG. 9

FIG. 8



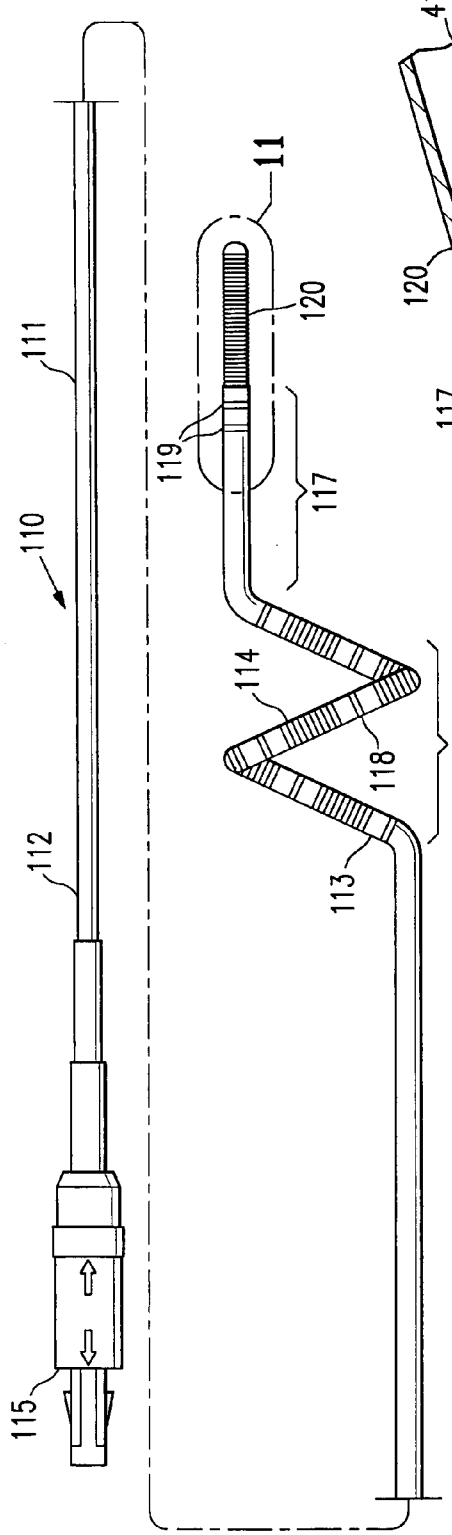


FIG. 10

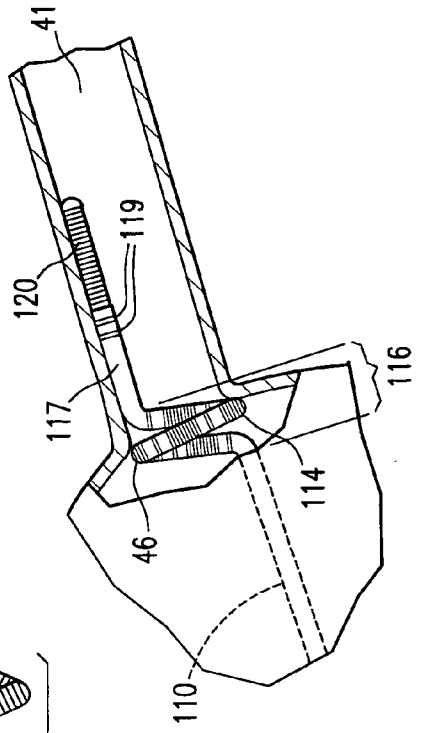


FIG. 12

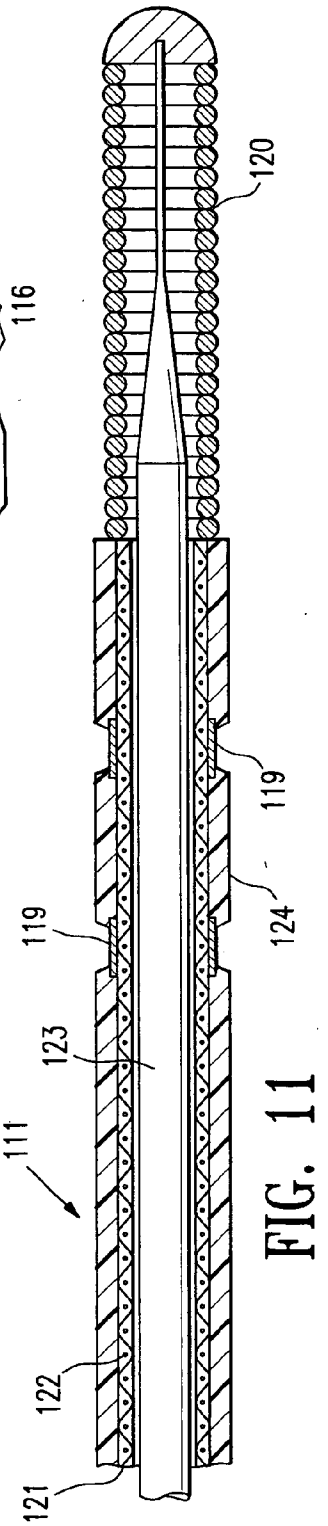


FIG. 11

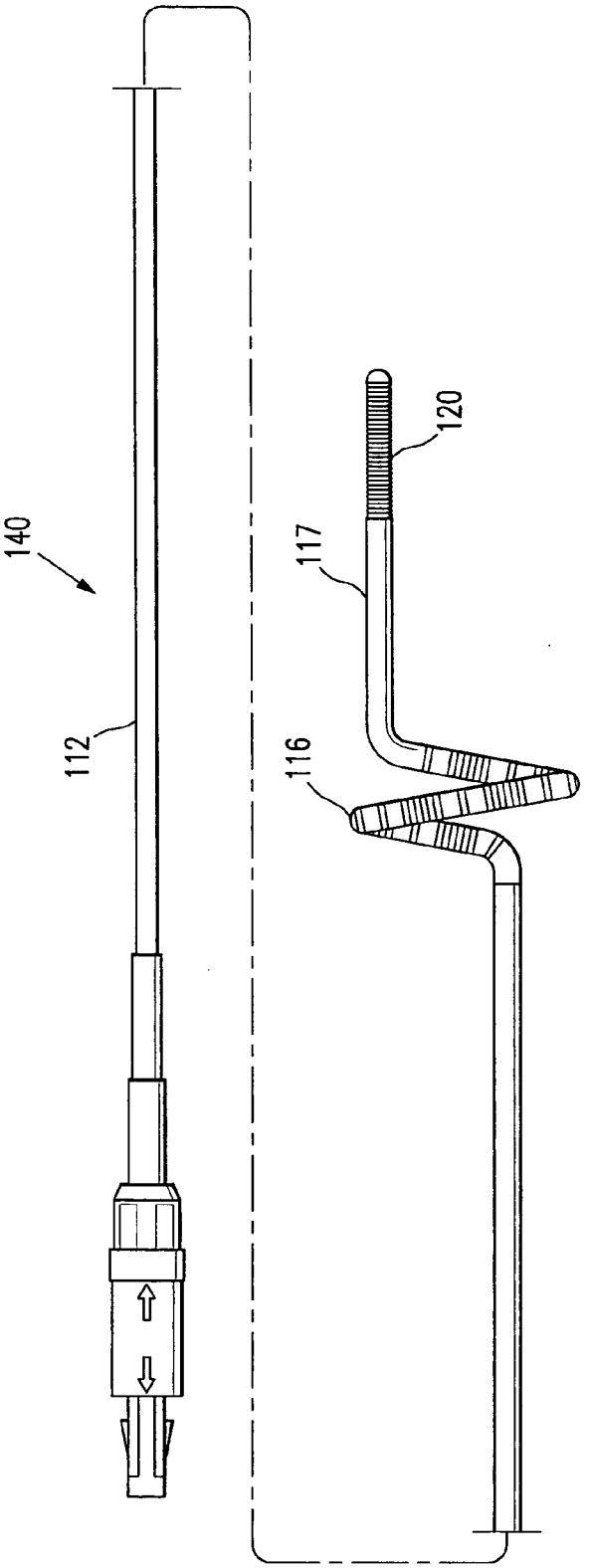


FIG. 13

HELICALLY SHAPED ELECTROPHYSIOLOGY CATHETER

BACKGROUND OF THE INVENTION

[0001] This invention generally relates to the treatment of cardiac arrhythmia and particularly atrial fibrillation and atrial flutter.

[0002] Atrial fibrillation is the disorganized depolarization of a patient's atrium with little or no effective atrial contraction. Prior methods for treating a patient's arrhythmia include the use of anti-arrhythmic drugs such as sodium and calcium channel blockers or drugs which reduce the Beta-adrenergic activity. Other methods include surgically sectioning the origin of the signals causing the arrhythmia or the conducting pathway for such signals. However, the surgical technique is quite traumatic and is unacceptable to a large number of patients. A more frequently used technique to terminate the arrhythmia involves destroying the heart tissue which causes the arrhythmia by ablative energy, e.g., applying a laser beam or high frequency electrical energy such as RF or microwave energy, to a desired arrhythmogenic site or pathway on the patient's endocardium. In the latter method, intravascular electrophysiological (EP) devices can be used to form lesions within a patient's atrial chamber to provide results similar to the surgical segregation techniques in terminating atrial fibrillation, but with significantly reduced trauma.

[0003] Typically, the EP device is advanced within a patient's vasculature and into a heart chamber, and a lesion is formed on the endocardium when RF electrical energy is emitted from electrodes of the device. RF ablation techniques produce lesions of a small area, so that several lesions are typically formed to completely ablate an area. A major problem of RF ablation techniques is forming a lesion of the requisite size, which completely ablates the area of interest but does not unnecessarily destroy surrounding healthy tissue.

[0004] What has been needed is an ablation device which allows for improved creation of lesions of a requisite shape. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

[0005] This invention is directed to an electrophysiology (EP) device for ablating tissue within a patient's body lumen. The EP device of the invention generally comprises an elongated shaft having a distal shaft section with a helical shape and at least one electrode on an exterior portion thereof. One aspect of the invention comprises a method of performing a medical procedure, such as treating a patient for atrial arrhythmia, by forming a lesion using an EP device embodying features of the invention. The terminology helically shaped should be understood to refer to at least one turn having a distal portion of the turn longitudinally spaced from a proximal portion of the turn, at least when the helically shaped section is not in a reversibly stacked, longitudinally collapsed configuration.

[0006] In one embodiment, the helical shape of the distal shaft section is configured to conform to the inner diameter of a patient's body lumen, to form one or more lesions which extend around a wall defining the body lumen. Thus, the turns of the helical distal shaft section have an outer diameter which is not significantly smaller or significantly larger than the inner diameter of the body lumen at the desired site of the lesion. In a presently preferred embodiment, the diameter of the turns is substantially equal to the inner diameter of the body lumen, so that the turns contact the wall defining the body lumen without significantly expanding and injuring the body lumen wall.

[0007] In another embodiment, the distal shaft section has a proximal portion with a helical shape and a distal portion with a noncoiled shape, and at least one electrode on the distal shaft section. The noncoiled distal portion, which thus is not wound into circular or helically spiraled configuration, in one presently preferred embodiment has a substantially straight shape. The terminology "substantially straight" should be understood to mean a portion configured to extend in a line, although some minor variations in the shape of the portion may be present. In a presently preferred embodiment, electrodes for ablation, and optionally also for sensing and pacing, are on the helical proximal portion. In one embodiment, electrodes for sensing and/or pacing are provided on the noncoiled distal portion of the distal shaft section, which can be used to map electrical activity in the region of the electrodes, or to pace the electrical activity of a region of the patient's anatomy such as the patient's heart.

[0008] In a presently preferred embodiment, the EP device has a core member extending within the elongated shaft. The core member preferably has a helically shaped distal section to provide the helical shape to the distal shaft section of the EP catheter. The core member may be fixed within the shaft, or alternatively, slidably disposed therein. In the embodiment in which the core member is slidably disposed within the shaft, a variety of different core members may be provided allowing the physician to choose a core member comprising a particularly suitable size, shape or material. Thus, an EP device with a distal shaft section having a desired shape is provided by inserting a core member having the desired shape therein. The core member may be provided with one or more jackets, which may be electrically insulating, having a total thickness of preferably less than about 0.001 inch (0.025 mm).

[0009] The distal shaft section of the EP device is preferably reversibly deformable from the helically shaped configuration to a lower profile configuration for advancement within the patient's vasculature. In one embodiment, the EP device of the invention is slidably disposed in the lumen of a guiding catheter, so that the radial force of the guiding catheter against the device reversibly collapses the turns of the helically shaped distal section to smaller diameter turns which fit within the guiding catheter. In another embodiment, the turns of the helically shaped distal section are configured to reversibly collapse completely, so that the guiding catheter straightens the helically shaped distal section to a straight configuration. The EP device distal shaft section is thus constrained from assuming the expanded helical configuration until the device is displaced out a distal end of the guiding catheter.

[0010] The one or more electrodes on the helically shaped distal shaft section can be used as ablation electrodes to form a lesion from within a patient's body lumen when electrical energy, and preferably high frequency energy such as RF energy, is emitted therefrom. The ablation electrode(s) on the helically shaped distal shaft section may be a combina-

tion ablation and sensing electrode, which is capable of ablation and detection of electrical activity from within a lumen of the patient's body. In a presently preferred embodiment, the ablation electrode on the helically shaped distal shaft section is a helical coil for improved device flexibility, although other electrode designs are suitable including cylindrical bands, arcuate bands, ribbons or the like. A temperature sensor such as a thermocouple may be provided on the EP device. In one embodiment, the device includes one or more electrodes for mapping and/or pacing are provides on the shaft proximal and/or distal to the helically shaped section in addition to the electrodes on the helically shaped section. Preferably, the electrodes on the helically shaped distal shaft section are configured for unipolar use during ablation, and bipolar use during sensing, by use of a multiplexing switchbox. The sensing/pacing electrodes proximal and/or distal to the helically shaped section are preferably configured for bipolar use, but may be configured for unipolar mode use. In the unipolar sensing/pacing mode, a separate, return electrode which is not on the EP device shaft but which is in contact with the exterior surface of the patient's body is used.

[0011] In a method of the invention, the helically shaped distal shaft section of the EP device is placed at an ostium or within a body lumen at a desired location. The terminology "body lumen" should be understood to include a variety of structures in the body, including a blood vessel and a heart chamber. Typically, an EP device assembly comprising the EP device of the invention within a guiding catheter is advanced within a patient's body lumen to a desired location therein. The EP device distal shaft section is then deformed from the low profile configuration to the helical configuration by displacing the EP device relative to the guiding catheter so that the distal shaft section of the device extends at least in part outside of the guiding catheter lumen in the body lumen. The helically shaped distal shaft section of the device contacts a wall defining the body lumen or ostium. The electrodes are then used to detect electrical activity from within the body lumen to determine the desired site for forming a lesion. One or more of the electrodes on the helically shaped distal shaft section contact the wall defining the ostium or the inner surface of the body lumen, so that delivery of high frequency energy to the electrodes forms a lesion extending in whole or in part, one or more times, around the ostium or the inner surface of the body lumen. The lesion may be a helically shaped lesion extending spirally along a length of the body lumen, or may be one or more circular lesions. The helical shape of the distal shaft section is configured to provide lesions particularly suitable for treatment of atrial arrhythmia including atrial fibrillation or flutter. In one embodiment, a plurality of discontinuous lesions are formed, which thus limits or avoids the possible disadvantageous results, such as stenosis formation and spasms in the ablated region, which otherwise occur from a continuous lesion extending around the full circumference of the ostium or body lumen.

[0012] The EP device of the invention provides for improved lesion formation due to the ablation electrodes on the helically shaped distal section having at least one 360° turn. The helically shaped distal section allows for the formation of lesions extending in whole or in part around the inner surface of a patient's body lumen. The turns of the helically shaped distal shaft section can be moved closer together or further apart within the patient to provide the desired lesion pattern. Additionally, the device has a low profile configuration for advancement within the patient which self expands into the helically shaped configuration for easy of deployment within the patient. These and other advantages of the invention will become more apparent from the following detailed description and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] **FIG. 1** is an elevational view of an EP device embodying features of the invention, having a helically shaped distal shaft section.

[0014] **FIG. 2** is a transverse cross-sectional view of the EP device shown in **FIG. 1**, taken along the lines **2-2**.

[0015] **FIG. 3** is an elevational view, partially in section, of an EP device assembly embodying features of the invention, illustrating an EP device in a low profile configuration within a guiding catheter.

[0016] **FIG. 4** is an enlarged longitudinal cross-sectional view of the EP device assembly shown in **FIG. 3** taken along the lines **4-4**, illustrating the EP device distal tip within the guiding catheter.

[0017] **FIG. 5** is an enlarged longitudinal cross-sectional view of the EP device assembly shown in **FIG. 3** taken along the lines **5-5**, illustrating a portion of the EP device distal shaft section within the guiding catheter.

[0018] **FIG. 6** is a transverse cross sectional view of the EP device assembly shown in **FIG. 5**, taken along lines **6-6**.

[0019] **FIG. 7** is a transverse cross sectional view of an alternative embodiment of an EP device assembly embodying features of the invention, having a core wire slidably disposed in a lumen in the device shaft.

[0020] **FIG. 8** is an elevational view, partially in section, of a patient's heart and an EP device assembly embodying features of the invention, with the distal end of the EP device transeptally positioned within a pulmonary vein.

[0021] **FIG. 9** is an elevational view, partially in section, of the EP device assembly of **FIG. 8**, with the turns of the helically shaped distal shaft section moved closer together in a stacked configuration.

[0022] **FIG. 10** is an elevational view of an alternative embodiment of an EP device embodying features of the invention comprising a distal shaft section having a proximal portion with a helical shape and a distal portion with a noncoiled shape with a pair or sensing and/or pacing electrodes on the distal portion.

[0023] **FIG. 11** is a longitudinal cross sectional view of the distal end of the EP device of **FIG. 10**, taken within circle **11**.

[0024] **FIG. 12** is an elevational view, partially in section, of the EP device of **FIG. 10**, positioned in contact with a wall defining a pulmonary vein ostium, with the turns of the helically shaped distal shaft section moved closer together in a stacked configuration.

[0025] **FIG. 13** is an elevational view of an alternative embodiment of an EP device embodying features of the invention comprising a distal shaft section having a proxi-

mal portion with a helical shape with one and one quarter turns, and a distal portion with a noncoiled shape.

DETAILED DESCRIPTION OF THE INVENTION

[0026] **FIG. 1** illustrates one embodiment of the EP device **10** of the invention, generally comprising an elongated shaft **11** having a proximal shaft section **12**, a helically shaped distal shaft section **13**, and a plurality of electrodes **14** on the distal shaft section **13**. An electrical connector **15** and an adapter **16** are on the proximal end of the device. **FIG. 2** illustrates a transverse cross section of the distal end of the device **10** shown in **FIG. 1**, taken along lines **2-2**.

[0027] **FIG. 3** illustrates the EP device **10** within a guiding catheter **20** for introduction and advancement within the patient. The guiding catheter generally comprises an elongated shaft **21** having a proximal end **22**, a distal end **23**, a port **24** in a proximal shaft section, a port **25** in a distal shaft section, and a lumen **26** extending within the shaft to the port in the distal shaft section. As illustrated in **FIG. 3**, the helically shaped distal shaft section of the EP device **10** is reversibly deformed from the helical configuration to a low profile configuration within the lumen **26** of the guiding catheter. In the embodiment illustrated in **FIG. 3**, with the EP device slidably disposed within guiding catheter lumen **26**, the radial force of the guiding catheter **20** against the device reversibly straightens the helically shaped distal section to form a straight configuration. The helically shaped distal shaft section **13** is preferably self expanding, so that the EP device **10** can be advanced out the distal end of the guiding catheter **20**, or the guiding catheter **20** proximally retracted, causing the distal shaft section of the EP device to return to the helically shaped configuration illustrated in **FIG. 1**. In alternative embodiments (not shown), the helically shaped distal shaft section reversibly collapses to a helical shape with turns having a smaller outer diameter when the distal shaft section is within the guiding catheter lumen **26**.

[0028] In a presently preferred embodiment, the EP device **10** includes a core member **17** having a helically shaped distal section, disposed within the shaft **11**. As best illustrated in **FIG. 5**, showing a longitudinal cross section of the of the EP device shown in **FIG. 3**, taken along lines **5-5**, the shaft **11** comprises a tubular member **18** disposed about the core member **17**. The core member **17** extends within the tubular member to the distal end of the device, and the tubular member **18** is helically shaped by the core member therein. **FIG. 6** illustrates a transverse cross section of the EP device shown in **FIG. 5**, taken along lines **6-6**.

[0029] The core member **17** is preferably formed of a superelastic material, such as a NiTi alloy, or stainless steel, and has a maximum diameter of about 0.01 inch (0.25 mm) to about 0.018 inch (0.46 mm). The core member **17**, and preferably a distal section thereof, may be tapered as shown in **FIG. 4**, or optionally flattened. In a presently preferred embodiment, the core member has an insulating coating **30**, such as a polyester or polyimide coating. The coating **30** is preferably about 0.0005 inch (0.0127 mm) thick. In the embodiment illustrated in **FIG. 4**, coating **30** extends distally to a point distal to the shaft **11** distal end and proximal to the distal end of core member **17**. In the embodiment illustrated in **FIGS. 5 and 6**, the coating **30** on the core member **17** contacts an inner surface of the tubular member **18**. The core member **17** is secured to the tubular member **18** by applying heat to the device to melt and fuse the tubular member to the core member coating. However, a variety of suitable means of securing the core member within the tubular member may be used, such as an adhesive (not shown) between the core member and the tubular member. In an alternative embodiment of the invention illustrated in **FIG. 7**, the core member **17** is slidably disposed within and removable from a lumen **19** of the tubular member.

[0030] As best illustrated in **FIG. 4**, a flexible coiled tip **27** is provided on the distal end of the EP device **10**. The tip **27** has a closed distal end, and includes a flexible coil **28** extending beyond the distal end of the shaft **11** enclosed within a soft coating **29** preferably formed of a polymeric material. In the embodiment illustrated in **FIG. 4**, the tip **27** has an open center region for increased flexibility. A presently preferred polymeric material for the tip **27** is a fluoropolymer such as THV available from 3M. In the embodiment illustrated in **FIG. 4**, the core member **17** is secured to the distal end of the coil **28**, by suitable material such as gold-tin solder. In another embodiment of the invention, the coil **28** may be omitted, and the distal end of the EP device preferably provided with a soft tip to minimize traumatic engagement with a blood vessel wall.

[0031] In the embodiment illustrated in **FIGS. 5 and 6**, the electrodes **14** comprise helical coils which are electrically connected to insulated electrical conductors **31**. In a presently preferred embodiment, the EP device **10** shaft includes thermocouples **32**, connected to temperature sensor electrical conductors **33** and **34** (i.e., thermocouple wires). Thermocouples are preferably located between adjacent electrodes on an outer surface of the shaft **11**, although they may alternatively be at other locations on the EP device as is conventionally known. A conducting member **35**, such as a gold band, covers the thermocouples, and a polymeric jacket **36**, preferably formed from THV, covers the conducting member **35** and insulates the thermocouple **32** from noise (e.g. RF noise) present as a result of the energy sent to the electrodes. In the embodiment illustrated in **FIG. 5**, the electrical conductors **31** and thermocouple wires **33**, **34** are braided within the tubular member **18**. However, the electrical conductors **31** and thermocouple wires **33**,**34** may have a variety of suitable configurations, including braided or wound configurations different from that shown in **FIG. 5** or a nonbraided configuration. In an alternative embodiment (not shown), the individually insulated electrical conductors may be within the tubular member lumen **19** or at least in part within an outer jacket of the core member in the embodiment in which the core member is secured to the tubular member. The proximal ends of the electrical conductors **31** and thermocouple wires **33**, **34** are electrically connected to individual pins of multi-pin connector **15** (**FIG. 1**) on the proximal end of the shaft.

[0032] In a method of treating a patient for atrial fibrillation or flutter, the EP device of the invention is used to form a lesion extending around an inner surface of the patient's pulmonary vein. **FIG. 8** illustrates an assembly in a patient's heart **40**, with the EP device **10** in a pulmonary vein **41**. The device **10** is introduced into the patient's vascular system, e.g. the femoral vein, percutaneously or by way of a cut-down, within the guiding catheter **20**. The assembly is preferably advanced into the right atrium **42** from the

inferior vena cava **43**, and positioned in the left atrium **44** transeptally, as illustrated in **FIG. 8**. The EP device **10** distal section extends out of the port in the distal end of the guiding catheter, so that the helically shaped distal shaft section of the device is positioned within the pulmonary vein **41** of the heart. The pulmonary vein **41** is mapped using electrodes on the device **10**, and if a pulmonary vein potential is detected, the electrodes on the distal shaft section are used to form a lesion(s) extending at least in part around the wall defining the pulmonary vein lumen or in the left atrium just outside a pulmonary vein ostium. The position of the lesion is preferably chosen to interrupt the conduction path to the atrium. Alternatively, the lesion may be located to ablate the actual focal origin in the pulmonary vein.

[**0033**] Typically, RF current is delivered to one or two electrodes to perform a first ablation and then to adjacent electrodes, one or two electrodes at a time, until an ablation of desired length is obtained in the body lumen. This reduces the overall power requirements for the assembly. The temperature sensors can be used to detect the temperature of the heart wall between the adjacent electrodes, to control the high frequency energy and determine when the lesions formed by adjacent electrodes overlap to form continuous lesions on the wall defining the body lumen. Additionally, feedback of the temperature data can be used to modulate the power and prevent thrombus in the preferred use, and cooling fluid can also be used. After the ablation, the electrodes **14** can be employed to detect electrical activity to ensure that the ablation has been effective in terminating the fibrillation or flutter. Typically, the procedure is performed for the left and right, superior and inferior pulmonary veins.

[**0034**] The EP device of the invention can be used to form a helical lesion, a closed circular lesion, or a curvilinear segmental (i.e., discontinuous) lesion. For example, in the embodiment illustrated in **FIG. 8**, a helical lesion on the body lumen wall can be formed by delivering RF energy to the electrodes which as illustrated are contacting the pulmonary vein wall in a helical array. Typically, the helical lesion is formed to extend continuously along the body lumen wall, wherein the individual lesions formed by the longitudinally adjacent electrodes on the shaft overlap to produce one continuous lesion. The helical lesion comprises a spiral having a distal end, and a proximal end longitudinally spaced from the distal end of the spiral. In an alternative embodiment of the invention, the lesion formed extends in a closed circle around the body lumen wall, i.e., a lesion having ends that close together to form a circle. A closed circle lesion can be formed by displacing the device distal section to change the electrode position on the body lumen wall after an initial lesion is formed. For example, in one embodiment of the method of forming a closed circular lesion, a helically shaped lesion is first formed on the body lumen wall, and then the helically shaped distal shaft section of the EP device is rotated or longitudinally displaced proximally or distally, and a second lesion which overlaps with the first lesion is formed, to thereby form at least one closed circular lesion. Alternatively, as illustrated in **FIG. 9**, the helically shaped distal shaft section of the EP device can be provided with closely spaced, stacked adjacent turns which facilitate the formation of a closed circle lesion.

[**0035**] The spacing between adjacent turns of the helically shaped distal shaft section can be changed by the physician during deployment of the EP device within the body lumen. To increase the spacing between the helical turns of the device, the distal extremity of the EP device is displaced out of the distal end of the guiding catheter so that it is placed in contact with the body lumen wall. The guiding catheter is displaced proximally, while a proximal portion of the EP device is displaced proximally to stretch the turns of the helically shaped distal shaft section apart, so that the portion of the EP device distal shaft section that is still inside the guiding catheter is deployed therefrom with the spacing between the turns increased. Similarly the spacing between the turns may be decreased by retracting the guiding catheter proximally while a proximal portion of the device is displaced distally, to stack the turns of the helically shaped distal shaft section together.

[**0036**] **FIG. 10** illustrates an alternative embodiment of an EP device **110** which embodies features of the invention, generally comprising an elongated shaft **111** having a proximal shaft section **112**, a distal shaft section **113**, and a plurality of electrodes **114** on the distal shaft section **113**. An electrical connector **115** is on the proximal end of the device **110**. The distal shaft section **113** comprises a proximal portion **116** with a helical shape having one or more turns, and a distal portion **117** extending from the proximal portion with a noncoiled shape. In the embodiment illustrated in **FIG. 10**, the noncoiled distal portion **117** has a straight shape with an outer surface aligned or parallel with an outer surface of the proximal shaft section **112**. As illustrated in **FIG. 10**, the noncoiled distal portion **117** has a width about equal to or less than the width of the proximal shaft section **112**. Thus, the noncoiled distal portion **117** does not have the enlarged outer diameter formed by the turns of the helically shaped proximal portion **116**. The electrodes **114** on the helically shaped proximal portion preferably comprise coiled electrodes, and temperature sensors **118** are located between the coiled electrodes **114**, preferably on an outer surface of the shaft, as discussed above in relation to the embodiment of **FIG. 1**. In a presently preferred embodiment, each electrode **114** has a length of about 3 to about 6 mm. Although 5 electrodes **114** are illustrated in **FIG. 10**, the number of electrodes **114** may vary, and in a presently preferred embodiment, about 8 electrodes are provided on EP device **110**. A pair of sensing electrodes **119** for mapping and/or pacing are on the distal portion **117** of the distal shaft section. In an alternative embodiment (not shown) at least a second pair of sensing and pacing and pacing electrodes **119** may be provided on the shaft proximal to the helically shaped proximal portion,**116**. The sensing and pacing electrodes are preferably spaced away from the helically coiled section **116**, and in one embodiment are about 1 to about 3 cm, preferably about 1.5 to about 2 cm from the helically coiled section. In a presently preferred embodiment, the electrodes **114** on the helically shaped portion **116** are configured for unipolar use during ablation, and bipolar use during sensing. The distal sensing and pacing electrodes **119** are configured for use a bipolar electrodes during sensing and pacing. A flexible coiled tip **120** is secured to the distal end of the distal portion **117**, to facilitate guiding the EP device to a desired location within the patient. In a presently preferred embodiment, the tip coil **120** is about 1 to about 3 cm, most preferably about 2 cm in length, and is formed of a radiopaque metal such as platinum.

[**0037**] The turns of the helical proximal section **116** are illustrated in a relaxed configuration in **FIG. 10**. However, the turns of the helical proximal section **116** can be moved

closer together or further apart within the patient by urging the proximal end of the catheter distally or proximally, respectively, with the distal end of the catheter in a stabilized position within the patient and as discussed above in relation to the embodiment of **FIG. 1**.

[**0038**] Each electrode **114** is spaced apart from one or more adjacent electrodes **114** on the shaft **111**, i.e., the electrodes **114** extend discontinuously along the shaft. However, depending on the duration and power level used during an ablation procedure, the lesion(s) formed by electrodes **114** can be discontinuous or alternatively, can be joined together and thus continuous.

[**0039**] In the embodiment illustrated in **FIG. 10**, the helical proximal portion **116** forms one full 360° loop and half of a second loop. In a presently preferred embodiment, about one full 360° loop is provided, although the number of loops may vary. Because the proximal portion **116** is helical, a proximal section of the 360° loop is longitudinally spaced apart from the distal section thereof which completes the circumference of the loop in the relaxed configuration illustrated in **FIG. 10**. Consequently, the helical proximal portion forms at least one open or helical 360° loop in the relaxed configuration, and the electrodes **114** thereon form an open or helical 360°, discontinuous loop. The circumference of one 360° loop of the helically proximal portion **116** varies depending on the desired use of the EP device. In a presently preferred embodiment, the circumference of one 360° loop is about 15 mm to about 40 mm, preferably about 15 mm to about 30 mm. Depending on the circumference of the loop and the number and length of the electrodes **114**, the electrodes **114** may or may not extend the length of one or more 360° loops. In a presently preferred embodiment, the electrodes **114** extend along the length of at least one 360° loop of the helical proximal portion **116**, so that the electrodes can be used to form a lesion which extends in a continuous 360° loop, or a discontinuous, partial segment of a 360° loop. However, in alternative embodiments, the helical proximal portion **116** has a partial loop of less than 360° (not shown), or the electrode number or length is sufficiently small such that the electrodes extend along a length of a partial loop of less than 360° on the helical proximal portion. The circumference of the helical section, i.e., the length of the helical section if it was stretched out to a straight, nonhelical shape, is about 5 to about 40 mm, preferably about 5 to about 20 mm.

[**0040**] **FIG. 11** illustrates an enlarged, longitudinal cross sectional view of the distal end of the device **110**, taken within circle **11**. As illustrated in **FIG. 11**, the shaft **111** comprises a tubular member **121**, having braided electrical conductors **122** in the wall of the tubular member **121**, and having a core member **123** in a lumen of the tubular member **121**. In the embodiment illustrated in **FIG. 11**, the core member **123** is secured to the flexible coiled tip **120**. An outer layer **124** on an outer surface of the tubular member **121** overlaps the ends of the sensing and pacing electrodes **119**.

[**0041**] **FIG. 12** illustrates the device **110** with the helically coiled proximal portion **116** of the distal shaft section **113** in position at the ostium **46** of a pulmonary artery which forms the junction between the pulmonary artery and the right atrium of the patient's heart. As illustrated in **FIG. 12**, the turns of the helically shaped proximal portion **116** are in a stacked configuration after having been moved closer together than the natural relaxed spacing shown in **FIG. 10**, by distally forcing the catheter against the wall defining the ostium of the pulmonary artery. As a result, the electrodes **114** extend discontinuously, completely around the ostium. High frequency energy is delivered to one or more of the electrodes **114** to form a lesion extending at least in part around the ostium. The lesion can be caused to be a continuous or a discontinuous circular lesion depending on the energy level and the length of time of the ablation, and by rotating the catheter one or more times between delivery of ablation energy to electrodes **114**. As illustrated in **FIG. 12**, the distal portion **117** of the distal shaft section is positioned within the pulmonary vein **41**, to allow for mapping and/or pacing from within the pulmonary vein. Thus, the sensing electrodes allow for sensing electrical activity before and after the ablation energy is delivered to electrodes **114**, to determine the appropriate location of the device, and whether the lesions formed therefrom sufficiently treated the atrial arrhythmia. Although not illustrated, in one embodiment of performing a medical procedure, the helically shaped proximal portion **116**, and the distal portion **117** of the EP device **110** are both positioned within the pulmonary vein **41**, similar to the embodiment illustrated in **FIGS. 8 and 9**.

[**0042**] **FIG. 13** illustrates an alternative embodiment of an EP device **140** embodying features of the invention, similar to catheter **110** but with helical proximal portion **116** forming one full 360° loop and one quarter of a second loop, and with no electrodes **119** on the noncoiled distal portion **117**. A presently preferred method of using EP device **140** comprises positioning the helical proximal portion **116** just outside a pulmonary vein at the ostium thereof, with the noncoiled distal portion **117** used as an anchoring section within and in contact with the pulmonary vein. The helical proximal portion **116** is pushed against the atrial tissue just outside the pulmonary vein ostium, thereby ensuring good contact with atrial tissue for ablation purposes. Pushing the shaft distally with the helically shaped section braced against the atrial tissue thus collapses the helix and may advance a distal section of the proximal shaft section proximal to the helically shaped distal portion and through the ostium. The electrodes on the helical proximal portion **116** are used to map for pulmonary vein potentials and only a discontinuous, segmental lesion, rather than an entire circumference, continuous lesion, is formed by RF ablation, to barricade the pulmonary vein potentials from exiting the pulmonary vein.

[**0043**] In one method of the invention, the lesion comprises one or more closed circles on the endocardium. However, the lesion may alternatively comprise a discontinuous, partially open circle formed by a plurality of smaller lesions. Additionally, the lesion may be formed by the helical distal shaft section in the noncollapsed configuration to extend helically along a length of the body lumen, or the lesion may be formed by the helical distal shaft section in the collapsed configuration to extend only around the circumference of the body lumen and not helically along a length of the body lumen. Typically, the lesion formed with the EP device **10/110/140** of the present invention has a width of about 2 to about 7 mm, preferably about 3 to about 4 mm. The circumference of the lesion (forming a continuous closed circle, or a discontinuous partially open circle) is about 5 to about 40 mm, preferably about 5 to about 20 mm.

A lesion extending only circumferentially around the body lumen and not helically along a length of the body lumen (forming either a continuous closed circle, or a discontinuous partially open circle) has a length of about the thickness of the EP device shaft. A helical lesion extending helically along a length of the body lumen has a length of about to about 5 mm to about 50 mm, preferably about 5 to about 10 mm. Preferably, in the embodiment in which a plurality of continuous, closed circle lesions are formed on the body lumen wall, the lesions are formed near the transition zone between the left atrial tissue and the pulmonary vein tissue.

[**0044**] The EP device 10/110/140 has a total length, including the connector **16**, of about 100 cm to about 200 cm, and preferably between 150 and 180, e.g. about 165 cm. The length of the distal shaft section **13/113** having electrodes **14/114** is about 2 cm to about 15 cm, and preferably about 4 to about 8 cm, e.g. about 6 cm. The outer diameter of the distal shaft section of the device is typically about 1.0 mm (3.0 French) to about 2.0 mm (6.0 French), and preferably about 1.3 mm (4 French) to about 1.7 mm (5 French). The maximum outer dimensions of the electrodes are generally about 1.0 mm (3 Fr) to about 1.3 mm (4 Fr), and preferably about 1.22 mm (3.7 Fr). The electrode length is about 2 mm to about 8 mm, and preferably about 4 to about 7 mm, e.g. about 6 mm. The interelectrode spacing is generally about 1 mm to about 3 mm, and preferably about 2 mm. In a presently preferred embodiment, the interelectrode spacing is uniform. However, the electrode spacing may alternatively be nonuniform. In a presently preferred embodiment, about 4 to about 12 individual electrodes are provided on the shaft distal section, however, the device may have larger number of electrodes if the diameter of the distal section is increased to greater than 5 Fr.

[**0045**] Typically, the device is used within the patient's vasculature, although it may also be used to create lesions within other body lumens. The device may be advanced retrogradely through the aorta and left ventricle via a femoral artery access site. As illustrated in **FIG. 8**, the guiding catheter may have a bent or deflectable distal end. Torquing the proximal section **22** of the guiding catheter, which extends out of the patient during the procedure, will cause the distal section thereof to be rotatably displaced within the body lumen and allow the EP device **10** to be properly positioned.

[**0046**] To the extent not already discussed herein, the EP device components can be formed of conventional materials. The core member **17/123** can be formed of a variety of suitable materials including high spring-back metals, or superelastic metals, or shape memory metals, such as ELGILOY available from Carpenter Technology of Pennsylvania, MP35N, available from SPS Technologies, high tensile strength steel including **304** vacuum-melted steel, and titanium alloys including Ti-GAI-4V, C_p Titanium, and NiTi.

[**0047**] The electrical connector **14** on the proximal end of the device may be a commercially available electrical connector such as Part No. PAB-M08-GLA39J or PAB-M08-TLA39J for an eight pin connector or Part No. PAB-M08-GLA39A for a connector with a greater number of pins, e.g. 9-16. The above connectors are available from Lemo USA, Inc. in Santa Rosa, Calif. Suitable connectors for accessory cables connectable to the above connectors include PRB-M08-GLL65J for eight pin connectors and PRB-M08-GII65A for connectors with more than eight pins. The latter connectors are also available from the same source.

[**0048**] While the invention has been described herein in terms of certain preferred embodiments directed to the detection and treatment of atrial fibrillation and flutter, those skilled in the art will recognize that the invention may be employed in a wide variety of procedures. A variety of modifications and improvements may be made to the present invention without departing from the scope thereof. Moreover, although individual features of embodiments of the invention may be shown or discussed in relation to some of the embodiments and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment.

1. An electrophysiology device for ablating tissue in a patient's body, comprising:

a) an elongated shaft having a proximal end, a distal end, and a distal shaft section with a helically shaped proximal portion which has one or more turns and which has a longitudinal axis; and a straight distal portion which extends distally from the helically shaped proximal portion of the distal shaft section and which has a longitudinal axis parallel to and off-set from the longitudinal axis of the helically shaped proximal portion

b) at least one ablation electrode on the helically shaped proximal portion of the distal shaft section.

2. The device of claim 1 wherein the turns of the helically shaped proximal portion of the distal shaft section have a diameter substantially equal to or greater than a diameter of an ostium of a body lumen.

3. The device of claim 1 wherein the helically shaped proximal portion of the distal shaft section has at least one and one quarter turns having substantially equal diameters.

4. The device of claim 1 wherein the distal shaft section has a core member which extends through at least a part of the helically shaped proximal portion and at least part of the straight portion.

5. The device of claim 4 wherein the core member in the distal section has a helical shape.

6. The device of claim 4 wherein the core member is formed at least in part of a NiTi alloy.

7. The device of claim 4 wherein the shaft has a lumen extending therein configured to slidably receive the core member.

8. The device of claim 1 including a plurality of sensing and pacing electrodes on the distal shaft section.

9. (Cancelled)

10. (Cancelled)

11. The device of claim 1 wherein the straight distal portion has a flexible coiled tip extending from the distal end thereof.

12.-**15**. (Cancelled)

16. The device of claim 1 wherein the straight distal portion has at least two sensing electrodes.

17. The device of claim 1 wherein the straight distal portion has at least two sensing.

18. (Cancelled)

19. The device of claim 1 wherein the straight distal portion has a length of about 2 to about 8 cm.

20. The device of claim 1 wherein the helical proximal portion has a length of about 0.5 to about 1 cm.

21. The device of claim 1 wherein the helical proximal portion has a circumference of about 5 to about 40 mm.

22. (Cancelled)

23. A method of performing a medical procedure, comprising:

a) providing an electrophysiology device, comprising

an elongated shaft having a proximal end, a distal end, and a distal shaft section having a helically shaped proximal portion having one or more turns and a straight distal portion; and

at least one ablation electrode on the helically shaped proximal portion; and

b) positioning at least part of the helically shaped proximal portion in contact with a wall defining an ostium of a patient's body lumen; and

c) delivering high frequency energy to the at least one ablation electrode to form a lesion,

24. The method of claim 23 including after (b), moving the turns of the helically shaped proximal portion closer together by distally forcing the catheter against the wall defining the ostium.

25. The method of claim 23 wherein the ostium is a junction of a pulmonary vein with a left atrium, and (c) comprises forming a plurality of discontinuous lesions around the ostium.

26. The method of claim 23 wherein the ostium is a junction of a pulmonary vein with a left atrium, and the device has at least one sensing electrode on the distal portion, and wherein the pulmonary vein is mapped by sensing electrical activity with the sensing electrode.

27. The method of claim 23 wherein delivering high frequency energy to the at least one ablation electrode forms a lesion extending at least in part around the ostium of the body lumen.

28. The method of claim 27 wherein the helically shaped proximal portion of the distal shaft section of the device Is placed In a junction between a pulmonary vein and an atrium of a patient to form a lesion to treat the patient for atrial arrhythmia.

29. The method of claim 28 wherein the device has a plurality of electrodes on the helically shaped proximal portion of the distal shaft section, and wherein a plurality of discontinuous lesions are formed at the junction between the pulmonary vein and an atrium to treat the patient for atrial arrhythmia.

30. (Cancelled)

31. The method of claim 28 wherein the device has a plurality of electrodes on the helically shaped proximal portion of the distal shaft section, and including after (c), moving the turns of the helically shaped proximal portion closer together and delivering high frequency energy to at least one electrode on the helically shaped proximal portion to form a second lesion continuous with the first lesion.

32. The method of claim 28 wherein the helically shaped proximal portion has a plurality of ablation electrodes, and the straight distal portion has at least one sensing electrode, and wherein the pulmonary vein is mapped by the at least one sensing electrode sensing electrical activity.

33. The device of claim 1 wherein the straight distal portion has at least two pacing electrodes.

34. The device of claim 1, wherein the helically shaped proximal portion has a longitudinal axis coincident with the longitudinal axis of the elongated shaft.

35. The device of claim 1, wherein the straight distal portion of the distal shaft section has a core member which is at least in part tapered over a length thereof.

36. The device of claim 1, wherein the straight distal portion anchors the distal shaft section.

37. The device of claim 1 wherein the core member is at least in part formed of a material selected from the group consisting of high spring-back metals, superelastic metals and shape-memory metals.

38. The device of claim 37 wherein the superelastic material is a NiTi alloy.

39. An electrophysiology device for detecting electrical activity within a patients heart chamber, comprising:

a. an elongated shaft having a proximal end, a distal end, and a distal shaft section which is at least in part helically shaped with at least one turn and which has at least one electrode for detecting electrical activity on the helically shaped portion of the distal shaft section and which has a longitudinal axis; and

b. a straight distal portion which extends distally from the helically shaped proximal portion of the distal shaft section and which has a longitudinal axis parallel to and off-set from the longitudinal axis of the helically shaped proximal portion.

40. The electrophysiology device of claim 39 wherein the at least one electrode is about 2 to about 8 mm in length.

41. An electrophysiology device for a procedure within a patient's heart chamber, comprising an elongated shaft which has a helically shaped distal shaft portion having a plurality of spaced apart electrodes and being configured to engage an ostia within the patients heart chamber.

42. The electrophysiology device of claim 40 wherein the spacing between at least two adjacent electrodes is not more than about 3 mm.

43. The electrophysiology device of claim 40 wherein the spacing between at least two adjacent electrodes is not less than about 1 mm.

44. The electrophysiology device of claim 40 wherein the distal shaft section has at least one temperature sensor.

45. The electrophysiology device of claim 44 wherein the at least one temperature sensor is disposed between two adjacent electrodes.

46. The electrophysiology device of claim 40 wherein the helically shaped distal shaft portion has at least four electrodes.

47. The electrophysiology device of claim 40 wherein the helically shaped distal shaft portion has up to about 12 electrodes.

48. The electrophysiology device of claim 40 wherein a plurality of the electrodes are ablation electrodes.

49. The electrophysiology device of claim 40 wherein a plurality of the electrodes are sensing electrodes.

50. The electrophysiology device of claim 40 wherein the elongated shaft has a straight distal shaft portion extending distally from the helically shaped distal shaft portion.

51. The electrophysiology device of claim 50 wherein the straight distal portion has a longitudinal axis parallel to and off-set from a longitudinal axis of the helically shaped distal shaft portion.

52. The electrophysiology device of claim 40 wherein the helically shaped distal shaft portion has a core member.

53. The electrophysiology device of claim 52 wherein the core member Is formed of a material selected from the group consisting of high spring-back metals, superelastIc metals and shape-memory metals.

54. The electrophyslology device of claim 53 wherein the superelastic material is a NiTi alloy.

55. The electrophysiology device of claim 41 wherein at least one of the spaced apart electrodes is about 2 to about 8 mm in length.

56. An electrophysiology device for a procedure within a patient's heart chamber, comprising an elongated shaft which has an expandable distal shaft portion having a plurality of spaced apart electrodes and being configured to engage an ostia within the patients heart chamber.

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