A mapping catheter (230) for an intravascular catheter assembly (10) includes a corewire (454) that at least partially extends through a central lumen (223). The corewire (454) includes a proximal core (464) and a distal core (466). The proximal core (454) and the distal core (466) are secured to one another at a core junction (468). The proximal core (464) and the distal core (466) can be formed from materials so that the proximal core (464) has a stiffness that is greater than a stiffness of the distal core (466). A ratio of the stiffness of the proximal core (464) to the stiffness of the distal core (466) can be at least approximately 1.5:1, 2:1, 2.5:1, or 3:1; or approximately 30:1. The proximal core (464) can be formed from stainless steel and the distal core (466) can be formed from nickel titanium. The proximal core (464) and the distal core (466) can be welded to one another at the core junction (468). The corewire (454) can include a linear or helical groove (968) that can retain a conductor array (980A, 980E).

**FiG. 4A**
COREWIRE FOR MAPPING CATHETER FOR
INTRAVASCULAR CATHETER SYSTEM

BACKGROUND

[0001] Cardiac arrhythmias involve an abnormality in the electrical conduction of the heart and are a leading cause of stroke, heart disease, and sudden cardiac death. Treatment options for patients with arrhythmias include medications, implantable devices, and catheter ablation of cardiac tissue.

[0002] Catheter ablation involves delivering ablative energy to tissue inside the heart to block aberrant electrical activity from depolarizing heart muscle cells out of synchrony with the heart's normal conduction pattern. The procedure is performed by positioning the tip of an energy delivery catheter adjacent to diseased or targeted tissue in the heart. The energy delivery component of the system is typically at or near the most distal (farthest from the operator) portion of the catheter, and often at the tip of the device. Various forms of energy are used to ablate diseased heart tissue. These can include radio frequency (RF), balloon cryotherapy which uses cryoballoons, ultrasound and laser energy, to name a few. The tip of the catheter is positioned adjacent to targeted tissue, at which time energy is delivered to create tissue necrosis, rendering the ablated tissue incapable of conducting electrical signals. The dose of energy delivered is a critical factor in increasing the likelihood that the treated tissue is permanently incapable of electrical conduction. At the same time, delicate collateral tissue, such as the esophagus, the bronchus, and the phrenic nerve surrounding the ablation zone can be damaged and can lead to undesired
complications. Thus, the operator must finely balance delivering therapeutic levels of energy to achieve intended tissue necrosis while avoiding excessive energy leading to collateral tissue injury.

[0003] Atrial fibrillation (AF) is one of the most common arrhythmias treated using balloon cryotherapy. Atrial fibrillation is typically treated by pulmonary vein isolation (PVI), a procedure that removes unusual electrical conductivity in the pulmonary vein. In the earliest stages of the disease, paroxysmal AF, the treatment strategy involves isolating the pulmonary vein(s) from the left atrial chamber. Recently, the use of balloon cryotherapy procedures to treat AF has increased. In part, this stems from ease of use, shorter procedure times and improved patient outcomes. When a cryoballoon is used during a PVI procedure, it is important that the cryoballoon completely occludes the pulmonary vein prior to ablation to increase the likelihood of full circumferential contact with the ostium of the pulmonary vein. If this is the case, then the application of cryoenergy could reasonably result in electrically isolating the pulmonary vein. For this reason, it is desirable to use a mapping catheter with the cryoballoon catheter which can provide real-time electrical mapping to assess pulmonary vein isolation. Having this capability offers the user the opportunity to prematurely terminate or pause the procedure if the balloon is incorrectly or not optimally positioned.

[0004] The mapping catheter takes the place previously served by a guidewire. The function of the guidewire is to direct and position the cryoballoon ablation catheter at the ablation site at the ostium of a pulmonary vein. The guidewire tip is placed deep into a branch off the main pulmonary vein to help position the cryoballoon. The selection of the pulmonary branch chosen to insert the guidewire is made to provide optimized overlap of the balloon to vein ostium so that a complete and contiguous ablation encircling the pulmonary vein results. This is best achieved when the balloon is positioned so that vein occlusion results. Subsequent to initial positioning, the function of the guidewire is to provide support to the cryoballoon catheter so that it remains immobilized in its intended position.

[0005] In using a cryoablation catheter, oftentimes when an operator switches from static inflation to ablation, the sudden onrush of refrigerant through the inside of the balloon at high pressures can cause balloon dislodgment. In other words, the
balloon pops out of position. This requires the operator to abort the freeze cycle and reposition the catheter, repeating the entire process needed to position the balloon and initiate a freeze. It is advantageous to position the circular mapping catheter as close as practical to the ablation site. This enables real-time monitoring of pulmonary vein potentials (PVPs) during ablation. A technique that positions the loop section of the mapping catheter close to the ablation site and providing stability for the balloon position is to prolapse the mapping catheter so that the proximal shaft segment extends past the loop section. There is an unmet need for a mapping catheter designed to be used with a cryoballoon ablation catheter that offers improved guidewire performance such as improved torque performance, improved freedom of kinking and improved prolapsing ability.

[0006] The mapping catheter is designed to interrogate tissue to direct therapy. Current limitations include not being able to position the loop of the mapping catheter close to the ablation site. An improved structure that more easily facilitates close placement of the sensors in the mapping catheter to the ablation site is needed. A further improvement needed is to package conductors in a more space efficient manner to increase the number of sensors at the distal end of the mapping catheter and to reduce manufacturing complexity and cost.

SUMMARY

[0007] The present invention is directed toward a mapping catheter for an intravascular catheter assembly that is used during a pulmonary vein isolation procedure in a patient. The intravascular catheter assembly includes a handle assembly and a central lumen. In various embodiments, the mapping catheter includes a corewire assembly that at least partially extends through the central lumen. The corewire assembly includes a corewire having a proximal core and a distal core. The proximal core is positioned nearer to the handle assembly than the distal core. The proximal core and the distal core are secured to one another at a core junction. In various embodiments, the proximal core and the distal core are formed from materials that are different from one another.
In certain embodiments, the proximal core has a stiffness that is greater than a stiffness of the distal core. In some such embodiments, a ratio of the stiffness of the proximal core to a stiffness of the distal core is at least approximately 1.5:1, 2:1, 2.5:1, or 3:1, or approximately 30:1. In some embodiments, the proximal core is formed from stainless steel and the distal core is formed from nickel titanium.

In various embodiments, the proximal core and the distal core are each formed as a solid, non-hollow structure.

In certain embodiments, the proximal core and the distal core are welded to one another at the core junction.

The distal core can form at least a portion of a distal section that includes a somewhat circular hoop. The hoop can include a plurality of electrodes that sense a physiological parameter of the patient.

In some embodiments, the proximal core forms at least a portion of a proximal section. The proximal section can include at least a portion of a conductor that extends from one of the plurality of electrodes.

The proximal section can include a shaft tubing that encircles at least a portion of the proximal core. The shaft tubing can encapsulate at least a portion of the plurality of electrodes. The conductor can be wrapped in a helical configuration around the proximal core. Alternatively, the conductor can extend in a substantially linear manner along the proximal core.

In certain embodiments, the corewire can include a groove that is adapted to retain at least one of the plurality of conductors. The groove can be oriented in a substantially lengthwise manner along the corewire. The groove can have a helical configuration along at least a portion of the proximal core of the corewire.

In various embodiments, the groove can have a helical configuration along an entire length of the proximal core of the corewire. The groove can have a radius of curvature that is less than one-third of a diameter of the proximal core of the corewire. Alternatively, the groove can have a radius of curvature that is greater than one-third of a diameter of the proximal core of the corewire.

The intravascular catheter assembly can include an inflatable balloon that is at least partially secured to the central lumen.
In another embodiment, the mapping catheter can include a corewire assembly that at least partially extends through the central lumen. In some embodiments, the corewire assembly can include a corewire having a proximal core. The proximal core can include a groove that is adapted to retain at least one conductor. The groove can be oriented in a substantially lengthwise manner along a length of the proximal core.

The groove can have a helical configuration along at least a portion of the length of the proximal core. In one embodiment, the groove can have a helical configuration along the entire length of the proximal core.

The present invention can also include a method for manufacturing a mapping catheter for an intravascular catheter assembly having features as shown and described herein.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

- **Figure 1** is a schematic side view illustration of a patient and one embodiment of an intravascular catheter assembly having features of the present invention;
- **Figure 2** is a simplified side view of a portion of a patient and a portion of one embodiment of the intravascular catheter assembly including a balloon catheter having a mapping catheter;
- **Figure 3A** is a side view of a portion of one embodiment of the intravascular catheter assembly including a connector assembly and one embodiment of the mapping catheter;
- **Figure 3B** is an end view of the portion of the intravascular catheter assembly illustrated in Figure 3A including the connector assembly and the mapping catheter;
- **Figure 3C** is an end view of a distal section of the mapping catheter.
illustrated in Figure 3A;

[0026] Figure 3D is a cross-sectional view of the mapping catheter taken on line 3D-3D in Figure 3C;

[0027] Figure 4A is a side view of a portion of one embodiment of the mapping catheter including a corewire;

[0028] Figure 4B is an end view of a distal section of the corewire illustrated in Figure 4A;

[0029] Figure 5A is a portion of a proximal section of one embodiment of the mapping catheter;

[0030] Figure 5B is a portion of the proximal section of another embodiment of the mapping catheter;

[0031] Figure 6A is a cross-sectional view of one embodiment of the proximal section of the mapping catheter;

[0032] Figure 6B is a cross-sectional view of another embodiment of the proximal section of the mapping catheter;

[0033] Figure 7A is a side view of one embodiment of a collapsing tube having features of the present invention;

[0034] Figure 7B is a side view of the collapsing tube illustrated in Figure 7A and a portion of a mapping catheter shown in a hoop position;

[0035] Figure 7C is a perspective view of a portion of the collapsing tube illustrated in Figure 7B and a portion of the mapping catheter illustrated in Figure 7B, shown in a partially straightened position;

[0036] Figure 7D is a perspective view of a portion of the collapsing tube and a portion of the mapping catheter illustrated in Figure 7B, shown in a straightened position;

[0037] Figure 8 is a side view of a portion of the intravascular catheter system including an embodiment of a portion of a mapping catheter including a corewire assembly;

[0038] Figure 9A is a simplified side view of a portion of an intravascular catheter system including an embodiment of a portion of the corewire assembly;

[0038] Figure 9B is a simplified cross-sectional view of the corewire assembly taken on line 9B-9B in Figure 9A, including a corewire, a corewire sheath and a
plurality of conductor assemblies;

[0039] Figure 9C is a cross-sectional view of the corewire illustrated in Figure 9B;

[0040] Figure 9D is a close-up cross-sectional view of one of the conductor assemblies illustrated in Figure 9B; and

[0041] Figure 9E is a simplified cross-sectional view of another embodiment of the corewire assembly.

DESCRIPTION

[0042] Embodiments of the present invention are described herein in the context of an intravascular catheter assembly (also hereinafter sometimes referred to as an "catheter assembly"). Those of ordinary skill in the art will realize that the following detailed description of the present invention is illustrative only and is not intended to be in any way limiting. Other embodiments of the present invention will readily suggest themselves to such skilled persons having the benefit of this disclosure. Reference will now be made in detail to implementations of the present invention as illustrated in the accompanying drawings.

[0043] In the interest of clarity, not all of the routine features of the implementations described herein are shown and described. It will, of course, be appreciated that in the development of any such actual implementation, numerous implementation-specific decisions must be made in order to achieve the developer's specific goals, such as compliance with application-related and business-related constraints, and that these specific goals will vary from one implementation to another and from one developer to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking of engineering for those of ordinary skill in the art having the benefit of this disclosure.

[0044] Although the disclosure provided herein focuses mainly on cryogenics, it is understood that various other forms of energy are used to ablate diseased heart tissue. These can include radio frequency (RF), ultrasound and laser energy, to name a few. The present invention is intended to be effective with any or all of these forms of energy.
Figure 1 is a schematic side view of one embodiment of an intravascular catheter system 10 (also sometimes referred to herein as a "catheter system") for use with a patient 12, which can be a human being or an animal. Although the catheter system 10 is specifically described herein with respect to an intravascular catheter system, it is understood and appreciated that other types of catheter systems and/or ablation systems can equally benefit by the teachings provided herein. For example, in certain non-exclusive alternative embodiments, the present invention can be equally applicable for use with any suitable types of ablation systems and/or any suitable types of catheter systems. Thus, the specific reference herein to use as part of an intravascular catheter system is not intended to be limiting in any manner.

The design of the catheter system 10 can be varied. In certain embodiments, such as the embodiment illustrated in Figure 1, the catheter system 10 can include one or more of a control system 14, a fluid source 16, a balloon catheter 18, a handle assembly 20, a control console 22, a graphical display 24 and a differential pressure limiter 26. It is understood that although Figure 1 illustrates the structures of the catheter system 10 in a particular position, sequence and/or order, these structures can be located in any suitably different position, sequence and/or order than that illustrated in Figure 1. It is also understood that the catheter system 10 can include fewer or additional components than those specifically illustrated and described herein.

In various embodiments, the control system 14 is configured to monitor and control the various processes of the ablation procedure. More specifically, the control system 14 can control release and/or retrieval of a cryogenic fluid 28 to and/or from the balloon catheter 18. In certain embodiments, the control system 14 can control various structures described herein that are responsible for maintaining and/or adjusting a flow rate and/or fluid pressure of the cryogenic fluid 28 that is released to the balloon catheter 18 during a cryoablation procedure. In such embodiments, the catheter system 10 delivers ablative energy in the form of cryogenic fluid 28 to cardiac tissue of the patient 12 to create tissue necrosis, rendering the ablated tissue incapable of conducting electrical signals. Additionally, in various embodiments, the control system 14 can control activation and/or
deactivation of one or more other processes of the balloon catheter 18 described herein. Further, or in the alternative, the control system 14 can receive data and/or other information (hereinafter sometimes referred to as "sensor output") from various structures within the catheter system 10. In some embodiments, the control system 14 can assimilate and/or integrate the sensor output, and/or any other data or information received from any structure within the catheter system 10. Additionally, or in the alternative, the control system 14 can control positioning of portions of the balloon catheter 18 within the body of the patient 12, and/or can control any other suitable functions of the balloon catheter 18.

[0048] The fluid source 16 contains the cryogenic fluid 28, which is delivered to the balloon catheter 18 with or without input from the control system 14 during the cryoablation procedure. The type of cryogenic fluid 28 that is used during the cryoablation procedure can vary. In one non-exclusive embodiment, the cryogenic fluid 28 can include liquid nitrous oxide. In another non-exclusive embodiment, the cryogenic fluid 28 can include liquid nitrogen. However, any other suitable cryogenic fluid 28 can be used.

[0049] The design of the balloon catheter 18 can be varied to suit the specific design requirements of the catheter system 10. As shown, the balloon catheter 18 is inserted into the body of the patient 12 during the cryoablation procedure. In one embodiment, the balloon catheter 18 can be positioned within the body of the patient 12 using the control system 14. Stated in another manner, the control system 14 can control positioning of the balloon catheter 18 within the body of the patient 12. Alternatively, the balloon catheter 18 can be manually positioned within the body of the patient 12 by a health care professional (also sometimes referred to herein as an "operator"). As used herein, health care professional and/or operator can include a physician, a physician's assistant, a nurse and/or any other suitable person and/or individual. In certain embodiments, the balloon catheter 18 is positioned within the body of the patient 12 utilizing at least a portion of the sensor output received from the balloon catheter 18. For example, in various embodiments, the sensor output is received by the control system 14, which can then provide the operator with information regarding the positioning of the balloon catheter 18. Based at least partially on the sensor output feedback received by the control system 14, the
operator can adjust the positioning of the balloon catheter 18 within the body of the patient 12 to ensure that the balloon catheter 18 is properly positioned relative to targeted cardiac tissue. While specific reference is made herein to the balloon catheter 18, as noted above, it is understood that any suitable type of medical device and/or catheter may be used.

[0050] The handle assembly 20 is handled and used by the operator to operate, position and/or control the balloon catheter 18. The design and specific features of the handle assembly 20 can vary to suit the specific design requirements of the catheter system 10. In the embodiment illustrated in Figure 1, the handle assembly 20 is separate from, but in electrical and/or fluid communication with the control system 14, the fluid source 16 and/or the graphical display 24. In some embodiments, the handle assembly 20 can integrate and/or include at least a portion of the control system 14 within an interior of the handle assembly 20. It is understood that the handle assembly 20 can include additional components than those specifically illustrated and described herein.

[0051] In the embodiment illustrated in Figure 1, the control console 22 includes at least a portion of the control system 14, the fluid source 16, the graphical display 24 and the differential pressure limiter 26. However, in alternative embodiments, the control console 22 can contain additional structures not shown or described herein. Still alternatively, the control console 22 may not include various structures that are illustrated within the control console 22 in Figure 1. For example, in one embodiment, the control console 22 does not include the graphical display 24.

[0052] In various embodiments, the graphical display 24 is electrically connected to the control system 14. Additionally, the graphical display 24 provides the operator of the catheter system 10 with information that can be used before, during and after the cryoablation procedure. For example, the graphical display 24 can provide the operator with information based on the sensor output, and any other relevant information that can be used before, during and after the cryoablation procedure. The specifics of the graphical display 24 can vary depending upon the design requirements of the catheter system 10, or the specific needs, specifications and/or desires of the operator.

[0053] In one embodiment, the graphical display 24 can provide static visual
data and/or information to the operator. In addition, or in the alternative, the graphical display 24 can provide dynamic visual data and/or information to the operator, such as video data or any other data that changes over time. Further, in various embodiments, the graphical display 24 can include one or more colors, different sizes, varying brightness, etc., that may act as alerts to the operator. Additionally, or in the alternative, the graphical display 24 can provide audio data or information to the operator.

[0054] The differential pressure limiter 26 maintains, controls and/or limits a differential fluid pressure of the cryogenic fluid 28 delivered to the catheter system 10. The design of the differential pressure limiter 26 can be varied depending upon the specific design requirements of the catheter assembly 10. In various embodiments, the control system 14 can control activation and/or deactivation of one or more processes of the differential pressure limiter 26 described herein. In the embodiment illustrated in Figure 1, the differential pressure limiter 26 can be integrated, included and/or positioned within the control console 22. The differential pressure limiter 26 can be positioned at any location within the control console 22. In other embodiments, the differential pressure limiter 26 may not be integrated, included and/or positioned within the control console 22. The differential pressure limiter 26 can be positioned at any location outside the control console 22. Additionally, and/or alternatively, the differential pressure limiter 26 can be integrated, included and/or positioned within any other suitable structure of the catheter system 10.

[0055] In certain embodiments, the catheter system 10 and/or the differential pressure limiter 26 may include one or more conduits 29, cables or other means of transferring fluids or electrical signals. In the embodiment illustrated in Figure 1, the conduits 29 connect the differential pressure limiter 26 with the fluid source 16 and/or the handle assembly 20. In this embodiment, the conduits 29 can allow the flow of cryogenic fluid 28 from the fluid source 216 to the handle assembly 20 and ultimately to the balloon catheter 18 that is positioned within the patient 12. In certain embodiments, the conduits 29 can include relatively small diameter tubes through which the cryogenic fluid 28 flows and/or moves. Alternatively, the conduits 29 may include any other suitable design.
Figure 2 is a simplified side view of a portion of a patient 212 and a portion of one embodiment of the intravascular catheter assembly 210. The cooling fluid source 16 (illustrated in Figure 1) has been omitted from Figure 2 for clarity. In the embodiment illustrated in Figure 2, the intravascular catheter assembly 210 includes a balloon catheter 218 and a handle assembly 220.

The design of the balloon catheter 218 can be varied to suit the design requirements of the intravascular catheter assembly 210. In this embodiment, the balloon catheter 218 includes one or more of a central lumen 223, a catheter shaft 224, one or more inflatable balloons (also sometimes referred to herein simply as a "balloon") including at least one of an inner balloon 226 and an outer balloon 228, and a mapping catheter 230. As used herein, the generic term "balloon" can refer to either the inner balloon 226 or the outer balloon 228. Further, it is recognized that the balloon catheter 218 may include only one balloon. Moreover, it is understood that the balloon catheter 218 can include other structures as well. However, for the sake of clarity, these other structures have been omitted from the Figures.

In the embodiment illustrated in Figure 2, the balloon catheter 218 is positioned within the circulatory system 232 of the patient 212. The mapping catheter 230 is first fed through the circulatory system 232 and into a pulmonary vein 234 of the patient 212. Once the mapping catheter 230 has been positioned as desired, the central lumen 223, the catheter shaft 224 and the balloons 226, 228 are moved along the mapping catheter 230 to near an ostium 236 of the pulmonary vein 234. Stated another way, in certain embodiments, the mapping catheter 230 coaxially extends through the central lumen 223 and the catheter shaft 224 and acts as a guidewire over which the balloons 226, 228 are moved into position at or near the ostium 236 to be treated.

Additionally, as provided in greater detail herein, a portion of the mapping catheter 230 selectively can form a somewhat circular hoop 238 that abuts or otherwise engages the ostium 236 and/or the pulmonary vein 234 at various times during operation of the balloon catheter 218. As illustrated in Figure 2, due to the design of the mapping catheter 230 described herein, a portion of the mapping catheter 230 can extend (also referred to herein as "prolapse") through the hoop 238 to a position that is more distal from the handle assembly 220 than the hoop 238.
provided in greater detail herein, once the hoop 238 has seated at or near the ostium 236, additional movement of the mapping catheter toward the pulmonary vein 234 can cause a portion of the mapping catheter 230 to prolapse in a distal direction through the hoop 238.

[0060] In one embodiment, a pressure sensor 239 (such as a MEMS pressure sensor, in one embodiment) can be mounted cantilever-style in a sensor housing (not shown) distal to the hoop 238 of the mapping catheter 230 when the mapping catheter 230 is in a prolapsed position (as illustrated in Figure 2). This may or may not include an atraumatic length that can extend distally from the pressure sensor 239. This design can provide real-time venous pressure waveform data that feed directly or indirectly to the control system 14 (illustrated in Figure 1) and can be used to assess occlusion quality prior to cryoballoon ablation. In an alternative embodiment (not shown in Figure 2), the pressure sensor 239 can be mounted cantilever-style in a sensor housing proximal to the hoop 238 of the mapping catheter 230. The pressure sensor 239 can alternatively be mounted distally to the hoop 238 when the mapping catheter 230 is not in the prolapsed position.

[0061] The design of the handle assembly 220 can vary. In the embodiment illustrated in Figure 2, the handle assembly 220 can include a controller 240 that can form a portion of the control system 14. Alternatively, the controller 240 can transmit electrical signals such as the sensor output or otherwise provide data to the control system 14 as described herein. In one embodiment, the controller 240 can include a printed circuit board having one or more integrated circuits, or any other suitable controller. In an alternative embodiment, the controller 240 can be omitted, or can be included within the control system 14, which in various embodiments can be positioned outside of the handle assembly 220.

[0062] Figure 3A is a side view of a portion of one embodiment of the intravascular catheter assembly 310 including a connector assembly 342 and one embodiment of the mapping catheter 330. In this embodiment, the mapping catheter 330 includes a proximal section 344 and a distal section 346 that is connected and/or secured to the proximal section 344. The specific lengths and widths of the proximal section 344 and the distal section 346 can vary depending upon the design requirements of the intravascular catheter assembly 310. However, the proximal
section 344 is positioned nearer to the handle assembly 220 (illustrated in Figure 2) than the distal section 346.

[0063] The proximal section 344 can be relatively linear and somewhat rigid, although the proximal section 344 can have some pliability or resilience. The distal section 346 includes a hoop 338 and a curved section 348 that is connected to the hoop 338. In one embodiment, the hoop 338 is somewhat circular in shape. In alternative embodiments, the hoop 338 can have a different configuration.

[0064] Figure 3B is an end view of the portion of the intravascular catheter assembly 310 illustrated in Figure 3A including portions of the connector assembly 342 and the mapping catheter 330. In this embodiment, the hoop 338 is substantially concentric relative to the connector assembly 342 and the proximal section 344.

[0065] Figure 3C is an end view of the distal section 346 of the mapping catheter 330 illustrated in Figure 3A. In this embodiment, the curved section 348 extends from the proximal section 344 (illustrated in Figure 3A), and is connected to the hoop 338. In this embodiment, the hoop 338 includes a plurality of electrodes 350 and a tapered tip 352. The plurality of electrodes 350 can be spaced equidistantly from one another around a circumference of the hoop 338. In an alternative embodiment, the electrodes 350 can be unevenly spaced apart. In the embodiment illustrated in Figure 3C, eight electrodes 350 are included in the hoop 338. However, any suitable number of electrodes 350 can be used. The electrodes 350 can be made from platinum or a platinum alloy such as 95-5 Platinum Ruthenium or 90-10 Platinum Iridium, for example. Other materials such as gold or gold alloys can alternatively be used.

[0066] Figure 3D is a cross-sectional view of the mapping catheter 330 taken on line 3D-3D in Figure 3C. In Figure 3D, line 3D-3D is shown in the area of one of the electrodes 350. In this embodiment, the mapping catheter 330 can include one or more of a corewire 354, an insulation tube 356, a plurality of conductors 358, a conductor housing 360, distal tubing 362 and the electrode 350.

[0067] Referring back to Figure 3C, the corewire 354 extends from the connector assembly 342 (illustrated in Figure 3A) to the tapered tip 352 of the hoop 338. The corewire 354 in the region of the distal section 346 can be formed from any suitable material(s). In one embodiment, and as provided in greater detail herein, the
distal section 346 of the corewire 354 can be at least partially formed from a nickel-titanium compound, such as nitinol and/or a nitinol compound, as non-exclusive examples.

[0068] In the embodiment illustrated in Figure 3D, the insulation tube 356 electrically insulates the conductors 358 from the corewire 354. Each conductor 358 connects one electrode 350 to the connector assembly 342. The conductor housing 360 retains the conductors 358. The conductor housing 360 can be formed from a dielectric material, in one non-exclusive embodiment. The distal tubing 362 surrounds the various other structures of the distal section 346 of the mapping catheter 330.

[0069] In certain embodiments, the electrodes 350 and the corewire 354 are electrically connected to the connector assembly 342. The connector assembly 342 electrically connects the electrodes 350 (and/or one or more other sensors) of the mapping assembly 330 to the control system 14. The electrodes 350 and/or other sensors may be optimized to measure electrograms of the heart or other physiological parameters of the patient 12 (illustrated in Figure 1).

[0070] Figure 4A is a side view of a portion of one embodiment of the mapping catheter 430 including a corewire 454. In the embodiment illustrated in Figure 4A, the corewire 454 includes a proximal core 464 and a distal core 466. The location of the proximal core 464 and the distal core 466 substantially correlate with the location of the proximal section 344 (illustrated in Figure 3A) and the distal section 346 (illustrated in Figure 3A), respectively. The proximal core 464 can be secured, attached or otherwise connected to the distal core 466 at a core junction 468 by any suitable process. In one embodiment, the proximal core 464 and the distal core 466 can be welded to one another in a manner known to those skilled in the art. With this design, discontinuity at the core junction 468 facilitates easier prolapsing of a distal end of the mapping catheter 430, as previously described. In one embodiment, the core junction 468 can be positioned near the hoop 438. Alternatively, the core junction 468 can be positioned more proximally (away from) to the hoop 438 to avoid high stresses. In one non-exclusive embodiment, a distance of the proximal core 464 to the hoop 438 can be approximately 0-5 cm. Alternatively, the distance can be more than 5 cm.
The proximal core 464 can be formed from any suitable material. In the embodiment illustrated in Figure 4A, the proximal core 464 can be a solid formed from a relatively high modulus, high tensile strength material such as stainless steel. For example, the proximal core 464 can include 304 stainless steel (Young's modulus = E = approximately 30 x 10^6 psi) round wire. Further, or in the alternative, the proximal core 464 can be cold worked to approximately 400 kpsi. The proximal core 464 of the corewire 454 can include a solid, cold worked, diamond die drawn corewire 454 made using wire drawing processes commonly employed to make intravascular guidewires. For example, the material can be any grade of stainless steel such as 304 or 17-7PH. In addition, or alternatively, special alloys such as NP35N can be used. The proximal core 464 can be welded or otherwise connected in ways known to those skilled in the art to a more flexible, lower modulus material such as nitinol (Young's modulus = E = approximately 11 x 10^6 psi), in one non-exclusive embodiment. Thus in one embodiment, a ratio of the modulus of the proximal core 464 to the distal core 466 of the corewire 454 is at least approximately 30:1. In non-exclusive alternative embodiments, other materials can be used for the proximal core 464 and/or the distal core 466 so that the ratio of the modulus of the proximal core 464 to the distal core 466 of the corewire 454 is at least approximately 1.5:1, 2:1, 2.5:1, 3:1, 3.5:1 or 4:1. Still alternatively, the ratio of the modulus of the proximal core 464 to the distal core 466 of the corewire 454 can be greater than 4:1 or less than 1.5:1.

Figure 4B is an end view of the distal core 466 of the corewire 454 illustrated in Figure 4A.

Figure 5A is a portion of one embodiment of a proximal section 544A of a mapping catheter 530A. Each electrode 350 (illustrated in Figure 3C) is joined to a corresponding conductor 558A (eight conductors 558A are illustrated in Figure 5A). The conductors 558A are routed along a length of the mapping catheter 530A into the handle assembly 220 (illustrated in Figure 2) and soldered to a connector (not shown) positioned outside the body. The conductor 558A can be a 40 gauge copper wire with a polyimide or nylon insulator, for example. In this embodiment, the conductors 558A can be fused together to create a multi-filar wire arrangement that facilitates manufacturing in scale. The electrodes 350 are mounted outside a shaft
tubing 572A, made from an insulative material, while the conductors 558A are routed inside the shaft tubing 572A. The shaft tubing 572A can be made from Pebax 7033 or Pebax 7233 or Pebax 6033, for example. Alternatively, polyurethane can be used for the shaft tubing 572A. In the embodiment illustrated in Figure 5A, the conductors 558A can be wrapped around the corewire 554A in a somewhat spiral or helical configuration.

[0074] Figure 5B is a portion of one embodiment of a proximal section 544B of a mapping catheter 530B. Each electrode 350 (illustrated in Figure 3C) is joined to a corresponding conductor 558B (eight conductors 558B are illustrated in Figure 5B). The conductors 558B are routed along a length of the mapping catheter 530B into the handle assembly 220 (illustrated in Figure 2) and soldered to a connector (not shown) positioned outside the body. The conductor 558B can be a 40 gauge copper wire with a polyimide or nylon insulator, for example. In this embodiment, the conductors 558B can be fused together to create a multi-filar wire arrangement that facilitates manufacturing in scale. The electrodes 350 are mounted outside a shaft tubing 572B, made from an insulative material, while the conductors 558B are routed inside the shaft tubing 572B. In certain embodiments, the shaft tubing 572B can be formed from Pebax 7033 or Pebax 7233 or Pebax 6033, as non-exclusive examples. Alternatively, polyurethane can be used for the shaft tubing 572B. Other polymeric insulative tubing material can also be used as the shaft tubing 572B. In the embodiment illustrated in Figure 5B, the conductors 558B can be oriented longitudinally along the corewire 554B.

[0075] Figure 6A is a cross-sectional view of one embodiment of the proximal section 644A of the mapping catheter 630A. In this embodiment, the conductors 658A are spaced apart from one another and are positioned within a shaft tubing 672A that encapsulates the corewire 654A. In one embodiment, the shaft tubing 672A can be made from PEEK or Polyimide that encapsulates the conductors 658A, and can be used to reduce the need for open space inside the mapping catheter 630A. The shaft tubing 672A may have individual slots or lumens to feed the conductors 658A into, or the shaft tubing 672A may be extruded with the conductors 658A fed into the structure.

[0076] Figure 6B is a cross-sectional view of another embodiment of the
proximal section 644B of the mapping catheter 630B. In this embodiment, the conductors 658B are positioned adjacent to one another, as illustrated in Figure 5A and 5B, for example. The conductors 658B are positioned within a shaft tubing 672B that encapsulates the corewire 654B. In one embodiment, the shaft tubing 672B can be made from PEEK or Polyimide that encapsulates the conductors 658B, and can be used to reduce the need for open space inside the mapping catheter 630B. The shaft tubing 672B may have individual slots to feed the conductors 658B into, or the shaft tubing 672B may be extruded with the conductors 658B fed into the structure. Other insulative materials with slots or lumens can alternatively be used to house the conductors 658B.

[0077] Figure 7A is a side view of one embodiment of a collapsing tube 774 having features of the present invention.

[0078] Figure 7B is a side view of the collapsing tube 774 illustrated in Figure 7A and a portion of a mapping catheter 730 shown in a hoop position. In this embodiment, the collapsing tube 774 includes an outer tubular member 776 that can be actuated from the handle assembly 220 (illustrated in Figure 2) to move over the hoop 738 and form a guidewire-like, J-shaped distal tip. With this design, steerability is improved to allow physicians to more efficiently advance the mapping catheter 730 to each of the pulmonary veins 234 (illustrated in Figure 2).

[0079] Figure 7C is a perspective view of a portion of the collapsing tube 774 illustrated in Figure 7B and a portion of the mapping catheter 730 illustrated in Figure 7B, shown in a partially straightened position. In Figure 7C, the outer tubular member 776 has begun to move over the hoop 738.

[0080] Figure 7D is a perspective view of a portion of the collapsing tube 774 and a portion of the mapping catheter 730 illustrated in Figure 7B, shown in a straightened position. In Figure 7D, the outer tubular member 776 has moved substantially completely over the hoop 738 and in so doing, has taken much or all of the curvature out of the hoop 738, e.g., substantially straightened the hoop 738.

[0081] Figure 8 is a side view of a portion of one embodiment of the intravascular catheter system 810. The portion of the intravascular catheter system 810 illustrated in Figure 8 includes a portion of a balloon catheter 818 having a mapping catheter 830. In the embodiment illustrated in Figure 8, for ease of
understanding, only the mapping catheter 830 of the balloon catheter 818 is shown. The design of the mapping catheter 830 can be varied to suit the design requirements of the balloon catheter 818. In the embodiment illustrated in Figure 8, the mapping catheter 830 includes a corewire assembly 878.

[0082] In this embodiment, the mapping catheter 830 includes a proximal section 844 and a distal section 846 that is connected to the proximal section 844. The proximal section 844 is positioned between the handle assembly 220 (illustrated in Figure 2) and the distal section 846. The specific lengths and/or widths of the proximal section 844 and the distal section 846 can vary depending upon the design requirements of the intravascular catheter assembly 810 and the balloon catheter 818. In one embodiment, the corewire assembly 878 forms at least a portion, if not the entire proximal section 844 of the mapping catheter 830. However, the corewire assembly 878 can also form a portion of the distal section 846.

[0083] The proximal section 844 can be relatively linear and somewhat rigid, although the proximal section 844 can have some pliability or resilience. In the embodiment illustrated in Figure 8, the distal section 846 can include a hoop 838 and a curved section 848 that is connected or otherwise secured to the hoop 838. In one embodiment, the hoop 838 is substantially circular in shape. In alternative embodiments, the hoop 838 can have a different configuration. In this embodiment, the hoop 838 includes a plurality of electrodes 850 (only three electrodes 850 are visible in Figure 8). The electrodes 850 can be spaced equidistantly from one another around a circumference of the hoop 838. In an alternative embodiment, the electrodes 850 can be unevenly spaced apart. Any suitable number of electrodes 850 can be used. In certain embodiments, the electrodes 850 can be made from platinum or a platinum alloy such as 95-5 Platinum Ruthenium or 90-10 Platinum Iridium, for example. Other suitable materials, such as gold or gold alloys as non-exclusive examples, can alternatively be used.

[0084] Figure 9A is a simplified side view of a portion of an intravascular catheter system 910A including an embodiment of a portion of a mapping catheter 930A having a corewire assembly 978A. In this embodiment, the corewire assembly 978A includes one or more conductor arrays 980A (only one conductor array 980A is illustrated in Figure 9A for clarity). It is understood that although the corewire
assembly 978A illustrated in Figure 9A is at least partially included in a proximal section 944A of the mapping catheter 930A, in certain embodiments, the corewire assembly 978A can also (or alternatively) extend at least partially into a distal section 846 (illustrated in Figure 8) of the mapping catheter 930A.

[0085] Figure 9B is a simplified cross-sectional view of the portion of an intravascular catheter system 910A including the corewire assembly 978A taken on line 9B-9B in Figure 9A. In this embodiment, the corewire assembly 978A includes the conductor array 980A, a corewire 954A and a corewire sheath 982A. In certain embodiments, the conductor array 980A includes a plurality of individual conductor assemblies 984. Any suitable number of conductor assemblies 984 can be included within the conductor array 980A. The conductor assemblies 984 can be arranged in a pattern that conserves space, or the conductor assemblies 984 can have a more random or semi-random positioning. In the embodiment illustrated in Figure 9B, the conductor assemblies 984 are arranged in a pattern that conforms to the shape of the corewire 954A, as explained in greater detail herein.

[0086] The corewire 954A has a somewhat circular cross-sectional shape. However, in various embodiments, the corewire 954A includes one or more grooves 986 (only one groove 986 is illustrated in Figure 9B for clarity) that receives, retains and/or otherwise houses one or more of the conductor arrays 980A. In one embodiment, the groove 986 can run substantially lengthwise along the corewire 954A. Alternatively, the groove 986 have a somewhat spiral or helical pattern or another suitable pattern around the corewire 954A. The diameter of the corewire 954A can vary to suit the design requirements of the intravascular catheter system 910A. For example, in one non-exclusive embodiment, the corewire 954A can have a diameter of approximately 0.033 inches, although it is understood that the diameter of the corewire 954A can be greater than or less than 0.033 inches.

[0087] The corewire sheath 982A encircles and/or otherwise covers the corewire 954A and the conductor array 980A so that the conductor array 980A is maintained substantially within the groove 986. The corewire sheath 982A can be formed from any suitable material. For example, in one embodiment, the corewire sheath 982A can be formed from any suitable polymer, metal or metal alloy materials. Further, the corewire sheath 982A can have any suitable configuration
that substantially conforms to the exterior of the corewire 954A, while leaving space within the groove 986 to retain the conductor array(s) 980A. In the embodiment illustrated in Figure 9B, the corewire sheath 982A has a substantially circular cross-sectional shape.

[0088] Figure 9C is a cross-sectional view of the corewire 954A illustrated in Figure 9B, with the corewire sheath 982A and the conductor array 980A omitted for clarity. In this embodiment, the corewire 954A includes the groove 986. The corewire 954A can be formed from any suitable material. In one embodiment, the corewire 954A can be formed from stainless steel, such as 304 stainless steel hardened to in excess of 300 kpsi. Alternatively, other types of stainless steel can be used. Still alternatively, other metals or other suitable materials can be used to form the corewire 954A. In one non-exclusive embodiment, the groove 986 can be formed in the corewire 954A by the corewire 954A being cold drawn through a single crystal diamond die (not shown). However, any suitable method can be used to generate and/or form the groove(s) 986.

[0089] The shape and/or size of the groove 986 can vary depending upon the shape and/or size of the corewire 954A. In the embodiment illustrated in Figure 9C, the groove 986 can have a somewhat semi-circular or arc-shaped configuration. However, it is recognized that the groove 986 can have any suitable shape that can retain one or more conductor assemblies 984 (illustrated in Figure 9B). In non-exclusive alternative embodiments, each groove 986 can be "V" shaped, "U" shaped, "C" shaped, "D" shaped, "J" shaped, "W" shaped, or any other suitable shape.

[0090] In one non-exclusive embodiment, the groove 986 is arc-shaped and has a radius of curvature of approximately 0.01 inches. In an alternative embodiment, the groove 986 has a radius of curvature of approximately 0.009 inches. Thus, in certain embodiments, the radius of curvature of the groove 986 is approximately one-third of the diameter of the corewire 954A. In another embodiment, the radius of curvature of the groove 986 can be less than one-third of the diameter of the corewire 954A. In an alternative embodiment, the radius of curvature of the groove 986 can be greater than one-third of the diameter of the corewire 954A. However, it is recognized that the foregoing sizes of the groove 986 are not limiting, and that the groove 986 can have any suitable radius of curvature.
[0091] Figure 9D is a close-up cross-sectional view of one of the conductor assemblies 984 illustrated in Figure 9B. In the embodiment illustrated in Figure 9D, the conductor assembly 984 includes a conductor 988 and a conductor insulator 990. The conductor 988 can be formed from any suitably conductive material, such as various metals and/or metal alloys. In various non-exclusive embodiments, the conductors 988 can be formed at least partially from nickel, copper or a copper beryllium alloy, for example. The conductor insulator 990 can be formed from any substantially non-conductive material, such as polyimide, nylon, other suitable plastics, etc.

[0092] Figure 9E is a simplified cross-sectional view of a portion of one embodiment of an intravascular catheter system 910E including another embodiment of a corewire assembly 978E. In this embodiment, the corewire assembly 978E includes a conductor array 980E that is positioned substantially within the groove 986 of the corewire 954E. In the embodiment illustrated in Figure 9E, the conductor array 980E includes a plurality of conductor assemblies 984 that are substantially similar or identical to the conductor assemblies 984 previously described herein. However, in this embodiment, the conductor assemblies 984 are bundled together to form the conductor array 980E rather than being arranged to conform to the shape of the groove 986 of the corewire 954E. As with any of the conductor arrays 980A, 980E, described herein, any suitable number of conductor assemblies 984 can be included.

[0093] It is understood that although a number of different embodiments of the intravascular catheter assembly and the mapping catheter have been illustrated and described herein, one or more features of any one embodiment can be combined with one or more features of one or more of the other embodiments, provided that such combination satisfies the intent of the present invention.

[0094] While a number of exemplary aspects and embodiments of an intravascular catheter assembly and the mapping catheter have been discussed above, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope.
What is claimed is:

1. A mapping catheter for an intravascular catheter assembly that is used during a pulmonary vein isolation procedure in a patient, the intravascular catheter assembly including a handle assembly and a central lumen, the mapping catheter comprising:
   
a corewire that at least partially extends through the central lumen, the corewire including a proximal core and a distal core, the proximal core being positioned nearer to the handle assembly than the distal core, the proximal core and the distal core being secured to one another at a core junction, the proximal core and the distal core being formed from materials that are different from one another.

2. The mapping catheter of claim 1 wherein the proximal core has a stiffness that is greater than a stiffness of the distal core.

3. The mapping catheter of claim 2 wherein a ratio of the stiffness of the proximal core to a stiffness of the distal core is at least approximately 1.5:1.

4. The mapping catheter of claim 2 wherein a ratio of the stiffness of the proximal core to a stiffness of the distal core is at least approximately 2.5:1.

5. The mapping catheter of claim 2 wherein a ratio of the stiffness of the proximal core to a stiffness of the distal core is approximately 30:1.

6. The mapping catheter of claim 1 wherein the proximal core is formed from stainless steel and the distal core is formed from nickel titanium.

7. The mapping catheter of claim 1 wherein the proximal core and the distal core are each formed as a solid, non-hollow structure.
8. The mapping catheter of claim 1 wherein the proximal core and the distal core are welded to one another at the core junction.

9. The mapping catheter of claim 1 wherein the distal core forms at least a portion of a distal section that includes a somewhat circular hoop.

10. The mapping catheter of claim 9 wherein the hoop includes a plurality of electrodes that sense a physiological parameter of the patient.

11. The mapping catheter of claim 10 wherein the proximal core forms at least a portion of a proximal section, the proximal section including at least a portion of a conductor that extends from one of the plurality of electrodes.

12. The mapping catheter of claim 11 wherein the proximal section includes a shaft tubing that encircles at least a portion of the proximal core, the shaft tubing encapsulating at least a portion of the conductor.

13. The mapping catheter of claim 11 wherein the conductor is wrapped in a helical configuration around the proximal core.

14. The mapping catheter of claim 11 wherein the conductor extends in a substantially linear manner along the proximal core.

15. The mapping catheter of claim 11 wherein the corewire includes a groove that is adapted to retain at least one of the plurality of conductors, the groove being oriented in a substantially lengthwise manner along the corewire.

16. The mapping catheter of claim 15 wherein the groove has a helical configuration along at least a portion of the proximal core of the corewire.

17. The mapping catheter of claim 15 wherein the groove has a helical configuration along an entire length of the proximal core of the corewire.
18. The mapping catheter of claim 15 wherein the groove has a radius of curvature that is less than one-third of a diameter of the proximal core of the corewire.

19. The mapping catheter of claim 15 wherein the groove has a radius of curvature that is greater than one-third of a diameter of the proximal core of the corewire.

20. The mapping catheter of claim 1 wherein the intravascular catheter assembly includes an inflatable balloon that is at least partially secured to the central lumen.

21. A mapping catheter for an intravascular catheter assembly that is used during a pulmonary vein isolation procedure in a patient, the intravascular catheter assembly including a central lumen, the mapping catheter comprising:

   a corewire assembly that at least partially extends through the central lumen, the corewire assembly including a corewire having a proximal core, the proximal core including a groove that is adapted to retain at least one conductor, the groove being oriented in a substantially lengthwise manner along a length of the proximal core.

22. The mapping catheter of claim 21 wherein the groove is adapted to retain a plurality of conductor assemblies.

23. The mapping catheter of claim 21 wherein the groove has a helical configuration along at least a portion of the length of the proximal core.

24. The mapping catheter of claim 21 wherein the groove has a helical configuration along the entire length of the proximal core.
25. The mapping catheter of claim 21 wherein the groove has a radius of curvature that is less than one-third of a diameter of the proximal core.

26. The mapping catheter of claim 21 wherein the groove has a radius of curvature that is greater than one-third of a diameter of the proximal core.

27. The mapping catheter of claim 21 wherein the intravascular catheter assembly includes a handle assembly, and wherein the corewire includes a distal core that is positioned more distally from the handle assembly than the proximal core, the proximal core and the distal core being secured to one another at a core junction, the proximal core and the distal core being formed from materials that are different from one another.

28. The mapping catheter of claim 27 wherein the proximal core has a stiffness that is greater than a stiffness of the distal core.

29. The mapping catheter of claim 28 wherein a ratio of the stiffness of the proximal core to a stiffness of the distal core is at least approximately 1.5:1.

30. The mapping catheter of claim 28 wherein a ratio of the stiffness of the proximal core to a stiffness of the distal core is at least approximately 2.5:1.

31. The mapping catheter of claim 28 wherein a ratio of the stiffness of the proximal core to a stiffness of the distal core is approximately 30:1.

32. The mapping catheter of claim 27 wherein the proximal core is formed from stainless steel and the distal core is formed from nickel titanium.

33. The mapping catheter of claim 27 wherein the proximal core and the distal core are each formed as a solid, non-hollow structure.
34. The mapping catheter of claim 27 wherein the proximal core and the distal core are welded to one another at the core junction.

35. The mapping catheter of claim 27 wherein the distal core forms at least a portion of a distal section that includes a somewhat circular hoop.

36. The mapping catheter of claim 35 wherein the hoop includes a plurality of electrodes that sense a physiological parameter of the patient.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61 B 5/042 (2018.01)
CPC - A61 B 5/042, 5/6853, 5/6856

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History Document

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

Electronic database consulted during the international search (name of data base and, where practicable, search terms used)
See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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<td>US 2009/0043186 A1 (JUNG et al) 12 February 2009 (12.02.2009) see especially para [0037], [0038], [0040]-[0045], [0072], [0074], fig 1-8</td>
<td>1-6, 9-11, 14, 20</td>
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<td>Y</td>
<td>US 2007/0282270 A1 (MATHews et al) 6 December 2007 (06.12.2007) see especially para [0068]-[0071], [0098], [0099], [0104], fig 1-2</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

Date of the actual completion of the international search: 5 July 2018
Date of mailing of the international search report: 26 JUL 2018

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