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(54) **STEERABLE SHEATH ACCESS DEVICE ASSEMBLY**

LENKBARE VORRICHTUNG FÜR DEN ZUGRIFF AUF HÜLLEN

DISPOSITIF D'ACCÈS À GAINE ORIENTABLE

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Description

BACKGROUND OF THE INVENTION

a. Field of the Invention

[0001] The present invention relates to a steerable sheath access device or introducer assembly such as those used in epicardial procedures, for the treatment of atrial fibrillation and ventricular tachycardias.

b. Background Art

[0002] Many medical procedures require the introduction of specialized medical devices into and/or around the human heart. In particular, there are a number of medical procedures that requires the introduction of specialized devices, including but not limited to catheters, dilators, and needles, to areas such as into the pericardial sac surrounding the heart in order to access the epicardial or outer surface of the heart. Catheters and access sheaths or introducers have been used for medical procedures for a number of years. It is necessary for introducers and catheters to exhibit a degree of flexibility to be able to maneuver through the vasculature of a patient during the performance of cardiac procedures. In additional, various configurations of introducers are necessary for the treatment of different cardiac conditions.

[0003] Atrial fibrillation and ventricular tachycardias are cardiac arrhythmias that result in an irregular heartbeat due to the irregular conduction of electrical impulses to the ventricles of the heart. It is believed that one method of treating atrial fibrillation is through the locating, accessing, stimulating, and ablation of epicardial neuroganglia. It is believed that atrial fibrillation can be controlled more completely by ablating neuroganglia heads located under (or inside) fat pads located on the epicardial surface of the heart. The fat pads are located at the junctions of the pulmonary veins, the inferior vena cava, and in the margin between the aorta and the superior vena cava, all of which may in fact be a major source of fibrillation. Current treatments that involve ablating alternate pathways internal to the heart may be ineffective in truly reaching neuroganlia and instead targets the legs of the neuroganglia, which can necessitate multiple ablations. As a result it is desirable to develop a method of targeting the neuroganlia heads so that the entire circuit can be resolved by ablating the head embedded in or below the fat pad.

[0004] In order to ablate the head of the fat pad located on the epicardial surface, it is necessary to use an ablation catheter that is able to access the epicardial surface of the heart. Traditional approaches to treating atrial fibrillation include the use of introducers or catheter systems that are inserted within the internal chambers of the heart to target areas for ablation. Traditional catheters and access devices, such as introducers, access these endocardial areas through a rigid elongated body that includes a curved portion for accessing areas of the heart and related vasculature for ablation. These traditional catheters and access devices can be too long in length to be used in certain pericardial procedures such as that for potential treatment of atrial fibrillation. Moreover, these traditional devices are not able to be maneuvered or steered to reach the epicardial surfaces for treatment or they may have to be curved throughout the pericardial sac and around the heart to reach the tissue areas of interest.

[0005] A steerable sheath access device for the treatment of atrial fibrillation is known from US 2005/0234436 A1. The catheter body of this known device can have any number of flexible segments, such as two, three, four, five, six, etc., at least one of which has a different stiffness than the others. The flexible segments can have any stiffness configuration that allows the catheter to move within the heart or surrounding area. The catheter further comprises a pull wire to deflect its flexible tip. The distal end of the pull wire can be anchored to the wall of the catheter body with the aid of an anchor ring.

BRIEF SUMMARY OF THE INVENTION

[0006] The invention is defined in the independent claim 1. Preferred embodiments are set forth in the dependent claims. Embodiments of the present invention including shorter steerable access sheaths or introducers may provide epicardial access for various ablation tools and devices for the performance of various ablation procedures or procedures involving alternate energy sources. The steerable access device provides an elongated member that exhibits primary and secondary curvatures for access to ablative surfaces or targets.

[0007] Accordingly, steerable sheath access device assemblies as provided by the present invention may be provided to enhance and perform the method of ablating epicardial surface for the treatment of atrial fibrillation and ventricular tachycardias.

[0008] The foregoing and other aspects, features, details, utilities, and advantages of embodiments of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009]

Figure 1 is an isometric view of steerable sheath access device according to an embodiment of the present invention;

Figures 2-4 are illustrative views of the steerable sheath access device positioned in relation to the epicardial surface of the heart during an ablation procedure;

Figure 5 is an isometric view of steerable sheath access device according to an embodiment of the

present invention;

Figure 6 is an isometric view of steerable sheath access device according to an embodiment of the present invention;

Figure 7 is an isometric view of steerable sheath access device according to an embodiment of the present invention showing the original position of the access sheath in phantom;

Figure 8 is an illustrative drawing showing the deflection points of the access sheath in accordance with an embodiment of the present invention;

Figure 9 is an illustrative drawing of pull wires associated with the access sheath in accordance with an embodiment of the present invention;

Figures 10 and 11 are isometric views of anchor rings provided within a steerable sheath access device in accordance with an embodiment of the present invention; and

Figure 12 is a cross-sectional view of the steerable sheath access device in accordance with an embodiment of the present invention;

DETAILED DESCRIPTION OF THE INVENTION

[0010] In general, the present invention relates to a steerable short sheath access device assembly for use in epicardial procedures, such as those used for the treatment of atrial fibrillation and ventricular tachycardia. The steerable access device of the assembly provides an elongated member that exhibits primary and secondary curvature for access, for example, to epicardial surfaces for performing ablation. For purposes of this description, similar features among the various embodiments described herein will be referred to by the same reference number. As will be appreciated, however, the structure of the various aspects may differ with respect to alternate embodiments.

[0011] The steerable access device, or introducer, of the assembly according to the present invention may be shorter in length than the traditional access devices to provide more effective access to the epicardial surface of the heart through the pericardial sac. In an embodiment, a steerable access device is comprised of a flexible elongated member that can readily reflect or adapt or conform to the curvature or profile of organs, such as the heart, therein defining a gradual curvature of the sheath for positioning the access device within the pericardial sac and ultimately in relation to the epicardial target surface of the heart for performance of various procedures.

[0012] As generally shown in the embodiment illustrated in Figure 1, the sheath access device 10 may comprise part of a steerable sheath access device assembly 12. The steerable sheath access device assembly 12 may be configured to facilitate access to the epicardial surface of the heart through the pericardial sac. Alternately, assembly 12 may be used, for example, for a number of different procedures. In an embodiment, the steerable sheath access device assembly 12 includes sheath access device 10 connected to a handle assembly 14 for controlling the deflection and movement of device 10, and may further include a valve assembly 16 for allowing introduction of medical device components through aperture 17 accessing inner cavity (not shown) of handle assembly 14, as well as a stopcock 18 that may be used to restrict the flow of liquid or gas through assembly 12 or to flush the assembly to disperse trapped air. Figures 2-12 below, describe alternate embodiments and illustrate exemplary applications of sheath access device 10.

[0013] As generally illustrated in Figure 1, sheath access device 10 is connected to handle assembly 14 as part of steerable sheath access device assembly 12. Sheath access device 10, also often referred to as an introducer, comprises an elongated member 20. Elongated member 20 includes a proximal end 22 and a distal end 24. Elongated member 20 further includes an inner lumen 32, e.g. as shown in Figures 2-4, that provides for the insertion and positioning of various medical tools and devices, including but not limited to, catheters, dilators, electrode tips for ablation, needles, and guide wires. Access sheath 10 facilitates the introduction and positioning of devices to establish contact with targeted tissue areas, such as the epicardial surface of the heart within the pericardial sac. Elongated member 20 further includes a proximal section 26 and a distal section 28. Proximal section 26 and distal section 28 may be integral with one another therein providing a single unitary elongated member 20. Moreover, proximal section 26 is positioned more distally with respect to proximal end 22 of elongated member 20 and distal section 28 is positioned more distally with respect to proximal section 26 of elongated member 20. Portions of proximal section 26 and distal section 28 intersect with one another and the components form a unitary sheath 10. Elongated member 10 further includes a distal tip portion 30. Distal tip portion 30 is provided yet further distally with respect to distal section 28 and extends to distal tip 24 of elongated member 20. Distal tip portion 30 may be tapered to form a desirable transition with devices that may be inserted through the inner lumen of elongated member 20. Distal tip 24 may be chamfered to provide a smooth transition end to elongated member 20 of sheath 10 and further provides an outlet for the inner lumen, so that the dilators, catheters, or other devices may exit sheath 10.

[0014] Sheath 10 is generally comprised of a biocompatible polymer material that exhibits various degrees of flexibility and rigidity, depending on the design and performance requirements. In an embodiment, elongated member 20 of sheath 10 is comprised of a thermoplastic material, such as, without limitation, PEBAX®. Throughout the length of elongated member 20 various materials such as thermoplastics (e.g. PEBAX®) that exhibit different degrees of hardness (or durometer) may be used. In addition, the material made be braided or provided in alternate configurations to achieve a desired degree or measure of rigidity and/or flexibility. The device may also be lined with Teflon in order to reduce friction during in-

sertion of various instruments. In an embodiment, proximal section 26 is made of a different material than the material comprising distal section 28, such that the hardness or durometer of proximal section 26 is greater than the hardness or durometer of distal section 28. According to an embodiment of the present invention, proximal section 26 may include a hardness/rigidity within the range of 50-70 durometer. For some embodiments the range may be 55-65 durometer. Distal section 28 includes a hardness/rigidity within the range of 35-45 durometer, and may, for example, be about a 40 durometer. In another embodiment, distal tip portion 30 is made of material, such that the hardness/rigidity of distal tip portion 30 is even less than distal section 28. This softness or flexibility can be provided to prevent damage to the pericardial sac and epicardial surface of the heart. Accordingly, distal tip portion 30 may have a hardness/rigidity within the range of 20-30 durometer, and for some embodiments may be approximately 25 durometer. In alternate embodiments, various sections of elongated member 20 may be radiopaque or include various fluorescent markers such that the access sheath is visible through fluoroscopy.

[0015] Variations in size and shape of sheath 10 may be used and are intended to encompass all applicable uses, including use on pediatric patients, as well as in adult human hearts. It is recognized that based on the application of device 10, the length of elongated member 20 may vary slightly to reflect the size of the patient being treated. Sheath 10, in accordance with the present invention, is generally 30,5 cm-43,2 cm (12-17 inches) in length. For some embodiments, sheath 10 may be about 43,2 cm (17 inches) in length. Accordingly, the length of proximal section 26 ranges from about 34,3 cm (13.5 inche) to about 39,4 cm (15.5 inches. For some embodiments, proximal section 26 is approximately 36,8 $\pm$ 1,3 cm (14.5 $\pm$ 0.5 inches) in length. Distal section 28 ranges from about 3,8 cm (1.5 inches) to about 8,9 cm (3.5 inches). For some embodiments, distal section 28 is approximately 6,4 cm$\pm$0,3 cm (2.5$\pm$0.1 inches) in length. Slight variations may be made to the length depending on the design or manufacturing of the system. Distal tip portion 30 is further provided and is only approximately 3,75 mm-3,683 mm (0.125-0.145 inches) in length. For some embodiments, distal tip portion 30 is about 3,683 mm (0.145 inches) in length.

[0016] As further seen in Figure 1 and in accordance with an embodiment of the present invention, sheath 10 includes two curves as provided by proximal section 26 and distal section 28 of elongated member 20. The curvatures may be created or formed via either one set or a plurality of sets of pull wires that run or extend along the length of elongated member 20 and are controlled by mechanisms provided within handle assembly 14. In one embodiment, for example, as shown in Figure 1, distal section 28 may include a primary curve that has an inner radius (r_1) that ranges from about 0.5 to about 2.0 centimeters depending on the deflection forces created or imparted by the user through the use of handle assembly 14. In an embodiment, the inner radius (r_1) is about 1.0 centimeters. Proximal section 26 further defines a secondary curve that includes an inner radius (r_2) that is substantially greater than the inner radius of the primary curve of distal section 28. As seen in Figure 1, secondary curve may also further includes a second inner radius (r_3) as further provided by a portion of the secondary curve. The arc or overall curve of the secondary curve of proximal section 26 may vary slight such that multiple radi (r) may define the radius of curvature of the secondary curve. Overall, and in accordance with the embodiments of the present invention, the inner radi (r_2, r_3) of the secondary curve provided by proximal section 26 are each substantially greater than (e.g., at least 3, 4, or more times) the inner radius (r_1) of the primary curve provided by distal section 28.

[0017] As seen in Figures 2-4, illustrative views of steerable sheath access device 10 positioned in relation to the epicardial surface of the heart during an ablation procedure are provided. Each of the Figures illustrate the various degrees of curvature of the proximal sections 26 and distal sections 28 as required during the performance and operation of the sheath access device 10. As can further be seen in comparing Figures 2-3 with Figure 4, as the inner radius of the primary curve decreases and creates a tighter curve, the inner radius of the secondary curve also decreases, although at a much lesser degree. Accordingly, as the primary curve is deflected by the tension applying to pull wires provided throughout elongated member 20, this results in the formation of or increase in secondary curve of proximal section 26.

[0018] In Figures 5-7, alternate embodiments of sheath access device 10, shown connected to handle assembly 14 as part of steerable sheath access device assembly 12, are provided. Figures 5-7 further disclose an embodiment of a sheath 10 that further includes a plurality of ring electrodes 36 disposed on the outer surface about distal section 28 of elongated member 20. Ring electrodes 36 may be provided in a number of combinations and distributed along distal section 28 of elongated member 20, so long as not to prevent or impede the primary curve configured by distal section 28 of sheath 10, as shown in Figure 7. Ring electrodes 36 may be used for mapping or ablation or any other type of procedure that might involve the incorporation of ring electrodes on the outer surface of distal section 28 of sheath 10. Ring electrodes 36 may be used for mapping or visualization of the tissue surface such that the information received from the mapping electrodes may be transmitting to a visualization or mapping processor or system, such as those found and used by the ENSTTE® NavX Navigation and Visualization Technology, referred to as the ENSITE® system developed by St. Jude Medical, Inc.

[0019] Figure 5 provides a steerable sheath access device assembly 12 having sheath 10 in a fully extended position/configuration. Accordingly, the deflection portion 34 of handle assembly 14 has not been rotated to

exert force or tension on the pull wires internal to elongated member. Overall, traditional handle assemblies used for sheath or other catheter assemblies may be incorporated for use with the present invention. Accordingly, either a unidirectional or a bidirectional handle may be used to control the deflection of sheath 10.

[0020] Figure 6 further provides an alternate view of an embodiment of the present invention including mapping electrodes 36 and further providing an electrical connector 40 for supplying electrical energy to handle assembly 14 and ultimately to mapping electrodes 36 provided on distal section 28 of elongated member 20.

[0021] Figure 7 illustrates the deflection of proximal section 26 and distal section 28 of the sheath 10. The distal section 28 may include, for example, one or more mapping electrodes 36. In accordance with an embodiment of the present invention, the primary curve provided by the deflection of distal section 28 has a smaller (and typically significantly smaller) inner radius than the inner radius corresponding to the secondary curve provided by the deflection of proximal section 26 of elongated member 20 of sheath 10.

[0022] The short access sheath 10 as provided and described above is steerable through the incorporation of and use of pull wires that extend from handle assembly 14, as shown in Figure 1, through elongated body 20 of sheath 10. In one embodiment, a single set of pull wires, i.e. 2-4 pull wires, are provided and disposed within sheath 10 for deflecting the movement of sheath 10 and creating the primary and secondary curves. In an embodiment, each pull wire may be separated by from 90-180 degrees from one another and may be integrated within elongated member 20 so as to extend to the region where distal section 28 intersects with distal tip portion 30. Accordingly, as rotation force from deflection member 34 of handle assembly 14 is applied, the pull wires undergo force which results in the deflection of proximal section 26 and distal section 28. Upon the application of force on the distal ends of pull wires, provided within distal section 28 of sheath 10, distal section 28 comprised of a less rigid material deflects at a great angle therein defining a smaller radius of curvature in comparison to the secondary curvature defined by proximal section 26.

[0023] Figures 8-12 illustrate an alternate embodiment of access sheath 10 wherein two sets of pull wires are incorporated within elongated member 20 and positioned to separately acuate deflection of distal section 28 at a primary deflection point (A) and proximal section 26 at a secondary deflection point (B), independently. In particular, Figure 8 is an illustrative drawing showing sample deflection points (A, B) of access sheath 10 in accordance with an embodiment of the present invention. Moreover, Figure 9 provides a corresponding illustration of pull wires associated with the access sheath in accordance with the embodiment of access sheath 10, for example as shown in Figure 8. The deflection of distal section 28 may be controlled by a primary set of pull wires 42 which extend along elongated member to the distal end of distal section 28. Primary pull wires 42, such as shown in Figure 9, are secured to distal end 44 of distal section 28 by an anchor ring 50, which may be configured as generally shown in Figure 10. A secondary set of pull wires 46 extends along elongated member 20 to at or about the point where distal section 28 intersects with proximal section 26. Secondary pull wires 46 are secured to the elongated member of sheath 10 by an anchor ring 52 as that shown in Figure 11. Although only distal section 28 is shown as deflected in Figure 8, proximal section 26 may deflect therein to provide a primary curve formed by distal section 28 and a secondary curve formed by proximal section 26. As previously described, distal section 28 includes a material that is comparatively more flexible and is less rigid that the material of proximal section 26. As a result, even with primary pull wires 42 to control and acuate the deflection of distal section 28, and secondary set of pull wires 46 control and acuate the deflection of proximal section 26, the inner radius (r_1) of curvature of distal section 28 is less than the inner radius of curvature (r_2, r_3) of proximal section 26.

[0024] Figures 10 and 11 provide illustrative views of the anchor rings 50, 52 used to secure primary pull wires 42 and secondary pull wires 46 within elongated member 20 of sheath 10. As previously discussed, anchor ring 50 is positioned at distal end 44 of distal section 28. Anchor ring 50 is generally cylindrical and may reflect the size and/or shape of elongated member 20 such that anchor ring 50 fits within elongated member and may be reflowed into position once primary pull rings are secured to anchor ring 50 through attachment mechanisms known in the industry. As seen in Figure 11, anchor ring 52 may comprise a clover-like design and can be provided with recessed grooves 54 for receiving primary pull wires 42 and secondary pull wires 46. In an embodiment anchor ring 52 is positioned at the secondary deflection point wherein proximal section 26 intersects with distal section 28. In one embodiment, pull wires may be stainless steel, such as for example the 304 type, and may be either round or rectangular in cross section. In another embodiment, nitinol wire may be used as pull wires.

[0025] Figure 12 shows a cross-sectional view of steerable sheath access device 10 in accordance with an embodiment of the present invention as taken along lines 12-12 of Figure 8 at the secondary deflection point. The pull wires may, for example, be encased in a polyimide or Teflon guide tubing 56. Secondary pull wires 46 can be secured to anchor ring 52 through various attachment mechanisms as known in the art. Access sheath 10 further comprises an outer body 58 thermoplastic material that can be provided in a braided configuration to achieve the flexibility and desired hardness of the proximal and distal sections 26, 28. An outer coating of (e.g. PEBAX®) may then be provided to create an outer surface 60 of elongated member 20 of sheath 10.

[0026] Access sheath device 10 as previously described in the various embodiments may be provided as part of an assembly or kit which provides and incorpo-

rates the use of various tools and devices that correspond or are appropriately configured for a given size of access sheath 10. Because it may be desirable to have a shortened access device, it may be further desirable to include various medical tools that may be inserted within the inner lumen of access sheath 10 for procedures on the epicardial surface of the heart.

[0027] In particular, various catheters, including RF ablation catheters, such as the medium-sweep Safire cooled directional catheter, may be included to have a shortened catheter shaft (e.g. ranging from 76,2 cm-88,9 cm (30-35 inches) in length, such that the catheter shaft may be readily incorporated within access sheath for performing ablative procedures. Other types of energy sources may also be used in connection with access sheath device 10 of the present invention, such as ultrasound (e.g. HIFU), laser, or other energy used for performing ablative procedures. Additional electrode tips may be used and configured, such as a closed loop cooled tip, for incorporation with the shorted catheter assembly for insertion within access sheath device 10.

[0028] Additional medical devices for incorporation in the access sheath include a dilator exhibiting an increased softer shaft, similar to the hardness of the material comprising distal section 28 of elongated member 20, described above. The dilator may include a blunt nose tip and a shorted shaft. The device could include several dilators a rather stiff device which is used to access the pericardial space, a softer tipped device to aid in pericardial navigation and finally a soft blunt tipped dilator which is used to plug sheath when device is left in position for extended periods of time while physician performs endocardial procedure. The dilator may further provide a soft closed nosed dilator that may be used after access to the pericardial sac is gained and the access sheath is left in position while other procedures are being performed, in order to aid in keeping pericardial fluid in the area. In an embodiment, the dilator is provided to open the needle puncture in the pericardium and provide a smooth transition between the guidewire and the sheath outside diameter.

[0029] A Touhy needle may also be used to gain access to the pericardial sac, more particularly for example a 1,15 mm x 11,43 cm (17 ga x 4.5") long needle (e.g. Soda technique). A guidewire may also be used, such as a long floppy tip guidewire. Each of these components may aid in the physician being able to access and ablation in the pericardial space using radiofrequency techniques, although other energy sources may be used.

[0030] An assembly or kit for use in treating atrial fibrillation through performing ablative procedures on the epicardial surface of the heart may include shortened steerable access sheath device 10, as such described in accordance with the multiple embodiments of the present invention.

[0031] Although a number of embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention. All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting.

Claims

1. A steerable sheath access device assembly (12), comprising
a handle assembly (14), and
a sheath access device (10), comprising:

an elongated member (20) having a proximal end (22), a distal end (24), and a lumen (32) extending through the elongated member (20) from the proximal end (22) to the distal end (24); the elongated member (20) having a proximal section (26) made of a first material and a distal section (28) made of a second material, the proximal section (26) extending from the proximal end (22) to an intersection of the proximal section (26) and the distal section (28), and the distal section (28) extending from the intersection of the proximal section (26) and the distal section (28) to the distal end (24), wherein the handle assembly (14) is connected to the proximal end (22) of the elongated member (20),
a primary pull wire (42) connected to the elongated member (20), the primary pull wire (42) extending along the length of the elongated member (20) from the handle assembly to a first anchor ring (50) at a distal end of the distal section (28), wherein the first anchor ring (50) is provided at least in part within the lumen of the elongated member (20), and
a secondary pull wire (46) connected to the elongated member (20), the secondary pull wire (46) extending along the length of the elongated member (20) from the handle assembly to a second anchor ring (52) at the intersection of the proximal section (26) and the distal section (28), wherein the second anchor ring (52) is provided at least in part within the lumen of the elongated

member (20), wherein the first material of the proximal section (26) is more rigid than the second material of the distal section (28);
wherein the elongated member (20) is configured such that deflection of the distal section (28) defines a primary curve including a first inner radius (r_1) of curvature, wherein the elongated member (20) is configured such that deflection of the proximal section (26) defines a secondary curve including a second inner radius (r_2, r_3) of curvature, and wherein the first inner radius (r_1) of curvature of the primary curve is less than the second inner radius (r_2, r_3) of curvature of the secondary curve.

2. The assembly (12) of claim 1, wherein the distal section (28) has a hardness less than the hardness of the proximal section (26).

3. The assembly (12) of claim 1 or 2, including a tip portion (30) disposed on the distal end of the distal section (28).

4. The assembly (12) of claim 3, wherein the tip portion (30) is less rigid than the proximal section (26) and distal section (28) of the elongated member (20).

5. The assembly (12) of any one of the preceding claims, wherein the length of the elongated member (20) ranges from about 30,5 cm to about 43,2 cm (12 to about 17 inches).

6. The assembly (12) of any one of the preceding claims, wherein the length of the proximal section (26) is 36,8 $\pm$ 1,3 cm (14.5 $\pm$ 0.5 inches).

7. The assembly (12) of any one of the preceding claims, wherein the length of the distal section (28) ranges from about 3,8 cm (1.5 cm inches) to about 8,9 cm (3.5 inches).

8. The assembly (12) of claim 5, wherein the length of the distal section (28) is 6,4 cm $\pm$ 0,3 cm (2.5 $\pm$ 0.1 inches).

9. The assembly (12) of any one of the preceding claims, wherein a plurality of primary pull wires (42) is provided and the second anchor ring (52) includes a plurality of depressions (54) for receiving the primary pull wires (42) an exterior surface of the second anchor ring (52).

10. The assembly (12) of any one of the preceding claims, wherein a plurality of secondary pull wires (46) is provided and the secondary pull wires (46) are connected to an interior portion of the second anchor ring (52).

11. The assembly (12) of any one of the preceding claims, wherein the elongated member (20) is comprised of a thermoplastic.

12. The assembly (12) of any one of the preceding claims, wherein the arc length of the secondary curve of the proximal section (26) is longer than the arc length of the primary curve of the distal section (28).

13. The assembly (12) of any one of the preceding claims, including an electrode (36) connected to the distal section (28) of the elongated member (20).

14. The assembly (12) according to any one of the previous claims;
wherein the handle assembly (14) includes an outer body portion having a proximal end and a distal end, the distal end of the assembly is coupled to the proximal end (22) of the elongated member (20), the handle assembly further including a deflection handle portion for controlling the deflection and movement of the elongated member (20) and an inner cavity extending along the length of the handle assembly; and
wherein the assembly (12) further comprises a valve assembly (16) having an opening coupled to the inner cavity of the handle assembly (14) and the lumen (32) of the elongated member (20) therein providing a passageway.

15. An ablation assembly for use in performing ablation procedures, comprising:

steerable sheath access device assembly (12) according to claim 14;
a dilator for insertion into the passageway defined by the steerable sheath access device assembly (12);
an ablation catheter comprising a catheter shaft and an ablation electrode for insertion into the passageway defined by the steerable sheath access device assembly (12);
a needle for insertion through the steerable sheath access device (10); and
a guidewire for use in positioning the steerable sheath access device assembly (12).

Patentansprüche

1. Lenkbare Hüllrohrzugriffsvorrichtungsbaugruppe (12) mit:

einer Handgriffbaugruppe (14), und
einer Hüllrohrzugriffsvorrichtung (10) mit einem länglichen Bauteil (20), das ein proximales Ende (22), ein distales Ende (24) und ein Lumen (32) aufweist, das sich durch das läng-

liche Bauteil (20) von dem proximalen Ende (22) zu dem distalen Ende (24) erstreckt, wobei das längliche Bauteil (20) einen proximalen Abschnitt (26), der aus einem ersten Material hergestellt ist, und einen distalen Abschnitt (28) aufweist, der aus einem zweiten Material hergestellt ist, wobei sich der proximale Abschnitt (26) von dem proximalen Ende (22) zu einem Übergang des proximalen Abschnitts (26) und des distalen Abschnitts (28) erstreckt, und der distale Abschnitt (28) sich von dem Übergang des proximalen Abschnitts (26) und des distalen Abschnitts (28) zu dem distalen Ende (24) erstreckt, bei dem die Handgriffbaugruppe (14) mit dem proximalen Ende (22) des länglichen Bauteils (20) verbunden ist,
einem ersten Ziehdraht (42), der mit dem länglichen Bauteil (22) verbunden ist, wobei sich der erste Ziehdraht entlang der Länge des länglichen Bauteils (20) von der Handgriffbaugruppe zu einem ersten Ankerring (50) an einem distalen Ende des distalen Abschnitts (28) erstreckt, bei dem der erste Ankerring (50) zumindest teilweise innerhalb des Lumens des länglichen Bauteils (20) vorgesehen ist, und
einem zweiten Ziehdraht (46), der mit dem länglichen Bauteil (20) verbunden ist, wobei sich der zweite Ziehdraht (46) entlang der Länge des länglichen Bauteils (20) von der Handgriffbaugruppe zu einem zweiten Ankerring (52) an dem Übergang des proximalen Abschnitts (26) und des distalen Abschnitts (28) erstreckt,
bei dem der zweite Ankerring (52) zumindest teilweise innerhalb des Lumen des länglichen Bauteils (20) vorgesehen ist,
bei dem das erste Material des proximalen Abschnitts (26) steifer als das zweite Material des distalen Abschnitts (28) ist,
bei dem das längliche Bauteil (20) so konfiguriert ist, dass eine Auslenkung des distalen Abschnitts (28) eine erste Kurve definiert, die einen ersten Krümmungsinnenradius (r_1) enthält, wobei das längliche Bauteil (20) so konfiguriert ist, dass die Auslenkung des proximalen Abschnitts (26) eine zweite Krümmung definiert, die einen zweiten Krümmungsinnenradius (r2, r3) enthält, und wobei der erste Krümmungsinnenradius (r_1) der ersten Krümmung kleiner als der zweite Krümmungsinnenradius (r_2, r_3) der zweiten Krümmung ist.

2. Baugruppe (12) nach Anspruch 1, bei dem der distale Abschnitt (28) eine Härte kleiner als die Härte des proximalen Abschnitts (26) aufweist.

3. Baugruppe (12) nach Anspruch 1 oder 2, die einen Spitzenteil (30) enthält, der an dem distalen Ende des distalen Abschnitts (28) angeordnet ist.

4. Baugruppe (12) nach Anspruch 3, bei dem der Spitzenteil (30) weniger steif als der proximale Abschnitt (26) und der distale Abschnitt (28) des länglichen Bauteils (20) ist.

5. Baugruppe (12) nach einem der vorhergehenden Ansprüche, bei der die Länge des länglichen Bauteils (20) in einem Bereich von ungefähr 30,5 cm bis etwa 43,2 cm (12 bis etwa 17 Inch) liegt.

6. Baugruppe (12) nach einem der vorhergehenden Ansprüche, bei der die Länge des proximalen Abschnitts (26) 36,8 $\pm$ 1,3 cm (14,5 $\pm$ 0,5 Inch) ist.

7. Baugruppe (12) nach einem der vorhergehenden Ansprüche, bei der die Länge des distalen Abschnitts (28) in einem Bereich zwischen etwa 3,8 cm (1,5 Inches) bis etwa 8,9 cm (3,5 Inches) ist.

8. Baugruppe (12) nach Anspruch 5, bei dem die Länge des distalen Abschnitts (28) 6,4 cm $\pm$ 0,3 cm (2,5 $\pm$ 0,1 Inches) ist.

9. Baugruppe (12) nach einem der vorhergehenden Ansprüche, bei der eine Mehrzahl von ersten Ziehdrähten (42) vorgesehen ist und der zweite Ankerring (52) eine Mehrzahl von Vertiefungen (54) zum Aufnehmen der ersten Ziehdrähte (42) an einer äußeren Oberfläche des zweiten Ankerrings (52) enthält.

10. Baugruppe (12) nach einem der vorhergehenden Ansprüche, bei der eine Mehrzahl von zweiten Ziehdrähten (46) vorgesehen ist und die zweiten Ziehdrähte (46) mit einem inneren Teil des zweiten Ankerrings (52) verbunden sind.

11. Baugruppe (12) nach einem der vorhergehenden Ansprüche, bei der das längliche Bauteil (20) aus einem Thermoplast hergestellt ist.

12. Baugruppe (12) nach einem der vorhergehenden Ansprüche, bei der die Bogenlänge der zweiten Krümmung des proximalen Abschnitts (26) länger als die Bogenlänge der ersten Krümmung des distalen Abschnitts (28) ist.

13. Baugruppe (12) nach einem der vorhergehenden Ansprüche, die eine Elektrode (36) enthält, die mit dem distalen Abschnitt (28) des länglichen Bauteils (20) verbunden ist.

14. Baugruppe (12) nach einem der vorhergehenden Ansprüche,
bei der die Handgriffbaugruppe (14) einen äußeren Körperteil enthält, der ein proximales Ende und ein distales Ende aufweist, wobei das distale Ende der Baugruppe mit dem proximalen Ende (22) des läng-

lichen Bauteils (20) gekoppelt ist, wobei die Handgriffbaugruppe weiter einen Auslenkungshandgriffteil zum Steuern der Auslenkung und Bewegung des länglichen Bauteils (20) und einem inneren Hohlraum enthält, der sich entlang der Länge der Handgriffbaugruppe erstreckt, und
bei der die Baugruppe (12) weiter eine Ventilbaugruppe (16) aufweist, die eine Öffnung aufweist, die mit dem inneren Hohlraum der Handgriffbaugruppe (14) und dem Lumen (32) des länglichen Bauteils (20) gekoppelt ist und darin einen Passagenweg vorsieht.

15. Ablationsbaugruppe zur Verwendung beim Ausführen von Ablationsprozeduren, mit einer lenkbaren Hüllrohrzugriffsvorrichtungsbaugruppe (12) nach Anspruch 14,
einem Dilator zur Einführung in den Passagenweg, der durch die lenkbare Hüllrohrzugriffsvorrichtungsbaugruppe (12) definiert ist,
einem Ablationskatheter, der einen Katheterschaft und eine Ablationselektrode aufweist, zur Einführung in den Passagenweg, der durch die lenkbare Hüllrohrzugriffsvorrichtungsbaugruppe (12) definiert ist,
einer Nadel zur Einführung durch die lenkbare Hüllrohrzugriffsvorrichtung (10), und einem Führungsdraht zur Verwendung bei der Positionierung der lenkbaren Hüllrohrzugriffsvorrichtungsbaugruppe (12).

Revendications

1. Ensemble (12) de dispositif d'accès à gaine orientable, comprenant
un ensemble manche (14), et
un dispositif d'accès (10) à gaine, comprenant un élément allongé (20) ayant une extrémité proximale (22), une extrémité distale (24) et une lumière (32) s'étendant à travers l'élément allongé (20) depuis l'extrémité proximale (22) jusqu'à l'extrémité distale (24) ; l'élément allongé (20) ayant une section proximale (26) composée d'un premier matériau et une section distale (28) composée d'un second matériau, la section proximale (26) s'étendant depuis l'extrémité proximale (22) jusqu'à une intersection de la section proximale (26) et de la section distale (28), et la section distale (28) s'étendant depuis l'intersection de la section proximale (26) et de la section distale (28) jusqu'à l'extrémité distale (24), dans lequel l'ensemble manche (14) est relié à l'extrémité proximale (22) de l'élément allongé (20),
un fil de traction primaire (42) relié à l'élément allongé (20), le fil de traction primaire (42) s'étendant sur la longueur de l'élément allongé (20) depuis l'ensemble manche jusqu'à un premier anneau d'ancrage (50) au niveau d'une extrémité distale de la section distale (28), dans lequel le premier anneau d'ancrage (50) est disposé au moins en partie dans la lumière de l'élément allongé (20), et
un fil de traction secondaire (46) relié à l'élément allongé (20), le fil de traction secondaire (46) s'étendant sur la longueur de l'élément allongé (20) depuis l'ensemble manche jusqu'à un second anneau d'ancrage (52) au niveau de l'intersection de la section proximale (26) et de la section distale (28),
dans lequel le second anneau d'ancrage (52) est disposé au moins en partie dans la lumière de l'élément allongé (20),
dans lequel le premier matériau de la section proximale (26) est plus rigide que le second matériau de la section distale (28) ; dans lequel l'élément allongé (20) est configuré de telle sorte que la déviation de la section distale (28) définit une courbe primaire incluant un premier rayon intérieur (r_1) de courbure, dans lequel l'élément allongé (20) est configuré de telle sorte que la déviation de la section proximale (26) définit une courbe secondaire incluant un second rayon intérieur (r_2, r_3) de courbure, et dans lequel le premier rayon intérieur (r_1) de courbure de la courbe primaire est inférieur au second rayon intérieur (r_2, r_3) de courbure de la courbe secondaire.

2. Ensemble (12) selon la revendication 1, dans lequel la section distale (28) présente une dureté inférieure à la dureté de la section proximale (26).

3. Ensemble (12) selon la revendication 1 ou 2, incluant une partie pointe (30) disposée sur l'extrémité distale de la section distale (28).

4. Ensemble (12) selon la revendication 3, dans lequel la partie pointe (30) est moins rigide que la section proximale (26) et la section distale (28) de l'élément allongé (20).

5. Ensemble (12) selon l'une quelconque des revendications précédentes, dans lequel la longueur de l'élément allongé (20) est comprise dans la plage d'environ 30,5 cm à environ 43,2 cm (12 à environ 17 pouces).

6. Ensemble (12) selon l'une quelconque des revendications précédentes, dans lequel la longueur de la section proximale (26) est de 36,8 ± 1,3 cm (14,5 ± 0,5 pouce).

7. Ensemble (12) selon l'une quelconque des revendications précédentes, dans lequel la longueur de la section distale (28) va d'environ 3,8 cm (1,5 pouce) à environ 8,9 cm (3,5 pouces).

8. Ensemble (12) selon la revendication 5, dans lequel la longueur de la section distale (28) est de 6,4 ± 0,3 cm (2,5 ± 0,1 pouce).

9. Ensemble (12) selon l'une quelconque des revendications précédentes, dans lequel une pluralité de fils de traction primaires (42) est prévue et le second anneau d'ancrage (52) inclut une pluralité de renfoncements (54) pour recevoir les fils de traction primaires (42) sur une surface extérieure du second anneau d'ancrage (52).

10. Ensemble (12) selon l'une quelconque des revendications précédentes, dans lequel une pluralité de fils de traction secondaires (46) est prévue et les fils de traction secondaires (46) sont reliés à une partie intérieure du second anneau d'ancrage (52).

11. Ensemble (12) selon l'une quelconque des revendications précédentes, dans lequel l'élément allongé (20) se compose d'un thermoplastique.

12. Ensemble (12) selon l'une quelconque des revendications précédentes, dans lequel la longueur d'arc de la courbe secondaire de la section proximale (26) est supérieure à la longueur d'arc de la courbe primaire de la section distale (28).

13. Ensemble (12) selon l'une quelconque des revendications précédentes, incluant une électrode (36) reliée à la section distale (28) de l'élément allongé (20).

14. Ensemble (12) selon l'une quelconque des revendications précédentes ;
dans lequel l'ensemble manche (14) inclut une partie corps extérieur ayant une extrémité proximale et une extrémité distale, l'extrémité distale de l'ensemble est accouplée à l'extrémité proximale (22) de l'élément allongé (20), l'ensemble manche incluant en outre une partie manche de déviation pour commander la déviation et le déplacement de l'élément allongé (20) et une cavité intérieure s'étendant sur la longueur de l'ensemble manche ; et
dans lequel l'ensemble (12) comprend en outre un ensemble clapet (16) ayant une ouverture accouplée à la cavité intérieure de l'ensemble manche (14) et la lumière (32) de l'élément allongé (20) dans celui-ci procurant un passage.

15. Ensemble d'ablation à utiliser pour réaliser des procédures d'ablation, comprenant :

l'ensemble (12) de dispositif d'accès à gaine orientable selon la revendication 14 ;
un dilatateur pour insertion dans le passage défini par l'ensemble (12) de dispositif d'accès à gaine orientable ;
un cathéter d'ablation comprenant une tige de cathéter et une électrode d'ablation pour insertion dans le passage défini par l'ensemble (12) de dispositif d'accès à gaine orientable ;
une aiguille pour insertion à travers le dispositif d'accès (10) à gaine orientable ; et
un fil-guide à utiliser pour positionner l'ensemble (12) de dispositif d'accès à gaine orientable.

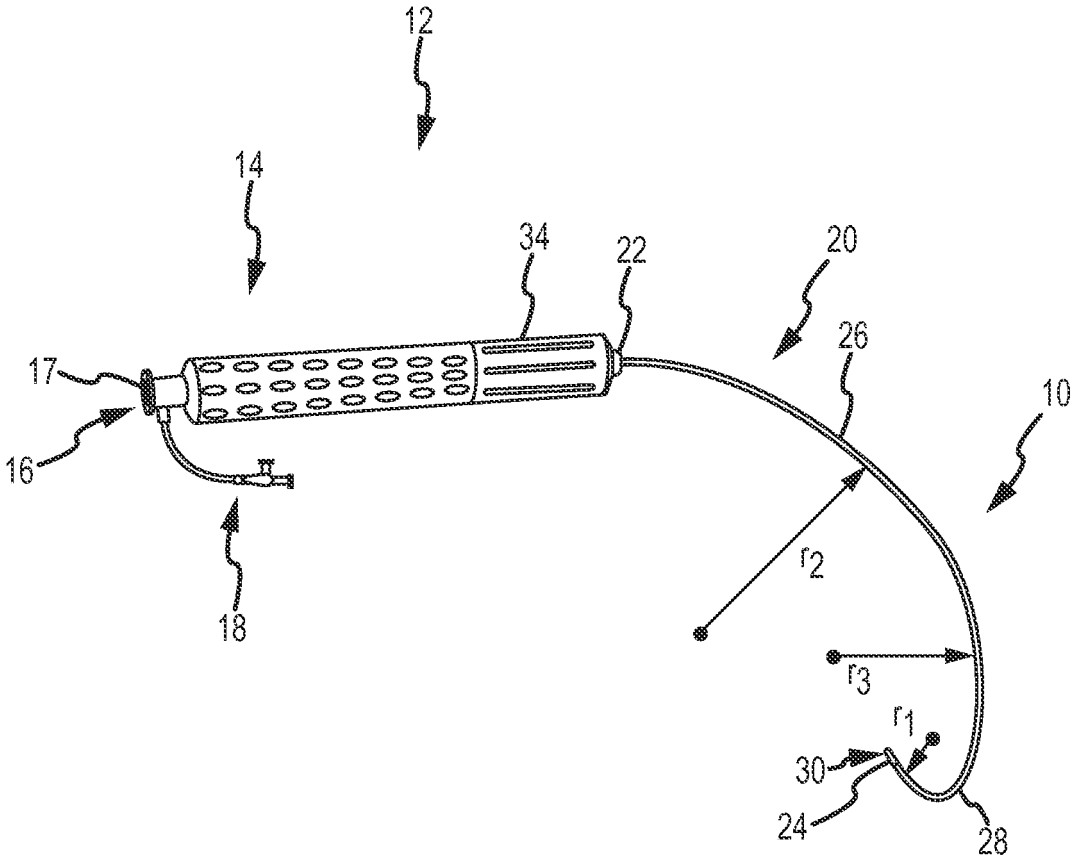

FIG.1

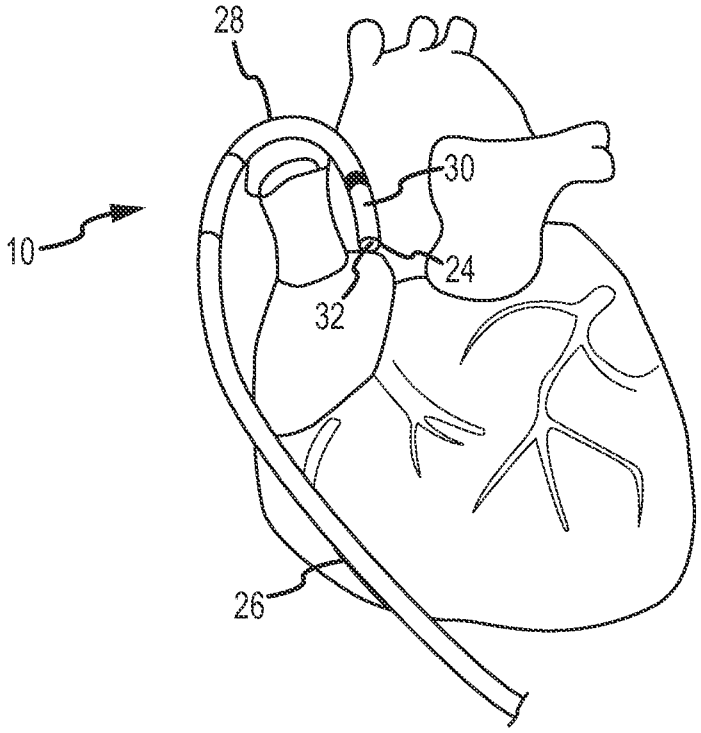

FIG.2

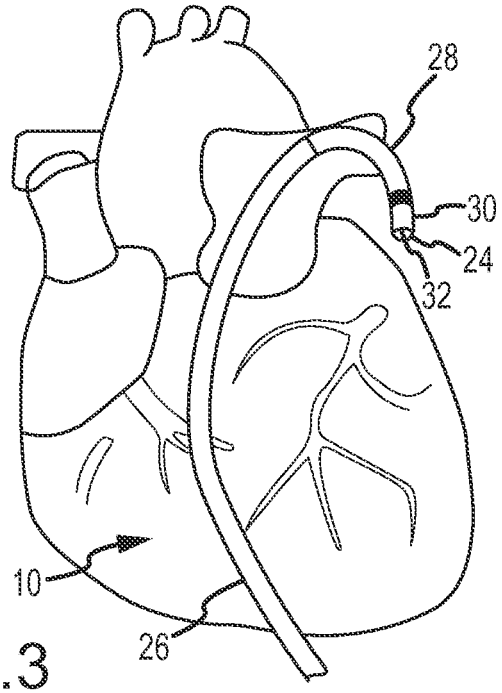

FIG.3

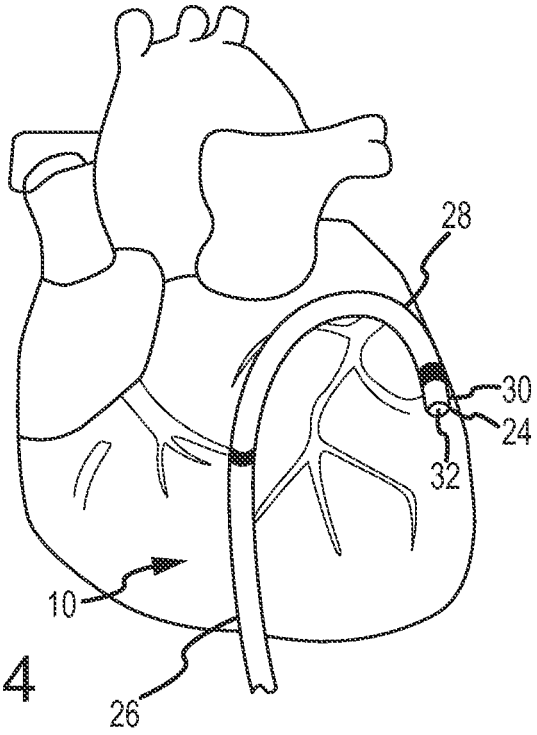

FIG.4

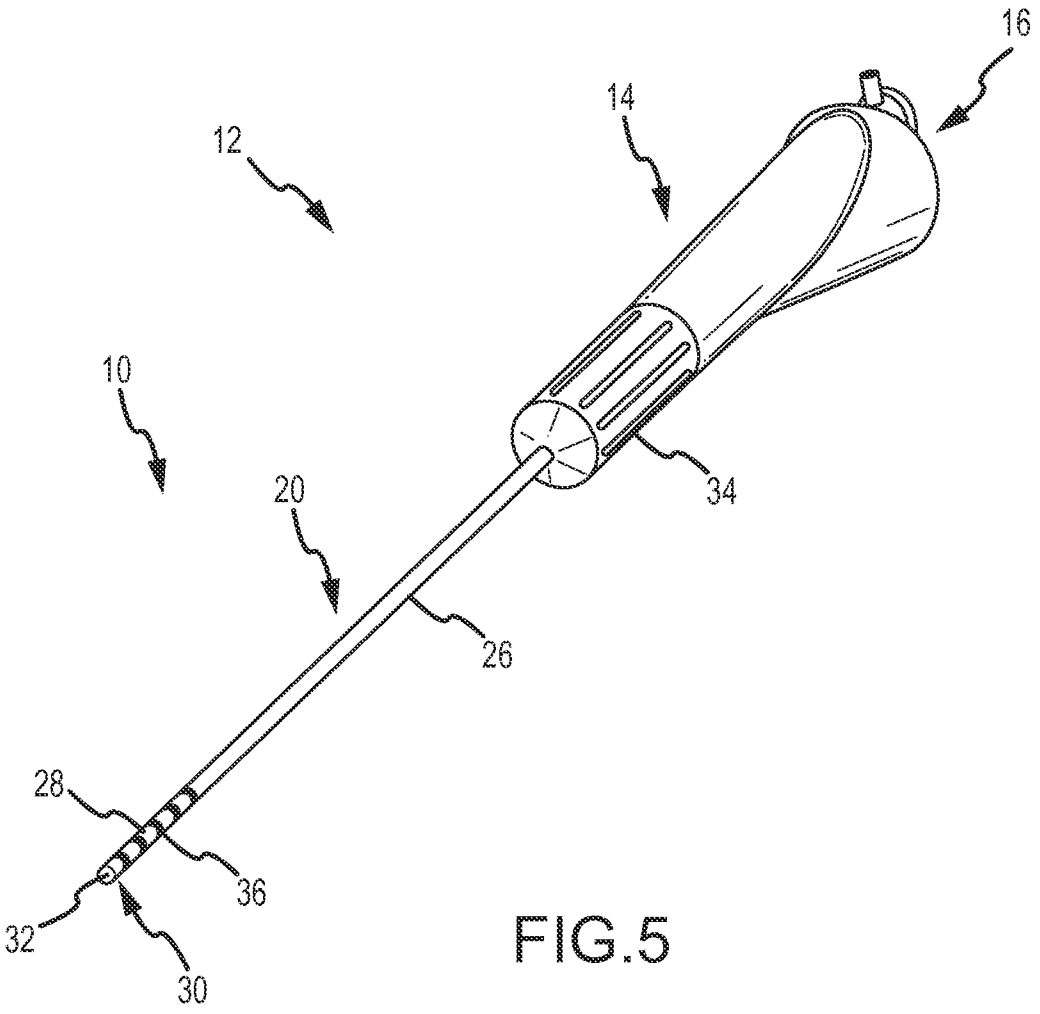

FIG.5

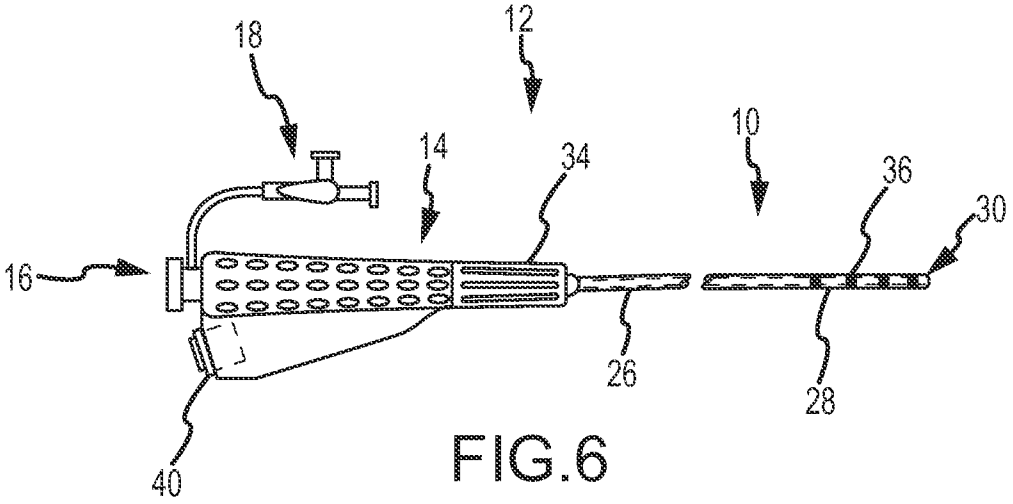

FIG.6

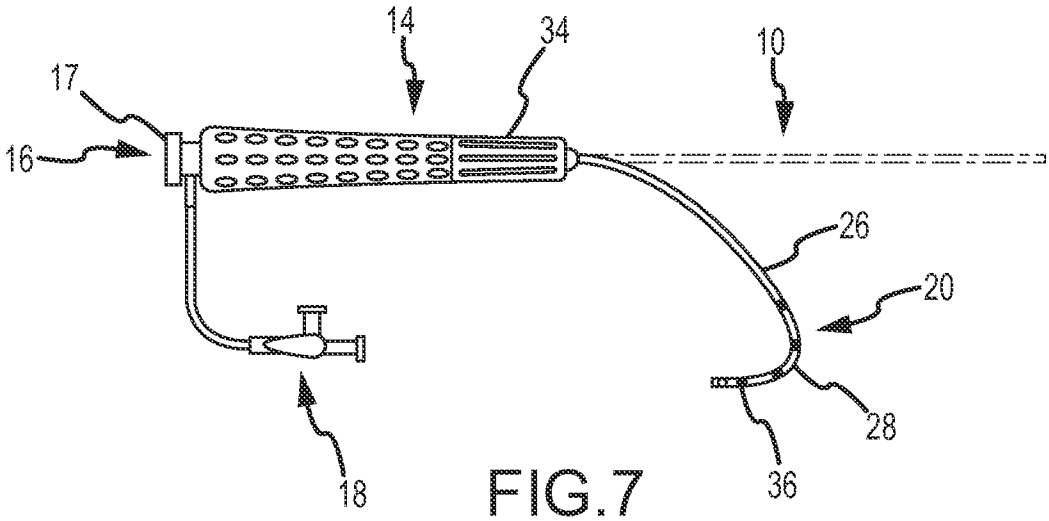

FIG.7

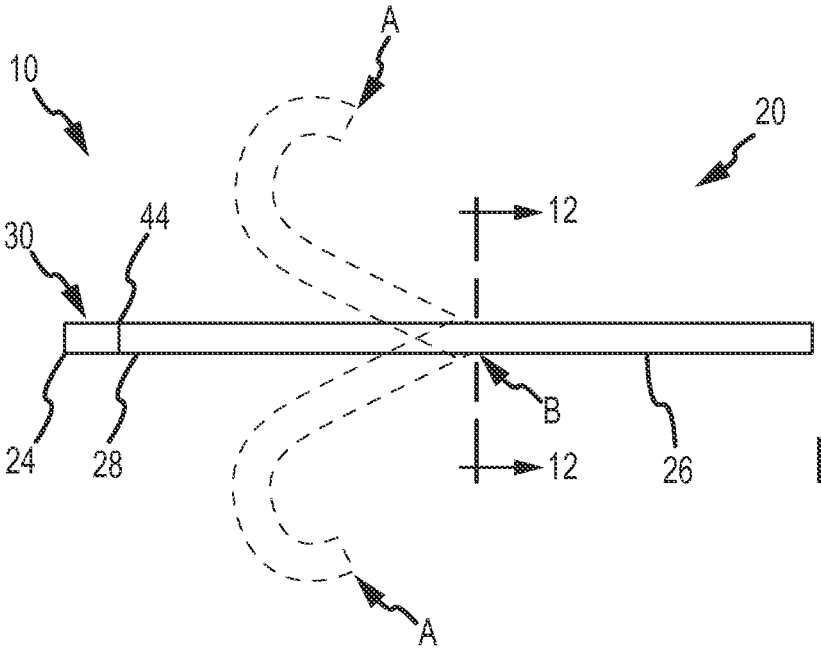

FIG.8

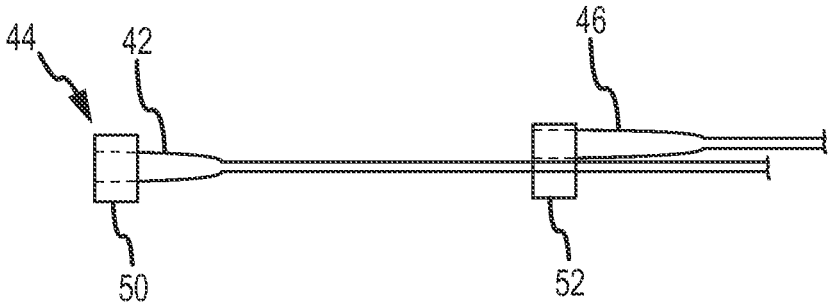

FIG.9

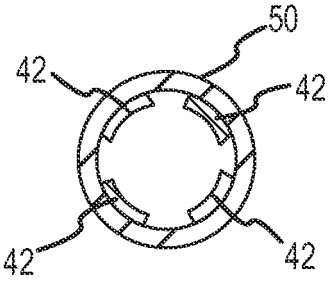

FIG.10

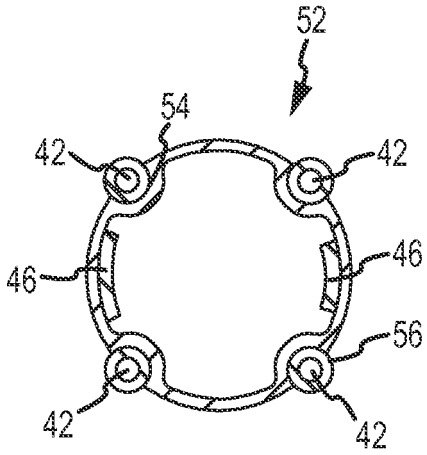

FIG.11

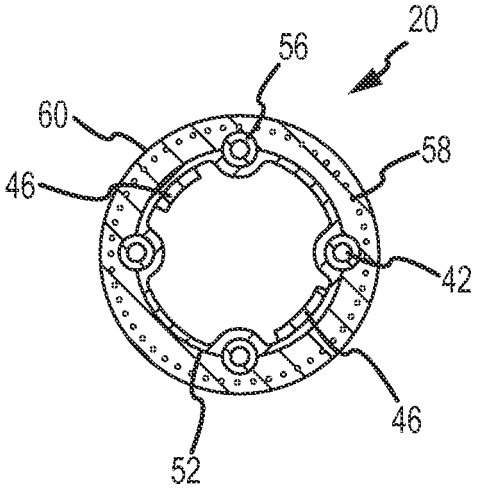

FIG.12

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 20050234436 A1 **[0005]**

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申请(专利权)人(译)	ST.犹达医疗用品，房颤DIVISION，INC.		
当前申请(专利权)人(译)	ST.犹达医疗用品，房颤划分，		
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代理机构(译)	KRAMER - HARSH - 施密特陈		
优先权	60/828939 2006-10-10 US		
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外部链接	Espacenet		

摘要(译)

公开了配置用于将电极（28、126、228）连接到导管或护套的电路（10、110、210）。回路（10、110、210）包括具有纵轴（14、214）并构造成沿导管或鞘管的长度的至少一部分延伸的构件（12、112、212）。电路（10、110、210）还包括印在构件（12、112、212）上的迹线（16、116、230），其中迹线（16、116、230）包括至少一个纵向段（18）。大体上沿着纵向轴线（14、214）的至少一部分延伸的第一部分118、118）和大体上横向于纵向轴线（14、214）延伸的横向部分（20、120）。在一个实施例中，电路还包括在迹线（16、116、230）的横向段（20、120）附近与电路（10、110、210）成一体并从其延伸的焊盘（26、126、226）。 。还公开了一种导管或护套组件，其包括电路（10、110、210）和连接至电路（10、110、210）的电极（28、126、228）。还提供了一种形成导管或护套组件的方法。