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(54) **HIGH RESOLUTION CARDIAC MAPPING ELECTRODE ARRAY CATHETER**

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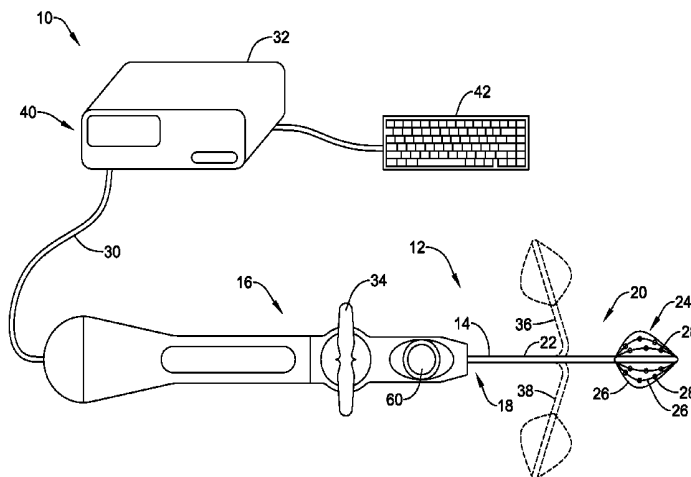
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(57) **ABSTRACT**
Devices, systems, and methods for performing a mapping procedure on body tissue are disclosed. An example mapping device for mapping a tissue surface includes an elongate shaft and an electrode assembly. The electrode assembly includes a plurality of splines and a plurality of electrodes disposed on at least some of the splines. The electrode assembly is capable of moving between a collapsed configuration and an expanded configuration. In the expanded configuration, the electrode assembly may have a generally planar structure.

20 Claims, 4 Drawing Sheets



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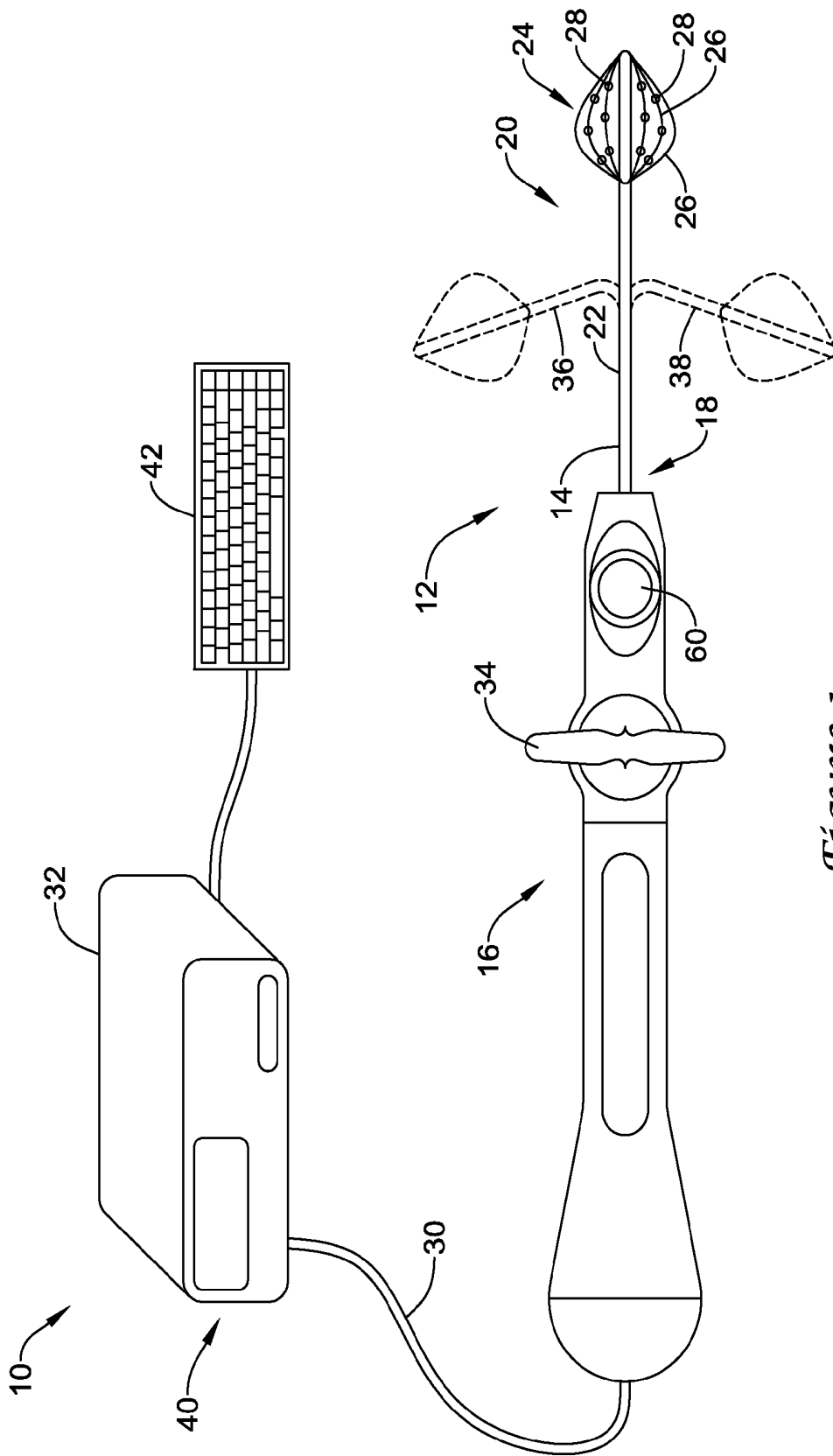


Figure 1

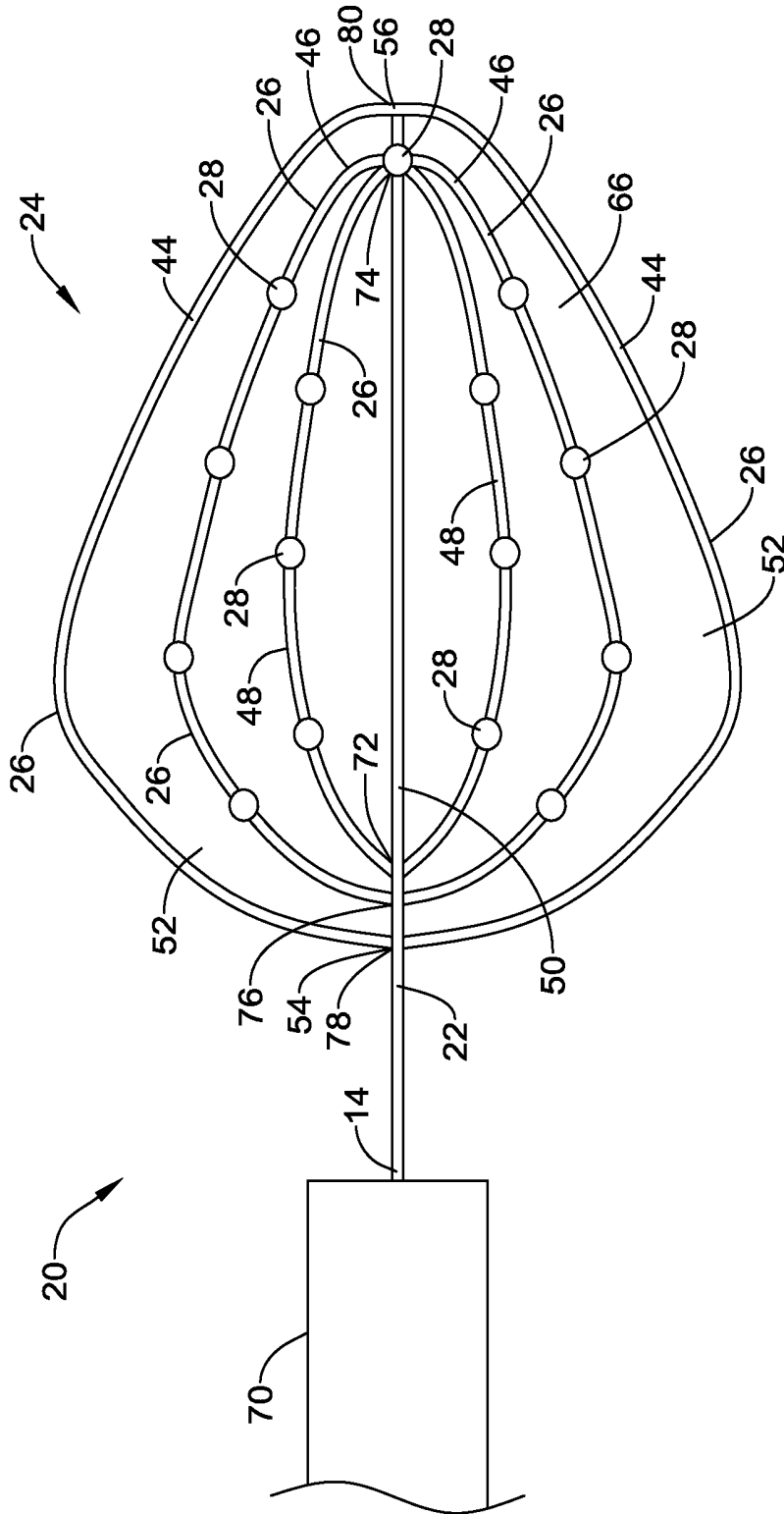


Figure 2

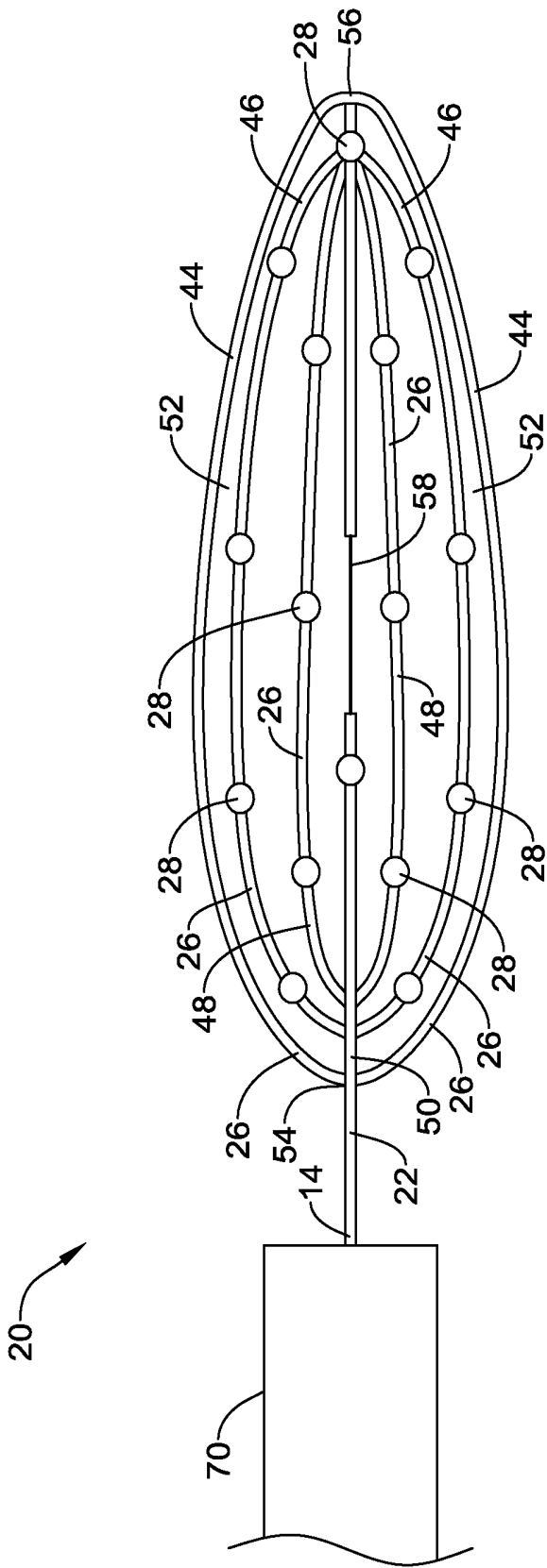


Figure 3

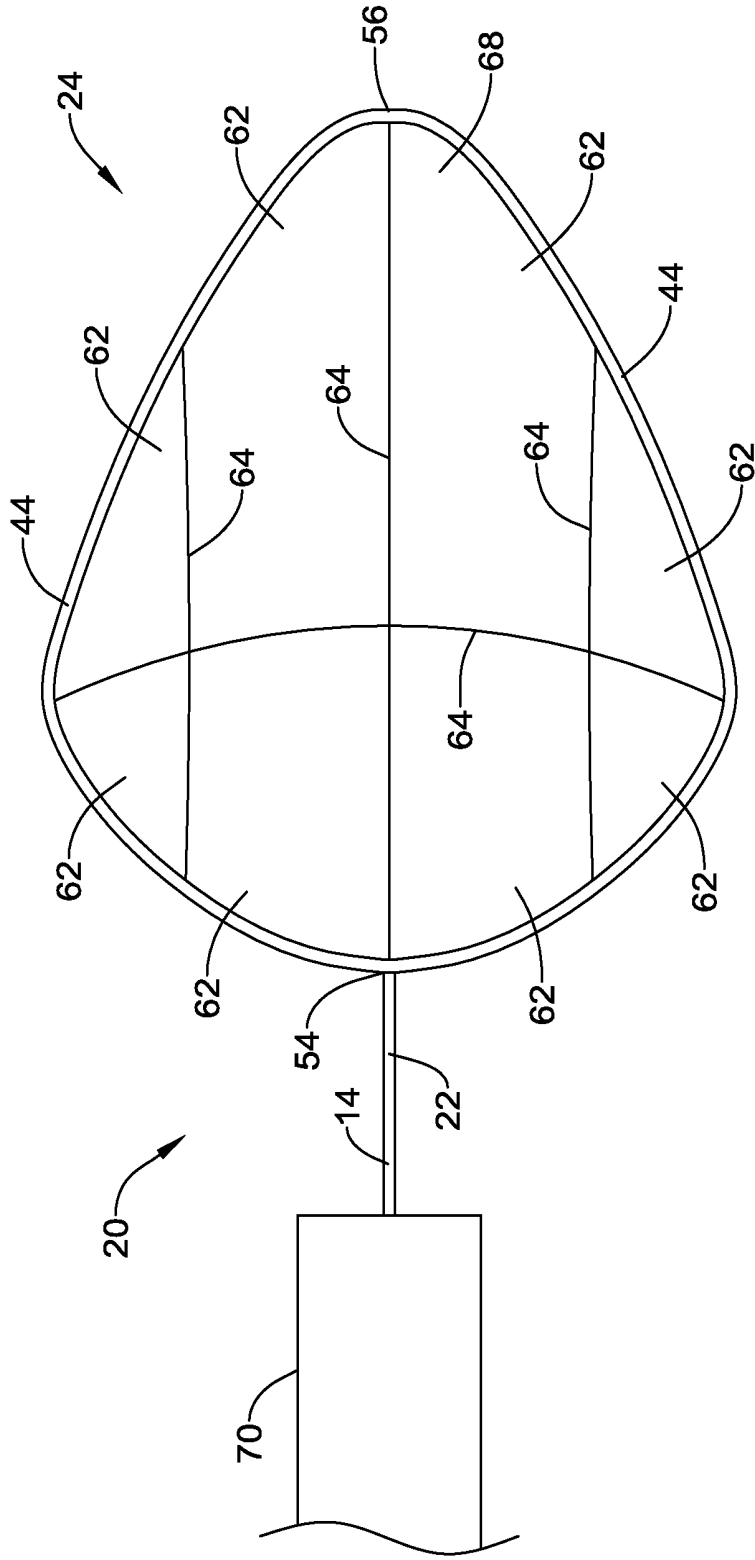


Figure 4

HIGH RESOLUTION CARDIAC MAPPING ELECTRODE ARRAY CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Ser. No. 61/890,733, filed Oct. 14, 2013, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

The present disclosure relates generally to a medical device for creating anatomical and electrical maps of the heart. More specifically, the present disclosure pertains to a steerable catheter with a conformal planar electrode array for creating high resolution anatomical and electrical maps of the heart.

BACKGROUND

Cardiac mapping has become a standard practice in the cardiac electrophysiology practice. An anatomical map created by a catheter and mapping system provides a means of navigating the intercardiac space with minimal use of fluoroscopy. More importantly the voltage and activation maps generated using these system provide crucial information to diagnose and treat various arrhythmias. However, it may be desirable to provide a device for high resolution mapping of the epicardial surface.

SUMMARY

The disclosure relates generally to a mapping device including a generally planar electrode assembly for mapping body tissue. Accordingly, one illustrative embodiment is a mapping device for analyzing body tissue including an elongate shaft having a proximal section and a distal section. An electrode assembly having a first side surface and a second side surface may be coupled to the distal section of the elongate shaft. The electrode assembly may be capable of moving between a collapsed configuration and an expanded configuration. The electrode assembly may further include a plurality of splines including a central mid spline and a plurality of electrodes disposed on at least some of the plurality of splines.

Another illustrative embodiment is a mapping system for analyzing body tissue including an imaging and control system and a handle in electrical communication with the imaging and control system. The system may further include an elongate shaft having a proximal section and a distal section, the proximal section connected to the handle and extending distally therefrom. An electrode assembly having a first side surface and a second side surface may be coupled to the distal section of the elongate shaft. The electrode assembly may include a central mid spline, a first spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline, and a second spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline. The proximal ends of the first and second splines may be secured to the central mid spline at a first location along a length of the central mid spline and the distal ends of the first and second

splines are secured to the central mid spline at a second location along the length of the central mid spline, the second location distal to the first location. The electrode assembly may further include a first plurality of electrodes secured to the central mid spline, a second plurality of electrodes secured to the first spline, and a third plurality of electrodes secured to the second spline.

Another illustrative embodiment is a mapping system for analyzing body tissue including an imaging and control system and a handle in electrical communication with the imaging and control system. The system may further include an elongate shaft connected to the handle and extending distally therefrom. The elongate shaft may have a proximal section and a distal section. An electrode assembly having a first side surface and a second side surface may be coupled to the distal section of the elongate shaft. The electrode assembly may include an elastomeric polymeric backing on the second side surface. The electrode assembly may further include a central mid spline including a telescoping region and having a length extending from a proximal end to a distal end of the electrode assembly and a first pair of splines each having a proximal end, a distal end, and an intermediate region laterally spaced a distance from the central mid spline, the proximal ends of the first pair of splines secured to the central mid spline at a first location along the length of the central mid spline and the distal ends of the first pair of splines secured to the central mid spline at a second location distal to the first location along the length of the central mid spline. The electrode assembly may also include a second pair of splines each having a proximal end, a distal end, and an intermediate region laterally spaced a distance from the central mid spline, the proximal ends of the second pair of splines secured to the central mid spline at a third location proximal to the first location along the length of the central mid spline and the distal ends of the second pair of splines secured to the central mid spline at the second location along the length of the central mid spline and a third pair of splines each having a proximal end, a distal end, and an intermediate region laterally spaced a distance from the central mid spline, the proximal ends of the third pair of splines secured to the central mid spline at a fourth location proximal to the third location along the length of the central mid spline and the distal ends of the third pair of splines secured to the central mid spline at a fifth location distal to the second location along the length of the central mid spline. The electrode assembly may further include a first plurality of electrodes secured to the central mid spline, a second plurality of electrodes secured to the first pair of splines, and a third plurality of electrodes secured to the second pair of splines. The first, second, and third plurality of electrodes may be disposed on the first side surface of the electrode assembly.

The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. 1 is a schematic view of a mapping device in accordance with an illustrative embodiment;

FIG. 2 illustrates a distal end region of an illustrative mapping device in a first configuration;

FIG. 3 illustrates the mapping device of FIG. 2 in a second configuration; and

FIG. 4 illustrates an alternative view of the mapping device of FIG. 2 in the first configuration.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term “about”, whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the term “about” may be indicative as including numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

Although some suitable dimensions ranges and/or values pertaining to various components, features and/or specifications are disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges and/or values may deviate from those expressly disclosed.

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

For purposes of this disclosure, “proximal” refers to the end closer to the device operator during use, and “distal” refers to the end farther from the device operator during use.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into an additional embodiment unless clearly stated to the contrary.

For certain types of minimally invasive medical procedures, endoscopic visualization of the treatment site within the body is unavailable or does not assist the clinician in guiding the needed medical devices to the treatment site. Examples of such procedures are those used to diagnose and treat supra-ventricular tachycardia (SVT), atrial fibrillation (AF), atrial flutter (AFL) and ventricular tachycardia (VT). VT, AFL, AF and VT are conditions in the heart which cause abnormal electrical signals to be generated in the endocardial tissue to cause irregular beating of the heart.

A procedure for diagnosing and treating SVT or VT involves measuring the electrical activity of the heart using an electrophysiology catheter introduced into the heart via the patient’s vasculature. The catheter carries mapping elec-

trodes which are positioned within the heart and used to measure electrical activity. The position of the catheter within the heart is ascertained using fluoroscopic images. A map of the measured activity is created based on the fluoroscopic images and is shown on a graphical display. A physician uses the map to identify the region of the endocardium which s/he believes to be the source of the abnormal electrical activity. An ablation catheter is then inserted through the patient’s vasculature and into the heart where it is used to ablate the region identified by the physician. In some instances, it may be desirable to measure the activity of the epicardial surface.

FIG. 1 is a schematic view of a mapping system 10 in accordance with an illustrative embodiment. As shown in FIG. 1, the mapping system 10 may include a catheter 12 including an elongate shaft 14 and a handle 16. The elongate shaft 14 may include a proximal section 18, a distal section 20, and at least one lumen 22 extending through the shaft 14 between the proximal and distal sections 18, 20. A generally planar electrode assembly 24 including a plurality of splines 26 and electrodes 28 may be coupled to the distal section 20 of the elongate shaft 14. The assembly 24 can be collapsed for delivery to a desired treatment location and expanded once it is located at the desired location. In some embodiments, and as further described below, a plurality of radiofrequency electrodes 28 located on the assembly 24 may be used to acquire an anatomical and/or electrical map at a desired location. While the mapping system 10 may be described as a system for mapping a cardiac surface, it is contemplated the devices and methods described herein may be used in other locations within the body. In some instances, the mapping system 10 may be used in combination with an ablation catheter and/or a reference catheter.

A handle 16 coupled to the proximal section 18 of the shaft 14 can be used by the clinician for manipulating and steering the assembly 24 to a target site or for positioning the assembly 24 at the desired location. In some embodiments, the handle 16 includes a connector 30 to electrically couple the catheter 12 and its components to a control and imaging system 32. The handle 16 may further include a steering mechanism 34 including a rotatable actuation mechanism to maneuver the elongate shaft 14 through the vascular system to the heart. The steering mechanism 34 can be actuated by the clinician to engage a number of steering wires located within the shaft 14. Left rotation of the steering mechanism 34 may cause the distal portion 20 to bend to the left to position 36, for example, and right rotation of the steering mechanism 34 may cause the distal portion 20 to bend to the right to position 38, for example. It is further contemplated that a slider or lever mechanism can be used as an actuation mechanism for the steering mechanism 34. The handle 16 may further include an actuation mechanism 60 for actuating the electrode assembly 24 between a collapsed and an expanded configuration. The actuation mechanism 60 may be any suitable mechanism, such as, but not limited to a slider mechanism, a lever mechanism, a rotatable mechanism, etc.

During delivery of the catheter 12 to a target region within the body, the steering mechanism 34 can be engaged to deflect the distal end region of the elongate shaft 14, allowing the clinician to better navigate the catheter 12 through the vasculature and providing improved control over the positioning of the assembly 24. In some embodiments, the catheter 12 may be advanced through the vasculature along with a steerable sheath 70 (shown in FIGS. 2-4). However, a steerable sheath 70 is not required. In some embodiments, the sheath 70 may not have steering capabili-

ties. In such an instance, the catheter 12 may be disposed within a lumen of the sheath 70. The sheath 70 may provide macro steering during advancement through the vasculature. Once the catheter 12 disposed adjacent to the target region, the sheath 70 may be proximally retracted. The steering mechanism 34 provided with the catheter 12 may then be used to steer the distal end of the elongate shaft 14 in order to place the assembly 24 in contact with the target location, as will be discussed in more detail below.

The imaging and control system 32 may provide radio-frequency (RF) energy to the electrodes 28 as well as enable the user to record, view and analyze intracardiac electrogram and EKG signals, as well as to view a real-time graphic representation of the catheters being used. The imaging and control system 32 may comprise an RF generator, a computer or other processing device, and memory or other storage device. Alternatively, the processing device and the storage device can be one or more separate units. In some instances, real time images and/or data may be generated and displayed on one or more displays 40 of the imaging and control system 32. The mapping system 10 may also include an input device 42, such as a keyboard or mouse, for programming the mapping system 10 and for controlling certain functions of the mapping system 10. These functions may include the powering up of the RF generator to supply energy to one or more of the electrodes 28 for mapping cardiac tissue, for example. In accordance with the invention, the input device 42 may also be used by the physician to preprogram the mapping system 10 before a procedure so that the system 10 will perform a predetermined function in response to an input.

FIG. 2 illustrates an enlarged view of the generally planar electrode assembly 24 in an expanded configuration. The generally planar assembly 24 may have a generally leaf or spear-like shape in the expanded configuration and extend generally in line with or generally parallel with a longitudinal axis of the elongate shaft 14. For example, the assembly 24 may have a wide region adjacent the proximal end 54 thereof which tapers into a narrower, generally pointed, distal end 56. The assembly 24 may include a first surface 66 and a second surface 68 (shown in FIG. 4). In the expanded configuration, the first and second surfaces 66, 68 may have a generally planar configuration. A plurality of splines 26 may extend from the proximal end 54 to the distal end 56 of the assembly 24. In some instances, the splines 26 may be formed from nitinol, or other shape memory material. The shape memory material may be treated such that the splines 26 assume the expanded assembly 24 shown in FIG. 2 when in an unstressed condition. In other instances, the splines 26 may be formed from an electroactive polymer (EAP). The EAP may change size and/or shape when stimulated by an electric field. For example, the splines 26 may assume a collapsed position, as shown in FIG. 3, until an electrical field is applied to the splines 26. Upon application of the electric field, the splines 26 may assume an expanded configuration, as shown in FIG. 2. The reverse configuration is also contemplated. It is further contemplated that the splines 26 may be formed from expandable balloon-like structures. In such an instance, the handle 16 may include a fluid port for delivering an inflation fluid to the splines 26. One or more inflation lumens may be disposed within the elongate shaft 14 and in fluid communication with the fluid port and the splines 26. It is contemplated that the clinician may control the expansion of the assembly 24 by inflating the splines 26 to a desired level.

While the shape of the assembly 24 may be characterized as generally planar, leaf or spear-like, or the like, this is not

intended to be limiting. Other shapes and/or configurations are contemplated. For example, the assembly 24 may have a circular, rounded, oval, semi-circular, semi-oval, polygonal, or other suitable shape. In some embodiments, the shape of the assembly 24 may be considered symmetrical or “regular” whereas in other embodiments, the shape of the assembly 24 may be considered non-symmetrical or irregular. In addition, by virtue of being “generally planar”, the assembly may be understood as having a reduced depth (e.g., the dimension in the “Z” direction according to the conventional Cartesian coordinate system) relative to the length and/or width (e.g., the dimensions in the “X” and “Y” directions according to the conventional Cartesian coordinate system). In other words, “generally planar” may be understood as or planar, flat, somewhat flattened, larger in two dimensions than the third, or the like. In at least some embodiments, generally planar may merely represent a shape that differs from typical constellation catheters that may have a plurality of struts or splines that form a generally spherical structure.

The splines 26 may be attached to the elongate shaft 14 and/or a central mid spline 50. The central mid spline 50 may extend from the proximal end 54 to the distal end 56 of the assembly 24. In some embodiments, the assembly 24 may include three pairs of splines, a first inner pair 48, a second intermediate pair 46, and a third outer pair 44. The pairs 44, 46, 48 may include a spline 26 positioned on either side of the central mid spline 50. However, it is contemplated that the splines 26 need not be arranged in pairs or symmetrically arranged. Each of the outer splines 44, intermediate splines 46, and inner splines 48 may be attached at their proximal end and distal end to the mid spline 50 while the region between the proximal and distal ends may be laterally spaced a distance from the mid spline. The first pair of splines 48 may be secured at their proximal ends at a first location 72 along the length of the mid spline 50 and at their distal ends at a second location 74 along the length of the mid spline 50. The second location 74 may be located distal to the first location 72. The second pair of splines 46 may be secured at their proximal ends at a third location 76 proximal to the first location and at their distal ends at the second location 74. However, it is contemplated that the distal ends of the second pair of splines 46 may be attached at a different location than the distal end of the first pair of splines 48. For example, the distal ends of the second pair of splines may be attached at a location distal to the second location 74. The third pair of splines 44 may be secured at their proximal ends at a fourth location 78 proximal to the third location 76 and at their distal ends to a fifth location 80 distal to the second location 74. In some instances, the fourth location 78 may correspond to the proximal end 54 of the assembly 24 and the fifth location 80 may correspond to the distal end 56 of the assembly, although this is not required. In some embodiments, each pair of splines 44, 46, 48 may be formed as a unitary structure. In other embodiments, each pair of splines 44, 46, 48 may be formed as an individual spline 26. It is further contemplated that each pair of splines 44, 46, 48 need not have their proximal and distal ends secured at the same longitudinal location. In some instances, the proximal and distal ends of each pair of splines 44, 46, 48 may be staggered.

It is contemplated that the assembly 24 may include any number of splines 26 desired. For example, the assembly 24 may include in the range of four to eight splines. However, fewer than four or more than eight splines may be used, as desired. In some instances, the splines 26 may be embedded in an elastomeric, insulating polymer backing 52. It is

contemplated that the splines 26 may be formed as individual components and subsequently assembled or the splines 26 may be formed as a unitary structure. In the expanded configuration, the assembly 24 may have a length extending from the proximal end 54 to the distal end 56 of approximately 20 to 40 millimeters. However, shorter or longer lengths may also be used. In the expanded configuration, the assembly 24 may have a width extending between outer splines 44 of approximately 10 to 25 millimeters at the widest point. However, narrower or wider widths may also be used.

The assembly 24 may further include one or more electrodes 28 distributed along the lengths of the intermediate splines 46, inner splines 48, and mid spline 50. The electrodes 28 may include an array of electrodes arranged in a generally leaf or spear like pattern. In some instances, the outer splines 44 may be free of electrodes 28. However, this is not required. In some embodiments, while not explicitly shown, electrodes 28 may also be positioned on the outer splines 44. Each spline 46, 48, 50 may have any number of electrodes 28 desired, such as, but not limited to one, two, three, four, or more. It is contemplated that the assembly 24 may include approximately 16-64 electrodes 28. However, in some instances, fewer than 16 or more than 64 electrodes may be used, as desired. The electrodes 28 may be evenly distributed about the assembly 24. The configuration of the electrodes 28 can vary from that shown, however. Each electrode 28 may be positioned on the same generally planar surface, such as surface 66, of the assembly 24 such that the electrodes 28 contact or are capable of contacting the tissue to be mapped, although this is not required. It is contemplated that positioning the electrodes 28 in such a manner may reduce far-field effects (e.g. the ambient electrical activity away from the electrodes 28).

In some embodiments, the electrodes 28 may be flexible circuits affixed to the splines 26. In other embodiments, the electrodes 28 may be formed from a suitably conductive metal such as platinum, gold, stainless steel, cobalt alloys, or other non-oxidizing materials. Conductive leads (not explicitly shown) may electrically couple the electrodes 28 to the imaging and control system 32. The electrodes 28 may be suitably insulated from the splines 26 by an insulating backing, the polymer backing 52, and/or by coating the splines 26 with a non-conductive material. Conductive leads may also be electrically isolated from components of the catheter shaft 12.

FIG. 3 illustrates an enlarged view of the generally planar electrode assembly 24 in a generally collapsed configuration. The electrode assembly 24 may include a telescoping mid spline 50 to allow the assembly 24 to be biased into the collapsed configuration. For example, the mid spline 50 may include a telescoping region 58 that allows the mid spline 50 to elongate or lengthen. The telescoping region 58 may include one or more portions in combination with the mid spline 50 that slide in a proximal or distal direction in overlapping sections to compress or lengthen the length of the mid spline 50. As the mid spline 50 elongates, the outer splines 44, intermediate splines 46, and inner splines 48 may be deformed into a straighter profile, thus reducing the overall width of the assembly 24. In some embodiments, the telescoping region 58 may be elongated through manipulation of the actuation mechanism 60 on the handle 16. For example, the telescoping region 58 and the actuation mechanism may be connected to a push wire slidably disposed within the lumen 22 of the elongate shaft 14. Proximal or distal actuation of the actuation mechanism 60 may result in the proximal or distal movement of the telescoping region

58. It is contemplated that the assembly 24 can be collapsed without the use of an actuation mechanism 60. Applying an external force to the assembly 24 may cause the assembly to collapse and the telescoping region 58 to elongate. The assembly 24 may be maintained in the collapsed position using an appropriate sheath, such as sheath 70.

FIG. 4 illustrates an alternative view of the generally planar electrode assembly 24 in an expanded configuration. In some embodiments, the second generally planar surface 68 may include a plurality of air or fluid pockets 62, or other inflatable structures. The pockets 62 may be separated by a plurality of seams 64 to allow the assembly to curve into a desired orientation. In some instances, the pockets 62 may cover the entire surface 68 of the assembly 24. In other instances, the pockets 62 may be disposed over a portion of the assembly 24. The pockets 62 and/or seams 64 may be arranged in any manner desired to achieve the desired curvature in the expanded state. It is contemplated that the seams 64 may be arranged generally parallel to a longitudinal axis of the assembly 24, generally orthogonal to the longitudinal axis of the assembly 24, or at an oblique angle to the longitudinal axis of the assembly 24. It is further contemplated that the seams 64 may extend outward from a central location on the assembly 24 in a spoke-like manner. The seams 64 may be straight or curved as desired. The pockets 62 may take any shape desired. For example, the pockets 62 may be elongated strips, circular, square, polygonal, etc. It is further contemplated that the curvature of the assembly 24 may be controlled by adjusting the inflation of the pockets 62. This may be done prior to introducing the assembly 24 into the body or once the assembly 24 has been positioned adjacent to the target location. The catheter 12 may include the necessary inflation lumens and ports to allow an inflation fluid to be introduced into pockets 62, as desired. In some instances, the inflation of each individual pocket 62 may be controlled independently, while in other instances, the pockets 62 may be inflated simultaneously.

As discussed above, a sheath 70 may be used in cooperation with the mapping system 10 to facilitate advancement of the catheter 12 to the desired treatment location. The sheath 70 may be slidably disposed over the elongate shaft 14. During use, the sheath 70 may extend over the electrode assembly 24. The electrode assembly 24 may be compressed, or collapsed, within the sheath 70 so that the assembly can be easily moved through the patient's body to the desired location. In some instances, the catheter 12 may be advanced through the body to the pericardial or epicardial space to map the epicardial surface. However, it is contemplated that the system 10 may also be used to map the endocardial surface. Once the assembly 24 is positioned adjacent to the desired region, the sheath 70 may be proximally retracted to allow the assembly 24 to open into its expanded configuration, either through spring action of the splines 26 or actuation mechanism 60. The steering mechanism 34 may be employed to further position (deflect) the assembly 24 adjacent to the target region such that the electrodes 28 are in contact with the tissue. When so provided, pockets 62 may be used to curve the surface 66 of the assembly 24 to better fit the local anatomy of the heart. The degree of the deflection and/or inflation of pockets 62 may be selected by the clinician to provide the best contact between the electrodes 28 and the target tissue.

Once the assembly 24 is in position and expanded, the imaging and control system 32 can then be set to activate the electrodes 28. The electrodes 28, and associated control system 32, may detect the electrical activity of underlying cardiac tissue to acquire an anatomical and electrical map. In

some instances, the mapping system **10** may be used to fully characterize a ventricular scar and to assess the transmural-ity of a lesion. In other instances, the system **10** may be used to characterize the tissue prior to performing an ablation procedure.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departure in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

1. A mapping device for analyzing body tissue, comprising:

an elongate shaft having a proximal section and a distal section;

an electrode assembly having a first side surface and a second side surface coupled to the distal section of the elongate shaft, the electrode assembly having a collapsed configuration and an expanded configuration;

a plurality of inflatable pockets disposed on the second side surface, the plurality of inflatable pockets being separated by one or more seams that enable the electrode assembly to curve into a desired orientation;

a steering mechanism coupled to the distal section, the steering mechanism configured to steer the distal section; and

wherein the electrode assembly includes a plurality of splines including a central mid spline and a plurality of electrodes disposed on at least some of the plurality of splines, wherein the electrode assembly has a generally planar structure when expanded.

2. The mapping device of claim **1**, wherein the central mid spline includes a telescoping region.

3. The mapping device of claim **1**, wherein the plurality of splines including the central mid spline are embedded in an elastomeric polymeric backing.

4. The mapping device of claim **1**, wherein the electrodes are evenly distributed about the electrode assembly.

5. The mapping device of claim **1**, wherein the electrodes comprise a flexible circuit.

6. The mapping device of claim **1**, wherein the plurality of splines includes in the range of four to eight splines.

7. The mapping device of claim **1**, wherein the plurality of electrodes includes in the range of sixteen to sixty-four electrodes.

8. The mapping device of claim **1**, wherein the plurality of electrodes are disposed on the first side surface of the electrode assembly.

9. The mapping device of claim **1**, wherein outer splines of the plurality of splines do not include electrodes.

10. The mapping device of claim **1**, wherein the generally planar structure includes a region having a first width adjacent a proximal end thereof and tapers into a narrower second width adjacent a distal end thereof.

11. A mapping system for analyzing body tissue, comprising:

an imaging and control system;

a handle in electrical communication with the imaging and control system;

an elongate shaft connected to the handle and extending distally therefrom, the elongate shaft having a proximal section and a distal section; and

an electrode assembly having a first side surface and a second side surface coupled to the distal section of the elongate shaft, the electrode assembly capable of moving between a collapsed configuration and an expanded

configuration, wherein the second side surface includes a plurality of inflatable pockets attached thereto, the plurality of pockets being separated by one or more seams that allow the plurality of inflatable pockets to curve into a desired orientation, the electrode assembly comprising:

a central mid spline;

a first spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline; and

a second spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline;

a first plurality of electrodes secured to the central mid spline;

a second plurality of electrodes secured to the first spline; and

a third plurality of electrodes secured to the second spline.

12. The mapping device of claim **11**, wherein the proximal ends of the first and second splines are secured to the central mid spline at a first location along a length of the central mid spline and the distal ends of the first and second splines are secured to the central mid spline at a second location along the length of the central mid spline, the second location distal to the first location.

13. The mapping system of claim **12**, further comprising: a third spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline; and

a fourth spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline;

wherein the proximal ends of the third and fourth splines are secured to the central mid spline at a third location along a length of the central mid spline, the third location proximal to the first location and the distal ends of the third and fourth splines are secured to the central mid spline at the second location along the length of the central mid spline.

14. The mapping system of claim **13**, further comprising a fourth plurality of electrodes secured to the third spline and a fifth plurality of electrodes secured to the fourth spline.

15. The mapping system of claim **14**, wherein the first, second, third, fourth, and fifth plurality of electrodes are disposed on the first side surface of the electrode assembly.

16. The mapping system of claim **13**, further comprising: a fifth spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline; and

a sixth spline having a proximal end secured to the central mid spline, a distal end secured to the central mid spline, and an intermediate region laterally spaced a distance from the central mid spline;

wherein the proximal ends of the fifth and sixth splines are secured to the central mid spline at a fourth location along a length of the central mid spline, the fourth location proximal to the third location and the distal ends of the fifth and sixth splines are secured to the central mid spline at a fifth location along the length of the central mid spline, the fifth location distal to the second location.

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17. The mapping system of claim 11, further comprising an elastomeric polymeric backing on the second side surface.

18. The mapping system of claim 11, wherein when in the expanded configuration, the electrode assembly has a generally planar structure extending in line with a longitudinal axis of the elongate shaft. 5

19. The mapping device of claim 11, wherein the first and second splines are formed from an electroactive polymer such that the first and second splines move between a collapsed configuration and an expanded configuration in response to a presence or an absence of an electric field. 10

20. A mapping system for analyzing body tissue, comprising:
 an imaging and control system; 15
 a handle in electrical communication with the imaging and control system;
 an elongate shaft connected to the handle and extending distally therefrom, the elongate shaft having a proximal section and a distal section; and 20
 an electrode assembly having a first side surface and a second side surface coupled to the distal section of the elongate shaft, the electrode assembly comprising:
 an elastomeric polymeric backing on the second side surface comprising a plurality of inflatable pockets, wherein each pair of adjacent inflatable pockets, of the plurality of inflatable pockets, are separated by one or more seams that allow the plurality of inflatable pockets to curve into a desired orientation; 25
 a central mid spline including a telescoping region and having a length extending from a proximal end to a distal end of the electrode assembly; 30
 a first pair of splines each having a proximal end, a distal end, and an intermediate region laterally spaced a distance from the central mid spline, the proximal ends of the first pair of splines secured to 35

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the central mid spline at a first location along the length of the central mid spline and the distal ends of the first pair of splines secured to the central mid spline at a second location distal to the first location along the length of the central mid spline;

a second pair of splines each having a proximal end, a distal end, and an intermediate region laterally spaced a distance from the central mid spline, the proximal ends of the second pair of splines secured to the central mid spline at a third location proximal to the first location along the length of the central mid spline and the distal ends of the second pair of splines secured to the central mid spline at the second location along the length of the central mid spline;
 a third pair of splines each having a proximal end, a distal end, and an intermediate region laterally spaced a distance from the central mid spline, the proximal ends of the third pair of splines secured to the central mid spline at a fourth location proximal to the third location along the length of the central mid spline and the distal ends of the third pair of splines secured to the central mid spline at a fifth location distal to the second location along the length of the central mid spline;
 a first plurality of electrodes secured to the central mid spline;
 a second plurality of electrodes secured to the first pair of splines; and
 a third plurality of electrodes secured to the second pair of splines;
 wherein the first, second, and third plurality of electrodes are disposed on the first side surface of the electrode assembly.

* * * * *

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申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
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外部链接	Espacenet USPTO		

摘要(译)

公开了用于在身体组织上执行映射程序的装置，系统和方法。用于绘制组织表面的示例性映射装置包括细长轴和电极组件。电极组件包括多个花键和设置在至少一些花键上的多个电极。电极组件能够在收缩配置和扩展配置之间移动。在扩展配置中，电极组件可以具有大致平面的结构。

