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

ELEKTRODENARRAYKATHETER FÜR HOCHAUFLÖSENDE KARDIALE KARTIERUNG

CATHÉTER DE CARTOGRAPHIE CARDIAQUE À HAUTE RÉOLUTION COMPORTANT UN ENSEMBLE D'ÉLECTRODES

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## Description

### TECHNICAL FIELD

**[0001]** 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

**[0002]** 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 systems provide crucial information to diagnose and treat various arrhythmias. Document US 2002/0177766 discloses a catheter with a plurality of electrodes disposed on a plurality of splines. WO 2013/028998 discloses a catheter and an expandable support member having a folded and an expanded planar configuration. The support member can comprise splines and electrodes. Document EP 0 779 059 discloses a mapping catheter with an electrode array which can be in a folded or unfolded state. The array is supported by a two-compartment balloon where the compartments can be inflated so as to conform to the mapped tissue. However, it may be desirable to provide a device for high resolution mapping of the epicardial surface.

### SUMMARY

**[0003]** 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.

**[0004]** 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.

**[0005]** 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.

**[0006]** 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

**[0007]** 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:

Figure 1 is a schematic view of a mapping device in accordance with an illustrative embodiment;  
 Figure 2 illustrates a distal end region of an illustrative mapping device in a first configuration;  
 Figure 3 illustrates the mapping device of Figure 2 in a second configuration; and  
 Figure 4 illustrates an alternative view of the mapping device of Figure 2 in the first configuration.

#### DETAILED DESCRIPTION

**[0008]** For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

**[0009]** 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.

**[0010]** 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).

**[0011]** 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.

**[0012]** 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.

erwise.

**[0013]** 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.

**[0014]** 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.

**[0015]** 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.

**[0016]** 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 electrodes 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.

**[0017]** Figure 1 is a schematic view of a mapping system 10 in accordance with an illustrative embodiment. As shown in Figure 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.

**[0018]** 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.

**[0019]** 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 Figures 2-4). However, a steerable sheath 70 is not required. In some embodiments, the sheath 70 may not have steering capabilities. 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.

**[0020]** 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.

**[0021]** Figure 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 Figure 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 Figure 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 Figure 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 Figure 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.

**[0022]** 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.

**[0023]** 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.

**[0024]** 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.

**[0025]** 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).

**[0026]** 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 insulting 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.

**[0027]** Figure 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.

**[0028]** Figure 4 illustrates an alternative view of the generally planar electrode assembly 24 in an expanded configuration. In the invention the second generally planar surface 68 includes a plurality of air or fluid pockets 62, or other inflatable structures. The pockets 62 are 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.

**[0029]** 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.

**[0030]** 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 of a lesion. In other instances, the system 10 may be used to characterize the tissue prior to performing an ablation procedure.

#### 45 Claims

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

50 an elongate shaft (14) having a proximal section (18) and a distal section (20); a generally planar electrode assembly (24) having a first side surface (66) and a second side surface (68) coupled to the distal section (20) of the elongate shaft (14), the electrode assembly (24) having a collapsed configuration and an expanded configuration;

55 wherein the electrode assembly (24) includes a

- plurality of splines (26) including a central mid spline (50) and a plurality of electrodes (28) disposed on at least some of the plurality of splines (26); and  
 wherein the mapping device further comprises a plurality of inflatable pockets (62) disposed on the generally planar second side surface (68) of the electrode assembly (24), wherein the pockets (62) are separated by a plurality of seams (64) to allow the electrode assembly (24) to curve into a desired orientation.
2. The mapping device of claim 1, further comprising a steering mechanism (34).
  3. The mapping device of any one of claims 1-2, wherein in the expanded configuration, the electrode assembly (24) has a generally planar structure.
  4. The mapping device of claim 3, wherein the generally planar structure includes a region having a first width adjacent a proximal end (54) thereof and tapers into a narrower second width adjacent a distal end (56) thereof.
  5. The mapping device of any one of claims 1-4, wherein the central mid spline (50) includes a telescoping region (58).
  6. The mapping device of any one of claims 1-5, wherein the plurality of splines (26) including the central mid spline (50) are embedded in an elastomeric polymeric backing (52).
  7. The mapping device of any one of claims 1-6, wherein the electrodes (28) are evenly distributed about the electrode assembly (24).
  8. The mapping device of any one of claims 1-7, wherein the electrodes (28) comprise a flexible circuit.
  9. The mapping device of any one of claims 1-8, wherein the plurality of splines (26) includes in the range of four to eight splines (26).
  10. The mapping device of any one of claims 1-9, wherein the plurality of electrodes (28) includes in the range of sixteen to sixty-four electrodes (28).
  11. The mapping device of any one of claims 1-10, wherein the plurality of electrodes (28) are disposed on the first side surface (66) of the electrode assembly (24).
  12. The mapping device of any one of claims 1-11, wherein the seams (64) are 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), or extend outward from a central location on the assembly (24) in a spoke-like manner.
13. A mapping system (10) for analyzing body tissue, comprising:
    - an electrode assembly (24) of any one of the preceding claims;
    - an imaging and control system (32);
    - a handle (16) in electrical communication with the imaging and control system (32);
    - wherein the elongate shaft (14) of the electrode assembly (24) is connected to the handle (16) and extending distally therefrom; and
 wherein the electrode assembly (24) comprises:
    - a central mid spline (50);
    - a first spline having a proximal end secured to the central mid spline (50), a distal end secured to the central mid spline (50), and an intermediate region laterally spaced a distance from the central mid spline (50); and
    - a second spline having a proximal end secured to the central mid spline (50), a distal end secured to the central mid spline (50), and an intermediate region laterally spaced a distance from the central mid spline (50);
    - wherein the proximal ends of the first and second splines are secured to the central mid spline (50) at a first location along a length of the central mid spline (50) and the distal ends of the first and second splines are secured to the central mid spline (50) at a second location along the length of the central mid spline (50), the second location distal to the first location;
    - a first plurality of electrodes (28) secured to the central mid spline (50);
    - a second plurality of electrodes (28) secured to the first spline; and
    - a third plurality of electrodes (28) secured to the second spline.
  14. The mapping system of claim 13, further comprising:
    - a third spline having a proximal end secured to the central mid spline (50), a distal end secured to the central mid spline (50), and an intermediate region laterally spaced a distance from the central mid spline (50); and
    - a fourth spline having a proximal end secured to the central mid spline (50), a distal end secured to the central mid spline (50), and an intermediate region laterally spaced a distance from the central mid spline (50);
    - wherein the proximal ends of the third and fourth

splines are secured to the central mid spline (50) at a third location along a length of the central mid spline (50), 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 (50) at the second location along the length of the central mid spline (50).

15. The mapping system of claim 14, further comprising a fourth plurality of electrodes (28) secured to the third spline and a fifth plurality of electrodes (28) secured to the fourth spline.

### Patentansprüche

1. Kartierungsvorrichtung zum Analysieren von Körpergewebe, welche aufweist:

eine längliche Welle (14) mit einem proximalen Abschnitt (18) und einem distalen Abschnitt (20);

eine im Allgemeinen ebene Elektrodenanordnung (24) mit einer ersten Seitenfläche (66) und einer zweiten Seitenfläche (68), die mit dem distalen Abschnitt (20) der länglichen Welle (14) gekoppelt ist, wobei die Elektrodenanordnung (24) eine zusammengelegte Konfiguration und eine expandierte Konfiguration hat;

wobei die Elektrodenanordnung (24) mehrere Splines (26) enthält, die eine zentrale mittlere Spline (50) und mehrere Elektroden (28) enthalten, die auf zumindest einigen der mehreren Splines (26) angeordnet sind; und wobei die Kartierungsvorrichtung weiterhin mehrere aufblasbare Taschen (62) aufweist, die auf der im Allgemeinen ebenen zweiten Seitenfläche (68) der Elektrodenanordnung (24) angeordnet sind, wobei die Taschen (62) durch mehrere Nähte (64) getrennt sind, um der Elektrodenanordnung (24) zu ermöglichen, in eine gewünschte Orientierung gekrümmt zu sein.

2. Kartierungsvorrichtung nach Anspruch 1, weiterhin aufweisend einen Lenkmechanismus (34).

3. Kartierungsvorrichtung nach einem der Ansprüche 1-2, bei der die Elektrodenanordnung (24) in der expandierten Konfiguration eine im Allgemeinen ebene Struktur hat.

4. Kartierungsvorrichtung nach Anspruch 3, bei der die im Allgemeinen ebene Struktur einen Bereich mit einer ersten Breite benachbart einem proximalen Ende (54) hiervon enthält und sich in eine schmalere zweite Breite benachbart einem distalen Ende (56) hiervon verzüngt.

5. Kartierungsvorrichtung nach einem der Ansprüche 1-4, bei der die zentrale mittlere Spline (50) einen Teleskopbereich (58) enthält.

6. Kartierungsvorrichtung nach einem der Ansprüche 1-5, bei der die mehreren Splines (26) enthaltend die zentrale mittlere Spline (50) in eine elastomere Polymerstütze (52) eingebettet sind.

7. Kartierungsvorrichtung nach einem der Ansprüche 1-6, bei der die Elektroden (28) gleichmäßig über die Elektrodenanordnung (24) verteilt sind.

8. Kartierungsvorrichtung nach einem der Ansprüche 1-7, bei der die Elektroden (28) eine flexible Schaltung aufweisen.

9. Kartierungsvorrichtung nach einem der Ansprüche 1-8, bei der die mehreren Splines (26) in dem Bereich von vier bis acht Splines (26) enthalten.

10. Kartierungsvorrichtung nach einem der Ansprüche 1 - 9, bei der die mehreren Elektroden (28) in dem Bereich von sechzehn bis vierundsechzig Elektroden (28) enthalten.

11. Kartierungsvorrichtung nach einem der Ansprüche 1 - 10, bei der die mehreren Elektroden (28) auf der ersten Seitenfläche (66) der Elektrodenanordnung (24) angeordnet sind.

12. Kartierungsvorrichtung nach einem der Ansprüche 1 - 11, bei der die Nähte (64) im Allgemeinen parallel zu einer Längsachse der Anordnung (24) im Allgemeinen senkrecht zu der Längsachse der Anordnung (24) oder unter einem schrägen Winkel zu der Längsachse der Anordnung (24) angeordnet sind oder sich von einem zentralen Ort auf der Anordnung (24) in einer speichenartigen Weise erstrecken.

13. Kartierungssystem (10) zum Analysieren von Körpergewebe, welches aufweist:

eine Elektrodenanordnung (24) nach einem der vorhergehenden Ansprüche;

ein Abbildungs- und Steuersystem (32);

einen Handgriff (16) in elektrischer Verbindung mit dem Abbildungs- und Steuersystem (32);

wobei die längliche Welle (14) der Elektrodenanordnung (24) mit dem Handgriff (16) verbunden ist und sich distal von diesem weg erstreckt; und

wobei die Elektrodenanordnung (24) aufweist:

eine zentrale mittlere Spline (50);

eine erste Spline mit einem proximalen Ende, das an der zentralen mittleren Spline (50) befestigt ist, einem distalen Ende, das

an der zentralen mittleren Spline (50) befestigt ist, und einem Zwischenbereich, der einen seitlichen Abstand von der zentralen mittleren Spline (50) hat; und  
 eine zweite Spline mit einem proximalen Ende, das an der zentralen mittleren Spline (50) befestigt ist, einem distalen Ende, das an der zentralen mittleren Spline (50) befestigt ist, und einem Zwischenbereich, der einen seitlichen Abstand von der zentralen mittleren Spline (50) hat;  
 wobei die proximalen Enden der ersten und der zweiten Spline an der zentralen mittleren Spline (50) an einem ersten Ort entlang einer Länge der zentralen mittleren Spline (50) befestigt sind und die distalen Enden der ersten und der zweiten Spline an der zentralen mittleren Spline (50) an einem zweiten Ort entlang der Länge der zentralen mittleren Spline (50) befestigt sind, wobei der zweite Ort distal von dem ersten Ort; mehrere erste Elektroden (28), die an der zentralen mittleren Spline (50) befestigt sind;  
 mehrere zweite Elektroden (28), die an der ersten Spline befestigt sind; und  
 mehrere dritte Elektroden (28), die an der zweiten Spline befestigt sind.

**14.** Kartierungssystem nach Anspruch 13, welches weiterhin aufweist:

eine dritte Spline mit einem proximalen Ende, das an der zentralen mittleren Spline (50) befestigt ist, einem distalen Ende, das an der zentralen mittleren Spline (50) befestigt ist, und einem Zwischenbereich, der einen seitlichen Abstand von der zentralen mittleren Spline (50) aufweist; und  
 eine vierte Spline mit einem proximalen Ende, das an der zentralen mittleren Spline (50) befestigt ist, einem distalen Ende, das an der zentralen mittleren Spline (50) befestigt ist, und einem Zwischenbereich, der einen seitlichen Abstand von der zentralen mittleren Spline (50) aufweist;  
 wobei die proximalen Enden der dritten und der vierten Spline an der zentralen mittleren Spline (50) an einem dritten Ort entlang einer Länge der zentralen mittleren Spline (50) befestigt sind, der dritte Ort proximal des ersten Orts ist und die distalen Enden der dritten und der vierten Spline an der zentralen mittleren Spline (50) an dem zweiten Ort entlang der Länge der zentralen mittleren Spline (50) befestigt sind.

**15.** Kartierungssystem nach Anspruch 14, weiterhin mehrere vierte Elektroden (28), die an der dritten

Spline befestigt sind, und mehrere fünfte Elektroden (28), die an der vierten Spline befestigt sind, aufweisend.

**Revendications**

**1.** Dispositif de cartographie pour analyser un tissu d'un corps, comprenant :

un arbre allongé (14) qui comporte une section proximale (18) et une section distale (20) ;  
 un ensemble d'électrodes de forme générale plane (24) qui comporte une première surface latérale (66) et une seconde surface latérale (68) en couplage sur la section distale (20) de l'arbre allongé (14), l'ensemble d'électrodes (24) présentant une configuration repliée et une configuration déployée ; dans lequel :

l'ensemble d'électrodes (24) inclut une pluralité de cannelures (26) qui incluent une cannelure intermédiaire centrale (50) et une pluralité d'électrodes (28) qui sont disposées sur au moins certaines de la pluralité de cannelures (26) ; et dans lequel :

le dispositif de cartographie comprend en outre une pluralité de poches gonflables (62) qui sont disposées sur la seconde surface latérale de forme générale plane (68) de l'ensemble d'électrodes (24), dans lequel les poches (62) sont séparées par une pluralité de coutures (64) de manière à permettre que l'ensemble d'électrodes (24) soit courbé selon une orientation souhaitée.

**2.** Dispositif de cartographie selon la revendication 1, comprenant en outre un mécanisme de direction/d'orientation (34).

**3.** Dispositif de cartographie selon l'une quelconque des revendications 1 et 2, dans lequel, dans la configuration déployée, l'ensemble d'électrodes (24) présente une structure de forme générale plane.

**4.** Dispositif de cartographie selon la revendication 3, dans lequel la structure de forme générale plane inclut une région qui présente une première largeur en une position qui est adjacente à son extrémité proximale (54) et qui présente une conicité selon une seconde largeur plus étroite en une position qui est adjacente à son extrémité distale (56).

**5.** Dispositif de cartographie selon l'une quelconque des revendications 1 à 4, dans lequel la cannelure intermédiaire centrale (50) inclut une région télescopique (58).

**6.** Dispositif de cartographie selon l'une quelconque des revendications 1 à 5, dans lequel les cannelures

- de la pluralité de cannelures (26) qui incluent la cannelure intermédiaire centrale (50) sont intégrées dans un renfort polymérique élastomérique (52).
7. Dispositif de cartographie selon l'une quelconque des revendications 1 à 6, dans lequel les électrodes (28) sont distribuées/réparties de façon uniforme sur l'ensemble d'électrodes (24). 5
8. Dispositif de cartographie selon l'une quelconque des revendications 1 à 7, dans lequel les électrodes (28) comprennent/constituent un circuit flexible. 10
9. Dispositif de cartographie selon l'une quelconque des revendications 1 à 8, dans lequel les cannelures de la pluralité de cannelures (26) incluent un nombre de cannelures qui s'inscrit dans la plage qui va de quatre à huit cannelures (26). 15
10. Dispositif de cartographie selon l'une quelconque des revendications 1 à 9, dans lequel les électrodes de la pluralité d'électrodes (28) incluent un nombre d'électrodes qui s'inscrit dans la plage qui va de seize à soixante-quatre électrodes (28). 20
11. Dispositif de cartographie selon l'une quelconque des revendications 1 à 10, dans lequel les électrodes de la pluralité d'électrodes (28) sont disposées sur la première surface latérale (66) de l'ensemble d'électrodes (24). 25
12. Dispositif de cartographie selon l'une quelconque des revendications 1 à 11, dans lequel les coutures (64) sont agencées de façon générale parallèlement à l'axe longitudinal de l'ensemble d'électrodes (24), de façon générale perpendiculairement à l'axe longitudinal de l'ensemble d'électrodes (24) ou selon un angle oblique par rapport à l'axe longitudinal de l'ensemble d'électrodes (24), ou elles s'étendent vers l'extérieur depuis un emplacement central sur l'ensemble d'électrodes (24) à la façon de rayons de roue. 30
13. Système de cartographie (10) pour analyser un tissu d'un corps, comprenant : 35
- un ensemble d'électrodes (24) selon l'une quelconque des revendications qui précèdent ;  
un système d'imagerie et de commande (32) ;  
un manche (16) qui est en communication électrique avec le système d'imagerie et de commande (32) ; dans lequel : 40
- l'arbre allongé (14) de l'ensemble d'électrodes (24) est connecté au manche (16) et il s'étend de façon distale depuis celui-ci ; et dans lequel : 45
- l'ensemble d'électrodes (24) comprend :

une cannelure intermédiaire centrale (50) ;  
une première cannelure qui comporte une extrémité proximale qui est fixée à la cannelure intermédiaire centrale (50), une extrémité distale qui est fixée à la cannelure intermédiaire centrale (50) et une région intermédiaire qui est espacée latéralement d'une certaine distance par rapport à la cannelure intermédiaire centrale (50) ; et  
une deuxième cannelure qui comporte une extrémité proximale qui est fixée à la cannelure intermédiaire centrale (50), une extrémité distale qui est fixée à la cannelure intermédiaire centrale (50) et une région intermédiaire qui est espacée latéralement d'une certaine distance par rapport à la cannelure intermédiaire centrale (50) ; dans lequel :

les extrémités proximales des première et deuxième cannelures sont fixées à la cannelure intermédiaire centrale (50) au niveau d'un premier emplacement suivant une longueur de la cannelure intermédiaire centrale (50) et les extrémités distales des première et deuxième cannelures sont fixées à la cannelure intermédiaire centrale (50) au niveau d'un deuxième emplacement suivant la longueur de la cannelure intermédiaire centrale (50), le deuxième emplacement étant distal par rapport au premier emplacement ;  
une première pluralité d'électrodes (28) qui sont fixées à la cannelure intermédiaire centrale (50) ;  
une deuxième pluralité d'électrodes (28) qui sont fixées à la première cannelure ; et  
une troisième pluralité d'électrodes (28) qui sont fixées à la deuxième cannelure.

14. Système de cartographie selon la revendication 13, comprenant en outre :

une troisième cannelure qui comporte une extrémité proximale qui est fixée à la cannelure intermédiaire centrale (50), une extrémité distale qui est fixée à la cannelure intermédiaire centrale (50) et une région intermédiaire qui est espacée latéralement d'une certaine distance par rapport à la cannelure intermédiaire centrale (50) ; et

une quatrième cannelure qui comporte une extrémité proximale qui est fixée à la cannelure intermédiaire centrale (50), une extrémité distale qui est fixée à la cannelure intermédiaire centrale (50) et une région intermédiaire qui est espacée latéralement d'une certaine distance par rapport à la cannelure intermédiaire centrale (50) ; dans lequel :

les extrémités proximales des troisième et quatrième cannelures sont fixées à la cannelure intermédiaire centrale (50) au niveau d'un troisième emplacement suivant une longueur de la cannelure intermédiaire centrale (50), le troisième emplacement étant proximal par rapport au premier emplacement, et les extrémités distales des troisième et quatrième cannelures sont fixées à la cannelure intermédiaire centrale (50) au niveau du deuxième emplacement suivant la longueur de la cannelure intermédiaire centrale (50).

15. Système de cartographie selon la revendication 14, comprenant en outre une quatrième pluralité d'électrodes (28) qui sont fixées à la troisième cannelure et une cinquième pluralité d'électrodes (28) qui sont fixées à la quatrième cannelure.

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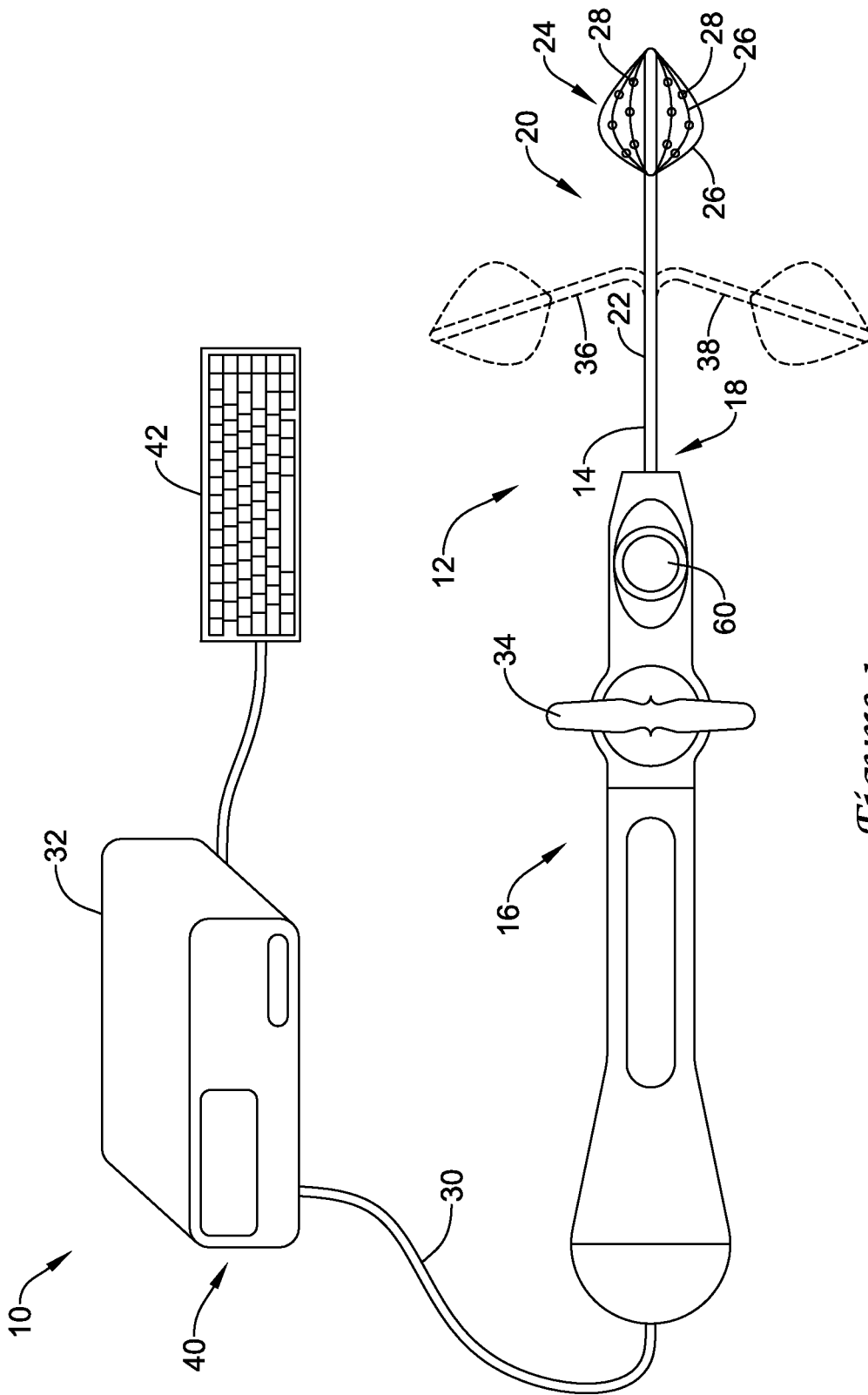


Figure 1

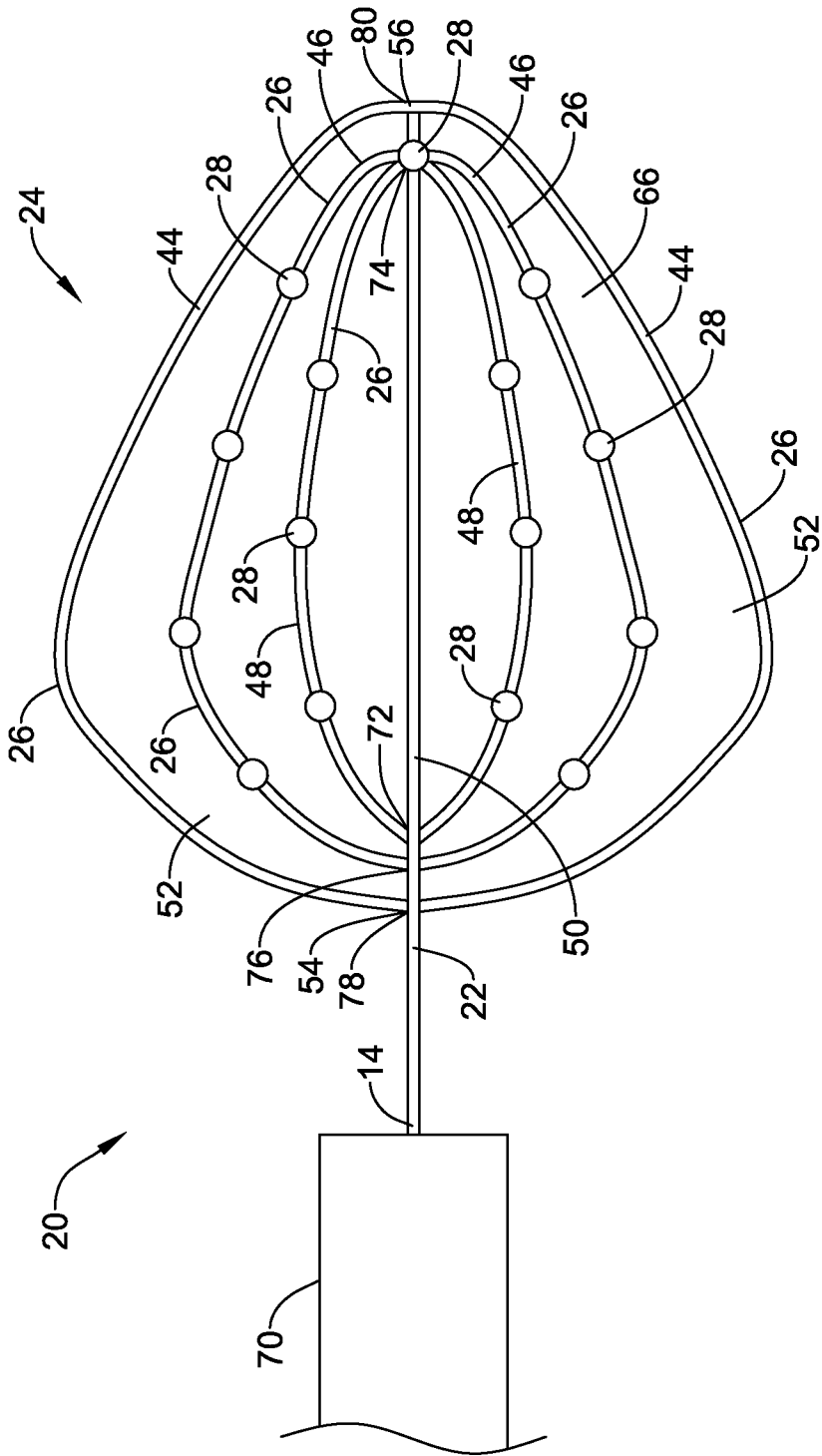


Figure 2

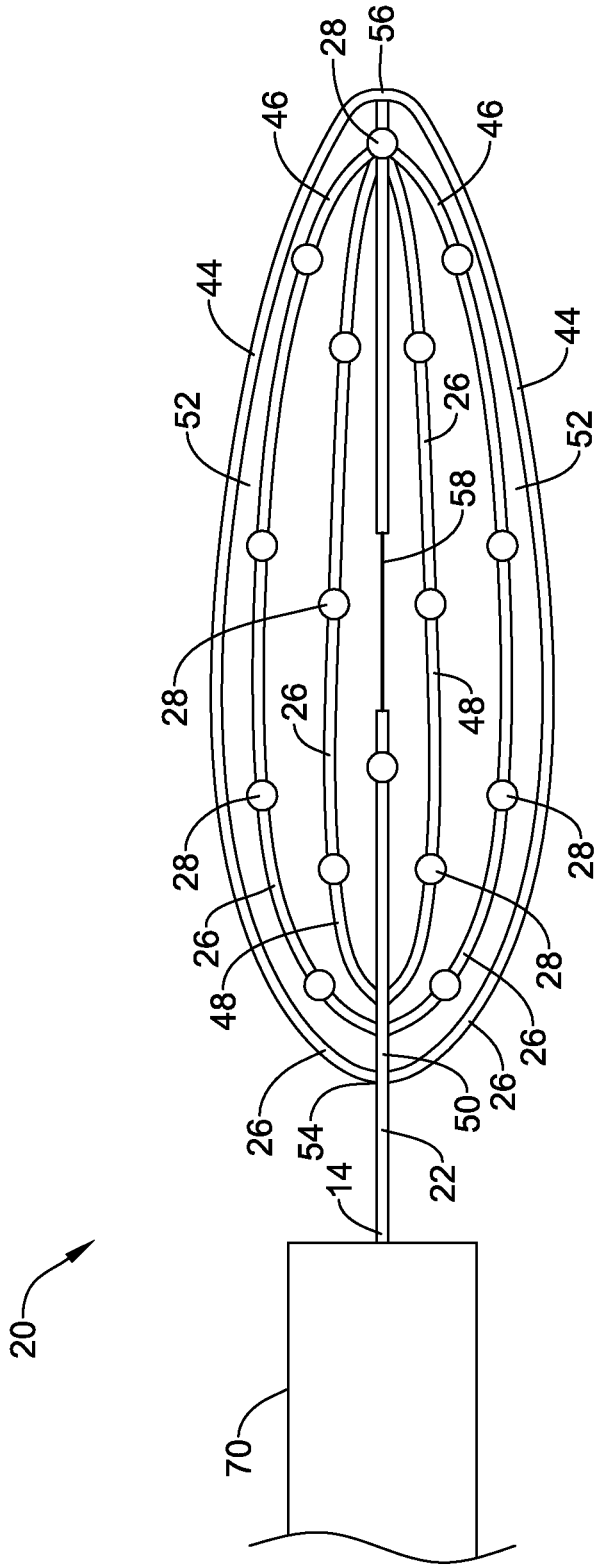


Figure 3

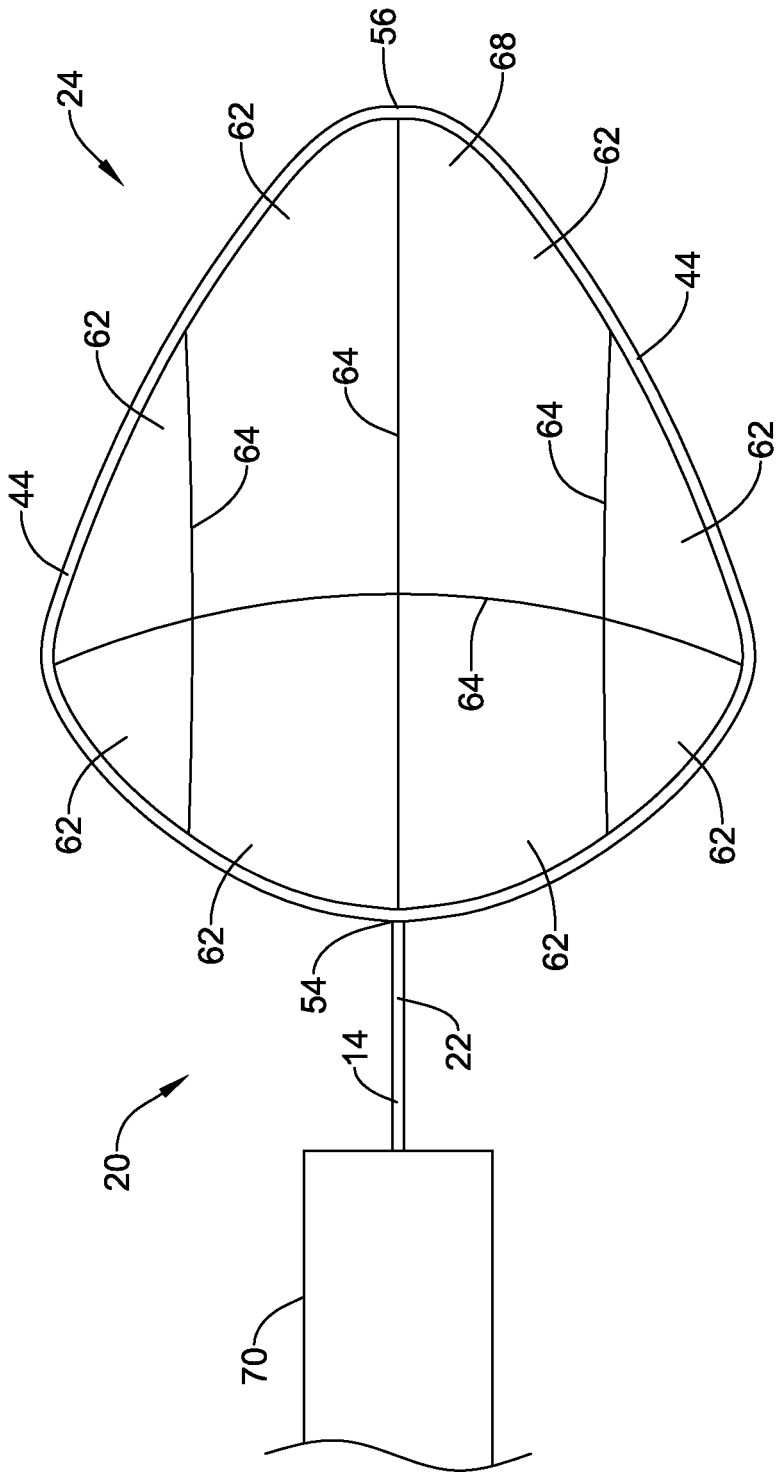


Figure 4

**REFERENCES CITED IN THE DESCRIPTION**

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专利名称(译)	高分辨率心脏标测电极阵列导管		
公开(公告)号	<a href="#">EP3057488B1</a>	公开(公告)日	2018-05-16
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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。

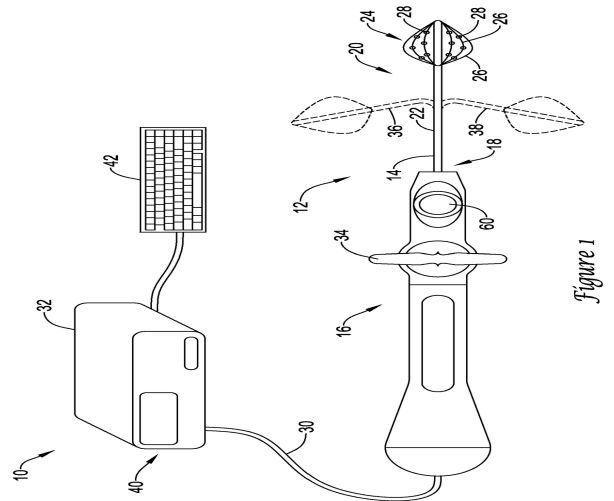


Figure 1