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(54) **ELECTRODE CATHETER, POTENTIAL DETECTION DEVICE, AND POTENTIAL DETECTION METHOD**

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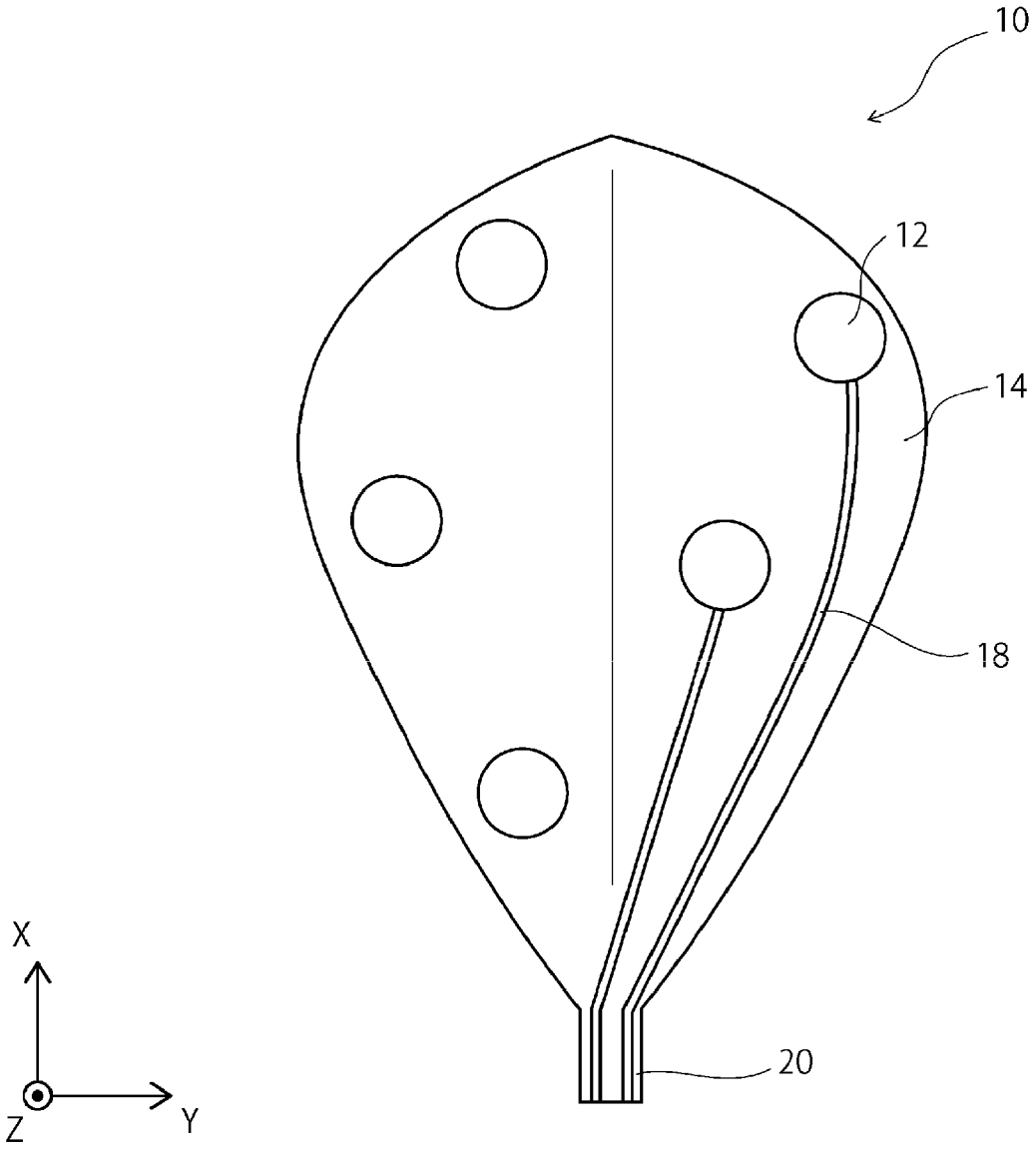
(57) **ABSTRACT**

An electrode catheter includes a base material having a thin-film shape, a shape support structure of the base material, and a plurality of electrodes provided on the base material. At least some of the plurality of electrodes are exposed on a front surface and a back surface of the base material. This can improve followability with respect to a dissection.



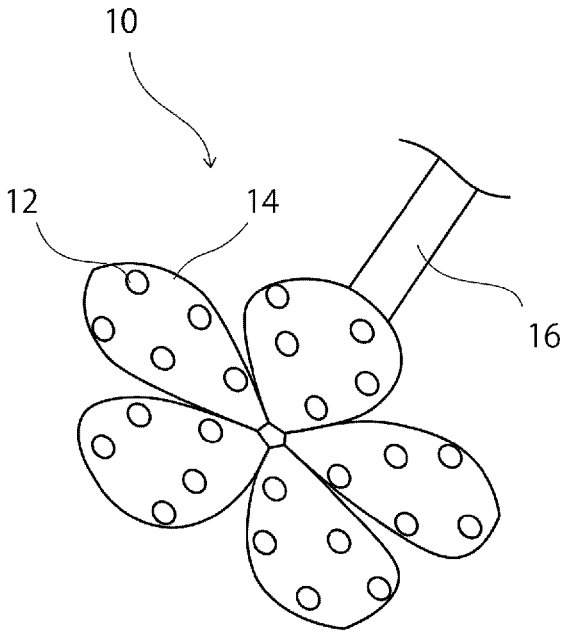


FIG. 1

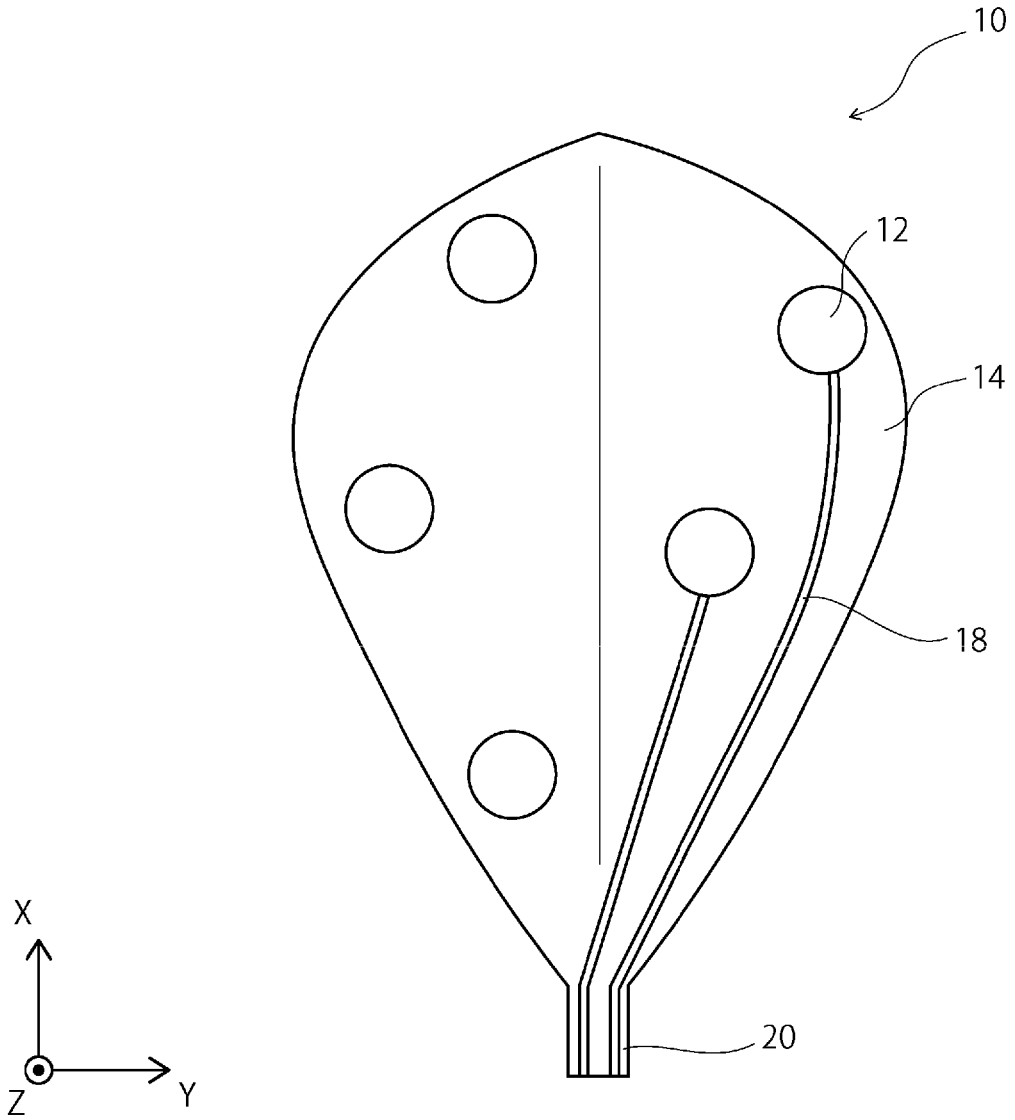


FIG. 2

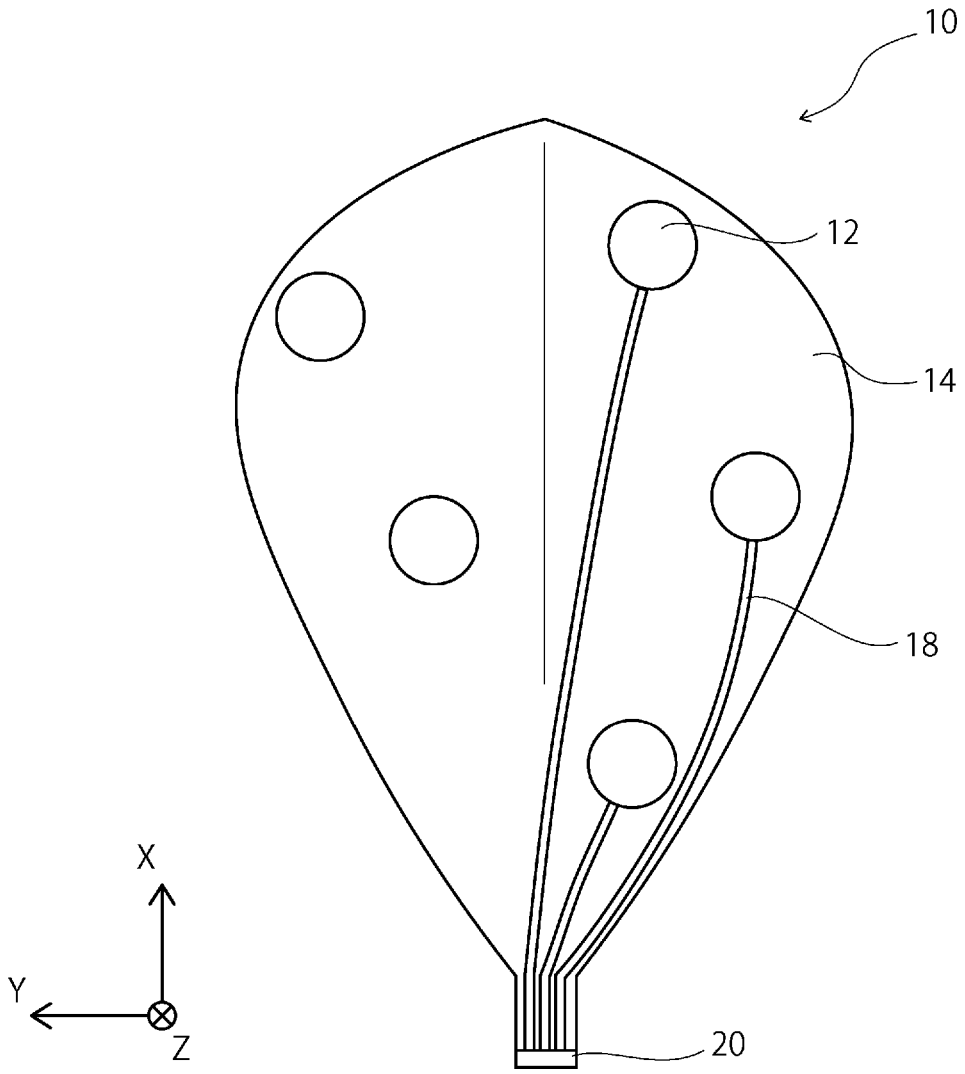


FIG. 3

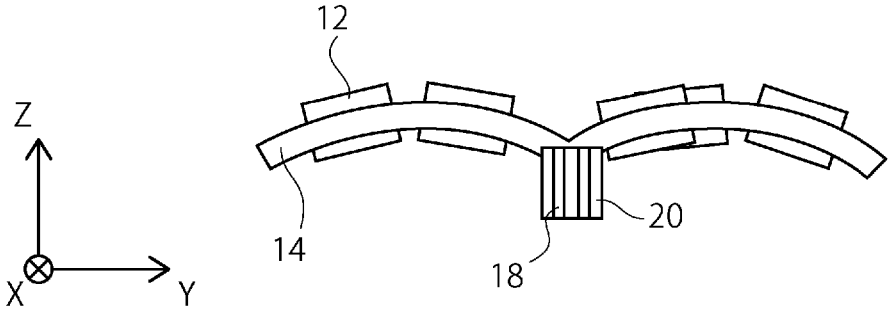


FIG. 4

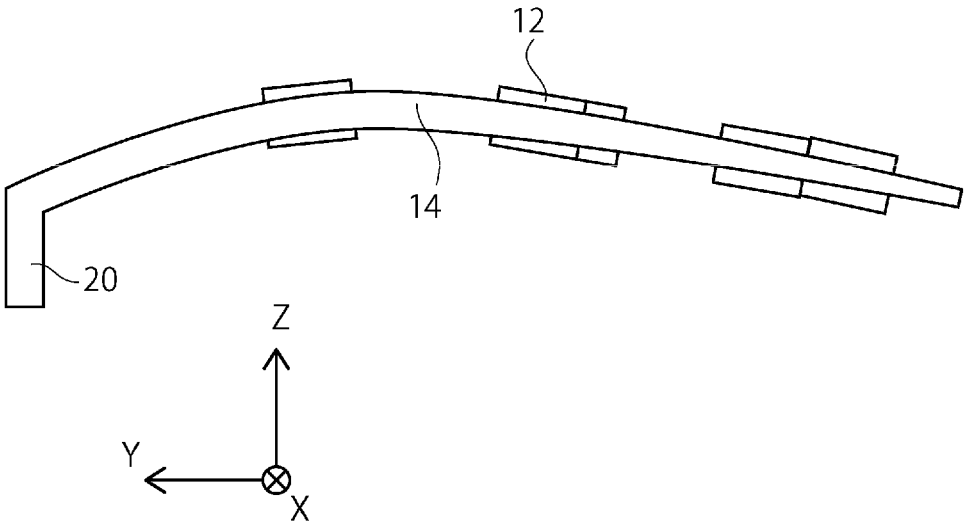


FIG. 5

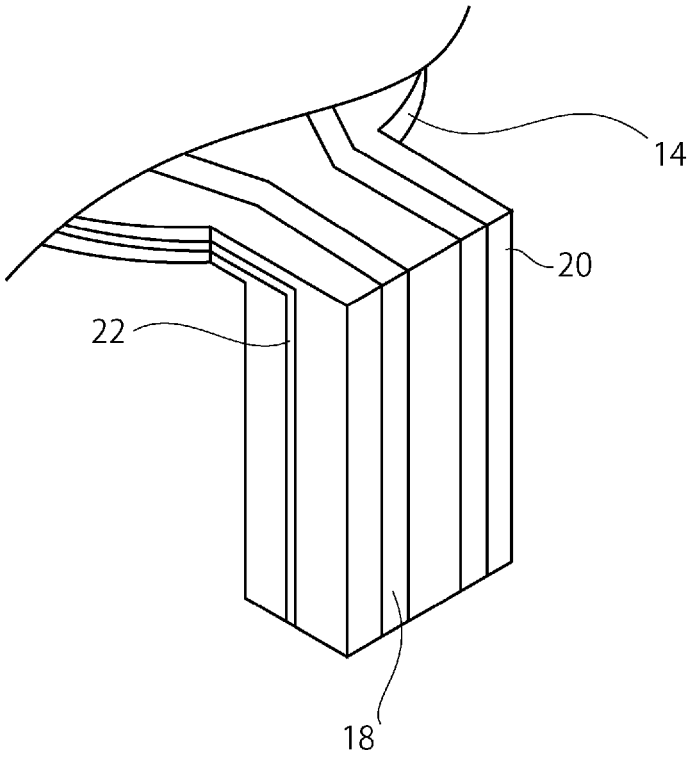


FIG. 6

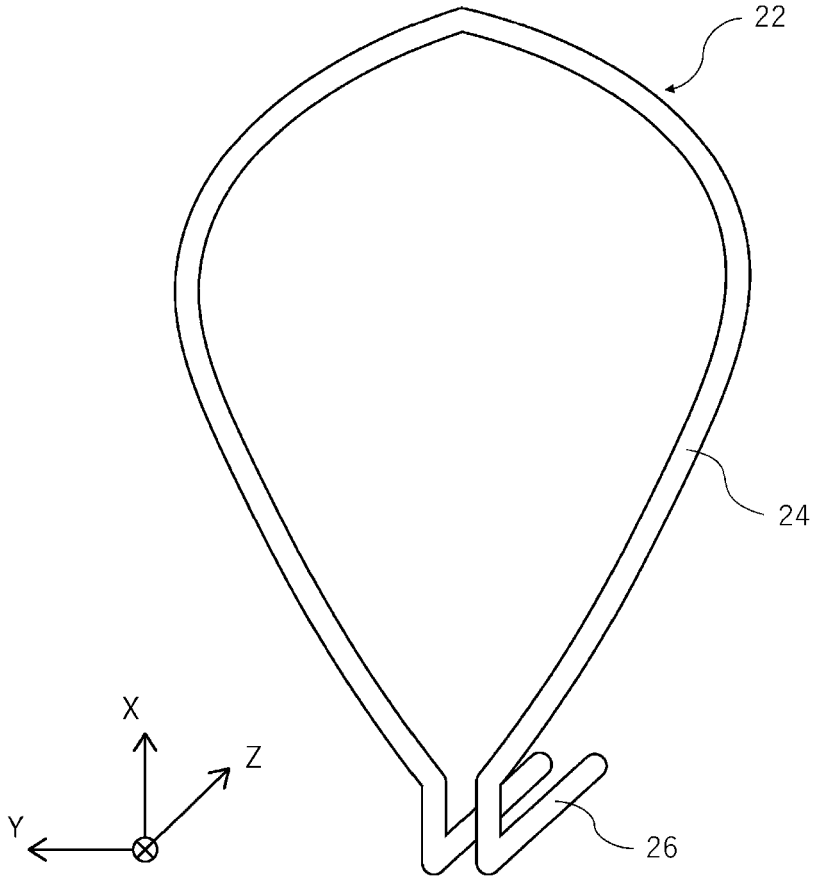


FIG. 7

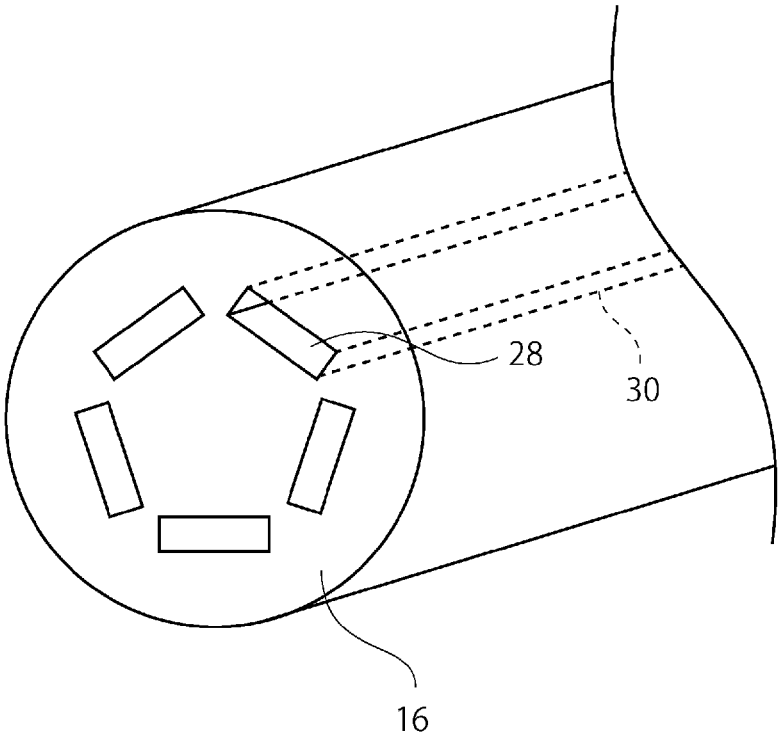


FIG. 8

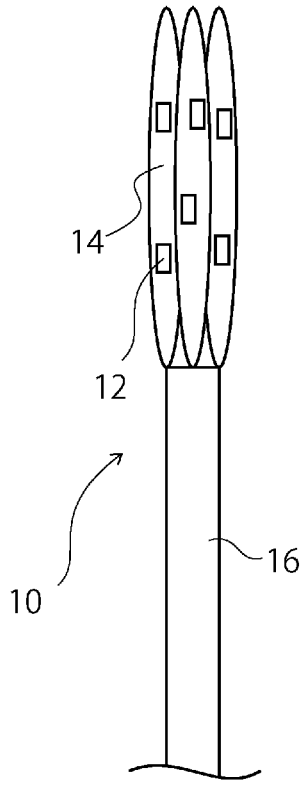


FIG. 9

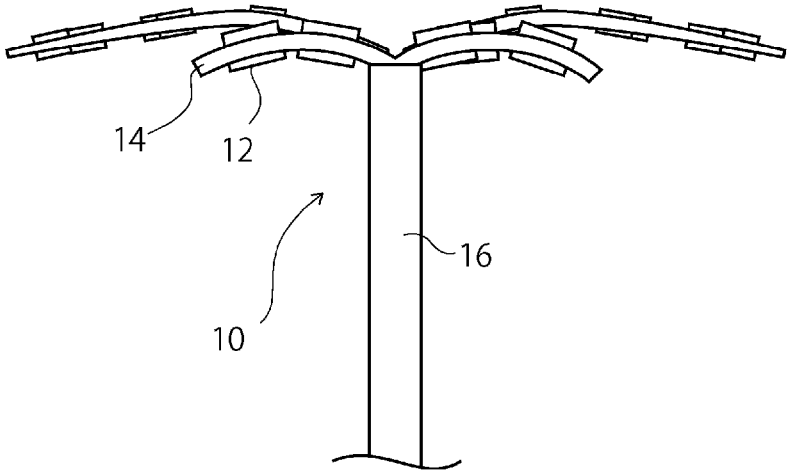


FIG. 10

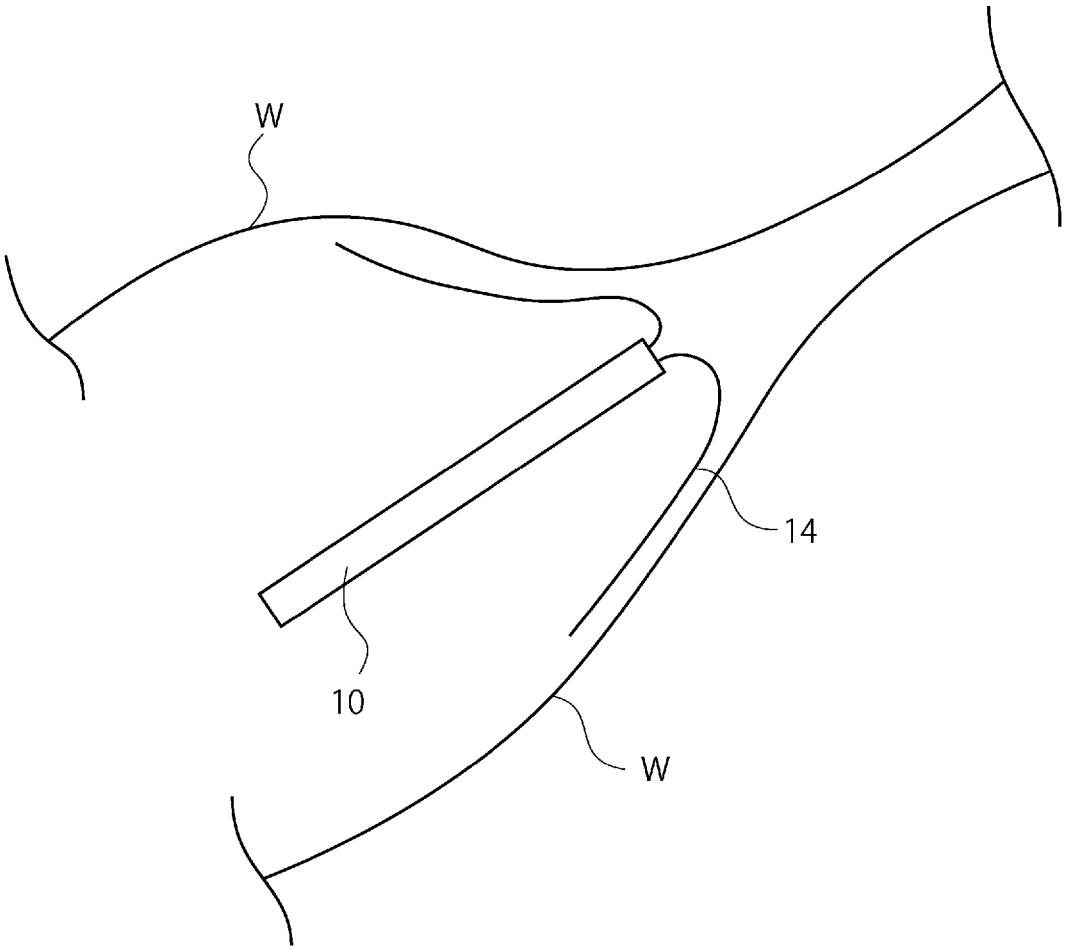


FIG. 11

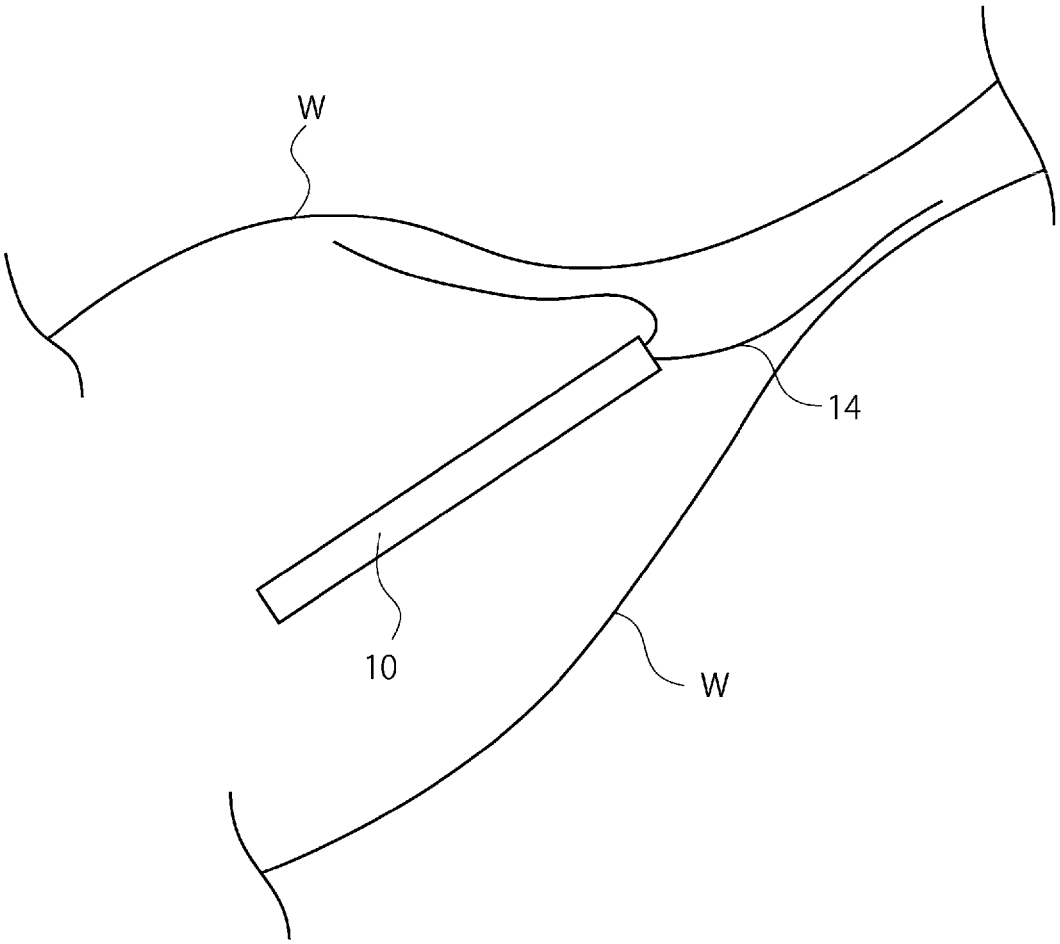


FIG. 12

ELECTRODE CATHETER, POTENTIAL DETECTION DEVICE, AND POTENTIAL DETECTION METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to Japanese Patent Application Number 2023-018905 filed on Feb. 10, 2023. The entire contents of the above-identified application are hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present invention relates to an electrode catheter, a potential detection device, and a potential detection method.

BACKGROUND

[0003] In the related art, an electrode catheter disclosed in JP 6528010 B is known as an electrode catheter for detecting a potential of an organ such as the heart. The electrode catheter of JP 6528010 B includes four arms extending substantially in parallel, each of which is provided with a plurality of electrodes.

SUMMARY

[0004] The electrode catheter disclosed in JP 6528010 B has low shape followability with respect to a dissection having a complex shape, and it is sometimes difficult to cause the electrode to contact the dissection as the operator (therapist) desires.

[0005] An object of the present disclosure is to provide an electrode catheter with improved followability with respect to a dissection.

[0006] To solve the above problem, one aspect of the present disclosure includes a base material having a thin-film shape, a shape support structure of the base material, and a plurality of electrodes provided on the base material. At least some of the plurality of electrodes are exposed on a front surface and a back surface of the base material.

BRIEF DESCRIPTION OF DRAWINGS

[0007] FIG. **1** is a perspective view of an electrode catheter according to an embodiment.

[0008] FIG. **2** is a schematic diagram of a base material of the electrode catheter.

[0009] FIG. **3** is a schematic diagram of the base material of the electrode catheter.

[0010] FIG. **4** is a schematic diagram of the base material of the electrode catheter.

[0011] FIG. **5** is a schematic diagram of the base material of the electrode catheter.

[0012] FIG. **6** is a perspective view illustrating an overview of the base material.

[0013] FIG. **7** is a perspective view illustrating a shape support structure.

[0014] FIG. **8** is a schematic diagram illustrating a shaft.

[0015] FIG. **9** is a side view of the electrode catheter.

[0016] FIG. **10** is a side view of the electrode catheter.

[0017] FIG. **11** is a diagram illustrating a usage state of the electrode catheter.

[0018] FIG. **12** is a diagram illustrating a usage state of the electrode catheter.

DESCRIPTION OF EMBODIMENTS

[0019] An embodiment of the present disclosure will be described below. In the embodiment, a so-called mapping electrode catheter is used as an example of a potential detection device. The present disclosure can be used to detect a potential of various objects having a complex surface shape. In the following embodiment, three-dimensional Cartesian coordinates may be used to describe direction. The Z-axis of the three-dimensional Cartesian coordinate is defined to extend in the axial direction of a shaft, with the distal side of the shaft (distal side viewed from an operator) referring to the negative direction and the proximal side of the shaft (proximal side viewed from the operator) referring to the positive direction. The X-axis extends in a direction orthogonal to the axis of the shaft, that is, in the radial direction of the shaft. For the convenience of description, the X-axis extends in the longitudinal direction of a base material (any one of a plurality of base materials) described below. The root side of the base material refers to the negative direction of the X-axis and the tip side of the base material refers to the positive direction of the X-axis. The Y-axis is orthogonal to the X-axis and Z-axis.

[0020] FIG. **1** is a perspective view of the electrode catheter according to the embodiment. As illustrated in FIG. **1**, an electrode catheter **10** mainly includes a plurality of electrodes **12**, a base material **14**, and a shaft **16**. As an example, the electrode catheter **10** is a so-called mapping catheter used to obtain a potential at a plurality of locations in the heart and create a three-dimensional map from the obtained results.

[0021] FIGS. **2** to **5** are schematic diagrams of the base material of the electrode catheter. More specifically, FIG. **2** is a view of the base material **14** viewed from one main surface direction (from the front side, i.e., +Z direction), and FIG. **3** is a view of the base material **14** viewed from the other main surface direction (from the back side, i.e., −Z direction). FIG. **4** is a view of the base material **14** viewed from −X direction, and FIG. **5** is a view of the base material **14** viewed from −Y direction. As illustrated in FIGS. **2** to **5**, the base material **14** has a shape imitating a so-called lanceolate leaf. More specifically, the base material **14** has a shape in the XY plane in which the width gradually increases from the root side to the tip side and then gradually decreases through an inflection point. The base material **14** has a curved shape in both the XZ and YZ planes. The base material **14** is formed by processing a thin film sheet into a predetermined shape. As a material constituting the base material **14**, a nonwoven fabric in which a resin material such as a fibrous polyurethane, polytetrafluoroethylene, nylon, polyethylene terephthalate, polyvinyl alcohol or the like is randomly accumulated can be used. The so-called electrospinning technique can be used as the fiber integration method. In other words, it can be said that the base material **14** is a nonwoven fabric sheet. Any base material **14** may be used as long as the base material **14** has a thin-film shape and the material constituting an electrode **12** can be impregnated. Thus, a woven fabric may be used as the base material **14**.

[0022] The plurality of electrodes **12** (**5** electrodes in the illustrated example) are provided on the base material **14**. Each electrode **12** is provided to be exposed on both sides of the base material **14**. That is, when the base material **14** is viewed from the front surface and from the back surface, the plurality of electrodes **12** are provided at corresponding

positions. The electrodes **12** in the corresponding position may be an integral piece formed so that one electrode **12** penetrates the base material **14**, or may be two independent electrodes **12** that are electrically connected to each other. When the electrode **12** is formed to penetrate the base material **14**, the electrode **12** may be formed by impregnating the base material **14** with conductive ink. In order to form the electrode **12** by impregnating the base material **14** with conductive ink, a cloth (nonwoven fabric or woven fabric) may be used as the base material **14**. The number of electrodes **12** can be appropriately selected according to the application and the part to be applied. As an example, the number of electrodes **12** (total number of electrodes **12**) may be 20 or more.

[0023] The plurality of electrodes **12** may be randomly and diffusely arranged on the base material **14**. The plurality of electrodes **12** may also be arranged on the base material **14** at approximately equal intervals from each other. Although the electrode catheter **10** includes a plurality of the base materials **14**, the arrangement patterns of the electrodes **12** arranged on each base material **14** may be all the same, or may be different on each or a part thereof.

[0024] Each electrode **12** is connected to a conducting wire **18**. The conducting wire **18** extends from each electrode **12** to a root portion **20** of the base material **14** along the front surface or the back surface of the base material **14**. In other words, a plurality of the conducting wires **18** are provided on the base material **14**. All of the plurality of conducting wires **18** are aggregated into the root portion **20**. Some of the plurality of conducting wires **18** extend along the front surface (corresponding to a first surface) of the base material **14**, and the remaining others extend along the back surface (corresponding to a second surface) of the base material **14**. The number of conducting wires **18** arranged on the front surface of the base material **14** and the number of conducting wires **18** arranged on the back surface of the base material **14** may be substantially the same. When the number of conducting wires **18** is odd, the number of conducting wires **18** arranged on one surface of the front surface or the back surface of the base material **14** may be required to be increased (or decreased) by one as compared with the other surface. The conducting wires **18** are not electrically connected to each other and are arranged so as not to overlap.

[0025] FIG. **6** is a perspective view illustrating an overview of the base material. Specifically, FIG. **6** is an enlarged view of the root portion **20** of the base material **14**. As illustrated in FIG. **6**, the root portion **20** is formed by a support extending along a direction (Z-axis direction) intersecting the main surface of the base material **14**. In the illustrated example, the root portion **20** has a square cylinder shape, but is not limited thereto. Some of the plurality of conducting wires **18** (conducting wires **18** extending along the front surface) extend on one surface (−X side surface) of the root portion **20**. The remaining others of the plurality of conducting wires **18** (conducting wires **18** extending along the back surface) extend on the other surface (+X side surface) of the root portion **20**. That is, the plurality of conducting wires **18** extend along a surface (the surface of the root portion **20**) that is continuous with the surface of the base material **14** on which the conducting wires **18** are arranged.

[0026] FIG. **7** is a perspective view illustrating a shape support structure. The shape support structure is constituted by a shape memory member **22** processed into a predetermined shape. The shape memory member **22** includes a first portion **24** extending along the periphery (around the Z-axis) of the base material **14** and a second portion **26** extending along the root portion **20**. The first portion **24** and the second portion **26** are formed of one continuous wire rod. The shape memory member **22** is preferably formed of NiTi, for example. The first portion **24**, like the base material **14**, has an outline imitating a lanceolate leaf. The ends of the first portion **24** are spaced apart from each other. The second portion **26** is formed of two wire rods each extending along the Z-axis from the end of the first portion **24**. The shape memory member **22** is joined along the periphery of the base material **14**, and when no external force is applied to the shape memory member **22**, the base material **14** is pulled and stretched (expanded) by the shape memory member **22**. The shape memory member **22** is shaped so that the base material **14** can maintain the expanded state. Thus, the base material **14**, in a state with no force acting, assumes a posture (expanded state) extending in the XY plane from the root portion **20**.

[0027] FIG. **8** is a schematic diagram illustrating the shaft. Specifically, FIG. **8** illustrates the vicinity of the end face of the shaft **16** in the +Z-axis direction. For clarity, only one lumen is illustrated in FIG. **8**. A plurality of openings **28** are provided on the end face of the shaft **16**. An opening **28** is a doorway to a lumen **30** that extends through the shaft **16**. The plurality of lumens **30** each extends axially across the shaft **16** to the other end face. The root portion **20** of the base material **14** is inserted into each opening **28** and fixed by a fixing means such as an adhesive. One base material **14** is inserted into one opening **28**. The conducting wires **18** of each base material **14** enter the shaft **16** through the opening **28** and exit shaft **16** through the opposite end face. Each lumen **30** is spatially independent of each other, and the plurality of conducting wires **18** are insulated between each other.

[0028] FIGS. **9** and **10** are side views of the electrode catheter. Specifically, FIG. **9** illustrates the electrode catheter **10** in a contracted state, and FIG. **10** illustrates the electrode catheter **10** in an expanded state.

[0029] As illustrated in FIG. **10**, in the electrode catheter **10**, the base material **14** extends radially outward in the expanded state. The plurality of base materials **14** are arranged so that the electrodes **12** do not overlap each other. In the transition between the expanded state and the contracted state, it is preferable that the base materials **14** do not overlap in order to make it difficult for the base materials **14** to interfere with each other. When no external force is acting on the electrode catheter **10**, the restoring force of the shape memory member **22** keeps the electrode catheter **10** in the expanded state. When an external force of a predetermined value or more acts on the base material **14**, the base material **14** deforms against the restoring force of the shape memory member **22**. The base material **14** is deformable in both the front surface direction and the back surface direction. The base materials **14** may be deformed independently of each other.

[0030] As illustrated in FIG. **9**, in the electrode catheter **10**, all of the base materials **14** extend along the axis of the shaft **16** in the contracted state. That is, in the contracted state, all of the base materials **14** are aggregated along the axis of the shaft **16**. As a result, the outer diameter of the electrode catheter **10** is entirely reduced. The electrode catheter **10** is contracted in a delivery sheath upon delivery.

[0031] Next, an operation of the electrode catheter **10** will be described.

[0032] FIGS. **11** and **12** are diagrams illustrating usage states of the electrode catheter. FIGS. **11** and **12** illustrate a state in which a potential near the confluence point between the left atrium and the left pulmonary vein is mapped. In FIGS. **11** and **12**, the electrode catheter **10** is in an expanded state. In FIG. **11**, it can be seen that the surfaces (potential detection surface) of all base materials **14** of the electrode catheter **10** are in contact with a dissection wall W (potential detection target surface). On the other hand, in FIG. **12**, the front surfaces of some of the base materials **14** are in contact with the dissection wall W, and the back surfaces of some of the base materials **14** are in contact with the dissection wall W.

[0033] When the electrode catheter **10** is moved from the contracted state to the expanded state, it may be difficult to control which face of the base material **14** contacts the dissection wall W, depending on the shape of the dissection wall W. On the other hand, since the electrode **12** is present on both sides of the base material **14**, the electrode catheter **10** can perform mapping no matter which side of the base material **14** contacts the dissection wall W.

[0034] The embodiment is only one aspect of the present disclosure, and each configuration of the embodiment may be modified as appropriate without departing from the spirit of the present disclosure.

[0035] The tip of the base material **14** may be rounded in the XY plane or recessed to the root side. With this, the sharp shape of the tip of the base material **14** can be removed.

[0036] Adjacent base materials **14** may be connected to each other by a tensile member such as a tether. This can reduce the amount of deviation of the relative positions between each other of the base materials **14** in the circumferential direction.

[0037] While preferred embodiments of the disclosure have been described above, it is to be understood that variations and modifications will be apparent to those skilled in the art without departing from the scope and spirit of the disclosure. The scope of the disclosure, therefore, is to be determined solely by the following claims.

1. An electrode catheter, comprising:
a base material having a thin-film shape;
a shape support structure of the base material; and
a plurality of electrodes provided on the base material, wherein
at least some of the plurality of electrodes are exposed on a front surface and a back surface of the base material.

2. The electrode catheter according to claim **1**, wherein
at least some of the plurality of electrodes are each connected to a conducting wire that extends along the front surface of the base material, and
a remainder of the plurality of electrodes is each connected to a conducting wire that extends along the back surface of the base material.

3. The electrode catheter according to claim **1**, wherein the shape support structure is a shape memory member arranged along a periphery of the base material.

4. The electrode catheter according to claim **1**, comprising:
a plurality of the base materials, wherein
the electrode catheter further comprises a shaft that holds a root of each of the plurality of the base materials; and
a connecting member that connects adjacent ones of the plurality of the base materials, and
the plurality of the base materials are arranged circumferentially around the shaft and are capable of assuming an expanded state and a contracted state.

5. The electrode catheter according to claim **4**, wherein
at least some of the plurality of electrodes are each connected to a front-side conducting wire that extends along the front surface of the base material,
a remainder of the plurality of electrodes is each connected to a back-side conducting wire that extends along the back surface of the base material, and
the front-side conducting wire and the back-side conducting wire are axially provided on outer surfaces of a root along the root of the base material.

6. The electrode catheter according to claim **5**, wherein
the root of the base material comprises a first surface facing a front side of the base material and a second surface facing a back side of the base material,
the front-side conducting wire is provided on the first surface, and
the back-side conducting wire is provided on the second surface.

7. The electrode catheter according to claim **1**, comprising:
20 or more of the plurality of electrodes.

8. A potential detection device, comprising:
a base material having a thin-film shape;
a shape support structure of the base material; and
a plurality of electrodes arranged on the base material, wherein
at least some of the plurality of electrodes are exposed on a front surface and a back surface of the base material.

9. A potential detection method, comprising:
expanding a plurality of thin-film shaped base materials supported by a shape support structure in a contracted state; and
contacting a front surface of each of some of the plurality of thin-film shaped base materials with a potential detection target surface, and contacting a back surface of each of a remainder of the plurality of thin-film shaped base materials with the potential detection target surface.

* * * * *