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(54) **ENDOCARDIAL MAPPING SYSTEM**

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(63) Continuation-in-part of application No. 08/376,067, filed on Jan. 20, 1995, now Pat. No. 5,553,611, which is a continuation of application No. 08/178,128, filed on Jan. 6, 1994, now abandoned, application No. 10/706,484, which is a continuation-in-part of application No. 07/949,690, filed on Sep. 23, 1992, now Pat. No. 5,311,866, and a continuation-in-part of application No. 07/950,448, filed on Sep. 23, 1992, now Pat. No. 5,297,549.

(51) **Int. Cl.**
A61B 5/0402 (2006.01)

(52) **U.S. Cl.** **600/374**; 600/509; 607/122

(58) **Field of Classification Search** 606/372, 606/374, 509, 547; 607/116, 119, 122, 123, 607/125–128
See application file for complete search history.

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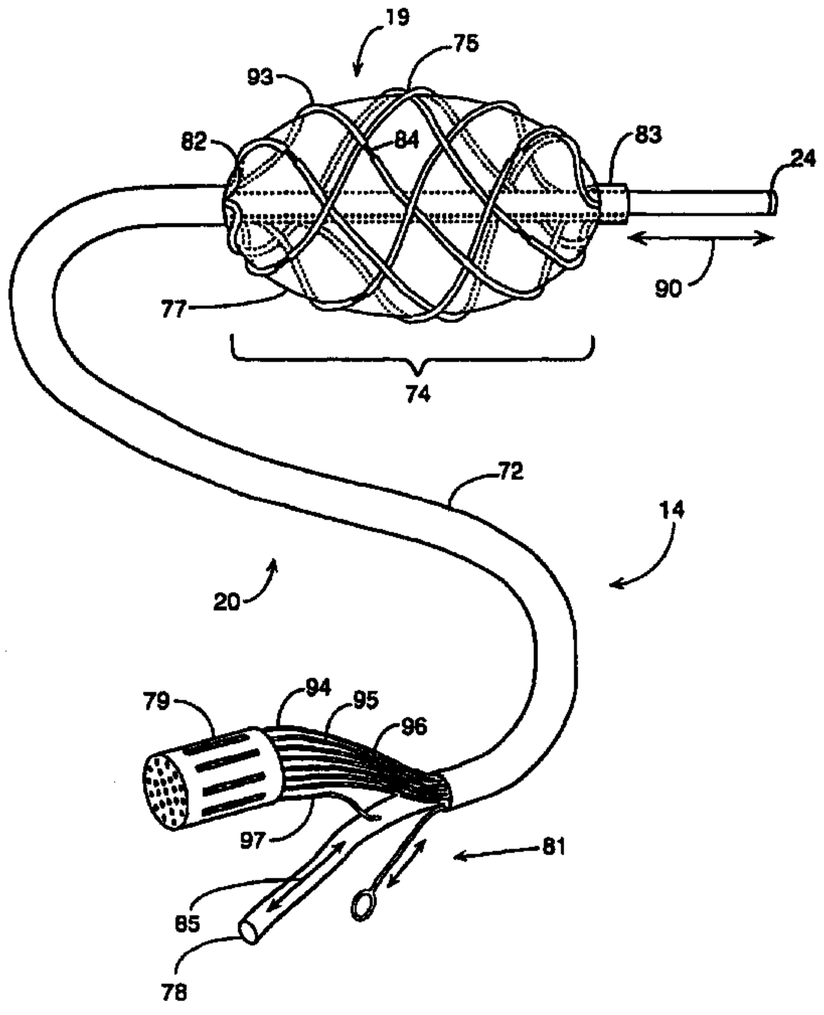
(57) **ABSTRACT**

A system for mapping electrical activity of a patient's heart includes a set of electrodes spaced from the heart wall and a set of electrodes in contact with the heart wall. Voltage measurements from the electrodes are used to generate three-dimensional and two-dimensional maps of the electrical activity of the heart.

19 Claims, 8 Drawing Sheets



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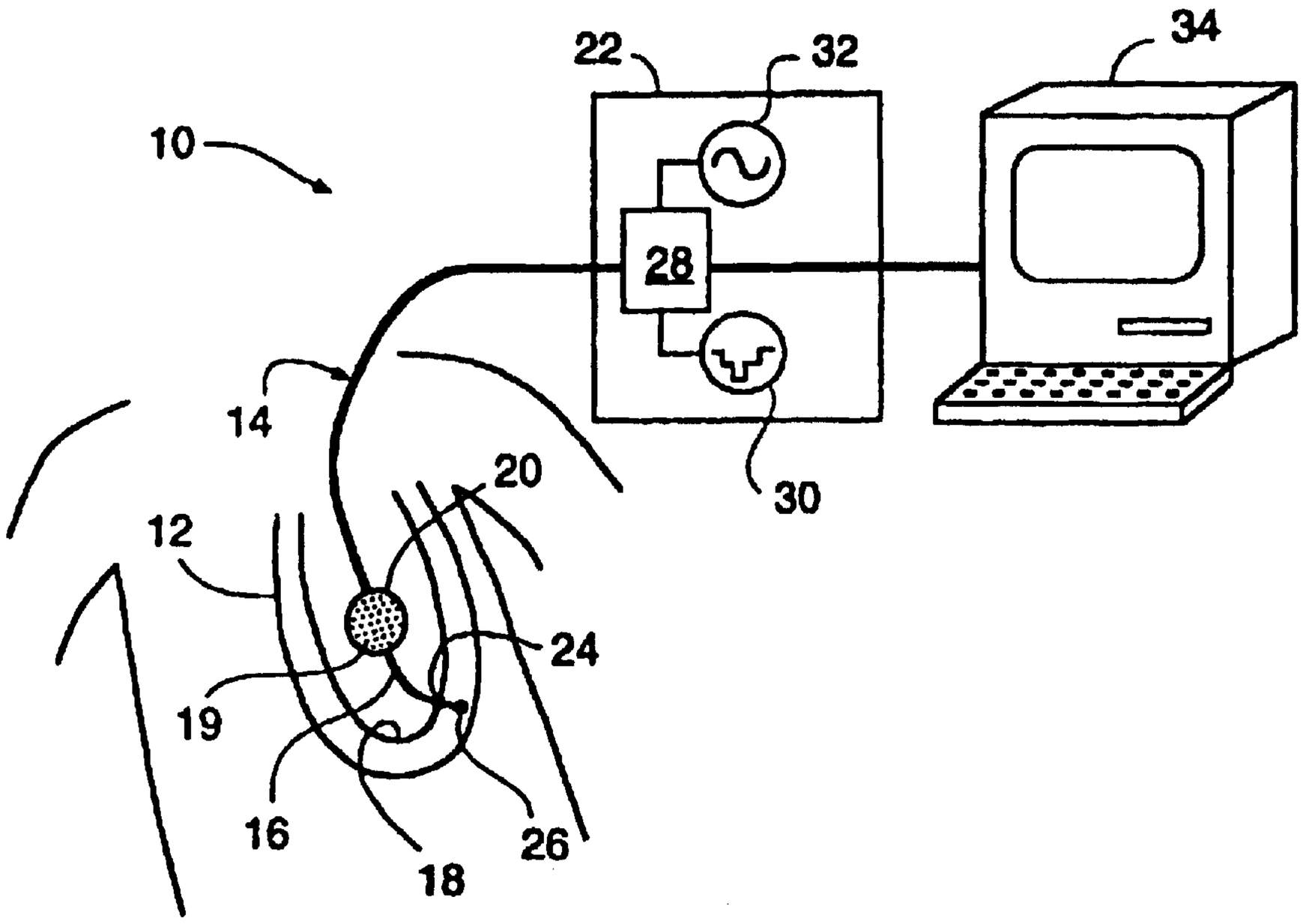

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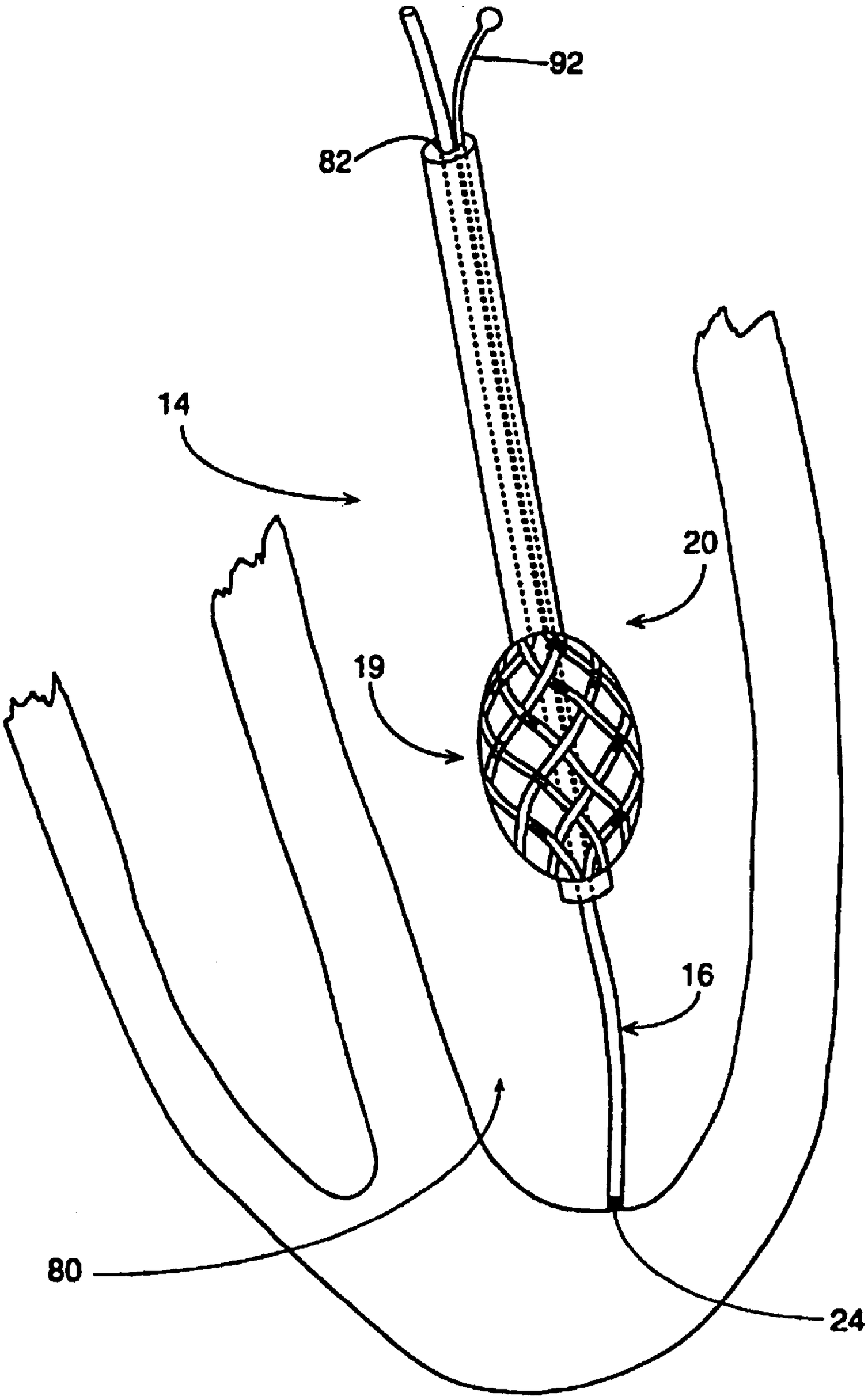


FIG. 2

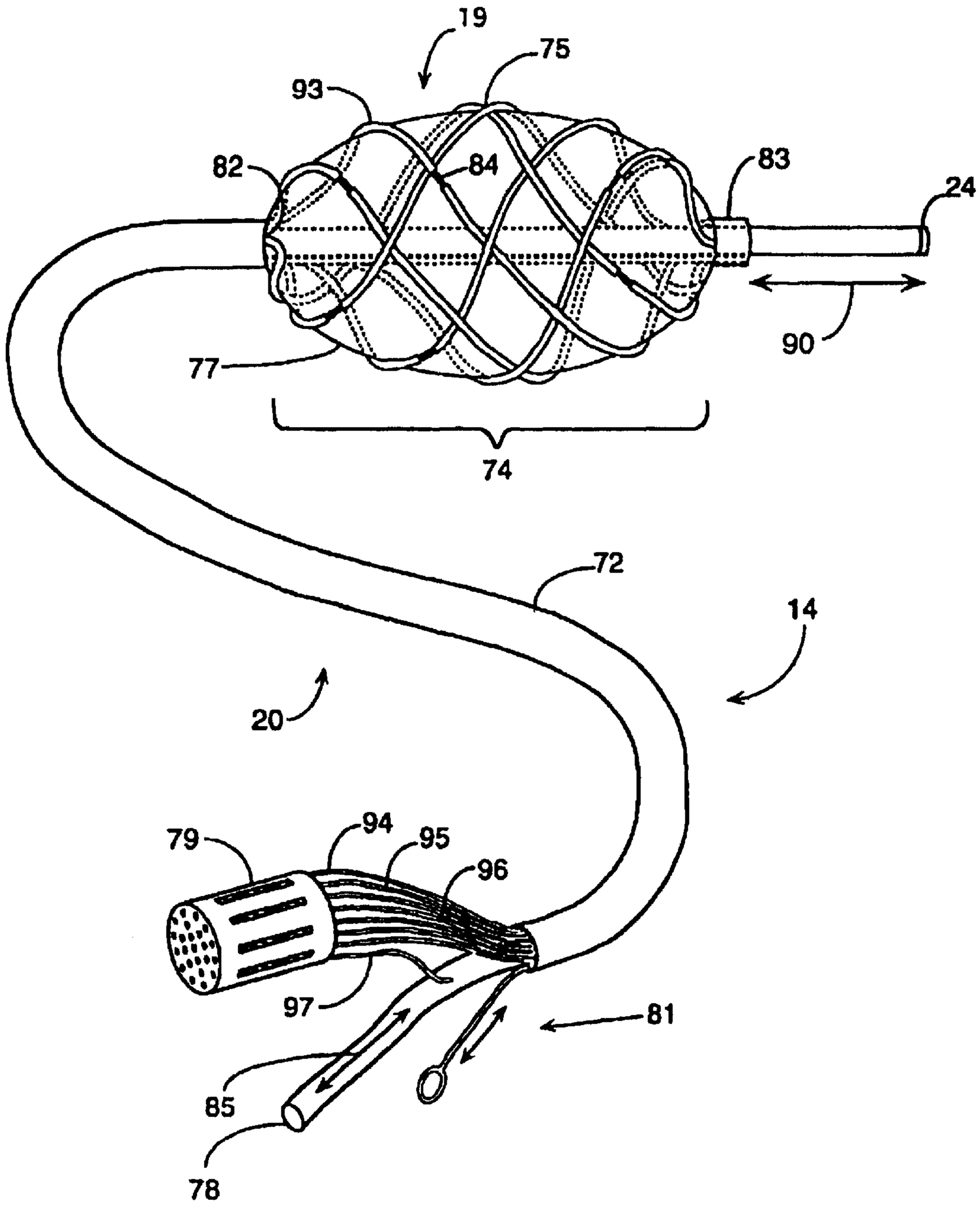
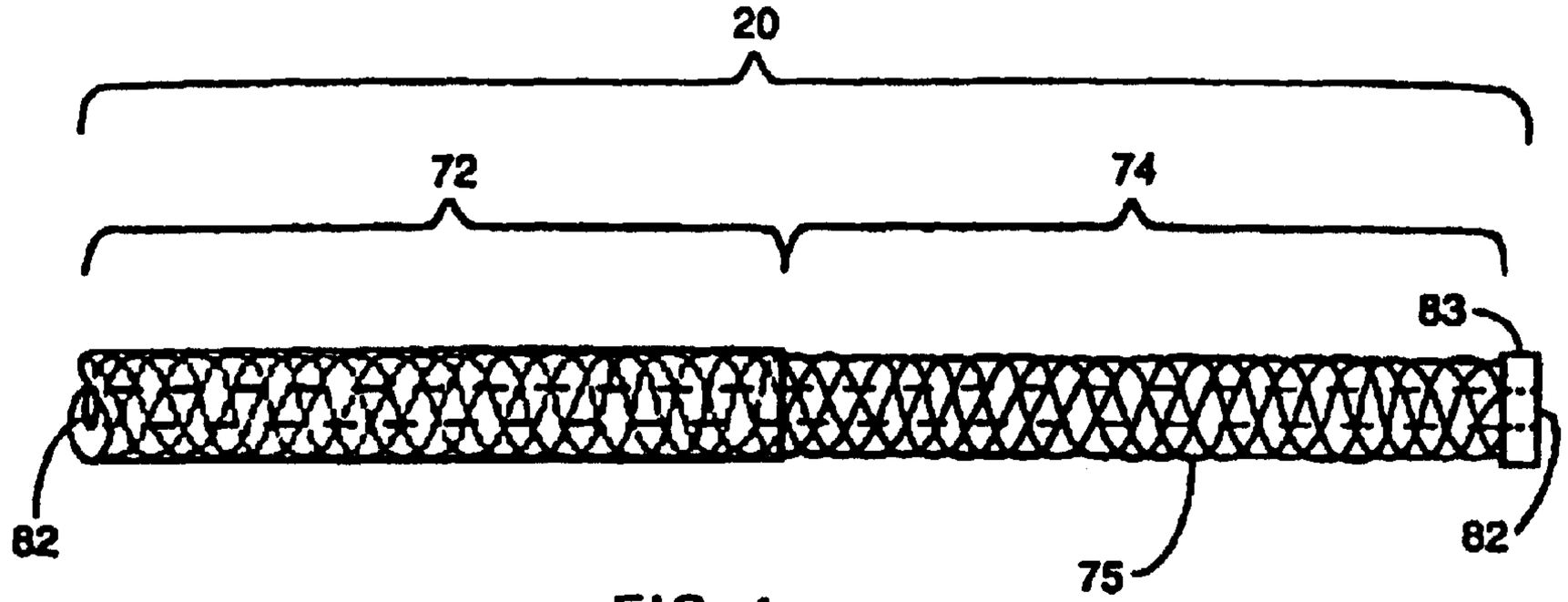


FIG. 3



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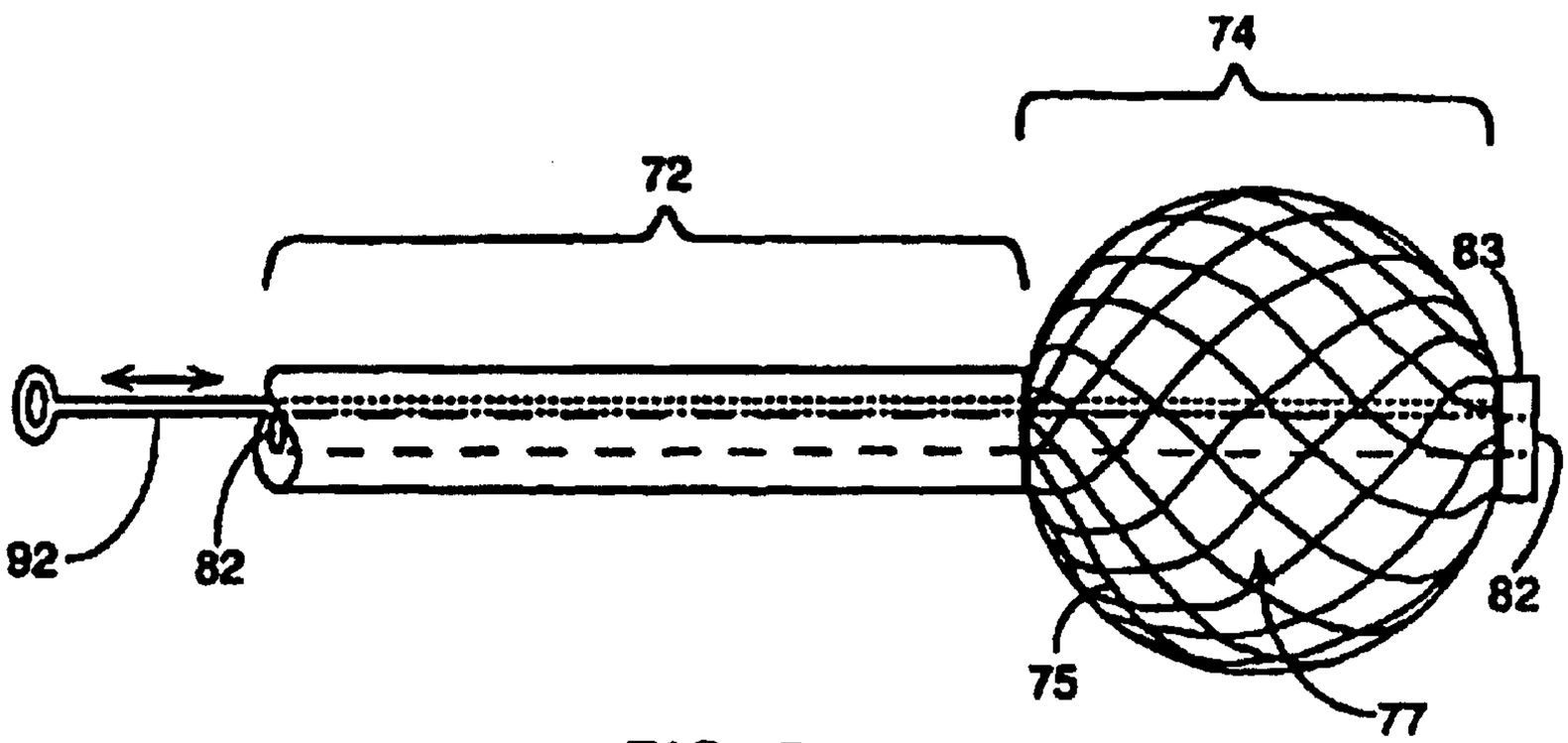

FIG. 5

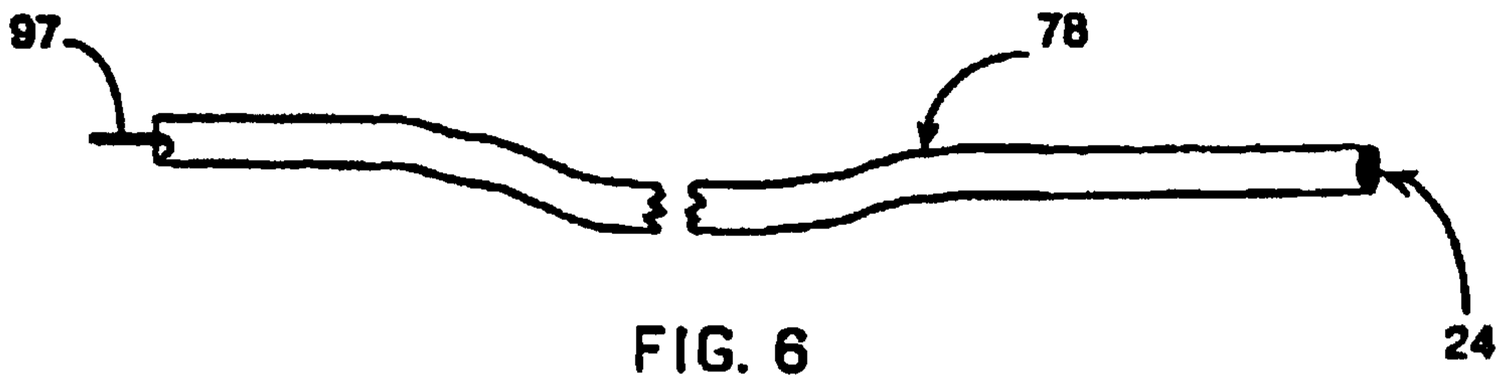

FIG. 6

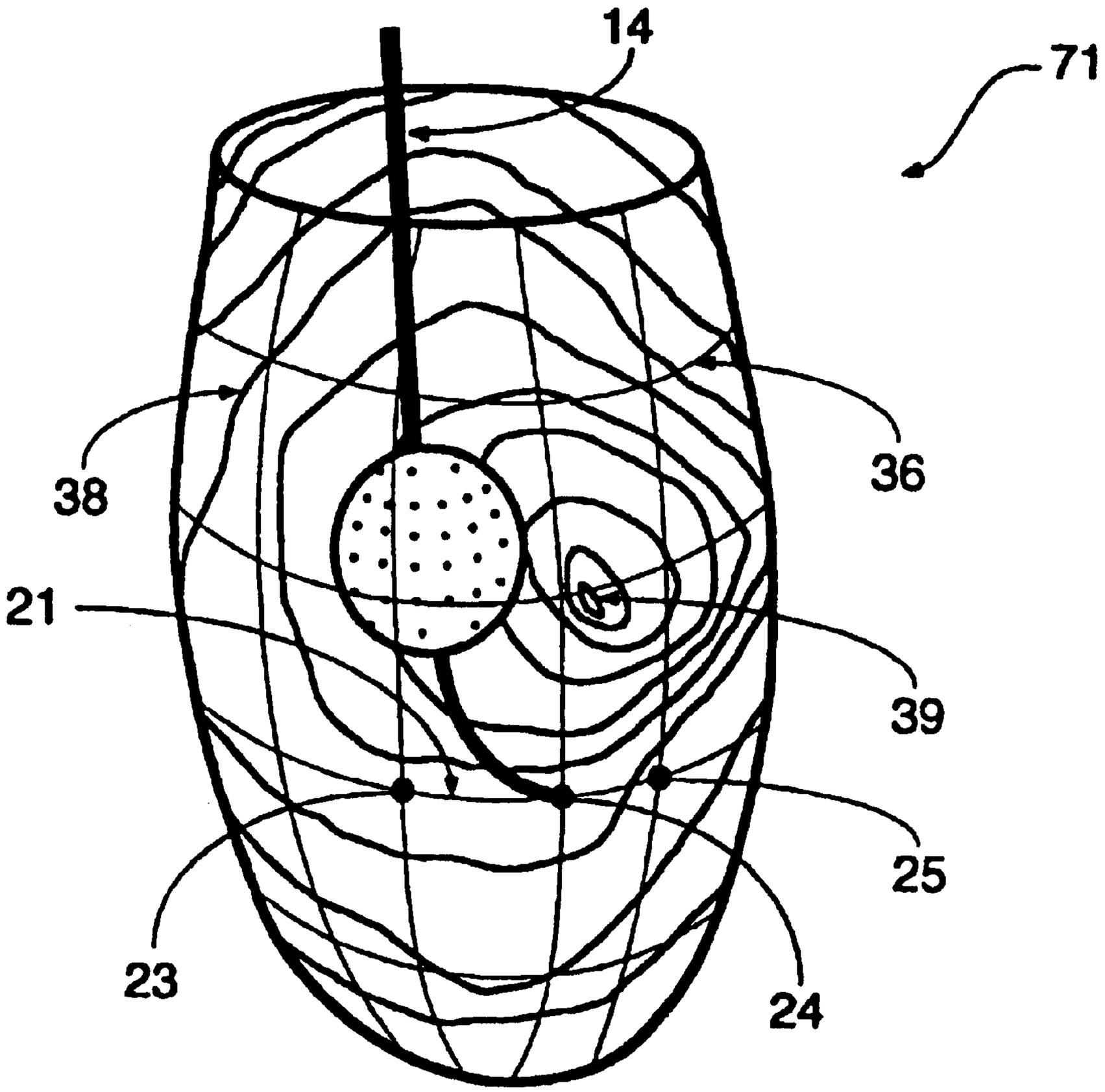

FIG. 7

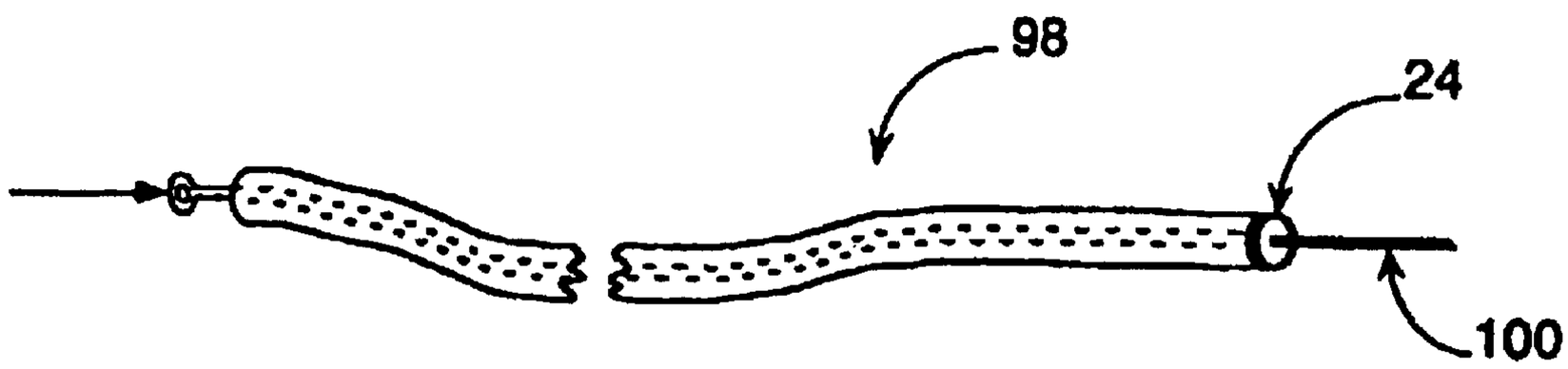

FIG. 8

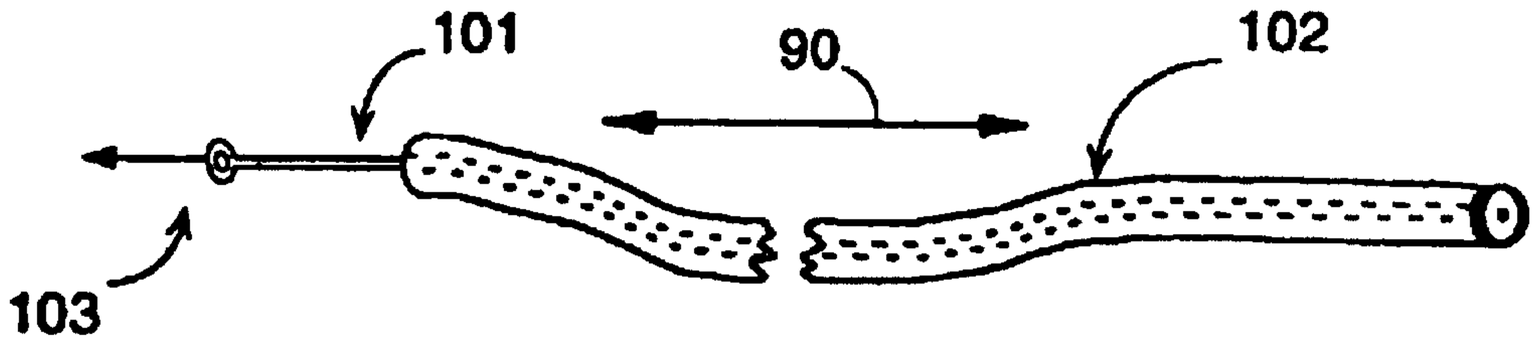

FIG. 9

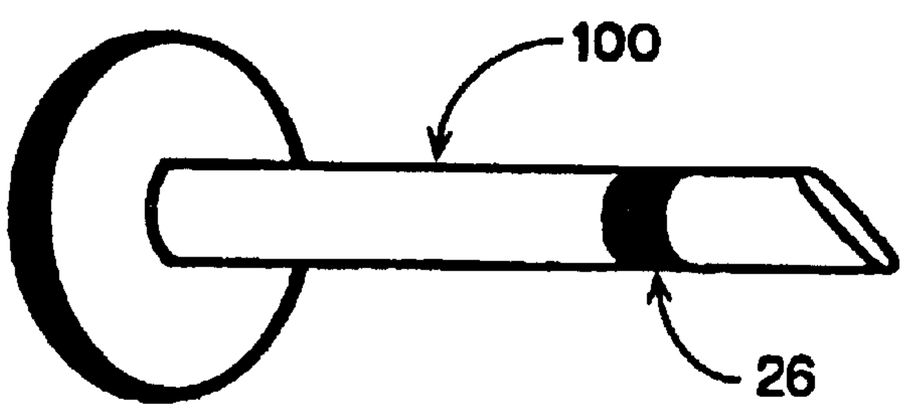

FIG. 10

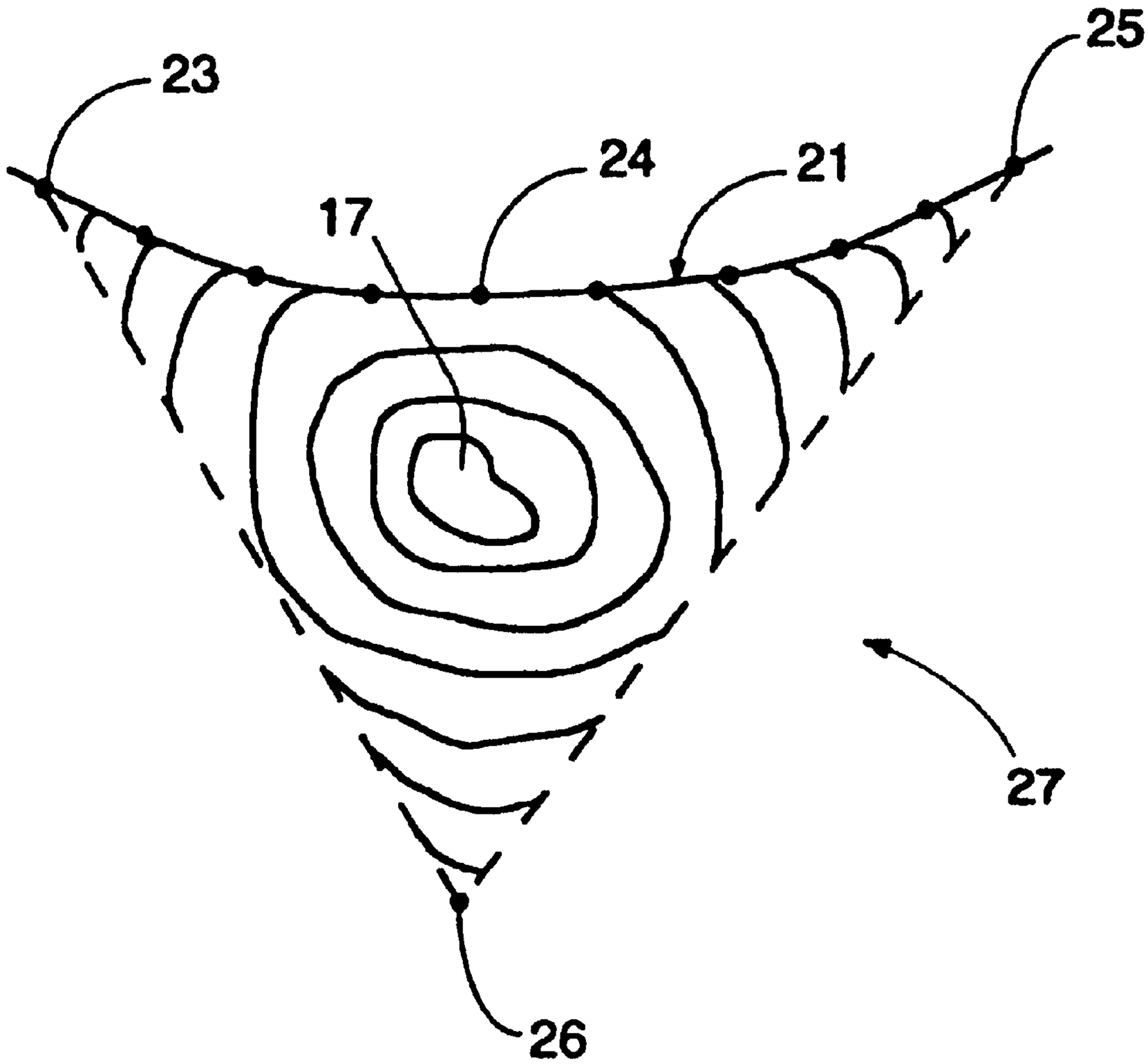

FIG. 11

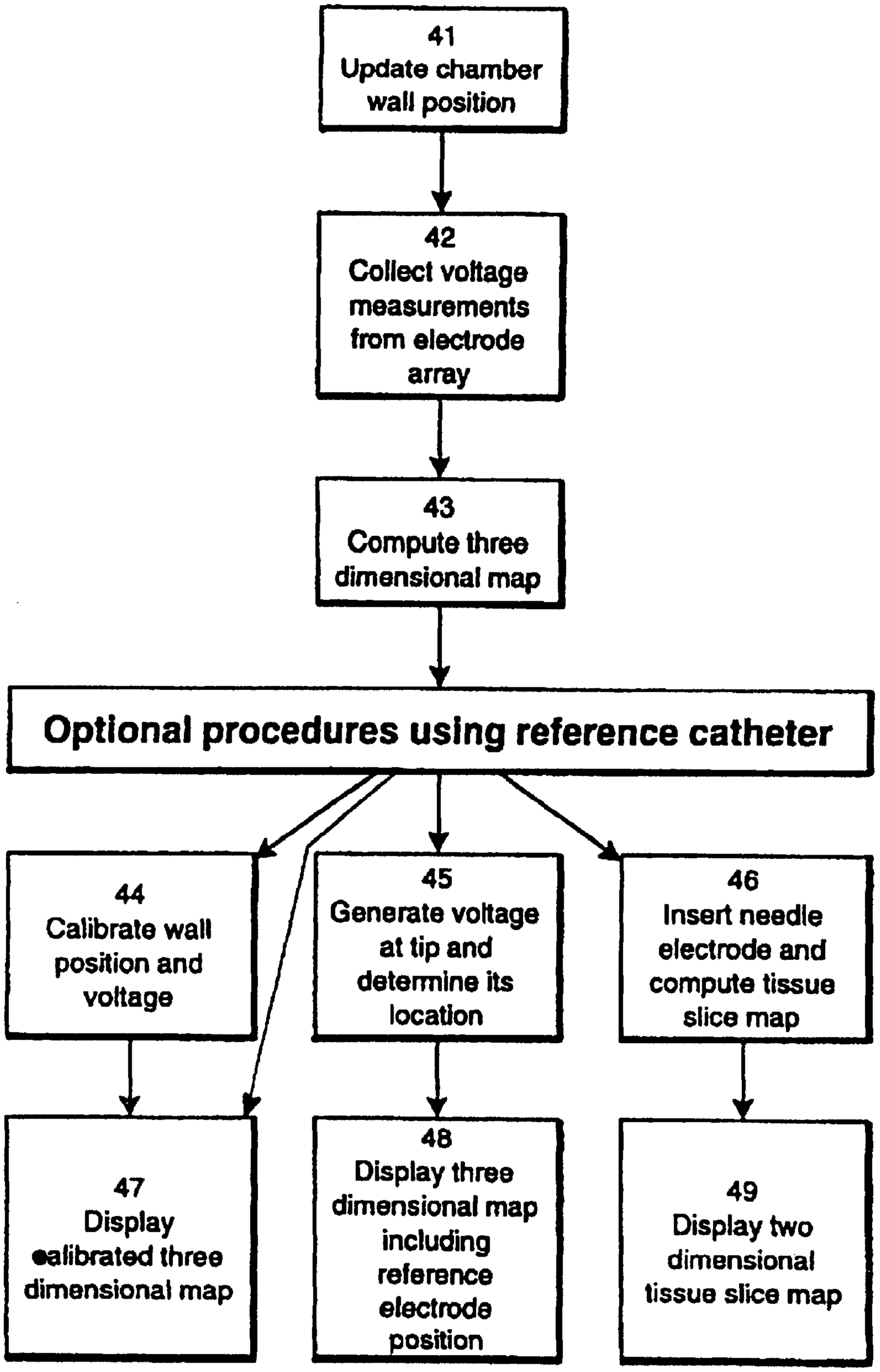
41
Update chamber wall position
42
Collect voltage measurements from electrode array
43
Compute three dimensional map
Optional procedures using reference catheter
44
Calibrate wall position and voltage
45
Generate voltage at tip and determine its location
46
Insert needle electrode and compute tissue slice map
47
Display calibrated three dimensional map
48
Display three dimensional map including reference electrode position
49
Display two dimensional tissue slice map

FIG. 12

ENDOCARDIAL MAPPING SYSTEM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. nonprovisional application Ser. No. 08/376,067, filed Jan. 20, 1995, now U.S. Pat. No. 5,553,611, which is a continuation of U.S. nonprovisional application Ser. No. 08/178,128, filed Jan. 6, 1994, now abandoned. This application is a reissue of U.S. nonprovisional application Ser. No. 08/387,832, filed May 26, 1995, now U.S. Pat. No. 6,240,307, which is a 371 of PCT/US1993/09015, filed Sep. 23, 1993, which is a continuation-in-part of U.S. nonprovisional application Ser. No. 07/950,448, filed Sep. 23, 1992, now U.S. Pat. No. 5,297,549 and U.S. nonprovisional application Ser. No. 07/949,690, filed Sep. 23, 1992, now U.S. Pat. No. 5,311,866.

Applicants have filed a child application of the present reissue of U.S. Pat. No. 6,240,307. The child application is application Ser. No. 10/955,894.

TECHNICAL FIELD

The invention discloses the apparatus and technique for forming a three-dimensional electrical map of the interior of a heart chamber, and a related technique for forming a two-dimensional subsurface map at a particular location in the endocardial wall.

BACKGROUND ART

It is common to measure the electrical potentials present on the interior surface of the heart as a part of an electrophysiologic study of a patient's heart. Typically such measurements are used to form a two-dimensional map of the electrical activity of the heart muscle. An electrophysiologist will use the map to locate centers of ectopic electrical activity occurring within the cardiac tissues. One traditional mapping technique involves a sequence of electrical measurements taken from mobile electrodes inserted into the heart chamber and placed in contact with the surface of the heart. An alternative mapping technique takes essentially simultaneous measurements from a floating electrode array to generate a two-dimensional map of electrical potentials.

The two-dimensional maps of the electrical potentials at the endocardial surface generated by these traditional processes suffer many defects. Traditional systems have been limited in resolution by the number of electrodes used. The number of electrodes dictated the number of points for which the electrical activity of the endocardial surface could be mapped. Therefore, progress in endocardial mapping has involved either the introduction of progressively more electrodes on the mapping catheter or improved flexibility for moving a small mapping probe with electrodes from place to place on the endocardial surface. Direct contact with electrically active tissue is required by most systems in the prior art in order to obtain well conditioned electrical signals. An exception is a non-contact approach with spot electrodes. These spot electrodes spatially average the electrical signal through their conical view of the blood media. This approach therefore also produces one signal for each electrode. The small number of signals from the endocardial wall will result in the inability to accurately resolve the location of ectopic tissue masses. In the prior art, iso-potentials are interpolated and plotted on a rectilinear map which can only crudely represent the unfolded interior surface of the heart. Such two-dimensional maps are generated by interpolation processes which "fill in" contours based upon a limited set of measurements. Such interpolated two-dimensional maps have significant deficiencies. First, if a localized ectopic focus is between two electrode views such a map will at best show the ectopic focus overlaying both electrodes and all points in between and at worst will not see it at all. Second, the two dimensional map, since it contains no chamber geometry information, cannot indicate precisely where in the three dimensional volume of the heat chamber an electrical signal is located. The inability to accurately characterize the size and location of ectopic tissue frustrates the delivery of certain therapies such as "ablation".

SUMMARY DISCLOSURE

In general the present invention provides a method for producing a high-resolution, three-dimensional map of electrical activity of the inside surface of a heart chamber.

The invention uses a specialized catheter system to obtain the information necessary to generate such a map.

In general the invention provides a system and method which permits the location of catheter electrodes to be visualized in the three-dimensional map.

The invention may also be used to provide a two-dimensional map of electrical potential at or below the myocardial tissue surface.

Additional features of the invention will appear from the following description in which the illustrative embodiment is set forth in detail in conjunction with the accompanying drawings. It should be understood that many modifications to the invention, and in particular to the preferred embodiment illustrated in these drawings, may be made without departing from the scope of the invention.

FIG. **1** is a schematic view of the system.

FIG. **2** is a view of the catheter assembly placed in an endocardial cavity.

FIG. **3** is a schematic view of the catheter assembly.

FIG. **4** is a view of the mapping catheter with the deformable lead body in the collapsed position.

FIG. **5** is a view of the mapping catheter with the deformable lead body in the expanded position.

FIG. **6** is a view of the reference catheter.

FIG. **7** is a schematic view representing the display of the three-dimensional map.

FIG. **8** is a side view of an alternate reference catheter.

FIG. **9** is a side view of an alternate reference catheter.

FIG. **10** is a perspective view of an alternate distal tip.

FIG. **11** is a schematic view representing the display of the subsurface two-dimensional map.

FIG. **12** is a schematic flow chart of the steps in the method.

DETAILED DISCLOSURE

In general, the system of the present invention is used for mapping the electrical activity of the interior surface of a heart chamber **80**. The mapping catheter assembly **14** includes a flexible lead body **72** connected to a deformable distal lead body **74**. The deformable distal lead body **74** can be formed into a stable space filling geometric shape after introduction into the heart cavity **80**. This deformable distal

lead body **74** includes an electrode array **19** defining a number of electrode sites. The mapping catheter assembly **14** also includes a reference electrode preferably placed on a reference catheter **16** which passes through a central lumen **82** formed in the flexible lead body **72** and the distal lead body **74**. The reference catheter assembly **16** has a distal tip electrode assembly **24** which may be used to probe the heart wall. This distal contact electrode assembly **24** provides a surface electrical reference for calibration. The physical length of the reference catheter **16** taken with the position of the electrode array **19** together provide a reference which may be used to calibrate the electrode array **19**. The reference catheter **16** also stabilizes the position of the electrode array **19** which is desirable.

These structural elements provide a mapping catheter assembly which can be readily positioned within the heart and used to acquire highly accurate information concerning the electrical activity of the heart from a first set of preferably non-contact electrode sites and a second set of in-contact electrode sites.

The mapping catheter assembly **14** is coupled to interface apparatus **22** which contains a signal generator **32**, and voltage acquisition apparatus **30**. Preferably, in use, the signal generator **32** is used to measure the volumetric shape of the heart chamber through impedance plethysmography. This signal generator is also used to determine the position of the reference electrode within the heart chamber. Other techniques for characterizing the shape of the heart chamber may be substituted. Next, the signals from all the electrode sites on the electrode array **19** are presented to the voltage acquisition apparatus **30** to derive a three-dimensional, instantaneous high resolution map of the electrical activity of the entire heart chamber volume. This map is calibrated by the use of a surface electrode **24**. The calibration is both electrical and dimensional. Lastly this three-dimensional map, along with the signal from an intramural electrode **26** preferably at the tip of the reference catheter **16**, is used to compute a two-dimensional map of the intramural electrical activity within the heart wall. The two-dimensional map is a slice of the heart wall and represents the subsurface electrical activity in the heart wall itself.

Both of these "maps" can be followed over time which is desirable. The true three-dimensional map also avoids the problem of spatial averaging and generates an instantaneous, high resolution map of the electrical activity of the entire volume of the heart chamber and the endocardial surface. This three-dimensional map is an order of magnitude more accurate and precise than previously obtained interpolation maps. The two-dimensional map of the intramural slice is unavailable using prior techniques.

Hardware Description

FIG. **1** shows the mapping system **10** coupled to a patient's heart **12**. The mapping catheter assembly **14** is inserted into a heart chamber and the reference electrode **24** touches the endocardial surface **18**.

The preferred array catheter **20** carries at least twenty-four individual electrode sites which are coupled to the interface apparatus **22**. The preferred reference catheter **16** is a coaxial extension of the array catheter **20**. This reference catheter **16** includes a surface electrode site **24** and a subsurface electrode site **26** both of which are coupled to the interface apparatus **22**. It should be understood that the electrode site **24** can be located directly on the array catheter. The array catheter **20** may be expanded into a known geometric shape, preferably spherical. Resolution is enhanced by the use of larger sized spherical shapes. A balloon **77** or the like should be incorporated under the electrode array **19** to exclude blood from the interior of the electrode array **19**. The spherical shape and exclusion of blood are not required for operability but they materially reduce the complexity of the calculations required to generate the map displays.

The reference electrode **24** and/or the reference catheter **16** serves several purposes. First they stabilize and maintain the array **19** at a known distance from a reference point on the endocardial surface **18** for calibration of the shape and volume calculations. Secondly, the surface electrode **24** is used to calibrate the electrical activity measurements of the endocardial surface **18** provided by the electrode array **19**.

The interface apparatus **22** includes a switching assembly **28** which is a multiplexor to sequentially couple the various electrode sites to the voltage acquisition apparatus **30**, and the signal generator apparatus **32**. These devices are under the control of a computer **34**. The voltage acquisition apparatus **30** is preferably a 12 bit A to D convertor. A signal generator **32** is also supplied to generate low current pulses for determining the volume and shape of the endocardial chamber using impedance plethysmography, and for determining the location of the reference catheter.

The computer **34** is preferably of the "workstation" class to provide sufficient processing power to operate in essentially real time. This computer operates under the control of software set forth in the flow chart of FIG. **12**.

Catheter Description

FIG. **2** shows a portion of the mapping catheter assembly **14** placed into a heart chamber **80**. The mapping catheter assembly **14** includes a reference catheter **16** and an array catheter **20**. In FIG. **2** the array catheter **20** has been expanded through the use of a stylet **92** to place the electrode array **19** into a stable and reproducible geometric shape. The reference catheter **16** has been passed through the lumen **82** of the array catheter **20** to place a distal tip electrode assembly **24** into position against an endocardial surface. In use, the reference catheter **16** provides a mechanical location reference for the position of the electrode array **19**, and the tip electrode assembly **24** provides an electrical potential reference at or in the heart wall for the mapping process.

Although the structures of FIG. **1** are preferred there are several alternatives within the scope of the invention. The principle objective of the preferred form of the catheter system is to reliably place a known collection of electrode sites away from the endocardial surface, and one or more electrode sites into contact with the endocardium. The array catheter is an illustrative structure for placing at least some of the electrode sites away from the endocardial surface. The array catheter itself can be designed to mechanically position one or more electrode sites on the endocardial surface. The reference catheter is a preferred structure for carrying one or more electrode sites and may be used to place these electrode sites into direct contact with the endocardial surface.

It should be understood that the reference catheter could be replaced with a fixed extension of the array catheter and used to push a segment of the array onto the endocardial surface. In this alternate embodiment the geometric shape of the spherical array maintains the other electrodes out of contact with the endocardial surface.

FIG. **3** shows the preferred construction of the mapping catheter assembly **14** in exaggerated scale to clarify details of construction. In general, the array catheter **20** includes a flexible lead body **72** coupled to a deformable lead body **74**. The deformable lead body **74** is preferably a braid **75** of insulated wires, several of which are shown as wire **93**, wire **94**, wire **95** and wire **96**. An individual wire such as **93** may be traced in the figure from the electrical connection **79** at

the proximal end **81** of the flexible lead body **72** through the flexible lead body **72** to the distal braid ring **83** located on the deformable lead body **74**. At a predetermined location in the deformable lead body **74** the insulation has been selectively removed from this wire **93** to form a representative electrode site **84**. Each of the several wires in the braid **75** may potentially be used to form an electrode site. Preferably all of the typically twenty-four to one-hundred-twenty-eight wires in the braid **75** are used to form electrode sites. Wires not used as electrode sites provide mechanical support for the electrode array **19**. In general, the electrode sites will be located equidistant from a center defined at the center of the spherical array. Other geometrical shapes are usable including ellipsoidal and the like.

The proximal end **81** of the mapping catheter assembly **14** has suitable electrical connection **79** for the individual wires connected to the various electrode sites. Similarly the proximal connector **79** can have a suitable electrical connection for the distal tip electrode assembly **24** of the reference catheter **16** or the reference catheter **16** can use a separate connector. The distance **90** between the electrode array **19** and the distal tip assembly **24** electrode can preferentially be varied by sliding the reference catheter through the lumen **82**, as shown by motion arrow **85**. This distance **90** may be "read" at the proximal end **81** by noting the relative position of the end of the lead body **72** and the proximal end of the reference catheter **16**.

FIG. **4** is a view of the mapping catheter with the deformable lead body **74** in the collapsed position.

FIG. **5** shows that the wire stylet **92** is attached to the distal braid ring **83** and positioned in the lumen **82**. Traction applied to the distal braid ring **83** by relative motion of the stylet **92** with respect to the lead body **72** causes the braid **75** to change shape. In general, traction causes the braid **75** to move from a generally cylindrical form seen in FIG. **4** to a generally spherical form seen best in FIG. **2** and FIG. **5**.

The preferred technique is to provide a stylet **92** which can be used to pull the braid **75** which will deploy the electrode array **19**. However, other techniques may be used as well including an optional balloon **77** shown as in FIG. **3**, which could be inflated under the electrode array **19** thereby causing the spherical deployment of the array **19**. Modification of the braid **75** can be used to control the final shape of the array **19**. For example an asymmetrical braid pattern using differing diameter wires within the braid can preferentially alter the shape of the array. The most important property of the geometric shape is that it spaces the electrode sites relatively far apart and that the shape be predictable with a high degree of accuracy.

FIG. **6** shows a first embodiment of the reference catheter **16** where the distal electrode assembly **24** is blunt and may be used to make a surface measurement against the endocardial surface. In this version of the catheter assembly the wire **97** (FIG. **2**) communicates to the distal tip electrode and this wire may be terminated in the connector **79**.

FIG. **8** shows an alternate reference catheter **98** which is preferred if both surface and/or subsurface measurements of the potential proximate the endocardial surface are desired. This catheter **98** includes both a reference electrode **24** and an extendable intramural electrode body **100**.

FIG. **9** illustrates the preferred use of an intramural electrode stylet **101** to retract the sharp intramural electrode body **100** into the reference catheter lead body **102**. Motion of the intramural electrode body **100** into the lead body **102** is shown by arrow **103**.

FIG. **10** shows the location of the intramural electrode site **26** on the electrode body **100**. It is desirable to use a relatively small electrode site to permit localization of the intramural electrical activity.

The array catheter **20** may be made by any of a variety of techniques. In one method of manufacture, the braid **75** of insulated wires **93**,**94**,**95**,**96** can be encapsulated into a plastic material to form the flexible lead body **72**. This plastic material can be any of various biocompatible compounds with polyurethane being preferred. The encapsulation material for the flexible lead body **72** is selected in part for its ability to be selectively removed to expose the insulated braid **75** to form the deformable lead body **74**. The use of a braid **75** rather than a spiral wrap, axial wrap, or other configuration inherently strengthens and supports the electrodes due to the interlocking nature of the braid. This interlocking braid **75** also insures that, as the electrode array **19** deploys, it does so with predictable dimensional control. This braid **75** structure also supports the array catheter **20** and provides for the structural integrity of the array catheter **20** where the encapsulating material has been removed.

To form the deformable lead body **74** at the distal end of the array catheter **20**, the encapsulating material can be removed by known techniques. In a preferred embodiment this removal is accomplished by mechanical removal of the encapsulating material by grinding or the like. It is also possible to remove the material with a solvent. If the encapsulating material is polyurethane, tetrahydrofuran or cyclohexanone can be used as a solvent. In some embodiments the encapsulating material is not removed from the extreme distal tip to provide enhanced mechanical integrity forming a distal braid ring **83**.

With the insulated braid **75** exposed, to form the deformable lead body **74** the electrodes sites can be formed by removing the insulation over the conductor in selected areas. Known techniques would involve mechanical, thermal or chemical removal of the insulation followed by identification of the appropriate conducting wire at the proximal connector **79**. This method makes it difficult to have the orientation of the proximal conductors in a predictable repeatable manner. Color coding of the insulation to enable selection of the conductor/electrode is possible but is also difficult when large numbers of electrodes are required. Therefore it is preferred to select and form the electrode array through the use of high voltage electricity. By applying high voltage electricity (typically 1–3 KV) to the proximal end of the conductor and detecting this energy through the insulation it is possible to facilitate the creation of the electrode on a known conductor at a desired location. After localization, the electrode site can be created by removing insulation using standard means or by applying a higher voltage (eg. 5 KV) to break through the insulation.

Modifications can be made to this mapping catheter assembly without departing from the teachings of the present invention. Accordingly the scope of the invention is only to be limited only by the accompanying claims.

Software Description

The illustrative method may be partitioned into nine steps as shown in FIG. **12**. The partitioning of the step-wise sequence is done as an aid to explaining the invention and other equivalent partitioning can be readily substituted without departing from the scope of the invention.

At step **41** the process begins. The illustrative process assumes that the electrode array assumes a known spherical shape within the heart chamber, and that there are at least twenty-four electrodes on the electrode array **19**. This preferred method can be readily modified to accommodate unknown and non-reproducible, non-spherical shaped arrays. The location of each of these electrode sites on the

array surface is known from the mechanical configuration of the displayed array. A method of determining the location of the electrode array **19** and the location of the heart chamber walls (cardiac geometry) must be available. This geometry measurement (options include ultrasound or impedance plethysmography) is performed in step **41**. If the reference catheter **16** is extended to the chamber wall **18** then its length can be used to calibrate the geometry measurements since the calculated distance can be compared to the reference catheter length. The geometry calculations are forced to converge on the known spacing represented by the physical dimensions of the catheters. In an alternative embodiment reference electrode **24** is positioned on array catheter **20** and therefore its position would be known.

In step **42** the signals from all the electrode sites in the electrode array **19** are sampled by the A to D converter in the voltage acquisition apparatus **30**. These measurements are stored in a digital file for later use in following steps. At this point (step **43**) the known locations of all the electrodes on the electrode array **19** and the measured potentials at each electrode are used to create the intermediate parameters of the three-dimensional electrical activity map. This step uses field theory calculations presented in greater detail below. The components which are created in this step (Φ_{lm}) are stored in a digital file for later use in following steps.

At the next stage the question is asked whether the reference catheter **16** is in a calibrating position. In the calibrating position, the reference catheter **16** projects directly out of the array catheter **20** establishing a length from the electrode array **19** which is a known distance from the wall **18** of the heart chamber. This calibration position may be confirmed using fluoroscopy. If the catheter is not in position then the process moves to step **45**, **46** or **47**.

If the reference catheter **16** is in the calibrating position then in step **44** the exact position of the reference catheter **16** is determined using the distance and orientation data from step **41**. The available information includes position in space of the reference catheter **16** on the chamber wall **18** and the intermediate electrical activity map parameters of the three-dimensional map. Using these two sets of information the expected electrical activity at the reference catheter surface electrode site **24** is determined. The actual potential at this site **24** is measured from the reference catheter by the A to D converter in the voltage acquisition apparatus **30**. Finally, a scale factor is adjusted which modifies the map calculations to achieve calibrated results. This adjustment factor is used in all subsequent calculations of electrical activity.

At step **47** the systems polls the user to display a three-dimensional map. If such a map is desired then a method of displaying the electrical activity is first determined. Second an area, or volume is defined for which the electrical activity is to be viewed. Third a level of resolution is defined for this view of the electrical activity. Finally the electrical activity at all of the points defined by the display option, volume and resolution are computed using the field theory calculations and the adjustment factor mentioned above. These calculated values are then used to display the data on computer **34**.

FIG. **7** is a representative display **71** of the output of process **47**. In the preferred presentation the heart is displayed as a wire grid **36**. The iso-potential map for example is overlaid on the wire grid **36** and several iso-potential lines such as iso-potential or isochrone line **38** are shown on the drawing. Typically the color of the wire grid **36** and the iso-potential or isochrone lines will be different to aid interpretation. The potentials may preferably be presented by a continuously filled color-scale rather than iso-potential or isochrone lines. The tightly closed iso-potential or isochrone line **39** may arise from an ectopic focus present at this location in the heart. In the representative display **71** of process **47** the mapping catheter assembly will not be shown.

In step **45** a subthreshold pulse is supplied to the surface electrode **24** of the reference catheter **16** by the signal generator **32**. In step **54** the voltages are measured at all of the electrode sites on the electrode array **19** by the voltage acquisition apparatus **30** One problem in locating the position of the subthreshold pulse is that other electrical activity may render it difficult to detect. To counteract this problem step **55** starts by subtracting the electrical activity which was just measured in step **44** from the measurements in step **54**. The location of the tip of the reference catheter **16** (i.e. surface electrode **24**), is found by first erforming the same field theory calculations of step **45** on this derived electrode data. Next, four positions in pace are defined which are positioned near the heart chamber walls. The potentials at these sites are calculated using the three-dimensional electrical activity map. These potentials are then used to triangulate, and thus determine, the position of the subthreshold pulse at the surface electrode **24** of the reference catheter **16**. If more accurate localization is desired then four more points which are much closer to the surface electrode **24** can be defined and the triangulation can be performed again. This procedure for locating the tip of the reference catheter **16** can be performed whether the surface electrode **24** is touching the surface or is located in the blood volume and is not in contact with the endocardial surface.

At step **48** the reference catheter's position in space can be displayed by superimposing it on the map of electrical activity created in step **47**. An example of such a display **71** is presented in FIG. **7**.

When step **46** is reached the surface electrode **24** is in a known position on the endocardial surface **18** of the heart chamber which is proper for determining the electrical activity of the tissue at that site. If the intramural or subsurface extension **100** which preferentially extends from the tip of the reference catheter **102** is not inserted into the tissue then the user of the system extends the subsurface electrode **26** into the wall **18**. The potentials from the surface electrode **24** and from the intramural subsurface **26** electrode are measured by voltage acquisition apparatus **30**. Next a line **21** along the heart chamber wall which has the surface electrode **24** at its center is defined by the user of the system. The three-dimensional map parameters from step **43** are then used to compute a umber of points along this line including the site of he reference catheter surface electrode **24**. These alculations are adjusted to conform to the measured alue at the reference catheter surface electrode **24**. ext a slice of tissue is defined and bounded by this line **21** (FIG. **7**) and the location of the intramural subsurface electrode **26** (FIG. **11**) and computed positions such as **23** and **25**. Subsequently a two-dimensional map **27** of the electrical activity of this slice of tissue is computed using the center of gravity calculations detailed below in the section on algorithm descriptions. Points outside of the boundary of the slice cannot be computed accurately. In step **49** this map **27** of electrical activity within the two-dimensional slice is displayed as illustrated in FIG. **11**. In this instance the iso-potential line **17** indicates the location within the wall **18** of the ectopic focus.

Description of the Preferred Computing Algorithms

Two different algorithms are suitable for implementing different stages of the present invention.

The algorithm used to derive the map of the electrical activity of the heart chamber employs electrostatic volume-

conductor field theory to derive a high resolution map of the chamber volume. The second algorithm is able to estimate intramural electrical activity by interpolating between points on the endocardial surface and an intramural measurement using center of gravity calculations.

In use, the preliminary process steps identify the position of the electrode array **19** consequently the field theory algorithm can be initialized with both contact and non-contact type data. This is one difference from the traditional prior art techniques which require either contact or non-contact for accurate results, but cannot accommodate both. This also permits the system to discern the difference between small regions of electrical activity close to the electrode array **19** from large regions of electrical activity further away from the electrode array **19**.

In the first algorithm, from electrostatic volume-conductor field theory it follows that all the electrodes within the solid angle view of every locus of electrical activity on the endocardial surface are integrated together to reconstruct the electrical activity at any given locus throughout the entire volume and upon the endocardium. Thus as best shown in FIG. **7** the signals from the electrode array **19** on the catheter **20** produce a continuous map of the whole endocardium. This is another difference between the present method and the traditional prior art approach which use the electrode with the lowest potential as the indicator of cardiac abnormality. By using the complete information in the algorithm, the resolution of the map shown in FIG. **7** is improved by at least a factor of ten over prior methods. Other improvements include: the ability to find the optimal global minimum instead of sub-optimal local minima; the elimination of blind spots between electrodes; the ability to detect abnormalities caused by multiple ectopic foci; the ability to distinguish between a localized focus of electrical activity at the endocardial surface and a distributed path of electrical activity in the more distant myocardium; and the ability to detect other types of electrical abnormalities including detection of ischemic or infarcted tissue.

The algorithm for creating the 3D map of the cardiac volume takes advantage of the fact that myocardial electrical activity instantaneously creates potential fields by electrotonic conduction. Since action potentials propagate several orders of magnitude slower than the speed of electronic conduction, the potential field is quasi-static. Since there are no significant charge sources in the blood volume, Laplace's Equation for potential completely describes the potential field in the blood volume:

$$\bar{v}\Phi=0$$

LaPlace's equation can be solved numerically or analytically. Such numerical techniques include boundary element analysis and other interative approaches comprised of estimating sums of nonlinear coefficients.

Specific analytical approaches can be developed based on the shape of the probe (i.e. spherical, prolate spherical or cylindrical). From electrostatic field theory, the general spherical harmonic series solution for potential is:

$$\phi(r,\theta,\varphi)=\sum_{\infty}^{i-0}\sum_{m=-1}^{l}\{A_1 r^{l}+B_1 r^{-(i-1)}\}\phi_{lm}Y_{lm}(\theta,\varphi)$$

In spherical harmonics, $Y_{lm}(\theta, \psi)$ is the spherical harmonic series made up of Legendre Polynomials. Φ_{lm} is the lm^{th} component of potential and is defined as:

$$\phi_{lm}=\int V(\theta,\psi)Y_{lm}(\theta,\psi)d\Omega$$

where $V(\theta, \phi)$ is the measured potential over the probe radius R and $d\Omega$ is the differential solid angle and, in spherical coordinates, is defined as:

$$d\Omega=\sin\theta d\theta d\psi$$

During the first step in the algorithmic determination of the 3D map of the electrical activity each Φlm component is determined by integrating the potential at a given point with the spherical harmonic at that point with respect to the solid angle element subtended from the origin to that point. This is an important aspect of the 3D map; its accuracy in creating the 3D map is increased with increased numbers of electrodes in the array and with increased size of the spherical array. In practice it is necessary to compute the Φ_{lm} components with the subscript set to 4 or greater. These Φ_{lm} components are stored in an 1 by m array for later determination of potentials anywhere in the volume within the endocardial walls.

The bracketed expression of equation 1 (in terms of A_1, B_1, and r) simply contains the extrapolation coefficients that weight the measured probe components to obtain the potential components anywhere in the cavity. Once again, the weighted components are summed to obtain the actual potentials. Given that the potential is known on the probe boundary, and given that the probe boundary is non-conductive, we can determine the coefficients A_1 and B_1, yielding the following final solution for potential at any point within the boundaries of the cavity, using a spherical probe of radius R:

$$\phi(r,\theta,\varphi)=\sum_{l=0}^{\infty}\sum_{m=-1}^{l}\left[\left(\frac{l+1}{2l+1}\right)\left(\frac{r}{R}\right)^{l}+\left(\frac{l}{2l+1}\right)\left(\frac{r}{R}\right)^{-i-1}\right]\phi_{lm}Y_{lm}(\theta,\varphi)$$

on exemplary method for evaluating the integral for Φ_{lm} is the technique of Filon integration with an estimating sum, discretized by p latitudinal rows and q longitudinal columns of electrodes on the spherical probe.

$$\phi_{lm}\geq\frac{4\pi}{pq}\sum_{i=1}^{p}\sum_{j=1}^{q}V(\theta_i,\varphi_j)Y_{lm}(\theta_i,\varphi_j)$$

Note that p times q equals the total number of electrodes on the spherical probe array. The angle θ ranges from zero to π radians and ψ ranges from zero to 2π radians.

At this point the determination of the geometry of the endocardial walls enters into the algorithm. The potential of each point on the endocardial wall can now be computed by defining them as r, θ, and ψ. During the activation sequence the graphical representation of the electrical activity on the endocardial surface can be slowed down by 30 to 40 times to present a picture of the ventricular cavity within a time frame useful for human viewing.

A geometric description of the heart structure is required in order for the algorithm to account for the inherent effect of spatial averaging within the medium (blood). Spatial averaging is a function of both the conductive nature of the medium as well as the physical dimensions of the medium.

Given the above computed three-dimensional endocardial potential map, the intramural activation map of FIG. **11** is estimated by interpolating between the accurately computed

endocardial potentials at locations **23** and **25** (FIG. **7**), and actual recorded endocardial value at the surface electrode **24** and an actual recorded intramural value at the subsurface electrode **26** site. This first-order estimation of the myocardial activation map assumes that the medium is homogenous and that the medium contains no charge sources. This myocardial activation estimation is limited by the fact that the myocardial medium is not homogeneous and that there are charge sources contained within the myocardial medium. If more than one intramural point was sampled the underlying map of intramural electrical activity could be improved by interpolating between the endocardial surface values and all the sample intramural values. The center-of-gravity calculations can be summarized by the equation:

$$V(\overline{r_x}) = \frac{\sum_{i=1}^{n} V_i(|\overline{r_x} - \overline{r_i}|^{-k})}{\sum_{i=1}^{n} |\overline{r_x} - \overline{r_i}|^{-k}}$$

where, $V(_x)$ represents the potential at any desired point defined by the three-dimensional vector $_x$ and, V_i represents each of n known potentials at a point defined by the three-dimensional vector $_i$ and, k is an exponent that matches the physical behavior of the tissue medium.

From the foregoing description, it will be apparent that the method for determining a continuous map of the electrical activity of the endocardial surface of the present invention has a number of advantages, some of which have been described above and others of which are inherent in the invention. Also modifications can be made to the mapping probe without departing from the teachings of the present invention. Accordingly the scope of the invention is only to be limited as necessitated by the accompanying claims.

We claim:

1. An endocardial mapping catheter assembly comprising:

(a) a plurality of insulated wires braided throughout their length into an interlocking weave;

(b) a distal portion of the interlocking weave being expandable from a first generally cylindrical shape to a second expanded shape; and

(c) a plurality of electrodes on the distal portion of the insulated wires, each electrode in electrical communication with a single wire, and with each wire being in electrical communication with no more than a single electrode.

2. The endocardial mapping catheter assembly of claim **1**, further comprising

d) an electrical plug on the proximal end of the interlocking weave, the electrical plug having a plurality of connections, each in electrical communication through one of the insulated wires to one of the electrodes.

3. The endocardial mapping catheter assembly of claim **1**, wherein the interlocking weave further comprises a proximal non-expanding portion having a generally cylindrical shape.

4. The endocardial mapping catheter assembly of claim **3**, wherein the proximal non-expanding portion is encapsulated in a biocompatible material.

5. The endocardial mapping catheter assembly of claim **4** wherein the biocompatible material is polyurethane.

6. The endocardial mapping catheter assembly of claim **4** wherein the distal expanding portion is not encapsulated in the biocompatible material.

7. The endocardial mapping catheter assembly of claim **1** wherein the second expanded shape is generally spherical.

8. The endocardial mapping catheter assembly of claim **1** wherein there are at least twenty-four electrodes.

9. The endocardial mapping catheter assembly of claim **1** further comprising an expandable balloon within the expandable distal portion of the wires.

10. An endocardial mapping catheter assembly comprising

(a) an elongated flexible lead body having an interior lumen and proximal and distal ends;

(b) at least twenty-four insulated wires in the lumen extending from the proximal to the distal end of the lead body, the wires collectively being braided together to form a wire assembly;

(c) an expandable portion of the wire assembly near the distal end of the flexible lead body, the expandable portion being expandable from a first generally cylindrical shape to a second expanded shape;

(d) the majority of wires in the wire assembly each having a single electrode in the expandable portion of the wire assembly;

(e) an electrical plug on the proximal end of the flexible lead body, the electrical plug having a plurality of connections, each connection being in electrical communication with one of the wires.

11. An endocardial mapping catheter assembly comprising:

(a) a plurality of insulated wires surrounded by an insulating material,

(b) a braid comprised of a combination of the insulated wires in an interlocking weave,

(c) a flexible material surrounding a first portion of the braid, forming a flexible lead body, the flexible material not surrounding a second portion of the braid, the second portion of the braid forming an array, the array being deformable into a predictable geometric shape,

(d) at least twenty-four electrodes on the braided wire array, each electrode in electronic communication with a single wire in the array.

12. The catheter assembly of claim **11** wherein the electrode is a gap in the insulating material surrounding the wire.

13. The catheter assembly of claim **11**, wherein the flexible material is polyurethane.

14. The catheter assembly of claim **11**, further comprising

e) an expandable balloon within the array.

15. The catheter assembly of claim **11**, wherein the braid forms a lumen.

16. The catheter assembly of claim **15** further comprising a reference catheter in the lumen, the reference catheter having a tip electrode.

17. The catheter assembly of claim **16** wherein the reference catheter is movable relative to the braid within the lumen.

18. The catheter assembly of claim **17**, further comprising

e) an electrical connector adapted for connection to an external monitoring device, the tip electrode of the reference catheter as well as each wire in the braid having an electrode being in electrical communication with a particular location on the electrical connector.

19. The catheter assembly of claim **11**, further comprising

e) an electrical connector adapted for connection to an external monitoring device, each wire in the braid having an electrode being in electrical communication with a particular location on the electrical connector.

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