(12) STANDARD PATENT (11) Application No. **AU 2010241407 B8**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Catheter with pressure measuring tip

(51) International Patent Classification(s)
A61B 18/14 (2006.01) ***A61M 25/01*** (2006.01)

(21) Application No: **2010241407** (22) Date of Filing: **2010.11.12**

(30) Priority Data

(31) Number	(32) Date	(33) Country
12/627,327	**2009.11.30**	**US**

(43) Publication Date: **2011.06.16**
(43) Publication Journal Date: **2011.06.16**
(44) Accepted Journal Date: **2015.07.02**
(48) Corrigenda Journal Date: **2015.07.23**

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(56) Related Art
US 2008/0294158
US 2004/0064024

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ABSTRACT

A medical probe, consisting of a flexible insertion tube, having a distal end for insertion into a body cavity of a patient, and a distal tip, which is disposed at the distal end of the flexible insertion tube is configured to be brought into contact with tissue in the body cavity. The probe also includes a coupling member, which couples the distal tip to the distal end of the insertion tube and which consists of a tubular piece of an elastic material having a plurality of intertwined helical cuts therethrough along a portion of a length of the piece.

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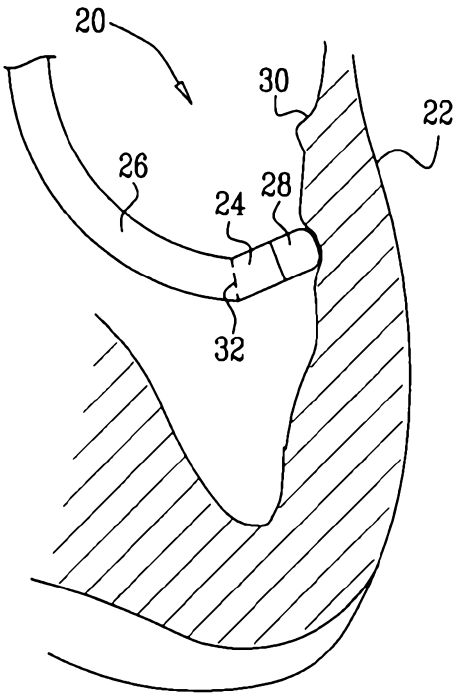

FIG. 1

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AUSTRALIA

Patents Act 1990

ORIGINAL

COMPLETE SPECIFICATION

INVENTION TITLE:

CATHETER WITH PRESSURE MEASURING TIP

The following statement is a full description of this invention, including the best method of performing it known to us:-

CATHETER WITH PRESSURE MEASURING TIP

FIELD OF THE INVENTION

The present invention relates generally to invasive medical devices, and specifically to the construction of probes for insertion into body organs.

BACKGROUND OF THE INVENTION

In some diagnostic and therapeutic techniques, a catheter is inserted into a chamber of the heart and brought into contact with the inner heart wall. In such procedures, it is generally important that the distal tip of the catheter engages the endocardium with sufficient pressure to ensure good contact. Excessive pressure, however, may cause undesired damage to the heart tissue and even perforation of the heart wall.

For example, in intracardiac radio-frequency (RF) ablation, a catheter having an electrode at its distal tip is inserted through the patient's vascular system into a chamber of the heart. The electrode is brought into contact with a site (or sites) on the endocardium, and RF energy is applied through the catheter to the electrode in order to ablate the heart tissue at the site. Proper contact between the electrode and the endocardium during ablation is necessary in order to achieve the desired therapeutic effect without excessive damage to the tissue.

A number of patent publications describe catheters with integrated pressure sensors for sensing tissue contact. As one example, U.S. Patent Application Publication 2007/0100332 to Saurav et al., whose disclosure is incorporated herein by reference, describes systems and methods for assessing electrode-tissue contact for tissue ablation. An electro-mechanical sensor within the catheter shaft generates electrical signals corresponding to the amount of movement of the electrode within a distal portion of the catheter shaft. An output device receives the electrical signals for assessing a level of contact between the electrode and a tissue.

The description above is presented as a general overview of related art in this field and should not be construed as an admission that any of the information it contains constitutes prior art against the present patent application.

SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, therefore, there is provided a medical probe, including: a flexible insertion tube, having a distal end for insertion into a body cavity of a patient; a distal tip having an electrode fixedly mounted thereon, which is disposed at the distal end of the flexible insertion tube and is configured to be brought into contact with tissue in the body cavity; a coupling member separate from the electrode, which couples the distal tip to the distal end of the flexible insertion tube and which includes a tubular piece of an elastic material having a plurality of intertwined, single helics formed by a plurality of multiple start, longitudinally adjacent helical cuts therethrough along a portion of a length of the tubular piece and a tubular part connected by a fixed connection to the tubular piece and to the distal end of the flexible insertion tube; a magnetic field generator within the tubular part configured to generate a magnetic field; and a position sensor within the tubular piece, the position sensor configured to sense a position of the distal tip relative to the distal end of the insertion tube, the position changing in response to deformation of the coupling member and wherein the position sensor is configured to generate a signal in response to the magnetic field, wherein the signal is indicative of the relative position of the distal tip to the distal end.

Typically, at least one of the helical cuts includes an enlarged termination, and the enlarged termination may include a partial ellipse.

In some embodiments the plurality of helical cuts includes n cuts, where n is an integer greater than 1, and the cuts may be configured so that the tubular piece has n-fold rotational symmetry about an axis of the piece.

In a disclosed embodiment, at least one of the helical cuts subtends an angle between 360° and 720° about an axis of the tubular piece.

In one embodiment, the coupling member is configured to bend in response to pressure exerted on the distal tip when the distal tip engages the tissue, and at least

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one of the helical cuts has a width chosen so as to provide a predetermined angular limit on initial bending of the coupling member.

Typically, the coupling member includes a tubular part connected by a fixed connection to the tubular piece. The tubular piece may include a stem, and the fixed connection may consist of the stem welded to the tubular part.

The tubular part and the tubular piece may be arranged so as to form a common circumference thereto, and the fixed connection may include welds on the common circumference absent regions thereon proximal to respective terminations of the helical cuts.

In another embodiment, a position sensor may be within the tubular piece. Typically, the position sensor may be configured to sense a position of the distal tip relative to the distal end of the insertion tube, the position changing in response to deformation of the coupling member. Typically, the position sensor may be configured to generate a signal in response to a magnetic field, and the signal is indicative of a position of the distal tip. The probe may include a magnetic field generator within the tubular part for generating the magnetic field.

Typically, the insertion tube, the distal tip and the coupling member are configured for insertion through a blood vessel into a heart of a patient.

In accordance with another aspect of the present invention there is provided a method for performing a medical procedure, including: inserting into a body cavity of a patient a probe, which includes a flexible insertion tube and a distal tip, having an electrode fixedly mounted thereon, which distal tip is disposed at a distal end of the flexible insertion tube, and a coupling member separate from the electrode, which couples the distal tip to the distal end of the flexible insertion tube and comprises a tubular piece of an elastic material having a plurality of intertwined, single helics formed by a plurality of multiple start, longitudinally adjacent helical cuts therethrough along a portion of a length of the tubular piece and a tubular part

connected by a fixed connection to the tubular piece and to the distal end of the flexible insertion tube, a magnetic field generator within the tubular part for generating a magnetic field, and a position sensor within the tubular piece, the position sensor configured to sense a position of the distal tip relative to the distal end of the insertion tube, the position changing in response to deformation of the coupling member and wherein the position sensor is configured to generate a signal in response to the magnetic field, wherein the signal is indicative of a position of the distal tip; bringing the distal tip into contact with tissue in the body cavity; and determining pressure exerted on and by the distal tip using the signal.

Typically, the method includes ablating the tissue with which the distal tip is in contact.

There is also provided, according to a further alternative embodiment of the present invention, a method for producing a medical probe, including:

providing a flexible insertion tube, having a distal end for insertion into a body cavity of a patient, and a distal tip, which is disposed at the distal end of the insertion tube and which is configured to be brought into contact with tissue in the body cavity; and

coupling the distal tip to the distal end of the insertion tube using a coupling member, which includes a tubular piece of an elastic material having a plurality of intertwined helical cuts therethrough along a portion of a length of the piece.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings in which:

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic sectional view of a heart chamber with a catheter in contact with the heart wall inside the chamber, according to an embodiment of the present invention;

Fig. 2 is a schematic sectional view of the catheter, according to an embodiment of the present invention;

Fig. 3 is a schematic side view of a portion of a coupling member, according to an embodiment of the present invention;

Fig. 4A is a schematic perspective view of the coupling member, according to an embodiment of the present invention; and

Fig. 4B is a schematic section of the coupling member, according to an embodiment of the present invention.

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DETAILED DESCRIPTION OF EMBODIMENTS

OVERVIEW

Embodiments of the present invention provide a novel design of an invasive probe, such as a catheter. The probe comprises a flexible insertion tube for insertion into a body cavity of a patient. A distal tip of the probe is coupled to the distal end of the insertion tube by a coupling member. The coupling member comprises a tubular piece of elastic material with a plurality of intertwined helices, typically a double helix, cut in a portion of the piece.

The plurality of intertwined helices permit the coupling member to bend in response to pressure exerted on the distal tip when the tip engages tissue in the body cavity. The bending is significantly greater, and is more uniform, than would be achieved by a single helix cut in the coupling member, for the same exerted pressure. The greater and more uniform bending facilitates improved measurement of the pressure causing the bending. In addition, dimensions of the helices may be chosen to significantly reduce the size of the coupling member, compared to that required by a coupling member having only one helix.

DETAILED DESCRIPTION

Fig. 1 is a schematic sectional view of a chamber of a heart 22, showing a flexible insertion tube 26 of a catheter 20 inside the heart, according to an embodiment of the present invention. The catheter is typically inserted into the heart percutaneously through a blood vessel, such as the vena cava or the aorta. An electrode 28 on a distal tip 24 of the catheter engages endocardial tissue 30. Pressure exerted by the distal tip against the endocardium deforms the endocardial tissue locally, so that electrode 28 contacts the tissue over a relatively large area. In the pictured example, the electrode engages the endocardium at an angle, rather than head-on. Distal tip 24 therefore bends at an elastic joint 32 relative to insertion tube 26 of the catheter. The bend facilitates optimal contact between the electrode and the endocardial tissue.

Because of the elastic quality of joint 32, the angle of bending of the joint is typically proportional to the pressure exerted by tissue 30 on distal tip 24 (or equivalently, the pressure exerted by the distal tip on the tissue). Measurement of the

bend angle thus gives an indication of this pressure. The pressure indication may be used by the operator of catheter 20 to ensure that the distal tip is pressing against the endocardium firmly enough to give the desired therapeutic or diagnostic result, but not so hard as to cause undesired tissue damage. U.S. Patent Application 20090093806, to Govari et al., filed October 8, 2007, whose disclosure is incorporated herein by reference, describes a system that uses a pressure-sensing catheter in this manner. Catheter 20 may be used in such a system.

Fig. 2 is a schematic, sectional view of catheter 20, showing details of the distal end of the catheter, according to an embodiment of the present invention. A coupling member 40 forms joint 32 between distal tip 24 and the distal end of insertion tube 26. By way of example, coupling member 40 is assumed to be formed in two parts, a first part 42 and a second part 44, the two parts being fixedly joined together. The two parts of coupling member 40 are generally tubular, and are joined so that the coupling member also has a tubular form. Although there is no necessity that coupling member 40 be formed of two parts, the two part implementation simplifies assembly of a magnetic field generator and magnetic position sensor into the member, as is described in more detail below. The two part implementation is typically also facilitated by incorporating an attaching stem into one of the parts, as is also described in more detail below.

Coupling member 40 has a plurality 46 of intertwined helices cut along a portion of the length of first part 42 of the member. Plurality 46 may comprise any integral number of single helices greater than one, such as, but not limited to two, three or four helices. For simplicity, unless otherwise stated, in the following description the plurality is assumed to comprise two intertwined single cut helices, a first cut helix 48 and a second cut helix 50, and is also referred to herein as a double helix. Those having ordinary skill in the art will be able to adapt the description without undue experimentation, to encompass a plurality of intertwined helices where the plurality is more than two single helices.

Coupling member 40 (along with the distal end of catheter 20 generally) is typically covered by a flexible plastic sheath 52. When catheter 20 is used, for example, in ablating endocardial tissue by delivering RF (radio-frequency) electrical energy through electrode 28, considerable heat is generated in the area of distal tip

24. For this reason, it is desirable that sheath 52 comprises a heat-resistant plastic material, such as polyurethane, whose shape and elasticity are not substantially affected by exposure to the heat.

Catheter 20 comprises a position sensor 54 within a distal portion of first part 42. The distal portion of the first part is located within distal tip 24. The position sensor is connected via a conductor 56 to a processing unit (not shown) at the proximal end of insertion tube 26. Conductor 56 may typically comprise a twisted-pair cable. Position sensor 54 is configured to sense the position of the distal tip relative to the distal end of insertion tube 26. As explained above, the position changes in response to deformation of the coupling member, and the processing unit may thus use the position reading in order to give an indication of the pressure exerted on and by the distal tip.

For intracardiac operation, insertion tube 26 and distal tip 24 should generally have a very small outer diameter, typically of the order of 2-3 mm. Therefore, all of the internal components of catheter 20, such as conductor 56, are also made as small and thin as possible and are arranged so as to, as much as possible, avoid damage due to small mechanical strains.

Position sensor 54 may comprise one or more coils, which are configured to generate signals in response to a magnetic field. These signals are indicative of the position and orientation of distal tip 24. The magnetic field may be produced by a miniature magnetic field generator 58 located within second part 44 of the coupling member. Generator 58 is typically activated by the proximal end processing unit, via a conductor 60. Thus, when coupling member 40 bends, the signals generated by the position sensor change and can be analyzed by the processing unit to determine the pressure on the distal tip. Additional magnetic fields may be generated by field generators (not shown) in fixed locations external to the patient's body. These fields cause position sensor 54 to generate additional signals that are indicative of the position and orientation of distal tip 24 in the fixed frame of reference of the external field generators. These aspects of the operation of position sensor 54 are described in detail in the above-mentioned U.S. Patent Application 11/868,733. They are outside the scope of the present invention.

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Catheter 20 typically comprises a pair of pull-wires 62, 64 for use by an operator in steering the catheter. The pull-wires pass through insertion tube 26 and are anchored at respective anchor points 66, 68 in the distal end of the insertion tube, typically on opposite sides of the tube. The operator tightens the pull-wires (typically by turning a knob – not shown – at the proximal end of the catheter) in order to bend the distal end of the catheter either "up," or "down." (The references to "up" and "down" are purely with respect to Fig. 2, and are not to be construed as limiting the motion of the catheter in any particular direction.) When the operator releases the pull-wires, the catheter straightens due to the resilience of the insertion tube.

Fig. 3 is a schematic side view of first part 42 of coupling member 40, according to an embodiment of the present invention. Fig. 4A is a schematic perspective view of the two parts joined to form the coupling member, and Fig. 4B is a schematic section of the coupling member, according to embodiments of the present invention.

Both parts of coupling member 40 comprise generally tubular pieces of an elastic material, typically a metal material. The elastic material is typically the same for both parts, for example, a superelastic alloy such as nickel titanium (Nitinol). For intracardiac applications, the overall length of member 40 may be approximately 8.5 mm, with an outer diameter of approximately 2.0 mm. Second part 44 is in the form of a cylinder having a length of approximately 5.2 mm and a wall thickness of approximately 0.08 mm. First part 42 has a wall thickness of approximately 0.27 mm. Alternatively, in other applications, the parts of coupling member 40 and its overall dimensions may be larger or smaller.

As shown in Fig. 3 and as stated above, first part 42 of coupling member 40 has two intertwined single helices cut into the part, first helix 48 and second helix 50. The two helices may be cut by laser machining of the first part. For the dimensions given above, each helix is typically opened by the laser to a width of about 0.1 mm. While the widths of each helical cut are typically the same, there is no requirement that this is the case, and some embodiments may have the helical cuts of different widths. Furthermore, in some embodiments the width of one or both of the cuts may be varied along the cut, typically to add strength to member 40.

To give an appropriate balance between flexibility and stiffness for intracardiac applications, each helix typically subtends an angle between approximately 360^{O} and approximately 720^{O} about a central axis 70 (Fig. 4A) of member 40. For the intracardiac applications described above, and as illustrated in Fig. 3, each helix subtends about 450^{O}, so that each helix has an angular extent of approximately 1.25 turns. The inventors have found that approximately 1.25 turns give a good balance between conflicting requirements of member 40, such as ensuring its radial symmetry with respect to deflection, and that the member is sufficiently strong. Alternatively, larger or smaller angular extents may be used for each helix, and the angular extents may not be equal, depending on application requirements.

The terminations of each helix of part 42 may be enlarged for the purposes of strain relief so that the part does not break during use. The enlargement is typically in the form of a partial ellipse. Thus, helix 48 terminates in a first partial ellipse 72 and a second partial ellipse 74, and helix 50 terminates in a first partial ellipse 76 and a second partial ellipse 78. In some embodiments the enlargements may be implemented as portions of circles having a diameter greater than the width of the helix. The enlargements may be oriented in relation to their respective helices so as to minimize the length of part 42, and so that, consequently, the distance between position sensor 54 and generator 58 may be minimized.

The helices of plurality 46 have rotational symmetry about axis 70, according to the number of helices in the plurality. Thus, the double helix described herein has 2-fold rotational symmetry. In general, if plurality 46 comprises n helices, where n is a positive integer, the helices are configured to have n-fold rotational symmetry about axis 70.

The configuration of the multiple helices of plurality 46 may be compared to the configuration of threads of a multiply-threaded screw, also termed a multiple-start screw. (In the same way, a single helix may be compared to the thread of a single-threaded, or single-start, screw.) Using this comparison, for the embodiment exemplified above (wherein the overall length of member 40 is approximately 8.5 mm), plurality 46 corresponds to a doubly-threaded screw having a pitch of

approximately 0.5 mm, and a lead that is double this value, i.e., approximately 1.0 mm.

First part 42 typically comprises a generally rectangular stem 80, to be used in attaching part 42 to second part 44. The stem may be formed by cutting material from the tube used to produce part 42, so that the stem has the same wall thickness as the wall thickness of the remainder of part 42.

As illustrated in Fig. 4A, member 40 is formed by sliding first part 42 into second part 44, so that stem 80 is enclosed by part 44, and so that partial ellipses 72 and 76 approximately contact the edge of part 44. Once positioned as shown to have a common circumference, the two parts are then fixedly connected together, typically by keyhole welding the edges of stem 80 to the inner surface of part 44. In addition, for extra rigidity, and as shown in Fig. 4B, the two parts are also welded together where the edge of part 44 contacts part 42, i.e., around the common circumference. The circumferential welding is partial, so that regions 82, encompassing the helical cut terminations comprising partial ellipses 76 and 72, are not welded. The partial welding distributes the stresses between the two parts of the coupling member more symmetrically than that of a single helix, as well as reducing the stress at any one location by virtue of the two parts.

The plurality of helical cuts in coupling member 40 cause the member to behave as a spring, allowing the member to bend. By having more than one helical cut, the bending is more uniform than the bending (for the same range of external forces) as that of a tube with a single helical cut and the same number of turns as the plurality of cuts. The plurality of helical cuts also provide greater side stiffness compared to a tube with a single helical cut. The bending extends up to an angle, for example, 30^{O}, at which the sides of the helical cuts on the inside of the bend come into contact. At this point, the locations in contact essentially become "inactivated," although the locations not in contact remain available for bending. The width of the helical cuts may thus be chosen to provide a desired, predetermined, angular limit on the initial bending of the coupling member, which is useful in preventing damage to components of catheter 20 that may be caused by excessive bending.

Furthermore, having a plurality of helical cuts eliminates the single point of failure that occurs with a single helical cut coupling member. Plurality 46 of helical

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cuts requires a corresponding plurality of failures for first part 42 of coupling member 40 to break.

Although the operation and construction of catheter 20 are described above in the context of catheter-based intracardiac procedures, the principles of the present invention may similarly be applied in other therapeutic and diagnostic applications that use invasive probes, both in the heart and in other organs of the body. Furthermore, the principles of the implementation of catheter 20 and coupling member 40 may also be applied to enhance flexibility in catheter designs of other types, such as lasso and "Pentarray" type catheters. In a helical lasso catheter, for example, resilient elements like coupling member 40 may be incorporated into the helical lasso in order to enhance the ease of use and accuracy of alignment of the lasso in the desired position within the heart.

It will thus be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form or suggestion that the prior art forms part of the common general knowledge in Australia.

The claims defining the invention are as follows:

1. A medical probe, including:

a flexible insertion tube, having a distal end for insertion into a body cavity of a patient;

a distal tip having an electrode fixedly mounted thereon, which is disposed at the distal end of the flexible insertion tube and is configured to be brought into contact with tissue in the body cavity;

a coupling member separate from the electrode, which couples the distal tip to the distal end of the flexible insertion tube and which includes a tubular piece of an elastic material having a plurality of intertwined, single helics formed by a plurality of multiple start, longitudinally adjacent helical cuts therethrough along a portion of a length of the tubular piece and a tubular part connected by a fixed connection to the tubular piece and to the distal end of the flexible insertion tube;

a magnetic field generator within the tubular part configured to generate a magnetic field; and

a position sensor within the tubular piece, the position sensor configured to sense a position of the distal tip relative to the distal end of the insertion tube, the position changing in response to deformation of the coupling member and wherein the position sensor is configured to generate a signal in response to the magnetic field, wherein the signal is indicative of the relative position of the distal tip to the distal end.

2. The probe according to claim 1, wherein at least one of the helical cuts includes an enlarged termination.

3. The probe according to claim 2, wherein the enlarged termination includes a partial ellipse.

4. The probe according to any one of claims 1 to 3, wherein the plurality of intertwined helical cuts includes n cuts, where n is an integer greater than 1, and wherein the cuts are configured so that the tubular piece has n-fold rotational symmetry about an axis of the piece.

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5. The probe according to any one of the preceding claims, wherein at least one of the helical cuts subtends an angle between 360O and 720O about an axis of the tubular piece.

6. The probe according to any one of the preceding claims, wherein the coupling member is configured to bend in response to pressure exerted on the distal tip when the distal tip engages the tissue, and wherein at least one of the helical cuts has a width chosen so as to provide a predetermined angular limit on initial bending of the coupling member.

7. The probe according to any one of the preceding claims, wherein the insertion tube, the distal tip and the coupling member are configured for insertion through a blood vessel into a heart of a patient.

8. The probe according to any one of the preceding claims, wherein the tubular piece includes a stem, and wherein the fixed connection includes the stem welded to the tubular part.

9. The probe according to claim 8, wherein the tubular part and the tubular piece are arranged so as to form a common circumference thereto, and wherein the fixed connection includes welds on the common circumference absent regions thereon proximal to respective terminations of the helical cuts.

10. The probe according to any one of the preceding claims, and including a position sensor within the tubular piece.

11. The probe according to claim 10, wherein the position sensor is configured to sense a position of the distal tip relative to the distal end of the insertion tube, the position changing in response to deformation of the coupling member.

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12. The probe according to claim 10, wherein the position sensor is configured to generate a signal in response to a magnetic field, and wherein the signal is indicative of a position of the distal tip.

13. The probe according to claim 12, and including a magnetic field generator within the tubular part for generating the magnetic field.

14. A method for performing a medical procedure, including:

inserting into a body cavity of a patient a probe, which includes a flexible insertion tube and a distal tip, having an electrode fixedly mounted thereon, which distal tip is disposed at a distal end of the flexible insertion tube, and a coupling member separate from the electrode, which couples the distal tip to the distal end of the flexible insertion tube and comprises a tubular piece of an elastic material having a plurality of intertwined, single helics formed by a plurality of multiple start, longitudinally adjacent helical cuts therethrough along a portion of a length of the tubular piece and a tubular part connected by a fixed connection to the tubular piece and to the distal end of the flexible insertion tube, a magnetic field generator within the tubular part for generating a magnetic field, and a position sensor within the tubular piece, the position sensor configured to sense a position of the distal tip relative to the distal end of the insertion tube, the position changing in response to deformation of the coupling member and wherein the position sensor is configured to generate a signal in response to the magnetic field, wherein the signal is indicative of a position of the distal tip;

bringing the distal tip into contact with tissue in the body cavity; and

determining pressure exerted on and by the distal tip using the signal.

15. The method according to claim 14, wherein inserting the probe includes passing the probe through a blood vessel into a heart of the patient.

16. The method according to claim 14 or claim 15, and including ablating the tissue with which the distal tip is in contact.

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17. The method according to any one of claims 14 to 16, wherein at least one of the helical cuts includes an enlarged termination.

18. The method according to claim 17, wherein the enlarged termination includes a partial ellipse.

19. The method according to any one of claims 14 to 18, wherein the plurality of helical cuts includes n cuts, where n is an integer greater than 1, and including configuring the n cuts so that the tubular piece has n-fold rotational symmetry about an axis of the piece.

20. The method according to any one of claims 14 to 19, wherein at least one of the helical cuts subtends an angle between 360° and 720° about an axis of the tubular piece.

21. The method according to any one of claims 14 to 20, including configuring the coupling member to bend in response to pressure exerted on the distal tip when the distal tip engages the tissue, and configuring at least one of the helical cuts to have a width chosen so as to provide a predetermined angular limit on initial bending of the coupling member.

22. The method according to claim 21, wherein the coupling member includes a tubular part connected by a fixed connection to the tubular piece.

23. A medial probe, substantially as described herein with reference to the accompanying drawings.

24. A method for performing a medical procedure, substantially as described herein with reference to the accompanying drawings.

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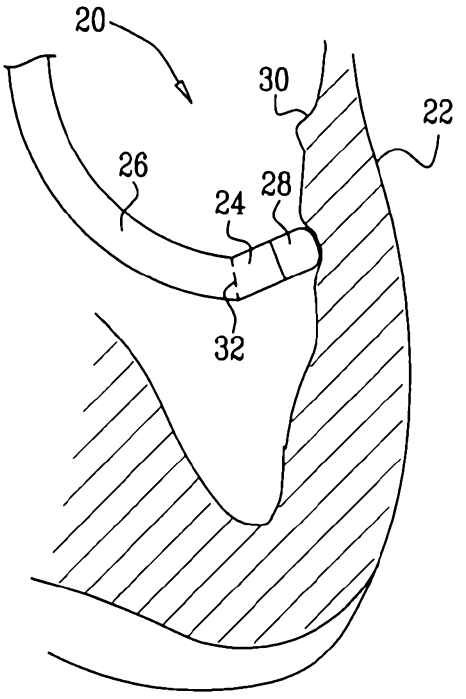

FIG. 1

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FIG. 2

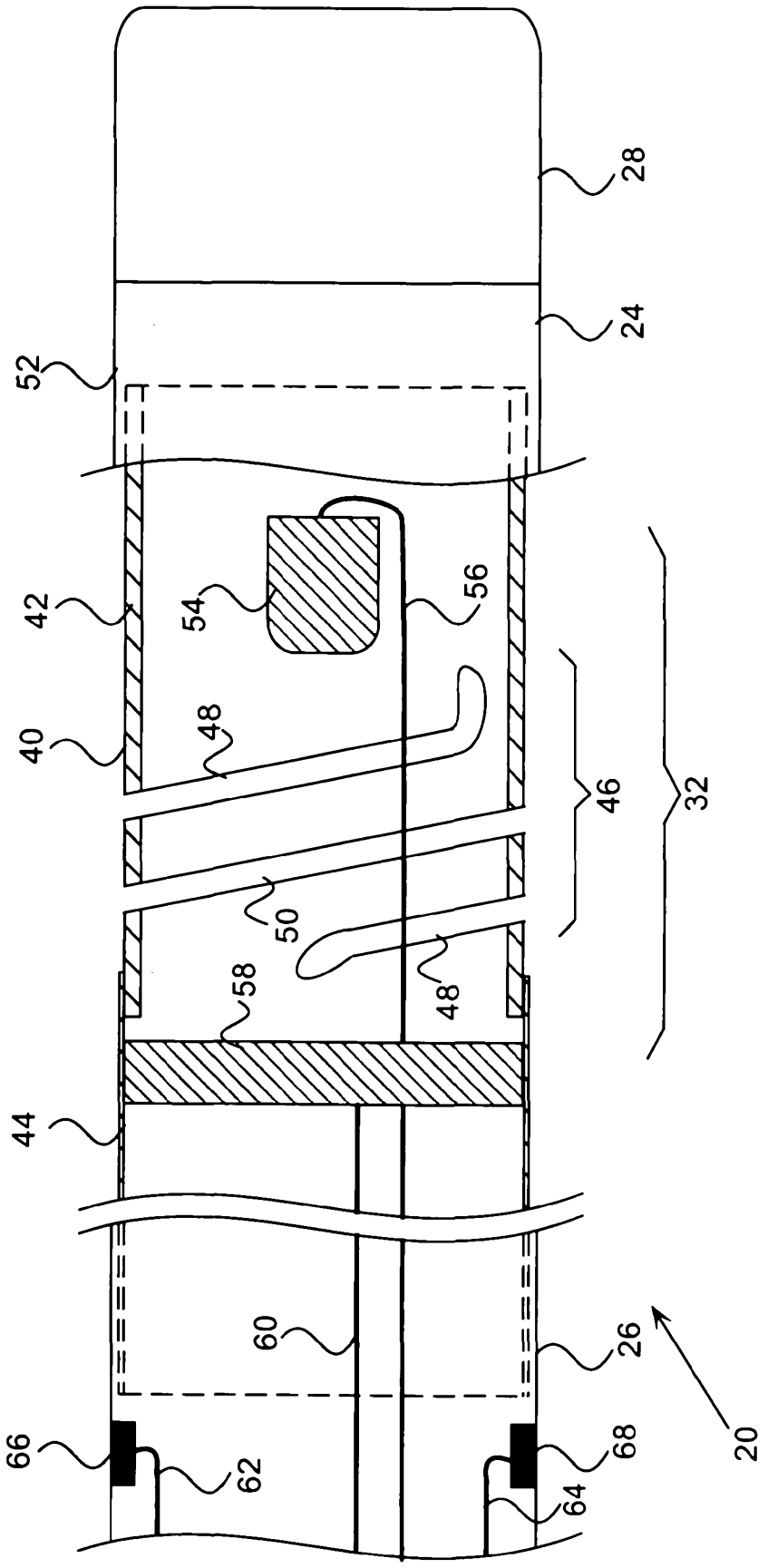
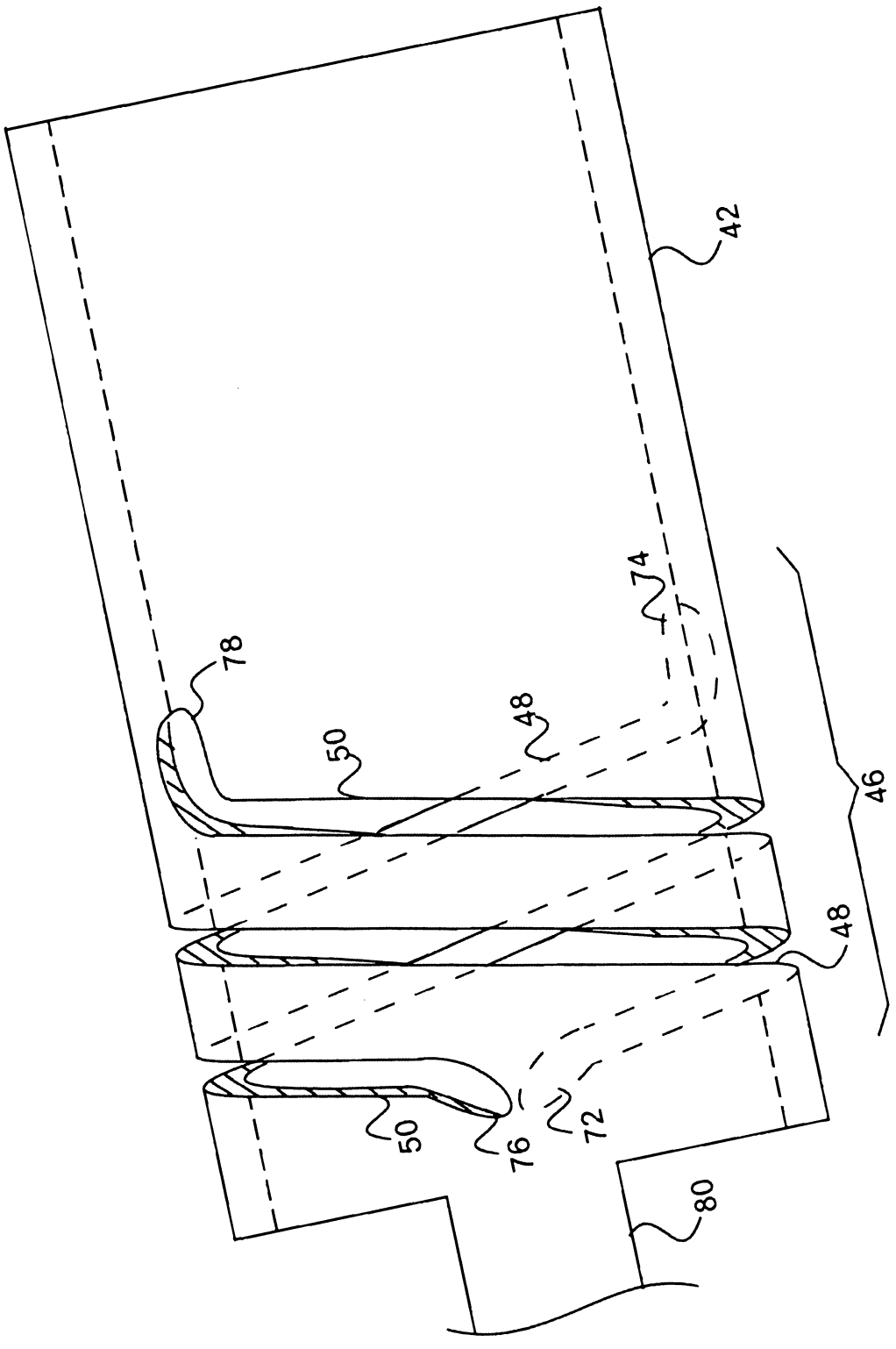


FIG. 3



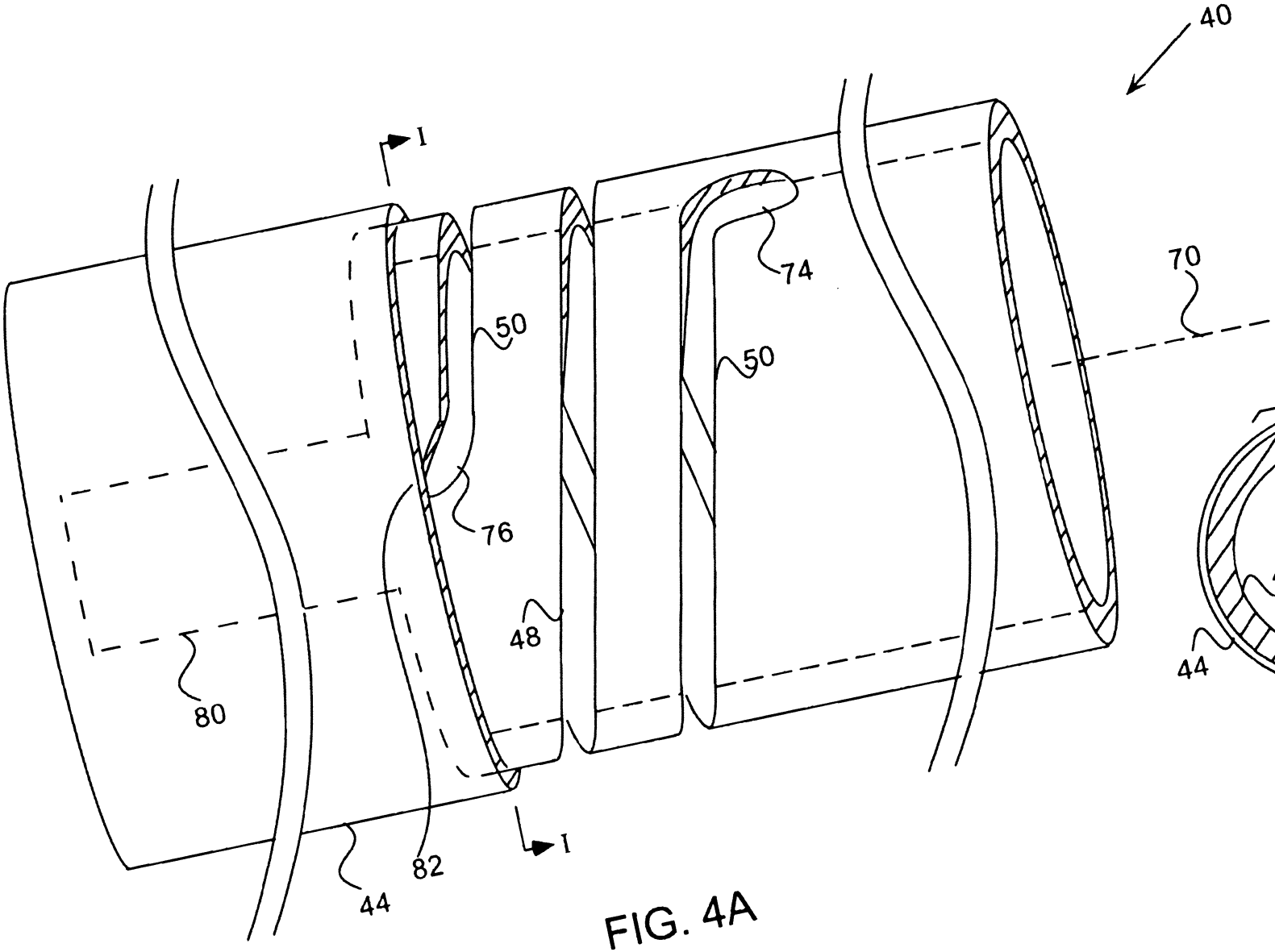


FIG. 4A

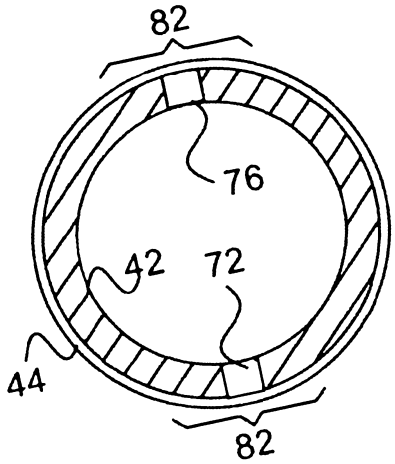


FIG. 4B