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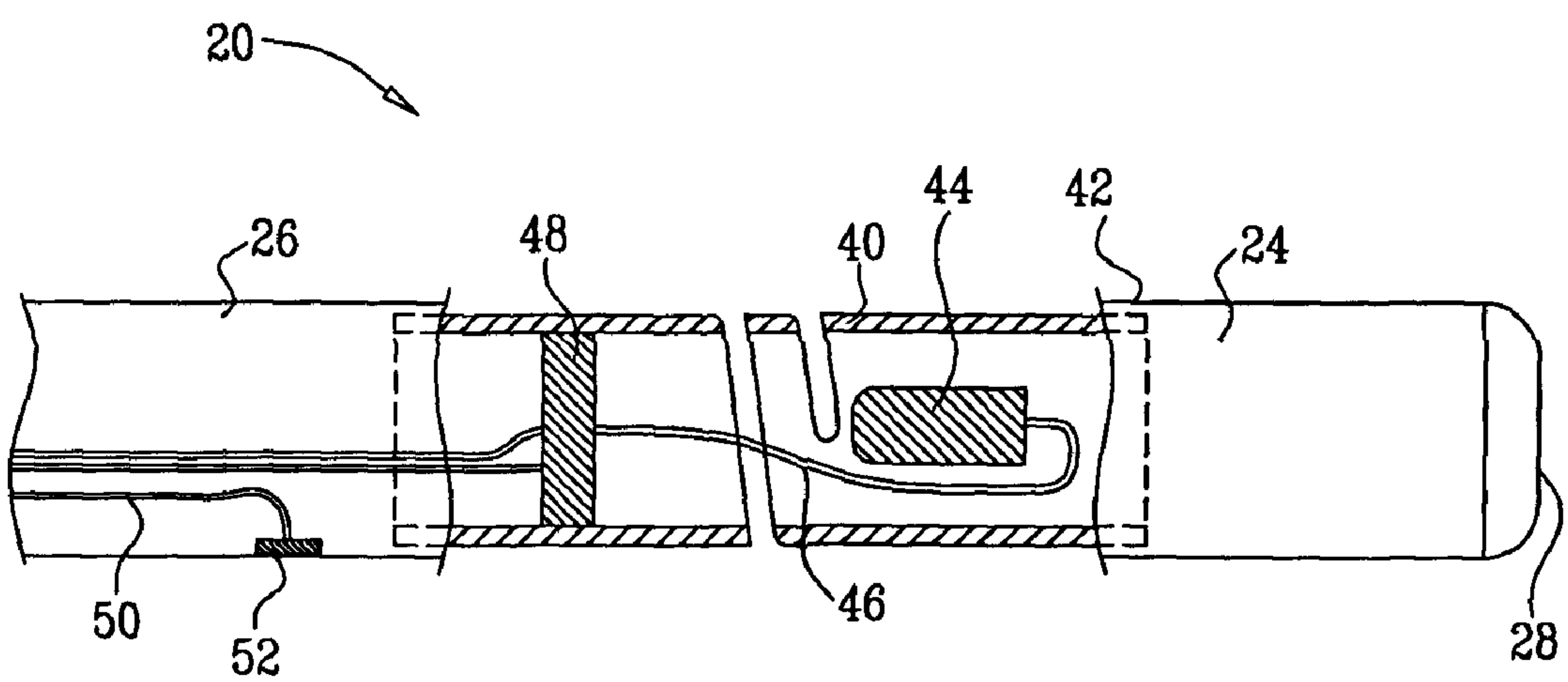
(54) **Titre : CATHETER AVEC EXTREMITE A FLECHISSEMENT**
(54) **Title: CATHETER WITH BENDABLE TIP**



(57) **Abrégé/Abstract:**
A medical probe includes 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 is configured to be brought into contact with tissue in the body cavity. A coupling member couples the distal tip to the distal end of the insertion tube and includes a tubular piece of an elastic material having a helical cut therethrough along a portion of a length of the piece.

ABSTRACT

A medical probe includes 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 is configured to be brought into contact with tissue in the body cavity. A coupling member couples the distal tip to the distal end of the insertion tube and includes a tubular piece of an elastic material having a helical cut therethrough along a portion of a length of the piece.

CATHETER WITH BENDABLE 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, describes systems and methods for assessing electrode-tissue contact for tissue ablation. An electro-mechanical sensor within the 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.

SUMMARY OF THE INVENTION

The embodiments of the present invention that are described hereinbelow provide a novel design of an invasive probe, such as a catheter. The probe comprises a flexible insertion tube, having a distal end for insertion into a body cavity of a patient. The 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 an elastic material, such as a superelastic alloy, with a helical cut running along a portion of the length of the piece.

The coupling member permits the distal tip to bend in response to pressure exerted on the distal tip when the distal tip engages tissue in the body cavity. Typically, the bend angle is proportional to the pressure and may be measured in order to determine the force of contact between the probe and the tissue. On the other hand, the width of the helical cut may be chosen so as to inhibit bending of the distal tip beyond a certain angular limit in order to avoid damaging the probe.

There is therefore provided, in accordance with an embodiment of the present invention, a medical probe, including:

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

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

a coupling member, which couples the distal tip to the distal end of the insertion tube and includes a tubular piece of an elastic material having a helical cut therethrough along a portion of a length of the piece.

In one embodiment, the position sensor is configured to generate a signal in response to a magnetic field, wherein the signal is indicative of a position of the distal tip. The probe includes a magnetic field generator within the distal end of the insertion tube for generating the magnetic field.

In a disclosed embodiment, the elastic material includes a superelastic alloy, and the helical cut subtends an angle between 360^{0} and 720^{0} about an axis of the tubular piece.

Typically, the coupling member is configured to bend in response to pressure exerted on the distal tip when the distal tip engages the tissue, and the helical cut has a width chosen so as to inhibit bending of the distal tip beyond a predetermined angular limit.

In some embodiments, the probe includes a position sensor within the distal tip, wherein the position sensor is configured to sense a position of the distal tip relative to the distal end of the insertion tube, which changes in response to deformation of the coupling member. Additionally or alternatively, the probe includes an electrical conductor, which is coupled to a distal side of the position sensor and is curved to pass in a proximal direction around the position sensor and through the insertion tube so as to convey position signals from the position sensor to a proximal end of the insertion tube.

In some embodiments, the probe includes a pull-wire for use by an operator of the probe in steering the probe, wherein the pull-wire passes through the insertion tube and is anchored at a point in the distal end of the insertion tube that is proximal to the helical cut in the coupling member. Alternatively or additionally, the probe includes a heat-resistant plastic sheath covering at least the coupling member.

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

Also disclosed is 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, which is disposed at a distal end of the insertion tube, and a coupling member, which couples the distal tip to the distal end of the insertion tube and includes a tubular piece of an elastic material having a helical cut therethrough along a portion of a length of the piece; and

bringing the distal tip into contact with tissue in the body cavity.

In a disclosed embodiment, inserting the probe includes passing the probe through a blood vessel into a heart of the patient, and the method includes ablating the tissue with which the distal tip is in contact.

There is additionally provided, 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 configured to be brought into contact with tissue in the body cavity; and

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

In one embodiment, there is provided a method for producing a medical probe, comprising:

providing a flexible insertion tube, having a distal end for insertion into a body cavity of a patient, the distal end of the insertion tube having a magnetic field generator positioned therein for generating a magnetic field, and a distal tip, which is configured to be brought into contact with tissue in the body cavity;

inserting a position sensor in the distal tip, wherein the position sensor is configured to generate a signal in response to the magnetic field, and wherein the signal is indicative of a position of the distal tip;

coupling the distal dip to the distal end of the insertion tube using a coupling member, which comprises a tubular piece of an elastic material having a helical cut 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:

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, in accordance with an embodiment of the present invention;

Fig. 2 is a schematic sectional view of a catheter, in accordance with an embodiment of the present invention; and

Fig. 3 is a schematic side view of a coupling member, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Fig. 1 is a schematic sectional view of a chamber of a heart 22, showing an insertion tube 26 of a catheter 20 inside the heart, in accordance with 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 the insertion tube 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 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 is ensuring 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 8,357,152, filed October 8, 2007, 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, in accordance with an embodiment of the present invention. A coupling member 40 forms the joint between distal tip 24 and the distal end of insertion tube 26. The coupling member has the form of a tubular piece of an elastic material, with a helical cut along a portion of its length, as shown more particularly in Fig. 3. Typically, the coupling member (along with the distal end of catheter 20 generally) is covered by a flexible plastic sheath 42. When catheter 20 is used, for example, in ablating endocardial tissue by delivering RF electrical energy through electrode 28, considerable heat is generated in the area of distal tip 24. For this reason, it is desirable that sheath 42 comprise 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 44 within distal tip 24. (In the pictured embodiment, the position sensor is contained within a part of coupling member 40 that is inside the distal tip of the catheter.) The position sensor is connected via a conductor 46 to a processing unit (not shown) at the proximal end of insertion tube 26. Conductor 46 may typically comprise a twisted-pair cable. Position sensor 44 is configured to sense the position of the distal tip relative to the distal end of the insertion tube. As explained above, this 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 on the order of 2-3 mm. Therefore, all of the internal components of catheter 20, such as conductor 46, are also made as small and thin as possible and are thus susceptible to damage due to even small mechanical strains. To avoid damage to conductor 46 when coupling member 40 bends, the conductor is coupled to the distal side of position sensor 44, as shown in Fig. 2, rather than to the proximal side, from which the path of the conductor would be shorter. The conductor is then curved to pass in a proximal direction around the position sensor and through insertion tube 26 so as to convey position signals from the position sensor to the processing unit via the proximal end of the insertion tube.

Position sensor 44 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 48 within the distal end of the insertion tube. 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 44 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 44 are described in detail in the above-mentioned U.S. Patent 8,357,152. They are outside the scope of the present invention.

Catheter 20 may comprise a pull-wire 50 for use by an operator in steering the catheter. The pull-wire passes through insertion tube 26 and is anchored at an anchor point 52 in the distal end of the insertion tube. The operator tightens the pull-wire (typically by turning a knob - not shown - at the proximal end of the catheter) in order to bend the distal end of the catheter. When the operator releases the pull-wire, the catheter straightens due to the resilience of the insertion tube. In catheters that are known in the art, the pull-wire is anchored near the distal tip of the catheter. In catheter 20, however, anchor point 52 is proximal to the helical cut in coupling member 40, and may be proximal to the coupling member altogether, as shown in Fig. 2. This relatively proximal positioning of the anchor point means that the pull-wire steers the catheter as a whole, rather than bending the coupling member and distal tip.

Fig. 3 is a schematic side view of coupling member 40, in accordance with an embodiment of the present invention. As noted earlier, the coupling member comprises a tubular piece 60 of an elastic material, typically a metal material. For example, the coupling member may comprise a superelastic alloy, such as nickel titanium (Nitinol). For intracardiac applications, the Nitinol tube may typically have a length of 10 mm, with outer diameter 2.0 mm and wall thickness 0.05 mm. Alternatively, in other applications, the tube may have larger or smaller dimensions.

A helical cut 62 is made along a portion of the length of tubular piece 60, and thus causes the tubular piece to behave like a spring in response to forces exerted on distal tip 24. Cut 62 may be made by laser machining of the tubular piece. For the tube dimensions given above, cut 62 is typically opened by the laser to a width of about 0.1 mm. To give the appropriate balance between flexibility and stiffness for intracardiac applications, cut 62 typically subtends an angle between 360^{0} and 720^{0} about the central axis of the tubular piece, as illustrated in Fig. 3 (in which the cut subtends about 540^{0}). Alternatively, larger or smaller angular extents may be used depending on application requirements.

The spring-like behavior of coupling member 40 extends up to a certain angle of bending of tubular piece 60, for example, 30^{0}. Above this angle, the sides of cut 62 on the inner side of the bend will come into contact, thereby inhibiting any further bending of the distal tip. The width of the cut may thus be chosen so as to impose a predetermined angular limit on the bending of joint 32 (Fig. 1). This sort of bend limit is useful in preventing damage that may occur to the delicate internal components of catheter 20 due to excessive bending.

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, helix, and "Pentarray" type catheters. In a helical lasso catheter, for example, resilient elements like coupling member 40 may be incorporated in the helix 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.

CLAIMS

1. A medical probe, comprising:

a flexible insertion tube, having a distal end for insertion into a body cavity of a patient, the insertion tube comprising a magnetic field generator within the distal end of the insertion tube for generating a magnetic field;

a distal tip, which is disposed at the distal end of the insertion tube and is configured to be brought into contact with tissue in the body cavity, the distal tip comprising a position sensor within the distal tip, wherein the position sensor is configured to generate a signal in response to the magnetic field, and wherein the signal is indicative of a position of the distal tip;

a coupling member, which couples the distal tip to the distal end of the insertion tube and comprises a tubular piece of an elastic material having a helical cut therethrough along a portion of a length of the piece.

2. The probe according to claim 1, wherein the elastic material comprises a superelastic alloy.

3. The probe according to claim 1 or 2, wherein the helical cut subtends an angle between 360° and 720° about an axis of the tubular piece.

4. The probe according to any one of claims 1 to 3, 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 the helical

cut has a width chosen so as to inhibit bending of the distal tip beyond a predetermined angular limit.

5. The probe according to any one of claims 1 to 4, wherein the position sensor is configured to sense a position of the distal tip relative to the distal end of the insertion tube, which changes in response to deformation of the coupling member.

6. The probe according to any one of claims 1 to 5, and comprising an electrical conductor, which is coupled to a distal side of the position sensor and is curved to pass in a proximal direction around the position sensor and through the insertion tube so as to convey position signals from the position sensor to a proximal end of the insertion tube.

7. The probe according to any one of claims 1 to 6, and comprising a pull-wire for use by an operator of the probe in steering the probe, wherein the pull-wire passes through the insertion tube and is anchored at a point in the distal end of the insertion tube that is proximal to the helical cut in the coupling member.

8. The probe according to any one of claims 1 to 7, and comprising a heat-resistant plastic sheath covering at least the coupling member.

9. The probe according to any one of claims 1 to 8, wherein the insertion tube, distal tip and coupling member are configured for insertion through a blood vessel into a heart of a patient.

10. The probe according to any one of claims 2 or 3 to 9 when dependent on claim 2, wherein the superelastic alloy is a nickel titanium alloy.

11. A method for producing a medical probe, comprising:

providing a flexible insertion tube, having a distal end for insertion into a body cavity of a patient, the distal end of the insertion tube having a magnetic field generator positioned therein for generating a magnetic field, and a distal tip, which is configured to be brought into contact with tissue in the body cavity;

inserting a position sensor in the distal tip, wherein the position sensor is configured to generate a signal in response to the magnetic field, and wherein the signal is indicative of a position of the distal tip;

coupling the distal dip to the distal end of the insertion tube using a coupling member, which comprises a tubular piece of an elastic material having a helical cut therethrough along a portion of a length of the piece.

12. The method according to claim 11, wherein the elastic material comprises a superelastic alloy.

13. The method according to claim 11 or 12, wherein the helical cut subtends an angle between 360° and 720° about an axis of the tubular piece.

14. The method according to any one of claims 11 to 13, 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 the helical cut has a width chosen so as to inhibit bending of the distal tip beyond a predetermined angular limit.

15. The method according to any one of claims 11 to 14, and comprising:

coupling an electrical conductor to a distal side of the position sensor; and

passing the electrical conductor in a proximal direction around the position sensor and through the insertion tube so as to convey position signals from the position sensor to a proximal end of the insertion tube.

16. The method according to any one of claims 11 to 15, and comprising inserting a pull-wire through the insertion tube, and anchoring the pull-wire at a point in the distal end of the insertion tube that is proximal to the helical cut in the coupling member.

17. The method according to any one of claims 11 to 16, and comprising covering at least the coupling member with a heat-resistant plastic sheath.

FIG. 1

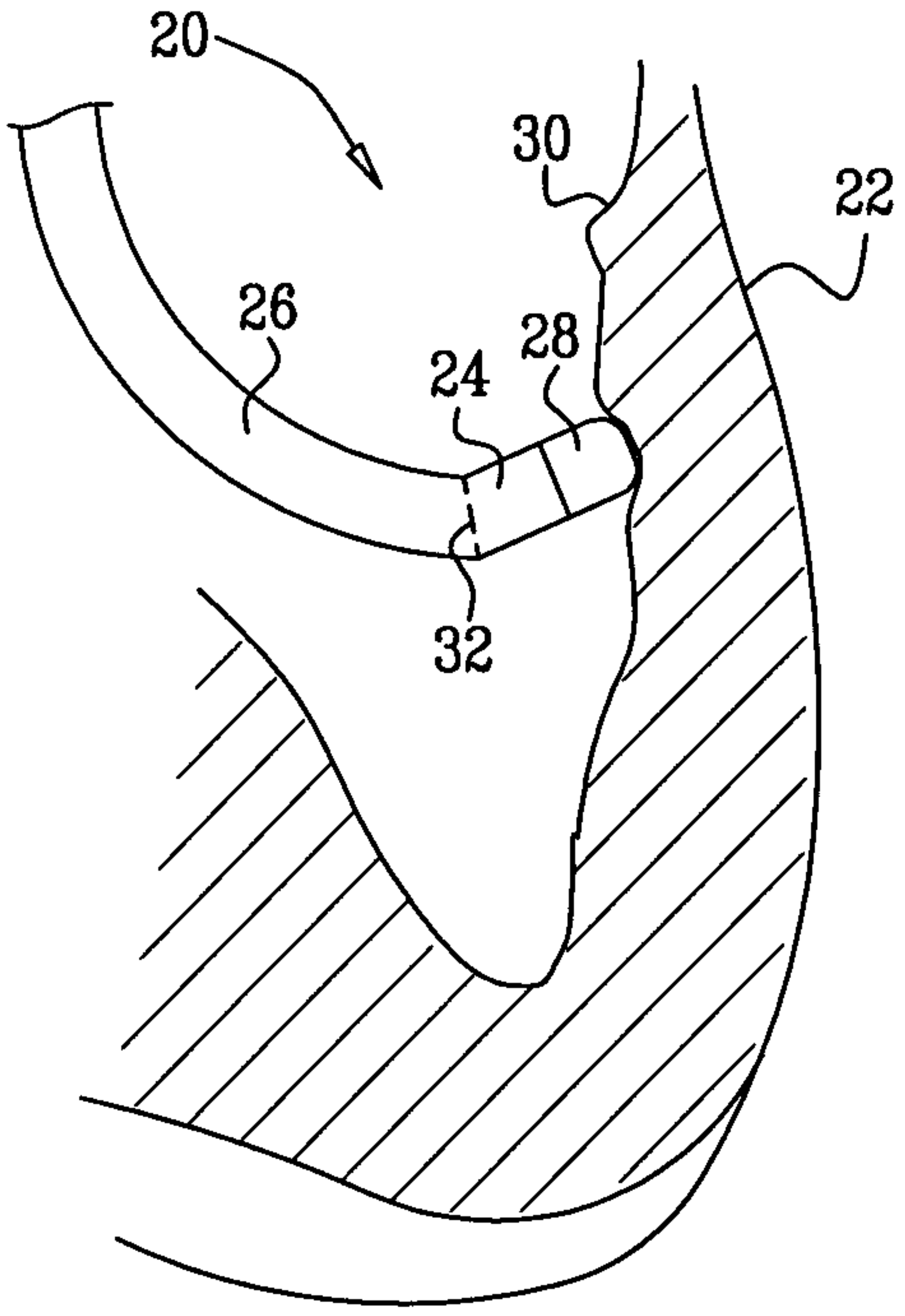
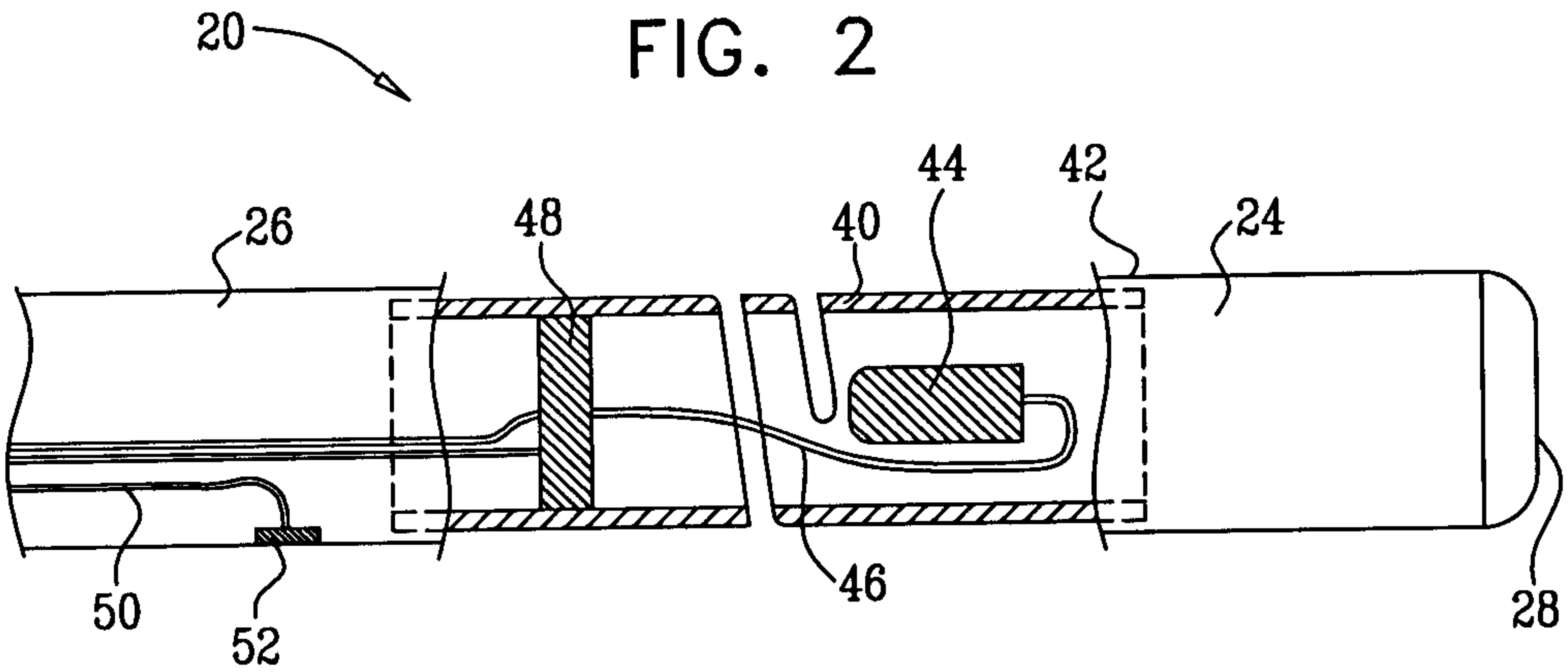


FIG. 2



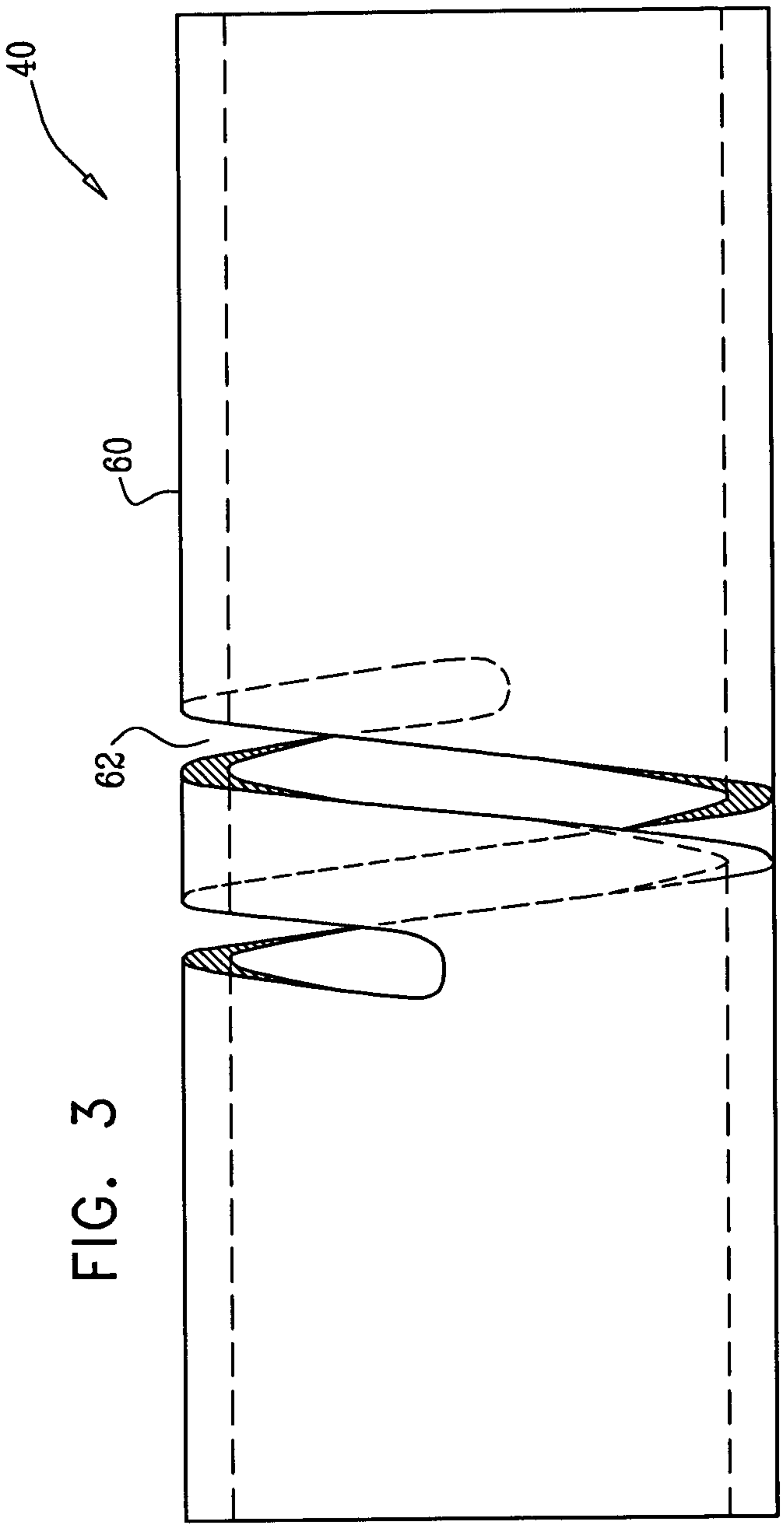
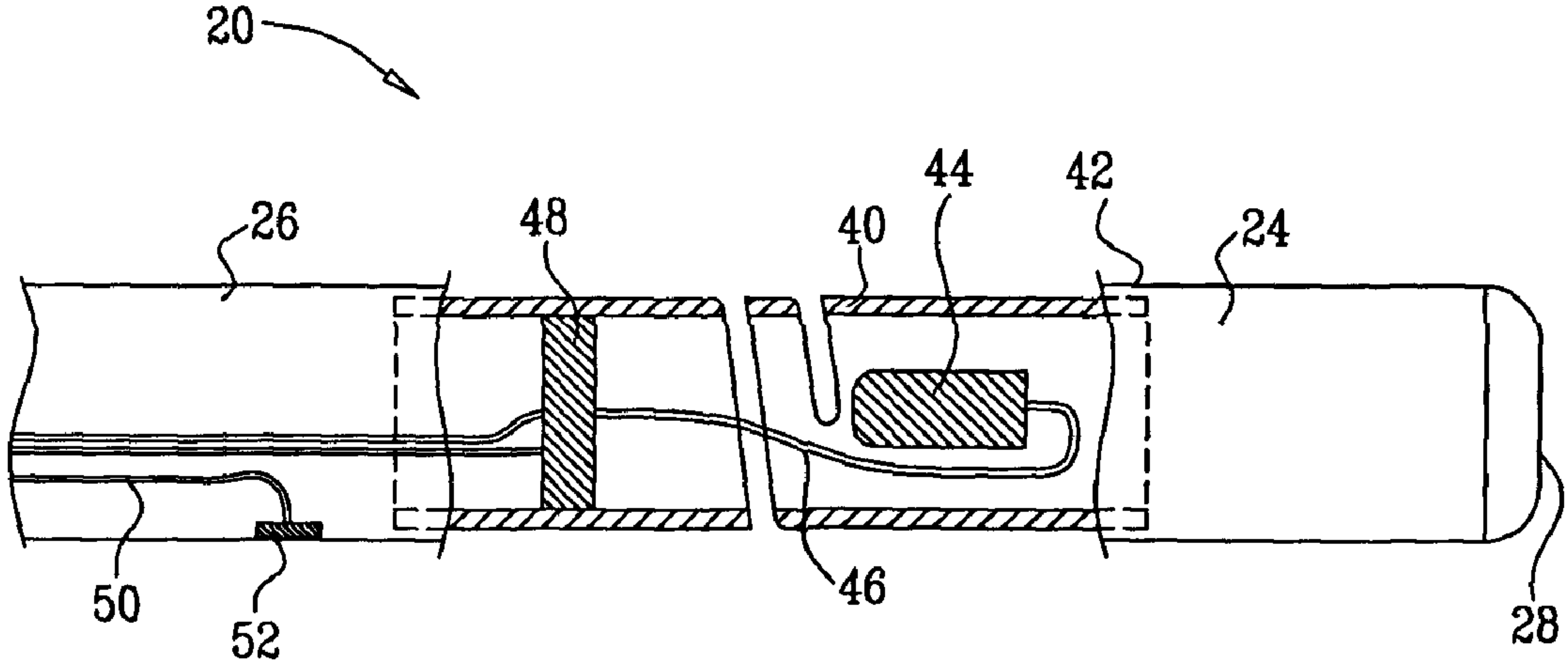


FIG. 3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