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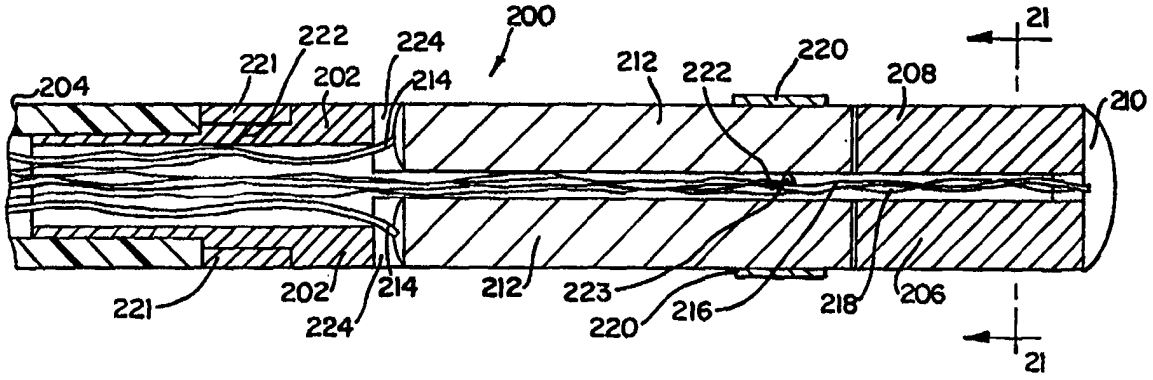

(57) Abstract

Methods and apparatus are disclosed for use in procedures related to the electrophysiology of the heart, such as identifying or evaluating the electrical activity of the heart, diagnosing and/or treating conditions associated with the electrophysiology of the heart. An apparatus (200) having thermocouple elements (206, 208) of different electromotive potential conductively connected at a junction (210) is introduced into the interior of the heart and a section of heart tissue is contacted with the junction (210). An electrical current is passed through the thermocouple elements (206, 208) to reduce the temperature of the junction in accordance with the Peltier effect and thereby cool contacted heart tissue. The effect of the cooling may be monitored and, if desired, the section of heart tissue may be treated.

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APPARATUS AND METHODS FOR PROCEDURES RELATED TO THE ELECTROPHYSIOLOGY OF THE HEART

This application is a continuation-in-part of co-pending application U.S. Serial No. 670,177 filed on June 20, 1996, which is a division of U.S. Serial 294,478, filed on August 19, 1994, now U.S. Patent No. 5,529,067.

FIELD OF INVENTION

The present invention relates generally to methods and apparatus for diagnosing or treating electrophysiological conditions of the heart. More specifically, the present invention relates to novel methods and apparatus for evaluating the electrical activity of the heart, for identifying an electrophysiological source of heart arrhythmia, and for treating heart arrhythmia.

BACKGROUND ART

As is well known, the human heart has four chambers for receiving blood and for pumping it to various parts of the body. In particular, the two upper chambers of the heart are called atriums, and the two lower chambers are called ventricles.

During normal operation of the heart, oxygen-poor blood returning from the body enters the upper right chamber known as the right atrium through the superior vena cava and inferior vena cava. The right atrium fills with blood and eventually contracts to expel the blood through the tricuspid valve to the lower right chamber known as the right ventricle. Contraction of the right ventricle ejects the blood in a pulse-like manner from the right ventricle to the pulmonary artery which divides into two branches, one going to each

lung. As the oxygen-poor blood travels through the lungs, it becomes oxygenated (i.e. oxygen-rich).

The oxygenated blood leaves the lungs through the pulmonary veins and fills the upper left chamber of the heart known as the left atrium. When the left atrium contracts, it sends the blood through the mitral valve to the lower left chamber called the left ventricle. Contraction of the left ventricle, which is the stronger of the two lower chambers, forces blood through the main artery of the vascular system known as the aorta. The aorta branches into many smaller arteries and blood vessels that eventually deliver the oxygen-rich blood to the rest of the body.

As is apparent from the description above, the proper sequence of contraction and relaxation of the heart chambers is fundamental to its operation. Contraction of the heart chambers is controlled by the heart's conduction system, which includes areas of specialized "nodal" tissue or "nodes" capable of generating and transmitting electrical impulses. The ability to generate electrical impulses is known as "automaticity."

The natural pacemaker of the heart is called the SA (sino-atrial) node. It lies in the groove where the superior vena cava joins the right atrium. The SA node contains two types of cells, one of which exhibits automaticity.

In general, the conduction of an electrical impulse generated by the SA node proceeds as follows. The cardiac impulse travels across the walls of the atria, eventually causing the atria to contract. The impulses generated by the SA node are also transmitted to the atrio-ventricular (AV) node located in the lower portion of the right atrium near the right ventricle. From the AV node, the impulses travel through another area of nodal tissue known as the bundle of His and eventually to the Purkinje's fibers that envelop the ventricles. When the impulses reach these fibers, they cause

the ventricles to contract.

More specifically, from the SA node the cardiac impulse spreads radially along ordinary atrial myocardial fibers. A special pathway, the anterior interatrial myocardial band, conducts the impulse from the SA node directly to the left atrium. In addition, three tracts, the anterior, middle, and posterior internodal tracts or pathways constitute the principal routes for conduction of the cardiac impulse from the SA to the AV node. These tracts consist of ordinary myocardial cells and specialized conducting fibers.

The AV node is situated posteriorly on the right side of the muscle wall dividing the heart's right and left atria, (known as the interatrial septum). The AV node also contains cells that exhibit automaticity. The AV node receives and relays the impulses through the septum to a cluster of fibers between the ventricles known as the bundle of His.

The bundle of His passes down the right side of the inter ventricular septum (the muscle wall between the right and left ventricles) and then divides into the right and left bundle branches. The right bundle branch is a direct continuation of the bundle of His and it proceeds down the right side of the interventricular septum. The left bundle branch, which is considerably thicker than the right, branches almost perpendicularly from the bundle of His and bisects the interventricular septum. On the surface of the left side of the interventricular septum the main left bundle branch splits into a thin anterior division and a thick posterior division.

The right bundle branch and the two divisions of the left bundle branch ultimately subdivide into a complex network of conducting fibers called Purkinje's fibers which envelop the ventricles.

As an impulse travels from the region of the atria to the ventricles, the first portions of the ventricles to be excited

are the interventricular septum and the papillary muscles. The wave of activation spreads to the septum from both its left and its right endocardial surfaces (the inner membrane of the heart wall). Early contraction of the septum tends to make it more rigid and allows it to serve as an anchor point for the contraction of the remaining ventricular myocardium (the middle layer of muscle that comprises the heart wall).

The endocardial surfaces of both ventricles are activated rapidly, but the wave of excitation spreads from endocardium to the outer membrane or sheath of the heart wall known as the epicardium at a slower velocity. Because the right ventricular wall is appreciably thinner than the left, the epicardial surface of the right ventricle is activated earlier than that of the left ventricle. The last portions of the ventricles to be excited are the posterior basal epicardial regions and a small zone in the basal portion of the interventricular septum.

Cardiac arrhythmia refers to a disturbance in the rhythm of contraction and relaxation of the heart's chambers. In cardiac arrhythmia, the atria and/or ventricles do not contract and relax in the regular and sequential pattern described above, and may instead contract prematurely and/or randomly. In the most serious types of arrhythmia, such as fibrillation, the impulses may fragment into multiple, irregular circuits which are incapable of causing coordinated contractions of the heart chamber and, therefore, may adversely affect the pumping of blood.

Various causes of arrhythmia have been identified. One cause of cardiac arrhythmia may be a disorder in the formation of the impulse. For example, although the primary source of impulse formation is the SA node, it is known that most cardiac cells are capable of exhibiting automaticity. If an impulse traveling, for example, from the SA node is delayed or diverted, other cardiac cells or clusters of cells outside the areas of nodal tissue may spontaneously initiate an impulse.

These cells or cell clusters are known as ectopic foci. The impulses generated by ectopic foci may be transmitted to the atria and/or ventricles prior to the impulse that is traveling along the normal conductive pathway, thereby causing premature contraction of the heart chamber.

Arrhythmia may also be caused by disorders in the conduction or transmission of an impulse from one region of the heart to another region. In this case, injury to a section of the heart tissue that is part of the normal conductive pathway may slow, block or even divert transmission of the impulse from its normal path. Impulses traveling along a different pathway proximal to the blocked pathway may attempt to reenter the blocked pathway. If the impulse reenters the blocked pathway, it may prematurely stimulate other nodal tissue causing the atria or ventricles to contract before these chambers have returned to their relaxed state.

One known method of treating cardiac arrhythmia, includes ablating the focal point of the arrhythmia within the heart tissue with the tip of a catheter or other surgical device. The devices used for treating arrhythmia typically have elongated, small diameter tubular bodies that include tips that can be heated, super-cooled or are capable of emitting radiofrequency energy. Typically, the device is introduced and advanced through the vascular system of the patient until the tip of the device reaches the desired location (e.g. the suspected source of the arrhythmia for treatment). When applied to the source of the arrhythmia, these heated, super-cooled or otherwise energized catheter tips ablate the section of tissue responsible for the cardiac arrhythmia.

One such method for treating disorders associated with the conduction of electrical signals in cardiac tissue is described in U.S. Patent No. 4,641,649. There, an antenna located at the distal tip of the catheter receives electrical signals from the heart which aids the physician in determining the source of the cardiac disorder. Once the source has been

located, radiofrequency or microwave frequency energy is applied to the section of tissue through the tip of the catheter to ablate the source of the electrical disorder. The ablation can be controlled by means of an attenuator which regulates the amount of power radiated by the antenna.

Another example of a method and apparatus for ablating a portion of body tissue is described in U.S. Patent No. 5,147,355. There, a catheter is guided through the patient's body to the area of tissue to be ablated. An electrode located at the catheter tip monitors electrical activity of the tissue and transmits the information to a monitor display. After the physician has positioned the tip of the catheter at the suspected source of the arrhythmia, the tip of the catheter is cryogenically super-cooled to ablate the desired section of heart tissue. The device in this patent includes a flow control valve to regulate the amount of cryogenic liquid delivered to the catheter tip, and thereby try to control the temperature and rate of tip cooling. It is unclear from the description in U.S. Patent No. 5,147,355 how or whether the operator is able to determine the tip temperature. If during the course of cryoablation, an arrhythmic signal continues to be detected by the electrode, the cryoablation may be curtailed and the catheter tip repositioned to cryoablate another section of tissue suspected of being the source of the arrhythmia.

The catheter described in U.S. Patent No. 5,147,355 includes first and second concentric fluid flow passages adjacent the tip portion for the flow of cryogenic fluid. Accordingly, the flow passages of the catheter must be made of a rigid material such as stainless steel or other material capable of withstanding the high pressures and temperatures as low as -60°C associated with liquid-to-gas phase change in a cryogenic fluid. As a result, the catheter is necessarily less flexible and more difficult to maneuver than is desirable when advancing the catheter through the vascular system of a patient.

One of the drawbacks with the above-described method for treating cardiac arrhythmia is that it does not allow for precise control of the probe tip temperature. For example, in the cryoablation method described in U.S. Patent No. 5,147,355, the temperature of the catheter tip is regulated by the amount of cryogenic fluid delivered to the catheter tip. Using this method, change in the temperature of the probe tip is gradual, and rapid and precise temperature adjustment to the probe tip over a broad range of temperatures is difficult to achieve. The inability to quickly adjust the probe tip temperature may result in some destruction of sections of heart tissue that are not responsible for the arrhythmia.

Although it is known that cooling the heart tissue can cause observable changes in the electrical activity of the heart, Hariman et al., "Cryothermal Mapping of the Sinus Node in Dogs: A Simple Method of Localizing Dominant and Latent Pacemakers," Cardiovascular Research, 1989, Vol. 23, pp. 231-238 and Gessman, "Localization and Mechanism of Ventricular Tachycardia by Ice-Mapping 1-Week After the Onset of Myocardial Infarction in Dogs," Circulation, Vol. 68, No. 3, September 1983, pp. 657-666, which are incorporated by reference herein, the present methods for treating arrhythmia, as described above, typically have not utilized cooling of the heart tissue for purposes of identifying the foci of the aberrant signals, but have used low-temperature cooling for ablation.

SUMMARY DISCLOSURE OF THE INVENTION

The present invention is generally directed to methods and apparatus for use in procedures related to the electrophysiology of the heart, such as identifying or evaluating the electrical activity of the heart, or diagnosing and/or treating conditions associated with the electrophysiology of the heart. In accordance with one aspect of the present invention, the apparatus includes an elongated body having proximal and distal end portions. One or more pairs of thermocouple elements or "legs" are located within

said distal end portion. One end of one of the thermocouple elements is conductively connected to one end of the other thermocouple element at a junction. The other end of at least one thermocouple element is connected to a heat sink. The temperature of the junction may be affected by applying a voltage across the thermocouple elements in accordance with the Peltier effect and by said heat sinks.

In accordance with another aspect of the present invention, a probe for use in cardiac-related procedures is also provided. The probe includes a carrier having low thermal and electrical conductivity and at least two thermocouple elements conductively connected at a junction and mounted on the carrier. The probe also includes at least one electrode.

In accordance with another aspect of the present invention, a method is provided wherein an apparatus having thermocouple elements of different electromotive potentials, which are conductively connected at a junction is introduced into the interior of the heart. The junction is brought into contact with a section of the heart tissue. An electrical current is passed through the thermocouple elements to reduce the temperature of the junction in accordance with the Peltier effect, and thereby cool the heart tissue without damaging the heart tissue. The heart is monitored for any effect of the cooling (by, for example, direct observation by a physician or by sensing or recording by a machine). After cooling, the temperature of the heart tissue is returned to normal, such as by actually warming the heart tissue or by allowing the heart tissue to warm on its own.

Finally, in accordance with another aspect of the present invention, a method for treating electrophysiological disorders in the heart is also provided. As in the method referred to above, an apparatus having thermocouple elements of different electromotive potentials conductively connected at a junction is introduced into the interior of the heart,

and a section of heart tissue is contacted with the junction. The junction is cooled by passing an electrical current through the thermocouple elements in accordance with the Peltier effect, and thereby cool the heart tissue without damaging the heart tissue. The heart may be monitored for an effect of such cooling. By monitoring for the effect of the cooling on the electrophysiology of the heart, the physician is able to determine whether or not the source of the arrhythmia has been located. If it is determined that the source of the arrhythmia has been correctly identified, the section of tissue may be immediately treated, for example, by ablating the desired area while the junction is still in contact with the section of heart tissue, so as to substantially permanently interrupt the source of the arrhythmia. During ablation electrical current is passed through the thermocouple elements in accordance with the Peltier effect.

DESCRIPTION OF DRAWINGS

Fig. 1 is a cross-sectional view of a human heart with the apparatus embodying the present invention disposed within the heart at different locations;

Fig. 2 is a longitudinal cross-sectional view of the distal end portion of an apparatus utilizing the Peltier effect;

Fig. 3 is a plan view of the apparatus embodying the present invention;

Fig. 4 is a longitudinal cross-sectional view of the distal end of the apparatus of Fig. 3;

Fig. 5 is a transverse cross-sectional view taken through 5-5 of the distal end of Fig. 4;

Fig. 6 is a more detailed elevational view of the distal end of the apparatus of Fig. 3;

Fig. 7 is a plan view of another embodiment embodying the apparatus of the present invention;

Fig. 8 is a longitudinal cross-sectional view of the distal end of the apparatus Fig. 7;

Fig. 9 is a transverse cross-sectional view taken through 9-9 of the distal end of Fig. 8;

Fig. 10 is a more detailed elevational view of the distal end of the apparatus of Fig. 7;

Fig. 11 is a longitudinal cross-sectional view of another embodiment of the distal end of an apparatus embodying the present invention;

Fig. 12 is a transverse cross-sectional view taken through 11-11 of the apparatus of Fig. 11;

Fig. 13 is a transverse cross-sectional view of another embodiment of the distal end of an apparatus embodying the present invention;

Fig. 14 is longitudinal cross-sectional view of another embodiment embodying the present invention.

Fig. 15 is a plan view of an embodiment of a thermocouple carrier that may be used in the present invention;

Fig. 16 is a longitudinal cross-sectional view of an alternative embodiment of a thermocouple carrier that may be used in the present invention;

Fig. 17 is a transverse cross-sectional view, taken through 17-17 of the thermocouple carrier of Fig. 16;

Fig. 18 is a plan view of another embodiment of the apparatus embodying the present invention;

Fig. 19 is a longitudinal cross-sectional view of the apparatus of Fig. 18;

Fig. 20 is a cross-sectional view of the apparatus of Fig. 18 taken along 20-20;

Fig. 21 is a cross-sectional view of the apparatus of Fig. 19 taken along 21-21;

Fig. 22 is a plan view of the distal tip of the apparatus embodying the present invention with a distal end cap;

Fig. 23 is a longitudinal cross-sectional view of the distal tip of Fig. 22;

Fig. 24 is a cross-sectional view of the distal tip of Fig. 23 taken along 24-24;

Fig. 25 is a plan view of an alternative distal tip of the apparatus embodying the present invention;

Fig. 26 is a longitudinal cross-sectional view of the tip of Fig. 25;

Fig. 27 is a cross-sectional view of the tip in Fig. 26 taken along 27-27;

Fig. 28 is a cross-sectional view of an alternative embodiment of the apparatus embodying the present invention;

Fig. 29 is a cross-sectional view of another alternative embodiment of the apparatus embodying the present invention;

Fig. 30 is a cross-sectional view of another alternative embodiment of the apparatus embodying the present invention; and

Fig. 31 is a cross-sectional view of another alternative embodiment of the apparatus embodying the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Turning now to the drawings, Fig. 1 shows a distal end portion of an elongated catheter 10, as it may be used in accordance with the present invention, disposed within a human heart 12. More particularly, the distal end portion includes a catheter probe 14 in contact with a selected area of heart tissue. Herein, the term "probe" refers to an apparatus located at the distal end portion of the catheter that includes the thermocouple elements of different electromotive potential, as described in more detail below. As used herein, the term "catheter" is intended to refer to the entire catheter apparatus from proximal to distal ends, and including the "probe."

The probe 14 employed in the catheter 10 incorporates a thermocouple generally of the type described in U.S. Patent No. 4,860,744. As set forth in that patent, such thermocouples may comprise two elements or "legs" of differing materials having a large difference in electromotive potential (i.e., different Seebeck coefficients). The difference in electromotive potential between the two elements or "legs" is achieved by doping the elements to produce either positive (P-type) or negative (N-type) elements. The two elements are conductively joined at one end to form a junction. When current flows through the elements, one end of each thermocouple element is cooled while the other end of each thermocouple element is heated. The direction of the current determines which end is cooled and which is heated. This phenomenon is known as the Peltier effect. A detailed description of the Peltier effect and a probe 14 (shown in Fig. 2) utilizing the Peltier effect is set forth in U.S. Patent No. 4,860,744 titled "Thermoelectrically Controlled Heat Medical Catheter" which is incorporated by reference herein.

As described in U.S. Patent No. 4,860,744 and generally shown in Fig. 2 of the present application, probe 14 utilizes a single thermocouple design sometimes referred to as a

unicouple. The unicouple utilizes one pair of P and N thermocouple elements or legs. The P leg 16 and N leg 18 are electrically separated along their lengths, but are conductively joined at one end. These ends of the thermocouple are referred to as junctions 24, 24'. The P and N legs 16, 18 are separately connected to connector wires 20, 20' through which electrical current is fed. In general, thermoelectric heating of junctions 24, 24' occurs when an electrical current is passed through the couple in the P to N direction. When the direction of the current is reversed, by reversing the voltage, the tip of probe 14 is cooled in accordance with the above-described Peltier effect.

It should be noted that the above-identified patent is particularly directed to the use of the Peltier effect for heating a probe tip to melt or vaporize deposits in a patient's body such as atheromatous plaque -- an application very different from that claimed herein.

One embodiment of the apparatus of the present invention is shown in Fig. 3. More particularly, Fig. 3 shows a catheter 40 for cardiac-related procedures such as identifying or evaluating the electrical activity of the heart (by, for example, mapping), identifying an electrophysiological source of heart arrhythmia and/or treating heart arrhythmia.

Catheter 40 comprises an elongated hollow tube constructed of any suitable, biocompatible material. The material used for the catheter should be flexible so that the catheter may be easily guided through the vascular system of the patient. An example of such a material is polyurethane. Braiding or other stiffening material may be used in accordance with known techniques, as desired, to allow improved control of the catheter or to permit insertion of the catheter without the use of a guiding device.

As shown in Fig. 3, catheter 40 includes a proximal end portion 42 and a distal end portion 43. Distal end portion 43

of catheter 40 includes a probe portion or "probe" 44 for contacting the heart tissue. To assist in the positioning of the probe 44 within the interior of the heart, a steering wire 46 may be provided, which extends through the catheter 40 essentially between distal end portion 43 (at or near the probe) and a slidable hub 48 located near or within the proximal portion 42. As seen in Fig. 3, sliding hub 48 causes the distal end portion 43 (and the probe 44) of catheter 40 to bend. This may assist in guiding the probe to the desired location and bringing the probe 44 into contact with the surface of the heart tissue. Once the probe 44 has been positioned at or near the desired location of the heart tissue, the electrical activity of the heart may be identified, evaluated or mapped, and electrophysiological sources of arrhythmia may be identified and/or treated.

As shown in Figs. 4 and 6, probe 44 includes a thermocouple carrier 47, for retaining and supporting the heating and cooling elements described below. In general, thermocouple carrier comprises a molded body, approximately 10mm in length, for supporting thermocouple elements or "legs" 48 and 50. The thermocouple carrier should be made of a rigid material that is relatively easy to machine and/or mold. Furthermore, the material used for the thermocouple carrier should have low thermal conductivity and low electrical conductivity. One such suitable material is a polyether ether ketone (PEEK).

The thermocouple carrier 47 of Figs. 4 and 6 is shown without thermocouple elements 48 and 50 in Figs. 16 and 17. As seen in Fig. 16, thermocouple carrier 47 is generally cylindrical and includes distal bore 47a, proximal bore 47b and recessed area 49 between the bores for receiving thermocouple elements 48 and 50. A groove 51 below recessed area 49 forms an off-center passageway, which provides a conduit for the different wires and sensors used in the probe. (These wires and sensors are described in more detail below.) Wall portion 53 separates and insulates groove 51 (and the

wires that typically extend therethrough) from recessed area 49 (and the thermocouple elements typically disposed therein). An opening 53a in wall portion provides a conduit (for a temperature sensor described below) between recessed area 49 and groove 51. The location of the wires within the thermocouple carrier 47 relative to the thermocouple elements is more clearly seen in Fig. 4.

As shown in Fig. 4, thermocouple elements or legs 48 and 50 are positioned within thermocouple carrier 47 in a longitudinally extending end-to-end arrangement (i.e. the thermocouple element 50 being positioned in a more distal location relative to the other thermocouple element 48). Both of the thermocouple elements 48 and 50 are connected at their ends to a power supply (as generally shown in Fig. 1) via connecting wires 52 and 54 for applying a voltage and inducing current through the thermocouple elements 48 and 50. Typically, connecting wires 52 and 54 are soldered to the thermocouple elements 48 and 50, although other attachment means also may be used. The other ends of thermocouple elements 48 and 50 are joined to form a junction 56 which may be cooled or heated depending on the direction of the current and in accordance with the above-described Peltier effect. As shown in Figs. 4 and 6, in the preferred embodiment, junction 56 is spaced from the very tip of probe 44. Placement of junction 56 at a location spaced from the probe tip (i.e., on the "side" of probe 44) makes it easier to position and maintain the probe in contact with the pulsating heart.

Thermoelectric cooling of the junction 56, occurs when an electrical current is passed from a power supply through wires 52 and 54 to thermocouple elements 48 and 50. When the direction of the current is reversed by reversing the voltage in the power supply, the junction 56 is heated. Thus, by controlling the voltage of the power supply and the current through thermocouple elements, one can effectively and quickly control and adjust the temperature of junction 56.

As cooling or heating of junction 56 is achieved by introducing a current through the thermocouple elements 48 and 50 in a specific direction, it is desirable that the thermocouple elements be made of a material that can be quickly and efficiently cooled and/or heated. Although several different materials may be used, preferably the thermocouple elements are made of alloys including Bismuth-Telluride (Bi-Te). The thermocouple elements may include other materials or be appropriately doped (as described in U.S. Patent No. 4,860,744) to produce a P-type element and an N-type element. For example, in the present invention, the p-type element may include 72% Antimony Telluride (Sb_2Te_3), 25% Bismuth Telluride (Bi_2Te_3) and 3% Antimony Selenide (Sb_2Se_3) doped with excess Tellurium (Te). The n-type element may include 90% (Bi_2Te_3), 5% (Sb_2Se_3) and 5% (Sb_2Te_3) doped with Antimony Triodide (Sb I_3).

The wires that connect the thermocouple elements 48 and 50 to the power supply should be flexible, having a low electrical resistance and a large surface area for heat transport such as, for example, a Litz wire available from Kerrigan Lewis Manufacturing Co. of Chicago, IL (part or product no. 210/48). Junction 56 is preferably formed by soldering the ends of thermocouple elements 48 and 50 with an organic biocompatible solder that has a high melting point, high thermal conductivity and has a high degree of electrical conductivity. An example of such an organic solder is part or product no. 5N60PB4066 available from Kester Solder Co. of Des Plaines, IL.

Gaps between the ends of elements 48 and 50 and the carrier are preferably filled with a thermally conductive epoxy 57. The epoxy 57 may be finished to provide a smooth exterior surface for the probe. The epoxy also assists in drawing heat from the hot ends of the thermocouple elements, thereby assisting in maintaining the cool ends of the thermocouple elements at the desired temperature. One such epoxy believed to be suitable is Oxy Cast made by Resin

Technology of Easton, Massachusetts.

Precise temperature control of the junction 56 may be achieved by precalibration of the power supply so that the temperature achieved by a given current flow is accurately known. Alternatively, the temperature of the junction 56 may be actually monitored. Various devices for monitoring the temperature of junction 56 may be used without departing from the present invention. In the illustrated embodiment the temperature of junction 56 may be measured and monitored by a temperature sensor 58 which is embedded in the solder junction 56. Temperature sensor 58 extends from junction 56, through opening 53a, groove 51 and proximal bore 47b of thermocouple carrier 47, through the body of catheter 40 and is attached to a standard temperature monitoring display (not shown). In this embodiment, the temperature sensor 58 may be made of an iron/constantan material that is teflon insulated and has a diameter of about 1.1mm (0.005 inches). The length of temperature sensor will naturally depend on the length of the probe and catheter. Such a sensor is available from OMEGA Engineering of Stanford, CN and sold as product or part no. 5SC-TT-J-36-72. Alternatively, a thermocouple thermometer may be used to monitor the temperature of the junction. Still other means for monitoring the temperature of the probe 40 are set forth in U.S. Patent No. 4,860,744, and in U.S. Patent No. 5,122,137, assigned to Boston Scientific and also incorporated by reference.

In addition, as shown in Figs. 4 and 6, probe 44 also includes spaced electrodes 62 and 64 for monitoring the electrical signals in the heart tissue. By monitoring the electrical signals in the heart, the electrodes assist in identifying the location of the heart arrhythmia or damaged heart tissue. The distal electrode 62, shown in Figs. 4 and 5, is located at the tip of the probe 44. Distal electrode may be made of stainless steel (such as SS316) or any other suitable electrically conductive and biocompatible material. Proximal electrode 64, shown in Figs. 4 and 6, is

approximately 1.5 mm in length and is also made of an electrically conductive and biocompatible material. Distal and proximal electrodes 62 and 64 are preferably spaced equal distances from junction 56.

As shown in Fig. 4, distal electrode 62 is connected to a monitoring device 37 (as generally depicted in Fig. 1) such as an ECG by wire 65 which is soldered or otherwise connected to the distal electrode 62 and extends through passageway 49 of thermocouple carrier 47. Proximal electrode 64 is also connected by a soldered wire (not shown) to a monitoring device 37. The wires that connect the distal and proximal electrodes to the monitoring device 37 should be of a flexible material having a small diameter and a low electrical resistance. A wire believed to be suitable in this and the other embodiments described herein is a copper wire, 36 AWG with polyamide insulation, available from Mid-West Wire Specialties Co. of Chicago, IL.

Turning now to Fig. 7, another embodiment of the apparatus of the present invention is shown. In particular, Fig. 7 shows an apparatus such as catheter 66 which may be used for cardiac-related procedures such as evaluating (by, for example, mapping) the electrical activity of the heart, identifying the source of heart arrhythmia and/or treating heart arrhythmia. Catheter 66 has a hollow body portion and is made of a suitable, flexible, biocompatible material such as polyurethane. As seen in Fig. 7, catheter 66 includes a proximal portion 67 and a distal end portion 68. Distal end portion 68 includes a probe portion or "probe" 69 for contacting the heart tissue. Directional control of the probe may be achieved by steering wire 70 in the manner previously described.

A general view of the probe 69 is seen in Fig. 10 and a more detailed cross-sectional view of probe 69 is shown in Fig. 8. As seen in Fig. 8, thermocouple elements or legs 72 and 74 are arranged on thermocouple carrier 76 in a parallel

or "side-by-side" arrangement. A more detailed view of thermocouple carrier 76 is shown in Fig. 15. As seen in Fig. 15, thermocouple carrier 76 includes a hollow body portion 76a and two thin, elongated, spaced apart support members 76b and 76c extending between and supporting the thermocouple elements 72 and 74 in a spaced apart relationship. Referring back to Fig. 8, wires 78 and 80 are connected (as by soldering) to the proximal ends of thermocouple elements 72 and 74 and extend through the hollow body portion 76a of thermocouple carrier 76 and through the body of the probe 69 and catheter 66 (as seen in Fig. 8) to a power supply (shown generally in Fig. 1). The distal ends of thermocouple elements 72 and 74 are soldered to distal electrode 82 to form a "junction" between the elements of the thermocouple. In this manner, distal electrode/junction 82 may be cooled or heated by applying a voltage across the thermocouple elements 72 and 74 to induce an electrical current through thermocouple elements 72 and 74.

As described above in connection with the earlier embodiment, thermocouple elements 72 and 74 should be made of a material that can be quickly and efficiently cooled (e.g. Bi-Te). In addition, thermocouple elements may include other materials or be appropriately doped to provide a P-type element and an N-type element as discussed above in connection with the embodiment of Figs. 3-6. Wires 78 and 80 should be flexible, have a low electrical resistance and a large surface area for heat transport such as, for example, the above-described Litz wire.

A thermoconductive epoxy 83 of the type described above may be used to fill the gaps between the proximal ends of the thermocouple elements 72, 74 and body portion 76a of thermocouple carrier to form a smooth continuous outer surface of probe 69. In addition, epoxy 83 draws heat from the ends of the thermocouple elements and, thereby, assists in keeping the other ends of elements 72 and 74 cool.

Referring still to Fig. 8, a temperature sensor 84

extends through the body of catheter 66 and through probe 69 between thermocouple elements 72 and 74, where it is preferably embedded in the solder used to conductively connect the thermocouple elements 72 and 74 to the distal electrode 82.

In addition to distal electrode/junction 82, probe 69 also includes a proximal electrode 86. Like distal electrode 82, the proximal electrode assists in locating the diseased heart tissue. The proximal electrode can also serve as a backup for the distal electrode/junction 82 if, for example, the electrode function of the distal electrode/junction 82 is adversely affected by the conductivity of the attached thermocouple elements. Finally, proximal electrode 86 may be used to ground the system.

Distal electrode/junction 82 and proximal electrode 86 are connected to a monitor, such as an ECG, (shown in Fig. 1) which records the amplitudes of the electrical signals detected by the electrodes 82 and 86. More specifically, proximal electrode 86 is connected to the monitor via wire 88. Distal electrode/junction 82 transmits electrical signals through wires 78 and/or 80 to the monitor via a switching device (not shown) for establishing an electrical connection between wires 78 and/or 80 and the monitoring device. Alternatively, wires 78 and/or 80 may be detached from the power supply and connected to the monitoring device. As in the earlier embodiment, electrodes 82 and 86 should be of an electrically conductive and biocompatible material. In the present embodiment, for example, distal electrode 82 comprises a silver cap. Wire 88 should be flexible, have a small diameter and have a low resistance.

Still another embodiment of the present invention and, in particular of, a probe is shown in Figs. 11-12. As seen, for example, in Fig. 11, probe 90 includes two sets of thermocouple elements and utilizes a "two stage cooling process." More specifically, probe 90 includes a primary set

of two thermocouple elements 92 and 94 (i.e. located near the distal tip of probe 90) and a secondary set of two thermocouple elements 96 and 98 spaced from elements 92 and 94. Both sets of thermocouple elements are supported by thermocouple carrier 100 similar to the thermocouple carrier shown in Fig. 8. The thermocouple elements are made of the same material as the elements described above and/or may be doped or otherwise combined with other materials to provide P-type and N-type elements.

A thermoconductive epoxy 102 may be used to fill the gaps between the primary and secondary sets of thermocouple elements and the thermocouple elements and carrier 100. As described above in connection with the other embodiments, epoxy 102 also draws heat from the proximal ends of thermocouple elements 92 and 94 to allow for greater cooling capacity at probe tip. As in the above-described embodiments, the thermocouple elements are connected to a power supply (not shown) via wires 104, 106, 108 and 110 for introducing electrical current to the thermocouple elements. Wires 104, 106, 108 and 110 are preferably Litz wires of the type described above, but can also be any flexible wire having a low electrical resistance and a large surface area for heat transport. Probe 90 also includes a distal electrode (and junction) 112 and a proximal electrode (not shown). As described above the electrodes are connected to a monitor which records the amplitudes of the electrical signals of the heart tissue.

Cooling of the probe 90 occurs at the distal electrode/junction 112 which is electrically connected (soldered) to thermocouple elements 92 and 94. The secondary set of thermocouple elements 96 and 98 are also conductively connected to form junction 112a. When cooling of the probe is desired, the distal ends of thermocouple elements 92, 94, 96 and 98 and more specifically, junctions 112 and 112a are cooled while the proximal ends of legs 92 and 94 and legs 96 and 98 are heated. Because some heat transfer from the

proximal ends of legs 92 and 94 to the distal ends of legs 92 and 94 may occur, complete cooling of distal electrode/junction 112 may not be attained. Accordingly, the cooled junction 112a of the second set extracts heat from the proximal ends of the first set to provide greater cooling capacity at the distal ends of legs 92 and 94. Alternatively, and by the same principle, if the current is reversed, greater heat capacity can be obtained at the distal ends of legs 92 and 94, and, in particular, distal electrode/junction 112. A temperature sensor 114 of the type described above may also be used to monitor the temperature of distal electrode/junction 112. One end of temperature sensor is embedded in the solder used to connect thermocouple elements 92 and 94 to distal electrode/junction 112 and the other end to a temperature monitoring device.

Fig. 13 shows a cross-sectional view of another variant of the two-stage cooling probe similar to the embodiment shown in Figs. 11-12. In the embodiment of Fig. 13, the primary (distal) thermocouple comprises two thermocouple elements as described above. As seen in Fig. 13 which is a transverse cross-sectional view taken through the secondary set of thermocouple elements, the secondary (proximal) thermocouples comprise two sets of two thermocouple elements 113 a,b, c and d. Typically, these thermocouple elements are smaller in size than the thermocouples in the primary set. Element 113a is joined to element 113d at one junction (to form one thermocouple) and elements 113b and 113c are joined at a second junction (to form a second thermocouple). In all other respects, the probe of Fig. 13 is analogous to probe 90 of Figs. 11-12.

Finally, another embodiment of the present invention and, in particular, of a probe, is shown in Fig. 14. This particular embodiment, is essentially the same as described in connection with Figure 4, except that a heatable tip is provided for use in ablating or treating heart tissue. For example, in Fig. 14, thermocouple elements 116 and 118 are

arranged in an end-to-end arrangement within thermocouple carrier 120 with junction 122 formed between thermocouple elements 116 and 118. Elements 116 and 118 are connected, via wires 118b and 118a, to a power supply (shown generally in Fig. 1) for applying a voltage across the thermocouple elements and introducing a current through elements 116 and 118 to cool junction 122. The temperature of junction 122 is monitored by temperature sensor 124. If it is desired to ablate tissue by heating, however, the tip 126 of the probe is heated. As shown in Fig. 14, wire 128 for introducing radio frequency or other ablation energy extends from a power supply to the distal tip 126. In all other respects, the materials used are similar to the materials and method set forth above.

Turning now to the methods of using the foregoing apparatus in carrying out procedures related to the electrophysiology of the heart, such as evaluating (by mapping) the electrical activity of the heart, identifying the electrophysiological source of cardiac arrhythmia and treating the arrhythmia, the catheter (10, 40, 66) is introduced into a patient percutaneously and advanced into proximity with the desired section of the heart 12 (Fig. 1). The present invention is not limited to the means by which the catheter is advanced through the vascular system of the patient. For example, the catheter may be advanced through a guiding or positioning catheter or sheath, or over a guide wire. For in-the-heart procedures a guiding or positioning catheter may be preferred over a guide wire. In addition to known apparatus and techniques for advancing the catheter through the vascular system of patients, a novel positioning catheter such as the one described in U.S. Serial No. 08/197,122 filed on February 16, 1994 and assigned to the assignee of the present application may also be used.

As described in more detail below, after the catheter has been sufficiently advanced into the vascular system of the patient, the probe (14, 44, 69, 90) is introduced into the heart interior and brought into contact with the desired

section of the heart tissue as generally shown in Fig. 1. More specifically, the junction (24, 56, 82, 112, 122) of the probe is brought into contact with the desired section of tissue. An electrical current is then passed through the thermocouple elements to reduce the temperature of the junction (in accordance with the Peltier effect) and thereby cool the contacted heart tissue. The effect of the cooling on the heart and specifically the effect on the electrical activity of the heart, if any, may be monitored.

The desired section of heart tissue contacted by the probe may be pre-selected by the physician or may be determined based on the presence or absence of electrical activity at that section as detected by the electrodes (62, 64, 82, 86) on the probe and displayed on the ECG 37 or other device.

In accordance with a further aspect of the present invention, the location of the electrical activity in the desired section may be accurately determined.

For example, in the embodiment of Figures 3-6, the junction 56 is midway between the electrodes 62 and 64. If the amplitudes of the signals received and transmitted by electrodes 62 and 64 are not substantially equal, this is an indication the sensed electrical activity is not located between the two electrodes. In that case, the probe may be repositioned until the signals are of approximately equal amplitude. Equal amplitudes for the signals being received by the proximal and distal electrodes 64, 62 indicates (to the physician) that the desired section of tissue is located at equal distances between the two electrodes 62 and 64 and, ideally, opposite the location of junction 56 (which, as described above, is also located at equal distances between electrodes 62 and 64). If desired, additional electrodes may also be used to monitor the electrical activity of the heart.

After the junction is placed at the desired section of

heart tissue, cooling is achieved by establishing a voltage across the thermocouple elements so as to cause a flow of electric current through the thermocouple elements in order to cool the junction. The temperature of the junction is determined by the directional flow of current (P to N or N to P) as described in U.S. Patent No. 4,860,744 which has been incorporated by reference. With the junction in contact with the heart tissue, the effect of such cooling on the electrophysiology of the heart, can be observed on the monitoring device 37 (Fig.1) connected to electrodes.

In the present invention, the junction preferably is cooled to a temperature necessary to affect the electrical activity of the heart at the particular section of tissue without permanently damaging the heart tissue. It is preferred, however, that the junction be cooled to a temperature between approximately -50°C and 37°C, although any cooling below 27°C is generally adequate to affect the rate of conduction. For example, the probe may be cooled to between approximately -15°-32°C. In fact, it has been shown that cooling the heart tissue by at least 10°C can be sufficient to affect and/or suppress the electrical activity of the heart tissue. Whatever the temperature of the probe junction, it is desirable that the temperature of the contacted heart tissue not be lowered below 6°C and be maintained between approximately 6°-27°C or 10°-20°C.

Once the junction has been cooled to its desired temperature, contact between the junction and the heart tissue is maintained for, in general, between about 1 second and 15 minutes, depending on the temperature of the junction and the likely depth of the source of the electrical activity within the heart tissue. Electrophysiological changes will also depend on where in the heart the signal is monitored. The contact time will generally be less when the probe and, more specifically, the junction is particularly cold, for example, 20°C or less and/or when the suspected electrical focus is at a shallow depth within the heart tissue. On the other hand,

when the junction is not cooled below about 27°C, the contact time may require several minutes to affect the electrical signal foci that are at a significant depth within the tissue. In either case, the junction is preferably cooled only to the extent necessary to affect the electrical activity without resulting in permanent damage to the heart tissue. A significant benefit of the present invention is that it allows the physician precise and immediate control over the temperature of the probe tip, thereby reducing the risk of unnecessary damage to the heart tissue.

The particular steps which follow the steps described above will vary, depending on the objective of the procedure. If the objective of the procedure is to identify or "map" the electrical activity of the heart, then the probe may be repositioned at different locations of the heart and the above steps of contacting a section of heart tissue with the junction of the probe and cooling the junction and monitoring are repeated.

If the objective of the procedure is to identify the electrophysiological source of heart arrhythmia, the above steps may also be carried out until the source of the arrhythmia is located. If upon cooling of the junction, it is determined that the electrophysiological source of arrhythmia has not been located, the heart tissue may be returned to its normal temperature by terminating the flow of current and allowing the tissue to warm on its own or, for example, by reversing the current (in accordance with the Peltier effect) and warming the heart tissue with the probe. The probe may then be repositioned and the steps of contacting and cooling repeated at the new location.

If the source of the arrhythmia is located and the objective of the procedure is to treat the heart arrhythmia, then the probe may be further cooled or otherwise energized or heated (at, for example, the junction 24, 56, 82, 112 or the tip 126 in Fig. 14). More specifically, the probe is further

cooled, energized or heated to treat or ablate the section of heart tissue believed to be the source of the arrhythmia so as to permanently interrupt the aberrant electrical signal.

The precise temperature control provided by the apparatus described above is particularly advantageous in diagnosing and treating arrhythmia. For example, if during cooling of the junction, it is determined that the arrhythmic signal has not been located, cooling of the junction may be quickly terminated by, for example, terminating the flow of current or reversing the flow of current so as to heat the junction. On the other hand, if it is determined that the arrhythmic signal has, in fact, been located, the probe (and specifically the junction) may be immediately energized by, preferably, radio frequency (RF) energy. The radio frequency energy may be introduced from the same power supply used to introduce the Peltier heating but modified to also generate RF waves. Alternatively, a separate power supply for specifically generating the RF waves may be used. Regardless of the source, RF waves are transmitted through wires (e.g. 52 and 54 in Fig. 4 which may be connected to a different power supply) to the thermocouple elements to ablate the contacted tissue. Alternatively, further Peltier cooling or heating, electrical heating, or microwave energy may be used to ablate or otherwise treat the section of tissue at the source of the arrhythmia. For effective ablation, it is preferred that the energized junction (or tip 126 of Fig. 14) be kept in contact with the heart tissue for between about 1 second and 15 minutes to permanently effect treatment.

As set forth above, the present invention includes alternative embodiments wherein the Peltier effect is used to cool the probe junction and energy such as radio frequency (RF) waves or microwave energy may be applied to the junction from a separate energy source for ablation. In these embodiments, application of current in accordance with the Peltier effect cools the probe junction and allows the probe to be used for "mapping" the electrophysiology of the heart in

the manner described above. During ablation (by supplying energy to the junction from a separate energy source), application of current in accordance with the Peltier effect may be continued so as to cool the junction or, more specifically, assist in controlling the temperature of the junction during ablation. Such embodiments are discussed in more detail below. In discussing these embodiments, it should be understood that unless indicated otherwise, the components, materials, dimensions and methods of operation of the catheter and probe are the same or similar to components, materials, dimensions and methods of operation described above.

One such embodiment is shown in Figs. 18-21. As shown in detail in Fig. 19, probe 200 includes a carrier 202 attached to the polyurethane body 204 of the catheter. Thermocouple (Peltier) elements 206 and 208 are soldered together to form junction 210 at the distal tip of the probe. The proximal ends of thermocouple elements 206 and 208 are electrically and thermally conductively connected, as by soldering, to heat sinks 212. Heat sinks are connected to wires 214 at their proximal ends. Wires 214 are in turn connected to a power supply (not shown) for introducing current to the probe in accordance with the Peltier effect.

Junction 210 is separately connected to an energy source such as a radio frequency ("RF") energy generator or microwave energy source via wire(s) 216. Also, junction 210 may be connected to a temperature sensor 218 which extends through probe 200 and catheter body 204 to a monitoring device for monitoring the temperature of the junction 210. (As in all embodiments of the present application, it is preferred that the various connecting wires be insulated to contain the electrical current and reduce the amount of heat generated in the vicinity of the thermocouple elements (which may compromise the cooling ability of the elements).

As in the earlier described embodiments, a thermally conductive epoxy 224 can be used to fill in the gaps within

the carrier 202. Also, any of the embodiments described herein may include a electrically insulative polymer jacket or coating (not shown) to cover the probe. The polymer jacket insulates the components within the probe, protects the patient from exposure to solders that may contain heavy metals or are otherwise not biocompatible and assists in keeping the components of the probe in place. The polymer jacket may be a thin layer of polyester heat shrink tubing or a thin coating of another electrically insulating polymeric or other material such as epoxy.

Electrodes in the form of pole rings 220 and 221 are spaced along probe 200 for monitoring the electrical activity of the heart. Each pole ring 220 is connected to a separate wire 222 which is connected to the pole ring through an opening 223 adjacent to polering in the carrier and an opening in the polymer jacket. Wire(s) 222 extends through the probe and catheter body to an ECG device which is used to monitor, display and record the activity of the heart. As shown in Fig. 19, the pole rings may be disposed on the outer surface of the probe (220) or may be disposed within a recessed annular groove in the probe and/or catheter body (221). If the pole rings 220 and/or 221 are located within a recessed annular groove, it is preferred that the pole rings not be recessed within the thermocouple elements 206 and 208. Cutting into the thermocouple elements to, for example, provide the annular groove for the pole rings reduces the surface area of the elements 206 and 208, may cause the current to find alternate paths to bypass the gap created by the annular groove which may provide less efficient cooling. Also, it should be understood that pole rings 220 and/or 221 are exposed for contacting heart tissue and are not encased by the polymer jacket 226. Proximal pole ring 221 may be used to ground the system.

Preferably, probe 200 includes at least 3 electrodes (pole rings 220 and 221 and junction 210), although probe 200 may include as many electrodes as necessary and as can be

accommodated by the probe. Additional pole rings or electrodes may be placed in other locations at or near the distal end portion of the catheter body. The pole rings are approximately 1.5 mm long and are spaced approximately 2 to 5 or 2 to 10 mm apart. The pole rings or electrodes 220 and/or 221 may be made of any biocompatible material that can conduct the electrical signals within the heart. However, it is preferred that the electrodes or pole rings be made of either stainless steel or platinum iridium. The pole rings or electrodes described above may be used in any of the embodiments described herein.

Like the secondary thermocouple elements shown, for example, in Fig. 11, heat sinks 212 extract heat from the thermocouple elements connected to junction 210. The heat sinks may be any size suitable for extracting heat from the thermocouple elements. However, it has been found that more effective and efficient extraction of heat is achieved when the heat sinks 212 are at least as large as the thermocouple elements. The width and thickness of heat sinks 212 should be the same as the width and thickness of thermocouple elements so that the heat from the thermocouple elements is efficiently extracted from the thermocouple elements. Additionally, a uniform width for the thermocouple elements and heat sinks creates a uniform catheter diameter. The heat sinks may be of any suitable length, although for more efficient heat extraction, the heat sinks should typically be as long or longer than the thermocouple elements to which they are attached or connected.

For example, where the thermocouple elements are four millimeters in length, it is preferred that the heat sinks be approximately eight millimeters (or approximately twice as long), as the thermocouple elements. However, the length of the thermocouple elements should not be so long as to compromise the flexibility of the probe and distal end portion of the catheter. Accordingly, it is preferred that the length of the heat sinks be as long as necessary to efficiently

extract heat from the Peltier elements without reducing the flexibility of the distal probe. The heat sinks 212 should be of a high thermally and electrically conductive material such as silver or gold.

By extracting heat from the thermocouple elements and, as a result, keeping the junction sufficiently cool during mapping, the heat sinks described above enhance the cooling provided by the thermocouple elements in a way that was previously unattainable using only thermocouple elements alone. In fact, it has been discovered that by connecting heat sinks to the thermocouple elements, the temperature at the junction along the distal tip of the probe can be further decreased (i.e. in addition to the cooling provided by the thermocouple elements) by approximately an additional 12-20° C.

In accordance with the present invention, the distal tip of the probe may be modified to provide additional surface area for contacting the heart tissue. The additional surface area allows for easier reading of the electrical signals generated within the heart tissue during mapping and allows for a greater area of the tissue to be treated during ablation. Providing a greater surface area for contact with the tissue means that precise placement of the probe tip relative to the tissue is less critical. For example, as shown in Figs. 22-24, the probe 200 and, more specifically, the distal tip of the probe may include a cap 230 that covers the junction 210 (when the junction is located at the distal end or distal tip) and extends over a portion of the thermocouple elements 206 and 208. Cap 230 may be made of any thermally and electrically conductive material such as silver and may be soldered to the distal tip of the probe.

Alternatively, the distal tip of the probe may be angled to provide for greater surface area (for the reasons described above) at the distal end portion. As shown in Figs. 25-27, the thermocouple elements are angled and a soldered junction

210 is formed across the angled tip. The soldered junction 210 may be bulbous or rounded as shown in Fig. 25, or substantially flat.

Another alternative embodiment of the probe is shown in Figs. 28-29. As in the embodiments shown in Figs. 4 and 14, the junction 210 is located along the "side" of the probe 200. As described in connection with Fig. 4, placement of the junction on the "side" of the probe (as shown in Figs. 28-31) makes it easier to position and maintain the probe in contact with the pulsating heart. Junction 210 is formed by soldering the ends of thermocouple elements 206 and 208. The other ends of thermocouple elements 206 and 208 are conductively connected to heat sinks 212. Heat sinks 212 are connected via wires 214 to an energy source that provides Peltier current. The thermocouple elements 206 and 208, junction 210 and heat sinks 212 are contained within the carrier 202 which is used to attach the probe to the catheter body 204. A thermoconductive epoxy 224 is attached to the catheter body 204. A thermoconductive epoxy 224 may be used to fill in gaps between the carrier and other parts of the probe 200.

In Fig. 29, junction 210 is connected to a temperature sensor wire 218 (for measuring the temperature of the junction) and wire 216 which is connected to a separate energy source to provide RF, microwave or other energy to the junction for ablation. Thus, in the embodiment of Fig. 29, cooling and heating (for ablating) occur at junction 210 and heat sinks 212 extract heat from the ends of thermocouple elements 206 and 208 nearest the heat sinks in the manner described above.

In Fig. 28, junction 210 is used for cooling only and heating for ablation occurs at the distal cap 226. Distal cap 226 (which can be made of any conductive and biocompatible material) is connected to wire 216 which is connected to a separate energy (RF, microwave etc.) source. In this embodiment, heat sinks 212 also extract heat from distal cap

226.

Still other embodiments of the probe 200 are shown in Figs. 30 and 31 wherein heat sinks 212 are located along the "sides" of thermocouple elements 206 and 208. As shown in Fig. 30, thermocouple elements 206 and 208 are soldered together at their ends to form junction 210. At their opposite ends, thermocouple elements 206 and 208 are connected to heat sinks 212 by wires 234. As shown in Fig. 30, heat sinks 212 are located alongside and parallel to thermocouple elements 206 and 208. Heat sinks 212 are connected by wires 214 to an energy source (not shown) for providing Peltier current to the heat sinks and thermocouple elements as described above.

Probe 200 shown in Fig. 30 also includes a distal electrode (cap) 226 which is connected to an ECG device via wire 236. In this embodiment and the embodiments of Figs. 28-29 and 31, additional electrodes (not shown) may be spaced along the probe or catheter body.

Thermocouple elements 206 and 208, junction 210 and heat sinks are located within carrier 204. Carrier 204 includes a passageway 238 for the wires described above to extend through probe 200.

Junction 200 is connected to a separate energy source via wire 216 and to a temperature sensor wire 218. Thus junction 200 shown in Fig. 30 may be cooled in accordance with the Peltier effect or heated (for ablation) by the separate energy source as described above. Heat sinks 212 assist in providing greater cooling at the junction and in controlling the temperature of the junction during ablation.

In contrast to the junction shown in Fig. 30, the junction shown in Fig. 31 is not connected to a separate energy source. In Fig. 31 (as in Fig. 28), distal electrode (cap) 226 is connected to a separate energy source via wire

236 and is used for ablation and some heat generated at distal electrode 226 is extracted by the distal most heat sink 212.

In all other respects, the probe shown in Figs. 31 operates in a manner identical to the probe of Figs. 30 described above.

As with the previously described embodiments, the probes shown in Figs. 18-31 may be used to map the electrophysiology of the heart and also treat the sources of electrophysiological disorders (e.g. arrythmia) by ablation. In accordance with the present method, application of a Peltier current from an energy source through the heat sinks 212 and thermocouple elements 206 and 208 cools junction 210. As described above, cooling of the junction 210 when it is in contact with the heart tissue causes changes in the electrical impulses travelling through the heart. This allows the operator to "map" the heart and determine the location of the electrophysiological disorder as described above. Once the source of the electrophysiological disorder has been located, energy from a separate source is applied to the junction 210 to energize the junction and, thereby, ablate the portion of the heart tissue responsible for the electrophysiological disorder. (It should also be understood that the ablation energy can also be provided by the thermocouple elements in accordance with the Peltier effect as described above.)

Whether it is radiofrequency, microwave or other type, the energy applied (and the resistance created at the point of contact between the junction and tissue) will cause an increase in the temperature at junction 210. While maximum power at the junction to provide for effective ablation (i.e. deep lesions) is desirable, excessive heating is to be avoided. Excessive heating of the junction and consequent warming of the heart tissue can produce formation of clots and cause the coagulation of blood at the point of contact between the junction and the tissue. Formation of blood clots and coagulation can, in turn, cause an electrical impedance which

impedes the flow of the ablation energy current and results in the generation of additional and undesirable heat at the distal tip. Generally, a rise in the impedance typically begins at temperatures of above 60° C. Thus, the heat generated at the junction point must be controlled without sacrificing the ability of the energy generated by the probe to penetrate the heart tissue and create, if necessary, deeper lesions.

The temperature of the junction may be controlled and an impedance rise prevented by reducing the energy applied to the junction by the RF, microwave or other energy source. Alternatively, the junction may be cooled by introducing saline solution into the catheter at the point of contact with the heart tissue. In accordance with the present invention, if the catheter probe includes secondary thermocouple elements or heat sinks as described above, the ablating junction temperature may be maintained within the desired range by extracting heat from the thermocouple elements connected to the junction.

More specifically, while the energy for ablation is continuously applied to the junction from, for example, a separate energy source, simultaneous cooling of the junction takes place by continuous introduction of current through the Peltier elements conductively connected to the junction. The Peltier current allows for cooling of the distal ends of the thermocouple elements and, thus, allows for cooling of the heated junction 210. As described above, as the distal ends of the Peltier elements are cooled, the proximal ends of the Peltier elements witness an increase in heat. The heat generated at the proximal ends of the thermocouple elements is extracted by heat sinks 212 (or secondary thermocouple elements as shown Fig. 11 and 13), thus keeping the thermocouple elements cool and, consequently junction 210 within a desired temperature range. Of course, the Peltier current can also be controlled to ensure that thermocouple elements are not cooled more than necessary.

The method and apparatus for cooling the junctions as used in the present invention provides a more efficient alternative to the more traditional methods and apparatus for regulating the temperature at the junction. For example, regulating the temperature of the junction by controlling the amount of ablation energy to the junction requires that the energy source be turned off when, because of the increased energy required for deep penetration of the tissue, the temperature of the junction approaches, more than, for example 60° C. This makes the entire ablation procedure more time consuming. Application of saline, while satisfactory for cooling the probe tip, is also less efficient because the temperature of the saline also rises as it travels through the catheter and, therefore, the saline is not as cool as desired when it reaches the distal probe tip. In addition, application of saline to the catheter requires high pressures to effectively flush the catheter with saline. The high pressure applied may cause the catheter to stiffen or even move and possibly displace the junction from its desired location. Systems where saline is introduced directly to the point of contact between the distal tip and tissue are also less desirable because addition of liquid to the heart should be avoided.

In sum, in accordance with the present invention, the Peltier effect may used for evaluating, such as by mapping, the electrical activity of heart, identifying the electrophysiological source of arrhythmia and, if desired, ablating a specific area of the heart tissue suspected of being responsible for the arrhythmia. Alternatively, the Peltier effect may be used for mapping and identifying the electrophysiological source of arrhythmia or other cardiac disorder and a separate energy source (e.g. RF, microwave) may be used to ablate or otherwise treat the heart tissue. This allows the physician to use the same probe for both identifying the source of arrhythmia and treating it, and permits mapping and ablating in one procedure without removing the catheter from the body of the patient.

Although the present invention has been described in terms of the preferred embodiment as well as other alternative embodiments, various modifications, some immediately apparent, and others apparent only after some study, may be made without departing from the present invention. The scope of the present invention is not to be limited by the detailed description of the preferred embodiment but, rather, is to be defined by the claims appended below.

CLAIMS:

1. Apparatus for use in cardiac procedures, said apparatus including an elongated body with a proximal end portion and a distal end portion, said distal end portion comprising:

at least two thermocouple elements located within said distal end portion, each of said thermocouple elements having a first end and a second end;

said thermocouple elements being conductively connected at said first ends at a junction;

a heat sink conductively connected to the second end of at least one thermocouple element;

whereby application of a voltage across said thermocouple elements in accordance with the Peltier effect and said heat sinks affect the temperature of said junction.

2. The apparatus of Claim 1 wherein said second ends of said thermocouple elements are conductively connected to said heat sinks.

3. The apparatus of Claim 1 wherein said junction is conductively connected to an energy source for heating said junction.

4. The apparatus of Claim 3 wherein said energy source provides radiofrequency energy to said junction.

5. The apparatus of Claim 1 comprising a distal end cap conductively connected to and disposed over said junction.

6. The apparatus of Claim 1 comprising at least two pole rings spaced along said distal end portion.

7. The apparatus of Claim 6 wherein pole rings are proximally spaced from said junction.

8. The apparatus of Claim 6 wherein one of said pole rings is distally spaced from said junction.

9. The apparatus of Claim 1 wherein said distal end portion comprises an angled distal tip.

10. The apparatus of Claim 1 further comprising a fixture for supporting said thermocouple elements and said heat sinks within said distal end portion.

11. A method for treating electrophysiological disorders in the heart comprising:

introducing an apparatus into the interior of the heart said apparatus having elements of different electromotive potential, said elements being conductively connected at a junction;

contacting the interior of the heart at a selected location with the junction;

passing an electrical current through said elements to reduce the temperature of the junction in accordance with the Peltier effect and thereby cool the contacted heart tissue without damaging the heart tissue;

monitoring for the effect of the cooling on the heart to determine whether the source of the arrhythmia has been located;

treating the heart tissue to substantially permanently interrupt said source of the electrophysiological disorder by introducing heat energy to said junction from a separate energy source and thereby ablate said source while continuing to pass electrical current in accordance with the Peltier effect through said elements.

12. The method of Claim 11 wherein the temperature of said junction does not exceed 60 C°.

13. The method of Claim 11 wherein the temperature of said junction prior to treating said heart tissue is between 6 and 15 C°.

FIG. 1

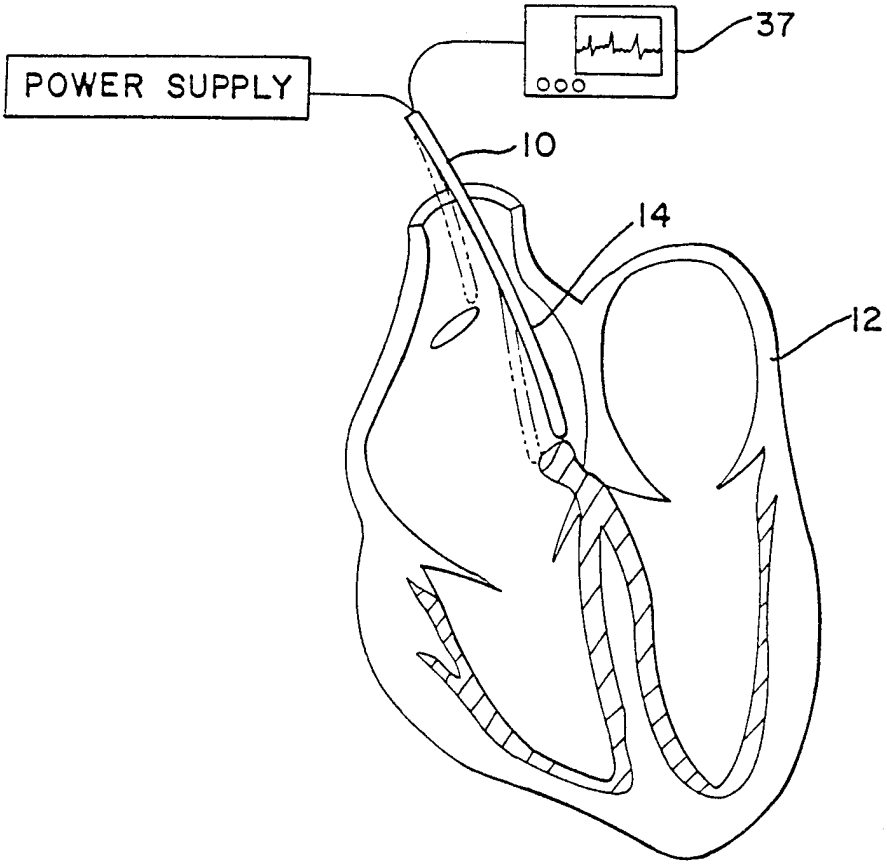


FIG. 2

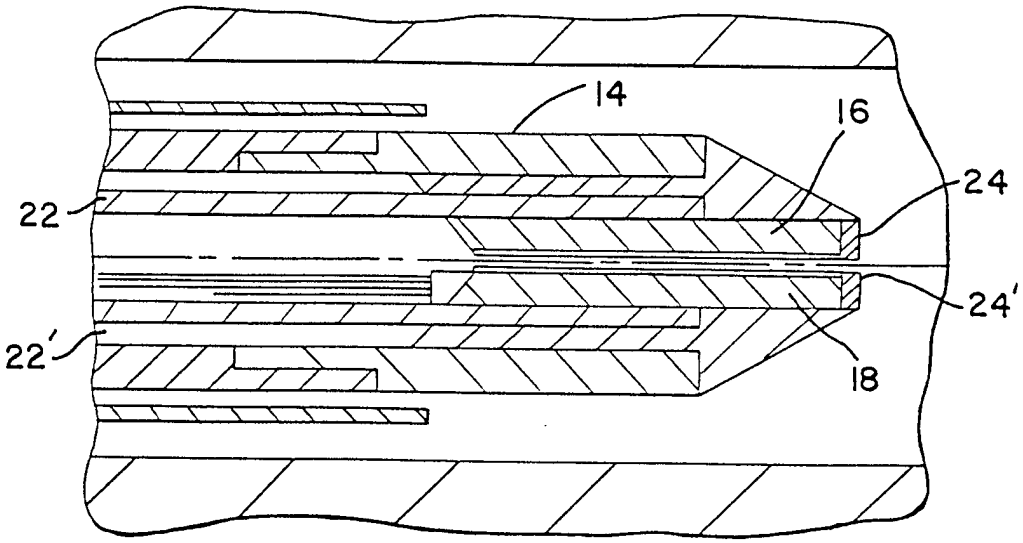
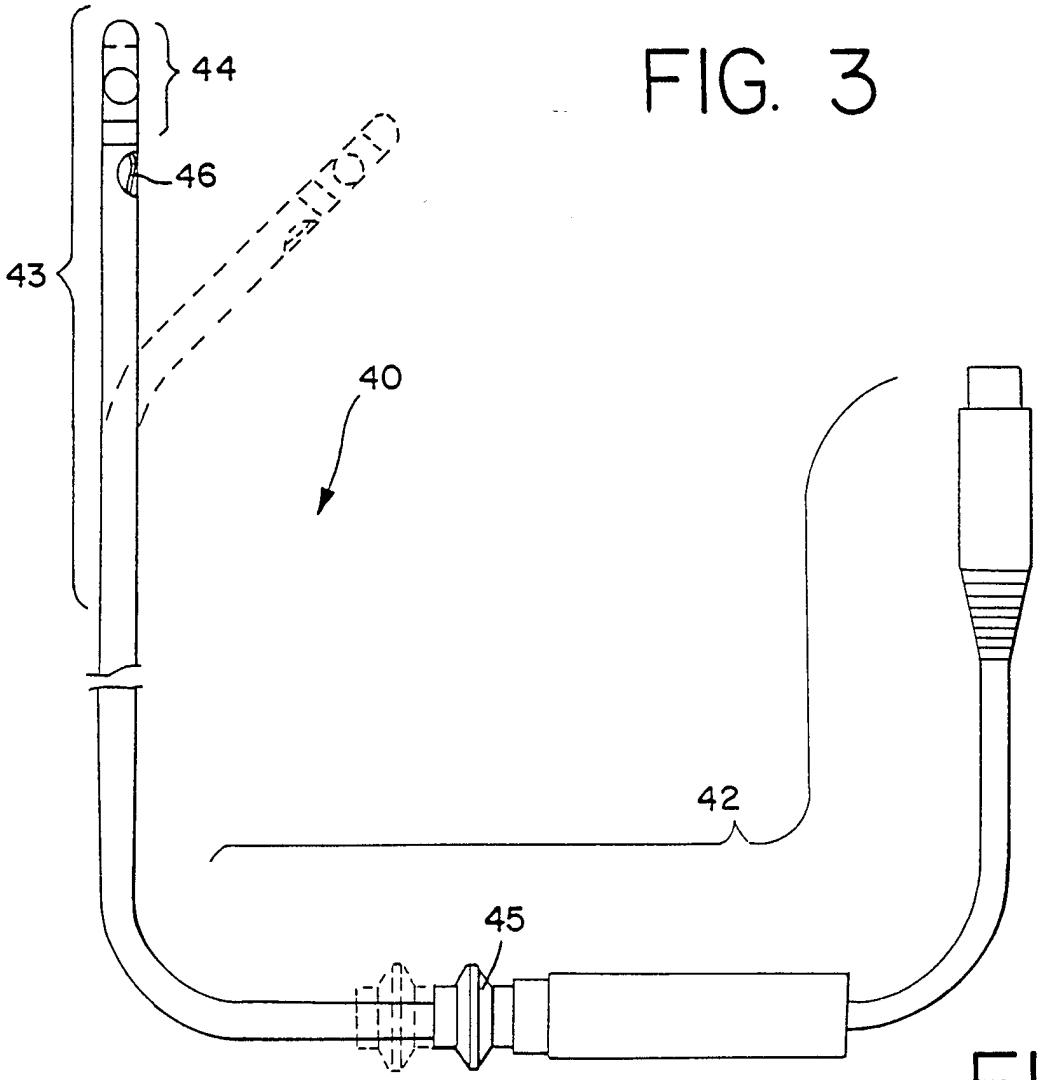


FIG. 3



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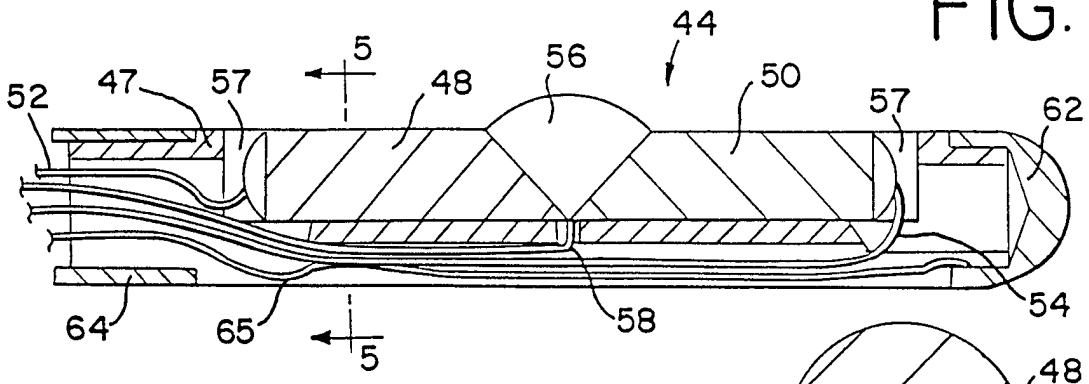
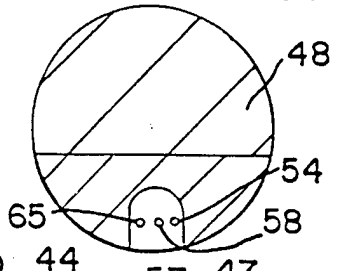


FIG. 5



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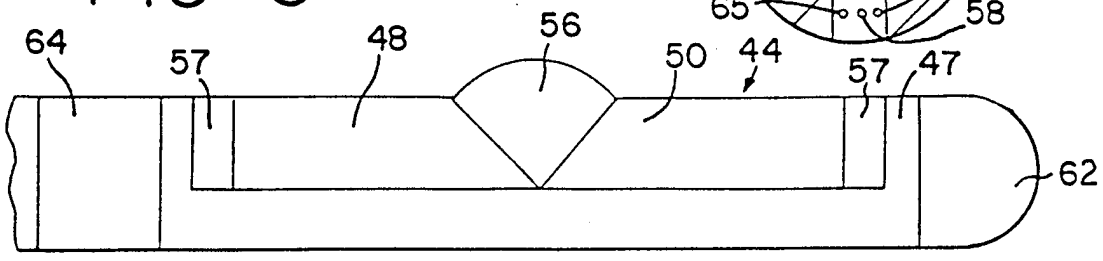


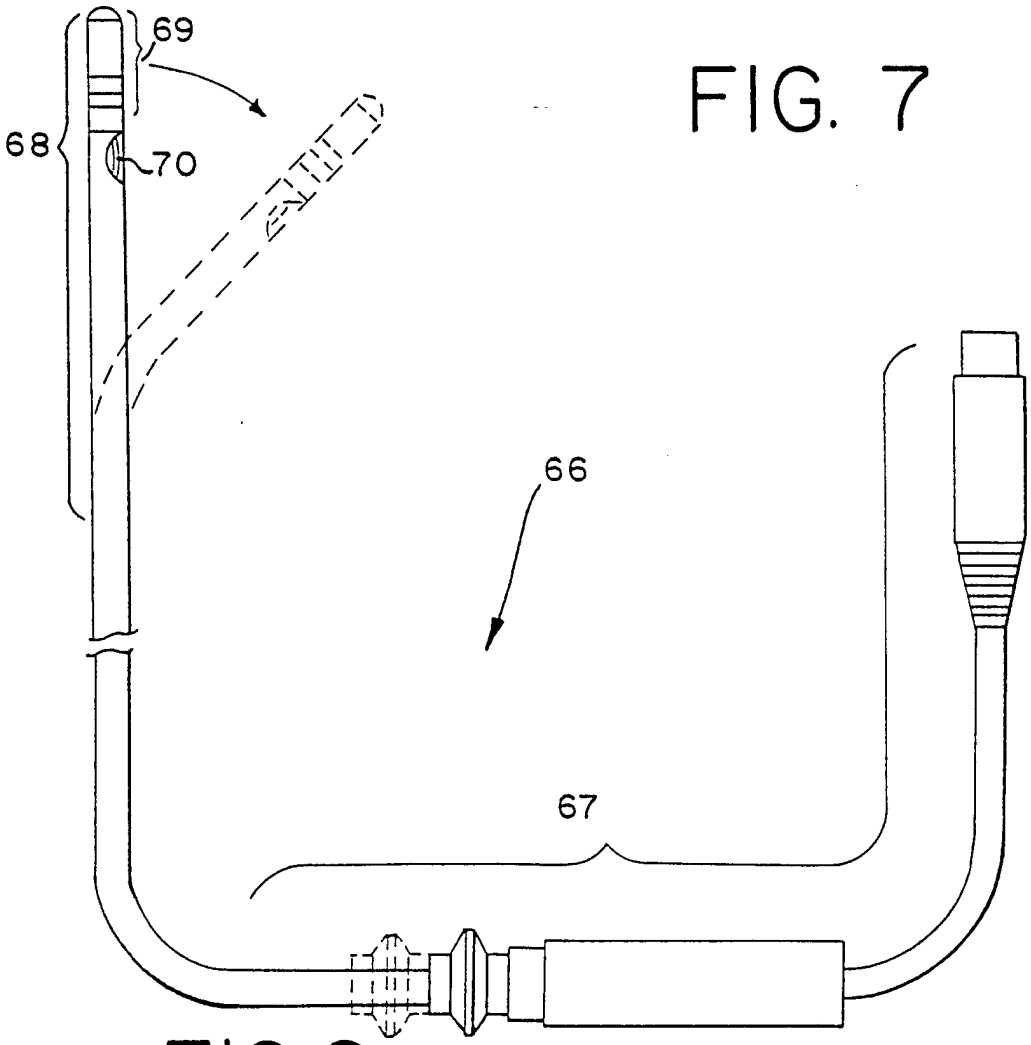


FIG. 7

FIG. 8

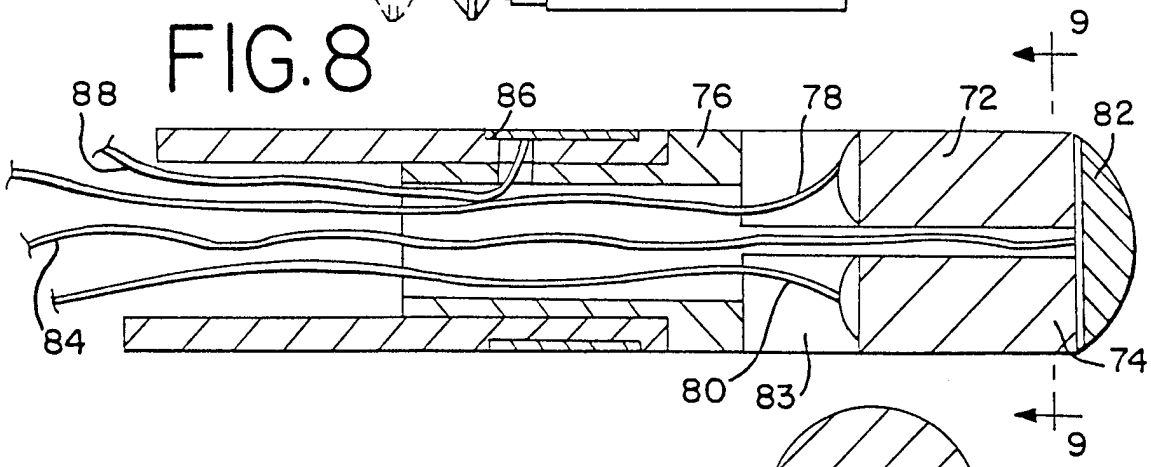
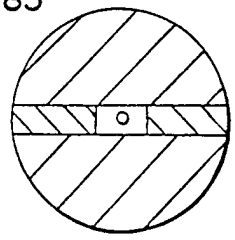


FIG. 10



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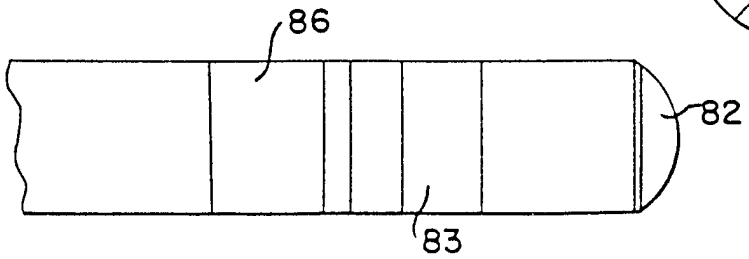

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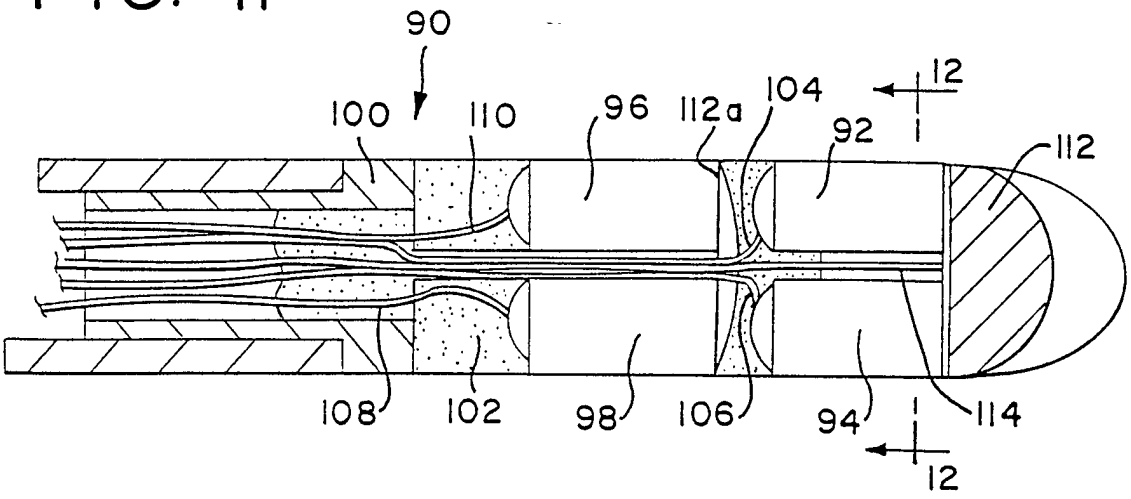

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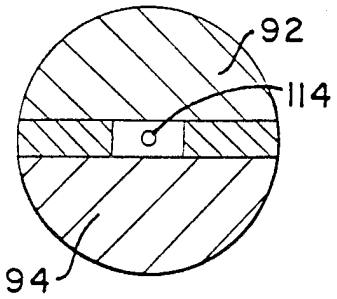

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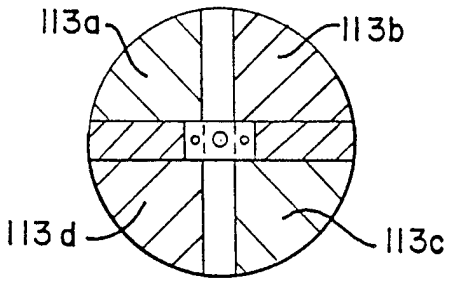

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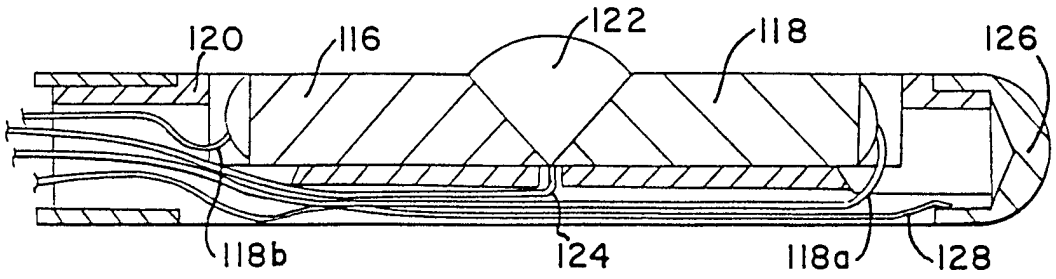

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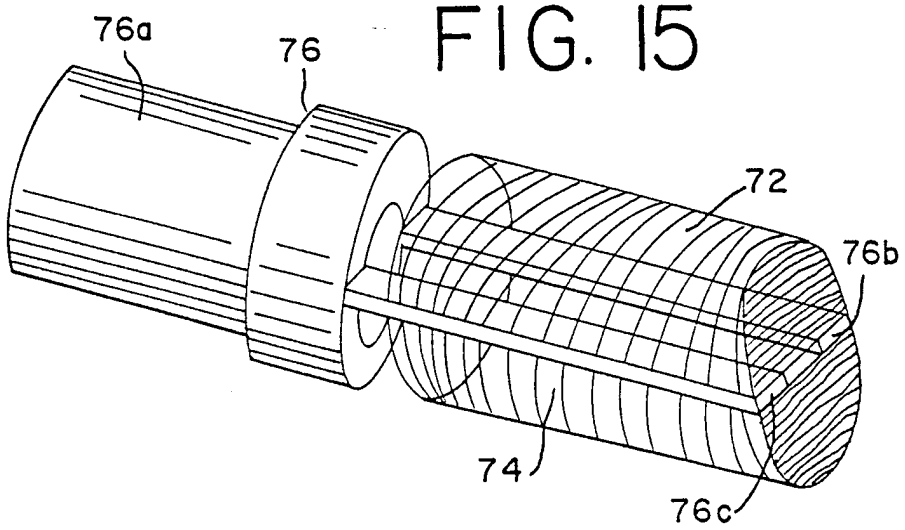

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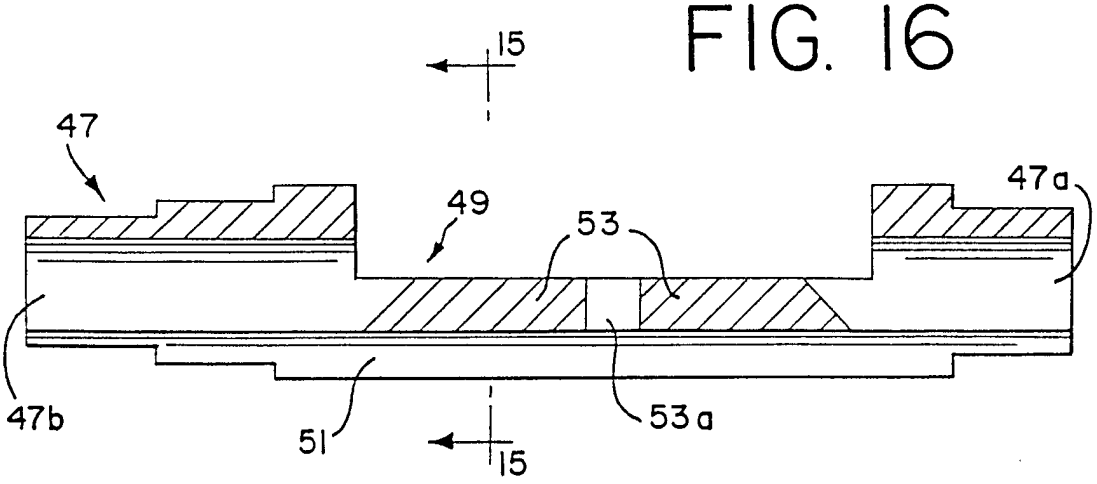

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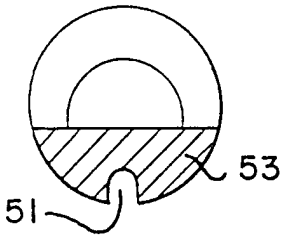


FIG.20

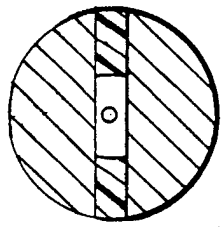


FIG.18

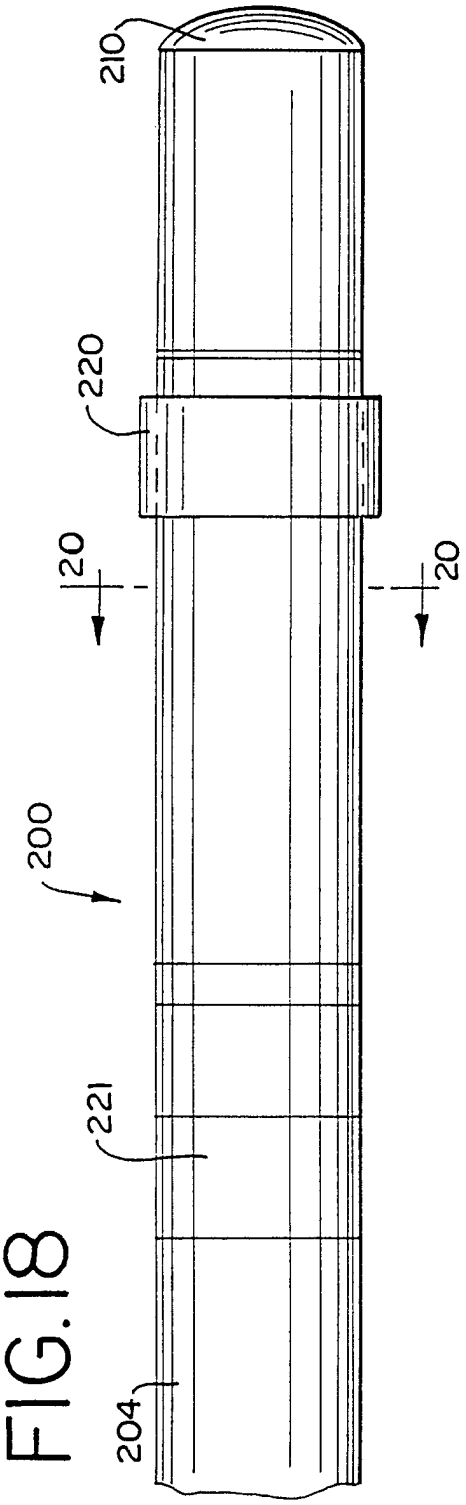


FIG.21

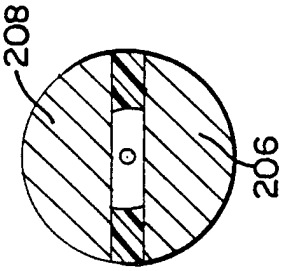


FIG.19

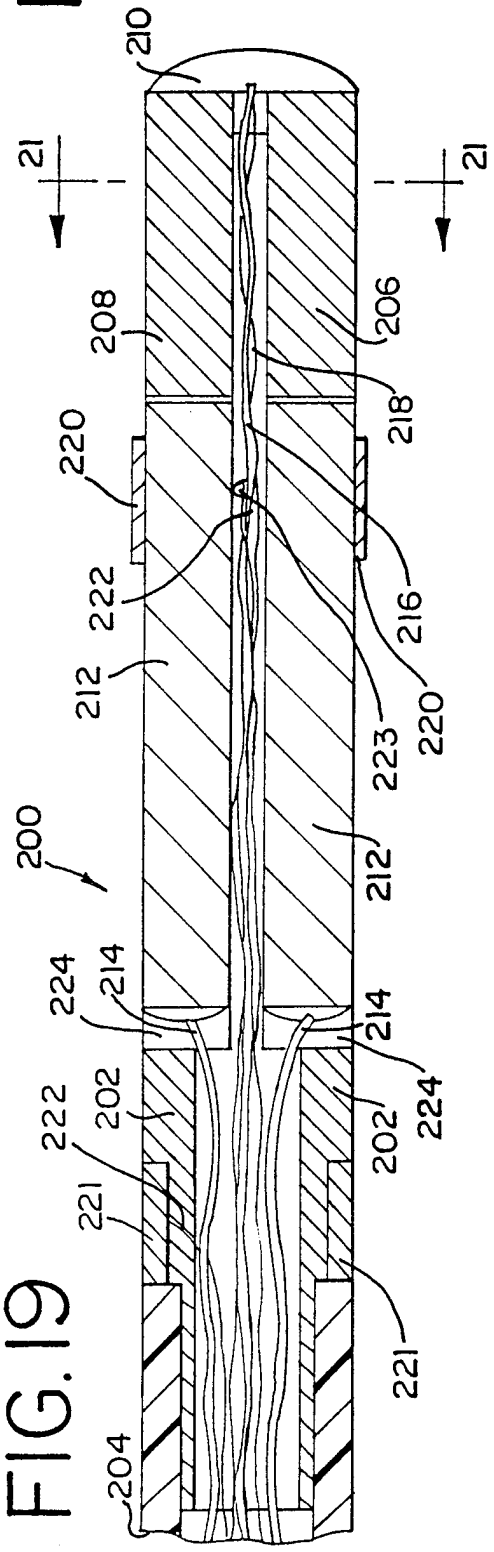


FIG.22

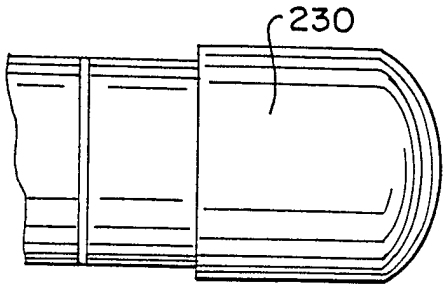


FIG.23

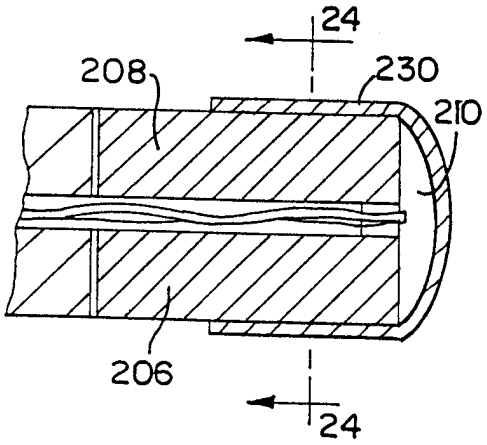


FIG.24

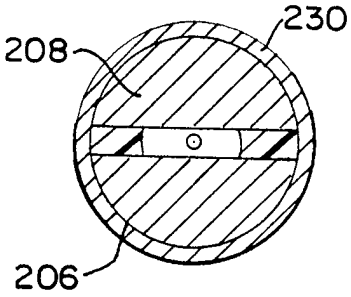


FIG.25

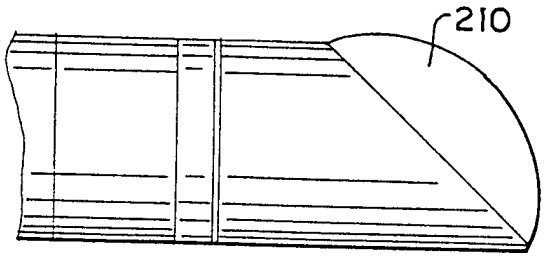


FIG.26

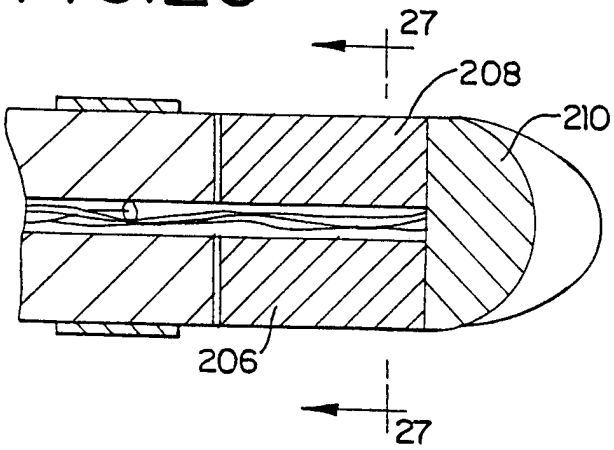
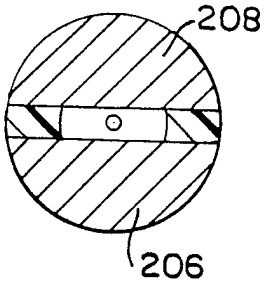


FIG.27



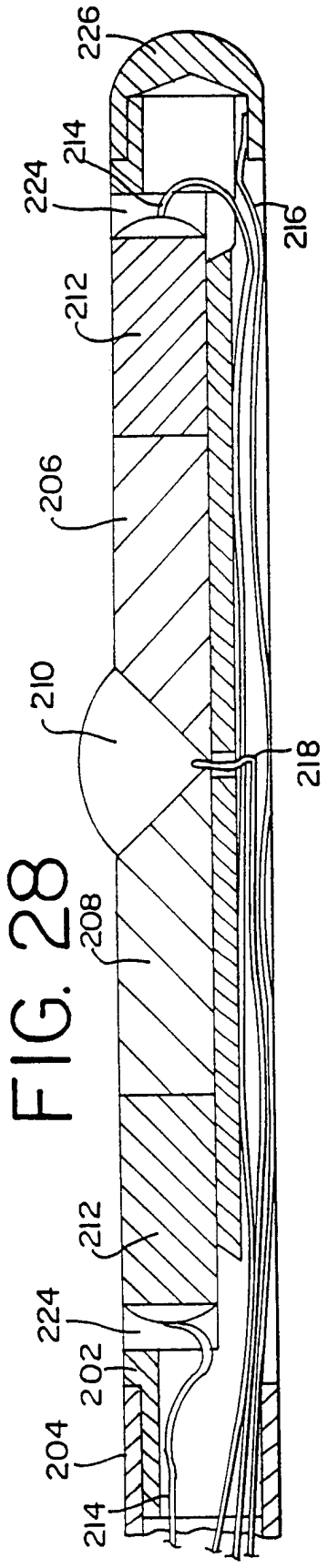

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FIG. 28

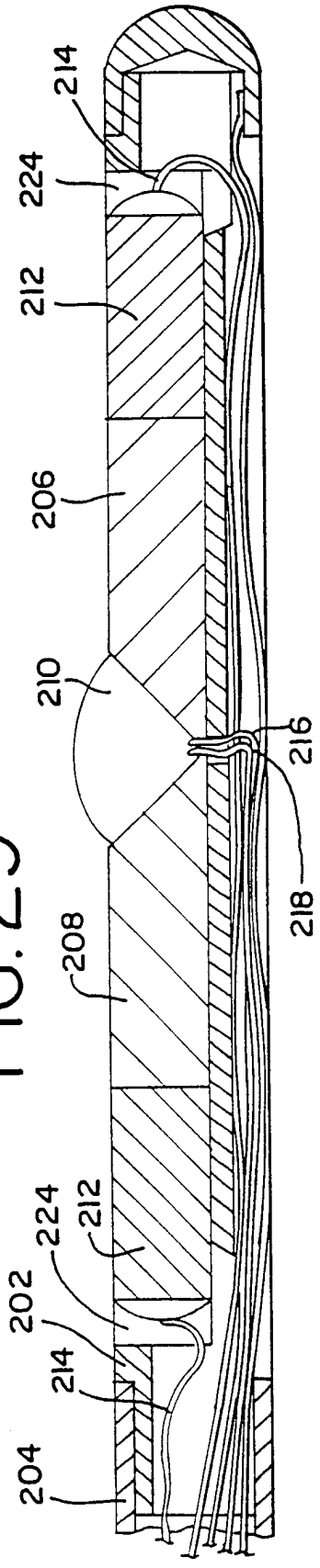
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FIG. 29

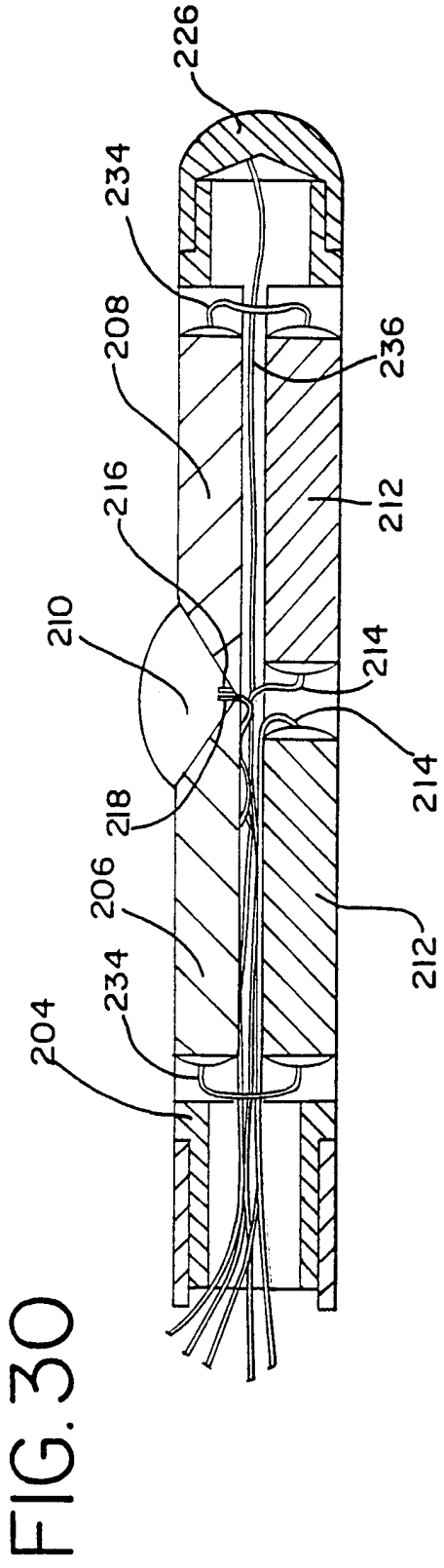
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FIG. 30

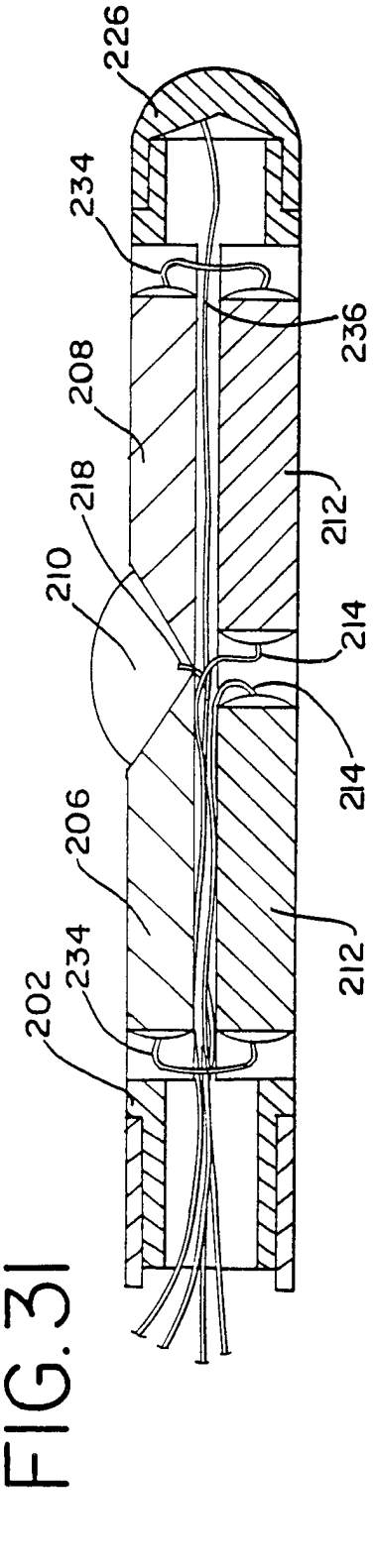
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FIG. 31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/20067

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 5/0402, 17/38; A61N 5/02
US CL :600/374; 606/21, 28, 41; 607/99, 113
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/374; 606/20, 21, 28, 29, 41; 607/99-102, 113, 119

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,860,744 A (JOHNSON et al) 29 August 1989, entire document.	1-13
A	US 5,139,496 A (HED) 18 August 1992, entire document	1-13
A	US 5,207,674 A (HAMILTON) 04 May 1993, entire document.	1-13
A	US 5,281,215 A (MILDER) 26 January 1994, entire document.	1-13
A	US 5,348,554 A (IMRAN et al) 20 September 1994, see col. 2 line 58 to col. 5 line 63.	1-13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
21 JANUARY 1998

Date of mailing of the international search report
19 FEB 1998

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