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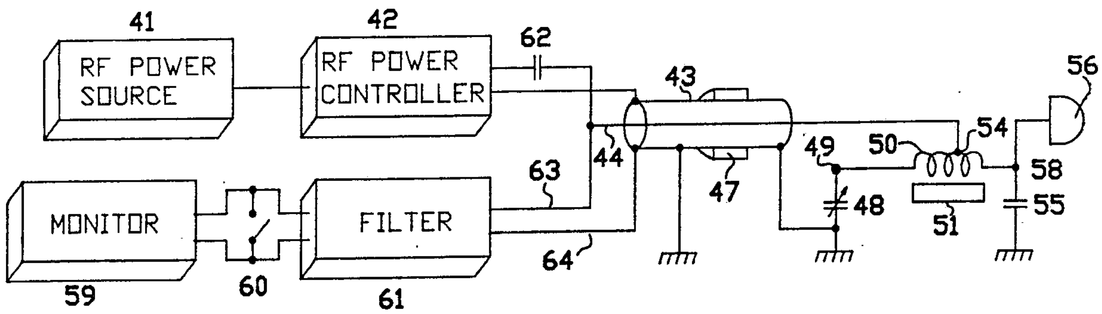

(57) Abstract

A cardiac ablation apparatus including a solenoidal antenna (50) monitoring electrodes (47, 56), and a coupling network at a distal end of a catheter transmission line, and another coupling network at the proximal end of the catheter transmission line to connect the catheter to the source of radiofrequency (RF) power (4) and to an intracardiac electrogram monitor (59). Solenoidal antenna design includes single and multiple windings with varying geometrical features. Plated plastic tri-axial design of a transmission line offers unitary fabrication. A catheter with variable impedance electrode and gap coatings has features useful for both ablation and for hyperthermia applications.

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RADIOFREQUENCY ABLATION CATHETER

This application is a continuation-in-part of U.S. Application Serial No. 07/276,294, Catheter with Radiofrequency Heating Applicator, filed November 25, 1988.

Technical Field

This invention pertains to a catheter designed to couple radiofrequency (RF) energy to biological tissue surrounding the catheter tip. Typical application is in thermal ablation of cardiac tissue. This invention further pertains to an apparatus used to guide a cardiac ablation catheter to ablate arrhythmia-causing myocardial tissue and to monitor the ablation procedure by detecting, processing, and displaying endocardial EKG signals.

Background Art

Percutaneous thermal destruction (ablation) of problem myocardial tissue (arrhythmogenic focus) is a therapeutic procedure used with increasing frequency for treatment of cardiac arrhythmias (e.g., ventricular tachycardia).

Medically, ablation is covered in Ablation in Cardiac Arrhythmias, G. Fontaine & M. M. Scheinman (Eds.), Futura Publishing Company, New York, 1987. A recent review of the ablation field is given in a chapter by D. Newman, G. T. Evans, Jr., and M. M. Scheinman entitled "Catheter Ablation of Cardiac Arrhythmias" in the 1989 issue of Current Problems in Cardiology, Year Book Medical Publishers. Catheter ablation of ventricular tachycardia was first described in 1983 as a nonsurgical method of destroying an arrhythmogenic focus. Typically, a pacing catheter is introduced percutaneously and advanced under fluoroscopic guidance into the left heart ventricle. It is manipulated until the site of earliest activation during ventricular tachycardia is found, indicating the location of problem tissue. One or more high voltage direct-current pulses from a standard defibrillator are then applied between the distal electrode of the catheter and an external large-diameter chest wall electrode. This procedure works by destroying cardiac tissue responsible for the arrhythmia.

Although this treatment is effective in some patients, there are serious drawbacks to high voltage direct-current pulses as an ablative energy source. The shock is painful, so general anesthesia is required. More importantly, the discharge produces arcing and explosive gas formation at the catheter tip. The resultant shock wave is responsible for serious side effects. The scar created by a direct-current pulse tends to have a large border zone of injured but still viable tissue that may serve as a new focus for ventricular tachycardia.

These problems have prompted a search for alternatives to direct-current pulse as a source of ablative energy. Radiofrequency (RF) energy is a promising method being investigated. (RF without qualifiers refers here to the electromagnetic spectrum from 10 kHz to 100 GHz, as per ANSI/IEEE Standard 100-1988.) Laser energy is also being considered for catheter ablation of arrhythmias (see Cohen, U.S. Patent No. 4,685,815) but is not pertinent to the RF implementation considered here.

RF ablation using electrosurgical power units is in clinical investigation, as a safer ablation alternative to high voltage direct current pulses. At present, continuous, unmodulated current in the range of 0.5 MHz to 1.2 MHz, such as that supplied by an electrosurgical RF power supply, is applied to the endocardium via an electrode catheter in the same manner as with a direct-current pulse. Ablative injury is produced by heating, generated by an electric field emanating from the catheter electrode. There is no gas or shock wave formation, and therefore no risk of serious barotraumatic side effects. However, as discussed in more detail later, the small size of the resulting lesion remains a problem even with RF ablation.

In order to discuss and evaluate the technical state of the art of RF ablation catheters and to compare it with embodiments of this invention, one must first establish pertinent performance requirements. A general geometrical requirement of catheter-based applicators is that they must be confined in a slender cylindrical structure with a radius commensurate with the catheter diameter. Subcutaneous insertion into the heart dictates that the catheter body must be a flexible tube no more than 2 mm in diameter and about 1 meter long. The diameter is constrained by the size of blood vessels used for catheter insertion into the heart. The length is dictated by the length of the catheter inside of the patient's body plus the length of the catheter between the patient and the external equipment.

In the discussion of catheter performance which follows, it is convenient to adopt a cylindrical coordinate system with the z-axis coincident with the catheter axis and pointed toward the distal end. The radial component is in the direction normal to the catheter z-axis, and the circumferential component has a direction around the z-axis. Radius is measured from the catheter axis.

A simple cylindrical wire heat applicator antenna is shown in FIG. 1A. Applicator antenna 10 is a conductor immersed in a lossy dielectric medium which has electrical properties typical of muscle tissue. The radius of applicator antenna 10 is "a" and its height is "h". In spite of the simple geometry and low frequency approximation used in the description, FIG. 1 retains the salient features of a radial-field coupling of pacing catheters used as an RF antenna.

In FIG. 1A, RF potential V14 is applied in a unipolar manner between applicator antenna 10 and a remote boundary 15 which corresponds to a neutral electrode applied to the skin. The exact location of boundary 15 is not important to the shape of the radial electric field E near applicator antenna 10. Electric field E16 coincides with current density vector $J_r = \sigma E_r$ in the tissue, where σ is the conductivity of the tissue.

Continuity of current in the cylindrical geometry in FIG. 1A results in current density J_r which decreases with the inverse of the radius r: $J_r = J_0 a/r$ for $r < h$ and power dissipation $P = J_r^2/\sigma = (J_0^2/\sigma)\ (a/r)^2$. For $r > h$, the spherical geometry is a more appropriate approximation and results in $J_r = J_0(a/r)^2$, and the corresponding electrical power dissipation is $P = J_r^2/\sigma = (J_0^2/\sigma)\ (a/r)^4$. The result is that the heating of tissue, decreases with the radius within the bounds of the second to the fourth power of a/r. This behavior of the electric field applies to a conducting medium below the microwave region. In the microwave region ($f > 900$ MHz), the radial attenuation of electric field is even faster due to the "skin depth" attenuation.

Clinical experience indicates that in order to effectively ablate ventricular tachycardia, it is desirable to thermally destroy (ablate) tissue over an area of 1-2 cm^2 of the myocardium (e.g., see Moran, J. M., Kehoe, R. F., Loeb, J. M., Lictenthal, P. R., Sanders, J. H. & Michaelis, L. L. "Extended Endocardial Resection for the Treatment of Ventricular Tachycardia and Ventricular Fibrillation", Ann Thorac Surg 1982, 34: 538-43). As mentioned earlier, in order to accomplish percutaneous insertion into the left ventricle, the heating applicator radius is limited to 1 mm. In order to heat a 2 cm^2 area, a 2 cm long applicator can be used provided an effective heating diameter of 1 cm can be reached. To overcome present shortcomings of the RF ablation method, the size of the lesion must be increased and this requires the minimization of the radial attenuation of the electric field and the associated heat dissipation.

The destructive ablation of tissue requires a temperature of approximately 50°C; this temperature defines the outer radius R of the ablation region. It is therefore desirable to heat tissue to 50°C up to 5 mm from the catheter axis. Yet at 100°C, undesirable charring and desiccation takes place. So, ideally, the maximum temperature at the applicator electrode boundary should be under 100°C.

Ignoring for a moment heat conduction in the tissue, the rise in tissue temperature is proportional to the electric power dissipation which in turn is proportional to the square of the current density. In order to maintain a 100°C/50°C or a factor of 2 temperature ratio between the temperature at a radius of 1 mm and the temperature at a radius of 5 mm, the ratio of the power dissipation ratio should be 2 at these two distances. Yet the performance of the current density in FIG. 1A gives at best a power dissipation at the catheter surface of $(R/a)^2$ or 25, and at worse $(R/a)^4$ or 625 times more intense than heat dissipation at a 5 mm radius.

In order to examine the effect of this wide range of heat dissipation, it is useful to divide the lossy medium in FIG. 1A into three cylindrical shells: first shell R11 adjacent to the applicator antenna 10, followed by shell R12, and R13 beginning at the 10 mm radius. Since the shells are traversed by the same current, and the potential drop across the shells is additive, power delivery can be schematically represented by three resistances R11, R12, and R13, as shown in FIG. 1B, connected in series with the source of RF potential V14.

The heat required to obtain adequate ablation at a 5mm radius tends to desiccate blood or tissue close to the applicator antenna 10, increasing the resistivity of R11. This in turn further increases the relative power dissipation in R11 in comparison with R12 and R13, until effective impedance of the desiccated region R11 becomes, in effect, an open circuit shutting off the flow of RF power to the tissue beyond R11.

This indeed is the problem with state-of-the-art RF ablation catheters which severely limits the effective heat delivery to more distant tissue. The currently used RF ablation technique, based on a surgical RF power supply and a pacing catheter, suffers from a steep temperature gradient, reported to decay sharply (Haynes, D.E., Watson, D.D.: PACE. June, Vol. 12:962-976, 1989), and has the associated problem of charring which disrupts and limits heating and ablation.

Insulation of the applicator antenna 10 from the tissue does not reduce the heat dissipation gradient: If the applicator antenna 10 is insulated from the lossy medium by a thin dielectric tube, the effect of the dielectric can be represented by capacitor (not shown) in series with the source of RF potential V14. Now the applicator must be operated at a frequency high enough so that the impedance of the sum of resistances R11 and R12 and R13 must be higher than the capacitive impedance of the dielectric tube. R11 still dominates the heat distribution.

Effective ablation heating also requires that the heating along the heat applicator axis should be as uniform as possible. Heating should then rapidly attenuate to a negligible value along the portion of the catheter acting as a transmission line.

A key improvement requirement is therefore the ability to ablate areas significantly wider than the catheter diameter, confined only to the region of the heat applicator. Heating should not be limited by charring and desiccation at the catheter boundary.

Therefore, there is a need for a catheter-compatible RF energy delivery system which dissipates heat more uniformly in the radial direction and is well defined in the z direction, thereby leading to a more accurately controlled and larger ablated region. It is also desirable to eliminate the effect of desiccation of tissue, adjacent to the electrode, on heat dissipation to surrounding tissue.

An effective cardiac ablation catheter must satisfy three additional performance requirements:

(1) The body of the catheter should act as an efficient and reproducible RF power transmission line with the heat applicator transforming the impedance of tissue (electrically a lossy medium) to match the characteristic impedance of the transmission line.

(2) The detection of an endocardial potential, needed for mapping of location of the arrhythmogenic tissue to be ablated, must coexist, without interference, with the heating function.

(3) All of the above must be accomplished in a flexible catheter, about 2 mm in diameter so as to allow percutaneous insertion into the left ventricle.

U.S. Patent No. 4,641,649 issued February 10, 1987 to P. Walinski, A. Rosen, and A. Greenspon describes a cardiac ablation catheter consisting of a miniature coaxial line terminating in a short protruding inner conductor applicator. This system operates at 925 MHz. To applicant's knowledge, no heat dissipation profiles for the Walinski catheter are published. However, the small area of the stub-like applicator results in an E-field attenuation which is even more precipitous than in the case of the pacing catheter electrode discussed in conjunction with FIG. 1A.

Microwave ablation catheter experiments have been reported by K. J. Beckman, & J. C. Lin et al, "Production of Reversible Atrio-Ventricular Block by Microwave Energy" abstracted in Circulation 76 (IV): IV-405, 1987. Technical details of a folded dipole applicator catheter used by Beckman have been described by J.C. Lin and Yu-jin Wang in "An Implantable Microwave Antenna for Interstitial Hyperthermia" in Proceedings of the IEEE, Vol. 75 (8), p. 1132, August, 1987. The heating profile indicates an unacceptably high heat dissipation along the transmission line. Neither of the two Lin references address the all important issue of integration of monitoring of endocardial potential with the folded dipole heat applicator.

There is a large body of technical knowledge concerned with the RF catheter heating developed for oncological applications. The catheters are inserted typically to the depth of a few centimeters into a cancerous tumor and heat the tumor tissue by a few degrees centigrade. It was found that heated tumor tissue is more susceptible to chemotherapy.

A variety of oncological applicators have been proposed including:

- a helix:

(LeVeen, US 4,154,246 22,4,1986; Pchelnikof SU 1,266,548-A-1, 30.10.1986; and Hines et al, US 4,583,556, 22.4.1986);

- a helix and a gap:

(Stauffer et al, US 4,825,880, 5.2.1989);

- linear dipoles:

(B.E. Lyons, R.H. Britt, and J.W. Strohbehn in "Localized Hyperthermia in the Treatment of Malignant Brain Tumors Using an Interstitial Microwave Antenna Array:, <u>IEEE Trans on Biomedical Engineering</u> Vol. BME-31 (1), pp. 53-62, January, 1984;

- folded dipoles:

(J.C. Lin and Yu-jin Wang "An Implantable Microwave Antenna for Interstitial Hyperthermia" in <u>Proceedings of the IEEE</u>, Vol. 75 (8): 1132, August, 1987); and

- co-linear arrays:

(Kasevich et al, US 4,700,716, 20.10.1987).

RF cardiac ablation and oncological applications have the common objective of uniform heating of tissue. There are, however, a number of differences in the requirements for ablation vs. hyperthermia.

Ablation applications require uniform heating, combined with accurate monitoring of the endocardial potential, without interference and preferably without introduction of any additional catheter wires. None of the oncological references quoted above address the issue of monitoring of endocardial potential. Other differences between hyperthermia and ablation are:

(a) Ablation heating must create significantly higher temperature differentials (30°C for ablation vs. 5°C for hyperthermia) and must operate in the presence of rapid blood flow, and therefore requires significantly higher power levels. The capabilities of the power supply and the power carrying capability of transmission lines must therefore be higher.

(b) The problem of charring and desiccation, described earlier, is absent in hyperthermia, but it can be a very important obstacle in ablation.

(c) Power leakage on the outside of the catheter transmission line is unimportant in hyperthermia, yet it is unacceptable in cardiac ablation.

(d) Typically in heating of a tumor, an array of antennas is used and so the interaction of the antennas is important. In ablation, only a single element is used so interactive properties are unimportant.

Disclosure of the Invention

Accordingly, a principal object of the invention is an RF cardiac ablation catheter, optimized for deep and uniform heat dissipation, and incorporating means for accurate pickup of an endocardial EKG potential in the proximity to the catheter tip. This applicator exhibits deeper and more uniform heat dissipation and is less subject to power reduction from desiccation of tissue in the proximity of the applicator, typical of state-of-the-art devices.

A further object of the invention is a cardiac ablation system which provides monitoring and control of RF power supplied to the catheter and which also provides endocardial signal processing and monitoring, and an electrogram display of the endocardial signal, optimized for convenient mapping of arrhythmogenic tissue.

Yet another object of the invention is an improvement in hyperthermia catheters for application such as hyperthermia treatment of cancer where the catheter with RF energy applicator offers adjustable depth of heating compatible with a tumor size.

Further advantages of the invention will become apparent from the consideration of the drawings and the ensuing description thereof.

Brief Description of the Drawings

FIG. 1A shows a radial electric field of an antenna represented by a conductor immersed in a lossy dielectric medium.

FIG. 1B is an equivalent circuit describing the heat delivery of the radial electric field antenna in FIG. 1A.

FIG. 2A shows a solenoidal antenna in the form of a helix immersed in a lossy dielectric medium and generating an azimuthal electric field.

FIG. 2B is an equivalent circuit describing the heat delivery of an azimuthal electric field in FIG. 2A.

FIG. 3 shows details of a solenoidal antenna mounted on a catheter tip, with endocardial signal monitoring capability.

FIGS. 3A and FIG. 3B show magnified details of FIG. 3.

FIG. 4 is a block diagram of an RF heating and intracardiac electrogram monitoring catheter ablation system.

FIG. 5 shows a tri-axial catheter constructed from plated plastic.

FIG. 6 shows an embodiment of the invention utilizing a helix having a variable strip width.

FIG. 7 shows an embodiment of the invention utilizing a variable gap helix.

FIG. 8 shows an embodiment of the invention utilizing a bifilar helical antenna.

FIG. 9 shows an embodiment of the invention utilizing a cross-wound helical antenna.

FIG. 10 shows an embodiment of the invention utilizing a variable surface impedance catheter antenna.

Modes for Carrying Out the Invention

FIG. 1A shows a radial electric field (E16) antenna represented by a conductor immersed in a lossy dielectric medium. FIG. 1B is an equivalent circuit of heat delivery of the radial electric field antenna. Both figures have been discussed in the Background Art section above.

FIG. 2 shows a conductor in the form of a helix 20 traversed by RF current I24. The radius of helix 20 in a catheter application is typically $a = 1$ mm and the maximum desired radius of tissue heating for cardiac ablation is $R = 5$ mm.

Generally, a helix can support two modes of operation: transverse electric (TE) and transverse magnetic (TM) mode. In the transverse electric mode (E field transverse to the z-axis), shown in FIG. 2A, the dominant component of the electric field is the azimuthal E_θ component shown as E_{21}, E_{22} and E_{23}. The corresponding magnetic field lines H_{21}, H_{22}, and H_{23} have axial H_z and radial H_r components. In the transverse magnetic mode (not shown), the lines of E and H are interchanged: magnetic field H_θ circles the axis and the electric field forms arcs with E_r and E_z components. FIG. 1 is a special case of the TM mode showing only the radial component of the electric field.

The azimuthal electric field E_θ in the TE mode, and the associated current density $J_\theta = \sigma E_\theta$, is unique in the sense that it does not be begin or end at the catheter surface but in effect circulates around it. In FIG. 2B, the tissue (electrically a lossy medium) is, as in FIG. 1B, divided into three regions: The shell of the lossy medium adjacent to the helix is energized by E21, the shell at the intermediate distance energized by E22, and the shell corresponding to the boundary of the ablation region is energized by E23. The resulting current paths are parallel to each other and so appear in FIG. 2B as parallel resistances R21, R22, and R23 respectively, fed by the current source I24.

Now, if desiccation occurs adjacent to the helix, resistance R21 increases. This reduces power dissipation in R21 and increases power dissipation in resistances R22 and R23. In general then, as power is increased to a point of desiccation at a catheter surface, the heat delivered to a desiccated volume decreases in a TE mode antenna while it increases in a TM antenna. Thus, the azimuthal electric field in a TE mode antenna is much less likely to cause excessive desiccation but even if desiccation occurs, it will not lead to a decrease in power dissipation in more remote tissue.

The TE mode dissipates significant amounts of power in the tissue at 915 MHz or above. The TM mode has the advantage that it is effective even at much lower frequencies. The E_z field in the TM mode has somewhat better radial heating penetration capabilities than the E_θ field. Since there is no clear advantage between the E_θ in the TE mode and E_z in the TM mode of operation, the choice depends on the application and both the TE, TM and hybrid mode designs are considered here.

A solenoidal antenna is defined here as a heating applicator antenna comprising one or more helical windings. One embodiment of the solenoidal antenna in an ablation catheter, with a wire wound helix, is shown in FIG. 3. The antenna in FIG. 3 consists of a helix 50 with three terminals: a proximal end terminal 49 (FIG. 3A), a feed terminal 54 (FIG. 3B), and a distal end terminal 58 (FIG. 3). A heat-shrunk PTFE (also known under trademark TEFLON) plastic sleeve 53 covers the helix 50.

In some applications, it may be desirable to distort the axisymetrical form of the induced E-field. This can be accomplished by partially covering the dielectric sleeve 53 with a metal screen (not shown). Currents induced in the screen will modify the shape of a heating pattern and so serve as an aperture antenna. An asymmetrical field pattern can also be accomplished by a loop antenna, e.g., located in the r-z plane.

A transmission line which connects the distal end of the catheter to external equipment has the form of a coaxial line 43 shown in FIG. 3. In a preferred embodiment, coaxial line 43 includes a center conductor 44 (approximately 0.16 mm diameter), a dielectric 46 (approximately 1.35 mm outside diameter), a metal braid shield 45 and an insulating sleeve 57 (approximately 1.8 mm outside diameter). A small diameter and flexible construction make the coaxial line 43 suitable for biomedical catheter applications.

A distal monitoring electrode 56 is connected to a distal end terminal 58 of helix 50 and to bypass capacitor 55. Bypass capacitor 55 is connected to shield 45 through metallized coating 52 inside of core 51. The function of the bypass capacitor 55 is to ground RF power. Thus when the RF power is applied to the helix 50, distal monitoring electrode 56 has little RF voltage thereby preventing distal monitoring electrode 56 from acting as a heat applicator. Distal monitoring electrode 56, in conjunction with a proximal monitoring electrode 47, picks up an endocardial potential. In this embodiment, the distance from a beginning of proximal monitoring electrode 47 to an end of the distal electrode 56 is approximately 20 mm.

When operated in a TE mode the number of turns of helix 50 is chosen so that at an operating frequency of 915 MHz, the helix is somewhat short of being at a quarter wavelength resonance. Helix 50 is wound on a dielectric core 51. The proximal end terminal 49 of helix 50 is connected to a variable tuning capacitor 48 (FIG. 3A). Variable tuning capacitor 48 is moved with respect to proximal monitoring electrode 47 during manufacture for tuning to a resonance at operating conditions. Tuning capacitor 48 is controlled by adjusting a space 40 between capacitor electrodes 47 and 48. At lower frequencies, the capacitance of inter-electrode space is insufficient and the capacitor is implemented by a discrete component.

RF power is coupled to a helical resonator by connecting the center conductor 44 to helix 50 at the feed terminal 54 (see FIG. 3B). The position of feed terminal 54 on the helix is selected for a good match between the characteristic impedance of the coaxial line 43 and the impedance of the resonator under typical operating conditions. Under some circumstances the best match can be obtained when the feed terminal 54 and the distal end terminal 58 coincide, and the helix 50 is fed at its distal end terminal. The choice of an axial quarter wavelength resonator is by no means unique. One could just as well select any multiplicity of quarter wavelengths, such as a half-wavelength resonator.

When in operation in the TM mode, the frequency of operation can be much lower, e.g., 27 MHz. Helix 50 can then be viewed as a discrete inductance, tuned into series resonance by a discrete component capacitor 48. In the TM mode, core 51 on which helix 50 is wound, can be made from a ferrite. At 27 MHz, a ferrite core can significantly increase inductance of the helix and decrease losses in the tuned circuit. In order to use the E_Z electric field component in the TM mode, sleeve 53 is removed to allow direct contact between the winding of the helix and the surrounding tissue.

In cardiac ablation, it is essential to be able to monitor endocardial potential just before and after the application of heat. Before application of heat, it is necessary to locate the arrhythmogenic tissue to be ablated. Afterward, endocardial potential is used to assess effectiveness of destruction of arrhythmia-causing myocardial tissue. FIG. 4 shows a block diagram of a system which combines controlled heat delivery by a solenoidal antenna, with monitoring of endocardial potential.

Distal monitoring electrode 56, in conjunction with the proximal monitoring electrode 47, picks up a local endocardial potential and feeds this signal through coaxial line 43 to capacitor 62. Capacitor 62 represents a short circuit for the RF power and an open circuit for a much lower frequency band (typically 0.1 Hz to 100 Hz) associated with endocardial signals. An endocardial signal travels unobstructed on lines 63 and 64 to an input to a low-pass filter 61.

Low-pass filter 61 has a high input impedance to the RF power and therefore blocks the transmission of RF power to switch 60 while allowing passage of the endocardial signal. Switch 60 is closed simultaneously with application of RF power, thus providing additional protection for monitor 59. Intracardiac signal processing, display, and recording is accomplished by monitor 59 which displays the intracardiac electrogram. Existing equipment is suitable for application as monitor 59.

RF power is generated in an RF power source 41. The RF power is controlled and monitored in controller 42 which couples the RF power to the coaxial line 43 through capacitor 62, which for RF represents substantially a short circuit.

Fig. 5 shows an alternative implementation of a catheter using metal plating on plastic, such as silver on PTFE. Such plating offers a number of advantages over the design shown in FIG. 3. One advantage is a unitary design: the plating process can in one step create coaxial shield 69, helix 71, and disk 82 serving as a capacitive coupling electrode. In microwave application, shield 69 may be used alone or in conjunction with a secondary shield made from a metal braid (not shown).

Another advantage is that helix 71 made from a metal strip provides a more effective use of the metal cross-section than the circular cross-section wire such as used in the helix 50 in FIG. 3. For silver or copper, the RF current penetrates only .01 mm at 27 MHz and 0.002 mm at microwave frequencies. This so called "skin depth" is so small in good conductors that plating thickness easily exceeds it. In round wires, the current flows only on the surface, yet the wire adds two diameters to the diameter of the catheter, without any contribution to conduction.

Fig. 5 shows a tri-axial design of the catheter. A coaxial RF transmission line is formed between coaxial shield 69, plated on the outside of the plastic tube 72, and an inner conductor 73 plated on the outside of a smaller plastic tube 74. A stranded small-gauge center wire 75, along the axis of plastic tube 74, is shielded from the RF by plated inner conductor 73. Center wire 75 is used to transmit endocardial signals from distal monitoring electrode 80. Optionally a ferrite bead 83 acts as a RF choke to further decouple RF from distal monitoring electrode 80. A proximal monitoring electrode 76, in the form of a ring, is seated on and makes electrical contact with the shield 69.

A proximal end terminal 81 of the plated helix 71 seamlessly joins with the shield 69. A distal end terminal 77 of the helix 71 seamlessly joins with plated disk 82, plated on an end surface of plastic tube 72. Metal disk 79 connects along its inside diameter to inner conductor 73. Dielectric disk 78 separates the metal disk 79 from the plated disk 82. The three discs 82, 78 and 79 form a capacitor between inner conductor 73 and the helix 71. The role of this capacitor is to tune the inductance of the helix 71 to resonance so that under operating conditions, the transmission line sees a resistive load equal to a characteristic impedance of the coaxial line.

A capacitance between the turns of the helix 71 in the plated strip design is much smaller than a comparably spaced circular cross-section wire. It is therefore possible to make the gap 84 between turns significantly smaller in a plated strip design. This narrow-gap geometry generates an intense electric field between turns, primarily z-axis oriented across the gap, with a rather steep attenuation in the radial direction. As a result, most of the E_z field passes through the dielectric cover tube 70 without penetrating into the outside tissue. The dominant component of the electric field in the tissue is the azimuthal field E_θ induced by current in helix 71. The advantages of the E_θ field have been discussed earlier.

Yet another advantage of metal-on-plastic plating is that a variety of antenna patterns can be readily and accurately implemented. For example, a helical strip 85 in FIG. 6 has a variable width constant-gap winding. A helical strip 86 in FIG. 7 has a constant width variable-gap winding. This type of helical strip (85 or 86) design allows control of the electric field distribution in the z-direction.

An antenna in FIG. 8 consists of two interspaced helices 87 and 88, wound in the same sense and defining a bifilar antenna geometry. The bifilar helices have two proximal end terminals and two distal terminals. The proximal end terminals can be connected to the transmission line and the distal end terminals can be shorted or preloaded with an RF impedance to optimize the power flow.

An antenna in FIG. 9 consists of a helix 89, plated on a plastic sleeve 90 (shown partially cut), and helix 91 plated on a plastic tube 92. The two helices 89 and 91 are wound in an opposite sense and therefore cross over each other, defining a cross-wound antenna geometry. Like the bifilar antenna, a cross-wound antenna has two proximal end terminals 93 and 94 and two distal end terminals 95 and 96. The proximal end terminals can be connected to a transmission line and the distal end terminal can be shorted or preloaded with an RF impedance to optimize the power flow. It should be noted that in this configuration, unlike the bifilar configuration of FIG. 8, current entering at proximal end terminal 93 and flowing up through helix 89 circulates around the axis in the same direction as the current flowing down through helix 91 and exiting at proximal terminal 94. An effect on induced azimuthal fields E_θ is therefore additive. The polarity of the E_z field caused by the up current in helix 89 and the down current in helix 91 is opposite, and thus tends to cancel each other. The cross-wound antenna is therefore an efficient source of the azimuthal E_θ field.

All of the antennas described thus far are of the solenoidal variety, i.e., include one or more helices. The antenna shown in FIG. 10 is different. FIG. 10 shows a proximal ring electrode 25 and a distal tip electrode 26, mounted or plated on a catheter tube 24 and shaped very similarly to the currently used pacing catheters. An electrical connection is maintained by a twisted pair transmission line 27. Unlike currently used catheters where the electrodes are made from plain metal, proximal ring electrode 25 and distal tip electrode 26 have their metallic surface coated with control coatings 28 and 29 respectively. Optionally, the gap between proximal ring electrode 25 and distal tip electrode 26 can be filled with gap coating 30. (Thickness of coatings is exaggerated in FIG. 10 for the sake of clarity.)

The control coatings vary in thickness as a function of the axial distance from the inter-electrode gap, being thickest along the edges of the inter-electrode gap and thinning away from the gap. Without the coating, the strongest E_z field is adjacent to the inter-electrode gap. The coatings, by changing the surface impedance, equalizes the external electric field and improve radial penetration of the field.

The coatings 28, 29, and 30 can be made from a resistive material or from a dielectric. A resistive coating, introduces the highest resistance close to the inter-electrode gap. As a result, the external field adjacent to inter-electrode gap is reduced, the external field intensity is equalized and the radial penetration is improved. A capacitive coating, made from a dielectric, exhibits a smallest capacitive impedance near the inter-electrode gap and accomplishes field equalization similar to the resistive coating. There is, however, significantly less heat dissipation in the capacitive coating than in the resistive coating.

While certain specific embodiments of improved electrical catheters and systems have been disclosed in the foregoing description, it will be understood that various modifications within the scope of the invention may occur to those skilled in the art. Therefore it is intended that adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed embodiments.

Claims

1. In a cardiac ablation system, wherein a thin and flexible catheter transmission line having a proximal end and a distal end is connected at its proximal end to a source of radiofrequency (RF) power (41) and to an intracardiac electrogram monitor (59), and is connected at its distal end to an antenna in operation immersed in an intracardiac medium, the combination:

a solenoidal antenna connected to the distal end of the catheter transmission line (20, 50, 71, 85, 86, 87, 88, 89, 91);

at least one endocardial signal monitoring electrode connected to the distal end of the catheter transmission line (56, 80, 26);

a proximal coupling means interconnecting the source of RF power (41) and the intracardiac electrogram monitor to the proximal end of the catheter transmission line (42, 62, 64, 65, 61); and

a distal coupling means interconnecting the distal end of the catheter transmission line to said solenoidal antenna and to said at least one endocardial signal monitoring electrode (48, 50, 54, 55, 81, 83), for transmitting RF power from the source of RF power (41) to said solenoidal antenna and for transmitting an endocardial signal from said at least one endocardial signal monitoring electrode to the intracardiac electrogram monitor.

2. An apparatus in accordance with claim 1, wherein:

the catheter transmission line is a coaxial line (43), comprising a center conductor (44) and a shield (45) separated by a dielectric (46);

said solenoidal antenna comprises a helix (50) with a proximal end terminal (49), a feed terminal (54), and a distal end terminal (58);

said distal coupling means comprising:

a connection between the center conductor (44) and said feed terminal (54);

a tuning capacitive impedance between said shield (45) and said proximal end terminal (49) (FIG. 3A);

a bypass capacitive impedance between said shield (45) and said distal end terminal (55);

wherein said at least one endocardial signal monitoring electrode comprises a distal monitoring electrode (56) and a proximal monitoring electrode (47) for providing contact surface to the intracardiac medium, said apparatus further including:

a connection between said proximal monitoring electrode and said shield (45); and

a connection between said distal monitoring electrode and said distal end terminal of said helix.

3. An apparatus in accordance with claim 1, wherein:

the catheter transmission line is a coaxial line, comprising a center conductor (73) and a shield (69) separated by a dielectric (72);

said solenoidal antenna comprises a helix (71) having a proximal end terminal (81) and a distal end terminal (77); and

said at least one endocardial signal monitoring electrode comprises a distal monitoring electrode (80) and a proximal monitoring electrode (76) for providing contact surface to the intracardiac medium;

said distal coupling means comprising:

a connection between said shield (69) and said proximal end terminal (81);

a capacitive impedance (79, 78, 77) between said center conductor (75) and said distal end terminal (77) for tuning;

a connection between said proximal monitoring electrode (76) and said shield (69); and

an RF blocking impedance between said distal monitoring electrode and said distal end terminal of said helix.

4. An apparatus in accordance with claim 3, wherein said RF blocking impedance comprises a ferrite bead (83) on a conductor connecting said distal monitoring electrode and said distal end terminal of said helix.

5. An apparatus in accordance with claim 1, wherein:

the catheter transmission line is a coaxial line, comprising a center conductor and a shield separated by a dielectric;

said solenoidal antenna comprising a helix with a proximal end terminal and a distal end terminal; and

said at least one endocardial signal monitoring electrode comprises a unipolar proximal monitoring electrode for providing contact surface to the intracardiac medium;

said distal coupling means comprising:

a connection between said center conductor and said distal end terminal;

a capacitive impedance between said shield and said proximal end terminal for tuning; and

a connection between said proximal monitoring electrode and said shield.

6. An apparatus in accordance with claim 5, wherein said capacitive impedance includes a space (40) between said shield and said proximal end terminal of said helix.

7. An apparatus in accordance with claim 1, comprising a flexible insulating sleeve (53, 57, 70) covering the catheter transmission line and said solenoidal antenna except at said at least one endocardial signal monitoring electrode.

8. An apparatus in accordance with claim 1, wherein:

the catheter transmission line is a coaxial line, comprising a center conductor (73) and a shield (69) separated by a dielectric (72); and

the dielectric is a plastic tube (72) and the shield (69) and said solenoidal antenna (71) are an integral coating on a surface of the plastic tube (72).

9. An apparatus in accordance with claim 1, wherein said solenoidal antenna comprises a conductor loop tuned and coupled to the catheter transmission line for assuring efficient flow of RF power from the source of RF power (41) through the transmission line and said solenoidal antenna to the intracardiac medium.

10. An apparatus in accordance with claim 1, wherein said solenoidal antenna is wound on a ferrite core (51) for increasing antenna inductance.

11. An apparatus in accordance with claim 1, wherein said solenoidal antenna is partially covered by a screen for controlling an external electromagnetic field and for monitoring said endocardial signal.

12. In a heating catheter system, wherein a catheter transmission line having a proximal end and a distal end is connected at the proximal end to a source of radiofrequency (RF) power (41), and at the distal end to an antenna in operation immersed in a lossy medium, said system characterized by:

the antenna comprising a helix made from a conductive strip of varying width (85 in FIG. 6) for heating of said lossy medium.

13. In a heating catheter system, wherein a catheter transmission line having a proximal end and a distal end, is connected at the proximal end to a source of radiofrequency (RF) power (41) and at the distal end to an antenna in operation immersed in a lossy medium, said system characterized by:

the antenna comprising a helix made from a conductive strip with a varying gap (86 in FIG. 7) between turns for heating of said lossy medium.

14. In a heating catheter system, wherein a catheter transmission line having a proximal end and a distal end, is connected at the proximal end to a source of radiofrequency (RF) power (41), and at the distal end to an antenna in operation immersed in a lossy medium, the system characterized by:

the antenna comprising at least two bifilar helical windings (87, 88 in FIG. 8) for heating of said lossy medium.

15. In a heating catheter system wherein a catheter transmission line having a proximal end and a distal end, is connected at the proximal end to a source of radiofrequency (RF) power (41) and at the distal end to an antenna in operation immersed in a lossy medium, the system characterized by:

the antenna comprising cross-wound helical windings (89, 91 in FIG. 9) for heating of said lossy medium.

16. In a electrical catheter, having a proximal end and a distal end, connected at the proximal end to an electrical system, and at the distal end to at least one electrode (71), the electrical catheter characterized by:

a plastic tube body (72) having a proximal end and a distal end;

a first transmission line conductor comprising a metal plating (69) on an outside of said plastic tube body;

at least one second conductor (73, 75) interiorly embedded in the plastic tube body; and

said at least one electrode (71) comprising a metal plating of a pattern on said outside of said plastic tube body (72), said first transmission line conductor (71) and said at least one second conductor (73, 75) electrically connected to said at least one electrode.

17. An electrical catheter in accordance with claim 16, wherein said at least one second conductor (73) comprises a metal plating on an outside of a second plastic tube (74) having a diameter smaller than a diameter of said plastic tube body (72).

18. An electrical catheter in accordance with claim 17, further comprising a third conductor (75) interiorly embedded in the second plastic tube (74), said third conductor electrically connected to said at least one electrode (80).

19. In a catheter for electrical heating, wherein a catheter transmission line having a proximal end and a distal end, is connected at the proximal end to a source of electrical power and at the distal end to an at least one electrode, said at least one electrode in operation immersed in a lossy medium, said catheter characterized by:

a variable impedance coating (28, 29) deposited on a surface of the at least one electrode (26, 25) for shaping an electric field in the lossy medium outside of said at least one electrode.

20. A catheter for electrical heating in accordance with claim 19, wherein said variable impedance coating (28, 29) comprises a resistive coating of a varying thickness deposited on a metallic substrate (26, 25).

21. A catheter for electrical heating in accordance with claim 19, wherein said variable impedance coating (28, 29) comprises a dielectric coating of a varying thickness deposited on a metallic substrate (26, 25).

22. A catheter for electrical heating in accordance with claim 19, further comprising an electrical impedance coating (30) located in the gap and electrically interacting with said at least one electrode (25 and 26).

23. A tri-axial transmission line comprising:

a first plastic tube (72) plated on an outside with a first coating of metal (69);

a second plastic tube (74) plated on an outside with a second coating of metal 73, an outside diameter of said second plastic tube with said second coating of metal being no greater than an inside diameter of said first plastic tube;

a center conductor (75) located along an axis of said second plastic tube (74), said second plastic tube (74) located inside of said first plastic tube (72), forming a transmission line whereby said first coating (69) of metal is a first conductor, said second coating (73) of metal is a second conductor, and said center conductor (75) is a third conductor.

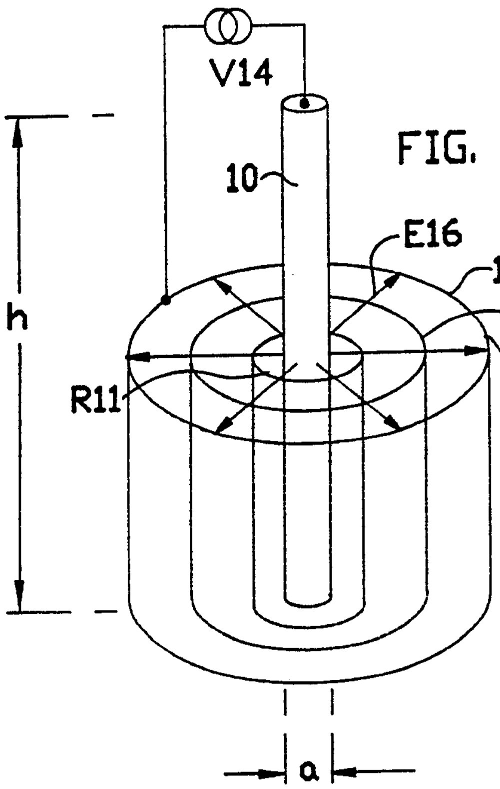


FIG. 1A

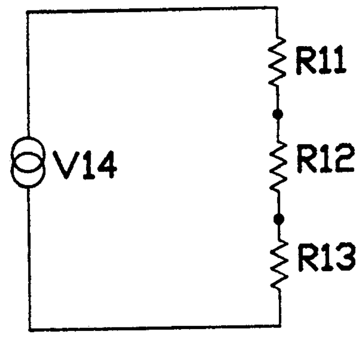
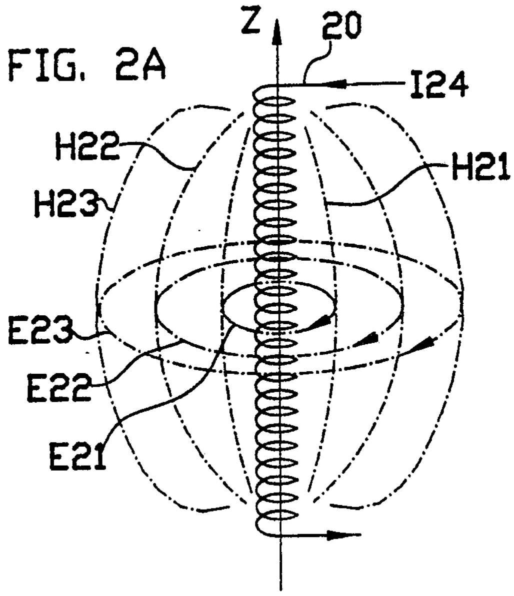


FIG. 1B

FIG. 2A



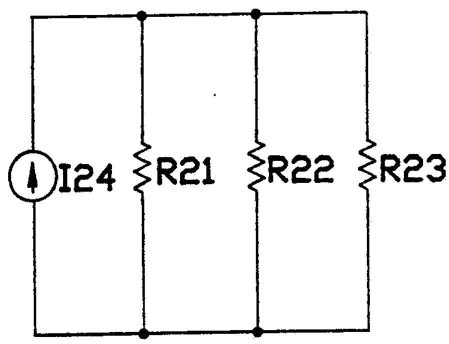


FIG. 2B

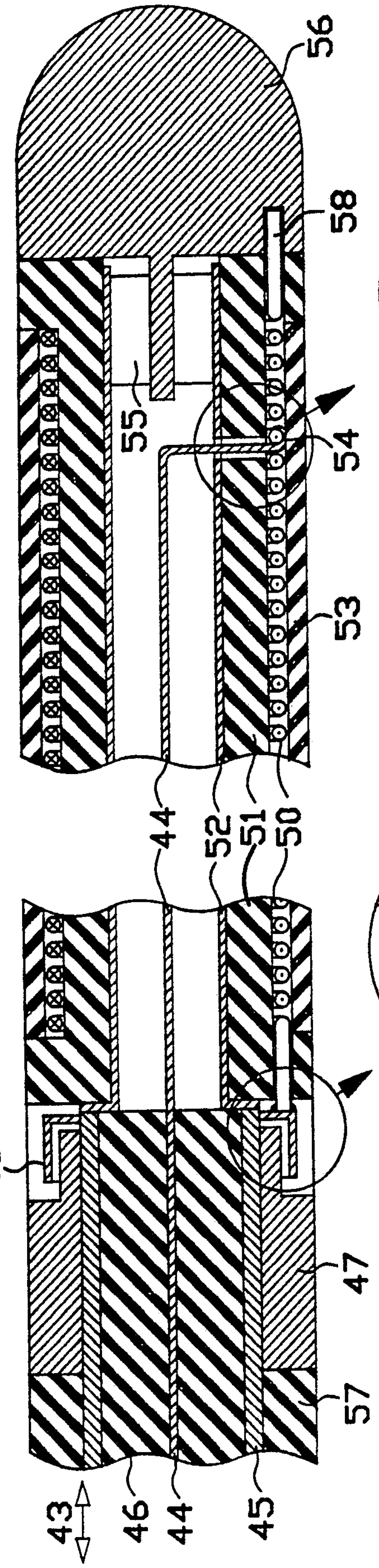


FIG. 3

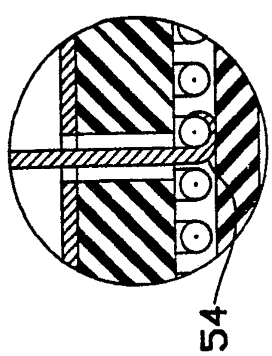


FIG. 3B

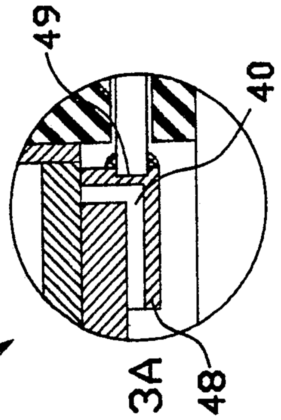


FIG. 3A

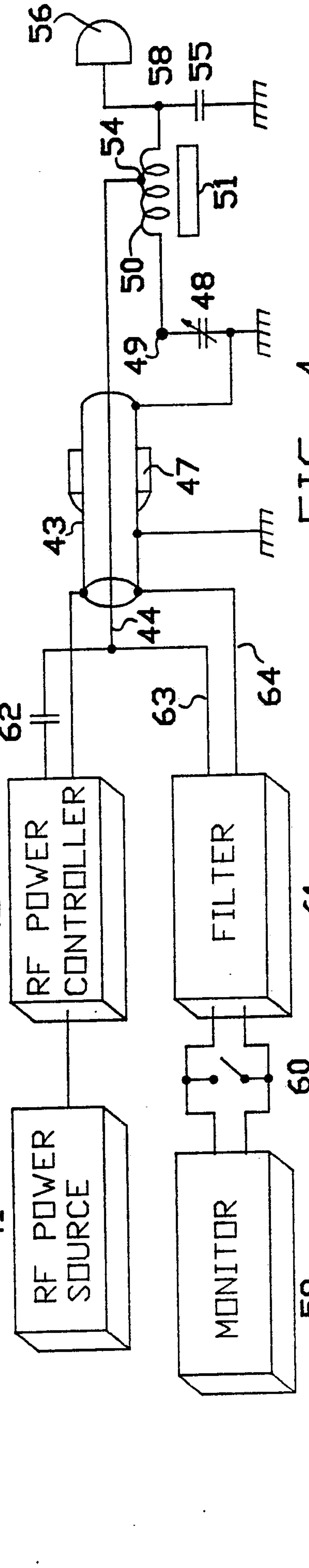


FIG. 4

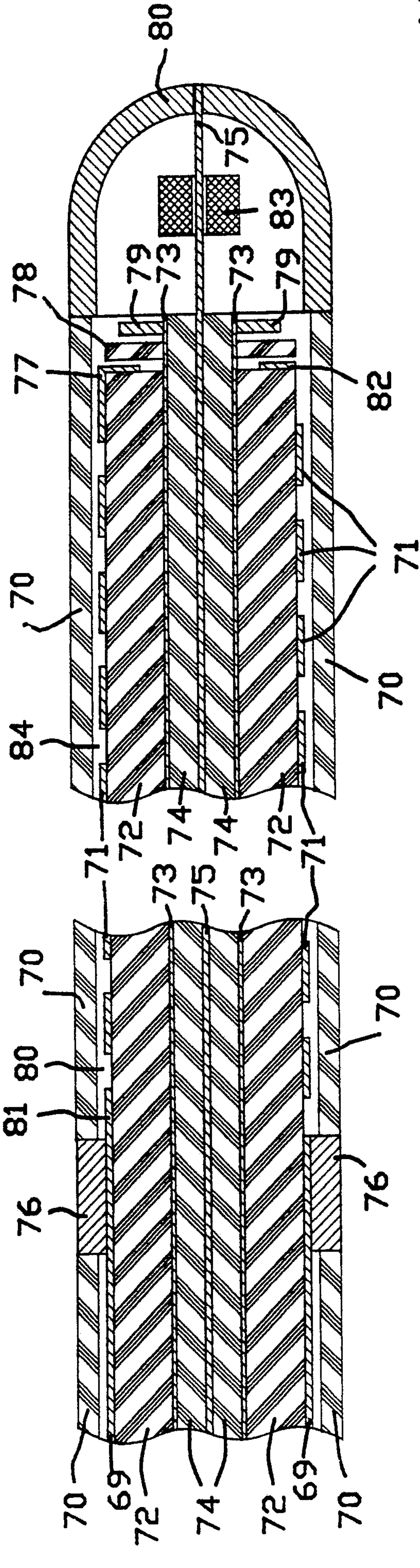

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FIG. 5

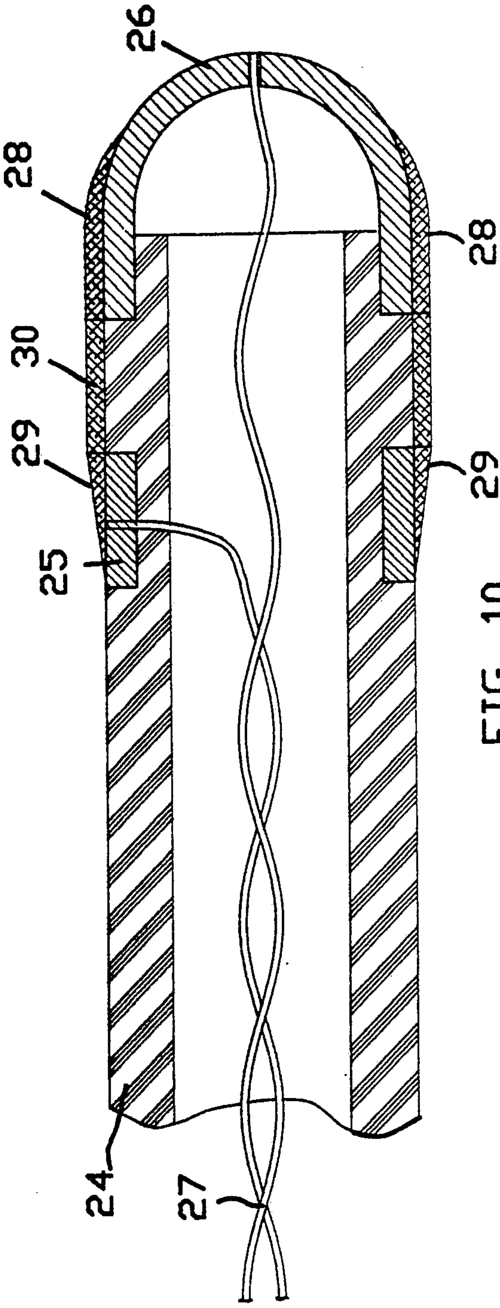
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FIG. 10

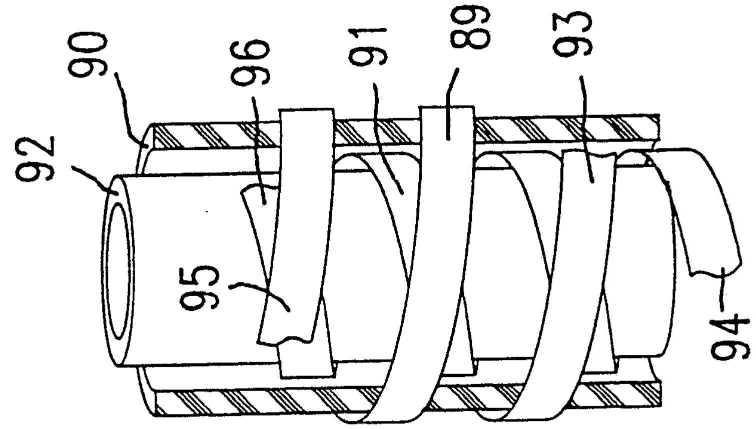

FIG. 9

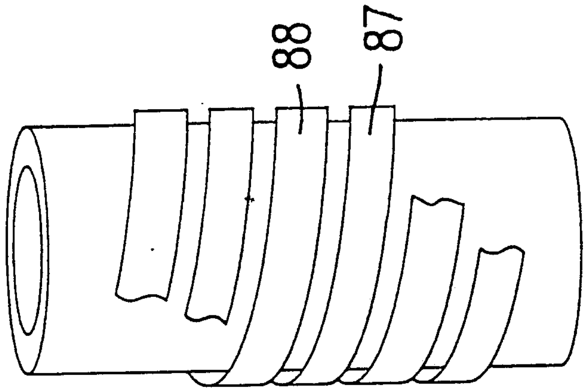

FIG. 8

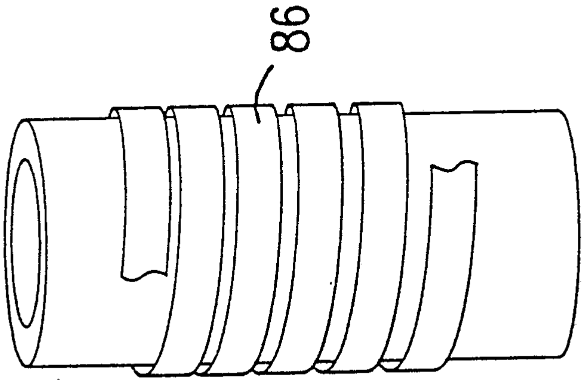

FIG. 7

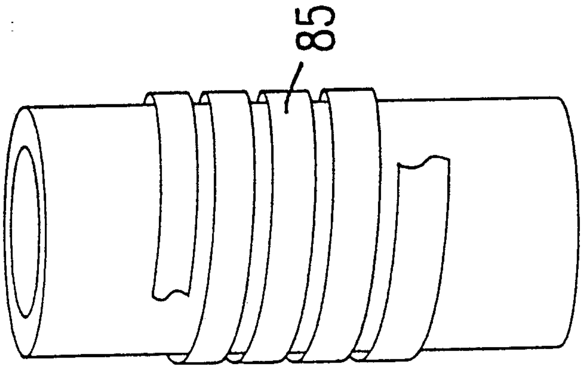

FIG. 6

DRAWING REFERENCE SIGNS

a	radius of antenna 10
E16	electric field
E_{21}, E_{22} and E_{23}	electric field
h	height of antenna 10
H_{21}, H_{22} and H_{23}	magnetic field lines
I24	RF current
R11, R12, R13	series resistances
R21, R22, R23	parallel resistances
V14	RF potential
z	axis
10	applicator antenna
15	remote boundary
20	helix
24	catheter tube
25	proximal ring electrode
26	distal tip electrode
27	twisted pair transmission line
28,29	control coatings
30	gap coating
40	capacitive impedance space
41	RF power source
42	controller
43	coaxial line
44	center conductor
45	shield
46	dielectric
47	proximal monitoring electrode
48	variable tuning capacitor
49	proximal end terminal
50	helix
51	core
52	metallized coating
53	PTFE sleeve
54	feed terminal
55	bypass capacitor
56	distal monitoring electrode
57	insulating sleeve
58	distal end terminal
59	monitor
60	switch
61	low-pass filter
62	capacitor
63,64	lines
69	shield
70	dielectric cover tube
71	helix
72	plastic tube
73	inner conductor
74	smaller plastic tube
75	center wire
76	proximal monitoring electrode
77	distal end terminal
78	dielectric disk
79	metal disk
80	distal monitoring electrode
81	proximal end terminal
82	plated disk
83	ferrite bead
84	gap between turns
85	helical strip, variable width
86	helical strip, variable gap
87,88	bifilar helices
89	helix
90	plastic sleeve
91	helix
92	plastic tube
93,94	proximal end terminals
95,96	distal end terminals

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US89/05179

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5) A61B 5/0402, A61N 1/00
U.S. CL. 128/642, 128/401, 128/786,128/804, 606/33,174/105R

II FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	128/784/786/804/401/642 174/ 105R 600/12 606/33

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No [13]
A	US,A, 4,154,246 (LEVEEN) 15 May 1979, See entire document	1-11
X / A	US, A, 4,583,556 (HINES) 22 April 1986, See entire document.	14-18,23 / 1-11
A	US, A, 4,641,649 (WALINSKY) 10 February See entire document	1-11
Y / A	US,A, 4,700,716 (KASEVICH) 20 October 1987, See entire document.	19-22 / 1-11
A	US, S, 4,785,815 (COHEN) 22 November 1988 See entire document.	1-11
A	SU, A, 1,266,548 (MOSE) 30 October 1986 See entire document	1-11
A	DD, A, 249,631 (GUNTHER) 16 September 1987 See entire document.	1-11
X	US, A, 4,658,836 (TURNER) 21 April 1987 See entire document	14-16
X / Y P	US, A, 4,841,988 (FETTER) 27 June 1989 See entire document	13 / 12

* Special categories of cited documents: [10]

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

"E" earlier document but 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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20 APRIL 1990	15 MAR 1990
International Searching Authority	**Signature of Authorized Officer**
ISA/US	LEE S. COHEN-SDJ-4-25-90

Form PCT/ISA/210 (second sheet) (Rev.11-87)

SUBSTITUTE SHEET

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

X P / Y	US, A, 4,825,880 (STAUFFER) 02 May 1989, See entire document.	13 / 12
Y	GB, A, 2,122,092 (JAMES) 11 January 1984 See entire document.	19-22

V.☐ **OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE** [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.☐ Claim numbers , because they relate to subject matter [12] not required to be searched by this Authority, namely:

2.☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3.☐ Claim numbers ________, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI.☒ **OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING** [2]

This International Searching Authority found multiple inventions in this international application as follows:

I Ablation System: claims 1-11
II Heating Catheter System: claims 12-15
III Electrical Catheters: claims 16-18
IV Heating Catheter: claims 19-22
V Transmission line: claims 23

1.☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2.☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3.☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4.☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

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