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(54) **SYSTEMS AND METHODS FOR
CONTROLLING TISSUE ABLATION USING
MULTIPLE TEMPERATURE SENSING
ELEMENTS**

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Aug. 8, 1994, now abandoned, and which is a con-
tinuation-in-part of application No. 08/287,192, filed
on Aug. 8, 1994, now abandoned.

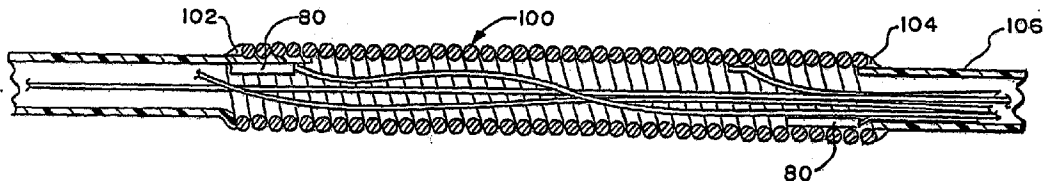
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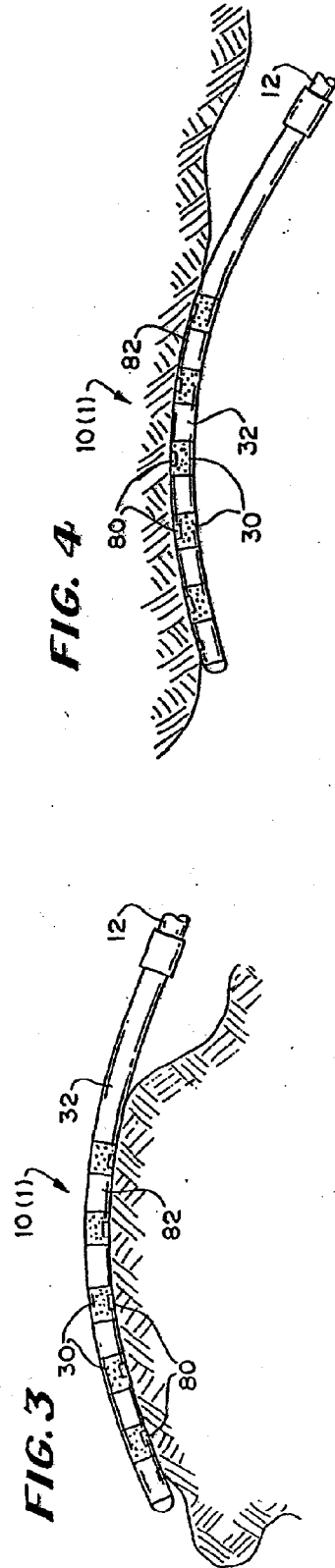
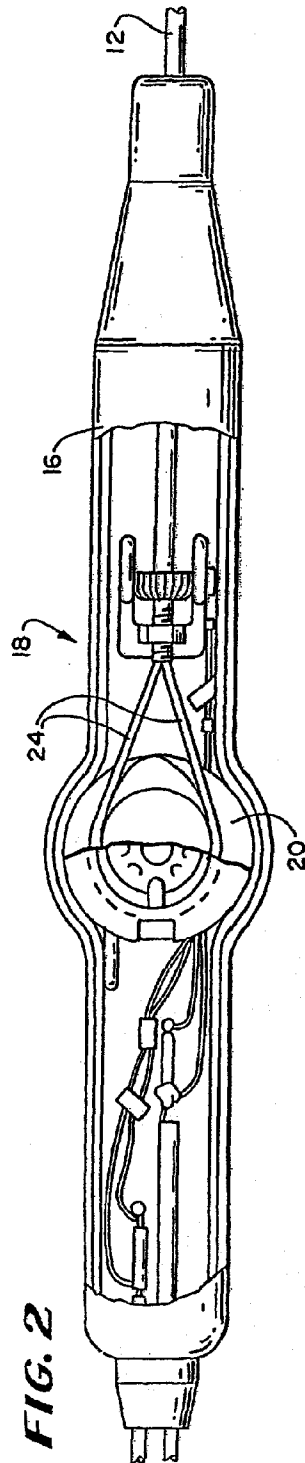
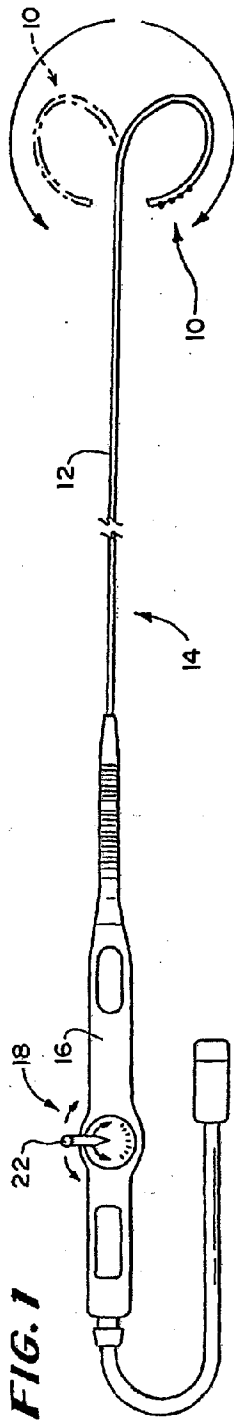
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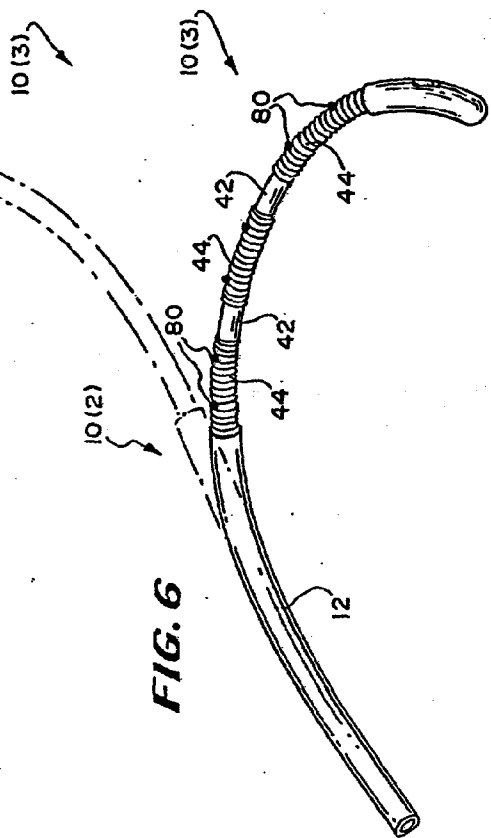
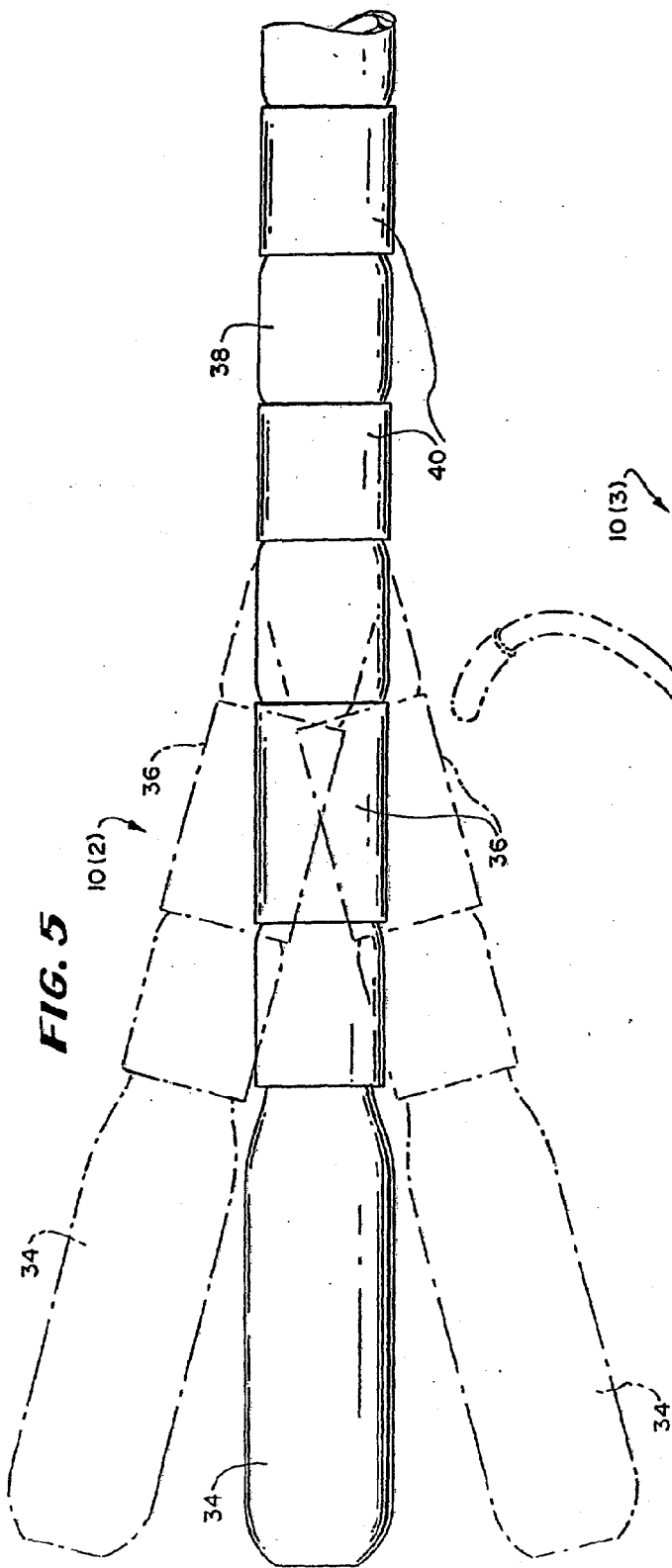
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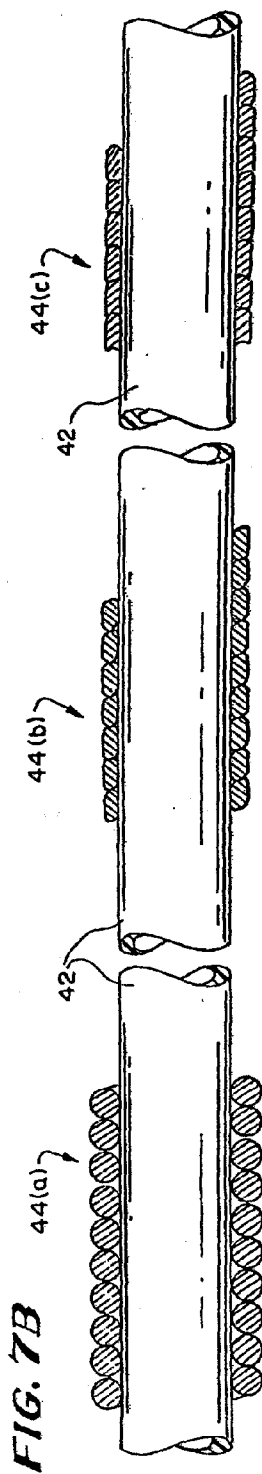
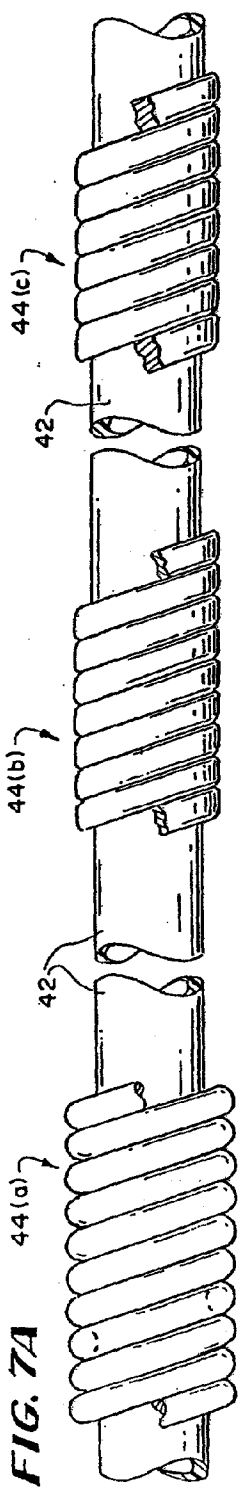
(57) **ABSTRACT**

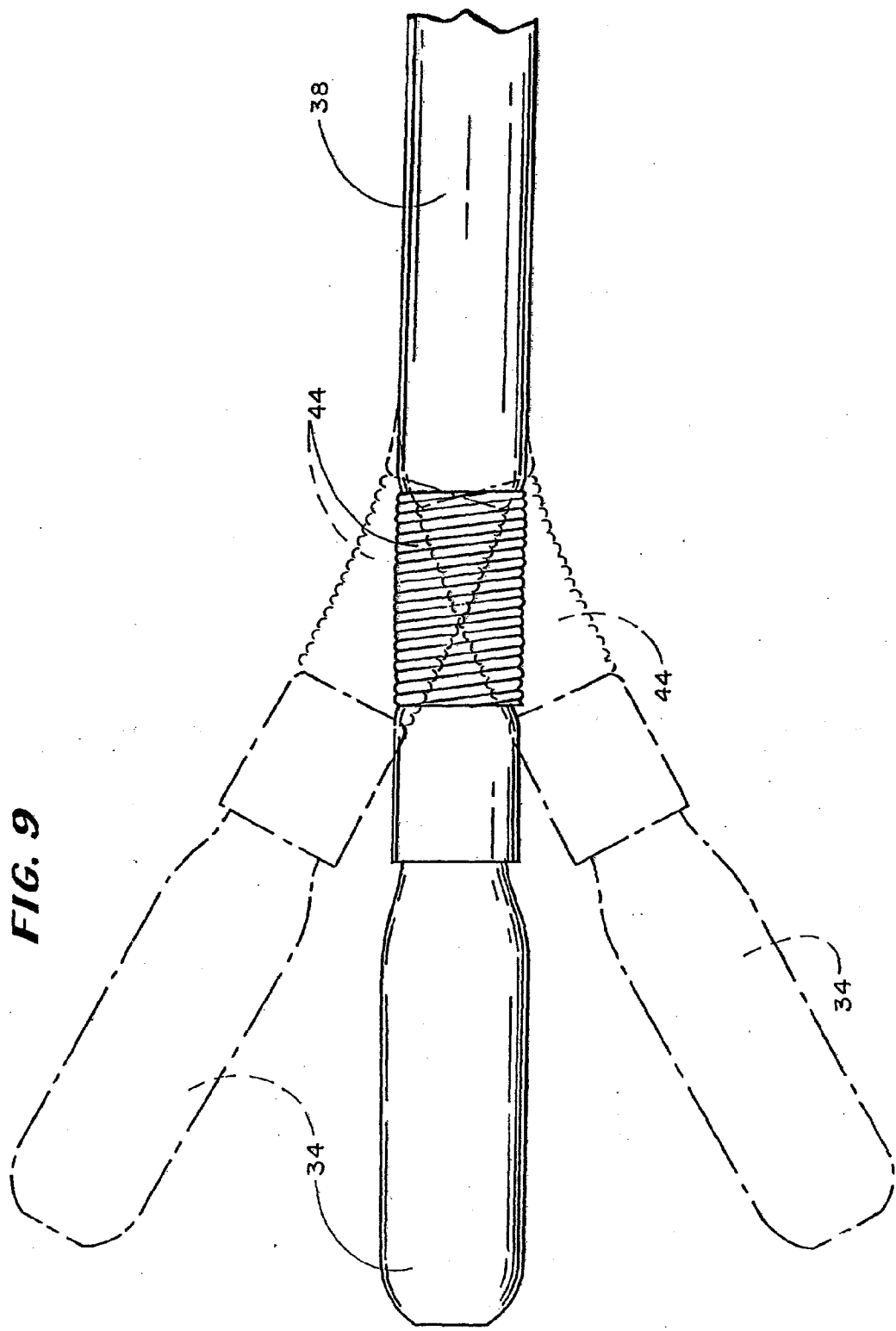
Systems and associated methods place a temperature sensing
element in an "edge region" between an energy transmitting
electrode and a non-electrically conducting support body,
where higher temperatures are likely to exist. Reliable
temperature sensing, which is sensitive to variations in
temperatures along the electrode, results.

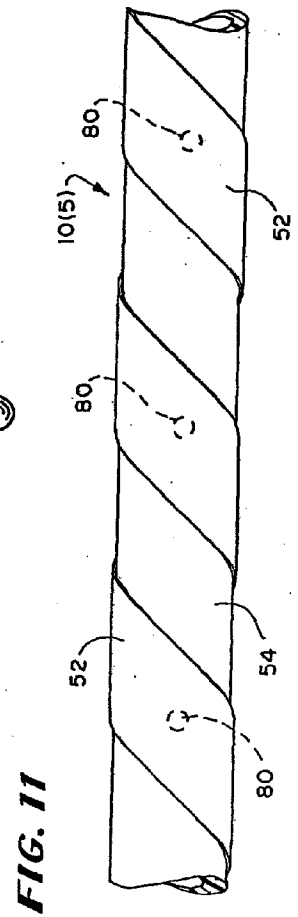
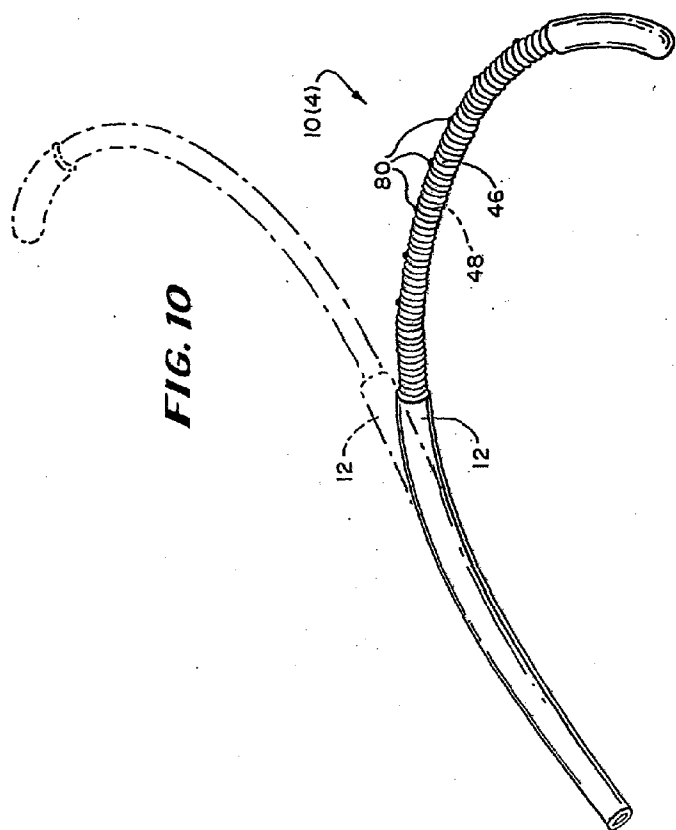


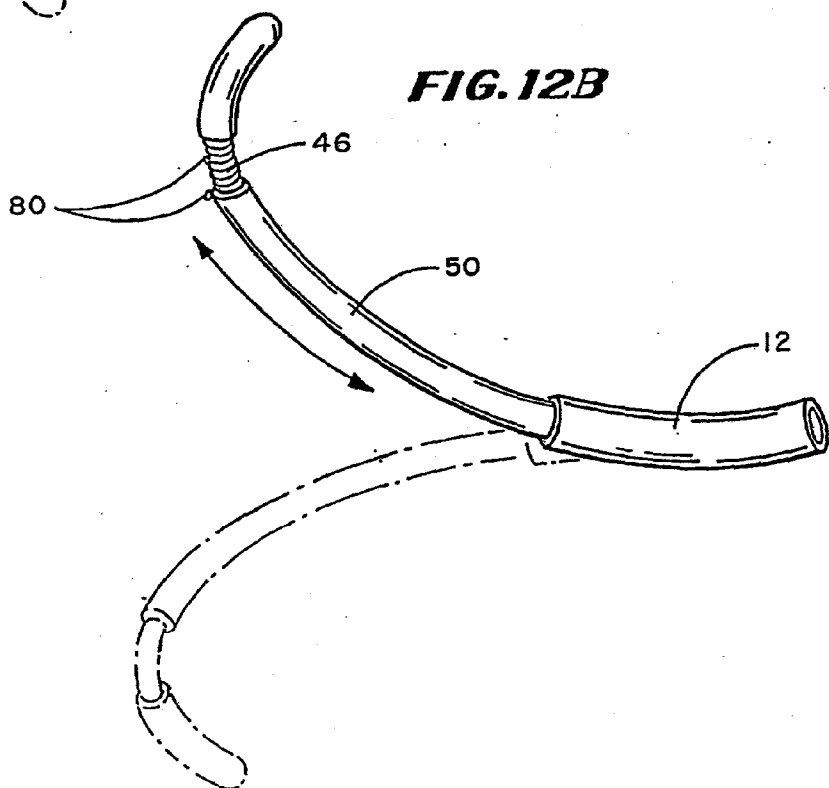
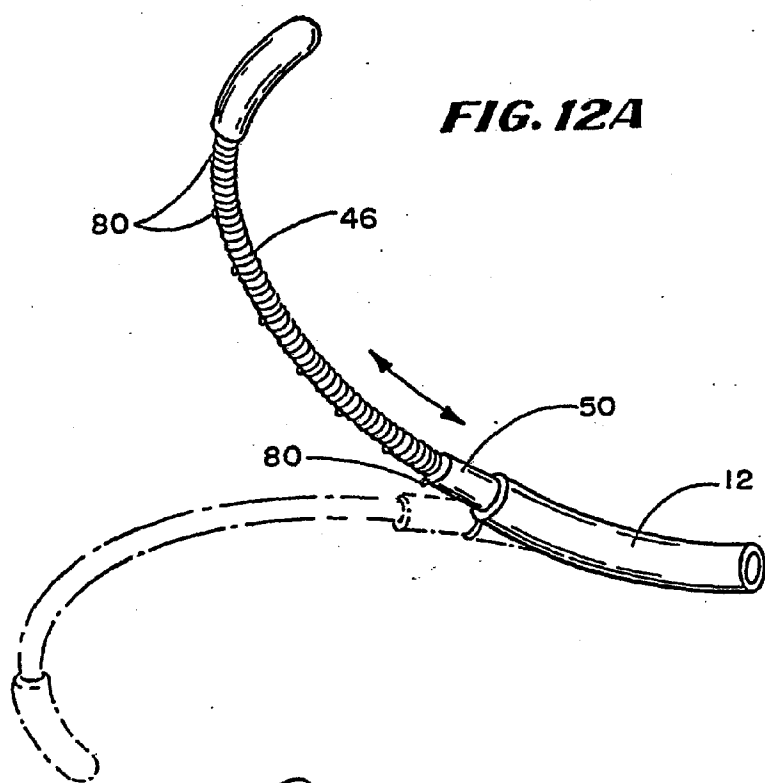












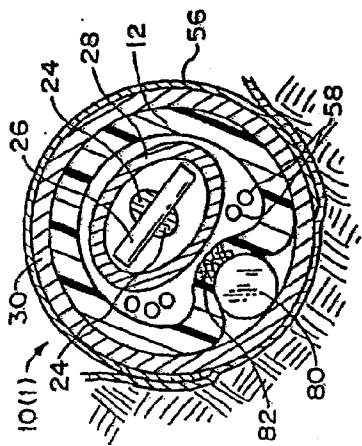


FIG. 13

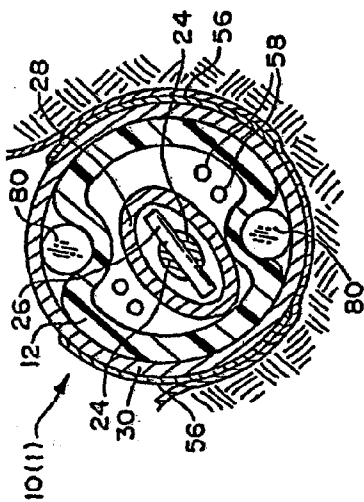


FIG. 14

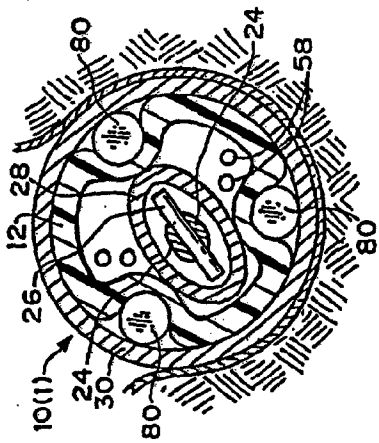


FIG. 15

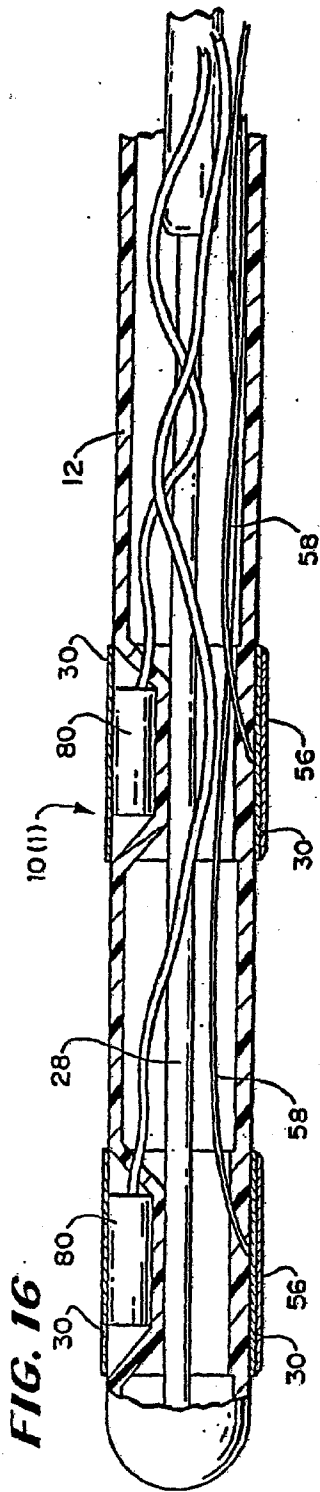


FIG. 16

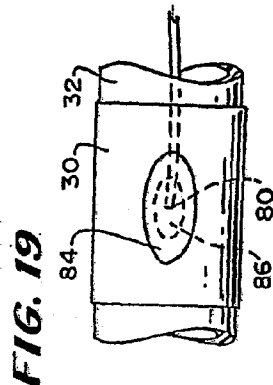
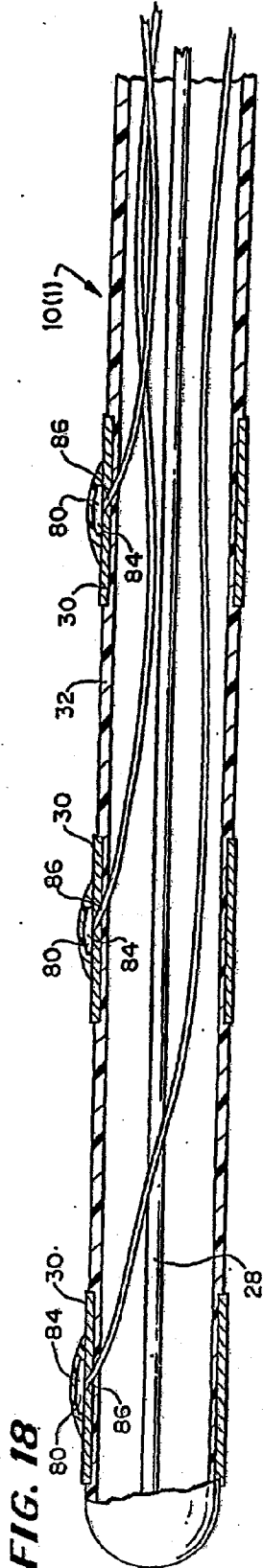
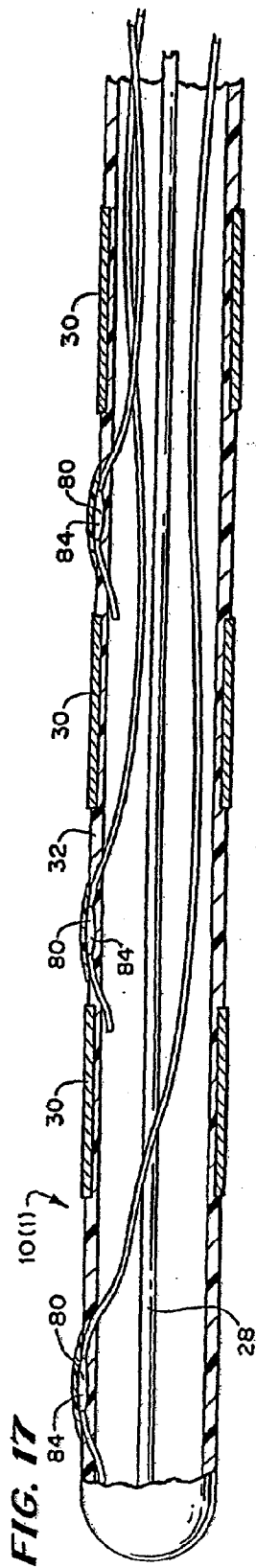


FIG. 20

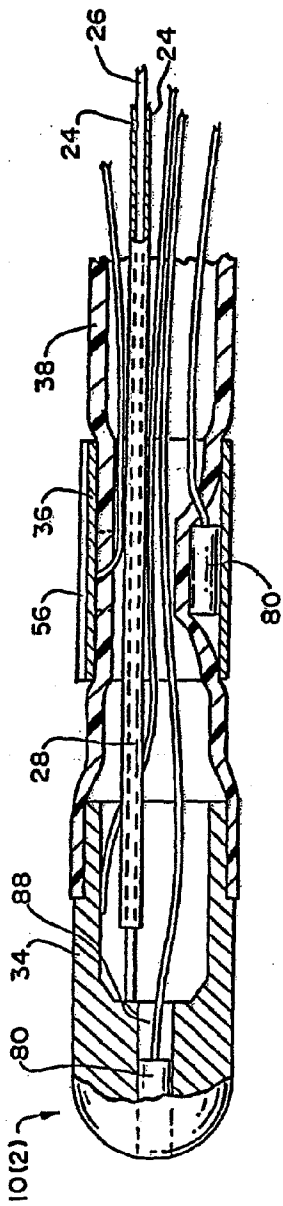
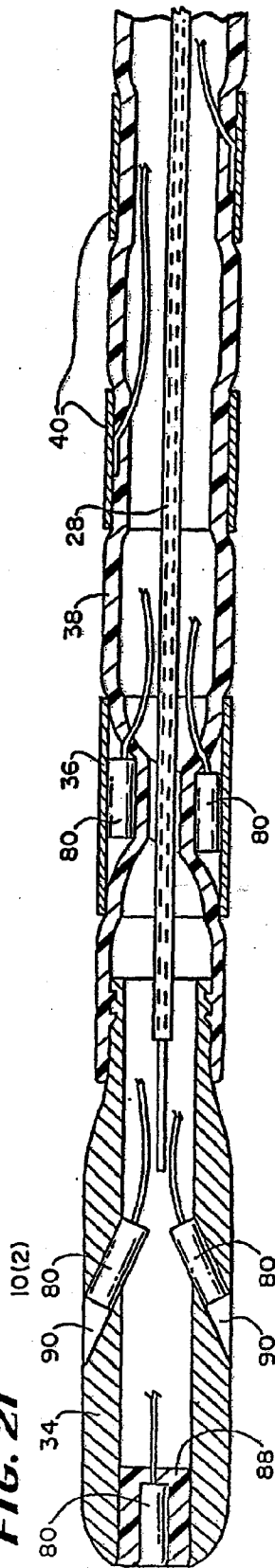
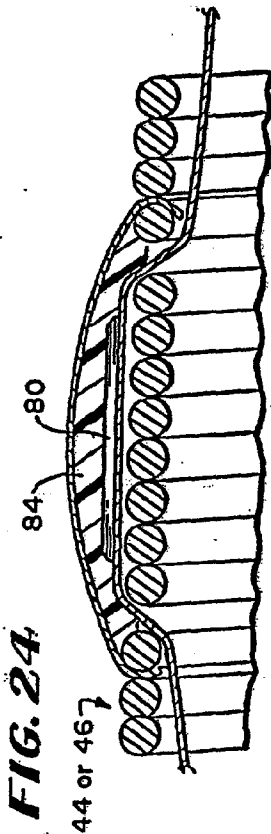
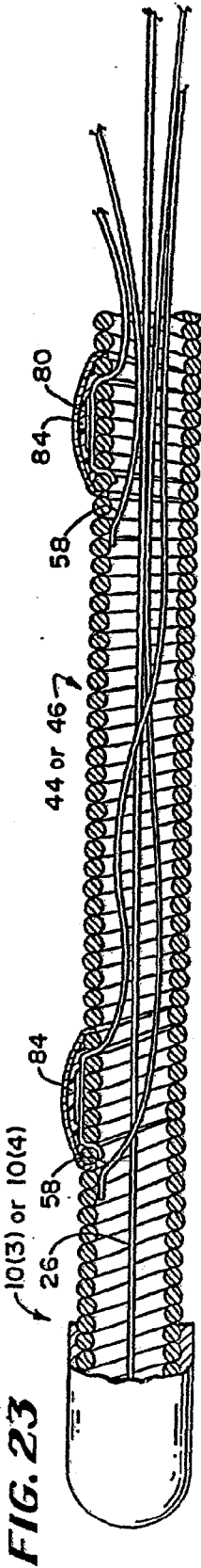
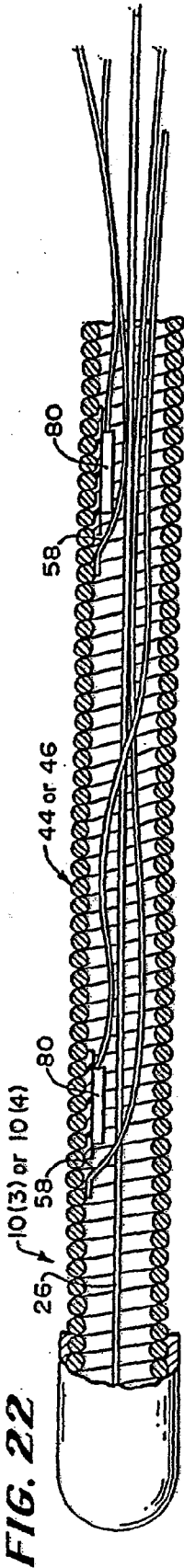
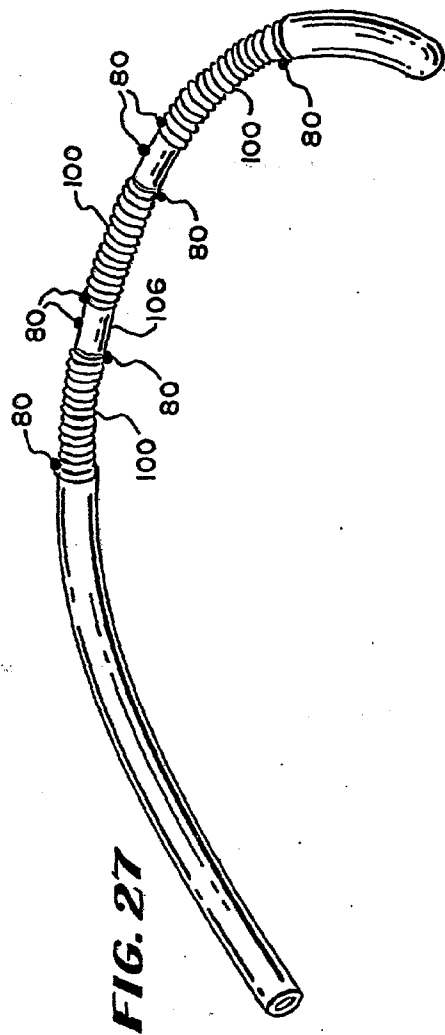
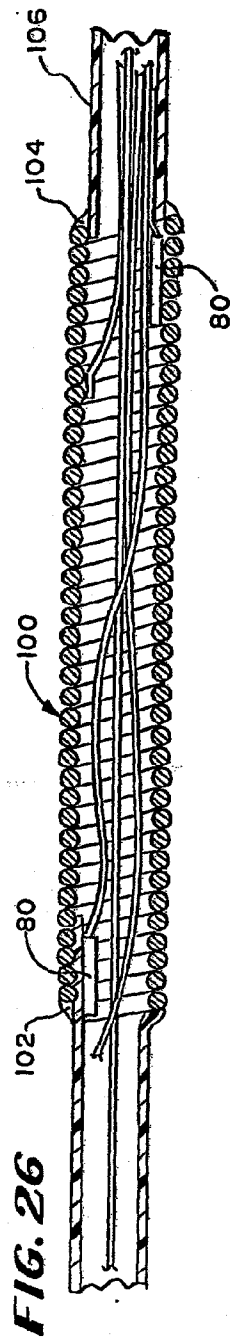
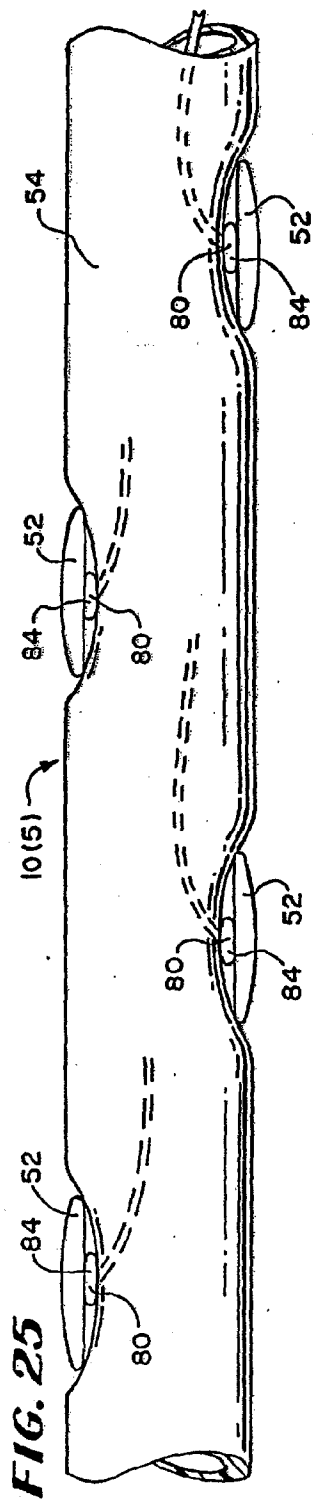
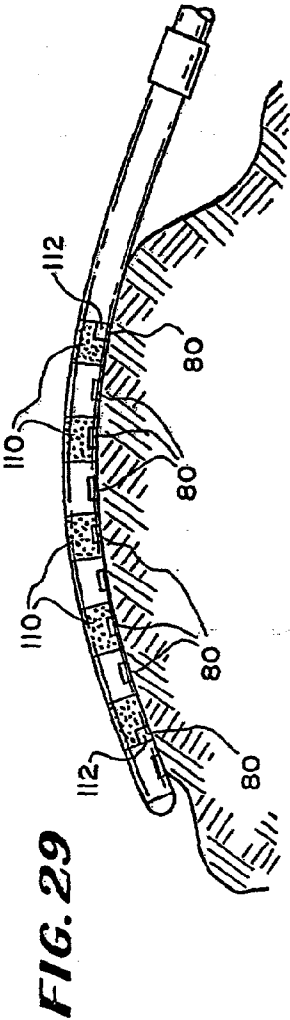
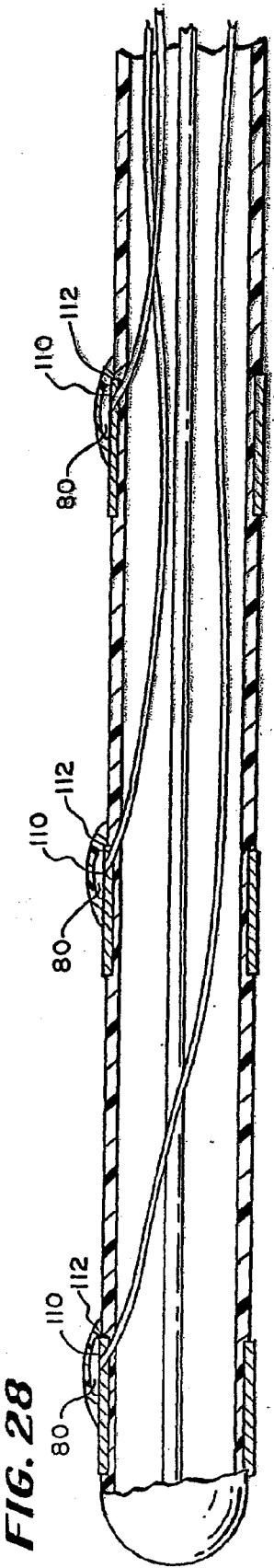


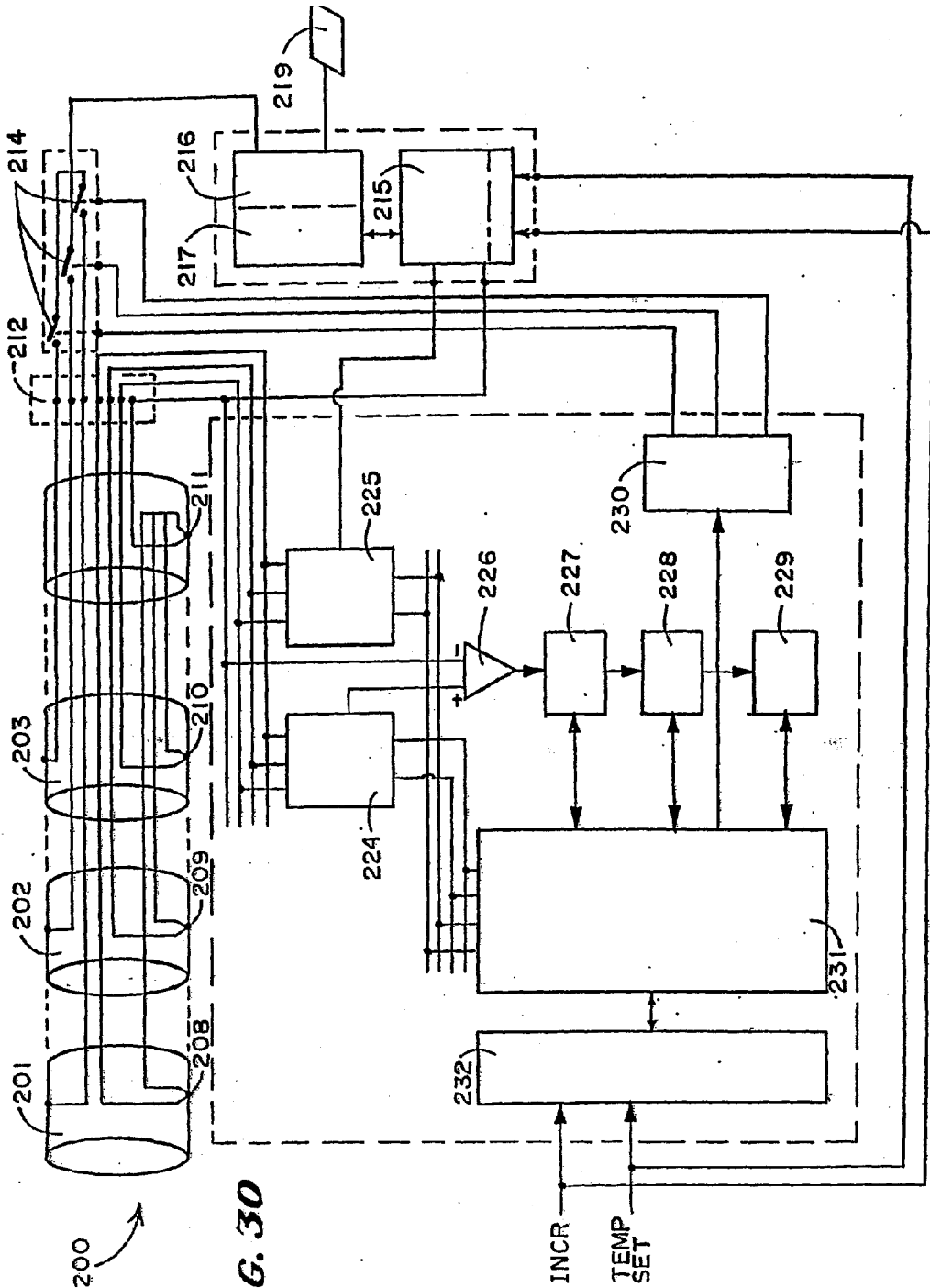
FIG. 21











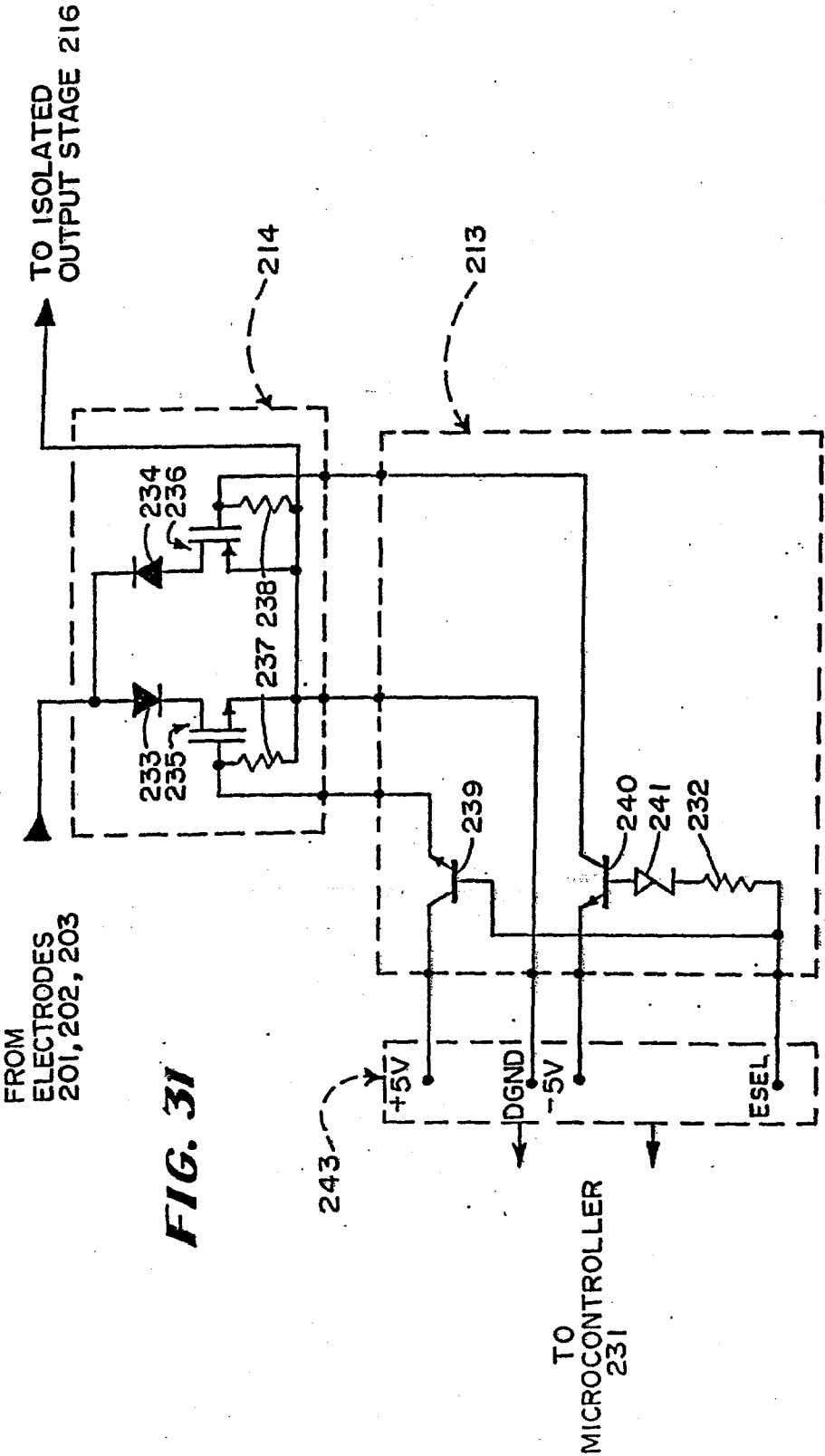


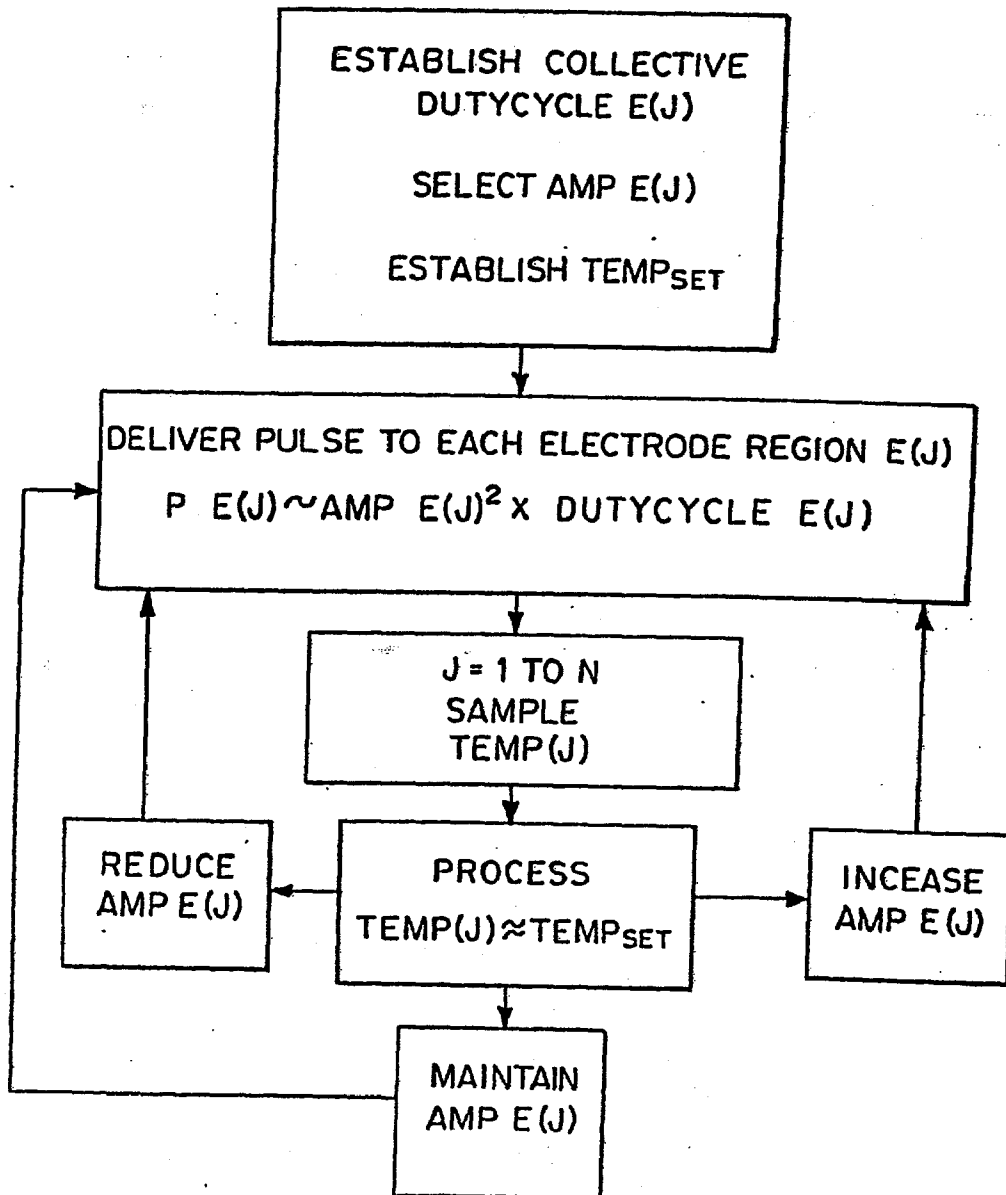
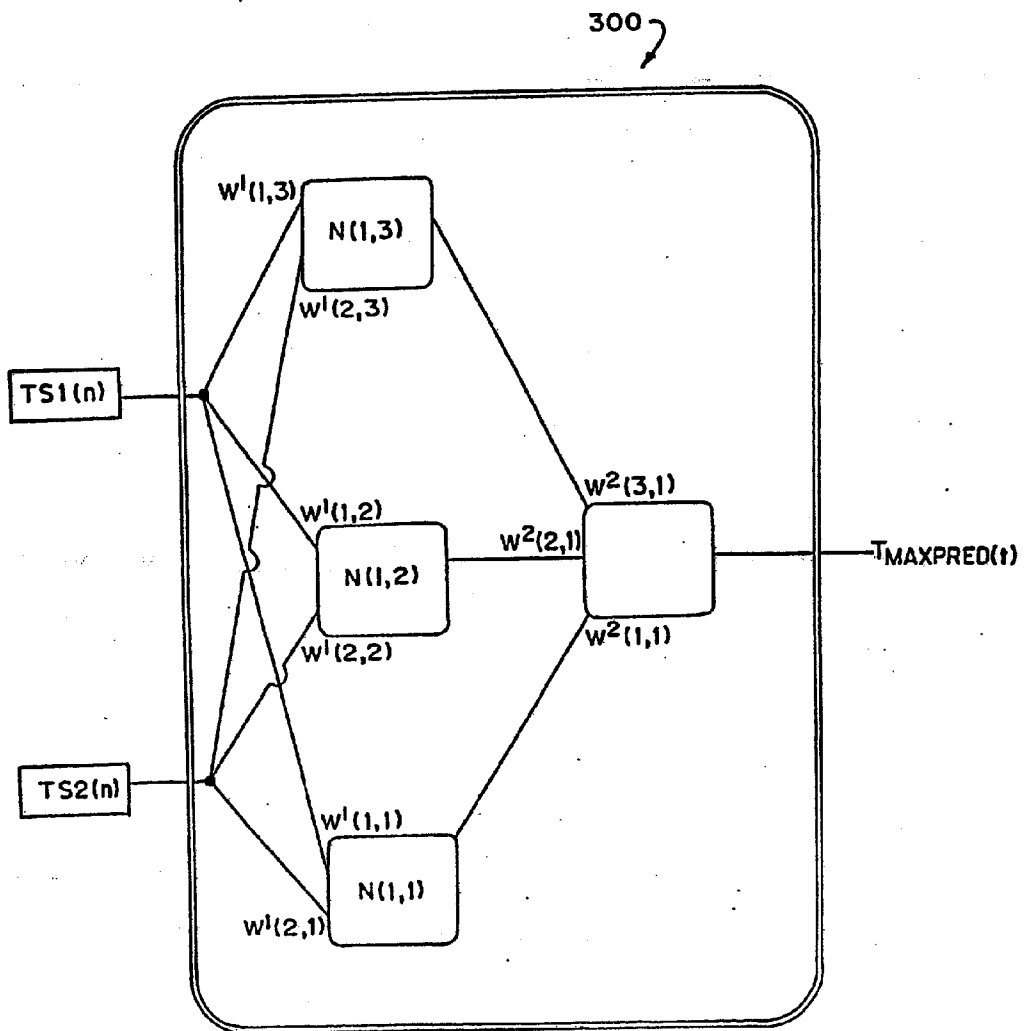
FIG. 32

FIG. 33



SYSTEMS AND METHODS FOR CONTROLLING TISSUE ABLATION USING MULTIPLE TEMPERATURE SENSING ELEMENTS

RELATED CASES

[0001] This case is a continuation-in-part of U.S. application Ser. No. 08/286,930, filed Aug. 8, 1994, entitled "Systems and Methods for Controlling Tissue Ablation Using Multiple Temperature Sensing Elements." This case is also a continuation-in-part of U.S. application Ser. No. 08/287,192, filed Aug. 8, 1994, entitled "Systems and Methods for Forming Elongated Lesion Patterns in Body Tissue Using Straight of Curvilinear Electrode Elements."

FIELD OF THE INVENTION

[0002] The invention relates to systems and methods for ablating myocardial tissue for the treatment of cardiac conditions.

BACKGROUND OF THE INVENTION

[0003] Physicians make use of catheters today in medical procedures to gain access into interior regions of the body to ablate targeted tissue areas. It is important for the physician to be able to precisely locate the catheter and control its emission of energy within the body during tissue ablation procedures.

[0004] For example, in electrophysiological therapy, ablation is used to treat cardiac rhythm disturbances.

[0005] During these procedures, a physician steers a catheter through a main vein or artery into the interior region of the heart that is to be treated. The physician places an ablating element carried on the catheter near the cardiac tissue that is to be ablated. The physician directs energy from the ablating element to ablate the tissue and form a lesion.

[0006] In electrophysiological therapy, there is a growing need for ablating elements capable of providing lesions in heart tissue having different geometries.

[0007] For example, it is believed the treatment of atrial fibrillation requires the formation of long, thin lesions of different curvilinear shapes in heart tissue. Such long, thin lesion patterns require the deployment within the heart of flexible ablating elements having multiple ablating regions. The formation of these lesions by ablation can provide the same therapeutic benefits that the complex suture patterns that the surgical maze procedure presently provides, but without invasive, open heart surgery.

[0008] As another example, it is believed that the treatment of atrial flutter and ventricular tachycardia requires the formation of relatively large and deep lesions patterns in heart tissue. Merely providing "bigger" electrodes does not meet this need. Catheters carrying large electrodes are difficult to introduce into the heart and difficult to deploy in intimate contact with heart tissue. However, by distributing the larger ablating mass required for these electrodes among separate, multiple electrodes spaced apart along a flexible body, these difficulties can be overcome.

[0009] With larger and/or longer multiple electrode elements comes the demand for more precise control of the ablating process. The delivery of ablating energy must be governed to avoid incidences of tissue damage and coagu-

lum formation. The delivery of ablating energy must also be carefully controlled to assure the formation of uniform and continuous lesions, without hot spots and gaps forming in the ablated tissue.

SUMMARY OF THE INVENTION

[0010] The invention provides device and methods for ablating body tissue. The devices and methods include an electrode carried by a support element made of a material that does not conduct tissue ablation energy. The electrode is made of a material that transmits ablation energy. The electrode has at least one edge that contacts the material of the support element. The devices and methods also include at least one temperature sensing element carried by the electrode adjacent to the at least one edge.

[0011] Another aspect of the invention provides systems and methods for controlling the ablation of body tissue. The systems and methods supply ablation energy to an electrode carried by a support element made of a material that does not conduct ablation energy. The electrode has at least one edge that contacts the material of the support element. The systems and methods sense temperature with at least one temperature sensing element carried by the electrode adjacent to the at least one edge. The systems and methods control the supply of ablation energy based, at least in part, upon temperature sensed by the at least one temperature sensing element.

[0012] The invention places the temperature sensing element in an "edge region" between an electrode and a non-electrically conducting support body. The edge region presents an area where electrical conductivity is discontinuous. The resulting rise in current density in this region generates localized increases in power densities, and, therefore, it is a region where higher temperatures are likely to exist. The invention places the temperature sensing element just where localized "hot spots" are to be expected. Reliable temperature sensing, which is sensitive to variations in temperatures along the electrode, results.

[0013] Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1, is a view of a probe that carries a flexible ablating element having multiple temperature sensing elements;

[0015] FIG. 2 is an enlarged view of the handle of the probe shown in FIG. 1, with portions broken away and in section, showing the steering mechanism for flexing the ablating element;

[0016] FIGS. 3 and 4 show the flexure of the ablating element against different tissue surface contours;

[0017] FIG. 5 is a side view of a flexible ablating element comprising a rigid tip electrode element and a rigid body electrode segment;

[0018] FIG. 6 is a perspective view of a segmented flexible electrode element, in which each electrode segment comprises a wrapped wire coil;

[0019] FIGS. 7A/B are, respectively, side and side section views of different wrapped wire coils comprising flexible electrode elements;

[0020] FIGS. 8A/B are, respectively, a side and side section view of multiple wrapped wire coils comprising a flexible electrode element;

[0021] FIG. 9 is a side view of a flexible ablating element comprising a rigid tip electrode element and a flexible body electrode segment;

[0022] FIG. 10 is a perspective view of a continuous flexible electrode element comprising a wrapped wire coil;

[0023] FIG. 11 is a perspective view of a continuous flexible electrode element comprising a wrapped ribbon;

[0024] FIGS. 12A/B are views of a flexible ablating element comprising a wrapped wire coil including a movable sheath for changing the impedance of the coil and the ablating surface area when in use;

[0025] FIG. 13 is an end section view of an ablating electrode element carrying one temperature sensing element;

[0026] FIG. 14 is an end section view of an ablating electrode element carrying two temperature sensing elements;

[0027] FIG. 15 is an end section view of an ablating electrode element carrying three temperature sensing elements;

[0028] FIG. 16 is a side section view of a flexible ablating element comprising multiple rigid electrode elements, showing one manner of mounting at least one temperature sensing element beneath the electrode elements;

[0029] FIG. 17 is a side section view of a flexible ablating element comprising multiple rigid electrode elements, showing another manner of mounting at least one temperature sensing element between adjacent electrode elements;

[0030] FIG. 18 is a side section view of a flexible ablating element comprising multiple rigid ablating elements, showing another manner of mounting at least one temperature sensing element on the electrode elements;

[0031] FIG. 19 is an enlarged top view of the mounting the temperature sensing element on the rigid electrode shown in FIG. 18;

[0032] FIGS. 20 and 21 are side section views of the mounting of temperature sensing elements on the ablating element shown in FIG. 5;

[0033] FIG. 22 is a view of a flexible ablating element comprising a continuous wrapped coil, showing one manner of mounting temperature sensing elements along the length of the coil;

[0034] FIG. 23 is a view of a flexible ablating element comprising a continuous wrapped coil, showing another manner of mounting temperature sensing elements along the length of the coil;

[0035] FIG. 24 is an enlarged view of the mounting of the temperature sensing element on the coil electrode shown in FIG. 23;

[0036] FIG. 25 is a view of a flexible ablating element comprising a continuous wrapped ribbon, showing a manner of mounting temperature sensing elements along the length of the ribbon;

[0037] FIG. 26 is a side section view of a large electrode with temperature sensing elements positioned at its edges;

[0038] FIG. 27 is a perspective view of an array of long electrodes with temperature sensing elements positioned at each long electrode edge and in between each long electrode;

[0039] FIG. 28 is a side section view of an array of short electrodes, each one carrying a temperature sensing element at one edge;

[0040] FIG. 29 is a side view of an array of short electrodes, with temperature sensing elements positioned at the edge of the short electrodes beginning and ending the array, as well in the middle of each intermediate short electrode;

[0041] FIGS. 30 and 31 are schematic views of a system for controlling the application of ablating energy to multiple electrodes using multiple temperature sensing inputs;

[0042] FIG. 32 is a schematic flow chart showing an implementation of the temperature feedback controller shown in FIGS. 30 and 31, using individual amplitude control with collective duty cycle control; and

[0043] FIG. 33 is a schematic view of a neural network predictor, which receives as input the temperatures sensed by multiple sensing elements at a given electrode region and outputs a predicted temperature of the hottest tissue region.

[0044] The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0045] This Specification discloses multiple electrode structures that embody aspects of the invention. This Specification also discloses tissue ablation systems and techniques using multiple temperature sensing elements that embody other aspects of the invention. The illustrated and preferred embodiments discuss these structures, systems, and techniques in the context of catheter-based cardiac ablation. That is because these structures, systems, and techniques are well suited for use in the field of cardiac ablation.

[0046] Still, it should be appreciated that the invention is applicable for use in other tissue ablation applications. For example, the various aspects of the invention have application in procedures for ablating tissue in the prostate, brain, gall bladder, uterus, and other regions of the body, using systems that are not necessarily catheter-based.

[0047] I. Flexible Ablating Elements

[0048] FIG. 1 shows a flexible ablating element 10 for making lesions within the heart.

[0049] The element 10 is carried at the distal end of a catheter body 12 of an ablating probe 14. The ablating probe 14 includes a handle 16 at the proximal end of the catheter body 12. The handle 16 and catheter body 12 carry a steering mechanism 18 for selectively bending or flexing the ablating element 10 in two opposite directions, as the arrows in FIG. 1 show.

[0050] The steering mechanism 18 can vary. In the illustrated embodiment (see FIG. 2), the steering mechanism 18 includes a rotating cam wheel 20 with an external steering lever 22 (see FIG. 1). As FIG. 2 shows, the cam wheel 20 holds the proximal ends of right and left steering wires 24. The wires 24 pass through the catheter body 12 and connect to the left and right sides of a resilient bendable wire or spring 26 (best shown in FIGS. 20 and 23) enclosed within a tube 28 inside the ablating element 10.

[0051] Further details of this and other types of steering mechanisms for the ablating element 10 are shown in Lundquist and Thompson U.S. Pat. No. 5,254,088, which is incorporated into this Specification by reference.

[0052] As FIG. 1 shows, forward movement of the steering lever 22 flexes or curves the ablating element 10 down. Rearward movement of the steering lever 22 flexes or curves the ablating element 10 up.

[0053] Various access techniques can be used to introduce the probe 14 into the desired region of the heart. For example, to enter the right atrium, the physician can direct the probe 14 through a conventional vascular introducer through the femoral vein. For entry into the left atrium, the physician can direct the probe 14 through a conventional vascular introducer retrograde through the aortic and mitral valves.

[0054] Alternatively, the physician can use the delivery system shown in pending U.S. application Ser. No. 08/033,641, filed Mar. 16, 1993, and entitled "Systems and Methods Using Guide Sheaths for Introducing, Deploying, and Stabilizing Cardiac Mapping and Ablation Probes."

[0055] The physician can verify intimate contact between the element 10 and heart tissue using conventional pacing and sensing techniques. Once the physician establishes intimate contact with tissue in the desired heart region, the physician applies ablating energy to the element 10. The type of ablating energy delivered to the element 10 can vary. In the illustrated and preferred embodiment, the element 10 transmits electromagnetic radio frequency energy.

[0056] The flexible ablating element 10 can be configured in various ways. With these different configurations, the flexible ablating element can form lesions of different characteristics, from long and thin to large and deep in shape.

[0057] a. Segmented, Rigid Electrode Elements

[0058] FIGS. 3 and 4 show one implementation of a preferred type of flexible ablating element, designated 10(1). The element 10(1) includes multiple, generally rigid electrode elements 30 arranged in a spaced apart, segmented relationship upon a flexible body 32.

[0059] The flexible body 32 is made of a polymeric, electrically nonconductive material, like polyethylene or polyurethane. The body 32 carries within it the resilient bendable wire or spring with attached steering wires (best shown in FIGS. 20 and 23), so it can be flexed to assume various curvilinear shapes.

[0060] The segmented electrodes 30 comprise solid rings of conductive material, like platinum. The electrode rings 30 are pressure fitted about the body 32. The flexible portions of the body 32 between the rings 30 comprise electrically nonconductive regions.

[0061] The body 32 can be flexed between the spaced apart electrodes 30 to bring the electrode 30 into intimate contact along a curvilinear surface of the heart wall, whether the heart surface curves outward (as FIG. 3 shows) or curves inward (as FIG. 4 shows).

[0062] FIG. 5 shows an implementation of another preferred type of a flexible ablating element, of the same general style as element 10(1), designated 10(2). Element 10(2) includes two generally rigid electrode elements 34 and 36 arranged in a spaced apart relationship at the distal tip of a flexible body 38. The flexible body 38 is made of electrically insulating material, like polyurethane and PEBAX® plastic material. The body 38 carries one relatively large, rigid metal electrode 34 at its tip, which comprises a body of electrically conductive material, like platinum. The body 38 also carries another rigid electrode 36, which comprises a solid ring 36 of electrically conductive material, like platinum, pressure fitted about the body 38. As FIG. 5 shows, the ablating element 10(2) can also include one or more conventional sensing ring electrodes 40 proximally spaced from the ablating ring electrode 36. The sensing ring electrodes 40 serve to sense electrical events in heart tissue to aid the physician in locating the appropriate ablation site.

[0063] As shown in phantom lines in FIG. 5, the flexible body 38, when pressed against the endocardial surface targeted for ablation, bends to place the sides of the rigid electrodes 34 and 36 in intimate contact against the particular contour of the surface. The flexible nature of the ablating element 10(2) can be further augmented by the inclusion of the resilient bendable wire or spring 26 within it (best shown in FIG. 20). In this embodiment, the steering wires 24 connect to the left and right sides of the bendable wire 26. The opposite ends of the steering wires 24 connect to a steering mechanism of the type previously described and shown in FIG. 2. In this arrangement, the physician can use the steering mechanism to remotely flex the electrodes 34 and 36 in the manner shown in FIG. 5.

[0064] Preferably, as FIG. 20 shows, the steering wires 24 are secured to the bendable wire 26 near its distal end, where the bendable wire 26 is itself secured to the tip electrode 34. Bending of the wire 26 thereby directly translates into significant relative flexing of the distal end of the catheter body 38, which carries the electrodes 34 and 36.

[0065] Alternatively, the region between the electrodes 34 and 36 can be stiff, not flexible. In this arrangement, pressing the 34 and 36 against tissue brings the tissue into conformance about the electrodes 34 and 36.

[0066] The generally rigid, segmented electrodes 30 in element 10(1) and 34/36 in element 10(2) can be operated, at the physician's choice, either in a unipolar ablation mode or in a bipolar mode. In the unipolar mode, ablating energy is emitted between one or more the electrodes 30 (in element 10(1)) or electrodes 34/36 (in element 10(2)) and an external indifferent electrode. In the bipolar mode, ablating energy is emitted between two of the electrodes 30 (in element 10(1)) or the electrodes 34 and 36 (in element 10(2)), requiring no external indifferent electrode.

[0067] B. Flexible Electrode Elements

[0068] FIG. 6 shows an implementation of another preferred style of a flexible ablating element, designated 10(3).

The element **10(3)**, unlike elements **10(1)** and **10(2)**, includes generally flexible electrode elements **44** carried on a likewise flexible body **42**.

[**0069**] The flexible body **42** is made of a polymeric, electrically nonconductive material, like polyethylene or polyurethane, as the flexible body of elements **10(1)** and **10(2)**. The body **42** also preferably carries within it the resilient bendable wire or spring **26** with attached steering wires **24** (best shown in **FIGS. 29 and 30**), so it can be flexed to assumed various curvilinear shapes, as **FIG. 6** shows.

[**0070**] The body **32** carries on its exterior surface an array of segmented, generally flexible electrodes **44** comprising spaced apart lengths of closely wound, spiral coils. The coil electrodes **44** are made of electrically conducting material, like copper alloy, platinum, or stainless steel. The electrically conducting material of the coil electrode **44** can be further coated with platinum-iridium or gold to improve its conduction properties and biocompatibility.

[**0071**] The coils **44** can be made of generally cylindrical wire, as the coil **44(a)** shown in **FIGS. 7A/B**. Alternatively, the wire forming the coils **44** can be non-circular in cross section. The wire, for example, have a polygon or rectangular shape, as the coil **44(b)** shown in **FIGS. 7A/B**. The wire can also have a configuration in which adjacent turns of the coil nest together, as the coil **44(c)** shown in **FIGS. 7A/B**. Coils **44(b)** and **44(c)** in **FIGS. 7A/B** present a virtually planar tissue-contacting surface, which emulates the tissue surface contact of the generally rigid electrode **30** shown in **FIGS. 3 and 4**. However, unlike the electrode **30**, the coils **44(b)** and **44(c)**, as well as the cylindrical coil **44(a)**, are each inherently flexible and thereby better able to conform to the surface contour of the tissue.

[**0072**] In another alternative arrangement, each coil **44** can comprise multiple, counter wound layers of wire, as the coil **44(d)** shown in **FIGS. 8A/B**. This enhances the energy emitting capacity of the coil **44(d)**, without significantly detracting from its inherent flexible nature. The multiple layer coil **44(d)** structure can also be formed by using a braided wire material (not shown).

[**0073**] An alternative arrangement (shown in **FIG. 9**) uses the generally rigid tip electrode **34** (like that in element **10(2)**, shown in **FIG. 5**) in combination with a generally flexible electrode segment **44** made of a closely wound coil. Of course, the tip electrode **34**, too, could comprise a generally flexible electrode structure made of a closely wound coil. It should be apparent by now that many combinations of rigid and flexible electrode structures can be used in creating a flexible ablating element.

[**0074**] Furthermore, the inherent flexible nature of a coiled electrode structures **44** makes possible the construction of a flexible ablating element (designated **10(4)** in **FIG. 10**) comprising a continuous elongated flexible electrode **46** carried by a flexible body **48**. The continuous flexible electrode **46** comprises an elongated, closely wound, spiral coil of electrically conducting material, like copper alloy, platinum, or stainless steel, wrapped about the flexible body. For better adherence, an undercoating of nickel or titanium can be applied to the underlying flexible body. The continuous coil electrode **46** can be arranged and configured in the same fashion as the segmented coil electrodes **44** shown in **FIGS. 7A/B and 8A/B**.

[**0075**] The continuous coil electrode **46** is flexible and flexes with the underlying body **48**, as **FIG. 10** shows. It can be easily placed and maintained in intimate contact against heart tissue. The continuous flexible coil structure shown in **FIG. 10** therefore makes possible a longer, flexible ablating element.

[**0076**] In an alternative arrangement (shown in **FIGS. 12A/B**), the elongated coil electrode **46** can include a sliding sheath **50** made of an electrically nonconducting material, like polyamide a stylet (not shown) attached to the sheath **50** extends through the associated catheter body **12** to a sliding control lever carried on the probe handle **16** (also not shown). Moving the sheath **50** varies the impedance of the coil electrode **46**. It also changes the surface area of the element **10(4)**.

[**0077**] Further details of this embodiment can be found in copending U.S. patent application Ser. No. 08/137,576, filed Oct. 15, 1993, and entitled "Helically Wound Radio Frequency Emitting Electrodes for Creating Lesions in Body Tissue," which is incorporated into this Specification by reference.

[**0078**] **FIG. 11** shows another implementation of a generally flexible element, designated element **10(5)**. The element **10(5)** comprises a ribbon **52** of electrically conductive material wrapped about a flexible body **54**. The ribbon **52** forms a continuous, inherently flexible electrode element.

[**0079**] Alternatively, the flexible electrodes can be applied on the flexible body by coating the body with a conductive material, like platinum-iridium or gold, using conventional coating techniques or an ion beam assisted deposition (IBAD) process. For better adherence, an undercoating of nickel or titanium can be applied. The electrode coating can be applied either as discrete, closely spaced segments (to create an element like **10(3)**) or in a single elongated section (to create an element like **10(4)** or **10(5)**).

[**0080**] The flexible electrodes of elements **10(1)** to **10(5)** can be operated, at the physician's choice, either in a unipolar ablation mode or in a bipolar mode.

[**0081**] The ablating elements **10(1)** to **10(5)**, as described above, are infinitely versatile in meeting diverse tissue ablation criteria.

[**0082**] For example, the ablating elements **10(1)** and **10(3)** to **10(5)** can be conditioned to form different configurations of elongated (i.e., generally long and thin) lesion patterns. These elongated lesion patterns can be continuous and extend along a straight line or along a curve. Alternatively, these elongated lesion patterns can be segmented, or interrupted, and extend along a straight line or along a curve. Elongated lesion patterns can be used to treat, for example, atrial fibrillation.

[**0083**] Alternatively, the ablating elements **10(1)** to **10(5)** can be conditioned to form larger and deeper lesions in the heart. These lesion large and deep lesion patterns can be used to treat, for example, atrial flutter or ventricular tachycardia.

[**0084**] Various ways to control the characteristics of lesions formed by the ablating elements **10(1)** to **10(5)** are disclosed in detail in U.S. application Ser. No. 08/287,192, filed Aug. 8, 1994, entitled "Systems and Methods for

Forming Elongated Lesion Patterns in Body Tissue Using Straight or Curvilinear Electrode Elements.”

[0085] II. Temperature Sensing

[0086] In the illustrated and preferred embodiments, each flexible ablating element 10(1) to 10(5) carries at least one and, preferably, at least two, temperature sensing element 80. The multiple temperature sensing elements 80 measure temperatures along the length of the element 10.

[0087] a. Temperature Sensing with Rigid Electrode Elements

[0088] In the segmented element 10(1) (see FIGS. 3 and 4), each electrode segment 30 preferably carries at least one temperature sensing element 80. In this configuration, the sensing elements 80 are preferably located in an aligned relationship along one side of each segmented electrode 30, as FIGS. 3 and 4 show.

[0089] The body 32 preferably carries a fluoroscopic marker (like the stripe 82 shown in FIGS. 3 and 4) for orientation purposes. The stripe 82 can be made of a material, like tungsten or barium sulfate, which is extruded into the tubing 12. The extruded stripe can be fully enclosed by the tubing or it can be extruded on the outer diameter of the tubing making it visible to the eye. FIG. 5 shows the marker in the wall of the tubing 12. An alternative embodiment can be a fluoro-opaque wire like platinum or gold which can be extruded into the tubing wall. Yet another embodiment is to affix a marker in the inner diameter of the tubing during manufacturing.

[0090] The sensing elements 80 can be on the same side as the fluoroscopic marker 82 (as FIGS. 3 and 4 show), or on the opposite side, as long as the physician is aware of the relative position of them. Aided by the marker 82, the physician orients the element 10(1) so that the temperature sensing elements 80 contact the targeted tissue.

[0091] Alternatively, or in combination with the fluoroscopic marker 82, the sensing elements 80 can be consistently located on the inside or outside surface of element 10(1) when flexed in a given direction, up or down. For example, as FIG. 3 shows, when the element 10(1) is flexed to the down, the sensing elements 80 are exposed on the inside surface of the element 10(1). As FIG. 4 shows, when the element 10(1) flexed to the upward, the sensing elements 80 are exposed on the outside surface of the element 10(1).

[0092] Each electrode segment 30 can carry more than a single temperature sensing element 80. As FIGS. 13 to 15 show, each electrode segment 30 can carry one, two, three, or more circumferentially spaced apart temperature sensing elements 80. The presence of multiple temperature sensing elements 80 on a single electrode segment 30 gives the physician greater latitude in positioning the ablating element 10(1), while still providing temperature monitoring.

[0093] As FIG. 13 shows, a mask coating 56 of an electrically and thermally insulating material can also be applied to the side of the single sensor-segmented electrode 30 opposite to the temperature sensing element 80, which, in use, is exposed to the blood pool. As FIG. 14 shows, the mask coating 56 lies between the two sensors 80 on the bi-directional segmented electrode 30. The mask coating 56 minimizes the convective cooling effects of the blood pool upon the regions of the electrode segment 80 that are

exposed to it. The temperature condition sensed by the element 80 facing tissue is thereby more accurate. When more than two temperature sensors 80 are used on a given electrode segment 30, masking becomes less advisable, as it reduces the effective surface of the electrode segment 30 available for tissue contact and ablation.

[0094] The temperature sensing elements 80 can comprise thermistors or thermocouples. When using thermocouples as the sensing elements 80, a reference or cold junction thermocouple must be employed, which is exposed to a known temperature condition. The reference thermocouple can be placed within the temperature processing element itself. Alternatively, the reference thermocouple can be placed within the handle 18 of the catheter probe 14.

[0095] Further details regarding the use of thermocouples can be found in a publication available from Omega, entitled *Temperature*, pages T-7 to T-18. Furthermore, details of the use of multiple thermocouples as temperature sensing elements 80 in tissue ablation can be found in copending patent application Ser. No. 08/286,937, filed Aug. 8, 1994, entitled “Systems and Methods for Sensing Temperature Within the Body.”

[0096] The sensing element or elements 80 can be attached on or near the segmented electrodes 30 in various way.

[0097] For example, as FIG. 16 shows for the element 10(1), each sensing element 80 is sandwiched between the exterior of the flexible body 32 and the underside of the associated rigid electrode segment 30. In the illustrated embodiment, the sensing elements 80 comprise thermistors. The body 32 is flexible enough to fit the sensing element 80 beneath the electrode segment 30. The plastic memory of the body 32 maintains sufficient pressure against the temperature sensing element 80 to establish good thermal conductive contact between it and the electrode segment 30.

[0098] In an alternative embodiment (as FIG. 17 shows), the temperature sensing element 80 is located between adjacent electrode segments 30. In this arrangement, each sensing element 80 is threaded through the flexible body 32 between adjacent electrode segments 30. In the illustrated embodiment, the temperature sensing elements 80 comprise thermocouples. When the sensing element 80 comprises a thermocouple, an epoxy material 46, such as Master Bond Polymer System EP32HT (Master Bond Inc., Hackensack, N.J.), encapsulates the thermocouple junction 84, securing it to the flexible body 32. Alternatively, the thermocouple junction 84 can be coated in a thin layer of polytetrafluoroethylene (PTFE) material. When used in thicknesses of less than about 0.002 inch, these materials have the sufficient insulating properties to electrically insulate the thermocouple junction 84 from the associated electrode segment 30, while providing sufficient thermally conducting properties to establish thermal conductive contact with electrode segment 30. The use of such materials typically will not be necessary when thermistors are used, because conventional thermistors are already encapsulated in an electrically insulating and thermally conducting material.

[0099] In another alternative embodiment (as FIGS. 18 and 19 show), the temperature sensing element 80 physically projects through an opening 86 in each electrode segment 30. As in the embodiment shown in FIG. 17, the

sensing elements **80** comprise thermocouples, and a thermally conducting and electrically insulating epoxy material encapsulates the thermocouple junction **84**, securing it within the opening **86**.

[0100] It should be appreciated that some sensing elements **80** can be carried by the electrode segments **30**, while other sensing elements **80** can be carried between the element segments **30**. Many combinations of sensing element locations are possible, depending upon particular requirements of the ablating procedure.

[0101] In the element **10(2)** (see FIG. 20), each electrode segment **34** and **36** carries at least one temperature sensing element **80**. In the illustrated embodiment, the sensing element **80** comprises a thermistor.

[0102] The tip electrode segment **34** carries a temperature sensing element **80** within a cavity **88** drilled along its axis. The body electrode segment **36** also carries at least one temperature sensing element **80**, which is sandwiched beneath the electrode segment **36** and the flexible body **38**, in the manner previously described and shown in FIG. 16. The sensing element **80** in the electrode segment **36** can be alternatively secured in the manners previously described and shown in FIGS. 17 and 18. Alternatively, as earlier described, the side of the electrode segment **36** opposite to the single sensing temperature element **80** can carry the mask coating **56**.

[0103] As shown in FIG. 21, either or both electrodes **34** and **36** of element **10(2)** can carry more than one temperature sensing element **80**. In this arrangement, the tip electrode **34** carries additional temperature sensing elements **80** in side cavities **90** that extend at angles radially from the axis of the electrode **34**. The body electrode segment **36** carries additional sensing elements **80** in the manner shown in FIGS. 14 and 15.

[0104] As the diameter of the electrodes **34** and **36** increases, the use of multiple temperature sensing elements **80** becomes more preferred. The multiple sensing elements **80** are circumferentially spaced to assure that at least one element **80** is in thermal conductive contact with the same tissue area as the associated electrode **34** or **36**.

[0105] B. Temperature Sensing with Flexible Electrode Elements

[0106] In the flexible electrode elements **10(3)** and **10(4)** (earlier shown in FIGS. 6 and 10), the multiple temperature sensing elements **80** are preferably located at or near the electrical connection points between the wires **58** and the coil electrode segments **44** or continuous coil electrode **46**, as FIGS. 22 and 23 best show. This location for the temperature sensing elements **80** is preferred because higher temperatures are typically encountered at these connection points along the coil electrode **44** or **46**.

[0107] As FIG. 22 shows, the sensing elements **80** can be secured to the inside surface of the coil electrode **44** or **46**. Alternatively, the sensing elements **80** can be sandwiched between the inside surface of the electrode **44** or **46** and an underlying flexible body, as FIGS. 15A/B show. In FIGS. 15A/B and 29, the sensing elements **80** comprise thermistors.

[0108] Alternatively, as FIGS. 23 and 24 show, the sensing elements **80** can be threaded up through the windings in

the coil electrode **44** or **46** to lay upon its exterior surface. In the illustrated embodiment, the sensing elements **80** comprise thermocouples, and the thermocouple junction **84** is encapsulated in an epoxy or PTFE coating, as previously described.

[0109] When the elongated electrode **46** includes a sliding sheath **50** see FIGS. 12A/B), the movable sheath **50** carries, in addition to the temperature sensing elements **80** spaced along the length of the coil electrode **56**, another temperature sensing element **80** at its distal end.

[0110] In the case of flexible electrode element **10(5)** (earlier shown in FIG. 11), the sensing elements **80** are sandwiched between the wrapped ribbon **52** and the underlying flexible body **54**, as FIG. 25 shows. In the illustrated embodiment, the sensing elements **80** comprise thermocouples having junctions **84** encapsulated in an electrically insulating and thermally conducting coating.

[0111] C. Location of Temperature Sensing Elements

[0112] The positioning of the temperature sensing elements **80** on the electrode elements is important for achieving reliable temperature sensing, particularly when the length of an individual electrode on the element **80** exceeds about 10 mm, or when the element **10** comprises arrays of shorter, segmented electrodes. Without proper placement of the temperature sensor elements **80** under these circumstances, variations in tissue temperature, and in particular the presence of "hot spots," can go undetected. Also, with predetermined placement of the temperature sensing elements, temperature gradients along the element **10** can be obtained for ablation control purposes.

[0113] Electrode elements having lengths exceeding about 10 mm will be called "long" electrodes, which is identified by the numeral **100** in FIG. 26. The elongated coil electrode **46** shown in FIG. 10 exemplifies a typical long electrode. FIGS. 6 and 9 also show an arrangement in which each coil electrode segment **44** could comprise a long electrode.

[0114] As FIG. 26 shows, in a preferred embodiment, the temperature sensing elements **80** are preferably located at the edges **102** and **104** of the long electrode **100**. The edges **102** and **104** are where the electrode **100** abuts the underlying, non-electrically-conductive support body **106**. RF current densities are high at these edges **102** and **104**, because the edges **102** and **104** are regions where electrical conductivity is discontinuous. The resulting rise in current density at the electrode edges **102** and **104** generates localized regions of increased power density and, therefore, regions where higher temperatures exist. In long electrode elements **100**, temperature sensing elements **80** should preferably be located in these edge regions where high localized temperatures are to be expected.

[0115] Most preferably, as FIG. 26 shows, two temperature sensing elements **80** should be located on each long electrode **100**, with the temperature sensing elements **80** positioned in oppositely spaced relationship on each edge **102** and **104** of the long electrode **100**.

[0116] When sequences of long electrodes **100** are used (see FIG. 27), an additional temperature sensing element **80** should also preferably be located in between adjacent long electrodes **100**. When positioned in this way, the temperature sensing elements **80** can acquire temperature gradients

along the entire electrode element **10**, which can be used to control the application of ablation energy, as will be described later.

[0117] The use of multiple temperature sensing elements **80** on opposite sides of long electrode **100** also reduces the sensitivity of temperature control to poor electrode contact with tissue, and also reduces errors should one or more temperature sensing elements face blood instead of tissue. This is because the probability of at least one sensor facing the tissue is increased.

[0118] Electrode elements having lengths less than about 10 mm will be called "short" electrodes, which are identified by the numeral **110** in FIG. 28. The segmented electrodes **30** shown in FIG. 3 exemplify a typical sequence of short electrodes. FIGS. 6 and 9 also show an arrangement in which each coil electrode segment **44** could comprise a short electrode.

[0119] When sequences of short electrodes **110** are used (see FIG. 28), the temperature sensing elements **80** are also preferable located at one edge **112** of each short electrode **110**, for the same reasons explained above in connection with long electrodes **100**. Still, when the electrodes **110** are very short (for example, less than about 5 mm) (see FIG. 29), a centrally located temperature sensing element **80** can be used (as FIGS. 3 and 18 also show, for example). In this arrangement (see FIG. 29), the short electrodes **110** that begin and end the electrode sequence should preferably carry temperature sensing elements **80** located at their edges **112**. In such an arrangement (as FIG. 29 also shows), it is also preferable to locate additional temperature sensing elements **80** generally midway between adjacent short electrodes **110**. The temperature sensing elements **80** are thereby positioned to obtain temperature gradients along the entire length of the electrode element **10**.

[0120] III. Control of Cardiac Ablation Using Multiple Temperature Feedback Control

[0121] FIG. 30 shows, in schematic form, a representative system **200** for applying ablating energy by multiple emitters based, at least in part, upon local temperature conditions sensed by multiple sensing elements **80**.

[0122] In FIG. 30, the multiple sensing elements **80** comprise thermocouples **208**, **209**, and **210** individually associated with the multiple emitters of ablating energy, which comprise electrode regions **201**, **202**, and **203**. The system **200** also includes a common reference thermocouple **211** carried within the coupler element **211** for exposure to the blood pool. Alternatively, other kinds of temperature sensing elements can be used, like, for example, thermistors, fluoroptic sensors, and resistive temperature sensors, in which case the reference sensor **211** would typically not be required.

[0123] The system **200** further includes an indifferent electrode **219** for operation in a uni-polar mode.

[0124] The ablating energy emitters **201**, **202**, **203** can comprise the rigid electrode segments **30** previously described. Alternatively, the electrode regions **201**, **202**, **203** can comprise a continuous or segmented flexible electrode of wrapped wire or ribbon. It should be appreciated that the system **200** can be used in association with any ablating element that employs multiple, independently actuated ablating elements.

[0125] The system **200** includes a source **217** of ablating energy. In FIG. 30, the source **217** generates radio frequency (RF) energy. The source **217** is connected (through a conventional isolated output stage **216**) to an array of power switches **214**, one for each electrode region **201**, **202**, and **203**. A connector **212** (carried by the probe handle) electrically couples each electrode region **201**, **202**, **203** to its own power switch **214** and to other parts of the system **200**.

[0126] The system **200** also includes a microcontroller **231** coupled via an interface **230** to each power switch **214**. The microcontroller **231** turns a given power switch **214** on or off to deliver RF power from the source **217** individually to the electrode regions **201**, **202**, and **203**. The delivered RF energy flows from the respective electrode region **201**, **202**, and **203**, through tissue, to the indifferent electrode **219**, which is connected to the return path of the isolated output stage **216**.

[0127] The power switch **214** and interface **230** configuration can vary according to the type of ablating energy being applied. FIG. 31 shows a representative implementation for applying RF ablating energy.

[0128] In this implementation, each power switch **214** includes an N-MOS power transistor **235** and a P-MOS power transistor **236** coupled in between the respective electrode region **201**, **202**, and **203** and the isolated output stage **216** of the power source **217**.

[0129] A diode **233** conveys the positive phase of RF ablating energy to the electrode region. A diode **234** conveys the negative phase of the RF ablating energy to the electrode region. Resistors **237** and **238** bias the N-MOS and P-MOS power transistors **235** and **236** in conventional fashion.

[0130] The interface **230** for each power switch **214** includes two NPN transistors **239** and **240**. The emitter of the NPN transistor **239** is coupled to the gate of the N-MOS power transistor **235**. The collector of the NPN transistor **240** is coupled to the gate of the P-MOS power transistor **236**.

[0131] The interface for each power switch **214** also includes a control bus **243** coupled to the microcontroller **231**. The control bus **243** connects each power switch **214** to digital ground (DGND) of the microcontroller **231**. The control bus **243** also includes a (+) power line (+5V) connected to the collector of the NPN transistor **239** and a (−) power line (−5V) connected to the emitter of the NPN interface transistor **240**.

[0132] The control bus **243** for each power switch **214** further includes an E_{SEL} line. The base of the NPN transistor **239** is coupled to the E_{SEL} line of the control bus **243**. The base of the NPN transistor **240** is also coupled to the E_{SEL} line of the control bus **243** via the Zener diode **241** and a resistor **232**. E_{SEL} line connects to the cathode of the Zener diode **241** through the resistor **232**. The Zener diode **241** is selected so that the NPN transistor **240** turns on when E_{SEL} exceeds about 3 volts (which, for the particular embodiment shown, is logic 1).

[0133] It should be appreciated that the interface **230** can be designed to handle other logic level standards. In the particular embodiment, it is designed to handle conventional TTL (transistor transfer logic) levels.

[0134] The microcontroller 231 sets E_{SEL} of the control bus 243 either at logic 1 or at logic 0. At logic 1, the gate of the N-MOS transistor 235 is connected to (+) 5 volt line through the NPN transistors 239. Similarly, the gate of the P-MOS transistor 236 is connected to the (-) 5 volt line through the NPN transistor 240. This conditions the power transistors 235 and 236 to conduct RF voltage from the source 217 to the associated electrode region. The power switch 214 is "on."

[0135] When the microcontroller 231 sets E_{SEL} at logic 0, no current flows through the NPN transistors 239 and 240. This conditions the power transistors 235 and 236 to block the conduction of RF voltage to the associated electrode region. The power switch 214 is "off."

[0136] The system 200 (see FIG. 30) further includes two analog multiplexers (MUX) 224 and 225. The multiplexers 224 and 225 receive voltage input from each thermocouple 208, 209, 210, and 211. The microcontroller 231 controls both multiplexers 224 and 225 to select voltage inputs from the multiple temperature sensing thermocouples 208, 209, 210, and 211.

[0137] The voltage inputs from the thermocouples 208, 209, 210, and 211 are sent to front end signal conditioning electronics. The inputs are amplified by differential amplifier 226, which reads the voltage differences between the copper wires of the thermocouples 208/209/210 and the reference thermocouple 211. The voltage differences are conditioned by element 227 and converted to digital codes by the analog-to-digital converter 228. The look-up table 229 converts the digital codes to temperature codes. The temperature codes are read by the microcontroller 231.

[0138] The microcontroller 231 compares the temperature codes for each thermocouple 208, 209, and 210 to preselected criteria to generate feedback signals. The preselected criteria are inputted through a user interface 232. These feedback signals control the interface power switches 214 via the interface 230, turning the electrodes 201, 202, and 203 off and on.

[0139] The other multiplexer 225 connects the thermocouples 208, 209, 210, and 211 selected by the microcontroller 231 to a temperature controller 215. The temperature controller 215 also includes front end signal conditioning electronics, as already described with reference to elements 226, 227, 228, and 229. These electronics convert the voltage differences between the copper wires of the thermocouples 208/209/210 and the reference thermocouple 211 to temperature codes. The temperature codes are read by the controller and compared to preselected criteria to generate feedback signals. These feedback signals control the amplitude of the voltage (or current) generated by the source 217 for delivery to the electrodes 201, 202, and 203.

[0140] Based upon the feedback signals of the microcontroller 231 and the temperature controller 215, the system 200 distributes power to the multiple electrode regions 201, 202, and 203 to establish and maintain a uniform distribution of temperatures along the ablating element. In this way, the system 200 obtains safe and efficacious lesion formation using multiple emitters of ablating energy.

[0141] The system 200 can control the delivery of ablating energy in different ways. Representative modes will now be described.

[0142] Individual Amplitudes/Collective Duty Cycle

[0143] The electrode regions 201, 202, and 203 will be symbolically designated $E(J)$, where J represents a given electrode region ($J=1$ to N).

[0144] As before described, each electrode region $E(J)$ has at least one temperature sensing element 208, 209, and 210, which will be designated $S(J, K)$, where J represents the electrode region and K represents the number of temperature sensing elements on each electrode region ($K=1$ to M).

[0145] In this mode (see FIG. 32), the microcontroller 316 operates the power switch interface 230 to deliver RF power from the source 217 in multiple pulses of duty cycle $1/N$.

[0146] With pulsed power delivery, the amount of power ($P_{E(J)}$) conveyed to each individual electrode region $E(J)$ is expressed as follows:

$$P_{E(J)} \sim \text{AMP}_{E(J)}^2 \times \text{DUTYCYCLE}_{E(J)}$$

[0147] where:

[0148] $\text{AMP}_{E(J)}$ is the amplitude of the RF voltage conveyed to the electrode region $E(J)$, and

[0149] $\text{DUTYCYCLE}_{E(J)}$ is the duty cycle of the pulse, expressed as follows:

$$\text{DUTYCYCLE}_{E(J)} = \frac{\text{TON}_{E(J)}}{\text{TON}_{E(J)} + \text{TOFF}_{E(J)}}$$

[0150] where:

[0151] $\text{TON}_{E(J)}$ is the time that the electrode region $E(J)$ emits energy during each pulse period,

[0152] $\text{TOFF}_{E(J)}$ is the time that the electrode region $E(J)$ does not emit energy during each pulse period.

[0153] The expression $\text{TON}_{E(J)} + \text{TOFF}_{E(J)}$ represents the period of the pulse for each electrode region $E(J)$.

[0154] In this mode, the microcontroller 231 collectively establishes duty cycle ($\text{DUTYCYCLE}_{E(J)}$) of $1/N$ for each electrode region (N being equal to the number of electrode regions).

[0155] The microcontroller 231 may sequence successive power pulses to adjacent electrode regions so that the end of the duty cycle for the preceding pulse overlaps slightly with the beginning of the duty cycle for the next pulse. This overlap in pulse duty cycles assures that the source 217 applies power continuously, with no periods of interruption caused by open circuits during pulse switching between successive electrode regions.

[0156] In this mode, the temperature controller 215 makes individual adjustments to the amplitude of the RF voltage for each electrode region ($\text{AMP}_{E(J)}$), thereby individually changing the power $P_{E(J)}$ of ablating energy conveyed during the duty cycle to each electrode region, as controlled by the microcontroller 231.

[0157] In this mode, the microcontroller 231 cycles in successive data acquisition sample periods. During each sample period, the microcontroller 231 selects individual

sensors S(J, K), and voltage differences are read by the controller **215** (through MUX **225**) and converted to temperature codes TEMP(J).

[0158] When there is more than one sensing element associated with a given electrode region (for example, when edge-located sensing elements are used, as **FIGS. 26 and 27** show), the controller **215** registers all sensed temperatures for the given electrode region and selects among these the highest sensed temperature, which constitutes TEMP(J).

[0159] In this mode, the controller **215** compares the temperature TEMP(J) locally sensed at each electrode E(J) during each data acquisition period to a set point temperature TEMP_{SET} established by the physician. Based upon this comparison, the controller **215** varies the amplitude AMP_{E(J)} of the RF voltage delivered to the electrode region E(J), while the microcontroller **231** maintains the DUTYCYCLE_{E(J)} for that electrode region and all other electrode regions, to establish and maintain TEMP(J) at the set point temperature TEMP_{SET}.

[0160] The set point temperature TEMP_{SET} can vary according to the judgment of the physician and empirical data. A representative set point temperature for cardiac ablation is believed to lie in the range of 40° C. to 95° C., with 70° C. being a representative preferred value.

[0161] The manner in which the controller **215** governs AMP_{E(J)} can incorporate proportional control methods, proportional integral derivative (PID) control methods, or fuzzy logic control methods.

[0162] For example, using proportional control methods, if the temperature sensed by the first sensing element TEMP(1) > TEMP_{SET}, the control signal generated by the controller **215** individually reduces the amplitude AMP_{E(1)} of the RF voltage applied to the first electrode region E(1), while the microcontroller **231** keeps the collective duty cycle DUTYCYCLE_{E(1)} for the first electrode region E(1) the same. If the temperature sensed by the second sensing element TEMP(2) < TEMP_{SET}, the control signal of the controller **215** increases the amplitude AMP_{E(2)} of the pulse applied to the second electrode region E(2), while the microcontroller **231** keeps the collective duty cycle DUTYCYCLE_{E(2)} for the second electrode region E(2) the same as DUTYCYCLE_{E(1)}, and so on. If the temperature sensed by a given sensing element is at the set point temperature TEMP_{SET}, no change in RF voltage amplitude is made for the associated electrode region.

[0163] The controller **215** continuously processes voltage difference inputs during successive data acquisition periods to individually adjust AMP_{E(J)} at each electrode region E(J), while the microcontroller **231** keeps the collective duty cycle the same for all electrode regions E(J). In this way, the mode maintains a desired uniformity of temperature along the length of the ablating element.

[0164] Using a proportional integral differential (PID) control technique, the controller **215** takes into account not only instantaneous changes that occur in a given sample period, but also changes that have occurred in previous sample periods and the rate at which these changes are varying over time. Thus, using a PID control technique, the controller **215** will respond differently to a given proportionally large instantaneous difference between TEMP(J) and TEMP_{SET}, depending upon whether the difference is getting larger or smaller, compared to previous instantaneous differences, and whether the rate at which the difference is changing since previous sample periods is increasing or decreasing.

[0165] Deriving Predicted Hottest Temperature

[0166] Because of the heat exchange between the tissue and the electrode region, the temperature sensing elements may not measure exactly the maximum temperature at the region. This is because the region of hottest temperature occurs beneath the surface of the tissue at a depth of about 0.5 to 2.0 mm from where the energy emitting electrode region (and the associated sensing element) contacts the tissue. If the power is applied to heat the tissue too quickly, the actual maximum tissue temperature in this subsurface region may exceed 100° C. and lead to tissue desiccation and/or micro-explosion.

[0167] **FIG. 33** shows an implementation of a neural network predictor **300**, which receives as input the temperatures sensed by multiple sensing elements S(J, K) at each electrode region, where J represents a given electrode region (J=1 to N) and K represents the number of temperature sensing elements on each electrode region (K=1 to M). The predictor **300** outputs a predicted temperature of the hottest tissue region T_{MAXPRED}(t). The controller **215** and microcontroller **231** derive the amplitude and duty cycle control signals based upon T_{MAXPRED}(t), in the same manners already described using TEMP(J).

[0168] The predictor **300** uses a two-layer neural network, although more hidden layers could be used. As shown in **FIG. 32**, the predictor **300** includes a first and second hidden layers and four neurons, designated N_(L,X), where L identifies the layer 1 or 2 and X identifies a neuron on that layer. The first layer (L=1) has three neurons (X=1 to 3), as follows N_(1,1), N_(1,2), and N_(1,3). The second layer (L=2) comprising one output neuron (X=1), designated N_(2,1).

[0169] Temperature readings from the multiple sensing elements, only two of which—TS1(n) and TS2(n)—are shown for purposes of illustration, are weighed and inputted to each neuron N_(1,1), N_(1,2), and N_(1,3) of the first layer. **FIG. 33** represents the weights as W_(K,N)^L, where L=1; k is the input sensor order; and N is the input neuron number 1, 2, or 3 of the first layer.

[0170] The output neuron N_(2,1) of the second layer receives as inputs the weighted outputs of the neurons N_(1,1), N_(1,2), and N_(1,3). **FIG. 32** represents the output weights as W_(O,X)^L, where L=2; O is the output neuron 1, 2, or 3 of the first layer; and X is the input neuron number of the second layer. Based upon these weighted inputs, the output neuron N_(2,1) predicts T_{MAXPRED}(t). Alternatively, a sequence of past reading samples from each sensor could be used as input. By doing this, a history term would contribute to the prediction of the hottest tissue temperature.

[0171] The predictor **300** must be trained on a known set of data containing the temperature of the sensing elements TS1 and TS2 and the temperature of the hottest region, which have been previously acquired experimentally. For example, using a back-propagation model, the predictor **300** can be trained to predict the known hottest temperature of the data set with the least mean square error. Once the training phase is completed, the predictor **300** can be used to predict T_{MAXPRED}(t).

[0172] Other types of data processing techniques can be used to derive T_{MAXPRED}(t). See, e.g., copending patent application Ser. No. 08/266,934, filed Jun. 27, 1994, and entitled "Tissue Heating and Ablation Systems and Methods Using Predicted Temperature for Monitoring and Control."

[0173] The illustrated and preferred embodiments use digital processing controlled by a computer to analyze

information and generate feedback signals. It should be appreciated that other logic control circuits using micro-switches, AND/OR gates, invertors, analog circuits, and the like are equivalent to the micro-processor controlled techniques shown in the preferred embodiments.

[0174] Various features of the invention are set forth in the following claims.

We claim:

1. A device for ablating body tissue comprising
 - a support element made of a material that does not conduct tissue ablation energy,
 - an electrode carried by the support element for contact with tissue, the electrode being made of a material that transmits ablation energy, the electrode having at least one edge that contacts the material of the support element, and
 - at least one temperature sensing element carried by the electrode adjacent to the at least one edge.
2. A device according to claim 1
 - and further including at least one additional temperature sensing element carried by the electrode away from the at least one edge.
3. A device for ablating body tissue comprising
 - a support element made of a material that does not conduct tissue ablation energy,
 - an electrode carried by the support element for contact with tissue, the electrode being made of a material that transmits ablation energy, the electrode having opposed edges that contact the material of the support element, and
 - temperature sensing elements carried by the electrode adjacent to the opposed edges.
4. A device according to claim 3
 - and further including at least one additional temperature sensing element carried by the electrode away from the opposed edges.
5. A device according to claim 1 or 2 or 3 or 4
 - wherein the electrode comprises a metallic material attached about the support element.
6. A device according to claim 1 or 2 or 3 or 4
 - wherein the electrode comprises wire wrapped about the support element.
7. A device according to claim 1 or 2 or 3 or 4
 - wherein the support element is flexible and includes means for flexing the support element.
8. A device according to claim 7
 - wherein the electrode is flexible and flexes with the support element.
9. A device according to claim 1 or 2 or 3 or 4
 - wherein the temperature sensing element comprises a thermistor.
10. A device according to claim 1 or 2 or 3 or 4
 - wherein the temperature sensing element comprises a thermocouple.
11. A device according to claim 1 or 2 or 3 or 4
 - and further including at least one additional temperature sensing element carried by the support body.
12. A device for ablating body tissue comprising
 - a support element made of a material that does not conduct tissue ablation energy, and
 - an array of spaced apart electrodes carried by the support element for contact with tissue, each electrode being made of a material that transmits ablation energy, each electrode having opposed edges that contact the material of the support element, and
 - at least one temperature sensing element carried by one of the electrodes adjacent to at least one of its opposed edges.
13. A device according to claim 12
 - wherein each electrode carries at least one temperature sensing element adjacent to at least one of its opposed edges.
14. A device according to claim 12
 - wherein the array of electrodes includes a first electrode that begins the array and a second electrode that ends the array, and
 - wherein both the first and second electrodes carry at least one temperature sensing element adjacent to at least one of its edges.
15. A device according to claim 14
 - wherein the array of electrodes includes at least one intermediate electrode between the first and second electrodes.
16. A device according to claim 15
 - wherein the at least one intermediate electrode carries at least one temperature sensing element adjacent to at least one of its edges.
17. A device according to claim 15
 - wherein the at least one intermediate electrode carries at least one temperature sensing element.
18. A device according to claim 12
 - wherein the support body carries at least one temperature sensing element.
19. A device according to claim 12
 - wherein the at least one electrode comprises a metallic material attached about the support element.
20. A device according to claim 12
 - wherein the at least one electrode comprises wire wrapped about the support element.
21. A device according to claim 12
 - wherein the support element is flexible and includes means for flexing the support element.
22. A device according to claim 21
 - wherein the array of electrodes is flexible and flexes with the support element.
23. A device according to claim 12
 - wherein the temperature sensing element comprises a thermistor.
24. A device according to claim 12
 - wherein the temperature sensing element comprises a thermocouple.
25. A system for ablating body tissue comprising
 - a generator for supplying ablation energy,
 - a support element made of a material that does not conduct ablation energy,

an electrode carried by the support element for contact with tissue, the electrode being made of a material that transmits ablation energy, the electrode having at least one edge that contacts the material of the support element,

at least one temperature sensing element carried by the electrode adjacent to the at least one edge, and

a controller coupled to the temperature sensing element and the generator to control the supply of ablation energy based, at least in part, upon temperature sensed by the at least one temperature sensing element.

26. A system for ablating body tissue comprising

a generator for supplying ablation energy,

a support element made of a material that does not conduct ablation energy,

an electrode carried by the support element for contact with tissue, the electrode being made of a material that transmits ablation energy, the electrode having opposed edges that contact the material of the support element,

temperature sensing elements carried by the electrode adjacent to the opposed edges, and

a controller coupled to the temperature sensing elements and the generator to control the supply of ablation energy based, at least in part, upon temperatures sensed by the temperature sensing elements.

27. A system according to claim 26

wherein the controller includes means for selecting a temperature sensed by one of the temperature sensing elements that is higher than a temperature sensed by the other temperature sensing element and for controlling the supply of ablation energy based, at least in part, upon the selected temperature.

28. A system for ablating body tissue comprising

a generator for supplying ablation energy,

a support element made of a material that does not conduct ablation energy, and

an array of spaced apart electrodes carried by the support element for contact with tissue, each electrode being made of a material that transmits ablation energy, each electrode having opposed edges that contact the material of the support element, the array including a first electrode that begins the array and a second electrode that ends the array,

first and second temperature sensing elements carried by, respectively, the first and second electrodes adjacent to one of their respective opposed edges, and

a controller coupled to the first and second temperature sensing elements and the generator to control the supply of ablation energy to the array of electrodes based, at least in part, upon temperatures sensed by the first and second temperature sensing elements.

29. A method for ablating body tissue comprising the steps of

supplying ablation energy to an electrode carried by a support element made of a material that does not conduct ablation energy, the electrode having at least one edge that contacts the material of the support element,

sensing temperature with at least one temperature sensing element carried by the electrode adjacent to the at least one edge, and

controlling the supply of ablation energy based, at least in part, upon temperature sensed by the at least one temperature sensing element.

30. A method for ablating body tissue comprising the steps of

supplying ablation energy to an electrode carried by a support element made of a material that does not conduct ablation energy, the electrode having opposed edges that contact the material of the support element,

sensing temperatures with temperature sensing elements carried by the electrode adjacent to the opposed edges, and

controlling the supply of ablation energy based, at least in part, upon temperatures sensed by the temperature sensing elements.

31. A method according to claim 30

wherein, in controlling the supply of ablation energy, a temperature sensed by one of the temperature sensing elements is selected that is higher than a temperature sensed by the other temperature sensing element and the supply of ablation energy is controlled based, at least in part, upon the selected temperature.

32. A method for ablating body tissue comprising the steps of

supplying ablation energy to an array of spaced apart electrodes carried by a support element made of a material that does not conduct ablation energy, each electrode in the array having opposed edges that contact the material of the support element, the array including a first electrode that begins the array and a second electrode that ends the array,

sensing temperatures with first and second temperature sensing elements carried by, respectively, the first and second electrodes adjacent to one of their respective opposed edges, and

controlling the supply of ablation energy to the array of electrodes based, at least in part, upon temperatures sensed by the first and second temperature sensing elements.

33. A device according to claim 1 or 2 or 3 or 4

wherein the temperature sensing element is carried inside the electrode.

34. A device according to claim 1 or 2 or 3 or 4

wherein the temperature sensing element is carried outside the electrode.

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