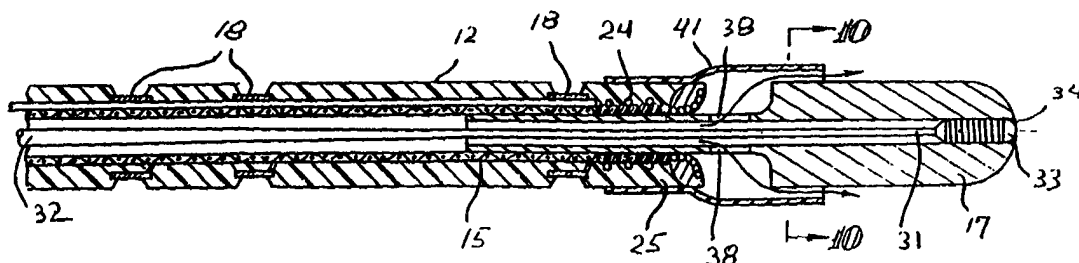




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(54) Title: OVER-THE-WIRE EP CATHETER



(57) Abstract

An over-the-wire (32) electrophysiology catheter (10) which has an emitting electrode (17) on the distal tip (12) electrically connected to a source of high frequency electrical energy. The intravascular device (10) is configured to be advanced through a patient's cardiac veins or coronary arteries and preferably is also provided with sensing electrodes (18) for detecting electrical activity of the patient's heart from within a blood vessel of the heart. The device forms large lesions in tissue adjacent to the blood vessel in which the device is located without significantly damaging the blood vessel to effectively terminates signals causing arrhythmia.

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OVER-THE-WIRE EP CATHETER**RELATED APPLICATIONS**

This application is a continuation in part application of application Serial No.
5 08/447,351, filed on May 23, 1995, which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention generally relates to an intravascular catheter for ablating tissue
of a patient's heart and particularly to an ablation catheter which can be advanced
through the patient's coronary arteries or cardiac veins to treat arrhythmia from
10 within the blood vessel.

Prior methods for treating a patient's arrhythmia include the use of
antiarrhythmic drugs such as sodium and calcium channel blockers or drugs which
reduce the Beta-adrenergic activity. Other prior methods include surgically
sectioning the origin of the signals causing the arrhythmia or the conducting pathway
15 for such signals. More frequently, however, to terminate the arrhythmia the heart
tissue which causes the arrhythmia is destroyed by heat, e.g. applying a laser beam
or high frequency electrical energy (RF or microwave) to a desired location on the
patient's endocardium.

In the latter instance, the location of the tissue site causing or involved with
20 the arrhythmia must be accurately know in order to e able to contact the desired
location with a tissue destroying device . A major problem with ablating the site of
the origin of the signals or a conductive pathway is to accurately determine the
location of the site so that an excessive amount of healthy tissue is not damaged or
destroyed along with the arrhythmogenic site, while at the same time ensuring that
25 the arrhythmia does not return. For example, the average arrhythmogenic site
consists of an area of about 1.4 cm² of the endocardial tissue, whereas a re-entrant
site might be much larger. RF ablation techniques produce lesions about 0.5 cm²
in area, so several lesions may be necessary to completely ablate an area of
interest. If the arrhythmogenic or re-entrant site is not accurately mapped, much
30 healthy tissue surrounding the site will be unnecessarily damaged or destroyed.

A variety of prior methods have been used to detect electrical activity within a patient's heart to facilitate the mapping of electrical activity causing the arrhythmia. A number of these prior methods are disclosed in U.S. Patents which use elongated intravascular signal sensing devices with one or more electrodes on a distal portion of the device which are advanced through the patient's vasculature until the distal portions of the sensing devices are disposed within one or more of the patient's heart chambers with one or more electrodes in contact with the endocardial lining. While this procedure is widely used, it does not always allow the site of the arrhythmogenic signals to be accurately determined.

In U.S. Patent No. 5, 509,411 (Littmann et al.) which issue on April 23, 1996, reference is made to intravascular devices which are advanced through a patient's coronary arteries or cardiac veins to desired locations in the patient's epicardium where electrical activity is detected by means of electrodes on the distal ends of the devices to locate arrhythmogenic sites or conductive pathways causing or involved with the arrhythmia. In copending application Serial No. 08/207,918, filed March 8, 1994 an intravascular device is described which uses RF energy to occlude a blood vessel in order to destroy tissue distal to the catheter by creating ischemic conditions therein.

While these prior devices provided many advantages, there were no ways of controlling the temperatures of the emitting electrodes.

SUMMARY OF THE INVENTION

This invention is directed to an elongated intravascular device for creating a lesion in tissue of a patient's body and particularly tissue adjacent a patient's blood vessel from within a patient's blood vessel. The device preferably has means for detecting electrical activity in adjacent tissue from within the blood vessel to facilitate accurate placement of the device within the blood vessel to ensure creating an effective lesion. The device is particularly suitable for creating a lesion in a patient's heart which terminates the electrical activity causing an arrhythmia.

The intravascular device of the invention comprises an elongated shaft with proximal and distal ends, a port in the distal end and a guidewire lumen extending through at least the distal section of the shaft to the guidewire port in the distal

section. The distal section of the shaft is configured so as to be advanceable through the desired blood vessel or other desired body lumen, such as the patient's coronary arteries or cardiac veins. The device may also be used in blood vessels or other body lumens in other parts of the patient's body.

5 In accordance with the invention, distal shaft section is provided with at least one emitting electrode which is electrically connected by means of a conductor which extends through the shaft to a high frequency electrical energy source exterior to the patient. The emitting electrode on the distal shaft section preferably forms the distal tip of the elongated shaft and has an inner lumen extending to the port in the
10 distal end which is a continuation of the lumen extending within the shaft. This allows the intravascular device to be advanced over a guidewire to the desired location within a patient's body where the ablation is to occur.

To form an effective lesion in the tissue adjacent to a body lumen without causing unnecessary tissue damage, the temperature of the emitting electrode
15 should be controlled during emission between about 70°C and 100°C and preferably about 75°C - 85°C.

To effectively cool the electrode, it is preferably provided with one or more fluid directing passageways which extend radially or longitudinally to facilitate passage of cooling fluid when the emitting electrode is in operation. Alternatively,
20 the emitting electrode may be provided with a sheath on the exterior thereof which directs cooling fluid along the outer surface to control surface temperatures. The emitting electrode may be provided with a proximal tubular extension which is secured by a suitable adhesive within the inner lumen extending within the shaft.

In one presently preferred embodiment, a plurality of sensing electrodes are
25 also provided on the distal shaft section proximal to the emitting electrode so that electrical activity can be detected in tissue adjacent to the body lumen to ensure accurate placement of the emitting electrode within the body lumen and effective lesion formation. The sensing electrodes may be electrically configured for monopolar or multipolar operative modes. Up to 15 or more sensing electrodes may
30 be provided along the distal shaft section. The sensing electrodes may have constant or variable electrode spacings and they may be arranged in a first array of sensing electrodes with a compact spacing and a second array of sensing

electrodes with a much greater spacing than that in the first array. In this latter embodiment, the second array of sensing electrodes may be used to detect the general location of electrical activity, such as an arrhythmogenic site or pathway, and then the first array may be utilized to more accurately pinpoint the area of interest based upon the general location detected by the first array of sensing electrode means. The interelectrode spacing in the second array of electrodes should be between about 0.25 and about 2 mm, preferably between about 0.5 and about 1.5 mm, and the interelectrode spacing between the electrodes in the first array may be about 1 to about 10 mm. When a bipolar or multipolar mode of sensing is to be used, the spacing between a pair of bipolar electrodes may be much less than the spacing between pairs of bipolar electrodes.

The shaft of the intravascular device is preferably formed of a plurality of individually insulated electrical conductors braided or wound into an elongated tubular member with the inner lumen extending therein. However, not all of the braided strands which make up the tubular member need be electrical conductors. Some may be high strength fibers such as nylon, Kevlar® and the like. The insulation on individual electrical conductors is exposed adjacent to each of the electrodes to facilitate an electrical connection with the electrode and the electrode may be secured to the exposed conductor by means of a suitable solder or brazing material. The sensing electrodes may be secured by their inner periphery to the underlying tubular member formed of electrical conductors by a suitable adhesive to further ensure maintenance of electrical contact between the electrodes and the exposed conductors.

In another embodiment of the invention where the emitting electrode on the distal end of the device is in the form of a helical coil formed of conducting metallic material, a supporting tube is provided within the helical coil forming the electrode which is formed of braided strands, preferably metallic, which has an open weave construction so as to allow fluid passing through the shaft of the device to pass through the braided strands, contacting and thus cooling the helical coil of the emitting electrode.

The sensing electrodes may be circular bands about 0.25 to about 1 mm in width (the longitudinal dimension when on the device) and are preferably made from conducting material such as gold which is biocompatible with the body fluids.

A plastic jacket, preferably a lubricous polymer such as a thermoplastic fluoropolymer, Pebax or a polyethylene may be provided on the exterior of the shaft with a slight overlap of the jacket over the edges of the individual electrodes formed of bands to prevent exposure of a sharp metallic edge which can cause damage when the elongated device is advanced through blood vessels. The entire exterior of an electrode need not be exposed. For example, the plastic jacket may be disposed about the distal shaft section on which the electrodes are mounted and holes may be made in the jacket to expose small portions of the underlying electrodes. The proximal ends of the electrical conductors connected to the electrodes are electrically connected to one or more multi-pin connectors on the proximal end of the shaft which may be configured to be connected to a receiving member in electrical communication with a video unit which can display representations of the electrical activity sensed.

When using the intravascular device of the invention, a guiding catheter is first introduced into the patient's vasculature and advanced therein until the distal tip of the guiding catheter is seated within the ostium of the coronary sinus or the ostium of a coronary artery. A guidewire is then advanced through the guiding catheter out the distal end thereof and then directed to a desired venous or arterial branch. The intravascular device of the invention is advanced over the guidewire to the desired location where the lesion is to be formed. The sensing electrodes on the distal section of the intravascular device are used to detect the electrical activity causing or involved with the arrhythmia. Once located, the position of the intravascular device can be adjusted to the extent necessary to place the emitting electrode on the distal tip of the device within the vessel as close as possible to the tissue causing or involved with the arrhythmia so, when the lesion is formed by emitting high frequency electrical energy, the tissue in question is within the lesion.

With the device of the invention, the arrhythmogenic site is accurately detected and the lesion formed is large enough to encompass the site with little damage to tissue not involved with the arrhythmia so as to effectively and

permanently terminate the arrhythmia. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view of an intravascular device having features of the invention wherein an emitting electrode is provided on the distal end of the device for the delivery of high frequency electrical energy.

10 Fig. 2 is a transverse cross-sectional view of a distal portion of the intravascular device shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is a longitudinal cross-sectional view of a distal portion of an alternative embodiment of the invention wherein a plurality of radially extending passageways are provided in the emitting electrode to allow for the passage of cooling fluid.

15 Fig. 4 is a transverse cross-sectional view of the embodiment shown in Fig. 3 taken along the lines 4-4.

Fig. 5 is a longitudinal cross-sectional view of a distal portion of another alternative embodiment of the invention wherein a plurality of longitudinally extending passageways are provided in the emitting electrode to allow for the passage of cooling fluid.

20 Fig. 6 is a transverse cross-sectional view of the embodiment shown in Fig. 5 taken along the lines 6-6.

Fig. 7 is an elevational view, partially in section, of another alternative embodiment of the invention wherein a portion of the emitting electrode is provided with an insulating sheath.

25 Fig. 8 is a transverse cross-sectional view of the catheter shown in Fig. 7 taken along the lines 8-8.

30 Fig. 9 is an elevational view, partially in section, of another alternative embodiment of the invention wherein a sheath is positioned on the exterior of the proximal end of the emitting electrode to direct cooling fluid onto the outside of the electrode.

Fig. 10 is a transverse cross-sectional view of the catheter shown in Fig. 9 taken along the lines 10-10.

Fig. 11 is an elevational view, partially in section, of another alternative embodiment of the invention wherein an expandable balloon is provided on one side of the distal section of the device so when it is inflated, the emitting electrode will be urged against the interior of the body lumen.

Fig. 12 is a transverse cross-sectional view of the catheter shown in Fig. 11 taken along the lines 12-12.

Fig. 13 is a longitudinal cross-sectional view of another alternative embodiment of the invention wherein the distal section of the device is provided with an emitting electrode formed of a coiled wire.

Fig. 14 is a transverse cross-sectional view of the catheter shown in Fig. 13 taken along the lines 14-14.

Fig. 15 is a longitudinal cross-sectional view of an embodiment similar to that shown in Figs. 13 and 14 but with separate guidewire and fluid lumens.

Fig. 16 is a transverse cross-section of the catheter shown in Fig. 15 taken along the lines 16-16.

Fig. 17 is a longitudinal cross-sectional view of the distal section of another embodiment of the invention.

Fig. 18 is a transverse cross-sectional view of the embodiment shown in Fig. 17 taken along the lines 18-18.

Fig. 19 is an elevational view, partially in section, of another embodiment of the invention which has a braided internal tubular support member extending within a helical coil which forms the emitting electrode on the distal end of the device.

Fig. 20 is a transverse cross-sectional view of the device shown in Fig. 19 taken along the lines 20-20.

Fig. 21 is a transverse cross-sectional view of the device shown in Fig. 19 taken along the lines 21-21.

Fig. 22 is a transverse cross-sectional view of the device shown in Fig. 19 taken along the lines 22-22.

DETAILED DESCRIPTION OF THE INVENTION

Reference is made to Figs. 1-2 which schematically illustrate an embodiment of the invention wherein the elongated intravascular device 10 includes shaft 11 with a distal section 12 and a proximal section 13 and an inner lumen 14 extending within the shaft. The shaft 11 has a braided tubular member 15 formed of a plurality of electrical conductors 16. All the strands forming the tubular member 15 need not be conductors 16, some may be formed of polymer materials such as nylon or Kevlar®. The distal section 12 of the shaft 11 is provided with an emitting electrode 17 at the distal tip and a plurality of sensing electrodes 18 located proximal to the emitting electrode.

The emitting electrode 17 has a proximal tubular extension 19 which extends within the inner lumen 14 and is secured by suitable adhesive to the interior surface of the braided tubular member 15. One or more individual insulated electrical conductors 16 are electrically connected by solder 20 to the emitting electrode 17. Individual insulated electrical conductors 16 are also electrically connected to the sensing electrodes 18 by solder (not shown). The conductors 16 extend to the proximal end of the shaft 11 where they are bundled and formed into cable 21 leading to multiple pin electrical connector 22 where each electrical conductor is connected to a separate pin (not shown). The proximal extremity of the conductor or conductors electrically connected to the emitting electrode 17 are electrically connected through the pins to a source of high frequency electrical energy (RF or microwave) and the proximal extremities of the conductors electrically connected to sensing electrodes 18 are connected through the pins to a display system (not shown) where representations are presented on the signal received by the sensing electrodes.

Preferably a safety wire 23 extends within the wall of the shaft 11 and is secured by its distal end to the emitting electrode 17 to prevent its loss within the patient. The distal extremity 24 of the safety wire 23 is coiled within the shaft wall proximal to the emitting electrode 17 and is bonded by suitable adhesive 25 to the proximal extension 19. The proximal end of the safety wire may be secured to the a band (not shown) in the shaft 11 spaced proximal to the emitting electrode 17.

A conventional adapter 27, which is secured to the proximal end of the shaft 11, has a central arm 28 for entry of a guidewire into the inner lumen 14 and a side arm 29 also in fluid communication with the inner lumen 14 for delivery of flushing or cooling fluid to the emitting electrode 17 on the distal section of the shaft. An O-ring
5 may be provided in the proximal hub of the central arm 28 to prevent the escape of fluid.

The embodiment shown in Figs. 3 and 4 is essentially the same as the embodiment shown in Figs. 1 and 2 (and is similarly numbered) except that a plurality of radially extending passageways 30 extend between the inner lumen 14
10 and the exterior of the electrode 17. The guidewire 31, having a core 32 and a coil 33 on the distal extremity of the core, is slidably disposed within the inner lumen 14 and the coil on the distal end of the guidewire extends beyond the passageways 30 and to a significant extent occludes the inner lumen 14 and reduces considerably the passage of fluid through the port 34 in the distal tip of the emitting electrode 17.
15 Fluid flowing through the inner lumen 14 will then be forced to flow through the radial passages 30 thereby cooling the emitting electrode 17.

Another embodiment is shown in Figs. 5 and 6 where the emitting electrode 17 has longitudinally disposed passageways 35 for directing cooling fluid from the inner lumen 14 through the electrode and out the ports 36 in the distal tip of the
20 electrode. A tubular sheath 37 formed of a high strength polymer material, such as polyimide, extends between the body of adhesive 25 securing the coiled distal extremity of the safety wire 24 to the tubular extension 19 of the emitting electrode 17 to the proximal end of the electrode to direct fluid which passes from the inner lumen 14 through the ports 38 in the tubular extension 19 to the passageways 35 as
25 indicated by the arrows shown in Fig. 5. The intravascular device shown is otherwise essentially the same as the prior devices and is similarly numbered. A guidewire 31 may be used to occlude inner lumen 14 as in the prior embodiment to ensure an adequate flow of cooling fluid through passageways 35 to maintain the temperature of the emitting electrode 17 at a desired level.

30 Figs. 7 and 8 illustrate yet another embodiment of the invention wherein an arcuate insulating sheath 40 is secured about an exterior portion of the emitting electrode 17 to ensure a more focused emission of high frequency electrical energy

from a smaller exposed portion of the electrode toward the tissue to be treated to control the size of the lesion formed. This device is for the most part the same as the previously discussed embodiments, except for insulation sheath 40, and is therefore similarly numbered.

5 Another embodiment is depicted in Figs. 9 and 10 wherein a fluid control sheath 41 which is secured by its proximal extremity to the adhesive 25 and extends over the exterior of the emitting electrode 17. The inner diameter of the distal end of the sheath 41 is slightly larger than the outer diameter of the electrode 17 to provide an annular gap 42 therebetween which directs cooling fluid along the exterior
10 surface of the electrode as indicated by the arrows. The cooling fluid passes from the inner lumen 14 through the ports 38 in the tubular extension 19 and through the annular gap 42. In this embodiment a guidewire 31 is disposed within the inner lumen 14 with the coil 33 at least partially occluding the distal portion of the inner lumen so that an adequate flow of cooling fluid passes along the exterior of the
15 electrode 17 to ensure sufficient cooling thereof.

In larger blood vessels, it frequently is difficult to maintain contact between the emitting electrode 17 and the blood vessel wall. To overcome this problem, it is desirable to provide an expandable positioning member, such as an inflatable balloon 43, which when inflated ensures contact between a desired portion of the
20 blood vessel wall 44 and the emitting electrode 17 as shown in Figs. 11 and 12. An inflation lumen 45 extends through the shaft 11 from its proximal end to a location within the interior of the balloon 43. To accommodate for the extra lumen a three arm adapter (not shown) is secured to the proximal end of the shaft. While only one sensing electrode 18 is shown in the drawings, a plurality of sensing electrodes may
25 be provided proximal to the balloon 43. The maximum transverse dimension of the balloon 43 as measured from the opposite side of the shaft 11 may range from about 0.5 to about 5 mm, preferably about 1.5 to about 4 mm.

Figs. 13 and 14 represent another embodiment where the emitting electrode
50 is a helical coil on the distal end of the shaft 11. The proximal end of the coil 51
30 is secured by solder 52 to the distal end of the shaft 11 shown in Fig. 13 to facilitate an electrical connection with the conductors 16 in the shaft 11 and the distal end of the coil is secured by adhesive to the enlarged distal end 53 of the lining 54.

Perfusion holes 55 are provided in lining 54 to allow fluid passing through inner lumen 14 to contact and thus cool the coil 51.

In the embodiment shown in Figs. 15 and 16 the inner lumen 14 is disposed within the inner tubular member 60 which extends to the distal tip 61. Annular lumen 62 extends between the interior surface of braided tubular member 15 and the exterior surface of inner tubular member 60. Electrode coil 63 is secured by its proximal end to the shaft 11 by solder 64 and is electrically connected to a conductor of the braided tubular member 15. The distal end of the coil 63 is secured to the distal tip 61 by a suitable adhesive or by fusing the distal tip about the distal end of the coil. In this embodiment the delivery of cooling fluid through the annular lumen 62 is independent of a guidewire (not shown) in lumen 14.

Figs. 17 and 18 illustrate the distal portion of yet another embodiment of the invention where an emitting coil electrode 70 is secured to the distal tip of shaft 11 by means of adhesive or solder. A safety wire 71, which extends through the shaft 11 as in the previous embodiments, is soldered to the distal tip of the emitting coil electrode 70. Sensing electrodes 18 are provided on shaft 11 proximal to the emitting electrode coil 70 as in the previous embodiments. The details of shaft 11 are the same as shown in the prior embodiments.

Figs. 19-22 schematically illustrate another embodiment of the invention wherein the device 100 has an elongated shaft 101 with a distal shaft section 102, proximal shaft section 103 and a first inner lumen 104 extends through the shaft. An inner tubular member 105 is disposed within the first inner lumen 104 of the shaft 101 and defines a second inner lumen 106 that extends to the port 107 in the distal tip 108 of the shaft 101. The distal tip 108 is preferably formed of relatively soft polymeric material such as Pebax 4033 and is secured by a suitable adhesive to the distal end of the inner tubular member 105. An emitting electrode 109 in the form of an expanded coil is provided on the distal shaft section 103 spaced a short distance from the distal tip 108 and a plurality of sensing or mapping electrodes 110 in the form of coils are longitudinally spaced along a length of the distal shaft section spaced proximal to the emitting electrode.

The tubular structure of shaft 101 is formed in part by braided strands of insulated electrical conductors 111, insulated thermocouple wires 112 and metallic

ribbon 113, likewise preferably insulated, which are embedded in polymer jacket 114. The distal ends of individual electrical conductors 111 are electrically connected by solder 116 (or other suitable means) to the sensing electrodes 110 and one or more of the electrical conductors are electrically connected by their distal ends to the emitting electrode 109 by solder 117. The proximal extremities of the electrical conductors 111 are bundled together and provided with a polymeric jacket to form a connector lead 118 extending out of the adapter 119. The proximal ends of the conductors 111 are electrically connected to a multi-pin electrical connector 119 for connection to a high frequency electrical source (not shown). The distal ends of thermocouple wires 112 are connected to thermocouple 120 (e.g. Type T, Copper-Constantan) provided within the interior of emitting electrode 109. The proximal extremities of the thermocouple wires 112 are likewise bundled and jacketed to form a lead 121 with the proximal ends of the thermocouple wires connected to the connector 122 which is configured to be electrically to a temperature read out device (not shown). The leads 118 and 121 may also be bundled and provided with a jacket upon exiting from the adapter 119 as shown in Fig. 19.

The braided insulated metallic ribbons 113 extend through the interior of the emitting electrode 109 and are secured to the proximal end of the emitting electrode by solder 117 and to the distal end of the emitting electrode by solder 123. The braid of metallic ribbons 113 is of open weave construction so that cooling fluid such as saline passing through the first inner lumen 104 can pass through the open weave construction and cool the expanded coil of the emitting electrode 109 as shown by the arrows in Figs. 19 and 20.

The coil forming the emitting electrode 109 generally has a central or intermediate section which has exposed uninsulated turns 124 and proximal and distal sections which have exposed insulated turns 125 and 126 respectively.

The adapter 118 is provided with a central arm 127 with a guidewire port 128 which is in fluid communication with the second inner lumen 106 of the inner tubular member 105 and which is preferably configured to receive guidewires having diameters of about 0.01 to about 0.018 inch (0.25-0.46 mm), preferably about 0.01 to about 0.015 inch (0.25-0.38) and to guide such guidewires to the second inner

lumen. Cooling fluid can be introduced into first inner lumen 104 through side arm 129 of adapter 119.

The overall length of the intravascular devices of the invention may range from about 80 to about 300 cm, typically about 120 to about 175 cm for delivery through the femoral artery or vein and about 80 to about 120 cm for delivery through the brachiocephalic artery or internal jugular vein. Because the intravascular device is to be advanced over a guidewire, the guidewire must be longer than the catheter by about 20 to about 60 cm. The outer diameter of the shaft of the intravascular device should be not _____ greater than about 0.08 inch (1 mm) and the distal sections 12 and 102 about 0.035-0.072 inch (0.89-1.8 mm). The inner lumen within the inner tubular member has a diameter of about 0.02 to about 0.04 inch (0.5-1 mm) to facilitate the reception and advancement of a guidewire therethrough, which is typically about 0.010 to about 0.018 inch (0.25-0.46 mm) in outer diameter. The diameter of the inner lumen through the emitting electrode may be smaller than the diameter of the inner lumen in the more proximal portions of the shaft 11. The distal section 12 of the shaft is about 3 to about 20 cm in length. An intermediate section having an intermediate stiffness may be provided between the proximal section 13 and the distal section 12 with a length of about 5 to about 40 cm in length, typically about 20 cm in length. The radial passageways 30 are typically about 0.02 inch (0.5 mm) in diameter and the longitudinal passageways 35 are typically about 0.01 inch (0.25 mm). The emitting electrode is generally longer than about 2 mm. For solid electrodes the length is generally less than about 10 mm, but for an emitting electrode in the form of helical coil the length may be about 2 to about 30 mm, preferably about 2 to about 10 mm.

To the extent not previously described, the materials of construction of the intravascular device of the invention may be formed of conventional materials. The electrical conductors 16 may be electrical grade copper wire about 0.003 inch (0.08 mm) in diameter which are provided with a thin insulated jacket or coating of polyimide or other suitable insulator. The outer jacket may be a thermoplastic polyurethane such as PBAX which is available from Eif Atochem Polymers of Philadelphia, Pennsylvania. The jacket of the proximal section is preferably Pebax 1147 or 6833, the jacket of the intermediate section is preferably Pebax 6333 and

the jacket of the distal section is Pebax 4033 or 3533. The sensing and emitting electrodes are preferably formed of an alloy of platinum and iridium, e.g. 90% Pt and 10% Ir (wt.%) or of Gold (100%). If the emitting electrodes are in coil form, the wire forming the coil is typically about 0.005 inch (____ mm) in diameter. The safety wire
5 23 may be a stainless steel wire about 0.003 inch (0.08 mm) in diameter with a polyimide coating. The preferred solder used to join the electrical conductors to the various electrodes is 95% Sn - 5% Ag or 80% Au - 20% Sn.

One presently preferred method of using the elongated intravascular device includes first advancing a guiding catheter through the patient's vascular system
10 until the distal tip of the guiding catheter is seated within the coronary sinus ostium or the ostium of one of the coronary arteries. The guiding catheter is torqued by its proximal extremity which extends out of the patient to guide the distal tip into the selected ostium. Once the distal end of the guiding catheter is seated, the intravascular device of the invention with a guidewire slidably disposed within the
15 inner lumen thereof are advanced through the guiding catheter and out the distal end thereof. The guidewire is first advanced into the target vein or artery and the intravascular device of the invention is advanced over the guidewire into the target blood vessel. The sensing electrodes 18 or 110 on the intravascular device of the invention are used to detect electrical activity which allows the physician or operator
20 to determine the location of the arrhythmogenic focus. When the focus is located, the intravascular device is moved within the blood vessel, as required, to position the emitting electrode 17 or 109 as close as possible to the focus. High frequency electrical energy, preferably in the RF range, is directed through the electrical conductors 16 or 111 connected to the emitting electrode 17 or 109 to form the
25 desired lesion which encompasses the arrhythmogenic focus. Energy levels of about 5 Watts to about 100 Watts, preferably about 30 Watts to about 70 Watts are suitable to terminate most arrhythmias. Typical lesions formed are about 3 mm to about 20 mm in diameter and about 3 mm to about 20 mm in length. In some instances, where the site of the arrhythmic activity is detected by other means, an
30 intravascular device may be utilized which does not have sensing electrodes. For example, the guidewire utilized to advance the intravascular device of the invention into the desired blood vessel may be provided with sensing electrodes for detecting

the electrical activity of interest. A suitable device is described in U.S. Patent No. 5,509,411 which issued on April 23, 1996, which is incorporated herein by reference.

While there are several means described herein to cool the emitting electrode, a wide variety of means can be used to control the temperature of the emitting electrode. For example, the electrical energy to the emitting electrode can be controlled so as to maintain the temperature thereof. A thermistor or other temperature sensing device can be employed to monitor the electrode temperature and the temperature sensed is used to control in a conventional feedback arrangement the electrical power delivery.

Although individual features of one embodiment of the invention may be described herein and shown in one or more of the drawings and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment of the invention. Various modifications and improvements may be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. An intravascular catheter for sensing electrical activity from within a blood vessel of a patient's heart and forming a lesion in the patient's heart from within the blood vessel by means of high frequency electrical energy comprising:

5 a) an elongated shaft having proximal and distal ends, a port in the distal end, an inner lumen which is configured to slidably receive a guidewire and which extends within the shaft to the port in the distal end;

 b) a plurality of sensing electrodes on a distal shaft section;

 c) an emitting electrode at the distal end of the elongated shaft;

10 d) an electrical conductor extending from each of the sensing electrodes; and

 e) an electrical conductor extending from the emitting electrode and configured to be electrically connected to a high frequency electrical energy source.

15 2. The intravascular catheter of claim 1 wherein a safety wire extends through the catheter shaft and is secured to the emitting electrode.

 3. The intravascular catheter of claim 1 wherein an adapter is provided on the proximal end of the catheter shaft having an arm with an inner lumen therein in fluid communication with the inner lumen of the catheter shaft.

20 4. The intravascular catheter of claim 3 wherein the adapter has a second arm with a second inner lumen therein in fluid communication with the inner lumen of the catheter shaft.

 5. The intravascular catheter of claim 4 wherein the second inner lumen of the adapter intersects with the first inner lumen of the adapter.

25 6. The intravascular catheter of claim 1 wherein the emitting electrode forms the distal end of the elongated shaft and the inner lumen extends therethrough.

7. The intravascular catheter of claim 1 wherein means are provided to control the temperature of the emitting electrode.

8. The intravascular catheter of claim 7 wherein the means to control the temperature of the emitting electrode include at least one passageway in fluid communication with the inner lumen extending through the emitting electrode to an exterior region about the emitting electrode to facilitate passage of cooling fluid from the inner lumen.

9. The intravascular catheter of claim 8 wherein a guidewire is slidably disposed within the inner lumen and has an occluding distal tip to restrict fluid flow out the port in the distal end of the catheter and facilitate fluid flow through at least one passageway extending through the emitting electrode.

10. The intravascular catheter of claim 8 wherein at least one passageway extends longitudinally through the emitting electrode and is in fluid communication with the inner lumen extending within the catheter shaft.

11. The intravascular catheter of claim 8 wherein at least one passageway extends laterally through the emitting electrode and is in fluid communication with the inner lumen extending within the catheter shaft.

12. The intravascular catheter of claim 7 wherein the means to control the temperature of the emitting electrode includes a sheath disposed about a proximal portion of the emitting electrode to direct cooling medium about the exterior surface of the electrode.

13. The intravascular catheter of claim 12 wherein the sheath has an interior in fluid communication with the inner lumen extending within the catheter shaft.

14. The intravascular catheter of claim 1 wherein the emitting electrode has an exterior surface which is in part covered with an insulation sheath to prevent transmission of electrical energy therefrom.

15. The intravascular catheter of claim 14 wherein the insulation sheath covers about 25% to about 75% of the peripheral exterior surface of the emitting electrode.

16. The intravascular catheter of claim 15 wherein the sheath extends on a side of the emitting electrode along a length thereof.

17. The intravascular catheter of claim 1 wherein an expandable positioning member is provided on one side of the distal section of the catheter shaft so that the expandable positioning member may be expanded when the distal section of the catheter shaft is disposed within a patient's blood vessel to laterally position the distal section within the blood vessel.

18. The intravascular catheter of claim 1 wherein the inner lumen of the catheter shaft is configured to slidably receive a guidewire having an outer diameter of about 0.008 inch to about 0.03 inch.

19. The intravascular catheter of claim 1 wherein the inner lumen of the catheter shaft is configured to slidably receive a guidewire having an outer diameter of about 0.010 to about 0.02 inch.

20. The intravascular catheter of claim 1 wherein the emitting electrode has a proximal tubular extension which is secured within the inner lumen of the catheter shaft.

21. The intravascular catheter of claim 1 wherein the catheter shaft comprises at least in part a tubular member formed by strands which include individually insulated electrical conductors.

22. The intravascular catheter of claim 21 wherein the strands are braided.

23. The intravascular catheter of claim 1 wherein the emitting electrode is a helical coil.

24. The intravascular device of claim 1 wherein the sensing electrodes are circular bands of electrical conducting materials having widths of about 0.25 to about 1 mm.

25. An intravascular catheter for forming a lesion in the patient's heart from within the blood vessel by means of high frequency electrical energy comprising:

a) an elongated shaft having proximal and distal ends, a port in the distal end, an inner lumen which is configured to slidably receive a guidewire and which extends within the shaft to the port in the distal end;

b) an emitting electrode at the distal end of the elongated shaft;

and

c) an electrical conductor extending from the emitting electrode and configured to be electrically connected to a high frequency electrical energy source.

26. The intravascular catheter of claim 25 wherein a safety wire extends through the catheter shaft and is secured to the emitting electrode.

27. The intravascular catheter of claim 25 wherein an adapter is provided on the proximal end of the catheter shaft having an arm with an inner lumen therein in fluid communication with the inner lumen of the catheter shaft.

28. The intravascular catheter of claim 27 wherein the adapter has a second inner lumen therein in fluid communication with the inner lumen of the catheter shaft.

29. The intravascular catheter of claim 28 wherein the second inner lumen of the adapter intersects with the first inner lumen of the adapter.

30. The intravascular catheter of claim 25 wherein means are provided to control the temperature of the emitting electrode.

31. The intravascular device of claim 30 wherein the means to control the temperature of the emitting electrode include at least one passageway therethrough to facilitate passage of cooling fluid from the inner lumen therein.

32. The intravascular device of claim 31 wherein at least one passageway is oriented radially.

33. The intravascular device of claim 31 wherein at least one passageway is oriented longitudinally.

5 34. The intravascular catheter of claim 31 wherein the means to control the temperature of the emitting electrode includes a sheath disposed about a proximal portion of the emitting electrode to direct cooling medium about the exterior surface of the electrode.

10 35. The intravascular catheter of claim 34 wherein the sheath has an interior in fluid communication with the inner lumen extending within the catheter shaft.

15 36. The intravascular catheter of claim 31 wherein a guidewire is slidably disposed within the inner lumen which has an occluding distal tip to restrict fluid flow out the port in the distal end of the catheter and facilitate fluid flow through the at least one passageways extending through the emitting electrode.

37. The intravascular catheter of claim 36 wherein the inner lumen of the catheter shaft is configured to slidably receive a guidewire having an outer diameter of about 0.008 to about 0.03 inch.

20 38. The intravascular catheter of claim 25 wherein the emitting electrode forms the distal end of the elongated shaft and the inner lumen extends therethrough.

39. The intravascular catheter of claim 25 wherein the emitting electrode has an exterior surface which is in part covered with an insulation sheath to prevent transmission of electrical energy therefrom.

25 40. The intravascular catheter of claim 39 wherein the insulation sheath covers about 25% to about 75% of the peripheral exterior surface of the emitting electrode.

41. The intravascular catheter of claim 40 wherein the sheath extends on a side of the emitting electrode along a length thereof.

42. The intravascular catheter of claim 25 wherein an expandable positioning member is provided on one side of the distal section of the catheter shaft so that the expandable positioning member may be expanded when the distal section of the catheter shaft is disposed within a patient's blood vessel to laterally position the distal section within the blood vessel.

43. The intravascular catheter of claim 25 wherein the emitting electrode has a proximal tubular extension which is secured within the inner lumen of the catheter shaft.

44. The intravascular catheter of claim 25 wherein the catheter shaft comprises at least in part a tubular member formed by strands which include individually insulated electrical conductors.

45. The intravascular catheter of claim 44 wherein the strands are braided.

46. The intravascular catheter of claim 25 wherein the emitting electrode is a solid electrode about 2 to about 10 mm in length.

47. The intravascular device of claim 25 wherein the emitting electrode is a helical coil.

48. The intravascular device of claim 46 wherein the helical coil is about 2 to about 30 mm.

49. The intravascular device of claim 40 wherein the helical coil is about 2 to about 20 mm.

50. A method of treating a patient's heart experiencing arrhythmia comprising:

a) providing an intravascular catheter having

an elongated shaft having proximal and distal ends, a port in the distal end, an inner lumen extending within the shaft to the port in the distal end,

an emitting electrode on the distal end of the elongated shaft,

5 at least one electrical conductor extending from the emitting electrode and configured to be electrically connected to a high frequency electrical energy source;

b) percutaneously introducing a guidewire into the patient's vasculature, advancing the guidewire into the coronary sinus or coronary artery of the patient's heart and steering the guidewire into a branch blood vessel of the coronary sinus or coronary artery;

10 c) advancing the intravascular device over the guidewire to a desired location within said branch blood vessel;

d) detecting electrical activity within the patient's heart to determine the location of a source of arrhythmogenic signals or a conducting pathway therefore;

e) positioning the intravascular device within the blood vessel so that the emitting electrode is adjacent to the location; and

20 f) emitting high frequency electrical energy from the emitting electrode to form a lesion within the patient's heart encompassing tissue at said source or in the conducting pathway.

51. The method of claim 50 wherein the guidewire has a plurality of sensing electrodes on a distal portion thereof and the electrical activity is detected by said sensing electrodes.

25 52. The method of claim 50 wherein the temperature of the emitting electrode is controlled to less than about 100°C.

53. The method of claim 50 wherein the emitting electrode has at least one passageway extending therethrough in fluid communication with the inner lumen of the shaft and the temperature of the emitting electrode is controlled by directing

cooling fluid from the inner lumen through at least one passageway in the emitting electrode.

54. An intravascular catheter for sensing electrical activity of a patient's heart and forming a lesion in the patient's heart from within the blood vessel thereof by means of high frequency electrical energy comprising:

a) an elongated shaft having proximal and distal ends, a port in the distal end, an inner lumen which is configured to slidably receive a guidewire and which extends within the shaft to the port in the distal end;

b) a plurality of sensing electrodes on a distal shaft section;

c) an emitting electrode on the distal extremity of the elongated shaft distal to the sensing electrodes comprising a helical coil of metallic material;

d) an electrical conductor extending proximally from and in electrically conducting relationship with each of the sensing electrodes;

e) an electrical conductor in an electrically conducting relationship with and extending distally from the emitting electrode and having a proximal end configured to be electrically connected to a high frequency electrical energy source; and

f) an open weave tubular support member extending within the interior of the emitting electrode which is formed of a plurality of braided strands.

55. The intravascular catheter of claim 54 wherein the tubular support member has proximal and distal ends secured to the proximal and distal ends of the helical coil forming the emitting electrode.

56. The intravascular catheter of claim 54 wherein the strands forming the tubular support member are formed of metallic materials.

57. The intravascular catheter of claim 56 wherein the strands are metallic ribbons.

58. An intravascular catheter for forming a lesion in the patient's heart by means of high frequency electrical energy comprising:

a) an elongated shaft having proximal and distal ends and an inner lumen which extends within the shaft to a location spaced proximal to the distal end;

b) an emitting electrode on a distal extremity of the elongated shaft formed of a helical coil of metallic material;

c) an electrical conductor having a distal end electrically connected to the emitting electrode and a proximal end configured to be electrically connected to a high frequency electrical source; and

d) a tubular support member extending within the helical coil forming the emitting electrode which is formed of braided strands..

59. The intravascular catheter of claim 58 wherein the tubular support member has proximal and distal ends secured to the proximal and distal ends of the helical coil forming the emitting electrode.

60. The intravascular catheter of claim 58 wherein the strands forming the tubular support member are formed of metallic materials.

61. The intravascular catheter of claim 60 wherein the strands are metallic ribbons.

62. The intravascular catheter of claim 58 wherein braided strands of the tubular support member have an open weave structure to facilitate the passage of fluid therethrough.

63. The intravascular catheter of claim 58 wherein the helical coil forming the emitting electrode is at least in part expanded so that adjacent turns of the helical coil are spaced from each other.

64. The intravascular catheter of claim 58 wherein the inner lumen is defined by a tubular member. 65. The intravascular catheter of claim 58 wherein the shaft has a port in the distal end thereof and the inner lumen defined by the tubular member extends to and is in fluid communication with the port in the distal end. 66. The intravascular catheter of

claim 58 wherein the braided strands forming the tubular support member extend proximally from and form at least part of a wall portion of the shaft.

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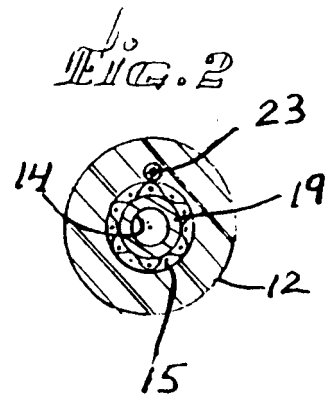
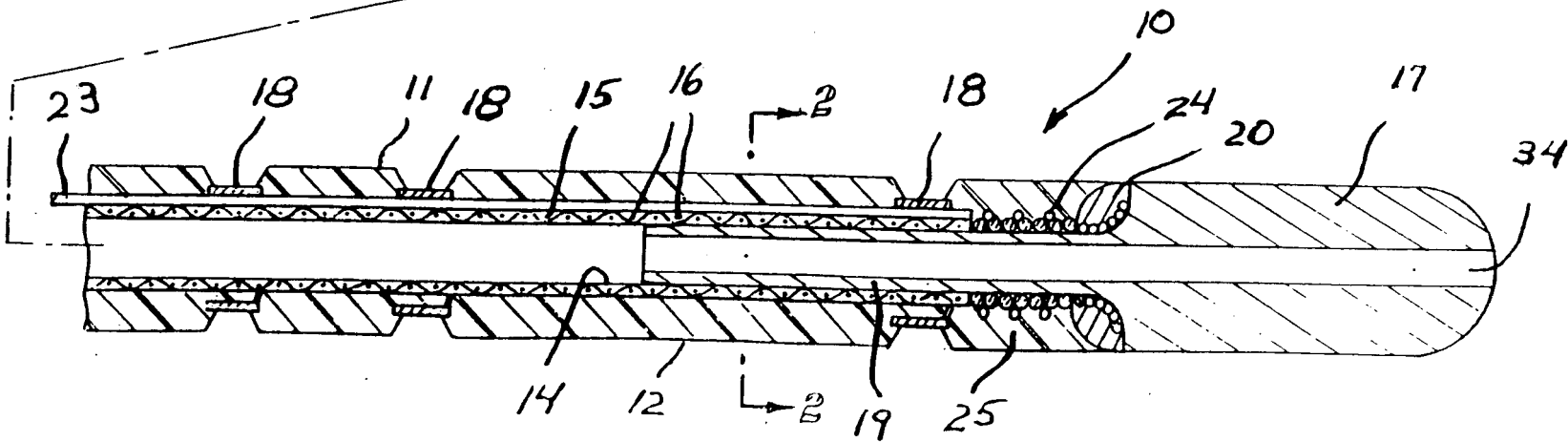
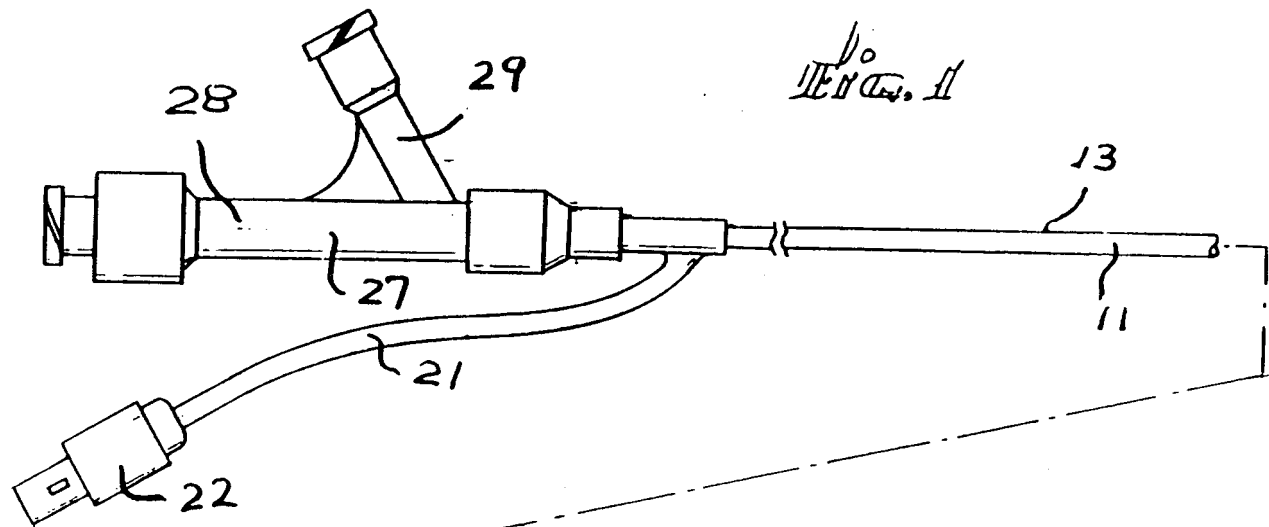


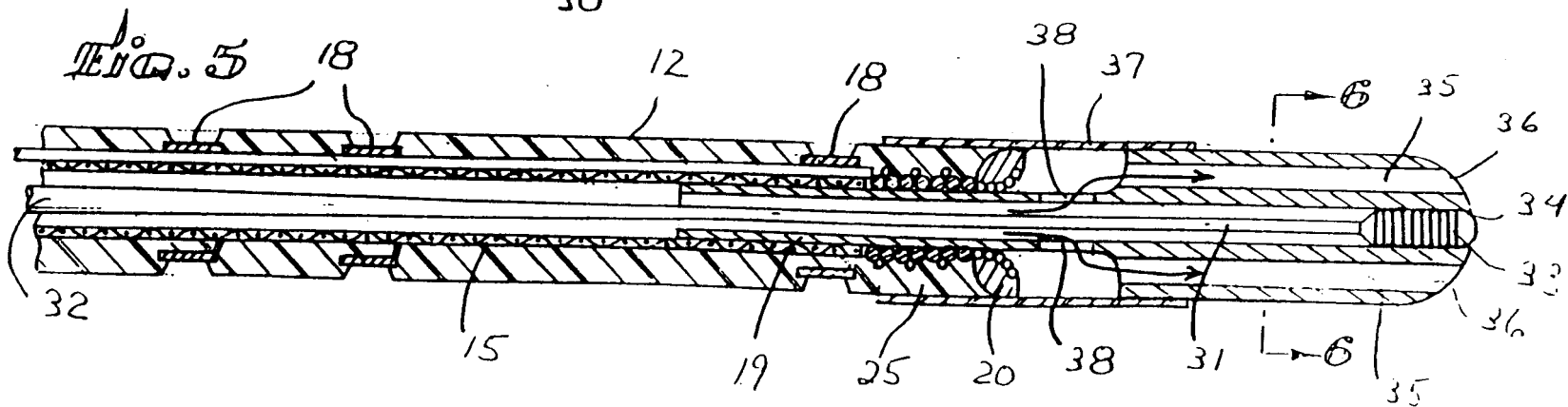
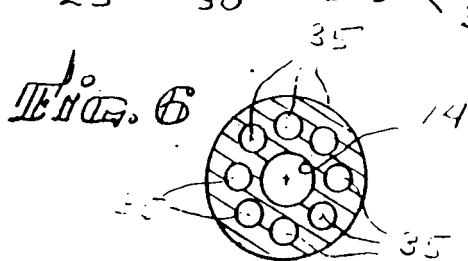
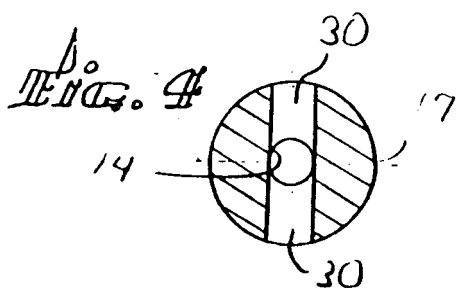
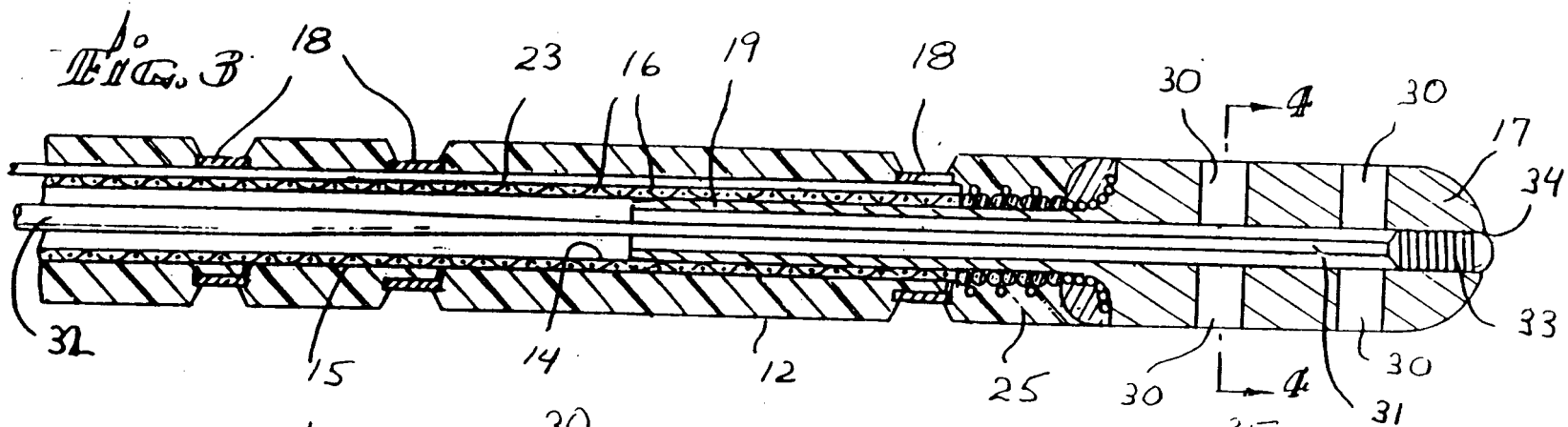
FIG. 1



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FIG. 12

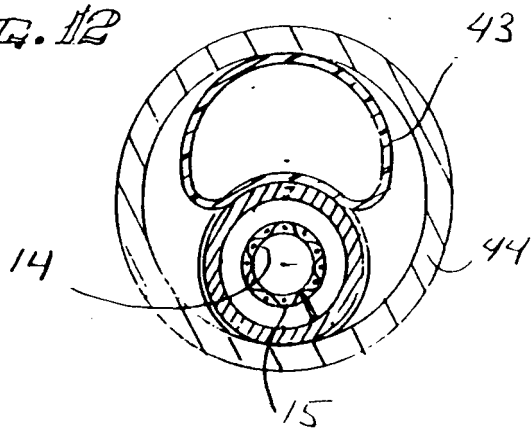
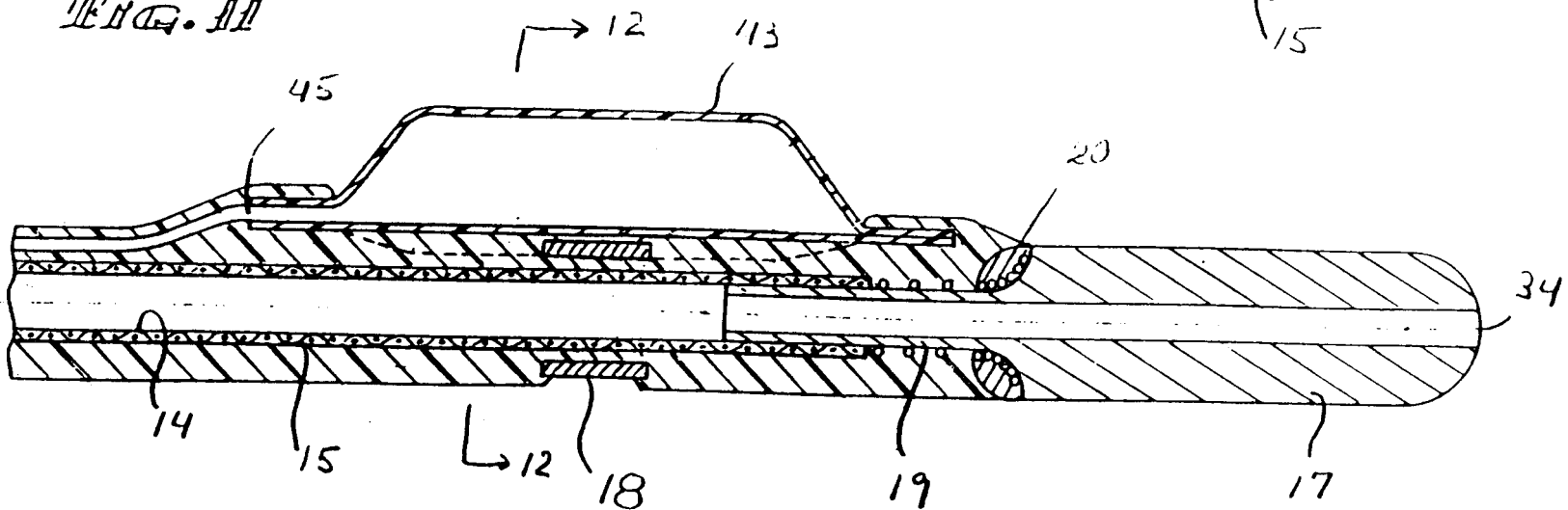
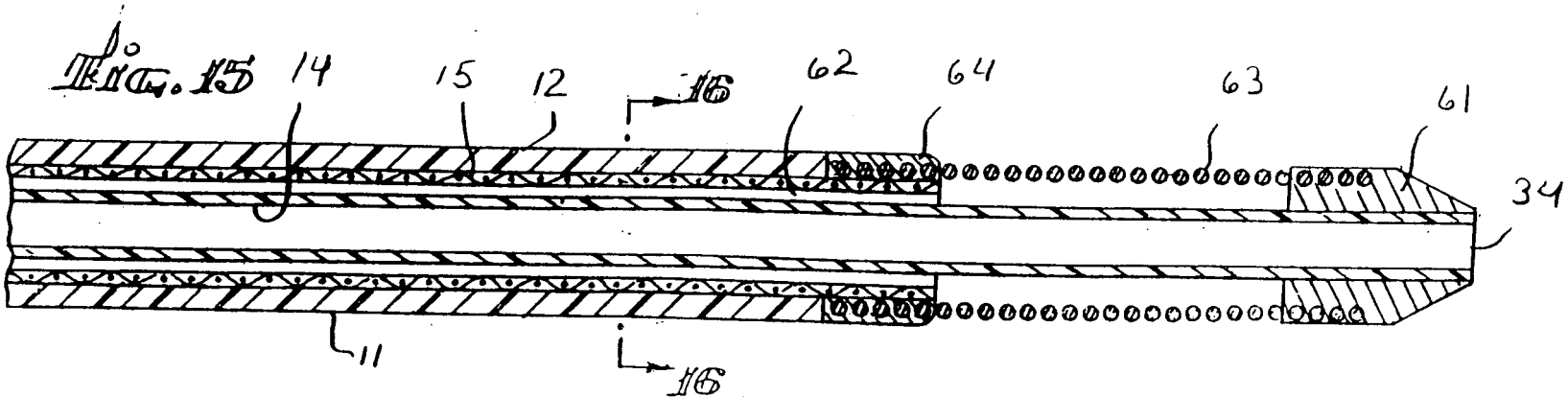
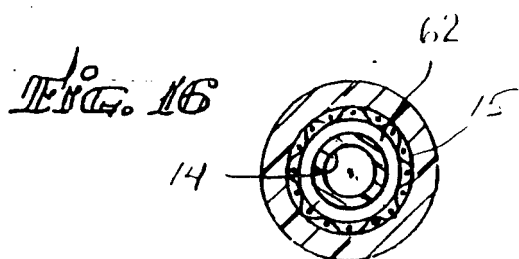
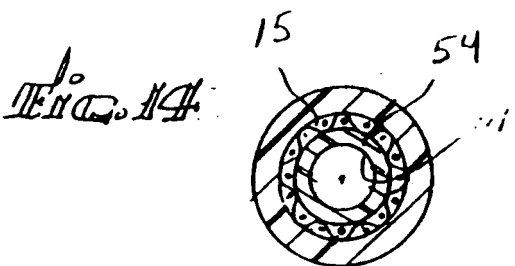
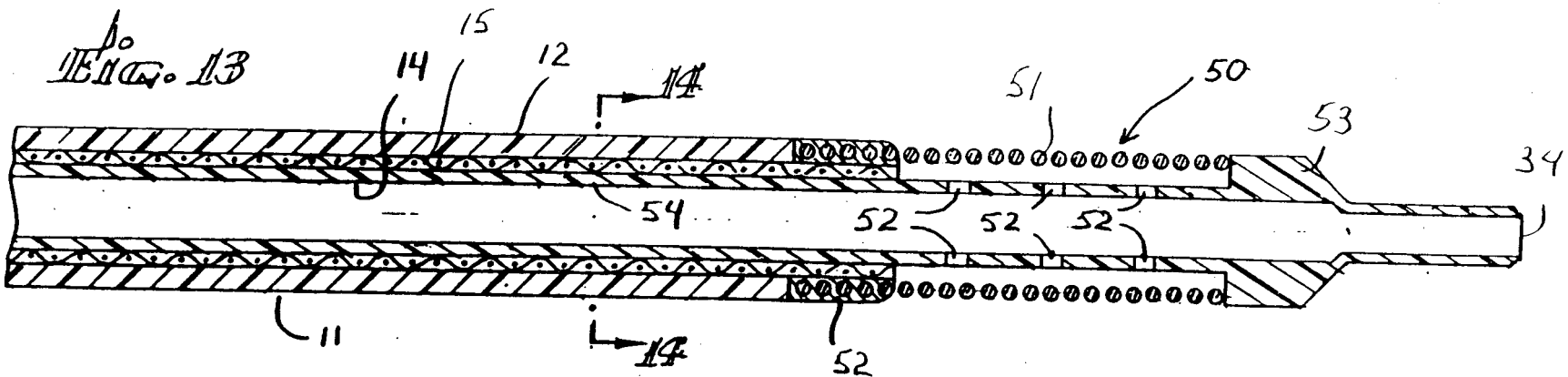


FIG. 11



CARDINAL



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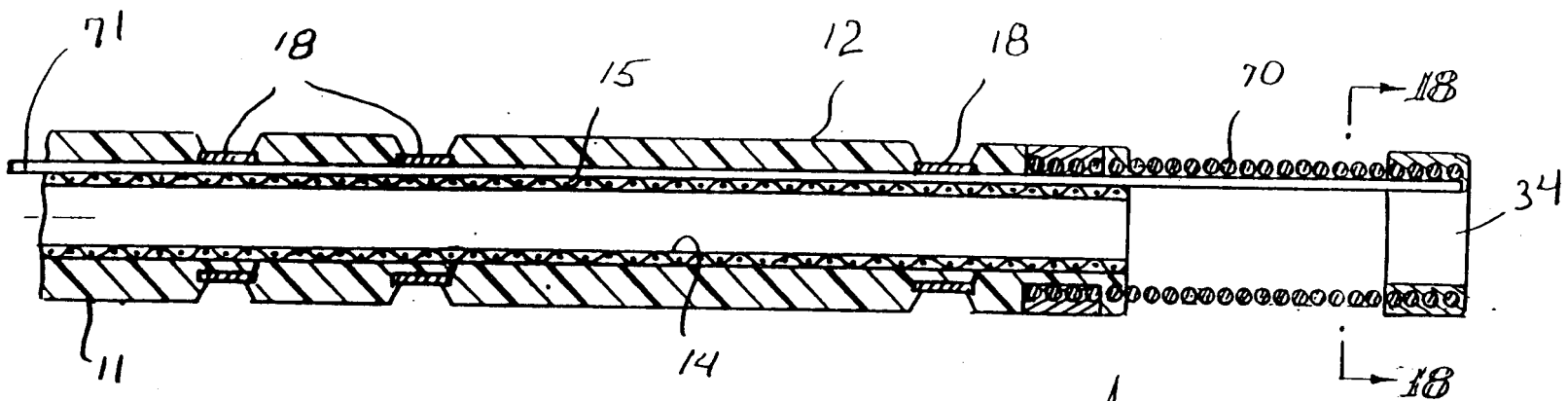


FIG. 17

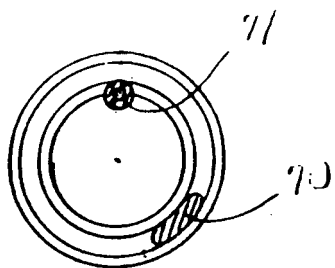


FIG. 18

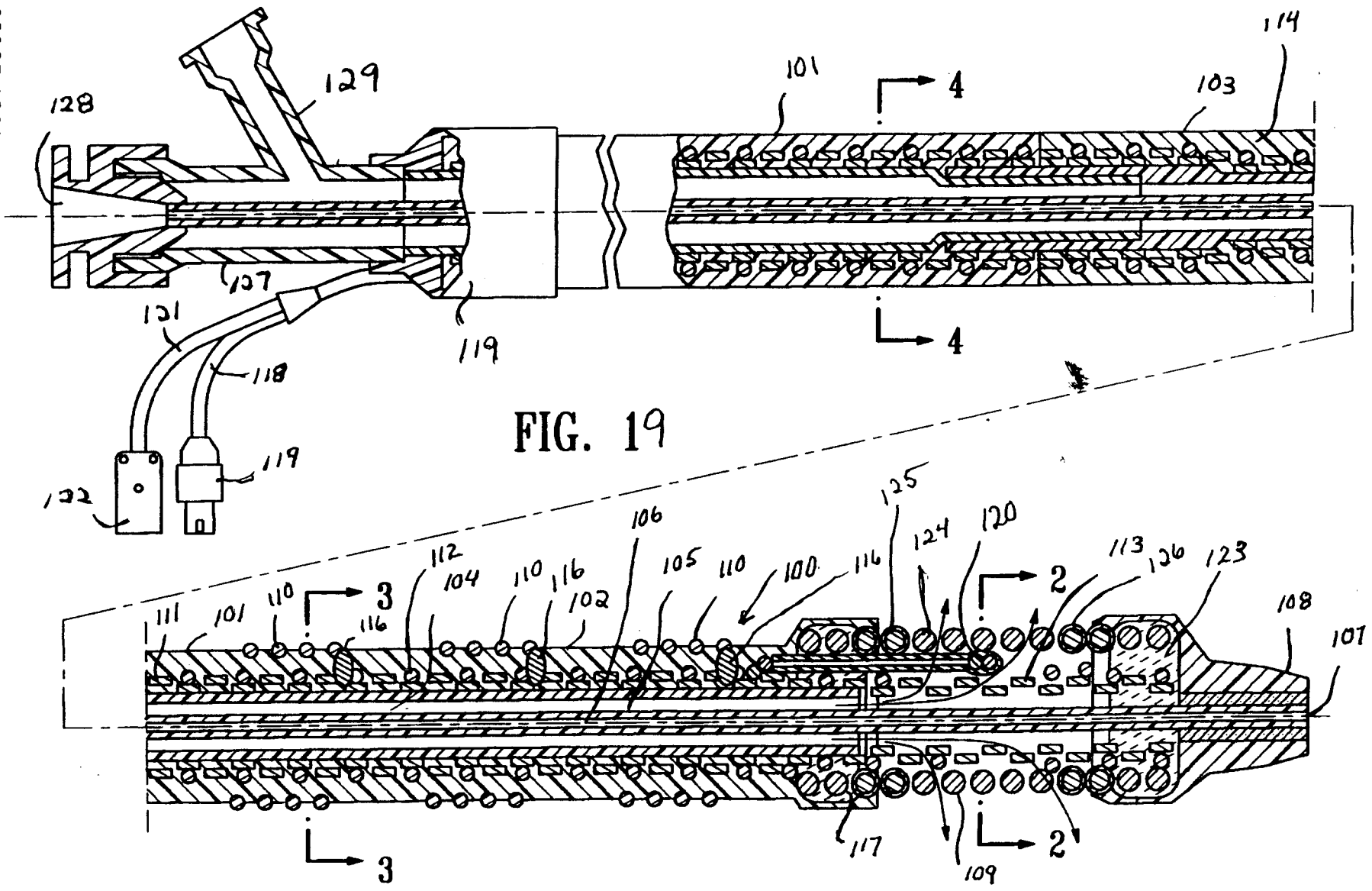
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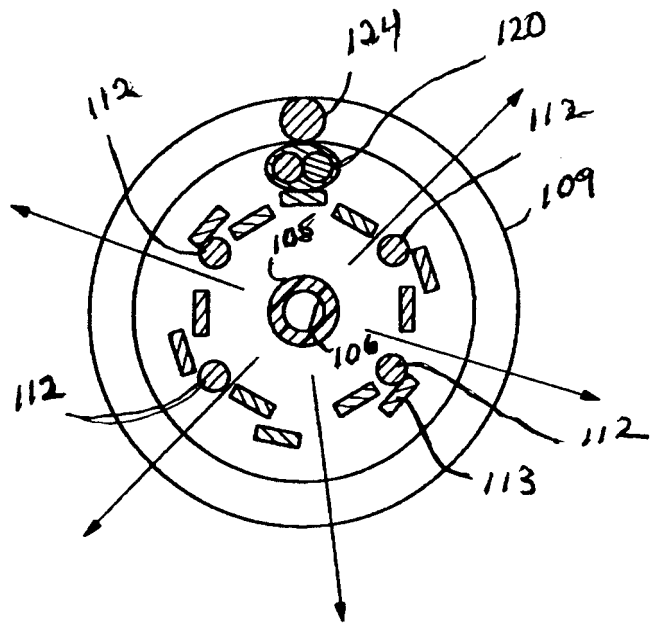


FIG. 20

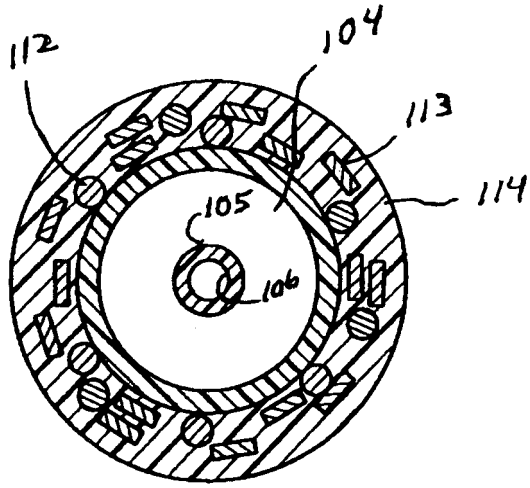


FIG. 422

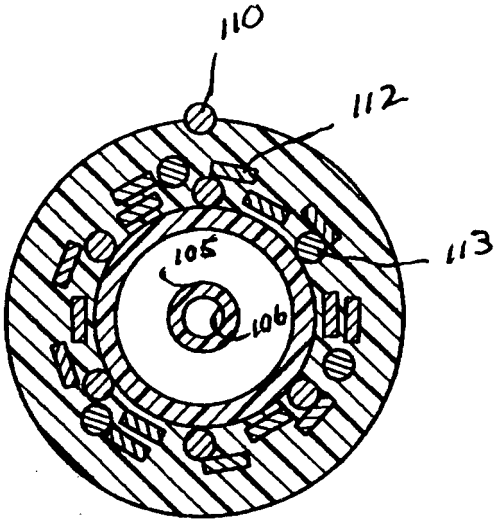


FIG. 321

INTERNATIONAL SEARCH REPORT

International Application No

PC1/US 98/04574

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B5/042 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 96 37146 A (CARDIMA) 28 November 1996 see the whole document	1-66
X	WO 95 05771 A (WEBSTER) 2 March 1995	1,3-8, 10,11, 18-20, 24,25, 27-33, 38,43,46
A	see the whole document	58, 60-62, 64-66



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

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

"E" earlier document 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 when the document is taken alone

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

"&" document member of the same patent family

Date of the actual completion of the international search

15 May 1998

Date of mailing of the international search report

22.05.98

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Authorized officer

Lemercier, D

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/04574

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 16619 A (CARDIMA) 4 August 1994	1,6,18, 19,21, 22,24
Y	see the whole document	3,4,6-8, 10, 14-17, 20,23, 44,45
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Y	EP 0 608 609 A (CARDIAC PATHWAYS) 3 August 1994	3,4,6-8, 27,28, 30-33, 36-38
A	see the whole document	11,12,46
X	EP 0 499 491 A (CARDIAC PATHWAYS) 19 August 1992	1,18,19, 25
Y	see the whole document	10,27, 28, 30-33, 36-42, 44,45,47
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Y	WO 95 10322 A (EP TECHNOLOGIES) 20 April 1995	14-17, 23, 39-42,47
	see abstract; figures 7-12,49,50	
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	see abstract; figures 1-6	
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A	WO 94 02077 A (ANGELASE) 3 February 1994	1,3-7, 23-25, 27-30, 46-49, 54-58,64
	see page 5, line 12 - page 6, line 30 see page 14, line 13 - page 16, line 14	

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 184 621 A (VOGEL & AL.) 9 February 1993 see column 7, line 4 - column 8, line 25 ----	1,2,6, 23-26
A	CA 2 032 883 A (MEDICAL ENGINEERING & DEVELOPMENT) 30 June 1991 see page 8, line 25 - line 35 see page 9, line 33 - page 10, line 7 ----	2,26,63
A	US 4 519 403 A (MEDTRONIC) 28 May 1985 see column 2, line 28 - line 42 see column 3, line 18 - line 33 ----	17,42
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A	EP 0 573 311 A (CARDIAC PATHWAYS) 8 December 1993 see abstract; figures 1-5 -----	1,25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/04574

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 50-53
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
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, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ 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 claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/04574

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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