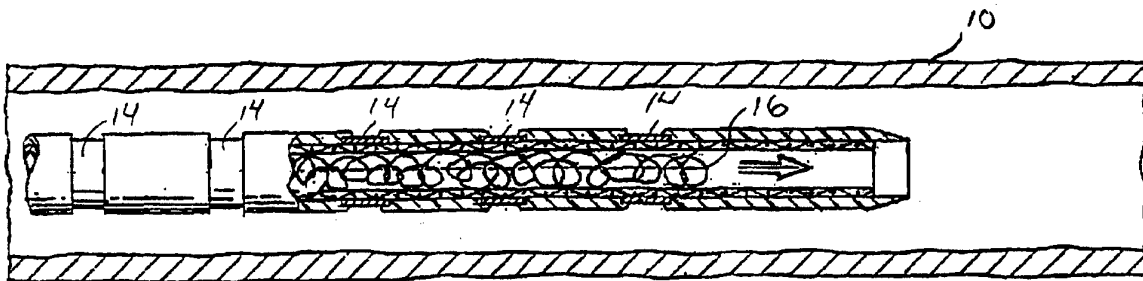




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>5</sup> :</b> <b>A61B 17/12, 5/042</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 94/16632</b> <b>(43) International Publication Date:</b> 4 August 1994 (04.08.94)												
<b>(21) International Application Number:</b> PCT/US94/01018 <b>(22) International Filing Date:</b> 28 January 1994 (28.01.94) <b>(30) Priority Data:</b> <table border="0"> <tr> <td>08/010,818</td> <td>29 January 1993 (29.01.93)</td> <td>US</td> </tr> <tr> <td>08/043,449</td> <td>5 April 1993 (05.04.93)</td> <td>US</td> </tr> <tr> <td>08/057,294</td> <td>5 May 1993 (05.05.93)</td> <td>US</td> </tr> <tr> <td>not furnished</td> <td>27 January 1994 (27.01.94)</td> <td>US</td> </tr> </table> <b>(71) Applicant:</b> CARDIMA, INC. [US/US]; 47201 Lakeview Boulevard, Fremont, CA 94538 (US). <b>(72) Inventors:</b> SUNG, Ruey; 1000 Rowan Tree Lane, Hillsborough, CA 94010 (US). SAMSON, Gene; 32916 Great Salt Lake Street, Fremont, CA 94536 (US). <b>(74) Agents:</b> LYNCH, Edward, J. et al.; Crosby, Heafey, Roach & May, 1999 Harrison Street, Oakland, CA 94612 (US).		08/010,818	29 January 1993 (29.01.93)	US	08/043,449	5 April 1993 (05.04.93)	US	08/057,294	5 May 1993 (05.05.93)	US	not furnished	27 January 1994 (27.01.94)	US	<b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
08/010,818	29 January 1993 (29.01.93)	US												
08/043,449	5 April 1993 (05.04.93)	US												
08/057,294	5 May 1993 (05.05.93)	US												
not furnished	27 January 1994 (27.01.94)	US												
<b>(54) Title:</b> INTRAVASCULAR METHOD AND SYSTEM FOR TREATING ARRHYTHMIA   <b>(57) Abstract</b> <p>A method and system for treating a patient's heart exhibiting arrhythmia by first detecting electrical activity within the patient's heart to determine the location of the arrhythmogenic site or conductive pathway causing the arrhythmia and then creating an infarct within the region of the patient's heart where the arrhythmogenic site or the conductive pathway causing the arrhythmia is located by delivering an occluding element to a coronary artery which delivers oxygenated blood to said region of the patient's heart. In one presently preferred embodiment the occluding element is a flaccid or limp coil which when disposed in a coronary arterial passageway forms a randomly shaped, intertwined mass which quickly forms thrombus within the coronary artery to block the passage of oxygenated blood therethrough. The flaccid coil may be delivered through an inner lumen of a catheter which has a distal portion extending within the coronary artery.</p>														

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

**INTRAVASCULAR METHOD AND SYSTEM FOR TREATING ARRHYTHMIA****RELATED APPLICATIONS**

5                    This application is a continuation-in-part application of application Serial No. 08/010,818, filed January 29, 1993, application Serial No. 08/043,449, filed April 5, 1993, and application Serial No. 08/057,294, filed May 5, 1993, which are incorporated herein in their entirety by reference.

10                    **BACKGROUND OF THE INVENTION**

                    This invention generally relates to the treatment of arrhythmia and particularly an intravascular method and system for treating arrhythmia.

                    Prior methods for treating a patient's arrhythmia include the  
15                    use of antiarrhythmic drugs such as sodium and calcium channel blockers or drugs which reduce the Beta-adrenergic activity. Other methods include the surgically sectioning the origin of the signals causing the arrhythmia or the conducting pathway for such signals. More frequently, however, in order to terminate an arrhythmia the arrhythmogenic site

which causes the arrhythmia or conductive pathways which propagate aberrant signals are destroyed by heat, e.g. applying a laser beam or radio frequency (RF) energy to a desired location on the patient's endocardium.

A major problem of ablating the origin of the signals or a conductive  
5 pathway is to accurately determine the location of the site so that an excessive amount of good tissue is not destroyed adjacent the site.

For example, the average arrhythmogenic site consists of about 1.4 cm<sup>2</sup> of endocardial tissue, whereas a re-entrant site might be much larger. RF ablation techniques produce lesions about 0.5 cm<sup>2</sup> in  
10 diameter, so a number of lesions might be generated in order to completely ablate the area of interest. If the site is not accurately mapped, much of the good tissue surrounding the site will be unnecessarily destroyed.

Other methods to terminate arrhythmia have been tried but  
15 they have not been used clinically to any great extent for a variety of reasons. For example, ethanol may be injected into a branch of a coronary artery which feeds an arrhythmogenic region of the patient's heart or a conductive pathway therein to occlude the arterial passage and create a controlled infarct at the arrhythmogenic site or the conductive  
20 pathway to terminate the arrhythmia. However, due to reflux of the ethanol, it is not always possible to control the region of cytotoxic activity within the heart. Additionally, over time, it has been found that

the occluded arterial passageway frequently is subject to recanalization which can allow the arrhythmia to return.

What has been needed is an effective method and system for permanently occluding a portion of a patient's coronary artery which  
5 feeds the tissue of a patient's heart causing the arrhythmia, such as an arrhythmogenic or re-entrant site or a conductive pathway, in order to the terminate an arrhythmia.

### **SUMMARY OF THE INVENTION**

This invention is directed to a method and system for  
10 treating a patient's heart exhibiting arrhythmia by effectively occluding an arterial passageway which feeds oxygenated blood to heart tissue causing the arrhythmia and which preferably includes the intravascular detection of electrical activity or signals within a patient's heart causing the arrhythmia.

15 In accordance with one aspect of the invention, the tissue causing the arrhythmia such as an arrhythmogenic or re-entry site or a conductive pathway, is first located within a patient's heart, preferably intravascularly, and then an occluding element is advanced through the patient's coronary arterial system to a small arterial vessel where the  
20 occluding element is deposited to block the flow of oxygenated blood therethrough. The ischemic conditions created by such blockage distal to the occluding element ultimately leads to an infarct which terminates the arrhythmia. The occluding element of the invention remains in the

coronary arterial passageway, so there is little tendency for recanalization to occur which might lead to the recurrence of the arrhythmia.

In one presently preferred embodiment of the invention, the occluding member is an open-bodied element such as a flexible helical coil or a braided tubular element which, when deposited in a small coronary  
5 arterial passageway, will promptly form thrombus and thereby occlude the arterial passageway. Preferably, the thrombus forming element is limp or flaccid so that when introduced into the arterial passageway it will form a randomly shaped, intertwined mass in which thrombus quickly forms to  
10 occlude the arterial passageway. Other means for occluding the arterial passageway include expandable occluding elements such as an inflatable balloon or an expandable mechanical element which blocks fluid flow through the passageway. The occluding means is preferably delivered to the desired location within the arterial passageway of the patient's heart  
15 by an intravascular catheter which has an inner lumen extending therein to a discharge port in the distal end of the catheter.

One presently preferred embodiment of the invention is an exceptionally flexible, ultrasoft vaso-occlusive or embolism device which is made of a radiopaque material which may be braided or coiled to form a  
20 long, thin threadlike device having little rigidity or column strength. The diameter of the device may be less than about 0.010 inches (0.25 mm), preferably less than about 0.0075 inches (0.19 mm) in diameter. The wire making up the device is typically of a diameter less than about 0.002

(0.05 mm) inches. The device is sufficiently flexible and small that it may be hydraulically delivered to a site within a coronary artery of a human heart using a catheter. The device is so light that it typically cannot be pushed from the catheter in the way that coils are often introduced into  
5 vascular site. Because of their flexibility and size, there is little opportunity for friction to develop with the catheter lumen.

The occluding device typically assumes a loose, random, intertwined mass after being ejected from the catheter tip at the selected arterial site. The device, whether coil or braid, may be used in  
10 conjunction with larger coils or braids to achieve a denser occlusion.

This embodiment also includes first introducing a vaso-occlusive coil having a larger diameter to the vascular site desired by the attending physician, followed by the introduction of the flaccid coil of this embodiment so as to fill the interstices left by the larger coil and thereby  
15 form a denser occlusion. The coils may also be introduced by themselves, if so desired.

In another presently preferred embodiment, an elongated intravascular catheter used for delivering the occluding element has a plurality of sensing electrodes on the distal section thereof. After the  
20 occluding element is delivered into the arterial passageway through the inner lumen of the catheter, the sensing electrodes on the distal section of the catheter may be used to monitor the electrical activity from within the arterial passageway to determine whether the arrhythmia has been

effectively terminated. If it is determined that the arrhythmia has not been completely terminated by injecting a first occluding coil, other step may be taken such as delivering a second occluding element such as a coil through the inner lumen of the catheter to the blockage site to further  
5 occlude the arterial passageway to ensure the complete termination of the arrhythmia.

Once the arrhythmia has been terminated in accordance with the present invention, there is little likelihood that recanalization of the arterial passageway will occur and that the arrhythmia will reappear.

10

The preferred method to detect electrical activity within the patient's heart tissue causing arrhythmia is to position one or more elongated intravascular devices having sensing electrode on the distal section thereof within coronary arteries and/or cardiac veins of patient's  
15 heart. A suitable intravascular device has an elongated shaft with a proximal section and a distal section which is configured to be considerably more flexible than the proximal section and to be advanceable through a patient's tortuous coronary anatomy. The distal section has a plurality of electrodes spaced along a length of the distal  
20 section. Preferably, up to 20 or more bipolar electrode pairs may be provided along the distal section of the shaft. The sensing electrodes are electrically connected to electrical conductors which extend from the electrode to which they are connected to the proximal end of the shaft.



In a presently preferred embodiment, the shaft of the intravascular sensing device is formed of a plurality of insulated electrical conductors which are braided or woven into an elongated tubular member, although not all of the strands which make up the braided or woven tubular member need be electrical conductors. Underneath each sensing electrode, the insulation on an individual conductor is removed to expose the bare conductor so that an electrical connection can be made between the electrode and the conductor. The electrical connection should be secured by suitable means such as conductive solder or brazing material.

Moreover, the electrodes should also be secured to the underlying tubular member by other suitable means such as an adhesive to ensure that appropriate electrical contact with the exposed conductors is maintained even though there is a brazed or soldered electrical connection.

One form of a suitable elongated intravascular sensing device is a guidewire. The distal section of the guidewire having a plurality of sensing electrodes has a flexible tip coil which is distal to the length on which the electrodes are mounted and which is disposed about the distal extremity of a core member which extends through the interior of the shaft. The distal end of the core member may be manually shapable by the physician to facilitate steering the guidewire when it is being advanced within the patient's coronary anatomy by torquing the proximal end which extends outside of the patient. A smooth rounded tip is provided at the distal end of the coil to avoid damage to the patient's

vasculature when being advanced therethrough. A safety or shaping ribbon may extend from the distal end of the core member to the rounded tip in conventional guidewire fashion, commonly called a "floppy tip", to allow the distal portion to be manually shaped and also to prevent the  
5 loss of the distal tip of the guidewire within the patient's coronary vasculature.

The intravascular sensing device may also be in the form of a catheter which has proximal and distal sections with the distal section being more flexible than the proximal section and having a plurality of  
10 electrodes as in the guidewire form. In addition, the catheter has an elongated inner lumen extending from the proximal end to a discharge or guidewire port in the distal end of the device. The distal end of the catheter having the discharge port may be provided with a soft tip to minimize traumatic engagement with a blood vessel wall when being  
15 advanced therein. The catheter form allows an occluding element to be passed through the inner lumen into the arterial passageway and the sensing electrodes on the distal section thereof allows electrical activity to be monitored in order to determine the effectiveness of the arterial blockage and particularly whether the arrhythmia has been terminated.  
20 The inner lumen of the catheter may be configured to facilitate the slidable disposition of a conventional guidewire or a guidewire version of the sensing device of the invention such as described above.

The use of a plurality of elongated intravascular devices is preferred so that they can be advanced into separate blood vessels of the patient's heart to detect electrical activity in a plurality of intravascular locations, thereby providing more comprehensive or global mapping of the patient's heart and a more accurate location of tissue causing an arrhythmia. The positions of the intravascular sensing devices may be adjusted within the individual blood vessels to optimize the reception of the electrical activity to provide a greater degree of accuracy in detecting the ectopic foci.

The use of intravascular sensing devices to locate the tissue causing the arrhythmia simplifies the treatment procedures and reduces the overall time for the procedure. If the sensing device is a catheter, the occluding element can be quickly advanced through the inner lumen thereof. If the sensing device is a guidewire, a catheter with an inner lumen may be quickly advanced over the in-place guidewire, the guidewire removed and an occluding element advanced through the inner lumen of the catheter.

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

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 is a longitudinal cross-sectional view of catheter-guidewire assembly for detecting electrical signals within a coronary artery.

5 Fig. 2 is a longitudinal cross-sectional view of the catheter shown in Fig. 1 with the guidewire removed and a mass of occluding coil being hydraulically propelled along the inner lumen of the catheter.

Fig. 3 is a longitudinal cross-sectional view of the distal portion of the catheter shown in Fig. 1 with the mass of coil deposited within the arterial passageway an thrombus formed in the mass occluding the passageway of the coronary artery.

10

Fig. 4 is an anterior view of coronary arteries and cardiac veins of a human heart with portions of the right coronary artery, the anterior interventricular branch of the left coronary artery and the great cardiac vein being in section to illustrate intravascular devices disposed therein.

15

Fig. 5 is an elevational view of a guidewire suitable for detecting electrical activity.

Fig. 6 is an enlarged longitudinal cross-sectional view of a distal portion of the guidewire shown in Fig. 5.

20 Fig. 7 is an enlarged longitudinal cross-sectional view of the distal portion of a guidewire similar to the one shown in Fig. 6 but having a shaft formed of a plurality of braided layers.

Fig. 8 is a transverse cross-sectional view of the distal portion of the guidewire shown in Fig. 7 taken along the lines 8-8.

Fig. 9 is a longitudinal cross-sectional view of an intermediate portion of the guidewire shown in Fig. 5 taken along the lines 9-9.

Fig. 10 is an elevational view, partially in section of a catheter suitable for detecting electrical activity.

Fig. 11 is a transverse cross-sectional view of the catheter of Fig. 10 taken along the lines 11-11.

Fig. 12 is a longitudinal cross-sectional view of a guidewire having a releasable occluding element on its distal end.

Fig. 13 is an elevational view of an occluding element suitable for use with the invention.

Fig. 14 is an elevational view of another occluding element suitable for use with the invention.

Fig. 15 is an elevational view of another occluding element suitable for use with the invention.

Fig. 16 is an elevational view of another occluding element suitable for use with the invention.

#### **DETAILED DESCRIPTION OF THE INVENTION**

Figs. 1-3 illustrate one presently preferred method of the invention wherein electrical activity of a patient is detected from within a coronary artery 10 of the patient's heart to determine the location of

tissue causing arrhythmia and then occluding the coronary artery which directs oxygenated blood to such tissue to create an infarct therein and thereby terminate the arrhythmia. As is shown in Fig. 1, an intravascular catheter 11 is disposed within coronary artery 10 and an intravascular  
5 guidewire 12 is slidably disposed within inner lumen 13 of catheter 11. Catheter 11 has a plurality of sensing electrodes 14 on the distal section thereof and guidewire 12 has a plurality of sensing electrodes 15 on the distal portion thereof for detecting electrical activity so that tissue causing the arrhythmia can be located within the patient's heart. When the tissue  
10 causing the arrhythmia is located, the guidewire 12 is withdrawn from the inner lumen 13 of the catheter 11 and an elongated flaccid coil 16 is hydraulically delivered within a bolus of suitable liquid, such a saline solution, through the inner lumen 13, as illustrated in Fig. 2. When the coil 16 is deposited into the passageway of the coronary artery 10, it  
15 forms a randomly shaped intertwined mass 17. Thrombus 18 quickly forms within the interstices of the coil mass to effectively occlude the arterial passageway.

As shown in Fig. 4, electrical activity of the patient's heart may be detected by a plurality of elongated intravascular sensing devices,  
20 with one sensing device 20 being disposed within the anterior interventricular branch of the left coronary artery 21, a second sensing device 22 in the great cardiac vein 23 and a third sensing device 24 in

the right coronary artery 25. As shown, the intravascular sensing devices are guidewires.

Reference is made to Figs. 5-9 which schematically illustrate in greater detail an elongated intravascular sensing device useful in the present invention which is in the form of a guidewire 30 which includes shaft 31 with a distal portion 32 and a proximal portion 33. The shaft 31 is formed of a tubular member 34 formed of a plurality of braided or woven electrical conductors 35. While it is preferable that the conductors 35 be interwoven into the tubular member 34, they may be twisted or wound about a mandrel or the core member 38. In the latter case the inner and outer layers of conductors would be laid out diagonally but the conductors of one layer would be laid in the opposite direction to that of the conductors in the other layer. Usually, the wound or twisted conductors are secured together by suitable adhesive which makes the shaft relatively stiff, whereas with the interwoven conductors there is sufficient interlocking of the conductors that adhesives are not usually needed with the result of a more flexible shaft 31. The distal section 32 of the shaft 31 is provided with a plurality of electrodes 36 which are preferably arranged as pairs 37 to facilitate a bipolar or multipolar mode of operation. A core member 38 is disposed within the inner lumen of the braided tubular member 34 and extends beyond the distal end thereof. The distal end 39 of the core member 38 is preferably flattened, as shown in Fig. 6, and extends and is joined to a smooth rounded distal tip

40 which is formed when a distal coil 41, which is disposed about the distal end of the core member, is secured thereto by soldering, brazing, welding or a body of adhesive and the like. The core member 38 may be provided with one or more tapers 42 as with conventional guidewires.

- 5 The proximal portion 33 of the shaft 31 has two extensions 43 and 44 which have multi-pin connectors 35 and 46 on the proximal ends thereof with each of the electrical conductors 45 being electrically connected to a separate pin.

Details of the catheter form of the sensing device are best  
10 illustrated in Figs. 10 and 11. In this embodiment, catheter 50 has an elongated shaft 51 with an inner lumen 52 defined by an inner tubular element or lining which is preferably formed of lubricous material such as fluoropolymers, e.g. Teflon® and polysulfones and hydrophilic polymers such as polyvinylpyrrolidone, polyethylene oxide and acrylate-based  
15 polymers. A tubular member 53 is disposed about tubular lining and is formed of at least one braided layer 54 comprising a plurality of the strands 55 which are insulated electrical conductors electrically connected to electrodes 57, preferably arranged in pairs 58 to facilitate bipolar mode operation. While not shown in the drawing, a plurality of  
20 braided layers may be desirable with more than eight electrode pairs 58. Some of the strands 55 in each of the layers may be formed of nonconducting materials such as nylon. An outer jacket 56 extends the length of the shaft 51 and the portion of the jacket extending beyond the



distal end of the braided tubular member 52 is tapered to provide a nontraumatic flexible distal tip 59. As in the previously described embodiments, the outer jacket 56 overlaps the edges of the electrodes 57 to avoid exposing a sharp metal edge when advancing the catheter through a patient's blood vessel. A guidewire 60 (shown in phantom) is slidably disposed within the inner lumen 52.

The catheter 50 may be used to direct diagnostic or therapeutic fluids to distal locations within a patient's coronary vasculature. For example, fluids containing cardioplegic materials such as iced saline, solutions of KCl, lidocaine, procaineamide hydrochloride and the like can be delivered to a region of the patient's heart which is believed to contain the tissue causing the arrhythmia. If the arrhythmia stops upon the delivery of the cardioplegic agent through a coronary artery feeding the region of the patient's heart, then the operator is assured that the artery through which the agent is delivered feeds the tissue causing the arrhythmia. The intravascular catheter 48 may be utilized in conjunction with a conventional guidewire or with an intravascular device with a plurality of electrodes on a distal portion thereof such as described above.

When using an approach to the patient's heart through the femoral artery or femoral vein, it is frequently helpful to utilize one or more guiding catheters (as shown in Fig. 4) to guide the intravascular sensing devices of the invention to the coronary artery ostium or the

coronary sinus ostium. Such guiding catheters frequently have specially shaped distal tips to facilitating the seating thereof within the desired ostium. The use of guiding catheter eliminates the need to direct the distal tip of a catheter or a guidewire of the invention into the desire  
5 ostium.

The electrodes on the distal portions of the sensing devices are typically gold bands with widths of about 0.5 mm. The distance between the electrodes of an electrode pair is typically about 1 mm and the distance between electrode pairs is typically about 7-8 mm.

10 The overall length of the intravascular devices of the invention depend upon the site of introduction into the patient's peripheral vasculature but may range from about 80 to about 300 cm, typically about 135 cm for delivery through the femoral artery or vein and about 90 cm for delivery through the brachiocephalic artery or internal jugular  
15 vein. The flexible distal portions of the intravascular sensing devices are about 10 to about 50 cm in length and are configured to be readily advanceable through a patient's coronary arteries or cardiac veins. The outer diameter of the catheter form of the sensing device should be less than about 0.055 inch (1.4 mm) and preferably about 0.035 inch (0.89  
20 mm) and the inner lumen thereof is about 0.012 to about 0.022 inch (0.3-0.56 mm) in diameter to facilitate the reception and advancement of a guidewire therethrough. The distal portion of the guidewire is about 15 to about 40 cm in length and about 0.008 to about 0.022 inch (0.2-0.56

mm) in outer diameter to facilitate advancement through blood vessels having native diameters of less than 1 mm, frequently less than 0.75 mm. The distal coil on the guidewire is about 2 to about 10 cm in length and is formed of wire about 0.0003 to about 0.006 inch (0.0076-0.15 mm) in diameter. It is preferably formed of platinum to facilitate fluoroscopic observation thereof within the patient, but it may be formed in whole or in part with other material such as stainless steel, titanium, palladium, niobium, iridium, rhodium and alloys thereof.

To the extent not previously described, the materials of construction of the various guidewire and catheter parts may be formed of conventional materials. The electrical conductors may be electrical grade copper wire about 0.005 inch (0.127 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 fluoropolymer such as THV which is available from 3M Corporation. The core wire of the guidewire may be formed of stainless steel or a superelastic NiTi type alloy, the latter exhibiting a stable austenite phase at body temperature. Proximal and distal sections of the core member may be formed of different materials so as to provide a stronger proximal section for greater pushability and a more flexible distal section to facilitate passage through tortuous coronary anatomy. Manufacturing techniques used in making catheters and guidewires for angioplasty procedures may be used in the making of the intravascular devices of the invention.

An alternative embodiment of the invention in the form of a guidewire 70 is shown in Fig. 12 which has a single pair of electrodes 71 on distal section 72. A coil 73 is disposed about the distal portion of core member 74 distal to the distal electrode 71 and it is secured to the core member by a suitable means 75. Such securing may be effected by soldering, brazing, welding or suitable adhesive depending upon the materials from which the coil 73 and the core member 74 are made. The distal end of the guidewire 70 has a detachable vaso-occlusive coil 76 attached at the most distal end of the guidewire. The core member 74 is extended past the separator tip 77 and forms an electrical connection with vaso-occlusive coil 7 at the connection 75.

The intravascular device shown in Fig. 12 may be used in the following fashion. The guidewire 70 is advanced out of an intravascular catheter into a desired location within a coronary artery of the patient and the connection between the vaso-occlusive coil 76 and the core member 74 is severed by electrolytic activity so that the coil 76 is released from the guidewire. When released, the coil 86 forms a randomly shaped intertwined mass similar to that shown in Fig. 3. Thrombus quickly forms within the interstices of the coiled mass to occlude the arterial passageway. The sensing electrodes 71 on the distal section of the guidewire 20 may be used to monitor electrical activity to ensure that the arrhythmia has been terminated.

Figure 13 shows a coil (90) suitable for use with this invention. It preferably has a diameter (91) of about 0.00075 to about 0.00225 inches, more preferably about 0.001 to about 0.002 inches. A separate end cap (92) or termination piece may be included at each end of the coil 90 to prevent the coil from catching on the interior of the catheter or a blood vessel. The end cap or termination piece (92) may be a separate piece or a fused portion of the coil 90 or a bit of a filled material such as an epoxy.

The coil 90 is typically produced as a single-layer coil with a minimum helical pitch, i.e. the windings are fairly closely packed. The outside diameter of the coil should be less than 0.010 inches, (0.25 mm) preferably between about 0.004 and 0.0095 inches (0.1 - 0.24 mm), and most preferably between 0.004 and 0.0075 inches (0.1 - 0.19 mm). The soft, flexible coil thus produced is cut to desired lengths after the formation thereof. The coil is especially suitable for the noted service when the device (coil, braid, or combination) deflects more than about 20° (preferably more than about 35°) under its own weight over the first centimeter of length, when supported at a single end. The length of the coil may be between about 2 mm and about 120 cm, typically between about 30 cm and 120 cm.

Instead of the wire shown in Figure 13, the coil 90 may be produced from a ribbon whose major axis is between about 0.001 and about 0.002 (0.025 - 0.05 mm) inches and whose minor axis is about

0.0005 and about 0.001 inches (0.013 - 0.025 mm) . Coils produced from ribbons are often moderately stiffer than those produced from wire. Smaller diameter coils are often more readily produced.

The regularity of winding shown in Figure 13 is not  
5 mandatory; the windings may be irregular or of varying pitch. The coil (90) shown in Figure 13 (and the variations of the invention which are described below) may be produced from any of a number of different materials. The material should be radiopaque so that the coil and its position may be readily monitored within the human vasculature. Suitable  
10 materials include biocompatible metals, polymers, and alloys. for instance, biocompatible, radiopaque metals include silver, gold, palladium, platinum, tungsten, iridium, rhodium, various stainless steels and alloys thereof. A particularly suitable alloy is 92% (by weight) platinum and 8% (by weight ) tungsten. The platinum-tungsten alloys desirably have a  
15 tensile strength of at least about 180 ksi (124 MPa) and, for a wire of a nominal 0.001" diameter, have a breaking load of 0.17 lb. with a minimum elongation of 2% measured at a speed of 1.0 in/min. Various biocompatible polymers including polyethylene, polyurethane, polypropylene, and the like are suitable for use in these devices, but,  
20 because of their lack of radiopacity, must usually be teamed with a radiopaque marker to allow proper positioning of the coil within the body. Similarly, other inorganic materials such as fibrous carbon are suitable and may be used in the invention.

Figure 14 shows a braided (or otherwise) woven vaso-occlusive device 100 suitable for use in the invention. The braided occlusive device 100 is tubular and produced by weaving fibers or wires over a mandrel much in the same way the coil of Figure 13 was made.

5 Woven braids of this size are not common but are made according to known techniques. The wire or fibers in this variation of the invention may be any of the radiopaque or polymeric materials noted above, and additionally the braid may be made of a combination of those materials either alone or in combination with other suitable polymeric or filamentary  
10 materials such as dacron, cotton, or other materials. Natural or synthetic polymer fibers such as dacron or cotton provide a ready substrate for clot formation in the interior region of a vessel. Often the radiopaque portion of the coil provides only a way to anchor the acyl onto the vessel wall at the site of release.

15 The Figure 14 braid or woven device 100 is of a diameter 101 similar to the diameter of the device shown in Figure 13. The braid may have a termination pieces 103 or end sections similar in constitution to the analogous portion shown in Figure 11 above. The length of the braid may similarly be 2 mm to 120 cm.

20 Figure 15 shows a side view of a combination coil/braid vaso-occlusive device 110 according to the invention. This combination is a sequence of coils 111 and braids 112 similar in make-up and size as the devices shown in Figures 12 and 13. Lengths of various coils 111

and braids 112, each often 2 mm to 20 cm in length, are joined together at their respective ends to form the combination device. The overall length of the device 110, as with those above, may be 2 mm to 120 cm. The device 110 may also have caps or termination pieces (113) on the  
5 ends of the device.

Figure 16 shows another variation of a coil/braid combination 120. In this variation, however, as is shown by the cutaway insert, the substrate coil 121 is identical to the coil shown in Figure 11 herein. The braid 122 is woven on the exterior of the coil. In this instance, the braid  
10 is more desirably a fibrous material such as dacron or cotton. The braid may, however, be a radiopaque material such as the metals and alloys and polymers discussed above. The braid may be joined by welding, melting, or by adhesion to the underlying coil 121.

Each of the variations discussed above, when provided in the  
15 proper size range and materials, is an extremely soft and flexible device, whether the device by coil or braid. These devices exert little, if any, radial force on the blood vessels into which they are placed. The fluid-like properties of the coil within a carrier fluid enable it to conform to the complex geometry of certain fragile, abnormal blood vessels, and in so  
20 doing, minimize the risk of causing trauma to or perforation of those blood vessels. Such flow properties also enable coil placement in coronary vasculature currently unreachable by other occluding elements.



Vaso-occlusive coils and their method of introduction are discussed in detail in U.S. Patent No. 5,122,136 (Gugliemi *et al.*). In cardiac occlusion, the length of the coil is fairly short to allow "microcontrol" of the occlusion of the small cardiac arteries and resultant control of the arrhythmia. The Gugliemi *et al.* patent is incorporated herein in its entirety by reference.

Alternative vaso-occlusive devices including tubular braids, as found in Serial No. 07/965,973, and coils with or without fibrous attachments, such as found in Serial No. 07/771,013 or 07/978,230, may simply be pushed through the catheter lumen using a guidewire. The aforesaid applications are incorporated herein in their entirety by reference.

The present invention has been described herein in terms of certain preferred embodiments but various modifications and improvements may be made to the present invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

- 1           1.     A method for treating a patient's heart exhibiting arrhythmia,  
2     comprising:
  - 3               a)     locating tissue within the patient's heart which is  
4               causing the arrhythmia; and
  - 5               b)     delivering an occluding element to a coronary arterial  
6               passageway which feeds oxygenated blood to the tissue causing  
7               the arrhythmia to block the flow of oxygenated blood to said tissue  
8               creating an infarct therein and thereby terminating the arrhythmia.
- 1           2.     The method of claim 1 wherein the occluding element  
2     occludes the arterial passageway by forming thrombus therein.
- 1           3.     The method of claim 1 wherein the occluding element  
2     permanently occludes the arterial passageway.
- 1           4.     The method of claim 1 wherein the tissue causing the  
2     arrhythmia is located by means of at least one elongated intravascular  
3     device having a plurality of electrodes on a distal portion thereof which is  
4     disposed within a coronary artery or a cardiac vein.

1           5.     The method of claim 1 wherein the occluding element is a  
2     helically wound wire coil.

1           6.     The method of claim 1 wherein the occluding element is  
2     releaseably secured to a distal end of a guidewire, the guidewire is  
3     advanced through the patient's coronary artery until the releaseably  
4     secured occluding element is positioned at a desired location within the  
5     coronary artery and the occluding element is released to occlude the  
6     arterial passageway at the desired location.

1           7.     The method of claim 1 wherein a catheter having proximal  
2     and distal ends and an inner lumen extending therein to a port in the  
3     distal end thereof is advanced through the coronary artery until the distal  
4     end of the catheter is at the desired location and the occluding element is  
5     advanced through the inner lumen of the catheter until it extends out the  
6     port in the distal end of the catheter into the coronary artery where the  
7     occluding member occludes the arterial passageway.

1           8.     The method of claim 7 wherein the tissue causing the  
2     arrhythmia is located by means of a plurality of sensing electrodes on a  
3     distal portion of the catheter which detect electrical activity from such  
4     tissue.

1           9.     The method of claim 8 wherein the electrical activity is  
2     detected in a bipolar mode.

1           10.    A method for treating a patient's heart exhibiting arrhythmia,  
2     comprising:

3               a)     determining the location of tissue of the patient's  
4     heart which causes the arrhythmia;

5               b)     providing an intravascular catheter having proximal  
6     and distal ends, a discharge port in the distal end and an inner  
7     lumen extending therein to the discharge port.

8               c)     advancing the intravascular catheter through a  
9     patient's coronary artery to a location therein which feeds oxygenated  
10    blood to the tissue of the patient's heart which causes the  
11    arrhythmia; and

12              d)     directing an occluding element through the inner  
13    lumen of the catheter into the coronary artery to the location to  
14    occlude the arterial passageway to create an infarct in the tissue  
15    and thereby terminate the arrhythmia.

1           11.    The method of claim 10 wherein the occluding element  
2     introduced into the arterial passageway is a flaccid coil which forms a  
3     randomly shaped, intertwined mass when introduced into the arterial  
4     passageway.

1           12. The method of claim 11 wherein the flaccid coil is  
2           hydraulically delivered through the inner lumen of the catheter into the  
3           arterial passageway.

1           13. The method of claim 11 wherein the coil has a diameter of  
2           less than 0.01 inch.

1           14. The method of claim 13 wherein the helically wound wire  
2           coil is releaseably secured to a distal end of a guidewire which is  
3           advanced through the inner lumen of the catheter.

1           15. The method of claim 11 wherein the flaccid coil forms  
2           thrombus which occludes the coronary artery passageway.

1           16. The method of claim 11 wherein the region of the patient's  
2           heart causing the arrhythmia is determined by advancing at least one  
3           intravascular sensing device having a plurality of sensing electrodes on a  
4           distal section thereof within a coronary artery or a cardiac vein of the  
5           patient's heart and sensing electrical activity by means of sensing  
6           electrodes on the distal section of the intravascular sensing device from  
7           within the coronary artery or the cardiac vein.

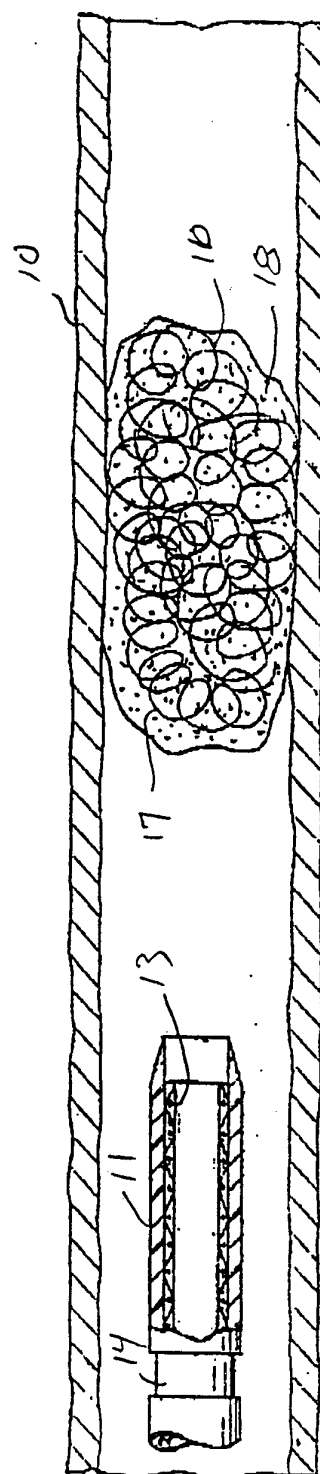
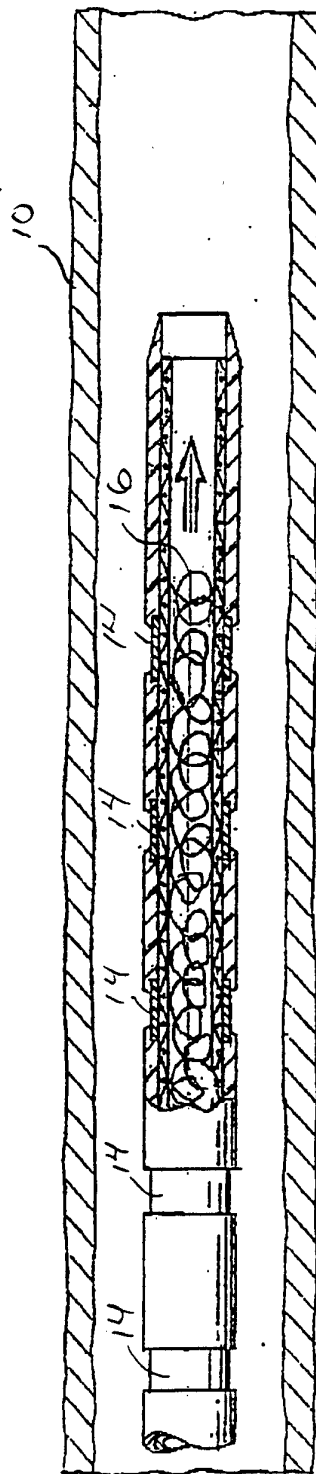
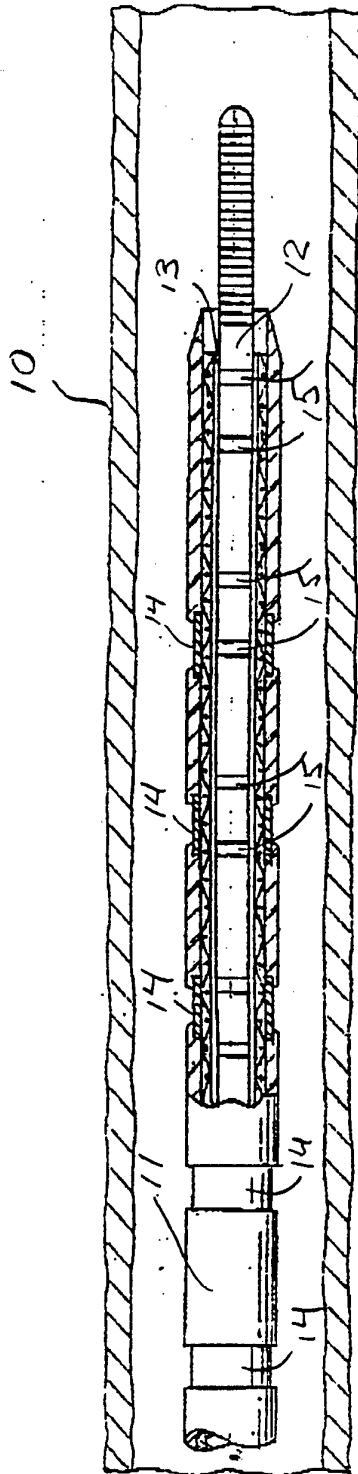
- 1           17.    An elongated intravascular device for treating a patient's  
2   heart which exhibits arrhythmia, comprising:
- 3           a)    an elongated shaft having a proximal section and a  
4           distal section which is much shorter than the proximal section and  
5           which is configured to be advanced within a coronary artery  
6           disposed within a region of the patient's heart from which electrical  
7           activity causing the arrhythmia originates or is conducted;
- 8           b)    a plurality of sensing electrodes spacially disposed on  
9           the distal shaft section which are adapted to receive electrical  
10          signals from within the coronary artery disposed within the region  
11          of the patient's heart;
- 12          c)    a plurality of electrical conductors which are  
13          electrically connected to separate sensing electrodes on the distal  
14          shaft section, which extend to a proximal extremity of the  
15          elongated shaft, and which are adapted to transfer electrical signals  
16          received by the sensing electrode connected thereto; and
- 17          d)    a occluding element releaseably secured to the distal  
18          end of the intravascular device which is adapted to form thrombus  
19          when disposed within a patient's coronary artery and to thereby  
20          occlude the artery.

- 1           18.    The elongated intervacular device of claim 17 wherein the  
2   occluding element is a helical coil.

1           19.   The elongated intravascular device of claim 18 wherein a  
2           proximal portion of the helical coil is secured by a solder to the distal end  
3           of the shaft.

1           20.   The elongated intervascular device of claim 19 wherein the  
2           solder securing the proximal portion of the helical coil to the distal end of  
3           the shaft is subject to electrolysis when disposed within a patient's  
4           coronary artery to sever the helical coil from the distal end of the shaft.

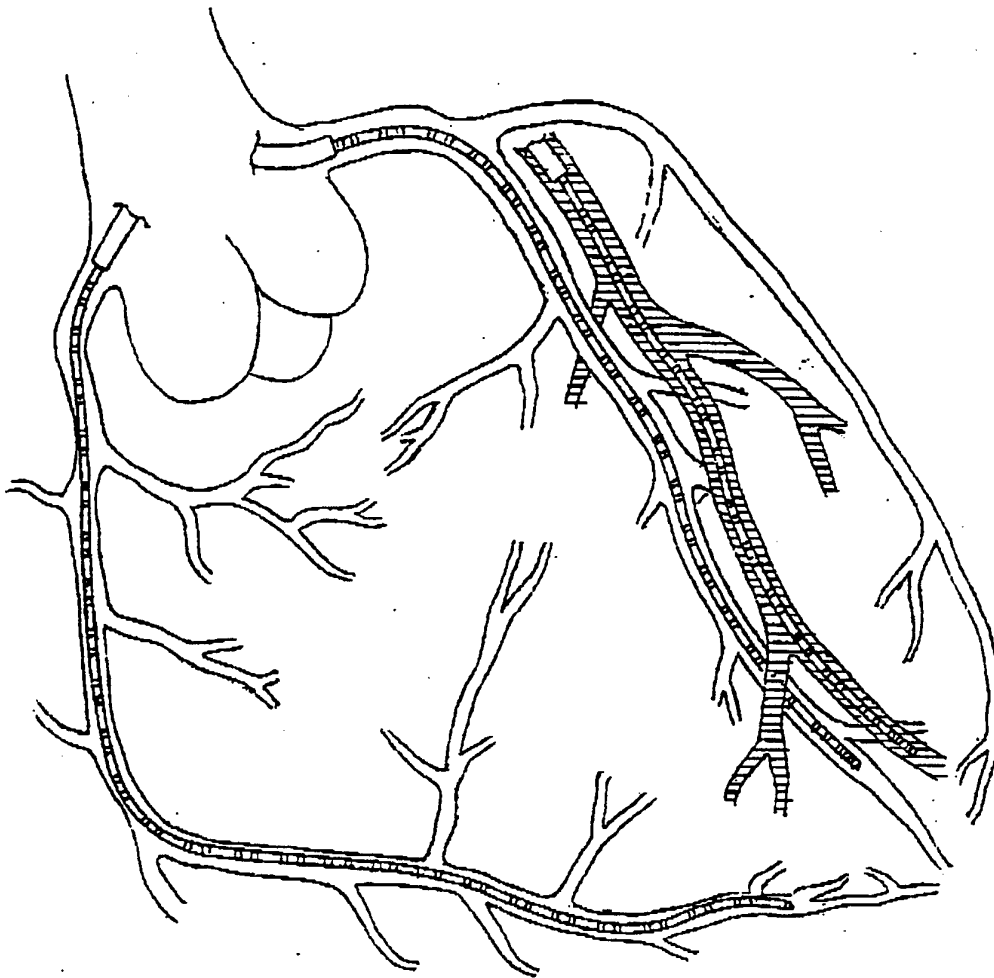
18961.

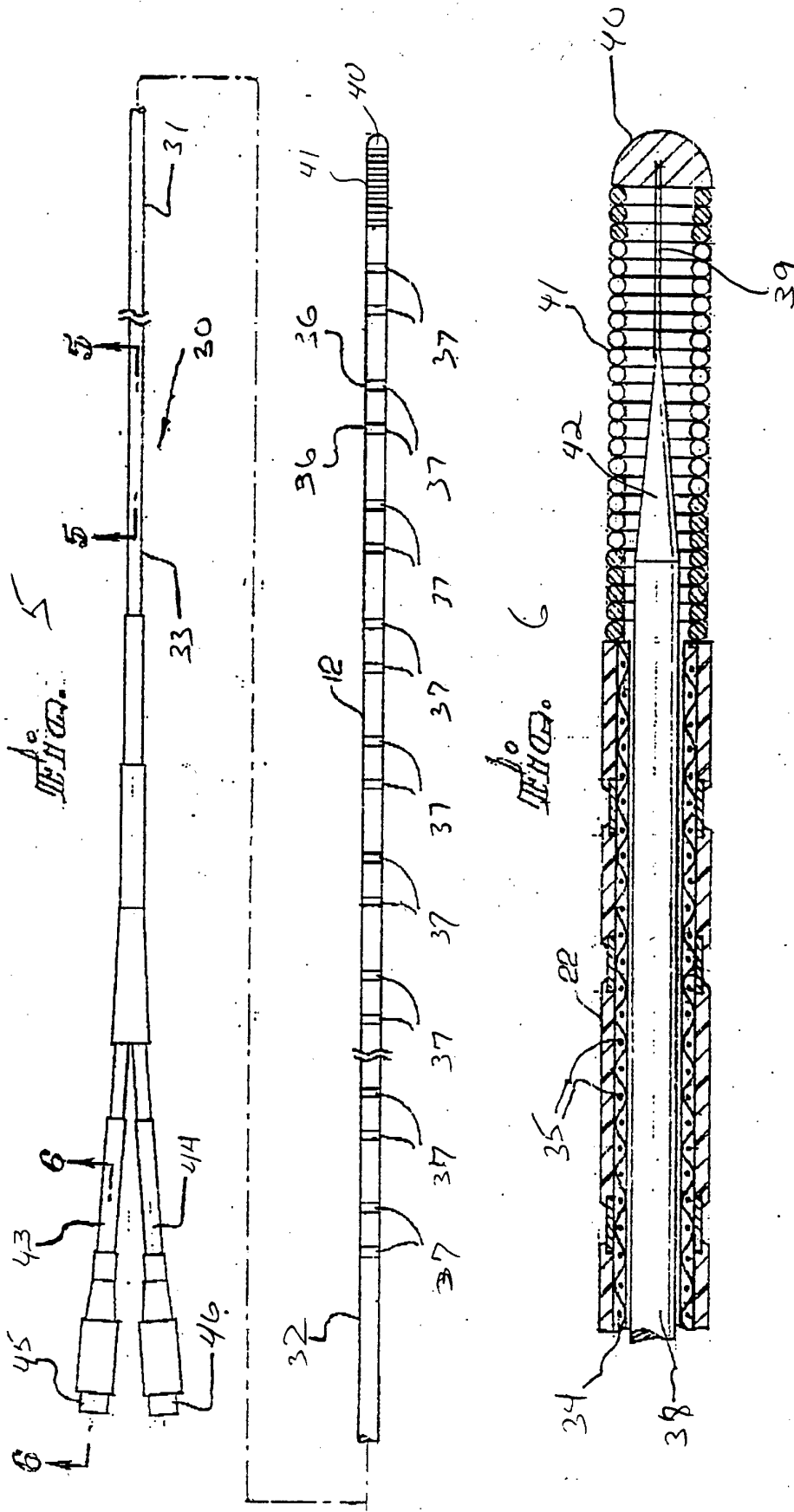


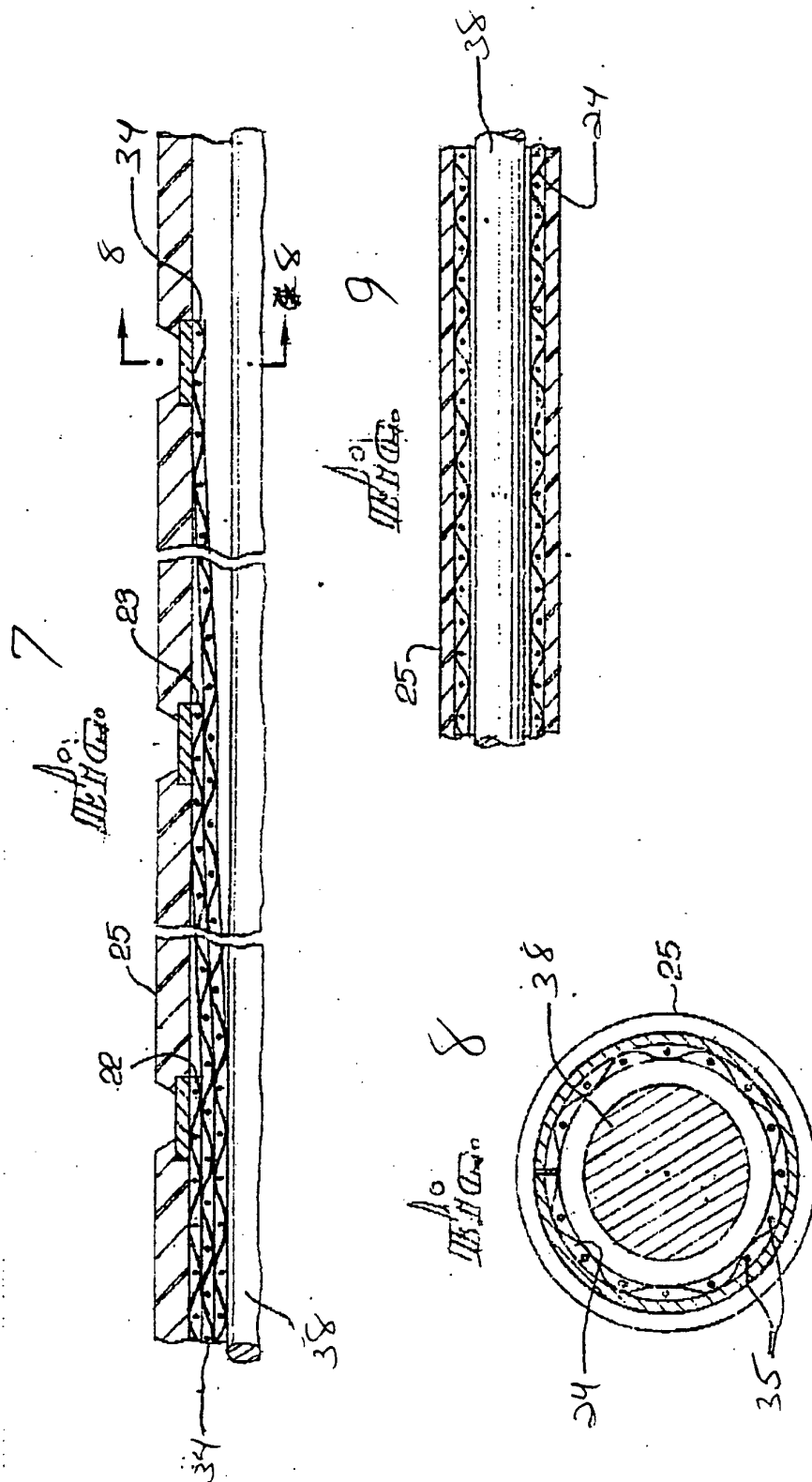


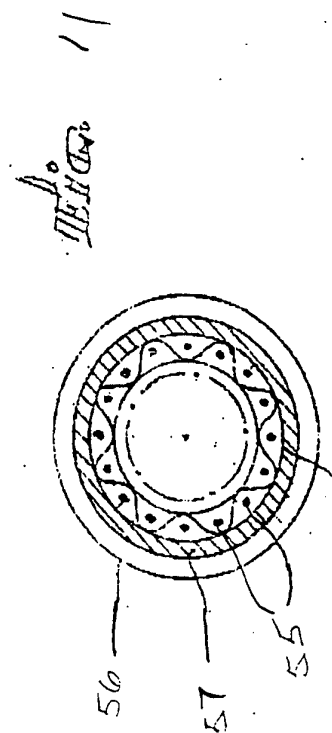
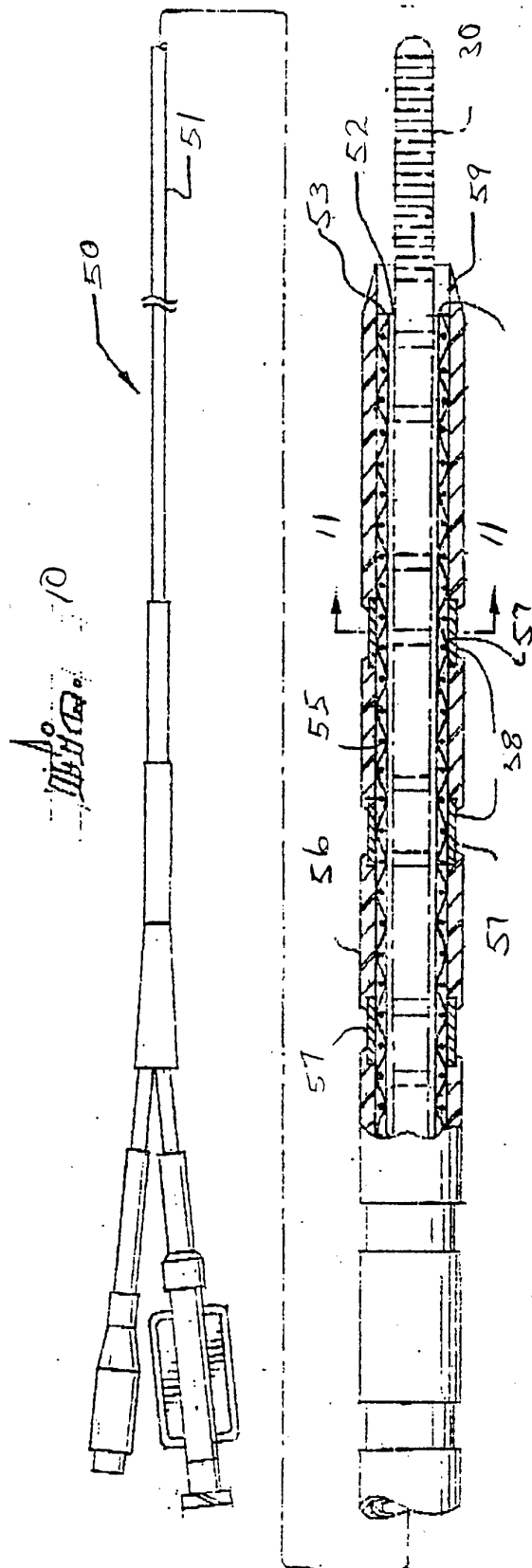
18961.0005.0

FIG. 4









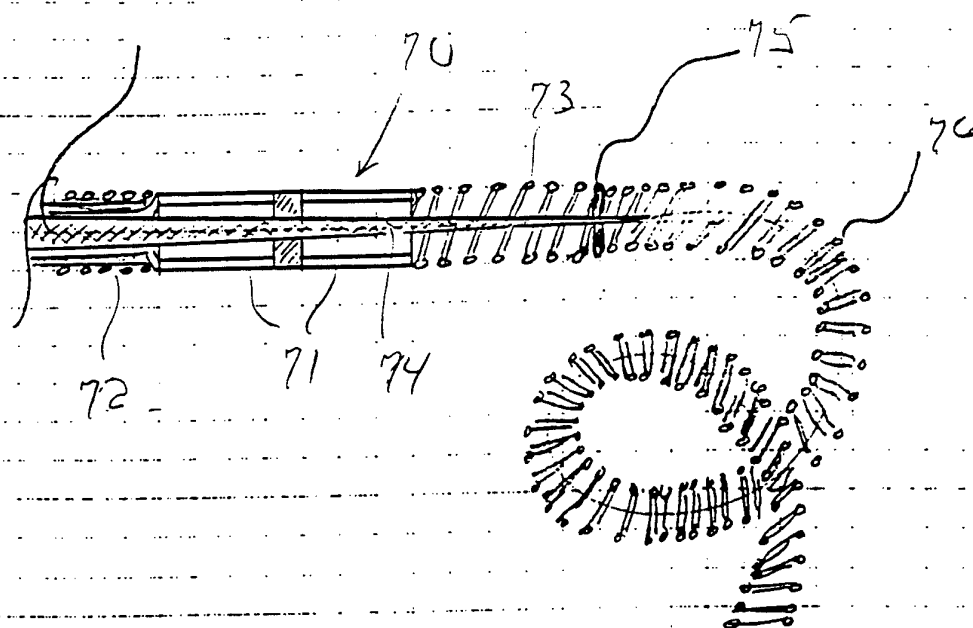
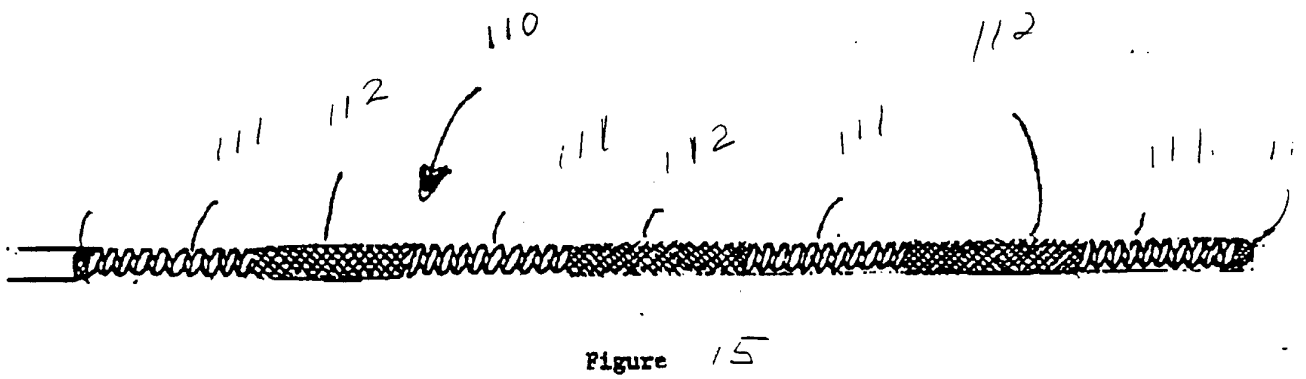
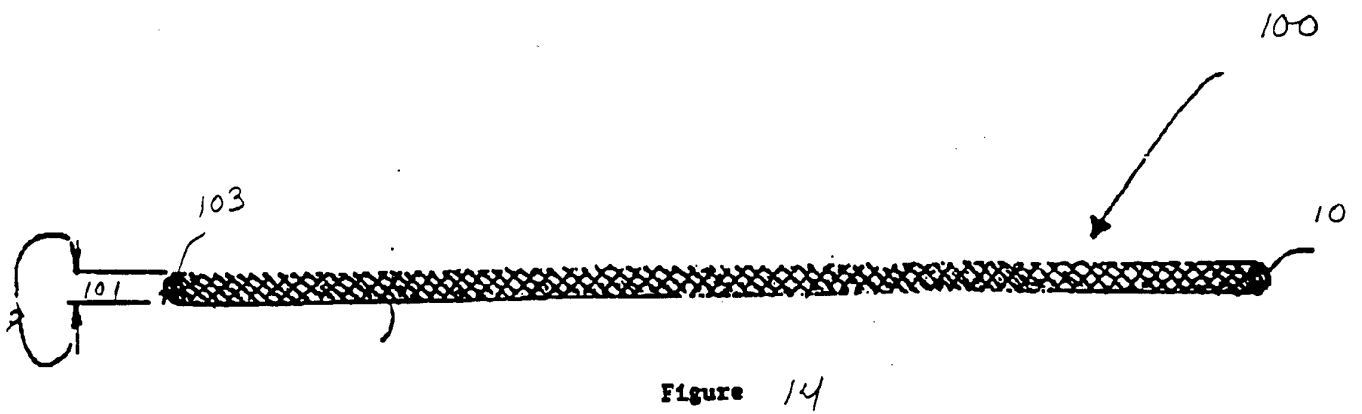
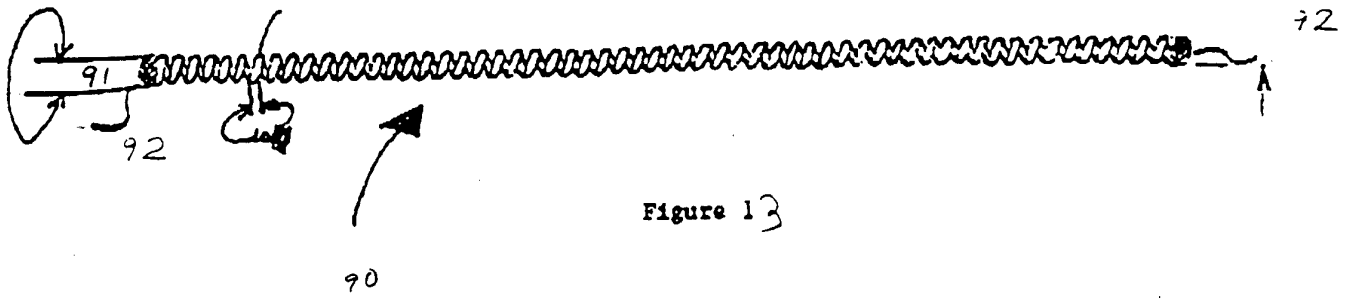


Fig. 12



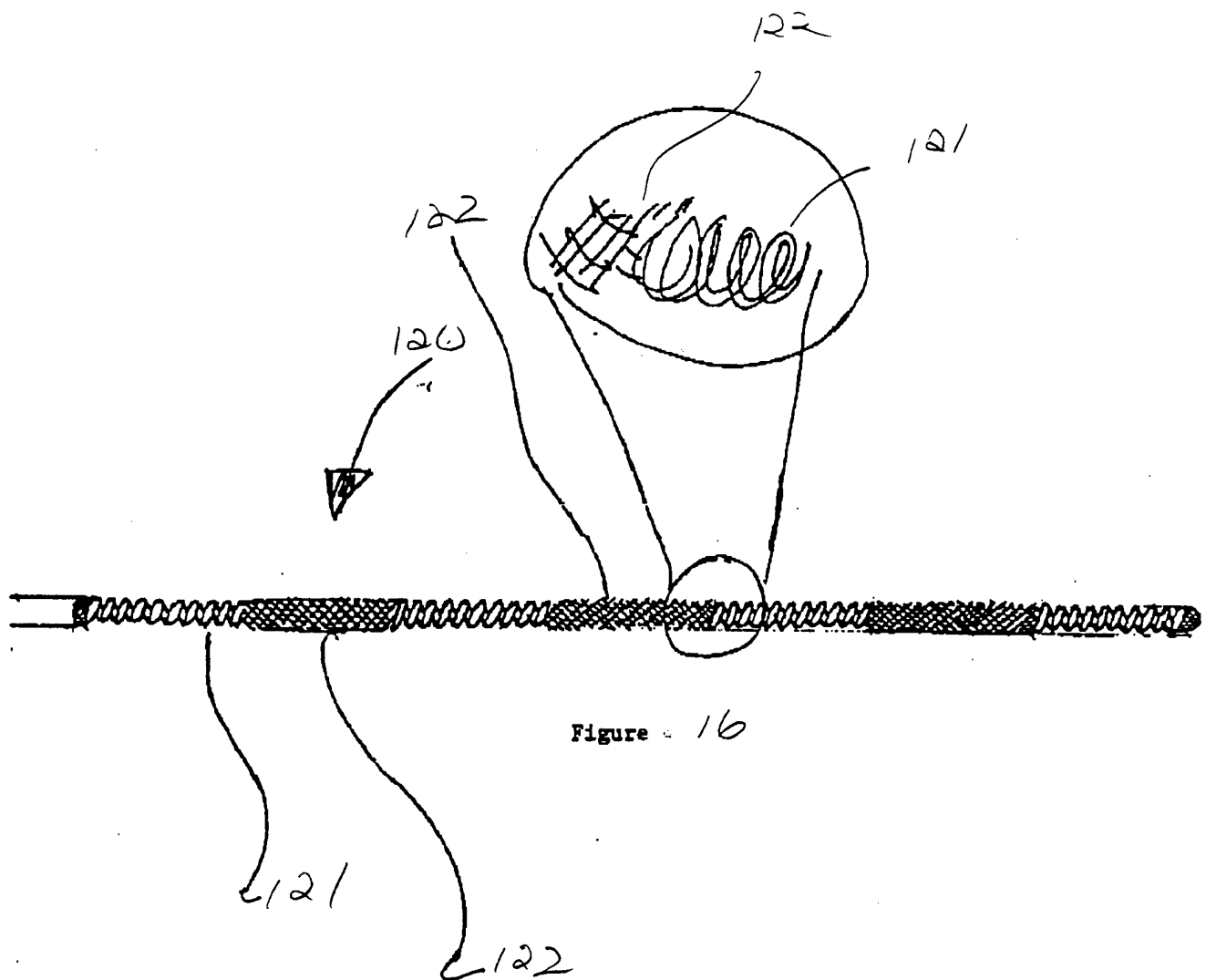


Figure 16

## INTERNATIONAL SEARCH REPORT

Inter. onal Application No

PCT/US 94/01018

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 5 A61B17/12 A61B5/042

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 5 A61B A61N

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.
A	WO,A,90 03151 (BRIGHAM & WOMEN'S HOSPITAL) 5 April 1990 see page 6, line 31 - page 7, line 29; figure 2 ---	17
A	US,A,5 122 136 (GUGLIELMI ET AL.) 16 June 1992 cited in the application see abstract; figures 3,4 ---	1
A	WO,A,92 21278 (EP TECHNOLOGIES) 10 December 1992 see abstract; figure 4 ---	1
A	US,A,5 095 917 (VANCAILLIE) 17 March 1992 see claims 1-4; figures 4-6 -----	1

☐ 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

1 June 1994

Date of mailing of the international search report

08.06.94

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+ 31-70) 340-3016

Authorized officer

Moers, R



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 94/01018

**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.: 1-16  
because they relate to subject matter not required to be searched by this Authority, namely:  
Method for treatment of the human or animal body by surgery.  
Please see Rule 39.1(iv) PCT.
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 94/01018

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9003151	05-04-90	US-A- 5147355 AU-A- 4342689	15-09-92 18-04-90
US-A-5122136	16-06-92	AU-B- 636217 AU-A- 7447491 CA-A- 2055492 EP-A- 0484468 JP-T- 5500322 WO-A- 9113592	22-04-93 10-10-91 14-09-91 13-05-92 28-01-93 19-09-91
WO-A-9221278	10-12-92	AU-A- 1899292 AU-A- 1998892 EP-A- 0588864 WO-A- 9221285	08-01-93 08-01-93 30-03-94 10-12-92
US-A-5095917	17-03-92	NONE	