

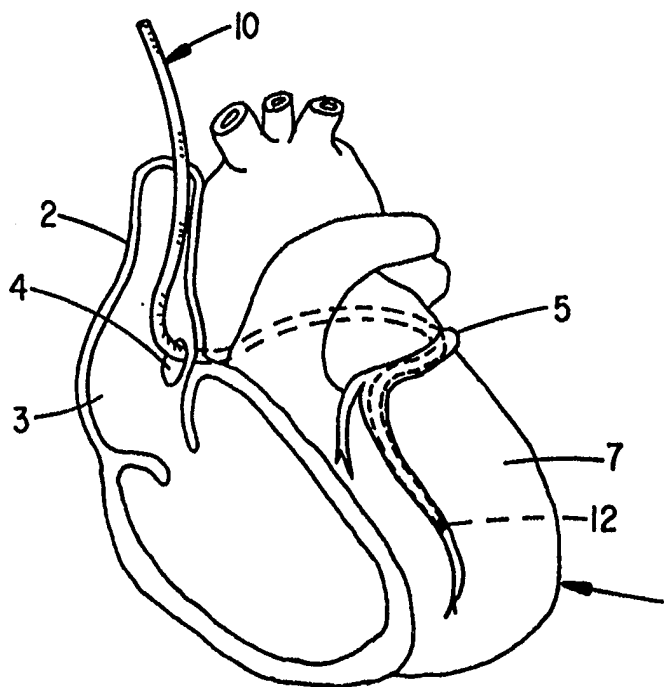


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61N 1/04, 1/05	A1	(11) International Publication Number: WO 98/32486 (43) International Publication Date: 30 July 1998 (30.07.98)
(21) International Application Number: PCT/US98/01362 (22) International Filing Date: 23 January 1998 (23.01.98) (30) Priority Data: 08/787,308 24 January 1997 (24.01.97) US (71) Applicant: CARDIAC PACEMAKERS, INC. [US/US]; 4100 Hamline Avenue North, St. Paul, MN 55112-5798 (US). (72) Inventors: CHASTAIN, Stuart, R.; 3430 Chatsworth Street, Shoreview, MN 55126 (US). WESTLUND, Randall, W.; 2618 16th Avenue South, Minneapolis, MN 55407 (US). TOCKMAN, Bruce, A.; 21788 Pomroy Avenue North, Scandia, MN 55073 (US). (74) Agents: NIKOLAI, Thomas, J. et al.; 820 International Centre, 900 Second Avenue South, Minneapolis, MN 55402 (US).		(81) Designated States: CA, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: CARDIAC LEAD ARRANGEMENT**(57) Abstract**

Intravenous cardiac leads (10) having at least one electrode (12) intended to be implanted within the coronary veins (4, 5), are disclosed. Also disclosed are structures and techniques for advancing such leads through the atrium (3) and coronary sinus (4) into the coronary veins (5) overlaying the left ventricle (7).



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.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

- 1 -

CARDIAC LEAD ARRANGEMENT
BACKGROUND OF THE INVENTION

I. Field of the Invention

This invention relates to cardiac leads used in combination with a cardiac rhythm management device, e.g., heart pacemakers or defibrillators, to monitor and control the rhythm of the heart. This invention is more particularly directed toward lead configurations adapted to be implanted in the coronary veins on the left side of the heart and to methods for implanting such leads.

II. Discussion of the Prior Art

As explained in U.S. Patent 4,928,688 to Morton M. Mower dated May 29, 1990, under normal circumstances impulses from the SA node affect contraction of the atria and then propagate to the AV node. The AV node then emits a second nerve impulse which affects contraction of the ventricles. In healthy individuals this is done in a coordinated manner to circulate blood through the body. However, many patients suffer from conditions which inhibit the transfer of nerve impulses from the SA node to the AV node and from there to the ventricles. In such cases, the chambers of the heart do not contract in a coordinated fashion and hemodynamic efficiency of the heart is decreased. This has profound adverse implications for the health and well-being of the patient. In minor cases, the quality of life is considerably reduced. More severe cases can result in death.

The Mower 4,928,688 patent describes a method for improving the hemodynamic efficiency of a sick heart. The method proposed in that patent is to place electrodes in both the right and left ventricles, monitor the cardiac signals originating in the right and left ventricles, analyze these signals and the absence thereof in a control circuit, and provide stimulating pulses to one or both ventricles within a time interval designed to improve the heart's hemodynamic efficiency.

- 2 -

Others have discussed the advantages of implanting leads in both the right and left ventricles to permit a sick heart to be more effectively defibrillated. See, for example, U.S. Patent 4,922,407 to Williams; U.S. Patent 5,099,838 to Bardy; and U.S. Patents 5,348,021, 5,433,729, and 5,350,404 all to Adams et al. Each of the patents describe inserting a lead through the right atrium and coronary sinus into one of the coronary veins. None of these patents, however, discuss the difficulties encountered in doing so.

Important health advantages are achieved by positioning an electrode in a branch of the great vein of the heart. A lead so positioned can be used to stimulate the left ventricle. While it would be possible to position the electrode within the left ventricle, this can increase the potential for clot formation. If such a clot were released to the brain, the situation could be life threatening. However, traditional leads are not well suited for implantation in the coronary vein. Traditional leads tend to be too big, tend to have some type of fixation device (such as tines or a screw) that must be altered to advance the lead into the sinus, or tend to require a stylet for positioning which is not flexible enough to negotiate the coronary vessels.

An arrangement intended to address such difficulties associated with the implantation of leads is disclosed in U.S. Patent 5,304,218 granted to Clifton A. Alferness on April 19, 1994. The arrangement disclosed in this patent includes a lead having an electrode. The electrode has a follower means for slidably engaging a guide wire. The electrode is implanted by feeding the guide wire along the desired path, engaging the follower means to the guide wire, advancing the lead along the guide wire until the electrode resides at the implant site, and retracting the guide wire from the follower means after the electrode is implanted at the implant site.

- 3 -

A review of the specification and drawings of U.S. Patent 5,304,218 and an understanding of the anatomy and physiology of the heart demonstrates several problems with this approach. First, the path through which the lead must
5 be fed is very restricted. The increased size of the distal end of the lead, given the presence of the follower, may make it more difficult to advance such a lead along the desired path so as to be positioned on myocardial tissue of the left ventricle. Second, the direction of blood flow
10 through the veins tends to force electrodes implanted there out of the vein. This problem is likely to be exacerbated by the increase in the profile area of the distal end given the presence of the follower. Third, the profile of the distal end of a lead implanted in a coronary vein may need
15 to be made as small as possible to limit occlusion and permit blood to flow as freely as possible through the blood vessel when the lead is in place and to limit damage to the vessels and/or myocardium.

SUMMARY OF THE INVENTION

20 The present invention provides an improved lead for implantation of an electrode into a coronary vein on the left side of the heart. The lead includes an elongated, flexible body member made of an electrically insulative material. The body member includes a proximal end and a
25 distal end. A lumen extends through the body member from the proximal end toward the distal end. The lumen may extend all the way to the distal end so that the distal end includes an opening. The lead also includes a conductive member extending through the body member from the proximal
30 end toward the distal end. Electrically coupled to the conductive member near its distal end is an electrode. Additional lumens, electrodes and conductive members may be included within and on the lead body.

35 Leads made in conformance with the present invention can be inserted in a number of different ways. For example, a guide catheter can be inserted and then the lead passed through the guide catheter until it is properly

- 4 -

positioned. The lead can be coated with a lubricious coating to reduce friction in the guide catheter. The guide catheter can then be retracted. Similarly, a guide wire can be advanced to the implant site alone or through
5 a guide catheter. Using the open distal lumen, the lead can be slid over the guide wire until the electrode is properly positioned. The guide wire or guide catheters can then be retracted. Also, the lead can be temporarily fixed to a guide catheter. The fixator may be designed to be
10 dissolved by body fluids. The lead is then inserted along with the guide catheter. After the electrode is in place and the fixator dissolves, the guide catheter can be retracted.

Alternative embodiments of the present invention offer
15 other advantages and features. For example, the wall of the lumen can be coated with a lubricious coating or a polymer with a low coefficient of friction to reduce friction between a guide wire and the wall of the lumen. The lumen can also be used to deploy a separate electrode
20 past the distal end of the lead's body member. Additional lumens can be provided and the cross-section of the body member can be modified to provide a channel for a guide wire. These features are shown in the drawings and discussed in further detail below.

25 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of an intravenous cardiac lead having an electrode positioned in a coronary vein.

Figure 2 is a cross-section of a distal end portion of the intravenous cardiac lead shown in Figure 1.

30 Figure 3 is a longitudinal cross-section view of a distal end portion of an intravenous coronary lead of the present invention with a tapered end and deployable electrode.

Figure 4 is a longitudinal cross-section of a distal
35 end portion of an intravenous coronary lead inserted within and temporarily fixed to a guide catheter.

- 5 -

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows a human heart 1 with the intravenous coronary lead 10 of the present invention passing through the superior vena cava 2, the right atrium 3, and the coronary sinus 4 into the great vein of the heart 5 so that a surface electrode 12 on the lead 10 is implanted in a branch of the coronary vein. When positioned as shown, the electrode 12 can be used to sense the electrical activity of the heart or to apply a stimulating pulse to the left ventricle 7 and without the need of being in the left ventricular chamber.

Figure 2 shows in greater detail the structure of the intravenous coronary lead shown in Figure 1. As shown in Figure 2, the lead 10 includes an elongated body member 14 having a proximal end 16 and a distal end 18. The body member 14 is preferably made of a flexible, electrically insulative material. The outer surface of the body member 14 is preferably treated to prevent fibrotic attachment and to reduce inflammation response to the lead. Such a treatment could include a carbon coating, a steroid embedded in the material, a steroid eluting collar, or the like.

The body member 14 encapsulates a flexible electrically conductive member 20 extending from the proximal end 16 toward the distal end 18 of the lead's body member 14. Conductive member 20 is shown as a flexible wire coil in Figure 2. Alternatively, the conductor member 20 could be in the form of a conductive wire, a thin ribbon, a plurality of fine wires formed as a cable, or a flexible tube without deviating from the invention.

Figure 2 also shows the lead 10 as including a central lumen 22 extending from the proximal end 16 to the distal end 18 of the body member 14. In fact, in this embodiment, there is an opening 24 through the distal end 18 to the lumen 22. A coating of a material such as polytetrafluoroethylene (Teflon) preferably forms the wall 26 of the lumen 22 to increase its lubricity. The coating

- 6 -

material, of course, could be some other polymer having a low coefficient of friction.

The electrode 12 shown in Figure 2 is preferably created by removing an annular portion of the insulative body member 14 to expose a portion of the underlying conductive member 20. When the conductive member 20 is a coil as shown in Figure 2, the turns of the coil can be melt-banded such as by application of laser energy, to form the surface electrode 12. Those skilled in the art will recognize that a ring electrode electrically coupled to the conductive member 20 will also suffice. Likewise, the position of the electrode 12 along the body member 14 can be changed. Certain advantages may be achieved, for example, if the electrode 12 is at the tip of the lead.

The lumen 22 can be put to many uses. For example, a surgeon can advance a guide wire through the coronary sinus and coronary veins to the proper position for the electrode 12. The free proximal end of the guide wire can then be inserted through the opening 24 in the distal end 18 and the lead 10 slid over the guide wire to position the electrode 12. The guide wire can then be retracted through the lumen 22. The lumen 22 can also be used to insert a small separate structure with an electrode or sensor deployable beyond the tip of the lead. This allows separation of the electrodes and can be used for bipolar pacing or for a combination of pacing and defibrillation. Likewise, the lumen could be used to inject a contrast fluid to facilitate fluoroscopic viewing. The lumen can also be used to deploy a fixation mechanism, deploy an extraction mechanism, or deploy a plug to close the opening 24 and seal the lumen.

Figure 3 shows how the lead 10 can be modified to provide a tip 40 of a reduced diameter. The body member 14 of lead 10 has a distal end 18 with an opening 24 in communication with the lumen 22. Figure 3 shows how the lumen 22 can be used to deploy a separate structure such as second, miniaturized lead 42. The deployable lead 42 has

- 7 -

a lead body 44, an electrode 46 and a conductive member (not shown) coupled to electrode 46 and running from the electrode 46 to the proximal end of the lead body 44. The lead body 44 may be designed to coil after it exits the lumen to fix the electrode 46 in the correct position. Figure 3 also shows a ring electrode 47 surrounding a portion of the tip 40. The ring electrode 47, when present, is electrically coupled to conductive member 20. Additional electrodes and conductors can be added for sensing, pacing or defibrillating as desired. As indicated above, the ring electrode can also be formed by exposing and laser bonding the coils of the conductive member 20. The electrode 46 may be multipolar. It can be used for defibrillating and the electrode 47 is used for pacing. Alternatively, electrode 46 may be used for pacing and the electrode 47 used for pacing. Electrodes 47 and 46 could also be used for sensing electrical activity of the heart. Electrodes 47 and 46 can also be used together for bipolar pacing. Without limitation, the main portion of body member 14 could have an outside diameter in the range of 0.020 inches to 0.100 inches. If, for example, the main portion of the body member has an outside diameter of 0.058 inches, the diameter of the tip 40 could have an outside diameter of approximately 0.046 inches and the deployable lead 42 could have an outside diameter of 0.014 inches. When used, the main lead body can be positioned first over a guide wire. Once the lead is in place the guide wire is removed and replaced with the deployable structure which can be advanced beyond the tip of the larger lead body.

Figure 4 is provided to assist in explaining an alternative method for implanting an electrode 12 in a coronary vein. As shown in Figure 4, the lead 10 is loaded and temporarily fixed to the inside of a guide catheter 70 designed to be placed in the coronary sinus. The fixation means 72 may consist of a material such as mannitol which will dissolve after short exposure to blood. Once the guide catheter 70 is properly positioned and the fixation

- 8 -

means 72 is dissolved, the guide catheter 70 can be retracted leaving the lead in place with an electrode at a desired position. The lead can then be advanced further if necessary using a stylet and/or guide wire as previously described.

While not shown in any of the views, each lead will have one or more connectors of a type known in the art at its proximal end for mating with the pacer and/or defibrillator pulse generator whereby depolarization signals originating in the heart can be sensed and stimulating pulses applied in accordance with the device's control algorithms.

The foregoing discussion is intended to illustrate various preferred arrangements for meeting the objections of the present invention. Modifications and variation can be made by those skilled in the art without departing from the invention. Accordingly, the invention is limited only by the scope of the following claims which are intended to cover all alternate embodiments and modifications as may fall within the true scope of this invention.

What is claimed:

- 9 -

CLAIMS

1. For use with a cardiac rhythm management device, an intravenous lead having:

5 (a) an elongated, flexible body member made of an electrically insulative material, said body member having a proximal end and a distal end, said body member being of a size to permit the distal end to be advanced through the right atrium and coronary sinus into the coronary veins;

10 (b) a lumen extending through the body member from the proximal end toward the distal end of the body member and open to both the proximal end and distal end of the body member;

15 (c) a conductive member extending through the body member from the proximal end toward the distal end of the body member; and

(d) an electrode electrically coupled to said conductive member.

2. The lead defined by claim 1 wherein said lead has a sleeve made of a polymer with a low coefficient of friction lining the wall of said lumen.

3. The lead defined by claim 1 wherein said conductive member is a helical coil.

4. The lead defined by claim 1 wherein said conductive member is a tube made of a conductive polymer.

25 5. The lead defined by claim 1 wherein said electrode is formed by an opening in the body member exposing a portion of the conductive member.

- 10 -

6. The lead defined by claim 1 wherein said electrode is a ring electrode affixed to the surface of the body member and electrically coupled to said conductive member.

7. The lead defined by claim 1 further including a second
5 electrode.

8. The lead defined by claim 1 including a plurality of electrodes.

9. The lead of claim 1 having a separate structure deployable past the distal end through the lumen, said
10 separate structure including an electrode.

10. The lead of claim 9 wherein the electrode on said separate structure is multipolar.

11. The lead of claim 9 wherein the electrode on said separate structure may be used for pacing while an
15 electrode on the lead body is used for defibrillation.

12. The lead of claim 9 wherein the electrode on said separate structure may be used for defibrillation while an electrode on the lead body is used for pacing.

13. The lead of claim 9 wherein the electrode on the
20 separate structure is used along with an electrode on the lead body for bipolar pacing.

14. The lead of claim 9 wherein the separate structure coils when deployed to fix the electrode in the desired position.

25 15. The lead of claim 1 wherein the distal end is tapered.

16. The lead of claim 1 wherein said body member is treated with an anti-inflammatory agent.

- 11 -

17. The lead of claim 1 wherein said lead body member is treated with an antifibrotic agent.

18. The lead of claim 1 further including dissolvable means for securing the lead to a guide catheter.

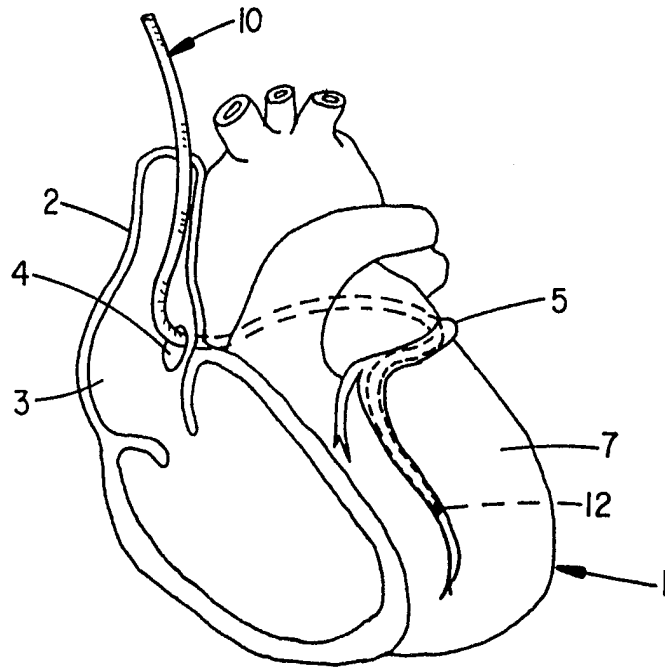
5 19. The lead of claim 1 having a fixation mechanism deployable past the distal end through the lumen.

20. The lead of claim 1 having an extraction mechanism deployable past the distal end through the lumen.

21. The lead of claim 1 having a plug to seal the lumen.

10 22. The lead of claim 1 wherein a contrast fluid can be injected through said lumen and out the opening in the distal end.

1/4

*FIG. 1*

2/4

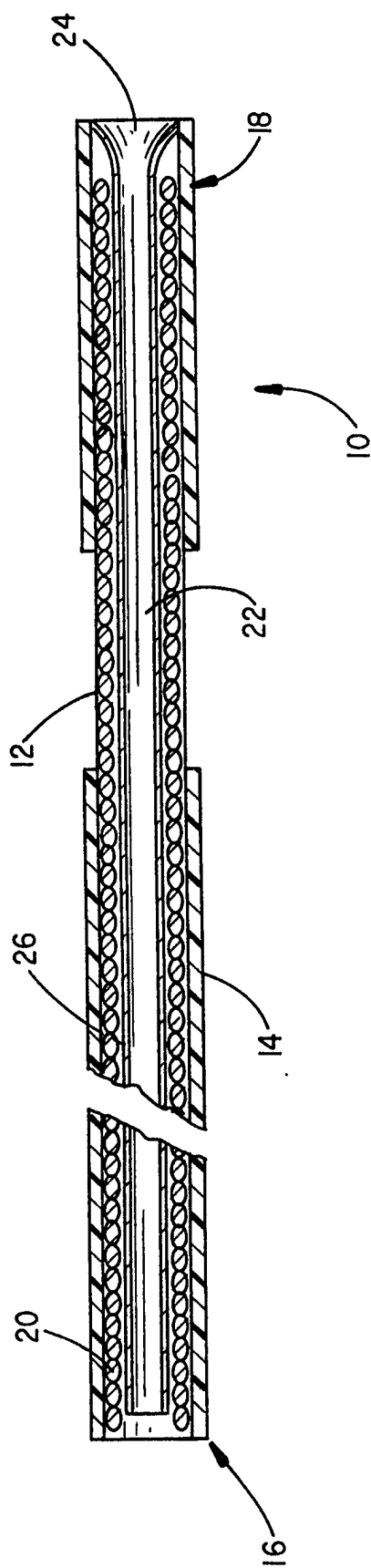


FIG. 2

3/4

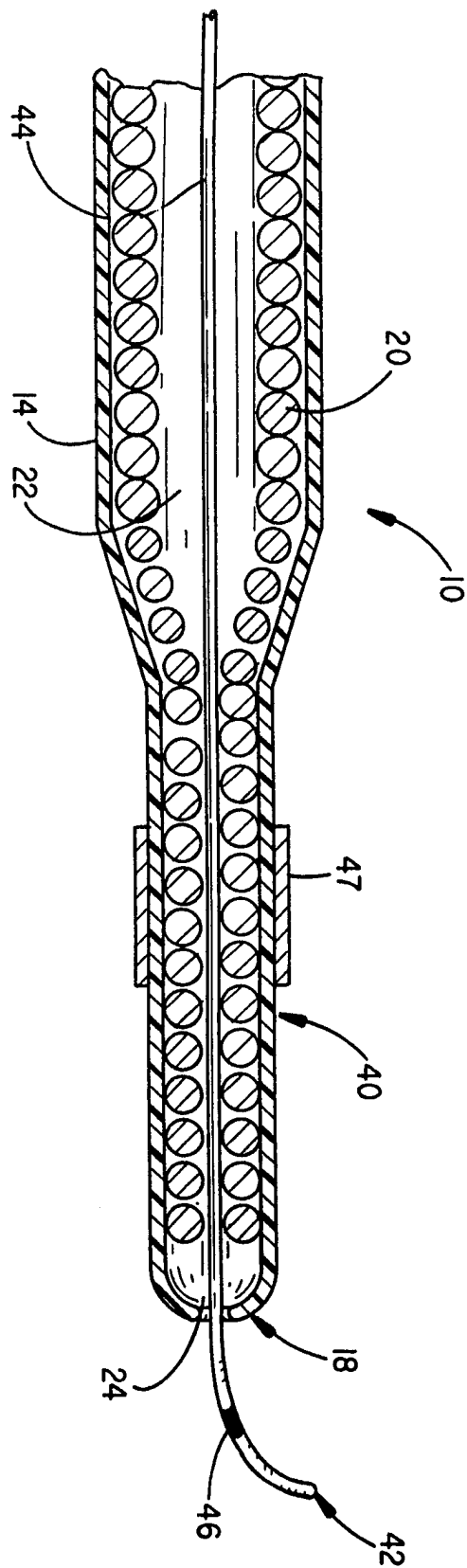


FIG. 3

4/4

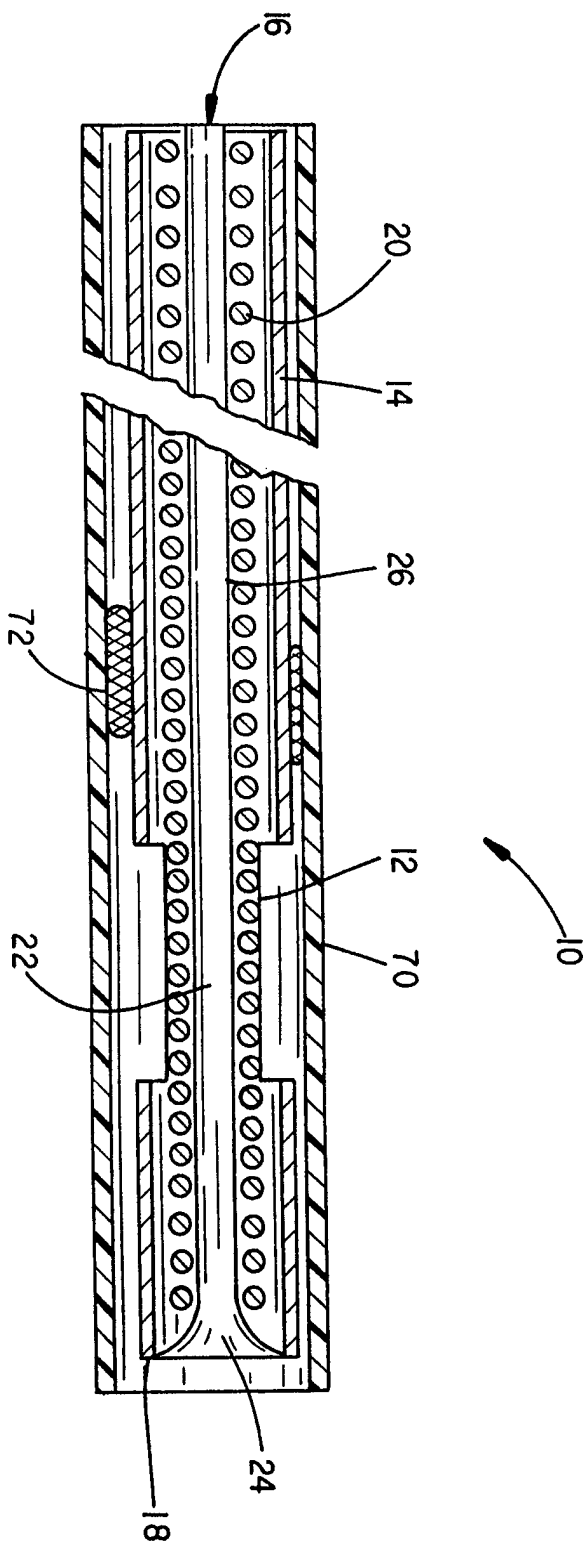


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/01362

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 1/04, 05

US CL :607/119, 122

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/119, 122

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,476,498 A (AYERS) 19 DECEMBER 1995, FIG. 1 CARDIAC LEAD (36) WITH ELECTRODE (44) IN CORONARY SINUS (22), AND GREAT VEIN (23); AND FIG. 3.	1, 3, 5, 7, 8, 15
Y	US 5,016,646 A (GOTTHARDT ET AL) 21 MAY 1991, FIGS. 1-5	5, 6
A, P	US 5,609,622 A (SOUKUP ET AL) 11 MARCH 1997, FIGS. 3 AND 5, COL. 6 LINE 14 TO BOTTOM.	1-4, 7-9, 11-13, 17, 19, 21
A, E	US 5,713,944 A (KROLL) 03 FEBRUARY 1998, FIGS. 4-6, 9 AND 10.	5-8



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*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
A document defining the general state of the art which is not considered to be of particular relevance	*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
E earlier document published on or after the international filing date	*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
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)	*Z* document member of the same patent family
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	

Date of the actual completion of the international search

30 MARCH 1998

Date of mailing of the international search report

24 APR 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

CARL H. LAYNO

Telephone No. (703) 308-3694