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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 :		(11) International Publication Number: WO 88/ 05672
A61N 1/372, 1/362, 1/05	A1	(43) International Publication Date: 11 August 1988 (11.08.88)

(21) International Application Number: PCT/IT88/00005

(22) International Filing Date: 21 January 1988 (21.01.88)

(31) Priority Application Numbers: 47581 A/87
48070 A/87

(32) Priority Dates: 29 January 1987 (29.01.87)
17 June 1987 (17.06.87)

(33) Priority Country: IT

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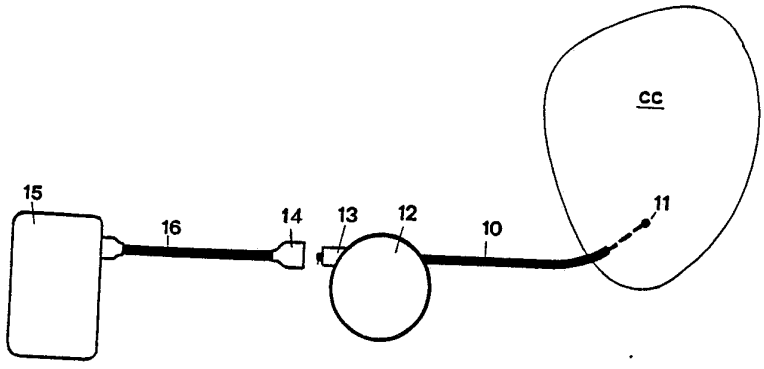
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(81) Designated States: AT (European patent), AU, BE (European patent), BG, CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KP, KR, LU (European patent), NL (European patent), NO, RO, SE, SE (European patent), SU, US.

Published
With international search report.

(54) Title: EPI-CARDIAL ELECTRODE WITH AN INCORPORATED CARDIAC RADIO-FREQUENCY RECEIVER (CRR) FOR TEMPORARY HEART STIMULATION FROM THE OUTSIDE, PRE-ARRANGED FOR PERMANENT STIMULATION



(57) Abstract

Equipment with an incorporated cardiac radio-frequency receiver (CRR) (12) for temporary heart stimulation from the outside in case of open-heart operation, suitable to be left in-situ to provide permanent stimulation if subsequently necessary. The equipment is formed of an electrode (10) with epi-cardial stimulation tip (11), and a quick jack-type connection (13, 14) emerging from said cardiac radio-frequency receiver (12) and suitable to rapidly and easily connect a permanent pacemaker (15).

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EPI-CARDIAL ELECTRODE WITH AN INCORPORATED CARDIAC RADIO-FREQUENCY RECEIVER (CRR) FOR TEMPORARY HEART STIMULATION FROM THE OUTSIDE, PRE-ARRANGED FOR PERMANENT STIMULATION

This invention relates to equipment with an incorporated cardiac radioreceiver (CRR) for temporary heart stimulation from the outside in case of open-heart operation, suitable to be left in situ to provide a permanent stimulation if subsequently necessary. The equipment is formed by an electrode with an epicardial stimulation tip, a cardiac radio-frequency receiver, and a quick jack-type connection emerging from said cardiac radio-frequency receiver and suitable to rapidly and easily connect a permanent pacemaker.

As known, during open-heart surgical operations, the possibility of temporary artificial stimulation of the heart is always maintained; this is achieved by utilizing an electrode, the stimulation tip of which is temporarily fixed with a simple technique to the epimyocardium in a position corresponding to the left ventricle.

When the patient's thorax is closed, the free extremity of the electrode comes out through the thoracic wall and is connected to an external pacemaker.

After the prescribed period of rest and when artificial stimulation of the heart is no longer necessary, the electrode is extracted from the outside simply by pulling it. By doing so, whenever the patient's need for artificial stimulation becomes evident, it is necessary to perform another opera-

tion in order to implant a normal pacemaker.

The equipment described overcomes said drawback and offers more advantages.

According to the invention, the equipment with epi-cardial electrode is provided, in fact, with an incorporated cardiac radio-frequency receiver for temporary stimulation in case of open-heart operation, and is provided also with a device for connection to a permanent pacemaker.

After the necessary period of rest, the receiver is left permanently in situ.

Preferably, the device for connecting the electrode to a permanent pacemaker is essentially constituted of a quick jack-type connection, as described later. The equipment is implanted during the open-heart operation with the quick connection duly insulated, but the stimulating tip of the electrode is permanently fixed to the epimyocardium.

In this way the following objectives are attained:

a) The extremity of the electrode is not connected to an external pacemaker and does not pass through the thoracic wall since the temporary stimulation is supplied, via the cardiac radio-frequency receiver, by an external radio-frequency transmitter (Personal pacemaker); since the extraction of the electrode is not required, risks of sepsis are avoided;

b) In the event of the patient needing artificial stimulation of the heart, subsequent to the prescribed period of rest, it is always possible to supply

such stimulation in a timely way from the outside using the Personal pacemaker;

c) In the event of persistence of the need of artificial stimulation (indication of a need for a permanent pacemaker implantation) it is possible to implant a pacemaker with a simple superficial operation since only the pacemaker pocket has to be prepared; then the pacemaker can be connected to the cardiac radio-frequency receiver (CRR) using a length of electrode equipped with the plug for connecting it to the pin of the jack.

The advantages for the patient are:

- Elimination of the electrode through the thoracic wall during the phase of temporary stimulation and reduction of the risks of sepsis.
- Elimination of the always bothersome intervention of extracting the temporary electrode.
- Possibility to maintain a temporary stimulation from the outside, for urgent needs.
- Possibility to maintain a temporary stimulation from the outside in case of urgent indication of need for the permanent stimulation.
- Great simplicity of the operation for the implantation of a permanent pacemaker when indicated.
- Possibility to maintain the stimulation during the above-mentioned operation.
- Possibility of periodic in-hospital checks of the pathological conditions of the patient (by means of the Personal pacemaker in the "laboratory" version).

- Possibility of therapeutical interventions in the event the patient undergoes arrhythmic events; this therapy requires the use of the Personal pacemaker in the "antiarrhythmic" version that is capable to carry out the following antiarrhythmic programs: overdrive; underdrive; coupled stimulation; burst stimulation.

- Great phychological support to the patient and his family since the Personal pacemaker can be easily operated by non-specialized persons who have been given the necessary instructions.

The invention will now be described in more detail with reference to the attached figures where:

Fig. 1 is a schematic view of the equipment and of the heart that has to be stimulated;

Fig. 2 is a schematic view of the equipment of Fig. 1 as implanted in a patient;

Fig. 3 is a view, similar to that of Fig. 1, of a second embodiment of the invention;

Fig. 4 is a view, similar to that of Fig. 2, concerning the equipment of Fig. 3;

Fig. 5 is a view similar to that of Fig. 1 of a third embodiment of the invention;

Fig. 6 is a view similar to that of Fig. 2 concerning the equipment of Fig. 5.

From the view of Fig. 1, the equipment is essentially formed of: an epi-cardial uni-polar electrode 11, one extremity of which stimulates the heart CC of the patient; a receiver of radio-frequency 12,

clamped on uni-polar electrode 10 without interrupting its mechanical continuity; a quick jacktype connection 13 for connecting the other extremity 14 of the uni-polar electrode 10.

The equipment is permanently implanted during the operation by stitching stimulation tip 11 of electrode 10 on the epimyocardium of heart CC of the patient; the radio-frequency receiver 12, constituted by a passive coil with a plate for the return signal closing through the patient's tissue, is located in a subcutaneous position (Fig. 2).

The cardiac stimulation that should it be the case would be required during or immediately after the operation is supplied by an external pacemaker (Personal pacemaker) transmitting the stimulation signals by radio-frequency to radioreceiver 12. The return signal closes from the epi-cardial electrode onto the radioreceiver plate through the patient's tissue.

The equipment is then left in situ after the necessary period of rest has elapsed.

In case artificial stimulation of the patient's heart CC subsequently becomes necessary, immediate and temporary use of a Personal pacemaker can be made, or, in the event permanent stimulation is indicated, a permanent uni-polar pacemaker can easily and rapidly be implanted by simply opening the skin at the location of radioreceiver 12 and connecting it to permanent pacemaker 15 using a length of uni-

polar electrode 16 connected to the extremity 18 by means of quick connection 13.

As an alternative embodiment of the invention, it is possible to utilize, instead of the quick jack-type connection 13 emerging from radio-frequency receiver 12 as in Fig. 1, a well-insulated free length of uni-polar electrode of suitable length indicated as 119 in Fig. 3, emerging from radio-receiver 112, that can easily be connected to permanent uni-polar pacemaker 115 by a universal adaptor of a known type (not shown); the permanent pacemaker is implanted in a sub-cutaneous pocket previously prepared as normally done in permanent pacemaker implantations, as show in Fig. 3 and 4. The return signal closes from the epimyo-cardical electrode onto radio-frequency receiver 12 through the patient's tissue. It may be noted that the equipment in this second version is identical to that of Fig. 1 as regards the uni-polar electrode, here referred to by 110, stimulating tip 111 thereof and the radioreceiver referred to by 112. Radioreceiver 112 is clamped on electrode 110 at a certain distance from its free extremity in order to leave a free length or "tail" of uni-polar electrode 110 to which the permanent pacemaker, as mentioned, can easily be connected.

From Fig. 5, it is possible to observe an alternative of the invention wherein use is made of an epi-cardial bipolar embodiment electrode 211 formed by two stimulation tips screwed on the epimyocardium

and positioned by means of a base 220 made of the material known under the Trade Mark Tygon or other biocompatible material stitched to the epimyocardium.

In this version the length of electrode 210 is bipolar and radio-frequency receiver 212 has the advantage of being miniaturized since its dimensions are no longer determined by the size of the signal return plate, which in this case is absent; moreover, the absence of the signal return plate avoids muscular contractions which are always possible due to accidental tipping of the radio-frequency receiver or to high current density.

The length of electrode 219 intended to connect permanent pacemaker 215 can be indifferently uni-polar or bipolar, according to the type of permanent pacemaker utilized uni-polar or bipolar. The connection between permanent pacemaker 215 and electrode 219 is easily obtained by utilizing a universal adaptor of a known type, uni-polar or bipolar as appropriate (not shown).

The advantages obtained with this third embodiment of the invention are:

- Avoiding contractions of muscles always possible in patients.
- Complete miniaturization of the radio-frequency receiver.

It can be noted that in this third embodiment of the invention the equipment is identical with the equipment of Fig. 1 in its conceptual design, but the

same utilizes a length of bipolar electrode 210, a bipolar epi-cardial electrode with two stimulation tips 211 screwed on the epimyocardium and positioned by means of a base 220 of a bio-compatible material stitched to the heart CC, and a radio-frequency receiver 212, clamped on the conductors of bipolar electrode 210. Owing to the absence of the signal return plate this equipment is quite small.

CLAIM:

1. An equipment for temporary heart stimulation from the outside in case of open-heart surgery, by means of an external pacemaker transmitting radio-frequency signals, pre-arranged in such a way as to be left in situ to provide permanent stimulation if subsequently needed, characterized in that it comprises: an electrode with epi-cardial stimulation tip, a cardiac radio-frequency receiver clamped on said electrode and capable of receiving radio-frequency stimulation signals, a connecting device for the easy and rapid connection of said electrode to a permanent pacemaker, the parts being so arranged that said equipment allows, at any time after the operation, the supply of either an emergency radio-frequency stimulation or a permanent stimulation without the need for a new heart operation.

2. The equipment of claim 1, wherein said device for connecting the electrode to the permanent pacemaker comprises a quich jack-type connection directly emerging from said radio-frequency receiver.

3. The equipment of claim 1, wherein said device for connecting the electrode to the permanent pacemakers comprises a free length or "tail" of said electrode, accurately insulated, emerging from said radio-frequency receiver.

4. The equipment of claim 3, wherein the length of electrode between heart and radio-frequency receiver is bipolar as well as the two stimulation tips

screwed on the epimyocardium and positioned by means of a base of a bio-compatible material; and wherein the device for connecting said radio-frequency receiver to a permanent pacemaker comprises a free length or "tail" of said electrode, appropriately insulated, emerging from said radio-frequency receiver.

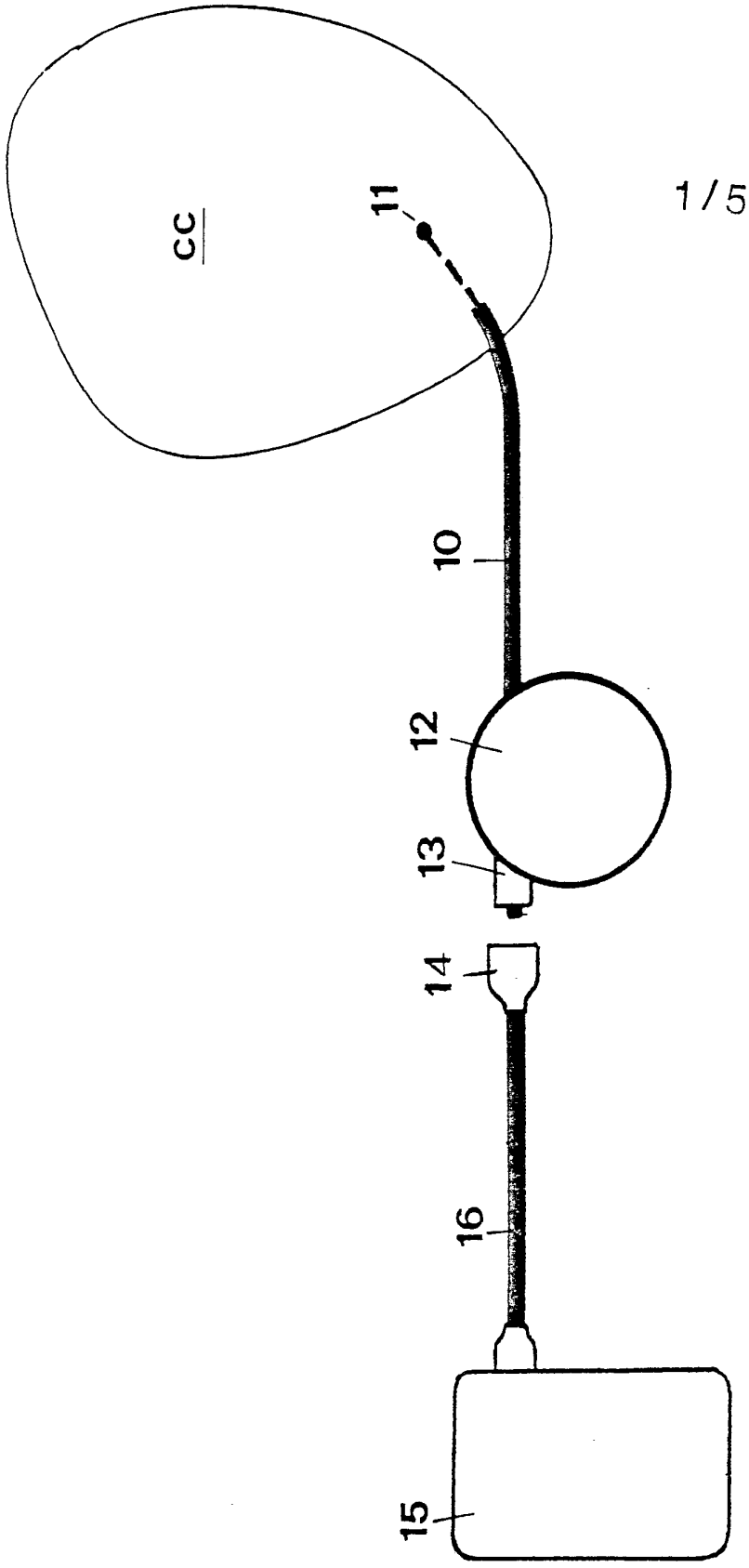


FIG 1

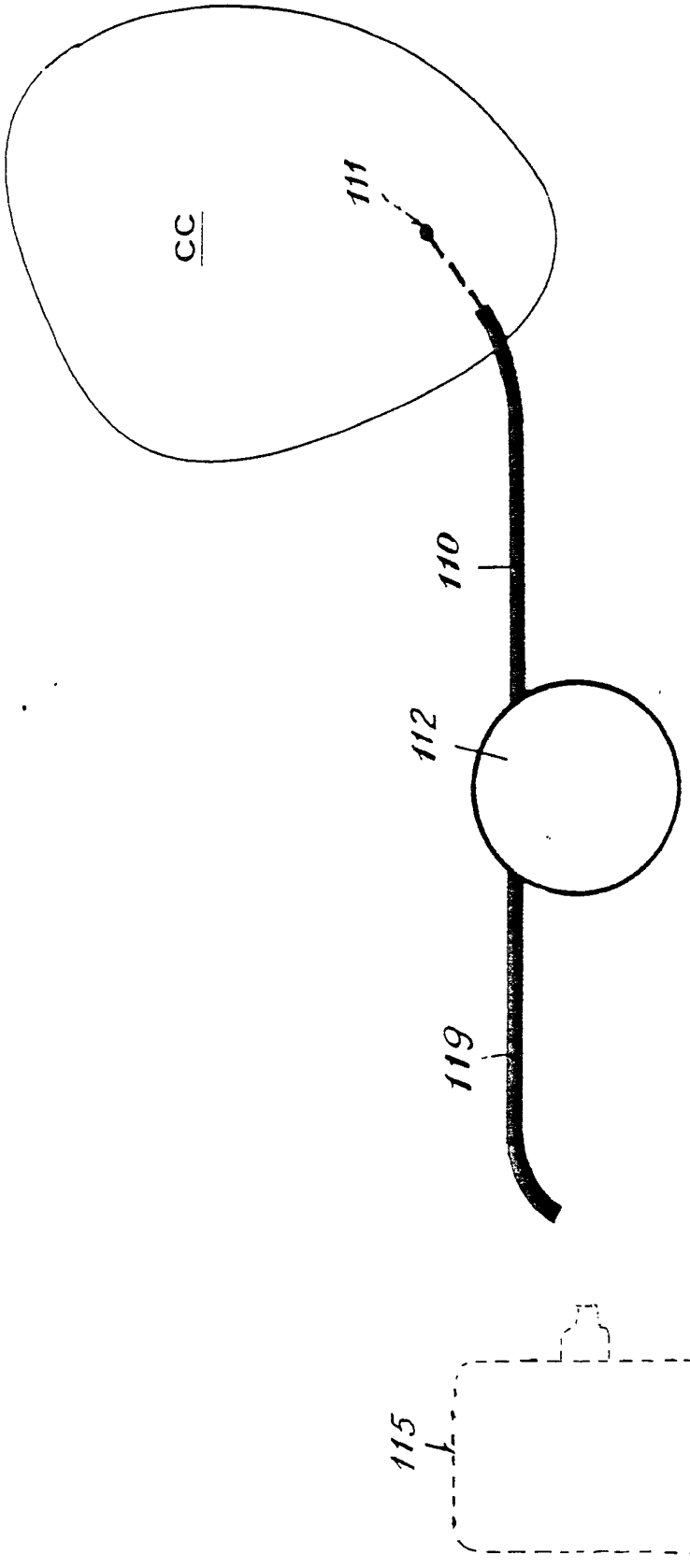


FIG.3

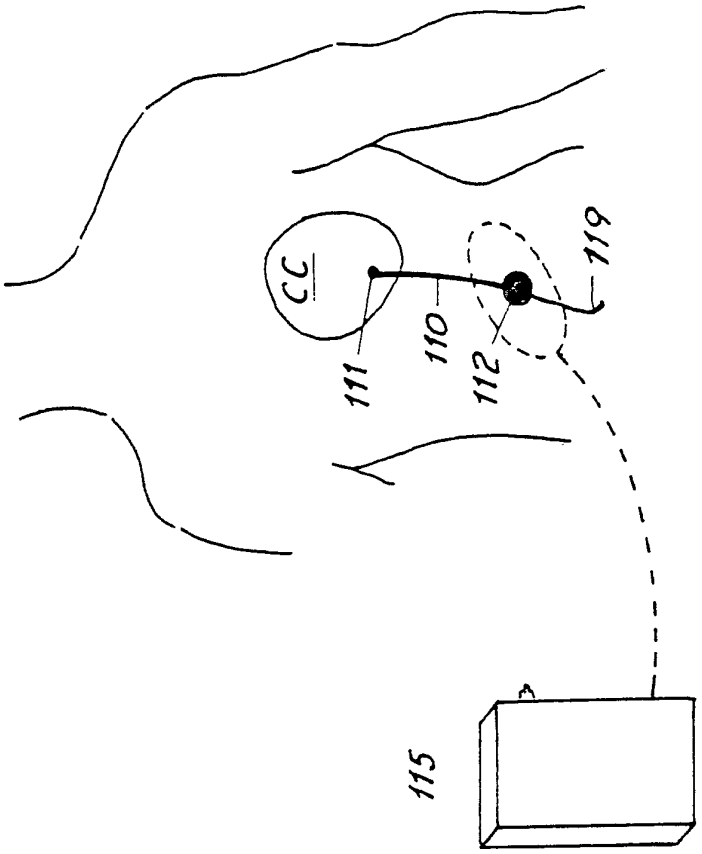


FIG. 4

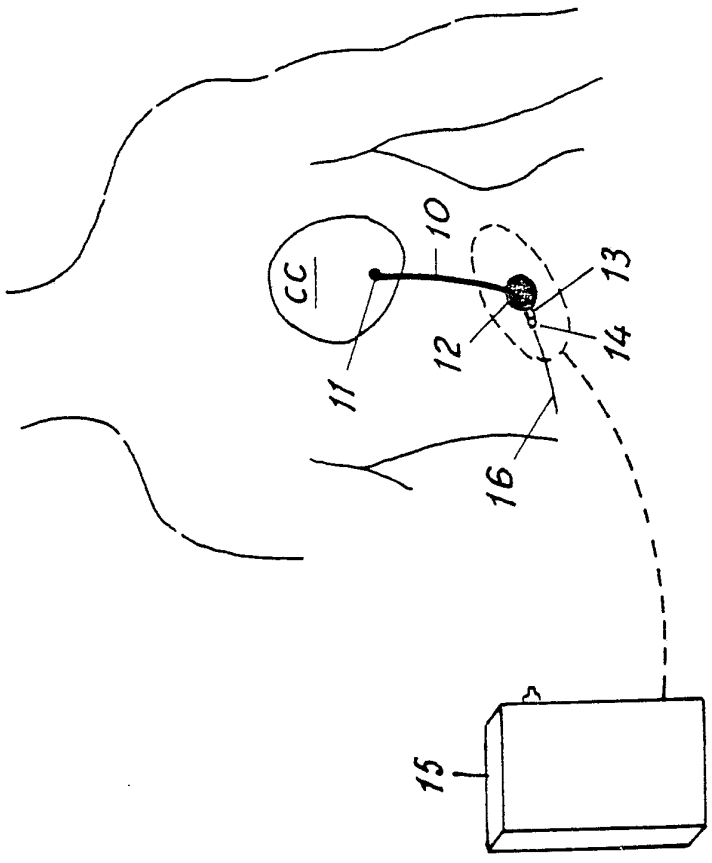


FIG. 2

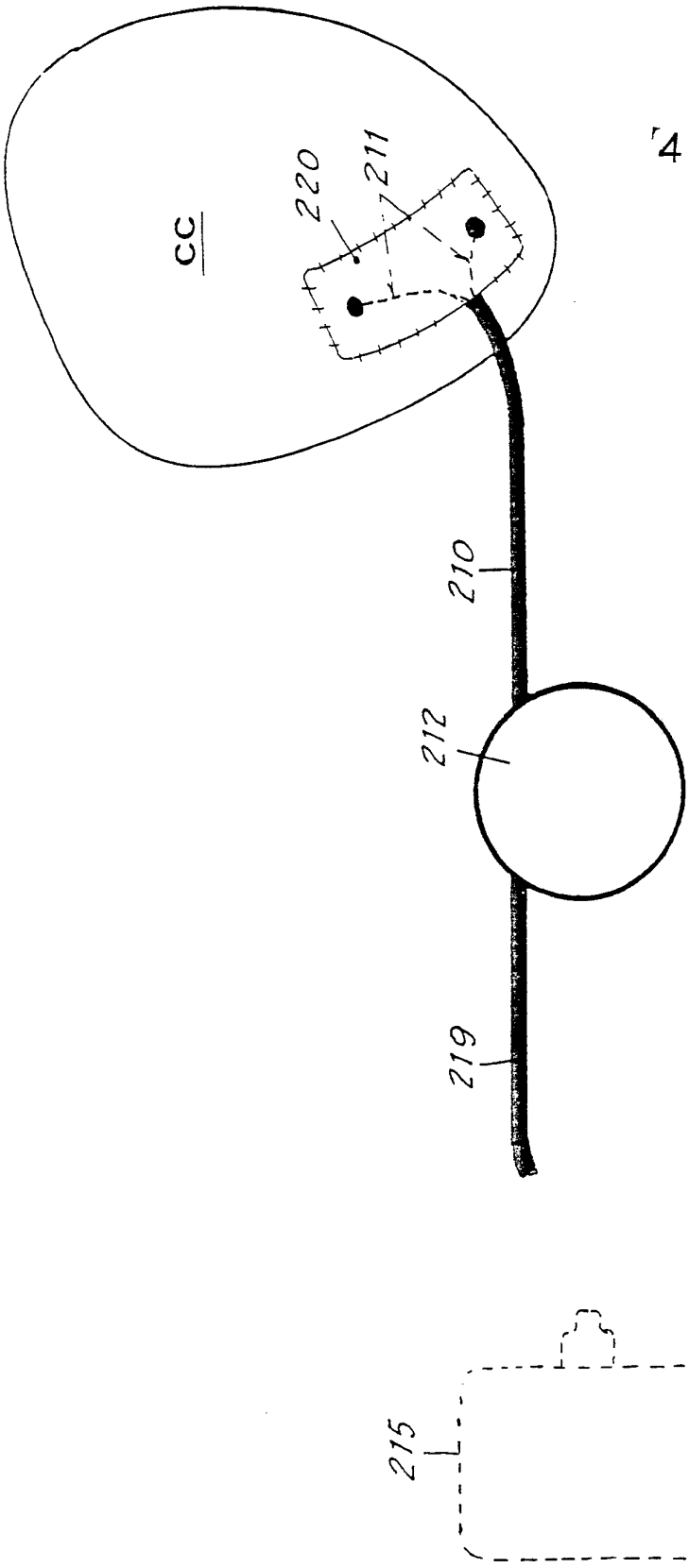


FIG.5

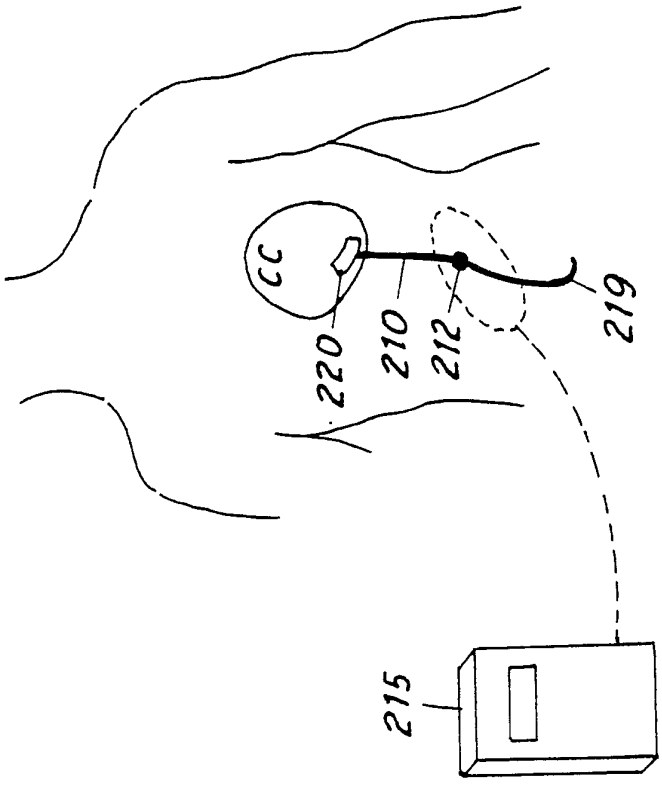


FIG.6

INTERNATIONAL SEARCH REPORT

International Application No PCT/IT 88/00005

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

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

IPC[4]: A 61 N 1/372; A 61 N 1/362; A 61 N 1/05

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 N

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

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	FR, A, 2058872 (ARION) 28 May 1971 see page 3, lines 6-11; figure 8 --	1
A	US, A, 4270549 (HEILMAN) 2 June 1981 see column 8, line 50 - column 9, line 11; figure 10 --	1-4
A	US, A, 4030509 (HEILMAN) 21 June 1977 see abstract --	1
A,P	US, A, 4640285 (DECOTE) 3 February 1987 see column 3, line 55 - column 4, line 17	1

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20th April 1988	26 MAY 1988
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. IT 8800005 SA 20393

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 17/05/88
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A- 2058872	28-05-71	None	
US-A- 4270549	02-06-81	None	
US-A- 4030509	21-06-77	NL-A- 7610830	01-04-77
		DE-A,C 2643956	18-05-77
		GB-A- 1567025	08-05-80
		CA-A- 1091304	09-12-80
US-A- 4640285	03-02-87	None	