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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 November 2003 (13.11.2003)

PCT

(10) International Publication Number
WO 03/092809 A1

(51) International Patent Classification[7]: A61N 1/375

(21) International Application Number: PCT/SE03/00636

(22) International Filing Date: 17 April 2003 (17.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0201321-7 30 April 2002 (30.04.2002) SE

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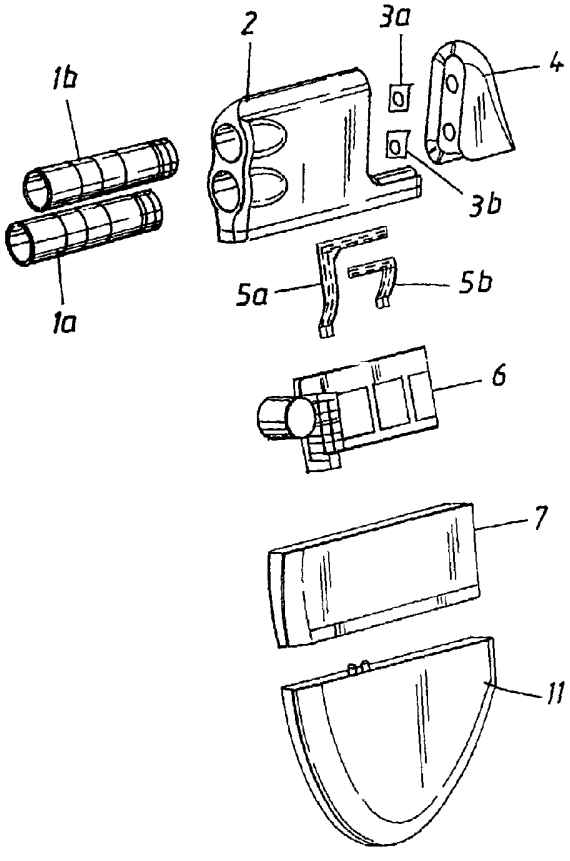
(81) Designated State *(national)*: US.

(84) Designated States *(regional)*: European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

**Published:**
— *with international search report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: AN IMPLANTABLE MEDICAL DEVICE AND A MANUFACTURING METHOD THEREOF




(57) Abstract: The invention concerns an implantable medical device and a manufacturing method thereof. The implantable medical device comprises at least an electronics module and a battery module. Each of the modules contribute functionally as well as to the shape of the outer enclosure of the implantable medical device. New implantable medical devices can be developed and manufatured rapidly by combining modules with different specification.

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# An implantable medical device and a manufacturing method thereof

## BACKGROUND OF THE INVENTION

### 1. Field of the invention

The present invention relates to an implantable medical device and a manufacturing method thereof in accordance with the preamble of the independent claims.

### 2. Description of the prior art

Several different ways to modularize and manufacture an implantable medical device are known.

US-A-5 370 669 describes an implantable defibrillator in which the components of the active implantable device are housed within an implantable casing having three orthogonal dimensions of height, width and thickness. The height and width are substantially greater than the thickness. The implantable defibrillator comprises three major subsystems, specifically, the batteries, the power capacitors, and the electronics. Each of the three sub-systems lie in parallel height-width planes, each plane being adjacent another in the thickness dimension.

US-A-5 103 818 describes an arrangement which enables rapid and effective termination of electrical junctions for an implantable medical device such as a heart pacemaker or an implantable defibrillator. The electronics subsystem and the battery are placed in one half of the housing that also comprises the feedthrough. At this moment the battery and the feedthrough contacts the electronics subsystem through female connectors on the electronics subsystem. The electrical connections are then fusion welded. Following the

fusion weld of the electrical connections the other half of the housing is mounted and the enclosure welded to become hermetic.

US-A-5 814 091 describes an arrangement in which the battery is integrated with the outer enclosure of the implantable medical device.

## 3. Summary of the invention

One object of the present invention is to provide a modularized device which makes it economically feasible to manufacture a large number of models of an implantable medical device and yet to limit the number of components needed for the entire model program.

A further object is to simplify the process of assembling the finished product.

A still further object is to shorten the development time for new products.

A still further object is to minimize the number of parts required for the completed implantable medical device.

The objects of the invention are achieved by a modularized medical device having the features of the characterizing portion of claim 1.

The implantable device is divided into modules, each of said modules being a portion of the the outer shape of the implantable medical device as well as a well defined function of said implantable device. A very important aspect is that one of the modules can be modified witout any need to modify any of the other modules. The modules themselves have an open interface to other modules and as a consequence of this the modules themselves are not hermetically sealed but hermeticity will be obtained when the modules are permanently attached to ech other through e.g. laser welding. This will make it easy to develop and manufacture different models of the implantable medical device which have different connector modules or different battery modules with a minimal cost for product development. If

there are e.g. three different battery modules available, three different connector modules and three different electronics modules available then 27 different models of the finished proucts can be manufactured from the nine available modules. This will make it much easier for the manufacturer to adapt the production to varying market demands on battery capacity or on connector type. It is also possible to upgrade production with a more advanced electronics module while connector module and battery module remain unchanged.

The present invention is particularly suitable for use in an implantable cardioverter defibrillator (ICD). In the ICD application the requirements regarding longevity and shock energy may vary significantly depending on market requirements. One possible modularization for an ICD is to divide the ICD into four different modules according to the invention. The individual modules may be as follows: module (a) could essentially comprise a connector subsystem, module (b) could essentially comprise a power electronics subsystem including shock energy storage capacitors, power transformers etc, module (c) could essentially comprise low voltage electronics such as pacing/sensing circuitry, module (d) could essentially comprise a battery subsystem. By varying the size of module (b) with the power electronics subsystem the shock energy can be adapted to different needs through the use of shock energy capacitors of different capacitance. By varying the size of module (d) the battery subsystem capacity the can be adapted to different requirements regarding longevity and number of shocks available. It is also feasible to use a general set of modules suitable for pacemakers and for ICD:s. In a bradycardia pacemaker (a), (c) and (d) would be used while in an ICD modules (a), (b), (c), and (d) would be used. The invention can also be utilized to add features to a standard pacemaker or ICD. As an example a diagnostic data collection module could be added to a standard pacemaker or ICD.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig 1 shows a schematic assembly drawing of an implantable medical device according to the invention.

Fig 2 shows how the manufacturing method can be implemented using three different types for each of the three different modules necessary for the production of an implantable medical device.

DESCRIPTION OF PREFERRED EMBODIMENTS

Figure 1 shows an example of an implantable cardiac pacemaker built according to the invention. In this embodiment the cardiac pacemaker is manufactured using three modules. Each of the modules contributes functionally as well as to the shape of the enclosure of the implantable medical device. The following modules are used in this particular cardiac pacemaker: connector module 1a,1b,2,3a,3b,4, electronics module 5a,5b,6,7 and battery module 11.

The connector module 1a,1b,2,3a,3b,4 in this example is of the type in which the lead connectors are integrated into the housing without a moulded plastic connector top. The connector module comprises the following parts: metallic/ceramic connector tubes 1a,1b, a portion 2 of the outer enclosure of the cardiac pacemaker, lead pin locking washers 3a,3b, a transparent plastic component 4, and flex circuits 5a,5b. The metallic/ceramic connector tubes may for example be of the type disclosed in international publication WO 00/12174. The flex circuits 5a,5b provides electrical connection between the metallic/ceramic lead connecting tubes 1a,1b and the electronics module 6. During manufacture the flex circuits 5a,5b are welded to a feedthrough portion of the connector tubes 1a,1b. The end

portions of the connecting tubes 1a,1b are made of metal and are adapted to be welded in both ends to the enclosure portion 2. Each of the flex circuits 5a,5b is rolled on a connector tube and then the connector tube is inserted into the enclosure portion 2. After inserting the flex circuit 5a,5b it is rolled out and the connector tube 1a,1b is welded in both ends to the enclosure portion 2. The final step in assembling the connector module is to mount the locking washers 3a,3b and the transparent plastic component 4. The purpose of the plastic component 4 is to provide visible confirmation that the lead connecting pin is fully inserted into the implantable cardiac pacemaker at the time of implantation. The finished connector module is a complete connector for the implanted lead, as well as a part of the outer shape of the enclosure of implantable device and it is adapted for a quick electrical connection to an electronics module. During manufacture it is simply connected to the electronics module and then welded to the outer enclosure portion 7 of the electronics module. To facilitate manufacturing the enclosure portion 2 of the connector module and enclosure portion 7 of the electronics module should be designed so that they have a very good fit to each other. Preferably outer enclosure portions such as 2 and 7 mentioned above should have a mechanical click action when they are properly oriented in relation to each other.

The electronics module 6,7 comprises an electronic circuit 6 and a portion of the enclosure 7. The electronics circuit 6 should preferably be fixed to the enclosure portion 7 through glueing, or moulding or other method. The electronic circuit 6 has connection means for a quick electrical connection of the connector top and the battery. These connection means should preferably be of a snap in type in order to make welding, soldering or other more complicated connection methods unnecessary. However, none of the mentioned connection methods is excluded from the scope of the invention.

The battery module 11 serves as power source as well as a portion of the outer enclosure. In a preferred embodiment the battery's enclosure is manufactured from titanium or any metal suitable for direct contact with tissue. In that case the electrochemical potential of the battery enclosure will become the enclosure potential of the implantable cardiac pacemaker. Thus one of the battery's electrical terminals is in direct contact with the patient's body tissue. This arrangement is particularly suitable for Lithium/Carbon Monofluoride batteries which can be manufactured whith an enclosure of titanium. The outer enclosure of the battery module 11 should preferably extend slightly above the lid of the battery so that the outer enacpsulation portion 7 of the electronics module 5a,5b,6,7 can be welded directly to the battery module's 11 enclosure with no risk that the hermeticity of the battery is jeopardized during welding. In a more conventional embodiment an isolation layer is provided between the battery and the outer surface of the battery module to be able to more freely decide the electrical potential of the finished implantable device's enclosure.

Figure 2 is a schematic drawing indicating how an implantable medical device can be built from different modules. 21 shows a conventional connector top while 22 shows a connector module of the type described above which has no conventional moulded connector top while 23 is a closed connector top without the feature of visual confirmation that the lead is properly inserted. The conventional connector top 21 comprises a lower metallic portion comprising a connector top bottom and a flange to allow to weld it to the electronic module 24, 25, 26. The metallic portion comprises conventional feedthru's to allow an electric connection between the electronic module 24, 25, 26 and the electrode lead connectors in the connector top without compromising hermeticity. The connector top 21 can also be manufactured in a ceramic material. In the latter

case there must be a metallic flange to allow welding of the connector top to the remainder of the encapsulation. Feedthru's are not necessary if the connector top is manufactured in a ceramic material. Connection wires for connection between electrode lead connectors and and the electronic module will be located inside the ceramic material in a fashion similar to a conventional feedthru. 24,25 and 26 represent electronic modules of different size and shape. 27, 28 and 29 represent battery modules of different size and capacity and also possible different electrochemical composition.

Fig 3 shows the connector module 21 in a more detailed fashion. The top portion of the connector top is ecaxtly similar to a conventional connector top. The metallic lower portion 31 comprises a bottom of the connector top and a flange 36 used to weld the connector top 21 to an electronics module 24, 25, 26. A feedthru 30 is welded to the lower metallic portion. The top portion comprises a conventional molded portion 32, connector block with setscrew 33, a wire connection 34 for connection between connector block 33 and feedthru 30.

Fig 4 shows a more detaled view of a connector module manufactured of a ceramic material. The top portion of the connector top is manufactured in a ceramic material $Al_2O_3$. Metall ribbons 39a, 39b provides electrical connection between a heart electrode connector and the electronics module 24,25,26 with a maintained hermeticity for the enclosure for the electronics. A metal rim 38 is soldered to the lower portion of the connector module. The connector module is welded to the electronics module 24,25,26 by welding to the metal rim 38.

Every battery module 27,28,29 can be combined with every electronics module 24,25,26 and every electronics module can be combined with every connector module 21,22,23. Thus 27

different models of the implantable medical device can be produced using 9 different modules. This technique will make it easier to tailor the production to requirements from the market. If for example one market requires a particular battery size or battery capacity the battery module can easily be replaced with a suitable module while no other changes have to be made. The connector modules 21,22,23 can also be used for implantable medical devices having a conventional encapsulation.

CLAIMS

1. A manufacturing method for an active implantable medical device provided with an outer enclosure and comprising at least two functional subsystems such as e.g. a battery subsystem (27, 28, 29), an electronic subsystem (24, 25, 26), a connector subsystem (21, 22, 23) or combinations thereof, each subsystem being located in a respective module, different versions of said respective modules being available, characterized by the following steps;

- specifying the requirements on the complete implantable
- device; and
- selecting the modules that are to form the complete device based on said requirements; and
- joining said modules permanently to form the complete hermetically sealed outer enclosure;

2. The manufacturing method of claim 1 characterized in that the electrochemical case potential of said battery subsystem is the same as the enclosure potential of said implantable medical device.

3. The manufacturing method of claim 1 characterized in that the electrochemical case potential of the battery subsystem is isolated from the enclosure potential of said implantable medical device.

4. The manufacturing method of claim 1 characterized in that said battery subsystem utilizes a battery chemistry of any of the types Lithium-Iodine, Lithium-Silver Vanadium Oxide or Lithium-Carbon MonoFluoride or a combination of Lithium-Silver Vanadium Oxide and Lithium-Carbon MonoFluoride.

5. The manufacturing method of claim 1 characterized in that the enclosure of the battery subsystem is a part of the enclosure of said implantable medical device.

6. The manufacturing method of claim 1 characterized in that said connector subsystem is available in versions comprising one to four pacing/sensing terminals.

7. The manufacturing method of claim 1 characterized in that said electronics subsystem is available in versions comprising one to four pacing/sensing terminals.

8. The manucturing method of claim 1 characterized in that;
- said connector subsystem comprises a connector tube (1a, 1b) adapted to be welded to the outer encapsulation portion of said connector subsystem; and
- a flex circuit (5a, 5b) is utilized for electrical connection between said connector tube (1a, 1b) and said electronic subsystem (5a, 5b, 6, 7); and
- said flex circuit is rolled on said connector tube before the connector tube is inserted into the outer encapsulation portion 2 of said connector subsystem; and
- said flex circuit is rolled out from said connector tube before the connector tube is welded to the encapsulation portion 2 of said connector subsystem.

9. An active implantable medical device comprising one single hermetically sealed outer enclosure and comprising at least two functional subsystems such as e.g. a battery subsystem (27, 28, 29), an electronic subsystem (24,25,26), a connector subsystem (21, 22, 23) or combinations thereof characterized in that;
- said implantable device comprises at least two modules, each module comprising a portion of the outer enclosure and at least one of said subsystems, each module comprising at least one interface portion adapted to correspond to a corresponding interface on another module, said modules being mechanically connectable to each other at said interface portions, such that said enclosure portion on each module together form said outer enclosure after sealing.

10. The active implantable device of claim 9 characterized in that the electrochemical case potential of the battery subsystem (27, 28, 29) is the same as the enclosure potential of said implantable medical device.

11. The active implantable device of claim 9 characterized in that the electrochemical case potential of the battery subsystem (27, 28, 29) is isolated from to the enclosure potential of said implantable medical device.

12. The active implantable device of claim 9 characterized in that said battery subsystem (27, 28, 29) utilizes a battery chemistry of any of the types Lithium-Iodine, Lithium-Silver Vanadium Oxide or Lithium-Carbon MonoFluoride or a combination of Lithium-Silver Vanadium Oxide and Lithium-Carbon MonoFluoride.

13. The active implantable device of claim 9 characterized in that the enclosure of the battery subsystem (27, 28, 29) is a portion of the enclosure of said implantable medical device.

14. The active implantable device of claim 9 characterized in that said connector subsystem (21, 22, 23) is available in versions comprising one to four pacing/sensing terminals.

15. The active implantable device of claim 9 characterized in that said electronics subsystem (24, 25, 26) is available in versions comprising one to four pacing/sensing terminals.

16. An active implantable medical device comprising;

- a hermetically sealed metal enclosure,
- an electronics module to be placed inside said
- hermetically sealed enclosure,

- and a premanufactured connector top for connection of
- an electrode lead to said electronics module;

characterized in that said connector top comprises a portion of said hermetically sealed metal outer enclosure, and in that said connector top is adapted to be welded to the remainder of said medical device's enclosure to form said hermetically sealed outer enclosure.

17. An active implantable medical device according to claim 1, characterized in that said portion of said hermetically sealed metal outer enclosure comprises feedthru's for connection between said electronics module and said connector top.

18. An active implantable medical device comprising;

- a hermetically sealed metal outer enclosure,
- an electronics module to be placed inside said
- hermetically sealed outer enclosure,
- and a premanufactured connector top for connection of
- an electrode lead to said electronics module;

characterized in that said connector top is manufactured in a ceramic material; and in that said connector top comprises a metallic edge portion which allows it to be welded to the remainder of said medical device's enclosure to form said hermetically sealed outer enclosure.

Fig. 1

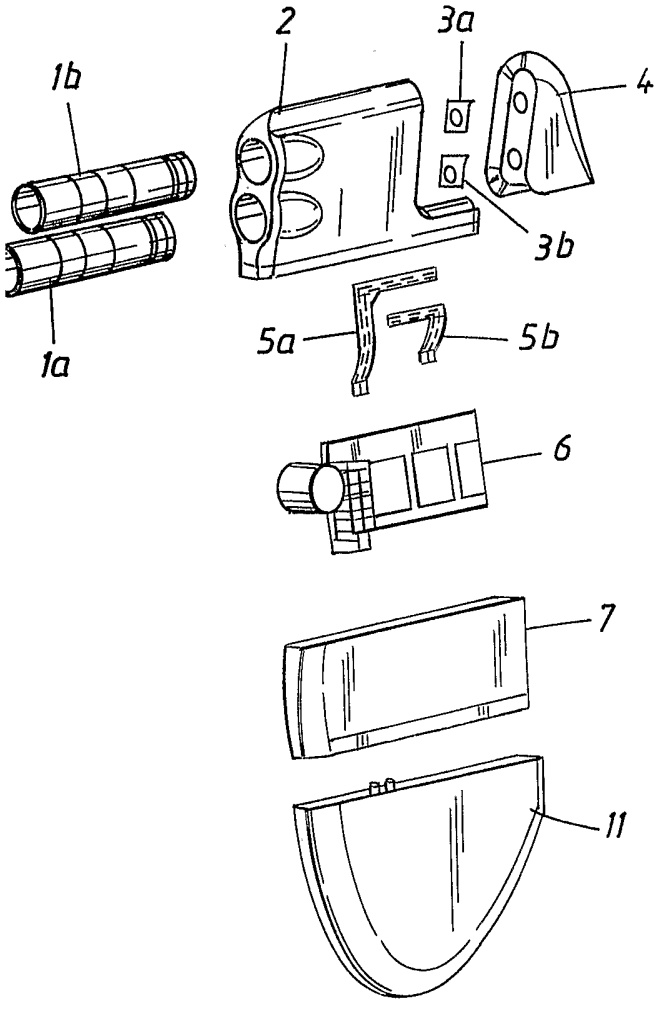


Fig. 2

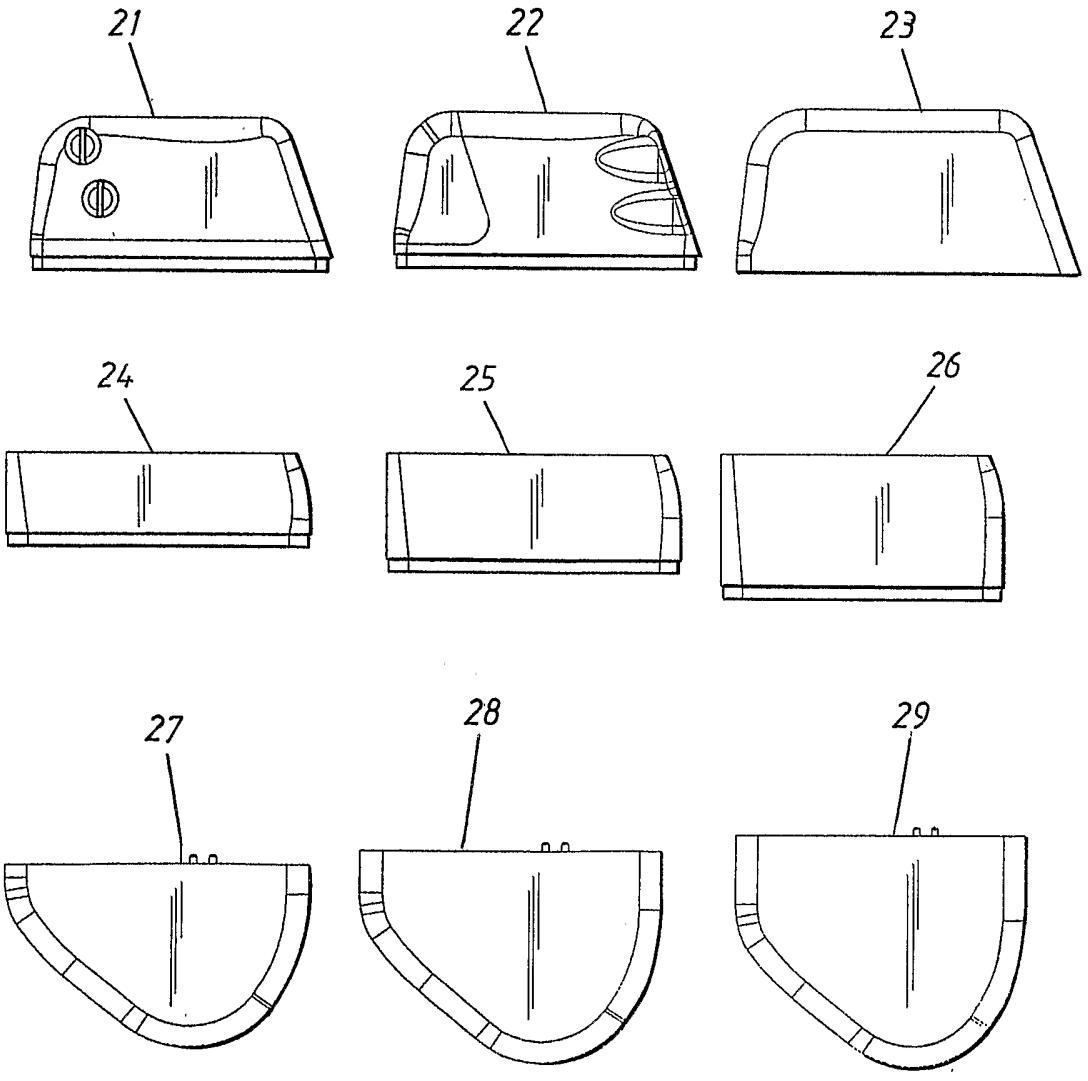


Fig. 3

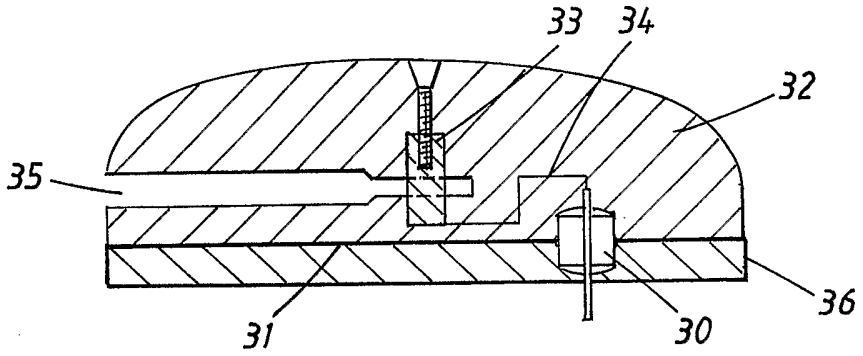
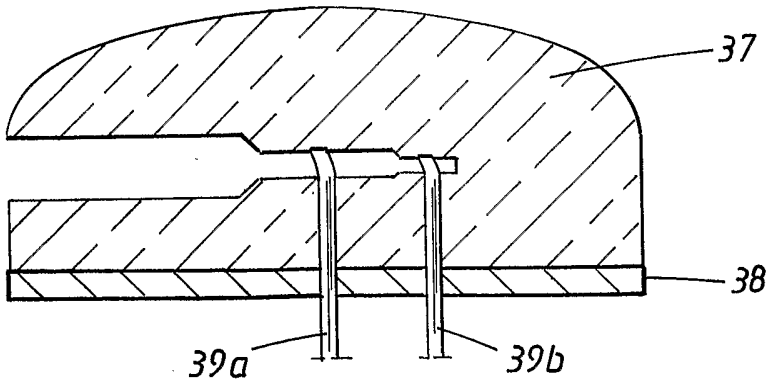



Fig. 4



# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00636

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/375
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)

IPC7: A61N

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

SE,DK,FI,NO classes as above

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

EPO-INTERNAL, WPI DATA, PAJ, INSPEC, MEDLINE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5103818 A (ROBERT E. MASTON ET AL), 14 April 1992 (14.04.92), column 3, line 16 - line 50, figure 1, abstract<br>--- | 1-18 |
| A | US 4785827 A (DAVID J. FISCHER), 22 November 1988 (22.11.88), abstract<br>--- | 18 |
| A | US 5919215 A (CRAIG L. WIKLUND ET AL), 6 July 1999 (06.07.99), abstract<br>---<br>-------- | 1-18 |

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 1 July 2003 | 08 -07- 2003 |
| Name and mailing address of the ISA/<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Sofie Carlsson/mj<br>Telephone No. +46 8 782 25 00 |

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## INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00636

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 5103818 A | 14/04/92 | NONE | |
| US 4785827 A | 22/11/88 | NONE | |
| US 5919215 A | 06/07/99 | US 5871514 A | 16/02/99 |
| | | US 5871515 A | 16/02/99 |
| | | US 5897578 A | 27/04/99 |