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(54) **Title:** MEDICAL IMPLANTABLE LEAD AND METHOD FOR MANUFACTURING THE SAME

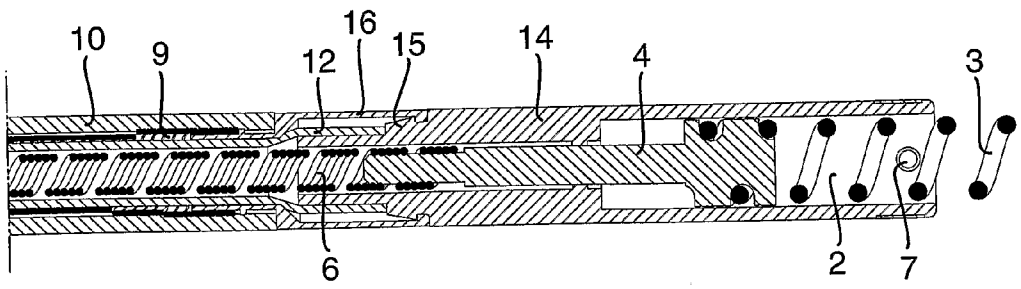

Fig 2

(57) **Abstract:** The invention relates to a medical implantable lead for monitoring and/or controlling of an organ inside a human or animal body, comprising two electrical conductors (6, 9), each connected to a respective electrode for re¬ ceiving or transmitting of electrical signals from or to the organ, and a tubular header (14) in a distal end of the lead. One electrode (3) is positioned in the outermost distal end of the lead whereas the other is a ring formed electrode (16), which is mounted by means of a coupling on the outside of the lead in a proximal end of the header. According to the invention the coupling (15) and the header (14) is integrated into one unitary piece of an electrically insulating material and the coupling is formed with a quick fixating connection (17, 19) in the proximal end of the header by means of which the ring electrode (16) is mounted to the header. The invention also relates to a method for manufac- turing of a medical implantable lead.

WO 2009/002239 A1

MEDICAL IMPLANTABLE LEAD AND METHOD FOR MANUFACTURING THE SAME

The invention relates to a medical implantable lead for monitoring and/or controlling of an organ inside a human or animal body, comprising two electrical conductors, each connected to a respective electrode for receiving or transmitting of electrical signals from or to the organ, and a tubular header in a distal end of the lead, wherein one electrode is positioned in the outermost distal end of the lead whereas the other is a ring formed electrode, which is mounted by means of a coupling on the outside of the lead in a proximal end of the header.

The invention also relates to a method for manufacturing of such a medical implantable lead.

Background of the invention

Medical implantable leads of the above kind are well known in the art. One common field of application is for monitoring and/or controlling of the function of a human or animal heart, in which case it is inserted into the body and attached with a distal end to the heart by means of a fixating member, such as a helix which can be screwed into the tissue. A proximal end of the lead is connected to an electronic device, for performing the monitoring and/or controlling, such as a pacemaker or an implantable cardiac defibrillator.

The most distal of the electrodes can be formed as a passive electrode, in which case it is formed in the end surface of the lead and bears against the surface of the heart while being fixated to the heart wall by means of fins, tines or the like, which during implantation engages the trabecular network inside the heart and subsequently are overgrown by a layer of tissue. The distal electrode can also be of an active type, which is used both for monitoring/controlling and for fixation in that the electrode is inserted into and is engaged with the tissue, such as for example a tip provided with barbs or a helix which is screwed into the tissue. The most proximal of the electrodes is formed as a ring on the outside of the lead and positioned on a suitable distance from the distal end. The distance from the distal end is determined by the desired amplitude of the signals and an acceptable interference level.

Normally, the ring electrode is positioned at the proximal end of a so called header, which is formed as a tubular and rigid housing positioned in the distal end of the lead and adapted to carry the electrodes and the fixating member, e.g. accommodating the helix inside an inner bore of the header. The most common way to accomplish the mounting of the ring electrode to the header, is to arrange a coupling member between the header and the ring electrode which is partly inserted into the tubular bore from the proximal end of the header and partly into the ring electrode. In this way a distance is achieved between the ring electrode and the distal electrode, which is suitable for most applications and the outer surface of the ring electrode can be mounted flush with the outer surface of the header or a sleeve covering the header such that the maximum diameter of the lead can be made advantageously small. The fixation of the ring electrode in relation to the coupling member is normally achieved by an adhesive, which has to result that the assembled header, coupling member and ring electrode have to be held immovable and fixated during the time for curing of the adhesive. This is a disadvantage since it has to effect that the manufacturing process of the lead has to be suspended for a while. Moreover, this manufacturing method of the lead is also disadvantageous in that there is not provided any fixed position for the ring electrode in relation to the header. This has to effect that the position and orientation of the ring electrode in relation to the header can vary and the production yield loss of this kind of leads is comparatively high due to failures when interconnecting the ring electrode and the header.

Normally, the header as well as the coupling member are manufactured of an electrically conducting material, such as titanium, which means that a separate electrically insulating layer must be provided since the ring electrode must be electrically insulated in relation to the header. However, in prior art is also known headers made of an electrical insulating material, such of PEEK (polyetheretherketone). In this case there is no need for an electrical insulation between the ring electrode and the header. In the prior art it is also known to place the ring electrode on the outside around and bearing directly against a header of an electrically insulating material. In this way it is possible to arrange a substantially fixed position for the ring electrode on the header such that, even though an adhesive may be used to finally fixate the ring electrode on the header, it is not necessary to suspend the manufacturing process during curing of the adhesive. One disadvantage with such a design of the lead is however, as mentioned before, that the ring electrode on the out-

side of the header will increase the overall diameter of the lead. Another disadvantage is that the ring electrode must be connected electrically, by means of a separate conductor, to a conductor in the lead. this adds additional components and manufacturing steps to the manufacturing process. Moreover, the ring electrode will be positioned closer to the distal end of the header which is suitably only for certain applications.

Summary of the invention

An object of the present invention is to improve medical implantable leads according to prior art and to provide a medical implantable lead which can be manufactured to a low cost. At least this object is achieved by a medical implantable lead according to claim 1.

The invention also relates to a method for manufacturing of a medical implantable lead, having essentially the same object as above. At least this object is achieved by a method according to claim 7.

The basis of the invention is the insight that the above object can be achieved by manufacturing the header of an electrically insulating material and to integrate the coupling member and the header into one unitary piece, wherein the coupling member is formed as a coupling portion in the proximal end of the header and formed in such a way that the ring electrode can be instantly fixated to the header by means of a quick fixating connection. Even though it is preferred to also use an adhesive for increased bonding strength and fluid tight sealing of the lead, it is in this way possible to fixate the ring electrode instantly without having to wait for the adhesive to cure before proceeding with subsequent manufacturing steps.

Within this overall inventive idea, the invention may be realized in many different ways within the scope of the associated claims. For example the quick fixating connection may be formed otherwise. In a hereinafter described embodiment of the invention, the quick fixating connection is formed as a snap fit attachment, such that the coupling portion in the proximal end of the header is provided with a circumferential groove on the outside into which an inner, circumferential bead in a distal end of the ring electrode can go into engagement by deformation of the material in the ring electrode. However, the snap fit attachment could be formed in many other ways and it would also be possible to arrange a quick fixating connection in form of e.g. a crimp connection or a thermo connection between the ring electrode and the header.

In the described and illustrated embodiment of the invention, the fixating member for fixating the lead to an organ inside a body, is formed as a helix, which is accommodated inside a bore in the header and which can be screwed out from the distal end and into the tissue of an organ. It is to be understood, however, that the fixating member can be formed in many other ways, such as for example as a sharp tip provided with barbs to be penetrated into the tissue or as fins or tines to be engaging the trabecular network inside a heart and to be subsequently overgrown by tissue. The lead can also be adapted for monitoring and/or controlling of other organs than a heart inside a body.

Brief description of the drawings

A detailed description of a prior art embodiment as well as an embodiment according to the invention, will hereinafter be given by way of example with reference to the drawings, in which:

Fig 1 is a longitudinal section through a distal end of a lead according to a prior art embodiment;

Fig 2 is a longitudinal section through a distal end of a lead according to an embodiment of the invention;

Fig 3 is an enlarged detail of the connection between the ring electrode and the header in longitudinal section in a disassembled state; and

Fig 4 is a partly exploded perspective view of the lead according to fig 3.

Detailed description of a prior art embodiment and an embodiment according to the invention

Reference is first made to fig 1 of the drawings, in which is illustrated a prior art embodiment of a distal end of a medical implantable lead. In the most distal end the lead comprises a tubular header 1 of an electrically conducting material such as titanium. In a distal bore 2 of the header, a helix 3 is accommodated, which is illustrated in a partially projecting state. The helix is mounted on a distal end of a shaft 4, which in its turn is journalled in a coupling member 5 such that it can be rotated as well as displaced in a longitudinal direction in relation to the coupling. The rotation of the helix 3 is actuated from the proximal end of the lead by rotation of an inner wire coil 6, which also functions as an electrical conductor from the proximal to the distal end.

The helix 3 is in engagement with a post 7 on the inside of the header 1, such that when the inner wire coil 6 is rotated, the helix will be screwed out and advanced forward out from the header, which will have to effect that also the shaft 4 and the inner wire coil 6 will be advanced forward. When implanting the lead into a body, the helix is screwed out and into an organ such that the distal end is attached to the organ and the helix will function as an electrode inside the organ. A second electrode is arranged in the proximal end of the header in form of a ring electrode 8, which is in electrical contact with the proximal end by means of an outer wire coil 9. Outside of the outer wire coil, an outer sleeve 10 is applied for protection of the lead.

Besides the function of rotationally bearing the shaft 4, the coupling member 5 also has the function of mounting and fixating the ring electrode 8. For this purpose, the coupling member 5 is formed with an intermediary section 11 having a comparatively large diameter, namely a diameter being equal to the outer diameter of the header 1, and end portions having a comparatively small diameter. When assembling the lead, one of the end portions of the coupling member is inserted into the header, as is illustrated in the drawing, and is interconnected by welding to the header, since also the coupling member is metallic. The other of the end portions is utilized for bearing of the ring electrode 8. However, since the header 1 and the coupling member 5 are metallic, they will have the same electrical potential as the shaft 4 and the helix 3. Accordingly, the ring electrode must be electrically insulated from the coupling member 5, which will have a different electrical potential. This is achieved by means of an inner sleeve 12, of silicone or the like, which surrounds the inner wire coil 6 and is extended up over a proximal end portion of the coupling member. The ring electrode 8 is positioned over the inner sleeve 12 and will accordingly be electrically insulated in relation to the coupling member 5, the header 1, the shaft 4 and the helix 3. However, the distal end of the ring electrode, is not allowed to come into electrical contact with the proximal end of the large diameter portion of the coupling member. Accordingly, when fixating the ring electrode to the coupling member by means of an adhesive, the ring electrode has to be held immovable, preferably in a fixture, in relation to the coupling member together with the header, for as long time as until the adhesive has been cured and the ring electrode is fixated. This means that the assembling of the lead has to be suspended for a while which is a disadvantage for the work flow when assembling the lead. Moreover, since there is no fixed position for the ring electrode on the coupling member,

it frequently happens that the distance between the distal end of the ring electrode and the proximal end of the large diameter portion of the coupling becomes too small, in which case there is a risk for shortcircuiting, or too large in which case it is a risk that the assembled header, coupling and ring electrode does not fit with the rest of the lead components. It also happens that the header and the ring electrode becomes misaligned in relation to each other or that the insulating inner sleeve becomes damaged when passing the distal end of the ring electrode over the coupling member and the inner sleeve. All of these situations may lead to a rejection of the lead and, in fact, the production yield loss for this type of leads is high, which results in an increased overall manufacturing cost. Moreover, since the header is electrically conductive and has the same electrical potential as the distal electrode, i.e. the helix, it has to be covered by an electrically insulating layer in form of a header sleeve 13, of e.g. silicone, which normally is bonded directly onto the header such that the adhesive also penetrates into the gap between the proximal flange of the ring electrode and the large diameter portion 11 of the coupling member.

As is evident from the above description, the distal end of a medical implantable lead according to prior art, is composed of many different components and several different assembling steps are required for the manufacturing. Accordingly, it is desirable to provide a medical implantable lead which contains less component parts and requires fewer assembling steps for manufacturing, in order to reduce costs.

Now reference is made to figs 2-4 for description of an embodiment of a medical implantable lead according to the invention. Here the coupling member and the header are integrated into one unitary piece and made of an electrically insulating material, e.g. of PEEK, in form of a header 14 having a coupling portion 15 in the proximal end. Moreover, the proximal coupling portion is formed with a quick fixating connection, which allows for an instant connection between the coupling portion and a properly adapted ring electrode 16. More precisely, the coupling portion of the header is formed with a circumferential groove 17 in its outer surface, whereas the ring electrode is formed with an inner, circumferential bead 18 in its distal end, such that the ring electrode can be snap-fit connected to the header. To facilitate the snap-fit engagement, the header is formed with an inclined surface 19 proximal to the groove 17, such that the bead 18 of the ring electrode, upon pressing the ring electrode and the header axially towards each other, may slide over the

inclined surface 19, while slightly deforming the ring electrode, and snap into the groove.

The header 12 according to the invention will accordingly serve several purposes. On the one hand it will accommodate the helix inside the header bore 2 such that the helix may be completely contained inside the bore during inserting of the lead into the body and may be screwed out from the distal end and into the tissue for fixating the lead to an organ. Moreover, the header will provide for bearing of the shaft 4 and allow rotation as well as longitudinal displacement of the shaft. The header also provides, as already described, for means for quick fixating of the ring electrode to the header. Finally, the header provides for electrical insulation of the inner wire coil 6, shaft 4 and helix 3 from the ring electrode 16 and the outer wire coil 9. Since the ring electrode 16 is supported by the header 14 and the inner sleeve 12, which is extended over the outside of a proximal portion of the header, no additional insulating components are required between these parts.

Accordingly, a medical implantable lead according to the invention, will facilitate assembling of the lead and reduces the number of components required. For example, no separate coupling member is required and since the header is manufactured of an electrical insulating material, no additional insulating layer, as the layer 13 in fig 1, is required on the outside of the header. Moreover, the lead can be manufactured with an increased precision which reduces production yield losses. All these factors allows for manufacturing of medical implantable leads to a lower cost.

CLAIMS

1. A medical implantable lead for monitoring and/or controlling of an organ inside a human or animal body, comprising two electrical conductors (6, 9), each connected to a respective electrode for receiving or transmitting of electrical signals from or to the organ, and a tubular header (14) in a distal end of the lead, wherein one electrode (3) is positioned in the outermost distal end of the lead whereas the other is a ring formed electrode (16), which is mounted on the outside of the lead by means of a coupling in a proximal end of the header, c h a r a c t e r i z e d in that the coupling and the header (14) are integrated into one unitary piece of an electrical insulating material, wherein the header is formed with a coupling portion (15) having a quick fixating connection (17, 19) in the proximal end of the header by means of which the ring electrode (16) is mounted to the header.

2. A medical implantable lead according to claim 1, c h a r a c t e r i z e d in that the quick fixating connection is a snap fit connection.

3. A medical implantable lead according to claim 2, c h a r a c t e r i z e d in that the snap fit connection comprises an outer, circumferential groove (17) in the proximal end of the header (14) and an inner, circumferential bead (18) in the distal end of the ring electrode (16).

4. A medical implantable lead according to claim 1, c h a r a c t e r i z e d in that the quick fixating connection is a crimp connection.

5. A medical implantable lead according to claim 1, c h a r a c t e r i z e d in that the quick fixating connection is a thermo connection.

6. A medical implantable lead according to any of the preceding claims, c h a r a c t e r i z e d in that besides the quick fixating connection, an adhesive is used for increased bonding strength and fluid sealing.

7. A method for manufacturing of a medical implantable lead of the type adapted for monitoring and/or controlling of an organ inside a human or animal body and comprising two electrical conductors (6, 9), each connected to a respective electrode for receiving or transmitting of electrical signals from

or to the organ, and a tubular header (14) in a distal end of the lead, wherein one electrode (3) is positioned in the outermost distal end of the lead whereas the other is a ring formed electrode (16), which is mounted by means of a coupling in a proximal end of the header, comprising the steps of:

integrating the coupling (15) and the header (14) into one unitary piece of an electrical insulating material;

forming the coupling with a quick fixating connection (17, 19) in the proximal end of the header;

and forming the ring electrode (16) with a mating engagement means (18) for engagement with the quick fixating connection.

8. A method according to claim 7, comprising the further step of forming the quick fixating connection as a snap fit connection.

9. A method according to claim 7 or 8, comprising the further step of using an adhesive between the header (14) and the ring electrode (16) for achieving an increased bonding strength and fluid tight seal.

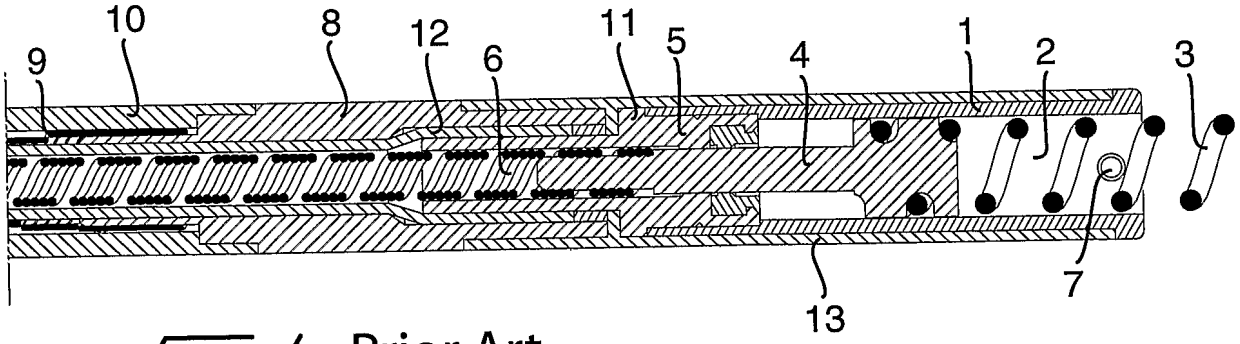

Fig 1 Prior Art

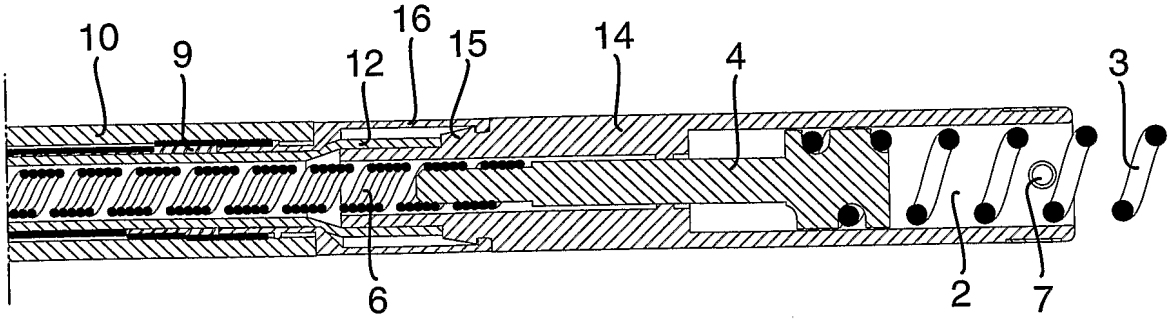

Fig 2

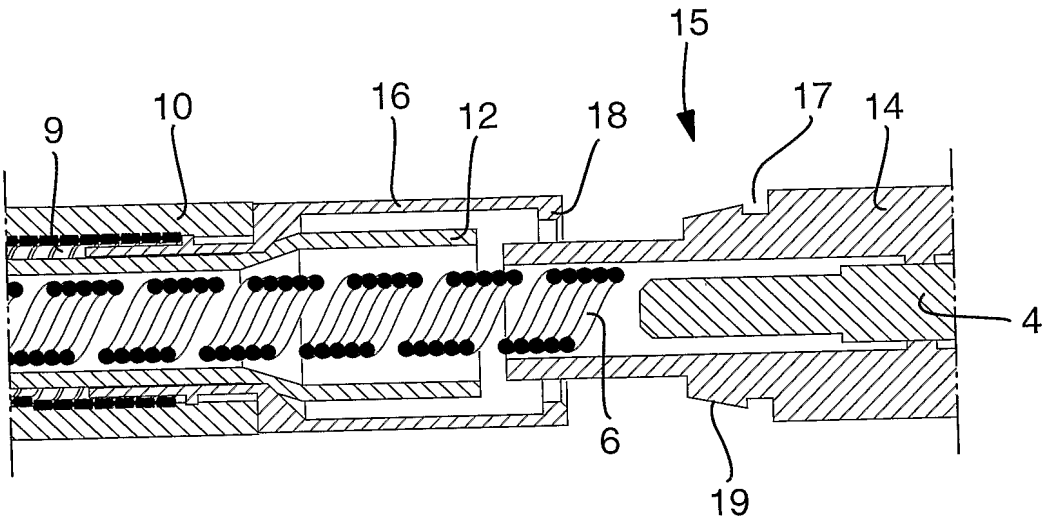

Fig 3

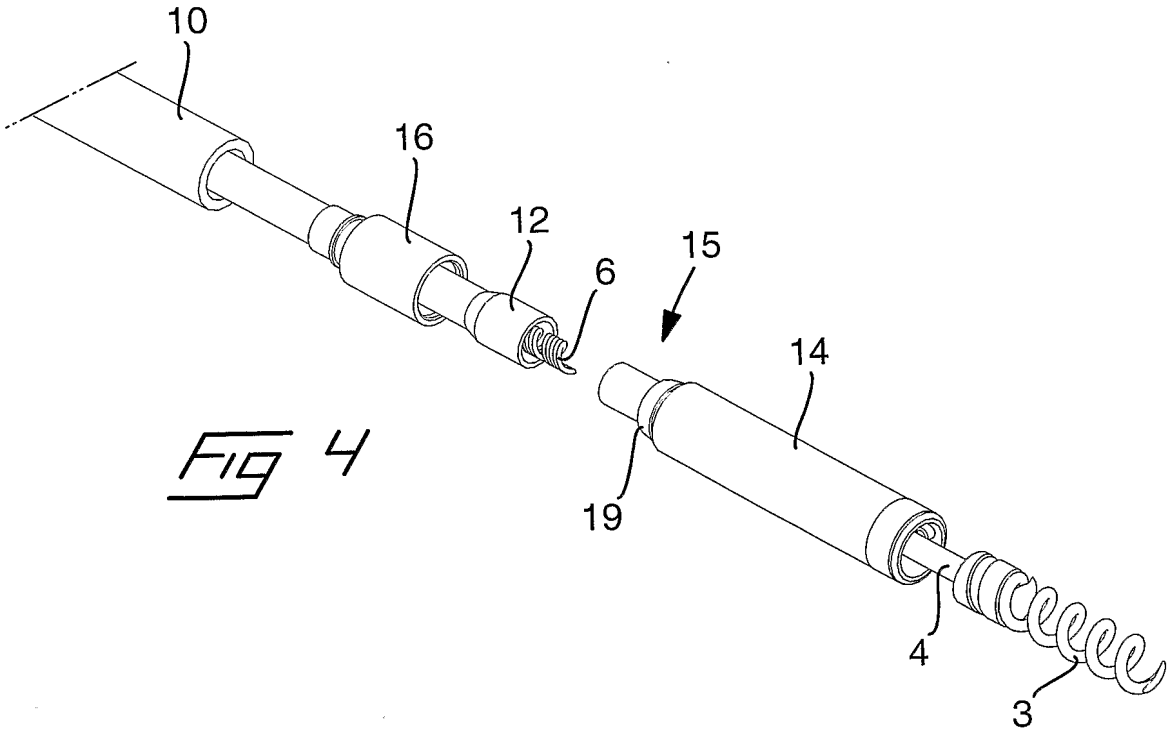

Fig 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/000634

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
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: 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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6489562 B1 (HESS, D N ET AL), 3 December 2002 (03.12.2002), column 3, line 14 - column 4, line 3, figure 2	1-9
A	US 6463334 B1 (FLYNN, D M ET AL), 8 October 2002 (08.10.2002), column 9, line 11 - column 10, line 9, figure 8	1-9
A	US 5741321 A (BRENNEN, K R), 21 April 1998 (21.04.1998), column 3, line 48 - column 4, line 23, figure 7	1-9

[X] Further documents are listed in the continuation of Box C. [X] 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
13 March 2008	20 -03- 2008
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Gordana Ninkovic /LR Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/000634

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A61N 1/05 (2006.01)

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Cited literature, if any, will be enclosed in paper form.

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