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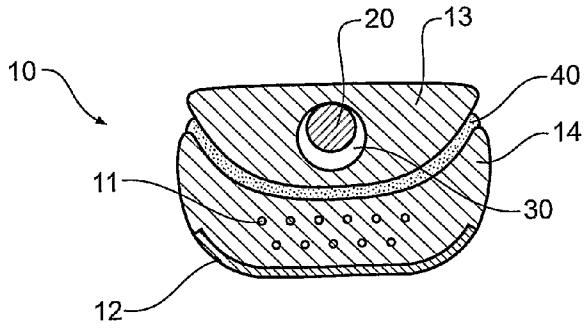


***Figure 2***

(57) **Abstract:** Disclosed is an electrode lead for a medical implant, and in one example, a cochlear implant. The electrode lead includes a lumen for receiving a stylet for assisting in implanting the device. The lumen of the electrode lead is removable from the electrode lead upon or after implantation.

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# COCHLEAR IMPLANT WITH IMPROVED LUMEN ARRANGEMENT

## TECHNICAL FIELD

The present invention relates to cochlear implants having a lumen for receiving a stylet for use during the insertion process.

## PRIORITY CLAIM

The present application claims priority from Australia Provisional Patent Application No. 2007906554 entitled "Cochlear Implant With Improved Lumen Arrangement". The entire content of this application is hereby incorporated by reference.

## INCORPORATION BY REFERENCE

The following description makes reference to:
International Patent Application No. PCT/AU99/00391 (WO 00/71063) entitled " A Cochlear Implant Electrode Array".

The entire content of this document is hereby incorporated by reference.

## BACKGROUND

A cochlear implant allows for electrical stimulating signals to be applied directly to the auditory nerve fibres of the patient, allowing the brain to perceive a hearing sensation approximating the natural hearing sensation. These stimulating signals are applied by an array of electrodes implanted into the patient's cochlea.

The electrode array is connected to a stimulator unit which generates the electrical signals for delivery to the electrode array. The stimulator unit in turn is operationally connected to a signal processing unit which also contains a microphone for receiving audio signals from the environment, and for processing these signals to generate control signals for the stimulator.

When inserting the implant into the patient's cochlea, great care must be taken to avoid damaging the delicate structure of the cochlea. Since the cochlea is a coiled structure, many cochlear implants are manufactured to have a natural curve to facilitate insertion and to fit more naturally in the cochlea once implanted.

However, while inserting a cochlear implant into the cochlea, it is necessary to straighten portions of the implant as it is being inserted, and then to allow it to naturally reassume its curled state after insertion by extracting the stylet from the lumen. To provide a means for straightening the implant, a rigid or semi-rigid spike, known as a stylet is used as a "spine" for the implant as it is being inserted. A portion of the

implant, known as a lumen, receives the stylet during the insertion process. FIGURE 1A shows a side view of a cochlear implant electrode lead 10, for supporting an array of electrode contacts (not shown) with lumen 30 and stylet 20. Stylet 20 is shown inserted into lumen 30 to straighten the natural curve of the electrode lead 10.

FIGURE 1B is a cross-sectional view of the electrode 10 in FIGURE 1 along the line A-A'. FIGURE 1B shows electrode lead 10 with lumen 30 and stylet 20 inserted in the lumen 30. FIGURE 1B also shows electrode conductive wires 11 and electrode contact 12, associated with one of the electrode conductive wires. The plurality of electrode conductive wires 11 and respective electrode contacts 12 form the electrode array supported by electrode lead 10.

A disadvantage of the prior art is that once the stylet has been removed, the lumen adds bulk to the electrode lead. Furthermore, the lumen may become a pathway for infection. In some arrangements, the lumen is sealed after insertion to prevent a free flow of fluids and cells into the cochlea. However, it is still possible to breach the lumen, since it is made from relatively thin silicone rubber.

It is accordingly an object of the present invention to reduce at least one of the problems of the prior art.

SUMMARY

According to one aspect of the present invention, there is provided an electrode lead for a medical implant, the electrode lead comprising a lumen for receiving a stylet, wherein the lumen is removable from the electrode lead.

In one form, the electrode lead further comprises a lumen portion defining the lumen and a main electrode lead portion, wherein the lumen portion is connected to the main electrode lead portion by a temporary connector.

In one form, the temporary connector is a degradable material.

In one form, the degradable material is a resorbable polymer.

In one form, the resorbable polymer is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

In one form, the electrode lead further comprises a lumen portion at least partially defining the lumen, and a main electrode lead portion, wherein the lumen portion is made from a degradable material.

In one form, the degradable material is a resorbable polymer.

In one form, the resorbable material is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

In one form, the lumen portion is also connected to the main electrode lead portion by a second temporary connector.
In one form, the second temporary connector is a resorbable polymer.

In one form, the electrode lead defines at least a portion of the lumen, and comprises a material disposed on at least a lower portion of the electrode lead defining the at least a portion of the lumen, that expands upon contact with fluid to fill the lumen.

In one form, the electrode lead has an opening above the lumen such that upon the material expanding, a stylet in the lumen is urged out of the lumen.

In one form, the medical implant is a cochlear implant.

According to another aspect of the present invention, there is provided a cochlear implant comprising a stimulator and an electrode lead supporting an array of electrode contacts, the electrode lead comprising a lumen for receiving a stylet, wherein the lumen is removable from the electrode lead.

In one form, the electrode lead further comprises a lumen portion defining the lumen and a main electrode lead portion, wherein the lumen portion is connected to the main electrode lead portion by a temporary connector.

In one form, the temporary connector is a degradable material.

In one form, the degradable material is a resorbable polymer.

In one form, the resorbable polymer is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

In one form, the electrode lead further comprises a lumen portion at least partially defining the lumen, and a main electrode lead portion, wherein the lumen portion is made from a degradable material.

In one form, the degradable material is a resorbable polymer.

In one form, the resorbable material is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

In one form, the lumen portion is also connected to the main electrode lead portion by a second temporary connector.

In one form, the second temporary connector is a resorbable polymer.

According to another aspect of the present invention, there is provided a cochlear implant comprising a stimulator and an electrode lead, the electrode lead defining at least a portion of the lumen, and comprising a material disposed on at least a lower portion of the electrode lead defining the at least a portion of the lumen, that expands upon contact with fluid to fill the lumen.

In one form, the electrode lead has an opening above the lumen such that upon the material expanding, a stylet in the lumen is urged out of the lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

The various aspects of the present invention will now be described in detail with reference to the following drawings in which:

Figure 1A shows a prior art electrode lead for a cochlear implant;
Figure 1B is a cross-sectional view of the electrode lead of Figure1A;
Figure 2 is a cross-sectional view of an electrode lead for a cochlear implant according to one embodiment of a first aspect of the present invention;
Figure 3A is a cross-sectional view of another embodiment of an electrode lead for a cochlear implant according to the first aspect of the present invention;
Figure 3B shows the arrangement of Figure 3A after separation;
Figure 4A is a cross-sectional view of an electrode lead for a cochlear implant according to another embodiment of the first aspect of the present invention;
Figure 4B is a cross-sectional side view of the electrode lead of Figure 4A;
Figure 5 is a cross-sectional view of a further embodiment of the electrode lead for a cochlear implant according to the first aspect of the invention;
Figure 6 is a perspective view of a further embodiment of the electrode lead according to the first aspect of the present invention;
Figure 7 is a side view of one embodiment of an electrode lead for a cochlear implant according to a second and third aspect of the present invention;
Figure 8 is a side view of another embodiment of an electrode lead for a cochlear implant according to the second and third aspects of the present invention;
Figure 9 is a side view of a further embodiment of an electrode lead for a cochlear implant according to the second and third aspects of the present invention;

Figure 10 is a side view of yet a further embodiment of an electrode lead for a cochlear implant according to both the first and the second aspects of the present invention combined;
Figure 11 is a side view of yet a further embodiment of an electrode lead for a cochlear implant according to both the first and the second aspects of the present invention combined;
Figure 12A is a cross-sectional view of one embodiment of an electrode lead for a cochlear implant according to a fourth aspect of the present invention;
Figure 12B shows the electrode lead of Figure 12A showing swelling of the swelling polymer; and
Figure 12C shows the electrode lead of Figures 12A and 12B showing further swelling of the swelling polymer;
Figure 12D shows the electrode lead of Figures 12A, 12B and 12C showing even further swelling;
Figure 13A shows an electrode lead according to another embodiment of the present invention;
Figure 13B shows the electrode lead of Figure 13A with the lumen removed; and
Figure 14 shows an example of a cochlear implant with an electrode lead to which one or more of the various aspects of the present invention may be applied.

DETAILED DESCRIPTION

The various aspects of the present invention will now be described in detail with reference to one or more embodiments of the invention, examples of which are illustrated in the accompanying drawings. The examples and embodiments are provided by way of explanation only and are not to be taken as limiting to the scope of the invention. Furthermore, features illustrated or described as part of one embodiment may be used with one or more other embodiments to provide a further new combination.

It will be understood that the present invention will cover these variations and embodiments as well as variations and modifications that would be understood by the person skilled in the art.

During the following description, the term "lumen" will be used to refer to the cavity formed within the electrode lead or a portion of the electrode lead for receiving an insert such as a stylet.

While the various aspects of the present invention will be described with specific reference to a cochlear implant, it will be understood that the principles of the various aspects of the present invention may be applied to other types of medical implants. For example:

ABI (Auditory Brainstem Implant, electrode for hearing, placed in the brainstem) such as Cochlear Corporation's Nucleus 24 [R] Multichannel Auditory Brainstem Implant (Multichannel ABI)

The auditory brainstem implant consists of a small electrode that is applied to the brainstem where it stimulates acoustic nerves by means of electrical signals. The stimulating electrical signals are provided by a signal processor processing input sounds from a microphone located externally to the user. This allows the user to hear a certain degree of sound.

FES (Functional Electrical Stimulation)

FES is a technique that uses electrical currents to activate muscles and/or nerves, restoring function in people with paralysis-related disabilities.

Injuries to the spinal cord interfere with electrical signals between the brain and the muscles, which can result in paralysis.

SCS (Spinal Cord Stimulator).

This system delivers pulses of electrical energy via an electrode in the spinal area and may be used for pain management. An example of a commercially available system is the RESTOREPRIME system by Medtronic, Inc, USA.

Figure 2 shows a cross-sectional view of an electrode lead 10 according to one embodiment of the present invention. Shown is the electrode lead 10 provided as two separate parts – a lumen portion 13 and a main electrode lead portion 14. Lumen portion 13 defines the lumen 30, for receiving stylet 20, while main electrode lead portion 14 contains the plurality of electrode contacts 12 and respective conductive pathways or electrode conductive wires 11, which convey stimulation signals to respective electrode contacts 12 for stimulation of the patient's or recipient's tissue.

Connecting lumen portion 13 to main electrode lead portion 14 is a temporary connector 40. Temporary connector 40 may be a polymer, and in one example, a resorbable polymer, such as Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA), (or any combination thereof) which, after a preset time lapse, or upon contact with fluid, begins to soften or dissolve, allowing lumen portion 13 to be separated from main electrode lead portion 14. After implantation of the implant into the patient's cochlea, the surgeon can pull out both the stylet 20 and the lumen portion 13, leaving only the main electrode lead portion 14 in the cochlea. The result is an implant of reduced bulk, and no easy path for passage of fluid to cause infection.

Figure 3A shows a variation of the electrode lead 10 of Figure 2. Specifically, electrode lead 10 is still made up of the lumen portion 13 and the main electrode lead portion 14 with wires 11 and electrode contact 12, however, instead of only a single temporary connector 40, there is now a second temporary connector 50.

In this embodiment, temporary connector 40 may be a similar material to that used in the examples given with reference to Figure 2, such that it will soften or dissolve after a preset time period and/or contact with fluid. This will be designed to allow relatively fast separation of lumen portion 13 from main electrode lead portion 14 to allow removal of lumen portion 13 as previously described.

Figure 3B shows the lumen portion 13 with lumen 30 separated from main electrode lead portion 14 with both temporary and second temporary connectors dissolved.

Second temporary connector 50 may be of a different material such as a resorbable polymer – for example Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA). This material is designed to dissolve more slowly than temporary connector 40, and may slowly release drugs such as antibiotics or neurotrophins into the cochlea to facilitate the healing and recovery process and reduce the likelihood of infection.

In a further embodiment of this aspect of the invention, the lumen portion 13 defining lumen 30 may be made entirely of the dissolving material as previously mentioned. Figure 4A shows electrode lead 10 made up of lumen portion13 defining lumen 30, and main electrode lead portion 14 containing wires 11 and electrode contact 12. In this embodiment, lumen portion 13 is made substantially of the dissolving material and is disposed on top of main electrode lead portion 14. Stylet 20 will in use, be received in lumen 30 during or prior to the implant procedure, and after a preset amount of time or contact with fluid, the entire lumen portion 13 will begin to dissolve, leaving stylet 20 completely separated from main electrode lead portion 14, and able to be pulled out of the cochlea by the surgeon. Alternatively, the surgeon may remove the stylet during insertion, leaving the lumen portion 13 to dissolve over time. In this embodiment, the lumen portion 13 may also release drugs while dissolving.

Figure 4B shows a side view of an electrode lead 10 according to this embodiment as shown in Figure 4A. In this view, stylet 20 is not shown. Shown is main electrode lead portion 14 supporting electrode contacts 12 and 12' with respective electrode wires or conductors 11, 11'. Lumen portion 13 is shown, connected to main electrode portion 14, and defines lumen 30. After insertion, lumen portion 13 slowly dissolves, removing lumen 30 and leaving behind main electrode lead portion 14 with associated electrode array.

In yet a further embodiment as shown in Figure 5, main electrode lead portion 14 may be shaped to provide a channel in which at least a part of lumen portion 13 may be disposed. As in the embodiment described above in relation to Figures 4A and 4B, lumen portion 13 is made up entirely of the dissolving material, which upon dissolving releases stylet 20 (not shown) from main electrode lead portion 14 allowing it to be removed. This particular design provides for an even less bulky main electrode lead portion that is left in the patient's cochlea.

Figure 6 shows a similar design as that shown in Figure 5; however, main electrode lead portion 14 defines a lower half of electrode lead 10, while lumen portion 13 defines the upper half of electrode lead 10. In this embodiment, lumen 30 is defined by both portions, and upon dissolving of the lumen portion 13 material, stylet 20 is freed to be removed by the surgeon.

According to second and third aspects of the present invention, there is shown an embodiment of electrode lead 10 in which no stylet 20 and therefore no lumen 30 is required at all.

Figure 7 shows electrode lead 10 having electrode contacts 12, 12' and 12'' with a layer of swelling material 60 which upon contact with fluid such as saline or water, or by some other trigger such as humidity, begins to swell. This causes a positive pressure on the surface of electrode lead 10, causing it to bend or curl. This allows the electrode lead 10 to be manufactured without an inherent curl, providing a much more simplified manufacturing and handling process, and removes the need for a lumen and stylet.

The function of this aspect of the invention may be enhanced by designing electrode lead 10 to have one or more grooves 15 which are filled with the swelling material 60. This further enhances the curling action of electrode 10 as material 60 swells.

Examples of suitable materials for swelling material 60 include any type of suitable water-expanding material. One example is Silastic A ™ silicone polymer, mixed for example with a finely-ground NaCl as will be known to the person skilled in the art. The curling effect can be even further enhanced by proving a layer of dissolvable material 70 on the side opposite the swelling material. Dissolving material 70 provides a counter force to swelling material 60 when it is present; however this counter force disappears once material 70 has dissolved. This allows more precise design of curling parameters.

Figure 8 shows a further alternative of the embodiment shown in Figure 7, in which electrode lead 10 also has slits or grooves 16 on the side opposite to slits or grooves 15, and filled with the dissolving material 70. Having material 70 in slits or grooves 16 provides a greater counter curling force to the curling force provided by swelling material 60; however, the presence of slits or grooves 16 when devoid of dissolving material 70 facilitates the curling caused by swelling material 60. Examples of suitable dissolving materials include those previously mentioned.

Figure 9 shows electrode lead 10 in its curled position as slits or grooves 15 are made larger by swelling material 60, while slits or grooves 16 are made smaller by the disappearance of dissolving material 70 (not shown in this view).

The degree of curling of electrode 10 can also be controlled by controlling the shape and volume of slits or grooves 15 and 16 during the manufacturing process for example. These may be balanced by the strength or resilience of the electrode 10.

In these embodiments, the dissolving layers of material 70 may also contain antibiotics, neurotrophins or other drug compounds.

It will of course be understood that any other combination of the layers, materials and slits or grooves may be used and will not be limited to only those illustrated.

While the embodiments described with reference to Figures 7 to 9 may not require a lumen and stylet, it will be appreciated that such can be provided if required. Figure 10 shows a side cross-sectional view of an electrode lead 10 supporting electrode contacts 12 having slits or grooves 15 and dissolving material 70 in which stylet 20 may be embedded. Upon material 70 dissolving, stylet 20 is released to be removed from the cochlea, while also "emptying" slits or grooves 15 to allow them to "open" or expand, thereby causing electrode 10 to curl. In this embodiment, the dissolving material 70 may act to "pull together" the slits or grooves 15, and upon dissolving, release them to promote curving.

In another embodiment, the portion of lumen portion 13 above the lumen 30 as seen in Figures 10 and 11 may be made from a dissolving material while a lower portion (below lumen 30) may be made from a swelling material. Upon contact with fluid after insertion, the top portion dissolves, removing lumen 30, while the lower portion swells, to provide even greater curving forces as described above with reference to Figures 7-9.

Figure 11 shows a similar embodiment to that of Figure 10, except that dissolving material 70 is provided in discrete portions, retaining stylet 20 only at discrete points for release upon dissolving.

According to a fourth aspect of the present invention, electrode lead 10 may be shaped to define a partial lumen 30 or at least a portion of the lumen 30, to retain stylet 20 in place, and a swelling material may then be used to eject stylet 20 from electrode lead 10 as required after insertion. Figure 12A shows electrode lead 10 shaped so as to provide a recess (which could be referred to as a partial lumen 30) for retaining stylet 20. Electrode lead 10 also supports wires 11 and electrode contacts 12.

Once electrode lead 10 is inside the cochlea of the patient, a swelling material 80 coating a lower portion of partial lumen 30 begins to swell as shown in Figure 12B. This results in stylet 20 being urged out of partial lumen 30. Figure 12C shows the swelling material 80 even more swollen, further expelling stylet 20 from partial lumen 30, and able to be removed by the surgeon. Figure 12D shows the electrode lead 10 after the swelling material 80 has swelled to the extent that it entirely, or almost entirely, fills the cavity that was once lumen 30, thereby effectively removing lumen 30 from electrode lead 10. This embodiment will reduce the likelihood of fluids entering a cavity within electrode lead 10 that may subsequently promote infection.

In a further variation of this embodiment, as shown in Figure 13A, the electrode lead 10 can define the entire lumen 30, which has disposed therein, a material 80 that swells upon contact with fluid. In this

arrangement, the stylet may be removed manually by the surgeon during or after the implantation, to leave lumen 30, which then is effectively removed, as material 80 begins to swell.

Figure 13B shows electrode lead 10 without lumen 30, as material 80 has swelled to fill the cavity. Again, this embodiment will reduce the likelihood of fluids entering a cavity within electrode lead 10 that may subsequently promote infection.
Figure 14 shows a cochlear implant 100 having stimulator 90 and electrode lead 10. Electrode lead 10 could have any one or more of the features described above.

The various forms of electrode lead 10 described above may be made in any manner known as would be apparent to the person skilled in the art. For example, in manufacturing the electrode lead 10 shown in Figure 2, the following method may be used.

In order to form the electrode array, the electrode contacts 12, 12', 12'' are placed in a U-shaped holding die. In this case, the electrode contacts 12, 12', 12'' may be welded or otherwise electrically connected to their respective electrode wires or conductors 11, 11', 11" in sequential order, starting from the most proximal electrode contact. Once all of the wires 11, 11', 11" have been connected to their respective electrode contacts 12, 12', 12", a droplet of adhesive 41, such as adhesive silicone, is placed in the trough of each electrode contact in order to secure the wires in place.

A production stylet (for example, a PTFE coated wire) is suspended or otherwise placed over the electrode array before filling each trough with more silicone. The production stylet is used to hold the electrode contacts in spaced relationship to each other and provide further support to the electrode array, and is later removed to form a lumen in the lead. The holding die is then placed in an oven to cure the silicone.

The formed electrode lead in one form, could then be split into two portions – the main lead portion 14 and the lumen portion 13, and then reconnected by applying an amount of material 40 between them and allowing this to set.

In an alternative method, prior to the step of introducing the production stylet, silicone may be poured into the trough to a level just above the electrode contacts and wires, allowed to cure, and then applying a layer of material 40 over the partially-constructed electrode lead. This partially-constructed electrode lead may then have the remainder of the silicone applied over the layer of material 40 using a production stylet to form the lumen, to form the 2-part electrode lead as shown in Figure 2, with material 40 therebetween.

In a further alternative method, the two parts 14 and 13 may be formed separately and then combined using material 40 as described above.

In forming the arrangement shown in Figure 4A, the main lead portion 14 could be formed by conventional means, and then lumen portion 13 could be either formed separately and adhered to portion 14, or by pouring and allowing to set on top of portion 14, material 40, using a production stylet to form the lumen.

In forming the electrode lead as shown in Figure 12A, the silicone could be poured up to about half way up to the top of the production stylet. The production stylet could then be removed, and an amount of material 80 could be placed in the semi-lumen thus created, and then cured. The production stylet could then be reintroduced and the silicone continued to be poured to cover the production stylet to form the full lumen, and then processed as described above.

Once formed, the electrode lead 10 may then be removed from the U-shaped holding die and placed in a curved moulding die, if a curved electrode lead is desired, as will be known to the person skilled in the art. These methods may also be combined with appropriate parts or appropriately modified parts of methods as described in International Patent Application No. PCT/AU99/00391 (WO 00/71063) to the present applicant, previously incorporated by reference.

It will be understood that the above has been described with reference to particular embodiments and that many variations and modifications may be made within the scopes of the different aspects of the present invention.

Throughout the specification and the claims that follow, unless the context requires otherwise, the words "comprise" and "include" and variations such as "comprising" and "including" will be understood to imply the inclusion of a stated integer or group of integers, but not the exclusion of any other integer or group of integers.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement of any form of suggestion that such prior art forms part of the common general knowledge.

CLAIMS:

1. An electrode lead for a medical implant, the electrode lead comprising a lumen for receiving a stylet, wherein the lumen is removable from the electrode lead.

2. An electrode lead as claimed in claim 1, the electrode lead further comprising a lumen portion defining the lumen and a main electrode lead portion, wherein the lumen portion is connected to the main electrode lead portion by a temporary connector.

3. An electrode lead as claimed in claim 2 wherein the temporary connector is a degradable material.

4. An electrode lead as claimed in claim 3 wherein the degradable material is a resorbable polymer.

5. An electrode lead as claimed in claim 4 wherein the resorbable polymer is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

6. An electrode lead as claimed in claim 1, the electrode lead further comprising a lumen portion at least partially defining the lumen, and a main electrode lead portion, wherein the lumen portion is made from a degradable material.

7. An electrode lead as claimed in claim 6 wherein the degradable material is a resorbable polymer.

8. An electrode lead as claimed in claim 7 wherein the resorbable material is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

9. An electrode lead as claimed in claim 2 wherein the lumen portion is also connected to the main electrode lead portion by a second temporary connector.

10. An electrode lead as claimed in claim 9 wherein the second temporary connector is a resorbable polymer.

11. An electrode lead as claimed in claim 1, the electrode lead defining at least a portion of the lumen, and comprising a material disposed on at least a lower portion of the electrode lead defining the at least a portion of the lumen, that expands upon contact with fluid to fill the lumen.

12. An electrode lead as claimed in claim 12 wherein the electrode lead has an opening above the lumen such that upon the material expanding, a stylet in the lumen is urged out of the lumen.

13. An electrode lead as claimed in claim 1 wherein the medical implant is a cochlear implant.

14. A cochlear implant comprising a stimulator and an electrode lead supporting an array of electrode contacts, the electrode lead comprising a lumen for receiving a stylet, wherein the lumen is removable from the electrode lead.

15. A cochlear implant as claimed in claim 14, the electrode lead further comprising a lumen portion defining the lumen and a main electrode lead portion, wherein the lumen portion is connected to the main electrode lead portion by a temporary connector.

16. A cochlear implant as claimed in claim 15, wherein the temporary connector is a degradable material.

17. A cochlear implant as claimed in claim 16 wherein the degradable material is a resorbable polymer.

18. A cochlear implant as claimed in claim 17 wherein the resorbable polymer is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

19. A cochlear implant as claimed in claim 14, the electrode lead further comprising a lumen portion at least partially defining the lumen, and a main electrode lead portion, wherein the lumen portion is made from a degradable material.

20. A cochlear implant as claimed in claim 19 wherein the degradable material is a resorbable polymer.

21. A cochlear implant as claimed in claim 20 wherein the resorbable material is any one or more of Polyacrylic acid (PAA), Polyvinyl alcohol (PVA), Polyactic acid (PLA) or Polyglycolic acid (PGA).

22. A cochlear implant as claimed in claim 15 wherein the lumen portion is also connected to the main electrode lead portion by a second temporary connector.

23. A cochlear implant as claimed in claim 22 wherein the second temporary connector is a resorbable polymer.

24. A cochlear implant comprising a stimulator and an electrode lead, the electrode lead defining at least a portion of the lumen, and comprising a material disposed on at least a lower portion of the

electrode lead defining the at least a portion of the lumen, that expands upon contact with fluid to fill the lumen.

25. A cochlear implant as claimed in claim 24, wherein the electrode lead has an opening above the lumen such that upon the material expanding, a stylet in the lumen is urged out of the lumen.

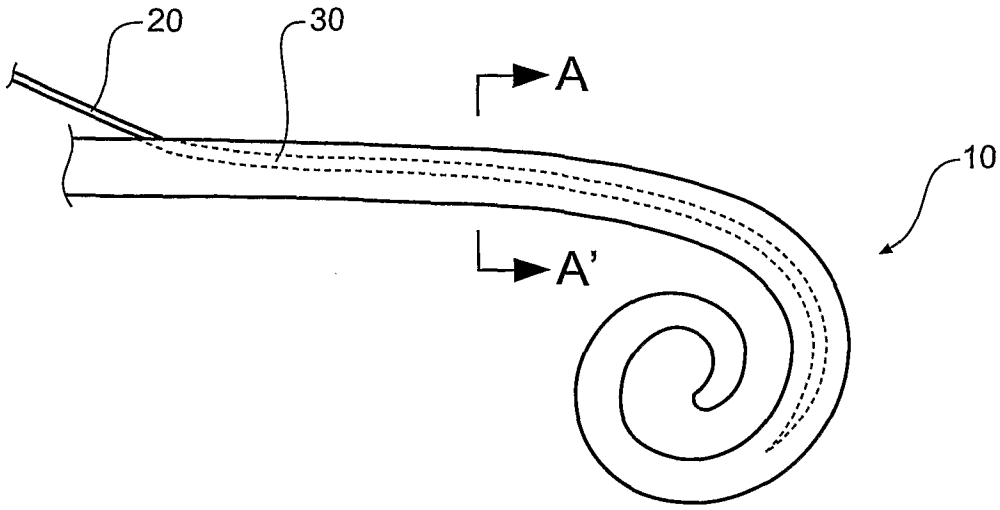


***Figure 1A***

Prior Art

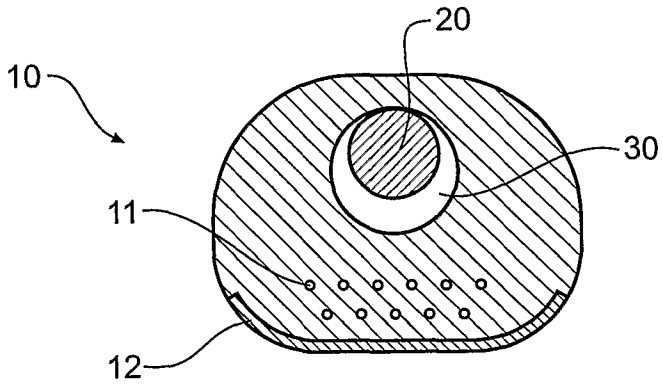


***Figure 1B***

Prior Art

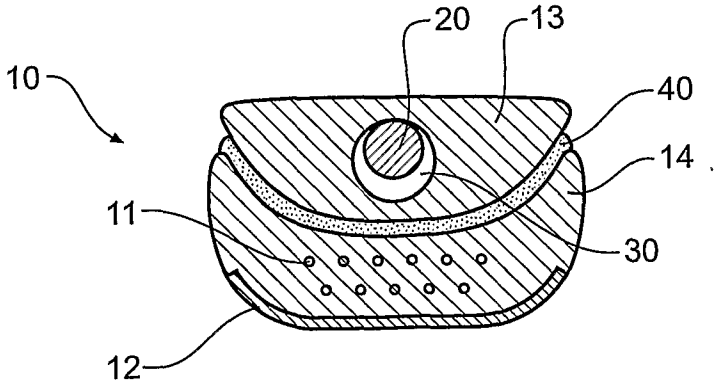


***Figure 2***

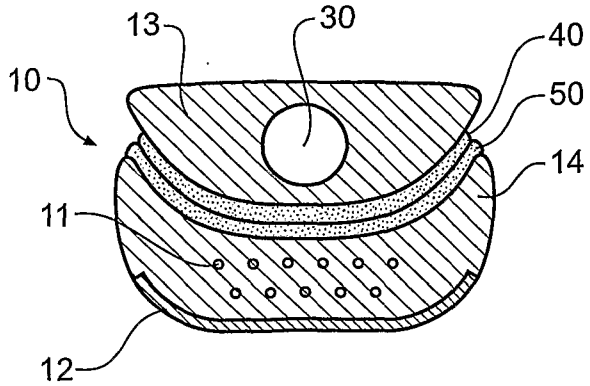


Figure 3A

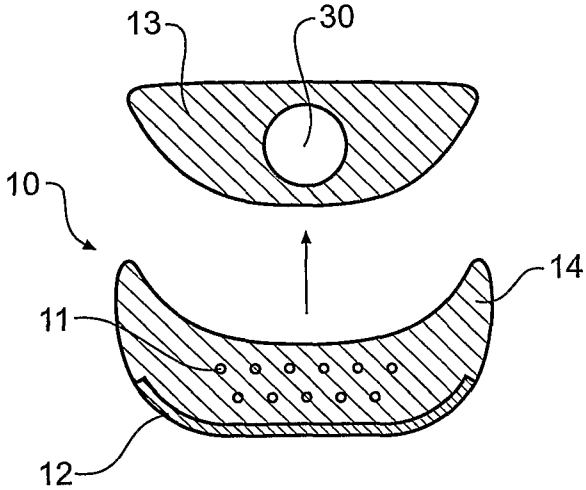


Figure 3B

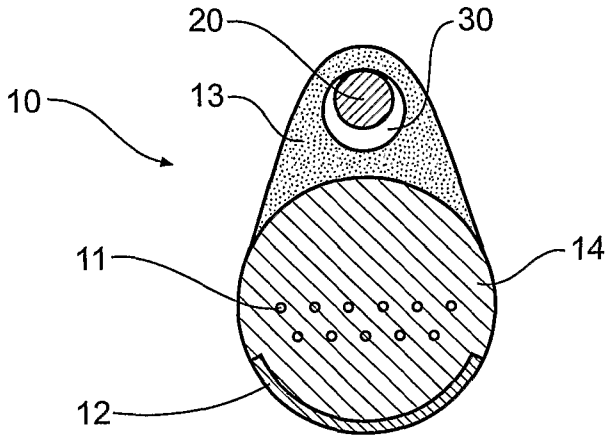


Figure 4A

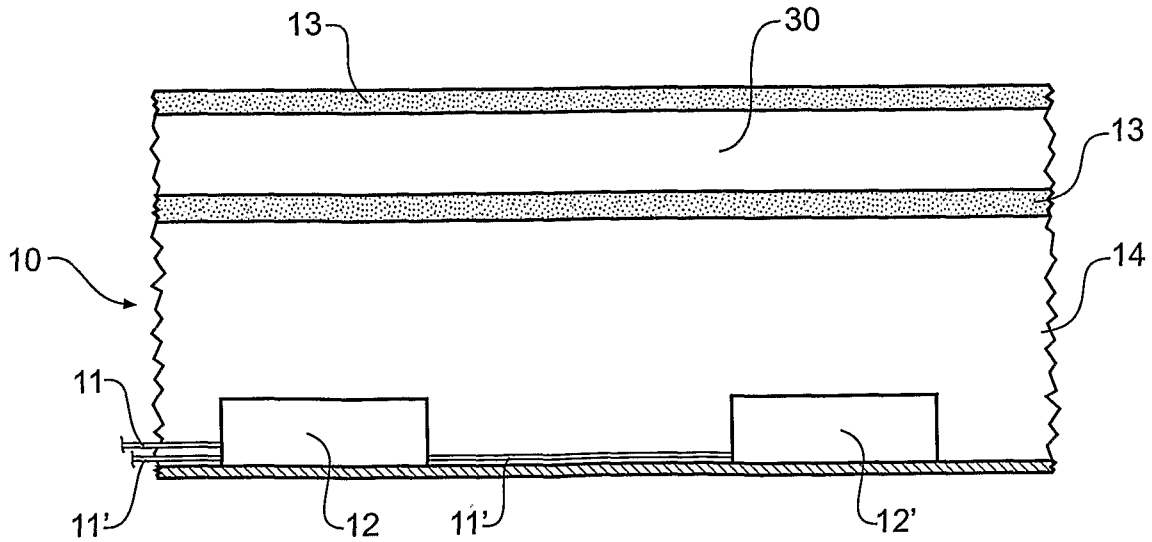


Figure 4B

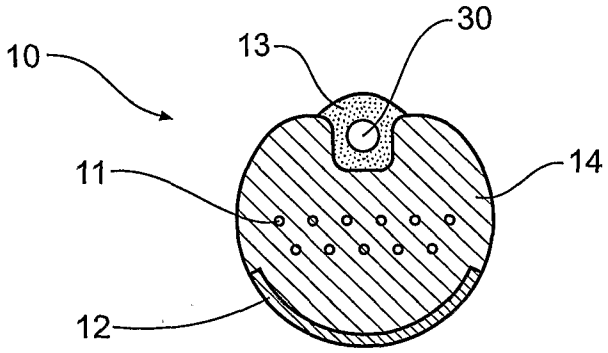


*Figure 5*

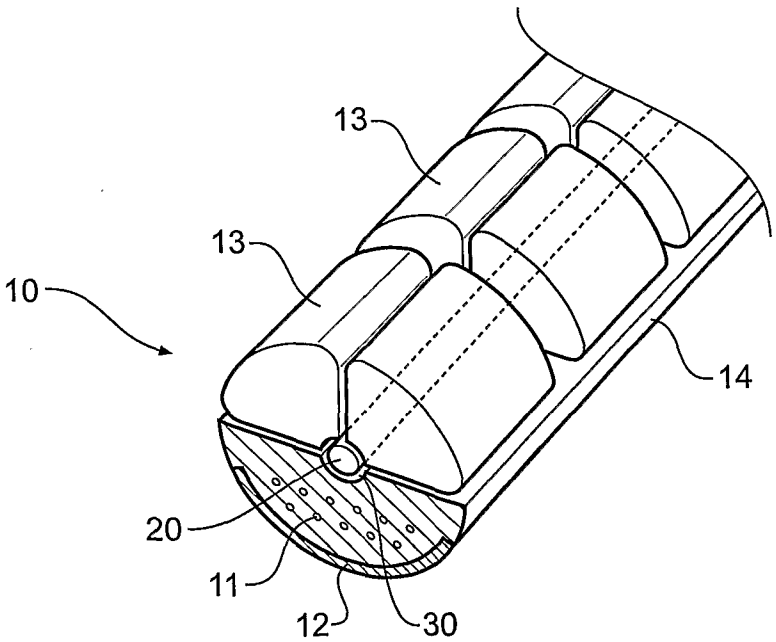


*Figure 6*

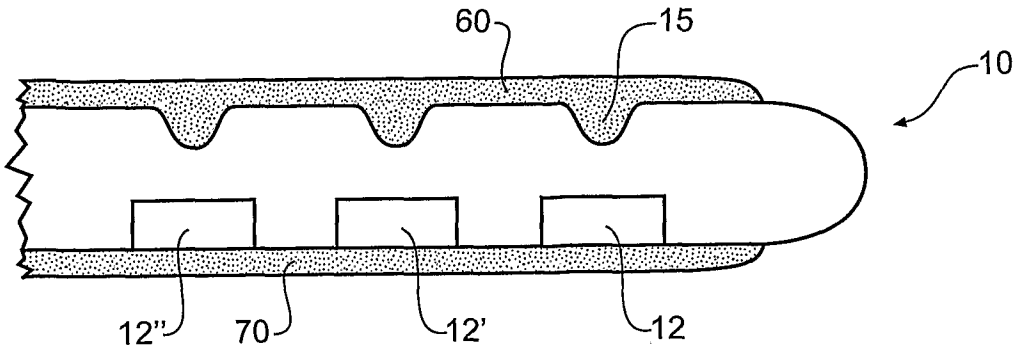


*Figure 7*

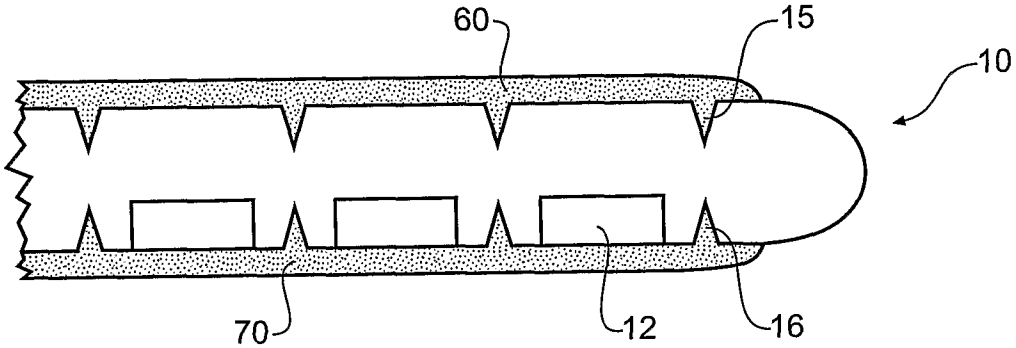


*Figure 8*

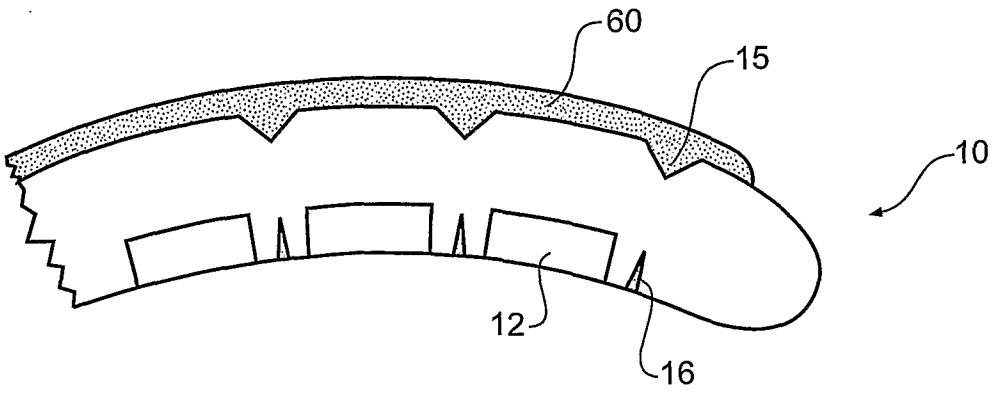


*Figure 9*

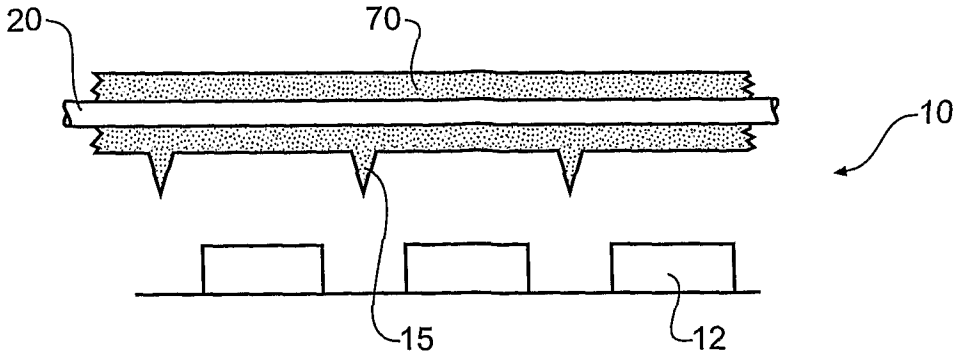


Figure 10

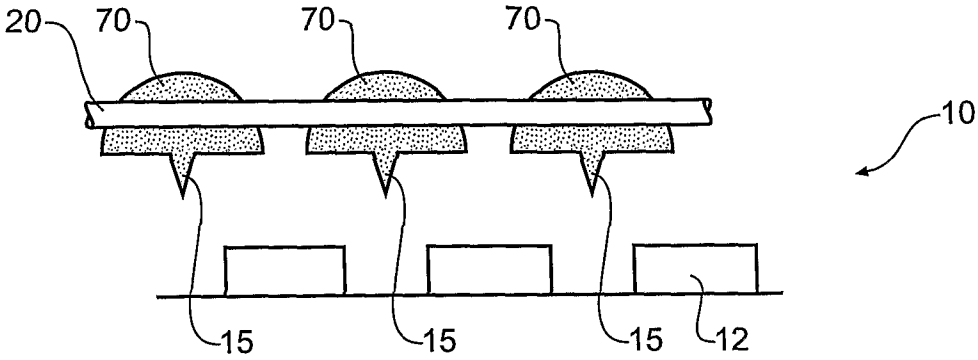


Figure 11

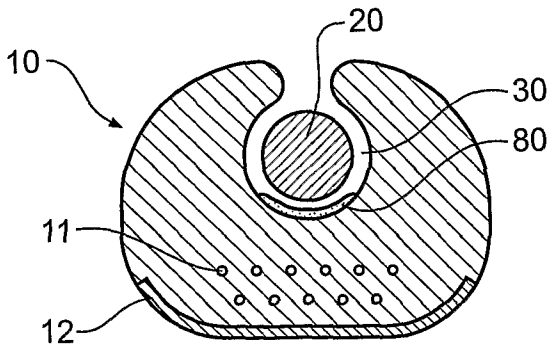


Figure 12A

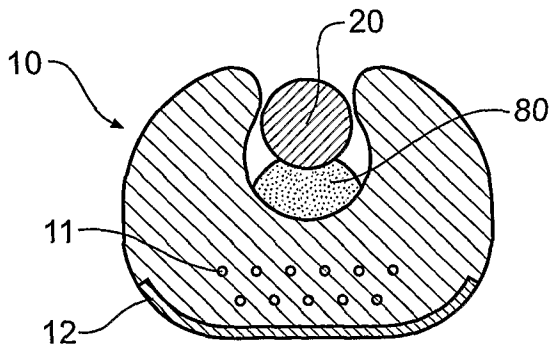


Figure 12B

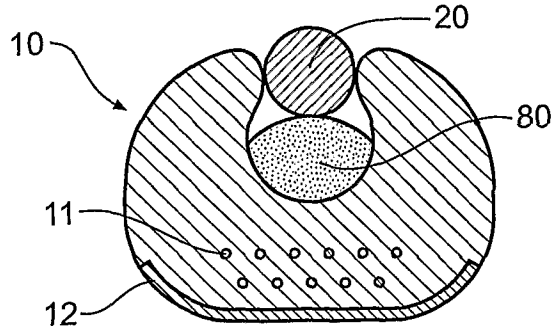


Figure 12C

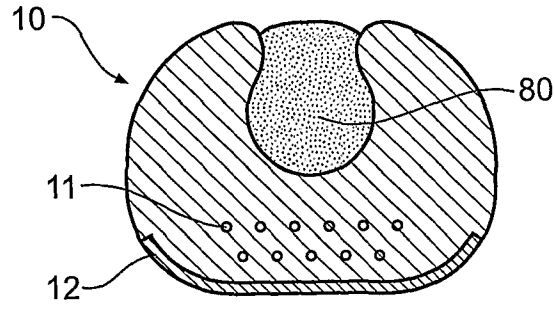


Figure 12D

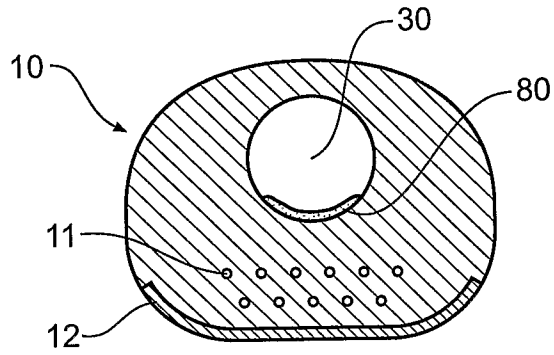


Figure 13A

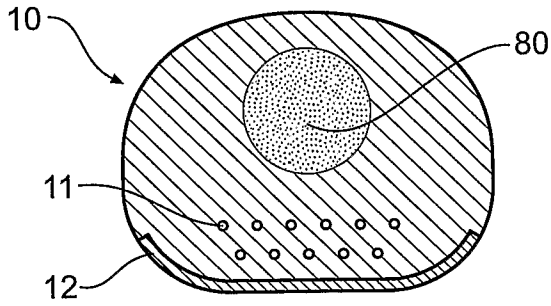


Figure 13B

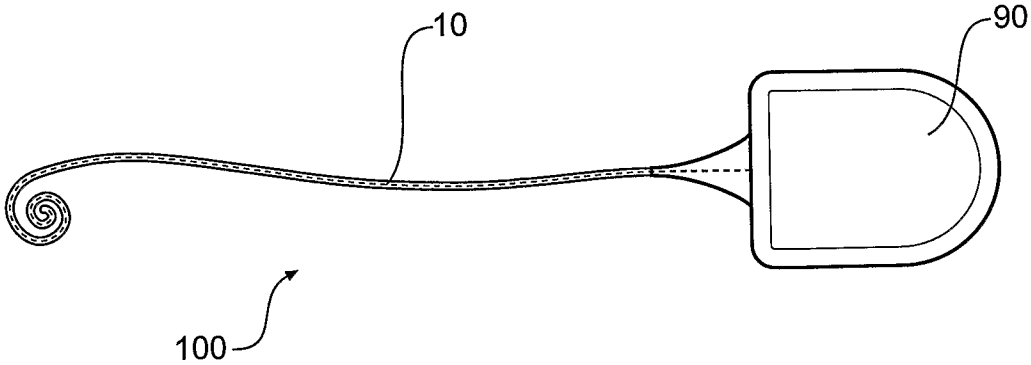


Figure 14

**INTERNATIONAL SEARCH REPORT**

International application No.
**PCT/AU2008/001776**

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

*A61F 11/04* (2006.01) *A61N 1/05* (2006.01)

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)

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)
EPOQUE: IPC & ECLA: A61F 11/-, A61N 1/- and Keywords: Cochlear, Ear, Electrode-lead, Lumen, Pipe, Tube, Catheter, Cannula, Stylet, Wire, Probe, Removable, Detachable, Replaceable and like terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 7050858 B1 (KUZMA et al.) 23 May 2006<br>See Abstract, Col.2 – Lines 1-4, Col.2 – Lines 5-16, Col.4 – Lines 5-18 | 1-8, 13-21 |
| X | US 2007/0127745 A1 (GIBSON et al.) 07 June 2007<br>See Abstract, Para [0020] & [0030] | 1-8, 13-21 |
| X | US 5769858 A (PEARSON et al.) 23 June 1998<br>See Abstract, Col.5 – Lines 13-20, Col.10 – Lines 34-39 | 1-8 |
| X | WO 2000/064529 A1 (ADVANCED BIONICS CORPORATION) 02 November 2000<br>See Abstract, Page 6 – Lines 25-34, Page 2 – Lines 22-28, Page 15 – Lines 8-22 | 1-23 |

☐ Further documents are listed in the continuation of Box C ☒ See patent family 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 application or patent 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
11 February 2009

Date of mailing of the international search report 19 FEB 2009

Name and mailing address of the ISA/AU

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2008/001776

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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.:
because they relate to subject matter not required to be searched by this Authority, namely:

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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:
This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

**Continued to Supplemental Box - I**

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 additional fees, this Authority did not invite payment of additional fees.
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.: 1-23

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

**Supplemental Box I**
(To be used when the space in any of Boxes I to IV is not sufficient)

**Continuation of Box No: III**

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-23 are directed to an electrode lead for a medical implant, the electrode lead comprises a lumen for receiving a stylet. It is considered that the lumen is removable from the electrode lead, comprises a first distinguishing feature.

- Claims 24-25 are directed to a cochlear implant comprises a stimulator and an electrode lead, which defines at least a portion of the lumen and consists a material disposed on a lower portion of the electrode lead. It is considered that a portion of the lumen which expands upon contact with fluid to fill the lumen comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.
**PCT/AU2008/001776**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | | | |
|---|---|---|---|---|---|---|---|
| US | 7050858 | NONE | | | | | |
| US | 2007/0127745 | NONE | | | | | |
| US | 5769858 | NONE | | | | | |
| WO | 2000/064529 | AU | 43168/99 | AU | 46550/00 | AU | 47129/00 |
| | | AU | 48460/00 | AU | 64049/99 | AU | 79720/98 |
| | | AU | 92074/98 | BG | 104068 | BR | 9810555 |
| | | CA | 2296012 | CA | 2302667 | CA | 2324978 |
| | | CA | 2362478 | CA | 2367195 | CA | 2370860 |
| | | CA | 2371125 | CN | 1270589 | CZ | 20000058 |
| | | EE | 200000013 | EP | 1009475 | EP | 1019389 |
| | | EP | 1082466 | EP | 1159027 | EP | 1173250 |
| | | EP | 1185331 | EP | 1185332 | EP | 1493738 |
| | | EP | 1526133 | EP | 1531153 | HK | 1026905 |
| | | HU | 0103111 | ID | 23771 | IL | 133613 |
| | | JP | 2007291121 | LT | 99153 | LV | 12569 |
| | | NO | 20000076 | NZ | 501198 | PL | 338003 |
| | | SK | 181799 | US | 6038484 | US | 6045993 |
| | | US | 6070105 | US | 6078841 | US | 6119044 |
| | | US | 6125302 | US | 6129753 | US | 6144883 |
| | | US | 6149657 | US | 6163729 | US | 6195586 |
| | | US | 6228577 | US | 6259951 | US | 6266568 |
| | | US | 6304787 | US | 6309410 | US | 6321125 |
| | | US | 6397110 | US | 6503704 | US | 6604283 |
| | | US | 6605599 | US | 6754537 | US | 6862805 |
| | | US | 6889094 | US | 6968238 | US | 7125899 |
| | | US | 7241755 | US | 2003/220295 | US | 2004/230254 |
| | | US | 2006/287371 | US | 2007/255055 | WO | 2000/047272 |
| | | WO | 2000/069512 | WO | 2000/069513 | WO | 1999/002514 |
| | | WO | 1999/011321 | WO | 1999/063118 | ZA | 9805938 |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX