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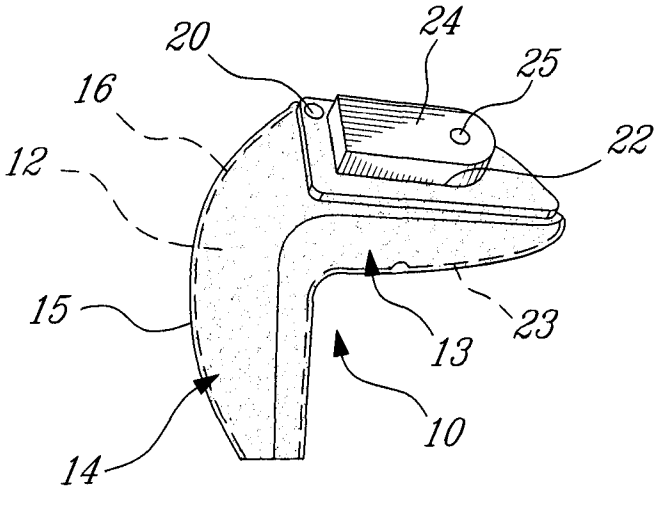
(54) Title: METHOD FOR CUSTOMIZING AN IN-EAR DEVICE



(57) Abstract: A method for customizing an in ear device to an individual's ear, comprising providing an in ear device (10) having an expandable region (16). A settable compound (26) is injected into the expandable region (16) of the in ear device (10). The in ear device (10) with the settable compound (26) in a non-set state is inserted into a desired position in the ear of the individual such that the in-ear device (10) conforms to the shape of the ear. The in ear device (10) is removed from the ear only once the settable compound (26) has substantially solidified.

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METHOD FOR CUSTOMIZING AN IN-EAR DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

The present patent application claims priority on United States Provisional Patent Application No. 60/869,414, filed on December 11, 2006.

BACKGROUND OF THE APPLICATION

1. Field of the Application

The present application relates to in-ear devices such as hearing-aid devices, sound-filter earplugs and the like, and more particularly to a method for customizing an in-ear device.

2. Background Art

In-ear devices of many different types are found in various applications. Essentially, in-ear devices (also known as in-the-ear interfaces) are received in the ear canal so as to block or transmit selected sound/noise, for instance with selected acoustic equipment/electronics, such as microphones, receivers, speakers, micro-controllers and associated components. For instance, in-ear interfaces are part of hearing-aid devices, earplugs, headsets, audio transmitters, amongst other devices. With the high demand for in-ear interfaces, customized in-ear interfaces (i.e., custom-shaped to an ear canal) have been developed to specifically suit consumers.

A few design factors are to be considered in designing and fabricating customized in-ear interfaces. The in-ear interface must generally match a portion of the geometry of the ear canal, so as to be efficient in transmitting/blocking sound, as well as be comfortable to wear. Also, the time and costs involved in producing

customized in-ear interfaces is also an important design factor.

U.S. Patent No. 6,754,357, issued on June 22, 2004 to McIntosh et al., describes an expandable in-ear device that involves a settable compound. The in-ear device of U.S. Patent No. 6,754,357 is inserted into an individual's ear canal and cavum concha. A settable compound is subsequently injected into an expandable portion of the in-ear device, in such a way that the in-ear device assumes the shape of the ear canal and cavum concha, thereby forming a customized fit.

One of the issues associated with the in-ear device of U.S. Patent No. 6,754,357 is that the method involves the injection of settable compound when the in-ear device is in the individual's ear. Accordingly, this method of customization involves precise manipulations and skilled personnel.

SUMMARY OF THE APPLICATION

It is an aim of the present application to provide a novel method for customizing an in-ear device.

Therefore, in accordance with the present application, there is provided a method for customizing an in-ear device to an individual's ear, comprising: providing an in-ear device having an expandable region; injecting a settable compound into the expandable region of the in-ear device; inserting the in-ear device with the settable compound in a non-set state into a desired position in the ear of the individual such that the in-ear device conforms to the shape of the ear; and removing the in-ear device from the ear only once the settable compound has substantially solidified.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an in-ear device as used in a method in accordance with an embodiment of the present application, prior to an injection of a settable compound;

Fig. 2 is a perspective view of the in-ear device of Fig. 1, during the injection of the settable compound therein;

Fig. 3 is a perspective view of the in-ear device of Fig. 1, as inserted in the ear of an individual; and

Fig. 4 is a flow chart illustrating a method for customizing an in-ear device in accordance with an embodiment of the present application.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figs. 1 to 3, there is shown an expandable in-ear device 10 according to a preferred embodiment. The device 10 illustrated is adapted for being customizable in situ to the shape of the ear canal C and cavum concha V of an individual. It is, however, pointed out that the method of the present application may be applied to devices that are customizable to the shape of the ear canal C or of the cavum concha V. For simplicity purposes, the following description will refer to the device 10 being customized to both the ear canal C and the cavum concha V, even though other embodiments are considered.

The device 10 includes a core-form 12 having a platform portion 13 and a nipple portion 14 integral to and extending from the platform portion 13. The platform portion 13 is accommodated in the cavum concha V of the individual, and is an interface for plugs, sound filters, electronic equipment or the like. The nipple portion 14 engages the canal C of the individual.

A stretchable or deformable sheath 15 covers a portion of the core-form 12 and substantially assumes its shape in a generally overlying relationship relative, so as to define an in-between region or spacing 16 therebetween.

The platform portion 13 is adapted for allowing a settable compound material to be injected therethrough, to reach and fill the in-between region 16 and stretch or deform the sheath 15 away from the core-form 12 to generally assume and occlude the ear canal C and the cavum concha V when the device 10 is engaged in the ear.

The core-form 12 has various configurations as a function of its contemplated use. In a preferred embodiment, a first sound bore 20 extends generally from an end of the nipple portion 14 to an exposed surface of the platform portion 13 through the body of the core-form 12, for conducting sound from an environment outside the ear canal C to inside of the ear canal C. A second sound bore 21 extends from the end of the nipple portion 14 to a cavity 22 of the platform portion 13. It is pointed out that the sound bores 20 and 21 are optional in the in-ear device 10. The in-ear device 10 may be provided with only one of these sound bores, or without any of these sound bores.

The cavity 22 is provided to accommodate the equipment that is optionally used with the device 10. For instance, the device 10 may be used with plugs, noise filters, amplification equipment, emitters and like electronics. In the illustrated embodiment, a generic insert 24 is accommodated in the cavity 22 of the core-form 12.

To inject the settable compound material inside the in-between region 16 of the device 10, an aperture 23 is provided in the platform portion 13, as illustrated in Fig. 1. As illustrated in Fig. 2, the

aperture 23 is typically a slit that deforms to releasably receive a nozzle N of an injection device such as a syringe S containing the settable compound material. There are other configurations considered for the in-ear device 10 to inject the settable compound in the in-between region 16. For instance, in a configuration, the settable compound is injected in the in-between region 16 by passing the syringe directly between the core-form 12 and the sheath 15, with means to close-off the opening once the syringe is withdrawn (e.g., a pressure ring, an elastic, etc.)

Now that its basic components have been described, the method for customizing of the in-ear device 10 to the shape of the ear of an individual is described.

Referring to Fig. 1, the in-ear device 10 is ready to be used, in that the sheath 15 covers the core-form 12 so as to define the in-between region. The core-form 12 may come in various sizes. In such a case, a suitable size of core-form 12 is selected as a function of the individual's ear. More specifically, a visual inspection or a measurement of the ear may be required to select the size of core-form 12.

Following the selection of the core-form 12 with sheath 15, a settable compound 26 is injected into the region 16. The insert 24 has a bore 25 through which the nozzle N of the syringe S is passed to reach the aperture 23. The nozzle N of the syringe S is inserted into the aperture 23 by passing through the bore 25 of the insert 24. The nozzle N is fitted into the aperture 23, but kept at a distance from the sheath 15 so as not to inadvertently puncture the latter. The pressure of injection is sufficient to have the settable compound reach the region 16.

Referring to Fig. 2, a target quantity of a settable compound 26 is injected into the region 16,

which will expand because the sheath 15 is extensible. The sheath 15 is pushed away from the core-form 12 by the pressure of the settable compound 26. The settable compound 26 gives a rounded shape to the in-ear device 10, with an uneven distribution of the compound 26, as is illustrated in Fig. 2. It may be required to massage the in-ear device 10 prior to its insertion into the ear canal of the individual so as to spread the settable compound 26 more evenly in the region 16.

The fact that the injection of settable compound 26 is performed out of the ear is advantageous in that the depth of the nozzle N within the in-ear device 10 is readily controlled. Moreover, the distribution of the settable compound 26 in the region 16 can be adjusted, through the massaging manipulations.

In order to control the amount of the settable compound 26 injected into the region 16, it is considered, as an option, to fill up the region 16 at 50% to 80% of the suitable amount of settable compound 26 required. The remainder of the settable compound 26 is injected with the in-ear device 10 in the ear. This allows to ensure the uniform distribution of the settable compound 26 in the region 16, and the integrity of the sheath 15. Moreover, an overfill of the region 16 is avoided. However, it is preferred that the correct amount of settable compound 26 be evaluated initially, to avoid the injection of compound in the ear.

Accordingly, it is considered to provide prefilled syringes with predetermined amounts of settable compound (i.e., a target quantity). The prefilled syringes are selected as a function of the size of core-form 12, and following the visual inspection of the ear of the individual. However, this is an optional solution, as the syringes may also be filled with a quantity of settable compound

substantially larger than the target quantity required to fill the region 16 for an appropriate fit of the in-ear device 10.

Once the settable compound 26 has been injected in the region 16 of the in-ear device 10 and is still in a non-set liquid/gelatinous state (i.e., not yet set into a solid), the in-ear device 10 is inserted into the ear cavity of the individual, as illustrated in Fig. 3. It may be required to apply a lubricant on the sheath 15 to facilitate its insertion in the ear cavity. It may also be required as mentioned previously to insert some of the settable compound 26 to ensure the proper fit of the in-ear device 10.

Accordingly, as the settable compound 26 is still in its liquid/gelatinous state, the in-ear device 10 deforms to substantially assume the shape of the ear canal C and cavum concha V, thereby substantially blocking the ear. The in-ear device 10 is kept in the ear at a selected position, as illustrated in Fig. 3, until the curing time of the settable compound 26 has lapsed. A technician may verify that the in-ear device 10 is properly positioned within the ear cavity. Once the ear piece has been positioned properly the fitter then applies pressure on the platform portion 13 of the in-ear device 10 in order to cause the settable compound to flow into the nipple portion 14 of the in-ear device 10, such that the nipple portion 14 takes the shape of the ear canal C.

The device 10 is then removed from the ear cavity after the compound material 26 is set. Therefore, the in-ear device 10 has adopted the shape of the ear cavity, and is therefore customized to the individual's ear cavity.

Optional steps of testing the effectiveness of the seal provided by the customized in-ear device 10 may be performed, as well as the installation of acoustic

equipment (plugs, filters, emitters, etc.). The sound bore 20 is as an example used for the testing of the in-ear device 10. In the latter case, the generic insert 24 is either removed from core-form 12 to expose the cavity 22, or the insert 24 is a platform to receive the acoustic equipment. The generic insert 24 ensures that the cavity 22 keeps its shape during the steps of injection and insertion in the ear cavity.

The core-form 12 is generally solid and rigid enough with substantial inherent structural rigidity, while the stretchable sheath 15 is a thin material with substantially no inherent structural rigidity. In an embodiment, the core-form 12 and the sheath 15 are a single molded member made out of a silicone type of material or the like, with a hardness value of preferably less than thirty (30) shore-A. The settable compound material 26 is preferably a rubber-like type of material once it is fully cured, with a hardness value of preferably less than thirty (30) shore-A.

In an embodiment, the sheath 15 extends integrally away from the nipple portion 14 of the core-form 12 in a sheath first configuration or an unfolded configuration thereof. The sheath 15 is substantially a replication of the shape of the core-form 12 and is adapted to be folded inside-out over the core-form 12 and in a sheath second configuration or a folded configuration of the sheath 15, as shown in Fig. 1. The sheath 15 is progressively folded inside-out over the core-form 12. Preferably, the sheath 15 tightly assumes the core-form 12 such that the in-between region 16 is substantially fluidless, with no air entrapped therein.

In a preferred embodiment, the slit channel defining the aperture 23 is made using a sharp tool perforating the platform portion 13 prior to folding the sheath 15 over the core-form 12, so as not to damage the sheath 15. Such a slit channel is advantageous as it is

self-closing upon retraction of the nozzle N therefrom to prevent any back flow of the settable compound material 26 just after injection in the in-between region 16.

Because of the conical aspect of the nipple portion 14, the device 10 needs to be prevented from coming out of the ear canal C. The shape of the platform portion 13 as covered by the sheath 15 is such that the platform portion 13 accommodated into the cavum concha V provides the required retention.

The insert 24 is preferably made out of a polymeric material such as a silicone-type material or the like having a hardness value typically varying between twenty (20) and thirty (30) shore-A.

As shown in Figs. 1 to 3, the insert 24 can be a plug member to simply close off the second sound bore 21, whereby the device 10 is an earplug device.

The insert 24 may define a cavity adapted to accommodate an electronic circuit that amplifies and transmits sound within a predetermined frequency range from the environment outside the ear canal C to the second sound bore 21, whereby the device 10 is a hearing aid device, known as an in-the-ear (ITE) hearing aid. Moreover, the electronics can be any other sound transmitting device. Similarly, the electronic equipment can be a simple sound bore extension, (not shown) adapted to be engaged by an external hearing aid device, such as a commonly known behind the ear (BTE) hearing aid or the like, at a distal extremity and communicating with the second sound bore 21 at a proximal extremity, whereby the device 10 is a hearing-aid-adaptable device.

To prevent an individual from losing his/her in-ear devices 10, in-ear devices 10 can be paired up to be releasably engaged by a respective resilient plug member (not shown) secured to a respective extremity of

a cord or the like, thereby securing both devices 10 together.

Referring to Fig. 4, a flow chart is generally illustrated at 100, and features steps of the method for customizing an in-ear device in accordance with the present application.

In Step 102, an in-ear device having an expandable region is provided, such as the in-ear device 10 of Fig. 1.

In Step 104, a settable compound is injected into the expandable region of the in-ear device.

In Step 106, the in-ear device with the settable compound in the non-set state is manually shaped prior to inserting the in-ear device in the ear of the individual.

In Step 108, a lubricant is applied on the in-ear device prior to inserting the in-ear device with the non-set settable compound in the ear of the individual.

In Step 110, the in-ear device with the settable compound in a non-set state is inserted into a desired position in the ear of the individual such that the in-ear device conforms to the shape of the ear.

In Step 112, an additional amount of said settable compound is injected into the expandable region of the in-ear device after inserting the in-ear device in the ear of the individual.

In Step 114, the in-ear device is removed from the ear only once the settable compound has substantially solidified.

In Step 116, an electronic device is inserted in a sound bore of the in-ear device after removing the in-ear device from the ear.

It is pointed out that although the Steps 102 to 116 are illustrated in a given sequence, other suitable sequences are considered. Moreover, it is pointed out that the in-ear device may be customized

without having gone through all steps of the method 100, as some steps are clearly optional.

CLAIMS:

1. A method for customizing an in-ear device to an individual's ear, comprising:

providing an in-ear device having an expandable region;

injecting a settable compound into the expandable region of the in-ear device;

inserting the in-ear device with the settable compound in a non-set state into a desired position in the ear of the individual such that the in-ear device conforms to the shape of the ear; and

removing the in-ear device from the ear only once the settable compound has substantially solidified.

2. The method according to claim 1, further comprising manually shaping the in-ear device with the settable compound in the non-set state prior to inserting the in-ear device in the ear of the individual.

3. The method according to claim 1, wherein inserting the in-ear device in the ear of the individual comprises inserting the in-ear device at least in the ear canal of the ear of the individual, with the in-ear device conforming to the shape of the ear canal.

4. The method according to claim 1, further comprising applying a lubricant on the in-ear device prior to inserting the in-ear device with the non-set settable compound in the ear of the individual.

5. The method according to claim 1, wherein injecting the settable compound into the expandable region comprises injecting the settable compound with a syringe.

6. The method according to claim 5, wherein injecting the settable compound with a syringe comprises injecting the full content of a syringe prefilled with a target quantity.

7. The method according to claim 1, further comprising inserting an electronic device in a sound bore of the in-ear device after removing the in-ear device from the ear.

8. The method according to claim 1, further comprising injecting an additional amount of said settable compound into the expandable region of the in-ear device after inserting the in-ear device in the ear of the individual.

9. The method according to claim 8, wherein injecting an additional amount of said settable compound comprises injecting between 20% and 50% of the total amount of settable compound injected in the expandable region of the in-ear device.

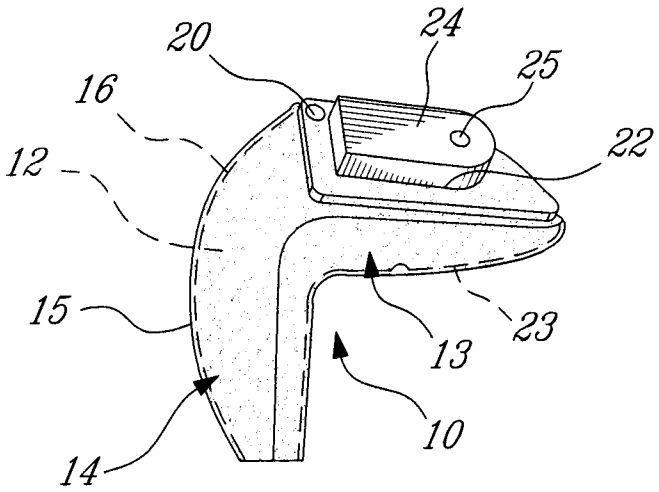

Fig-1

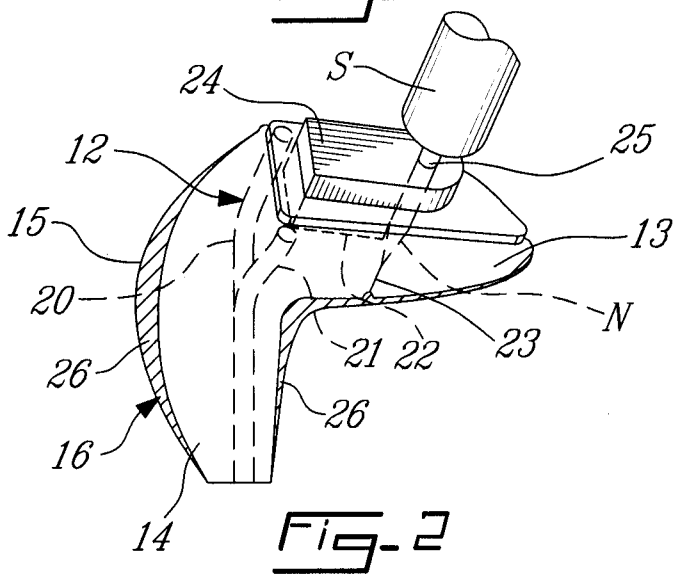

Fig-2

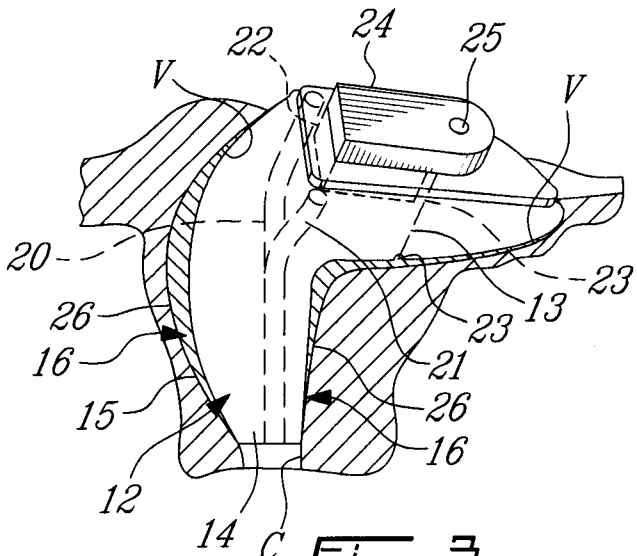

Fig-3

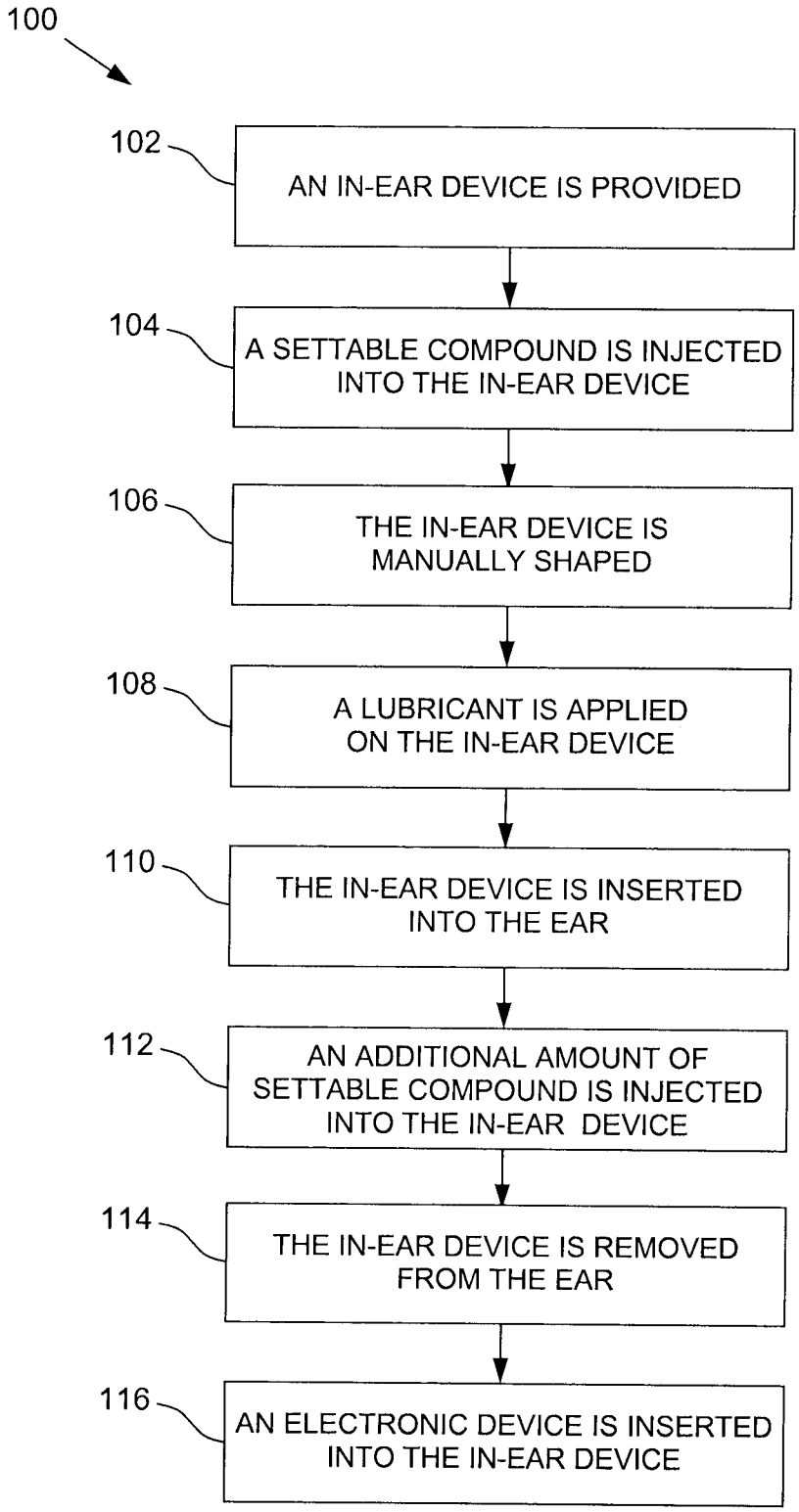
100
102
AN IN-EAR DEVICE IS PROVIDED
104
A SETTABLE COMPOUND IS INJECTED INTO THE IN-EAR DEVICE
106
THE IN-EAR DEVICE IS MANUALLY SHAPED
108
A LUBRICANT IS APPLIED ON THE IN-EAR DEVICE
110
THE IN-EAR DEVICE IS INSERTED INTO THE EAR
112
AN ADDITIONAL AMOUNT OF SETTABLE COMPOUND IS INJECTED INTO THE IN-EAR DEVICE
114
THE IN-EAR DEVICE IS REMOVED FROM THE EAR
116
AN ELECTRONIC DEVICE IS INSERTED INTO THE IN-EAR DEVICE

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2007/002240

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61F 11/10*** (2006.01) , ***H04R 25/02*** (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)
IPC2008: A61F 11/10, A61F 11/00, H04R 25/02, H04R 25/00
USPC: 181/130, 181/135, 181/129, 381/322

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Delphion, Esp@cenet, Canadian Patent Database
Keywords: ear, hearing-aid, deaf-aid, ear plug, interface, canal, method, shaping, shape, mould, mold, expand, set, inject, impression,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US 6339648 B1 (MCINTOSH, I. et al.) 15 January 2002 (15-01-2002) *Col. 5, lines 7-29; Figs. 1 & 2*	8, 9
Y	US 6754357 B2 (MCINTOSH, I. et al.) 22 June 2004 (22-06-2004) *Col. 6, lines 5-17; Fig. 7*	8, 9
A	US 6513621 B1 (DESLAURIERS, R. et al.) 04 February 2003 (04-02-2003) *Entire Disclosure*	1-9

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2007/002240

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