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443, Notre-Dame Est, #1, Montréal, Québec H2Y 1C9  
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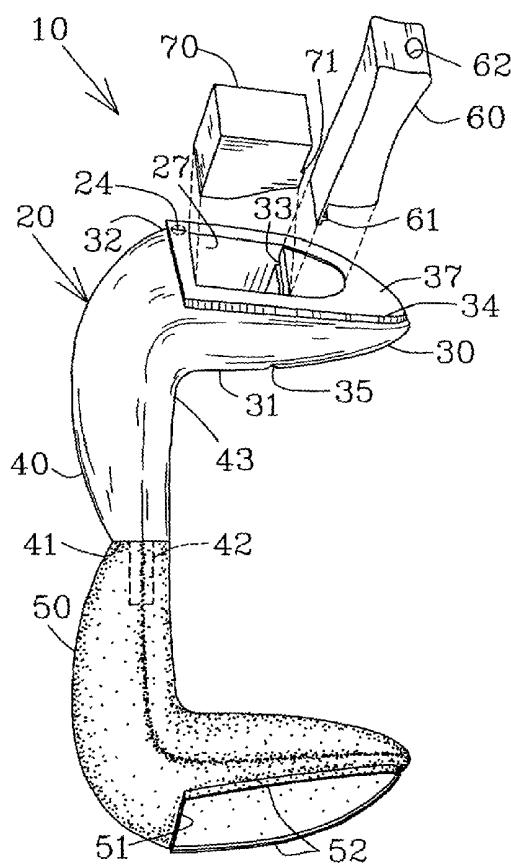
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(71) Applicant: SONOMAX INC. [CA/CA]; Suite 550, 1, Westmount Square, Montréal, Québec H3Z 2P9 (CA).

(72) Inventors: McINTOSH, Ian; 55, St-George East, Alexandria, Ontario K0C 1A0 (CA). SAULCE, Roger;

(54) Title: EXPANDABLE IN-EAR DEVICE



(57) Abstract: An expandable in-ear device (10) for being custom fitted in-situ into the ear canal (C) and cavum concha (V) of an individual by injection of a settable compound material (23) therein. The device (10) includes a core-form (20) with a platform section (30) and a nipple section (40) being integral to and extending from the platform proximal end (31) for engaging the canal (C). A sound bore (21) extends from the nipple proximal end (41) to the platform distal end (32) to conduct sound from the environment to inside the ear canal (C). A stretchable sheath (50) is integral to and freely extends away from the nipple proximal end (41) in an unfolded configuration of the device (10). The sheath (50) is a mirror image of the shape of the core-form (20) and has an aperture (51) for assuming a periphery (52) of the platform distal end (32). The sheath (50) folds inside-out over the core-form (20) to substantially assume the latter and to define an in-between region (22) therebetween in the folded configuration. The platform section (30) allows for the settable compound material (23) to be injected therethrough and reach the in-between region (22), thereby expanding the device (10) fitted inside the ear canal (C) by stretching the sheath (50) away from the core-form (20) to perfectly assume and occlude the ear canal (C).

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## EXPANDABLE IN-EAR DEVICE

### FIELD OF THE INVENTION

The present invention generally relates to in-ear devices such as earplugs, hearing aid devices and the like, and more particularly, to custom-fitting 5 in-ear devices that are formed in-situ to perfectly assume the inside of the ear canal and cavum concha of an individual.

### BACKGROUND OF THE INVENTION

Hearing protection devices (HPDs) are often passive (i.e. not powered) and some simply amount to a plug in the ear; while more sophisticated 10 (but still passive) HPDs may include acoustic chambers and filters, for passing or attenuating selected frequencies.

The term hearing device includes active devices, either of a hearing protection nature, or of a hearing aid nature, in which some or all of the batteries and other components are mounted behind the ear, or remotely, in a box, which 15 communicates with the in-ear unit by means of a sound-tube, or by wires; and includes active devices in which a microphone, speaker, and all the associated sound-processing circuitry and components, including a battery, are contained within the in-ear unit.

Recent trends in digital hearing devices seek to overcome the 20 traditional inconsistency-of-fit problem by providing multi-channel sound transmission.

The expectation that a good fit can be achieved quickly, every time, gives a new incentive to the development of the audio side of hearing-aid (and hearing-protection) technology.

It is recognized that the performance of all in-ear hearing devices is highly dependent upon the fit of the device in the ear. If the HPD is a poor fit, sound simply by-passes around the HPD. The tendency therefore is for the HPD to be too tight, which leads to poor wearer-comfort, whereby the wearer tends not 5 to keep the HPD in for long periods.

Recent development in hearing aids aimed at by-passing the need for a good fit, by eliminating feedback.

Different in-ear devices are presently used in a wide range of human activities. From the performance standpoint, HPDs, like hearing aids, 10 really have to be custom-fitted.

US Patent No. 5,006,055 issued to Lebisch et al. on August 4, 1989 discloses an apparatus for manufacturing in-ear device directly in the ear of a hearing-impaired person with a deformable envelope being pulled over a die or over a shell or over an overlayed over-shell. This rather long and tedious 15 process requires many steps of assembly.

US Patents No. 5,333,622 and No. 5,131,411 issued to Casali et al. on August 2, 1994 and on July 21, 1992 respectively disclose a custom-molded earplug that can be used for selecting pre-sized earplugs or as a cast for creating a mold for earplugs or hearing aids. This earplug is not appropriate for custom 20 fitting in-situ of an ear canal of an individual.

Canadian patent application No. 2,302,962/A1 of McIntosh et al. filed on March 23, 2000 and laid open on September 26, 2000 discloses a hearing apparatus adapted to be inflated in-situ using an inflation-medium. The apparatus includes a core portion that is generally covered by a separate sheath. 25 The proper installation of the sheath requires extensive delicate care, especially

when bonding the far end of the sheath to the core using the far-seal-means without obstructing the acoustic tube.

### SUMMARY OF THE INVENTION

It is therefore a general object of the present invention to provide an  
5 expandable in-ear device that obviates the above mentioned disadvantages.

An advantage of the present invention is that the expandable in-ear device can be very properly re-inserted by an individual repeatedly.

A further advantage of the present invention is that the expandable in-ear device is molded out into a single piece.

10 Still another advantage of the present invention is that the expandable in-ear device is customized depending on the user's need to be an earplug, a filtered earplug, a hearing aid device, a communication device or the like.

Still a further advantage of the present invention is that the  
15 expandable in-ear device is comfortable for users.

Yet another advantage of the present invention is that the expandable in-ear device is adaptable to be side specific, either a left or right-hand-side device.

Yet a further advantage of the present invention is that the  
20 expandable in-ear device is customized depending on the user's need to releasably receive any type of communication device therein.

According to the present invention, there is provided an expandable in-ear device for being custom fitted in-situ of an ear canal of an individual by injection of a settable compound material therein, the device comprises:

- a core-form defining a platform section and a nipple section and having a core-form shape, the platform section defining a platform proximal end and a generally opposed platform distal end, the platform distal end defining a platform distal end periphery, the nipple section defining a nipple proximal end and a generally opposed nipple distal end, the nipple section integrally extends from the platform proximal end for engaging the ear canal, the core-form further defines a sound bore generally extending from the nipple proximal end to the platform distal end through both the nipple and platform sections for conducting sound from an environment surrounding the individual to inside of the ear canal;
- 5 10 - a stretchable sheath being integral to and freely extending away from the nipple proximal end of the core-form adjacent the sound bore in an unfolded configuration of the device, the sheath defining a sheath shape being substantially a mirror image of the core-form shape, the sheath being configured and sized so as to substantially assume the core-form shape when folded inside-
- 15 20 out over the core-form in a folded configuration of the device, the sheath further defining a sheath-to-core-form in-between region when in the folded configuration, the sheath having a sheath aperture generally assuming the platform distal end periphery when in the folded configuration;
  - the platform section allowing for the settable compound material to be injected therethrough to reach the in-between region, thereby expanding the device fitted inside the ear canal by stretching the sheath away from the core-form to perfectly assume and occlude the ear canal.

Preferably, the platform distal end periphery defines a platform protruding surface, the platform protruding surface protruding outwardly from the

platform distal end and defining a protruding surface perimeter, the sheath aperture having a shape to assume the surface perimeter.

Typically, the sheath is a thin and stretchable polymer material with substantially no inherent structural rigidity.

5 Preferably, the core-form is generally solid with a material hardness value of less than thirty (30) shore-A.

Typically, the sheath tightly assumes the core-form when in the folded configuration as to have the in-between region being substantially fluidless.

10 Preferably, the in-ear device is made out of a single molded piece.

Preferably, the protruding surface perimeter defines a perimeter groove extending therealong, the sheath aperture defining an aperture perimeter, the aperture perimeter being reinforced with a integral bulge tightly engaging the perimeter groove when in the folded configuration so as to substantially close off 15 the in-between region.

Preferably, the sound bore is a first sound bore, the platform section defining a cavity substantially extending inwardly therein from the protruding surface, whereby the cavity is for removably, tightly and at least partially house an insert member therein, the core-form further defining a second sound bore 20 generally extending from the nipple proximal end to the cavity through both of the nipple and platform sections for conducting sound from the cavity to inside of the ear canal, whereby the insert member is in sound communication with inside of the ear canal via the second sound bore.

Preferably, the cavity includes an insert retaining means for 25 releasably retaining the insert member therein.

Typically, the platform distal end includes a slit membrane temporarily closing off the sound bore, the slit membrane allows for a remote instrument to be releasably inserted therethrough to get in communication with the sound bore.

5 Preferably, the device includes a handle member secured to the platform section adjacent the platform distal end for handling the in-ear device.

Preferably, the platform section includes an injection slit channel substantially extending therethrough between the platform distal end to the in-between region to be in fluid communication therewith, the injection slit channel 10 for releasably receiving part of an injection device therein to inject the settable compound material therethrough into the in-between region.

Typically, the injection slit channel is generally rectilinear, the handle member being generally elongated and defines a longitudinal reach-through hole being substantially in-line with the injection slit channel of the 15 platform section, the reach-through hole for guiding an injection device containing the settable compound material into the injection slit channel within the platform section. The reach-through hole of the handle member includes a close-off membrane at one end thereof, the close-off membrane being in contact with the platform section of the core-form.

20 Preferably, the injection slit channel self closes upon retraction of the injection device therefrom.

Alternatively, the platform distal end defines a generally convex shape, the convex shape has a generally elongated apex and is substantially symmetrical thereabout, the convex shape defining two substantially planar 25 surfaces with the elongated apex defining a common distal edge therebetween,

the planar surfaces generally extending away from each other from the common distal edge and towards the platform proximal end.

Preferably, one of the two surfaces includes the platform distal end periphery defining a platform protruding surface, the platform protruding surface 5 protruding outwardly from the platform distal end and defining a protruding surface perimeter, the sheath aperture having a shape to assume the surface perimeter, the other of the two surfaces being fully covered by the sheath when in the folded configuration to form part of the in-between region for being custom fitted in-situ of a cavum concha of the individual corresponding to the ear canal 10 so as to perfectly assume the cavum concha.

Other objects and advantages of the present invention will become apparent from a careful reading of the detailed description provided herein, within appropriate reference to the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

15 In the annexed drawings, like reference characters indicate like elements throughout.

Figure 1 is an exploded side view of an embodiment of an expandable in-ear device according to the present invention; showing the sheath integrally extending out of the core-form, in the unfolded configuration;

20 Figure 2 is a bottom view of the embodiment of Fig. 1;

Figure 3 is a side view of the embodiment of Fig. 1 with the sheath folded inside-out over the core-form, in the folded configuration;

Figure 4 is a bottom view of the embodiment of Fig. 2;

25 Figure 5 is a partial enlarged section view taken along line 5-5 of Fig. 3; showing the handle member secured to the platform section;

Figure 6 is an enlarged section view taken along line 6-6 of Fig. 3;

Figure 7 is a section view of the embodiment of Fig. 2 inserted in the ear canal and cavum concha of an individual and being expanded by a settable compound material to perfectly assume the same; and

5 Figure 8 is a perspective view of another embodiment of the insert member engaging the cavity.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to the annexed drawings the preferred embodiments of the present invention will be herein described for indicative purpose and by no 10 means as of limitation.

Referring to Figs. 1 to 8, there is shown an embodiment 10 of an expandable in-ear device according to the present invention. The device 10 is adapted for being custom fitted in-situ inside the ear canal C and cavum concha V of an individual by injection of a settable compound material 23 therein. The 15 device 10 includes a core-form 20 defining a platform section 30 and a nipple section 40 and having a core-form shape. The platform section 30 that essentially fits into the cavum concha V defines a platform distal end 32 and a generally opposed platform proximal end 31, the latter defining a platform distal end periphery 34. The nipple section 40 that essentially fits into the ear canal C defines a nipple distal end 43 and a generally opposed nipple proximal end 41. The 20 nipple section 40 integrally extends from the platform proximal end 31 for engaging the ear canal C. A sound bore 21 generally extends from the nipple proximal end 41 to the platform distal end 32 through both the nipple 40 and the platform 30 sections, for conducting sound from an environment to inside of the 25 ear canal C.

A stretchable sheath 50, shown in Fig. 1, is integral to and freely extends away from the nipple proximal end 41 of the core-form 20 in an unfolded configuration of the device 10. The sheath 50 defines a sheath shape that is substantially a mirror image of the shape of the core-form 20. The sheath 50 is 5 configured and sized so as to substantially assume the core-form shape when folded inside-out over the core-form 20 in a folded configuration of the device 10. The sheath 50 further defines a sheath-to-core-form in-between region 22 when in the folded configuration, as shown in Fig. 3. The sheath 50 has a sheath aperture 51 generally assuming the platform distal end periphery 34.

10 The platform section 30 allows for the settable compound material 23 to be injected therethrough to reach the in-between region 22 and stretch the sheath 50 away from the core-form 20 so as to expand the device 10 fitted in the ear canal C such that it perfectly assume and occlude the latter and the cavum concha V, thereby forming a unitary piece with the device 10 after the settable 15 compound material 23 is fully set. For obvious reasons to one skilled in the art, the in-between region 22 does not communicate with the sound bore 21.

The in-ear device 10 also preferably includes a handle member 60 secured, preferably glued, to the platform distal end 32. The device 10 includes a handle positioning means for positioning the handle 60 relative to the platform 20 section 30. In order to properly position the handle 60 relative to the core-form 20, the handle 60 preferably has a notch 61 for engaging a corresponding notch recess 33 on the platform section 30, the notch 61 and the notch recess 33 forming the handle positioning means, as shown in Fig. 5.

25 To ensure a better flow of the settable compound material 23 inside the in-between region 22 of the device 10, the platform proximal end 31 includes

a preferably semi-circular recess 35, adjacent the nipple section 40, as illustrated in Fig. 1. To allow for the compound material 23 to reach the in-between region 22 via the semi-circular recess 35 from the distal end 32 of the platform 30, a communicating injection slit channel 36 substantially extends through the 5 platform section 30, between the platform distal end 32 and the semi-circular recess 35 in fluid communication with the in-between region 22. The injection slit channel 36, preferably rectilinear, is made to releasably receive a needle N of an injection device such as a syringe S containing the settable compound material 23. Obviously, the injection slit channel 36 is made using a sharp tool perforating 10 the platform 30 prior to folding the sheath 50 over the core-form 20, thereby not damaging the sheath 50.

The handle 60 is generally elongated and preferably defines a longitudinal reach-through hole 62 to be in-line with the injection slit channel 36 for alternatively guiding the perforating tool and the needle N of the syringe S 15 (shown in dashed lines in Fig. 7).

The hole 62 of the handle 60 is preferably includes a thin close-off membrane 63 at a proximal end thereof getting in contact with the core-form 20 in order to prevent any back flow of glue within the hole 62 when the handle 60 is glued onto the platform 30. Similarly, to prevent any back flow of the settable 20 compound material 23 just after injection of the same inside the in-between region 22, the injection slit channel 36 is preferably self closing upon retraction of the needle N therefrom.

As shown in Fig. 7, the platform distal end periphery 34 defines a platform protruding surface 37 slightly protruding outwardly from the platform 25 distal end 32 and defining a protruding surface perimeter. Accordingly, the

sheath aperture 51 has a shape to assume the surface perimeter of the platform protruding surface 37. Preferably, the sheath aperture 51 has its perimeter reinforced with a bulge 52 integral therewith for tightly engaging a corresponding groove 38 on the perimeter of the platform protruding surface 37. The sheath 5 aperture bulge 52 is preferably bonded (or glued) into the groove 38 of the platform protruding surface 37 to essentially close off the in-between region 22. The distal end 21d of the sound bore 21 is located within the platform protruding surface 37 and is preferably terminated by a slit membrane 24 temporarily closing off the same whenever not releasably inserted therethrough by a remote 10 instrument (not shown) such as a microphone of a measurement apparatus or the like.

Also illustrated in Figs. 2 and 6, the platform distal end 32 preferably defines a generally convex shape with a generally elongated apex 26 and, is substantially symmetrical about the apex 26. The convex shape defines 15 two substantially planar surfaces 25 with the apex 26 defining a common distal edge therebetween. Both planar surfaces 25 generally extend downwardly and away from each other from the common distal edge 26 and towards the platform proximal end 31 in a proximal direction. Only one of the two surfaces 25 includes the platform distal end periphery 34 defining the platform protruding surface 37 20 while the other one is fully covered by the sheath 50 in the folded configuration of the in-ear device 10 as to form part of the in-between region 22 that is custom fitted in-situ of a cavum concha V of the individual to perfectly assume the same. Obviously, the sheath aperture 51 is located on the same side as the corresponding protruding surface 37. This slope of the convex shape forming the 25 surfaces 25 enables the device 10 to be side specific, either a left or right-hand-

side device and have only the handle 60 secured to the protruding surface 37 protruding out of the ear of the individual.

Furthermore, because of the generally conical aspect of the nipple section 40 required for its insertion into the ear canal C, the device 10 needs a 5 retaining member to prevent it from slidably coming out of the ear canal C. Accordingly, the side of the platform 30 with the surface 25 entirely covered by the sheath 50 is configured and sized to sit into the cavum concha V of the ear and provide the required retention.

After the handle 60 has been installed and the injection slit channel 10 36 has been made, the sheath 50 is progressively folded inside-out over the core-form 20. Preferably, the sheath 50 tightly assumes the core-form 20 such that the in-between region 22 is substantially fluidless, with no air entrapped therein. For safety, after folding of the sheath 50, its aperture 51 is bonded all around the protruding surface 37, then the in-between region 22 is typically 15 vacuumed to remove air entrapped therein. At this time, the device 10 is ready to be inserted into the ear canal C and have the settable compound material 23 injected into the in-between region 22 for the in-situ custom fitting of the in-ear device 10, as shown in Fig. 7. The sheath 50 is then stretched away from the core-form 20 to perfectly assume and occlude the ear canal C. Similarly, the 20 retaining member area of the device 10 also have a simultaneous expansion of its part of the in-between region 22 being filled by the settable compound material so as to perfectly assume the shape of the cavum concha V of the individual. The device 10 is then removed from the ear canal C after the compound material 23 is completely set.

The core-form 20 is generally solid and rigid enough with substantial inherent structural rigidity while the stretchable sheath 50 is a thin material with substantially no inherent structural rigidity, both of them being preferably a single molded piece made out of a silicone type of material or the like with a hardness value of preferably less than thirty (30) shore-A. Accordingly, as shown in Fig. 1, core-form protrusions 42 at the nipple proximal end 41 are present preferably only for molding purposes of the sound bores 21, 28. They are preferably simply chopped off after folding over of the sheath 50, as shown in Figs. 3 and 4. The settable compound material 23 is preferably a rubber-like type material once it is fully cured with a hardness value of preferably less than thirty (30) shore-A.

Additionally, the platform section 30 of the in-ear device 10 preferably defines a cavity 27 for removably, tightly and at least partially house an insert member 70 therein considering the fact that the core-form 20 material is substantially resilient. The cavity 27 substantially extends inwardly from the protruding surface 37. The core-form 20 further defines a second sound bore 28 generally extending from the nipple proximal end 41 to the cavity 27 of the platform 30 through both of the nipple 40 and platform 30 sections for conducting sound from the cavity 27 to inside of the ear canal C such that the insert member 70 can be in sound communication with inside of the ear canal C. The second sound bore 28 runs generally parallel to the first one 21 except in the region adjacent the platform distal end 32 where they slightly diverge from each other.

The cavity preferably includes an insert retaining means for releasably retaining the insert 70 therein. The insert retaining means is

preferably formed by the lower section of the handle 60 defining a step to be releasably engaged by a complementary locking step 71 of the insert 70.

Both the handle 60 and the insert 70 are preferably made out of silicone type material or the like having a hardness value typically varying 5 between fifty (50) and eighty (80) shore-A.

As shown in Figs. 1 to 7, the insert member 70 can be a plug member to simply close off the second sound bore 28, whereby the in-ear device 10 is a typical earplug device.

Optionally, the insert member 70 includes a communication element 10 72 for communicating with the second sound bore 28. Accordingly, the communication element 72 can be a band-pass filter, preferably in the form of an adequately sized extension of the second sound bore 28, for allowing an acceptable frequency range to reach inside the ear canal C, whereby the in-ear device 10 is a typical filtered earplug device.

15 Also, as shown in Fig. 8, the communication element 72 of the insert 70a can be an insert cavity 73 adapted to be releasably engaged by an electronic circuit (not shown and well known in the art) or the like for amplifying sound within a pre-determined frequency range from the environment to the second sound bore 28, whereby the in-ear device 10 is a typical hearing aid 20 device, more commonly known as an in-the-ear (ITE) hearing aid. Similarly, the communication element 72 could 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 end thereof and communicating with the second sound bore 28 at a proximal end thereof, 25 whereby the in-ear device 10 is a typical hearing aid adaptable device.

Alternatively, either the communication element 72 or simply the insert member 70 could be a simple audio output connector, being wireless or not, from a typical electronic device such as a computer, a laptop-type computer, a cellular-type (or GSM – Global System for Mobile communications) phone, a 5 hand-held-type (or palm) computer or the like that is adapted to releasably fit within the insert cavity 73.

To prevent an individual from loosing his/her in-ear devices 10 of the present invention when a pair of them are worn, each hole 62 of both handles 60 can be releasably engaged by a respective resilient plug member (not shown) 10 secured to a respective end of a cord or the like, thereby securing both devices 10 together.

Although the present expandable in-ear device has been described with a certain degree of particularity it is to be understood that the disclosure has been made by way of example only and that the present invention is not limited to 15 the features of the embodiments described and illustrated herein, but includes all variations and modifications within the scope and spirit of the invention as hereinafter claimed.

CLAIMS

1. An expandable in-ear device (10) for being custom fitted in-situ of an ear canal (C) of an individual by injection of a settable compound material  
5 (23) therein, said device comprising:
  - a core-form (20) defining a platform section (30) and a nipple section (40) and having a core-form shape, said platform section (30) defining a platform proximal end (31) and a generally opposed platform distal end (32), said platform distal end (32) defining a platform distal end periphery (34), said nipple section 10 (40) defining a nipple proximal end (41) and a generally opposed nipple distal end (43), said nipple section (40) integrally extends from said platform proximal end (31) for engaging said ear canal (C), said core-form (20) further defines a sound bore (21) generally extending from said nipple proximal end (41) to said platform distal end (32) through both said nipple (40) and platform (30) sections  
15 for conducting sound from an environment surrounding said individual to inside of said ear canal (C);
    - a stretchable sheath (50) being integral to and freely extending away from said nipple proximal end (41) of said core-form (20) adjacent said sound bore (21) in an unfolded configuration of said device (10), said sheath (50) 20 defining a sheath shape being substantially a mirror image of said core-form shape, said sheath (50) being configured and sized so as to substantially assume said core-form shape when folded inside-out over said core-form (20) in a folded configuration of said device (10), said sheath (50) further defining a sheath-to-core-form in-between region (22) when in said folded configuration, said sheath

(50) having a sheath aperture (51) generally assuming said platform distal end periphery (34) when in said folded configuration;

- said platform section (30) allowing for said settable compound material (23) to be injected therethrough to reach said in-between region (22), thereby

5 expanding said device (10) fitted inside said ear canal (C) by stretching said sheath (50) away from said core-form to perfectly assume and occlude said ear canal (C).

2. The device (10) of claim 1, wherein said platform distal end periphery (34) defining a platform protruding surface (37), said platform protruding surface (37) protruding outwardly from said platform distal end (32) and defining a protruding surface perimeter, said sheath aperture (51) having a shape to assume said surface perimeter.

15 3. The device (10) of claim 1, wherein said sheath (50) being a thin and stretchable polymer material with substantially no inherent structural rigidity.

4. The device (10) of claim 3, wherein said core-form (20) being generally solid with a material hardness value of less than thirty (30) shore-A.

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5. The device (10) of claim 1, wherein said sheath (50) tightly assumes said core-form (20) when in said folded configuration as to have said in-between region (22) being substantially fluidless.

6. The device (10) of claim 1, wherein said in-ear device (10) being made out of a single molded piece.

7. The device (10) of claim 2, wherein said protruding surface 5 perimeter defining a perimeter groove (38) extending therealong, said sheath aperture (51) defining an aperture perimeter, said aperture perimeter being reinforced with a integral bulge (52) tightly engaging said perimeter groove (38) when in said folded configuration so as to substantially close off said in-between region (22).

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8. The device (10) of claim 1, wherein said sound bore (21) being a first sound bore, said platform section (30) defining a cavity (27) substantially extending inwardly therein from said protruding surface (37), whereby said cavity (27) is for removably, tightly and at least partially house an insert member (70) 15 therein, said core-form (20) further defining a second sound bore (28) generally extending from said nipple proximal end (41) to said cavity (27) through both of said nipple (40) and platform (30) sections for conducting sound from said cavity (27) to inside of said ear canal (C), whereby said insert member (70) is in sound communication with inside of said ear canal (C) via said second sound bore (28).

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9. The device (10) of claim 8, wherein said cavity (27) includes an insert retaining means for releasably retaining said insert member (70) therein.

10. The device (10) of claim 1, wherein said platform distal end (32) 25 includes a slit membrane (24) temporarily closing off said sound bore (21), said

slit membrane (24) allows for a remote instrument to be releasably inserted therethrough to get in communication with said sound bore (21).

11. The device (10) of claim 1, including a handle member (60)  
5 secured to said platform section (30) adjacent said platform distal end (32) for handling said in-ear device (10).

12. The device (10) of claim 11, including a handle positioning means for positioning said handle member (60) relative to said platform  
10 section (30).

13. The device (10) of claim 12, wherein said handle member (60) includes a notch (61) to engage a corresponding notch recess (33) on said platform section (30), said notch (61) and said notch recess (33) forming said  
15 handle positioning means.

14. The device (10) of claim 8, including a handle member (60) secured to said platform section (30) adjacent said platform distal end (32) for handling said in-ear device (10).

20

15. The device (10) of claim 14, wherein said platform section (30) includes an injection slit channel (36) substantially extending therethrough between said platform distal end (32) to said in-between region (22) to be in fluid communication therewith, said injection slit channel (36) for releasably receiving

part of an injection device (N) therein to inject said settable compound material (23) therethrough into said in-between region (22).

16. The device (10) of claim 15, wherein said injection slit channel  
5 (36) being generally rectilinear, said handle member (60) being generally  
elongated and defines a longitudinal reach-through hole (62) being substantially  
in-line with said injection slit channel (36) of said platform section (30), said  
reach-through hole (62) for guiding an injection device (N) containing said  
settable compound material (23) into said injection slit channel (36) within said  
10 platform section (30).

17. The device (10) of claim 16, wherein said reach-through hole  
(62) of said handle member (60) includes a close-off membrane (63) at one end  
thereof, said close-off membrane (63) being in contact with said platform section  
15 (30) of said core-form (20).

18. The device (10) of claim 16, wherein said injection slit channel  
(36) self closes upon retraction of said injection device (N) therefrom.

20 19. The device (10) of claim 1, wherein said platform distal end (32)  
defining a generally convex shape, said convex shape has a generally elongated  
apex (26) and is substantially symmetrical thereabout, said convex shape  
defining two substantially planar surfaces (25) with said elongated apex (26)  
defining a common distal edge therebetween, said planar surfaces (25) generally

extending away from each other from said common distal edge and towards said platform proximal end (31).

20. The device (10) of claim 19, wherein one of said two surfaces
- 5 (25) includes said platform distal end periphery (34) defining a platform protruding surface (37), said platform protruding surface (37) protruding outwardly from said platform distal end (32) and defining a protruding surface perimeter, said sheath aperture (51) having a shape to assume said surface perimeter, the other of said two surfaces (25) being fully covered by said sheath (50) when in said folded
- 10 configuration to form part of said in-between region (22) for being custom fitted in-situ of a cavum concha (V) of said individual corresponding to said ear canal (C) so as to perfectly assume said cavum concha (V).

