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EARLIEST PRIORITY CLAIMED

COUNTRY	NUMBER	DATE
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TITLE OF INVENTION

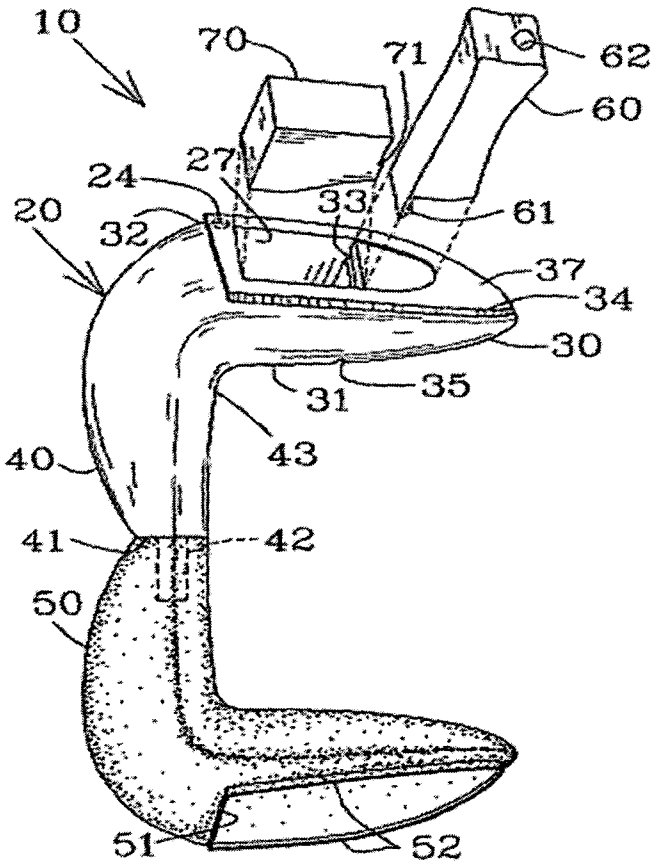
54	EXPANDABLE IN-EAR DEVICE

57	ABSTRACT (NOT MORE THAT 150 WORDS)	NUMBER OF SHEETS	32

If no classification is finished, Form P.9 should accompany this form.
The figure of the drawing to which the abstract refers is attached.

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 frely 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 (34) 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).



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 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 (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 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 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.

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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 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, 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 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 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.

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 expandable in-ear device that addresses 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.

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 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 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, the in-ear device being implantable within an ear canal of an

individual and being customizable in-situ to the shape of the ear canal using a settable compound, the in-ear device comprises:

- a core-form defining a nipple section thereof, the nipple section being insertable into the ear canal,

- a sound bore extending through the nipple section from a position located outside the ear canal to a position located inside the ear canal for allowing sound transmission therethrough, and

- a deformable sheath extending integrally from the core-form, the deformable sheath being deformable between a sheath first configuration and a sheath second configuration wherein when the sheath is in the sheath first configuration the sheath extends generally away from the nipple section while remaining attached to the core-form, the sheath being foldable inside-out from the sheath first configuration to the sheath second configuration wherein the sheath is in a generally overlying relationship relative to the core-form so as to substantially cover the nipple section while defining a spacing between the sheath and the core-form, the spacing being fillable by the settable compound.

Typically, the core-form further defines a platform section, the platform section defining a platform distal end and a generally opposed platform proximal end, the nipple section extending generally away from a position adjacent the platform proximal end, the nipple section defining a nipple distal end and a generally opposed nipple proximal end;

- the sheath extending integrally away from a position adjacent the nipple proximal end when in the sheath first configuration and being in a generally overlying relationship relative to the core-form so as to substantially cover the

nipple and platform sections when in the sheath second configuration, the sheath defining an aperture therethrough, the aperture generally overlying the platform distal end when the sheath is in the sheath second configuration.

Typically, the platform distal end has a platform distal end periphery defining a platform protruding surface slightly protruding away therefrom, the aperture of the sheath having a shape to generally assume a perimeter of the platform protruding surface.

Typically, the sound bore extends generally from a position adjacent the nipple proximal end inside the ear canal to a position adjacent the platform distal end outside the ear canal.

In one embodiment, the sheath tightly covers the core-form with the spacing being substantially fluidless when the sheath is in the sheath second configuration.

In one embodiment, the in-ear device is a single molded member.

In one embodiment, the aperture of the sheath has a perimeter reinforced with a bulge extending integrally from the sheath for tightly engaging a corresponding groove on the perimeter of the platform protruding surface of the platform distal end, thereby closing the spacing.

In one embodiment, the platform section includes a cavity extending generally inwardly thereinto from a position adjacent the platform distal end, the in-ear device further comprising an insert member removably tightly engaging the cavity of the platform section, and a second sound bore extending generally from a position adjacent the nipple proximal end to the cavity of the platform section

through both of the nipple and platform sections for allowing sound transmission therethrough.

In one embodiment, the insert member is a plug member to close the second sound bore, whereby the in-ear device is an earplug device.

In one embodiment, the insert member includes a communication element for sound communication with the second sound bore.

In one embodiment, the communication element is a band-pass filter for allowing an acceptable frequency range to reach inside the ear canal, whereby the in-ear device is a filtered earplug device.

Alternatively, the communication element is a second cavity extending generally inwardly into the insert member for being releasably engaged by an electronic circuit member that amplifies and transmits sound within a pre-determined frequency range from outside the ear canal to the second sound bore, whereby the in-ear device is a hearing aid device.

Alternatively, the communication element is a sound bore extension extending through the insert member, the sound bore extension communicating with the second sound bore at a proximal end thereof and for being engaged by an external hearing aid device at a distal end thereof, whereby the in-ear device is a hearing aid adaptable device.

In one embodiment, the first sound bore is terminated at a position adjacent the platform distal end by a slit opening, the slit opening closing the first sound bore whenever not engaged by a remote instrument.

In one embodiment, the device further comprises a handle member secured to a position generally adjacent the platform distal end.

In one embodiment, the handle member is glued to the platform section of the core-form.

Typically, the handle member includes a notch to engage a corresponding recess on the platform section for properly positioning the handle member relative to the core-form, the handle member having a longitudinal reach-through hole for guiding an injection device containing the settable compound into a slit channel within the platform section, the slit channel communicating with the spacing so as to allow the settable compound to flow from the slit channel to the spacing.

In one embodiment, the hole of the handle member is closed off by a thin membrane in contact with the core-form.

In one embodiment, the slit channel self closes upon retraction of the injection device therefrom.

In one embodiment, 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 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.

Typically, one of the two surfaces has a platform distal end periphery defining a platform protruding surface slightly protruding away therefrom, the sheath aperture having a shape to generally assume a perimeter of the platform protruding surface, the other of the two surfaces being fully covered by the sheath when in the folded configuration and being customizable

in-situ to the shape of a cavum concha of the individual corresponding to the ear canal.

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

BRIEF DESCRIPTION OF THE DRAWINGS

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;

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;

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

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 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 customizable in-situ to the shape of 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 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 nipple section 40 integrally extends from the platform proximal end 31 for engaging the ear canal C. A sound bore 21 extends generally from a position adjacent the nipple proximal end 41 to a position adjacent the platform distal end 32 through both the nipple 40 and the platform 30 sections, for conducting sound from an environment outside the ear canal C to inside of the ear canal C.

A stretchable or deformable sheath 50, shown in Fig. 1, extends integrally away from the nipple proximal end 41 of the core-form 20 in a sheath first configuration or an unfolded configuration thereof. The sheath 50 defines a sheath shape that is substantially a mirror image or a replication of the shape of the core-form 20. The sheath 50 is configured and sized so as to substantially

assume the core-form shape in a generally overlying relationship relative to the core-form 20 so as to substantially cover the latter when folded inside-out over the core-form 20 in a sheath second configuration or a folded configuration thereof. 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.

The platform section 30 allows for the settable compound material 23 to be injected therethrough to reach and fill the in-between region 22 and stretch or deform 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 generally assumes and occludes the latter and the cavum concha V, thereby forming a unitary piece with the device 10 after the settable 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 a position adjacent the platform distal end 32. The device 10 includes a handle positioning means for positioning the handle 60 relative to the platform 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.

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 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 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 (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 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 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 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 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 generally symmetrical about the apex 26. The convex shape defines two substantially planar surfaces 25 with the apex 26 defining a common distal edge therebetween. Both planar surfaces 25 extend generally 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 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 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 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 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 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 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 a position adjacent the nipple proximal end 41 to a position adjacent the cavity 27 of the platform 30 through both of the nipple 40 and platform 30 sections for allowing sound transmission between the cavity 27 and the 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 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 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.

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 that amplifies and transmits sound within a pre-determined frequency range from the environment outside the ear canal C to the second sound bore 28, whereby the in-ear device 10 is a typical hearing aid 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, 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 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) 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 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, said in-ear device being implantable within an ear canal of an individual and being customizable in-situ to the shape of the ear canal using a settable compound, said in-ear device comprising:

- a core-form defining a nipple section thereof, said nipple section being insertable into the ear canal,

- a sound bore extending through said nipple section from a position located outside the ear canal to a position located inside the ear canal for allowing sound transmission therethrough, and

- a deformable sheath extending integrally from said core-form, said deformable sheath being deformable between a sheath first configuration and a sheath second configuration wherein when said sheath is in said sheath first configuration said sheath extends generally away from said nipple section while remaining attached to said core-form, said sheath being foldable inside-out from said sheath first configuration to said sheath second configuration wherein said sheath is in a generally overlying relationship relative to said core-form so as to substantially cover said nipple section while defining a spacing between said sheath and said core-form, said spacing being fillable by the settable compound.

2. A device as defined in claim 1, wherein said core-form further defines a platform section, said platform section defining a platform distal end and a generally opposed platform proximal end, said nipple section extending

generally away from a position adjacent said platform proximal end, said nipple section defining a nipple distal end and a generally opposed nipple proximal end;

- said sheath extending integrally away from a position adjacent said nipple proximal end when in said sheath first configuration and being in a generally overlying relationship relative to said core-form so as to substantially cover said nipple and platform sections when in said sheath second configuration, said sheath defining an aperture therethrough, said aperture generally overlying said platform distal end when said sheath is in said sheath second configuration.

3. A device as defined in claim 2, wherein said platform distal end has a platform distal end periphery defining a platform protruding surface slightly protruding away therefrom, said aperture of said sheath having a shape to generally assume a perimeter of said platform protruding surface.

4. A device as defined in claim 2, wherein said sound bore extends generally from a position adjacent said nipple proximal end inside the ear canal to a position adjacent said platform distal end outside the ear canal.

5. A device as defined in claim 1, wherein said sheath tightly covers said core-form with said spacing being substantially fluidless when said sheath is in said sheath second configuration.

6. A device as defined in claim 1, wherein said in-ear device is a single molded member.

7. A device as defined in claim 3, wherein said aperture of said sheath has a perimeter reinforced with a bulge extending integrally from said sheath for tightly engaging a corresponding groove on said perimeter of said platform protruding surface of said platform distal end, thereby closing said spacing.

8. A device as defined in claim 2, wherein said platform section includes a cavity extending generally inwardly thereinto from a position adjacent said platform distal end, said in-ear device further comprising an insert member removably tightly engaging said cavity of said platform section, and a second sound bore extending generally from a position adjacent said nipple proximal end to said cavity of said platform section through both of said nipple and platform sections for allowing sound transmission therethrough.

9. A device as defined in claim 8, wherein said insert member is a plug member to close said second sound bore, whereby said in-ear device is an earplug device.

10. A device as defined in claim 8, wherein said insert member includes a communication element for sound communication with said second sound bore.

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11. A device as defined in claim 10, wherein said communication element is a band-pass filter for allowing an acceptable frequency range to reach inside the ear canal, whereby said in-ear device is a filtered earplug device.

12. A device as defined in claim 10, wherein said communication element is a second cavity extending generally inwardly into said insert member for being releasably engaged by an electronic circuit member that amplifies and transmits sound within a pre-determined frequency range from outside the ear canal to said second sound bore, whereby said in-ear device is a hearing aid device.

13. A device as defined in claim 10, wherein said communication element is a sound bore extension extending through said insert member, said sound bore extension communicating with said second sound bore at a proximal end thereof and for being engaged by an external hearing aid device at a distal end thereof, whereby said in-ear device is a hearing aid adaptable device.

14. A device as defined in claim 2, wherein said first sound bore is terminated at a position adjacent said platform distal end by a slit opening, said slit opening closing said first sound bore whenever not engaged by a remote instrument.

15. A device as defined in claim 10, further comprising a handle member secured to a position generally adjacent said platform distal end.

16. A device as defined in claim 15, wherein said handle member is glued to said platform section of said core-form.

17. A device as defined in claim 15, wherein said handle member includes a notch to engage a corresponding recess on said platform section for properly positioning said handle member relative to said core-form, said handle member having a longitudinal reach-through hole for guiding an injection device containing the settable compound into a slit channel within said platform section, said slit channel communicating with said spacing so as to allow the settable compound to flow from said slit channel to said spacing.

18. A device as defined in claim 17, wherein said hole of said handle member is closed off by a thin membrane in contact with said core-form.

19. A device as defined in claim 17, wherein said slit channel self closes upon retraction of the injection device therefrom.

20. The device of claim 2, wherein said platform distal end defines a generally convex shape, said convex shape has a generally elongated apex and is substantially symmetrical thereabout, said convex shape defining two substantially planar surfaces with said elongated apex defining a common distal

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

21. The device of claim 20, wherein one of said two surfaces has a platform distal end periphery defining a platform protruding surface slightly protruding away therefrom, said sheath aperture having a shape to generally assume a perimeter of said platform protruding surface, the other of said two surfaces being fully covered by said sheath when in said folded configuration and being customizable in-situ to the shape of a cavum concha of the individual corresponding to the ear canal.

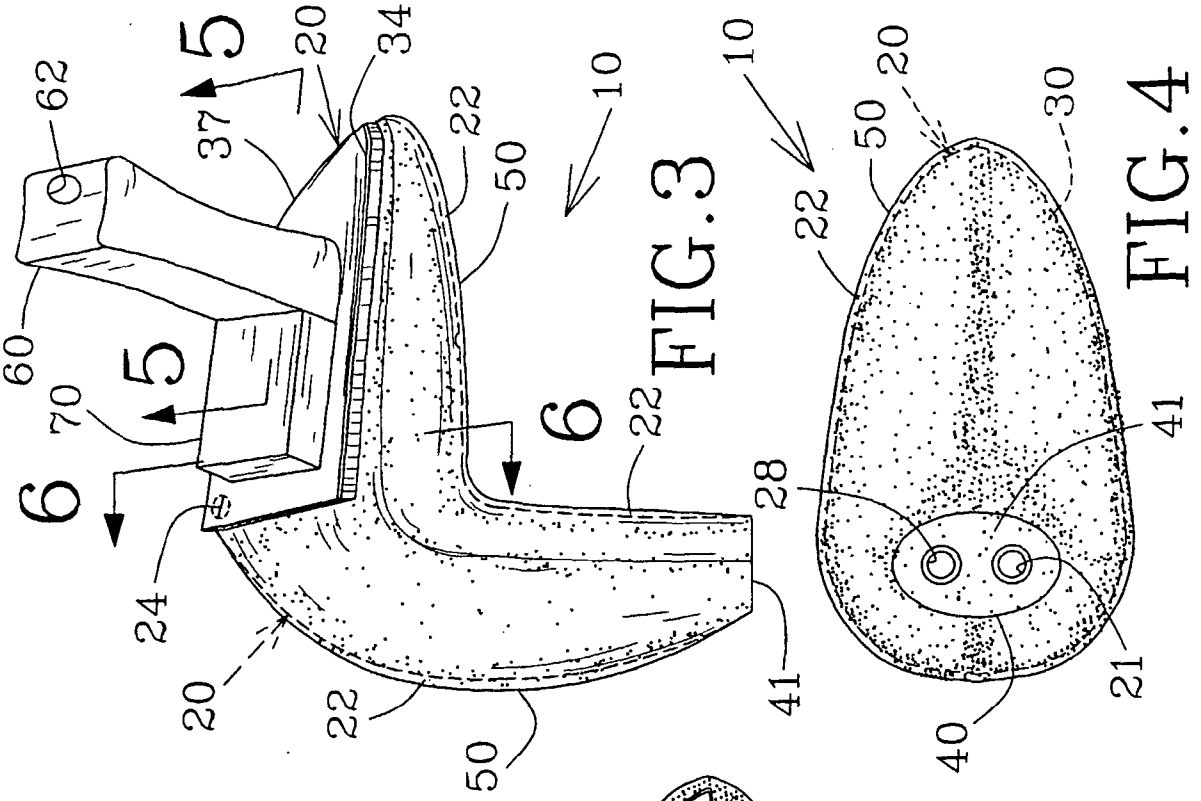


FIG.3

FIG.4

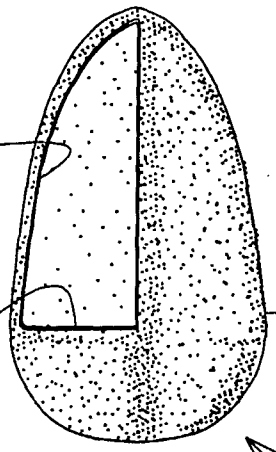


FIG.2

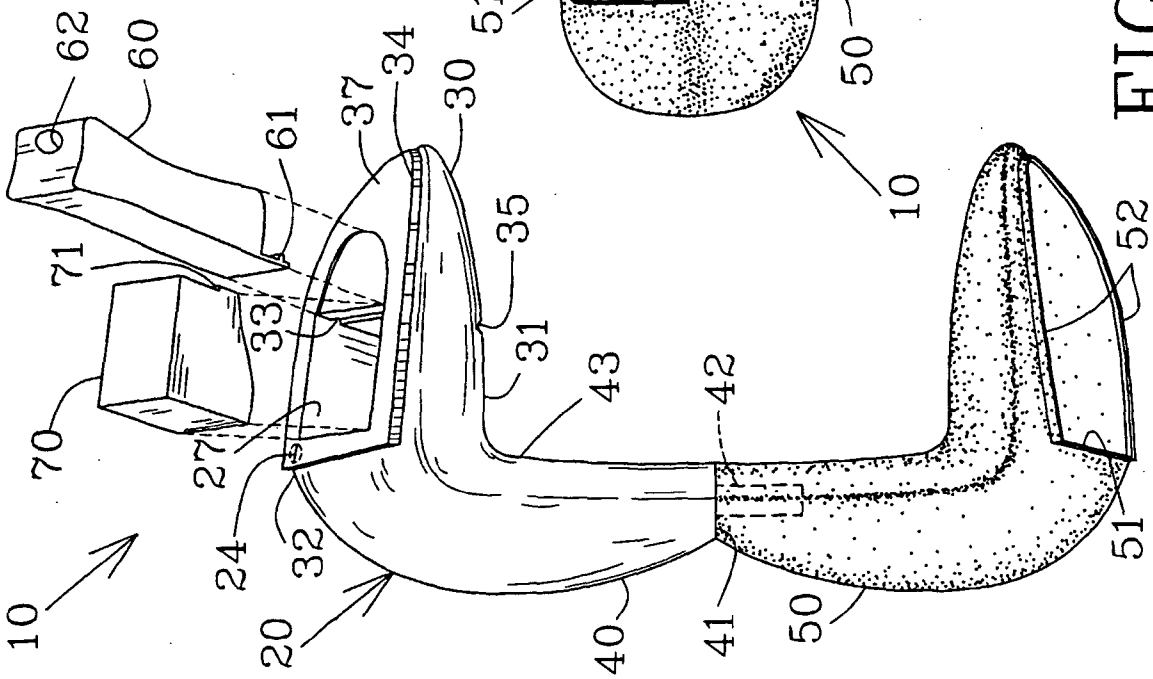
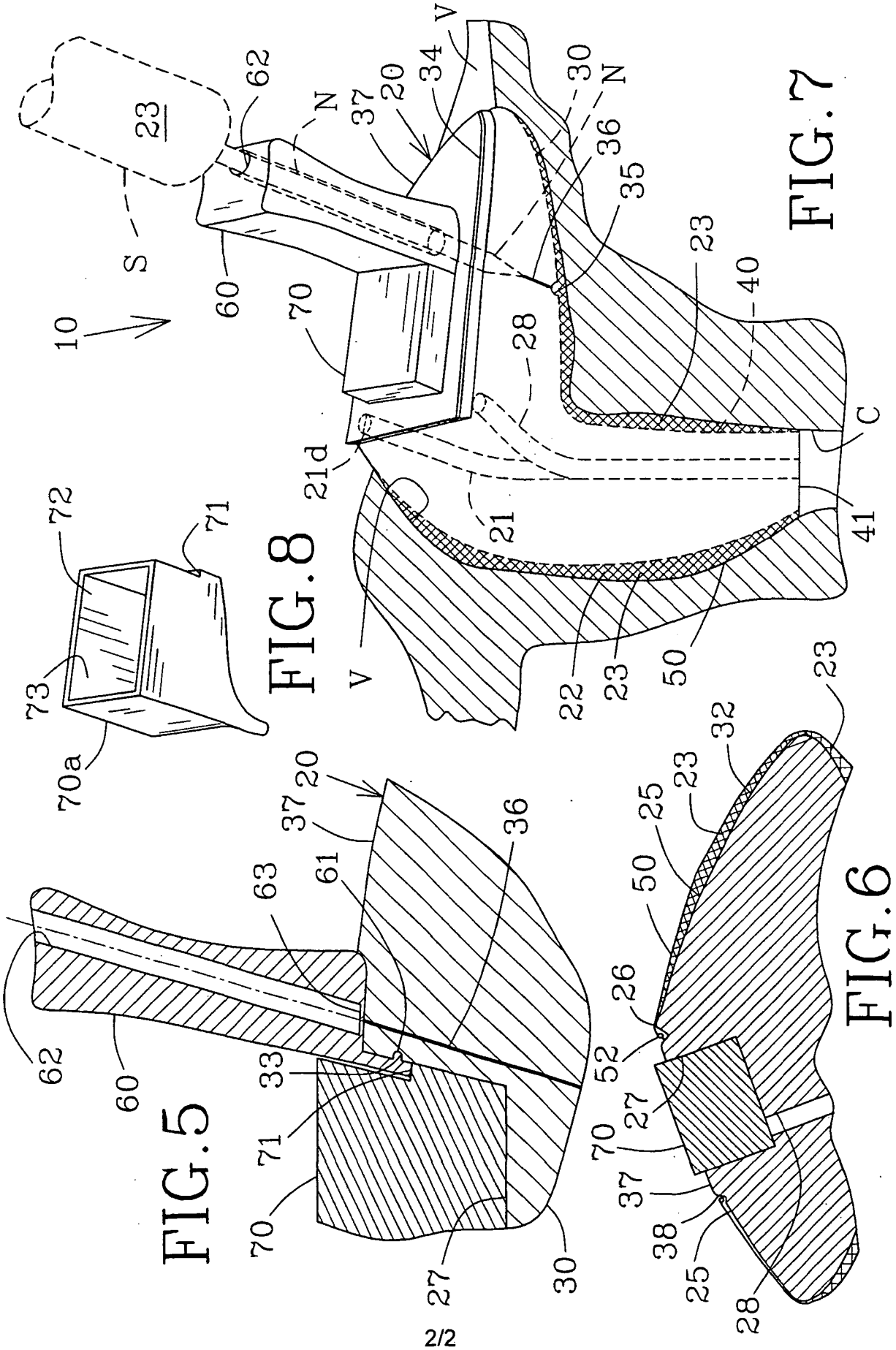


FIG.1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V
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C
21d
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72
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70a
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FIG.5
FIG.8
FIG.7
FIG.6
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