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(54) **MIDDLE EAR DIRECT ACTION IMPROVED HEARING AID AND RELATED INSTALLATION METHOD**

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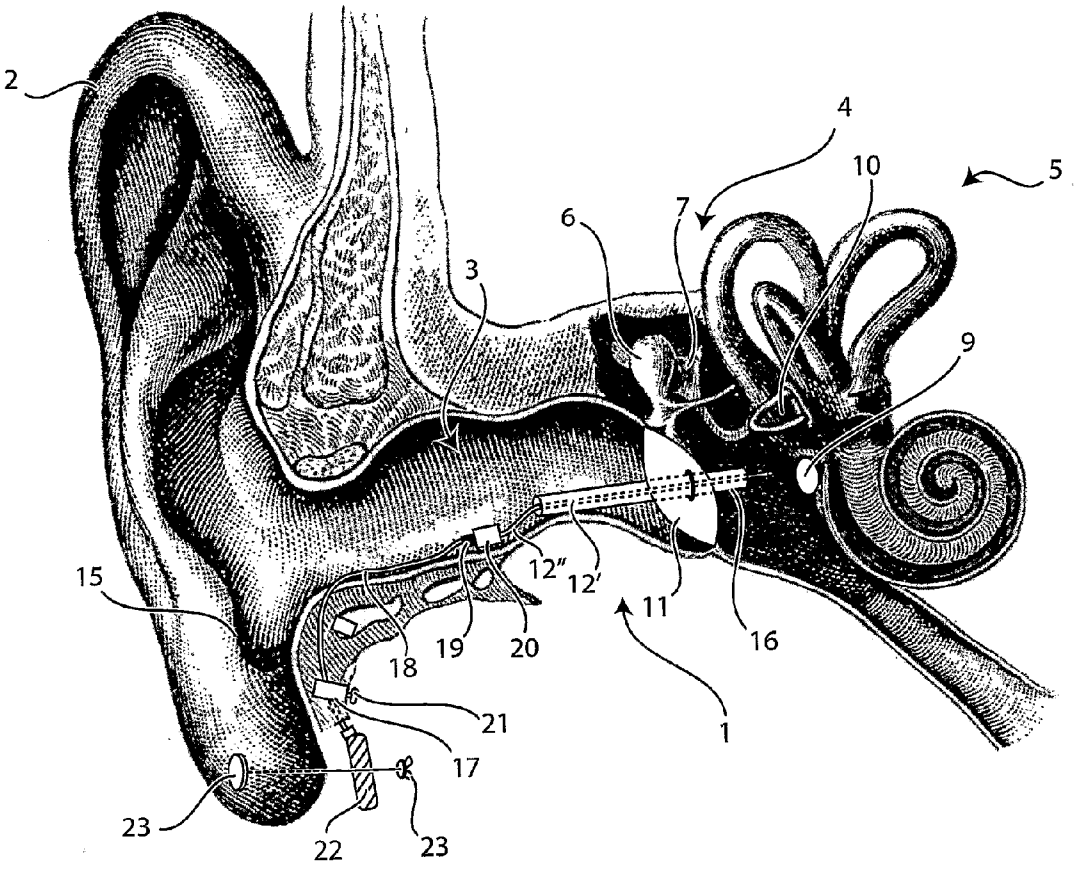
(57) **ABSTRACT**

The present invention relates to an improved acoustic prosthesis (**1**) having a direct action of medium ear, comprising a tubular shaped conveyor (**12**), canalising acoustic waves; at least a microphone picking up surrounding sounds; and amplifier, electrically connected with said microphone for amplifying picked up sounds at a suitable level; at least an audio transducer connected with said amplifier and said conveyor (**12**), said transducer transforming electric signals arriving from said acoustic wave amplifier, said acoustic waves being conveyed in said conveyor (**12**); and supply means for said amplifier and for said microphone; said acoustic prosthesis (**1**) being characterised in that said conveyor (**12**) comprises a main portion (**12'**), one end (**12'***a*) of which can be placed within the medium ear (**4**) while its other end (**12'***b*) can be placed within the outer ear (**3**) channel; and at least one more portion (**12"**, **12"'**) that can be coupled at the end of said main portion (**12'**) and at said at least an audio transducer. The invention further relates to a process for installing an acoustic prosthesis.



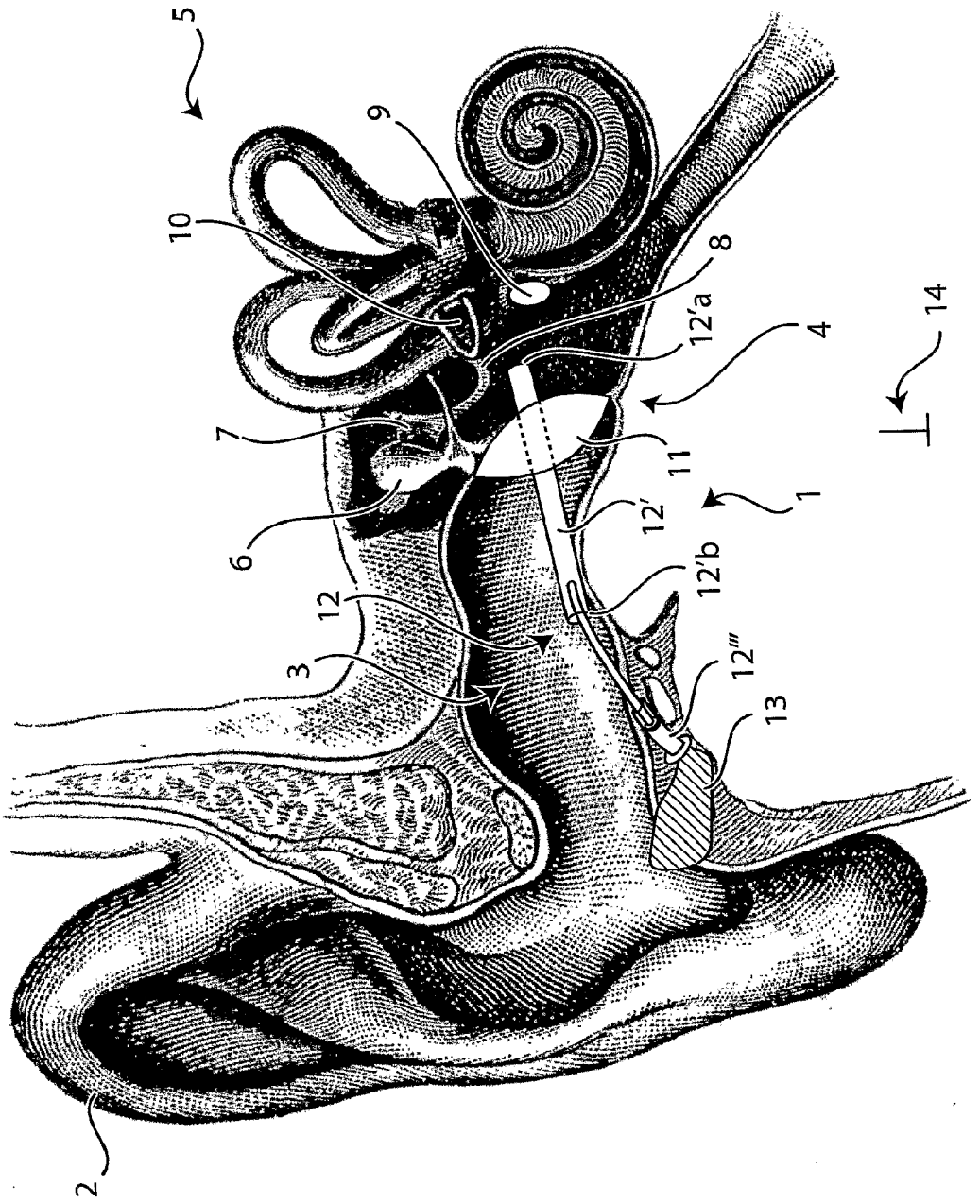


Fig. 1

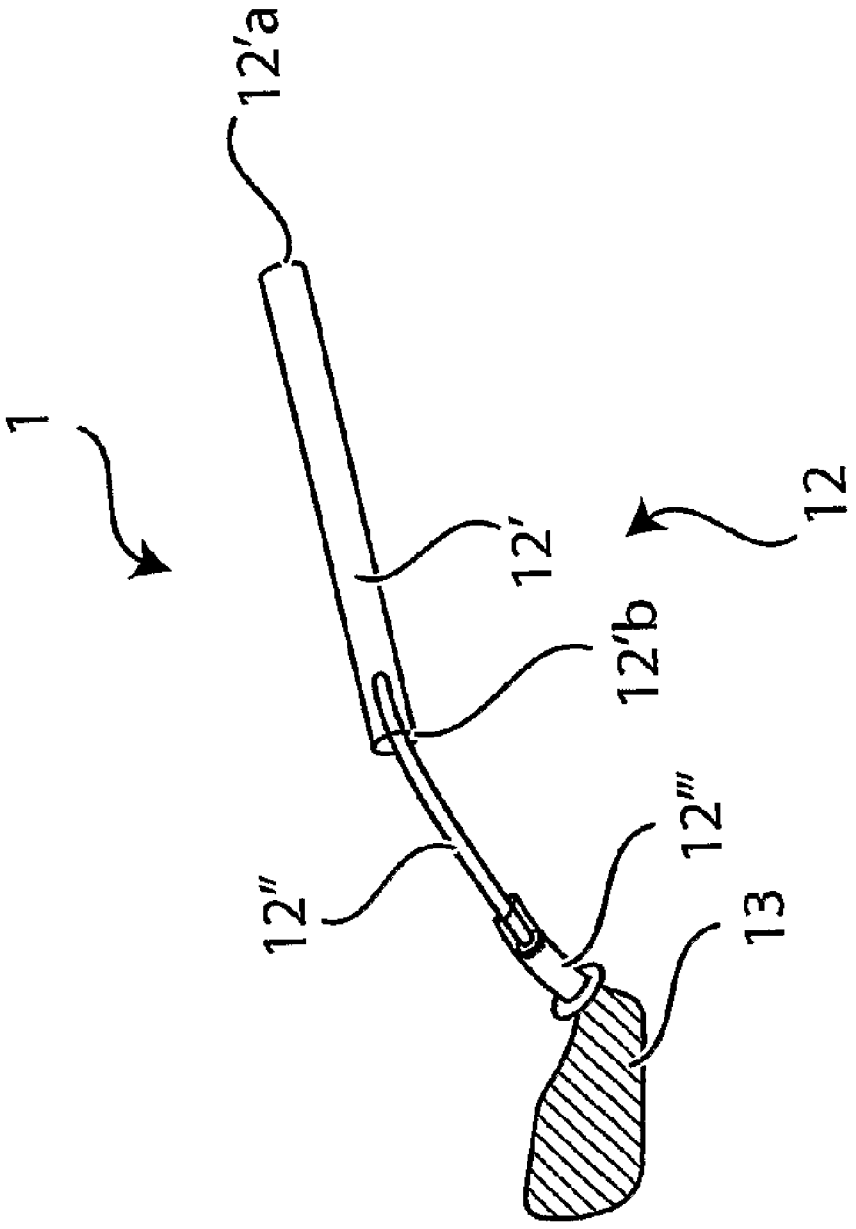


Fig. 2

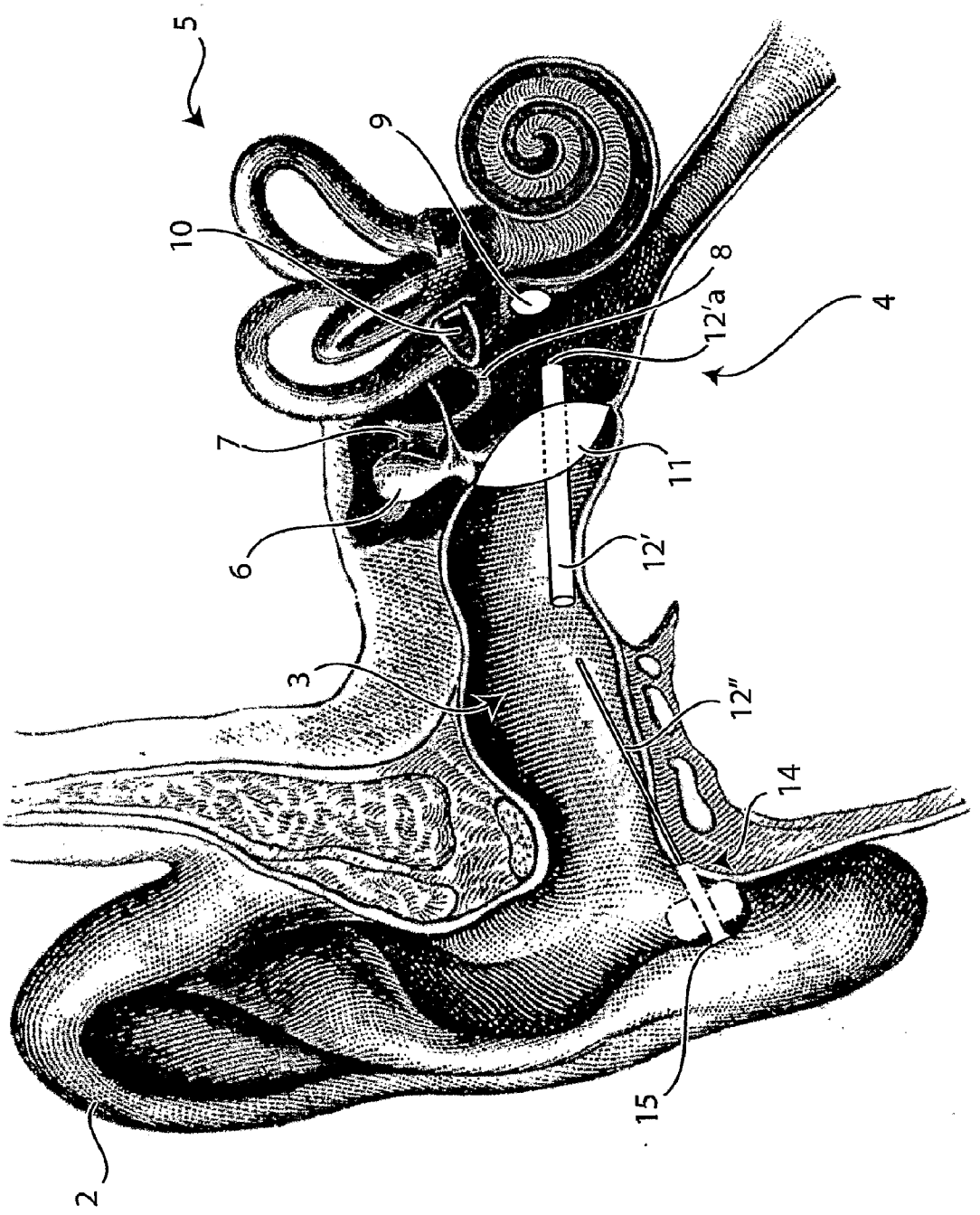
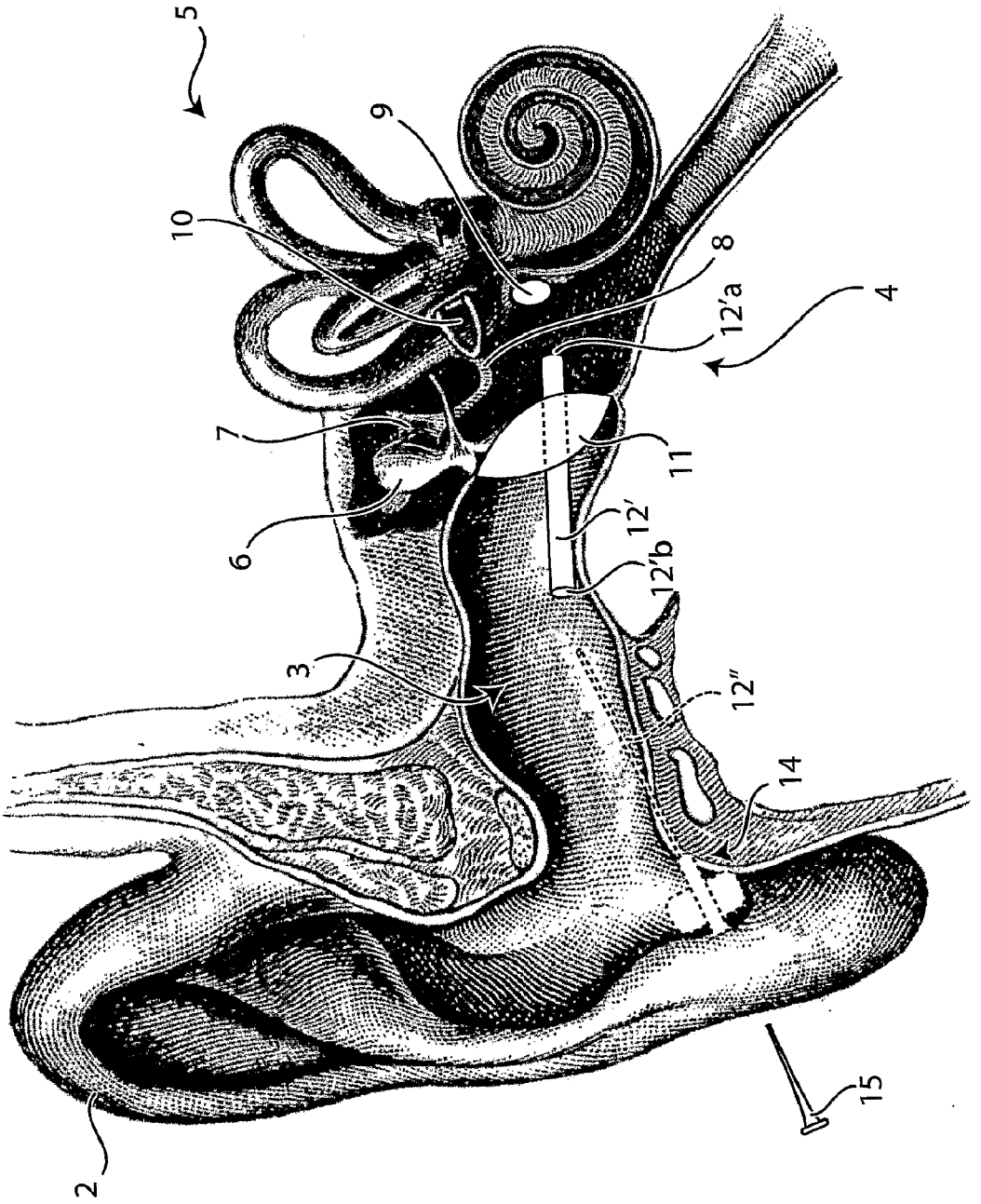


Fig. 3



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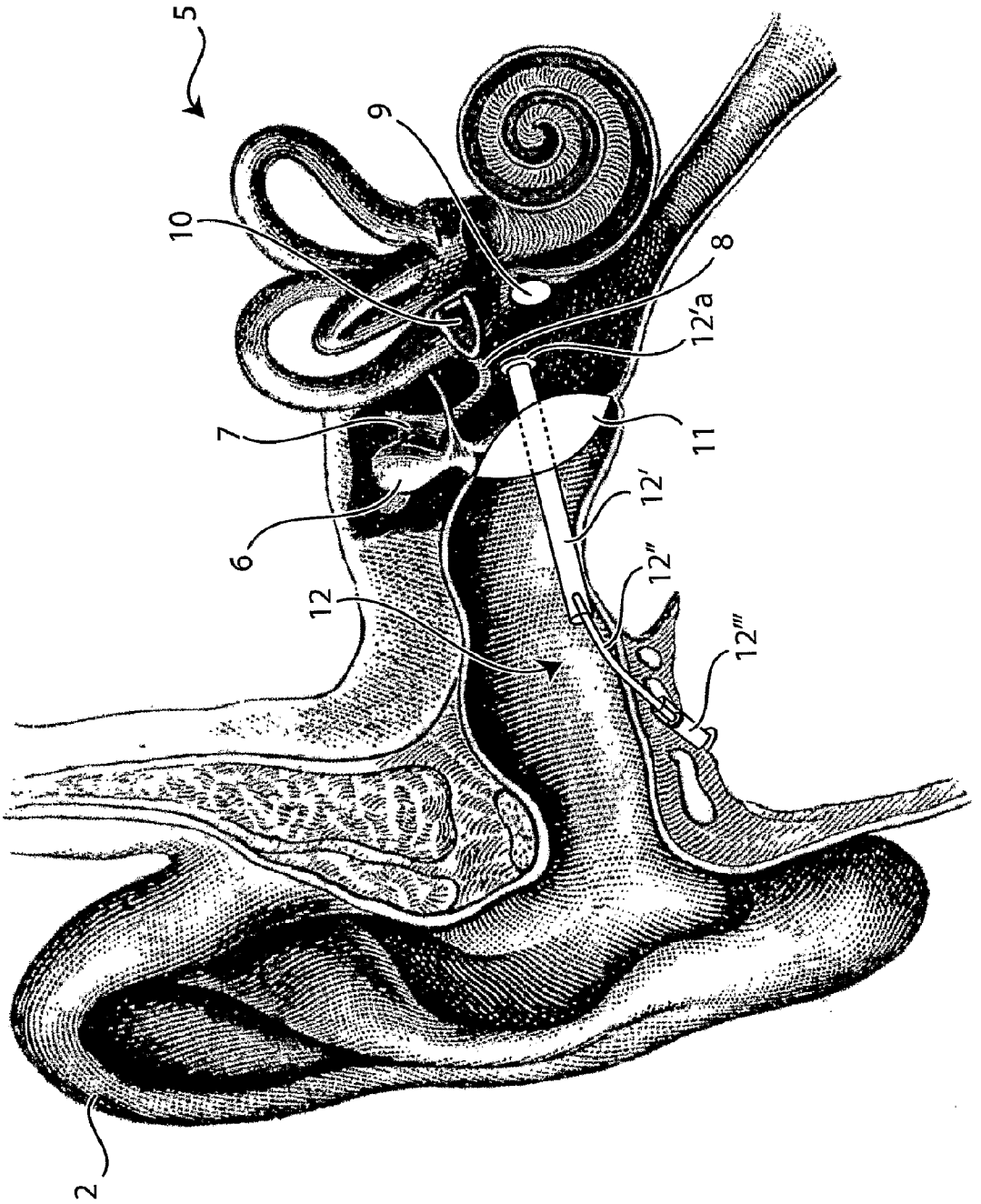

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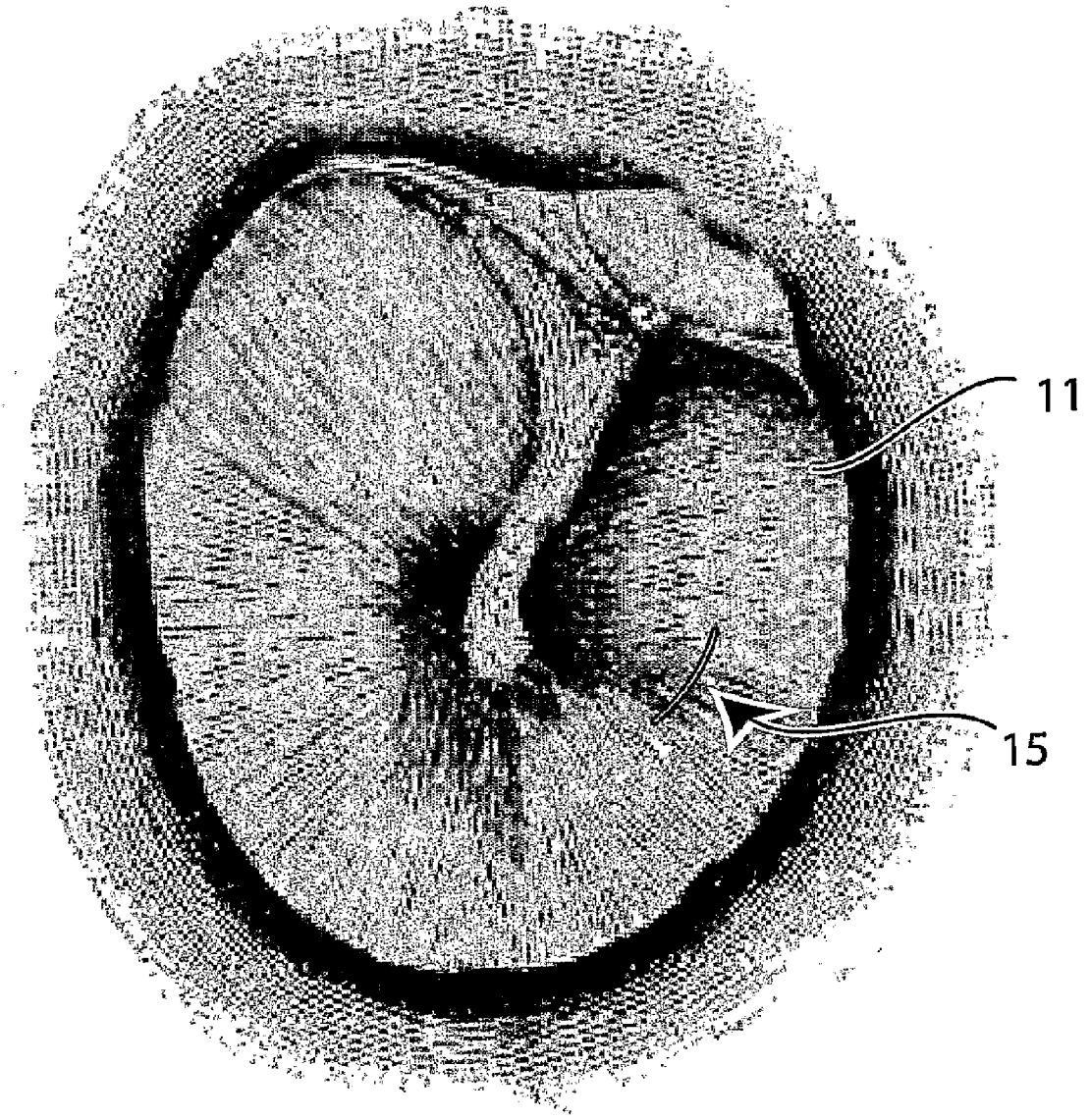

Fig. 6

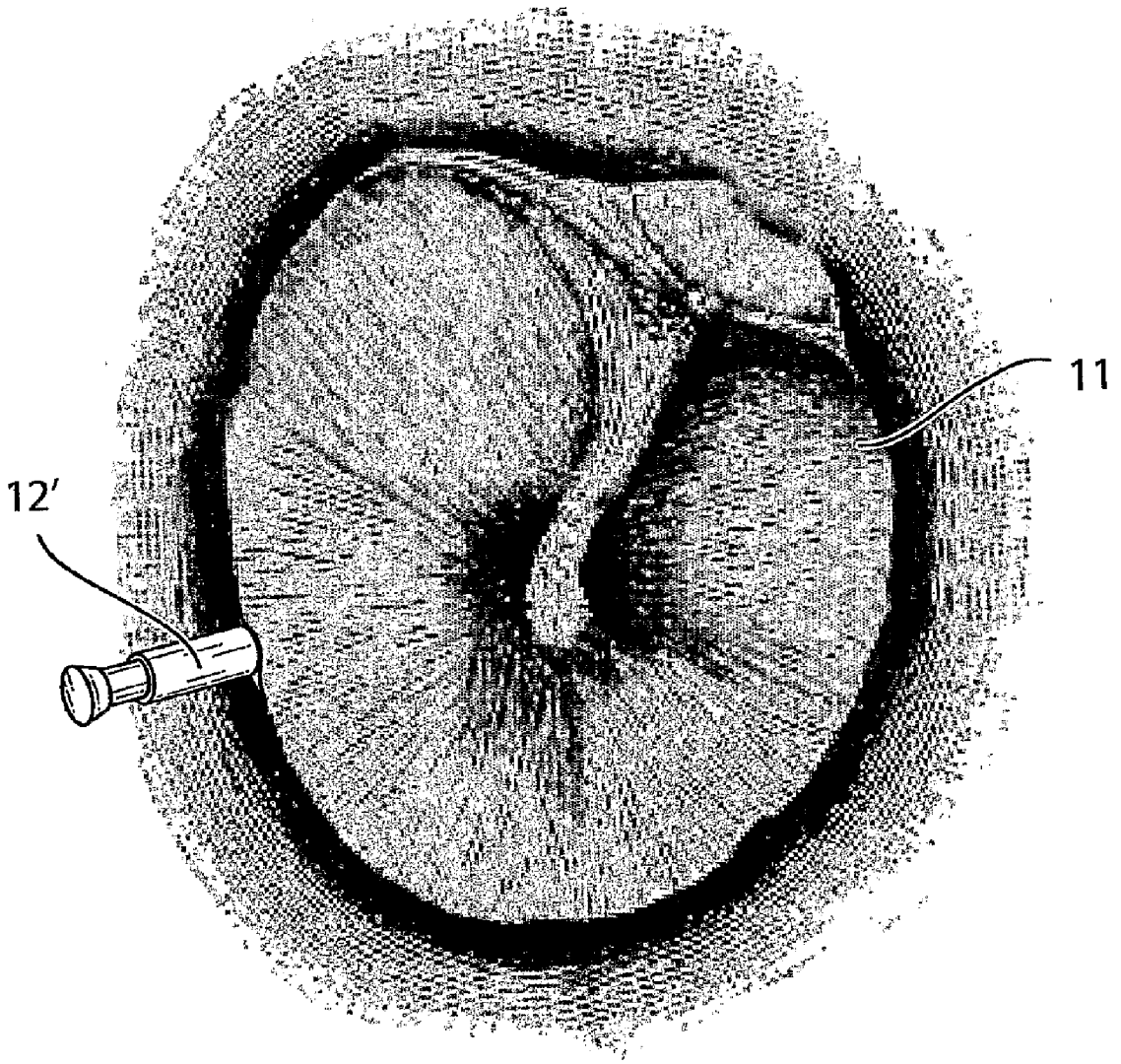

Fig. 7

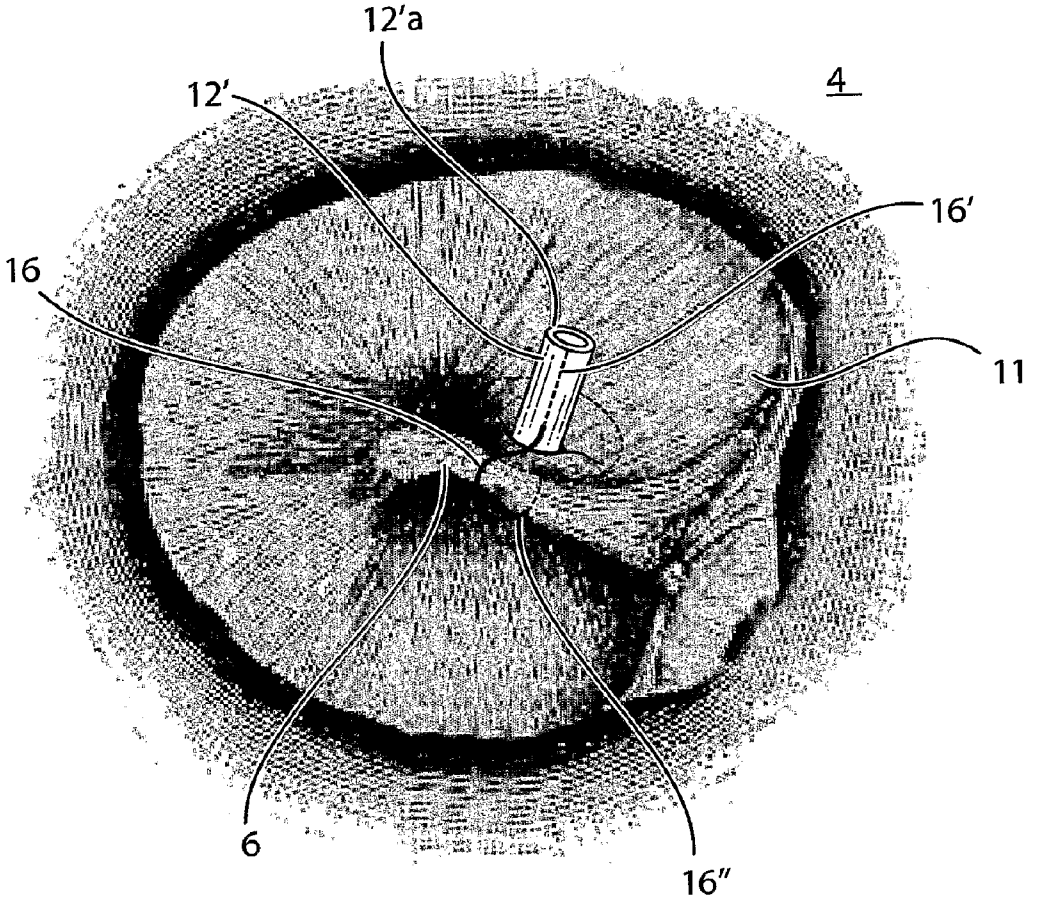

Fig. 9

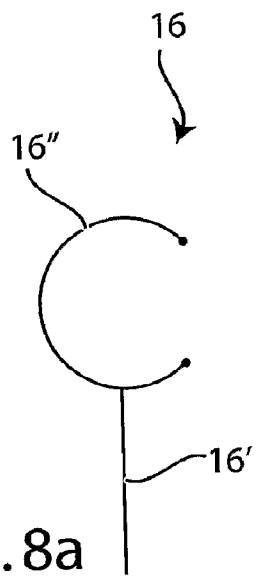

Fig. 8a

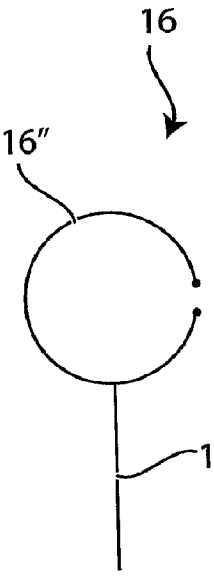

Fig. 8b

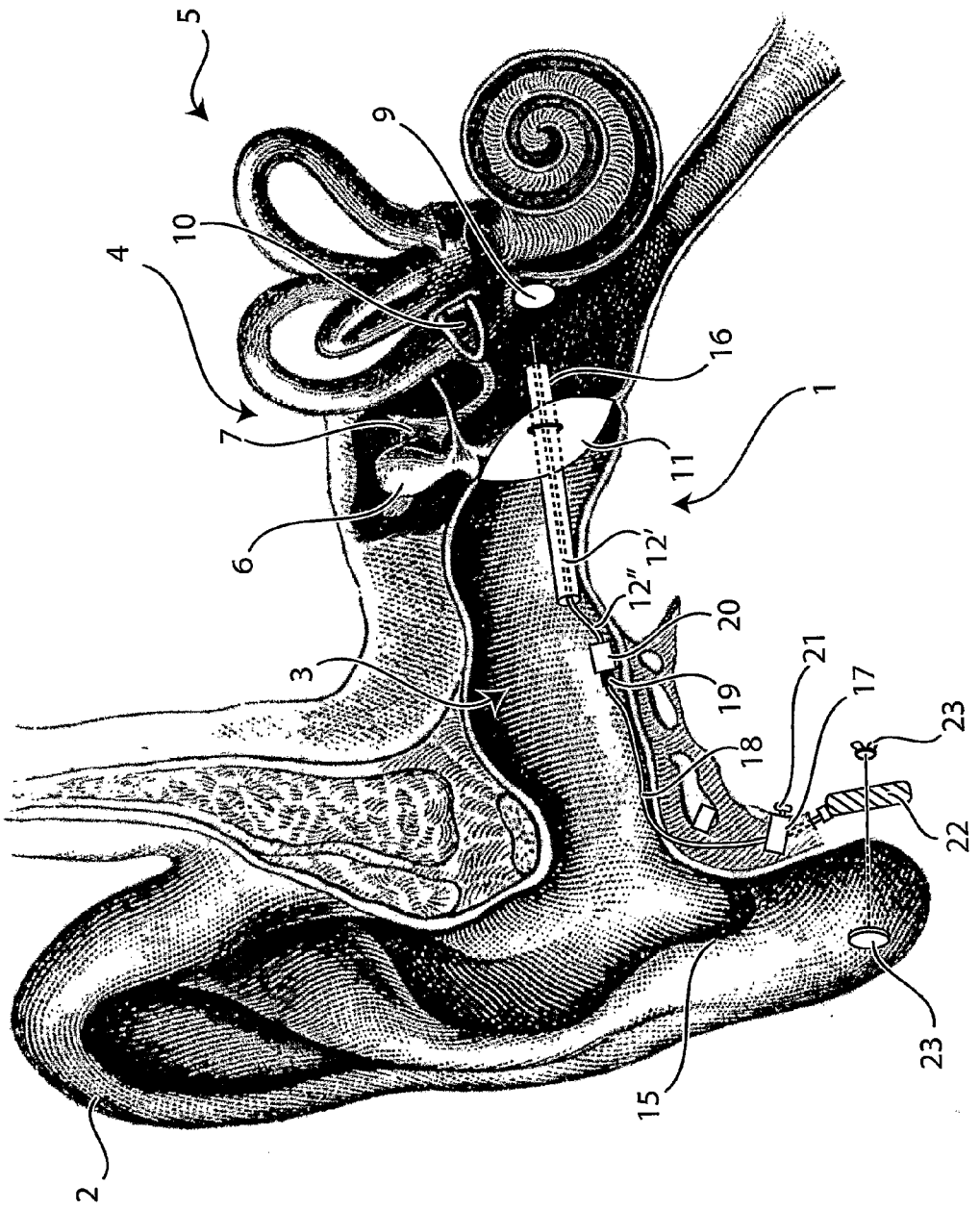

Fig. 10

MIDDLE EAR DIRECT ACTION IMPROVED HEARING AID AND RELATED INSTALLATION METHOD

[0001] The present invention relates to middle ear direct action improved hearing aid and related installation method. More specifically, the invention concerns an acoustic prosthesis having a direct action on medium ear, by-passing membrane and bones (Malleus, incus, stapes) and permitting very good use conditions by the patient on which it has been implanted, as well as a high hygiene level.

[0002] It is well known that auditory apparatus can be affected by different malfunctions. In case of a reduction of sensibility, it is a case of perceptive hypacusia, while when the medium ear is damaged, both for congenital reasons and as a consequence of chronic or traumatic infections, or due to surgical trauma, such as in case of radical or radical modified otomastoidotomy, then it is a case of transmissive/mixed hypacusia.

[0003] A large number of acoustic prosthesis is presently available in order to solve the above-mentioned pathologies. Among these, it is worthwhile mentioning those having a direct action on medium ear.

[0004] The above prosthesis having a direct action on medium ear generally comprise a microphone, possibly processing means for sound signal, a loudspeaker or acoustic transducer and a conveyor of waves that can directly reach the oval window bypassing membrane and bones. In these acoustic prostheses, electronic units (microphone, possibly processing means for sound signal, a loudspeaker or acoustic transducer) are placed within the channel of the outer ear and are connected with supply batteries by electric wires.

[0005] This kind of acoustic prosthesis has different problems for the user in case they must be at least temporarily removed. In fact, often the user must be able to remove the prosthesis from the ear, e.g. for making sport activities such as swimming.

[0006] It is necessary removing the acoustic prosthesis also for medical reasons. In fact, it is known that when exams are made, such as brain Computerised Axial Tomography (CAT) or magnetic resonance, it is not possible wearing metal objects. Thus, it is suitable that this kind of prosthesis can be easily removed by a third party, such as a doctor or a medical attendant or the same patient, for permitting to the patient to be subjected to urgent diagnostic exams.

[0007] Certain phenomenons put into evidence by studies about neurophysiopathology of audio-prosthesyzation have always more relevance, such as:

[0008] secondary adaptability or acclimatization phenomenon;

[0009] effects due to deprivation described by some researchers.

[0010] It is known that central nervous system (CNS) must get used again to reintroduction of disappeared or attenuated sounds, when they are reintroduced by amplification of auditory circuit prosthesis.

[0011] In cases of perceptive deafness, a reduction of auditory input from periphery to central nervous system occurs and it can occur an adaptation, following an acclimatising period, or a negative reaction.

[0012] As for all the various human body zones, maps exist for cerebral cortex to which neurons corresponds arriving from zones of basal membrane (Organ of Corti). Low frequencies are placed at the vertex of Archimedean screw, while high frequencies are provided at the base.

[0013] In cases of unilateral perceptive hypacusia for high frequencies, an alteration, or reduction or degeneration of nervous fibre myelin, of cells of Organ of Corti occurs, while other cells or fibres are undamaged.

[0014] Thus, after some time, due to lack of stimulation from periphery to the centre, alterations are created at the central nervous system, corresponding to the projection areas.

[0015] Reduction or lack of inhibitors inputs that should reduce spontaneous activity of central nervous system creates meaningful alterations of the same central nervous system. Thus, it is possible understanding that reintroduction of amplified sounds can find a very different environment, modified by anatomical and physiological alterations, such as:

[0016] thinning of myelin of neurons and synapses; and/or

[0017] alterations of spontaneous activity and inhibition.

[0018] Introduction of amplified sounds thus causes a remarkable reaction in a system that already adapted to a previous situation, even if a pathologic situation, and therefore adaptability period can be more or less longer.

[0019] Summarising, a reorganisation of the auditory frequencies map is created by an acoustic prosthesis, "using again" neurons that did no more reply to stimulations exerted on a damaged cochlear region. Thus it is promoted the hearing of some frequencies that can be still heard. Thus, if no more received frequencies are now restored by acoustic prosthesis, a competition will be created by their old neurons, thus determining an unbalance in coding sound maps.

[0020] Thus, reversibility phenomenon is a very important factor. But if a secondary re-adaptability with prosthesis cannot be introduced, it is generally better not insist on it.

[0021] From the above it is understood how much difficult is adaptability induced by a prosthesis in a subject affected by drop bilateral perceptive hypacusia, trying to rehabilitation maps of debilitated neurons of high frequencies, but at the same time acting also on neutrons still perfectly operating at low frequencies.

[0022] After very deepened clinical studies on patients with known prostheses, particularly prostheses described in Italian Patent n° 1294267, in the name of the same Applicants, wherein same prosthesis provided amplifier within the auditory channel along with microphone, these secondary adaptability and acclimatization phenomenons are still present, even if very low, in 25%-27% of patients.

[0023] Therefore, it has been decided that it is preferred, in order to overcome the above problems of the known prostheses, reducing at most occupation of channel, maintaining at the same time a more direct action on medium ear.

[0024] A further technical problem of known acoustic prostheses is that of anchoring of the end of conveyor end. Fixing of said element permits maintaining stable sound conveying action on medium ear nervous cells, improving user's response for secondary adaptability and acclimatization phenomenons.

[0025] At present, metal hooks are provided fixed to Malleus in order to anchor conveyor. This solution has different problems. In fact, said hooks:

[0026] can be safely difficulty coupled at the end of conveyor provided within the medium ear;

[0027] can de-couple from hooks;

[0028] being comprised of metal, they do not permit to the patient to be subjected to exams such as head CAT or magnetic resonances, for the reasons mentioned in the above; and

[0029] after some time they deteriorate Malleus.

[0030] In view of the above, it is therefore specific object of the present invention a prosthesis leaving substantially unobstructed channel of outer ear, thus improving adaptability of the user to the same prosthesis.

[0031] It is further object of the invention that of suggesting an acoustic prosthesis permitting excluding amplifier from channel, building it in outside the same in contact with battery, thus also eliminating Larssen phenomenon (prosthesis whistle).

[0032] It is another object of the invention that of permitting an efficient anchoring of conveyor of said acoustic prostheses within the medium ear.

[0033] It is therefore specific object of the present invention an improved acoustic prosthesis having a direct action of medium ear, comprising a tubular shaped conveyor, canalising acoustic waves; at least a microphone picking up surrounding sounds; and amplifier, electrically connected with said microphone for amplifying picked up sounds at a suitable level; at least an audio transducer connected with said amplifier and said conveyor, said transducer transforming electric signals arriving from said acoustic wave amplifier, said acoustic waves being conveyed in said conveyor; and supply means for said amplifier and for said microphone; said acoustic prosthesis being characterised in that said conveyor comprises a main portion, one end of which can be placed within the medium ear while its other end can be placed within the outer ear channel; and at least one more portion that can be coupled at the end of said main portion and at said at least an audio transducer.

[0034] Always according to the invention, said prosthesis can comprise a plastic hooking element, comprising a rigid longitudinal portion and a ring fixed to one end of said rigid longitudinal portion, said rigid longitudinal portion being coupable close to said end of conveyor main portion by a piercing of the same main portion, and said ring being openable and that can be positioned about the Malleus, without eroding the same and that can be easily removed.

[0035] Still according to the invention, said end of said conveyor main portion can be suitable to be placed close to the oval window or to the round window or to the promontory of medium ear.

[0036] Advantageously, according to the invention, said conveyor main portion can be inserted under the tympanic annulus by tympanotomy under the annulus.

[0037] Always according to the invention, said conveyor main portion can be inserted through tympani by myringotomy.

[0038] Still according to the invention, said at least a further portion can be coupled with said conveyor main portion by coupling.

[0039] Furthermore according to the invention, said conveyor main portion and said at least a further portion can be telescopically coupled each other.

[0040] Preferably, according to the invention, said conveyor can be comprised of semirigid material.

[0041] Advantageously, according to the invention, at least one of said portions of said conveyor can be comprised of a Silverstein tube.

[0042] Always according to the invention, at least one of said portion of said conveyor can be comprised of a needle-cannula. An upturned Silverstein tube is coupled on needle-cannula, on which spout of the same prosthesis is inserted.

[0043] Advantageously, according to the invention, said prosthesis can comprise a connector having a first and a second elements, that can be mechanically removably coupled, said connector being suitable to connect said at least further portion with said at least audio transducer.

[0044] Preferably, according to the invention, said connector can be comprised of gold.

[0045] Still according to the invention, said prosthesis can comprise a unit, wherein said at least a microphone, said amplifier, said at least an audio transducer and said supply means are integrated; and in that said conveyor comprises a second portion that can be coupled with said main portion and a third portion that can be coupled with said second portion and with said unit, said portion being closable by a closure element when said unit is separated with respect to said conveyor.

[0046] Furthermore according to the invention, said closure element can be comprised of a Silverstein spindle and thus waterproof.

[0047] Advantageously, according to the invention, said unit can be placed under the ala auris.

[0048] Always according to the invention, said prosthesis can comprise a first unit wherein said at least a microphone and said amplifier are integrated, said first unit comprising a further conveyor suitable to convey surrounding sound waves on said microphone, said first unit can be positioned under the skin, under and behind ala auris of the prosthesis user, so that said further conveyor can surface from skin; and a second unit comprising said at least an audio transducer, said second unit can be positioned within the outer ear channel and connected with said first unit by electric cables; and in that said supply means are connected by electric cables to said first unit, that can be positioned behind the ear and that can be fixed by a ear-ring to the ala auris; and said conveyor comprising a second portion that can be coupled at its first end with said main portion and at its second end with said second unit.

[0049] Still according to the invention, said first unit and said second unit can be connected by a releasable connector.

[0050] Furthermore, according to the invention, said prosthesis can comprise signal processing means connected with said microphone, filtering audio frequencies.

[0051] Preferably, according to the invention, said signal processing means are digital means.

[0052] Advantageously, according to the invention, said prosthesis can comprise adjustment means connected with said amplifier.

[0053] Always according to the invention, said adjustment means can comprise a trimmer.

[0054] Still according to the invention, said supply means can comprise a battery, preferably a rechargeable battery.

[0055] It is further object of the present invention, a process for installing an acoustic prosthesis having a direct action on the medium ear, characterised in that it comprises the following steps:

[0056] (a) placing end of first portion of a conveyor;

[0057] (b) introducing a needle-cannula in the rear lower portion of the channel through the skin and not through cartilage, said needle-cannula comprising a needle and a cannula suitable to realise the second portion of conveyor;

[0058] (c) removing needle of needle-cannula;

[0059] (d) introducing cannula within end of first portion of conveyor; and

[0060] (e) coupling a unit to said conveyor.

[0061] Always according to the invention, said process can comprise the step of making a myringotomy or a tympanotomy of medium ear annulus before step (a) for positioning the end of said conveyor first portion within medium ear.

[0062] Still according to the invention, said process can further comprise the following step:

[0063] (f) positioning a third portion of said conveyor coupled with said second portion and said unit.

[0064] The present invention will be now described, for illustrative but not limitative purposes, according to its preferred embodiments, with particular reference to the figures of the enclosed drawings, wherein:

[0065] FIG. **1** shows a lateral view of auditory channel with a first embodiment of improved acoustic prosthesis according to the present invention acting directly on medium ear;

[0066] FIG. **2** shows a lateral view of acoustic prosthesis of FIG. **1**;

[0067] FIG. **3** shows a first step of process for applying the acoustic prosthesis according to the invention;

[0068] FIG. **4** shows a second step of process for applying the acoustic prosthesis according to the invention;

[0069] FIG. **5** shows a third step of process for applying the acoustic prosthesis according to the invention;

[0070] FIG. **6** shows a tympanic membrane to which a myringotomy is made for positioning a conveyor;

[0071] FIG. **7** shows a tympanic membrane to which a tympano patreatment is made under annulus for positioning a conveyor;

[0072] FIG. **8***a* shows a Cousse prosthesis open;

[0073] FIG. **8***b* shows a Cousse prosthesis closed;

[0074] FIG. **9** shows a Cousse prosthesis applied to a Malleus; and

[0075] FIG. **10** is a section lateral view of auditory channel to which it is applied a second embodiment of the improved acoustic prosthesis according to the invention directly acting on medium ear.

[0076] Making reference to FIGS. **1** and **2**, it is possible observing a first embodiment of the acoustic prosthesis **1**.

[0077] Particularly, FIG. **1** shows a section of human auditory apparatus, from which it is possible observing ala auris **2**, channel of outer ear **3**, medium ear **4** and inner ear **5**.

[0078] Bones of medium ear are put into evidence, namely Malleus **6**, incus **7** and stapes **8**, oval window **9** and round window **10**. As it is well known, Malleus **6** is mechanically coupled with tympanic membrane **11**.

[0079] Acoustic prosthesis **1** comprises a conveyor **12**, coupled with unit **12**, in which a microphone, permitting picking up surrounding sounds, and an amplifier, for amplifying sounds picked up by said microphone, are integrated. It is also present an audio transducer, such as a loudspeaker, connected with said amplifier, the sound waves of which are conveyed, through said conveyor **12**, within the medium ear **4**.

[0080] Acoustic prosthesis **1** can also comprise an inner processing unit for digital signal, particularly suitable to filter audio signal.

[0081] Amplifier, microphone and possible signal inner processing unit are electrically supplied by a battery integrated within unit **13**.

[0082] Said conveyor **12** comprises a first portion **12'**. End **12'***a* of which can be positioned within medium ear **4**, and a second portion **12"**. End **12'***a* can be positioned within medium ear by myringotomy, passing through tympanic membrane **11** (as in FIG. **1**) or under tympanic annulus, by tympanotomy under annulus.

[0083] Within medium ear **4**, said end **12'***a* can be preferably positioned close to oval window **10** or close to round window **9**.

[0084] First portion **12'** and second portion **12"** can be coupled each other. Particularly, in the present embodiment, said second portion **12"** is coupled by coupling within said first portion **12'** in said first end **12'***a*.

[0085] Other end of second portion **12"** is coupled in a third conveyor portion **12'"** connected with unit **13**.

[0086] First conveyor **12** portion **12'** can be comprised of a Silverstein tube.

[0087] Prosthesis **1** provides positioning only conveyor **12** in channel of outer ear **3**. It permits obtaining the following advantages:

[0088] wires and electric cables from channel to outer ear **3** are no more necessary,

[0089] outer ear **3** channel remains substantially free. In fact, first conveyor **12** portion **12'** of outer ear **3**. i.e. Silverstein tube, comes out from channel **3** skin only for 1-2 mm;

[0090] unit **13** can be easily handled by the user.

[0091] Prosthesis **1** can be tuned and generally managed by an audio-prosthesis technician once otorhinolaryngologist has completed implant of first portion **12"** of conveyor **12**;

[0092] materials employed are sterile materials, well known in the field, already available on the market;

[0093] Larssen phenomenon is not present, thanks to the fact that amplifier contained within unit **13** is outside channel **3**;

[0094] In case user wishes swimming or has to be subjected to a CAT or magnetic resonance, it is sufficient removing outer unit **13** and closing tube of third portion **12"** of conveyor **12** by a closure element **14**, such as a Silverstein spindle.

[0095] Making now reference to FIGS. **3-5**, it is possible observing that inventive acoustic prosthesis can be easily installed.

[0096] Particularly, figures show the following installation steps:

[0097] placing end **12'***a* of first portion **12'** of a conveyor **12**, Silverstein tube, by myringotomy or tympanotomy of medium ear annulus (FIG. **3**);

[0098] introducing a needle-cannula **14**, comprising a needle **15** and a cannula that will be then the second conveyor **12** portion **12"**, in the rear lower portion of the channel through the skin and not through cartilage (FIG. **3**)

[0099] removing needle **15** of needle-cannula **14**;

[0100] introducing cannula **12"** or second conveyor **12** portion **12"** within end **12'***b* of first portion **12'** of conveyor **12**;

[0101] positioning a Silverstein tube, realising third conveyor portion **12'"**;

[0102] introducing said second portion **12"** in said third conveyor portion **12'"**.

[0103] Now, conveyor **12** is positioned between medium ear **4** and outer ear channel **3**. it is sufficient coupling unit **13** to said third portion **12'"** to complete the work.

[0104] As it can be noted, second conveyor **12** portion **12"** is a standard needle-cannula, also known as "vein-flow".

[0105] FIGS. **6** and **7** show the two main techniques by which it is possible inserting first portion **12'** of conveyor **12** within medium ear.

[0106] Particularly, FIG. **6** shows incision line **15**, to make myringotomy or tympanotomy.

[0107] Surrounding area is usually anaesthetised by 80% saturated phenol.

[0108] FIG. **7** shows instead that first conveyor **12** portion **12'** is inserted under tympanic annulus, by tympanotomy under annulus. It is observed from figure timpani **11** re-positioned and a Silverstein tube **12'**.

[0109] As already said, a very important technical problem of prosthesis with a direct action on medium ear comprising a conveyor concerns fixing ends **12'***a* of first conveyor portion **12'** within medium ear **4**.

[0110] To this end, in the present invention it is preferably used a hook element **16**, known as Cousse prosthesis, completely comprised of plastic material, illustrated in FIGS. **8***a* and **8***b*.

[0111] Cousse prosthesis **16** is well known in the otorhinolaryngology field, but it is usually used hooking it to lenticular process of incus by stapedectomy by interposition in otosclerosis. Said prosthesis is comprised of a rigid longitudinal portion **16'** and of an openable ring **16"**. Ring **16"**, once open, due to the elasticity features of material used, takes some time to close again. It permits an easy implant of the same prosthesis.

[0112] Fixing of Cousse prosthesis **16** at the end **12'**a of portion **12'** occurs, as it can be noted from FIG. **9**, "passing through said portion **12'** by rigid longitudinal portion **16'**. Then, it is possible opening ring **16"** and placing it about Malleus **6**.

[0113] Thus, conveyor **12** is fixed within medium ear **4**. further, being said Cousse prosthesis **16** comprised of plastic material, user can, for example, be subjected to Cat or magnetic resonance, without the need of removing the whole prosthesis **1**, but only outer electronic unit **13**.

[0114] FIG. **10** shows a second embodiment of an acoustic prosthesis **1** implanted according to the present invention.

[0115] It is observed conveyor **12** comprised of a first and a second portion **12'**, **12"**. End **12'***a* of said first portion **12'** is inserted within medium ear **4** through timpani **11** by myringotomy.

[0116] Acoustic prosthesis **1** comprises a first **17** and a second **20** units. Second portion **12"** is connected to said second unit **20**, containing a transducer, connected, by an electric cable **18** and a removable connector **19**, with said first unit **17**, in which an amplifier and a microphone are integrated.

[0117] As it can be observed, first unit **17** is supplied by a battery **22** that can be placed behind ear and fixed to the same by a earring **23**.

[0118] Acoustic prosthesis **1** according to the present embodiment is very discrete. Thanks to the fact that all components are waterproof, it is sufficient closing inlet conveyor **21** by closure element **14** (see FIG. **1**). User can thus immersing in water without removing any part of the prosthesis.

[0119] In any case, acoustic prosthesis **1** can be easily removed also thanks to presence of connector **19**.

[0120] In a further embodiment of the present invention, third conveyor portion **12'"** and said unit **13** can be removably connected by a connector provided with two parts:

[0121] a male element, one end of which is tightly fixed to said third conveyor portion **12'"** (plastic tube exiting from behind ear ala auris, in touch with skin);

[0122] a female element, assembled with prosthetic apparatus (unit **13** or more generally with said audio transducer), pressure fit on male element, so that patient can remove and put prosthesis very easily.

[0123] Said connector is preferably comprised of gold and can be closed by a closure element.

[0124] On the basis of the previous specification it can be observed that basic feature of the present invention is leaving outer ear channel substantially free, not altering sound, as well as permitting an efficient anchoring of conveyor.

[0125] The present invention has been described for illustrative but not limitative purposes, according to its preferred embodiments, but it is to be understood that modifications and/or changes can be introduced by those skilled in the art without departing from the relevant scope as defined in the enclosed claims.

What is claimed is:

1-30. (canceled)

31. A middle ear prosthesis device comprising:

a sensing microphone for converting an acoustic audio signal into a corresponding electrical audio signal;

a sensing amplifier for amplifying the electrical audio signal;

an audio transducer for converting the amplified electrical audio signal into a corresponding amplified acoustic audio signal; and

a sound conveyor for conducting the amplified acoustic audio signal from the audio transducer to the middle ear and including:

i. a main tubular portion having an outer end for placement in the outer ear canal and an inner end for placement in the middle ear, and

ii. an extension portion having an outer end coupleable to the audio transducer and an inner end coupleable to the outer end of the main tubular portion.

32. A device according to claim **31**, further comprising:

a hook element having a rigid longitudinal portion with:

i. a first end coupled to the inner end of the main tubular portion of the sound conveyor, and

ii. a second end having a ring adapted for positioning about the malleus in the middle ear.

33. A device according to claim **32**, wherein the hook element is a Cousse prosthesis.

34. A device according to claim **31**, wherein the main tubular portion of the sound conveyor is adapted for insertion through the tympani by myringotomy.

35. A device according to claim **31**, wherein a portion of the sound conveyor forms a Silverstein tube.

36. A device according to claim **31**, wherein the outer end of the extension portion of the sound conveyor includes a needle cannula for receiving a needle.

37. A device according to claim **31**, further comprising:

a gold connector for coupling the outer end of the extension portion of the sound conveyor to the audio transducer.

38. A device according to claim **31**, further comprising:

a closeable connector for coupling the outer end of the extension portion of the sound conveyor to the audio transducer.

39. A device according to claim **31**, wherein the closeable connector is a Silverstein spindle.

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