

INTRA COCHLEAR ADMINISTRATION DEVICE

FIELD OF INVENTION

[0001] The present invention relates to administration devices for administration inside
5 the inner ear of a patient.

BACKGROUND OF INVENTION

[0002] Nowadays, addressing hearing disorders, among which genetic diseases, necessitates a broad range of therapeutic approaches, sometimes including the
10 administration of fluids inside a patient's inner ear.

[0003] It is well known that a human ear comprises an outer ear 101 (the visible part), a middle ear 102 and an inner ear 103 (see figure 1). One of the challenge of fluids intended for the inner ear 103, is about delivering the appropriate fluid amount directly into the inner ear 103, for example into the cochlea 104. This kind of administrations is
15 challenging because the inner ear 103, is well known to be surrounded by very hard bone (called otic capsule) except for two semipermeable membranes 105, 106, which are exposed to the middle ear 102:

- the round window closed by the round window membrane (RWM) 105, and
- the oval window closed by the stapes footplate (OW) 106.

20 [0004] To summarize, the outer ear 101 captures the sound which is then transmitted to the tympanic membrane M_T for amplification and modulation by the ossicles of the middle ear 102. That enables the sound waves 200 to be carried to the inner ear 103, through the oval window 106, which then results in the movement of fluid within the cochlea 104.

25 [0005] It is well known that within the inner ear 103, there are two types of fluids:

- endolymph (in the cochlear canal), and

- perilymph (in the vestibular and tympanic canals).

Both fluids are separated by membranes, and this inner ear 103 structure thus looks somewhat like a "balloon within a balloon" arrangement. The fluid compartments containing perilymph and endolymph are isolated from the systemic circulation by a
5 blood-inner ear barrier, called blood-labyrinth barrier, consisting of tight junctions and other inter-cellular structures that limit access of molecules to inner ear targets.

[0006] Therefore, any system for the delivery of medicinal product addressing inner ear disorders 103 shall enable the administration of fluid directly into the inner ear 103 (in particular directly into the cochlea 104); the most accessible and surgically validated route
10 is through the round window membrane 105.

[0007] Documents US 2021/154452 A1 and WO 2021/242926 A1 illustrate the current state of the art.

[0008] Moreover, the fluid volume to be administered must consider the need to maintain if not the homeostasis at least the volume of the perilymph (which is known to
15 be fundamental in the inner ear 103 physiology), and is thus kept relatively small, ranging from 40 to 90 μ L depending on the patients 'anatomy. The flow rate should also be controlled very precisely, in order to optimize precision on the administered volume, and therefore the dose. This will prevent from high pressure that could damage the inner structure, in particular the hair cells.

20 [0009] In this context, the invention is intended to propose a catheter specifically conceived ENTs use in a surgical environment to access patient's inner ear, regardless of the anatomy, and perform a discrete and/or punctual small volume administration, while limiting procedure-related risks. "ENT" stands for "Ear, Nose and Throat" professionals, which is the common calling of otolaryngologist surgeons. Furthermore, the design of the
25 invention proposes a device which can be connected to active devices which, in association, ensure increased and optimized control on the administration key parameters, being the administration volume and flowrate.

SUMMARY

[0010] This invention thus relates to an elongated passive administration device configured to be introduced inside the cochlea of a patient's ear, said administration device extending along a fluid administration axis X and comprising a fluidic conduct
5 with three sections arranged along the fluid administration axis X, each section presenting an inner diameter and an outer diameter:

- an up-flow section with a first inner diameter and a first outer diameter,
- a middle section with a second inner diameter and a second outer diameter,
- a downflow section configured to be introduced inside the patient's ear with the
10 third inner diameter and a third outer diameter,

wherein the first inner diameter is smaller than the third inner diameter, and the first outer diameter is larger or equal than the third outer diameter.

[0011] Thus, this solution achieves the above objective. In particular, it allows to obtain a device presenting a variable inner diameter/outer diameter ratio enabling an improved
15 control of flexibility and administration pressure, thus improving administration safety.

[0012] The device according to the invention may include one or more of the following characteristics, taken in isolation from one another or in combination with one another:

- the third inner diameter of the downflow section is the same than the second inner diameter,
- 20 - the first outer diameter is larger than the third outer diameter,
- the elongated administration device may comprise a transition section with an up-flow extremity connected to the up-flow section and a downflow extremity connected to the middle section, the transition section presenting an increasing inner diameter, said inner diameter being equal to the first inner diameter at the
25 up-flow extremity and equal to the second inner diameter at the downflow extremity of the transition section,
- the outer diameter of the transition section may be equal to the first outer diameter,
- the elongated administration device may comprise a sealing section or part with an up-flow extremity connected to the middle section and a downflow extremity
30 connected to the downflow section, the sealing section or part presenting a

- decreasing outer diameter, said outer diameter being at least equal to the first outer diameter at the up-flow extremity and equal to the third outer diameter at the downflow extremity of the sealing section or part,
- the elongated administration device may comprise a sealing section or part with an up-flow extremity connected to the middle section and a downflow extremity connected to the downflow section, the sealing section or part presenting a decreasing outer diameter, said outer diameter being at least equal to the first outer diameter at the up-flow extremity and slightly larger to the third outer diameter at the downflow extremity of the sealing section or part,
 - the outer diameter of the up-flow extremity of the sealing section or part may be larger than the first outer diameter,
 - the inner diameter of the sealing section or part may be equal to the second inner diameter,
 - the sealing section or part may present a general conical shape,
 - the downflow extremity may present a tip with a flat edge,
 - the downflow section may present at least one depth marker,
 - the up-flow section may present a flexibility lower than a flexibility of the downflow section,
 - the first outer diameter from 0,6 to 2mm, and the first inner diameter may range from 0,1mm to 0,2mm,
 - the second outer diameter may range from 0,5 to 2mm,
 - the second inner diameter may range from 0,25mm to 0,35mm,
 - the third inner diameter may range from 0,25mm to 0,35mm,
 - the third outer diameter ranges from 0,5 to 0,7mm,
 - the up-flow section may comprise, at an up-flow extremity, a connection portion presenting an outer thread configured to connect the administration device to an active administration device.

[0013] The present invention further has for object an administration kit comprising an elongated passive administration device presenting at least one of the technical features presented here-above, and an active administration device configured to be connected to said elongated passive administration device.

[0014] The present invention also has for object an administration method. It is carried out by means of the administration kit mentioned here-above, comprising following steps:

- connecting the connection portion of the up-flow section to an active administration device, said active administration device comprising fluid to be administered,
- priming the device,
- performing a visual control of the absence of air or bubbles in the fluidic conduct after the priming has been performed,
- getting rid of any residual air/bubbles,
- placing the downflow section of the administration device in the administration site of the patient's ear,
- activating the active administration device and administering the fluid to be administered through the passive administration device towards the inner ear of the patient.

15 BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The invention will be better understood, and other aims, details, characteristics and advantages thereof will emerge more clearly on reading the detailed explanatory description which follows, of embodiments of the invention given by way of illustration, purely illustrative and non-limiting examples, with reference to the accompanying drawings:

- **figure 1** is schematical diagram of a human ear,
- **figure 2** is a schematical diagram of the administration device according to the invention inserted inside the ear of a patient,
- **figure 3** is a perspective view of one embodiment of a device according to a first embodiment of the present invention,
- **figures 4a, 4b, 4c, and 4d** are transversal views of, respectively, the up-flow section, the middle section, the sealing section and the downflow section according to the first embodiment the present invention,
- **figure 5** is a perspective view of one embodiment of a device according to a second embodiment of the present invention,

- **figures 6a, 6b, 6c, 6d and 6e** are transversal views of, respectively, the up-flow section, the middle section, the sealing section and the downflow section according to a second embodiment of the present invention,
- **figures 7a, 7b, 7c** are transversal views of a transition section 18 according to the
5 second embodiment,
- **figures 8a, 8b, 8c** are schematic longitudinal transparent views of the transition section according to figures 7a, 7b, 7c,
- **Figures 9a, 9b and 9c** are schematic views of a sealing section according to the embodiment of figure 5 of the present invention,
- 10 - **Figure 10** is a longitudinal schematic section view of a transition section according to a different embodiment than figures 3 and 5 of the present invention,
- **Figure 11** is an administration kit according to the present invention.

DETAILED DESCRIPTION

15 [0016] As can be seen on figures 2, 3 and 11, this invention thus relates to an elongated passive administration device 10 configured to be introduced inside the cochlea 104 of a patient's ear 100.

20 [0017] As can be seen on figure 1, the cochlea 104 is a spiraled, hollow, conical chamber surrounded by bone, in which sound waves propagate 200 from the base (near the middle ear 102 and the oval window 106) to the apex. For humans, the spiral canal of the cochlea 104 is approximately 30 mm long and makes 2^{34} turns about its axis. The cochlea 104 is the part of the inner ear 103 involved in hearing. A core component of the cochlea 104 is the organ of Corti 107, the sensory organ of hearing, which is distributed along the partition separating the fluid chambers in its spiral canal. It was found that the cochlea 104 is completely developed and has reached adult size at birth.

25 [0018] As can be seen on figure 3 the administration device 10 according to the present invention extends along a fluid administration axis X and comprises a fluidic conduct 12 with three sections 12a, 12b, 12c, arranged along the fluid administration axis X.

[0019] Preferably, the duct 12 is one single technical functional element. More preferably, the duct 12 is one single tube. One single tube can be made of several parts presenting different physical properties like flexibility.

[0020] Each section 12a, 12b, 12c presents an inner diameter D_{11} , D_{12} , D_{13} and an outer diameter D_{01} , D_{02} , D_{03} .

[0021] The fluidic conduct thus 12 presents an up-flow section 12a, a middle section 12b and a downflow section 12c.

[0022] Considering the difficulty to access and the shape variability of the intended administration destination, the downflow section 12c is configured to be flexible, ideally more flexible than a thin cochlear implant electrode array. Considering the usability of the device 10 and of the conduct 12 in particular, the up-flow section 12a part is configured to be less flexible than the downflow section 12c. However, flexibility is an important technical issue regarding the manipulation comfort and ease for the operator and thus the safety for the patient. In other words, regarding the flexibility of the duct 12: a balance has to be found between the willingness to have enough flexibility for manipulation and the risk for the duct 12 to be too loose and thus presenting the risk to fall back.

[0023] The global tubular flexibility of the duct 12 is affected by the different inner and outer diameter ratios and by the material used. This ratio is also referred to as the tube wall thickness. A thinner wall thickness results in a more flexible duct 12, while a thicker wall thickness will result in a stiffer duct 12.

Ratios Inner/Outer	D_{11}/D_{01}	D_{12}/D_{02}	D_{12}/D_{20a} OR D_{12}/D_{21a-22}	D_{12}/D_{03}
Example value	3/16	3/8	3/14	1/2
Potential range	2/16 up to 4/16	3/7 up to 3/9	2/14 up to 4/14	2/5 up to 3/5
Material	Pebax	Silicone	Silicone	Silicone
Rational	This section is preferably more rigid than flexible in order to enhance the duct 12 stability during administration.	This section is preferably more flexible than rigid in order to facilitate the duct 12 handling during insertion.	This section is preferably more rigid than flexible to resist crushing by the surgeon's forceps.	This section is preferably more flexible than rigid in order to avoid damage to the inner ear 103.

[0024] Considering the criticality of the intended site of administration, the conduct 12 is configured to ensure biocompatibility with the patient's ear 100 tissues (all inner, middle and outer ear 101, 103) while delivering any sort of fluid to the cochlea 104. Regarding the specific case of a fluid being an adeno-associated virus (AAV) gene therapy vector-based solution, the chosen material for the duct 12 is preferably inert to or compatible with the AAV solution. In this context, the wording "inert" refers to a stability-in-use while using the AAV solution, and not necessarily to a global chemical non reactivity.

[0025] It is commonly known in the state of the art, that AAV gene therapy refers to the use of AAV vectors to deliver genetic material that are missing or damaged to target human cells. AAVs are known to be small viruses not causing disease in humans on their own, hence they are considered as ideal vector for gene therapy, in particular to address hearing disorders of genetic origins.

[0026] As can be seen on figures 3 4a, 5 and 6a, the up-flow section 12a of the conduct 12 presents a first inner diameter D_{I1} and a first outer diameter D_{O1} . Preferably, the first outer diameter D_{O1} of the up-flow section 12a ranges from 0,6 to 2mm. It is preferably constant. This range is compatible with the usual tools used for ear surgeries. Preferably, the first inner diameter D_{I1} of the up-flow section 12a ranges from 0,1mm to 0,2mm. It is preferably constant. Considering the specifics of the administration procedure (to be detailed further below), the up-flow section 12a presents a length ranging from 800 to 1000mm. This length allows the operator to be positioned outside of the operating field while:

- limiting the dead volume, and
- enabling the downflow section 12c in a sterile area of the operation room.

[0027] As can further be seen on figures 3 and 5, the up-flow section 12a may comprise, at an up-flow extremity, a connection portion 14 configured to connect the administration device 10 to an active administration device 300 (to be described further below). This connection portion 14 should enable a safe connection which renders an unwanted or accidental pullout of the passive administration device 10 from the active administration device 300. In the embodiment of figures 3 and 5, the connection portion 14 presents an

outer thread which can be screwed inside a corresponding threaded hole of the active administration device 300. This active administration device 300 could, for example, be a standard 1mL syringe. Therefore, in order to connect the duct 12 to a standard 1 mL syringe, the connection portion 14 of the up-flow section 12a of the duct 12 may be configured to allow a safe and compatible connection to a standard, commercially available, connector. In an alternative embodiment, the active administration device 300 might be an automatic or electrically driven administration pump. Strong and safe connection to such an active administration device is therefore needed.

[0028] As already mentioned, the fluidic conduct 12 further presents a middle section 12b with a second inner diameter D_{I2} and a second outer diameter D_{O2} . Regardless of the size of the first, second and third outer diameters D_{O1} , D_{O2} , D_{O3} the first inner diameter D_{I1} is preferably smaller than the third inner diameter D_{I3} . In an alternative embodiment, regardless of the size of the first, second and third outer diameters D_{O1} , D_{O2} , D_{O3} , the first inner diameter D_{I1} is preferably smaller than the second inner diameter D_{I2} . In some embodiments, the first inner diameter D_{I1} is equal to the second inner diameter D_{I2} . Preferably, the second inner diameter D_{I2} of the middle section 12b ranges from 0,25mm to 0,35mm. It is preferably constant. Preferably, the first and second outer diameters D_{O1} , D_{O2} are the same. Preferably, the second outer diameter D_{O2} of the middle section 12b ranges from 0,6mm to 2mm. It is preferably constant.

[0029] The technical advantage of the middle section 12b lies in its high flexibility compared to the up-flow section 12a, as mentioned in paragraph [0022].

[0030] Considering the small volume of fluid available (around 250 μ L), the inner diameters D_{I1} , D_{I2} shall allow the minimization of the dead volume.

Size examples	Up-flow section 12a	Middle + downflow sections 12b, 12c
Length	90 cm	10 cm
Inner Diameter	0.150 mm	0.300 mm
Actual Volume	15,9043 mm ³	7,0686 mm ³
Ratio	69% of the dead space volume for 90% of the length	31% of the dead space volume for 10% of the length

Potential range	Preferably not over 75% of the dead space volume while representing not more than 95% of the length	Preferably not lower than 25% of the dead space volume while representing not less than 5% of the length
Rational	A fluid within a tubular section is susceptible to transition from laminar to tubular flow. The transition from laminar to tubular flow is driven by the inner diameter and the flowrate. There is a risk that below 25% of the dead space volume and 5% of the length, the fluid could remain at a tubular flow state.	

[0031] The increase of diameter enables a drop in the fluidic pressure inside the duct 12 and leads to a safer fluid delivery inside the patient’s ear 100. In other word, the increasing diameter between the up-flow section 12a and the downflow section 12c of the duct 12 enables the imitation of the overpressure effect. To be more detailed, it is important to consider the fluidic pressure at the downflow section 12c of the duct 12 in order to prevent any risk of cellular damages. The pressure at the downflow section 12c of the duct 12 must thus be limited. The pressure inside the duct 12 is linked to the Hagen-Poiseuille equation, and the pressure slowly drops along the axis X of the duct 12. The equation describes the laminar flow of an incompressible fluid through a cylindrical pipe or tubular section.

[0032] The equation is as follows: $\Delta P = 8\mu LQ / \pi r^4$, where ΔP is the pressure drop across the tubular section, μ is the dynamic viscosity of the fluid, L is the length of the tubular section, Q is the volumetric flow rate, and r is the radius of the tubular section. Thus, for a constant flow rate and constant viscosity, a longer length or a thinner radius will increase the pressure drop.

[0033] The total pressure drop across both tubes is the sum of the pressure drops across each tube:

- a. $\Delta P_{total} = \Delta P_1 + \Delta P_2$
- b. $\Delta P_1 = 8 \times 0.001 \text{ Pa}\cdot\text{s} \times 0.9 \text{ m} \times 0.5\text{E}^{-10} \text{ m}^3/\text{s} / \pi(0.000075 \text{ m})^4 \approx 1.8 \text{ Pa}$
- c. $\Delta P_2 = 8 \times 0.001 \text{ Pa}\cdot\text{s} \times 0.1 \text{ m} \times 0.5\text{E}^{-10} \text{ m}^3/\text{s} / \pi(0.00015 \text{ m})^4 \approx 0.066 \text{ Pa}$
- d. $\Delta P_{total} \approx 1.8 \text{ Pa} + 0.066 \text{ Pa} \approx 1.87 \text{ Pa}$

Therefore, the total pressure drop across both tubes is approximately 1.87 Pa.

[0034] The pressure drop is decreased by doubling the radius of the distal section while maintaining a constant flow rate of fluid. By doubling the radius, the cross-sectional area

of the tubular section is quadrupled in accordance with the equation $A = \pi r^2$, where A represents the cross-sectional area and r represents the radius. As a result, the fluid velocity in the tubular section decreases by a factor of 4, in accordance with the continuity equation $Q = A_1 V_1 = A_2 V_2$, where Q represents the volumetric flow rate, A_1 and V_1 represent the cross-sectional area and fluid velocity in the initial tubular section, and A_2 and V_2 represent the cross-sectional area and fluid velocity in the doubled tubular section.

[0035] Additionally, Bernoulli's principle states that for an incompressible fluid flowing through a tubular section, the total energy of the fluid remains constant along a streamline. At the end of the tubular section the pressure is equal to the force divided by the area. By doubling the radius, the cross-sectional area of the tubular section is quadrupled in accordance with the equation $A = \pi r^2$, where A represents the cross-sectional area and r represents the radius. Therefore, the pressure at the end of the tubular section decreases by a factor of 4 due to the decrease in fluid velocity, which is proportional to the square of the pressure according to Bernoulli's principle.

[0036] The present invention with two or three inner diameters D_{I1} , D_{I2} , D_{I3} thus provides a means for regulating fluid velocity and pressure in a tubular section, and leads to a significant increase in administration safety.

[0037] The downflow section 12c of the fluidic conduct 12 is configured to be introduced inside the patient's ear 100. More particularly, as can be seen on figure 2, the downflow section 12c is configured to enter the cochlea 104 of the patient's ear 100 through the round window membrane 105. Preferably, the downflow section 12c presents a third outer diameter D_{O3} and the same second inner diameter D_{I2} than the middle-part 12b. In an alternative embodiment, the downflow section 12c presents a third outer diameter D_{O3} and a third inner diameter D_{I3} different from the second inner diameter D_{I2} . Preferably, the third inner diameter D_{I3} of the downflow section 12c ranges from 0,25mm to 0,35mm. It is preferably constant. The length of the downflow section 12c is enough to reduce the fluid velocity at the outlet of the fluidic conduct 12. The first outer diameter D_{O1} is larger than the third outer diameter D_{O3} . Preferably, the third outer diameter D_{O3} ranges from 0,5 to 0,7mm. The downflow section 12c presents a tip which could be either flat or bevelled. A flat shape is currently the most reliable shape in terms of safety and

visibility. However, a beveled shape could be an interesting option for some specific surgical approach and could help for better access and/or increasing the visibility for the surgeon in case in which angles are drastically different to the usual. A beveled shape could also appear to be preferable in case some tool had to be added to the downflow section 12c, as a beveled shape might be more adequate to connect the tool.

[0038] As mentioned above, in some embodiments, the tip 13 might be adapted for the addition (or connection) of any suitable surgery tool intended for tissue separation, puncture or cut (e.g., needle, blade). The shape of the tip 13 and the eventual tooling of said tip 13 should preferably be adapted to a canalostomy (which designates an administration through the posterior and/or lateral semi-circular canals, more precisely, a procedure during which, after a post-auricular incision from the left retro-auricular groove, and a dissection of the muscle covering the temporal bone and after drilling of the mastoid bone which enables to expose the posterior and lateral semi-circular canals (PSC and LSC), a small hole is made in the middle portion of the canal through which the administration will be performed. Regardless of the shape of the tip 13, and considering the shape and size variability of the average round window 105 in human ears 100, the cross section of the tip 13 ranges from 0,5mm to 2mm in order to enable administration both in the paediatric and adult population.

[0039] Preferably, the downflow section 12c further presents a length ranging from 4 to 15mm. In order to control the insertion depth of the downflow section 12c inside the patient's ear 100, the downflow section 12c comprises at least one depth marker 16. Said depth marker 16 can for example be a blue or black line drawn on an outer wall of the downflow section 12c (ink marking). It could also be some groove caved inside the outer wall of the downflow section 12c (physical marking). Preferably, the downflow section 12c comprises two depth markers 16. The depth markers 16 are preferably at a distance of 5mm from each other.

[0040] In order to prevent inner ear structures damages, the insertion depth of the duct 12 and therefore, the length of the downflow section 12c is limited and ranges from 4 to 15 mm.

[0041] The elongated administration device 10 according to the present invention may further comprise a transition section 18 with an up-flow extremity 18a connected to the up-flow section 12a and a downflow extremity 18b connected to the middle section 12b of the duct 12. This transition section may present different designs, depending on the
5 embodiment.

[0042] In a first embodiment, depicted in figure 3, the transition section 18 presents a variable inner diameter, more particularly an increasing inner diameter. This variable inner diameter varies from the first inner diameter D_{I1} to the second inner diameter D_{I2} preferably in a continuous way. This way, the variable inner diameter is equal to the first
10 inner diameter D_{I1} at the up-flow extremity 18a and equal to the second inner diameter D_{I2} at the downflow extremity 18b of the transition section 18. In an alternative embodiment, depicted in figures 5, 7b, 7c, 8a, 8b and 8c, the transition section 18 presents a constant diameter. In one embodiment, the transition section 18 presents, on most of its length downwards from its up-flow extremity 18a, a constant inner diameter (see figures
15 7a, 8a, 7b and 8b), corresponding to the inner diameter D_{I1} . However, at its downflow extremity 18b, its inner diameter suddenly increases to equal the second inner diameter D_{I2} (see figures 7c and 8c). In this embodiment, the transition section 18 preferably corresponds to the embedding of the middle section 12b on the up-flow section 12a (see figure 7b and 8b). This way, the inner diameter all along the transition section 18 is equal
20 to the first inner diameter D_{I1} from its up-flow extremity 18a towards its downflow extremity 18b, and equal to the second inner diameter D_{I2} at its downflow extremity 18b. In an alternative embodiment (see figure 10), the inner diameter of the transition section 18 increases and decreases in different stages. Said inner diameter thus first suddenly increases and then gradually decreases. For example, said inner diameter first goes
25 abruptly from 0,15 to 0,8mm, and from there decreases gradually (due to the deformed silicone tube) from 0,8 to 0,3mm. However, regardless of the embodiment, the inner diameter of the transition section 18 globally increases from its up-flow extremity 18a to its downflow extremity 18b.

[0043] Regardless of the embodiment, preferably, in order to present the same flexibility
30 than the up-flow section 12a, the outer diameter of the transition section 18 is equal to the

first outer diameter D_{O1} . The length of the transition section 18 is preferably between 5 to 15 mm to ensure the connection integrity.

[0044] As can be seen on figure 3, the duct 12 preferably comprises a sealing section 20 with an up-flow extremity 20a connected to the middle section 12b and a downflow extremity 20b connected to the downflow section 12c of the duct 12. The section 20 is preferably a silicone over-mold allowing the connection of the two sections 12b and 12c of the duct 12 as depicted in the figures 9a, 9b and 9c.

[0045] In the embodiment depicted on figure 3, the sealing section 20 presents a conical shape. In some alternative embodiment, it might present a conical shape with possibility of fixing a tool / gripping. In an alternative embodiment, it might present a cylindrical shape. The sealing section 20 also works as an insertion stop, preventing the downflow section 12c to be inserted too deep inside the patient's ear 100. The sealing section 20 also ensures the tightness of the fluidic conduct 12 and avoidance of leakage at the round window membrane 105 of the patient's ear 100.

[0046] The sealing section 20 thus presents a decreasing outer diameter, said decreasing outer diameter being at least equal to the first outer diameter D_{O1} at the up-flow extremity 20a of the sealing section 20 and equal to the third outer diameter D_{O3} at the downflow extremity 20b of the sealing section 20. In an alternative embodiment, the decreasing outer diameter is at least equal to the first outer diameter D_{O1} at the up-flow extremity 20a of the sealing section 20 and slightly larger (preferably below 1,4mm) than the third outer diameter D_{O3} at the downflow extremity 20b of the sealing section 20 (see figure 9c). It has to be smaller than the hole made in the round window membrane 105. Preferably, the outer diameter D_{20a} of the up-flow extremity 20a of the sealing section 20 is larger than the first outer diameter D_{O1} . The inner diameter of the sealing section 20 is equal to the second inner diameter D_{I2} . In some alternative embodiment (see figure 9c), the inner diameter of the sealing section 20 can vary gradually or abruptly from the second inner diameter D_{I2} towards the third inner diameter D_{I3} . In order to be used both during transcanal and standard transmastoid facial recess approaches (to be explained further below), and considering the diameters of classic endoscopic middle ear surgery tools

(usually up to 3 mm), the maximum outer diameter of the up-flow extremity 20a of the sealing section 20 shall be of 2,5 mm.

[0047] In some embodiments, for example depicted on figure 5, the sealing section 20 may also be a handling section. In those embodiments, the sealing section 20 comprises
5 a sealing part 21 and a handling part 22.

[0048] Similar to the first embodiment, the sealing part 21 is configured to avoid leakage once the round window membrane 105 of the patient's ear 100 is opened and is configured to works as a sealing ring.

[0049] The sealing part 21 also presents a conical shape. In some alternative
10 embodiment, it also might present a conical shape with possibility of fixing a tool / gripping. In an alternative embodiment, it might present a cylindrical shape. The sealing part 21 also works as an insertion stop, preventing the downflow section 12c to be inserted too deep inside the patient's ear 100.

[0050] Logically, the sealing part 21 thus presents a decreasing outer diameter, said
15 decreasing outer diameter being at least equal to the first outer diameter D_{O1} at the up-flow extremity 21a of the sealing part 21 and equal to the third outer diameter D_{O3} at the downflow extremity 21b of the sealing part 21. Preferably, the outer diameter D_{21a} of the up-flow extremity 21a of the sealing part 21 is larger than the first outer diameter D_{O1} . The inner diameter of the sealing and handling section 20 is equal to the second inner
20 diameter D_{I2} .

[0051] The handling part 22 presents a constant outer diameter at least equal to the first outer diameter D_{O1} and equal to the outer diameter D_{21a} . Preferably, the outer diameter D_{22} of the up-flow extremity 22a of the handling part 22 is larger than the first outer diameter D_{O1} . This ensures that the proportions ratio (hence difference of flexibility and
25 rigidity) between the two sections 12a and 12b provide optimal usability features, in alignment with the present specification in section [0019]. This enables to slightly increase the rigidity with the change of materials (i.e., different silicon) and the ratio increase.

[0052] In order to be used both during transcanal and standard transmastoid facial recess approaches, and considering the diameters of classic endoscopic middle ear surgery tools (usually up to 3 mm), the maximum outer diameter of the up-flow extremity 20a of the sealing and handling section 20 shall be of 2,5 mm.

- 5 [0053] The transcanal approach is a minimally invasive surgical technique that allows access to the middle ear 102 through the ear canal, without external incisions. It involves lifting of the tympanic membrane M_T (raising a small external ear canal flap) to access the middle ear structures. On the other hand, the standard transmastoid facial recess approach is a surgical technique used to access the middle ear 102 by creating an opening
10 in the mastoid bone and drilling away some of the bone to create a pathway to the middle ear 102. This procedure exposes to a risk of lesion of the facial nerve.

[0054] While surgery is performed and the middle ear 102 is rendered accessible to the fluidic conduct 12 of the administration device 10 according to the present invention, the administration of the fluid is being prepared. The priming of the catheter and the
15 connection between the syringe, catheter and syringe-pump will happen during the surgery. The objective is to be ready to administer as soon as the round window membrane 105 is opened. To do so, the administration device 10 according to the present invention is configured to be connected and cooperate with an active administration device 300. Such an active administration device 300 may comprise:

- 20 - an elongated container with a piston configured to comprise the fluid to be administrated and a connection system to enable the connection to the connection portion 14 of the administration device 10, and
- an activation system configured to activate the piston and enable the ejection of the fluid towards the administration device 10 and thus towards the patient's ear
25 100.

[0055] The present invention and the active administration device 300 thus form an administration kit which enables to carry out an administration method comprising following steps:

- connecting the connection portion 14 of the up-flow section 12a to an active administration device 300, said active administration device 300 comprising for example a 1mL syringe containing the fluid to be administrated,
- priming the invention,
- 5 - performing a visual control of the absence of air or bubbles in the fluidic conduct 12 after the priming has been performed (manually or mechanically via the active administration device 300),
- getting rid of any residual air/bubbles,
- placing the downflow section 12c of the administration device 10 in the
10 administration site of the patient's ear 100,
- activating the active administration device 300 and injecting the fluid through the passive administration device 10 according to the present invention towards the inner ear 103 of the patient.

[0056] Preferably just before the introduction of the device 10 in the patient's inner ear
15 100, the two last steps of surgery are performed: first, the oval window 106 (OW) is fenestrated using a laser fiber, the fenestration is called a stapedotomy. This fenestration allows to maintain the inner ear 103 volume and pression into an equilibrium state. Once the stapedotomy is performed, the round window membrane 105 (RWM) is opened with a retrobulbar needle or another sharp surgical instrument such as a taper surgical point or
20 a micro surgical hook and the small vertical opening is plugged with hyaluronic acid gel. A canalostomy, allowing an administration through the posterior and/or lateral semi-circular canals, or a cochleostomy, allowing an administration through a separate opening into the cochlea and not an extension of the RWM, could also be performed in lieu of the RWM fenestration. After that, the administration is ready to be performed, and the active
25 administration device 300 can be activated.

[0057] The administration is separated in three distinct phases:

Phase 1: Pre-administration phase. The middle ear 102 should be accessible to perform the administration. To do so, either the transcanal approach or the standard transmastoid facial recess approach is performed. The surgeon could decide to do both to get a better
30 access to the middle ear. The transcanal approach is a minimally invasive surgical

technique that allows access to the middle ear 102 through the ear canal, without external incisions. It involves lifting of the tympanic membrane M_T to access the middle ear structures. On the other hand, the standard transmastoid facial recess approach is a surgical technique used to access the middle ear 102 by creating an opening in the mastoid bone and drilling away some of the bone to create a pathway to the middle ear 102. This procedure, as already mentioned above, can lead to a lesion of a facial nerve.

Phase 2: the administration of the fluid by activating the active device 300. First, the downflow section 12c of the administration device 10 is placed in the administration site of the patient's inner ear 100, and then activating the active administration device 300 and administering the fluid through the passive administration device 10 towards the inner ear 103 of the patient. This phase preferably requires the use of Hyaluronic acid to prevent the loss of fluids and further facilitate the insertion of the administration device 10.

Phase 3: post administration. At the end of the administration, the fluidic conduct 12 is removed carefully and the round window 105 is immediately sealed using gel or with a small piece of soft tissue or fat; the same is performed for the oval window. Then, depending on the surgery approach, either a surgical glue could be put into the mastoid and resorbable sutures are set-up at the retro-auricular incision site or, for the transcanal approach the repositioning of the tympanic membrane and cutaneous flap.

[0058] In conclusion, the small diameters of the duct 12 of the present invention allow the dead volume limitation, the optimization of manoeuvrability administration, while the two or three different inner diameters D_{11} , D_{12} D_{13} ensure the limitation of the overpressure effect. More particularly, one of the main technical benefits of the present invention is to avoid the creation of an overpressure within the cochlea 104 as it's already filled with the perilymph during the procedure, despite adding supplementary fluid to it, and to avoid the risk of damaging the inner hair cells, which would result in stripping the patient from any (remaining) ability to transmit auditory information to the brain.

CLAIMS

1. Elongated passive administration device (10) configured to be introduced inside the cochlea (104) of a patient's ear (100), said administration device (10) extending along a fluid administration axis X and comprising a fluidic conduct (12) with three sections (12a, 12b, 12c) arranged along the fluid administration axis X, each section (12a, 12b, 12c) presenting an inner diameter (D_{I1} , D_{I2}) and an outer diameter (D_{O1} , D_{O2} , D_{O3}):
- an up-flow section (12a) with a first inner diameter (D_{I1}) and a first outer diameter (D_{O1}),
 - a middle section (12b) with a second inner diameter (D_{I2}) and a second outer diameter (D_{O2}),
 - a downflow section (12c) configured to be introduced inside the patient's ear (100) with a third inner diameter (D_{I3}) and a third outer diameter (D_{O3}),
- wherein** the first inner diameter (D_{I1}) is smaller than the third inner diameter (D_{I3}), and the first outer diameter (D_{O1}) is larger than or equal to the third outer diameter (D_{O3}).
2. Elongated administration device (10) according to the precedent claim, **wherein** the third inner diameter (D_{I3}) of the downflow section (12c) is the same than the second inner diameter (D_{I2}).
3. Elongated administration device (10) according to anyone of the precedent claims, **wherein** the first outer diameter (D_{O1}) is larger than the third outer diameter (D_{O3}).
4. Elongated administration device (10) according to anyone of the precedent claims, **wherein** it comprises a transition section (18) with an up-flow extremity (18a) connected to the up-flow section (12a) and a downflow extremity (18b) connected to the middle section (12b), the transition section (18) presenting an increasing inner diameter, said inner diameter being equal to the first inner diameter (D_{I1}) at the up-flow extremity (18a) and equal to the second inner diameter (D_{I2}) at the downflow extremity (18b) of the transition section (18).

5. Elongated passive administration device (10) according to the precedent claim, **wherein** the outer diameter of the transition section (18) is equal to the first outer diameter (D_{O1}).
6. Elongated passive administration device (10) according to anyone of the precedent claims, **wherein** it comprises a sealing section or part (20; 21) with an up-flow extremity (20a; 21a) connected to the middle section (12b) and a downflow extremity (20b; 21b) connected to the downflow section (12c), the sealing section or part (20, 21) presenting a decreasing outer diameter, said outer diameter being at least equal to the first outer diameter (D_{O1}) at the up-flow extremity (20a; 21a) and equal to the third outer diameter (D_{O3}) at the downflow extremity (20b; 21b) of the sealing section or part (20; 21).
7. Elongated passive administration device according to the preceding claim, **wherein** the outer diameter (D_{20a} ; D_{21a}) of the up-flow extremity (20a; 21a) of the sealing section or part (20; 21) is larger than the first outer diameter (D_{O1}).
8. Elongated passive administration device (10) according to claims 4 to 5, **wherein** the inner diameter of the sealing section or part (20; 21) is equal to the second inner diameter (D_{I2}).
9. Elongated passive administration device (10) according to any one of claims 4 to 6, **wherein** the sealing section or part (20; 21) presents a general conical shape.
10. Elongated passive administration device (10) according to any one of the preceding claims, **wherein** the up-flow section (12a) presents a flexibility lower than a flexibility of the downflow section (12c).
11. Elongated passive administration device (10) according to any one of the preceding claims, **wherein** the first outer diameter (D_{O1}) ranges from 0,6 to 2mm, and the first inner diameter (D_{I1}) ranges from 0,1mm to 0,2mm.
12. Elongated passive administration device (10) according to any one of the preceding claims, **wherein** the third outer diameter (D_{O3}) ranges from 0,5 to 0,7mm, and third inner diameter (D_{I3}) ranges from 0,25mm to 0,35mm.

13. Elongated passive administration device (10) according to any one of the preceding claims, **wherein** the up-flow section comprises (12a), at an up-flow extremity, a connection portion (14) presenting an outer thread configured to connect the administration device to an active administration device (300).
- 5 14. Administration kit comprising an elongated passive administration device (10) according to any one of the precedent claims, and an active administration device (300) configured to be connected to said elongated passive administration device (300).
- 10 15. Administration method characterized in it is carried out by means of the administration kit of the preceding claim, comprising following steps:
- connecting the connection portion (14) of the up-flow section (12a) to an active administration device (300), said active administration device (300) comprising fluid to be administered,
 - priming the device (10),
 - 15 - performing a visual control of the absence of air or bubbles in the fluidic conduct (12) after the priming has been performed,
 - getting rid of any residual air/bubbles,
 - placing the downflow section (12c) of the administration device (10) in the administration site of the patient's ear (100),
 - 20 - activating the active administration device (300) and administrating the fluid to be administered through the passive administration device (10) towards the inner ear (103) of the patient.