[0005] In some embodiments, design elements of the described devices and systems include maintenance of sterility of injected fluid; minimization of bubbles introduced to the inner ear; ability to deliver small volumes precisely at a controlled flow rate (for example, when coupled with the use of a standard pump); allowance for visualization of the round window membrane (RWM) during delivery through the external auditory canal by a surgeon; minimization of damage to the RWM, or to inner ear structures beyond the RWM; and minimization of test article leaking through the RWM.

[0005a] In an aspect, the present disclosure refers to a device to deliver fluid to an ear, the device comprising:

a handle portion comprising a proximal end and a distal end;

a needle sub-assembly coupled to the distal end of the handle portion, the needle sub-assembly comprising a bent needle; and a stopper coupled to the bent needle, the stopper comprising a stopper tapered portion comprising a radius that gradually increases from a proximal end of the stopper toward a distal end of the stopper; and,

tubing coupled to the proximal end of the handle portion,

wherein the bent needle extends through a hollow interior of the handle portion and fluidly connects directly to the tubing.

[0006] In one example, the present disclosure provides a device to deliver fluid to an ear including: a handle portion including a proximal end and a distal end; a telescoping support coupled to the distal end of the handle portion; a needle sub-assembly coupled to the distal end of the handle portion and coupled to the distal end of the telescoping support, the needle sub-assembly including a bent needle, the bent needle including: an angled tip for piercing at least one membrane; and a bent portion; and tubing coupled to the proximal end of the handle portion. The bent needle extends through a hollow interior of the handle portion and fluidly connects directly to the tubing.

[0006a] In a second example, the present disclosure provides a system for delivering a therapeutic fluid to a portion of an inner ear of a patient comprising: means for developing a posterior tympanomeatal flap; means for creating an opening in a stapes footplate of the inner ear; and a fluid delivery device comprising a needle positioned at a distal end of the fluid delivery device, wherein the needle is configured to pierce a round window of the inner ear, wherein the fluid delivery device is configured to be positioned at a desired insertion depth within the round window; wherein the fluid delivery device is configured to deliver the therapeutic fluid to the inner ear, and wherein the therapeutic fluid comprises at least one viral gene therapy.

[0006b] In a third example, the present disclosure provides a system for delivering a therapeutic fluid to a portion of an inner ear of a patient comprising: means for performing a transcanal tympanotomy; means for preparing a round window of the patient; means for performing a laser-assisted micro-stapedotomy; a delivery device configured to inject the therapeutic fluid to the inner ear; means for applying sealant around at least one of the round window and an oval window of the patient; and means for lowering a tympanomeatal flap of the patient to an anatomical position, wherein the means for performing the laser-assisted micro-stapedotomy comprises at least one of a KTP otologic laser and a CO_2 otologic laser, and wherein the therapeutic fluid comprises adeno-associated virus (AAV) vector that comprises an Anc80 AAV vector or a coding region encoding hOTOF.

[0007] In some examples, the device includes a telescoping support coupled to a proximal end of the needle sub-assembly.

[0008] In some examples, the distal end of the handle is coupled to a proximal end of the telescoping support.

[0009] In some examples, the telescoping support includes multiple nested hypotubes.

[0010] In some examples, the bent needle includes: an angled tip for piercing at least one membrane; and a bent portion.

[0011] In some examples, the device includes a strain relief feature coupled to the proximal end of the handle portion.

[0012] In some examples, the device includes a camera (for example, a distal tip camera). The distal tip camera is positioned within the needle sub-assembly.

[0013] In some examples, the tubing couples to the bent needle within a hollow interior of the handle portion.

[0014] In some examples, the device includes an inner diameter from about 0.005 inches to about 0.01 inches.

CLAIMS

What is claimed is:

1. A device to deliver fluid to an ear, the device comprising:

a handle portion comprising a proximal end and a distal end;

a needle sub-assembly coupled to the distal end of the handle portion, the needle sub-assembly comprising a bent needle; and a stopper coupled to the bent needle, the stopper comprising a stopper tapered portion comprising a radius that gradually increases from a proximal end of the stopper toward a distal end of the stopper; and,

tubing coupled to the proximal end of the handle portion,

wherein the bent needle extends through a hollow interior of the handle portion and fluidly connects directly to the tubing.

2. The device of claim 1, further comprising a telescoping support coupled to the distal end of the handle portion and coupled to a proximal end of the needle sub-assembly, wherein the telescoping support comprises multiple nested hypotubes, each of the nested hypotubes comprising a gauge from 10 to 30, and each of the nested hypotubes comprising stainless steel.

3. The device of any one of the preceding claims, comprising:

a strain relief feature coupled to the proximal end of the handle portion,

wherein the strain relief feature prevents kinking and/or deformation of the tubing, and

wherein the strain relief feature comprises layered extrusions.

4. The device of any one of the preceding claims, comprising a distal tip camera positioned within the needle sub-assembly.

5. The device of any one of the preceding claims, wherein the bent needle comprises an angled tip for piercing at least one membrane; and a bent portion,

wherein the bent portion has a length from 0.5 mm to 5 mm,

wherein the angle of the angled tip is from 20 degrees to 70 degrees, and

wherein the angled tip projects from the bent portion of the bent needle to form an outlet for dispensing fluid.

6. The device of any one of the preceding claims wherein the stopper is shaped and sized for positioning within the inner ear and controlling a distance that the angled tip projects into a cochlea.

7. The device of any one of the preceding claims,

wherein the stopper is molded in place onto the bent needle at a distance of 0.2 mm to 1.2 mm from a distal end of the angled tip,

wherein the stopper prevents the bent needle from being inserted into at least one membrane beyond a desired amount, and

wherein the stopper is seated around a stopper anchoring groove disposed within the bent needle.

8. The device of any one of the preceding claims, wherein the handle portion further comprises:

machined grooves for tactility and control; and

a tapered portion disposed at the distal end of the handle, the telescoping support coupling to the tapered portion wherein the handle tapers down to the distal end such that the proximal end of the telescoping support is coupled to first distal end,

wherein the telescoping support tapers from an outer diameter of 0.2 inches or less at a proximal end to an outer diameter of 0.01 inches or more at a distal end.

9. The device of any one of the preceding claims, wherein the tubing is coupled to the bent needle via a compression fit,

wherein the tubing comprises polyether ether ketone (PEEK),

wherein the tubing comprises an inner diameter from 0.0003 inches to 0.01 inches,

wherein the tubing comprises an outer diameter from 1/64 inches to 1/16 inches, and

wherein the tubing comprises a length greater than 20 inches.

10. The device of claim 3, further comprising:

at least one machined barb disposed at the proximal end of the handle portion, wherein the at least one machined barb interfaces with the strain relief feature and prevents axial movement between the handle portion and the strain relief feature; and

an annular brace disposed at an interface between the telescoping support and the handle portion.

11. The device of any one of proceeding claims, wherein the stopper further comprises a chamfer disposed at the distal end of the stopper.