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 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 comprising a bent needle, the bent needle comprising:

an angled tip for piercing at least one membrane; and

a bent portion; 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, 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 portion of the bent needle 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, the device comprising a stopper coupled to the bent needle, 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 comprises a cylindrical disk shape with a diameter from 0.2 mm to 1.2 mm and a height from 0.2 mm to 1.0 mm,

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. A system comprising:

the device of any one of the preceding claims;

a sterilized syringe fluidly coupled to the tubing; and

a pump fluidly coupled to the tubing,

wherein the pump controls flow of a fluid through the device at a flow rate from 10 μL/min to 200 μL/min.

12. 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.

13. The system of claim 12, further comprising:

an imaging device; and

a monitor communicatively coupled to the imaging device, the monitor viewable by a surgeon;

wherein the imaging device is activated prior to piercing the round window;

wherein the imaging device is configured to monitor at least one of a flow rate of therapeutic fluid and a distribution of therapeutic fluid across the inner ear , and

wherein the imaging device comprises at least one of a distal tip camera, an endoscope, and an operating microscope.

14. The system of claim 12, wherein the means for developing a posterior tympanomeatal flap comprises at least one of a micro curette and a drill for cutting the posterior tympanomeatal.

15. The system of claim 12, further comprising:

means for preparing and draping the ear prior to developing the posterior tympanomeatal flap, wherein the patient is positioned prior to preparing and draping the ear;

means for inducing anesthesia prior to positioning the patient; and

means for marking the ear prior to inducing anesthesia.

16. The system of claim 12, further comprising:

an upstream pump;

tubing for connecting the fluid delivery device to the upstream pump, wherein the tubing is connected prior to developing the posterior tympanomeatal flap; and

means for sterilizing the fluid delivery device prior to developing the posterior tympanomeatal flap,

wherein the system is primed prior to developing the posterior tympanomeatal flap.

17. The system of claim 12, wherein the fluid delivery device is removed from the inner ear after delivery of the therapeutic fluid; and

wherein at least one skin treatment is applied to at least one of the round window membrane and the stapes footplate after removal of the fluid delivery device; and

the system further comprising means for returning the posterior tympanomeatal flap back to an original position after application of the at least one skin treatment,

wherein the at least one skin treatment comprises at least one of sodium hyaluronate and hyaluronic acid.

18. The system of claim 12, further comprising means for removing bone from the junction of the bony canal and the tympanic membrane, and/or pseudomembrane overhanging bone, after developing the posterior tympanomeatal flap, wherein the means for removing bone comprises at least one of a diamond drill and an otologic drill.

19. The system of claim 12, wherein the means for creating an opening in the stapes footplate comprises an otologic laser.

20. The system of claim 12, further comprising means for applying at least one of an anesthetic and an adrenaline to the ear canal of the patient prior to developing the posterior tympanomeatal flap.

21. The system of claim 15, wherein the means for preparing the ear comprises means for applying at least one antiseptic to the ear, wherein the at least one antiseptic comprises at least one of povidone-iodine, iodopovidone, betadine, wokadine, and pyodine.

22. The system of claim 12, wherein the desired insertion depth comprises a depth from 0.7 mm to 1.0 mm.

23. The system of claim 12,

wherein the fluid delivery device is configured to deliver the therapeutic fluid to the inner ear at a flow rate from 20 μL/min to 100 μL/min,

wherein the fluid delivery device is configured to deliver to the inner ear a total volume of therapeutic fluid in a range from 0.07 mL to 0.11 mL, and

wherein the fluid delivery device is configured to deliver the therapeutic fluid for a time duration in a range from 0.5 min to 5 min.

24. 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.