

Instructions for Use

Tula[◇] Tympanostomy System

EN English



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CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

R_x only Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Product Description

The Tula[®] Tympanostomy System enables placement of tympanostomy tubes under local anesthesia. The Tula Tympanostomy System is comprised of an Iontophoresis System (IPS), TYMBION[®] (lidocaine hydrochloride and epinephrine otic iontophoretic drug) and a Tube Delivery System (TDS).

Iontophoresis System

The IPS (**Figure 1**) is a single-patient-use device used with the TYMBION otic iontophoretic drug. The IPS employs electric current to transport lidocaine and epinephrine ions into the tympanic membrane to provide local anesthesia.

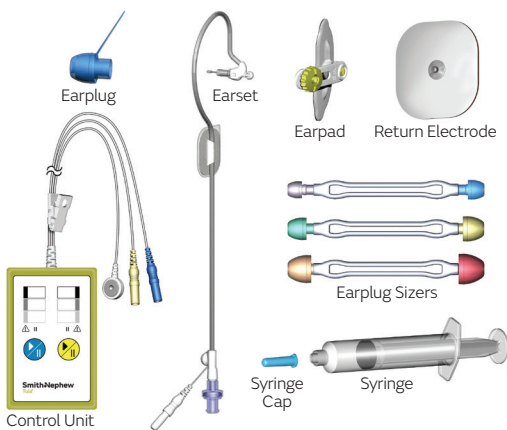


Figure 1. Tula Iontophoresis System

The IPS consists of three components:

The Earset System

The Earset System (**Figure 2**) includes an Earset, an attachable/detachable Earplug and an adhesive backed Earpad. The Earset consists of an integrated fill system, and an integrated electrode and cable through which electrical current is delivered to the TYMBION solution. The integrated fill system allows for the administration of the drug solution to the ear canal, as needed. The Tubeset is routed behind the ear and secured using a Tubeset Patch that comes installed on the tubing.

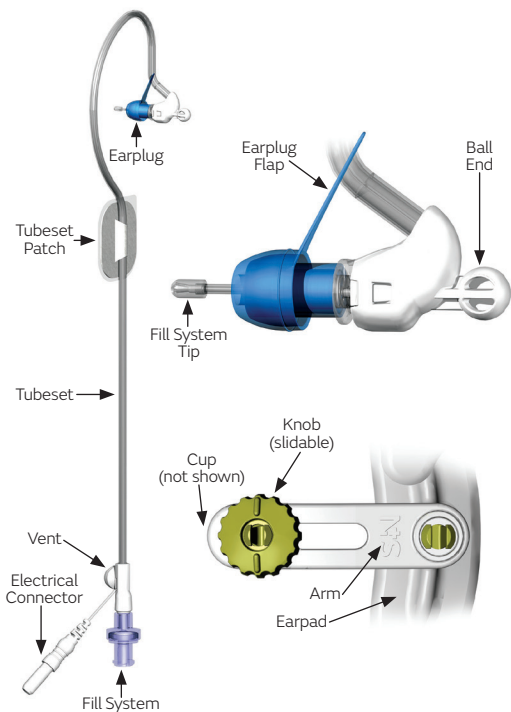


Figure 2. Details of the Earset

The Earset includes a small reservoir with a vent at the proximal end of the fill system that serves as a visual indicator of proper ear canal fill. The venting system limits the pressure in the ear canal during fill. The Earplug provides a seal to keep the drug solution in the ear canal, and is attached to the Earset after the appropriate size Earplug is selected. The Earpad is an adhesive backed pad that is installed on to the skin adjacent to the ear (the preauricular area) and contains an Arm used to position and retain the Earset in place by applying a medial force. The Arm features a slidable Knob that interfaces with the handle of the Earset. The Knob allows the user to orient the Earset relative to the ear canal and, when rotated into the locked position, fix the desired position of the Earset. Multiple color-coded Earplug sizes are available to accommodate variation in patient anatomy. For bilateral drug delivery, two Earset Systems are required.

The Control Unit

The Control Unit provides two independent channels of electrical current that share a single return electrode. The Control Unit monitors and delivers a fixed amount of charge and informs the operator when current delivery is complete. A cable connects the Control Unit to the Return Electrode and Earset(s).

The Control Unit (**Figures 3 and 4**) is a single-use, battery-powered, disposable medical device. It contains a microprocessor that is programmed to deliver a specific iontophoresis current profile.

The Control Unit consists of two buttons, corresponding to the blue and yellow electrical channels. The Blue Button controls the electrical current through the Earset attached to the blue connector, and the Yellow Button controls the electrical current through the Earset attached to the yellow connector. Above each button are two Indicator Symbols, Pause and Alert. An amber light will illuminate the Indicator Symbol to inform the user the mode is active. A Fault Light is present at the top center of the Control Unit, and will illuminate red, indicating an irrecoverable fault and the need to replace the Control Unit.

Above each set of Indicator Symbols is an array of three Progress Bars. Lights at the center of each Progress Bar will illuminate green to track the progress of the current delivery program. Each bar represents approximately one-third of the total time of the electrical current delivery program, starting from the bottom bar to the top. The Control Unit may be clipped to the patient or parent's clothing.

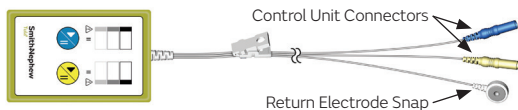


Figure 3. Details of the Control Unit

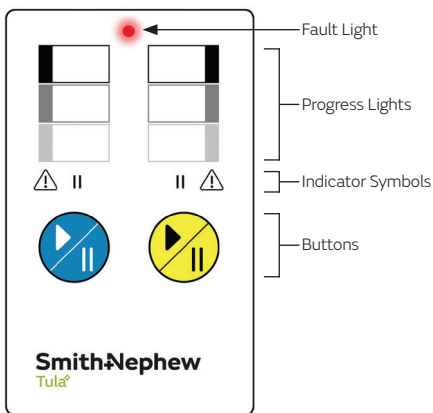


Figure 4. Control Unit buttons and indicators

The Return Electrode

The Return Electrode attaches to the patient's skin to complete the electrical circuit and is connected to the Control Unit via the return electrode snap.

Accessories to the Tula^o IPS include:

The Syringe

The Syringe is a single patient use device that allows for administration of the drug solution through the Earset into the ear canal.

The Syringe Cap

The Syringe Cap is a single patient use device that is used to limit possible interaction of drug with the environment or potential contaminants.

The Earplug Sizers

The Earplug Sizers are used to determine the Earplug size that optimally fits the patient's anatomy. They are color-coded to correspond to the equivalent Earplug size. The Earplug Sizers can be cleaned, disinfected and re-used.

Iontophoresis Program

The Control Unit delivers a programmed current profile to drive ions of lidocaine and epinephrine into the tympanic membrane. The profile consists of a ramp-up phase, a steady-state phase, and a ramp-down phase, as shown in **Figure 5**. Steady-state current is 0.8 mA, and total charge delivery (dose) is 6.36 mAmin. The blue and yellow channels operate independently. The user may choose to start both channels simultaneously, operate only one channel, or start the two channels at different times. The Control Unit will track the charge delivery independently on both channels. The nominal iontophoresis cycle takes 10 minutes to complete but could be lengthened if Pause or Reduce is implemented (see User Controls).

The total charge delivered is not user-adjustable. The amount of drug delivered into the tissue is proportional to the electrical charge delivered, and so the charge and drug dose are the same for each ear. The total charge delivered in a completed program is consistent even if the program is paused, reduced or otherwise interrupted.

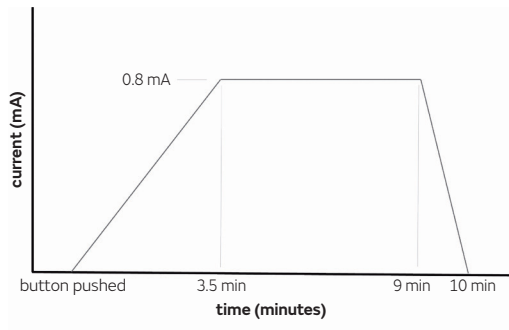


Figure 5. Iontophoresis current profile

User Controls

The user may choose to **Pause** current delivery at any time during the program, which causes a ramp-down to zero current. The **Pause** feature may be used if the user determines that the procedure needs to be interrupted, for example, in the event of unresolved patient discomfort.

The user may choose to **Reduce** the current if the user detects that the patient is experiencing some discomfort related to the current delivery. The **Reduce** feature lowers the current by 25%. If the **Reduce** feature is activated, the Control Unit will automatically lengthen the iontophoresis time to deliver the appropriate total charge accordingly. The user can also exit the **Reduce** state, which will cause the device to ramp up to the nominal current profile for completion of the current delivery program. The **Reduce** feature is not available during the first two minutes of the iontophoresis program or the first two minutes after resuming the program from a paused state.

Progress Bar Light Patterns

The Progress Lights indicate whether the device is delivering current and also approximates the time remaining in the iontophoresis program. There are three states for the Progress Lights (**Figure 6**):

Ready: When the device is Ready but not delivering current, the Progress Light will blink fully on and off in a repeated pattern.

Run: When iontophoresis is proceeding nominally, the Progress Light corresponding to the portion of the iontophoresis program will fade slowly on and off, repeatedly. This indicates that the device is delivering current according to the programmed profile.

Complete: When the iontophoresis program has completed a segment of the program, the Progress Light will illuminate solidly. For example, when approximately 1/3rd of the iontophoresis program has completed, the bottom-most Progress Light will be illuminated solidly (ie, not blinking). When the bottom-most Progress Light stops blinking and transitions to complete (illuminated solidly), the ramp-up phase of the iontophoresis program (**Figure 5**) is complete. Similarly, both the bottom and middle Progress Lights will illuminate solidly when 2/3rds of the program are complete.

When the entire iontophoresis program is complete, all three Progress Lights will illuminate solidly, and remain lit for 30 minutes after iontophoresis completion.

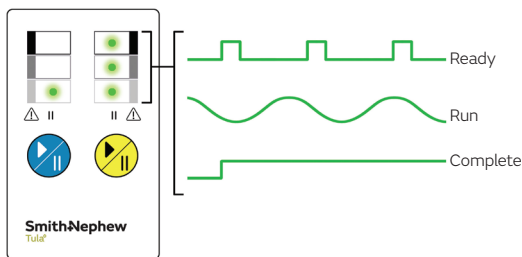


Figure 6. Progress Light patterns

Note: If the Fault Light (red light at top center of the device) illuminates at any point during the iontophoresis sequence, the device has malfunctioned. It will stop operating, and will need to be replaced.

Report the malfunction to your Smith+Nephew representative. Note that the device will attempt a ramp-down when it detects a fault condition, and so Progress Lights may indicate current delivery until ramp down is complete.

Tube Delivery System

The TDS (**Figure 7**) provides a means to create a myringotomy through which a tympanostomy tube is placed by single button-controlled activation. Once the button is pushed, the TDS executes a series of automated actions in rapid fashion, creating the myringotomy and delivering the tube in less than 500 msec. The cutting component of the TDS is recessed within the device, and is only briefly exposed upon TDS actuation. The cutting component extends no more than 3 mm from the distal edge of the device, and immediately retracts back into the device.

The TDS may be used in conjunction with standard otolaryngology instruments such as an ear speculum and an otologic visualization system, such as an operating microscope.

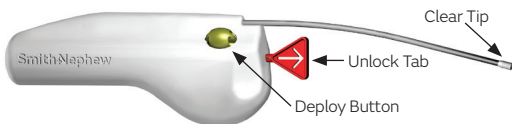


Figure 7. Tube Delivery System

The TDS comes pre-loaded with a silicone tympanostomy tube (**Figure 8**). The Tula^o Tympanostomy Tube has an inner lumen diameter of 1.14 mm, with medial, lateral and inter-flange dimensions as noted in **Figure 8**.

The TDS is compatible with ear specula that have a minimum inner diameter of at least 3.0 mm. To enhance visualization, it is recommended to use the largest speculum that is comfortable for the patient.

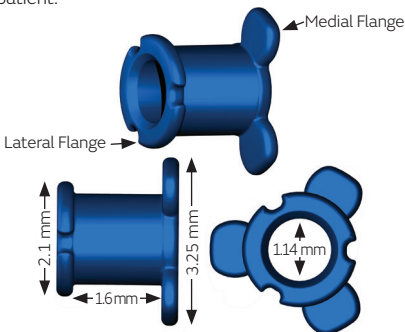


Figure 8. Tympanostomy Tube

The TDS is a single patient-use device that is provided sterile and non-pyrogenic, through a sterilization process using ethylene oxide gas.

TYMBION[®] Drug

TYMBION consists of lidocaine hydrochloride 2% (20 mg/mL, equivalent to lidocaine 16.2 mg/mL) and epinephrine 1:100,000 (0.01 mg/mL) otic solution for iontophoretic delivery. TYMBION is a sterile, nonpyrogenic solution with sodium metabisulfite 0.5 mg/mL and citric acid, anhydrous 0.2 mg/mL, added as stabilizers. Methylparaben 1 mg/mL is added as a preservative and the solution may contain hydrochloric acid to adjust pH to 4.5 (range 3.3 to 5.5).

WARNING: Only TYMBION lidocaine with epinephrine solution has been studied with the Tula[®] IPS and is indicated for iontophoretic administration. Do not use any other lidocaine with epinephrine solutions.

See the Prescription Drug Labeling contained in the TYMBION packaging for more details on the drug.

Indications for Use

The Tula Tympanostomy System is intended to create a myringotomy and insert a tympanostomy tube using the Tula Tube Delivery System in pediatric (aged 6 months and older) and adult patients indicated to receive tympanostomy tubes. The Tula Tympanostomy System is used to deliver a tympanostomy tube under local anesthesia induced using the Tula Iontophoresis System and TYMBION, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist.

Contraindications

- Cases in which the tympanic membrane is significantly atrophic, significantly retracted in the target location for tube delivery, or completely atelectatic.
- Patients presenting with TM (Tympanic Membrane) perforation(s). It is recommended that otoscopy and tympanometry be used in the assessment of the TM.
- Active or recent conditions of the tympanic membrane (eg, prior myringotomy with incomplete wound healing or re-epithelialization)
- Hemotympanum or other suspicion of aberrant vasculature (eg, carotid artery; high riding jugular bulb) impacting the tympanic membrane or middle ear.
- Patients presenting with lacerations/abrasions to the external auditory canal.
- Patients presenting with dimeric or monomeric tympanic membrane.
- Presence of otitis externa.
- Patients with electrically sensitive medical support systems (eg, pacemakers, defibrillators, cochlear implants).
- Patients with a history of sensitivity or allergic reaction to lidocaine HCl, tetracaine, epinephrine, or any hypersensitivity to local anesthetics of the amide type, or any component of the anesthetic drug formulation.
- Patients with a familial history of insensitivity to lidocaine or other local anesthetics.
- Anatomy/visualization that necessitates tympanostomy tube placement in the posterior half of the tympanic membrane.

Warnings and Precautions

- The Tula^o Tympanostomy System should only be used by qualified persons who have received training on the use of the Tula Tympanostomy System by Smith+Nephew.
- Appropriate patient selection should be completed by a physician. The Tula Tympanostomy System should be operated by a healthcare professional.
- No modifications of the Tula devices are allowed.

IPS

- The IPS (except for the Earplug Sizers) is intended for single patient use only. **DO NOT REUSE.**
- Do not use the IPS if the Control Unit appears damaged or if the Fault Light is illuminated, which indicates an unrecoverable error with the battery, hardware, or software.
- Do not use the Return Electrode if gel is dry.
- Apply the Return Electrode only as specified within these Instructions for Use. Misplacement of Return Electrodes may result in superficial burns.
- Warm drug solution before administering in order to minimize caloric stimulation that can cause temporary patient dizziness.
- Do not remove or disconnect the Earset or Return Electrode while current is being delivered, as this action will abruptly shut off the device and may cause temporary patient dizziness.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment; avoid equipment or environments that may result in electromagnetic interference.
- The IPS is not intended to anesthetize the ear canal as the anesthetic is preferentially delivered to the tympanic membrane.
- The Control Unit is not suitable for use in the presence of a flammable anesthetic mixture.
- Monitor the amount of drug solution instilled into the ear canal. A 2-year old child has an ear canal volume of approximately 0.45 ml, whereas an 11-year child has an ear canal volume of approximately 0.75 ml, although the relationship between ear canal volume and age is not directly linear, and volumes can vary.¹ The “dead-space” volume of the drug fill system (ie, the tubing and reservoir) is approximately 0.6 mL. If you do not see fluid entering the reservoir after instillation of the approximate anticipated volume, discontinue instillation as you may be administering drug through an undetected tympanic membrane perforation.

¹ Noh H, and Lee DH. Direct measurement of ear canal volume in a pediatric population: Can we explain its individual variation in terms of age and body weight? Int J Ped Otorhinolaryngol 76:658-662, 2012.

TDS

- **The TDS is intended for single use only. Do NOT re-sterilize and/or reuse, as this can compromise device performance and increase the risk of cross contamination.**
- **Do not use the TDS if the integrity of the sterile packaging has been compromised or the device appears damaged.**
- **Avoid the posterior-superior and posterior-inferior quadrants of the tympanic membrane when using the TDS to avoid critical middle ear structures.**
- **Excursion of the myringotomy blade past the clear tip does not exceed 3.0 mm. Avoid placing the TDS directly over a retraction pocket when deploying the tube.**
- **Do not use the TDS if adequate visualization of or access to the tympanic membrane cannot be achieved.**
- **Do not deploy the TDS directly over a sclerotic region of the TM, as this may impact cutter functionality.**

Instructions for Use

Note that the TDS may be used in patients undergoing tympanostomy tube placement in the Operating Room (OR) under general anesthesia, if desired (ie, without concomitant use of the Iontophoresis System or TYMBION®). Skip to Step 22 if the TDS is to be used in the OR with general anesthesia.

1. If necessary, clean ear canal(s) per standard ear cleaning techniques, making sure the tympanic membrane is not blocked by cerumen.
2. If required, wipe the lateral ear canal as well as the opening of the ear canal to remove any visible oils, wax or debris from the skin.
3. Via otoscopic exam, confirm that the tympanic membrane has no perforation or other exclusionary condition.
4. Choose the appropriate Earplug size to fit the patient's anatomy
 - a. To assess fit, place the soft silicone Earplug of the Earplug Sizer inside the ear canal. Ensure that the rib of the Earplug (**Figure 9**) sits flush with the posterior outer limit of the ear canal (**Figure 10**). The Earplug should provide a good seal while being comfortable for the patient.

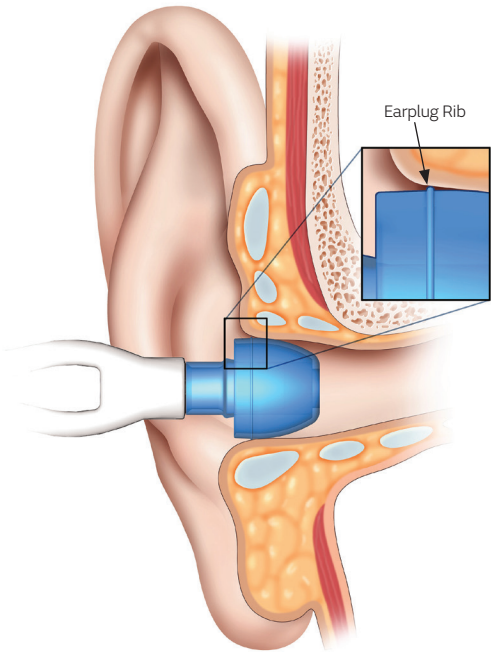
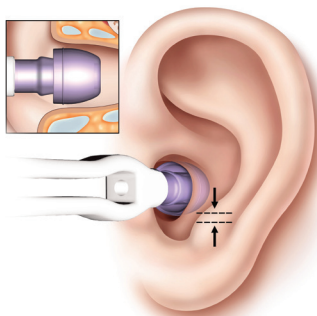


Figure 9. Earplug Rib

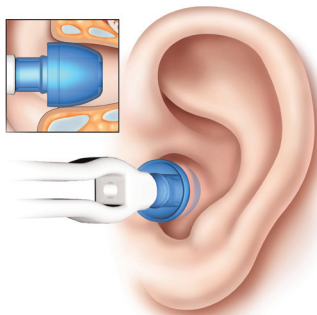
5. Examine the Earplug and check for full circumferential contact between the Earplug and the ear canal. If a gap or pleat is observed between the Earplug and canal wall, or if the Earplug is too deep in the canal or too far out, a different Earplug size may be required. Pay special attention to the inferior and superior aspects of the Earplug and ear canal.

TOO SMALL



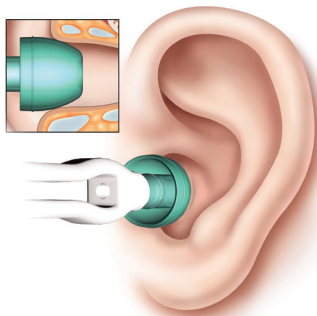
Earplug size is too small if there is a gap between the Earplug and the canal wall when the Earplug Rib is flush with the posterior outer limit of the ear canal.

GOOD FIT



Correct Earplug size should provide a good seal along the canal wall and the Earplug Rib should sit flush with the posterior outer limit of the ear canal.

TOO LARGE



Earplug size is too large if the Earplug pleats or does not insert easily when advanced to the depth where the Earplug Rib sits flush with the posterior outer limit of the ear canal.

Figure 10. Examples of Proper and Improper Earplug Fit

- To select the appropriate Earplug size, match the color of the Earplug or the embossed number on the Earplug Sizer with the label of the Earplug packaging. Repeat for the second ear, as needed.

Note: The left and right ears may require different size Earplugs.

6. Return Electrode and Control Unit

- a. Using the clip on the Control Unit, secure the Control Unit to the patient's clothing, or place the Control Unit in a secure location near the patient.

Note: For smaller children, it is recommended that the Control Unit be placed in a location that is not easily reached by the child.

Note: Do not clip the Control Unit to a surface where the buttons could be inadvertently pressed (eg, to the back of a parent who may lean back in a chair).

- b. Attach the Return Electrode to the cable at the return electrode snap (**Figure 3**).
- c. Find a clean, dry site, such as the arm or back, that is clear of lesions, bony protuberances, and excessive hair.
- d. Peel off the adhesive liner and attach the Return Electrode to the skin. Confirm the entire Return Electrode is affixed to the skin and there are not pleats or parts of the Electrode peeling off the skin. Readjust the Return Electrode if full electrode-to-skin contact is not noted.

7. Attach Earplug to Earset

- a. Once the proper Earplug size has been selected, remove the Earplug from its blister pack. Remove the Earset from its packaging by grasping the handle of the Earset.
- b. Hold the Earplug such that the Earplug Flap aligns with the Tubeset of the Earset (**Figure 11**).

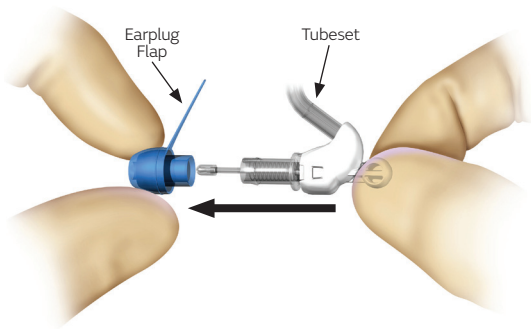


Figure 11. Attachment of Earplug to Earset

- c. Push the Earset straight into the Earplug, taking care not to bend or kink the Fill Tip. Push the Earset into the Earplug until the Earplug abuts the Earset Stop (**Figure 12**). Confirm the Fill Tip isn't bent or kinked (**Figure 13**).

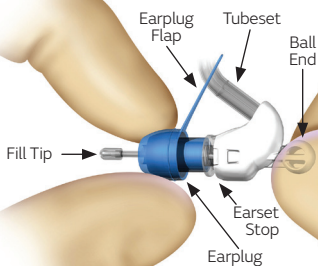


Figure 12. Attachment of Earplug to Earset

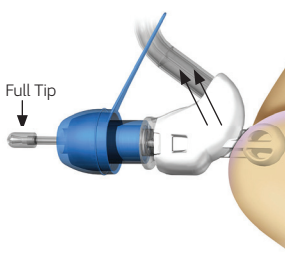


Figure 13. Earplug Properly Inserted

If the incorrect Earplug has been inserted, or if the Earplug needs to be replaced for other reasons, it can be removed from the Earset and another Earplug attached.

- d. Grasp the Earplug by the Earplug Flap and pull the Earplug straight off of the Earset (**Figure 14**). Take care not to accidentally pull the fill tip during removal. Discard the used Earplug. A new Earplug can now be inserted onto the Earset following the procedures in Steps 7a-7c.

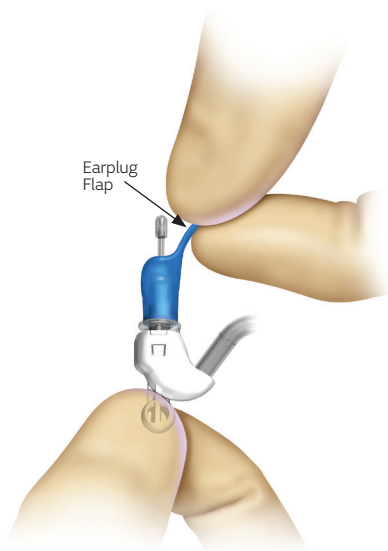


Figure 14. Earplug Removal

8. Place the Earset
 - a. Rotate the Arm position perpendicular to the Ear Pad and pointing anteriorly away from the ear to allow room for Earset application (**Figure 15**).

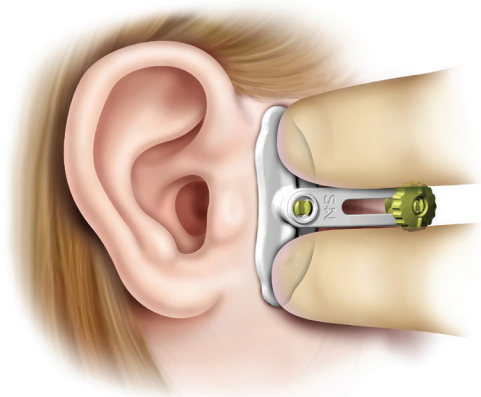


Figure 15. Ear Pad Placement & Arm Orientation

- b. Using the peel tab on the Ear Pad, remove the adhesive liner and apply the Ear Pad to the patient's skin in the preauricular area adjacent to the tragus (**Figure 15**). Take care to avoid the patient's hairline and gently apply pressure for a few seconds to the whole pad ensuring all edges are fully adhered to the skin before continuing.

- c. While holding the Earset handle with the Fill Line and Earplug Flap facing the top of the head, straighten the ear canal by pulling the pinna towards the back of the head, and carefully insert the Earplug into the patient's ear canal. Ensure the Earplug is inserted in a medial (and not anterior) orientation, to facilitate the TYMBION[®] drug properly reaching the tympanic membrane (**Figure 16**).

Note: Ensure the fill system tip is not bent or kinked during insertion.

Note: Be careful not to cause trauma to the external auditory canal.

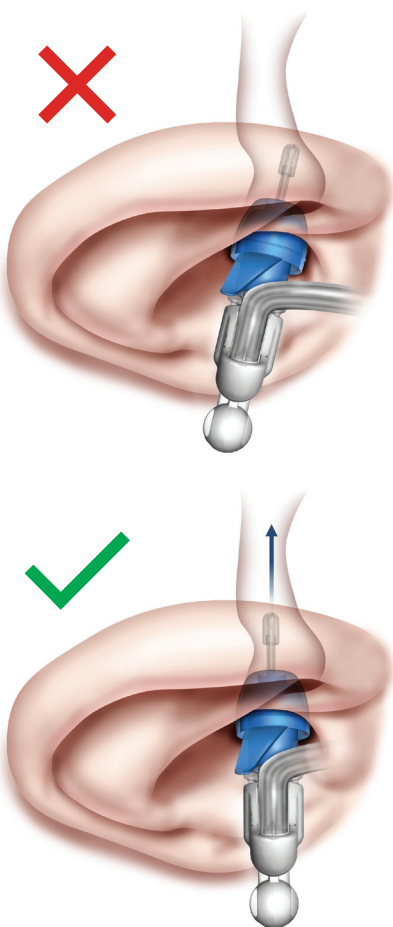


Figure 16. Improper (Top) and Proper (Bottom) Earset Insertion Angles

- d. Fully insert the Earplug into the ear canal, such that the rib of the plug is flush with the posterior outer limit of the ear canal, as assessed during sizing.

- e. Once the Earplug is appropriately positioned in the ear canal, and while holding the Earset in position, rotate the Arm of the Ear Pad towards the Earset and gently lift and seat the cup portion over the ball end of the Earset (**Figure 17**).

Note: Be careful not to allow the Arm to snap down onto the Earset as this can generate sounds uncomfortable for the patient.

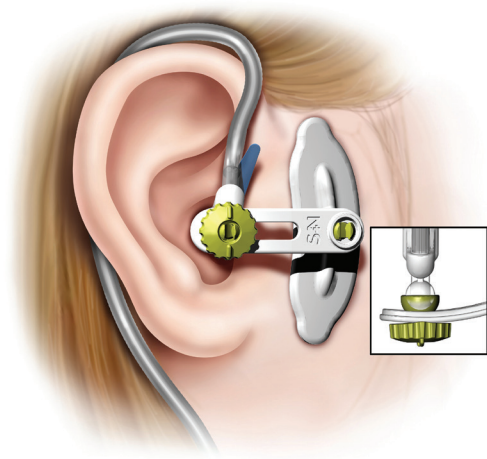


Figure 17. Positioning the Arm of the Earpad on the Earset

- f. Once interfaced with the Earset, if needed, adjust the position of the Knob by placing it in the unlocked position (**Figure 18 top**) and aligning the embossed line on the Knob parallel with the Arm slot. Holding the Knob, position the Earset by moving the Arm along the slot such that the Earplug is inserted in a medial (and not anterior) orientation, to facilitate the drug reaching the tympanic membrane. To lock the position of the Earset, rotate the Knob approximately a $\frac{1}{4}$ turn or 90 degrees clockwise to the Arm axis (**Figure 18 bottom**).



Figure 18. Unlocked Position of the Earpad Knob (Top) and Locked Position of the Earpad Knob (Bottom)

Note: Examine the Earplug and check for full circumferential contact between the Earplug and the ear canal. If a gap or pleat is observed between the Earplug and canal wall, a different Earplug size may be required.

- g. Route the Tubeset behind the ear, and secure the Tubeset by removing the adhesive liner from the Tubeset Patch and placing it behind the patient's ear or upper neck. Take care to avoid sticking the Tubeset Patch over hair. Ensure that the Tubeset sits snugly over the ear (**Figure 19**).

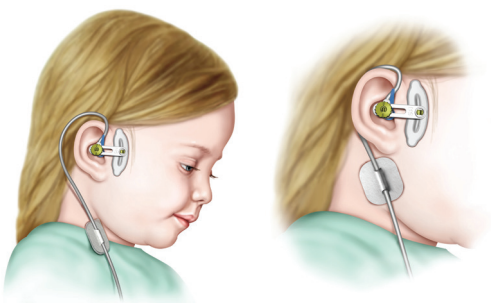


Figure 19. Earset Insertion and Orientation (left) and Earset Cable Routing around Ear (right)

9. Fill ear canal with drug solution
 - a. Fill the provided Syringe with 5 mL of TYMBION[®], using techniques that avoid introducing air bubbles into the Syringe.

- b. Warm the solution to approximately body temperature. This is to avoid dizziness which may result if a cold solution is applied into the ear canal. The Syringe Cap may be used to cover the Syringe after it has been filled with drug.
- c. With the Earplug properly positioned in the ear, recline the patient and tilt the patient's head posteriorly and laterally to achieve a near vertical ear canal orientation (**Figure 20**).

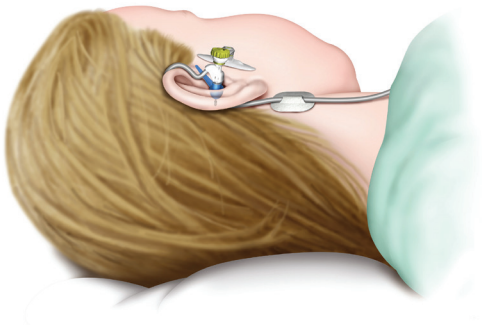


Figure 20. Near vertical ear canal orientation

Note: Head tilting is important to ensure proper fluid fill of the ear canal. Improper head position may result in air bubbles that may interfere with the drug delivery.

- d. Attach the Syringe to the luer end of the fill system and steadily fill the ear canal with the drug solution. Look for fluid to seep out of the Earset Vent (**Figure 2**) to confirm fill. Overfill the ear canal to ensure all air has been evacuated.

Note: A typical ear canal (+ tubing and reservoir volume) will accommodate approximately 1-2 mL of fluid, depending on the age of the patient, which is generally correlated with the size of the ear canal.

Note: If solution is seen leaking from around the Earplug, adequate seal has not been achieved, and a different Earplug size or insertion technique may be required.

10. For patients who require bilateral procedures, it is recommended that the steps be performed in the following sequence; 1) warm TYMBION[®] drug in both 5 mL Syringes that are provided, 2) size both ears, 3) attach both Earplugs to the Earsets, 4) attach Earpad and insert Earsets and repeat for second side, 5) fill both ear canals with TYMBION. Altering the sequence is acceptable per physician preference and patient temperament.

Note: Do not discard excess drug that may remain in the Syringe, as it may be needed to “top off” the ear canal if any leaks develop during iontophoresis.

11. For cable management convenience, the wires to the yellow and blue Control Unit connectors are provided in a single cable until close to the connectors. The yellow and blue channel wires may be separated by pulling the yellow and blue connectors apart, as desired.
12. Mate the electrical connectors from the Earset(s) and Control Unit (**Figure 3**). Note which colored electrical connector is connected to the patient's right and/or left ear.

Note: The Earset electrical connector is white and universally designed to connect with either the yellow or blue Control Unit electrical connector.

13. Power on

Pull and remove the battery tab located on the back of the Control Unit. All lights will briefly flash to confirm proper LED operation.

Note: Pull the battery tab just prior to use, so as not to unintentionally drain the battery capacity of the device.

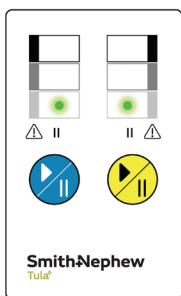


Figure 21. Control Unit Ready

The bottom-most progress bar lights will blink on and off on both the left and right sides, indicating that the device is Ready, but not delivering current (**Figure 21**). Both left and right lights will illuminate, even if the procedure is unilateral and only one channel is connected to an Earset.

14. Initiate Iontophoresis

Press and hold the Yellow and/or Blue buttons on the Control Unit for two seconds to start current delivery. Each button controls an independent channel, with button colors corresponding to the yellow and blue electrical connectors.

The bottom most Progress Light will indicate current delivery with a Run pattern, fading on and off (**Figure 22**).

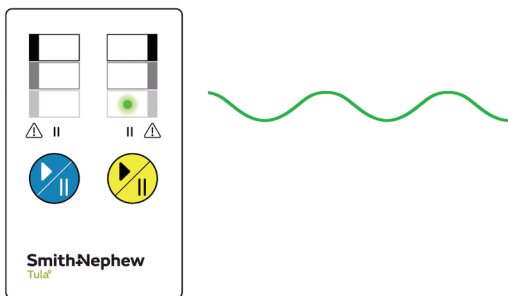


Figure 22. Yellow Channel Delivering Current on the 1st Segment

15. Monitor Progress

The Progress Lights will illuminate solidly (Complete pattern) when that third of the iontophoresis program has completed. **Figure 23** shows the Yellow channel with two segments Complete and the third Progress Light showing a Run pattern, indicating current flow in the final third of the iontophoresis program.

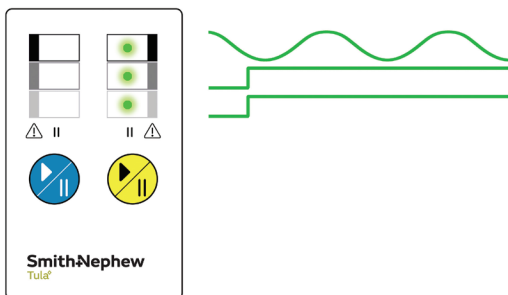


Figure 23. Yellow Channel Delivering Current on the 3rd Segment

16. Address Sensation: Reduce Mode and/or Top-Off

If the patient expresses some discomfort in the ear or return electrode, or a “pressure” sensation in the ear canal area, the user can choose to either reduce the current level or “top-off” the drug solution to address sensation.

- a. **Reduce Mode:** By pressing the button twice in rapid succession (ie, double-click), the user can put the selected channel into Reduce mode. This will cause the selected channel to ramp-down until it reaches a new steady-state current that is 25% less than nominal. The Progress Light will fade on and off at a slower rate, indicating reduced current delivery. **Figure 24** shows the Yellow channel with two segments Complete and the third Progress Light in a slower Run pattern, indicating current flow in the reduced state in the final third of the iontophoresis program.

The iontophoresis program can be completed in Reduce mode, but will take longer to deliver the programmed charge.

To exit the Reduce mode and return to nominal current delivery, the user double-clicks the button. The Progress Lights will return to a normal Run pattern to indicate nominal current delivery.

Note: The Reduce mode is not available during approximately the first two minutes of a ramp-up sequence.

- b. **Top Off:** Alternately, if the physician believes the sensation may be related to an air bubble or fluid leak, they can choose to add additional drug to the ear canal through the Earset. This may be done while the iontophoresis device is running. As with the initial fill, the ear canal should be vertical during top off.

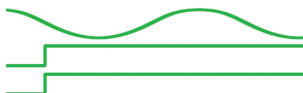
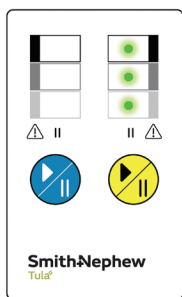


Figure 24. Yellow Channel Delivering Current on the 3rd Segment in Reduce Mode

17. Pause

At any time during the procedure, the user can Pause the iontophoresis program by pressing and holding the blue or yellow button for two seconds. This will initiate a ramp-down to zero current delivery. The Pause indicator light will illuminate amber when the user requests a Pause.

During the ramp-down, the Progress Light will breathe normally, as current is still being delivered. Once ramp-down is complete, the Progress Light will illuminate in a blink pattern, indicating a ready state without current delivery, as shown in **Figure 25**.

To exit the Pause, the user presses and holds the button for at least two seconds. This will initiate a ramp-up, and the Pause indicator light will go off.

Note: The ramp-up after a Pause is identical to the nominal iontophoresis program ramp-up, as shown in **Figure 5**, and takes approximately 3.5 minutes.

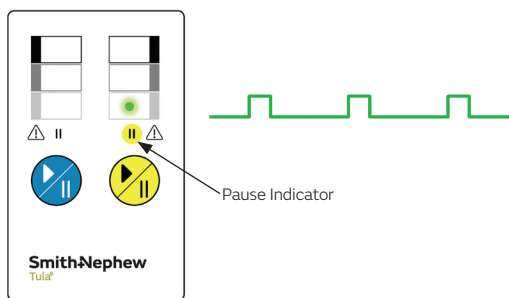


Figure 25. Yellow Channel in Pause

18. Device Alert

If the device detects an interruption in the current delivery, it will initiate a ramp-down and illuminate the Alert Indicator in amber. This most typically happens if there is an air bubble, or if fluid has leaked out of the ear canal.

Wait for the ramp-down to complete (Progress Light changes from Run to Ready, see **Figure 26**). Check the fit of the Earplugs, ensure electrical connections are not disconnected, and add additional drug solution to the ear that is in the Alert state by positioning the patient as described in Step 9c. Note that in a bilateral procedure, if the Alert Indicator illuminates in both channels simultaneously, this likely indicates an issue with the shared Return Electrode (eg, connection to the patient, or connection to the Control Unit cable).

To resume the procedure, press and hold the blue or yellow button for two seconds.

Note: Device Alerts can occur independently on either channel. One channel can be proceeding nominally while the other detects an Alert.

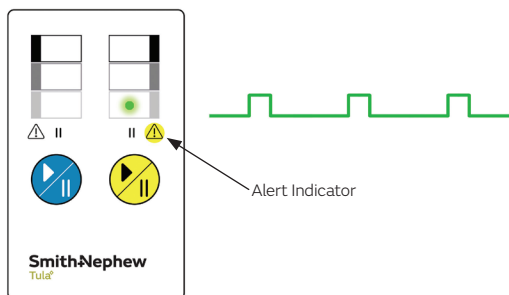


Figure 26. Yellow Channel After Device Alert

19. Iontophoresis Complete

Once the iontophoresis profile is Complete in a particular channel, all three Progress Lights for that channel will illuminate solidly (**Figure 27**). The Progress Lights will remain solidly illuminated for 30 minutes after the iontophoresis procedure has completed, and then turn off.

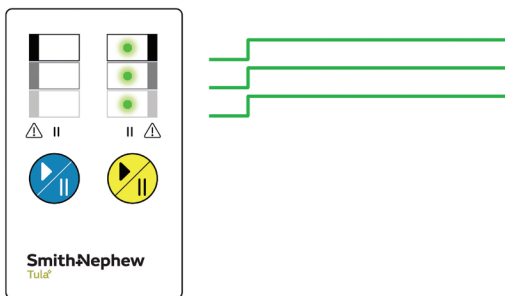


Figure 27. Yellow Channel Iontophoresis Complete

20. Device/Drug Removal

- Gently lift the Arm off the ball end of the Earset and rotate out of the way.
- Gently peel the Tubeset Patch off the patient and remove the Earset from the patient's ear.
- Gently hold the top or bottom tip of the Earpad and slowly peel away from the skin to remove. Note: The Earpad may be left in place until completion of tube delivery to avoid potential patient discomfort from the peeling of the Earpad adhesive.
- Remove the drug solution either by tilting the head and/or using a wick.
- Remove the Return Electrode from the skin by gently peeling it away. Note: Mild redness at the return electrode is expected in most cases. The Return Electrode may be left in place until completion of tube delivery to avoid potential patient discomfort from the peeling of the adhesive.
- Confirm complete drug removal using visualization of the ear canal and tympanic membrane.

21. Test Anesthesia

Note: Ensure the patient's head is firmly stabilized whenever an instrument or the TDS is passed into the ear canal.

- Visualize the tympanic membrane. Note that ear canal material may have been mobilized during the iontophoresis procedure requiring an ear cleaning to facilitate visualization.
- Using a dull otologic probe or the tip of the TDS, gently touch the TM at the planned location of tube placement (anterior-inferior aspect). Confirm that the TM is sufficiently numb to proceed with tube placement by observing the patient reaction to the touch on the TM. If the local anesthesia is not sufficient, the iontophoresis system cannot be run again.

The safety of repeat iontophoretic administration of TYMBION[®] has not been evaluated in humans, and repeat administration (to the same ear) is not recommended.

Note: TYMBION, when administered with the Tula[®] Iontophoresis System, provides local anesthesia of the tympanic membrane, and not the external ear canal. Avoid impacting the ear canal wall with otologic instruments.

22. Place Tympanostomy Tube

Note that TDS model number TDS114G (refer to IFU007011) may also be used to place a tympanostomy tube after local anesthesia with the IPS.

- a. Inspect the TDS sterile packaging to ensure integrity prior to use. Remove the TDS device from the tray.
- b. Remove the red Unlock Tab from the TDS by pulling in the direction of the arrow. Prior to device actuation, the TDS may be re-locked by inserting the Unlock Tab fully into the pinhole.

Note: Once the Unlock Tab is removed, the device is active. Caution should be taken to prevent inadvertent depression of the Deploy Button.

- c. Through a speculum and using a visualization system, advance the device through the ear canal to the tympanic membrane. Care should be taken to avoid contact or trauma to the ear canal during placement.
- d. Position the Clear Tip against the tympanic membrane, at the intended myringotomy site. Confirm that adequate visualization of the TM and necessary structures is achieved with the device in place.
- e. Maintain apposition of the device against the tympanic membrane by applying gentle pressure on the TM until slight tension is felt (**Figure 28**). The Clear Tip should be perpendicular to and fully apposed against the TM. Avoid excessive pressure

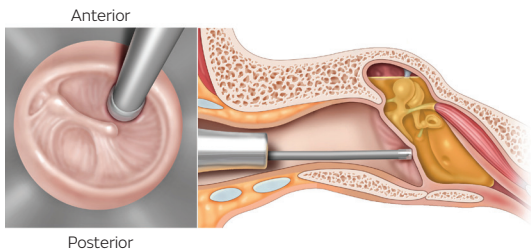


Figure 28. Positioning the TDS Against the TM

- f. To deploy the tympanostomy tube, press the Deploy Button on the TDS while keeping the tip of the device immobile. The TDS will create a myringotomy and insert a pre-loaded tympanostomy tube in one automated step. The entire process will take less than 500 msec, and the myringotomy blade will retract inside the clear tip after actuation. The TDS has buttons on both the left and right sides, for left and right-handed users. Only one of the buttons is pushed to actuate the TDS.

CAUTION: In a conscious patient, ensure the head is stationary prior to inserting the Tula^o TDS into the ear canal.

Note: It is important to maintain stability and apposition of the TDS against the TM during tube deployment.

Take caution not to push the device forward upon actuation or pull the device back prematurely.

Note: It is recommended to stabilize the hands to the patient's head such that if the patient moves, the hands will move in tandem with the patient.

Note: If the clear tip is not fully apposed against the TM, it is possible that the tube will not fully deploy across the TM. Standard otologic tools may then be used to perform the final positioning of the tube.

- g. Once tube delivery is complete, hold the TDS briefly against the TM to ensure TDS actuation is complete. Withdraw the TDS by slowly pulling the handle straight back and away from the tympanic membrane.
- h. Inspect the tympanic membrane for proper placement of the tympanostomy tube. If required, the user may adjust tympanostomy tube position with standard otologic instruments or make additional TDS attempts if tissue is suitable.

Compatible Devices/Devices used with

Part No.	Description
72290089	TULA KIT - UNILATERAL
72290090	TULA KIT - BILATERAL
72290091	TULA EARPLUG 10-PACK SIZE 1
72290092	TULA EARPLUG 10-PACK SIZE 2
72290093	TULA EARPLUG 10-PACK SIZE 3
72290094	TULA EARPLUG 10-PACK SIZE 4
72290095	TULA EARPLUG 10-PACK SIZE 5
72290096	TULA EARPLUG 10-PACK SIZE 6
72290097	TULA TDS 1.14 GROMMET
72290098	TULA EARSET SPARE
72290099, TYMB001	TYMBION AND SYRINGE PACK
72290100	TULA EARPLUG SIZERS
72290103	TULA CONTROL UNIT SPARE
72290104	TULA IONTOPHORESIS PATCH

Ototoxicity and Pharmacokinetics

See the package insert for TYMBION[®] for details on the completed ototoxicity and pharmacokinetics studies.

Clinical Trials

The safety and efficacy of iontophoretically-administered TYMBION used to facilitate tympanostomy tube placement was evaluated in two studies. In both studies, TYMBION was administered via the Tula[®] IPS in a physician's office setting to provide local anesthesia of the tympanic membrane, followed

by tympanostomy tube insertion using the Tula TDS. Study 1 enrolled 30 adult patients (ages 21-83 years) and Study 2 enrolled 222 pediatric patients (ages 6 months through 12 years). An additional 47 pediatric patients were enrolled as “lead-in” cases in Study 2, data from which are included in the safety analyses only.

Study 1 (NCT03197558):

Study 1 was a non-randomized multicenter study in 30 adult patients (mean age 54.9 years, 43% male, 70% White/17% Black or African American/3% Asian/10% Other, 3% Hispanic or Latino) undergoing tympanostomy tube placement. TYMBION was administered either unilaterally or bilaterally using the Tula IPS, as clinically indicated. Once iontophoresis was completed, local anesthesia of the tympanic membrane was assessed by lightly tapping the TM with a dull otologic instrument. Tympanostomy tubes were then placed using the TDS and pain was assessed using a 0 to 100 mm Visual Analog Scale, where 0=“no pain” and 100=“worst possible pain.”

After TYMBION was administered with the Tula IPS, 29/30 (97%) patients were determined by the investigator to have adequate local anesthesia to proceed with tympanostomy tube placement. In these 29 patients, tympanostomy tubes were successfully placed in 37 out of 37 targeted ears (100%). The mean (standard deviation) VAS score upon tube insertion, using the higher of two scores if both ears were treated, was 9.4 mm (15.7 mm) and the median was 3.0 mm (out of a maximum of 100 mm). The maximum VAS pain score reported was 64 mm.

Study 2 (NCT03323736):

Study 2 was a non-randomized multicenter study, with 17 sites in the U.S. and 1 site in Canada, in pediatric patients with recurrent acute otitis media or chronic otitis media with effusion requiring tympanostomy tube placement per clinical practice guidelines. To gain experience with the Tula^o technology, each investigator was required to treat two patients under general anesthesia in the operating room (OR lead-in cohort) using the TDS. A total of 68 procedures were performed in the OR lead-in cohort (mean age 3.4 years, 59% male, 78% White/9% Black or African American/4% Asian/9% other, 21% Hispanic or Latino). Each investigator was then required to treat two patients in the office lead-in cohort using the Tula Iontophoresis System. A total of 47 procedures were performed in the office lead-in cohort (mean age 4.8 years, 57% male, 77% White/13% Black or African American/2% Asian/8% other, 13% Hispanic or Latino). Once the OR and office lead-in patients were treated, the investigator could enroll patients in the pivotal treatment cohort.

There were 120 patients aged 6 months through 4 years (mean age 2.3 years, 54% male, 91% White/8% Black or African American/3% Asian/2% Other, 9% Hispanic or Latino) and 102 patients aged 5 years through 12 years (mean age 7.6 years, 63% male, 76% White/18% Black or African American/ 0% Asian/7% Other, 20% Hispanic or Latino) treated with TYMBION^o using the Tula Iontophoresis System in the pivotal treatment cohort. All children were treated in a physician's office setting, without

the use of sedatives, anxiolytics, or papoose restraints. Once adequate local anesthesia was achieved, as assessed by lightly tapping the TM with a dull otologic instrument, tympanostomy tubes were placed using the Tula TDS. The study had one primary endpoint for children in the younger age group and two primary endpoints for children in the older age group.

Primary Endpoint 1: The percentage of children who had successful procedures (ie, tubes placed in all indicated ears) had to be superior to a prespecified performance goal of 68%.

Primary Endpoint 2: For children ages 5 to 12 years, the pain associated with tube placement had to be superior to (ie, less than) 4.2 (out of a maximum score of 10) on the Faces Pain Scale – Revised (FPS-R). This endpoint was not collected in children under 5 years of age, based on their inability to reliably complete self-reported pain scales; however, pediatric distress in this age group was assessed using the Faces, Legs, Activity, Cry, Consolability (FLACC) Scale.

Table 1 shows the results for the two primary endpoints. Procedural success was 86% in younger children and 89% in older children. The mean FPS-R score for tympanostomy tube placement was 3.3 (out of 10) with a median of 2.0. Mean and median FPS-R scores five minutes after tube insertion were 1.7 and 0, respectively.

Table 1. Primary Efficacy Endpoint Results (Study 2)

	Ages 6mo-4yr	Ages 5yr-12yr
Procedural Success (rate) ^a	86% (103/120) (95% credible interval: 80%, 91%)	89% (91/102) (95% credible interval: 82%, 93%)
Tube Placement Tolerability (mean FPS-R Score) ^b		3.3 (out of 10) (95% confidence interval: 2.6, 4.0)

^a The procedural success endpoint was evaluated in a Bayesian Hierarchical framework. The success rate in each age group was compared to the performance goal of a 68% success rate. Success was declared for each age group if the lower bound of the 95% credible interval exceeded the performance goal of a 68% success rate. The study designed to evaluate each age group separately, with data borrowing between groups.

^b The mean Tube Placement Tolerability score was compared to a performance goal of 4.2. Success was declared if the upper bound of the 95% confidence interval was less than 4.2 on the FPS-R.

Table 2 summarizes the reasons for procedural failure for the pivotal treatment cohort in Study 2.

Table 2. Reasons for Procedure Failure (Study 2)

Reason for Procedure Failure	Pivotal Cohort, % (n/N)
Patient Behavior	5% (11/222)
Inadequate Anesthesia	3% (7/222)

Discomfort/ Anxiety	2% (4/222)
Anatomic Challenges	1% (3/222)
Iontophoresis Intolerability	1% (2/222)
Partially Medialized Tube	0.5% (1/222)

Pediatric distress was assessed in Study 2 using FLACC scores, reported on a scale of 0 (lowest) to 10 (highest). FLACC scores for each treated patient were assigned by a Core Lab, using video recordings of the procedures, scoring each major procedural phase separately. **Table 3** shows mean FLACC results for key procedural phases for the younger and older pivotal treatment cohort patients who had successful procedures.

Table 3. FLACC, by Phase/Age (means)

FLACC Phase	Ages ^a 6mo-4yr	Ages 5yr-12yr
Pre-procedure Otoscopy	0.7	0.1
Earset / drug fill	1.4	0.1
Iontophoresis	0.8	0.0
Tube placement	4.0	0.4
3 min post procedure	1.3	0.2

^a Sample sizes for younger children were 100-101 and for older children 87-88. Video data was not available for all phases for a few children due to video technical issues or obstructed views.

Table 4 summarizes tube retention at 3 weeks, 6, 12, 18 and 24-months for the pivotal treatment cohort, reported by ear.

Table 4. Tube Retention

Tube Retention ^a	Pivotal Cohort, % (n/N ^b)
3-Week	99.5% (380/382)
6-Month	91.0% (334/367)
12-Month	65.4% (219/335)
18-Month	36.9% (117/317)
24-Month	19.9% (63/316)

^a Mean months to tube extrusion (95% CI): 16.79 (16.16, 17.42).

^b Overall N is the number of ears with known tympanostomy tube status at the follow-up visit, including ears in which the tube had been determined to have been extruded or removed at a prior visit.

Adverse Events

For adverse events related specifically to the TYMBION[®] otic solution, please see the TYMBION package insert.

In addition to Study 1 and Study 2, adverse event information for the IPS/ TYMBION alone (without the TDS) is also supplied from three additional studies that were conducted in healthy adult volunteers (n=60), for a total IPS/TYMBION safety database of n=359 patients. In Study 2, inadequate anesthesia, defined as a response to the tympanic membrane assessment, was recorded as an adverse event in 4% (12/269) of treated patients. Because inadequate anesthesia could have been IPS-related or drug-related, these adverse events are also described in the TYMBION Package Insert (as adverse reactions).

There were no other adverse events related to the IPS device that occurred at a rate greater than 2%.

In addition to adverse events that the investigators determined were related or potentially related to the Tula[®] Tympanostomy System, additional adverse events were recorded that represent common sequelae of tympanostomy procedures in general.

Table 5 shows total adverse event rates for otorrhea and tube occlusion, which are common post-tympanostomy sequelae. The rates reported in **Table 5** are for adverse events in the Study 2 pivotal cohort captured in the first month after the procedure, and the denominator includes only those ears that received Tula tympanostomy tubes.

Table 5. Common Tympanostomy Post-Procedure Sequelae (within 1 month, by ear)

Adverse Event	Rate
Otorrhea	5% (20/384)
Tube Occlusion	3% (11/384)

Potential Adverse Events

In addition to the adverse events noted during the OTTER Study, additional adverse events are possible.

It is anticipated that patients receiving a tympanostomy tube via the Tula^o technology will have similar risks as patients receiving tubes using traditional techniques. Additional risks may be presented by the iontophoretic administration process.

Risks include:

- Tube occlusion, resulting in failure to perform intended purpose.
- Infection could occur from airborne or water pathogens entering the middle ear.
- Early extrusion of the tube.
- Failure of the tube to self-extrude, requiring surgical intervention.
- Dislocation of the tube into middle ear space.
- Deployment of the tube into middle ear space.
- Persistent or permanent perforations, requiring surgical intervention.
- Tympanosclerosis.
- Local or diffuse atrophy of tympanic membrane.
- Patient allergy or sensitivity to silicone, resulting in tissue irritation.
- Unintended TM perforation.
- Blood in ear related to the myringotomy.
- Recurring or persistent otorrhea.
- Granuloma and/or cholesteatoma formation.
- Temporary aural fullness.
- Conductive hearing loss due to damage to middle ear structures.
- Abrasion of the external auditory canal or meatus requiring treatment.
- Erythema or burn at return electrode site.
- Dizziness/vertigo during or after iontophoresis.
- Temporary tongue numbness or taste disturbance.
- Sensations of pressure or discomfort during the iontophoresis process.
- Temporary appearance of small fluid-filled vesicles/blebs on the surface of the TM, and temporary sensation of muffled hearing.
- Major bleeding due to contact with aberrant vasculature.
- Allergic reaction to the anesthetic.
- Swallowing of drug solution in the presence of an undetected tympanic membrane perforation, leading to high systemic exposure.
- Inadequate anesthesia.

Risks associated with the use of TYMBION^o can be found in the TYMBION package insert.

Sterility

The TDS, Syringe and Syringe Cap are provided sterile. The TDS and Syringe are sterilized with ethylene oxide gas. The Syringe Cap is sterilized by Gamma irradiation. The Control Unit, Return Electrode, Earset, Earplug Sizer, and Earplugs are provided non-sterile and do not require sterilization.

Single Use

The TDS is a single-use device with a single pre-loaded tympanostomy tube. Do NOT re-sterilize or reuse, as this can compromise device performance and increase the risk of cross contamination due to improper processing.

The IPS and accessories (except for Earplug Sizers, see Cleaning Instructions) are all single-use devices.

Storage and Operating Conditions

- Operating Environmental Conditions:
10-40°C (50-104°F), 30-70% relative humidity.
- Storage Environmental Conditions:
10-27°C (50-81°F), 20-80% relative humidity.
- Storage conditions for TYMBION[®] can be found in the TYMBION package insert.

Disposal

Dispose of the TDS in biohazard containers approved for the disposal of sharps in accordance with country, federal, state and local regulations. The Control Unit, Return Electrode, Earsets, Earpad, Earplugs, Syringes, and Syringe Caps are single use only devices. There are no risks associated with proper disposal of the Control Unit. Follow any applicable country, state, or local regulations regarding proper disposal of used electronic equipment. Do not dispose of the Control Unit in general waste or landfill.

Cleaning Instructions: Earplug Sizers

The Earplug Sizers may be reused following proper cleaning and disinfection. Inspect the Earplug Sizers before use. If any of the following conditions are observed, dispose of the Earplug Sizers and use a new set; visible cracks and/or sharp edges on external surfaces, signs of melting or shape change and/ or discoloration.

Earplug Sizer Cleaning and Disinfection Instructions:

Note: It is recommended that Earplug Sizers are reprocessed as soon as reasonably practical following use, typically within two hours.

1. No disassembly required
2. Clean the Earplug Sizers
 - a. Remove excess wax and other visible material with a disposable paper towel wet with tap water.

- b. Prepare the enzymatic detergent solution (for example, Enzol[®]) per the detergent manufacturer's instructions.
- c. Fully immerse the Earplug Sizers in the prepared enzymatic detergent solution, and ensure there are no bubbles on the devices. If bubbles are observed, gently agitate the Earplug Sizers.
- d. Soak for at least five minutes.
- e. Brush the devices completely while immersed in the detergent solution, including the channels, with an appropriately sized soft pipe cleaner for at least 1 minute. Cleaning validation was performed with a 2.7mm diameter pipe cleaner.

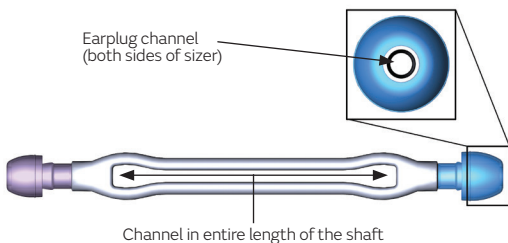


Figure 29. Channels in the Earplug Sizers

- f. Rinse the Earplug Sizers in warm tap water for at least one minute to wash away any detergent.
 - g. Visually inspect the Earplug Sizers to ensure that there is no debris left on the devices. If there is any debris left, repeat Steps 2 a-g.
 - h. Dry devices with a lint-free cloth.
3. Disinfect the Earplug Sizers.
- Note:** For effective disinfection, cleaning is required (see Step 2).
- a. Prepare Cidex[®] (2.4% glutaraldehyde) per the disinfectant manufacturer's instructions. Refer to manufacturer's instructions for use and MSDS for warnings, contraindications, and precautions.
 - b. Fully immerse the Earplug Sizers in the prepared Cidex solution, and ensure there are no bubbles on the devices. If bubbles are observed, gently agitate the Earplug Sizers.
 - c. After 45 minutes, remove the devices from the disinfectant and rinse the devices with sterile water. Rinse them three times for a minute each with fresh sterile water.
 - d. Dry devices with a lint-free cloth.









Symbols Glossary










Standard titles used in the Symbols Glossary are:

ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.

EN 50419: Marking of electrical and electronic equipment in accordance with Article 11 (2) of Directive 2002/96/EC (WEEE).

IEC 60878: Graphical symbols for electrical equipment in medical practice.

Symbol	Symbol Title and Identifier	Standard Number
	Batch code 5.1.5	ISO 15223-1
	Indicates the manufacturer's batch code so that the batch or lot can be identified.	
	Catalogue number 5.1.6	ISO 15223-1
	Indicates the manufacturer's catalogue number so that the medical device can be identified.	
	Manufacturer 5.1.1	ISO 15223-1
	Indicates the medical device manufacturer.	
	Date of manufacture 5.1.3	ISO 15223-1
	Indicates the date when the medical device was manufactured.	
	Sterilized Using Ethylene Oxide 5.2.3	ISO 15223-1
	Indicates a medical device that has been sterilized using ethylene oxide.	
	Sterilized Using Irradiation 5.2.4	ISO 15223-1
	Indicates a medical device that has been sterilized using irradiation.	
	Do not re-use 5.4.2	ISO 15223-1
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	
	Consult instructions for use 5.4.3	ISO 15223-1
	Indicates the need for the user to consult the instructions for use.	

Symbol	Symbol Title and Identifier	Standard Number
	Use-by date 5.1.4	ISO 15223-1
	Indicates the date after which the medical device is not to be used.	
	Keep away from sunlight 5.3.2	ISO 15223-1
	Indicates a medical device that needs protection from light sources.	
	Do not use if package is damaged 5.2.8	ISO 15223-1
	Indicates a medical device that should not be used if the package has been damaged or opened.	
	Keep dry 5.3.4	ISO 15223-1
	Indicates a medical device that needs to be protected from moisture.	
	Non-sterile 5.2.7	ISO 15223-1
	Indicates a medical device that has not been subjected to a sterilization process.	
	Separate collection facilities	EN 50419
	Indicates a medical device that must be sent to separate collection facilities for recovery and recycling (EU only).	
	Type BF Applied Part 5333	IEC 60878
	To identify a type BF applied part complying with IEC 60601-1. Note 1- B=Body. Note 2-F=Floating applied part.	
	Temperature limit 5.3.7	ISO 15223-1
	Indicates the temperature limits to which the medical device can be safely exposed.	
	Non-pyrogenic 5.6.3	ISO 15223-1
	Indicates a medical device that is non-pyrogenic.	

IPS Control Unit Specifications

- Internally Powered Equipment
- Battery Type: 2 AAAA Batteries
- Output Power: 800 μ A over a patient load of 5k Ω to 30k Ω
- Splash/ Water Ingress Rating: IPX0
- Continuous Operation
- Total Charge Dose: 6.36 mAmin

The Tula^o Iontophoresis System is designed to output an electrical current of less than 1330 μ A.

Electromagnetic Environmental Guidance

The Tula Iontophoresis System does not require interconnection with other equipment.

Portable and mobile RF communications equipment can affect operation of the Tula Iontophoresis System.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: The Tula Iontophoresis System has not been tested for known sources of electromagnetic interference such as Magnetic Resonance Imaging (MRI), Computerized Tomography (CT), diathermy, radio frequency identification (RFID) systems, and electromagnetic security systems such as metal detectors, and should not be used in conjunction with or in proximity to such technology.

Electromagnetic Emissions

The Tula^o Iontophoresis System is intended for use in the electromagnetic environment specified below. The customer or the user of the Tula Iontophoresis System should ensure that it is used in such an environment.

Table 6. Emission tests

Emissions test	Compliance	Environmental guidance
RF emissions CISPR 11	Group 1	The Tula Iontophoresis System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Electromagnetic Immunity

The Tula^o Iontophoresis System is intended for use in the electromagnetic environment specified below. The customer or the user of the Tula Iontophoresis System should ensure that it is used in such an environment.

Table 7. Immunity tests

Immunity test	IEC 60601 test / Compliance level	Environmental guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	N/A	
Surge IEC 61000-4-5	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	The Tula Iontophoresis System will be used no closer than 15 cm to sources of power frequency magnetic field.
Conducted RF IEC 61000-4-6	3 V r.m.s 0.15 MHz – 80 MHz 6 V r.m.s in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Tula Iontophoresis System including cables. Otherwise, degradation of the performance of this system could result.
	Proximity fields from RF wireless Communications equipment: 9 V/m to 28V/m per sub clause 8.10, table 9	