

CPT code 0583T
Category III

+ Ear tubes done differently

An in-office alternative to traditional tympanostomy

Smith+Nephew

Tula®
In-office Tympanostomy System



In-office tympanostomy system

The Tula[®] System is FDA-approved for patients 6 months of age and older¹

1

Revolutionary, local anesthesia

The Tula Iontophoresis System applies a low-level electrical charge to the TYMBION™ ionic local anesthetic, accelerating drug uptake into the tympanic membrane. The child may play quietly, watch videos or snack during the process.

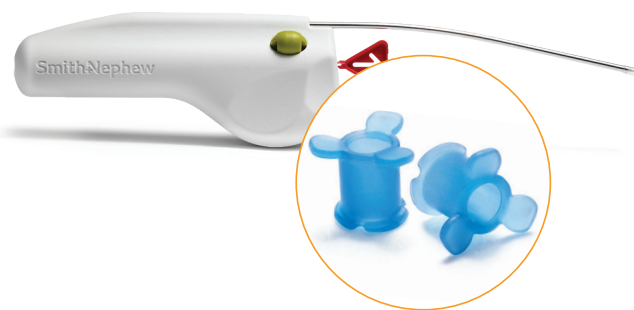


Not all Tula System components are included in this image.

2

1-click tube delivery

The Tula Tube Delivery Device allows a physician to create a myringotomy and insert a silicone 1.14mm ID grommet in one, automated step without the use of mechanical restraints.²

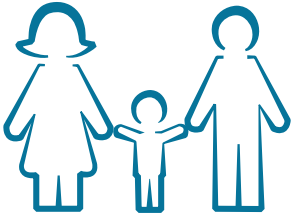


Behavioral management program

The Tula System is supported with an educational and training program designed by input from experts in pediatric psychology, medical stress and pain management.



Tula[®] is safe + effective



High parent satisfaction

95% of parents were VERY satisfied²



Safe

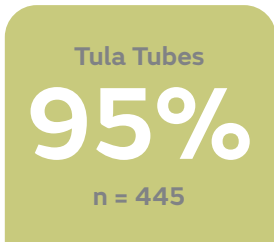
Zero serious device or drug related events²



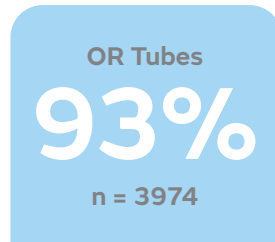
Effective

87% in-office procedural success rate²

Patency by tube at 3 weeks*²



Tula all in-office treated³
(3-week)



Kay et. al., Meta-Analysis⁴
(various timepoints)

Mean intubation period

16.8
months

Median intubation 15.8 months**^{6,7}

Effusion clears without suction²

96.5%

of ears with mucoid effusion at the time of surgery were clear at 3-week follow-up^{2,5}

* Suction was performed in 12.3% and 7.6% of Office lead-in and Pivotal patients, respectively.

** Probable date of extrusion was calculated as the midpoint between the date when tube position across the tympanic membrane was last confirmed and the date when the tube was first noted to be extruded.

Contact your local sales representative to see videos and more.

The Tula 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 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 include certain abnormal ear anatomy, sensitivity/allergy to lidocaine or other local anesthetics, and reliance on electrically sensitive medical implants such as a pacemaker. Risks may include, but are not limited to, inadequate local anesthesia, dizziness, and common tympanostomy procedure risks. For full prescribing information, see the Tula IFU and TYMBION Drug Package Insert at [Tulatubes.com/IFU](https://www.tulatubes.com/ifu). Rx only.

Learn more at [tulatubes.com/physician](https://www.tulatubes.com/physician)

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23174 V5 01/25 MKT007048 Rev. D

References

1. IFU007011, available at www.tulatubes.com/ifu **2.** Lustig LR, Ingram A, Vidrine M, et. al. In-Office Tympanostomy Tube Placement in Children Using Iontophoresis and Automated Tube Delivery. *Laryngoscope* 130; S1-S9, 2020. **3.** Data on file. Tula Pivotal Study Results for in-office lead-in and pivotal cohorts combined, n=445 ears. **4.** Kay DJ, Rosenfeld RM. Meta-Analysis of Tympanostomy Tube Sequelae. *Otolaryngol Head Neck Surg*, 124(4); 374–380, 2001. **5.** 115 ears with mucoid effusion at time of procedure, 111 of these were clear of effusion at 3 week follow-up. **6.** Data on file. Tula Pivotal Study final data. Results from all cohorts combined. **7.** Waldman EH, Ingram A, Vidrine DM, et al. Two-Year Outcomes After Pediatric In-Office Tympanostomy Using Lidocaine/Epinephrine Iontophoresis and an Automated Tube Delivery System [published online ahead of print, 2023 Apr 1]. *Otolaryngol Head Neck Surg*. 2023;10.1002/ohn.336. doi:10.1002/ohn.336