

+ Ear tubes done differently

An in-office alternative to traditional tympanostomy
using a revolutionary, local anesthesia system
and an automated, 1-click tube delivery device

Smith+Nephew

Tula[®]
Tympanostomy System



In-office ear tube placement system

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

Revolutionary, local anesthesia

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

1-click tube delivery

The Tula Tube Delivery Device allows a physician to create a myringotomy and insert a 1.14 mm ID grommetone, 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.



The Tula pivotal study^{2, 5}

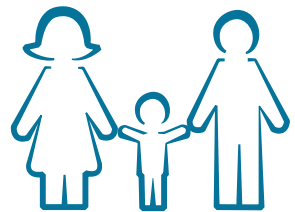
Prospective, multicenter study evaluating the safety and effectiveness of the Tula System in children aged 6 months to 12 years²

Children were enrolled into one of three successive cohorts: Operating room lead-in (n=68), Office lead-in (n=47), Pivotal (n=222)



Safe

Zero serious device or drug related events²



High parent satisfaction

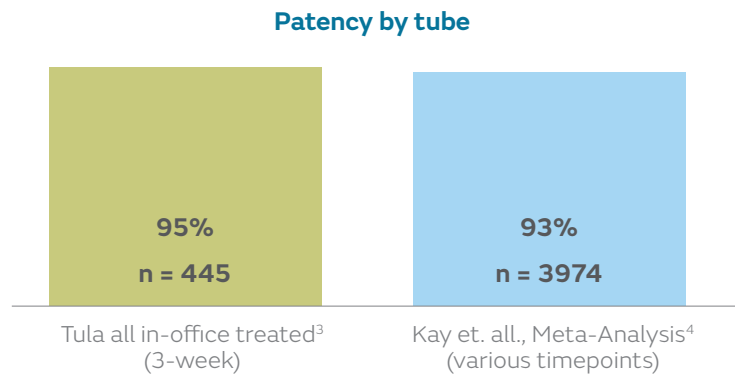
95% of parents were VERY satisfied²



Practical

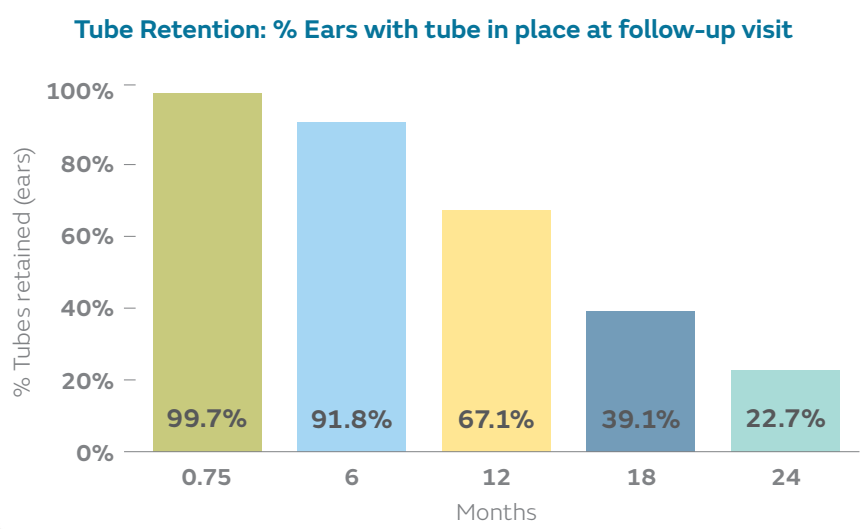
87% in-office procedural success rate²

High patency at 3-week follow-up despite low suction rates^{2*}
(Office lead-in and pivotal cohorts combined)



Effusion clears without suction²
.....
96.5%
of ears with mucoid effusion at the time of surgery were clear at three-week follow-up^{2, 5}

Mean intubation period of 16.8 months
(median 15.8 months)^{6, 7**} (All cohorts combined)



* 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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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