

Introducing a more convenient, in-office alternative to traditional tympanostomy for pediatric patients:

- REVOLUTIONARY, CHILD-FRIENDLY local anesthesia
- QUICK, SAFE AND EFFECTIVE insertion technology enables
 1.14 mm grommet-style ear tube delivery in < 500 milliseconds¹
- 95% VERY SATISFIED parents²



IN-OFFICE EAR TUBE PLACEMENT SYSTEM

The Tula system is FDA-approved for patients as young as six months old.









CHILD-FRIENDLY LOCAL ANESTHESIA

The needle-free Tula iontophoresis system applies a low-level electrical charge to an ionic drug, accelerating drug uptake into the eardrum. The child may play quietly, watch videos or snack during the process.

RAPID TUBE DELIVERY

The Tula Tube Delivery System allows a physician to create a myringotomy and insert a 1.14 mm ID grommet in less than half a second, minimizing the amount of time the child needs to remain still.'

BEHAVIORAL MANAGEMENT PROGRAM

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

CONTACT YOUR LOCAL REPRESENTATIVE TO SEE CASE VIDEOS AND MORE

THE TULA PIVOTAL STUDY

337 subjects ages 6 months to 12 years



SAFE

Zero serious device or drug related events



PRACTICAL

87% in-office procedural success rate³



95% of parents were VERY satisfied

HIGH PATENCY RATES²

TULA ALL IN-OFFICE (3-WEEK) n = 443 95% KAY ET AL. META-ANALYSIS* (VARIOUS TIMEPOINTS) 93%

PATENCY, BY TUBE

EFFUSION CLEARS WITHOUT SUCTION⁴

96.8%

of ears with mucoid effusion at the time of surgery were clear at 3-week follow-up.

- $1. \ Tube \ deployment \ is < 500 \ milliseconds \ and \ over all \ mean \ procedure \ time \ is \ 33 \ minutes. \ Tusker \ data \ on \ file.$
- 2. PMA P190016 FDA Summary of Safety and Effectiveness Data.
- 3. Defined as tube placement in all indicated ears. 222 patients, 91% percent bilaterally indicated, evaluated for procedural success with 86% (103/120) success with patients under 5 years old and 89% (91/102) success with patients 5-12 years old 68 OR lead-in and 47 office lead-in not included, as per the study protocol.
- 4. Tusker data on file. As measured by otoscopy, n=95.
- 5. Kay, David J., et al. "Meta-Analysis of Tympanostomy Tube Sequelae." Otolaryngology-Head and Neck Surgery, vol. 124, no. 4, Apr. 2001, pp. 374–380

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 lontophoresis 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 lidocatine 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 www.tulatubes.com/IFU. Rx only.