

# Tula<sup>®</sup> System

**Once upon a time, there was only one option for ear tubes. Now there's an alternative.**

**Children can get middle ear infections when they have a cold or other respiratory infection. Recurrent ear infections and/or persistent fluid in the middle ear may become a chronic problem leading to other issues such as:**

- **Hearing loss<sup>1</sup>**
- **Poor school performance**
- **Behavioral problems**
- **Speech problems**

**When this occurs, ear tube surgery (which is an insertion of ear tubes by an Ear, Nose and Throat doctor) may be considered.**

**What are the benefits of Ear Tubes?**

Inserting ear tubes may:<sup>2</sup>

- **Reduce the risk of future ear infection**
- **Address hearing loss caused by middle ear fluid**
- **Help with speech and balance problems associated with otitis media**
- **Improve behavior and sleep problems caused by recurrent ear infections**

**Each year in the US, approximately 700,000 ear tube surgeries are performed on children in an operating room, making it the most common childhood surgery performed with general anesthesia.<sup>3</sup> Despite this track record, parents commonly have concerns about general anesthesia and potential complications from surgery.<sup>4</sup>**

**We are pleased to share that ENT Specialists of Austin is now offering in-office ear tube procedures without general anesthesia using the Tula<sup>®</sup> System.**

**The innovative Tula System gives parents an option for in-office placement of ear tubes using a child-friendly system to numb the eardrum while the child can play or watch videos. Throughout the procedure, parents may stay with their child. The Tula system has been shown to be safe and effective in clinical studies, and 95% of parents in the most recent study were satisfied with the procedure.<sup>5,6</sup> Doctors were able to successfully insert tubes in 87% of the children, and most children can return to normal activity immediately after the procedure.<sup>5</sup>**

**To learn more or to schedule an appointment with one of our physicians, please visit ENT Specialists of Austin- <https://entsaustin.com/> or call us at [\(512\) 346-7600](tel:5123467600).**

## About Tula

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 including procedural success rates, contraindications, warnings and precautions, see the Tula IFU (IFU0007011) and TYMBION Drug Package Insert (IFU0007010) at [www.tulatubes.com/IFU](http://www.tulatubes.com/IFU). Rx only.

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**1** Cai T, McPherson B. Hearing loss in children with otitis media with effusion. *Int J Audiology* 56(2); 65-76, 2017.

**2** Rosenfeld RM, Schwartz SR, Pynnonen MA, et al. Clinical practice guideline: Tympanostomy tubes in children. *Otolaryngol Head Neck Surg* 149(1S); S1-S35, 2013. Guideline from the American Academy of Otolaryngology- Head and Neck Surgery.

**3** Hall MJ, Schwartzman A, Zhang J, Liu X. Ambulatory surgery data from hospitals and ambulatory surgery centers: United States, 2010. National health statistics reports; no 102. Hyattsville, MD: National Center for Health Statistics. 2017.

**4** Data on file. Among all who have children younger than 10 years and who have heard of ear tube surgery, n= 429.

**5** 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. Results from parents of children who participated in the Tula pivotal clinical study, n=201-203.

**6** Yen DM, Murray MT, Puchalski R, et al. In-office tympanostomy tube placement using Iontophoresis and automated tube delivery. *OTO Open* 4(1): 1-7, 2020.