

## TYMPANOSTOMY TUBE SYSTEM

### INSTRUCTIONS FOR USE

**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.**

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

The Hummingbird® Tympanostomy Tube System (H-TTS) is a disposable inserter pre-loaded with a sterile tympanostomy tube for use in patients 6 months and older in office or hospital settings.

#### Intended Use

The Hummingbird Tympanostomy Tube System (H-TTS) is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, and positioning and placing a ventilation tube across the TM.

#### Indications for Use

- Pediatric Use in children 6 months and older in an office setting

The Hummingbird Tympanostomy Tube System (H-TTS) is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for children 6 months and older.

- Pediatric Use under general anesthesia in an operating room setting
- Adult Use in any setting

The Hummingbird Tympanostomy Tube System (H-TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

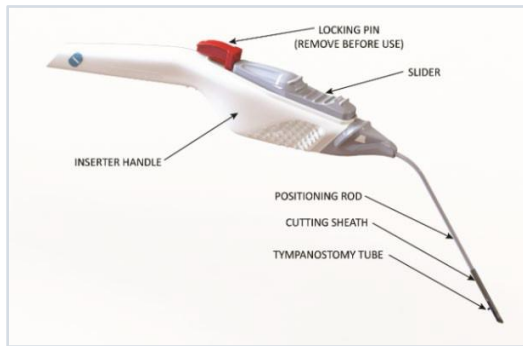


Figure 1 - Hummingbird Tympanostomy Tube Inserter

#### WARNINGS

- The H-TTS is intended for single patient use. DO NOT REUSE.
- Do not use the H-TTS device if the visual depth markers provided (a visual tab located on the lateral end of the ventilation tube, and/or a marker band located on the cutting sheath) cannot be seen during use within the ear canal.
- Do not advance the visual depth markers past the tympanic membrane to avoid over insertion of the ventilation tube and potential damage to the middle or inner ear.
- The patient's head should be restrained to prevent inadvertent head movement during (i) application of local anesthesia and/or (ii) insertion of the TTS through the tympanic membrane and deployment of the tube

#### Contraindications

- Known allergy to implant materials (medical grade silicone and colorant).
- Patient not indicated for a tympanostomy procedure.
- Anatomy precludes visualization and access to the tympanic membrane.
- Hemotympanum or other suspicion of aberrant vasculature (eg, carotid artery; high riding jugular bulb) impacting the tympanic membrane or middle ear.

#### Potential Complications

Possible risks associated with the device may include but are not limited to acute tube extrusion, bleeding, chronic tube extrusion, facial nerve injury, hearing loss, infection, injury to the tympanic membrane or ossicles, nausea, otorrhea, tube clogging, tube dislocating into middle ear and vertigo.

#### Clinical Data for Pediatric Use in an Office Setting: 6-24months

In a multi-site study in children 6-24 months old, a total of 180 children (360 ears) underwent tympanostomy procedures in an ear, nose, and throat (ENT) office using the HTTS. The mean age of the patients was 13 months (range of 6-24 months). An immobilization board and/or swaddling with a nurse or medical assistant holding the child's head was used on all patients, and Phenol as a local anesthetic was used on 173 out 180 patients. Results:

- 178/180 (98.9%) children received tympanostomy tubes in the office as planned.
- The rate of procedural adverse events was 2/360 ears (0.56%), and there were no serious or unanticipated adverse events reported.
- The median bi-lateral procedure time was five minutes (range of 2.0 to 15.5 minutes).
- The recovery of the child was evaluated by the ENT surgeon and staff, and 177/180 (98.3%) children were judged as calm and/or no inappropriate crying before leaving the clinic.
- In 7/360 (1.9%) ears, tympanostomy tube delivery was completed using additional instruments to the HTTS.
- 84.5% of ears were completed in one surgical pass; 97.7% were completed in two passes or less; and 2.3% required more than 2 passes.
- In 130 parent surveys collected at follow-up, 93.1% of parents strongly agreed or agreed that it was important to have an alternative to general anesthesia and that they would recommend the H-TTS office procedure to other parents.
- A committee of clinicians with ENT and/or pediatric specialty experience independently reviewed 30 procedure videos to evaluate how the child tolerated the procedure. At each stage of the procedure, the clinician reviewers rated the response of the child in the following categories: no response, mild, moderate, or significant. In all 30 cases, each of the reviewers deemed that the child tolerated the procedure acceptably. A bar graph tabulation of the committee video review is shown in Figure 2

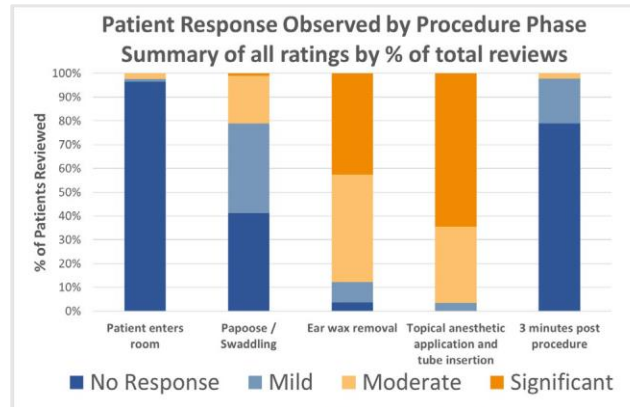


Figure 2 Patient Response Observed by Procedure Phase

#### Clinical Data for Pediatric Use in an Office Setting: 2 years and older

In a multi-site study in children 2-17 years old, a total of 48 children (74 ears) underwent tympanostomy procedures in an ENT office using the HTTS. (An immobilization board and/or swaddling with a nurse or MA holding the child's head was used on all patients. Phenol was used as a topical anesthetic on all patients. Results:

- 46/48 (95.8%) children received ventilation tubes in the office as planned (success).
- There were zero adverse events (safety).
- The median bi-lateral procedure time was 4'20" (range of 1'54"-18'06").
- In 72/74 ears (97.3%), tube delivery was successfully delivered using the HTTS (efficacy).
- The recovery of the child was evaluated by the ENT and staff, and 48/48 (100.0%) children were judged as calm and/or no inappropriate crying before leaving the clinic.
- In 36 parent surveys collected at follow-up, 97.2% of parents strongly agree or agree that it was important to have an alternative to general anesthesia and 94.4% strongly agreed or agreed that they would recommend the HTTS office procedure to other parents.
- 87.5% of ears were completed in one surgical pass; 95.8% were completed in two passes or less; and 4.2% required more than 2 passes.
- In 7/72 ears (9.7%), additional instruments were used for tympanostomy tube adjustment.

#### Precautions For In Office Use in Pediatric Patients 6 months and older

When using the H-TTS for tympanostomy tube placement in children 6 months and older in an otolaryngology office setting:

- Assess suitability of the H-TTS procedure using shared decision making between the parents and the physician.
- Local anesthesia should be used on the tympanic membrane to increase the child's comfort.
- The head should be gently restrained by a nurse or medical assistant.
- For children under three years old, an immobilization board and/or swaddling should be used to mitigate the child's body movement.
- For children three years and older, discuss with the parents and child whether to use an immobilization board to mitigate the child's body movement.

#### Restrictions

The H-TTS should only be operated by physicians experienced in tympanostomy procedures who have read these Instructions for Use and understand the use of the H-TTS.

#### Maintenance

The device is a sterile, single patient-use product. No maintenance is required.

#### H-TTS Function and Operation

Figure 3 illustrates the steps to perform tympanostomy tube placement with the H-TTS. A close-up of the front tip of the device is shown illustrating the tympanic membrane, the positioning rod, the cutting sheath, and the tympanostomy tube. The tympanostomy tube is constrained within the cutting sheath and is held in place by friction. A slot in the cutting sheath and a visualization tab (Vis-Tab) keep the position of the tympanostomy tube visible throughout the procedure. The cutting sheath retracts by sliding over the positioning rod when the slider on the handle is moved backwards away from the tip of the device. This releases the tympanostomy tube from the sheath and into position across the tympanic membrane.

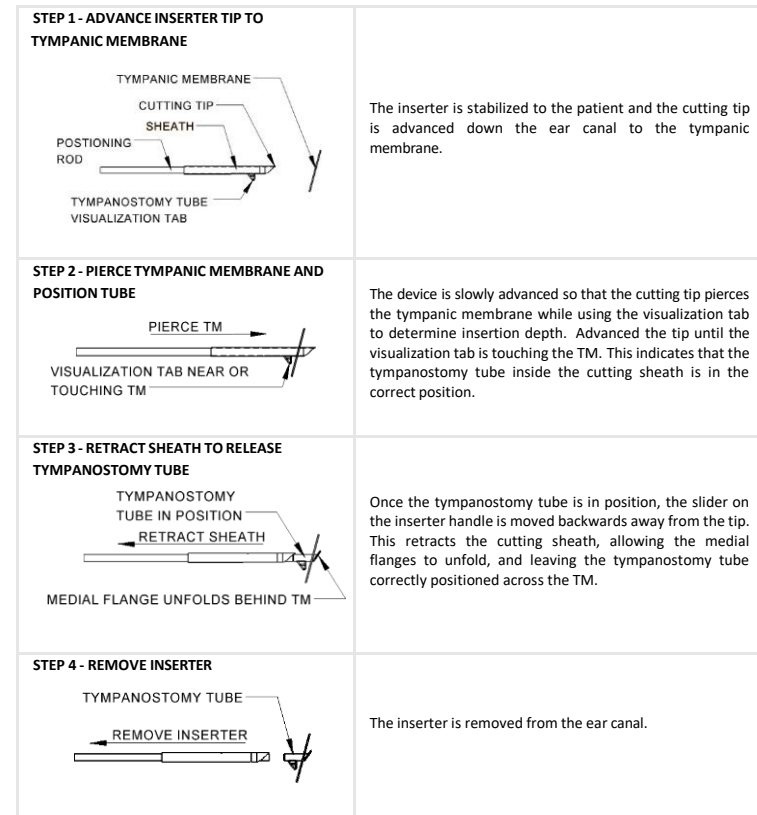


Figure 3 - H-TTS Function and Operating Steps

Visualization Tab (VisTab) Description

To accommodate user preference, the H-TTS inserter is offered with the visualization tab (“VisTab”) of the vent tube oriented in two different directions, -90 degrees from vertical (-90 Tip) or +90 degrees from vertical. (+90 Tip) See Figure 4. The vent tube (implantable) is the same in both versions; only the orientation in the inserter tip is different.

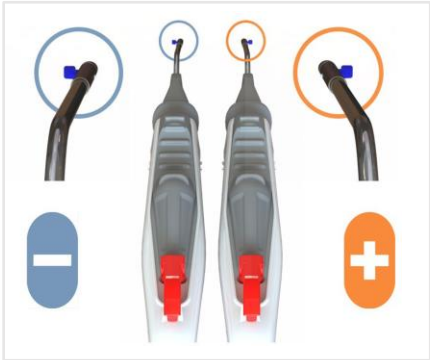


Figure 4 –The two Vistab orientations of the H-TTS. When the inserter is viewed as shown, the Vistab points to the left (or -90 degrees from vertical) in the -90 H-TTS. The Vistab points to the right (or +90 degrees from vertical) in the +90 H-TTS.

H-TTS Components

Disposable Components (provided ethylene oxide (EO) Sterilized):

- H-TTS (Tympanostomy Tube System)
- Pre-loaded Tympanostomy Tube

Other Recommended Equipment (not provided)

- Ear speculum
- Curette
- Topical Anesthetic
- Suction tubes, tubing, and vacuum system
- Swaddling blankets or immobilization board to mitigate motion during the procedure

Setup

**CAUTION** Inspect the packages and devices carefully. Do not use if the package is damaged.

**CAUTION** Open the packaging and remove the devices carefully to ensure the devices are not damaged.

**CAUTION** Do not use if the expiration dates are exceeded.

**CAUTION** Do not use if the device is damaged.

**CAUTION** Do not bend or shape the device. This may cause device damage.

1. Carefully remove the H-TTS from the packaging.
2. Inspect the H-TTS upon removal from packaging to make sure the device is not damaged.
3. Verify that the tympanostomy tube is properly loaded within the cutting sheath and that the lateral flange, or Vis-Tab, is visible (see Figure 5)

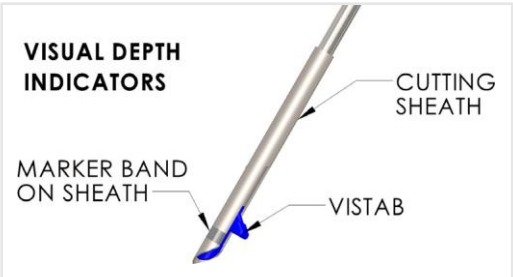


Figure 5 - Close up of loaded tympanostomy tube showing correct lateral and medial flange location within cutting sheath and sheath depth indicator.

4. When ready to use the device, remove the locking pin from the inserter handle by pulling on the red tab. The locking pin prevents accidental movement of the slider actuator. Once the locking pin is removed, be careful not to move the slider until ready to deploy the tympanostomy tube from the device (See Procedural Step #4 below).

Procedural Steps:

**CAUTION** Follow standard hospital/clinic policies and procedures.

**CAUTION** Use the H-TTS with an ear speculum to avoid injury to the auditory canal.

**CAUTION** Ensure the auditory canal is sufficiently clean to allow direct visualization of the TM and of the H-TTS device during tube placement.

**CAUTION** Insertion location of the H-TTS on the tympanic membrane should be chosen to avoid damage to the ossicular chain.

**CAUTION** For an awake patient, if the patient expresses pain upon contact with the tympanic membrane, additional local anesthesia may be required.

**CAUTION:** In patients with moderate to severely retracted tympanic membranes, there may be insufficient space behind the TM to allow the H-TTS to deploy the tube.

**CAUTION** Avoid excessive penetration depths with the H-TTS device to reduce the risk of injury to vasculature or nerves in the case of abnormal anatomy.

1. Insert an ear speculum into the outer ear canal following routine preparation. The ear canal and area around the tympanic membrane must be cleaned sufficiently to allow for good visualization of the tympanic membrane and the Vis-Tab.
2. Hold the H-TTS so that the slider is prevented from moving during incision. Stabilize the operating hand holding the H-TTS to the speculum or to the patient. Under visualization, for example through an operating microscope, manually advance the H-TTS through the speculum and down the ear canal such that the cutting component pierces the tympanic membrane in the location indicated for tympanostomy tube insertion
3. Advance the H-TTS until the beveled portion of the cutting sheath is completely through the TM and the Vis-Tab on the tube is visible lateral to the TM (or the marker band on the cutting sheath is located proximal to the TM).
4. Move the slider located on the device handle backwards away from the tip (see Figure 6) to retract the cutting sheath and position the tympanostomy tube across the TM. Continue to move the slider through its full range of motion to fully retract the cutting sheath.

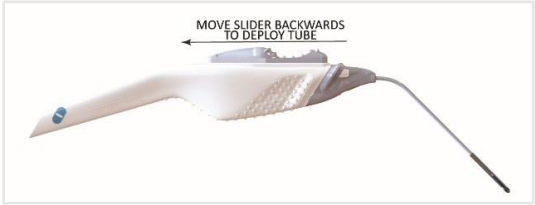


Figure 6 - Slider Movement

5. Once the tympanostomy tube is deployed, remove the H-TTS inserter from the ear canal and dispose of appropriately.

**CAUTION:** Single Use Device. Do not attempt to re-load a deployed tympanostomy tube or to load a new tympanostomy tube into the H-TTS device.

Definitions of Symbols

| Symbol | Std Ref* | Title        | Description of symbol                                                                                             |
|--------|----------|--------------|-------------------------------------------------------------------------------------------------------------------|
|        | 5.4.2    | Do not reuse | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure |
|        | 5.1.5    | Batch code   | Indicates the manufacturer’s batch code so that the batch or lot can be identified.                               |
|        | 5.1.4    | Use by date  | Indicates the date after which the medical device is not to be used.                                              |

| Symbol | Std Ref* | Title                            | Description of symbol                                                                                                                                         |
|--------|----------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 5.4.3    | Read Instructions for Use        | Indicates the need for the user to consult the instructions for use.                                                                                          |
|        | 5.1.1    | Manufacturer                     | Indicates the medical device manufacturer.                                                                                                                    |
|        | 5.1.6    | Catalog Number                   | Indicates the manufacturer’s catalogue number so that the medical device can be identified.                                                                   |
|        | 5.2.3    | Sterilized Using Ethylene Oxide  | Indicates a medical device that has been sterilized using ethylene oxide.                                                                                     |
|        | 5.2.8    | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened.                                                                 |
|        | None     | +90 Tip                          | Indicates the HTTS has a +90 Tip orientation. When the inserter is viewed as shown in Figure 5, the Vistab points to the right (or +90 degrees from vertical) |
|        | None     | -90 Tip                          | Indicates the HTTS has a -90 Tip orientation. When the inserter is viewed as shown in Figure 5, the Vistab points to the left (or -90 degrees from vertical)  |

\*Standard Designation and Reference # - ISO 15223-1:2021(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements

| System Component Specifications      |                          |                                                                           |
|--------------------------------------|--------------------------|---------------------------------------------------------------------------|
| Tympanostomy Tube Inserter           | Cutting Sheath Diameter  | 0.072" (1.8 mm)                                                           |
|                                      | Positioning Rod Diameter | 0.060" (1.5 mm)                                                           |
|                                      | Positioning Rod Length   | 1.9" (47 mm)                                                              |
|                                      | Overall Length (approx.) | 7.00" (18 cm)                                                             |
| Tympanostomy Tube                    | Inside Diameter          | 0.039" (1.0 mm)                                                           |
|                                      | Material                 | Medical grade silicone and colorant<br>Not made with natural rubber latex |
| Catalog Numbers                      |                          |                                                                           |
| Hummingbird Tympanostomy Tube System | 05-1001-652              | -90 Inserter Containing One Pre-Loaded Tympanostomy Tube                  |
|                                      | 05-1001-653              | +90 Inserter Containing One Pre-Loaded Tympanostomy Tube                  |



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