CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

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

Indications for Use
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.

Intended Use
The 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.

Clinical Data
In two studies (an initial feasibility study followed by a multi-site study), a total of 69 children (136 ears) underwent tympanostomy procedures under moderate sedation using the Preceptis H-TTS. The mean age of the patients was 2.4 years (range of 8 months to 8.9 years). Results:

- 100% of the children received ventilation tubes as planned.
- There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within peer-reviewed literature reported rates.
- Moderate sedation was per definition from the ASA guidelines, Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia.
- The moderate sedation regimen was determined by the surgeon and anesthesiologist. In these two studies, the surgeon and anesthesiologist chose to use nitrous oxide (50-70%) in all cases.
- In the 1st study, there were 12 conversions (30%) from moderate sedation to general anesthesia due to surgical challenges. In the 2nd study, 2 cases (7%) were converted. The reduction in the conversion rate was likely due to increased surgical experience and design improvements to the TTS to improve visibility and repeatability.
- In most cases during the study, the surgeon chose to use a local anesthetic on the tympanic membrane to reduce discomfort for the patient. Under moderate sedation, local anesthesia of the tympanic membrane should be used to reduce the risk of head movement and increase patient comfort.
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 damage to the middle or inner ear.
- **When using the H-TTS for tympanostomy tube placement in children:**
  - Either general anesthesia or moderate sedation with local anesthesia of the tympanic membrane is recommended.
  - The anesthetic regimen should be determined by the attending otolaryngologist and anesthesia professional.
  - The tympanostomy procedure should only be performed in a hospital or ambulatory surgical center setting, with the anesthesia delivered by an anesthesia professional.
  - In all cases performed under moderate sedation with local anesthetic, general anesthesia must be available as back-up

contraindications

- Known allergy to implant materials.
- Patient not indicated for a tympanostomy procedure.
- Anatomy precludes visualization and access to the tympanic membrane.

potential complications

Possible risks associated with the device may include but are not limited to:

- Otorrhea
- Acute tube extrusion
- Chronic tube extrusion
- Tube dislocating into middle ear
- Tube clogging
- Bleeding
- Vertigo
- Nausea
- Infection
- Hearing loss
- Facial nerve injury
- Injury to the tympanic membrane or ossicles
Restrictions
The H-TTS should be only operated by physicians experienced in tympanostomy procedures, which have reviewed this Instruction for Use and understood the use of the H-TTS.

Maintenance
The device is a single patient-use disposable product. No maintenance is required.

H-TTS Components

Disposable Components (provided EO Sterilized):
- H-TTS (Tympanostomy Tube System)
- Pre-loaded Ventilation tubes (PN 05-1026-009)

Other Recommended Components (not provided)
- Ear speculum
- Curette
- Topical Anesthetic
- Suction tubes, tubing, and vacuum system

Figure 1. Tympanostomy Tube Inserter
**Setup**

1. Carefully remove the H-TTS from the packaging.

   **CAUTION:** Use caution in opening the packaging and removing the devices to insure the devices are not damaged.

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

2. Inspect the H-TTS upon removal from packaging to make sure the device is not damaged.

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

3. Verify that the ventilation tube is properly loaded within the device and that the depth indicator, or Vis-Tab, is visible (see figure 2).

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

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**Figure 2.** Close up of loaded ventilation tube showing correct placement within cutting sheath and depth indicators.
Procedural Steps:

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

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 visual depth indicator located on the H-TTS.

   **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.

2. 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 ventilation tube insertion

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

3. Advance the H-TTS until the beveled portion of the cutting sheath is completely through the TM and the visual depth indicator (visualization tab on the tube or visualization marker band on the cutting sheath) is visible lateral to the TM.

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

4. Rotate the scroll wheel located on the device handle BACKWARDS (see figure below) to retract the cutting sheath and position the ventilation tube across the TM. Continue to rotate the scroll wheel through its full range of motion to fully retract the cutting sheath.
5. Retract the H-TTS from the ear canal and dispose of appropriately.

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

The H-TTS tip assembly is user adjustable to three different angular orientations to provide improved ergonomics for the user (see figures below). The following three figures show the three tip orientations possible. The tip is adjusted by grasping the tip adjustment tab and twisting it while holding the handle. Do not adjust the tip by grasping the positioning rod as this may damage the tip assembly.
The following schematic illustrates the steps taken with the device to perform ventilation tube placement. A close up of the front of the device is shown illustrating the tympanic membrane, the stainless steel positioning rod, the cutting sheath, and the ventilation tube. The ventilation tube is constrained within the cutting sheath and is held in place by friction. A slot in the cutting sheath allows direct visualization of the vent tube throughout the procedure. The cutting sheath retracts axially along the positioning rod when the scroll wheel on the handle is turned.

**Stage 1** – The device is manually advanced down the ear canal.

**Stage 2** – The entire device is manually advanced so that the cutting tip pierces the tympanic membrane. A slot in the cutting sheath allows visualization of the vent tube, ensuring it is positioned correctly in relation to the TM.

**Stage 3** – Using the scroll wheel on the handle, the clinician retracts the cutting sheath. The positioning rod remains stationary and pushes the vent tube out of the cutting sheath, leaving it correctly positioned across the TM.

**Stage 4** - The device is then retracted from the ear canal.

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**Operating and Storage Conditions**

**Disposal**
All components of the H-TTS are single patient-use.

**Functional Life**
All components of the H-TTS are single patient-use devices and must be used prior to the stated expiration date.

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**Definitions of Symbols**

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<th>Symbol</th>
<th>Description</th>
<th>Code/Code Word</th>
<th>Additional Information</th>
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### Specifications Table

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<tr>
<th>System Component</th>
<th>Specification</th>
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<tbody>
<tr>
<td>Tympanostomy Tube Inserter</td>
<td>Cutting Sheath Diameter 0.072” (1.8 mm)</td>
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<tr>
<td></td>
<td>Positioning Rod Diameter 0.060” (1.5 mm)</td>
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<tr>
<td></td>
<td>Positioning Rod Length 1.9” (47 mm)</td>
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<td>Overall Length 5.125 in. (13 cm)</td>
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<tr>
<td>Ventilation Tube</td>
<td>Inside Diameter 0.039” (1.0 mm) Medical Grade Silicone</td>
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<th>Catalog Numbers</th>
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