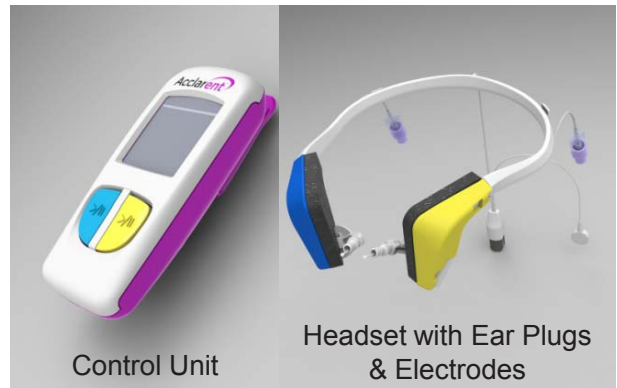


Iontophoresis System with Headset

Patient Information Sheet

General Information

- The Acclarent Iontophoresis System with Headset provides a means to numb the ear drum by using a low level electric current to deliver anesthetic solution to the ear drum.
- Once the ear drum has been numbed, the doctor will proceed with the indicated tube placement procedure.



Procedural Details

- The doctor will examine and clean the ears (if needed).
- The device looks like a headphone set. It has ear plugs that sit in the openings of the ear canals and ear electrodes that connect to the control unit. The patient's ears will be sized to determine the appropriate device size for the patient's anatomy.
- An anesthetic solution consisting of commonly used anesthetic agents will be placed in the patient's ear.
- The patient will wear the headset and have solution in their ears for about 10 minutes while the control unit sends a low electrical current to the ear electrodes. Once complete, the system will automatically shut off.
- If the sensation is intolerable at any time, the current delivery can be stopped by the doctor.
- When the 10 minutes are done, the doctor will gently take out the ear plugs and headset and solution.
- After removing the system, the doctor will use a dull ear probe to test the patient's ear drum for numbness. If the anesthetizing effect is insufficient, the doctor may treat the patient using an alternative method of anesthesia.
- At this time, the doctor will continue with the indicated tube placement procedure.

Note: If a patient chooses to participate in the clinical study, full disclosure of the procedure's risks and benefits will be explained in a consent form and by the research doctor.

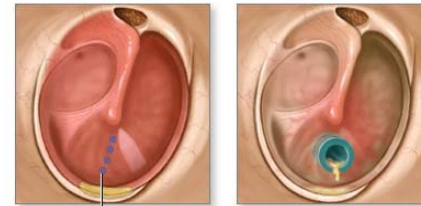
Tympanostomy Tube Delivery System

Patient Information Sheet

Background

More than 1,000,000 ear tubes are inserted annually in North America, making it one of the most common surgical procedures performed in children.¹ Most tubes are inserted by otolaryngologists (Ear, Nose, and Throat physicians) with the patient under general anesthesia.

Acclarent has developed a medical device that facilitates the insertion of ear tubes in patients. The Acclarent tube is made of silicone and is similar to other ear tubes. The Acclarent device performs the same sequence of actions as the standard surgical procedure, but integrates multiple instruments into one device. It delivers the tube with the push of a button.




A small incision is made in the tympanic membrane

Tube inserted to drain fluid

The objective of this study is to evaluate the safety and performance of the Acclarent device for the placement of ear tubes in patients who require such treatment.

ADAM.

Comparison of Current Surgical Approach and Acclarent Device

Current Surgical Approach	Acclarent Device
<ul style="list-style-type: none"> The surgeon uses a surgical knife to create a incision in the eardrum (tympanic membrane) at the target site for tube insertion. The surgeon uses surgical instruments to pick up the tube and insert it through the incision. Another surgical instrument may be used to help position the tube. 	<ul style="list-style-type: none"> The surgeon places the blunt tip of the Acclarent device against the eardrum (tympanic membrane) at the target site for tube insertion. The surgeon presses a button to activate the device, which will sequentially make a small incision and place a tube through the eardrum. 

Potential Benefits of Acclarent Device

- Device is designed to make an incision that is smaller than those made manually.
- Device is designed to precisely control the depth of incision.

Potential Risks

Possible side effects are very similar to the current standard surgical procedure and may include: Tube clogging or blockage, tube falling out (extruding) early or failing to self-extrude, tube dislocating into the middle ear space, eardrum perforation (a hole in the eardrum), eardrum thickening and hardening or shrinking, infection, bleeding, hearing loss, or anesthesia complications. The device in this study is investigational. Not all risks or side effects are known.

Note: If a patient chooses to participate in the clinical study, full disclosure of the procedure's risks and benefits will be explained in a consent form and by the study doctor.

¹Isaacson, GC. "Overview of tympanostomy tube placement and medical care of children with tympanostomy tubes," *Up to Date*, October 2008, 7 Aug 2008
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