

Perf-Fix Study for Chronic Tympanic Membrane Repair

Status: RECRUITING

Eligibility Criteria

Age: 5 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Willing and able to provide informed consent, legally authorized representative (LAR) consent, or LAR consent and assent when age appropriate * Females and males at least 5 years old * Perforation involves >25% of the tympanic membrane * Perforation has not spontaneously closed after 4 weeks of watchful waiting * Perforation is not actively healing * Perforation can be visualized by an endoscope or microscope * Ear wax does not occlude the perforation

Exclusion Criteria:

* Perforation is marginal (a perforation that has an area with no tympanic membrane between the perforation and the bony canal) * Active otitis media, with or without effusion * Otorrhea from the middle ear for more than 3 months * History of cleft palate * Receiving radiation therapy or taking corticosteroids, immunosuppressive agents, or chemotherapy * Currently taking systemic antibiotics, antibiotic ear drops, and/or steroid ear drops * Current bacterial or viral infection * Fever (Temperature >100°F) at time of index procedure * Diagnosed with cholesteatoma mass in the tympanic cavity * Known history of malignant ear canal tumors within 3 years of screening for eligibility * Abrasions/lacerations to the external auditory canal * Significant medical condition that could prevent full participation in the procedures required for the study * Investigator feels the subject will be unable to cooperate with the application procedure * Parent/LAR feels the subject will be unable to cooperate with the application procedure * Allergy to shellfish * Known to be or could be pregnant * Adults lacking capacity to consent

Conditions & Interventions

Interventions:

DEVICE: Perf-Fix Otologic Gel Patch

Conditions:

Tympanic Membrane Perforation

Keywords:

tympanic membrane, eardrum, pediatric, tympanoplasty, myringoplasty

More Information

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Principal Investigator:

Phase: NA

IRB

Number:

System ID: NCT06083181

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