THE ONLY* EUSTACHIAN TUBE BALLOON DILATION SYSTEM
FDA-CLEARED FOR PATIENTS AGES 8 AND ABOVE[1]

ACCLARENT AERA®
Eustachian Tube Balloon Dilation System

Think beyond ear tubes

When ear tubes are not enough, treat the source not the symptoms

*As of May 9, 2025

Acclarent®
AN INTEGRA LIFESCIENCES COMPANY

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Persistent Eustachian tube dysfunction (ETD)

ETD affects children and adults and can lead to severe consequences, including hearing loss, chronic otitis media, and cholesteatoma.[2]

Obstructive Eustachian tube dysfunction (OETD) is a common form of ETD, defined as the inability of the Eustachian tube to equalize pressure and ventilate the middle ear.[3]

Approximately **1.48 million adolescents** in the U.S. suffer from OETD[4]

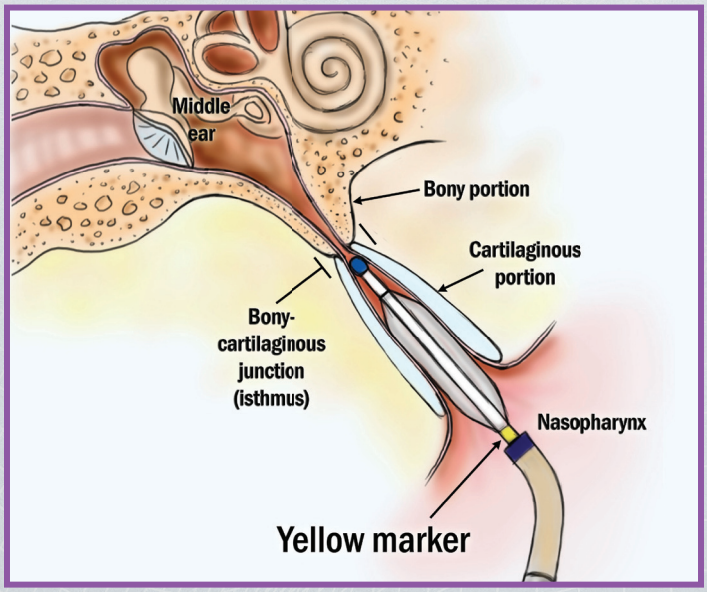
Current therapies

Medical management involves the use of intranasal steroids, systemic antibiotics, decongestants, and antihistamines.[5]

Studies have shown that medical management does not always improve OETD in the majority of patients.[6]

Surgical management can include insertion of tympanostomy tubes (TT) alone, performing adenoidectomy alone or TT along with adenoidectomy.

A study by Drs. Kay, Nelson, and Rosenfeld showed that the use of tympanostomy tubes can be associated with long-term complications including an increased relative risk of ear drum perforation by 3.5 and cholesteatoma by 2.6.[7]



And now, **ACCLARENT AERA®** is the only* Eustachian tube balloon dilation (ETBD) System FDA-cleared for patients ages 8 and above.[1]

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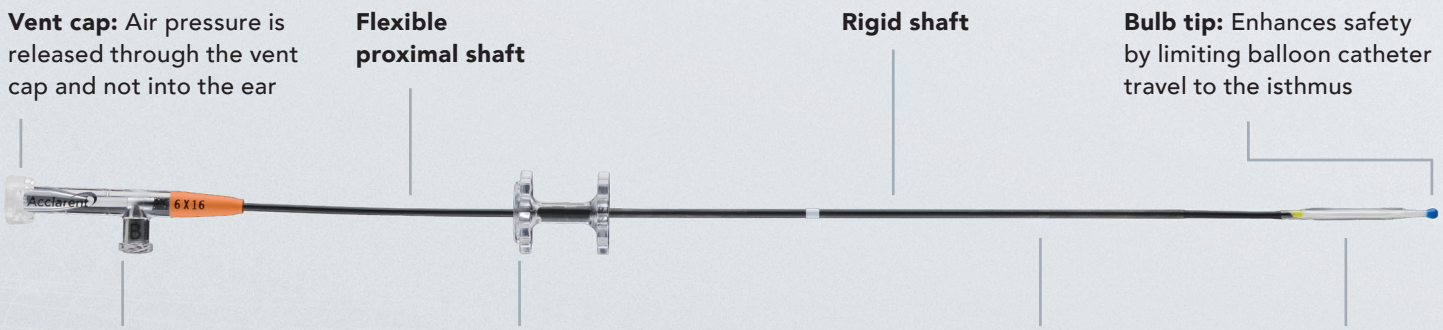
Specifically designed to treat the source of ETD for enduring relief**

ACCLARENT AERA® is the first device*** exclusively designed to treat persistent Eustachian tube dysfunction

- Preserves natural anatomy with minimally invasive transnasal access
- Offers the flexibility to adapt to the s-shaped curve of the Eustachian tube
- Designed specifically for the Eustachian tube anatomy

ACCLARENT AERA®
has specific, differentiated safety features[8]



ACCLARENT AERA® Guide Catheter is designed to provide a means to access the Eustachian tube.

The Inflation Device is a high-pressure syringe barrel, ergonomic piston handle, and a gauge used to confirm and monitor balloon pressure.

* As of May 9, 2025.
** Based on a sample size of 69 ears that reported 84% failure free rate after a mean of 2.7 years of follow up.
*** In the United States.

Anatomical similarities in the Eustachian tube between adults and children 8+ years

Essential anatomies involved in Eustachian tube balloon dilation (ETBD) for patients ages 8-18 years are not statistically significantly different compared to patients 18 years and older.

ET angle

Three studies demonstrated that there is no significant difference between patients 8-18 years and patients >18 years in ET angle for patients with Otitis media with effusion (OME).[9, 11-12]

ET Angle, degree[11]	Mean (95% CI)		p-value
	8-18 years	>18 years	
Horizontal°	22-24	23-25	0.11
Sagittal°	140-142	140-142	0.44

Table 1. ET Angle measurements by age group [data from Magro et al (2021)

ET length

Four studies measured ET length and observed that the ET length is within the same range for patients >8 years and >18 years due to slow growth of ET after the age of 8.[9-12]

ET Length, mm	Mean (95% CI)		p-value
	8-18 years	>18 years	
Total ET length (mm)	40-41	39-41	0.021
Cartilaginous ET length (mm)	27-29	27-28	0.59

Table 2. ET Length measurements by age group [data from Magro et al (2021)

Distance between the ET's bony-cartilaginous junction and the internal carotid artery

Noonan et al (2019)[13] and Margo et al (2021)[16] measured the distance between the ET's bony-cartilaginous junction and the internal carotid and reported no statistically significant difference between group of age 8-18 years and >18 years.[13]

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Evidence demonstrates significant benefits in adults

ACCLARENT AERA® is backed by a prospective, multicenter, randomized clinical trial to demonstrate better performance compared to medical management[8]:

99.7%

technical success in dilating the Eustachian tube

63% vs. 26%

tympanogram improvement at 6 weeks[**2]**

56% vs. 8%

improvement in the quality of life measure from the Eustachian Tube Dysfunction Questionnaire (ETDQ-7)[**]**

Now expanding those significant benefits to children[***]

Real-world evidence on pediatric ETBD, with data from published literature based on retrospective studies.[1,14]

97.7%

Success rate in dilating the Eustachian tube from a published study[14]

84%

Failure free rate after a mean of 2.7 years of follow-up[****1]

75%

Of procedures reported an improvement in tympanometry[†1]

0

Reported serious adverse events[‡*****1]

Real-world evidence supports that ETBD with ACCLARENT AERA® is comparable if not superior to tympanostomy tube placement alone in the treatment of chronic otitis media with effusion in the pediatric population.[1]

* As of May 9, 2025.
** Compared to control subjects treated with medical management alone.
*** Pediatric population ages 8-17 years who are refractory to at least one surgical intervention.
**** 84% of ears were failure-free after a mean of 2.7 years of follow-up (failure was defined as whether further surgery was needed to treat the patient's ETD, e.g., tympanostomy tube insertion or revision ETBD).
***** A serious adverse event is any adverse event that: 1) Results in death, 2) Is life-threatening or places the participant at immediate risk of death from the event as it occurred, 3) Requires or prolongs hospitalization, 4) Causes persistent or significant disability or incapacity.
† Sample size - 20 patients.
‡ Reported adverse events have included epistaxis and transient otalgia in rare instances.

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Pediatric patient selection*[1]

- ☐ Patients ages 8 – 17 years old.
- ☐ Persistent obstructive Eustachian tube dysfunction (OETD) from inflammatory pathology, resulting in chronic otitis media with effusion:
- ☐ COME: Chronic Otitis Media with Effusion; defined as persistent OME (otitis media with effusion) lasting 3 months.
- ☐ Refractory to at least one surgical intervention for persistent OETD.
- ☐ Absence of internal carotid artery dehiscence into the Eustachian tube lumen or history of ipsilateral patulous Eustachian tube.

"In cases where symptoms continue and additional procedures are required, Eustachian tube balloon dilation could treat the underlying cause of persistent OETD. With this FDA-clearance, physicians will be able to offer their pediatric patients an effective alternative that provides enduring ETD relief, reducing stress and concerns for parents"

Dennis Poe, M.D.,Ph.D.

Professor of Otolaryngology–Head and Neck Surgery, Harvard Medical School, and Associate in the Department of Otolaryngology and Communication Enhancement at Boston Children's Hospital

Dr. Poe is a paid consultant to Acclarent, Inc.
* Patient selection criteria for data presented in 510(K) summary.

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Extend ETD relief to your pediatric patients**

We are here to support your journey. Acclarent offers various resources so that your pediatric patients can benefit from this exclusive technology.

GET CERTIFIED

Contact your representative or email our professional education team at dl-accus-profedcourses@its.jnj.com

CONNECT WITH AN EXPERT

Our team will connect you with an ENT with ETBD experience dl-accus-profedcourses@its.jnj.com

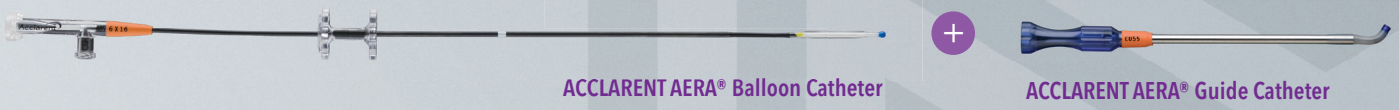
REIMBURSEMENT RESOURCES

Pediatric Patient Access Program: 1-877-340-6466.

* As of May 9, 2025.

** Pediatric population ages 8-17 years who are refractory to at least on surgical intervention.

Catalog number	Description
EU061655	ACCLARENT AERA® Eustachian Tube Balloon Dilation System



ACCLARENT AERA® Balloon Catheter

ACCLARENT AERA® Guide Catheter

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Indications

The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is intended to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older. For patients ages 8-17 years, The ACCLARENT AERA Eustachian Tube Dilatation System, alone or in combination with adjunctive procedures, is intended to treat patients with objective signs of persistent obstructive Eustachian tube dysfunction from inflammatory pathology, resulting in chronic otitis media with effusion and are refractory to at least one surgical intervention for persistent obstructive Eustachian tube dysfunction.

Important Safety Information: ACCLARENT AERA® Eustachian Tube Balloon Dilation System is intended for use by physicians who are trained on Acclarent Technology. Eustachian tube balloon dilation has associated risks, including tissue and mucosal trauma, infection, or possible carotid artery injury. Prior to use, it is important to read the Instructions for Use and to understand the contraindications, warnings, and precautions associated with these devices.

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