

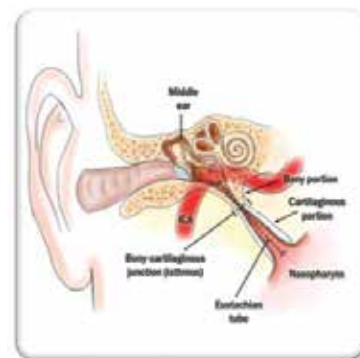
## ACCLARENT AERA® Eustachian Tube Balloon Dilation System FACT SHEET

### Description of Disease State:

The Eustachian tube is a narrow tube which links the back of the nose to the middle ear. It is normally closed but opens when we swallow, yawn or chew. It has three main functions: to protect the middle ear from sources of disease, to ventilate the middle ear, and to help drain secretions away from the middle ear.<sup>1</sup>

Eustachian tube dysfunction (ETD) is the inability of the Eustachian tube to adequately perform these functions and failure of the valve of the Eustachian tube to open and/or close properly.<sup>2</sup>

ETD (Eustachian tube dysfunction) is estimated to affect up to 5% of the adult population.<sup>3</sup>



**Narrowing of the Eustachian tube causes patients to experience ear pain, pressure, fullness, popping, ringing, or muffled sounds in the affected ear(s).**

### Symptoms and causes:

Normally, the Eustachian tubes are working properly so you don't notice them at all.

Anything that prevents the tube from opening or closing properly can cause Eustachian tube dysfunction.

Eustachian tube dysfunction may occur when the mucosal lining of the tube is swollen, or does not open or close properly. It can occur after the start of a cold and other nose, sinus, ear and throat infections.<sup>1</sup>



When they are not working properly, the patient can possibly experience the following symptoms: muffled hearing, fullness of the ear, pain in the ear, inability to equilibrate middle ear (ME) pressure, tinnitus, and dizziness.<sup>4</sup>

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### Complications from untreated ETD:

Persistent Eustachian Tube Dysfunction can be associated with several serious conditions.

- Long-term ETD has been associated with damage to the middle ear and the eardrum.<sup>1</sup>
- Otitis media with effusion, atelectasis of the ME, adhesive otitis, perforation of eardrum and Cholesteatoma.<sup>4</sup>

1. Llewellyn A, Norman G, Harden M, et al. Interventions for adult Eustachian tube dysfunction: a systematic review. *Health Technol Assess.* 2014;18(46):1-vi.  
 2. Grimmer, J.F., & Poe, D.S. Update on Eustachian Tube Dysfunction and the Patulous Eustachian Tube. *Curr Opin Otolaryngol Head and Neck Surg*, 13: 277-282.  
 3. Shan A, Ward BK, Goman AM, et al. Prevalence of Eustachian Tube Dysfunction in Adults in the United States. *JAMA Otolaryngol Head Neck Surg.* 2019;145(10):974-975.  
 4. Randrup, T.S. & Ovesen, T. (2015) Balloon Eustachian Tuboplasty: A Systematic Review. *Otolaryngology–Head and Neck Surgery*, 152(3); 383–392.



### Treatment options:

Now, your physician has another option in treating Eustachian tube dysfunction (ETD).

The ACCLARENT AERA® Eustachian Tube Balloon Dilation System is the first\* device in the US indicated to treat persistent Eustachian tube dysfunction (ETD), a condition in which pressure, pain or clogged or muffled sensations occur in the ear. The ACCLARENT AERA® device is intended to dilate the Eustachian tube for treatment of persistent ETD in patients ages 18 and older.<sup>5</sup>

With the ACCLARENT AERA® system, a catheter is used to insert a small balloon through the patient's nose and into the Eustachian tube. Once inflated, the balloon opens up a pathway for mucus and air to flow through the Eustachian tube, which may help restore proper function. After the Eustachian tube is dilated, the balloon is deflated and the catheter is removed.

### Clinical Support

- Results from a clinical study demonstrated a 99.7 percent technical success rate in Eustachian tubes dilated.<sup>5</sup>
- This study also found a greater rate of tympanogram normalization than control subjects treated with medical management alone (51.8 vs. 13.9 percent), as well as a greater improvement in quality of life measures.<sup>5</sup>
- 56.1% vs. 8.5% improvement in the Quality of Life measure from the Eustachian Tube Dysfunction Questionnaire (ETDQ-7).
- Additionally, there were zero reported serious device- or procedure-related adverse events.<sup>5,6</sup>
- A 1-year follow up demonstrated that the beneficial effects of Eustachian Tube Balloon Dilation (ETBD) with Medical Management on tympanogram normalization and patients with refractory obstructive eustachian tube dysfunction were durable and clinically relevant through 52 weeks.<sup>7</sup>



**The ACCLARENT AERA® Balloon is inflated to dilate the Eustachian Tube to relieve the symptoms of ETD.**

The initial clinical trial of the ACCLARENT AERA® device only included patients under general anesthesia.<sup>6</sup> The most recent clearance recognizes that there is evidence of the ACCLARENT AERA® device being used under local anesthesia with appropriate preparation, which may include supplemental medication for patient management. Your physician will determine the appropriate practice setting and type of anesthesia to be used.<sup>5</sup>

5. ACCLARENT AERA® Eustachian Tube Balloon Dilation System Instructions for Use. Irvine, CA: Acclarent, Inc; 2023. IFU005146 Rev G.

6. Poe D, Anand V, Dean M, Roberts WH, Stolovitzky JP, Hoffmann K, Nachlas NE, Light JP, Widick MH, Sugrue JP, Elliott CL, Rosenberg SI, Guillory P, Brown N, Syms CA 3rd, Hilton CW, McElveen JT Jr, Singh A, Weiss RL Jr, Arriaga MA, Leopold JP. Balloon dilation of the Eustachian tube for dilatory dysfunction: A randomized controlled trial. *Laryngoscope*. 2017 Sep 20. doi: 10.1002/lary.26827.

7. Anand, V., Poe, D., Dean, M., et al. (2019). Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group. *Otolaryngology- Head and Neck Surgery*, 1–8.

\* September 16, 2016

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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