

**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>

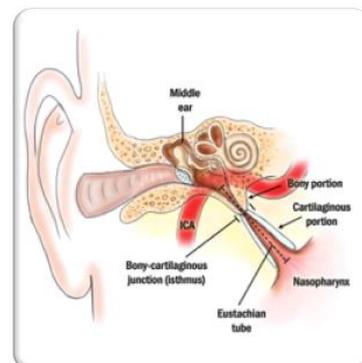
ETD (Eustachian tube dysfunction) is estimated to effect up to 5% of the adult population.<sup>3</sup>

**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 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>



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



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When they are not working properly, the patient can possibly feel 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>

**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>

<sup>1</sup> Llewellyn, A., Norman, G., Harden, M., Coatesworth, A., Kimberling, D., Schilder, A. and McDaid, C. (2014). Interventions for adult Eustachian tube dysfunction: a systematic review. *HEALTH TECHNOLOGY ASSESSMENT*, 18; 1-180.

<sup>2</sup> 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.

<sup>3</sup> Ockermann, T., Reineke, U., Upile, T., Ebmeyer, F., Sudhoff, H.H. (2010). Balloon Dilatation Eustachian Tuboplasty: A Clinical Study. *Laryngoscope*, 120:1411-1416.

<sup>4</sup> Randrup, T.S. & Ovesen, T. (2015) Balloon Eustachian Tuboplasty: A Systematic Review. *Otolaryngology-Head and Neck Surgery*, 152(3); 383-392.

**Treatment options:**

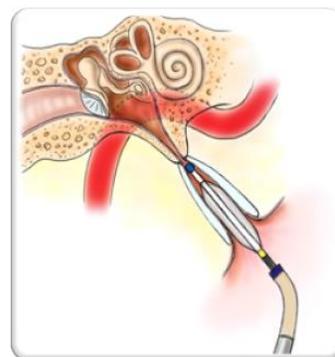
Now, your physician has another tool (or option) in treating Eustachian tube dysfunction (ETD).

The ACCLARENT AERA™ Eustachian Tube Balloon Dilation System is the first device in the US indicated to dilate the Eustachian tube. The ACCLARENT AERA™ system uses a small balloon to treat persistent Eustachian tube dysfunction (ETD), a condition in which pressure, pain or clogged or muffled sensations occur in the ear.

With the ACCLARENT AERA™ system, a doctor uses a catheter 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, a doctor deflates and removes the balloon.

**Clinical Support**

- Results from clinical studies demonstrated a 99.7 percent technical success rate in Eustachian tubes dilated.
- Studies 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.
- 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</sup>



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

Caution: Federal (U.S.) law restricts the sale, distribution or use of the ACCLARENT AERA™ by or on the order of a physician who is trained in the use of 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.

For Physicians: ACCLARENT AERA™ 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.

For Patients: 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. Consult your physician for a full discussion of risks and benefits to determine whether this procedure is right for you.

<sup>5</sup> ACCLARENT AERA™ Eustachian Tube Balloon Dilation System Instructions for Use. Irvine, CA: Acclarent, Inc; 2016. IFU005146 Rev D