

Balloon device approved for Eustachian tube problems

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(HealthDay)—A small device inflated inside the tube that helps regulate pressure inside the ear has been approved by the U.S. Food and Drug Administration.

The Aera Eustachian Tube Balloon Dilation System is designed to treat Eustachian tube dysfunction (ETD), a condition that leads to sensations of pain, pressure or clogging inside the ear.

The Eustachian tube is a valve-like apparatus that connects the [middle ear](#) to the back of the throat. It's normally filled with air and helps equalize pressure inside the ear with the surrounding environment, the FDA explained in a news release. When the tube doesn't function properly, it can lead to symptoms including reduced hearing, [frequent ear infections](#) and ringing in the [ears](#).

The new device is inserted through the nose into the Eustachian tube, where a small balloon is inflated and creates a path for mucus and air. The balloon is then deflated and removed, the agency said.

In clinical trials, 52 percent of participants given the device had normal Eustachian tube test results six weeks after the procedure, compared with 14 percent who were treated with a conventional nasal spray.

The most common side effects included Eustachian tube puncture, minor bleeding and worsening ETD.

The device shouldn't be used by people under age 22, among those whose Eustachian tube is always open, or among people with a condition in which the carotid artery protrudes through a gap in the bone that surrounds the Eustachian tube.

The [device](#) is produced by Irvine, Calif.-based Acclarent Inc.

More information: The FDA has more about [this approval](#).

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