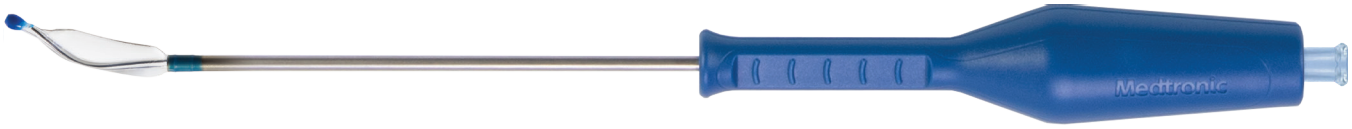
Medtronic

NuVent™ eustachian tube dilation balloon

Value analysis committee packet



Item description

The NuVent™ eustachian tube dilation balloon is a manually controlled balloon catheter system that when inserted into the Eustachian tube canal and pressurized, the balloon expands and dilates the Eustachian tube canal.

The system consists of two major components, the balloon handpiece and the inflator:

The shape of the balloon handpiece enables easy access and entry into the eustachian tube from the nasal opening with the aid of endoscopic guidance. An atraumatic tip at the distal end of the flexible balloon section is meant to reduce the potential for risk of injury to the Eustachian tube and surrounding tissues. The rigid shaft and handle extending to the balloon provide stability and tactile feedback when moving the balloon through the nasal passages and into the Eustachian tube canal. The 6 x 16 mm long rigid balloon is located near the distal tip of the device where it expands the Eustachian tube canal tissue and cartilage.

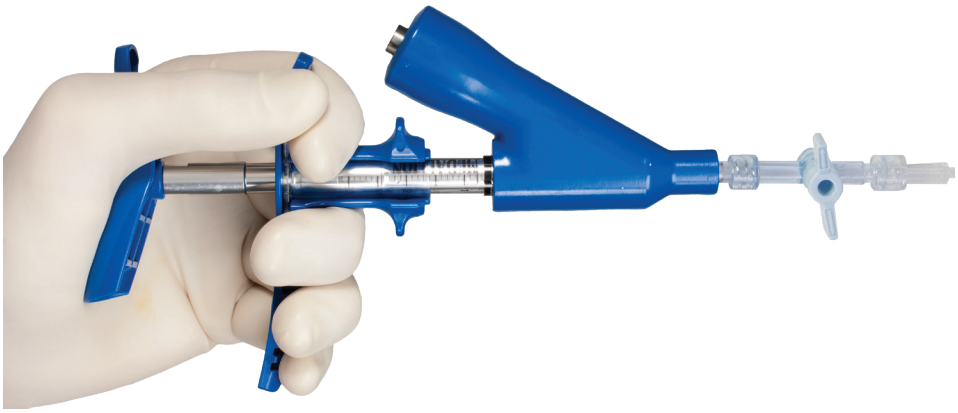
The Medtronic NuVent™ inflator is used in conjunction with the balloon to provide inflation pressure.

Intended use and indications for use

The NuVent™ eustachian tube dilation balloon is intended to dilate the Eustachian tube canal. The NuVent™ eustachian tube dilation balloon is indicated for use in patients 18 years and older who need treatment for persistent Eustachian tube dysfunction.

1. Date of FDA clearance and clearance number.

Device	NuVent™ eustachian tube dilation balloon
Regulation Name	Eustachian tube balloon
Regulatory Class	Class II
Product Code	PNZ
Regulation Number	21 CFR 874.4180
Submission Type	510(k)
Clearance Date	August 16,2021
Clearance Number	K210841



2. Description of the procedure/technology/product/therapy:

Approximately 4.6% of adults in the US suffer from Eustachian tube dysfuntion.[1] The NuVent™ Eustachian Tube Dilation Balloon is a manually controlled balloon catheter system that when inserted into the Eustachian tube canal and pressurized, the balloon expands and dilates the Eustachian tube canal.

Prepare the inflator
Firmly connect the stopcock valve, packaged in the balloon handpiece tray, directly to the inflator and firmly connect the extension tube to the other end of the valve and ensure it is in the open, parallel position.

Prime the inflator
Fill a sterile container with sterile saline solution and place the end of the inflator extension tube in the container of saline. With the inflator pointed up and the extension tube fitting immersed in the saline solution, prime the inflator by pulling and pushing on the inflator plunger, drawing saline solution into and out of the inflator ending with the inflator plunger fully extended and saline drawn into the inflator. Repeat at least five times to remove all air bubbles from the extension tube and inflator. Inspect the extension tube and inflator for air bubbles. Repeat until air bubbles are no longer present in the inflator and extension tube. Remove the extension tube from the sterile saline solution and set the inflator aside while preparing the Eustachian tube dilator.

Connect eustachian tube handpiece to inflator
Grasp the Eustachian tube balloon handpiece on the narrow portion of the handle and connect the inflator's extension tube to the Luer fitting of the balloon handpiece by rotating the Luer fittings firmly together.

Dilate the eustachian tube
With the guidance of an endoscope, carefully insert the balloon handpiece into the nasal passage on the side of the Eustachian tube to be dilated. Introduce the balloon into the nasal passage with the tip facing inferiorly. Guide the tip of the handpiece to the opening of the Eustachian tube being careful not to bend the angle of the balloon catheter on tissues of the nasal passages. Due to varied anatomy and to enable easier insertion you may adjust the angle of the flexible balloon section by bending it to the angle to best fit the patient's anatomy.

When at the depth of the opening of the eustachian tube, rotate the tip to align the balloon catheter with the trajectory of the eustachian tube. Gently advance the balloon catheter into the Eustachian tube. If the user feels unexpected resistance prior to the tip of the balloon reaching the bony isthmus of the Eustachian tube, then stop advancement and retract the handpiece and adjust trajectory before gently re-advancing the balloon catheter. When the tip of the catheter has reached the bony isthmus of the Eustachian tube, the user feels resistance and the blue colored marker at the proximal end of the balloon is near the opening of the Eustachian tube. Note: the blue marker is approximately 30 mm from the tip of the balloon. Prior to pressurizing the balloon handpiece, align the stopcock handle parallel with the tubing from the inflator to the balloon handpiece. This opens the fluid flow path.

When ready for balloon pressurization, fully squeeze the handle of the inflator. Confirm the inflator pressure indicator moves out indicating that therapeutic pressure is being delivered. To retain balloon pressure without continued hand pressure on the inflator, once the inflator handle is fully depressed and the indicator is confirmed out, rotate the stopcock handle 90 degrees so the handle is perpendicular to the tubing closing off the fluid flow between the inflator and handpiece. The user may now release hand pressure. The stopcock maintains pressure in the balloon even as the inflator indicator retracts. Maintain stopcock handle position for two minutes. Do not exceed two minutes.

Release pressure in the balloon by turning the stopcock handle back 90 degrees to align parallel with the tubing opening it to allow fluid flow back into the inflator from the balloon handpiece. Retract the inflator handle to deflate the balloon. When the pressure is released and the balloon is fully evacuated, gently remove the balloon from the Eustachian tube canal following the same trajectory used to advance it.

If the user wants to dilate the contralateral Eustachian tube in the same patient, then first confirm the balloon angle is adjusted for easy insertion. If not, adjust the angle of the malleable balloon section by bending it at the center of the curved balloon to the desired shape. Upon completion of the procedure, discard the inflator and balloon handpiece in a biohazard container.

3. Endorsement(s) by recognized medical associations

This product was launched in September 2021. It has not yet been endorsed by medical associations.

4. Related patient selection criteria

Selection criteria include those patients with persistent, obstructive Eustachian tube dysfunction.

5. Contraindication, warnings, and precautions of NuVent™ eustachian tube balloon

Contraindications:
The NuVent™ eustachian tube dilation balloon is contraindicated for use in a Eustachian tube with an ipsilateral carotid artery that is dehiscent into the Eustachian tube lumen or history of ipsilateral patulous eustachian tube

Warnings:

- Prior to use, examine the product and its packaging for damage, deterioration, and expired shelf life. Replace it with an unused system and contact Medtronic customer service.
- Use a sterile handling technique to maintain sterile condition of devices.
- Prior to surgery, confirm the carotid artery is not dehiscent into the Eustachian tube canal.
- Only use the Medtronic-provided Inflator to inflate the Eustachian tube balloon.
- Do not inflate the balloon with air. Use sterile saline only.
- Ensure air bubbles are removed during priming of the inflator.
- Confirm connection of the inflator to the balloon handpiece to avoid over-tightening the connection, leaks, and low-pressure during balloon expansion.
- Do not insert the balloon when resistance of unknown cause is present as damage to tissue, or carotid artery may occur.
- Insert and remove balloon catheter in line with the Eustachian tube canal to prevent tissue damage.
- Maintain pressure in the balloon for 2 minutes, or a reduced level of therapeutic benefit may result.
- Ensure the balloon is fully inserted into the Eustachian tube prior to and during use. The visual marker on the balloon main shaft at proximal end of the balloon should be near the opening of the eustachian tube.
- Fully deflate the balloon prior to insertion and removal from the Eustachian tube.
- The product is single-use only and should be properly disposed of following use. Do not attempt to reuse.
- The product is provided sterile and should not be re-sterilized. Re-sterilization may damage the integrity of the product.
- Dispose of the used product following healthcare facility guidelines on proper disposal of contaminated materials.

Precautions:
Avoid contact between the balloon, sharp objects, and/or hot surfaces (for example, an endoscope light) to avoid damaging the balloon.

6. Education and training requirements

The FDA requires all surgeons to have cadaveric training on the safe & on-label use of the Eustachian Tube Balloon. Additionally, routine in-servicing and attention to the product instructions for use (IFU) is required to familiarize the staff with preparation, setup and disposal of the product. This training is provided by a Medtronic representative.

7. Qualification criteria for safe use of NuVent™ eustachian tube dilation balloon

This device is intended for use by healthcare practitioners trained in the treatment described in the indications for use. Routine in-service training is provided by Medtronic with simulated virtual or cadaver demonstration. This training includes attention to the product instructions for use (IFU) to familiarize the staff with preparation, setup and disposal of the product.

8. Projected monthly outcome/usage across hospital

Monthly volume will be dependent on the number of Eustachian tube procedures performed in the facility per month and based on surgeon preference.

9. Reimbursement by third party payers

CPT Codes for balloon dilation of eustachian tube procedures were effective January 1, 2021:

- 69705 Nasopharyngoscopy, surgical, with dilation of the eustachian tube (i.e. balloon dilation); unilateral
- 69706 Nasopharyngoscopy, surgical, with dilation of the eustachian tube (i.e. balloon dilation); bilateral

Payer coverage is expanding so please consult with your local Medicare Administrative Contractor and commercial payers to determine current coverage status. For additional information, please reference Medtronic ENT Nasal and Sinus Endoscopy Procedures Coding Guide: **https://www.medtronic.com/content/dam/medtronic-com/products/ear-nose-throat/coding-and-reimbursement/nasal-sinus-endoscopy-procedures-coding-guide.pdf**

Product ordering information

Part number	Description	Pack quantity
1830616EST	Eustachian tube balloon	1
18INFKIT *	Inflator Kit	1

* Please note: This is the same inflator kit that is used with the NuVent™ sinus balloons.

Reference
1. Prevalence of Eustachian Tube Dysfunction in Adults in the United States, JAMA Otolaryngology Head Neck Surgery 2019, 145 (10):974-975, Research Letter.

Rx only. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications.

For further information, please call Medtronic ENT at 800.874.5797 or consult Medtronic's website at **medtronicent.com**.

Medtronic

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