

NeilMed®

Eustachi®

by Dr. Mehta™

Eustachi®– Ear Pressure Relief Device
Model: ME8203

INDICATION FOR USE

The Eustachi is indicated for the treatment of negative middle ear pressure. Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing, and hearing loss. The Eustachi provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss.

CONTRAINDICATIONS (WHEN THE EUSTACHI SHOULD NOT BE USED)

Do not use Eustachi if you have heavy nasal congestion, a bloody nose, an ear infection, or a perforated eardrum. Consult with your doctor before using Eustachi if you have recently had eye, ear or nose surgery, or any ear trauma.

WARNINGS

- Close adult supervision is necessary when using the Eustachi on children.
- Do not attempt to modify the Eustachi device. Modification may result in damage to the device or injury to the user.
- Do not attempt to service or maintain the Eustachi during use to prevent damage to the device or injury to the user.
- Remove batteries when storing the Eustachi for 6 months or more to prevent damage from battery leakage.
- Do not swallow batteries. Swallowing batteries can cause choking or injury.
- Do not use Eustachi for more than two weeks at a time. Stop using Eustachi and contact your doctor if you experience pain with use, or if you don't see any results after two weeks.

PRECAUTIONS

- Do not force the Eustachi into the nasal cavity to prevent possible discomfort or injury.
- The Eustachi is made of ABS plastic. Allergies to this material are rare, however users should not touch the Eustachi device with bare hands if they have known allergies to this material.
- Do not submerge the Eustachi in water. Submerging the device may result in product failure.
- User should read all instructions prior to operating the Eustachi.

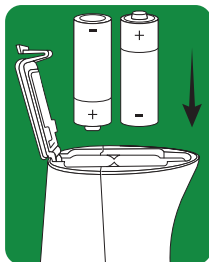
BATTERY PLACEMENT

Two AA batteries are required to operate the Eustachi. Insert batteries prior to first use following the instructions below. Batteries should be replaced when the unit no longer runs. Do not swallow batteries. New batteries may provide up to 9 hours of operation.

1. Open battery compartment located on the bottom of the unit and insert two AA batteries.
2. Check the unit for proper operation: Press and hold the power button to turn on the unit. You should feel a slight vibration and hear a soft buzzing or humming sound. You should feel air coming out of the nosepiece. Put your finger tightly over the hole in the nosepiece, the sound should change. If none of these things happen, consult the TROUBLESHOOTING section.
3. Your Eustachi is now ready to use.

OPERATING INSTRUCTIONS

1. Keep a glass of water ready and take a large gulp of water in the mouth but do not swallow.
2. Please select the nostril that feels more open and less congested.
3. Now hold the Eustachi firmly against nostril and maintain a tight seal with the



nostril.

4. Using your finger, close the opposite nostril to prevent air leakage.
5. Turn the power on and in about 10 seconds, pressure will build. Now swallow the water rapidly but carefully. The Eustachian tubes will open as you swallow, and you should feel a popping sensation in your ears indicating that tubes opened up.
6. Repeat the same procedure with the other nostril, if needed. This is particularly useful if one nasal passage is not fully open compared to the other side.
7. The eustachian tubes will open only during the act of swallowing, otherwise, they will not open.
8. Please note that this is for temporary relief.

If you haven't felt a popping sensation, it's possible that the Eustachian tubes have not opened because:

1. You did not have enough water or saliva in your mouth as you swallowed, or did not have your nostril sealed tightly enough. A large swallow and a tight seal are necessary elements for the Eustachian tubes to open. For a successful opening of the tubes, all the steps must be followed in the precise proper order. It is not uncommon that only one side opens at times.
2. You have nasal obstruction due to severe congestion caused by excessive mucus, congested mucosal lining of the eustachian tubes, significantly deviated septum, nasal polyps, etc.
3. The device battery needs to be replaced. After four or five back-to-back failed attempts, please seek medical attention.

HOW OFTEN CAN YOU USE THE EUSTACHI?

Eustachi should be used as needed. Most people find that using it as their ears are getting clogged (like landing in an airplane) or when their ears are plugged (during allergy season, etc.) works best and the results are immediate. If ears have been clogged for a while, then we recommend using Eustachi a few times a day until they clear up. Try alternating which nostril you use as well. Use it in one nostril, then the next nostril right away. Try it for up to two weeks for those really stuffy ears.

WHEN TO STOP USE AND CONTACT YOUR DOCTOR?

Stop using Eustachi and contact your doctor if you experience pain with use, or if you don't see any results after two weeks.

CLEANING AND MAINTENANCE OF THE EUSTACHI

- Thoroughly rub all surfaces of the Eustachi with isopropyl alcohol wipes (70-90%) after each use. Ensure all grooves, gaps, and spaces are cleaned with alcohol, including the hole of the nosepiece.
- Re-apply alcohol as needed to keep alcohol on surface for at least 1 minute.
- Check for any visible residue. Repeat steps 1 and 2 if any visible residue remains

DO NOT SUBMERGE THE EUSTACHI.

- Replace batteries as indicated in Battery Placement section when the unit no longer runs

USE AND STORAGE

- Use and store the Eustachi in a clean dry location to protect it from damage and dirt.
- Eustachi should be used between 41° and 104°F (5° and 40°C).
- Eustachi can be operated within one hour after it is moved from the highest storage and transportation environment temperature 158° F (70° C) to a room temperature (approximately 68° F / 20° C)
- Eustachi can be operated within one hour after it is moved from the lowest storage and transportation environment temperature -13° F (-25° C) to a room temperature (approximately 68° F / 20° C)
- Allow Eustachi to rest at room temperature for 1 hour before use.
- Keep the Eustachi away from sources of pets, pests, children, heat or moisture to prevent device damage
- Remove batteries for prolonged storage (6 months or more).

EUSTACHI DISPOSAL

Dispose of Eustachi and batteries according to national or local regulations. The Eustachi contains no lead, cadmium, mercury or bromide flame-retardants

EXPECTED PRODUCT LIFE

Your Eustachi should last for up to 5 years with proper care.

WARRANTY

This Eustachi is warranted to be free from manufacturing defects for a period of one year from the date of purchase under normal use. This excludes damage to the product resulting from accident or misuse. **CONTACT INFORMATION**

For assistance in setting up, using or maintaining the Eustachi, to report unexpected operation or events, or for other questions or comments, please go to our website:

www.eustachi.com or email us at info@eustachi.com

ELECTRICAL SAFETY INFORMATION

Electrical classification:

Internally powered ME Equipment

Ingress protection rating: IP22. The first digit, 2, indicates protection against a solid object greater than 12.5mm such as a finger. The second digit, 2, indicates protection against vertical falling drops of water with enclosure tilted up to 15 degrees.

Duty cycle: 30 seconds on / 2 minutes off

Operating Environment:

Temperature: 41°F to 104°F (5°C to 40°C)

Humidity: 15 to 90%

Atmospheric Pressure: 21 to 32 inHg
(700 hPa to 1,060 hPa)

Storage and Transportation Environment:

Temperature: -13°F to 158°F (-25°C to 70°C)

Humidity: up to 90%
















Intended Operator: Adult patient or adult caregiver

Applied Part: air outlet (hole) of the nosepiece

TROUBLESHOOTING

Issue	Action
Motor isn't running or motor is running slow	Ensure batteries are installed correctly. Replace batteries.
I don't feel any difference	1. Ensure you have an airtight fit between the nosepiece and your nostril. 2. Ensure you have your other nostril pinched tightly. 3. Ensure you are swallowing while the Eustachi is running. 4. If still no difference, verify there is no air leak (see below). 5. If still no difference, contact your doctor
Suspected air leak	1. Push the power button and at the same time plug the nosepiece hole with your finger. 2. The sound of the motor should change when you plug the hole. If you don't hear a change in the motor, there may be an air leak.

SYMBOLS GLOSSARY

Symbol	Std Reference	Definition
	ISO 15223-1:2016 symbol 5.4.4	Caution see accompanying documents
	ISO 15223-1:2016 symbol 5.4.3	Consult instructions for use
	ISO 15223-1:2016 symbol 5.1.6	Catalog, model, part number
	ISO 15223-1:2016 symbol 5.1.5	Lot (batch) number
	ISO 15223-1:2016 symbol 5.1.3	Date of manufacture (YYYY-MM-DD)
	ISO 15223-1:2016 symbol 5.1.1	Manufacturer
	ISO 7000:2019 symbol 2725	Not made with natural rubber latex
	ISO 15223-1:2016 symbol 5.2.7	Non-sterile
	ISO 15223-1:2016 symbol 5.3.4	Keep dry
IP22	IEC 60529	Ingress protection rating. The first digit, 2, indicates protection against a solid object greater than 12.5mm such as a finger. The second digit, 2, indicates protection against vertical falling drops of water with enclosure tilted up to 15 degrees.
	IEC 60601-1 Table D.1 Symbol 20	Type BF applied part: electrically connected to patient but not directly connected to the heart
	ISO 15223-1:2016 symbol 5.3.7	Temperature limits
	ISO 15223-1:2016 symbol 5.3.8	Humidity limits
	ISO 15223-1:2016 symbol 5.3.9	Atmospheric pressure limits
	IEC 60601-1 Table D.1 symbol 29	Stand-by; press and hold to power on device
	EN 50419	Do not throw in trash