



REF

EP-2100A/EP-2100

MIDDLE EAR INFLATION DEVICE

INSTRUCTIONS FOR USE





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Middle Ear Inflation Device

INDICATIONS FOR USE

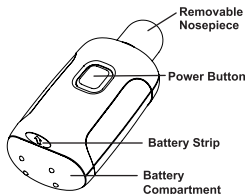
The EarPopper is indicated for use in the treatment of negative middle ear pressure.

Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing and hearing loss. The EarPopper provides a method for ventilating the middle ear by introducing air through the nose and Eustachian tube into the middle ear. Equalizing middle ear pressure can prevent the accumulation of fluid and prevent hearing loss.

PRECAUTIONS

- **CAUTION : A LICENSED HEALTH CARE PROFESSIONAL SHOULD BE CONSULTED PRIOR TO USE.**
- To ensure compliance, the physician should demonstrate the proper use of the device when first recommending the EarPopper.
- Do not force the instrument into the nasal cavity.
- Do not use without a clean, intact nose piece attached.
- Close adult supervision is necessary when using this product on children.
- Submerging device in water may result in product failure.

PARTS OF THE EARPOPPER



CONTRAINDICATIONS

Do not use the EarPopper in the presence of severe ear infection, upper respiratory infection, heavy nasal congestion, cold symptoms or a perforated eardrum.

If condition does not improve, consult your healthcare professional.

OPERATING INSTRUCTIONS

1. Pull battery strip and remove before use.
2. Hold the nosepiece portion of the EarPopper firmly against one nostril. Press the other nostril closed using the index finger of the other hand. (See Fig. 1) It is very important to establish a good seal. Press the power button to begin airflow and swallow with mouth closed while the device is running.

Note:

- Holding a small amount of liquid in mouth prior to the procedure will aid in swallowing.
- The treatment only occurs during the swallow.

Fig. 1:



If the user does not feel any change in the ear, repeat the procedure making sure the EarPopper remains firmly against the nostril, while the user swallows with mouth closed.

3. Release power button after swallowing.
4. Repeat steps 2-3 for the other nostril.

Wait five minutes and repeat steps 2-4. This will complete one treatment.

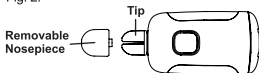
TREATMENT RECOMMENDATIONS:

- Treatment recommendations are guidelines based on clinical studies. Always consult your health care professional before beginning any treatment.
- For fluid behind the eardrum (Otitis Media with Effusion), use twice daily for 7-11 weeks, or until hearing returns to normal.
- For negative ear pressure problems, use as needed.

CARE, CLEANING, & STORAGE

Remove the nosepiece for periodic cleaning. (See Fig. 2) Clean with mild soap and water. After cleaning, rinse with warm water and allow to thoroughly dry before using.

Fig. 2:



The outside of the device may be cleaned by wiping with a soft, damp cloth. **DO NOT AUTOCLAVE, OR USE ABRASIVE CLEANERS, OR CHEMICALS, OR DISINFECTANTS, AND DO NOT SUBMERGE THE EARPOPPER DEVICE IN LIQUID OF ANY KIND.**

Operating environment is (5° C to 40° C, 15 - 93% RH, 700 hPa - 1060 hPa).

Store the EarPopper in a clean dry location at room temperature (-25°C to 70°C; up to 93% RH; 700 hPa to 1060 hPa) with the clean nosepiece in place to protect tip from damage and dirt. The device is not intended for multiple users. Remove battery for prolonged storage (6 months or more).

BATTERY REPLACEMENT:

To check for a dead battery use the following steps:

1. Place finger over hole in the end of the nosepiece.
2. Press the Power Button to activate device.
3. If motor runs intermittently or stops, replace the battery.

Open the battery compartment by depressing the thumb tab on the back of the device, then rock the battery cover forward and then remove. Install 4 new AAA batteries. Replace the cover by placing the front tab in the device and then rock the thumb tab into place. See Fig. 3:

Battery life: more than 4 hours of continuous operation.

Fig 3.



DEVICE DISPOSAL

Dispose of device and battery according to national or local regulations. Contains no lead, cadmium, mercury or bromide flame retardants.

WARNINGS

- The EarPopper will not interfere with any device or EMI.
- No modification of this equipment is allowed.
- This product contains small parts (batteries, nosepiece).
- Risk of choking hazard - keep small parts away from children under age 4 and pets.
- This product is not known to cause allergic reactions.
- No known environmental effects caused by lint, light, sunlight, etc.

WARRANTY

This device 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 device resulting from accident or misuse. 1 year service life.

CUSTOMER SERVICE

For questions concerning the operation of the EarPopper, or to request accessories and replacement parts, please visit www.earpopper.com or call or write using the contact information on the back of this manual.

TECHNICAL INFORMATION

Product Safety Compliance Testing : (IEC 60601-1)

IEC 60601-1-1

CLASSIFICATIONS : IEC 60601-1 : protection against electrical shock : internally powered equipment, type BF applied parts protection against harmful ingress of water or particulate matter : IP22 Mode of operations : continuous.

IEC 60601-1-2

EN61000-4-2 Electrostatic Discharge	PASS	8 KV air 6 KV contact
EN61000-4-3 Radiated Immunity	PASS	10 V/M
EN61000-4-4 Electrical Fast Transients	N/A	—
EN61000-4-5 Surge Immunity	N/A	—
EN61000-4-6 Conducted Immunity	N/A	—
EN61000-4-8 Power Frequency Magnetic Field	PASS	1 amp/M
EN61000-4-11 Voltage Dips, Interrupts, and Fluctuations	N/A	—



Symbol Reference Key

REF

Catalog Number

IUSA

For US audiences only



Equipment not suitable for use in the presence of a flammable anesthetic mixture

Symbol Reference Key

IP22

Enclosure protects against ingress of solid foreign objects ≥ 12.5 mm diameter. Protects against ingress of water dripping. (15° tilted) see appended instruction for use.



Consult instructions for use



Direct Current



Symbol Reference Key



Quantity



Type BF Applied Part



Date of manufacture

Not made with natural rubber latex.