



EarClean

Instructions for use

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Safely deliver controlled rinsing fluid to the external ear canal while simultaneously or subsequently removing fluid and discharge via suction, without causing injury to the ear or unnecessary discomfort to the user.

Contact information



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Any serious incident involving the device shall be reported to the manufacturer or the relevant authority in the user's member state. Malfunctions should be reported to the manufacturer.

Intended use

EarClean is a single-use pipette for the gentle cleaning and rinsing of the ear canal. EarClean functions by removing discharge through suction and then rinsing the ear canal with liquids. The device is designed to support the management of ear infections associated with discharge from the ear.

EarClean can be used by healthcare professionals and lay persons on both children and adults.

Medical Indications

Irrigation of the ear canal.

Cleaning the ear canal of a healthy ear.

Cleaning the ear canal during an infection, such as otitis externa.

Patient Population

Healthy adults and children 1 years and older for gentle cleaning

Adults and children 1 years and older with ear infections, such as otitis externa.

Intended Users

Adults, healthcare workers, parents, or caregivers of children.

Intended Use Environment

At home or in a healthcare facility.

Contraindications

If you suspect there is a hole in the eardrum, do not use EarClean. See a healthcare professional.

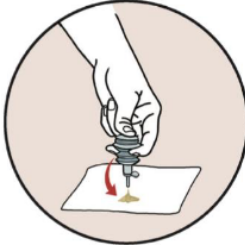


Instructions for use



Step 1: Prepare for use

- You need a solution to rinse the ear, and one bowl or tissue to keep under the ear.
- Wash your hands with soap and water.
- Find a clean, well-lit place
- Assemble the bellow and nozzle



Step 2: Draw out the fluid or discharge

- Squeeze the device gently and place the top inside the ear opening.
- Slowly release the pipette to suck out the discharge.
- Empty the discharge into a tissue, cloth, or bowl.
- Repeat the rinsing a few times if needed



Step 3: Rinse the ear with the solution

- Fill the pipette with the hand-warmed or lukewarm solution (squeeze the bellow and place the tip into the solution, then release it to fill).
- Gently place the pipette just inside the ear (do not push deep).
- Squeeze evenly to rinse the ear with the solution.
- Let the liquid drain out naturally.
- Repeat if necessary.



Step 4: Dispose of the device

- Throw the pipette away after use—do not reuse it.
- Recycle EarClean as plastic
- Reuse can cause re-infection.

Use EarClean for one ear only. Risk for reinfection.

Disposal

After use, dispose as plastic waste in accordance with local regulations.



Warnings



DO NOT push the pipette deep into the ear to avoid making it too tight, as it can create pressure in the ear.



DO NOT irrigate the ear with cold solution. Warm the liquid so that it is close to the temperature of the body.



DO NOT continue treatment if you or your child feels pain or discomfort.

When to stop treatment

Stop immediately if you or your child has pain, dizziness, fever, or swelling in the outer ear canal.

Visit a healthcare worker if the ear is still discharging after 10 days.

Precautions

Children

The healthcare provider shall follow the instructions carefully. Ear irrigation in children should preferably be performed at a doctor's office or healthcare centre.

Hearing Instrument Users

Put the hearing instrument in place after ear irrigation and when the ear is dry.

Problems with coordination

If you have coordination difficulties, let someone help you.

Possible side effects

Discomfort in the ear canal, skin irritation, and temporary dizziness may occur.

Regulatory information



This product is a medical device, compliant with EU Regulation 2017/745 on medical devices.



Warnings

EarClean (10 pcs)

UDI-DI: 07350186950013



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EarClean (5 pcs)

UDI-DI: 07350186950006



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Manufacturing date



Batch number



Expiry date



Do not reuse



Keep away from sunlight

Approximately fill volume: 10 mL