

OtoClear® Tip

INSTRUCTIONS FOR USE



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This manual applies to the **REF** numbers indicated below:

#7200 #7202 #7270 #7275
#7280 #7245 #7290 #7295
#7240 #7235



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ENGLISH

OTOCLEAR® TIP - USER INSTRUCTIONS

Intended use: The intended use of the OtoClear is to flush cerumen and/or foreign bodies from a patient's ear canal without causing injury.

Indications for use: The OtoClear is indicated for use on patients 6 months or older with impacted cerumen and/or foreign bodies occluding the ear canal where no infection and/or eardrum perforation is known or suspected.

How to Use

The BIONIX® OtoClear Tip was designed to make ear irrigation safer, quicker and more effective using The Ear Lavage System or the Spray Wash Bottle. OtoClear Tips are also compatible with a Tabletop Waterpik or Luer lock Syringe. These instructions are written in order to help you, and therefore, your patients, get the greatest benefit possible from the irrigation procedure.

Before You Begin:

Examine the ear canal and tympanic membrane with an otoscope noting the type and location of any cerumen. Hard or impacted wax may require a cerumenolytic agent.

⚠ CAUTION: DO NOT perform irrigation if the tympanic membrane is perforated or if tympanostomy tubes are present. Discontinue irrigation immediately if bleeding, irritation or other trauma to the ear canal or tympanic membrane occurs.

If you are using the Spray Wash Bottle, first connect the inner tube to the bottle.

1. Grasp the OtoClear tip and twist onto the luer lock fitting of the adapter wand until it stops.
2. Fill the water reservoir of the delivery device with warm water (approximate body temperature). DO NOT use cold or hot water as it may cause dizziness in some patients.
3. Prime the unit by discharging into a sink.
4. Insert OtoClear tip fully into the ear canal. The flared design of the OtoClear tip protects against over-insertion. Tip: Fully inserting OtoClear Tip will help eliminate backsplash.
5. Place a basin beneath the outer ear to capture draining effluent. Note: The OtoClear tip directs the water towards the walls of the ear canal creating a turbulent lavage that effectively dislodges the cerumen. The exit portals control backsplash and deliver the effluent into the basin.
6. Reexamine the ear canal. Repeat the irrigation procedure as needed. Sometimes a large plug of wax will not exit through the portal. In these cases, we recommend the use of a Safe Ear Curette™ to extract any remaining cerumen.
7. Remove any remaining water in the ear canal with an absorbent sponge. When procedure is complete, remove and dispose of the single-use OtoClear tip.

⚠ WARNINGS:

- Use only warm water (98°F - 104°F / 37°C - 40°C) to reduce the risk of dizziness or vertigo
- If pain or discharge occurs see your physician
- Cross-contamination risk. Do not reuse the disposable OtoClear Tips as this may spread contamination from one patient to another patient.

Medical Device Reporting: Notice to Users and/or Patients in EU:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Benefits: Indicated in Intended Use.

Contraindications:

- The person has previously had complications following ear irrigation procedures
- There is a history of a middle ear infection in the last six weeks
- There is discharge from the ear canal or ear pain or tenderness
- The person has or suspects an ear drum perforation
- The person has had ANY form of ear surgery
- The person has cleft palate, repaired or not
- The person has tympanostomy tubes
- There is a foreign body present in the ear canal
- There is a history of inner ear problems (especially vertigo)

Residual Risk: Risk associated with the use of this product has been reduced as far as possible, but the product cannot completely eliminate potential patient or user harm arising from the following:

- Harm from mechanical hazards
- Harm from misuse, or use error
- Harm from unanticipated origins

	Medical Device		Do Not Use if Package is Damaged
	Manufacturer		Do Not Reuse Single-Use Device
	Date of manufacture		Single patient-multiple use
	Use-By Date		Consult Instructions For Use (IFU)
	Lot Code		Caution
	Reorder Number		Warning
	Serial number		Authorized representative in the European Community
	Sterilized using irradiation		European Conformity
	Do Not Resterilize		Prescription Only or "For Use by or on the order of a licensed medical professional"
	Non-sterile		Temperature limitation