

Symbol Glossary

(Note: All symbols may not be applicable to this product)

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

OTOCLEAR TIPS ARE SINGLE USE ONLY

www.bionix.com

OTOCLEAR TIPS ARE
MADE IN THE USA

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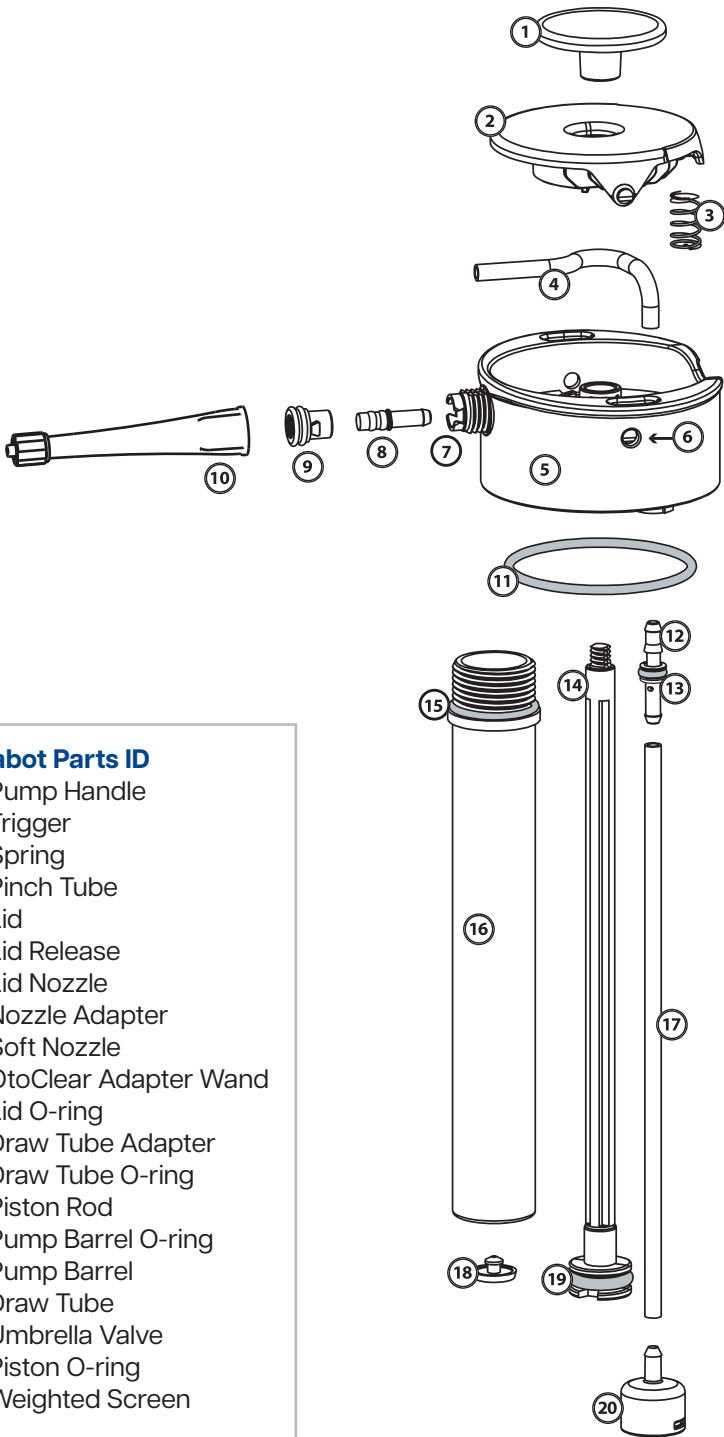
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www.bionix.com | RM95-7275 | 2025/4/15 | Rev. 03



Aquabot Parts ID

- Pump Handle
- Trigger
- Spring
- Pinch Tube
- Lid
- Lid Release
- Lid Nozzle
- Nozzle Adapter
- Soft Nozzle
- OtoClear Adapter Wand
- Lid O-ring
- Draw Tube Adapter
- Draw Tube O-ring
- Piston Rod
- Pump Barrel O-ring
- Pump Barrel
- Draw Tube
- Umbrella Valve
- Piston O-ring
- Weighted Screen



OtoClear® Powered by Aquabot®
Ear Irrigation Kit

INSTRUCTIONS FOR USE



Product Offering

#7270 - (1) Aquabot® Bottle, (20) OtoClear® Tips, (1) Ear Basin
#7275 - (1) Aquabot® Bottle, (5) OtoClear® Tips, (1) Ear Basin

Troubleshooting Chart

PROBLEM	REASON	SOLUTION
Unit does not build or hold pressure	Lid O-ring is missing	Email bionix@bionix.com or call 800.551.7096
	Pump Barrel is too loose	Tighten Pump Barrel
	Something else	Email bionix@bionix.com or call 800.551.7096
Builds pressure but does not spray	Pinch Tube is kinked	Remove trigger and unkink Pinch Tube
	Something Else	Email bionix@bionix.com or call 800.551.7096
Water is getting inside of pump barrel	Umbrella Valve is not sealing	Email bionix@bionix.com or call 800.551.7096
	Pump Barrel is too loose	Tighten Pump Barrel
Water is leaking from under trigger	Pinch Tube is damaged	Email bionix@bionix.com or call 800.551.7096
	Something else	Email bionix@bionix.com or call 800.551.7096
Leaks around Nozzle Cap	Soft Nozzle is missing	Email bionix@bionix.com or call 800.551.7096
	Wear and tear on Soft Nozzle	Email bionix@bionix.com or call 800.551.7096
	Something else	Email bionix@bionix.com or call 800.551.7096

Contents include:

- Aquabot® Bottle
- Adapter wand
- Either 20 OtoClear Tips or 5 OtoClear Tips
- Ear basin

If any item is missing please contact your distributor.

Intended use: The intended use of the OtoClear Powered by Aquabot Ear Irrigation Kit is to flush cerumen and/or foreign bodies from a patient’s ear canal without causing injury.

Indications for use: The OtoClear Powered by Aquabot Ear Irrigation Kit 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.

⚠ 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.

⚠ WARNINGS:

- Use only body temperature water 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.
- Do not over-pressurize the unit.
- **CHOKING HAZARD** Unit contains small parts. Not suitable for children under 3 years.
- Only use lid with Aquabot bases.
- Do not use lid on any metal or glass bases.
- Do not use if the Aquabot base is cracked or exhibits any signs of crazing.
- Store out of direct sunlight.
- Do not store pressurized for more than 36 hours.

FAILURE TO READ AND FOLLOW THE ABOVE WARNINGS AND OPERATING INSTRUCTIONS COULD LEAD TO SERIOUS BODILY INJURY.

OtoClear® powered by Aquabot® – USE INSTRUCTIONS

Before you begin: Exam 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.

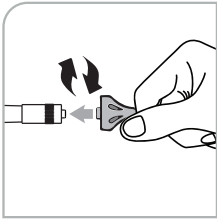
1. Fill the water reservoir of the delivery device with body temperature water to 1" from the top. **DO NOT** use cold or hot water as it may cause dizziness in some patients.
- ⚠ WARNING: DO NOT USE if the bottle is cracked or exhibits signs of crazing.**



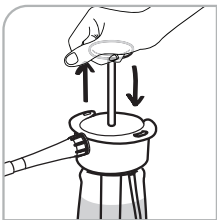
2. Attach Aquabot to top of bottle and close firmly by rotating clockwise.



3. Grasp the OtoClear Tip and twist onto the luer lock fitting of the adapter until it stops.



4. Pump no more than 6 times. This will pressurize the unit to approximately 35 psi. Take note of the force required on the last pump and use this as a guide for when to stop pumping on future charges so that you do not over-pressurize the unit.



5. Insert OtoClear tip fully into the ear canal. The flared design of the OtoClear tip protects against over-insertion. Tip: Fully inserting OtoClear Tip into the ear will help eliminate backsplash.

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.

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 history of inner ear problems (especially vertigo)
- Button or hearing aid batteries are indications for emergent ENT consultation

Clinical Benefits: Indicated in Intended Use.

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

Aquabot Maintenance:

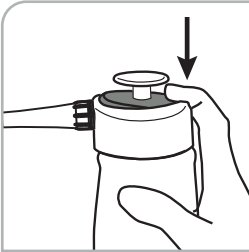
- Spray air through the unit to dry out the silicone tube before storing for long periods.

Cleaning and Disinfection Instructions:

Please visit **bionix.com** or **scan the QR Code below** to view our cleaning and disinfection instructions for this device.



6. Place a basin beneath the outer ear to capture draining effluent. Note: The OtoClear Tip directs the water toward 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.



7. To release water and irrigate the ear canal, firmly press the colored circle on the back of the trigger.

8. Re-examine the ear canal. Repeat the irrigation procedure as needed. Sometimes a large plug of wax will not exit through the portal. In these cases, it is recommended to use a Bionix Ear Curette to extract any remaining cerumen.

9. Remove any remaining water in the ear canal with an absorbent sponge. When the procedure is complete, remove and dispose of the single-use OtoClear Tip.

10. The safest method to depressurize the Aquabot unit is to hold it upside down while keeping the weighted screen above the water line. Press the trigger to release compressed air.

⚠ WARNING: Failure to remove the OtoClear Tip increases the risk of cross contamination between patients. The OtoClear Tip is designed to be a single-use product.