

OtoClear[®] SprayWash Kit

INSTRUCTION MANUAL



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Reorder Numbers:

#7290 - 1 SprayWash bottle,
20 OtoClear tips, 1 Ear Basin

#7295 - 1 SprayWash bottle,
5 OtoClear tips, 1 Ear Basin

ENGLISH

	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

Thank you for purchasing the Bionix OtoClear® SprayWash Kit.

The Bionix OtoClear SprayWash Kit provides a simple, yet effective, solution to patient safety, patient discomfort, and compacted cerumen removal. The key to this system is the OtoClear ear irrigation tips that are attached to the end of the wand. OtoClear ear irrigation tips direct water to the ear canal wall at 30 degree angles avoiding directly impacting the tympanic membrane.

This manual is designed to explain the proper assembly instructions for the entirety of the kit, including bottle assembly, cleaning, and tip placement. **Note:** Any other use for the product outside of the intended use stated herein, Bionix shall not be held liable.

Getting Started:

Unpacking and Verifying Contents:

Before continuing, inspect the package for any damage during shipping. If you find any damage notify your local distributor.

Next, check to ensure that your OtoClear SprayWash Kit is complete.

Contents include:

- OtoClear SprayWash bottle (with temperature gauge)
- Bottle head with wand attached

- 20 OtoClear Tips (for #7290) or 5 OtoClear Tips (for #7295)
- Ear basin

If any item is missing please contact your distributor.

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.

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 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:

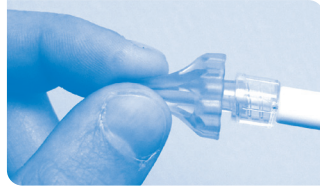
- Harm from mechanical hazards
- Harm from misuse, or use error
- Harm from unanticipated origins

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.

Bionix SprayWash Bottle Assembly Instructions:

01. Remove SprayWash Bottle (herein referred to as 'water reservoir') and the spray head from packaging
02. Grasp the water reservoir firmly.
03. Turn on water source.
04. Fill reservoir with body temperature water. **Note:** if the temperature of the water is above 130° F (54° C) it will show a blue tail and below 80° F (27° C) it will not register on the temperature gauge.
05. After filling, place water reservoir on secure, stable platform.
06. Grasp the head and guide the tube into the opening on the water reservoir until fully inserted.
07. Point the head and wand in the same direction as the larger end of the reservoir base.
08. Secure head with one hand, rotate the blue fastening ring at the base of the head clockwise until tight.
09. Grasp the OtoClear Tip (as shown) and twist onto the luer lock fitting of the adapter until it stops.



Bionix SprayWash Bottle Use Instructions:

01. Assure that the temperature gauge reads "OK" before continuing.
02. This is to indicate that the water is approximately body temperature.
03. **DO NOT use cold or hot water as it may cause dizziness in some patients.**
04. Prime the unit by discharging into a sink.
05. Insert the OtoClear tip fully into the ear canal. The flared design of the OtoClear Tip protects against over-insertion. Tip: Fully inserting the OtoClear Tip will help eliminate backsplash.
06. Place a basin beneath the outer ear to capture draining effluent.
Note: The OtoClear Tip directs water towards the walls of the ear canal creating a turbulent lavage that effectively dislodges cerumen. The Exit portals control backsplash and deliver the effluent into the basin.
07. 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™ or Lighted Ear Curette™ to extract any remaining cerumen.
08. 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.



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

Cleaning the Bionix OtoClear SprayWash Bottle:

It is recommended to clean the Bionix SprayWash bottle daily following the procedure below.

01. Prepare a solution of dishwashing liquid and water.
02. Ensure the SprayWash bottle and spray head are completely drained of water.
03. Wash the outside of the bottle and spray head with the dishwashing solution.
04. Fill the bottle with the dishwashing solution and reattach the spray head.

05. Shake the SprayWash bottle and pump until soapy water discharges.
06. Rinse the outside of the SprayWash bottle with water until all suds is removed.
07. Remove the spray head from the bottle and empty the dishwashing solution from the bottle.
08. Rinse and refill the bottle with water, repeat until no suds is visible in the bottle's rinse water.
09. Refill the bottle with water and reattach the spray head.
10. Pump the spray head until no suds is evident in the discharged rinse water.
11. Remove the spray head from the bottle.
12. Pump the spray head until all water is discharged.
13. Drain all water from the bottle.
14. Dry the outer surfaces of the bottle & spray head and leave them separated to allow complete drying.
15. Clean the ear basin using the same solution. Rinse thoroughly and dry.

High Level Disinfection of the Bionix OtoClear SprayWash Bottle:

It is recommended to high level disinfect the Bionix SprayWash Bottle after any use where there was contact with blood, infectious material, or non-intact skin.

01. Use one of the following high level disinfecting (HLD) solutions that are compatible with the Bionix SprayWash Bottle:
 - Ortho-Phthalaldehyde Solution (0.55% maximum)
 - Accelerated Hydrogen Peroxide Solution (2% maximum)
 - Glutaraldehyde Solution (3.0% maximum)
02. Prepare the HLD solution per the manufacturer's instructions.
03. Remove the spray head from the bottle.
04. Ensure all water has been drained from the bottle and the spray head.
05. Fill the SprayWash bottle with the HLD solution and reattach the spray head.
06. Pump the SprayWash bottle until HLD solution discharges.
07. Remove the spray head and completely fill the bottle with HLD solution.
08. Reattach the spray head.
09. Allow the HLD solution to soak in the Bionix SprayWash Bottle per the HLD manufacturer's instructions for use.
10. After the manufacturer's recommended soak, remove the spray head from the bottle and empty the HLD solution from the bottle.
11. Thoroughly rinse the outer surfaces of the bottle and spray head with water.
12. Fill the bottle with clean rinse water and reattach the spray head.
13. Pump until half of the bottle is discharged.
14. Repeat steps 11 - 13 until the bottle has been rinsed three times.
15. Remove the spray head from the bottle.
16. Drain all water from the bottle.
17. Pump the spray head until all water is discharged.
18. Dry the outer surfaces of the bottle and spray head and leave them separated to allow complete drying.
19. To high level disinfect the ear basin, repeat steps 1 & 2 and follow the manufacturer's instructions.

Importer, Importeur, Importör,
Importador, Importateur,
Εισαγωγέας, Importeur,
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MedEnvoy

Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands

MD



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EC REP

Obelis s.a • Boulevard Général Wahis 53 • 1030 Brussels, BELGIUM

Tel: +(32) 2.732.59.54 • Fax: +(32) 2.732.60.03 • E-Mail: mail@obelis.net



Bionix LLC • 1670 Indian Wood Circle | Maumee, Ohio 43537 | United States

Phone: +1 419.727.8421 • Fax: +1 800.455.5678 • www.Bionix.com

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1670 Indian Wood Circle | Maumee, Ohio 43537

United States | Phone: 800.551.7096 | Fax: 800.455.5678

Email: bionix@bionix.com | bionix.com

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