



bionix OtoClear SprayWash Kit Instruction Manual

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OtoClear SprayWash Kit

Reorder Numbers:

#7290 – OtoClear/SprayWash, 20 tips, 1 Ear Basin

#7295 – OtoClear/SprayWash, 5 tips, 1 Ear Basin

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 Bionix OtoClear SprayWash Kit is intended to be used for Ear Irrigation by a medical professional.

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.



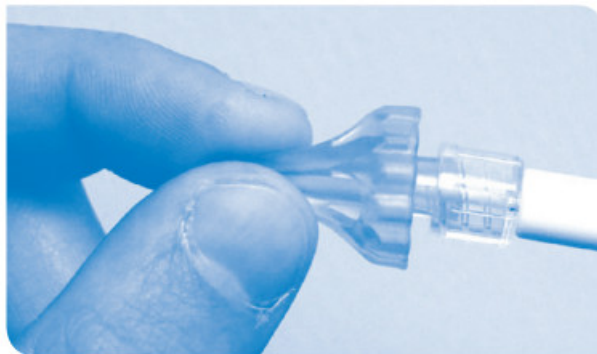
WARNING: DO NOT perform irrigation if the tympanic membrane is perforated or if tympanostomy tubes are present. Discontinue irrigation immediately if bleeding, irritation, or other trauma to the ear canal or tympanic membrane.

Bionix SprayWash Bottle Assembly Instructions:

1. Remove SprayWash Bottle (herein referred to as 'water reservoir') and the spray head from packaging
2. Grasp the water reservoir firmly.
3. Turn on water source.
4. Fill reservoir with body temperature water.

Note: if the temperature of the water is above 130 OF (54 OC) it will show a blue tail and below 80 OF (27OC) it will not register on the temperature gauge.

5. After filling, place water reservoir on secure, stable platform.
6. Grasp the head and guide the tube into the opening on the water reservoir until fully inserted.
7. Point the head and wand in the same direction as the larger end of the reservoir base.
8. Secure head with one hand, rotate the blue fastening ring at the base of the head clockwise until tight.
9. Grasp the OtoClear Tip (as shown) and twist onto the luer lock fitting of the adapter until it stops.



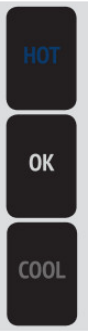
Bionix SprayWash Bottle Use Instructions:

1. Assure that the temperature gauge reads "OK" before continuing.
2. This is to indicate that the water is approximately body temperature.

3. DO NOT use cold or hot water as it may cause dizziness in some patients.
4. Prime the unit by discharging into a sink.
5. 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.
6. 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.

7. 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.
8. 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.

1. Prepare a solution of dishwashing liquid and water.
2. Ensure the SprayWash bottle and spray head are completely drained of water.
3. Wash the outside of the bottle and spray head with the dishwashing solution.
4. Fill the bottle with the dishwashing solution and reattach the spray head.
5. Shake the SprayWash bottle and pump until soapy water discharges.
6. Rinse the outside of the SprayWash bottle with water until all suds is removed.
7. Remove the spray head from the bottle and empty the dishwashing solution from the bottle.
8. Rinse and refill the bottle with water, repeat until no suds is visible in the bottle's rinse water.
9. 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.

1. 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)

2. Prepare the HLD solution per the manufacturer's instructions.
3. Remove the spray head from the bottle.
4. Ensure all water has been drained from the bottle and the spray head.
5. Fill the SprayWash bottle with the HLD solution and reattach the spray head.
6. Pump the SprayWash bottle until HLD solution discharges.
7. Remove the spray head and completely fill the bottle with HLD solution.
8. Reattach the spray head.
9. 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.
14. Remove the spray head from the bottle.
15. Drain all water from the bottle.
16. Pump the spray head until all water is discharged.
17. Dry the outer surfaces of the bottle and spray head and leave them separated to allow complete drying.
18. To high level disinfect the ear basin, repeat steps 1 & 2 and follow the manufacturer's instructions.



MADE IN THE USA



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 Development Corp., 5154 Enterprise Blvd. Toledo, OH, 43612, U.S.A.



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

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©2019 Bionix Development Corp.
5154 Enterprise Blvd., Toledo, Ohio 43612
Phone: 800.551.7096 | Fax: 800.455.5678
Email: bionix@bionix.com | bionix.com
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RM95-0035 ,Rev. B

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