



# General Cleaning Instructions for Bionix® OtoClear Ear Irrigation Devices and Basin

To ensure proper maintenance and sanitation, all OtoClear Ear Irrigation devices should be cleaned using a mild dishwashing detergent and warm water. Follow these steps to complete the cleaning process:

- 1. Prepare the Cleaning Solution: Mix a dishwashing detergent with warm water.

  NOTE: There is no specific detergent concentration required for general cleaning, add enough detergent to create a sudsy solution.
- 2. Clean the Device: Gently wipe the outer surfaces with a soft cloth or sponge dampened with the cleaning solution. To ensure thorough cleaning, pump the cleaning solution through the device.
  - **MARNING:** DO NOT submerge the irrigation device as this may damage the unit.
- **3. Rinse Thoroughly:** Rinse the device with clean water to remove any soap residue. Repeat the rinsing process with fresh water until no suds remain.
- 4. Dry Completely: Allow the device to fully dry before storage.

**Important:** Avoid using abrasive materials or harsh chemicals, as they may damage the device.

## **Compatible Disinfection Active Ingredients for OtoClear Ear Irrigation Systems and Basin:**

A comprehensive review of all OtoClear Ear Irrigation Systems and basin components materials and their respective chemical compatibilities was conducted to ensure the safe and effective use of disinfectants. This evaluation considered component material composition, potential chemical interactions, and long-term durability under exposure to various disinfecting agents. Based on the findings, tables of approved disinfectant active ingredients for both low level and high level disinfection were developed, listing only those solutions that meet compatibility requirements while preserving the integrity and performance of the components.

It is important to note that the chemical compatibility review only evaluates the chemical/material compatibility; it does NOT include cleaning/disinfection efficacy testing. Bionix, LLC is not responsible for improper disinfection practices, it is the responsibility of the end user to ensure the disinfection method meets their facility's protocols, standards and/or local regulations.

Additionally, the use of any cleaning agent not listed as "COMPLIANT" or "COMPLIANT W/ RINSE" in the matrix below is at the sole risk of the customer. Bionix assumes no responsibility for any damage or adverse effects that may result from using unapproved cleaning agents or from exposing the device to extended dwell times beyond those recommended by the cleaning agent manufacturer.

The following compatibility classifications are referenced in the matrices below:

#### · COMPLIANT:

**COMPLIANT** 

The disinfectant solution may be used routinely per your facility's protocols, standards or local regulations, following the solution manufacturer's instructions.

#### · COMPLIANT W/ RINSE:

COMPLIANT W/RINSE

The disinfectant may be used routinely in accordance with your facility's protocols, standards or local regulations, following the disinfection solution manufacturer's instructions. Prolonged exposure beyond the disinfection solution manufacturer's recommended dwell time, and failure to perform an immediate freshwater rinse after disinfection, may lead to chemical degradation of device materials, potentially resulting in premature device failure.

### NOT RECOMMENDED:

NOT RECOMMENDED

The disinfectant solution should NOT be used, as it is incompatible with the device materials.

LOW LEVEL DISINFECTION								
Disinfection Active Ingredient	Disinfection Product Examples (NOT all-inclusive list)	OtoClear SprayWash	OtoClear Aquabot	OtoClear Portable Electronic Irrigator	Basin			
Ethyl Alcohol	EPA's Disinfectants for Use Against SARS-CoV-2 [List N]: • Purell Professional Surface Disinfectant Wipes	COMPLIANT	COMPLIANT W/ RINSE	COMPLIANT W/ RINSE	COMPLIANT			
Isopropyl Alcohol (70%)	EPA's Disinfectants for Use Against SARS-CoV-2 [List N]: • Ecolab Klercide 70/30 IPA	COMPLIANT	COMPLIANT W/ RINSE	COMPLIANT W/ RINSE	COMPLIANT			
Quaternary Ammonium	EPA's Disinfectants for Use Against SARS-CoV-2 [List N]:  • Clorox Disinfecting Wipes,  • Clorox Commercial Solutions Clorox Disinfecting Wipes  • Clorox Healthcare VersaSure Wipes	COMPLIANT W/ RINSE	COMPLIANT W/ RINSE	NOT RECOMMENDED	COMPLIANT			
Sodium Hypochlorite (>100 ppm)	EPA's Disinfectants for Use Against SARS-CoV-2 [List N]:  • Clorox Healthcare Bleach Germicidal Wipes  • Clorox Healthcare Spore10 Defense Cleaner Disinfectant  • Metrex Caviwipes Bleach  • Metrex Cavicide Bleach	COMPLIANT W/ RINSE	NOT RECOMMENDED	NOT RECOMMENDED	COMPLIANT			

HIGH LEVEL DISINFECTION							
Disinfection Active Ingredient	Disinfection Product Examples (NOT all-inclusive list)	OtoClear SprayWash	OtoClear Aquabot	OtoClear Portable Electronic Irrigator	Basin		
Glutaraldehyde	FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices: Cetylcide-G Wavicide-O1 TD-5 HLD Rapicide HLD Procide 14 NS Omnicide Plus Omnicide Long Life Metricide Plus 30 Metricide Metricide 28 MedSci 3%, Cidex Cidex Plus Cidex Formula 7 Cidex Activated Banmicide Advanced	COMPLIANT	COMPLIANT W/ RINSE	COMPLIANT W/ RINSE	COMPLIANT		
Hydrogen Peroxide	FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices: Sporex Sterilizing & Disinfection Solution	COMPLIANT	NOT RECOMMENDED	NOT RECOMMENDED	COMPLIANT		
ortho-Phthalaldehyde (OPA)	FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices: Cidex OPA Rapicide OPA-28 HLD Opaciden OPA 30	COMPLIANT	COMPLIANT W/ RINSE	COMPLIANT W/ RINSE	COMPLIANT		

Additionally, please note that the disinfectant examples listed in the tables above do NOT represent an all-inclusive list. If needed, comprehensive lists of disinfectants can be found on the websites listed below:

- EPA-Registered Disinfectants:
   <a href="https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants">https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants</a>
- FDA-Cleared Sterilants and High-Level Disinfectants:
   https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and

For additional guidance on selecting the appropriate disinfection method for your application, refer to the CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities*. This document provides valuable information on disinfection methods and can be accessed at the website listed below:

 Guideline for Disinfection and Sterilization in Healthcare Facilities: https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html#toc

