

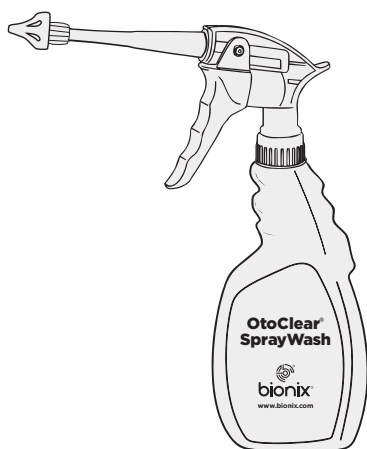
OtoClear® Single-Use SprayWash Kit

INSTRUCTIONS FOR USE

REORDER #7291

CONTENTS

- (1) Bionix SprayWash Bottle
- (1) Trigger Sprayer
- (1) OtoClear Tip
- (1) Adapter Wand



**SINGLE
USE ONLY**



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**OTOCLEAR TIPS
ARE MADE IN
THE USA**



bionix®

DEVICE DESCRIPTION

A single-use ear irrigation kit that includes the Bionix SprayWash Bottle, the Trigger Sprayer, one OtoClear® Tip and the Adapter Wand.

PACKAGE CONTENTS

#7291 OtoClear® Single-Use SprayWash Kit includes:

- (1) Bionix SprayWash Bottle
- (1) Trigger Sprayer
- (1) OtoClear Tip
- (1) Adapter Wand

INTENDED USE

The intended use of the OtoClear Single-Use SprayWash Kit is to flush cerumen and/or foreign bodies from a patient's ear canal without causing injury.

INDICATIONS FOR USE

The OtoClear Single-Use SprayWash 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.

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



WARNINGS

- **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.
- **Single-Use ONLY**

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.

Bionix® SprayWash Bottle Assembly Instructions:

01. Remove the OtoClear Tip from inside of the SprayWash Bottle and set aside.
02. Grasp the SprayWash Bottle firmly.
03. Turn on water source.
04. Fill SprayWash Bottle with body temperature water. **DO NOT** use cold or hot water as it may cause dizziness in some patients.
05. After filling, place SprayWash Bottle on secure, stable platform.
06. Grasp the Trigger Sprayer and guide the tube into the opening on the SprayWash Bottle until fully inserted.
07. Point the Trigger Sprayer and Adapter Wand in the same direction as the larger end of the SprayWash Bottle's base.
08. Secure the Trigger Sprayer with one hand, rotate the blue fastening ring at the base of the head clockwise until tight.
09. Grasp the OtoClear Tip and twist onto the luer lock fitting of the Adapter Wand until it stops (**Figure A**).



Figure A

OtoClear Single-Use SprayWash Kit Use Instructions:

01. Prime the unit by discharging into a sink.
02. 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.
03. 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.
04. Pump the SprayWash to irrigate the ear canal.
05. 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.
06. Remove any remaining water in the ear canal with an absorbent sponge. When procedure is complete, dispose of the entire OtoClear® Single-Use SprayWash Kit.

	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