



US

INSTRUCTIONS FOR USE

Double Ended

Disposable Ear Curettes



Manufacturer:
Premier® Medical Products Company
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premiermedicalco.com/promise

IFU# 10389 0321064 Rev0 PDF

Intended Use:

Removal of cerumen and wax from the ear canal. Aid in the manipulation and guidance of foreign objects in removal from the ear canal.

Device Description:

Premier Double-Ended Ear Curettes are flexible ENT surgical instruments, which feature the functionality of metal curettes while providing the comfort, safety and convenience of a disposable plastic instrument. Three different styles meet procedural requirements, patient's anatomy and clinical preference. Unique position indicators provide accurate tip orientation in the ear canal.

Contraindications:

Ear Curettes should not be used under the following conditions –

- Active infection or irritation in tympanic membrane.
- Trauma in ear canal that is visible on examination.

PRECAUTIONS:

- Do not use if the package is damaged/broken, prior to use.
- Prior to use, examine the device for breaks, cracks and/or fractures.
- Discard the device, if any thinning breaks, cracks/fractures are noticed.
- Single-patient use only, disposable.
- Working end should not be inserted into the other ear after use in ear. Other end or second instrument can be used in different ear.
- Do not apply excessive force on the curette during operative procedure, breakage of instrument could occur and may cause temporary discomfort in ear canal.
- Prescription device, Rx only.

WARNINGS:

- Do NOT reuse the device on other patients.
- Discontinue curettage immediately if bleeding occurs in ear canal or tympanic membrane during procedure.
- Use of excessive force should be avoided.
- Do not bend these instruments more than 90° from its longitudinal axis.

Adverse Effect:

- Temporary pain or discomfort.

Contents and Setup:

Item No.	Device styles
1038041	Child-Scoop
1038042	Curve-Loop
1038043	Mini-Loop

Materials:

Ear Curettes	Material used
Child-Scoop	Polypropylene Homopolymer – FDA 21 CFR Part 177.1520
Curve-Loop	
Mini-Loop	

Directions for Use:

1. Select the appropriate style ear curette for the type of patient and cerumen occlusion.
 - Child-Scoop for smaller children and infants.
 - Curve-Loop for general procedures in children's and adults.
 - Mini-Loop for hardened wax.
2. Straighten out ear canal by gently pulling the ear up and away from the patient. Use the curette to loosen and draw cerumen from the ear canal.
3. As cerumen and wax may shift position or move during curettage procedure, unique position indicators helps to identify the presence and location of shifted cerumen.
4. Repeat otoscope exam. Determine location of any remaining cerumen.
5. Repeat curettage procedure until sufficient cerumen is removed to allow adequate visualization of the tympanic membrane.

Cleaning:

The instrument can be wiped down with isopropyl alcohol, prior to use. Do NOT reuse on other patients.

Storage:

- Always store the device in original protective packaging, prior to usage.
- Device storage and handling temperature should not exceed (37.7° C) 100° F.
- Extra care should be taken while handling and avoid the Ear Curettes from coming in contact with aggressive and/or caustic solutions.

Shelf Life:




Premier Disposable Ear Curettes have an indefinite shelf life.

Disposal:

Dispose the instruments as biohazardous medical waste in accordance to facility or institutional guidelines/procedures after each use on a patient.

For Further Information:

Please visit premiermedicalco.com

Symbols	Symbol Meaning
	Manufacturer
	Caution: See instructions for use
Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Do not reuse