

# ClearLook® CeraSpoon®

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## INSTRUCTIONS FOR USE

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**R<sub>x</sub> ONLY**



**ASSEMBLED IN THE USA**

ClearLook® Lighted Ear Curette™ US Patent #s: 12402974, D1036670, D1090838

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RM95-0108 | Rev. 01



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## ENGLISH

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**Intended use:** The intended use of the Lighted Ear Curette is to remove cerumen and/or foreign bodies from and illuminate a patient's ear canal without causing injury.

**Indications for use:** The Lighted Ear Curette is indicated for use in cases of impacted cerumen and/or foreign bodies occluding the ear canal.

### Assembly:

**a. To assemble using the Original Light Source:**

Insert the end of the tool into the Light Source by aligning the pegs on the end of the tool with the grooves inside the Light Source. Push down and **FIRMLY** twist clockwise until rotation stops. This will lock the tool into place and activate the light.

**b. To assemble using the Rechargeable Light Source:**

Align the end of the tool with the threaded opening of the Rechargeable Light Source. Turn the Light Source clockwise until secure. Do not overtighten.

**c. To attach the Magnification Lens:** Snap the lens onto the neck of the Light Source so that the top of the lens angles toward the tip of the tool.

### Disassembly:

**a. To disassemble from the Original Light Source:**

Push the tool into the Light Source and rotate counterclockwise. The light will go off when the tip is removed.

**b. To disassemble from the Rechargeable Light Source:**

Simply twist the Light Source in a counterclockwise direction until the Light Source has loosened.

### Instructions For Cerumen Removal

1. Use an otoscope to examine the ear canal and determine cerumen location.
2. Select the appropriate style Lighted Ear Curette for the type of patient and cerumen occlusion. Assemble according to instructions.
3. Use Lighted Ear Curette to remove cerumen from the ear canal.
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.
6. Disassemble the Lighted Ear Curette, and discard the used curette in the usual fashion. Save the Light Source for the next curettage procedure. Lighted Ear Curette Tips are intended for single patient use only.

 **CAUTION:** Discontinue curettage immediately if bleeding, irritation, or other trauma to the ear canal or tympanic membrane occurs.

 **CAUTION:** This product is a spring-loaded device; improper assembly may cause ejection of the ear curette.

 **CAUTION:** DO NOT hold device by Light Source as accidental ejection of curette may occur if not assembled properly.

 **WARNING:** Cross-contamination risk. Do not reuse disposable curette 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:** There are no absolute contraindications for cerumen removal.

**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

	Manufacturer		Do Not Use if Package is Damaged
	Date of manufacture		Do Not Reuse Single-Use Device
	Lot Code		Prescription Only or "For Use by or on the order of a licensed medical professional"
	Reorder Number		Consult Instructions For Use (IFU)
	Caution		Warning