The Lighted Articulating Ear Curette

INSTRUCTIONS FOR USE

MD

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℞ ONLY

MADE IN THE U.S.A.

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This manual applies to the REF numbers indicated below:

#2511 – Lighted Articulating VersaScoop®

bionix®

ENGLISH

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

Assembly/Disassembly:

1. To assemble the Lighted Articulating Ear Curette, insert the end of the curette into the light source by aligning the pegs with the grooves inside the light source. Push down and twist FIRMLY clockwise until rotation stops. This will lock the curette into place and activate the light.
2. To attach the magnification lens, snap the lens onto the neck of the blue light source so that the top of the lens angles toward the curette tip.
3. To disassemble, push the curette into the light source and rotate counter clockwise to remove. The light will go off when the curette is removed. Discard the used curette and keep the light source and magnification lens for the next procedure.

Instructions for Cerumen Removal - Using the Lighted Articulating Ear Curette™ with Magnification

The Lighted Articulating Ear Curette offers a new approach to cerumen and foreign body removal, with an articulating, lighted tip that can be made to flex and firmly, yet gently, remove obstructing wax or objects.

To use the Lighted Articulating Ear Curette:

1. Position the patient comfortably on the examination table. Smaller children may be restrained on their parent's lap or shoulder during the procedure. Visit www.Bionix.com and view the Bionix Cerumen Removal Tips and Techniques videos for more detail.
2. Using an otoscope, examine the ear canal noting the presence and location of any obstructing cerumen or foreign body.
3. Straighten the ear canal by gently pulling the ear up and away from the patient. Position the tip of the Lighted Articulating Ear Curette adjacent to the obstruction or behind it if there is room between the obstruction and the ear canal wall.
4. Grasp the handle of the Lighted Articulating Curette in your palm placing your index finger in the trigger and gently pull back. This will cause the tip of the curette to bend.
5. Hold the tip in the flexed position and gently roll the obstruction from the ear canal.
6. Use an otoscope to re-examine the ear canal, noting the presence and location of any remaining obstruction.
7. Repeat the above procedure as needed to until the tympanic membrane can be adequately visualized, or the foreign body has been removed.
8. Remove the otoscope and discard the curette tip.

⚠ **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. Special Note: The Lighted Articulating Ear Curette is intended for single-patient use. Discontinue use of the curette if the hinge no longer functions. Re-use of the curette can cause the hinge to stop functioning. Use of alcohol wipes or cold sterilization can also negatively affect the functioning of the curette. The light source and magnification lens are designed for multi-procedure use.

⚠ **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

MD	Medical Device		Do Not Use if Package is Damaged
	Manufacturer	2	Do Not Reuse Single-Use Device
	Date of manufacture	1	Single patient-multiple use
	Use-By Date		Consult Instructions For Use (IFU)
LOT	Lot Code	⚠	Caution
REF	Reorder Number	⚠	Warning
SN	Serial number	EC REP	Authorized representative in the European Community
STERILE R	Sterilized using irradiation	CE	European Conformity
2 STERILIZE	Do Not Resterilize	℞ ONLY	Prescription Only or "For Use by or on the order of a licensed medical professional"
NON STERILE	Non-sterile		Temperature limitation