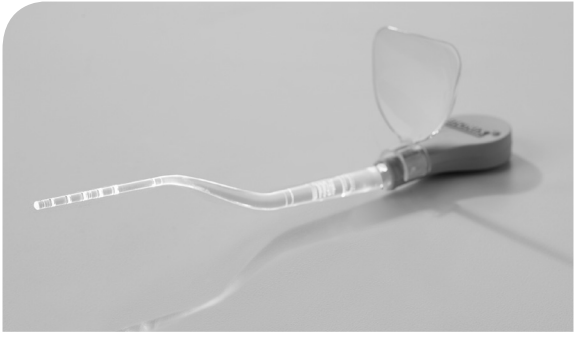
LIGHTED PLACEMENT TOOL
USER INSTRUCTIONS



℞ ONLY **MADE IN THE U.S.A.**

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REORDER NUMBERS:

#2850 - LIGHTED PLACEMENT TOOL
(1 LIGHT SOURCE, 1 MAGNIFICATION LENS, 15 LIGHTED PLACEMENT TIPS)
#2200 - EXTRA LIGHT SOURCE
#2265 - PACK OF 5 MAGNIFICATION LENSES
#2299 - LIGHT SOURCE LANYARD

bionix®

LIGHTED PLACEMENT TOOL - USER INSTRUCTIONS

Assembly/Disassembly:

1. To assemble the Lighted Placement Tool, insert the blunt end of the tip 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 tip 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 lighted tip.
3. To disassemble, push the Lighted Placement Tool into the light source and rotate counter clockwise to remove. The light will go off when the tip is removed.

The Lighted Placement Tool is intended for single-patient use. The light source and magnification lens are designed for multi-procedure use. A light source and lens are provided in each box of product.

Instructions for Use:

1. Follow the mold manufacturer's instructions for ear examinations before placing the foam block.
2. Use the Lighted Placement Tool to insert the block into the ear canal and to make any slight adjustments.
   For your convenience, the Lighted Placement Tool is marked with grooves every 5mm from the tip. Once the block is placed, use an otoscope to verify proper placement.
3. Once placement is verified, remove the Lighted Placement Tip and dispose. Save the magnification lens and light source for your next procedure.

⚠ **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 Lighted Placement Tool.

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

⚠ **CAUTION:** The Lighted Placement Tool is an aid to help visualize the ear canal when placing a foam block for the ear mold process. Improper use can cause trauma to the ear canal and/or tympanic membrane.

Symbol	Title of Symbol	Description of Symbol	Symbol Designation Number	Title of Symbol Standard Development Org. Standard
MD	Medical Device	Indicates the item is a medical device.	5.7.7	ISO/DIS 15223-1:2020(E) DRAFT
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	ISO 15223-2016
EC REP	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2	ISO 15223-2016
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	ISO 15223-2016
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-2016
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-2016
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6	ISO 15223-2016
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	5.1.7	ISO 15223-2016
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4	ISO 15223-2016
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	5.2.6	ISO 15223-2016
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-2016
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	ISO 15223-2016
	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	5.4.1	ISO 15223-2016
	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	ISO 15223-2016
	Single patient-multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient	5.4.12	ISO/DIS 15223-1:2020(E) DRAFT
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-2016
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	5.4.4	ISO 15223-2016
CE 0459	European Conformity	EC Declaration of Conformity by Notified Body	Annex XII	MDD 93/42/EEC:2007
CE	European Conformity	EC Declaration of Conformity by Manufacturer	Annex XII	MDD 93/42/EEC:2007
℞ ONLY	By Prescription Only	Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.	N/A	FDA 81 Federal Register pg. 38911-38931
MR	MR Safe	Indicates an item that poses no known hazards in all MR environments.	7.4.3.1 or 7.4.4.1	F2503-13
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	5.3.7	ISO 15223- 1:2016