CLEANING

Detailed cleaning and disinfection instructions can be found on the Bionix website under Resources on the product page.

WARNING: Do not immerse the Rechargeable Light Source in any liquid.

DISPOSAL PROCEDURE

This device contains a Lithium-lon battery and must be disposed of properly in accordance with local, state and federal regulations. Do not incinerate, crush, puncture or expose it to high temperatures.

To safely dispose of the battery:

- Follow your local electronic waste (e-waste) disposal guidelines.
- Take the device to an authorized battery recycling facility or an approved electronics recycler.
- Do not dispose of it in regular trash, municipal waste or a landfill.

For more information on proper disposal, contact your local waste management authority or visit https://www.epa.gov/recycle/used-lithium-ion-batteries.

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

Designed and Assembled in the USA



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Rechargeable Light Source Instructions for Use



R ONLY

REF	Description	
3600	Rechargeable Light Source and Charging Cord	
3645	ClearLook® Lighted Ear Curette™ Variety Pack with Rechargeable Light Source and Charging Cord	



INTENDED USE

The intended use of the Rechargeable Light Source and the Original Light Source is to provide illumination during examination, inspection and treatments of patient(s).

INDICATIONS

The Rechargeable Light Source and Original Light Source are indicated for use on all patient populations for any medical procedures requiring illumination.

CONTRAINDICATIONS

There are no absolute contraindications for use of the Rechargeable Light Source.

CLINICAL BENEFITS

Indicated in Intended Use.

RESIDUAL RISKS

Risks associated with the use of this product have 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 errors
- · Harm from unanticipated origins



Cross-contamination risk. Do not reuse disposable instruments, e.g. curettes, as this may spread contamination from one patient to another patient.

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

CHARGING

To charge the Rechargeable Light Source:

- Connect the provided cable to the USB-C port on the device and plug the other end into a compatible power adapter (see recommended power adapters below).
- 2. Plug the power adapter into a power outlet.
- 3. While charging, the Rechargeable Light Source power button will glow red. Once fully charged, the red light will turn off.
- 4. Note: The Rechargeable Light Source will not function while charging. Ensure the device is fully charged and disconnected from the power source before use.

Charger and Battery Specifications			
Recommended Power Adapter Output Specifications	DC Output; 5 Vdc Output Current: 1 A		
Estimated Time to Fully Charged Battery	~105 minutes		
Estimated Continuous Use Run Time – from a fully charged battery	~120 minutes		

INSTRUCTIONS FOR USE Initial Setup

Before first use, remove the Rechargeable Light Source from its packaging and **fully charge** it.

Assembly

- Attach the Rechargeable Light Source to a Lighted Bionix Instrument (e.g., curette, lighted forceps, etc.).
- Align the instrument's end with the threaded opening of the Rechargeable Light Source, ensuring the pegs are properly positioned.
- 3. **Turn clockwise** until secure. Do not overtighten.
- 4. Attach the Magnification Lens Snap the Magnification Lens onto the neck of the Rechargeable Light Source; ensure the top of the lens angles toward the tip of the lighted instrument.

Operation

- 1. To Turn ON: Press the button in the center of the Rechargeable Light Source.
- 2. To Turn OFF: Press the button again.

Disassembly and Storage

- 1. Rotate the disposable tool counterclockwise to detach it from the Rechargeable Light Source.
- 2. Discard disposable curette after use.
- 3. Return the Rechargeable Light Source to the charger as needed or store in a clean, dry environment.