Lighted MicroSuction System

INSTRUCTIONS FOR USE





R_x ONLY



Lighted Suction Handles are Single-Use Only



USE VIDEO



Thank you for purchasing the Bionix Lighted MicroSuction System. This System combines the Bionix Lighted Suction Handle, Rechargeable Light Source and Magnification Lens with a hospital-grade rechargeable suction pump to perform safe, effective microsuction for cerumen (earwax) and foreign body removal.

Package Contents

- · (1) Rechargeable, Hospital-Grade Suction Pump
- (10) Lighted Suction Handles
- · (1) Rechargeable Light Source
- · (1) Magnification Lens
- · (1) Flexible Suction Tubing (39.4")
- · (1) Cerumen Catcher
- · (2) Charging Cables
- · (2) Charging Blocks

Intended Use

The intended use of the Lighted MicroSuction System is to illuminate and magnify a patient's ear canal or nasal passage to remove obstructions quickly and safely.

Indications for Use

The Lighted MicroSuction System is indicated for use by healthcare professionals, on all patient populations, in cases of obstruction of either the ear canal or nasal passage.

Before Use

- 1. Inspect all components for damage. Do not use damaged parts.
- 2. For maximum suction performance, fully charge the suction pump using the supplied charging cable and charging block.

Assembly (See Figure 1)

- 1. Connect the Cerumen Catcher **(D)** to the suction pump **(C)** by placing it onto the suction port on the top of the pump.
- 2. Plug the tubing **(G)** into the hole on the top of the Cerumen Catcher **(D)**.
- Connect the tubing from the Cerumen Catcher to the barbed adapter (H) on the bottom of the Lighted Suction Handle (F).
- 4. Attach the Rechargeable Light Source (A) to the Lighted Suction Handle (F). Align the end of the instrument with the threaded opening of the Rechargeable Light Source. Turn the Light Source clockwise until secure. Do not overtighten.
- If desired, snap the Magnification Lens (B) onto the neck of the Rechargeable Light Source.
- 6. Ensure all connections are secure before operating.



Figure 1: Lighted MicroSuction System Components

Instructions for Use

- Examine the ear canal with an otoscope and note the location and depth of cerumen or foreign body.
- 2. Turn the pump on using the power button.
 - a. Select the desired suction level (low, medium or high) by depressing the power button.
- 3. Hold the Lighted Suction Handle **(F)** and, with direct visualization from the Light Source and Magnification Lens, gently advance toward the obstruction.
- 4. Once in contact with the obstruction, place your thumb over the suction port **(E)** on the back of the handle to initiate suction.
 - a. Tip: If the handle becomes clogged, draw hot water through it to help clear the blockage. Be careful not to overfill the Cerumen Catcher.
- 5. Once the procedure is complete, turn off the suction pump, disassemble and dispose of the used Suction Handle. Empty and clean the Cerumen Catcher and tubing. Save the Rechargeable Light Source and Magnification Lens for future use.
- Charge the pump and Rechargeable Light Source as needed.

Recharging the Suction Pump

1. When the battery charge becomes low, the

- lights on the suction pump will change from green to orange.
- 2. Three orange lights will appear and flash briefly on the pump when there is insufficient battery to start the pump.
- 3. Connect one end of the charging cable to the pump and the other to the provided charging block. CAUTION: Use only the charging cable and block provided with this product.
- 4. Charging status is indicated by the following:
 - a. One flashing green light: 0-33% chargedb. One solid, one flashing green light: 33-66% charged
 - c. Two solid, one flashing green light: 66-99% charged
 - d. Three solid green lights: 100% charged
- 5. The pump cannot be used while charging.

Cleaning & Maintenance

- Do not reuse the Lighted Suction Handle. It is intended to be used on one patient to prevent cross-contamination.
- 2. Wipe down the Cerumen Catcher, tubing and the suction pump exterior with a disinfectant wipe or mild soap solution. Do not immerse the pump in water. Detailed cleaning and disinfection instructions for the Rechargeable Light Source and Magnification Lens can be found on the Bionix website under Resources on the product page.

3. Store the pump in a clean, dry place.

⚠ Warnings & Precautions

1. Discontinue use if the patient experiences pain, bleeding or trauma.

Specifications

Operating/storage temperature range:

32 to 95°F (0 to 35°C)

Maximum operating humidity: 85% RH

Battery nominal voltage: 7.2 V **Battery capacity:** 200 mAh

Input: 5 VDC, 0.5A

Maximum pump flow rate: 13.5 L/min

Nominal pump flow rate: 8 L/min

Maximum pump suction pressure: 78 kPa **Nominal pump suction pressure:** 60 kPa

Auto-shutoff: 3 minutes

Electromagnetic compatibility (EMC)

Electromagnetic radiation disturbance: Class B, Group 1 CISPR 11:2009+AMD1:2010

Mains terminal disturbance voltage:

Class B, Group 1 CISPR 11:2009+AMD1:2010

Disposal

- 1. Dispose of single-use handles in accordance with local medical waste regulations.
- Recycle suction pump and Rechargeable Light Source according to local guidelines for electronics.

Register your Bionix® Lighted MicroSuction System today!

- Confirm Your Warranty & Support
 Ensure your system is covered and get priority access if service or troubleshooting is needed.
- 2. Stay Informed for Patient Safety

 Be the first to receive clinical advisories,
 updated instructions or safety notices.
- **3. Access Training & Resources**Unlock exclusive how-to guides, videos and clinical tips to maximize performance.
- **4. Get Early Product Updates**Receive notifications on new tips, accessories and system enhancements.
- **5. Contribute to Product Development**Share feedback that helps shape the next generation of Bionix ear, nose and throat solutions.



SCAN TO REGISTER YOUR PRODUCT

Symbols Glossary

| <u>~</u> | Manufacturer | ® | Do Not Use if Package is Damaged |
|---------------|--|----------|---------------------------------------|
| M | Date of manufacture | 2 | Do Not Reuse Single-Use Device |
| LOT | Lot Code | []i | Consult Instructions For Use (IFU) |
| REF | Reorder Number | Ŵ | Caution |
| SN | Serial number | Ŵ | Warning |
| R ONLY | Prescription Only or "For Use by or on the order of a licensed medical professional" | | |



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