

Lighted Magnetic Tool for Foreign Body Removal

INSTRUCTIONS FOR USE



R_x ONLY

**ASSEMBLED
IN THE USA**



**HOW TO
USE VIDEO**



bionix[®]

Package Contents

- (5) Lighted Magnetic Foreign Body Removal Tools

Intended Use

The Magnetic Foreign Body Removal (MFBR) Tool is intended for use by trained healthcare professionals to assist in the removal of ferromagnetic foreign bodies from the ear, nose, and throat during routine clinical procedures. The device incorporates magnetic attraction and illumination to aid in visualization and retrieval of ferromagnetic objects.

Indications for Use

The Magnetic Foreign Body Removal Tool (MFBR) is indicated for the removal of superficial ferromagnetic foreign bodies from the external auditory canal, anterior nasal cavity, and oropharynx under direct visualization by trained healthcare professionals for all patient populations.

Contraindications

Do not use:

- To remove non-ferromagnetic foreign bodies
- On foreign bodies located beyond direct visualization in airway management

Clinical Benefits

Indicated in Intended Use.

Residual Risks

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 errors
- Harm from unanticipated origins

WARNINGS

- Cross-contamination risk. Do not reuse disposable instruments as this may spread contamination from one patient to another patient.
- Use only under direct illumination and visualization to prevent trauma.
- Do not insert the device if active bleeding or suspected tympanic membrane perforation is present.
- Device is not intended for use in airway management. Seek additional medical guidance if airway is occluded.
- **Button battery ingestion is a medical emergency** requiring immediate removal per clinical guidelines.

CAUTION

- Discontinue use immediately if bleeding, pain, irritation, coughing, gagging, or patient distress occurs, if airway is occluded or if breathing is impaired.
- Use gentle, controlled motion to avoid trauma to the ear canal, nasal cavity, or oropharynx.
- Keep all magnets away from credit cards, magnetic storage media, medical implants like pacemakers, piercings and other sensitive devices.

Instructions For Use

Assembly

1. Attach the Lighted Magnetic Foreign Body Removal Tool to the Rechargeable Light Source:
 - a. Align the end of the instrument with the threaded opening of the Rechargeable Light Source.
 - b. Turn the Light Source clockwise until secure. Do not overtighten.
2. If desired, snap the Magnification Lens onto the neck of the Rechargeable Light Source.
3. Ensure all connections are secure before operating.

A. Ear Canal Removal

1. Gently straighten the ear canal by pulling the auricle.
2. Examine the ear canal under direct illumination and determine the location and depth of the foreign body.
3. Insert the illuminated magnetic tip under direct visualization.
4. Slowly approach the ferromagnetic object until magnetic engagement occurs.
5. When the magnet engages the foreign body, remove cautiously with controlled withdrawal.
6. Inspect the canal for remaining objects or irritation.
7. Remove the Light Source, dispose of the Magnetic Foreign Body Removal Tool and foreign body.

B. Nasal Cavity Removal

1. Examine the anterior nasal cavity under direct illumination and determine the location and depth of the foreign body.
2. Insert the magnetic tip carefully along the floor of the nasal passage.
3. When the magnet engages the foreign body, remove cautiously with controlled withdrawal.
4. Assess for mucosal irritation or residual objects.
5. Remove the Light Source, dispose of the Magnetic Foreign Body Removal Tool and foreign body.

C. Oropharyngeal Removal

1. Depress the tongue if required to maintain visualization.
2. Examine the oropharynx under direct illumination and determine the location and depth of the foreign body.
3. Introduce the device while monitoring for gag reflex.
4. When the magnet engages the foreign body, remove cautiously with controlled withdrawal.
5. Ensure the airway remains protected throughout.
6. Remove the Light Source, dispose of the Magnetic Foreign Body Removal Tool and foreign body.

Disposal Procedure

Dispose of used, single-use instruments in accordance with local, state or facility medical waste regulations. Do not attempt to clean or reprocess.

Symbols Glossary

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



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