

MEDORAH® FOREIGN BODY GRASPING FORCEPS

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® Foreign Body Grasping Forceps

Intended Use

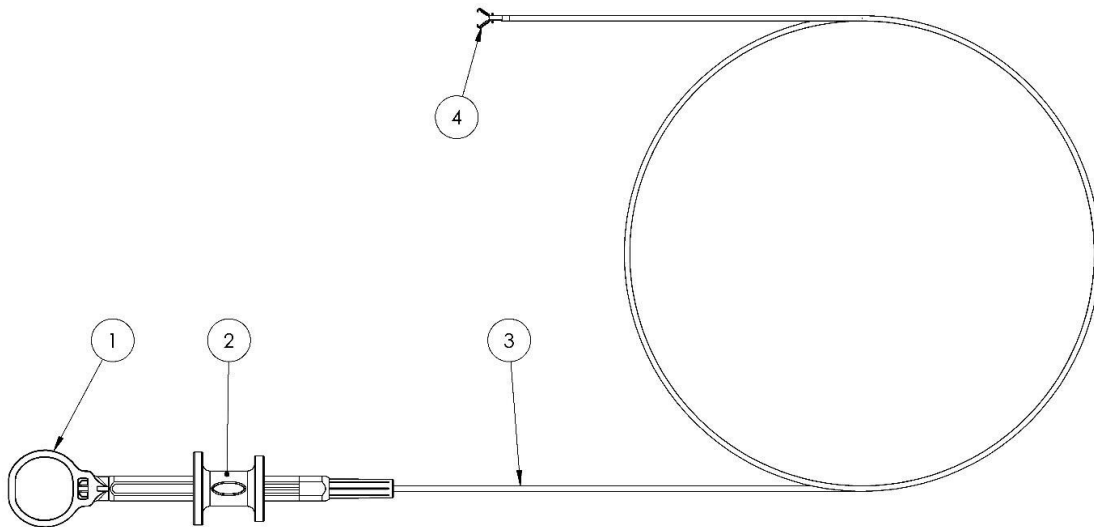
MEDORAH® Foreign Body Grasping Forceps are intended to be used to grasp tissue, retrieve foreign bodies and remove tissues from within the gastrointestinal tract.

MEDORAH® Foreign Body Grasping Forceps is single use and supplied sterile.

Device Description

MEDORAH® Foreign Body Grasping Forceps are used for endoscopic removal of tissue or foreign bodies from GI tract.

This device consists of several components including a handle, slider, catheter and jaws. The proximal end features a slider integrated into the handle. The slider controls the opening and closing of the jaws at the distal end. The jaws are designed with a hybrid configuration, combining alligator and rat tooth features to provide a firm grip. These jaws offer the flexibility of 360°, 1:1 rotation, facilitated by the handle.



①	Handle
②	Slider
③	Catheter
④	Jaws

Contraindications

Contraindications include but are not limited to:

- Coagulopathy
- Contraindications related to endoscopy
- Endoscopic procedures to remove a foreign body or food bolus
- Endoscopic procedures performed in combination with over tube.
- Using this device with electrosurgical unit is not recommended according to intended use.

Potential Complications

- Hypotension
- Fever
- Respiratory depression or arrest
- Perforation
- Cardiac arrhythmia or arrest
- Hemorrhage
- Infection
- Sepsis
- Aspiration
- Allergic reaction to contrast or medications

Warnings

- This device is intended for single use only. Do not reuse, reprocess or sterilize several times. Reuse, reprocessing or repeated sterilization of the instrument may affect its structural integrity and cause malfunction, resulting in contamination, infection and serious injury.
- Do not use the device after the expiration date.
- All components should be carefully checked for compatibility and integrity before use. Do not use defective device.
- Do not use the product outside the recommended intended use.
- Do not apply excessive force on devices into the working channel of endoscope.

- Foreign body removal must be performed under direct endoscopic visualization.
- Patients should be informed about the potential risks and complications associated with the procedure, including the possibility of injury, illness, or even death.
- Keep traction on the device during retrieval in order for the retrieved object not to become loose, dislodged or, if in the lung, aspirated into the trachea.
- Do not insert the device into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury.
- Do not insert the instrument into the endoscope while the forceps are open. Otherwise, patient injury, such as perforation, bleeding or mucous membrane damage could occur.

Procedure

- Choose the appropriate forceps that are compatible with the channel of the endoscope.
- Open the sterile pouch and carefully take out the forceps. Inspect them for any kinks or damage.
- Remove the forceps caps and move the slider several times to ensure the jaws open and close properly.
- With gentle pressure on the handle to keep the forceps closed, insert the forceps through the endoscopic channel until the forceps are visible.
- Direct the forceps towards the targeted site. Open the forceps jaws by moving the slider distally. Carefully advance the opened forceps over the target site and close them with minimal pressure to grasp the foreign body. Avoid excessive force to prevent misaligned or fail.
- Continue to apply gentle pressure on the handle during withdrawal of forceps from the channel. Once forceps have grasped the object, slowly withdraw the object together with the endoscope from the patient.
- Do not retract the device and the object into the endoscope; this could cause damage to the endoscope and the device.
- Once the endoscope and the device have been withdrawn from the patient, open the forceps jaws, and remove the object.
- If additional objects need to be removed, ensure the grasping jaws open and close smoothly and repeat the steps as needed.

Storage

Store the device under defined temperature limit and avoid direct sunlight Follow the First-in, First-out rules and do not use the device beyond its expiry date.















Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

Disposal of a used device

The device used must be disposed off according to the hospital, local and country regulations. Disposal is the responsibility of the user.

Explanation of symbols

	Date of Manufacturing		Use-By Date
	Catalogue Number		Do not re-use
	Consult Instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry
	Do not re-sterilize		Sterilized using Ethylene Oxide

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.



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