MEDORAH MEDITEK

MEDORAH® FOREIGN BODY RETRIEVAL NET

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

FORENET® Foreign Body Retrieval Net

Intended Use / Indications for use

FORENET® Foreign Body Retrieval Net is intended to be used to grasp tissues/polyps and/or retrieve foreign bodies from the gastrointestinal tract.

FORENET® Foreign Body Retrieval Net is supplied sterile and is intended for single use only.

Device Description

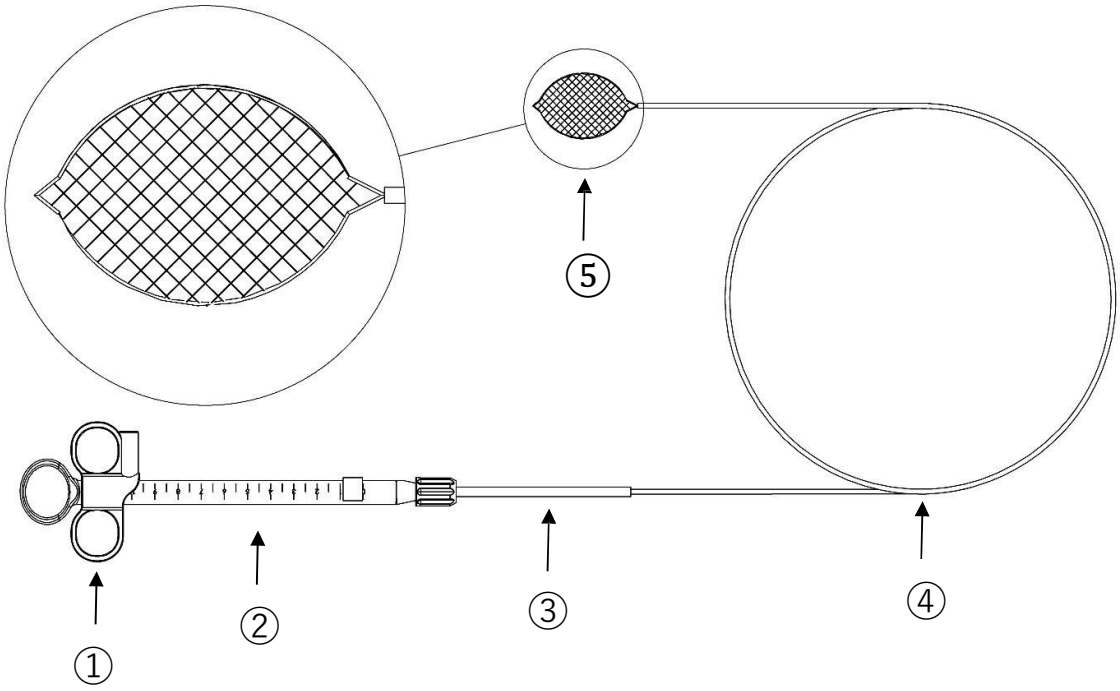
FORENET® Foreign Body Removal Net is designed to retrieve the foreign body, food bolus and excised tissue such as polyps during endoscopic procedures. Foreign Body retrieval net is a rotatable device that provides better capturing on the target side. It is composed of a net attached at the distal end of the inner wire and proximal part of the wire is connected to the Slider. The slider provides a force to the grasping ends that may be pointed or may have loop tips. The distal end of the tube is an open tip and the proximal end of the tube is connected to the handle hub. They are typically used for retrieving soft objects, such as polypectomy specimens and food boluses.

FORENET® Foreign Body Retrieval Net Specifications

Tube Length: 120 cm, 160 cm, 230 cm and 260

cm Tube O.D: 1.8 mm and 2.5 mm

Minimum Working Channel: 2.8 mm



①	Slider
②	Handle
③	Heat Shield tube
④	Outer Sheath
⑤	Net

Contraindications

Contraindications include those specific to any endoscopic procedure, as well as those specific to biopsy/foreign body retrieval.

Warnings

The entire User's Manual must be read thoroughly before using the device. A detailed knowledge of the techniques, procedures, clinical applications and risks associated with the procedure is necessary before using the device.

- This device is intended for single use only. Do not **reuse, reprocess or resterilize**. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- This device is only meant to be used for the purposes specified.
- Do not use the device beyond its expiration date.
- Prior to use, visually inspect the package for any tears, irregularities or damage. If an abnormality is detected, the sterile condition of the device may have been compromised. Do not use.
- Check the condition of the catheter, handle and net. If any abnormalities or damage such as significant deformations or excessive bends are found, do not use the device.
- Dispose of product and packaging according to hospital, administrative and local government policy.

Precautions

- Check the package label for the minimum channel size required for this device.
- The endoscopic retrieval of foreign objects, food bolus, tissue samples or excised polyps should only be performed by persons having sufficient training in clinical endoscopic technique.
- Avoid inadvertently grasping tissue or organs not intended for retrieval.
- Carefully, apply gentle traction on the device during retrieval so that the retrieved object does not become loosened, dislodged or aspirated into the trachea.
- Any use for procedures, other than those indicated in these instructions, is not recommended.
- Avoid excessive force, it may cause damage to the forceps.
- Device is not recommended for the retrieval of sharp foreign objects.
- If the retrieved material does not exit the net upon deployment, the material should be removed from the net by rinsing the net into water; do not "pick" retrieved material from the net with a finger or tool as this may damage the net.

Procedure

- Peel the pouch and remove the device. Visually inspect the device for kinks, loose or broken parts.
- Pass the distal end of the catheter slightly past the object, bolus, or polyp to be retrieved. If the entire lumen is blocked, do not blindly pass the device past over the object, bolus, or polyp.
- Open the device by advancing the handle forward until it stops. check the net is fully open via endoscopic observation.
- Endoscopically position the retrieval net over the object, bolus, or polyp.
- Adjust the net positioning by rotating the handle in the desired direction.
- Close (retract) the handle until resistance is felt and the object, bolus, or polyp is entrapped in the net.
- Now keep the device closed by applying continuous traction to the handle.
- Hold and slightly pull the proximal end of the device to bring the collected object close to the tip of the endoscope making sure not to obscure the endoscopic view.
- Endoscopic observation is necessary during removal so as to not lose sight of the object, bolus, polyp, or surrounding tissue during removal.
- Secure the object in the net then withdraw the object together with the endoscope from the patient.
- Avoid retracting 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, the retrieved object, bolus, or polyp can be removed from the net by advancing the handle forward to open the device.

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

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

Storage

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

Explanation of Symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Single use only
	Read instructions before use		Caution
	Keep away from direct sunlight		Batch Code
	Keep dry		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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