



GRAPPLER® GASTROINTESTINAL ENDOSCOPIC CLIP

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

GRAPPLER™ GASTROINTESTINAL ENDOSCOPIC CLIP

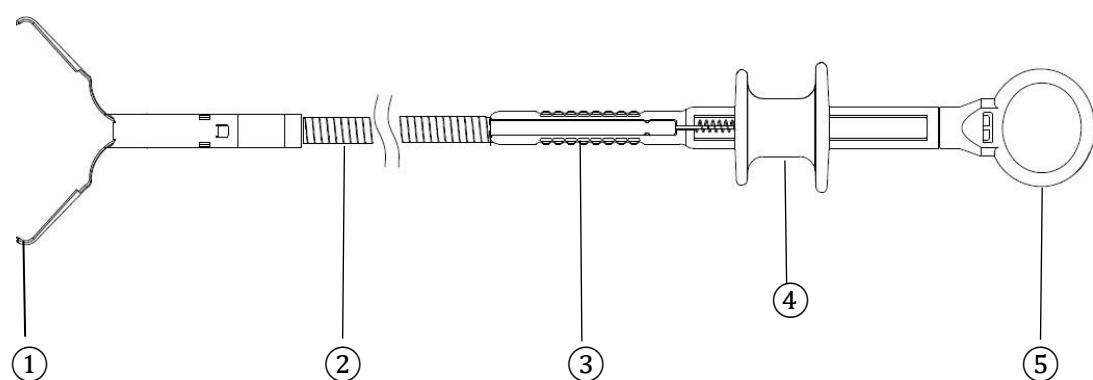
Device Description

The GRAPPLER™ Clip consists of a single-use clip with 13mm clip opening, pre-loaded on a flexible, rotatable delivery system. The GRAPPLER™ Clip is designed to be compatible with forward-viewing endoscopes with working channels equal to or greater than 2.8 mm. The clip can be opened, closed, and rotated infinitely prior to deployment, allowing precise repositioning at the lesion site. Reopening, closing and rotation capability may be limited by clinical circumstances and patient anatomy, among other factors.

Intended Use

GRAPPLER™ Endoscopic Clip is intended for single use only and is used to deploy GRAPPLER™ clips within the Gastrointestinal (GI) tract for the following purposes:

- Endoscopic marking of lesions
- Hemostasis and tissue approximation for:
 - Mucosal/sub-mucosal defects (< 3 cm)
 - Bleeding ulcers
 - Arterial lesions (< 2 mm)
 - Polyps (< 1.5 cm in diameter)
 - Diverticula in the colon, and
 - Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection,
- Anchoring to affix jejunal feeding tubes to the wall of the small bowel
- As a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.



| | |
|---|-------------|
| ① | Metal claw |
| ② | Spring tube |
| ③ | Slide rod |
| ④ | Slide ring |
| ⑤ | Handle |

Contraindications

- Patients with bad basic conditions cannot undergo the endoscopic examination.
- The patient has a narrow upper alimentary canal and the endoscope cannot get through.
- Patients have coagulopathy and hemorrhagic disease.
- Patients are allergic to this product and medicine used in the operation.
- Patients who are not recommended to use this product after diagnosis.

Complications

- Unintended Clip Deployment
- Failure to Deploy / Malfunction
- Damage to Endoscope
- Injury to Patient
- Retention of Device
- Cross-contamination / Infection
- Perforation
- Hemorrhage
- Aspiration
- Fever
- Infection
- Allergic reaction to medication
- Hypotension
- Respiratory depression or arrest
- Cardiac arrhythmia or arrest
- Hematemesis
- Transient dysphagia
- Aspiration pneumonia

- Wound dehiscence
- Minimal acute inflammatory tissue reaction
- Transitory local irritation
- Migration of clip into the bile duct
- Anatomy disruption

Warnings:

- This device has not been evaluated for anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with esophageal strictures or malignant obstructions
- Failure to follow the recommended MR conditional labeling may result in a deployed GRAPPLER™ clip dislodging from tissue or heating of tissue at the GRAPPLER™ clip location. This could cause re-bleeding, serious injury, or death
- This clip contains ferromagnetic material. There may be a potential risk of clip dislodgment and re-bleeding if used in friable or healing tissues due to magnetic forces in or near an MRI scanner
- Failure to apply slight pressure to the handle during removal can result in tissue damage from the device.
- Do not use the instrument if the spring tube of the delivery system is distorted. Otherwise, the clip may become stuck at the edge of the spring tube and fail to detach properly.

Precautions

- Do not forcibly pull back on a deployed clip still attached to the coil, as this may tear tissue, cause severe bleeding, or perforation.
- Keep a wire-cutter available to cut the coil near the handle if detachment fails; urgent surgery may be required to remove the clip safely.
- Premature detachment may cause re-bleeding, failed tube anchoring, failed marking, or incomplete defect closure.
- Though rare, recurrent bleeding, ineffective clipping, or complications may require surgical intervention.
- Use in contaminated sites may increase or prolong infection.
- Clipping hard or fibrotic tissue may result in ineffective hemostasis, failed anchoring, failed marking, or incomplete closure. Additional measures may be required.
- Contains nickel; may cause allergic reactions in nickel-sensitive patients.
- The GRAPPLER™ Clip is designed for forward-viewing endoscopes with ≥ 2.8 mm channels. Use with side-viewing scopes may hinder or prevent deployment, risking patient injury.

Procedure

- Tear open the packaging bag and remove the product.
- a) Pull the slide ring slowly to ensure the metal jaws are in a pre-closed position, then remove the protective tube from the spring tube.



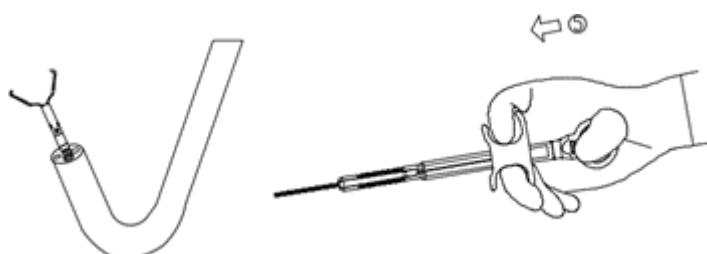
- b) Confirm that the metal jaws are securely connected to both the sleeve and the spring tube.

- Gently insert the disposable GRAPPLER™ clip and delivery system into the working channel of the endoscope.



Cautions:

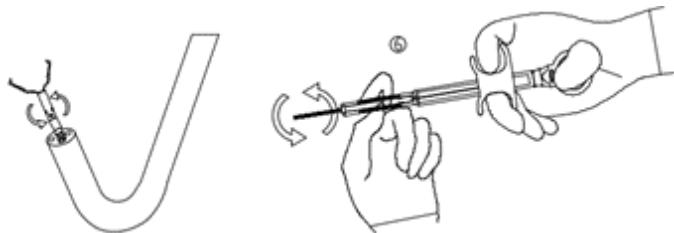
- a) Pull the slide ring slowly to ensure the metal jaws remain in the pre-closed state. Pulling it too hard may cause the jaws to detach from the delivery system before use.
- b) If the bending section of the endoscope is too tightly curled for the clip to pass, straighten the section as much as possible until the clip advances and the jaws become visible in the endoscopic field of view. Then reposition the endoscope appropriately.
- Once the clip is visible in the endoscopic field, push the slide ring forward to open the clip to its maximum width.



Caution: Do not continue pushing once the clip is fully open. Excessive force may cause

the sleeve to detach from the spring tube.

- Rotate the slide rod to adjust the clip's orientation for optimal placement.



Cautions:

- a) Do not rotate the slide rod too quickly, as this may cause the clip to snap suddenly.
- b) If rotation is restricted due to excessive bending of the endoscope, extend the remaining length of the delivery system outside the working channel to straighten it and enable smooth rotation.

- Position the clip at the target site. Pull the slide ring back slightly to confirm correct placement when resistance is felt.



- If placement is correct, continue pulling the slide ring to deploy the clip.



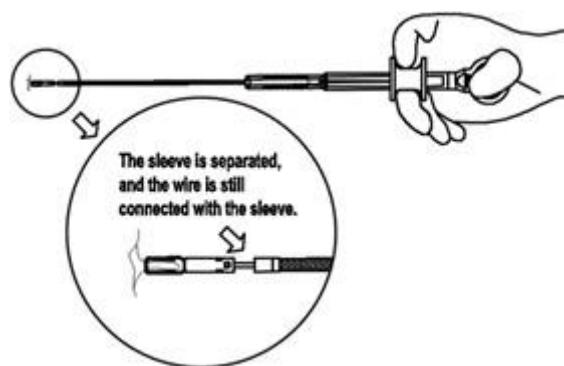
- If placement is not correct, gently push the slide ring forward to reopen the clip, then repeat the steps above until the clip is positioned properly.





Cautions:

- a) Stop pulling the slide ring once resistance is felt, as continuing may cause the clip to detach from the spring tube prematurely.
- b) If the clip closes and detaches from the spring tube incorrectly while the wire remains connected to the sleeve, use both hands to pull back the slide ring and deploy the clip. Use another device to repeat the procedure if necessary.



- After deployment, withdraw the spring tube from the endoscope working channel.
- Dispose of all remaining parts according to local regulations and medical waste disposal guidelines.

Emergency Disposal Instructions:

- If the clip fails to detach from the instrument, do not withdraw it through the endoscope's working channel. Doing so may cause patient injury, such as perforation, bleeding, or tissue damage.
- If the spring tube tip is damaged, the clip may fail to detach from the tube.

Storage Conditions

Temperature: -10°C ~ 40°C;

Relative humidity: ≤80%;

Well-ventilated room without corrosive gas;

Keep away from poisonous and harmful stuff.

Disposal of a used device

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

Symbols used on product label

| | | | |
|--|----------------------------------|---|---------------------------|
|  | Manufacturing Date |  | Expiry Date |
|  | Catalogue Number |  | Do Not Reuse |
|  | Consult Instructions for use |  | Caution |
|  | Keep away from direct sunlight |  | Batch Code |
|  | Do not use if package is damaged |  | Manufacturer |
|  | Non-Pyrogenic |  | Keep dry |
|  | Do Not Resterilize |  | Sterile by Ethylene Oxide |

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein which are beyond Medorah Meditek Pvt. Ltd. control such as warranties implied to the application of law, sales or specially purpose suitability after handling over, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. 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 product other than the replacement of it. Medorah Meditek Pvt. Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other persons related to this product.



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