



MEDORAH® Hemostasis Clip

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® Hemostasis Clips

Intended Use / Indications for use

Intended use- MEDORAH® Hemostasis clips are intended to be used in clip placement within the gastrointestinal tract. This device is placed within the GI tract for the following purposes:

- Endoscopic marking
- Hemostasis for:
 - Bleeding ulcers
 - Mucosal/sub-mucosal defects (< 3 cm)
 - Arteries (< 2 mm)
 - Polyps (< 1.5 cm in diameter)

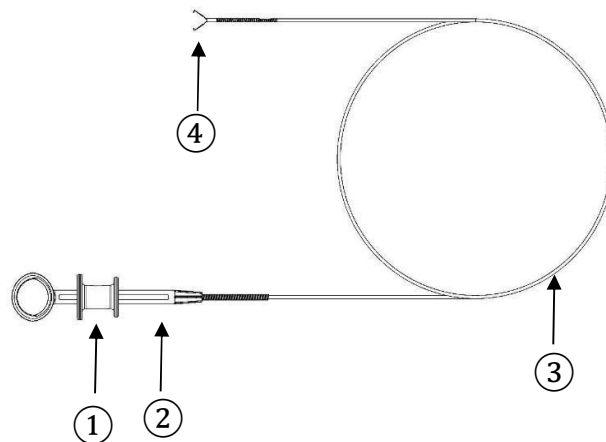
MEDORAH® Hemostasis clips are supplied sterile.

Device Description

MEDORAH® Hemostasis clips are used for endoscopic clip placement within the gastrointestinal tract for the purpose of endoscopic marking, hemostasis for mucosal/sub mucosal defects less than 3 cm in the upper GI tract, bleeding ulcers, arteries less than 2 mm and polyps less than 1.5 cm in diameter.

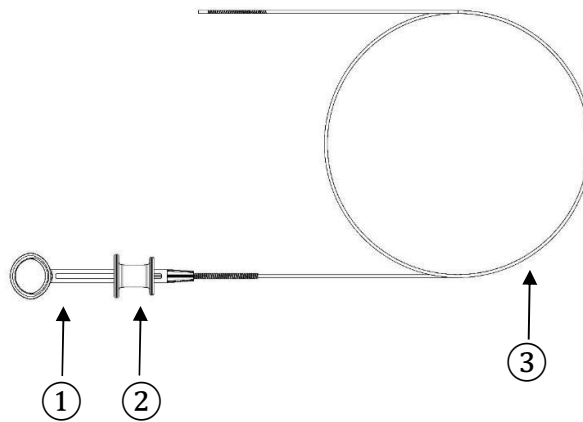
MEDORAH® Disposable hemostasis clip

This device comprises various components including a handle, slider, catheter and clip. It features a single-lumen tube with a metallic wire extending through it. The clip has a V-shaped design attached to the distal end. The proximal end has a slider located at the handle. These clips offer the flexibility of 360°, 1:1 rotation, facilitated by the handle. Subsequently, the slider is pulled with controlled force to secure the clips at the target location. The clip is then detached from the metallic wire by moving the slider in the opposite direction.



| | |
|---|----------|
| ① | Slider |
| ② | Handle |
| ③ | Catheter |
| ④ | Clip |

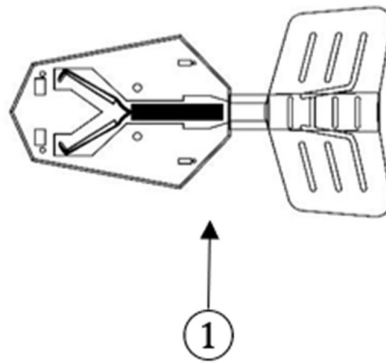
MEDORAH® Reusable Clipping device facilitates reusability and does not come pre-loaded with clips. Its construction includes a handle, slider and catheter. The catheter is designed in such a manner it can be attached to clips one after another. The distal end of the clipping device serves as a male component, inserted into cartridge functioning as the female part.



| | |
|---|----------|
| ① | Handle |
| ② | Slider |
| ③ | Catheter |

MEDORAH® Disposable clip cartridge

This clip is used with the clip applicator mentioned above. The clip is designed for single use only. The clip is attached at the distal tip of the clip applicator.



| | |
|---|----------------|
| ① | Clip Cartridge |
|---|----------------|

Contraindications

- Mucosal or Submucosal defects larger than 3cm.
- Polyps larger than 1.5cm in diameter.
- Arteries greater than 2 mm.
- Patient who cannot tolerate endoscopy and has poor overall health.
- Patient with narrow digestive tract, making it difficult for the endoscope to pass through it.
- Patient with serious coagulation disorders and hemorrhagic diseases.
- Patient who is allergic to the device and the drugs used during operation.

Potential Complications

Those associated with gastrointestinal endoscopy and endoscopic hemostasis include, but are not limited to:

- Perforation
- Haemorrhage
- Aspiration
- Fever
- Infection
- Allergic reaction to medication
- Hypotension
- Respiratory depression
- Cardiac arrhythmia
- Transient dysphagia
- Aspiration pneumonia

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 only meant to be used for the purposes specified.
- Do not use the device beyond its expiration date.

- DO NOT use if the package is damaged.
- DO NOT attempt to repair non-functional or damaged devices.
- Depending on local situation, bleeding may occur on the clipping site. Check the patient for any re-bleeding after the procedure as appropriate.
- Check the endoscopic image during the operation. If the clip deploys prematurely, remove it with the help of a foreign body retrieval net.
- Physicians should know about the potential risks and complications, which may lead to illness or injury to a patient.
- Do not use the Clip in the presence of bacterial contamination it may lead to prolong infection.
- Clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
- Ensure the instruments are not kept near chemicals, disinfectants, or radioactive radiation.
- The number of clips required for hemostasis may vary depending on the anatomical site, histology, lesion type, and patient condition and history.
- The clips are made of stainless steel. Do not use them on a patient who is severely allergic to metals.
- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstance takes place.

Precautions

- Read the entire instruction for use before using the MEDORAH® Hemostasis Clips.
- It may be necessary to straighten the endoscope to facilitate the device passage in a difficult endoscope position.
- Care should be taken while passing of clip through a retroflexed or tortuous path may result in clip separation from the catheter and potentially kinking or damaging the device.
- When introducing the clip into endoscopic channel, it must be closed. If the clip is opened it may harm to patient and endoscope.
- Do not detach the clip, it may lead to re-bleeding within 24 hours.
- Minimum required endoscopic working channel is 2.8mm.
- To use this device, one must be completely aware of the technical concepts, clinical uses, and hazards related to hemostasis clips.

Procedure

MEDORAH® Disposable Hemostasis Clips.

- i. Open the pouch and carefully check the device for any kinks or damage.
- ii. Remove the device from the protective tube while slightly moving the slider backward to close the clip.
- iii. Insert the device into endoscopic channel, ensuring that the clip is in the closed position.
- iv. Advance the clip towards the target site. Once in the endoscopic channel, do not apply closure pressure to the handle.
- v. When in the endoscopic view, slowly open the clip by sliding the slider forward.

- vi. To rotate the clip in either a clockwise or counter-clockwise direction, slowly spin the handle component until it reaches the desired position. During rotation, the handle component and slider should be allowed to rotate.
- vii. When the clip is positioned at the desired location, slowly move the slider distally to open the clip jaws.
- viii. While holding clip at a desired position, pull back the slider until tactile resistance is felt in the handle.

Note: Clip can be opened and closed unlimited times before deployment in Disposable Hemostasis Clips.

Caution

Avoid keep to pulling back on the slider further beyond tactile resistance until you are ready to deploy the clip, otherwise, you may not be able to re-open the clip. If you hear or feel a click, the clip cannot be re-opened.

- ix. If necessary, re-open and reposition the clip.
- x. Permanently deploy the clip by continuing to pull back on the slider beyond the tactile resistance point.

Caution

Check the clip is pressed firmly against the target site for maximum tissue capture.

- xi. When the clip detaches from the delivery device, release the slider and withdraw the device from endoscope.
- xii. After completion of procedure, dispose of device or component according to hospital, local and country regulations.

MEDORAH® Reusable clipping device & MEDORAH® Disposable clip cartridge

- xiii. Carefully open the pouch for reusable clipping device and thoroughly check the device for any kink or damage.
- xiv. Before placing the device into the endoscopic channel, load clips into the reusable clipping device using the clip cartridge.
- xv. Attach the distal end of the catheter to the channel of the clip cartridge.
- xvi. Push the slider forward to insert the inner connector tube of the catheter into the tail portion of the clip.
- xvii. Pull back the slider to retract the clips into the catheter, ensuring they are securely positioned for use.
- xviii. Refer steps from (iv) to (viii) of MEDORAH® Disposable hemostasis clip.

Caution: Clip cannot be opened and closed unlimited times.

- xix. Follow the steps (x) and (xi) of MEDORAH® Disposable hemostasis clip.
- xx. The reusable clipping device is designed for multiple clipping purposes. It allows for detaching the catheter from one clip and attaching it to another as needed during the procedure.

MRI Safety Information

This device is MR conditional. A patient with this clip can be safely scanned in an MR System that meets the following conditions:

Magnetostatic field

Static magnetic field of 3.0 or 1.5 T strength

Maximum spatial field gradient is 2900 Gauss/cm

Maximum MRI system reported, Whole body averaged specific absorption rate (SAR) of 2.0 W/Kg

Temperature

Under the scan conditions defined, the hemostasis clip is expected to produce a maximum temperature rise of 2°C after 15 minutes of continuous scanning

Artifact Information

Simulation test results indicate that in 3.0T MR system, image distortion may occur in the 63.4mm region when utilizing gradient echo sequence or spin wave sequence to obtain image.

Note

It is still unknown what effects an MRI scan will have if there are several Hemostasis clips in one area of the body and they come into contact with one another. When faced with a similar situation, it is advised to remove the hemostasis clip from the connective tissue before doing an MRI scan.

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.









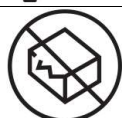





Disposal of a used device

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 |  | 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 resterilize |  | 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.



MEDORAH MEDITEK

Mfd. By: Medorah Meditek Pvt. Ltd.

353, Udyog Vihar, Phase-IV, Gurugram, Haryana-122015 (INDIA)

Phone: 0124-4712471 | E-mail: info@medorah.com

www.medorah.com

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