CAELARIS

Please read all instructions before using this device .

VYSE Hemoclip

Instructions for use

Rx ONLY

STERILE EO

CAELARIS

VYSE Hemoclip

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【**Device Name**】VYSE Hemoclip

【**Intended use**】

The clip is compatible with endoscope, which is indicated for clip placement within digestive tract for the purpose of mechanical pressure treatment of bleeding of small arteries and pulsation. The device is intended for single use.

【**Intended patient population**】 Adult

【**Key Components**】Handle, Slider, Spring end, Spring tube, Clip.

【**Diagram**】

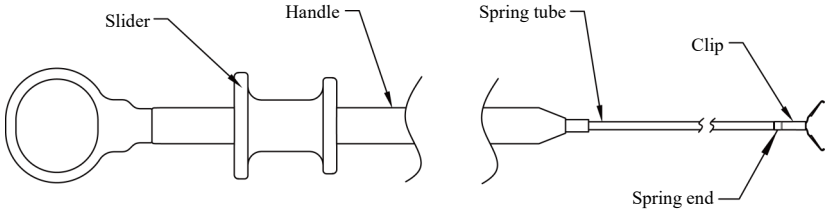


Figure 1

【**Model and Dimension**】

Model	Specification	O.D ±0.1 （mm）	Opening Span ±1.5 （mm）	Claw angle ±15(°)	Working Length ±10(cm)	Plastic covered	Rotatable	Removable
Reposition	HC9,HC11,HC 13,HC16,HC18	2.6	9/11/13/16 /18	135	230	Yes	Yes	No
Reposition	HC9R,HC11R, HC13R,HC16R ,HC18R	2.6	9/11/13/16 /18	135	230	Yes	Yes	Yes

【**Indications for use**】

The hemoclip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:

1. Endoscopic marking,
2. Hemostasis for:
   - Mucosal/sub-mucosal defects <3cm
   - Bleeding ulcers
   - Arteries<2mm
   - Polyps<1.5cm in diameter
   - Diverticula in the colon
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel.
4. As a supplementary method, closure of GI tract luminal perforations<20mm that can be treated conservatively.

【**Contraindications**】

1. Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view.
2. Arteries greater than 2mm.
3. Polyps greater than 1.5cm in diameter.
4. Mucosal/Submucosal defects greater than 3cm.
5. The patient has serious narrow upper digestive tract where the endoscope cannot pass through.
6. The patient has serious coagulation disorders and hemorrhagic diseases.

【**Notes**】

1. Lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with a forward viewing endoscope.
2. Treatment of esophageal varices may require clipping in combination with a sclerosing agent, or other therapies.
3. Clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
4. The number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type, and patient condition and history.
5. Re-bleeding may occur if clips detach within 24 hours.
6. The use of clips in the presence of bacterial contamination may potentiate or prolong infection.
7. The device is suitable for endoscopes with a minimum channel diameter of 2.8mm.

8. The device is not made with natural rubber latex.
9. When the clip enters the working channel of endoscope, a doctor or nurse is required to pull the handle back a bit until the clip appears in the endoscopic view.

【Possible Complications】

1. The use of clips in the presence of bacterial contamination may increase or prolong infection.
2. Re-bleeding may occur if the clips detach within 24 hours.
3. Although rates of occurrence are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.

【MRI Safety Information】



MR Conditional

Non-clinical testing demonstrated that the Hemoclip is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 T or 3.0 T.
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

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

In non-clinical testing, the image artifact caused by the Hemoclip extends approximately 30mm from the hemoclip when imaged using a gradient echo pulse sequence and a 3.0 T MRI system.

Warning

1.Failure to follow the recommended MR Conditional labeling may result in a deployed GI hemoclip dislodging from tissue or heating of tissue at the GI hemocilp dislodgement may result in rebleeding requiring additional interventionor surgery, serious injury, or death.

2.This clip contains ferromagnetic material. Follow your institutional protocols to determine whether or not an xray should be performed prior to an MRI exam. There may be asmall potential risk of clip dislodgement and rebleeding if the clip is used in friable or healing tissues due to magnetic forces acting on the clip when in or near an MRI scanner.

【Precautions prior to use】

1.Passage of clip through a retroflexed or tortuous path, may result in the clip separation from the delivery system and potentially kinking or damaging the device. If the delivery system or clip part kinks or becomes damaged during device insertion or passage, do not use it.

2.Applying tangential pressure to an opened or closed clip may result in the clip separating from the delivery system and potentially kinking or damaging the device. If the delivery system or clip part kinks or becomes damaged during device insertion or passage, do not use it.

3.In a difficult scope position, it may be necessary to straighten the endoscope to facilitate the device passage, then reposition scope for treatment. If the delivery system or clip part kinks or becomes damaged during device insertion or passage, do not use it.

4. The clip is intended for single use and supplied sterile. Carefully examine the unit before use to verify that neither the contents nor the sterile package has been damaged in shipment. Do not use if damaged. After use, dispose of it according to local and institutional guidelines.

【Preparation】

1. Open the pouch and remove the device.
2. Inspect the device for kink or damage. Do not attempt to repair nonfunctional or damaged devices.

【Direction for use】

1. Take out the hemoclip from protective tube/ protective cap and slightly move the slider proximally to close the clip, as shown in Figure 2-1 and Figure 2-2.
2. Carefully insert the clip through the biopsy channel of the endoscope with short, deliberate 2 to 3 centimeter strokes, so as to avoid damaging to the device and endoscope channel, especially when resistance is met.

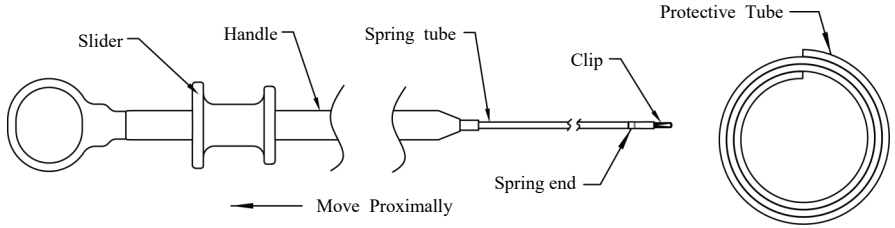


Figure 2-1 Remove the protective tube

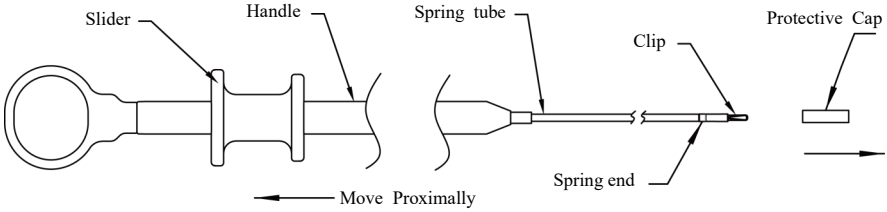


Figure 2-2 Remove the protective cap

Note: In a difficult scope position, it may be necessary to straighten the endoscope to facilitate the device passage, then reposition scope for treatment.

3. When the clip is at the desired location, gently move the slider distally to open the clip jaws, as shown in Figure 3. The clip device with over-sheath---it needs to remove the limitation block and move the over-sheath to expose the clip.

   For rotating models：

   Rotate the clip into a suitable position to clip the desired area more easily by using your thumb and forefinger to spin the arrowed portion of the handle slowly.

   For other models:

   If the angle of the distal clip is inappropriate for being deployed, it could be adjusted by rolling the whole product, which can be driven by rotating the handle part or twisting the spring-tube part.

   Additionally, the doctor may also need to adjust the endoscope to a suitable angle to clip the desired area more easily.

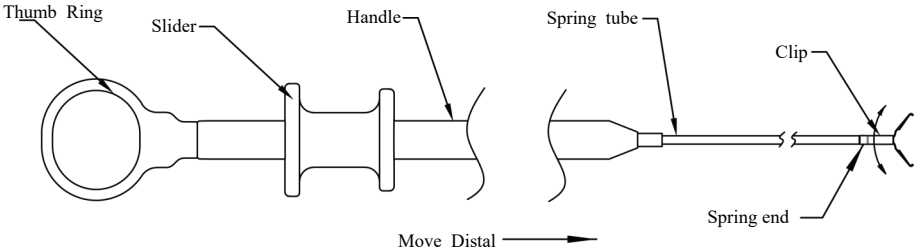


Figure 3

4. To close the clip and treat the desired location, move the slider proximally until tactile resistance is felt in the handle. Endoscopic observation to confirm that the tissue is closed by the clip, as shown in Figure 4.

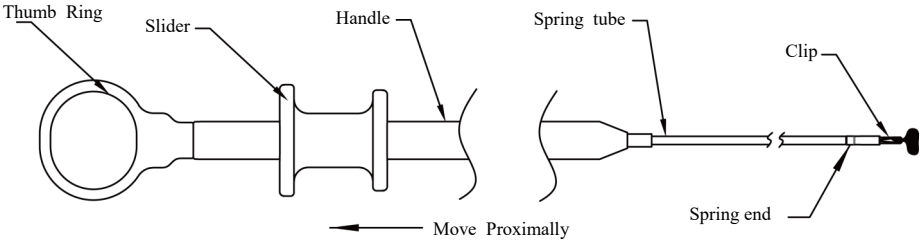


Figure 4

Note: Clip position can be assessed prior to deployment.

Caution: Do not continue moving the slider proximally beyond the 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, go to Option 2 to complete clip deployment.

5. At this point, there are 2 options:

   Option 1: The clip can be re-opened and repositioned.

   To re-open and re-position the clip to another location, gently move the slider distally to open the clip jaws, and position the clip on the desired location, as shown in Figure 3.

   Note: The clip is engineered to enable opening and closing more than five times prior to deployment, aiding in repositioning of the clip at the lesion site. Reopening and closing capability may be limited by clinical circumstances and patient anatomy, among other factors.

   Option 2: The clip can be permanently deployed,

   To permanently deploy the clip, continue moving the slider proximally beyond the tactile resistance point, at which point, the resistance suddenly disappears, continue moving the slider proximally until it reaches the thumb ring, and

hear or feel a click, as shown in Figure 5.

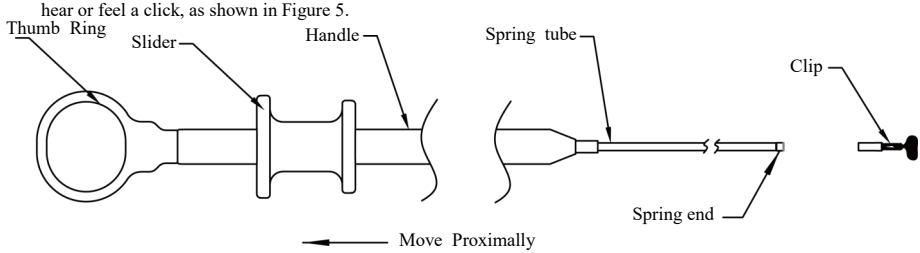


Figure 5

Note: If the resistance suddenly disappears when moving the slider proximally, this represents that the first connection part of the clip has been damaged by pull force. At this time, if the clinician continues moving the slider proximally, it will damage the second connection part between the clip and delivery system. If a click is heard, it shows that the two connection parts are damaged and the clip has been separated from the delivery system completely.

6. Once the clip has been deployed, gently move the slider distally to separate the clip from the delivery device. Once the clip separates from the delivery device, release the slider and withdraw the delivery system from biopsy channel of endoscope.

【Warnings】

1.If the clip has not been deployed, move the slider proximally to close the jaws (as shown in Figure 6), and endoscopic observation to confirm that the clip is closed. Then, use a slight pull force, withdraw the device slowly from the endoscope.

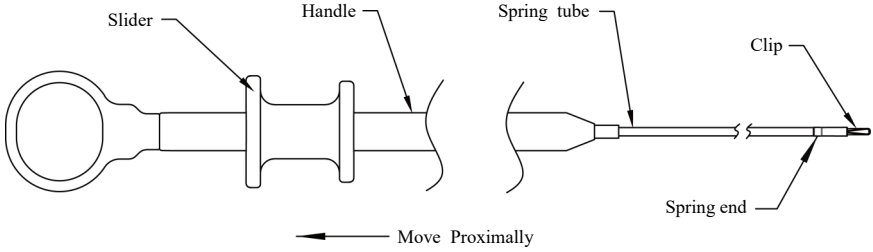


Figure 6

Note: Endoscope must remain as straight as possible when withdrawing the device.
If the clip does not immediately detach from the delivery system, then apply gently movement to the delivery system or endoscope to detach the clip.
Caution: Do not remove an unsheathed open clip through the endoscope working channel, otherwise endoscope working channel damage may result.

2. If the clip has not been deployed, but the tissue has been already clipped and the slider is continue moving proximally, the clinician can still move the slider distally to open the clip again, in order to release the tissue from the clip. Then moving the slider proximally to close the clip, withdraw the device slowly through the endoscope, and change to another device.
3. If the tissue has been already clipped, but the clip has not been deployed, bleeding may be caused when the device is removed.
   a) For an area left with what is deemed a small amount of bleeding, the clinician can change to another hemoclip to treat the bleeding area immediately.
   b) For an area left with what is deemed a large enough bleeding, inject adrenalin in that area to stop the bleeding may be necessary, and then allow the clinician to manage further with additional clips or other means.

   If the clip has been deployed, but its position is not satisfactory, or it affects the field of vision, we can remove i

   （Not applicable to HC9,HC11,HC13,HC16,HC18 series）
4. Please refer to the following steps:
   a) Select a snare with wire diameter between 0.30~0.41mm, entangling the snare to the groove of the clip's bottom (as shown in Figure 7).



Figure 7



Figure 8

b) Gently shrink the snare, and tighten the snare until the closed clip is re-opened, then remove it from the lesion tissue (as shown in Figure 8).
c) Treat the removed clip in the same way as the removed foreign body.

5. Operation of this device is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the delivery system or if any other unexpected circumstance takes place.
6. Always have pliers and/or wire cutters ready to cut the delivery system at the handle if the clip cannot be detached.
7. The clip portion of the product will stay in vivo, in most cases it will fall off on its own within 2 to 4 weeks, mixes with food residue, and excreted through feces. In some cases, it may have a relatively long retention time in vivo, so, after 2 to 4 weeks, the need for endoscopy or X-ray inspection may be warranted, if clip portion still has not fall off on its own, the need to remove the stranded clip portion to prevent the occurrence of symptoms may be warranted as well.
8. The product is only intended for adult populations.
9. Please use this device according to this IFU. If the end user does not comply with this IFU, there may be an increased risk related to infection control, perforation, or mucosal damage, which may harm the patient(s) or effect the safety of the end user(s).
10. Do not use if the package is damaged.
11. Do not use if it's expired.
12. The device is sterile for single use, which must be disposed of after use. It's forbidden to reuse.
13. The device should be only used by trained users.
14. Operating Environment Requirement: ambient environment:10—40℃, Relative humidity:30—85%.

【Packaging】 One device per pouch, outside with carton and box.

【Date of Manufacture】 It can be found on the package labels.

【Sterilization Method】 EO sterilization.

【Expiration for Sterilization】 Three years after sterilization.

【Storage】

After packaging, the device shall be stored in an environment of relative humidity below 80%, temperature of -10℃ ~40℃, atmospheric pressure limitation of 86~106kPa, and noncorrosive gases and well-ventilated room.

【Labeling Instructions】

	Do not re-use		Consult instructions for use or consult electronic instructions for use		To sale by or on the order of a physician
	Use by date		Batch code		Catalogue number
	Date of manufacture		Sterilized using ethylene oxide		Medical Device
	Fragile，handle with care		Stacking no more than 6 layers		Keep away from sunlight
	Up		Manufacturer		Do not resterilize
	MR Conditional		Keep dry		Do not use if package is damaged and consult instructions for use
	Atmospheric pressure limitation		Temperature limit		Humidity limitation
	Single sterile barrier system		Single sterile barrier system with protective packaging outside		Unique Device Identifier
	Caution				



Manufactured For:
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Made in China