

Single Use Hemoclip



INSTRUCTIONS FOR USE

STERILE	EO
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Rx ONLY CAUTION: This device should be sold by or on the order of a physician.

WARNING:

1. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your ANREI MEDICAL representative.
2. For single use only. **DO NOT REUSE, REPROCESS OR RESTERILIZE.** Reuse, reprocessing or resterilization 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 resterilization 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 infections disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
3. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

【Device Name】

Single Use Hemoclip

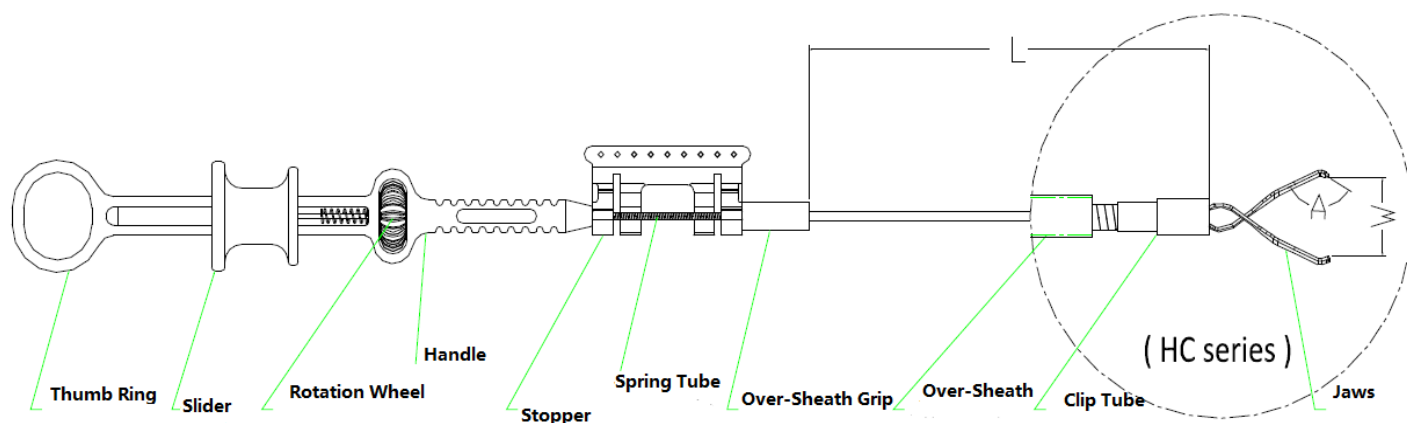
【Intended Use】

Single Use Hemoclip is indicated for clip placement within the Gastrointestinal (GI) 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.

【Structure】

Single Use Hemoclip consists of a pre-loaded ,rotatable, radiopaque, single-use clip, a flexible delivery system used to delivery ,operate and deploy the clip. It is designed to be compatible with Gastrosopes and colonoscopes with working channels equal to or greater than 2.8 mm.



L= Working length, W= Clip opening, A= Clip angle.

Figure 1: Single Use Hemoclip Structure

【Specifications】

The Single Use Hemoclip

No.	Specification	Working length	Clip opening	Clip angle	Over-Sheath or not	outside diameter
		(L cm±10cm)	(W mm±1.5mm)	(A°±15°)		(ØDmm±0.1mm)
1	HC- I -1	270	9	90	YES	2.6
2	HC- I -2	230				
3	HC- I -3	195				
4	HC- I -4	165				
5	HC- I -5	270		135		
6	HC- I -6	230				
7	HC- I -7	195				
8	HC- I -8	165				
9	HC- II -1	270	12	90	YES	2.6
10	HC- II -2	230				
11	HC- II -3	195				
12	HC- II -4	165				
13	HC- II -5	270		135		
14	HC- II -6	230				
15	HC- II -7	195				
16	HC- II -8	165				
17	HC- III -1	270	6	90	YES	2.6
18	HC- III -2	230				
19	HC- III -3	195				
20	HC- III -4	165				
21	HC- III -5	270		135		
22	HC- III -6	230				
23	HC- III -7	195				
24	HC- III -8	165				

【Direction for Use】

1. Instructions for Use of the Single Use Hemoclip

1.1. Inspect the package to make sure it is intact. Remove Single Use Hemoclip from the package, as shown in Figure 1.1

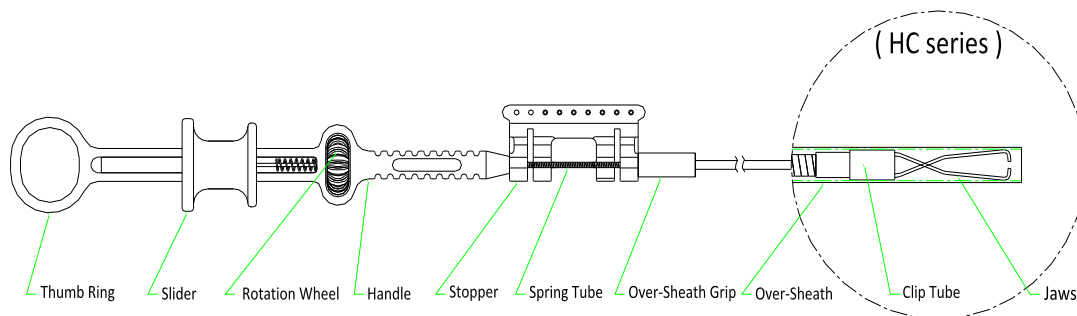


Figure 1.1: The initial state of the HC series of the product

1.2. Carefully insert Single Use Hemoclip through the biopsy channel of the endoscope with short, deliberate 2 to 3 centimeter strokes.

1.3. Once Single Use Hemoclip can be observed exiting the tip of the endoscope under direct visualization, remove the stopper located between the over-sheath grip and the handle, as shown in Figure 1.2. Push the handle distally until handle rests against the over-sheath grip, as shown in Figure 1.3.

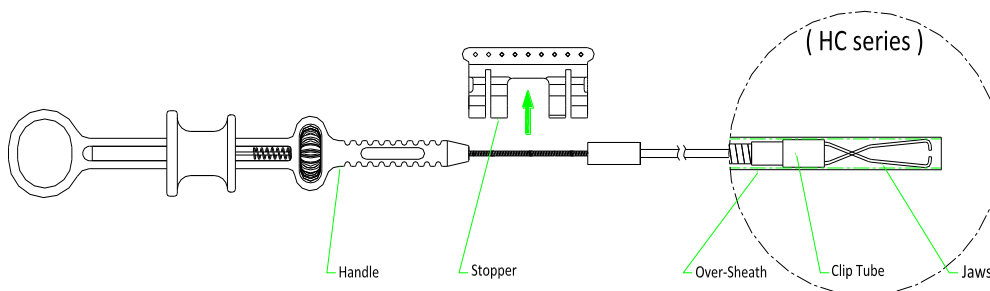


Figure 1.2: Remove the Stopper

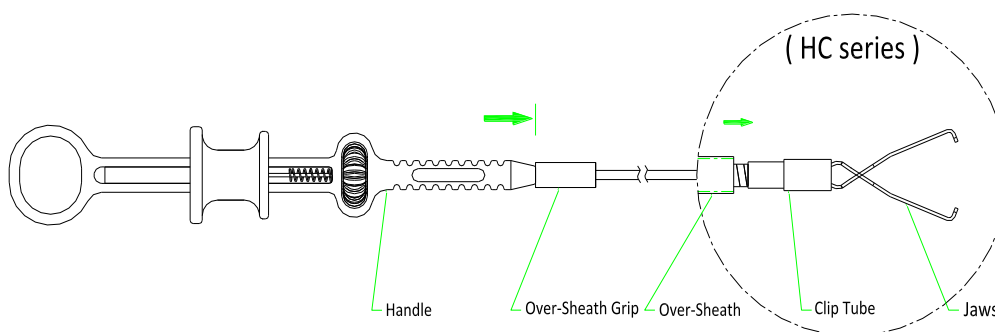


Figure 1.3: Expose the Clip

1.4. When the Clip is at the desired location, move slowly the slider proximally (close to the thumb ring) to open the Clip jaws, as shown in Figure 1.4.

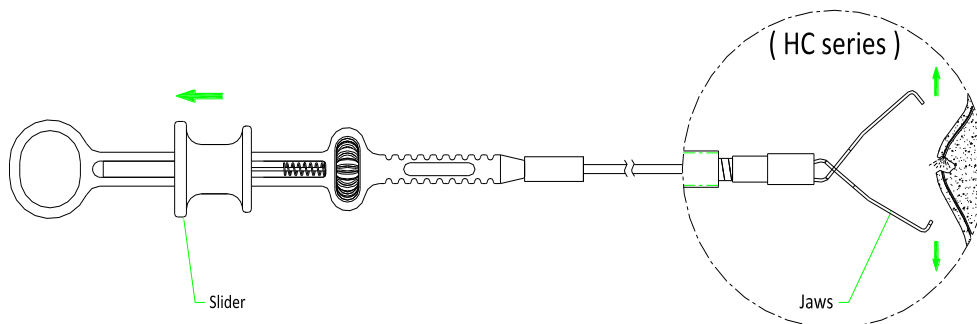


Figure 1.4: Open the Clip jaws

1.5. To rotate the rotation wheel to adjust the angle between the clip and the lesion, until the clip is in the proper position for clipping. In order to obtain a better effect of the rotation, move the slider distally. As shown in Figure 1.5.

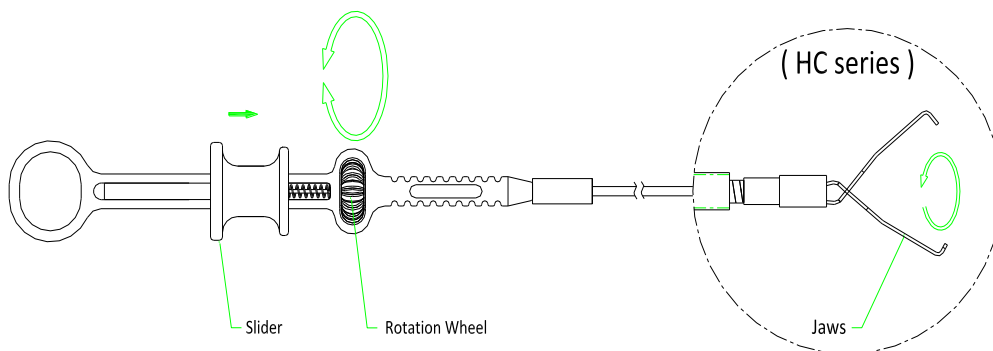


Figure 1.5: Rotate the Clip

1.6. To close the clip Jaws on the desired location, moving the slider toward the thumb ring beyond the 1st tactile resistance point, as shown in Figure 1.6.

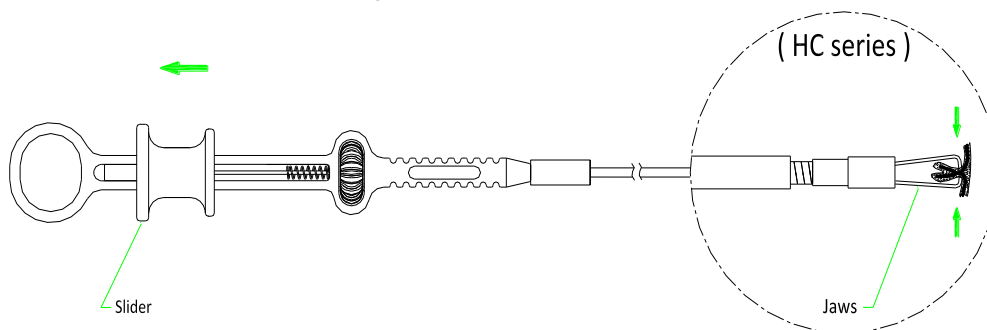


Figure 1.6: Close the Clip

Warning: Do not try to forcibly remove the clip if it become caught on the distal end of the coil sheath. Forcible removal of the clip could cause patient injury such as perforation, bleeding, or mucous membrane damage.

1.7. To permanently deploy the clip, continue moving the slider toward the thumb ring beyond the 2nd tactile resistance point, at this point a 2nd click may be heard or felt. Continue moving the slider toward the thumb ring until a second tactile resistance point and/or click is heard or felt. Continue moving the slider until it reaches the thumb ring, as shown in Figure 1.7.

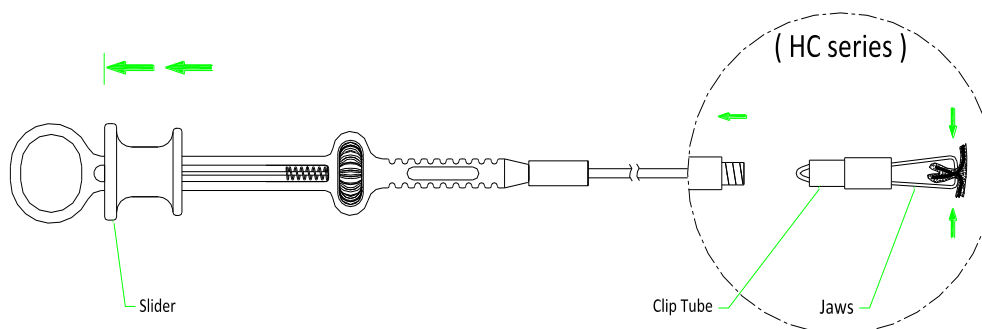


Figure 1.7: The Clip Permanently Deployed

【Contraindications】

1. Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view.
2. Do not perform MRI procedures on patients who have had clips placed within their gastrointestinal tract, as this could be harmful to the patient.
3. Arteries greater than 2 mm.
4. Polyps greater than 1.5 cm in diameter.
5. Mucosal / Sub-Mucosal defects greater than 3 cm.

【Caution】

1. Do not use if the package is open or damaged when received.
2. Do not use if an abnormality is detected that would prohibit proper working condition.
3. Do not use if it is expired.
4. The device is a single-use sterile product. Destroy after use. Do not reuse.
5. The device must be operated by trained clinicians.

【Warning】

1. 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. In this case, refer to chapter “**Emergency Treatment**”.
2. It might be impossible to stop bleeding depending on the hemorrhage situation because the clip performance for hemostasis is limited .prepare more than one hemostatic device and select appropriate hemostatic device or use it together to respond to different hemorrhage situations appropriately.choose a surgical hemostasis if necessary.
3. Re-bleeding may occur on the clipping site dependng on the local condition or the grasping condition .check the patient for any re-bleeding after the operation as appropriate
4. Use this instrument in an environment equipped to accommodate open surgery and have the hospitalization plan prepared in case any problem occurs that may not be resolved endoscopically.

【Note】

1. Limited studies indicate that lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with a forward-viewing endoscope.
2. Limited studies indicate that the treatment of esophagus varices may require clipping in

combination with a sclerosing agent.

3. Limited studies indicate that clipping hard or severely fibrotic lesion to achieve hemostasis may be more difficult.
4. Limited studies have shown that the number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type, and patient condition and history. A sufficient quantity of clips should be prepared in consideration of all of these factors prior to the procedure.
5. Limited studies indicate that the hemostasis clips remain in place for an average of 9.4 days; re-bleeding may occur if the clips detach within 24 hours.
6. Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.

【Emergency Treatment】

Withdrawing the instrument from the endoscope if the clip cannot be detached

Warning: Do not try to forcibly withdraw the instrument from endoscope if the clip cannot be detached from the instrument. Forcibly withdrawing the instrument could cause patient injury such as perforation, bleeding, or mucous membrane damage.

If the clip cannot be detached from the instrument, follow the procedures described in this section. If the distal end of the coil sheath or clip pipe is crushed or deformed, it may not be possible to detach the clip from the instrument.

Step 1: Straighten out the portion of the endoscope that extends from the patient.

Straighten out the portion of the endoscope that extends from the biopsy valve.

Straighten out the coil sheath that extends from the distal end of the endoscope. At the same time, the distal of clips keep as straight as possible.

Step 2: Confirm that the slider has been pulled out as far as possible,

Step 3: Push the slider to release the clip.

If when the clip cannot be detached from the instrument.

Step 4: Cut the coil sheath, tube sheath and operation wire using pliers and/or wire cutters.

Step 5: A certain amount of force is sometimes required to withdraw the endoscope

Step 6: Carry out open surgery or other possible treatment. And Leave the clip in place until tissue necrosis occurs and the clip comes free. This may take some time

Removal of an aspirated clip

If a clip is accidentally aspirated into the endoscope, follow the procedure below to remove it.

Step 1: Withdraw the endoscope from the body cavity, keeping the insertion portion and bending section straight. Leave the biopsy valve mounted on the endoscope.

Step 2: Remove the suction tube and connect a syringe filled with tap water to the endoscope's suction connector.

Step 3: While gently pressing the suction valve, inject the tap water into the endoscope's suction

Step 4: Irrigation should discharge the clip from the endoscope. If one injection is not enough to discharge the clip, repeat Step 2 and 3 until the clip is discharged.

NOTE: If the clip cannot be discharged after Step 4 has been repeated, pass a channel cleaning brush from the suction cylinder up to the distal end of the endoscope and repeat Step 2 and 3.

【Packaging】

Pouch: 1 set per pouch



















Box: 10 pouches per box







Carton: 10 boxes per carton

【Date of Manufacture】

Please refer to the label on pouch.

【Symbol Instruction】

	Manufacturer		Authorized representative in the EC
	Date of manufacture		Use-by date
	Batch code		Catalogue number
	Sterilized using ethylene oxide		Do not use if package is damaged
	Fragile, handle with care		Keep away from sunlight
	Consult instructions for use		Keep dry
	This way up		Stacking limit by number
	Temperature limit		Do not re-use
	Do not re-sterilize		Caution

	Diameter		EC notified body identification number
	Bronchial device		Gastric device
	Colonic device		ERCP device

【Shelf Life】

2 years after sterilization.

【Manufacturer】 Anrei Medical (HZ) Co., Ltd

【Address】No.3 Ave. 8, Hangzhou Economic Development Area, Hangzhou, People's Republic of China

【Zip Code】 310018

【Telephone Number】 400-8096118

【Fax Number】 86-571-87603502

【Website】 www.anrei.com.cn

EC	REP	Shanghai International Holding Corp. GmbH (Europe)
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