
Disposable Hemostasis Clips



Instruction For Use

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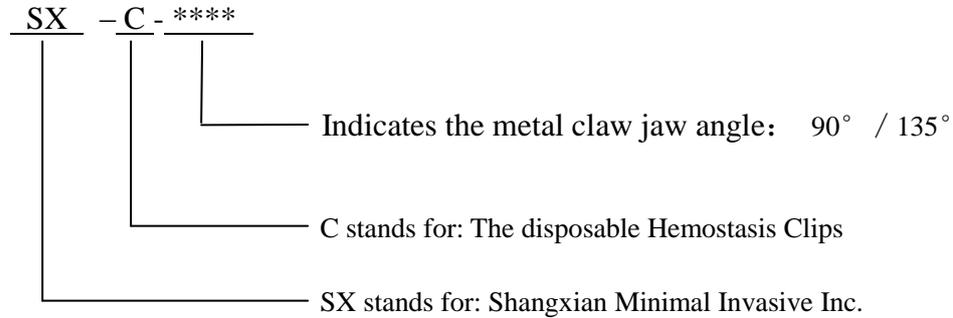
For the use of medical staff only.

Please read this manual carefully before using the product and keep it properly for future need.

Product:

Disposable Hemostasis Clips

Specifications and type:



Components:

The clip consists of a metal claw, fixed rod, a metal ring, a sleeve and a pull rod, as shown in Diagram 1.

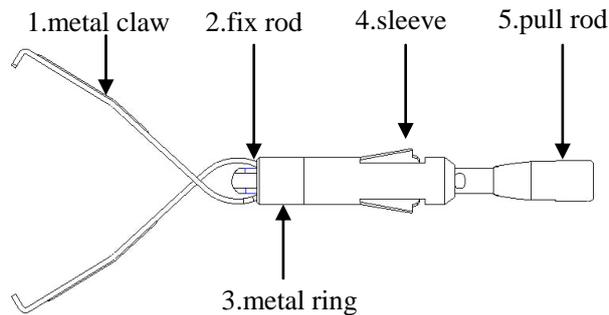


Diagram 1 Structure of Clip

1. Metal claw 2. Fixed rod 3. Metal ring 4. Sleeve 5. Pull rod

Application:

The clip is intended use for clamping the mucosa tissue of gastrointestinal track under the guide of endoscope.

Specifications:

For the specifications, please refer to Form 1.

Form 1: Model、 size and Specifications of Clip

Models	A (°) $\pm 10^\circ$	H (mm)	W (mm) ± 0.2
SX-C-90	90	$\cong 8$	1.4
SX-C-135	135	$\cong 8$	1.4

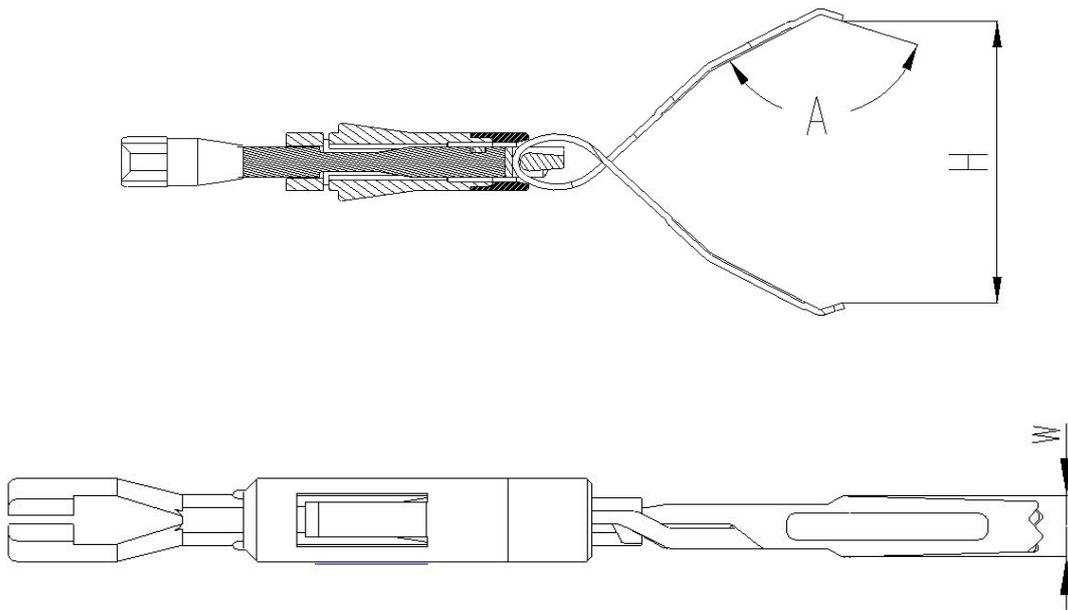


Diagram 2 Size Diagram of Clip

A: clip claw jaw angle;

H: clip claw opening distance;

W: clip claw width;

Indication:

1. To make marking under the endoscope procedure;
2. Hemostasis for:
 - Mucosa/sub-mucosa defects less than 3cm in diameter;
 - Bleeding ulcer;
 - polyp site is less than 1.5cm in diameter;
 - diverticulum in the colon;
3. If the lumen puncture of alimentary canal is less than 20mm in

diameter, and conservative treatment is possible, the instrument can be used to assist in treatment.

Contraindications:

- Patients of bad basic conditions cannot undergo the endoscopic examination.
- Patient has a narrow upper alimentary canal and the endoscope cannot get through.
- Patients have coagulation disorders 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.
- Patients who or whose family are not cooperate with the treatment.

Preparations:

1. Prepare disposable hemostasis clips and delivery system;
2. Guarantee the product to be used is in its term of service before use;
3. Check whether the instrument is bent or damaged before use.
4. Always have pliers or wire cutters ready to cut the spring tube and guide wire in case the clip cannot be detached from the spring tube

Warnings:

Should any package damage, un-tight sealed or water leakage, do not use the instrument and use a spare instead.

Should any distortion on the spring tube of delivery system, do not use the instrument. Otherwise the clip may be stuck at the spring tube edge, and cause failure of separating from spring tube.

If there are any malposition, buckling, or distortion, please do not use the instrument. And doing so may cause the instrument fail to go through

the endoscope channel. If insert the instrument with force, the instrument may stick out from the distal end of endoscope in a sudden which may cause the patient injury, such as perforation, bleeding or mucosa injury.

Usage:

1. Tear out the clip packing bag, take out the plastic clip container.
2. Tear out the delivery system packing bag, take out the delivery system.
3. Insert the spring tube of delivery system into the hole of the clip cartridge to the end, and press the wide end of the clip cartridge with force to avoid the spring tube sliding down;
4. Push forward the slide ring of delivery system with index finger and middle finger until there is a “ka-da” sound heard, then pull back the slide ring, draw out the clip from the clip cartridge until it goes into spring tube completely;

Caution:

- When pushing forward the slide ring of delivery system and drawing out the clip from the clip cartridge, make sure the spring tube of delivery system is to the hole end of the clip cartridge and can't moving, otherwise the clip can't get into the spring tube of delivery system successfully or the clip closed forward in the spring tube.

- New please do not push forward the slide ring, doing so may cause the clip come off from the spring tube.

5. Double check the clip has entered the spring tube.
6. Insert the spring tube into the endoscope channel, until the top end of spring tube appeared in field of view.
7. Push the slide ring slightly, ensure the clip stretch out of the spring tube , until the two white wings on the clip appeared.

Caution :

when the white wings appeared , please do not keep pushing the slide ring. Doing this may cause the falling off of the clip from the spring sheath . If the falling off occurred, do not retrieve the clip through endoscope channel. Doing so may lead damage to the endoscope channel.

8. Pull the slide ring slowly to user side in order to make the clip open to maximum opening situation

Caution :

Pull back the slide ring slowly at this moment, do not pull the slide ring fast, doing so may lead the clip close bring forward.

9. Hold the thumb ring on the handle, rotate the handle to adjust the axial direction for clipping tissues easily.

Caution:

- The slide ring will rotate along with the handle rotation. So please do not touch the slip ring when rotate the handle with care.

- Do not rotate the handle too quick, doing so may cause the clip bouncing. Please rotate slowly.
- If the endoscope is over curling, the clip may rotate with delay when rotate the handle.
- If the clip does not rotate smoothly, please stretch the spring tube exposing out of the endoscope channel entrance as straight as possible, then resume rotating the handle.

10. Deploy the clip against the target lesion, then pull back the slide ring with proper force, close the clip and clip the target tissues.

11. Keep pulling back the slide ring until reach end of the handle. Ensure the clip depart from the spring tube completely.

12. Withdraw the delivery systems from the endoscopy working channel.

13. Push the slide ring until the clip plastic rod coming out of the spring tube. Pull down the plastic rod to the vertical situation to the spring tube, then pull back the plastic rod and get it off from the hook.

14. Dispose it properly according to local medical waste disposal rules and laws.

Notes:

- This clip is disposable, so it is not allowed to reuse it;
- Do not operate the clip too hard, or the clip may be damaged;
- During the operation, do observe the endoscope image to make sure this instrument is in the vision of the endoscope and every step goes well; if the clip falls off from the endoscope, please use grasping forceps to

retrieve it;

- One condition for the application of this instrument: should the clip be unable to detach from the delivery system or there are any other incident, an open surgery should be conducted;
- Please make sure the endoscope has a clear vision before use;
- After the operation, dispose of this instrument in accordance with the regulations of the relevant agency on the management of biologically dangerous medical waste;
- Have food according to the doctor's advice, and it is not suitable to eat in the first days after the operation. Improper diet, hard defecation, cough and all other activities that may add burden to the alimentary canal will make the clip fall off and cause bleeding in the body.
- The metal claw of the clip is made of stainless steel, so please do not apply this product to patients who are allergic to the metal.
- According to the few studies that are accomplished, the clip will remain in the original position for 7-14 days on average.

Possible complications:

- inflammation, puncture, hemorrhage or mucosa tissue injury;
- infection and sepsis, etc.;
- other complications which may exist yet be unknown or undiscovered.

[Packaging]

Clip packing:

The clip packing use the injection molding materials, then sealed with PE box and Tyvek dialyzing paper.

Middle packing of clip: pack individual packs into box, 30 individual packs per inner box.

Clip master packing: 10pcs middle box in one cardboard outer box.

Storage

Storage conditions:

Temperature: 10°C ~ 40°C ;

Relative humidity: \cong 80%;

Well-ventilated room without corrosive gas;

Keep away from poisonous and harmful stuff.

Storage duration

3 years. (the valid term of sterilization)

Emergency Treatment

Warning:

Do not try to forcibly withdraw the instrument from the endoscopy if the clip cannot be detached from the delivery system (spring tube or operation wire). Forcibly withdrawing the instrument could cause patient injury such as mucous damage.

If the clip cannot be detached from the instrument, follow the procedures described in this section.

Firstly, Straighten out the portion of the endoscopy that extends from the patient.

Secondly, Confirm that the slide ring has been pulled out at the bottom of the slide rod.

Thirdly, Push the slide ring slowly and then pull the slide ring quickly to release the clip. If the clip still cannot be detached from the instrument, Carry out open surgery or other possible treatment or leave the clip in place until tissue necrosis occurs and the clip comes free. This may take some time.

Packaging symbols:

	Prohibited to re-use
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	Do not use when the package broken.
	Sterilize with ethyleneoxide
	Re-sterilization is not allowed.
	Avoid rain.
	Avoid sunshine.
	Refer to the instruction manual.
	Term of service
	Attention; refer to the attachments.

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Production date: to see product label

Product validity: to see product label