



Instructions For Use

[Product name]

Disposable hemostasis clips and delivery systems

[Structure &Component]

The hemostasis clips and delivery systems are mainly consist of delivery system and clip assembly.

The delivery system comprises a hook, a guide wire, a spring tube, a slide rod, a slide ring and a handle

[Intended use]

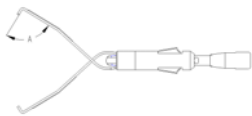
This product is intended use for clamping the mucosa tissue of alimentary cavity under the guide of endoscope.

Delivery systems:



REF NO	L (mm) ±100mm	D (mm)
SX-H-1650	1650	≤2.75
SX-H-1950	1950	≤2.75
SX-H-2300	2300	≤2.75

Disposable hemostasis clips:



Model	A (°) ±15°
SX-C-090	90
SX-C-135	135

[Indication]

To make marking under the endoscope procedure;

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;

If the lumen defeat of alimentary cavity is less than 20mm in diameter, when the conservative treatment is possible, the instrument can be used to assist in treatment.

[Contraindications]

- Patients of bad basic conditions can't take the endoscope examination.
- Patient has a narrow upper alimentary cavity and can't make the intubation of endoscope.
- 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.
- Patients who or whose family are not cooperate with the treatment.
- Patients who have clips in their gastrointestinal tract should not have MRI procedure, or it may cause damage or injury.

[Preparations]

To make clip assembly and delivery system ready for use;

Guarantee the product to be used is in its term of service before use;

Check whether the instrument is bent or damaged before use.

[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 assembly may be stuck at the spring tube edge, and cause failure of separating from spring tube.

If there are any mal-position, 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 abruptly, 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.

Should there be any doubtable questions or phenomenon on the products, please do not continue to use the instrument.

Usage:

Tear out the clip assembly packing bag, take out the plastic clip assembly pack.

Tear out the delivery system packing bag, take out the delivery system.

Press the wide ends of the clip assembly pack with force, after insert the spring tube of delivery system into the hole of the clip assembly end, make the spring tube top end to reach the end of hole. Push forward the slip ring of delivery system on hands, until there is "ka-da" sound heard, then pull back the slip ring, draw out the clip assembly from the clip assembly pack until it goes into spring tube completely.

Caution: Now please do not push forward the slip ring, doing so may cause the clip assembly come off from the spring tube.

Double check the clip assembly has entered into the spring tube.

Insert the spring tube into the endoscope channel, until the top end of spring tube appeared in field of view.

Push forward the slip ring slightly, ensure the clip stretch out of the spring tube, until the two white wings on the clip assembly appeared.

Caution: when the white wings appeared, please do not keep pushing the slip ring. Doing this may cause the coming off of the clip assembly from the spring tube. If the coming off happened, do not retrieve the clip assembly through endoscope channel. Doing so may lead damage to the endoscope channel.

Pull back the slip ring slowly, open the clip assembly entirely.

Caution: At this moment please pull back the slip ring slowly, do not push the slip ring fast, doing so may cause the clip assembly closed before use.

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

Caution:

The slip 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 assembly bouncing. Please rotate slowly.

If the endoscope stays too much curling, the clip assembly may rotate with delay when rotate the handle.

If the clip assembly do not rotate smoothly, please stretch the exposing part of spring tube out of the endoscope channel entrance as straight as possible, then resume rotating the handle.

Push the clip assembly against the lesion, then pull back the slip ring with proper force, close the clip assembly to close the target mucosa tissues.

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

Take out the spring tube of the delivery system from the endoscope channel.

Push the slip ring until the clip assembly plastic rod coming out of the spring tube. Pull down the plastic rod to the vertically on the spring tube, then move out the plastic rod from the delivery system spring tube and dispose the plastic rod properly.

Notes:

- The clip is single-use, and it is not allowed to reuse;
- During the operation, please observe the endoscope viewing carefully to make sure this instrument is in vision and every step goes well; if the clip comes off from the endoscope, please use grasping forceps to retrieve it; should the clip be unable to detach from the delivery system or there are any other incident, a surgery can be conducted;
- After the operation, dispose of this instrument in accordance with the regulations of the relevant agency on the management of biologically dangerous medical waste;
- 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, perforation, hemorrhage or mucosa tissue injury; infection and sepsis, etc.;

other complications which may exist yet be unknown or undiscovered

Cleaning and Sterilization:

1. Immerse the entire instrument in the ultrasonic cleaner containing detergent solution, clean ultrasonically for 20 minutes.
2. Remove the instrument from the detergent solution and rinse the instrument under clean running tap water to remove the residual detergent, make sure that no debris is left on the surface of the instrument;
3. Wipe the exterior of the instrument with a clean and dry lint-free cloth.
4. Push forward and back the handle of the instrument for 3 times for lubricating.
5. Seal the instrument into the bag.
6. Put instrument in bag into the auto-clave sterilization machine, dry the package in the auto-clave sterilization machine with the dry function, or open the door of the machine to air-dry it.
7. Sterilize the instrument auto-clave with temperature 121.3°C and pressure 103.4kPa (1.05kg/cm²), for 15~20 minutes consecutively.
8. When sterilization procedure finished, take out the clip delivery system after the air pressure and temperature return normal.
9. Cool the instrument naturally and put it back to the normal position.

[Storage]

The storage environment temperature range in 10~40°C, relative humidity ≤ 80%, non-erosive air, well ventilated, do not store with toxic and dangerous matters. The storage life is in accordance with the sterile validity, which is 3 years

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