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Reusable Delivery Systems for the Disposable  
Hemostasis Clips



## Instructions For Use

Version: 2.0 Date: 23th/Nov/2021

For the use of medical staff only.

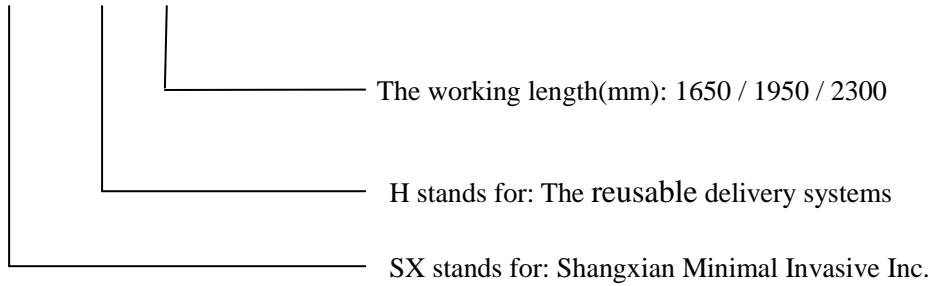
Please read this manual carefully before using the product and keep it properly for future need.

**Product:**

Reusable Delivery Systems for the Disposable Hemostasis Clips

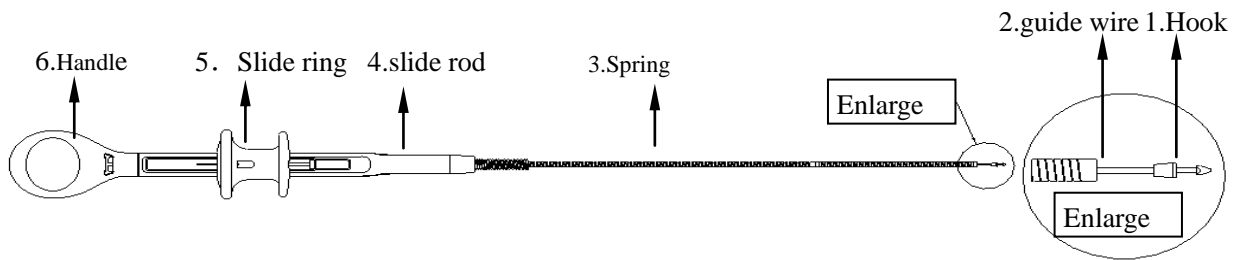
**Specifications instruction:**

SX - H - \*\*\*\*



**Components:**

The reusable delivery system comprises a hook, a guide wire, a spring tube, a slide rod, a slide ring and a handle, as shown in Diagram 1.



**Intended use:**

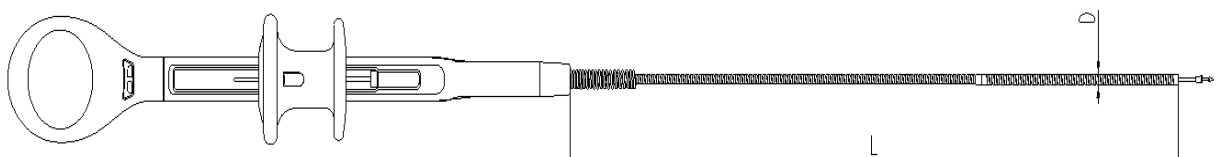
This product is intended use for connecting and controlling the clip to clamp the mucosa tissue of gastrointestinal track under the guide of endoscope.

**Specifications:**

For the specifications and type of reusable delivery system please refer to Form 1

Form 1 Specifications of reusable delivery systems

Model	L (mm) ±100mm	D (mm)
SX-H-1650	1650	≤2.75
SX-H-1950	1950	≤2.75
SX-H-2300	2300	≤2.75



## Diagram 2 size specification of delivery system

D: the maximum outer diameter of spring tube;

L: the working length of product, or the length between two ends of the spring tube;

### **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 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.
- Patients who have clips in their gastrointestinal tract should not have MRI procedure, or it may cause damage.

### **Preparations:**

1. To make clip assembly and delivery system ready for use;
2. Make sure the product to be used is within the validity period;
3. Make sure the instrument is not bent or damaged before use.

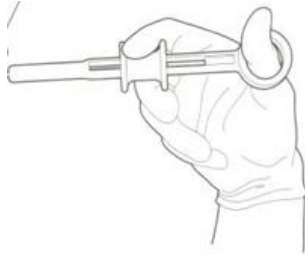
### **Warnings:**

1. Should any distortion on the spring tube of delivery system, do not use the instrument. Otherwise the clips may be stuck at the spring tube edge and cause failure of clip unloading
2. Please do not use the instrument if it is dislocated, bent or distorted, otherwise it may cause failure to go through the endoscope channel. It may stretch out of the distal end of endoscope abruptly and cause injury to patients if forcing the instrument into the endoscopy channel
3. Please do not continue to use the instrument if there is any doubtful questions or problems in operation

### **Usage:**

1. Tear out the clip assembly packing bag to take out the plastic clip pack;
2. Tear out the delivery system packing bag to take out the delivery system and hold the

handle as below picture show:



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 not moving, otherwise the clip can not 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 into 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 forward 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 coming off of the clip from the spring tube. If the coming off happened, do not retrieve the clip through endoscope channel. Doing so may lead damage to the endoscope channel.

8. Pull back the slide ring slowly, open the clip entirely.

Caution : At this moment please pull back the slide ring slowly, do not pull the slide ring fast, doing so may cause the clip closed before use or reduce the clip claw opening distance.

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

**Caution:**

- The slide ring will rotate along with the slide rod, please do not hold the slide ring too tight when rotate the handle;
- Do not rotate the handle too quick, doing so may cause the clip bouncing. Please rotate slowly;
- If the endoscope stays too much curling, the clip may rotate with delay when rotate the handle;
- If the clip 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.

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

11. Keep pulling back the slide ring until reach end of the handle to ensure the clip departs from the spring tube completely;

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

13. Push forward the slide ring until the clip 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 .

14. Dispose the plastic rod properly.

**Notes:**

- Do not operate the clip too hard, or the clip may be damaged;
- 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;
- One condition before use of this instrument should be required, should the clip be unable to unloaded 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;
- It is suggested to have food upon the doctor's advice and it is not suitable to eat in the early days after the operation. Improper diet, hard defecation, cough and all other activities that may force the gastrointestinal track and make the clip coming off to cause bleeding .
- The metal claw of the clip assembly is made of stainless steel, so please do not apply this product to patients who are allergic to the metal.
- According to current studies, 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 to be discovered.

**[Packaging]**

Product packaging

1.Primary package:

One piece delivery system is sealed with PE cover film and Tyvek paper

2.Middle package:

One bag is Packed in one while middle paper box

3.Outer package:

10 pieces boxes are packed in on cardboard outer box.

**[Storage]**

temperature: 10°C ~ 40°C ; Relative humidity  $\cong$  80%; well-ventilated room without corrosive gas, please do not store it together with poisonous or harmful goods.

**[Storage duration]**

Valid for 3 years

## **[Cleaning and Sterilization]**

**Warning:** The instrument is not sterilized before delivery. For the first use, it should be sterilized according to the local regulations and requirements strictly. Using the unsterilized instruments would cause infection and inflammation to patients.

### **1.General principles**

Lots of cross infection accidents are recorded in the medical literature because of improper cleaning and sterilization. The staff responsible for cleaning and sterilization of medical instruments should be well trained to well-acknowledged of the regulations and policies of cleaning and sterilization in local country and hospitals. It is suggested for hospital to have staffs specialized for cleaning and sterilization in endoscope room.

1. All the staff responsible for cleaning and sterilization should be well acknowledged of:
  - a. The cleaning and sterilization procedure of the hospitals
  - b. The occupational health safety regulations
  - c. The regulations and policies of the country and local hospitals.
  - d. The rules in this instruction
  - e. The mechanical knowledge of endoscopy equipments
  - f. The symbols and labels instruction of biocide

### **Warning**

- a. This equipment will touch the tissue of patients, improper cleaning or sterilization would cause danger to patients. To reduce the risk of cross infection, careful and complete cleaning and sterilizations are required after use in the endoscopy procedure.
- b. It is required to cleaning the instrument completely before sterilization, otherwise residues will cause inefficient sterilization.
- c. The debris of patients and the chemical agents used for cleaning、sterilization are dangerous, operators should ware personal protective equipment, such as appropriate, goggles, masks, waterproof clothing and protective gloves. Protective equipment should be of appropriate size and long enough to prevent skin from exposure. Before leaving the sterile area, the protective clothing should be removed.
- d. The cleaning and sterilization procedure mentioned in the manual should be done on the

day of using, any delay would lead to the concretion of debris and makes it difficult to clean and sterilize.

Protective equipments	Suitable Goggles, Mask, Waterproof Clothing and Protective gloves
Basin contains detergent solution	To ensure the instruments can be totally immerse, the basin of proper size and depth with the coiled diameter of the insertion portion should be not less than 20cm.
Washing liquid for soaking	Medical washing liquid with neutral PH value and low foam
Medical ultrasonic cleaner	Frequency range:38 to 47kHz, proper depth and diameter. The insertion portion coiled diameter should be not less than 20cm.
Medical ultrasonic cleaning fluid	neutral PH value, low foam and non abrasive
Lubricant	Medical water soluble or low viscosity emulsion type lubricant.
Basin contains lubricant	To ensure the instruments can be totally immerse, the basin of proper size and depth with the coiled diameter of the insertion portion should be not less than 20cm.
Lint-free cloth	
Steam sterilization packaging	To ensure the instruments can be totally immerse, the steam sterilization packaging (auto-clavable) should be with proper diameter and depth, the coiled diameter of the insertion portion should be not less than 20cm.
The sealing machine for the aseptic packaging	The hermetic package will need the seal machine, like the air heater, suitable sealing machine should be prepared according to package
Autoclave sterilization machine	Autoclave sterilization machine that could be operated according to “5.Sterilization”

e. After using, immediate cleaning and sterilization should be conducted. Firstly, immerse the instrument in a neutral, low foam medical washing liquid for cleaning, and then sterilize it in accordance with the sterilization process of the clip device.

### **Tools for cleaning and sterilization**

Protective equipments, washing liquid, containers, lubricant, as below sheet:



## **2. Cleaning**

### **Warming**

- a. when cleaning, please don't touching the liquid over-flowed out and the chemical agents to directly to avoid being skin irritation and infection
- b. Please keep the coiled diameter of the insertion portion no less than 20cm, otherwise it will be damaged.
- c. Please don't operate the instrument with over force to avoid any damage.

### **(1) Soaking**

#### **Warming**

After use, please immerse the instrument into detergent solution immediately, any delay may cause the inefficient cleaning.

- a. Soak the instrument as long as the manufacturer required, if no indications, it suggested to be 5minutes to 3 hours.
- b. Remove the instrument from the detergent solution;

### **(2) Medical ultrasonic cleaning**

- a. Immerse the instrument into the ultrasonic cleaning machine totally.
- b. Set up the machine to clean the instrument for 30 minutes. The operation of the ultrasonic cleaning machine should be complied with its manual.
- c. Pick out the instrument from the machine.

### **(3) Rinsing**

- a. 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.
- b. Wipe the exterior of the instrument with a clean and dry lint-free cloth.

### **(4) Lubricating**

- a. Immerse the instrument into the lubricants for 2-3 seconds.
- b. Pick out the instrument from the lubricants
- c. Push forward and back the handle of the instrument for 3 times for lubricating.
- d. Wipe the exterior of the instrument with a dry lint-free cloth and keep it air dried.

### **(5)Sterilization**

#### **Warming**

Before packing the instrument into the bag, please make sure the hook has been retrieved back into the spring tube to avoid the hook damage the bag.

Please keep the coiled diameter of the insertion portion no less than 20cm, otherwise it will be damaged.

Please don't operate the instrument with over force to avoid any damage.

- a. Before sterilization, the instrument must be well cleaned and dried.
- b. Wrap up the instrument and put instrument into the bag.

## **(6) Auto-clave sterilization**

### **Warming**

The biological indicator should be used according to all the regulations, policies and instructions of the country, the manufacturer and the local hospital.

There should be space between each package to ensure efficient sterilization.

Dry the package in the auto-clave sterilization machine with the dry function, or open the door of the machine to air-dry it

There are many factors that will affect the validation of the sterilization, like the package, the placement, please use biological indicator or chemical indicator to validate the sterilization.

- a. Put instrument that sealed in the bag into the auto-clave sterilization machine and sterilize the instrument under the below sheet 5.1. When operation the machine, please refer to the manual of manufacturer.

	Temperature	Sterilize time
Pre-vacuum	132-134°C (270-274°F)	15 min

Sheet 5. Recommended conditions for auto-clave sterilization

- b. When finished, cool the instrument naturally, sudden temperature change will change and damage the instrument.

### **[Times of repeated sterilization]**

Maximum 100 times

## Product Material General Indication of Chemical Resistance

<b>General chemicals</b>	
Alcohols	Good
Acids, Concentrated	Good
Acids, Diluted	Excellent
Bases, Concentrated	Excellent
Baes, Diluted	Excellent
Esters	Poor
Hydrocarbons, Aliphatic	Excellent
Hydrocarbons, Aromatic	Poor
Hydrocarbons, Chlorinated	Poor
Ketones	Poor
<b>Hospital Disinfectants</b>	
Asentisol	Excellent
Bleach Solutions, 10%	Excellent
Cavicide®	Excellent
Envirocide®	Excellent
Cidex®	Excellent
Lysetol®	Good
Grotanat®	Poor
Hydrogen Peroxide, 3%	Excellent
Isopropyl Alcohol, 70%	Good
Manu-Klenz®	Excellent
Phenols, 2%	Poor
Puristeril Plus®	Good
Quaternaries	Good
Sani-Cloth® HB	Excellent
Sani-Cloth® Plus	Poor
Sporotal® 100	Good
Super Sani-Cloth®	Good
Wex-Cide®	Poor

Excellent = No change






Good = Minor effects, no serious loss of properties

Attack = Rupture or dissolution

A general indication of the chemical resistance of product material is shown above table.

Chemical resistance was also evaluated by immersing bars for seven days at room temperature in various media.

**[Packaging symbols]**

	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