MICRO-TECH™
ENDOSCOPY

SureClip®

Repositionable Hemostasis Clip

Instructions for Use

Micro-Tech (Nanjing) Co., Ltd.

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INDICATIONS FOR USE

The SureClip® Repositionable Hemostasis Clip is indicated for Endoscopic clip placement within the Gastrointestinal tract in adult populations only via a straight or side viewing flexible endoscope for the purpose of :

(1)Endoscopic marking,

(2)Hemostasis for

(a) Mucosal/sub-mucosal defects < 3 cm,

(b) Bleeding ulcers,

(c) Polyps < 1.5 cm in diameter,

(d) Diverticula in the colon,

(e) Arteries < 2 mm,

(f)Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection.

(3)As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively

CONTRAINDICATIONS

1. Mucosal / submucosal defects greater than 3cm;
2. Polyps greater than 1.5 cm in diameter;
3. The patient with poor general condition who cannot tolerate endoscopy;
4. The patient has narrow upper digestive tract where endoscope cannot pass through;
5. The patient has serious coagulation disorders and hemorrhagic diseases;
6. The patient is allergic to the device and the drugs used in the operation;
7. The patient who is not suitable to use the product per the diagnosis;
8. The patient or the families are uncooperative.

POTENTIAL COMPLICATIONS

1. Inflammation of tissue, perforation, bleeding or mucosal damage for the patient;
2. Infection, septicemia, etc;
3. Complications which are not currently known or observed may be present.

WARNINGS

1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization or reprocessing 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. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
2. Do not use this instrument for any purpose other than its intended use.
3. The product is only intended for adult populations.
4. The clips are stainless steel. Do not use them on a patient who is severely allergic to metals. This device is not made with natural rubber latex.
5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
6. 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.
7. **The instrument is intended for use under the direct supervision of a suitably trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
8. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.
9. Do not use this instrument when hemostasis cannot be verified visually within the endoscopic field of view.
10. Do not operate the spiral tube and clip with excessive force as this may cause damage to the device.
11. It may be difficult to stop bleeding depending on the situation. Prepare more than one hemostasis device. Some devices may be used together for best result.
12. Bleeding may occur on the clipping site, depending on the local condition. Check the patient for any re-bleeding after the procedure as appropriate.
13. Always observe the endoscopic image during operation. If the clip deploys prematurely, remove it with foreign body retrieval forceps.
14. Limited studies indicate that lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with forward-viewing endoscope.
15. Limited studies indicate that the treatment of esophageal varices may require

clipping in combination with a sclerosing agent.

16. Limited studies indicate that clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
17. 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.
18. Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.
19. For Usage in a side viewing endoscope: before actuating the elevator to the full position, assure that the clip body has projected adequately past the distal end of the scope, to prevent inadvertent detachment of the clip or damage to the device. Fully lower the elevator prior to removing the device following clip deployment.
20. This clip contains ferromagnetic material. Follow your institutional protocols to determine whether or not an x-ray should be performed prior to an MRI exam. There may be a small 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

【 Product Name 】SureClip© Repositionable Hemostasis Clip

【 Packaging 】Packed in pouch

【 Production Date 】 See packaging

【 Sterilization 】 Sterilized by EO (ethylene oxide) gas

【 Shelf Life】 3 years

【 Compatible Working Channel 】≥ φ2.8mm

STRUCTURE

SureClip® Repositionable Hemostasis Clip includes a clip component, distal end of spring tube, proximal end of spring tube and handle component (Fig.1).

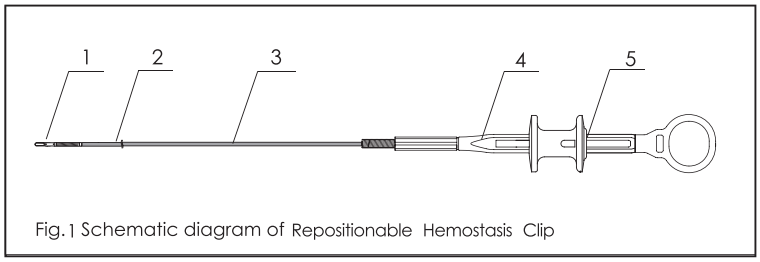

Fig.1 Schematic diagram of Repositionable Hemostasis Clip

1. Clip component 2. Distal end of spring tube 3. Proximal end of spring tube
4. Handle component 5. Finger Ring

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged.
4. Verify the expiration date. Do not use if expired.
5. Open the package carefully using acceptable aseptic technique.
6. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
7. Before use, check the clip and the spring tube to ensure that there are no sharp edges. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
8. Prior to use, remove the protective sleeve and gently open and close the device to confirm it is functioning.

NOTE: Excessive force may result in the clip deploying before use.

NOTE: Hyper-extending the finger rings away from thumb ring should be avoided. Excessive force may damage the device and affect performance.

INSTRUCTIONS FOR USE

1. The device is compatible with an endoscope channel of 2.8mm or larger.

2. Carefully insert device into endoscope channel, ensuring that the clip is in the closed position (See Fig.2).

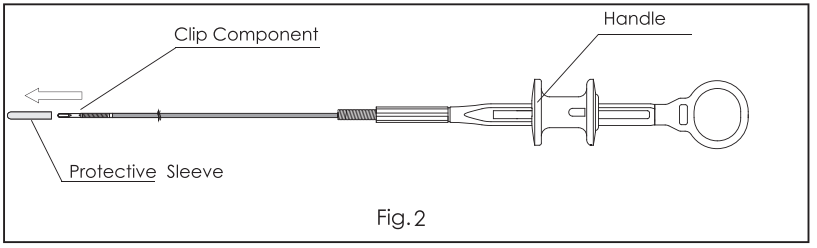

Fig. 2

3. Advance the clip in small incremental movements towards the target site. Once in the instrument channel, there is no need to apply closure pressure on the handle.

NOTE: Applying excessive closure pressure to the handle during insertion, may result in detachment of the clip.

NOTE: Endoscope should remain as straight as possible when inserting the device.

NOTE: When introducing the device, in an endoscope in a tortuous position, straightening the endoscope may improve passage and exposure of the clip. With the clip in place, carefully reposition the endoscope for treatment.

4. When in endoscopic view, gently open the clip by gently sliding the finger ring forward.

5. Clip can be rotated clockwise or counter-clockwise by slowly turning the handle component until desired position is achieved. During rotation, the handle component and finger ring should be allowed to rotate. (See Fig.3)

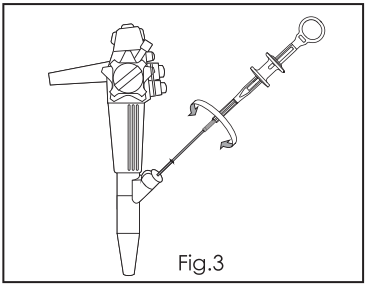

Fig.3

6. Advance the device until contact is made with the targeted site.

7. When satisfied with clip positioning, close the clip onto the tissue by pulling the finger rings back until tactile resistance is felt in the handle. The clip position may now be assessed prior to deployment. (See Fig.4)

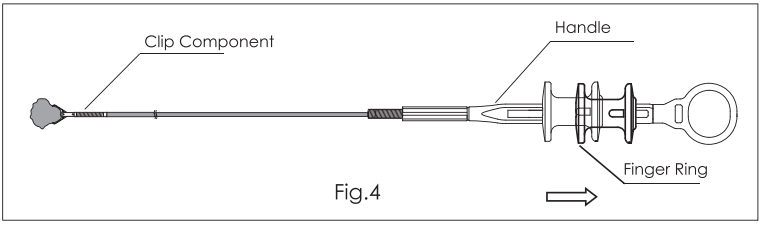

Fig.4

If the clip is not in its desired position, the clip may be re-opened and repositioned.

NOTE: Do not continue to pulling back the finger rings 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.

8. To deploy the clip, use both hands to pull back the finger ring beyond the tactile resistance point. You will hear on audible snap when the clip component detaches. (See Fig. 5).

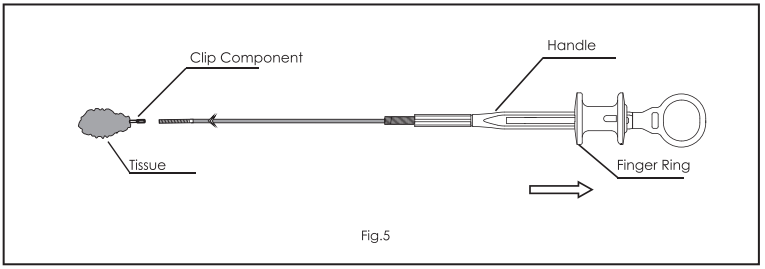

Fig.5

NOTE: If the clip did not immediately detach from the catheter, then apply gently movement of the catheter or endoscope to unseat the clip.

NOTE: Do not advance the finger rings after deployment as this may damage the device.

9. Remove sheath from endoscope by slowly retracting the device.

NOTE: Endoscope should remain as straight as possible when withdrawing the device.

MR Safety Information

MR Conditional

A person with the SureClip® Repositionable Hemostasis Clip may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	SureClip® Repositionable Hemostasis Clip
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	40 T/m or 4000 gauss/cm
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (normal operating mode)
Maximum Head SAR	3.2 W/kg (first level control mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF with less than 2 degrees temperature rise
MR Image Artifact	The presence of this implant may produce an image artifact at 25 mm away from the device.

Precaution: It is recommended that healthcare providers distribute patient implant cards with the name of the clip and date it was placed

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.

Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

The product shelf life is 3 years.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

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