MICRO-TECH ENDOSCOPY

SureTrac™ Elastic Traction System

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.

INTENDED USE

The Elastic Traction System is indicated for adult only for use in flexible Endoscopy to provide retraction to assist in tissue resection, exposure, and removal of tissue within the stomach and colon.

CONTRAINDICATIONS

- A patient with a poor general condition who cannot tolerate endoscopy
- A patient with a narrow upper digestive tract where the endoscope cannot pass through
- Severe coagulation disorders and hemorrhagic diseases
- Patient with a severe allergy to a component of the devices or the drugs used in the procedure
- When any tissue defect closure cannot be verified endoscopically

POTENTIAL COMPLICATIONS

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

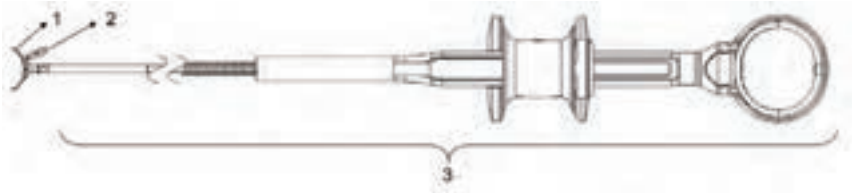
WARNINGS

1. The product is intended for single use only! DO NOT reuse, re-sterilize, and or reprocess. Reuse, 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. Reuse, 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 endoscopic view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without a 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 operate the spiral tube and clip with excessive force as this may cause damage to the device.
10. Always observe the endoscopic image during operation. If the clip deploys prematurely, remove it with foreign body retrieval forceps.

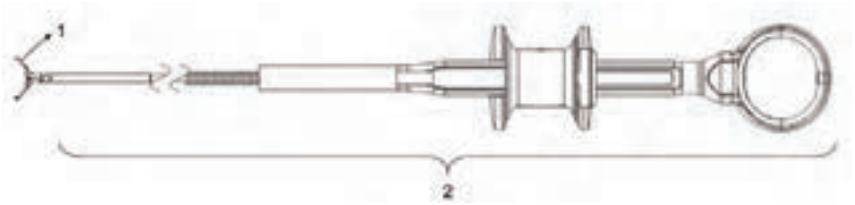
【Product Name】 SureTrac™ Elastic Traction System
【Packaging】 Packed in Pouch
【Production Date】 See packaging
【Sterilization】 Sterilized by Ethylene Oxide (EO)
【Shelf Life】 2 years
【Compatible Working Channel】 ≥φ2.8mm

STRUCTURE

The Elastic Traction System is a single use tissue traction device. The Elastic Traction System consists of 2 components, an Elastic Traction Device and a clipping device. The 2 components are separately in single pouch. The Elastic Traction Device consists of a preloaded super elastic silicone band, attached on one of the arms/jaws of a clip, and is applied utilizing a catheter driven delivery system. The clipping Device is a tissue clip.



Component 1-Elastic Traction Device
（1-Clip 2-Silicone band 3-Delievery System）



Component 2-Clipping Device
（1-Clip 2-Delievery System）
Fig.1

PRIOR TO CLINICAL USE:

1. Familiarize yourself with the device and read all the Instructions for Use (IFU).
2. Carefully examine the unit to verify that neither the contents nor the package have been damaged in shipment. If the device shows any signs of damage do not use the product.
3. Open pouch and remove the device.
4. Uncoil device.
5. Inspect device for kinks or damage. If the device shows any signs of damage DO NOT use this product and contact your local Micro-Tech representative.
6. DO NOT attempt to repair a non-functional or damaged device.
7. Prior to use, remove the protective clamshell / sleeve and gently open and close the device to confirm it is functioning correctly.
   NOTE: Excessive force may result in the clip deploying before use.
   NOTE: Hyper-extending the finger rings away from the thumb ring should be avoided. Excessive force may damage the device and affect performance.

INSTRUCTIONS FOR USE

1. The device is compatible with on endoscope channel of 2.8mm or larger.
2. Open the pouch of the Elastic Traction Device (Hereinafter referred to ETD) and remove blister package from the distal portion of the clip to expose the clip with the pre-loaded silicone band. Carefully insert the device into the endoscope channel, ensuring that the clip is in the closed position.
   NOTE: Wet the endoscope instrument channel and distal portion of device with normal saline before inserting the device into the channel.
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: Do not retract the device during the inserting process.
   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 endoscopic view, carefully reposition the endoscope for treatment.
4. Visually confirm that the device has exited the endoscope with the preloaded silicone band still attached. If for some reason, the device exits the endoscope without the silicone band attached, remove the device and retrieve the band is appropriate. Select another device.
   NOTE: You could retrieve the silicone band through clipping it with the clip of the device and then take them together out of the working channel.
5. The clip can be rotated clockwise or counter-clockwise by slowly turning the handle component until the desired position is achieved. During rotation, the handle component and finger ring should be allowed to rotate.
6. Position distal tip of the device toward the targeted site.
7. Open the clip, with preloaded silicone band attached and advance device into contact with the targeted site to properly anchor the clip to the tissue.
8. When satisfied with clip position, 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. If clip is not in desired position, gently reopen the finger rings and repositioned the device.
   NOTE: Do not continue to pull back the finger ring 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.
   To deploy the clip, continue pulling back the finger rings beyond the tactile resistance point. You will hear an audible snap when the clip component detaches.

Warning: If separation of clip is not immediate, gently move catheter back and forth. Do not forcibly pull back on the clip which will tear the tissue and likely result in severe bleeding.

A wire-cutter should be available on the endoscopy cart and be used to cut the coil where it exits the endoscope. The endoscope can then be removed leaving the clip and coil intact. The patient may require an URGENT SURGICAL intervention if there is active bleeding from the site.

9. At this point, the primary clip should be anchored to the desired tissue. The silicone band is attached to one of the arms/jaws of the anchored clip.
10. Open the pouch of Clipping Device, Hereinafter referred to the second clip The second clip is used to engage the silicone looped band of the previously anchored clip.

    NOTE: Please refer to the instructions for the operation method of second clip.
11. Once the arm/jaw of the second clip has engaged with/traversed through the distal loop of the silicone band, it may be properly positioned to be engaged onto tissue to provide the desired traction/counter-traction/triangulation.

    NOTE: The Elastic Traction System is designed for application over a minimum relaxed tissue distance of 20mm and a maximum relaxed tissue distance of 50mm. Do not over extend the band. Over extending the band may cause the band to break and result in tissue damage or injury. Once the second clip is engaged with the targeted tissue and connected to the silicone band of the primary clip, it is deployed from the catheter assembly as per step 8 above.

    NOTE: As the dissection goes on, the elastic force will decline due to shortened traction distance. Don't use another clip to attach the previous silicone band again for traction. The maximum number of the clipping device that can be used with the silicone band at one time is one piece. If required, use a new elastic traction system as per the steps above.
12. Endoscopic Techniques: There is two distinct techniques used to position both clips to achieve the desired result of traction and tissue exposure.

    NOTE: Only use clips from Micro-Tech with this device.

    NOTE: The clips are made from stainless steel and can conduct RF energy. Care should be taken to avoid direct metal to metal sparking or direct contact with an active electrode, if electrosurgery is used during tissue resection or for hemostasis.

Technique A:
The first technique utilizes the "tissue bloc to tissue bloc" connection thus, anchoring the primary clip (with the silicone band attached) to one end of the resected tissue bloc and the secondary clip engaging the band and connected to the other end of the tissue bloc (see Figures 2a, 2b, 2c and 2d below). As the targeted tissue is cut and freed from its position the tension from the band connecting the two clips, raises the flaps of tissue to expose the underlying tissue and proper cutting angles to assist in the resection process.
At the end of the procedure, the resected tissue, attached clips and silicone band are moved using an appropriate retrieval device.

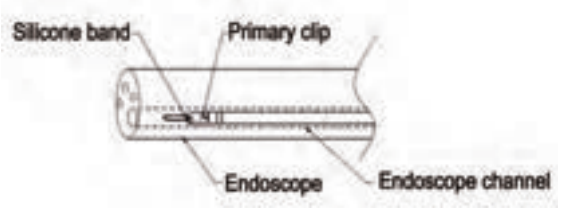


Fig. 2a

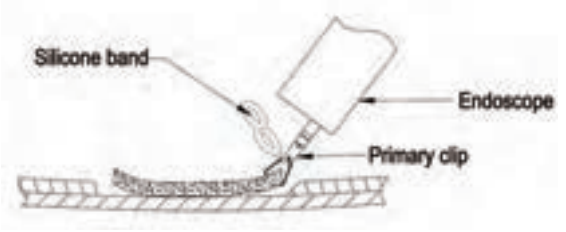


Fig. 2b

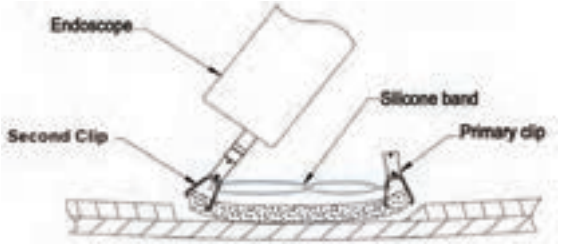


Fig. 2c

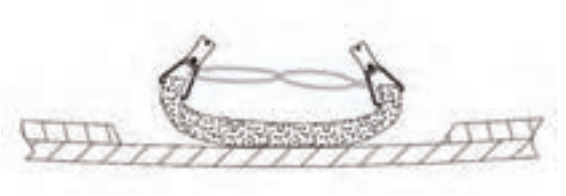


Fig. 2d

Technique B:
The second technique utilizes the "wall to tissue bloc" connection thus, anchoring the primary clip (with the silicone band attached) to the targeted resection tissue and the second clip engaging the band and connected to the gastrointestinal wall (see Figures 3a and 3b). As the targeted tissue is cut and freed from its position the tension from the band, connecting the two clips, raises the flap of tissue to expose the underlying tissue and enhance proper cutting angles to assist in the resection process.
At the end of the procedure, remove the second clip with a grasper and then retrieve the resected tissue with clips attached together with endoscope. If required you can use an Endoscopic scissor to cut the silicone band to remove the primary clip, silicone band and lesion together. And leave the secondary clip in place.

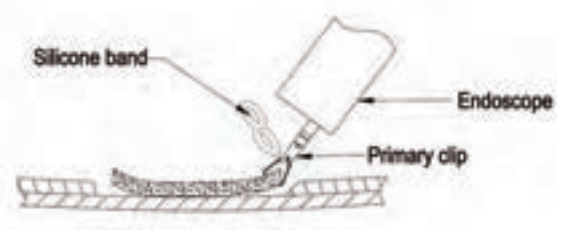


Fig. 3a

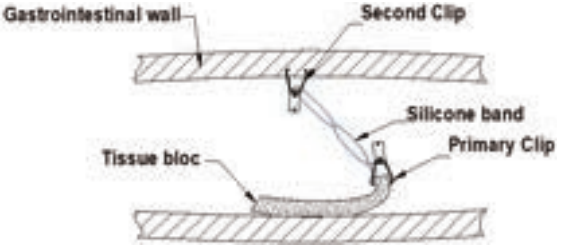


Fig. 3b

MR Safety Information

MR Conditional

Non-clinical testing has demonstrated that the Clipping Device is MR Conditional.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3T only
- Maximum spatial field gradient of 4,000 gauss/cm (40T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

  Under the scan conditions defined above, the Clipping Device is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning.

  In non-clinical testing, the image artifact caused by the device extends approximately 25mm from the Clipping Device when imaged with a gradient echo or spin echo pulse sequence in a 3 Tesla MRI system.

STORAGE

1. Handle all packaging with Care.
2. Do not expose to sunlight, ionizing radiation or ultraviolet light.
3. Keep all Packaging and Contents dry.
4. Do not expose to organic solvents.

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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