



Disposable Dual Action Tissue 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.

INTENDED USE

The Disposable Dual Action Tissue Clip is intended for use in flexible endoscopy for the compression of tissue in the gastrointestinal tract for adult patient only.

The Disposable Dual Action Tissue Clip is indicated for clip placement within the gastrointestinal tract for the purpose of:

- Endoscopic marking,
- Hemostasis for
 - Mucosal/sub-mucosal defects < 3 cm,
 - Bleeding ulcers,
 - Polyps < 1.5 cm in diameter,
 - Diverticula in the colon,
 - Arteries < 2 mm,
- As a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

CONTRAINDICATIONS

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

POTENTIAL COMPLICATIONS

1. Inflammation of tissue, perforation, bleeding or mucosal damage for the patient;
2. Infection, septicemia, etc;

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 product for any purpose other than its intended use.
3. The product is only intended for adult populations.
4. The clip is made of stainless steel and gold. Do not use them on a patient who is severely allergic to metals. This product 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 product is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the product or if any other unexpected circumstance takes place.
7. The product 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 product 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 product when hemostasis cannot be verified visually within the endoscopic field of view.
10. Don't use too much force to operate as this may cause damage to the product.
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. the clips should be at least 3cm away from each other. the clips should be at least 3cm away from each other.
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.

【 Product Name 】 Disposable Dual Action Tissue Clip

【 Packaging 】 Packed in a flexible peel pouch

【 Production Date 】 See packaging

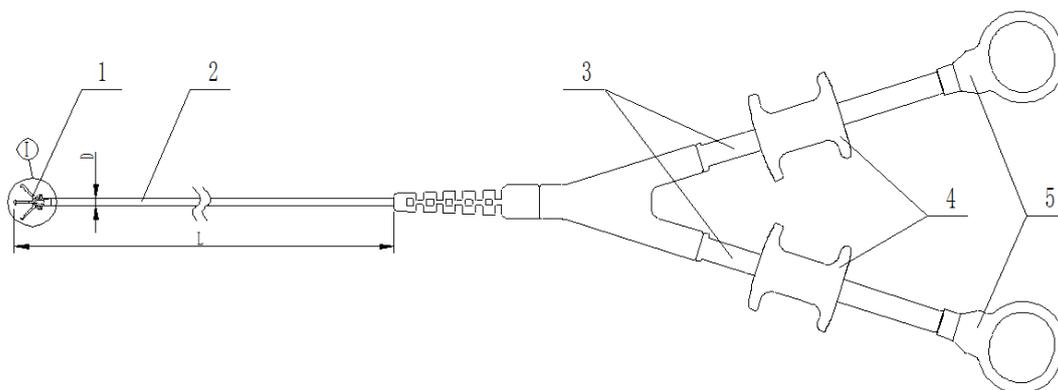
【 Sterilization 】 Sterilized by EO (ethylene oxide) gas

【 Period of Validity 】 1 year

【 Compatible Working Channel 】 $\geq 3.2\text{mm}$

STRUCTURE

Specific structure and main components are shown in fig 1 :



1. Clip component 2. Spring tube (coated / uncoated) 3. Core Bar 4. Slide block 5. Handle ring
- L-Working length D-Maximum outer diameter of insertion part

Fig.1: Disposable Dual Action Tissue Clip

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use. 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. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
8. 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.

INSTRUCTIONS FOR USE

Note: Only one of the specifications is selected in the picture below.

1. Device insertion:
 - A. Remove the jaw protective sleeve of the front end of Disposable Dual Action Tissue Clip (as shown in Fig 2), control the two handles with two hands respectively, pull the slide block to the handle ring position and maintain the appropriate tension until the clip is completely closed.

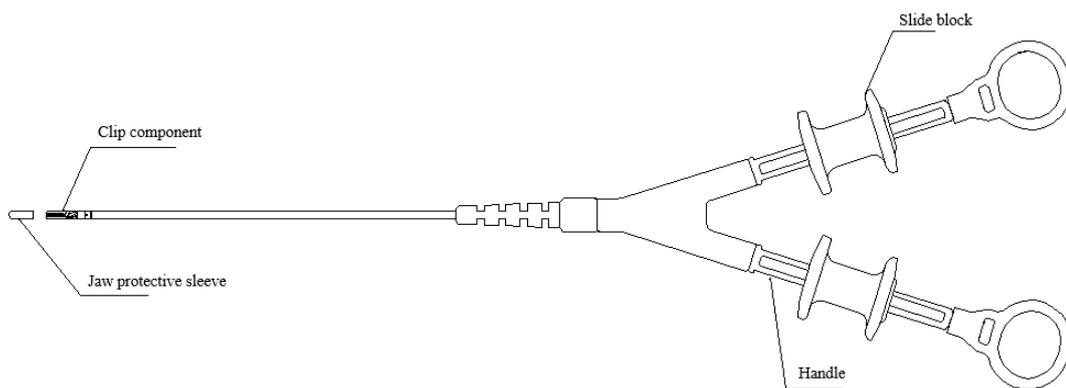


Fig 2 Remove the jaw protective sleeve

- B. Insert the distal end of the Disposable Dual Action Tissue Clip carefully into the endoscopic biopsy tract, advancing only 2 to 3 cm each time.

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

Note: When removing the jaw protective sleeve gently remove it along the axial direction of the instrument. Incorrect operation may cause Disposable Dual Action Tissue Clip to separate from the outer tube, kink or damage the device.

Note: When the instrument is inserted into the biopsy channel, the distal end of the endoscope should be kept as straight as possible to avoid the separation, kinking or damage of Disposable Dual Action Tissue Clip from the outer tube when the instrument passes through the retroversion or bending path.

Note: When the instrument is inserted into the biopsy channel, Disposable Dual Action Tissue Clip must be completely closed, otherwise the biopsy channel will be damaged.

2. Confirm the device has completely passed through the working cavity of the endoscope, and Disposable Dual Action Tissue Clip appears in the field of vision;

3. Open Disposable Dual Action Tissue Clip:

When Disposable Dual Action Tissue Clip is in the desired position (one side of the wound), gently operate the slide block on the first handle to open the clip on the corresponding side. (as shown in Fig 3)

Note: To open the gold clip, push the yellow slide block on the handle; to open the metallic clip, push the blue slide block on the handle;

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.

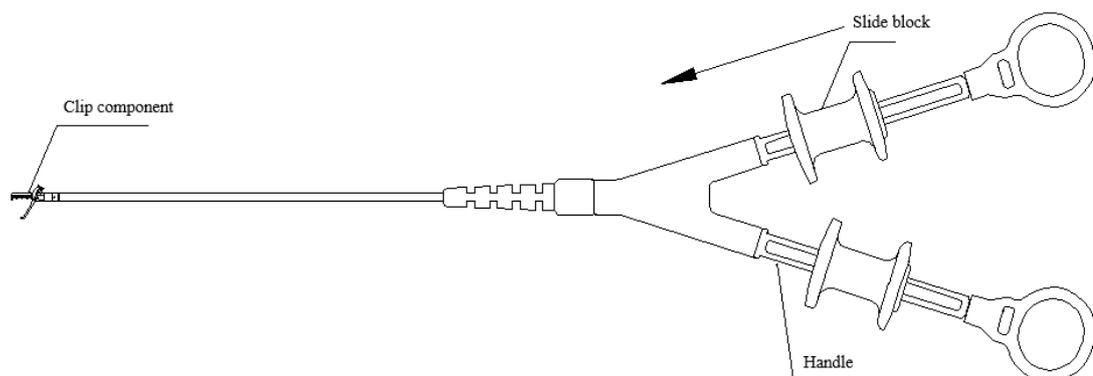


Fig 3 Open Disposable Dual Action Tissue Clip

4. Clamping:

A. Close Disposable Dual Action Tissue Clip at the required position, and slowly move the slide block to the direction of the handle ring until there is resistance on the handle, so that Disposable Dual Action Tissue Clip is gradually closed, but not released; if it is found that the position is not good at this time, you can re-open the clip until the clamping of the tissue is completed. (as shown in Fig 4)

Note: After feeling the resistance, do not continue to move the slide block to the handle ring, otherwise the clip may not be opened again. If you hear a click, the clip cannot be re-opened. Please go to step 7 to complete the closing of the clip;

Note: In the process of clamping, the slide block needs to be operated slowly. If it is operated too fast, the clip may not be clamped and fall off on the human body;

Note: Disposable Dual Action Tissue Clip has no rotating function. Do not rotate the handle during operation.

B. During the closing process, there are two options:

Option 1: Disposable Dual Action Tissue Clip has no rotating function, If the position of the clip is not suitable, Disposable Dual Action Tissue Clip can be re opened and repositioned. (see Step 3)

Note: Disposable Dual Action Tissue Clip can be opened and closed several times to assist in locating the clips at the injured site. The ability to re-open and close may be limited by clinical environment, lesion location and other factors;

Option 2: The position of clamping is suitable, permanent closure of Disposable Dual Action Tissue Clip. (see Step 5)

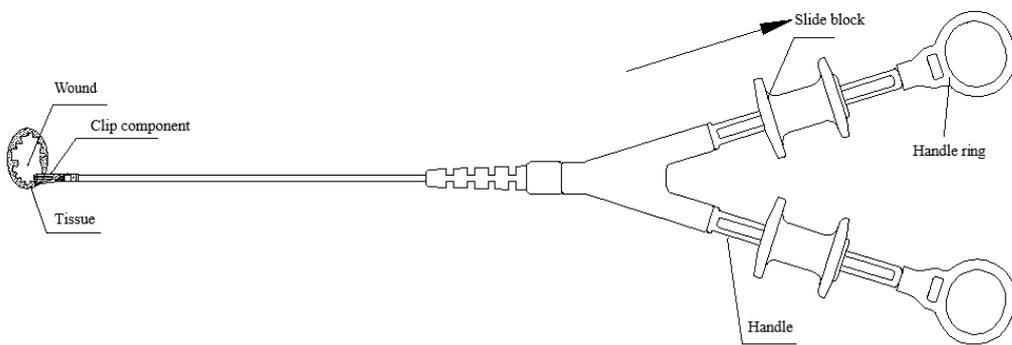


Fig 4 Clamping

5. Move the wound tissue to the other side of the wound through the endoscope. At this time, the handle that controls the clip's closure remains closed. (as shown in Fig 5)

Note: Disposable Dual Action Tissue Clip should be closed completely when pulling the wound tissue to prevent it from falling off.

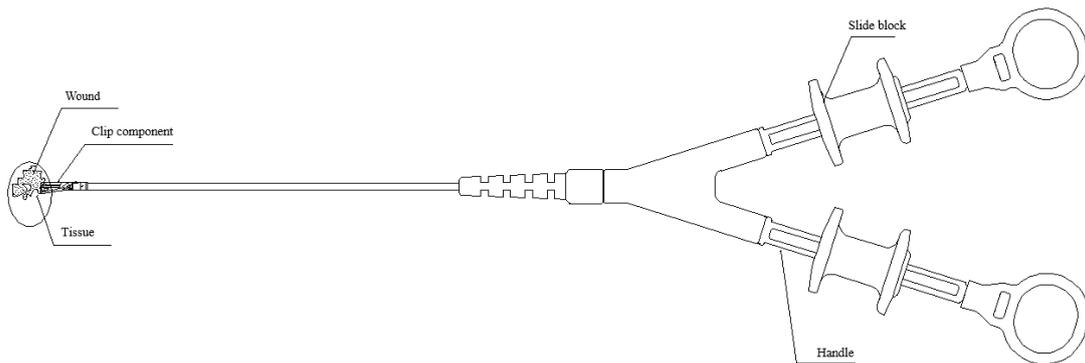


Fig 5 Traction tissue

6. According to the third step, operate the slide block on the second handle to open the clip on the corresponding side (as shown in Fig 6); then according to the fourth step, complete the clamping of the clip on the tissue. (as shown in Fig 7)

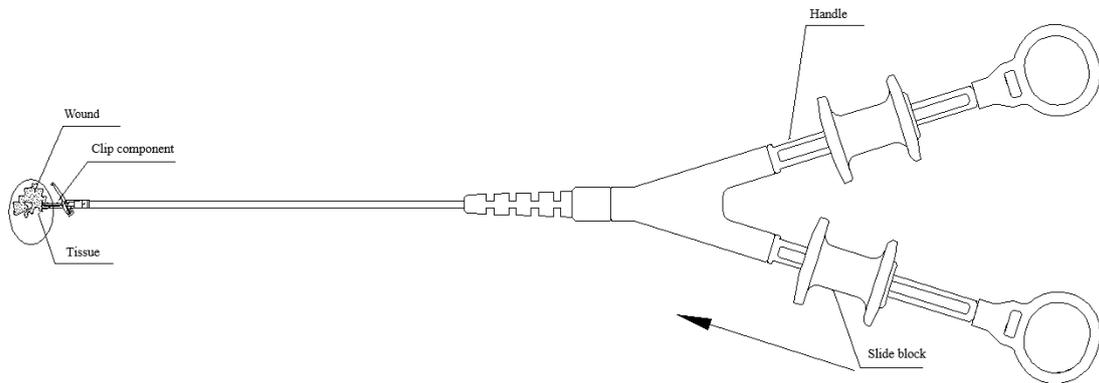


Fig6 Open the other clip

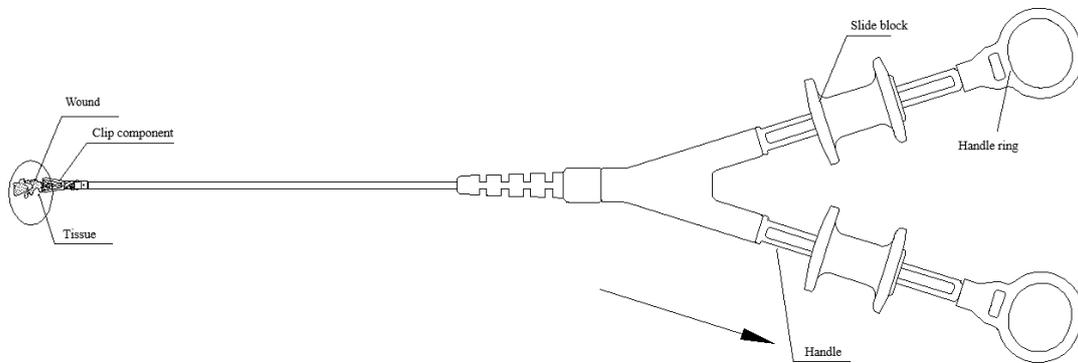


Fig 7 Clamping

7. To permanently close Disposable Dual Action Tissue Clip, you can move the slide block towards the handle ring after the resistance is felt. At this time, you can feel or hear the click, which indicates the clip has been released (as shown in Fig 8); after release, the clip and the device can be separated by the following two methods:

- A. The sheath is separated from the clip by gently pulling the spring tube;
- B. By gently moving the slide block away from the handle ring, the clip is separated from the spring tube .

Note: There are two separate points in the release process of the clip. When only one separate point is completed in the release process, the clip can not be opened at this time, so we must continue to pull the slide block toward the handle ring until the clip is released.

Note: To permanently close Disposable Dual Action Tissue Clip, please use two hands to move the slide block towards the handle ring until the Disposable Dual Action Tissue Clip is released. At this time, you can feel or hear the click, which indicates the clip has been released.

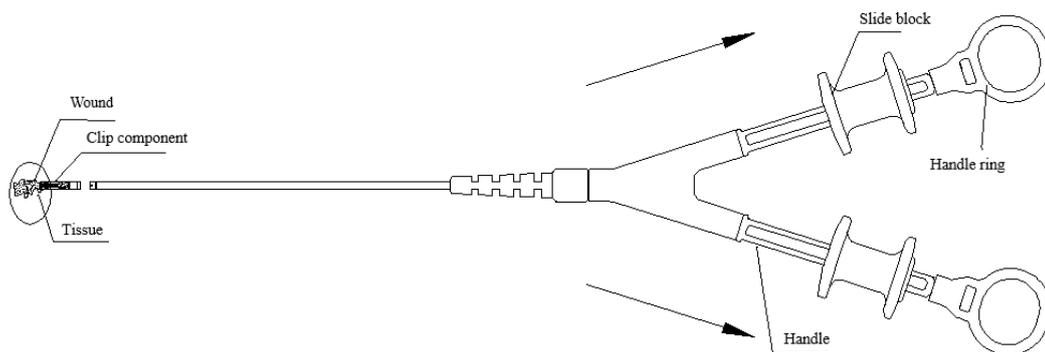


Fig 8 Release

8. After confirming the clip has separated from the device, slowly withdraw the device from the endoscope.

Note: Do not withdraw the device immediately after release of the clip. Observe under the endoscope that the clip and the device have been separated, and then slowly withdraw from the endoscope.



MR Conditional

A person with the Disposable Dual Action Tissue Clip may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Disposable Dual Action Tissue Clip
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m or 3000 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 33 mm away from the device

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 1 year.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations

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