Disposable Dual Action Tissue Closure Device
Instructions for Use

Micro-Tech (Nanjing) Co., Ltd.

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. Bleeding may occur on the clipping site, depending on the local condition. Check the patient for any re-bleeding after the procedure as appropriate.

4. The product is only intended for adult populations, Not intended for children, pregnant or breastfeeding women.

5. 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.

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. 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.

8. Do not use this product when hemostasis cannot be verified visually within the endoscopic field of view.

DEVICE NAME

【COMMON NAME】

Disposable Dual Action Tissue Closure Device

DEVICE DESCRIPTION

【MODEL NUMBER】

STA00001/ STA00002/ STA00003/ STA00004/ STA00005/ STA00006

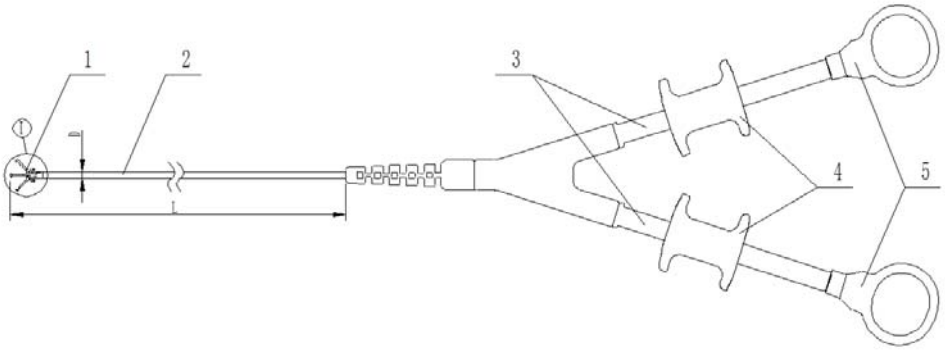
【SPECIFICATION】

unit：mm

REF	Open Width（L1）	Maximal Outer Diameter of the Insertion Part D	Working Channel	Coating	Working Length（L）
STA00001	15	3.0	≥3.2	Coated grey	1650
STA00002	15	3.0	≥3.2	Coated grey	1950
STA00003	15	3.0	≥3.2	Coated grey	2350
STA00004	15	3.0	≥3.2	Uncoated	1650
STA00005	15	3.0	≥3.2	Uncoated	1950
STA00006	15	3.0	≥3.2	Uncoated	2350

【STRUCTURE】

Specific structure and main components are shown in fig1 :



1. Clip component 2. Spring tube (coated grey/ 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 Closure Device

【USER INFORMATION/TRAINING/QUALIFICATIONS】

This device is intended for use by trained health care professional only. As an accessory of digestive endoscopy, the product shall be used by professionals familiar with the operation technique of digestive endoscopy .

【MR SAFETY INFORMATION】

MR Conditional

Non-clinical testing demonstrated that the Micro-Tech Disposable Dual Action Tissue Closure Device is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the Micro-Tech Disposable Dual Action Tissue Closure Device is expected to produce a maximum temperature rise of 1.8 ˚C after 15-minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the Micro-Tech Disposable Dual Action Tissue Closure Device extends approximately 33.2 mm from this implant when imaged using a T1-weighted spin echo sequence and a 3-Tesla MR system.

INTENDED USE

The device is designed to be used with conventional through-the-scope clips for compression and manipulation of tissues in the gastrointestinal tract.

INDICATIONS

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

- Hemostasis for
  - Mucosal/sub-mucosal defects ： 3~5 cm,
  - Polyps < 1.5 cm in diameter,
- 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.

ADVERSE EVENTS

The potential adverse effects associated with Disposable Dual Action Tissue Closure Device may include :

Bleeding

Perforation

Pain

Infection

Septicemia

Inflammation of tissue

Mucosal damage

Complications which are not currently known or observed may be present

CAUTION

1. 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.

2. Patient should be informed and expressed his/her acceptance for the details of the operation and all the potential risks and complications, which may lead to injury, illness or death of the patients.

3. Please read the instructions for use entirely before use.

4. Don't use too much force to operate as this may cause damage to the product.

NOTES

1. Always observe the endoscopic image during operation. If the clip deploys prematurely, remove it with foreign body retrieval forceps.

2. Limited studies indicate that clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.

3. 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.

4.The use of clips in the presence of bacterial contamination may potentiate or prolong infection.

5. A notice to the user and / or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

HOW SUPPLIED

Product packaging intact and has been sterilized (EO sterilization)
One-time use, for one patient to use only

STORAGE

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

COMPATIBILITY

The device is intended to use in endoscopic surgery of digestive tract. The specifications of digestive tract endoscopes should comply with the following requirements:

1) Channel diameter ≥3.2mm.

2) Working length < the working length of proposed device.

DIRECTIONS FOR USE

【PREPARATIVE CHECK AND PREPARATION】

Read the product instruction for use and label, confirm the specification and the expiry date of sterilization. If the package is damaged or opened unintentionally before use, replace it with a new device

【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 Closure Device (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.

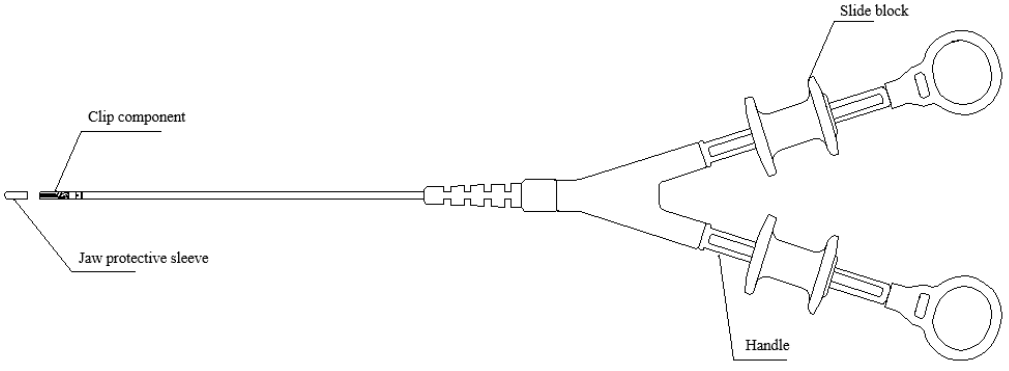


Fig 2 Remove the jaw protective sleeve

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

Note 1: When removing the jaw protective sleeve, gently remove it along the axial direction of the instrument. Incorrect operation may cause Disposable Dual Action Tissue Closure Device to separate from the outer tube, kink or damage the device.

Note 2: 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 Closure Device from the outer tube when the instrument passes through the retroversion or bending path.

Note 3: 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 Closure Device appears in the field of vision.

3. Open Disposable Dual Action Tissue Closure Device.

When Disposable Dual Action Tissue Closure Device 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;

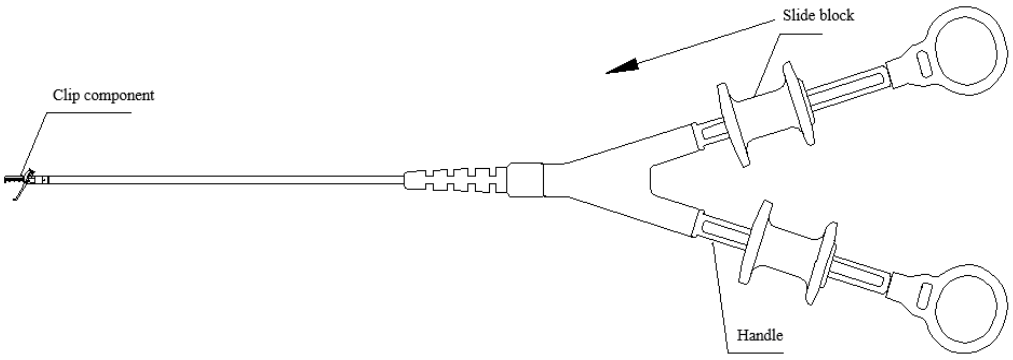


Fig 3 Open Disposable Dual Action Tissue Closure Device

4. Clamping:

A. Close Disposable Dual Action Tissue Closure Device 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 Closure Device 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 1: 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 2: 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.

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

Option 1: If the position of the clip is not suitable, Disposable Dual Action Tissue Closure Device can be reopened and repositioned. (see Step 3)

Note: Disposable Dual Action Tissue Closure Device 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 Closure Device. (see Step 5)

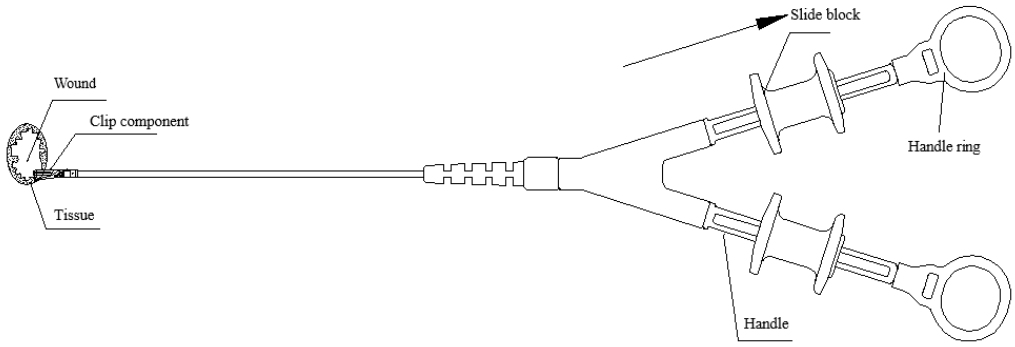


Fig 4 Clamping

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 Closure Device should be closed completely when pulling the wound tissue to prevent it from falling off.

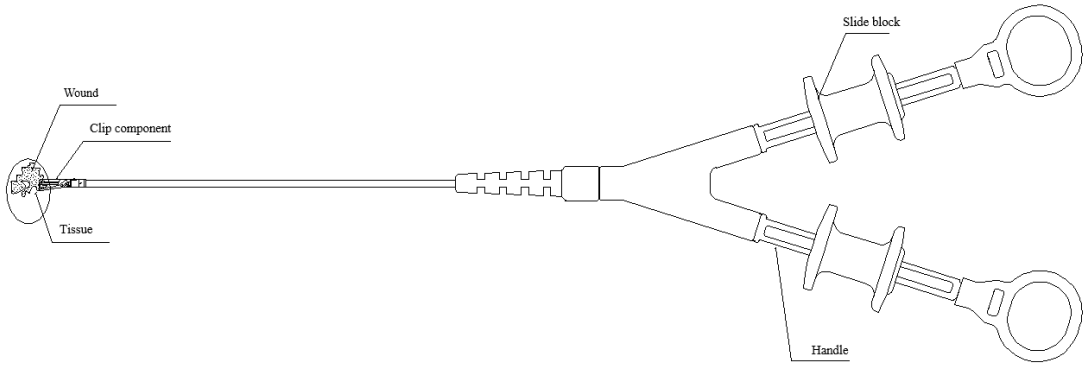


Fig 5 Traction tissue

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)

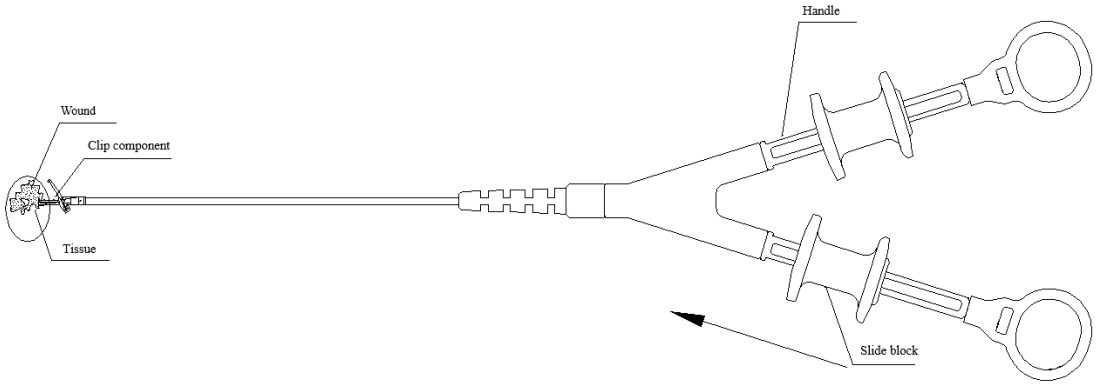


Fig 6 Open the other clip

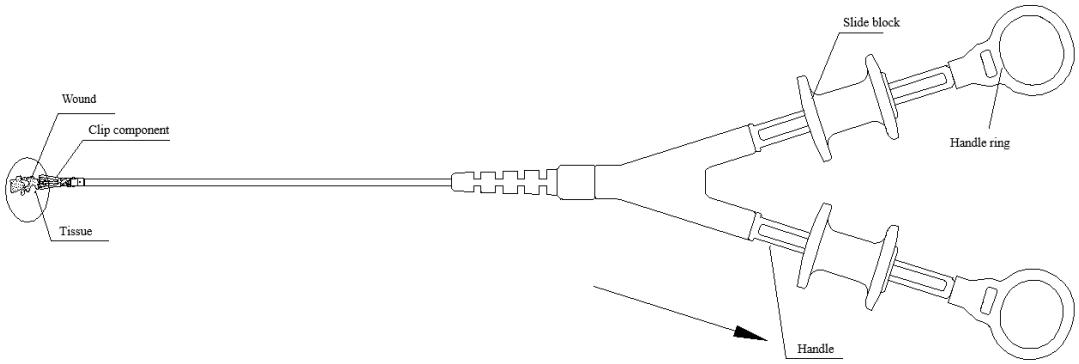


Fig 7 Clamping

7. To permanently close Disposable Dual Action Tissue Closure Device, 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 1: There are two fracture points in the release process of the clip. When only one fracture 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 2: Both hands should move the slide block towards the handle ring at simultaneously to release the two clips at the same time.

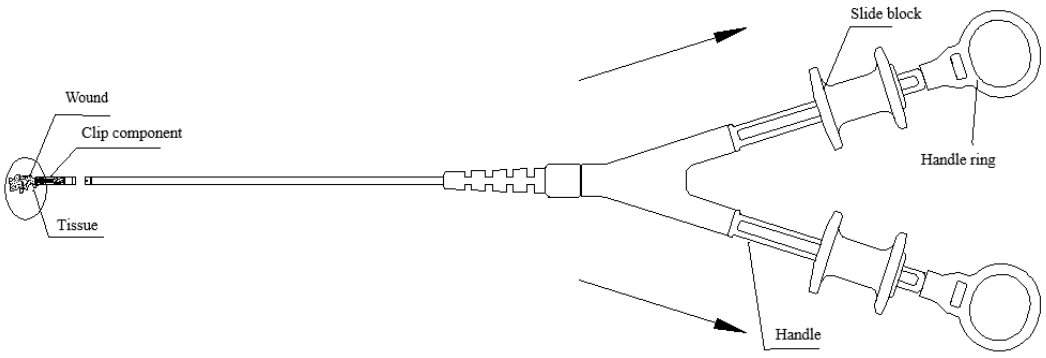


Fig 8 Release

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.

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.

POST-PROCEDURE

1.After surgery, follow the doctor's advice on diet. Improper diet, forcible defecation, cough and other activities increasing abdominal pressure will result in forcible fling off of the clip and bleeding afterwards.

2. Patients are followed up regularly. Generally, some patients' clips will fall off spontaneously with in 1 month and excreted out of the body with the digestive system, while a few clips are excreted out of the body with in 3 months; In rare cases, the duration is more than 3 months, and if the clip does not fall off more than 6 months, the doctor can remove the clip with a grasping forceps or other auxiliary devices.

CLINICAL BENEFIT

Disposable Dual Action Tissue Closure Device can close the wound to achieve hemostasis or close perforation.

SYMBOL INDICATIONS

	Do not re-use		Do not resterilize
	Date of Manufacture		Manufacturer
	Use-by date		Not made with natural rubber latex.
	Contents		Batch code
	Catalogue Number		Sterilized using ethylene oxide
	MR conditional		Keep away from sunlight

	Authorized representative in the European Community /European Union		Do not use if package is damaged and consult instructions for use
	Keep dry		Compatible working channel
	Consult instructions for use or Consult electronic instructions for use		Sterile barrier system
	Diameter		Caution
	Medical Device		Importer

【Packaging】 Packed in the preformed rigid tray with a die-cut lid

【Production Date】 See packaging

【Sterilization】 Sterilized by EO (ethylene oxide) gas

【Period of Validity】 3 years

WARRANTY

Micro-Tech Nanjing (MT) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning, and sterilization of this instrument as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond MT's control directly affect the instrument and the results obtained from its use. MT's obligation under this warranty is limited to the repair or replacement of this instrument and MT's shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. MT neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. MT assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for intended use, with respect to such instrument.

Instruction page for Electronic instructions for use website

To access the instructions for use, please go to

https://eifu.micro-tech.com.cn

by entering the product-specific IFU code STA01.

For a paper copy, provided in 7 days at no cost,

please call + 49(0)211 73 27 626-0

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