DuraClip

DuraClip Repositionable Hemostasis Clip
Instructions for Use

CONMED CORPORATION

ENGLISH/ INSTRUCTIONS FOR USE

CONMED DuraClip

Important information

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
- This device is intended for use by trained physicians only.
- 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 the instructions, please contact CONMED.
- Patients should be informed of the potential risks and complications which may lead to injury, illness or death of the patient.
- Do not use this device when hemostasis cannot be verified visually within the endoscopic field of view.
- Do not operate the spiral tube and clip with excessive force as this may cause damage to the device.
- Always observe the endoscopic image during operation. If the clip deploys prematurely, it may be removed with an endoscopic retrieval device.
- Confirm that the endoscopy view is clear before use.
- Not made with natural rubber latex.
- Federal (USA) Law restricts this device sale, distribution, and use by or on the order of a physician.
- This device is only intended for adult populations above 18 years old.

WARNINGS

- This product is intended for single use only! DO NOT reuse, reprocess or resterilize the device. Reuse, reprocessing or resterilization 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 or reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Do not use this device for any purpose other than the stated indications
  Operation of this device is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the device, or if any other unexpected circumstance takes place.
- It might impossible to stop bleeding because the clip performance for hemostasis is limited. Prepare more than one hemostatic device. Select the most appropriate hemostatic device for different hemorrhage situations. Some devices may be used together for the best result.

- Bleeding may recur at the clipping site, depending on the local condition. Check the patient for any recurring bleeding after the operation, as appropriate.
- 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.

Intended Use

The DuraClip Repositionable Hemostasis Clip is intended to be used for the placement within the gastrointestinal tract for the purpose of:

Endoscopic marking
Hemostasis for
a. mucosal/sub-mucosal defects <3 cm
b. bleeding ulcers
c. polyps <1.5 cm in diameter
d. diverticula in the colon
As a supplementary method, closure of gastrointestinal tract luminal perforations <20 mm that can be treated conservatively.

Device overview

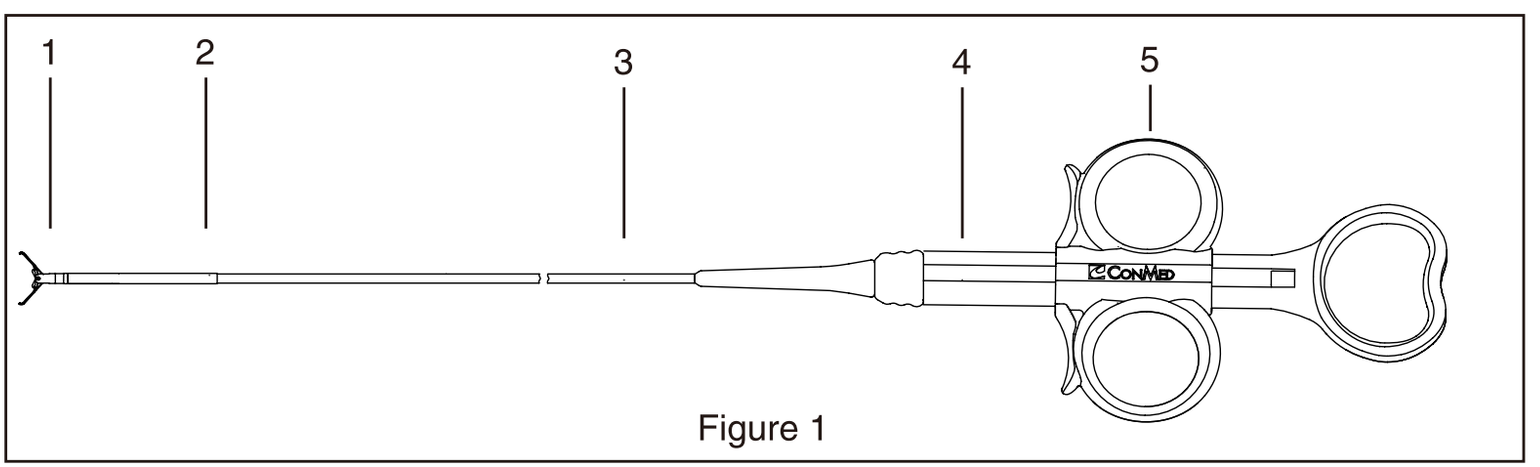

Figure 1

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

Contraindications

1. Mucosal/submucosal defects greater than 3 cm.
2. Polyps greater than 1.5 cm in diameter.
3. The patient with poor general condition that cannot tolerate endoscopy.
4. The patient has narrow upper digestive tract where endoscope cannot pass through.
5. The patient has serious coagulation disorders and hemorhagic 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 according to 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.

Preparation

1. Check use by date. Do not use device if expired.
2. Do not use the device if the packaging is damaged.
3. Open and take the device out of the package following sterile procedure.
4. Do not use the device if there are any function abnormalities or questions.

Instructions for Use

1. The device is compatible with an endoscope channel of 2.8 mm or larger.
2. Remove the protective sleeve. Carefully insert the device into endoscope channel, ensuring that the clip is the closed position (See Fig. 2).

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

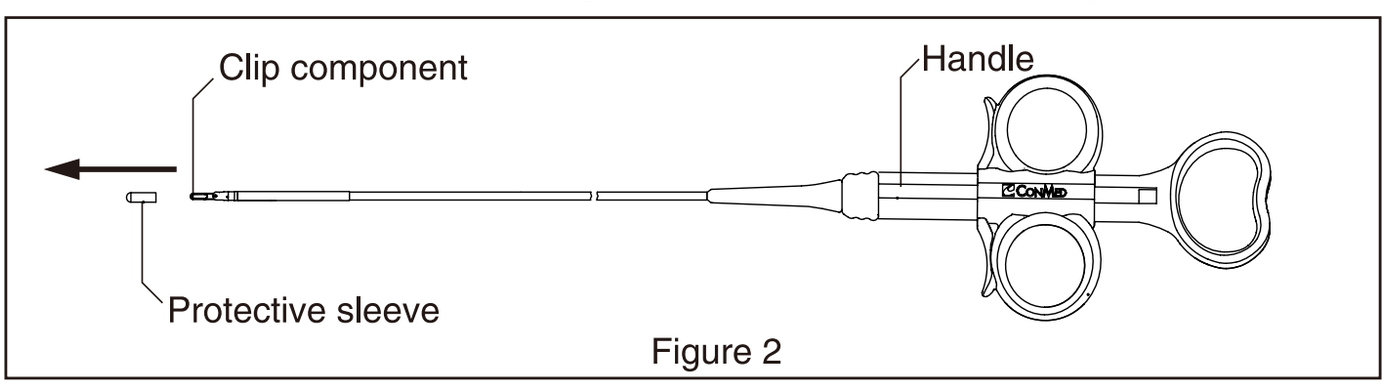

Figure 2

3. Pass the clip through the endoscope channel towards targeted site. Open the clip pushing slider forward (See Fig. 3).
4. Clip can be rotated clockwise or counter clockwise by turning handle until correct position is achieved. Advance device until contact is made with targeted site (See Fig. 4).

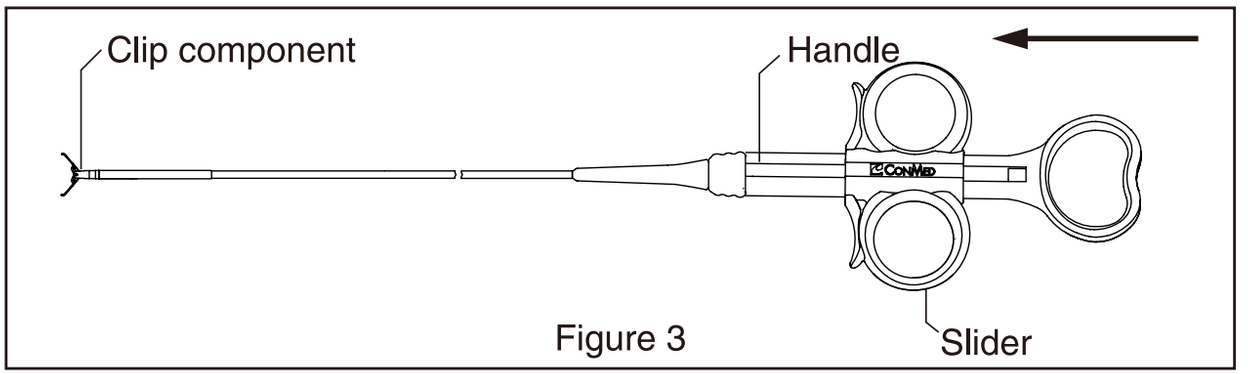

Figure 3

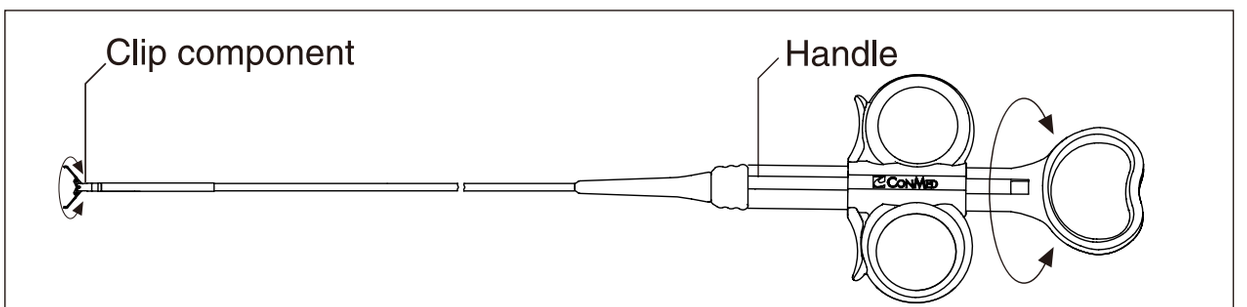

Figure 4

5. When satisfied with clip position, close the clip component against the tissue by pulling back the slider until tactile resistance is felt in the handle. Clip position may now be assessed prior to deployment. If clip is not in desired position, clip may be re-opened and repositioned (See Fig. 5).
Note: Do not continue to pull back the slider further 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.

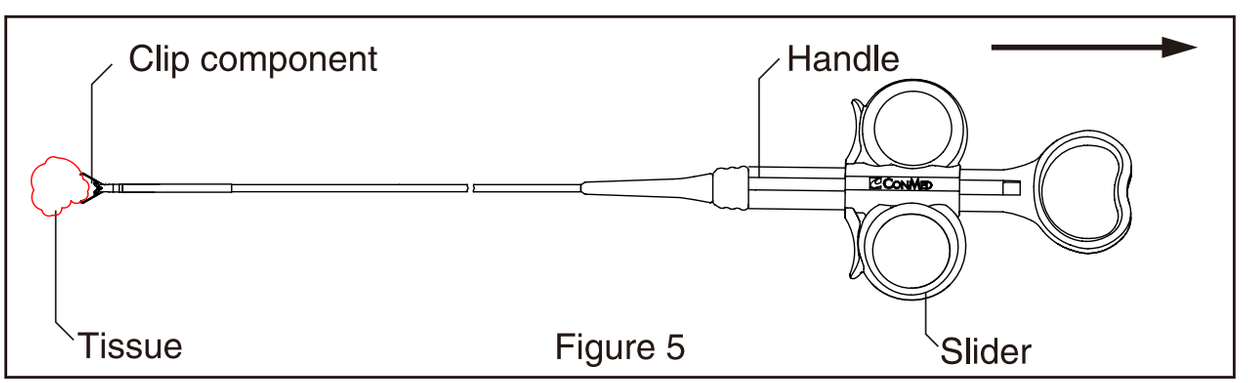

Figure 5

6. To deploy the clip, continue pulling back the slider beyond the tactile resistance point. You will hear an audible snap as clip component detaches (See Fig. 6).

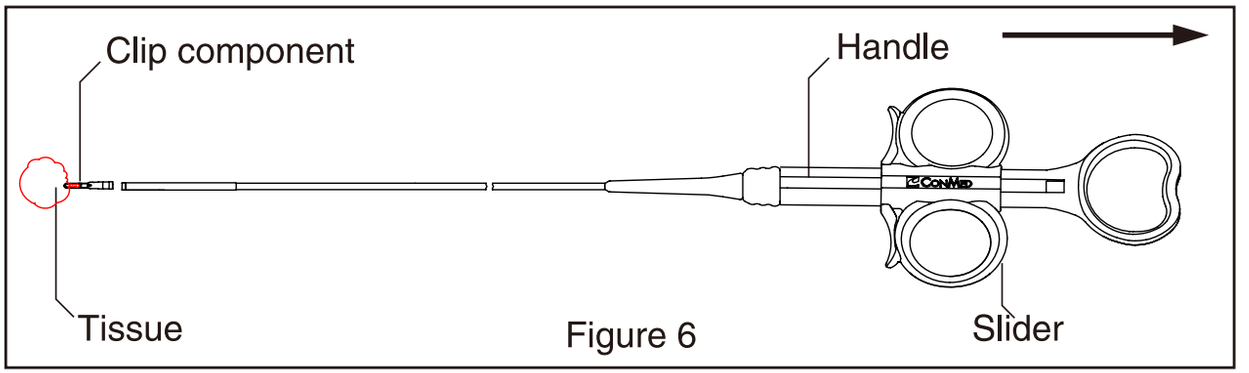

Figure 6

7. Remove sheath from endoscope.
   Note: Endoscope must remain as straight as possible when withdrawing the device.

Notes

1. After procedure ensure patient does not consume food too soon. Improper diet, forcible defecation, cough and other activities which increase abdominal pressure may detach the clip and cause bleeding.
2. 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.
3. Limited studies indicate that the treatment of esophageal varices may require clipping in the combination with sclersoing agent.
4. Limited studies indicate that clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
5. Limited studies have shown that the number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion, type, patient condition and history. A sufficient quantity of clips should be prepared in consideration of all of these factors prior to the procedure.
6. Limited studies indicate that the hemostasis clips remain in place for an average of 9.4 days. Bleeding may recur if the clips detach within 24 hours.
7. Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.

Storage

- Keep the device in a cool, dark and dry place.
- Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
- The sterilization is valid for 3 years. Prior to use, check the expiration date of sterilization on the label of the package.

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.

Symbol key

	**Do not reuse**		**Contents**
	**Use by**		**Diameter**
	**Manufacturer**		**Compatible working channel**
	**Sterilization using ethylene oxide**		**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician**
	**Lot number**		**Catalogue number**
	**Working length**		**Date of manufacturer**
	**Consult Instructions for use**		**Authorized representative in the European Community**
	**CE sign with the number of the notified body**		**MR Conditional**

Distributed by:

CONMED CORPORATION

CONTACTS
Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road, Nanjing National
Hi-Tech, Industrial Development Zone,
Nanjing 210032 Jiangsu Province, PRC
TEL:+ 86 25 58609879, 58646393
FAX:+ 86 25 58744269
Email: info@micro-tech.com.cn
www.micro-tech.com.cn

CONMED Corporation
525 French Road
Utica, NY 13502-5994 USA
1-800-448-6506
315-797-8375
www.conmed.com

MTN-ROCC-SM-CM
REV:A/1