MICRO-TECH®
ENDOSCOPY

In-Sight™ Multi-Band Ligator

Instructions for Use

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 USA.

INTENDED USE

The In-Sight Multi-Band Ligator is used to ligate internal hemorrhoids in adult patients only.

CONTRAINDICATIONS

- Contraindications specific to hemorrhoidal banding include but are not limited to; severe inflammatory bowel disease, coagulopathy or anal strictures.

POTENTIAL COMPLICATIONS

- Potential complications associated hemorrhoidal banding include but are not limited to, pain, bleeding, urinary symptoms, swelling, edema, tissue ulceration, and band dislodgement.
- Hemorrhoidal banding may result in severe pain if the procedure is performed below the dentate line.

WARNINGS AND PRECAUTIONS

- The product is intended for single use only! DO NOT re-use, and/or reprocess. Re-use, 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, 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, or reprocessed.
- Do not use this instrument for any purpose other than its intended use.
- The product is only intended for adult populations.
- Hemorrhoid banding may result in severe pain if the procedure is performed below the dentate line.
- Banding should begin at the most proximal location from the anal sphincter and proceed distally because passing the ligator over a previously placed band may dislodge band.
- 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.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

【 **Product Name** 】In-Sight Multi-Band Ligator

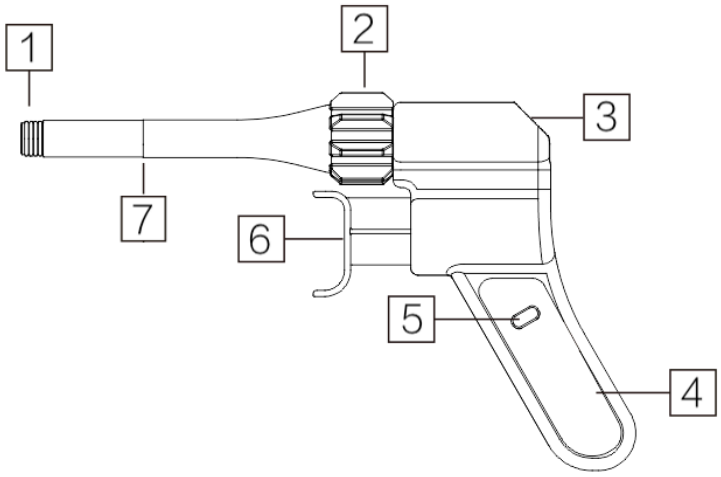
【 **Production Date** 】 See packaging

【 **Shelf Life**】 1 year

This device is not made with natural rubber latex.

STRUCTURE

The In-Sight Multi-Band Ligator provides illumination, suction, direct visualization and ligation capabilities in a single use device.



1. Ligator bands 2. Band actuation knob 3. Viewing pathway 4. Handle
5. Light on/off button 6. Vacuum drawing trigger 7. Depth indicator

Fig. 1 Diagram of In-Sight Multi-Band Ligator

PREPARATION

1. Inspect the package before use for any damage. Do not use if package is damaged.
2. Verify the expiration date. Do not use if expired.
3. Open the package and carefully remove the ligator. Inspect its integrity and proper placement of bands. Confirm function of the light by pressing the light on/off button.
4. If this device shows any signs of damage, or the light fails to illuminate, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

1. Lubricate the anus, perform rectal exam and insert an anoscope.
2. Activate the light of the ligator by pressing the on/off button on the ligator handle.
3. Inspect the lumen of the distal rectum for hemorrhoids with the ligator.
4. If ligation is indicated, grasp the ligator. Place the index finger on the vacuum drawing trigger and three other fingers and thumb around the ligator handle.
5. Squeeze the vacuum drawing trigger to force air out of the device.
6. Insert the ligator through the anoscope toward the hemorrhoids.
7. When the view through the anoscope becomes obstructed by the ligator, use

the viewing pathway of the ligator to maintain direct visualization of the hemorrhoids.

8. Position the tip of the ligator just above the hemorrhoids and press gently against the targeted area.
9. Release pressure on the trigger to activate suction.
10. Inspect the amount of tissue sucked into the tip of the ligator.
11. Confirm that the patient feels pressure and not pain.
12. Place the tip of the index finger on the band actuation knob and rotate clockwise. The rotation of the actuation knob will deploy a single band off the distal tip of the ligator.
13. Remove the ligator from the anoscope for repeat inspection of banding or ligate additional tissue without pulling the ligator out (repeat above steps as needed).
14. If direct visualization cannot be achieved, use the indicator groove on the ligator barrel to confirm tip location.
15. After the procedure is complete, turn off the light and dispose of the device in an approved manner.

Note: Repeat rectal examination should be performed after the final banding to document that the band was properly placed and that only mucosa was banded. Banded tissue must have a narrow “neck.”

Note: If the patient experiences pain or if the banded tissue has a thick “neck” then pushing the band up from the base of the banded tissue must be performed to release deeper layers of the rectal wall.

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.

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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