MICRO-TECH™
ENDOSCOPY

Multiple Band Ligator Set

Instructions for Use（USA）

-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 Multiple Band Ligator Set is used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids in adult patients only.

CONTRAINDICATIONS

- Those specific to the primary endoscopic procedure performed in gaining access to the desired banding site.
- Those specific to esophageal banding including but not limited to: cricopharyngeal or esophageal narrowing or strictures, tortuous esophagus, diverticula, known or suspected esophageal perforation, esophageal rings or webs, coagulopathy.
- Those specific to hemorrhoidal banding include but are not limited to: severe inflammatory bowel disease, coagulopathy or anal strictures.

POTENTIAL COMPLICATIONS

- Those associated with the primary endoscopic procedure.
- Those which may occur with esophageal banding including but not limited to: retrosternal pain, nausea, laryngeal laceration, esophageal perforation, stricture formation, obstruction.
- Those which may occur with hemorrhoidal banding include but are not limited to: severe pain, bleeding, urinary symptoms, swelling and edema, tissue ulceration and band dislodgement.
- Hemorrhoidal banding may result in severe pain if the procedure is performed below the dentate line.

WARNINGS

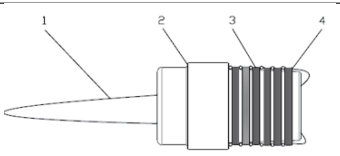
- **The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess.** Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization 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.
- Do not use this instrument for any purpose other than its intended use.
- The product is only intended for adult populations.
- Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
- The instrument is intended for use under the direct supervision of a suitable trained physician only. A thorough understanding of the technical principles, clinical applications, associated risks is expected before usage.

【**Product Name**】Multiple Band Ligator Set
【**Packaging**】Tray, Tyvek and PETG
【**Production Date**】See packaging
【**Sterilization**】Sterilized by EO (ethylene oxide) gas
【**Shelf Life**】1 year
【**Compatible Working Channel**】≥φ2.8 mm
【**Endoscope Diameter**】See packaging

STRUCTURE

The Ligator Cartridge with preloaded bands and Trigger Thread, The Handle Unit, Pull Wire and Irrigation Needle.

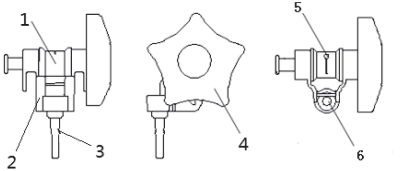
1. **The Ligator Cartridge with preloaded bands;** This is a transparent barrel with a soft elastic cap that allows it to be fixed on the distal end of the endoscope. Latex-free bands are mounted on to the barrel in a stretched condition. Each band is yellow with the second from last band being black. The Trigger Thread with release beads are placed under the rubber bands. The Trigger Thread has a loop on the proximal end for attachment to the Pull Wire. The Pull Wire is passed through the working channel of the endoscope and is attached to the Handle Unit. The bands are designed to be released by pulling the Trigger Thread using the Pull Wire and Handle Unit.



1. Trigger Thread；2. Soft Cap；3. Band；4. Barrel

Fig 1. The Ligator Cartridge with preloaded bands

2. The Handle Unit; When assembled, rotating the Knob of the Handle Unit in a clockwise direction, pulls the Pull Wire and wraps it around the Winding Drum. Continued winding of the Pull Wire results in band deployment. To assist in set up, pulling the Knob away from the Handle Unit, permits free clockwise or counter-clockwise rotation. Pushing the Knob towards the Handle Unit will lock it for clockwise rotation during use.



1. Winding Drum; 2. Handle Base; 3. Mounting Base; 4. Knob;
5. Pull Wire Tie Hole; 6. Valve Opening

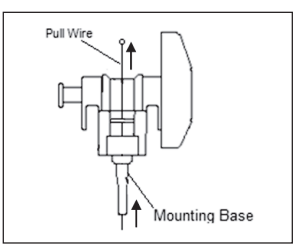
Fig 2. The Handle Unit

3. Irrigation Needle; A blunt irrigation needle is provided in a protective cover. Remove the cover prior to use.

Fig 3. Irrigation Needle

PREPARATION

1. Read the product label and select the appropriate device for the procedure and endoscope in use.
2. Inspect the package before use for any damage. Do not use if package is damaged.
3. Open the package carefully after verifying the expiration date.
4. The contents are supplied STERILE. Inspect the tray for damage, if damaged do not use.
5. Carefully remove the device from its packaging and uncoil the Pull Wire.
   Note: Do not use excessive force as this may damage the device and affect performance.
6. Visually inspect the device with attention to bends or breaks. If it appears damaged, do not use the device. Use the Irrigation Needle to puncture the self-sealing valve on the top of the Mounting Base of the Handle Unit.
7. Assemble the endoscope and open the endoscopes' biopsy valve cover. Insert the Handle Unit into the biopsy valve and secure the Handle Unit to the endoscope using the Velcro strap.
8. Introduce the looped end of the Pull Wire into the valve until it emerges out of the distal end of the endoscope.
9. Attach the free end of the Trigger Thread from the Ligator Cartridge to the loop at the end of the Pull Wire. Ensure that the Trigger Thread is securely attached to the Pull Wire.



10. Slip the white bead on the opposite end of the Pull Wire into the Pull Wire Tie Hole on the Winding Drum of the Handle Unit. Pull gently on the Pull Wire so that the bead disappears into the Tie Hole and the Pull Wire is firmly anchored to the Winding Drum.
11. Push the Knob of the Handle Unit in towards the Lock position to engage the rotation lock. Start rotating the Knob in a clockwise direction to remove the slack from the Pull Wire. Stop rotating when the Ligator Cartridge touches the end of the endoscope.
12. Secure the Ligator Cartridge onto the distal end of the endoscope by pushing the Soft Cap over the tip of the endoscope.
    Note: Ensure the cartridge is securely attached to the endoscope before proceeding.
13. Slowly rotate the Knob to take up any remaining slack until the distal tip of the endoscope begins to move slightly. This indicates that all the slack has been taken up and the device is ready for use.
14. Attach a water/saline-filled syringe to the Irrigation Needle to be used as needed.

INSTRUCTIONS FOR LIGATION OF ESOPHAGEAL VARICES

1. Introduce the endoscope, with Ligator Cartridge attached, into the esophagus.
2. Visualize the target varix.
3. Press the distal tip of the Ligator Cartridge Barrel against the varix.
4. Once complete contact is made around the varix, activate the suction of the endoscope and draw the tissue into the housing of the Ligator Cartridge Barrel. When the tissue is completely sucked into the housing, a “red out” will be observed.
5. Slowly rotate the Knob on the Handle Unit clockwise until a band is released. The tension on the Pull Wire and Knob of the Handle Unit will be reduced immediately after the band has been released and deployed.
   Note: Usually a band will deploy by turning the Knob slightly more than half a turn. If a band does not deploy even after a full turn, pull the Knob away from the Handle Unit to release the rotation lock. Ease the tension on the

Pull Wire and then push the Knob towards the Handle Unit to return to the locked position. Repeat step 5.

6. Release suction and confirm band placement in endoscopic view.
7. Rotate the Knob of the Handle Unit clockwise to take up any residual slack in the Pull Wire.
8. To ligate another varix, visualize a new target and repeat steps 3 to 7.
   Note: A black band indicates that one more ligation band is available for use.

INSTRUCTIONS FOR LIGATION OF INTERNAL HEMORRHOIDS

1) Introduce the endoscope, with Ligator Cartridge attached, into the rectum.
2) Visualize the target internal hemorrhoid.
3) Press the distal tip of the Ligator Cartridge Barrel against the internal hemorrhoid.
4) Once complete contact is made around the internal hemorrhoid, activate the suction of the endoscope and draw the tissue into the housing of the Ligator Cartridge Barrel. When the tissue is completely sucked into the housing, a “red out” will be observed.
5) Slowly rotate the Knob on the Handle Unit clockwise until a band is released. The tension on the Pull Wire and Knob of the Handle Unit will be reduced immediately after the band has been released and deployed.
   Note: Usually a band will deploy by turning the Knob slightly more than half a turn. If a band does not deploy even after a full turn, pull the Knob away from the Handle Unit to release the rotation lock. Ease the tension on the Pull Wire and then push the Knob towards the Handle Unit to return to the locked position. Repeat step 5.
6) Release suction and confirm band placement in endoscopic view.
7) Rotate the Knob of the Handle Unit clockwise to take up any residual slack in the Pull Wire.
8) To ligate another hemorrhoid, visualize a new target and repeat steps 3 to 7.
   Note: A black band indicates that one more ligation band is available for use.

REMOVING THE MULTI-BAND LIGATOR

1) Upon completion of the procedure, remove the endoscope from the patient while maintaining endoscopic view.
2) Dismantle the device.
   - If any bands remain on the Barrel:
     Place the Handle Base in the unlock position, loosen the Pull Wire, and remove the handle assembly from the endoscope biopsy valve.
     Detach the Pull Wire from the Winding Drum. Remove the Barrel from the endoscope tip, pulling the wire out from the distal end of the endoscope.
   - If all bands have been fired:
     Remove the handle assembly and pull wire from the endoscope.
     Remove the Barrel from the endoscope tip.

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 state and federal laws and regulations.

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