

Multi-band Ligator Instructions for Use



INTENDED USE

This device is used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

WARNINGS

- This device is designed for single use only. Attempts to reprocess, resterilize and/or reuse may lead to device failure and/or transmission of disease.
- This device is supplied non-sterile. Do not use this device for any purpose other than stated intended use.
- If package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks.
- If an abnormality is detected that would prohibit proper working condition, do not use.
- Use of this device restricted to a trained healthcare professional.
- Store in a dry location, away from temperature extremes.

CONTRAINDICATIONS

Those specific to primary endoscopic procedure to be performed in gaining access to desired banding site.

Those specific to esophageal banding include, but are not limited to: cricopharyngeal or esophageal narrowing or stricture, tortuous esophagus, diverticula, known or suspected esophageal perforation, asymptomatic rings or webs, coagulopathy.

Those specific to hemorrhoidal banding include, but are not limited to: severe inflammatory bowel disease, coagulopathy or anal strictures.

Use of ligation bands is contraindicated in patients with a known hypersensitivity to latex.

POTENTIAL COMPLICATIONS

Those associated with esophageal banding include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

Those which can occur with esophageal banding include, but are not limited to: retrosternal pain nausea, laryngeal laceration, esophageal, perforation, stricture formation, obstruction.

Those associated with esophageal banding include, but are not limited to: severe pain, bleeding, urinary symptoms, swelling and edema, tissue ulceration and band dislodgement.

Those which can occur with hemorrhoidal banding may result in severe pain if the procedure is performed below the dentate line.

PRECAUTIONS

- Refer to package label for minimum channel size required for this device.
- Band ligation may not be effective when applied to small varices.
- Esophageal ligation devices are not intended for ligation of varices below gastroesophageal junction.
- Current literature address management of acutely bleeding esophageal varices and does not address prophylactic use of banding.
- Passing endoscope over a previously placed band may dislodge band.
- Prior to assembling device, routine endoscopic examination is recommended to confirm diagnosis requiring treatment of esophageal varices or internal hemorrhoids.
- It is vital that the integrity of the working channel is intact as grooves or other obstruction in the working channel can potentially cause the string to catch, resulting in band deployment difficulty.
- Use of an endoscope in a sound state of repair is a prerequisite for a successful multi-band ligation procedure.

COMPONENT PARTS

Multi-Band Ligator handle, Loading catheter (with stainless steel pull wire inside), Irrigation adapter, Barrel with preloaded bands and attached trigger cord.

SYSTEM PREPARATION

1. Examine features of handle. It has two positions which control rotation. Firing position (fig.1) allows handle to be rotated in forward direction only. Two-way position (fig.2) allows handle to rotate in both directions. Prior to introducing endoscope, keep handle in two-way position.
2. Insert handle into endoscope accessory channel following instructions below for appropriate endoscope.
Olympus- With rubber cap on accessory channel, lift plug on cap and insert stem of handle. (fig.3a)
Pentax- Remove rubber cap from accessory channel. Place stem of handle through cap. Replace cap and inserted handle, as a unit, onto Luer lock fitting of accessory channel. (fig.3b)
Fujinon- Place stem of handle through rubber cap attached to endoscope accessory channel. (fig.3c)
3. Confirm that the loading catheter exits tip of endoscope. (fig.4)
4. Withdraw the loading catheter and discard it, exposing the pull wire round buckle. (fig.5) Dispose of loading catheter per institutional guidelines for biohazardous medical waste.
5. Bolt the trigger cord to the round buckle of the pull wire(fig.6) , and then attach barrel to tip of endoscope, ensuring barrel is advanced onto tip as far as possible. (fig.7)
6. With handle in two-way position, slowly rotate handle clockwise to wind pull wire onto handle spool until it is taut. (fig.8) Note: Care must be taken to avoid deploying a band while winding pull wire.
7. Check endoscopic view. To maximize visualization, position of trigger cord may be altered by rotating barrel. Note: Endoscopic view broadens after each band deployment.
8. Lubricate endoscope and exterior portion of barrel. Caution: Do not place lubricant inside barrel. Caution: Do not apply alcohol to device.

INSTRUCTIONS FOR LIGATION OF VARICES

1. With handle in two-way position, introduce endoscope into esophagus or rectum. (fig.9) After intubation, place handle in firing position.

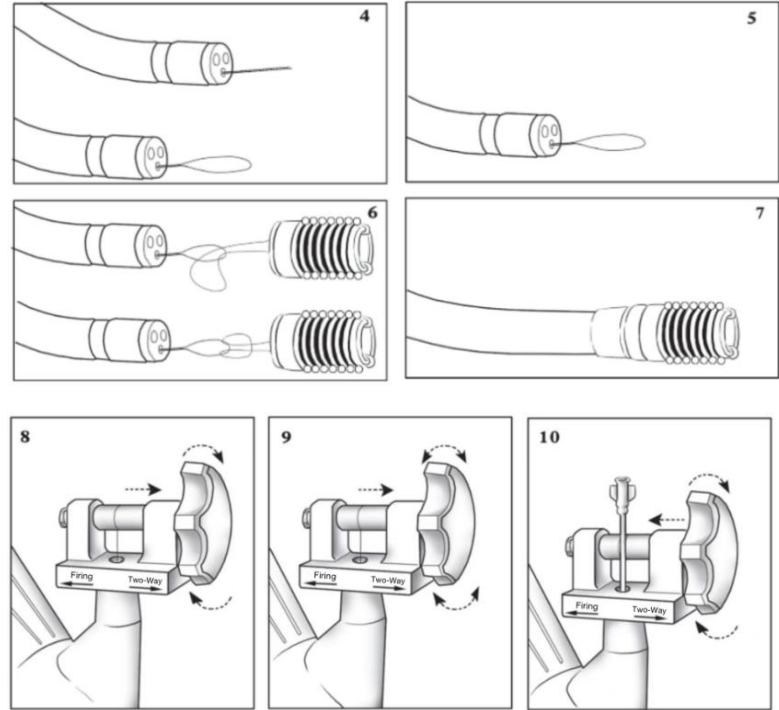
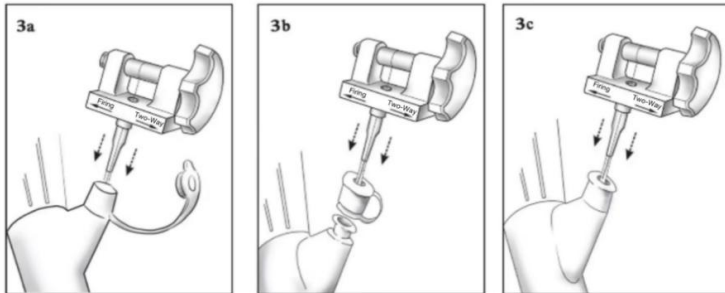
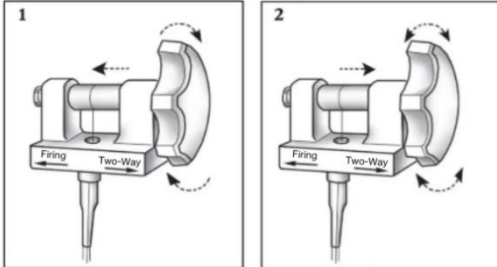
2. Visualize selected varix or internal hemorrhoid and aspirate it into barrel.

Caution: before releasing the bands, the physician's hand must be on the instrument handle, not the endoscope controls.

3. Maintain suction and deploy band by rotating handle clockwise until band release is felt, indicating deployment. Note: If band will not deploy, place handle in two-way position and loosen trigger cord slightly. Place handle in firing position and continue with procedure.

4. Release suction button of endoscope, insufflate air, then withdraw scope slightly to release ligated varix or internal hemorrhoid. Note: An irrigation adapter is provided with each device. If irrigation of accessory channel is desired to clear viewing field, attach adapter to a syringe filled with sterile water and insert into white seal of handle. Irrigate as necessary. (fig. 10)

5. Repeat ligation process as needed. Note: More than one ligation band for each varix or internal hemorrhoid may be required to control acute bleeding.



REMOVING THE MULTI-BAND LIGATOR

1. Upon completion of ligation procedure, remove endoscope from patient.
2. Dismantle device as follows:

If all the bands have been fired:

- Remove handle and pull wire from accessory channel.
- Remove barrel from endoscope tip.

If any unfired bands remain on the barrel:

















- Put the handle in the two-way position.
- Remove the barrel from endoscope tip, cut the trigger cord, and then pull the pull wire through the channel and out endoscope tip.

Upon completion of procedure, dispose of device per institutional guidelines for biohazardous medical waste.

STORAGE AND TRANSPORT CONDITIONS

Please store in a cool, dry place away from light.


INSTRUCTION OF SYMBOL

	CE certified by TUV SUD		Reference number
	Consult Instructions for Use		Single use
	Prescription only		Do not use if package opened or damaged
	Contains or presence of natural rubber latex		Non-sterile
	Keep Dry		Keep away from radiation and heat sources
	Lot number		Date of manufacture
	Date of Expiration		UDI
	Manufacturer		European Union representative

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FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN