

Surgi Band - Multiple Ligator

Description:

- Surgi Band Ligator Barrel with 6 bands
- Surgi Band Ligator Kit with 6 bands

Configuration:

See brochure

Intended use:

Used to ligate esophageal varices at and above the gastroesophageal junction.

Contraindications:

- Contraindications include, those specific to the primary endoscopic procedure to be performed in gaining access to the desired banding site.
- Contraindications 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.

Complications:

Possible complication associated with the gastrointestinal endoscopy include and not limited to perforations, fever, aspirations, hemorrhage, infections, hypotension, allergic reactions to medication, cardiac arrhythmia or arrest, respiratory depression or arrest. Furthermore complication that may occur with esophageal banding include but not limited to chest tightness, retrosternal pain, dysphagia or odynophagia and post-EVL (endoscopic variceal ligation) ulcer with or without bleeding, increase of portal hypertensive gastropathy, bacteremia, nausea, laryngeal pain, retrosternal pain, laceration, stricture formation, esophageal perforation, obstructions.

Caution:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Use of ligation bands is contraindicated in patients with known hypersensitivity to latex.
- A thorough understanding of the technical principles, clinical applications & risk associated with GI endoscopy and endoscopic banding is necessary before using this device. Surgi Band- multiple ligator should only be used by, or under supervision of, physicians thoroughly trained in therapeutic endoscopy and vessel banding.
- Banding should begin at the gastroesophageal junction and proceed up the esophagus. Passing the endoscope over a previously placed band may dislodge the band.
- Prior to assembling Surgi Band - multiple ligator, routine endoscopic examination is recommended to confirm the diagnosis requiring treatment of esophageal varices or internal hemorrhoids.

Precautions:

The coordination of endoscope accessory channel size with compatible devices is essential in obtaining optimal results during a procedure. The Surgi Band - multiple ligator requires a minimum

channel diameter of 2.8mm and maximum accessory channel length of 122cm.

Warning / Precaution:

- Do not use this device for any purpose other than stated intended use.
- If the product package is open or damaged when received, do not use the device.
- Inventory rotation of this device is essential. Verify the expiration date on the package label. If the expiration date has lapsed, do not use this device.
- Storage temperature between 5°C to 30°C.
- Single use only.
- Only experienced surgeons should use this device.
- Dispose in accordance with recognized medical practice and under observance of applicable law & regulation.

Instruction for Use:
Components:


- Surgi Band barrel with 6 bands & attached nylon thread.
- Surgi Band handle
- Loading hook catheter
- Irrigation adapter

Preparation:

1. Visually inspect the package and device for kinks, bends, breaks etc. If found abnormal, do no use. Please contact the company for information.
2. The handle is inspected for functionality for the two positions a) Firing: which allows the handle to be rotated in the forward direction only and b) Two-way position: which allows the handle to be rotated in both directions.
3. The stem of the handle is inserted into the accessory channel of the endoscope depending on the make.
4. Introduce the locking hook catheter through the septum / white seat in the handle and advance until it exits from the tip of the endoscope.
5. Attach the end of the nylon thread into the hook with 2 cm extending between the knot and the hook. Withdraw the hook catheter hooked with nylon thread through the handle.
6. Attach the Surgi Band barrel to the tip of the endoscope, ensuring tight fit.
7. With the endoscope tip straight, place the nylon thread into the groove of the supporter in the centre of the handle, and pull down till the knot is fixed into the slot, firmly.
8. With the Surgi Band handle in the two-way position, rotate the handle clockwise to wind the nylon thread on to the supporter until it is tight. Be careful not to tighten with force otherwise, band may get fired.
9. Check the endoscopic view which broadens after deployment of each band.
10. Lubricate the outside surface of the Surgi Band barrel and the scope.

REF Catalogue Number

LOT Batch Code

 Date of Manufacture

 Use By

 Consult Instruction for use

Rx only

Caution : Federal (USA) law restricts device to sale by or on the order of a physician.



Non Sterile



Keep out of sunlight



Keep Dry



Product contains natural rubber latex

11. With the handle in two way position, introduce the endoscope into the esophagus. After intubation, place the handle in the firing position.
12. Visualizing the farthest varix, aspirate it into the Surgi Band barrel.
13. Maintaining the suction, deploy the band by rotating the handle clockwise until the band “fire” is felt.
14. Releasing the suction button, insufflate air, and then withdraw the scope slightly to release the ligated varix.
15. Repeat the process as per requirements. More than one ligator band for each varix may be required to control acute bleeding.
16. If more bands are needed, remove the endoscope and attach a new barrel with preloaded bands.

Do not reuse, reprocess & resterilize:

Reuse and Reprocessing may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:

The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

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  Keep out of sunlight
  Keep Dry
  LATEX Product contains natural rubber latex



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