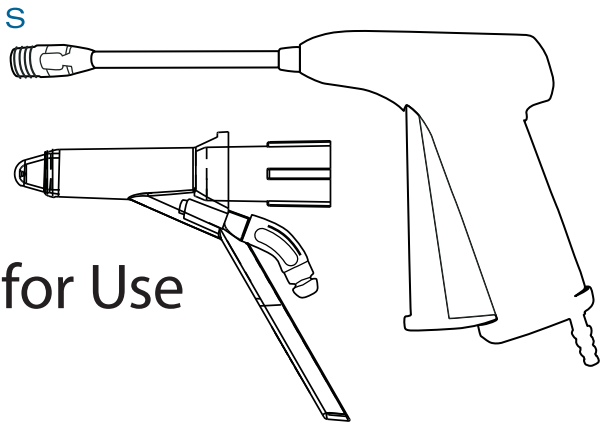
Sureband™ Ligator Kit Instructions for Use



by Orion Concepts Inc.
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INTENDED USE and INDICATIONS FOR USE

Sureband™ Ligator Kit consists of a multi-band ligator and anoscope with light guide and is used for the treatment of Grades 1, 2 and 3 internal haemorrhoids in adult patients. The kit is a disposable device.

The anoscopes may be used with or without a light source.

Sureband™ Ligator Kit: These devices are supplied clean and non-sterile in a sealed package and are meant for one-time use only. After use please dispose of in a suitable disposal unit and/or in accordance with local regulations.

Preparation for use

1. Remove the Sureband™ and Anoscope from the package and inspect for any visual damage prior to use.
2. Connect the Sureband™ multi-ligator to a medically approved suction source (>400 mmHg) and ensure that suction is functioning and present at device.
3. Insert light guide into GreenStar™ LED Endoscopic Illuminator (2) Leave obturator (3) in place during insertion
4. A suitable lubricant may be applied to the tip of the obturator and device tube.

Procedure

1. With obturator in place, insert the anoscope into the anus.
2. Remove obturator and view lumen to align tip of anoscope with the haemorrhoid to be banded and then pass anoscope over haemorrhoid to target tissue at neck.
3. Introduce the multi-ligator through the anoscope and lightly place the tip of the multi-ligator on the hemorrhoid and gently squeeze the trigger to the marked line. This will activate the suction to pull the haemorrhoid into the tip and secure an adequate amount of tissue.
4. Continue to pull the trigger to its final position to apply the band, and then release the trigger to reduce the suction and free the haemorrhoid.
5. When the trigger is released, the multi-ligator is automatically reloaded with the next band ready for immediate use on another hemorrhoid on the same patient.
6. After use dispose of the multi-ligator in a suitable disposal unit and/or in accordance with local regulations.

Positioning of the Band

The band is to be applied to the neck of the hemorrhoid so as to contain 1-2 mm of tissue to maximize its effectiveness in treatment. The ischemia from this stimulates a fibrous reaction, which gradually glues the mucosa to the wall of the rectum and anal canal and constricts the dilated vessels inside the hemorrhoid. This process deals with the 2 elements forming the hemorrhoid body, namely: the mucosal prolapse and the dilated vessels. As the aim of the treatment is not to strangulate the hemorrhoid, but to deal with the 2 elements of its pathogenesis, the place for the application is important and has to be at the highest point of the hemorrhoid.

WARNINGS & CAUTIONS

WARNING: Devices in transit or storage may be subject to damage beyond the control of the manufacturer or supplier.
WARNING: Inspect each device before use.
WARNING: Treat used multi-ligators and anoscopes as bio-hazardous, infectious material. Dispose of in a suitable disposal unit and/or in accordance with local regulations.
WARNING: Devices are not compatible with gamma radiation or auto-claving.

CAUTION: To be used by trained personnel only.
CAUTION: Do not use this device for any purpose other than the intended use.
CAUTION: If the package is opened or damaged when received, do not use. Visually inspect the devise and If an abnormality is detected that would prohibit proper working condition, do not use. Contact Orion Concepts Inc for a Return Authorization.
CAUTION: Rx Only. US Federal law restricts this device to sale by or on the order of a physician.
CAUTION: Obturator must be in place while inserting anoscope in patient.
CAUTION: Multi-band ligator and anoscopes are single-use only and must be disposed of after use to prevent possible risk of infection.
CAUTION: Protect from sunlight.
CAUTION: Use with caution when treating patients on anticoagulants i.e. Warfarin.

Contraindications

The bands are latex free however do not use to treat; 4th degree, continuously prolapsed haemorrhoids or Anal Polyps (In the presence of perineal infection, can be used after the infection has settled.)

Precaution

Use of Medical Drugs/ Medicines: Medical drugs such as aspirin and other antiplatelet agents should be discontinued 5-7 days before the procedure, and restarted 5-7 days after the procedure. This is due to the fact such drugs affect platelet dysfunction that can increase the risk of perioperative bleeding/ hemorrhage.

Stage of Haemorrhoid: Banding should not be the method used when there is not enough tissue to be secured into the nozzle of the device such as grade 4 haemorrhoids. In cases of grade 4 haemorrhoids, surgical intervention would be a more appropriate form of treatment such as standard haemorrhoidectomy or stapled haemorrhoidectomy.

Adverse Effects

The procedure of band ligation can cause common side effects such as light bleeding and slight discomfort; this is normal as the band detaches from the human body. Other effects, although infrequent, may be experienced post-procedure such as: perioperative bleeding/haemorrhage, severe pain due to bands placed above dentate line and close to anal canal, infection in anal area/sepsis, recurrence of haemorrhoid/(s), vasovagal response and band slippage.

Follow-up Treatment(s)

Additional treatments may be considered at 4-6 week intervals if required, such as prescribed pain medicines/ antibiotics. Success rates for banding are high, yet in some instances a further banding procedure is required if no change to condition has been reported.

Reference Chart		
Device	Class	Product Code
Sureband™ Ligator Kit – Includes multi-band ligator, medium anoscope and light-guide	II	40811
Sureband™ Ligator Kit – Includes multi-band ligator, large anoscope and light-guide	II	40811-3
Sureband™ – Multi-band ligator	II	40810
GreenStar™ LED Endoscopic Illuminator	I	GS-LEI-A-HP

Alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.

"WARNING" Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device

Caution, consult accompanying documents

Date of manufacture (yyyy-mm)

Recyclable Packaging Materials

REF Catalogue number

Temperature limitation

Keep away from rain

Do not use if package is damaged

Protect from sunlight

Manufacturer

LOT Batch code

Use by the date

LATEX Latex-Free

NON STERILE Non-sterile

Do not reuse

CUSTOMER SERVICE
2-451 Enfield Rd., Burlington ON, Canada L7T 2X5
Phone (289) 288-1448 Fax (289) 288-1450

ONLY TRAINED PERSONNEL SHALL USE ANOSCOPES.

Printed in Canada
IFU 1606 R6