Haemoband Plus Multi-band Ligator (H1002)

Instructions for Use

By Haemoband Surgical Ltd CE 0050

www.haemobandsurgical.com

INTENDED USE and INDICATIONS FOR USE

Haemoband Plus Multi-band ligator is a class IIa latex free, single use, disposable instrument used for the band ligation of internal 1st, 2nd, and 3rd degree haemorrhoids of adults (18+ years) . The Haemoband Plus is a clean and non-sterile device designed to reduce procedure times for band ligation and simplify the procedure by requiring less people.

Preparation for use

1. Remove the Haemoband Plus Band-ligator from the airtight non-sterile pack.
2. Attach a flexible tube from an approved medical suction pump, or internal suction system using the universal connector located at the bottom of the multi-ligator handle. Negative pressure for optimum use, 600mmHg.

Procedure

1. Introduce the Haemoband Plus through a proctoscope/anoscope.
2. Place the tip of the multi-ligator on the hemorrhoid and gently squeeze the trigger to the marked line. This will induce the amount of suction necessary to secure an adequate amount of tissue.
3. 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.
4. When the trigger is released, the Haemoband Plus is automatically reloaded with the next band ready for immediate use on another haemorrhoid on the same patient.
5. After use the device should be disposed of in the appropriate manner.

WARNING & CAUTIONS

WARNING: Devices in transit or storage maybe subject to damage beyond the control of the manufacture or supplier.

WARNING: Inspect each device before use.

WARNING: Treat used Hameoband Plus as bio-hazardous, infectious material. Dispose of in a suitable disposal unit and/or in accordance with local regulations.

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 received open or damaged, do not use. Visually inspect the device if an abnormal defect is detected that would prohibit proper working condition, do not use. Contact the supplier or Haemoband Surgical Ltd for return.

CAUTION: Haemoband Plus is a single-use device and must be disposed of after use to prevent risk Infection.

CAUTION: Protect from UV light

CAUTION: Use with caution when treating patients on anticoagulants.

CONTRAINDICTIONS

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.)

PERCAUTION

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/ haemorrhage.

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 TREATMENTS

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.

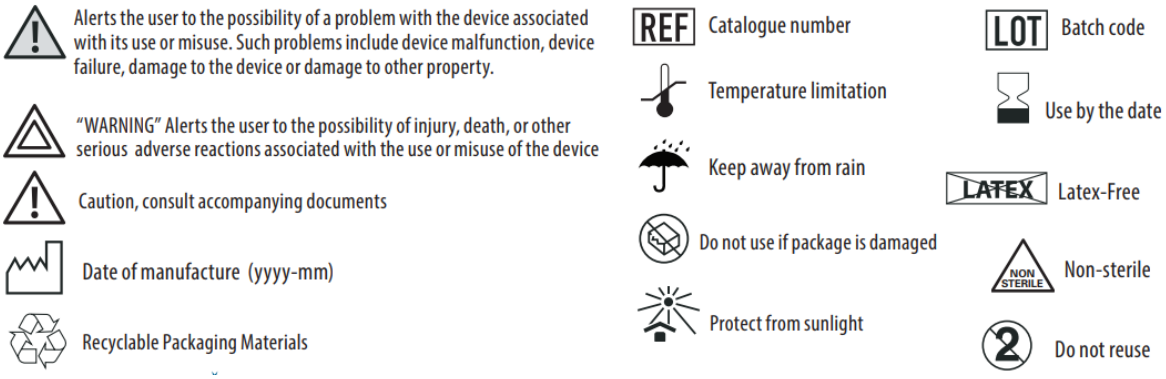
STORAGE

The multi-ligators are supplied in boxes of 10. They are kept in these boxes during storage in clean conditions and at room temperatures- recommended between 5°C and 30°C. Multi-ligators should be used within 18 months of manufacture.

The use by date is clearly printed on the cover of each pack.

NOTICE

In the event of a serious incident in relation to the device please notify the manufacture and the competent authority in which the user and/or patient is established.



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