



Haemoband Plus Multi-band Ligator (H1002)

Instructions for Use

By Haemoband Surgical

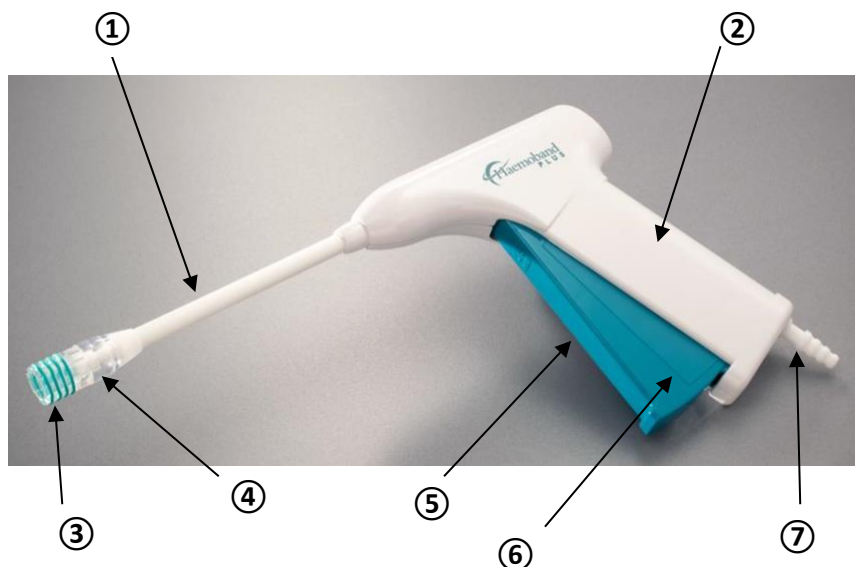
CE 0050

www.haemobandsurgical.com

INTENDED PURPOSE

Haemoband Plus Multi-band ligator is a class IIa latex free, single use, disposable instrument used for the band ligation of 1st, 2nd, and 3rd degree internal 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. The standard band is one size fits all, for all qualified patients.

The Haemoband Plus Multi-Ligator device is best used in combination with general purpose equipment that includes: negative pressure suction apparatus (portable or fixed source) and anal dilator.



Number	Component Name
①	Neck Tube
②	Handle
③	Latex free bands
④	Ligator tip
⑤	Multi-functional handle
⑥	Halfway mark line (to initiate suction)
⑦	Universal suction connector

INTENDED USE

To be used by a qualified medical doctor specialising in either General Surgery, Colorectal or Gastrointestinal specialities.

INSTRUCTIONS FOR USE

Preparation for use

1. Remove the Haemoband Plus Band-ligator from the airtight non-sterile pack and inspect each device before use.
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. The Haemoband Plus requires a low-pressure surgical aspirator up to a maximum of -600 mmHg.

Procedure

1. Introduce the Haemoband plus into the anus through an appropriate dilator.
2. Place the tip of the multi-ligator device onto the neck of the haemorrhoidal tissue at the highest point, in the upper section of the anal canal, thus ensuring maximum distance from the pectinate line (or dentate line).
3. Gently squeeze the trigger of the multi-functional handle to the marked on the trigger, inducing the negative pressure suction of the tissue into the barrel of the tip.
4. Once enough tissue has been drawn into the barrel, continue to pull the trigger to its fully squeezed position to apply the band. Then release the trigger to its original state, which will reduce and cease the negative pressure suction and therefore freeing the haemorrhoidal tissue from the barrel of the tip.
5. When the trigger is released, the Haemoband Plus will automatically reload with the next band ready for immediate use on another haemorrhoid on the same patient.
6. After use the device should be disposed of in the appropriate manner.

WARNINGS & PRECAUTIONS

WARNING: Do not use if the package is received open or damaged.

WARNING: Inspect each device before use. Do not use if defect or abnormality is detected on either the device or packaging. If an abnormal defect is detected contact the supplier or Haemoband Surgical Ltd for return.

WARNING: Do not use negative pressure suction exceeding 600mmHg.

WARNING: Do not use this device for any purpose other than the intended 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: Do not ligate tissue on or below the pectinate line (or dentate line).

CAUTION: Medical drugs such as antiplatelet agents should be discontinued 7 days before the procedure and restarted 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.

CAUTION: Do not use the device for more than one procedure (one patient only). Haemoband Plus is a single-use device and must be disposed of after use to prevent risk of cross-contamination.

CONTRAINDICATIONS

- Do not use on Anal Polyps
- Do not use on grade IV haemorrhoids or continuously prolapsed haemorrhoids
- Do not use on patients with a perineal infection
- Do not use on patients on anticoagulants or with bleeding disorders
- Do not use on patients with an anal fissure
- Do not use on patients who are pregnant

INDICATIONS FOR USE

- Band ligation of 1st, 2nd, or 3rd degree internal haemorrhoids.
- Adults (18+) who are exempt from contraindications list.

STORAGE

The multi-ligators are supplied in boxes of 10. They are kept in these boxes during storage in clean (non-sterile) conditions and at room temperatures - recommended between 5°C and 30°C, away from direct sunlight. Haemoband Plus Multi-ligators should be used within 18 months of manufacture. The use by date is clearly printed on the cover of each pack.

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 below 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.

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.

SYMBOLS

	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.		Catalogue number		Batch code
	"WARNING" Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device		Temperature limitation		Use by the date
	Caution, consult accompanying documents		Keep away from rain		Latex-Free
	Date of manufacture (yyyy-mm)		Do not use if package is damaged		Non-sterile
	Recyclable Packaging Materials		Protect from sunlight		Do not reuse

CE The presence of the logo on commercial products indicates that the manufacturer or importer affirms the goods' conformity with European health, safety, and environmental protection standards.

R_x Caution: Federal law restricts this device to sale by or on the order of a licensed Practitioner



Haemoband Surgical Ltd.
The Mount Business Centre
2 Woodstock Link
Belfast, BT6 8DD
Northern Ireland (UK)
Tel: +44 (0)28 90 737 283

