

Speedband Superview Super 7™ Multiple Band Ligator

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

RX Only

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

Warnings

Contents supplied NON-STERILE. Do not use if damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Indications For Use

The Speedband Superview Super 7 Multiple Band Ligator is used for endoscopic ligation of esophageal varices and anorectal hemorrhoids.

Contraindications

The Speedband Superview Super 7 Multiple Band Ligator is contraindicated for patients with bleeding disorders, unless the bleeding disorder is first identified and treated appropriately, and is contraindicated for any other condition which would otherwise contraindicate gastrointestinal endoscopy. The Speedband Superview Super 7 Multiple Band Ligator is not intended for ligation of esophageal varices below the gastroesophageal junction.

Adverse Events

Of Esophageal Variceal Ligation

- Esophageal ulceration.
- Retrosternal chest pain secondary to initial banding or ulceration at banding sites.
- Treatment-related bleeding secondary to ulceration at banding sites.
- Esophageal stricture formation.
- Esophageal perforation.
- Esophageal obstruction.

Of Anorectal Hemorrhoidal Ligation

- Severe pain, which may result from treatment of hemorrhoids below the dentate line.

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Precautions

- The Speedband Superview Super 7 Multiple Band Ligator should only be used by or under the supervision of physicians trained in variceal and hemorrhoidal band ligation. A thorough understanding of the technical principles, clinical applications and risks associated with variceal and hemorrhoidal band ligation is necessary before using this device.
- The materials used in this device have been found to be an irritant in animal studies.
- Any use of this device, other than those indicated in these instructions, is not recommended.