



Brief Summary Document

Overview

Product	Speedband Superview Super 7™ Multiple Band Ligator – IFU 52073322
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Rx Statement

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

Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

Content

INTENDED USE/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.

WARNINGS

- 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.

- Ensure the trip wire is secured; failing to do so could lead to deployment failures which could lead to a delay in treatment.
- Do not remove the shrink wrap until specified, premature removal of the shrink wrap could lead to ligator thread becoming dislodged and result in deployment issues which could lead to a delay in treatment.
- If the Black Stripe is not aligned with the working channel, the bands may fire improperly or not at all, and the field of vision may be impaired leading to a delay in treatment.
- Esophageal variceal ligation may not achieve complete fibrosis of inner wall of esophagus which may be necessary to prevent rebleeding or recurrence of varices.
- Hemorrhoidal ligation should only be performed on internal hemorrhoids above the dentate line. Treatment below (caudal to) this level may result in severe pain.

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.
- A thorough understanding of the technical principles, clinical applications, and risks associated with endoscopic variceal and anorectal hemorrhoidal band ligation is necessary before using the device.
- Do not use any component if the package is damaged or opened.
- Do not use if components are broken or damaged.
- If Black Stripe is not aligned with working channel, bands may fire improperly or not at all and field of vision may be impaired.
- Unless the shrink wrap is removed, bands will not fire.
- Caution: Hemorrhoidal ligation should only be performed on internal hemorrhoids above the dentate line. Treatment below (caudal to) this level may result in severe pain.
- Caution: Ligating bands may be difficult to apply to small (Grade 1) varices. It is not generally necessary to ligate Grade 1 varices.
- Caution: Esophageal variceal ligation may not achieve complete fibrosis of inner wall of esophagus which may be necessary to prevent rebleeding or recurrence of varices.
- 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.

ADVERSE EVENTS

Complications associated with any use of the Speedband Superview Super 7 Multiple Band Ligator may include:

- Allergic Reaction
- Discomfort
- Dysphagia
- Embolism

- Gastrointestinal Symptoms
- Hemorrhage
- Infection
- Inflammation
- Obstruction
- Pain
- Perforation
- Stricture formation
- Tissue Damage
- Treatment-related bleeding secondary to ulceration at banding sites
- Ulceration
- Vasovagal Symptoms

Additional complications associated with Anorectal Hemorrhoidal ligation may include:

- Incontinence
- Prolapse of Organ
- Urinary Retention