Speedband SuperView Super7™ Multiple Band Ligator

Prescriptive Information

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

Intended Use/Indications for Use

The SpeedBand SuperView Super 7 Multiple Band Ligator is used for endoscopic ligation of esophageal varices and anorectal hemmorrhoids.

Contraindications

The SpeedBand SuperView Super 7 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.

Contents supplied non-sterile. Do not use if damaged. If damage found, call your Boston Scientific representative.

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

Potential Adverse Events

Potential adverse events of esophageal variceal ligation may include, but are not limited to: 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, and esophageal obstruction.

Potential adverse events of anorectal hemorrhoidal ligation may include, but are not limited to: severe pain, which may result from treatment of hemorrhoids below the dentate line.

Please be aware that potential adverse events may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

Cautions

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.