



Product Name: SpyGlass™ Retrieval Snare

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

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.

REUSE WARNING

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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.

INTENDED USE/INDICATIONS FOR USE

The SpyGlass Retrieval Snare is indicated for the endoscopic retrieval of foreign bodies in the pancreaticobiliary system. This device should not be used for any purpose other than its intended application.

CONTRAINDICATIONS

Contraindications for this device are those specific to endoscopic retrograde cholangiopancreatography (ERCP).

WARNINGS

- Do not contact any electrified instrument with the SpyGlass Retrieval Snare in order to avoid patient and/or user injuries such as electric shock.
- Do not use the SpyGlass Retrieval Snare to retrieve metal stents.
- The device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- Do not use SpyGlass Retrieval Snare for polypectomy.
- If the device fails to operate properly in any way or shows any signs of damage, DO NOT USE IT in order to avoid device performance issues and/or patient injury. Call Boston Scientific Customer Service and return the product.

PRECAUTIONS

- DO NOT force the snare through the working channel in order to avoid device damage.

POTENTIAL ADVERSE EVENTS

Possible complications that may result from an ERCP procedure include, but may not be limited to:

- Allergic reaction
- Cholangitis
- Cholecystitis
- Hemorrhage
- Inflammation
- Pancreatitis
- Perforation
- Septicemia/infection
- Tissue Damage