



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

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

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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.

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

Intended Use/ Indications For Use

The SpyGlass Retrieval Basket is indicated for endoscopic removal of stones, stone fragments, or foreign bodies in the pancreaticobiliary system. The retrieval basket should not be used for any purpose other than its intended application. This basket is not indicated for lithotripsy.

Contraindications

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

Warnings

- To avoid basket impaction, use fluoroscopy or x-ray and direct visualization to determine the size of the stone or foreign body.
- Do not use basket if stone or foreign body cannot be removed endoscopically or held in the basket.
- The device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- Do not contact any electrified instrument with the SpyGlass Retrieval Basket.
- Do not use the SpyGlass Retrieval Basket to retrieve metal stents.

Precautions

The SpyGlass™ Retrieval Basket should only be used by or under the supervision of physicians trained in ERCP. A thorough understanding of the technical principles, clinical applications and risks associated with ERCP is necessary before using this device.

Before using, inspect the pouch for any breach of the package to ensure a sterile product.

Adverse Events

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

- Basket impaction
- Perforation
- Hemorrhage
- Septicemia/infection
- Cholangitis
- Pancreatitis
- Cholecystitis
- Allergic reaction