

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

Intended Use/Indications for Use

The SpyBite Biopsy Forceps are indicated for tissue acquisition in the pancreaticobiliary system.

Contraindications

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

Warnings

The SpyBite Biopsy Forceps should only be used to biopsy tissue where possible hemorrhage will not present a danger to patients.

The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies.

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 patient 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.

Potential Adverse Events

Complications associated with the use of the SpyBite Biopsy Forceps may include: bleeding, perforation, infection, peritonitis, and inflammation.

Please be aware that potential adverse effects 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.