

# SpyBite™ Max Single-Use Biopsy Forceps

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.  
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

The SpyBite Max Single-Use Biopsy Forceps are designed to collect tissue samples endoscopically for histologic examination. These instruments should not be used for any purpose other than the intended function.

## Indications for Use

The SpyBite™ Max Single-Use 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 Max Single-Use 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.

## Precautions

Read the entire directions for use before using the SpyBite Max Single-Use Biopsy Forceps.

The packaging and the device should be inspected prior to use. Do not use the device if the product or packaging is damaged

## Adverse Events

Complications associated with the use of the SpyBite Max Single-Use Biopsy Forceps may include:

- Bleeding
- Perforation
- Infection
- Peritonitis
- Inflammation