



## Brief Summary Document

### Overview

---

**Product** SpyBite™ Max Single-Use Biopsy Forceps – IFU 52024603-01A

---

### 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.*

### Content

#### INTENDED USE

The SpyBite Max Single-Use Biopsy Forceps is designed to endoscopically collect tissue samples 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 is indicated for tissue acquisition in the pancreaticobiliary system.

#### CONTRAINDICATIONS

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

## **WARNINGS**

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

### **GENERAL 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**

- Kinks in the shaft will hinder the mechanical operation of the SpyBite Max Single-Use Biopsy Forceps.
- When the forceps are employed with other instruments or accessories in a procedure, verify their compatibility in advance to avoid device damage.
- DO NOT force the forceps through the working channel as this may result in device damage.
- Applying excessive force to the instrument may damage it. The forceps should be held with the index finger and middle finger around the spool with the thumb in the ring at the end of the handle.
- If for any reason the biopsy jaws fail to close properly or completely, DO NOT try to withdraw partially open forceps through the delivery device. Pull the forceps back to the channel opening and then withdraw the delivery device and forceps together in order to avoid scope and/or device damage.
- When using an endoscope as the delivery device, lower the elevator before withdrawing forceps through the working channel in order to avoid scope and/or device damage.

### **POTENTIAL ADVERSE EVENTS**

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

- Bleeding
- Cholangitis
- Embolism
- Infection
- Inflammation
- Pain
- Pancreatitis
- Perforation
- Peritonitis
- Tissue Damage