



## **Product Name:** SpyGlass™ Retrieval Basket

### **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 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**

- Use fluoroscopy or x-ray and direct visualization to determine the size of the stone or foreign body in order to avoid basket impaction and patient injury.
- Do not use basket if stone or foreign body cannot be removed endoscopically or held in the basket to avoid patient injuries such as tissue damage, bleeding and/or additional interventions to remove the object from the patient.
- 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 in order to avoid patient and/or user injuries such as electric shock.
- Do not use the SpyGlass Retrieval Basket to retrieve metal stents.
- 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 basket through the working channel in order to avoid device damage.
- Some stones are very soft and may be broken if too much pressure is applied. Stones or foreign bodies should not be removed through the working channel of the SpyGlass delivery device. In order to remove stones or foreign bodies the SpyGlass delivery device and SpyGlass Retrieval Basket must be removed simultaneously from the pancreaticobiliary system.

## POTENTIAL ADVERSE EVENTS

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

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