

RX Cytology Brush

Wireguided Cytology Brush

Prescriptive Information

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

Caution/Rx Only:

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

Warnings:

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 RX Cytology Brush Wireguided Cytology Brush is used endoscopically to collect cells or to obtain a cholangiogram in the biliary system.

Contraindications:

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

Precautions:

The RX Cytology Brush Wireguided Cytology Brush should only be used by or under the supervision of physicians thoroughly trained in endoscopic biliary procedures. A thorough understanding of the technical principles, clinical applications, and risks associated with ERCP and ES is necessary before using this device.

Monitor the catheter position with contrast media injection and fluoroscopy.

The RX Cytology Brush Wireguided Cytology Brush is designed for use with an endoscope working channel that has a diameter of at least 2.8 mm.

Due to various tolerances among manufacturers, it is recommended that the RX Cytology Brush Wireguided Cytology Brush be used with a Boston Scientific 0.035 in (0.89 mm) guidewire.

Any use of this device, other than those indicated in these instructions, is not recommended.

Adverse Events:

Potential complications include, but may not be limited to:

- Perforation
- Hematoma
- Pancreatitis
- Septicemia/Infection
- Hemorrhage
- Cholangitis
- Allergic reaction to contrast medium