



RX Biliary Wireguided Cytology Brush

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

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.

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.

INTENDED USE / INDICATIONS FOR USE

The RX Biliary Wireguided Cytology Brush is used endoscopically to collect cells and/or to aid in the delivery of contrast during a cholangiogram in the biliary system.

CONTRAINDICATIONS

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

WARNINGS

- While brushing, monitor the catheter position with contrast media injection and/or fluoroscopy in order to avoid patient injury.
- Any use of this device, other than those indicated in these instructions, is not recommended and could result in patient injury.

PRECAUTIONS

Before using, inspect the package for any breach to confirm the product's sterility. If the package has been opened, do not use the catheter.

POTENTIAL ADVERSE EVENTS

Potential complications include, but may not be limited to:

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