



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

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/ Indications For Use

The RX ERCP Cannulas are indicated for use to cannulate and inject contrast media to obtain a cholangiogram of the biliary duct system. The contrast media is injected through the cannula and fluoroscopy or x-ray is performed to obtain the cholangiogram.

Contraindications

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

Adverse Events

Possible complications include, but may not be limited to:

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