



Product

RX ERCP CANNULA – IFU 51570330-01B Rev. A

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.

DEVICE DESCRIPTION

Contents

One (1) RX ERCP Cannula

The RX ERCP Standard, Tapered and Ball Tip Cannulas are double lumen ERCP cannulas tapered from 8.5F (2.8 mm) to 5F (1.7 mm) over the distal 25 cm (250 mm). The RX ERCP Standard, Tapered and Ball Tip Cannulas are capable of accepting 0.035 in (0.89 mm) Jagwire Guidewire. Injection of contrast media is delivered through a dedicated injection lumen. If a guidewire is in place, the contrast will flow through the guidewire lumen for the final 25 cm (250 mm).

User Information

The RX ERCP Standard, Tapered and Ball Tip Cannulas may be placed with or without the aid of a guidewire. Color-coded, endoscopic visual markers are located on the distal tip to endoscopically aid in the assessment of the catheter cannulation and insertion into the biliary system. A distal radiopaque marker aids in catheter visualization during fluoroscopy/cholangiography.

Catheter Shaft

The guidewire channel of the catheter accommodates a 0.035 in (0.89 mm) Jagwire Guidewire through the length of the RX ERCP Cannula. Contrast media injection may be achieved by attaching a contrast filled syringe to the side port of the proximal luer.

Catheter Tip

The distal tip of the catheter contains a radiopaque (RO) marker. This RO marker can be used to fluoroscopically monitor and/or confirm position.

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).

WARNINGS

- Monitor the catheter position with contrast medium injection and fluoroscopy in order to prevent patient injury.
- Any use of this device, other than those indicated in these instructions, is not recommended as this may result in a patient injury.

PRECAUTIONS

- The RX ERCP Cannulas should only be used by or under the supervision of physicians trained in ERCP and/or ES. A thorough understanding of the technical principles, clinical applications and risks associated with ERCP and ES is necessary before using this device.
- The RX ERCP Cannulas are designed for use with an endoscope working channel that has a diameter of 3.2 mm or larger.
- The RX ERCP Cannulas are recommended to be used with Boston Scientific's 0.035 in (0.89 mm) Jagwire Guidewire.

OPERATIONAL INSTRUCTIONS

PRECAUTIONS

Kinks in the catheter will hinder injection capability. Do not use the RX ERCP Cannula if any defects are found during inspection. Please notify Boston Scientific and return for replacement.

The RX ERCP Cannulas are designed to pass through a 3.2 mm (or larger) working channel endoscope and into the biliary system.

Advance the cannula using short deliberate 2-3 cm (20-30 mm) movements to prevent kinking of the catheter.

Once the RX ERCP Cannula has been removed and a guidewire has been left in the biliary system, the cannula cannot be reloaded over the positioned 0.035 in (0.89 mm) Jagwire Guidewire.

ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Allergic reaction
- Cholangitis
- Hematoma
- Hemorrhage
- Pancreatitis
- Perforation
- Septicemia/Infection

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