



Brief Summary Document

Overview

Product

Tandem™ XL Triple Lumen ERCP Cannula – IFU 52177894

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.*

Content

INTENDED USE/INDICATIONS FOR USE

The Tandem XL Triple Lumen ERCP Cannula is used to inject contrast medium to obtain a cholangiogram of the biliary duct system. The contrast medium is injected through the cannula, and fluoroscopy or X-ray is performed to obtain the cholangiogram.

CONTRAINDICATIONS

Only those contraindications specific endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic to sphincterotomy (ES).

WARNINGS

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.

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 Tandem XL Triple Lumen ERCP Cannula should only be used by or under the supervision of physicians trained in ERCP and/or ES. A thorough understanding of the technical principals, clinical applications and risks associated with ERCP and ES is necessary before using this device.

The Tandem XL Triple Lumen ERCP Cannula is designed for use with an endoscope working channel that has a diameter of 2.8 mm or larger.

The Tandem XL Triple Lumen ERCP Cannula is to be used only with 0.035 in (0.89 mm) guidewires.

Kinks in the catheter will hinder injection capability. Do not use the Tandem XL Triple Lumen ERCP Cannula if any defect is found during inspection. Please notify Boston Scientific and return for replacement.

The Tandem XL Triple Lumen ERCP Cannula is designed to pass through a 2.8 mm working channel (or larger) endoscope and into the biliary system.

Advance the cannula using short deliberate 2-3 cm movements to prevent kinking of the catheter.

Once the Tandem 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) guidewire.

POTENTIAL ADVERSE EVENTS

Possible complications that may result from cholangiographic procedures include, but may not be limited to:

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