



Brief Summary Document

Overview

Product

Extractor™ Pro RX Retrieval Balloon Catheter and Extractor™ Pro RX-S Retrieval Balloon Catheter – IFU 51878205

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 Extractor Pro RX Retrieval Balloon Catheter and the Extractor Pro RX-S Retrieval Balloon Catheter are indicated for use endoscopically to remove stones from the biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

CONTRAINDICATIONS

Contraindications for this device are those specific to endoscopic retrograde cholangiopancreatography (ERCP), endoscopic 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.

Check for proper position of the balloon catheter using contrast medium injection and fluoroscopy. Balloon inflation in an improper location may lead to patient injury.

If resistance is met during procedure, do not advance the balloon without first determining the cause or resistance and taking remedial action.

DO NOT EXCEED THE LARGER O.D. (OUTSIDE DIAMETER) OF THE BALLOON INDICATED ON THE ENCLOSED PRE-STAKED SYRINGE WHEN INFLATED.

This product contains NATURAL RUBBER LATEX, which may cause allergic reactions.

PRECAUTIONS

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

Due to various guidewire tolerances among manufacturers, it is recommended the Extractor Pro RX Retrieval Balloon Catheter and the Extractor Pro RX-S Retrieval Balloon Catheter family of catheters be used with a Boston Scientific 0.035 in (0.89 mm) guidewire.

Read the entire Directions for Use before using the Extractor™ Pro RX Retrieval Balloon Catheter and the Extractor Pro RX-S Retrieval Balloon Catheter. The Extractor Pro RX Retrieval Balloon Catheter and the Extractor Pro RX-S Retrieval Balloon Catheter should only be used by or under the supervision of physicians thoroughly trained in endoscopic procedures. A thorough understanding of the technical principles, clinical applications, and risk associated with this procedure are necessary before using this device.

A thorough understanding of the technical principles, clinical applications, and risks associated with endoscopic sphincterotomy (ES) and endoscopic retrograde cholangiopancreatography (ERCP) is necessary before using this product.

The Extractor Pro RX Retrieval Balloon Catheter and the Extractor Pro RX-S Retrieval Balloon Catheter are supplied in a sealed sterile pouch. Prior to use, inspect the pouch for any breach to ensure a sterile device.

Kinks in the catheter will hinder injection capability. Do not use the Extractor Pro RX Retrieval Balloon Catheter or the Extractor Pro RX-S Retrieval Balloon Catheter if any defect is found during inspection.

The Boston Scientific RX biopsy cap is not recommended to be used with the Extractor Pro RX 15-18 mm Retrieval Balloon Catheter or with the Extractor Pro RX-S 15-18 mm Retrieval Balloon Catheter.

The Extractor Pro RX Retrieval Balloon Catheter and the Extractor Pro RX-S Retrieval Balloon Catheter should be advanced through the endoscope using short, deliberate 2-3 cm movements to prevent inadvertent damage to the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Allergic Reaction
- Cholangitis
- Hematoma
- Hemorrhage
- Pancreatitis
- Perforation
- Septicemia/infection
- Stone impaction