



## Brief Summary Document

### Overview

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#### Product

Extractor™ Pro XL Retrieval Balloon Catheter – IFU 51878206

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### 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 XL Retrieval Balloon Catheter is used endoscopically to 1) remove stones from the biliary system; or 2) 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) and 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.

Read the entire Instructions for Use before using the Extractor Pro XL Retrieval Balloon Catheter. The Extractor Pro XL 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.

- The Extractor Pro XL Retrieval Balloon Catheter should only be used by or under the supervision of physicians thoroughly trained in endoscopic retrograde cholangio-pancreatography.
- Monitor balloon inflation under fluoroscopy.
- The Extractor Pro XL Retrieval Balloon Catheter is designed for use with endoscopes which have a working channel of at least 3.2 mm (or larger).
- Due to various guidewire tolerances among manufacturers, it is recommended the Extractor Pro XL Retrieval Balloon Catheter family of catheters be used with a Boston Scientific 0.035 in (0.89 mm) guidewire.
- The Extractor Pro XL Retrieval Balloon Catheter is supplied sterile. If the catheter package is opened or damaged, do not use catheter.

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 XL Retrieval Balloon Catheter is 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 Extractor Pro XL 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 XL 15-18 mm Retrieval Balloon Catheter.

The Extractor Pro XL 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