

Extractor™ Pro RX, XL, and DL Retrieval Balloon Catheters

Prescriptive Information

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

The Extractor Pro Retrieval Balloon Catheters 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) and endoscopic sphincterotomy (ES).

Warnings

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 of resistance and taking remedial action.

Contents supplied STERILE. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

Adverse Events

Possible complications include but may not be limited to:

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

Precautions

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

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

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