

Extractor™ Pro XL Retrieval Balloon Catheter

Prescriptive Information

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

Caution/Rx Only:

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

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Device Description

The Extractor Pro XL Retrieval Balloon Catheter is a triple lumen retrieval balloon catheter.

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

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

- 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.

Precautions

Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

- 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).

Extractor™ Pro DL Retrieval Balloon Catheter

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- 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.

Adverse events

Possible complications include, but may not be limited to:

- pancreatitis
- perforation
- hemorrhage
- hematoma
- cholangitis
- stone impaction
- septicemia/infection
- allergic reaction to contrast medium