

Extractor™ RX Retrieval Balloon

Compatible with the RX Biliary System™

EXTRACTOR RX RETRIEVAL BALLOON

Order Number	Balloon O.D. (mm)	Injection	Catheter O.D. (Fr)	Recommended Guidewire*
M00546900.....	9.0 - 12.0	Injection Above.....	7 - 6.....	.035".....
M00546910.....	12.0 - 15.0	Injection Above.....	7 - 6.....	.035".....
M00546920.....	15.0 - 18.0	Injection Above.....	7 - 6.....	.035".....
M00546930.....	9.0 - 12.0	Injection Below.....	7 - 6.....	.035".....
M00546940.....	12.0 - 15.0	Injection Below.....	7 - 6.....	.035".....
M00546950.....	15.0 - 18.0	Injection Below.....	7 - 6.....	.035".....

*Recommended guidewire: .035" Hydra Jagwire™ Guidewire

INSTRUCTIONS FOR USE

Refer to the operator's manual for complete instructions for use.

INDICATIONS

The Extractor RX Retrieval Balloon is 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).

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

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.

Contents supplied STERILE. 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.

POTENTIAL ADVERSE EFFECTS

Potential Adverse Effects include, but may not be limited to: pancreatitis, perforation, hemorrhage, hematoma, cholangitis, stone impaction, septicemia/infection and allergic reaction to contrast medium.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



Boston Scientific Endoscopy
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Ordering Information
1.800.225.3226

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