

Trapezoid™ RX

Wireguided Retrieval Basket

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: 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.

Intended Use/Indications for Use

The Trapezoid RX Wireguided Retrieval Basket is indicated for endoscopic crushing and removal of biliary calculi. The lithotripter compatible basket should not be used for any other purpose other than its intended application.

Important: In the event the biliary calculi cannot be crushed, the Trapezoid RX Wireguided Retrieval Basket has been designed for the basket tip to disengage minimizing the potential for stone entrapment in the basket. Flushing may follow.

Contraindications

The Trapezoid RX Wireguided Retrieval Basket is contraindicated whenever Endoscopic Retrograde Cholangiopancreatography (ERCP) or Endoscopic Retrograde Sphincterotomy (ERS) would be contraindicated.

Caution: Trapezoid RX Wireguided Retrieval Basket is not intended for use in the pancreas.

Adverse Events

Possible complications include, but may not be limited to:

- Pancreatitis
- Bleeding
- Stone impaction
- Cholangitis
- Septicemia
- Perforation by catheter tip

Precautions

Do not use this product without reading and understanding the complete instructions enclosed herein.

Trapezoid™ RX

Wireguided Retrieval Basket

Prior to Use

Precautions:

This device should only be used by or under the supervision of physicians trained in ERCP with mechanical lithotripsy. A thorough understanding of the technical principles, clinical applications and risks associated with ERCP and with mechanical lithotripsy is necessary before using this device.

This device is supplied sterile. Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged in shipment. Do not use if damaged. Immediately return damaged product to Boston Scientific Corporation.

Any use of this device, other than those indicated in these instructions, is not recommended.

This device is for use with an endoscope with a working channel that is 3.2 mm or greater.