



Product Name: Trapezoid™ RX Wireguided Retrieval Basket

Rx Statement

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

REUSE WARNING

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.

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.

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.

CONTRAINDICATIONS

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

WARNINGS

- Trapezoid RX Wireguided Retrieval Basket is not intended for use in the pancreas. Use in the pancreatic ducts may result in patient injury such as laceration, pancreatitis, perforation, and tissue damage.
- If excessive resistance is encountered and insertion becomes difficult, lower the elevator, advance the catheter and then operate the elevator again. Monitor the catheter under fluoroscopy to ensure the tip is at the proper angle to minimize the force against the wall of the bile duct. Failure to do so may result in patient injury such as hemorrhage, inflammation, laceration, perforation, and tissue damage.

PRECAUTIONS

- Do not use this product without reading and understanding the complete instructions enclosed herein.
- The Trapezoid RX Wireguided Retrieval Basket should be advanced through the endoscope using short, deliberate 2-3 cm (20-30 mm) strokes to prevent inadvertent damage to the device.

EMERGENCY PRECAUTIONS

In the event that the **Trapezoid RX Wireguided Retrieval Basket will not crush the calculus** and the basket tip has not disengaged, use the following guidelines:

If the calculus can be removed: Release the calculus from the basket, retract the basket into the catheter and remove the Trapezoid device.

If calculus cannot be removed from the basket, follow clinical and/or surgical standards of practice. The Sohendra Lithotripsy System may be utilized for endoscopic calculus removal. Using wire cutting pliers, cut the handle off the basket sheath, leaving the basket wire behind with the calculus in situ followed by the Sohendra Lithotripsy System or other lithotripsy.

If the basket wires are broken:

- Slowly withdraw the basket into the catheter and withdraw the catheter from the scope.
- In the event the **damaged part of the wire cannot be withdrawn** into the catheter, be careful not to injure the duct wall with the basket wire.
- In the event that **all four basket wires are broken** and the **distal tip of the basket has come off**, withdraw basket wires into catheter and remove. Flushing may follow.

Note: 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

POTENTIAL ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Cholangitis
- Device entrapment
- Hemorrhage
- Infection
- Inflammation
- Laceration
- Pancreatitis
- Perforation
- Stone impaction
- Tissue Damage