Helical Stone Retrieval Basket

Prescriptive Information

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

Intended Use/Indications for Use

The Helical Stone Retrieval Basket is used endoscopically to entrap and remove calculi and other foreign objects from the ureter.

Contraindications

None known.

Warnings

- For single use only. Do not reuse, reprocess or resterilize.
- Use of this device should be restricted to use by or under the supervision of physicians trained in urologic endoscopic procedures. Care should be exercised to prevent perforation or trauma of the linings and associated tissue of vessels or ducts.
- Some objects may be too large to be removed endoscopically with a retrieval basket. To avoid object impaction, fluoroscopy or x-ray should be used to determine the size of the object; do not use the Helical Stone Retrieval Basket if the object is too large to be removed endoscopically or held in the basket.
- Warnings can be found in the product labeling supplied with each device.

Potential Adverse Events

Adverse events generally recognized with the use of stone retrieval basket devices include, but are not limited to:

- Perforation
- Entrapment of calculi too large to be removed
- Evulsion
- Hemorrhage
- Inability to disengage from irretrievable stone
- Edema

Precautions

- Kinks in the sheath will hinder the mechanical operation of the basket.
- It is recommended that the ureter be predilated before endoscopy and object retrieval to prevent object impaction when retracting the object.
- Objects may be too large once captured in the basket to withdraw the basket fully into the sheath. Do not exert excessive force to withdraw basket into sheath or scope. Carefully maintain basket position to hold the object in place.
- Precautions 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.