

Helical Stone Retrieval Basket Prescriptive Information

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Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

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

Contraindications

None known.

Warnings

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.

The Helical Stone Retrieval Basket is for single patient use and has no other user serviceable parts.

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

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

Precaution: Before using, inspect the blister pouch for any breach of the package to ensure a sterile product and inspect product for any damage. If seal has been broken or product is damaged DO NOT USE. Immediately return package and product to Boston Scientific.

Precaution: Kinks in the sheath will hinder the mechanical operation of the basket.

Precaution: It is recommended that the ureter be predilated before endoscopy and object retrieval to prevent object impaction when retracting the object.

Warning

- To avoid object impaction, use fluoroscopy or x-ray to determine the size of the object. Do not use basket if object is too large to be removed endoscopically or held in the basket.
- This device must not come in contact with any electrified instrument.
- This device should not be directly fired upon by a pulsed dye laser. To do so may damage the device and could result in patient injury.

Caution: If resistance is encountered during advancement or withdrawal of the device, DO NOT EXERT EXCESSIVE FORCE.

Precaution: 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.