

LithoCatch™ 12 Wire Helical Immobilization Device

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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 LithoCatch 12 Wire Helical Immobilization Device is intended to be used during urological procedures to endoscopically grasp, manipulate and remove calculi and other foreign objects.

Contraindications

None known.

Warnings

- This device must not come in contact with any electrified instrument.
- Use of this device should be restricted to use by or under the supervision of physicians trained in endoscopic procedures.
- Care should be exercised to prevent perforation or trauma of the linings and associated tissue of vessels or ducts.
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Adverse Events

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

- Ureteral perforation
- Kidney perforation
- Ureteral evulsion
- Edema
- Hemorrhage
- Basket inversion

Precaution

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

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

Precaution: It is recommended that the ureter be predilated prior to insertion of the endoscope.

Precaution: Unfragmented stones may be too large to be captured by the LithoCatch 12 Wire Helical Immobilization Device. Fluoroscopy or x-ray should be used to determine the size of the stone and if fragmentation is required.

Caution

Do not pull open basket against end of scope, otherwise damage to scope may occur. If resistance is encountered while attempting to withdraw the LithoCatch 12 Wire Helical Immobilization Device through the scope, stop and access reason for resistance before proceeding. DO NOT EXERT EXCESSIVE FORCE.