

Escape™ Nitinol Stone Retrieval Basket Prescriptive Information

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

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.

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

This basket is intended to be used endoscopically to grasp, manipulate and remove calculi from the urinary tract.

Contraindications for Use

- Pregnancy
- Renal malignancy
- Sepsis
- Anticoagulation or bleeding disorders
- Presence of very large stones that in the past have failed lithotripsy with basket retrieval

Warnings

- The use of this device should be restricted to use by or under the supervision of physicians trained in urological endoscopic procedures.
- Exercise care to prevent perforation or trauma of the linings of the urinary tract and associated tissues.
- Some stones may be too large to be removed endoscopically with the stone retrieval basket. Use fluoroscopy or x-ray to determine the size of the stone prior to instrumentation. Do not use the basket if the stone is too large to be removed endoscopically. To do this may result in stone impaction and patient injury.
- If resistance is encountered while attempting to withdraw the basket, DO NOT EXERT EXCESSIVE FORCE.
- Do not fire the laser directly upon the basket.
- If a basket wire is broken during lasing, discontinue lasing immediately. Good surgical procedures should be followed for basket removal.
- This basket has no serviceable parts. Do not attempt to repair or alter the device. Do not resterilize the device. Any use of the device other than those indicated is not recommended.
- Do not use this basket without the pre-packaged Y-adapter. Doing so may result in inability to advance the laser fiber through the working channel of the scope.
- This device must not come in contact with any electrified instrument.

Adverse Events

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

- Edema
- Stone impaction
- Entrapment
- Stone migration

- Evulsion
- Urinary frequency
- Fever
- Urinary tract infection
- Hemorrhage
- Ureteral trauma (including stripping, abrasion or perforation)
- Pain

There may be other potential adverse events that are unforeseen at this time.

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 your Boston Scientific representative.

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

Precaution: It is recommended that the ureter be pre-dilated before endoscopy and stone retrieval to prevent impaction when retracting the stone.

Warning: Refer to the Directions for Use supplied by the manufacturer of the laser and the laser fiber.

Warning: Do not fire the laser if you cannot see the aiming beam. Do not fire the laser directly upon the basket.