

OptiFlex™ Nitinol Stone Retrieval Basket

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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 OptiFlex Nitinol Stone Retrieval Basket is intended to be used endoscopically to grasp, manipulate and remove calculi and other foreign objects from the urinary tract.

Contraindications

The OptiFlex Nitinol Stone Retrieval Basket is contraindicated for:

- Renal malignancy
- Sepsis
- Anticoagulation or bleeding disorders

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 nitinol 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 for endoscopic removal. To do so may result in stone impaction and patient injury.
- If resistance is encountered while attempting to withdraw the basket, DO NOT EXERT EXCESSIVE FORCE.
- This device should not be directly fired upon by a lithotrite. To do so may damage the device and could result in patient injury.
- If a basket wire is broken during use, discontinue use 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 the device without the Introducer as this may result in damage to the basket.
- This device must not come in contact with any electrified instruments.

Adverse Events

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

- Edema
- Stone impaction

- Entrapment
- Stone migration
- Ureteral Avulsion
- Urinary frequency
- Fever
- Urinary tract infection
- Hemorrhage
- Pain
- Ureteral Intussusception
- Ureteral Stricture
- Ureteral trauma (including stripping, abrasion or perforation)

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

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 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 predilated before endoscopy and stone retrieval to prevent impaction when extracting the stone.