

Brief Summary Document

Product

OptiFlex™- Nitinol Stone Retrieval Basket. IFU 90998360-01

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

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

WARNING

- 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.

PRECAUTIONS

- It is recommended that the ureter be predilated before endoscopy and stone retrieval to prevent impaction when extracting the stone.

POTENTIAL 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)