

Brief Summary Document

Product

ZeroTip™ Nitinol Stone retrieval Basket
Seguar Hemishpere™ Stone Retrieval Basket
IFU 50940729-01

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 Stone Retrieval Basket is intended to be used during urological procedures to endoscopically grasp, manipulate and remove calculi and other foreign objects.

WARNING

- 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 Stone Retrieval Basket if the object is too large to be removed endoscopically or held in basket.
- This device should not be directly fired upon by any lithotrite. To do so may damage the device and could result in patient injury.

PRECAUTIONS

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

POTENTIAL ADVERSE EVENTS

Adverse events generally recognized with the use of stone retrieval basket devices include, but are not limited to: Perforation; Evulsion; Edema; Basket inversion; Entrapment; Hemorrhage; Inability to disengage from irretrievable object; Pain/discomfort; Infection; Abrasion; Stone Migration