

# Dakota™ Nitinol Stone Retrieval with OpenSure™ Handle

## Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

### Intended Use/Indications for Use

The Stone Retrieval Basket is intended to be used during urological procedures to endoscopically grasp, manipulate, release and remove calculi and other foreign objects from the upper urinary tracts (ureter, renal pelvis and calyces.)

### Contraindications

Use in patients with an untreated urinary tract infection.

### Warnings

- The use of this device must 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 objects may be too large to be removed by the retrieval basket without being fragmented into smaller pieces. Appropriate imaging should be done in advance of the procedure to anticipate whether fragmentation will be necessary.
- This device must not come in contact with any electrified instrument.
- This device should not be directly fired upon by any lithotrite (laser, EHL, etc.). Doing so may damage the device and could result in a patient injury.
- If a basket wire is broken during laser lithotripsy, discontinue laser use immediately. Good surgical procedures should be followed for basket removal.
- Use of device without introducer may cause damage to the basket.
- This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

### Potential Adverse Events

Possible complications generally recognized with stone retrieval procedures and/or the use of stone retrieval basket devices include, but may not be limited to:

- Ureteral perforation
- Ureteral avulsion
- Ureteral edema
- Ureteral laceration
- Ureteral stricture
- Urothelial damage
- Pain/Discomfort
- Infection/Sepsis
- Stone impaction

- Stone migration
- Entrapment of stone and basket
- Hemorrhage
- Inability to release a grasped object

### **Precautions**

- 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.
- Kinks in the sheath will hinder the mechanical operation of the basket.
- If the ureter is too small to accommodate a ureteroscope and to safely remove the stone or stone fragments then prestenosing should be considered.
- Ensure If resistance is encountered during advancement or withdrawal of the device, DO NOT EXERT EXCESSIVE FORCE.

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

©2016 Boston Scientific Corporation or its affiliates. All rights reserved.  
URO-428907-AA Sept 2016