

Brief Summary Document

Overview

Product

DAKOTA™

Nitinol Stone Retrieval Device

Escape™

IFU 51455591-01

OptiFlex™**Zero Tip™**

Nitinol Stone Retrieval Basket

Rx Statement

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

This device is restricted to use by or under the supervision of physicians trained in urological endoscopic procedures.

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 Dakota, Escape, OptiFlex, and Zero Tip nitinol retrieval baskets are intended to be used during urological procedures to endoscopically grasp, manipulate, release, and remove calculi and other foreign objects from the urinary tract.

CONTRAINDICATIONS

The Dakota, Escape, OptiFlex, and Zero Tip nitinol retrieval baskets are contraindicated for patients with:

- Sepsis
- An untreated urinary tract infection
- Anticoagulation or uncorrected bleeding disorders

WARNINGS

- If resistance is encountered while attempting to withdraw the basket, DO NOT EXERT EXCESSIVE FORCE. Excessive force can either damage the basket or result in the object and basket becoming lodged into the ureter, the sheath, or the endoscope. Excessive force can also result in ureteral laceration or avulsion.
- 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 device 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 should not be directly fired upon by any lithotrite (laser, electrohydraulic lithotripsy, 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 the Dakota, OptiFlex, and Zero Tip devices without the introducer may cause damage to the basket.
- Do not use the Escape device without the pre-packaged Y-Adapter. Doing so may result in the inability to advance the laser fiber through the working channel of the endoscope.

PRECAUTIONS

- Use in patients with renal malignancy should be carefully considered.
- Kinks in the sheath will hinder the mechanical operation of the basket.
- Ensure the basket is in the closed position during insertion and advancement through the working channel of the endoscope. Insertion or advancement of an open basket may result in basket inversion (Dakota only) or device damage.

POTENTIAL ADVERSE EVENTS

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

- Allergic reaction
- Hemorrhage
- Hydronephrosis
- Infection
 - Fever
 - Sepsis
 - Urinary tract infection
- Inflammation
- Obstruction
- Pain/Discomfort
- Stone impaction
- Stone migration
- Tissue damage
- Unretrieved device fragment
- Ureteral avulsion
- Ureteral edema
- Ureteral laceration
- Ureteral perforation
- Ureteral stenosis
- Urinary symptoms
 - Dysuria
 - Urgency
 - Urinary retention

Adverse events may require additional medical or surgical intervention.