

**INSTRUCTIONS FOR USE  
FLEXSTONE BASKET**

Manufacturer



Use by date



Batch code



Catalogue number



Sterilized using irradiation



Single sterile barrier system with protective packaging outside



Single sterile barrier system



Do not reuse



Keep away from sunlight



Unique device identifier



Federal law (US) restricts this device to the sale by or on the order of a physician



Do not use if package is damaged



Operating Instructions



Keep Dry

**Manufactured For:**  
**EndoTheia, Inc.**  
1720 West End Ave, Suite 520  
Nashville, TN 37203

# FlexStone Basket

The FlexStone Basket is a single-use steerable basketing device that is used for the removal of renal and ureteral stones.

## INTENDED USE

The EndoTheia FlexStone Basket is intended to be used in urological procedures to endoscopically manipulate and remove calculi and other foreign bodies.

## GENERAL WARNING AND SAFETY PRECAUTIONS

Federal Law (US) restricts this device to the sale by or on the order of a physician.

This device is restricted to use by medical professionals trained in urological procedures.

Do not use the device if there is any indication that the sterility of the device has been compromised.

This device must not come into contact with any electrified instrument.

The device is sterile.

The device is single-use.

After use, the FlexStone Basket device should be considered biological waste and disposed of following standard hospital procedure.

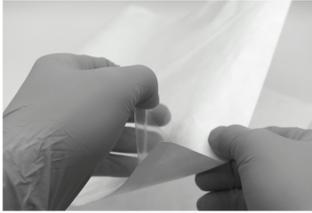
Kinks or deformations in the sheath can impede the device's mechanical function, affect its insertion or withdrawal, and potentially damage the endoscope's instrument channel.

Avoid directly firing upon this device with any lithotripsy equipment. This can cause damage to the device and patient injury.

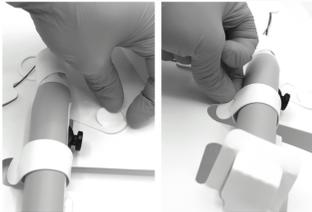
Some objects may be too large to be removed using this retrieval device. Do not use the EndoTheia FlexStone Basket if the object is too large to be removed safely.

Do not deflect the steerable tip while inside the endoscope instrument channel.

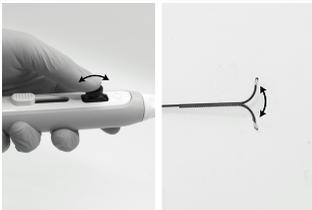
In the event that the basket needs to be separated from the handle, cut the basket distal to the strain relief using scissors.

**DIRECTIONS FOR USE****STEP 1:**

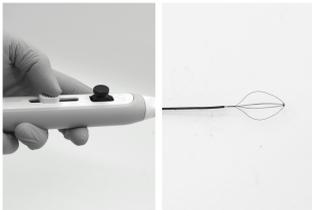
Examine the pouch for any obvious defects or damages. Unpack the device by tearing open the pull-tabs and removing the backer card from the pouch.

**STEP 2:**

Remove the handle of the device from the backer card by opening the strap holding the handle to the backer card and the strap restraining the tip of the handle. Carefully unwind the device from the backer card.

**STEP 3:**

Actuate the steerable tip by rotating the joystick lever on the handle shown in the image. Confirm that the tip of the device bends to either side.

**STEP 4:**

Confirm that the basket can be opened and closed by pushing the slider forwards and backwards as shown in the image.

**STEP 5:**

Slowly insert the FlexStone Basket device into the endoscope instrument channel, using short throws to ensure the device does not get damaged. Make sure to insert the FlexStone Basket device until it exits the tip of the endoscope.