

## Instruction for Use

### Three Face Stone Basket

#### Device Description

Stone Retrieval Baskets is an instrument passed through an endoscope to capture and extract urinary calculi. Delivered in sterile peel-open tray packs. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

Family	Size (Fr)	Length (Cm)
Three Face Stone Basket	1.5	70
	1.9	90
	2.0	110
	2.2	115
	2.4	120
	2.5	125
	2.8	
	3.0	
	3.5	
	4.0	
	5.0	

#### Intended Purpose

Stone retrieval baskets are used to entrap and remove renal calculi via a rigid or flexible endoscope during trans ureteral urological procedures.

#### Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

#### Medical Conditions to Be Treated

- Kidney stones (renal calculi)
- Stone fragments post-laser lithotripsy
- Stone fragments post-ureterorenoscopy (URS)

#### Performance Characteristics of the Device

The device is designed to offer advantages of both a stone grasper and a stone basket. It allows easy grasp, release and removal of stones of various sizes throughout the urinary tract.

#### Indications

In patients diagnosed with kidney stones.

Collect the small fragments of stone after a laser lithotripsy and Ureterorenoscopy.

#### Contraindications

- Untreated Urinary Tract Infection
- Endoscopy without appropriate antibiotic coverage
- Uncorrected Bleeding Diathesis
- Uncooperative Patient

#### Precautions, Warnings & Complications

Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

##### Precautions:

- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Store the Stone Cone Type at a temperature between 12-35°C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

##### Warnings:

- The device is intended for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.
- Do not use the device if the object is too large to be removed. The use of fluoroscopy and/or x-ray to determine the size of the object is recommended.

#### Intended Patient Population

- Three Face Stone Basket is used in adult patients. The device can be used in both male and female patients.

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#### Shelf-life

The shelf life of the Three Face Stone Basket is 3 years (Indicated on product label with the following use-by date symbol).

#### Sterility – This product is Sterile unless the package has been opened or damaged

- The Three Face Stone Basket have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- Exposure to high levels of Ethylene Oxide may result in residual ETO which leads to Toxic Reaction in the body resulting in tissue damage.
- If the sterile package is damaged or possibly opened, do not use.
- The Three Face Stone Basket is packed single. Product in each pack must be utilized immediately when opened.

#### Directions for Use

- The Three Face Stone Basket is inserted through an ureterorenoscope. After the stone is grasped in the basket, the basket is closed and carefully removed. If necessary (e.g. change of instruments) the handle can be removed temporarily:
- Detachment of Three Face stone basket: Remove the protective cover after penetrating the perforation with sterile scissors or forceps. Press fixation knob as far as it will go. Remove basket (Should the basket get caught by mechanism it will be released again through pushing the slider back until it stops).
- Reconnection of the basket: Insert basket in handle as far as it will go. Ensure that slide and button are open Press slide down all the way. While pressing, move the slide until it snaps and keep in position.




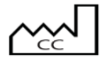










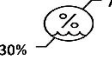

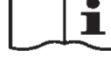


#### Removal Instructions

- Retrieve cystoscopically by gently pulling on Three Face Stone Basket. If resistance is encountered during withdrawal of the device, stop and determine the source of the resistance before proceeding. As continued resistance may damage the device and could result in patient injury.

#### Disposal Instructions

Dispose of all equipment in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

#### Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		Unique Device Identifier		Do not re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		

#### Bibliography

- Single Use Medical Device:  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/956268/Single\\_use\\_medical\\_devices.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf)
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.