

## Instruction for Use

### Stone Grasper

#### Device Description

Stone Grasper is available as three Prong and Forceps. Delivered in sterile peel-open tray packs. Rigid Stone Grasper is made of Stainless Steel, Flexible Grasper is made of Polypropylene. Sterile device, Intended for single use. Duration of Contact with the body is 1 day. Stone Graspers have a detachable handle.

The configurations available include:

Family	Type	Size (Fr.)	Length (cm)	Catalogue Number
Stone Grasper (SG)	Flexible	2.5	70	AMPLSR003
	Rigid	3	90	
	Alligator	4	110	
	Spoon	5		
	Straight			

#### Intended Purpose

This device is intended for stone, foreign body manipulation and removal from the urinary tract to alleviate the urinary flow interruption.

#### Performance Characteristics of the device

The device is equipped with a tri prong atraumatic forceps at distal tip for providing maximum grasping efficiency with an ergonomic handle. The inner shaft of the device is made of stainless steel and outer sheet is made from polypropylene. The handle is detachable.

#### Indications

It is used to 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

Carefully read all instructions for use. 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:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgement. The doctor must be trained in the proper use of the device.
- The Intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.
- Visually inspect the device with particular attention to kinks, bends or breaks.
- Objects that are too large to be recovered through the sheath or through the scope channel will require the scope and the basket to be removed simultaneously from the urinary tract. If resistance is encountered during advancement or withdrawal of the device, stop and determine the source of the resistance, as continued resistance may damage the device and could result in patient injury. Take action to alleviate the resistance. Where necessary, use of the lithotripsy may be required to reduce the stone burden within the basket, providing that no direct contact is made with the stone grasper.

##### Warnings:

- The device is for Single use only.
- Some objects may be too large to be removed endoscopically using a retrieval device. The use of fluoroscopy and/or x-ray to determine the size of the object is recommended: do not use the stone grasper if the object is too large to be removed endoscopically. 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 regulations.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient:
- Biocontamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- This device should be administered to humans only by physicians authorized by the competent authority of the country in which the physician is practicing.

#### Intended Patient Population

- Stone grasper is used for the urology procedures in patients diagnosed with stone in Ureter and Kidney.
- The device can be used in patients of all age groups as specified below:
- 1.5Fr, 1.9Fr, 2Fr, 2.2Fr, 2.4Fr, 2.5Fr, 2.8Fr and 3Fr stone grasper is used in Infants and Children.
- 3Fr to 5Fr stone grasper is used for adults.

#### Shelf-life and Storage Condition of the Product

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

Store the Stone Grasper at a temperature between 12°-35°C and a Humidity range of 30%-75%.

Store in a dry, cool place. Avoid extended exposure to sun light.

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

- The Stone Graspers have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage in the Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The “Stone Graspers” are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

#### Directions for Use

- Open the package at the Chevron Side (‘V’ Notch) of the pouch.
- Suggested instructions for using Stone Grasper are:

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- With grasper fully retracted into sheath, insert device into accessory channel. Advance device through channel until grasper sheath exists endoscope.
- After confirming desired position of grasper sheath relative to target, advance grasper by pushing forward on handle. Place grasper around object and slowly retract handle until entrapment is achieved.
- Withdraw grasper into sheath while maintaining entrapment. Support object against endoscope tip and withdraw endoscope from patient. Maintain endoscopic visualization to ensure continued entrapment of object. While withdrawing device, wipe secretions from outer sheath.
- Prepare extracted specimen per institutional guidelines.
- Upon completion of procedure, dispose of device per institutional guidelines for bio hazardous medical waste.
- Duration of contact with the body is 1 day.


















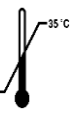



### Removal Instructions

Retrieve cystoscopically by gently pulling on retrievers. If resistance is encountered during removal of the retrievers, stop and determine cause of resistance before proceeding.

### 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		CE Mark		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		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

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### Bibliography

- Contraindications: <https://emedicine.medscape.com/article/451329-overview#:~:text=Diagnostic%20ureteroscopy%20has%20few%20contraindications,bleeding%20diathesis%20are%20relative%20contraindications.>
- 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.