

Instruction for Use Stone Basket Nitinol

Device Description

Stone Retrieval Baskets is an instrument passed through an endoscope to capture and extract urinary calculi. They are provided with a detachable handle. The configurations available include:

Family	Size (Fr.)	Wire	Length (cm)	Form	Tip	Catalogue Number
Stone Basket	2.5	3	70	Segura (S)	With Tip (T)	AMPLSR001
Nitinol (SBN)	3	4	90	Helical (H)	"O" Tip (Z)	
	4	5	110			
	5					

Intended Purpose

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

Performance Characteristics of the Device

The device is available in 3,4 and 5 wire for providing maximum grasping efficiency and for easy retrieval of large stones. The tipless basket design helps with atraumatic retrieval of stones from the ureter and calyces. Dismantlable handle. The device offers a kink-resistant and flexible design for the better extraction of stone.

Indications

- It is used to collect the small fragments of stone after a laser lithotripsy and Ureterorenoscopy

Contraindications

The contraindications result from the restrictions of the ureterorenoscopy such as:

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

Precautions & Warnings

Carefully read all instructions for use and product labeling. 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.
- 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 basket.

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 basket 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 Basket Nitinol is used for the urology procedures in patients diagnosed with Kidney Stones.
- The device can be used in patients of all ages as specified below:
- 1.9Fr, 2Fr, 2.2Fr, 2.4Fr, 2.8Fr and 3Fr stone basket is used in Infants and Children.
- 3.5Fr to 5Fr stone basket is used for adults.

Shelf-life and Storage Condition of the Product

- The shelf life of the Stone Basket Nitinol is 3 years (Indicated on product label with the following use-by symbol).
- Store the Stone Basket Nitinol 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 Baskets Nitinol 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 presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of 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 Baskets Nitinol are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

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Directions for Use

- Open the package at the Chevron Side ('V' Notch) of the pouch.
- Suggested instructions for using Stone Basket Nitinol:
- The stone retrieval 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 stone retrieval 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.
- Duration of contact with the body is 1 day.













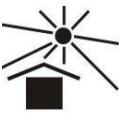




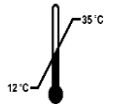



Removal Instructions

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 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
- 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.