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ASTER MEDISPRO PRIVATE LIMITED

CE 2803

Instruction for Use

Stent Remover

Device Description

This device is designed for easy removal of stents. Delivered in sterile peel-open tray packs. Stent Remover is made of Hi-Tensile Stainless-Steel Wire with Hi- Torque. Intended for single use. Duration of Contact with the body is 1day. The configurations available include:

Family	Size (Fr.)	Length (cm)	Catalogue Number
Stent Remover (SR)	4 5	70	AMPLGP009

Intended Purpose

Stent Removers are intended for the endoscopic or ureteroscopic removal of Double J Stent.

Performance Characteristics of the device

The Stent Remover forceps aids in the removal of stents. The forceps have a strong grasping feature. The device has an alligator jaw which provides a strong grip.

Indications

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

Contraindications

- Kidney or ureter infection
- Bladder damage or infection
- Severe Pain
- Re-blockage of ureter with stone fragments not removed leading to severe pain

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:

- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device based on his 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.

Warnings:

- The device is for single use only.
- Dispose of all components as infectious waste. Users of this device have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient: Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infections.
- 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

- Stent remover is used to remove the stents placed in patients with Ureteral Obstruction.
- The device can be used in patients of all age groups.

Shelf-life and Storage condition of the Product

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

Store the Stent Remover 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 Stent Removers have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown 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 we will replace the product.
- The Stent Removers 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 Stent Removers:
- With triprong fully retracted into sheath, insert triprong into accessory channel. Advance triprong through channel until device’s sheath exists endoscope.
- After confirming desired position of trirpong sheath relative to target, advance triprong by pushing forward on handle. Place triprong around Double J Stent and slowly retract handle until entrapment is achieved.
- Withdraw triprong 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.

- 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 the device. If resistance is encountered during removal of the Stent Remover, 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
REF	Catalogue Number	CE 2803	CE Mark	2 STERILIZE	Do not Re sterilize	CC	Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	UDI	Unique Device Identifier
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35°C 12°C	Temperature Limit		Do Not Use if Package is Damaged	EC REP	Authorized Representative in the European community
75% 30%	Humidity Limit								

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Bibliography

- 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.