ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use
Ureteral Catheter

CE 2803

Device Description

The Ureteral Catheters are sterile medical devices provided for use in Urology procedures used for drainage and navigation of a tortuous ureter. The tapered tip eases placement as there are no edges to interfere with the ureteral orifice. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

Family	Accessories	Size (Fr.)	Length (cm)	Type	Catalogue Number	Color
Ureteral Catheter (UC)	Stylet Connector	3 4 5 6 7 8	70 72	Close Tip (CLT) Open Tip (OT) Angle Tip (AT) Cone Tip (CT) Whistle Tip (WT) Male Luer Lock, Female Luer Lock	AMPLCT003	Blue Grey

Intended Purpose

Ureteral Catheter is used to relieve obstruction by aiding in the drainage of fluids from Urinary Tract and for the access, advancement or exchange of ancillary devices including guidewires and for the delivery of contrast media.

Performance Characteristics of the Device

Ureteral Catheters are used for drainage and navigation of a tortuous ureter and are manufactured in such a way that they provide proper flexibility and resistance to kinking. They are available in various sizes and tip configurations.

Cone Tip: Used for netrograde pyelogram. The cone tip occludes the ureteral orifice.

Angle Tip: Used for directing a flexible Guide Wire in the ureter. The angle tip allows passage of the catheter past a ureteral stone in preparation for E.S.W.L.

Whistle Tip: Used for drainage and netrograde pyelogram.

Close Tip: Used for drainage and navigation of a tortuous ureter. Closed tip catheter will have a stainless-steel stylet in which helps the catheter to straighten. No need to use guide wire.

Open Tip: Used for drainage and navigation of a tortuous ureter. Catheter placement should be over the guide wire only.

Olive Tip: Olive Tip Catheter is a type of coude tip catheter, which features a rounded or ball-shaped tip with a slight curve. It allows for easy and comfortable insertion by providing a smooth passage around the obstructions in the bladder.

Indications

- Bladder/Kidney Stones and Kidney Failure
- Urinary Retention (Can't Urinate on your own)
- Urinary Incontinence (Leakage)

Contraindications

- Blood at the meatus, Insertion the catheter can worsen the underlying injury.
- Gross Haematuria
- Evidence of Urethral Infection
- Urethral Pain or discomfort
- Lower Bladder Volume/compliance
- Patient Refusal

Precautions & Warnings

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.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Ureteral Catheter at a temperature between 12-35^{0}C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- All components of the Ureteral Catheters are 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 Urinary 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.

Intended Patient Population

- The ureteral catheter can be used in patients of all age groups based on doctors' decision.
- The device can be used in both male and female patients.

Shelf-life

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

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

- The Ureteral Catheters 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 Urinary System.
- The Ureteral Catheters are packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

Open the package from the Chevron side ('V' Notch) of the pouch. Suggested instructions for using Ureteral Catheters:

- Initially insert a guide wire slowly through the urethral opening and into the bladder and to the ureter.
- Gently insert the ureteral catheter over the previously placed guidewire while maintaining the guidewire position.
- Pass the catheter over the previously placed guide wire while maintaining the guide wire position.
- Withdraw the guidewire slowly once the catheter is in position.

Removal Instructions

- Remove the catheter by gently pulling on the end.
- If resistance is encountered during the removal of the catheter, stop and determine the 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	2	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

- Contraindications: https://www.ncbi.nlm.nih.gov/books/NBK560748/
- 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.