ASTER
....Where Research is Routine

ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Ureteral Dilator Set

Device Description

The Ureteral Dilator Sets are provided for use in Urology procedures used for dilation of the ureter. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

Family	Size (Fr.)	Length (cm)	Catalogue Number	Color
Ureteral Dilator Set (UDS)	6 7 8 10 12 14 16	70	AMPLDL001	Grey

Intended Purpose

Ureteral Dilator Sets for dilation of the ureter prior to ureteroscopy and/or stone manipulation.

Performance Characteristics of the Device

The Ureteral Dilators have smooth surface for the ease of introduction into the system and is uniformly tapered to reduce trauma.

Indications

Dilatation of the ureter during ureteroscopy procedures.

Contraindications

- Active Urinary Tract Infection
- Uncorrected Bleeding Diathesis
- Irritable Bladders (e.g., Neurogenic Bladder, tuberculosis cystitis, hemorrhagic cystitis, radiation cystitis)
- Gross Hematuria
- Un cooperative 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 judgment. 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 urology disorders or related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

Warnings:

- All components of the Ureteral Dilator Sets 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: Bio-contamination 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

- Ureteral Dilator Set is used in patients diagnosed with Ureteral Strictures (due to vicious cycle of ischemia and scarring, by external trauma or may develop after treatment for another condition) and Hydronephrosis.
- The device is used in treatment of patients above the age of 18yrs having the above-mentioned conditions.
- The above-mentioned sizes are not intended for use in infants and children.

Shelf-life and storage condition of the Product

- The shelf life of the Ureteral Dilator Set is 3 years (Indicated on product label with the following use-by symbol).
- Store the Ureteral Dilator Set 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 Ureteral Dilator Sets 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 of Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.

ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Ureteral Dilator Set

- The Ureteral Dilator Sets 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 from the Chevron Side ('V' Notch) of the pouch.
- Suggested instructions for using Ureteral Dilator Sets:
- Progressing from the smallest to the largest appropriate size, pass the dilators over the previously placed guide wire while maintaining the guide wire position.
- NOTE- Dilators up to approximately 12 French may be passed through the working channel of the cystoscope. However, the telescope and inner scope elements must be removed – leaving the sheath – to accommodate the larger size.
- Duration of contact with the body is 1 day.

Dilator Removal Instructions

Retrieve cystoscopically by gently pulling on dilator or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the dilator, 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								

Aster Medispro Pvt. Ltd
S.P.181, 10th Main, 1st Stage,
DR.B.R.Ambedkar Industrial Estate (KSSIDC)
Jigani Industrial area, Jigani,
Bangalore- 560105, Karnataka, India.
Tel: +91 80-42062716
Email: info@astermedispro.net
Web: www.astermedispro.net

EC REP

M/sCMC Medical Devices& Drugs S.L.
located in C/Horacio Lengo N° 18, CP29006,
Málaga, Spain
Tel : +34951214054, Fax: +34952330100
E-mail : mmateos@cmcmedicaldevices.com
Web : www.cmcmedicaldevices.com

Bibliography

- Contraindications and Conditions of Use: https://www.sciencedirect.com/topics/medicine-and-dentistry/ureter-dilatation
- 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.