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ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Renal Dilators

Device Description

Renal Dilators are used to dilate the tract before endoscopic renal procedure to adapt the passage of Nephroscope and accessories. Renal Dilator is used for progressive dilatation of the nephrostomy tract prior to percutaneous kidney stone removal. Sterile. 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
Renal Dilator (RD)	18	30	AMPLDL011	Blue
	20			
	22			
	24			
	26			
	28			
	30			

Intended Purpose

Renal Dilators are intended for use in stretching and enlarging the fascial tissue prior to a nephrostomy procedure and to introduce amplatz sheath which is intended for percutaneous dilation of tissue surrounding a dilator which is previously placed.

Performance Characteristics of the Device

Renal Dilator aids in the dilation of a tract prior to Kidney stone removal. The devices used are highly radiopaque for better visualization.
Smooth surface for ease of introduction into the body and is uniformly tapered to reduce the trauma.

Indications

- Used to dilatation of the nephrostomy tract
- To allow insertion and passage of instrumentation

Contraindications

- Uncorrected bleeding Diathesis
- Severe Hyperkalemia
- Uncontrolled Arrythmia
- 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 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 any 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 Renal Dilators 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

- Renal Dilator is used in patients to dilate the tract in conditions such as Kidney Stones, Kidney Cysts or other Blockages.
- The device is intended for use in patients above the age of 18yrs.
- 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 Renal Dilator is 3 years (Indicated on product label with the following use-by symbol).
- Store the Renal Dilator 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 Renal Dilators 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.
- The Renal Dilators 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 Renal Dilators:
- After puncturing the tract to the kidney and application of the guide wire, start dilatation with sequential dilation starting from smaller size to bigger size.
- Put the guiding catheter over the wire
- Complete system dilatation over the catheter till requested size.
- Slide the sheath of the requested dilator over it
- Remove the dilator and leave sheath in place
- Duration of contact with the body is 1 day.

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								

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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.