ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Urethral Dilator

Device Description

Urethral Dilators are used for dilation of the urethra. Intended for single use. Duration of Contact with the body is 1day and the device is supplied Sterile. The configurations available include:

Family	Size (Fr.)	Length (cm)	Catalogue Number	Color
Urethral Dilator (UTHD)	8	40	AMPLDL010	Grey Black
	10			
	12			
	14			
	16			
	18			
	20			
	22			

Intended Purpose

Urethral Dilators are used for urethral dilation in cases of Stricture, or narrowing of the tube which inhibits the flow of urine and cause serious health problems.

Performance Characteristics of the Device

Urethral Dilators is used for the Urethral Dilation in patients. The smooth surface aids in the ease of introduction of device into the body and is uniformly tapered to reduce trauma.

Indications

- Urethral dilator used stricture of the urethra.
- Occasionally dilatation is done prior to the passage of a large instrument through the urethra

Contraindications

- Acute Urethral Infection
- Uncorrected Bleeding Diathesis
- Uncooperative Patients

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 Urinary 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 Urethral 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 the 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

- Urethral Dilator is used in patients diagnosed with Urethral Strictures, treatment of urge incontinence and metal stenosis and narrowing of the bladder opening.
- The device is used in treatment of patients above the age of 18yrs having the above-mentioned conditions.
- The above-mentioned sizes is not recommended for use in infants and children.

Shelf-life and storage condition of the Product

- The shelf life of the Urethral Dilator is 3 years (Indicated on product label with the following use-by symbol).
- Store the Urethral 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 Urethral 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 Urethral Dilators are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Urethral Dilator

Directions for Use

- Open the package at the Chevron Side ('V' Notch) of the pouch.
- Suggested instructions for using Urethral Dilators:
- Pass the dilators over the previously placed guide wire while maintaining the guide wire position.
- 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		Do not Re sterilize		Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier stem 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 thylene oxide		Consult Instructions for Use	35 °C 12 °C	Temperature Limit		Do Not Use if Package is Damaged	EC REP	Authorized epresentative in the uropean community
75°C % 30°C	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: https://www.oregonurologyalliance.com/urethra-dilation-urological-surgeon-tualatin-or.html#:~:text=Indications%20and%20Contraindications%20for%20Urethral%20Dilation&text=The%20main%20goal%20of%20the,disease%2C%20bleeding%20and%20untreated%20infection.
- 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.