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ASTER MEDISPRO PRIVATE LIMITED

CE 2803

Instruction for Use

Meatal Dilator

Device Description

Used for dilation of urethral meatus. Supplied sterile in individual peel-open packages. Intended for single patient use only. Intended for single use. Duration of Contact with the body is 1 day. The Configurations available include:

Family	Size (Fr.)	Length (cm)	Type	Catalogue Number	Colors
Meatal Dilator (MD)	6/16	9	Meatal Dilator Male Meatal Dilator Female Meatal Dilator Pediatric	AMPLDL013	Blue

Intended Purpose

Meatal Dilators are used for dilation of urethral meatus for male (penile urethral meatus) and female. In women, meatal dilators are commonly used to open the cervix.

Performance Characteristics of the Device

Meatal Dilator aids in the dilation of Urethral Meatus. The smooth surface of the device helps in ease of introduction into the urethra, special atraumatic design and designed in a manner to configure to the direction of the urethra. Separate designs are available for male, female and pediatric urethral dilation process.

Indications

- Meatal Dilator used for self dilation of the penile urethral meatus and female
- To treat stricture.

Contraindications

- Active Urinary Tract Infection
- Uncorrected bleeding Diathesis
- 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 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:

- All components of the Meatal Dilators are for single use only.
- Wear sterile rubber gloves, if desired, to keep hands sterile while performing this procedure. If you have not been properly trained in inserting this device, do not attempt.
- 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

- Meatal Dilator is used in patients diagnosed with Meatal Stenosis and Ureteral Strictures.
- The device can be used in patients of all age groups.

Shelf-life and storage condition of the Product

- The shelf life of the Meatal Dilator is 3 years (Indicated on product label with the following use-by symbol).
- Store the Meatal 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 Meatal Dilators have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color 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 Meatal Dilators 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 Meatal Dilators:
- Wash hands with antibacterial liquid or soap. Open the sterile device packaging.
- Select clean and hygienic area where the dilator will be inserted.
- Slowly insert the dilator with the tip facing up. Try to keep the dilator as straight as possible when you are inserting it, although you might have to rotate the catheter as you insert it.
- Duration of contact with the body is 1 day.

Removal Instructions

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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.