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ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Urethral Filliform Dilators

Device Description

Urethral filliforms and followers are used for self-dilation of the urethra. Sterile and intended for single use. Duration of Contact with the body is 1 day.
The configurations available include:

Family	Prox. Size (Fr.)	Distal Size (Fr.)	Prox. Length (cm)	Distal Length (cm)	Catalogue Number	Color
Urethral Filliform Dilator (UTHFD)	8	/6	26.5	3.5	AMPLDL006	Blue
	10	/6	26.5	3.5		
	12	/7	26.5	3.5		
	14	/7	26.5	3.5		
	16	/8	26.5	3.5		
	18	/8	26.5	3.5		
	20	/8	26.5	3.5		
	22	/8	26.5	3.5		

Intended Purpose

Urethral Filiforms and followers are intended to help negotiate the true path of the urethral lumen and access the bladder.

Performance Characteristics of the Device

Urethral Filiform Dilator aids in traversing and dilating urethral strictures. The filiform tip replaces the need for separate filiform and followers to dilate the urethra. It has a smooth surface for ease of Introduction and uniform taper to reduce trauma.

Indications

- Used for traversing and dilating urethral strictures
- Dilation often can relieve symptoms by widening the urethra.

Contraindications

- Uncorrected Bleeding Diathesis
- Uncontrolled or untreated Urinary Tract Infection
- Uncooperative Patient
- Complicated strictures associated with fistulae
- In acute retention, it is preferable to avoid dilatation in all but the simplest cases and one should relieve retention by suprapubic puncture.

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 deice is a Urologist specialized 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 Filliform 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 filliform Dilator is used in patients diagnosed with Urethral Strictures.
- 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 storage condition of the Product

- The shelf life of the Urethral Filiform Dilator is 3 years (Indicated on product label with the following use-by symbol).
- Store the Urethral Filiform 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.

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

- The Urethral Filliform Dilators 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.
- If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- The Urethral Filliform 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 Urethral Fillliform 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.\
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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

- Contraindications: https://jpma.org.pk/PdfDownload/5590
- 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.