ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Fascial Dilators

Device Description

Used to facilitate/smooth the passage for Nephrostomy Catheter or Malecot Catheter. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

Family	Size (Fr.)	Length (cm)	Catalogue Number	Colors
Fascial Dilator (FD)	6 7 8 9 10 12 14 16 18 20 22 24	22 40	AMPLDL009	Grey

Intended Purpose

Fascial Dilators is used for fascial dilation and is intended for stretching or enlarging the fascial tissue covering a cavity, tract or opening prior to an interventional procedure.

Performance Characteristics of the Device

Fascial Dilators are used for dilation of ureter prior to ureteroscopy/ stone manipulation. It has a smooth surface for ease of introduction and is uniformly tapered to reduce the trauma.

Indications

This medical device is dilation prior to nephroscopy and for stone manipulation.

Contraindications

- Uncorrected Bleeding Diathesis, most commonly uncontrollable coagulopathy.
- Severe Hyperkalemia.
- 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 Fascial 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

Fascial Dilator is used in patients diagnosed with:

- Nephrostomy, abscess drainage and with gastrostomy tubes.
- Large kidney Stones, blocking more than one branch of the collecting system of the kidney (known as staghorn kidney stones).
- Presence of larger stones in ureter.
- Fascial Dilator 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 Fascial Dilator is 3 years (Indicated on product label with the following use-by symbol).
- Store the Fascial 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 Fascial 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 Fascial Dilators are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Suggested instructions for using Fascial Dilators:
- Open the package from the Chevron Side ('V' Side) of the pouch.
- Pass the dilators over the previously placed guide wire while maintaining the guide wire position. Dilate the Musculo fascial tract by progressing from the smallest to the largest dilator provided.
- 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								

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EC REP

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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.