ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Ureteral Access Sheath

Device Description

The Ureteral Access Sheaths are provided for use in Urology procedures. Intended for Single use. Duration of Contact with the body is not more than 30 days(short term). The configurations available include:

Family	Size (Fr.)	Length (cm)	Sheath size (Fr.)	Sheath Length (cm)	Catalogue Number
Ureteral Access Sheath (UAS)	8 10 12 14 16 18 20 22 24	28 35 40 45 50 60 70	10 12 14 16 18 20 22 24 26	23 30 35 40 45 55 65	AMPLGP002

Intended Purpose

Ureteral Access Sheaths are used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes or other instruments and injection of fluids into the urinary tract.

Performance Characteristics of the Device

The Ureteral Access Sheath consists of a tapered dilator tip which is used for continuous renal drainage, it decreases the intra renal pressure of the patient, provides improved visibility and repeated access to the kidney. Hydrophilic coating is applied to the dilator/sheath assembly to ease placement.

Indications

- To facilitate passage of Endoscopes, Urological Instruments.
- Injection of fluids into the Urinary Tract.

Contraindications

- Ureteral Trauma
- Patients with tight stricture as it would limit the use of the device.
- Patients who are contraindicated for antegrade urologic procedures including, but not limited to patients with blood clotting anomalies due to Coagulopathies or pharmacological anticoagulation
- Patients who are contraindicated for retrograde urological procedures.
- Presence of large obstructing distal ureteral calculi.
- 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:

- The Intended User of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures, authorized by the competent authority of the country in which the physician is practicing.
- Do not use the device if there is any indication that the sterility of the device has been compromised.
- Do not use this product without reading and understanding the complete instructions enclosed herein.

Warning:

- The device is for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as: Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.
- If resistance is encountered during advancement or withdrawal of the device, STOP. DO NOT continue without first determining the cause of the resistance and taking remedial action.

Intended Patient Population

- Indicated for use in patients for treatment of Urolithiasis and Retrograde Intrarenal Surgery (RIRS) to decrease Intrarenal Pressure, improve visibility and provide easy access to the renal pelvic-calyceal system and reducing the risk of bleeding and infections.
- 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 below 18yrs.

Shelf-life and storage condition of the Product

The shelf life of the Ureteral Access Sheath is 3 years (Indicated on product label with the following use-by date symbol).

Store the Ureteral Access Sheath at a temperature between 12-35^{0}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 Ureteral Access Sheaths 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 Ureteral Access Sheaths 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 from the Chevron Side ('V' Notch) of the pouch.
- Suggested instructions for using Ureteral Access Sheaths:
- Place an 0.038 inch. (0.97 mm) diameter guide wire the desired length into the ureter to establish a working tract.
- Grasp the sheath just below the instrument adapter and advance the dilator/sheath assembly over the guide wire and into the ureter. NOTE: Be sure the dilator is securely locked onto the Instrument adapter, ensuring the dilator/sheath assembly can be placed as a single unit, allowing one-hand placement.
- Confirm the dilator/sheath assembly is properly placed via fluoroscopy.
- While holding the sheath in position, unlock the fitting and remove the dilator and leave the sheath in place.
- Introduce the desired endoscope or instrument as needed.

Removal Instructions

Retrieve by gently pulling on the access sheath. If resistance is encountered during removal of the device, 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 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.