ASTER MEDISPRO PRIVATE LIMITED

# Instruction for Use
## Urethral Stent

CE 2803

### Device Description
Urethral Stent is a device used for stenting the Urethra after Hypospadias or Epispadias repair. Delivered in sterile peel open package. Intended for Single use. Duration of Contact with the body is 1 day. The configurations available include:

| Family | Accessories | Size (Fr.) | Length | Color | Catalogue Number |
|---|---|---|---|---|---|
| Urethral Stent (UTHS) | Urine Bag Connector | 5<br>6<br>7<br>8<br>10 | 25<br>30 | Blue (B)<br>Green (G)<br>White (W) | AMPLST007 |

### Intended Purpose
Urethral Stents are used to provide urethral drainage following hypospadias or epispadias repair and to provide postoperative drainage of the bladder.

### Performance Characteristics of the Device
The smooth surface of the device aids in the ease of introduction into the urethra. The device is highly radiopaque for better visualization.

### Indications
- Urethral Stent is used to provide urine drainage in patients post hypospadias and epispadias repair.
- To open the blockage or stricture (narrowing) of the urethra.
- To prevent blockage and allow easy drainage of urine from the bladder.

### Contraindications
- Acute Prostatitis
- Active Infection of the Urethra or Bladder
- Cystolithiasis
- Penile Urethral Stricture
- Stricture involving the external urethral sphincter
- Recurrent bladder tumor
- Uncooperative Patient

### Precautions & Warnings
Carefully read all instructions for use and product labeling. Do not use this product without reading and understanding the complete instructions enclosed herein. 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.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Urethral Stents at a temperature between 12-35$^0$ C and a Humidity range of 30-75%.
- Store at a dry, cool place. Avoid extended exposure to sun light.

**Warnings**:
- All components of the Urethral Stents are for single use only.
- The product must not be re-used. Reusing of 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 use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- 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.

### Intended Patient Population
Intended for use in children.

### Shelf-life
The shelf life of the Urethral Stents is 3 years (Indicated on product label with the use-by symbol and date).

### Sterility – This product is Sterile unless the package has been opened or damaged
- The Urethral Stents 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.
- The “Urethral Stents” are packed single. Product in each pack must be utilized immediately when opened. Open the package from the Chevron Side (“V” Notch) of the pouch.

### Directions for Use
- Insertion of the stent is to be done after local anesthesia.
- Insert an endoscope to visualize the inside of the urethra.
- A suitable guidewire is then guided through the endoscope.
- Once the guidewire is in place, remove the endoscope.
- Advance the stent over the guide wire, into the urethra.
- Remove the guide wire once the stent is in place and allow the drainage of urine.

### Removal Instructions

- Retrieve the urethral stent by gently pulling on Stent.
- If resistance is encountered during removal of the Stent, 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


- Contraindications:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312172/#:~:text=of%20the%20ureter.,CONTRAINDICATIONS,Uncorrectable%20coagulopathy%20is%20a%20contraindication.
- 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.