

Instruction for Use
Mono J Stent
Device Description

Mono J Stent is a specially designed device with several unique features for the drainage and irrigation of urine from kidney. It contains drainage openings in the shaft over a length of 30 cm from the pigtail of the catheter. The device is designed in such that the extended curl of the Mono J's pigtail vastly improves positional stability and traumatic characteristics in the renal pelvis. Delivered in sterile peel-open package. Intended for single use. Duration of Contact with the body is not more than 30 days. The configurations available include:

| Family | Accessories | Size (Fr.) | Length(cm) | Type | Catalogue Number |
|--------------------|--|------------|------------|---|------------------|
| Mono J Stent (MJS) | Urine Bag | 5 | 70 | One End Open (OEO) Both Ends Open (BEO) Both End Open No Holes (BEOH) | AMPLST006 |
| | Connector, | 6 | | | |
| | Female Luer | 7 | | | |
| | Lock, Male Luer | 8 | | | |
| | Lock and Metal Straightener | | | | |
| | NOTE: The accessories mentioned above are provided based on the customer device requirement. | | | | |

Intended Purpose

Mono J Stents are used for drainage and irrigation of urine from the kidney and also for intraoperative placement in the ureter during percutaneous, endoscopic or operative procedures.

Performance Characteristics of the Device

Mono J Stent contains drainage openings in the shaft over a length of 30cm from the pigtail of catheter for the drainage of urine. The pig tail tip configuration aids in retention of the distal tip in the renal pelvis. Improved positional stability and traumatic characteristics in the renal pelvis through the extended curl of the pigtail. Good drainage not only in the pigtail section, but also along the entire catheter even with strictures and insufficient peristalsis of the ureter through perforation. It is radiopaque in nature which helps in better visualization.

Indications

- Drainage of urine in patients with Urinary Obstruction, Urinary Incontinence and Kidney Stones.
- For drainage after a ureteral conduit construction and urinary diversion procedures.

Contraindications

- Patients with Urinary Bladder Outlet Obstruction.
- Bladder Fistulas
- Spastic/ noncompliant bladder
- Uncorrectable Coagulopathy
- 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.
- Monitor the stent as required. It is recommended that indwelling time should not exceed THIRTY (30) days to avoid cord encrustation.
- 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 Mono J Stents 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.
- Note: Guide wire is not provided with this Mono J Stent.
The following is recommended: Mono J Stent accepts 0.038" PTFE guide wire.

Warnings:

- All components of the Mono J 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

- The stent is used in both male and female patients above the age of 18yrs.
- Not recommended for usage in children.

Shelf-life

The shelf life of the Mono J Stents is 3 years (Indicated on product label with the use-by symbol).

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

- The Mono J Stents 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.
- The Mono J Stents are packed single. Product in each pack must be utilized immediately when opened. Open the package at the Chevron Side (“V” Notch) of the pouch.

Directions for Use

- Insert a cystoscope through the urethra into the bladder, visualizing the opening to the ureter.
- A suitable guidewire is then guided through the cystoscope into the renal pelvis.
- While holding the guidewire in position, pass the Mono J Stent, pigtail first, over the guidewire through the ureter and into the renal pelvis.
- Verify that the pigtail is in the correct position by standard radiographic procedure or fluoroscopy. The pigtail should be in the center of the renal pelvis.
- Withdraw the guidewire slowly, followed by the cystoscope while maintained the Mono J Stent position.
- Connector can be attached to the Mono J Stent for irrigation or connection of a drainage system.


















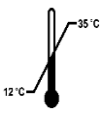



Removal Instructions

- Insert a cystoscope through the urethra into the bladder of the patient.
- The stent is grasped using a stent remover and removed.
- 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 |
|---|---------------------------------|---|------------------------------|---|-------------------------|--|----------------------------------|---|--|
|  | Catalogue Number |  | CE Mark |  | Do not Re sterilize |  | Country of Manufacture |  | Medical Device |
|  | Manufacturer |  | Date of manufacture |  | Keep Dry |  | Caution |  | Single Sterile barrier system with protective packaging inside |
|  | Batch Code |  | Use by Date |  | Keep Away from Sunlight |  | Do not re-use |  | Unique Device Identifier |
|  | Sterilized using ethylene oxide |  | Consult Instructions for Use |  | Temperature Limit |  | Do Not Use if Package is Damaged |  | Authorized Representative in the European community |
|  | Humidity Limit | | | | | | | | |

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|  | <p>Aster Medispro Pvt. Ltd S.P.181, 10th Main, 1st Stage, DR. B.R. Ambedkar Industrial Estate (KSSIDC) Jigani Industrial area, Jigani, Bangalore- 560105, Karnataka, India. Tel: +91 80-42062716 Email: info@astermedispro.net Web: www.astermedispro.net</p> |  | <p>M/sCMC Medical Devices & Drugs S.L. located in C/Horacio Lengo N° 18, CP29006, Málaga, Spain Tel : +34951214054, Fax: +34952330100 E-mail : mmateos@cmcmedicaldevices.com Web : www.cmcmedicaldevices.com</p> |
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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.