ASTER MEDISPRO PRIVATE LIMITED

CE 2803

Instruction for Use

Endopyelotomy Stent

Device Description

Endopyelotomy Stent is used for temporary drainage from the ureteropelvic junction to the bladder following incision of a stricture. 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	Size (Fr.)	Proximal Length (cm)	Distal Length (cm)	Type	Accessories	Catalogue Number
Endopyelotomy Stent (ES)	10/5 12/6 14/7 16/7	12 15	24 30	Both Ends Open (BEO) One End Open (OEO)	Pusher- supplied along with the device	AMPLST004

Intended Purpose

Endopyelotomy Stents are used for stenting the ureteropelvic junction and the ureter following a percutaneous endopyelotomy or incision of a stricture while providing both nephrostomy and ureteral drainage.

Performance Characteristics of the Device

Endopyelotomy Stent features a dual diameter and tapered end design to minimize the trauma during the placement of the stent. The larger diameter at the incised Ureteropelvic Junction aids in optimal healing. The segment with no side ports prevents postoperative narrowing of the ureteral lumen while preventing ingrowths of the ureteral wall to the stent.The pigtail shape provides better retention of the stent inside the body. The stent is soft and flexible for patient comfort.

Indications

Some of the indications for placement of Endopyelotomy stent are as follows:

- Narrowing of renal pelvis of the kidney in patients with Ureteropelvic Junction Obstruction.
- Extrinsic compression of ureter
- Ureteral Incision
- Ureteropelvic junction incision
- Stricture Dilation

Contraindications

- Long Stricture
- Large redundant renal pelvis
- Presence of crossing lower pole vessels
- Ureteral avulsion

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. Stent must not remain indwelling more than 30 days. If the patient's status permits, the stent may be replaced with a new stent. These stents are not intended as permanent indwelling devices.
- 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.
- Do not force components during removal or replacement. Carefully remove the components if any resistance is encountered.
- A pregnant patient must be more closely monitored for possible stent encrustation due to calcium supplements.
- Individual variations of interaction between stents and the urinary system are unpredictable. Periodic evaluation via cystoscope or radiographic means suggested. The stent must be replaced if encrustation hampers drainage.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Double J Stent at a temperature between 12-350 C and a Humidity range of 30-75%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- All components of the "Endopyelotomy 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 both male and female patients above the age of 18yrs.
- Not recommended for use in children.

Shelf-life

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

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

- The Endopyelotomy 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.

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- The Endopyelotomy 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

Antegrade Placement of Endopyelotomy Stent

- After the completion of the pyeloplasty procedure by incision below the rib, endopyelotomy stent is to be placed.
- Insert a dilator tube to the distal side of the ureter.
- Insert the guidewire into the dilator tube.
- Remove the dilator tube slowly and insert the endopyelotomy stent along the guidewire.
- Advance the stent up to bladder. Check the position of the larger diameter of the stent in the ureter.
- Assure the position of the stent is placed within the ureteropelvic junction (UPJ) to prevent post-operative structuring.
- Remove the guide wire slowly. Confirm for a full coil in the bladder and that the larger stent section is located in the ureteropelvic junction fluoroscopically.

Retrograde Placement of Endopyelotomy Stent

- After the completion of pyeloplasty procedure, endopyelotomy stent is to be placed.
- Insert a cystoscope through the urethra, under the direct visualization by cystoscope, a suitable guidewire is passed through the ureter.
- The Endopyelotomy Stent is passed over the guidewire.
- Withdraw the guidewire slowly to allow distal coil to form in the renal pelvis.
- Assure the position of the stent is placed within the ureteropelvic junction (UPJ) to prevent post-operative structuring.
- Confirm the position of the stent fluoroscopically.
- Once the stent is firmly in place, remove the cystoscope.

Removal Instructions

- Removal of the stent to be done after treating the patient with a local anesthetic.
- 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
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								

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

EC REP

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

Bibliography

- Contraindications: https://pubmed.ncbi.nlm.nih.gov/8284881/#:~:text=The%20primary%20contraindication%20to%20endoscopic,be%20relative%20contraindications%20as%20w

ell.

- 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.