Instruction for Use

Long Pusher for Double J Stent

CE 2803

Device Description

The Long Pusher for Double J Stents are provided for use in Urology procedures for use in cystometry and urethral pressure profilometry. Intended for Single use. Duration of Contact with the body is short term. The configurations available include:

Family	Size (x0,1Fr.)	Length (cm)	Catalogue Number
Long pusher for Double J Stent (PUSH)	**3.5** **4.0** **4.5** **5.0** **5.5** **6.0** **6.5** **7.0** **7.5** **8.0**	**45** **60** **70**	**AMPLST010**

Intended Purpose

The pusher is used to deliver the stent into position across a suitably stiff guidewire.

Performance Characteristics of the Device

The Long Pusher in Double J Stents aids in the placement of plastic stents over a guidewire with or without a guiding cathetendications

Indications

- The DJ stent is then passed over the guide wire and pushed in using a pusher.

Contraindications

- Perforation and infection.
- Bladder Fistulas
- Spastic/ noncompliant bladder
- Uncorrectable Coagulopathy
- Uncooperative Patient

Precautions & Warnings

Carefully read all instructions for use. 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.
- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- 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.

Warnings:

- The device is 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 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

Long Pusher for Double J Stent is used for the urology procedures in patients of all ages.
3.5Fr Pusher is used for infants till 12yrs, 3.5Fr to 4.5Fr Pusher is used for children from 12 to 18 yrs. 5Fr to 8Fr Pusher is used for adults (above 18 yrs).

Shelf-life of the Product

The shelf life of the Long Pusher for Double J Stents is 3 years (Indicated on product label with the following use-by symbol).

Store the Long Pusher for Double J Stent at a temperature between 12-35^{0}C and a Humidity range of 30-75%.

Store the Long Pusher for Double J Stent at dry, cool place. Avoid extended exposure to sun light.

Instruction for Use

Long Pusher for Double J Stent

CE 2803

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

- The Long Pusher for Double J 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 pf 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 "Long Pusher for Double J Stents" are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Open the package at the Chevron Side ('V' Notch) of the pouch.
- The involved renal collecting system should be visualized via intravenous or retrograde pyelography.
- Select the appropriate size Stent for patient's anatomy. A well sized Stent should be fully coiled within the renal pelvis with the loops free floating in the bladder.
- 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.
- The retrieval line can be removed prior to placement if desired or the retrieval line can be left intact to extend externally.
- Insert flexible end of guide wire into the renal pelvis for DJS Both Ends Open or the rigid end of guide wire for DJS One End Open, using clinically. For DJS Both Ends Closed use rigid end of Guide wire through the side hole of the stent using appropriate retrograde technique.
- Pass tapered tip of Stent over guide wire and through cystoscope.
- Advance Stent up the ureter.
- Withdraw guide wire slowly to allow distal coil to form in the renal pelvis. Placement should be confirmed under fluoroscopy or x-ray.
- Monitor the Stent as required. Retrieval line indwelling time should not exceed THIRTY (30) days for blue, green and white DJS to avoid possible cord encrustation.

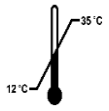
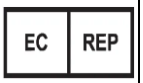
Removal Instructions

Retrieve cystoscopically by gently pulling on Stent or retrieval line with grasping forceps or equivalent. 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								

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://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.