ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Double J Stent Long Duro

Device Description

The Double J Stents Long Duro are provided for use in Urology procedures. The configurations available include:

Family	Size (x0.1Fr.)	Length (cm)	Type	Color/Material	Options
Both Ends Single Loop (DJSBES) One End Multiloop (DJSOEM) Both Ends Multiloop (DJSBEM)	3.0 3.5 38 4.0 4.5 4.7 4.8 5.0 5.5 6.0 6.5 7.0 8.0	12 14 16 18 20 22 24 26 28 30	One End Open (OEO) Both Ends Open (BEO) Both Ends Closed (BEC)	Yellow-Long Duro (*LD)	With Clamp (/C) With Guide wire (/G) With Clamp + Guide wire (/CG) With Suture (/S) With Suture + Clamp (/SC) With Suture + Clamp + Guide Wire (/SCG)

Intended purpose

The Double J Stent Long Duro are indicated for use in Urology procedures to ensure the patency of a Ureter.

Intended User

This device is intended for the coagulation of soft tissue during surgical procedures. It must be used only by qualified urologists trained in surgical techniques and authorized by the Competent Authority in the country where they practice. The device is for professional use only in controlled clinical or surgical environments.

Medical Conditions to be Treated

- Ureteral obstruction due to calculi, strictures, or external compression
- Post-operative support of the ureter following endoscopic or open urological surgery
- Prevention of obstruction after stone removal or ureteral manipulation
- Management of hydronephrosis by maintaining urinary drainage
- Support of ureteral healing following trauma or surgical intervention

Performance Characteristics of the Device

The term “Double J” refers to the curled ends of the stent, with one “J” anchored in the renal pelvis and the other positioned inside the bladder to prevent displacement. The Double J Stent Long Duro is placed in the ureter, which functions as a low-pressure, flexible tube with intrinsic peristalsis. The stent ensures continuous urinary drainage and maintains ureteral patency in cases of obstruction. Placement of the Double J Stent Long Duro may be performed through an antegrade approach by an interventional radiologist or a retrograde approach by a urologist. This device may be used as an alternative to percutaneous nephrostomy performed in acute settings. The Long Duro variant is specifically designed for extended indwelling time, providing durable support while internalizing urinary drainage without the external disadvantages of a nephrostomy.

Indication.,

The insertion of a Double J (DJ) Long Duro is indicated in various urological situations where there is a need to address conditions affecting the ureter or maintain proper urine flow between the kidney and the bladder.

Contraindications

Perforation and infection.

Precautions, Warnings & Adverse effects

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.

- Caution: Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device based on his own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- Warning: All components of the “Double J Stents Long Duro” are for single useonly.
- Caution: Do not use the device if there is any indication that the sterility of the device has been compromised.
- Adverse effects: Possible adverse effects of guide wire placement are documented. Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

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- This device is only use only. Re-use may result in clinical complications.

Intended Patient Population

Double J Stent Long Duro is used for the urology procedures. 3Fr Stent is used for infants till 12yrs, 3Fr to 4Fr Stent is used for children from 12 to 18 yrs. 5Fr to 8Fr Stent is used for adults.

Shelf-life of the Product

The shelf life of the Double J Stent Long Duro is 3 years (Indicated on product label with the following use-by symbol and date).

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

- The Double J Stent Long Duro 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.
- If the sterile package is damaged or possibly opened, do not use. Contact "Distributor" and replace the product.
- The "Double J Stent Long Duro" are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- 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, For Long Duro DJS (yellow) retrieval line indwelling time should not exceed NINETY (90) days to avoid possible cord encrustation. It is recommended that when long term use is indicated the Stent should be evaluated every 30 days.

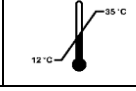
Removal Instructions

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 Symbo
	Catalogue Number		Unique Device Identifier		Do not re sterilize		Country of Manufacture		Medical De
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Ste barrier sys with protec packaging i
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity L
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

- Indication: https://dreminozbek.com/en/ureteral-double-j-cathether/#:~:text=The%20insertion%20of%20a%20Double,the%20kidney%20and%20the%20bladder..
- 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.