Instructions for Use
Loop Stent

CE 2803

Device Description

Loop stent is a soft, hollow, plastic tube with unique bladder loops placed temporarily into the ureter. The two unique bladder loops provide an average of 69% less material in patient's bladder than a traditional stent. The device has a specific position designed to mimic fluoroscopic placement as compared to a traditional Double J Stent. 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	Colors
Loop Stent (LS)	Pusher & Straightener- (supplied along with device)	4.0 5.0 6.0	24 26 28 30	One End Open (OEO) Both Ends Open (BEO)	AMPLST003	White Yellow Blue

Intended Purpose

Loop Stents are intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically or during an open surgical procedure. They are used to ensure the patency of a ureter.

Performance Characteristics of the Device

The loop stent has a regular pigtail at the renal retention portion and two soft loops in the bladder to prevent migration, decrease discomfort and facilitate cystoscopic removal. Loop Stent also has an advantage due to the unique bladder design; it has an average of 69% less material in the bladder when compared to a traditional Double J Stent. The pigtail tip is tapered to avoid atraumatic access and has graduated circumference markings to confirm the placement.

Indications

To provide drainage through a ureter that is obstructed, leaking, dysfunctional or strictured in patients with Urinary Obstruction or Kidney Stone.

Contraindications

- Antegrade Placement
- Poor surgical risk patients
- Unexplained Hematuria
- Unrepaired ureteral avulsion
- 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 Double J Stent at a temperature between 12-35^0 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 Loop 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 intended patient population for the device is patients of age 18 years and above.
- Recommended for use in both Male and Female patients.

Shelf-life

The shelf life of the Loop 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 Loop 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 Loop Stents are packed single. Product in each pack must be utilized immediately when opened.

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.
- Insert flexible end of guide wire into the renal pelvis using clinically appropriate retrograde technique.
- Pass tapered tip of the stent over guide wire and through cystoscope.
- Load the loop positioner over the guide wire proximal to the stent and advance stent up the ureter. The black mark on the Loop stent, located just above the bladder loops, should be positioned at the ureteral orifice.
- Withdraw guide wire slowly to allow distal coil to form in the renal pelvis. Placement should be confirmed under fluoroscopy or X-ray.
- Indwelling time should not exceed THIRTY (30) days.

Removal Instructions

- Insert a cystoscope through the urethra into the bladder of the patient.
- The loop stent is grasped using a stent remover. It is recommended to grasp both loops prior to extracting the stent and remove gently.
- If resistance is encountered during the removal of the stent, stop and determine the 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.