ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use
Prostate Stent

CE 2803

Device Description
A Prostate Stent is a device used to keep the urethra open which improves the flow of urine. It is inserted through the urethra to the point of constriction, where it is allowed to expand. The pressure exerted by the stent on the inside wall of the urethra widens its bore and reduces the obstruction to urinary flow. 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)	Catalogue Number
Prostate Stent (PS)	Pusher Straightener Suture- (Supplied along with the device)	12 14 16	3 4 5	AMPLST008

Intended Purpose
Prostate Stents are intended for temporary use in men with Bladder Outlet Obstruction (BOO) to reduce elevated Post Void Residual (PVR) and improve voiding symptoms.

Performance Characteristics of the Device
Prostatic Stents are tiny, springlike devices that can be endoscopically placed into the prostatic urethra which tends to open the prostatic tissue and relieves the Bladder Outlet Obstruction. When expanded, it pushes back the surrounding tissue and widens the urethra allowing normal voiding in patients with a functioning detrusor.

Indications
- To relieve bladder outlet obstruction.
- To keep urethra, open to improve the flow of urine.
- In men who are not fit for surgery but who are still able to empty the bladder on their own.

Contraindications
- Prostate medial lobe enlargement.
- Positive urine culture or active urinary tract infection.
- History of urinary tract disease including urethral stricture, bladder neck contracture, bladder or kidney stones, other significant urological condition or abnormal urethral anatomy.
- History of difficult urethral catheterization.
- Prior pelvic irradiation therapy.
- 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.
- Do not use petroleum-based ointments or lubricants with the device.
- Appropriate patient education, training and monitoring by a qualified healthcare professional is required for safe patient use.
- Patient should be instructed not to pull on retrieval suture visible at the urethral meatus and not to attempt to remove the device.
- The device has not been evaluated for use with MRI; therefore, it should be removed prior to MRI use.
- 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 12-350 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 Prostate 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 device is intended for use in adults. Not recommended for use in infants and children.
- Recommended for use in Men only.

Shelf-life
The shelf life of the Prostate 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 Prostate 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 Prostate 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.

- Placement of the stent to be done after treating the patient with a local anesthesia.
- Insert a cystoscope through the urethra.
- A suitable guidewire is then guided through the cystoscope.
- Place the straighter over the stent for closing both sides of the flower/ straighten the stent.
- Pass the stent along with the straightener over the previously placed guide wire till the bladder neck.
- Once position is achieved, remove the straightener to open the flower.
- Retrieval suture should be placed in the urethra for an easy removal of stent.
- Once the stent is in position withdraw the guidewire slowly followed by cystoscope.
- Instruct the patient to be careful not to pull on the retrieval suture as it could dislodge the stent.

Removal Instructions

- The Stent can be removed by gently pulling the suture attached to the stent.
- 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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EC REP

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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.