Instructions for Use
Tumor Stent

CE 2803

Device Description
The Tumor Stent is a device used for palliative drainage in case of ureteral compressions. The reinforced internal layer provides excellent resistance to compression. 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.)	Length (cm)	Type	Accessories	Catalogue Number
Tumor Stent (TS)	10/5 12/6 14/6 14/7	22 24 26 28 30	Both Ends Open (BEO)	Pusher- supplied along with the device	AMPLST005

Intended Purpose
Tumor Stents is used for temporary as well for palliative treatments of internal urinary drainage when tumors are present in ureteral tract. The stent optimize drainage, even in cases where the ureter is extremely compressed.

Performance Characteristics of the Device
The Tumor Stent is designed such that the dual durometer aids in the easy insertion and placement while retaining great flexibility. The soft material of the pigtail section offers high patient comfort, while the special stiffened shaft portion helps to prevent the stent from collapsing. The tumor stent side holes are strategically placed to allow drainage and to prevent the ingrowth of tissue into the stent.

Indications
- Ureteral cancer/Bladder Cancer
- To provide drainage through a ureter that is obstructed or strictured due to presence of tumor.

Contraindications
- Patients with Urinary Bladder Outlet Obstruction.
- Bladder Fistulas
- Spastic/ noncompliant bladder
- Uncorrectable Coagulopathy
- 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. 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.
- 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.
- 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 Tumor 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 sunlight.

Warnings:
- All components of the Tumor 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: 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
Tumor Stent is used in both male and female patients above the age of 18 yrs.

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

Sterility – This product is Sterile unless the package has been opened or damaged
- The Tumor 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 Tumor 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.

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Directions for Use
- Insert a cystoscope through the urethra into the bladder, visualizing the opening to the ureter.
- A Suitable guidewire is then guided through the cystoscope, up the ureter.
- Advance the stent over the guidewire.
- Once the stent is in position, with the distal tip of the stent coiled in the renal pelvis and the larger diameter of the stent in the position where the ureter is obstructed or strictured to relieve the obstruction.
- Remove the guide wire slowly.
- Check for at least a full coil in the bladder and that the larger stent section is in the uretero pelvic junction, confirm the position using a fluoroscope.
- Once the stent is firmly in place, remove the cystoscope.

Removal Instructions
- Insert a cystoscope through the urethra into the bladder of the patient.
- The stent is grasped using a stent remover and remove by pulling slowly.
- 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								

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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.