allwin® Medical Devices

Carbothane Ureteral Stents

Description:
Carbothane Ureteral Stents are designed to be placed endoscopically, fluoroscopically or via open surgery. The Surgisoft Ureteral stent are made up of radiopaque, soft, flexible and bio-compatible material The Stents are designed with curl(s) so as to facilitate anchoring. The stent with suture help physician easy positioning and/or removal.

Configuration:
See brochure

Intended use:
The Carbothane Ureteral Stent is intended to temporarily facilitate drainage of urine from kidney to bladder by trained physician.

Indication:
- Obstruction of ureteral lumen by stones or clots.
- Ureteral strictures or stenosis.
- Compression of the ureter by tumors or during pregnancy.
- Stone Fragments due to extracorporeal shock wave lithotripsy.
- Ureter perforation incision.
- Ureteral carcinoma.
- Retroperitoneal fibrosis.
- Endopyelotomy
- Nephrolithototomy
- Pyeloplasty

Contraindications:
- Untreated infected urinary congestion of the kidneys (pyonephrosis), vascular abnormalities of the renal pelvis outlet, acute urethral trauma.
- Do not attempt stent placement in a patient with suspected ureteral avulsion.
- Do not use when, in the judgment of the physician, such a procedure would be contrary to the best interests of the patient.

Complications:
The potential complications associated with the use of the stent which includes, but are not limited to:

- Migration or dislodgement
- Encrustation
- Infection
- Fragmentation
- Flank pain
- Extravasation
- Sepsis
- Urgency
- Dysuria
- Stone Formation
- Obstruction
- Erosion
- Catheter Occlusion
- Peritonitis
- Mucosal irritation or inflammation
- Mucus Secretion
- Reflux
- Hemorrhage
- Loss of renal function
- Perforation of the renal pelvis, ureter or bladder

Caution:
Federal (USA) law restricts this device to sale by or on the order of a physician.

Warning/ Precaution:
- The Carbothane Ureteral stent is provided sterile by ethylene oxide and is intended for single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Do not use if product or sterile packaging is damaged.
- If resistance is encountered during removal, fluoroscopically determine stent position and cause of resistance.
- Fluoroscopy or standard radiography should be used to confirm the correct size and placement of the stent. Phenolic evaluation is recommended to evaluate the device efficiency and to observe for possible complications.
- It is recommended that the cumulative indwelling Time not exceed 90 days.
- Check compatibility of the guidewire before use.
- Suture indwelling time is not to exceed 14 days. Remove suture if indwelling time is longer than 14 days.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Storage temperature between 5ºC to 30ºC
- Only experienced surgeon should place this device
- For single use only.

Carbothane Stent	Compatible Guidewire
4.8F	0.035”
6F	0.038”

Instruction for Use:
Use an appropriate imaging technique to estimate the length of the patient’s ureter and add 1cm to determine the proper stent length. The stent length is distance between two coils. Correct stent placement ¡s necessary to ensure proper drainage and maximum patient comfort.

For closed tip:
1. Thread the Carbothane Ureteral Stent, open end first on to the stiff end of the compatible guidewire
2. Thread the pusher onto the other end of the guidewire.
3. Insert the system through the working channel of the cystoscope upto the renal pelvis, under fluoroscopic control.
4. Once correct placement within the renal pelvis is achieved remove the guidewire and then the pusher carefully.
5. Confirm bladder coil formation cystoscopically.
6. Remove cystoscope.

For open tip:
1. Insert the flexible tip of the compatible guidewire into the working channel of the cystoscope upto the renal pelvis, using endoscopic and fluoroscopic control.
2. Thread the Carbothane ureteral stent onto the guidewire and advanced it upto the renal pelvis using the pusher after final placement, keep the pusher in position.
3. Once correct placement within the renal pelvis is achieved remove the guidewire and thon the pusher, carefully.
4. Confirm stent position with fluoroscopy, radiography or cystoscopy.

Stent Removal:
1. Either using the suture or cystoscopically, retrieve the stent by gentle pulling.
2. If any resistance is encountered during removal, fluoroscopically determine stent position and cause of resistance.

Storage:
The device should be stored in a clean, dry area. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Storage temperature between 5ºC to 30ºC. The devices must be used prior to the sterilization expiration date on package.

How Supplied:
The Ureteral Stent is provided sterile by ethylene oxide and is intended for single use only. Do not resterilize, reuse or reprocess.

Do not reuse, reprocess & resterilize:
Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages.
The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only Caution : Federal (USA) law restricts device to sale by or on the order of a physician.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | STERILE EO Sterilized using ethylene oxide | Temperature Limit

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