INSTRUCTIONS FOR USE

Description

The Q Urological pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent is made of hydrophilic polymer material. An ALL hydrogel stent is produced using a proprietary process.

This hydrogel stent does not have a bonded coating; rather the entire device is comprised of the hydrogel material. The stent has a bulbous shape at each end to serve as an anchoring device. The bulbous portion of the stent is easily compressed conforming to the ureter lumen diameter during implantation.

After positioning, the bulbous anchorage end expands into the pelvis of the renal collecting system thus preventing the stent from slipping out of position. The anchorage end is radiopaque for proper positioning.

Indications

The Q Urological pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent is used to facilitate temporary internal urinary drainage from the kidney to the bladder and stenting of the ureter in a pediatric patient no less than 2 years old and not more than 12 years old. The stent may be placed endoscopically, percutaneously, or using open surgical techniques. The stent should not be implanted for more than **30** days. This product is not intended as a permanent indwelling device.

Contraindications

(1) Do not insert stent if a complete obstruction is noted.
(2) Do not insert if partial or complete transection of the ureter is present.
(3) Do not use if active fungal infection is present.
(4) Do not use if active bleeding or clotting is present.

Suggested Instructions for Using Endoscopic / Retrograde placement

(1) Keep the stent in the package if opening prior to use. When ready to advance the stent over a guide-wire, immerse the stent in sterile saline for at least three (3) minutes.

(2) Under direct cystoscopic vision and with fluoroscopic guidance, pass the tip of a flexible guide-wire (0.018 to 0.012 inch diameter) beyond the obstruction to the renal pelvis. In cases where the guide-wire must negotiate tortuous or obstructed ureters, combining the use of an open ended ureteral catheter may be helpful.

(3) A retrograde ureterogram should be conducted prior to stent placement to evaluate the ureteral and renal collecting system anatomy as well as to determine precise stent dimensions.

(4) Then pass the stent over the guide-wire pushing the stent up the ureter with a pusher catheter under direct cystoscopic vision using intermittent fluoroscopy.

(5) Watch for the proximal stent end to develop spontaneously, and halt advancement. Gently pull back to insure proper anchorage is achieved.

(6) Fluoroscopy or conventional radiography should be used to confirm the correct placement of the stent.

Removal or exchange

During a procedure to exchange the stent, fluoroscopic monitoring will insure that access to the upper collecting system is not lost by checking that the proximal position of the stent is not withdrawn past the level of the obstruction.

To remove, visualize the bladder end of the stent cystoscopically. With a flexible grasper (alligator forceps), gently withdraw the stent from the renal collecting system and ureter under direct vision. Withdraw the stent until the distal anchorage end just exits the urethral meatus.

Sizing

The Physician is responsible for selecting the proper stent diameter and length. To minimize the risk of migration, the stent length should be sufficient to allow for deployment of the anchorage system both in the kidney and in the bladder. The stent is only available as a 4 French diameter, with a fixed length. However several lengths are available. Trimming the bulbous radiopaque anchorage end IS NOT recommended. This stent will accept a 0.018 inch diameter guide-wire (not included).

Warnings and Precautions

(1) To avoid damage to stent, **do not** withdraw or manipulate through a metal device with sharp edges.

(2) The stent is packaged hydrated, fully saturated in sterile saline. Keep in package if opened prior to use. Otherwise before advancing stent over the guide-wire, immerse the stent in **only** sterile saline for at least three (3) minutes.

(3) Hydrophilic catheters are very slippery when wet. However the stent should be handled without difficulty using gloved hands. If problems are encountered maintaining control when manipulating, use a sponge squeezing between fingers applying gentle pressure.

(4) If the stent appears to become damaged, such as an obvious tear or evidence that suggests the stent may break, immediately exchange it for a new one.

(5) Stent must be saturated in **pH :(5.5 / 7.0)** sterile saline.

(6) Stent should not be implanted for more than 30 days. This product is not intended as a permanent indwelling device.

(7) Do not reuse.

(8) Do not re-sterilize.

Complications

Patients or their representative should be informed of the possible complications with the use of ureteral stents. Complications may include, but are not limited to:

(1) Proximal or distal migration, possibly necessitating medical or surgical intervention to reposition or remove the stent.
(2) Encrustation.
(3) Compromised urine flow due to stent blockage or ureteral occlusion.
(4) Infection.
(5) Perforation with possible injury to adjacent organs during procedure or after.
(6) Stent breakage, possibly necessitating endoscopic or surgical retrieval of the device.
(7) Bleeding may occur.
(8) Improper placement could occur.
(9) Bladder irritation could occur.

Special Instructions

Keep Stent in package or sterile saline prior to use before advancing stent over a guide-wire. Insure that the stent is adequately hydrated; the stent should be soft, slippery and flexible. If the stent becomes dehydrated, exhibiting a degree of rigidity; soak in sterile saline for at least (3) three minutes

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician

Manufactured in the U.S.A. by:
TBD

Sterilized by Electron Beam
FOR SINGLE USE ONLY - DO NOT RESTERILIZE OR REUSE
This stent can not be re-sterilized and can only be used for a single procedure on one patient.

In case of emergency, and for any questions please call 781 245 2232 (9AM to 6PM EST) or 508 728 1031 24 hours a day.

EXCLUSIVE DISTRIBUTION THROUGH
Q Urological Corporation
P.O. Box 793
Natick, MA. 01760
781 245 2232

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