Retromax™ Plus Endopyelotomy Stent with HydroPlus™ Coating

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

Some of the indications for placement of a Retromax Plus Stent are:
- Extrinsic compression of ureter
- Ureteral incision
- Ureteropelvic junction incision
- Stricture dilatation

Contraindications

The use of ureteral stents should be reconsidered if the following conditions exist:
- Poor surgical risk patients
- Unexplained hematuria
- Unrepaired ureteral avulsion

Warnings

- For single use only. Do not reuse, reprocess or resterilize.
- Warnings can be found in the product labeling supplied with each device.

Potential Adverse Events

Adverse events associated with retrograde and antegrade positioned indwelling ureteral stents:
- Pain
- Ureteral reflux
- Extravasation
- Occlusion
- Dislodgment, fragmentation
- Hemorrhage
- Sepsis
- Perforation of kidney, renal pelvis, ureter and bladder
- Peritonitis
- Urinary tract infections
- Encrustation
- Urinary Symptoms (frequency, urgency, incontinence)
- Hydronephrosis
- Stone Formation
- Erosion

Precautions
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Recommended for one-time use only.
- Avoid bending or kinking the stent during or prior to placement as to do so could damage the integrity of the stent.
- If resistance is encountered during advancement or withdrawal of the stent, STOP. Do not continue without first determining the cause of resistance and taking remedial action.
- Periodic radiographic, isotopic, or cystoscopic examinations are recommended to evaluate stent efficiency and to observe for possible complications. When long term use is indicated, it is recommended that indwelling time not exceed 365 days. The stent should be evaluated for replacement at three (3) month intervals. This stent is not intended to be a permanent implant device.
- Use of this device should be restricted to physician specialists with comprehensive knowledge of the indications, techniques and risks of the procedure.
- Precautions can be found in the product labeling supplied with each device.

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