CATHEGENIX

Endura™ Ureteral Stent and Stent Set

Instructions for Use

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Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, discard and replace with a new one.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result inpatient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

【PRODUCT NAME】

Endura™ Ureteral Stent and Stent Set

【DEVICE DESCRIPTION】

Ureteral stents are flexible tubular devices made of radiopaque polyurethane, featuring coiled pigtail self-retaining loops at both ends. The entire length of the stent (including the pigtail loop sections) is equipped with multiple side holes and marked with indicators to facilitate intraoperative imaging visualization, advancement manipulation, and precise positioning. The stents are provided either as standalone products or as part of a stent set, including both the basic and full configurations.

• Basic Set: Includes a ureteral stent, pigtail straightener, and positioner.

• Full Set: Includes a ureteral stent, pigtail straightener, positioner, and J-tip guide wire.

*Note: 4.5, 4.7 and 6Fr stents are compatible with a .028" guidewire and 7, 8, 8.5 and 10 Fr stents are compatible with a .038"guidewire. In vitro testing of the Endura™ Ureteral Stent has shown a reduction in encrustation compared to a control. The correlation between in vitro test data and clinical outcomes has not been established.

【INTENDED USE】

The device is indicated to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions in the ureter. The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic techniques. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.

【CONTRAINDICATIONS】

No known contraindications for use.

【DIRECTION FOR USE】

• Determine the proper stent length for the patient. This is generally calculated from the baseline pyelogram. Accurate measurements will optimize drainage efficiency and patient comfort.

• Insert the cystoscope then pass the guidewire* through the scope until the tip is in the renal pelvis.

• Move the pigtail straightener over the proximal end (kidney coil end) of the ureteral stent allowing easier insertion onto the guidewire. Remove pigtail straightener once the stent is secure on the guidewire.

• Pass the stent over the guidewire through the cystoscope by using the push catheter for proper placement.

• Watch the distal end (bladder coil end) of the stent or the radiopaque, proximal end of the pusher. Stop advancing when the stent's distal end marker reaches the ureterovesical junction (UVJ).

• Withdraw the guidewire slowly. The stent will form a pigtail automatically.

• Carefully remove the push catheter.

• *For the use of the guidewire, please refer to the J-Tip Guide Wire instructions for use (IFU).

【PRECAUTIONS】

• Avoid improper handling of stent such as bending, kinking, tearing, etc. Misuse could damage the overall integrity of the stent.

• Ureteral stents should be checked periodically for signs of encrustation and proper function. Periodic checks of the stent by cystoscopic and/or radiographic procedures are recommended at intervals deemed to be appropriate by the physician in consideration of the individual patient's condition and other patient specific factors. When long-term use is indicated, it is recommended that indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.*

• With any ureteral stent, migration is a possible complication, which could require medical intervention for removal. Selection of too short a stent may result in migration.

• Care should be exercised when removing the stent from the inner polybag to eliminate tearing or fragmentation.

• The insertion of a ureteral stent should only be done by those individuals who have comprehensive training in the techniques and risks of the procedure.

【URETERAL STENT REMOVAL】

1.Have the patient lie flat in the lithotomy position.
2.Urethral surface anesthesia is typically applied, supplemented with sedation and analgesia if necessary.
3.Under saline irrigation, introduce a cystoscope through the urethra into the bladder and locate the intravesical end of the ureteral stent under direct visualization.
4.Pass a foreign body forceps through the working channel and gently grasp the bladder end of the stent.
5.Maintain a secure hold on the stent and withdraw the cystoscope and stent together in a controlled, steady motion until the stent is fully removed.
6.After the stent is removed, observe the patient for any adverse reactions
7.Advise the patient to maintain adequate hydration, rest, and avoid strenuous activity. Follow-up evaluations should be scheduled as clinically appropriate.

【POTENTIAL COMPLICATIONS】

Potential complications associated with retrograde/antegrade positioning of indwelling ureteral stents include the following:

• Edema	• Stone formation
• Extravasation	• Ureteral reflux
• Fistula formation	• Loss of renal function
• Hemorrhage	• Pain/Discomfort
• Hydronephrosis	• Ureteral erosion
• Infection	• Urinary symptoms
• Stent encrustation	• Peritonitis
• Stent dislogdgement, fragmentation,migration,occlusion	
• Perforation of kidney, renal, pelvis, ureter and/or bladder	

【SYMBOLS】

Symbol	Description	Symbol	Description
	*Manufacturer*		*Date of manufacture*
	*Catalogue number*		*Batch code*
	*Unique device identifier*		*Use-by date*
	*Do not re-use*		*Do not resterilize*
	*Sterilized using ethylene oxide*		*Single sterile barrier system*
	*Do not use if package is damaged and consult instructions for use*		*Consult instructions for use or consult electronic instructions for use*
	*Keep dry*		*Federal law restricts this device to sale by or on the order of a physician*
	*Keep away from sunlight*		*CAUTION:DESTROY AFTER USE*
	*Fragile, handle with care*		

【PRODUCTION DATE】 See packaging

【STERILIZATION】 Sterilized by EO (ethylene oxide) gas

【PERIOD OF VALIDITY】 3 years

CONTACT

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