Clinical data summary

Black Silicone Filiform Double Pigtail Ureteral Stent Set

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Sources	
1. Cormio L, Koivusalo A, Mäkisalo H, et al. The effects of various indwelling JJ stents on renal pelvic pressure and renal parenchymal thickness in the pig. *Br J Urol*. 1994;74(4):440–443. https://eurekamag.com/pdf/009/009573693.pdf	**Objective:** To study the effects of indwelling JJ stents on renal function.
	Key point: Polyurethane stents, as opposed to silicone stents, could have a negative impact on renal function.
2. Choong SK, Wood S, Whitfield HN. A model to quantify encrustation on ureteric stents, urethral catheters and polymers intended for urological use. *BJU Int*. 2000;86(4):414–421. http://onlinelibrary.wiley.com/doi/10.1046/j.1464-410X.2000.00861.x/pdf	**Objective:** To study stent material as it relates to encrustation.
	Key point: Polyurethane stents encrusted more than silicone stents, and silicone stents developed only about half as much encrustation as stents with hydrogel or hydrophilic coating.
3. Chen GL, Bagley DH. Fluoroscopic placement of double-pigtail ureteral stents. *Diagn Ther Endosc*. 2001;7(3–4):175–180. http://jdc.jefferson.edu/cgi/viewcontent.cgi?article=1024&context=urologyfp	**Objective:** To investigate the fluoroscopic placement of ureteral stents.
	Key point: The authors of this study used a silicone stent any time the stent was expected to remain indwelling for longer than a month.
4. Watterson JD, Cadieux PA, Stickler D, et al. Swarming of *Proteus mirabilis* over ureteral stents: a comparative assessment. *J Endourol*. 2003;17(7):523–527. https://www.ncbi.nlm.nih.gov/pubmed/14565887	**Objective:** To investigate the encrustation-resistant properties of three ureteral stents.
	Key point: Silicone stents may be less susceptible to bacterial infection and thus encrustation and may therefore offer benefits to patients who are at risk of encrustation.
5. Gadzhiev N, Gorelov D, Malkhasyan V, et al. Comparison of silicone versus polyurethane ureteral stents: a prospective controlled study. *BMC Urol*. 2020;20(1):10. https://bmcurol.biomedcentral.com/track/pdf/10.1186/s12894-020-0577-y	**Objective:** To evaluate the safety of, and the intensity of the symptoms associated with, silicone and polyurethane ureteral indwelling stents.
	Key point: Silicone may be a preferable alternative to polyurethane stents for patients who are currently experiencing or who have previously experienced stent-related symptoms (SRSs).

Black Silicone Filiform Double Pigtail Ureteral Stent

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

INTENDED USE: This product is used for temporary internal drainage from the ureteropelvic junction to the bladder. The device is not intended to remain indwelling more than twelve months.

CONTRAINDICATIONS: This device is contraindicated in the presence of conditions which create unacceptable risk during catheterization.

WARNINGS: Sterilized by Ethylene Oxide gas. Do not use if sterile barrier is damaged. The device is intended for one-time use.

PRECAUTIONS: Complications of ureteral stent placement are documented. Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance with follow-up procedures. • Do not force set components during placement, replacement, or removal. Carefully remove the set components if any resistance is encountered. • The tether should be removed if the stent is to remain indwelling longer than 14 days. • The stent must not remain indwelling more than twelve months. If the patient's status permits, the stent may be replaced with a new stent. • The included stent is not intended as a permanent indwelling device. • A pregnant patient must be more closely monitored for possible stent encrustation due to calcium supplements. • Improper handling can seriously weaken the stent. Acute bending or overstressing during placement may result in subsequent separation of the stent at the point of stress after a prolonged indwelling period. Angulation of the stent should be avoided. • Individual variations of interaction between stents and the urinary system are unpredictable. • Periodic evaluation via cystoscopic, radiographic, or ultrasonic means is suggested. The stent must be replaced if encrustation hampers drainage. • The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects. • If problems occur using this device, please call your Cook Urological sales representative or contact our Customer Service department at the address/phone listed at www.cookmedical.com.

POTENTIAL ADVERSE EVENTS: Migration and dislodgement • Pain and discomfort • Urinary frequency and urgency • Perforation and fistula formation • Stent obstruction by stone or tissue • Stent fragmentation

See Instructions for Use for full product information.

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