













Clinical data summary

Black Silicone Filiform Double Pigtail Ureteral Stent

Click on each link below to view the article or abstract.

Sources

<p>1. Gadzhiev N, Gorelov D, Malkhasyan V, et al. Comparison of silicone versus polyurethane ureteral stents: a prospective controlled study. <i>BMC Urol.</i> 2020;20(1):10.**</p> <p>https://bmcurol.biomedcentral.com/track/pdf/10.1186/s12894-020-0577-y</p>	<p> Objective: To evaluate the safety of, and the intensity of the symptoms associated with, silicone and polyurethane indwelling ureteral stents.</p>
	<p> 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).</p>
<p>2. Hendlin K, Dockendorf K, Horn C, et al. Ureteral stents: coil strength and durometer. <i>Urology.</i> 2006;68(1):42-45.</p> <p>https://www.ncbi.nlm.nih.gov/pubmed/16844448</p>	<p> Objective: To evaluate how a stent's coil strength and stiffness impact performance and comfort.</p>
	<p> Key point: While not as stiff as other stents, the Black Silicone stent has a strong coil strength. A stent's stiffness and coil strength may be helpful when determining which stent to use for a case.*</p>
<p>3. Watterson JD, Cadieux PA, Stickler D, et al. Swarming of <i>Proteus mirabilis</i> over ureteral stents: a comparative assessment. <i>J Endourol.</i> 2003;17(7):523-527.**</p> <p>https://www.ncbi.nlm.nih.gov/pubmed/14565887</p>	<p> Objective: To investigate the encrustation-resistant properties of three ureteral stents.</p>
	<p> 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.</p>
<p>4. Chen GL, Bagley DH. Fluoroscopic placement of double-pigtail ureteral stents. <i>Diagn Ther Endosc.</i> 2001;7(3-4):175-180.</p> <p>http://jdc.jefferson.edu/cgi/viewcontent.cgi?article=1024&context=urologyfp</p>	<p> Objective: To investigate the fluoroscopic placement of ureteral stents.</p>
	<p> 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.</p>
<p>5. Choong SK, Wood S, Whitfield HN. A model to quantify encrustation on ureteric stents, urethral catheters and polymers intended for urological use. <i>BJU Int.</i> 2000;86(4):414-421.**</p> <p>http://onlinelibrary.wiley.com/doi/10.1046/j.1464-410X.2000.00861.x/pdf</p>	<p> Objective: To study stent material as it relates to encrustation.</p>
	<p> 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.</p>
<p>6. 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. <i>Br J Urol.</i> 1994;74(4):440-443.**</p> <p>https://pubmed.ncbi.nlm.nih.gov/7820420/</p>	<p> Objective: To study the effects of indwelling JJ stents on renal function.</p>
	<p> Key point: Polyurethane stents, as opposed to silicone stents, could have a negative impact on renal function.</p>

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details.

*The authors did not confirm a link between the stent's coil strength and stiffness and comfort; further study is required.

**Articles reference Cook silicone stents, not specifically Black Silicone stents.

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.

