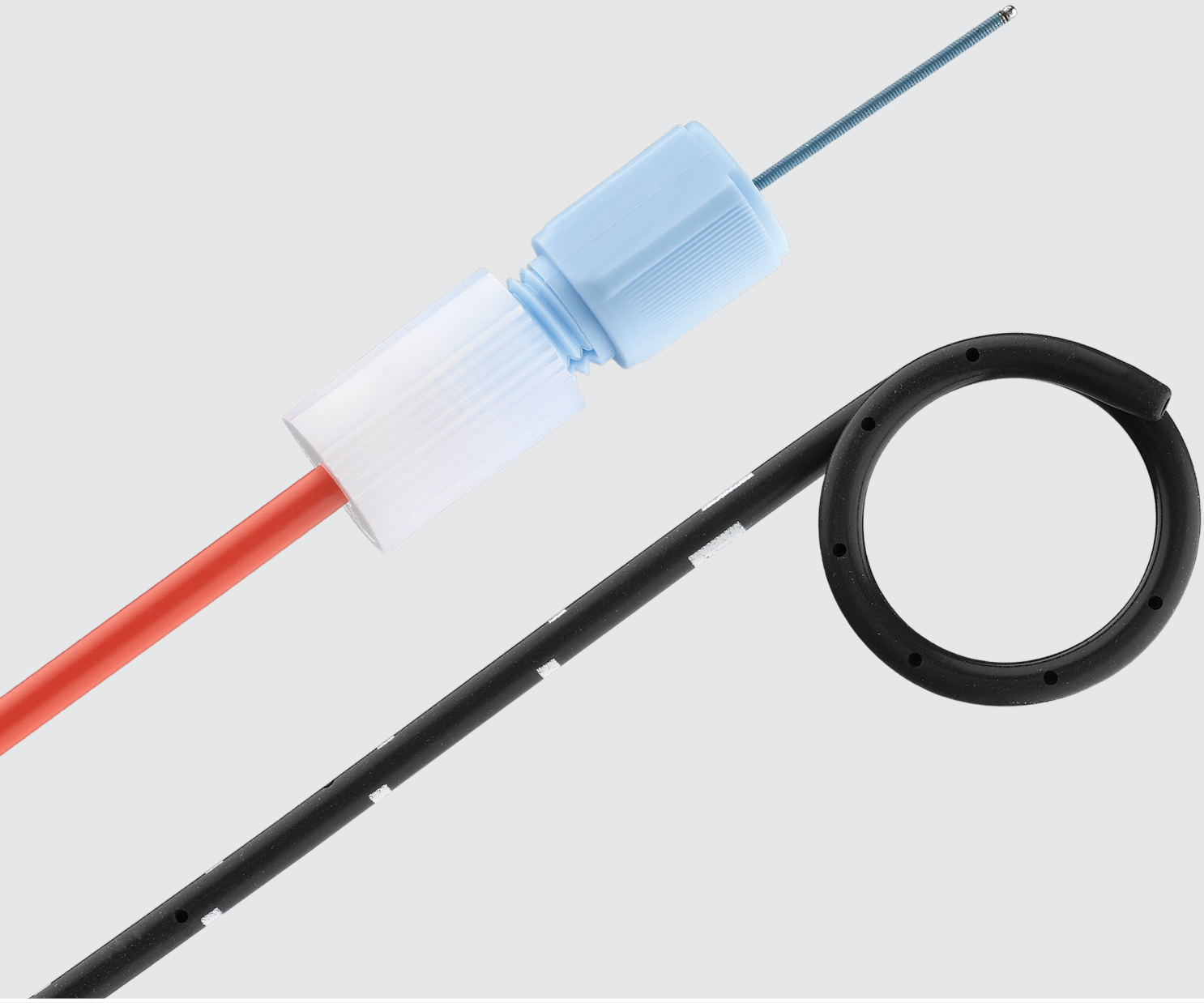
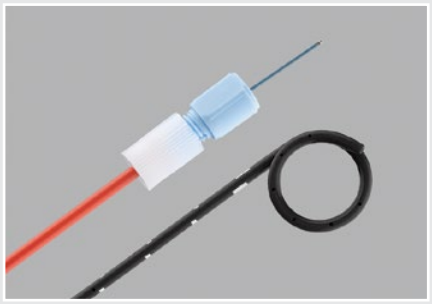
Make softness a priority.



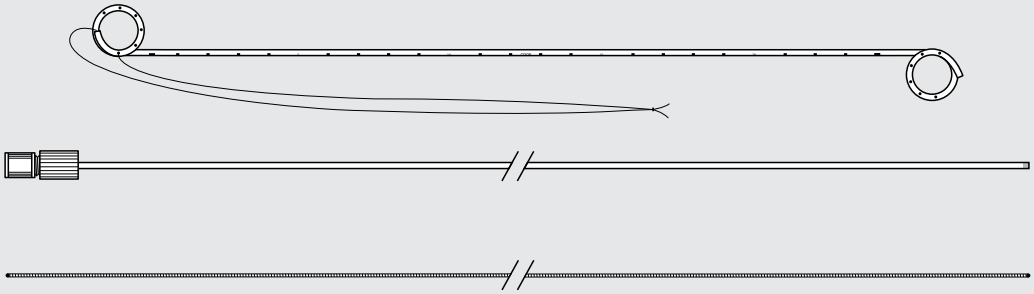
BLACK SILICONE FILIFORM DOUBLE PIGTAIL URETERAL STENT SET

COOK® MEDICAL



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.

The set includes a stent, a wire guide, and a stent positioner. The product also comes with a "T inserter" that can be used to introduce the wire guide into the positioner.



Order Number	Reference Part Number	Fr	Length cm
G46443	133620-01	6.0	20
G46438	133622-01	6.0	22
G46439	133624-01	6.0	24
G46440	133626-01	6.0	26
G46441	133628-01	6.0	28
G46442	133630-01	6.0	30
G46430	133722-01	7.0	22

Order Number	Reference Part Number	Fr	Length cm
G46429	133724-01	7.0	24
G46431	133726-01	7.0	26
G46432	133728-01	7.0	28
G46434	133822-01	8.5	22
G46435	133824-01	8.5	24
G46437	133826-01	8.5	26
G46436	133828-01	8.5	28

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

Black Silicone Filiform Double Pigtail Ureteral Stent Set

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: Manipulation of the wire guide requires appropriate imaging control. Use caution not to force or over-manipulate the wire guide when gaining access. • When using a wire guide through a metal cannula/needle, use caution as damage may occur to the outer coating. • When exchanging or withdrawing an instrument over the wire guide, secure and maintain the wire guide in place under fluoroscopy in order to avoid unexpected wire guide displacement. • The included wire guide is not intended for PTCA use. • Hydrophilically coated wires are very slippery when wet. Always maintain control of the wire guide when manipulating it through any device. • 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. • It is imperative that the filiform flexible end of the wire guide be introduced into the ureter first. • 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 wire guide or 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.

AB_T_BSFDP_REV0

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