

Patency under pressure



Resonance[®]
METALLIC URETERAL STENT

Used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction, the Resonance Metallic Ureteral Stent is specifically designed to mitigate the problems encountered with traditional plastic ureteral stents and other forms of treatment. Its tightly wound coil maintains patency so urine can drain continuously under extrinsic (malignant and benign) ureteral compression.

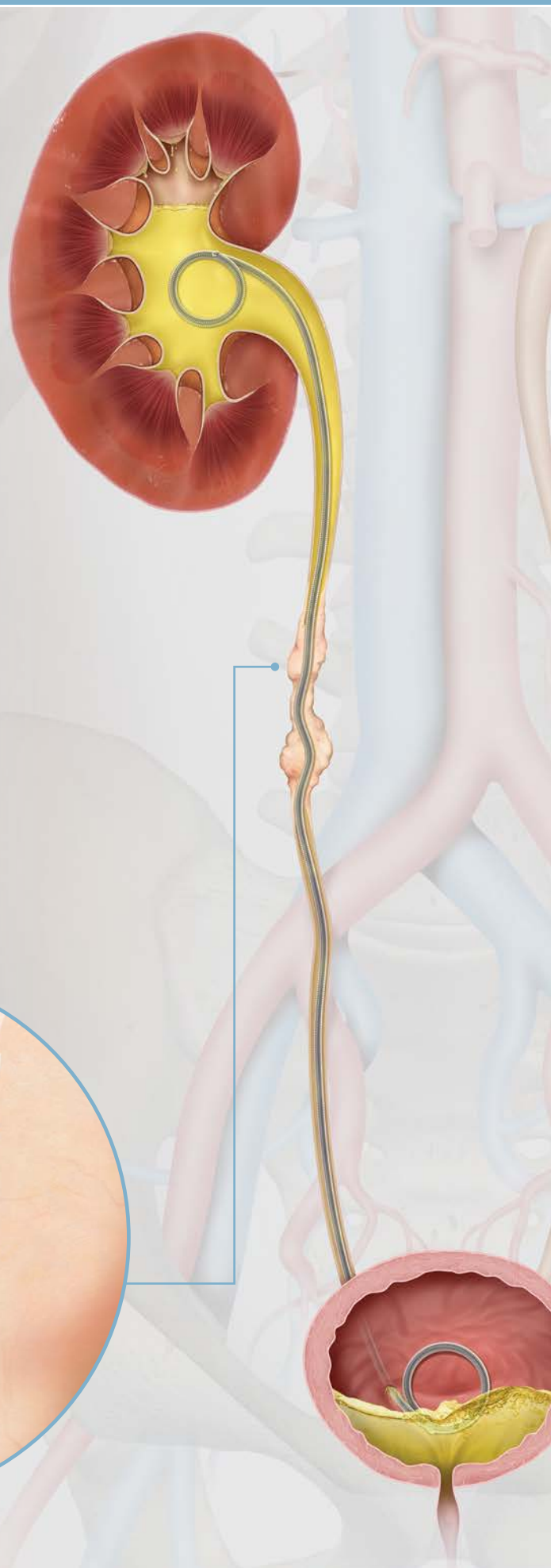
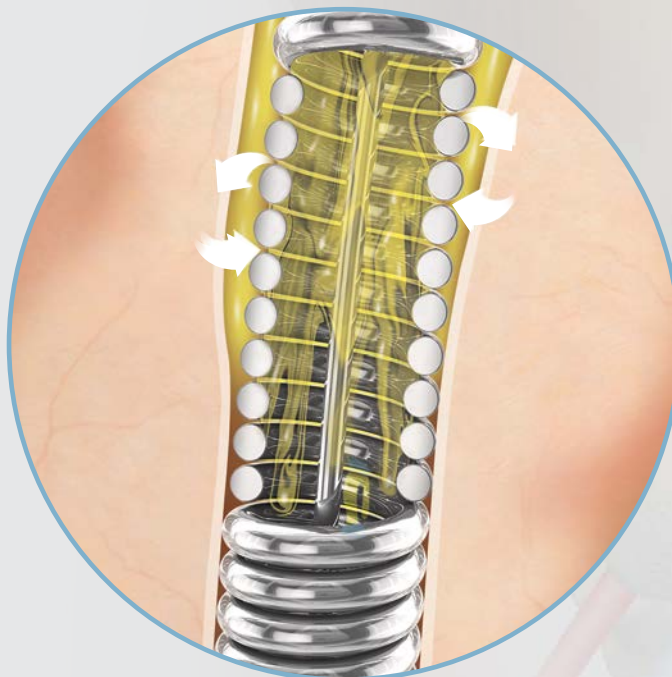
The optimized compressive and radial strength of the Resonance stent, and its resistance to encrustation,¹ allow the stent to remain indwelling for up to 12 months.

Resist compression

The Resonance provides radial strength without compromising longitudinal flexibility. In vitro testing found that the Resonance stent is more resistant to external compression than traditional polymer stents.²

Resist encrustation

The Resonance is more resistant to encrustation than traditional polymer stents, which may result in longer indwelling times and may reduce the number of exchange procedures needed.³



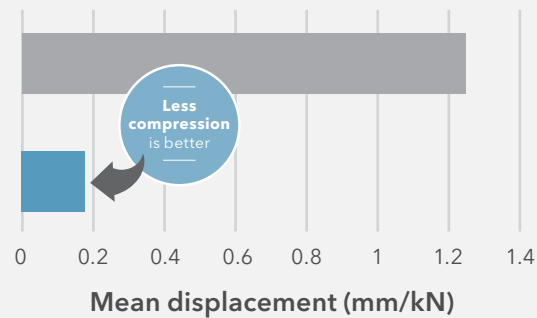
Unique stent performance characteristics

Compression testing

Stent type

Best-performing plastic stent

Resonance

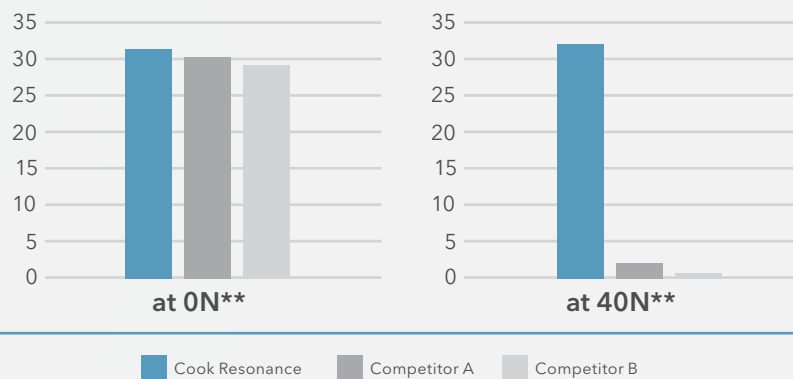


Compression testing shows the Resonance stent compresses less than the plastic stents tested.*

*Reference document number: VAL05-0058-REPORT (Rev 2) (2019). Testing was conducted on four different plastic stents manufactured by Cook Medical: Sof-Flex Double-Pigtail Stent, Cook Double-Pigtail Graduated Stent, Black Silicone Filiform Double-Pigtail Ureteral Stent, and Cook Double-Pigtail Stent.

Comparative flow study

Flow rates under extrinsic loading



A comparative flow study shows the Resonance stent has superior flow rates to the plastic stents studied under comparable extrinsic compression testing conditions.***

**Newtons

***Reference document number: RWP1106 (2006). Testing was conducted on 6 Fr ureteral stents from different manufacturers: Cook Medical Resonance® Metallic Ureteral Stent, Boston Scientific Percuflex® Ureteral Stent, and Bard InLay® Ureteral Stent, respectively.

Cost savings

The Resonance stent has a maximum indwelling time of 12 months, which reduces the need for frequent stent changes. **As a result, the Resonance stent may be a cost-effective option for treating chronic patients.** Fewer stent exchanges may be required for the Resonance compared to standard plastic ureteral stents, which means it may be less costly to treat patients using the Resonance.^{1,6}

Example

Assume your hospital performs 100 ureteral stenting procedures per year. By placing the Resonance, you can potentially eliminate 198 exchanges, save \$362,961.36 per year, and free up time to perform other procedures.

	Resonance metallic stents	Polymeric stents
Estimated number of exchanges per patient per year ¹	1.91	3.89
Total number of exchanges expected per year	191	389
Estimated average cost per year due to exchanges (includes procedure cost* and stent cost)**	\$687,852.12	\$1,050,813.48

a. The procedure cost is the averaged geometric mean cost of CPT codes 50693, 50694, 50695, and 52310 from the CY2023 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. Centers for Medicare & Medicaid Services Web site. <https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-fc>. Accessed December 15, 2022.

b. The estimated cost of each Resonance Metallic Ureteral Stent is \$1,000, and the estimated cost of each polymeric stent is \$100.

Resonance® Metallic 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: Used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction. Intended for one-time use.

CONTRAINDICATIONS: There are no known contraindications.

WARNINGS: These stents are not intended as permanent indwelling devices. • The stent must not remain indwelling more than twelve (12) months. If the patient's status permits, the stent may be replaced with a new stent. • Patients should be checked at regular intervals utilizing techniques such as abdominal X-ray (KUB film). Patients using calcium supplements must be more closely monitored for possible stent encrustation. The stent must be removed if encrustation hampers drainage. • Individual variations of interaction between stents and the urinary system are unpredictable. • Change in urine viscosity may hamper drainage. • Hematuria and Incontinence may indicate fistula formation. • If the package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization. • This device is designed for single use only. Attempts to reprocess, sterilize, and/or reuse may lead to device failure and/or transmission of disease. • The stent contains

nickel which may cause an allergic reaction in individuals with nickel sensitivity.

PRECAUTIONS: This product is intended for use by physicians trained and experienced in urology techniques. Standard techniques for urology procedures should be employed. Do not use this device for any purpose other than the stated intended use. The Resonance stent must only be used with the positioning system provided and vice versa. Do not force components during removal or replacement. Carefully remove the components if any resistance is encountered. Improper handling of the stent prior to insertion into the ureter may harm the functionality of the stent. Bending, stretching or any other type of improper handling may deform the stent. It is important that the stent is handled with care.

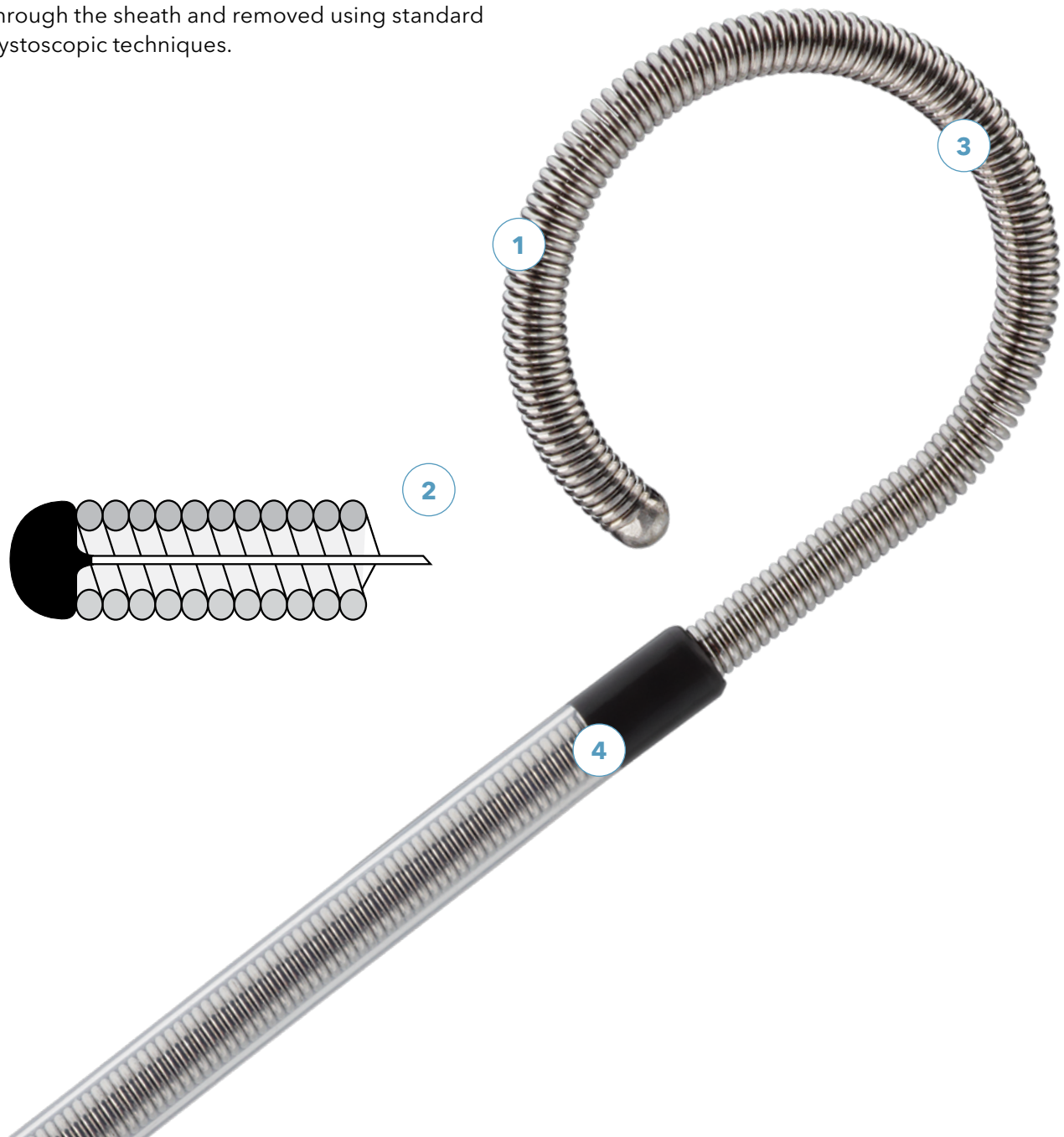
POTENTIAL ADVERSE EVENTS: Potential adverse events associated with indwelling ureteral stents include: allergic reaction to nickel • bladder spasm • diminished urine drainage/stent occlusion • fever • fistula formation including arterioureteral fistula • hemorrhage • hydronephrosis • infection • insufficient urine drainage • loss of renal function • pain/discomfort • perforation of kidney, renal pelvis, ureter and/or bladder • peritonitis • pyuria • stent degradation/fracture • stent dislodgement/migration • stent encrustation • stent failure • tissue ingrowth • ureteral reflux • urinary symptoms (frequency, urgency, incontinence, dysuria, hematuria) • urinary tract tissue erosion.

See Instructions for Use for full product information.

The stent's unique coil construction allows urine to flow even in instances of compression.^{4, 5}

- 1 The stent is made of a cobalt-chromium-nickel-molybdenum alloy (MP35N).
- 2 An internal wire (also made from MP35N) extends the full length of the stent and joins the stent at either extremity. This wire prevents the elastic elongation of the stent; prevention of stent elongation is particularly important during stent removal.
- 3 The tightly wound coil design helps maintain continuous drainage by allowing urine to flow in and out of the coils.
- 4 A stent positioner and clear sheath provide enhanced visualization and reference points for first and second pigtail deployment.

The stent may be placed using either an antegrade or retrograde technique—introduced coaxially through the sheath and removed using standard cystoscopic techniques.



Resonance Metallic Ureteral Stent Set

Used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction.
This stent is intended for one-time use.

Order Number	Reference Part Number	Fr	Length cm
Stent and Positioning System			
G34108	RMS-060020-R	6	20
G34109	RMS-060022-R	6	22
G34110	RMS-060024-R	6	24
G34111	RMS-060026-R	6	26
G34112	RMS-060028-R	6	28
G34176	RMS-060030-R	6	30

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



Nonclinical testing has demonstrated that the Resonance stent is MR Conditional.
Refer to the product's IFU for more information.

1. López-Huertas HL, Polcari AJ, Acosta-Miranda A, et al. Metallic ureteral stents: a cost-effective method of managing benign upper tract obstruction. *J Endourol.* 2010;24(3):483-485.
2. Polcari AJ, Hugen CM, López-Huertas HL, et al. Cost analysis and clinical applicability of the Resonance Metallic Ureteral Stent. *Expert Rev Pharmacoecon Outcomes Res.* 2010;10(1):11-15.
3. Rao MV, Polcari AJ, Turk TM. Updates on the use of ureteral stents: focus on the Resonance stent. *Med Devices (Auckl).* 2011;4:11-15.
4. Borin JF, Melamud O, Clayman RV. Initial experience with full-length metal stent to relieve malignant ureteral obstruction. *J Endourol.* 2006;20(5):300-304.
5. Taylor ER, Benson AD, Schwartz BF. Cost analysis of metallic ureteral stents with 12 months of follow-up. *J Endourol.* 2012;26(7):917-921.
6. Kadlec AO, Ellimoottil CS, Greco KA, et al. Five-year experience with metallic stents for chronic ureteral obstruction. *J Urol.* 2013;190(3):937-941.

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