

Resonance[®]

METALLIC URETERAL STENT SET

Value analysis^{*}

AND PRODUCT
INFORMATION
PACKET

2023
UPDATE



COOK[®]
MEDICAL

SUSTAINABLE PATENCY ATTRIBUTED TO METALLIC COIL DESIGN 12-MONTH INDWELL

^{*}Prepared for value analysis committees in a hospital setting

Disclaimer: The information provided herein reflects Cook's analysis of the procedure(s) and/or device(s), based upon the instructions for use (IFU), from sources that may include, but are not limited to, published journal articles, data on file with the manufacturer, physician and consultant input, the CPT coding system, and Medicare payment systems. This analysis is provided for general information purposes only, and Cook does not warrant or assume any liability or legal responsibility for this information. The entity assessing the product is solely responsible for determining the accurate cost of treatment at its site and the codes assigned to the services and items in the medical record. Each entity should use its own economic data to fully assess the assumptions and analysis stated herein.

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Product overview

The Resonance® Metallic Ureteral Stent is specifically designed to mitigate the problems encountered with traditional plastic ureteral stents and other forms of treatment. The metallic composition allows the stent to remain indwelling for a maximum of 12 months, and its tightly wound metal coil maintains patency so that urine can drain continuously under extrinsic compression. The Resonance is introduced coaxially through a sheath and removed using standard cystoscopic techniques.

Key product features:

A maximum indwelling time of 12 months:	The Resonance reduces the need for frequent stent changes with a maximum indwelling time of 12 months.
A clear introducer system:	The Resonance's stent positioner and clear sheath provide enhanced visualization and reference points for first and second pigtail deployment for all stent sizes.
A metal alloy construction:	The Resonance is composed of nonmagnetic nickel, chromium, cobalt, and molybdenum.
An MRI-conditional status (up to 3 Tesla):*	The Resonance can be safely scanned under the MR conditions described in the IFU .

The Resonance was designed to provide value for:

Hospitals:	The Resonance produces positive clinical outcomes with potentially fewer stent exchanges required. ^{1,2}
Healthcare providers:	The Resonance provides a 12-month indwell option for patients with extrinsic ureteral obstruction. ^{1,2,3,4}
Patients:	Use of the Resonance results in potentially fewer stent exchanges. ^{5,6}
Payers:	The Resonance is a feasible solution for chronic ureteral obstruction, with a maximum indwell time of 12 months. ^{1,4}

*Data on file with manufacturer. Reference document number: VAL05-0058-REPORT (Rev 2).



The key considerations for your value analysis include the following:

1. The product:

The Resonance is a potentially cost-effective renal drainage solution for patients with extrinsic ureteral obstructions. Its optimized metallic design allows it to remain indwelling for up to 12 months.^{1,4}

Construction features include the following:

- The stent is constructed of a metal alloy material consisting of nonmagnetic nickel, chromium, cobalt, and molybdenum.
- The internal wire extends the full length of the stent and is welded to both ends to help prevent elongation (especially during removal).

2. The financial impact:

- The Resonance is potentially a cost-effective option for treating patients with chronic ureteral obstructions, since fewer stent exchanges may be required compared to standard plastic ureteral stents, which means it may be less costly to treat patients using the Resonance.^{1,2,4}

Product information

Product design

The Resonance's unique coil design allows urine to flow even in instances of compression.^{2,3} The Resonance has an outer diameter of 6 Fr and is available in lengths of 20, 22, 24, 26, 28, and 30 cm between the antimigration pigtails at either end. The stent is constructed of closely coiled cobalt-chromium-nickel-molybdenum alloy (MP35N) wire. Adjacent spirals of the coiled wire are in close contact to minimize tissue ingrowth. 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.



Product intended use

The Resonance is used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction.

References may be found on page [22](#) of this packet.



Value analysis

Overview

Using Cost, Quality and Clinical Outcomes to make evidence-based decisions

Healthcare professionals understand the importance of a high-quality product and one that makes economic sense as well. In this ever-changing healthcare landscape, healthcare providers must not only focus on the best clinical option for their patients, but also the most cost-effective option. They can no longer focus solely on the individual procedure, but must also be mindful of the total care of that patient, including follow-up, the patient's return to work, and the patient's overall quality of life.

Our product's value analysis focuses on the variable that can be controlled, stent choice, thus allowing healthcare providers to make evidence-based decisions to treat their patients.



Use of the Resonance potentially benefits multiple entities, including the following:

Patients:

Because fewer stent exchanges are potentially required, fewer visits to the doctor's office or the hospital may be necessary.^{5,6}

Healthcare providers:

A 12-month maximum indwell means potentially fewer reinterventions, freeing up time for healthcare providers to perform other procedures.^{1,2,3,4}

Hospitals:

Positive clinical outcomes have been observed with the use of the Resonance, with potentially fewer stent exchanges required; it may thus be less costly to treat patients with the Resonance.^{1,2}

Payers:

By reducing the number of exchanges required, the Resonance may reduce the number of procedures requiring coverage and payment.^{1,4}

Indwelling stent placement and related procedures put the patient at additional risk. For the list of potential adverse events associated with indwelling ureteral stents, please refer to the [IFU](#).

References may be found on page [22](#) of this packet.



Economic value analysis

In the treatment of extrinsic compression, frequency of stent exchange is a significant factor in determining a product’s economic value. For example, a plastic stent might cost a fraction of the price of a metal stent but may need to be exchanged three to six times per year,^{2,4} depending on labeled indwell time and medical need. Even with plastic stents costing significantly less, the overall cost of care must be considered as part of the value analysis.

More frequent stent exchanges may have negative consequences, including increasing the overall cost to treat the patient.

- The average cost of a **hospital outpatient** placement of a ureteral stent without complications has been estimated at **\$2,763.32**.⁷
- Stent placement and exchange procedures are reimbursed on average at **\$2,867.56^a** by Medicare. Thus the average reimbursement is only slightly more than the average cost of the procedure.

Assume your hospital performs 100 ureteral stenting procedures per year.

	Resonance metallic stents	Polymeric stents
Estimated number of exchanges per patient per year ⁸	1.91	3.89
Total number of exchanges expected per year	191	389
Estimated average cost per year due to exchanges (includes procedure cost + stent cost) ^{b,c}	\$687,852.12	\$1,050,813.48
Eliminate 198 exchanges and save \$362,961.36 per year.		

NOTE: By eliminating exchange procedures, you may free up time to perform other procedures.

For more information on this economic value analysis and to further understand the use of the Resonance, please contact your local Cook representative.

^a The average Medicare reimbursement rate was calculated using CPT codes 50693, 50694, 50695, and 52310.

^b 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/hospitaloutpatientpps/hospital-outpatient-regulations-and-notice/cms-1772-fc>. Accessed December 15, 2022.

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

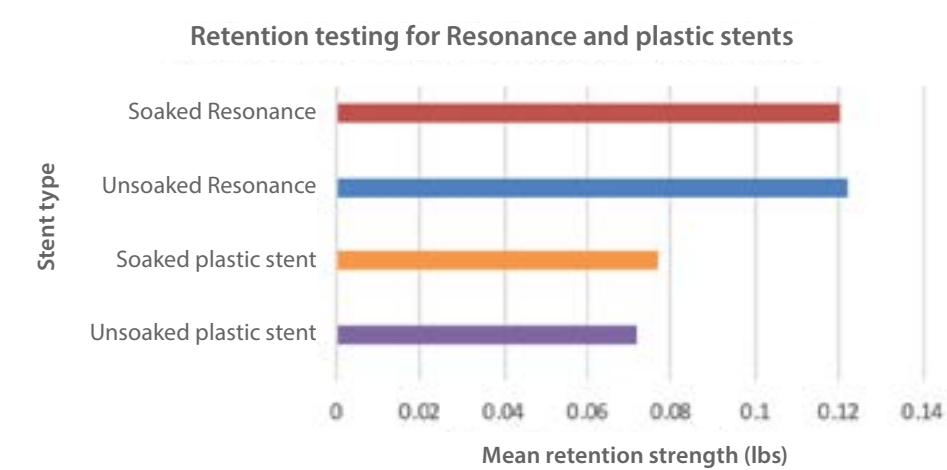
References may be found on page 22 of this packet.



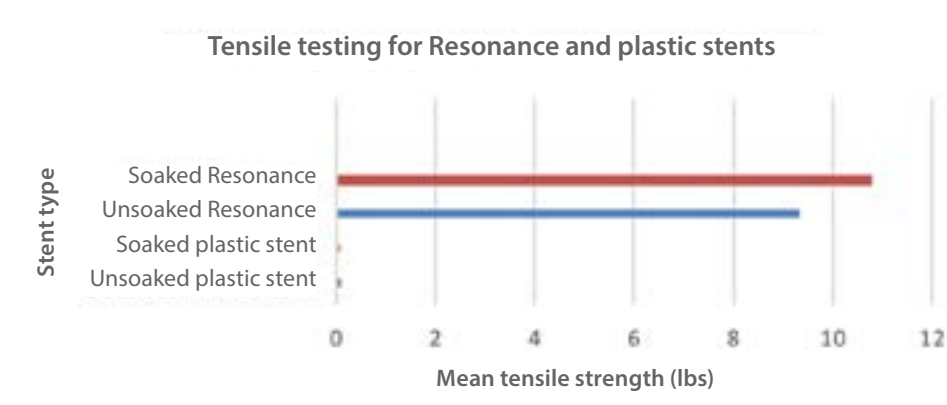
Nonclinical data analysis

The urinary tract is an extremely harsh environment for devices to maintain their integrity. Testing has been conducted on both the Resonance and plastic stents to compare retention strength, tensile strength, elongation, and compression when soaked and not soaked in simulated urine.

The Resonance exhibits greater retention strength and tensile strength and elongates less than Cook plastic stents.*



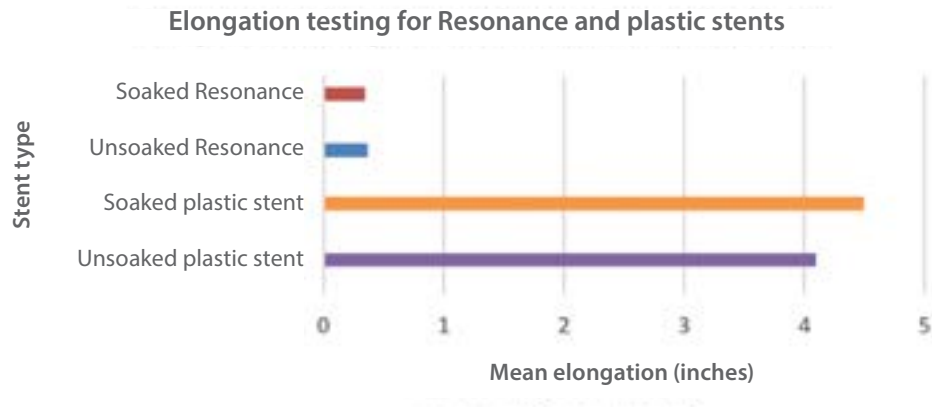
The results of the retention strength testing show that the retention strength for the Resonance is greater than that for the plastic stents tested.*



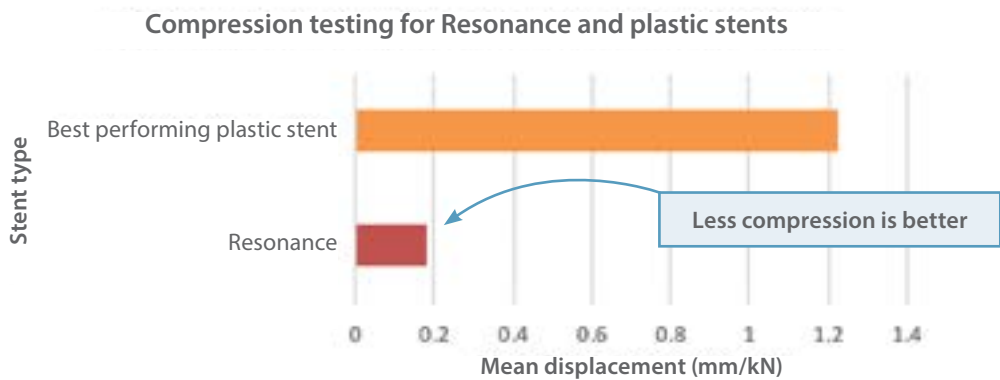
The results of the tensile strength testing show that the tensile strength for the Resonance is greater than that for the plastic stents tested.*

*Data on file with manufacturer. Reference document number: VAL05-0058-REPORT (Rev 2).

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.



The results of the elongation testing show that the Resonance displaces less than the plastic stents tested.*



Less is better. The results of the compression testing show that the Resonance compresses less than the plastic stents tested.*

*Data on file with manufacturer. Reference document number: VAL05-0058-REPORT (Rev 2).
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.



Summary

Treating extrinsic ureteral compression can be complicated, but stent choice does not have to be. The data referenced throughout this document can help healthcare providers make evidence-based decisions. Using information about cost, quality, and clinical outcomes, providers can determine whether the Resonance is ideal for their patients.

The Resonance was designed to provide value for:

Hospitals:	Positive clinical outcomes with potentially fewer stent exchanges required ^{1,2}
Healthcare Providers:	A 12-month indwell option for patients with extrinsic ureteral obstruction ^{1,2,3,4}
Patients:	Results in potentially fewer stent exchanges required ^{5,6}
Payers:	A feasible solution in chronic ureteral obstruction, with a maximum indwell time of 12 months ^{1,4}

The key considerations for your value analysis include the following:

1. The product:

The Resonance is a potentially cost-effective renal drainage solution for patients with extrinsic ureteral obstructions. Its optimized metallic design allows it to remain indwelling for up to 12 months.^{1,4}

Construction features include the following:

- The stent is constructed of a metal alloy material consisting of nonmagnetic nickel, chromium, cobalt, and molybdenum.
- The internal wire extends the full length of the stent and is welded to both ends to help prevent elongation (especially during removal).

2. The specialties impacted:

- Urology
- General surgery
- Nephrology
- Emergency medicine

References may be found on page 22 of this packet.



3. The financial impact:

- The Resonance is potentially a cost-effective option for treating chronic patients; the possibility of fewer stent exchanges compared to standard plastic ureteral stents means that it may be less costly to treat patients using the Resonance.^{1,2,4}

4. The impact on patients:

- Because the Resonance has a 12-month maximum indwell time, the patient will potentially be required to make fewer visits to the doctor's office or hospital for exchange procedures, thus leaving them more time to focus on other life events.^{5,6}

References may be found on page [22](#) of this packet.



Materials management information

Order numbers and sizing

Order Number	Reference Part Number	French Size	Length (cm)
STENT AND POSITIONING SYSTEM			
G34108	RMS-060020-R	6.0	20
G34109	RMS-060022-R	6.0	22
G34110	RMS-060024-R	6.0	24
G34111	RMS-060026-R	6.0	26
G34112	RMS-060028-R	6.0	28
G34176	RMS-060030-R	6.0	30

If you like these Cook products, you may also be interested in these other offerings from Cook Medical: <https://www.cookmedical.com/products/>

Product specifications

The Resonance is used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction.

Material composition

The Resonance is a composite of nonmagnetic nickel-cobalt-chromium-molybdenum that is configured as a continuous coil with an inner safety wire welded to both ends that prevents elastic elongation, especially during removal. The tightly wound metallic coil maintains its patency so that urine can drain continuously under severe extrinsic compression. The Resonance is introduced coaxially through a sheath and removed using standard cystoscopic techniques.

Coding and reimbursement

For the most up-to-date information, please visit www.cookmedical.com/support/reimbursement/ and click on the Urology tab under “Coding and Reimbursement Guides.”



FDA 510(k) clearance letter

(This document is also available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=k063742>.)

MAY 8 2007		Section 5.0 510(k) Summary	K063742
Name:	Cook Ireland Ltd		
Address:	O'Halloran Road National Technology Park Limerick, Ireland		
Phone:	353 61 334440		
Fax:	353 61 334441		
Contact Persons:	Emmett Devereux, Quality & Regulatory Manager Sinead Burke, Regulatory Affairs Supervisor		
Phone:	353 61 334440		
Fax:	353 61 334441		
Date:	December 14, 2006		
Trade Name:	Resonance™ Metallic Ureteral stent		
Common Name:	Ureteral stent		
Classification Name:	Stent, ureteral		
Legally Marketed Devices:	Bioteq Double Pigtail Ureteral Stent set (K033210) Cook Endo-Sof™ Double Pigtail Stent (K961446)		
Description of the Device:	The Resonance™ Metallic ureteral stent is a device which is intended to achieve normal urine flow from the kidney to the urinary bladder in situations where obstructive pathological processes prevent it. The stent extends from the renal pelvis to the urinary bladder via the ureter and is placed by either endoscopic retrograde or percutaneous antegrade insertion.		



USDA, FEDERAL RESERVE*** FEDERAL RESERVE BANK	Page 10 of 10	Company Comments
Indications for use:	Used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction. Intended for one-time use only.	
Comparison of Characteristics:	We believe the proposed device the Resonance™ Metallic ureteral stent to be substantially equivalent to the currently marketed predicate devices Bioteq Double Pigtail Ureteral Stent set as cleared by (K033210) and Endo-Sof™ Double Pigtail Stent as cleared under (K961446).	
Performance Data:	<p>Non clinical testing was carried out on the stent to determine the equivalence of the Resonance™ Metallic ureteral stent to the predicate devices and to verify the safety and effectiveness of the stent. The following is a summary of the testing carried out: flow, elongation / yield and tensile strength, stent migration and retention.</p> <p>Clinical testing was carried out to primarily gather information on adverse events and stent function.</p>	



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 8 2007

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Sinead Burke
Regulatory Affairs Supervisor
Cook Ireland Ltd.
O'Halloran Road
National Technology Park
Limerick
IRELAND

Re: K063742
Trade/Device Name: Resonance™ Metallic Ureteral Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: April 23, 2007
Received: April 26, 2007

Dear Ms. Burke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health



Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Section 4.0 Indications for Use

510(k) Number (if known): K063742

Device Name: Resonance™ Metallic Ureteral Stent

Indications for Use:

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

Prescription Use ☒ AND/OR Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Gordon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063742

Page 1 of 1



Instructions for use (IFU)

RESONANCE METALLIC 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)

DEVICE DESCRIPTION

The Resonance Metallic Ureteral Stent Set contains (set components may vary):

- Resonance metal stent with pigtail straightener
- Radiopaque introduction catheter and sheath

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 interactions between stents and urinary system are unpredictable.

- Change in urine viscosity may hamper drainage.
- Hematuria and Incontinence may indicate fistula formation.
- The stent contains nickel which may cause an allergic reaction in individuals with nickel sensitivity.
- This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.
- 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.

MR CONDITIONAL

Nonclinical testing has demonstrated that the Resonance Metallic Ureteral Stent is MR Conditional. It can be scanned safely under the following conditions:

At 1.5 Tesla Static Magnetic Field	At 3 Tesla Static Magnetic Field
<ul style="list-style-type: none">• Spatial gradient field of 450 Gauss/cm or less; and• Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 min. of scanning	<ul style="list-style-type: none">• Spatial gradient field of 720 Gauss/cm or less; and• Maximum whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 min. of scanning
In non-clinical testing the stent produced a temperature rise during scanning of less than 0.80° C at an SAR of 1.5 W/kg for 20 min.	In non-clinical testing the stent produced a temperature rise during scanning of less than 1.3° C at an SAR of 3 W/kg for 15 min.



Note: MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the stent. The image artifact extends approximately 16 mm from the device when scanned in non-clinical testing using: GRE sequence in a 3.0 Tesla Siemens Magnetom Trio, A Tim System (Software Numaris/4) with the body coil. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with indwelling ureteral stents include:

- Allergic reaction to nickel
- Bladder spasm
- Fever
- Insufficient urine drainage
- Diminished urine drainage/stent occlusion
- Fistula formation including Arterioureteral Fistula
- Hemorrhage
- Hydronephrosis
- Infection
- 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

- Tissue ingrowth
- Ureteral reflux
- Urinary symptoms (frequency, urgency, incontinence, dysuria, hematuria)
- Urinary tract tissue erosion

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.

PLACEMENT AND REMOVAL

Note: Use with wire guide with 0.038" diameter.

Stent may be utilized with either an antegrade or retrograde placement technique.

1. Using a baseline pyelogram, estimate the proper stent length. Accurate measurement enhances drainage efficiency and patient comfort. To facilitate this, the introduction catheter may be utilized for the injection of contrast media using a syringe.
2. Over a previously placed wire guide, pass introduction catheter and sheath into appropriate position utilizing fluoroscopic guidance or direct vision. Rigid cystoscopes with a sheath size of 21 Fr or larger allow for insertion of an introduction catheter and sheath with a maximum outside diameter as specified on the product label.



3. With introduction catheter and sheath in proper position, remove introduction catheter and wire guide to allow passage of the stent.
4. Use the pigtail straightener to introduce the stent to the sheath. **Note:** Once stent is in the sheath pull the pigtail straightener away from the hub.
5. Use the introduction catheter to advance the stent through the sheath until the numbered marker corresponding to the stent length being deployed reaches the hub on the sheath. At this point the first pigtail will have fully deployed from the sheath. **Note:** The sheath tip is radiopaque to aid placement.
6. To prevent further deployment of the stent in the kidney hold the introduction catheter in place and retract the sheath.
7. When the hub of the sheath aligns with the proximal ink mark on the introduction catheter the second pigtail is about to deploy. At this point retract both the sheath and the introduction catheter completely.
8. The stent may be removed using conventional cystoscopic techniques utilizing forceps or graspers.

Upon completion of the procedure, dispose of device(s) per institutional guidelines for biohazardous medical waste.

HOW SUPPLIED

Store in a dark, dry location away from temperature extremes. Inventory rotation of sterile products is essential. Verify the expiration date on the package label prior to using the product.



Solutions portfolio

Clinical

Vista® training and educational programs

Cook Medical's Vista education and training programs set a high standard for product education via peer-to-peer interaction. The Vista training and the educational dinner program are facilitated by Cook-selected qualified faculty. The programs focus on product education; Cook-specific content training and peer-to-peer interaction are included in every session.

Visit <https://vista.cookmedical.com> for more information, or speak to your local Cook sales representative for upcoming events in your area.

Reimbursement

Cook's policy is to offer information that is complete, accurate, straightforward, and consistent with the statutes and regulations of the federal government and well-accepted coding guidelines as established by the Centers for Medicare and Medicaid Services (CMS), the American Medical Association (AMA), the American Hospital Association (AHA), and other relevant professional societies.

Cook's reimbursement assistance team (email: Reimbursement@CookMedical.com) can provide Medicare reimbursement rates, assessment of Medicare and commercial insurance coverage policies, and coverage appeals support.

Purchasing

Digital catalog

Cook can provide a URL to an image for each product in the Cook Medical catalog. These URLs are delivered to a customer in a spreadsheet that can be uploaded to display the images in the customer's purchasing platform (ERP) or clinical information system. Product images allow end users to view and validate the items.

E-commerce

We can help you order electronically. E-commerce is an automated, paper-free method of transacting purchase orders, acknowledgments, invoices, and dispatch and receiving notifications. Cook offers value-added-network (VAN), direct EDI, XML, and web-based methods of e-commerce transactions.

GS1

GS1 is an international, not-for-profit association that creates and implements standards to bring efficiency and visibility to supply chains across multiple industries. The GS1 standards for healthcare focus on improving patient safety and supply-chain efficiency. They do this by providing unique product identification (GTINs), clean data (GDSN), and location information numbers (GLNs).

All our products are GS1 compliant. Having GS1-compliant products gives systems improved visibility in the supply chain.



Customer Support and Distribution

Distribution support

At Cook Medical, we partner with health systems to identify the distribution model that best fits their needs. We're glad to engage in a discussion regarding the desire to ship Cook Medical items through a third-party distributor or customer's self-distribution center.

Shipping

Standard shipping is included for most orders, although Cook may require a minimum order quantity or dollar amount. Expedited shipping may be available and subject to an additional cost, which will be prepaid by Cook and invoiced to the customer. Cook's shipping policy is subject to change and may be updated from time to time. Please refer to www.cookmedical.com/support/ordering-returns for current order requirements and further information about shipping options.

Item master clean-up

Cook Medical can perform an item master clean-up for its customers. This includes, but is not limited to, helping customers correct pricing discrepancies, discovering unit-of-measure discrepancies, locating unavailable or invalid part numbers, providing GTINs, and offering contract information. This will ensure that the ordering process between the customer and Cook Medical is seamless.

Product use and SKU reduction

Cook Medical can provide cross-referencing to all customers who request it. This includes cross-referencing between a competitor and Cook as well as between Cook's stock and nonstock items.

Consolidated packaging

Cook's consolidated packaging program combines separate product orders in clear, heat-sealed plastic bags that ensure that the integrity of each purchase order (PO) is maintained. A packing slip with scannable barcode is included in each heat-sealed pack. Our process includes placing individually bagged POs into as few boxes as possible by using a mutually agreed-upon order cutoff time. Fewer boxes means a more streamlined receiving process, reduced shipping and freight costs, and reduced cardboard recycling waste and expense.

Sustainability

At Cook, we strive to perform in an environmentally responsible manner by incorporating the best management practices, fostering the sustainable use of natural resources, promoting pollution prevention, reducing waste generation, and recycling and reusing materials where possible within our operations. Cook has a corporate sustainability team responsible for finding new ways to reduce waste for our customers and for us. Currently, our sustainability strategy is focused mainly on improving the environmental performance of our facilities and our packaging, and on recycling.



References

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. 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.
3. 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.
4. 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.
5. Benson AD, Taylor ER, Schwartz BF. Metal ureteral stent for benign and malignant ureteral obstruction. *J Urol*. 2011;185(6):2217-2222.
6. Cauda V, Fiori C, Cauda F. Ni-Cr-Co alloy ureteral stent: scanning electron microscopy and elemental analysis characterized after long-term indwelling. *J Biomed Mater Res B Appl Biomater*. 2010;94(2):501-507.
7. 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-notice/cms-1736-fc>. Accessed January 21, 2021.





Additional references

Frederick L, Ellimoottil C, Kadlec A, et al. Cost analysis of metallic stents for chronic ureteral obstruction: a multicenter study. *Urol Pract.* 2017;4(1):21-24.

Liatsikos E, Kallidonis P, Kyriazis I, et al. Ureteral obstruction: is the full metallic double-pigtail stent the way to go? *Eur Urol.* 2010;57(3):480-486.

Li CC, Li JR, Huang LH, et al. Metallic stent in the treatment of ureteral obstruction: experience of single institute. *J Chin Med Assoc.* 2011;74(10):460-463.

Kallidonis P, Goulimi E, Ntasiotis P, et al. Experience with Resonance stent. *Hellenic Urology.* 2016;28(2):62-69.

Nagele U, Kuczyk MA, Horstmann M, et al. Initial clinical experience with full-length metal ureteral stents for obstructive ureteral stenosis. *World J Urol.* 2008;26(3):257-262.

Patel C, Loughran D, Jones R, et al. The Resonance® metallic ureteric stent in the treatment of chronic ureteric obstruction: a safety and efficacy analysis from a contemporary clinical series. *BMC Urol.* 2017;17(1):16.

Pavlovic K, Lange D, Chew BH. Stents for malignant ureteral obstruction. *Asian J Urol.* 2016;3(3):142-149.

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.

Wah TM, Irving HC, Cartledge J. Initial experience with the Resonance metallic stent for antegrade ureteric stenting. *Cardiovasc Intervent Radiol.* 2007;30(4):705-710.

Wang HJ, Lee TY, Luo HL, et al. Application of Resonance metallic stents for ureteral obstruction. *BJU Int.* 2001;108(3):428-432.

Memon NA, Talpur AA, Memon JM. Indications and complications of indwelling ureteral stenting at NMCH, Nawabshah. *Pak J Surg.* 2007;23(3):187-191.

Miyaoka R, Monga M. Ureteral stent discomfort: etiology and management. *Indian J Urol.* 2009;25(4):455-460.

Smedley FH, Rimmer J, Taube M, et al. 168 double J (pigtail) ureteric catheter insertions: a retrospective review. *Ann R Coll Surg Engl.* 1988;70(6):377-379.

Richter S, Ringel A, Shalev M, et al. The indwelling ureteric stent: a 'friendly' procedure with unfriendly high morbidity. *BJU Int.* 2000;85(4):408-411.

Altunal N, Willke A, Hamzaoglu O. Ureteral stent infections: a prospective study. *Braz J Infect Dis.* 2017;21(3):362-364.

Al-Marhoon MS, Shareef O, Venkiteswaran KP. Complications and outcomes of JJ stenting of the ureter in urological practice: a single-centre experience. *Arab J Urol.* 2012;10(4):372-377.



George V, Ionut V. Part of the solution and part of the problem-report on the ureteric stent use in a tertiary referral center in Australia. *Med Sur Urol*. 2017;6(2). <https://www.omicsonline.org/open-access/part-of-the-solution-and-part-of-the-problemreport-on-the-ureteric-stent-use-in-ateritary-referral-center-in-australia-2168-9857-1000186.pdf>. Accessed February 20, 2019.

Ahmad I, Pansota MS, Tariq M, et al. Comparison between double J (DJ) ureteral stenting and percutaneous nephrostomy (PCN) in obstructive uropathy. *Pak J Med Sci*. 2013;29(3):725-729.

Hao P, Li W, Song C, et al. Clinical evaluation of double-pigtail stent in patients with upper urinary tract diseases: report of 2685 cases. *J Endourol*. 2008;22(1):65-70.

Srivastava A, Gupta R, Kumar A, et al. Routine stenting after ureteroscopy for distal ureteral calculi is unnecessary: results of a randomized controlled trial. *J Endourol*. 2003;17(10):871-874.

Netto NR, Ikonomidis J, Zillo C. Routine ureteral stenting after ureteroscopy for ureteral lithiasis: is it really necessary? *J Urol*. 2001;166(4):1252-1254.

El-Faqih SR, Shamsuddin AB, Chakrabarti A, et al. Polyurethane internal ureteral stents in treatment of stone patients: morbidity related to indwelling times. *J Urol*. 1991;146(6):1487-1491.

Lifshitz DA, Winkler HZ, Gross M, et al. Predictive value of urinary cultures in assessment of microbial colonization of ureteral stents. *J Endourol*. 1999;13(10):735-738.

Baumgarten AS, Hakky TS, Carrion RE, et al. A single-institution experience with metallic ureteral stents: a cost-effective method of managing deficiencies in ureteral drainage. *Int Braz J Urol*. 2014;40(2):225-231.

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, resterilize, 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.

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