ReSolve ConvertX®
Nephroureteral Stent System

PATIENT INFORMATION LEAFLET

PLEASE PROVIDE TO THE PATIENT

DEVICE DESCRIPTION AND INTENDED PERFORMANCE OF THE DEVICE

The ReSolve ConvertX Nephroureteral Stent System is used to allow passage of urine from the kidney into the bladder or out of the body. The stent system is placed into the kidney, ureter, and bladder. Urine enters through drainage holes in the proximal end of the stent. The urine exits the stent through the drainage holes located in the distal end of the stent. The urine may also exit the system through the hub into a collection reservoir.

INDICATIONS FOR USE

The ReSolve ConvertX Nephroureteral Stent System with releasable drainage catheter is delivered percutaneously and is intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage.

For patients for whom external drainage is not, or no longer desirable, the releasable drainage catheter may be removed, leaving the stent to provide internal drainage from the ureteropelvic junction to the bladder.

KIND OF PATIENT ON WHOM THE DEVICE IS INTENDED TO BE USED AND EXPECTED DEVICE LIFETIME

The stent system is used in patients that have a narrowing in the ureter that prevents or slows the passage of urine from the kidney to the bladder. Your healthcare provider will give you specific instructions on how to care for your stent system based on your individual circumstances including the need for flushing the catheter to help it function appropriately and what to do if the performance or fluid output changes. The duration of time you will need this stent system will depend on what is causing the urine to not drain from the kidney into the bladder naturally. The drainage stent system should be removed within the first 30 days of placement. Stent system occlusion could cause the stent system to need to be replaced sooner than 30 days. Your physician will discuss with you how often you should follow up with them.

POTENTIAL COMPLICATIONS

- Encrustation
- Ureteral reflux
- Extravasation
- Catheter occlusion
- Catheter dislodgement
- Hemorrhage
- Infection/Sepsis/Peritonitis
- Pain
- Dysuria and Frequency and/or Urgency
- Perforation
- Pneumothorax
- Fistula

If you are experiencing the same symptoms when the catheter was initially placed, this could mean the stent system is not functioning appropriately. You should follow up with your healthcare provider.

MRI INFORMATION

MR CONDITIONAL

Non-clinical testing has demonstrated the ReSolve ConvertX Nephroureteral Stent System (complete device, non-detached system) is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions::

- Static magnetic field of 1.5-Tesla or 3-Tesla, only.
- Maximum spatial field gradient magnetic field of 4000-gauss/cm (40-T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the ReSolve ConvertX Nephroureteral Stent System (complete device, non-detached system) is expected to produce a maximum temperature rise of 5.3 ° C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the ReSolve ConvertX Nephroureteral Stent System (complete device, non-detached system) extends approximately 20-mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

QUALITATIVE/QUANTITATIVE INFORMATION ON PATIENT EXPOSURE TO MATERIALS AND SUBSTANCES

ReSolve ConvertX Nephrouretal Stent System	Component	Material	Duration of Exposure	Level of Patient exposure
Releasable Drainage Catheter	Catheter Shaft	Pellethane	24 hrs -30 days	Externally Communicating Device with Tissue/ Bone/Dentin
	Reinforced Coil w/ Loops	Stainless Steel and Silver		
	Adhesive	Cyanoacrylate		
	Reinforcement Sleeve	Pellethane		
	I.D. Reinforcement Tube (Hypotube)	Stainless Steel and Silver		
	Tubing, Single Lumen	Pellethane		
Releasable Drainage Catheter Accessories	Lock Suture	Polyethylene		
	Telescoping Connector	Nitinol and Polyester		
Stent	Stent Shaft	Pellethane	24 hrs -30 days	Externally Communicating Device with Tissue/ Bone/Dentin
	Reinforced Coil w/ Loops	Stainless Steel and Silver		
	Reinforcement Sleeves	Pellethane		
	Radiopaque Marker Band	Platinum and Iridium		
	Adhesive	Cyanoacrylate		
	Extruded Tube	Pellethane		
	I.D. Reinforcement Tube (Hypotube)	Stainless Steel		

Hub Triple Arm O-Ring Assenbly	Triple Arm Connector	Polycarbonate		No patient Contact
	O-Rings	Silicone		
	Hub Lock	HDPE	24 hrs -30 days	Surface Device with Skin Contact
	Pull Tabs	White Sabic, ABS		No Patient Contact
	Shells (Top)	White Sabic, ABS	24 hrs -30 days	Surface Device with Skin Contact
	Hub, Cap	White Sabic, ABS		
	Adhesive	Cyanoacrylate		No Patient Contact
	Strain Relief	HDPE	24 hrs -30 days	Surface Device with Skin Contact
	Tamper Seals	Silver Vinyl w/ Adhesive		
	Lubricant	Silicone Fluid	24 hrs -30 days	Externally Communicating Device with Tissue/ Bone/Dentin
	Lock Key	White Sabic ABS		No Patient Contact
	Loop Straightener	PEBAX		
Metal Stiffener	Cannula	Stainless Steel	≤24 hrs	Externally Communicating Device with Tissue/ Bone/Dentin
	Tip	PEBAX		
	Outer Hub, Stiffener	White Sabic, ABS		
	Inner Hub, Stiffener	White Sabic, ABS		
	Adhesive	Cyanoacrylate		
Plastic Stiffener	Plastic Stiffener	PEBAX	≤24 hrs	Externally Communicating Device with Tissue/ Bone/Dentin
	Hub and Luer Cap	Polycarbonate		
	Adhesive	Cyanoacrylate		
Accessories	Fast Break Connector w/O-Ring Assembly	Atlantic Rubber	24 hrs -30 days	Surface Device with Skin Contact
		Silicone		
		Xenoy		
		Green Colorant		
	Connector, Female; Half-Turn Breakaway	Xenoy		
		Green Colorant		

ALWAYS FOLLOW YOUR HEALTHCARE PROVIDERS INSTRUCTIONS AND PROMPTLY TELL YOUR CARE TEAM ABOUT ANY UNUSUAL SYMPTOMS OR PAIN.

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

The information presented here should not be construed as specific medical advice, diagnosis, treatment or recommendation. This material is not a substitute for a consultation or physical examination by a physician. Always seek the advice of a qualified physician regarding any medical questions or conditions. Merit Medical assumes no responsibility for a patient's success as results may vary.

Any serious incident that occurs in relation to the ReSolve ConvertX Nephroureteral Stent System should be reported to the manufacturer and to the Therapeutic Goods Administration at www.tga.gov.au

PRODUCT CODES TABLE

Catalog Number	Stent Length (cm)	Distal Stent Diameter	Proximal Stent Diameter	Releasable Drainage Catheter Length (cm)
RCX10-8-038	10	8.3F	10.3F	20
RCX12-8-038	12	8.3F	10.3F	20
RCX14-8-038	14	8.3F	10.3F	20
RCX20-8-038	20	8.3F	10.3F	30
RCX22-8-038	22	8.3F	10.3F	30
RCX24-8-038	24	8.3F	10.3F	30
RCX26-8-038	26	8.3F	10.3F	30
RCX28-8-038	28	8.3F	10.3F	30
RCX10-10-038	10	10.3F	10.3F	20
RCX12-10-038	12	10.3F	10.3F	20
RCX14-10-038	14	10.3F	10.3F	20
RCX20-10-038	20	10.3F	10.3F	30
RCX22-10-038	22	10.3F	10.3F	30
RCX24-10-038	24	10.3F	10.3F	30
RCX26-10-038	26	10.3F	10.3F	30
RCX28-10-038	28	10.3F	10.3F	30

Merit Medical Australia
53 Canterbury Rd
Braeside VIC 3195
Australia
1300 696 374

Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748

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For more information on the ReSolve Nephroureteral Stent System, please refer to its Instructions for Use.

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