INSTRUCTIONS FOR USE

1. DEVICE DESCRIPTION
The Resolve ConvertX™ Nephroureteral Stent System with releasable drainage catheter is used for temporary internal drainage from the ureteropelvic junction to the bladder. The device has two primary components: a double pigtail stent with distal and proximal loops and a releasable drainage catheter. See the figure below.

2. 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.

3. CONTRAINDICATIONS
The system may rapidly obstruct where mycotic or fungal infections (e.g. candida albicans) are present. Chronic stone formers more rapidly cause encrustation.

4. WARNINGS
Do not use the stent for feeding tube/gastrostomy procedures. Exposure to gastric fluids may damage stent.

5. PRECAUTIONS
• Carefully read all instructions prior to use.
• Do not use if the product or sterile packaging is opened or damaged.
• This device was designed and tested for single patient use only. Do not reuse, reprocess, or resterilize this device.
• If resistance is encountered during advancement or withdrawal of the stent, STOP. Do not continue without first determining the cause of the resistance and taking remedial action.
• Periodic radiographic, isotopic or cystoscopic examinations are recommended to evaluate stent efficiency and to observe for possible complications.
• Do not use if the product or sterile packaging is opened or damaged.
• Do not use if the product or sterile packaging is opened or damaged.

6. ADVERSE EVENTS
Potential complications associated with indwelling ureteral stents and drainage catheters include but are not limited to:

Magnetic Resonance Imaging (MRI) Safety 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.
- Maximum spatial field gradient magnetic field of 2000-gauss/cm (20-T/m).
- Maximum gradient 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).
• Encrustation
• Ureteral reflux
• Extravasation
• Catheter occlusion
• Catheter dislodgement
• Hemorrhage
• Infection/Sepsis/Peritonitis
• Pain
• Dysuria and Frequency and/or Urgency
• Perforation
• Pneumothorax
• Fistula

7. OPERATIONAL INSTRUCTIONS

A. PLACEMENT PREREQUISITES
1. The involved renal collecting system should be visualized via antegrade pyelography.
2. A stent of proper length should be available. Ideally, the proximal loop should lie within the renal pelvis while the distal loop recurses at the ureteral orifice.
3. Fluoroscopy is recommended for more precise control of stent placement. Standard radiography may also be used.

B. STENT PLACEMENT
1. Establish entry into involved renal pelvis using a percutaneous access set.
2. Pass the flexible end of guidewire down ureter into bladder.
3. Expand access utilizing increasingly larger sheaths until at least 1F size larger than stent system.
4. Pass appropriate open-end ureteral catheter over guidewire to confirm entrance into bladder lumen and to indicate feasibility of stent placement. Placement of a semi-rigid sheath of appropriate size into the access tract is a useful adjunct at this point.
5. Advance the loop straightener over the proximal loop to aid advancement of the metal stiffening cannula or plastic stiffening cannula.
6. Insert metal stiffening cannula or plastic stiffening cannula into Resolve ConvertX catheter while maintaining gentle tension on loop forming suture. Lock stiffening cannula to luer. CAUTION: Inspect distal end of Resolve ConvertX system to ensure that the stiffening cannula does not exit the tip of the stent. If the cannula exits the stent do not use the system and replace the device.
7. Remove the loop straightener
8. Pass the tapered tip of the Resolve ConvertX system over guidewire and advance down ureter.
9. If a change of stiffeners (plastic to metallic or metallic to plastic) is desired during insertion, remove system and exchange stiffeners outside of the body, and then reintroduce system.
10. Confirm distal loop to be in bladder and proximal loop within renal pelvis. Remove guidewire and stiffening cannula while stabilizing Resolve ConvertX system.
11. Gently pull suture to form proximal loop. Turn stopcock 180° from the unlocked to locked position following the directional arrows to lock suture in place. CAUTION: Do not use excessive force to form the proximal loop in order to avoid kinking or damaging device. System can be left in place without forming a full loop. If the hub is twisted or torqued during formation of the proximal loop, be sure to allow catheter to relax or untwist before locking the loop.
12. Trim suture and either attach drainage tube or luer cap to luer.
13. Secure the system in place with a suture at the skin so that it can be easily maintained in place by the patient without changing position of the stent. When securing the system, use padding around the catheter to avoid potential kinks from forming.
14. Note on the patient chart and/or implant card the Resolve ConvertX system position using the drainage catheter external markings.

ATTENTION ATTENDING PHYSICIAN:
If you will not follow the patient through course of treatment, it is recommended that IFU or a note directing attending physician to link of electronic IFU (www.merit.com/ifu) be attached to patient chart.

NOTE: If you plan to remove releasable drainage catheter at the time of system insertion, turning the stopcock and locking the loop suture in step 11 above is not needed. Instead form the proximal loop, trim the loop suture, and then go to step D.3 below for the steps to remove the drainage catheter.

C. METHOD TO REMOVE ENTIRE SYSTEM
1. CAUTION: Confirm tamper seal for cap #3 (for the stent pull release wire) is not broken. If this tamper seal is broken then follow step 4 below for system removal. Note – if upon learning that the tamper seal was broken and it is desired to deploy the stent follow the standard deployment steps in Section D below.
2. Disconnect drainage tube or cap from drainage port on Resolve ConvertX hub. Unlock suture by rotating stopcock 180° following the directional arrows to the unlock position. a. If access is to be maintained post removal, follow the below steps:
i. Prior to inserting a guidewire first remove the Resolve ConvertX system’s loop suture. Unscrew cap #2 and pull out suture. When removing the loop suture hold the catheter so that it comes straight out of the body without any excessive bends. Suture must be completely removed. **CAUTION: Do not cut or slice the Releasable Drainage Catheter.**

ii. Insert guidewire (≤0.038”) into lumen and advance past distal tip of stent system.

3. Gently withdraw the Resolve ConvertX system by pulling from the hub or pulling from the catheter adjacent to the hub.

4. If tamper seal for cap #3 is broken and you believe the stent pull release wire may have been inadvertently pulled and then pushed back into place, follow the below steps to remove the system or disconnect the drainage catheter. If the release wire was pulled then these steps will remove the drainage catheter while leaving the internal stent in place. If the release wire was not pulled then these steps will allow the entire system to be removed.
   a. Disconnect drainage tube or cap from drainage port on Resolve ConvertX hub. Unlock suture by rotating stopcock 180° following the directional arrows to the unlock position.
   b. Unscrew cap #2 and pull out suture. Suture must be completely removed.
   c. Withdraw the Resolve ConvertX system by pulling from the hub or pulling from the catheter adjacent to the hub.

D. METHOD TO DEPLOY STENT / RELEASE DRAINAGE CATHETER

1. Verify stent placement.

2. Disconnect drainage tube or cap from drainage port on Resolve ConvertX hub. Unlock suture by rotating stopcock 180° following the directional arrows to the unlock position.

3. Unscrew cap #2 and pull out suture. When removing the loop suture hold the catheter so that it comes straight out of the body without any excessive bends. Suture must be completely removed. **CAUTION: If suture cannot be completely removed, entire system should be removed following system removal instructions.**

4. **Unscrew cap #3 and pull release wire 3-4 cm or until tension is felt.** **CAUTION:** If release wire cannot be pulled a minimum of 2 cm (0.75 in.), stent may not have been deployed. Placement of stent or release of catheter should be confirmed before removal.

D. TROUBLESHOOTING

If any of the previously listed techniques do not work, please contact 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

E. SYMBOLS AND MARKINGS

Indicated below are the symbols and markings on the Resolve ConvertX packaging label and on the Resolve ConvertX Hub.
<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESIGNATION</th>
</tr>
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<tbody>
<tr>
<td>REF</td>
<td>Catalog Number</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>STERILE EO</td>
<td>Sterilized Using Ethylene Oxide</td>
</tr>
<tr>
<td>⚠️</td>
<td>Do not resterilize</td>
</tr>
<tr>
<td>🔄</td>
<td>Caution</td>
</tr>
<tr>
<td>🔄</td>
<td>Single Use</td>
</tr>
<tr>
<td>📚</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>🔄</td>
<td>Do not use if package is damaged and consult Instructions for Use.</td>
</tr>
<tr>
<td>🔄</td>
<td>Date of Manufacture</td>
</tr>
<tr>
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</tr>
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<td>Single Sterile Barrier System</td>
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<tr>
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<tr>
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<tr>
<td>🔒</td>
<td>Break Tamper Seal Per Direction of Physician Only</td>
</tr>
<tr>
<td>🖄️</td>
<td>Locked</td>
</tr>
<tr>
<td>🖇️</td>
<td>Unlock</td>
</tr>
</tbody>
</table>

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