COOK®

**Cook Medical Europe**
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# Urgent Field Safety Notice

**Commercial name of the affected product:** Bander Ureteral Diversion Open-End Stent Set, Percutaneous Entry Set, Percutaneous Pigtail Nephrostomy Set, PTFE Wire Guide, Roadrunner® Hydrophilic PC Wire Guide, Sof-Flex® Double Pigtail Ureteral Stent Set, Sof-Flex® Multi-Length Ureteral Stent Set, Universa® Soft Ureteral Stent Set, Urethral Dilation Balloon Catheter with Open Tip
**Manufacturer :** Cook Incorporated - Spencer
**Cook Reference Number:** 2018FA0012
**Type of action:** Field Safety Corrective Action (FSCA)

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Date: 02 Jan 2019

Attention: Chief Executive / Risk Management / Purchasing

**Details on affected devices:**

| PRODUCT BRAND NAME | REFERENCE PART NUMBER (RPN) | ORDER NUMBER | LOT NUMBER |
|---|---|---|---|
| Bander Ureteral Diversion Open-End Stent Set | 025707-S1 | G14822 | 8011030, 8417632 |
| Percutaneous Entry Set | 080000 | G14649 | 8109245 |
| Percutaneous Pigtail Nephrostomy Set | 080008 | G14094 | 8112670 |
| | 080010 | G14095 | 8113259 |
| | 080012 | G14899 | NS8070847 |
| PTFE Wire Guide | 635413-10 | G34134 | 8065959 |
| | 638413-10 | G34133 | 8073949, 8074014, 8074015 |
| | 638813 | G15067 | 8077583 |
| Roadrunner® Hydrophilic PC Wire Guide | RFSPC-035145-0-I-AQ | G18629 | 7853241, 8283322, 8407934, 8474898 |
| | RFSPC-038145-0-I-AQ | G17866 | 7936207 |
| Sof-Flex® Double Pigtail Ureteral Stent Set | 039516 | G14840 | NS8070692 |
| Sof-Flex® Multi-Length Ureteral Stent Set | 039500-8-20 | G17852 | 8193001, 8172131 |
| Universa® Soft Ureteral Stent Set | USH-624 | G49941 | 7998422, 7998423, 8594610 |
| | USH-728 | G49951 | NS8599665 |
| | USH-826 | G49958 | NS8421573 |
| Urethral Dilation Balloon Catheter with Open Tip | UDBS-070029-OW | G17844 | 8494465, 8552050, 8567256, 8659206, NS8513228 |

 

**Description of the problem:**
Cook Medical is initiating a voluntary recall of the specific lots listed above. Cook Medical has identified that the affected lots may contain a wire guide that was incorrectly loaded into the wire guide holder. This could lead to the stiff tip of the wire guide being introduced into the patient instead of the flexible tip.

Potential adverse events that may occur if an affected product is used include a delay in procedure or tissue and/or organ injury.

**Advise on action to be taken by the user:**

1. Immediately collect all remaining affected products as per the specified lot listing from your inventory.

2. Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Response form.

   Product should be addressed to:
   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Credit will be provided for the returned affected products where applicable.

3. Send the Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61239294). Do not enclose the response form with the returned product.

4. Please report any adverse events to Cook Medical by contacting our Customer Support Department.

**Transmission of this Field Safety Notice**:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

**Contact reference person:**
Larry Pool
Post Market Director
Cook Incorporated
750 Daniels Way, PO Box 489, Bloomington, IN 47402, United States

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Should you have any questions, please feel free to contact us for more information
(e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

Larry Pool
Post Market Director
Cook Incorporated

 