

COOK®

Cook Medical EuropeO'Halloran Road,
National Technological Park,
Limerick, Ireland.

Phone: + 353 61 334440

Fax: + 353 61 334441

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)

-- Date: 08 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)

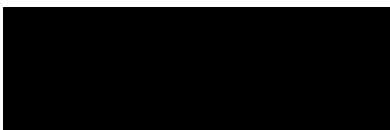
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

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