COOK®

Cook Medical Europe
O'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:

- **Bush DL™ Ureteral Illuminating Catheter Set**
- **Bush SL™ Ureteral Illuminating Catheter Set**

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0004
Type of action: Field Safety Corrective Action

Date: 20 March 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	GPN
Bush DL™ Ureteral Illuminating Catheter Set	084520	G16747
	084510	G16143
	J-BICS-078000	G16262
Bush SL™ Ureteral Illuminating Catheter Set	084100	G16745
	084120	G16746
	J-BICS-058020	G16737

Description of the problem:

Cook Medical is initiating a voluntary recall of all lot numbers of the Cook Bush SL™ and Bush DL™ Ureteral Illuminating Catheters, as listed above. We have received an increased number of reports where the proximal black component that connects to the distal transparent component of the catheter may overheat and melt.

There have been no reports of overheating along the transparent component of the catheter, which is the part of the device that comes into contact with the patient's urethra, bladder, and ureter.
Potential adverse events that may occur if these devices overheat and come into direct contact with skin include burns to the skin.

This notice is directed to you because our records indicate that you have received product of the listed catalog numbers identified that have not expired.

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.

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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 61 334441). Do not enclose the response form with the returned product.

4. Please report any adverse event to Cook Medical Customer Relations by contacting our Customer Services 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.

Please transfer this notice to other organisations on which this action has an impact.

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

Contact reference person:

Sinead Burke
Director, Regulatory Affairs
Regulatory Affairs
Cook Ireland
Limerick, IRELAND
Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

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

We confirm that this notice has been notified to the appropriate Regulatory Agency.

Annemarie Beglin
Quality Systems Manager

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