COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: Cirrus®-14 Wire Guide AQ® Hydrophilic Coating
Manufacturer: William Cook Europe Aps, Sandet 6, 4632 Bjaeverskov, Denmark
Cook Reference Number: 2018FA0007
Type of action: Recall of products with incorrect wire length according to label

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Date: 04 June 2018

Attention: Health Care Provider / Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Catalogue Identifier	Lot Number	Qty
Cirrus®-14 Wire Guide AQ® Hydrophilic Coating	TPMG-14-180-CIR-HC	E3704223 E3706982 E3706984	20 20 20

Description of the Problem:
Cook Medical is initiating a voluntary recall of three specific lot numbers of TPMG-14-180-CIR-HC which contain wire guides with incorrect wire length. Cook Medical received two complaints of "guide wire too short" and initial investigation confirms that the wire length should have been 180cm but is mixed with wire lengths of 135cm.

The Cirrus®-14 Wire Guide AQ® Hydrophilic Coating is intended for diagnostic and interventional procedures.

The potential risk of using a shorter wire guide than planed is that the wire guide may not reach the intended target site and exchanging the wire will prolong the procedure.

Only the three lot numbers listed above are affected by this recall.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products 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 devices 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 to 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:
Thomas Hessner Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

Or

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

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. 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.

Thomas Hessner Kirk
Team Lead, Regulatory Reporting, Regulatory Affairs