



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:

- **Wills-Oglesby Percutaneous Gastrostomy Set**

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US

Cook Reference Number: 2017FA0016

Type of action: Field Safety Corrective Action

Date: 19 October 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

| Product Brand Name | Reference Part Number | GPN | Lot Number |
|--|-----------------------|--------|---|
| Wills-Oglesby Percutaneous Gastrostomy Set | WOGS-1200 | G05274 | 7360624 7428977 7580747 7580749 7852593 7897499 8032023 |

Description of the problem:

Cook Medical is initiating a voluntary recall of specific lots of the products listed above. Cook has identified that the affected lots may contain wire guides that were loaded backwards into the wire guide holder. This would lead to the stiff tip of the wire guide exiting the holder instead of the flexible tip.

Potential adverse events if the products are used may include a delay in procedure or damage ranging from minor injury to full perforation of the stomach wall.

This notice is directed to you because our records indicate that you have received product of the listed catalogue 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.

The Product to be returned 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 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:

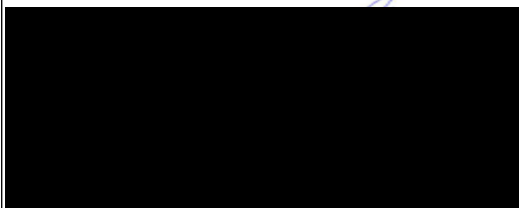
Thomas Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe ApS
Sandet 6, DK-4632 Bjaeverskov, Denmark

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.





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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action Reference no. : 2017FA0016

Affected device:

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|---|-----------------------|--------|---|
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Please indicate the following:

Customer Number: _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____

(Please Print)

Please indicate which of the following applies to your facility:

None of the affected product remains in our inventory

We are returning our remaining inventory for credit, see details listed below

**Proforma Invoice Required for Return of Product(s): Yes No

