



Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
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Urgent Field Safety Notice

Commercial name of the affected product: Zenith Branch Iliac Endovascular Graft (ZBIS)

Manufacturer : William A. Cook Australia Pty Ltd

Cook Reference : 2018FA0002, QCR-83

Type of Action: Field Safety Corrective Action

Date: 12 Feb 2018

Attention: Chief Executive Officer / Risk Management / Purchasing / Director of Nursing

Details on affected devices:

Product Brand Name	Reference Part Number (RPN)	Global Part Number (GPN)	Lot Numbers
Zenith Branch Iliac Endovascular Graft (ZBIS) - Patient Card	ZBIS-12-61-58 ZBIS-12-61-41 ZBIS-12-45-58 ZBIS-12-45-41 ZBIS-10-61-41 ZBIS-10-45-41	G38344 G38618 G38617 G38616 G38614 G38612	Please see the included listing for the specific lot numbers that are affected

Description of the Problem:

Cook Medical has become aware that an incorrect patient card may have been included in the Zenith Branch Endovascular Graft - Iliac Bifurcation (ZBIS) devices supplied to you between November 2017 and January 2018. A product defect correction will be performed on all used and unused ZBIS devices at your premises by a Cook representative.

The difference between the correct and incorrect cards is minor. The device name on the incorrect patient card is Zenith p-Branch and the MRI image artefact radius specified on the ZBIS patient card is slightly different from the image artefact radius on the incorrect patient card. There is a very low risk that the incorrect information on the patient card could lead to a lower quality image during an MR scan. There is no risk to the patient as there is no fault with the device.

Field Action:

- **Unused devices:**
A Cook representative will inspect the products at your premises and replace incorrect patient cards.
- **Used devices:**
A Cook representative will provide you with replacement patient cards which are to be completed and provided to the patient.

Advise on action to be taken by the user:

1. Please complete the enclosed Customer Response Form within 5 business days to acknowledge receipt of this Field Safety Notice Letter.
2. Send the completed 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).
3. 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 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 of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

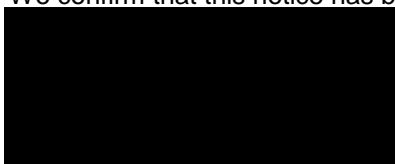
Michael Galvin
Regulatory Affairs Manager
COOK Ireland
O'Halloran Road, National Technology Park, Limerick, IRELAND

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