COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: CHORION VILLUS BIOPSY NEEDLE SET
Manufacturer : William A Cook Australia Pty Ltd
Cook Reference Number: QCR-86 / 2018FA0008
Type of action: Field Safety Corrective Action

Date:28 June 2018

Attention: Chief Executive Officer, Director of Nursing, Operating Theatres, Purchasing Officers/Stores Manager and OBGYN Department.

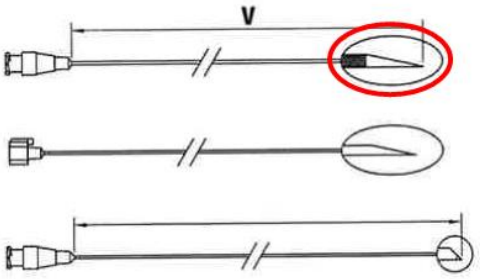
Details on affected devices:

PRODUCT BRAND NAME	CATALOGUE IDENTIFIER	ORDER NUMBER	LOT
CHORION VILLUS BIOPSY NEEDLE SET	K-CVNS-1821-ROBINSON-ET	G26661	All lots manufactured up to 4 June 2018 (As per listing provided with Customer Response Form)

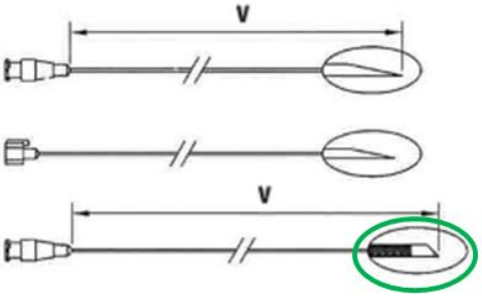
Description of the problem:

Cook Medical is initiating a medical device recall of the Chorion Villus Biopsy Needle Set (K-CVNS-1821-Robinson-ET). The diagram on the product label is incorrect. It shows that the 18GA needle has an echotip, and the 21GA needle does not, whereas the product is designed such that the 21GA needle has the echotip and the 18GA needle does not.

INCORRECT LABEL



CORRECT LABEL



The tip of the larger gauge guide needle is likely to be visible on the ultrasound regardless of a non-echogenic tip. Therefore the risks associated with the labelling error are extremely low. In the event that the labelling error resulted in a clinician expecting the echogenic tip to be present on the guide needle, instead of the sampling needle, the clinician may not be able to adequately identify the tip of the inserted access needle. It is unlikely that use of the mislabelled product will result in occurrence of an adverse event.
There are no factors that may contribute to the risk associated with the use of K-CVNS-1821-ROBINSON-ET containing a misrepresentation of echotip on the label. Manufacturing needle echotipping procedures are not impacted by label graphics. There is no effect on product, it is a label error only.

Action to be taken by the user:

1. Immediately collect all remaining affected products as per the specified lot listing (included with the Customer Response Form) from your inventory, quarantine the affected product and return it as per instructions in step 2.

2. Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organise the return and issue you with the relevant Returns Authorisation 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 61 334441). 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:

Please pass this notice on to the appropriate personnel, including down to the user level, within your organisation or to any organisation where the potentially affected devices have been transferred.

Please retain this letter in a prominent position for one month should there be any product in transit.

Contact reference person:
Sinead Burke,
Director of Regulatory Affairs
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

Thank you for your immediate attention to this matter. We recognise this disrupts your normal operations and for this, we sincerely apologise. Should you have any questions or concerns, please contact Cook Medical Customer Service or your local field representative at Cook Medical for more information. Please use European.FieldAction@CookMedical.com, or call +353 61 334440. We look forward to your response.

This action has been undertaken after consultation with the appropriate Regulatory Agency.

_____

Annemarie Beglin
Quality Systems Manager

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: QCR-86 / 2018FA0008
Affected device: CHORION VILLUS BIOPSY NEEDLE SET [K-CVNS-1821-ROBINSON-ET]

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____
(Please Print)

Please indicate which of the following applies to your facility:

1. I have received the QCR-86 / 2018FA0008 Field Safety Notice and understand the recall instructions provided in the letter. ☐Yes ☐No
2. I have examined my inventory and have no affected product. ☐Yes ☐No
3. I have examined my inventory and have affected product to be returned. ☐Yes ☐No

If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

When you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.