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: Captura Biopsy Forceps
Manufacturer: Cook Endoscopy/Wilson-Cook Medical, Inc.
Cook Reference Number: 2018FA0013
Type of action: Field Safety Corrective Action

Date: DD/December/2018

Attention: Healthcare Provider, Chief Executive, Risk Manager, and Purchasing

Details on affected devices:

PRODUCT BRAND NAME	Catalog Identifier	Lot Numbers
Captura Biopsy Forceps	DBF-2.4SN-230SP-20-S and DBF-2.4SL-230-20-S	W4035256 and W4035257

Intended Use: This device is used to obtain endoscopic mucosal tissue biopsies and/or foreign body retrieval.

Description of the problem:
As detailed above, the product is being recalled because Captura Serrated Forceps with Spike (DBF-2.4SN-230SP-20-S) were mislabeled as Captura Serrated Large Forcep-No Spike (DBF-2.4SL-230-20-S) and Captura Serrated Large Forcep-No Spike (DBF-2.4SL-230-20-S) were mislabeled as Captura Serrated Forceps with Spike (DBF-2.4SN-230SP-20-S). This has the potential to cause injury to the patient, including perforation and bleeding. We are aware of five (5) product failures and three (3) complaints related to the problem. We have not received any reports of adverse events.

As stated above, the mislabeled devices may cause injury to the patient because the user may not be aware that the size of the actual forceps cups is different from what they expect. The mislabeling may result in a deeper or larger biopsy than expected, resulting in perforation or bleeding, necessitating intervention.

Advise on action to be taken by the user:

1. Please review the impacted Catalogue and Lot numbers to identify and quarantine any affected product that remains in your stock.

2. Please complete the enclosed Customer Response Form and return by DD/December/2018 <two weeks from date of letter>. 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 Authorization number. Please include contact details on the Customer Response form.

3. Please return only the impacted Catalogue and Lot numbers affected by this Field Safety Corrective Action.

   Send the removed devices to:

   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

Replacement or credit will be provided for the returned devices where applicable.

4. Where devices have already been used in a patient, there is no risk to the patient and no need for any further action.

5. Complete and return via email or facsimile the attached **Field Action Customer Response Form** by e-mail to European.FieldAction@CookMedical.com or by fax to + 353 61 239294.

Transmission of this Customer Communication:

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.

Please report any adverse events to Cook Medical by contacting our Customer Support Department. (e-mail SSCProduct.Complaints@CookMedical.com, phone +353 61 239252).

Also, report all device-related incidents to the national Competent Authority if appropriate, as this provides important feedback.

Contact reference person:

Scottie Fariole
Regulatory Reporting Manager
Cook Endoscopy/Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105 USA

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334441).

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. We look forward to receiving your response.

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

Scottie Fariole
Regulatory Reporting Manager