COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: Hemospray Endoscopic Hemostat
Manufacturer: Cook Endoscopy/Wilson-Cook Medical, Inc.
Cook Reference Number: 2019FA0007
Type of action: Field Safety Corrective Action

Date: DD/July/2019

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

Details on affected devices:

PRODUCT BRAND NAME	Catalog Identifier	Lot Number
Hemospray Endoscopic Hemostat	HEMO-10-EU HEMO-7-EU	W4180860, W4181071, W4189223, and W4189224

Description of the problem:
The product is being recalled because Cook has received eight (8) complaints of the Hemospray device being unable to spray powder due to misassembly of devices. This has been reported to have led to an inability to achieve haemostasis, so the patient was transferred to surgery. There is also a potential risk of death if haemostasis is unable to be achieved in emergent cases.

As stated above, the devices may not spray powder resulting in an inability to achieve haemostasis. In these cases, additional haemostasis may be required, haemostasis may be delayed, and/or the patient may need to be transferred to surgery. Ultimately, if haemostasis cannot be achieved in a timely manner in emergent cases, this may result in death.

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 and return the enclosed Customer Response Form by DD/July/2019 <two weeks from the projected date letter will be sent>. 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 Numbers and Lot Numbers that are affected by this Field Safety Corrective Action.

   Send the removed devices to:

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

   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 61239294.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on 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:

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