



Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
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Urgent Field Safety Notice

Commercial name of the affected product: Acusnare Polypectomy (Duck Bill Shaped) Snare
Manufacturer: Cook Endoscopy/Wilson-Cook Medical, Inc.
FSCA-identifier: 2018FA0014
Type of action: Field Safety Corrective Action

Date: DD/December/2018

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

Details on affected devices:

PRODUCT BRAND NAME	Catalog Identifier	Lot Number	Date of Manufacture
Acusnare Polypectomy (Duck Bill Shaped) Snare	ASDB-15-015-S and ASDB-25-015-S	As per attached list of lots.	 2018-MM-DD

Description of the problem:

The product is being recalled because Cook has received thirty-five (35) complaints of the snare loop not completely retracting and/or misshaping of the snare loop. This has been reported to have led to perforation or could potentially lead to non-endoscopic retrieval of impacted snare (surgery).

As stated above, the devices may cause injury to the patient because the snare may not fully retract, or the snare loop may become misshapen. It has been reported that this has caused or contributed to perforation. It could also lead to an impacted snare, needing to either attempt to perform polypectomy with an additional snare, or retrieval by surgery.

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/January/2019 <two weeks from the projected date last 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 manufactured in 2018 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 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.

Signature

Scottie Fariole
Regulatory Reporting Manager

	Quality System Form			
	Document Number: D00060364	Revision: 012	QMS Owner: Cook Medical Europe Ltd.	Page: 1 of 2
	Title: Field Action Customer Response Form			
Legacy Number:		F14-00B		



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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2018FA0014

Affected device: Acusnare Polypectomy (Duck Bill Shaped) Snare

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:


☐ None of the affected product remains in our inventory

☐ We are returning our remaining inventory, please see details listed below

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

☐ Yes

☐ No

	Quality System Form			
	Document Number: D00060364	Revision: 012	QMS Owner: Cook Medical Europe Ltd.	Page: 2 of 2
	Title: Field Action Customer Response Form			
Legacy Number:		F14-00B		

If 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 239294.

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