COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product:

- Vue Optic Visualization Source
- Flexor Vue Deflecting Endoscopic System

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0010
Type of action: Field Safety Corrective Action

Date: 07 June 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

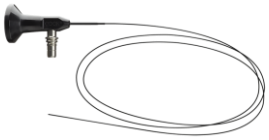
Product Brand Name	Reference Part Number	GPN
Vue Optic Visualization Source	FVO-150	G25343
Flexor Vue Deflecting Endoscopic System	FV-090075-150	G50972
	FV-090045-150	G34306

Description of the problem:

COOK Medical is initiating a voluntary correction of the products listed above. We have identified that the reprocessing instructions do not provide sufficiently detailed information for the cleaning, disinfection, and sterilization of these products. Our preliminary investigation indicates that validation data related to the reprocessing of these devices do not meet the current guidance.

There have been no reports of adverse reactions related to inadequate cleaning, disinfection, or sterilization associated with these devices.

Potential adverse events that may occur if the products are not adequately reprocessed include urological infections and systemic infections from a urological origin as well as events resulting from chemical residual exposure.

PRODUCT FAMILY	INTENDED USE	PRODUCT IMAGE
Vue Optic Visualization Source	Used during endoscopic procedures for direct visualization of body cavities or organs.	
Flexor Vue Deflecting Endoscopic System	The Flexor 180 Deflecting Ureteral Access Sheath is intended for use during endoscopic procedures to provide working access to body cavities or organs, as well as protection for the Vue Optic Visualization Source. The Vue Optic Visualization Source is intended for use during endoscopic procedures for direct visualization of body cavities or organs.	

This notice is directed to you because our records indicate that you have received product of the listed catalog numbers identified.

Distribution of the Vue Optic Visualization Source and Flexor Vue Deflecting Endoscopic System products will not occur until the reprocessing instructions in the Instructions for Use have been corrected.

You can continue to use the Vue Optic Visualization Source and Flexor Vue Deflecting Endoscopic System by following the attached document for Reprocessing Instructions.

Advise on action to be taken by the user:

1. Immediately examine your inventory to identify and quarantine those affected products.
2. Implement the updated Reprocessing Instructions.
3. Please complete the enclosed Customer Response Form.
4. 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).
5. Please report any adverse event to Cook Medical Customer Relations by contacting our Customer Services Department.

Transmission of this Field Safety Notice:
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.

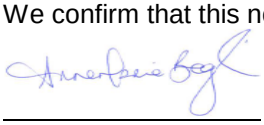
Contact reference person:
Sinead Burke
Director, Regulatory Affairs
Regulatory Affairs
Cook Ireland
Limerick, IRELAND

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

