COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
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Urgent Field Safety Notice

Commercial name of the affected product:

- **Cook Multi-Use Holmium Laser Fibers**

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0009
Type of action: Field Safety Corrective Action

Date: XX May 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

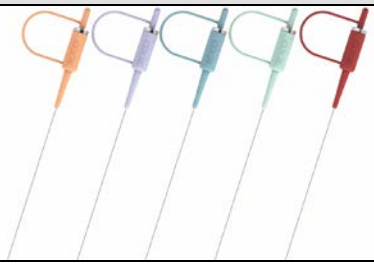
Product Brand Name	Reference Part Number	GPN
Cook Multi-Use Holmium Laser Fibers	HLF-M273-H30	G23668
	HLF-M365-H30	G23667
	HLF-M550-H30	G23666
	HLF-M940-H30	G23665
	HLF-M273-HSMA	G25298
	HLF-M365-HSMA	G25299
	HLF-M550-HSMA	G25300
	HLF-M940-HSMA	G25301

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
Cook Multi-Use Holmium Laser Fibers	Used with holmium laser systems for the treatment of kidney, ureter, and bladder stones, as well as soft tissue ablation.	

This notice is directed to you because our records indicate that you have received product of the listed catalog numbers identified.
Distribution of the Cook Multi-Use Holmium Laser Fibers will not occur until the reprocessing instructions in the Instructions for Use have been corrected. Single use fibers are available. Contact your local sales representative for further information.

You can continue to use your inventory of Cook Multi-Use Holmium Laser Fibers by following the attached Suggested Fiber 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 Suggested Fiber 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.

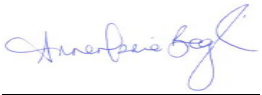
Contact reference person:
Sinead Burke
Director, Regulatory Affairs
Regulatory Affairs
Cook Ireland
Limerick, IRELAND

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

