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:

- **OptiLite Multi-Use Holmium Laser Fibers**

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0008
Type of action: Field Safety Corrective Action

Date: 09 May 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	GPN
OptiLite Multi-Use Holmium Laser Fibers	HLF-M273-CNV	G48611
	HLF-M273-SMA	G48522
	HLF-M365-CNV	G48613
	HLF-M365-SMA	G48618
	HLF-M550-CNV	G48615
	HLF-M550-SMA	G48619
	HLF-M940-CNV	G48617
	HLF-M940-SMA	G48621

Description of the problem:

COOK Medical is initiating a voluntary recall 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 (color may vary)
OptiLite Multi-Use Holmium Laser Fibers	Used with the Odyssey 30™ Holmium Laser System for fragmentation of urinary calculi and soft tissue applications including incision/excision, ablation, and coagulation	 (CNV) (SMA)

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

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products as per the specified lot listing from your inventory and **discard these products.**

2. Please complete the enclosed Customer Response Form.

   Credit will be provided once you confirm on the Customer Response Form the quantities, part numbers, and lot numbers that you have discarded.

3. 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).

4. 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.

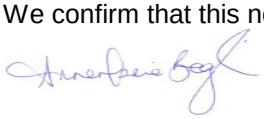
Contact reference person:
Sinead Burke
Director, Regulatory Affairs
Regulatory Affairs
Cook Ireland
Limerick, IRELAND

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

