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 products: StoneBreaker® Pneumatic Lithotripter
StoneBreaker Exhaust Cap, StoneBreaker Exhaust Line, StoneBreaker Probe Cap, StoneBreaker Sterilization Cap, StoneBreaker CO2 Cartridge, StoneBreaker Single Use Probe

Manufacturer: Cook Incorporated-Spencer, 1100 W Morgan St, Spencer, Indiana 47460

Cook Reference Number: 2018FA0004

Type of action: Field Safety Corrective Action

Date: 07 Mar 2018

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

PRODUCT BRAND NAME	CATALOG IDENTIFIER	ORDER NUMBER	LOT NUMBER
StoneBreaker Pneumatic Lithotripter	SBL-KIT1	G52604	All lots
StoneBreaker Exhaust Cap	SBA-EC	G52599	
StoneBreaker Exhaust Line	SBA-EL	G52600	
StoneBreaker Probe Cap	SBA-PC	G52601	
StoneBreaker Sterilization Cap	SBA-SC	G52602	
StoneBreaker CO_2 Cartridge	SBC-10	G52603	
StoneBreaker Single Use Probe	SBP-010500 SBP-010605 SBP-016500 SBP-016605 SBP-020425	G52607 G52605 G52606 G52609 G52608	

Description of the problem:

Cook Medical is initiating a voluntary recall of the StoneBreaker® Pneumatic Lithotripter and associated accessories. The product is intended for reprocessing at the user facility. We have identified that the interior of the product may not be sterilized to the appropriate sterility assurance level when following the reprocessing instructions provided in the Instructions for Use. Potential adverse events that may occur include urinary tract infection (UTI), pyelonephritis, and urosepsis.

This notice is directed to you because our records indicate that you have received this product.

Advise on action to be taken by the user:

1. Please complete the enclosed Customer Response Form and send 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).

2. Please include contact details on the Customer Response Form. Used devices being returned should be double-bagged, placed inside an outer puncture free package with sufficient cushioning material to prevent movement between the secondary container and the outer package. An

itemized list of the components must be placed in the container and the outer package marked "Used Medical Device".

Product should be returned and addressed to:

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

Credit will be provided for the returned affected products where applicable.

3. Please report any adverse events to Cook Medical by contacting our Customer Support Department.

Transmission of this Field Safety Notice:

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 of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

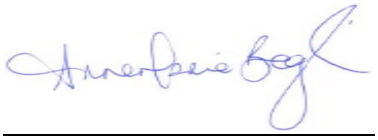
Michael Galvin
Regulatory Affairs Manager
COOK Ireland
O'Halloran Road, National Technology Park, Limerick, IRELAND

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