

**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:

- **Willscher Vas Reapproximator Set**
- **Willscher Vas Skewers**
- **Willscher Vas Reapproximator Plate**
- **Endoscopic Curved Needle Driver**
- **LapSac[®] Introducer**
- **LapSac[®] Introducer Set**

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US

Cook Reference Number: 2017FA0007

Type of action: Field Safety Corrective Action

Date: 27 April 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:


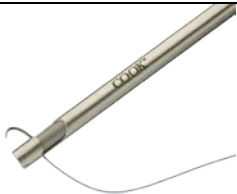


Product Brand Name	Reference Part Number	GPN
Willscher Vas Reapproximator Set	092000	G14500
Willscher Vas Skewers	092001	G14512
Willscher Vas Reapproximator Plate	092002	G15612
Endoscopic Curved Needle Driver	096511	G15573
	J-ENH-033100	G16426
	J-ENH-053100	G16427
	J-ENH-053120	G16428
	J-ENH-053130	G16429
LapSac [®] Introducer	J-LSI-102500	G16500
LapSac [®] Introducer Set	054300	G15771

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 localized surgical site infection to deeper organ space infection as well as chemical residual exposure

PRODUCT FAMILY	INTENDED USE	PRODUCT IMAGE
Willscher Vas Reapproximator set	Used to stabilize the vas ends during microscopic vasovasostomy.	
Willscher Vas Skewers		
Willscher Vas Reapproximator Plate		
Endoscopic Curved Needle Driver	Used for internal suturing under direct vision during intraabdominal endoscopic procedures. The needle driver design affords precise placement and control of standard curved suture needles, similar to open abdominal suturing.	
LapSac® Introducer	Used to aid in the introduction of a LapSac during endoscopic surgical procedures	
LapSac® Introducer Set		

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:

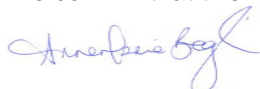
Sinead Burke
Director, Regulatory Affairs
Regulatory Affairs
Cook Ireland
Limerick, IRELAND

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