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:

- Stamey Needle
- Clarke-Reich Laparoscopic Knot Pusher
- Endoscopic Introducer/Extractor
- Pereyra Ligature Carrier '75®
- Pereyra-Raz Ligature Carrier™

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0006
Type of action: Field Safety Corrective Action

Date: 24 April 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	GPN
Stamey Needle	J-SYN-931630 J-SYN-931615 J-SYN-931600	G16632 G16631 G16630
Clarke-Reich Laparoscopic Knot Pusher	J-CRKP-042900	G16681
Endoscopic Introducer/Extractor	J-EIE-051500	G16417
Pereyra Ligature Carrier '75®	J-PLC-751810	G16557
Pereyra-Raz Ligature Carrier™	J-RSN-901600	G16568

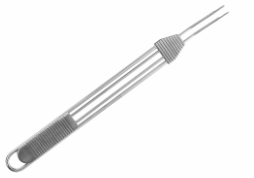
Description of the problem:

COOK Medical is initiating a voluntary recall of all the products as listed above. We have identified the reprocessing instructions do not provide sufficient 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
Stamey Needle	Used for pulling sutures from a vaginal incision into the suprapubic area during bladder suspension surgery. The double needle design permits simultaneous suture placement. This instrument is reusable.	

Clarke-Reich Laparoscopic Knot Pusher	Used to place extracorporeally tied sutures into a laparoscopic surgical field. Reusable; may be re-sterilized by ethylene oxide gas (ETO), steam autoclave or cold soak.	
Endoscopic Introducer/Extractor	Used for the introduction of endoscopic instruments into the abdominal cavity through an access port for intra-abdominal endoscopic procedures, or to facilitate the removal of resected tissue from the abdominal cavity without contamination.	
Pereyra Ligature Carrier '75®	Used for pulling sutures from a vaginal incision into the suprapubic area during bladder suspension surgery. The double needle design permits simultaneous suture placement. This instrument is reusable.	
Pereyra-Raz Ligature Carrier™	Used for pulling sutures from a vaginal incision into the suprapubic area during bladder suspension surgery. The double needle design permits simultaneous suture placement. This instrument is reusable.	

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.

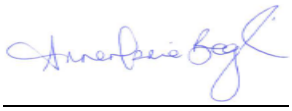
Contact reference person:
Sinead Burke
Director, Regulatory Affairs
Regulatory Affairs
Cook Ireland
Limerick, IRELAND

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

COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2017FA0006
Affected product:

- Stamey Needle
- Clarke-Reich Laparoscopic Knot Pusher
- Endoscopic Introducer/Extractor
- Pereyra Ligature Carrier '75®
- Pereyra-Raz Ligature Carrier™

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____
(Please Print)

Please indicate which of the following applies to your facility:

☐ None of the affected product remains in our inventory

☐ We have the affected products and confirm we have now discarded these products.

**If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

If you have discarded the affected product, please indicate the part number, lot number and quantity to receive credit:

Product Part Number	Product Lot Number	Quantity

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.

