COOK®

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

Commercial name of the affected product:

- Pereyra-Raz Ligature Carrier™
- Pereya Ligature Carrier '75®
- Stamey Needle

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0005
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
Pereyra-Raz Ligature Carrier™	090002	G15057
Pereyra Ligature Carrier '75®	090100	G15433
Stamey Needle	095030 095015 095000	G15082 G15081 G15080

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
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.	
Pereya 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.	

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.	

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

Contact reference person:
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

