

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: CloverSnare 4-Loop Vascular Retrieval Snare

Manufacturer : Cook Incorporated

FSCA-identifier: 2014FA005

Type of action: Field Safety Corrective Action

Date: 17 July 2014

Attention: Chief Executive

Details on affected devices:

Product Name: CloverSnare 4-Loop Vascular Retrieval Snare

Catalogue Number: VRS-6.0-90

Lot Number: *The following Lot numbers ONLY are impacted by this field action 4319591 & 4319575*

Description of the problem:

The CloverSnare 4-Loop Vascular Retriever is intended for use in the cardiovascular system to manipulate and retrieve foreign objects, including, but not limited to, wire guides, coils, balloons, catheters, and filters. Cook Medical has received six reports of separation of the snare loop from the shaft of the device.

Potential adverse events that may occur as a result of separation include: Loss of device function; medical intervention to retrieve separated snare.

Our investigation into these reports has identified the failures to be related to lateral forces applied to the snare loop / shaft connection. For instance, in three of the reports, separation occurred after attempts by the user to reshape the tip. To avoid further occurrence and potential harm, Cook Medical is initiating a voluntary recall of all lots in distribution.

Our records indicate your facility has received CloverSnare 4-Loop Vascular Retrievers distributed between March 8, 2013 and July 1, 2014.

Advise on action to be taken by the user:

- 1) Please review the attached list of affected products and lot numbers shipped to your account, and quarantine any affected product that remains unused.
- 2) Immediately collect and return all unused affected products to Cook Medical for credit. Please contact our Customer Services Department to arrange pick up.

Send the removed products to:

**Cook Medical Europe,
Attn: Product Complaints,
O'Halloran Road,
National Technology Park
Limerick
Ireland**

Please attach the enclosed Recall Product Return Form referencing RA # 2014FA0005 to the outside of the shipping carton.

Credit will be provided for the returned devices where applicable.

- 3) Where devices have been used on a patient, there is no risk to the patient and no need for any further action.
- 4) Please complete the attached Customer Response Form, which lists the product and lot numbers affected and return via email to European.Complaints@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Complaints/Customer Quality Assurance as soon as possible to +353 61334441.

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. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (If appropriate)

Contact reference person:

Emmett Devereux
Director of Quality and Regulatory Affairs
COOK Medical Europe
O'Halloran Road,
National Technology Park,
Limerick,
IRELAND

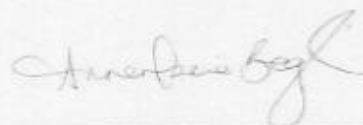
Or

Annemarie Beglin
Quality Assurance Supervisor
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.Complaints@CookMedical.com, phone +353 61 334440).

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. We look forward to receiving your response.

We confirm that this notice has been notified to the appropriate Regulatory Agency.



Annemarie Beglin
Quality Assurance Supervisor