

COOK

Cook Medical Europe
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Limerick, Ireland.
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Urgent Field Safety Notice

Commercial name of the affected product: HEMOSPRAY ENDOSCOPIC HEMOSTAT
Manufacturer : Cook Endoscopy/Wilson-Cook Medical, Inc.
FSCA-identifier: 2014FA0002
Type of action: Field Safety Corrective Action

Date: 20/May/2014

Attention: Chief Executive

Details on affected devices:

Product name: HEMOSPRAY ENDOSCOPIC HEMOSTAT

Catalogue number: HEMO- *Please see attached list for complete catalog numbers*

Lot number: *Please see attached list for the affected products/lots shipped to your account.*

Description of the problem:

Cook Medical has received a small number of reports related to the inability to spray the powder for the Hemospray Endoscopic Hemostat. These reports involve difficulty spraying the Hemospray powder from the delivery system. Adverse events that may occur due to spraying difficulties include inadequate treatment.

Advise on action to be taken by the user:

1. Please review the attached customer list and quarantine any affected product that remains in your stock.
2. Immediately collect all remaining unused products. The remaining unused products should be returned as soon as possible via DHL quoting Cook Medical's account number: 952049139 to arrange pick up.

Send the removed devices to:

COOK Medical Europe
O'Halloran Road,
National Technology Park,
Limerick,
Ireland

Apply the following text to the Air Way Bill (AWB) label:

Non Flammable Gas, Can ship under DRG Special provision A98
Include no more than 30 devices per shipping container

Please attach the enclosed Recall Product Return Form referencing RA # 2014FA0002 to the outside of the shipping carton.

Replacement or credit will be provided for the returned devices where applicable.

3. Where devices have already been used in a patient, there is no risk to the patient and no need for any further action. The small number of occurrences related to the inability to spray the powder are in no way related to the performance of the hemostatic agent once used.
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.

Contact reference person:

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

Annemarie Beglin
Quality Assurance Supervisor
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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.

Signature

Quality Assurance Supervisor