COOK

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
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Field Action Customer Communication

Commercial name of the affected product: Spirotome™ Soft-Tissue Biopsy Needle Set
Manufacturer: MEDINVENTS, Belgium
FSCA-identifier: 2014FA0007
Type of action: Field Safety Corrective Action

Date: 07/Oct/2014

Attention: Chief Executive / Risk Management

Details on affected devices:
Product Name: Spirotome™ Soft-Tissue Biopsy Needle Set
Catalogue Number: *See list below*

RPN	GPN	Needle Gage	Needle Length (CM)
SS-08-06	G31987	8	6
SS-08-10	G31985	8	10
SS-08-15	G31998	8	15
SS-10-06	G32709	10	6
SS-10-10	G31988	10	10
SS-10-15	G32000	10	15
SS-14-06	G31993	14	6
SS-14-10	G31991	14	10
SS-14-15	G32752	14	15

Lot Number: *See attached list.* Lot numbers on the attached list **ONLY** are impacted by this field action.

Description of the problem:
MEDINVENTS, the manufacturer of the above products, has initiated a voluntary product recall involving the Spirotome™ Soft-Tissue Biopsy Needle Set distributed by Cook Medical. The recall has been initiated due to customer complaints that the protective caps were dislodged in the pouch. Further investigation disclosed potential dislodging of protective caps on the needle tips on other distributed products. Use of the affected products could create risk for non-sterile use or accidental puncture.

Our records indicate that your institution has purchased one or more of the above listed devices distributed by Cook Medical. Please refer to the enclosed Cook Medical listing that contains specific part numbers and lot numbers affected by this recall.

To assist MEDINVENTS in its recall, Cook Medical is requesting that you examine your inventory and quarantine any product subject to the recall.

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 # 2014FA0007 to the outside of the shipping carton.

Credit will be provided for the returned devices where applicable.

3) Please complete the attached Customer Response Form 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.

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:

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 by MEDINVENTS.

Annemarie Beglin
Quality Assurance Supervisor