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: Osteo-Site® Murphy Side Bevel Bone Biopsy Needle Set
Manufacturer : Cook Incorporated
Cook Reference Number: 2015FA0008
Type of action: Field Safety Corrective Action

Date: November 05, 2015

Attention: Risk Management/Recall Administration

Details on affected devices:

Product Name:

Brand Name	Catalog Number	GPN	Lot Number
Osteo-Site® Murphy Side Bevel Bone Biopsy Needle Set	DBBN-11-10.0-M1M	G13761	5896000

Description of the problem:

Cook Medical is initiating a voluntary recall of the Osteo-Site® Murphy Side Bevel Bone Biopsy Needle Set for a specific lot number due to a manufacturing error. Cook Medical has received two complaints where an Osteo-Site® Murphy Side Bevel Bone Biopsy Needle Set was packaged incorrectly with the wrong needle bevel. Preliminary investigation has revealed that the product catalog DBBN-11-10.0-M1M, Lot # 5896000, was packaged with a diamond bevel during the manufacturing process. To avoid further occurrence and potential harm, Cook Medical is initiating a voluntary recall of the specific affected lot in distribution.

In this situation where the needles are mislabeled, it is highly likely that the wrong needle tip would be noticed prior to the procedure. If the wrong needle were to be used, the potential harms may include nuisance to provider and patient, delayed pain resolution for vertebroplasty patient, and requiring a repeat biopsy procedure. This event is not likely to lead to an adverse patient/user outcome and/or is obvious to the user. The overall risk is low.

Our records indicate that your facility has received devices that are subject to this field action.

Advise on action to be taken by the user:

1. Please review the attached list of affected products and lot numbers that were shipped to your account, and quarantine any affected product that remains unused.

2. Immediately collect and return all unused affected products to Cook Medical as soon as possible for credit. Please contact our Customer Services Department to arrange pick up.
   Send the removed products to:
   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

Please attach the enclosed Recall Product Return Form referencing RA # 2015FA0008 to the outside of the shipping carton.

Credit will be provided for the returned devices where applicable.

3. Please complete the enclosed Customer Response Form and send 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:

Marianne Høy
Manager, Support Services
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

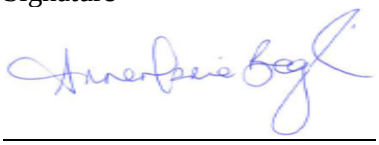
Or

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.

Signature



Annemarie Beglin
Quality Systems Manager