

To Whom it may concern

26 January 2018

Coloplast A/S
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CVR-nr. 69749917

FIELD SAFETY NOTICE ref.: FSCA_Biatain_Ag Ibu_20180105

Coloplast recommends to cease use of and to return the devices Biatain Ag and Biatain Ibu dressings listed in Table A.

Background information and scope of the product recall

The sterility of mentioned medical devices made by Coloplast may be compromised due to a quality issue that has occurred in the production process. Investigations to find the root cause and to solve this matter are ongoing.

Sukhjit Gill Køfer
Vigilance Officer

dksgk@coloplast.com

Safety concerns

Biatain Ag and Biatain Ibu are both sterile, single use foam dressings intended for management of highly exuding and painful wounds. The quality issue can affect the sterility of the finished product, potentially compromising user safety, however the probability (potential risk of infection) is rather low.

We want to stress that the recall is a precautionary measure as no users, customers or authorities have filed complaints or adverse events related to this issue, however we want to maintain the highest standards for product and end user safety.

Advice on preventive action to be taken by the user:

The customers affected by this Field Safety Notice (FSN) are kindly advised to cease use of the listed devices and return these to Coloplast.

Transmission of this Field Safety Notice:

Please forward this message to relevant persons in your organization. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

In addition, if you have further distributed this product, please notify the consignees at once of this notification. Your notification to your customers may be enhanced by including a copy of this notification letter. This notification should be carried out to the user level. Your assistance is appreciated and necessary.

The undersigned confirms that this notice has been forwarded to the appropriate Competent Authorities.

Yours sincerely,



Sukhjit Gill Køfer

Table A: country, product, item no, lot no.

Country	Ireland (IE)	
Product	Biatain Ag	Biatain Ibu
Item numbers		3415501006
Lot numbers		5836916

FSN ref.: FSCA_Biatain_Ag Ibu_20180105

Confirmation of receipt of the FSN

Please fill out the form and send it to the email address given below - even if you do not have the products on your stock please fill out the document.

E-mail: gjbs@coloplast.com**Recalled products: Biatain Ag and Biatain Ibu**

Country:	Ireland (IE)	
Product	Biatain Ag	Biatain Ibu
Item number:		
Lot number:		
Volume (number of eaches) in your possession to return:		

 We have checked all the stocks and the products concerned are not on stock.

Name of customer: _____

Name / profession: _____

Date / signature:

Return address: Coloplast Ltd, Nene Hall
Peterborough Business Park
Peterborough, PE2 6FX

Att.: Joanna Busse

Please return the confirmation of receipt no later than: 01 March 2018