

To Whom it may concern

12 January 2018

Coloplast A/S
Holtedam 1
3050 Humlebæk
Denmark
Tel: +45 4911 1111
www.coloplast.com
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.

Sukhjit Gill Køfer
Vigilance Officer

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.

dksgek@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.

1

Country	United Arabic Emirates (UAE)	
Product	Biatain Ag	Biatain Ibu
Item numbers		3410501647
Lot numbers		5922559

2

Country	Austria (AT)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3963201038 3962301038 3963101038	3410501038 3412001038
Lot numbers	5832306 5926673 5976686	6018366 5879288

3

Country	Canada (CA)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962501404 3962301404 3510501404 3962501404 3510501404	3412001404
Lot numbers	5857211 5879285 5879456 5942515 5959214	5874664

4

Country	Belgium (BE)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962501017 3346401017	
Lot numbers	5846971 5857624 5910482 5926694 5950231	

5

Country	Switzerland (CH)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3510501039	3410501039
Lot numbers	5847089 5964570	5879460

6

Country	Germany (DE)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3510501004 3962301004 3962501004 3962801004 3963101004 3964101004 3964301004	3412001004
Lot numbers	5857411 5892477 5942545 5964562 5842709 5959170 5977422 5865498 5883650 5883712 5912308 5872785 5881599 5900564 5910483 5926873 5928213 5942925 5965022 5980304 5984629 5926872 5952657 5984654	5891825

7

Country	Denmark (DK)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962301008	3410501008
	3962501008	3412001008
Lot numbers	5959166	5847094
	5976501	5836908
		5865255
		5879283

8

Country	Spain (ES)	
Product	Biatain Ag	Biatain Ibu
Item numbers		3415201011
Lot numbers		5918185

9

Country	France (FR)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3344801001	3411701001
	3356901001	3415301001
	3346101001	3415401001
	3356701001	3415601001
		3415901001
		3416301001
		3416401001
		3416701001
Lot numbers	5846974	5886985
	5846975	5923554
	5864417	5891823
	5868693	5964524
	5874660	6018410
	5891822	5770293
	5903215	5895081
	5956322	5918367
	5964561	5849913
	5976514	5886996
5984327	5868796	
	5892486	

10

Country	Great Britain (GB)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962301006 3510501006 3962501006	3410501006 3415501006 3416501006
Lot numbers	5868695 5926768 5942519	5847125 5892487 5942557 5836916 5883788 5918199 5964534

11

Country	Greece (GR)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3964301009 3964101009	3412001009
Lot numbers	5918419 5942632	5942524 5977445 5989468

12

Country	India (IN)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962501664	
Lot numbers	5892377 5904657	

13

Country	Israel (IL)	
Product	Biatain Ag	Biatain Ibu
Item numbers		3410501624
Lot numbers		5922559

14

Country	Italy (IT)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962301005 3964101005 3962801005	
Lot numbers	5842706 5903216 5959245 5985495	

15

Country	Korea (KR)	
Product	Biatain Ag	Biatain Ibu
Item numbers		3410501728
Lot numbers		5847102 5857422 5905727

16

Country	Poland (PL)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962501060 3346401060 3962501060	
Lot numbers	5846986 5857619 5959193	

17

Country	Saudi Arabia (SA)	
Product	Biatain Ag	Biatain Ibu
Item numbers		3410501632
Lot numbers		5864394 5874610 5876657 5922559 5935621 6004059

18

Country	Slovakia (SK)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3964301063 3962501063 3510501063 3964101063	
Lot numbers	5847749 5879296 5879607 5918420 5942526 5942567 5959248 5964539 5984664	

19

Country	Sweden (SE)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962801030	
Lot numbers	5879461	

20

Country	United States (US)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962501400	
Lot numbers	5959191	

21

Country	South Africa	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962501388	
Lot numbers	5976526	

22

Country	Australia (AU)	
Product	Biatain Ag	Biatain Ibu
Item numbers	3962801800	
Lot numbers	5868783	

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: XXXXXXXX@coloplast.com

Recalled products: Biatain Ag and Biatain Ibu

Country:		
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 **XX**
 Street / no.
 Postal code / city

Att.: **Name**

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