FSCA Ref: CA100001300

Date: Mar 12, 2024

Urgent Field Safety Notice (FSN)
regarding the recall of
Leukoplast® Compress Cotton Gauze T17 10x10 cm
Leukoplast® Compress Viskers Gauze T17 18x20 cm

Dear customer,

This letter is to inform you about a recall that we are conducting as a precautionary field safety corrective action on two of our cotton gauze products.

Information on affected devices

Leukoplast® Compress Cotton Gauze T17 10x10 cm
REF 71237-00005-00
LOT 301152, 309152, 313152, 316152, 324152, 338152

Leukoplast® Compress Viskers Gauze T17 18x20 cm
REF 71296-00000-00
LOT 301152, 305152, 316152, 319152, 322152

Description of the product problem

Leukoplast® cotton gauzes are sterile absorbent type 17 cotton gauzes for use in wound care and for surgical procedures. Due to a production error, it is possible that the cotton gauze is caught in the seal of the primary packaging. Since this seal is part of the sterile barrier system, we cannot exclude that affected products are unsterile.

The problem affects single products per LOT only and it is easily detectable. The faulty devices are not freely movable inside the blister pack, but they are stuck between the top and bottom part of the blister at the sealed edge.

If the defective sterile barrier is not detected when opening the packs, it is possible that unsterile products are used e.g. during a surgical procedure. This could lead to surgical site infections and further consequent complications related to infections in general.

As a precautionary measure we are hereby recalling the affected products.

Type of Action to mitigate the risk

Please check your stock of the affected REF/LOT combinations mentioned above of Leukoplast cotton gauzes.

Do not use these devices for any medical purpose, but send them back or discard any of the products you hold on stock.

BSN medical GmbH
Schützenstraße 1-3
22761 Hamburg
Germany

+49 (0) 40 593612-100
info@medical.essity.de
www.essity.com

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To simplify processing for you, please find attached a response form. Please indicate:

- the number of goods to be taken back,
- the date of when we may collect the goods, and
- the place where we can pick up the items.

Please also use the response form to inform us in case you have already used up all the products from the above-mentioned lots in full.

After having received the response, we will arrange for collection of the affected goods.

We apologize for any inconvenience that might be associated with this recall.

Please be assured that the quality of our products and their reliability in daily use are our highest priority.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations 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.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact Person

Our colleague, [...] is at your disposal for any questions.

[…]

Sincerely,

Essity/BSN medical GmbH

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Field Safety Notice - Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CA100001300
FSN Date	March 12, 2024
Product/ Device name	Leukoplast® Compress Cotton Gauze T17 10x10 cm
Product Code(s)	71237-00005-00
Batch/Serial Number (s)	301152, 309152, 313152, 316152, 324152, 338152
Product/ Device name	Leukoplast® Compress Viskers Gauze T17 18x20 cm
Product Code(s)	71296-00000-00
Batch/Serial Number (s)	301152, 305152, 316152, 319152, 322152

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

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3. Customer Action				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
☐	I performed all actions requested by the FSN.			
☐	The information and required actions have been brought to the attention of all relevant users and executed.			
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned:
		Qty:	Lot/Serial Number:	Date Returned:
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction			
☐	Other Action (Define):			
☐	I do not have any affected devices.			
☐	I have a query please contact me (e.g. need for replacement of the product).	Comments:		

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Print Name	
Signature	
Date	

4. Contact details for reply	
Email	
Contact person	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form	

Please confirm the receipt of this urgent field safety notice by returning the completed response form to us.

Your feedback serves as evidence for the correct implementation of this field safety corrective action.

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