

ESSITY/BSN-Letterhead

BSN ADDRESS

NAME OF RESPONSIBLE (The responsible for the recall in this country)

DATE

Customer's address

Urgent Field Safety Notice

Recall
concerning

CUTISOFT COTTON XR 10cm x 10cm

Concering all users of Cutisoft Cotton XR 10cm x 10cm

Identification of Affected Devices:

CUTISOFT COTTON XR 10cm x 10cm

REF No.: 71759-01

LOT-Code(s): 92951
92961
92971
93011
93021
93031

Description of the problem:

We would like to inform you about a possible problem with the X-Ray thread of the *Cutisoft Cotton XR 10cm x 10cm* dressing gauze.

We were informed by our supplier that the afore mentioned dressing gauze can potentially contain crumbling X-ray detectable thread.

So far, we have not received any complaints or reports about adverse events from the market.

Potential hazards: This problem may result in leaving a fragment of the device in the patient's body, and as a result may cause additional complications, granulomas formation, severe patient pain, and the possibility of reoperation.

What measures should be taken from you?

Please check your stock of *Cutisoft Cotton XR 10cm x 10cm*

and send back all goods of REF number **71759-01**, LOT numbers **92951, 92961, 92971, 93011, 93021, 93031** you hold on stock.

To simplify processing for you, please find attached a fax response form and prepared labels for the return.

Please indicate on the fax response form:

- _ 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 fax form to inform us in case you have already used up all the products from the above-mentioned lots in full.

After having received your fax response we will arrange for collection of the affected goods by **NAME OF COURIER TO BE FILLED IN**.

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.

Disclosure of the information described here

Please ensure that all users and individuals to be informed in your organization receive informational aware of this Urgent Field Safety Notice.

If you supply products to third parties, please forward a copy of this information or inform the contact person listed below.

Please keep this information at least as long, until the recall action has been completed.

The German competent authority - Bundesinstitut für Arzneimittel und Medizinprodukte - has been provided with a copy of this Urgent Field Safety Notice.

Contact Person

Our colleague, **NAME; PHONE NUMBER TO BE FILLED IN** is at your disposal for any questions.

Yours sincerely,

Essity/BSN medical GmbH

Attachment: Fax response form

Field Safety Notice Customer Reply Form

Recall Cutisoft Cotton XR 10cm x 10cm

1. Field Safety Notice (FSN) information	
FSN Reference number*	CA 10000605
FSN Date*	27.01.2020
Product/ Device name*	Cutisoft Cotton XR 10cm x 10cm dressing gauze
Product Code(s)	71759-01
Batch/Serial Number (s)	92951 92961 92971 93011 93021 93031

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*	

3. Customer action undertaken on behalf of Healthcare Organisation			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:
		Qty:	Date Returned (DD/MM/YY):
		N/A	Comments:
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have a query please contact me	Customer to enter contact details if different from above and brief description of query	

	(e.g. need for replacement of the product).	
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.