FSN Ref: 2024-07(01)
Date: 06-Aug-2024

FSCA Ref: 2024-07(01)

Urgent Field Safety Notice
Mölnlycke® Extremity Drape

For Attention of Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages Name: Local Customer Care contact will be added for each specific market Email: XXX.XXX@molnlycke.com Telephone: +XXXXXXXXXXXXX

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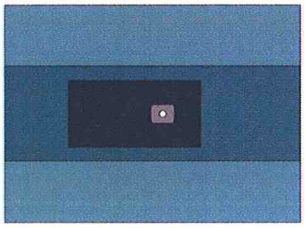
1. Information on Affected Devices	
1.	1. Device Type(s)
	Product codes: 60212-00 Extremity Drape 230x315cm, ap 7cm elasti Elastic aperture, Patched, Wrapped - Sterile 
1.	2. Commercial name(s)
	Extremity Drape
1.	3. Primary clinical purpose of device(s)
	The surgical patient drapes are intended to be used as protective patient covering to create a sterile field for a surgical procedure.
1.	4. Device Model/Catalogue/part number(s)
	See Appendix I Product Table
1.	5. Affected serial or lot number range
	See Appendix I Product Table

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem*
	Mölnlycke has identified that some Extremity Drape Items were packed in a way that affects the homogeneity of the RET, potentially impacting sterilization parameters. Although the risk is low, we cannot exclude the possibility of a packaging error during the last sterilization revalidation. This means there is a slight chance that products sterilized under normal conditions may not have received the full sterilization dose. As a precaution Mölnlycke has decided to perform a **Recall** of the impacted batches.
2.	2. Hazard giving rise to the FSCA*
	Using nonsterile drapes during surgery can increase the risk of local infection. Whilst we cannot be certain that the product has received full sterilization dose, It is likely to contain fewer micro-organisms than that of a non-sterile product and as such, we believe that with combined standard infection control measures taken during surgery, the likelihood of infection is considered to be low.

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	3. Type of Action to mitigate the risk	
3.	1. Action To Be Taken by the User ☒ Identify Device ☒ Quarantine Device ☒ Return Device We need your help in ensuring that **all affected products** are located and that below actions are performed. Please follow below instructions: 1. **Identify and isolate** the unused Mölnlycke® Extremity Drape at your facility, please see Appendix I for affected product information. 2. Fill out the **Customer Reply Form** or **Distributor Reply Form** with quantity of identified affected products. Please sign and email/fax the **Customer Reply Form** or **Distributor Reply Form** per its instructions within 10 business days. 3. Even if you no longer have any concerned Mölnlycke® Extremity Drape, fill out the **Customer Reply Form** or **Distributor Reply Form** and return it back within 10 business days. Mölnlycke needs to be sure all customers are aware of the situation. 4. Mölnlycke will contact you and arrange for collection of the product(s) from your facility, as soon as you return the **Customer Reply Form** or **Distributor Reply Form**. Mölnlycke will issue a credit for the goods returned. 5. If you have forwarded any affected products to other healthcare institutions, please send them a copy of this **Field Safety Notice**. Make sure they act accordingly. 6. If you are a distributor, please inform your customers by sending them a copy of this **Field Safety Notice**. Make sure they act accordingly and return the **Distributor Reply Form** with information collected from your end users. We apologize for any inconvenience this will cause you, and rest assured it is our utmost intent to make this process as easy for you as possible. In addition, Mölnlycke appreciates your help in collecting data on product complaints and/or incidents related to the concerned product. Please follow the reporting procedures established by your facility.	
3.	Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes (Within 10 business days)

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	4. General Information	
4.	FSN Type	New
4.	Further advice or information already expected in follow-up FSN?	No
4.	1. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Mölnlycke Health Care AB
	b. Address	
	c. Website address	
4.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	List of attachments/appendices:	Appendix I Product table Customer Reply Form Distributor Reply Form
4.	Name/Signature	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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.

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Appendix I

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Product table

To be added for each market