FSN Ref: 2022-06(01)
Date: 22 JUN 2022

FSCA Ref: 2022-06(01)

Urgent Field Safety Notice
Mölnlycke® Primary High Performance Surgical Gown

For Attention of: Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)
Name: Local Customer Care contact will be added for each specific market Email: XXX.XXX@molnlycke.com Telephone: +XXXXXXXXXXXXX

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Urgent Field Safety Notice (FSN)
Mölnlycke® Primary High Performance Surgical Gown

	1. Information on Affected Devices
1.	1. Device Type(s)
	98000725 – Surgical Gown Primary
1.	2. Commercial name(s)
	See Appendix I Product Table
1.	3. Primary clinical purpose of device(s)
	The Surgical Gowns are single use, disposable, fluid repellent garments intended to be used as sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material.
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 become aware of a potential safety issue with the outer seal of the packaging layer of the surgical gown. During an inspection, weakness of the seal has been detected on certain batches of surgical gowns. The integrity of the package cannot be guaranteed. There have been no reports made relating to patients being harmed due to this occurrence. Molnlycke has decided to perform a **Field Safety Corrective Action**. The FSN suggests the user to inspect the product package before use and discard if the product package sterility is compromised. This FSN aims to bring information to the attention of all relevant personnel before use. The products can be used moving forward with information clearly communicated.
2.	2. Hazard giving rise to the FSCA*
	Compromised sterility due to weakness of seal may result in potentially serious patient risk i.e. surgical site infection.

	3. Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Take note of amendment: affix a copy of this FSN to each Mölnlycke® Primary High Performance Surgical Gown and make this FSN information available for the user.

	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 product at your facility, please see Appendix I for affected product information. 2. **Affix a copy of this Field Safety Notice (FSN) to each Mölnlycke® Primary High Performance Surgical Gown make sure that its contents is brought to the attention of all relevant personnel to read before use**. 3. The Field Safety Notice suggests the user to inspect the product package before use and discard if the product package sterility is compromised. 4. Fill out the **Customer Reply Form or Distributor Reply Form,** and return it back to Mölnlycke within 10 business days, even if you do not have affected products. Mölnlycke needs to be sure all customers are aware of the situation. 5. Mölnlycke will contact you as soon as you return the **Customer Reply Form or Distributor Reply Form**. Mölnlycke will issue a credit for the affected products. 6. 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. 7. 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 **Customer reply form** to you. 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.	2. Is customer Reply Required?	Yes (Within 10 business days)

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	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Mölnlycke Health Care AB
	b. Address	Box 130 80, SE-402 52 Gothenburg, Sweden
	c. Website address	www.molnlycke.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Appendix I Product table Customer Reply Form Distributor Reply Form
4.	6. Name/Signature	Annika Hallberg Global Product Complaints Manager
		

	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

Product table

MATERIAL	MATERIAL DESCRIPTION	BATCH
98000725-01	Surgical Gown PR HP XLL	21336505