FSN Ref: 2020-09 (02)
Date: DD.MMM.2020

FSCA Ref: 2020-09 (02)

Urgent Field Safety Notice
Mölnlycke® Procedure Trays

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® Procedure Trays
Compromised package integrity of breather bag

	1. Information on Affected Devices
1.	1. Device Type(s)
	Mölnlycke® Procedure Trays consist of customized configurations of several sterilized components, which are assembled and delivered sterile within one procedure Tray.
1.	2. Commercial name(s)
	See Appendix I Product Table
1.	3. Primary clinical purpose of device(s)
	The clinical purpose of Mölnlycke® Procedure Trays is to provide a customized sterile co-packing of components for different clinical interventions.
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 a potential safety issue. During a regular inspection, a fault in the sealing machine was identified. The weakness of the seal has been detected after a quality test on some of the breather bags. So, we cannot guarantee the integrity of the package. Mölnlycke has decided to perform a **Recall**.
2.	2. Hazard giving rise to the FSCA*
	Compromised sterility due to weakness of seal may result in potentially serious patient risks i.e. surgical site infection.

	3. Type of Action to mitigate the risk
3.	1. Action To Be Taken by the User
	☒ Identify 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® Procedure Trays at your facility, please see Appendix I for affected product information. 2. Fill out the **Customer Reply Form,** Appendix II with quantity of identified affected products. Please sign and email/fax the **Customer Reply Form** per its instructions within 10 business days.

	3. Even if you no longer have any concerned Mölnlycke® Procedure trays, fill out the **Customer 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**. 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 **Customer 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.	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 Appendix II Customer Reply Form
4.	6. Name/Signature	Linda Magnusson, Post Market Surveillance and Site Quality Director 

	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

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Appendix II

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2020-09 (02)
FSN Date	DD.MMM.2020.
Product/ Device name	See Appendix I Product table
Product Code(s)	See Appendix I Product table
Batch/Serial Number (s)	See Appendix I Product table

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		
☐	• I confirm receipt of the Field Safety Notice and that I read and understood its content. • I do not have any affected devices.	
☐	• I confirm receipt of the Field Safety Notice and that I read and understood its content. • I have quarantined affected devices ready for return. • I have completed the table with the details of affected devices quantity, its article and lot/batch number.	**Quantity** / **Article/Material Number** / **Lot/Batch Number** N/A / Comments:
Print Name*		
Signature*		
Date*		

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4. Return acknowledgement to sender	
Email	vigilance@molnlycke.com
Customer Helpline	+XXXXXXXXXXXXX
Postal Address	Mölnlycke Health Care, Box 130 80, SE-402 52 Gothenburg, Sweden
Fax	+46 31 722 34 00
Deadline for returning the customer reply form*	Within 10 days

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.