FSN Ref: 2019-08 (01)
Date: 29.08.2019.

FSCA Ref: 2019-08 (01)

Urgent Field Safety Notice
Barrier® Sets

For Attention of: Theater Manager

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

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Urgent Field Safety Notice (FSN)
Barrier® Sets
Compromised package integrity

	1. Information on Affected Devices
1.	1. Device Type(s)
	Sets for orthopaedic and universal draping, which are supplied sterile.
1.	2. Commercial name(s)
	See Appendix I Product Table
1.	3. Primary clinical purpose of device(s)
	Surgical drapes, when sterilized, are intended to minimize the spread of micro-organisms, in order to reduce the risk for post-operative wound infection.
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 an investigation of a product complaint, pin-holes have been detected after immersion test on some of Barrier® Sets. Despite that all Barrier® Sets are produced in a clean environment and then sterilised we cannot guarantee the integrity of the sterile package.
2.	2. Hazard giving rise to the FSCA
	Compromised sterile barrier due to mechanical damage of the primary packaging 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 product at your facility, please see Appendix I for affected product information. 2. Fill out the Customer Reply Form, Appendix II, 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.

	3. 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. 4. 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. 5. 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** in **Appendix II** to you. We apologize for any inconvenience this will cause you, but 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.	1. Is customer Reply Required?	Yes (Within 10 business days)

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	4. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. Further advice or information already expected in follow-up FSN?	No
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Mölnlycke Health Care
	b. Address	Box 130 80, SE-402 52 Gothenburg, Sweden
	c. Website address	www.molnlycke.com
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	6. List of attachments/appendices:	Appendix I Product table Appendix II Customer Reply Form
4.	7. 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	2019-08 (01)
FSN Date	23.08.2019.
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 have affected devices ready for return - enter number of devices ready for return and date complete.	Qty:	Lot/Serial Number:	Date Returned
		Qty:	Lot/Serial Number:	Date Returned
		Qty:	Lot/Serial Number:	Date Returned
		Qty:	Lot/Serial Number:	Date Returned
		Qty:	Lot/Serial Number:	Date Returned
		Qty:	Lot/Serial Number:	Date Returned
		Qty:	Lot/Serial Number:	Date Returned
		N/A	Comments:	
☐	I do not have any affected devices.			
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.

2019-08-29

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Affected Barrier® Sets Globally

Product name	Product number	LOT number	GMDN code
Extremity Set	60204-00	19234790	33961 General/plastic surgical procedure kit, non-medicated, single-use
	60208-00	19222344	
	60209-00	19239134	
		19239134	
Extrmitäten set	60209-00	19239134	
Hand/Foot Set	60303-00	19244796	
Hip Set	60606-00	19222340	
Hip Set	60608-00	19237341	
		19222345	
Laparotomy Set	697100-11	19210811	
Split Sheet Set	60620-00	19234789	
Universal Set Basic	698900-07	19239130	
Universal Set Standard	66200-00	19222335	
Universal Set Standard	66300-00	19222347	
Universal Set Standard	699054-07	19239128	
		19232897	
Universal Set Standard	699140-07	19239132	
Universal Set Standard	699340-07	19244802	
		19244794	
Univerzalni set bez navleku na stol.	699340-07	19244802	