

FSN Ref: 2020-01 (01)
Date: 23.01.2020.

FSCA Ref: 2020-01 (01)

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: +XXXXXXXXXXXXXXXXXX

Urgent Field Safety Notice (FSN)
Mölnlycke® Procedure Trays
Compromised packaging integrity of the component within
Mölnlycke® Procedure Trays

1. Information on Affected Devices	
1.	1. Device Type(s) Mölnlycke® Procedure Trays consist of customized configurations of components, which are assembled and delivered sterile within one packaging.
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 recently been informed by the legal manufacturer Medtronic that they are performing a voluntary recall on a component CL915 Suture Polysorb 1 GS-24 1/2 40mm T which Mölnlycke includes in some of the Mölnlycke® Procedure trays. The reason for this recall is because Medtronic has detected that some units of their component have a potential packaging integrity issue and as a consequence the humidity or sterility of the product may be compromised.
2	2. Hazard giving rise to the FSCA* Information from Medtronic's FSN: <i>The use of products with a compromised sterile barrier may result in a potentially increased risk for infection. There have been no reports of patient injury associated with these issues.</i>

3. Type of Action to mitigate the risk	
3.	1. Action To Be Taken by the User <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device We need your help in ensuring that <u>all affected products</u> are located and that below actions are performed.

FSN Ref: 2020-01 (01)
Date: 23.01.2020.

FSCA Ref: 2020-01 (01)

	<p>Please follow below instructions:</p> <ol style="list-style-type: none"> 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. <p>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.</p> <p>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.</p>	
3.	2. Is customer Reply Required?	Yes (Within 10 business days)

FSN Ref: 2020-01 (01)
Date: 23.01.2020.

FSCA Ref: 2020-01 (01)

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	
	[Redacted Signature]	
	[Redacted Name]	

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>

FSN Ref: 2020-01 (01)

Date: 23.01.2020.

Appendix I

FSCA Ref: 2020-01 (01)

Product table

To be added for each market

FSN Ref: 2020-01 (01)

FSCA Ref: 2020-01 (01)

Date: 23.01.2020.

Appendix II

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2020-01 (01)
FSN Date	23.01.2020.
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														
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content. I do not have any affected devices.													
<input type="checkbox"/>	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	<table border="1"> <tr> <td>Qty:</td> <td>Lot/Serial Number:</td> </tr> <tr> <td>Qty:</td> <td>Lot/Serial Number:</td> </tr> <tr> <td>Qty:</td> <td>Lot/Serial Number:</td> </tr> <tr> <td>Qty:</td> <td>Lot/Serial Number:</td> </tr> <tr> <td>Qty:</td> <td>Lot/Serial Number:</td> </tr> <tr> <td>N/A</td> <td>Comments</td> </tr> </table>	Qty:	Lot/Serial Number:	Qty:	Lot/Serial Number:	Qty:	Lot/Serial Number:	Qty:	Lot/Serial Number:	Qty:	Lot/Serial Number:	N/A	Comments
Qty:	Lot/Serial Number:													
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Qty:	Lot/Serial Number:													
Qty:	Lot/Serial Number:													
Qty:	Lot/Serial Number:													
N/A	Comments													
Print Name*														
Signature*														
Date*														

4. Return acknowledgement to sender	
Email	vigilance@molnlycke.com
Customer Helpline	+XXXXXXXXXXXXXXXXXX
Postal Address	Mölnlycke Health Care, Box 130 80, SE-402 52

FSN Ref: 2020-01 (01)
Date: 23.01.2020.

FSCA Ref: 2020-01 (01)

	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.