

FSN Ref: 2021-04 (03)
Date: 19 May 2021

FSCA Ref:

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

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Mölnlycke® Procedure Trays
Label error on the Insert Card

1. Information on Affected Devices	
1.	<p>1. Device Type(s)</p> <p>Mölnlycke Tray Component: 2316563-00; Bonewax., white 2,5g; Surgical Specialities.</p>  <p>Mölnlycke® Procedure Trays consist of customized configurations of components, which are assembled and delivered sterile within one packaging. Bone wax from Surgical Specialities is one of these components</p>
1.	<p>2. Commercial name(s)</p> <p>See Appendix I Product Table</p>
1.	<p>3. Primary clinical purpose of device(s)</p> <p>The clinical purpose of Bone wax is used for control of bleeding from bone surfaces during surgical procedures. Mölnlycke® Procedure Trays provide a customized sterile co-packing of components for different clinical interventions.</p>
1.	<p>4. Device Model/Catalogue/part number(s)</p> <p>See Appendix I Product Table</p>
1.	<p>5. Affected serial or lot number range</p> <p>See Appendix I Product Table</p>

2 Reason for Field Safety Corrective Action (FSCA)	
2.	<p>1. Description of the product problem*</p> <p>Mölnlycke® has identified a potential safety issue. There is a discrepancy in the labelling of the expiry date for the Tray (Insert Card) and the Bone wax component contained within. The Insert Card on the Tray reflects a later expiry date than the Bone wax component shelf life.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p>

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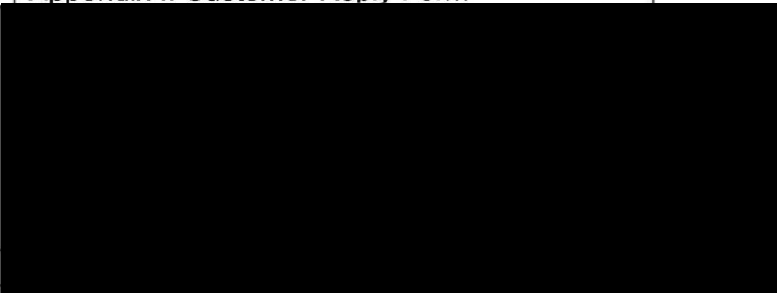
	<p>Based on medical opinion, the use of the product beyond its expiry date can result in surgical site infection including bone infection. So the overall risk severity level is critical. Please ensure that the affected Mölnlycke® Procedure Trays are identified to verify the expiry date of the Bone wax component before use. It is advisable to not use the expired component. The component package itself has its own shelf life information. It is safe to use the other components within the Mölnlycke tray, as detailed in the instructions below.</p>
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3. Type of Action to mitigate the risk		
3.	<p>1. Action To Be Taken by the User</p> <p><input checked="" type="checkbox"/> Identify Device</p> <p><input checked="" type="checkbox"/> Quarantine Device</p> <p><input checked="" type="checkbox"/> Take note of amendment: attach a copy of this FSN to each Mölnlycke® Procedure tray and make this FSN information available for the user</p> <p>We need your help in ensuring that all affected products are located and that below actions are performed.</p> <p>Please follow below instructions:</p> <ol style="list-style-type: none"> Identify and isolate the product at your facility, please see Appendix I for affected product information. Attach a copy of this Field Safety Notice (FSN) to each Mölnlycke® Procedure tray and make sure that its contents is brought to the attention of all relevant personnel to read before use. 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. At the point of use of Tray, identify the bone wax component and check the expiry date. If expiry date has passed, discard the component. Mölnlycke will issue a credits for the affected components, as soon as you return the Customer Reply Form. 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. 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 be 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.	<p>2. Is customer Reply Required?</p>	<p>Yes (Within 10 business days)</p>

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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	

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>

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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	FSN 2021-04 (03)
FSN Date	19 May 2021
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. The information and required actions have been brought to the attention of all relevant users and executed.	Qty:	Lot/Serial Number:
		N/A	Comments
<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.		
Print Name*			
Signature*			
Date*			

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4. Return acknowledgement to sender	
Email	vigilance@molnlycke.com
Customer Helpline	+XXXXXXXXXXXXXXXXXX
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.