FSN Ref: 2024-01(01)
Date: 23 Jan 2024

FSCA Ref: 2024-01(01)

Urgent Field Safety Notice
Mölnlycke® Procedure Trays

For Attention of: Operating room manager, Intensive care unit managers, Emergency care unit manager, Hospital sourcing manager for emergency care specialties.

Contact details of local representative (name, e-mail, telephone, address etc.)
Name: Molnlycke Healthcare UK Email: csc.uk@molnlycke.com Telephone: +0800 917 4918

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	1. Information on Affected Devices
1.	1. Device Type(s)
	Mölnlycke Procedure Trays consist of customized configurations of several sterilized medical devices, which are packed together and delivered sterile in 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 medical devices 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 Procedure Trays have been supplied without the vital medical device Sternal retractor which is an instrument used to actively separate the edges of a surgical incision or wound, or can hold back underlying organs and tissues, so that body parts under the incisions may be accessed. As a result, Molnlycke is initiating a **Field Safety Corrective action** on specific batches of Mölnlycke® Procedure Trays. The Field Safety Notice will notify the affected customers about the missing device 2325470-00 , Sternal retractor 30x19 cm 4 blades and advise the customer to discard the affected trays.
2.	2. Hazard giving rise to the FSCA*
	Sternal retractors are considered lifesaving and used in emergency situations. This missing device, may result in delay of patient treatment during an emergency procedure. There is no threat to public health. Information in relation to the missing device is described on Insert card; which should be checked before the surgical intervention.

	3. Type of Action to mitigate the risk
3.	1. Action To Be Taken by the User ☒ Identify Device ☒ Destroy Device We need your help in ensuring that **all affected products** are located and that below actions are performed. Please follow below instructions:

	1. Please use the information in the **Product table** in **Appendix I** to identify all affected, unused Mölnlycke® Procedure Trays at your facility. 2. **Discard** the affected, **unused Mölnlycke® Procedure Trays** at your facility. 3. Fill out the **Customer Reply Form** or **Distributor Reply Form** with the quantity of identified affected products. Please sign and email/fax the **Customer Reply Form** or **Distributor Reply Form** per its instructions within 10 business days. 4. When completed and signed Customer Reply form or Distributor Reply form is received by Molnlycke, Molnlycke will contact you regarding the compensation for the affected products. 5. Even if you no longer have any concerned Mölnlycke® Procedure trays, fill out the **Customer Reply Form** or **Distributor Reply Form** and return it back within 10 business days. Mölnlycke needs to be sure all customers are aware of the situation. 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 **Distributor 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 Customer Reply Form Distributor Reply Form
4.	6. Name/Signature	Annika Schoser, Global Product Complaints Manager.
		Annika Schoser *Electronically signed by: Annika Schoser Reason: Approver Date: Jan 25, 2024 15:32 GMT+1*

	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

Product Number	Product Description	Batch Number
97039083-00	Emergency Chest Re-opening Pack	23477379