FSN Ref: 2023-09(04)
Date: 18 Oct 2023

FSCA Ref: 2023-09(04)

Urgent Field Safety Notice
Mölnlycke® Procedure Trays

For Attention of: Operating Theater 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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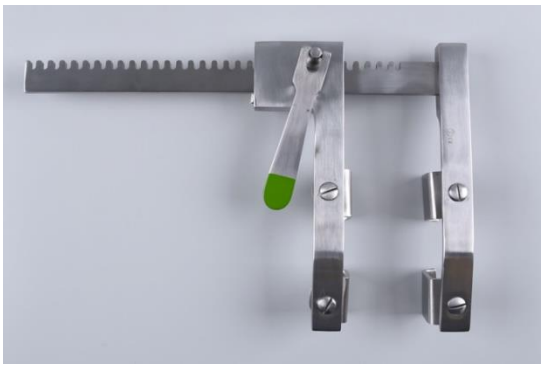
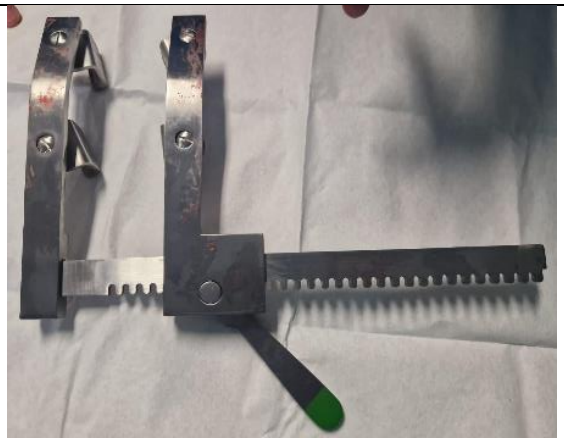
Urgent Field Safety Notice (FSN)
S.R.R Surgical component within Mölnlycke® Procedure Trays

1. Information on Affected Devices	
1.	1. Device Type(s)
	S.R.R Surgical Company component: 2325470-00 - Sternal retractor 30x19 cm 4 blades  This is included in various Mölnlycke® Procedure Trays. Mölnlycke® Procedure Trays consist of customized configurations of several sterilized components, 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 instrument is 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. 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 been notified by a customer of an incident involving the S.R.R Surgical Company product 24-170-00 Sternal retractor 30x19 cm 4 blades, which is included in some Mölnlycke® Procedure Trays under component number 2325470-00 The lever (handle) used to separate the blades during the procedure was mounted on the incorrect side of the blade which causes it to malfunction. As a result, the product does not work as intended.



Wrong assembly example

Mölnlycke has decided to do a **Recall** of all potentially affected trays where this component is included.

2. Hazard giving rise to the FSCA*

If the lever/handle is mounted on the wrong side of the blade the component will not function and it will render the retractor unable to fulfil its intended purpose. This may result in delay of patient treatment during an emergency procedure.

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the User

☒ Identify Device

☒ If non-affected devices are in stock and available for use, quarantine affected devices only.

☒ Due to the emergency nature of this product, if only affected devices are available for use, we would advise you to be aware of the issue and have a back-up product available for any emergency procedure, if needed, until replacement units are delivered.

☒ 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** the unused Mölnlycke® Procedure Trays at your facility, please see Appendix I for affected product information.
2. If non-affected products are available at your facility and are ready to be used if needed**, isolate the unused** Mölnlycke® Procedure Trays affected.
3. Due to the emergency nature of this product, if only affected devices are available for use, we would advise you to be aware of the issue and have a back-up product available for any emergency procedure, if needed, until replacement units are delivered.
4. Fill out the **Customer Reply Form** or **Distributor Reply Form** with 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.
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. Mölnlycke will contact you and arrange for collection of the product(s) from your facility, as soon as you return the **Customer Reply Form** or **Distributor Reply Form**. Mölnlycke will issue a credit for the goods returned. 7. 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. 8. 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 Distributor Reply Form
4.	6. Name/Signature	Viktoria Wennberg, Global Director Quality Systems
		 *Electronically signed by: Viktoria Wennberg Reason: Approver Date: Oct 18, 2023 11:02 GMT+2*

	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

MATERIAL	MATERIAL DESCRIPTION	BATCH
97039083-00	Emergency Chest Re-opening Pack	22193052
97039083-00	Emergency Chest Re-opening Pack	22193051
97039083-00	Emergency Chest Re-opening Pack	23040863
97039083-00	Emergency Chest Re-opening Pack	23199114
97039083-00	Emergency Chest Re-opening Pack	23276321
97039083-00	Emergency Chest Re-opening Pack	23219291
97039083-00	Emergency Chest Re-opening Pack	23319457
97039083-00	Emergency Chest Re-opening Pack	23346708