FSN Ref: 2023-06(03)
Date: 11 Jul 2023

FSCA Ref: 2023-06(03)

Urgent Field Safety Notice
Mölnlycke® Procedure Trays

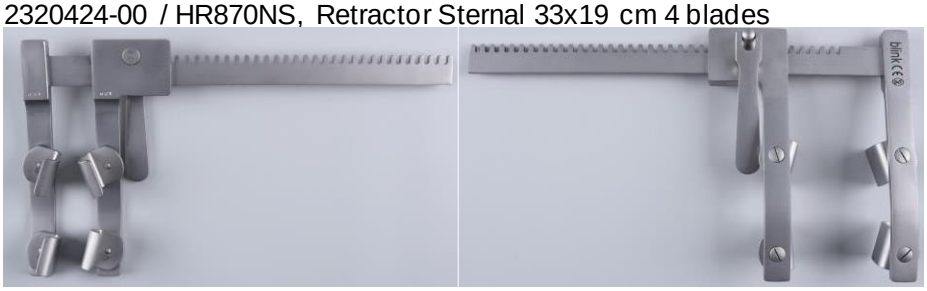
For Attention of: Theatre Manager

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: +XXXXXXXXXXXXX

FSN Ref: 2023-06(03)
Date: 11 Jul 2023

FSCA Ref: 2023-06(03)

Urgent Field Safety Notice (FSN)
Mölnlycke® Procedure Trays
Blink Medical component within Mölnlycke® Procedure Trays

1. Information on Affected Devices	
1.	1. Device Type(s)
	Blink Medical Component: 2320424-00 / HR870NS, Retractor Sternal 33x19 cm 4 blades  Included in various Mölnlycke® Procedure Trays. Mölnlycke® Procedure Trays consist of customized configurations of several sterilized components, which are assembled and delivered sterile within one procedure Tray.
1.	2. Commercial name(s)
	See Appendix I Product Table
1.	3. Primary clinical purpose of device(s)
	The instrument is to be used to open & hold in position tissue/bone during sternotomy surgical procedures. 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 Blink Medical, that they are performing a recall on products 2320424-00 / HR870NS, Retractor Sternal 33x19 cm 4 blades, which Mölnlycke includes in some of our Mölnlycke® Procedure trays. Mölnlycke will assist withthe legal manufacturer's Field Safety Notice and perform a **Recall.**
2.	2. Hazard giving rise to the FSCA*
	Information from Blink Medical FSN: There is a potential increased risk that the performance of the mechanical opening/closing of the retractor could malfunction with the mechanism becoming stuck/jammed and rendering the retractor unable to fulfil its intended purpose. This may result in a delay in patient treatment.

FSN Ref: 2023-06(03) FSCA Ref: 2023-06(03)
Date: 11 Jul 2023

3. Type of Action to mitigate the risk

3. **1. Action To Be Taken by the User**

☒ Identify Device
☒ Quarantine 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 unused Mölnlycke® Procedure Trays at your facility, please see Appendix I for affected product information.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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** 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)

FSN Ref: 2023-06(03) FSCA Ref: 2023-06(03)
Date: 11 Jul 2023

	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	… Systems
		Electronically signed by: … *Date: Jul 11, 2023 23:23 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.

FSN Ref: 2023-06(03)
Date: 11 Jul 2023
Appendix I

FSCA Ref: 2023-06(03)

Product table

To be added for each market.

2023-06(03) FSN Mölnlycke trays_Blink Medical_EN_Final

Final Audit Report 2023-07-11

Created:	2023-07-11
By:	…
Status:	Signed
Transaction ID:	CBJCHBCAABAABURBFtoWifFnMvDEyfAoyopugxWgbHvK

"2023-06(03) FSN Mölnlycke trays_Blink Medical_EN_Final" History

Document created by …
2023-07-11 - 13:49:39 GMT

Document emailed to …
2023-07-11 - 13:50:00 GMT

Email viewed by …
2023-07-11 - 21:18:53 GMT

…
2023-07-11 - 21:23:26 GMT

…
Signing reason: Author
Signature Date: 2023-07-11 - 21:23:26 GMT - Time Source: server

Agreement completed.
2023-07-11 - 21:23:26 GMT