



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

FSCA Ref:

**Urgent Field Safety Notice**  
**Mölnlycke® Procedure Trays**

For Attention of: Theatre Manager

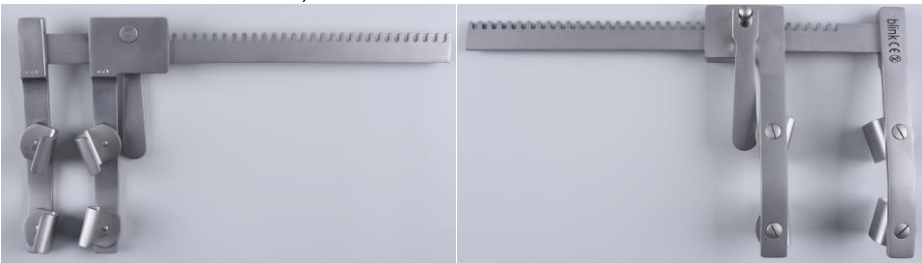
Contact details of local representative (name, e-mail, telephone, address etc.)

Name: Mölnlycke Healthcare UK  
Email: csc.uk@mölnlycke.com  
Telephone: +0800 917 4918

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

<b>1. Information on Affected Devices</b>	
1.	<p style="text-align: center;"><b>1. Device Type(s)</b></p> <p>Blink Medical Component: 2320424-00 / HR870NS, Retractor Sternal 33x19 cm 4 blades</p>  <p>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.</p>
1.	<p style="text-align: center;"><b>2. Commercial name(s)</b></p> <p>See Appendix I Product Table</p>
1.	<p style="text-align: center;"><b>3. Primary clinical purpose of device(s)</b></p> <p>The instrument is to be used to open &amp; 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.</p>
1.	<p style="text-align: center;"><b>4. Device Model/Catalogue/part number(s)</b></p> <p>See Appendix I Product Table</p>
1.	<p style="text-align: center;"><b>5. Affected serial or lot number range</b></p> <p>See Appendix I Product Table</p>


<b>2 Reason for Field Safety Corrective Action (FSCA)</b>	
2	<p style="text-align: center;"><b>1. Description of the product problem*</b></p> <p>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.</p> <p>Mölnlycke will assist with the legal manufacturer's Field Safety Notice and perform a <b>Recall</b>.</p>
2	<p style="text-align: center;"><b>2. Hazard giving rise to the FSCA*</b></p> <p>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.</p>

<b>3. Type of Action to mitigate the risk</b>		
<b>3.</b>	<p style="text-align: center;"><b>1. Action To Be Taken by the User</b></p> <p><input checked="" type="checkbox"/> Identify Device  <input checked="" type="checkbox"/> Quarantine Device  <input checked="" type="checkbox"/> Return Device</p> <p>We need your help in ensuring that <b>all affected products</b> are located and that below actions are performed.</p> <p>Please follow below instructions:</p> <ol style="list-style-type: none"> <li>1. <b>Identify and isolate</b> the unused Mölnlycke® Procedure Trays at your facility, please see Appendix I for affected product information.</li> <li>2. Fill out the <b>Customer Reply Form</b> or <b>Distributor Reply Form</b> with quantity of identified affected products. Please sign and email/fax the <b>Customer Reply Form</b> or <b>Distributor Reply Form</b> per its instructions within 10 business days.</li> <li>3. Even if you no longer have any concerned Mölnlycke® Procedure trays, fill out the <b>Customer Reply Form</b> or <b>Distributor Reply Form</b> and return it back within 10 business days. Mölnlycke needs to be sure all customers are aware of the situation.</li> <li>4. Mölnlycke will contact you and arrange for collection of the product(s) from your facility, as soon as you return the <b>Customer Reply Form</b> or <b>Distributor Reply Form</b>. Mölnlycke will issue a credit for the goods returned.</li> <li>5. If you have forwarded any affected products to other healthcare institutions, please send them a copy of this <b>Field Safety Notice</b>. Make sure they act accordingly.</li> <li>6. If you are a distributor, please inform your customers by sending them a copy of this <b>Field Safety Notice</b>. Make sure they act accordingly and return the <b>Customer Reply Form</b> with information collected from your end users.</li> </ol> <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>	
<b>3.</b>	<b>2. Is customer Reply Required?</b>	Yes (Within 10 business days)

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<b>4. General Information</b>	
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 Viktoria Wennberg, Global Director Quality Systems
	 Electronically signed by: Viktoria Wennberg Reason: Approver Date: Jul 11, 2023 23:26 GMT+2

<b>Transmission of this Field Safety Notice</b>	
	<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**

FSCA Ref:

**Product table**

Material	Material Description	Batch
97039083-00	Emergency Chest Re-opening Pack	22105489







# 2023-06(03) FSN Mölnlycke trays\_Blink Medical\_IE

Final Audit Report

2023-07-11

Created:	2023-07-11
By:	Jimena Martinez de Castro (Jimena.MartinezdeCastro@molnlycke.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAkPfcCOFI7qkHRMTHyLjexHXXaCeC-Ke

## "2023-06(03) FSN Mölnlycke trays\_Blink Medical\_IE" History

-  Document created by Jimena Martinez de Castro (Jimena.MartinezdeCastro@molnlycke.com)  
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-  Document emailed to Viktoria Wennberg (viktoria.wennberg@molnlycke.com) for signature  
2023-07-11 - 13:50:46 GMT
-  Email viewed by Viktoria Wennberg (viktoria.wennberg@molnlycke.com)  
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-  Viktoria Wennberg (viktoria.wennberg@molnlycke.com) authenticated with Adobe Acrobat Sign.  
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