FSN Ref: 2023-02(02)
Date: 22-Feb-2023

FSCA Ref: 2023-02(02)

Urgent Field Safety Notice
Mölnlycke® Barrier TUR Set

For Attention of Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages Name: Local Customer Care contact will be added for each specific market Email: XXX.XXX@molnlycke.com Telephone: +XXXXXXXXXXXXX

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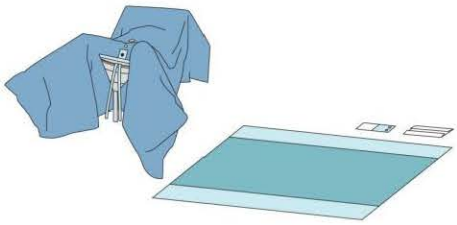
Mölnlycke® Barrier TUR Set

1. Information on Affected Devices	
1.	1. Device Type(s)
	Product codes: 888224-22 TUR Set Surgical drape, general/plastic surgical procedure kit, non-medicated, single-use Sterile 
1.	2. Commercial name(s)
	BARRIER TUR Set
1.	3. Primary clinical purpose of device(s)
	Surgical drapes, when sterilised, are intended to minimise the spread of micro-organisms, in order to reduce the risk for post operative wound infection.
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*
	Molnlycke have identified a composition error in the TUR Set. The incorrect drape has been included within the set. Drape ***965520-22*** has been included instead of drape ***965522-22***. A dose mapping was performed on the product and underdose on some parts of the product was detected. As a result, Mölnlycke cannot guarantee the full sterility of the product. As a precaution Mölnlycke has decided to perform a **Recall.**
2.	2. Hazard giving rise to the FSCA*
	If non sterile drapes are used during a surgical procedure, there is a potential risk of a local infection.

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	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® BARRIER TUR Set 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® BARRIER TUR Set, 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 **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.	Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes (Within 10 business days)

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	4. General Information	
4.	FSN Type	New
4.	Further advice or information already expected in follow-up FSN?	No
4.	1. 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.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	List of attachments/appendices:	Appendix I Product table Customer Reply Form Distributor Reply Form
4.	Name/Signature	[redacted], Global Product Complaints Team [redacted] *Electronically signed by:* [redacted] *Reason: Approver* *Date: Feb 22, 2023 16:40 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

Material	Material Description	Batch
888224-22	TUR Set	22515334

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2023-02(02)
FSN Date	22 Feb 2023
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			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. I do not have any affected devices.		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. I have quarantined affected devices ready for return - enter number of devices ready for return	Qty:	Lot/Serial Number:
		Qty:	Lot/Serial Number:
		Qty:	Lot/Serial Number:
		Qty:	Lot/Serial Number:
		Qty:	Lot/Serial Number:
		N/A	Comments
Print Name*			
Signature*			
Date*			

4. Return acknowledgement to sender	
Email	vigilance@molnlycke.com
Customer Helpline	+46 20-79 82 64
Postal Address	Mölnlycke Health Care, Box 130 80, SE-402 52 Gothenburg, Sweden

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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.

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Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2023-02(02)
FSN Date*	22 Feb 2023
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. Distributor Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	vigilance@molnlycke.com
Distributor Helpline	+46 20-79 82 64
Postal Address	Mölnlycke Health Care, Box 130 80, SE-402 52 Gothenburg, Sweden
Web Portal	https://www.molnlycke.com/
Deadline for returning the Distributor reply form*	Within 10 business days

4. Distributors (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined affected trays	
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have quarantined affected devices ready for return – enter number of quarantined devices ready for return	Qty: Product name and Lot Number: Qty: Product name and Lot Number: Qty: Product name and Lot Number: Qty: Product name and Lot Number:

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		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		N/A	Comments:
☐	Neither I nor any of my customers has any affected devices in inventory		
Print Name*			
Signature*			
Date *			

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.