FSN Ref: 2023-11(01)
Date: 01 Dec 2023

FSCA Ref: 2023-11(01)

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

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Urgent Field Safety Notice (FSN)
Mölnlycke® Procedure Trays
Dispo Medical Insufflation tube within Mölnlycke® Procedure Trays

1. Information on Affected Devices	
1.	1. Device Type(s)
	Component from Dispo Medical: Insufflation tube OD 30Ch ID 22Ch 3,7m HEPA filter 22mm connector LL  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 insufflation tube may only be used by authorized and specially trained staff for the transportation of fluids or gasses by systolic pressure. 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 of an action initiated by Dispo Medical, who is the legal manufacturer of the device listed above. The issue is relating to an error which occurred during the injection moulding process of one of the filter connectors during production. A relatively small part of these connectors appears to be impenetrable and is blocked from the inside by an occluding fleece, as picture 1 below.

Picture 1 – Incorrect filter connectors with occluding fleece.

These faulty connectors may be incorporated into some of the Dispo Medical devices, which Mölnlycke subsequently includes in Mölnlycke® Procedure trays.

Mölnlycke has decided to follow the legal manufacturer FSN and perform a Field Safety Corrective Action. At the point of use of these Mölnlycke® Procedure trays, the user is required to identify the affected component 2323184-00 (Insufflation tube) and check whether the connector is open. If you encounter a blocked connector, please discard, and inform vigilance@molnlycke.com

2.	2. Hazard giving rise to the FSCA*
	Information from Dispo Medical: There is no immediate danger to the patient, however the product will not function due to the fact gas cannot flow through it. A blocked connector will cause discomfort during use and may delay the procedure using the medical device in question.

3. Type of Action to mitigate the risk

3.

1. Action To Be Taken by the User

☒ Identify Device

☒ Quarantine Device

☒ Take note of amendment: affix a copy of this FSN to each Mölnlycke® Procedure tray and make this FSN information available for the user

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. **Affix a copy of this Field Safety Notice (FSN) to each Mölnlycke® Procedure tray and make sure that its contents is brought to the attention of all relevant personnel to read before use**.
3. **At the point of use of the tray**, the user is required to check whether the connector is open. If you encounter a blocked connector, please discard, and inform vigilance@molnlycke.com
4. 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.

	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, if you encounter a blocked connector inform vigilance@molnlycke.com	
3.	1. Is customer Reply Required?	Yes (Within 10 business days)

	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 Appendix II Tag to attach on affected Trays Customer Reply Form Distributor Reply Form
4.	6. Name/Signature	Viktoria Wennberg, Global Director Quality Systems
		 *Electronically signed by: Viktoria Wennberg Reason: Approver Date: Dec 1, 2023 11:42 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

To be added for each market

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Appendix II

Tag to be attached to affected Mölnlycke® Procedure Trays(unused)

Action To Be Taken by the User

ATTENTION

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