FSN Ref: 2023-02(03)
Date: 03 March 2023

FSCA Ref: 2023-02(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

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Urgent Field Safety Notice (FSN)
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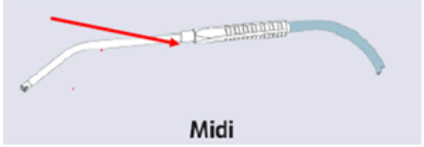
1. Information on Affected Devices	
1.	1. Device Type(s)
	Component: **Suction Set Yankauer slit tip 15Ch tube 17Ch 3,5m PVC** Included in various Mölnlycke® Procedure Trays Mölnlycke® Procedure Trays consist of customized configurations of components, which are assembled and delivered sterile within one packaging solution.
1.	2. Commercial name(s)
	See Appendix I Product Table
1.	3. Primary clinical purpose of device(s)
	Suction Set Yankauer slit tip is intended for removal of body fluids during surgery. Intended for suction in various surgery applications, depending on the requirement of the procedure. Not validated for use in cardiac surgery, surgery involving direct contact with the central circulatory system, or central nervous system. The clinical purpose of Mölnlycke® Procedure Trays is to provide 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 received a Field Safety Notice issued by the Legal Manufacturer Mediplast. This is regarding the component Suction Set Yankauer slit tip, which are included in certain Mölnlycke® Procedure Trays. Mediplast has noted a variation in the strength of the attachment between the handpiece and the suction tip which could cause these to separate from each other. No serious incident has been reported.  Midi Mölnlycke will follow the legal manufacturer's FSN and perform a Field Safety Corrective Action on specific batches of the Procedure Trays that contain the affected component.

	At the point of use of these Mölnlycke® Procedure trays, the user is required to check the component by slightly pulling the handle and the tip before use and discard the component if faulty.
2.	2. Hazard giving rise to the FSCA*
	Information from Mediplast FSN: Mediplast has noted a variation in the strength of the attachment between the handpiece and the suction tip. No serious incident has occurred, but Mediplast is choosing to provide information about this, as low strength in the attachment between the handpiece and the suction tip could cause these to separate from each other.

	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: attach a copy of this FSN to each Mölnlycke® Procedure tray and make this FSN information available for the user ☒ Discard Device (If faulty) 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. **Attach the FSN** to all unused Mölnlycke® Procedure trays. Make sure that its content is brought to the attention of all relevant personnel to read before use. 3. 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. 4. 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. 5. At the point of use of Tray, **identify and check the Suction Set Yankauer slit tip component. If faulty, discard the component.** 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 follow the reporting procedures established by your facility.

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3.	2. Is customer Reply Required? (If yes, form attached specifying deadline for return)	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 Customer Reply Form Distributor Reply Form
4.	6. Name/Signature	Annika Hallberg, Global Product Complaints Team
		 *Electronically signed by: Annika Hallberg* *Reason: Approver* *Date: Mar 3, 2023 09:56 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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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

At the point of use, the user is required **to inspect the component 2313513-00 Suction Set Yankauer slit tip**.

Please pull the handle and the tip before use. **If the attachment between the parts feels unstable, discard the component.**

Please see the FSN for further details.