FSN Ref: 2022-04 (01)
Date: 12 APR 2022

FSCA Ref: 2022-04 (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
SOL-M™ Blunt Fill Needle within Mölnlycke® Procedure Trays

1. Information on Affected Devices	
1.	1. Device Type(s)
	SOL-M™ Component: SOL-M™ Blunt Fill Needle sterile  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 SOL-M™ Blunt Fill Needle is used to pierce the medicine vial septum or ampule and aspirate medication into a syringe. Once the medication is aspirated into a syringe, the contents of the syringe may be injected into an I.V. System or pre-slit septum covering injection sites. The Sol-M Blunt Fill Needle may be removed and replaced with a needle and the contents of the syringe can be injected into individuals. The Sol-M Blunt Fill Needle is not intended for human injections. 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 SOL-M™ that they are performing a voluntary recall on components Blunt Fill Needle sterile, which Mölnlycke includes in some of the Mölnlycke® Procedure trays. The reason for this recall is that SOL-M has determined an increase in coring of the vial rubber stoppers of medication when reconstituting diluent and accessing vials. Once the medication is reconstituted, visible pieces of rubber were found floating in the medication, in the barrel of the syringe used to aspirate the medication, and in the IV bag used to administer the medication. No patient harm has been reported. 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 and discard it.

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2.	2. Hazard giving rise to the FSCA*
	Information from SOL-M FSN: Wherever a blunt fill needle is used to aspirate a medication from a vial with a rubber stopper there is the risk of abrasion, tearing, and cutting of the rubber during the passing of the needle through the rubber stopper. This can result in rubber particles entering the medication vial or being retained in the needle or cannula during events known as fragmentation/coring. During insertion, the needle bevel heel can also scoop out large fragments from the stopper. For a rubber particle present in the injection fluid to be injected into the human body, it has to be smaller than the inner diameter of the needle/catheter used for injection. The risk is mitigated by the end-user during the medication preparation procedure. It is an obligatory standard for the end-user to check each medication that is withdrawn into the syringe for the presence of discoloration or foreign particles before the medication is administrated into the patient body. In case the medication contains any visible particles, the vial or the syringe must be discarded and cannot be used for the patient.

	3. Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Destroy 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. **Attach the FSN** to all unused Mölnlycke® Procedure trays. 3. **At the point of use of the tray**, the user is required to **remove the affected component** from the Mölnlycke® Procedure tray and **destroy them**. 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. Mölnlycke will contact you as soon as you return the **Customer Reply Form** or **Distributor Reply Form**. Mölnlycke will issue a credit for the goods destroyed. 7. 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. 8. 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.	2. 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 Customer Reply Form Distributor Reply Form
4.	6. Name/Signature	…
		…

	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