FSN Ref: 2023-12(01)
Date: 21 Dec 2023

FSCA Ref: 2023-12(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
Vostra Rhinotamp within Mölnlycke® Procedure Trays

1. Information on Affected Devices	
1.	1. Device Type(s)
	Component from Vostra: 2305872-00; Nose tampon foam 1x2x7,5cm String 2/1  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)
	Haemostasis and stabilization after operations in the area of the nasal and paranasal sinuses for the following indications: Conchotomy, maxillary sinus / ethmoid operations, nosebleeds, rhinoplasty. 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 Vostra, who is the legal manufacturer of the device listed above. As part of the PMS activities, VOSTRA has become aware of a case of use with the product RHINOTAMP in which a user pulled on the reinforcing threads with his hands, contrary to the instructions in the instructions for use. In this case, a tamponade / tamponade component remained in situ after detamponation. The complaint is due to two application errors/errors in use, as the user acted contrary to the warnings in the instructions for use and did not take into account the state of the art and good clinical practice.

	The FMECA considers the error and application case. The FSCA is intended to provide the user with revised instructions for use that now explicitly provide implicit information from the state of the art and the GCP. Mölnlycke has decided to follow the legal manufacturer FSN and perform a Field Safety Corrective Action. Mölnlycke will issue an Advisory notice and provide the new Instruction for use to the affected customer.
2.	**2. Hazard giving rise to the FSCA***
	Information from Vostra: In this case, a tamponade component remained in situ after detamponation. The possible hazard is that parts of the components could remain in situ. Removal after with forceps or similar instruments would be carried out to retrieve the tampon. In conclusion, it is unlikely that the string breaking would create a problem as the tampon is normally removed with forceps.

	3. Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify 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) and new revision rev.5 of Instruction for use 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 **identify the affected component 2305872-00 (Nose tampon foam 1x2x7,5cm String 2/1)** and read new revision rev.5 of Instruction for use. 4. Fill out the **Customer Reply Form** with the quantity of identified affected products. Please sign and email/fax the **Customer 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** 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. 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.	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 Instruction for use, rev.5
4.	6. Name/Signature	[redacted] Global Director Quality Systems *Electronically signed* [redacted] *Reason: Approver* *Date: Dec 21, 2023 14:35 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

At the point of use of these Mölnlycke® Procedure trays, the user is required to identify the affected component 2305872-00 (Nose tampon foam 1x2x7,5cm String 2/1) and read new revision rev.5 of Instruction for use attached to this FSN .

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2023-12(01)
FSN Date	21 DEC 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.	*Customer to complete or enter N/A*
☐	• I confirm receipt of the Field Safety Notice and that I read and understood its content. • I have identified affected components and the action will be performed at the point of use of the tray. • I have completed the table with the details of affected devices quantity, its article and lot/batch number.	**Quantity** / **Article/Material Number** / **Lot/Batch Number** N/A / Comments:
Print Name*		*Customer print name here*
Signature*		*Customer sign here*
Date*		

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4. Return acknowledgement to sender	
Email	vigilance@molnlycke.com
Customer Helpline	0800 917 4920
Postal Address	Mölnlycke Health Care, Box 130 80, SE-402 52 Gothenburg, Sweden
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.

Mölnlycke Ref: 2023-12(01) - Product Table							
Field Safety Notice Ref: 2023-12(01) - Mölnlycke® Procedure Trays				Affected Products numbers and class globally			
Product	LOT	Product Name	Material group descripton	GMDN code	GMDN term	GMDN definition	MDD Class
97026022-05	22148074	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	22211115	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	22309176	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	22337262	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	22423919	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	23029175	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	23079879	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	23112846	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	23214414	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	23253257	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-05	23300499	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-07	23344661	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-07	23409242	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-07	23420841	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA
97026022-07	23484137	Septum Set	Nose	P44069	ENT surgical procedure kit, non-medicated, single-use	A collection of various sterile ear/nose/throat (ENT) surgical instruments, dressings and the necessary materials used to perform an ENT surgical procedure. It does not contain pharmaceuticals. This is a single-use device.	IIA