FSN Ref: 2024-11(01)
Date : 03. Dec.2024.

FSCA Ref: 2024-11(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)
PDS™ II (polydioxanone) and MONOCRYL™ (poliglecaprone 25) sutures within Mölnlycke® Procedure Trays

1. Information on Affected Devices

1. 1. Device Type(s)

Component Name:	Molnlycke Component code
MONOCRYL™ (poliglecaprone 25) Suture	2301570-00
PDS™ II (polydioxanone) Suture	2303378-00

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)

MONOCRYL™ sutures are intended for use in general soft tissue approximation and/or ligation where an absorbable material is indicated.

PDS™ II sutures are intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery These sutures are particularly useful where the combination of absorbable suture and extended wound support (up to six weeks) is desirable.

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 Ethicon, the legal manufacturer of the device in question, that they are initiating a Field Safety Corrective Action on specific batches of the sutures, which Mölnlycke includes in some of the Mölnlycke® Procedure trays.

The Ethicon identified a manufacturing issue on a specific packaging machine that resulted in a hole in the primary packing of the small percentage **of MONOCRYL™ sutures and PDS™ II sutures and** manufactured between January 27 and March 27, 2024.

The occurrence of this defect is rare with an estimated rate of 0.011% of products presenting the condition (99.9% of products are not impacted by this defect). When present, the **hole always occurs in the same location on the bottom side foil cavity** of the package towards the peelable flaps as shown in below figure.

Mölnlycke has decided to follow the legal manufacturer FSN and perform a Field Safety Corrective Action.

2. Hazard giving rise to the FSCA*

Information from Ethicon´s Field Safety Notice:

Ethicon has not received any complaints or reports of injuries related to this issue.
It is likely that this issue will be detected prior to use in surgery. If the defect is not detected, the breach in sterility could introduce pathogens to the patient and cause infection. This may necessitate medical interventions such as use of antibiotics and/or surgical intervention. The chance of systemic infection is very unlikely because of the small inoculum of bacteria that would likely be present and the use of prophylactic antibiotics prior to or after surgery. Therefore, the probability of harm to the patient is extremely rare.
A hole in the foil cavity of the package also exposes the product to the environment which could potentially compromise its physical properties leading to treatment failure, which may require additional surgical intervention or prolonged surgery.
The health risk is limited to those products with compromised packaging.
Other products in the field with no hole in the foil cavity are unaffected. Health care practitioners who have treated patients using these products lots should follow those patients post-operatively in the usual manner with no additional action required.

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the User

☒ Identify Device
☒ Quarantine Device
☒ Destroy the 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 **tag in Appendix II** only to all unused **Mölnlycke® Procedure trays and make sure that Field Safety Notice (FSN) contents are brought to the attention of all relevant personnel to read before use**. 3. Fill out the **Customer reply form or Distributor reply form** with the **quantity of identified affected products**. Please sign the Customer reply form or Distributor reply form and send email to vigilance@molnlycke.com per its instruction within 10 business days. 4. Even if you no longer have affected products, 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 the tray, the user is required to identify the **MONOCRYL™ sutures and PDS™ II suture and discard it.** 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. Please return the Customer reply form to you and return it to Molnlycke. 8. When completed and signed **Customer Reply Form** or **Distributor Reply Form** is received by Mölnlycke, Mölnlycke will contact you regarding compensation for the affected components. In addition, Mölnlycke appreciates your help in collecting data on product complaints and/or incidents related to the product concerned. Please follow the reporting procedures established by your facility.	
3.	9. Is customer Reply Required?	Yes (Within 10 business days)

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	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 be attached to affected Mölnlycke® Procedure Trays(unused) 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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Appendix I

Product table with GMDN code

MATERIAL	MATERIAL DESCRIPTION	BATCH	GMDN Code	GMDN terms
97008779-05	Pelviskopie Set	24182618	P44096	Laparoscopic surgical procedure kit, non-medicated, single-use
	Pelviskopie Set	24210177	P44096	Laparoscopic surgical procedure kit, non-medicated, single-use
97032000-10	HSØ Craniotomipakke Ullevål	24155059	P44063	Neurosurgical procedure kit, non-medicated, single-use
	HSØ Craniotomipakke Ullevål	24276208	P44063	Neurosurgical procedure kit, non-medicated, single-use
	HSØ Craniotomipakke Ullevål	24276207	P44063	Neurosurgical procedure kit, non-medicated, single-use
	HSØ Craniotomipakke Ullevål	24302072	P44063	Neurosurgical procedure kit, non-medicated, single-use
97060112-12	Laparoskopiset galla Katrineholm	24160270	P44096	Laparoscopic surgical procedure kit, non-medicated, single-use
97076903-03	OK Pijn tray	24198782	P44063	Neurosurgical procedure kit, non-medicated, single-use
97112367-02	GYN laparoskopi Katrineholm	24204760	P44096	Laparoscopic surgical procedure kit, non-medicated, single-use
97115263-04	Ligamentoplastie	24215153	P44093	Arthroscopic surgical procedure kit, non-medicated, single-use
97118088-01	Zestaw Nos Orthos	24199088	P33961	General surgical procedure kit, non-medicated, single-use
97130301-00	NOS	24255905	P33961	General surgical procedure kit, non-medicated, single-use

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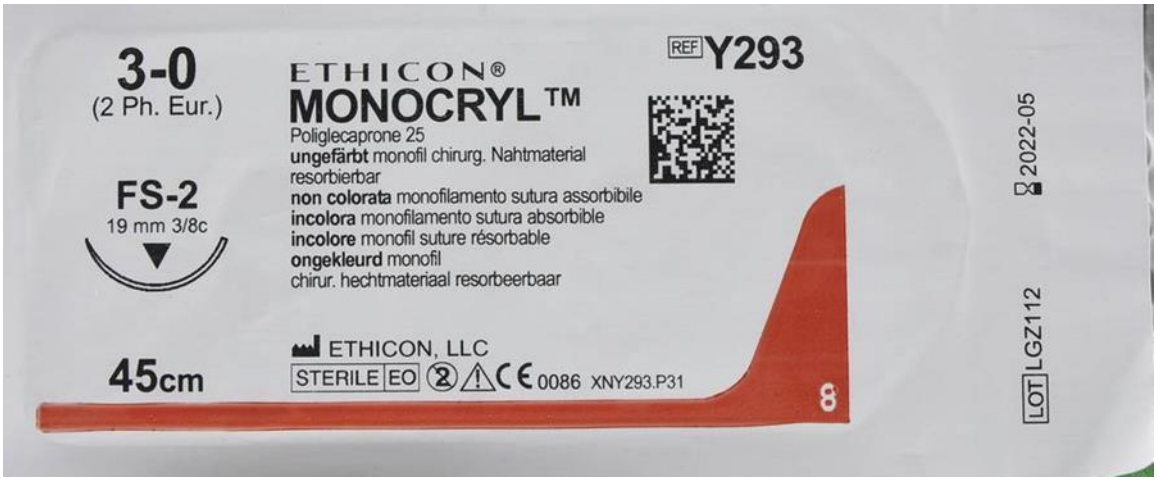
Appendix II

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

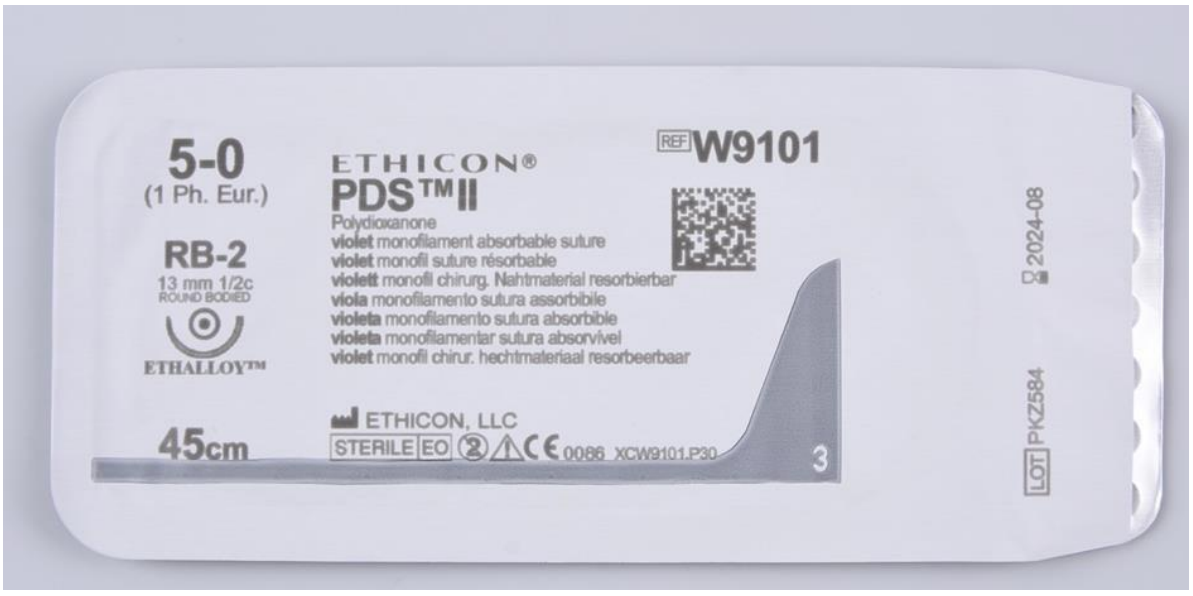
Action To Be Taken by the User

At the point of use of these Mölnlycke® Procedure trays, the user is required to **identify and discard the** affected components below.

2301570-00 MONOCRYL™ (poliglecaprone 25) Suture



2303378-00 PDS™ II (polydioxanone) Suture



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Final Audit Report 2024-12-03

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By:	
Status:	CBJCHBCAABAAVSZkgj7OPrCICEIU8gwlSTsHOZroSBd4
Transaction ID:	

"2024-11(01) FSN Mölnlycke trays Ethicon_Final" History

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