FSN Ref: 2019-03 (02)
FSCA Ref: 2019-03 (02)
Date:28 Mar 2019

Urgent Field Safety Notice
Mölnlycke® Detachable EndoRetrieval Pouch

For Attention of:Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)
Name: Local market 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® Detachable EndoRetrieval Pouch
Instruction For Use (IFU) not available for user

1. Information on Affected Devices	
1.	1. Device Type(s)
	Tissue extraction bag for use during laparoscopic procedures. Supplied sterile.
1.	2. Commercial name(s)
	Mölnlycke® Detachable EndoRetrieval Pouch
1.	3. Primary clinical purpose of device(s)
	The Detachable EndoRetrieval Pouch is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during laparoscopic surgical procedures.
1.	4. Device Model/Catalogue/part number(s)
	899103-01
1.	5. Affected serial or lot number range
	6251809030

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Product has been supplied without Instructions For Use (IFU)
2.	2. Hazard giving rise to the FSCA
	No IFU available for user may lead to incorrect use of the product: - Patent risk: The usage of a damaged or mislabelled packaging, leading to an infection. - Patient risk: Use of excessive force to remove the pouch, leading to a breakage in the pouch and a prolonged surgical procedure.

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	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Make Instructions For Use (IFU) available for user We need your help with ensuring that **all affected products** are located and that below actions are performed. Please follow below instructions: 1. Identify the product at your facility, please see Appendix I for affected product information. 2. Print the IFU for the Mölnlycke® Detachable EndoRetrieval Pouch, attached to this Field Safety Notice. 3. Place the printed IFU in appropriate place, adjacent to the product, making the IFU available for user. 4. Fill out the Customer Reply Form, Appendix I, and return it back to Mölnlycke within 10 business days, even if you do not have affected products. Mölnlycke needs to be sure all customers are aware of the situation. 5. If you have forwarded any affected products to other healthcare institutions, please send them a copy of this **Field Safety Notice including the IFU**. Make sure they act accordingly. 6. If you are a distributor, please inform your customers by sending them a copy of this **Field Safety Notice including the IFU**. Make sure they act accordingly and return the **Customer reply form** in **Appendix I** to you. We apologize for any inconvenience this will cause you, but 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)

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	2. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. Further advice or information already expected in follow-up FSN?	No
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Mölnlycke Health Care
	b. Address	Box 130 80, SE-402 52 Gothenburg, Sweden
	c. Website address	www.molnlycke.com
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	6. List of attachments/appendices:	-Appendix I-Customer Reply Form -Instructions For Use (IFU)
4.	7. Name/Signature	Linda Magnusson, Global Product Complaints Manager 

	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.

Mölnlycke®

Appendix I

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2019-03 (02)
FSN Date	2019-03-28
Product/ Device name	Mölnlycke® Detachable EndoRetrieval Pouch
Product Code(s)	899103-01
Batch/Serial Number (s)	6251809030

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.	Customer to complete or enter N/A
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	I do not have any affected devices.	Customer to complete or enter N/A
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	vigilance@molnlycke.com
Customer Helpline	0800 – 1862 187
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 business 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.