المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

The protective flanges come away from trocar cannula

Device/ Product Description:	Procedure Trays & Single Packed Sterile Trocars	
Manufacturer:	Molnlycke Health Care AB.	
Problem Summary:	Situations where the protective flanges come away from trocar cannula. The incident could lead to significant delay to surgery or various post-operative complications. For more information, please check the attachment below. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center	
	AR name:	Branch of Molnlycke Health Care AB
	Assigned Contact Person:	Ahmed Alharbi
	Mobile/Phone:	+(966) 555144531
	Email:	Ahmed.Alharbi@Molnlycke.com

FSN Ref: 2021-01 (01)
Date: 21.JAN.2021

FSCA Ref: 2021-01 (01)

Urgent Field Safety Notice
Mölnlycke® Procedure Trays & Single Packed Sterile Trocars

For Attention of: Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)
Name: Customer Service Center DE Email: MOLNLYCKECSC.GERMANY@molnlycke.com Telefon: +49 800/1862180

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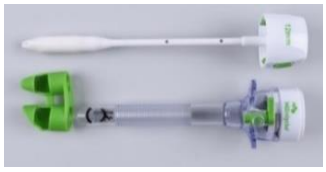
Urgent Field Safety Notice (FSN)
Mölnlycke® Procedure Trays & Single Packed Trocar
Protective flanges coming away from trocar cannula

1. Information on Affected Devices

1. Device Type(s)

Components:	Product code	Component code	
Trocar Bladeless Dilating Tip			
11mm/100mm	899310-01, 899310-02	2319408-00	
12mm/100mm	899312-01	2319447-00	
Trocar Hasson			
11mm/100mm	N/A	2319444-00	
12mm/100mm	N/A	899307-02, 2319445-00	
Hasson Balloon Trocar			
12mm/100mm	899329-01, 899329-02	N/A	
Optical Trocar - Pistol Gr			
12mm/100mm	899315-01	2319409-00	
Optical Trocar			
11mm/100mm	899318-01	2319464-00	
12mm/100mm	899319-01, 899319-02,	2319428-00 N/A	
12mm/150mm	899326-01	2321494-00, 899326-02.	
Optical Balloon Trocar			
12mm/100 mm	899328-02	2321500-00	
Universal Trocar Cannula			
11mm/100mm	N/A	2319466-00	
12mm/100mm	899323-01	2319467-00	

	Shielded Bladed Trocar			
	11mm/100mm	899302-01	N/A	
	12mm 100mm	899304-01 899304-02	2319424-00 N/A	

Mölnlycke® Procedure Trays consist of customized configurations of several sterilized components, which are assembled and delivered sterile within one procedure Tray.

These trocars are also delivered as single packed sterile products.

1. 2. Commercial name(s)

See Appendix I Product Table

1. 3. Primary clinical purpose of device(s)

A trocar consists of an obturator and a cannula that are assembled and locked together during insertion through the abdominal wall tissue layers to create a port to the abdominal cavity.
The Bladeless Dilating Tip Trocar is a sterile single patient use instrument consisting of an obturator and a transparent cannula. The obturator is equipped with a bladeless tip that allows individual tissue layer separation during insertion.

The Hasson Trocar is a sterile single patient use instrument consisting of an obturator with a blunt tip and a cannula with an anchoring device. The Hasson Trocar is designed for laparoscopic surgery with open-entry technique to the fascia. Upon entry into a free space in the abdominal or chest cavity, the blunt tip aids in reducing the potential risk for injury to internal structures.

The Shielded Bladed Trocar is a sterile single patient use device. The trocar is designed to establish a port of entry for endoscopic instruments during minimally invasive surgical procedures. The secondary function is to maintain pneumoperitoneum in the abdominal cavity.

The Optical Trocar is a sterile single patient use device. The trocar is designed to establish a port of entry for endoscopic instruments during minimally invasive surgical procedures. The secondary function is to maintain pneumoperitoneum in the abdominal cavity. The Optical Trocar can be used with or without visualization for primary and secondary insertions.

The Universal cannulas, included in the trocar range, are seen as accessories since they can't be used without using an obturator from the trocar.

The trocar cannula assembly has two sealing systems, to minimise gas leakage during insertion and withdrawal of instruments through the trocar, and a luer stopcock port that provides attachment for gas insufflation and desufflation.
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

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	2 Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem*
	Mölnlycke has, through our product complaint system, become aware of situations where the protective flanges come away from trocar cannula. No patient harm has been reported. The same issue has previously been communicated by Mölnlycke to relevant affected customers through a Field safety notice's 2020-09(01), 2020-12(01) in October and December 2020. Based on additional complaints received and further investigation, Mölnlycke is initiating a **Field Safety Corrective Action**. This Field safety notice (FSN) is applicable to specific batches of the trocars, which can be either a Single Packed Trocar or included as a component in identified Mölnlycke® Procedure trays.
2.	2. Hazard giving rise to the FSCA*
	The reported incidents are potentially serious to patients as the disconnected flanges could cause a significant delay to surgery. When not retrieved, foreign bodies can lead to various post-operative complications and the need for a new surgery. So there is a possibility of potential risk of injury to 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 **<u>all affected products</u>** are located and that below actions are performed. Please follow below instructions: 1. **Identify and isolate** the unused Mölnlycke® Procedure Trays or Single packed Trocars at your facility, please see Appendix I for affected product information. 2. Attach Appendix II only to all unused Mölnlycke® Procedure trays. 3. Fill out the **Customer Reply Form** or **Distributor Reply Form,** with quantity of identified affected products. Please sign and email 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 or Single packed trocars, 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. Mölnlycke will contact you regarding compensation for the affected components/products as soon as you return the **Customer Reply Form** or **Distributor Reply Form**. 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 continuous 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 Appendix II Tag to attach to affected Mölnlycke® Procedure trays
4.	6. Name/Signature	[redacted]
	Trans	
	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

Product Number	Product Description	Lot/Batch Number
899302-01	Shielded Bladed Trocar 11mm/100mm	6591812132
899304-01	Shielded Bladed Trocar 12mm/100mm	6591812134
	Shielded Bladed Trocar 12mm/100mm	6591901020
	Shielded Bladed Trocar 12mm/100mm	6591905061
899318-01	Optical Trocar 11mm/100mm	6681901016
899319-01	Optical Trocar 12mm/100mm	6681901017
	Optical Trocar 12mm/100mm	6681911012
	Optical Trocar 12mm/100mm	6681912017
899319-02	Optical Trocar 12mm/100mm	6682009007
899323-02	Universal Trocar Cannula 12mm/100mm	6612005046
	Universal Trocar Cannula 12mm/100mm	6612006069
899329-01	Hasson Balloon Trocar 12mm/100mm	6051812098
97003509-07	MIC Galle Set	19092350
	MIC Galle Set	19110950
	MIC Galle Set	19463226
	MIC Galle Set	20022062
	MIC Galle Set	20025314
	MIC Galle Set	20026694
	MIC Galle Set	20055142
	MIC Galle Set	20301358
	MIC Galle Set	20323331
	MIC Galle Set	20358595
	MIC Galle Set	19441953
	MIC Galle Set	20278686
97009969-10	GERD	19145402
	GERD	19187225
	GERD	19231791
	GERD	19289713
	GERD	19350627
	GERD	19357595
	GERD	19500115
97009969-11	GERD	20315721
	GERD	20463789
97027682-08	Lap-Sigma Set	20516054
97067632-01	Laparoskopie Set	19114613
	Laparoskopie Set	19157985
	Laparoskopie Set	19114480
	Laparoskopie Set	19170300

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	Laparoskopie Set	19145404
	Laparoskopie Set	19257175
	Laparoskopie Set	19227552
	Laparoskopie Set	19298882
	Laparoskopie Set	19297172
	Laparoskopie Set	19274895
97073156-04	Adipositas-Set Johanniter-KH Bonn	19176643
	Adipositas-Set Johanniter-KH Bonn	19318249
97073156-05	Adipositas-Set Johanniter-KH Bonn	20313888
	Adipositas-Set Johanniter-KH Bonn	20515470
97074075-02	LAP radikale Prostatektomie Tray	20041606
97081744-04	Bariatrie Set Münster- Hiltrup	19190763
97098953-00	Laparoskopie set Rochus KH	19113880
	Laparoskopie set Rochus KH	19137411
	Laparoskopie set Rochus KH	19157435
	Laparoskopie set Rochus KH	19163873
	Laparoskopie set Rochus KH	19184036
	Laparoskopie set Rochus KH	19212286
	Laparoskopie set Rochus KH	19212226
	Laparoskopie set Rochus KH	19284018
	Laparoskopie set Rochus KH	19284036
	Laparoskopie set Rochus KH	19325445
	Laparoskopie set Rochus KH	19344430
	Laparoskopie set Rochus KH	19437800
	Laparoskopie set Rochus KH	19500239
97098953-01	Laparoskopie Set Rochus KH Gyn	20265914
	Laparoskopie Set Rochus KH Gyn	20266050
	Laparoskopie Set Rochus KH Gyn	20266049
	Laparoskopie Set Rochus KH Gyn	20317378
97106080-00	MIC Tray Mustertray	19205249
97107825-01	Laparoskopie Set Schotten	19437048
	Laparoskopie Set Schotten	19437046
	Laparoskopie Set Schotten	19437047
	Laparoskopie Set Schotten	20025771
97107825-02	Laparoskopie Set Schotten	20443065
97110226-00	Laparoskopie Set ACH Rochus KH	20302541
	Laparoskopie Set ACH Rochus KH	20302465
	Laparoskopie Set ACH Rochus KH	20257079
97110226-01	Laparoskopie Set ACH Rochus KH	20376411
	Laparoskopie Set ACH Rochus KH	20376449
	Laparoskopie Set ACH Rochus KH	20456552

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Appendix II

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

Description of the product problem
Mölnlycke has, through our product complaint system, become aware of situations where the protective flanges come away from trocar cannula. No patient harm has been reported.

Mölnlycke is initiating a **Field Safety Corrective Action** on specific batches of the trocars, which Mölnlycke includes as a component in some of the Mölnlycke® Procedure trays.

Hazard giving rise to the FSCA
The reported incidents are potentially serious to patients as the disconnected flanges could cause a significant delay to surgery. When not retrieved, foreign bodies can lead to various post-operative complications and the need for a new surgery. So there is a possibility of potential risk of injury to the patient..

Action To Be Taken by the User

At the point of use the user is required to **remove affected components** from the Mölnlycke® Procedure tray and **destroy them**.

Trocar Bladeless Dilating Tip 11mm 100mm, Mölnlycke component code 2319408-00,
Trocar Bladeless Dilating Tip 12mm 100mm, Mölnlycke component code 2319447-00.

Trocar Hasson 11mm 100mm, Mölnlycke component code 2319444-00,
Trocar Hasson 12mm 100mm, Mölnlycke component code 899307-02, 2319445-00

Optical Trocar - Pistol Gr, 12mm 100mm, Mölnlycke component code 2319409-00.

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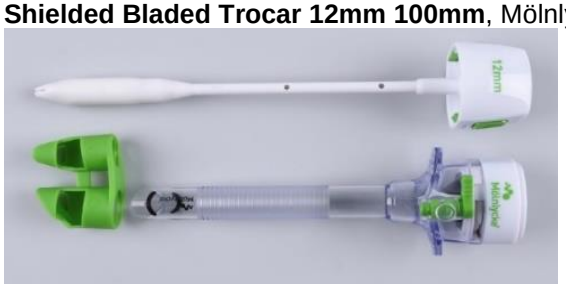
Optical Trocar 11mm 100mm, Mölnlycke component Code : 2319464-00
Optical Trocar 12mm 100mm, Mölnlycke Component Code: 2319428-00
Optical Trocar 12mm 150mm, Mölnlycke Component Code: 2321494-00, 899326-02

Optical Balloon Trocar 12mm 100 mm, Mölnlycke component code 2321500-00

Universal Trocar Cannula 11mm 100mm, Mölnlycke component code 2319466-00
Universal Trocar Cannula 12mm 100mm, Mölnlycke component code 2319467-00

Shielded Bladed Trocar 12mm 100mm, Mölnlycke component code 2319424-00



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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2021-01 (01)
FSN Date	21 JAN 2021
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.

☐
- I confirm receipt of the Field Safety Notice and that I read and understood its content.
- I have identified affected components and they will be destroyed 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:	

☐
- I confirm receipt of the Field Safety Notice and that I read and understood its content.
- I have destroyed the affected single packed devices.
- 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*			
Signature*			
Date*			

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.

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Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2021-01 (01)
FSN Date*	21 JAN 2021
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. Distributor Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	Pre-filled by manufacturer/sender/requester
Distributor Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Deadline for returning the Distributor reply form*	Pre-filled by manufacturer/sender/requester

4. Distributors (Tick all that apply)

☐ *I confirm the receipt, the reading and understanding of the Field Safety Notice.

☐ I have checked my stock and identified affected trays/ affected single packed devices.

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:	

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☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected Single packed devices . 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:
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		
Signature*		
Date *		

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.