FSN Ref: 2020-12 (01)
Date: 22.DEC.2020

FSCA Ref: 2020-12 (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: Mölnlycke Customer Care France, Customer Service Center DE<br>Email: csc.fr@molnlycke.com, MOLNLYCKECSC.GERMANY@molnlycke.com<br>Telephone: 0800 910 289, +49 800/1862180 |

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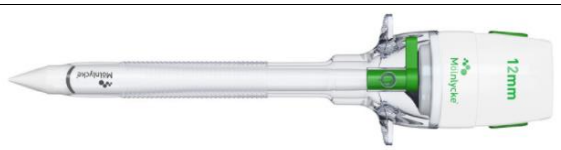
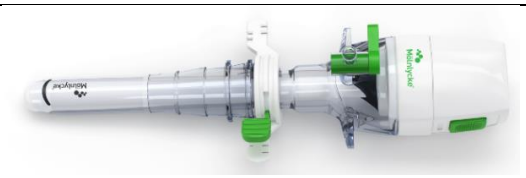
# Urgent Field Safety Notice (FSN)
# Mölnlycke® Procedure Trays & Single Packed Trocar
# Protective flanges coming away from trocar cannula

## 1. Information on Affected Devices

### 1. 1. Device Type(s)

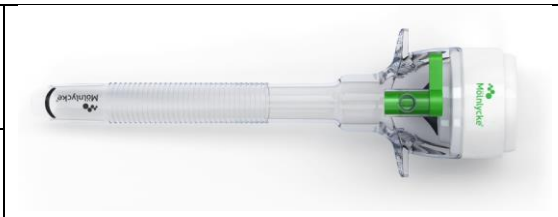
Components:

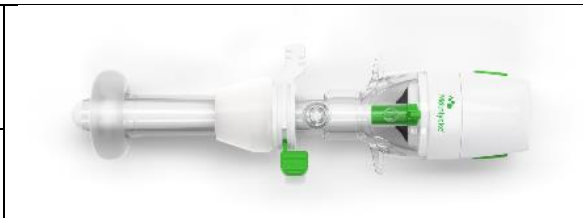
| | |
|---|---|
| **Trocar Bladeless Dilating Tip** 11mm/100mm, Product Code: 899310-01, 2319408-00 |   |
| **Trocar Bladeless Dilating Tip** 12mm/100mm, 899312-01, 2319447-00. | |

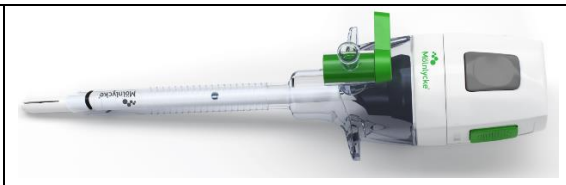
| | |
|---|---|
| **Trocar Hasson** 11mm/100mm Product Code: 899306-01, 2319444-00 |  |
| **Trocar Hasson** 12mm/100mm, Product Code: 899307-02, 2319445-00 | |

| | |
|---|---|
| **Optical Trocar - Pistol Gr** 11mm/100mm Product Code: 899314-01 |  |
| **Optical Trocar - Pistol Gr** 12mm/100mm Product Code: 899315 -01 | |

| | |
|---|---|
| **Optical Trocar** 11mm / 100mm, Product Code: 899318-01, 2319464-00 |   |
| **Optical Trocar** 12mm / 100mm, Product Code: 899319-01, 2319428-00 |  |
| **Optical Trocar** 12mm / 150mm, Product Code: 899326-01, 2321494-00 | |

| | |
|---|---|
| **Universal Trocar Cannula**<br>11mm / 100mm,<br>Product Codes:<br>899322-01, 2319466-00 |  |
| **Universal Trocar Cannula**<br>12mm / 100mm,<br>Product Codes:<br>899323-01, 2319467-00 | |

| | |
|---|---|
| **Hasson Balloon Trocar**<br>12mm/100 mm<br>Product Code:<br>899329-01 |  |
| **Optical Balloon Trocar**<br>12mm/100 mm<br>Product Code:<br>899328-01, 2321500-00 | |

| | |
|---|---|
| **Shielded Bladed Trocar**<br>11mm/100mm, 12mm/100 mm<br>Product codes:<br>899302-01, 2319424-00 |  |

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.<br><br>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.<br><br>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.<br>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, 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 2020-09(01) in October 2020.<br><br>Based on additional complaints received, further investigation and a FSN (Field Safety Notice) from the legal manufacturer (Unimax), Mölnlycke is initiating in cooperation with Unimax a **Field Safety Corrective Action** for customers of the additional received complaints.<br><br>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**<br>☒ Identify Device<br>☒ Destroy Device<br><br>We need your help in ensuring that **all affected products** are located and that below actions are performed.<br><br>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.<br>2. Attach Appendix II only to all unused Mölnlycke® Procedure trays.<br>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.<br>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.<br>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**.<br>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.<br>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**.**<br><br>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.<br><br>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<br>(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<br>Appendix II Tag to attach to affected Mölnlycke® Procedure trays |
| 4. | 6. Name/Signature | Annika Hallberg, Global Product Complaints Manager |

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| | 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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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 code | Product Name | Lot Number |
|---|---|---|
| 899310-01 | Klingenloser Trokar mit Dilatationsspitze 11mm/100mm | 6461904013 |
| 899312-01 | Klingenloser Trokar mit Dilatationsspitze 12mm/100mm | 6461812128 |
| | Klingenloser Trokar mit Dilatationsspitze 12mm/100mm | 6461904011 |
| 899329-01 | Hasson-Ballontrokar 12mm/100mm | 6052002001 |

| Product code | Product Name | Lot Number |
|---|---|---|
| 97069251-03 | Laparoskopie-Set | 19477460 |
| | Laparoskopie-Set | 19477460 |
| | Laparoskopie-Set | 20238772 |
| 97085861-03 | Lap. Appendektomie Set - Wetzikon | 20114931 |
| | Lap. Appendektomie Set - Wetzikon | 20186823 |
| 97085863-03 | Lap. Cholezystektomie Set - Wetzikon | 19495315 |
| 97085863-04 | Lap. Cholezystektomie Set - Wetzikon | 20050538 |
| | Lap. Cholezystektomie Set - Wetzikon | 20186923 |
| | Lap. Cholezystektomie Set - Wetzikon | 20400069 |
| 97094361-02 | Lap. Hernien Set - Wetzikon | 20315003 |
| 97099467-02 | TAPP Set - Klinik Birshof | 20055079 |
| 97099467-03 | TAPP Set - Klinik Birshof | 20201384 |
| | TAPP Set - Klinik Birshof | 20257453 |
| | TAPP Set - Klinik Birshof | 20355773 |
| | TAPP Set - Klinik Birshof | 20391781 |
| | TAPP Set - Klinik Birshof | 20472363 |
| 97102211-01 | Pack Lap Gynéco Clinique des vergers | 20365518 |
| | Pack Lap Gynéco Clinique des vergers | 20390259 |
| | Pack Lap Gynéco Clinique des vergers | 20408551 |
| | Pack Lap Gynéco Clinique des vergers | 20486360 |
| 97103184-00 | Lap. Hernien Set - Spital Uster | 19494924 |
| 97103184-03 | Lap. Hernien Set - Spital Uster | 19496797 |
| | Lap. Hernien Set - Spital Uster | 20022809 |
| | Lap. Hernien Set - Spital Uster | 20046408 |
| | Lap. Hernien Set - Spital Uster | 20219486 |
| 97103187-00 | Lap. Cholezystektomie Set - Spital Uster | 19464958 |
| 97103187-03 | Lap. Cholezystektomie Set - Spital Uster | 20064707 |
| | Lap. Cholezystektomie Set - Spital Uster | 20067052 |
| | Lap. Cholezystektomie Set - Spital Uster | 20124240 |
| | Lap. Cholezystektomie Set - Spital Uster | 20140255 |
| 97103188-00 | Lap. Appendektomie Set - Spital Uster | 20011802 |
| 97103188-02 | Lap. Appendektomie Set - Spital Uster | 20385570 |
| | Lap. Appendektomie Set - Spital Uster | 20392570 |
| | Lap. Appendektomie Set - Spital Uster | 20385565 |

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| | | |
|---|---|---|
| 97105179-01 | Ambulante Hernie grün - Regionalspital E | 19458976 |
| | Ambulante Hernie grün - Regionalspital E | 19458984 |
| | Ambulante Hernie grün - Regionalspital E | 19487480 |
| | Ambulante Hernie grün - Regionalspital E | 20055081 |
| | Ambulante Hernie grün - Regionalspital E | 20087658 |
| | Ambulante Hernie grün - Regionalspital E | 20105491 |
| | Ambulante Hernie grün - Regionalspital E | 20105490 |
| 97111119-00 | Lap. Hernien Set - Spital Schaffhausen | 20033841 |
| 97111149-00 | Lap. Hernien Set - Spital Obwalden | 20049774 |
| 97113340-01 | Amb. Hernie TAPP/TEP - Spital STS AG Thu | 20261856 |
| 97113341-00 | LSC Appendektomie | 20263090 |
| 97114090-00 | Lap. Cholezystektomie Set - RSS | 20370405 |
| 97114095-00 | Lap. TAPP Set - RSS | 20371452 |
| 97102211-01 | Pack Lap Gynéco Clinique des vergers | 20365518 |
| | | 20390259 |
| | | 20408551 |
| | | 20408551 |
| | | 20486360 |

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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.

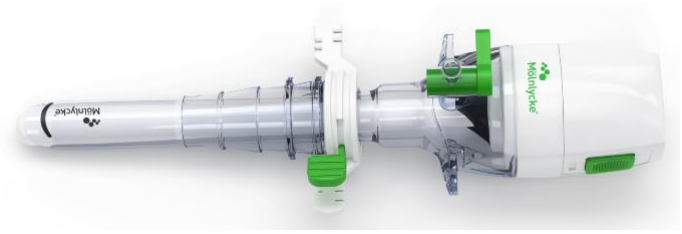
**Hazard giving rise to the FSCA**
The reported incidents are potentially serious to patients as the disconnected flanges could cause a significant delay to surgery. When not retrieved, foreign bodies can lead to various post-operative complications and the need for a new surgery. So there is a possibility 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 2319445-00

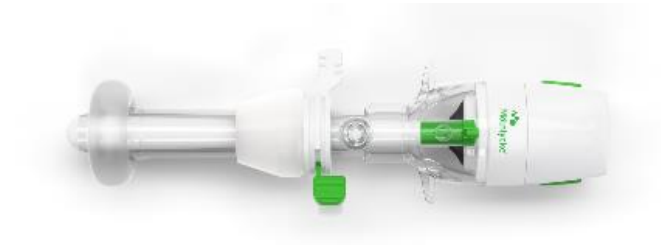


**Optical Trocar 11mm 100mm,** Mölnlycke component code 2319464-00.

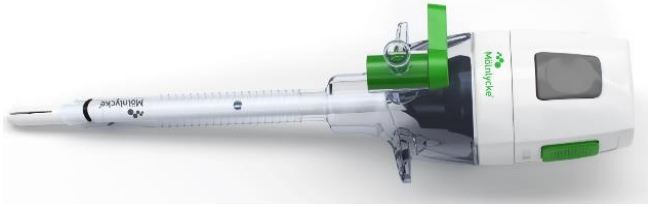

**Optical Trocar 12mm 100mm,** Mölnlycke Component Code: 2319428-00
**Optical Trocar 12mm 150mm**, Mölnlycke Component Code: 2321494-00


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


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



**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 | 2020-12 (01) |
| FSN Date | 22.DEC.2020 |
| 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 | +XXXXXXXXXXXXX |
| Postal Address | Mölnlycke Health Care,<br>Box 130 80, SE-402 52<br>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* | 2020-12 (01) |
| FSN Date* | 22.DEC.2020 |
| 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 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 | |

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| | | | | |
|---|---|---|---|---|
| ☐ | I have destroyed affected devices – enter number destroyed and date complete. | **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.