Recipient:

[redacted]

Date: 16.12.2024

Urgent Precautionary Product Safety Notice
FSN-24-01

Attention: Clinical Engineering Managers, Clinical Personnel, Risk Managers, Medical Device Safety Officers

Urgent precautionary safety information for Sterile Ophthalmic Procedure Packs from Trusetal Verbandstoffwerk GmbH, containing the following items:

TRUPACK® Sterile Ophthalmic Procedure Pack containing: **XL Care Dermic Film 10x12cm halved**		
REF	Description	LOT
NLKA002-07	TRU-PACK® Eyescan Utrecht RCC	32AQ24
NLKA002-07	TRU-PACK® Eyescan Utrecht RCC	43AQ24
NLKA011-06	TRU-PACK® Eyesc Emmen	27AE24
NLKA011-06	TRU-PACK® Eyesc Emmen	28BA24
NLKA011-06	TRU-PACK® Eyesc Emmen	32AM24
NLKA011-06	TRU-PACK® Eyesc Emmen	48AV24
NLKA011-07	TRU-PACK® Eyesc Emmen	42AN24
NLKA011-07	TRU-PACK® Eyesc Emmen	46AU24

We would like to inform you about an important measure: A safety corrective action has been initiated for the above-mentioned batches of our products. This decision has been made as a precautionary measure in line with our commitment to the highest safety and quality standards.

Description of the issue relevant to TRUPACK®

Customer feedback indicates that during the production of the packaging films for the above-mentioned surgical sets, a faulty cutting process occurred. In rare cases, this may result in small residual pieces of the backing film being present in the set.

Clinical Risk:

If a small piece of paper enters the eye, potential complications may arise, though these are usually minor. The severity depends on the size, shape, position, and duration of the foreign object in the eye. Possible complications include:

1. **Mechanical Irritation**
   - **Foreign body sensation:** A small piece of paper may cause an uncomfortable sensation as it irritates the sensitive tissues of the eye, particularly the conjunctiva or cornea.
   - **Redness and tearing:** The body reacts to the foreign object with increased tear production and enhanced blood circulation.

2. **Corneal scratches (corneal erosion)**
   - The piece of paper can cause fine scratches on the cornea through eyelid movements or mechanical pressure. This can be painful and may temporarily impair vision.
   - Without treatment, such scratches could increase the risk of infection.

Required Actions for Distributors:

1. Please check if you have the affected sets in stock.
2. **Quarantine the products:** Ensure that all products from the above-mentioned batches are immediately quarantined and no longer used.
3. **Prepare for collection:** Prepare the affected products for collection by our logistics team. We will coordinate the pickup with you quickly and efficiently.
4. Complete the response form in Appendix I by **January 6, 2025**, and send it to **quality@tshs.eu**.
5. Request your end customers to complete the attached response form in Appendix II by **January 6, 2025**, and send it to **quality@tshs.eu**.

Required Actions for End Users:

1. Check Inventory: Please check whether you have the affected sets in stock.
2. Choose between the following two options until replacement products are delivered:

Option 1: Return of the affected sets and delivery of replacement products
If you choose this option, the following steps must be taken: a) **Quarantine the products:** Ensure that all products from the above-mentioned batches are immediately quarantined and no longer used. b) **Prepare for collection:** Prepare the affected products for collection by our logistics team. We will coordinate the pickup with you quickly and efficiently.
Option 2: On-site inspection by the user during surgical preparation until replacement products are delivered
If you choose this option, the following conditions must be observed: a) Only use the affected sets if the cancellation of the surgery is expected to endanger the patient's health. b) Use the listed sets only until the replacement products arrive. If the above conditions are met, please take the following steps: c) Carefully inspect the listed surgical sets during preparation to ensure that any residual pieces of film are identified before the set is used in the surgical process. During the internal investigation, we identified the following potential locations where residual pieces of film may be present within the set: • On the film itself • Along the edge of the film • On the components within the wrapping d) Additionally, tap the film on the sterile wrapping of the set before surgery begins to loosen any residual cut pieces. Please note that it is also possible for small loose film pieces to become detached when peeling off the edge of the film. If you identify any film residue or have any doubts, please do not use the set. Dispose of it and replace it with a new one. A replacement will be provided for the discarded set.

Actions to be Taken by Distributors and End Users:

Please ensure the following actions are taken within your organization:

1. Make sure that all users of the above-mentioned products, as well as other relevant individuals within your organization, are informed about this urgent precautionary safety notice.
2. Complete the relevant response form (**Appendix I for distributors** and **Appendix II for end users**) and return it to **quality@tshs.eu** by **January 6, 2025**.
3. If you have forwarded the products to third parties, please share a copy of this notice with them as well.

Next Steps

The production of replacement products is already underway, and we are committed to delivering the new products as quickly as possible to minimize disruptions to your operations. The first replacement deliveries will be available during the following calendar weeks of 2025: **Week 2, Week 5, and Week 7**.

Our team will contact you shortly to arrange the logistics for collecting the affected products and to confirm the timeline for replacement deliveries.

Should you have any questions or require further assistance, please do not hesitate to contact us at any time.

We sincerely regret any inconvenience caused and thank you for your cooperation and understanding as we work together to uphold the highest standards of quality and safety.

Yours Sincerely
Trusetal Verbandstoffwerk GmbH

Sinah Wendt
Verantwortlichen Person
gem. Artikel 15 EU-Verordnung 2017/745

i.V. Tanja Kerins
Bereichsleitung TRUPACK®

Appenix I

Response Form for Distributors –
Urgent Precautionary Product Safety Notice FSN-24-01

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NLKA011-06	TRU-PACK® Eyesc Emmen	48AV24
NLKA011-07	TRU-PACK® Eyesc Emmen	42AN24
NLKA011-07	TRU-PACK® Eyesc Emmen	46AU24

Sender:
Trusetal Verbandstoffwerk GmbH | Konrad-Zuse-Straße 15 |
33758 Schloss Holte-Stukenbrock, Deutschland

Distributor **xxx**
Distributing the above-mentioned products.

Actions:

Check your inventory for the specified batches and quarantine them.

Please inform all customers using these products about this precautionary safety notice and confirm the following *(please check):*

☐ That you no longer possess the listed products.
☐ That you have quarantined the affected products from the TRUPACK® surgical sets and ceased distributing them.
☐ That you have informed third parties (customers or end users), if they received the listed products from you, about the safety notice for the affected TRUPACK® surgical sets.

Please return this response form to **quality@tshs.eu** by **January 6, 2025**.

Signatory:

Name (printed)	
Position	
Department / Institution	
Phone and E-Mail	
Date / Signature	

Apendix II

Response Form for End Users –
Urgent Precautionary Product Safety Notice FSN-24-01

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Sender:
Trusetal Verbandstoffwerk GmbH | Konrad-Zuse-Straße 15 |
33758 Schloss Holte-Stukenbrock, Deutschland

End User: **xxx**
Who received the above-mentioned products.

Actions:

Check your inventory for the specified batches and choose one of the listed options. The signatory confirms the following *(please check)*:

☐ That they no longer possess the listed products.

☐ That they have chosen **Option 1**, quarantined the affected products from the TRUPACK® surgical sets, and ceased using them.

☐ That they have chosen **Option 2** and:

- Only use the affected sets if cancelling the surgery would pose a risk to the patient's health.
- Perform the described inspections.
- Use the affected sets only until replacement products are received.

Please return this response form to **quality@tshs.eu** by **January 6, 2025**.

Signatory:

Name (printed)	
Position	
Department / Institution	
Phone and E-Mail	
Date / Signature	