Recipient:

Urgent precautionary product safety notice
FSN-23-01

Date: 16.03.2023

For the attention of: Managers in the medical technology sector, hospital staff, medical practices, risk managers, medical device safety officers

Urgent precautionary safety information for sterile ophthalmological customer sets made by Trusetal Verbandstoffwerk GmbH containing the following articles:

TRU-PACK® Sterile ophthalmological customer sets containing: **Incision instrument 3.5 + 4.00 mm round handle**		
REF	Description	LOT
CHIV002-01	TRU-PACK® [redacted] THPI 15754-02	01AX23, 38AI22, 44AA22
CHIV003-02	TRU-PACK® Set [redacted] (HFR) THPI188107-01	41AF22, 37AD22
CHIV003-03	TRU-PACK® Set [redacted] (HFR) THPI188107-02	01AA23, 06AF23, 46AJ22
CHIV011-01	TRU-PACK® IVI Set [redacted] THPI409701-02	34AN22, 39AO22
CHIV023-01	TRU-PACK® Set injection [redacted] THPI441703-05	03AJ23, 03AL23, 09AR23, 34AQ22
CHIV027-01	TRU-PACK® Set Injection [redacted]- THPI42386-07	37AO22
CHIV032-01	TRU-PACK® IVI [redacted] THPI4617-10	41AM22, 42AL22

We would like to inform you that, in the interest of patient safety, we are implementing a precautionary product safety measure. It concerns a product that is included in some of our TRU-PACK® surgical sets.

Description of the issue pertaining to TRU-PACK®

Customer feedback is indicating that an incision template (incision instrument) is showing soiling inside the injected material. Investigations have revealed that this is solely a matter of inclusions in the material. There is no soiling on the product itself. The manufacturer of the incision template says that this was a case of a variation in the injection moulding process.

The safety and performance of the products are not compromised by colour inclusions in the material and continue to be guaranteed. This is purely an optical defect. In order to

uphold our Tru-Pack® quality standards, we are nevertheless now replacing the incision templates.

Clinical risk:

The inclusions in the incision template material do not pose a clinical risk to users or patients. It is an optical defect in the material. Given that users may confuse the inclusions with soiling on the product and could be unsure of whether or not to use it, we are exchanging the product for sterile replacements that do not contain any colour inclusions.

As a result of this precautionary measure, the incision marker in the above-mentioned TRU-PACK® sets **must not be used**.

Measures to be taken by retailers:

Retailers:

1. Please check whether you have the set in question in stock. If this is the case, block the goods until the sterile replacements provided by Trusetal arrive.
2. Forward the product safety notice to your end customers immediately and ask them not to use the sets in question until the replacements arrive.
3. Ask your end customers to return the enclosed reply form to **quality@tshs.eu** by **28.04.2023**.

Measures to be taken by end users:

End users:

1. Please check whether you have the set in question in stock. If this is the case, block the goods until the sterile replacements provided by your retailer arrive.
2. **As a result of this precautionary measure**, the incision template included in the set in question **must not be used**. Do not use the sets until the replacements that your retailer will send you have arrived.
3. Destroy the incision template included in the set and use the sterile replacement instead.

Measures to be taken by retailers and end users:

Please make sure that all users of the above products and other persons who need to be informed in your organisation are made aware of this **urgent precautionary safety notice**, and return the enclosed reply form, duly completed, to **quality@tshs.eu** by **28.04.2023**.

In the event that you have given the products to any third parties, please forward a copy of this information to them.

Yours faithfully,
Trusetal Verbandstoffwerk GmbH

Sinah Wendt

Person Responsible for Regulatory Compliance
as per Article 15 EU Regulation 2017/745

p.p. Tanja Kerins

TRU-PACK® Division Manager

Reply Form Urgent Precautionary Product Safety Notice FSN-23-01

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

Addressees:

& all users who use the products mentioned above.

Measures:
Check your stock for the batches mentioned above and block them. If an end user: Destroy the incision template included in your customer set.

Please inform all employees using the products about this precautionary safety notice and confirm to us that this product will not be used.

The undersigned confirms (*please tick*):
[ ] that he/she no longer owns the specified products
[ ] that he/she has not given the specified products to any third parties
[ ] that he/she has informed all third parties, in the event that they have received the specified products from him/her, about the safety information and not to use the products in question contained in the TRU-PACK® surgical sets
[ ] if an end user: that he/she will not use the products in question contained in the TRU-PACK® surgical sets and that he/she will destroy the products
[] if a retailer: that he/she has blocked the sets in question until the replacements arrive
[ ] that he/she has informed all persons involved about this important information concerning the product mentioned above

Please return this reply form to **quality@tshs.eu** by **28.04.2023**.

Signatory:

Name in block capitals	
Position	
Department / Institution	
Telephone and e-mail	
Date / Signature	