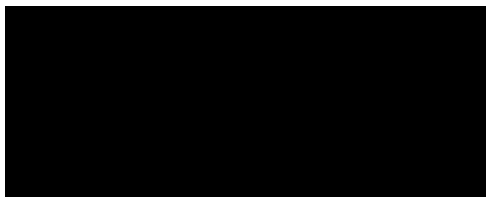


Recipient:



Date: 25/05/2022

## Urgent Product Safety Notice

### FSN-22-01

**To the attention of:** executive staff in the field of medical technology, hospital staff, risk managers, representatives for medical product safety

**Urgent safety information for sterile, ophthalmological client sets of Trusetal Verbandstoffwerk GmbH that contain the following items:**

TRU-PACK® sterile ophthalmic client sets containing:		
BD Connecta™ three-way stopcock, white without extension, without colour coding plug (BD 396400) Batch: 1085634 and 1083414		
REF: <b>NLAC001-01</b>	<b>CUSTOM PACK DSAEK PROCEDURE OZR</b>	LOT: <b>08AM22</b>

With regard to patient safety, we would like to inform you that "Becton Dickinson" (BD) is conducting a product safety measure related to products contained in some of our TRU-PACK® surgical sets.

#### Description of the issue related to TRU-PACK®

Via customer feedback, BD has confirmed that some BD Connecta™ three-way stopcocks may exhibit leakage from the body portion of the stopcock.

#### Clinical risk as reported by BD:

A leak may result in the delay or interruption of treatment, exposure to the infusion solution, medicinal products and biohazard materials, underdosing or under-infusion, contamination and/or entry of air.

The BD Connecta™ three-way stopcock from the affected sets **must not be used**.

#### **Measures to be taken by distributors:**

For distributors:

1. Please check whether you have the affected sets in stock. Should this be the case, block the goods until replacement goods, provided by Trusetal, arrive.
2. Forward the product safety notice to your end customers immediately and ask them not to use the affected sets until the replacement goods have arrived.

#### **Measures to be taken by end users:**

By end user:

1. The BD Connecta™ three-way stopcock from the affected sets **must not be used**. Please use the sets only after the replacement goods (BD Connecta™ three-way stopcock) have arrived, which your distributor will send you.
2. After receiving the replacement goods, destroy the three-way stopcocks in the set and use the replacement goods instead.

#### **Measures to be taken by distributors and end users:**

Please ensure that all users of the above products and other persons to be informed within your organisation are made aware of this **Urgent Safety Notice** and please fill out the attached reply form and return it to [quality@tshs.eu](mailto:quality@tshs.eu) by **June 20th, 2022**.

If you distributed the products to third parties, please forward a copy of this information to these persons.

Sincerely yours,  
Trusetal Verbandstoffwerk GmbH

...

...

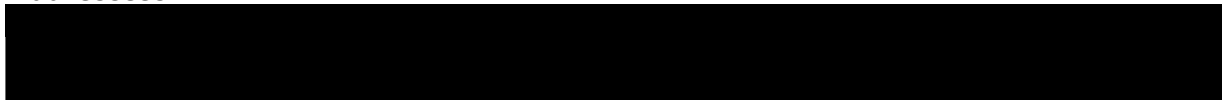
according to article 15 EU regulation 2017/745

## Reply Form Urgent Product Safety Notice FSN-22-01

TRU-PACK® sterile ophthalmic client sets containing:		
BD Connecta™ three-way stopcock, white without extension, without colour coding plug (BD 396400) Batch: 1085634 and 1083414		
REF: <b>NLAC001-01</b>	<b>CUSTOM PACK DSAEK PROCEDURE OZR</b>	LOT: <b>08AM22</b>

Sender:  
Trusetal Verbandstoffwerk GmbH  
Konrad-Zuse-Strasse 15  
DE 33758 Schloss Holte-Stukenbrock

Addressees:



& all users who use the above products.

### Measures:

Please inform all employees using the products of this 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 dispensed the specified products to third parties
- that he/she has informed third parties, provided they have received the specified products from him/her, about the safety information and non-use of the affected products from the TRU-PACK® surgical sets
- in the case of the end user: that he/she will not use the affected products from the TRU-PACK® surgical sets and that he/she will destroy the products
- in the case of the distributor: that he/she has blocked the affected sets until the arrival of replacement goods
- that he/she has informed all persons involved about this important information about the above product

Please return this reply form to [quality@tshs.eu](mailto:quality@tshs.eu) by **June 20th, 2022**

### Signatory:

Date/signature	
Name in block letters	
Position	
Department / institution	
Phone and email	