TRUSETAL
VERBANDSTOFFWERK GMBH

[redacted]

Date: 30.03.2021

Field Safety Notice

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

Field Safety Notice for sterile ophthalmological customised kits produced by Trusetal Verbandstoffwerk GmbH containing the syringes and cannulas listed below:

Item Description	REF	Manufacturer
Injekt® Luer Solo	misc.	B. Braun
Injekt® Luer Lock Solo	misc.	B. Braun
Injekt® Luer Duo	misc.	B. Braun
Sterican® Cannulas	misc.	B. Braun
Injekt®-F Luer Solo	misc.	B. Braun
Injekt®-H Luer Solo	misc.	B. Braun
Sterican® Safety Needles	misc.	B. Braun
Omnifix®-F Luer Lock Solo	misc.	B. Braun
Omnifix®-F Luer Solo	misc.	B. Braun
Omnifix®-H Luer Solo	misc.	B. Braun
Omnifix® Luer Lock Solo	misc.	B. Braun
Omnifix® Luer Solo	misc.	B. Braun
BD 1 ml Syringe Luer-Lok™ Tip	309628	BD
BD Plastipak™ 1 mL Luer	303172	BD
BD Blunt Fill Needle with 18G x 1 1/2 Filter	305211	BD
BD Microlance™ 3 30G x ½" 0.3 x 13 mm	302809	BD
BD Microlance™ 3 30G x ½" 0.3 x 13 mm	304000	BD

For reasons of patient safety we should like to draw your attention to the fact that "Becton Dickinson" (BD) and the company B. Braun have issued a Field Safety Notice regarding sterile syringes and cannulas (see Table 1) which are contained in some of our TRU-PACK® surgical kits.

MED CERT

[redacted]

We have received the following information from BD:

Intraocular use is not validated by BD

BD has become aware that when syringes and cannulas are used for intraocular injections, the potential exists for "floaters" in patients' eyes which are believed to be due to silicone. (Note: syringes and cannulas manufactured by BD have silicone applied to the inside of the barrels to provide lubrication for the plunger stopper, allowing it to move easily). The potential hazard is deposition of silicone oil droplets in the vitreous humour. The potential harm could be symptomatic "floaters" in the patient's field of vision which, normally, are tolerable and resolve over a few months. However, if sufficiently bothersome, floaters may lead to a vitrectomy for their removal.

BD became aware of other potential risks associated with intraocular injections, such as endophthalmitis (inflammation of the interior of the eye), which may be associated with faults not previously identified by BD. To reduce this risk of silicone floaters and inflammation or irritation that may occur, healthcare professionals should only use syringes and cannulas that are provided with ocular medications and are specifically designed and labelled for intravitreal injection. Following reports of use in intra-ocular procedures BD is updating the Instructions for Use. Future products shipped by BD will contain this caution.

We have received the following information from B.Braun:

Syringes:

***The silicone-coated syringe products listed above are not intended to be used for intravitreal injections**. Should there be a medical need to use the product **off-label** for intravitreal injections, the application has to be subject to an individual risk benefit assessment by the treating ophthalmologist. The patient must be informed of the risk.*

Cannulas:

Known complications of intravitreal injections include infectious and non-infectious endophthalmitis, cataract, ocular hypertension, vitreous haemorrhage, or retinal detachment caused by the intravitreal injection procedure and the inherent trauma to the vitreous body. They are also labelled side effects of drugs that are typically administered as an intravitreal injection. Furthermore, intravitreal silicone oil droplets may occur after intravitreal injection, which may appear as symptomatic "floaters" in the patient's field of vision.

Intravitreal injection should therefore only be performed after careful benefit risk assessment by the attending physician.

[redacted]

The affected products were immediately quarantined in our warehouse and will no longer be used for the production of TRU-PACK® surgical kits.

This does not apply to kits that are expressly approved by the user. The user must perform an individual, patient-related risk/benefit analysis. The patient must be informed of the risk.
The user may approve off-label use based on the results of the analysis.
The attached form F-VK-06-DE may be used for this purpose.

For the remaining TRU-PACK® surgical kits available in our warehouse, appropriate "warning stickers" will be applied.

This kit may contain one or more drawing up needles and syringes.

THESE ARE ONLY TO BE USED INTRAOCULARLY AFTER A PATIENT-RELATED RISK/BENEFIT ANALYSIS IS PERFORMED AND THE PATIENT HAS BEEN INFORMED OF THE RISK!

Please ensure in your organisation that all users of the products listed above and other persons to be informed are made aware of this **Field Safety Notice** and complete and return the enclosed confirmation to us.

If you have given the products to third parties, please forward a copy of this Notice to them.

We thank you in advance for your cooperation and ask for your understanding.

Yours sincerely,
Trusetal Verbandstoffwerk GmbH

[redacted]

[redacted]

Attachment 1
Field Safety Notice for sterile ophthalmological customised kits produced by Trusetal Verbandstoffwerk GmbH containing syringes and cannulas for intraocular use
(sent by fax to 05207 / 991688-28)

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

Addressees:
[redacted]
and all users of the products listed above.

Field Safety Notice
for sterile ophthalmological customised kits produced by Trusetal Verbandstoffwerk GmbH containing syringes and cannulas for intraocular use.

Action required:
Please stop using the syringes and cannulas from the TRU-PACK® surgical kits for intraocular injections.

Please inform all employees who use the products of this Field Safety Notice and confirm to us that you do not use these products without the explicit approval of the treating physician.

The undersigned confirms, *(please tick)*:
[ ] that he/she will not use the affected products from the TRU-PACK® surgical kits without conducting a risk/benefit analysis and informing the patient of the risks and obtaining approval from the treating physician, or will stop using such products entirely

[ ] that he/she has informed all persons involved about this important information concerning the above-mentioned product

[ ] that he/she no longer possesses the specified products

[ ] that he/she has not given the specified products to third parties

[ ] that he/she has informed third parties, if they have received the specified products from him/her, about the Field Safety Notice and non-use of the products concerned from TRU-PACK® surgical kits.

Customer:

Date/signature	
Name in block letters	
Position:	
Department/institution:	
Telephone and e-mail:	