

Lohmann & Rauscher GmbH · Postfach/P.O. Box 222 · 1141 Wien/Vienna

## Field Safety Notice

22.02.2021

Mediq Eest OÜ  
 Kungla tn 2, linn Saue vald  
 76505 Saue  
 Estonia

### Urgent Field Safety Notice for L&R sterile ophthalmic Kitpacks/Raucosets containing B.Braun syringes or needles for intravitreal injection

Dear Sir or Madam,

Today we would like to draw your attention to the fact that B.Braun has issued an information regarding sterile syringes and needles for use in intravitreal injections (see Table 1), which are included in some L&R sterile Kitpacks/Raucosets.

**Table 1: List of the affected products**

Syringes	Needles
Injekt® Luer Solo Injekt® Luer Lock Solo Injekt® Luer Duo	Sterican®
Injekt®-F Luer Solo Injekt®-F Luer Duo Injekt®-H Luer Solo Injekt®-H Luer Duo	Sterican® Safety Needle
Omnifix®-F Luer Duo Omnifix®-F Luer Lock Solo Omnifix®-F Luer Solo Omnifix®-H Luer Solo Omnifix® Luer Duo Omnifix® Luer Lock Duo Omnifix® Luer Lock Solo Omnifix® Luer Solo	

We have received the following information from B.Braun:

#### Syringes:

*The above mentioned products 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 about the risk.*

**Needles:**

*Known complications of intravitreal injections include infectious and noninfectious endophthalmitis, cataract, ocular hypertension, vitreous hemorrhage, or retinal detachment caused by the procedure of the intravitreal injection and the inherent trauma of 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.***

The affected products were immediately quarantined in our warehouse. The B.Braun syringes will no longer be used for the production of ophthalmic Kitpacks/Raucosets for intravitreal injections.

For the remaining Kitpacks/Raucosets available in our warehouse, appropriate "warning stickers" will be applied.

**„Do NOT use the syringes for intravitreal injections.  
Needles ONLY to be used after benefit-risk assessment by the physician for intravitreal injections.“**

**Please observe the instructions for the B.Braun needles mentioned above.**

The Kitpacks/Raucosets in stock at L&R can only be delivered after labelling and customer confirmation (see enclosure Field Safety Notice).

The other components of the respective Kitpack/Raucoset procedure packs are not affected and can be used as usual.

L&R has not been able to identify any alternatives for the affected B.Braun products and is therefore unable to offer a sterile alternative at present.

Our customer service will contact you to discuss details for a credit for the B.Braun components removed from your sterile customer sets. Please provide us with a contact person for this purpose in the enclosed safety notification.

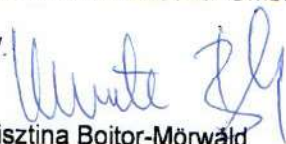
Please ensure in your organisation that all users of the products listed below and other persons to be informed are made aware of this Field Safety Notice and complete and return the enclosed confirmation to us.

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

The authorities were informed about this Field Safety Notice by Lohmann & Rauscher.

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

Yours sincerely  
Lohmann & Rauscher GmbH

i.V.   
Kristzina Bojtor-Mörwald  
Head of Sales Export Europe

i.V.   
Boris Dpsen  
Regional Vigilance Officer





**Urgent Safety Notice**  
**for L&R sterile ophthalmic Kitpacks/Raucosets containing B.Braun syringes or needles for intravitreal injection**

**Sender:** Lohmann & Rauscher GmbH  
Johann Schorsch Gasse 4  
1140 Wien

**Addressee:** Mediq Eesti OÜ  
Kungla tn 2, linn Saue vald  
765065 Saue  
Estonia  
& all users who use the products mentioned below.

**Description:** Urgent Field Safety Notice  
for L&R sterile ophthalmic Kitpacks/Raucosets containing B.Braun syringes or needles  
for intravitreal injection

**Corrective actions:**

**Please do not use the affected B.Braun syringes from the ophthalmic Kitpack/Raucoset procedure packs for intravitreal injections any more.**

**Please observe the instruction on B.Braun needles regarding their use for intravitreal 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.

The undersigned confirms, (please tick):

- that he/she will not use the affected products from the Kitpack/Raucoset procedure packs,
- that he/she has informed all persons involved about this important information concerning the above-mentioned product,
- that he no longer possesses the specified products,
- that he has not given the specified products to third parties,
- that he has informed third parties, if they have received the specified products from him, about the Field Safety Notice and non-use of the products concerned from the Kitpack/Raucoset procedure packs.

