Karlstein am Main, 01.04.2021

URGENT SAFETY INFORMATION

Note on the safety of medical devices

Attention: Purchasing, medical device safety officer

Concerning: Urgent Safety Notice for Sterile Customer Kits Manufactured by M.E.D. Medical Products GmbH that contain BD components

MED Reference: FSN-21-01

Description: Sterile customer kits manufactured by M.E.D. Medical Products GmbH that contain BD components

Affected products: see the table below

Dear ladies and gentlemen,

This letter indicates that the supplier Becton Dickinson has issued a safety notice with regard to syringes and needles (see table), which are included in some M.E.D. Medical Products sterile customer kits include:

Product safety notficiation – MPS-18-1209	
309628	BD 1-ml-syringe with Luer-Lok™ top
303172	BD Plastipak™ 1-ml-Luer
305211	BD blunt filling needle with filter 18G x 1 1/2 (1,2 mm x 40 mm) (5 µm)
302809	BD Microlance™ 3 30G x ½" 0,3 x 13 mm
304000	BD Microlance™ 3 30G x ½" 0,3 x 13 mm

"As part of post-market surveillance, it was determined that the Instructions for Use (IFU) for the products listed in Table 1 above should be given a warning.

This product safety notification contains the necessary warning notices and BD recommends that you observe them when using the product.

Intraocular use of BD not validated

BD has found that using syringes and needles for intraocular injections can create vitreous opacities in patients' eyes that are believed to be due to silicone. (Note: The syringes and cannulas

manufactured by BD are coated with silicone on the inside of the syringe and needle bodies to lubricate the plunger stopper so that it can be moved more easily). A potential danger exists in the deposition of silicone oil droplets in the vitreous. This can potentially cause symptomatic vitreous opacities in the patient's field of vision that are normally tolerable and go away over the course of a few months. However, if they are increasingly bothersome, vitreous opacities can be removed by vitrectomy.

BD became aware of other potential risks associated with intraocular injections, such as: B. Endophthalmitis (inflammation of the inside of the eye) which may be associated with defects not yet identified by BD.

To reduce the risk of silicone-related vitreous opacity and possible inflammation or irritation, healthcare professionals should only use syringes and needles that are provided with eye medication and are specifically designed and intended for intravitreal injection. " BD Field Safety Notice MPS-18-1209

The following measures must be carried out:

1. Fill out the reply form and send it as soon as possible, but not later than by **April 30, 2021,** by fax or email.
2. If you no longer have the affected M.E.D. Sets or no longer use them, please indicate this on the response form and send it to M.E.D. so we can update our records.
3. Do not use the affected BD products if they are being used for intraocular application.

M.E.D. has not been able to identify an alternative to the BD 1ml syringe or the BD MicrolanceTM cannulas and therefore cannot offer a sterile alternative. M.E.D. will therefore produce new, sterile sets without these syringes and needles.

The responsible authorities have been informed about this safety notice.

We apologize for the inconvenience this has caused.

Kind regards

Thomas Neumann
-Geschäftsleitung-

Julienne Höfel
-QMB/RA-

M.E.D. Medical Products GmbH * Am Sportplatz 11 * 63791 Karlstein * Tel: +49 (0)61 88 / 91691-0 * Fax: +49 (0) 6188 / 91691-15 * www.med-products.de

Safety information response form
FSN 21-01

Please return to M.E.D. by April 15, 2021. Medical Products

Fax: +49 6188 916 9115 or

E-Mail: julienne.hoefel@med-products.de

Please fill out the confirmation form and send it back as soon as possible, but no later than April 30, 2021, by fax or e-mail.
If you transfer this product to other facilities or departments within your facility, please forward a copy of this notice to them.

If you are a dealer or reseller who has sold affected products to other customers, please inform your customers and confirm to us that your customers have been notified.

☐ I have read and understood the safety information. With my signature I confirm receipt of the FSN 21-01.

Date: _____

Name: _____

Position: _____

Address (Street/Place): _____

Country: _____

Customer Number: _____

Telephone: _____

Fax: _____

Signature: _____