Medline International Germany GmbH
Medline-Straße 1-3
D-47533 Kleve
Tel: +49 (0) 2821 – 7510 – 0
Fax: +49 (0) 2821 – 7510 – 7802

Regulatory Affairs
Quality Department
gmb-eu-ra-kleve@medline.com
Tel: +49 (0) 2821 – 7510 – 7528
Fax: +49 (0) 2821 – 7510 – 7804

www.medline.com/de

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

Kleve, March 3rd, 2021

For the attention of: the Pharmacist/Risk Management responsible for medical device vigilance and the Biomedical Engineering Department.

SECURITY INFORMATION of Medline Ophthalmic Sterile Procedure Trays including BBraun Syringes

Medline reference:	**FSN – 21/05**
MoH reference:	
Description:	«BBraun» Syringes, included in Medline Ophthalmic Sterile Procedure Trays
Product Codes concerned:	See details in the **Table 1** of the acknowledgment form (The Table will be completed and modified for each customers)

Dear Customer,

This letter is to advise you that BBraun is providing its customer information concerning Syringes (see table below) included in some Medline Sterile Procedure Trays. Medline has not received any reports of incidents, but as Medline was informed of such risks, this information is being communicated to its customers.
These syringes have been discontinued and have not been included in any Medline Sterile Procedure packs since 2019.
There are no sterile procedure packs containing these syringes in any Medline warehouses, this will only impact packs in your stock.

Syringes
Injekt® Luer Solo
Injekt® Luer Lock Solo
Injekt® Luer Duo
Injekt®-F Luer Solo
Injekt®-F Luer Duo
Injekt®-H Luer Solo
Injekt®-H Luer Duo
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

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The following is the communication announced by BBraun –

Intraocular use is not validated by BBraun

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.

All references of Sterile Procedure Trays mentioned in the acknowledgement form in Table 1 are concerned

The relevant competent authorities are informed of this safety notice.

We apologize for the inconvenience caused.

Yours Sincerely,
Kenneth Smith
International Quality and Regulatory Affairs Manager.

This urgent safety information is only addressed to facilities that had received the concerned Sterile Procedure Trays.

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Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822
or send by email to: gmb-eu-ra-kleve@medline.com

Reference: FSN-21/05

Could you please complete the acknowledgment form and send it back by either fax or email as soon as possible, but **not later than April 16th, 2021.**

Table 1:

Sterile Procedure Trays concerned by this notification delivered to you are listed in the below table.

Item Number	Lot number

☐ I have read and understand the instructions provided. I acknowledge receipt of the FSN-21/05 by signing this document.

I also agree to further distribute and communicate this important information within my facility as required.

If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are a dealer, wholesaler, distributor/reseller, that distributed any affected products to other facilities, please distribute this notification to customers and confirm us that your customers have been notified.

Date: _____
Customer Number: _____
Name: _____
Position: _____
Facility: _____
Address: _____
City: _____
Telephone: _____
Fax: _____
Signature: _____