

B. Braun Melsungen AG  
Division Hospital Care  
Safety Officer Medical Devices  
34209 Melsungen

Our reference: FSCA-2025-10-16

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Date: October 16, 2025

## RECALL - URGENT Field Safety Corrective Action - Injekt® Luer Solo

### Attention: To whom it may concern

Dear Valued Customer,

The B. Braun Melsungen AG has decided to proactively recall the article/batch combinations Injekt® Luer Solo listed below in the course of a Field Safety Corrective Action from the market.

Article Number	Article Name	Batch
4606108N	Injekt® Luer Solo	25H11C8, 25H14C8, 25H18C8, 25H28C8

### Reason for the Recall

In the course of our quality surveillance activities, we identified a risk of holes in the primary packaging, which may compromise the sterility for the article-batch combinations listed above of Injekt® Luer Solo.

The deviation might harbour the risk for the patient of microbial contamination.

Based on the current available root cause analysis, the effect can be limited to the listed article batches combinations.

In view of the identified risks, we decided to recall all affected devices from the market.

### Actions to be taken

Our records have shown that your institution has received articles of the affected article batch combination.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organization and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify and locally destroy affected articles.
- Do not use affected devices anymore.

Chairwoman of the Supervisory Board:  
Anna Maria Braun, LL.M.

Executive Board:  
Markus Strotmann  
(Chairman)  
Priv.-Doz. Dr. Stefan Ruppert  
Dieter Gemmer

Corporate Office: Melsungen  
Register Court:  
Local Court Fritzlar  
HRB 11 000  
WEEE-Reg.-No. DE 42690900

Address:  
B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Germany

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- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided by 31.10.2025.

If more information is needed, please contact

Local contact 1

Local contact 2

Name

Title

Email

telephone

This FSCA has also been reported to the respective national competent authority and the notified body.

We believe in improving people's health through everything we do. Patient and user safety is our highest priority.

Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Yours sincerely,