

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

Our reference: FSCA-2025-04-16

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Date: April 17, 2025

## URGENT Field Safety Corrective Action - Ringer B. Braun

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall the following article/batch combination of Ringer B. Braun in the course of a Field Safety Corrective Action from the market.

Article Number	Article Name	Batch
FREU984	Ringer B. Braun	250537672

### Reason for the Recall

In the course of our quality surveillance activities, we identified the risk for leakage at the Click Connector Portsystem within the above mentioned batch. Complaints from the market or patient injuries in this regard are not known to us. Based on internal controls, the effect can be limited to the listed article-batch combination.

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

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, quarantine and return affected articles.
- Do not use affected devices anymore.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.



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If more information is needed or you require devices for replacement, please contact

Local contact 1

Name

Title

Email

telephone

Local contact 2

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,



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