B|BRAUN

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

34209 Melsungen

Our Reference FSCA-2023-07-05

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URGENT Field Safety Corrective Action – 2 PIECE SYRINGE blister leakage

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall the defined article/batch combination of the 2-piece syringes in the course of a Field Safety Corrective Action from the market:

Article Number	Article Name	Batch
4608667	EXADORAL 10 ML 2-TLG LILA KOLBEN STERIL	22N19C8
4100-000V0	10 ML (12 ML) HENKE-JECT® 2 TLG	22M28C8
4100-000V0	10 ML (12 ML) HENKE-JECT® 2 TLG	23A09C8
4100-X00V0	10 ML (12 ML) HENKE-JECT® 2 TLG LL	22M14C8
4100-X00V0	10 ML (12 ML) HENKE-JECT® 2 TLG LL	22M28C8
4100-X00V0	10 ML (12 ML) HENKE-JECT® 2 TLG LL	23A16C8
4606108V	INJEKT 10 ML	22M21C8
4606108V	INJEKT 10 ML	22N08C8
4606108V	INJEKT 10 ML	22N12C8
4606108V	INJEKT 10 ML	22N19C8
4606108V	INJEKT 10 ML	23A02C8
4606108V	INJEKT 10 ML	23A05C8
4606108V	INJEKT 10 ML	23A16C8
4606728V	INJEKT 10 ML LL	22M21C8
4606728V	INJEKT 10 ML LL	22N12C8
4606728V	INJEKT 10 ML LL	23A09C8
4645103V	INJEKT 10 ML DUO 21GX1 1/2"	22M14C8
4645103V	INJEKT 10 ML DUO 21GX1 1/2"	22N12C8
4645103V	INJEKT 10 ML DUO 21GX1 1/2"	23A16C8

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Article Number	Article Name	Batch
NJ-4606108	10 ML NORM-JECT BBRAUN	22M28C8
NJ-4606108	10 ML NORM-JECT BBRAUN	22N12C8
NJ-4606108-02	10 ML NORM-JECT BBRAUN AIR-TITE	22M28C8
NJ-4606108-02	10 ML NORM-JECT BBRAUN AIR-TITE	23A09C8
NJ-4606728-02	10 ML NORM-JECT LL BBRAUN AIR-TITE	22M21C8
NJ-4606728-02	10 ML NORM-JECT LL BBRAUN AIR-TITE	23A09C8

Reason for the Recall

In the course of Post Market Surveillance activities and our internal quality checks, we identified that in a subset of the above mentioned article batch combinations the sterile packaging barrier might be damaged.

Whilst no injuries to patients, users, or third parties have been reported to date, the deviation might harbor the risk of local, regional and systemic infections up to patients' death.

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

The effect can be limited to the above mentioned article batches combination. No other batches or products are affected.

Actions to be taken

Our records have shown that your institution has received one or more of the affected article batch combinations.

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.

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

Local contact 1
Name
Title
Email
telephone

Local contact 2

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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,