

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

Your reference:
Our reference: FSN 2021-02-18 AS/STK

Contact:

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Date: February 18, 2021

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICES Convenience Kit 4

To whom it may concern,

B. Braun Melsungen AG has decided to inform its customers in the context of a FIELD SAFETY NOTICE on an issue for the following product:

Article Number	Article Name	Batch
900-V4EU01	APPLICATIONKIT FOR SUBC. ADMIN. V4EU01	12745200

Reason for the FSN

In the course of our post market surveillance activities we observed that one component of the kit has a shelf life approximately one month shorter than the complete kit (see picture below). Whilst the Sterican Safety Needle has a shelf life until 2024-04-01 the complete kit has a shelf life until 2024-05-05. The described failure is limited to the above mentioned product and batch number. No other kits or batches are affected by this Field Safety Notice.

Chairman of the Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Anna Maria Braun, LL.M.
(Chief Executive Officer)
Dr. Annette Beller
Dr. Meinrad Lukan

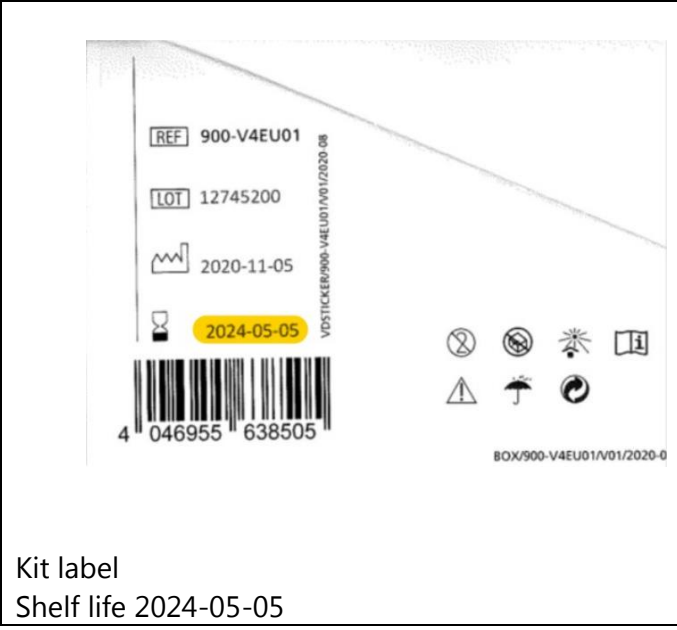
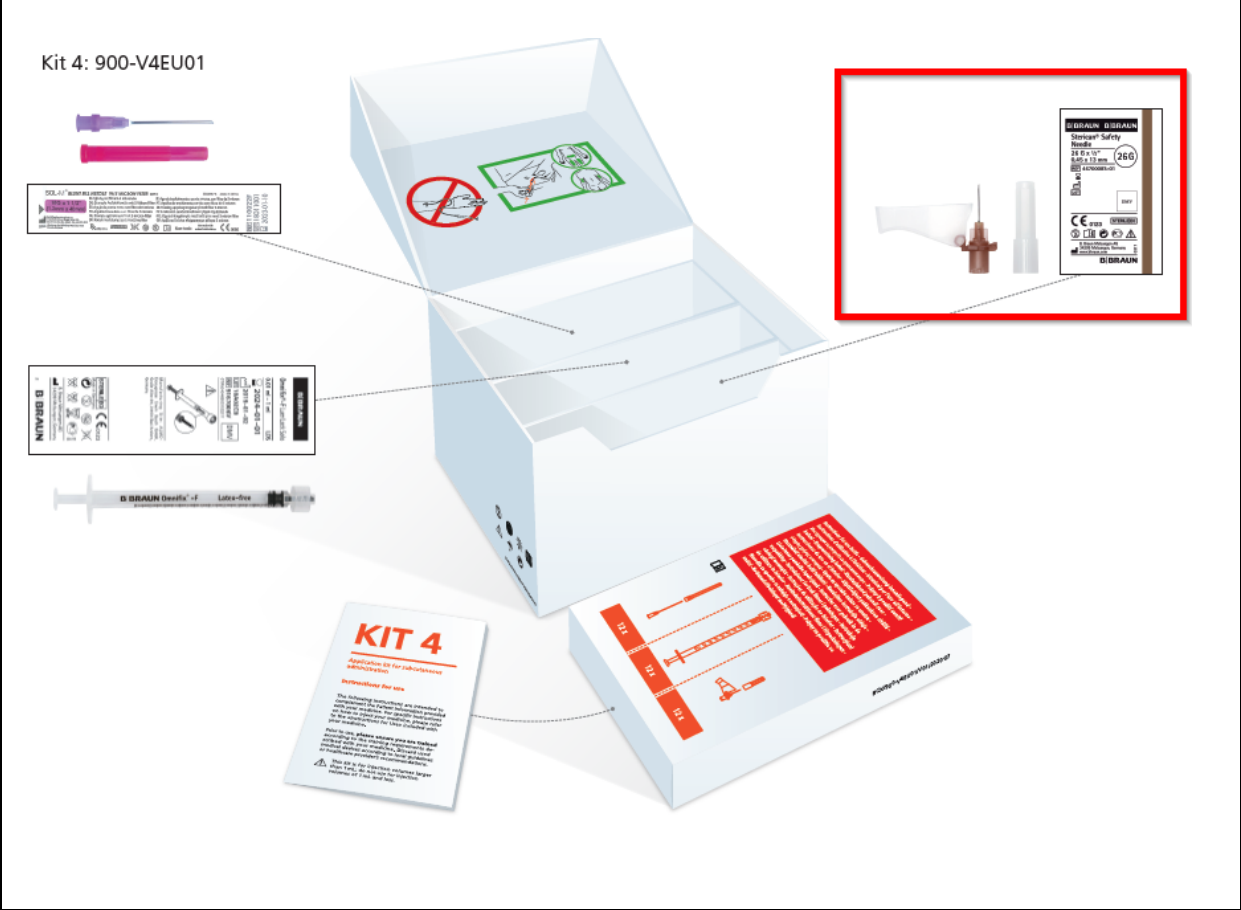
Dr. Joachim Schulz
Markus Strotmann
Priv.-Doz. Dr. Stefan Ruppert
(Deputy Member)

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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Kit label
Shelf life 2024-05-05



Component label (Sterican Safety Needle):

Shelf life 2024-04-01

There is a minor risk of using a Sterican Safety Needle for injection, which is out of shelf life. Injury to patients is very unlikely. Under these conditions we advise the following actions:

Actions to be taken

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 products 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.
- 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, please contact

Local contact 1

Local contact 2

Name

Title

Email

telephone

Kindly accept our apologies for any inconveniences.

Yours sincerely,