

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach

www.bbraun.ch

Customer

Sempach, 19 February 2021

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

Urgent FIELD SAFETY NOTICE (FSN)

Please inform all relevant departments / customers immediately!

Product Name: Application Kit for subc. Admin. V4EU01
Article Number: 900-V4EU01
Batch: 12745200

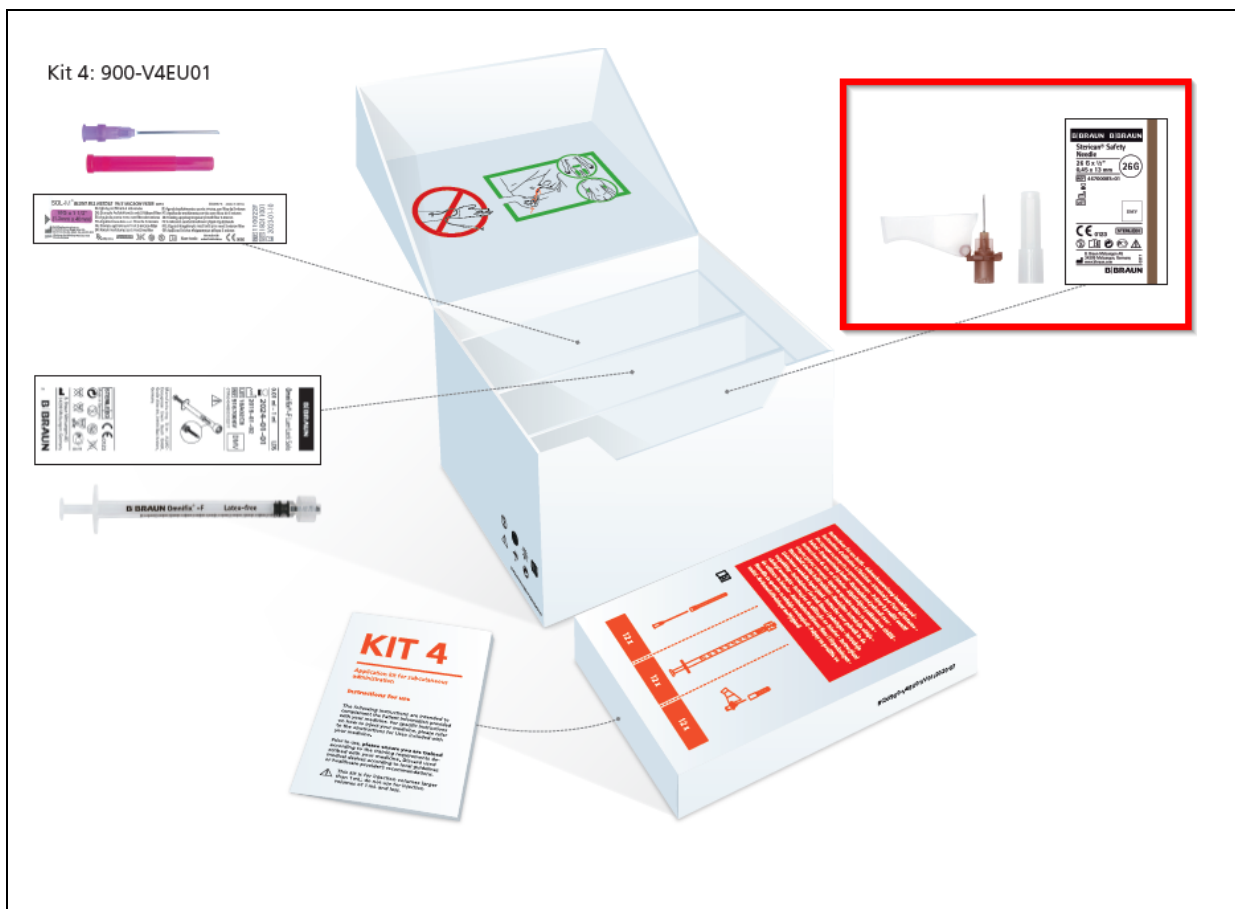
To whom it may concern,

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.



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:

Customer

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:

Contact	Function	Contact Details
Rebecca Buob	Senior Project Manager	rebecca.buob@bbraun.com Direct +41 58 258 57 69

The Swiss national competent authority Swissmedic has a copy of this letter.

Kindly accept our apologies for any inconveniences.

Yours sincerely,

B. Braun Medical AG

Dr. Karin Birbaum
Stv. FvP & Safety Officer Swiss Sales
Divisions / TL Complaint Handling CH

Rebecca Buob
Senior Project Manager

Answer Sheet

Our reference: FSN 2021-02-18 AS/STK
Datum 19.02.2020

FSN – Convenience Kit 4

Please return to:

**B. Braun Medical AG
Qualitätsmanagement Vertrieb Schweiz
Seesatz 17
6204 Sempach
fsn.ch@bbraun.com**

We ask you to acknowledge receipt of this letter as follows.

I have received the letter, read it and taken the appropriate action.

Date

Organisation, Place

Name / Prenom
(in Blockschrift)

Signature