

B. Braun Melsungen AG Division Hospital Care

Safety Officer Medical Devices

34209 Melsungen

Your reference:

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

Contact:

TO WHOM IT MAY CONCERN

Date: February 18, 2021

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:	Executive Board:	Corporate Office: Melsungen	Address:
		 Register Court: Local Court Fritzlar	B. Braun Melsungen AG
		 HRB 11 000	Carl-Braun-Straße 1
		 WEEE-RegNo. DE 42690900	34212 Melsungen
			Germany

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BOX/900-V4EU01/V01/2020-0 Kit label Shelf life 2024-05-05



Component label (Sterican Safety Needle): Shelf life 2024-04-01

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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 Name Title Email telephone Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,