

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

Your reference:

Our reference: 2523676-4/30/21-002-R

Contact:

TO WHOM IT MAY CONCERN

Internet: <http://www.bbraun.com>

Date: May 26, 2021

Urgent FIELD SAFETY CORRECTIVE ACTION Caresite Extension Set - Leakage

To whom it may concern,

We, the B.Braun Melsungen AG, are recalling the following article from the market on behalf of B.Braun Medical Inc.

Article Number	Article Name	Lot No.
470108-01	Caresite Extension Set	0061744004

Reason for the FSCA

In the course of post market surveillance activities we observed defects at the spin-lock adapter on the above referenced Extension Sets.

This defect might cause leakage of the infused solution or blood with the potential for mild to serious injury to patients, including bloodstream infection, which could be life threatening.

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.
- Identify, quarantine and return affected goods.
- 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

Chairwoman of the Supervisory Board:
Dr. Annette Beller

Executive Board:
Dr. Meinrad Lüggen
(Chairman)
Priv.-Doz. Dr. Stefan Ruppert
Jürgen Stihl

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

Local contact 1

Name

Title

Email

telephone

Local contact 2

Kindly accept our apologies for any inconveniences, that this issue may have caused you and your facility, but we appreciate your understanding of our commitment to assuring our products are safe and effective for both health care professionals and patients.

Yours sincerely,