

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices
34209 Melsungen

Your reference:
Our reference: FSCA-2025-08-13

Contact: Dr. Stephan Krause

Fon: 05661 71-1339
Fax: 05661 71-
Email: stephan.krause@bbraun.com
Internet: <http://www.bbraun.de>

Date: August 14, 2025

RECALL - URGENT Field Safety Corrective Action for spare parts for syringe pumps

Attention: Service Technicians

Dear Valued Customer,

We would like to inform you about a Field Safety Corrective Action (FSCA) for the following spare parts and batch/lot numbers:

Article	Article Number	Order number
Drive complete PSP, green claws	34521041	92204627 92204263
Space ^{plus} Perfusor Drive complete	34523140	97088537 97089719
Space ^{plus} Perfusor Drive Head with Claws & Tube	34523142	97088136

Reason for the FSCA

During routine in-process inspections, certain components of the drive unit from specific spare part batches showed geometric deviations that exceed the defined manufacturing tolerances.

Under normal conditions, contact between the drive head and plunger plate triggers an infrared sensor that enables controlled deceleration and claw engagement.

In affected units, a geometric deviation prevents the membrane plate from retracting, causing the infrared sensor to fail and the drive head to continue moving uncontrolled.

Potential Risks to Health

If the drive head moves beyond its intended stopping point, the syringe may be fully emptied into a potentially connected patient. Depending on the medication administered, this could lead to serious harm, including the risk of fatal outcomes.

Please also consider the instruction in the IfU:

“Only connect to patient once the syringe has been inserted correctly and there is proper fixation of the syringe pressure plate by the claws of the drive head. Interrupt connection during syringe change to prevent incorrect dose delivery.”

Nature of the FSCA

B. Braun is recalling the affected spare parts.

Pumps that have been repaired utilizing one of the affected parts, need to be identified and restored by you as instructed within the attached FSI.

Actions to be taken

Our records have shown that your institution has received the affected articles.

We kindly ask you to initiate the following activities with priority:

- Please review this Field Safety Corrective Action Notice in its entirety and ensure that all service technicians / service hubs within your institution are informed about this Field Safety Corrective Action Notice.
- Confirm receipt of this information immediately by completing the attached confirmation slip and return this to B. Braun using the contact details provided below.
- Identify affected spare parts of the aforementioned batches according to the procedure of the attached FSI.
- Quarantine affected spare parts of the aforementioned batches and return them to the following address:

B. Braun Melsungen AG
to attn: Matthias Bieber
Servicewerkstatt
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

- In addition to the stock-check, also trace back all spare parts built-in to the devices from May 09 2025 onwards.
You must identify and list all repairs, utilizing the affected spare parts, in the provided list .
Communicate the list of identified devices and the status to B. Braun using the contact details provided.
- If the affected spare part has been assembled within a pump, which is no longer in your control, you must inform affected users immediately and ensure that the pump is returned to you for check and potential repair according to the attached FSI.
You have to document the respective customer feedback.

Page 3 to the letter of August 14, 2025 to

- To do so, finalize the provided customer communication draft (enter identified products and serial numbers and your contact details) and forward it to the identified users (Attention: Clinical Personnel)
The customer is required to finalize the action until 2025-08-31.
- You must finalize the actions above by 2025-09-15, latest.

If more information is needed, please contact

Local contact 1

Name

Title

Email

telephone

Local contact 2

This FSCA has also been reported to the respective national competent authority and the notified body.

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. As a true partner we develop smart solutions and set standards to improve health care.

Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Yours sincerely,