

Your reference:
Our reference: FSCA 2021-07-06 AS/STK

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Date: July 06, 2021

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE PERFUSOR SPACE, INFUSOMAT SPACE

Dear Sir or Madam,

B. Braun Melsungen AG has decided to conduct a FIELD SAFETY CORRECTIVE ACTION for the following four (4) Space Pumps:

Article Number	Article Name	Serial Number
8713050	INFUSOMAT SPACE	775894
8713050	INFUSOMAT SPACE	750811
8713050	INFUSOMAT SPACE	758485
8713030	PERFUSOR SPACE	583723

Reason for the Recall

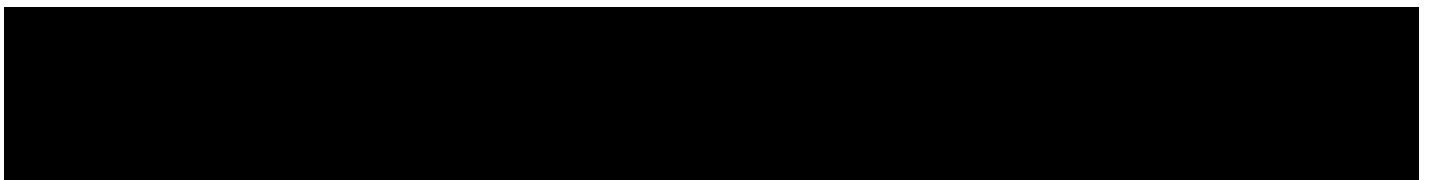
In the course of our regular quality reviews we identified that for overall four (4) Space pumps documentation for final controls was incomplete. As we cannot fully exclude that a final control has not been conducted, it was decided to recall the four (4) pumps in question. No other products or other serial numbers are affected by this Field Safety Corrective Action.

Due to the incomplete documentation of final controls a residual risk to patients cannot be fully excluded. We therefore 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 product 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 customer.



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- Identify, quarantine and return the affected pump.
- Do not use affected device anymore.
- 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,