

Your reference:
Our reference: FSCA 2022-01-07

Contact: Dr. Stephan Krause

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Date: January 7th, 2022

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE - Perfusor Space

Dear Sir or Madam,

We, the B. Braun Melsungen AG, have decided to execute additional control-procedures on a limited set of Perfusor Space pumps in the context of a Field Safety Corrective Action. Our distribution data indicate that you received one or more of the affected pumps as referenced in the APPENDIX.

Reason for the Field Safety Corrective Action

There is ~~evidence-indication~~ that one individual may not have conducted certain steps in the final inspection of defined Perfusor Space Pumps. ~~were not conducted by a single person.~~ We therefore cannot exclude the risk that potentially non-conforming pumps have left the manufacturing and went into clinical use.

The risk can be allocated to a limited set of serial numbers of pumps manufactured between Jul-2021 and Dec-2021. Up to now, no harm or any other adverse patient outcome, which could be associated to the above described failure, has been reported to the B. Braun Melsungen AG.

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 potentially affected product serial numbers (see annex) 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.
- Identify and quarantine the affected devices.

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- Your responsible B.Braun service organization will contact you immediately for completion of the missed out final inspection procedures.
- 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

B.Braun Medical A/S~~Local contact 1~~

~~Local contact 2~~

~~Name~~ Jan Christensen

~~Title~~ Servicechef

~~Email~~ Jan.christensen@bbraun.com

~~Tlf.nr.~~ 51419911~~telephone~~

Kindly accept our apologies for any inconveniences.

Yours sincerely,

B.Braun Medical A/S

Lone Hesner

Produktchef

Lone.hesner@bbraun.com

Tlf.nr. 20294303

Appendix - Affected Serial Numbers

Article number	Article Name	Serial Number
8713030	PERFUSOR SPACE	xxxxxx 640299
8713030	PERFUSOR SPACE	yyyyyy 642199
8713030	PERFUSOR SPACE	zzzzzz 642209