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

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Our reference: FSCA-2024-06-12

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URGENT Field Safety Corrective Action
Spaceplus Infusomat® - Wave Spring

Dear Valued Customer,

We would like to inform you about a Field Safety Corrective Action (FSCA) for the following articles and serial numbers:

Article	Article Number	Serial Number
SPACEPLUS INFUSOMAT®	8719050	A list of all affected Serial Numbers is provided as ATTACHMENT 1

Reason for the FSCA
As part of our internal product quality control activities, we have identified that a wave spring installed in Spaceplus Infusomat® infusion pumps may have reduced spring force in a certain batch due to deformation in some cases. Consequently, the occlusion pressure of the peristaltic may be less than specified. This effect is limited to the listed serial numbers of pumps. No other devices are affected.

Potential Risks to Health
In clinical practice Wave Springs with reduced force in combination with an electronic cut-off pressure settings > P5 could potentially lead to standstill without alarm. In rare cases, this may be associated with potential patient risks ranging from no clinical relevance to serious injury or death. However, post market surveillance data did not indicate the occurrence of a technical failure or patient injury.

In view of the identified risks, a decision was reached to voluntarily execute the below described actions in the market.

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Nature of the FSCA
B. Braun will be exchanging the Wave Spring built in the mentioned serial numbers of SpacePlus Infusomat® Infusion Pumps. After receipt of your completed acknowledgement form, your local B. Braun representative will contact you to arrange for replacement of the wave spring.

In the meantime, the pump can be operated with electronic pressure setting of ≤ P5. This excludes the occurrence of standstill without alarm due to the described defect.

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 users of the above mentioned product in your organization and other concerned persons are informed about this Field Safety Corrective Action Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify affected pumps and adjust the electronic pressure cut off to ≤ P5 (IfU section 9.11.2) until the pump has been repaired. Alternatively, take the affected device out of operation if an operation with the mentioned limitation is not feasible.
- 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

Patient and user satisfaction is our highest priority. We are sorry for any inconvenience. Thank you in advance for your cooperation to resolve this matter quickly.