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URGENT Field Safety Corrective Action Change to Instruction for Use (IfU) for Space^{®plus} Perfusor[®]

Dear Valued Customer,

We would like to inform you about upcoming updates to the Instructions for Use (IfU) for Space^{®plus} Perfusor[®] pumps, specifically within the section 11.6 'Take Over Mode (TOM)' as part of a Field Safety Corrective Action (FSCA).

Reason for the FSCA

This FSCA is limited to a correction of the Instructions for Use (IfU) only and does not involve any change to the product itself.

The IfU of the syringe pumps includes a chapter explaining the feature of the Take Over Mode. This feature supports the user during syringe changes by automatically starting a second syringe pump once the first pump has completed its infusion. During the transition a delay in infusion may occur due to the physical characteristics of the syringe, known as the start-up effect. To help reduce this effect, recommendations were previously communicated in a whitepaper and were incorporated into IfU version 2.0.

The whitepaper also included a specific reference to cardiovascular drugs. This reference has not yet been transferred into the IfU. We will now add this information as a warning in IfU version 3.0.

Potential Risks to Health

A delay in reaching the effective flow rate on the second syringe pump may temporarily reduce the infusion rate. This could lead to changes in vital parameters such as blood pressure, particularly when administering highly potent cardiovascular drugs with short half-lives, such as vasopressors or inotropes.

In rare cases, this may be associated with potential patient harm ranging from no clinical relevance to serious injury or death.

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In view of the identified risks, a decision was made to update the respective section of the IfU with a warning.

Nature of the FSCA

This FSCA concerns **only an update of the Instructions for Use (IfU)** of the Space[®]plus Perfusor[®] to ensure that all recommendations for minimizing the start-up effect of syringes are clearly reflected in the documentation. The following recommendations, which were already communicated in IFU version 2.0, are reiterated here to raise awareness:

- Use prepared syringes as soon as possible and avoid storage time to prevent the lubrication in the cylinder from dissolving.
- The medication from the second syringe should be administered into the same flow stream as the first infusion. For example, connect the extension lines of both syringes to a three-way stopcock or a y-extension, and then attach the stopcock or y-extension directly to a central venous catheter lumen to create one stream of infusion.
- Avoid the use of back-check valves to avoid higher counter pressure.
- Prime the IV system properly before use to prevent air in line

In addition, we want to inform you that the next IFU release will include the following:

- Additional recommendation:
In particular for critically ill patients with unstable vital signs, it is preferable to use low concentration drug solutions at high flow rates rather than highly concentrated solutions at very low flow rates.
- Adapted recommendation regarding the use of back-check valves:
Avoid the use of back-check valves between the two paired syringe pumps to avoid higher counter pressure. During Take Over Mode, these pumps can be operated safely without back-check valves, as the syringe plunger is secured by the drive mechanism to prevent backflow
- New Warning:
These physical characteristics of syringes can lead to alterations in corresponding vital parameters such as blood pressure or heart rate, especially when infusing highly potent cardiovascular drugs with short half-lives, such as vasopressors and inotropes.

Actions to be taken

Our records have shown that your institution has enabled the use of TOM with one of your Space[®]plus Perfusor[®] pumps.

As this FSCA concerns **only a correction and update of the Instructions for Use (IfU)**, 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 TOM users in your organization and other concerned persons are informed about the IfU correction.
- If you are a distributor, please forward this correction notification to your customers.
- Adhere to the recommendations to minimize the Startup Effect of the syringe as described above under 'Nature of the FSCA'
- Special attention should be given to critical patients requiring higher doses of vasopressors or inotropies to ensure stable medication delivery. Closely monitor vital signs during and immediately after the syringe changeover.

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- 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

Local contact 2

Name

Title

Email

telephone

We appreciate your cooperation in ensuring that this IFU correction is communicated and implemented appropriately.