Important Customer Notice

**Field Safety Notice B** **Braun Infusomat Space Transfusion Line - Leakage**

Category Tower 1 Ward Based Consumables

Contract Title Infusion Pumps, Administration Sets and Associated Products

Field Safety Notice FSCA-2023-01-20

ICN: 2021

Date: 06/02/2023

NHSSC: 88

**Alert:**

* In addition to earlier communications B Braun is proactively informing all customers of potential quality issues with Infusomat Space Transfusion Lines, namely the risk of leakage between the tube and the patients' Luer connector.
* **This latest Field Safety Notice is not a recall.**
* B Braun advise no serious injuries to patients, users, or third parties have been reported to date, however the deviation might harbour the risk for the patient of microbial contamination, under supply, open patient access, or air infusion.
* B Braun advise treatment with the affected article is possible, users should refer to the ‘actions to be taken’ section of the Field Safety Notice.
* Please note this latest Field Safety Notice **does not affect the batches previously recalled** on ICN1991.These batch numbers are still being recalled <https://www.supplychain.nhs.uk/icn/field-safety-notice-b-braun-infusomat-space-transfusion-line-leakage/>

**Products Affected:**

* The product affected is available from NHS Supply Chain:

|  |  |  |  |
| --- | --- | --- | --- |
| **NPC** | **Product Description** | **Supplier Code / MPC** | **Affected Batches** |
| FSB2495 | Administration set for Infusomat Space Volumatic Pump | 8270066SP-01 | Refer to Appendix One of the Field Safety Notice |

* Be aware orders placed with NHS Supply Chain may be supplied with the batch numbers listed in the Field Safety Notice.

**Next Steps:**

* Read and follow the full instructions in the Field Corrective Notice and share with all users of the affected products. These include:
	+ Continue current ongoing treatment with affected devices.
	+ Observe the connection between the tube and patient connector during priming of the line for leakage. In case of a leakage, please change the line and file a complaint at B Braun.
	+ Mechanical stress from repeated movement, or similar, at the Luer might lead to a delayed leakage. Therefore, repeatedly observe for leakage during the entire usage of the product.
* If you can switch from pump-driven treatment to gravity-treatment, you also may want to consider the opportunity of using alternative products designed for gravity transfusion treatment.
* If you experience any issues when using these administration sets, please raise a product complaint with your local NHS Supply Chain Customer Service Advisor and with B Braun, email Kieren Bruce at Kieren.bruce@bbraun.com
* NHS Supply Chain is working with B Braun and the relevant authorities to support the management of this situation and provide further information and guidance as a matter of urgency.
* This ICN will be updated as soon as further information is available.

NHS Supply Chain will provide further updates as information becomes available in the meantime if you have any further questions, please contact your local NHS Supply Chain Customer Service Advisor or Customer Relationship Manager.