

Date:
 July 23, 2021

Ref: FSCA 2021-07-21

Urgent FIELD SAFETY NOTICE – ProSet Infusomat® Space Line

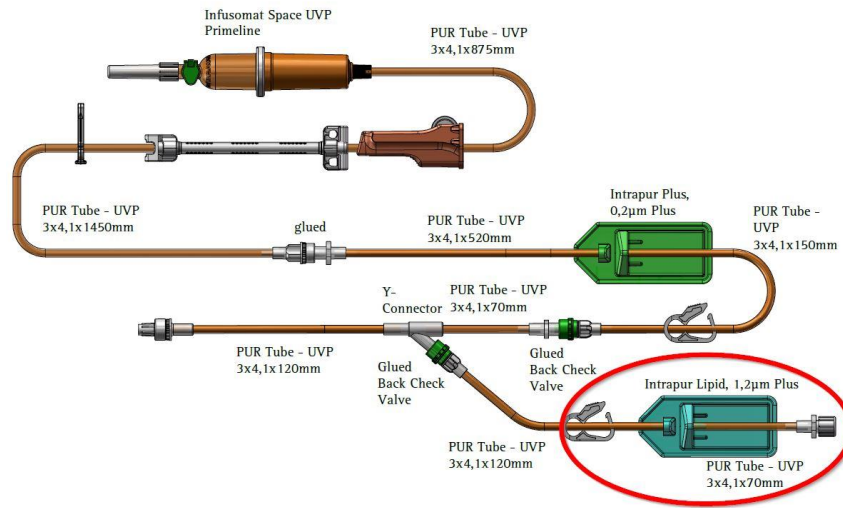
Dear Sir/Madam,

B. Braun Melsungen AG has decided to recall the below mentioned article in the course of a Field Safety Corrective action from the market:

Article Number	Article Name	Batch
4186842SP	PROSET INFUSION SET W. INTRAPUR FILTERS	All (See Appendix)

Reason for the Recall

It has been identified that the inline Intrapur Lipid 1.2µm Plus Filter (marked in red) has been assembled in the wrong direction.



Therefore, it does not fulfill its function for air elimination and gives the potential for an air infusion.

The failure is limited to the above mentioned article number. No other products are affected. Up to now, no harm or any other adverse patient outcome, which could be associated with the above described failure, has been reported to 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 the above mentioned product in your organisation and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Confirm receipt of this information by completing and signing the attached 'Field Safety Notice Confirmation Form' and return this to B. Braun using the contact details provided.

*Please return the completed form by **Monday 26th July 2021**, or sooner if possible.*

A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose the Batch Recall Confirmation Form with this collection.

Credit will be provided for any affected product returned.

The Health Products Regulatory Authority has been informed of this action.

If more information is needed, please contact:

AJ Cotter
Business Unit Manager
B. Braun Medical Ltd
Tel: 087-124 8637
Email: anthony.cotter@bbraun.com

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,

AJ Cotter
Business Unit Manager

Roberta Egan
Regulatory Affairs Manager

Appendix to FSN

Affected Batches
21D30F0000
21D21F0000
21B08F0000
21A19F0000
20N03F0000
20K18F0000
20H27F0000
20H25F0000
20G09F0000
20E27F0000
20E04F0000
20D15F0000
20C09F0000
20B03F0000
19N18F0000
19M26F0000
19N04F0000
19L24F0000
19K17F0000
19G29F0000