

Date
April 30, 2015

BATCH RECALL – INFUSOMAT SPACE LINE, UV-PROTECT

Article Number	Product Name	Batch Numbers
8700127SP	INFUSOMAT SPACE LINE, UV-PROTECT	14M22F00H2 14N03F00H2 14N04F00H2

Dear Sir/Madam,

B. Braun Melsungen AG wishes to inform you of the voluntary precautionary recall of the above listed batches of the **Infusomat Space Line UV-Protect**. These batches are being recalled with immediate effect.

Reason for the Recall

During the normal course of internal quality checks, a low probability of occurrence was identified of possible leakage at the tubing connection to the drip chamber due to an assembly issue. Therefore we have decided to recall the concerned batches as a preventive measure.

Actions to be taken by the USER

Our records show that your hospital has received Infusomat Space Line UV-Protect sets from one or more of the batches specified in the table above, which were distributed on the Irish market from 30th January 2015 to 4th March 2015.

We kindly ask you to initiate the following activities immediately and with priority:

- Identify, quarantine and return affected product.
- Do not use affected product anymore.
- Inform the responsible personnel/users in the affected departments/facilities.
- Complete and sign the enclosed 'Batch Recall Confirmation Form' and fax this back to us (fax no. 01-7091889) to confirm that you have received this notice and advise the quantity of affected product to be returned.

*Please return the completed form by **Friday 8th May 2015**, 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.

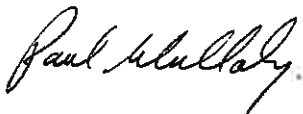
Credit will be provided for any affected product returned. A new order should be placed for any replacement product you may require.

If more information is needed, please contact:

Ciarán McGuinness
Sales & Product Manager
Automated Infusion Systems
Telephone: 086 2588019
Email: ciaran.mcguinness@bbraun.com

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

Yours sincerely,



Paul Mullaly
Managing Director



Roberta Egan
Regulatory Affairs Manager

April 30, 2015

BATCH RECALL CONFIRMATION FORM**Infusomat Space Line, UV-Protect**

Please complete this form, even if you do not have any of the concerned product and fax this form back to Fax No. 01-7091889

1. We acknowledge receipt of the recall-notification from B. Braun Medical.

2. Please mark accordingly:

- We do not have any of the affected product in stock.
- We will return the following products:

Article Number	Device Name	Batch Number	Quantity to be Returned
8700127SP	Infusomat Space Line, UV-Protect	14M22F00H2	
		14N03F00H2	
		14N04F00H2	

Hospital:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	