B|BRAUN

B. Braun Medical Ltd.
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http://www.bbraun.com

Date
October 21, 2014

Urgent FIELD SAFETY NOTICE – OMNIFIX 20ML LUER SOLO

Article Number	Article Name	Batch Number
4616200V	OMNIFIX 20ML LUER SOLO	4H11048

Dear Sir/Madam,

B. Braun Melsungen AG wishes to inform you of the voluntary precautionary recall of the above mentioned batch of the **Omnifix 20ml Luer Solo** syringe, within the context of a Field Safety Corrective Action. This recall relates only to **article number 4616200V, batch 4H11048**. No other syringes or batches are affected.

Reason for the Recall

During the normal course of continuous market surveillance activities, it was identified that, for a low percentage of the above specified batch, cracks may be present in the paper of the primary packaging (blister). In affected packaging, the cracks were observed in the paper directly over the pressure plate of the plunger.

To date no harm or any other adverse patient outcome which could be associated with this described observation has been reported to B. Braun Melsungen AG. Nevertheless, it has been decided to recall the affected products from the market as a precautionary measure.

Actions to be taken by the USER

Our records show that your hospital has received potentially affected devices as specified in the table above which were distributed on the Irish market from 3rd – 12th September 2014.

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

- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Inform the responsible personnel in the affected departments/facilities.

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- Complete and sign the enclosed 'Customer Response 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 Tuesday 28th October 2014, 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 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:

Robert Egan
Sales Manager, Safety Products
Telephone: 086 2606917
Email: rob.egan@bbraun.com

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

Yours sincerely,

Leo Halpenny
Director Sales & Marketing

Roberta Egan
Regulatory Affairs Manager

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FIELD SAFETY CORRECTIVE ACTION

RECALL CONFIRMATION FORM

Omnifix 20ml Luer Solo

Please complete this form, even if you do not have any of the concerned products 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
4616200V	Omnifix 20ml Luer Solo	4H11048	

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