04 April 2013

Urgent Field Safety Notice
1L Receptal System (Liner and Canister)

Product name:	1L Receptal System (Liner and Canister)
List Number:	43449 Canister OL 212 (PVC) Liner OL213 (PE) Liner
EMEA FA ID:	Q.FA.EMEA.2013.015
Date:	04th April 2013

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. has received customer reports for the 1L Receptal System not achieving vacuum and/or improper fit. This letter details the potential malfunction and recommended steps for users to take if you currently have these products in your inventory.

Affected Units: All

Issue: The Receptal System is a closed disposable suction system that is used to isolate suction waste. The Receptal System consists of a reusable hard canister and single-use liner, which are assembled in sequence. The vacuum needed to create the suction cannot be created if the hard canister and the single-use liner are not properly seated during use, or if the liner separates from the canister during use.

Hospira has not received reports of serious injury or death related to this issue.

Risk to Health: The severity in the delay/interruption in use is dependent upon the underlying condition of the patient. **A delay/interruption in use has a worst case potential to result in a significant injury or death.**

Required Action: **Please check your inventory of the 1L Receptal System and immediately seek alternatives. Once an alternative is available immediately quarantine any affected product. Please return your affected product to your local Hospira office.**

Please forward this Urgent Field Safety Notice to all colleagues within your organization who need to be aware of it or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice until all products from the impacted list numbers have been removed from your facility

An investigation has been initiated to determine the root cause and corrective and preventive actions.

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Please complete the attached Reply Form indicating the number of impacted devices at your facility and return it to the fax number or e-mail address on the form, even if you do not have the affected product.

Hospira is committed to providing you with the highest level of service, product quality and reliability. We appreciate your understanding and we regret any inconvenience that may cause you.

Should you have any further questions please do not hesitate to contact your local Hospira office:

Hospira contact	Contact details	Areas of support
Hospira EMEA Product Safety	T: +44 1926 834 400 Email to: devicecomplaintsemea@hospira.com	To report adverse events or product complaints
Hospira EMEA Quality	T: +31 36 5274 720 F: +31 36 5274 701 Email to: *devicesfieldactions@hospira.com*	Additional information and technical assistance
Local Contacts		

The Competent Authorities in all countries affected by this action have been informed of this Urgent Field Safety Notice

Yours sincerely,

W. Kennedy 04 APR 13

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EMEA Devices Quality Manager

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Hospira ref:	**Q.FA.EMEA.2013.015**

Section A
Hospital / Facility Details
Please fill out the information below and fax the completed form to Hospira at [local fax number].

Name of Hospital / Facility:	
Hospital / Facility Address:	
Telephone Number:	
Name:	
Signature:	
Date:	

Section B
☐ I have read and understood the contents of this Urgent Field Safety Notice, circulated it to all staff/departments that use this product and confirm that our inventory has been checked and we have no inventory of the listed products.

OR

Section C
☐ I have read and understood the contents of this Urgent Field Safety Notice, and circulated it to all staff/departments that use this product. All products listed within this notice will be returned to the local Hospira office with immediate effect.

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