06th Sep 2013

FIELD SAFETY NOTICE
Appropriate Use of Receptal System Liners and Canisters

Product name:	Receptal™ System Liners and Canisters
List Number:	See attached.
Lot Numbers:	All.
EMEA FA ID:	Q.FA.EMEA.2013.020
Date:	06th Sep 2013

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. (Hospira) has become aware of improper usage of Receptal liners and canisters in the clinical setting. This improper usage is **not** covered in the current Instructions for Use for this product range. Hospira will be updating the instructions for use associated with the Receptal system to reflect the appropriate use of the correctly sized liners with the correctly sized canisters.

Issue: Hospira has become aware that customers may be inappropriately using incorrectly sized Receptal liners with Receptal canisters (e.g. 1.5L liner, 2L liner or 3L liner with a 1L canister). It is possible that if the incorrectly sized liners are used with different size canisters, the lid may not fit and the vacuum/suction will not be sufficient and/or consistent. To date, Hospira has received reports associated with this practice, including one that resulted in a serious injury and one that resulted in a death, and recommends against this practice

Please note that the 1L Receptal canisters and Liners are currently on recall as noted in previous FSNs dated April 2013 and July 2013.

Risk to Health: Receptal is a closed disposable suction system that is used to remove waste, blood or other fluids during surgeries or to clear patient airways, throat or wounds to allow treatment.

If suction is compromised and detected during a general surgical procedure, the fluids may impair the surgeon's vision and ability to expeditiously complete the procedure. The harm includes progression of the untreated condition that may result in symptoms such as hypertension, hypotension, tachycardia and bradycardia. Furthermore, the delay may result in a prolonged exposure to any anaesthesia used during the procedure.

Compromised suction leads to diminished efficacy of the product and/or delay in therapy if it needs to be addressed, both of which can result in life threatening situations if airway clearance or gastric suction is needed. When Receptal fails while being used in an emergency procedure related to the airway, the potential for death exists.

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Therefore, Hospira recommends that Hospira/Abbott Receptal canisters should only be used with appropriately sized Hospira/Abbott Receptal lid/liners.

Affected Product Details: The products impacted by this issue are identified below:

List Number	Product Description
77042	Abbott canister
43449	1L canister
43423-8911	1.5L canister
43445-6111	2L canister
43503-6118	3L canister
L212A52	Abbott Suction Liner
L213A52	Abbott Suction Liner
0L212	1L Liner (PVC)
0L213	1L Liner (PE)
0G903-9701	1.5L Liner
0G904-9701	1.5L Valved Liner
0L654-9701	1.5L Valved Liner
0F807-9701	1.5L Liner
0G661-9701	2L Valved Liner with safeguard (PVC)
0G901-9701	2L Liner
0G902-9701	2L Valved Liner
0G905-9701	2L Liner
0G915-9701	2L Valved Liner with tubing (PVC)
0L650-9701	2L Valved Liner
0P507-9701	2L Liner with pourspout
0P508-9701	2L Valved Liner with pourspout
0E098-9701	2L Liner
0F806-9701	3L Liner
0L655-9701	3L Valved Liner
0L656-9701	3L Liner
0M908-9701	3L Liner

Instructions: Hospira recommends that users follow the Receptal set up instructions which state to fully extend and insert your required liner. This is to only be accomplished by placing the correctly sized liner into the canister as indicated below:

- 1L liner with a 1L canister
- 1.5L liner with a 1.5L canister
- 2L liner with a 2L canister
- 3L liner with a 3L canister
- Hospira/Abbott liners with Hospira/Abbott canisters

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Product correction: Hospira will be updating the instructions for use associated with the Receptal system to reflect the appropriate use of the correctly sized liners with the correctly sized canisters.

***Please complete the attached Reply Form 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.

Please forward this 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 Hospira notifies you of completion.

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 field safety notice.

Yours sincerely,

WJ Kennedy 06 Sep 13

Wilson Kennedy
EMEA Devices Quality Manager

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FIELD SAFETY NOTICE RECEPTAL AND CANISTER REPLY FORM

Product name:	**Receptal System Liners and Canisters**
List Number:	**As Listed Above**
Lot Number/s:	**All Lots**
Hospira Reference:	**Q.FA.EMEA.2013.020**

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 Field Action, and circulated it to all staff/departments that use this product.

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