22 October 2013

Urgent Field Safety Notice – RECALL

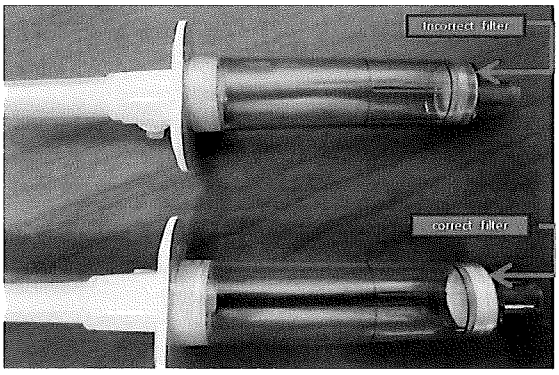
Incorrect Fluid Filter in Sight Chamber of Lifeshield, Latex-Free, Non-DEHP, Primary Plumset, 15 Micron Filter In Sight Chamber, Prepierced Y-Site, 272 CM

Product name:	**Lifeshield, Latex-Free, Non-DEHP, Primary Plumset, 15 Micron Filter In Sight Chamber, Prepierced Y-Site, 272 CM**
List Number:	**14000-92-28 & 14001-92-38**
Lot Number:	**27112-5H & 30079-5H (14000-92-28), 28187-5H (14001-92-38)**
EMEA FA ID:	**Q.FA.EMEA.2013.028**
Date:	**22nd October 2013**

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. (Hospira) has become aware that some Latex Free Non DEHP 15 Micron Filter PlumSet IV Administration Sets have been manufactured with an incorrect fluid filter.

Issue: Hospira is issuing this urgent product recall for the PlumSets listed above as three (3) lots of the device identified above have been manufactured with the incorrect fluid filter within the sight chamber. The correct fluid filter is identified by a white clip ring that holds the filter in place. The incorrect filter has a transparent clip ring. To date, there have been no reported complaints related to this issue.



Risk to Health: Use of PlumSets manufactured with the incorrect fluid filter may generate allergic reactions, particularly when administering parenteral lipid emulsions. Severe allergic reactions may result in serious injury or death.

Affected Product Details:

The Hospira Latex Free Non DEHP 15 Micron Filter PlumSets identified below are affected by an incorrect fluid filter within the sight chamber.

List Number:	Lot Number(s):	Set Description:
14000-92-28	27112-5H	LIFESHIELD, LATEX-FREE, NON-DEHP, PRIMARY, PLUMSET, 15 MICRON FILTER IN SIGHT CHAMBER, PREPIERCED Y-SITE, 272 CM
	30079-5H	
14001-92-38	28187-5H	LIFESHIELD, LATEX-FREE, NON-DEHP, PRIMARY PLUMSET, 15 MICRON FILTER IN SIGHT CHAMBER, CLAVE PORT, CLAVE Y-SITE, 272 CM

Action to be taken:

In order to minimize the risk of harm due to biocompatibility reaction and/or intravenous particulate matter, Hospira recommends users follow the instructions below:

1. **Do not use affected product lots.**
2. **Please check your inventory and immediately quarantine any affected product.**
3. Search storage areas, supply carts, and other patient care areas for affected lots, paying special attention to areas with critically ill patients. Remove all affected sets immediately.
4. Work with your local Hospira office to arrange the return of affected product.
5. Ensure your facility's protocols for administering fluids are completely followed.
6. Should your facility experience a biocompatibility reaction or intravenous particulate matter event, report the issue 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 or persons where the potentially affected devices have been transferred.

Please maintain awareness of this notice until all products from the impacted lot numbers have been removed from your facility.

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 this notice may cause you.

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Facsimile +44 (0)1926 835 250
www.hospira.com
Registered in England No. 1923357

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,

WJ Kennedy 22Oct13

Wilson Kennedy
EMEA Quality Manager – Medical Devices

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Hospira ref:	**Q.FA.EMEA.2013.028**

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 product.

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 product listed within this notice will be returned to the local Hospira office with immediate effect.

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