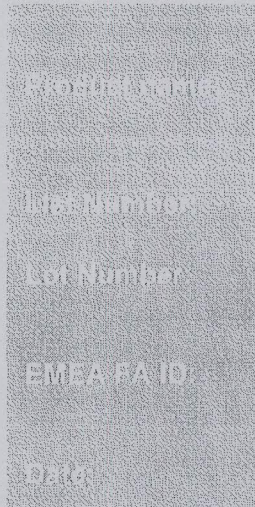


14 October 2013

## 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

**Lot Number** 14000-28 & 14001-38

**Lot Number** 27112-5H & 30079-5H (14000-92-28),  
28187-5H (14001-92-38)

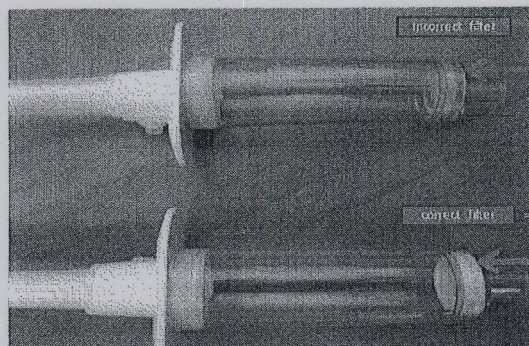
**EMEA PA ID** Q.FA.EMEA.2013.028

**Date** 14<sup>th</sup> October 2013

**Dear Healthcare Professional and Hospira Customer,**

Hospira Inc. (Hospira) has become aware that some 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. 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 15 Micron Filter PlumSets identified below are affected by an incorrect fluid filter within the sight chamber.

<u>List Number:</u>	<u>Lot Number(s):</u>	<u>Set Description:</u>
14000-92-28	271125H	LIFESHIELD, LATEX-FREE, NON-DEHP, PRIMARY, PLUMSET, 15 MICRON FILTER IN SIGHT CHAMBER, PREPIERCED Y-SITE, 272 CM
	300795H	
14001-92-38	281875H	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.

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.

Hospira UK Limited  
Queensway  
Royal Leamington Spa  
Warwickshire CV31 3RW  
United Kingdom  
Telephone +44 (0)1926 820 820  
Facsimile +44 (0)1926 835 250  
www.hospira.com  
Registered in England No. 1923357