URGENT FIELD SAFETY NOTICE- RECALL

Redistributed Recalled Product: Potential to Puncture the Outer Wall of Non-ISO 3826-1 Compliant Blood Bags

Product name:	**Hospira Plum Blood Sets**
List Numbers:	**14202-92-28** **14205-92-28** **14212-92-28**
Lot Numbers:	**220485H** **334165H** **401245H** **331925H** **334085H**
EMEA FA ID:	**Q.FA.EMEA.2014.011**
Date:	**20th November 2014**

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. (Hospira) has become aware of recalled product having been released in error. **Hospira is only recalling product from markets where non-ISO 3826-1 compliant blood bags are utilised.**

The European market should not be impacted by this issue as the use of ISO compliant bags is required. Additionally, ISO compliant bags can be identified by the CE marking that is present on the labelling.

Issue: Hospira inadvertently redistributed product previously recalled due to the potential for certain blood sets to puncture the outer wall of non-ISO 3826-1 compliant blood bags whilst inserting the ISO 1135-4 compliant piercing pin on certain Hospira Plum blood sets. To date, Hospira has not received any complaints associated with the redistributed recalled product regarding punctured blood bags. **This issue does not affect countries where only ISO 3826-1 compliant blood bags are in use.**

Risk to Health: Hospira Plum blood sets are used for the administration of blood and blood products. If the piercing pin on this product punctures the outer wall of a blood bag, it may result in spillage of the blood products stored in the bag resulting in a delay in therapy. The severity of the delay in therapy is dependent upon the underlying condition of the patient and the duration of the delay in therapy. **Delay in therapy has a worst case potential to result in significant injury or death.** Spillage of blood products has the potential to result in exposure to the healthcare professional.

Affected Product Details:

The Hospira Plum blood set list and lot numbers detailed below are impacted by this issue.

Hospira List Number	Hospira Product Description	Hospira Lot Number(s)
14202-92-28	LIFESHIELD Blood Set,100mL Burette with Float Valve, 170Micron Filter, Pre-pierced injection site, Non-vented 178cm/19mL	220485H
14205-92-28	LIFESHIELD Y-Type Blood Set 200 Micron Filter, convertible pin 203cm/47mL	334165H 401245H
14212-92-28	NDEHP PLUM Y-BLOOD SET W/FLR CLAVE 279cm	331925H 334085H

Actions to be taken:

1. Determine if your facility has any of the lot numbers listed above, which are non-ISO 3826-1 compliant.
2. If your facility does have non-ISO 3826-1 compliant blood bags, please follow the actions detailed below.
3. Please check your inventory and immediately quarantine any of the affected Hospira sets listed above.
4. Inform healthcare professionals in your organization of this notification.
5. 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 or utilise ISO 3826-1 compliant blood bags.
6. If impacted, work with your local Hospira office to arrange return of the affected Hospira sets.

Should your facility experience leaking blood bags due to puncturing the outer wall during insertion of the piercing pin, report the issue to your local Hospira office.

Product correction:

In March 2013, Hospira began distributing sets with a blunter piercing pin that is shorter than the pins in the Plum blood sets identified in the "Affected Product Details" section of this Field Safety Notice. Additionally, Hospira has initiated an investigation to identify root cause of the redistribution of recalled product.

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.

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.

If your facility utilises Non-ISO 3826-1 Compliant blood bags 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 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.

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

Areas of support	Contact details	Hospira contact
Additional information Technical Assistance	**Central Saudi Arabia** **Mohamed Ayash +966505210241** **Ammar Isoud +966554877173** **Omar Abbas +966564664565** **Eastern Saudi Arabia** **Islam Hosny +966546337004** **Ahmed Alsukkari +966549276656** **Western Saudi Arabia** **Fareed Waheed +966545546114** **Hisham Fakeeh +966556667349** --- **Head of Service Department** **Emad Siddiq +966505865824** **Email** emad.siddiq.hosp@alkamal-sa.com	**Hospira - Alkamal Import Saudi Arabia**
To report adverse events or product complaints	**T: +44 1926 834 400** **Email to:** devicecomplaintsemea@hospira.com	**Hospira EMEA Product Safety**
Additional information and technical assistance	**T: +31 36 5274 720** **F: +31 36 5274 701** **Email to:** devicesfieldactions@hospira.com	**Hospira EMEA Quality**

The Competent Authorities in all countries affected by this action have been informed of this field safety notice.

Yours sincerely,

24, Nov 2014

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Hospira ref:	**Q.FA.EMEA.2014.011**

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 - recall, 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.