



رقم المحفوظات: ٣١/٢٥
رقم الصادر: ١٢/١/٢٥٥٥٥٤
بيروت، في: ٣٠ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Infusion and transfusion, administration sets infusion
pump set. Primary Plumset

الجهاز المعنى بالمتابعة:

- Infusion and transfusion, administration sets infusion pump set. Primary Plumset
- Trade Mark: Hospira Inc
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد
أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات
المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

14th May 2013

FIELD SAFETY NOTICE PRIMARY PLUMSET™

Product name:	PRIMARY PLUMSET™
List Number:	<p><u>12193</u> Plum A+™ infusion set with two Clave™ needle free ports above pump. Polyethylene lined light protected set. Flotation ball in drip chamber.</p> <p><u>12194</u> Plum A+™ infusion set with two Clave™ needle free ports above pump. Flotation ball in drip chamber.</p> <p><u>12195</u> Plum A+™ infusion set with four Clave™ needle free ports above pump. Polyethylene lined light protected set. Flotation ball in drip chamber.</p> <p><u>12196</u> Plum A+™ infusion set with four Clave™ needle free ports above pump. Transparent polyethylene lined set. Flotation ball in drip chamber.</p>
Lot Numbers:	All.
EMEA FA ID:	Q.FA.EMEA.2012.018
Date:	14 th May 2013

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. has received customer complaints involving The Plum A+™ infusion set with Clave™ needle free ports. The Plum A+™ infusion set with Clave™ needle free ports above the pump can be used for treatments that include the sequential administration of up to 4 medications plus a primary diluent (such as saline or glucose) in appropriately assessed patients. As result of sequential administration of up to 4 medications, there can be the potential for contamination of the primary diluent (saline) between the administrations of more than one drug.

Issue: If the fluid level is not maintained in the sight chamber during infusion it is possible that manipulations to refloat the ball in the chamber may result in a small amount of retrograde flow of drug from the secondary (medication) line into the primary (diluent) line.

Risk to Health: This scenario may result in retrograde fluid flow from one secondary medication line to the primary diluent container and/or to another secondary medication line. There is the potential for the primary diluent to become contaminated by cytostatic drugs in a multi-therapy oncology administration. Contamination of primary diluent(s) with cytostatic drugs may cause Risk to Health of (a) Under-delivery if administration of primary medication is not completed per clinical practice, or (b) Particulate Matter resulting from mixing of incompatible medications.

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Registered in England No. 1923357

Required Action:

When priming and flushing with more than one secondary medication

- Ensure that the primary set is fully primed with fluid before beginning the infusion, such that the site chamber is 1/3 full.
- Maintain fluid in the sight chamber during infusion. Do not let it dry.
- If fluid level in sight chamber drops - Using one of the free CLAVE ports above the drip chamber and a 5mL syringe add 2mL of diluent to the drip chamber close the pinch clamp of the primary line above the drip chamber and gently squeeze the base of the drip chamber just to release the ball.
- Flush set from primary diluent bag between multiple medication infusions, as clinically appropriate
- Swab Clave Y site(s) before use
- Do not use needles in Clave Y site(s)
- When using Clave Y site(s), always verify flow
- At the end of secondary medication infusion, clamp secondary set, If primary sight chamber is empty, using one of the free CLAVE ports above the drip chamber and a 5mL syringe, add 2mL of diluent to the drip chamber, close the pinch clamp of the primary line above the drip chamber and gently squeeze the base of the drip chamber just to release the ball.
- Administer medication and flush per healthcare provider policy
- During treatment, periodically check all parameters related to the pump and infusion equipment per good clinical practice.

Delivery of sequential medications per healthcare provider policy:

- Recommendation to set a VTBI (Volume to be Infused) sufficiently smaller than the bag volume; in order to avoid an empty drip chamber.
- Always maintain fluid in the drip chamber during administration. Never let it dry.
- Recommendation on how to re-float the ball in the sight chamber: Close the pinch clamp of the primary line and then using one of the free CLAVE ports above the drip chamber and a 5mL syringe add 2mL of diluent to the drip chamber after that gently squeeze the base of the drip chamber just to release the ball.

Hospira Action: As a precaution measure to avoid possible contamination of the diluent, Hospira is updating the patient information leaflet and training literature. Hospira will be providing a training implementation plan to all applicable Healthcare Professionals.

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 complete the attached reply form to acknowledge receipt of this FSN and return it via fax to the number on the form.

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.

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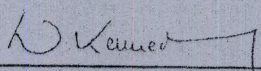
Please maintain awareness of this notice until Hospira notifies you of completion.

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,



Wilson Kennedy
EMEA Devices Quality Manager