RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٧/٢٥
رقم الصادر: ١٢/١/٣٢٨٩
بيروت، في: ٣١ تشرين الأول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Infusion and transfusion, administration sets infusion pump set. Administration sets (infusion pump, intravenous & blood transfusion)

الجهاز المعني بالمتابعة:

- Infusion and transfusion, administration sets infusion pump set. Administration sets (infusion pump, intravenous & blood transfusion)
- 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

الجمهورية اللبنانية
المديرية العامة
وزارة الصحة العامة

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

8th August 2013

FIELD SAFETY NOTICE
PRIMARY PLUMSET™ Clave secondary port

Product name:	**Administration sets (infusion pump, Intravenous & Blood transfusion)**
List Numbers:	**See below.**
Lot Numbers:	**All – manufactured after July 2007**
EMEA FA ID:	**Q.FA.EMEA.2013.019**
Date:	**8th August 2013**

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. (Hospira) has become aware of fluid leaking at the CLAVE secondary port of Hospira Plum-Set IV administration sets.

Issue: Hospira has received reports, including one that resulted in a serious injury, of fluid leaking at the CLAVE secondary port of Hospira Plum-Set IV administration sets during infusion due to the breaking of the bond between the CLAVE and the secondary port of the Plum™ cassettes. The breaking of the bond can manifest itself as either cracking of the bond between the CLAVE and the secondary port or the complete separation of the CLAVE from the secondary port.

Risk to Health: Breakage of the bond between the CLAVE connector and the secondary port of the Plum cassette may result in a health hazard due to a delay of therapy while the clinician obtains and installs another administration sets. Also, If there is a leak/break, there is a risk of skin exposure to chemotherapy medications. Complete separation of the CLAVE from the secondary port may lead to a gross leakage of fluid which should be immediately obvious. Cracking of the bond may not be easily identified and any leak may not be immediately obvious.

During an interrupted therapy, injuries may result which may be reversible with medical intervention. It is possible a patient receiving life-sustaining therapy will need medical intervention when therapy stops unexpectedly. Worst case in this situation is a progression of the untreated condition which does not readily reverse once therapy is resumed. Death or permanent harm such as that resulting from sepsis, including septic shock, could ensue during a prolonged delay in recognizing the defect.

Leakage of a caustic substance such as an oncolytic can result in short term harms such as pain or chemical burns, or a long-term harm such as tissue necrosis. Exposure to chemotherapeutic agents may result in several acute symptoms including cough; irritation of the mucosa, eyes, and skin; nausea, vomiting, diarrhoea; light headedness; and alopecia.

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

The risk of death or serious injury from these hazardous situations is extremely unlikely in the general patient population and unlikely in critically ill in patients receiving intravenous medications. The most reasonable harm expected in both populations is an injury that is medically reversible with medical intervention. In a hospital setting, this is expected to take place rapidly due to the presence of trained healthcare professionals.

Affected Product Details:

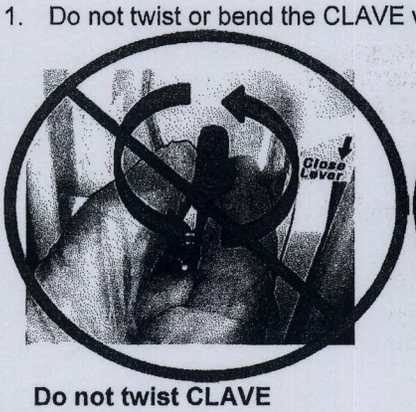
All lots manufactured after July 2007 from the list numbers detailed below are impacted by this issue.

121939228	121949228	121959228	121969228
140149228	121948424	121958424	140010728
140018328	140018428	140019228	140179228
140229228	142120428	142129228	146870428
196735324			

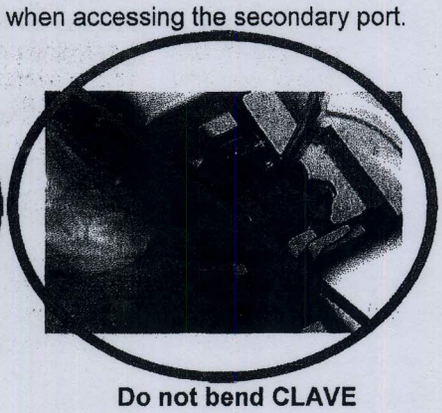
Instructions:

At this time there is no need to discontinue use of or return your Hospira Plum-Sets. In order to minimize the possibility of separation or breakage of the CLAVE directly bonded to the secondary port of the Plum cassette, Hospira recommends users follow the instructions below:

1. Do not twist or bend the CLAVE when accessing the secondary port.



Do not twist CLAVE



Do not bend CLAVE

2. Ensure all instructions for use included with the PlumSet are completely followed.
3. Ensure your facility's protocol for administering fluids and blood products are completely followed.

Product correction:

Hospira will be updating the instructions for use to reflect the recommendations above and will also be working to determine a different method by which the CLAVE can be bonded to the secondary port of Plum cassettes.

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 caused to you.

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

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.

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,

pp G. Hazlewood 08 Aug 2013

Wilson Kennedy
EMEA Devices Quality Manager

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