12 December 2012

URGENT FIELD SAFETY NOTICE
ALL HOSPIRA PLUM™ A+ FAMILY OF INFUSERS
Door Roller

Product name:	**Plum A+ Family of Infusers**
List Number:	**11005 Plum A+ Hyperbaric Infusion System** **11971 + 12391 Plum A+ single channel infusion system** **12348 + 12618 Plum A+3 infusion pump system** **20678 Plum A+3 Infusion Pump with Hospira MedNet™ Software** **20792 – Plum A+ infusion pump with Hospira MedNet™ software**
EMEA FA ID:	**Q.FA.EMEA.2012.015**
Date:	**12 December 2012**

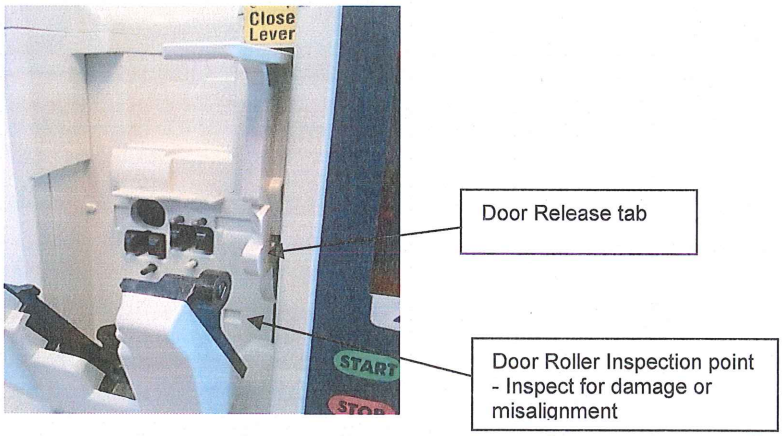
Dear Healthcare Professional and Hospira Customer,

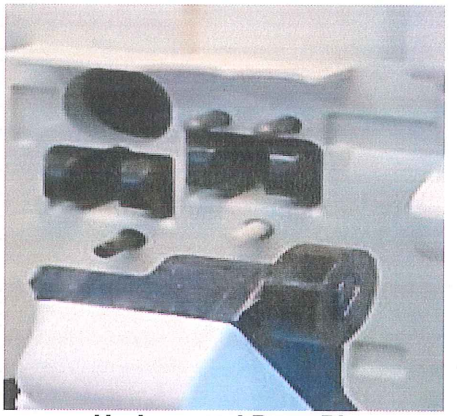
Hospira, Inc. is issuing this Field Safety Notice to inform you that the door roller assembly on the Plum A+/A+3 infuser family has the potential to break which can lead to possible unrestricted flow and/or over-delivery during the removal of the IV administration set's cassette from the pump. The IV administration set's cassette contains a flow regulator that is designed to close upon cassette removal to prevent accidental flow. In the event the door roller assembly is broken the regulator closer may not close properly and unrestricted flow and/ or over-delivery can occur which has the potential to contribute to life-threatening adverse events.

To correct this issue, Hospira has redesigned the door roller to improve the strength and reduce the potential for the door roller assembly to break. Hospira will be contacting you shortly to arrange for replacement door rollers. Until the door assembly is replaced, please inspect the door assembly prior to loading a cassette for signs of damage.

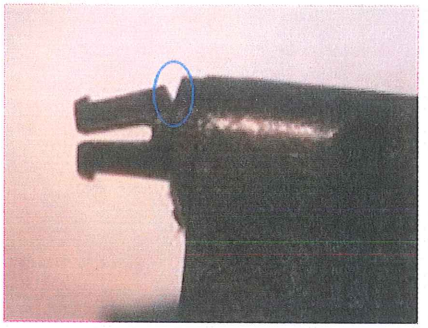
Please follow these steps to inspect your door roller assembly:

- Unlatch the cassette door from the opener handle assembly by pushing on the door release tab and open the door fully. (See picture below)
- Visually inspect the door roller for any evidence of damage or misalignment.
- Ensure that the door roller spins smoothly with a finger touch.

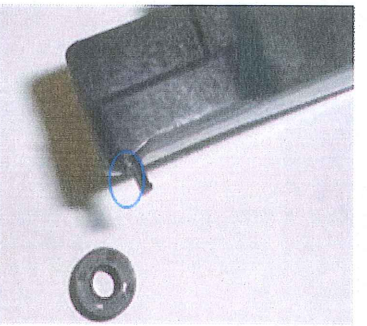




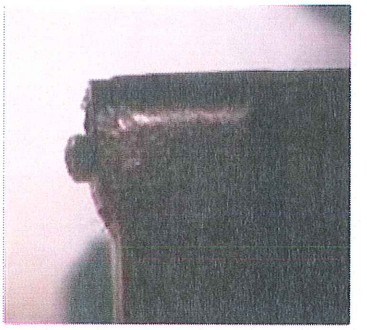
Undamaged Door Pin



Half of the pin damaged



Half of the pin broke off



Most of the pin broke off

If the door roller or axel appears loose, broken, or missing, then the device needs to be taken out of service until the door assembly is replaced with a corrected door assembly.

It is recommended to keep the cassette door securely closed while the product is not in use to avoid cassette door damage.

Additionally, to avoid the potential for accidental flow, close the slide clamp or CAIR™ roller clamp on the administration set prior to opening the door.

***Please complete the attached Reply Form indicating the number of impacted Plum A+ infusers 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.* It is important that you indicate the correct number of infusers on the reply form. Upon receipt of the FSN reply form, Hospira will work with customers to arrange Door Roller replacement at no charge, based on the number indicated on the reply form.

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 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.

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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 field safety notice.

Yours sincerely,

W. Kennedy

Wilson Kennedy
EMEA Devices Quality Manager

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URGENT FIELD NOTICE REPLY FORM

Product name:	**Plum A+ Family of Infusers**
List Number:	**11005, 11971, 12348, 12391, 12618, 20678, 20792.**
Lot Number/s:	

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:	**12 December 2012**

Section B

☐ I have read and understood the contents of this Field Action, 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 products.

OR

Section C

☐ I have read and understood the contents of this Field Action, and circulated it to all staff/departments that use this product.

OR

Section D

☐ Please indicate the number of Infusion Devices at your location.

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