CareFusion Switzerland 317 Sàrl
A-One Business Centre
Zone d'activités, Vers-la-Pièce No 10
Rolle, CH-1180
Switzerland
carefusion.com

Name
Address

URGENT FIELD SAFETY NOTICE

Product Name: **Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump**

Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005, 8007**

Product Name: **Asena™ GS, GH, CC, TIVA, PK Syringe Pumps**
Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005**

FSCA Identifier: **RA-2017-02-02**

Date: **March 2017**

Type of Action: **Field Safety Notice**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Description of the Problem

Based on reports from one customer in late 2016, BD/Carefusion identified a potential risk of syringe siphonage with Alaris Syringe Pumps which have a broken "plunger backplate spring" in the plunger backplate assembly.

It has been identified that a breakage of the plunger backplate spring may allow movement of the syringe plunger within the plunger holder mechanism which could result in siphonage. In some circumstances, this may result in a **clinically significant over infusion. Neonatal and paediatric patients, or those receiving critical drugs, at low infusion rates, would be considered to be the most at risk if small volumes of fluids reach the patient due to siphoning.**

The movement of the syringe within the plunger holder mechanism may cause the following system effects:

a) If the syringe plunger is not held firmly in place within the plunger holder mechanism, movement of the syringe plunger may result in siphonage and an unintended bolus of fluid/medication may occur.
b) The volume of the overinfusion will be dependent on factors such as the syringe brand, syringe size, syringe stiction (changing levels of friction as the plunger

moves) and the height of the pump above the patient. However, based on our analysis of the recommended syringes, the volume of the bolus may be between 0.14ml and 0.78ml.

c) The impact of the overinfusion may have increased clinical significance at lower infusion rates.
d) If the syringe plunger loses contact with the plunger button, the pump will audibly alarm, visually display "Check Syringe", and the infusion will stop.
e) Continued use of the pump following "Check Syringe alarms" may lead to multiple boluses being delivered, and as a result, increase the total volume of fluid delivered via siphonage

Action Required

1) The plunger backplate spring (see Appendix 4) should be replaced on syringe pumps older than three (3) years from date of manufacture. To identify the age of the pump, please refer to the label on the rear case, which will identify the date of manufacture.

2) The highest priority should be given to clinical areas such as neonatal, paediatric and critical care areas, where critical drugs are delivered at lower infusion rates.

3) If you see a "Check Syringe" alarm and there is no identifiable cause, the pump should be removed from clinical use and examined by qualified service personnel in accordance with the Alaris Syringe Pump Technical Service Manual.

The recommended method of detecting a broken spring is for a qualified service person to open the plunger assembly and visually inspect the spring.

Additional Alarms and Warnings in the Directions For Use (DFU)

As a result of this issue, we have updated the products' Directions For Use (DFU) to provide further clarification of what a "check syringe" alarm indicates, and the actions to take as a result:

> A "Check Syringe" alarm may indicate the incorrect size of syringe has been fitted; the syringe has not been positioned correctly, or has been disturbed during operation, for example, the user opens the syringe clamp, or If the syringe plunger loses contact with the plunger button.
>
> "If there is no identifiable cause for the "Check Syringe" alarm(s) then the pump should be removed from clinical use and examined by qualified service personnel in accordance with the Alaris Syringe Pump Technical Service Manual."

Preventative Maintenance and Correction

It has been identified that in syringe pumps older than three years, a broken plunger back-plate spring could lead to siphonage. Therefore the back-plate spring should be replaced. To identify the age of the pump, please refer to the label on the rear case, which will identify the date of manufacture. Please refer to the Alaris Syringe Pump Technical Service Manual via the following urls:

Syringe Pump Technical Service Manual MK3

http://www.bd-products.com/assets/supportdocs/protected/TSM_manual/1000SM00001.pdf

Syringe Pump Technical Service Manual MK4

http://www.bd-products.com/assets/supportdocs/protected/TSM_manual/1000SM00024.pdf

BD/CareFusion has changed the preventative maintenance recommendations in the Technical Service Manuals. BD/Carefusion has also released an Information Notice (IN0221).

This includes instructions on how to replace the plunger back-plate spring. Customers with Alaris syringe pumps will be requested to review the associated Alaris Syringe Pump Technical Service Manuals (10000SM00001 Issue 31, page 28 and 1000SM00024 Issue 4, page 22).

Preventative maintenance inspections should be performed at least every three years as detailed in the Technical Service Manual.

Prioritisation:

High priority should be given to clinical areas such as neonatal, paediatric and critical care areas, where critical drugs are delivered at lower infusion rates.
Particular attention should be paid to pumps older than 3 years. To identify the age of the pump, please refer to the label on the rear case, which will identify the date of manufacture.

Your competent authority has already been notified of this Field Safety Notice by BD/CareFusion's Authorised EU Representative.
Should you have any questions or require assistance relating to this Field Safety Notice, please contact your Local BD/CareFusion representative.
Please also refer to Appendix 3: Frequently Asked Questions.

We sincerely apologise for any inconvenience this action may have caused you or your staff.

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.
If you are no longer in possession of these pumps please pass this notice and all the related documentation on to the current user.

Sincerely,

Appendix 1 – To be completed and returned by End User

URGENT FIELD SAFETY NOTICE – Acknowledgement Form

Product Name: **Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump**

Product codes with prefix (all variants):**8001, 8002, 8003, 8004, 8005, 8007**

Product Name: **Asena™ GS, GH, CC, TIVA, PK Syringe Pumps**

Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005**

FSCA Identifier: **RA-2017-02-02**

Date: **March 2017**

Type of Action: **Field Safety Notice**

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

☐ I have read and understood the contents of this Field Safety Notice and will distribute this notice to all those who need to be made aware.

☐ I have reviewed and I am aware of the changes made to the Technical Service Manual and Directions for Use in relation to this matter.

☐ I will notify BD/CareFusion of the serial numbers of pumps in which the springs have been replaced and if the existing spring was found to be intact.

Please return to:

Local BD/CareFusion representative

Address:

Via Fax:

Via Email: