



Name  
Address

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### URGENT FIELD SAFETY NOTICE

Product Name: **Alaris™ / Asena™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump**  
Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005, 8007**  
FSCA Identifier: **RA-2018-03-01**  
Date: **May 2018**  
Type of Action: **Field Safety Notice**

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### ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Dear valued customer,

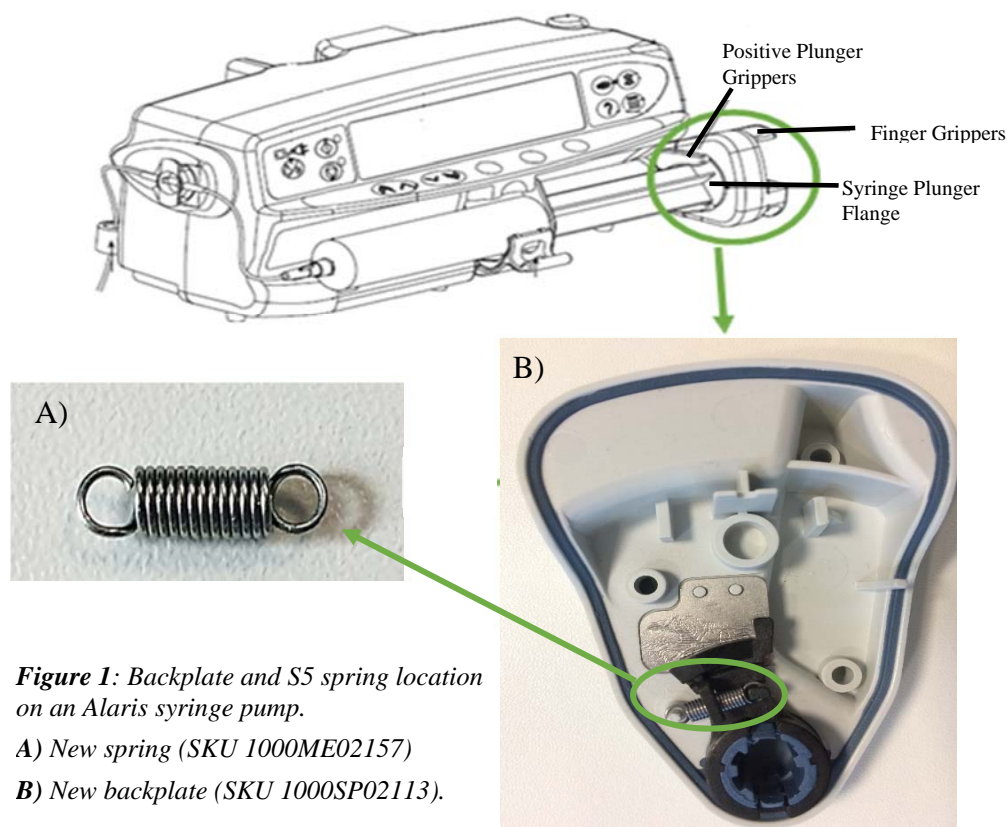
BD continuously strives to improve our product's performance and quality, with safety at the forefront of product development.

BD is undertaking a corrective action on its Alaris™ / Asena™ syringe pumps to replace the existing gripper plate actuating spring (S5) design with a new improved design, which is located on the back-plate of the syringe plunger holder as shown in Figure 1 A) and B). This is being undertaken to improve performance and reliability of the S5 spring to reduce the risk of harm to patients. This corrective action supersedes the Alaris™ / Asena™ syringe pump S5 spring replacement, FSN RA-2017-02-02, issued in March 2017.

### Description of the Problem

The S5 spring is located on the back-plate of the syringe plunger holder and ensures that the syringe plunger flange sits tightly between the positive plunger gripper and the back-plate.

BD has identified that the gripper plate actuating spring (S5), can break and may prevent the gripper fingers from securing the syringe plunger within the plunger holder mechanism which causes a small gap between the syringe plunger flange and the syringe drive mechanism. See Figure 1.



In some circumstances the gap between the syringe plunger flange and back-plate 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.

Specifically, the gap between the syringe plunger flange and back-plate may lead to the following hazardous situations:

1. Over infusion due to syringe siphoning of <1mL (0.37ml for 5mL syringes to 0.87ml for 50mL syringes) volume of fluid.
2. Delayed start of infusion when the system detects the syringe plunger flange is not in contact with the back-plate and will generate a Check Syringe alarm.

In addition, trouble-shooting of the CHECK SYRINGE alarm may result in the following use errors:

1. Continued use after receiving CHECK SYRINGE alarm without determining cause is contrary to the syringe pump Directions for Use (DFU). The DFU instructs users to "remove the pump from clinical use and have it examined by Qualified Service Personnel in accordance with the TSM if there is no identifiable cause for the CHECK SYRINGE alarm(s)".
2. While trouble shooting the CHECK SYRINGE alarm, the user may push the plunger holder against the plunger without first closing the in-line clamp. If the tubing is attached to a patient, unintended boluses and over infusion may result.

### **Alarms and Warnings in the Directions for Use (DFU)**

Users should be aware of the alarms and warnings highlighted in the new version of the Alaris™ syringe pump DFU, which provides clarification of what a "Check Syringe" alarm indicates and the actions to be taken 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."

Following feedback from the market, additional information regarding siphonage has been added to the DFU which the user should consider:

" When more than one pump is being used on a patient, those containing high risk, critical medications must be positioned as close to the patient's heart level as possible to avoid the risk of variations in flow or siphoning."

Further information relating to the positioning of the pump has been added in the *Syringe Loading* section of the new DFU.

**Please note:** The latest updated version of the DFU will be available on the BD website [www.bd.com/int-alaris-technical](http://www.bd.com/int-alaris-technical) by .....



## **Action Required**

- 1) Please acknowledge receipt of this Field Safety Notice (FSN) by completing and returning the Acknowledgement Form (Appendix I). Using the Acknowledgement Form, please confirm your preferred option for remediation. Please note that if you choose option 2 below, the FSCA acknowledgement form needs to be returned to BD prior to ordering the backplate assembly part number SKU 1000SP02113.

- a. **OPTION 1:** BD to carry out the backplate assembly replacement.

If you wish BD to provide this replacement service, please contact your local BD representative as soon as possible to make necessary arrangements.

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

- b. **OPTION 2:** The customer to carry out the backplate assembly replacement.

If you wish to perform the replacement yourself, please follow the backplate assembly replacement instructions accompanying this FSN (Appendix II). In this scenario, please contact your local BD representative to order the correct quantity of replacement backplate assemblies.

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

- 2) Before starting the backplate replacement activity as per this Field Safety Notice, please ensure that you scrap locally any spare parts or kits that include old backplates and the previous design of the S5 spring as per your internal procedures.

**Please note:** The action to replace the Alaris™/ Asena™ syringe pump S5 spring under this Field Safety Notice supersedes the S5 spring replacement under the Field Safety Notice RA-2017-02-02 issued in March 2017. Therefore the actions required under this Field Safety Notice should be carried out as soon as reasonably possible.



### **Preventative Maintenance and Correction**

It is highly recommended that routine preventative maintenance is carried out as per the Technical Service Manual. Preventative maintenance inspections should be performed at least every three years as detailed in the Technical Service Manual.

**Please note:** The Technical Service Manual has been updated to include the new backplate replacement instructions for routine preventative maintenance.

The latest updated version of the Technical Service Manual is located on the BD.com website, which can be found at [www.bd.com/int-alaris-technical](http://www.bd.com/int-alaris-technical).

Additionally, you can find the instructions on backplate replacement in Appendix II of this Field Safety Notice.

### **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 the Alaris™/ Asena™ syringe pumps included in this Field Safety Notice, please pass this notice and all the related documentation on to the current user(s).

Your competent authority/regulatory agency has already been notified of this Field Safety Notice by BD.

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your local BD representative.

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

**Sincerely,**



## Appendix 1 – To be completed and returned by End User

### URGENT FIELD SAFETY NOTICE – Acknowledgement Form

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

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

FSCA Identifier: **RA-2018-03-01**

Date: **May 2018**

Type of Action: **Field Safety Notice**

<b>Name of Hospital / Facility</b>	
<b>Hospital / Facility Address</b>	
<b>Telephone Number</b>	
<b>Name</b>	
<b>Signature</b>	
<b>Date</b>	

Please confirm the following by checking the box:

☐ I have read and understood the contents of this Field Safety Notice

**If your facility does not have any affected syringe pumps listed in this Field Safety Notice**, please confirm the following by checking the box:

☐ I confirm that our facility **does not have any** of the affected syringe pumps listed in this Field Safety Notice.

Please pass this notice and all the related documentation on to the current user if applicable.

**If your facility has any of the affected syringe pumps listed in this Field Safety Notice**, please complete Sections A, B and C below:

**Section A:** Please confirm **both** actions by checking the boxes

☐ I will distribute this Field Safety Notice to all those who need to be made aware.



- ☐ I have scrapped spare parts or kits that include backplate and previous design of S5 spring, following local procedure.

**Section B:** Please confirm **one** of the following options:

- ☐ BD to carry out the backplate assembly replacement.  
I will contact my local BD representative to make necessary arrangements.
- ☐ The customer facility will carry out the backplate assembly replacement.  
I confirm to bear the responsibility of correcting all the pumps in my possession as described in this Field Safety Notice. I will follow the backplate assembly replacement instructions in Appendix II. I will contact my local BD representative to order the correct quantity of replacement backplate assemblies.

**Section C:** To assist us to reconcile the models and numbers of syringe pumps at your facility, please provide the information below:

Syringe Pump Model	Number of syringe pumps
Alaris™/ Asena™ GS	
Alaris™/ Asena™ GH	
Alaris™/ Asena™ CC	
Alaris™/ Asena™ TIVA	
Alaris™/ Asena™ PK	
Alaris™/ Asena™ Enteral Syringe Pump	

Please return your completed Acknowledgement Form to:

Local BD representative

Address:

Or preferred option; please scan the Acknowledgement Form and send via email to:  
country specific inbox

## Appendix II – Plunger Backplate Replacement for RA-2018-03-01

When receiving the new backplate please follow the instructions below which outlines the method for replacing the backplate assembly.

See below for spring identification.

New Backplate



Old Backplate



For further information, please contact your local BD representative.

**A Plunger Back Plate Assembly Kit is available, part number 1000SP02113.**

1. Remove three screws holding plunger backplate.
2. Remove the plunger backplate.

**Note:** Be cautious when removing as parts may become loose. Placing the Pump in a vertical orientation may assist with maintaining components in place.

3. Visually inspect the interior of the plunger, follow the Technical Service Manual *Corrective Maintenance* for further details.
4. Refit the replacement plunger backplate assembly.
5. Fit the three screws into the plunger backplate. Make sure the backplate assembly is secure.
6. Discard the old backplate assembly following local procedure.

