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Name
Address

URGENT FIELD SAFETY NOTICE

Product Name:	**Alaris SMARTSITE ADD-ON BAG ACCESS DEVICE**
Product Number:	**10013365-0006**
Batch Numbers:	**15055147, 15065148, 15065656, 15075252, 15075795, 15076168, 15085110, 15085157**
FSCA Identifier:	**RA-2016-11-24**
Date:	**April 2018**
Type of Action:	**Removal & Destruction of Affected Products**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Description of the Problem

BD has received an increased rate of reports for separation and/or leakages at the spike port and the drip chamber spike connection.

BD is not aware of any report of injury attributed to this defect; however continued use of the affected products may cause the following:

- The clinician cannot immediately start the infusion at the first attempt causing a delay in receiving the treatment.
- During infusion, clinician notices a leakage. Clinician required to replace drug and infusion set up.

Please contact your local BD representative to order alternative products.

Products Potentially Affected

Our traceability analysis determined that you have received products that may present this defect.

Action Required

In order that the potentially affected products are removed from use and destroyed please follow instructions below:

<table>
<tr><th>Step</th><th colspan="2">Action</th></tr>
<tr><td rowspan="4">1</td><td colspan="2">Inspect inventory for product 10013365-0006 as applicable</td></tr>
<tr><td>If.....</td><td>Then.....</td></tr>
<tr><td>No affected Batch Numbers are found</td><td>• Complete sections A & B of Appendix 1</td></tr>
<tr><td>Affected Batch Numbers are found</td><td>• Complete sections A & C of Appendix 1
• Destroy affected product according to hospital protocol</td></tr>
<tr><td>2</td><td colspan="2">Return completed verification form (Appendix 1) to your BD representative no later than 31 July 2018</td></tr>
<tr><td>3</td><td colspan="2">Please contact your local BD representative to order alternative products.</td></tr>
</table>

On receipt of the completed verification form Appendix 1, BD will credit you for any product destroyed.

Your competent authority has already been notified of this Field Safety Corrective Action by BD's Authorised EU Representative.

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

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

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

Sincerely,

BD Representative

Appendix 1 – page 1

URGENT FIELD SAFETY NOTICE – Verification Form

Product Name:	**Alaris SMARTSITE ADD-ON BAG ACCESS DEVICE**
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Section A

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

Section B

☐ I have read and understood the contents of this Field Action and confirm that our inventory has been checked and we have no inventory of the listed products.

Section C

☐ I have read and understood the contents of this Field Action and confirm that our inventory has been checked and the following products have been destroyed:

Appendix 1 – page 2

URGENT FIELD SAFETY NOTICE – Verification Form

Product Name:	**Alaris SMARTSITE ADD-ON BAG ACCESS DEVICE**
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Date:	**April 2018**
Type of Action:	**Removal & Destruction of Affected Products**

Batch Number	Quantity Destroyed	Batch Number	Quantity Destroyed
15055147		15085157	
15065148			
15065656			
15075252			
15075795			
15076168			
15085110			

Please return to:

Address /email: