CareFusion International
A-One Business Centre
Z.A. Vers-la-Piece No 10
CH-1180 Rolle
Switzerland

carefusion.com

Name
Address

URGENT FIELD SAFETY NOTICE

Product Name:	**Alaris® SmartSite® Needle-Free Valve**
Product Reference:	**2000E7D**
Lot Numbers:	**Various lots with Polycarbonate Material**
FSCA Identifier:	**RA-2014-01-01**
Date:	**February 2014**
Type of Action:	**Removal & Destruction of Affected Products**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Description of the Problem

CareFusion has identified a potential risk with various lot numbers of the Alaris® SmartSite® Needle-Free Valve - 2000E7D made with Polycarbonate. The affected SmartSite connector lots may unintentionally disconnect from a female Luer, may be difficult to disconnect from a female Luer, or may fail to disconnect from a female Luer once attached. In rare occasions limited leakage may also be observed if the connector disconnects from the female Luer during infusion. An inability to disconnect may require replacement of a central or PICC line or catheter.

Note: This recall does NOT involve CareFusion's MaxPlus or MaxZero needle-free connectors. This recall does not affect any other SmartSite configurations or item numbers.

Potential Risk

A disconnection from the female Luer can cause a delay in the infusion, an interruption of infusion, an under infusion and/or potentially air entering the fluid path and/or limited leakage. An inability to disconnect can cause delay in infusion or an interruption to an infusion. We have not received any reports of serious injuries or death related to this issue.

Root Cause

The root cause is still under investigation. Preliminary analysis has indicated that SmartSite with polycarbonate material may cause incompatibility issues with the male Luer or thread housing when attaching to a female Luer.

SmartSite with acrylic material does not appear to cause these incompatibility issues and is not affected by this FSCA. There is a visible colour difference between the polycarbonate and acrylic base. The polycarbonate material is bluish-grey whilst the acrylic material is clear. As shown in the pictures below.

Polycarbonate Base

Acrylic Base

Products Potentially Affected

Lot numbers of SmartSite with polycarbonate are as follows:

13086202, 13086263, 13086309, 13095185, 13095913, 13095914, 13096487, 13096488, 13096489, 13105366, 13105478, 13106563, 13106710, 13106711, 13115316

Our traceability analysis has determined that you have received single SmartSite valves with polycarbonate material and therefore might experience 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 affected lot numbers of 2000E7D. (listed in Appendix 1)</td></tr>
<tr><td>If…</td><td>Then…</td></tr>
<tr><td>No affected lot numbers are found</td><td>• Complete sections A & B of Appendix 1</td></tr>
<tr><td>Affected lot 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 CareFusion representative no later than 31 May 2014</td></tr>
<tr><td>3</td><td colspan="2">Please contact your local CareFusion representative to order alternative products.</td></tr>
</table>

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

Your competent authority has already been notified of this Field Safety Corrective Action by CareFusion.

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 CareFusion 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,

Mirela Boureanu
Quality & Regulatory Affairs Manager
CareFusion UK
+44 (0)1256 38 8479 office direct
+44 (0)7834 016 979 mobile

Appendix 1

URGENT FIELD SAFETY NOTICE – Verification Form

Product Name:	**Alaris® SmartSite® Needle-Free Valve**
Product Reference:	**2000E7D – Various Lots**
FSCA Identifier:	**RA-2014-01-01**
Date:	**February 2014**
Type of Action:	**Removal & Destruction of Affected Products**

Section A

Name of Hospital / Facility	
Hospital / Facility Address	
Name of distributor (if applicable)	
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:

Batch Number	Quantity Destroyed	Batch Number	Quantity Destroyed	Batch Number	Quantity Destroyed
13086202		13095914		13105478	
13086263		13096487		13106563	
13086309		13096488		13106710	
13095185		13096489		13106711	
13095913		13105366		13115316	

Please return no later than **31 May 2014** to:
CareFusion representative: Miss Mirela Boureanu, mirela.boureanu@carefusion.com