Safety Notice
Medical Devices

IRISH MEDICINES BOARD

Alaris® SmartSite® Needle-Free Valve
Product Reference: 2000E7D

Priority 2 – Recall

IMB Safety Notice: SN2014(27) **Issue Date: 23 June 2014**

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
CareFusion Switzerland	V20264

ISSUE

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

ACTION OR RECOMMENDATIONS

The IMB advises that users:

(1) Forward this safety notice to all those who need to be aware of this action within your organisation, and to any other persons/organisations where these devices have been transferred. Maintain awareness of this safety notice for an appropriate time period.

(2) Inspect inventory for product affected lot numbers of 2000E7D, remove from use and destroy.

(3) Return the completed verification form in appendix 1 of the field safety notice (copy attached) to your local distributor representative.

TARGET GROUPS

Hospital CEO's Risk Managers Procurement Managers Clinical Personnel Biomedical Personnel	HSE Offices Ambulance Services Nursing Managers Nursing Staff

BACKGROUND

CareFusion initiated a product removal of Alaris® SmartSite® Needle-Free Valve, product reference 20007ED. CareFusion is requesting users to inspect inventory for affected product, remove from use and destroy.

Affected lot numbers of SmartSite, product reference 20007ED, with polycarbonate are as follows:

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

CareFusion's investigation is ongoing. Preliminary analysis has indicated that SmartSite, product reference 20007ED, 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 action.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Ms. Mirela Boureanu
CareFusion UK
The Crescent
Jays Close
Basingstoke
Hampshire RG22 4BS
United Kingdom

Telephone: +44-1256-388-479
E-mail: mirela.boureanu@carefusion.com
Website: www.carefusion.com

Enquiries to the **distributor** should be addressed to:

Ms. Paula Dillon
Aquilant Specialist Healthcare Services
Aquilant House
21 Fonthill Business Park
Fonthill Road
Clondalkin
Dublin 22

Telephone: 01-4048330
Fax: 01-4597169
E-mail: paula.dillon@aquilantservices.com
Website: www.aquilantservices.com

IMB CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Irish Medicines Board
Human Products Monitoring
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: 01-6764971
Fax: 01-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie