Medical Device Alert

Ref: MDA/2014/017 Issued: 21 May 2014 at 15:00

Device

Alaris® SmartSite® needle-free valve

Product reference: 2000E7D
Manufactured by CareFusion

Specific lot numbers

Problem

Risk of disconnection or inability to disconnect from the SmartSite could result in delay to treatment due to:

- air entering the fluid path
- replacement of a central catheter or PICC
- under-delivery and leakage of medication.

CareFusion issued a Field Safety Notice (FSN) in February 2014 providing advice on this problem.

Action

- Quarantine affected lot numbers of SmartSite as listed in the FSN.
- Follow instructions in the FSN including returning verification form to CareFusion.
- Ensure all users are aware of manufacturer's FSN
- Arrange for replacement devices.

Action by

All those responsible for the use, purchase, supply and distribution of these devices.

CAS deadlines

Action underway: 04 June 2014

Action complete: 18 June 2014

Note: These deadlines are for systems to be in place to remove affected devices from hospital stock and not for the completion.

Contact

Manufacturer
Mirela Boureanu
CareFusion UK
Tel: 01256 388 479
Email: mirela.boureanu@carefusion.com

Device

The Smartsite is a needle-free IV access device. Affected devices are made from a polycarbonate material.

The affected lot numbers are:
13086202, 13086263, 13086309, 13095185, 13095913, 13095914, 13096487, 13096488, 13096489, 13105366, 13105478, 13106563, 13106710, 13106711, 13115316.

If relevant to you, the national supply codes are as follows:
England NPC: FSW165
Scotland SKU: 066032
Northern Ireland BSO: does not have a PALS reference number
Wales NSV: FSN342

Only product code 2000E7D is affected and other configurations or item numbers are not affected.

This Medical Device Alert does not affect CareFusion's MaxPlus or MaxZero needle-free connectors.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS a|nd SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- A&E directors
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Clinical governance leads
- District nurses
- Health and safety managers
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Nursing executive directors
- Palliative care teams
- Paramedics
- Radiology departments
- Radiology directors
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospices
- Hospitals in the independent sector
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Mirela.Boureanu
CareFusion UK

Tel: 01256 388 479

Email: mirela.boureanu@carefusion.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/017** or **2014/003/018/081/001**

Technical aspects
Louise Mulroy and Patrick Sweeney
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7344 or 6898
Fax: 020 8754 3965

Email: louise.mulroy@mhra.gsi.gov.uk
patrick.sweeney@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965

Email: mark.grumbridge@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Email: improvingpatientsafety@wales.gsi.gov.uk