Medical Device Alert

Ref: MDA/2014/028 Issued: 11 July 2014 at 14:00

Device

Update to MDA/2014/022.

Procedure packs containing various central venous catheters: pressure injectable, multi-lumen and multi-lumen with Arrowg+ard® antimicrobial surface.

Specific product references and part numbers are affected.

Manufactured by Arrow International (a division of Teleflex).

Problem

Risk of incorrect lumen selection.

The extension lumen may have the wrong exit (proximal, medial, distal) and size printed on it, although the hub colour coding remains correct.

For example the distal lumen may be printed with the words ‘medial 18 GA’ instead of ‘distal 16GA’.

Arrow International issued a second Field Safety Notice (FSN) dated 20 June 2014, which informed users of an extension to their original FSN dated 15 May 2014. This extension now includes affected devices in procedure packs.

This Medical Device Alert is an update to MDA/2014/022 issued on 12 June 2014.

Action by

All those responsible for the insertion and use of these devices.

Action

Identify all additional affected stock using Appendix 2 of the FSN.

NHS supply chain codes are detailed below.

Ensure that all relevant clinicians and nursing staff are aware of this issue and receive a copy of the Arrow International second FSN.

Be guided by Arrow’s hub colour coding, not by what is printed on the lumen.

Arrow’s hub colour coding is:
White = proximal lumen = 18 GA
Grey = medial lumen 1 = 14 GA
Blue = medial lumen 2 = 18 GA
Brown = distal lumen = 16 GA

Report any cases of misprinted lumens to MHRA.

CAS deadlines

Action underway: 25 July 2014
Action complete: 08 August 2014

Note: These deadlines are for staff and patients to be aware of the problem and the advice in the manufacturer’s FSN.

Contact

Supplier
Hélène Sauvage
Teleflex
Tel: 01494 532 761
Email: orders.uk@teleflex.com

Device

Check Appendix 2 of the FSN for the full list of **additional** affected product codes.

If relevant to you, the national supply codes are as follows:

England NPC:

NHS Supply chain code	Manufacturer's part number	Product description
FSQ1653	AR12854-MRI	Manchester 4L CVC INS Pack 8.5Fr x 16cm
FSQ1311	AR22854-HCH	HCH 4L AGB CVC PACK 8.5FR 16CM
FSQ372	AR22854-INSP	INSP 16CM 4L AGB ARS CVC PACK
FSQ1654	AR22854-MRI	MANCHESTER ROYAL INFIRMARY AGBQUAD

Northern Ireland:

Manufacturer's codes as in Appendix 2 of the FSN.

Scotland SKU:

Manufacturer's codes as in Appendix 2 of the FSN.

Wales NSV:

Manufacturer's codes as in Appendix 2 of the FSN.

Problem

Clinicians and nursing staff may rely on the printed information on the catheter lumens to identify them and to select the appropriate lumen to deliver blood and other fluids.

Misprinted lumens could lead to a range of problems, if used inappropriately.

Action

MHRA is not proposing a recall or elective replacement of in situ catheters.

Please make appropriate checks and ensure that lumens are used according to your organisation's protocol.

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)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- Public Health England (for information)

Onward distribution

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

Trusts

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

- A&E consultants
- A&E departments
- A&E nurses

- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Clinical perfusionists
- Coronary care departments
- Coronary care nurses
- Endocrinology units
- Endocrinology, directors of
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Hospital at home units
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- 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
- Medical oncologists
- Medical oncology, directors of
- Neonatology departments
- Nutrition nurses
- Obstetricians
- Obstetrics and gynaecology departments
- Oncology nurse specialists
- Orthopaedic surgeons
- Paediatric intensive care units
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatricians
- Paediatrics departments
- Peritoneal dialysis units
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiologists
- Radiology departments
- Renal medicine departments
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Nutritional nurse specialists

Independent distribution

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

This alert should be read by:

- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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

Supplier

Hélène Sauvage
Arrow International Inc.
c/o Teleflex
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath
Ireland

Tel: 01494 532761
Fax: 01494 524650
Email: orders.uk@teleflex.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/028** or **2014/005/016/291/001**

Technical aspects

Elke Kerwick & Sharon Knight
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6826 / 7202
Fax: 020 8754 3965
Email: elke.kerwick@mhra.gsi.gov.uk
sharon.knight@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
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London SW1W 9SZ

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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