

Medical Device Alert

Ref: MDA/2014/022 Issued: 12 June 2014 at 14:00

Device

Central venous catheters:
various 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	Action
<p>Risk of incorrect lumen selection.</p> <p>The extension lumen may have the wrong exit (proximal, medial, distal) and size printed on it, although the hub colour coding remains correct.</p> <p>For example the distal lumen may be printed with the words 'medial 18 GA' instead of 'distal 16GA'.</p> <p>Arrow International issued a Field Safety Notice (FSN) dated 15 May 2014.</p>	<p>Identify all affected stock using Appendix 1 of the FSN.</p> <p>NHS supply chain codes are detailed below.</p> <p>Ensure that all relevant clinicians and nursing staff are aware of this issue and receive a copy of the Arrow International Field Safety Notice (FSN).</p> <p>Be guided by Arrow's hub colour coding, not by what is printed on the lumen.</p> <p>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</p> <p>Report any cases of misprinted lumens to MHRA.</p>
Action by	
<p>All those responsible for the insertion and use of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 26 June 2014 Action complete: 10 July 2014</p> <p>Note: These deadlines are for staff and patients to be aware of the problem and the advice in the manufacturer's FSN.</p>	<p>Supplier Hélène Sauvage Teleflex Tel: 01494 532 761 Email: orders.uk@teleflex.com</p>

Device

Check Appendix 1 of the [FSN](#) for the full list of 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
FSQ489	BR-10854	8.5FR x 11cm set plus 3 way tap and scalpel
FSQ607	BR-12854	8.5FR x 16cm Hi Flo with stop cocks
FSQ443	BR-15854	8.5FR x 20cm set plus 3 way tap and scalpel
FSQ965	BR-20854	8.5FR x 11cm Quad lumen antimicrobial CVC with 3 way stopcock
FSQ609	BR-22854	8.5FR x 16cm anti-microbial Arrow Gard blue mid range set with stop cocks
FSQ611	BR-25854	8.5FR x 20cm anti-microbial Arrow Gard blue mid range set with stop cocks
FSQ599	CK-15854E	8.5FR x 20cm comprehensive pack
FSQ545	CS-12854-E	8.5FR x 16cm set with Raulerson syringe
FSQ444	CS-14854-E	8.5FR x 30cm set with Raulerson syringe
FSQ1458	CS-15854-E	8.5FR x 20cm Quad-lumen central venous catheterization set with blue flextip catheter
FSQ447	CS-22854-E	8.5FR x 16cm set with Raulerson syringe and Arrowgard plus blue antimicrobial surface treatment
FSQ448	CS-25854-E	8.5FR x 20cm set with Raulerson syringe and Arrowgard plus blue antimicrobial surface treatment
FSQ1461	CS-42854-E	8.5FR x 16cm 4 lumen central venous catheter with arrowg+ard blue plus antimicrobial technology.
FSQ440	CV-12854	8.5FR x 16cm set
FSQ441	CV-15854	8.5FR x 20cm set
FSQ445	CV-22854	8.5FR x 16cm set with Arrowgard plus antimicrobial surface treatment
FSQ446	CV-25854	8.5FR x 20cm set with Arrowgard plus antimicrobial surface treatment

Northern Ireland:

FVB000031	BR-15854	ARROW	AKI	BR-15854 4L CVC SET 8.5FR 20CM STOPCOCKS(5)
FVB000024	BR-22854	ARROW	AKI	BR-22854 4L CVC SET AGB 8.5FR 16CM STOPCOCKS(5)
FVB000025	BR-25854	ARROW	AKI	BR-25854 4L CVC SET AGB 8.5FR 20CM STOPCOCKS(5)
FVB000028	CS-12854-E	ARROW	AKI	CS-12854-E CATHETER QUAD LUMEN, 8.5FR, 16CM, WITHOUT COATING
FVB000367	CS15854E	ARROW	AKI	4 LUMEN CVC SET ARS 8.5FR 20CM (5)
FVB000029	CS-15854-E	ARROW	AKI	CS-15854-E CATHETER QUAD LUMEN, 8.5FR, 20CM, WITHOUT COATING
FVB000022	CS-22854-E	ARROW	AKI	CS-22854-E CATHETER QUAD LUMEN, 8.5FR, 16CM, WITH ARROW GUARD
FVB000023	CS-25854-E	ARROW	AKI	CS-25854-E CATHETER QUAD LUMEN, 8.5FR, 20CM, WITH ARROW GUARD
FVB000026	CV22854SR	ARROW	ACW	CV22854SR 4L CVC SET AGB 8.5FR 16CM ONC

Scotland SKU:

028030	BR-12854	CVC SET:4 LUMEN 8.5 FR X 16CM
137954	CS-22854-E	CVC SET:4 LUMEN 8.5 FR X 16CM
083053	CS-25854-E	CVC SET:4 LUMEN 8.5 FR X 20CM
061693	CV-12854	CVC SET:4 LUMEN 8.5 FR X 16CM
091065	CV-22854	CVC SET:4 LUMEN 8.5 FR X 16CM

Wales NSV:

Manufacturer's codes as in Appendix 1 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

- Dermatologists
- Endocrinology units
- Endocrinology, directors of
- ENT departments
- ENT medical staff
- 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
- Palliative care teams
- Peritoneal dialysis units
- Phlebotomists
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiographers
- Radiologists
- Radiology departments
- Renal medicine departments
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Sterile services departments
- 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/2014/022** 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
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.irc@nhs.net

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

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