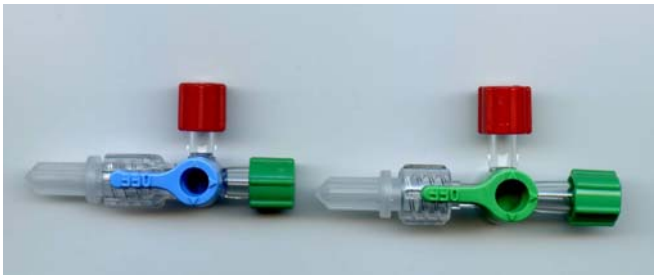
Medical Device Alert

Action

Ref: MDA/2009/047 Issued: 27 July 2009 at 16:00

Device

Stopcocks (catalogue numbers W20058 and W21372) and specific products containing non-lipid resistant stopcocks, manufactured by Arrow®.



Problem

Risk of leakage or air embolism due to hub cracking at the female Luer connector during delivery of infusions containing lipids.

Action

- Identify if you have any of the affected devices.
- Do not administer lipid-containing infusions using these devices.

Action by

All Medical and nursing staff.

CAS deadlines

Action underway: 17 August 2009

Action complete: 07 September 2009

Contact

Manufacturer/supplier
Helen Sauvage
UK customer Service
Teleflex Medical

Tel: 01494 532 761

E-mail: hsauvage@teleflexmedical.com

Link to full Medical Device Alert

Device

The stopcocks are manufactured by Arrow® International, which is a subsidiary of Teleflex Medical.

Product codes AH-05050-G, AI-07077-G, AH-05050-PU, AI-07077-PU (regardless of batch number) contain non-lipid resistant stopcocks. Only product codes with batch numbers ZFxxxxxxx contain lipid resistant stop cocks. This is summarised in the table below:

Product codes	Lipid resistant batches	Non-lipid resistant batches
AH-05050-G	None	All
AH-05050-PU		
AI-07077-G		
AI-07077-PU		
All product codes listed in Appendix A of the Field Safety Notice	Lot numbers beginning with the letter ZF and followed by seven digits, e.g. ZFxxxxxxx.	All other Lot numbers

Problem

Teleflex Medical has determined that the material used in the manufacture of these stopcocks is not lipid resistant and could be weakened during the administration of lipid solutions. These stopcocks, and the kits containing them, should be used only to administer non-lipid containing solutions. Teleflex originally issued a Field Safety Notice (FSN) in March 2009 that highlighted these risks. However, the sample product label in this FSN carried an extra warning not to use 70% isopropyl alcohol on the stopcocks. After further testing, Teleflex has determined that these stopcocks (distributed in the United Kingdom) can in fact be wiped with 70% isopropyl alcohol solutions without harmful effects. As a consequence, Teleflex has now issued an amended FSN in July 2009 with a revised product label.

This Medical Device Alert has been issued due to the widespread use of these stopcocks and to ensure that all users are aware of this amended field safety corrective action.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- HSC Trusts in Northern Ireland (Chief Executives)
- NHS Boards in Scotland (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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

- All clinical departments
- All wards
- Anaesthetists
- Chief pharmacists
- Clinical governance leads
- Clinical perfusionists
- Day surgery units
- Infection prevention and control directors
- IV nurse specialists
- Medical directors
- Medical staff
- Nursing executive directors
- Nursing staff
- Paramedics
- Resuscitation officers and trainers

- Risk managers
- Supplies staff
- Theatres

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be of importance to:

- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

Primary care trusts to:

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

- Community children's nurses
- Community hospitals
- Community nurses
- District nurses

Contacts

Manufacturer/supplier
Helen Sauvage
UK customer Service
Teleflex Medical
Tel: 01494 532 761
E-mail: hsauvage@teleflexmedical.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/047 or 2009/003/010/061/004.**

Technical aspects
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Clinical aspects
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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 (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523 704
Fax: 02890 523 900

E-mail: 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

Enquiries and adverse incident reports in Scotland should be addressed to:

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

Tel: 0131 275 7575
Fax: 0131 314 0722

E-mail: 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:

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E-mail: Haz-Aic@wales.gsi.gov.uk