

Medical Device Alert

Ref: MDA/2013/047 Issued: 27 June 2013 at 14:00

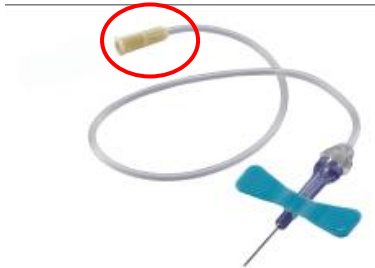
Device
<p>Safety blood collection and infusion sets.</p> <p>Various item and lot numbers.</p> <p>Manufactured by Greiner Bio-One.</p>

Problem	Action
<p>Risk of leakage of blood or infusion fluid, or under-filling of evacuated blood collection tubes or blood culture bottles.</p> <p>This product is being recalled due to potential cracking of the Luer connector on these devices.</p>	<p>Identify and quarantine affected products.</p> <p>Greiner Bio-One issued a Field Safety Notice (FSN) in March 2013 recalling affected products.</p> <p>Confirm receipt of the FSN to Greiner Bio-One and arrange for the return and replacement of unused affected devices.</p>
Action by	
<p>All health and care workers who use these devices and those involved in their purchase, supply and distribution.</p>	
CAS deadlines	Contact
<p>Action underway: 11 July 2013</p> <p>Action complete: 29 July 2013</p> <p>Note: These deadlines are for unused, affected products to be removed from use.</p>	<p>Manufacturer Noel Ennett Greiner Bio-One Ltd Tel: 01453 852283 Email: noel.ennett@gbo.com</p>

Device

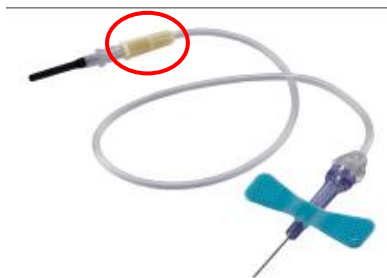
The affected devices are illustrated below. The area where the crack may occur is circled. A list of the affected item codes and lot numbers are provided in the [FSN](#). The NHS Supply Chain codes (England only) corresponding to the manufacturer's item codes are given as below.

Safety infusion sets



Greiner Bio-One code	NHS Supply Chain code	LOT Numbers
450092	KFK 024	12H23

Safety blood collection sets with Luer adapter



Greiner Bio-One code	NHS Supply Chain code	LOT Numbers
450081	KFK 134	12H23, 12H24, 12I17, 12I26, 12H30
450082	KFK 136	12H21, 12H22, 12H30
450083	none	12I16
450084	none	12H29
450095	KFK 302	12H19, 12I22
450099	none	12H26

Safety blood collection sets with Luer adapter and holder



Greiner Bio-One code	NHS Supply Chain code	LOT Numbers
450086	KFK 138	12H28, 12H25, 12H27, 12I26, 12I24, 12I25

Safety blood collection sets with blood culture holder



Greiner Bio-One code	NHS Supply Chain code	LOT Numbers
450182	KFK 416	12H21, 12H30,
450184	KFK 418	12H22, 12H23,
450185	KFK 419	12H24, 12H23, 12I20

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

- All clinical departments
- All staff
- All wards
- Clinical governance leads
- Community children's nurses
- Community hospitals
- Community midwives
- Community nurses
- District nurses
- Equipment stores
- Hospital at home units
- IV nurse specialists
- Medical directors
- NHS walk-in centres
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Phlebotomists
- Purchasing managers
- Risk managers
- Supplies managers
- Walk-in centres

NHS England area teams

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

- Practice managers
- Practice nurses

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- 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

Manufacturer

Noel Ennett

Greiner Bio-One Ltd, Brunel Way, Stroudwater Business Park, Stonehouse, Gloucestershire, GL10 3SX

Tel: 01453 852283

Email: noel.ennett@gbo.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/047** or **2013/004/002/081/007**.

Technical aspects

Ainsley Wickens or Francesca Edelmann

Medicines & Healthcare Products Regulatory Agency

Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7273 / 6716 Fax: 020 8754 3965

Email: ainsley.wickens@mhra.gsi.gov.uk
francesca.edelmann@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge

Medicines & Healthcare Products Regulatory Agency

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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

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

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk

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