Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/041 Issued: 04 December 2019 at 12:00

Spectra Optia apheresis: anticoagulant bags used with ‘Correct Connect’ connectors – risk of unbroken ‘frangible’ connector during use

Summary

Manufactured by Terumo BCT – inadequately broken anticoagulant ‘frangible’ may lead to clotting and inadequate therapy during apheresis procedures.

Action

- Identify affected apheresis systems in your organisation

- Ensure that:
  - Staff are aware that anticoagulant bags used with Correct Connect will have a component called a ‘frangible’ connector that needs to be broken when used with the Spectra Optia apheresis system.
  - Note the manufacturer’s Field Safety Notice and to ensure that the relevant set up information in the Quick Reference Guides is followed, particularly when connecting subsequent anticoagulant bags.
  - Return the Field Safety Notice acknowledgement form to Terumo BCT.
    The manufacturer hasn’t received enough responses.
  - If further training is required, contact the manufacturer directly to arrange this.
  - Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
Staff involved in donor and therapeutic apheresis treatments

Deadlines for actions
Actions underway: 27 December 2019
Actions complete: 24 January 2020

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

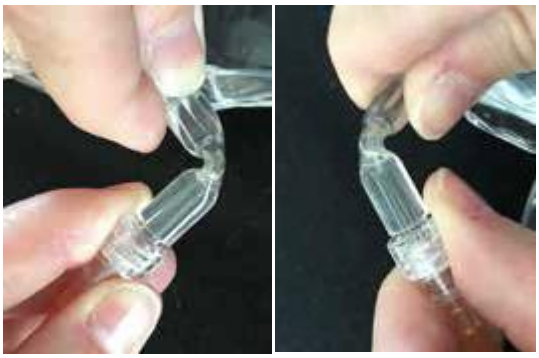
NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Affected apheresis systems are those used for donor and/or therapeutic apheresis procedures such as peripheral blood stem cell collection.

In July 2017 Terumo BCT introduced a new, connector for their anticoagulant (ACD-A) solutions used with donor and therapeutic apheresis devices. This connector is called CORRECT CONNECT and is designed to reduce the potential for accidental misconnections of the solution lines. The solution bag side of the connector contains a ‘frangible’ that must be broken by the apheresis operator to allow the flow of anticoagulant into the system. The frangible must be broken each time a new anticoagulant bag is connected during a procedure.



Problem / background

MHRA has received reports of users being unaware of an unbroken, or inadequately broken ‘frangible’ on anticoagulant (ACD-A) bags, particularly when a second bag has been connected during a procedure.

Manufacturer contacts

Terumo BCT
Tel: 00 32 27150314
Email: EMEAProduct.FSN@terumobct.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Biomedical engineering staff
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Fracture clinics
- Haematologists
- Intensive care medical staff/paediatrics

- IV nurse specialists
- Medical directors
- Medical oncologists
- Neonatology departments
- Neonatology directors
- Oncology nurse specialists
- Pathology departments
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Purchasing managers
- Radiation & medical oncology departments
- Supplies managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector
- Independent treatment centres

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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/041** or **2018/010/001/401/004**.

Technical aspects

Roopa Prabhakar or Emma Rooke MHRA
Tel: 020 3080 6000
Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).