



Medical Device Alert

MDA/2016/021

Issued: 27 October 2016 at 14:00

Total intravenous anaesthesia sets (TIVA) – risk of leakage during use

Summary

Manufactured by Global Components Medical Ltd – if propofol leaks from the check valve Luer lock connector patients could become aware during surgery.

Action

The manufacturer is due to release updated instructions for use to include recommendations for handling the Luer lock connectors in the anaesthesia set.

Whilst waiting for this advice, please ensure that you:

- identify whether you have stocks of any of the product codes listed on page 2
- use alternative devices if possible.

If no alternatives are available:

- contact the manufacturer to obtain advice on tightening the Luer connector in the anaesthesia set
- be vigilant over possible leakages, particularly after more than one use e.g. after multiple syringe changes.

Action by

All medical and nursing staff.

Deadlines for actions

Actions underway: 10 November 2016

Actions complete: 24 November 2016

Device details

Product code	Description
GCM-1003	10 METRE TIVA MRI SET
GCM-223	3 WAY TIVA SET 2.2 METRE
GCM-223B	3 WAY MULTIPLE INFUSION TIVA SET 2.2 METRE BASIC
GCM-253	3 WAY TIVA SET 2.5 METRE
GCM-253B	3 WAY MULTIPLE INFUSION TIVA SET 2.5 METRE BASIC
GCM-303B	3 WAY MULTIPLE INFUSION TIVA SET 3.0 METRE BASIC
GCM-304	4 WAY TIVA SET 4.0 METRE
GCM-SPCA	SEDATION PCA SET 2.2 METRE

Manufacturer contacts

Global Components Medical Ltd

Tel: 01276 679394

Email: regulatory@global-medical.co.uk

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

- All departments
- All wards
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Coronary care nurses
- Day surgery units
- Equipment stores
- General surgeons
- General surgery
- Infection prevention and control directors
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Theatres

Independent distribution

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

- Care homes providing nursing care (adults)
- Hospices
- 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 Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2016/021** or **2015/010/008/601/005**.

Technical aspects

Roopa Prabhakar or Helen Stidwill, MHRA

Tel: 020 3080 7293 / 7047

Email: roopa.prabhakar@mhra.gsi.gov.uk or helen.stidwill@mhra.gsi.gov.uk

Clinical aspects

Dr Camilla Fleetcroft, MHRA

Tel: 020 3080 6097

Email: Camilla.fleetcroft@mhra.gsi.gov.uk

Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

Northern Ireland

Alerts in Northern Ireland are distributed via the [NI SABS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
<https://www.health-ni.gov.uk/niaic>

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

Scotland

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

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – [report to Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – [report to Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

Wales

Enquiries in Wales should be addressed to:

Healthcare Quality Division
Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health
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