

Medical Device Alert

MDA/2015/005

Issued: 18 February 2015 at 15:00

CEM™ nosecones for use with CUSA® Excel/Excel+ ultrasonic aspirator.
Manufactured by Integra LifeSciences.

Summary

Risk of burns to patient or user if the blue COAG button on the CUSA Excel CEM nosecone sticks in the 'activated' position.

Action

- Identify affected devices.
- Ensure members of staff are aware of the updated advice and guidance detailed in the manufacturer's re-issued [Field Safety Notice](#) (FSN) dated 12 December 2014.
- Have spare nosecones readily available for use.
- Complete and return the manufacturer's acknowledgement form in the FSN.
- Use alternative devices where possible.
- Report any adverse incidents to Integra LifeSciences and MHRA (through [Yellow Card](#)).

Action by

- Operating theatre staff.
- Supplies department staff.
- Surgeons.

Deadlines for actions

Actions underway: 04 March 2015

Actions complete: 18 March 2015

Device details

CUSA CEM nosecones for use with the CUSA Excel/Excel+ ultrasonic aspirator.

Product codes: C6623 and C6636.

Problem / background

The blue COAG button on the CUSA Excel CEM nosecone can stick in the 'activated' position. Integra has received a number of complaints of tissue burn because of this problem.

Integra issued a FSN to users in December 2013 (see [MDA/2014/006](#)) but has re-issued the FSN (12 December 2014) as an update to the previous communication.

The FSN reminds users about important safety information, and provides clarification on device activation times. However, Integra has not received enough responses to be confident that users have received and acted on this information.

Integra is currently validating a new design, and new product should be available by June 2015.

Manufacturer contacts

Manufacturer

Angelique Aubert

Integra LifeSciences

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Distribution

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

Trusts

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

- All surgeons
- Biomedical engineering staff
- Clinical governance leads
- Equipment stores
- Health and safety managers
- Maternity units
- Medical directors
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

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 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/2015/005** or **2013/012/023/291/021**.

Technical aspects

Patrick Sweeney or Paul Sandhu, MHRA

Tel: 020 3080 6898 / 7266

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paul.sandhu@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge MHRA

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Email: mark.grumbridge@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 Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>**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: 01267 225278 / 02920 825510

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 an executive agency of the Department of Health

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