

# Medical Device Alert

Ref: MDA/2014/006 Issued: 26 February 2014 at 14:30

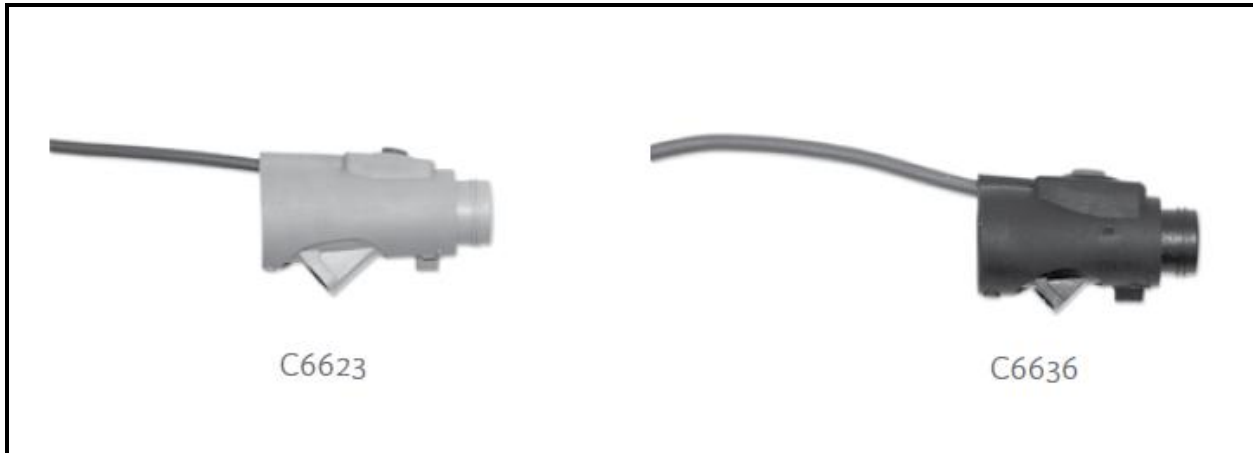
Device
<p>Electrosurgical devices.</p> <p>CUSA CEM™ nosecones for use with the CUSA® Excel/Excel+ ultrasonic aspirator.</p> <p>Product codes: C6623 and C6636.</p> <p>Manufactured by Integra Lifesciences.</p>

Problem	Action
<p>Risk of burns to patient or user.</p> <p>The manufacturer has identified that the blue COAG button on the CUSA® Excel CEM™ nosecone could stick in the 'activated' position. This failure can occur whilst the device is being used with the CUSA® Excel/Excel+ ultrasonic aspirator.</p> <p>Integra Lifesciences is in the process of modifying the design to mitigate the risk of failure. The new design will not be available before the end of September 2014.</p>	<p>Identify affected devices.</p> <p>Ensure members of staff are aware of the advice and guidance detailed in the manufacturer's <a href="#">Field Safety Notice</a>.</p> <p>Have spare nosecones readily available for use.</p> <p>Complete and return the manufacturer's acknowledgement form.</p> <p>Use alternative devices where possible.</p> <p>Report any adverse incidents to Integra Lifesciences and the MHRA.</p>
Action by	
<p>Operating theatre staff. Surgeons. Supplies department staff.</p>	
CAS deadlines	Contact
<p>Action underway: 05 March 2014</p> <p>Action complete: 19 March 2014</p> <p><b>Note: These deadlines are for systems to be in place to identify devices and be aware of the issues.</b></p>	<p><b>Manufacturer</b> Jean-Charles Moncenis Integra Lifesciences Tel: +33 (0) 4 37 47 59 00 Email: <a href="mailto:emea-fsca-neuro@integralife.com">emea-fsca-neuro@integralife.com</a></p>

## Device

CUSA CEM™ Nosecones, shown below, are for use with the CUSA® Excel/Excel+ Ultrasonic Aspirator.

Product codes: C6623 and C6636.



## 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 for information
- 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 surgeons
- All theatres
- Clinical engineering departments
- Clinical governance leads
- Equipment stores
- Health and safety managers
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses

### Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres
- 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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Integra LifeSciences Services  
Immeuble Sequoia 2  
97 allée Alexandre Borodine  
69800 Saint Priest  
France

Tel: +33 (0) 4 37 47 59 00

Fax: +33 (0) 4 37 47 59 30

Email: [emea-fsca-neuro@integralife.com](mailto:emea-fsca-neuro@integralife.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/006** or **2013/012/023/291/021**

### Technical aspects

Patrick Sweeney or Paul Sandhu  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 6898 / 7266

Fax: 020 8754 3965

Email: [patrick.sweeney@mhra.gsi.gov.uk](mailto:patrick.sweeney@mhra.gsi.gov.uk)  
[paul.sandhu@mhra.gsi.gov.uk](mailto:paul.sandhu@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto: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](mailto: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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other 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](mailto: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 5801

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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