

Medical Device Alert

Ref: MDA/2011/063 Issued: 06 June 2011 at 15:00

Device

Neonatal resuscitation systems.

Manufactured by Intersurgical Ltd.

Product codes 6181, 6308, 6315, 6354, 6354001 and 6356 are affected.



Problem

The manufacturer issued a Field Safety Notice (FSN) for this device on 19 May 2011.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

Action by

Healthcare professionals using these regulators.

CAS deadlines

Action underway: 20 June 2011

Action complete: 04 July 2011

Action

- Ensure that relevant members of staff are aware of the problem.
- If you have affected devices carry out the actions described in the manufacturer's FSN.

Contact

Manufacturer

Chris Randall
Intersurgical Ltd

Tel: 0118 965 6300

Email: cpr@intersurgical.co.uk

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care 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:

- A&E departments
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- Hospital at home units
- Maternity units
- Neonatal nurse specialists
- Operating department practitioners
- Paediatric intensive care units
- Paediatric wards
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Theatre nurses
- Theatres

Primary care trusts

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

- Community hospitals
- Minor injury units

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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

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Crane House
Molly Millars Lane
Wokingham
RG41 2RZ

Tel: 0118 965 6300

Fax: 0118 965 6356

Email: cpr@intersurgical.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/063** or **2011/001/012/401/011**

Technical aspects

Douglas McIvor or Nicola.Ridd
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7193 / 7039

Fax: 020 8754 3965

Email: douglas.mcivor@mhra.gsi.gov.uk
nicola.ridd@mhra.gsi.gov.uk

Clinical aspects

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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

Health Facilities Scotland

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:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

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

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Addressees may take copies for distribution within their own organisations

Appendix

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Urgent Field Safety Notice - Neonatal Resuscitation Systems

Manufacturer: Intersurgical Ltd

FSCA-identifier: 2011114

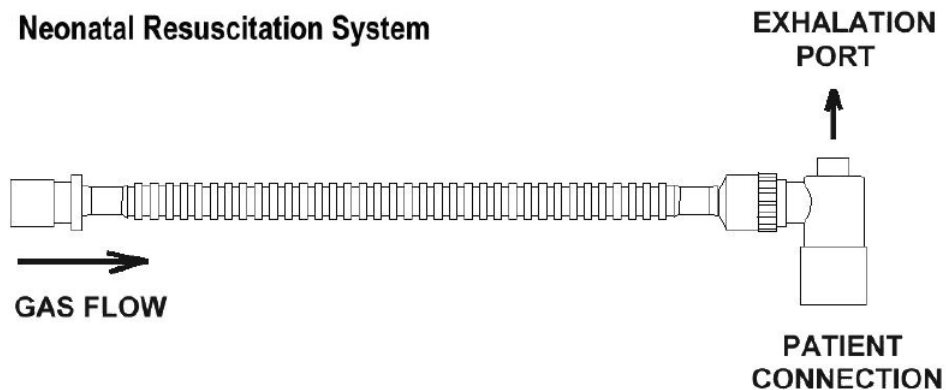
Date: 19 May 2011

Attention: All clinicians who may perform neonatal resuscitation.

Type of action: Dissemination of information describing a potential hazard associated with the use of neonatal resuscitation systems in which the exhalation port can be closed with a cap.

Details of Affected Devices:

All neonatal resuscitation systems which are provided with an exhalation port which can be closed with a cap. Intersurgical product codes REF 6181, 6308, 6315, 6354, 6354001, 6356.




Description of the problem: Neonatal resuscitation can be performed by using a constant flow of gas delivered to patient via a length of tubing which terminates at the patient end in a connector which has a port to allow exhalation. The clinician can inflate the patient's lungs by closing the exhalation port with his thumb, then opening the port to allow exhalation. If resuscitation is attempted with the exhalation port accidentally closed with a cap, there will be no exhalation pathway, and the patient's lungs will be subject to over-inflation, resulting in volume trauma.

Transmission of this Field Safety Notice: Intersurgical has notified the MHRA of this Field Safety Notice. This notice needs to be transmitted to all clinicians who may perform neonatal resuscitation. Please maintain awareness of this notice for an appropriate period, since Intersurgical resuscitation systems which are provided with an exhalation port which can be closed with a cap, may remain available for use for several months.

Action to be taken by the user: Never start resuscitation with a resuscitation system unless there is an exhalation pathway. If the exhalation pathway can be closed with a cap, always ensure that this cap is open before starting resuscitation.

Action being taken by Intersurgical in order to reduce the risk of accidental over-inflation of the patient's lungs:

1. Intersurgical neonatal resuscitation systems will no longer be manufactured with a cap which can close the exhalation port. The instructions which accompany the products which have had the cap removed will highlight to the user that the cap has been removed.
2. Some Intersurgical neonatal resuscitation systems will be manufactured with a patient elbow connection which has variable PEEP control. This elbow also allows the peak inspiratory pressure (PIP) to be set prior to use, and prevents the complete closure of the exhalation pathway.

<p>Contact Reference Person: Chris Randall Intersurgical Ltd. Crane House Molly Millars Lane Wokingham Berkshire RG41 2RZ United Kingdom Tel: +44 (0)118 9656 300 Fax.: +44 (0)118 9656 356 Email: cpr@intersurgical.co.uk</p>	<p>The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency</p>  <p>Roger Le Poidevin Regulatory Affairs Director, Intersurgical</p>
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There is no need for recipients of this notice to contact Intersurgical to confirm receipt.