

1. DEVICE/EQUIPMENT:

Solus laryngeal mask airway manufactured by Intersurgical - Product code: 8002, lot no: 380009

This single-use airway management device is intended for use in anaesthesia and emergency care.

2. PROBLEM:

Possibility of moulding defects in the device's 15mm connector, which could cause it to break off during use.

3. ACTION BY:

All staff who use, supply or purchase this device.

4. ACTION:

- Identify and quarantine those devices affected by this Alert.
- Contact Intersurgical for replacements of affected devices.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- A&E departments
- A&E directors
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic nursing staff
- Anaesthetists
- Day surgery units
- Health and safety managers
- Medical directors
- Operating department practitioners
- Paramedics
- Purchasing managers
- Resuscitation officers
- Risk managers
- Supplies managers
- Theatre managers
- Theatres
- Independent Health and Social Care Providers – Private Hospitals and Clinics

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Intersurgical Customer Care
Molly Millars Lane
Wokingham
Berkshire
RG41 2RZ

Tel: 0118 9656 376

Fax: 0118 9656 356

E-mail: sop@intersurgical.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2008/077 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

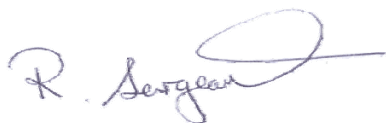
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
10th Oct 2008

Action Under Way:
29th Oct 2008

Action Complete:
19th Nov 2008



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

APPENDIX to MDEA(NI)2008-077

Date: 26 August 2008

Customer Details:

Hospital Name & Address

INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS

Crane House Molly Millars Lane
Wokingham Berkshire RG41 2RZ England

Customer Care

Tel: +44 (0)118 9656 376

Fax: +44 (0)118 9656 356

Email: sop@intersurgical.co.uk

Urgent Field Safety Notice

Product Intersurgical *Solus* Laryngeal Mask Airway – Size 2
Product Code REF: 8002 NHS Supply Chain Number FDD749
Lot No: 380009 (only this lot number is affected)

Description of the problem:

The 15mm Male taper connection may have a fault in the moulding that could cause it to fracture, or break off during connection or disconnection from a mating 15mm Female taper.

This Field Safety Notice is only relevant to product code 8002, lot 380009. No other Intersurgical *Solus* device is affected in this way.

Risk

This fault could result in the loss of pressure, or disconnection during use on a patient, and so as a precautionary measure Intersurgical has decided to remove these products from the market.

Action

Please quarantine and destroy any products you have in stock from lot 380009, and contact our Customer Care department on 0118 9656 351.

**To arrange replacement or credit of these products, we must receive the attached form.
Please email it to sop@intersurgical.co.uk or fax it to 0118 9656 356**

FSCA-identifier - 2008186

Transmission of this Field Safety Notice:

Can you please ensure this notice is circulated to all departments within your organisation who need to be aware of this potential fault with this product.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

APPENDIX to MDEA(NI)2008-077

Intersurgical Contact Details:

Customer Care

Tel: +44 (0)118 9656 376

Fax.: +44 (0)118 9656 356

Email: sop@intersurgical.co.uk

I confirm that this notice has been notified to the appropriate Regulatory Agencies, including the MHRA.

Roger Le Poidevin
Regulatory Affairs Director, Intersurgical

Please complete the form below.

INTERSURGICAL LTD. URGENT FIELD SAFETY NOTICE

Date: 21 August 2008

Hospital Name:

Hospital Address:

Please complete either section A or B below, and fax back to Intersurgical on 0118 9656 356, or email it to sop@intersurgical.co.uk.

SECTION A:

I confirm we have no stock of code 8002, Lot 380009 remaining in our premises/hospital.

Name:

Department:

Contact No:

Date:

----- OR -----

SECTION B:

I confirm we have the following products and quantities located in our premises/hospital:

REF: 8002, LOT 380009 – Qty. - ____

I CONFIRM THE ABOVE QUANTITY OF AFFECTED PRODUCTS HAVE BEEN LOCATED WITHIN
OUR PREMISES/HOSPITAL, AND HAVE BEEN DESTROYED.

Name:

Department:

Contact No:

Date:

Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, England
Customer Care, Tel: 0118 9656 376 Fax: 0118 9656 356 Email: sop@intersurgical.co.uk