

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/058

Issued: 23rd July 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Smiths Medical Portex™ Blue Line Ultra tracheostomy kits, lot no. 499265.</p>	▶ ①
<p>Problem: Blue Line Ultra Suctionaid tracheostomy change kits (product code 100/880/080) from lot 499265 will contain a Blue Line Ultra fenestrated, uncuffed tube. Although this tube will maintain an airway if used, it will reduce ventilation efficiency and will not provide any direct suctioning ability. Smiths Medical is recalling these devices due to the incorrect labelling (see appendix).</p>	▶ ②
<p>Action by: Supplies department, operating theatre, A&E, ITU and ENT staff involved in the supply and use of these devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine those devices affected by this alert. Contact Smiths Medical for replacements of affected devices. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>	
<p>Acknowledge Receipt of Alert: 25th July 2008</p>	▶ ⑦
<p>Action Under Way: 12th Aug 2008</p>	
<p>Action Complete: 2nd Sept 2008</p>	

This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

Tracheostomy kits for the ongoing care of adult patients.

Portex™ Blue Line Ultra tracheostomy kit, smooth inner cannula, fenestrated, Orator speaking valve uncuffed 8.0mm ID. Product code: 100/833/080, lot no. 499265.

Portex™ Blue Line Ultra tracheostomy change kit, Suctionaid, smooth inner cannula, Soft Seal profile cuff. Product code: 100/880/080, lot no. 499265.

2. PROBLEM:

Mislabelling of device may result in the use of a fenestrated suction tube, reducing both suction and ventilation. The manufacturer has recalled all stock supplied directly to trusts. However, affected devices have also been distributed via third party suppliers and are not yet accounted for.

3. ACTION BY:

Supplies department, operating theatre, A&E, ITU and ENT staff involved in the supply and use of these devices.

4. ACTION:

- Identify and quarantine those devices affected by this alert.
- Contact Smiths Medical 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
- Adult intensive care units
- Anaesthetists
- ENT departments
- Intensive care units
- Medical managers
- Supplies managers
- Theatre managers
- Theatres
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Ms Jennie Hounsell
Nonconformity Coordinator
Smiths Medical International Limited
Boundary Road
Hythe
CT21 6JL
Tel: 01303 260 551
Fax: 01303 236 995

E-mail: jennie.hounsell@smiths-medical.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/058 and be addressed to:

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

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

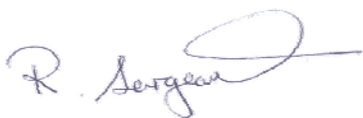
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
25th July 2008

Action Under Way:
12th Aug 2008

Action Complete:
2nd Sept 2008



Robert Sergeant
NIAIC Operational Manager

APPENDIX to MDEA(NI)2008/058

smiths medical
bringing technology to life

Smiths Medical International Limited
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www.smiths-medical.com

Urgent Field Safety Notice

Affected Devices:	Portex™ 'Blue Line Ultra Tracheostomy Kit, Smooth Inner cannula, Fenestrated, Orator® Speaking valve Uncuffed 8.0mm ID Product Code: 100/833/080 Portex™ 'Blue Line Ultra Tracheostomy Change Kit, Suctionaid, Smooth Inner Cannula, Soft-Seal Profile Cuff Product code 100/880/080
	Batch/Lot: 499265
Type of Action:	Field Safety Corrective Action
Manufacturers Reference:	PC 2884
Date:	8 th July 2008
Attention:	Risk/ Safety Managers, Distributors, Clinicians, Nursing Staff and other users of the above device.

Details on affected devices: One batch only affected see above.

Description of the problem:

Smiths Medical International Limited have incorrectly labelled a number of Portex™ 'Blue Line Ultra Tracheostomy Kit, Smooth Inner cannula, Fenestrated, Orator® Speaking valve Uncuffed products from lot 499265 as Blue Line Ultra Suctionaid Tracheostomy Change kits (Product code 100/880/080).

Therefore 100/880/080 Blue Line Ultra Suctionaid Tracheostomy Change kits from Lot 499265 will contain a 'Blue Line Ultra Fenestrated, uncuffed tube . Although this tube will maintain an airway if used, it will reduce ventilation efficiency and will not provide any direct suctioning ability.

This issue was caused by an operator error following a shortfall in the initial labelling print run. Changes have been implemented to ensure that labelling information is checked against the manufacturing order details each time there is a labelling run.

Advice on action to be taken by the user:

- Identify the affected products
- Contact our Nonconformity Coordinator on the number below to arrange collection and replacements at no charge

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Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on to all personnel who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (if appropriate).

Please transfer this notice to other organisations on which this action has an impact (if appropriate).

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

In order to fulfil regulatory obligations, Smiths Medical International Limited requires that you complete and return the confirmation form (see Attachment 1). Please return the confirmation form by faxing to +44 (0)1303 236995 or by regular mail to the address below.

A copy of this field safety notice has been passed to the MHRA who are aware of the proposed actions.

Thank you for your cooperation in this matter.

John Tullett
RA Manager (International)

Tel +44 (0) 1303 236815
E-mail: EU.Rep@smiths-medical.com

Eva Hruskova
International Product Manager,
Tracheostomy, HMEs & filters
Tel +44 (0)1303 236714
E-mail: Eva.hruskova@smiths-medical.com

Contact reference person for return of goods:

Jennie Hounsell
Nonconformity Coordination

Smiths Medical International Limited
Boundary Road
Hythe, CT21 6JL
Tel: +44 (0)1303 260 551
Fax: +44 (0) 1303 236995

E-Mail: jennie.hounsell@smiths-medical.com

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For Communication with Customer

Affected Devices: Portex™ Blue Line Ultra Tracheostomy Kit, Smooth Inner cannula,
Fenestrated, Orator® Speaking valve Uncuffed
Product Code: 100/833/080

Type of Action: Field Safety Corrective Action

Manufacturers Reference: PC2884

Date: 30th June 2008

Details on affected devices: Batch/Lot: 499265

Complete and Fax Promptly to your Distributor.

Customer Name: <<Print Your Company name here>>

Contact Name: << Print Your Contact Name & email address here>>

Fax No.: <<Print Your Fax No. here>>

Section 1 - fill in regardless of inventory status:

Printed Name: _____ Department: _____

Signature: _____ Date: _____

Facility Name: _____

Address: (Enter your facility address details here i.e. Street, City, State, Post Code, etc)

Tel No.: _____ Ext: _____ Fax No.: _____ E-mail: _____

We **DO NOT** have any affected inventory remaining in stock
We **HAVE** the affected inventory

SECTION 2 - ANSWER ALL ITEMS BELOW

1. Affected product you have on hand:

Quantity _____ Do you want
 REPLACEMENTS or CREDIT

2..Print Name and Address of person to be contacted regarding return of affected inventory (if different from above)

Printed Name: _____ Department: _____

Facility Name: _____

Address: (Enter your facility address details here i.e. Street, City, State, Post Code, etc)

Tel No.: _____ Ext: _____ Fax No.: _____ E-mail: _____

Questions should be directed to your distributor at the address shown above.

For Smiths Medical Use Only		
Customer Account No.	_____	RG# _____
		<input type="checkbox"/> Copy to Returns