

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/78

Issued: 12th September 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Endotracheal tubes: Microcuff paediatric endotracheal tubes manufactured by Kimberly-Clark NV/SA.</p>	▶ ①
<p>Problem: The device may kink during use, which may impede or prevent ventilation.</p>	▶ ②
<p>Action by: Anaesthetists, intensive care specialists, paediatrics and neonatology medical and nursing staff.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine stock from all batches of affected product range (see overleaf for product list). The manufacturer is recalling all potentially affected devices. See manufacturer recall letter in the appendix. Contact the manufacturer to arrange the return of affected stock and reimbursement for returned product. 	▶ 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 contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None Required.</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

All batches of the following products are affected by this recall:

Product Name	Product Code
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 3.0mm	35111-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 3.5mm	35112-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 4.0mm	35113-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 4.5mm	35114-07
Microcuff* Pediatric Oral Curved endotracheal tube 3.0mm	35161-07
Microcuff* Pediatric Oral Curved endotracheal tube 3.5mm	35162-07
Microcuff* Pediatric Oral Curved endotracheal tube 4.0mm	35163-07
Microcuff* Pediatric Oral Curved endotracheal tube 4.5mm	35164-07

2. PROBLEM:

The device may kink during use, which may impede or prevent ventilation.

3. ACTION BY:

Anaesthetists, intensive care specialists, paediatrics and neonatology medical and nursing staff.

4. ACTION:

- Identify and quarantine stock from all batches of affected product range (see overleaf for product list).
- The manufacturer is recalling all potentially affected devices. See manufacturer recall letter in the appendix.
- Contact the manufacturer to arrange the return of affected stock and reimbursement for returned product.

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
- Ambulance services directors
- Anaesthetists
- Clinical governance leads
- Day surgery units
- ENT departments
- Equipment stores
- Health and safety managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Intensive care units (adult and paediatric)
- Medical directors
- Neonatology departments
- Nursing executive directors
- Outpatient theatre managers
- Paediatrics departments (medical and surgical)
- Palliative care teams
- Paramedics
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Dr Holger Most
Kimberly-Clark NV/SA
Belgicastraat 13
Zaventem
Belgium
1930

Tel: +32 2 711 2642

Fax: +31 84 2220 589

E-mail: Holger.Most@kcc.com

Enquiries to NIAIC should quote reference number MDEA(NI)2007/78 and be addressed to:

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

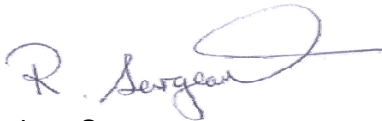
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required.



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)2006/01. 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)2007/78

URGENT: Medical Device Recall

Dear valued customer:

This letter will serve to notify you of a voluntary medical device recall being conducted by Kimberly-Clark Health Care.

All lot numbers of the following products are subject to the Product Recall

<u>Product Name</u>	<u>Product code</u>	<u>Product Name</u>	<u>Product Code</u>
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 3.0mm	35111-07	Microcuff* Pediatric Oral Curved endotracheal tube 3.0mm	35161-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 3.5mm	35112-07	Microcuff* Pediatric Oral Curved endotracheal tube 3.5mm	35162-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 4.0mm	35113-07	Microcuff* Pediatric Oral Curved endotracheal tube 4.0mm	35163-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 4.5mm	35114-07	Microcuff* Pediatric Oral Curved endotracheal tube 4.5mm	35164-07

Reason for the Product Recall?

Complaints have been received indicating that the endotracheal tube may kink during use which may impede or prevent ventilation.

What should I do in response to this Product Recall?

Our records indicate that one or more of the affected product codes were shipped to you.

Please check your inventory to determine if you have any of the affected product codes on hand. I would ask you please to complete the attached '**Recall Response Sheet**' and fax or email for the attention of Katrien De Ceulaer
Tel: +32 2 711 26 61 Fax: +32 2 711 26 91 Email: cshealthcare@kcc.com
with the quantity of product to be collected. We will organise collection from your organisation as soon as possible and will arrange a separate credit note for the product returned. Please include a copy of the completed Recall Response Sheet with your products.

What else do I need to do?

It is important that the appropriate clinical staff be informed of this recall so we would ask that you forward this notification to other departments such as Anesthesiology, Respiratory Therapy; Pediatrics, Neonatology and others as you deem necessary.

The attached Product Recall Response Sheet will serve as a Packing Slip to accompany any returned product and assist us in accounting for the returned product. However, even if you do not have any of the affected product in your inventory, **to assist us in ensuring an effective product recall, please complete and enclose with returned product or if no inventory fax +32 2 711 26 91 the Recall Response Sheet to us.**

The competent authorities as well as other appropriate agencies will be notified of this product recall. Kimberly-Clark Health Care is dedicated to manufacturing and distributing superior quality products, and apologizes for any inconvenience the product recall may cause you.

NOTE: Please contact Holger Most, Recall Coordinator at +32 2 711 26 42 for assistance.

Sincerely,
Holger Most
Regulatory Affairs

Appendix to MDEA(NI)2007/78

Product Recall Response Sheet

Kimberly-Clark Health Care Belgicastraat 13 1930 Zaventem Belgium Telephone: +32 2 711 2600 • Facsimile +32 2 711 26 91

Microcuff Pediatric Magill and Oral Curved Endotracheal Tubes

Customer Name:

Our records indicate that you have received one or more of the affected product below:

Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 3.0mm	35111-07	Microcuff* Pediatric Oral Curved endotracheal tube 3.0mm	35161-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 3.5mm	35112-07	Microcuff* Pediatric Oral Curved endotracheal tube 3.5mm	35162-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 4.0mm	35113-07	Microcuff* Pediatric Oral Curved endotracheal tube 4.0mm	35163-07
Microcuff* Pediatric Oral/Nasal Magill endotracheal tube 4.5mm	35114-07	Microcuff* Pediatric Oral Curved endotracheal tube 4.5mm	35164-07

[] Please check this box if you have no remaining inventory of the product indicated above.

IF AFFECTED PRODUCT IS IN EXISTING INVENTORY

In the appropriate spaces in the chart below, please indicate the product and number of units being returned.

Product Number	Lot Number	Units Returning

REIMBURSEMENT FOR RETURNED PRODUCT

Complete the information below and enclose this sheet with any product returned to Kimberly-Clark. Be sure to identify your shipping container with "Product Recall" clearly noted. If you have no product to return, you may simply fax (+32 2 711 26 91) or mail this form to the above address, attention Katrien De Ceulaer.

Date Recall Response Sheet Completed: _____

Name and Title of Person Completing this form: _____

(Name – signature)

(Name – print)

(Title)

Phone _____