

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/70

Issued: 21 November 2006

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section										
<p><b>Medical Device/Equipment:</b> Examination gloves. Ansell (UK) Ltd – Micro-Touch® Ultra PF powder free latex. Product codes: 5282, 5284, 5286, 5288. Lot numbers beginning with: 0511, 0602, 0603, 0605, 0607.</p>	▶ ①										
<p><b>Problem:</b> Recall of specific lot numbers. Some gloves may be subject to premature aging.</p>	▶ ②										
<p><b>Action by:</b> All users of Micro-Touch® Ultra PF powder free latex examination gloves.</p>	▶ ③										
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Identify and do not use affected gloves.</li> <li>Contact your supplier to arrange return and replacement of affected stock.</li> <li>Ensure that any adverse incidents with these gloves are reported to the manufacturer Ansell (UK) Ltd and the MHRA.</li> </ul>	▶ ④										
<p><b>Distributed by NIAIC to:</b></p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>General Dental Practitioners</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Community Pharmacists</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td>Optometrists</td> </tr> <tr> <td></td> <td>Hospices</td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	General Dental Practitioners	Chief Executive of each Agency	Community Pharmacists	NIAIC Liaison Officers	Optometrists		Hospices	▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners										
Chief Executive of each HSS Trust	General Dental Practitioners										
Chief Executive of each Agency	Community Pharmacists										
NIAIC Liaison Officers	Optometrists										
	Hospices										
<p><b>Contacts</b></p> <p>Details of manufacturer/supplier contacts and NIAIC contact for technical aspects.</p>	▶ ⑥										
<p><b>Feedback Requirements to NIAIC</b></p>	▶ ⑦										

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

## 1. DEVICE/EQUIPMENT:

Examination gloves.

Ansell (UK) Ltd – Micro-Touch® Ultra PF powder free latex.

Product codes: 5282, 5284, 5286, 5288.

Lot numbers beginning with: 0511, 0602, 0603, 0605, 0607.

## 2. PROBLEM:

Manufacturer testing of glove samples following accelerated aging showed that some products did not meet the European standard requirements for tensile strength. Therefore affected products manufactured since July 2005 are being recalled from the market.

## 3. ACTION BY:

All users of Micro-Touch® Ultra PF powder free latex examination gloves.

## 4. ACTION:

- Identify and do not use affected gloves.
- Contact your supplier to arrange return and replacement of affected stock.
- Ensure that any adverse incidents with these gloves are reported to the manufacturer Ansell (UK) Ltd and the NIAIC.

## 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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Wheelchair Service Managers
- Occupational Therapists
- Physiotherapists
- Rehabilitation Engineers
- Fire Officers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Practice Nurses
- Pharmacy Managers
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Sterile Services Departments
- Operating Theatre Staff
- Outpatient Departments
- Infection Control Staff
- Laboratories
- Accident & Emergency Departments
- Allied Health Professionals
- Coronary Care
- Intensive Care
- Resuscitation Officers
- Day Procedure Units
- Residential and Nursing Homes

## 6. CONTACTS:

Enquiries to the supplier/manufacturer should be addressed to:

Mr Colin Maskell  
Southern Syringes Services Limited  
George House  
Unit 6 Delta Park Industrial Estate  
Millmarsh Lane  
Enfield  
London EN3 7QJ

Tel: 0870 873 4900  
Fax: 0870 873 4902

E-mail: [cmaskell@southern-syringe.co.uk](mailto:cmaskell@southern-syringe.co.uk)

Mr Phillip Bates  
Regulatory Affairs Director  
Ansell(UK)Ltd  
30-32 Mariner  
Lichfield Road Industrial Estate  
Tamworth  
Staffordshire B79 7UL

Tel: 01827 302 121  
Fax: 01827 302 102

E-mail: [pbates@eu.ansell.com](mailto:pbates@eu.ansell.com)

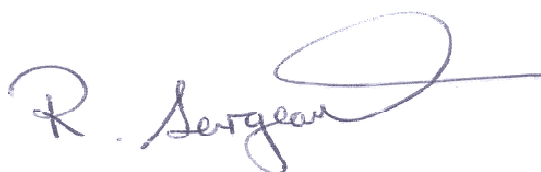
Enquires to NIAIC should quote reference number MDEA(NI)2006/70 and be addressed to:

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](mailto: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/niac](http://www.dhsspsni.gov.uk/niac)

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



**RECALL NOTICE**  
Micro-Touch® Ultra PF  
Powder Free Latex Examination glove

From Southern Syringe Services Ltd.

To the attention of :



Size	XS	S	M	M	XL
Product code	5280	5282	5284	5286	5288

Brussels, 13 September 2006

Dear Customer,

We are writing you to inform you that we have recently identified a potential issue associated with our Micro-Touch Ultra PF latex examination gloves. We have concerns that the shelf life of the gloves in the lot numbers attached may not be as stated on the labelling, and therefore may not meet the European quality standards and requirements. No other Micro-Touch products are affected by this recall.

Ansell is committed to protecting and enhancing the safety of healthcare workers or patients, and we have therefore decided to effect an immediate voluntary removal of certain Micro-Touch Ultra PF gloves from the market, and replace them with suitable alternatives. Therefore we need to ask you to return to us the Micro-Touch Ultra PF gloves that you recently bought.

- The lot numbers of the products that are relevant to you are in the list attached to this letter. Please isolate these products. Please indicate on the attached forms the number of products used, and the number of products you will be returning to us. Thank you for returning the completed form to us by fax , or via e-mail . We would appreciate if you could return the completed forms to us within the next 2 weeks.
- In order to have your return shipment managed in the most efficient way, your customer service or sales representative will contact you to arrange the return and the replacement of the products.

**Ansell Healthcare Europe N.V.**

Riverside Business Park, Spey House Boulevard International 55 B-1070 Brussels, Belgium  
Tel. +32 (0) 2 528 74 00 Fax +32 (0) 2 528 74 01 Fax Customer Service +32 (0) 2 528 74 03  
<http://www.anselleurope.com> E-mail [info@eu.ansell.com](mailto:info@eu.ansell.com)



SO 9001 Certificate  
Number FM 40130



**RECALL NOTICE**  
Micro-Touch® Ultra PF  
Powder Free Latex Examination glove

- Please do not return the goods until your customer service or sales representative has made contact with you.
- Ansell will carry the costs of this return shipment and will replace the goods at no cost to you.

We apologize for the inconvenience this return may cause to you and your employees, but we hope you appreciate our concern and dedication to supply all our customers with only the best quality gloves. We thank you for your cooperation in this matter.

Yours sincerely,

A handwritten signature in black ink, appearing to read "W. Heintz".

Werner Heintz  
Sr. Vice President – Regional Director  
Ansell Healthcare Europe

A handwritten signature in black ink, appearing to read "H. Fürstenberg".

Holger Fürstenberg  
European Marketing Director  
Ansell Healthcare Europe

**Ansell Healthcare Europe N.V.**

Riverside Business Park, Spey House Boulevard International 55 B-1070 Brussels, Belgium  
Tel. +32 (0) 2 528 74 00 Fax +32 (0) 2 528 74 01 Fax Customer Service +32 (0) 2 528 74 03  
<http://www.anselleurope.com> E-mail [info@eu.ansell.com](mailto:info@eu.ansell.com)



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