

# Medical Device Alert

Ref: MDA/2011/049 Issued: 17 May 2011 at 14:30

## Device

Powder free examination gloves  
– Latex (LMPF100) and Vinyl  
(FT100 and MPF25).

Manufactured by BM Polyco Ltd.

Specific lots (Appendix 1).

NHS supply codes (Appendix 2).



Problem	Action
<p>Gloves from the affected lots may have pinholes, which could increase the risk of cross infection and leakage.</p> <p>This alert has been issued in support of the manufacturer's actions to ensure that all relevant healthcare staff are aware of the problem.</p>	<ul style="list-style-type: none"> <li>• If you have any of the affected stock, contact the manufacturer for collection and replacement.</li> <li>• Customers in England may also have received a Customer Notice from NHS Supply Chain</li> </ul>
Action by	
<p>All staff using these gloves, suppliers and distributors.</p>	
CAS deadlines	Contact
<p>Action underway: 02 June 2011</p> <p>Action complete: 16 June 2011</p>	<p><b>Manufacturer</b> John Spashett Technical Manager BM Polyco Tel: 020 8443 9006 Email: <a href="mailto:john.spashett@polyco.co.uk">john.spashett@polyco.co.uk</a></p>

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards 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
- All departments
- All staff
- All theatres
- All wards
- Ambulance staff
- Clinical pathology directors
- Day surgery units
- Dental departments
- Infection control nurses
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers

### Health Protection Agency

Directors for onward distribution to:

- Health protection nurses

### Primary care trusts

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

- Community hospitals
- Community midwives
- District nurses
- General dental practitioners
- General practitioners
- Health protection units
- Health visitors
- Infection control nurses
- NHS walk-in centres
- Practice managers
- Practice nurses

### Independent distribution

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

This alert should be read by:

- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### **Manufacturer**

John Spashett  
Technical Manager  
BM Polyco  
Crown Road  
Enfield  
EN1 1TX

Tel: 020 8443 9006

Email: [john.spashett@polyco.co.uk](mailto:john.spashett@polyco.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/049** or **2011/004/006/601/004**

### **Technical aspects:**

Mojisola Ajeneye or Sally Mounter  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7271 / 7168

Fax: 020 8754 3965

Email: [mojisola.ajeneye@mhra.gsi.gov.uk](mailto:mojisola.ajeneye@mhra.gsi.gov.uk)  
[sally.mounter@mhra.gsi.gov.uk](mailto:sally.mounter@mhra.gsi.gov.uk)

### **Clinical aspects:**

Jonathan Plumb  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@mhra.gsi.gov.uk)

## 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>

The NHS Supply Chain issued a Customer Notice on 03 May (see Appendix 2) about the recall and can give advice on alternative suppliers; contact your local customer services representative, quoting reference ICN 2011/155.

## 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](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

In Northern Ireland the Regional Procurement Pharmacist (Pharmacy & Medicines Management Centre) and/or Procurement and Logistics Service (Pals) can give advice on alternative suppliers if appropriate.

### 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](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

In Scotland the National Distribution Centre (NDC) and/or National Procurement can give advice on alternative suppliers if appropriate.

## 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](mailto:Haz-Aic@wales.gsi.gov.uk)

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Addressees may take copies for distribution within their own organisations

## Appendix 1



To whom it may concern,

It has come to our attention that some product was despatched to medical customers that did not fully conform to the requirements of the EN455 standard. The products in question are as follows:

Product Code	Lot Number	Delivery Period
LMPF100	PP0639	June 2010 – December 2010
	PP0796	July 2010 – January 2011
	PP1058	December 2010 – February 2011
	PP1387	December 2010 – February 2011
FT100	PP0478	February 2010 – August 2010
	PP0530	March 2010 – July 2010
MPF25	POR10358	September 2010

Recent examination and trending of the quality control data associated with these products has shown that some portions of the delivery failed to meet the pinhole requirement for AQL 1.5 that is required by the standard. We will of course replace any stock which remains with you or with one of your customers immediately.

If you could let me know where any remaining stock is we will arrange collection and replacement as quickly as possible.

Kind regards

A handwritten signature in black ink, appearing to read "J Spashett", is written over a vertical line.

John Spashett  
 Technical Manager – Medical  
 john.spashett@polyco.co.uk

## Appendix 2



# Important Customer Notice



NHS Supply Chain

Ref: NHS SC Recall 006  
Ref: ICN 2011/155  
3<sup>rd</sup> May 2011

## Product Recall BM Polyco Examination Gloves

NHS Supply Chain would like to notify customers of a product recall received from PH Medisavers regarding two types of BM Polyco Examination Glove

This recall is due to a number of Lots (batches) not achieving the correct AQL rating which is required by the EN455 standards. Affected gloves may have pinholes which could increase the risk of cross infection and leakage

Product details:

NPC	Base description	Secondary description	Brand	Manufacturers Code
FTE003	Gloves examination latex powder free non sterile singles	Small - double chlorinated	BM Polyco Finex PF	LMPF100/01
FTE004	Gloves examination latex powder free non sterile singles	Medium - double chlorinated	B M Polyco Finex PF	LMPF100/02
FTE006	Gloves examination latex powder free non sterile singles	Large - double chlorinated	B M Polyco Finex PF	LMPF100/03
FTE091	Gloves examination latex powder free non sterile singles	Extra small - double chlorinated	BM Polyco Finex PF	LMPF100/00
FTE092	Gloves examination latex powder free non sterile singles	Extra large - double chlorinated	BM Polyco Finex PF	LMPF100/04
FTG073	Gloves examination vinyl pigmentised powder free non sterile singles	Small	BM Polyco Finity	FT100/01
FTG128	Gloves examination vinyl pigmentised powder free non sterile singles	Medium	BM Polyco Finity	FT100/02
FTG129	Gloves examination vinyl pigmentised powder free non sterile singles	Large	BM Polyco Finity	FT100/03
FTG144	Gloves examination vinyl pigmentised powder free non sterile singles	Extra small	BM Polyco Finity	FT100/00
FTG145	Gloves examination vinyl pigmentised powder free non sterile singles	Extra large	BM Polyco Finity	FT100/04

The Lot numbers are detailed below:

Product Code	Lot Number	Delivery Period
LMPF100 (FTE003 – FTE092)	PP0639	June 2010 – December 2010
	PP0796	July 2010 – January 2011
	PP1058	December 2010 – February 2011
	PP1387	December 2010 – February 2011
FT100 (FTG073 – FTG145)	PP0478	February 2010 – August 2010
	PP0530	March 2010 – July 2010

Please note only the lot numbers listed are affected.

Please check your stocks of these products and return any identified Lots to NHS Supply Chain for a full credit. Replacement stock is available and should be ordered in the normal manner.

Please contact your NHS Supply Chain Customer Service Advisor to arrange return, quoting reason code 7 "Supplier Recall", **all products to be returned no later than Friday 20<sup>th</sup> May 2011**

Copy of Supplier correspondence available by clicking [here](#)

The manufacturers recall includes their product code MPF25, this item is not available from NHS Supply Chain, please contact BM Polyco direct for return of this product

For further information, or to discuss the return of any of the affected batch, please contact your local NHS Supply Chain Customer Services representative or your Account Manager ([click here for contact detail](#))