

Medical Device Alert

Immediate action

Ref: MDA/2010/025 Issued: 31st March 2010 at 15:00

Device

Silicone gel filled breast implants manufactured by Poly Implant Prothese (PIP).
All models and lot numbers.

Problem

On Tuesday 30 March 2010 the French medical device regulatory authority (AFSSAPS) informed the MHRA that it has suspended the marketing, distribution, export and the use of silicone gel filled breast implants manufactured by PIP (a French breast implant manufacturer). It has recalled all of these devices.

AFSSAPS recently carried out an inspection of the PIP manufacturing plant and established that most breast implants manufactured by the company since 2001 have been filled with a silicone gel with a composition different from that approved.

The MHRA does not yet know if the use of the unapproved material affects the safety of the implants. We understand that AFSSAPS is carrying out urgent testing and has undertaken to provide further information as soon as it is available.

The MHRA will provide further advice on patient management, as necessary, when more information is available.

Action by

- Medical directors.
- Plastic surgeons and all surgeons involved in breast reconstruction.
- Directors of surgical units involved in breast reconstruction.
- Nurse executive directors.
- Specialist nurses involved in breast cancer care.

Action

Implanting centres

- Do not implant these devices.
- Quarantine and return all of these devices to the distributor.

GPs

- Advise patients who are concerned about their PIP implants to consult their implanting surgeon.

Implanting surgeons

- Await further advice from the MHRA regarding clinical management of patients implanted with these devices.

Contact

Supplier

Andrew Hay (Director) 
Clover Leaf Products Ltd
Tel : 01494 876 990
E-mail: andy@cloverleafproducts.com

CAS deadlines

Action underway: 07 April 2010
Action complete: 28 April 2010

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- 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 all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Medical directors
- Plastic surgeons and all surgeons involved in breast reconstruction
- Directors of surgical units involved in breast construction
- Nurse executive directors
- Specialist nurses involved in breast cancer care

Primary care trusts to:

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

- General practitioners
- Practice managers
- Practice nurses

Contacts

Supplier

Andrew Hay (Director) 
Clover Leaf Products Ltd
6-10 Church Farm Courtyard
High Street
Chalfont St Giles
HP9 4QH

Tel: 01494 876 990

Fax: 01494 876 991

E-mail: andy@cloverleafproducts.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/025** or **2010/003/030/081/019**

Technical aspects

Bayode Adisa or Ian Smith or Khalid Razak
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3223/3306/3200

Fax: 020 7084 3106

E-mail: bayode.adisa@mhra.gsi.gov.uk
ian.smith@mhra.gsi.gov.uk
khalid.razak@mhra.gsi.gov.uk

Clinical aspects

Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 020 7084 3123
Fax: 020 7084 3111
E-mail: susanne.ludgate@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>

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
E-mail: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

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

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

E-mail: Haz-Aic@wales.gsi.gov.uk

MHRA is an executive agency of the Department of Health
© Crown Copyright 2010

Addressees may take copies for distribution within their own organisations