Medical Device Alert

Ref: MDA/2012/011 Issued: 15 March 2012 at 15:30

Device

Silicone gel filled breast implants manufactured by Poly Implant Prothese (PIP).

All implanted devices.

Problem

In March 2010 the MHRA was informed by the French regulatory authorities (AFSSAPS) that most PIP silicone gel breast implants manufactured from January 2001 were filled with an unapproved silicone gel material. The MHRA's advice for the management of women implanted with PIP silicone gel breast implants after 1 January 2001 was given in MDA/2010/078, published in October 2010.

Updated information from AFSSAPS suggests that there is no guarantee that PIP silicone gel breast implants manufactured prior to 2001 contained the approved filler. Therefore, all women implanted with PIP silicone gel breast implants should be supported and managed in line with the Department of Health's recommendations of January 2012.

Information recently received from the UK supplier of PIP breast implants suggests that up to 7,000 women may have received PIP silicone gel breast implants prior to January 2001. This is in addition to the approximately 40,000 women previously believed to have received affected implants after 1 January 2001.

CAS deadlines

Action underway: 18 April 2012
Action complete: 17 May 2012

Action

Implanting surgeons

- Identify additional women who were implanted with PIP silicone gel breast implants prior to 1 January 2001.
- Offer all women with these implants the support and management as set out on **the Department of Health's website**.

GPs

- Follow the advice provided by **the Department of Health on its website**.

Note: the recommendations in this MDA update the advice given in MDA/2010/025 and MDA/2010/078.

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.

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

Independent distribution

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

This alert should be read by:

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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 and requesting this facility.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/011**or **2010/003/030/081/019**

Technical aspects

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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

Email: 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

Email: nss.iric@nhs.net

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

Wales

Enquiries in Wales should be addressed to:
Dr Chris Jones
Medical Director
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk