Medical Device Alert

Immediate action update

Ref: MDA/2010/078 Issued: 04 October 2010 at 16:30

Device

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

All devices implanted after 01 January 2001.

Problem

Clinical management of women implanted with PIP silicone gel filled implants.

Action by

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

CAS deadlines

Action underway: 18 October 2010
Action complete: 29 November 2010

Action

Implanting surgeons/implanting centres

- Identify women who were implanted with PIP silicone gel filled implants after 01 January 2001.
- Reassure them that there is no current evidence of health risk associated with the filler and there is no indication for routine action in the form of explantation or ultrasound.
- Advise them that further information about the testing (see problem) is available on the MHRA website and that further information about clinical management is available on the websites of the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) and the Association of Breast Surgery (ABS).

GPs

- Advise women who are concerned about their PIP implants to consult their implanting surgeon or implanting centre.

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

Problem

On Tuesday 30 March 2010 the French medical device regulatory authority (AFSSAPS) informed the MHRA that it had suspended the marketing, distribution, export and the use of silicone gel filled breast implants manufactured by PIP (a French breast implant manufacturer). AFSSAPS recalled all of these devices. The MHRA issued MDA/2010/025 on 31 March 2010 advising UK clinicians not to implant these devices.

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

AFSSAPS has carried out testing of affected implants to look at the genotoxicity (potential for cancer), chemical toxicity of the filler material and mechanical properties of the implant shell. The MHRA also commissioned tests to look at genotoxicity and chemical toxicity.

Test results have not shown any evidence of genotoxicity or chemical toxicity of the filler material. One of the French genotoxicity tests was, however, inconclusive and further testing will be conducted by AFSSAPS with results expected in early 2011.

Mechanical testing of the implant shells carried out by AFSSAPS suggests that there may be an increased risk of rupture. However, the Therapeutic Goods Administration (TGA) of the Australian government also carried out tests on PIP silicone gel filled breast implants and found that these implants conformed to the relevant international standards for this type of product, including those for gel cytotoxicity and shell strength.

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:

- Directors of surgical units involved in breast construction
- Medical directors
- Nurse executive directors
- Plastic surgeons and all surgeons involved in breast reconstruction or augmentation
- 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

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

The MHRA considers this information to be important to:

- Breast augmentation centres
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/078 or 2010/003/030/081/019**

Please note that telephone numbers for the MHRA contacts below will change on 25 October 2010. From that date please contact the MHRA Central Enquiry Point on 020 3080 6000 and ask for the person by name.

Technical aspects
Bayode Adisa or Ian Smith

Tel: 020 7084 3223/3306

Email: bayode.adisa@mhra.gsi.gov.uk
ian.smith@mhra.gsi.gov.uk

Clinical aspects
Dr Susanne Ludgate

Tel: 020 7084 3123

Email: 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

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 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