Medical Device Alert

Ref: MDA/2014/027  Issued: 10 July 2014 at 15:00

Device
Breast Implants. All types, makes and models.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Action</th>
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<tr>
<td>Since publishing MDA/2011/017 in February 2011 requesting healthcare professionals to report cases of anaplastic large cell lymphoma (ALCL) in women with breast implants we have received three reports of ALCL in the UK and more cases worldwide have been identified in the peer reviewed literature (see background).</td>
<td>No change to current best practice is needed. There is no indication for any routine action in the form of explantation or regular radiological or MRI examination.</td>
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<td>The MHRA continues to collect and analyse information from UK healthcare professionals and other sources about this issue in order to build a fuller picture of the occurrence of this rare disease in association with breast implants.</td>
<td>If you are contacted by concerned women about this issue, reassure them that ALCL is a rare form of cancer, which can be treated if detected in the early stages.</td>
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<td>The MHRA is issuing this alert to further encourage healthcare professionals to report cases of ALCL in women who have breast implants or who have had them removed.</td>
<td>Always strongly encourage women to continue self-examination of their breasts and axillae (underarms) for any changes such as lumps, swelling or distortions and to consult their doctor if they have any concerns.</td>
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<tr>
<td>We urge you to report any confirmed cases of ALCL in women who have breast implants or who have had them removed to the MHRA (in England and Wales) to NIAIC (in Northern Ireland) or to IRIC (in Scotland).</td>
<td></td>
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</tbody>
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Action by
- Directors of surgical units involved in breast reconstruction and augmentation.
- Medical directors.
- Plastic surgeons and all surgeons involved in breast reconstruction and augmentation.
- Nurse executive directors.
- Specialist nurses involved in breast cancer care.
- Radiation & medical oncology departments
- General practitioners (for information only).

CAS deadlines
Action underway: 24 July 2014
Action complete: 21 August 2014
Background
Anaplastic large cell lymphoma (ALCL) is a rare type of non-Hodgkin’s lymphoma (NHL), a cancer involving the cells of the immune system. It accounts for less than 1% of all breast malignancies.

In January 2011 the FDA published a Safety Communication entitled ‘FDA Medical Device Safety Communication: Reports of Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants’.

In a review by the FDA of scientific literature published from January 1997 to May 2010, they identified 34 cases of ALCL in women with breast implants worldwide. The FDA’s adverse event reporting system also contained 17 reports of ALCL in women with breast implants.

In May 2014 the final report on PIP silicone breast implants was published by the European Commission and its non-food Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) which identified 130 case reports worldwide of patients with all types of breast implants who had developed ALCL.

This is a very small proportion of the 5-10 million women who have received breast implants worldwide.

The MHRA will analyse any further reports in order to build a fuller picture of the occurrence of this rare disease in association with breast implants.

Distribution
This MDA has been sent to:
- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Special health authorities for information

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:
- Directors of surgical units involved in breast reconstruction or augmentation
- Haematologists
- Medical directors
- Nursing executive directors
- Plastic surgeons and all surgeons involved in breast reconstruction or augmentation
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiology departments
- Radiology directors
- Specialist nurses involved in breast cancer care

Independent distribution
Establishments registered with the Care Quality Commission (CQC) (England only)
This alert should be read by:
- Breast augmentation centres
- 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 and requesting this facility.
England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number MDA/2014/027 or 2011/002/002/291/003

Technical aspects
Mr Ian Smith or Mrs Sonal Vara
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7306 / 7710
Fax: 020 8754 3965
Email: ian.smith@mhra.gsi.gov.uk
        sonal.vara@mhra.gsi.gov.uk

Clinical aspects
Dr Camilla Fleetcroft
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 6097
Fax: 020 8754 3965
Email: camilla.fleetcroft@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.

For patients from Northern Ireland, please report any confirmed cases of ALCL in women with breast implants to the MHRA via the NIAIC or duplicate the report to both.

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

Other enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre
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

How to report adverse incidents in Scotland
Please report directly to IRIC, further information can be found on our website

Wales

Enquiries in Wales should be addressed to:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ
Email: improvingpatientsafety@wales.gsi.gov.uk

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