

Medical Device Alert

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

Device

Breast Implants. All types, makes and models.

Problem

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).

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.

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.

Action

No change to current best practice is needed. There is no indication for any routine action in the form of explanation or regular radiological or MRI examination.

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.

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.

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).

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

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Clinical 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.

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.irc@nhs.net

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

How to report adverse incidents in Scotland

Please report directly to IRIC, further information can be found on our website

<http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-irc/how-to-report-an-adverse-incident/>

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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