Safety Notice 003/21

Breast implant associated-anaplastic large cell lymphoma (BIA-ALCL)

1 March 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Surgery
- Plastic and Reconstructive Surgeons
- Directors of Oncology
- Directors of Nursing and Midwifery
- Directors of Medical Services
- Medical Records Departments

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- NSW Breast Implant Expert Advisory Panel

Clinical Excellence Commission

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Internet Website:
https://www.health.nsw.gov.au/sabs/

Intranet Website:
http://internal.health.nsw.gov.au/quality/sabs/

Review date:

March 2022

Obsolete

Regulatory action of breast implant devices

On 25 July 2019, the Therapeutic Goods Administration (TGA) issued a Sponsor Initiated Medical Device Recall and Hazard Alert of Allergan macro-textured breast implants and tissue expanders. This was in response to reported rare incidents of BIA-ALCL in Australia and internationally.

Since then, the TGA have issued a number of actions, including the removal and suspension of several breast implant products from the Australian Register of Therapeutic Goods (ARTG), with conditions imposed on remaining products.

A list advising the current status of breast implant products in Australia, including those removed and suspended from the ARTG, is available on the TGA website. This list may be updated as new information emerges.

What is BIA-ALCL?

BIA-ALCL is a rare form of non-Hodgkin lymphoma (a cancer that affects the immune system) which develops in the fluid and scar tissue that forms around a breast implant.

Symptoms usually involve a swelling of the breast due to fluid accumulation, typically 3 to 14 years (an average of 8 years) after the operation to insert the breast implant. Less commonly, BIA-ALCL can take the form of a lump in the breast or armpit.

The vast majority of BIA-ALCL cases in NSW are detected in early stages and completely cured by removal of the implant and the surrounding capsule. However, in patients with no symptoms and/or signs of BIA-ALCL or other breast implant related complications, removal or replacement of breast implants or tissue expanders is not recommended.

Risk of BIA-ALCL varies depending on breast implant type

The estimated risk of BIA-ALCL is between 1-in-2,000 and 1-in-36,000 people with implants depending on the implant type.

All Australian cases of BIA-ALCL have involved textured implants, or implants that have polyurethane coating (described as Grade 2, 3 or 4). No cases have involved smooth surface (Grade 1) implants.

Risk of developing BIA-ALCL is considered highest for grade 3 and 4 textured implants, however all patients with a breast implant should undergo regular surveillance regardless of implant type (as with any medical device, other complications can emerge over time).

There have been over 100 reported cases of BIA-ALCL confirmed in Australia.

NSW Health actions to date

- Distribution of the TGA list of suspended or recalled products to all local health districts, private health facilities and relevant clinical networks advising these products should not be used and must be quarantined (September 2019)
- Formation of an expert panel including senior clinicians to provide advice on NSW Health actions (first convened October 2019)
- A sample of medical records for people who had a breast implant procedure performed was reviewed in consultation with professional groups. This confirmed that those with a breast implant would be able to obtain the required information
- Development of a communications campaign and resources to target impacted people and health professionals, including GPs
- Working with the TGA, Australian Commission on Safety and Quality in Health Care, professional societies, colleges and other jurisdictions to develop consistent information and clinical advice for patients and clinicians.

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Recommendations for NSW health facilities

1. Informed consent

For patients undergoing breast implant procedures, surgeons should comprehensively discuss all potential risks and benefits of the procedure, including the risk of BIA-ALCL, when obtaining informed consent for insertion of breast implants.

Manufacturer Patient Information Leaflets (PIL) outlining the risks of BIA-ALCL, imposed as part of the TGA conditions, should be provided to all patients considering surgery.

2. Provision of patient information

Patients undergoing breast implant procedures should:

In accordance with Information Bulletin IB2019_035 'Strengthening Practice – Implantable Medical Devices',

- be provided with written information following their surgery regarding the name, type of implant and procedure performed, in the form of:
  - the manufacturer's Patient Information Leaflet
  - the patient-specific implant card
  - a discharge summary
- have all information documented in their medical records.
- be encouraged to have their information captured in the Australian Breast Device Registry (ABDR)

Patients with implants already in situ should:

- be advised regarding recommended ongoing clinical surveillance (see below)
- be assisted to determine their implant type, if seeking this information. Options include:
  1. the patient-specific implant card
  2. their medical record

Where health information sought relates to continued treatment and/or future management, no charge should be raised as per NSW Health policy directive *Health Records and Medical/Clinical Reports – Charging Policy* (PD2006_050). Patients should be aware that some private health facilities may raise a fee for access to medical records.

  3. contacting the Australian Breast Device Registry (ABDR) if surgery was from 2015 onwards (03 9903 0205 or 1800 998 722), or the Australian Society of Plastic Surgeons for surgery prior to 2015 (02 9437 9200), noting these registries require the consent of the patient and surgeon for information to be held.

- be advised that in some cases, records may not have been retained or will be unable to identify the implant type and the recommended action is ongoing clinical surveillance (see below).

3. Ongoing clinical surveillance

- Current expert opinion recommends patients should undergo 12 monthly review (involving history and clinical examination) by their surgeon or GP for the duration of the breast implant remaining in situ, irrespective of implant type
- In addition, patients should be:
  - advised to become familiar with the usual features of their breasts
  - made aware of the common presenting symptoms of BIA-ALCL and other complications
  - conduct regular self-examination as they would for routine breast cancer awareness
  - encouraged to present for immediate clinical assessment should there be any change in size, shape or symptoms related to the breast and/or implant.

References / Other useful information can be found at:

TGA website:	Breast Implant Hub
NSW Health website:	Breast implants and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)
FDA Guidelines:	Breast Implants - Certain Labelling Recommendations to Improve Patient Communication.

Suggested Actions by Local Health Districts/Networks:

1. Distribute this Safety Notice to all relevant staff
2. Review and revise local protocols in line with this Safety Notice
3. Report any incidents associated with breast implants into IMS+, the TGA and (if relevant) in the ABDR.