



Recall of Allergan textured breast implants: what you should know as a health professional

On 2 August 2019, Allergan recalled their un-implanted Biocell® macro-textured breast implants and tissue expanders. This was due to the rare risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

If your patient already has an Allergan Biocell® implant, this fact sheet provides information to support your discussions with your patients.

Not all breast implants are affected

The recall on 2 August 2019 applies only to Allergan Biocell® macro-textured breast implants from the Natrelle product range. These implants have been returned to the supplier and are no longer available.

Allergan smooth and Allergan BRST Microcell® breast implants are not affected by the recall and are still available.

About BIA-ALCL

BIA-ALCL is a rare form of non-Hodgkin lymphoma—it is not breast cancer and there is no evidence of increased risk of breast cancer if a patient develops BIA-ALCL. In 2016, the World Health Organisation (WHO) classified BIA-ALCL as a distinct clinical entity, separate from other categories of ALCL.

Unique characteristics of BIA-ALCL include being purely T-cell; having no anaplastic lymphoma kinase gene translocation (ALK-); being CD30 receptor protein positive on immunohistochemistry (CD30+); and being in close anatomical association with a breast implant.

The aetiology of BIA-ALCL has not been confirmed, but it appears complex and multi-factorial and includes patient genetic predisposition.

It is hypothesised that T-cell stimulation due to a chronic bacterial biofilm infection increases the risk of BIA-ALCL. Implants with the highest surface area and surface roughness have shown higher rates of bacterial growth and T-cell activation. As bacterial

contamination at the time of surgery may cause the inflammation, standard-of-care precautions ([14 operative strategies](#)) such as antibiotic prophylaxis, pocket irrigation, sterility, and skin preparation should be maintained when placing an implant.

In over 4% of BIA-ALCL cases, BIA-ALCL has incidentally been found in the contralateral breast.

BIA-ALCL can develop whether the breast implant is inserted for augmentation or reconstruction purposes. It can occur with both saline and silicone gel filled implants.

Implants with a higher surface area and surface roughness (textured or polyurethane implants) are associated with a significantly higher risk of developing BIA-ALCL. No cases of BIA-ALCL have been reported following confirmed use of only smooth breast implants. For the latest data on BIA-ALCL cases in Australia go to the [TGA breast implant hub](#).



Diagnosis of BIA-ALCL

The mean period from implantation to presenting symptoms is eight years, with a range from six months to 37 years.

BIA-ALCL usually presents as enlargement of the breast due to a spontaneous late seroma. Less commonly, symptoms may include pain; a rash on the breast; a lump in the breast; or lymphadenopathy.

Initial diagnostic imaging should include ultrasound evaluation for fluid collection, breast masses, and enlarged regional lymph nodes. Note that a mammogram is not useful for detecting BIA-ALCL.

Any symptomatic peri-prosthetic effusions occurring more than six months after implantation should be aspirated and screened for cytology, flow cytometry and CD30 immunohistochemistry.

Further imaging by CT scan or MRI of the breast may be required. PET scan is useful to assess regional or systemic spread.

Routine laboratory blood tests include a complete blood count with differential, biochemistry and liver function profile.

Any tissue excised in the operative treatment of suspected BIA-ALCL must be sent for histopathological examination.

Management of BIA-ALCL

A multidisciplinary team approach is required for the [management of a patient with BIA-ALCL](#).

In about 80% of cases, the disease is limited to the seroma surrounding the implant and is cured by surgery. The surgical goals are removal of the breast implant, complete excision of the surrounding fibrous capsule, excision of any associated capsular mass and excisional biopsy of suspicious lymph node(s). There is no role for radical mastectomy, sentinel lymph node biopsy, or full axillary dissection.

If there are breast implants in both breasts, a bilateral procedure is performed, even if symptoms are only unilateral.

Additional surgery, radiotherapy and/or adjuvant chemotherapy may be required for treatment of local residual, unresectable or systemic disease.

If your patient has symptoms

Patients with symptoms of BIA-ALCL, or those who are unsure about changes in their breast, should see their general practitioner (GP) and surgeon as soon as possible.

The GP should review the patient and confirm who the implanting surgeon was. The patient should be referred to the implanting surgeon, or to a different surgeon if the original surgeon has retired or cannot be contacted. It is preferable for the GP to speak with the surgeon and arrange for diagnostic imaging scans and blood tests to be performed so that results are available at the time of the patient's appointment with the surgeon. Patients may seek a referral to another surgeon for a second opinion if they are unsure or feel that they need more help to be fully informed.

If your patient is asymptomatic

Evidence-based recommendations maintain that prophylactic removal of textured breast implants from an asymptomatic patient is unwarranted. This is because BIA-ALCL is a rare cancer with excellent cure rates if it is detected early, and the risk of developing BIA-ALCL is lower than the risks associated with an anaesthetic and surgery. Capsulectomy also carries risks. The complication rate of revision surgery involving implant removal or replacement is higher with each revision procedure. As many as one in four patients may require multiple revision procedures, and the time between operations may be significantly shorter for the second revision procedure.

In the event that a patient without symptoms or evidence of implant complications does undergo explantation, with or without replacement of implants, there is no scientific data to support complete removal of an implant capsule. However, if a capsulectomy is performed, both solid tissue and any seroma fluid (if present) should be sent for pathological examination. Cases where ALCL was diagnosed after implant removal without capsulectomy all had a history of seroma (presumably undiagnosed BIA-ALCL) at the time of implant removal. Pathologists can provide advice prior to surgery about transporting and testing of the specimens.

Review your patients regularly

It is important to advise your patients with breast implants to perform breast self-examination regularly, just like they would do to check for breast cancer.

In most cases, a seroma will not be due to BIA-ALCL, but it is important that all patients with suspected seroma are reviewed as soon as possible by their implanting surgeon.

All breast implants are considered to have a limited lifespan of 10 to 15 years. The risk of complications such as rupture, hardness, loss of shape, or change in position may increase with time. With the added risk of BIA-ALCL, experts advise that patients with breast implants should be reviewed annually by their implanting surgeon.



Record details of your patient's implant

If available, all patients should be given a patient implant card at the time of surgery that describes the type of implant and date of surgery. This information should also be recorded in the patient's operation sheet and also detailed in the patient's hospital discharge summary to their general practitioner (GP). Both GPs and surgeons should retain implant device details in their patient's medical records.

Where the implanting surgeon cannot be contacted, but it is known that the surgery was performed in a public hospital, patients can be advised to contact the hospital's medical records department for details of their breast implants.

Surgeons and their patients who provided information about the breast implant surgery to the Australian Breast Device Registry (ABDR) may apply to access their own information by contacting the Registry Coordinator on **1800 998 722**.

The [Breast Implant Registry \(BIR\)](#) was the precursor to the ABDR and ceased to register new patients from 6 May 2015. However, the Australian Society of Plastic Surgeons continues to maintain the BIR legacy data and to administer patient access to the unique data stored on the BIR. The BIR can be contacted at bir@plasticsurgery.org.au or on **(02) 9437 9200**.

Contribute to the Australian Breast Device Registry (ABDR)

The [Australian Breast Device Register \(ABDR\)](#) is the central repository of data for all breast device issues, including BIA-ALCL. The registry collects comprehensive data about breast implants, breast tissue expanders and dermal mesh. The ABDR will hold information about breast implants if both the patient and the surgeon consented to provide the information at the time of surgery.

The registry is independently managed by Monash University and is endorsed by Australian surgical societies representing plastic and reconstructive surgeons, cosmetic surgeons and general breast surgeons. The best results for monitoring long term device performance to improve patient safety will come from having a complete data set contributed by 100 per cent of surgeons who implant or explant breast devices.

Medicare rebates for services related to BIA-ALCL

Whether or not the original implantation surgery attracted a Medicare benefit, services for investigation and treatment of BIA-ALCL for all breast implant recipients are eligible for payment of Medicare benefits.

As with any other cancer, if the patient cannot afford to be treated as a private patient, a symptomatic patient can be referred to a public hospital.

Under the usual Medicare benefits arrangements, the cost of implants is not covered. Patients with

private health insurance should contact their insurer to find out if their policy would cover the cost of the implant, private hospital accommodation and hospital theatre costs.

Medicare benefits are payable for the following:

Consultations – As usual, for GP attendances, and for specialist attendances with a valid referral.

Investigations – Where medically necessary, Medicare Benefits Schedule (MBS) payments are also available for diagnostic imaging investigations, including MRI (MBS item 63547). Medicare rebates are also available for pathology services undertaken in the investigation or treatment of BIA-ALCL.

Management – As with any other service eligible for payment of Medicare benefits, the MBS item billed should be appropriate for the procedure that is medically necessary for the treatment of the patient.

- A Medicare benefit is payable under MBS item 45551 for removal of each breast implant and its surrounding capsule.
- Medicare benefits are also available under MBS item 45554 for implant removal, capsulectomy and replacement of breast implants if the original implant was inserted in the context of breast cancer or developmental abnormality.
- Other MBS items are available for lymph node procedures and for other types of breast surgery if required.

No Medicare benefits are payable for removal of breast implants in a patient who has no medical reason for the procedure.

Report adverse events

It is essential for the ongoing monitoring of breast implant devices that you [report problems with breast implants](#) to the TGA as well as to the ABDR. For more information see the TGA [Incident Reporting and Investigation Scheme \(IRIS\)](#).

Useful links

The Breast Implant Registry (BIR)
<https://plasticsurgery.org.au/protecting-patient-safety/new-australian-breast-device-registry-abdr>

The Australian Breast Device Registry (ABDR)
<https://www.abdr.org.au>

TGA resources

BIA-ALCL: Information for health professionals
<https://www.tga.gov.au/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alc>

Safety alert: Breast implants and anaplastic large cell lymphoma <https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma>

Breast implant hub
<https://www.tga.gov.au/hubs/breast-implants>

Report adverse events with a breast implant device
<https://www.tga.gov.au/reporting-problems>

Incident Reporting and Investigation Scheme (IRIS)
<https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris>

Further reading

Clemens MW, Jacobsen ED, Horwitz SM (2019) '2019 NCCN consensus guidelines on the diagnosis and treatment of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)', *Aesthet Surg J*; 39(Supplement_1): S3-S13; https://academic.oup.com/asj/article/39/Supplement_1/S3/5304919

Deva AK, Adams WP, Jr, Vickery K (2013) 'The role of bacterial biofilms in device-associated infection', *Plast Reconstr Surg*; 132(5):1319-1328.

Forster NA, Künzi W, Giovanoli P (2013) 'The reoperation cascade after breast augmentation with implants: what the patient needs to know', *J Plast Reconstr Aesthet Surg*, Mar; 66(3):313-22

Magnusson M, Beath K, Cooter R, et al. The epidemiology of breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants. *Plast Reconstr Surg*. 2019;143(5):1285-1292.

McGuire PA, Deva AK, Glicksman CA et al (2019) 'Management of Asymptomatic Patients With Textured Surface Breast Implants', *Aesthetic Surgery Journal Open Forum*; <https://academic.oup.com/asjopenforum/advance-article/doi/10.1093/asjof/ojz025/5552845>