Australian Government
Department of Health
Therapeutic Goods Administration

Recall of Allergan textured breast implants: what you should know if you have implants

On 2 August 2019, Allergan recalled their un-implanted Biocell® macro-textured breast implants and tissue expanders. This is due to the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a rare cancer of the immune system. If you already have an Allergan Biocell® implant in place, this fact sheet provides information to help you understand what the recall means for you.

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.

If you don't have symptoms, you don't have to remove your implants

Experts do not recommend removing your breast implants if you do not have symptoms of BIA-ALCL. This is because BIA-ALCL is a rare cancer with excellent cure rates if it is detected early.

The risk of developing BIA-ALCL is lower than the risks associated with an anaesthetic and surgery. The complication rate of revision surgery involving implant removal or replacement is also higher with each revision procedure.

Check your breasts regularly for symptoms

Whether you have breast implants or not, it is always recommended that you self-examine your breasts regularly to check for any changes.

The most common symptom of BIA-ALCL is swelling of a breast caused by fluid around the implant. Swelling is expected immediately after surgery, but you should see your doctor if swelling persists or if it occurs after the normal recovery period. In most cases, BIA-ALCL will not be the cause of swelling, but it's important to see your doctor to check.

BIA-ALCL may also present as persistent pain in the breast, a rash on the breast, or a lump in the breast, armpit or elsewhere.

Symptoms of BIA-ALCL, on average, occur at about eight years after insertion of the breast implants. However, BIA-ALCL has been known to occur as soon as 6 months after implantation and as late as 37 years after the operation.

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.

Talk to your doctor if you notice changes in your breast

If you have symptoms such as pain, swelling, a rash or a lump in your breast, or you are not sure about changes in your breast, you should see your general practitioner (GP) and surgeon as soon as possible.

Your GP can assess you and provide you with a referral to see your original surgeon (or a different surgeon if your original surgeon has retired or cannot be contacted). Your GP may also arrange for any diagnostic imaging scans or blood tests to be performed so that results can be available at your appointment with your surgeon.

When you meet with your surgeon, it is important you raise your concerns so they can assess you and discuss appropriate next steps for managing your implants. This may involve yearly check-ups.

If treatment is required, your surgeon will describe the options available. You may decide to have the implants removed without replacement, removed and replaced with another type of implant, or look at other breast reconstruction methods using natural tissue.

If you are concerned or unsure about the advice you receive, or you would just like to seek a second opinion, speak to your GP about getting a referral to another surgeon.

Detection and treatment of BIA-ALCL

BIA-ALCL is a rare cancer of the lymphatic system—it is not breast cancer. There is no evidence of increased risk of breast cancer if a patient develops BIA-ALCL.

BIA-ALCL can develop regardless of whether the implant is inserted for cosmetic reasons or for reconstruction of the breast following breast cancer. It can occur with both saline and silicone gel filled implants.

BIA-ALCL is a rare cancer of the lymphatic system—it is not breast cancer

With BIA-ALCL, cancer cells usually grow in the fluid (seroma) and scar tissue (capsule) that develops around the breast implant. Less commonly, BIA-ALCL can present as a lump in the breast or a lump in the armpit (lymph node) or elsewhere.

When BIA-ALCL is suspected, imaging by ultrasound and CT scan or MRI of the breast is performed. A mammogram is not useful for detecting BIA-ALCL. Other tests such as a PET scan may also be used to assess spread of the cancer. Diagnosis is confirmed by a pathologist looking at cells taken from a sample of fluid from around the breast implant.

Most cases of BIA-ALCL are cured by surgery alone, with removal of the implant and surrounding capsule. If there is a breast implant in each breast, then both implants are removed even if symptoms are only on one side.

If there is a solid lump or the cancer has spread, chemotherapy, radiotherapy or additional surgery may be required.

How many people are diagnosed with BIA-ALCL

All Australian cases (as of August 2019) have occurred in women who have had textured or polyurethane implants. There have been no cases in Australia involving women who have only had smooth implants. For the latest data go to the TGA breast implant hub.

In about 80% of cases, the disease is detected in the early stage and is curable, with cancer cells limited to the fluid surrounding the implant.

How to know what type of implant you have

Check the details on your implant card if you were given one at the time of surgery.

If you didn't receive an implant card, contact the surgeon who performed your breast implant surgery to find out what implant was used. The process may differ depending on where you had your surgery:

- If your surgery was performed in a public hospital, contact the hospital's medical records department for the details, which should have been recorded in your operation sheet.
- If your surgery was performed in a private hospital, then your surgeon will hold the patient record.

Your state or territory health department can assist with information about your legal rights to accessing your medical records.

Since 2014, the Australian Breast Device Registry (ABDR) is the central repository of data for all breast device issues, including BIA-ALCL. The ABDR will only hold information about your breast implant if both you and your surgeon consented to provide the information at the time of surgery. You may apply to access your own information at any time 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 (ASPS) continues to maintain the BIR legacy data and administer patient access to the unique data stored on the BIR. If you have questions about your participation in the BIR, please contact bir@plasticsurgery.org.au or call **(02) 9437 9200**.

Medicare help with the cost of testing or removal

In Australia, Medicare rebates are available to any patient whose doctor decides there is a clinical need to remove a breast implant. It does not matter whether or not original implantation surgery attracted a Medicare benefit at the time, 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, they 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 replacement implants, private hospital accommodation and hospital theatre costs.

Medicare pays rebates as follows:

Consultations – Consumers who have had breast implants are encouraged to consult with their doctor(s) regarding the need for clinical follow-up or radiological investigation. Normal Medicare arrangements are available for these consultations.

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

Management – Medicare rebates contribute to the medical costs, including those of the surgeon, anaesthetist and any surgical assistants. 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, for example, in a healthy person who has no symptoms or complications with the breast implants.

Where to go if you are concerned about the quality of your health care

If you have concerns about your breast implant surgery or follow-up care, you should firstly discuss this with your treating practitioner or hospital liaison officer. You may also wish to discuss your complaint with the relevant state or territory health authority, or the agency responsible for regulating health practitioners:

ACT ACT Human Rights Commission: https://hrc.act.gov.au

NSW Health Care Complaints Commission: https://www.hccc.nsw.gov.au

QLD Office of the Health Ombudsman: https://www.oho.qld.gov.au

SA Health and Community Services Complaints Commissioner: https://www.hcscc.sa.gov.au

TAS Health Complaints Commissioner Tasmania: https://www.healthcomplaints.tas.gov.au

VIC Health Complaints Commissioner: https://hcc.vic.gov.au

WA Health and Disability Services Complaints Commission: https://www.hadsco.wa.gov.au/home

ALL Australian Health Practitioner Regulation Agency (AHPRA): https://www.ahpra.gov.au

Useful links

Your first point of call for information relating to your breast implants should be your GP or surgeon. Useful information may also be found at the following webpages.

TGA patient resources

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

Report a problem with your breast implant device:
https://www.tga.gov.au/reporting-problems

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

Breast implant associated cancer (BIA-ALCL): Information for consumers:
https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl

Other organisations

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

Plastic surgeons

Australian Society of Plastic Surgeons:
https://plasticsurgery.org.au

Royal Australasian College of Surgeons:
https://www.surgeons.org

Breast surgeons

Breast Surgeons of Australian & New Zealand:
https://www.breastsurganz.org

Cosmetic physicians/surgeons

The Australasian College of Cosmetic Surgery:
https://www.accs.org.au

General practitioners

The Royal Australian College of General Practitioners:
https://www.racgp.org.au

Other consumer support

Breast Cancer Network Australia:
https://www.bcna.org.au