

# Information for people with breast implants

It is important to be aware:

- breast implants are not intended to be lifelong devices and most breast implants need replacement or removal within 10-15 years of initial insertion
- although many people with breast implants will not experience any issues, there are some common and some less common complications that can occur
- people with breast implants are recommended to regularly self-examine their breasts and see their GP or surgeon every 12 months for a clinical review to assess for complications or other concerns.

#### What are some of the complications associated with breast implants?

Like any medical device, people with breast implants can experience complications associated with the surgery to insert them (e.g. infection or bleeding) or with the breast implant itself (e.g. rupture).

Complications can occur during the immediate period after surgery (e.g. bleeding) or months or years later (e.g. capsular contracture where scar tissue that has formed around the implant hardens and squeezes the implant).

In very rare cases, breast implants can cause an immune cell cancer called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

Other complications can include:

- breast pain
- changes in nipple and breast sensation
- asymmetry (one breast appears different in size or shape to the other)
- malposition/ displacement (a breast implant moves out of its intended position)
- ptosis (sagging of the breast)
- skin rash
- wrinkling/rippling
- dissatisfaction with the result
- additional surgeries.

#### How common are complications, including BIA-ALCL?

It can be difficult to estimate the risk of developing complications from breast implants because we do not know the exact number of implants inserted and information on complications has not been recorded for every person with an implant in a single database

The Australian Breast Device Registry (ABDR) currently collects information on people who have had a breast implant procedure<sup>[1]</sup>. For 5,886 people who had revision (a second) surgery for a breast implant in 2018, complications recorded from least to most common were:

- capsular contracture: 41 of every 100 people were found to have capsular contracture
- device malposition: Nearly 28 of every 100 people were found to an implant that had moved position

- device rupture: 1 in 5 people were found to have an implant rupture
- seroma/haematoma: 3 of every 100 people were found to have a fluid collection or bleeding and bruising
- deep wound infection: 1 of every 100 people were found to have a severe wound infection
- BIA-ALCL: 4 of every 1000 people were found to have BIA-ALCL.

#### What is **BIA-ALCL**?

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare T cell non-Hodgkin lymphoma that develops around breast implants. It is a cancer of the immune system, not a breast cancer.

Symptoms of BIA-ALCL usually include sudden swelling (due to a build-up of fluid around the implant) or pain in a breast or the armpit, and occasionally a lump or rash.

Most cases of BIA-ALCL recorded so far have developed on average 7-8 years after original insertion of the implant (range 3 -14 years after original insertion).

BIA-ALCL can be diagnosed by taking a sample of fluid (if present) or tissue from the breast using ultrasound (known as Fine Needle Aspiration), or can be diagnosed by histopathology of capsule tissue after implant removal. It cannot be diagnosed by a blood test.

If diagnosed early, surgical removal of the implant and capsule is generally curative, i.e. no further treatment such as chemo is required.

#### Where can I find out more information about BIA-ALCL?

- The <u>Therapeutic Goods Administration (TGA) breast implant hub</u> has general information on breast implants, complications and BIA-ALCL and has developed a <u>video of frequently asked questions</u>.
- <u>The Australian Society of Plastic Surgeons</u>

#### Does the type of implant affect the risk of complications?

Breast implants can be classified in different ways, by the:

- brand or manufacturer
- contents e.g. silicone or saline, or both
- shape e.g. round or 'anatomical'
- surface usually described by grade e.g. grade 1 (smooth) through to grade 4 (highly textured). The higher the grade, the more rough the surface.

Some complications are more common with different types of implants, and also more common depending on the reason for surgery in the first place, i.e. cosmetic augmentation or mastectomy reconstruction.

For example, smooth implants may be more likely to move position compared to some textured implants; and saline implants may be more likely to rupture than silicone implants.

The risk of developing BIA-ALCL has also been found to increase with the grade (roughness of texturing) of the implant:

- as of January 2020, no reported cases of BIA-ALCL have occurred in people with a known history of **only** smooth (grade 1) implants.
- for higher grade implants, the estimated risk varies from 1 in 36000 implants for a grade 2 implant to 1 in 2000 for a grade 4 implant:

| Implant grade | Example implant type | Estimated risk[2]  |
|---------------|----------------------|--------------------|
| 4             | Silimed Polyurethane | 1 in 2000 - 2500   |
| 3             | Allergan Biocell     | 1 in 2500 - 3000   |
| 2 - 3         | Nagor Textured       | 1 in 5000 - 6000   |
| 2             | Mentor Siltex        | 1 in 15000 - 36000 |

### How can I find out what type of implant I have?

There are a few options to find out your implant type:

- 1. Many people are given a wallet size card ('patient implant card') after their surgery which has the details (brand, model, size etc) of the breast implant recorded on it.
- 2. Contact the original surgeon (including overseas if this is where you had your surgery).
- 3. Contact the Breast Implant Registry (BIR) if surgery was prior to 2015 or the Australian Breast Device Registry (ABDR) if surgery was from 2015 onwards:
  - BIR: Australian Society of Plastic Surgeons (ASPS) at 02 9437 9200 or bir@plasticsurgery.org.au
  - <u>ABDR</u>: 03 9903 0205 or 1800 998 722 or <u>abdr@monash.edu</u>

Note: Both the ABDR and BIR require individuals to consent to their information being held so not all people will have a record.

4. Contact the hospital medical records department (including overseas if this is where you had your surgery).

Usually, individuals are required to pay a fee to the hospital to access their medical records. For people who had breast implant surgery in a NSW public hospital, NSW Health is waiving this fee, in accordance with NSW Health policy directive <u>Health Records and Medical/Clinical Reports - Charging</u> <u>Policy</u> (PD2006\_050). However, please be aware that some private health facilities may raise a fee for access to medical records.

It is also important to be aware that in some cases records of implant type may not be available because surgery was further back than records are kept, in other cases records may have been lost or the implant device was never recorded.

Knowing the type of implant you have can help you understand the risks, but it is not essential. Most experts are now recommending people with implants have regular follow-up by their GP or surgeon every 12 months to assess for complications, this is regardless of the type of implant or reason for its insertion.

#### If I have a breast implant, what should I do?

Everyone with a breast implant should regularly self-examine their breasts, implants and armpits for any changes, including any unusual swelling or lumps, change in the shape or feel of your breasts, or any nipple and skin changes.

If you're unsure how to examine your breasts, these websites have useful information:

- Family Planning NSW Breast Awareness
- Sydney Breast Cancer Foundation
- Search for videos in your online search engine

If you notice any changes or you have concerns (including about BIA-ALCL), see your GP. If you are still under the care of your surgeon, for example you are still followed-up by your surgeon after reconstructive surgery, you can also see them.

Everyone with a breast implant should see their GP or surgeon every 12 months for clinical review, regardless of whether you have noticed any breast changes or what type of implant you have. Clinical review will usually include being asked some questions about whether you have any symptoms or have noticed any changes and an examination of your breasts, implants and armpits. In some cases, the doctor may order an ultrasound.

People who are eligible for breast cancer screening through BreastScreen NSW (women aged 50-74 years) should attend for their mammogram when called. Mammograms are safe to be done with breast implants, just tell a staff member or indicate on any forms that you have a breast implant.

BreastScreen NSW has more information at **BreastScreen NSW - Screening and Breast Implants**.

## Should I have my implants removed even if I don't have symptoms of a complication or BIA-ALCL?

Experts are not recommending removal of breast implants where there are no symptoms or signs anything is wrong. This is because:

- BIA-ALCL is currently seen as rare
- BIA-ALCL has a high rate of cure once diagnosed
- surgery to remove breast implants is technically complicated and can do more harm than good if there is no clinical reason to remove the implant
- any surgery and anaesthetic has risk if you do not have any symptoms, it is unlikely you have a complication, including BIA-ALCL.

The best course of action is to continue to regularly self-examine your breasts, monitor for any changes and see your GP or surgeon every 12 months for a review, or earlier if you have concerns.

It is always best to see your GP for advice before consulting a surgeon offering 'easy' removal of breast implants.

It is ok to get a second opinion if you still feel unsure or are not satisfied with the information given to you by your GP or surgeon. Bringing a partner, family member or friend to your appointment to support you, ask questions or take notes may help.

#### References

- Individuals have to consent to have their information recorded in the ABDR so the registry is not a complete record of all surgeries in Australia. Reference: Hopper I, parker E, Pelligrini B et al. The Australian Breast Device Registry 2018 Annual Report. Monash University, Department of Epidemiology and Preventive Medicine, October 2019
- Based on sales data and implant exposure of Australian BIA-ALCL cases. Reference: Loch-Wilkinson A, Beath KJ, Magnusson MR et al. <u>Breast implant-associated anaplastic large cell lymphoma: a</u> <u>longitudinal study of implant and other related risks</u>. Aesthetic Surgery Journal. 2019. Sjz333. More information is available on the <u>Therapeutic Goods Administration breast implant hub</u>.