



The Australasian College of Cosmetic Surgery *Raising Standards, Protecting Patients*

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PATIENT INFORMATION

TGA ban of certain textured breast implants

Australia's peak body for cosmetic surgeons has issued the following advice in response to the Therapeutic Goods Administration's (TGA) [suspension/cancellation] of certain textured surfaced breast implants:

- Australians who have received textured implants should be aware that the bans have not been made because the risk has changed – it remains very low for all implants including those that will now no longer be available.
- For example, the TGA has decided to ban one type of implant that has had only had a single case of non-malignant ALCL in Australia and only one other non-malignant case in the world.
- For the many Australians who have the banned implants, they will want to know what their risks are and what they should do.
- There is no cause for alarm.
- The advice from the TGA and all experts in the field remains: there is no need to remove these implants as a precaution.
- The risk of developing BIA-ALCL for those with textured breast implants remains very low and the risk of developing a cancer that spreads is extremely small.
- If you do not have any symptoms (see below), there is no need for any action.

The Australasian College of Cosmetic Surgery (ACCS) is a national leader on research concerning BIA-ALCL and some of its Fellows sit on the TGA's Expert Advisory Panel on Breast Implants.

Further patient information on textured breast implants:

- BIA-ALCL is a rare condition and the TGA's ban does not change this.
- BIA-ALCL usually involves a swelling of the breast, typically 3 to 14 years after the operation to insert breast implants. 50% of cases occur by 7-8 years after implantation. This swelling is due to an accumulation of fluid and is known as a seroma. Less commonly, BIA-ALCL can take the form of a lump in the breast or a lump in the armpit.
- Currently, the worst-case estimate of the risk for the implants affected by the suspension/cancellation remains very low, about 1 in 1,000. This means that 99.9 per cent of women with these implants will not get BIA-ALCL.

- We now know that at least 80-90% of those 1 in 1000 patients will have the abnormal cells only in the fluid around the implant and that this is not a cancer. A published peer-reviewed paper in the respected journal *Aesthetic Plastic Surgery* which explains the evidence for this can be found [here](#).
- This paper's findings have subsequently been supported in the leading Journal *Plastic and Reconstructive Surgery* where Professor Bill Adams wrote in May 2019, *"It is indeed not accurate to call disease in a patient with only positive cells in a seroma a lymphoma when there is no tissue-based source or vascularized malignant process histologically identified in the capsule"*
- Fluid only patients have a pre-cancerous condition which, if untreated, might in some patients develop into a cancer.
- Fluid only patients are completely cured by removal of the implants and the capsule or membrane around them and it is essential that all women who are diagnosed with fluid only BIA-ALCL have the curative surgical treatment.
- This leaves one or two women in 10,000 who do have a cancer beyond the fluid. In most of these, the cancer cells are localised in the capsule. These patients are also cured by the removal surgery and do not need any other treatment.
- The risk of developing an invasive cancer that needs chemotherapy and/or radiotherapy in addition to the removal is less than 1 in 10,000 and, when this is needed, it is usually curative. The risk of dying from BIA-ALCL does exist but is so small it cannot be reliably calculated. It is considered to be less than 1 in 1 million.
- A peer reviewed paper published in the journal [Aesthetic Plastic Surgery](#) also helps to put the risk into perspective. This showed the risk of death from skiing for one day was twice as high as having textured breast implants and the risk of driving for 8 hours was 40 times higher. More information is available [here](#) and [here](#) is a video of the authors explaining their findings.
- To put this into further perspective, the risk of any Australian woman, with or without breast implants, of developing breast cancer (not BIA-ALCL) is one in eight. The lifetime risk of developing any kind of lymphoma is one in 50.
- If you experience unexplained enlargement of one or both breasts, or if you find a lump, you should speak to your doctor. If you have further questions you should speak to your GP or your surgeon.

More information:

Information for consumers about BIA-ALCL, its symptoms and treatments is available on the TGA Breast Implant Hub [here](#)

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