



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

11 July 2019

### **MEDIA RELEASE**

#### **RESPONSE TO TGA PROPOSAL TO BAN CERTAIN BREAST IMPLANTS**

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

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.

Expert Adviser to the TGA and ACCS' BIA-ALCL Safety Committee Chair Dr Daniel Fleming said Australians who have received textured implants should consider all of the evidence before taking any decisive action.

"For the many Australians who have these implants, they will want to know what their risks are and what they should do," he said.

"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 patients do not have any symptoms, there is no need for any action because of this TGA announcement."

#### **Further consumer information on textured breast implants:**

- BIA-ALCL is a rare condition and the TGA's review 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. 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 proposed 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.
- For the 1 in 1,000 patient who does develop BIA-ALCL there is an 8-9 out of 10 chance they will have a version of the disease that is confined to the fluid around the implant. This is 100 per cent cured by removal of the implants and the capsule (membrane) surrounding them.

- This leaves one or two women in 10,000 who 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 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.
- It is increasingly believed by researchers that the vast majority of women in whom these cells are found, have a version of the condition that does not behave like a cancer but remains benign. A published peer-reviewed paper in the respected journal Aesthetic Plastic Surgery which explains the evidence for this can be found [here](#). The surgeons in the video link above also support the view that most patients have a non-malignant version of the disease.
- While this is encouraging, **it is essential that all women who are diagnosed with BIA-ALCL have the surgical treatment that is known to be curative.**
- If you have concerns, you should speak to your surgeon.

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

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#### About the Australasian College of Cosmetic Surgery

Established in 1999, the Australasian College of Cosmetic Surgery (ACCS) is a not-for-profit, multi-disciplinary fellowship-based body of Cosmetic Surgeons, cosmetic physicians, plastic surgeons, general surgeons, maxillofacial surgeons, dermatologists, ear nose and throat surgeons, ophthalmologists and other doctors and health care practitioners who practice in cosmetic medicine and surgery. The primary goal of the ACCS is to ensure the safe provision of cosmetic medicine and cosmetic surgical procedures to the Australian community through the supply of appropriately trained and certified health care practitioners. The ACCS is the only medical college which provides education and training leading to fellowship specifically in cosmetic medicine and surgery. Fellows of the College are medical doctors who have completed post-graduate education and training and demonstrated competency specifically in cosmetic medicine and surgery. To become an ACCS Surgical Fellow, doctors must typically complete a minimum of 12 years of medical and surgical education and training. For additional information about the ACCS, please visit: <http://www.accs.org.au/>