## Media Release



## 26 September 2019

## TGA prioritises patient safety in their review into textured breast implants

As the preeminent body representing Specialist Plastic Surgeons who specialise in cosmetic surgery, the Australasian Society of Aesthetic Plastic Surgeons (ASAPS) has welcomed the Therapeutic Goods Administration (TGA) findings into breast implants and breast tissue expanders that were released today.

Dr Naveen Somia, President of the ASAPS, said today is a good day for patients.

"This review has prioritised patient safety with the breast implants that have the highest risk of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) suspended for six months. However, it still leaves viable options for patients on the market.

"ASAPS was concerned about the proposed removal of all tissue expanders, so it's pleasing to see these devices remain available. Tissue expanders are an essential component in breast reconstruction surgery, and many women would be significantly disadvantaged if these were not available.

"Another vulnerable group who will benefit from today's decision to leave the micro-textured, or Grade 2 devices on the register, are those who suffer from breast deformities due to radiation, burns, or congenital disabilities.

"It seems the TGA has listened to the advice of its independent expert review panel," Dr Somia said.

The TGA review was prompted by an increasing number of cases of BIA-ALCL detected in women with a history of breast implants and tissue expanders.

Dr Somia said due to its rarity, it's difficult to be sure about the exact level of risk of developing this disease.

"The risk of developing BIA-ALCL with textured implants differs with different grades of texture from one in 2,800 to one in 80,000. Comparatively, breast cancer occurs in one in every eight women.

"Patients need to remember that BIA-ALCL is very rare, and the clinical advice remains that, without symptoms, it is not necessary to remove your breast implants. Instead, patients who have breast implants, should regularly check their breasts and see their doctor if they notice any changes," Dr Somia said.

By seeking out the services of a Specialist Plastic Surgeon for your breast surgery, ensures your safety is the top priority by having a surgeon who:

- 1. Is accredited as a Specialist Surgeon by the Australian Health Practitioner Regulation Agency (AHPRA).
- 2. Uses stringent breast implant infection control standards, such as the 14-Point-Plan.
- 3. Operates only in Licensed Facilities.
- 4. Only uses TGA approved products.
- 5. Is committed to lifelong learning in cosmetic surgery to stay at the forefront of developments.

ASAPS acknowledges the vital role played by the TGA in keeping Australians safe. Especially over the past few months with an enormous amount of work conducted including commissioning internal scientific reviews, meeting with external advisory groups, liaising with overseas regulatory authorities and research groups to advance public safety on sound scientific evidence.

For detailed information on the decision, visit the TGA's website: *Breast implants and anaplastic large cell lymphoma* and *Breast implant hub*.

## Ends

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