Australian Society *of* Plastic Surgeons

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Textured Breast Implants: What do I need to know?

The TGA (Therapeutic Goods Administration) has notified manufacturers that certain textured breast implants may be removed from the market (cancelled) and others may be suspended for 6 months for review depending on the nature of the texturing of their surface.

This is a notice of intent only and nothing has changed in legislation at the present. The breast implant manufacturers will have util the 24th of July to respond to this proposal. The TGA is responding to international scientific papers, including many from Australia, which show a possible link between the degree of texturing of an implant and the risk of developing a Breast Implant Associated Anaplastic Large Cell Lymphoma. (BIA: ALCL) Until the TGA announce their final decision, textured implants and tissue expanders are available for insertion. **ASPS encourage their members to consider the least textured implant that will achieve a satisfactory result for their patient.**

Commonly, the surface types are broken into Polyurethane, Macro-textured (heavily textured silicone surface) Micro-textured (less textured silicone surface), and smooth. The risks with these devices are the highest with Polyurethane covered implants, then Macro-textured, then Micro-textured. Smooth implants are thought to carry no risk or negligible risk.

The TGA has reinforced international expert opinion that current implants do not need to be removed from patients in the absence of symptoms. Patients who have implants should know about the symptoms that are relevant. A swelling of the breast or a lump in the breast should be checked and investigated. It is important for a patient to know the type of surface on their implant or tissue expander. This information should be available from your surgeon or from the breast implant registry if you are registered and your surgeon is no longer in practice.

The majority of ALCL cases occur in free fluid (seroma) around the implant and are cured by removal of the implant and the implant capsule. Occasionally, a solid tumour arises and this can be more advanced disease and may require more extensive treatment. In Australia over the last decade, out of the total 99 confirmed cases, 4 women have died. Whilst tragic, the individual risk of death from this disease is low and the risk of developing the disease itself is very low. The rise in risk of death from ALCL in a given patient with textured implants is thought to be in the range of the rise in risk from riding a bike for 17miles or living 2 days in NYC (Sieber and Adams ASJ 2017) Monitoring of polyurethane and heavily textured implants will likely be recommended at more frequent intervals than minimally textured implants. We await consensus internationally on this topic. There is no thought that smooth implants require special attention or monitoring because of this release.

ASPS has international representation on committees that advise on policy and guidelines for the safe use and monitoring of implants.

Other jurisdictions such as France and Canada who have preceded us with this change have not restricted the use of minimally textured breast implants and tissue expanders.

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ASPS is primarily concerned with patient safety. In this light, we are concerned about a change in availability of textured tissue expanders and implants for breast reconstruction. Whilst the needs of many cosmetic patients may be met with smooth round implants, there are a significant group of reconstructive patients where texturing is required to stabilise the position of an anatomical implant or tissue expander. If these devices are not available in the future to Australian women, the choice of reconstruction will be narrowed and more patients will be pushed towards autologous reconstruction (using their own tissues from elsewhere in the body) or not offered any reconstruction at all. Autologous breast reconstruction offers good results for patients but is a more complex and expensive procedure, carries some higher-grade complications and is less readily available in Australia than prosthetic (implant) reconstruction.

Australian research from ASPS members has shaped the world view on this condition. Our Australian Breast Device Register continues to monitor and assess the risks.

The following extract by Australian researchers highlights the leading role we are playing in relation to BIA-ALCL:

"The predominance of effusion-limited disease as the major presentation of BIA-ALCL with good cure rates in our series further emphasizes the importance of early detection and treatment. The findings of significantly higher implant-specific risk for grade 3 *(macro textured)* and 4 *(polyurethane)* implant surfaces will allow better communication of risk to patients and serve to aid the surgeon in choice of implant surface type when using breast implants for any indication." Magnusson et al, Plastic and Reconstructive Surgery, May 2019 Volume 143

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