



MEDIA RELEASE – 20th December 2016

Specialist Plastic Surgeons' statement on Breast Implant Associated Anaplastic Large Cell Lymphoma

Australian specialist plastic surgeons have identified a higher than previously suspected risk of women with breast implants developing a rare form of lymphoma.

Today the Therapeutic Goods Administration (TGA) issued an update reporting an increased risk associated with textured and polyurethane breast implants and breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

"Australian specialist plastic surgeons have been at the forefront of research into this lymphoma and are working closely with the TGA to share information, including recent research identifying an increased risk of the disease," says taskforce chair and president of the ASAPS Dr Mark Magnusson.

Previously the risk was estimated between one in 3 million to 1 in 50,000. The TGA now estimates the risk ranges between 1 in 10,000 and 1 in 1,000.

The disease is still categorised as 'rare' and the TGA does not recommend implant removal as a preventative measure, but advises women to monitor their breasts for any changes and consult their surgeon if they have concerns.

BIA-ALCL is not breast cancer and is highly treatable with most cases cured by removal of the implant and the capsule surrounding the implant.

A BIA-ALCL Joint Task force which includes the Australian Society of Plastic Surgeons (ASPS), Australasian Society of Aesthetic Plastic Surgeons (ASAPS), New Zealand Association of Plastic Surgeons was established in 2015 in response to an increase in cases in Australia and New Zealand.

"While the known risk has increased, we have been aware of the link for some years and have supported a 14-point safety plan, developed by Australian plastic surgeons, that outlines strategies to minimise bacterial contamination at the time of implant insertion," said Dr Mark Magnusson.

"While the cause of BIA-ALCL remains unproven, the importance of stringent standards and infection control is critical in light of a growing body of evidence that suggests a link between the growth of

bacteria on the surface of breast implants leading to the development of BIA-ALCL over time,” said Dr Magnusson.

“It’s important to emphasise that the risk still remains very low, so unless there are associated symptoms such as a sudden swelling of the breast or a lump women do not need to have implants removed. However, we recommend women get their implants checked regularly,” said Australian Society of Plastic Surgeons president, Dr James Savundra.

“The vast majority of women with swelling of the breast do not have BIA-ALCL but it should be investigated via an ultrasound scan with the fluid around the implant analysed.

“Plastic surgeons are informing all patients undergoing breast implant surgery of the risk of BIA-ALCL and we recommend patients with breast implants be followed with annual clinical examinations.

To date there have been 46 cases identified in Australia and three deaths. The time lag between the time of implant to presentation of BIA-ALCL is anywhere between 3 and 14 years.

“This reinforces the need for a mandated Breast Device Registry that captures all women with breast implants. The Australian Government has supported the development of a new registry and we would encourage all women undergoing breast implant surgery to ensure they are included on the registry and for government to help make this happen,” said Dr Savundra.

“A robust Breast Device Registry is an important resource that helps researchers access and utilise meaningful data for research to help us better understand any problems associated with breast implants, and acts as an early warning system if issues do arise..”

While there is an increased risk of the disease associated with textured surface and polyurethane implants the risk is considered ‘extremely rare’ when only smooth implants are used.

The task force is continuing its research into this disease in collaboration with other major local and international research groups to increase our knowledge and understanding of BIA-ALCL.

Plastic surgeons are also working closely with the government, manufacturers and regulatory bodies in the interests of protecting patient safety.

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To read the full TGA update: www.tga.gov.au

For more information on BIA-ALCL: www.plasticsurgery.org.au or www.asaps.org.au