

FREQUENTLY-ASKED QUESTIONS ON THE RISK OF BREAST IMPLANT ASSOCIATED-ANAPLASTIC LARGE CELL LYMPHOMA

Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)

1. What is BIA-ALCL?

Breast Implant Associated-Anaplastic Large Cell Lymphoma or BIA-ALCL is a rare type of lymphoma that usually develops around breast implants. It is a cancer of the immune system and is not a type of breast cancer. It usually involves a swelling around the implant and has been reported to occur as early as 1 year and as late as 37 years after the breast implant surgery.

2. Why is there a higher incidence of BIA-ALCL in textured implants as compared to smooth-surface implants?

Currently, the causes and the associated risk factors for BIA-ALCL are still unclear and are being actively investigated globally. The extent to which the surface of the breast implants being a risk factor in developing BIA-ALCL is also under investigation. While the majority of patients who have developed BIA-ALCL globally have had textured implants, there have been a few unconfirmed reports of BIA-ALCL in patients who have received smooth-surfaced implants. The possible association is currently being investigated.

HSA will continue to monitor and update the public should there be any significant new findings.

3. Have there been any deaths associated with BIA-ALCL in Singapore?

There have been no deaths associated with BIA-ALCL locally.

4. Aside from BIA-ALCL, what are the other common side effects associated with breast implants?

Some of the known adverse effects or complications associated with breast implants include implant rupture (a tear or hole in the implant's outer shell), reoperation/ implant removal and capsular contracture (tightening of the tissue capsule around an implant, resulting in hardening of the breast).

Advisory to consumers

5. I have breast implants. How do I know if I have BIA-ALCL?

You are advised to conduct regular breast self-examinations. If you notice enlargement, swelling or a lump, or experience pain around your implant, you should consult your doctor as soon as possible.

You should also continue with the periodic follow-up post-implantation, as scheduled by your doctor. Post-operative follow-up plays an important role for early detection of BIA-ALCL.

6. I have textured breast implants. Should I have them removed?

The Expert Panel convened by HSA, as well as the Chapter of Plastic, Reconstructive and Aesthetic Surgeons, do not recommend removal of implants for patients who do not experience any symptoms such as swelling or pain around the implant. If you are concerned about the risks of the implants, you should discuss your options with your doctor.

Generally, breast implants typically may require removal after 10 to 15 years, regardless of the risk of BIA-ALCL.

7. I am considering breast implantation. What factors should I consider when choosing between textured or smooth surfaced breast implants? Are smooth surfaced implants safer?

You should discuss the risks and benefits of breast implants and the different types of implants with your doctor, regardless of whether the implant is for reconstruction or augmentation purposes.

Your doctor would be best positioned to advise on the suitability of the different implants for you, by taking into consideration factors such as the nature of the surgery, as well as your physical and medical condition.

Regulation and usage of breast implants locally

8. How are breast implants regulated in Singapore?

Breast implants are classified as high risk medical devices in Singapore. These products are subject to registration by the Health Sciences Authority (HSA) to evaluate their safety, quality and efficacy prior to supply and usage in Singapore.

HSA also conducts post marketing surveillance to monitor the safety profile of marketed products and will take the necessary actions to remove the products from the market should any safety concerns be detected. Companies are also required to report serious adverse events related to their medical devices to HSA.

9. How many brands of breast implants are available in Singapore?

HSA has registered 8 brands of breast implants as of April 2019.

10. Are the other brands of breast implants registered for use in Singapore safe?

All breast implants are subject to registration by HSA to evaluate their safety, quality and efficacy prior to supply and usage in Singapore. This is complemented with a post market surveillance programme to monitor the safety profile of marketed products.

Global reports have indicated increased incidence of BIA-ALCL with the use of macro-textured breast implants. Currently, Allergan Natrelle breast implant is the only macro-textured breast implant registered in Singapore. As a precautionary measure, HSA has disallowed the sale of the Allergan Natrelle breast implant in Singapore since April 2019.

The remaining registered breast implants are smooth or textured (not macro-textured as defined by the international standard for breast implants). We are closely monitoring the evolving scientific information and global reports regarding the continued safety of the breast implants. Consumers will be updated on any new significant information.