



FOR IMMEDIATE RELEASE
HEALTH SCIENCES AUTHORITY
PRESS RELEASE
10 MAY 2019

RISK OF BREAST IMPLANT ASSOCIATED-ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

The Health Sciences Authority (HSA) would like to alert the public to the risk of Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL), a rare type of lymphoma that usually develops around breast implants. This is in view of more information that has recently come to light on this risk. HSA advises persons with breast implants to consult their doctors if they experience pain or swelling around their implants after the surgical incision has healed. Those who are considering breast implants should discuss the benefits and risks of the different types of implants with their doctors.

ABOUT BREAST IMPLANTS & BIA-ALCL

2. Breast implants have a silicone outer surface that is either smooth or textured. Globally, the majority of persons with breast implants who have developed BIA-ALCL have had textured implants. The estimated incidence rates of BIA-ALCL reported in literature¹ range from one in 3,817 to one in 30,000 persons with textured breast implants. Further review of the global reports on BIA-ALCL indicates a relatively higher incidence rate in those implanted with macro-textured breast implants.

3. There are also a few unconfirmed reports of BIA-ALCL in patients who have received smooth-surfaced implants². The possible association is currently being investigated by regulators globally.

4. BIA-ALCL is a cancer of the immune system and 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. An estimated 10 to 35 million breast implants have been implanted worldwide (as approximated in the scientific literature). There have been approximately 800 reports (both confirmed and unconfirmed reports) of BIA-ALCL.

¹ Loch-Wilkinson et al, 2017 and Doren et al, 2017 (Plastic Reconstruction Surgery)

² "Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)", 2019, FDA, US Food and Drug Administration

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

5. If diagnosed early, BIA-ALCL can be successfully treated with surgery. However, in cases where the cancer has spread to other parts of the body, further treatment such as radiation or chemotherapy and targeted immunotherapy have been used.

LOCAL SITUATION

6. Since 2017, following emerging scientific reports on BIA-ALCL, HSA has required manufacturers of breast implants to include cautionary statements regarding the risk of BIA-ALCL in the package inserts of breast implants registered in Singapore. HSA had also informed relevant healthcare professionals in October 2017 to highlight the risk of BIA-ALCL and the possible association with textured surface breast implants to patients, and to report any BIA-ALCL cases they encounter to HSA.

7. Given the growing global concerns on BIA-ALCL, HSA convened an Expert Panel³ in February 2019 to assess the evolving situation and risk of BIA-ALCL as well as relevant mitigation measures. Based on current scientific data, the Expert Panel assessed that textured surface implants appeared to be associated with a higher risk than the smooth ones. However, the risk factors associated with the disease are still unclear. The panel noted that BIA-ALCL occurrences are rare and the associated mortality rates remain low. While regulatory agencies are actively investigating the risk of BIA-ALCL, it is advised that timely detection and appropriate clinical management remain the key factors in managing BIA-ALCL effectively.

8. There are currently eight registered brands of breast implants in Singapore. Macro-textured breast implants are associated with the highest risk of BIA-ALCL, and the Allergan Natrelle breast implant is the only macro-textured breast implant registered in Singapore. HSA has taken the precautionary measure of disallowing the sale of the Allergan Natrelle breast implant in Singapore since April 2019. This decision was supported by the Expert Panel.

9. To date, HSA has received one report of BIA-ALCL locally. The patient, who was diagnosed early, is recovering.

ADVISORY TO CONSUMERS

10. HSA advises persons considering breast implants for reconstruction or augmentation purposes to discuss their options with their doctors, including the risks and benefits of different types of implants.

11. HSA advises persons who have breast implants to take note of the following:

³ The Expert Panel comprises a group of healthcare professionals from both public and private hospitals.

- Consult your doctor if you develop swelling, lumps or pain around your implant after the surgical incision has healed.
- Conduct regular breast self-examination and 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 the disease.
- While removal of breast implants is not necessary if you have not experienced any problems with the implant, please consult your doctor to discuss your options if you have concerns.

12. Professor Ong Yee Siang, Head and Senior Consultant of Plastic, Reconstructive and Aesthetic Surgery at the Singapore General Hospital and HSA's Expert Panel member on Breast Implants, advises: "BIA-ALCL is a rare type of lymphoma that could develop around breast implants. Removal of breast implants is not necessary for patients implanted with breast implants if you have no symptoms of swelling, lumps or pain around your implant. Consult your doctor to discuss your options if you are concerned. In addition, patients considering breast implants should discuss the risks and benefits of the different types of implants with your doctor."

13. HSA has prepared an infographic on the risk and presenting symptoms of BIA-ALCL, as well as a list of frequently asked questions on this topic. Please refer to Annexes A and B. These materials can also be found on our website at www.hsa.gov.sg/bia-alcl.

14. HSA will continue to closely monitor the global developments and review the evolving scientific information regarding this safety issue. HSA will update the public with more information should there be any significant new findings.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
10 MAY 2019**

About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and

adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

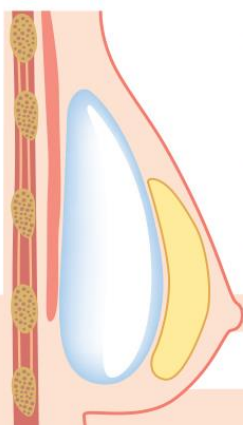
About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

RISK OF BREAST IMPLANT ASSOCIATED-ANAPLASTIC LARGE CELL LYMPHOMA

MAY 2019

WHAT IS BREAST IMPLANT ASSOCIATED-ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)?



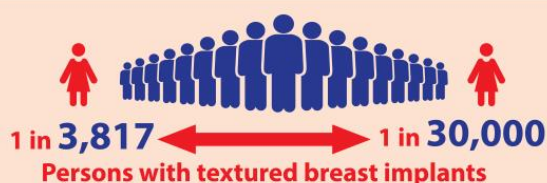
- A rare type of non-Hodgkin's lymphoma (cancer of the immune system) that usually develops around breast implants. It is not a cancer of the breast tissue.
- Usually involves swelling of the breast, which can occur as early as 1 year after the surgery, and as late as 37 years after the surgery.
- In some cases, it can spread to other parts of the body.

WHO IS AT RISK OF BIA-ALCL?

- Majority of patients who have developed BIA-ALCL globally have had **textured implants**. Further review of the global reports indicates a relatively higher incidence rate in patients implanted with macro-textured implants.
- There were also a few unconfirmed reports of BIA-ALCL in patients who have received **smooth-surfaced implants**¹. The possible association is currently being investigated.

WHAT IS THE RISK OF BIA-ALCL?

Estimated incidence rates
reported in literature²



- The Expert Panel on Breast Implants³, convened by the Health Sciences Authority in February 2019, noted that BIA-ALCL occurrences are rare and the associated mortality rates **remain low**.

IF YOU ARE CONSIDERING BREAST IMPLANT

It is important to discuss with your doctor on the risks and benefits of the different types of implants, whether for reconstruction or augmentation purposes.

IF YOU HAVE A BREAST IMPLANT

- Monitor and check for swelling, lumps or pain around your implant after the surgical incision has healed. Consult your doctor immediately if you have any of the symptoms.
- Continue with regular follow-up with your doctor post implantation.

¹ "Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)", 2017, FDA, US Food and Drug Administration. <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>
² Loch-Wilkinson et al, 2017 and Doren et al, 2017

³ Expert Panel comprises a group of healthcare professionals from both public and private hospitals.

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.