

FREQUENTLY ASKED QUESTIONS ABOUT BIA-ALCL

FOR PATIENTS CONSIDERING BREAST IMPLANTS

WHAT IS BIA-ALCL?

BIA-ALCL is **B**reast **I**mplant-**A**ssociated **A**naplastic **L**arge **C**ell **L**ymphoma, a T-cell lymphoma that can arise around breast implants placed for either reconstructive or cosmetic indications.¹ Currently, the cause of BIA-ALCL is not clearly understood.¹

IS BIA-ALCL A TYPE OF BREAST CANCER?

BIA-ALCL is **not** a cancer of the breast tissue itself, but a type of cancer that develops around the scar tissue from the implant, and in some cases, can spread throughout the body.¹

IS BIA-ALCL COMMON?

It is estimated that there are 35 million women worldwide who have breast implants.² The true incidence of BIA-ALCL is hard to estimate.³ To date, the estimated incidence rates in scientific literature range from 0.03% to 0.003%, or 1 in 3,817 to 1 in 30,000.^{4-7*}

* Publications referenced here include patient populations with breast implants and patients specifically with textured breast implants.

WHAT CAUSES BIA-ALCL?

International health regulatory agencies are proactively working with implant manufacturers to study BIA-ALCL.⁸⁻¹² To date, no specific risk factors have been identified, however implant texture, genetics, and bacteria have been implicated and are undergoing further study.¹

WHAT ARE THE SYMPTOMS OF BIA-ALCL?

BIA-ALCL is most commonly reported at an average of 8–10 years following implant placement.¹³ The first symptoms are usually a swelling of the breast—often caused by fluid building up around the implant.¹ Other symptoms can include pain, lumps, and unevenness between breasts.¹

IS BIA-ALCL TREATABLE?

Yes. When diagnosed early by a surgical specialist, BIA-ALCL can be treated, often successfully.¹ In most cases, BIA-ALCL can be treated by removing the breast implant and surrounding scar capsule, however, additional treatment may be necessary depending on the individual.¹ In cases where the disease has spread throughout the body, rare cases of death have been reported.^{1,14}

WHAT TYPES OF IMPLANTS ARE ASSOCIATED WITH BIA-ALCL?

BIA-ALCL has been associated with both saline and silicone implants, round and anatomic implants, all gel types, and all projections, as well as implants for both reconstructive and cosmetic purposes.¹

WHAT ARE TEXTURED IMPLANTS AND HOW DO THEY AFFECT MY RISK OF DEVELOPING BIA-ALCL?

Breast implants have different surface textures, including smooth or textured. For cases reported to date, BIA-ALCL has been seen most often in patients with textured implants¹, however the risk of developing BIA-ALCL with textured implants is low.⁶ Although it is difficult to quantify the true incidence and prevalence of BIA-ALCL³, to date the estimated incidence rates range from 0.03% to 0.003%, or 1 in 3,817 to 1 in 30,000.^{4-7*}

* Publications referenced here include patient populations with breast implants and patients specifically with textured breast implants.

SHOULD MY SURGEON STILL CONSIDER A TEXTURED IMPLANT?

Surgeons have varying reasons for selecting a textured implant. Some implant types, such as anatomically shaped implants, are only available with a textured surface.¹⁵ Make sure to discuss the varying options with your surgeon, as every woman is different and has different needs

WHAT DO INTERNATIONAL HEALTH REGULATORY AGENCIES HAVE TO SAY ABOUT TEXTURED IMPLANTS?

For patients who currently have implants and are not experiencing any problems, international health regulatory agencies (i.e., United States Food and Drug Administration [FDA], Health Canada, United Kingdom Medicines and Healthcare Products Regulatory Agency [MHRA], France's Agence Nationale de Sécurité du Médicament [ANSM], Australia's Therapeutic Goods Administration [TGA]) do not recommend removal of the implants or any changes to their routine medical care.⁸⁻¹²

WHO SHOULD I CONTACT IF I HAVE MORE QUESTIONS OR CONCERNS?

If you are considering getting implants, ask your surgeon about the risks of BIA-ALCL, and what it means.

WHAT IS ALLERGAN DOING ABOUT BIA-ALCL?

Patient safety is Allergan's first priority. They are working closely with leading surgeons worldwide to increase awareness of the disease and the importance of early diagnosis. Allergan will continue to work with the medical community to further the understanding of this disease.

Allergan also provides rare-events coverage, up to \$5,000 USD, for its products in cases of BIA-ALCL. Patients with Allergan implants are eligible for assistance with out-of-pocket surgical costs, not covered by insurance, including removal of the breast implant(s) and associated tissue.

REFERENCES 1. Clemens MW, Nava MB, Rocco N, Miranda RN. Understanding rare adverse sequelae of breast implants: anaplastic large-cell lymphoma, late seromas, and double capsules. *Gland Surg.* 2017;6(2):169-84. 2. Sieber DA, Adams WP, Jr. What's Your Micromort? A Patient-Oriented Analysis of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). *Aesthet Surg J.* 2017;37(8):887-91. 3. Shahriri N, Ferenczi K, Heald PW. Breast implant-associated anaplastic large cell lymphoma: A review and assessment of cutaneous manifestations. *Int J Womens Dermatol.* 2017;3(3):140-4. 4. Campanale A, Boldrini R, Marletta M. 22 Cases of Breast Implant-Associated ALCL: Awareness and Outcome Tracking from the Italian Ministry of Health. *Plast Reconstr Surg.* 2018;141(1):11e-9e. 5. de Boer M, Dan Der Hulst R, Van Leeuwen F, de Jong D, Rakhorst H, editors. Breast-implant associated anaplastic large cell lymphoma (BIA-ALCL): Relative and absolute risk assessment based on 100% of all national cases of BIA-ALCL in the Netherlands. 28th EURAPS Annual Meeting; 2017; Pisa, Italy. 6. Doren EL, Miranda RN, Selber JC, Garvey PB, Liu J, Medeiros LJ, et al. U.S. Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Plast Reconstr Surg.* 2017;139(5):1042-50. 7. Loch-Wilkinson A, Beath KJ, Knight RJW, Wessels WLF, Magnusson M, Papadopoulos T, et al. Breast Implant-Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand: High-Surface-Area Textured Implants Are Associated with Increased Risk. *Plast Reconstr Surg.* 2017;140(4):645-54. 8. U.S. Food and Drug Administration. Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) 2018 [last accessed 2018 January 22]. Available from: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995>. 9. Health Canada. Summary Safety Review - Breast Implants - Assessing the potential risk of cancer (Breast implant associated-anaplastic large cell lymphoma) 2017 [last accessed 2018 January 22]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/breast-implants-assessing-potential-risk-cancer.html>. 10. U.K. Medicines and Healthcare Products Regulatory Agency. Breast implants and Anaplastic Large Cell Lymphoma (ALCL) 2017 [last accessed 2018 January 22]. Available from: <https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl>. 11. Australian Therapeutic Goods Administration. Update - additional confirmed cases of anaplastic large cell lymphoma 2017 [last accessed 2018 January 22]. Available from: <https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma#reduce-risk>. 12. ANSM. Lymphome Anaplasique à Grandes Cellules associé aux implants mammaires (LAGC-AIM): Point sur les investigations en cours - Point d'Information 2016 [last accessed 2018 January 22]. Available from: <http://ansm.sante.fr/S-informer/Points-d-information/Points-d-information/Lymphome-Anaplasique-a-Grandes-Cellules-associe-aux-implants-mammaires-LAGC-AIM-Point-sur-les-investigations-en-cours-Point-d-Information>. 13. Clemens MW, Horwitz SM. NCCN consensus guidelines for the diagnosis and management of breast implant-associated anaplastic large cell lymphoma. *Aesthet Surg J.* 2017;37(3):285-9. 14. Clemens MW. Reply: Global Adverse Event Reports of Breast Implant-Associated ALCL: An International Review of 40 Government Authority Databases. *Plast Reconstr Surg.* 2018;141(1):179e-80e. 15. Nahabedian MY. Shaped versus round implants for breast reconstruction: indications and outcomes. *Aesthet Surg J.* 2014;2(3):e116.

FREQUENTLY
ASKED QUESTIONS
ABOUT BIA-ALCL

F O R P A T I E N T S
C O N S I D E R I N G
B R E A S T I M P L A N T S