

EVIDENCE BASED PERSPECTIVE: Breast Implant-Associated Anaplastic Large Cell Lymphoma

What do we know about BIA-ALCL?

- BIA-ALCL is not breast cancer—it is a type of non-Hodgkin’s lymphoma (cancer of the immune system), that affects lymphocytes (immune cells), typically taking between 8-10 years to develop.¹
- Individuals who have been implanted with textured breast implants at some point during their clinical history have a risk of developing BIA-ALCL.
- In most cases (>85%), BIA-ALCL is found in the implant effusion (fluid surrounding the implant), which current data suggest may be cured by removal of the implant and capsule.²
- In some cases (10-15%), BIA-ALCL can present as a mass attached to the breast implant capsule. In these cases, the cancer may spread to the lymph nodes and can metastasize.²

Current hypotheses regarding possible causes of BIA-ALCL include:

- ▶ Chronic Irritation over Time
- ▶ Bacterial Contamination
- ▶ Particulate Matter in the Breast Implant Capsule
- ▶ Genetic Predisposition
- ▶ Surface Texturing

How common is BIA-ALCL?³

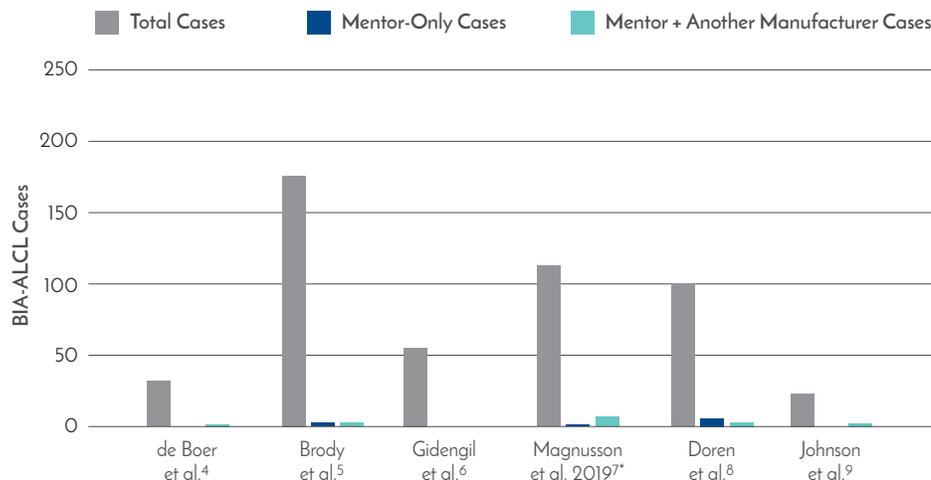
As of

February 8, 2019

688 Confirmed cases of BIA-ALCL worldwide

17 Deaths attributed to metastases or complications from cancer therapy

Multiple studies have shown a consistently low number of BIA-ALCL cases associated with MENTOR® breast implants as compared to those of other manufacturers.



*The Mentor + Another Manufacturer Cases includes 3 cases with Mentor smooth implant in patients who also had other textured implant of another manufacturer (there are currently no confirmed cases of BIA-ALCL in patients whose implant history included only smooth implants).

Does surface texture make a difference?

Recent literature suggests that the risk of developing BIA-ALCL differs between different textured devices. Current estimate, from a significant study conducted in Australia and New Zealand, put the risk at:¹⁰

1 IN 2,832

Polyurethane Implants

1 IN 3,345

Allergan Biocell® Implants

1 IN 86,029

MENTOR® SILTEX® Implants

What can I do to reduce the likelihood of BIA-ALCL for my patients?

- To date, there have been no cases of BIA-ALCL diagnosed in patients in which only smooth implants were used in their clinical history.
- Recent data suggests that preventing bacterial contamination may reduce the risk of developing BIA-ALCL.
For more information, visit www.saferbreastimplants.org
- While textured breast implants have established clinical benefits, leading researchers recommend that clinicians should consider the relative risk of developing BIA -ALCL when selecting a textured implant for their patient; clinical need should be adequately justified when selecting higher surface area implants like Biocell and Polyurethane.

Where do I find resources on BIA-ALCL, diagnosis, and treatment?

Source	Website	Focus
National Comprehensive Cancer Network (NCCN) Guidelines	https://www.nccn.org/patients/guidelines/cancers.aspx	Diagnosis & Treatment
Patient Registry and Outcomes for Breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE)	https://www.thepsf.org/research/registries/profile	Registry for reporting and tracking cases of BIA-ALCL
FDA	https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm	Report on FDA's findings and recommendations on BIA-ALCL
Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma	Report on TGA's findings and recommendations on BIA-ALCL
Medicines and Healthcare Products Regulatory Agency	https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl	Report on MHRA's findings and recommendations on BIA-ALCL
Health Canada	https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/breast-implants-assessing-potential-risk-cancer.html	Report on Health Canada's findings and recommendations on BIA-ALCL
American Society of Plastic Surgeons (ASPS)	www.plasticsurgery.org/alcl	BIA-ALCL Physician Resources
American Society for Aesthetic Plastic Surgeons (ASAPS)	www.surgery.org/professionals	BIA-ALCL Physician Resources
Association of Breast Surgery	https://associationofbreastsurgery.org.uk/clinical/bia-alcl/	BIA-ALCL Physician Resources
Mentor	http://www.mentorwllc.com/global-us/SafetyInformation.aspx	Information for women considering breast implants

What resources does Mentor provide for me and my patients?

In March 2018, Mentor began contributing to an industry-funded BIA-ALCL Patient Assistance Fund for uninsured patients diagnosed with BIA-ALCL.

All Mentor Breast Implants come with a free, limited warranty program that offers lifetime product replacement and limited financial assistance if needed. More information on Mentor's warranty program can be found at:

<https://www.breastimplantsbymmentor.com/breast-implants/warranties>

1. Clemens, M.W., et al., How to Diagnose and Treat Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Plastic and Reconstructive Surgery*, 2018. 141(4): p. 586e-599e. 2. Deva, A.K. Breast Implant Associated Large Cell Lymphoma (BIA-ALCL) - Key Update. *Plastic Surgery Hub*. <https://www.plasticsurgeryhub.com.au/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl-key-update/>, June 8, 2018, accessed Aug 7, 2018. 3. ASPS. BIA-ALCL Physician Resources. February 8, 2019. Available at: <https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources>. 4. de Boer, M., et al. Breast implants and the risk of anaplastic large-cell lymphoma in the breast. *JAMA Oncology*, 2018. 4(3): p. 335-341. 5. Brody, G.S., et al. Anaplastic Large Cell Lymphoma Occurring in Women with Breast Implants: Analysis of 173 Cases. *Plastic and Reconstructive Surgery*, 2015. 135(3): p. 695-705. 6. Gidengil, C.A., et al. Breast Implant-Associated Anaplastic Large Cell Lymphoma: A Systematic Review. *Plastic and Reconstructive Surgery*, 2015. 135(3): p. 713-720. 7. Magnusson M, Beath K, Cooter R, Locke M, Prince HM, Elder E, Deva AK. Special Update: The epidemiology of Breast Implant Associated Large Cell Lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants. *Plast Reconstr Surg*. 2019 Feb 13. doi: 10.1097/PRS.0000000000005500; with further details provided in Loch-Wilkinson et al., *Plast Reconstr Surg*. 2017;140(4):645-654. 8. Doren, E.L., et al., U.S. Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Plastic and Reconstructive Surgery*, 2017. 139(5): p. 1042-1050. 9. Johnson, L., et al., Breast implant associated anaplastic large cell lymphoma: The UK experience. Recommendations on its management and implications for informed consent. *Eur J Surg Oncol*, 2017. 43(8): p. 1393-1401. 10. Deva, A.K. 'BIA-ALCL: Translating Science Into Practice.' The Aesthetic Meeting of ASAPS, April 29, 2018, Javits Center, New York, NY. Lecture in Panel: Hot Topics in Breast Surgery--ALCL, Texture, Biofilms.

Important Safety Information:

MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryShape® Breast Implants, and MENTOR® Saline-filled Breast Implants are indicated for breast augmentation in women (at least 22 years old for MemoryGel® Implants and MemoryShape® Implants, and 18 years old for Saline Implants) or for breast reconstruction. Breast implant surgery should not be performed in women with active infection anywhere in their body, with existing cancer or precancer of their breast who have not received adequate treatment for those conditions, or who are currently pregnant or nursing.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery.

The most common complications for breast augmentation and reconstruction with MemoryGel® Implants include any reoperation, capsular contracture, and implant removal with or without replacement. The most common complications with MemoryShape® Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. The most common complications with MemoryShape® Implants for breast reconstruction include reoperation for any reason, implant removal with or without replacement, and capsular contracture. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture. The most common complications with MENTOR® Saline-filled Implants include reoperation, implant removal, capsular contracture, breast pain, and implant deflation.

For MemoryGel® Implants, patients should receive a copy of *Important Information for Augmentation Patients about MENTOR® MemoryGel® Breast Implants* or *Important Information for Reconstruction Patients about MENTOR® MemoryGel® Breast Implants*. For MemoryShape® Implants, patients should receive a copy of *Patient Educational Brochure - Breast Augmentation with MENTOR® MemoryShape® Breast Implants* or *Patient Educational Brochure - Breast Reconstruction with MENTOR® MemoryShape® Breast Implants*, and a copy of *Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants*. For MENTOR® Saline-filled Implants, patients should receive a copy of *Saline-Filled Breast Implants: Making an Informed Decision*. Your patient needs to read and understand the information regarding the risks and benefits of breast implants, with an opportunity to consult with you prior to deciding on surgery.

The ARTOURA™ Breast Tissue Expander or CONTOUR PROFILE™ Breast Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months. Do not use the ARTOURA™ Tissue Expander nor CONTOUR PROFILE™ Tissue Expander in patients where an MRI may be needed. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas.

For detailed indications, contraindications, warnings, and precautions associated with the use of all MENTOR® Implantable Devices, which include MENTOR® Saline-filled Implants, MemoryGel® Implants, MemoryShape® Implants, ARTOURA™ Expanders, and CONTOUR PROFILE™ Expanders, please refer to the Product Insert Data Sheet provided with each product or visit www.mentorwllc.com.

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