

# 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.<sup>1</sup>
- 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.<sup>2</sup>
- 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.<sup>2</sup>

Current hypotheses regarding possible causes of BIA-ALCL include:

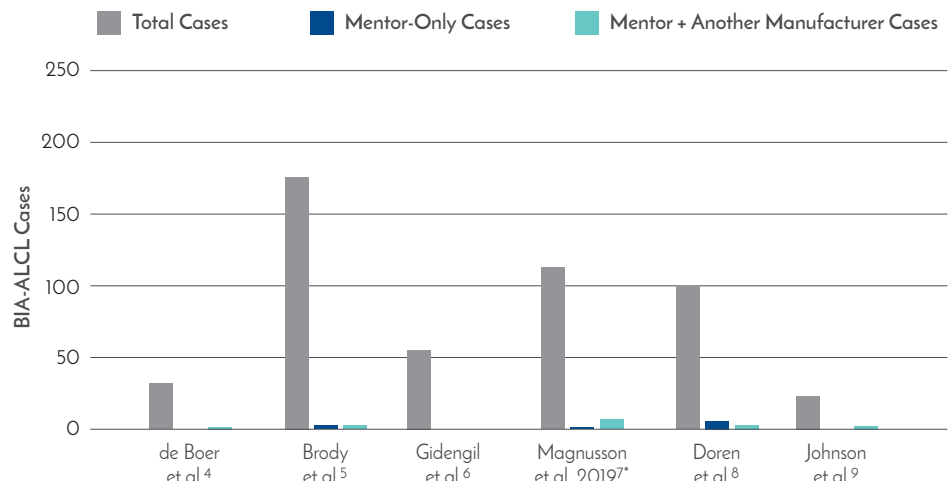
- ▶ Chronic Irritation over Time
- ▶ Bacterial Contamination
- ▶ Particulate Matter in the Breast Implant Capsule
- ▶ Genetic Predisposition
- ▶ Surface Texturing

## How common is BIA-ALCL?<sup>3</sup>

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:<sup>10</sup>

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

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.

Before using any medical device, review all relevant Instructions for Use, Package Inserts or Summary of Product Characteristics. We do not endorse the use or promotion of unapproved products or indications. Any demonstrations of approved medical devices should be considered as information only and are not a surgical training guide.

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.

Please refer to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

The third party trademarks used herein are trademarks of their respective owners.

Mentor is a business of Johnson & Johnson Medical Pty Ltd

AUSTRALIA: 1-5 Khartoum Road, North Ryde, NSW 2113, ABN 85 000 160 403

NEW ZEALAND: Johnson & Johnson (NZ) Limited, 507 Mt Wellington Highway, Mt Wellington, Auckland NZ

© 2019 Johnson & Johnson Medical Pty Ltd

© Mentor Worldwide LLC 2019 069179-190307 AUS: 115814-190604

*\*This website is not owned by Johnson & Johnson Medical Pty Ltd, and we do not review or control the content of this website. Products discussed on this website may not be approved for use, or may be approved for different indications in your country. Before using any medical device, review all relevant Instructions for Use, Package Inserts or Summary of Product Characteristics. We do not endorse the use or promotion of unapproved products or indications. Any demonstrations of approved medical devices should be considered as information only and are not a surgical training guide.*

