see your skills in sientra®

BIA-ALCL

frequently asked questions and resources

SIENTRA MEDICAL AFFAIRS

see your skills in

sientra®

breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)

Sientra's highest priority is patient safety. The following information and FAQ is provided as a reference for plastic surgeons regarding the current known information on BIA-ALCL.

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

BIA-ALCL is a rare and highly treatable T-cell lymphoma that can develop following breast implantation. BIA-ALCL is NOT breast cancer. To date, BIA-ALCL occurs more frequently in women with textured implants than smooth implants. BIA-ALCL has been diagnosed in women with silicone and saline-filled breast implants and in cosmetic and reconstructive patients. The average time to develop the condition is approximately 8-10 years post-implantation.[1-4]

Case reports of ALCL associated with other implantable medical devices have been reported in literature including: tibial implants, dental implants, chemotherapy ports, total joint prostheses, gastric bands, and gluteal implants.[4]

PATIENT INFORMED CONSENT

Patients considering breast implants should discuss BIA-ALCL with their surgeon as part of the informed consent process. The Sientra Patient Educational Brochures include a section with information on BIA-ALCL. This can be provided to patients in hardcopy and is also available online at sientra.com/resources.php. It is also important that patients are provided adequate time to review the complete brochure and sign the **Acknowledgement of Informed Decision** located in Section 14 of the brochure.

WHAT ARE THE SYMPTOMS OF BIA-ALCL?

BIA-ALCL most commonly presents as a delayed seroma (>1 year) or a palpable mass. Patients should be aware of these symptoms, and contact their surgeon to report delayed onset of swelling, pain and any other breast changes.

WHAT ARE THE RISKS?

It is important to understand how rare the occurrence is and put the numbers into perspective. Literature indicates the current lifetime risk is ~1 in 20,000 patients with textured implants.[4] It is important to note that all textures should not be considered one-in-the-same. Independent analysis of manufacturer data reports BIOCELL® has a 7x to 8x greater incidence of BIA-ALCL compared to all other manufacturers' textures, including Sientra Texture and Siltex.[4] Geographic regions also reported variable risks including: Australia 1 in 3,345 for BIOCELL and 1 in 86,029 for Siltex.[5] In 2018, over 400,000 women underwent breast augmentation and reconstruction with implants in the U.S.[6] Some comparative rates:

- The average woman's risk of developing breast cancer in her lifetime is **12.5%**.[7]
  - This means that 1 out of 8 women may develop breast cancer in her lifetime.
- The risk of developing recurrent breast cancer after mastectomy is **5-8%**.[8]
  - This means that 5 to 8 out of 100 women may develop recurrent breast cancer after mastectomy.
- The risk of capsular contracture through 10-years is **~14%**.[9]
  - This means that 14 out of 100 patients may experience capsular contracture within 10 years after receiving implants.
- The risk of breast implant rupture through 10-years is **~8**.[9]
  - This means that 8 out of 100 patients may experience implant rupture within 10 years after receiving implants.
- The risk of developing BIA-ALCL from a textured breast implant is **~0.005%**.[4]
  - This means that 1 out of 20,000 women with textured implants may develop BIA-ALCL.

WHAT IS THE REPORTED NUMBER OF CASES IN THE 2020 FDA UPDATE?*

There were 733 unique* medical device reports (MDRs) related to breast implants and ALCL submitted to FDA's Manufacturer and User Facility Device Experience (MAUDE) database as of January 5, 2020 and may contain information that is incomplete, inaccurate or not verified. In addition, the incidence or prevalence of BIA-ALCL cannot be determined from the MAUDE reporting system alone due to potential under-reporting, duplicate reporting of events, and the lack of information about the total number of patients who have breast implants.[10] Of those MDR reports:

Implant Surface:

- 496 were textured implants (68%)
- 28 Smooth implants** (4%)
- 209 Surface not specified (28%)

Implant Fill:

- 447 Silicone-filled implants (61%)
- 248 Saline-filled implants (34%)
- 38 implant fill not specified (5%)

Manufacturer:

- 10 Sientra implants (1%)
- Unknown manufacturer (6%)

* Patients with bilateral BIA-ALCL are counted as 2 cases of BIA-ALCL.

** In the 28 cases of smooth implants, 10 have unknown prior history of implants, 8 have a history of at least one textured implant, 9 have a history of prior implants with unknown texture, and 1 has a history of one smooth implant and no known textured implant. It should be noted that many MDR reports do not contain information, or contain incomplete information, on the prior implant history of the patient. Therefore, this section may be updated as new information emerges. As of January 5, 2020, there are no reports of cases associated with tissue expanders.

IS THE FDA UPDATE BASED ON A STUDY?

No, the information provided in the FDA updates is based on the BIA-ALCL MDRs submitted to FDA's Manufacturer and User Facility Device Experience (MAUDE) database. Importantly, the FDA notes that the 733 MDRs received may contain incomplete or unverified data and therefore, should not be interpreted as a definitive number of cases. The FDA's update was released to increase awareness of the symptoms and the defined diagnostic and treatment protocol with patients and health care providers.

HOW IS BIA-ALCL DIAGNOSED? WHAT SYMPTOMS SHOULD PATIENTS BE AWARE OF?

If a woman develops a fluid collection (>50mL) more than one-year after surgery (most commonly at 8 to 10 years) or a palpable mass adjacent to the implant:

- Perform an ultrasound scan.
- If fluid is detected, drain and test for cytology, flow cytometry for T cell clone, Immunohistochemistry for CD30 to diagnose BIA-ALCL.[11]
- In confirmed cases PET-CT scans will be performed following a positive diagnosis to stage the disease.
- It is important to note that most late-forming seromas are not BIA-ALCL; however, fluid testing should be used to confirm.
- Mammograms are not useful in diagnosing BIA-ALCL; however, they are important for detecting breast cancer.[3]

HOW IS BIA-ALCL TREATED?

The majority of patients who are diagnosed with BIA-ALCL can be cured[3]:

- Bilateral total capsulectomy and implant removal should be performed.
- The majority of patients require no additional treatment.
- In rare cases, patients may need to undergo adjuvant therapies, such as radiation, chemotherapy, or other systemic therapies.[4]

SHOULD WOMEN WITH BREAST IMPLANTS BE SCREENED FOR BIA-ALCL?

FDA states, "If you have breast implants, there is no need to change your routine medical care and follow-up."[10]
Expert consensus advises that asymptomatic women without breast changes do not require more than routine follow-up.

SHOULD PATIENTS HAVE THEIR IMPLANTS REMOVED PROPHYLACTICALLY?

Neither the FDA nor any of the Plastic Surgery societies suggest removal of implants in patients without signs or symptoms.[10]

WHY USE TEXTURED BREAST IMPLANTS?

Smooth and textured implants are both safe and effective and each has associated benefits and risks.

- Surgeons may select textured implants to better maintain implant positioning, address capsular contracture and reduce rotation in shaped implants.
- Sientra's textured implants demonstrate a decreased risk of capsular contracture and a lower rupture rate.[9,12]
- Surface textures vary across manufacturers and Sientra stands behind the demonstrated safety and benefits of both its smooth and textured implants.[13]

WHAT CAUSES BIA-ALCL?

Researchers are making remarkable progress to better understand the U.S. cases. A tremendous body of literature has been published on this condition. In March 2019, 16 peer-reviewed articles by 55 authors were published in ASJ and PRS Supplements. Current evidence supports a multi-factorial etiology including: genetic predisposition, implant texturization, bacterial infection/biofilm formation and chronic inflammation.[14]

Certain geographic locations have demonstrated variable risks (many countries and ethnicities have zero cases). Additionally, literature indicates that the increased association of BIA-ALCL in textured implants with the most surface area may be due to the higher bacterial load with these types of devices.[15]

HAVE THERE BEEN ANY DEATHS DUE TO BIA-ALCL?

There have been 36 known deaths* worldwide attributed to BIA-ALCL since the disease was first reported nearly 20 years ago. It has been estimated that worldwide 10-20 million women currently have breast implants. It is important to note that of these 36, most were significantly delayed in receiving treatment or were inadequately treated, and most commonly progressed to invasion of the chest wall.[4,16] Of the 36 worldwide deaths attributed to BIA-ALCL, 15 deaths have been attributed to Allergan implants, 1 death has been attributed to Mentor implants, and 20 deaths attributed where the manufacturer is unknown. Zero deaths have been attributed to Sientra implants worldwide to date.

* FDA reports of BIA-ALCL Deaths from MDRs and Literature reported as MDRs, as of 1/5/2020
https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma

WHERE TO REPORT CASES?

It is critical that all pathologically confirmed cases of BIA-ALCL are reported to the manufacturer, the FDA and the PROFILE Registry of the American Society of Plastic Surgery www.thepsf.org/PROFILE.

SUMMARY

Patient safety is Sientra's highest priority. Sientra continues to support all medical research, education and FDA initiatives to better understand BIA-ALCL and to provide women with the highest quality and safest implant options. We want women to remain confident in the safety of FDA-approved Sientra OPUS® breast implants and in their decision to have breast augmentation or reconstructive surgery. We encourage you and your patients to visit our updated Commitment to Safety page, to ensure both surgeons and patients have our most current information.

For any questions please contact your Plastic Surgery Consultant or Sientra Medical Affairs at 888.708.0808.

IMPORTANT INFORMATION SOURCES

- ASAPS: www.surgery.org/professionals
- ASPS: www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources
- FDA: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

RECENT KEY BIA-ALCL LITERATURE

- *Molecular Drivers of Breast-Implant Associated Anaplastic Large Cell Lymphoma* (Blombery et al, 2019)
  https://journals.lww.com/plasreconsurg/Fulltext/2019/03001/Molecular_Drivers_of_Breast_Implant_Associated.10.aspx
- *Long-Term Safety of Textured and Smooth Breast Implants* (Calobrace et al, 2018)
  https://doi.org/10.1093/asj/sjx157
- *2019 NCCN Consensus Guidelines on the Diagnosis and Treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)* (Clemens et al; *ASJ* 2019):
  https://academic.oup.com/asj/article/39/Supplement_1/S3/5304919
- *Current Risk Estimate of Breast Implant–Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants* (Collett et al, *PRS* 2019):
  https://journals.lww.com/plasreconsurg/Fulltext/2019/03001/Current_Risk_Estimate_of_Breast_Implant_Associated.7.aspx
- *The Inflammatory Effects of Breast Implant Particulate Shedding: Comparison With Orthopedic Implants* (Hallab et al, *ASJ* 2019)
  https://academic.oup.com/asj/article/39/Supplement_1/S36/5304922
- *What Cytokines Can Tell Us About the Pathogenesis of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)* (Kadin et al, *ASJ* 2019)
  https://academic.oup.com/asj/article/39/Supplement_1/S28/5304920
- *Theories of Etiopathogeneis of Breast Implant-Associated Anaplastic Large Cell Lymphoma* (Rastogi et al, *PRS* 2019)
  https://journals.lww.com/plasreconsurg/Fulltext/2019/03001/Theories_of_Etiopathogenesis_of_Breast.6.aspx

For questions from patients due to media pieces, the following report may be provided for more balanced and easier to understand information:
http://www.allure.com/story/fda-update-on-breast-implants-causing-cancer

SIENTRA PATIENT EDUCATIONAL BROCHURES

Information for women regarding this potential risk is included in the Sientra Patient Educational Brochure:
http://sientra.com/Content/pdfs/Patient_Educational_Brochure_Breast_Augmentation_with_Sientra_Silicone_Gel_Breast_Implants.pdf
http://sientra.com/Content/pdfs/Patient_Educational_Brochure_Breast_Reconstruction_with_Sientra_Silicone_Gel_Breast_Implants.pdf

REFERENCES

1 Clemens MW. Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL): by the numbers, and what they mean. https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources/by-the-numbers. Accessed March 28, 2019.

2 US Food & Drug Administration. Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ breastimplants/ucm241086.htm. Accessed March 28, 2019.

3 American Society of Plastic Surgeons. BIA-ALCL Resources: Summary and Quick Facts. https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources/summary-and-quick-facts. Accessed March 28, 2019.

4 Clemens MW. Breast Implant Associated-ALCL: MD Anderson Cancer Center Experience. https://www.fda.gov/ downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM634740.pdf. Accessed March 28, 2019.

5 Magnusson M, et al. The epidemiology of breast implant–associated anaplastic large cell lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants. Plast Reconstr Surg. 2019;143.

6 American Society of Plastic Surgeons. 2018 National plastic surgery statistics. https://www.plasticsurgery.org/ documents/News/Statistics/2018/plastic-surgery-statistics-report-2018.pdf. Accessed March 28, 2019.

7 Feuer EJ, et al. The lifetime risk of developing breast cancer. J Natl Cancer Inst. 1993; 85(11): 892-897.

8 Carlson, RW. 2014. Surveillance of patients following primary therapy In Diseases of the Breast, 5th edition (pp.871-879). Philadelphia, PA: Lippincott Williams and Wilkins.

9 Stevens WG, et al. Ten -year Core Study Data for Sientra's Food and Drug Administration–Approved Round and Shaped Breast Implants with Cohesive Silicone Gel. Plast Reconstr Surg. 2018; 141(4S): 7S-19S.

10 US Food & Drug Administration. Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm. Accessed March 28, 2019.

11 National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas. https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed March 28, 2019.

12 Stevens WG, et al. Risk factor analysis for capsular contracture: a 5-year Sientra study analysis using round, smooth, and textured implants for breast augmentation. Plast Reconstr Surg. 2013; 132(5): 1115-1123.

13 Calobrace MB, et al. Long-term safety of textured and smooth breast implants. Aesthet Surg J. 2018;38(1): 38–48.

14 Rastogi P, et al. Theories of Etiopathogenesis of Breast Implant–Associated Anaplastic Large Cell Lymphoma. Plast Reconstr Surg. 2019;143(3S): 23S-9S.

15 Hu H, et al. Bacterial biofilm infection detected in breast implant-associated anaplastic large-cell lymphoma. Plast Reconstr Surg. 2016; 137(6): 1659-69.

16 Collins MS, et al. Characteristics and Treatment of Advanced Breast Implant–Associated Anaplastic Large Cell Lymphoma. Plast Reconstr Surg. 2019;143(3S): 41S-50S.

sientra

Sientra® is a trademark of Sientra, Inc.
© 2021 Sientra, Inc. All rights reserved.

MDC-0365 R2