



Friday, 24 March 2017

Notice Regarding FDA Update on BIA-ALCL

Dear Clinicians,

By now you may have seen the U.S. Food and Drug Administration (FDA) update on reported cases of Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL). We continue to work with industry groups, physician scientists and health authorities globally to better understand the associated risks and causes of BIA-ALCL. As a result of continued research we have updated our [Evidence Based Perspective](#) and in response to requests from our customers we've developed a [Patient Information Brochure](#) for your use. Below is a summary of key messages for your reference:

The number of reported cases suggests the risk of developing ALCL is extremely rare

- The U.S. Food and Drug Administration (FDA) reported that they had received a total of 359 medical device reports (MDRs) of BIA-ALCL.¹ However, the FDA cautioned that the MDR system may contain incomplete, inaccurate, untimely, unverified, biased, under-reported or duplicate reporting of events.¹
- The FDA had previously estimated that there were 5-10 million women with breast implants worldwide.^{2,3}
- The French and Australian health authorities agree that BIA-ALCL remains rare compared to the number of breast implant procedures.^{4,5}
- There are currently no confirmed cases of BIA-ALCL in patients whose implant history included only smooth implants.⁶
- The FDA does not recommend the removal of implants in asymptomatic patients with no identifiable abnormalities.¹

We stand behind the safety and efficacy of both our textured and smooth breast implants

- The newest generation of MemoryShape® Breast Implants is textured to reduce movement of the implant. Textured implants have other benefits in reducing complications, such as capsular contracture, which may occur more frequently than BIA-ALCL and may require reoperation under general anesthesia.⁷
- Recent scientific and health authority data regarding diagnosed cases of BIA-ALCL has consistently shown a low representation of MENTOR® SILTEX® “microtextured” Breast Implants.^{4,6,8,9,10,11}

MENTOR® Breast Implants have been chosen by surgeons for millions of patients worldwide for over 30 years. Patient safety is Mentor's top priority, and our FDA-approved implant products are supported by several 10-year clinical studies.

Where to go for more information

Mentor continues to closely monitor reports of and information about BIA-ALCL. Mentor fully supports the U.S. Food and Drug Administration's (FDA) efforts to gather additional data and study ALCL in patients with breast implants.

The American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), The Plastic Surgery Foundation (PSF), the International Society of Aesthetic Plastic Surgery (ISAPS) and FDA continue to surveil the scientific evidence in relation to BIA-ALCL and provide recommendations to their members and patients.^{1,12,13,14,15,16} More information can be found at:

- ASPS: www.plasticsurgery.org/alcl
- ASAPS: www.surgery.org/professionals
- PSF: www.thepsf.org/research/clinical-impact/profile.htm
- FDA: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm
- ISAPS: www.isaps.org

Best regards,



John W. Canady, M.S., M.D., D. Sc. (hon), FACS, FAAP

Vice President and Franchise Medical Lead
Cardiovascular & Specialty Solutions (CSS) Group

Part of the Johnson & Johnson Family of Companies

Medical Information Request | Voicemail: 1-800-888-9234 ext. 3800 Email:
Eth_Medical_Info@its.jnj.com

¹ Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL): US Food and Drug Administration; 22 March 2017 [cited 2017 22 March]. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/>

BreastImplants/ucm239995.htm

² Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants: Preliminary FDA Findings and Analyses: Center for Devices and Radiological Health, U.S. Food and Drug Administration; January 2011 [cited 2017 26 February]. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm>

- ³ Anaplastic large cell lymphoma (ALCL). US Food and Drug Administration; 20 January 2016 [cited 2017 26 February]. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>
- ⁴ Lymphome Anaplasique à Grandes Cellules associé aux implants mammaires (LAGC-AIM): Point sur les investigations en cours- Point d'Information.: L'Agence nationale de sécurité du médicament et des produits de santé (ANSM). 06 July 2016 [cited 2016 06 July]. 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>
- ⁵ Breast Implants: Expert Advisory Panel Advice on Association with Anaplastic Large Cell Lymphoma.: Australian Government Department of Health Therapeutic Goods Administration.; 20 December 2016 [cited 2017 26 February]. Available from: <http://www.tga.gov.au/alert/breast-implants>
- ⁶ Doren EL, Miranda RN, Selber JC, Garvey PB, Liu J, Medeiros LJ, et al. United States Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Plast Reconstr Surg*. 2017. Epub 2017/02/06. doi: 10.1097/prs.0000000000003282. PubMed PMID: 28157769
- ⁷ Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015
- ⁸ Brody GS, Deapen D, Taylor CR, Pinter-Brown L, House-Lightner SR, Andersen JS, et al. Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases. *Plast Reconstr Surg*. 2015;135(3):695-705. Epub 2014/12/10. doi: 10.1097/prs.0000000000001033. PubMed PMID: 25490535
- ⁹ Gidengil CA, Predmore Z, Mattke S, van Busum K, Kim B. Breast implant-associated anaplastic large cell lymphoma: a systematic review. *Plast Reconstr Surg*. 2015;135(3):713-20. Epub 2014/12/10. doi: 10.1097/prs.0000000000001037. PubMed PMID: 25490539
- ¹⁰ Robert Knight A-ML-W, William Wessels, Timothy Papadopoulos, Mark Magnusson, Julian Lofts, Tony Connell, Ingrid Hopper, Kenneth Beath, Stephen Lade, Henry Prince, Anand Deva. Epidemiology and Risk Factors for Breast Implant-Associated Anaplastic Large Cell Lymphoma BIA-ALCL) in Australia and New Zealand. *Plastic Surgery The Meeting: American Society of Plastic Surgeons*; Los Angeles, CA: Plastic and Reconstructive Surgery Global Open; 2016. p. 82-3
- ¹¹ Srinivasa DR, Miranda RN, Kaura A, Francis AM, Campanale A, Boldrini R, et al. Global Adverse Event Reports of Breast Implant-Associated ALCL: An International Review of 40 Government Authority Databases. *Plast Reconstr Surg*. 2017. Epub 2017/02/06. doi: 10.1097/prs.0000000000003233. PubMed PMID: 28157770
- ¹² Information on BIA-ALCL: American Society of Plastic Surgeons; 2017 [cited 2017 26 February]. Available from: <http://www.plasticsurgery.org/patient-safety/information-on-bia-alc>
- ¹³ ASPS/ASAPS Update Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) Quick Facts and FAQs: The American Society For Aesthetic Plastic Surgery & American Society of Plastic Surgeons. Available from: <http://www.surgery.org/downloads/blasts/BIA-ALCL/>

¹⁴ Joint ASPS & ASAPS Statement on Breast Implant-Associated ALCL 2016 [cited 2017 26 February]. Available from: <http://www.surgery.org/downloads/private/joint-asps-asaps-statement-on-breast-implant-associated-alcl.pdf>

¹⁵ International Society of Aesthetic Plastic Surgery (ISAPS) 2017. Available from: <http://www.isaps.org>

¹⁶ Frequently Asked Questions (FAQ): A Guide to Breast Implant-Associated Anaplastic Large Cell Lymphoma: American Society of Plastic Surgeons and The Plastic Surgery Foundation; 2016 [cited 2017 22 March]. Available from: <http://www.thepsf.org/Documents/Clinical/PROFILE/profile-faq.pdf>

© Mentor Worldwide LLC 2017 069687-170323