

11 July 2019

Dear Clinicians,

Today the Australian Therapeutic Goods Administration (TGA) announced its proposal to suspend a number of textured breast implants and expanders, which includes all MENTOR® SILTEX® Microtextured Breast Implants and Expanders. A full list of the Mentor products included in the notice appear in the appendix of this letter. The TGA also announced its proposal to cancel the licence and issue a recall of another manufacturer's textured implants. The regulatory announcement follows the TGA's formal review of textured breast implants available in Australia and their connection to Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

It is important to understand that the proposed suspensions are *proposed* and that no decision has been made to suspend MENTOR® products at this time. The TGA also affirmed that because BIA-ALCL is rare, experts do not recommend preventative removal of breast implants where there are no problems with the implant. Until a decision is made by the TGA, all Mentor products will remain available for use in Australia.

We understand this announcement may raise some questions and concerns from you and your patients. Nothing is more important to Mentor than the health and safety of the women who choose our breast implants and expanders. We would like to assure you that Mentor adheres to the highest standards of quality, and the safety and clinical performance of MENTOR® Breast Implants is supported by long-term clinical data, including three, 10-year, prospective clinical trials.^{1,2,3} Current literature, and real world evidence, concludes that the risk of developing BIA-ALCL differs between different textured devices and has been shown to be rare with MENTOR® Breast Implants.^{4,5,6,7,8,9,10,11,12}

If the TGA decides to move forward with a suspension of our devices, they have confirmed that the suspension will be for a period of 6 months to allow sufficient time for TGA to review additional data and detailed information from around the world regarding the performance and safety of MENTOR® SILTEX® textured devices. We have been working with the TGA throughout their review process and will be providing them additional data and detailed information which affirms the safety of our MENTOR® SILTEX® Microtextured Breast Implants and Expanders to help clarify any concerns they may have prior to them making a decision.

¹ Summary of the Safety and Effectiveness of Mentor's MemoryGel® Silicone Gel-Filled Implants in Patients who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction, or Revision. 10-Year Core Gel Final Clinical Study Report. April 2013.

² Mentor Worldwide, LLC. MemoryShape™ Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015.

³ Bielefeld, B. A Prospective Clinical Study of Mentor Corporation Saline-filled Mammary Prosthesis, Siltex® Saline-filled Mammary Prosthesis, and Siltex® Saline-filled Post-operatively Adjustable Mammary Prosthesis (Spectrum TM) for Augmentation Mammoplasty and Reconstruction Mammoplasty. Nov 10, 1999.

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 Loch-Wilkinson, A., et al., Breast implant associated Anaplastic Large Cell Lymphoma in Australia and New Zealand - high surface area textured implants are associated with increased risk. Plastic and Reconstructive Surgery, 2017. 140(4): p. 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 Srinivasa, D.R., et al., Global Adverse Event Reports of Breast Implant-Associated ALCL: An International Review of 40 Government Authority Databases. Plast Reconstr Surg, 2017. 139(5): p. 1029-1039.

¹⁰ 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.

¹¹ 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

¹² Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). US Food & Drug Administration. March 2018 [accessed 12DEC2018]. <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

While MENTOR® Breast Implants have a low rate of BIA-ALCL, and there are zero cases of BIA-ALCL associated with our MENTOR® SILTEX® Expanders, it remains a concern we take seriously. We closely monitor reports of BIA-ALCL through clinical studies, international registries and post market surveillance activities and continue to work with industry groups, physicians, scientists and health authorities to enhance our understanding of the associated risks and causes of this type of lymphoma. We will continue to provide you with transparent and balanced information so that you and your patients can evaluate the benefits and risks associated with breast implants. As a reminder, we have communication tools we created for you to provide to your patients and to guide you in your conversations with them. These include a two-page brochure which discusses the common complications and BIA-ALCL, patient educational brochures, and product insert data sheets.

If you have questions or would like to discuss further, please don't hesitate to reach out to one of us. For Medical Information Requests (MIR) please contact Dr Lydia Arrogante directly on (02) 9815 4115.

Regards



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APPENDIX

The TGA has informed MENTOR® of a “*Notice of Proposal to Suspend*” (**Notice**) for a period of six (6) months relating to the following products:

- MENTOR® SILTEX® Cohesive I / 354-4400 (ARTG 110588)
- MENTOR® SILTEX® CPG 334-1304 (ARTG 110589)
- MENTOR® SILTEX® Contour Profile Becker 35 Expander 324-1305 (ARTG 110592)
- MENTOR® SILTEX® Round Becker 25 Expander 354-8000 (ARTG 130678)
- MENTOR® SILTEX® Cohesive II / 324-4350 (ARTG 119809)
- CPX4 Breast Tissue Expander (ARTG 226977)
- CPX4 Breast Tissue Expander with Suture Tabs (ARTG 226982)