Mentor Worldwide LLC | 33 Technology Drive, Irvine, CA 92618 USA | 800-235-5731 | www.mentorwwllc.com

4 April 2019

Dear Clinicians,

Today France's Health Authority, Agence Nationale de Sécurité du Médicament's (ANSM), announced a recall and prohibition on the marketing, distribution, advertising and use of thirteen macrotextured and polyurethane breast implants from six manufacturers, ALLERGAN, POLYTECH, NAGOR, EUROSILICONE, ARION, and SEBBIN, which goes into effect on 5 April 2019. Additionally, Health Canada announced its intention to suspend its license for ALLERGAN Biocell breast implants as a precautionary measure due to their safety review of breast implants which showed that 86% of the country's BIA-ALCL cases involved ALLERGAN Biocell breast implants.

These regulatory actions do not include MENTOR® SILTEX™ Imprinted Microtextured[1,2] Breast Implants and have no impact on the availability of MENTOR® Breast Implants or Breast Tissue Expanders in Europe, Canada, or anywhere around the world. We maintain our CE Marking certification, along with our FDA, Health Canada, and other international approvals for both our smooth and MENTOR® SILTEX™ Microtexture Breast Implants. In fact, we received renewal of our CE Marking for all MENTOR® Silicone Gel Breast Implants in February 2019.

Nothing is more important to Mentor than the health and safety of the women who choose our breast implants. 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.[3,4,5] Current literature concludes that the risk of developing BIA-ALCL differs between different textured devices and has been shown to be rare with MENTOR® Breast Implants.[6,7,8,9,10,11,12,13,14]

While MENTOR® Breast Implants have a low rate of BIA-ALCL, it remains a concern we take seriously. Mentor closely monitors reports of BIA-ALCL through clinical studies, registries and post market surveillance activities and continues 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.

If you have questions or would like to discuss further, please don't hesitate to reach out to one of us. Medical Information Requests (MIR) can also be submitted to our official MIR website.

Regards,

Warren Foust
Worldwide President, Mentor
WFOUST@its.jnj.com

John W. Canady, M.S., M.D., D. Sc. (hon), FACS, FAAP
Integrated Leader Clinical and Medical Affairs, Mentor
jcanady@its.jnj.com

1 Atlan M, Nuti G, Wang H, Decker S, Perry T. Breast implant surface texture impacts host tissue response. J Mech Behav Biomed Mater. 2018 Dec;88:377-385
2 Derby BM, Codner MA. Textured silicone breast implant use in primary augmentation: core data update and review. Plast Reconstr Surg. 2015 Jan;135(1):113-24.
3 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.
4 Mentor Worldwide, LLC. MemoryShape™ Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015.
5 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.
6 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
7 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.
8 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.
9 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.
10 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.
11 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.
12 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.
13 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
14 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

Mentor Worldwide LLC | 33 Technology Drive, Irvine, CA 92618 USA | 800-235-5731 | www.mentorwwllc.com

Important Safety Information

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

There are risks associated with breast implant surgery. Breast implants are not lifetime devices and breast implantation is not necessarily a one-time surgery.

The most common complications with MENTOR® MemoryGel™ Breast Implants include re-operation, implant removal, capsular contracture, asymmetry, and breast pain. A lower risk of complication is implant rupture, which is most often silent. The health consequences of a ruptured silicone gel-filled breast implant have not been fully established. Screenings such as mammography, MRI, or ultrasound are recommended after initial implant surgery to assist in detecting implant rupture.

The most common complications with MENTOR® Saline-Filled Implants include re-operation, implant removal, capsular contracture, wrinkling, deflation, asymmetry, and breast pain.

MENTOR® CPX™4 Breast Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures.

These expanders are intended for temporary subcutaneous or submuscular implantation.*

CONTOUR PROFILE™ Tissue Expanders are devices that contain magnetic injection domes and are NOT MRI compatible. Do not use the CONTOUR PROFILE™ Tissue Expander in patients where an MRI may be needed. DO NOT use the CONTOUR PROFILE™ Tissue Expander in patients that have a previously implanted device that could be affected by a magnetic field. 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: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has previously been performed.

Your patient needs to be informed and understand the risks and benefits of breast implants, and provided with an opportunity to consult with you prior to deciding on surgery.

For detailed indications, contraindications, warning and precautions associated with the use of all MENTOR® Implantable Devices, please refer to the Product Insert Data Sheet provided with each product, or review the Important Safety Information provided at www.mentorwwllc.eu.