

Safety Information

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

Mentor continues to work with industry groups, physician scientists and health authorities globally to better understand the associated risks and causes of BIA-ALCL. As patient safety has been and always will be Mentor's first priority, Mentor continues to closely monitor reports of and information about BIA-ALCL.

-  [IMPORTANT INFORMATION FOR WOMEN CONSIDERING BREAST IMPLANTS](#)

Rare Health Conditions

A recent study claiming silicone breast implants were associated with a higher risk of some rare health conditions was published in the Annals of Surgery. Science and long-term data from multiple clinical studies, including two 10-year prospective clinical trials, support the safety and clinical performance of breast implants. The FDA has stated that they respectfully disagree with the author's conclusions. Along with the presidents-elect of both the American Society of Aesthetic Plastic Surgery and Plastic Surgery Foundation, and surgeons from Harvard Medical School and Memorial Sloan Kettering Cancer Center, the FDA also warned patients and surgeons to view the assessment with caution.

The conclusions in the article rely on an analysis of study data with significant flaws that have been acknowledged by FDA, unbiased medical experts and breast implant manufacturers. In fact, the article uses data from original studies that were replaced with redesigned studies because they were inadequate to determine associations with the rare health effects outlined in the article.

Mentor fully supports ongoing research and continues to partner with independent groups and the FDA to further scientific evidence related to breast implant safety. We share updated product safety information with surgeons in our product labeling, with patients in brochures, and online as appropriate. There are inherent risks associated with breast implants and MENTOR warns of such known risks in its Product Insert Data Sheets (PIDS) provided to surgeons and patient brochures provided to patients.

It is important for every woman considering breast implants to review all this information with her surgeon.

Click [here](#) to view the FDA's full statement on the manuscript published in the Annals of Surgery.

Important Safety Information

MENTOR® MemoryShape® Breast Implants

MENTOR® MemoryShape® Breast Implants are indicated for breast augmentation in women at least 22 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 who have not received adequate treatment for those conditions, or who are pregnant or nursing.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. The most common complications with MENTOR® MemoryShape® Breast Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. The most common complications with MENTOR® MemoryShape® Breast Implants for breast reconstruction include reoperation for any reason, implant removal with or without replacement, and capsular contracture. A lower risk complication is rupture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture.

Patients should receive a copy of Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants or Patient Educational Brochure – Breast Reconstruction with MENTOR® MemoryShape® Breast Implants, and a copy of Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants. 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.

For detailed indications, contraindications, warnings, and precautions associated with the use of MENTOR® MemoryShape® Breast Implants please refer to the Product Insert Data Sheet provided with each product, or visit www.mentorwillc.com.