

Health Care Provider Letter for Breast Implants FDA Safety Updates

FDA Breast Implant Safety Update

www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants

Dear Health Care Providers of All Specialties in Arizona,

This letter is to inform you of recent safety updates and restrictions on all breast implants that are marketed and sold in the United States. Per the [FDA Website](#), a number of patients and clinicians use the term “breast implant illness” or “BII” to describe a variety of systemic symptoms which may be reported by some women following reconstruction or augmentation with breast implants. They include, but are not limited to, fatigue, problems with memory or concentration (“brain fog”), joint and muscle pain, hair loss, weight changes and anxiety/depression. The appearance of such symptoms has been reported with all types of breast implants regardless of filling, shape or surface characteristic, and their onset anywhere from immediately after implantation to years later.¹

Scientific studies show that women report improvement or resolution of symptoms following removal of the implants, the cause of the symptoms and the degree to which they may be related to the implants are unclear at the current time. Research continues to be performed to better understand any potential association with breast implants. The purpose of this communication is to alert you of systemic symptoms that you may be seeing in patients who have breast implants. Patients typically see multiple practitioners of different specialties in search of answers. This communication will help all medical professionals to learn and understand the complications of breast implant related issues. With the knowledge gained, we can improve the standard of care in managing these symptoms in patients with breast implants. For more information on the systemic symptoms related to breast implants and the most common symptoms that are experienced, please visit <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants>.

FDA Actions

- In March 2019, the FDA held a [public advisory panel meeting](#) and concluded that there was an opportunity to do more to protect women who are considering breast implants.²
- In March 2019, it was discovered that over 446,000 breast implant adverse event reports were withheld from the public, leading to the FDA discontinuing the use of [Alternative Summary Reporting](#)³ for adverse events in the MAUDE database.
- In July 2019, the FDA requested that [Allergan recall](#)⁴ all textured breast implants and tissue expanders worldwide due to risk of developing cancer (Breast Implant Associated Anaplastic Large Cell Lymphoma).
- In 2021, the FDA took several new actions to [strengthen breast implant communication](#).⁵
 - FDA restricted sale and distribution to only health care providers and facilities who provide manufacturer brochure Patient Decision Checklist to be signed by the patient and the physician implanting the device.
 - FDA approved new labeling for all legally marketed breast implants that includes the following:
 1. Boxed warning, also known as “Black Box Warning,” on all breast implants. This is the strictest labeling that the FDA uses for the most dangerous drugs and medical devices.
 2. Updated silicone gel-filled breast implant rupture screening recommendations. (MRI at 5 years and every 2-3 years after)
 3. Device description with a list of specific materials in the device.
 4. Patient device card containing manufacturer, model, and serial number.

Please keep these safety updates in mind if you have patients who have breast implants and are experiencing unexplained symptoms or complications. Below is a list of common symptoms and autoimmune diagnoses that are associated with implant illness. The list can be used to track and monitor symptoms before and after breast implant removal surgery. Please report all adverse events to the FDA MedWatch Program.

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>.

COMMON SYMPTOMS OF BREAST IMPLANT ILLNESS

- Fatigue
- Chronic Pain
- Brain Fog
- Cognitive Dysfunction
- Muscle Pain/Weakness
- Joint Pain
- Hair Loss
- Dry Skin & Hair
- Premature Aging
- Weight Problems
- Inflammation
- Insomnia/Poor Sleep
- Dry Eyes
- Vision problems
- Thyroid problems
- Adrenal problems
- Hormone Imbalance
- Low Libido
- Slow Healing
- Choking Feeling
- Difficulty Swallowing
- Difficulty Breathing
- Sinus Infections
- Digestive Issues
- Fevers/Night Sweats
- Temperature Intolerance
- Skin Rashes
- Ear Ringing
- Food Intolerance
- Headaches/Migraines
- Heart Palpitations
- Flu-like Symptoms
- Swollen Lymph Nodes
- Dehydration
- Frequent Urination
- Numbness/Tingling limbs
- Liver/Kidney Dysfunction
- Anxiety/Depression
- Leaky Gut/IBS
- Feel like you are dying
- BIA-ALCL Lymphoma
- Acid Reflux/GERD
- Vertigo/Dizziness
- Frequent Infections

Autoimmune diseases: Fibromyalgia, Raynaud's, Lupus, Hashimoto's, Rheumatoid Arthritis, Lyme, Sjögren's Syndrome, Scleroderma, Connective Tissue Disease, Multiple Sclerosis, ASIA

Related Resources

- 1 <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants>
- 2 <https://www.fda.gov/news-events/press-announcements/statement-fda-principal-deputy-commissioner-amy-abernethy-md-phd-and-jeff-shuren-md-jd-director-fdas>
- 3 <https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-increase-transparency-medical-device-reporting>
- 4 <https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan>
- 5 <https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants>
- <https://www.fda.gov/news-events/press-announcements/fda-updates-analysis-medical-device-reports-breast-implant-illness-and-breast-implant-associated>
- <https://www.fda.gov/consumers/consumer-updates/fda-warns-against-injectable-silicone-and-dermal-fillers-large-scale-body-contouring-and-enhancement>
- <https://www.mdanderson.org/newsroom/largest-ever-study-shows-silicone-breast-implants-associated-with-rare-diseases.h00-159227301.html>
- https://journals.lww.com/annalsplasticsurgery/fulltext/2020/07001/understanding_breast_implant_illness_befor_e_and.19.aspx
- <https://pubmed.ncbi.nlm.nih.gov/34513545/>
- <https://www.dovepress.com/the-breast-tumor-microenvironment-could-silicone-breast-implant-elicite-peer-reviewed-fulltext-article-BCTT>
- <https://www.breastimplanthealthsummit.com>
- www.GPACunited.org