

## BREAST IMPLANT PATIENT DECISION CHECKLIST

### INTRODUCTION

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery for either breast augmentation or breast reconstruction. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This patient decision checklist is intended to supplement the additional patient labeling that should be provided to you by your physician. You should receive a manufacturer patient booklet/brochure that includes important information about your specific breast implant, as well as a boxed warning and patient decision checklist. After reviewing the information in the patient information booklet/brochure for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read the materials and that your physician has answered all questions to your satisfaction.

### BLACK BOX WARNING

In October 2019, the FDA recommended a “black box warning” label on all breast implants. This is designed to call attention to a serious or life-threatening risk and highlights that surgeons must review this with patients in advance of using the device. **This is the strictest warning label that the FDA uses on the most dangerous medical devices and drugs that cause severe harm, illness, cancer, or death.** This checklist is intended to cover all parts of the warning in detail.

#### WARNING:

- Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

Breast implants can cause a type of cancer of the immune system called BIA-ALCL (Breast Implant Associated Anaplastic Large Cell Lymphoma). People with silicone or saline breast implants have developed this rare disease, which can be deadly if not treated early. Almost all women who have developed BIA-ALCL have had textured breast implants or expanders at some point.

Several studies also suggest that women with breast implants have a small but significant increase in their chances of developing certain autoimmune or connective tissue diseases. Women with silicone gel or saline breast implants have reported symptoms that are sometimes serious, such as joint or muscle pain, fibromyalgia, mental confusion, and painful skin conditions.

Many of these symptoms improve partially or completely when their breast implants and the surrounding capsule (scar tissue) are removed and not replaced.

### MEDICAL DEVICE REPORTS FOR SYSTEMIC SYMPTOMS IN WOMEN WITH BREAST IMPLANTS

Medical Device Reporting (MDR) is one of the post-market surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

FDA conducted a query of the MDR database for all reports posted between January 1, 2008 and October 31, 2019 referring to a saline- or silicone-filled breast prosthesis whose event narrative included one or more of the terms listed in Table 1, or one of the following terms or phrases:

- BII
- Breast implant illness
- Generalized/unexplained illness
- Unexplained systemic symptoms.

**Table 1. Search Terms Relevant to Systemic Symptoms Referred to as BII Used by FDA in its 2020 MDR Query**

acid reflux	EBV	intoleran <sup>a</sup>	Reflux
adrenal	fibromyalgia	Joint	rheumatoid arthritis
allergy	fog	joint pain	Scleroderma
allergies	frequent urination	Kidney	shortness of breath
anxiety	gallbladder	leaky gut	SIBO
arthritis	gastritis	Libido	Sick
autoimmune	Fatigue	Liver	Sinus
candida	fever	Lupus	Sjogren
chest discomfort	Gastrointestinal issues	Lyme disease	Sleep
choking	GERD	memory loss	slow healing
cold	GI issues	menopause	slow muscle recovery
connective tissue	hair loss	metallic taste	throat clearing
cough	Hashimoto	Migraine	Thyroid
dehydration	headaches	multiple sclerosis	Tingling
depression	heart pain	muscle pain	Toxic
difficulty swallowing	heart palpitations	night sweats	toxic shock
dry eyes	heart rate	Numbness	urinary tract
dry hair	hormone	pancreatitis	Vertigo
dry skin	hysterectomy	panic attack	Weight
dying	IBS	Parathyroid	Yeast
ear ringing	illness	premature aging	
early menopause	inflammation	Rash	
easy bruising	insomnia	Raynaud	

<sup>a</sup> Use of the \* wildcard will capture all words that begin with “intoleran”, including intolerance and intolerant

FDA’s query identified a total of 3,577 MDRs meeting the established search criteria. Table 2 provides the top 10 most frequent systemic-related search terms appearing in the reports of breast implant illness.<sup>1</sup>

**Table 2. Most Common Systemic Signs or Symptoms Listed in Breast Implant Medical Device Reports, January 1, 2008 – October 31, 2019**

SYMPTOM	PERCENTAGE OF REPORTS LISTING SYMPTOM (N=3,577)
Fatigue	49%
“Brain Fog”	25%
Joint Pain	25%
Anxiety	24%
Hair Loss	21%
Depression	19%
Rash	18%
Autoimmune Diseases*	18%
Inflammation	18%
Weight Fluctuation	18%

\* Any mention of autoimmune disease, which can include symptoms or diagnosis of autoimmune diseases

**DECISION CHECKLIST – PLEASE READ CAREFULLY AND INITIAL WHERE PROMPTED**

The purpose of this checklist is to provide information for patients considering breast implants for augmentation or reconstruction, so that they can carefully weigh the risks and benefits of breast implants and make the decision that is right for them. The risks in this checklist are in addition to common surgical risks such as infection, necrosis (skin death), or problems with anesthesia.

After reviewing the breast implant manufacturer Patient Information Booklet and any additional patient information materials provided by your surgeon, please read and discuss the items in this checklist with your surgeon. You should not initial or sign the document, and should not undergo the procedure, if you do not understand each of the issues listed.

**CONSIDERATIONS**

**How Long Do Implants Last?** I understand that breast implants are not expected to last for the rest of my life. Implants may rupture or leak at any time, and that is more likely the longer you have them. In addition, it is likely that I will need other surgeries related to my breast implants over the course of my life. If I am a cosmetic surgery patient, my health insurance policy may refuse to cover these surgeries. These additional surgeries and procedures can include implant removal with or without replacement, muscle and tissue repair, scar revisions, MRI diagnostic exams, or other procedures. I understand that undergoing multiple surgeries may increase my chances of permanent breast deformity, increased scarring, and capsular contracture, which can become tight and painful.

Patient Initials \_\_\_\_\_

**Who May Not Be A Candidate For Breast Implant Surgery?** I understand that the safety of breast implants was never specifically studied for people who have autoimmune symptoms or diseases, or a family history of those diseases. Breast implants may be more likely to cause serious health problems and symptoms for these people. In addition, breast implants may not be safe for anyone with a weakened immune system or certain genetic risk factors that have not yet been identified.

Patient Initials \_\_\_\_\_

<sup>1</sup> Patients are encouraged to read the full FDA webpage on these reports at <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants>

I understand I am not a candidate for breast implants at the present time if any of the following situations applies to me:

- I have an active infection anywhere in my body
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated
- I am pregnant or nursing

Patient Initials \_\_\_\_\_

I understand that if I have any of the following conditions, I may be at higher risk for a poor surgical outcome

- Autoimmune disease or family history of autoimmune disease (e.g., Hashimoto’s, Lupus, Rheumatoid Arthritis)
- Medical condition that affects my body’s ability to heal (e.g., diabetes, connective tissue disorder)
- Active smoker or a former smoker
- Currently taking drugs that weaken the body’s natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide)
- History of chemotherapy or planned chemotherapy following breast implant placement
- History of radiation therapy or planned radiation following breast implant placement
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, antithrombin III deficiency, or systemic lupus erythematosus or personal and/or family history of venous thromboembolic disorder)
- Reduced blood supply to the breast tissue

Patient Initials \_\_\_\_\_

I understand the following conditions have not been conclusively studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g., Hashimoto’s, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease)
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder)
- Have other products permanently implanted in the breast.

Patient Initials \_\_\_\_\_

#### **RISKS – GENERAL**

***Chemicals and Metals in Breast Implants:*** I understand that all breast implants contain chemicals and heavy metals that may cause health problems. I understand that most of these chemicals are confined to the shell of the implant or stay inside the shell. However, quantities have been found to diffuse (bleed) from or through the implant shell, even if the implant is intact and not ruptured. A list of the components, chemicals, and heavy metals is available in the patient information booklet/brochure. Be sure to ask your surgeon to provide you with that booklet/brochure for the manufacturer of your implants.

Patient Initials \_\_\_\_\_

***BIA-ALCL:*** I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA- ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA’s website. I have received information regarding the overall incidence rates of BIA- ALCL and the rates as they pertain to my specific breast implant. I understand that this cancer has been reported more frequently for textured breast implants, but that patients with smooth surfaced implants have also been diagnosed.

Patient Initials \_\_\_\_\_

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

Patient Initials \_\_\_\_\_

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of include swelling, breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.<sup>2</sup>

Patient Initials \_\_\_\_\_

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials \_\_\_\_\_

**Breast Implant Illness:** I understand that we are still learning about the health issues that result from breast implants.

Since the inception of the use of breast implants in 1962, hundreds of thousands of women have reported adverse events related to their breast implant. These have included a variety of systemic symptoms that they attribute to their breast implants. These symptoms may occur immediately after getting implants or years later. **These symptoms include some or all of the following: joint and muscle pain, weakness, fatigue, rash, memory loss, chronic pain, depression, chronic flu-like symptoms, headaches/migraines, rashes or skin problems, frequent infections, difficulty breathing, heart palpitations, anxiety, insomnia and “brain fog.”** These symptoms have collectively been labeled breast implant illness. While the causes of these symptoms are unclear, patients have reported, and studies have shown relief of these symptoms with removal of their implants and surrounding scar tissue capsule. Researchers are working to better understand the possible link between breast implants and these symptoms.

Patient Initials \_\_\_\_\_

**Other Systemic Diseases:** Several studies of women with breast implants have shown that they are significantly more likely to be diagnosed with one or more of the following diseases compared to other women:

- CTDs (connective tissue diseases) occur when the patient’s immune system rejects parts of its own body tissues or cell types, including the connective tissues of the body, like fibrous tissues (tendons), cartilage and bones. These include
  - o Lupus – inflamed soft tissues and organs
  - o Rheumatoid Arthritis - inflamed and deteriorating joints
  - o Polymyositis - inflamed, weakened muscles
- Scleroderma – hardening and tightening of the skin and connective tissues. Can also affect blood vessels, internal organs, and the digestive tract
- Sclerosis - damaged skin or organs because of excess collagen, the main protein in connective tissue
- Melanoma – serious form of skin cancer that can spread to other organs
- Sjögren’s Syndrome – dry eyes, mouth, throat, dry cough; can also affect thyroid, liver, kidneys, lungs, skin
- Fibromyalgia – ongoing fatigue, widespread pain in muscles and joints, which can cause difficulty sleeping, morning stiffness, and cognitive difficulty
- Chronic Fatigue Syndrome – ongoing mental and physical exhaustion, often associated with muscle and/or joint pain
- Epstein Barr Virus – fatigue and general malaise. Can cause chronic illness, including immune and lymphoproliferative syndromes
- Raynaud’s Syndrome – areas of your body, such as fingers and toes, can feel numb and cold in response to cold temperatures or stress. Smaller arteries that supply blood to your skin narrow, limiting blood circulation to affected areas

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<sup>2</sup> “Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma,” available at <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma>

- Hashimoto's – immune system attacks the thyroid, impacting the endocrine system and the hormones that coordinate many of your body's functions
- Multiple Sclerosis – potentially disabling disease of the brain and spinal cord (central nervous system). Causes communication problems between your brain and the rest of your body. Eventually can cause permanent damage or deterioration of nerves

Although women who develop these symptoms or diseases can't be certain that they were caused by breast implants, several studies indicate that most symptoms improve partially or completely after having their implants and capsules removed.

Patient Initials \_\_\_\_\_

***Other Implanted Devices/Materials/Products:*** As part of my breast surgery, I understand that my surgeon may use other medical devices or materials that may not be approved by the FDA. These devices may be used "off label" or for experimental purposes, including but not limited to mesh (acellular dermal matrix) and other devices, products, or materials. My surgeon has informed me of all materials that will be used in my surgery and what those products are made of (human tissue, animal tissue or synthetic materials). **I understand that in addition to my surgeon disclosing the use of all materials, my surgeon must also disclose the current FDA approval status of that product for use in breast implant surgery.**

Patient Initials \_\_\_\_\_

**RISKS – BREAST IMPLANT-SPECIFIC**

***Rupture and Leakage:*** I understand that the longer my breast implants are in place, the more likely they are to rupture, especially after the first few years. When a saline implant ruptures, it usually deflates quickly. When a silicone gel implant ruptures, I may not notice any changes and the rupture may not be detected by my doctor or by mammogram, MRI, or sonogram. I understand that an MRI is recommended for silicone gel breast implants at 5-6 years after my initial implant surgery and then every 2-3 years thereafter to check for silent rupture, and that these MRIs often are not covered by health insurance.

Patient Initials \_\_\_\_\_

I understand that silicone may migrate from the implant into nearby tissues such as the chest wall, lymph nodes, upper abdominal wall, and into organs such as the liver or lungs where it cannot be removed. Migrated silicone can health problems including but not limited to cause breast hardness, nerve damage, and/or breakdown of the body tissues around the gel. Since migrated silicone can cause health problems, **it is currently recommended that any ruptured silicone implant should be removed as soon as possible.** I understand that, if needed, treatment of these conditions may be at my own expense and not covered by insurance or a manufacturer warranty.

Patient Initials \_\_\_\_\_

***Capsular Contracture:*** I understand that one of the most common complications of breast implants is when the scar tissue capsule that forms around the implant hardens. In some cases, this can be quite painful, distort the shape of the breast, and can make mammography more painful and less accurate. Removing the implant and capsule without replacing the implant is the only recommended way to guarantee that this problem is corrected.

Patient Initials \_\_\_\_\_

***Mammography and Implants:*** I understand that all breast implants can interfere with mammography and breast exams, which could delay the diagnosis of breast cancer in women undergoing cosmetic augmentation, as well as a delay in the diagnosis of recurrent breast cancer in women after mastectomy and implant-based reconstruction. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

Patient Initials \_\_\_\_\_

***Interference with Breastfeeding:*** I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed. There are studies that have found silicone gel and platinum in breast milk of nursing mothers. While a causal link between breast implants and these reported health problems in children has not been demonstrated, more research is needed

Patient Initials \_\_\_\_\_

**Loss of Sensation to Breast or Nipple(s):** I understand that breast implants and breast surgery may cause the nipple or breast to be painful, or to have decreased sensation. These changes may be temporary or permanent, and may affect sexual response or the ability to nurse a baby

Patient Initials \_\_\_\_\_

**Cosmetic Complications:** For example: asymmetry, implant displacement, ptosis (drooping). I understand that if my breasts had slightly different shapes before surgery, they may remain slightly different after surgery. I understand that the implants may cause the breasts to look slightly different in size or shape. I understand that the implant may move from the original placement location and that may result in asymmetry or other cosmetic problems. Breast implants can cause the breasts to sag (ptosis) over time due to the weight of the implants. I understand that if I am not happy with the results, I may need future surgeries to improve the appearance of my breasts. This may cause further scarring and deformity.

Patient Initials \_\_\_\_\_

I understand that there are risks of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include: breast pain, skin or nipple areola sensitivity changes or loss, asymmetry, impact of aging or weight change on size and shape of breast, infection requiring possible removal of implant, swelling, scarring, fluid collections (seroma), hematoma, tissue death of breast skin or nipple, inability to breast feed, complications of anesthesia, bleeding, chronic pain, damage to surrounding tissue, such as muscle, nerves, and blood vessels, and impact on imaging of breast tissue.

#### **HOW WILL I KNOW IF THERE IS A PROBLEM WITH MY IMPLANTS IN THE FUTURE?**

Just like a car, your implants come with a warranty. Be sure to ask your surgeon the exact details of your implants and warranty and to have your surgeon register the implants with the implant manufacturer. In addition, the Plastic Surgery Foundation has developed the National Breast Implant Registry (NBIR).

(<https://www.thepsf.org/documents/Research/Registries/NBIR/nbir-patient-faq.PDF>).

**National Breast Implant Registry (NBIR):** This registry is dedicated to quality improvement and safety surveillance and focused on you, the patient. Any surgeon that is putting in breast implants can register free of charge. The NBIR allows for surgeons to have all breast implant data in one place, easily accessible for them to track patient outcomes and device performance. Be sure to ask your doctor if they participate in the NBIR, to register if they do not, and to enter your breast implant data into the registry.

\_\_\_\_\_ I discussed the NBIR and asked my surgeon to register my implants in all appropriate places

I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be entered. The NBIR may help understand the long-term safety and performance of breast implants.

Patient Initials \_\_\_\_\_

**Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE):** I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials \_\_\_\_\_

**Device Card:** I understand that I will receive a patient device card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case I or my physician need to know what kind of implant I have many years later.

Patient Initials \_\_\_\_\_

**Recommended Follow Up:** Even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture at any time, an MRI is recommended.

I understand that I will need routine and regular follow-up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

Patient Initials \_\_\_\_\_

**OPTIONS FOLLOWING MASTECTOMY**

I understand that breast reconstruction is an elective procedure which I can choose to do or not. I understand that I may choose not to have breast reconstruction (“going flat”) and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes. I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue (“autologous reconstruction”).

Patient Initials \_\_\_\_\_

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin. I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

Patient Initials \_\_\_\_\_

I have discussed all of the options for breast reconstruction with my provider, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials \_\_\_\_\_

**BREAST AUGMENTATION OPTIONS**

I understand that breast augmentation is an elective procedure to increase the size of my breasts. I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or different incision size or location. If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials \_\_\_\_\_

**MANUFACTURER PATIENT INFORMATION MATERIALS**

I have been provided either in hardcopy or electronic format, the manufacturer patient information materials “Breast Implant Patient Information Booklet” on the implants that will be used in the used in the surgery.

Patient Initials \_\_\_\_\_

**REPORTING ADVERSE EVENTS**

I have been provided with information on how I can report adverse events associated with breast implants to the US Food and Drug Administration.

Patient Initials \_\_\_\_\_

**CONFIRMATION OF DISCUSSION OF RISKS: PATIENT**

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials \_\_\_\_\_

I acknowledge that I have received and read the patient information booklet/brochure for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their benefits and risks.

Patient Initials \_\_\_\_\_

**CONFIRMATION OF DISCUSSION OF RISKS: PHYSICIAN**



I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information booklet/brochure and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

Physician Initials \_\_\_\_\_