

## Breast Implant Patient Checklist

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document are critical steps in making the decision whether you should choose breast implant surgery. 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 surgery consents 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 this 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.** The draft warning is included here and the checklist is intended to cover this information in detail.

- **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.**

Elaborating on the FDA’s final point, women with breast implants may have an increase in their chances of developing certain autoimmune or connective tissue diseases with symptoms that are

sometimes serious, such as joint or muscle pain, fibromyalgia, mental confusion, painful skin conditions, chronic fatigue, frequent infections, difficulty breathing, headaches/migraines, heart palpitations, anxiety, depression, and insomnia. Some of these women have also been diagnosed with autoimmune diseases such as Raynaud's, Lupus, Lyme Disease, Hashimoto's, Rheumatoid Arthritis, Sjögren's Syndrome, Scleroderma, Multiple Sclerosis, and ASIA (Autoimmune Syndrome Induced by Adjuvants). Many of these symptoms improve partially or completely when their breast implants and capsules are removed and not replaced.

# BREAST IMPLANT PATIENT/DOCTOR CHECKLIST

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*, 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 below.

**How long do breast implants last?** I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to require a reoperation requiring the replacement or removal of my breast implant. 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 and increased scarring which can become tight and painful.

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

**Who shouldn't get breast implants?** 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.

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

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

I understand that if I have any of the following conditions, I may be at higher risk for a poor surgical outcome and serious health problems / symptoms:

- Autoimmune disease or family history of autoimmune disease (eg Hashimoto's, Lupus, Rheumatoid Arthritis)
- Medical condition that affects my body's ability to heal (eg 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 (eg 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 the immune system or blood clotting (eg hemophilia, von Willebrand disease, factor V leiden, hyperhomocysteinemia, protein C deficiency, anti- thrombin III deficiency, or systemic lupus erythematosus)
- Reduced blood supply to the breast tissue

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

**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, ***SEE APPENDIX A for list of chemical ingredients and metals found in breast implants and their shell***

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

**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 3 years following surgery and every 2 years after that to check for silent rupture, and that these MRIs often are not covered by health insurance. 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 cause breast hardness, numbness/tingling in extremities, 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\_\_\_\_\_

**BIA-ALCL (Breast Implant Associated Anaplastic Large Cell Lymphoma):** I understand that there is a risk for me to develop BIA-ALCL, a cancer of the immune system. BIA-ALCL is a type of lymphoma that develops on or around the scar tissue (capsule) that surrounds the breast implant. I understand that the symptoms of BIA-ALCL include breast swelling, lumps, pain, and asymmetry that develop after surgical incisions are completely healed, usually years after implant surgery. In rare instances, women have developed BIA-ALCL and they did not display any symptoms and the cancer metastasized (spread outside of the scar tissue (capsule) into the lymph nodes and other parts of the body.)

Treatment for BIA-ALCL includes removal of the implant and scar tissue (capsule), and, if not treated early, may include chemotherapy and radiation. This diagnosis and treatment may be at my own expense and is not always covered by insurance.

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

**Symptoms of “Breast Implant Illness:”** I understand that we are still learning about the health problems that result from breast implants.

I understand that some patients who have received breast implants have reported 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 labelled called breast implant illness. While the causes of these symptoms are unclear, some patients have reported 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.

## **Other Systemic Diseases**

Women with breast implants have reported being diagnosed with one or more of the following diseases.

CTDs (connective tissue diseases) are caused when the patient’s immune system mistakenly attacks parts of its own body tissues or cell types, including the connective tissues of the body, like fibrous tissues (tendons), cartilage and bones.

Lupus - inflammation and tissue damage in different body parts and organs

Melanoma – serious form of skin cancer that can spread to other organs rapidly if not treated at an early stage

Rheumatoid Arthritis - inflamed and deteriorating joints

Polymyositis - inflamed, weakened muscles

Sjögren’s Syndrome – dry eyes, mouth, throat, dry cough; can also damage thyroid, liver, kidneys, lungs, skin

Sclerosis - damaged skin or organs because of excess collagen, the main protein in connective tissue

Fibromyalgia – ongoing fatigue, widespread pain in muscles and joints, difficulty sleeping and morning stiffness

Chronic Fatigue Syndrome – ongoing mental and physical exhaustion, often with muscle and/or joint pain

Lyme Disease – inflammatory disease characterized by rash, headache, fever, chills, arthritis and neurological and cardiac disorders.

Epstein Barr Virus – fatigue and general malaise. Chronic illness, including immune and lymphoproliferative syndromes.

Raynaud’s Syndrome – causes areas of your body, such as fingers and toes, to 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.

Hashimotos – immune system attacks the thyroid. The thyroid gland is part of the endocrine system, which produces hormones that coordinate many of your body’s functions.

Scleroderma – hardening and tightening of the skin and connective tissues. Scleroderma also harms blood vessels, internal organs and the digestive tract. Signs and symptoms vary.

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.

While the association with these diseases is unclear, patients have reported relief of these diseases with removal of their implants and surrounding scar tissue (capsule).

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 additional 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 \_\_\_\_\_

**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 recommended procedure to minimize the risk of recurrence.

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

**Breast Cancer:** I understand that all breast implants can interfere with mammography and breast exams, possibly delaying the diagnosis of breast cancer. I understand that if I get breast implants, I should inform the mammography technologist about the implants and ask for additional views to improve the accuracy. I understand that mammography can also cause the breast implant to rupture or leak.

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.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. 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\_\_\_\_\_

## CONFIRMATION OF DISCUSSION OF RISKS

**Patient:** *I acknowledge that I have received and read the Breast Implant Patient Information Booklet and this checklist. I have had time to discuss the information in both with my doctor, and understand the benefits and risks of the implants and surgery.*

\_\_\_\_\_Patient Signature & Date

**Physician:** *I acknowledge that I have discussed the benefits and risks of breast implants as described in the Breast Implant Patient Information Booklet and this checklist. I have encouraged the patient to ask questions, and answered all questions accurately.*

\_\_\_\_\_Physician Signature & Date

## Appendix A

<b>Heavy Metals</b>	
Metal	Concentration (ppm) Parts per million
Antimony	0.014
Arsenic	0.123
Barium	0.001
Beryllium	0.006
Cadmium	0.002
Cobalt	0.052
Copper	0.025
Lead	0.011
Magnesium	0.391
Mercury	0.004
Molybdenum	0.001
Nickel	0.050
Platinum	0.299
Selenium	0.069
Silver	0.001
Tin	0.004
Titanium	0.033
Vanadium	0.310
Zinc	0.034