

The Breast Implant Working Group's Breast Implant Black Box Warning and Patient Checklist

The Working Group consists of Dr. Diana Zuckerman, Dr. Scot Glasberg, Dr. Alan Matarasso, Jamee Cook, Raylene Hollrah, and Karuna Jaggar. We are urging the FDA to include a black box warning about the risks of cancer and other serious health problems for women considering breast implants. We are also urging the FDA to require a Checklist to be read and signed by all patients, to make sure they are aware of the many risks of breast implants.

BLACK BOX WARNING: 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 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 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 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.

Patient Initials _____

Who shouldn't get breast implants? I understand that the safety of breast implants was never 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 _____

Chemicals and Metals in Breast Implants: I understand that all breast implants contain chemicals and small amounts of 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, small quantities have been found to diffuse (bleed) from or through the implant shell, even if the implant is intact and not ruptured.

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. 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 small 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 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.

Treatment for BIA-ALCL includes removal of the implant and scar 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 because of the lack of long-term safety data, we are still learning about the health problems that result from breast implants. To date, thousands of women have reported to the FDA or to researchers that they have experienced serious health problems that several studies have linked to their breast implants. This may occur either immediately after getting implants or years later. These often include symptoms such as: joint and muscle pain or weakness, memory and concentration problems, chronic pain, depression, fatigue, chronic flu-like symptoms, migraines, or rashes and skin problems.

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: • Chronic Fatigue Syndrome • Multiple Sclerosis (MS) • Rheumatoid Arthritis (RA) • Sjögren’s syndrome • Systemic Sclerosis/Scleroderma

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 _____

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 _____

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. No long-term research has been conducted to determine the possible transmission of chemicals and heavy metals in the breast milk of women with implants.

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: Asymmetry, Implant Displacement, Ptosis 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 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.

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