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patient decision checklist

Jamie, Actual Sientra Patient

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 is a critical step 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 labeling that should be provided to you by your physician. You should receive a 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.

CONSIDERATIONS FOR A CANDIDATE FOR SUCCESSFUL BREAST IMPLANTATION

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 or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

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

- 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, anti- thrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately 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); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

RISKS OF BREAST IMPLANT SURGERY

I understand that there are risks1 of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include:

- breast pain (reported in up to 2.6% of patients),
- skin or nipple areola sensitivity changes or loss (nipple sensation changes reported in up to 3.2% of patients; skin sensation changes reported in up to 0.9% of patients),
- asymmetry (reported in up to 8.7% of patients),
- impact of aging or weight change on size and shape of breast (ptosis reported in up to 2.0% of patients),
- infection requiring possible removal of implant (reported in up to 5.1% of patients),
- swelling (reported in up to 2.0% of patients),
- scarring (reported in up to 3.1% of patients),
- fluid collections (seroma) (reported in up to 2.4% of patients),
- hematoma (reported in up to 0.9% of patients),
- tissue death of breast skin or nipple (reported in up to 0.4% of patients),
- inability to breast feed (reported in up to 8.0% of patients),
- complications of anesthesia, (may occur but specific rates are not publicly available),
- bleeding (may occur but specific rates are not publicly available),
- chronic pain (may occur but specific rates are not publicly available),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available)
- impact on imaging of breast tissue (may occur but specific rates are not publicly available)

My physician has discussed these risks and has provided me with the patient information booklet/brochure (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My Physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

RISK OF CANCER - BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA (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.[2]

I have received information regarding the overall incidence rates of BIA-ALCL and the rates as they pertain to my specific breast implant.[3]

I understand that the current literature reports various estimates for the incidence of BIA-ALCL. As of July 2019, these estimated rates range from a high of 1 in 3,817 patients to a low estimate of 1 in 30,000 patients.71-73

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.

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

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.

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: _____

SYSTEMIC SYMPTOMS

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have 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, however not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

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. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

BREAST-IMPLANT SPECIFIC RISKS

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. As many as 11.4 percent of women who received Sientra Breast Implants for augmentation had their implants removed within 3 years, but my implants may last for a shorter or longer time (the percentage reported is from the 3-year Core study for Sientra breast implants. This rate specified represents the largest reported cumulative 3-year rate across all groups of augmentation patients in the study (both primary and revision).

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of chemicals diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, be costly, and the expense may not be covered by my medical insurance.

I understand that silicone can migrate from my implant into nearby tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs) where it may not be possible to remove.

I understand that all breast implants can interfere with mammography and breast exams, which could delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks[4] of breast implants may include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture) (capsular contracture III/IV reported in up to 8.8% of patients),
- rupture or leaking of the implant (reported in up to 2.5% of patients),
- wrinkling of the implant (reported in up to 2.4% of patients),
- visibility of the implant edges (reported in up to 1.0% of patients),
- shifting of the implant (implant malposition reported in up to 5.5% of patients), or
- reoperation (reported in up to 42.5% of patients).

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.

I understand that all breast implants contain chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant, but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking. A list of the components, chemicals, and heavy metals is available in the patient information booklet/brochure.

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.

National Breast Implant Registry (NBIR): 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 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: _____

QUESTIONS FOR MY PHYSICIAN

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: _____

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”).

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.

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: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: 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.

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Patient Signature and Date

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.

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Physician Signature and Date

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SCAN FOR BLACK BOX WARNING AND FULL ELECTRONIC PATIENT EDUCATION GUIDE

SCAN TO REVIEW FULL QUICK FACTS GUIDE

IMPORTANT SAFETY INFORMATION

Sientra's Silicone Gel Breast Implants are indicated for breast augmentation in women at least 22 years old and for breast reconstruction. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of primary breast augmentation surgery. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery. Breast implant surgery is contraindicated in women with active infection anywhere in their bodies, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions and, who are pregnant or nursing. Key complications include capsular contracture, implant removal, rupture and reoperation. For more detailed information about the risks and benefits of Sientra breast implants, please visit sientra.com/resources or call Sientra at 888.708.0808. Sientra breast implants with high-strength cohesive silicone gel are only available through board-certified or board-eligible plastic surgeons.

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Sientra, Inc.

REFERENCES

1. Risk data include worst-case data for primary and revision reconstruction and augmentation patient cohorts per Sientra's CORE Study with 3 years of data
2. See "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.
3. See www.Sientra.com
4. Risk data include worst-case data for primary and revision reconstruction and augmentation patient cohorts per Sientra's CORE Study with 3 years of data