

## **INHERENT RISKS OF AUGMENTATION MAMMAPLASTY SURGERY**

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications or adverse events associated with them. In addition, every procedure has limitations in terms of the outcome that patients will achieve afterwards. Additional information concerning breast implants may be obtained from the FDA, package-insert sheets supplied by the implant manufacturer, or other information pamphlets required by individual state laws.

An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. While all patients do not experience these complications or adverse events, you should discuss each of them with your plastic surgeon to make sure you understand all possible consequences of breast augmentation. Adverse events associated with breast implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. Additional advisory information regarding this subject should be reviewed by patients considering surgery that involves breast implants.

While every patient experiences her own individual risks and benefits following breast implant surgery, clinical data suggests that most women will be satisfied with the outcome of breast implant surgery despite the occurrence of problems inherent with the surgery.

## **SPECIFIC RISKS OF SILICONE GEL-FILLED BREAST IMPLANTS**

### **Implants:**

Breast implants, similar to other medical devices, can fail. When a silicone gel-filled implant ruptures, the gel material is usually contained within the scar tissue surrounding the implant (intracapsular rupture). In some cases, the gel may escape beyond the capsule layer and go into the breast tissue itself (extracapsular rupture and gel migration) or to more distant locations. Migrated silicone gel may be difficult or impossible to remove. Rupture of a breast implant may or may not produce local firmness in the breast. Patients are advised to refer to individual manufacturer's informational materials regarding the incidence of device rupture reported during pre-market studies.

It is impossible to predict the biologic response that a patient's tissues will exhibit to the placement of breast implants or how you will heal following surgery.

Rupture can occur as a result of an injury, from no apparent cause or during mammography. Rupture of a silicone breast implant is most often undetected (silent rupture). It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. According to the FDA, ruptured or damaged implants require replacement or removal. Breast implants can wear out, they are not guaranteed to last a lifetime and future surgery may be required to replace one or both implants.

A MRI (magnetic resonance imaging) study is advised to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity. It should be noted that the FDA recommends regular screening MRI examinations. Specifically, patients are advised to follow recommendations for serial MRI examinations, starting at 3 years after surgery and then every 2 years thereafter.

### **Capsular Contracture:**

Scar tissue, which forms internally around the breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may occur on one side, both sides or not at all. It is more common with implant

placement in front of the chest muscle layer. Treatment for capsular contracture may require surgery, implant replacement, or implant removal. Capsular contracture may reoccur after surgical procedures to treat this condition and it occurs more often in revision augmentation than primary augmentation. Some surgeons believe that preventative antibiotics during dental work and treatment for sinus infections and urinary tract infections may decrease this incidence. Discuss this with your surgeon. There may be an Off-Label FDA use for a drug called Singulair, which may have a softening effect on the capsule.

#### **Implant Extrusion / Tissue Necrosis:**

Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. Atrophy of breast tissue may occur. An implant may become visible at the surface of the breast as a result of the device pushing through layers of skin. If tissue break down occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur.

#### **Skin Wrinkling and Rippling:**

Visible and palpable wrinkling of implants and breast skin can occur. Some wrinkling is normal and expected with silicone gel-filled breast implants. This may be more pronounced in patients who have silicone gel-filled implants with textured surfaces or thin breast tissue. Palpable wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated.

#### **Calcification:**

Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications.

#### **Chest Wall Irregularities:**

Chest wall irregularities have been reported secondary to the use of tissue expanders and breast implants. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

#### **Implant Displacement and Tissue Stretching:**

Displacement, rotation, or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape (visible rippling of the skin). Unusual techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to attempt to correct this problem. It may not be possible to resolve this problem once it has occurred.

#### **Surface Contamination of Implants:**

Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the implant at the time of insertion. The consequences of this are unknown.

#### **Unusual Activities and Occupations:**

Activities and occupations which have the potential for trauma to the breast could potentially break or damage breast implants, or cause bleeding/seroma.

#### **Silicone Gel Bleed:**

The evidence is mixed regarding whether there are any clinical consequences associated with silicone gel bleed. Over time, extremely small amounts of silicone gel material and platinum can pass through the shell layer of the implant and coat the outside of the implant. Studies indicate that

a small amounts of platinum in its most biologically compatible (zero oxidation) state are contained within silicone gel. Microgram amounts of platinum in this state have been found to diffuse outside of breast implants. This may contribute to capsular contracture and lymph node swelling. The overall body of available evidence supports that the extremely low levels of gel bleed is of no clinical consequence.

**Change in Nipple and Skin Sensation:**

You may experience a diminished (or loss of) sensitivity of the nipples and the skin of your breast. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur occasionally. Changes in sensation may affect sexual response or the ability to breast feed a baby.

**Anaplastic Large Cell Lymphoma (ALCL):**

Women with saline and silicone gel breast implants may have a very small and possibly increased risk of developing anaplastic large cell lymphoma (ALCL) in the scar capsule adjacent to the implant. This is a very rare disease and is currently being investigated as to its relationship to breast implants, and whether this is even a cancer or a Lymphoproliferative Disorder. ALCL is an extremely rare cancer of the immune system which can occur anywhere in the body. The National Cancer Institute estimated 1 in 500,000 women per year in the U.S. are diagnosed with ALCL. ALCL in the breast is even rarer with approximately 3 in 100 million women in U.S diagnosed per year. The relationship between breast implants and ALCL is unclear and is currently under investigation. In most cases, women observed changes in the look or feel of the area surrounding the implant after their initial surgical sites were fully healed.

Patients with breast implants should be followed by a surgeon over time and seek professional care for implant-related symptoms such as pain, lumps, swelling, or asymmetry. Patients should monitor their breast implants with routine breast self exams and follow standard medical recommendations for imaging (e.g. Mammography, Ultrasound, MRI). Abnormal screening results or implant-related symptoms may result in additional costs and expenses for tests and/or procedures to properly diagnose and treat your condition. Tests and procedures could include but may not be limited to: obtaining breast fluid or tissue for pathology and laboratory evaluation and surgery to remove the scar capsule around the breast implant, implant removal or implant replacement.

**Breast Disease:**

Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and seek professional care should a breast lump be detected. In the event that suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.