

## Specific Risks of Capsulectomy with Breast Implant Replacement

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although most patients do not experience these complications, you should discuss them with your plastic surgeon at The Aesthetic Center by Kaiser Permanente to make sure you understand all possible risks of capsulectomy with breast implant replacement surgery.

### **Specific Risks of Capsulectomy with Implant Replacement Using Saline-Filled Implants**

Breast implants, similar to other medical devices, can fail. When a saline-filled implant ruptures, the saline material is absorbed by the body, but the shell material remains. Rupture can occur as a result of an injury, from no apparent cause (silent rupture), or during mammography. It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. Ruptured or damaged implants require replacement or removal. Breast implants can wear out, they are not guaranteed or expected to last a lifetime and additional or unplanned surgery may be required at any time after implant placement and for any of a number of reasons to replace one or both implants. An MRI (magnetic resonance imaging) study may be necessary to evaluate the possibility of implant rupture or deflation, yet may not be 100% accurate in diagnosing implant integrity. Saline-filled breast implants may not have the same contour or feel as silicone-filled breast implants. The shape of your breasts after surgery depends on many factors such as your skin thickness, position, placement of the implants, and technique. You should discuss with your surgeon the possibility of a different and less than desirable contour-shape as well as feel of your result.

### **Specific Risks of Capsulectomy with Implant Replacement Using Silicone Gel-Filled 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 completely 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 or expected to last a lifetime and additional or unplanned surgery may be required at any time after implant placement and for any of a number of reasons to replace one or both implants. An 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.

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### **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.

### **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.

### **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.

### **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.

### **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.

### **Skin Wrinkling and Rippling**

Visible and palpable wrinkling of implants and breast skin can occur. Some wrinkling is normal and expected with saline-filled breast implants. This may be more pronounced in patients who have saline-filled implants with textured surfaces or thin breast tissue. It may be possible to feel the implant fill valve. Some patients may find palpable valve and wrinkles cosmetically undesirable. Palpable valve, wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated.

### **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). Additional surgery may be necessary to attempt to correct this problem. It may not be possible to resolve this problem once it has occurred.

### **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.

### **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 or change in nipple erectile function may occur occasionally. Changes in sensation may affect sexual response or the ability to breast feed a baby.

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

Women with saline and silicone gel breast implants may have a very small but 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 with breast implants. ALCL is an extremely rare cancer of the immune system, which can occur anywhere in the body. The National Cancer Institute estimates approximately 2000 ALCL cases per year. Primary lymphoma of the breast is a disease of the breast parenchyma, representing 0.04-0.5% of breast cancers and 1-2% of all lymphomas. Incidence of ALCL of the breast is not known. Breast implant associated ALCL is estimated to be 1:300,000 women with breast implants but this likely is underestimated. (deJong. JAMA, 2008) ALCL 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.

### **Use of Acellular Dermal Matrix**

In order to place the implant in the right position and maintain that position, your plastic surgeon may choose to use biological materials. Most commonly, these materials are derived from human cadaver skin or pig skin. These materials are generally processed and do not carry any viable cells. You should ask your surgeon about these materials. They assist in contouring the pocket around the implant, provide additional cover to an implant, and become populated with your cells becoming similar to your own tissue. These acellular products may produce fluid and require drains for a prolonged period of time.

### **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.