

# **INFORMED CONSENT – BREAST IMPLANT REMOVAL & OPEN CAPSULECTOMY WITH BREAST IMPLANT REPLACEMENT USING SILICONE GEL-FILLED IMPLANTS**

## **BREAST IMPLANT REMOVAL**

### **INSTRUCTIONS**

This is an informed-consent document that has been prepared to help inform you about the procedure of removal of breast implant(s), its risks, and alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

### **GENERAL INFORMATION**

The removal of breast implants that have been placed either for cosmetic or reconstructive purposes is a surgical operation. Breast implant removal may be performed as a single surgical procedure or combined with additional procedures, for example:

- Simple breast implant removal, without removal of capsule tissue around implant
- Removal of tissue surrounding the breast implant (capsulectomy)
- Removal of silicone gel in breast tissue from silicone gel-filled implants
- Breast lift (mastopexy following breast implant and/or capsule removal)
- Replacement of breast implants

Implants that are found to be damaged or ruptured cannot be repaired; surgical removal or replacement is recommended. There are options concerning general versus local anesthesia for breast implant removal.

There are risks and potential complications associated with this operation.

**Individuals who choose to have revisions made in order to continue with breast implants must sign other consent documents for revision surgery. This document is intended for permanent removal of breast implants and/or capsule material that surrounds the implants or breast biopsy to remove silicone gel outside of the capsule layer.**

**Individuals who choose to undergo a breast lift (mastopexy) at the time of breast implant removal must sign an additional informed consent document for the breast lift (mastopexy).**

### **ALTERNATIVE TREATMENTS**

Alternative forms of non-surgical management consist of not undergoing breast-implant removal, or other procedures to replace, relocate, or revise existing situations where patients choose to continue with breast implants. Risks and potential complications are associated with alternative surgical forms of treatment.

### **RISKS OF SURGERY FOR BREAST IMPLANT REMOVAL**

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications involved with surgery to remove breast implant(s). 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 the majority of women do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast implant removal.

### **Specific Risks of Breast Implant Removal Surgery**

**Skin Wrinkling and Rippling:** Visible and palpable wrinkling of breast skin can occur. This may require additional surgery to tighten loose skin following breast implant removal surgery.

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**Ruptured Silicone Gel-Filled Breast Implants:** As with any man-made object implanted in the human body, device failure can occur. It is possible that an implant can rupture causing silicone gel to be released from the implant. Implants also can rupture during the removal process. If implant rupture has occurred, it may not be possible to completely remove all of the silicone gel that has escaped. Implant shell material of textured breast implants may be impossible to completely remove. Calcification around implants can occur and may require removal of the scar tissue surrounding the implant (capsulectomy). It may not be possible to completely remove the scar tissue that has formed around a breast implant, implant parts, calcifications, or silicone gel. Additional surgery may be necessary in the future.

**Delayed Healing and Tissue Necrosis:** Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. Areas of skin or nipple tissue may die. Tissue death (necrosis) can potentially occur when surgery is performed to remove implants, capsule tissue, and procedures to tighten the skin and move the nipples upward (mastopexy). Necrosis has also 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. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for delayed wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

**Change in Nipple and Skin Sensation:** You may experience a diminished (or loss) in the sensitivity of the nipples and the skin of your breast that usually resolves in 3 to 4 weeks. Partial or permanent loss of the nipple and skin sensation is rare. However, decreased or permanent loss in nipple sensation is more likely to occur if extensive surgical dissection is needed to remove scar tissue or silicone gel from a broken implant.

**Skin Contour Irregularities:** Contour and shape irregularities may occur. Visible and palpable wrinkling may occur. One breast may be smaller than the other. Nipple position and shape will not be identical one side to the next. 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.

## **ADDITIONAL SURGERY NECESSARY (Re-operations)**

There are many variable conditions that may influence the long-term result of breast implant removal surgery. It is unknown how your breast tissue may respond to implant removal or how wound healing will occur after surgery. Secondary surgery may be necessary at some time in the future to improve the outcome of breast implant removal surgery. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with breast implant removal surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

## **OPEN CAPSULECTOMY WITH BREAST IMPLANT REPLACEMENT USING SILICONE GEL-FILLED IMPLANTS**

## **INSTRUCTIONS**

# **INFORMED CONSENT – BREAST IMPLANT REMOVAL & OPEN CAPSULECTOMY WITH BREAST IMPLANT REPLACEMENT USING SILICONE GEL-FILLED IMPLANTS**

This is an informed-consent document that has been prepared to help inform you about open capsulectomy and breast implant exchange using silicone gel-filled implants, its risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

## **GENERAL INFORMATION**

The open capsulectomy is a surgical operation performed to treat scarring which occurs around breast implants or to revise the shape of the pocket where the implant is placed. This involves surgical cutting and removal of scar tissue that forms around a breast implant and the placement of new silicone gel breast implant(s).

Scar tissue, which forms internally around a breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after the original surgery or years later. 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. Calcification can occur within the scar tissue that surrounds breast implants. Treatment for capsular contracture may require surgery, removal of the capsule layer, implant replacement, or implant removal. Patients may elect to increase or decrease the size of their breast implants.

Individuals with old, damaged or broken implants (either saline or silicone gel-filled) may consider open capsulectomy surgery and replacement with silicone gel-filled implants as a way to maintain the long-term results from their original surgery, whether for cosmetic or reconstructive purposes. You may be advised by your surgeon to consider replacing your breast implants with new ones, irrespective of how long you have had them. In some situations, you may be advised to consider breast implants with a textured outer surface or to consider a different type of implant. Patients undergoing open capsulectomy surgery and breast implant exchange must consider the possibility of future revisionary surgery. Breast implants do not have an indefinite lifespan and will eventually require surgery for removal and/or replacement.

Depending on the extent of the scarring problem, it may be necessary to place the implant in a different location, partially underneath the pectoralis muscle on the chest, alternatively in front of the pectoralis muscle if the original placement was behind the muscle, or either completely or partially, known as a "dual plane". Incisions for the open capsulectomy procedure may be placed in different locations than those used in the original surgery. According to the FDA it is not recommended to use the peri-umbilical approach to insert gel-filled implants. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward. Conditions that involve sagging of the breast or diminished skin tone (stretch marks) may require additional surgical procedures (breast lift/mastopexy) to reposition the nipple and areola upward and to remove loose skin. Additional procedures to internally tighten or reshape the implant pocket may be needed to reposition implants.

Patients who consider secondary surgery to revise or maintain their results from breast implant surgery must consider that additional surgery may not correct or improve their results.

## **SILICONE GEL-FILLED BREAST IMPLANTS**

In November 2006, silicone gel-filled breast implant devices were approved by the United States Food and Drug Administration (FDA) for use in breast augmentation and reconstruction. **This includes their use in situations of surgery to revise or maintain the outcomes of individuals who have existing breast implants.** Silicone gel-filled breast implants can be used for revision of procedures in patients who have formerly undergone breast augmentation or reconstruction with silicone gel or saline-filled breast implants.

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Breast implant surgery is contraindicated in women with untreated breast cancer or pre-malignant breast disorders, active infection anywhere in the body, or individuals who are currently pregnant or nursing.

Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), conditions that interfere with blood clotting or wound healing, or have reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and a poor surgical outcome.

Silicone breast implants are approved by the FDA for use in women that are at least 22 years of age. Women that meet this age criteria may utilize the silicone implants for cosmetic breast augmentation or for revision surgery to correct or improve results of earlier cosmetic breast augmentation. There is no age restriction on breast reconstruction procedures to restore breast shape after cancer, trauma, or severe breast abnormalities. **Patients who receive silicone gel-filled breast implants must comply with FDA and manufacturer regulations concerning device tracking and post-market studies.**

Conditions which involve sagging of the breast or diminished skin tone (stretch marks) may require additional surgical procedures (breast lift) to reposition the nipple and areola upward and to remove loose skin.

Patients undergoing surgery that involves breast implants must consider the following:

- Breast augmentation, reconstruction, or revision with silicone gel-filled implants may not be a one time surgery.
- Breast implants of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
- Changes that occur to the breasts following augmentation, reconstruction, or revision with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants removed.
- Large volume primary augmentation, reconstruction or revision with larger sized implants (>350cc) may increase the risk of complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.

### **ALTERNATIVE TREATMENT**

Open capsulectomy with implant replacement using silicone gel-filled implants is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure, using saline-filled breast implants, or the transfer of other body tissues to rebuild breast size. Implant removal without replacement is also a surgical option if you elect to abandon the use of breast implants. Risks and potential complications are associated with alternative surgical forms of treatment.

### **RISKS OF OPEN CAPSULECTOMY WITH IMPLANT REPLACEMENT USING SILICONE GEL-FILLED IMPLANTS 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. 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, you should discuss each of them with your plastic surgeon to make sure you understand all possible consequences of breast implant revision surgery. Problems associated with breast implants can be inherent to this type of

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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.

## **Inherent 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, during removal, 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. Treating capsular contracture may require surgery, implant replacement, or implant removal. **Capsular contracture may reoccur after surgical procedures to treat this condition.**

**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 breakdown 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. Deposits of calcium can be seen on mammograms and can be mistaken as cancer, resulting in additional surgery for biopsy and/or removal of the implant.

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**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 that 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 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 are 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.

**Skin Contour Irregularities:** Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. 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.

**Delayed Healing:** Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to tissue from past surgery or radiation therapy may be at increased risk for delayed wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

## **Additional Breast Implant Advisory Information:**

**Mammography:** Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Any breast implant can impair the detection of breast cancer, regardless of the type of implant or where it is placed in relation to the breast. Implant rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of breast implants so that appropriate mammogram studies may be obtained. Patients with capsular contracture may find mammogram techniques painful and the difficulty of breast imaging will increase with the extent of contracture. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s). Because more x-ray views are necessary with specialized mammography techniques, women with breast implants will receive more radiation than women without

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implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays. Patients may wish to undergo a preoperative mammogram and another one after implantation to establish a baseline view of their breast tissue. You may be advised to undergo a MRI study in the future to verify the condition of your breast implants inside your body.

**Removal / Replacement of Breast Implants:** Future revision, removal, or replacement of breast implants and the surrounding scar tissue envelope involves surgical procedures with risks and potential complications. There may be an unacceptable appearance of the breasts following removal of the implant.

**Capsule Squeeze Procedures:** Closed capsulotomy, the process of forcefully squeezing the fibrous capsule around a breast implant to break up scarring is not recommended. This may result in rupture of the breast implant, bleeding, or other complications.

**Neurological Disease, Signs and Symptoms:** Some women with breast implants have complained of neurologic symptoms, which they believe are related to their implants. A scientific expert panel found that the evidence for a neurologic disease of symptom caused by or associated with breast implants is insufficient or flawed.

**Removal / Replacement of Breast Implants:** Future revision, removal, or replacement of breast implants and the surrounding scar tissue envelope involves surgical procedures with risks and potential complications. Implant replacement increases the risk of future complications. There may be an unacceptable appearance of the breasts following removal of the implant.

## **ADDITIONAL SURGERY NECESSARY (Re-Operations)**

There are many variable conditions that may influence the long-term result of breast surgery. It is unknown how your breast tissue may respond to implants or how wound healing will occur after surgery. Secondary surgery may be necessary at some time in the future to replace your breast implants or to improve the outcome of breast augmentation surgery. You may elect to or be advised to have your breast implants removed and not replaced in the future. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with breast augmentation surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

## **REGULATORY MATTERS**

Silicone gel implants are subject to device tracking by FDA regulations. Patients are advised to follow recommendations regarding periodic aftercare and guidelines for MRI imaging studies to rule out device rupture. Patients enrolled in post-market studies are advised to comply with the requirements of the studies.

## **General Risks of Surgery**

**Healing Issues:** Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, and the length of surgery and anesthesia that include a longer recovery and the possibility of additional surgery, prolonged recovery, color changes, shape changes,

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infection, not meeting goals and expectations, and added expense to the patient. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars during surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

**Bleeding:** It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Do not take any aspirin or anti-inflammatory medications for at least ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. In breast implant surgery, hematoma may contribute to capsular contracture, infection or other problems. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

**Infection in Breast Implant Patients:** Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the breast implant may have to be removed. After the infection is treated, a new breast implant can usually be reinserted. It is rare that an infection would occur around an implant from a bacterial infection elsewhere in the body, however, prophylactic antibiotics may be considered for subsequent dental or other surgical procedures. In extremely rare instances, life-threatening infections, including toxic shock syndrome have been noted after breast implant surgery. Individuals with an active infection in their body should not undergo surgery, including breast augmentation. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the insertion of a breast implant. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infections in other parts of the body, may lead to an infection in the operated area.

**Scarring:** All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases scars may require surgical revision or treatment.

**Firmness:** Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

**Skin Discoloration / Swelling:** Some bruising and swelling normally occur. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

**Skin Sensitivity:** Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.



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**Major Wound Separation:** Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

**Sutures:** Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

**Damage to Deeper Structures:** There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

**Fat Necrosis:** Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

**Seroma:** Infrequently, fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Should this problem occur, it may require additional procedures for drainage of fluid.

**Surgical Anesthesia:** Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

**Shock:** In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

**Pain:** You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

**Cardiac and Pulmonary Complications:** Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pain, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

**Venous Thrombosis and Sequelae:** Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins.

**Allergic Reactions:** In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

**Asymmetry:** Some breast asymmetry naturally occurs in most women. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to attempt improvement of asymmetry after a breast augmentation.

**Persistent Swelling (Lymphedema):** Persistent swelling in the legs can occur following surgery.

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**Breast Implant Associated Anaplastic Large Cell Lymphoma:** This is an extremely rare lymphoma that can develop in the setting of breast implants. Currently the lifetime risk of this is 1:30,000 in patients with textured implants. The FDA confirmed that BIA-ALCL is predominantly a texturing issue.

**Unsatisfactory Result:** Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of surgery. Asymmetry in implant placement, displacement, nipple location, unanticipated breast shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location may occur. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. It may be necessary to perform additional surgery to improve your results, change implant size or remove and not replace implants.

**Unknown Risks:** There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

**Disease:** Cancer can occur independently of surgery. Individuals with a personal history or family history of cancer may be at a higher risk of breast cancer than someone 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.

## **ADDITIONAL ADVISORIES**

### **Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):**

Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

{INITIALS} I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

{INITIALS} I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

{INITIALS} I have smoked and stopped approximately \_\_\_\_\_ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

**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. Care must be exercised during breast biopsy procedures to avoid damaging the breast implant.

# **INFORMED CONSENT – BREAST IMPLANT REMOVAL & OPEN CAPSULECTOMY WITH BREAST IMPLANT REPLACEMENT USING SILICONE GEL-FILLED IMPLANTS**

**Mammography:** It is important to continue to have regular mammography examinations and to perform periodic breast self-examination. Should a breast lump be detected with either mammography or self-examination, please contact your physician.

**Second-Generation Effects:** A review of the published medical literature regarding the potential damaging effect on children born of mothers with breast implants is insufficient to draw definitive conclusions that this represents a problem.

**Immune System Diseases and Unknown Risks:** A small number of women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosus, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. To date, after several large epidemiological studies of women with and without implants, there is no scientific evidence that women with either saline-filled or silicone gel-filled breast implants have an increased risk of these diseases. These diseases appear no more common in women with implants than those women without implants. The effect of breast implants in individuals with pre-existing immune system and connective-tissue disorders is unknown. There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

**Large Volume Breast Augmentation:** Patients who request an outcome of augmentation mammoplasty that produces disproportionately large breast size must consider that such a choice can place them at risk for a less than optimal long-term outcome and the need for re-operation and additional expenses. The placement of excessively-sized breast implants exceeds the normal dimensions of the breast, produce irreversible tissue thinning, implant drop out, and visible/palpable rippling.

**Breast Implant Technology / Technologic Improvements in Breast Implants:** The technology of breast implant design, development and manufacture will continue to progress and improve. Newer or future generations of implants may be better in some way from those currently available.

**Interference with Sentinel Lymph Node Mapping Procedures:** Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer.

**Breast and Nipple Piercing Procedures:** Individuals with breast implants seeking to undergo body piercing procedures to the breast region must consider the possibility that an infection could develop anytime following this procedure. Should an infection occur, it is possible that it could spread to the breast implant space. Treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the breast implant may have to be removed. Individuals who currently wear body-piercing jewelry in the breast region are advised that a breast infection could also develop.

**Breast Feeding:** Breast milk is the best food for babies. Many women with breast implants have successfully breast fed their babies. It is not known if there are increased risks in nursing for a woman with breast implants. A study measuring elemental silicon (a component of silicone) in human breast milk did not indicate higher levels from women with silicone-filled gel implants when compared to women without implants. Cow's milk contains higher levels of elemental silicon as compared to human milk. Implant placement techniques that involve incisions through the nipple and areola locations may reduce the ability to successfully breast feed. If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the side where the breast was removed.

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**Medications and Herbal Dietary Supplements:** There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

**Sun Exposure – Direct or Tanning Salon:** The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use of sun block or clothing coverage.

**Travel Plans:** Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

**Long-Term Results:** Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

**Female Patient Information:** It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

**Intimate Relations After Surgery:** Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

**Mental Health Disorders and Elective Surgery:** It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

**Psychological / Appearance Changes:** It is possible that after breast implant removal you may experience a strong negative effect on your physical appearance, including significant loss of breast volume, distortion, and wrinkling of the skin. Your appearance may be worse than prior to your surgery for the placement of the breast implants. There is the possibility of severe psychological disturbances including depression. It is possible that you or your partner will lose interest in sexual relations.

**Health Disorders Alleged To Be Caused By Breast Implants:** Currently there is insufficient evidence to state that the removal of breast implant(s) and capsule(s) will alter the course or prevent autoimmune or other disorders alleged to be caused by breast implants. **The removal of breast implants may be of no health benefit to you.**

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## **PATIENT COMPLIANCE**

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation around implants and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

## **REGULATORY MATTERS**

According to USFDA regulations, you must comply with the submission of personal information to a device registry if required to do so regarding implant removal surgery.

## **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical operations or any resulting complications. Please carefully review your health insurance subscriber-information pamphlet. **Most insurance plans exclude coverage for secondary or revisionary surgery due to complications of cosmetic surgery.**

## **FINANCIAL RESPONSIBILITIES**

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risks and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

I understand that with cosmetic surgery, I am responsible for the surgical fees quoted to me, as well as additional fees for anesthesia, facility (OR), and possibly laboratory, X-ray, and pathology fees.

{INITIALS} \_\_\_\_\_

Surgicenters, Outpatient Centers, and Hospitals often have rules that certain tissue/implants removed during surgery must be sent for evaluation which may result in additional fees. Please check with your surgeon to receive an estimate of any additional costs that you may be charged.

## **DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information that is based on all the facts in your particular case and the current state of medical knowledge.

# **INFORMED CONSENT – BREAST IMPLANT REMOVAL & OPEN CAPSULECTOMY WITH BREAST IMPLANT REPLACEMENT USING SILICONE GEL-FILLED IMPLANTS**

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

**It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.**

**INFORMED CONSENT – BREAST IMPLANT REMOVAL & OPEN CAPSULECTOMY  
WITH BREAST IMPLANT REPLACEMENT USING SILICONE GEL-FILLED  
IMPLANTS**

**CONSENT FOR SURGERY/ PROCEDURE or TREATMENT**

1. I hereby authorize \_\_\_\_\_ and such assistants as may be selected to perform the following procedure or treatment:

- ☐ Simple Breast Implant Removal Without Capsule Removal      ☐ Right ☐ Left ☐ Bilateral  
☐ Removal of Breast Implant With Capsule Removal (Capsulectomy) ☐ Right ☐ Left ☐ Bilateral  
☐ Breast Biopsy for Removal of Silicone Gel (extracapsular, outside of implant capsule layer)  
: ☐ Open Capsulectomy with Implant Replacement Using Silicone Gel-Filled Implants Surgery  
    ☐ Right Breast      ☐ Left Breast      ☐ Both Breasts

I have received the following information sheet: **INFORMED CONSENT – BREAST IMPLANT REMOVAL SURGERY & Open Capsulectomy with Breast Implant Replacement Using Silicone Gel-Filled Implants Surgery**

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts that may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
- a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
  - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
  - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

**INFORMED CONSENT – BREAST IMPLANT REMOVAL & OPEN CAPSULECTOMY  
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- d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-11). I AM SATISFIED WITH THE EXPLANATION.		
Patient Signature	_____	Date _____
Witness Signature	_____	Date _____
Physician Signature		Date _____