

INFORMED CONSENT – BREAST RECONSTRUCTION WITH TISSUE EXPANDER

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INSTRUCTIONS

This informed-consent document has been prepared to help inform you of breast reconstruction with a tissue expander, its risks, and alternative treatment.

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

There are a variety of surgical techniques for breast reconstruction. Breast cancer patients who are medically appropriate for breast reconstruction may consider tissue expander breast reconstruction, either immediately following mastectomy or at a later time. The best candidates, however, are women whose breast cancer, as far as can be determined, seems to be eliminated by mastectomy and other treatments.

Breast reconstruction has no known effect on altering the natural history of breast cancer or interfering with other forms of breast cancer treatment such as chemotherapy or radiation.

Breast reconstruction with tissue expansion is a **two-stage** process. It first involves the use of a silicone rubber balloon-like tissue expander that is inserted beneath the skin and chest muscle. Saline gradually is injected into the tissue expander to fill it over a period of weeks or months. This process allows the skin on the chest to be stretched over the expander, creating a breast mound. In most cases, once the skin has been stretched enough, the expander is surgically removed and replaced with a permanent breast implant. Some tissue expanders are designed to be left in place as a breast implant.

There are legitimate reasons to delay breast reconstruction. Some women may be advised by their surgeon or oncologist to wait until other forms of necessary cancer treatment are completed or disease staging has been accomplished. Other patients may require more complex breast reconstruction procedures. Women who smoke or who have other health conditions such as obesity may be advised to postpone surgery. 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 poor surgical outcome. In any case, being informed of your options concerning breast reconstruction can help you prepare for a mastectomy with a more positive outlook on the future.

The shape and size of your breasts prior to surgery will influence both the recommended placement of the tissue expander and the final shape of your reconstructed breast. Tissue expander breast reconstruction cannot produce an exact replica of the removed breast. Breast symmetry surgery on the opposite breast may be needed to produce similar size. The nipple and darker skin surrounding it, called the areola, may be reconstructed in a subsequent procedure after the breast mound is created through tissue expansion.

Since May 2000, saline-filled breast implant and tissue expander devices have been approved by the United States Food and Drug Administration (USFDA) for use in breast augmentation and reconstruction. The FDA approved silicone gel implants for use in breast augmentation and reconstruction in November 2006.

Patients undergoing breast surgery with tissue expanders and implants must consider the following:

- Breast augmentation or reconstruction with implants may not be a one-time surgery.
- Breast implants and tissue expanders 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 or reconstruction with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants or tissue expanders removed.

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ALTERNATIVE TREATMENTS

Breast reconstruction with tissue expander is an elective surgical operation. Alternative treatments would consist of the use of external breast prostheses or padding, breast reconstruction without tissue expansion, or the transfer of other body tissues for breast reconstruction. Potential risks and complications are associated with alternative surgical forms of treatment.

RISKS OF BREAST RECONSTRUCTION WITH TISSUE EXPANDER

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with breast reconstruction with tissue expander. 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. While 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 reconstruction with tissue expander.

Problems associated with breast implants and tissue expanders can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. Patients considering surgery that involves breast implants and tissue expanders should review additional advisory information regarding this subject. Additional information concerning breast implants and tissue expanders may be obtained from the FDA, package-insert sheets supplied by the device manufacturer, or other information pamphlets required by individual state laws.

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

Inherent Risks of Saline-Filled Breast Implants / Tissue Expanders

Tissue Expander / Implants: Tissue expanders and implants, similar to other medical devices, can fail. Tissue expanders and implants can break or leak. When a saline-filled implant or tissue expander ruptures, the body absorbs the saline material, but the shell material remains. Rupture can occur because of an injury, from no apparent cause (silent rupture), or during mammography. It is possible to damage a tissue expander or implant at the time of surgery or subsequently with a needle during the insertion of saline into the device. Damaged, leaking, or broken tissue expanders and implants cannot be repaired and require replacement or removal. Breast implants and tissue expanders can wear out, they are not guaranteed to last a lifetime and future surgery may be required to replace one or both implants. An MRI (magnetic resonance imaging) study may be necessary to evaluate the possibility of device rupture or deflation, but it may not be 100% accurate in diagnosing 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 or expanders, 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.

Capsular Contracture: Scar tissue, which forms internally around the tissue expander, 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 tissue expander placement in front of the chest muscle layer. Treating capsular contracture may require surgery, tissue expander replacement, or tissue expander 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 tissue expander or 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. A tissue expander or 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 tissue expander or implant becomes exposed, removal may be necessary. Permanent scar deformity may occur.

Change in Nipple and Skin Sensation: Breast reconstruction cannot restore normal sensation to the breast or nipple. Changes in sensation may affect sexual response or the ability to breast-feed a baby.

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Skin Wrinkling and Rippling: Visible and palpable wrinkling of implants or tissue expanders and breast skin can occur. Some wrinkling is normal and expected. This may be more pronounced in patients who have saline-filled implants with textured surfaces or thin tissue. It may be possible to feel the tissue expander 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.

Calcification: Calcium deposits can form in the scar tissue surrounding the tissue expander 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 or tissue expander 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 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: Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the tissue expander or 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 a tissue expander or implant, or cause bleeding/seroma.

MRI Examination During the Expansion Period: Most of the expanders have a magnet at the injection site to allow for easier localization of the injection port during the expansion period. MRI uses very strong magnetic fields which may cause movement, heating, or dislocation of the expander. For this reason, patients with a breast expander in place should not undergo MRI imaging until the expander is removed and replaced with an implant.

Use of Acellular Dermal Matrix: In order to place the expander 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.

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, 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.

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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. 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.

In breast implant surgery, hematoma may contribute to capsular contracture, infection or other problems.

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.

Change in Skin Sensation: It is common to experience diminished (or loss) of skin sensation in areas that have had surgery. Diminished (or complete loss of skin sensation) may not totally resolve. 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.

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.

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.

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Delayed Healing: 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. 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.**

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: Fluid may accumulate around the tissue expander following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around tissue expander or implant. This may contribute to infection, capsular contracture, or other problems.

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 after mastopexy. 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.

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

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/expander placement, displacement, nipple location, unanticipated breast shape and size, loss of function, wound disruption, poor

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healing, and loss of sensation may occur after surgery. Breast size may be incorrect and not match the opposite breast. Unsatisfactory surgical scar location may occur. Tissue expander breast reconstruction may fail due to complications attributable to the mastectomy or from later chemotherapy/radiation therapy treatments. It may be necessary to perform additional surgery to improve your results, change size or remove and not replace tissue expander/breast implant.

Additional Advisories Regarding Tissue Expander Surgery

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:

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

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

___ 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.

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 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.

Breast 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.

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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.

Interference with Sentinel Lymph Node Mapping Procedures: Breast procedures that involve cutting through breast tissue, similar to a breast biopsy in order to place breast implants, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer. If this is a concern, individuals considering breast augmentation by these approaches may elect to consider another surgical approach.

Breast and Nipple Piercing Procedures: Individuals with breast implants or tissue expanders 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: 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. Although many women with breast implants and normal breast tissue have successfully breast fed their babies, it is not known if there are increased risks in nursing for a woman with breast implants.

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.

Breast Disease: Current medical information does not demonstrate an increased risk of breast cancer in women who have tissue expander surgery. 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 they notice a breast lump. Care must be exercised during breast biopsy procedures to avoid damaging the tissue expander.

Radiation Therapy: Radiation therapy to the chest region before or after breast reconstruction with a tissue expander/breast implant can produce unacceptable firmness or other long-term complications.

Mammography: Breast implants and tissue expanders may make mammography more difficult and may obscure the detection of breast cancer. Any breast implant or expander can impair the detection of breast cancer, regardless of the type of implant or where it is placed in relation to the breast. Rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of breast implants or expanders 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 expander or implant(s). Because more x-ray views are necessary with specialized mammography techniques, women with breast implants or expanders will receive more radiation than women without implants/expanders who receive a normal exam. However, the benefit of the mammogram in finding cancer

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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 or expanders inside your body.

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

Removal / Replacement of Tissue Expander: Tissue expander breast reconstruction is a two-step process. Removal of the tissue expander, revision of the surrounding scar tissue envelope, or replacement of tissue expander with a permanent breast implant involves surgical procedures with risks and potential complications. There may be an unacceptable appearance of the breasts following removal of the implant.

Immune System Diseases And Unknown Risks: A small number of women with breast implants and tissue expanders 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 these implants, there is no scientific evidence that women with either silicone gel-filled or saline-filled breast implants/tissue expanders have an increased risk of these diseases. These diseases appear no more common in women with these implants than those women without implants. The effects of breast implants and tissue expanders 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.

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

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

ADDITIONAL SURGERY NECESSARY (Re-Operations)

Many variable conditions may influence the long-term result of breast reconstruction surgery with tissue expanders. It is unknown how your breast tissue may respond to implants/expanders or how wound healing will occur after surgery. Secondary surgery may be necessary at some unknown time to replace your tissue expanders / implants or to improve your outcome. You may elect to or be advised to have your breast implants/expander 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 reconstruction with tissue expander 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.

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 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.

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.

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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.

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 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.

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CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. Siamak Agha-Mohammadi and such assistants as may be selected to perform the following procedure or treatment: **BREAST RECONSTRUCTION WITH TISSUE EXPANDER**

I have received the following information sheet:

INFORMED CONSENT – BREAST RECONSTRUCTION WITH TISSUE EXPANDER

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 which 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 and other personally identifying data to appropriate agencies for legal reporting and medical-device registration.
10. I understand that the surgeon's 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. I realize that not having the operation is an option.
12. 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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12).
I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____