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**Aesthetic, Breast and Reconstructive Surgery**



## **INFORMED CONSENT – BREAST RECONSTRUCTION WITH TISSUE EXPANDER**

### **INSTRUCTIONS**

This is an informed-consent document that has been prepared to help inform you concerning breast reconstruction surgery with a tissue expander, its risks, as well as 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**

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, which is inserted beneath the skin and chest muscle. Saline is gradually 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 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 (the areola) may be reconstructed in a subsequent procedure after the breast mound is created through tissue expansion.

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Both saline-filled and silicone gel breast implant and tissue expander devices have been approved by the United States Food and Drug Administration (USFDA) for use in breast reconstruction.

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

- Breast reconstruction with breast implants and tissue expanders 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 device replacement or removal.
- Changes that occur to the breasts following reconstruction with implants and tissue expanders are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants or tissue expanders removed.

### **ALTERNATIVE TREATMENT**

Tissue expander breast reconstruction is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or use of external breast prostheses or padding, or the transfer of other body tissues for breast reconstruction. Risks and potential 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 these risks and the possible complications associated with them. In addition, every procedure has limitations. Additional information concerning breast implants and tissue expanders may be obtained from the USFDA, 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. Although the majority of 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 tissue expander breast reconstruction. 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. Additional advisory information regarding this subject should be reviewed by patients considering surgery that involves breast implants and tissue expanders.

While every patient experiences her own individual risks and benefits following tissue expander breast reconstruction surgery, 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 Breast Implants and Tissue Expanders:**

**Implants-** Tissue expanders, similar to other medical devices, can fail. Tissue expanders can break or leak. When a tissue expander ruptures, the internal material is absorbed by the body, but the shell material remains. Rupture can occur as a result of an injury, from no apparent cause (silent rupture), or during mammography. It is possible to damage a tissue expander at the time of surgery. Damaged or broken tissue expanders cannot be repaired. Ruptured or damaged tissue expanders 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 them. A MRI study may be necessary to evaluate the possibility of tissue expander rupture or deflation, yet may not be 100% accurate in diagnosing tissue expander integrity.

**Capsular Contracture-** Scar tissue, which forms internally around the breast 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. Treatment for capsular contracture may require surgery, tissue expander replacement, or tissue expander removal. Capsular contracture may reoccur after surgical procedures to treat this condition.

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**Implant Extrusion / Tissue Necrosis-** Lack of adequate tissue coverage or infection may result in exposure and extrusion of the tissue expander 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 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 becomes exposed, expander 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.

**Skin Wrinkling and Rippling-** Visible and palpable wrinkling of the tissue expander 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 breast 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. The consequences of chest wall deformity are of unknown significance.

**Implant Displacement-** Displacement, rotation, or migration of a breast tissue expander may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape. Unusual techniques of tissue expander placement may increase the risk of displacement or migration. Additional surgery may be necessary 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 tissue expander at the time of insertion. The consequences of this are unknown.

**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 tissue expanders 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 or tissue expanders.

**Unusual Activities and Occupations-** Activities and occupations which have the potential for trauma to the breast could potentially break or damage a tissue expander, or cause bleeding/seroma.

### **Inherent Surgical Risk of Tissue Expander Surgery:**

**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 blood transfusion. Intra-operative blood transfusion may also be required. Hematoma may contribute to capsular contracture, infection or other problems. Do not take any aspirin or anti-inflammatory medications for 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 following injury to the breast. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the Human Immunodeficiency Virus (the virus that causes AIDS).

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

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**Infection-** 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 tissue expander. Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the implant or tissue expander, or additional surgery may be necessary. Infections with the presence of a tissue expander are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the tissue expander may have to be removed. After the infection is treated, a new tissue expander can usually be reinserted. It is extremely rare that an infection would occur around a tissue expander 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 tissue expander and breast implant surgery. Individuals with an active infection in their body or weakened immune system should not undergo tissue expander breast reconstruction surgery.

**Scarring-** All surgery leaves scars, some more visible than others. Excessive scarring is uncommon. 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.

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

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

**Thrombosed Veins-** Thrombosed veins, which resemble cords, occasionally develop in the area of the breast and resolve without medical or surgical treatment.

**Pain-** You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after tissue expander surgery. Pain may be the result of improper expander size, placement, surgical technique, capsular contracture, or sensory nerve entrapment or injury. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

**Skin Discoloration/Swelling:** Some bruising and swelling normally occurs after tissue expander breast reconstruction surgery. 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 resolve during healing, but in rare situations it may be chronic.

**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 removal.

**Fat Necrosis:** Fatty tissue found deep to 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.

**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.

**Delayed Healing-** Wound disruption or delayed wound healing is possible. Some areas of the breast region may not heal normally and may take a long time to heal. Areas of skin or tissue may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals

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who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

**Deep Venous Thrombosis, Cardiac and Pulmonary Complications:** Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. 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 and fat 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 blood clots or swollen legs 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 pains, or unusual heart beats, seek medical attention immediately.** Should any of these complications occur, you may require hospitalization and additional treatment.

**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.

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

**Breast Disease-** Current medical information does not demonstrate an increased risk of breast cancer in women who have tissue expander surgery for either cosmetic or reconstructive purposes. It is recommended that all women perform periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and to seek professional care should a breast lump be detected. 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. Device rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of breast implants and tissue 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 implant(s). Because more x-ray views are necessary with specialized mammography techniques, women with breast implants and tissue expanders will receive more radiation than women without 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 and tissue 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.

**Long-term Results-** Subsequent alterations in breast shape may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your surgery. Breast sagging may normally occur.

**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 tissue expander placement, displacement, nipple location, unanticipated breast shape and

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size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. 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 or remove the tissue expander/breast implant.

**Removal / Replacement of Tissue Expander-** Tissue expander breast reconstruction is a two-step process. Future revision, removal, or replacement of the tissue expander 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 tissue expander.

**Capsule 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, bleeding, or other complications.

**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 them. The effect 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.

**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 device space. Treatment including antibiotics, possible removal of the device, or additional surgery may be necessary. Infections with the presence of a tissue expander are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the tissue expander 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 from this activity.

**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.

**Female Patient Information:** It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe 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. Increased activity that increased your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control of bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

**Medications:** There are many adverse reactions that occur as the result of taking over the counter, herbal, and/or prescription medications. 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. 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.

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**Breast Tissue Expander Technology / Technologic Improvements in Tissue Expanders-** The technology of tissue expander design, development and manufacture will continue to progress and improve. Newer generations of expanders, which may be better in some way from currently available ones, may be developed in the future.

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

Patients who are currently smoking, use tobacco products, 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, smokers 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 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.

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.

### **ADDITIONAL SURGERY NECESSARY**

There are many variable conditions that may influence the long term result of tissue expander breast reconstruction surgery. It is unknown how your breast tissue may respond to implants or tissue expanders or how wound healing will occur after surgery. Secondary surgery may be necessary at some unknown time in the future to replace your tissue expander or to improve the outcome of breast reconstruction surgery. You may elect to or be advised to have your tissue 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 tissue expander breast reconstruction 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 around implants and tissue expanders 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 FDA regulations, you must comply with the submission of personal information to a device registry before surgery and afterwards.

### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical operations such as a breast augmentation or any complications that might occur from surgery. Some carriers have excluded breast diseases in patients who have breast implants and tissue expanders. 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

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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. You may be advised some time in the future to have a MRI (magnetic resonance imaging) scan to determine the condition of your breast implants or tissue expanders. You would be responsible for future costs of such imaging studies. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

### **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 which is based on all the facts in your particular case and the 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.**



**INFORMED CONSENT – BREAST RECONSTRUCTION WITH TISSUE EXPANDER  
CONSENT FOR SURGERY / PROCEDURE or TREATMENT**

1. I hereby authorize Dr. \_\_\_\_\_ and such assistants as may be selected to perform the following procedure or treatment: **Tissue Expander Breast Reconstruction Surgery**

I have received the following information sheet:

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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 acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
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 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. 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 \_\_\_\_\_