INFORMED CONSENT-BREAST RECONSTRUCTION WITH TISSUE EXPANDER

INSTRUCTIONS

This is an informed-consent document that 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.

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 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.

As of 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. Breast implants and tissue expanders that contain silicone gel are currently restricted to women who meet eligibility criteria to participate in approved study programs.

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 expander removed.

ALTERNATIVE TREATMENT

Tissue expander breast reconstruction is an elective surgical operation. Alternative treatment 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. There exists the potential for risk and complications in alternative surgical treatments involving breast reconstruction.

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. 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.

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 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, 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 Breast Implants / Tissue Expanders:

Implants- Tissue expanders are similar to other medical devices, can fail. Tissue expanders can break or leak. When a saline-filled tissue expander deflates, its salt water filling will be absorbed by the body. Rupture can occur as a result of an injury, from no apparent cause, or during mammography. It is possible to damage a tissue expander at the time of surgery or subsequently with a needle during the insertion of saline into the device. Damaged, leaking, or broken tissue expanders cannot be repaired. Ruptured or deflated tissue expanders require replacement or removal. Breast implants and tissue expanders can wear out, they cannot be expected to last forever.

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. Treatment for capsular contracture may require surgery, tissue expander replacement, or 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 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 though layers of skin. If tissue breakdown occurs and the implant 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 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 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 deformity- Chest wall deformity has been reported secondary to the use of tissue expanders and breast implants. The consequences of chest wall deformity is of unknown significance.

Implant displacement- Displacement, rotation, or migration of a tissue expander may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape. Additional surgery may be necessary to correct this problem.

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 is 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 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.

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 (Hematoma)- 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 (hematoma). 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.

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. This may contribute to infection, capsular contracture, or other problems.

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 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 device may have to be removed. It is extremely 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 tissue expander and breast implant surgery.
Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), may be at greater risk for infection.

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.

Skin scarring- Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and of different color than surrounding skin. Additional surgery may be needed to treat abnormal scarring after surgery.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may result from drugs used during surgery and prescription medicines. 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- 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. Pain may occur during and after procedures to fill the tissue expander with saline fluid.

Additional Tissue Expander Advisory Information:

Breast cancer- Current medical information does not demonstrate an increased risk of breast cancer in women who have tissue expander surgery. 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. 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.

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.

Unsatisfactory result- You may be disappointed with the results of tissue expander breast reconstruction surgery. Unsatisfactory tissue expander placement, displacement, nipple location, unanticipated breast shape and size may occur after surgery. Breast size after tissue expander reconstruction 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 or remove tissue expander/breast implant.

Long term results- Subsequent alterations in breast mound shape after reconstruction may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to breast reconstruction.

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.

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 erythematosis, 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 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 or other complications.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions that may influence the long term result of breast reconstruction with tissue expander surgery. Secondary surgery may be necessary. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are the ones that 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.

HEALTH INSURANCE

Most insurance carriers consider breast reconstruction surgery a covered benefit. There may be additional requirements. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. Most insurance plans exclude coverage for secondary or revisionary surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, anesthesia, and 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. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital-day surgery charges involved with revisionary surgery would also be your responsibility.

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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). 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.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

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

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I have received the following information sheet:

INFORMED-CONSENT FOR TISSUE EXPANDER BREAST RECONSTRUCTION

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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 involves risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of 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 authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration if applicable.
9. 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

A. I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I HAVE BEEN ASKED IF I WANT A MORE DETAILED EXPLANATION, BUT I AM SATISFIED WITH THE EXPLANATION AND DO NOT WANT MORE INFORMATION.

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Patient or Person Authorized to Sign for Patient

Date_____ _____Witness

B. I CONSENT TO THE TREATMENT OR PROCEDURE AND ABOVE LISTED ITEMS (1-9).
I REQUESTED AND RECEIVED, IN SUBSTANTIAL DETAIL, FURTHER EXPLANATION OF THE PROCEDURE OR TREATMENT, OTHER ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT AND INFORMATION ABOUT THE MATERIAL RISKS OF THE PROCEDURE OR TREATMENT.

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Patient or Person Authorized to Sign for Patient

Date_____ _____Witness