PLASTIC SURGEONS OF ALASKA

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Informed Consent – Breast Reconstruction with Tissue Expanders

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about breast reconstruction surgery with tissue expanders, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely 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 candidates 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 have been 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 often also beneath chest muscles. Saline or air 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 a 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 implants 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.

A separate consent form for the placement of breast implants following breast reconstruction by tissue expansion is necessary.

ALTERNATIVE TREATMENTS

Breast reconstruction with tissue expander is an elective surgical operation. Alternative treatments include 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.

INHERENT 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.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH TISSUE EXPANDER

Tissue Expanders:

Tissue expanders, similar to other medical devices, can fail. Tissue expanders can break or leak. When a saline-filled 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 at the time of surgery or subsequently with a needle during the insertion of saline into the device for purposes of inflation. Damaged, leaking, or broken tissue expanders cannot be repaired and require replacement or removal. 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 or 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 (in the "prepectoral" position). Treatment for capsular contracture may require surgery, tissue expander replacement, or tissue expander removal. **Capsular contracture may reoccur after surgical procedures to treat it**. Some surgeons believe that preventative antibiotics during dental work and treatment for sinus infections and urinary tract infections may decrease its incidence. Discuss this with your surgeon.

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. Atrophy of breast tissue may occur. 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 will not likely restore normal sensation to the breast or nipple. Changes in sensation may affect sexual response or the ability to breastfeed a baby.

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. A palpable valve, wrinkling, and/or folds may be confused with palpable tumors and questionable cases should be investigated.

Calcification:
Calcium deposits can form in the scar tissue surrounding the tissue expander and may cause pain or firmness and may be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. If this occurs, 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 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.

Magnetic Resonance Imaging 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 that may cause movement, heating, or dislocation of the expander. For this reason, patients with a breast tissue expander in place should not undergo MRI until the expander is removed and replaced with an implant.

Use of Acellular Dermal Matrix:
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 to become similar to your own tissue. These acellular products may produce fluid and require drains for a prolonged period.

Anaplastic Large Cell Lymphoma (ALCL):
Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is an uncommon type of lymphoma that can develop in the scar capsule near saline or silicone breast implants. This disease is currently being investigated as to its relationship with breast implants. The family of ALCL is a rare cancer of the immune system, which can occur anywhere in the body. Based on adverse event reports, the United States Food and Drug Administration (FDA) estimates the total number of cases of BIA-ALCL to be over 573 cases. It has been noted that most BIA-ALCL has been estimated at 1:2,207 – 1:86,029 for women with textured implants, and BIA-ALCL risk is currently under investigation. BIA-ALCL usually involves swelling of the breast at an average of 8-10 years after the initial breast implant operation. Most cases were cured by removal of the implant; however, rare cases have required chemotherapy and/or radiation therapy for treatment.

Patients with breast implants should be followed by a surgeon over time and seek professional care for implant related symptoms such as pain, lumps, swelling, or with routine breast self-exams and follow standard medical recommendations for imaging (e.g., Mammography, Ultrasound, MRI). Abnormal screening results or implant-related symptoms may result in additional expenses for tests and/or procedures to properly diagnose and treat your condition. Tests and procedures could include but may not be limited to obtaining breast fluid or tissue for pathology and laboratory evaluation, surgery to remove the scar capsule around the breast implant, implant removal, or implant replacement.

For the most current information on BIA-ALCL please visit the FDA website at:
https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl

Breast Cancer:
Current medical information does not demonstrate an increased risk of breast cancer in women who have tissue expander surgery. A woman 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 if a breast lump is detected. If suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

Use of Drains:
During your surgery, your doctor may find it necessary to place drain(s). A drain is a small tube that drains fluid out from the area that was operated on. You will be instructed on the use of your drain. Placement of the drain may require a small separate incision. The drain will be removed when your doctor feels it is no longer necessary. The drain site may be closed at the time of drain removal. Closing the drain site may require special surgical tape or sometimes a suture. Your doctor may leave the site open to drain any residual fluid under the wound.

Informed Consent – Breast Reconstruction with Tissue Expanders

1. I, _____, hereby authorize Dr. _____ and assistants who may be selected to perform **breast reconstruction with tissue expanders.**

   I have received the following information sheet: **Breast Reconstruction with Tissue Expanders**

   Additions to surgical plan**:** _____

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those outlined above. I therefore authorize the above physician and assistants or designees to perform such other procedures, which are deemed necessary and desirable, based on his or her professional judgment. The authority granted under this paragraph shall include all conditions that require treatments and those not known to my physician at the time the procedure has begun.

3. I consent to the administration of such anesthetics as considered necessary or advisable. I understand that all forms of anesthesia involve risks and the possibility of complications, injury, and sometimes death.

4. I understand what my surgeon can and cannot do, and understand that 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 to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.

6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

7. I consent to the disposal of any tissue, medical devices, or body parts that may be removed.

8. I am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.

9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

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. I opt out of having this procedure _____.

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 Signature	**Surgeon Signature**
_____	_____
Date/Time	**Witness**