

INFORMED CONSENT-BREAST RECONSTRUCTION WITH TISSUE EXPANDER

INSTRUCTIONS

This is an informed-consent document that has been prepared to help Dr. Nemerofsky 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 Dr. Nemerofsky.

GENERAL INFORMATION

There are a variety of surgical techniques for breast reconstruction. Most mastectomy patients are medically appropriate for breast reconstruction, either immediately following breast removal or at a later time. The best candidates, however, are women whose cancer, as far as can be determined, seems to be eliminated by mastectomy. 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. Other patients may require more complex breast reconstruction procedures. Women who smoke or who have other health conditions such as obesity or high blood pressure may be advised to postpone surgery. 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.

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. Patients undergoing breast reconstruction with tissue expansion must consider the possibility of future revisionary surgery. Tissue expanders and breast implants cannot be expected to last forever.

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. 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.

Breast implants and tissue expanders that contain silicone gel have been restricted by the United States Food and Drug Administration (FDA) since February of 1992 to women who are participating in approved study programs. Saline-filled tissue expanders and saline breast implants continue to be available on an unrestricted basis, pending further review by the FDA. At the time of surgery, registration and device tracking documents are returned to the manufacturer.

Contraindications to tissue expander breast reconstruction procedure exist:

- Inadequate skin and deeper tissue to cover the tissue expander
- Local recurrence of breast cancer after mastectomy
- Skin problems resulting from radiation therapy to chest
- A patient who is medically or psychologically unsuitable for breast reconstruction

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 exist the potential for risk and complications in alternative surgical treatments involving breast reconstruction.

Risks of breast reconstruction with tissue expander surgery, continued

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 Dr. Nemerofsky to make sure you understand the risks, potential complications, and consequences of breast reconstruction with tissue expander.

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 (hematoma). Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding.

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 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 an implant from a bacterial infection elsewhere in the body, however, prophylactic antibiotics may be considered for subsequent dental or other surgical procedures.

Capsular contracture- Scar tissue, which forms internally around the tissue expander, can tighten and make the breast round, firm, and possibly painful. Excessive firmness can occur soon after surgery or years later. Although the occurrence of symptomatic capsular contracture is not predictable, it generally occurs in less than 20 percent of patients. The incidence of symptomatic capsular contracture can be expected to increase over time. Treatment for capsular contracture may require surgery, expander replacement, or removal.

Change in nipple and skin sensation- Some change in nipple sensation is not unusual right after surgery. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur occasionally.

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.

Tissue expanders- Tissue expanders, similar to other medical devices, can fail. Expanders can break or leak. When a saline-filled 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. Damaged or broken expanders cannot be repaired. Ruptured or deflated tissue expanders require replacement or removal. Tissue expanders cannot be expected to last forever .

Degradation of tissue expander - It is possible that small pieces of the tissue expander material may separate from the outer surface of the expander. This is of unknown significance.

Tissue coverage- Lack of adequate tissue coverage or infection may result in exposure and extrusion of the expander. Skin breakdown has been reported with the use of steroid drugs or after radiation therapy to breast tissue. If tissue breakdown occurs and the tissue expander becomes exposed, removal may be necessary. Smokers have a greater risk of skin loss and wound healing complications.

Risks of breast reconstruction with tissue expander surgery, continued

Mammography- Tissue expander may make mammography more difficult and may obscure the detection of breast cancer. Tissue expander rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of a tissue expander 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 tissue expander. Because more x-ray views are necessary with specialized mammography techniques, women with a tissue expander will receive more radiation than women without a tissue expander who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays.

Skin wrinkling and rippling- Visible and palpable wrinkling of a tissue expander can occur. Some wrinkling is normal and expected. This may be more pronounced in patients who have thin skin. It may be possible to feel the tissue expander injection site. Some patients may find palpable injection site and wrinkles cosmetically undesirable. Palpable injection site, wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated. An expander may become visible at the surface of the breast as a result of the device pushing through layers of skin.

Pregnancy and 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/tissue expander or if the children of women with these devices are more likely to have health problems. There is insufficient evidence regarding the absolute safety of breast implants/tissue expander in relation of fertility, pregnancy or breast feeding. Some women with breast implants have reported health problems in their breast fed children. Only very limited research has been conducted in this area and at this time there is no scientific evidence that this is a problem.

Calcification- Calcium deposits can form in the scar tissue surrounding the 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.

Expander displacement- Displacement or migration of a tissue expander may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape. Difficult techniques of expander placement may increase the risk of displacement or migration. Additional surgery may be necessary to correct this problem.

Surface contamination - Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the expander at the time of insertion. The consequences of this is unknown.

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.

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.

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

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.

Risks of breast reconstruction with tissue expander surgery, continued

Breast disease- Current medical information does not demonstrate an increased risk of breast disease or breast cancer in women who have a tissue expander placed for breast reconstruction. Breast disease can occur independently of a tissue expander. 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.

Seroma- Fluid may accumulate around the tissue expander following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation.

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

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

Immune system diseases and unknown risks- Some women with breast implants/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. A connection between implanted silicone and connective-tissue disorders has been reported in the medical literature. To date, 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, but the possibility cannot be excluded. If a causal relationship is established, the theoretical risk of immune and unknown disorders may be low. The effects of breast implants/tissue expanders in individuals with pre-existing connective-tissue disorders is unknown.

Unlike silicone gel-filled implants, the saline-filled tissue expanders contain salt water. Any risk related to silicone gel would not be associated with saline-filled devices. However, gel-filled and saline-filled devices have a silicone rubber envelope. An increased risk of autoimmune disease is possible even from saline-filled tissue expanders. Reliable medical laboratory tests to determine antibodies to silicone do not exist. It has not been proved that there is a relationship between silicone antibodies and disease in women with breast implants/tissue expander. Currently, there is insufficient evidence to state that there is a health benefit from removing either breast implant(s) and scar-tissue capsule(s) or that removal will alter autoimmune disease or prevent its potential occurrence.

In very few women who have breast implants/tissue expander, a variety of other symptoms and conditions have been reported, suggestive of an auto-immune multiple-sclerosis-like syndrome. Additional complaints involve the musculoskeletal, skin, nervous, and immune systems. The relationship of breast implants/tissue expander to these conditions has been hypothesized, although not scientifically proven. Because such disease states are rare, they are difficult to research.

Current studies have only looked for the symptoms of known autoimmune diseases, rather than the variety of symptoms that women report experiencing. Some of the reported symptoms include:

- swelling and/or joint pain or arthritis-like pain
- general aching
- unusual hair loss
- unexplained or unusual loss of energy
- greater chance of getting colds, viruses, flu
- swollen glands or lymph nodes
- rash
- memory problems, headaches
- muscle weakness or burning
- nausea, vomiting
- irritable bowel syndrome
- fever

Questions have been raised about the potential for the saline solution used to fill the tissue expander to become contaminated with bacteria or fungus. These organisms may present a risk to the patient in the event of implant leakage or deflation.

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

Toxic shock syndrome- This is an extremely rare complication following breast augmentation, reconstruction, or tissue expansion with silicone implants.

Risks of breast reconstruction with tissue expander surgery, continued

Radiation therapy- Radiation therapy to the chest region after breast reconstruction with a tissue expander may produce unacceptable firmness or other long-term complications.

Unsatisfactory result- You may be disappointed with the results of surgery. Asymmetry in tissue expander placement, breast shape and size may occur after surgery. Unsatisfactory surgical scar location or displacement may occur. Pain may occur following surgery. It may be necessary to perform additional surgery to improve your results.

Removal/replacement of tissue expanders- Future removal or replacement of a tissue expander and the surrounding scar tissue envelope involves a surgical procedure with risks and potential 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 to perform additional tightening or repositioning of the breasts. 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 Dr. Nemerofsky. Most insurance plans exclude coverage for surgery on the opposite breast and for secondary or revisionary surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by Dr. Nemerofsky, 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.

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. Dr. Nemerofsky 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 **Robert B. Nemerofsky, M.D.** and such assistants as may be selected to perform the following procedure or treatment:

Breast reconstruction with placement of a tissue expander

I have received the following information sheet:

INFORMED-CONSENT FOR TISSUE EXPANDER BREAST RECONSTRUCTION

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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____