

BREAST RECONSTRUCTION USING TISSUE EXPANDER, IMPLANT, OR FLAP

REQUEST FOR TREATMENT AND INFORMED CONSENT

DO NOT SIGN THIS FORM UNTIL YOU HAVE READ IT AND FULLY UNDERSTAND ITS CONTENTS

PATIENT: _____ DATE: ____/____/____ |

understand that the above named procedure has been explained and is to be performed on me.

The following has been explained to me in general terms and I understand that:

1. **The DIAGNOSIS REQUIRING THIS PROCEDURE** is congenital or surgical absence of the breast or congenital deformities of the chest wall. Absence of the breast usually results from surgery for cancer or for precancerous conditions.
2. The **NATURE OF THE PROCEDURE** is to attempt to rebuild the breast or breasts on the chest wall. The procedure involves the insertion of a prosthesis (tissue expander or implant), which is like a bag filled with salt water. This tissue expander or implant is generally placed under the skin and muscle of the chest wall in a site for breast mound reconstruction. The potential space is then filled postoperatively with saline by injecting it into the implant through the skin. Secondly, either the expander remains in place or it is exchanged for a different permanent implant. Alternatively, your own skin, muscle, and fat may be used to create a breast either alone or in combination with an implant. Skin, fat and muscle may be taken either from the abdomen (TRAM flap) or the back (Latissimus flap). These sections of tissue may be rotated into the area of missing breast tissue or they may be totally disconnected from the body, moved to the desired area and then reconnected to an artery and vein.
3. The **PURPOSE OF THIS PROCEDURE** is to attempt to reconstruct a breast-like mound using a tissue expander to stretch the skin to make room for the implant or use your own skin, muscle, and fat to recreate the breast.
4. **PRACTICAL ALTERNATIVES TO THIS PROCEDURE** include doing nothing and accepting the circumstances of my medical condition, utilizing an external prosthesis (padded bra), or reconstruction of the breasts with implants alone, reconstruction of the breasts with the muscle from the back or abdomen.
5. **IF I CHOOSE NOT TO HAVE THE ABOVE NAMED PROCEDURE, MY PROGNOSIS (future medical condition)** is not completely predictable and the medical condition may get better, may get worse or may stay the same. However, failure to have the procedure may result in possible progression of the medical condition and/or the possible need for more extensive surgery if the medical condition progresses and remains undiagnosed or untreated. Diet, exercise, pregnancy, aging and health problems may all contribute to future changes in my medical condition.
6. **MATERIAL RISKS OF THIS PROCEDURE:** As a result of this procedure being performed, there may be material risks of: INFECTION, ALLERGIC REACTION, TOXIC REACTION, DISFIGURING SCAR, SEVERE LOSS OF BLOOD, LOSS OR LOSS OF FUNCTION OF ANY LIMB OR ORGAN, BRAIN DAMAGE, CARDIAC ARREST OR DEATH.
7. In addition to these material risks, **OTHER POSSIBLE RISKS** involved in this procedure including but not limited to:
 - 1) scar tissue may build up and tighten around the implant causing unnatural firmness, discomfort, changes in the shape of the breast and/or wrinkling or displacement of the implant; there may be still unknown, unrecognized, or unproven risks;
 - 2) the implants, expanders, or filler valves may break or rupture, allowing saline (salt water) to leak into the surrounding tissues causing deflation of the implant or the inability to expand to the desired size;

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Initials _____ (person signing)

OTHER POSSIBLE RISKS (concluded):

- 3) the reconstructed breast may not match the opposite breast in size or shape;
 - 4) the abdomen may not heal properly resulting in hernia formation, necessitating additional surgery;
 - 5) a hematoma (blood clot or collections of bloody fluid) may occur at any operative site;
 - 6) infection may occur immediately after surgery or several weeks, months or years after insertion of the implant and if the infection does not subside properly with appropriate treatment, removal of the implant may be required;
 - 7) some tissue may slough (dissolve away) due to poor healing causing exposure of the implant through the skin and requiring removal of the implant;
 - 8) a portion or the entire flap may not survive in its new location yielding a loss of skin, fat, or muscle. This may result in the need for dressing changes, debridement, or choice of another reconstructive procedure;
 - 9) some fatty tissue may undergo fat necrosis (dissolve away) which may cause lumpiness or firmness in the breast.
 - 10) pneumothorax (deflation of lung) may occur related to surgery and/or anesthesia;
 - 11) fluid collections may accumulate around the implant, under the flap, or in the flap donor site which may require drainage;
 - 12) pain and discomfort may occur;
 - 13) numbness (sensory loss, loss of feeling) or increased sensitivity may occur around the nipple or other parts of the breast which may be temporary or permanent;
 - 14) tightness, firmness, areas of lumpiness and itching may occur which may be temporary or permanent;
 - 15) later recurrence (return) of breast cancer;
 - 16) scars will occur and may go from pink and firm to faded and soft over a period of six to 12 months; some scars may widen, become depressed, or appear raised, firm and "ropey" red which may take two years or longer to fade and soften; scars will be PERMANENT AND VISIBLE;
 - 17) bruising and swelling may occur and last a few weeks to several months;
 - 18) there may be a need for immediate or other additional surgery to treat the above complications or for other reasons;
8. I understand that the physician, medical personnel and other assistants will rely on statements made by me concerning my medical history and other information I provide in determining whether to perform the procedure or the course of treatment for my condition and in recommending the procedure which has been explained to me.
Withholding medical and/or health information may result in further complications.
9. Even though the risks and complications cited above are infrequent, they are the ones peculiar to the operation and are of greatest concern. Complications may also be increased due to the patient's individual medical condition and personal habits. Medications, i.e. **ASPIRIN**, may interfere with blood clotting and cause excessive bleeding. **SMOKING CIGARETTES** may interfere with the blood supply to the skin and may cause abnormal healing with tissue sloughing (dissolving away) and excessive scarring. **ALCOHOL** may cause excessive bleeding during and after surgery. Certain **HERBAL PREPARATIONS** may affect the blood clotting system and cause excessive bleeding while others may inhibit healing of the incisions. Colds, infections, boils and pustules may increase the risk of infection after surgery. Excessive sun exposure and/or tanning beds, heating pads and hot water bottles may cause severe burns at the surgery site if one has temporarily or permanently lost protective sensation.

There may be a need for immediate or other additional surgery to treat the above complications, which could include hospitalization, time off work and additional expense to me.

10. There is no increase or decrease in the incidence of breast cancer following breast reconstruction with tissue expander and implants. The implant, expander or flap neither prevents nor causes breast cancer. Breast examinations are not affected since the implants are placed behind breast tissue or muscle and NOT in breast tissue. However, the procedure of breast reconstruction using tissue expander or implant may interfere with the interpretation of mammograms due to scarring or the presence of the implant. Special views may have to be obtained on mammography following breast reconstruction.

Follow up for breast cancer detection will need to continue life long. Self breast examinations and examinations by my surgeon or primary care physician should be performed according to the American Cancer Society recommendations.

11. I understand that my expectations should be realistic and I should consider not undergoing the surgery if my expectations are greater than the reality of this treatment. Psychological problems may occur due to unrealistic expectations of the surgery or difficulties in accepting changes in the appearance, size and shape of my breasts.

12. I understand that the practice of medicine is not an exact science and that NO GUARANTEES OR ASSURANCES HAVE BEEN MADE TO ME CONCERNING THE RESULTS OF THIS PROCEDURE.

13. I consent to the taking of pictures during the course of my treatment for the purpose of helping to plan and assess the proposed therapy. No photographs will be shown to patients or physicians without my permission. If any portion of my surgery is to be billed to insurance (this does not include cosmetic procedures), I understand my insurance carrier may require photographs to process my claim.

14. On occasion, unplanned surgical revisions may be indicated following the original surgery. If planned or performed within one (1) year after the original surgery, there will be no charge by the surgeon. However, a fee will be charged by the facility for use of the operating room. There will also be a charge by the anesthesiologist if indicated.

15. I voluntarily consent to allow Dr. Gerstle and all medical personnel under his direct supervision and control and all other personnel who may otherwise be involved in performing such procedures to perform the procedure(s) described or otherwise referred to herein.

16. I have requested and received copies of the product description and risks supplied by the manufacturer.

17. BY SIGNING THIS FORM, I ACKNOWLEDGE THAT I HAVE READ OR HAD THIS FORM READ AND/OR EXPLAINED TO ME, THAT I FULLY UNDERSTAND ITS CONTENTS, THAT I HAVE BEEN GIVEN AMPLE OPPORTUNITY TO ASK QUESTIONS AND THAT ANY QUESTIONS HAVE BEEN ANSWERED SATISFACTORILY. ALL BLANKS OR STATEMENTS REQUIRING COMPLETION WERE FILLED IN.

Signature of person giving consent: _____ Date: _____

Relationship to patient if not the patient: _____

Witness: _____ Date: _____

Copy of consent form offered to patient

_____ Copy given _____ Declined