

BREAST AUGMENTATION

REQUEST FOR TREATMENT AND INFORMED CONSENT

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

PATIENT: _____ DATE: ____/____/____

I 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 **DESCRIPTION OF THIS PROCEDURE** is placement of breast implant(s) through an incision located on the breast or in the armpit. An endoscope (surgical telescope) may or may not be used.
2. The **DIAGNOSIS REQUIRING THIS PROCEDURE** is relatively small breast tissue and/or a personal desire to have enlargement of one or both breasts.
3. The **NATURE OF THE PROCEDURE** is to attempt to enlarge one or both breasts by surgically placing an implant or prosthesis (artificial material) behind the breast tissue or muscle. The implant/prosthesis is a bag (shell) filled with salt water (saline) or silicone gel, it may be smooth or textured on the outer surface.
4. The **PURPOSE OF THIS PROCEDURE** is to attempt to provide larger, fuller breast size and shape.
5. **PRACTICAL ALTERNATIVES TO THIS PROCEDURE** include doing nothing and accepting the circumstances of my medical condition or utilizing padded bras or external prostheses. There are variations in surgical techniques, implant materials, associated medicines, bandages and postoperative treatments. Various types of bras, bandages and postoperative exercises may be used. My doctor will recommend what he feels will most likely satisfy my needs and give the best results. Before undergoing breast enlargement, I should understand the choices on the placement of incisions (axilla [armpit], around the nipple and/or inframammary [breast] fold), types of implants and sites of placement of the implants as well as preoperative and postoperative management.
6. **IF I CHOOSE NOT TO HAVE THE ABOVE NAMED PROCEDURE, MY PROGNOSIS (future medical condition)** is that my breasts are expected to remain the same for the present, but will normally change with age, pregnancy, weight fluctuations and/or disease. It is expected that the enlarged breast will change its shape due to these factors also.
7. **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.
8. In addition to these material risks, there may be **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;
 - 2) the implants may break or rupture, allowing the filling material (saline or silicone gel) to leak into the surrounding tissues;
 - 3) the filler valves of inflatable implants may leak the saline (salt water), causing deflation of the implant;
 - 4) since prior to surgery most women's breasts are unequal, after surgery the breasts may have different sizes and shapes (unequal) and rib cage irregularities cannot be eliminated.
8. **OTHER POSSIBLE - RISKS (concluded):**
 - 5) there may be still unknown, unrecognized or unproven risks;
 - 6) a hematoma (blood clot or collections of bloody fluid) may occur at the operative site;

- 7) 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;
 - 8) some tissue may slough (dissolve away) due to poor healing causing exposure of the implant through the skin and requiring removal of the implant;
 - 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 and 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) scars will occur and may go from pink and firm to faded and soft over a period of 6 - 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;
 - 16) bruising and swelling may occur and last a few weeks to several months;
 - 17) the implant position may shift due to gravity, muscle activity, scar formation, trauma, or the inability of the tissue to support the weight of the implant;
 - 18) the breast size may be larger or smaller than desired;
 - 19) breast implants or scars from surgery may interfere with the ability to breast feed;
 - 20) there may be a need for immediate or other additional surgery to treat the above complications or for other reasons;
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.
10. 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.
11. There is no increase or decrease in the incidence of breast cancer following augmentation mammoplasty. The implant 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 augmentation mammoplasty may interfere with the interpretation of mammograms due to scarring or the presence of the implant. Follow up for breast cancer

detection will need to continue lifelong. Self breast examinations, physician exams, and radiographic studies (mammograms) should be performed in accordance with the guidelines of the American Cancer Society.

12. 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.
13. 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.
14. 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.**
15. 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.
16. On occasion, 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. Surgery specifically to replace a deflated implant will be performed at no surgeon's fee if necessary, within five (5) years of the original surgery. If surgery is required for treatment of capsular contracture, this will be performed with no surgeon's fee if planned or performed within one (1) year after the original surgery. Beyond that point standard surgical fees will apply. In all above circumstances, separate fees will be charged by the facility for use of the operating room and there will also be a charge by the anesthesiologist if indicated.
17. 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.
18. I have received and reviewed the FDA brochure "Making an Informed Decision" for saline filled implants and/or the "Augmentation Surgery with Silicone Gel – Filled Breast Implants Patient Planner" or other manufacturer literature for silicone gel filled implants. All of my questions regarding this information have been answered. I have completed all forms in the information and agree to comply with any device tracking requirements.
19. I understand that breast implants may not be lifetime devices and may require replacement or removal. Detection of a leaking or defective silicone gel filled implant may be difficult and may require performance of an MRI or other diagnostic study which may or may not be covered by my health insurance. Implant manufacturers and/or the FDA may recommend MRI studies or other diagnostic studies on a periodic basis. Health insurance premiums may increase, insurance coverage may be dropped, and future coverage may be denied based on the presence of breast implants.
20. **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