

**BREAST IMPLANT REMOVAL / EXCHANGE****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 Removal of implant(s) located in the \_\_\_\_\_ breast(s) with/without placement of new implant(s).
2. The **DIAGNOSIS REQUIRING THIS PROCEDURE** may include one or more of the following; capsular contracture, breast biopsy, breast cancer, removal of escaped silicone gel, preference to change the size of my breast(s), implant damage/rupture, other \_\_\_\_\_.
3. The **NATURE OF THE PROCEDURE** is to remove breast implant(s) that have been placed either for cosmetic or reconstructive purposes with or without placement of new implant(s).
4. The **PURPOSE OF THIS PROCEDURE** is to remove the implant(s). This may be due to my request or due to my medical condition.
5. **PRACTICAL ALTERNATIVES TO THIS PROCEDURE** include doing nothing and accepting the circumstances of my medical condition, including any risks associated with leaving potentially damaged/ruptured implant(s) in my body.
6. **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.
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) if the implant(s) are replaced, scar tissue may build up and tighten around the implant(s) 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 saline (salt water) or silicone to leak into the surrounding tissues;
  - 3) excessive firmness of the breasts can occur after surgery due to internal scarring. The occurrence of this is not predictable.
  - 4) since prior to surgery most women's breasts are unequal, after surgery the breasts may have different sizes and shapes (unequal). If the implant(s) are not replaced, rib cage irregularities may be visible and cannot be eliminated;

**OTHER POSSIBLE RISKS (concluded):**

- 5) the breast size and shape may be significantly changed after removal of the implant(s) with or without placement of a new implant(s). Removal of implant capsule(s), calcifications around the implant(s) or silicone gel may cause visible depressions, ripples or irregularities of the surface of the breast.
  - 6) the implants being removed may be intact, ruptured before surgery or rupture upon removal. This may result in silicone gel escaping into the breast. It may not be possible to remove all of the gel, which has escaped.
  - 7) if saline-filled implant(s) are replaced, the new implant(s) or it's valve may fail allowing saline to leak causing deflation of the implant;
  - 8) in regards to saline or silicone implants, there may be still unknown, unrecognized or unproven risks;
  - 9) a hematoma (blood clot or collections of bloody fluid) may occur at the operative site;
  - 10) infection may occur after surgery and if the infection does not subside properly with appropriate treatment, removal of the implant may be required;
  - 11) some tissue may slough (dissolve away) due to poor healing causing exposure of the implant(s) (if replaced) through the skin and requiring removal of the implant(s);
  - 12) some fatty tissue may undergo fat necrosis (dissolve away) which may cause lumpiness or firmness in the breast;
  - 13) fluid collections may accumulate around the implant or in the pocket left after removal of the old implant(s) and may require drainage;
  - 14) pain and discomfort may occur;
  - 15) numbness (sensory loss, loss of feeling) or increased sensitivity may occur at the nipple or other parts of the breast which may be temporary or permanent;
  - 16) tightness, firmness, areas of lumpiness and itching may occur which may be temporary or permanent;
  - 17) scars will occur and may go from pink and firm to faded and soft over a period of six to twelve 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;
  - 18) bruising and swelling may occur and last a few weeks to several months;
  - 19) 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 A mammogram may be recommended prior to surgery to determine if any suspicious areas are present that should be biopsied (removed and examined microscopically) prior to or during surgery. A mammogram is usually recommended approximately one year after breast surgery to establish a baseline for later reference according to the American Cancer Society's guidelines

12.

There is no increase or decrease in the incidence of breast cancer following implant removal or exchange. The implant neither prevents nor causes breast cancer. Breast examinations are not affected since the implants are/were placed behind breast tissue or muscle and NOT in breast tissue. However, the procedure of implant removal/exchange 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 should be done twice a month and an annual examination by my surgeon or primary care physician should be performed.

13 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.

14 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, shape, or function of my breasts. These changes may include the inability to nurse or to be sexually aroused, and could be associated with postoperative pain.

15 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**

16 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.

17 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. 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.

18 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

19. **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: \_\_\_\_\_

