INFORMED CONSENT FOR

SALINE BREAST IMPLANT DEFLATION

PLEASE REVIEW AND BRING WITH YOU ON THE DAY OF YOUR PROCEDURE

PATIENT NAME _____

I agree that I have SALINE (salt water) filled implants and NOT silicone gel filled implants or double lumen implants with both saline and silicone gel. Deflation of implants filled with silicone gel is NOT possible and may result in future problems and need for surgery.

PATIENT SIGNATURE _____

KAROL A. GUTOWSKI, MD, FACS

AESTHETIC SURGERY
CERTIFIED BY THE AMERICAN BOARD OF PLASTIC SURGERY
MEMBER AMERICAN SOCIETY OF PLASTIC SURGEONS

Patient Initials_____

INSTRUCTIONS
This is an informed-consent document that has been prepared to help inform you about breast implant deflation, its risks, and alternative treatments.

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.

INTRODUCTION
In some cases, it may be advantageous to deflate saline breast implants, before surgery or as an alternative to implant removal. To deflate the implant, a neede is placed through the skin, and a hole is made in the implant allowing removal of the salt water inside. This premanently damages the implant and voids the implant warrenty. The implant cannot be repaired and the results cannot be revered without placing a new implant. The implant may be left in place or removed at a later time.

For patients with SALINE-filled (not silicone gel) breast implants, an intentional deflation (breaking) of the implant may be done. Deflation may be performed in cases where a patient no longer desires the breast size or shape associated with the saline implant.

___ I herby state that I am certain the implants to be deflated are saline-filled and not silicone gel filled or filled with any other material.

___ I understand that if the implants are not saline-filled and an attempt is made to deflate them, it will result in the breast implant material being released into my body and will require surgery for removal.

___ I understand that by deflating an implant, it is permanently damaged and cannot be used again. The procedure is not reversible unless a new implant is placed which requires surgery.

___ I understand that after deflating an implant, I may not be happy with the result and that my breast cannot be brought back to its previous appearance, unless a new implant is placed which requires surgery.

___ I understand that I will be responsible for any costs associated with any problems related to an implant deflation procedure. This includes cost for any corrective or other surgeries or procedures due to me being unhappy with the result or if any complications occur.

ALTERNATIVE TREATMENT
Alternative treatments include removing the implant completely.

RISKS for BREAST IMPLANT DEFLATION
Every procedure involves a certain amount of risk and it is important that you understand the risks involved to deflate your breast implant(s). An individual's choice to undergo a procedure is based on the comparison of the risk to potential benefit. Although the majority of patients 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 implant removal.

Bleeding- It is possible, though rare, to experience a bleeding episode during or after this procedure. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding.

Infection- Infection is rare after this procedure. Should an infection occur, treatment including antibiotics or additional surgery may be necessary.

Skin scarring- In rare cases, a small scar may be seen at the site of the needle injection.

Seroma- Tissue fluid may accumulate in the space where the breast implant was located. Additional treatment or surgery may be necessary to remove this fluid.

Psychological/appearance changes- It is possible that after breast implant deflation you may experience a strong negative effect on your physical appearance, including significant loss of breast volume, distortion, and wrinkling of the skin. Your appearance may be worse than prior to your surgery for the placement of the breast implants. There is the possibility of severe psychological disturbances including depression. It is possible that you or your partner will lose interest in sexual relations.

Other- Breast asymmetry may occur after deflation. You may be disappointed with the results of the procedure. Additional surgery may be necessary to reshape breasts after implant deflation.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures such as the implant deflation or removal, and any complications that might occur from surgery. Please carefully review your health insurance subscriber information pamphlet and underwriting policies.

ADDITIONAL SURGERY NECESSARY

Should complications occur, additional surgery or other treatments may be necessary. 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.

FINANCIAL RESPONSIBILITIES

The cost of a procedure vary 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.

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).

However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon 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 Dr. Karol Gutowski and such assistants as may be selected to perform the following procedure or treatment: Breast Implant Removal
   I have received the following information sheet:

   INFORMED CONSENT FOR BREAST IMPLANT DEFLATION
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 METHODS OF TREATMENT
   c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED
10. I READ AND UNDERSTAND THIS DOCMENT. I ACCEPT THE RISKS EXPLAINED IN THIS DOCUMENT.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10). I AM SATISFIED WITH THE EXPLANATION.

_____

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____

AUTHORIZATION & CONSENT FOR RELEASE OF MEDICAL IMAGES

It is important that you read this information carefully and completely. After reviewing, please sign the consent as proposed by Dr. Gutowski or his representatives.

INTRODUCTION

Medical images (photographs, slides, videos, interviews or any other images of you, or components of your medical record) may be taken before, during, or after a surgical procedure or treatment. These images may be need to document your medical condition, used as supporting material for authorizing medical coverage and payments, and treatment planning. Consent is required to take, use and release such images. Since Dr. Gutowski is also an educator of other physicians, researcher, and medical writer, your images may be used for other purposes as described below.

1. CONSENT TO TAKE PHOTOGRAPHS, SLIDES, DIGITAL IMAGES, AND VIDEOTAPES

I hereby authorize Dr. Gutowski and or his associates to take any images before, during and after my treatments or surgeries.

2. CONSENT FOR RELEASE OF PHOTOGRAPHS/SLIDES/VIDEOTAPES

I hereby authorize Dr. Gutowski and or his associates to use any of these images for professional medical purposes deemed appropriate including but not limited to showing these images on public or commercial television, electronic digital networks including the internet, print or visual or broadcast media, for purposes of examination, testing, credentialing and/or certifying purposes for purposes of medical education, patient education, lay publication, or during lectures to medical or lay groups, for marketing and advertising, and for use in supporting documentation for insurance or third-party payer purposes, medical teaching, research or dissemination of medical information to medical and nonmedical audiences, including, but not limited to, journal or book publications, presentations, conferences, and print marketing material (magazine, newspaper, etc) or electronic media (television, internet, etc).

3. CONSENT FOR RELEASE TO PROFESSIONAL ORGANIZATIONS

I further authorize Dr. Gutowski or to release to the American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), and the American Board of Plastic Surgery (ABPS) such images. I provide this authorization as a voluntary contribution in the interests of public education. The images may be used for publication in print, visual or electronic media, specifically including, but not limited to, medical journals (such as *Plastic and Reconstructive Surgery, Annals of Plastic Surgery, Aesthetic Plastic Surgery)*, textbooks, lay publications, patient education or during lectures for the purpose of informing the medical profession or the general public about plastic surgery methods, medical education or examination material by ASPS, ASAPS, and ABPS. I understand that such images shall become the property of ASPS, ASAPS, and ABPS, and may be retained or released by these organizations for the limited purpose mentioned above. I also grant permission for the use of any of my medical records including illustrations, photographs, video or other imaging records created in my case, for use in examination, certifying and/or re-certifying purposes by ABPS.

I understand that I will <u>not</u> be identified by name in any release of these materials but in some cases the images may contain features that may make my identity recognizable. I release and discharge Dr. Gutowski and all parties acting on his authority from all rights that I may have in these images, and from any claims that I have related their use in the above mentioned manner.

I also release Dr. Gutowski and any employees or agents from all liability, including any claims of libel or invasion or privacy, directly or indirectly connected with, arising out of or resulting from the taking and authorized use of these images or recorded interviews.

I understand that I have the right to request cessation of recording or filming at any time.

I understand that I will not be entitled to monetary payment or any other consideration as a result of any use of these images and /or my interview.

Patient Name _____

Patient Signature _____ Date _____

Witness or Guardian/Parent_____ Date _____