INFORMED CONSENT FOR

BREAST AUGMENTATION

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

PATIENT NAME _____

Based on my discussions with Dr Gutowski, I agree with, and choose to have the following options as part of my breast augmentation:

Implant Type	Saline ___	Silicone ___	Smooth ___	Textured ___
Implant Size & Shape	Right_____ cc	Left _____cc	Shape _____	
Incision	Under breast ___	Around areola ___	Armpit ___	
Implant Pocket	Above muscle ___	Under fascia ___		
	Below muscle or dual plane ___			

Patient Signature _____ **Date** _____

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 augmentation mammaplasty, 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 by your plastic surgeon.

GENERAL INFORMATION.

Augmentation mammaplasty is a surgical operation performed to enlarge the breasts for a number of reasons: To enhance the body contour of a woman, who for personal reasons feels that her breast size is too small, to correct a loss in breast volume after pregnancy, to balance breast size, when there exists a significant difference between the size of the breasts, to restore breast shape after partial or total loss of the breasts for various conditions, to replace existing breast implants for cosmetic or reconstructive reasons.

Breast implant surgery is contraindicated in women with untreated breast cancer or pre-malignant breast disorders, active infection anywhere in the body, or individuals who are currently pregnant or nursing. Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), conditions that interfere with blood clotting or wound healing, or have reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcome.

According to the FDA, **silicone gel** breast implants for first-time cosmetic breast augmentation are approved for use in women at least 22 years of age. They are also approved for revision breast augmentation, correction of birth deformities, and breast reconstruction. **Saline-filled** breast implants are approved for use in women at least 18 years of age. If you do not fulfill these FDA criteria, you must understand that these implants may still be used, but are NOT approved by the FDA for this purpose.

Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue or under the chest muscles. Incisions are made to keep scars as inconspicuous as possible, usually under the breast, around the lower part of the areola, or in the armpit. Breast implants are manufactured in a variety of shapes, sizes, and with either smooth or textured surfaces. The method of implant selection and size, along with surgical approach for inserting and positioning breast implants will depend on your preferences, your anatomy and your surgeon's recommendation. The shape and size of the breasts prior to surgery will influence both the recommended treatment and the final results. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward.

Conditions which involve sagging of the breast or diminished skin tone (stretch marks) may require additional surgical procedures (breast lift) to reposition the nipple and areola upward and to remove loose skin.

Patients undergoing augmentation mammaplasty surgery must consider the following:

- Breast augmentation or reconstruction with implants may not be a one time surgery.

- Breast implants of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
- Changes that occur to the breasts following augmentation or reconstruction with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants removed.

ALTERNATIVE TREATMENT

Augmentation mammaplasty is an elective surgical operation. Alternative treatment would consist of the use of external breast prostheses or padding, or the transfer of other body tissues such as fat to enlarge breast size.

RISKS of AUGMENTATION MAMMAPLASTY SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with augmentation mammaplasty. Additional information concerning breast implants may be obtained from the FDA, package-insert sheets supplied by the implant 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. Although the majority of women do not experience the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast augmentation. Problems associated with breast implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. Additional advisory information regarding this subject should be reviewed by patients considering surgery that involves breast implants.

While every patient experiences her own individual risks and benefits following breast implant surgery, clinical data suggests that most women will be satisfied with the outcome of breast implant surgery despite the occurrence of problems inherent with breast implant surgery.

Implants- Breast implants, similar to other medical devices, can fail. Implants can break or leak. When a saline-filled implant 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 an implant at the time of surgery. Damaged or broken implants cannot be repaired. Ruptured or deflated implants require replacement or removal. Breast implants can wear out, they cannot be expected to last forever.

Capsular contracture- Scar tissue, which forms internally around the breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may occur on one side, both sides or not at all. It is more common with implant placement in front of the chest muscle layer. Treatment for capsular contracture may require surgery, implant replacement, or implant removal. Capsular contracture may reoccur after surgical procedures to treat this condition.

Implant extrusion / Tissue necrosis- Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, due to smoking,

microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. An implant may become visible at the surface of the breast as a result of the device pushing though layers of skin. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur.

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

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. Changes in sensation may affect sexual response or the ability to breast feed a baby.

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

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.

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

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

Breast feeding- Breast milk is the best food for babies. Many women with breast implants have successfully breast fed their babies. Implant placement techniques that involve incisions through the nipple and areolar locations may reduce the ability to successfully breast feed. 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.

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

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. Non-prescription "herbs" and dietary supplements

can increase the risk of surgical bleeding. Hematoma can occur at any time following injury to the breast.

Seroma- Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast implants. This may contribute to infection, capsular contracture, or other problems.

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 breast implant. Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the breast implant may have to be removed. After the infection is treated, a new breast implant 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. In extremely rare instances, life-threatening infections, including toxic shock syndrome have been noted after breast implant surgery.

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.

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.

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.

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

Pain- Pain of varying intensity and duration may occur and persist after breast implant surgery. Pain may be the result of improper implant size, placement, surgical technique, capsular contracture, or sensory nerve entrapment or injury.

Breast cancer- Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. 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. Care must be exercised during breast biopsy procedures to avoid damaging the breast implant.

Anaplastic Large Cell Lymphoma (ALCL)- Of the millions of breast implants placed, about 60 to 80 cases of a very rare type of immune system cancer have been associated with the implants. In most cases, this was associated with textured implants but at this time, it is difficult to determine if there is an increased risk for developing ALCL after breast augmentation.

Mammography- Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Implant rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of breast implants 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 implants. Because more x-ray views are necessary with specialized mammography techniques, women with breast implants will receive more radiation than women without implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays. Patients may wish to undergo a preoperative mammogram and another one after implantation to establish a baseline view of their breast tissue.

Second generation effects- A review of the published medical literature regarding potential damaging effect on children born of mothers with breast implants is insufficient to draw definitive conclusions that this represents a problem.

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 augmentation mammaplasty. Breast sagginess may normally occur.

Unsatisfactory result- You may be disappointed with the results of surgery. Asymmetry in implant placement, displacement, nipple location, unanticipated breast shape and size may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location may occur. It may be necessary to perform additional surgery to improve your results or remove implants.

Removal / replacement of breast implants- Future revision, removal, or replacement of breast implants and the surrounding scar tissue envelope involves surgical procedures with risks and potential complications. There may be an unacceptable appearance of the breasts following removal of the implant.

Capsule procedures- Closed capsulotomy, the process of forcefully squeezing the fibrous capsule around a breast implant to break up scarring is not recommended. This may result in rupture of the breast implant or other complications.

Immune system diseases and unknown risks- A small number of women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosis, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. To date, after several large epidemiological studies of women with and without implants, there is no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of these diseases. These diseases appear no more common in women with implants than those women without implants. The effects of breast implants in individuals with pre-existing immune system and connective-tissue disorders is unknown. There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

Death or serious injury – In very rare cases, serious complications such stroke, heart attack or even death have resulted from surgery.

Limited manufacturer warrantee- The implant manufacturer may offer a limited warrantee for the breast implant in case of implant failure (rupture and deflation) for an additional fee.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations such as the augmentation mammaplasty and any complications that might occur from surgery. Most insurance covers the first breast reconstruction operation. Insurance coverage for future revision, new breast implants, or additional doctor's visits may not be covered, depending on the policy. Health insurance premiums may be dropped, premiums may increase, or future coverage may be denied in patients with breast implants. 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. Even though risks and complications occur infrequently, the risks cited are particularly associated with augmentation mammaplasty; 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.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of implants and surgical supplies, anesthesia, laboratory tests, and possible outpatient 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.

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. 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 Augmentation
   I have received the following information sheet:
   INFORMED-CONSENT FOR BREAST AUGMENTATION
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.
11. I READ AND UNDERSTAND THE INFORMATION IN THE **FDA Breast Implant Consumer Handbook**. (Download at http://www.fda.gov/cdrh/breastimplants/)

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-11). 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 _____