INFORMED CONSENT FOR

BUTTOCK IMPLANTS

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

PATIENT NAME _____

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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 buttock implant surgery, 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.
Buttock implants are specially formed solid, biocompatible materials designed to enhance or augment the physical structure of your buttocks. The precise type and size of implants best suited for you requires an evaluation of your goals, the features you wish to correct and your surgeon's judgment. It's important to remember that the human body is normally asymmetric to some degree and your results may not be completely symmetric. Buttock implant surgery may be performed alone, or as a complement to other body contouring procedures.

ALTERNATIVE TREATMENT
Buttock implant placement is an elective surgical operation. Alternative treatment would consist of the use of injections, or the transfer of other body tissues such as fat.

RISKS of BUTTOCK IMPLANT SURGERY
Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with implant surgery. Additional information concerning implants may be obtained from the package-insert sheets supplied by the implant manufacturer.

An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of people 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 facial implants. Problems associated with implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure.

Implants- Buttock implants, similar to other medical devices, can fail. Implants can break and broken implants cannot be repaired and may require replacement or removal. It is possible that small pieces of implant material may separate from the outer surface of implants. This is of unknown significance, and has not been shown to result in disease.

Implant Extrusion & Tissue necrosis - Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to buttock tissue, due to smoking, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur.

Nerve Injury- Motor and sensory nerves may be injured during a buttock implant operation. Weakness, numbness, or pain may occur after surgery. Permanent numbness or painful nerve scarring is rare, but may occur.

Damage to Deeper Structures- Deeper structures such as nerves, blood vessels and muscles may be damaged during the course of surgery. The potential for this to occur varies with the type of implant procedure performed. Injury to deeper structures may be temporary or permanent.

Chronic Pain- Very infrequently, chronic pain may occur after implant surgery.

Implant Visabillity- Visible and palpable edges of implants can occur.

Change in skin sensation- Some change in skin sensation is not unusual right after surgery. After several months, most patients have normal sensation.

Implant displacement- Displacement, rotation, or migration of an implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in buttock shape. Additional surgery may be necessary to correct this problem.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should 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 buttock.

Seroma- Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around the 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 an 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 an implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed. After the infection is treated, a new 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 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.

Pain- Pain of varying intensity and duration may occur and persist after implant surgery.

Long term results- Subsequent alterations in buttock shape may occur as the result of aging, weight loss or gain, or other circumstances not related to surgery.

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

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

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations such as buttock implants 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. Even though risks and complications occur infrequently, the risks cited are particularly associated with implant surgery; 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: Buttock Augmentation
   I have received the following information sheet:
   INFORMED-CONSENT FOR BUTTOCK IMPLANT SURGERY
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 _____