

INFORMED CONSENT FOR

FACIAL IMPLANTS

PLEASE READ THIS DOCUMENT, INITIAL THE BOTTOM OF EACH PAGE
AND SIGN THE LAST TWO PAGES

BRING THIS DOCUMENT TO YOUR PRE-OPERATIVE APPOINTMENT

PATIENT NAME _____

Based on my discussions with Dr. Gutowski and/or Dr. Martin, I agree with, and choose to have the following facial implants:

___ Malar (cheek) implants

___ Nose implants

___ Chin implants

___ Lip implants

___ Jaw implants

___ Other _____

KAROL A GUTOWSKI, MD, FACS
ANDREA MARTIN, MD
(THE PHYSICIANS)

Patient Signature _____

Date _____

INFORMED CONSENT FOR FACIAL IMPLANTS, Continued

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about facial 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(s).

GENERAL INFORMATION.

Facial implants are specially formed synthetic, biocompatible implants designed to enhance or augment the physical structure of your face. 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)'s judgment. While any area of your face can be augmented with implants, the cheekbones, chin, lips, nose, and jaw are the most common sites for facial implants. Facial implants can bring balance and better proportion to the structural appearance of the face and they can help define the face by increasing projection and creating more distinct features. Facial implant surgery is best performed on people who have reached physical & skeletal maturity, which generally occurs in late adolescence. It's important to remember that the human face is normally asymmetric to some degree, and your results may not be completely symmetric. Facial implant surgery may be performed alone, or as a complement to other facial contouring procedures such as nose or ear surgery.

ALTERNATIVE TREATMENT

Facial 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 FACIAL IMPLANT SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with facial implant surgery. Additional information concerning facial 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 potential risks to benefits. Although the majority of people do not experience the following complications, you should discuss each of them with your plastic surgeon(s) to make sure you understand the risks, potential complications, and consequences of facial implants. Problems associated with implants can be inherent to the type of implanted medical device or relate to complications of the surgical procedure.

Implants- Facial implants, similar to other medical devices, can fail. Implants can break, and fractured 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 facial implants. This is of unknown significance, and has not been shown to result in disease.

Implant Extrusion & Tissue necrosis - Lack of adequate soft 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 facial tissue, due to smoking, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. If tissue

INFORMED CONSENT FOR FACIAL IMPLANTS, Continued

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 facial implant operation. Weakness or loss of facial movements in the mouth or upper eyebrow resulting in an uneven appearance may occur after surgery. Most individuals will notice a return of motor function; permanent weakness is rare. Injury may also occur to the sensory nerves of the face, neck and ear regions. Permanent numbness or painful nerve scarring is rare, but may occur, and may require treatment.

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

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

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

Change in skin sensation- Some change in skin sensation is expected after surgery. After several months, most patients have normal sensation.

Implant displacement- Displacement, rotation, or migration of a facial implant may occur after initial placement, and can be accompanied by discomfort and/or distortion in facial 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 stop, and to drain accumulated blood (hematoma). Do not take any aspirin or anti-inflammatory medications for 14 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 surgery in the face.

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 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. In extremely rare instances, life-threatening infections, including toxic shock syndrome have been noted after implant surgery.

INFORMED CONSENT FOR FACIAL IMPLANTS, Continued

Skin scarring- Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and a different color than surrounding skin. Additional treatment or 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 medications. 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 facial 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 facial 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 the facial 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 facial 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.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed treatment of a condition along with disclosure of risks and alternative forms of treatment(s). The informed

INFORMED CONSENT FOR FACIAL IMPLANTS, Continued

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.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined based on all 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 your questions answered before signing the consent on the next page.

INFORMED CONSENT FOR FACIAL IMPLANTS, Continued

CONSENT FOR SURGERY/ PROCEDURE or TREATMENT

1. I hereby authorize Dr. Karol Gutowski and/or Dr. Andrea Martin, and such assistants as may be selected, to perform the following procedure or treatment:

FACIAL IMPLANTS

I have received the following information sheet:

INFORMED CONSENT FOR FACIAL 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(s) 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(s) 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 involve risks, and the possibility of complications, or injury.
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 and video recording 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 PROCEDURES OR METHODS OF TREATMENT
c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).
I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Witness

Date

Time

INFORMED CONSENT FOR FACIAL IMPLANTS, Continued

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 The Physicians or their representatives.

INTRODUCTION

For your medical records, 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 needed 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 The Physicians are also educators of other physicians, researchers, and healthcare providers, your images may be used for other purposes as described below.

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

I hereby authorize The Physicians and/or their associates to take any images before, during and after my treatments or surgeries.

2. CONSENT FOR RELEASE OF PHOTOGRAPHS/SLIDES/ VIDEOGRAPHY

I hereby authorize The Physicians and their 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 medical education, patient education, lay publication, or during lectures to medical or lay groups, for marketing and advertising, and for use in 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 The Physicians and their associates to release such images to the American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), the American Board of Plastic Surgery (ABPS), the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS), and the American Board of Facial Plastic and Reconstructive Surgery (ABFPRS). 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, ABPS, AAFPRS and ABFPRS. I understand that such images shall become the property of ASPS, ASAPS, ABPS, AAFPRS and ABFPRS 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 and ABFPRS.

I understand that I will not 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 The Physicians and all parties acting on their 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 The Physicians and any employees or agents from all liability, including any claims of libel or invasion of 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 use of these images and /or my interview.

Patient Name _____

Patient Signature _____

Date _____

Witness or Guardian/Parent _____

Date _____