INFORMED CONSENT FOR

LABIAPLASTY

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

PLEASE REVIEW AND BRING WITH YOU ON THE DAY OF YOUR PROCEDURE OR TO YOUR PRE-OPERATIVE APPOINTMENT

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

PATIENT INITIALS _____

INSTRUCTIONS

This is an informed-consent document that has been prepared to help your plastic surgeon inform you about the risks and alternative treatments of labiaplasty surgery, which may include any combination of modification of the labia majora, labia minora, mons, pubic area, as well as liposuction.

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.

INTRODUCTION

Labiaplasty is a surgical procedure to remove excess skin and tissue from the gential area and is offered to women with excessive, redundant labia or tissue who suffer from unsightly contour and/or physical discomfort (ex.: pinching or chafing when sitting or walking, hindrance during intromission, and difficulty maintaining hygiene during menses or after defecation).

The term labiaplasty refers to the reduction in size of the labia minora. The labia minora are the bands of tissue on either side of the vagina that are directly inside the labia majora. These two flaps of skin extend down from the clitoris. Hormonal changes in the body brought on by pregnancy, puberty, menopause and age, can cause enlargement and darken the color of this tissues. Many women find these changes particularly disturbing as they may be obvious to them and their sexual partners. In some cases the labia minora can become so large that they will interfere with sexual intercourse. Labiaplasty is one of the most common genital rejuvenation procedures performed. The procedure involves cutting away the excess tissue and closing the incision. The aim of the surgery is to reduce the labia minora and not to totally remove them. Similarly, reduction of the labia majora, mons, or perineum, may also be included, with the same indications.

ALTERNATIVE TREATMENTS

Alternative forms of management consist of not treating the areas of excess skin and tissue.

RISKS OF LABIAPLASTY SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with ear surgery. An individual's choice to undergo a surgical procedure is based on the comparison of the potential risks to benefits. Although the majority of patients do not experience the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks of surgery.

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 stop, drain accumulated blood or blood transfusion. Do not take any aspirin or anti-inflammatory medications for two weeks before surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding, and should also be stopped (See "Medications To Avoid").

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

Pain- Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue after body contouring surgery.

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Change in skin sensation- Diminished (or loss of) sensation in the genital area may occur. This is usually temporary, but may be permanent.

Skin contour irregularities and discoloration- Contour irregularities and depressions may occur after labiaplasty surgery. Visible and palpable wrinkling of skin can occur. The skin in the treated area may change color.

Sexual dysfunction- Although uncommon, in some cases, the size or shape of the new labia, or the resulting scars, or other factors, may make sexual activity uncomfortable or painful. While this is usually temporary, it is possible that it could be permanent.

Skin scarring - Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive, thickened and/or a different color than surrounding skin. Occasionally, the scars may become wide and stretched causing webbing of the skin. Additional treatments including surgery may be necessary to treat abnormal scarring.

Surgical anesthesia- Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Asymmetry- Most patients have asymmetry of their labia. While symmetry is always the goal, perfect symmetrical may not be achieved from surgery.

Tissue distortion – Treated areas may stretch or become distorted over time. This may require further surgery.

Seroma- Fluid accumulations infrequently occur under the skin in the operative area. Should this problem occur, it may require additional procedures for drainage of fluid.

Delayed healing- Wound disruption or delayed wound healing is possible. Some areas of the body may not heal normally and may take a long time to heal. Some areas of skin may die, resulting in wound formation. This may require frequent dressing changes or further surgery to remove the non-healed tissue.

Smokers have a greater risk of skin loss and wound healing complications.

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 medications. Allergic reactions may require additional treatment.

Blood clots- Blood clots in the veins of the arms, legs, or pelvis and may result from surgery or immobilization. These clots may cause problems with the veins or may break off and flow to the lungs where they may cause serious breathing problems.

Pulmonary complications- Pulmonary (lung and breathing) complications may occur from both blood clots (pulmonary emboli) and partial collapse of the lungs after general anesthesia. Should either

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of these complications occur, you may require hospitalization and additional treatment. Pulmonary emboli can be life-threatening or fatal in some circumstances.

Long term effects- Subsequent alterations in labia minora, labia majora and mons may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to surgery.

Deeper sutures- Some surgical techniques use deep sutures. These sutures may be noticed by the patient following surgery. Sutures may spontaneously poke through the skin, be visible, or produce irritation that requires removal.

Prolonged Swelling- In some cases, the tissue may swell more than expected after surgery and may stay swollen. This may not improve and may require further treatment. It is more likely to happen in the arms and legs and less likely elsewhere in the body.

Other- You may be disappointed with the results of surgery. Infrequently, it is necessary to perform additional surgery to improve your results.

ADDITIONAL SURGERY

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

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations such as labiaplasty or any complications that might occur from surgery. Please carefully review your health insurance subscriber-information pamphlet.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of 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 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

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| INFORMED CONSENT FOR LABIAPLASTY |
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| 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.

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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:

LABIAPLASTY

I have received the following information sheet:

INFORMED CONSENT FOR LABIAPLASTY

- 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 T I AM SATISFIED WITH | REATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). THE EXPLANATION. |
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| | |
| Patient or Person Auth | rized to Sign for Patient |
| | |
| Witness | |
| | |
| Date | Time |

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 <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 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 |