INFORMED CONSENT FOR

HERNIA REPAIR HERNIA REPAIR WITH MESH

PATIENT NAME	



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

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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 hernia repair.

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

A hernia is a defect (hole) in a body structure that allows deeper organs to move through the defect. This can result in pain or injury to the organs involved. Not all hernias need to be repaired but in most cases, a repair can reduce the risk of future problems. Small hernias may be repaired by closing the defect with sutures while larger hernias may require a mesh (either temprorary or permanent man made device, or a human or animal tissue derived biologic product).

ALTERNATIVE TREATMENTS

Alternative forms of management consist of not treating the hernia or using an external device or garment such a binder.

RISKS OF HERNIA SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with hernia surgery. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. 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 consequences of surgery.

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 or blood transfusion. Do not take any aspirin 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 unusual after this type of surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary.

Change in skin sensation- Diminished (or loss of) skin sensation may not totally resolve after body contouring surgery.

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

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 treatments including surgery may be necessary to treat abnormal scarring.

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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- Asymmetrical body appearance may result from surgery.

Need for mesh removal – if the mesh becomes infected or causes problems, it may require further surgery to be removed.

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. 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 medicines. 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 of these complications occur, you may require hospitalization and additional treatment. Pulmonary emboli can be life-threatening or fatal in some circumstances. Fat embolism syndrome occurs when fat droplets are trapped in the lungs. This is a very rare and possibly fatal complication of liposuction.

Seroma- Fluid accumulations infrequently occur in between the skin and underlying muscle. Should this problem occur, it may require additional procedures for drainage of fluid.

Umbilicus- Malposition, scarring, unacceptable appearance or loss of the umbilicus (navel) may occur after hernia repair..

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

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

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

Injury to deeper structures – in very rare cases, deeper structures or organs may be injured during surgery or as a result of the mesh. More surgery may be need to repair the injury.

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Recurrence of hernia – The hernia repair may not be permanaent as in some cases, the defect can return despite a properly done surgery. Risk factors for failure of hernia repair include obesity, smoking, and other medical conditions.

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

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 hernia 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 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 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.

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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: Hernia Repair with Possible Mesh have received the following information sheet:

INFORMED-CONSENT FOR HERNIA REPAIR

- 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
 - 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 TREATME	ENT OR PROCEDURE AND THE ABOVE LISTED	
ITEMS (1-10). I AM SATISFIED WIT	TH THE EXPLANATION.	
Patient or Person Authorized to Sign for Patient		
Date	Witness	

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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