



Informed Consent

Breast Reconstruction with DIEP Flap

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about breast reconstruction with DIEP (deep inferior epigastric perforator) flap surgery, its risks, as well as alternative treatment(s).

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 and agreed upon by you.

GENERAL INFORMATION

There are a variety of surgical techniques for breast reconstruction. Most mastectomy patients are medically appropriate for breast reconstruction, either immediately following breast removal or at a later time. The best candidates, however, are women whose cancer, as far as can be determined, seems to be eliminated by mastectomy. There are legitimate reasons to delay breast reconstruction. Some women may be advised by their surgeon or oncologist to wait until other forms of necessary cancer treatment are completed. Other patients may require more complex breast reconstruction procedures. Women who smoke or who have other health conditions such as obesity or high blood pressure may be advised to postpone surgery. In any case, being informed of your options concerning breast reconstruction can help you prepare for a mastectomy with a more positive outlook on the future.

Breast reconstruction has no known effect on altering the natural history of breast cancer or interfering with other forms of breast cancer treatment such as chemotherapy or radiation.

The DIEP flap technique of breast reconstruction involves the use of lower abdominal skin and fatty tissue with as little as possible amount of the abdominal muscle. This tissue is transferred to the chest wall region in order to reconstruct a breast mound. The blood vessels providing circulation to the tissue are re-connected to the blood vessels on the chest to re-establish flow of blood to the tissue in the new position. This vascular connection usually requires microsurgical techniques. Following the reconstruction of the breast mound, the lower abdominal incisions are closed. This is a modification of TRAM abdominal muscle flap breast reconstruction, but attempts to preserve the “six-pack” muscle function. In some cases, your plastic surgeon may recommend that a breast implant be inserted underneath the flap to give the breast mound additional projection.

Tissue flap techniques of breast reconstruction are useful in the following situations:

- Inadequate chest wall tissue for breast reconstruction with implants or expanders
- Past history of radiation to chest wall after mastectomy
- Patients with concerns about breast implants.
- Failure of earlier breast reconstruction

Contraindications to DIEP flap breast reconstruction procedure exist:

- A patient who is medically or psychologically unsuitable for breast reconstruction
- A past history of abdominal surgery which has impaired DIEP flap blood supply

A separate consent form for the use of breast implants in conjunction with breast reconstruction with DIEP flap is necessary.

ALTERNATIVE TREATMENTS

DIEP flap breast reconstruction is an elective surgical operation. Alternative treatment would consist of the use of external breast prostheses or padding, tissue expansion breast reconstruction, saline or silicone gel breast implants or the transfer of other body tissues for breast reconstruction.

Potential risks and complications are associated with alternative techniques of breast reconstruction that involve surgery.

INHERENT RISKS OF BREAST RECONSTRUCTION WITH DIEP FLAP SURGERY

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with breast reconstruction with DIEP flap and the possible use of a breast implant in

addition to the flap. In the event that a DIEP flap is used without a breast implant, risks associated with breast implants would not be applicable. There is a higher incidence of risk and complications from the use of the DIEP flap for breast reconstruction than there is with other breast reconstruction techniques. 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 reconstruction with DIEP flap.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH DIEP FLAP SURGERY

Delayed Healing and Loss of Flap:

Wound disruption or delayed wound healing is possible. It is possible to have areas of the chest wall or DIEP flap die. This may require frequent dressing changes or further surgery to remove the non-living tissue. Some areas of the chest or DIEP flap skin may heal abnormally or slowly when there is reduced blood supply to tissue from prior surgery or radiation therapy treatments. Smokers have a greater risk of skin loss and wound healing complications. Second-hand smoke can also have similar negative effects on wound healing.

Implant Extrusion:

Lack of adequate tissue coverage may result in exposure and extrusion of a breast implant, if used, in addition to the DIEP flap. If tissue breakdown occurs and the breast implant becomes exposed, removal is necessary. It may not be possible to place a new implant at the same time. You may have to allow for complete wound healing without an implant before your breast reconstruction can be completed.

Firmness:

Excessive firmness of the breast can occur after surgery due to internal scarring or scarring around a breast implant if one is used. The occurrence of this is not predictable and additional treatment or surgery may be necessary. Radiation therapy to the chest region after breast reconstruction with a DIEP flap may produce unacceptable firmness or other long-term complications.

Microvascular Surgery:

Flap loss may result if a blockage occurs at the point of arterial or venous attachment to the DIEP flap. If there are no contraindications you will be on Aspirin for at least one month after the surgery. The blood flow through the vessels is monitored after the surgery. If there is an indication of a blockage urgent surgery may be necessary to remove the blockage and re-establish the circulation in the tissue flap. In a small number of patients this may not be successful and the flap tissue may die and have to be removed completely. Other reconstructive modalities can be considered at that point.

Weakness of Abdominal Muscle Function:

Following transfer of abdominal tissue there is anticipated muscle weakness. This is less prominent in case of a DIEP flap compared to the traditional TRAM flap. Usually, the patients are able to return to most of their usual activities in two to four months. Patients may notice a feeling of abdominal weakness while doing sit-up exercises or similar movements.

Abdominal Wall Hernia:

On rare occasions, the area of the abdominal wall where the muscle has been manipulated will become weak and produce a hernia. Very rarely, re-operation for repair of this hernia may be necessary. In some cases, a plastic mesh or other biologic material will be inserted at the time of the breast reconstruction procedure incision closure to help support and reinforce the abdominal wall.

Other Perforator and Tissue Flaps:

In addition to the lower abdominal area, other regions of the body can be used as a donor site for tissue to reconstruct the breasts after mastectomy. One of those areas is the buttock region. An elliptic segment of skin and fat can be removed from the upper buttock area (superior gluteal) or the lower buttock area close to the buttock crease (inferior gluteal). Generally, the attempt is made to remove the needed tissue and preserve the muscles in that region as far as possible. The skin and fatty tissue are removed with the

corresponding small blood vessels (perforators). These blood vessels are re-connected to the vessels on the chest later during the surgery to establish blood circulation to the transferred tissue. This process requires microsurgical techniques. If the tissue is removed from the upper buttock area the procedure is called superior gluteal artery perforator or SGAP flap. The tissue from the lower part of the buttock is called inferior gluteal artery perforator or IGAP flap. Removal of tissue from one buttock may cause asymmetry requiring future procedures to balance both buttocks and create a more symmetric appearance. In selected cases, skin and fatty tissue can be harvested from the thigh or hip region. These tissues can be transferred to the chest for breast reconstruction using microsurgical techniques in the same fashion as described earlier.

The risks involved in SGAP, IGAP, and other microvascular techniques are very similar to the risks of the DIEP flap reconstruction. Ask your surgeon for more details if you are considering one of these procedures.

Change in Nipple and Skin Sensation:

Breast reconstruction cannot restore normal sensation to your breast or nipple. Skin that is transferred as part of the muscle flap will lack sensation. Numbness may occur in the skin on the abdomen where the skin component of the DIEP flap was located. Changes in sensation may affect sexual response or the ability to breast-feed a baby.

Asymmetry:

Some breast asymmetry naturally occurs in most women. Differences in breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to correct asymmetry after a breast reconstruction with DIEP flap.

Breast Implants:

Risks associated with the potential use of breast implants are covered in a separate informed-consent form.

Unsatisfactory Result:

You may be disappointed with the results of breast reconstruction surgery. Asymmetry may occur after surgery in terms of the flap placement or breast shape and size. You may be dissatisfied with the flap placement or location of the surgical scar. It may be necessary to perform additional surgery to improve your results. Breast reconstruction by any technique may fail due to complications attributable to the mastectomy surgery or from chemotherapy/radiation therapy treatments which are independent of the DIEP flap procedure.

Breast Disease:

Current medical information does not demonstrate an increased risk of breast disease, breast cancer, or recurrence of breast cancer in women who have reconstructive breast surgery. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. 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 a breast lump be detected. In the event that suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

GENERAL RISKS OF SURGERY

Healing Issues:

Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as

swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars from surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

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 or you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Do not take any aspirin or anti-inflammatory medications for at least ten days before or after 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, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

In breast implant surgery, hematoma may contribute to capsular contracture, infection or other problems.

Infection:

Infection is unusual after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infection in other part of the body, may lead to an infection in the operated area.

Infection in Breast Implant Patients:

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 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. Individuals with an active infection in their body should not undergo surgery, including breast augmentation. Although 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. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infection in other part of the body, may lead to an infection in the operated area.

Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases scars may require surgical revision or treatment.

Firmness:

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not

predictable. Additional treatment including surgery may be necessary.

Change in Skin Sensation:

It is common to experience diminished (or loss of) skin sensation in areas that have had surgery. Diminished (or complete loss of) skin sensation may not totally resolve.

Skin Contour Irregularities:

Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Skin Discoloration / Swelling:

Some bruising and swelling will normally occur. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

Skin Sensitivity:

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

Major Wound Separation:

Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

Sutures:

Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

Delayed Healing:

Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. Smokers have a greater risk of skin loss and wound healing complications.

Damage to Deeper Structures:

There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Fat Necrosis:

Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

Seroma:

Infrequently, fluid may accumulate between the skin and the underlying tissues following surgery, trauma or vigorous exercise. Should this problem occur, it may require additional procedures for drainage of fluid.

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.

Shock:

In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or

excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Pain:

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis and Sequelae:

Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins.

Allergic Reactions:

In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Drug Reactions:

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you now regularly take.

Asymmetry:

Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish asymmetry.

Surgical Wetting Solutions:

There is the possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment including hospitalization may be necessary.

Persistent Swelling (Lymphedema):

Persistent swelling can occur following surgery.

Unsatisfactory Result:

Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The body is not asymmetric and almost everyone has some degree of unevenness which may not be recognized in advance. One side of the face may be slightly larger, one side of the face droopier. The breast and trunk area exhibits the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations as to results, the better your

results will be in your eye. Some patients never achieve their desired goals or results, at no fault of the surgeon or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results.

ADDITIONAL ADVISORIES

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):

Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying and delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

☐ I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

☐ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

☐ I have smoked and stopped approximately _____ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine test just before surgery may be done which will prove the presence of Nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

Sleep Apnea / CPAP:

Individuals who have breathing disorders such as "Obstructive Sleep Apnea" and who may rely upon CPAP devices (constant positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.

Please consider the following symptoms of sleep apnea:

☐ I am frequently tired upon waking and throughout the day

☐ I have trouble staying asleep at night

☐ I have been told that I snore or stop breathing during sleep

☐ I wake up throughout the night or constantly turn from side to side

☐ I have been told that my legs or arms jerk while I'm sleeping

☐ I make abrupt snorting noises during sleep

☐ I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

Off-Label FDA Issues:

There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is “Off-Label”, that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believes it to be safe and effective.

_____ I acknowledge that I have been informed about the Off-Label FDA status of _____
_____ and I understand it is not experimental and accept its use.

Medications and Herbal Dietary Supplements:

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Aleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Travel Plans:

Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

Long-Term Results:

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

Interference with Sentinel Lymph Node Mapping Procedures:

Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer.

Body-Piercing Procedures:

Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity.

Future Pregnancy and Breast Feeding:

This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breast feeding after this operation.

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations After Surgery:

Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

Mental Health Disorders and Elective Surgery:

It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

DVT/PE Risks and Advisory:

There is a risk of blood clots, Deep Vein Thrombosis (DVT) and Pulmonary Embolus (PE) with every surgical procedure. It varies with the risk factors below. The higher the risk factors, the greater the risk and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.

There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past or present history of any of the following:

- _____ Past History of Blood Clots
- _____ Family History of Blood Clots
- _____ Birth Control Pills
- _____ Swollen Legs
- _____ History of Cancer
- _____ Large Dose Vitamins
- _____ Varicose Veins
- _____ Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract.

_____ I understand the risks relating to DVT/PE and how important it is to comply with therapy as discussed with my surgeon. The methods of preventative therapy include:

- _____ Early ambulation when allowed
- _____ Compression devices (SCD/ICD)
- _____ ASA protocol when allowed (Aspirin)
- _____ Heparin protocol when allowed
- _____ Enoxaparin protocol when allowed

The risks of DVT/PE may be almost as great as the prophylactic therapy when involving Aspirin, Heparin, and Enoxaparin. Be aware that if your surgery is elective, those patients with very high risks should consider not proceeding with such elective surgery.

ADDITIONAL SURGERY NECESSARY (Re-Operations)

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be

necessary to perform additional tightening or repositioning of body structures. 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 this 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology and lab testing.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

REVISION POLICY

Surgical revision surgery is a common part of elective surgery. Your procedure will not stop you from aging, sagging, scarring, or experiencing ongoing skin changes that are more genetically controlled. If revision surgery is either desired or advisable within one year after the initial surgery, there may be a physician's fee. Additionally, there may be fees associated with the hospital, facility, anesthesia, pathology, lab, and any supplies such as implants, etc. Revision policy and courtesy discounts only apply to patients who comply with post-op orders and visits.

REGULATORY MATTERS

According to FDA regulations, you must comply with the submission of personal information to a device registry before surgery and afterwards if breast implants are used as a component of your breast surgery.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations or any resulting complications. Please carefully review your health insurance subscriber-information pamphlet. Most insurance plans exclude coverage for secondary or revisionary surgery due to complications of cosmetic surgery. It is unethical and fraudulent to bill insurance for cosmetic procedures. We cannot participate in such activities.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, 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. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

____ I understand that with cosmetic surgery, I am responsible for the surgical fees quoted to me, as well as additional fees for anesthesia, facility (OR), and possibly laboratory, X-ray, and pathology fees. Surgicenters, Outpatient Centers and Hospitals often have rules that certain tissue /implants removed during surgery must be sent for evaluation that may result in additional fees. Please check with your surgeon for approximate additional costs you will be responsible for.

**PATIENT CONSENT FOR USE OF CREDIT CARDS, DEBIT CARD, AND FINANCING -
DISCLOSURE OF PROTECTED HEALTH INFORMATION**

It may become necessary to release your protected health information to financial parties, credit card entities, banks, and financing companies, when requested, to facilitate your payment.

Services that are performed and are paid with a credit card, debit card, or financing third party are not eligible for payment challenges after services are provided. By signing this form, I am irrevocably consenting to allow Dr. _____ to use and disclose my protected health information to any credit card entity, bank, or financing company when they request such information to process an account and assist with payment.

_____ I will not challenge such credit, debit, or financing card payments once the services are provided. The practice encourages complete post-op care and follow-up interaction to address any issues that might arise, which are further addressed in the Revision Policy.

_____ I agree that this non credit card challenge agreement is irrevocable.

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), including no surgery. 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 current 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. _____ and such assistants as may be selected to perform the following procedure or treatment:

I have received the following information sheet:

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 involve risk and the possibility of complications, injury, and sometimes death.
4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after 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 that may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option.
12. 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 (1-12).
I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____