Informed Consent

Breast Reconstruction with TRAM Flap

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about breast reconstruction with transverse rectus abdominus musculocutaneous (TRAM) 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 candidates 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 have been 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. Some individuals who are of thin body habitus may not be suitable candidates for TRAM flap procedures. Individuals of obese body habitus are also advised of increased risk due to the effect of obesity on surgical complications.

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 TRAM flap technique of breast reconstruction involves the use of abdominal muscle flap(s) made from the rectus abdominis muscle. This muscle and a portion of lower abdominal skin and other tissue are repositioned to the chest wall region to reconstruct a breast mound. The muscle flap maintains its own blood supply and helps nourish the tissue that is transferred to the chest wall region. Following the reconstruction of the breast mound, the lower abdominal incisions are closed. There are several variations on the surgical technique of TRAM flap breast reconstruction, including micro vascular surgery, to attach the flap to the chest region. In some cases, your plastic surgeon may recommend that a breast implant be inserted underneath the muscle flap to give the breast mound additional projection.

Muscle 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
-Patient with concerns about breast implants
-Failure of earlier breast reconstruction

Contraindications to TRAM flap breast reconstruction procedure include:

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

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

ALTERNATIVE TREATMENTS

TRAM flap breast reconstruction is an elective surgical operation. Alternative treatments include the use of external breast prostheses or padding, tissue expansion breast reconstruction, 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 TRAM 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 TRAM flap and the possible use of a breast implant in addition to the muscle flap. If a TRAM 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 TRAM 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 TRAM flap.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH TRAM FLAP SURGERY

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. If postoperative bleeding occurs, it may require emergency treatment to drain accumulated blood (hematoma). Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Nonprescription "herbs" and dietary supplements can increase the risk of surgical bleeding, and should also be held prior to surgery. Heparin drugs that are given to decrease risk of deep vein thrombosis (DVT) during surgery can contribute to bleeding during surgery and afterwards.

Infection:

An infection is unusual after this type of surgery. If an infection occurs, treatment including antibiotics or additional surgery may be necessary. Infections with the presence of a breast implant (if used) are harder to treat than infections in normal body tissues. Infection in the abdomen or chest can be treated with antibiotics, local debridement, and secondary surgery.

Seroma:

Pockets of tissue fluid sometimes develop either in the abdomen or in the chest wall after a TRAM flap breast reconstruction. Additional procedures to drain this fluid accumulation may be necessary.

Skin Scarring:

Although good wound healing after a surgical procedure is expected, abnormal scars may occur both within the skin and deeper tissues. Scars may be unattractive and of a different color than surrounding skin tone. There is a possibility of visible marks from sutures used for wound closure. Additional treatments may be needed to treat abnormal scarring after surgery.

Flap Loss:

Flap loss may result if the blood supply to the flap is insufficient. Emergent reoperation may be necessary to attempt to salvage the flap. In some cases, partial or complete loss of the flap tissues can result, which can necessitate further surgery and may affect the cosmetic result. Blood clotting disorders can sometimes affect the blood supply to the TRAM flap, and it is important to inform your plastic surgeon of any history of abnormal clotting.

Delayed Healing and Loss of Flap:

Wound disruption or delayed wound healing is possible both at the chest wall and abdomen. This may require frequent dressing changes or further surgery to remove the nonliving tissue. Some areas of the chest or muscle flap skin may heal abnormally or slowly when there is reduced blood supply to tissue from prior surgery or radiation therapy treatments. Necrosis of the umbilicus can occur.

Change in 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 TRAM flap was located.

Fat Necrosis:
Fatty tissue found in the flap may die. This may produce areas of firmness within the flap. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the flap from fat necrosis.

Abdominal Wall Hernia:
Individuals undergoing TRAM flap breast reconstructions are advised that there is a possibility that abnormal bulging of their abdominal wall and contents can occur after this procedure. This may require additional surgery to correct.

Loss of Abdominal Wall Muscle Function:
There may be loss of normal function in the rectus abdominis muscle if a portion or all of it needs to be transferred with the TRAM flap. This can result in weakness in abdominal muscle movements, such as with sitting up. The amount of rectus abdominis muscle that must be sacrificed may not be known until the time of surgery.

Acellular Dermal Matrix Usage:
Acellular dermal matrix (ADM) products may be used to reinforce the deep layers of closure of your abdominal area during a TRAM flap procedure. These products are biologic but have no cells and rely on your own cells to repopulate the matrix yielding added strength. Complications may include a lack of complete population requiring partial removal or secondary surgery, seroma or fluid production around the material, and infection. Hernia/bulge can still result despite the use of ADM.

Surgical Mesh Usage:
Synthetic mesh may be used to reinforce the deep layer closure of your abdominal area during a TRAM flap procedure. Complications attributable to the use of surgical mesh including infection, pain, and palpability can occur and may require additional surgery to correct. Hernia/bulge can still result despite the use of synthetic mesh.

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

Implant Extrusion:
Lack of adequate tissue coverage may result in exposure and extrusion of a breast implant, if used, in addition to the TRAM flap. If tissue breakdown occurs and the breast implant becomes exposed, removal is necessary.

Pregnancy and Breastfeeding:
There is no evidence that TRAM flap surgery has any effect on fertility or pregnancy. If a woman has undergone a mastectomy, she would not be able to breastfeed a baby on the affected side. Pregnancy following TRAM flap surgery may alter the appearance of the abdomen, and/or result in laxity or bulging of the abdomen, which can sometimes require surgery to correct.

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 TRAM flap may produce unacceptable firmness or other long-term complications.

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 TRAM flap.

Unsatisfactory Result:

You may be disappointed with the results of breast reconstruction surgery. Asymmetry may occur after surgery in terms of muscle 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 TRAM flap procedure. Unsatisfactory results may NOT improve with each additional treatment.

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.

Use of Drains:

During your surgery, your doctor may find it necessary to place drain(s). A drain is a small tube that drains fluid out from the area that was operated on. You will be instructed on the use of your drain. Placement of the drain may require a small separate incision. The drain will be removed when your doctor thinks it is no longer necessary. The drain site may be closed at the time of drain removal. Closing the drain site may require special surgical tape or sometimes a suture. Your doctor may leave the site open to drain any residual fluid under the wound.

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 and produce a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early nonsurgical intervention resolves this. It is important to discuss postsurgical pain with your surgeon.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. If postoperative bleeding occurs, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. 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. Nonprescription "herbs" and dietary supplements can increase the risk of surgical bleeding. A 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. Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

Infection:

Infection, although uncommon, can occur after surgery. If an infection occurs, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, an open wound, recent upper respiratory infection/pneumonia, ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Infections in other parts of the body may lead to an infection in the operated area. Postoperative infections often result in more extensive scarring and predispose the patient to revision surgery.

Ileus:

The return of bowel function following surgery is important. An ileus is a disruption in bowel function caused by the failure of peristalsis or by hypomobility of your bowels/gut resulting in a lack of defecation and possibly repeated vomiting. Anesthetics and medications like pain medications given to you at the time of surgery can contribute to the development of an ileus in the postoperative period. An ileus can result in abdominal distention, vomiting, inability to absorb oral medications, and possibly hospitalization. Repeated vomiting could result in an aspiration pneumonia and respiratory failure. It is essential to have regular bowel function after your surgery.

Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. 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 a possibility of visible marks in the skin from sutures. These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to "hypertrophic" or "keloid" scars, which are prominent, raised, red scars that do not settle. Further treatments with medications and/or surgery may be required.

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.

Skin Sensitivity:

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

Major Wound Separation:

Wounds may separate after surgery. If this occurs, 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.

Damage to Deeper Structures:
There is the potential for injury to deeper structures including nerves, blood vessels, lymphatics, muscles, bowel, bladder, 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 a possibility of contour irregularities in the skin that may result from fat necrosis.

Surgical Anesthesia:
Both local and general anesthesia involve risk. There is a 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. If you are a chronic pain patient followed by a pain therapy practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the postoperative period. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

There are nerve endings that may become involved with healing scars from 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 nonsurgical intervention resolves this. It is important to discuss postsurgical pain with your surgeon.

Cardiac and Pulmonary Complications:
Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, 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 heartbeats, seek medical attention immediately. If any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis (Clot) 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. Personal history of bleeding and clotting problems may also 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. It is important to notify your physician of any previous allergic reactions.

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 regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Surgical Wetting Solutions:
There is a 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.

Fat/Air Embolism:
In rare cases, fat particles or air can enter the vascular system and can travel to the heart, lungs, or brain. This can result in significant complications including death.

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 symmetric and almost everyone has some degree of unevenness that may not be recognized in advance. One side of the face may be slightly larger or droopier. The breast and trunk areas exhibit 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 appear to you. 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. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:
There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix®, Coumadin®, Xarelto®, Effient®, or Pradaxa®, you should discuss management of these medications around the time of surgery with your plastic surgeon. Your plastic surgeon may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with medications that 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, know 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 of sunblock 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. Allow at least 10-14 days before travelling via air. Medications may be required should you have a long flight/trip to prevent DVT/pulmonary embolism (PE) in the immediate postoperative period.

Long-Term Results:
Subsequent alterations in the appearance of your body may occur as a 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:
Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity. Body-piercing jewelry should be removed prior to your surgical procedure.

Nails:
To determine your vital status during surgery, your anesthesia provider may require access to your fingernails for monitoring. Make sure to have at least two fingernails free of nail polish or acrylic nails on the date of your surgery.

Jewelry:
Jewelry should not be brought with you at the time of your surgical procedure. Items such as earrings, wedding rings, and necklaces should be removed and placed in a safe place. Do not bring your jewelry with you for your surgery.

Future Pregnancy and Breastfeeding:
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 breastfeeding after this operation.

Female Patient Information:

 _____ **Patient Initials**

It is important to inform your plastic surgeon if you use birth control pills or 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 coagulation 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 are often 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.

ADDITIONAL SURGERY NECESSARY (Reoperations)
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. If complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this surgery. Other complications and risks can occur but are less common. 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 if additional surgery is advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, and pathology and lab testing fees.

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 activities need to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful postoperative 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 important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery

ATTESTATIONS

Smoking, Secondhand 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 loss and delayed healing and additional scarring. Individuals exposed to secondhand 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 these types of complications. Please indicate your current status regarding these items below**:**

 _____ **Patient Initials**

__I am a nonsmoker and do not use nicotine products. I understand the potential risk of secondhand 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.

___ I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

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 or blood test just before surgery may be done that 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 continuous positive airway pressure (CPAP) devices 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 preexisting medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting to reduce risk of potential respiratory complications and to manage pain safely 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.

DVT/PE Risks and Advisory:

There is a risk of blood clots, DVT, and 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
_____ Use of Birth Control Pills
_____Use of Hormone Stimulating Drugs
_____ Swollen Legs
_____ History of Cancer
_____ Use of Large Dose Vitamins
_____ Varicose Veins
_____ Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract
_____History of Multiple Spontaneous Abortions or Miscarriages

_____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)

____Anticoagulation protocols when allowed

For high-risk patients, the risks of VTE are still high, even in the setting of appropriate chemoprophylaxis. If your surgery is elective and you are a high risk patient, it is best to consider with not proceeding with such elective surgery.

COMMUNICATION ACKNOWLEDGEMENT – CONSENT

There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communicating are by telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted to your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there is a delay in retrieving such messages. All attempts will be made to preserve your privacy in accordance with HIPAA rules.

Please confirm below all acceptable ways of communicating with you:

____ Telephone
____ Home (- -)
____ Work (- -)
____ Cell (- -)
____ Text
____ Pager – answering service if available
____ Email – with up-to-date email address (@)
____ Regular mail and delivery

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 that 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.

 _____ **Patient Initials**

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as may be selected to perform **Breast Reconstruction with TRAM Abdominal Muscle Flap Surgery**.

   I have received the following information sheet: **Breast Reconstruction with TRAM Abdominal Muscle Flap Surgery.**

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of their 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 am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.

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. I opt out of having this procedure _____.

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/Time _____ Witness _____

 _____ **Patient Initials**