BOICE-WILLIS CLINIC, PA

Patient Name: _____ DOB: _____ MRN: _____

Informed Consent

Breast Reconstruction with DIEP Flap

Patient Name: _____ DOB: _____ MRN: _____

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, and 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 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 of 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. However, breast reconstruction techniques and results may be affected by the administration of other forms of breast cancer treatment.

The DIEP flap technique of breast reconstruction involves the use of lower abdominal skin and fatty tissue with as little as possible 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 reconnected to the blood vessels on the chest to reestablish the 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 the TRAM (transverse rectus abdominis myocutaneous) abdominal muscle flap breast reconstruction but attempts to preserve the “six-pack” rectus abdominis 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
- History of radiation to chest wall after mastectomy
- Patients with concerns about breast implants
- Failure of earlier breast reconstruction

Contraindications to the DIEP flap breast reconstruction procedure include:

- A patient who is medically or psychologically unsuitable for breast reconstruction
- A patient who has a history of abdominal surgery that 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.

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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 a DIEP flap for breast reconstruction than there is with certain 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 tissue or DIEP flap die. This may require frequent dressing changes or further surgery to remove the dead 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. Secondhand 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 usually 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 substantial 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 may 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 reestablish 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, 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 may become weak and produce a hernia. Very rarely, reoperation 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.

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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, an 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 reconnected 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 flap 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 breastfeed 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 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 owing to complications attributable to the mastectomy surgery or to chemotherapy/radiation therapy, which are independent of the DIEP 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. Women 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, undergo mammography according to the American Cancer Society guidelines, and seek professional care should a breast lump be noticed. 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 a 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 separate, small incision. The drain will be removed when your doctor feels it is no longer necessary. The drain site may be closed at the time of drain removal. Closing the drain

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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 that need additional medical care, surgery, and prolonged hospitalization. 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. The recovery period may also be longer because of 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, sooner for some than for 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 may become too active during the healing period, producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage and early nonsurgical intervention resolve 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. Should postoperative bleeding occur, 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. 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 a risk of blood-related infections such as hepatitis and HIV (AIDS). Your surgeon may provide medications after surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can result in bleeding and decreased blood platelets.

Infection:

Infection, although uncommon, can occur 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 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 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 can be essential to have regular bowel function after your surgery.

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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 a different color from 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 high or low 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.

Damage to Deeper Structures:
There is potential for injury to deeper structures including nerves, blood vessels, lymphatics, 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 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 because of nerves becoming trapped in scar tissue or because of tissue stretching.

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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 may become too active during the healing period, producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage and early nonsurgical intervention resolve this. It is important to discuss postsurgical pain with your surgeon.

Cardiac and Pulmonary Complications:
Pulmonary complications may occur secondary 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 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 pain, or unusual heartbeats, seek medical attention immediately. Should 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 now 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 diluted 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, which may not be recognized in advance. One side of the face may be slightly larger, while one side of the face may be droopier. The breast and trunk areas exhibit the same possibilities. Many of these issues cannot be fully corrected with surgery. The more realistic your expectations as to results are, 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

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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 the formation of 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®, 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 using 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, 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 of 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 surgery can be appropriately scheduled. There are no guarantees that you will be able to resume all activities in the desired time frame. Allow at least 10–14 days to travel via an airplane. Medications may be required should you have a long flight/trip to prevent DVT/PE (deep vein thrombosis/pulmonary embolus) 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 informed that an infection could develop from this activity. Body-piercing jewelry should be removed prior to your surgical procedure.

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Nails:
To determine your vitals during surgery, your anesthesia provider may require access to your fingernails for monitoring. Make sure you 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.

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:
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 results 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 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 should additional surgery be 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 activity needs 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.

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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 the items below**:**

__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, which will prove the presence of nicotine. If positive, your surgery may be cancelled, and your surgery fee, 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 (continuous positive airway pressure) devices or utilize nighttime oxygen are informed that they are at a substantive risk of 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 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.

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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 greater the risk factors, the higher 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 the risk of clotting. Inform your doctor about any history of any of the following:

_____ 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 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 include telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted of 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

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DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with the 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.

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CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Karen Szymanski, DO, MPT and such assistants as may be selected to perform **Breast Reconstruction with DIEP Flap Surgery.**

   I have received the following information sheet: **Breast Reconstruction with DIEP 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 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 that 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 surgeon's fee is separate from the anesthesia and hospital charges, and the fee is 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**