

“MEDICAL INTERVENTION (SURGERY) RISKS” Annex #2

INFORMED CONSENT – FAT TRANSFER PROCEDURES

FAT GRAFTS AND INJECTIONS

INSTRUCTIONS

This is an informed-consent document that has been prepared to help your plastic surgeon inform you of fat transfer (fat grafts or fat injection procedures), its risks, and alternative treatments.

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

A person's own fat may be used to improve the appearance of the body by moving it from an area where it is less needed (usually the thighs or abdomen) to an area that has lost tissue volume due to aging, trauma, surgery, birth defects, or other causes. Typically, the transferred fat results in an increase in volume of the body site being treated. Before the procedure, the areas from where the fat is being removed may be injected with a fluid to minimize bruising and discomfort. The fat may be removed from the body by a narrow surgical instrument (cannula) through a small incision or may be excised (cut out) directly through a larger incision. In some cases the fat may be prepared in a specific way before being replaced back in the body. This preparation may include washing, filtering, and centrifugation (spinning) of the fat. The fat is then placed into the desired area using either a smaller cannula or needle, or it may be placed directly through an incision. Since some of the fat that is transferred does not maintain its volume over time, your surgeon may inject more than is needed at the time to achieve the desired end result. Over a few weeks, the amount of transferred fat will decrease. At times, more fat may need to be transferred to maintain the desired results. Fat transfer procedures may be done using a local anesthetic, sedation, or general anesthesia depending on the extent of the procedure.

ALTERNATIVE TREATMENTS

Alternative forms of nonsurgical and surgical management consist of injections of man-made substances to improve tissue volume (such as hyaluronic acid, polylactic acid, etc.), use of man-made implants, or other surgical procedures that transfer fat from the body (flaps).

Risks and potential complications are associated with alternative forms of treatment.

RISKS OF FAT TRANSFER PROCEDURES

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

Specific Risks of Fat Transfer Surgery

Change in Appearance: Typically the transferred fat loses some of its volume over time and then becomes stable. It is possible that more treatments may be needed to maintain the desired volume of the transferred fat and resulting appearance. Less commonly, if you experience significant weight gain, the transferred fat may increase in volume and cause an undesirable appearance. It is important to understand that more than one treatment may be needed and therefore to discuss with your surgeon the costs associated with repeat treatments.

Firmness and Lumpiness: While most transferred fat results in a natural feel, it is possible that some or all of the fat may become firm, hard, or lumpy. If some of the fat does not survive the transfer, it may result in fat necrosis (death of transferred fat tissue), causing firmness and discomfort or pain. Cysts may also form at the site of the transferred fat. Surgery may be required to improve such conditions.

Asymmetry: Symmetrical body appearance may not result from a fat transfer procedure. Factors such as skin

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tone, fatty deposits, bony prominence, and muscle tone may contribute to normal asymmetry in body features.

Long-Term Effects: Subsequent changes in the shape or appearance of the area where the fat was removed or placed may occur as the result of aging, weight loss or gain, or other circumstances not related to the fat transfer procedure.

Tissue Loss: In rare cases, the transferred fat may cause the skin over the treated area to be injured resulting in loss of the skin and surrounding tissue. This may leave scars and disfigurement and require surgery for treatment.

Fat Transfer to Breasts: Fat transfer has been used to improve the appearance of breasts reconstructed after cancer treatment, to improve the appearance of breast deformities, and to enlarge breasts for cosmetic purposes. While there is limited information regarding the long-term implications of such procedures, there are some potential concerns especially with regards to breast cancer detection. Since the transferred fat may become firm and cause lumps, it may be necessary to have radiological studies (mammogram, ultrasound, or MRI) performed to be sure these lumps are not due to cancer. It is also possible that the firmness may make it more difficult for you or your doctor to examine the breasts. It is also possible that a biopsy may be needed if there is concern about any abnormal findings in your breasts. However, there is no reason to believe that fat transfer procedures may cause breast cancer.

Serious Complications: Although serious complications have been reported to be associated with fat transfer procedures, these are very rare. Such conditions include, but are not limited to: **Fat embolism** (a piece of fat may find its way into the blood stream and result in a serious or life threatening condition), **stroke, meningitis** (inflammation of the brain), **serious infection, blindness or loss of vision, or death.**

Blood Clots: Blood clots in the veins of the arms, legs, or pelvis may result from from fat transfer if it is done as a surgical procedure. These clots may cause problems with the veins or may break off and flow to the lungs where they may cause serious breathing problems.

Pulmonary Complications: Pulmonary (lung and breathing) complications may occur from both blood clots (pulmonary emboli) and partial collapse of the lungs after general anesthesia. Should either of these complications occur, you may require hospitalization and additional treatment. Pulmonary emboli can be life- threatening or fatal in some circumstances. Fat embolism syndrome occurs when fat droplets are trapped in the lungs. This is a very rare and possibly fatal complication of fat transfer procedures.

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, and the length of surgery and anesthesia that include a longer recovery and the possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting goals and expectations, and added expense to the patient. 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 during 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 as-

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pirin 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 or 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, infections in other parts 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 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

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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 delayed 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 involve 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 both 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 pain, 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.

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.

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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, 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.

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 clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve. 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 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 sun block or clothing coverage.

Travel Plans: Any surgery holds the risk of complications that may delay healing and delay 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.

Disease: Cancer can occur independently of surgery. Individuals with a personal history or family history of cancer may be at a higher risk of breast cancer than someone 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.

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

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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 and 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.

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.

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.

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.