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Informed Consent For Fat Transfer Procedures (Fat Grafts and Fat Injections)

(PLEASE REVIEW AND BRING WITH YOU ON THE DAY OF YOUR PROCEDURE)

PATIENT NAME: _____

PROCEDURE NAME: _____

PROCEDURE DATE: _____ **TIME:** _____

Patient Initials _____

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you concerning 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 the procedure or surgery as proposed by your physician.

INTRODUCTION

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 minimized 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 physician 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 physician to make sure you understand the risks, potential complications, and consequences of the procedure.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after this procedure. Should bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Do not take any blood thinning medications, aspirin, or nonsteroidal anti-inflammatory medications (acetaminophen is acceptable) for ten days before the procedure, as these may contribute to a greater risk of bleeding or significant bruising. Tell your physician if you are on any of these medications before stopping them.

Seroma- Although unlikely, a collection of fluid may appear at the site where the fat was removed. This is usually treated by draining the fluid with a needle.

Infection- Infection is unusual after this procedure. Should an infection occur, additional treatment including antibiotics or surgery may be necessary.

Scarring- All invasive procedures leave scars, some more visible than others. Although good wound healing after a procedure is expected, abnormal scars may occur both within the skin and in the deeper tissues. Scars may be unattractive and of different color than the surrounding skin. There is the possibility of visible marks from sutures used to close the wound. Scars may also limit motion and function. Additional treatments including surgery may be needed to treat scarring.

Risks of Fat Transfer Procedures, continued

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 physician the costs associated of 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 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.

Pain- Chronic pain may occur rarely after fat removal or transfer.

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.

Damage to deeper structures- Deeper structures such as nerves, blood vessels, or muscles may be damaged during the course of this procedure. The potential for this to occur varies according to where on the body the procedure is being performed. Injury to deeper structures may be temporary or permanent.

Unsatisfactory result- There is the possibility of an unsatisfactory result from the procedure, resulting in unacceptable visible deformities, loss of function, wound disruption, skin death, or loss of sensation. You may be disappointed with the results of the procedure.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may result from drugs used during the procedure or prescription medicines. Allergic reactions may require additional treatment.

Surgical anesthesia- Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Risks of Fat Transfer Procedures, continued

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 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.

ADDITIONAL SURGERY NECESSARY

In some situations, it may not be possible to achieve optimal results with a single procedure. Multiple procedures may be necessary. Should complications occur, surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited above are the ones that are particularly associated with fat transfer procedures. 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 cannot be any guarantee or warranty expressed or implied on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of the procedure involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, depending on where the surgery is performed. Depending on whether the cost of the procedure is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the procedure. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY, PROCEDURE or TREATMENT

1. I hereby authorize _____ and such assistants as may be selected to perform the following procedure or treatment:

Fat transfer including fat injections and fat grafts

I have received the following information sheet:

INFORMED-CONSENT FAT TRANSFER PROCEDURES

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 acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
- a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE 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 (1-9). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____