

## **INFORMED CONSENT –FAT INJECTION**

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# INFORMED CONSENT – FAT INJECTION

## **INSTRUCTIONS**

This informed-consent document has been prepared to help inform you about Fat tissue-filler injection therapy (transfer of fat from one part of your body to another), 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 this procedure as proposed by your plastic surgeon and agreed upon by you.

## **GENERAL INFORMATION**

Fat transfer involves the harvest of fat with a cannula from one area of the body and the injection of that fat to another. Fat transfer allows for permanent soft tissue filling, but requires multiple applications for the best results. Fat transfer unlike other tissue fillers may be long-lasting, but it can not be taken off the self. This makes Fat transfer more complicated, time consuming, and costly than other tissue-fillers. Fat transfer is best performed in the Operating Room at the time of another cosmetic procedure or surgery.

Fat transfer should be customized for every patient, depending on his or her particular needs. Fat transfer cannot stop the process of aging, but it can result in long-lasting improvements when strategically placed. It can diminish the appearance of wrinkles and soft tissue depressions and provide soft tissue enhancement reflective of youth. Fat transfer may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Fat transfer usually requires regional nerve blocks, local anesthetic injections, or general anesthesia in both the area of injection and harvest to diminish discomfort. Soft tissue fillers, including Fat, produce temporary swelling, redness, and needle marks, which resolve after a several weeks time.

Multiple applications of fat are usually required to maintain a long-lasting effect. Fat once injected will be partially absorbed by the body. The results of Fat transfer can be unpredictable and requires multiple applications. Results are best in areas without scars or better blood flow such as the head and neck areas.

## **ALTERNATIVE TREATMENTS**

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, other skin procedures, or dermabrasion, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

## **COMPLICATIONS OF FAT INJECTIONS**

Every procedure to inject soft tissue fat involves a certain amount of risk, and it is important to understand the risks and potential complications involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should make sure you understand the risks, potential complications, limitations, and consequences of fat transfer with fat harvest and injections. Problems associated with the use of fat injection relate to normal occurrences or potential complications following tissue harvest or injections. Additional advisory information should be reviewed by patients considering fat transfer or injection.

## **NORMAL OCCURRENCES DURING FAT INJECTIONS**

**Bleeding and Bruising-** It is possible, though unusual, to have bleeding from a fat injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other "herbs / homeopathic remedies" may contribute to a greater risk of bleeding. Do not take any of these products for seven days before or after fat transfer.

**Swelling-** Swelling (edema) is a normal occurrence following the harvest and injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

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**Erythema (Skin Redness)**- Erythema in the skin occurs and can be present for a few days.

**Needle Marks**- Visible needle marks from the injections occur normally and resolve in a few days.

**Skin Eruptions**- Acne-like skin eruptions can occur and generally resolves within a few days.

**Skin Lumpiness**- Lumpiness can occur following the injection of fat. This tends to smooth out over time. In some situations, it may be possible to feel the injected fat for long periods of time. Sometimes surgery is required or steroid injection to treat lumpiness.

**Visible Tissue Filler Material**- It may be possible to see tissue filler material or fat that was injected in areas where the skin is thin or irregular.

**Asymmetry**- The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with fat transfer. There can be a variation from one side to the other in terms of the response to fat. This may require additional injections

**Pain**- Discomfort associated with fat transfer is normal and usually of a short duration.

**Skin Sensitivity**- Skin rash, itching, tenderness and swelling may occur following fat injections. After treatment, you should minimize excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling or any other procedure, or you have recently had such treatments and the skin has not healed completely, there is a possible increased risk of an inflammatory reaction.

### **RISKS OF FAT INJECTIONS**

**Infection**- Although infection following injection of tissue fillers or fat is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** infections around the mouth can occur following a fat transfer. This applies to both individuals with a past history of virus infections and individuals with no known history of virus infections in the mouth area. Specific medications must be taken both prior to and following the treatment to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

**Damage to Deeper Structures**- Deeper structures such as nerves, blood vessels, and soft tissues may be damaged during fat transfer. Injury to deeper structures may be temporary or permanent.

**Skin Necrosis**- It is very unusual to experience death of skin and deeper soft tissues after fat transfer. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary.

**Granulomas or Necrosis**- Painful masses in the skin and deeper tissues after fat injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.

**Allergic Reactions and Hypersensitivity**- As with all biologic products, allergic reactions and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

**Scarring**- Fat transfer should be avoided in patients with know susceptibility to keloid formation, hypertrophic scarring or pigmentation disorders.

**Skin Disorders**- Fat transfer should be avoided in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives).

**Antibodies to Fat** - Presence of antibodies to your own fat is rare but may reduce the effectiveness or produce a reaction in subsequent injections. The health significance of antibodies to fat tissue is unknown.

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**Accidental Intra-Arterial Injection**- It is extremely rare that during the course of injection, fat could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection of fat is not fully predictable or preventable.

**Under / Over Correction**- The injection of soft tissue fillers including fat to correct wrinkles and contour deficiencies will not usually achieve the desired outcome with one application. Only about 50% of the fat applied usually will be long-lasting. The amount of correction may also be inadequate or excessive. It may not be possible to control the process due to factors attributable to each patient's situation. If under correction occurs, you may want additional injections of tissue filler materials.

**Migration of Fat** – Fat may rarely migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

**Harvest of Fat** – Fat transfer requires the harvest of fat from an area of the body (usually the abdomen, flank, or thighs) for the transfer to another area of the body. The risks associated with the harvest of fat are the same risk associated with liposuction. The risks of fat harvest include contour irregularities, bleeding, fluid formation, numbness, pain, scarring, and poor cosmetic results. After fat is harvested a period of compression is required over that area to avoid complications and improve shape.

**Drug and Local Anesthetic Reactions**- There is the possibility that a systemic reaction could occur from either the local anesthetic or epinephrine used for sensory nerve block anesthesia when fat is transferred. This would include the possibility of light-headedness, rapid heart beat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

**Deep Venous Thrombosis, Cardiac and Pulmonary Complications**- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Fat embolism syndrome occurs when fat droplets are trapped in the lungs. This is a very rare and possibly fatal complication of fat transfer. 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 and fat 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 blood clots, swollen legs or the use of estrogen or birth control pills that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

### **ADDITIONAL ADVISORIES**

**Unsatisfactory Result**- Fat injections alone may not produce an outcome that meets your expectations. There is the possibility of a poor or inadequate response from fat transfer. Additional fat injections are almost always required for the best results. Surgical procedures or other treatments may be recommended in addition to fat transfer.

**Prosthetic or Medical Device Injury or Adverse Interaction**- Some patient have had medical devices or stimulators placed in proximity to Fat or Filler injection sites. Injection or harvest of Fat in or around these areas could injure, potentiate infection, deactivate, or result in removal or failure of such devices. In general, our practice will not inject in proximity to the probes. All patients with such devices will require a written release or letter of medical clearance prior to Fat Transfer or any other injection application. It is the patient's duty to report such devices to our practice and Dr. Lowe to avoid complications or incident.

**Unknown Risks**- There is the possibility that additional risks and complications attributable to the use of fat as a soft tissue filler material may be discovered.

**Combination of Procedures**- In some situations, BOTOX® injections or other types of tissue filler materials may be used in addition to fat in order to specifically treat areas to enhance the outcome. The

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effect of other forms of skin treatments (laser and other light therapies, micro-dermabrasion, dermabrasion, or chemical peels) on skin that has been treated with fat is unknown.

**Pregnancy and Nursing Mothers-** Animal reproduction studies have not been performed to fully determine if fat transfer could produce fetal harm. It is not known if fat or breakdown products can be excreted in human milk. Pregnant women or nursing mothers should not receive fat treatments.

**Drug Interactions-** It is not known for sure if fat reacts with other drugs within the body.

**Long-Term Effects-** Fat injections are a long term treatment for the correction of wrinkles and soft tissue depressions. There are some patients who partially or completely absorb fat injection materials. Over time, the fat material can be partially or fully absorbed by the body and wrinkles or soft tissue depressions will reappear. The area of concern will continue to age even if the fat remains. Multiple fat transfers are necessary in order to obtain full correction in most cases. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to fat injections. Future surgery or other treatments may be necessary. Fat injection does not arrest the aging process or produce permanent tightening of the skin.

### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for fat injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

### **ADDITIONAL TREATMENT NECESSARY**

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of fat transfer. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with fat injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. 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.

### **FINANCIAL RESPONSIBILITIES**

This treatment provides a defined amount of fat transfer for the treatment of wrinkles and other conditions. If additional interim treatments are needed in order to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. Additional costs of medical treatment would be your responsibility should complications develop from fat injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions along with the financial costs of all future treatments.**

### **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). 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 which is based on all of the facts pertaining to 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 Dr. Lowe and such assistants as may be selected to perform the following procedure or treatment:

**FAT INJECTION** (may list the anatomic areas where injected)

I have received the following information sheet:

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- 2. I recognize that during the course of the procedure 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 or representation has been given by anyone as to the results that may be obtained.
- 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 treatment room.
- 7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
- 8. 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.
- 9. I realize that not having the procedure is an option.
- 10. 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
  - d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10). I AM SATISFIED WITH THE EXPLANATION.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date \_\_\_\_\_ Witness \_\_\_\_\_