LIPODISSOLVE MICRO-INJECTIONS
FOR REDUCTION OF LOCALIZED FAT DEPOSITS

Informed Consent / Patient Agreement

To be completed by the patient, parent, or guardian
and signed by the health care provider

Read each item below and initial in the space provided if you understand each item and agree to follow your health care provider's (provider) instructions. A parent or guardian of a patient under age 18 must also read and understand each item before signing the agreement.

Do not sign this agreement and do not accept Lipodissolve therapy if there is anything that you do not understand of all the information you have been given about Lipodissolve.

1. I, _____,

(PATENT NAME) understand that Lipodissolve is a non-surgical procedure intended for the reduction of localized fat deposits for patients unwilling or unable to undergo surgical liposculpture. Lipodissolve is intended for body and facial contouring of small areas of localized fat. The therapy is not a weight loss therapy and does not guarantee loss of actual body weight. The therapy is not a replacement to surgical procedures.

Initials: _____

2. My provider has told me about my choices for body and facial contouring that may include surgery apart from Lipodissolve. I have been adviced to not accept the procedure if I suffer from any disease or am taking any medication that may cause unexpected reactions.

Initials: _____

3. In regards to my Lipodissolve consultation and treatment I have been thoroughly informed about the following contraindications, adverse indications and side effects:

Absolute Contraindications (must not be treated):
Children, pregnancy, nursing mothers, Diabetics (blood glucose disorder) with with vascular diseases (microangiopathies), Liver diseases, infectious diseases

Possible adverse indications from the medications:
- Autoimmunopathy (e.g. thyrosis)
- serious liver diseases
- acute infections and chronic infection risk (adipositas per magna BMIS>30)
- known hypersensitivity against one of the substances (e.g. soybean allergy)
- serious renal disease
- allergies
- coagulation defects
- menstrual cycle defects

General risks (that can occur with any injections):
- nervous lesions which might be permanent
- infection with subsequent scar formation
- e.g. abscess due to injections

Lipodissolve Expected Side effects:
- swelling and excessive warmth of the injection spot
- haematoma (bruising)
- serious adiposity
- sensitivity to touch
- pain in the treatment area
- itching

Lipodissolve: Possible side effects (of the body)**:**
- reddenings or discolorations which might remain long-term
- formation of nodes which might stay long-term
- temporary circulatory insufficiency; increased perspiration, feeling of nautia
- allergic reactions (very rare) like nettle rash, bronchial asthma, shock symptoms
- retribulbal bleeding/blindness from wrong injection (eye fat pads)

Initials: _____

In addition, the following facts have been discussed with me:

4. Although Lipodissolve is viewed as mild and safe cosmetic procedure, I understand that the possibility of other unknown or long-term reactions should not be ruled out due to the short known history of Lipodissolve with unavailable patient studies on long-term effects. Agreeing to treatment I accept 100% responsibility for these should they occur.

Initials: _____

5. I am informed that Lipodissolve therapy include the mixture of pharmaceutical agents in an injectable formula and can include Multivitamin or Vitamin B, E, Pentoxifyllin/Aminofyllin, Phosphatidylcholine, NaCl, Buflomedil. Unknown or unexpected allergies against these substances may require emergency care in a hospital setting. Any emergency care or continued treatment resulting from an emergency situation is the full financial and legal liability of the patient and is not covered by this clinic or the treating physician.

Initials: _____

6. I am aware that Lipodissolve require repeated sessions to obtain results and the time-frame for results wary from patient to patient. The procedure address the dissolution of fat, not of re-contouring of other tissue. I further understand that some patients have limited results from Lipodissolve therapy due to other conditions, or metabolic disorders, that may be unpredictable in advance (ex. hypothyreosis), or may require additional sessions than what has initially been evaluated. An estimated 4% of patients have *no response* to the therapy even after repeated sessions.

Initials: _____

7. Before I start accepting Lipodissolve therapy, I agree to tell my health care provider if, to the best of my knowledge, I have ever had symptoms of allergies against any medication or substance; if I am on medication; or if I may fall within category 3.

Initials: _____

8. I agree to return to see my physician every 30-60 days or as adviced when I undergo Lipodissolve therapy to complete the therapy, to evaluate my progress, and to inspect for signs of possible side effects.

Initials: _____

9. I have been informed that Lipodissolve therapy may include pharmaceutical agents that are administered off-label for fat dissolve procedures and have not been manufactured for the specific purpose of dissolving fat. These substances are administered for localized fat reduction procedures per my request and consent.

Initials: _____

10. I have decided I should undergo Lipodissolve therapy. I understand that I can stop taking Lipodissolve at any time even if prematurely at no liability to the physician or the clinic.

Initials:_____

The meaning of 'off-label' use

Lipodissolve is a therapy with off-label use of medications. In the United States, the regulations of the Food and Drug Administration (FDA) permit physicians to prescribe or use approved medications for other than their intended indications.

This practice is known as “off-label use” or “unlabeled uses”. Such uses are not indicative of inappropriate usage but are common. It means that the substances used in Lipodissolve are labeled for other conditions or uses than the clinical use, ex. the localized dissolution of fat. To access more information on off-label use please see FDA’s website: www.fda.gov/cder/

I now authorize my physician, Dr _____ to begin my treatment with Lipodissolve and release Dr_____ and the staff at _____ of any liabilities whatsoever, including legal fees or legal or medical liabilities, that may result from the therapy.

Patient signature _____

Date_____

Patient Name (print) _____

Patient Address_____

_____

Telephone (_____-_____-_____)

I have fully explained to the patient, _____, the nature and purpose of Lipodissolve treatment, including its benefits and possible even if unknown risks, and asked the patient if he/she has any questions regarding his/her treatment with Lipodissolve and answered those questions to the best of my ability.

Physician signature: _____ Date: _____