

| Dokuman No:   | YÖN.RB.135-01 |
|---------------|---------------|
| Yayın Tarihi: | 24.07.2014    |
| Rev.No:       | 00            |
| Rev.Tarihi:   |               |
| Sayfa no:     | 5/1           |
|               |               |

# LIPOSUCTION AND FAT INJECTION DERFOMAT INFORMED CONSENT FORM

| Date |          |      | /        | / /20      |   |
|------|----------|------|----------|------------|---|
| Dear | Patient. | Dear | Parent / | / Guardian | 1 |

This form has been prepared to inform patients and their relatives about the surgery. The form should be read and than approved as a legal requirement. The information forms are provided to explain the foreseen risks and adverse conditions (complications) of surgical treatments, and to disclose information about other treatment options. Most of the identified risks are defined to meet the needs of patients in many circumstances. However, this form should not be considered as a document containing the risks of all forms of therapy. Depending on your own personal health condition or medical knowledge, your plastic surgeon can provide you different or additional information.

Please read carefully all the information listed below and do not sign the form on the last page before finding the answers to all your questions.

#### **GENERAL INFORMATION:**

This is an informed consent form prepared to inform you about the risks and alternative therapy methods of "liposuction" by vacuum and injection of withdrawn fat or the application of derfomat graft taken out from another area. Please read the form carefully. If you have any questions or issues would like to clear, please consult your doctor. Your doctor will provide you an additional written statement upon your request.

Liposuction is a technique that allows the suction of the unwanted, excessive fat from certain areas of the body. The face, neck, cheeks, arms, abdomen, hips, outer thighs, anterior thighs, inner thighs, knees, buttocks and ankles are the most commonly treated areas. Liposuction is not a weight loss method. Liposuction is used to remove fat deposits which can't be eliminated with diet and exercise. Liposuction can be used as a single intervention in body contouring treatment, or together with other methods such as face lifts, abdominoplasty, thigh lifts.

The best candidates for liposuction are people who are of relatively normal weight, and have excess fat deposits in specific areas of the body. Having healthy and elastic skin will result in a better outcome after liposuction. However, sagging skin won't fit to the new contours and additional surgical procedures may have to adapt to achieve a lifted skin. The body contour defects caused by excessive tissue, except fat, may not be eliminated by liposuction. Liposuction can not remove, by itself, the orange peel appearance of the skin known also as, "cellulite".

There are different methods for liposuction and postoperative care techniques applied by plastic surgeons. Your surgeon may suggest transfusing one unit of your blood, in case it may be needed postoperatively.

#### **Alternative Therapy**

There is no alternative therapy for removing fat deposits. Diet and hard exercise can provide fat reduction in multiple areas. In some patients, in addition to liposuction, the excess skin and fat tissue may be necessary to taken out directly.

The risks and potential side effects are related with surgical methods as an alternative treatment.

## Risks of Liposuction Surgery:

Every surgical procedure has a certain amount of risk. There are also risks and complications in liposuction surgery. The comparison of risks and benefits of the intervention required by the person is essential. Although many patients don't experience below stated complications, please discuss the risks, possible complications and results with your plastic surgeon until you are convinced and sure to understand the issue at all points.

Selection of patient: Obese, people with unrealistic expectations, medical problems and weak skin tone can not be a candidate for liposuction.

<u>Bleeding</u>: a rare entity of bleeding is likely to encounter during or after surgery. In case of postoperative bleeding, the accumulated blood (hematoma) must be drained as an emergency. Starting ten days prior to surgery, Aspirin or non-steroid anti-inflammatory drugs must not be taken, since they may increase the risk of bleeding.



| D.I N.        | VÖN DD 405 04 |
|---------------|---------------|
| Dokuman No:   | YÖN.RB.135-01 |
| Yayın Tarihi: | 24.07.2014    |
| Rev.No:       | 00            |
| Rev.Tarihi:   |               |
| Sayfa no:     | 5/2           |

<u>Infection</u>: Infection is not a usual condition after this type of surgery. If any infection develops, the treatment includes use of antibiotics or an additional surgery.

<u>Change in Skin Sensation</u>: The formation of numbness after liposuction is a normal state. This is usually a temporary condition and generally disappears spontaneously. Reduced sensation and total lost may rarely occur and this may be also permanent.

<u>Scarification:</u> However a good wound healing after surgery is expected, abnormal scars may occur on the skin and deeper tissues. This situation occurs rarely. In case of abnormal scarification additional treatments, including surgery may be required.

<u>Skin Contour Disorders</u>: Some skin disorders and collapses may occur after liposuction. Visible wrinkles on the skin may occur and be felt by hand. Additional treatments including surgery may be needed to correct this situation.

<u>Asymmetry</u>: After liposuction, the symmetrical body appearance may not be obtained. The asymmetry may also present previously in the body, due to factors such as skin tonus, bone protrusions and muscle tonus.

<u>Surgical shock:</u> Occasionally, the interventions where especially more than one and large areas in a single session are treated, may cause severe trauma. Although severe side affects are rarely encountered, the infections and excessive dehydration may cause severe statements, even to death. In case post-surgical shock develops after liposuction, inpatient treatment may be needed.

<u>Pulmonary complications (negative results):</u> The fat embolism syndrome may develop due to the fat droplets to remain stuck in the lungs. This is very rare, though potentially fatal complication of liposuction. In case of fat embolism or other pulmonary complications (negative result) develop, inpatient treatment may be required.

Skin loss: Loss of skin after liposuction is rare. Additional treatments including surgery may be required.

<u>Seroma</u>: The fluid accumulation may rarely occur in the liposuction applied areas. Additional treatments or surgery may be required to drain this accumulation.

<u>Long-term effects</u>: Some changes in body contour may occur due to the reasons other than liposuction such as aging, weight gain / loss, pregnancy.

<u>Allergic Reactions</u>: In rare cases, allergic reactions to bandages and suture materials, or to creams have been reported. More serious systemic reactions may develop to drugs used during treatment or prescribed after surgery.

<u>Not Satisfactory Results</u>: You may be disappointed because of the result of the intervention you underwent. Additional surgery may be needed to correct this kind of results.

<u>Surgical anaesthesia</u>: Both local and general anesthesia carries risks. Unwanted situations even death likely to occur in all surgical anesthesia and sedation operations.

### **Dermofat graft or Fat Injection**

EE Methods to be used in various parts of the face and body to add volume and plump up are fat and tissue injections and dermofat graft applications. Sunken areas on cheeks, forehead, cheek-lip line, lips, chin tip, hips and legs are treated by this procedure.

Dermofat graft (consist of hard surface of the skin and a portion of fatty tissue and is obtained by peeling the upper layers of the skin) is harvested during intervention from another area or by entering from the scar of previous intervention you underwent, if any, or from a hidden area of the body. On the liposuction area remains more or less scar. 1 or 2 pieces of 3-4 mm long incision should be performed on the area where dermofat graft to be applied. Compared to fat injection, the remaining amount can be accurately predict in advance, however, since the liposuction amount is limited, is insufficient as a filling material for the large area.

Fat injection: Individual's own body fat is treated by some specific procedures like isolation and cleansing, and concentrated body cells obtained through this procedures are injected to related area by means of thin tubes. If also other interventions are performed in the same time, the tissues obtained in this operation can be also added to the



| Dokuman No:   | YÖN.RB.135-01 |
|---------------|---------------|
| Yayın Tarihi: | 24.07.2014    |
| Rev.No:       | 00            |
| Rev.Tarihi:   |               |
| Sayfa no:     | 5/3           |

fat tissue and injected. Since these are individual's own tissues, any undesirable effect and results are not expected. In addition, the injection is performed form very small points, so no scar on the injection area is expected.

In fat injection procedures, usually areas with excessive fat deposits are preferred for liposuction. These areas are often the abdomen, waist, and (generally in women) hips.

The tissue growing to be obtained by fat injection is limited. For this reason the expectations must be realistic. If an excessive amount of growth is desired, the use of permanent implants should be preferred. In order to test, first fat injection is performed, and than if desired, implant can be applied.

Since a portion of the injected tissues are absorbed by the body, new injections may be needed after a period of time. The application area, amount, situation of the obtainable tissues are evaluated and the effectiveness of this process and outcomes are discussed. Absorption rate may vary between 30-70%. This amount varies depending on the injection the area, whether it's moving or none. The retention and absorption rate in none moving areas such as chin tip and forehead is different compared to moving areas like mouth.

Another application in this matter is withdrawal of more than needed fat and tissue, during the first transaction and storing them in a tissue bank to make preparation for future injections.

Blood thinners agents such as aspirin should be avoided for a period of 10 days before the operation. In addition, eventual disorders in patient's history and continuously used drugs, if any, must be reported to doctor.

Fat injections can be performed with sedation and local anaesthesia or local anaesthesia only. Hospitalization is not required for this kind of intervention, so the patient may be discharged form hospital on the same day, few hours later than the operation.

As soon as the fat injection operation is completed, cold compress is applied to reduce swelling in the operation area. The cold application is done every one hour by using gels or ice-filled bags on related area for 15 minutes. The ice should not touch the skin directly. The ice or gel filled bag is wrapped with a cloth or towel and applied to operation area.

After the procedure, especially in the first two days, on the application area swelling beyond the amount of injection is expected. This swelling will decrease over time. However, the injection of lip area and the swelling may take longer, sometimes may be extreme. On the following day, the application area can be washed and applied moisturizing cream. Form the 4<sup>th</sup> -5<sup>th</sup> day, massaging lightly the application area may help to eliminate the swellings. Avoid extreme heat and steam, since they increase the swelling.

Fat injection, except for the first few days, in general do not cause disturbance to affect daily life of people. Due to edema and bruises that may occur in some areas, home rest in the first two days will be appropriate.

Small bandages placed on the fat injection site may be taken out after a few hours or the next day. For protective purpose, the use of antibiotics is recommended for about 5 days. From the 5<sup>th</sup> day, the use of antibiotics is not need. If in any stage, the dwindling edema increases, or sensitivity and temperature rise occurs in the area, this may be a sign of infection. In this case, call your physician.

In the early period after the procedure, the appearance of the face or the injection area won't be only in injected fat color. In addition, since it's a surgical intervention, although it's a small, an edema is likely to occur on the area. The edema and the fat injection should not be confused to each other. The Edema dissipates quickly in the following days after surgery, decreases and disappears over time. The tissue augmentation procedure performed is a permanent method.

## Risk and Complications of the method (unwanted results)

<u>Bleeding</u>: In intraoperative and postoperative periods bleeding can be seen in the areas of operation. According to the amount of blood lost, blood transfusion may be needed.

<u>Infection</u>: Infection may be seen in surgical areas accompanied by redness, swelling, foul-smelling discharge, abscess formation and may require the use of antibiotics. Small incision to drain the infected area may be required.

<u>Asymmetry and Contour Variations</u>: In the cheek-lip junction channels and / or in lips, asymmetry, surface irregularities, dimpling, creanation counter disorders may occur. This condition may be resolved spontaneously over



| Dokuman No:   | YÖN.RB.135-01 |
|---------------|---------------|
| Yayın Tarihi: | 24.07.2014    |
| Rev.No:       | 00            |
| Rev.Tarihi:   |               |
| Sayfa no:     | 5/4           |

time, as may be permanent. Similarly, these problems may be seen also in recipient site.

<u>Image:</u> Considering that a portion, of the injected amount will be absorbed, more than required amount (10-to 30% more) is injected (overcorrection). Accordingly, due to the effect of edema, in the first few weeks, more than a normal swelling may be seen. Dermofat graft usually will not be greater than necessary, because absorption is more limited.

Bruising: is likely to occur on the surgery area. This usually disappears within 2-6 weeks.

<u>The injected fat absorption</u>: In some cases, the injected fat may be absorbed by the body within weeks. Similarly, all injected fat may be absorbed within 5-6 months after surgery.

<u>Sensory</u>: Numbness extreme sensitivity may occur on the liposuction area. This condition is usually temporary but occasionally may be permanent. Similar complaints can be seen depending on stress on fat injected area.

<u>Fat embolism:</u> The fat particles withdrawn form recipient site during preoperative liquid application may pass through blood vessels and reached to systemic circulation and may damage the circulation of lungs, brain or other organs or tissue. This situation can lead to serious consequences up to paralysis or death.

<u>Scars</u>: As a result of abnormal wound healing, significant scarring may occur on the suture lines (hypertrophic scar / keloid). The scar may occur on the site where the Dermofat graft is performed. Depending on the amount applied in the Dermograft area may develop 4-5 mm indefinable scars. Rarely, it can turn into an evil scar.

#### Additional Surgical Procedures that may be needed

In the early and late periods, there are different situations that may affect the results. There are risks and complications (negative result) other than aforementioned ones, although these are rarer. In case of complications, additional treatment and surgical intervention may be needed. In medicine and surgery there is no certainty. Although good results are expected, no warranty or guarantee about the obtainable results can be given.

### **Financial Liabilities**

Please ask whether **s**urgical cost covers the hospital and doctor's fees and also methods of payment. You will be liable for some additional charges and payments for some unexpected situation and treatments. Additional charges may occur in case some surgical complications (negative result) emerge. Fees for hospitalization for secondary surgery or revision (revision) will be also on your charge.

## **Declarations**

Informed consent forms are intended to explain surgical treatment of the disease or condition as well as the risks and alternative treatment methods. Informed consent process is intended to provide information about the risks that many patients can benefit in many cases.

However, the informed consent forms do not cover other treatment methods, and all risks. Your plastic surgeon may provide additional information in a clear manner, according to your medical knowledge level.

Informed consent forms are not prepared as a standard of medical care and can not to be used in this manner. Standards of medical care are determined on the basis of reality of individual's state and are open to change in line with scientific developments. Please read carefully all the information listed below and do not sign the form on the last page before finding the answers to all your questions.

## Fat Suction by Vacuum "Liposuction" And Fat Injection Dermofat Graft

My doctor explained my medical status and the proposed surgical procedure. I understood the risks of the surgery, risks special to me, and possible both positive and negative conditions (complications). My doctor declared to me other treatment methods, the associated risks, my possible medical prognosis and possible risks in case not being treated.

One information form of anesthesia was given to me. One patient information form was given to me.

I had a chance to talk about my medical condition and risks, also my questions about alternative treatments. My questions and my concerns are discussed in a satisfactory manner.

I agree to blood transfusion during surgery, if it's needed.

I know that the organs or tissues may be removed during surgery and they will be kept for a certain period of time for



Date:...../....../

# LİPOSUCTION VE YAĞ ENJEKSİYONU DERFOMAT İNGİLİZCE BİLGİLENDİRİLMİŞ ONAM FORMU

| Dokuman No:   | YÖN.RB.135-01 |
|---------------|---------------|
| Yayın Tarihi: | 24.07.2014    |
| Rev.No:       | 00            |
| Rev.Tarihi:   |               |
| Sayfa no:     | 5/5           |
|               |               |

testing purposes and then will be discarded by the hospital.

Time:....

My doctor told me that life-threatening events may happen during the surgery. I understood that, photo and video images can be taken during the operation. These can then be used for training of health workers. I understood that there is no guarantee that the surgery will improve or deteriorate my condition. I understood that if any previously unknown cases emerge during or after surgery, or during anesthesia, additional procedures, other than aforementioned ones may be needed. In this case, I approve that the above-mentioned doctors and assistants may decide the necessary interventions and proceed accordingly, besides I agree that, specialist of relevant fields who are deemed appropriate by them may participate to surgical intervention.

I HEREBY CONFIRM THAT I AM SATISFIED WITH THE VERBAL AND WRITTEN EXPLANATIONS. I CONSENT CONSCIOUSLY AND WITH MY OWN WILL TO ALL TREATMENTS APPLIED IN THE INTERVENTION OR SURGERY, ALSO TO TREATMENTS WHICH MAY BE NEEDED AFTER THE OPERATION, AS WELL AS TO ALL ABOVE STATED ISSUES AND VERBAL STATEMENTS DECLARED.

|                            | IF THE PATIENT'S UNCONSCIOUS AND    |
|----------------------------|-------------------------------------|
| IF THE PATIENT'S CONSCIOUS | ACCOMPANIED BY HIS/HER LEGAL        |
|                            | REPRESENTATIVE                      |
| Patient's                  | legal representatives* or guardians |
| Name Surname :             | Name Surname :                      |
| Address:                   | Address:                            |
| Phone :                    | Phone :                             |
| Signature :                | Signature :                         |
|                            |                                     |
| Doctor                     | Doctor                              |
| Name Surname:              | Name Surname:                       |
| Signature:                 | Signature:                          |
|                            |                                     |
| Witness **:                | Witness **:                         |
| Name Surname:              | Name Surname:                       |
| Signature:                 | Signature:                          |
|                            |                                     |